Rx Only

Revised Feb 2026

BIOWAVEPRO®

SMARTER PAIN BLOCKING TECHNOLOGY

user's manual

The BioWavePRO Neurostimulator is used as part of the following neuromodulation pain therapy systems:

- **BIOWAVEPRO**
  Professional Neuromodulation Pain Therapy System
- **BIOWAVEPENS**
  Percutaneous Electrical Nerve Stimulation

Designed to Block Pain at the Source™

BioWave Corporation

Table of Contents

1. Indications For Use 7

2. Neurostimulator Description 8

2.1 Neurostimulator Accessories 9

2.1.1 Leadwire Cable 9

2.1.2 AC Charger 11

2.2 Electrodes 12

2.2.1 BioWave Noninvasive Reusable Electrodes (BioWavePRO) 13

2.2.2 BioWave Percutaneous Electrodes (BioWavePENS) 16

2.3 Neurostimulator Controls 17

2.3.1 Power Button 17

2.3.2 Plus Button 17

2.3.3 Minus Button 17

2.3.4 Time Button and OK Button 17

2.4 Neurostimulator Indicators 18

2.4.1 LCD Display 18

2.4.2 System Indicator Light 19

3. When the Neurostimulator Should Not Be Used (Contraindications), Risks/Benefits, Warnings, Precautions and Adverse Reactions 20

3.1 When the Neurostimulator Should Not Be Used (Contraindications) 20

3.2 Warnings 21

3.3 Precautions 22

3.4 Adverse Reactions 23

4. User Instructions 24

4.1 Set Up and Operating Instructions 24

4.2 Rationale for Electrode Placements 25

4.3 Focusing of the BioWave Signals and Electrode Placement 27

4.4 Body Position During the Treatment 28

4.5 Motion During the Treatment and Fine Tuning of the Treatment 29

(continued)

Table of Contents (continued)

4.6 Electrode Placement Examples for Noninvasive Electrodes 30

FOR PERCUTANEOUS ELECTRODE Placements, see BioWavePENS Quick Reference Guide or call Technical Support at 1-877-BioWave ext 1.

4.6.1 **LOW BACK PAIN - ELECTRODE PLACEMENT EXAMPLES** 31
4.6.1.1 Placement for Low back Pain in Two Locations (e.g.Bilateral Lumbar Pain) 31
4.6.1.2 Placement for Radiating Back Pain (e.g. Radiculopathies/Sciatica) 31
4.6.1.3 Placement for Pain at the Bottom of the Spine (e.g. from Sacroiliac (SI) Joint Pain 32
4.6.1.4 Placement for Pain Centered Over the Spine 32
4.6.1.5 Placement for Low Back Pain in One Location 33
4.6.1.6 Placement for Pain Over a Large Area on the Back (e.g. Pain from a rotational strain) 34
4.6.2 **HIP PAIN - ELECTRODE PLACEMENT EXAMPLE** 35
4.6.2.1 Placement for Hip Pain 35
4.6.3 **RIB OR OBLIQUE PAIN - ELECTRODE PLACEMENT EXAMPLE** 36
4.6.3.1 Placement for Rib or Oblique Pain 36
4.6.4 **GROIN & PELVIC FLOOR PAIN - ELECTRODE PLACEMENT EXAMPLES** 37
4.6.4.1 Placement for Groin Pain 37
4.6.4.2 Placement for Pelvic Floor Pain (e.g. Pain from Interstitial Cystitis) 37
4.6.4.3 Placement for Pain from Endemetriosis, Menstrual Cramps and Other Anterior Pelvic Floor Pain 38
4.6.5 **QUADRICEPS PAIN - ELECTRODE PLACEMENT EXAMPLE** 39
4.6.5.1 Placement for Quadriceps Pain 39
4.6.6 **HAMSTRING PAIN - ELECTRODE PLACEMENT EXAMPLE** 40
4.6.6.1 Placement for Hamstring Pain 40
4.6.7 **KNEE & LOWER LEG PAIN - ELECTRODE PLACEMENT EXAMPLES** 41
4.6.7.1 Placement for Pain Toward the Front of the Knee (e.g. from an ACL Sprain, Bursitis or Osteoarthritis) 41
4.6.7.2 Placement for Pain Throughout the Knee or for Pain in 2 Locations (e.g. from a Total Knee Replacement) 42
4.6.7.3 Placement for Pain Above the Knee Cap (e.g. Quadriceps Tendinitis) 43
4.6.7.4 Placement for Medial Knee Pain (e.g. from an MCL Sprain, Pes Anserine Bursitis or Osteoarthritis) 44
4.6.7.5 Placement for Pain Below the Knee Cap (e.g. Patellar Tendinitis) 45
4.6.7.6 Placement for Lateral Knee Pain (e.g. from an LCL Sprain, Bursitis or Osteoarthritis 46
4.6.7.7 Placement for Pain on the Outside of the Thigh (e.g. Illiotibial Band (IT Band) Pain 47
4.6.7.8 Placement for Posterior Knee Pain 48

(continued)

Table of Contents (continued)

4.6.7.9 Placement for Amputation Pain and Phantom Limb Pain (Lower Leg) 49

4.6.7.10 Placement for Amputation Pain and Phantom Limb Pain (Upper Extremities) 50

4.6.7.11 Placement for Pain on the Front of the Lower Leg (e.g.from Shin Splints) 51

4.6.7.12 Placement for Calf Pain (for example from a Gastrocnemius Strain) 52

4.6.8 **ANKLE AND FOOT PAIN - ELECTRODE PLACEMENT EXAMPLES** 53

4.6.8.1 Placement for Pain on the Foot or Ankle that results from Diabetic Neuropathy 53

4.6.8.2 Alternative Placement for Neuropathic Foot Pain 54

4.6.8.3 Placement for Lateral Ankle or Foot Pain (e.g. from a Low Ankle or Foot Sprain) 55

4.6.8.4 Placement for Pain Around the Ankle with only a Primary Pain Site (e.g. High Ankle Sprain) 56

4.6.8.5 Placement for Foot or Ankle Injury with Pain in 2 Locations 57

4.6.8.6 Placement for Pain on the Back of the Heel or Ankle (e.g. Achilles Tendinitis) 58

4.6.8.7 Placement for Medial Ankle or Foot Pain 59

4.6.8.8 Placement for Pain on the Bottom of the Foot (e.g. from Plantar Fasciitis) 60

4.6.8.9 Placement for Pain on Top of the Foot (e.g. from Phalange, Metatarsal, Neuroma or Turf Toe Pain) 61

4.6.9 **HEADACHE, NECK, CERVICAL & TMJ PAIN - ELECTRODE PLACEMENT EXAMPLES** 62

4.6.9.1 Placement for Headache Pain Originating in the Posterior of the Neck or Head (Occipital Neurostimulation) 62

4.6.9.2 Placement for Neck Pain in One Location or Radiating Neck Pain 63

4.6.9.3 Placement for Neck or Cervical Pain in 2 Locations 63

4.6.9.4 Placement for Bilateral Neck or Cervical Pain 64

4.6.9.5 Placement for Neck or Cervical Pain Over a Large Area 64

4.6.9.6 Placement for Neck or Cervical Pain in One Location 65

4.6.9.7 Placement for Temporomandibular Joint (TMJ) Pain 65

4.6.10 **SHOULDER PAIN - ELECTRODE PLACEMENT EXAMPLES** 66

4.6.10.1 Placement for Pain Inside the Shoulder Joint (e.g. Frozen Shoulder or Acromioclavicular (AC) Joint Sprain) 66

4.6.10.2 Placement for Anterior Shoulder Pain (e.g. from Biceps Tendinitis, Supraspinatus Tendinitis or a Superior Labrum Anterior to Posterior (SLAP) Tear) 67

(continued)

Table of Contents (continued)

4.6.10.3 Placement for Posterior Shoulder Pain (e.g. from an Infraspinatus Strain or Posterior Rotator Cuff Tendinitis) 68

4.6.10.4 Placement for Pain on the Anterior Clavicle (e.g. Pain from a Sternoclavicular (SC) Sprain) 69

4.6.10.5 Placement for Pain on the Edge of the Shoulder (e.g. from Rotator Cuff Tendinitis) 70

4.6.10.6 Placement for Shoulder Pain on the Trapezius 71

4.6.10.7 Placement for Two Locations of Pain in One Shoulder and Alternative Placement for Pain from Frozen Shoulder/Adhesive Capsulitis 72

4.6.10.8 Placement for Shoulder Pain in 2 Locations (e.g. Bilateral Trapezius Pain) 73

4.6.11 **ELBOW PAIN - ELECTRODE PLACEMENT EXAMPLES** 74

4.6.11.1 Placement for Lateral Elbow Pain (e.g. Lateral Epicondylitis) 74

4.6.11.2 Placement for Medial Elbow Pain (e.g. Medial Epicondylitis) 75

4.6.11.3 Placement for Posterior Elbow Pain (e.g. Triceps Tendinitis) 76

4.6.12 **WRIST, HAND & FINGER PAIN - ELECTRODE PLACEMENT EXAMPLES** 77

4.6.12.1 Placement for Posterior or Anterior Wrist Pain 77

4.6.12.2 Placement for Pain from a Triangular Fibrocartilage Complex (TFCC) Wrist Sprain 78

4.6.12.3 Placement for Hand or Finger Pain 79

4.6.12.4 Alternative Placement for the Larger Rectangular Electrode on Small Diameter Wrists 80

4.7 Placing BioWave Noninvasive Electrodes 81

4.8 Placing BioWave Percutaneous Electrodes 82

4.9 Turning on the BioWavePRO Neurostimulator 84

4.10 Using the BioWavePRO Neurostimulator 85

4.10.1 Starting Treatment 85

4.10.2 During Treatment 86

4.10.3 End of Treatment 86

4.11 Importance of Monitoring the Activity of the Neurostimulator 87

5. Treatment Regimen Protocols 88

5.1 Treatment Regimen with BioWave Noninvasive Electrodes for Athletic Training 88

5.2 Treatment Regimen with BioWave Noninvasive Electrodes for Physical Therapy and Postoperative Rehabilitation 89

5.3 Treatment Regimen with BioWave Percutaneous Electrodes for Patients with Severe Chronic, Acute or Postoperative Pain 89

(continued)

Table of Contents (continued)

6. Battery Indicator, Charging and Replacing the Battery 91

6.1 Battery Indicator 86
6.2 Charging the Battery 91
6.3 Replacing the Battery 92

7. Maintenance, Cleaning and Storage Instructions 93

7.1 Maintenance, Cleaning and Storage Instructions 93
7.2 Disposal of Waste Products 94

8. Troubleshooting and Other Functions 95

8.1 Troubleshooting Error Conditions on LCD Display 95

8.1.1 Leadwire Connection to the Neurostimulator 95
8.1.2 Electrode Connection to the Leadwire Cable 95
8.1.3 Electrode Connection to the Patient 96

8.1.3.1 Patient Has Lotion on Their Skin or Has Oily Skin 96
8.1.3.2 Electrode Has Lost Adhesion and Conductivity 96
8.1.3.3 Dry, Flaky Skin 96
8.1.3.4 Excessive Hair on Skin 97
8.1.3.5 Broken Connection Between Metal Connector and Gray Cord 97

8.2 Other Troubleshooting Issues 98

8.2.1 Leadwire Cable is Unplugged During Treatment 98
8.2.2 Electrode(s) Detach From Patient's Body During Treatment 98
8.2.3 Use of Non-BioWave Electrodes 99
8.2.4 Muscle Twitching 99
8.2.5 Patient Quickly Reaches Maximum Intensity 99

8.2.5.1 Maximum Intensity Reached Due To High Skin Impedance 99
8.2.5.2 Maximum Intensity Reached Due To Postoperative Loss of Proprioception 100

8.3 Automatic Safety Function 101

8.3.1 Intensity Decreases Automatically and/or Pressing Plus (+) Button Will Not Increase Intensity 101

8.4 Other Functions 102

8.4.1 Change Treatment Time 102
8.4.2 Pause Treatment Mid-Procedure 103
8.4.3 Change Contrast of LCD Display 103

9. Technical Specifications and Classifications 104

9.1 Technical Specifications 104
9.2 Classifications 105
9.3 Definition of Symbols 111

10. Contact Information and Warranty 112

10.1 Reorder Information and Technical Support 112
10.2 Limited Warranty 112

IMPORTANT!

Before using this product, read the following information thoroughly.

Rx Only

1. Indications for Use

Neuromodulation is the electrical stimulation of a nerve for the relief of pain. BioWave manufactures and sells two professional neuromodulation pain therapy systems which utilize the BioWavePRO Neurostimulator:

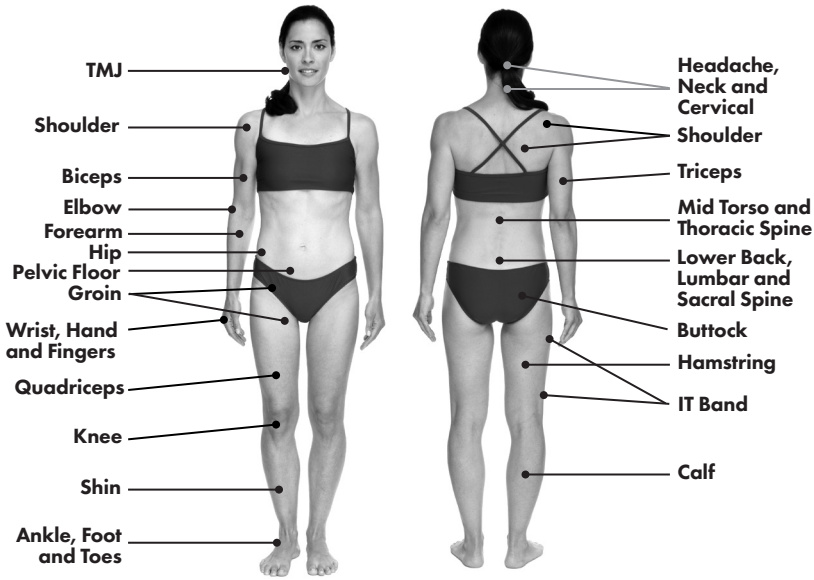
The **BioWavePRO** System is comprised of a BioWavePRO Neurostimulator and BioWave Noninvasive Electrodes.

The **BioWavePENS** System is comprised of a BioWavePRO or BioWaveHOME Neurostimulator and BioWave Percutaneous Electrodes.

Both the BioWavePRO and BioWavePENS Systems are indicated for symptomatic relief of pain, including:

- chronic, intractable pain
- post-traumatic acute pain
- post-operative pain

EXAMPLE AREAS OF TREATMENT



See Section 4.6 for examples of electrode placements.

2. Neurostimulator Description

The BioWavePRO® Neurostimulator is a medical device which utilizes a unique signal mixing technology to deliver electrical signals through skin to the surface of nociceptive pain fibers for inhibiting pain transmission and improving function.

The neurostimulator is comprised of a plastic housing containing the electronics and a rechargeable battery. On the face of the neurostimulator is a large LCD display showing signal intensity as a percent of maximum intensity, the treatment time selected, the remaining treatment time, a battery indicator and error indications (for example if the electrodes become disconnected from the patient). A System Indicator Light resides above the LCD display indicating the operating condition of the neurostimulator.

BioWavePRO®
Neurostimulator

There are 5 buttons that control the stimulator:

1. Power ON/OFF button
   Also used to PAUSE treatment

2. PLUS (+) button to increase intensity or increase treatment time

3. MINUS (–) button to decrease intensity or decrease treatment time

4. TIME button to enter TIME mode in order to change treatment time

5. OK button to accept and set a new treatment time

2.1 Neurostimulator Accessories

2.1.1 LEADWIRE CABLE

A "Y" shaped leadwire cable connects two disposable electrodes to the BioWavePRO® Neurostimulator. The single end of the leadwire cable plugs into the front of the neurostimulator as shown in the photo below.

Plugging Single End of Leadwire Cable into BioWavePRO Neurostimulator

Plugging the Leadwire Cable into the Neurostimulator

When the connector plugs into the neurostimulator, the red dot on the metal connector should face upwards. The notch on the connector mates with the keyhole in the opening on the neurostimulator and the connector gently slides in and clicks in place (see photo above).

Removing the Leadwire Cable from the Neurostimulator

To remove the leadwire cable, hold the Metal Barrel shown in the photo on the prior page with the thumb and index finger and gently pull straight back out of the neurostimulator. This will release the connector and it will slide straight out.

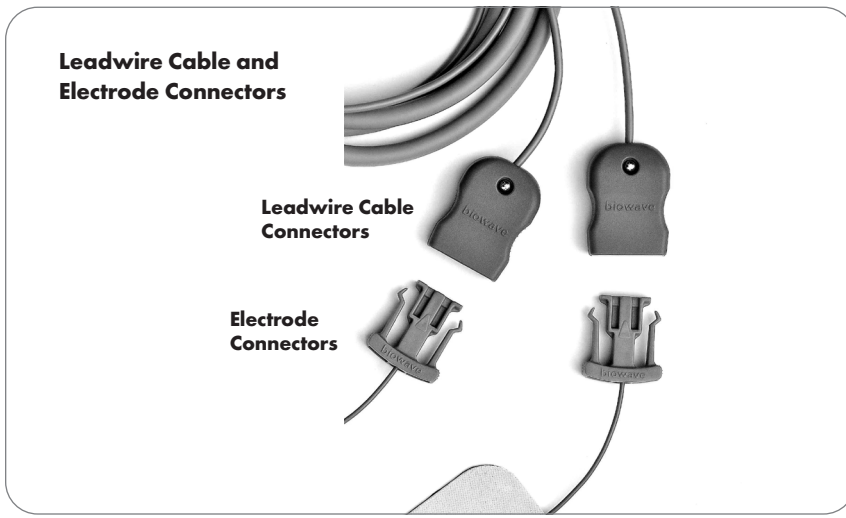
NEVER twist the connector;

NEVER pull on the strain relief or on the cord when trying to remove the leadwire cable from the neurostimulator.

Connecting the Leadwire Cable to Electrodes

BioWavePRO® uses two electrodes for a treatment. Either electrode can be connected to either blue connector at the end of the leadwire cable (see photo below).

Line up the leadwire cable and electrode connectors and plug them together until they click in place. When connected together, the electrode connector will partially stick out from the leadwire cable connector allowing an easy grip when pulling them apart.



Removing the Electrodes from the Leadwire Cable

To remove the electrodes from the leadwire cable, grasp each side of the blue connector with your thumb and index finger and pull them straight apart.

2.1.2 AC CHARGER

The Universal AC Charger is only used to recharge the battery in the neurostimulator. The cord from the AC Charger is plugged into the neurostimulator. A larger power cord is plugged into the other end of the AC Charger and into a standard electrical outlet (100-240 Volts, 50-60 Hz).

The leadwire cable must first be unplugged in order to allow room for the AC Charger to be plugged into the neurostimulator.

2.2 Electrodes

There are two types of BioWave Electrodes designed to work with the BioWavePRO Neurostimulator: BioWave Noninvasive Electrodes and BioWave Percutaneous Electrodes. When the neurostimulator is combined with noninvasive electrodes, the system is called **BioWavePRO**; when the neurostimulator is combined with percutaneous electrodes, the system is called **BioWavePENS**.

BioWave Noninvasive Reusable Electrodes

BioWave® Noninvasive Electrodes are reusable surface electrodes typically used to reduce pain and facilitate physical therapy in professional and college sports, in physical and occupational therapy and chiropractic settings. The BioWavePRO® Neurostimulator when used in conjunction with BioWave Noninvasive Electrodes is called BioWavePRO® and is FDA cleared as a Neuromodulation Pain Therapy System. BioWave® Noninvasive Electrodes can be reused typically 8-10 times depending upon skin condition and proper electrode maintenance.

BioWave Percutaneous Electrodes

BioWave® Percutaneous Electrodes utilize a patented technology involving an array of over 1000 needles to significantly facilitate the delivery of the BioWavePRO Neurostimulator's therapeutic signals through the skin, directly to the surface of nociceptive pain fibers. The BioWavePRO Neurostimulator when used in conjunction with BioWave Percutaneous Electrodes is called **BioWavePENS®** and is FDA cleared as Percutaneous Electrical Nerve Stimulation.

BioWave® Percutaneous Electrodes are sterile, single-use electrodes, and are used under the supervision of a physician typically in a pain or spine clinic, hospital or physician office setting to reduce severe chronic, acute or postoperative pain.

NOTE: Electrodes MAY BE PLACED directly over or in the proximity of implanted metal hardware, including total joint replacements, anchors, plates, rods, screws and pins.

Warning

ELECTRODES MUST NEVER TOUCH EACH OTHER

- **1.0 inch (2.6 cm) is the minimum spacing between electrodes on the back**
- **0.5 inches (1.3 cm) is the minimum spacing between electrodes on joints or extremities**
- **There is NO maximum spacing between any electrodes**
- **If the edges of the electrodes touch during the treatment, it may cause a burn**
- **Do NOT use BioWave Noninvasive Electrodes if:**
  - **The metal portion of the wire is exposed, or**
  - **The hydrogel has peeled apart from the black carbon/silver surface**

2.2.1 BioWave NONINVASIVE REUSABLE ELECTRODES

2.2.1 BioWave NONINVASIVE REUSABLE ELECTRODES

There are 2 different sized sets of BioWave Noninvasive Electrodes for focusing the therapeutic signals to different locations in the body:

- B-set
- E-set

2.2.1.1 B-Set: Two Locations of Pain or Back Pain

The B-set is comprised of two 2" diameter round equal area Pain Site electrodes that are placed:

- directly over 2 locations of pain;
- over the origin or source of pain, and over the most painful location that is closest to the origin of pain (for example, for sciatica, one pad is placed over the spine (origin) and one pad is placed on the buttock (most painful location closest to the origin);
- one inch apart from one another to treat a large area of pain

The B-Set is used for treating pain in the following areas:

- pain in one or two locations in the back including, buttocks, lower back or mid back region
- radiculopathies (radiating pain down the back or side of the leg)
- pain in two locations in the hip, groin or pelvic floor
- pain in two locations in the cervical spine, shoulders or knees
- pain centered directly in the spine
- pain presenting in a large area

2.2.1.2 E-Set: Single Location of Pain in the Extremities

The E-set is comprised of:

- One 1.375" diameter round Pain Site Electrode that is placed directly over the single location of pain; and
- One 2"x 4" rectangular Dispersive Electrode that is placed over a bony prominence (a comfortable location to receive stimulation) near the region being treated.

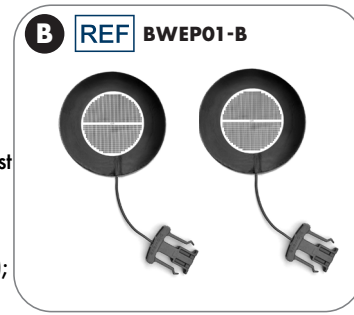
The E-Set is used for treating single locations of pain in the extremities:

- knees
- ankles, feet and toes
- neck
- shoulders
- elbows
- wrists
- hands and fingers

2.2.2 BioWave PERCUTANEOUS ELECTRODES

There are two different sized sets of BioWave® Percutaneous Electrodes for focusing the therapeutic signals to different locations in the body:

2.2.2.1 B-Set: Two Locations of Pain



The B-Set is comprised of two round same area Percutaneous Electrodes (2.5 inch diameter) which can be palced:

- directly over 2 locations of pain;
- over the origin or source of pain, and over the most painful location that is closest to the origin of pain (for example, for sciatica, one pad is placed over the spine (origin) and one pad is placed on the buttock (most painful location closest to the origin);
- one inch apart from one another to treat a large area of pain

The B-Set is used for treating pain in the following areas:

- pain in two locations in the back including, buttocks, lower back or mid back region
- radiculopathies (radiating pain down the back or side of the leg)
- pain in two locations in the hip or groin
- pain in two locations in the cervical spine, shoulders or knees
- pain centered directly in the spine
- pain presenting in a large area

2.2.2.2 E-Set: Single Location of Pain

The E-Set is comprised of:

- One 2.5" diameter round Percutaneous Electrode that is placed directly over the single location of pain; and
- One 2"x 4" rectangular Dispersive Electrode that is placed over a bony prominence (a comfortable location to receive stimulation) near the region being treated.

The E-Set is used for treating single locations of pain:

- back
- neck
- TMJ
- knees
- ankles, feet and toes
- shoulders
- elbows
- wrists
- hands and fingers

2.3 Neurostimulator Controls

2.3.1 POWER BUTTON

Power Button

The Power Button is located on the right side of the stimulator. Pressing the Power Button once and holding it down for about one second until the screen lights up, turns the neurostimulator on. While the neurostimulator is on, pressing the Power Button once pauses operation of the neurostimulator. Holding the button down for two seconds or more while the neurostimulator is on, turns the neurostimulator off.

The power should be turned on AFTER the leadwire is cable is connected on both ends and the electrodes are attached to the patient. Once the power is turned on, the LCD display should read 0.0% and the patient can begin pressing the PLUS (+) Button to increase intensity beginning the treatment.

2.3.2 PLUS BUTTON (+)

PLUS, MINUS, TIME and OK buttons

Pressing the PLUS (+) Button increases the intensity of the signal and the level of the tingling/pressure sensation felt by the patient. The PLUS (+) Button is also used to increase treatment time, after the TIME button is pressed.

2.3.3 MINUS BUTTON (–)

Pressing the MINUS (–) Button decreases the intensity of the signal and the level of the tingling/pressure sensation felt by the patient. The MINUS (–) Button is also used to decrease the treatment time, after the TIME button is pressed.

2.3.4 TIME BUTTON AND OK BUTTON

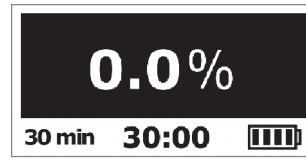
The treatment time is set to a default of 30 minutes. Pressing the TIME button allows the user to change the treatment time either before or during a treatment. After pressing the TIME Button, pressing the PLUS (+) Button or MINUS (–) Button increases or decreases the treatment time in 1-minute increments. The treatment time can be set from 5 to 60 minutes. After selecting the desired treatment time, pressing the OK button sets the treatment time.

2.4 Neurostimulator Indicators

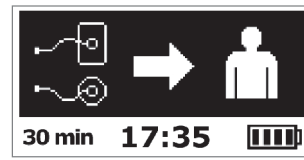
2.4.1 LCD DISPLAY

The LCD display on the front of the stimulator provides treatment information:

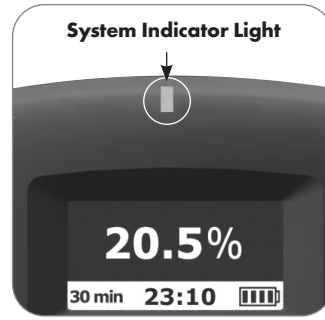
- **Signal Intensity** as a percent of maximum intensity, is indicated by the largest number in the middle of the display. At the beginning of a treatment the intensity should read 0.0% on the LCD display.



- **Total Treatment Time** is indicated on the lower left corner of the display
- **Remaining Treatment Time** is indicated on the lower middle of the display
- **Battery Strength Indicator** is indicated on the lower right corner of the display
- **Problems** - if a problem occurs, a picture will appear in the center of the display showing the action to correct the problem. For example if one or both electrodes become detached from the patient, the intensity will go to zero (0.0%), the treatment time will pause and a picture will appear showing that the electrodes should be placed back onto the patient's body (see Section 8 - Troubleshooting and Other Functions).



2.4.2 SYSTEM INDICATOR LIGHT



A single System Indicator Light is located above the LCD display on the neurostimulator. This Indicator Light shows the status of the treatment of the neurostimulator.

The Indicator Light remains solid GREEN during a treatment, begins flashing GREEN with 5 minutes left and turns solid YELLOW at the end of the treatment.

The Indicator Light will *flash* GREEN while the battery is charging. The Indicator Light will *flash* YELLOW when there is an Error Condition or Problem (see Section 8 - Troubleshooting and Other Functions).

3. When the Neurostimulator Should Not Be Used (Contraindications), Warnings, Precautions and Adverse Reactions

Read these instructions, including When the Neurostimulator Should Not Be Used (Contraindications) and all Warnings, Precautions and Adverse Reactions BEFORE using BioWavePRO® to ensure proper use of the BioWavePRO® System.

3.1 When the Neurostimulator Should Not Be Used (Contraindications)

- **DO NOT** use if you have an impanted cardiac pacemaker.
- **DO NOT** use if you have epilepsy or are prone to seizures.
- **DO NOT** place electrodes over the heart or across the thoracic volume (not on either side of the heart). Electrodes can be applied to the back of the thorax and lateral aspect of the upper limb (i.e. below/down the shoulder).
- **DO NOT** place electrodes on the front or side of the neck.
- **DO NOT** place electrodes on top of the head.
- **DO NOT** place electrodes over wounds, broken skin or sensitive skin areas (for example, sunburned skin).

3.2 Warnings

- **ELECTRODES MUST NEVER TOUCH EACH OTHER**
  - 1.0 inch (2.6 cm) is the minimum spacing between Pain Relief Pads on the back
  - 0.5 inches (1.3 cm) is the minimum spacing between electrodes on joints or extremities
  - There is NO maximum spacing between any Pain Relief Pads
  - If the edges of the Pain Relief Pads touch during the treatment, it may cause a burn.
  - Do NOT use BioWave Noninvasive Electrodes if:
    - The metal portion of the wire is exposed, or
    - The hydrogel has peeled apart from the black carbon/silver surface.
- BioWave Percutaneous Electrodes are sterile and can only be used for a single treatment.
- BioWave Percutaneous Electrodes must be disposed of in a sharps or biohazard disposal following the treatment.
- **DO NOT** plug into AC outlet during use. The neurostimulator is battery operated and will not operate while the AC Charger is plugged in.
- **DO NOT** use around water. Contact with water could cause electric shock, which can result in serious injury to the patient.
- The safety of the neurostimulator for use during **pregnancy** or **labor** has not been established.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- The neurostimulator treats pain and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the neurostimulator is in use.
- There may be a potential hazard from simultaneous connection of a patient to high frequency surgical equipment and the neurostimulator that may result in burns and possible equipment damage.
- During charging the battery, to avoid the risk of electric shock, this equipment must only

be connected to a supply mains with protective earth.

3.3 Precautions

- Use only the Power Supply provided with your BioWave device.
- The neurostimulator should be maintained and serviced by BioWave personnel, or other qualified personnel approved in writing by BioWave. Use this stimulator while following the safety precautions and operating instructions in this manual.
- Do not drop the neurostimulator as it could be damaged and will not function properly.
- Do not pull on the electrode cord, especially when sitting on the electrode.
- Do not exceed the treatment duration and frequency recommended in the operating instructions.
- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Consult your doctor before using if you have suspected or diagnosed heart problems.
- Consult your doctor before using when treating in the presence of the following:
  - Patients with a tendency to hemorrhage following acute trauma or fracture;
  - Painful area over the menstruating or pregnant uterus; and
  - Areas of the skin that lack normal sensation.
- Electrode placement and stimulation settings should be based on the instructions in this User's Manual.
- Avoid use of electrodes, conductive gels, leadwires, or accessories other than those supplied with the system or recommended by BioWave. The safety of other products has not been established and their use may result in skin irritations and burns beneath the electrodes.
- Keep the BioWaveGO neurostimulator away from children. However, BioWave

may be used on children if supervised.

- The long-term effects of chronic electrical stimulation are unknown.

3.4 Adverse Reactions

The following are potential adverse effects of using the BioWavePRO device:

- Skin irritation
- Rash
- Redness
- Mild discomfort or pain
- Burn
- Electric shock
- Interference with treatment of cancerous lesions
- Seizures or other neurological effects
- Pacemaker interference
- Cardiac arrhythmias from use over the heart
- Laryngeal and pharyngeal muscle spasms or changes in blood pressure from use over the front or side of the neck
- Infection from use of Percutaneous Electrodes

4. User Instructions

4.1 Set Up and Operating Instructions

1. Remove packing materials.

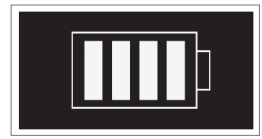
2. Place the BioWavePRO® Neurostimulator on a hard surface.

3. Make sure the neurostimulator is turned OFF. Plug the power cord into the AC Charger and into a wall outlet. Then plug the cord from the AC Charger into the BioWavePRO® Neurostimulator to begin charging the battery.

   The battery must be fully charged up before the first use.

   The LCD display will indicate an animated picture of the battery charging and the System Indicator Light above the display will begin *flashing* GREEN.

4. Once the neurostimulator is fully charged, the picture of the battery will stop animating and the LCD display will turn off after a couple of minutes.



5. Unplug the AC Charger from the neurostimulator. The AC Charger must first be unplugged in order to make room to allow the leadwire cable to be plugged into the neurostimulator.

6. Determine the patient's source of pain and the location(s) at which the pain condition presents. This will allow you to specify the correct size electrode set and proper electrode placement location (review the following sections, 4.2 through 4.10).

7. Choose appropriate size electrodes and plug each electrode into the blue connectors on the leadwire cable. The orientation of the connectors do not matter and either electrode can be plugged into either connector.

8. Make sure the patient's skin is clean. Place at least one round electrode over the pain site. Place the second electrode for the particular pain condition as shown in the appropriate photo in Section 4.4 - Electrode Placement Examples. Electrodes must not touch each other.

9. Gently plug the single end of the leadwire cable into the female port on the stimulator. (see Section 2.1.1 - Plugging Leadwire Cable into Stimulator).

10. Press the power button on the side of the stimulator so the LCD screen turns on. The screen should read 0.0% and the countdown timer should be set to 30:00 minutes.

11. Tell the patient to increase intensity by pressing the PLUS (+) button so the sensation felt is strong but still comfortable. During the remainder of the treatment, as the body adapts to the electrical field and the sensation fades, tell the patient to keep increasing the intensity to maintain a strong but comfortable sensation at the treatment location (see Section 4.10 - Using BioWavePRO).

12. The optimal body postion during treatment is when the tissue in the treatment area is a little bit taut or in a stretch position. This will cause the sensation felt encompassing the pain site to be stronger and in deeper tissue (see Section 4.4 - Body Position During Treatment).

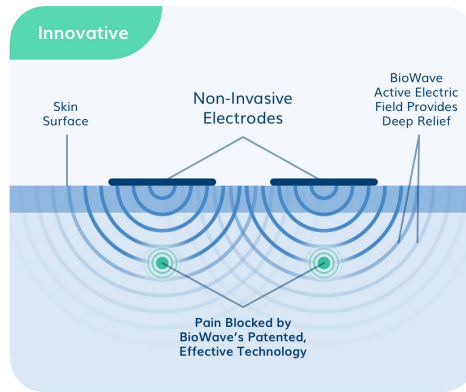
13. During the treatment, try gently moving the part of your body being treated - this will cause the location of the sensation from the electrical signals to slightly shift. Try to get the sensation you feel from the electrical signals to encompass your location of pain - this will provide the best treatment outcome (see Section 4.5 - Motion During Treatment).

4.2 Rationale for Electrode Placements

BioWavePRO® electrode placements are significantly different from all other forms of electrical stimulation including TENS, interferential current, high volt, Russian and muscle stimulation.

BioWave's electrical signal technology is a frequency conduction pain block. BioWave discovered that when two sinusoidal high frequency signals are summed (added) together in the device and then delivered into the body through a single electrode, the signals will pass into deep tissue and affect all polarized tissues including nociceptive pain fibers. As the summed signals pass through the body, polarized structures like the membrane of the C-fiber, A-delta fiber and muscle tissue act in a non-linear fashion and force the further multiplication of these signals, resulting in a new spectrum of signals.

Multiplication of the high frequency signals results in the formation of an active therapeutic low frequency electrical field focused in approximately a 3.5-inch diameter hemisphere beneath and surrounding each electrode, not across the surface of the skin between the electrodes. This active electrical field is thought to hyperpolarize the C-fiber inhibiting action potential propagation along pain fibers (Frequency Conduction Block Theory). The active electrical field also induces hypoesthesia 5 minutes into the treatment and causes an increase in blood flow in the volume of tissue beneath and surrounding each electrode.



Since the nerve fibers and muscle tissue under and surrounding the electrodes are encompassed by the low frequency electrical field, the two electrodes must be placed directly over two locations of pain, or over one location of pain and the origin of the pain.

BioWave neurostimulators deliver the two summed signals to the first electrode; they mix in the 3.5-inch diameter hemisphere volume of tissue beneath that electrode, then pass to the second electrode and return to the stimulator, completing the circuit. Instantaneously, the summed signals are then delivered to the second electrode; they mix in the volume of tissue beneath the second electrode, then pass to the first electrode and return to the stimulator. The stimulator alternates the delivery of the summed high frequency signals so quickly between the two electrodes that the patient cannot distinguish that the signals left either location. The net effect is there are two active electrodes, each of which can treat a distinct 3.5-inch diameter hemisphere in the volume of tissue under and surrounding each electrode and there is no noxious twitching sensation.

4.3 Focusing of the BioWave Signals and Electrode Placement

With BioWave, depending on the nature and location of the painful area, the electrical signals can be focused to different parts of the body by pairing electrodes of different ***sizes*** and ***types*** with one another. If two same type electrodes of equal area are used, then two distinct volumes of tissue can be treated equally. For example, if a patient has bilateral low back pain, two equal area electrodes can be placed over the respective painful areas on each side of the spine. Additionally, by moving these electrodes closer together so that there is only about 1.0 inch of space between them, the pair can also be used to treat one larger volume of tissue.

BioWavePRO - BioWave Noninvasive Electrodes

By pairing an electrode of smaller area with an electrode of larger area, the density of the therapeutic low frequency field is greater in the volume of tissue beneath the smaller area electrode. Therefore, the smaller electrode needs to be placed directly over a single location of pain. The larger electrode acts like a dispersive pad as the density of the electrical field is much lower and the sensation felt beneath it is significantly less. It is important that this electrode be placed in a comfortable location to receive stimulation, which is typically over a **bony prominence** near the treatment site. Placement of the larger electrode over a **bony prominence** allows the patient to more comfortably increase the intensity of the signal to higher levels allowing a stronger active electric field to encompass the pain site under the smaller Pain Site Electrode.

BioWavePENS - BioWave Percutaneous Electrodes

The electrical signals can be focused by not only pairing different area electrodes with each other, but also by combining a percutaneous with a noninvasive electrode. Since percutaneous electrodes provide a direct conductive pathway through skin, the summed high frequency signals pass into deep tissue more easily. The impedance is significantly less in the area beneath the percutaneous electrode than beneath a noninvasive electrode. By having an impedance difference between the electrodes, the therapeutic low frequency electric field is more concentrated where the impedance is lower. Therefore the percutaneous electrode, which is placed directly over the single location of pain, allows the nerve fibers and muscle tissue in this 3.5-inch diameter hemisphere beneath it to be more readily encompassed by the therapeutic low frequency field.

4.4 Body Position During the Treatment

Position of the body during the treatment is important. *Generally, the tissue being treated should be a little taut or in a stretch position, which allows deeper penetration of the electrical field.* Sitting upright in a supported position on a treatment table tends to be the most comfortable body position for most treatment locations on the body.

Low back and buttock electrode placements: Having the torso at approximately 90 degrees to the legs causes the tissue in the low back and buttocks to be more taut which provides for a better treatment result. The patient may either sit in a supported position or lay on their back with their torso at 90 degrees to their legs and their knees bent at 90 degrees supported by a cushion. If necessary, the patient may be in a prone position during a treatment.

Knee electrode placements: For anterior, lateral or medial treatments, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment which will yield the best outcome. For posterior knee treatments, the knee should be kept straight so the tissue on the posterior side is more taut.

Calf electrode placements: The patient should adjust the direction they point their toes either toward them or away from them to put the calf in tension. This allows the patient to tolerate a higher level of stimulation because it is a more comfortable position in which to receive stimulation in the calf.

Ankle, foot and toe electrode placements: The foot should be kept at approximately 90 degrees to the tibia and the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor or sitting on a training or physical therapy table with the knee bent and the foot flat on a wedge are the most ideal positions during the treatment. However, if necessary, the foot can be elevated during the treatment.

Neck and cervical spine electrode placements: The head should be bent slightly forward so the tissue on the back of the neck is more taut.

Shoulder electrode placements: Sitting or laying supine are the most comfortable positions during treatment. The arm should rest against the side of the body with the elbow slightly bent.

For anterior shoulder treatments, generally the patient should be sitting on a treatment table. If the patient can tolerate some internal rotation, the patient should gently move their hand behind their buttock and sit on the back side of their fingers. This helps to slightly open the subacromial space and allow the electrical field to focus on the supraspinatus tendon. If the patient cannot tolerate internal rotation, then the arm should rest near the side of the body.

Elbow, wrist, hand and finger electrode placements: Sitting is the best position during the treatment. The arm should rest at the side of the body with the elbow bent at approximately 80 degrees. The patient should rest their forearm in their lap or on a table and hold a ball or a rolled up towel to keep their hand and fingers in a comfortable position.

Hip and groin treatments: Lying supine with the legs straight is a comfortable position in which to receive stimulation. Placing a pillow under the buttocks to cause slighlty more extension may provide the best clinical results.

Hamstring treatments: Sitting with the torso at 90 degrees to the legs and the legs straight provides the best treatment outcome.

Quadriceps treatments: Sitting with the knee bent at 90 degrees hanging off of the treatment table provides the best treatment results.

4.5 Motion During the Treatment and Fine Tuning of the Treatment

Gentle motion during the treatment is encouraged. However, motion causes a change in the sensation felt by the patient because movement of the tissue in the region of the treatment causes a change in the impedance of the tissue.

During the treatment, moving in one direction may cause an increase in the sensation; moving in another direction may cause a decrease in the sensation. The patient needs to be aware that they may experience an increase in the sensation if they move. Motion may also change the location of the electrical field.

However, subtle motion during the treatment is encouraged to optimize the treatment. The patient should be encouraged to gently articulate the joint or area of their body being treated. This subtle movement will cause the location of the electrical field that forms inside the body to shift slightly. This shifting of the location of the electrical field is most noticeable when treating the elbow and to a lesser extent, the shoulder, wrist, hand, finger, ankle and foot.

The goal is to have the patient slightly shift the location of the sensation caused by the electrical field so that it focuses directly onto and encompasses the primary location of pain. This is a fine tuning of the treatment that will provide the best treatment result.

4.6 Electrode Placement Examples for Noninvasive Electrodes

For all noninvasive and percutaneous electrode placements, ELECTRODES MUST NEVER TOUCH EACH OTHER:

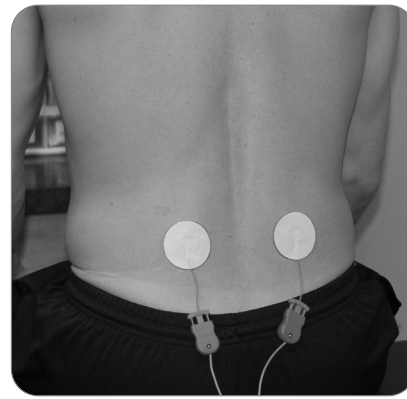
- **1.0 inch (2.6 cm) is the minimum spacing between electrodes on the back.**
- **0.5 inches (1.3 cm) is the minimum spacing between electrodes on extremities.**
- **There is NO maximum spacing between any electrodes.**
- **If the edges of the electrodes touch during the treatment, it may cause a burn.**

The following section shows photos of Examples of Pain Relief Pad placements for pain presenting in different parts of the body. Note: BioWave is not intended to treat any of the conditions provided as examples, only the associated, symptomatic pain.

For PERCUTANEOUS ELECTRODE PLACEMENTS, see BioWavePENS Quick Reference Guide or call 1-877-BIOWAVE (1-877-246-9283) for technical support.

4.6.1 LOW BACK PAIN - ELECTRODE PLACEMENT EXAMPLES

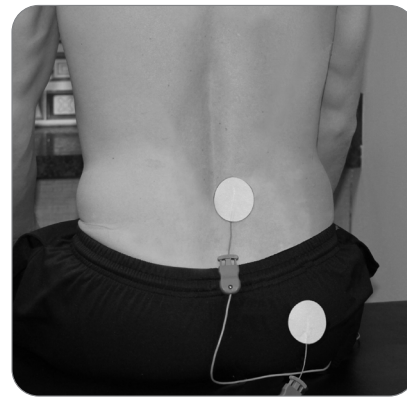
4.6.1.1 Placement for Low Back Pain in Two Locations (e.g. Bilateral Lumbar Pain)



Use the B-set: For low back pain on both sides of the spine, place the two round electrodes directly over each painful area on the lower back. See photo to the right. Similarly, the pair of electrodes can be placed over two areas of equal pain on the buttocks.

Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut. The patient can be in a supported sitting position or lying supine with their torso at 90 degrees to their legs and their knees bent and supported by a cushion.

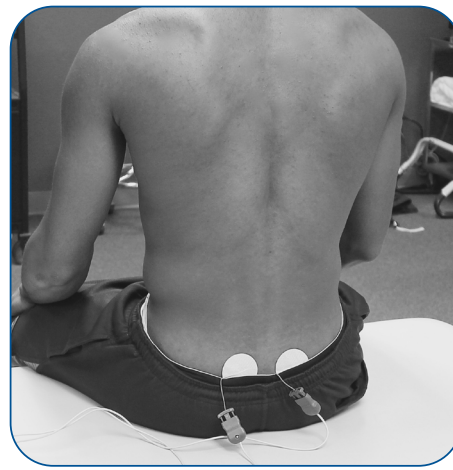
4.6.1.2 Placement for Radiating Pain (e.g. Pain from Radiculopathies/ Sciatica)



Use the B-set: Place one round electrode directly over where the pain first presents itself. For example, this may be on the buttock, proximally, where the pain first starts before it radiates down the sciatic nerve as in the photo to the right (the electrode must be placed on the skin, not over clothing). Place the second round electrode directly over the spine at the possible source of the pain. In this example, for a right side radiculopathy, the elctrode may be placed 0.5" to the right of the source of pain (e.g. a herniated disc located at L5) so that the active electrical field is capturing the nerve in the direction that the pain signals are traveling.

Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut. The patient can be in a supported sitting position or lying supine with their torso at 90 degrees to their legs and their knees bent and supported by a cushion.

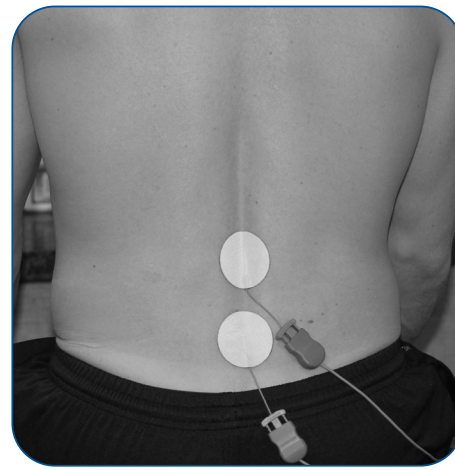
4.6.1.3 Placement for Pain at the Bottom of the Spine (e.g. Sacroiliac (SI) Joint Pain)



Use the B-set: Both electrodes may be placed bilaterally over the sacroiliac joint covering one or two pain sites (unilateral or bilateral SI joint pain). Make sure there is at least 1.0 inch of space between the electrodes (see photo to the right).

Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut.

4.6.1.4 Placement for Pain Centered Over the Spine

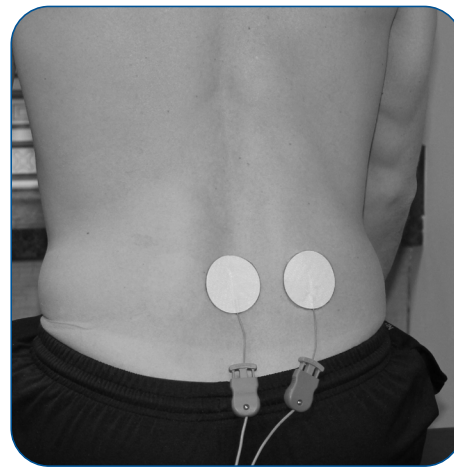


Use the B-set: Both electrodes may be placed in a vertical arrangement directly over the spine covering a primary pain site or multiple pain sites. For example, if the primary pain site is located at L3, then one round electrode should be placed over L3. The comfortable bony prominence location for the second electrode would be approximately over L5, directly beneath the first electrode. Make sure there is at least 1.0 inch of space between the electrodes (see photo to the right). If the primary pain site is located, for example, at S1, then one round electrode should be placed over S1. The comfortable bony prominence location for the second electrode would be above the first electrode located approximately over L4.

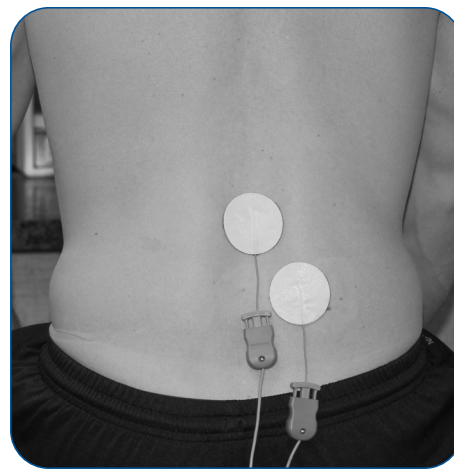
Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut. Therefore the patient can be in a supported sitting position or lying supine with their torso at 90 degrees to their legs and their knees bent and supported by a cushion. If necessary, the patient can be in a prone position during the treatment.

4.6.1.5 Placement for Low Back Pain in One Location

Use the B-set: Place one round electrode on the lower back directly over the painful area. Place the second round electrode directly over the spine horizontally next to the first electrode at the pain site (see photo to the right). The electrodes must be at least 1.0 inch apart from each other.

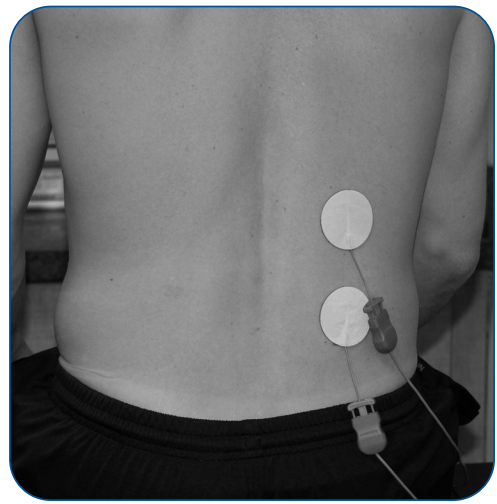


If there is not enough room to place the second round electrode over the spine horizontally next to the first electrode, then place the second round electrode either above or beneath the first electrode directly over the spine so that there is a minimum spacing of 1.0 inch between the two round electrodes (see second photo to the right which, for example, shows an electrode placement for pain from a facet joint).



Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut. Therefore the patient can be in a supported sitting position or lying supine with their torso at 90 degrees to their legs and their knees bent and supported by a cushion. If necessary, the patient can be in a prone position during the treatment.

4.6.1.6 Placement for Pain Over a Large Area on the Back (e.g. Pain from a Rotational Strain)

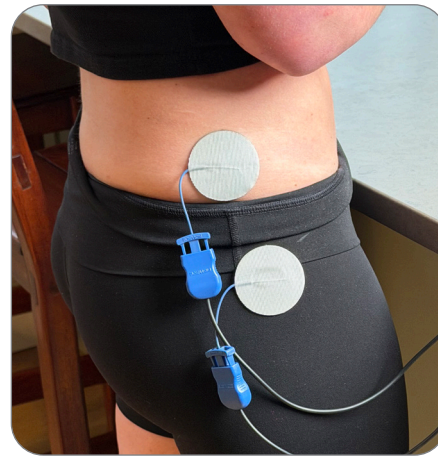


Use the B-set: Both electrodes should be placed over the painful area with a minimum space of about 1.0 inch between the electrodes. When the two round electrodes are about one inch apart from one another, the patient receives a treatment in a volume of tissue covered by the electrodes of approximately 6 inches by 3 inches. See placement example for a rotational strain in the photo to the right.

Body Position: The torso should be approximately at a right angle to the legs causing the tissue in the lower back and buttocks to be more taut. Therefore the patient can be in a supported sitting position or lying supine with their torso at 90 degrees to their legs and their knees bent and supported by a cushion. If necessary, the patient can be in a prone position during the treatment.

4.6.2 HIP PAIN - ELECTRODE PLACEMENT EXAMPLE

4.6.2.1 Placement for Hip Pain

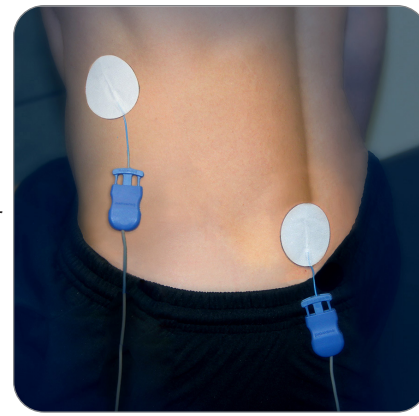


Use the B-set: Place one round Pain Site Electrode on the hip directly over the painful area. Place the second round Pain Site Electrode over a secondary location of pain, for example 1 -2 inches below the first electrode as shown in the photo to to the right. **(NOTE: electrodes must be placed directly on clean skin, not over clothing.)** Leave at least 1.0 inch of spacing between the two round Pain Site Electrodes. There is no limit on the maximum distance the electrodes can be placed apart from on another.

Body Position: For hip placements, sitting in a reclined position or lying down on your back with legs straight is the most desirable position during the treatment.

4.6.3 RIB OR OBLIQUE PAIN - ELECTRODE PLACEMENT EXAMPLE

4.6.3.1 Placement for Rib or Oblique Pain in One Location



Use the B-set: Place one round Pain Site Electrode directly over the painful area in the mid-torso region. The round Primary Electrode should NOT be placed directly over the heart. Place the second round Pain Site Electrode over a secondary location of pain. If there is no secondary location of pain, the most comfortable location is to place it in the lumbar area just to the side of the spine on the same side of the body as the first electrode is placed (see photo to to the right).

Body Position: For mid-torso placements, sitting in a supported upright or partially reclined position is the most comfortable position during the treatment. Legs may be bent or straight.

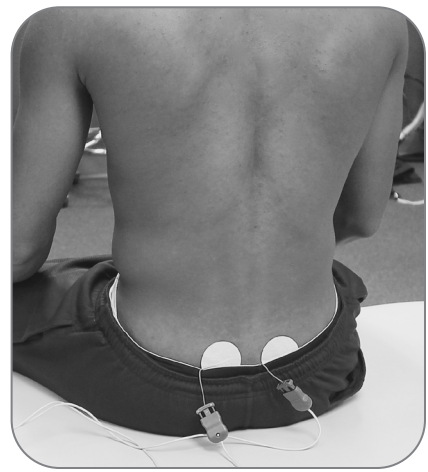
4.6.4 GROIN AND PELVIC FLOOR PAIN - ELECTRODE PLACEMENT EXAMPLES

4.6.4.1 Placement for Groin Pain

Use the B-set: Place one round Pain Site Electrode on the groin directly over the painful area. Place the second round Pain Site Electrode over a secondary location of pain, for example 1 -2 inches below the first electrode as shown in the photo to to the right. If hair is in the location of the painful area, then the hair must be shaved so that the electrode can make good electrical contact with the skin.

Body Position: For groin treatments, sitting reclined or lying down on your back with legs straight is the best position during the treatment.

4.6.4.2 Placement for Pelvic Floor Pain (e.g. Pain from Interstitial Cystitis)



Use the B-set: The recommended electrode placement for Interstitial Cystitis is to place both round Pain Site Electrodes bilaterally over the sacrum, as shown in the photo to the right, to stimulate the sacral nerves at the base of the spine. Leave approximately, but not less than, one inch of spacing between the electrodes.

An alternative placement is to use the B-set and place one round electrode over the pubis

where pain presents on the anterior of the body and one round electrode directly over the sacrum to stimulate the sacral nerves at the base of the spine. If hair is in the location of the pubis, then the hair must be shaved so that the electrode can make good electrical contact with the skin.

Consult your physician for additional information.

Body Position: For Interstitial Cystitis treatments, sitting in a supported position with the torso at approximately 90 degrees to the legs helps keep the tissue in the area of the sacrum more taut and the patient in a comfortable position during the treatment.

For the alternative placement with one electrode on the pubis and one on the sacrum, the patient should lie supine (on their back) with their legs straight during the treatment.

4.6.4.3 Placement for Pain from Endemetriosis, Menstrual Cramps and Other Anterior Pelvic Floor Pain

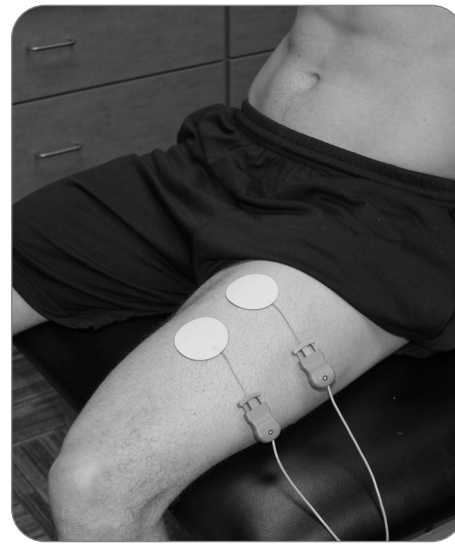
Use the B-set: The recommended electrode placement for Endometriosis or Menstrual Cramps, is to place both round Pain Site Electrodes over the center of the painful location on the anterior of the pelvic floor area as shown in the photo to the right.

Consult your physician for additional information.

Body Position: For Endometriosis or Menstrual Cramps, sit in a supported comfortable position during the treatment.

4.6.5 QUADRICEPS PAIN - ELECTRODE PLACEMENT EXAMPLE

4.6.5.1 Placement for Quadriceps Pain



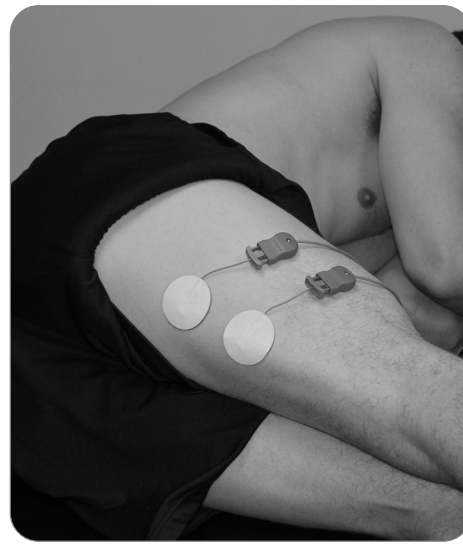
Use the B-set: Both Pain Site electrodes may be placed in a vertical arrangement on the quadriceps. The first electrode should be placed directly over the location where the pain first presents itself. The second electrode should be placed approximately 1.0 inch away from the first electrode and should also cover over the location that any additional pain presents itself. This placement will allow the therapeutic signals to capture the entire region beneath as well as between the electrodes.

NOTE: Treatment of the belly of a muscle (like the quadriceps in this example) will cause it to be held in tension in the volume of tissue beneath both round electrodes. Therefore take care to increase the intensity slowly and carefully.

Body Position: For quadriceps treatments, sitting upright in a supported position with the knee bent at 90 degrees is the best position during the treatment.

4.6.6 HAMSTRING PAIN - ELECTRODE PLACEMENT EXAMPLE

4.6.6.1 Placement for Hamstring Pain Over a Large Area



Use the B-set: Both Pain Site electrodes may be placed in a vertical arrangement on the hamstring. The first electrode should be placed directly over the location where the pain first presents itself. The second electrode should be placed approximately 1.0 inch away from the first electrode and should also cover over the location that any additional pain presents itself. This placement will allow the therapeutic signals to capture the entire region beneath as well as between the electrodes.

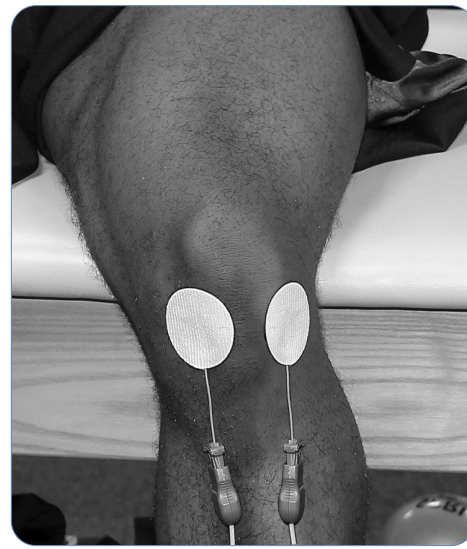
NOTE: Treatment of the belly of a muscle (like the hamstring in this example) will cause it to be held in tension in the volume of tissue beneath both round electrodes. Therefore take care to increase the intensity slowly and carefully.

Body Position: For hamstring treatments, sitting upright in a supported position with the leg straight at the knee is the best position during the treatment.

4.6.7 KNEE AND LOWER LEG PAIN - ELECTRODE PLACEMENT EXAMPLES

For all knee treatments, a self adhering cohesive wrap, elastic bandage or velcro strap should be used to hold both electrodes in place, particularly if range of motion, stretching, biking or other exercise therapy is to be performed during the treatment.

4.6.7.1 Placement for Pain Toward the Front of the Knee (e.g. Pain from an ACL Sprain, Bursitis or Osteoarthritis)

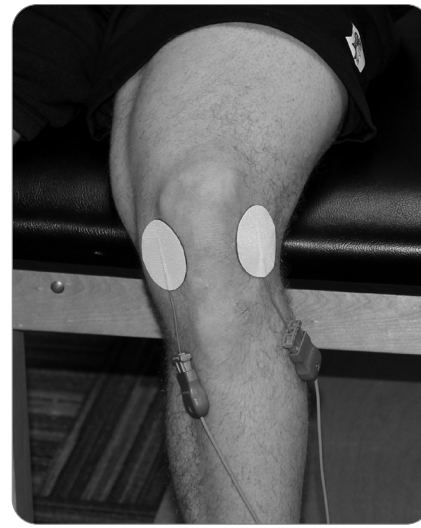


Use the B-set: Both round electrodes should be placed directly over locations of pain typically toward the front of the knee with the edges of the electrodes about one inch apart from each other as shown in the photo to the right.

The edges of the electrodes should typically cover the bottom portion of the patella (knee cap).

Body Position: For treatments on the anterior of the knee, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment which will yield the best outcome.

4.6.7.2 Placement for Pain Throughout the Knee or for Pain in Two Locations (e.g. Pain from a Total Knee Replacement)



Use the B-set: For pain throughout the knee, for example, following total knee arthroplasty, or an ACL repair utilizing the patient's own patellar tendon, one round electrode should be placed on the medial side of the joint line over a painful area; the second round electrode should be placed over the lateral side of the joint line, also over a painful area.

In some instances patients may have pain that presents both inferior and superior to the patella so one round electrode can be placed above the patella and one below the patella, both over painful areas. If the surgical incision has not yet healed, then the electrodes may not be placed over the incision, but may be placed very close to the edge of the incision.

Body Position: For treatments for pain from total knee arthroplasty, if possible, the knee should be bent as close to 90 degrees as possible, yet still comfortable for the patient. This angle provides the strongest sensation in the volume of tissue being treated which will yield the best outcome.

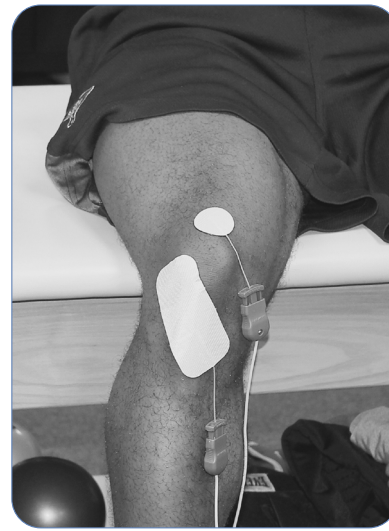
Motion: For patients rehabilitating from recent knee surgery, to facilitate exercise or range of motion therapy, BioWave should be used for 8 to 10 minutes first, with the knee in flexion. After 8 to 10 minutes, reduce the intensity by 5% to take the edge off of the sensation. Then while continuing the BioWave treatment, flexion or extension exercise or range of motion therapy can now be performed by the patient with significantly less pain. The patient may be able to achieve up to 10º of greater flexion while remaining more comfortable. Extension is typically improved as well. As the patient's body adapts to the electrical field, after each set of exercise, the patient may increase the intensity, if desired, for greater pain relief.

8 minutes first, with the knee in flexion. After 8 minutes, reduce the intensity by 3% to take the edge off of the sensation. Then while continuing the BioWave treatment, exercise

or range of motion therapy can now be performed by the patient with significantly less pain. For example, it is much easier for the patient to complete an eccentric quadriceps exercise during a BioWave treatment. As the patient's body adapts to the electrical field, after each set of exercise, the patient may increase the intensity, if desired, for greater pain relief.

4.6.7.3 Placement for Pain Above the Knee (e.g. Pain from Quadriceps Tendinitis)

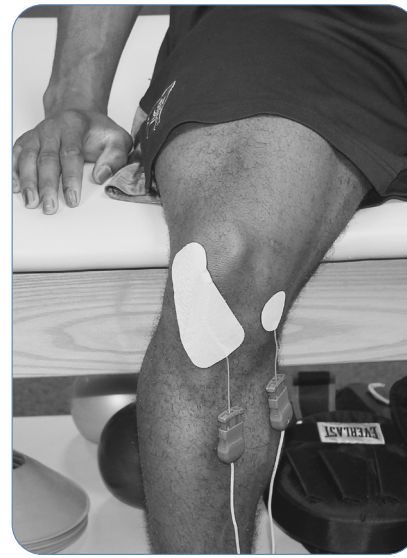
Use the E-set: The small round Pain Site Electrode should be placed directly over the primary source of pain typically over the quadriceps tendon just superior to the patella, as shown in the photo to the right.



The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is on the lateral side of the knee, three quarters of the way up the patella, touching the lateral edge of the patella, angled across the anterior of the knee, and running completely across the patellar tendon as shown in the photo to the right. This is the most comfortable place to receive stimulation into the knee and will allow the patient to achieve a higher intensity level so even more of the therapeutic signal develops in the volume of tissue beneath the small round Pain Site Electrode.

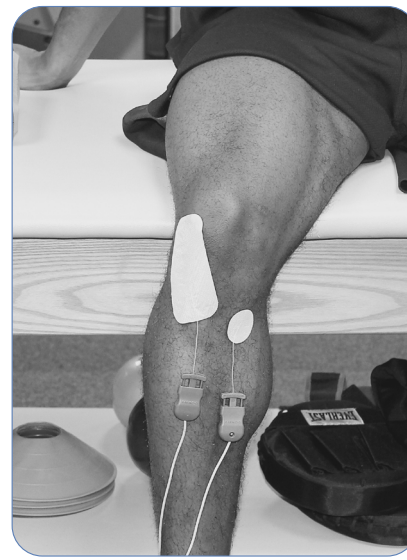
Body Position: For treatments for pain from quadriceps tendinitis, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the volume of tissue being treated which will yield the best outcome.

4.6.7.4 Placement for Medial Knee Pain (e.g. Pain from an MCL Sprain, Pes Anserine Bursitis or Osteoarthritis)



Use the E-set: For pain from an MCL sprain or pain near the medial joint line of the knee, the small round Pain Site Electrode should be placed directly over the primary source of pain on the medial side of the knee, as shown in the first photo to the right.

For pain from Pes Anserine Bursitis, the small round Pain Site Electrode should be placed directly over the primary source of pain over the Pes Anserine Bursa on the medial side of the knee, as shown in the second photo below.

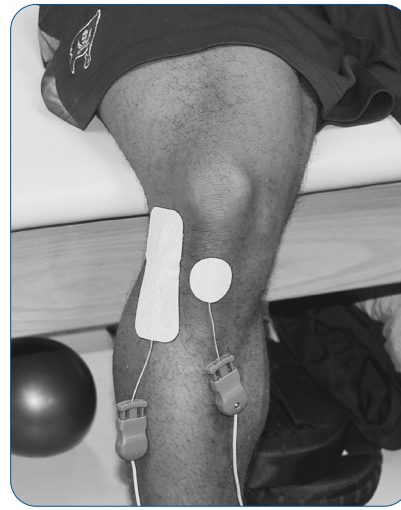


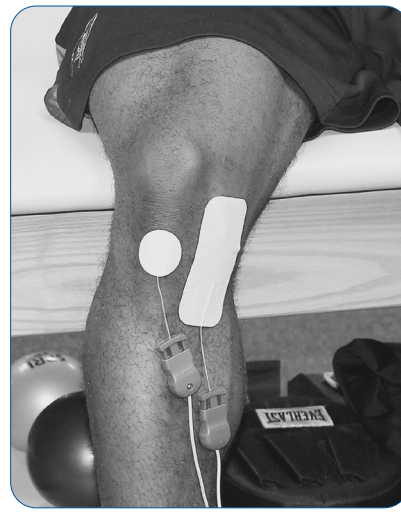
The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is on the lateral side of the knee, three quarters of the way up the patella, touching the lateral edge of the patella, angled across the anterior of the knee, and running completely across the patellar tendon as shown in both photos to the right. This is the most comfortable place to receive stimulation into the knee and will allow the patient to achieve a higher intensity level so even more of the therapeutic signal develops in the volume of tissue beneath the small round Pain Site Electrode.

Body Position: For treatments on the medial side of the knee, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment which will yield the best outcome.

Motion: To facilitate exercise or range of motion therapy, BioWave should be used for

4.6.7.5 Placement for Pain Below the Knee Cap (e.g. Pain from Patellar Tendinitis)





Use the E-set: The small round Pain Site Electrode should be placed directly over the **primary source of pain,** in this case, directly over the patellar tendon, as shown in both photos.

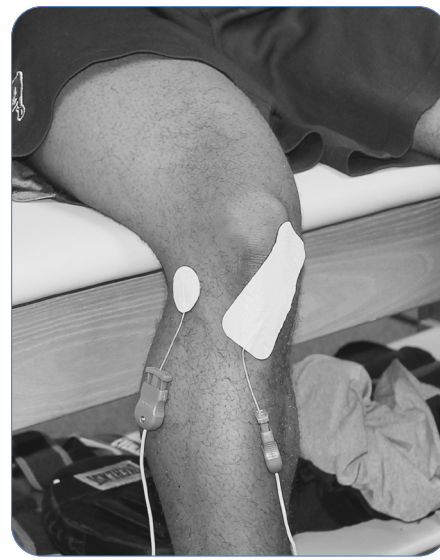
The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is preferably on the lateral side of the knee, starting from just above the midline of the knee, with most of the electrode placed below the midline angled just slightly toward the anterior of the knee (see first photo). The electrodes will be approximately 0.5 inches apart from one another which is the minimum spacing between the electrodes. The rectangular Dispersive Electrode should not be placed over the peroneal nerve and softer tissue on the posterior lateral side of the knee because delivering stimulation over the softer tissue or stimulating the peroneal nerve will limit the ability of the patient to achieve higher intensity levels and therefore not as strong an electrical field will be created under the smaller electrode over the pain site.

For patients bothered by stimulation of the peroneal nerve, an alternative is to place the rectangular Dispersive Electrode on the medial side of the knee starting at the midline of the joint and running at a slight angle toward the anterior of the knee (see second photo).

Body Position: For treatments for pain from patellar tendinitis, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the volume of tissue being treated which will yield the best outcome.

Motion: To facilitate exercise or range of motion therapy, BioWave should be used for 8 minutes first, with the knee in flexion. After 8 minutes, reduce the intensity by 3% to take the edge off of the sensation. Then while continuing the BioWave treatment, exercise or range of motion therapy can now be performed by the patient with significantly less pain. For example, it is much easier for the patient to complete an eccentric quadriceps exercise during a BioWave treatment. As the patient's body adapts to the electrical field, after each set of exercise, the patient may increase the intensity, if desired, for greater pain relief.

4.6.7.6 Placement for Lateral Knee Pain (e.g. Pain from an LCL Sprain, Bursitis or Osteoarthritis)

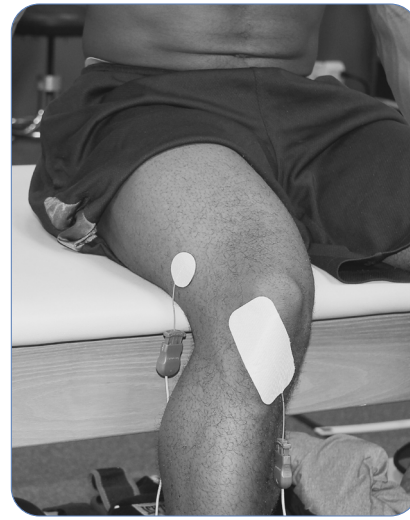


Use the E-set: The small round Pain Site Electrode should be placed directly over the **primary source of pain on the lateral side of the knee**, as shown in the photo to the right.

The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is on the medial side of the knee, starting three quarters of the way up the patella, touching the medial edge of the patella, angled to the anterior of the knee, and running across the patellar tendon as shown in the photo above. This is the most comfortable place to receive stimulation into the knee and will allow the patient to achieve a higher intensity level so even more of the therapeutic signal develops in the volume of tissue beneath the small round Pain Site Electrode.

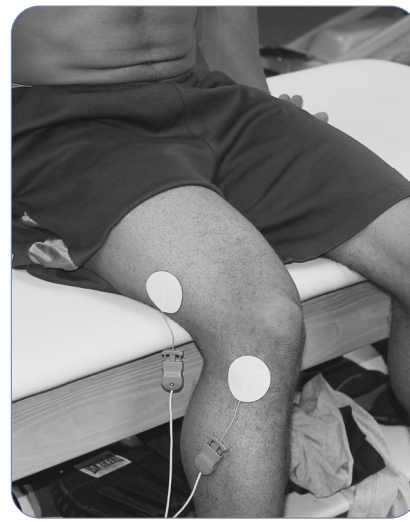
Body Position: For treatments on the lateral side of the knee, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment which will yield the best outcome.

4.6.7.7 Placement for Pain on the Outside of the Thigh (e.g. Pain from Illiotibial Band (IT Band) Pain)



Use the E-set for one location of pain: The small round Pain Site Electrode should be placed directly over the **primary source of pain, typically on the lateral superior side of the knee**, as shown in the first photo to the right.

The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is on the lateral side of the knee, starting just above the midline of the knee, and angled to the anterior of the knee, touching the lateral edge of the patella and running across the patellar tendon as shown in the first photo to the right.

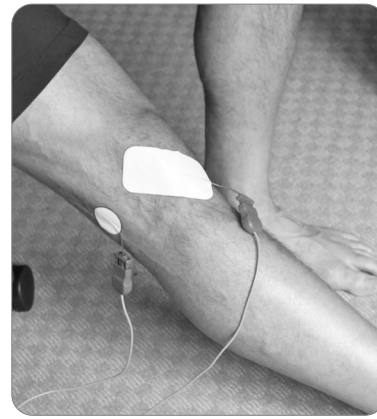


Use the B-set for two locations of pain: If pain presents at both the distal and proximal ends of the illiotibial band, then use the B-set electrodes to provide an equal treatment at each location simultaneously as in the second photo to the right. There is no maximum distance between the electrodes and the patient will not feel anything across the skin in between the electrodes. The only sensation will be within a 3 inch diameter hemisphere beneath each of the 2 inch diameter electrodes.

Make sure there is at least 1.0 inch of spacing between the electrodes.

Body Position: For IT Band treatments, the knee should be bent at between approximately 45 and 90 degrees. The patient should find the angle of bend at the knee that provides the strongest sensation from the electrical field in the IT Band during the treatment, as this will yield the best outcome.

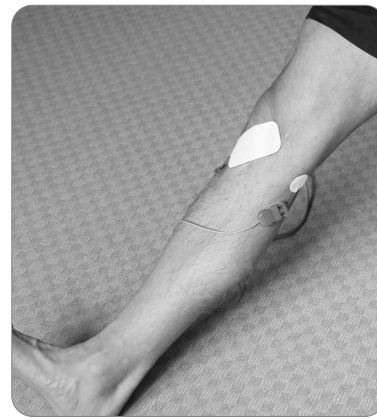
4.6.7.8 Placement for Posterior Knee Pain



Use the E-set: The small round Pain Site Electrode should be placed directly over the primary source of pain on the posterior side of the leg behind the knee.

The **bony prominence or comfortable location** for the rectangular Dispersive Electrode will vary depending upon the location of the small round Pain Site Electrode.

If the small round Pain Site Electrode is placed toward the posterior lateral side of the knee as in the first photo, then the rectangular Dispersive Electrode should be placed on the lateral side of the knee, starting just above the midline of the knee, and angled to the anterior of the knee, touching the edge of the patella and running across the patellar tendon as shown in the first photo above.



If the small round Pain Site Electrode is placed toward the posterior medial side of the knee as in the second photo, then the rectangular Dispersive Electrode should be placed on the medial side of the knee, starting just above the midline of the knee, and angled to the anterior of the knee, touching the edge of the patella and running across the patellar tendon as shown in the second photo to the right.

Body Position: For treatments for pain on the posterior of the knee, sitting with the knee straight at zero degrees so the tissue on the posterior of the knee is more taut, will produce the best treatment outcome.

4.6.7.9 Placement for Amputation Pain and Phantom Limb Pain (Lower Leg)

Use the B-set: The two round Pain Site Electrodes should be placed directly over the source or perceived source of pain around the stump. Electrodes may also be placed over nerves that are thought to be carrying the pain signal from a part of the body that no longer exists.

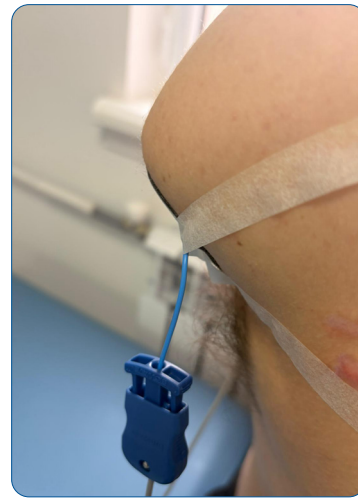
This protocol applies to both below the knee (BK) as well as to above the knee (AK) amputation and phantom limb pain.

Typical pad placements for each of the two pads may be in any two distinct locations around the stump: end of the stump and/or on the anterior, posterior, medial, or lateral side of the stump.

With amputation and phantom limb pain, the placement tends to be an iterative, trial and error process, until the patient receives relief from the optimized electrode placement that targets the nerves that are conducting the pain signals up to the brain.

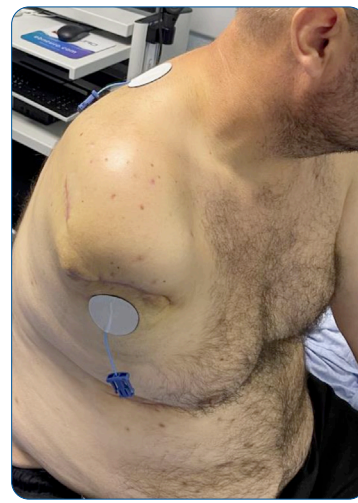
Once the optimized electrode placement location is determined, then a photo should be taken of the electrode placement for the patient, so they can repeat the exact same placement at home using their BioWaveHOME unit.

4.6.7.10 Placement for Amputation Pain and Phantom Limb Pain (Upper Extremities)



Use the B-set: The two round Pain Site Electrodes should be placed directly over the source or perceived source of pain around the stump. Electrodes may also be placed over nerves that are thought to be carrying the pain signal from a part of the body that no longer exists.

Typical pad placements for each of the two pads may be in any two distinct locations around the stump: end of the stump and/or on the anterior, posterior, medial, or lateral side of the stump.



Additionally one pad may be placed over pain experienced on or around the stump and a second electrode may be placed over a second location of pain for example over the trapezius as shown in the second photo to the right.

With amputation and phantom limb pain, the placement tends to be an iterative, trial and error process until the patient receives relief from the optimized electrode placement location targeting the nerves that are conducting the pain signals up ot the brain.

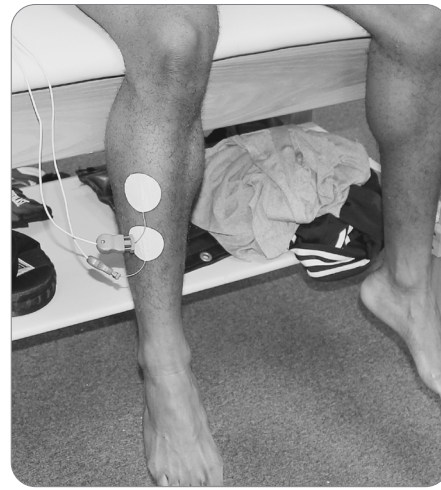
Once the optimized electrode placement location is determined, then a photo should be taken of the electrode placement for the patient, so they can repeat the exact same placement at home using their BioWaveHOME unit.

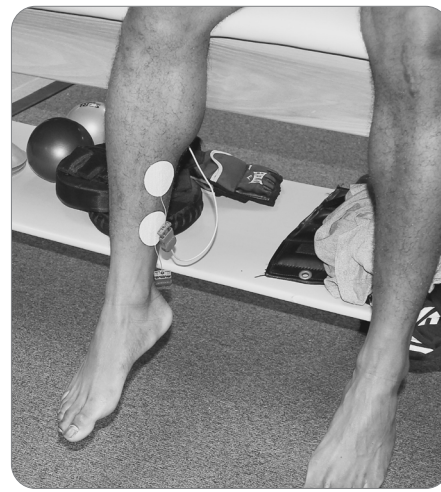
4.6.7.11 Placement for Pain on the Front of the Lower Leg (e.g. Pain from Shin Splints)

Use the B-set: The two round Pain Site Electrodes should be placed directly over the source of pain along the shin. Typical placements for pain from shin splints are shown in the two photos to the right.

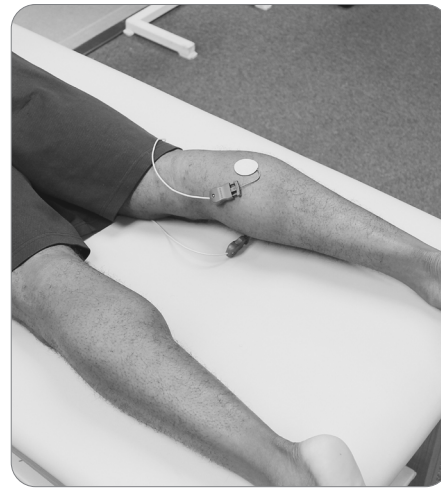
If the electrodes are placed about 1.0 inch apart from one another, the therapeutic electrical field formed beneath each electrode will overlap internally allowing the entire region beneath both electrodes of approximately 6 inches by 3 inches to be stimulated and treated.

Body Position: Sitting in a supported position with the knees at about 90 degrees is typically the most comfortable position in which to receive stimulation for shin splints.



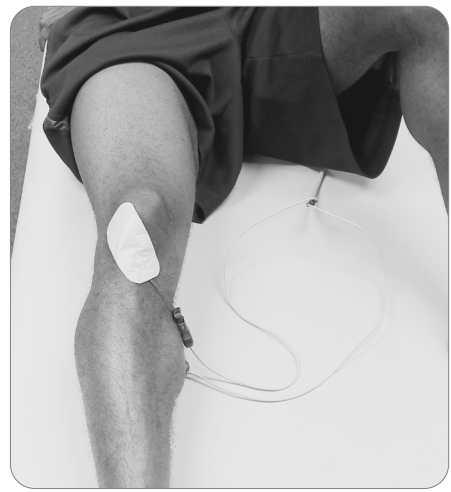


4.6.7.12 Placement for Calf Pain (e.g. pain from a Gastrocnemius Strain)



Use the E-set: For calf pain, for example from a Gastrocnemius strain, the small round Pain Site Electrode should be placed directly over the primary source of pain over the calf as shown in the first photo to the right.

The **bony prominence or comfortable location** for the rectangular Dispersive Electrode is on the lateral side of the knee, three quarters of the way up the patella, touching the lateral edge of the patella, angled across the anterior of the knee, and running completely across the patellar tendon as shown in the second photo to the right. This is the most comfortable place to receive stimulation into the knee and will allow the patient to achieve a higher intensity level so even more of the therapeutic signal develops in the volume of tissue beneath the small round Pain Site Electrode over the calf.

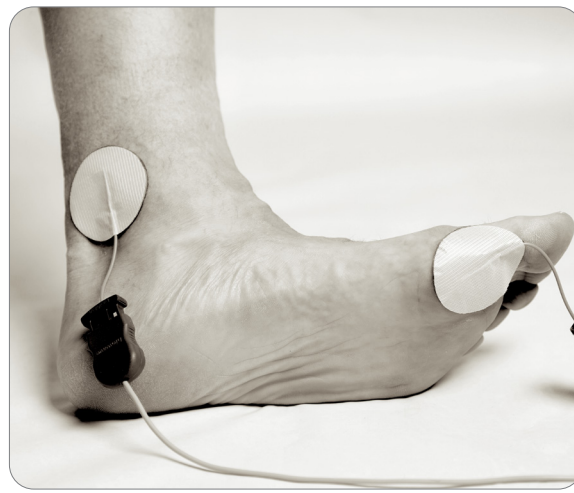


Body Position: For treatments for calf pain, sitting upright or partially reclined with the legs straight is the best position during the treatment. The patient should adjust the direction they point their toes either toward them or away from them to put the calf in tension. This allows the patient to tolerate a higher level of stimulation because it is a more comfortable position in which to receive stimulation in the calf.

4.6.8 ANKLE AND FOOT PAIN - ELECTRODE PLACEMENT EXAMPLES

For all ankle and foot treatments, a cohesive self adhering wrap, elastic bandage or velcro strap should be used to hold both electrodes in place, particularly if range of motion, exercise or stretching therapy is to be performed during the treatment.

4.6.8.1 Placement for Ankle or Foot Pain that Results from Diabetic Neuropathy



Use the B-set: For pain occurring in the foot or ankle that results from diabetic neuropathy, B-set Electrodes (two 2" diameter round pads) are each placed over the tibial nerve in different locations along the foot as shown in the photo to the right.

One electrode is placed on the medial aspect (inside) of the ankle just above and posterior to the malleolus (just above and behind the inside ankle bone). The second electrode is placed just behind the Great Toe on the bottom of the foot and slightly wraps onto the side of the foot just behind the big toe. The electrodes should be placed on the foot which is experiencing the pain. These two electrodes can be placed, both on the right foot or both on the left foot.

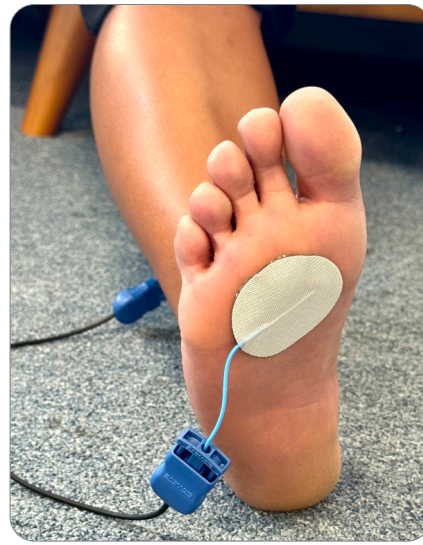
Body Position: The foot generally should be kept at approximately 90 degrees to the tibia and the bottom of the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor is the most ideal position during the treatment. However, if necessary, the foot can be elevated during the treatment.

4.6.8.2 Alternative Placement for Neuropathic Foot Pain

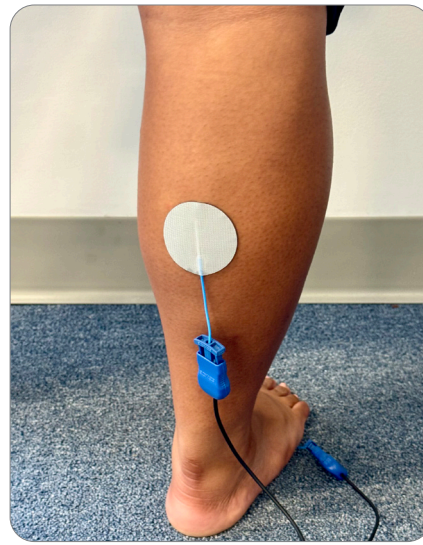
Use the B-set: For neuropathic pain occurring in the foot or ankle, place the first electrode over the center of the ball of the foot as shown in the photo to the right.

Place the second electrode on the back of the calf centered over the gastrocnemius as shown in the second photo below.

The electrodes should be placed on the foot which is experiencing the pain.

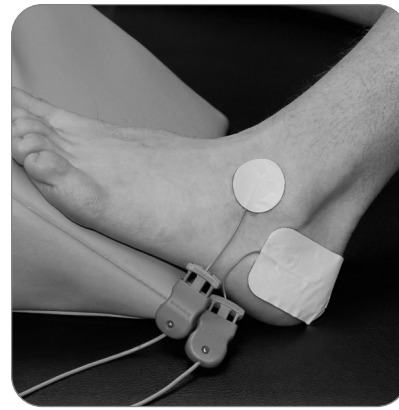


Body Position: The foot generally should be kept at approximately 90 degrees to the lower leg and the bottom of the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor is the most ideal position during the treatment. However, if necessary, the foot can be elevated during the treatment.



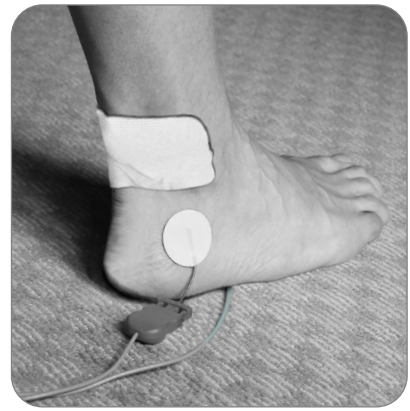
4.6.8.3 Placement for Lateral Ankle or Foot Pain (e.g. Pain from a Low Ankle or Foot Sprain)

Use the E-set: For pain occurring on the lateral side of the ankle or foot, for example from a sprain of the lateral collateral ligament complex, place the small round Pain Site Electrode **directly over the pain site as in the first photo to the right**.



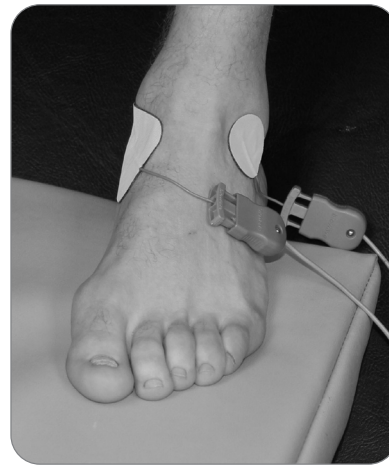
The bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the lateral side of the malleolus and wrapping around the Achilles tendon, a little higher up than shown in the first photo to the right.

If the primary point of pain is on the posterior lateral side of the heel, the small round electrode should be placed directly over the painful location as in the second photo to the right.



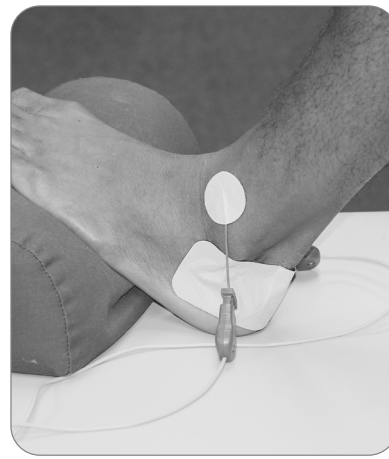
The comfortable bony prominence location for the rectangular Dispersive Electrode is on the lateral side of the malleolus wrapping around the Achilles tendon as shown in the second photo to the right.

If the primary pain site is on the lateral side of the foot but there is secondary compression pain on the medial side of the foot, then place the rectangular Dispersive Electrode over the secondary point of pain on the medial side of the foot as shown in the photo to the right.



Body Position: The foot generally should be kept at approximately 90 degrees to the tibia and the bottom of the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor or sitting on a training or physical therapy table with the knee bent and the foot resting flat on a wedge are the most ideal positions during the treatment. However, if necessary, the foot can be elevated during the treatment. The BioWave treatment may be done in combination with hot or cold therapy.

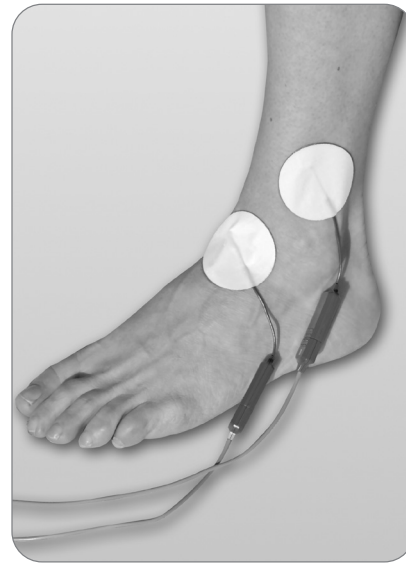
4.6.8.4 Placement for Pain Around the Ankle (e.g. Pain from a High Ankle Sprain with only a Primary Pain Site)



Use the E-set: For pain occurring from a high ankle sprain, primary pain often occurs above the ankle toward the anterior lateral side of the foot.

For this type of pain condition, place the small round electrode directly over the primary pain site as shown in the second photo to the right. The comfortable bony prominence location for the rectangular Dispersive Electrode is over the lateral side of the foot and heel wrapping around the calcaneus as in the second photo to the right. Avoid the medial side of the heel and ankle to avoid stimulation of the tibial nerve.

4.6.8.5 Placement for Foot or Ankle Injury with Pain in Two Locations

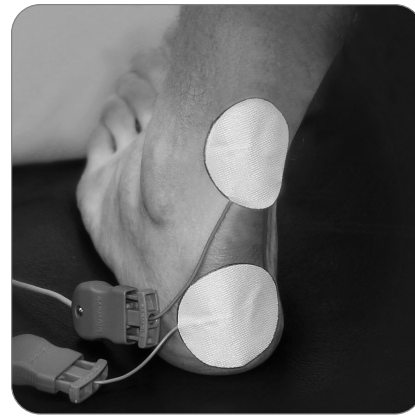


Use the B-set: For pain occurring from any foot or ankle injury where the magnitude of the pain is similar in two locations, the B-set of electrodes should be used. Both round Pain Site Electrodes should be placed **directly over both primary points of pain** as shown in the photo to the right.

Body Position: The foot generally should be kept at approximately 90 degrees to the tibia and the bottom of the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor or sitting on a training or physical therapy table with the knee bent and the foot resting flat on a wedge are the most ideal positions during the treatment. However, if necessary, the foot can be elevated during the treatment. The BioWave treatment may be done in combination with hot or cold therapy.

Motion: For all ankle and foot treatments, a self adhering wrap, elastic bandage or velcro strap should be used to hold the electrodes in place. While resting the foot against a flat surface it is recommended to gently articulate the ankle into flexion and extension to find a treatment position that causes the sensation felt by the electrical signals to focus directly onto and encompass the primary point of pain.

4.6.8.6 Placement for Pain from Achilles Tendinitis



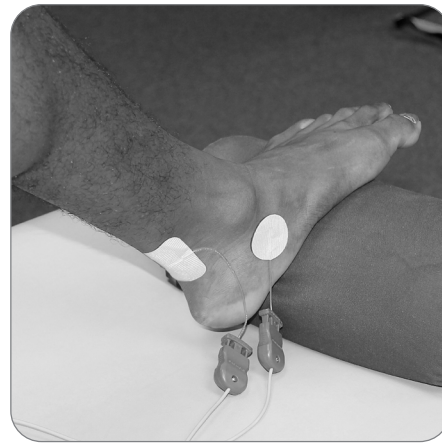
Use the B-set: Place the first Pain Site electrode over the painful location on the Achilles tendon. Place the second pain site electrode at the insertion point of the Achilles tendon on the back of the heel as shown in the photo to the right. Make sure there is at least one inch of spacing between the two round electrodes.

The use of a self adhering wrap, elastic bandage or velcro strap is recommended to hold both electrodes in place.

Body Position: For all Achilles tendonitis treatments, the foot should generally be kept at approximately 90 degrees to your leg and the bottom of the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor is the most ideal position during the treatment. However, if necessary, the foot may be elevated during the treatment.

Motion: While resting the foot on a flat surface it is recommended to gently move the ankle back and forth (into flexion and extension) to find a treatment position that causes the sensation felt by the electrical signals to focus directly onto the primary location of pain. **Make sure the edges of the electrodes do not touch each other if you are placing your foot into plantar flexion.**

4.6.8.7 Placement for Medial Ankle or Foot Pain

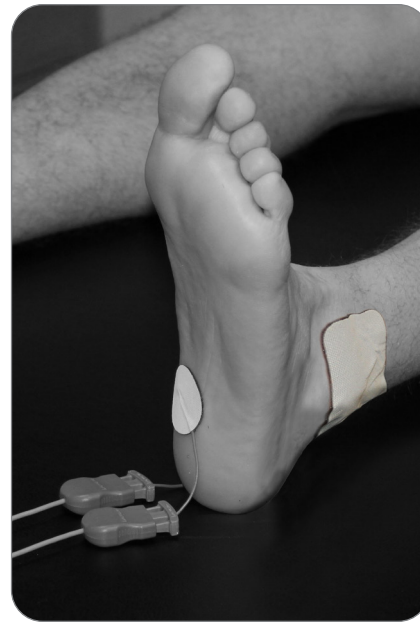


Use the E-set: For pain occurring on the medial side of the ankle or foot, place the small round Pain Site Electrode **directly over the pain site as in the photo to the right**. It is fine if stimulation on the medial side of the foot or ankle causes stimulation along the tibial nerve. The patient should adjust the intensity level of stimulation so that it is strong but still comfortable.

The bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the lateral side of the malleolus wrapping around the Achilles tendon as in the photo to the right.

Motion: While resting the foot on a flat surface it is recommended to gently articulate the ankle into flexion and extension to find a treatment position that causes the sensation felt by the electrical signals to focus directly onto and encompass the primary point of pain.

4.6.8.8 Placement for Pain on the Bottom of the Foot (e.g. Pain from Plantar Fasciitis)



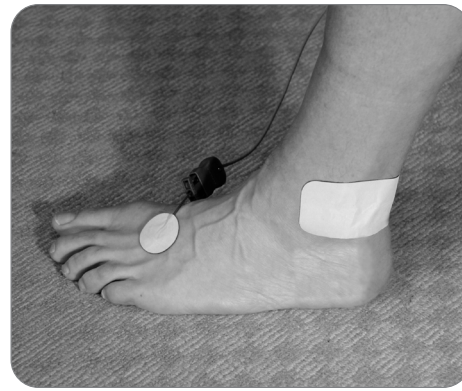
Use the E-set: For pain occurring in the bottom of the foot, for example, from plantar fasciitis, the small round Pain Site Electrode should be placed **directly over the pain site** as shown in the photo to the right. The comfortable bony prominence location for the rectangular Dispersive Electrode is on the lateral side of the malleolus wrapping around the Achilles tendon.

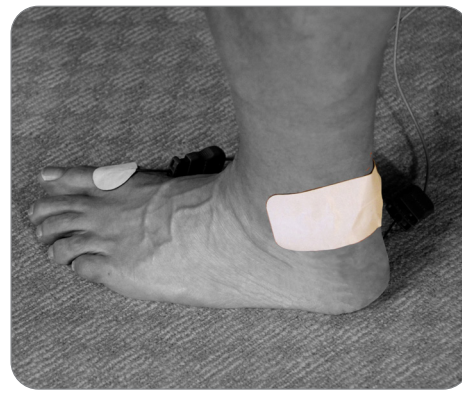
The use of a cohesive self adhering wrap, elastic bandage or velcro strap is recommended to hold both the round Pain Site Electrode and rectangular Dispersive Electrode in place.

Body Position: For all plantar fasciitis treatments, the foot should be kept at approximately 90 degrees to the tibia and the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor or sitting on a training or physical therapy table with the knee bent and the foot flat on a wedge are the most ideal positions during the treatment.

Motion: While resting the foot on a flat surface it is recommended to gently articulate the ankle into flexion and extension to find a treatment position that causes the sensation felt by the electrical signals to focus directly onto and encompass the primary point of pain.

4.6.8.9 Placement for Pain on the Top of the Foot (e.g. Pain from Phalange, Metatarsal, Neuroma or Turf Toe Pain)





Use the E-set: For pain occurring in a joint on the top of the foot, for example between the phalanges and metatarsal bones, the small round Pain Site Electrode should be placed **directly over the pain site on the top of the foot** as shown in the first photo to the right. If the pain presents from the side or bottom of the foot, the small round electrode should be placed over the painful area on the side or bottom of the foot. For pain over the big toe, for example from turf toe, the small round Pain Site Electrode should be placed **directly over the pain site on the top of the toe** as shown in the second photo to the right.

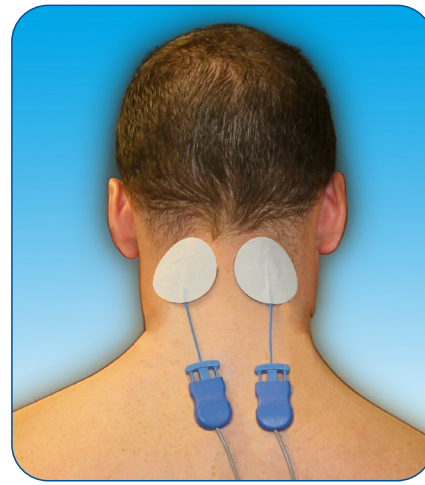
The comfortable bony prominence location for the rectangular Dispersive Electrode is on the lateral side of the malleolus wrapping around the Achilles tendon.

Body Position: For all ankle and foot pain, the foot should be kept at approximately 90 degrees to the tibia and the foot should rest against a flat surface. Therefore sitting in a chair with the foot flat on the floor or sitting on a training or physical therapy table with the knee bent and the foot flat on a wedge are the most ideal positions during the treatment.

4.6.9 HEADACHE, NECK, CERVICAL & TMJ PAIN - ELECTRODE PLACEMENT EXAMPLES

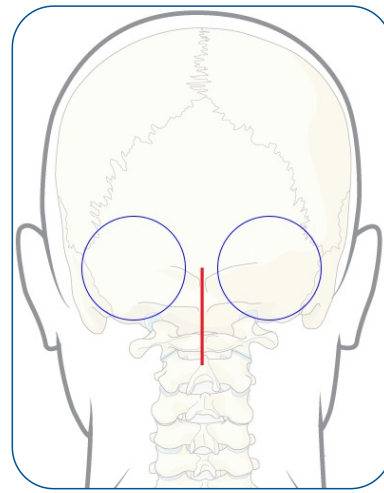
For all neck treatments, tape should be used to help hold the electrode(s) in place on the back of the neck.

4.6.9.1 Placement for Headache Pain Originating in the Posterior of the Neck or Head (Occipital Neurostimulation)



Use the B-set: For headache pain that initiates in the posterior of the neck or head, place 2 round Pain Site Electrodes bilaterally with the inside edges 0.5" apart from one another, and with the top edge of both electrodes right at the hariline. Electrodes should not be placed on the side or front of the neck.

An alternate placement is to position the electrodes bilaterally at the occiput on either side of the cervical spine. Spacing between the inner edges of the electrodes is 0.5". This may be used on bald patients. Patients with hair need to under-shave the base of the skull for electrode adhesion directly to skin.

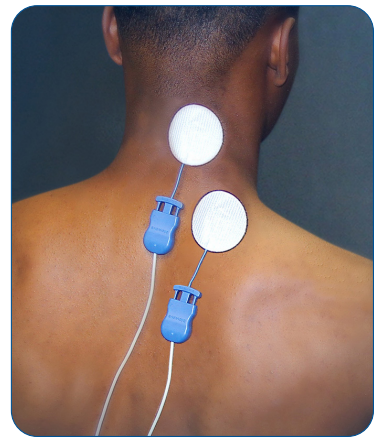


For both placements, medical tape can be used across both electrodes and onto both sides of the neck to help secure the electrodes in place.

Both these electrode placements capture the greater, lesser and third occipital nerves on each side of the cervical spine. As a result, the sensation felt is not only beneath and surrounding both electrodes, but also there is a very pleasant mild stimulation felt up the back of the head almost to the crown of the head.

Body Position: For all neck treatments, the head should be bent slightly forward so the tissue on the back of the neck or head is in a taut position. This will provide a better treatment outcome.

4.6.9.2 Neck Pain in One Location or Radiating Neck Pain



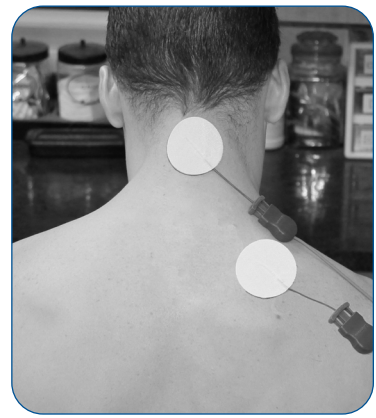
Place one Pain Site Electrode directly over the single location of pain on the back of the neck as shown in the photo to the right.

Place the other Pain Site Electrode one inch away beneath and to the side to which the pain may be radiating. In this example the second Pain Relief Pad is placed below and to the right of the first pad.

In addition to the strong sensation beneath and surrounding both electrode, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

Body Position: Sitting in a comfortable position with the head bent forward is the best position during the treatment.

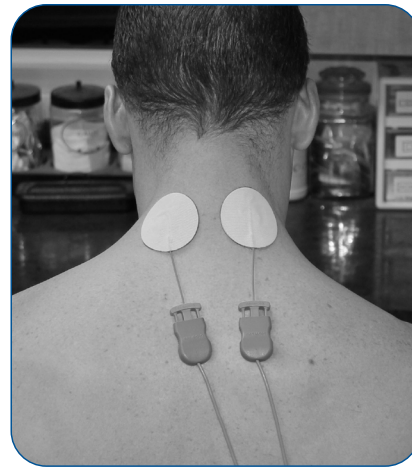
4.6.9.3 Placement for Neck or Cervical Pain in Two Locations



Use the B-set: For two separate painful locations, two round same size Pain Site Electrodes should be placed directly over the two painful areas. For example if pain presents on the back of the neck and in the trapezius or rhomboid as in the photo to the right, then each round Pain Site Electrode should be placed over each painful location. There is no maximum distance for the spacing between the electrodes.

Body Position: Sitting in a comfortable position with the head bent forward is the best position during the treatment.

4.6.9.4 Placement for Bilateral Neck or Cervical Pain

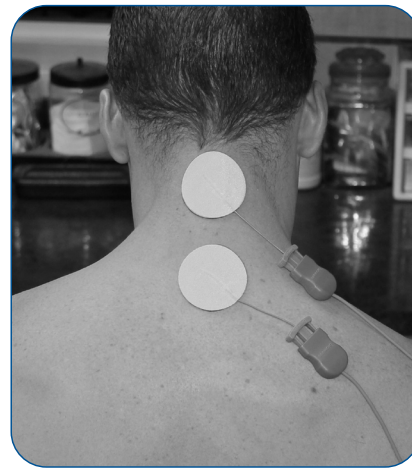


Use the B-set: For bilateral cervical pain across the spine, each round Pain Site Electrode should be placed directly over the painful areas. The two round electrodes should be approximately 1.0 inch apart from one another as shown in the first photo on the next page. The electrodes should not be placed on the side or front of the neck.

For all neck treatments, in addition to the sensation felt in the volume of tissue beneath the electrodes, patients may feel a mild comfortable tingling sensation running from the base of the skull to the crown of the head. This is due to stimulation of the occipital nerve.

Body Position: The head should be bent slightly forward so the tissue on the back of the neck is more taut. This will provide a better treatment outcome.

4.6.9.5 Placement for Neck or Cervical Pain Over a Large Area

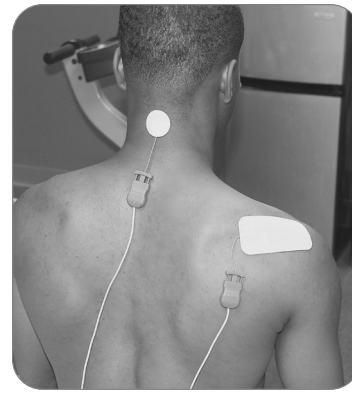


Use the B-set: For cervical pain centered over the spine over a large area, each round Pain Site Electrode should be placed over the spine in a vertical fashion directly over the painful areas. The two round electrodes should be approximately 1.0 inch apart from one another as shown in the photo to the right.

For all neck treatments, in addition to the sensation felt in the volume of tissue beneath the electrodes, patients may feel a mild comfortable tingling sensation running from the base of the skull to the crown of the head. This is due to stimulation of the occipital nerve.

Body Position: The head should be bent slightly forward so the tissue on the back of the neck and the cervical spine is more taut. This will provide a better treatment outcome.

4.6.9.6 Placement for Neck or Cervical Pain in One Location



Use the E-set: For unilateral pain occurring on the back of the neck, the small round Pain Site Electrode should be placed **directly over the pain site**. This placement may be directly over the spine or just to the side of the spine.

One corner of the rectangular Dispersive Electrode should be located just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. This is a very comfortable location to receive stimulation from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid because it may feel fatigued following the treatment and stimulation over the softer tissue in that region will prevent the patient from achieving a higher intensity level.

Body Position: The head should be bent slightly forward so the tissue on the back of the neck is more taut. This will provide a better treatment outcome.

4.6.9.7 Placement for Temporomandibular Joint (TMJ) Pain

Use the E-set: For pain occurring in the temporomandibular joint or along the trigeminal nerve, place the small round Pain Site Electrode **directly over the pain site** on the cheek as shown in the photo to the right. The skin on the cheek must be clean and free of hair or makeup.

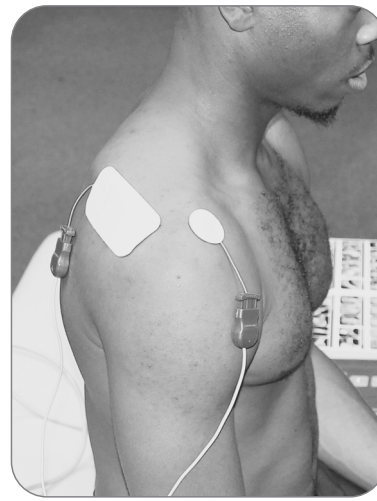
One corner of the rectangular Dispersive Electrode should be located just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. This is a very comfortable location to receive stimulation from the rectangular Dispersive Electrode.

It is normal for the facial muscles to pull toward the small round electrode and there may be slight twitching in the eye closest to the small round electrode. Patients may also feel stimulation into their molars if they have amalgam fillings.

4.6.10 SHOULDER PAIN - ELECTRODE PLACEMENT EXAMPLES

For all shoulder treatments, a wide self adhering wrap, medical tape, elastic bandage or velcro strap should be used to hold both electrodes in place, particularly if range of motion, exercise or stretching therapy is to be performed during the treatment.

4.6.10.1 Placement for Pain in the Acromioclavicular (AC) Joint or for Pain Inside the Shoulder Joint (e.g. from Frozen Shoulder/Adhesive Capsulitis)



Use the E-set: For pain occurring on the top of or inside the shoulder, for example, for pain from an Acromioclavicular (AC) sprain or from Adhesive Capsulitis (see photo to the right), the small round Pain Site Electrode should be placed **directly over the pain site at the AC joint**.

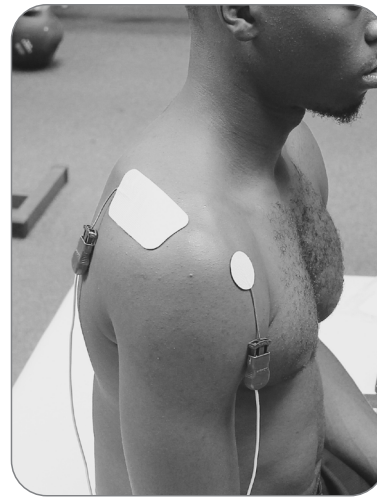
The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. The rectangular Dispersive Electrode should not touch the belly of the deltoid because the deltoid may feel fatigued following the treatment and stimulation over the softer tissue in that region will prevent the patient from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable. Maintain at least 0.5 inches of spacing between the two electrodes.

Generally the rectangular Dispersive Electrode is never placed over the anterior portion of the shoulder or chest as this is an uncomfortable place to receive stimulation.

Body Position: For all shoulder treatments, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.6.10.2 Placement for Anterior Shoulder Pain (for example from Biceps Tendinitis, Supraspinatus Tendinitis or a Superior Labrum Anterior to Posterior (SLAP) Tear)



Use the E-set: For pain occurring on the anterior of the shoulder, for example, for pain from Biceps Tendinitis, Supraspinatus Tendinitis or a Superior Labrum Anterior to Posterior (SLAP) Tear the small round Pain Site Electrode should be placed directly over the pain site on the anterior of the shoulder as shown in the photo to the right.

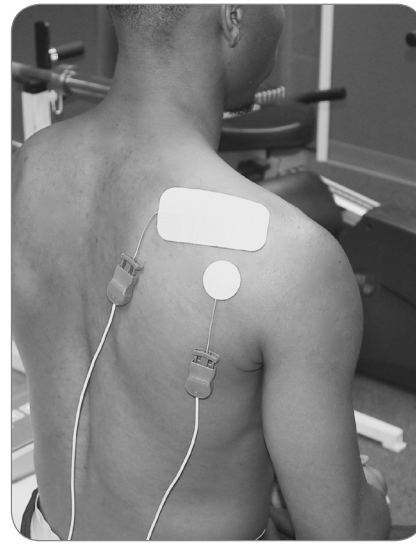
The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. The rectangular Dispersive Electrode should not touch the deltoid because it may feel fatigued following the treatment and stimulation over the softer tissue in that region will prevent the patient from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

Generally the rectangular Dispersive Electrode is never placed over the anterior portion of the shoulder or chest as this is an uncomfortable place to receive stimulation.

Body Position: For anterior shoulder treatments, generally the patient should be sitting in a supported position. If the patient can tolerate some internal rotation, the patient should gently move their hand behind their buttock and sit on the back side of their fingers. This helps to slightly open the subacromial space and allow the electrical field to focus on the supraspinatus tendon. If the patient cannot tolerate internal rotation, then the arm should rest near the side of the body or the patient may lie in a supine position on a treatment table.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focus directly over and encompasses the pain site.

4.6.10.3 Placement for Posterior Shoulder Pain (for example from an Infraspinatus Strain or Posterior Rotator Cuff Tendinitis)



Use the E-set: For pain occurring on the posterior of the shoulder, for example, from an infraspinatus strain or from posterior rotator cuff tendinitis, the small round Pain Site Electrode should be placed directly over the pain site on the posterior of the shoulder as shown in the photo to the right.

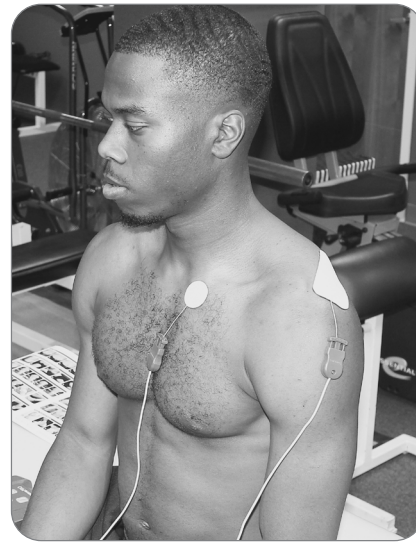
The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. The rectangular Dispersive Electrode should not touch the deltoid because it may feel fatigued following the treatment and stimulation over the softer tissue in that region will prevent the patient from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

Generally the rectangular Dispersive Electrode is never placed over the anterior portion of the shoulder or chest as this is an uncomfortable place to receive stimulation.

Body Position: For all shoulder treatments, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.6.10.4 Placement for Sternoclavicular (SC) Pain (for example from an SC Sprain)



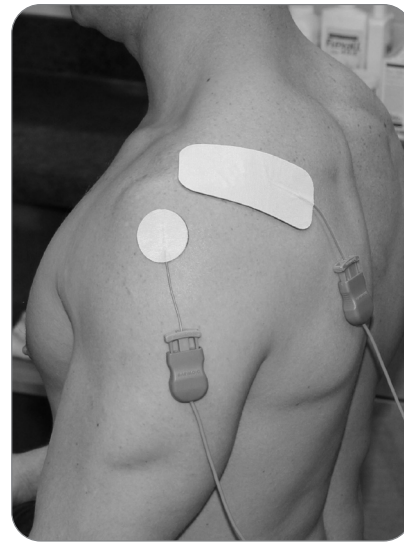
Use the E-set: For pain occurring on the sternoclavicular joint, for example, from a sternoclavicular (SC) sprain, the small round Pain Site Electrode should be placed directly over the pain site where the clavicle meets the sternum as shown in the photo to the right.

For this placement make sure the small electrode DOES NOT TOUCH the anterior of the neck.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. The rectangular Dispersive Electrode should not touch the deltoid because it may feel fatigued following the treatment and stimulation over the softer tissue in that region will prevent the patient from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

Body Position: For treatment of the SC joint, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

4.6.10.5 Placement for Pain on the Edge of the Shoulder (for example from Rotator Cuff Tendinitis)



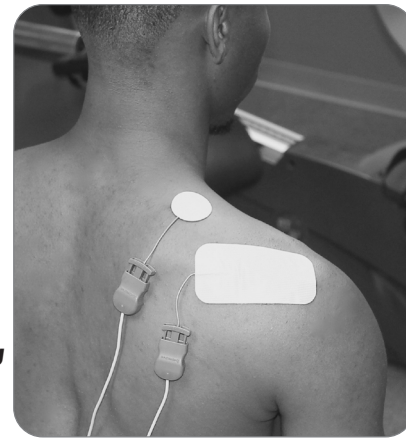
Use the E-set: For pain occurring on the edge of the shoulder, for example, from rotator cuff tendinitis, the small round Pain Site Electrode should be placed directly over the pain site on the edge of the shoulder as shown in the photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. Make sure there is at least one inch of spacing between the electrodes. If necessary the rectangular Dispersive Electrode may be placed across the spine of scapula if spacing along the spine of scapula is not available.

Body Position: For all shoulder treatments, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

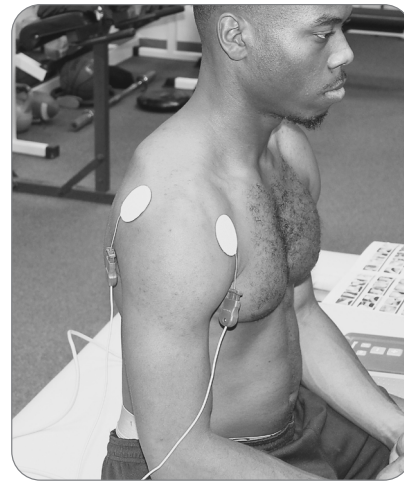
4.6.10.6 Placement for Shoulder Pain on the Trapezius



Use the E-set: For pain occurring on the posterior of the shoulder, for example on the trapezius, the small round Pain Site Electrode should be placed directly over the pain site on the trapezius as shown in the photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo to the right. Make sure there is at least one inch of spacing between the electrodes. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode.

4.6.10.7 Placement for Two Locations of Pain in One Shoulder and Alternative Placement for Pain from Frozen Shoulder/Adhesive Capsulitis

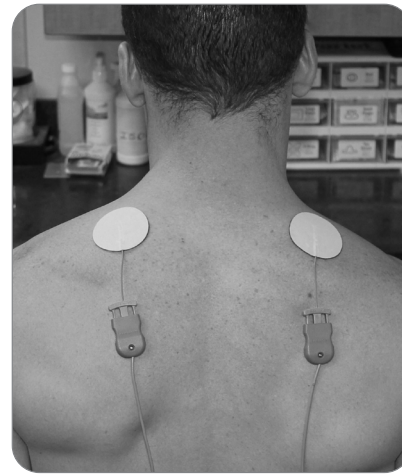


Use the B-set: For two equal locations of pain occurring in the shoulder or, as an alternative placement for pain inside the shoulder joint (Section 4.6.10.1), place each 2-inch diameter round electrode directly over each respective pain site on the anterior, top and/or posterior side of the shoulder as shown in the photo to the right.

Body Position: For all shoulder treatments, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focuses directly over and encompasses both pain sites.

4.6.10.8 Placement for Shoulder Pain in Two Locations (e.g. Bilateral Trapezius Pain)



Use the B-set: For pain occurring in both shoulders, for example, bilateral trapezius pain, two 2-inch diameter round electrodes should be placed directly over each respective pain site on the posterior side of each shoulder as shown in the photo to the right. There is no maximum distance limitation between the two electrodes.

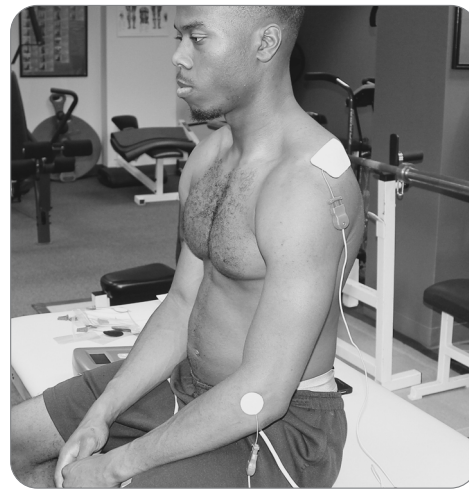
Body Position: For all shoulder treatments, lying in a supine position or sitting in a supported position is generally most comfortable with the arm resting near the side of the body.

Motion: The patient should gently articulate the shoulder joint to shift the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.6.11 ELBOW PAIN - ELECTRODE PLACEMENT EXAMPLES

For all elbow treatments, a self adhering wrap, elastic bandage or velcro strap should be used to hold the electrode on the elbow in place, particularly if range of motion, exercise or stretching therapy is to be performed during the treatment.

4.6.11.1 Placement for Lateral Elbow Pain (e.g. Pain from Lateral Epicondylitis)



Use the E-set: Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode is placed on the elbow.

For pain occurring on the lateral side of the elbow, for example, for pain from lateral epicondylitis, the small round Pain Site Electrode should be placed **directly over the pain site as shown in the photo to the right**.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo above. There is no maximum distance limitation between the two electrodes.

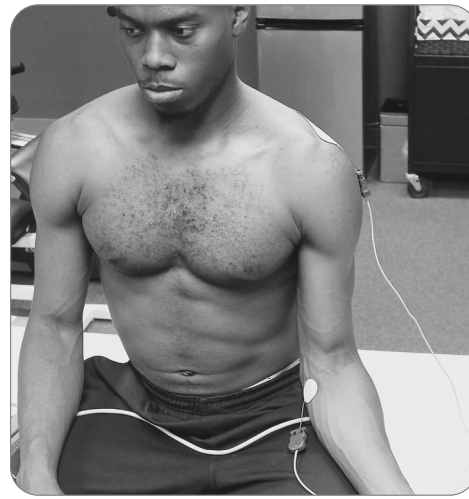
Body Position: The arm should rest at the side of the body with the elbow bent at approximately 80 degrees. The patient should rest their forearm in their lap and hold a ball or a rolled up towel to keep their fingers in a comfortable position.

Motion: The patient should gently articulate their elbow and wrist (rotation as well as extension and flexion) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

Rehabilitation may be facilitated for epicondylitis patients by using BioWave during therapy. BioWave should be used for 8 minutes first to allow the effect of the electrical field to take place on the affected nerves. After 8 minutes, reduce the intensity by 8%

to take the edge off of the sensation. Then while continuing the BioWave treatment, exercise or range of motion therapy can now be performed by the patient with significantly less pain. For example, it is much easier for the patient to achieve full extension during a BioWave treatment. As the patient's body adapts to the electrical field, after each set of exercise, the patient may increase the intensity, if desired, for greater pain relief.

4.6.11.2 Placement for Medial Elbow Pain (e.g. Pain from Medial Epicondylitis)



Use the E-set: Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode is placed on the elbow.

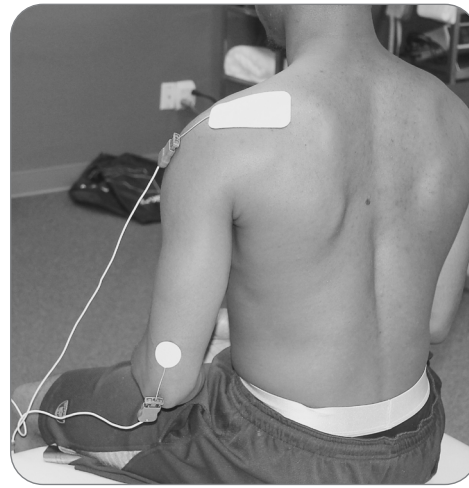
For pain occurring on the medial side of the elbow, for example, for pain from medial epicondylitis, the small round Pain Site Electrode should be placed **directly over the pain site as shown in the photo to the right**.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo above. There is no maximum distance limitation between the two electrodes.

Body Position: The arm should rest at the side of the body with the elbow bent at approximately 80 degrees. The patient should rest their forearm in their lap and hold a ball or a rolled up towel to keep their fingers in a comfortable position.

Motion: The patient should gently articulate their elbow and wrist (rotation as well as extension and flexion) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

4.6.11.3 Placement for Posterior Elbow Pain (e.g. Pain from Triceps Tendinitis)



Use the E-set: Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode is placed on the elbow.

For pain occurring on the posterior side of the elbow, for example, for pain from triceps tendinitis, the small round Pain Site Electrode should be placed **directly over the pain site** as shown in the photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is just posterior to the AC joint and be placed ***along*** the spine of scapula as shown in the photo above. There is no maximum distance limitation between the two electrodes.

Body Position: The arm should rest at the side of the body with the elbow bent at approximately 80 degrees. The patient should rest their forearm in their lap and hold a ball or a rolled up towel to keep their fingers in a comfortable position.

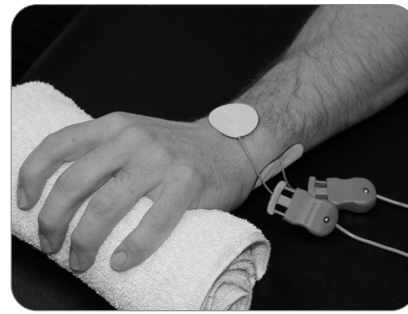
Motion: The patient should gently articulate their elbow and wrist (rotation as well as extension and flexion) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

Rehabilitation may be facilitated for patients with acute or chronic tendinopathies by using BioWave during therapy. BioWave should be used for 8 minutes first to allow the effect of the electrical field to take place on the affected nerves. After 8 minutes, reduce the intensity by 8% to take the edge off of the sensation. Then while continuing the BioWave treatment, exercise or range of motion therapy can now be performed by the patient with significantly less pain. For example, it is much easier for the patient to achieve full extension during a BioWave treatment. As the patient's body adapts to the electrical field, after each set of exercise, the patient may increase the intensity, if desired, for greater pain relief.

4.6.12 WRIST, HAND AND FINGER PAIN - ELECTRODE PLACEMENT EXAMPLES

For all wrist, hand and finger treatments, use a self adhering cohesive wrap, elastic bandage or a velcro strap to hold both electrodes in place, particularly if range of motion, exercise or stretching therapy is to be performed during the treatment.

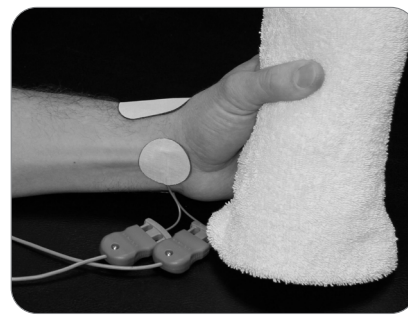
4.6.12.1 Placement for Posterior or Anterior Wrist Pain



Use the E-set: For pain occurring in the wrist, the small round Pain Site Electrode should be placed directly over the pain site. The rectangular Dispersive Electrode should generally be placed across the wrist in an opposing position to the location of the round Pain Site Electrode.

Make sure the small round Pain Site Electrode and the rectangular Dispersive Electrode do not touch each other and that there is at least 0.5 inches of spacing between them.

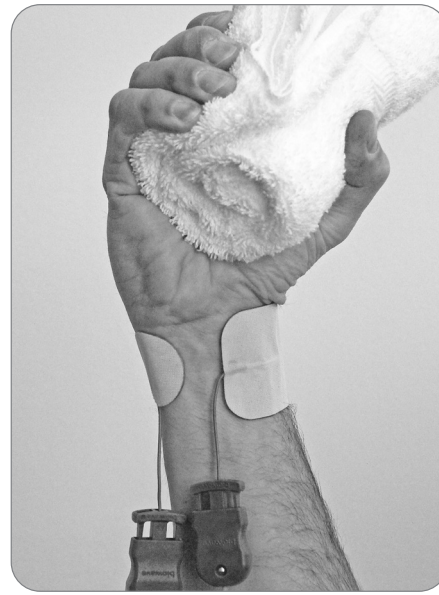
In the first example in the first photo above, the small round Pain Site Electrode is placed over the pain site on the **posterior side** of the wrist; the rectangular Dispersive Electrode runs ***across*** the anterior side of the wrist.



In the next example in the second photo to the right, the small round Pain Site Electrode is placed directly over the pain site on the **anterior side** of the wrist. The rectangular Dispersive Electrode is placed ***across*** the **posterior** side of the wrist in an opposing location.

If the patient has a small diameter wrist, in order to prevent the electrodes from touching one another, the rectangular Dispersive Electrode may be placed ***along*** the wrist instead of ***across*** the wrist as shown in the two photos in Section 4.6.12.4 on page 75.

4.6.12.2 Placement for Pain from a Triangular Fibrocartilage Complex (TFCC) Wrist Sprain



Use the E-set: For pain from a Triangular Fibrocartilage Complex (TFCC) injury, for example a TFCC wrist sprain, the small round Pain Site Electrode is placed over the pain site on the lateral side of the wrist. The rectangular Dispersive Electrode is placed in an opposing position across the medial side of the wrist as shown in the photo to the right.

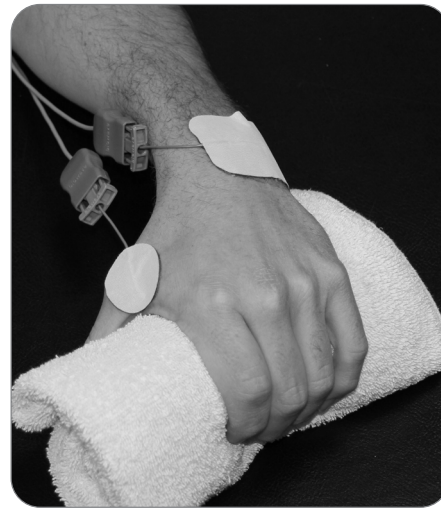
Make sure the small round Pain Site Electrode and the rectangular Dispersive Electrode do not touch each other and that there is at least 0.5 inches of spacing between them.

The use of a cohesive self adhering wrap, elastic bandage or velcro strap is recommended to hold both the round Pain Site Electrode and rectangular Dispersive Electrode in place.

Body Position: The arm should rest at the side of the body. The patient should hold a ball or a rolled up towel to keep their fingers in a comfortable position during the treatment.

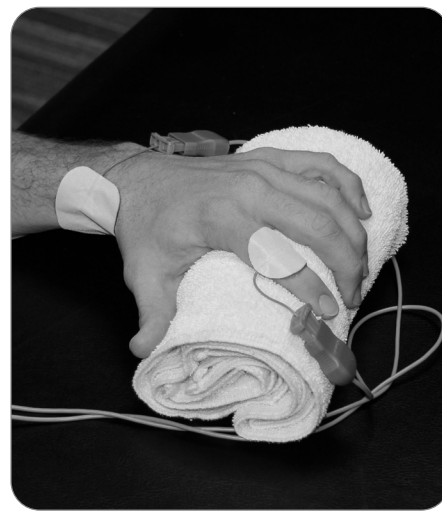
Motion: The patient should gently articulate their wrist (rotation as well as extension and flexion) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the wrist.

4.6.12.3 Placement for Hand or Finger Pain



Use the E-set: For pain occurring at the base of the thumb, for example from a thumb or UCL sprain, the small round Pain Site Electrode is placed over the pain site at the base of the thumb. The rectangular Dispersive Electrode is placed in an opposing position across the far side of the wrist as shown in the first photo to the right.

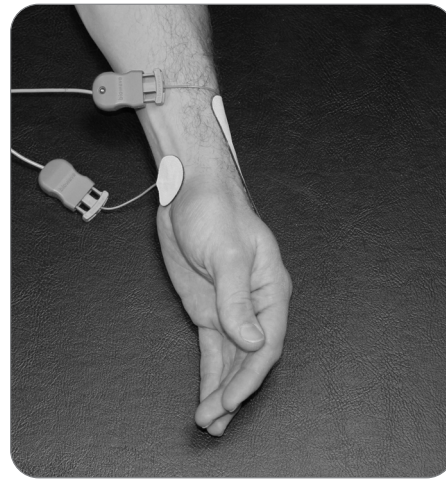
Make sure the small round Pain Site Electrode and the rectangular Dispersive Electrode do not touch each other and that there is at least 0.5 inches of spacing between them.



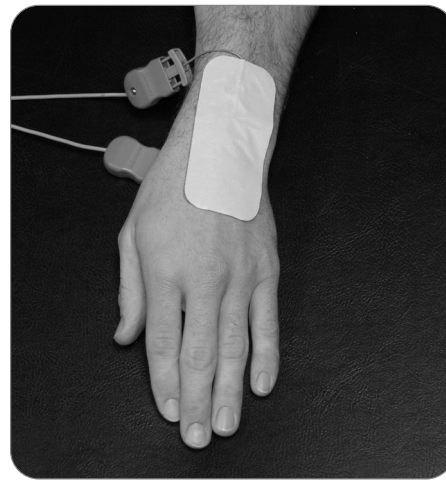
For pain occurring in a metacarpal phalangeal or interphalangeal joint, the small round Pain Site Electrode is placed directly over the pain site. The rectangular Dispersive Electrode is placed across the anterior side of the wrist as shown in the second photo to the right.

If the space is available, the anterior side of the wrist is the most comfortable location to receive stimulation from the rectangular Dispersive Electrode regardless of the location of the round Pain Site Electrode on the hand or finger.

4.6.12.4 Alternative Placement for the Larger Rectangular Electrode on Small Diameter Wrists



Use the E-set: If the patient has a small diameter wrist, in order to prevent the electrodes from touching one another, the rectangular Dispersive Electrode may be placed ***along*** the wrist instead of ***across*** the wrist in an opposing position to the small round Pain Site Electrode as shown in both photos to the right. Make sure the rectangular Dispersive Electrode stays off of the forearm and is partially covering the anterior or posterior of the bottom of the hand.



The use of a cohesive self adhering wrap, elastic bandage or velcro strap is recommended to hold both the round Pain Site Electrode and rectangular Dispersive Electrode in place.

Body Position: The arm should rest at the side of the body. The patient should hold a ball or a rolled up towel to keep their fingers in a comfortable position during the treatment.

Motion: The patient should gently articulate their wrist (rotation as well as extension and flexion) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the wrist.

4.7 Placing BioWave Noninvasive Electrodes

1. Select locations for electrodes (see Section 4.6)

2. Make sure skin is clean and dry. Use soap and water to clean the skin or use a damp towel and firmly rub the skin to remove lotion, oil and/or dead dry flaky skin in the locations where each electrode is to be placed. Do not use alcohol to clean the skin - wet alcohol under an electrode may cause a burn during a treatment.

3. Choose the appropriate electrode size, B, E or U:

   Use the B-set for pain in two locations; for bilateral or unilateral pain in the low back and buttocks; for bilateral pain in the cervical spine and shoulders; for radiculopathies; for pain in two locations in the hip or groin; for pain centered directly over the spine; for pain throughout the knee; and for pain over large areas. The B-set is comprised of two 2-inch diameter round electrodes.

   Use the E-set for a single location of pain in the extremities including the knee, ankle, foot, toe, neck, shoulder, elbow, wrist, hand and finger. The E-set is comprised of one 1.375-inch diameter round Pain Site Electrode for the single location of pain; and one 2 inch by 4 inch rectangular Dispersive Electrode to be placed over a comfortable location to receive stimulation - typically a ***bony prominence*** near the region being treated.

   Use the U-set for a single location of pain in the mid-torso region of the body including unilateral pain in the ribs, obliques, groin, hips, adductors, abductors, gluteus maximus, quadriceps or hamstrings. The U-set is comprised of one 2-inch diameter round Pain Site Electrode for the primary pain site; and one 5 inch by 8 inch large Dispersive Electrode to be placed horizontally across the lumbar region on the lower back - a comfortable and convenient location to receive stimulation.

4. Remove plastic liner and carefully align and place electrodes on the skin on the pre selected areas. Press firmly over entire electrode so hydrogel gets into the pores of the skin.

5. Save plastic liners and resealable bag for electrode storage following the treatment.

4.8 Placing BioWave Percutaneous Electrodes

1. Select locations for electrodes (see Section 4.6) and mark the center of each pain location with a Sharpie marker.

2. Use an alcohol prep to disinfect the skin in the location where the BioWave Percutaneous Electrodes are to be placed. Make sure the skin is dry (that there is no wet alcohol present) before placing the Percutaneous Electrode on the skin.

3. Choose the appropriate percutaneous electrode size, B or E:

B-set: The B-set is comprised of two 2.5-inch diameter round Percutaneous Electrodes.

Use the B-set to treat:

(i) **two locations of pain.** For example, bilateral pain in the lumbar, thoracic or cervical back; or pain throughout the knee, shoulder, hip or two other locations of pain.

(ii) **the origin or source of the pain, and the most proximal location of pain relative to the origin**. For example pain from lumbar or cervical radiculopathies. One percutaneous electrode is placed in the most proximal location the pain is first felt; for example for sciatica, over the buttock. The second percutaneous electrode is placed over the origin of the pain, in this example, over a herniated disc at L5. For a right side radiculopathy, the second eleactrode should actually be placed 0.5 inches to the right of L5 to capture the direction the pain signals are traveling down the nerve.

(iii) **pain over a large area.** For example, if the two percutaneous electrodes are placed one inch apart from one another, a treatment location equal to 7 inches by 3.5 inches by 1.5 inches in depth can be treated.

E-set: The E-set is comprised of one 2.5-inch diameter round Percutaneous Electrode and one 2 inch by 4 inch Noninvasive Electrode

Use the E-set to treat:

(i) **pain in a single location.** For example, pain in the extremities such as the

knee, ankle, foot, toe, neck, shoulder, elbow, wrist, hand and finger. The E-set can also be used to treat a single point of pain on the back, for example from a trigger point which may not be disc or spine related. The percutaneous electrode is placed directly over the location of the pain; the noninvasive electrode is placed over a bony prominence near the region being treated - a comfortable location to receive stimulation.

4. **Gently peel back the edge of the Percutaneous Electrode along the perimeter of the plastic cup to which it is attached. Be careful not to kink the array of metal needles.**

5. After removing the plastic cup from the percutaneous electrode, carefully align and place both Percutaneous Electrodes or the Primary Percutaneous Electrode and Dispersive Noninvasive Electrode on the pre selected areas.

   Percutaneous Electrodes must be pressed down very firmly. Apply approximately 10 pounds of force perpendicular to the entire back surface of the electrode to ensure that all of the needles have been inserted through the epidermis.

   Do not rub along the back surface of the Percutaneous Electrode while pressing it into the skin as the needles may bend and not penetrate through the skin. Also press firmly over the entire back of the Noninvasive Dispersive Electrode to assure firm adhesion to the skin.

4.9 Turning on the BioWavePRO Neurostimulator

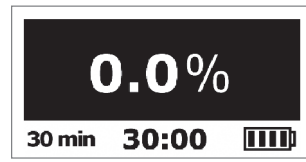
1. Once electrodes are placed on the patient's body, plug the blue connectors at the end of each electrode into the blue connectors on the leadwire cable so they click into place. The orientation of the blue connectors does not matter and either electrode can plug into either blue connector on the leadwire cable. When connected together, the electrode connector will partially stick out from the leadwire cable connector allowing an easy grip when pulling them apart.

2. Orient the metal connector at the single end of the leadwire cable so the red dot and notch are facing upwards. Line the notch up with the keyhole at 12 o'clock in the mating receptacle on the lower front side of the BioWavePRO neurostimulator. Gently plug the metal connector into its receptacle so that it clicks in place.

3. Turn the unit ON by firmly holding down the Power Button on the right hand side of the neurostimulator until the LCD screen turns on - then let go of the Power Button.

4. Check the battery indicator on the bottom RIGHT corner of the LCD display. Make sure the batteries are charged.

5. Make sure the LCD display shows a large "0.0%" in the middle of the display. This means the neurostimulator is ready for the patient to start the treatment.



4.10 Using the BioWavePRO Neurostimulator

4.10.1 STARTING TREATMENT

The patient is now ready to begin the treatment. The patient should control their own comfort level by pressing the Plus (+) Button to increase the intensity of the pain control effect.

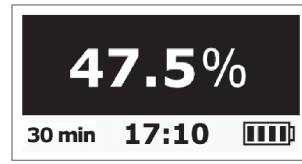
The Plus (+) Button can be held down or pressed repeatedly. If the Plus (+) Button is held down, after 2 seconds, the intensity will begin increasing at a steady, medium rate, which may be easier than repeatedly pressing the Plus (+) Button during the initial ramp up. The first time the intensity button is pressed, the countdown timer in the lower center of the LCD display will begin counting down. For each press of the Plus (+) Button, the large intensity number in the middle of the display will increase by 0.5%. **The patient should continue to increase the intensity and pain control effect until a strong tingling/pressure sensation is felt at the pain location (treatment site)**. This could be at an intensity level, for example, of 30 - 40% with BioWave Noninvasive Electrodes or 15 - 20% with BioWave Percutaneous Electrodes.

The body adapts quickly to the electric field in the first two minutes of treatment and the edge of the sensation felt by the patient will begin to diminish within several seconds. **The patient should then repeatedly press the Plus (+) Button to further increase the intensity so that they feel a very strong but comfortable tingling/pressure sensation.** Again their body will adapt to the electric field, however more slowly this time, causing the sensation to slightly diminish over a longer period of time. The patient should repeat this process of increasing the intensity until the sensation at and surrounding the pain site remains strong and is no longer diminishing. This is considered the therapeutic level.

For treatments with BioWave Noninvasive Electrodes, the patient should get above a minimum intensity level of 35%. Most patients advance in the first *two* minutes to an intensity level of between 30% and 60%.

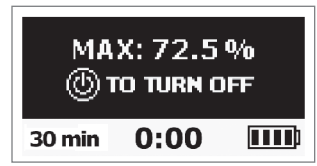
For treatments with BioWave Percutaneous Electrodes, the patient should get above a minimum intensity level of 18%. Most patients advance in the first *five* minutes to an intensity level of between 15% and 30%.

4.10.2 DURING TREATMENT



During the course of the procedure, it is normal to slightly increase the intensity level every few minutes as hypoesthesia develops around the pain site. To slightly increase the intensity level, the patient should press the Plus (+) Button 1 to 3 times. If the sensation becomes too strong, the patient can always press the Minus (–) Button to reduce the intensity. As an example, if a patient reaches an intensity level of 42% in the first two minutes, they may likely reach an intensity level of 62% by the end of the 30 minute treatment.

4.10.3 END OF TREATMENT



The end of the treatment occurs when the countdown timer reaches 0:00 minutes and seconds. The neurostimulator will emit three beeps and immediately reduce the intensity to zero (0.0%). The maximum intensity reached during the treatment will remain on the LCD display.

For treatments with BioWave Noninvasive Electrodes, remove both electrodes, place back onto their respective plastic release liners, return the electrodes into and reseal the resealable plastic bag.

For treatments with BioWave Percutaneous Electrodes, at the end of the treatment, gently peel the percutaneous electrode off of the patient's skin. A 1.5 inch diameter pink circle the size of the needle array with a dimple pattern showing the insertion location of the 1014 needles will be visible. In some cases there may be up to approximately 5 drops of blood visible at 5 of the 1014 insertion points. Use sterile gauze to clean up any drops of blood

and then apply a new sterile gauze pad over the treatment site with a piece of tape to hold it in place. This is the same procedure which is used following an injection. The pink circle typically resolves on its own within two hours post treatment.

BioWave Percutaneous Electrodes are sterile, single use electrodes and must be discarded into sharps disposal following the treatment.

Hypoesthesia (light numbness) may last for up to 20 minutes following a 30 minute treatment. A continued residual analgesic effect may last up to 72 hours and is proportional to the intensity of signal reached, length of treatment time and type of pain condition.

Unplug leadwires from the neurostimulator. Plug the AC Charger into a wall outlet and the other end into the charging port on the neurostimulator to begin recharging the battery.

4.11 Importance of Monitoring the Activity of the Neurostimulator

Before turning on BioWavePRO and starting a treatment, it is important to make sure the leadwires are properly plugged in and electrodes are properly placed on the patient's body. If everything is properly connected, the LCD Display shows a large 0.0% in the middle of the display. This means the neurostimulator is ready for the patient to start the treatment.

If the LCD does not show 0.0% it will show a picture of the action to take to correct the error condition (see Section 8, Troubleshooting and Other Functions).

5. Treatment Regimen Protocols

5.1 Treatment Regimen with BioWave Noninvasive Electrodes for Athletic Training

For treating acute or chronic pain in a sports setting, multiple treatments may produce a cumulative benefit. Athletes when performing in practice or a game are reaggravating their injury, so the following multiple treatment regimen is recommended:

1. The athlete should be treated for 30 minutes immediately preceding practice or a game. This allows the athlete to complete practice or the game more comfortably. This treatment may be completed in combination with heat if so desired. A thin waterproof plastic wrap should be placed over the BioWave Noninvasive Electrodes before placing a heating pad on top of them.

2. Since athletes may reaggravate their injury during practice or a game, the residual duration of the first BioWave treatment may be only 3 to 4 hours. Therefore, the athlete should also be treated immediately following practice or a game. This second treatment may be completed in combination with cold therapy if so desired. A thin waterproof plastic wrap should be placed over the BioWave Noninvasive Electrodes before placing ice on top of them. For use with cold therapy and compression devices, the electrodes should first be placed on the skin and then the cold/ compression cuff may be placed over the electrodes. Make sure the blue connectors reside outside of the compression cuff.

3. Time permitting, the athlete should receive a third 30 minute treatment approximately 2 to 3 hours following the second treatment.

Three 30-minute treatments each separated by 2 to 3 hours produce the best outcome. Individual treatment times should not be less than 20 minutes.
30 minutes is the optimal treatment time and provides the greatest efficacy and residual benefit in the shortest amount of time. Individual treatments longer than 30 minutes typically will not produce greater or longer lasting efficacy.

5.2 Treatment Regimen with BioWave Noninvasive Electrodes for Physical Therapy and Postoperative Rehabilitation

In addition to managing pain, BioWavePRO® is an excellent tool to facilitate motion and accelerate rehabilitation because of its profound pain relief, comfortable treatment and long carry over effect.

In physical therapy applications, BioWavePRO should be used first, in place of heat, for 8 minutes to allow the effect of the electrical field to take place on the affected nerve fibers. BioWavePRO may be used with heat if desired. For treatments on joints, use **a cohesive self adhering wrap, elastic bandage or velcro strap** to help hold the electrodes in place. After 8 minutes of treatment time, reduce the intensity by 5 - 10% to take the edge off of the sensation from the electrical signals. The shoulder, elbow and wrist are more sensitive to stimulation changes during motion, so the intensity may need to be reduced more, for example by 10 -15%, as compared to other locations on the body.

Next, have the patient begin active or passive range of motion, exercise or stretching therapy ***during*** the remainder of the 30 minute BioWavePRO treatment.

Depending upon the part of the body being treated and the intensity level the patient has reached, some patients may need to reduce the intensity more than 5 - 10% from their prior level in order to be comfortable during any type of motion therapy. **The sensation from the electrical field should NOT limit the patient from achieving their complete range of motion.**

After one to two sets of motion or exercise, the patient's body will continue to adapt to the electrical field and the patient may then increase the intensity with 1 to 3 presses of the Plus (+) button to help control pain caused by forcing the joint to a point of greater flexion or extension.

Patients can move more resistance through a greater range of motion with significantly less pain. For example, patients with a total knee replacement, ligament repair or other types of joint surgery can obtain both greater flexion and extension with less pain while they are receiving a BioWavePRO treatment.

BioWavePRO significantly facilitates the ability of the patient to perform therapy, particularly when pain is an inhibiting factor.

Additionally, because of the long carry over effect, patients have little post exercise soreness often for up to 24 hours or more following their physical therapy session.

5.3 Treatment Regimen with BioWave Percutaneous Electrodes for Patients with Severe Chronic, Acute or Postoperative Pain

For patients with more severe chronic, acute or postoperative pain, treatment with BioWavePENS utilizing BioWave Percutaneous Electrodes is recommended.

The recommended regimen for treatment with BioWave Percutaneous Electrodes is six 30-minute treatments over a one to three week period. Typically individual treatments are separated by not more than 72 hours. Depending upon patient availability though, the six treatments may occur over a longer time span than a three week period. Multiple treatments, particularly if spaced closer together for example once per day, may produce a cumulative benefit and reduce a patient's pain score to a new lower level that may last for up to several months.

BioWave Noninvasive Electrodes may also be used to treat chronic pain. Similarly, the recommended regimen is six 30-minute treatments over a two week period. With BioWave Noninvasive Electrodes though, treatments may be grouped more closely together than treatments performed with BioWave Percutaneous Electrodes. For example, patients could receive daily treatments instead of every 48 hours. Customers report that multiple treatments, particularly when spaced closer together, produce a cumulative benefit and reduce patient's pain scores to lower levels.

Depending upon their particular pain condition, some patients may need ongoing management of their pain, so the patient's physician may prescribe BioWaveHOME®, a home prescription version of BioWavePRO® that can utilize either BioWave Noninvasive or Percutaneous Electrodes.

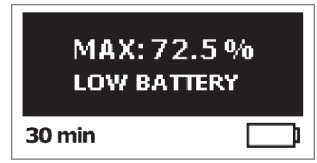
6. Battery Indicator, Charging and Replacing the Battery

6.1 Battery Indicator

The battery indicator is located in the lower RIGHT corner of the LCD. The indicator is comprised of 4 bars representing the amount of power left in the battery. When 4 bars appear, the battery is fully charged.

If LOW BATTERY appears on the LCD display mid treatment, the System Indicator Light on the top of the neurostimulator will flash YELLOW, an audible beep will occur for 5 seconds and then once per minute until the end of the treatment. The battery should have enough charge in it to allow the patient to complete the remainder of the treatment.

At the end of the treatment, when the battery is almost depleted, the neurostimulator will indicate LOW BATTERY on the LCD display along with the Maximum Intensity reached during the treatment. LOW BATTERY means that the stimulator cannot complete the next treatment with the remaining charge left on the battery and accordingly, it will not allow a treatment to start until the battery has been recharged.

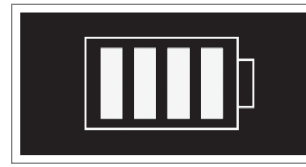


6.2 Charging the Battery

First, unplug the leadwire cable from the neurostimulator, revealing the opening for the plug on the AC Charger. Make sure BioWavePRO is turned off. Plug the AC Charger into the charging port on the neurostimulator. Plug one end of the power cord into the AC Charger and the other end into an electrical wall outlet to begin charging the battery. After about one minute, the bars inside the large picture of the battery on the LCD display will begin animating and the System Indicator Light above the display will begin *flashing* GREEN indicating that the battery is now being charged.

BioWave Li-ion batteries take approximately 4.5 hours to fully recharge from empty.

Once fully charged, the battery indicator will stop animating and will have 4 solid bars in the battery (see illustration to the right) and the System Indicator Light will be *solid* GREEN. After about one minute of being fully charged, the display will turn off and the



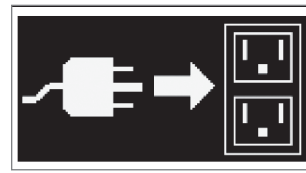
stimulator will continue to trickle charge the battery. There is no harm in leaving the stimulator plugged into the AC Charger.

It is recommended that the BioWavePRO Li-ion batteries be charged up every evening. There are no memory issues with the BioWavePRO battery system and Li-ion battery systems do not need to be fully discharged prior to recharging. Li-ion battery systems may also be recharged or "topped off" in between single treatments.

In order to use the neurostimulator and plug in the leadwire cable, the AC Charger must first be unplugged from the neurostimulator.

6.3 Replacing the Battery

The Li-ion battery system should last for 18 - 24 months depending upon usage. The battery system can only be replaced by BioWave Corporation. Contact Customer Service at 1-877-BIOWAVE (+1-877-246-9283) if the battery is not holding a charge and needs to be replaced.



After fully charging up the BioWavePRO neurostimulator, when attempting to start a new treatment, if the display shows a picture of a PLUG with an arrow pointing to an OUTLET (see illustration to the right), then the battery is not holding a charge and it is time to replace the battery system.

7. Maintenance, Cleaning and Storage Instructions

7.1 Maintenance, Cleaning and Storage Instructions

One of the design features of the BioWavePRO® Neurostimulator is that there is no calibration or maintenance required by the user, other than keeping the neurostimulator and leadwire cable clean and stored in the proper environment, as described below. All repair and/or service to the BioWavePRO® Neurostimulator must be done by the manufacturer. Any opening or disassembly of the neurostimulator immediately voids the warranty of the BioWavePRO® Neurostimulator, except for battery replacement with a specific battery that must be provided by BioWave Corporation.

- Wipe the neurostimulator with a cloth or paper towel that is lightly moistened with a non-abrasive alcohol or ammonia based cleaner. The neurostimulator does not require frequent cleaning if it is handled and used with clean hands.
- Keep food and liquids away from the neurostimulator, leadwire cable and electrodes.
- Never submerge the neurostimulator, leadwire cable or electrodes in water or any other liquid. Never pour or spray any liquid onto the neurostimulator, leadwire cable or electrodes. A few drops of saline may be placed on and rubbed into the hydrogel surface of the electrode to reactivate the hydrogel.
- The user should ensure that the neurostimulator, leadwire cable and electrodes are dry prior to using them. If the neurostimulator, leadwire cable and electrodes do become wet, DO NOT USE them. Please contact the manufacturer for technical support at 1-877-BioWave x1.

- Proper skin preparation and proper care of the BioWave® Noninvasive Electrodes will ensure that the patient can obtain up to 10 treatments from one set of electrodes. Remove both electrodes, place back onto their respective plastic release liners, and return the electrodes into and reseal the resealable bag. Adding 3 to 6 drops of saline to the hydrogel surface of the BioWave® Noninvasive Electrodes can help rehydrate and improve the conductivity and adhesion of the electrodes (see Section 8.1.3.2, page 91).
- BioWave® Percutaneous Electrodes are sterile single-use electrodes and must be disposed of in sharps disposal immediately following a treatment.
- Do not expose the BioWavePRO® Neurostimulator to extreme temperatures, humidity, or direct sunlight. Store at room temperature. The stimulator may not operate properly if it is exposed to extreme conditions.
- Cleaning should only be done after making sure that the AC Charger is not plugged into the stimulator. The cleaning solution could wet the AC Charger, which will damage the AC Charger and the BioWavePRO® Neurostimulator.

7.2 Disposal of Waste Products

- BioWave Percutaneous electrodes are sterile, single-use electrodes which should be disposed of in a manner similar to other sharps and/or infectious medical waste. Do not dispose of used BioWave Percutaneous electrodes in regular waste.

- When the Li-ion battery system is replaced in the BioWavePRO Stimulator, the old battery should be recycled appropriately. Similarly, at the end of its useful life disposal of the BioWavePRO Neurostimulator and power supply must comply with local regulations.

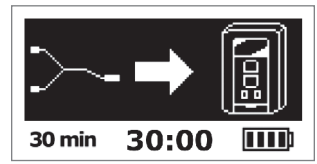
8. Troubleshooting and Other Functions

8.1 Troubleshooting Error Conditions on LCD Display

There are 3 connection related error conditions that can appear on the LCD Display:

8.1.1 LEADWIRE CONNECTION TO THE STIMULATOR

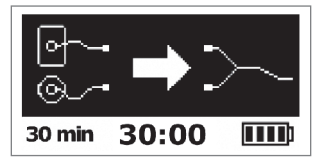
If the BioWavePRO Stimulator is turned on and the leadwire cable is not attached, the first error condition shown is a picture of the leadwire cable with an arrow pointing to the unit as shown in the illustration to the right. This means the stimulator does not see the leadwire connector plugged into the unit.



Make sure the notch on the metal connector of the leadwire cable mates with the keyhole in the opening on the stimulator and the connector gently slides in and ***clicks*** into place. If the screen does not change to show a different error condition or 0.0% intensity, then there may be a short in the leadwire cable between the gray cord and the metal connector and a new leadwire cable will be required to use the stimulator.

8.1.2 ELECTRODE CONNECTION TO THE LEADWIRE CABLE

The second error condition shows a picture of the electrodes with an arrow pointing to the leadwire cable as shown in the illustration to the right. This means the stimulator does not see the electrodes plugged into the leadwire cable.

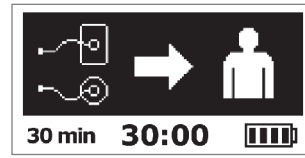


If the stimulator is connected to the patient yet this error condition appears, to correct this condition, unplug and replug each electrode back into the leadwire cable connector one to two times. This usually helps to establish a positive electrical connection and the screen should change to show a an intensity reading of 0.0% so the patient can begin the treatment. If the screen does not change to show 0.0% intensity, then there may be

an issue with one of the blue connectors in the leadwire cable and a new leadwire cable will be required to use the stimulator.

8.1.3 ELECTRODE CONNECTION TO THE PATIENT

The third error condition shows a picture of the electrodes with an arrow pointing to the body as shown in the illustration to the right. This means the patient's skin impedance is too high and the stimulator does not see the electrodes on the surface of the body.



If the stimulator is connected to the patient yet this error condition appears, there are five conditions that can cause this error to occur:

8.1.3.1 Patient Has Lotion on Their Skin or Has Oily Skin

Lotion, oil, ointment, disinfectants and other embrocations dramatically reduce adhesion and conductivity of the electrodes (particularly BioWave Noninvasive Electrodes) and can cause this error condition to appear. Use a washcloth with soap and water to clean the skin well and then dry thoroughly. Use a new set of electrodes and place onto the cleaned skin. The start screen with 0.0% intensity should appear on the LCD display. Press the Plus (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.10 Using BioWavePRO®.

8.1.3.2 Electrode Has Lost Adhesion and Conductivity

Use saline to restore the electrodes or use a new set of electrodes. The life of BioWave Noninvasive Electrodes can be prolonged by placing 3 to 6 drops of saline solution or spraying saline on the hydrogel surface and spreading the saline evenly with your finger over the hydrogel so the entire surface "glistens." Allow the saline to absorb into the hydrogel for about 60 seconds and then either place the electrodes back onto the body or onto the plastic liner and into the resealable plastic bag for storage. Alternatively, using a new set of electrodes will provide the greatest electrical conductivity through the skin.

8.1.3.3 Dry Flaky Skin

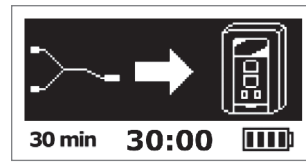
Dry flaky skin or heavily suntanned skin can cause the stimulator not to recognize the electrodes because the impedance of the skin is too high. Remove the electrodes from the skin. If they have a significant concentration of white flecks (dead skin) stuck to the

surface then discard them. Use a washcloth with soap and water to clean the skin well and then dry thoroughly. Use a new set of electrodes and place onto the cleaned skin. The start screen with 0.0% intensity should appear on the LCD display. The patient should press the Plus (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.10 Using BioWavePRO®.

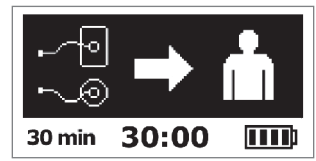
8.1.3.4 Excessive Hair on Skin

Excessive hair on the skin can prevent the electrodes from having adequate adhesion and electrical contact with the skin. As a result, the stimulator may not recognize the electrodes even though they appear to be properly placed on the skin. Remove the electrodes from the skin and discard them. Use a razor to shave the area where each electrode is to be placed. Place a new set of electrodes back into position on the clean shaved skin. The start screen with 0.0% intensity should appear on the LCD display. The patient should press the Plus (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.10 Using BioWavePRO®.

8.1.3.5 Broken Connection Between Metal Connector and Gray Cord



If the leadwire cable is treated roughly and bent forcefully at or more than 90 degrees where the gray cord connects to the metal connector then it is possible that one of the six connection points to the six wires inside the cable may break. Of the six wires, there are four, that if any one of their connection points are broken, will cause the first error condition to appear (a cable with an arrow pointing to the unit).

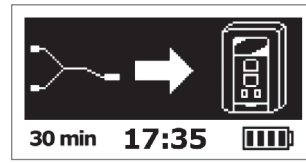


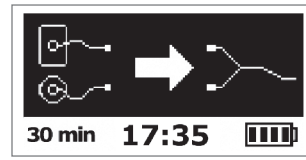
Of the six wires, there are two, that if either of their connection points are broken, will cause the third error condition to appear (two pads with an arrow pointing to the body).

For either of these scenarios, a new leadwire cable will be required to use the stimulator.

8.2 Other Troubleshooting Issues

8.2.1 LEADWIRE CABLE IS UNPLUGGED DURING TREATMENT

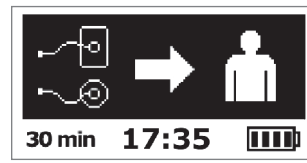




If during the procedure, the leadwire cable is unplugged from the BioWavePRO Stimulator (see first illustration to the right) or if either or both electrodes get disconnected from the leadwire cable (see second illustration to the right), immediately the intensity is reduced to zero (0.0%), the treatment time will pause and the relevant picture to the right will appear on the LCD display showing the appropriate corrective action.

Plug the leadwire cable back into the unit and/or the electrode(s) back into the leadwire cable and 0.0% should appear on the display. The patient can continue the treatment by pressing the Plus (+) Button to manually increase the intensity level from zero back up to a therapeutic level as described in Section 4.10 Using BioWavePRO®.

8.2.2 ELECTRODE(S) DETACH FROM PATIENT'S BODY DURING TREATMENT



If during the procedure, either electrode or both electrodes become detached from the patient's skin, immediately the intensity will go to zero (0.0%), the treatment time will pause and a picture will appear showing the electrodes should be placed back onto the patient's body.

Make sure the electrodes are clean and have not picked up any debris on the hydrogel. If they are clean, place the electrodes back onto the patient's skin in the correct location and 0.0% should appear on the display. If 0.0% does not appear on the display, place a new set of electrodes on the patient. Once 0.0% appears on the display, the patient can continue the treatment by pressing the Plus (+) Button to manually increase the intensity level from zero back up to a therapeutic level as described in Section 4.10 Using BioWavePRO®.

8.2.3 USE OF NON-BIOWAVE ELECTRODES

BioWave® Noninvasive or Percutaneous Electrodes must be used. The BioWavePRO® Neurostimulator will only recognize and work with BioWave® Noninvasive or Percutaneous Electrodes. The BioWavePRO® Neurostimulator will not work with non-BioWave electrodes and if connected, the patient may be at risk for receiving a burn.

8.2.4 MUSCLE TWITCHING

The muscle is typically held in comfortable tension during the treatment without any noticeable twitching. However, in some limited instances, for example on the anterior of the shoulder, patients may feel a small amount of muscle fasciculation under the smaller round Pain Site Electrode or under the round Percutaneous Electrode - this is normal. However, if the muscle twitching is uncomfortable, have the patient decrease the intensity by pressing the Minus **(−)** Button.

If the twitching still persists and is uncomfortable then press the Power Button once to pause the stimulator. The intensity will go to zero (0.0%) and the treatment time will pause. A Pause symbol will appear as shown in the LCD display to the right.

Change the location of the Noninvasive Pain Site or Percutaneous Electrode by moving it 0.5 to 1.0 inch away from its original location. For example, if the electrode was on the anterior of the shoulder, move it closer to the top of the shoulder. Once the electrode is in its new position, have the patient press the Plus (+) Button to manually increase the intensity level from zero back up to a therapeutic level as described in Section 4.10 Using BioWavePRO®.

8.2.5 PATIENT QUICKLY REACHES MAXIMUM INTENSITY

8.2.5.1 Maximum Intensity Reached Due to High Skin Impedance

A patient reaching maximum intensity (100.0% on the LCD) within the first several minutes usually indicates that their skin impedance is too high. Pause the treatment by pressing the Power Button once. The intensity will drop to zero (0.0%), the treatment time will pause and a Pause symbol will appear on the LCD display. Remove the

electrodes and thoroughly clean the skin with soap and water rubbing firmly with a washcloth. Rehydrate the electrodes with saline (see Section 8.1.3.2) and then place them back on the skin in the appropriate location. The display will return to 0.0%. Begin increasing the intensity using the Plus (+) Button. The patient will feel a stronger sensation at a lower intensity level because the impedance of the skin has been reduced.

8.2.5.2 Maximum Intensity Reached Due to Postoperative Loss of Proprioception

A second reason that a patient may reach maximum intensity within the first several minutes could be due to a loss of proprioception due to surgery. For example on postoperative ACL or total knee replacement patients, it is common for the patient to have reduced sensitivity on the anterior inferior portion of the knee.

Patients may receive BioWavePRO treatments at locations on the body with reduced sensitivity.

These patients will typically achieve higher than average intensity settings on the BioWavePRO Neurostimulator. The Automatic Safety Function described in the next section (Section 8.3) limits the maximum intensity received by a patient by actively monitoring power density at the skin surface and automatically controlling the intensity of the electrical signal in real time.

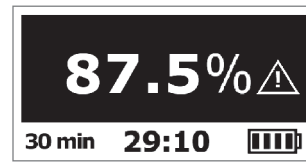
Therefore patients with reduced sensitivity due to postoperative loss of proprioception may safely use the BioWavePRO system to manage their pain condition.

8.3 Automatic Safety Function

8.3.1 INTENSITY DECREASES AUTOMATICALLY AND/OR PRESSING PLUS (+) BUTTON WILL NOT INCREASE INTENSITY

As an added safety precaution, the BioWavePRO® Neurostimulator has a patented technology that protects the patient from receiving too high a level of power during the treatment by actively monitoring power density at the skin surface and automatically controlling the intensity of the electrical signals in real time.

In some limited instances, a triangle with an exclamation mark may appear briefly to the right of the intensity number as shown in the LCD display to the right. If this occurs, then pressing the Plus (+) Button to increase the intensity will be disabled.



Simultaneously, the stimulator will automatically lower the intensity by 2 to 3% in approximately one quarter of a second or until a safe level is reached. Once a safe level is reached the triangle with an exclamation mark will disappear from the screen and the Plus (+) Button will again become active.

The active monitoring and adjustment of the signal occurs so quickly that the triangle with the exclamation mark may only appear for a fraction of a second.

The Minus **(–)** Button to reduce intensity always remains active.

There is no reason for concern and the patient should continue and complete the remainder of the treatment. The active monitoring and control of the signal helps prevent a patient from receiving a burn.

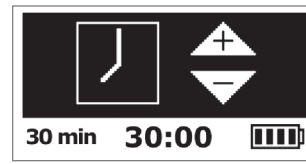
8.4 Other Functions

8.4.1 CHANGE TREATMENT TIME

The treatment time can only be changed when the LCD display reads "0.0%", during mid treatment or while charging. The treatment time cannot be changed if an error condition appears on the LCD display.

To change the treatment time:

1. **Press TIME button** to enter Time Mode. A clock symbol will appear as shown in the LCD display to the right, indicating it can be changed by pressing the PLUS (+) or MINUS (–) buttons.



2. **Press PLUS (+) button** to increase treatment time or MINUS (–) button to decrease treatment time in 1 minute increments to the desired treatment time. Minimum treatment time is 5 minutes. Maximum treatment time is 60 minutes.

3. **Press (OK) button to set the new treatment time**. Patient can now begin pressing the PLUS (+) button to increase intensity starting the treatment.

Changing the treatment time mid treatment will not interrupt the treatment.

8.4.2 PAUSE TREATMENT MID-PROCEDURE

Press the Power Button once to turn the intensity off and pause the treatment. A Pause symbol will appear as shown in the LCD display to the right.

Electrode placement, for example, can now be readjusted if desired, or the leadwire cable can be unplugged from the stimulator to allow a patient to go to the bathroom or to attend to some other need.

To restart the treatment, press the PLUS (+) button to manually increase the intensity from zero back up to a therapeutic level.

8.4.3 CHANGE CONTRAST OF LCD DISPLAY

Contrast ***can only be changed*** while the battery is charging, while the LCD reads 0.0%, or during mid treatment. The contrast cannot be adjusted if an error condition appears on the LCD display.

Changing the contrast mid treatment will not interrupt the treatment.

Should the contrast of the LCD display need to be adjusted, the user can adjust the contrast as follows:

To Increase the Contrast:

Hold down the OK Button while pressing the PLUS (+) Button many multiple times to increase the contrast.

To Decrease the Contrast:

Hold down the OK Button while pressing the MINUS (–) Button many multiple times to decrease the contrast.

9. Technical Specifications and Classifications

9.1 Technical Specifications

Physical Dimensions
Size (H x W x D): 8.80" x 6.31" x 3.07" / 22.35 cm x 16.02 cm x 7.79 cm
Weight: 2.9 lbs / 1.3 kg

Transport and Storage
– 25°C to + 5°C, and
+ 5°C to + 35°C at a relative humidity up to 90 %, non-condensing;
> 35°C to 70°C at a water vapour pressure up to 50 hPa

Environmental Conditions
Operating Temperature: + 5°C to + 40°C;
Relative Humidity: 15 % to 90 %, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa; and
Atmospheric Pressure: 700 hPa to 1060 hPa.

Signal Output
Feed Frequency 1: 3858 Hz
Feed Frequency 2: 3980 Hz
Output Voltage Range: 0 – 27.5 V rms
Maximum Output: 27.5 VAC RMS at 110 mA AC RMS for a 250 Ω load
Waveform: Sum of 2 sine waves. The output waveform retains its integrity, harmonic content and instant voltage level into a biological load with an
impedance range from 250 Ω to 1000 Ω

Power Source
10.8 V DC, 9400 mAh rechargeable Li-ion battery
Provides 9.0 hours of power at 100% output into 500 Ohms

Expected Service Life
Expected service life of the device is 5 years. When exhausted, dispose of device properly and in accordance with local codes and regulations.

AC Charger

The BioWavePRO Neurostimulator must only be used with the AC Charger provided:

Globtek Model # GTM96600-6018-R3A Power Supply, Output: 18V, 3.3A;
Input: 100-240 Volts, 50-60 Hz. Hospital Grade power cord, CE Mark Listed

Leadwire Cable

Rating complies with 21 CFR Part 898
(performance standards for electrode leadwires)

Applied Parts

BioWave Noninvasive Reusable Electrodes

BioWave® Noninvasive Reusable Electrodes are of a silver/carbon construction with a pre-applied hydrogel and are cleared for marketing under 510(k) numbers K962332, K900519, K915333, K052289 and K152437.

BioWave Percutaneous Electrodes

BioWave Percutaneous Electrodes are comprised of a 1.5 inch diameter needle array within a 2.5 inch diameter hydrogel-based single-use sterile electrode. The needle array is comprised of 1014 needles, 0.74 mm in length, made from 316L surgical stainless steel. BioWave Percutaneous Electrodes are cleared for marketing under 510(k) number K061166.

Software Version: 347

9.2 Classifications

⚠ Before using BioWavePRO, read this User's Manual.

Protection against electric shock classification: TYPE BF

Rx ONLY For sale by or on the order of a physician.

- Neurostimulator is internally powered.
- AC Charger (power supply) is classified as Class 1.
- Mode of operation is continuous.
- Neurostimulator is not protected for use with flammable anesthetics.
- Protection against liquid ingress: IPX0
- Neurostimulator conforms to all requirements of the following standards:

EN 60601-1:2006+A1:2013
EN 60601-2-10:2015+A1:2016
EN 60601-1-6:2010
EN 60601-1-2:2015
UL 60601-1

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

The BioWavePRO® Neurostimulator is intended for use in the electromagnetic environment specified below. Users of the BioWavePRO Neurostimulator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BioWavePRO Neurostimulator 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 emissions CISPR 11	Class B	The BioWavePRO Neurostimulator is suitable for use in all establishments, including hospitals and medical professional establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for commercial or domestic purposes.
Harmonic emissions*	Class A	
	Not applicable	

* Harmonic emissions, if any, that can impact on the electrical grid, can only occur during battery charging. During battery charging, the external power supply is the only connection to the mains. During normal use the BioWavePRO Neurostimulator has no connection to the mains. Therefore, the compliance class, as reported here, is dictated only by the compliance class of the BioWavePRO Neurostimulator's external power supply.

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

The BioWavePRO® Neurostimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the BioWavePRO Neurostimulator should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

The BioWavePRO® Neurostimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the BioWavePRO Neurostimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BioWavePRO Neurostimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as provided below. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 V (RMS) 150 kHz to 80 MHz	10 V	$d = 0.35 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioWavePRO Neurostimulator is used exceeds the applicable RF compliance level above, the BioWavePRO Neurostimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BioWavePRO Neurostimulator. For frequency ranges above 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
- Warning: operation in close proximity (1m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the BioWavePRO® Neurostimulator

The BioWavePRO® Neurostimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BioWavePRO Neurostimulator can help prevent electromagnetic interference by maintaining a minimum distance listed in meters below, between portable and mobile RF communications equipment (transmitters) and the BioWavePRO Neurostimulator based on the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts (W)	**Separation Distance (d) in Meters (m) According to Frequency of Transmitter**		
Watts (W)	**150 kHz to 80 MHz** $d = 0.35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.7\sqrt{P}$
0.01	0.035	0.035	0.07
0.1	0.11	0.11	0.22
1	0.35	0.35	0.7
10	1.11	1.11	2.21
100	3.5	3.5	7

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9.3 Definition of Symbols

Symbols	Definition
CE 1282	The device meets the requirements of directive 93/42/EEC for medical devices. It is authorized by an independent notified body for which it bears the CE symbol.
	See User's Manual and Quick Reference Guide for more information.
	See User's Manual and Quick Reference Guide for more information.
EC REP	Authorized Representative in the European Community
	The device is classified as type BF against electrical shock and leakage current. The device is suitable for use on patients according to the standards defined by IEC 60601-1.
Rx ONLY	Prescription use only
REF	Model Number
	Manufacturer
SN	Serial Number
	Caution
	Non-Sterile
STERILE R	Sterilized using irradiation
	Single-Use Only
	Use By
LOT	Lot Code
	Do not use if package is damaged
	The device complies with UL 60601-1 CSA C22.2 No. 601.1
E114972 	Disposal of waste products
MD	Medical Device

10. Contact Information and Warranty

10.1 Reorder Information and Technical Support

To reorder BioWave Noninvasive or Percutaneous Electrodes, other accessories or for Reimbursement or Technical Support, please contact your BioWave representative or contact BioWave Corporation directly at:

toll free: +1-877-BIOWAVE (+1-877-246-9283)

email: support@BioWave.com

web: BioWave.com

10.2 Limited Warranty

BioWave Corporation warrants the BioWavePRO® Neurostimulator against defects in material or workmanship for a period of ONE year from the date of original purchase. This Limited Warranty excludes the Leadwire Cable and Electrodes as well as the following items:

1. Damage caused during shipment;
2. Damage caused by accident, misuse, or abuse of operation contrary to the instructions specified in the User's Manual;
3. Damage resulting from modification or attempted repair by any person not authorized in writing by BioWave Corporation;
4. Damage caused by inserting and/or using a battery not approved by or purchased from BioWave Corporation; and
5. Cosmetic damage.

To obtain warranty service, you must you must first call BioWave Corporation at 1-877-BIOWAVE to receive a return manufacturer's authorization number (RMA#). Once you have obtained an RMA#, return your BioWavePRO unit via UPS or FEDEX in either its original packaging or packaging affording an equal degree of protection to BioWave Corporation.

BIOWAVE

SMARTER PAIN BLOCKING TECHNOLOGY

Need help? Contact us!

- +1 (877) BIOWAVE
  +1 (877) 246-9283
- support@biowave.com
- biowave.com

BIOWAVE

BioWave Corporation
19 Newtown Turnpike
Westport, CT 06880

MADE IN USA

EC REP

OBELIS S.A.
Bd. Général Wahis, 53
1030 Brussels,
Belgium

UK RESPONSIBLE PERSON

OBELIS UK LTD
Sandford Gate
East Point Business Park
Oxford OX4 6LB
United Kingdom

Rx ONLY

Device must only be used with power supply provided.

MD

CE 1282

MET E114972

Complies with
UL 60601-1
CSA C22.2 No.606.1

Rev 25 - 260203