

Percutaneous Electrical Nerve Stimulation

BIOWAVEPENS

SMARTER PAIN BLOCKING TECHNOLOGY

quick reference

for BioWave Percutaneous Electrodes
B-set and E-set



There are 5 buttons that control the neurostimulator:

1. Power ON/OFF button
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

DIRECTIONS FOR USE - PENS TREATMENTS

1. Use an alcohol prep to clean the skin in the location percutaneous electrode(s) are to be placed. Dry the skin with sterile gauze.
2. See Electrode Placement Examples inside to determine correct percutaneous electrode placement location.
3. Carefully peel off percutaneous electrode(s) along perimeter away from plastic cup. Place electrodes on skin over pain site and/or over source of pain. Using both thumbs press firmly with over 10 lbs of force perpendicular to back surface of electrode to ensure all microneedles pass through outer layers of skin.
4. Attach leadwire cable to electrodes. Either blue leadwire connector can be attached to either electrode.
5. Align red dot on metal connector at end of leadwire cable so it is facing up. Gently slide metal connector into device so it clicks in place.
6. Turn on device. Start up screen should read 0.0%
7. Patient starts treatment by pressing the PLUS (+) button.
8. Patient continues to press the PLUS (+) button throughout the treatment so a steady strong but comfortable tingling and pressure sensation is felt under the electrodes covering the pain sites.

See User's Manual for detailed instructions.

**Designed to Block Pain
at the Source™**

BioWave Percutaneous Electrodes

The BioWavePENS Percutaneous Electrical Nerve Stimulation System is comprised of either a BioWavePRO or BioWaveHOME neurostimulator and BioWave Percutaneous Electrodes. BioWavePENS is indicated for the treatment of chronic, acute or post-operative pain.

BioWave Percutaneous Electrode Arrays are sterile, single-use and comprised of over 1000 needles that are 0.74 mm in length within a 1.5" diameter array. These electrode arrays feel like Velcro to the touch and are designed to provide a direct conductive pathway through skin, bypassing the impedance of skin, and allowing the therapeutic electrical field to form in deep tissue encompassing pain nerves. BioWavePENS may only be used with BioWave Percutaneous Electrodes.



B-Set Two Locations of Pain

The BioWave Percutaneous B-Set Electrodes are sterile, single use and comprised of two 2.5" diameter round percutaneous electrodes. Used for treating:

- Two locations of pain,
- One location of pain and the source or origin of the pain,
- Pain over a large area



E-Set Single Location of Pain

The BioWave Percutaneous E-Set Electrodes are sterile, single use and comprised of one 2.5" diameter round percutaneous electrode placed over the single pain site, and one 2" x 4" rectangular dispersive electrode placed over a bony prominence - a comfortable location to receive stimulation. Used for treating:

- Single locations of pain on the neck, torso or extremities.

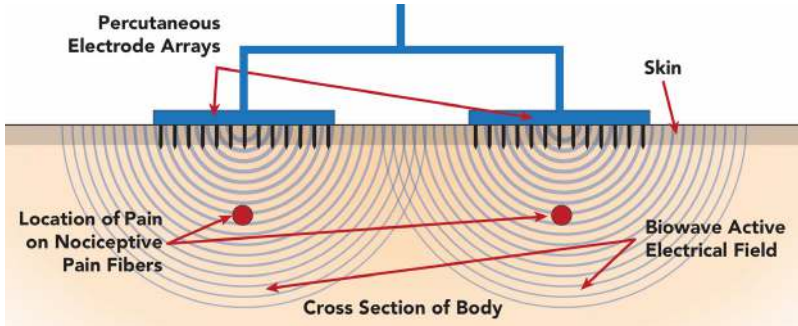


See opposite page for percutaneous electrode placement examples

WARNING: Electrodes must not touch each other.

Electrode Placement Rationale For Percutaneous Electrodes

BioWavePENS percutaneous electrode array placements are different from conventional surface electrical stimulation. The active therapeutic electrical field forms in a 3.5 inch diameter hemisphere beneath and surrounding each electrode, not along the surface of the skin between the electrodes - see illustration below:



As a result, electrodes need to be placed either:

- (1) directly over two locations of pain;
- (2) over one location of pain and the origin of the pain;
- (3) spaced one inch apart to cover a large area of pain.

Electrodes are independent of one another and there is no maximum distance between the two electrodes.

Electrodes must not touch each other.

Different Electrode Sets for Focusing the Electric Field

B-Set: 2 Locations of Pain

The B-Set is comprised of two percutaneous electrodes so two distinct pain sites can be treated simultaneously. If the two percutaneous electrodes are placed close together so that there is only 1.0 inch of space between them, the pair can be used to treat one larger volume of tissue. The B-Set is also used to treat pain from radiculopathies. One electrode is placed over the origin of the pain, for example, directly over the spine, but 0.5 inches to the side in the direction of the nerve root in which the pain signals are traveling. The second electrode is placed proximally over the location the pain first presents, for example, on the buttock.

E-Set: 1 Location of Pain

The E-Set is comprised of one percutaneous electrode and one noninvasive dispersive electrode. By pairing a percutaneous electrode with a noninvasive dispersive electrode, the impedance is much lower beneath the percutaneous electrode allowing for a stronger and deeper penetrating electrical field. Therefore, the percutaneous electrode needs to be placed directly over the primary painful area. The noninvasive rectangular electrode is still active but acts as a dispersive electrode and must be placed over a bony prominence typically near the treatment site. Placement of the noninvasive electrode over a bony prominence allows the patient to more comfortably increase the intensity of the signal to higher levels allowing a stronger electric field to encompass the pain site under the round percutaneous electrode.

Treatment Regimen Protocol

BioWave's Preauthorization Service typically preauthorizes 6, 30-minute treatments which are performed in an office setting over a 2-3 week period. Multiple treatments may provide a cumulative benefit. Additional treatments may be beneficial. The same pain site location may be treated up to two times per day with each 30-minute treatment separated by at least 8-hours.

Contraindications

- **DO NOT USE** on patients with an implanted pacemaker.
- **DO NOT PLACE** electrodes on top of the head, on the front or side of the neck or over the heart on the front of the chest.
- **DO NOT PLACE** electrodes over open wounds, broken or rashy skin.

NOTE: Electrodes MAY BE PLACED over locations on the body that have implanted metal hardware including total joint replacements, plates, rods, screws, anchors and clips. See User's Manual for more information.

Body Position During Treatment

The body should remain in a static position during the treatment. **The tissue being treated should be taut or in a stretch position.** Generally, sitting in a supported position in a comfortable chair is best for most treatment locations on the body.

Intensity Range

Patients should increase the intensity based on sensation (not an intensity number) to a level that is as strong as possible but still comfortable. The body adapts to the electrical field very quickly over the first 5 minutes and then less so over the remainder of the 30-minute treatment. As hypoesthesia is induced in the volume of tissue beneath the percutaneous electrodes and the sensation diminishes, patients should continue to increase the intensity level with individual presses of the PLUS (+) button.

Generally, patients should try to reach a minimum intensity level of 20%. Some patients may tolerate more, some less. Certain parts of the body may be more sensitive to stimulation and therefore harder to achieve higher intensity levels. **The typical maximum intensity level reached during the treatment ranges from 20% - 50%.**

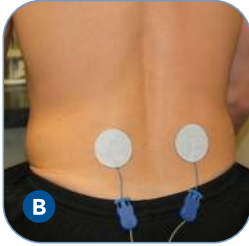
Motion During Treatment

The sensation from the treatment is a deep, smooth, strong tingling and pressure sensation. Generally patients should remain in a static position during the treatment. Motion may cause a stronger or weaker sensation and will cause the location of the electrical field to shift slightly internally. Shifting of the electrical field is most prevalent when treating upper and lower extremities.

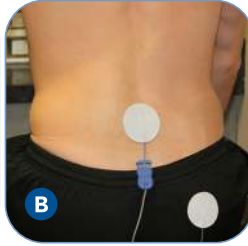
The goal is to have the patient very gently articulate the joint at the treatment location to shift the sensation caused by the electrical field so that it focuses directly onto and encompasses the primary pain location.

Percutaneous Electrode Placement Examples

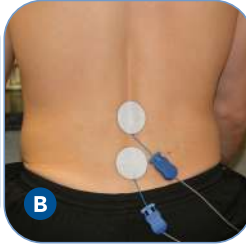
Lumbar



Bilateral Low Back Pain



Radiculopathy - Electrodes Over Source and Proximal Pain Site

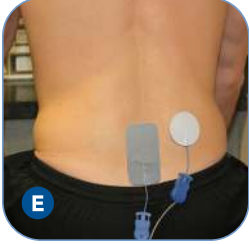


Low Back Pain Focused Over Multiple Discs

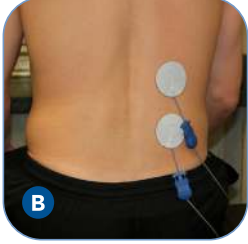


Low Back Pain Focused Over One Disc

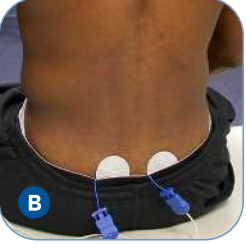
Lumbar



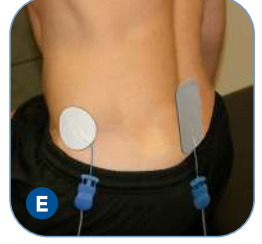
Unilateral Low Back Pain Focused on one Side of Spine



Pain Over Large Area (e.g. Rotational Strain)



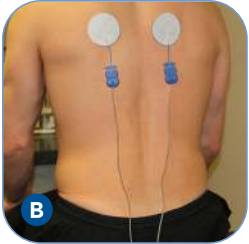
Sacroiliac (SI) Joint Pain (Sacral Nerve Stimulation)



Hip Pain in One Location

Hip

Thoracic

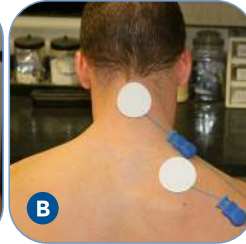


Bilateral Thoracic Pain (Two Locations of Pain)

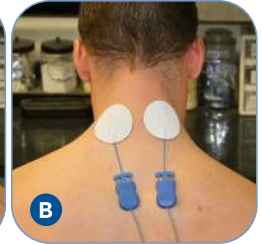
Cervical



Cervical or Neck Pain in One Location

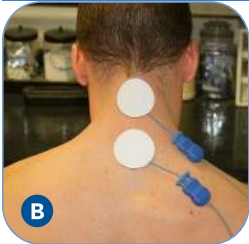


Cervical or Neck Pain in Two Locations or Radiculopathy



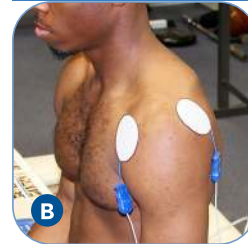
Bilateral Neck Pain (Two Locations of Pain)

Cervical

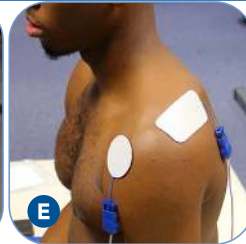


Cervical or Neck Pain Over Several Locations

Shoulders



Shoulder Pain in Two Locations, Adhesive Capsulitis



Anterior Shoulder Pain (e.g. Biceps Tendinitis)

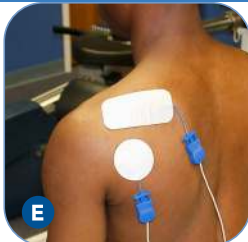


Pain at AC Joint or Inside the Shoulder (e.g. AC Sprain)

Shoulders



Pain at Edge of Shoulder (e.g. Rotator Cuff Strain or Tendinitis)



Posterior Shoulder Pain (e.g. Infraspinatus Strain)



Trapezius Pain in One Location (e.g. Trigger Point)



Bilateral Trapezius Pain (Two Locations of Pain)

B B-Set
2 Locations
of Pain

E E-Set
1 Location
of Pain

WARNING: Electrodes must not touch each other.
See back cover for electrode description.

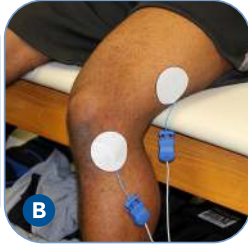
Knees



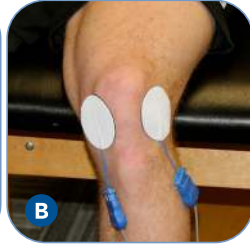
Patellar Tendinitis



Lateral Knee Pain (e.g. OA, Bursitis, LCL Sprain)



Iliotibial (IT) Band Pain in Two Locations



Pain Throughout Entire Knee (e.g. Total Knee Arthroplasty)

Knees



Central Knee Pain (e.g. OA, Bursitis, Meniscus, ACL Sprain)



Medial Knee Pain (e.g. OA, Bursitis, MCL Sprain)



Quadriceps Tendinitis

Ankles & Feet



Neuroma Pain or Metatarsal Joint Pain

Ankles & Feet



Pain from Diabetic Neuropathy (Tibial Nerve Stimulation)



Ankle or Foot Sprain with Pain in One Location



Achilles Tendinitis with Pain at the Tendon and Insertion Point



Achilles Tendinitis with Primary Pain at Insertion Point

Ankles & Feet



Plantar Fasciitis

Elbows



Lateral Elbow Pain (e.g. Lateral Epicondylitis)



Medial Elbow Pain (e.g. Medial Epicondylitis)



Posterior Elbow Pain (e.g. Triceps Tendinitis)

Wrists, Hands & Fingers



Anterior Wrist Pain (e.g. Sprains, Strains, Tendinosis, Carpal Tunnel Syndrome)



Placement of Rectangular Electrode for Anterior Wrist Pain



Posterior Wrist Pain (e.g. Sprains, Strains, Tendinosis)



Pain at Metacarpal Phalangeal or Interphalangeal Joint

B B-Set
2 Locations
of Pain

E E-Set
1 Location
of Pain

WARNING: Electrodes must not touch each other. See back cover for electrode description.



BIOWAVEPENS

Need help?

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

BIOWAVE



BioWave Corporation
8 Knight St., Suite 201
Norwalk, CT 06851

©2008-2020 BioWave Corporation

MADE IN
USA



P14 Medical Ltd.
65 Bath Road
Stroud GL5 3LA
United Kingdom



Device must only be
used with power
supply provided.



Rev 8 - 200401