Revised March 2026

Percutaneous Electrical Nerve Stimulation

BIOWAVEPENS

SMARTER PAIN BLOCKING TECHNOLOGY

quick reference

for BioWave Percutaneous Electrodes

*for use with **BioWavePRO***

There are 3 buttons that control the BioWavePRO neurostimulator:

1. **Power ON/OFF button**
2. **PLUS (+) button to increase intensity**
3. **MINUS (–) button to decrease intensity**

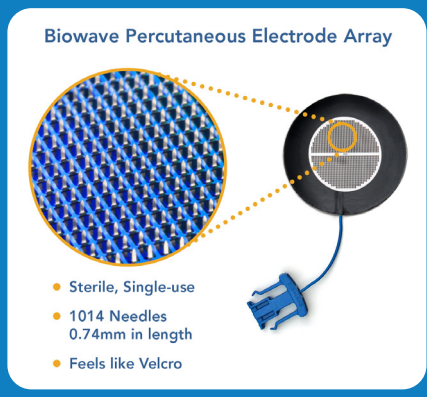
BioWavePRO also has a TIME button to change treatment time and an OK button to accept and set a new treatment time.

Designed to Block Pain at the Source™

BioWave Percutaneous Electrodes

The BioWavePENS Percutaneous Electrical Nerve Stimulation System is comprised of a BioWavePRO neurostimulator and BioWave Percutaneous Electrodes.

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

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

- 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

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

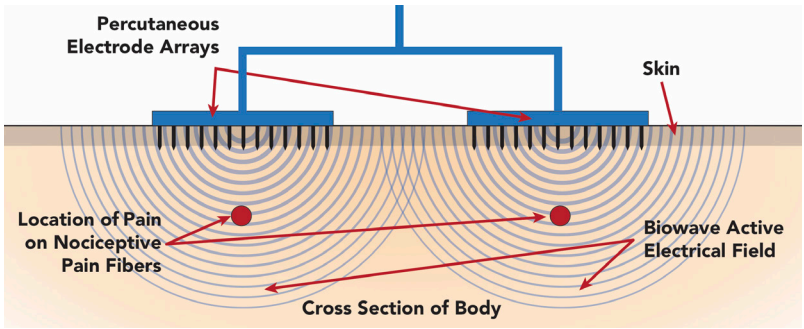
NOTE: Electrodes MAY BE PLACED directly over or in the proximity of implanted metal hardware, including total joint replacements, anchors, plates, rods, screws and pins.

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.

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 (volume of tissue the size of half of a grapefruit) 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 penetraring 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

Patients typically undergo 4-6, 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 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 the electrodes on the front or side of the neck.
- **DO NOT** place the electrodes on top of the head.
- **DO NOT** place electrodes over wounds, broken skin or sensitive skin areas (for example, sunburned skin).

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%.**

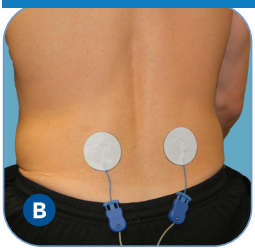
Motion During Treatment

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.

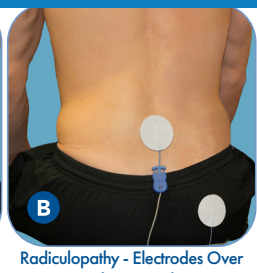
The goal is to have the patient very gently articulate the joint at the treatment location to shift the sensation caused by the electrical field so that it focuses directly onto and encompasses the primary pain location.

Percutaneous Electrode Placement Examples

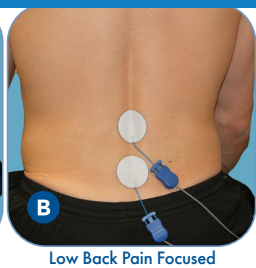
Lumbar



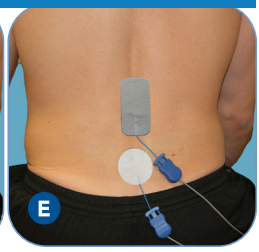
Bilateral Low Back Pain



Radiculopathy - Electrodes Over Source and Proximal Pain Site



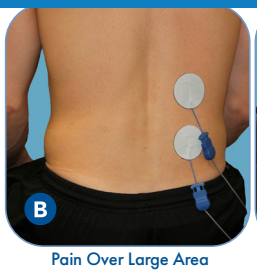
Low Back Pain Focused Over Multiple Discs



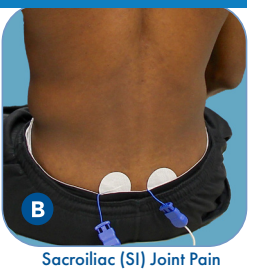
Low Back Pain Focused Over One Disc

Lumbar/Sacral

Unilateral Low Back Pain Focused on one Side of Spine



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

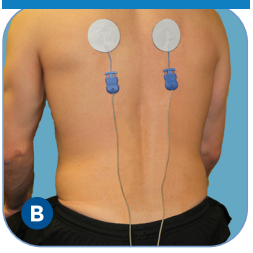


Sacroiliac (SI) Joint Pain (Sacral Nerve Stimulation)

Pelvic Floor

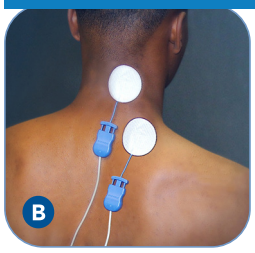
Pelvic Floor Pain (Pudendal Nerve Stimulation)

Thoracic



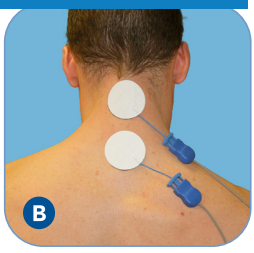
Bilateral Thoracic Pain (Two Locations of Pain)

Cervical



Cervical or Neck Pain in Two Locations or Radiculopathy

Bilateral Neck/Trap Pain (Two Locations of Pain)



Cervical or Neck Pain Over Several Levels

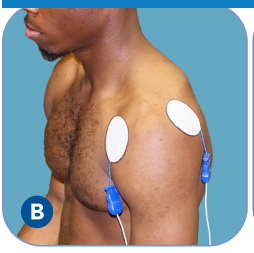
Cervical

Pain Originating in the Posterior of the Neck (Occipital Nerve Stimulation)

TMJ

Pain from TMJ and Trigeminal Neuralgia

Shoulders

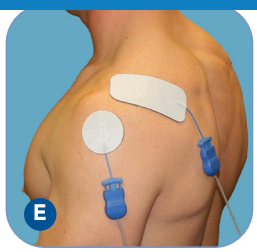


Shoulder Pain in Two Locations (e.g. Adhesive Capsulitis)

Anterior Shoulder Pain (e.g. Biceps Tendinitis)

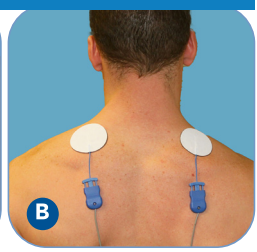
Shoulders

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



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

Posterior Shoulder Pain (e.g. Infraspinatus Strain)



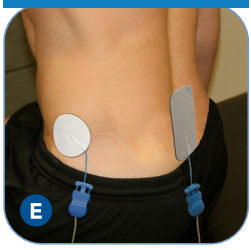
Bilateral Trapezius Pain (Two Locations of Pain)

B **B-Set**
2 Locations of Pain

E **E-Set**
1 Location of Pain

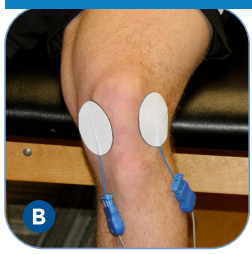
WARNING: **Electrodes must not touch each other.**
See back cover for electrode description.

Hip

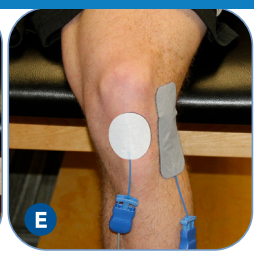


Hip Pain in One Location

Knees



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



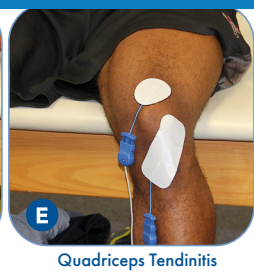
Patellar Tendinitis

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

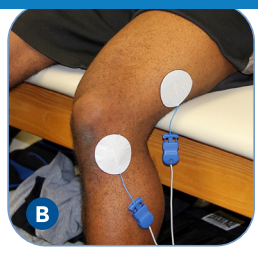
Knees

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

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



Quadriceps Tendinitis

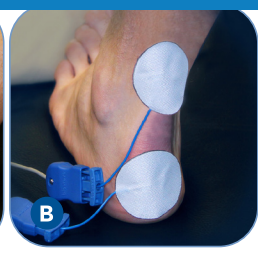


Illiotibial (IT) Band Pain in Two Locations

Ankles & Feet

Pain from Neuropathy (Tibial Nerve Stimulation)

Ankle or Foot Sprain with Pain in One Location



Achilles Tendinitis with Pain at the Tendon and Insertion Point

Plantar Fasciitis

Ankles & Feet

Neuroma Pain or Metatarsal Joint Pain

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 Dispersive Electrode for Anterior Wrist Pain

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

Pain at Metacarpal Phalangeal or Interphalangeal Joint

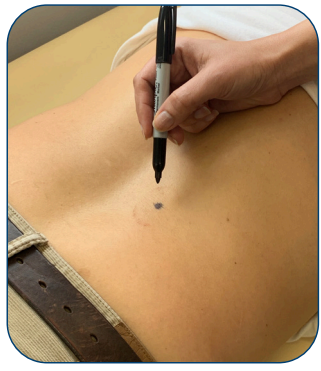
B B-Set 2 Locations of Pain

E E-Set 1 Location of Pain

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

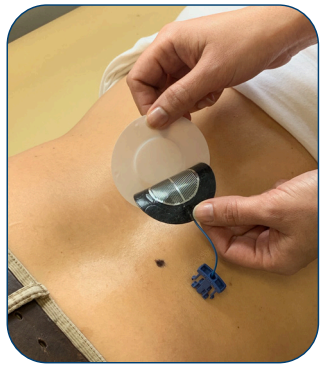
Protocol for Placing Percutaneous Electrodes

A



B

C



D

E

F

G

H

Directions for Use PENS Treatments

Treatment Set Up

1. See Photos of Percutaneous Electrode Placement Examples on prior pages and identify photo closest to the patient's pain condition
2. Determine B or E set electrodes for pain condition (B-set = 2 locations of pain, E-set = 1 location of pain)
3. Palpate to find center of pain location
4. Mark skin with Sharpie marker over center of each pain site - **See A**
5. Clean skin with alcohol prep - **See B**
6. Gently peel electrode from protective cup - **See C**
7. Place electrode centered over Sharpie mark - **See D**
8. Insert percutaneous electrodes through skin; press 3X applying 10 lbs of force perpendicular to the back of the electrode as follows:
    1. Use two thumbs next to each other in center of electrode - **See E**
    2. Use two thumbs at 12 o'clock and 6 o'clock over needle array - **See F**
    3. Use two thumbs at 9 o'clock and 3 o'clock over needle array - **See G**
9. Connect leadwire cable to percutaneous electrodes and stimulator
10. Turn stimulator on and sit in a comfortable position

Operation of the Device

11. User begins treatment by pressing PLUS button. User always controls the intensity setting and their comfort level.
12. Continue to increase intensity by pressing PLUS button to keep sensation strong during entire 30 minute treatment
13. During treatment, intensity level that you reach is about half the level you would have reached if you used non invasive electrodes
14. As hypoesthesia develops in first 5 minutes, initial sharper sensation is masked and treatment becomes even more comfortable

End of Treatment

15. When countdown timer reaches 0:00 minutes, intensity automatically is reduced to zero. Press power button to turn unit off.
16. Gently peel electrodes off of skin
17. Place needle side of electrodes together and dispose of in Sharps disposal
18. 1.5" diameter pink circle with 1014 dimple marks will appear at treatment site
19. 50% of patients have several tiny drops of blood present - **See H**
20. Clean skin with an alcohol prep or with a sterile gauze pad - no dressing is necessary
21. Pink circle resolves typically within 24 hours

BIOWAVEPENS

Need help? Contact us!

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East Point Business Park
Oxford OX4 6LB
United Kingdom

Rx ONLY

Device must only be used with power supply provided.

CE 1282

MET c us E114972

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

MD

Rev 18 - 260319