Professional Percutaneous Electrical Nerve Stimulation System for the Treatment of Pain

biowave® PENS

quick reference
for Biowave Percutaneous Electrodes

There are 5 buttons that control the device:
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 15 lbs of force perpendicular to back surface of electrode to ensure all microneedles pass through the 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 so it is facing up. Gently slide metal connector on leadwire cable into device so it clicks in place.
6. Turn on device. Start up screen should read 0.0%.
7. Start treatment by pressing the (+) button.
8. Continue to press the (+) button throughout the treatment so that a steady strong but comfortable tingling and pressure sensation is felt under the electrode(s) covering the pain site(s).

See User’s Manual for detailed instructions.

NEED TECHNICAL HELP?
CALL: 1-877-BIOWAVE x2
EMAIL: support@biowave.com

The Pathway to Pain Relief™
Biowave Percutaneous Electrodes

The BiowavePENS’ Percutaneous Electrical Nerve Stimulation System is comprised of a BiowavePRO stimulator and Biowave Percutaneous Electrodes.

Biowave Percutaneous Electrodes are sterile, single-use and comprised of over 1000 microneedles that are 0.74 mm in length. These electrodes feel like Velcro to the touch and are designed to provide a direct conductive pathway through skin into deep tissue bypassing the impedance of skin, allowing deeper penetration of the therapeutic electrical field. BiowavePENS may only be used with the following percutaneous electrodes manufactured by Biowave Corporation:

**B-Set** BWEP01-B: Back Pain, Bilateral Pain or Pain Over a Large Area

2 round equal area percutaneous electrodes (2.5” diameter) used for treating 2 equal points of pain, or over the location the pain presents and over the source or origin of the pain. Used for:

- bilateral pain in the low back and buttocks
- bilateral pain in the thoracic or cervical spine and shoulders
- pain of equal magnitude in two locations
- radiculopathies
- pain centered directly over the spine
- pain throughout the knee or shoulder
- pain over large areas

**E-Set** BWEP02-E: Extremity or Unilateral Pain

1 round percutaneous electrode for the primary pain site (2.5” diameter); and 1 rectangular noninvasive electrode (2” x 4”) to be placed over a bony prominence (a comfortable location) near the region being treated. Used for:

- unilateral pain in the extremities including the knees, ankles, feet, toes, neck, shoulders, elbows, wrists, hands and fingers
- unilateral pain including, single points of pain (up to 3 inches in diameter) in the lumbar, thoracic or cervical area of the back, ribs, obliques, hips, buttocks, groin or gluteus maximus

See opposite page for percutaneous electrode placement examples.

Warning: Electrodes must not touch each other.
Electrode Placement Rationale For Percutaneous Electrodes

BioWavePENS percutaneous electrode placements are different from conventional surface electrical stimulation. The active therapeutic electrical field forms in a 3-inch diameter hemisphere (volume of tissue) beneath and surrounding each electrode, not along the surface of the skin between the electrodes. As a result, electrodes need to be placed either (1) directly over points of pain; (2) over one point of pain and the source of the pain; or (3) over one point of pain and over a bony prominence.

Electrical signals can be focused to different parts of the body by pairing electrodes of different impedances and/or different areas with one another.

**B-Set: 2 Round Percutaneous Electrodes for 2 Equal Points of Pain or Pain Over a Large Area**

If two electrodes of equal area are used that are both percutaneous and of equal area (and therefore have the same low impedance) then two distinct volumes of tissue can be treated that each have a similar magnitude of pain. If the two same 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 directly over the source of the pain, for example, directly over the spine. The second electrode is placed proximally over where the pain first presents itself, for example, on the buttock.

**E-Set: 1 Round Percutaneous Electrode for a Single Point of Pain and 1 Larger Rectangular Noninvasive Electrode for a Bony Prominence (Comfortable Location)**

By pairing a percutaneous electrode with a noninvasive electrode of larger area, the impedance is much lower in the hemisphere beneath the percutaneous electrode. Therefore, the percutaneous electrode needs to be placed directly over the single painful area. The larger noninvasive rectangular electrode should be placed over a bony prominence near the treatment site because this is the most comfortable location to receive stimulation. 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 electric field to encompass the pain site under the percutaneous electrode.

Body Position During Treatment

The body should remain in a static position during the treatment. Generally, the tissue being treated should be a little 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.

**Low Back and Buttocks**

The torso should be at approximately 90 degrees to the legs causing tissue in the low back and buttocks to be more taut. If necessary, the patient can be in a prone position during the treatment.

**Hip and Groin**

Lying supine with the legs straight is best for hip or groin treatments.

Knees

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 of the knee is more taut.

**Ankles and Feet**

Sitting with the foot pressing on a flat surface is the best position. The foot should be at approximately 90 degrees to the tibia. If necessary, the foot may be elevated during treatment.

**Neck, Shoulders and Thoracic Back**

Generally, sitting is the most comfortable position during cervical, thoracic and shoulder treatments. For neck treatments, the head should be bent forward to keep the tissue on the back of the neck more taut.

**Elbows, Wrist, Hands and Fingers**

The arm should rest at the side of the body with the elbow bent at a small angle. The patient should hold a rolled up towel to keep their hand and fingers in a comfortable position during the treatment.

Treatment Regimen Protocol

Six 30-minute treatments over a 2 to 3 week period 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.

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 electrode(s) 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% - 35%.

Motion During Treatment

The sensation from the treatment is a deep 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 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 point of pain. This is a fine tuning of the treatment that will provide the best treatment result.
Percutaneous Electrode Placement Examples

**Lumbar Back**
- 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/Thoracic Back**
- Unilateral Low Back Pain Focused on one Side of Spine
- Unilateral Low Back Pain Focused Over a Facet Joint
- Sacroiliac (SI) Joint Pain
- Bilateral Thoracic Pain (Two Equal Points of Pain)

**Hips**
- Hip Pain in One Location

**Knees**
- Central Knee Pain (e.g. ACL Sprain, Meniscus, Bursitis, OA)
- Medial Knee Pain (e.g. MCL Sprain, Bursitis, OA)
- Patellar Tendinitis
- Lateral Knee Pain (e.g. LCL Sprain, Bursitis, OA)
- Illiotibial (IT) Band Pain in Two Locations
- Pain Throughout Entire Knee (e.g. Total Knee Arthroplasty)

**Ankles and Feet**
- Ankle or Foot Sprain with Pain in One Location
- Plantar Fasciitis
- Achilles Tendinitis
- Achilles Tendinitis with Primary Pain at Insertion Point

WARNING: Electrodes must not touch each other. See back cover for electrode descriptions.
Trapezius Pain in One Location (e.g. Trigger Point)

Ankles and Feet

Neuroma Pain or Metatarsal Joint Pain
Ankle or Foot Pain in Two Locations

Neck

Cervical or Neck Pain in One Location
Cervical or Neck Pain in Two Locations

Shoulders

Radioulnar - Electrodes Over Source and Proximal Pain Site
Neck Pain Over Several Cervical Discs
Bilateral Neck Pain (Two Equal Points of Pain)
Pain at AC Joint or Inside the Shoulder (e.g. AC Sprain)

Shoulders

Anterior Shoulder Pain (e.g. Biceps Tendinitis)
Posterior Shoulder Pain (e.g. Infraspinatus Strain)
Trapezius Pain in One Location (e.g. Trigger Point)
Shoulder Pain in Two Locations (Two Equal Points of Pain)

Elbows

Bilateral Trapezius Pain (Two Equal Points of Pain)
Lateral Elbow Pain (e.g. Lateral Epicondylitis)
Medial Elbow Pain (e.g. Medial Epicondylitis)
Posterior Elbow Pain (e.g. Triceps Tendinitis)

Wrist, Hands and 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)

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Device must only be used with power supply provided.

See User’s Manual for more information.

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