

Prescription Neuromodulation Pain Therapy System

Revised
Sept 2024

BIOWAVEHOME



quick reference for BioWave Noninvasive Electrodes

There are 4 buttons that control the device:

1. Power **ON/OFF** button
2. **PLUS (+)** button to increase intensity
3. **MINUS (-)** button to decrease intensity
4. **PAUSE** button to pause the treatment

Designed to
Block Pain
at the Source™

Battery Maintenance:

Please charge battery
at least 1x per week.

See User's Manual for detailed instructions at:
<https://biowave.com/support-biowave-home>

BioWave Noninvasive Electrodes

The BioWaveHOME Pain Therapy System can be used with the following BioWave Noninvasive Electrodes:

B-Set - Pain in Two Locations

The B-set is comprised of two 2.0" diameter round equal area pain site 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 one or two locations in the back, pelvic floor, buttocks, lower back or mid back region
- radiculopathies (radiating pain down the neck or lower back to the extremities)
- pain in one or two locations in the hip or groin
- pain in one or two locations in the cervical spine, shoulders or knees
- pain centered directly in the spine
- pain presenting in a large area



E-Set - Pain in a Single Location * 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, toes, neck, shoulders, elbows, wrists, hands and fingers



BioWaveHOME may be used with BioWave Percutaneous Electrodes as well.

See BioWavePENS Quick Reference Guide (QRG). Call Customer Service at: 1-877-BIOWAVE (1-877-246-9283) or GO TO:

- <https://biowave.com/all-products/biowavepens/>
Scroll down for Resources and click the BioWavePENS QRG button.

CONTRAINDICATIONS

- **DO NOT** use if you have an implanted 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).

WARNINGS

- **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 electrodes.
- **If the edges of the electrodes touch during the treatment, it may cause a burn.**
- **Upon starting the treatment if you increase intensity in less than one minute to:**
 - >80% using B-set or E-set electrodes OR**
 - >50% using BioWraps:**
 1. Immediately stop the treatment.
 2. Thoroughly clean your skin with a damp washcloth, then dry completely.
 3. Use a new set of electrodes OR reapply TheraCream and BioWrap.
 4. Restart the treatment.
- **CHECK used electrodes** prior to using them.
DO NOT USE IF:
 1. The metal portion of the wire is exposed.
 2. The gel has peeled apart from the black surface.
 3. The surface of the hydrogel is worn down.

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.

Directions For Use

Do not turn on unit until Step 6.

- 1. Plug in the AC charger** into your BioWaveHOME unit to charge up the battery. Once fully charged, remove plug and proceed to step 2.



- 5. Align cable connector** with mating keyhole in port as shown. **Plug CABLE into Unit** so it clicks in place.



- 2. Plug blue Pad CONNECTORS** into blue LEADWIRE CABLE CONNECTORS. Connectors will click in place and stick out partway so you can easily pull them apart after treatment.



- 6. Press Power Button to turn it on.** (AC Charger must be disconnected from unit.)



- 3. Find your PAD PLACEMENT PHOTO** for your specific pain condition in this **Quick Reference Guide** on the following pages or at: <https://biowave.com/support-biowave-home>

- 7. Press the PLUS (+) button to start treatment. Continue to press the PLUS (+) button throughout treatment** to keep a strong but comfortable sensation.



- 4. Clean your skin** with a damp washcloth in the location the PADS are placed. **Apply Pads directly over areas of pain.**



- 8. Unit turns off automatically at end of 30-minute treatment.** Plug in AC charger to recharge unit.

See User's Manual for detailed instructions at: <https://biowave.com/support-biowave-home>

Electrode Placement Rationale

BioWaveHOME electrode placements are different from conventional electrical stimulation. The mixing of the patented therapeutic signals occurs in a 3.5-inch hemisphere (the size of half of a grapefruit) beneath and surrounding each electrode, not along the surface of the skin between the electrodes.

As a result, electrodes need to be placed directly over specific locations of pain, or one electrode over a single location of pain and the second over a comfortable location to receive stimulation - typically over a bony prominence near the treatment site.

Electrical signals can be focused to different parts of the body by pairing electrodes of different sizes with one another.

B-Set: Two Locations of Pain

or one large area of pain. Two same size 2" diameter round Pain Site Electrodes.

E-Set: Single Location of Pain on Extremities.

One 1.375" diameter round Pain Site Electrode; One 2" x 4" rectangular Dispersive Electrode placed in a comfortable location (over a bony prominence).

For **BioWave Percutaneous Electrodes**, see **BioWavePENS Quick Reference Guide** for protocol and placement instructions.

Body Position During Treatment

Generally, the tissue being treated should be a little taut or in a stretch position. Sitting in a supported position in a chair, couch or bed is best for most treatment locations on the body. See User's Manual for more detailed information on optimal Body Position for different treatment locations.

Motion During Treatment

The sensation from the treatment is a deep smooth tingling and pressure sensation as the muscle is held in tension in the volume of tissue being treated. Motion may cause a stronger or weaker sensation and will cause the location of the internal electrical field to shift slightly. Shifting of the electrical field is most prevalent when treating shoulders, elbows, wrists, hands, fingers and feet.

The goal is to gently move 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 location of pain. This is a fine tuning of the treatment that will provide the best treatment result.

Treatment Regimen Protocols

Pain Management

- One to two 30-minute treatments per day or on an as needed basis.
- May be used as many times as needed each day. For best results, separate each 30-minute treatment by about 30 minutes. Multiple treatments may provide a cumulative benefit.

Athletic Training/Sports

- Three 30-minute treatments separated by 2-3 hours: immediately before practice or a game, immediately after practice or a game, and time permitting 2-3 hours later.
- BioWaveHOME is complimentary with heat or cold therapy. Use a towel or another barrier between the electrodes and a heating pad or ice.

Physical Therapy

- Use tape or wrap over the electrodes to help hold them in place.
- Before starting the treatment, move the treatment location through a range of motion to ensure that the edges of the electrodes do not touch each other.
- Begin a static treatment for 10 minutes to allow the effect of the electrical field to take place.
- After 10 minutes, decrease intensity by 5 - 10% to take the edge off of the sensation.
- Begin active or passive range of motion, exercise or stretching therapy *during remainder of treatment* to significantly increase range of motion with less pain and facilitate exercise therapy. You can move more resistance through a greater range of motion with less pain and because of long lasting residual pain relief, there may be little post exercise soreness.

End of Treatment

Place noninvasive reusable electrodes back on blue release liner and store in resealable bag. Leadwire cable may be wrapped over the front and then around the stimulator.

To remove leadwire cable, hold the black plastic end of the Dongle Adapter with one hand and pull on the blue plastic end of the Leadwire cable with your other hand to disconnect the cable. Never pull on the black wire portion of the Leadwire Cable to remove it from the Dongle Adapter.

A full charge on the battery will provide up to four 30-minute treatments.

Intensity Settings

Patients should increase the intensity slowly based on sensation (not an intensity number) to a level that is strong but always comfortable.

The body adapts to the electrical field very quickly over the first few minutes and then less so over the remainder of the 30-minute treatment. As a light numbness forms in the volume of tissue beneath each electrode and the sensation diminishes, continue to increase the intensity level with individual presses of the PLUS (+) button.

Patients typically tolerate more intensity in the Knees, Ankles and Feet; and a medium level of intensity in the Low/Mid Back and Shoulders. Patients tolerate a lower level of intensity in the Neck, Pelvic Floor, Elbow and Wrist/Hand/Finger.

Important

For patients who lack proprioception (lack sensation), for example from neuropathy, please contact Customer Service at 1-877-BLOWAVE (1-877-246-9283) for optimal Intensity Settings.

Electrode Placement Examples

Electrodes Must Never Touch Each Other:

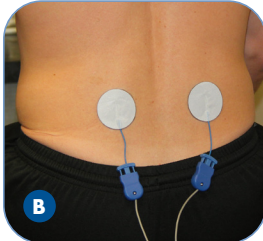
- 1.0 inch (2.6 cm) is the minimum spacing between electrodes on the back.
- 0.5 inches (1.3 cm) is the minimum spacing between electrodes on joints or extremities.
- There is NO maximum spacing between any electrodes.
- If the edges of the electrodes touch during the treatment, it may cause a burn.

The following section shows photos of Examples of Electrode 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.

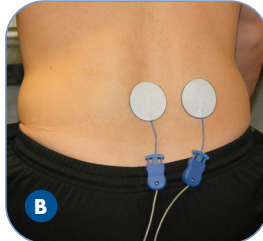
For **PERCUTANEOUS ELECTRODE PLACEMENTS**, contact your physician, see the **BioWavePENS Quick Reference Guide** or call technical support:

1-877-BIOWAVE • (1-877-246-9283)

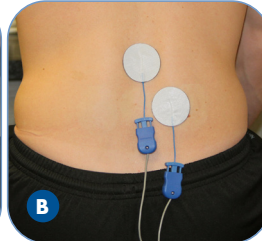
Low Back



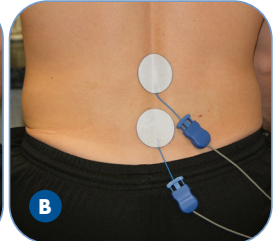
Back Pain in Two Locations
(e.g. Bilateral Lumbar Pain)



Low Back Pain on One Side of Spine
(e.g. Unilateral Pain)

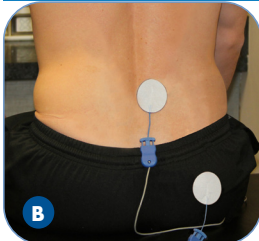


Low Back Pain Focused
Over a Facet Joint

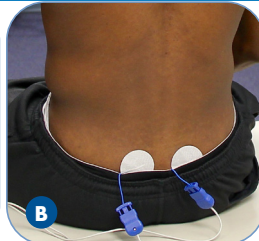


Low Back Pain Focused
Over the Spine

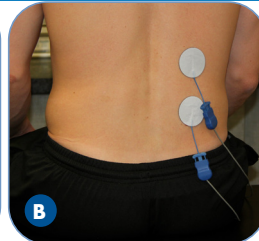
Low Back



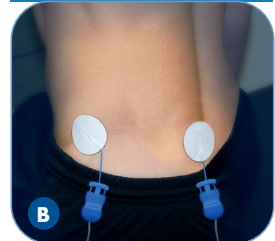
Radiating Back Pain - One Pad
Over Origin of Pain, One Pad
Over First Pain Site Closest to
Origin (Pads Must be on Skin)



Pain at the Bottom of the Spine
(e.g. Sacroiliac (SI) Joint Pain);
Pelvic Floor Pain (e.g. Pain from
Interstitial Cystitis)



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



Hip Pain

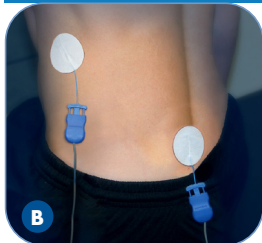
B B-Set
2 Locations of Pain

E E-Set
1 Location of Pain

WARNING: Electrodes must not touch each other.

Electrode Placement Examples (continued)

Ribs/Obliques



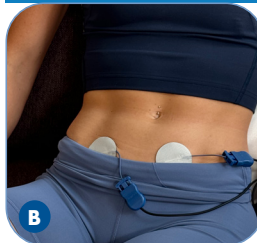
Rib or Oblique Pain

Groin

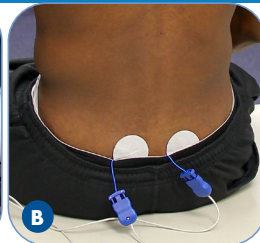


Groin Pain

Pelvic Floor/Menstrual Cramps

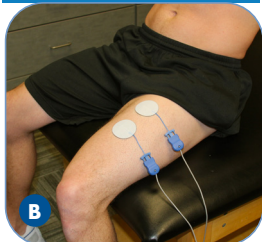


Pelvic Floor Pain,
Menstrual Cramps
(Pudendal Nerve Stimulation)



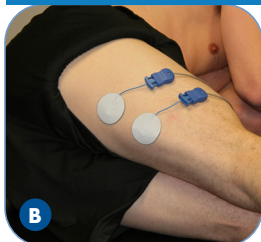
Interstitial Cystitis
(Sacral Nerve Stimulation)

Quadriceps



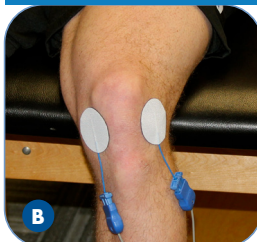
Quadriceps Pain

Hamstrings

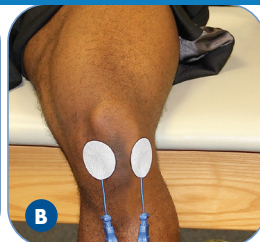


Hamstring Pain

Knees

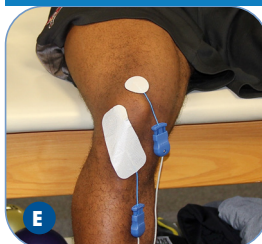


Pain Throughout Entire Knee
(e.g. OA or Total Knee
Replacement)

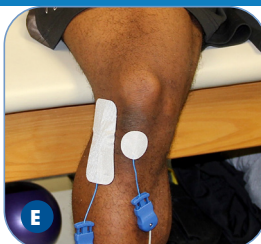


Pain Towards the Front of the Knee
(e.g. ACL Sprain)

Knees



Pain Above Knee
(e.g. Quadriceps Tendinitis)



Pain Below Kneecap
(e.g. Patellar Tendinitis)



Pain in Inside of Knee
(e.g. Bursitis, OA, MCL Sprain)



Pain in Outside of Knee
(e.g. Bursitis, OA, LCL Sprain)

B B-Set

2 Locations of Pain

E E-Set

1 Location of Pain

WARNING: Electrodes must not touch each other.

Knees

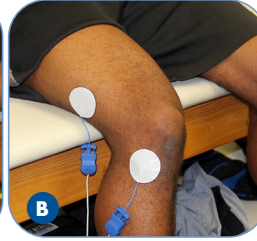


E
Pain in Back Side of Knee
(e.g. PCL Sprain)

Iliotibial (IT) Band

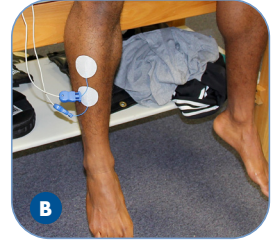


E
Pain on Outside of Thigh in One
Location (e.g. Iliotibial (IT) Band
Pain)



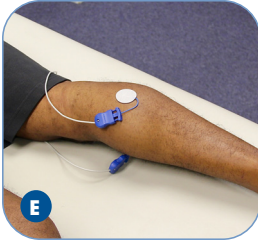
B
Pain on Outside of Thigh in Two
Locations (e.g. Iliotibial (IT) Band
Pain)

Shins

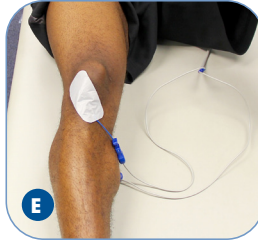


B
Pain on Front of Lower Leg
(e.g. Pain from Shin Splints)

Calves



E
Calf Pain in One Location
(e.g. Gastrocnemius Strain)

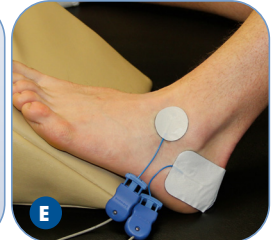


E
Calf Pain - Round Pad is Over Pain
Site, Rectangular Pad is Angled
Across Bottom of Kneecap

Ankles & Feet

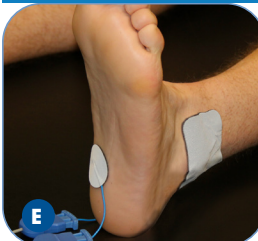


B
Foot or Ankle Pain in Two
Locations, (e.g. High Ankle Sprain)

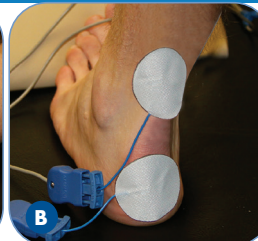


E
Lateral Low Ankle or Foot Pain
in One Location (e.g. Ankle Sprain)

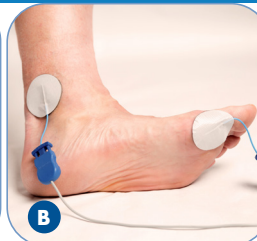
Ankles & Feet



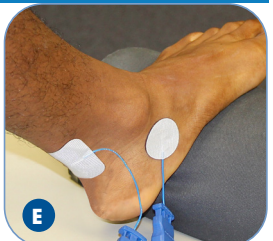
E
Pain on Bottom of Foot
(e.g. Plantar Fasciitis)



B
Pain at Back of Ankle & Heel
(e.g. Achilles Tendinitis)



B
Pain in Foot & Ankle
from Diabetic Neuropathy
(Tibial Nerve Stimulation)



E
Foot Pain Beneath Ankle on Inside
of Heel in One Location

B B-Set

2 Locations of Pain

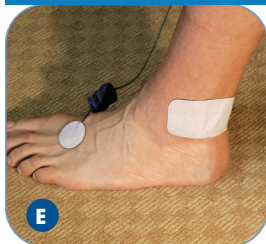
E E-Set

1 Location of Pain

WARNING: Electrodes must not touch each other.

Electrode Placement Examples (continued)

Ankles, Feet & Toes

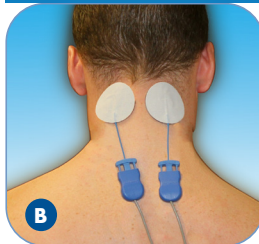


Pain in Top of Foot (e.g. Metatarsal or Neuroma Pain)



Pain in Toe Joint (e.g. Turf Toe or Phalange Pain)

Headache



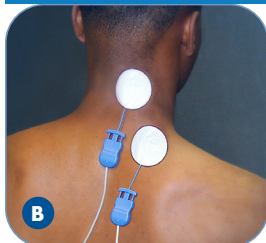
Headache Pain
(Headache Initiates from Posterior of Neck and/or Head)

TMJ

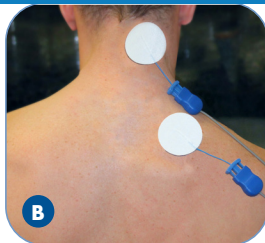


Temporomandibular Joint Pain or Pain Along Trigeminal Nerve

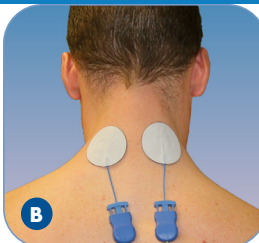
Neck



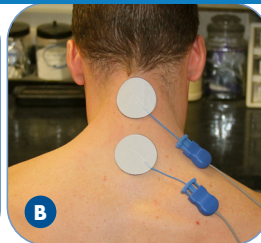
Radiating Neck or Cervical Pain



Neck or Cervical Pain in Two Locations

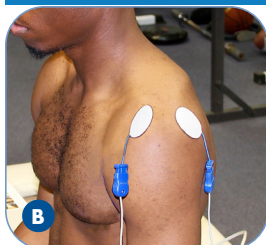


Neck Pain in Two Locations (e.g. Bilateral Neck/Cervical Pain)

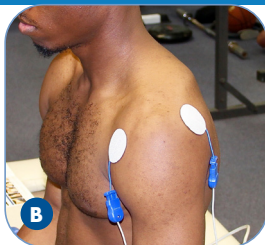


Neck or Cervical Pain in Multiple Discs

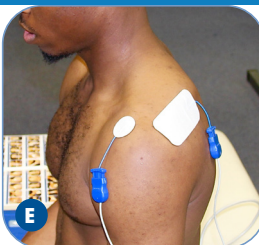
Shoulders



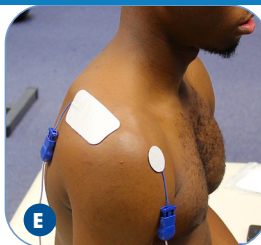
Shoulder Pain Throughout the Joint or Frozen Shoulder



Shoulder Pain in Two Locations (in same shoulder)



Pain at Top or Throughout Shoulder (e.g. AC Sprain or Frozen Shoulder)



Pain in Front of Shoulder (e.g. Biceps Tendinitis)

B B-Set

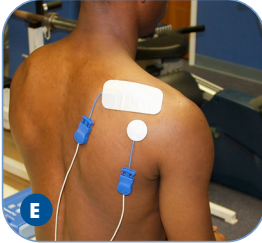
2 Locations of Pain

E E-Set

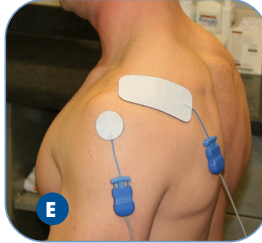
1 Location of Pain

WARNING: Electrodes must not touch each other.

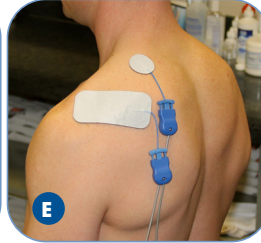
Shoulders



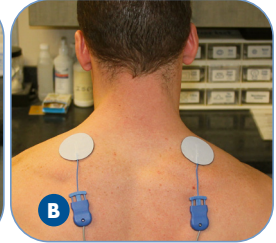
Pain in Back of Shoulder
(e.g. Infraspinatus Strain)



Pain in Edge of Shoulder
(e.g. Rotator Cuff Tendinitis)

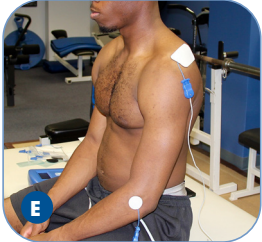


Trapezius Pain in One Location
(under small round pad)

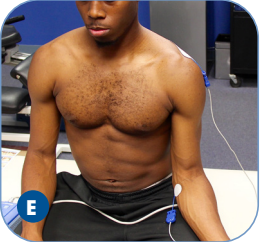


Shoulder Pain in Two Locations
(e.g. Bilateral Trapezius Pain)

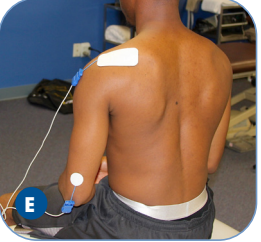
Elbows



Pain in Outside of Elbow
(e.g. Lateral Epicondylitis)

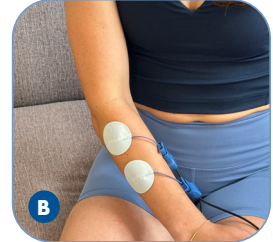


Pain in Inside of Elbow
(e.g. Medial Epicondylitis)



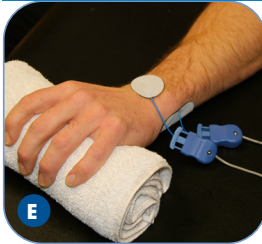
Pain Behind Elbow
(e.g. Triceps Tendinitis)

Forearm

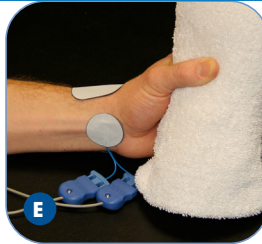


Temporomandibular Joint Pain or
Pain Along Trigeminal Nerve

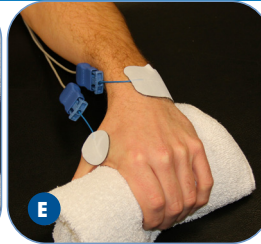
Wrists, Hands & Fingers



Pain in Back of Wrist (e.g. Sprains,
Strains, Tendinosis)



Pain in Front of Wrist (e.g. Sprains,
Strains, Tendinosis)



Thumb Pain (e.g. Thumb or UCL
Sprain)



Pain in Finger Joints (e.g.
Metacarpal Phalangeal Joints)

B B-Set
2 Locations of Pain

E E-Set
1 Location of Pain

WARNING: Electrodes must not touch each other.



BIOWAVEHOME

Need help?

Contact Us at:

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

Download the BioWaveHOME User's Manual at:
<https://biowave.com/support-biowave-home/>

BIOWAVE



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

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**MADE IN
USA**

EC REP

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

CE
1282

**UK RESPONSIBLE
PERSON**

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

MET
E114972

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



Device must only be
used with power
supply provided.



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