Rx Only

Revised April 2021

BIOWAVEHOME

Prescription Neuromodulation Pain Therapy System

User's Manual

Designed to Block Pain at the Source™

BioWave Corporation

Table of Contents

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Table of Contents (continued)

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Table of Contents (continued)

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Table of Contents (continued)

Table of Contents (continued)

IMPORTANT!

Before using this product, read the following information thoroughly.

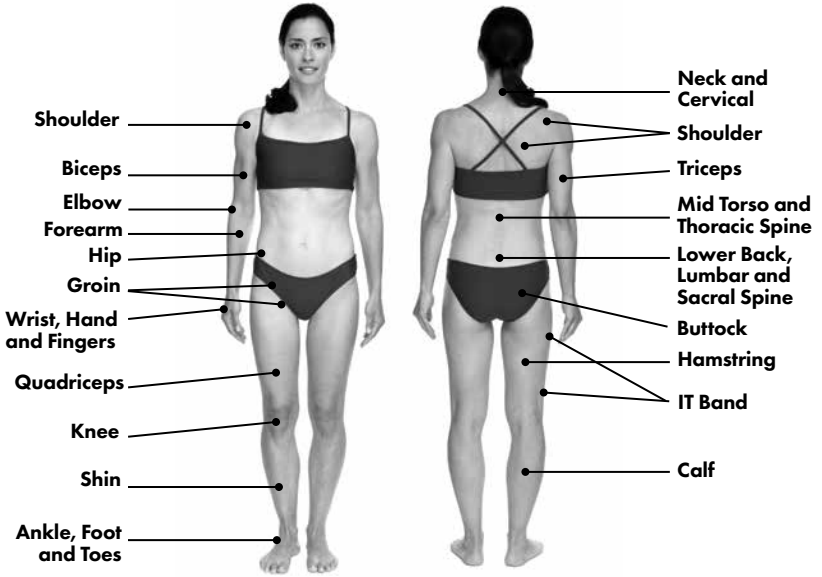
Rx Only

1. Indications for Use

Neuromodulation is the electrical stimulation of a nerve for the relief of pain. The BioWaveHOME® Neuromodulation Pain Therapy System is for patients age 6 and older and is indicated for:

- Symptomatic relief of chronic, intractable pain
- Symptomatic relief of post-traumatic acute pain
- Symptomatic relief of post-operative pain

AREAS OF TREATMENT



See Section 4.4 for examples of electrode placements.

2 . Stimulator Description

BioWaveHOME® is a pain therapy stimulator which utilizes a unique signal mixing technology to deliver electrical signals through the skin into deep tissue for blocking pain signals on pain nerves inside the body and for improving function.

The stimulator is comprised of a plastic housing containing the electronics and a rechargeable battery. On the face of the stimulator is a large LCD display showing signal intensity as a percent of maximum intensity, the remaining treatment time, a battery indicator and error indications (for example if the leadwire cable becomes disconnected from the electrodes). A blue Charging LED resides in the right lower corner indicating that the battery is charging when the AC charger is plugged into the stimulator.

BioWaveHOME®
Neuromodulation
Pain Therapy Stimulator

There are 4 buttons that control the stimulator:

1. Power ON/OFF button

2. PLUS (+) button to increase intensity

3. MINUS (–) button to decrease intensity

4. PAUSE (||) button to pause the treatment

The default treatment time is 30 minutes.

2.1 Stimulator Accessories

2.1.1 LEADWIRE CABLE

A "Y" shaped leadwire cable connects 2 disposable electrodes to the BioWaveHOME® stimulator. The single end of the leadwire cable plugs into a connector at the top of the stimulator, behind the LCD display as shown in the photo below.

Plugging the Leadwire Cable into the Stimulator

Lie the stimulator face down on a hard surface.

Align the lever on the connector so it is facing up as in the photo to the right. The lever on the connector mates with the keyhole in a receptacle inside the round opening on the stimulator and the connector gently slides in and clicks in place.

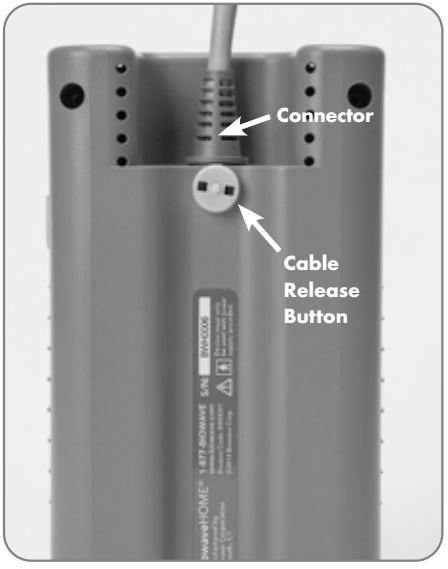
If the lever does not click into the keyhole, remove the cable and use your index finger to press down firmly on the small metal pin inside the round opening to the device (press in the direction toward the cable release button which is on the outside of the device). Next, re-insert the connector back into the keyhole and it should click into place. Pressing on the metal pin prevents it from resting on the lever and allows the cable to click in and lock in place.

Removing the Leadwire Cable from the Stimulator

Lie the stimulator face down on a hard surface. Press the Cable Release Button firmly on the back of the stimulator as shown in the photo to the right. While holding down the Release Button, gently pull the connector straight out of its socket. Once the connector is removed from the stimulator, stop pressing the Release Button.

NEVER pull on the connector or cable if the release button is NOT fully depressed.

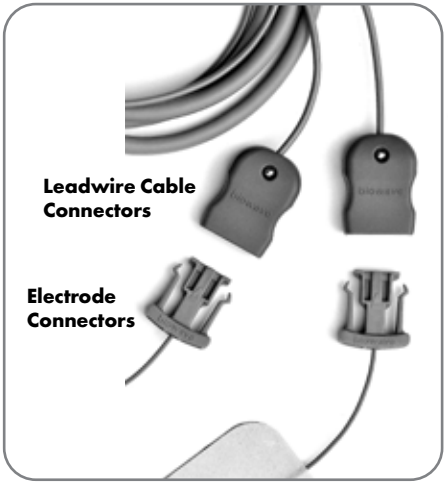
NEVER twist the connector; NEVER pull on the cable itself.



Connecting the Leadwire Cable to Electrodes

BioWaveHOME® uses 2 electrodes for a treatment. Either electrode can be connected to either blue connector at the end of the leadwire cable (see photo to the right). Orientation of the blue connectors (top or bottom side) does not matter.

Line up the leadwire cable and electrode connectors and plug them together until they click in place. When connected toegther, 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. You do **not** need to squeeze the prongs on the electrode connector to insert or remove them.

2.1.2 AC CHARGER

The universal AC Charger is only used to recharge the battery in the stimulator. The stimulator must first be turned off before plugging in the AC Charger. The stimulator will not operate while the AC Charger is plugged into the stimulator.

One end of the cord from the AC Charger is plugged into the receptacle on the side of the stimulator as shown in the photo to the right. The other end is plugged into a standard electrical outlet. (100-240 Volts at 50-60 Hz).

Location of Receptacle for AC Charger

2.2 BioWave Electrodes

There are two types of BioWave Electrodes designed to work with the BioWaveHOME Stimulator: BioWave Noninvasive Electrodes and BioWave Percutaneous Electrodes.

BioWave Noninvasive Reusable Electrodes

BioWave® Noninvasive Electrodes are reusable surface electrodes typically used to reduce pain and facilitate physical therapy activity such as active or passive range of motion, exercise and stretching.

BioWave Percutaneous Electrodes

BioWave® Percutaneous Electrodes utilize a patented technology involving an array of over 1000 needles to significantly facilitate the delivery of the BioWaveHOME Stimulator's therapeutic signals through the skin, directly into deeper tissue. BioWave Percutaneous Electrodes are 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. BioWave® Percutaneous Electrodes may also be purchased by patients with a prescription.

Warning

ELECTRODES MUST NEVER TOUCH EACH OTHER

- **1.0 inch is the minimum spacing between electrodes on the back**
- **0.5 inches 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**

2.2.1 BioWave NONINVASIVE REUSABLE ELECTRODES

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

- B-set
- E-set
- U-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 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

2.2.1.2 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

The E-set is **not** used in the mid torso region of the body.

2.2.1.3 U-Set: Single Location of Pain in the Mid Torso Region

The U-set is comprised of:

- One 2″ diameter round Pain Site Electrode that is placed directly over the primary pain site; and
- One 5″x 8″ large rectangular Dispersive Electrode that is placed horizontally across the lower back (a comfortable place to receive stimulation).

The U-Set is used for treating single locations of pain in the mid torso region:

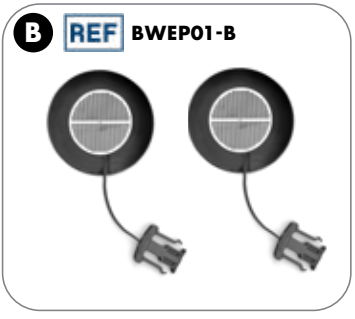
- rib
- oblique
- hip
- buttock
- groin
- adductor
- abductor
- gluteus maximus
- hamstring
- quadriceps

The U-set is **not** used for treating single locations of pain on the low back (use the B-set).

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



B-Set: Two round same area Percutaneous Electrodes (2.5 inch diameter) are placed over two equal locations of pain, or over the location the pain presents and over the source or origin of the pain. Used for treating:

- 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 (radiating pain)
- pain centered directly over the spine
- pain throughout the knee or shoulder
- pain over large areas

2.2.2.2 E-Set: Single Location of Pain

E-Set: One round Percutaneous Electrode (2.5 inch diameter) is placed over the primary pain site; and one rectangular noninvasive electrode (2 inch x 4 inch) is placed over a bony prominence near the region being treated
(a comfortable location to receive stimulation). Used for treating:

- unilateral pain in the extremities including the knees, ankles, feet, toes, neck, shoulders, elbows, wrists, hands and fingers
- unilateral pain including, single locations of pain (up to 3.5 inches in diameter) in the lumbar, thoracic or cervical area of the back, ribs, obliques, hips, buttocks, groin or gluteus maximus

2.3 Stimulator Controls

2.3.1 Power Button

Power Button

The Power Button is located on the right side of the stimulator. Pressing the Power Button turns the stimulator on. While the stimulator is on, pressing the Power Button turns the stimulator off.

Power should be turned on after the electrodes are attached to your body and to the cable, and the cable is plugged into the stimulator. Once the power is turned on, the LCD display should read 0.0% and you can begin pressing the PLUS (+) Button to increase intensity beginning the treatment.

2.3.2 PLUS Button (+)

PLUS, MINUS, and PAUSE buttons

Pressing the PLUS (+) Button increases the intensity of the signal and the level of the tingling/pressure sensation that you feel.

2.3.3 MINUS Button (–)

Pressing the MINUS (–) Button decreases the intensity of the signal and the level of the tingling/pressure sensation that you feel.

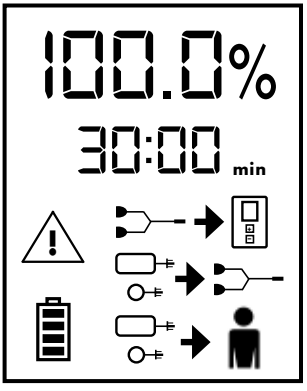
2.3.4 PAUSE Button (||)

Pressing the PAUSE (||) Button immediately reduces the intensity to 0.0% and pauses the countdown timer. The countdown timer will begin to flash. To restart the treatment, press the PLUS (+) button to manually increase the intensity of the signal from 0.0% back up to the desired level.

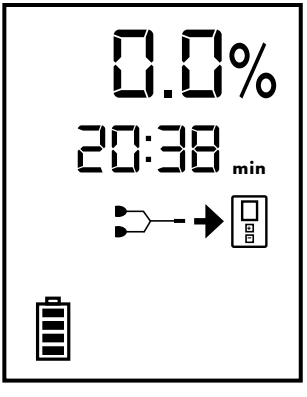
2.4 Stimulator Indicators

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 at the top of the display. At the beginning of a treatment the intensity should read 0.0%.
- Remaining Treatment Time is indicated beneath the intensity in minutes and seconds. The default treatment time is 30 minutes.
- Battery Strength Indicator is indicated on the lower left corner of the display
- Problems - if a problem occurs, intensity is immediately reduced to zero, an image of the error condition will appear and the ***arrow will flash*** indicating the correction to be made. For example if the leadwire cable becomes disconnected from the stimulator, the intensity will decrease to zero (0.0%), the treatment time will pause, a picture will appear showing a leadwire cable with a flashing arrow pointing to the stimulator, and the stimulator will sound an alert. This indicates the leadwire cable should be plugged back into the stimulator (see Section 8 - Troubleshooting).



2.4.2 Charging Indicator Light

A Charging Indicator Light is located in the lower right corner on the face of the stimulator as shown in the photo to the right. This BLUE LED Indicator Light shows the charging status of the battery.

The Indicator Light remains a ***steady*** BLUE during charging, and turns ***off*** when the battery is fully charged.

The BioWaveHOME stimulator cannot be operated while the AC charger is plugged in recharging the stimulator's battery system.

Blue Charging Indicator Light

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

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

3.1 When the Stimulator Should Not Be Used (Contraindications)

- **DO NOT** use if you have a cardiac pacemaker as the neurostimulator may interfere with its function.
- **DO NOT** use on patients prone to seizure (for example, epileptics).
- **DO NOT** place electrodes over the heart or across the thoracic volume. 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 the top of the head.
- **DO NOT** place electrodes over wounds, broken skin or sensitive skin areas.
- Electrodes MAY BE PLACED directly over or in the proximity of implanted metal hardware, including total joint replacements, anchors, plates, rods, screws and pins.
- Keep the BioWaveHOME Neurostimulator away from children. However, BioWave may be used on children if supervised.

3.2 Risks/Benefits

3.2.1 RISKS

- There is a risk of rash underneath the electrode area. If you have sensitive skin and routinely might have contact dermatitis (a rash), for example, from removing a Band-Aid® from the skin, then there is a risk of rash upon removal of the electrodes.
- The stimulator is programmed to deliver a limited amount of energy to the skin, to protect against discomfort. However, it is also important for protecting against discomfort, that BioWaveHOME® not be used on any area of your body that you are concerned may be overly sensitive to the impulses from the stimulator, for example, on sunburned skin.
- There is a risk of infection if the electrodes are placed on broken skin. Infection can be avoided by using the stimulator and placing electrodes on intact skin. Electrodes may be placed over healed scar tissue or over tatoos.

3.2.2 BENEFITS

- Customers report that BioWave treatments may provide the most profound treatment results for treating (i) pain from ligament and tendon related issues, for example from joint sprains, and from acute and chronic tendinopathies; (ii) pain from lumbar, thoracic and cervical issues in or near the spine including radiating pain; (iii) pain from osteoarthritis, bursitis and neuromas; (iv) myofascial pain; (v) pain from fibromyalgia; (vi) pain from contusions; (vii) pain from interstitial cystitis and (viii) postoperative pain.
- BioWaveHOME® is an easy to use 30-minute treatment.
- Treatment using the BioWaveHOME® System will provide temporary relief of pain or discomfort.
- Patients should expect to feel a light numbness in the volume of tissue treated, 5 minutes into the treatment, immediately after and for up to 20 minutes following a 30-minute treatment.
- Patients should expect to feel benefits including pain relief and functional improvement immediately after and for up to 24 hours following each treatment with BioWave Noninvasive Electrodes, and for up to 72 hours following each treatment with BioWave Percutaneous Electrodes.
- Most patients should start to feel a reduction of pain during and immediately after their first treatment. Patients should also experience an increase in range of motion, decrease in stiffness and reduction in muscle spasm immediately following the first treatment.

- Most patients should expect to feel a continued improvement in benefits with each successive BioWaveHOME® treatment if treatments are performed not longer than 24 hours apart.
- Treatment with BioWaveHOME® can be combined with heat, cold and compression therapies as well as with treatment via conventional medicine.

3.3 Warnings

- **Electrodes must never touch each other during a treatment.** Electrodes that touch each other during an active treatment will cause a burn. One inch is the minimum spacing between electrodes on the back. Half of one inch is the minimum spacing between electrodes on joints or extremities.
- BioWave Percutaneous Electrodes are sterile and can only be used for a single treatment. Do not use the Percutaneous Electrodes if the packaging is damaged or compromised in any manner.
- **DO NOT** plug into an AC outlet during use. The stimulator is battery operated and will not operate while the AC charger is plugged in.
- **DO NOT use around water or liquids.** Contact with water or liquids could cause electric shock, which can result in serious injury to the patient.
- **NO** modification of the BioWaveHOME unit or electrodes is allowed.
- The safety of the BioWaveHOME® stimulator for use during pregnancy or labor has not been established.
- The stimulator may not be effective for pain originating in the central nervous system.
- The stimulator should be used only under the continued supervision of a physician.
- The stimulator has no curative value.
- The stimulator provides a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- The case temperature of the stimulator, when operating at 100% intensity in 40˚C ambient temperature, can increase to 48˚C.
- If performing multiple treatments with the stimulator, wait a minimum of 30 minutes in between treatments.
- Do not rest the stimulator on the body during treatment.

- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the stimulator is in use.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the front or side of the neck. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically (across the heart) because the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or over skin eruptions, e.g. phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- The user should be careful to avoid strangulation from the leadwire cables.

3.4 Precautions

- It is important to keep this manual handy. It should be studied and reviewed periodically by users of BioWaveHOME®.
- Children should be supervised by an adult when using the BioWaveHOME device.
- If the BioWaveHOME device has been stored in an extreme temperature environment, allow the device to acclimate to room temperature prior to beginning a treatment.
- The stimulator 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 stimulator as it could be damaged and will not function properly.
- Do not exceed the treatment duration and frequency recommended in the operating instructions.
- BioWaveHOME® was designed and manufactured to ensure maximum safety of operation. Maintain the stimulator in strict compliance with the safety precautions and operating instructions in this manual.

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Effectiveness of BioWaveHOME® Neuromodulation Pain Therapy is highly dependent upon patient selection by a person qualified in the management of pain patients.
- Caution should be used 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.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or adhesive gel used with the electrodes (electrical conductive medium). The irritation can usually be reduced by using a different electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- 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.

3.5 Adverse Reactions

- Skin irritation, redness and electrode burns are possible adverse reactions.

4. User Instructions

4.1 First Time Set Up & Quick Operating Steps

4.1.1 First Time Set Up

1. Remove packing materials and place the BioWaveHOME® stimulator on a hard surface.

2. Make sure the stimulator is turned OFF. Plug AC Charger into a standard electrical wall outlet and the other end into the BioWaveHOME® stimulator to begin charging the battery. **The battery must be fully charged up before the first use.** While the stimulator is charging, the battery charging indicator light will remain a solid BLUE. Once the stimulator is fully charged, the charging indicator light will turn off. Unplug the charger from the stimulator.

4.1.2 Quick Operating Steps

The default treatment time is 30 minutes. One 30-minute treatment may provide up to 24 hours of pain relief. There is no limit to the number of treatments that can be performed in one day. Multiple treatments in the same location may provide a cumulative benefit. If you are having a severe pain episode, the best results can be obtained by performing multiple treatments in the same location but waiting 30 - 60 minutes in between each 30-minute duration treatment. You may perform back-to-back treatments on different pain locations on the body.

1. 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.

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

3. Gently plug the leadwire cable into the top of the stimulator. Make sure the lever on the cable connector aligns with the keyhole in the female side connector in the stimulator (see Section 2.1.1 - Plugging Leadwire Cable into Stimulator).

4. 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.

5. Increase intensity by pressing the PLUS (+) button so the sensation felt is strong but still comfortable. During the remainder of the treatment, as your body adapts to the electrical field and the sensation fades, keep increasing the intensity to maintain a strong but comfortable sensation at the treatment location (see Section 4.8 - Using BioWaveHOME).

6. 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 you feel encompassing your pain site to be stronger and in deeper tissue (see Section 4.6 - Body Position During Treatment).

7. 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 4.7 - Motion During Treatment).

4.2 Rationale for Electrode Placements

BioWaveHOME® electrode placements are significantly different from other forms of electrical stimulation including TENS, interferential and muscle stimulation devices.

The BioWaveHOME® stimulator utilizes two electrodes. The active electrical field is focused in a 2.5 - 3 inch diameter hemisphere in the volume of tissue under and surrounding each electrode. Since the nerve fibers and muscle tissue under and surrounding the electrodes are encompassed by this active electrical field inside the body, at least one electrode must be placed directly over the center of the painful area.

The BioWaveHOME® stimulator alternates the delivery of its electrical signals so quickly between the two electrodes that the treatment sensation feels as if it is continuously being delivered to both electrode locations simultaneously. The net effect is that there are two active independent electrodes, each of which can treat a distinct 2.5 - 3 inch diameter hemisphere in the volume of tissue under and surrounding each electrode.

The sensation felt at each location is a deep smooth tingling and pressure sensation. There is no uncomfortable twitching sensation that is common to other types of electrical stimulation devices.

4.3 Focusing of the BioWave Signals and Electrode Set Choice

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 areas with one another.

4.3.1 Two Locations of Pain

- **Use B-set Electrodes**

If there are two locations of pain, then two electrodes of equal size (the B-set which is comprised of two 2-inch diameter round Pain Site electrodes) can be used to treat the two locations of pain. For example, if you have bilateral low back pain that presents two inches to the right of your spine and two inches to the left of your spine, two equal size electrodes can be placed over the respective painful areas on each side of the spine. You will receive an equal treatment in both locations because the area of the electrodes is the same. You won't feel anything on your skin in between the electrodes, only in the volume of tissue beneath each electrode. Each 2-inch diameter round electrode will produce an active electrical field in approximately a 3-inch diameter hemisphere beneath them.

4.3.2 Large Area of Pain

- **Use B-set Electrodes**

If your pain presents over a larger area than 3 inches in diameter, then the B-set electrodes (two same size electrodes) can be placed 1.0 inch apart directly over the larger area where the pain is presenting. With this placement, both round Pain Site Electrodes can be used to treat one larger volume of tissue up to 6 inches long by about 3 inches wide.

4.3.3 Single Location of Pain in the Extremities (Knee, Ankle, Foot, Toes, Neck, Shoulder, Elbow, Wrist, Hand or Finger)

- **Use E-set Electrodes**

If you have a single location of pain on the extremities (legs, knees, ankles, feet, neck, shoulders, elbows, wrists, hands, fingers) two different size electrodes are paired together.

By using the E-set and pairing an electrode of smaller area (1.375" diameter round) with a large dispersive electrode (2" x 4" rectangle), the treatment is more concentrated in the volume of tissue beneath the smaller electrode. Therefore, the smaller round Pain Site Electrode needs to be placed directly over the primary painful area.

The larger 2" x 4" rectangular Dispersive Electrode is placed over a bony prominence which is a comfortable location to receive stimulation. This allows you to more comfortably increase the intensity of the signal to higher levels allowing a stronger electric field to encompass the pain site under the smaller Pain Site Electrode.

4.3.4 Single Location of Pain in Mid Torso Region

- **Use U-set Electrodes**

If you have a single location of pain in the mid torso region of the body, two different size electrodes are paired together (except if you are treating the low back).

By using the U-set and pairing an electrode of smaller area (2" diameter round) with a large dispersive electrode (5" x 8" rectangle), the treatment is more concentrated in the volume of tissue beneath the smaller electrode. Therefore, the smaller round Pain Site Electrode needs to be placed directly over the primary painful area.

The larger 5" x 8" rectangular Dispersive Electrode is placed in a comfortable location to receive stimulation which is horizontally across the low back. This allows you to more comfortably increase the intensity of the signal to higher levels allowing a stronger electric field to encompass the pain site under the smaller Pain Site electrode.

See **PHOTOS** for examples of optimal electrode placements in Section 4.4.

4.4 Electrode Placement Examples

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

- **1.0 inch is the minimum spacing between electrodes on the back.**
- **0.5 inches 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 electrode placement examples ONLY for noninvasive electrodes.

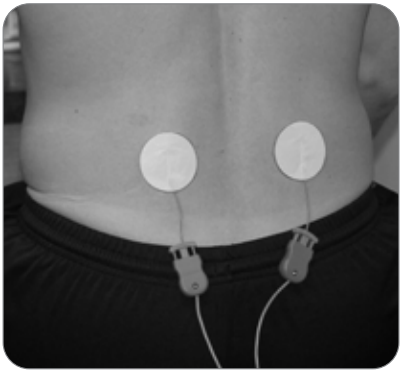
For PERCUTANEOUS ELECTRODE PLACEMENTS, contact your physician, see the BioWavePENS Quick Reference Guide and/or call for technical support:

1-877-BioWave ext 1

(1-877-246-9283 ext 1)

4.4.1 LOW BACK PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.1.1 Placement for Bilateral Pain Across Lower Back (Equal Pain in Two Locations)

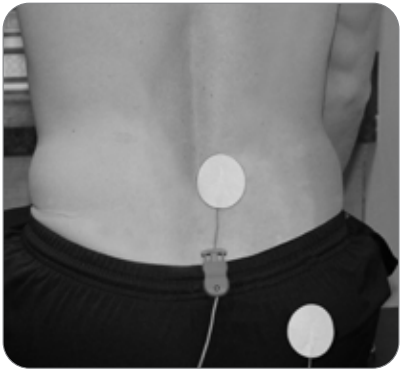


Use the B-set: For low back pain on both sides of the spine, place the two round Pain Site electrodes directly over each painful area on the lower back. See photo to the right.

Similarly, the pair of electrodes can be placed over two areas of pain on the mid area (thoracic area) of the back.

Body Position: Sitting is the best position during the treatment. The torso should be approximately at a right angle to the legs causing the tissue in the lower back to be more taut. However, if sitting causes pain, you may lie down during your treatment.

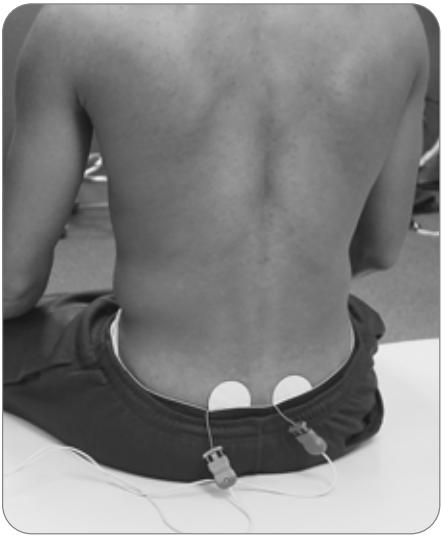
4.4.1.2 Placement for Radiating Back Pain (e.g. Sciatica)



Use the B-set: Place one round Pain Site electrode directly over where the pain first presents itself. For example, this may be on the buttock, 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 Pain Site electrode directly over the spine at the possible source of the pain, for example, directly over a herniated disc. Consult your physician to learn the location of the source of your radiating pain.

Body Position: Sitting is the best position during the treatment. The torso should be roughly at a right angle to the legs. This position keeps the tissue in the buttock and low back area a little taut which will provide for a better treatment result. However, if sitting causes pain, you may lie down during your treatment.

4.4.1.3 Placement for Sacoiliac (SI) Joint Pain (Pain in One or Two Locations)

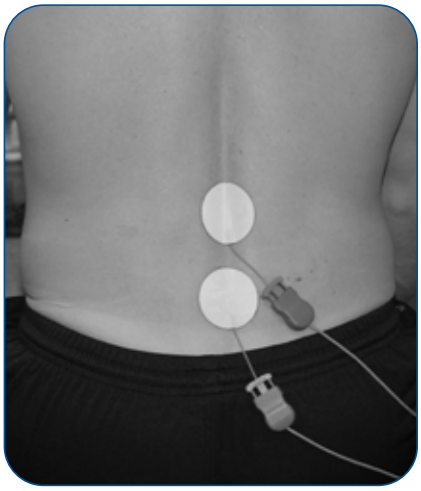


Use the B-set: For sacroiliac (SI) joint pain on the lower back, both Pain Site electrodes may be placed bilaterally over the SI joint covering one or two pain sites as shown in the photo to the right. This placement may be used to treat pain on one side or both sides of the SI joint. If pain is centered directly over the sacrum, one Pain Site electrode may be placed directly over the sacrum and the second electrode may be placed over a second location of pain at least one inch away in any direction from the first electrode.

Make sure there is at least 1.0 inch of space between the electrodes (see photo to the right).

Body Position: Sitting is the best position during the treatment. The torso should be approximately at a right angle to the legs causing the tissue in the lower back to be more taut. However, if sitting causes pain, you may lie down during your treatment.

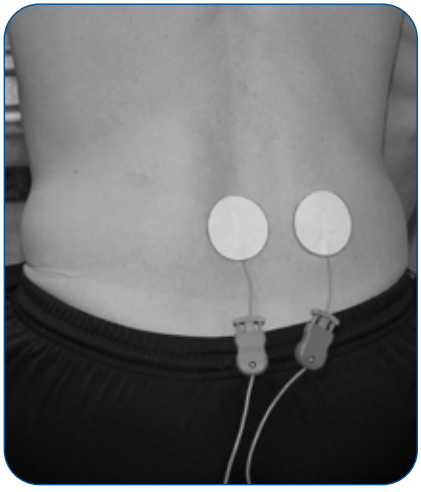
4.4.1.4 Placement for Pain Centered Over the Spine



Use the B-set: Both Pain Site electrodes may be placed in a vertical arrangement directly over the spine covering the entire region where the pain presents itself. For example, if the pain presents directly over the disc at L3, then one round electrode should be placed over L3. The second round electrode can be placed 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).

Body Position: Sitting is the best position during the treatment. The torso should be approximately at a right angle to the legs causing the tissue in the lower back to be more taut. However, if sitting causes pain, you may lie down during your treatment.

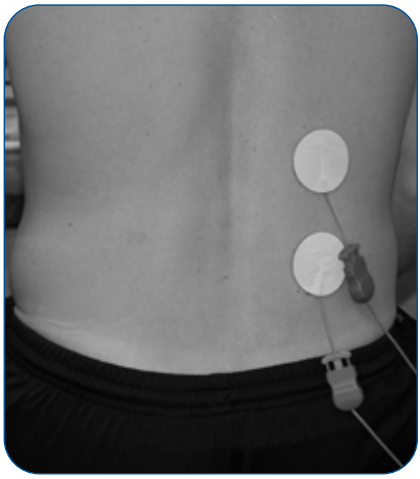
4.4.1.5 Placement for Low Back Pain in One Location



Use the B-set: Place one round Pain Site electrode on the lower back directly over the painful area. Place the second round Pain Site 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.

Body Position: Sitting is the best position during the treatment. The torso should be approximately at a right angle to the legs causing the tissue in the lower back to be more taut. However, if sitting causes pain, you may lie down during your treatment.

4.4.1.6 Placement for Pain Over a Large Area on the Back



Use the B-set: Both Pain Site electrodes should be placed over the painful area with a minimum space of about 1.0 inch between the electrodes. When the two round Pain Site electrodes are about one inch apart from one another, you are receiving a treatment in a volume of tissue covered by the electrodes of approximately 6 inches by 3 inches.

Body Position: Sitting is the best position during the treatment. The torso should be approximately at a right angle to the legs causing the tissue in the lower back to be more taut. However, if sitting causes pain, you may lie down during your treatment.

4.4.2 HIP PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.2.1 Placement for Hip Pain in One Location

Use the U-set: Place the round Pain Site Electrode on the hip directly over the painful area. The bony prominence or comfortable location for the large rectangular Dispersive Electrode is horizontally across the lumbar region on the lower back (see photo to to the right).

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.

4.4.2.2 Placement for Hip Pain in Two Locations

Use the B-set: Place each round Pain Site Electrode on the hip directly over each painful area. For example if your pain presents on the front side (anterior) of your hip and on the outside (lateral side) of your hip, then place each electrode over each respective location of pain. 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 a pillow under your buttocks and legs straight is the most desirable position during the treatment.

4.4.3 RIB OR OBLIQUE PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.3.1 Placement for Rib or Oblique Pain in One Location

Use the U-set: Place the round Primary Electrode directly over the painful area in the mid-torso region. The round Primary Electrode should NOT be placed directly over the heart. The bony prominence or comfortable location for the large rectangular Dispersive Electrode is horizontally across the lumbar region on the lower back, (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.

4.4.4 GROIN PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.4.1 Placement for Groin Pain in One Location

Use the U-set: Place the round Pain Site Electrode on the groin directly over the painful area. The bony prominence or comfortable location for the large rectangular Dispersive Electrode is horizontally across the lumbar region on the lower back. 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.

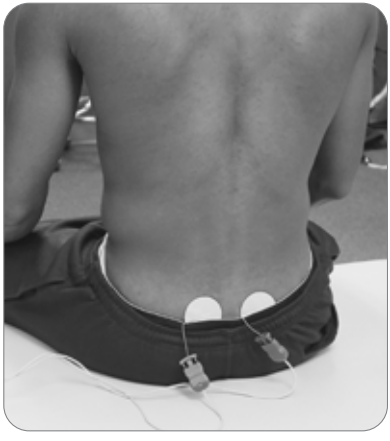
Body Position: For groin treatments, sitting reclined or lying down on your back with a pillow under your buttocks and legs straight is the best position during the treatment.

4.4.4.2 Placement for Groin Pain in Two Locations

Use the B-set: Place each round Pain Site Electrode on the groin directly over each painful area. 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. Leave at least 1.0 inch of spacing between the two Pain Site Round Electrodes. There is no limit on the maximum distance the electrodes can be placed apart from on another. If the electrodes are in close proximity to your genitals, use a barrier like a towel between the electrodes and genitals.

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

4.4.4.3 Placement for 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 to stimulate the sacral nerves at the base of the spine as shown in the photo to the right. Leave approximately one inch of spacing between the electrodes.

An alternative placement is to use the B-set and place one round Pain Site electrode over the pubis where pain presents on the front of the body and one round Pain Site 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, sit in a supported position with your body at approximately 90 degrees to your legs to help keep the tissue in the area of the sacrum more taut. For the alternative placement with one electrode on the pubis and one on the sacrum, you should lie down on your back with your legs straight during the treatment.

4.4.5 QUADRICEPS PAIN - ELECTRODE PLACEMENT EXAMPLES

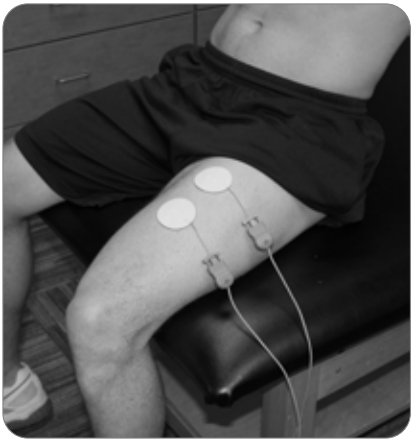
4.4.5.1 Placement for Quadriceps Pain in One Location

Use the U-set: Place the round Pain Site Electrode on the quadriceps directly over the painful area. The bony prominence or comfortable location for the large rectangular Dispersive Electrode is horizontally across the lumbar region on the lower back as shown in the photo to the right.

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 the round Pain Site Electrode. 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.

4.4.5.2 Placement for Quadriceps Pain Over a Large Area



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.

4.4.6 HAMSTRING PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.6.1 Placement for Hamstring Pain in One Location

Use the U-set: Place the round Pain Site Electrode on the hamstring directly over the painful area. The bony prominence or comfortable location for the large rectangular Dispersive Electrode is horizontally across the lumbar region on the lower back as shown in the photo to the right.

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 the round Pain Site Electrode. Therefore take care to increase the intensity slowly and carefully.

Body Position: For hamstring treatments, sitting upright or partially reclined in a supported position on a bed with the legs straight is the best position during the treatment. Keeping the hamstring in a slightly more taut position will provide a better treatment outcome.

4.4.6.2 Placement for Hamstring Pain Over a Large Area

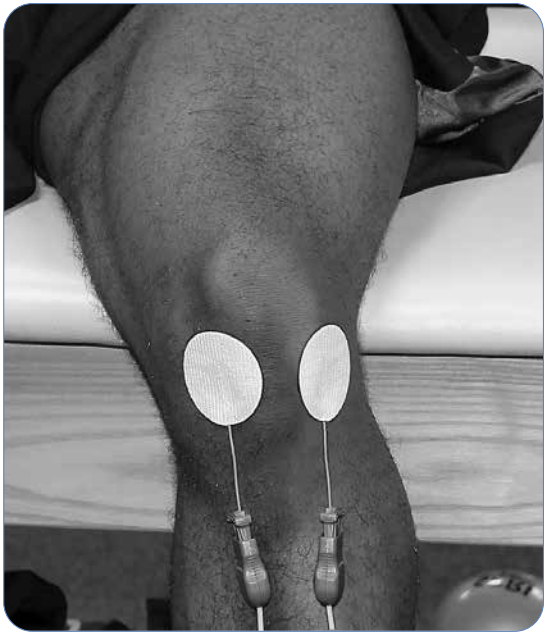
Use the B-set: Both Pain SIte electrodes may be placed in a vertical arrangement on the hamstring. The first electrode should be placed directly over the location where the pain first presents itself. The second electrode should be placed approximately 1.0 inch away from the first electrode and should cover the location where 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 or partially reclined in a supported position on a bed with the legs straight is the best position during the treatment. Keeping the hamstring in a slightly more taut position will provide a better treatment outcome.

4.4.7 KNEE AND LOWER LEG PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.7.1 Placement for Pain Toward the Front of the Knee (for example from an ACL Sprain, Bursitis or Osteoarthritis)

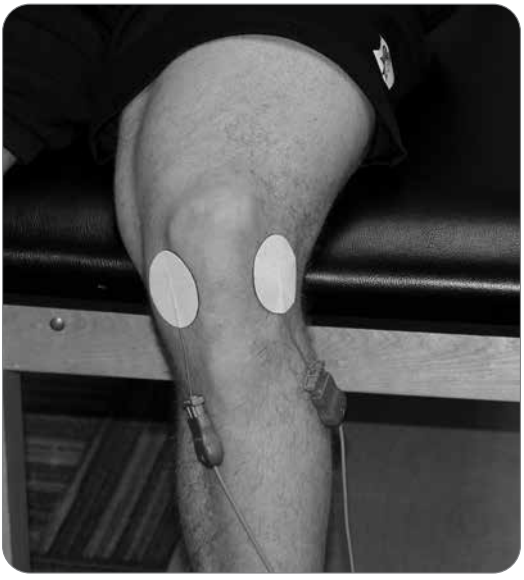


Use the E-set: The small round Pain Site Electrode should be placed directly over the primary source of pain as in the photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is on the outside (lateral side) of the knee, starting just above the midline of the knee, and angled to the front (anterior) of the knee as shown in the photo above. The rectangular Dispersive Electrode must not be closer than 0.5 inches from the small round Pain Site Electrode. If room permits, the Dispersive Electrode should touch the edge of the knee cap (patella) and run onto the patellar tendon below the knee cap as shown in the photo above. This is the most comfortable place to receive stimulation into the knee and will allow you 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 central knee pain, 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.

4.4.7.2 Placement for Pain Throughout the Knee or Pain in Two Locations (for example from a Total Knee Replacement or from Osteoarthritis Throughout the Knee)



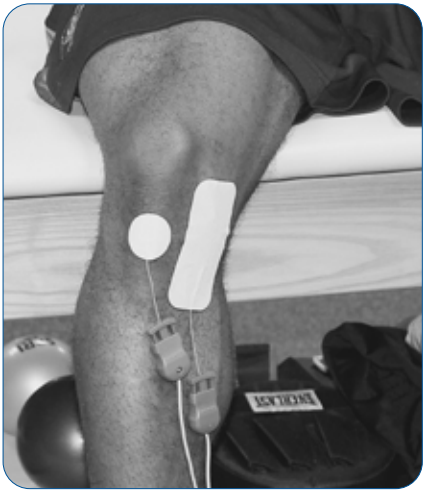
Use the B-set: For pain throughout the knee, for example, following total knee arthroplasty (TKA)/total knee replacement (TKR), or from osteoarthritis throughout the knee, each Pain Site electrode should be placed over a painful area. For example, one round electrode may be placed on the inside (medial side) of the knee over a painful area; the second round electrode may be placed on the outside (lateral side) of the knee, also over a painful area. The electrodes could also be placed above and below the knee cap if those are the locations of the painful areas.

However, if there is only a single location of pain, use the E-set Electrodes.

Body Position: For treatments for pain from TKA or TKR surgery, the knee should be bent at as great an angle as possible up to 90 degrees but the positioning should still be comfortable. This angle provides the strongest sensation in the volume of tissue being treated which will yield the best outcome. For patients rehabilitating from recent knee surgery, to facilitate exercise or range of motion therapy, BioWaveHOME should first be used for 10 minutes with the knee in flexion, preferably closer to 90 degrees if possible. Then while continuing the BioWave treatment, flexion or extension exercise or range of motion therapy can be performed with significantly less pain. You should be able to move more resistance through a greater range of motion both in flexion as well as extension. Consult your physician or physical therapist for more information.

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 knee

4.4.7.3 Placement for Pain Below the Kneecap (for example 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 to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is on the outside (lateral side) of the knee, starting from just above the midline of the knee, with most of the electrode placed below the midline angled slightly toward the front of the knee (see first photo to the right). 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 farther away though from the small Pain Site Electrode. The rectangular Dispersive Electrode should be kept off of the softer tissue toward the rear of the knee because delivering stimulation over the softer tissue will limit your ability to achieve higher intensity levels. Higher intensity levels, as long as the treatment is comfortable, produce greater efficacy.

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

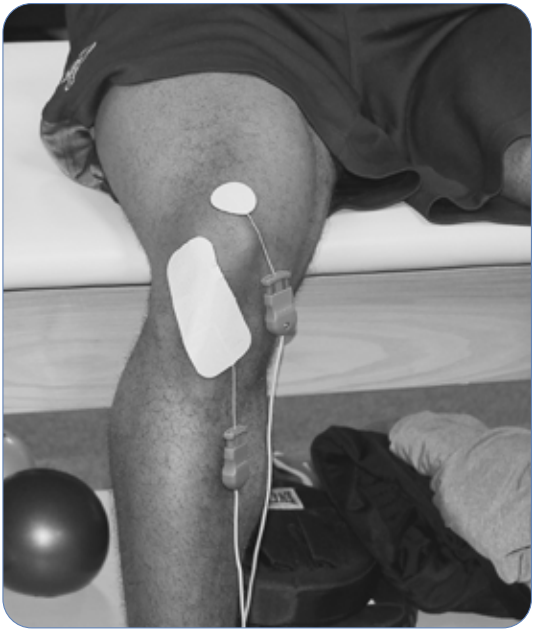
4.4.7.4 Placement for Pain on the Inside of the Knee (for example from an MCL Sprain, Bursitis or Osteoarthritis)

Use the E-set: The small round Pain Site Electrode should be placed directly over your single location of pain on the inside (medial side) of the knee. One example may be from an MCL sprain, as in the first photo to the right. Pain may present lower down on the inside of the knee, for example, from Pes Anserine Bursitis as shown in the second photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is on the outside (lateral side) of the knee, starting just above the midline of the knee, and angled to the front (anterior) of the knee, touching the edge of the kneecap (patella) and running across the patellar tendon beneath the kneecap as shown in both photos to the right. This is the most comfortable place to receive stimulation into the knee and will allow you 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 on the inside of the knee, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during the treatment and will yield the best outcome.

4.4.7.5 Placement for Pain Above the Kneecap (for example from Quadriceps Tendinitis)



Use the E-set: The small round Pain Site Electrode should be placed directly over a single location of pain typically over the quadriceps tendon just above the kneecap (patella) as shown in the photo to the right.

The bony prominence or comfortable location for the rectangular Dispersive Electrode is on the outside (lateral side) of the knee, starting just above the midline of the knee, and angled to the front (anterior) of the knee, touching the edge of the kneecap (patella) and running across the patellar tendon beneath the kneecap as shown in the photo above. This is the most comfortable place to receive stimulation into the knee and will allow you 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 knee during the treatment and will yield the best outcome.

4.4.7.6 Placement for Pain on the Outside of the Knee (for example from an LCL Sprain, Bursitis, or Osteoarthritis)

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

The bony prominence or comfortable location for the rectangular Dispersive Electrode is on the inside of the knee, starting just above the midline of the knee, and angled to the front of the knee, touching the edge of the kneecap and running across the patellar tendon beneath the kneecap as shown in the photo above. This is the most comfortable place to receive stimulation into the knee and will allow you 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 on the outside of the knee, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation in the knee during treatment and will yield the best outcome.

4.4.7.7 Placement for Illiotibial (IT) Band Pain

Use the E-set for one location of pain:
For illiotibial (IT) band pain in one location, the small round Pain Site Electrode should be placed directly over the primary source of pain on the IT Band which generally may be on the outside of the thigh, several inches up away from the outside of the knee. Place the rectangular Dispersive Electrode on the outside of the knee, starting just above the midline, angled to the front (anterior) of the knee, touching the edge of the kneecap (patella) and running across the patellar tendon beneath the kneecap as shown in the first photo to the right. Make sure there is at least 1.0 inch of spacing between the electrodes that are both on the outside of the knee and thigh.

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 pain site simultaneously. 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.

4.4.7.8 Placement for Pain on the Backside of the Knee

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

The rectangular Dispersive Electrode may be placed over any secondary source of pain in the region of the knee.

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

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

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

Body Position: For treatments for pain on the backside of the knee, sitting with the knee kept straight (not bent) so the tissue on the backside of the knee is more taut, will produce the best treatment outcome.

4.4.7.9 Placement for Pain from Shin Splints

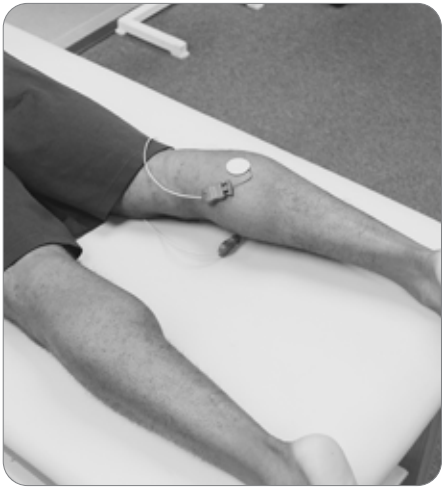
Use the B-set: The two round Pain Site Electrodes should be placed directly over the source of pain along the shin. Typical placements for pain from shin splints are shown in the two photos to the right.

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.

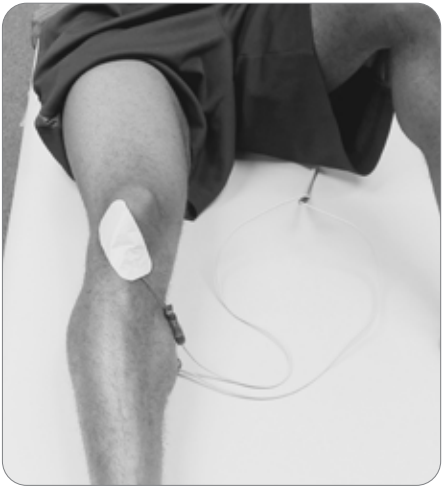
Body Position: Sitting in a supported position with the knees at about 90 degrees is typically the most comfortable position in which to receive stimulation for shin splints.

4.6.7.10 Placement for Calf Pain (for example 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 single location 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 starting on the outside (lateral side) just above the midline of the knee, angled to the front (anterior) of the knee, touching the edge of the kneecap (patella) and running across the patellar tendon beneath the kneecap as shown in the second photo to the right. This is the most comfortable place to receive stimulation into the knee and will allow you 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. Adjust the direction you point your toes either toward you or away from you to put the calf in tension, which is a more comfortable position in which to tolerate a higher level of stimulation in the calf.

4.4.8 ANKLE AND FOOT PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.8.1 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 inside of the ankle just above and behind the inside ankle bone. The second electrode is placed just behind the Big 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 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.

4.4.8.2 Placement for Pain on the Outside (Lateral Side) of the Ankle or Foot (for example from a Low Ankle or Foot Sprain)

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

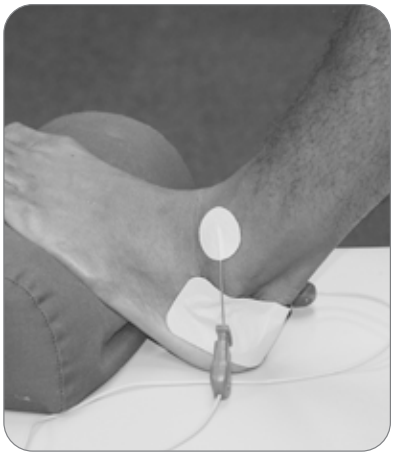
The bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the outside of the ankle, wrapping around the Achilles tendon, higher up than in the first photo to the right, but not touching the Pain Site Electrode.

If the primary location of pain is further back toward the outside of the heel (posterior lateral side), the small round Pain Site Electrode should be placed directly over the painful location as in the second photo to the right.

The ideal bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the outside of the ankle, wrapping around the Achilles tendon as shown in the second photo to the right.

Body Position: For all foot and ankle pain, 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.

4.4.8.3 Placement for a High Ankle Sprain with Pain in One Location



Use the E-set: For pain occurring from a high ankle sprain, primary pain often occurs above the ankle toward the front or the outside of the foot.

For this type of pain condition, place the small round Pain Site electrode directly over the primary location of pain as shown in the first photo to the right.

The bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the outside of the foot and heel wrapping around the back of the ankle but not touching the Pain Site Electrode as in the first photo to the right. The rectangular Dispersive Electrode can be placed higher on the ankle and wrapped around the Achilles tendon.

4.4.8.4 Placement for Pain on the Inside (Medial Side) of the Ankle or Foot

If the primary pain site is on the inside of the ankle or foot, place the small round Pain Site Electrode directly over the pain site as in the second photo to the right.

The bony prominence or comfortable location to place the rectangular Dispersive Electrode is on the outside of the ankle, wrapping around the Achilles tendon as shown in the second photo to the right.

4.4.8.5 Placement for Two Equal Locations of Pain in the Ankle or Foot

Use the B-set: For two locations of pain of approximately the same magnitude, place each 2-inch diameter round electrode directly over each respective pain site on the top, side and/or back of the foot or ankle as shown in the photo to the right.

Body Position: 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.

4.4.8.6 Placement for Pain from Achilles Tendinitis

Use the E-set: For pain occurring from achilles tendinitis, the small round Pain Site Electrode should be placed directly over the location where the pain presents itself, typically over the achilles tendon as shown in the photo to the right. The rectangular Dispersive Electrode should generally be placed in a horizontal fashion on the outside of the foot and heel wrapping around the back of the heel.

The rectangular electrode should not touch the inside of the heel. The electrodes should have at least one inch of spacing between them.

In some instances, the primary pain can occur on the back of the heel near the bottom of the heel at the insertion point of the Achilles tendon. If so, the small round Pain Site Electrode would be placed over the pain site as in the photo to the right. The rectangular Dispersive Electrode would be used to treat any secondary pain or stiffness occurring on the achilles tendon, so it should be placed vertically along the achilles tendon, with a minimum of at least one inch of spacing directly above the placement of the small round Pain Site Electrode.

The use of a wrap like an Ace Bandage is recommended to hold both electrodes in place over the tight contour of the tissue around the heel and the Achilles tendon.

Use the B-set: If pain occurs both on the Achilles tendon and at the insertion point of the Achilles tendon, then use the B-set and treat both locations simultaneously as in the seond 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.

4.4.8.7 Placement for Pain on the Bottom of the Foot (for example 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 rectangular Dispersive Electrode should generally be placed on the outside of the ankle, wrapping around the Achilles tendon as in the photo to the right. **The rectangular electrode should not touch the inside of the heel.**

Body Position: For all plantar fasciitis 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 articulate the foot 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.

4.4.8.8 Placement for Pain on the Top of the Foot (for example from Phalange, Metatarsal 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 Pain Site 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.

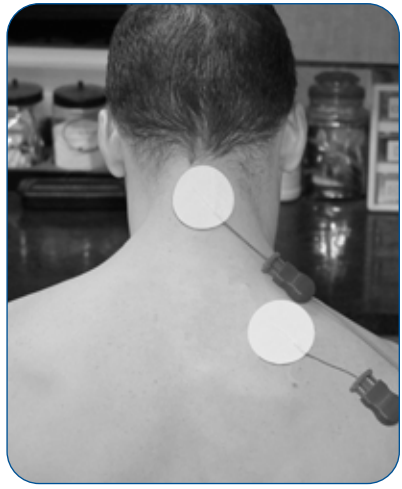
The rectangular Dispersive Electrode should generally be placed on the outside of the ankle, wrapping around the Achilles tendon as in the photos to the right. **The rectangular electrode should not touch the inside of the ankle or heel.**

Body Position: For all foot and ankle pain, 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 articulate the foot 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.

4.4.9 NECK, CERVICAL & TMJ PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.9.1 Placement for Neck or Cervical Pain in Two Locations

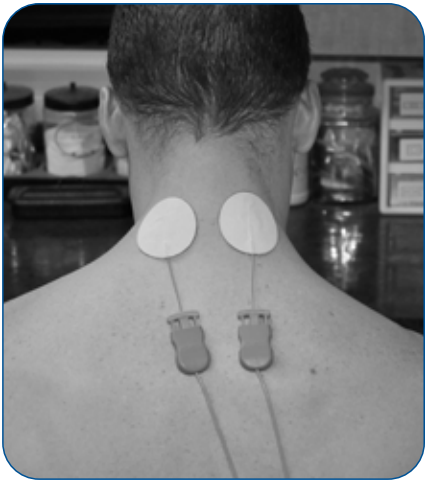


Use the B-set: For two separate painful locations, two round same size Pain Site Electrodes should be placed directly over the two painful areas. For example if pain presents on the back of the neck and in the trapezius or rhomboid as in the photo to the right, then each round Pain Site Electrode should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

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

For all neck treatments, in addition to the strong sensation beneath and surrounding both Pain Site Electrodes, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

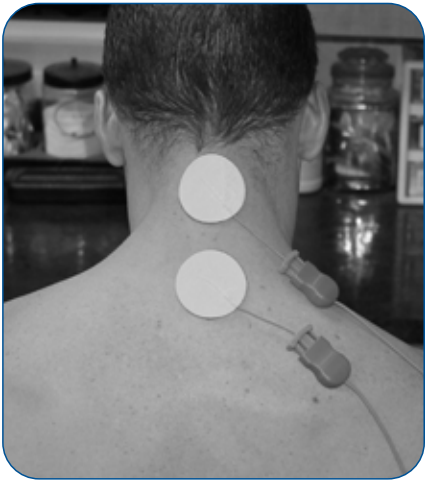
4.4.9.2 Placement for Bilateral Neck or Cervical Pain



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 photo to the right. The electrodes should not be placed on the side or front of the neck.

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

4.4.9.3 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 strong sensation beneath and surrounding the small round Pain Site Electrode, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

4.4.9.4 Placement for Neck or Cervical Pain in One Location

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

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top edge of the shoulder blade (spine of scapula) as shown in the first photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode.

4.4.9.5 Placement for Temporomandibular Joint (TMJ) Pain

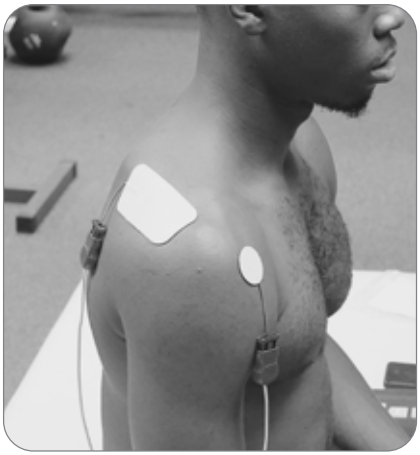
Use the E-set: For pain occurring in the temporomandibular joint or along the trigeminal nerve, place the small round Pain Site Electrode **directly over the pain site** on the cheek as shown in the photo to the right. The skin on the cheek must be clean and free of hair or makeup.

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder and be placed at an angle along the top of the shoulder blade (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.

4.4.10 SHOULDER PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.10.1 Placement for Pain on the Front of the Shoulder (For Example from Biceps Tendinitis, Supraspinatus Tendinitis or a Superior Labrum Anterior to Posterior (SLAP) Tear)



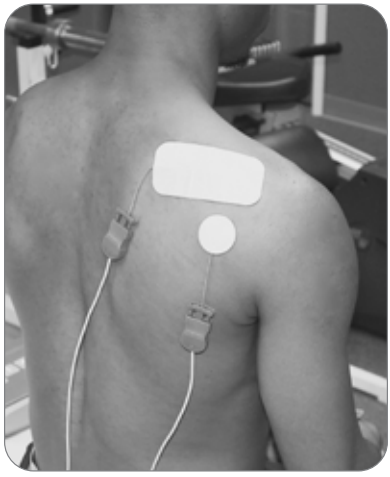
Use the E-set: For pain occurring on the front (anterior) of the shoulder, for example, for pain from Biceps Tendinitis, Supraspinatus Tendinitis or a Superior Labrum Anterior to Posterior (SLAP) Tear, the small round Pain Site Electrode should be placed directly over the pain site on the front of the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

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (the spine of scapula) as shown in the photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you 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 treatments on the front (anterior) of the shoulder, you should be in a cushioned seated position. If you can tolerate gently moving your hand behind your buttock and sitting on the back side of your fingers, this positioning helps to allow a greater focusing of the electrical field on the nerves, ligaments, and tendons present on the front side of your shoulder. If you cannot tolerate moving and holding your arm and shoulder in this position, then the arm should rest near the side of your body in a comfortable position.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.2 Placement for Pain on the Back of the Shoulder (For Example from an Infraspinatus Strain)



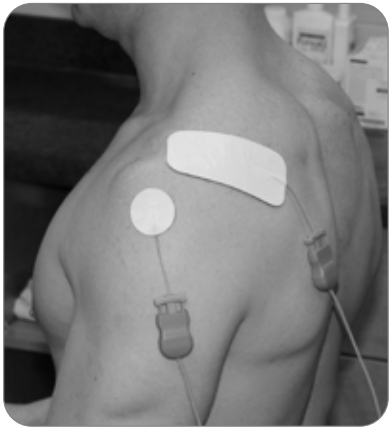
Use the E-set: For pain occurring on the back (posterior) of the shoulder, for example, from an infraspinatus strain or posterior rotator cuff pain, the small round Pain Site Electrode should be placed directly over the pain site on the back of the shoulder as shown in the photo to the right.

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (the spine of scapula) as shown in the photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you from achieving a higher intensity level. Generally the rectangular Secondary Electrode is never placed over the front of the shoulder or chest as this is an uncomfortable place to receive stimulation. Typically, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

Body Position: For all shoulder treatments, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.3 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 front corner of the rectangular Dispersive Electrode should start on a bony prominence on top of the shoulder about *one inch away* from the small round electrode and be placed *along* the spine of scapula at an angle as shown in the photo above.

Body Position: For all shoulder treatments, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.4 Placement for Pain on Top or Throughout the Inside of the Shoulder Joint (for example from pain in the Acromioclavicular (AC) Joint or from Frozen Shoulder/Adhesive Capsulitis)

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

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (the spine of scapula) as shown in the photo on the previous page. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable. There must be a minimum space of 0.5 to 1.0 inch between the two electrodes.

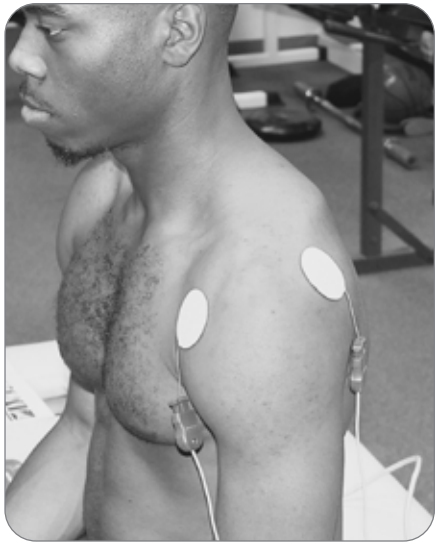
Generally the rectangular Dispersive Electrode is never placed over the front of the shoulder or chest as this is an uncomfortable place to receive stimulation.

Body Position: For all shoulder treatments, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.5 Placement for Two Locations of Pain in One Shoulder (Alternative Placement for Frozen Shoulder)

Use the B-set: For two locations of pain occurring in the shoulder or, as an alternative placement for pain inside the shoulder joint (Section 4.4.10.1), place each 2" diameter round electrode directly over each respective pain site on the front, top and/or back side of the shoulder as shown in the photo to the right.



Body Position: For all shoulder treatments, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.6 Placement for Trapezius Pain in One Location

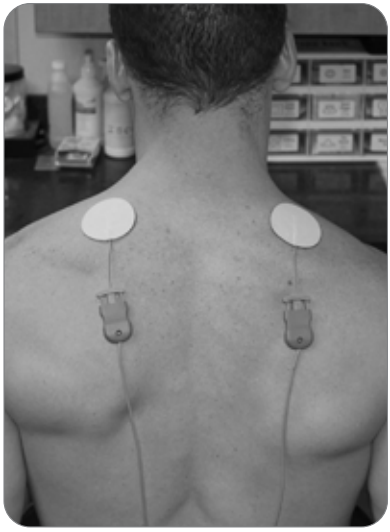
Use the E-set: For pain occurring on the posterior of the shoulder, for example on the trapezius, the small round Pain Site Electrode should be placed directly over the pain site on the trapezius as shown in the photo to the right.

The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed *along* the spine of scapula at an angle as shown in the photo above.

Body Position: For all shoulder treatments, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently and slowly move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.10.7 Placement for Trapezius Pain in Two Locations (Bilateral Trapezius Pain or Equal Pain in Two Locations)



Use the B-set: For pain occurring in both shoulders, for example, bilateral trapezius pain, two 2″ diameter round electrodes should be placed directly over each respective pain site on the back 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, sitting in a supported position is generally the best position during the treatment. The arm can rest against the side of the body with the elbow slightly bent.

Motion: Gently move the shoulder joint to shift the location of the electrical field so that the sensation from the electrical signals focuses directly over and encompasses the pain site.

4.4.11 ELBOW PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.11.1 Placement for Pain on the Outside of the Elbow (for example, Lateral Epicondylitis)

Use the E-set: For pain occurring on the outside (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.

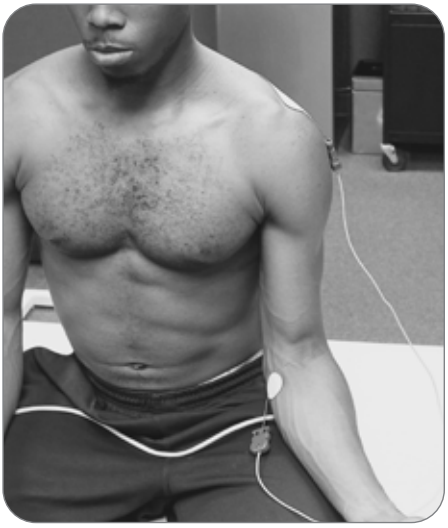
Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode, the small round Pain Site Site Electrode, is placed on the elbow.

The comfortable placement for the rectangular Dispersive Electrode is at the top of the shoulder on the same side as the elbow you are treating. The front corner of the rectangular Secondary Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (spine of scapula) as shown in the photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

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: Gently move your elbow and slowly rotate and/or bend your wrist to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

4.4.11.2 Placement for Pain on the Inside of the Elbow (for example, Medial Epicondylitis)



Use the E-set: For pain occurring on the inside (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.

Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode, the small round Pain Site Electrode, is placed on the elbow.

The comfortable placement for the rectangular Dispersive Electrode is at the top of the shoulder on the same side as the elbow you are treating. The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (spine of scapula) as shown in the photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

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: Gently move your elbow and slowly rotate and/or bend your wrist to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

4.4.11.3 Placement for Pain on the Back of the Elbow (for example, Triceps Tendinitis)

Use the E-set: For pain occurring on the backside (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.

Since elbow pain is typically focused in a single location and because the elbow is very sensitive to stimulation, only one electrode, the small round Pain Site Electrode, is placed on the elbow.

The comfortable placement for the rectangular Dispersive Electrode is at the top of the shoulder on the same side as the elbow you are treating. The front corner of the rectangular Dispersive Electrode should start at the edge of the bony prominence on top of the shoulder (just behind the AC joint) and be placed at an angle along the top of the shoulder blade (spine of scapula) as shown in the photo above. This is the most comfortable location to receive stimulation in the shoulder from the rectangular Dispersive Electrode. The rectangular Dispersive Electrode should not touch the deltoid muscle on the outside of the shoulder because it may feel fatigued following the treatment and stimulation over the softer tissue in that region on the side of the upper arm will prevent you from achieving a higher intensity level. Generally, the higher the intensity, the greater the efficacy, as long as the treatment remains comfortable.

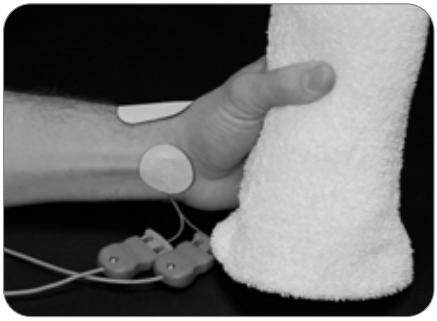
Body Position: The arm should rest at the side of the body with the elbow bent at approximately 80 degrees. The patient should rest their forearm in their lap and hold a ball or a rolled up towel to keep their fingers in a comfortable position.

Motion: Gently move your elbow and slowly rotate and/or bend your wrist to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the elbow.

4.4.12 WRIST, HAND AND FINGER PAIN - ELECTRODE PLACEMENT EXAMPLES

4.4.12.1 Placement for 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.**



In the first example, in the first photo to the right, the small round Pain Site Electrode is placed over the pain site on the back (posterior side) of the wrist; the rectangular Dispersive Electrode runs across the inside (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 inside (anterior side) of the wrist. The rectangular Dispersive Electrode is placed across the backside (posterior side) of the wrist in an opposing location.

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

Motion: Gently move your wrist (slow rotation as well as slight bending back and forth) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in the wrist.

4.4.12.2 Placement for Hand or Finger Pain

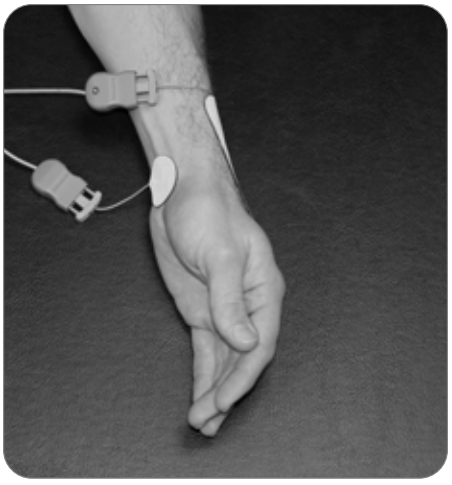
Use the E-set: For pain occurring at the base of the thumb, for example from a thumb sprain, the small round Pain Site Electrode is placed over the pain site at the base of the thumb. The rectangular Dispersive Electrode is placed in an opposing position across the far side of the wrist as shown in the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

Make sure the small round Pain Site Electrode and the rectangular Secondary Electrode do not touch each other.

For pain occurring in a finger joint (for example in a metacarpal phalangeal or interphalangeal joint), the small round Pain Site Electrode is placed directly over the pain site.

The rectangular Dispersive Electrode may be placed across the inside (anterior side) of the wrist as shown in the second photo to the right. An alternative comfortable placement for the rectangular Dispersive Electrode is across the back (posterior) of the wrist.

If you have 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.



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

Motion: Gently move your wrist (slow rotation as well as slight bending back and forth) to shift the electrical field so that the sensation from the electrical signals focuses on and encompasses the pain site in your hand or finger.

4.5 Electrode Placement Tips

1. **Select locations for electrodes** (see Section 4.4)
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:**

   Use the B-set for back pain or pain in 2 locations (bilateral pain); for pain in a single location in the low back, buttocks, mid back and cervical spine; for radiating pain from the low back down into the legs (radiculopathies); for pain centered directly over the spine; for pain throughout the knee or throughout the shoulder; and for pain over large areas. The B-set is comprised of two 2-inch diameter round Pain Site Electrodes.

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

   Use the U-set for unilateral pain - pain in a single location - just in the mid-torso region of the body including a single location of pain in the ribs, obliques, groin, hips, quadriceps or hamstrings. Do not use for single locations of pain on the low or mid back. The U-set is comprised of one 2-inch diameter round Pain Site Electrode for the single location of pain; and one 5 inch by 8 inch large Dispersive Electrode to be placed horizontally across the the lower back (a comfortable location to receive stimulation).
4. **Remove electrodes from plastic liner** by peeling up the edge of each electrode. Do not pull on the blue connector or wire to remove the electrode from the plastic liner. Carefully align and place electrodes on the skin on the pre selected areas. Press firmly over the entire electrode so the hydrogel gets into the pores of the skin. Electrodes must not touch each other.
5. **Save plastic liners and resealable bag for electrode storage** following the treatment. Electrodes may be placed back on either side of the plastic liner.

4.6 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. Sitting in a supported position in a comfortable chair is usually best for most treatment locations on the body.

4.6.1 Low Back

For low back and buttock electrode placements, having your torso at approximately 90 degrees to your legs causes the tissue in your low back and buttocks to be more taut which provides for a better treatment result. Therefore sitting in a comfortable supportive chair is the best position for a treatment. If sitting is uncomfortable, lie down on your bed on your side but bend your waist so your torso is approxiately 90 degrees to your legs, and your knees may be bent to a comfortable angle. If that position is not comfortable, then you may choose lying down on your back with your knees bent and some pillows placed under your knees for support during the treatment.

4.6.2 Knees

For knee electrode placements, the knee should be bent at approximately 90 degrees. This angle provides the strongest sensation inside the knee during the treatment which will yield the best outcome. For treatments on the backside (posterior side) of the knee, the knee and leg should be kept straight so the tissue on the backside of the knee is more taut.

4.6.3 Calves

Adjust the direction you point your toes, either toward you or away from you to put your calf in tension. This allows you to tolerate a higher level of stimulation because it is a more comfortable position in which to receive stimulation in the calf.

4.6.4 Ankles, Feet and Toes

For ankle, foot and toe electrode placements, the foot should be kept at approximately 90 degrees to your leg and the foot should be placed against a flat surface. Sitting in a chair with your foot flat on the floor is the most ideal position during the treatment. However, if your foot needs to remain elevated, you can still perform a treatment on your foot.

4.6.5 Neck

For neck electrode placements, the head should be bent forwards slightly to make the tissue on the back of the neck more taut.

4.6.6 Shoulders

For shoulder electrode placements sitting in a supported position tends to be the most comfortable position during the treatment. Your arm should rest against the side of your body with the elbow slightly bent.

For treatments on the front (anterior) of the shoulder, you should be in a cushioned seated position. If you can tolerate gently moving your hand behind your buttock and sitting on the back side of your fingers, this positioning helps to allow a greater focusing of the electrical field on the nerves, ligaments, and tendons present on the front side of your shoulder. If you cannot tolerate moving and holding your arm and shoulder in this position, then the arm should rest near the side of your body in a comfortable position.

4.6.7 Elbows, Wrists, Hands and Fingers

For elbow, wrist, hand and finger electrode placements, sitting is the most comfortable position during the treatment. The arm should rest at the side of the body with the elbow bent at a slight angle. You should rest your forearm in your lap or on a table and hold a ball the size of a tennis ball or baseball, or hold a rolled up hand towel to keep your hand and fingers in a comfortable position. Control the intensity by pressing the PLUS or MINUS buttons on the stimulator with your other hand.

4.6.8 Hamstrings

For hamstring treatments, sitting with the torso at 90 degrees to the legs and the legs and knees straight provides the best treatment outcome.

4.6.9 Quadriceps

For quadriceps treatments, sitting with the knee bent at 90 degrees provides the best treatment results.

4.6.10 Groin and Hips

For groin and hip treatments, lying on your back with your legs straight is the most comfortable position. Placing a pillow under your buttock can help provide a little more of a stretch in the area being treated.

4.7 Motion During the Treatment and Fine Tuning of the Treatment

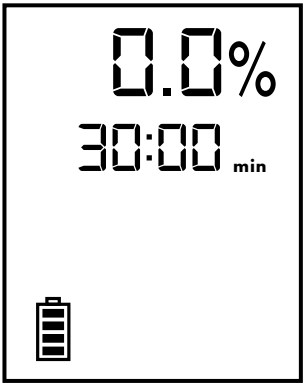
Slight movement or motion during the treatment is encouraged. However, motion causes a change in the sensation you feel. During the treatment, moving in one direction may cause an increase in the sensation; moving in another direction may cause a decrease in the sensation.

You need to be aware that you may experience an increase in the treatment sensation if you move the part of the body being treated. Gentle or slow movement during the treatment is encouraged because moving the joint or area of your body being treated will cause a slight change in location of the sensation from the electrical field that is forming inside your body. This slight shifting of the location of the electrical field is most noticable when treating the shoulder, elbow, wrist, hand, finger, ankle or foot.

The goal of motion is to slightly shift the location of the sensation caused by the electrical field so that it encompasses your primary location of pain. Adjusting your body position to direct and focus the electrical field to surround the pain site is a fine tuning of the treatment that will provide the best treatment result. The ideal treatment location is when you feel like saying, "wow, that's hitting the spot!"

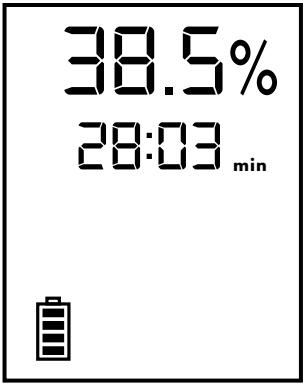
4.8 Using the BioWaveHOME Stimulator

4.8.1 STARTING TREATMENT



Once the electrodes are placed on your body and are plugged into the cable and the cable is plugged into the stimulator, press and hold the power button on the side of the stimulator until the LCD screen turns on - then let go of the power button. Make sure the LCD display shows a large "0.0%" at the top of the display and that the count down timer reads 30:00 min, like in the illustration to the right. This means the stimulator is ready for you to start the treatment.

Begin the treatment by pressing the PLUS (+) Button to increase the intensity of the pain control effect. You are in control of your own comfort level. The first time the intensity button is pressed, the countdown timer located beneath the intensity number will begin counting down from 30:00 minutes.



The PLUS (+) Button can be held down or pressed repeatedly. By holding down the PLUS (+) button, the instensity will increase at a quick steady pace. For each individual press of the PLUS (+) Button, the large intensity number at the top of the display will increase by 0.5%. **You 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%.

The body adapts quickly to the electric field in the first 2 - 5 minutes of treatment and the edge of the sensation you feel will begin to diminish

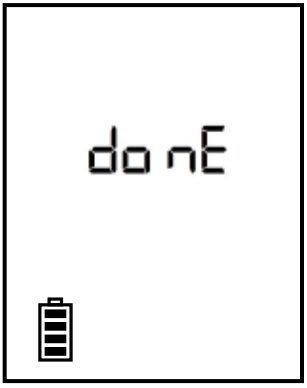
within several seconds. **You should then repeatedly press the Plus (+) Button to further increase the intensity so that you feel a very strong but comfortable tingling/pressure sensation.** Again your body will adapt to the electric field, however more slowly this time, causing the sensation to slightly diminish over a longer period of time. You 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 most treatments with BioWave Noninvasive Electrodes, you should try to get above a minimum intensity level of 30%. Most patients advance in the first 2 minutes to an intensity level of between 30% and 60%.

4.8.2 DURING TREATMENT

During the course of the procedure, it is normal to slightly increase the intensity level every few minutes as a light numbness (hypoesthesia) develops around the pain site. To slightly increase the intensity level, you should press the Plus (+) Button 1 to 3 times. If the sensation becomes too strong, you can always press the Minus (–) Button to reduce the intensity. As an example, if you reach an intensity level of 42% in the first 2 minutes, you may likely reach an intensity level of 60% by the end of the 30 minutes.

4.8.3 END OF TREATMENT



The end of the treatment occurs when the countdown timer reaches 0:00 minutes and seconds. The stimulator will emit three beeps and bring the intensity to zero and the display will read **"donE"**. Press the Power Button to turn the stimulator off.

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

Light numbness (hypoesthesia) may last for up to 20 minutes following a 30 minute treatment. A continued residual analgesic effect may last up to 24 hours with noninvasive electrodes and is proportional to the intensity of signal reached, length of treatment time and type of pain condition.

The leadwire cable may be wrapped over the front of the stimulator and then around the back of the stimulator and along the channel for storage.

Plug the AC Charger into a wall outlet and the other end into the BioWaveHOME stimulator to begin recharging the battery.

4.9 Importance of Monitoring the Activity of the Stimulator

Before turning on the stimulator and starting a treatment, it is important to make sure the leadwire cable is properly plugged in and electrodes are properly placed on your body. If everything is properly connected, the LCD Display shows a large 0.0% at the top of the display and no error conditions are displayed below. This means the stimulator is ready for the treatment to be started.

If there is a problem, the LCD shows a picture of the action to take to correct the error condition (see Section 8 - Troubleshooting).

5. Treatment Regimen Protocols

5.1 Treatment Regimen for Chronic Pain

For treating chronic pain the recomended treatment time with BioWave Noninvasive Electrodes is 30 minutes. Multiple treatments using BioWave Noninvasive Electrodes with about 2 to 3 hours of spacing between treatments may produce the most effective cumulative benefit and may knock down your pain to a new lower level.

The recommended daily treatment regimen is as follows:

Days 1 and 2:
3 30-minute treatments with 2 to 3 hours between treatments, or treat on an as needed basis.

Days 3, 4 and 5:
2 30-minute treatments with 2 to 3 hours between treatments, or treat on an as needed basis.

Day 6 and beyond:
1 30-minute treatment per day or treat on an as needed basis.

Individual treatments longer than 30 minutes typically will not produce greater or longer lasting efficacy.

For patients with more severe chronic pain, treatment with BioWave Percutaneous Electrodes is recommended. Please consult your physician.

5.2 Treatment Regimen for Acute Pain (For Example as Part of an Athletic Training Regimen)

For treating acute pain (or chronic pain) for example 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. Treat for 30 minutes immediately preceding practice or a game. This treatment may be completed in combination with heat if so desired but is not necessary. A barrier like a towel, an Ace bandage or another type of wrap should be placed over the BioWave Noninvasive Electrodes before placing a heating pad on top of them.

2. Treat a second time for 30 minutes immediately following practice or a game. This treatment may be completed in combination with cold therapy (ice) if so desired. A barrier like a towel, an Ace bandage or another type of wrap should be placed over the BioWave Noninvasive Electrodes before placing ice on top of them. For use with cold 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 do not rest underneath a compression cuff.

3. Time permitting, treat a third time for 30 minutes 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. Individual treatments longer than 30 minutes typically will not produce greater or longer lasting efficacy.

5.3 Treatment Regimen for Postoperative Pain and During Physical Therapy and Rehabilitation

5.3.1 USE FOR POSTOPERATIVE PAIN

For treating postoperative acute pain, the treatment regimen is the same as that for chronic pain listed in Section 5.1. Treatments may begin as soon as the morning following surgery. Electrodes should not be placed over open wounds or incisions that have not yet healed. Electrodes may be placed over scar tissue.

5.3.2 USE DURING REHABILITATION, EXERCISE, RANGE OF MOTION AND STRETCHING THERAPY

In addition to managing pain, BioWaveHOME® is an excellent tool to facilitate rehabilitation because of its long carry over effect with respect to pain relief and range of motion improvement. BioWaveHOME® should be used in place of heat immediately preceding exercise or range of motion therapy. The recommended treatment regimen is as follows:

1. Use wrap like an Ace Bandage, or cohesive wrap like Coban, or medical tape over the electrodes to help hold them in place.
2. Treat for 8 to 10 minutes, continually increasing the intensity to a strong but comfortable level.
3. At the 8 to 10 minute mark, reduce the intensity by about 10 percentage points to take the edge off of the sensation. For example if the LCD display reads 53.0%, reduce the intensity to 43.0% by pressing the MINUS button on the face of the stimulator.
4. Next, while continuing the treatment, begin exercise, active or passive range of motion or stretching exercises that have been taught to you by your physical therapist.

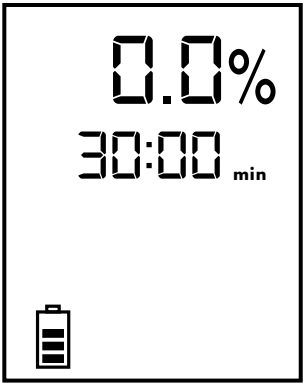
You can move more resistance through a greater range of motion with less pain. BioWaveHOME® significantly facilitates the ability of you to perform the exercise portion of physical therapy. In addition, because of BioWaveHOME's long carryover effect, you may experience little or no post-exercise soreness.

Consult your physical therapist for more information.

6. Battery Indicator and Charging the Battery

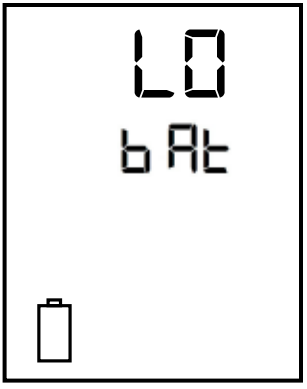
6.1 Battery Indicator

The battery indicator appears in the lower LEFT corner of the LCD display. The indicator is comprised of 4 bars representing the amount of power left in the battery. When 4 bars appear inside the battery, the battery is fully charged.



As more treatments are completed and the battery runs down, fewer bars inside the battery will be visible. When no bars are left inside the battery, the LCD display will show **"LO bAt"** and the battery needs to be recharged. The time required to recharge a completey empty battery is approximately 4 hours.

The battery may be recharged at any time regardless of the number bars visible on the Battery Indicator.



If the BioWaveHOME stimulator determines that there is not enough charge in the battery to complete a treatment, the LCD display will show **"LO bAt"** and the stimulator will not allow a treatment to start until the battery has been recharged.

6.2 Charging the Battery

The BioWaveHOME stimulator will not operate while it is charging.

To charge the battery, first, make sure the stimulator is turned off.

Plug the small connector on the AC Charger cord into the charging receptical on the lower right side of the BioWaveHOME® stimulator as shown in the photo to the right. Plug the other end of the AC Charger into a standard wall outlet to begin charging the battery. A bright BLUE Charging Indicator Light in the lower right corner of the stimulator will remain a ***steady*** BLUE indicating that the battery is now being charged.

Once fully charged, the Charging Indicator Light will turn ***off***. There is no harm in leaving the stimulator plugged into the AC Charger.

In order to use the stimulator the AC Charger must first be unplugged from the stimulator.

If the stimulator is not used on a regular basis, it is recommended that the stimulator be fully recharged a minimum of once every three (3) months.

Charging Indicator Light and Location For AC Charger

6.3 Replacing the Battery

The $LiFePO_4$ battery system should last for 18 to 24 months depending upon usage. The battery system is soldered to the internal circuit board and 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.

7. Maintenance, Cleaning and Storage Instructions

7.1 Maintenance, Cleaning and Storage Instructions

One of the design features of the BioWaveHOME® System is that there is no maintenance required by the user, other than keeping the stimulator and leadwire cable clean and stored in the proper environment, as described below. All repair and/or service to the BioWaveHOME® stimulator must be done by BioWave Corporation. Any opening or disassembly of the stimulator immediately voids the warranty of the BioWaveHOME® stimulator.

- Wipe the stimulator with a cloth or paper towel that is lightly moistened with a non-abrasive alcohol or ammonia based cleaner. The stimulator does not require frequent cleaning if it is handled and used with clean hands.
- Keep food and liquids away from the stimulator, leadwire cable, electrodes and AC Charger.
- Never submerge the stimulator, leadwires, electrodes or AC Charger in water or any other liquid. Never pour or spray any liquid onto the stimulator, leadwire cable or electrodes.
- The user should ensure that the stimulator, leadwires, electrodes and AC Charger are dry prior to using them. If the stimulator, leadwires, electrodes or AC Charger do become wet, DO NOT USE them. Please contact BioWave for technical support at 1-877-BioWave ext 2.
- 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. Following a treatment, remove both electrodes from your skin, place them back onto their respective plastic release liners, and return the electrodes into and reseal the

resealable bag. Applying and rubbing in 3 to 6 drops of saline into 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 - Electrode Connection to the Patient on page 80).

- BioWave Percutaneous Electrodes are sterile single-use electrodes and must be disposed of immediately following a single treatment.
- Do not expose the BioWaveHOME® stimulator to extreme temperatures, humidity, or direct sunlight. Store at room temperature. The stimulator may not operate properly if it is exposed to extreme conditions.
- NO modification of the BioWaveHOME unit or electrodes is allowed.
- 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 BioWaveHOME® stimulator.

7.2 Disposal of Waste Products

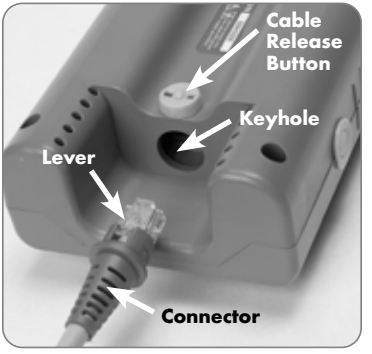
- BioWave Percutaneous electrodes are sterile, single-use electrodes which should be disposed of in a manner similar to other infectious medical waste.

- For battery replacement on the BioWaveHOME® stimulator, the entire stimulator should be returned to BioWave Corporation so that the $LiFePO_4$ battery system can be recycled appropriately. At the end of its useful life, disposal of the stimulator and power supply must comply with local regulations.

8. Troubleshooting

8.1 Leadwire Cable Won't Click into Device

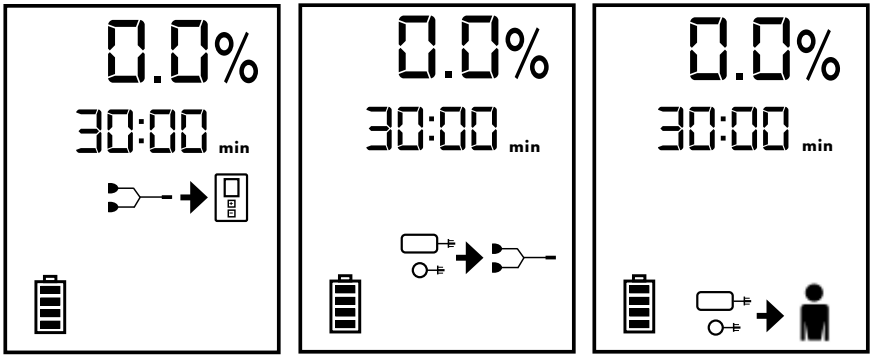
If the lever does not click into the keyhole, remove the cable and use your index finger to press firmly on the small metal pin inside the round opening to the device (press in the direction toward the cable release button which is on the outside of the device). Next, re-insert the connector back into the keyhole and it should click into place. Pressing on the metal pin prevents it from resting on the lever and allows the cable to click in and lock in place.



8.2 Error Conditions on LCD Display

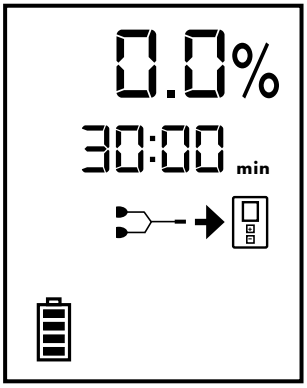
There are 3 error conditions that can appear on the LCD Display:

1. **Leadwire Cable Connection to the Stimulator**
2. **Electrode Connection to the Leadwire Cable**
3. **Electrode Connection to the Body**



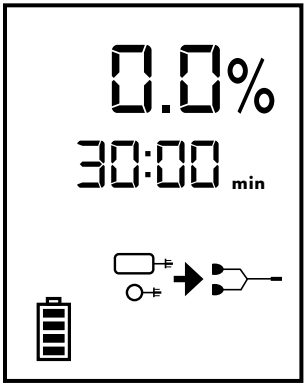
As shown in each of the three illustrations above, for these three error conditions, a picture will appear on the right side of the LCD display with a flashing arrow indicating the specific problem to be addressed.

8.2.1 LEADWIRE CABLE CONNECTION TO THE STIMULATOR



The first error condition shows a picture of the leadwire cable with a flashing arrow pointing to the stimulator as shown in the illustration to the right. This means the stimulator does not see the leadwire cable connector plugged into it. Gently plug the cable into the stimulator by aligning the plastic lever on the cable connector with the keyhole in the opening on the stimulator so it clicks in place (see photo in Section 2.1.1). If the screen still shows the same error condition to the right, then there may be a short in the leadwire cable between the cord and the plastic connector and a new leadwire cable will be required to use the stimulator.

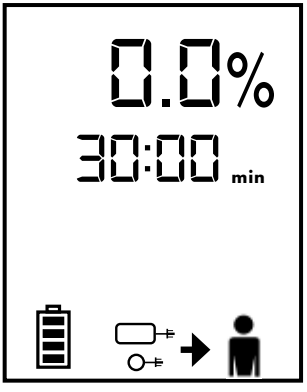
8.2.2 ELECTRODE CONNECTION TO THE LEADWIRE CABLE



The second error condition shows a picture of the electrodes with a flashing 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 an electrode connector has detached from the cable connector mid treatment, replug the electrode back into the leadwire cable to establish a positive electrical connection. The error condition should disappear, the LCD should show an intensity of 0.0% and the countown timer will be paused from when the error first appeared. Press the PLUS (+) button to resume the treatment from 0.0% and manually increase the intensity back up to your previous level.

8.2.3 ELECTRODE CONNECTION TO THE PATIENT



The third error condition shows a picture of the electrodes with a flashing arrow pointing to the body as shown in the illustration to the right. This means the stimulator does not see the electrodes on the surface of the body.

If the stimulator, cables and electrodes are all properly connected to each other and to the patient's body yet this error condition appears, then there are four conditions to check that can cause this error to occur:

1. **Lotion on the skin.**

   Lotion dramatically reduces adhesion and conductivity of the 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 error condition should disappear, the LCD should show an intensity of 0.0% and the countdown timer should read 30:00 min. Press the PLUS (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.8 - Using BioWaveHOME®.

2. **The electrode has been used too many times and has lost its adhesion and conductivity. Use saline to restore the electrode 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.

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 error condition should disappear, the LCD should show an intensity of 0.0% and the countdown timer should read 30:00 min. Press the PLUS (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.8 - Using BioWaveHOME®.

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 place them onto the plastic liner from which they came. Use a razor to shave the area where each electrode is to be placed. Place the electrodes back into position on the clean shaved skin. The error condition should disappear, the LCD should show an intensity of 0.0% and the countdown timer should read 30:00 min. Press the PLUS (+) Button to begin the treatment and continue to increase the intensity as described in Section 4.8 - Using BioWaveHOME®.

If during the procedure, either electrode or both electrodes get pulled off of your skin, 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.

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 your skin in the correct location and the error condition should disappear from the display. If the error condition does not disappear, place a new set of electrodes on yourself in the correct location. Once the error condition disappears from the display, you can press the PLUS (+) Button to manually increase the intensity level from zero back up to a therapeutic level as described in Section - 4.8 Using BioWaveHOME®.

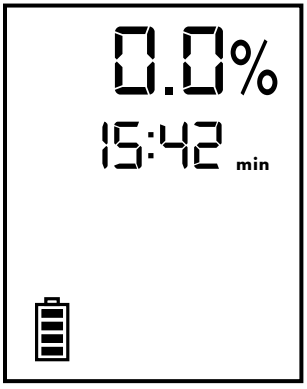
8.3 Use of Non-BioWave Electrodes

BioWave Nonivasive or BioWave Percutaneous Electrodes must be used. The BioWaveHOME stimulator will only recognize and work with BioWave Noninvasive Electrodes or BioWave Percutaneous Electrodes, which are designed to safely work with this stimulator.

8.4 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 front (anterior) of the shoulder, you may feel a small amount of muscle twitching under the smaller round Primary Electrode - this is normal. However, if the muscle twitching is uncomfortable, you may decrease the intensity by pressing the MINUS (**–**) Button.

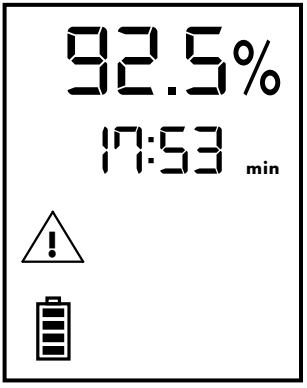
If the twitching still persists and is uncomfortable then press the PAUSE (||) Button once to pause the stimulator (the intensity will go to zero (0.0%) and the treatment time will pause).



Change the location of the Primary Electrode by moving it 0.5" to 1.0" away from its original location. For example, if the electrode was on the front of the shoulder, move it closer to the top of the shoulder. Once the electrode is in its new position, press the PLUS (**+**) Button to manually increase the intensity level from zero back up to a therapeutic level as described in Section 4.8 - Using BioWaveHOME®.

8.5 Automatic Safety Function

8.5.1 PRESSING PLUS (+) BUTTON WILL NOT INCREASE INTENSITY



As an added safety precaution, the BioWaveHOME® System has a patented technology that protects you from receiving too high a level of power during the treatment by actively monitoring current density at the skin surface and automatically controlling the intensity of the therapeutic signal in real time.

In some limited instances, a triangle with an exclamation mark will flash and appear briefly on the left side of the LCD display. 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 - 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 appear only for a fraction of a second.

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

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

8.5.2 ELECTRODE SPACING

8.5.2.1 Minimum Electrode Spacing

The minimum spacing between the B-set or U-set electrodes is one inch (1"). The minimum spacing between the E-set electrodes is half of one inch (0.5").

8.5.2.2 Maximum Electrode Spacing

There is NO maximum distance between the two electrodes. The electrodes are independent of one another.

9. Technical Specifications and Classifications

9.1 Technical Specifications

Physical Dimensions
Size (H x W x D): 6.0" x 3.75" x 1.75" / 15.24 cm x 9.53 cm x 4.45 cm
Weight: 1.0 lbs / 0.45 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
2 - 3.2 V DC, 3300 mAh rechargeable $LiFePO_4$ batteries
Provides 2 hours of power at 80% 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.

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

AC Charger
The stimulator must only be used with the universal AC Charger provided:
V-Infinity Model # EPSA090130U-P5P-EJ Power Adapter, or
Globtek Model # WR9HD1500C9PG2970(R).
9V DC, 1.3-1.5A, Power Output 12W, Cord Plug 2.1mm I.D. x 5.5mm O.D. x 9.5mm Female. Operating Altitude: 5000m. CE and UL Mark Listed.

Applied Parts

BioWave Noninvasive Electrodes
BioWave® Noninvasive Electrodes are of a silver/carbon construction with a pre-applied hydrogel and are cleared for marketing under 510(k) numbers K052289, K072123 and K152437.

BioWave Percutaneous Electrodes
BioWave Percutaneous Electrodes are supplied sterile via gamma radiation and are comprised of a 1.5 inch diameter microneedle array within a 2.5 inch diameter hydrogel-based electrode. The microneedle array is comprised of 1014 microneedles, 0.74 mm in length, made from 316L surgical stainless steel. Cleared for marketing under 510(k) number K061166.

Software Version: 25.2

9.2 Classifications

Before using BioWaveHOME, read this User's Manual.

Protection against electric shock classification: TYPE BF

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

- Neurotimulator is internally powered.
- AC Charger (power supply) is classified as Class 2.
- Mode of operation is continuous.
- Stimulator is not protected for use with flammable anesthetics.
- Protection against liquid ingress: IP21 - dripping water (vertically falling drops) shall have no harmfull effect. Unit is protected against objects >12.5mm.
- Neurotimulator 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 60601-1-11:2010
  EN 60601-1-2:2015
  UL 60601-1 CSA C22.2 No. 601.1

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The BioWaveHOME stimulator 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 BioWaveHOME stimulator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions*	Not applicable	
Voltage fluctuations/ flicker emissions	Not applicable	

BioWaveHOME has met these requirements of 60601-1-2:2015:

EMC Test	Compliance Information
Radiated Emissions	CISPR 11 Class B limits
Conducted Emissions Voltage	CISPR 11 Class B limits
Radiated RF EM Fields	10v/m, 80 MHz – 2.7 GHz, 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	Per table 8.10
Power Frequency Magnetic Fields	30 A/m, 50 Hz and 60 Hz
Electrical Fast Transients / Bursts	+/-2kV, 100 kHz repetition freq.
Surges	2kV line-to-line; 1kV line-to-ground
Conducted Disturbances induced by RF fields	3V, 0.15 MHz – 80 MHz. 6V in ISM and amateur radio bands. 80% AM at 1 kHz
Voltage Dips and Voltage Interruptions	0%, 0.5 cycles, at 0, 45, 90, 135, 180, 225, 270, and 315 degrees of the phase angle. 0%, 1 cycle, and 70%, 30 cycles, at 0 degrees of the phase angle. 0%, 300 cycles.
Electrostatic Discharge	+/-8kV contact

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

The BioWaveHOME® Neurostimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the BioWaveHOME 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 BioWaveHOME 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. Instability in the stimulator output may occur in close proximity (e.g. 1 m) to a shortwave or microwave therapy device or 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 BioWaveHOME Neurostimulator is used exceeds the applicable RF compliance level above, the BioWaveHOME 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 BioWaveHOME Neurostimulator. For frequency ranges above 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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

The BioWaveHOME® Neurostimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BioWaveHOME 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 BioWaveHOME 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.

10. Contact Information and Warranty

10.1 Reorder Information and Technical Support

To reorder BioWave Noninvasive or Percutaneous Electrodes, or for reimbursement, technical support or to report unexpected operation or events, 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 BioWaveHOME® System 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, abuse of operation contrary to the instructions specified in the User's Manual;

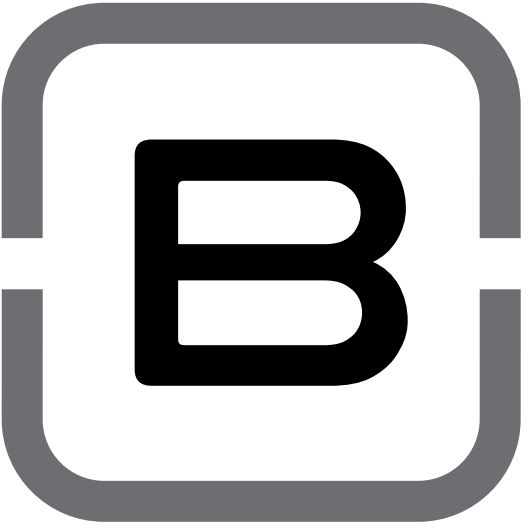
3. Damage resulting from modification or attempted repair by any person not authorized in writing by BioWave Corporation;

4. Cosmetic damage.

To obtain warranty service, you must deliver the product freight prepaid, in either its original packaging or packaging affording an equal degree of protection to BioWave Corporation.

NOTE: Before sending your BioWaveHOME® System for repair, you must call BioWave Corporation to receive return authorization (1-877-BIOWAVE).

Notes



BIOWAVE HOME

Need help? Contact us!

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

BIOWAVE

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

MADE IN USA

CLASSIFIED MET US
E114972

Rx ONLY

Device must only be used with power supply provided.

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