

BIOWAVEGO

**Rx
ONLY**

SMARTER PAIN BLOCKING TECHNOLOGY

User's Manual



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



Questions? Call us!

1-877-BIOWAVE
(1-877-246-9283)

support@biowave.com



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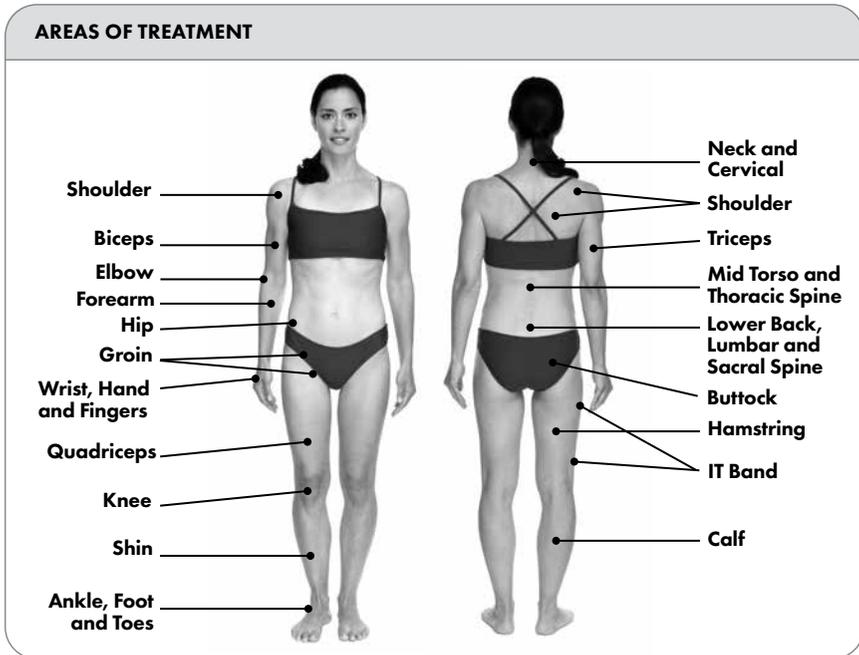
IMPORTANT!
Rx ONLY

Before using this product, read the following information thoroughly.

1. Indications for Use

BioWaveGO Rx is indicated for:

- the symptomatic relief of chronic intractable pain
- the symptomatic relief of post-traumatic acute pain
- as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain



See Section 4.4 for examples of Pain Relief Pad placements.

2. Device Description

BioWaveGO Rx is a prescription pain therapy neurostimulator 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 neurostimulator is comprised of a plastic housing containing the electronics and a rechargeable battery. On the face of the stimulator is a large LED Bar Graph which indicates the status of the device. The LED Bar Graph provides information on signal intensity, remaining treatment time, battery life, blue tooth connectivity and battery charging.

There are 3 buttons that control the neurostimulator:

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



BioWaveGO[®]
Neurostimulator

2.1 Device Accessories

Leadwire Cable

A “Y” shaped leadwire cable connects 2 disposable Pain Relief Pads to the BioWaveGO® neurostimulator. The single end of the leadwire cable plugs into a connector at the top of the neurostimulator as shown in the photo to the right below.



Leadwire Cable



**Leadwire Cable
Plugs into
Neurostimulator**

Connecting the Leadwire Cable to Pain Relief Pads

BioWaveGO Rx uses 2 Pain Relief Pads for a treatment. Either Pain Relief Pad 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 Pain Relief Pad connectors and plug them together until they click in place. When connected together, the Pain Relief Pad connector will partially stick out from the leadwire cable connector allowing an easy grip when pulling them apart.



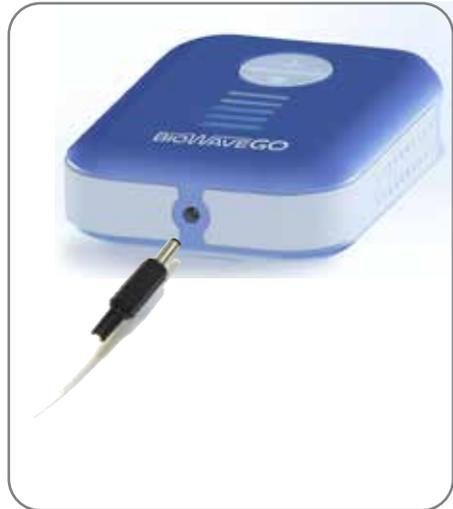
Removing the Pain Relief Pads from the Leadwire Cable

To remove the Pain Relief Pads 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 Pain Relief Pad connector to insert or remove them.

AC Charger

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

One end of the cord from the AC Charger is plugged into the receptacle on the bottom of the neurostimulator 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).



BioWaveGO Reusable Pain Relief Pads

BioWaveGO Pain Relief Pads 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. Only BioWaveGO Pain Relief Pads work with the BioWaveGO neurostimulator.

WARNING!

Pain Relief Pads MUST NEVER TOUCH EACH OTHER

- 1.0 inch (2.6 cm) is the minimum spacing between Pain Relief Pads
- There is NO maximum spacing between Pain Relief Pads
- If the edges of the Pain Relief Pads touch during the treatment, it may cause a burn.

BioWaveGO Pain Relief Pads are comprised of two 2" diameter round reusable electrodes that are placed:

- directly over 2 locations of pain.
- over a single location of pain and over a bony prominence (a comfortable location to receive stimulation).
- for radiating pain, one pad is placed over the source of the pain (for example over the spine), and the other pad is placed over the first location pain presents that is closest to the source.
- both pads can be placed one inch apart from one another directly over a large area of pain.



BioWaveGO Pain Relief Pads are reusable but must be tacky to the touch. If not, please use a new set of Pain Relief Pads.

BioWaveGO Pain Relief Pads must not touch each other when the unit is turned on. One inch is the minimum spacing.

2.2 Device Controls

Power Button

The Power Button is located on the top of the neurostimulator. Pressing the Power Button turns the neurostimulator on. While the neurostimulator is on, pressing the Power Button once immediately pauses the treatment (intensity is reduced to zero and the countdown timer pauses). Holding the Power Button down for 2 seconds turns the stimulator off.

Power should be turned on after the Pain Relief Pads are attached to your body and to the cable, and the cable is plugged into the stimulator.

PLUS Button (+)

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

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 Controls via the App Using Bluetooth (Recommended)

Using the BioWaveGO App will greatly enhance your BioWave experience. You can start, stop and adjust the intensity of your treatment using the app. You can also track your pain relief progress over time. The treatment can also be controlled simultaneously directly from the PLUS/MINUS button on the device.

To use the app follow these steps:

1. Download the BioWaveGO app from the App Store or Google Play.
2. Plug each Pain Relief Pad into the blue connectors on the leadwire cable.
3. Clean your skin with a damp wash cloth in the two locations the Pain Relief Pads are to be placed.
4. Place at least one Pain Relief Pad over the pain site on your body. Place the second Pain Relief Pad for your particular pain condition as shown in the appropriate photo in Section 4.4 - Pain Relief Pad Placement Examples. Pain Relief Pads must not touch each other.
5. Plug the leadwire cable into the top right corner of the device.
6. Press the power button on the top of the device. The device will connect with your Smartphone and emit a single tone when the connection is complete.
7. Launch the BioWaveGO app and follow the instructions:
 - a. Click on the “Pair Your Phone with BioWaveGO” message that appears.
 - b. Press the PLUS button to increase intensity on the main screen that appears to begin the treatment. Continue to increase the intensity to keep the sensation strong but comfortable.

The PLUS/MINUS button on the app exactly mimics the PLUS/MINUS button on the neurostimulator. Make sure your smartphone and the device are within 10 feet of each other to ensure quality of the bluetooth connection. If the bluetooth connection is lost, there is no effect on your treatment - you can continue to control the treatment using the buttons on the device. Radio frequency transmitters may affect the quality of the bluetooth connection. If you are using the app, make sure to perform the treatment at least 50 feet away from any radio frequency transmitter.

2.3 LED Bar Graph Indicator

The LED bar graph on the front of the device has 5 segments and provides treatment information in different colors:

- **Battery Strength Indicator - GREEN**
Remaining battery life is indicated in GREEN for 3 seconds when the device is first turned on.
- **Blue Tooth Connection - BLUE**
When the device is connected to a smartphone the top LED on the LED Bar Graph will blink BLUE while the connection is being established and will emit an audible tone for 1 second indicating a bluetooth connection to a smartphone.
- **Remaining Treatment Time - WHITE**
The remaining treatment time is displayed in WHITE. As the 30-minute treatment continues each bar dims and then turns off.
- **Signal Intensity - BLUE**
The intensity of the treatment is displayed in BLUE for 3 seconds after the PLUS or MINUS button is pressed. The higher the intensity, the more bars that are displayed in BLUE.
- **Charging the Battery - GREEN**
While the device is charging, each bar on the LED



**LED Bar Graph
Indicator Displaying
Signal Intensity**

Bar Graph will be in GREEN and will grow in brightness and then additional bars will light up as the battery charges up. Once the device is fully charged, the LED Bar Graph will turn off.

○ **Pause Treatment - WHITE**

Pressing the Power Button once quickly PAUSES the treatment. All 5 LEDs will breathe WHITE. To start back up, continue to press the PLUS button to manually increase the intensity from zero.

● **Troubleshooting - ORANGE**

When there is a connection problem all 5 LEDs will blink ORANGE, the intensity is immediately reduced to zero and the treatment time is paused. For example, after multiple uses, if the Pain Relief Pads are no longer tacky to the touch, the device may indicate a connection error because it does not see the Pain Relief Pads on the skin. Use a new set of Pain Relief Pads and reconnect the cable to the device and Pain Relief Pads. The LED bar graph will change to show WHITE bars if at the beginning of a new treatment, or if the error occurs mid treatment, the WHITE bars will be flashing on and off indicating the device is paused. To continue treatment, press the PLUS button to manually increase the intensity from zero to a strong but comfortable treatment level.

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

Read these instructions, including **When the Neurostimulator Should Not Be Used (Contraindications), Risks/Benefits, and all Warnings, Precautions and Adverse Reactions BEFORE** using BioWaveGO[®] to ensure proper use of the device.

3.1 When the Stimulator Should Not Be Used (Contraindications)

- **DO NOT** use if you have an implanted cardiac pacemaker.
- **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 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, rods, plates, screws, anchors and pins.
- Keep the BioWaveGO Rx Neurostimulator away from children.

3.2 Risks/Benefits

Risks

- There is a risk of rash underneath the electrode area. If the patient has 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 neurostimulator 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 the neurostimulator not be used on any area of your body that you are concerned may be overly sensitive to the impulses from the neurostimulator, for example, on sunburned skin.
- There is a risk of infection if the electrodes are placed on broken skin. Infection can be avoided when using the neurostimulator by placing new, clean electrodes on intact skin. Electrodes may be placed over healed scar tissue or over tattoos.

Benefits

- Customers report that BioWave treatments may provide significant pain relief.
- BioWaveGO[®] is an easy to use 30-minute treatment.
- Treatment using the BioWaveGO[®] System may 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.
- Most patients should start to feel a reduction of pain during and immediately after their first treatment.
- It is recommended that treatments are performed not longer than 24 hours apart, as this schedule

is intended to maximize the potential benefits of each successive BioWaveGO® treatment.

- Treatment with BioWaveGO® can be combined with heat, cold and compression therapies as well as with treatment via conventional medicine.

3.3 Warnings

- **PAIN RELIEF PADS MUST NEVER TOUCH EACH OTHER**
 - 1.0 inch (2.6 cm) is the minimum spacing between Pain Relief Pads on the back
 - There is NO maximum spacing between any Pain Relief Pads
 - If the edges of the Pain Relief Pads touch during the treatment, it may cause a burn.
- **DO NOT** plug into AC outlet during use. The neurostimulator is battery operated and will not operate while the AC Charger is plugged in.
- **DO NOT** use around water. Contact with water could cause electric shock, which can result in serious injury to the patient.
- The safety of the neurostimulator for use during pregnancy or labor has not been established.
- The neurostimulator should be used only under the continued supervision of a physician.
- The neurostimulator provides a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the neurostimulator is in use.
- There may be a potential hazard from simultaneous connection of a patient to high frequency surgical equipment and the neurostimulator that may result in burns and possible equipment damage.
- 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.
- During charging the battery, to avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

3.4 Precautions

- It is important to keep this manual handy. It should be studied and reviewed periodically by users of the neurostimulator.
- The neurostimulator 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 neurostimulator as it could be damaged and will not function properly.
- Do not exceed the treatment duration and frequency recommended in the operating instructions.
- The neurostimulator was designed and manufactured to ensure maximum safety of operation. Maintain the neurostimulator 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.
- 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 instructions in this User's Manual.
- 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 Pain Relief Pad burns are possible adverse reactions.

4. User Instructions

4.1 First Time Set Up & Quick Operating Steps

First Time Set Up

1. **The battery must be fully charged up before the first use.** While the device is charging, each bar on the LED Bar Graph will appear GREEN and will grow in brightness and then additional bars will light up as the battery charges up. Once the device is fully charged, the LED Bar Graph will turn off.

Quick Operating Steps

1. Plug each Pain Relief Pad into the blue connectors on the leadwire cable. The orientation of the connectors do not matter and either Pain Relief Pad can be plugged into either connector.
2. Make sure your skin is clean. Place at least one Pain Relief Pad over the pain site on your body. Place the second Pain Relief Pad for your particular pain condition as shown in the appropriate photo in Section 4.4 - Pain Relief Pad Placement Examples. Pain Relief Pads must not touch each other.
3. Plug the leadwire cable into the top right corner of the device.
4. Press the power button on the top of the device. The LED bar graph will glow GREEN indicating remaining battery life for 3 seconds. Then all 5 LEDs will be white indicating you have 30 minutes of treatment time remaining.
5. Start the treatment by pressing the PLUS (+) button to increase intensity so the sensation felt is strong but still comfortable. As you press the PLUS Button the LED Bar Graph will glow BLUE for 3 seconds after each press indicating the intensity level achieved. 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 BioWaveGO).

6. The optimal body position 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 so it feels like the treatment is really focused on the right spot. This will provide the best treatment outcome (see Section 4.7 - Motion During Treatment).

4.2 Rationale for Pain Relief Pad Placements

BioWaveGO[®] Pain Relief Pad placements are significantly different from other forms of electrical stimulation including TENS, interferential and muscle stimulation devices.

The BioWaveGO[®] neurostimulator utilizes two Pain Relief Pads. The active electrical field is focused in a volume of tissue the size of half of a grapefruit under and surrounding each Pain Relief Pad. Therefore at least one Pain Relief Pad must be placed directly over the center of the painful area.

The BioWaveGO[®] neurostimulator alternates the delivery of its high frequency electrical signals to both Pain Relief Pads so the sensation feels continuous in both Pain Relief Pad locations simultaneously. The Pain Relief Pads are independent of each other and each one can treat a distinct volume of tissue under and surrounding each Pain Relief Pad. The sensation felt at each location is a deep smooth tingling and pressure sensation.

4.3 Pad Placements for Different Pain Conditions

1. Two Locations of Pain

If there are two locations of pain, then place each Pain Relief Pad directly over each painful location. One inch is the minimum spacing between the Pain Relief Pads.

2. Single Location of Pain

If you have a single location of pain:

1. Place one Pain Relief Pad directly over the single location of the pain.
2. Place the second Pain Relief Pad over a bony location 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 electrical field to encompass the pain site.

3. Radiating Pain

If you have radiating pain from your back down your legs or from your neck down your arm:

1. Place one Pain Relief Pad over the origin of the pain one inch to the right or left of the center of the spine toward the direction the pain is radiating.
2. Place the second Pain Relief Pad over the first location you feel pain that is closest to the origin of the pain. For example, for radiating pain from your low back down your leg, the second Pain Relief Pad may be placed on your low back or buttock over a location of pain. For radiating pain from your neck, the second Pain Relief Pad for example may be placed on your trapezius muscle over a location of pain.

4. Large Area of Pain

If your pain presents over a larger area than 3 inches in diameter, then the Pain Relief Pads can be placed 1.0 inch apart directly over the larger area where the pain is presenting. With this placement, both Pain Relief Pads can be used to treat one larger volume of tissue up to 6 inches long by about 3 inches wide.

**See PHOTOS for examples
of optimal Pain Relief Pad
placements in Section 4.4.**

4.4 Pain Relief Pad Placement Examples

For all Pain Relief Pad placements, Pain Relief Pads *MUST NEVER TOUCH EACH OTHER* during the treatment:

- **1.0 inch (2.6 cm) is the minimum spacing between Pain Relief Pads.**
- **There is *NO* maximum spacing between any Pain Relief Pads.**
- **If the edges of the Pain Relief Pads touch during the treatment, it may cause a burn.**

The following section shows photos of Pain Relief Pad placement examples.

QUESTIONS? Call or email technical support:

1-877-BIOWAVE (1-877-246-9283)

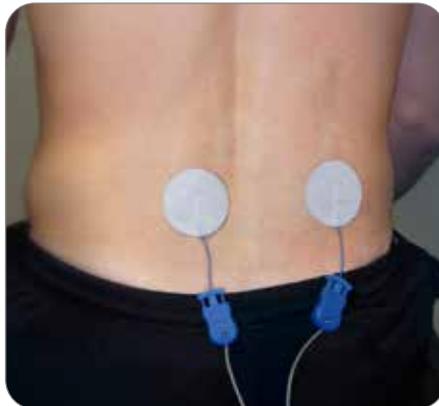
support@BioWave.com

Low Back Pain Pain Relief Pad Placement Examples

Pain in Two Locations Across Lower Back (for example, Bilateral Low Back Pain)

Place each Pain Relief Pad directly over a pain site as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting is the best position during the treatment.



Low Back Pain

Pain Relief Pad Placement Examples

Pain in One or Two Locations at the Bottom of the Lower Back (for example, Sacroiliac (SI) Joint pain)

Place Pain Relief Pads over one or two locations of pain directly on either side of the lower spine. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting is the best position during the treatment.



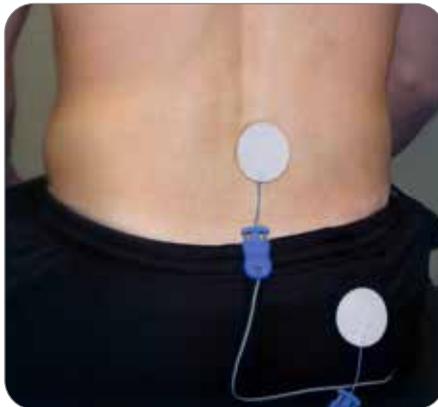
Low Back Pain Pain Relief Pad Placement Examples

Radiating Back Pain (for example, pain from Sciatica)

Place first Pain Relief Pad one inch to the right or left of the spine in the direction the pain is radiating (the photo to the right shows an example of pain radiating down the right side). Place second Pain Relief Pad over the first location that pain presents that is closest to the origin (for example on the buttock).

Pain Relief Pads must be placed on skin.

Body Position: Sitting is the best position during the treatment.



Low Back Pain

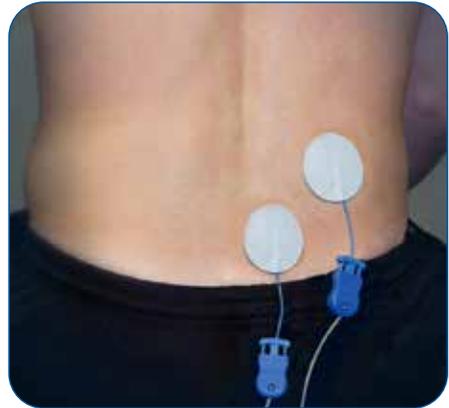
Pain Relief Pad Placement Examples

Low Back Pain in One Location

Place one Pain Relief Pad directly over the pain site - for example, on the right side of the lower back as in the photo to the right.

Place the second Pain Relief Pad one inch to the right or left of the spine in the direction closer to the pain site and closer to your waist line as in the photo. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting is the best position during the treatment.



Low Back Pain Pain Relief Pad Placement Examples

Pain Over a Large Area on the Back

Both Pain Relief Pads should be placed over the painful area with a minimum space of about 1.0 inch between the Pain Relief Pads.

When the two round Pain Relief Pads are about one inch apart from one another, you are receiving a treatment in a volume of tissue covered by the Pain Relief Pads of approximately 6 inches by 3 inches.

Body Position: Sitting is the best position during the treatment.



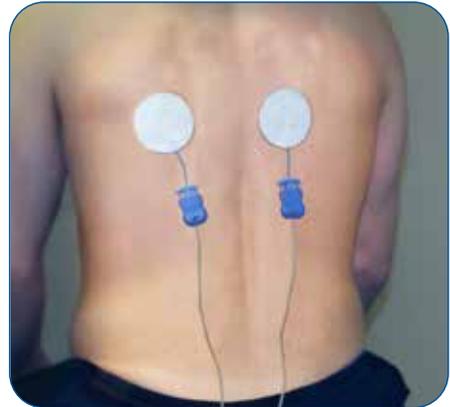
Mid Back Pain

Pain Relief Pad Placement Examples

Pain in Two Locations Across Mid Back

Place each Pain Relief Pad directly over a pain site as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting is the best position during the treatment.



Hip Pain

Pain Relief Pad Placement Examples

Hip Pain in One Location

Place one Pain Relief Pad on the hip directly over the painful area.

Place the other Pain Relief Pad one inch to the left or right of the spine in the direction closer to the Pain Relief Pad on the hip. In this example, the second pain relief pad is one inch to the left of the spine.

Body Position: Sitting in a reclined position or lying down is the most desirable position during the treatment.



Hip Pain in Two Locations

Place each round Pain Relief Pad on the hip directly over each painful area. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting in a reclined position or lying down is the most desirable position during the treatment.

Rib or Oblique Pain Pain Relief Pad Placement Examples

Rib or Oblique Pain in One Location

Place one Pain Relief Pad on the rib or oblique directly over the painful area.

Place the other Pain Relief Pad one inch to the left or right of the spine in the direction closer to the Pain Relief Pad over the pain site, near the waist line as in the photo to the right. In this example, the second pain relief pad is one inch to the left of the spine.

Body Position: Sitting in a reclined position or lying down is the most comfortable position during the treatment.



Rib or Oblique Pain in Two Locations

Place each Pain Relief Pad on the rib or oblique directly over each painful area. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting in a reclined position or lying down is the most desirable position during the treatment.

Groin Pain

Pain Relief Pad Placement Examples

Groin Pain

Place one Pain Relief Pad on the groin directly over the painful area. If hair is in the location of the painful area, then the hair must be shaved so that the Pain Relief Pad can make good electrical contact with the skin.

Place the other Pain Relief Pad over a second location of pain at least one inch away from the first pad.

Body Position: Sitting in a reclined position or lying down on your back with a pillow under your buttocks and legs straight is the best position during the treatment.



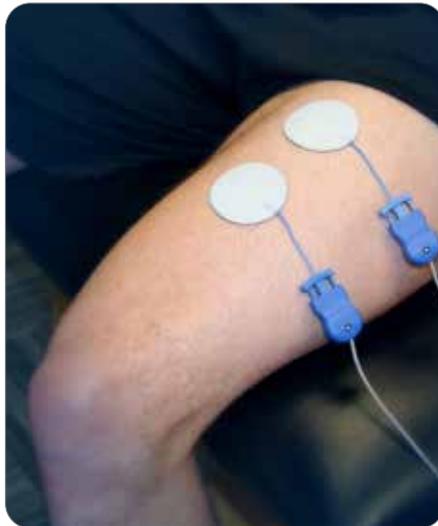
Quadriceps Pain

Pain Relief Pad Placement Examples

Quadriceps Pain

Place each round Pain Site Pain Relief Pad on the quadriceps directly over each painful area. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



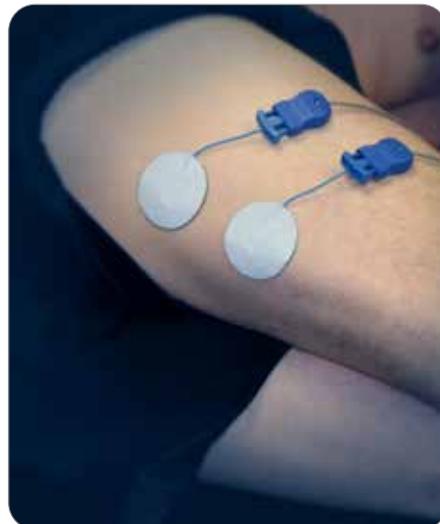
Hamstring Pain

Pain Relief Pad Placement Examples

Hamstring Pain

Place each round Pain Site Pain Relief Pad on the quadriceps directly over each painful area. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the leg straight is the best position during the treatment.



Knee Pain

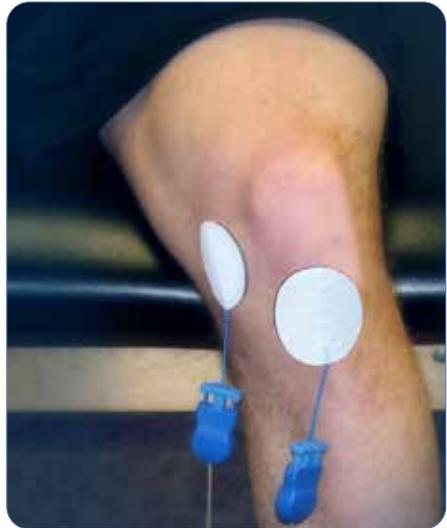
Pain Relief Pad Placement Examples

Pain on the Inside of the Knee (for example, pain from an MCL Sprain)

Place one Pain Relief Pad directly over your single location of pain on the inside (medial side) of the knee.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed touching the bottom part of the kneecap. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



Knee Pain

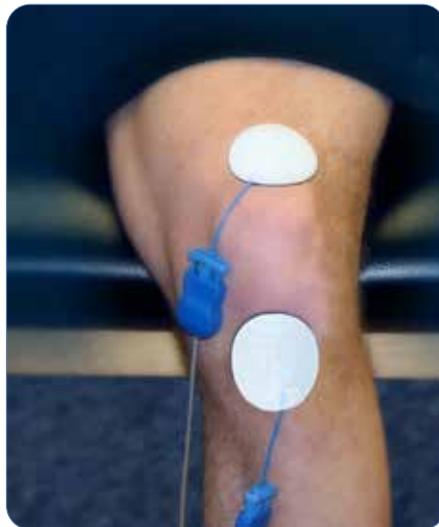
Pain Relief Pad Placement Examples

Pain Above the Kneecap (for example, pain from Quadriceps Tendinitis)

Place one Pain Relief Pad directly over your single location of pain above the knee.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed touching the bottom part of the kneecap. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



Knee Pain

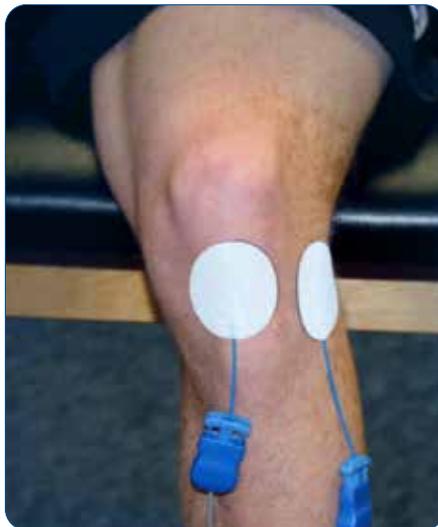
Pain Relief Pad Placement Examples

Pain Below the Kneecap (for example, pain from Patellar Tendinitis)

Place one Pain Relief Pad directly over your single location of pain just below the kneecap on the front of the knee.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed on the outside of the knee at the same level as the first pad over the pain site. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



Knee Pain

Pain Relief Pad Placement Examples

Pain on the Outside of the Knee (for example, pain from an LCL Sprain)

Place one Pain Relief Pad directly over your single location of pain on the inside (medial side) of the knee.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed touching the bottom part of the kneecap. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



Knee Pain

Pain Relief Pad Placement Examples

Pain Throughout the Knee (for example, pain resulting from Osteoarthritis)

Place each round Pain Site Pain Relief Pad directly over each painful area for example on the outside and inside of the knee as shown in the photo to the right.

One inch is the minimum spacing between Pain Relief Pads. There is no maximum spacing between the Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



Knee Pain

Pain Relief Pad Placement Examples

Pain Toward the Front of the Knee (for example, pain resulting from an ACL Sprain or Repair)

Place each round Pain Site Pain Relief Pad directly over each painful area for example on the outside and inside of the knee, but closer to the front of the knee and overlapping the sides of the knee cap so the edges of the electrodes are only one inch apart as shown in the photo to the right.

One inch is the minimum spacing between Pain Relief Pads. There is no maximum spacing between the Pain Relief Pads.

Body Position: Sitting upright with the knee bent at 90 degrees is the best position during the treatment.



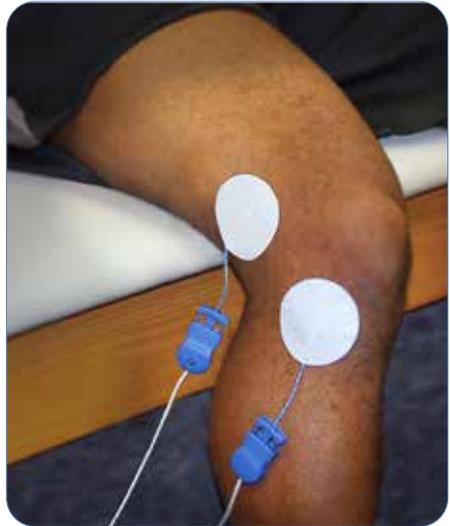
Knee Pain

Pain Relief Pad Placement Examples

Pain on the Outside of the Thigh or Knee (for example, Illiotibial Band (IT Band) pain)

Place one Pain Relief Pad directly over the pain site on the IT (illiotibial) Band which generally may be on the outside of the thigh, several inches up away from the outside of the knee.

Place the other Pain Relief Pad over a second location of pain. If there is no second location of pain, place the second pad over a bony prominence (comfortable location to receive stimulation). For this example the bony prominence is on the outside of the knee, below the level of the knee cap, as shown in the photo to the right. One inch is the minimum spacing between Pain Relief Pads.



Body Position: Sitting with the knee bent at 90 degrees is the best position during the treatment.

Knee Pain

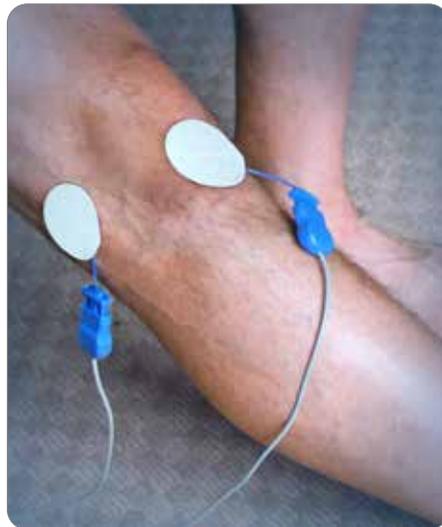
Pain Relief Pad Placement Examples

Pain on the Back Side of the Knee

Place one Pain Relief Pad directly over your single location of pain on the back side (posterior side) of the knee.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed touching the bottom part of the kneecap. One inch is the minimum spacing between Pain Relief Pads.

Body Position: Sitting with the knee straight is the best position during the treatment.



Lower Leg Pain

Pain Relief Pad Placement Examples

Shin Pain

The two Pain Relief Pads should be placed directly over the painful location on the shin as in the photo to the right.

If the Pain Relief Pads are placed about 1.0 inch apart from one another, the therapeutic electrical field formed beneath each Pain Relief Pad will overlap internally allowing the entire region beneath both Pain Relief Pads of approximately 6 inches by 3 inches to be stimulated and treated.

Body Position: Sitting with the knee bent is the best position during the treatment.



Lower Leg Pain

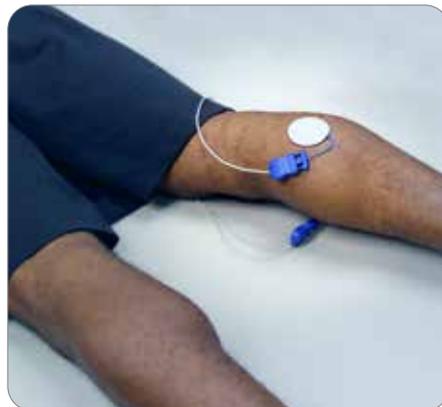
Pain Relief Pad Placement Examples

Calf Pain

Place one Pain Relief Pad directly over your single location of pain on the calf as shown in the first photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). For this example the other Pain Relief Pad should be placed touching the bottom part of the kneecap as in the second photo to the right. One inch is the minimum spacing between Pain Relief Pads. There is no maximum distance between Pain Relief Pads.

Body Position: Sitting with the knee straight or slightly bent is the best position during the treatment.



Ankle and Foot Pain

Pain Relief Pad Placement Examples

Pain Throughout the Foot (for example Pain from Diabetic Neuropathy)

Pain Relief Pads are each placed over the tibial nerve in different locations along the foot as shown in the photo to the right.

One Pad 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 Pads should be placed on the foot which is experiencing the pain.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



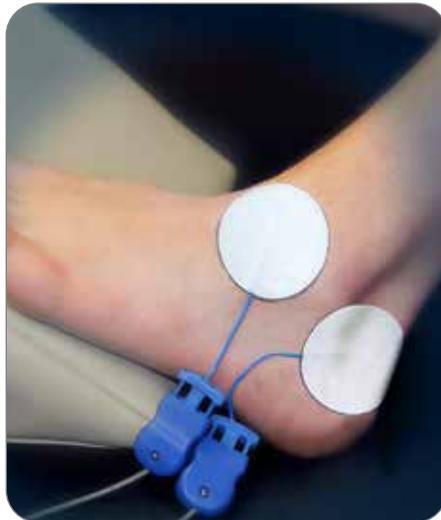
Ankle and Foot Pain Pain Relief Pad Placement Examples

Pain on the Outside of the Ankle or Foot (for example, pain from a Foot or Ankle Sprain)

Place one Pain Relief Pad directly over your single location of pain on the outside of the ankle as shown in the photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The example here shows the pad is placed on the outside of the heel and across the back of the heel and achilles tendon. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



Ankle and Foot Pain Pain Relief Pad Placement Examples

Two Locations of Pain in the Ankle or Foot

The two Pain Relief Pads should be placed directly over each respective pain site on the top, side, back and/or bottom of the foot or ankle as shown in the photo to the right.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



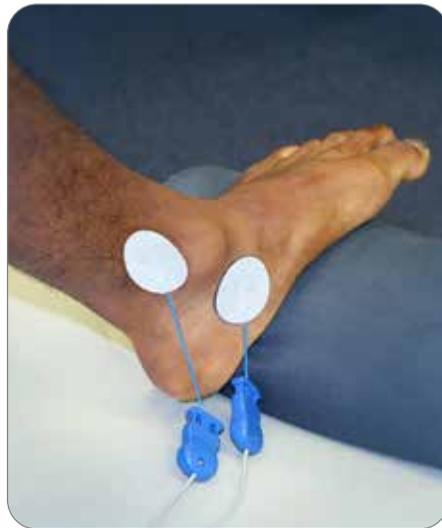
Ankle and Foot Pain Pain Relief Pad Placement Examples

Pain on the Inside of the Foot or Ankle

Place one Pain Relief Pad directly over your primary location of pain on the inside of the foot or ankle as shown in the photo to the right. In this example, the pain site is under the lower electrode on the foot beneath the ankle.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The ideal location is across the inside of the ankle as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



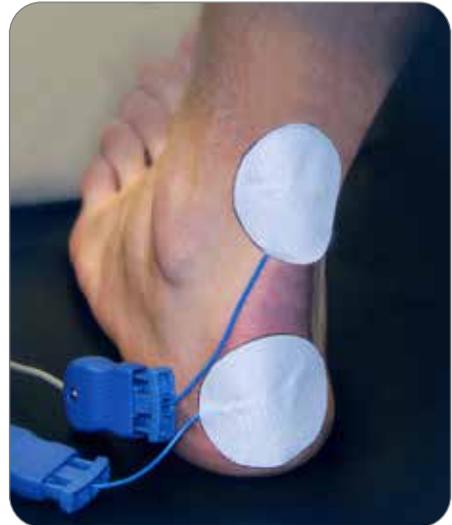
Ankle and Foot Pain Pain Relief Pad Placement Examples

Pain on the Back Side of the Heel or Ankle (for example, pain from Achilles Tendinitis)

Place one Pain Relief Pad directly over your location of pain on your Achilles tendon (the upper pad) as shown in the photo to the right.

Place the other Pain Relief Pad on the back lower part of the heel, also as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



Ankle and Foot Pain Pain Relief Pad Placement Examples

Pain on the Arch or Bottom of the Heel (for example, pain from Plantar Fasciitis)

Place one Pain Relief Pad directly over your single location of pain on the bottom of your foot, for example, over the plantar fascia as shown in the photo to the right.

Place the other Pain Relief Pad over a bony area (comfortable location to receive stimulation). The ideal location is across the outside of the heel and ankle as shown in the photo to the right.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



Ankle and Foot Pain Pain Relief Pad Placement Examples

Pain on Top or Bottom of the Foot (for example, Metatarsal pain)

Place one Pain Relief Pad directly over your single location of pain on the top of your foot as in the photo to the right.

Place the other Pain Relief Pad in an opposing position on the bottom of the foot.

Body Position: Sitting with the foot flat on the floor is the best position during the treatment.



Neck Pain

Pain Relief Pad Placement Examples

Neck Pain in One Location

Place one Pain Relief Pad directly over your single location of pain on the back of your neck as shown in the photo to the right.

Place the other Pain Relief Pad one inch away to the side to which the pain may be radiating. In this example the second Pain Relief Pad is placed below and to the right of the first pad.

In addition to the strong sensation beneath and surrounding both Pain Relief Pads, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

Body Position: Sitting in a comfortable position with the head bent forward is the best position during the treatment.



Neck Pain

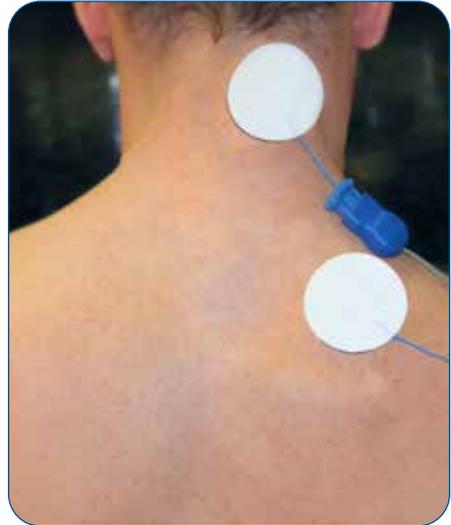
Pain Relief Pad Placement Examples

Neck Pain in Two Locations (for example neck pain radiating into the trapezius)

Place each Pain Relief Pad directly over a pain site. In this example, one Pain Relief Pad is placed one inch to the right of the spine on the back of the neck. The second Pain Relief Pad is placed over pain on the trapezius. One inch is the minimum spacing between the Pain Relief Pads.

In addition to the strong sensation beneath and surrounding both Pain Relief Pads, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

Body Position: Sitting in a comfortable position with the head bent forward is the best position during the treatment.



Neck Pain

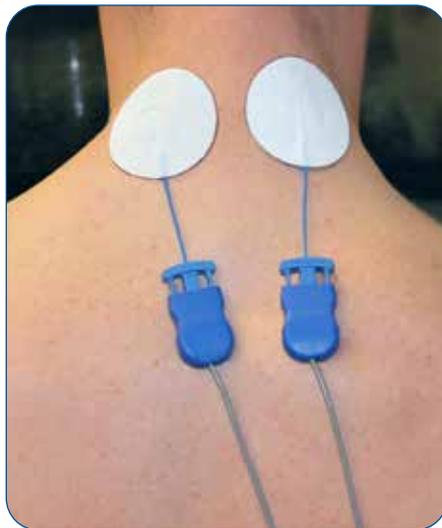
Pain Relief Pad Placement Examples

Neck Pain in Two Locations (for example, Bilateral Neck Pain)

Place each Pain Relief Pad directly over a location of pain on each side of the neck as in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

In addition to the strong sensation beneath and surrounding both Pain Relief Pads, it is common to feel a mild pleasant tingling sensation from the base of the skull up to the crown of the head.

Body Position: Sitting in a comfortable position with the head bent forward is the best position during the treatment.



Shoulder Pain

Pain Relief Pad Placement Examples

Pain on the Front of the Shoulder (for example, pain from Biceps Tendinitis)

Place one Pain Relief Pad directly over your single location of pain on the front of your shoulder as shown in the photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The ideal location is along the edge of your shoulder blade as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



Shoulder Pain

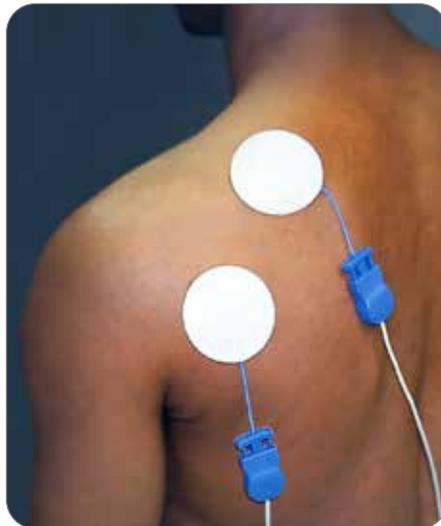
Pain Relief Pad Placement Examples

Pain on the Back of the Shoulder

Place one Pain Relief Pad directly over your single location of pain on the back of your shoulder as shown in the photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The ideal location is along the edge of your shoulder blade as shown in the photo to the right (this is the pad that is above and to the right of the first pad). One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



Shoulder Pain

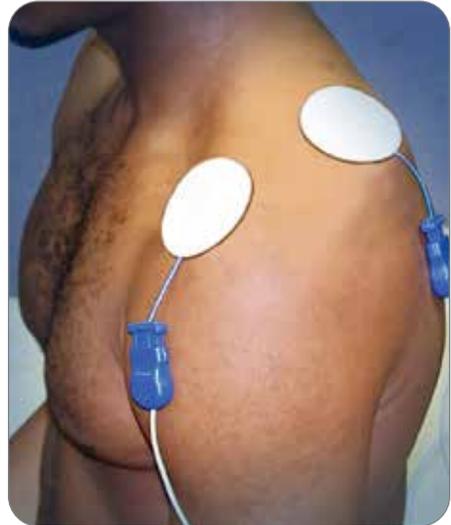
Pain Relief Pad Placement Examples

Pain on Top or Throughout the Inside of the Shoulder Joint (for example, pain from Frozen Shoulder/Adhesive Capsulitis)

Place one Pain Relief Pad directly over your single location of pain high on front of your shoulder as shown in the photo to the right.

Place the second Pain Relief Pad over the edge of your shoulder blade near the top of your shoulder as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



Shoulder Pain Pain Relief Pad Placement Examples

Two Locations of Pain or Pain Throughout the Shoulder Joint

For two locations of pain occurring for example, in the front of the shoulder and in the back of the shoulder (or as an alternative placement for pain inside the shoulder joint) place each Pain Relief Pad 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. Pain Relief Pads can be closer together than shown as in the photo on the previous page, however, one inch is the minimum spacing.

Body Position: Sitting in a comfortable position is the best position during the treatment.



Shoulder Pain

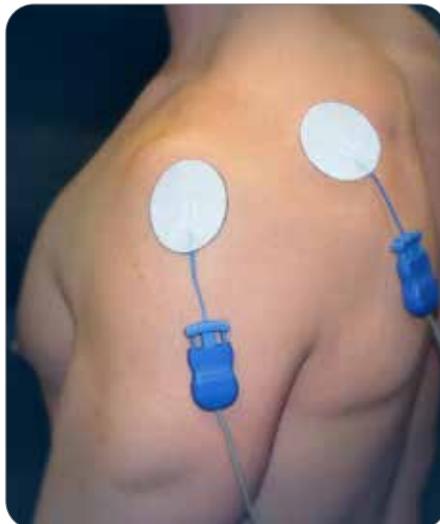
Pain Relief Pad Placement Examples

Pain on the Edge of the Shoulder (for example, pain from Rotator Cuff Tendinitis)

Place one Pain Relief Pad directly over your single location of pain on the edge of your shoulder as shown in the photo to the right.

Place the other Pain Relief Pad over a bony area (comfortable location to receive stimulation). The ideal location is along the edge of your shoulder blade as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



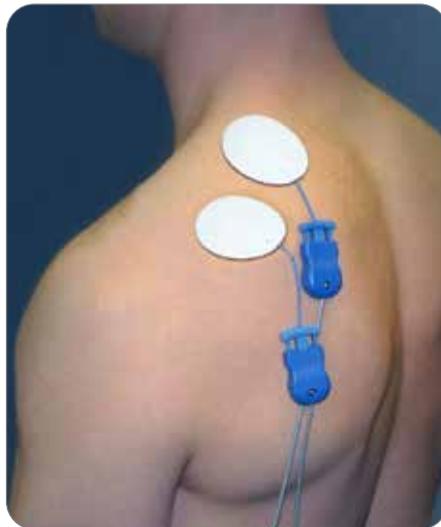
Shoulder Pain Pain Relief Pad Placement Examples

Single Location of Pain in the Muscle above the Shoulder Blade (for example, pain from a Trigger Point or Myofascial Pain in the Trapezius)

Place one Pain Relief Pad directly over your single location of pain on your trapezius as shown in the photo to the right.

Place the other Pain Relief Pad one inch away along the edge of your shoulder blade (a comfortable location to receive stimulation) as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



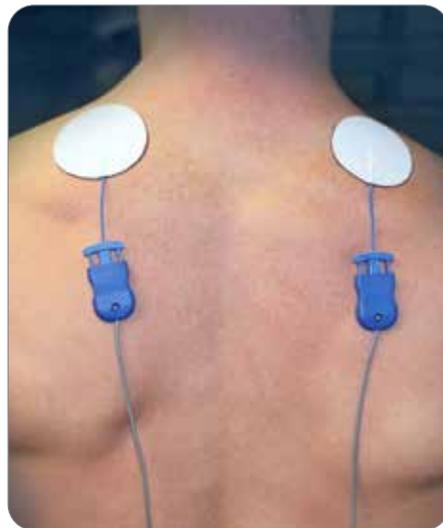
Shoulder Pain

Pain Relief Pad Placement Examples

Pain in both the Left and Right Muscles Above Each Shoulder Blade (for example, Bilateral Trapezius Pain)

For pain in the trapezius muscle in both shoulders, place each Pain Relief Pad directly over each respective pain site on each trap as shown in the photo to the right. Pain Relief Pads can be closer together or further apart than shown. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Sitting in a comfortable position is the best position during the treatment.



Elbow Pain

Pain Relief Pad Placement Examples

Pain on the Outside of the Elbow or Tennis Elbow

Place one Pain Relief Pad directly over your single location of pain on the outside of your elbow as shown in the photo to the right.

Place the other Pain Relief Pad on the bony part of the back side of your elbow. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball on the same side the elbow is being treated. This will keep your fingers in a comfortable position during the treatment.



Elbow Pain

Pain Relief Pad Placement Examples

Pain on the Inside of the Elbow or Golf Elbow

Place one Pain Relief Pad directly over your single location of pain on the inside of your elbow as shown in the photo to the right.

Place the other Pain Relief Pad on the bony part of the back side of your elbow. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball on the same side the elbow is being treated. This will keep your fingers in a comfortable position during the treatment.



Elbow Pain

Pain Relief Pad Placement Examples

Pain on the Back of the Elbow (for example, pain from Triceps Tendinitis)

Place one Pain Relief Pad directly over your single location of pain on the back of your elbow as shown in the photo to the right.

Place the other Pain Relief Pad on the bony area toward the outside/bottom of your elbow as in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball on the same side the elbow is being treated. This will keep your fingers in a comfortable position during the treatment.



Wrist Pain

Pain Relief Pad Placement Examples

Pain in Back of Wrist

Place one Pain Relief Pad directly over your single location of pain on the back of the wrist as shown in the photo to the right.

Place the other Pain Relief Pad in an opposing position on the opposite side of the wrist. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball in the same hand that the wrist is being treated. This will keep your fingers in a comfortable position during the treatment.



Wrist Pain

Pain Relief Pad Placement Examples

Pain in Inside of Wrist

Place one Pain Relief Pad directly over your single location of pain on the inside of your wrist as shown in the photo to the right.

Place the other Pain Relief Pad in an opposing position on the opposite side of the wrist. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball in the same hand that the wrist is being treated. This will keep your fingers in a comfortable position during the treatment.



Hand and Finger Pain Pain Relief Pad Placement Examples

Pain in the Thumb (for example, pain from a UCL Sprain)

Place the Pain Relief Pad directly over your single location of pain, for example, at the base of the thumb as shown in the photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The ideal location is on the back of the wrist as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball in the same hand that the wrist is being treated. This will keep your fingers in a comfortable position during the treatment.



Hand and Finger Pain Pain Relief Pad Placement Examples

Pain in a Finger

Place the Pain Relief Pad directly over your single location of pain, for example, at a joint on the index finger as shown in the photo to the right.

Place the other Pain Relief Pad over a bony prominence (comfortable location to receive stimulation). The ideal location is on the back of the wrist as shown in the photo to the right. One inch is the minimum spacing between the Pain Relief Pads.

Body Position: Roll up a washcloth and grip it with your hand or hold a tennis ball in the same hand that the wrist is being treated. This will keep your fingers in a comfortable position during the treatment.



4.5 Pain Relief Pad Placement Tips

- 1. Select locations for Pain Relief Pads** (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 Pain Relief Pad is to be placed. Do not use alcohol to clean the skin - wet alcohol under a Pain Relief Pad may cause a burn during a treatment.
- 3. Remove Pain Relief Pads from plastic liner** by peeling up the edge of each Pain Relief Pad. Do not pull on the blue connector or wire to remove the Pain Relief Pad from the plastic liner. Carefully align and place Pain Relief Pads on the skin on the pre selected areas. Press firmly over the entire Pain Relief Pad so the hydrogel gets into the pores of the skin.

Pain Relief Pads must not touch each other.

- 4. Save plastic liners and resealable bag for Pain Relief Pad storage** following the treatment. Pain Relief Pads may be placed back on one side of the plastic liner.
- 5. Pain Relief Pads are reusable but must be tacky to the touch.** If not, please use a new set of Pain Relief Pads

4.6 Body Position During the Treatment

For best results, 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.

Low Back - Sitting

Knees - Sitting with the knee bent at approximately 90 degrees. For treatments on the back side of the knee, the knee and leg should be kept straight

Calves - Adjust the direction you point your toes, either toward you or away from you. Find a position that allows you to most comfortably tolerate a higher level of stimulation.

Ankles, Feet and Toes - The foot should be kept at approximately 90 degrees to your leg and the foot should be placed against a flat surface.

Neck - The head should be bent forwards slightly.

Shoulders - Sitting with your arm in a comfortable position and elbow slightly bent.

Elbows, Wrists, Hands & Fingers - Sitting with your arm in a comfortable position and elbow slightly bent. Hold a rolled up hand towel to keep your fingers in a comfortable position.

Hamstrings - Sitting with the legs and knees straight.

Quadriceps - Sitting with the knee bent at 90 degrees.

Hips - Lying on your back with your legs straight. 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

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!”

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 noticeable when treating the shoulder, elbow, wrist, hand, finger, ankle or foot.

4.8 Using the BioWaveGO Stimulator

STARTING TREATMENT

1. Clean your skin
2. Place Pain Relief Pads over pain location(s)
3. Plug cable into unit and Pain Relief Pads
4. Press power button to turn unit on
5. Press and hold PLUS button so that tingling and pressure sensation become strong but are still comfortable
6. The body adapts quickly to the electric field in the first 5 minutes of treatment. 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.** Continue to repeat this process of increasing the intensity so the sensation at and surrounding the pain site remains strong throughout the treatment.

DURING TREATMENT

During the course of the procedure, it is normal to slightly increase the intensity level every few minutes as a light numbness develops around the pain site. To slightly increase the intensity level, you should press the Plus (+) Button 1 to 5 times. If the sensation becomes too strong, you can always press the Minus (-) Button to reduce the intensity.

END OF TREATMENT

The device will turn off automatically at the end of the 30-minute treatment which is indicated when the WHITE bars on the LED Bar Graph are all off.

Press the Power Button to turn the stimulator off.

Remove both Pain Relief Pads, place them back onto their respective plastic liners, return the Pain Relief Pads into and reseal the resealable bag.

Light numbness may last for up to 20 minutes following a 30 minute treatment. Continued residual pain relief may last up to 24 hours.

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 Pain Relief Pads are properly placed on your body. If everything is properly connected, the LED Bar Graph will display 5 WHITE bars which is the remaining treatment time. This means the stimulator is ready for the treatment to be started.

If there is a problem, all 5 bars on the LED Bar Graph will flash ORANGE indicating there is an error condition that needs to be corrected (see Section 8 - Troubleshooting).

5. Treatment Regimen Protocols

5.1 Treatment Regimen for Chronic Pain

For treating chronic pain the recommended treatment time with BioWave Noninvasive Pain Relief Pads is 30 minutes. Multiple treatments using BioWave Noninvasive Pain Relief Pads 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 the prescription strength BioWaveHOME is recommended. Please obtain a prescription from 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 Pain Relief Pads 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 Pain Relief Pads before placing ice on top of them. For use with cold and compression devices, the Pain Relief Pads should first be placed on the skin and then the cold/compression cuff may be placed over the Pain Relief Pads. Do not use the compression setting on the device during the BioWave treatment.
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. If you are time constrained, 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 Adjunct Treatment Regimen for Postoperative Pain and During Physical Therapy and Rehabilitation

POSTOPERATIVE PAIN

An adjunct treatment means BioWaveGO can be used in combination with other standards of care for postoperative pain, for example pain medication.

For an adjunct treatment for 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. Pain Relief Pads may be placed immediately next to an incision, but should not be placed over incisions that have not yet healed. Pain Relief Pads may be placed over scar tissue.

Please consult with your physician/surgeon prior to use as an adjunct treatment for postoperative pain.

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

BioWaveGO[®] is an excellent tool to facilitate rehabilitation because of its long carry over effect with respect to pain relief and range of motion improvement.

1. Use wrap like an Ace Bandage or medical tape over the Pain Relief Pads to help hold them in place.
2. While sitting still, 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 10% by pressing the minus button about 20 times

to take the edge off of the sensation.

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.

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

6. Battery Indicator and Charging the Battery

Battery Strength Indicator - GREEN

Remaining battery life is indicated in GREEN for 3 seconds when the device is first turned on.

Charging the Battery - GREEN

While the device is charging, each bar on the LED Bar Graph will be in GREEN and will grow in brightness and then additional bars will light up as the battery charges up. Once the device is fully charged, the LED Bar Graph will turn off.

If the neurostimulator is not used on a regular basis, it is recommended that the device be fully recharged a minimum of once per week.

Replacing the Battery

The LiFePO_4 battery system should last for 18 to 24 months depending upon usage. The long life LiFePO_4 battery system is plugged into the internal circuit board and can only be replaced by BioWave Corporation. Contact Customer Service at 1-877-BIOWAVE x2 (1-877-246-9283 x2) 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 BioWaveGO[®] 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 BioWaveGO[®] stimulator must be done by BioWave Corporation. Any opening or disassembly of the stimulator immediately voids the warranty of the BioWaveGO[®] stimulator.

- The stimulator should not be serviced while attached to the user.
- The stimulator does not require frequent cleaning if it is handled and used with clean hands. If it needs to be cleaned, wipe the stimulator with a damp cloth.
- Keep food and liquids away from the stimulator, leadwire cable, Pain Relief Pads and AC Charger. Never submerge the stimulator, leadwires, Pain Relief Pads or AC Charger in water or any other liquid. Never pour or spray any liquid onto the stimulator, leadwire cable or Pain Relief Pads.
- The user should ensure that the stimulator, leadwires, Pain Relief Pads and AC Charger are dry prior to using them. If the stimulator, leadwires, Pain Relief Pads or AC Charger do become wet, DO NOT USE them. Please contact BioWave for technical support at 1-877-BIOWAVE ext 2.

- Cleaning the skin prior to treatment and proper care of the BioWave Pain Relief Pads will ensure that the patient can obtain up to 10 treatments from one set of Pain Relief Pads. Following a treatment, remove both Pain Relief Pads from your skin, place them back onto their respective plastic release liners, and return the Pain Relief Pads into and reseal the resealable bag.
- Do not expose the BioWaveGO[®] 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.
- Cleaning should only be done after making sure that the AC Charger is not plugged into the stimulator.

8. Troubleshooting

8.1 Troubleshooting Error Conditions (All 5 LEDs will blink ORANGE)

There are 3 connections to check when all 5 LEDs blink ORANGE:

**1. Leadwire Cable
Connection to
the Device**

**2. Pain Relief Pad(s)
Connection to
Leadwire Cable**

**3. Pain Relief
Pad(s)
Connection
to the Body**

When there is a connection problem all 5 LEDs will blink ORANGE, and the device will not allow you to start the treatment.

If you are mid-treatment, and a connection problem occurs, the intensity is immediately reduced to zero and the treatment time is paused.

For example if the cable was accidentally unplugged, plugging the cable back in would correct the problem, the LED bar graph will change to show remaining treatment time in WHITE. You then have to manually ramp up the intensity from zero back to the prior treatment level to continue the treatment.

LEADWIRE CABLE CONNECTION TO THE DEVICE

Make sure the leadwire cable is plugged all the way into the device.

PAIN RELIEF PAD CONNECTION TO THE LEADWIRE CABLE

Make sure the blue connector on each of the two Pain Relief Pads is each plugged into each of the two blue connectors on the leadwire cable.

If an Pain Relief Pad connector has detached from the cable connector mid treatment, replug the Pain Relief Pad back into the leadwire cable to establish a positive electrical connection. The 5 LEDs will stop blinking ORANGE and the LED bar graph will change to show remaining treatment time in WHITE. You then have to manually ramp up the intensity from zero back to the prior treatment level to continue the treatment.

PAIN RELIEF PAD CONNECTION TO THE PATIENT

If the stimulator, cables and Pain Relief Pads are all properly connected to each other and to the patient's body yet the 5 LEDs are still blinking ORANGE, 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 Pain Relief Pads 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 Pain Relief Pads and place onto the cleaned skin. The 5 LEDs should stop blinking ORANGE and the LED bar graph will change to show remaining treatment time in WHITE. You may then start the treatment by pressing the PLUS button to ramp up the intensity to a strong but comfortable level.

2. The Pain Relief Pad has been used too many times and has lost its tackiness and adhesion.

Use a new set of Pain Relief Pads to establish proper electrical contact with the skin.

3. Dry flaky skin.

Dry flaky skin or heavily suntanned skin can cause the stimulator not to recognize the Pain Relief Pads because the impedance of the skin is too high. Remove the Pain Relief Pads 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 Pain Relief Pads and place onto the cleaned skin. The 5 LEDs should stop blinking ORANGE and the LED bar graph should change to show remaining treatment time in WHITE. You may then start the treatment by pressing the PLUS button to ramp up the intensity to a strong but comfortable level.

4. Excessive hair on skin.

Excessive hair on the skin can prevent the Pain Relief Pads from having adequate adhesion and electrical contact with the skin. As a result, the stimulator may not recognize the Pain Relief Pads even though they appear to be properly placed on the skin. Remove the Pain Relief Pads from the skin and place them onto the plastic liner from which they came. Use a razor to shave the area where each Pain Relief Pad is to be placed. Place the Pain Relief Pads back into position

on the clean shaved skin. The 5 LEDs should stop blinking ORANGE and the LED bar graph will change to show remaining treatment time in WHITE. You may then start the treatment by pressing the PLUS button to ramp up the intensity to a strong but comfortable level.

5. Pain Relief Pad(s) pull off of the skin.

If during the procedure, either Pain Relief Pad or both Pain Relief Pads get pulled off of your skin, the intensity will go to zero (0.0%), the treatment will pause and the 5 LEDs will blink ORANGE.

Make sure the Pain Relief Pads are clean and have not picked up any debris on the hydrogel. If they are clean, place the Pain Relief Pads back onto your skin in the correct location and the 5 LEDs should stop blinking ORANGE and the LED bar graph will change to show remaining treatment time in WHITE. If the LED Bar Graph is still blinking ORANGE, place a new set of Pain Relief Pads on yourself in the correct location. The 5 LEDs should stop blinking ORANGE and the LED bar graph will change to show remaining treatment time in WHITE. You then have to manually ramp up the intensity from zero back to the prior treatment level to continue the treatment.

8.2 Use of Non-BioWave Pain Relief Pads

BioWave Pain Relief Pads must be used. The BioWaveGO device will only recognize and work with a BioWave Leadwire Cable and BioWave Pain Relief Pads.

8.3 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 elbow or on the front of the shoulder, you may feel a small amount of muscle twitching under the smaller round Pain Site Pain Relief Pad - this is normal. However, if the muscle twitching is uncomfortable, you may decrease the intensity by pressing the MINUS (-) Button.

8.4 Automatic Safety Function

PRESSING PLUS (+) BUTTON WILL NOT INCREASE INTENSITY

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

If you are connected to the BioWave app on a smartphone, a triangle with an exclamation mark will flash and appear briefly toward the bottom of the smartphone display. If this occurs, then pressing the PLUS (+) Button to increase the intensity will be disabled.

Simultaneously, the device 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 smartphone 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 Pain Relief Pad Spacing

Pain Relief Pads MUST NOT TOUCH EACH OTHER

Minimum Pain Relief Pad Spacing

The minimum spacing between Pain Relief Pads is one inch (1”).

Maximum Pain Relief Pad Spacing

There is NO maximum spacing distance between the two Pain Relief Pads. The Pain Relief Pads are independent of one another.

9. Technical Specifications & Classifications

9.1 Technical Specifications

Physical Dimensions

Size (H x W x D): 4.0" x 3.0" x 1.0" / 10.16 cm x 7.62 cm x 2.54 cm

Weight: 0.375 lbs / 0.17 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: + 0°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: 3940 Hz

Feed Frequency 2: 4062 Hz

Output Voltage Range: 0 – 20.0 V rms

Maximum Output: 20.0 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 350 Ω to 1200 Ω

Software Version: 3.4

Power Source

3.2 V DC, 1200 mAh rechargeable LiFePO₄ battery
Provides 3 hours of power at 100% output into 500 Ohms
Battery cannot be changed by the user.

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.

AC Charger

The stimulator must only be used with the universal AC Charger provided:
5V DC, 1.0A, Power Output: 5W, Input Voltage: 90-264 VAC, Frequency 50-60Hz
Cord Plug 2.1 mm I.D. x 5.5mm O.D. x 14 mm Female. CE and UL Mark Listed.

Leadwire Cable

Rating complies with 21 CFR Part 898
(performance standards for Pain Relief Pad leadwires)

Applied Parts - BioWave Noninvasive Pain Relief Pads

BioWave Noninvasive Pain Relief Pads 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 Noninvasive Pain Relief Pads are a type BF applied part complying with IEC 60601-1.

Safety

BioWaveGO 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

Risk of injury if used improperly. The stimulator can produce physiological effects.

Bluetooth®

The Bluetooth word, mark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by BioWave Corporation is under license. Communication between the BioWaveGO Device and the Smartphone is via Bluetooth.

9.2 Classifications

 Before using BioWaveGO, read this User's Manual.

 Protection against electric shock classification: TYPE BF

- Protection against liquid ingress: IP22- vertically dripping water when tilted at an angle of up to 15 degrees shall have no harmful effect. Unit is protected against objects >12.5mm.
- Stimulator is internally powered.
- AC Charger (power supply) is classified as Class 2.
- Mode of operation is continuous.

Bluetooth Specifications

FCC ID:	2ASDQBWG-S	FCC Rules:	Part 15C
Hardware:	PSOC CY8C4248LQI-BL553 with BLE Low-Energy Radio	Frequency Range:	2402.0 - 2480.0
Transmit Power:	+0 dBm	Output Watts:	0.001W
Receiver Sensitivity:	-89 dBm	Security:	Encryption

FCC Statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Canada Statements

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Guidance & Manufacturer's Declaration – Electromagnetic Emissions

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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions (CISPR 11)	Group 1	The BioWaveGO Neurostimulator 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)	Group B	The BioWaveGO 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 (IEC 61000-3-2)	IEC 61000-3-2 Class	
Voltage Fluctuations/ Flicker Emissions (IEC 61000-3-3)	Complies	

Guidance & Manufacturer's Declaration – Electromagnetic Immunity

The BioWaveGO Neurostimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the BioWaveGO Neurostimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	± 2 kV for power ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	± 1 kV line(s) to line(s) ± 2 kV line(s) to Earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T for 5s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BioWaveGO requires continued operation during power mains interruptions, it is recommended that the BioWaveGO be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the A.C. mains voltage prior to application of the test level.

Guidance & Manufacturer's Declaration – Electromagnetic Immunity

The BioWaveGO Neurostimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the BioWaveGO Neurostimulator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V (RMS) 150 kHz to 80 MHz	6 V	<p>Portable and mobile RF communications equipment should be used no closer to any part of the BioWaveGO Neurostimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter as provided below.</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	<p>Recommended separation distance:</p> $d = 0.58 \sqrt{P}$ $d = 0.35 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 0.7 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>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 survey¹ should be less than the compliance level in each frequency range².</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

REFERENCES:

1. 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 BioWaveGO Neurostimulator is used exceeds the applicable RF compliance level above, the BioWaveGO 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 BioWaveGO Neurostimulator.
2. 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 BioWaveGO Neurostimulator

The BioWaveGO Neurostimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BioWaveGO 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 BioWaveGO 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		
	150 kHz to 80 MHz $d = 0.58 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0.01	0.058	0.035	0.07
0.1	0.18	0.11	0.22
1	0.58	0.35	0.7
10	1.8	1.1	2.2
100	5.8	3.5	7.0

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.

9.3 Definition of Symbols

Symbols	Definition
	See User's Manual and Quick Reference Guide for more information.
	See User's Manual and Quick Reference Guide for more information.
	Authorized Representative in the European Community
	The device is classified as type BF against electrical shock and leakage current. The device is suitable for use on patients according to the standards defined by IEC 60601-1.
	Prescription use only
	Model Number
	Manufacturer
	Serial Number
	Caution
	Non-Sterile
	Use By
	Lot Code
	Do not use if package is damaged

10. Contact Information and Warranty

10.1 Reorder Information and Technical Support

To reorder BioWave Pain Relief Pads, or for Technical Support, please contact BioWave 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 BioWaveGO[®] System against defects in material or workmanship for a period of ONE year from the date of original purchase. This Limited Warranty excludes Pain Relief Pads 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 first call BioWave Corporation to receive return authorization (at +1-877-BIOWAVE).





BIOWAVEGO

SMARTER PAIN BLOCKING TECHNOLOGY

Need help?

- **1-877-BIOWAVE**
- **support@BioWave.com**
- **BioWave.com**

BIOWAVE



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MADE IN
USA



Device must only be
used with power
supply provided.

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