Biowave High Frequency Neurostimulation

Sports & Athletic Training Training Guide

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Background on Pain
For Sales Representatives

What is **Pain?**

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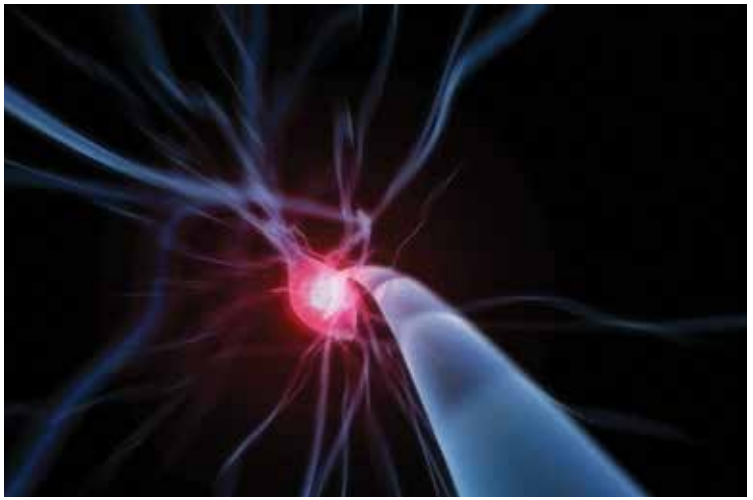
Pain is broadly divided into two groups: Nociceptive Pain and Neuropathic Pain



Nociceptive Pain

- Caused by intense or damaging stimuli
- Three classes of nociceptive pain:
  - Mechanical (stubbing a toe)
  - Thermal (burning a finger)
  - Chemical (putting alcohol on a cut)
- Examples include:
  - Post–operative pain
  - Pain associated with trauma
  - Chronic pain of arthritis

Neuropathic Pain

- Caused by nerve damage accompanied by tissue injury
- Damaged nerve fibers send incorrect signals to different pain centers
- Examples include:
  - Allodynia
  - Radiculopathies
  - Neuralgia
  - Postherpetic neuralgia (shingles)
  - Complex Regional Pain Syndrome (CRPS)
  - Phantom limb pain

Types of Pain Fibers

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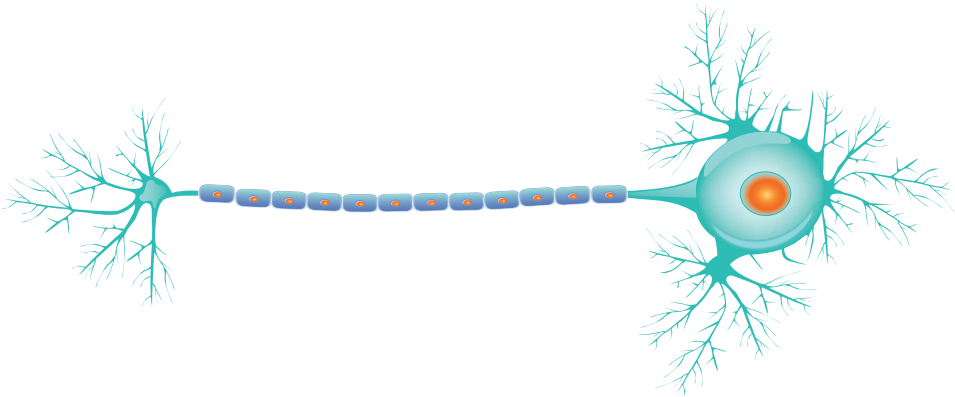
Nociceptors can be divided into two general types.



C-fibers

- Unmyelinated axons
- Conduct action potentials slowly
- Small-diameter cell bodies
- Mediate the slower, burning quality of pain
- Comprise around 70% of all nociceptor fibers

A-delta fibers

- Lightly myelinated axons
- Conduct action potentials rapidly
- Medium to large diameter cell bodies
- Mediate the fast, pricking quality of pain fibers

Acute vs. Chronic

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Acute pain and chronic pain differ in their time frame, etiology, pathophysiology, diagnosis and treatment.

Acute pain

- Less than 3-months in duration
- Results from trauma or postoperative pain
- Self–limiting and serves as a protective biological function by acting as a warning of ongoing tissue damage
- Symptom of a disease process experienced in or around the injured or diseased tissue
- Nociceptive in nature and occurs secondary to chemical, mechanical and thermal stimulation of A–delta and C–fiber pain receptors.

Chronic pain

- Greater than 3-months in duration
- Serves no protective biological function
- Chronic pain is itself a disease process
- Not self– limiting and can persist for years and even decades after the initial injury
- Can be refractory to multiple treatment modalities
- If inadequately treated, associated symptoms can include chronic anxiety, fear, depression, sleeplessness and impairment of social interaction predominately neuropathic in nature (except for cancer pain) and involves damage either to the peripheral or central nervous systems

How is **Pain Transmitted?**

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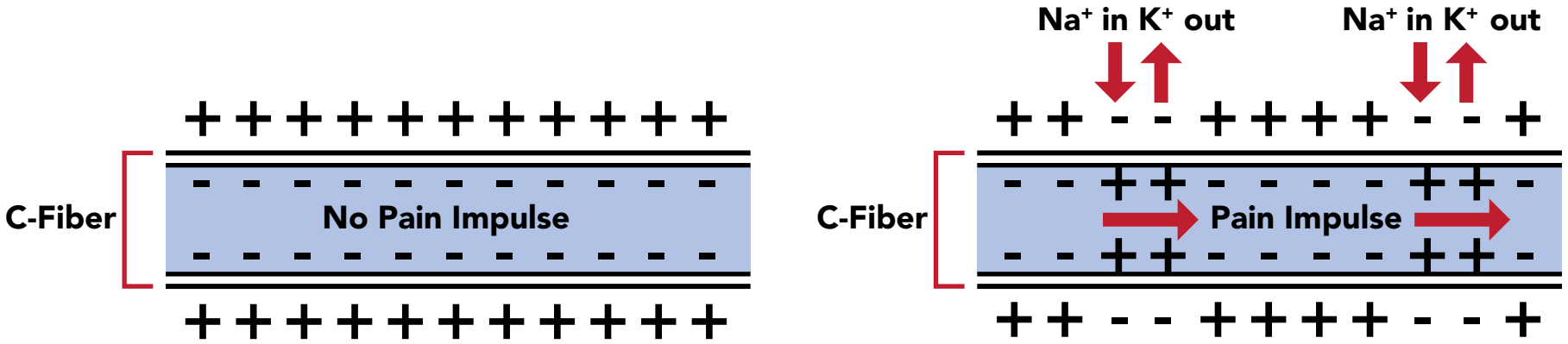
Pain is initiated by an external stimulus that exceeds a certain threshold.



- Stimulus from outside the body is above a certain threshold (for example, a person hits their thumb with a hammer)
- Sodium ion passes from the outside of the membrane of the C- fiber to the inside of the C-fiber
- Potassium ion moves from the inside of the C-fiber to the outside
- Sodium-potassium ion exchange causes a polarity change
- Plus charge formed on the inside of the C- fiber is the pain signal
- Pain signal propagates along C- fiber to dorsal horn of the spine and up to the brain
- Person feels pain

Different Ways to Treat Pain

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Tier 1

TENS

Electrical signals travel across surface of skin which may act as a distraction to pain

Gate Control Theory

NSAIDS

Reduces inflamation through peripheral inhibition of prostaglandin synthesis

Bio-feedback

Provides some control over physiological functions

Physical Therapy

Strengthens location surrounding injured area

Behavioral Modification

Reduces re-aggravation of pain condition

Tier 2

Opioids

Act on receptors located on neuronal cell membranes that inhibit neurotransmitter release

Nerve Blocks

Provides a chemical conduction block of the sodium channels which conduct electrical pain impulses

Injections

Suppresses the immune system reducing inflammation, pain and swelling at the site of the injury

Radio Frequency Ablation

Burns nerves to stop transmission of pain signals

Tier 3

Surgery

Mechanical correction or stabilization to reduce pain

SCS

Implanted device and leads stimulates affected nerves

Gate Control Theory

Drug Pumps

Provides a chemical conduction block of the sodium channels which conduct electrical pain impulses

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Clinical and Technical
Inservice on Biowave

Problem with Existing Stimulation Technologies

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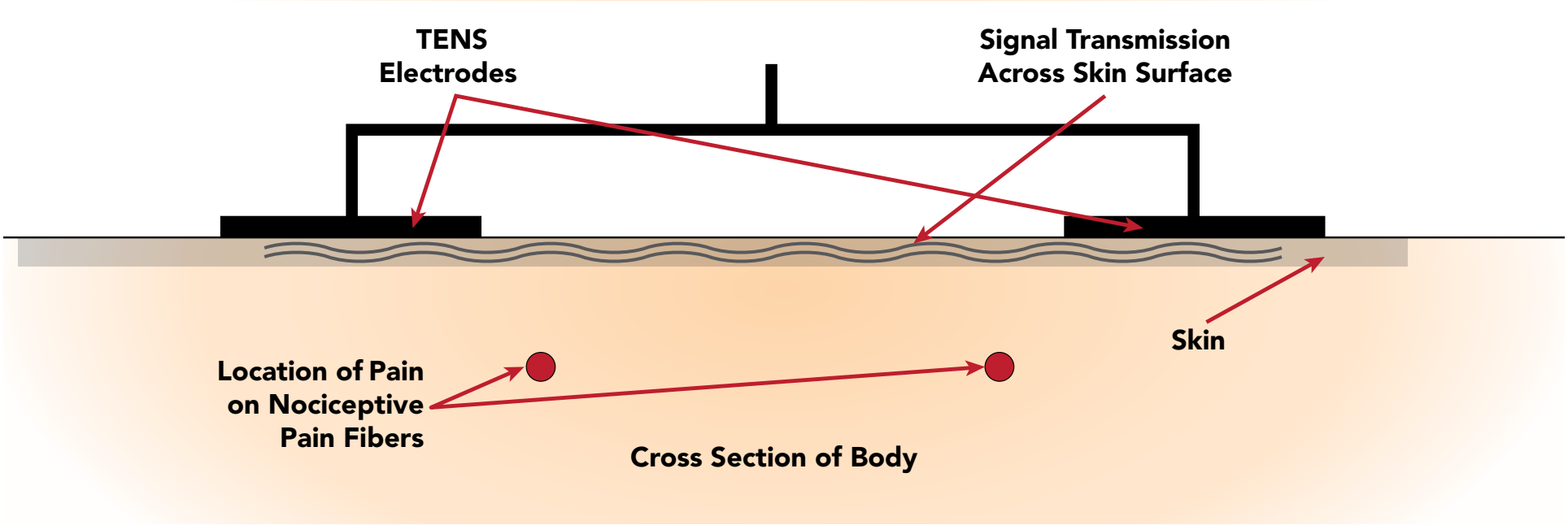

- Low Frequency signals (1-180 hz) affect nerve fibers
- Problem - skin has high impedance & capacitance
- Low Frequency (LF) signals regardless of the shape of the waveform cannot pass through skin - LF signals only travel across the surface of skin (Fundamental problem with TENS)
- PNS and SCS devices are implanted with leads placed in the proximity of the nerve to be stimulated

Solution to Problem

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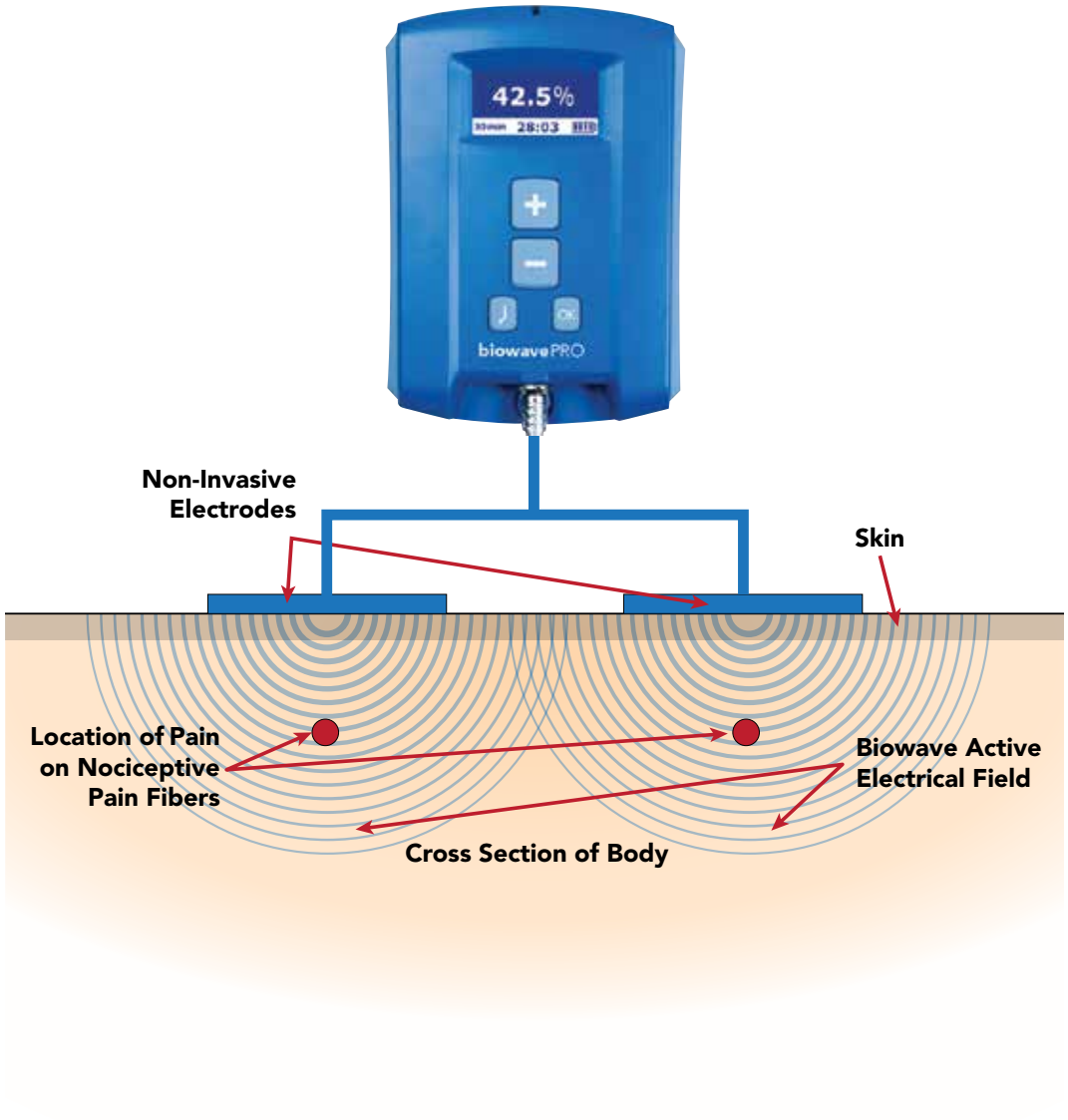
Patented Biowave Advanced Signal Technology



- Proven in a rabbit model
- Delivery of Biowave's two summed High Frequency (HF) signals (4000 hz + 3880 hz) alternates between two noninvasive electrodes
- As the 2 HF signals pass through skin into deep tissue, all polarized structures including nociceptive pain fibers (C-fiber, A-delta fiber) and muscle tissue cause a further multiplication of the 2 HF signals (this is known as a Fourier Transform)
- Result is a new spectrum of signals, one of which is a Low Frequency (LF) signal that forms an active electrical field in a 3" diameter hemisphere beneath each noninvasive electrode
- Body is producing LF internally at surface of pain nerves instead of:
  1. trying to force LF through skin from the outside like TENS, or
  2. needing to implant a lead next to the nerve like a spinal cord stimulator (SCS) or peripheral nerve stimulator (PNS)

Mechanisms of Action

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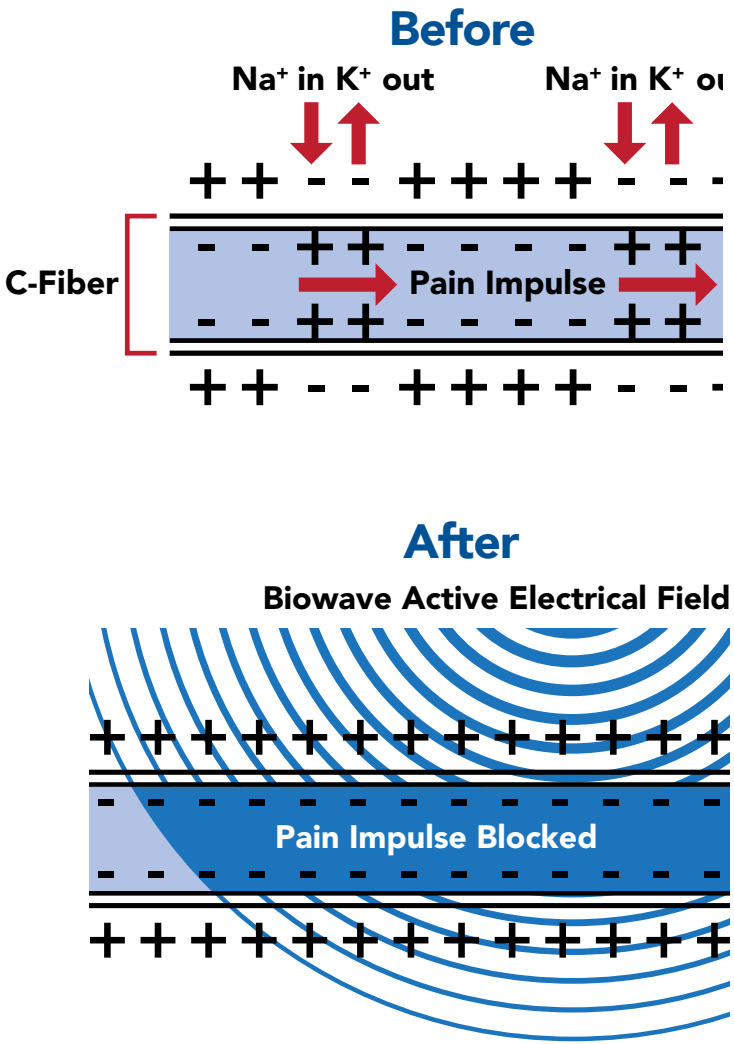
Biowave Treats Both Nociceptive and Neuropathic Pain



- Active electrical field forms at the surface of nerves in a 3" diameter hemisphere beneath both electrodes
- Hyperpolarization of C Fibers
  - Active electrical field inhibits sodium – potassium ion exchange across the membrane of C-fibers preventing action potential propagation
- Hypoesthesia is induced on A-delta Fibers:
  - Hypoesthesia is induced 5 min into the treatment
  - Light numbness lasts for up to 20 min following a 30-min treatment
- Blood flow is accelerated through volume of tissue in hemisphere where active electrical field is present
- Muscle tissue held in tension during treatment
- Deep smooth pressure sensation – Much more comfortable than IFC, NMES, TENS
- Long carry over effect from more efficient production of endogenous opiates – endorphins, enkephalins, serotonin

First **Human Study**

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Chronic Low Back Pain Dosage Study at Cornell Medical College/NY Hospital

- Abstract in Journal Anesthesia & Analgesia Mar 2003
- Discovered optimal set of HF signals for passing energy through skin
- Discovered optimal LF signal formed inside body for:
  - preventing action potential propagation along C-fibers (inhibiting transmission of pain signal)
  - inducing hypoesthesia on A-delta fibers – light numbness forms in the hemisphere beneath and surrounding each electrode

Result

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Very Simple to Use Neuromodulation Pain Therapy System

- No programming
- Signals are optimized for passing through skin and blocking pain directly on nociceptive fibers
- Only control is intensity
- Patients control their own comfort level
- Active feedback control prevents patients from receiving a burn
- Very simple to use
- FDA Cleared
- Manufactured in USA

Biowave **Clinical Studies**

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Clinical studies on acute, chronic and postoperative pain

- Long Term Use of BiowaveHOME High Frequency Neurostimulation for the Treatment of Chronic Pain in Veterans Following Successful BiowavePRO Neurostimulation Therapy in Veterans Administration Hospitals
- Randomized Controlled Study on the treatment of post-operative pain from TKA surgery - Hospital for Special Surgery, New York City - Podium Presentation at Eastern Orthopedic Association Annual Meeting, Oct 2008; Poster Presentation at AAOS Annual Meeting Feb 2009; Study submitted to the *Journal of Arthroplasty*
- Randomized Blinded Controlled Study Treating OA Knee Patients Rush Univ. Medical Center - Published in *ORTHOPEDICS* June 2007
- Weill Cornell Medical College Chronic Low Back Pain Study (Phase 1 + 2) - Abstract from *Anesthesia & Analgesia*, Mar 2003
- NY Giants White Paper - IRB approved study on treatment of Acute Sports Injuries on NY Giants football players June 2003-Dec 2005, 600 treatments on 90 players
- Clinical Study on treating extremities to reduce pain and improve range of motion - August 2005

Go to biowave.com/clinical to download studies

Biowave **Clinical Studies**

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Results from Clinical Studies

- **Excellent treatment outcomes**
  - 81% patient response rate
  - 50%-75% reduction in VAS pain scores
  - Significant increase in ROM, reduction in stiffness and muscle spasm
- **Long carry over effect**
  - 30-minute treatment provides up to 24 hours of continued pain relief and functional improvement
- **Extremely comfortable**
  - Deep smooth pressure sensation
  - Excellent patient compliance

Pain Treatment **Protocol**

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Static Treatment for Sports

In athletic training applications, because athletes may re-aggravate their pain condition during practices or games, the recommended protocol is as follow:

- Treat for 30 minutes immediately before practice or a game so the athlete may receive relief through practice or the game;
- Treat for 30 minutes immediately after practice or a game (which may be in combination with cold therapy) and
- Time permitting, treat a third time 2 to 3 hours later or in the evening. Multiple treatments with BiowavePRO and BiowaveHOME may provide a cumulative benefit.
- BiowavePRO and BiowaveHOME's portability allow for treatments to occur not only in the athletic training room, but while an athlete is watching film or in a meeting, or while traveling on a bus, airplane, in a hotel room or on the sidelines.

Physical Therapy Treatment **Protocol**

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Facilitate Motion, Accelerate Rehabilitation and Manage Pain Simultaneously

- Must use tape, cohesive wrap or velcro strap to help hold electrodes in place
- Use for 8 minutes first, preceding therapy
- Tissue in region of treatment area should be in a stretch position to allow for deeper penetration of the electrical field
- Patient continues to increase intensity to tolerance during first 8 min
- Motion changes the impedance of tissue, so before therapy reduce intensity by 5 - 10% to significantly reduce the sensation felt by the patient
- While Biowave treatment continues, begin AROM (active range of motion), PROM (passive range of motion), exercise or stretching therapy
- Patient can move more resistance through a greater ROM (range of motion) with significantly less pain
- Biowave allows the patient to more easily complete your therapy regimen while managing pain
- Long carryover effect limits post exercise soreness

Physical Therapy Treatment **Protocol**

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Facilitate Motion, Accelerate Rehabilitation and Manage Pain Simultaneously

- Can patient harm themselves by exercising too aggressively? Generally NO!
- Therapist plans the appropriate amount of resistance, ROM or therapy for the state of the patients' condition (early in the rehab process, later in the rehab process, or details relating to the specific injury)
- Pain relief is not so absolute that patient can move way beyond normal activity without Biowave
- ROM is greater, but there is a new limit to patients' range of motion
- Pain is still used as a guide relative to activity that can be tolerated
- Whether more resistance with AROM or extra flexion/extension of a joint with PROM, pain still limits one's activity or maximum ROM and prevents them from injuring themselves
- BIOWAVE REMOVES THE GUARDING EFFECT ASSOCIATED WITH PAIN

Body Position During Treatment

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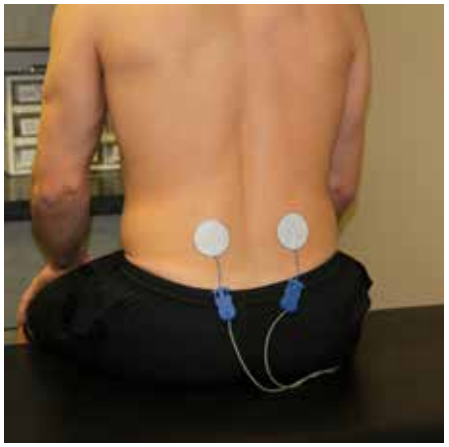
Tissue should be taut or in a stretch position to allow deeper penetration of the electrical field

- **Lumbar** – torso at 90° to legs
- **Neck** – tilted forward
- **Knee** – bent at 90°
- **Shoulder** – neutral position
- **Elbow, Wrist, Hand and Finger** – neutral position and hold a rolled up towel to keep fingers in a comfortable position during the treatment



Lumbar Position

Neck Position

Knee Position

Shoulder Position

Motion During Treatment

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Motion can change the location of the electrical field

Gently and slowly articulate the pain site location to find positioning that causes the ***sensation*** from the electrical field to be ***focused on and encompass*** the location of pain.

The sensation from the electrical field should feel like it's "hitting the spot"

Focusing of Active Electrical Field

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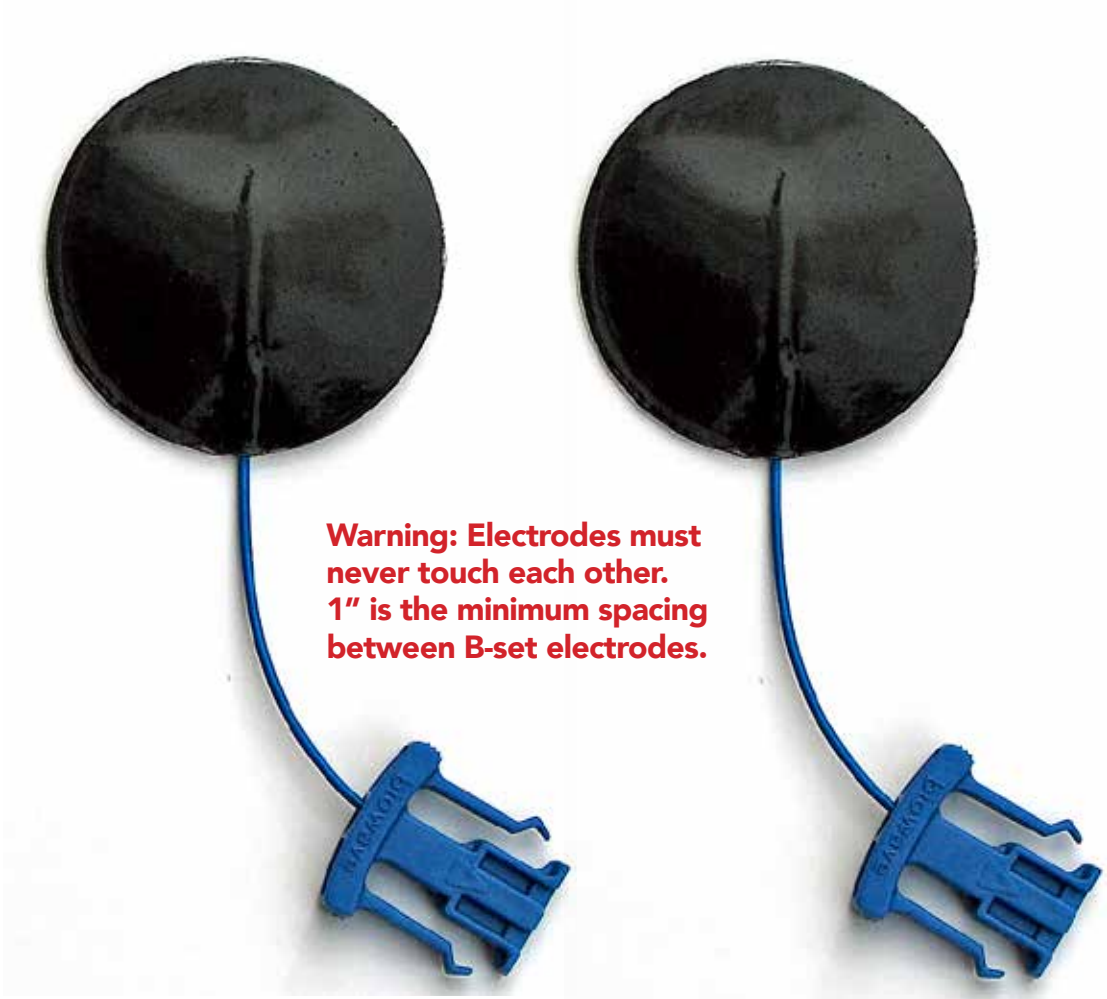
Active electrical field is focused by changing area of electrodes relative to one another



B – Set Electrodes

- Two 2" diameter noninvasive electrodes, both of equal area
- Density of electric field is equal beneath both electrodes
- Electrodes must be placed directly over 2 pain sites or over 1 pain site and over the origin of pain

Used for Treating:

- Two Locations of Pain
- One Pain Site and Origin of Pain
- One Large Area of Pain

Focusing of Active Electrical Field

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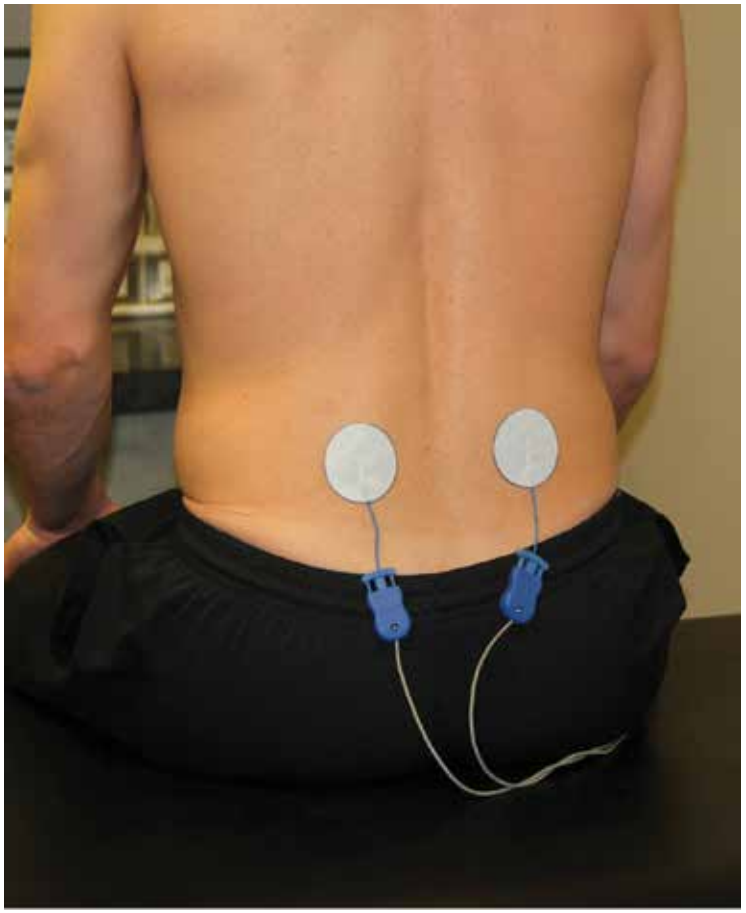
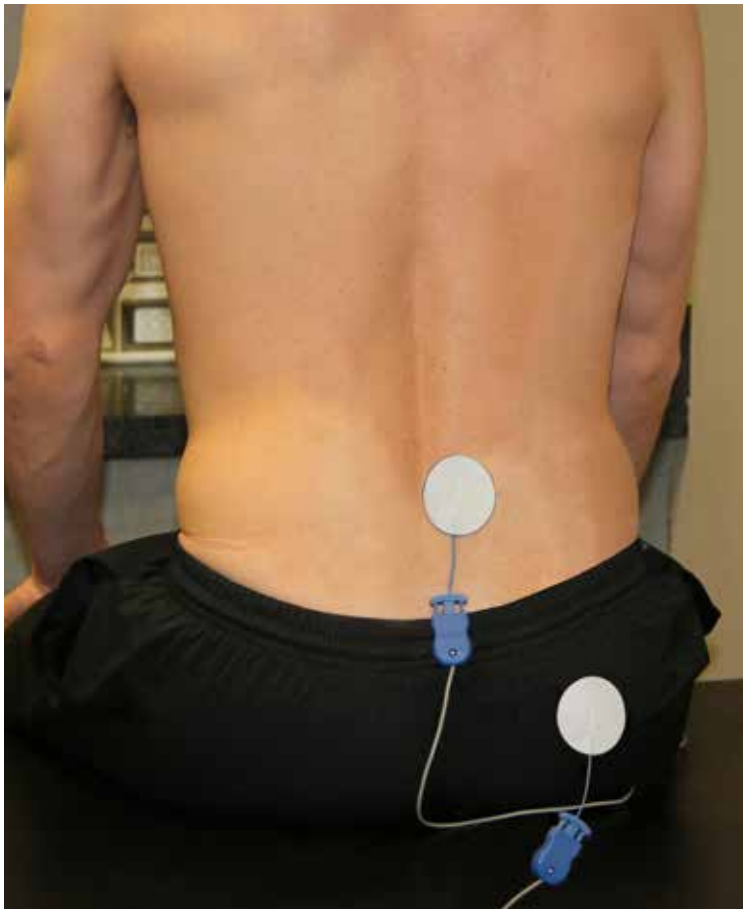
Electrode Placement Example - Two Locations of Pain or Radiculopathy



Two Distinct Locations of Pain e.g. Bilateral Lumbar Pain



Origin of Pain and Most Proximal Location of Pain e.g. Radiculopathy

Focusing of Active Electrical Field

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Electrode Placement Example - One Large Area of Pain

Chronic Pain Throughout the Knee e.g. Osteoarthritis (OA), Postoperative Pain from a Total Knee Replacement (TKR)

Chronic Pain Throughout the Shoulder e.g. Osteoarthritis (OA), Adhesive Capsulitis, Anterior and Posterior Shoulder Pain

Focusing of Active Electrical Field

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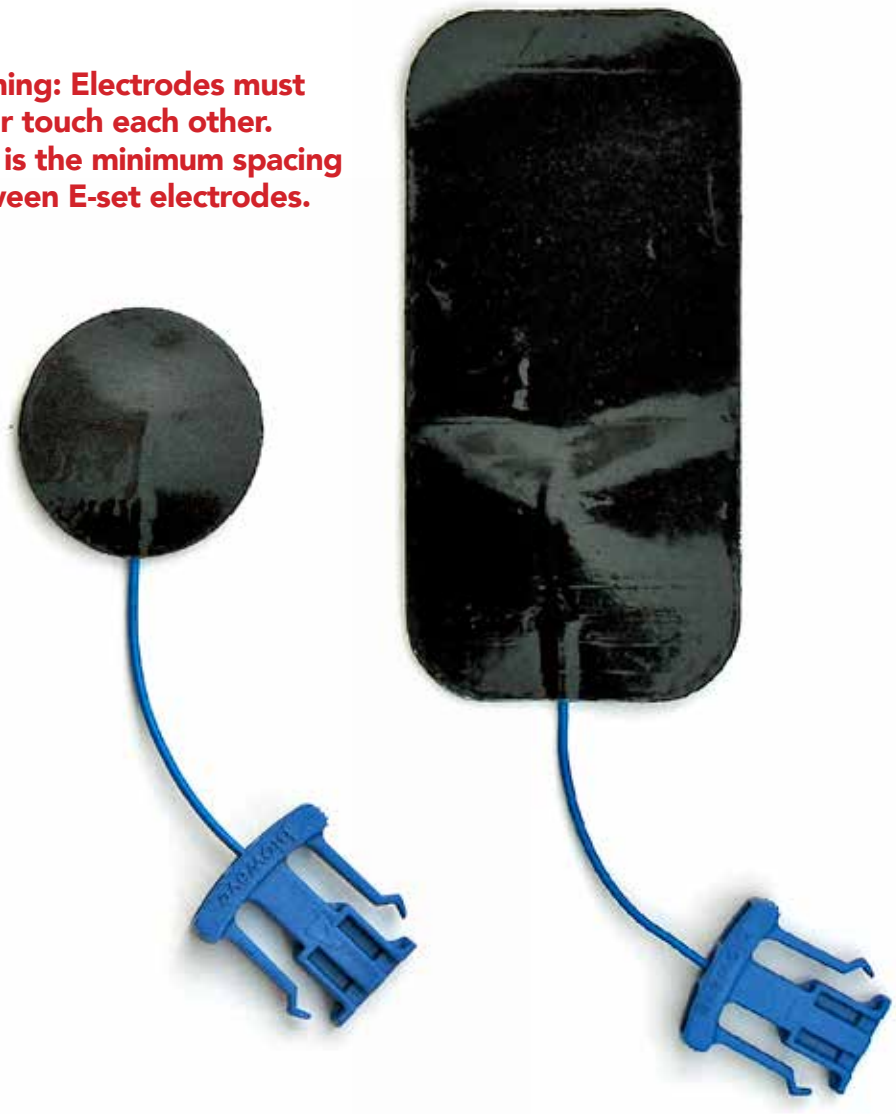
Active electrical field is focused by changing area of electrodes relative to one another

Warning: Electrodes must never touch each other. 1/2" is the minimum spacing between E-set electrodes.



E – Set Electrodes

- One small 1.375" diameter round noninvasive pain site electrode
- One large 2" x 4" rectangular noninvasive dispersive electrode
- Density of electrical field is much greater under smaller round electrode
- Small round electrode is placed directly over location of single pain site
- Larger dispersive electrode must be placed over BONY PROMINENCE near the region being treated
- Bony prominence is most comfortable place to receive stimulation
- Patient can achieve higher intensity under the smaller electrode. Higher intensity = greater efficacy and longer residual benefit

Used for Treating:

- One Location of Pain on the Extremities

Focusing of Active Electrical Field

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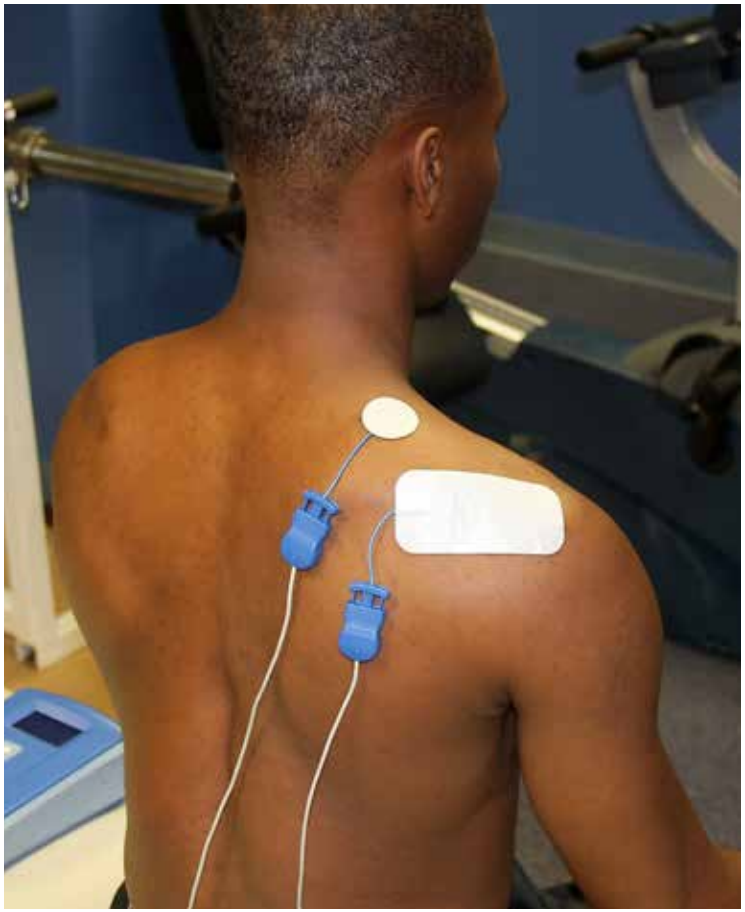
Electrode Placement Example - Single Location of Pain on the Extremities



Placement for Myofascial Pain in Trapezius

Placement for Patellar Tendinitis

Focusing of Active Electrical Field

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Active electrical field is focused by changing area of electrodes relative to one another

Warning: Electrodes must never touch each other. 1" is the minimum spacing between electrodes.

U – Set Electrodes

- One 2" diameter round noninvasive pain site electrode
- One large 5" x 8" rectangular noninvasive dispersive electrode
- Density of electrical field is much greater under smaller round electrode
- Small round electrode is placed directly over location of single pain site in mid torso region of the body
- Larger dispersive electrode is placed horizontally across the lumbar area of the back, a comfortable place to receive stimulation
- Patient can achieve higher intensity under the smaller electrode. Higher intensity = greater efficacy and longer residual benefit

Used for Treating:

- One Location of pain in the mid torso region of the body

Focusing of Active Electrical Field

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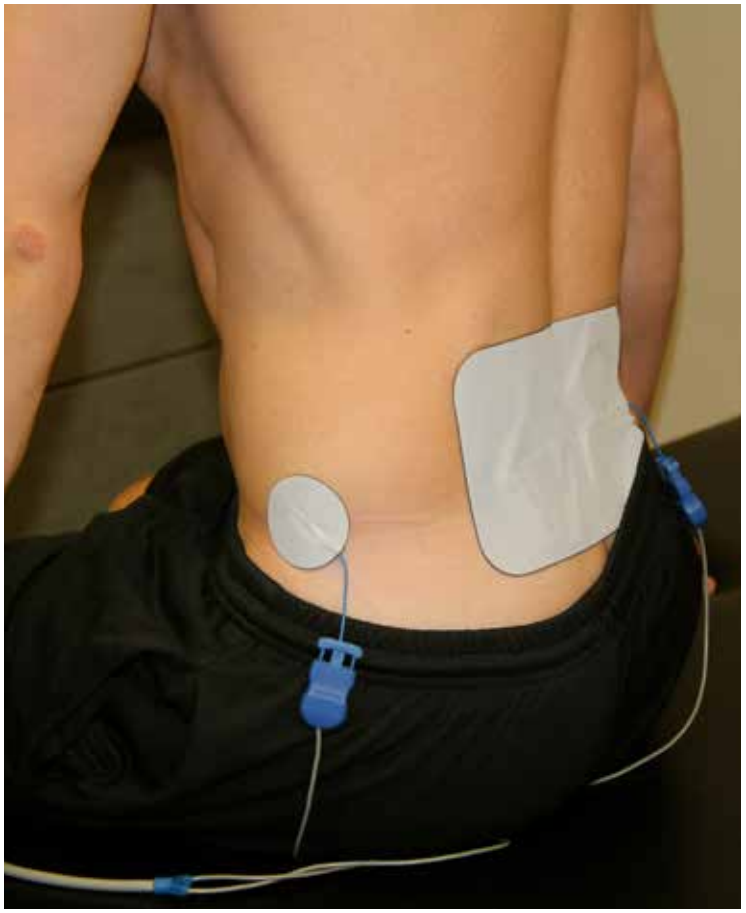
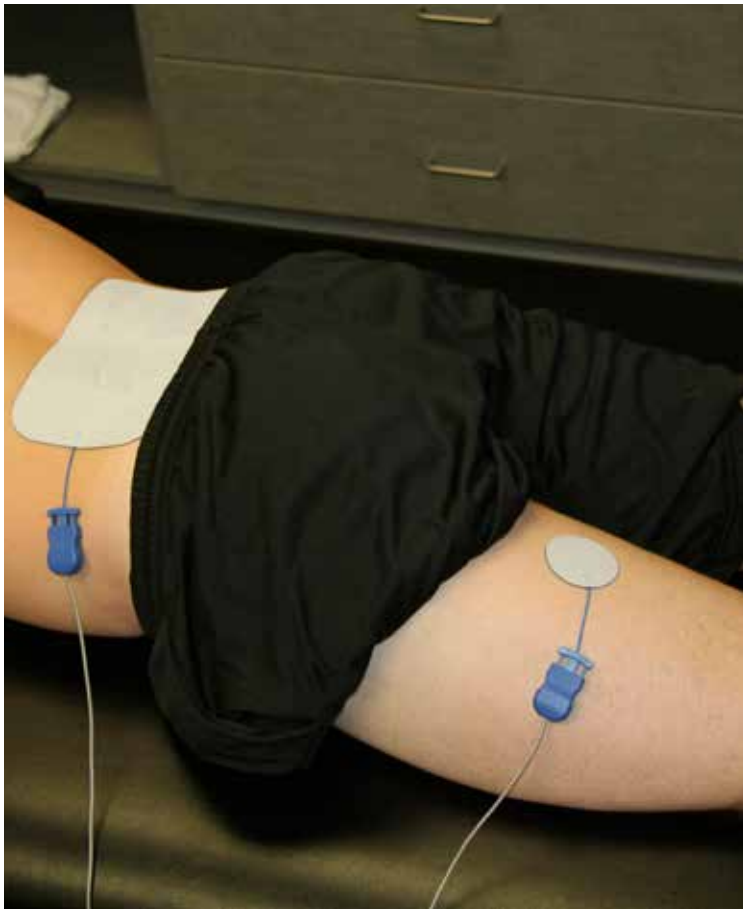
Electrode Placement Example - Single Location of Pain in the Mid-Torso Region



One Location of Pain
e.g. Hip



One Location of Pain
e.g. Hamstring

Treatment **Set Up**

- Treatment may be performed by a physician, PT, ATC, RN, PA, MA
- Determine B, E, or U-set electrodes for pain condition
- Palpate to find center of pain location
- Clean skin to remove oil, lotion and dead skin cells
- Apply noninvasive electrodes per the electrode placement examples
- Attach leadwire cable to electrodes. Either blue leadwire connector can be attached to either electrode.
- Align red dot on metal connector so it is facing up. Gently slide metal connector on leadwire cable into device so it clicks in place.
- Turn on device. Start up screen should read 0.0%.
- Stimulator may sit on counter or sideways on patient's lap so cable exits to the side
- No Programming
- Total set-up time is about 2 minutes

Operation of Device

Start of Treatment

- Patient begins treatment by pressing PLUS button
- Intensity increases in 0.5% increments with each press of PLUS button
- Patient should advance intensity to tolerance so sensation felt is strong but still comfortable
- As body adapts to electrical field, sensation diminishes
  - Patient should continue to advance intensity to keep sensation strong during entire 30 minute treatment
  - As hypoestheisa develops in first 5 minutes, tingling sensation is masked and treatment feels more like a deep massage
- Most patients advance the intensity level to:
  - 30% - 50%, 5-10 minutes into the treatment
  - 50% - 80% by the end of the 30-minute treatment
- Patients should keep advancing the intensity every few minutes throughout the entire treatment to keep the sensation at a strong but comfortable steady state level

Operation of Device

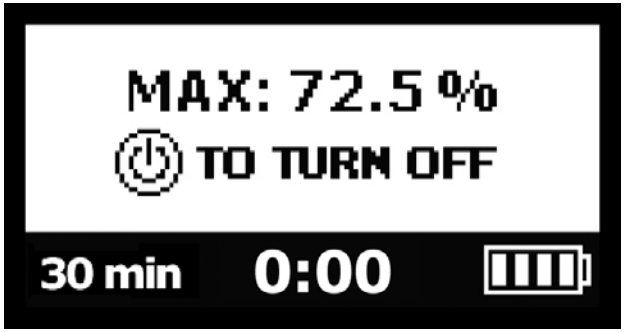
Intensity Range

Typical Intensity Ranges

- Knees, ankles, feet: 60% - 90%
- Lumbar and thoracic back, shoulders: 40% - 60%
- Neck, elbow, wrist: 30% - 50%

Generally patients should try to reach a minimum intensity level of 30%. Some patients may tolerate more, some less.

End of Treatment



- When countdown timer reaches 0:00 min/sec intensity immediately drops to 0.0%
- Max intensity is displayed on LCD and may be noted in Doctor's notes
- Gently peel electrodes off of skin
- Place electrodes back onto either side of blue plastic liner
- Place electrodes back in ziplock bag for storage

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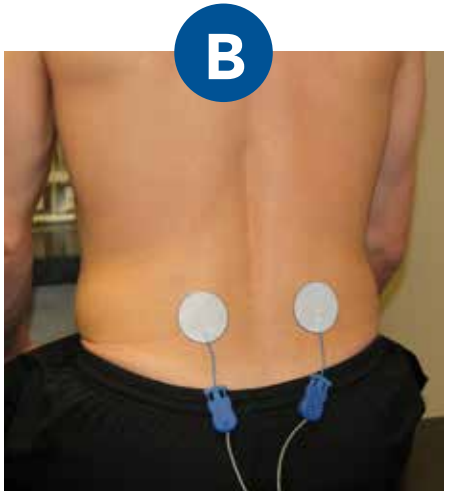
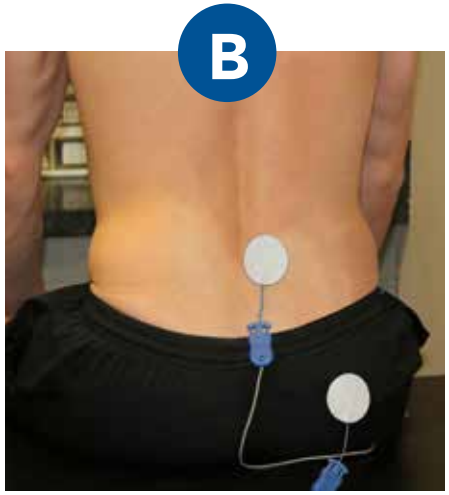
Noninvasive **Electrode Placement Examples**

Noninvasive **Electrode Placements**

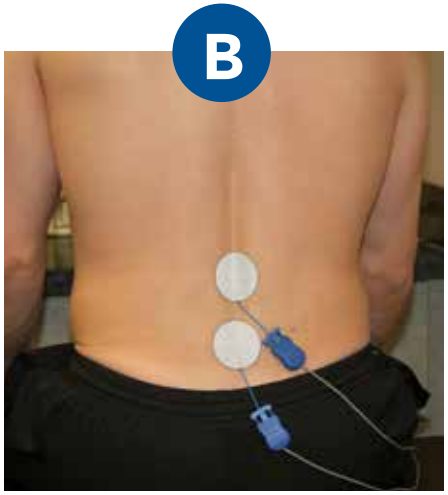
Lumbar Back



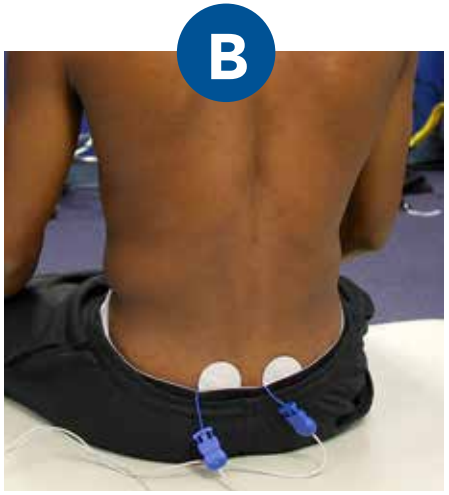
Bilateral Low Back Pain



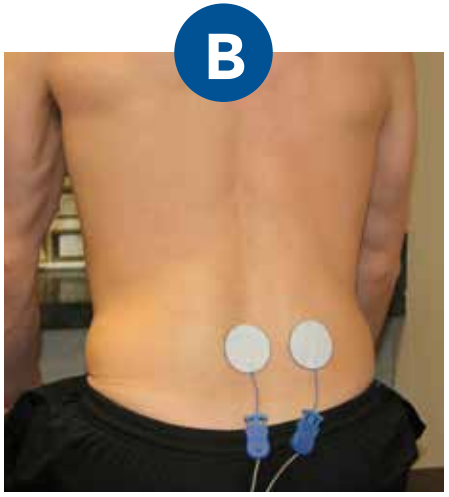
Radiculopathy –
Electrodes Over Source
and Proximal Pain Site



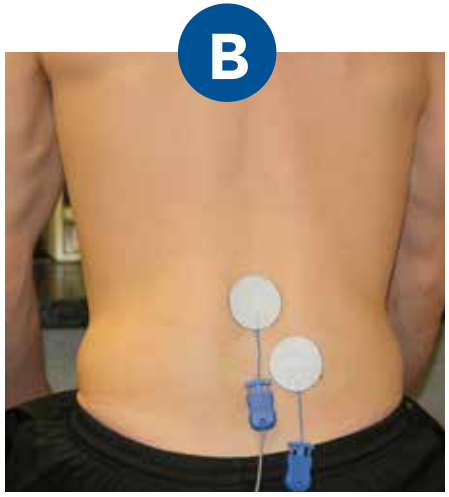
Low Back Pain
Focused Over Multiple Discs



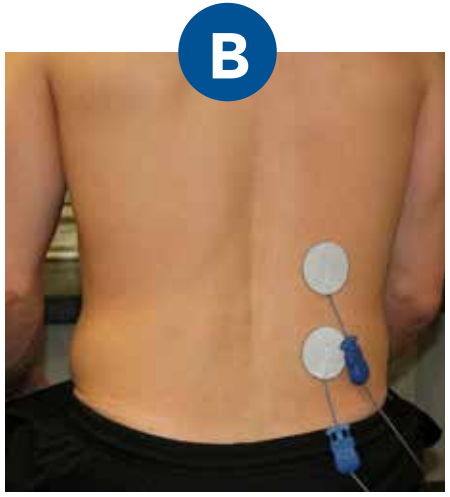
Sacroiliac (SI) Joint Pain



Unilateral Low Back Pain
Focused One Side of Spine



Unilateral Low Back Pain
Focused Over Facet Joint



Rotational Strain
Over Large Area

Noninvasive **Electrode Placements**

Hips, Ribs, Obliques, Groin, Quadriceps, Hamstring

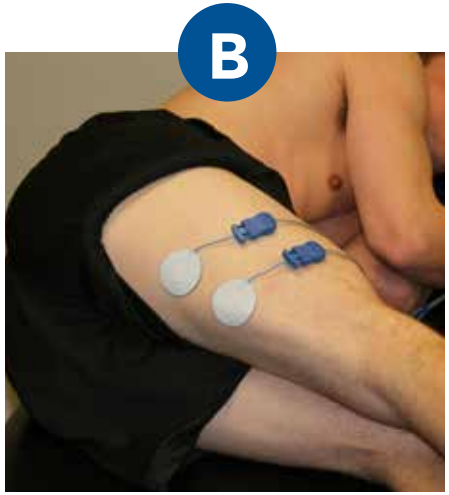
Hip Pain in One Location

Rib or Oblique Pain in One Location

Groin Pain in One Location

Quadriceps Pain in One Location

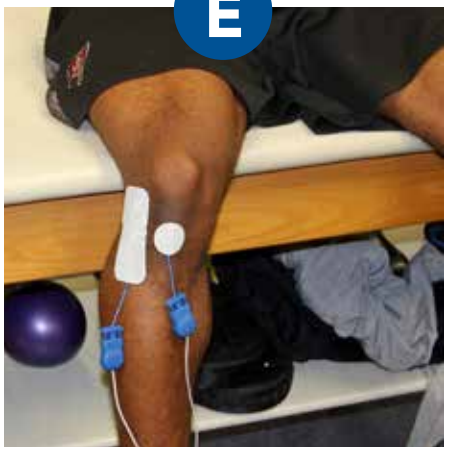
Hamstring Pain in One Location



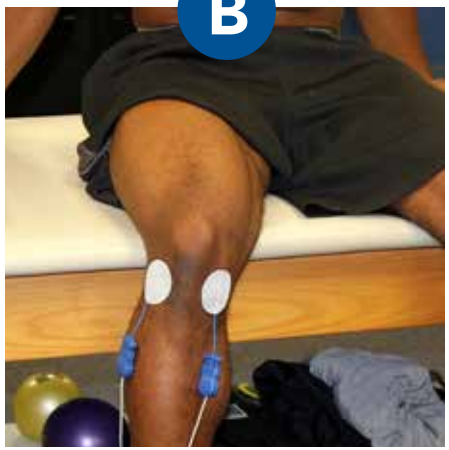
Hamstring Pain Over Large Area

Noninvasive **Electrode Placements**

Knees



Patellar Tendinitis



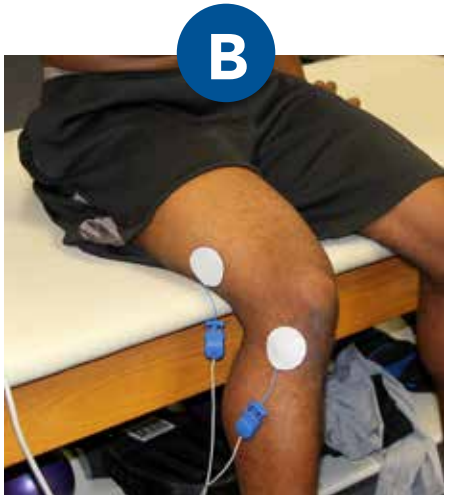
Pain Throughout the Knee
(e.g. OA, TKR, ACL)

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

Quadriceps Tendinitis

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

Illiotibial (IT) Band Pain
in One Location



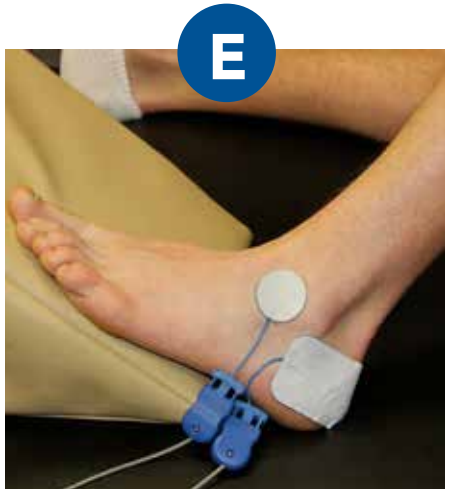
Illiotibial (IT) Band Pain
in Two Locations

Posterior Knee Pain

Noninvasive **Electrode Placements**

Ankles and Feet

Foot or Ankle Pain in Two Locations



Lateral Low Ankle or Foot Pain in One Location

Medial Low Ankle or Foot Pain in One Location

Lateral Posterior Foot Pain

Plantar Fasciitis

Achilles Tendinitis

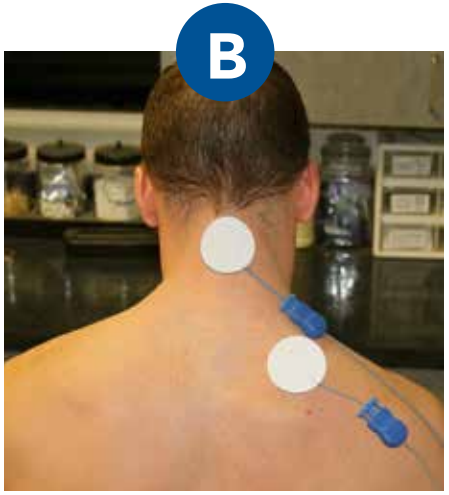
Achilles Tendinitis with Primary Pain at Insertion Point

Neuroma Pain, Metatarsal Joint Pain or Turf Toe Pain

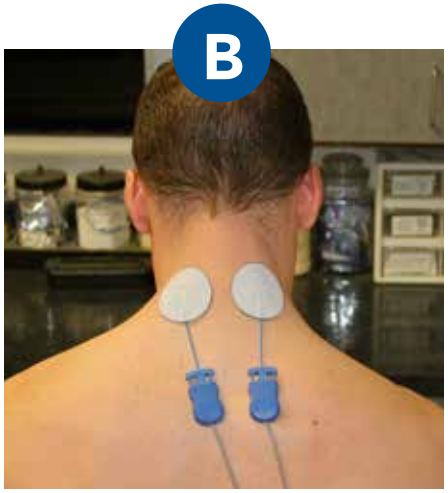
Noninvasive **Electrode Placements**

Neck

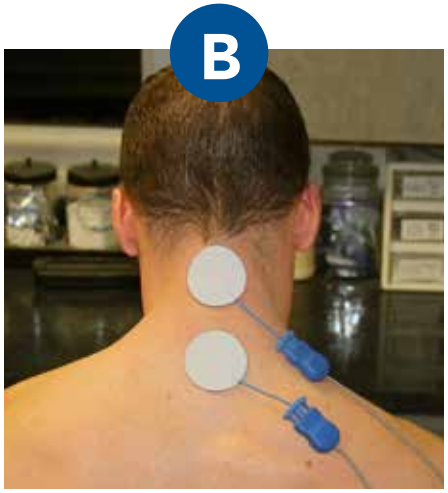
Cervical or Neck Pain in One Location



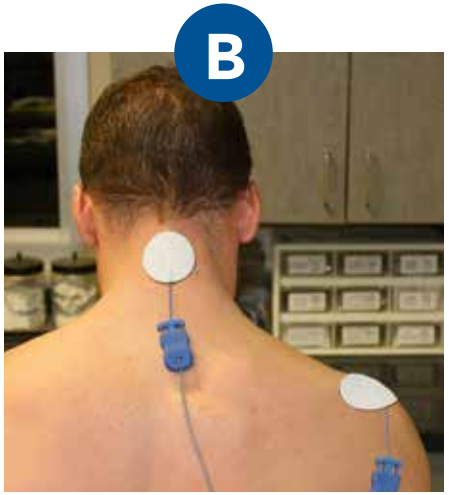
Cervical or Neck Pain in Two Locations



Bilateral Neck Pain



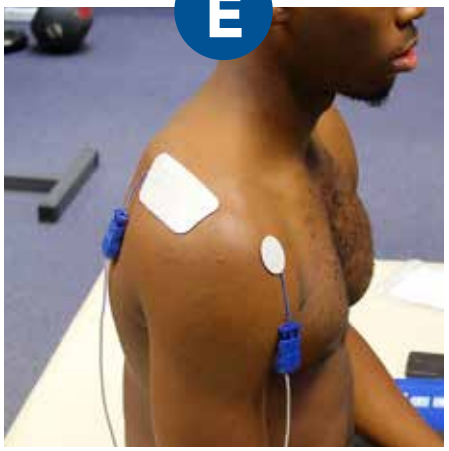
Neck Pain Over Several Cervical Discs



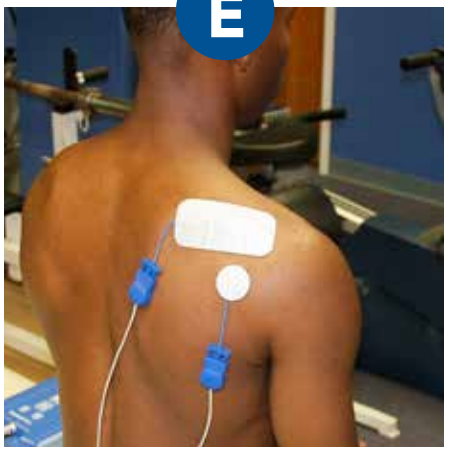
Cervical Radiculopathy

Noninvasive **Electrode Placements**

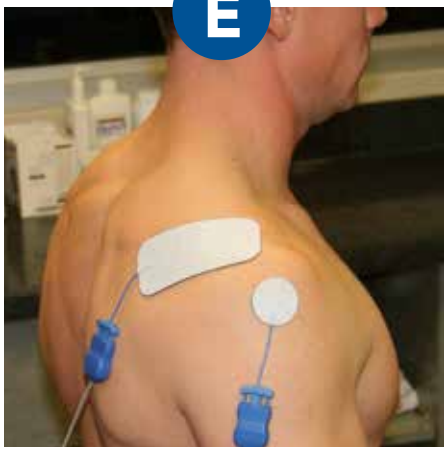
Shoulders



Anterior Shoulder Pain
(e.g. Biceps Tendinitis)

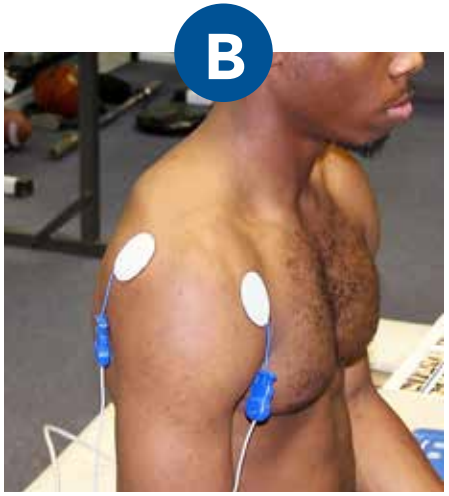


Posterior Shoulder Pain
(e.g. Infraspinatus Sprain,
Posterior Rotator Cuff)

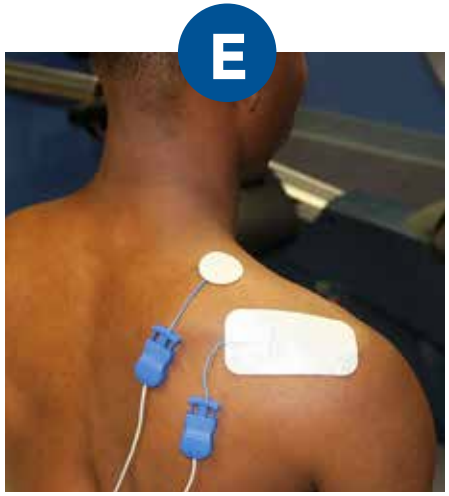


Pain at Edge of Shoulder (e.g.
Rotator Cuff Tendinitis)

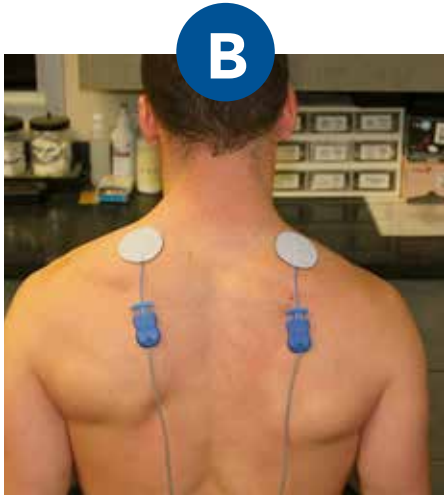
Pain at AC Joint or Inside the
Shoulder (e.g. AC Sprain)



Shoulder Pain in Two Locations
OA or Adhesive Capsulitis



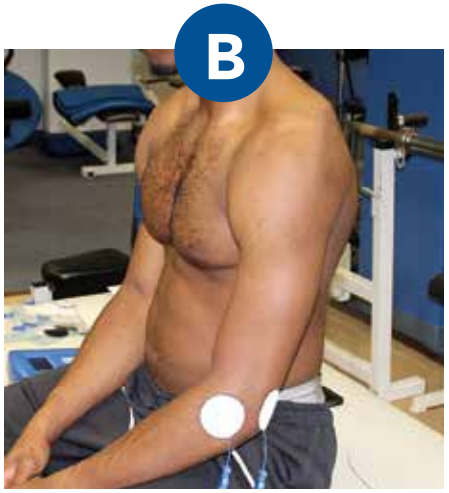
Trapezius Pain in One Location



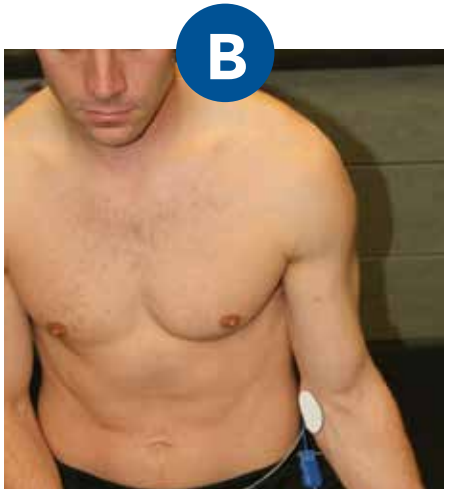
Bilateral Trapezius Pain

Noninvasive **Electrode Placements**

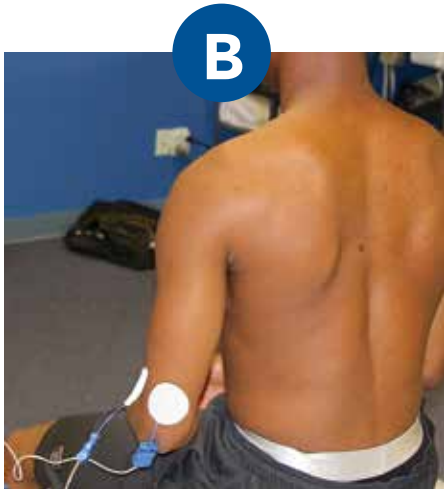
Elbows



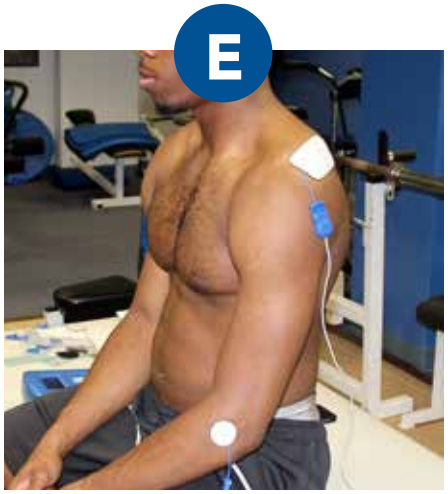
Lateral Elbow Pain
(e.g. Lateral Epicondylitis)



Medial Elbow Pain
(e.g. Medial Epicondylitis)



Posterior Elbow Pain
(e.g. Triceps Tendinitis)



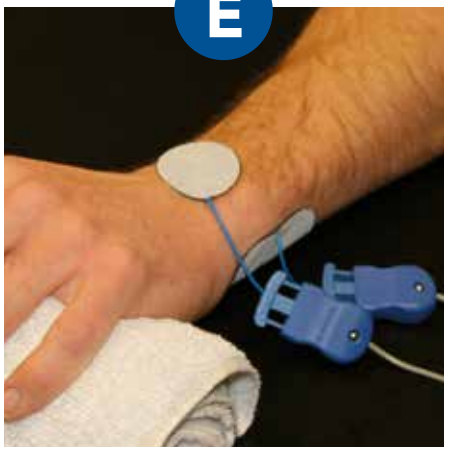
Lateral Elbow Pain
(e.g. Lateral Epicondylitis)

Medial Elbow Pain
(e.g. Medial Epicondylitis)

Posterior Elbow Pain
(e.g. Triceps Tendinitis)

Noninvasive **Electrode Placements**

Wrists, Hands, Fingers



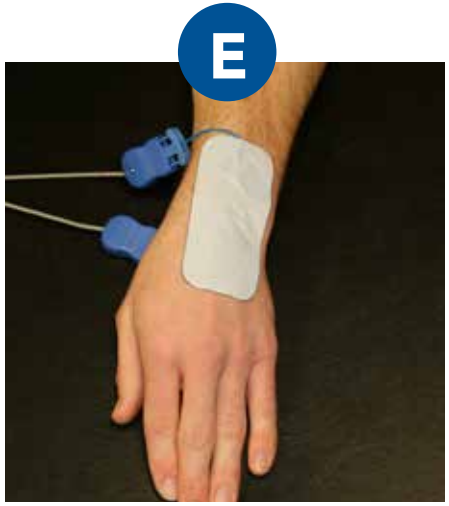
Posterior Wrist Pain (e.g. Sprains, Strains, Tendinosis)

Anterior Wrist Pain (e.g. Sprains, Strains, Tendinosis, Carpal Tunnel Syndrome)

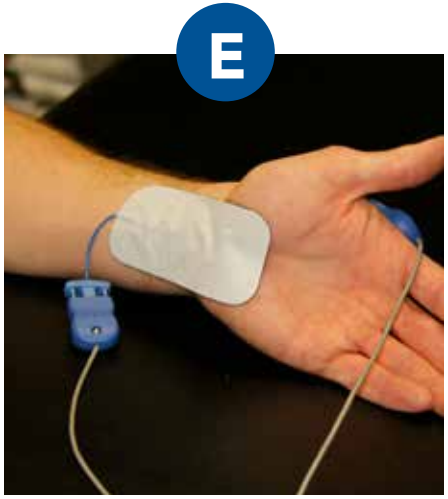
Lateral Wrist Pain (e.g. TFCC Sprain, Tendinosis)

Finger Sprain at Base of Thumb (e.g. UCL Sprain)

Pain at Metacarpal Phalangeal or Interphalangeal Joint



Alternative Placement of Rectangular Electrode for Small Diameter Wrists



Alternative Placement of Rectangular Electrode for Small Diameter Wrists