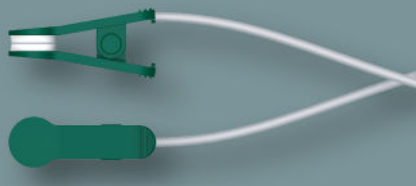
Alpha-Stim® M

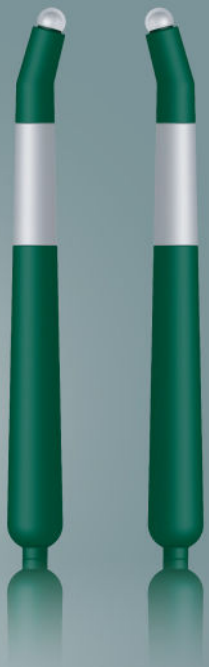
microcurrent & cranial
electrotherapy stimulator

Owner's Manual



ALPHA-STIM®

LET NOTHING STOP YOU™



ALPHA-STIM®

For a successful Alpha-Stim® treatment, follow these simple steps:

1. Scan QR code and watch videos on alpha-stim.com/training.

2. Do an Alpha-Stim® treatment.

3. Feel like yourself again!

Alpha-Stim® M Owner's Manual

Microcurrent and Cranial Electrotherapy Stimulator For Control of Anxiety, Insomnia and Pain

Type BF Equipment. Internally powered.

Consult operating instructions. Read manual thoroughly before using the device.

Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.

Reference Number.

Serial Number.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CE marking certifies that a product has met consumer safety, health or environmental requirements.

Single patient- multiple use.

Date of Manufacture.

Manufacturer.

Non-sterile.

Medical device.

Authorized Representative in the European Community.

IP22

Protection against ingress of solid foreign objects >12.5 mm and dripping water when tilted at 15 degrees.

Use-by-date.

Keep away from sunlight.

Do not use if package is opened or damaged.

Waste electrical and electronic equipment should not be discarded together with unseparated household waste, but must be collected separately.

Lot Number.

Medical Electrical Equipment classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards only in accordance with UL-60601-1 and CAN/CSA C22.2 No.601.1.

Unique Device Identifier.

Unique Device Identifier.

IFU-CUS-001 VER. 3

CONTENTS

FEATURES

The Alpha-Stim® M Device Package Contains:

- 1 set of Earclip Electrodes
- 1 50 ml bottle of Alpha-Stim® Conducting Solution
- 1 empty bottle for use with Alpha-Stim® Conducting Solution
- 2 sets of leadwires
- 100 Probe Electrode Pads (PEPS™)
- 4 silver AS-Trode single person multiple use self-adhesive electrodes
- 2 Smart Probes
- 256 Earclip Electrode Pads (EEPS™)
- Owner's Manual
- Lanyard
- Storage case
- 2 AA 1.5 volt lithium batteries

The Alpha-Stim® M Kit Comes Complete and Ready to Use With:

- Alpha-Stim® M device – The Alpha-Stim® M device is a battery powered electrical device that produces low level electrical current to treat anxiety, insomnia and pain. Device accessories connect to the Alpha-Stim® M to facilitate treatment. Part# 400
- Earclip Electrodes – The Earclip Electrodes are accessories to the Alpha-Stim® M. The Earclip Electrodes transfer the current from the Alpha-Stim® M device to the patient through the earlobes. Part# 401
- Smart Probes – The Smart Probes are electrodes that transfer current from the Alpha-Stim® M device to the patient. Smart Probes are applied in pairs to areas of pain so the Alpha-Stim® M can send current through the Smart Probes to the affected area. Probe Electrode Pads (PEPS™) are placed on the Smart Probes and Alpha-Stim® Conducting Solution is applied before use. Part# 402
- Leadwires – Leadwires are connected to the Smart Probes or AS-Trodes™ then attached to the Alpha-Stim® device to facilitate electrical connectivity. They have two distinct ends. The dual connection end plugs into the jack on either side of the Alpha-Stim® M. The pin plug goes into the Smart Probes or AS-Trodes™. Part# 403

- Alpha-Stim® Conducting Solution – The Alpha-Stim® Conducting Solution is an accessory to the Alpha-Stim® M device. It is supplied as a liquid in a separate bottle. It is a proprietary mineral salt solution that facilitates an efficient transfer of the Alpha-Stim® M current from the device to the electrodes and finally to the patient. Alpha-Stim® Conducting Solution is applied to the Probe or Earclip Electrode Pads to ensure the current can conduct properly. Part# SL50
- Probe Electrode Pads – Probe Electrode Pads (PEPS™) are accessories for the Alpha-Stim® M device. They are felt-like pads made from polyester that allow Alpha-Stim® Conducting Solution absorption to facilitate transfer of the current. The Probe Electrode Pads are held onto the Smart Probes by a rubber band affixed to the felt pad. The pads are saturated with Alpha-Stim® Conducting Solution to ensure proper current flow from the Alpha-Stim® device through the Smart Probes and to the patient. Part# PEP
- Earclip Electrode Pads (EEPS™) are also accessories for the Alpha-Stim® M device. They are felt-like pads made from polyester that allow Alpha-Stim® Conducting Solution absorption to facilitate transfer of the current. The pads have an adhesive backing allowing them to stick to the Earclip Electrodes The adhesive does not contact the patient's skin. The pads are saturated with Alpha-Stim® Conducting Solution to ensure proper current flow from the Alpha-Stim® device through the Earclip Electrodes and to the patient. Part# EEP
- AS-Trodes™ – Package of 4 self-adhesive silver electrode pads that are used with leadwires to transfer the electrical waveform from the Alpha-Stim® M device to the patient. Two AS-Trodes™ must always be used in order to complete the electrical circuit. AS-Trodes™ are composed of RG-63B Hydrogel. Part# AT7
- Owner's manual – Describes what items come with the device and how to use it. Includes a symbol table along with contraindications, warnings and precautions. Device use is the same for the healthcare provider as it is for use directly by the patient. Part# 405CUS
- Lanyard – The lanyard is an optional accessory for the Alpha-Stim® M device. It is a cloth cord to hold the Alpha-Stim® M device around the neck when in use, if desired. Part# 404
- Storage Case(s) – Alpha-Stim® M comes in a hard case. An optional soft case can be purchased separately. Part#s 406 & 407

- 2 AA batteries – The Alpha-Stim® M is powered by lithium batteries which are supplied in the initial order. They provide the energy source and are placed inside the Alpha-Stim® M before use. Batteries can be replaced with off-the-shelf lithium batteries as needed. Part# 4400

Alpha-Stim® M Features Include:

1. Full digital control for precision, consistency and reliability.
2. Choice of Earclip Electrodes, Smart Probes, or AS-Trode™ electrodes.
3. Back lighting when any button is pressed.
4. Continuous circuit checks when electrodes are in contact with skin.
5. 3 frequency selections (100,1.5 and 0.5 Hz). 0.5 Hz is recommended.
6. 10 second Smart Probe cycle begins on contact with skin.
7. 10, 20, 40 or 60 minutes countdown cycles to auto-off.
8. Continuous time elapsed timer.
9. Large timer display.
10. 2 independent channel controls providing 0 - 600 microamperes (μA) of current.
11. Frequency, current and treatment time may be locked to preset values throughout entire treatment session.
12. Mute option for all functions (except Smart Probe).
13. Cumulative timer.
14. Choice of belt clip or lanyard so the Alpha-Stim® M can be worn around the neck.
15. 30 minute auto-off when not in use.
16. Able to withstand electrostatic discharges of up to 15,000 volts.
17. Automatically and permanently disables itself should a single fault develop within the device causing the current to exceed 1300 μA.
18. Battery strength indicator.
19. Probe Electrode Pads (PEPS™) and Earclip Electrode Pads (EEPS™) requires Alpha-Stim® Conducting Solution (included).
20. 5 year limited warranty.
21. Protection against ingress of solid foreign objects >12.5 mm and dripping water when tilted at 15 degrees.
22. Uses 2 AA 1.5 volt batteries (included in the package but not installed).

INSTALLATION OF BATTERIES

Inserting batteries

- Slide the cover of the battery case on the back side of the device in the arrow direction.
- Insert the enclosed batteries according to the symbols (+/-) into the base of the battery case.
- Close the battery case again and push the cover towards the device until it snaps into position.
- When changing the batteries, only use 2 AA 1.5 volt lithium batteries.

Danger of chemical burns! Leaking battery acid may lead to chemical burns.

- Avoid contact between battery acid and skin, eyes and mucous membranes.
- If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of plain water immediately and seek medical attention if necessary. Keep batteries out of children's reach. If a battery has been swallowed seek medical attention immediately.
- Do not disassemble, recharge, short circuit batteries or dispose of them in fire. There is a risk of explosion.
- Remove batteries from the device if you do not use it for a prolonged period.
- Do not dispose of used batteries in the household garbage, instead dispose of them as special waste or at a battery collection point in a specialist outlet.

A Note to Healthcare Practitioners

Thank you for recommending the Alpha-Stim® M. This manual is written for the person who will use the Alpha-Stim® M, but your input will be invaluable to your patient. One way to help is to explain to your patient exactly where his or her problem is located. You might also suggest specific electrode locations where a particular pain may be originating from.

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." However, this does not mean that all CES devices have demonstrated effectiveness for all specific anxiety and insomnia categories. Evidence and information specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the specific populations for which EPI has evidence regarding benefits and risks. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Electromedical Products International, Inc. is available to help serve the needs of your patients. New research is often available that may have a direct bearing on a patient's specific disorder. Feel free to write, call, fax, or email EPI for any reason at all. Also, check the website regularly for new information. We welcome your input in the form of testimonial letters or emails.

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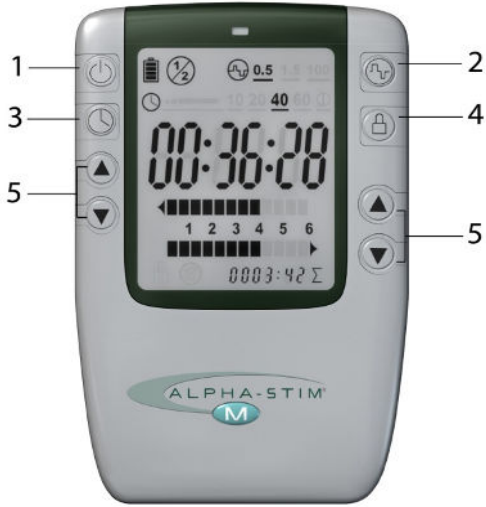
CONTROL BUTTONS



1. **On - Off**

2. **Frequency**. 0.5 Hz is the strongest frequency setting and the one most people will achieve the best results with for all applications (Earclip Electrodes, Smart Probes and AS-Trode™ electrodes).

3. **Timer**. Smart Probe 10 second waveform cycle starts when electrodes touch skin. Countdown timers: select **10, 20, 40 or 60 minutes.** **Continuous time elapsed timer**.

4. **Lock**. Press 2 times within 5 seconds to lock or unlock settings during treatment if desired.

5. or **Current**. Increases or decreases current for each channel. Increases at 50 microamperes (μA) per second when held down. Decreases at 100 μA per second. When the device is turned on, the current defaults to 100 μA except on Smart Probe setting which defaults to current setting from previous use.

LCD Display

1. **Light Sensor** lights LCD screen for 10 seconds in a dark room when any button is pushed.

2. **Test Circuit** symbol and an audio warning indicates device is not treating for one or both channels (the number of the Channel that is not working will appear). The timer will stop and shut down in 30 minutes if nothing else is done. Current must be set above 0 µA and moistened electrodes must be in contact with skin for Alpha-Stim® M to work. An audible signal and resumption of the timer occurs the instant the integrity check circuit determines everything is working properly.

3. **Battery Charge** indicator. Replace battery when only 1 bar remains at which time the device shall give out an audible low battery warning and repeat the warning every 10 minutes (unless the mute function is on).

4. **Frequency** setting indicator. 0.5, 1.5, or 100 Hz for both Channels.

5. **Timer** setting indicator. Select  Smart Probe 10 second cycle begins on contact with skin, 10, 20, 40 or 60 minutes countdown to auto-off or ⦶ Continuous count forward timer.

6. **Time** remaining on all settings except ⦶ Continuous which shows time elapsed.

7.  0 - 600 microamperes (μA) of current for **Channel 1**.

8.  0 - 600 microamperes (μA) of current for **Channel 2**.

9. **Lock** is on when display is lit.

10. **Mute** feature for all settings except Smart Probe. To turn on or off, press the key sequence: **Lock-Timer-Lock**.

11. **Σ Cumulative Timer** records total hours and minutes Alpha-Stim® M has been in use.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® M Microcurrent Electrical Therapy (MET) and Cranial Electrotherapy Stimulation (CES) device. You have purchased a quality medical device. In so doing, you have already taken the first step to a more comfortable life.

Electromedical Products International, Inc. (EPI) is a leading innovator of the finest state-of-the-art medical technology available to improve the quality of your life. EPI and its distributors are dedicated to helping those who use our products. We have technical experts available to assure you receive the best possible results from treatment. Telephone consultations in English may be scheduled with you or your doctor Monday through Friday, 9 AM until 5 PM, Central Time (Texas, USA). You may also communicate with us by mail, fax, or email. The company stands behind all our medical devices with a 5 year limited warranty.

The Alpha-Stim® M is a precision medical device used for treatment of anxiety, insomnia and pain. Potential side effects of drugs are avoided. After treatment, there are usually no physical limitations imposed so you can resume normal activities.

The treatment is simple and easily self-administered at any time. People using the Alpha-Stim® M usually report a pleasant, relaxed feeling of well-being.

The current is applied by hand-held Smart Probes or self-adhesive AS-Trode™ electrodes for pain control, or by Earclip Electrodes for anxiety and insomnia. During a treatment you may experience a mild tingling sensation at the electrode sites. If the current is too high, you might experience dizziness and nausea which can be alleviated by reducing the current.

Once you understand the basic product features and procedures, you will find the Alpha-Stim® M is easy to use. Please read this entire manual thoroughly before using it. Be sure to follow the general instructions given herein and any specific directions from your healthcare practitioner.

The Alpha-Stim® M was developed by Dr. Daniel L. Kirsch, a neuroscientist, and Raymond Chan, an engineer. Dr. Kirsch has been a leading pioneer in the field of electromedicine since 1972. He was board-certified in pain management by

the American Academy of Pain Management in 1990, and awarded the Richard S. Weiner Pain Educator of the Year Award by AAPM in 2008. He became a Fellow of the American Institute of Stress in 1997 where he was elected President in 2012. He was also the only American Member of InterPain, the organization for pain specialists in Germany and Switzerland. He was the Electromedical Department Editor of the journal, *Practical Pain Management* and Editor-in-Chief of *Contentment* and *Combat Stress Magazines*. Dr. Kirsch has served as Clinical Director of the Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center in New York City and the Sports Medicine Group in Santa Monica, California. He also served as an expert research and practice consultant to Veterans Affairs Medical Centers and the United States Army and Navy. He is an author of books and articles and lectured frequently to physicians and psychologists worldwide on pain and stress until his retirement in 2020.

DESCRIPTION

Results in electromedicine are based on the design of the waveform, the amount of current, the location of the electrodes, and the amount of time it is used. The Alpha-Stim® M is a microcomputer incorporating the latest advances in solid state electronics. All components are of the highest quality available to assure the user reliable and trouble-free performance. The design assures electrical safety by the use of readily available 1.5 volt AA batteries.

The Alpha-Stim® M was developed through original research by Electromedical Products International, Inc. It is a precision technology which generates a modified square, bipolar waveform of 0.5, 1.5, or 100 Hz (pulses per second), at 50 to 600 microamperes (1 μA is one-millionth of an ampere), in a 50% duty cycle.

The Alpha-Stim® M is small, compact and light-weight. It was designed to be versatile. It can be used in a healthcare practitioner's office, clinic or hospital, for portable and quick response needs such as emergency medical or military applications, as well as for self-administered treatment at home on a scheduled or as-needed basis.

The controls are fully digital for precision, consistency and reliability and at the same time simple and easy to operate. An adjustable timer and a locking option that freezes the treatment time, frequency and current assures the prescribed treatment waveform and dosage even if you are distracted or fall asleep. The amount of current can easily be decreased to assure comfort or increased to reduce treatment time.

The Alpha-Stim® M may be categorized into two general categories. *Microcurrent Electrical Therapy*, or MET, is a generic term used to describe low level current used for pain control typically applied for 2 to 5 minutes through Smart Probes, or AS-Trode™ self-adhesive electrodes for longer applications. It is distinguished from previous forms of transcutaneous electrical nerve stimulation (TENS) in that MET uses far less current but delivers the current in much longer pulses. Whereas TENS devices must be constantly worn because they offer virtually no residual effect, MET effects are long-lasting and cumulative. The second category, represented by the application using the Earclip Electrodes to treat the brain for anxiety and insomnia is known as *Cranial Electrotherapy Stimulation*, or CES. The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

One important feature of the Alpha-Stim® M is an electronic circuit which operates to maintain a nearly constant current flow to the electrodes minimizing the effects of skin resistance variations. The Alpha-Stim® M continuously performs self-diagnostics to assure that all aspects of the circuitry are always working properly, and the electrodes are making adequate contact with the skin. Ergonomic and user-friendly features (such as the Smart Probe, lock, auto-off timers and alarm that warns you if an electrode falls off) make the Alpha-Stim® M reliable, easy, quick, and fun to use.

ELECTROMEDICAL THERAPEUTICS

The application of electromedical currents is not a new concept. Ancients recognized the therapeutic value of naturally occurring electrical phenomena long before William Gilbert defined electricity in 1600. Both Aristotle and Plato referred to the Black Torpedo (electric ray fish) prescribed in 46 AD by the physician Scribonius Largus for the relief of a variety of medical conditions from headaches to gout (head to foot). In the 1800s dentists reported pain reduction using early and somewhat crude electromedical devices.

By the late 1800s electrical devices were in widespread use to manage pain and claimed to cure a variety of medical disorders. The exuberant claims of early electrical technologies facilitated by the political clout of the pharmaceutical lobbies caused this form of therapy to fall into disrepute by the medical profession in the early part of the 20th century. As a result, medical colleges stopped teaching electrotherapeutics. Biophysics was virtually eliminated from medical practice leaving chemistry as the master science and with it the burden of responsibility for curing all disease. Now, in the 21st century it is clear that chemistry as the sole therapeutic model for medicine has not lived up to its promise, causing modern medicine to re-examine the potential of biophysics.

Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Rouxeau of France in 1902. Initially, this method was called electrosleep as it was thought to be able to induce sleep. Research on using what is now referred to as Cranial Electrotherapy Stimulation (CES) for treatment of anxiety and insomnia began in Russia during the 1950s and first came to the USA in the 1960s.

In 1965 Drs. Ronald Melzack of Canada and Patrick Wall of the United Kingdom published a paper explaining a new comprehensive theory of how pain is processed by the nervous system. Their *Gate Control* theory also explained how electrical stimulation can influence the physiology of pain pathways. By 1967 electrical devices were surgically implanted to control severe low back pain. Surface electrical stimulation devices were used to test the person's response

as a means of screening surgical candidates and to determine the most effective electrode site for implantation. It was soon discovered that electromedical treatment through the skin (transcutaneous) was also effective and could be used for pain relief alone, avoiding surgery. Since then, these devices, known as transcutaneous electrical nerve stimulators (TENS), have become widely accepted by healthcare practitioners to control many forms of pain.

All life is of an electrochemical nature. There are extensive electrical fields at work throughout the universe and the body. The nervous system, for example, has long been known to work through both electrochemical and purely electrical signals. In fact, all molecules are held together by electrical bonding at the atomic level. Basic science research into the nature of bioelectrical control systems in humans and animals led medical scientists such as Dr. Robert O. Becker of the USA[1] and Dr. Björn Nordenström of Sweden[2] (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on our latest understanding of biophysics.

Alpha-Stim® technology incorporates these theories and is proven more efficacious than most other treatments for the conditions it treats. The original Alpha-Stim® Model 2000 weighed 40 pounds and cost $5,850 when it was first introduced in 1981. The Alpha-Stim® M utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate anxiety, insomnia and pain with far less current than used in previous technologies, and experience long term and cumulative relief with as little as only a few minutes of treatment every other day. When used properly, we trust your new Alpha-Stim® M will improve the quality of your life.

[1] Becker, Robert O. *The Body Electric*. New York: William Morrow and Co. 1985.
[2] Nordenström, Bjorn E.W. *Biologically Closed Electric Circuits*. Stockholm: Nordic Medical Publications, 1983.

Clean Skin

Clean the skin around the treatment area before applying electrodes. Use mild soap and water, alcohol pads or antibacterial wipes and allow skin to dry. Areas where skin oils or dirt have accumulated, or where cosmetics or hair spray have been used, must be thoroughly cleaned to ensure adequate conductivity. Monitor skin condition prior to and post treatment. Skin irritation may develop in light skin. If skin burns are noted following treatment, discontinue use and apply an appropriate skin cream. Varying electrode locations may minimize irritation.

Evaluate Your Pain

Evaluate your pain before and from time-to-time during and after each treatment. Your healthcare practitioner can give you guidelines to help you do a quick, simple evaluation. This may consist of simply moving into a position that causes you to be more aware of your pain, then noting the level of pain you are experiencing on a 0 (no pain) to 10 (maximum pain) scale at the beginning and end of each treatment. Moving the affected body part through its range-of-motion and observing the increased range along with the decreased pain after treatment are good indicators of progress. Because Alpha-Stim® works quickly for most people it is helpful to use these reference parameters to determine effectiveness throughout a single treatment session. Keeping a daily (or even as often as hourly) chart of changes in your pain locations and levels on a 0 to 10 scale will help track progress and may be useful in determining the best areas to treat. To help you understand this system, a description of pain levels follows (use odd numbers for between values, *e.g.,* Level 1 would indicate a very slight pain that does not interfere with activities):

Pain Level	Description
0	No pain.
2	Mild pain; only aware of pain when focused on it. Considered nagging and annoying but only slightly interferes with activities of daily living (ADL).
4	Tolerable pain; can be ignored somewhat.
6	Distressful pain; interferes significantly with ADL.
8	Severe pain; can not concentrate or do anything but simple tasks.
10	Disabling pain; unable to perform ADL.

It may also be helpful to keep a diary of Alpha-Stim® treatment times, duration of each treatment, frequency (Hz) and current (μA) settings along with the electrode locations you use.

USE THE ALPHA-STIM® M WITH CONFIDENCE

Because the Alpha-Stim® M uses such a low level of current, many people do not feel anything at all, even at the maximum current level. Do not be concerned if you can not feel the current; this is perfectly normal, and your perception of the current will not affect the results. The Alpha-Stim® M is working unless the **Test Circuit** symbol appears displaying the number 1 or 2 for the Channel you are using, or the low battery indicator is down to the last bar. Some people only achieve maximum relief when using the Alpha-Stim® M for hours every day, or even all the time. While this is rarely necessary it is also not harmful – so use the Alpha-Stim® M with confidence knowing you have a safe and effective tool and LET NOTHING STOP YOU™.

Quick Guide

Read the following instructions carefully. Then, after you have used the Alpha-Stim® M once, you simply press the Power button, place the Smart Probes, AS-Trode™ electrodes, or Earclip Electrodes in the appropriate place(s) and adjust the current to a comfortable level. The time and frequency parameters default to the previous settings until changed. *That's all there is to it!* Adjust the current up or down to a comfortable level at anytime during treatment, if necessary.

Microcurrent Electrical Therapy (MET) To Treat Pain with Smart Probes

1. Plug dual connector end of wires into **Channel 1** or **Channel 2** jack and pin plugs into **Smart Probes**. **Figure 1**.

2. Apply **Probe Electrode Pads (PEPS™)** to Smart Probes by placing clean Probe tip into **PEP™** in **PEP™** case. **PEP™** case opens with label on bottom. **Figure 2**.

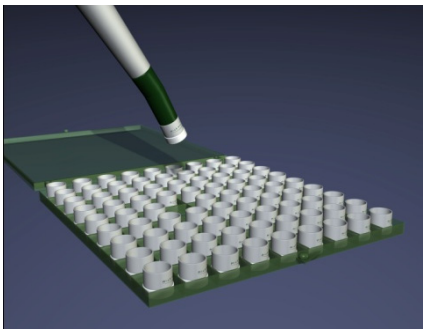


Figure 2

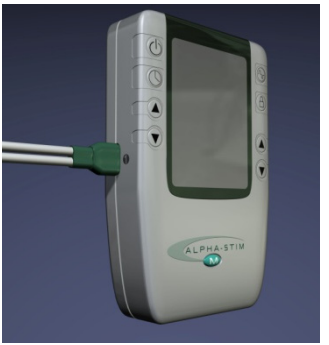


Figure 1

3. Press **Power** on.

4. Set **Frequency** to 0.5 Hz or desired setting. For joint problems (*e.g.,* shoulders, elbows, wrists, fingers, hips, knees, ankles, toes) use 100 Hz for 10 - 20 seconds immediately followed by 0.5 Hz. Try 1.5 Hz if 0.5 Hz is not effective.

5. Set **Timer** to Probe setting.

6. Set **Current** on Channel in use to 6 (600 µA). Decrease immediately if uncomfortable. When used on or near the head, immediately decrease the current if dizziness or nausea develops. This may happen initially or several minutes into treatment. Decreasing the current will immediately relieve these unpleasant feelings.

7. Saturate **PEPS™** thoroughly with several drops of **Alpha-Stim® Conducting Solution.** Repeat as necessary throughout treatment. **Figure 3**.

8. Note level of pain for all areas being treated and any limitations of movement in joints before, during, and at conclusion of treatment. It helps to keep a diary of pain levels where 0 is no pain and 10 is the worst the pain being treated has been, along with time of day, duration of treatment, frequency and current levels used, and the most effective electrode locations.

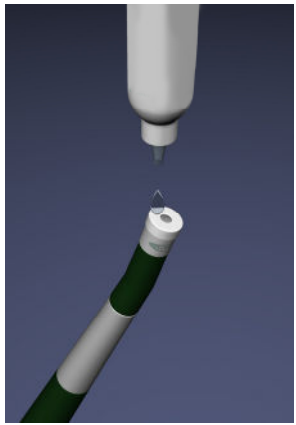


Figure 3

9. Apply **Smart Probes** to clean, dry skin. Cycle will start with 2 beeps on contact with skin and end with a single beep. Hold **Smart Probes** firmly against skin for the entire 10 second cycle before moving to next treatment location. Lift Probe off skin and replace to repeat treatment at the same location. See **Smart Probe Treatment Strategies** for guidelines for Probe placements. **Figure 4**.

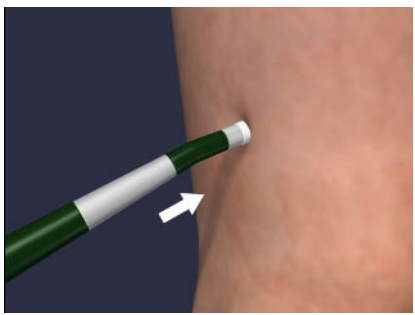


Figure 4

10. Always place the **Smart Probes** to direct the current between them through the area being treated. Two **Smart Probes** must always be used together to complete the electric circuit. **Figure 5**.

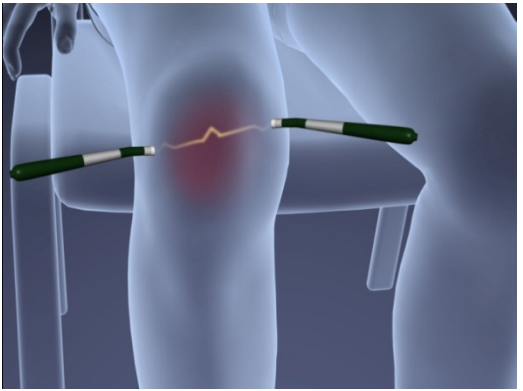


Figure 5

11. Continue treatment until pain is completely gone or maximum relief is achieved. There is usually an increased range of motion in treated areas. Sometimes treated areas of the body feel stiff or tight after the pain is gone. This will wear off over time.

12. Turn **Power** off.

13. Discard **PEPS™**.

14. Finish with **Cranial Electrotherapy Stimulation** (see directions on page 28).

15. Repeat as necessary. Results usually improve and last longer with additional treatments.

16. Store Alpha-Stim® M away from children.

SMART PROBE TREATMENT STRATEGY A

1. First treat beyond the treatment area (*e.g.,* the entire leg for knee pain) in at least 2 places directing the current between the **Smart Probes** through the treatment area. **Figure 6.1**.

2. Treat closer in, around and through the area being treated for about 1 minute applying the **Smart Probes** at about 6 different angles of approach with the **Smart Probes** always placed on opposite sides of the body (*e.g.,* front to back or side to side). **Figure 6.2**.

3. Treat the same body part on the opposite side of the body in at least 2 places (such as other knee, wrist, other side of back, etc.). **Figure 6.3**.

4. Connect the two sides by placing one **Smart Probe** below the treatment area and the other in the same place on the opposite side of the body in a few places. For example, follow "a line" under and around each knee placing the **Smart Probes** at intervals along the line. **Figure 6.4**. For back pain place **Smart Probes** in at least 3 places on both sides of the body at the level being treated and slightly above and below. This directs the current through the nerves and spinal cord. **Figure 7**.

5. Repeat as necessary, varying **Smart Probe** positions but always directing the current between the **Smart Probes** through the area being treated.

6. Continue treatment until pain is completely gone or maximum relief is achieved.

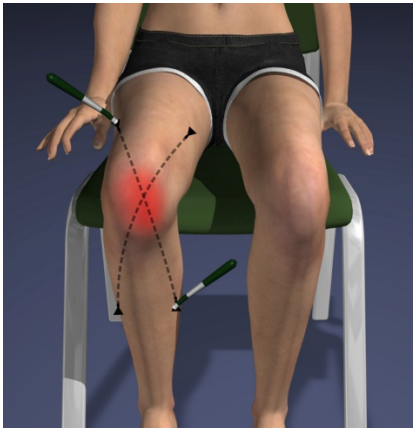


Figure 6.1

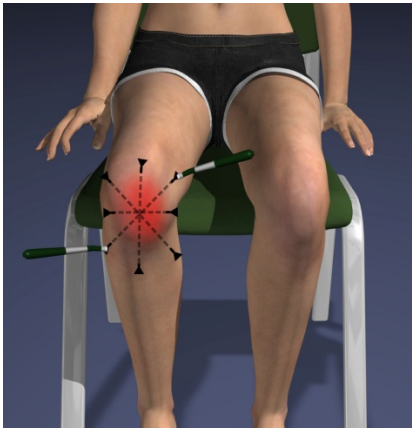


Figure 6.2

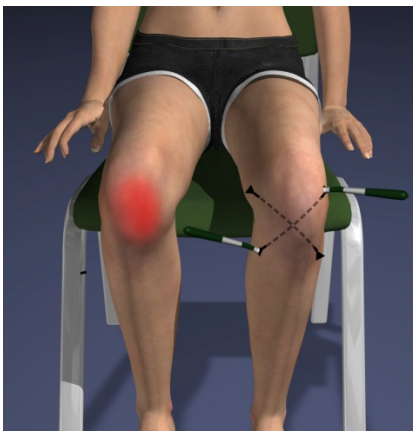


Figure 6.3

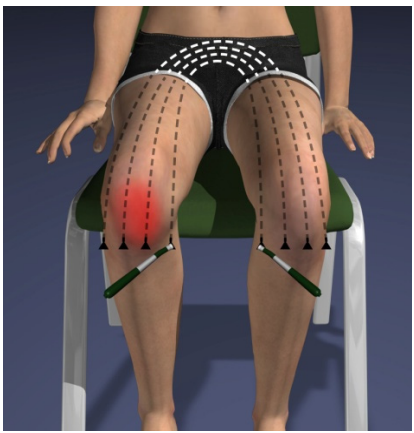


Figure 6.4

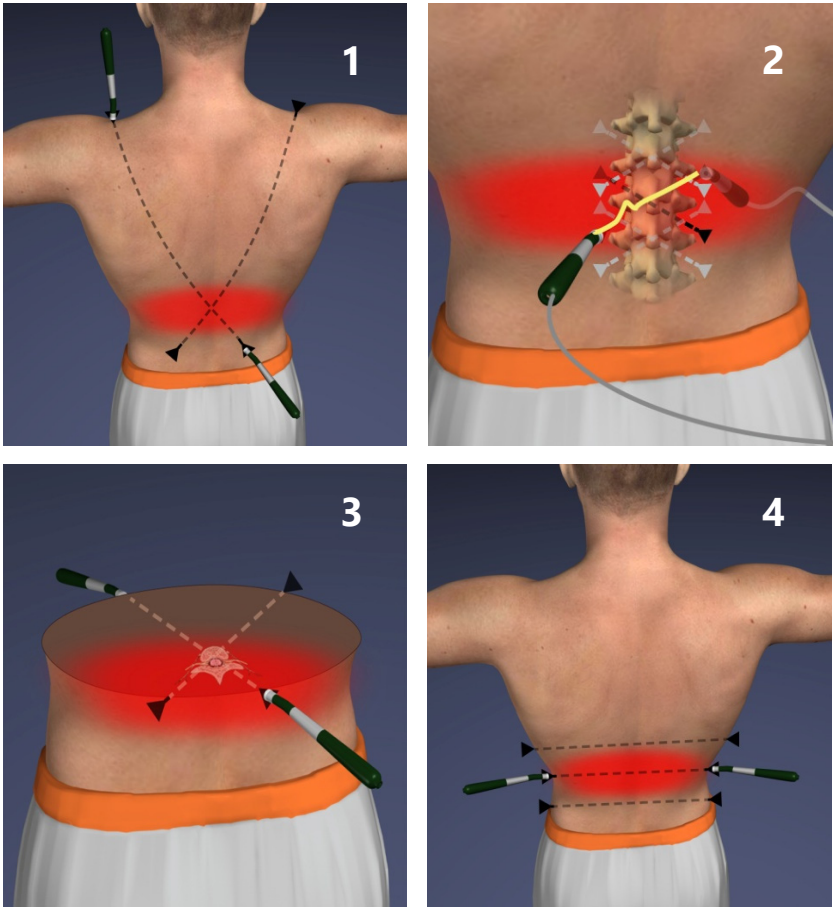


Figure 7

SMART PROBE TREATMENT STRATEGY B

1. To treat any problem in the neck and arms (*e.g.,* fingers, hand, wrist, elbow, shoulders) connect the two sides by placing one **Smart Probe** on one finger tip and the other **Smart Probe** in the same place on the corresponding finger tip of the other hand for 10 – 20 seconds (*i.e.,* thumb tip to thumb tip on other hand, index finger next, etc. for all 5 fingers). **Figure 8**. The same strategy applied to the toes may be used to treat any problem in the legs such as toes, feet, ankles and knees, but not hips. Hip pain requires local **Smart Probe** treatment as described in Strategy A.

2. Repeat as necessary, varying **Smart Probe** positions but always directing the current through the area being treated by placing the **Smart Probes** past that area, in a direction away from the spine.

3. Continue treatment until pain is completely gone or maximum relief is achieved.

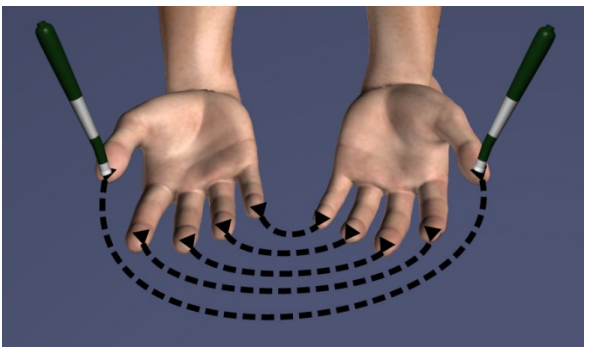


Figure 8

To Treat Pain with AS-Trode™ Electrodes

1. Plug dual connector end of wires into **Channel 1** and/or **Channel 2** jack and pin plug into **AS-Trodes™**. **Figure 1**.
2. Press **Power** on.
3. Mute the beeping if desired with the key sequence: **Lock-Timer-Lock**. To reinstate the audio alert, press the same key sequence.
4. Set **Frequency** to 0.5 Hz or desired setting; 1.5 or 100 Hz.
5. Set **Timer** to 10, 20, 40, 60 minutes or **Continuous**. This depends on the length of time necessary to effectively manage your pain. The cause and severity of the pain, your overall health, and any ongoing physical or psychological stress that might add to your condition are some of the factors determining length of treatment. Standard treatment time is 20 minutes to 1 hour per **AS-Trode™** location. Additional treatment time is usually not necessary. The Alpha-Stim® M may be used continuously all day for months or even years in severe cases but such usage is rarely necessary.
6. Set **Current** on the **Channel(s)** in use to desired setting. Use 6 (600 µA) for maximum pain relief; decrease immediately if uncomfortable. Use 1 (100 µA) when using **AS-Trodes™** for over 1 hour; increase as necessary to obtain relief but reduce current to lowest possible effective level (but not less than 100 µA) when used for long periods of time. This has shown to provide better results than when maintaining the maximum current level.
7. Press **Lock** button twice to lock settings if desired. Press **Lock** button twice again to unlock and change setting if necessary.
8. Note level of pain for all areas being treated and any limitation of movement in joints before, during, and at conclusion of treatment. It helps to keep a diary of pain levels where 0 is no pain and 10 is the worst that area of pain has been, along with time of day, duration of treatment, frequency and current levels used, and the most effective **AS-Trode™** locations.
9. Peel the self-adhesive **AS-Trodes™** off of the protective backing. Save the backing for storage of the **AS-Trodes™** after use. **Figure 9**. If the adhesive dries out and the **AS-Trodes™** do not stick well, you may wet them with a few drops of **Alpha-Stim® Conducting Solution** and lightly rub your finger over the electrode to spread the solution into the electrode gel. Be careful as too much **Alpha-Stim® Conducting Solution** will saturate the **AS-Trodes™** decreasing their ability to adhere to the skin.

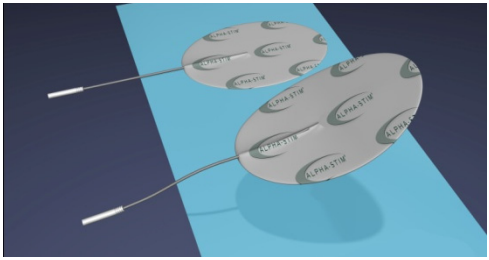


Figure 9

10. Apply **AS-Trodes™** to clean, dry skin. Always place the **AS-Trodes™** to direct the current between them through the area being treated. Two **AS-Trodes™** must always be used in pairs to complete the electrical circuit. **Figure 10**.

11. Move **AS-Trodes™** around as necessary to obtain the best results.

12. Continue treatment until pain is completely gone or maximum relief is achieved. There is usually an increased range of motion in treated areas. Sometimes areas of the body feel stiff or tight when the pain is alleviated, but this will wear off after a brief period of time.

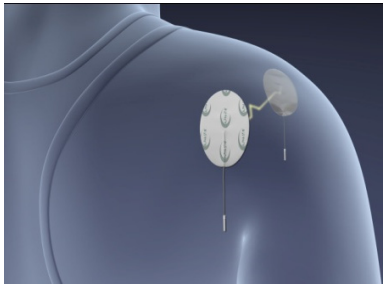


Figure 10

13. Replace **AS-Trodes™** in bag and seal bag. Discard and replace **AS-Trodes™** when adhesive has split or worn through to the conductive backing. Use only EPI **AS-Trodes™** brand silver electrodes available through your authorized Alpha-Stim® distributor. Many electrodes are significantly less conductive and will not allow the Alpha-Stim® current to penetrate the electrical resistance of the skin.

14. Finish with **Cranial Electrotherapy Stimulation** (see directions on following page).

15. Repeat as necessary. Results usually improve and last longer with additional treatments.

16. Store Alpha-Stim® M away from children.

Cranial Electrotherapy Stimulation (CES) to Treat Anxiety And/or Insomnia with Earclip Electrodes

1. Clean ear lobes with mild soap and water, alcohol pads or antibacterial wipes and allow skin to dry. Areas where skin oils or dirt have accumulated, or where cosmetics or hair spray have been used must be thoroughly cleaned to ensure adequate conductivity. Monitor skin condition prior to and after treatment. Skin irritation may develop in light skin. If skin burns are noted following treatment, discontinue use and apply an appropriate skin cream. Varying **Earclip Electrode** locations around the ear lobe may minimize irritation.
2. Plug dual connector end of **Earclip Electrode** wires into **Channel 1** or **Channel 2** jack.
3. Remove and discard old **Earclip Electrode Pads (EEPS™)** if present. Remove old glue residue, clean and dry **Earclip Electrodes** and attach 4 new **EEPS**™. Note that **EEP**™ case opens with label on bottom.
4. Saturate 4 new **Earclip Electrode Pads (EEPS™)** thoroughly with several drops of **Alpha-Stim® Conducting Solution** while on **Earclip Electrodes**.
5. Press **Power** on.
6. Mute the audio if desired with the key sequence: **Lock-Timer-Lock**. To reinstate the audio alerts, press the same key sequence again.
7. Set **Frequency** to 0.5 Hz.
8. Set **Timer**. 20 minutes is usually enough time if the current is set to at least 250 µA. 40 minutes to 1 hour is recommended if the current is at or below 200 µA.

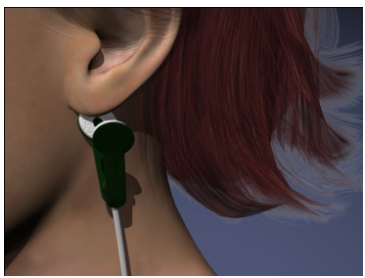


Figure 11

9. Squeeze **Earclip Electrodes** and apply one to each ear lobe. **Figure 11**.

10. **Current** defaults to 1 (100 µA) when the Alpha-Stim® M is turned on. Increase **Current** slowly (6 is the highest setting) until a slight vertigo is experienced (a dizzy feeling, similar to the sensation of rocking on a boat), then decrease *immediately* until the dizziness stops. Also decrease immediately if the normal tapping sensation felt on the ear lobes is uncomfortable. For people who have a history of experiencing vertigo such as motion sickness, treat at a subsensory current setting of 1 (100 µA) for one hour or more to prevent residual vertigo after treatment. The tolerable current level will be determined by the subjective feeling of vertigo which should subside immediately upon reducing the current. The current should always be reduced just below the level that causes vertigo.
11. Press **Lock** twice to lock settings if desired. Press **Lock** twice again to unlock and change settings if necessary.
12. Relax, if possible, during the treatment. It is best to sit quietly or lie down although it is also possible to read, work at a desk or watch television during treatment. Do not attempt to drive or operate any dangerous tools or machinery during treatment.
13. **Power** will turn off automatically at the conclusion of the timed cycle.
14. **Always complete a CES session.** When the timed session ends, and a "heavy" feeling is still experienced, resume treatment until at least 2 minutes after the heaviness lifts and a light feeling develops. Failure to do this can result in disorientation that can last for hours to days. Some people benefit the most from several hours of treatment in a given treatment session.
15. Remove and discard **EEPS**™. Clean and dry **Earclip Electrodes** and replace 4 **EEPS**™ for the next treatment session if desired. **EEP**™ case opens with label on bottom.
16. Store Alpha-Stim® M away from children.
17. CES may be used as often as necessary but for most people it is best to treat between once a day and twice a week. Results usually improve and last longer with additional treatments.

WHAT TO EXPECT

While the Alpha-Stim® M is effective when it is used correctly, it may not work for everyone. If obvious pain relief is not achieved after several Smart Probe locations are attempted, consider treating the primary area of pain at a lower current setting of 1 - 2 (100 to 200 µA) with AS-Trode™ electrodes for 60 minutes or more. If necessary, it can be used all day. It may also be necessary to treat all areas of pain anywhere on the body in order to get results. If the Alpha-Stim® M is not working well for you, contact your healthcare practitioner, your local authorized Alpha-Stim® distributor, or EPI for technical support. Pain control is usually experienced during a single treatment but may be experienced hours after treatment.

Anxiety reduction is usually experienced during a single treatment but may be experienced hours after treatment. Insomnia is usually improved after the initial treatment but may take 3 weeks. Most people can use it at bedtime and when awakened during the night. However, some people find they must conduct their 20 - 60 minute Alpha-Stim® CES treatment at least 3 hours before going to bed because the treatment may interfere with sleep. It may also be used in the morning to promote better sleeping at night.

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Following treatment, there are usually no physical limitations imposed so most users can resume normal activities immediately.

At present, there are over 100 research studies on using Cranial Electrotherapy Stimulation in humans and more than 30 animal studies. No significant lasting side effects have been reported. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. Any side effects which have occurred have all been mild and self-limiting.

PRESCRIBING INFORMATION

EPI is ISO Certified

Electromedical Products International, Inc. is an International Standards Organization (ISO) certified establishment. ISO is an International organization working with some 140 countries and the United Nations to maintain standards for all applications of technology for global industry. Requirements for the medical device industry relate to design controls, risk management, environmental controls, special processes (*e.g.* software validation), traceability, record retention, and regulatory actions such as vigilance.

CE Conformity Statement for Europe

The Alpha-Stim® M is a Class IIa, Type BF medical device. It has been independently tested by outside agencies to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

Electromagnetic Interference

This equipment has been independently tested by outside agencies and found to comply with the limits of Comité International Spécial des Perturbations Radioélectriques (CISPR). These limits are designed to provide reasonable protection against harmful interferences in a residential or clinical environment. However, it is still possible that interference could occur in a particular environment. In case interference does occur, increase the distance between this device and the equipment it interferes with. Consult Electromedical Products International, Inc. if the problem persists.

Indications

Alpha-Stim® M is a precision medical device and is an effective treatment with broad applications for a variety of syndromes involving pain, and for the management of anxiety and insomnia, or for the short term relief of symptoms associated with these indications. In many cases, it is the sole therapeutic method required. Effective results in pain management have been achieved during and/or subsequent to stimulation over affected body parts, adjacent areas, and areas distant from those in pain. As with any therapeutic intervention,

not all people will respond to the Alpha-Stim® M. The degree of efficacy will vary with the nature of the problem being treated, the overall health of the person, and with the method of treatment. As much as a one month initial trial may be required to see significant reductions in symptoms.

CES for Insomnia and Anxiety

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Warnings and Precautions

- Safety of stimulation has not been established during pregnancy.
- Do not stimulate directly on the eyes or press the probes over the carotid sinus (on the neck near the larynx). Application of the electrodes near the thorax may increase the risk of cardiac fibrillation.
- Potential hazard from simultaneous connection of a patient to a high frequency surgical medical equipment and stimulator may result in burns and possible damage to the stimulator.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy medical equipment may produce instability in the stimulator output.
- Modification of your Alpha-Stim® device or accessories is not allowed, it could result in injury.
- Do not place Alpha-Stim® in direct contact with lint, dust, light (including sunlight).

- For external use only. Small parts, keep out of reach of children, avoid inhalation or swallowing. Do not allow children to use or handle this device.
- This device is intended to be used in individuals who are 18 years of age or older.
- Brain development continues beyond 18 years of age. The long-term effects of electrical stimulation from this device on the brain has not been studied.
- Do not operate potentially dangerous machinery or vehicles during treatment, and in some cases for several hours after treatment.
- Do not plug leadwires into wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether the leadwires are attached to the stimulator or not.
- Patients should be monitored by their physician for signs of worsening.
- If a patient experiences headaches while using the device, they should consult their physician prior to continued use of the device.
- Caution Statement for United States: Federal law (USA only) restricts this device to sale by, or on the order of a licensed healthcare practitioner. Outside the USA it is available worldwide without a prescription but consultation with a qualified healthcare professional is recommended for difficult and unresponsive problems or when used with pharmaceuticals or other therapeutic intervention.

Contraindications

Use of an Alpha-Stim® M device is contraindicated with implanted pacemakers or implanted or wearable defibrillators.

Adverse Effects

Adverse effects are usually rare (occurring less than 1% of the time), mild, and self-limiting.

- dizziness
- skin irritation/electrode burns
- headaches

TECHNICAL SPECIFICATIONS

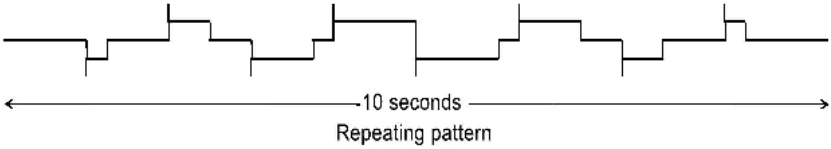
Electrical

Batteries	2 AA 1.5 volt (included). Replace with disposable batteries. Do not use rechargeable batteries. Dispose of batteries safely in accordance with local government regulations.
Timer	10 second Smart Probe activated by skin contact, 10, 20, 40, 60 minute countdown timers, and continuous time elapsed timer.
Current	0 to 600 microamperes (µA), +/- 5%, adjustable in 50 µA increments. When load is 1KΩ, maximum output current is 630 µA (waveform amplitude is 630 mV) and minimum output current is 570 µA (waveform amplitude is 570 mV).
Frequency	0.5, 1.5, or 100 Hz (pulses per second) combined with a constant 0.4 Hz. The average pulse repetition rate is 0.8 Hz at the most widely used setting of 0.5 Hz.
Pulse Widths	Varying between 0.25, 0.5, 0.75, and 1 second at 0.5 Hz.
Charge Per Pulse	At 600 µA and 0.5 Hz the charge per pulse varies between 150, 300, 450 and 600 microcoulombs (µC). Every 10 seconds the total charge is 1.5 millicoulombs (mC) in each direction.
Waveform	The impedance range within which the waveform parameters remain valid are from 100 Ω to 10 KΩ. The waveform is composed of bipolar asymmetric rectangular waves at a 50% duty cycle repeating periodically. At 0.5 Hz it repeats at 10 second intervals. The waveform is balanced to achieve 0 net current in either direction (see graphic).

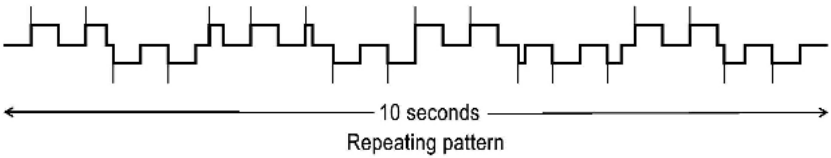
Device Dimensions

Height	11.0 cm
Width	7.2 cm
Depth	2.1 cm without belt clip
Weight	152 gm with batteries

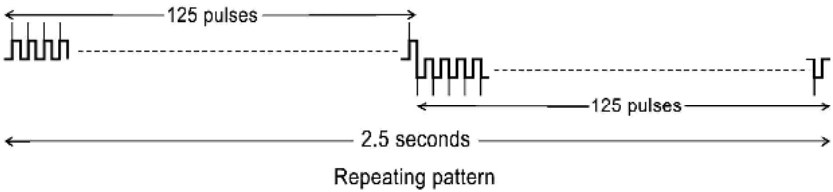
Characteristics of the Waveform



Alpha-Stim® 0.5 Hz Waveform



Alpha-Stim® 1.5 Hz Waveform



Alpha-Stim® 100 Hz Waveform

Alpha-Stim® M Output Waveform Parameters (Load resistance = 1000Ω)

Item Parameter	Alpha-Stim® Waveform 0.5 Hz	1.5 Hz	100 Hz
1. Average pulse repetition rate (pulses per second)	0.8	1.8	100
2. Pulse width (seconds)	0.25 0.5 0.75 1	0.083 0.167 0.25 0.333	0.005
3. Charge per pulse at 600 µA (µC)	150 300 450 600	49.8 100.2 150 199.8	3
4. Period (seconds)	10	10	2.5
5. Total charge in each direction in a period at 600 µA (mC)	1.5	1.5	0.375
6. Duty cycle (%)	50	50	50
7. Net current in either direction	0	0	0
8. Output current	0 to 600 µA adjustable in 50 µA increments	0 to 600 µA adjustable in 50 µA increments	0 to 600 µA adjustable in 50 µA increments

STORAGE AND CLEANING

Storage

Remove the batteries when storing the Alpha-Stim® M for an extended time of more than one month. Use the case to store and transport the Alpha-Stim® M. The Alpha-Stim® M and its accessories should be stored within a temperature range between -22^0 C and 55^0 C (-7^0 F and 131^0 F) and used within a temperature range between 5^0 C and 40^0 C (41^0 F and 104^0 F), with a relative humidity below 90%, at an atmospheric pressure between 912 to 1115 hPa.

Cleaning

Clean the Alpha-Stim® M device by gently wiping the surface of the case and screen with a damp cloth when dirty. Use mild soap and water if necessary. Use of other cleaning solutions may damage the case and screen. Never spray cleaners directly on the case and screen. Between treatments, the Probe Electrode Pads (PEPS™) and Earclip Electrode Pads (EEPS™) may be removed, and 70% isopropyl alcohol may be used on the Smart Probes and Earclip Electrodes. New PEPS™ and EEPS™ should be placed on the Smart Probes and Earclip Electrodes prior to the next treatment.

TROUBLE SHOOTING

Problem	Possible Solutions
There is no sensation of current. *Note: This is normal for some people, especially with Smart Probes.*	Try increasing the current or wetting electrodes with more Alpha-Stim® Conducting Solution.
There are no results.	1. Vary the electrode locations. 2. Treat all other areas of pain. 3. Try 1.5 Hz, or 100 Hz if 0.5 Hz is ineffective. 4. Treat more often or for a longer time at a lower current. 5. Some people require up to 3 weeks or more of treatment to begin to see an effect. 6. Consult your healthcare practitioner, authorized Alpha-Stim® distributor, or EPI for advice.
Electrodes do not stick well.	1. Wet AS-Trode™ electrodes with a few drops of Alpha-Stim® Conducting Solution, replace if they still do not stick well. 2. Apply EEPS™ to a clean, dry surface.
Smart Probes do not conduct current.	1. Use more Alpha-Stim® Conducting Solution. 2. Try other leadwires to determine if it is a broken wire.
The  symbol appears.	1. Make sure electrodes are touching skin firmly. 2. Make sure all plug/jack connections are firmly in place. 3. Try wetting PEPS™ or EEPS™ with more Alpha-Stim® Conducting Solution. 4. Change the batteries if the batteries are low.

SERVICE

The Alpha-Stim® M is not user serviceable.

To obtain service, first contact your authorized Alpha-Stim® distributor or Electromedical Products International, Inc. for advice or a Return Material Authorization number (RMA). If necessary, send the entire device, with all accessories, packed in the original case, if available, to:

In the United States:
Electromedical Products International, Inc.
2201 Garrett Morris Parkway
Mineral Wells, TX 76067
USA

In Europe:
Electromedical Products International, Inc.
p.a. HealthLink Europe BV
Mechie Trommelenweg 8
5145 ND Waalwijk
THE NETHERLANDS

In Asia:
Electromedical Products International (Asia), Ltd.
Unit 8, 19/F Fook Yip Bldg.
53-57 Kwai Fung Crescent
Kwai Chung, Hong Kong

Send it insured, freight prepaid, and include a copy of your invoice and a note describing the problem. Please do not forget to include your return address, including country, and your phone number, and if you have them, fax and email.

NOTES ON DISPOSAL

Device recycling and disposal

This device may not be disposed in the household garbage.

Every consumer is required by law to dispose electric or electronic equipment, regardless whether or not they contain hazardous substances* at a collection point in his/her city or at the retail outlet so that they can be disposed of in an environmentally friendly manner without batteries.

* Lead is the only hazardous substance that is present in the batteries.

Battery recycling and disposal

End-users can remove the batteries before they dispose the unit. Do not dispose used batteries in the household garbage, instead dispose them as special waste or at a battery collection point in a specialist outlet. End-users can contact their local administration or vendor with respect to disposal. If you're curious about how to recycle batteries, the best place to start is by visiting web pages referring this subject in your country.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI") the Alpha-Stim® M ("Product") is generally effective in relieving anxiety, insomnia and pain, healthcare is not an exact science and individual results will vary. Accordingly, EPI makes no warranties as to the effectiveness of its Products for a given individual.

Electromedical Products International, Inc. warrants to the original purchaser (and no one else) that each new Alpha-Stim® M is free of defects in workmanship and materials under normal use for a period of 5 years from the original purchase date, except for accessories. The warranty registration must be completed to validate the warranty. Warranty registration can be completed online by going to www.alpha-stim.com/product-registration.

Accessories such as batteries, leadwires, and electrodes are excluded from the warranty and are sold "as is" because they may be easily damaged before or during use.

During the warranty period, EPI's sole obligation shall be, at EPI's option, to replace or repair the Alpha-Stim® M without charge. In order to recover under this warranty, purchaser must first contact EPI by phone, mail, fax, or email to obtain a Return Material Authorization number (RMA). Purchaser must have a copy of the original invoice and have completed the warranty registration process to prove that the Product is still covered by warranty. The authorized return may then be shipped to EPI safely packaged with freight and insurance prepaid. EPI will not be responsible for damage due to improper packaging or shipment. If EPI determines there is a defect covered by this warranty**,** the

repaired or replaced Product will be shipped back, freight and insurance prepaid as soon as reasonably possible. If EPI determines in its sole discretion that the Product does not contain defective workmanship or materials, EPI will return the Product and bill for the return freight and insurance charges.

This warranty is voided immediately if the Product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, damage resulting from failure to follow operating instructions, alteration or disassembly by anyone other than EPI.

Electromedical Products International, Inc. shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the Product regardless of the form in which any legal or equitable action may be brought against EPI (such as contract, negligence, or otherwise). In no event shall EPI's liability under any cause of action relating to the Product exceed the purchase price of the Product.

Reporting Device Issues

Please contact EPI if you have any concerns with the device: Call EPI at 1-800-367-7246 or email alpha-stim@epii.com. If you are located outside of the US, please call +1-940-328-0788.

You may also report any adverse events to the FDA using the following information:

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your healthcare provider may choose not to complete the form. Your healthcare provider is not required to report to the information. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
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- Call FDA at 1-800-FDA-1088 to report by telephone.
- Reporting Form FDA 3500 is commonly used by health professionals. The form is available at: www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

Clinical Literature Summary on CES Devices In General for Anxiety and Insomnia

Below is a literature summary of different types of CES devices that have been studied in the literature for anxiety and insomnia. This information is not specific to Alpha-Stim® and is provided as a background for CES device types.

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." However, this does not mean that all CES devices have demonstrated effectiveness for all specific anxiety and insomnia categories. Evidence and information specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the specific populations for which EPI has evidence regarding benefits and risks. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Cranial Electrotherapy Stimulation (CES) Safety and Effectiveness

January 1, 1970, to November 8, 2022

Introduction

According to the final reclassification order ("Final Order") published in the Federal Register on December 20, 2019 (84 FR 70003), CES devices have been determined by FDA to collectively demonstrate a "class effect" of CES for treating anxiety and/or insomnia. The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim® technology can be found in the "Clinical Literature Summary on Alpha-Stim® for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use. Please see below for a summary of pertinent clinical literature that has been published using various combinations of CES devices, stimulation settings, and

electrode positions. Please note that not all combinations of parameters provided below have been studied for safety and effectiveness; therefore, individuals using this device should work with the prescribing medical provider to determine the best treatment settings to use and should not apply electrodes to locations that are not indicated in the specific product's labeling.

Anxiety

As of November 2022, 33 studies investigated the impact of Cranial Electrotherapy Stimulation (CES) on anxiety (14 randomized controlled trials (RCTs), 13 observational studies, 2 meta-analysis, and 4 reviews). Of the RCTs that were evaluated, some trials reported superiority of CES treatment versus placebo (Rosenthal, SH, 1972; Philip et al., 1991; Lee et al., 2013; Sousa et al., 1975; Gibson et al., 1987; Ryan et al., 1976; Kim et al., 2021) or control (Kang et al., 2020; Park et al., 2022) in reducing anxiety symptoms, while other studies demonstrated no impact on anxiety (Levitt et al., 1975; Passini et al., 1976; Scallet et al., 1976; Hearst et al., 1974). One study noted transient improvement in symptoms (Feighner et al., 1973). The majority of observational studies reported a positive association between CES treatment and reduction in anxiety symptoms (Flemenbaum et al., 1974; Overcash, 1999; Rosenthal et al., 1970; Smith et al., 1999; Ryan et al., 1977; Morriss et al., 2019; Morriss et al., 2020; Bystritsky et al., 2008). One observational study reported that CES was as effective as usual care (Royal et al., 2022). Only 2 observational studies reported that CES did not have a significant impact on anxiety based on clinical assessment and standard inventories (Moore et al., 1975; Von Richthofen and Mellor, 1980). A meta-analysis of 10 studies evaluating the effectiveness of cranial stimulation in treating depression noted an effect on anxiety as a secondary study outcome compared to sham (Cheng et al., 2022). Another meta-analysis of 14 RCTs evaluating the effectiveness of cranial stimulation indicated that CES versus sham treatment was associated with significantly improved anxiety (Klawansky et al., 1975). Similar findings were reported in a review that examined 34 controlled trials involving a total of 767 patients receiving CES and an additional 867 patients serving as controls (De Felice et al., 1997). Twenty six (26) of 34 studies (77%) reported decreased anxiety after treatment with CES and the remaining 8 of 34 studies (24%) reported no such benefit. Two other reviews of trials using CES in patients with anxiety and depression concluded that CES may provide a modest benefit in the treatment of anxiety (Shekelle et al., 2018; Brunye et al., 2021). A fourth review found several small studies reporting decreased anxiety with CES use in patients with various conditions, including 1 small study in individuals with anxiety disorder (Freire et al., 2020). In studies that reported improvement in anxiety with use of CES, the

reported stimulation parameters, electrode placement, and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all CES devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

Insomnia

As of November 2022, there were a total of 23 studies that evaluated the effectiveness of CES on insomnia. Of the 11 RCTs, some reported greater reduction in insomnia symptoms in the CES group compared to placebo (Rosenthal, 1972; Philip et al., 1991; Feighner et al., 1973; Weiss et al., 1973; Heffernan et al., 1995), while others reported no significant differences in measures of insomnia symptoms between the 2 groups (Levitt et al., 1975; Scallet et al., 1976; Hearst et al., 1974; Coursey et al., 1980; Chang et al., 2022; Aseem et al., 2022). Among the 8 observational studies, CES treatment was associated with less frequent (Rosenthal and Wulfshon, 1970) and less intense (Matteson et al., 1986) sleep disturbances, improved soundness of sleep (39), less difficulty falling asleep (Nagata et al. 1981; Cartwritght and Weiss, 1975; Itil et al., 1972) and feeling more rested (Cartwright and Weiss, 1975) or improved mood (Nagata et al., 1981) in the morning. Several observational studies reported no impact of CES on insomnia (Empson, 1973; Frankel et al., 1973) or reported an effect that did not persist after the first week (Moore et al., 1975). A meta-analysis of 14 RCTs indicated that CES versus sham treatment had no impact on insomnia (Klawansky et al., 1995). Lastly, 3 reviews evaluated the effectiveness of CES on insomnia. One review found 23 studies, 6 of which were RCTs of which only 2 studied participants with insomnia (Aseem et al., 2019). Of these two RCTs, only 1 showed improved patient-reported sleep latency and objective changes in sleep, while the other did not show any change (Aseem et al., 2019). The other 2 reviews concluded that studies evaluating the effectiveness of CES on insomnia were inconclusive (Shekelle et al., 2018) or inconsistent (Brunye et al., 2021). In studies that reported improvement in insomnia with use of CES, the reported stimulation parameters, electrode placement, and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all CES devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

CLINICAL LITERATURE SUMMARY ON ALPHA-STIM® FOR ANXIETY AND INSOMNIA

Below is a literature summary of clinical studies specific to the Alpha-Stim® technology for anxiety and insomnia as well as parameters studied.

Anxiety

In total, 27 studies investigated the impact of cranial electrotherapy stimulation (CES) delivered by the Alpha-Stim® devices on anxiety (13 randomized controlled trials (RCTs), 2 surveys, 3 retrospective studies, 9 single arm studies). Of the RCTs that were evaluated, 12 reported superiority of Alpha-Stim® treatment versus placebo or control groups (Barclay et al., 2014; Cork et al. 2004; Gong et al., 2016; Hill et al., 2015; Kim et al., 2008; Koleoso et al., 2013; Lee et al., 2013; Lu and Hu, 2014; Mellen & Mackey, 2008; Strentzsch et al., 2008; Voris et al., 1995; Winick et al., 1999) in reducing anxiety by a significant amount. One RCT demonstrated dramatic improvements in psychological factors including anxiety in patients receiving CES however the results were not found to be statistically significant likely due to a small sample size (Lichtbroun et al., 2001). Surveys showed that a majority of participants in both surveys reported having significant improvements in anxiety of greater 50% when compared to the baseline (Kirsch et al., 2014; Price et al., 2013). The majority of single arm studies reported a positive association between Alpha-Stim® treatment and reduction in anxiety symptoms (Bystritsky et al., 2008; Kirsch et al., 2019; Mellen et al., 2016; Morriss et al., 2019; Platoni et al., 2019; Royal et al., 2022, Yennurajalingam et al., 2018). One study did not measure the effect of CES on anxiety but did determine that there was a significant decrease in subjective units of distress after Alpha-Stim® treatment (Lande et al., 2018). The retrospective studies also noted significant improvements in anxiety scores (Libretto et al., 2015; Morrow et al., 2019; Overcash et al., 1999).

In studies that reported improvement in anxiety with use of CES, the reported stimulation parameters and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all Alpha-Stim® devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

Frequencies Studied:

- 0.5 Hz

Current Amplitudes Studied:

- 100 μA
- 100-500 μA
- 10-500 μA
- 200 μA
- 100-600 μA
- 50-500 μA
- 200-600 μA
- 300 μA

Treatment Schedules Studied:

- Daily for one hour (5 week study)
- Daily for one hour (6 weeks)
- 10-15 minutes once a day for 15 days, with a rest period of 2 days after every 5 days.
- 1 hour a day for 3 weeks.
- 30 minutes a day 5 times in a week, 10 times per course for a total of 3 courses.
- 1 hour for 1 session
- 20-60 minutes daily for 6 weeks.
- 45 minutes for each session for three days.
- 20 minutes the day before and the day prior to a surgery
- Daily for 3-8 weeks.
- 20 minutes daily from 3-15 days.
- 20 minutes for 20 daily sessions
- 20 minutes for 5 days daily.
- 60 minutes daily for 6 to 12 weeks
- 5 times a week for 2 weeks
- 1 hour daily for 3 weeks
- 1 hour per day for five days for three consecutive weeks
- 1 hour daily for eight weeks
- 20 minutes daily for 10 days.
- Over the course of a procedure
- 1 hour daily for four weeks

Please see below for a list of studies and patient population that have demonstrated improvements in anxiety with Alpha-Stim.

Randomized Control Studies:

- Barclay et al., 2014: Patients with anxiety disorder
- Voris et al., 1995: Patients diagnosed with anxiety
- Lu and Hu, 2014: Patients with anxiety disorders
- Strentzsch et al., 2008: Chronically mentally ill patients
- Cork et al., 2004: Patients diagnosed with fibromyalgia
- Gong et al., 2016: Patients with functional constipation
- Kim et al., 2008: Preoperative patients with anxiety
- Koleoso et al., 2013: Preoperative patients with dental anxiety
- Winick et al., 1999: Dental patients
- Lee et al., 2013: Preoperative female patients with anxiety
- Mellen & Mackey,2008: Correctional and law enforcement personnel
- Hill et al., 2015: College students

Non-Randomized Studies:

- Kirsch et al., 2014: Service members and veterans
- Price et al., 2013: Civilian, service members, and veterans
- Bystritsky et al., 2008: Patients with General Anxiety Disorder
- Kirsch et al., 2019: Teachers
- Mellen et al., 2016: Victims of domestic violence
- Morriss et al., 2019: Patients with general anxiety disorder
- Platoni et al., 2019: First responders
- Royal et al., 2022: University students
- Yennurajalingam et al., 2018: Patients with advanced cancer
- Libretto et al., 2015: Active duty service members with PTSD
- Morrow et al., 2019: Veterans
- Overcash et al., 1999: Patients with acute anxiety disorders

Insomnia

A total of 9 studies investigated the impact of cranial electrotherapy stimulation (CES) delivered by Alpha-Stim® devices on insomnia (3 RCTs, 2 surveys, 4 observational studies). Of the RCTs that were evaluated, 2 out of 3 reported superiority of Alpha-Stim® treatment versus placebo or control/sham groups (Lande et al., 2013; Taylor et al., 2013) in improving the amount of time slept, quality of sleep decreasing the amount of sleep disturbances. One study could determine no significant effect of CES on sleep deficiency (Wagenseil et al., 2018). The two surveys showed that a majority of participants in both surveys reported having significant improvements in insomnia of greater 50% when compared to the baseline (Kirsch et al., 2014; Price et al., 2013). The majority of single arm studies reported a significant reduction in insomnia following Alpha-Stim® treatment (Kirsch et al., 2019; Morriss et al., 2019; Platoni et al. 2019; Yennurajalingam et al., 2018).

In studies that reported improvement in insomnia with use of CES, the reported stimulation parameters and treatment schedule varied widely. Please see below for details.

Frequencies Studied:

- 0.5 Hz

Current Amplitudes Studied:

- 100 – 600 µA
- 100 µA

Treatment Schedules Studied:

- 20-60 minutes daily for 6 weeks.
- 60 minutes daily for 5 days
- 60 minutes daily for 3 weeks
- 60 minutes daily for 6 – 12 weeks.
- 1 hour daily for 8 weeks
- 60 minutes daily for 4 weeks.

Please see below for a list of studies and patient population that have demonstrated improvements in anxiety with Alpha-Stim.

Randomized Control Studies:

- Lande et al., 2013: Service members
- Taylor et al., 2013: Patients with fibromyalgia

Non-Randomized Studies:

- Kirsch et al., 2014: Service members and veterans
- Price et al., 2013: Civilian, service members, and veterans
- Kirsch et al., 2019: Teachers
- Morriss et al., 2019: Patients with general anxiety disorder
- Platoni et al. 2019: First responders
- Yennurajalingam et al., 2018: Patients with advanced cancer

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NOTES

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