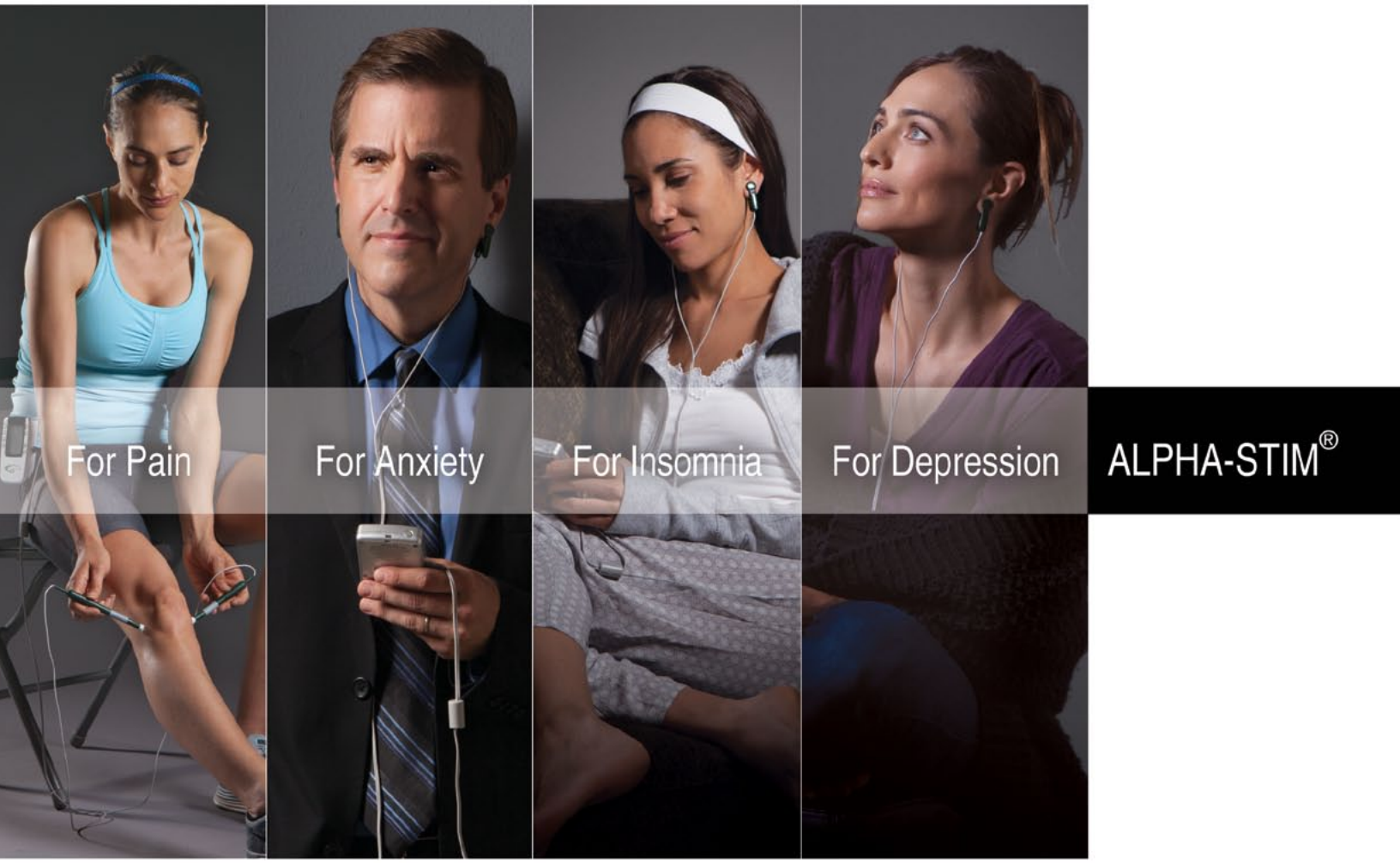
An Overview of Alpha-Stim® Technology for the Healthcare Professional



ALPHA-STIM®

LET NOTHING STOP THEM.™

An Overview of Alpha-Stim® Technology for Anxiety, Insomnia, Depression and Pain Management for the Healthcare Professional

Alpha-Stim is a medical device used worldwide by physicians, healthcare professionals, and more than 130 American Veterans Affairs and Military Medical Centers. The technology is used as an effective non-pharmacological choice for the treatment of anxiety, insomnia, depression and pain management. Alpha-Stim can be used in a clinical setting or ordered for home use.

Alpha-Stim is regulated in the USA by the Food and Drug Administration (FDA) and is approved in many other countries worldwide, including having a CE Mark for Europe. Doctor and patient surveys reveal it has helped 90% of the patients who tried it, and it is supported by over 100 completed independent research studies and published reports.

Alpha-Stim treats patients using two protocols: Cranial Electrotherapy Stimulation (CES) and Microcurrent Electrical Therapy (MET).

CES is the process of using an electrical current of less than one-half milliampere, delivered directly into the brain via earclip electrodes for 20 to 60 minute sessions in order to treat anxiety, insomnia and depression. MET is the process of directing a microcurrent of less than one milliampere per channel, through the body via Alpha-Stim Smart Probes or self-adhesive AS-Trodes™ with a 2 to 5 minute protocol for the treatment of peripheral pain.

Putative Mechanism

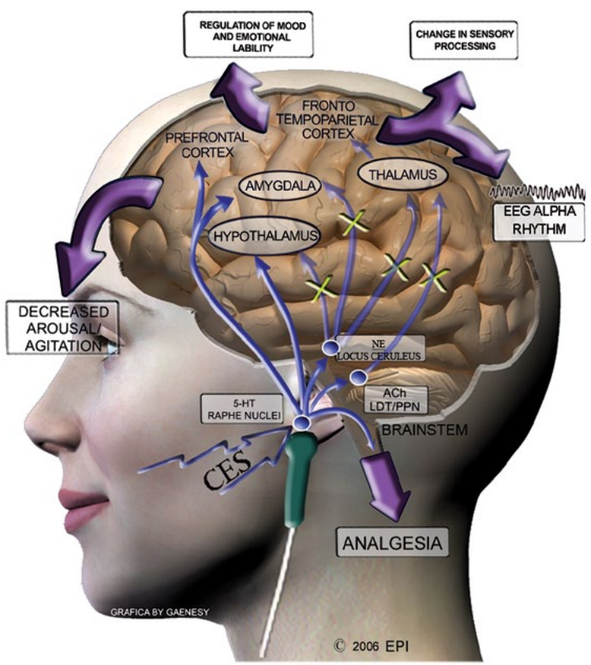


Figure 1

How Alpha-Stim Works

Evidence from published research and ongoing studies shows that the Alpha-Stim waveform activates particular groups of nerve cells that are located at the brainstem **(Figure 1)**. These groups of nerve cells produce the chemicals, serotonin and acetylcholine, which can affect the chemical activity of nerve cells that are both nearby and at more distant sites in the nervous system. These cells are situated to control the activity of afferent nerve pathways into the brain and efferent nerves that course down into the spinal cord. By changing the electrical and chemical activity of certain nerve cells in the brainstem, Alpha-Stim technology appears to amplify activity in some neurological systems and deactivate activity in others. This neurological 'fine tuning' is called neuromodulation, and occurs either as a result of, or together with the production of, a certain type of electrical activity pattern in the brain known as an alpha state which can be measured on an EEG.

Effects from Alpha-Stim can be produced after a single treatment as evidenced by fMRI, LORETA and EEG mechanistic studies and clinical double-blind randomly controlled trials in medicine, psychology and dentistry. Repeated treatments have been shown to increase the relative strength and duration of these effects. In some cases, effects have been stable, suggesting that the electrical and chemical changes evoked by Alpha-Stim technology have led to a durable retuning of aspects of the nervous system back to normal function.

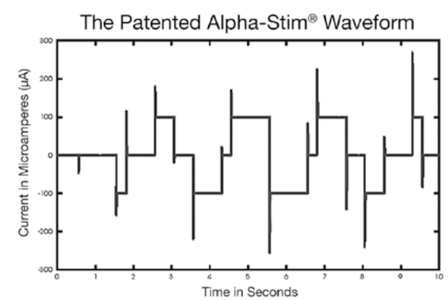


Figure 2

What Makes Alpha-Stim Unique?

It's the waveform **(Figure 2)**. Alpha-Stim generates a unique and patented waveform that no other device can replicate. The waveform in a therapeutic device is analogous to the precise chemical compound that differentiates one drug from another. Alpha-Stim's waveform is distinctive in its proven safety and efficacy. The waveform uses microcurrents (millionths of an ampere) delivered in a precise configuration via earclip electrodes which direct the current to the brain. The waveform is specifically designed to increase alpha brainwaves and decrease delta waves as seen on quantitative electroencephalogram (QEEG) brain maps **(Figure 3)**.

Alpha-Stim Provides Proof

Alpha-Stim's proven results are due to its proprietary, patented technology and protocols. While there are other CES devices on the market, no other device has the clinical results and research to support its technology. Our research is so good, even our competitor's use it. Just as every 5 mg white pill is not the same, Alpha-Stim's unique waveform produces results vastly different from its competitors. None provide as much proof of safety and efficacy as Alpha-Stim, if they provide any proof at all.

Why You Should Prescribe Alpha-Stim

Through extensive research and surveys, EPI has identified five major reasons a licensed healthcare professional would recommend an Alpha-Stim device for their patients:

1. Safety
2. Proven Efficacy
3. Research
4. Cost Effectiveness
5. Customer Service and Support

Alpha-Stim can easily be incorporated into your practice, providing you with an effective treatment choice for your patients.

Safety

Alpha-Stim provides therapeutic, lasting results without the risks of dangerous side effects, tolerance and addiction. Alpha-Stim allows your patients to resume normal, daily activities after treatment, and is suitable for clinical or home use.

Patients are becoming increasingly concerned about the dangers and potential side effects of most medications. Many patients are looking for a safer and more effective alternative to pharmaceuticals. Alpha-Stim is supported by over 100 research studies, published reports and ongoing research, as well as surveys of doctors, patients and professional endorsements.

In over three decades of studies involving approximately 8,800 people in active treatment groups, only minor, self-limiting side effects have been reported. The two most common side effects were headaches (0.10%) and skin irritation at the electrode sites (0.07%) only seen in people with very light skin. These are mild and self-limiting.

Proven Efficacy

Alpha-Stim is used extensively with military personnel by more than 200 practitioners within the Department of Defense (DOD) and over 130 Veterans Administration (VA) hospitals to treat anxiety, insomnia, depression and pain.

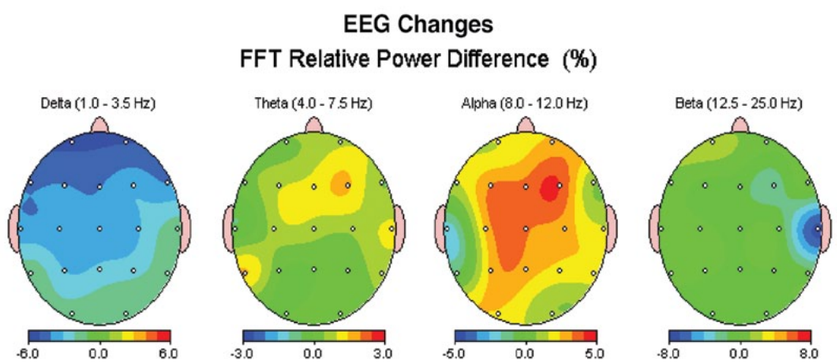


Figure 3. This quantitative EEG brain map shows the changes in brain activity by traditional EEG groupings in 30 university student volunteers after a single 20 minute treatment with Alpha-Stim at 0.5 Hz. Blue shows a decrease in activity of sleepy delta brainwaves while red shows an increase in activity of relaxing alpha brainwaves.

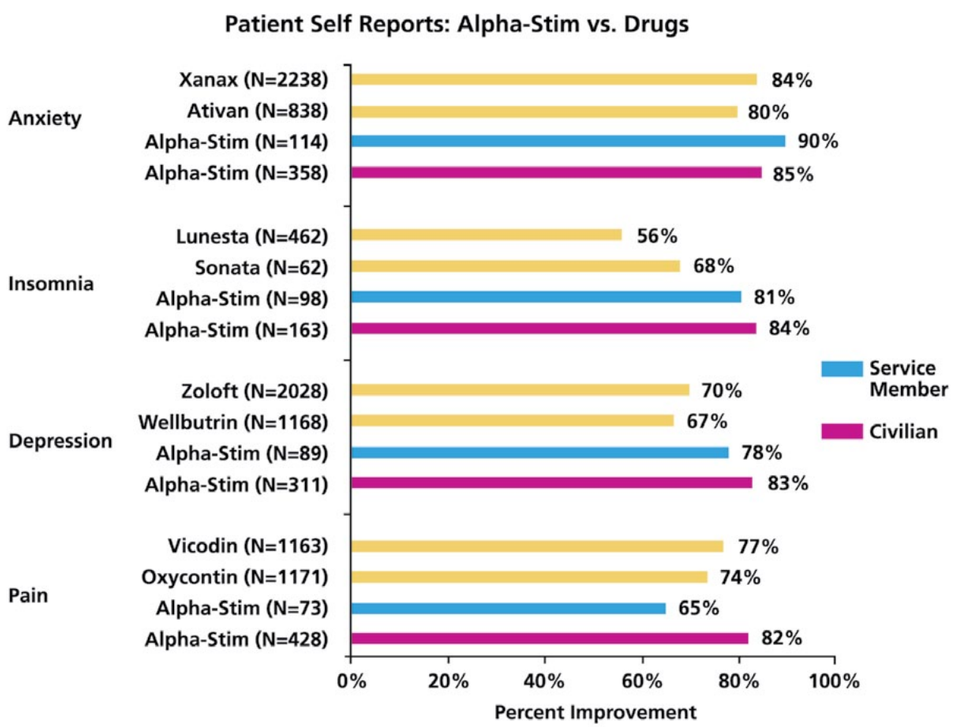


Figure 4. Kirsch DL, Price LR, Nichols F, Marksberry JA and Platoni KT. Efficacy of Cranial Electrotherapy Stimulation for Anxiety, PTSD, Insomnia, and Depression: US Military Service Members and Veterans Self Reports. *The Army Medical Department Journal*. October-December 2014:46-54.

In an August 2011 Survey, 99.9% users considered it effective!

Figure 4 presents results of the October 2011 Military Service Member Survey and Alpha-Stim Patient Survey. Alpha-Stim users – civilians and Service Members - consistently reported more positive responses than those that use pharmaceuticals.

In 2014, a study from Liberty University used Alpha-Stim CES to treat 108 patients diagnosed with generalized anxiety disorder (GAD) for 5 weeks **(Figure 5).** The study measured anxiety and co-morbid depression scores. The study showed significant reduction in anxiety ($p<0.001$) with 83% of the active treatment group cutting their scores in half. The results were consistent with depression also showing a significant reduction ($p<0.001$) with 82% of the active treatment group cutting their scores in half. Alpha-Stim was shown to be effective for anxiety and comorbid depression.

Research

Alpha-Stim's effectiveness is supported by more than 100 completed studies and many more studies that are currently in progress. There is more research supporting Alpha-Stim technology than there is for most drugs. It is important to note that Alpha-Stim research is funded independently. Funding sources include the National Institutes of Health, National Cancer Institute, Department of Defense and the US Department of Veterans Affairs.

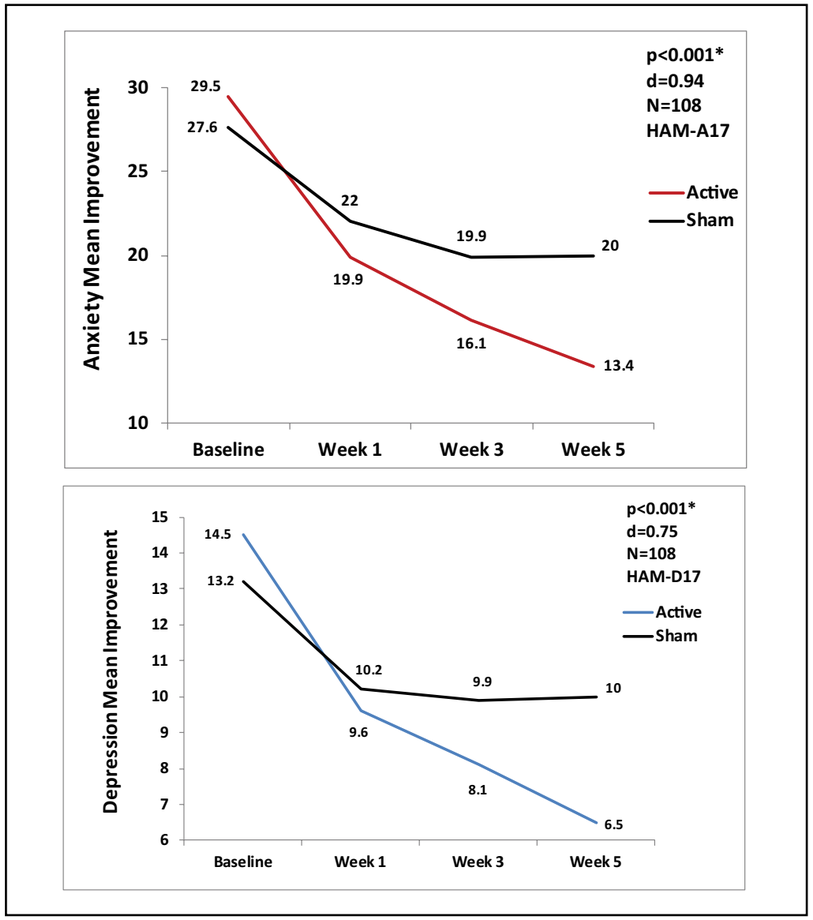


Figure 5. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*. 2014; 164:171-177. Presented at the American Psychological Association National Conference, Honolulu, HI, July 2013.

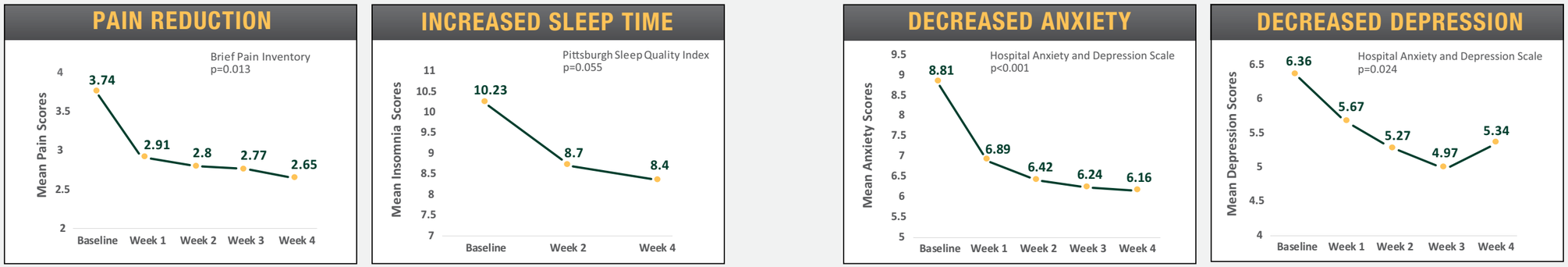


Figure 6. Yennurajalingam S, Kang D-H, Hwu W-J, et al. Cranial electrotherapy stimulation for the management of depression, anxiety, sleep disturbance, and pain in patients with advanced cancer: a preliminary study. *Journal of Pain and Symptom Management*. 2018, 55(2):198–206.

Latest Research

In February 2018, a study was published from leading cancer center MD Anderson, which used Alpha-Stim CES to treat pain, anxiety, insomnia and depression in advanced cancer patients. The study was carried out over 4 weeks and found significant reduction in pain, anxiety, depression, functionality as well as a significant reduction in sedative medication use. **(Figure 6).**

Cost Effectiveness

Over a five-year period, Alpha-Stim can save your patients thousands of dollars in comparison to drugs, CBT, TMS, ECT and competing medical devices, commonly prescribed for anxiety, insomnia, depression and pain **(Figure 7).**

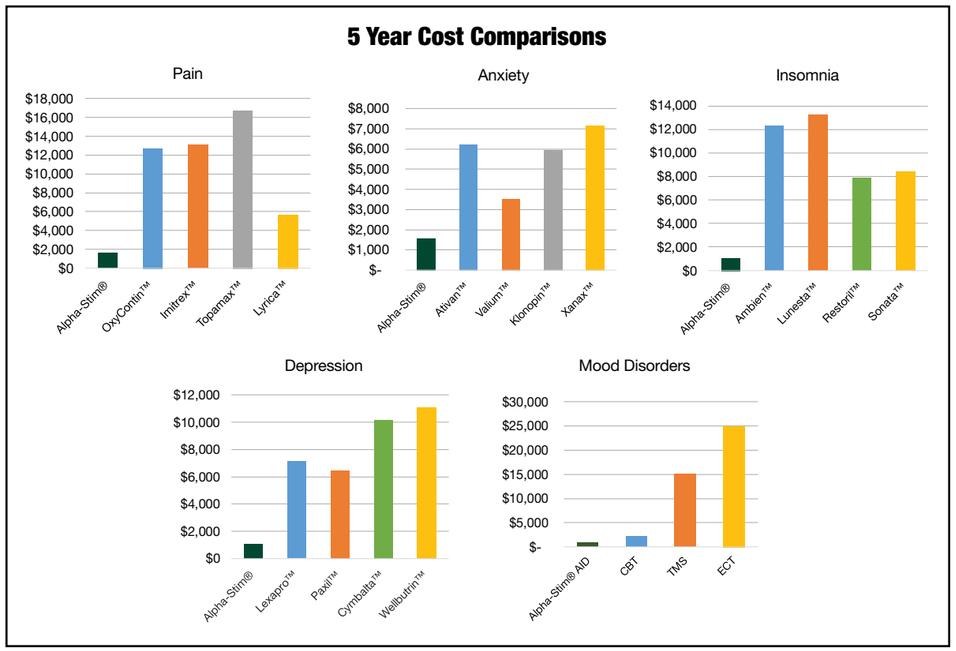


Figure 7. Drug prices are from www.drugpriceinfo.com. Treatment prices are from www.pyschologytoday.com and the American Psychological Association.

Customer Service and Support

EPI's outstanding customer service team is available to help you with any questions or concerns ranging from clinical and technical support to insurance billing or financing options for your patients. Over the years, EPI has developed a variety of resources to assist you and your patients at no additional cost. We pride ourselves on providing the best ongoing support of any medical device company.

EPI provides the following resources:

- Free live, comprehensive training webinars for practitioners (with CE credit available for some professions).
- Patient brochures for your office
- Illustrated Owner's Manuals
- Animated treatment procedures and protocols on our website
- www.alpha-stim.com
- Educational videos and articles

Electromedical Products International, Inc. and our well-trained distributors are dedicated to helping you seamlessly integrate Alpha-Stim into your treatment plans. Try Alpha-Stim on your treatment-resistant and drug-adverse patients first. You will be impressed with the changes you see.

Alpha-Stim and Your Practice

Try it FREE!

Ask about our Practitioner Loan Program to try Alpha-Stim free for 60 days (available in most areas).

To speak directly with a dedicated member of our customer service team and enroll in the Practitioner Loan Program, call: (800) FOR-PAIN if you are in the US. All other callers, dial (940) 328-0788. You may also email us at: info@epii.com.

Training

Attend a complimentary webinar hosted by a member of our clinical support staff and learn valuable insights to effectively integrate Alpha-Stim into your practice, as well as treatment protocols for the various indications of Alpha-Stim. On-site training is available in limited areas, depending on your location and needs.

Select the Alpha-Stim

Alpha-Stim technology is available in two user-friendly models, the M and the AID. Both are appropriate for clinical and home use.

Alpha-Stim M is a combined Microcurrent Electrical Therapy (MET) that treats pain and Cranial Electrotherapy Stimulator (CES) that treats sleep, anxiety and depression. Alpha-Stim M is the most complete and versatile model, and the only choice for those who want to treat pain. Alpha-Stim M comes complete with Smart Probes and self-adhesive AS-Trodes™ for treating pain, and Earclips for administering CES.

Alpha-Stim AID treats anxiety, insomnia and depression. See Table 1 below for a summary of product features.

Alpha-Stim® M
For treating multiple pain areas, anxiety, insomnia and depression.

Alpha-Stim® AID
For treating anxiety, insomnia and depression without pain.

Alpha-Stim® Product Features

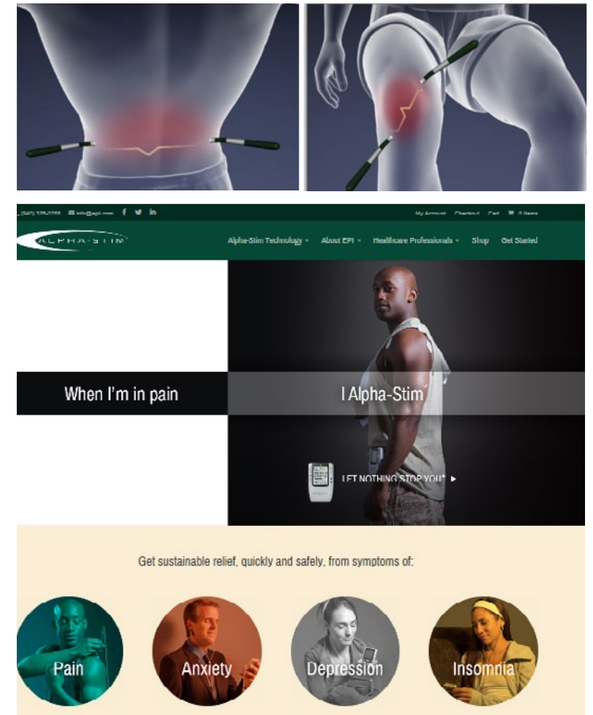
Primary Indications		
Pain	✔	
Anxiety	✔	✔
Insomnia	✔	✔
Depression	✔	✔
Treatment Methods		
Smart Probes for Pain	✔	
Electrodes for Pain	✔	
Earclips for CES	✔	✔
Plus		
Five (5) Year Warranty	✔	✔
Free access to clinical and technical support	✔	✔

Table 1

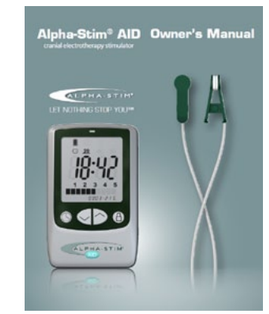
5 Year Limited Warranty
Alpha-Stim M and AID are warranted to be free from defects in materials and workmanship under normal use for a period of five years from the date of purchase (not including batteries and accessories).

30 Day Money Back Guarantee
While the Alpha-Stim is significantly effective when it is used correctly for 9 out of 10 people who use it, it will not work for everyone. If for any reason you wish to return your Alpha-Stim, you may return it within 30 days of purchase and get a full refund, less a 10% restocking fee. See full details at www.alpha-stim.com.

Education and Training



Step-by-step animated treatment procedures and protocols are available at alpha-stim.com/training



Illustrated owner's manuals

About EPI

Electromedical Products International, Inc. (EPI) was founded in 1981 by Dr. Daniel L. Kirsch, who developed Alpha-Stim technology. EPI was a recipient of the Best of Business Award in the Surgical and Medical Instruments category by the Small Business Commerce Association (SBCA).

EPI earned the American Institute of Stress Award for Distinction and Innovation based on the growing list of publications in peer reviewed journals demonstrating safety and efficacy of Alpha-Stim products.
EPI and its staff are dedicated to the pursuit of excellence in the treatment of medical and healthcare related issues.

EPI today is a global enterprise with representatives throughout the world. EPI is an FDA registered establishment with operations certified by the International Standards Organization (ISO) 13485:2016 standards for quality in medical devices. Alpha-Stim products maintain the CE mark signifying compliance with the European Medical Device Directive, and are licensed by Health Canada.

Alpha-Stim Inventor-Daniel L. Kirsch, PhD

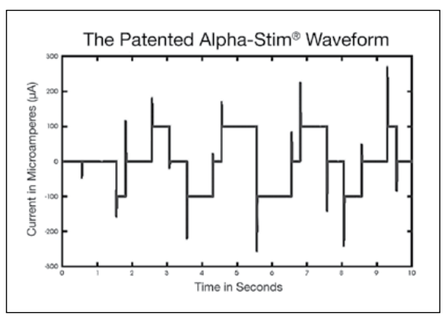
Dr. Kirsch is a world-renowned neuroscientist with over three decades of experience in the electromedical field, including extensive clinical practice experience. Throughout his career, Dr. Kirsch has designed medical instrumentation and their applications and developed clinical systems for managing pain, anxiety, insomnia and depression.

Dr. Kirsch was board-certified by the American Academy of Pain Management in 1990, and the 2008 Recipient of the prestigious AAPM Richard Weiner Educator of the Year Award in Pain Management, and was named a Fellow of the American Institute of Stress in 1997, and President in 2012. He is also a Member of the Board of Scientific and Professional Advisors of the Institute for Traumatic Stress and a Member of the International Society for Neurotherapy and Research and a Member of Inter-Pain (association for pain specialists in Switzerland and Germany).

Technical Specifications

Electrical

Batteries	Alpha-Stim M: 2 AA 1.5 volt, and Alpha-Stim AID: 2 AAA 1.5 volt (included).
Timer	Alpha-Stim M: 10 second Smart Probe activated by skin contact, 10, 20, 40, and 60 minute count down timers to auto-off, and continuous time elapsed timer on M, and Alpha-Stim AID: 20, 40 or 60 minute countdown timers to auto-off.
Current	0 to 600 microamperes (µA) for the M and 0 to 500 µA for the AID adjustable in 50 µA increments.
Frequency	Alpha-Stim M: 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. Alpha-Stim AID is preset at 0.5 Hz.
Pulse Widths	Varying between 0.25, 0.5, 0.75, and 1 second at 0.5 Hz.
Charge	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 wave form parameters remain valid are from 100 Ω to 10 K Ω. 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 below).



Mechanical

Alpha-Stim M	
Height	11.0 cm
Width	7.2 cm
Depth	2.1 cm without belt clip
Weight	152 gm with batteries

Alpha-Stim AID	
Height	9.8 cm
Width	6.3 cm
Depth	2.0 cm
Weight	101 gm with batteries

Alpha-Stim M
The Alpha-Stim M comes complete and ready to use with 1 set of Earclip electrodes, 1 15-ml bottle of Alpha Conducting Solution™ (250 ml refill bottles available), 2 sets of lead wires for 4 electrodes, 2 Smart Probes, 4 silver AS-Trode™ brand single person multiple use self-adhesive electrodes (good for approximately 2 weeks to 1 month of use), 100 Probe Electrode Pads (PEPS™), 256 Earclip Electrode Pads (EEPS), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AA Batteries.

Alpha-Stim AID
The Alpha-Stim AID comes complete and ready to use with 1 set of Earclip electrodes, 1 15-ml bottle of Alpha Conducting Solution™ (250 ml refill bottles available), 256 Earclip Electrode Pads (EEPS), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AAA Batteries.

Prescribing Information

What to Expect
When used correctly, Alpha-Stim technology is significantly effective for 9 out of 10 people. Patients suffering from pain, anxiety or insomnia may see noticeable results following a single treatment. Patients with depression typically require at least three weeks of daily treatment before experiencing significant improvement. Once the condition is under control, use of the Alpha-Stim can be decreased. If desired results are not achieved, please contact EPI or your local distributor for clinical support.

Following treatment, most physical activities may be resumed immediately. However, some patients may experience a euphoric feeling that may temporarily impair their mental and/or physical abilities for the performance of potentially hazardous tasks for up to several hours after treatment. Care should be taken when operating a motor vehicle or heavy machinery, until you know how Alpha-Stim might affect you.

No significant lasting side effects have been reported. Occasional headache, discomfort or skin irritation under the electrodes or lightheadedness may occur. These are all mild, self-limiting reactions.

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.

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.

CE Conformity Statement for Europe
The Alpha-Stim M and AID are Class IIa, Type BF medical devices. They have been independently tested by Underwriter Laboratories (UL) to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance.

Caution Statement for United States
Federal law (USA only) restricts these devices to sale by or on the order of a licensed practitioner. Outside of the USA, they are available world wide without a prescription but consultation with a qualified healthcare practitioner is recommended.

Indications
Alpha-Stim M is an effective treatment with broad applications for a variety of syndromes involving pain, and both the M and AID are used for the management of anxiety, insomnia and depression, or for the short-term relief of symptoms associated with these indications. In many cases, Alpha-Stim is the sole therapeutic method required. Effective results in pain management have been achieved during and/or subsequent to stimulation over effected body parts, adjacent areas, and areas distant from those in pain. As with any therapeutic intervention, not all people will respond to Alpha-Stim. 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.

Contraindications
Alpha-Stim may affect the operation of implanted demand type cardiac pacemakers and implanted defibrillators. Do not stimulate directly on the eyes, or press the Alpha- Stim M probes over the carotid sinus (on the neck near the larynx).

Precautions
For external use only. Do not allow children to use or handle these devices without adult supervision. Do not operate potentially dangerous machinery or vehicles during treatment, and in some cases for several hours after treatment. Caution is advised in cases where other forms of analgesia (pain control) would not be used; such as to retain the beneficial aspects of pain for diagnosis or in cases where people may overuse pain controlled areas.
Safety of stimulation has not been established during pregnancy.

Adverse Effects
Adverse effects are usually mild and self-limiting. Adverse effects from data on approximately 8,800 patients participating in 144 controlled studies, open clinical trials, and uncontrolled conditions, and by physician survey and reasonably associated with the use of CES and MET are dizziness (6 cases, 0.07%), skin irritation/electrode burns (6 cases, 0.07%), and headaches (9 cases, 0.10%). Prolonged CES treatment at currents higher than necessary may cause dizziness or nausea that can last for hours to days. Treatment immediately prior to going to sleep may cause difficulty sleeping. Paradoxical reactions such as increased anxiety and sleep disturbances may occur in the initial stages of treatment, but are rare.

Manufactured and marketed by:
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Made in the USA and in China to the exacting specifications of EPI, USA.

Alpha-Stim® and the Alpha-Stim logo are registered trademarks, and LET NOTHING STOP THEM is a trademark of Electromedical Products International, Inc. © 2019 Electromedical Products International, Inc. All rights reserved. Manufactured under US Patents 8,612,008; 8,457,765; and 8,463,406. Read a full disclosure of the minor and self-limiting risks here: alpha-stim.com/risk.

Type BF Equipment. This stimulator is internally powered only.

See instructions for use. Read the manual thoroughly before using.

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