

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



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, more than 70 American Veterans Affairs Medical Centers and in many Military Medical Centers worldwide as an effective, non-pharmacological choice for the treatment of anxiety, insomnia, depression and pain management. Alpha-Stim® is a stand-alone therapy and may also be used in conjunction with medications, behavioral therapies and other treatment modalities. 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 55 completed independent research studies and published reports.

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

CES is the process of using a microcurrent 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 millampere, 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.

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.

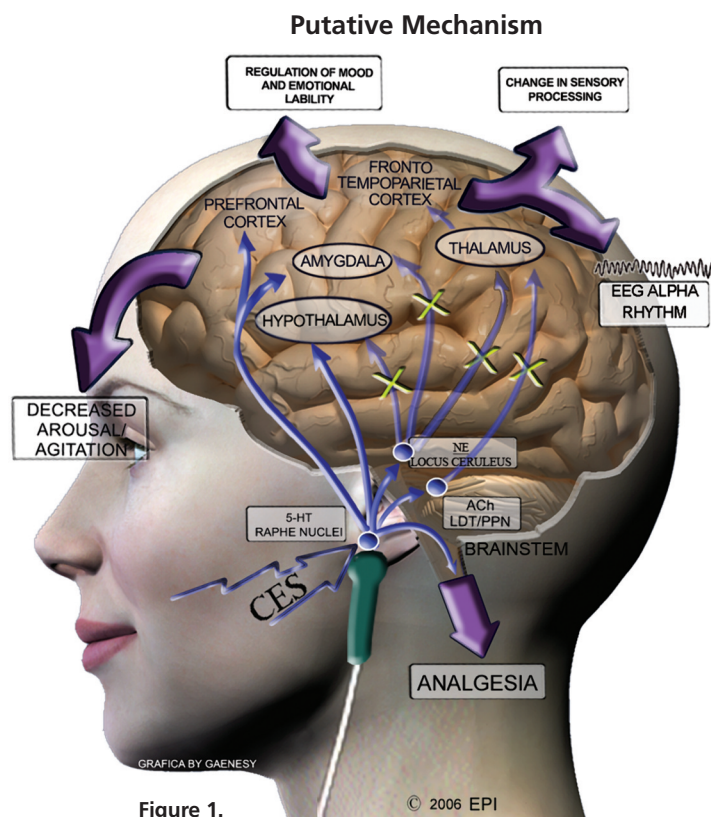
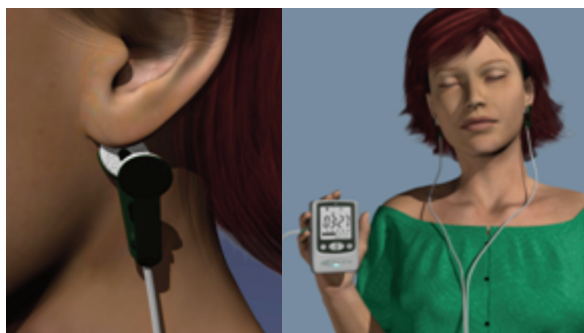


Figure 1.



Such alpha rhythms are accompanied by feelings of calm, relaxation and increased mental focus. The neurological mechanisms that are occurring during the alpha state appear to decrease stress-effects, reduce agitation, stabilize mood, and regulate both sensations and perceptions of particular types of pain.

These effects 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 (available at www.alpha-stim.com). Repeated treatments have been shown to increase the relative strength and duration of these effects. In some cases, effects have been stable and permanent, suggesting that the electrical and chemical changes evoked by Alpha-Stim® technology have led to a durable re-tuning of aspects of the nervous system back to normal function.

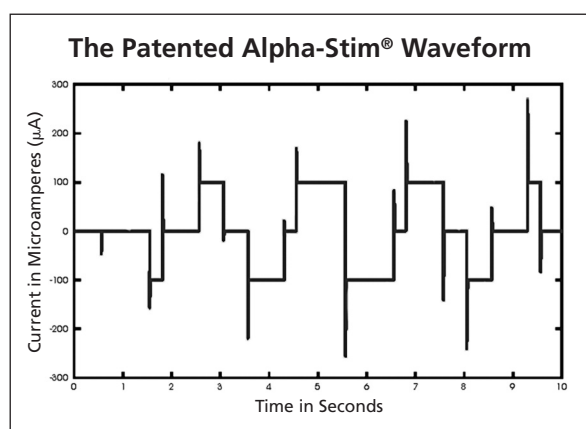


Figure 2.

What Makes Alpha-Stim® Unique?

It's the waveform (Figure 2). Alpha-Stim® generates a unique and proprietary 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 (associated with increased relaxation) and decrease delta waves (associated with increased alertness) 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. 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
3. 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, and may also be used as an adjunct to medication. 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 55 research studies, published reports and ongoing research, as well as surveys of doctors, patients and professional endorsements.

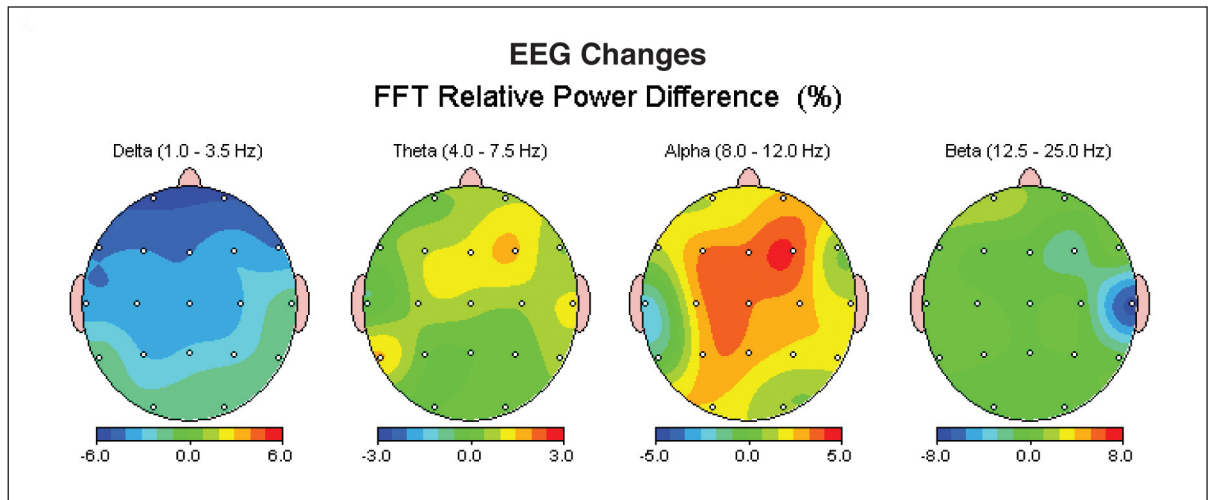


Figure 3. This quantitative EEG brain map shows the changes in brain activity by traditional EEG groupings in 30 university student volunteers after a single 20 minute treatment with Alpha-Stim® at 0.5 Hz. Blue shows a decrease in activity of sleepy delta brainwaves while red shows an increase in activity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

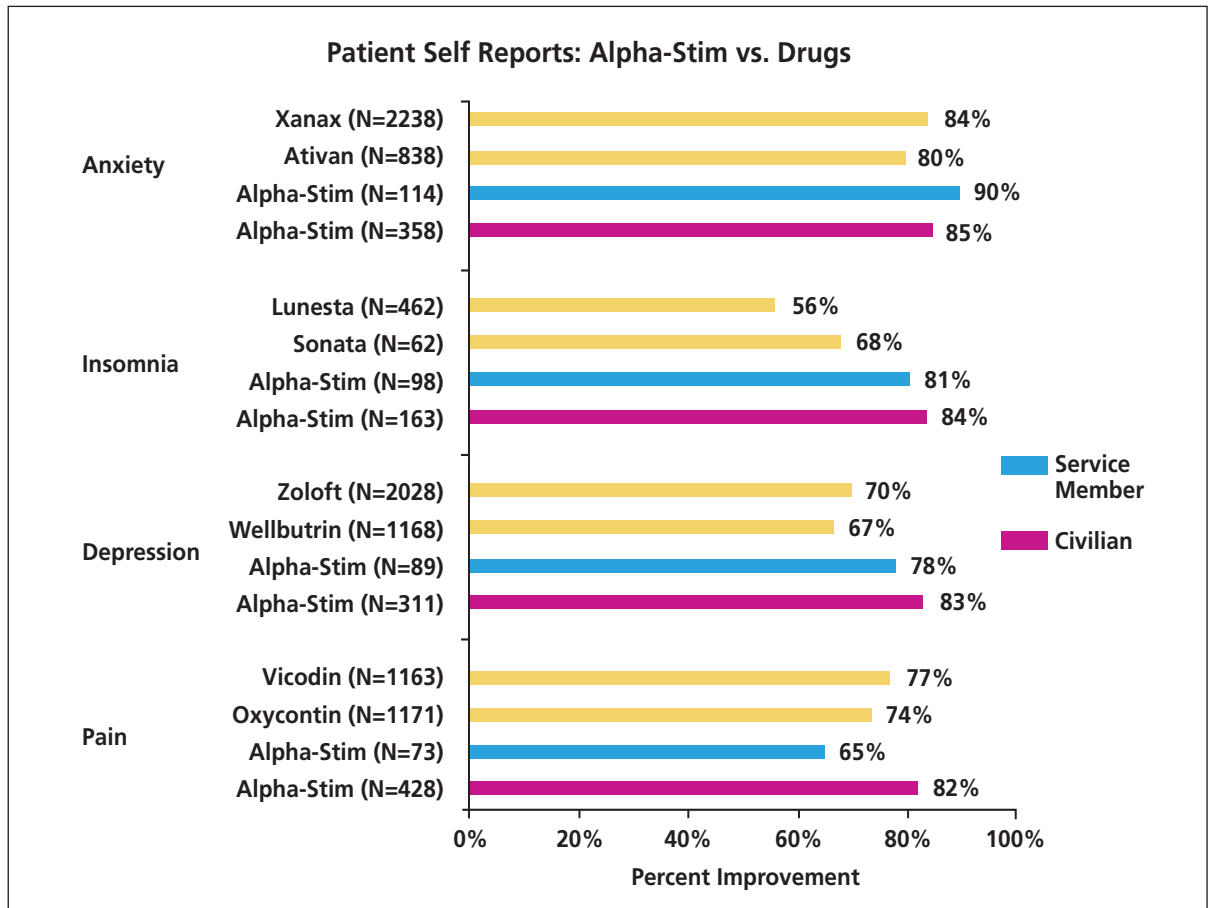


Figure 4. Patients who reported a positive response according to: WebMD Drug Surveys, and Alpha-Stim Service Member and civilian surveys. Alpha-Stim Data from 2011 Military Service Member Survey (N=152) and Alpha-Stim Patient Survey (N=1,745). Conducted by Larry Price, PhD, Associate Dean of Research and Professor of Psychometrics and Statistics, Texas State University. Pharmaceutical Survey Data from: www.WebMD.com/drugs. Accessed on October 28, 2011.

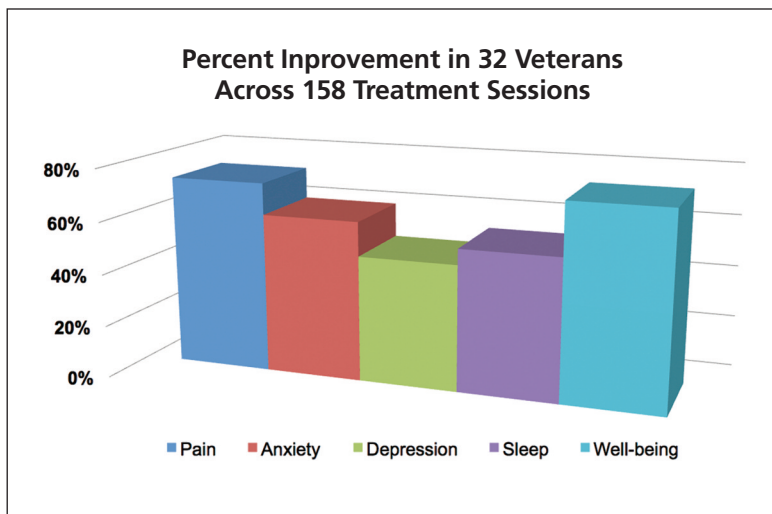


Figure 5. Tan, Gabriel, Dao, Tam K., Smith, Donna L., Robinson, Andrew and Jensen, Mark P. Incorporating Complementary and Alternative Medicine (CAM) Therapies to Expand Psychological Services to Veterans Suffering From Chronic Pain. *Psychological Services*, 7(3):148–161, 2010.

Patient Survey. Alpha-Stim® users – civilians and Service Members – consistently reported more positive responses than those that use pharmaceuticals.

When provided with a choice of complementary and alternative medicine therapies, veterans chose Alpha-Stim® 3 out of 4 times (73%) over other available therapies.

Figure 5 highlights the amount of improvement reported during that veteran study. Even in treatment resistant cases, most patients receive significant improvement from Alpha-Stim® therapy. (Table 1).

In another survey conducted from 2006 – 2011, respondents were also asked to report their

perceived improvement, in the form of a Likert rating scale, since beginning treatment. Figure 6 reveals that the effects are robust, with 60% improving 50% or more.

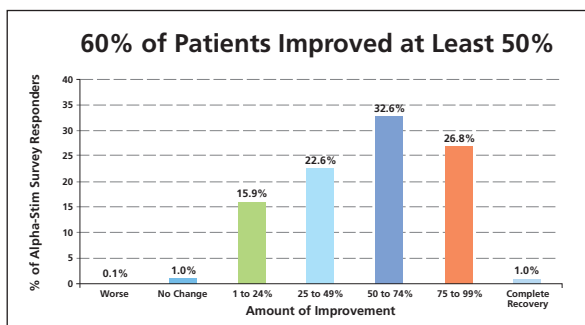


Figure 6. Results of a 2011 Alpha-Stim CES Patient Survey.

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.

Proven Efficacy

Alpha-Stim® is used extensively with military personnel by more than 200 practitioners within the Department of Defense (DOD) and over 70 Veterans Administration (VA) hospitals to treat post-traumatic stress disorder (PTSD), anxiety, insomnia, depression and pain.

In an August 2011 survey, 99.9% of 1,745 Alpha-Stim® users consider it effective!

Figure 4 presents results of the October 2011 Military Service Member Survey and Alpha-Stim®

Research

Alpha-Stim's® effectiveness is supported by 55 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.

In addition to current research, EPI has collected survey data from both doctors and patients that use Alpha-Stim®. Forty-seven doctors reported their results on 500 patients in 22 diagnostic categories resulting in a 50-page analysis published in the book *The Science Behind Cranial Electrotherapy Stimulation* by Dr. Daniel L. Kirsch (2nd Ed. Medical Scope Publishing, Edmonton, Alberta 2002).

That data correlates well with a published, peer-reviewed outcome study of 2,500 patients' self-reports (Table 2) where Alpha-Stim® was used for at least 3 weeks. In most diagnostic subcategories, both doctors and patients reported that 9 out of 10 people had significant results based on the survey standard of a minimum of 25% improvement. Effect sizes were robust with

Proven Efficacy: Results at a Glance

Condition	N	Worse	No Change	Slight <24%	Fair 25-49%	Moderate 50-74%	Marked 75-99%	Complete 100%	Significant >25%
Anxiety	349	0%	2.29%	4.01%	11.17%	25.50%	51.86%	5.16%	93.70%
Insomnia	135	0%	11.85%	8.89%	12.59%	25.19%	33.33%	8.15%	79.26%
Depression	184	0%	4.35%	5.89%	16.85%	20.65%	44.57%	7.61%	89.67%
Pain	286	.35%	1.75%	6.99%	16.78%	26.92%	37.76%	9.44%	90.91%

Table 1. Physician surveys showing percent improvement in 500 Alpha-Stim® patients where 25% or greater is considered significant.

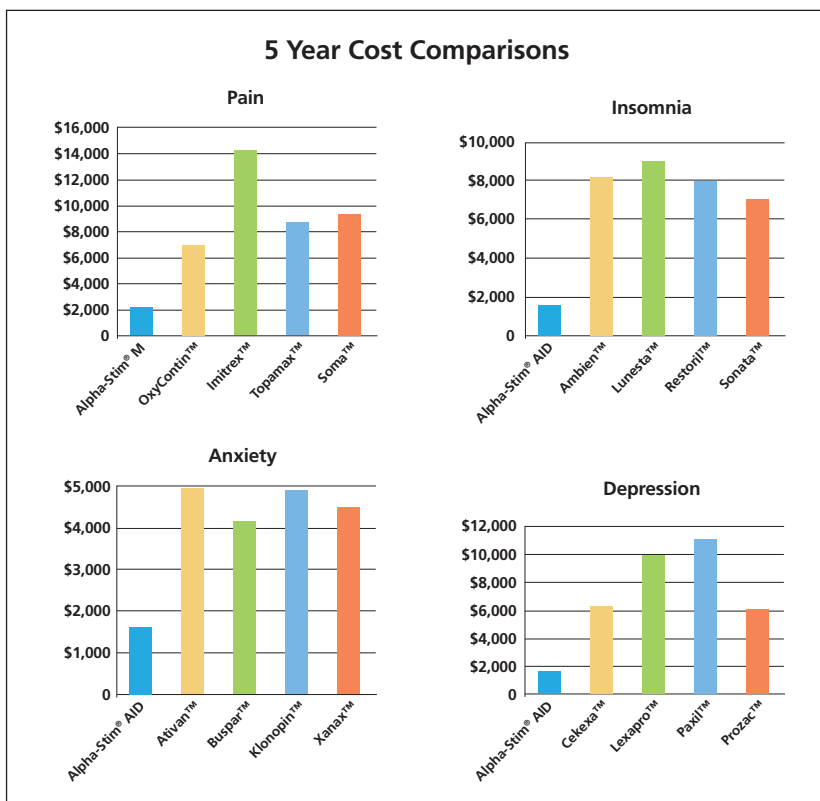


Figure 7. Drug prices are from www.drugpriceinfo.com

most Alpha-Stim® patients reporting at least 50% improvement in their symptoms. Combining the outcomes of both double-blind randomized clinical trials and comprehensive survey data assists in predicting treatment outcomes. There are hundreds of endorsements on www.alpha-stim.com, from physicians and other licensed healthcare professionals, sports teams and Alpha-Stim® users, which fill in the personal details about the Alpha-Stim® experience that scientific research reports omit.

For an in-depth list of research conducted for anxiety, insomnia, depression and pain management, see the research section of our website at www.alpha-stim.com.

Cost Effectiveness

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

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:

- Patient brochures
- Illustrated Owner's Manuals
- Animated treatment procedures and protocols on DVD
- Our award winning, comprehensive 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.

Results of Using Alpha-Stim® Technology for CES and MET

Condition	N	Slight <24%	Fair 25-49%	Moderate 50-74%	Marked 75-100%	Significant >25%
Psychological (all cases)	723	61 8.44%	175 24.20%	237 32.78%	250 34.58%	662 91.56%
Anxiety (alone)	128	13 10.16%	29 22.66%	42 32.81%	44 34.38%	115 89.84%
Anxiety (with other)	370	33 8.92%	85 22.97%	122 32.97%	130 35.14%	337 91.08%
Anxiety/Depression	58	3 5.17%	19 32.76%	19 32.76%	17 29.31%	55 94.83%
Depression (alone)	537	11 13.21%	23 20.75%	1 43.40%	2 22.64%	46 86.79%
Depression (with other)	265	29 10.94%	61 23.02%	93 35.09%	82 30.94%	236 89.06%
Stress	123	6 4.88%	30 24.39%	39 31.71%	48 39.02%	117 95.12%
Insomnia	163	10 6.13%	47 28.83%	47 28.83%	59 36.20%	153 93.87%
Pain	1,949	136 6.98%	623 31.97%	741 38.02%	449 23.04%	1,813 93.02%

Table 2. Patient Self Reports table represents results of using Alpha-Stim® technology for at least 3 weeks.

Alpha-Stim® and Your Practice

Try it RISK 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 or Canada. 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 some places, 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) and Cranial Electrotherapy Stimulator (CES) that treats pain, sleep and mood disorders like 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® Product Features	Alpha-Stim® M <i>For treating multiple pain areas, and anxiety, insomnia and depression.</i>	Alpha-Stim® AID <i>For treating anxiety, insomnia and depression without pain.</i>
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 3

Alpha-Stim® AID treats anxiety, insomnia and depression. It cannot be used to treat a specific pain site on the body, but may still be useful for people who suffer from pain related mood and sleep problems. See **Table 3** for a summary of product features.



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). See the Owner's Manual for complete details.

About EPI

Electromedical Products International, Inc. (EPI) was founded in 1981 by Dr. Daniel L. Kirsch, who developed Alpha-Stim® technology. Alpha-Stim® is a safe and effective solution for the treatment of pain, mood, and sleep disorders. In 2009 EPI

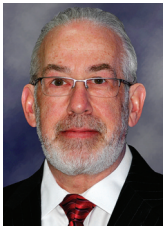
was a recipient of the Best of Business Award in the Surgical and Medical Instruments category by the Small Business Commerce Association (SBCA).

In 2011 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.



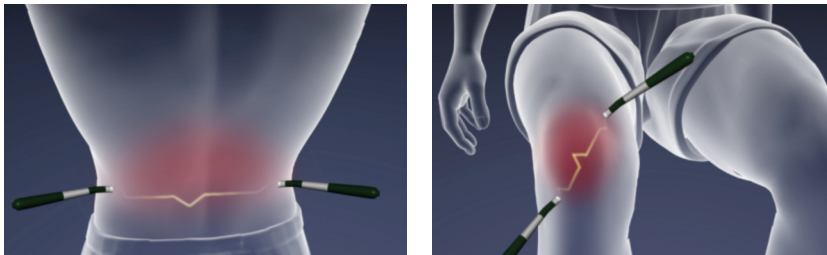
EPI today is a global enterprise with representatives throughout the world. EPI is an FDA registered establishment with operations certified by Underwriters Laboratories (UL) and the International Standards Organization (ISO) 13485:2003 standards for quality in medical devices. Alpha-Stim® products maintain the CE mark signifying compliance with the European Medical Device Directive, and are licensed by Health Canada.

Alpha-Stim® Inventor- Daniel L. Kirsch, PhD, DAAPM, FAIS

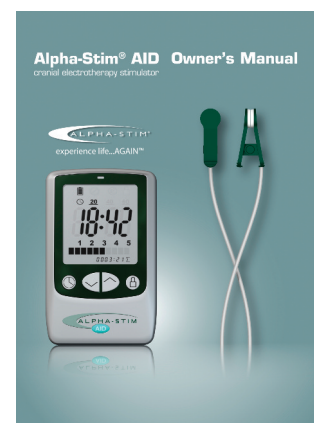


Dr. Kirsch is a world renowned neuroscientist with over three decades of experience in the electromedical field, including extensive clinical practice experience. Throughout his career Dr. Kirsch has designed medical instrumentation and their applications and developed clinical systems for implementing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

technologies. 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. He is also a Member of the International Society for Neurotherapy and Research and a Member of Inter-Pain (association for pain specialists in Switzerland and Germany). ■



Animated treatment procedures and protocols on DVD.

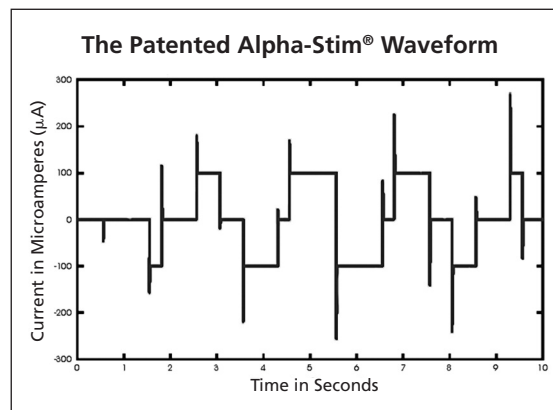


Illustrated owner's manuals.

Our award-winning, comprehensive website: www.Alpha-Stim.com.

Technical Specifications

Electrical	Alpha-Stim® M: 2 AA 1.5 volt, Batteries 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 (μ A) for the M and 0 to 500 μ A for the AID adjustable in 50 μ A 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 μ A and 0.5 Hz the charge per pulse varies between 150, 300, 450 and 600 microcoulombs (C). 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 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



Alpha-Stim® M

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, Instructional DVD, Lanyard, Storage Case, and 2 AAA Batteries.



Alpha-Stim® AID

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, Instructional DVD, Lanyard, Storage Case, and 2 AA Batteries.

Weight	101 gm with 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.

Alpha-Stim® may be used as an adjunct to medication, psychotherapy or other treatments. Some medications may need to be reduced as CES may augment the effects of prescribed medication.

Following treatment, most physical activities may be resumed immediately. However, some patients may experience a euphoric feeling, or deep relaxation, 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. When treating on the head, some patients will see flashing lights due to stimulation of the optic nerve during treatment. 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 healthcare 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 if the user experiences profound relaxation. 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. There have been reports of blood pressure being lowered in hypertensive patients by CES. Blood pressure should be monitored in people on blood pressure medications and the medication dosage should be lowered by the prescribing physician as necessary.

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 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 due to increased alertness. Paradoxical reactions such as hyperexcited states, increased anxiety, and sleep disturbances may occur in the initial stages of treatment, but are rare.



Manufactured and marketed by:



Electromedical Products International, Inc.

2201 Garrett Morris Parkway / Mineral Wells, Texas 76067-9034 USA

Tel: 1.800.367.7246 in the USA and CANADA, or 940.328.0788

Fax: 940.328.0888 / Email: info@epii.com

Authorized Representative for the European Union:



MediMark Europe

11, rue Émile Zola – BP 2332/38033 Grenoble Cedex2– France

Tél: +33 (0)4 76 86 43 22 / Fax: +33 (0)4 76 17 19 82

E-Mail: medimark@easynet.fr

Made in China to the exacting specifications of EPI, USA.

© Copyright 2012 by Electromedical Products International, Inc.
ALL RIGHTS RESERVED. Alpha-Stim® is registered in the U.S. Patent
and Trademark Office and Worldwide Patents Pending.

www.alpha-stim.com



Type B Equipment.
This stimulator
is internally
powered only.



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

