# Alpha-Stim<sup>®</sup> M and You

# When you're in pain Alpha-Stim®





# What is Alpha-Stim and How Does it Work?

Alpha-Stim is a clinically proven electromedical device that relieves pain, anxiety, depression and helps promote better sleep. Alpha-Stim generates a unique, patented waveform no other device can offer. Much like every white pill is not the same, the uniqueness of Alpha-Stim's waveform produces results vastly different from its competitors. Unlike medications which are introduced to your body in a chemical form and then broken down to smaller components such as electrons, Alpha-Stim begins at the electron level, allowing your body's cells to return to their natural functioning state. Alpha-Stim provides long lasting cumulative relief to you fast, allowing you to resume your normal daily activities.



# Is Alpha-Stim Safe?

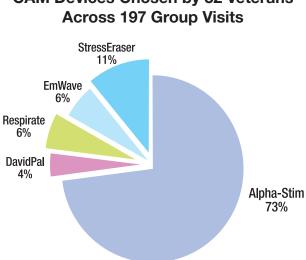
There are over 95 research studies and published reports, as well as ongoing research, surveys of patients and professional endorsements, all supporting the safety and efficacy of Alpha-Stim. Our research is so good, even our competitors use it. In over three decades of studies involving approximately 8,800 people, only minor, self-limiting side effects have been reported, with the two most common being headaches (0.10%) and skin reactions at the electrode sites (0.07%). In a recent 5 year period, 8,248,920 Alpha-Stim treatments resulted in only 14 instances of minor side effects, 11 of which were skin irritation at the electrode site.

# Effective

A survey was conducted which included 2,500 patients using cranial electrotherapy stimulation (CES) and microcurrent electrical therapy (MET) for the treatment of pain.<sup>1</sup> Nine out of 10 people reported significant relief of at least 25% improvement regardless of the cause of their pain.

### **Veterans Chose Alpha-Stim** 3 out of 4 Times

In a study at Michael E. DeBakey Veterans Affairs Medical Center in Houston, Texas, people who experience severe pain chose Alpha-Stim 3 out of 4 times. These were veterans who were suffering from chronic pain along with mood and sleep disorders. After being shown how to use 5 treatment options, they continued to choose Alpha-Stim 73% of the time.<sup>2</sup>



# CAM Devices Chosen by 32 Veterans

<sup>1.</sup> Kirsch, Daniel L. The Science Behind Cranial Electrotherapy Stimulation (2nd Ed), Medical Scope Publishing Corporation, Edmonton, Alberta, Canada, 2002.

<sup>2.</sup> 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.

# Why Veterans Preferred Alpha-Stim for Relief from Pain – Fast, Safe, Effective

Alpha-Stim uses MET for people suffering from acute, chronic or post-traumatic pain and CES for anxiety, insomnia and depression. The microcurrent waveform unique to Alpha-Stim technology produces long lasting and cumulative results, which means your relief will last and let you resume your normal activities.

There is more research supporting Alpha-Stim than any other therapeutic device in its class, and even more than most pharmaceuticals.

Developed in 1981 by Dr. Daniel L. Kirsch, a pain specialist and military consultant, Alpha-Stim has provided millions of people around the world with relief from chronic, acute and posttraumatic pain, even when other therapies have failed them. Fortunately, the same Alpha-Stim used by soldiers and veterans is also available to you now. So, if you are seeking relief from your pain, ask your healthcare provider about prescribing Alpha-Stim for you. If you live outside the USA, no prescription is necessary.

# **Testimonials**

"The Alpha-Stim has changed my life. After a decade of debilitating chronic pain, I can walk, sleep and function again. I emerged from a ten-week chronic pain management program with several techniques and tools to improve my quality of life and the Alpha-Stim is the best of all. I had tangible results immediately after my first treatment. I feel reborn and now have the energy and hope that I can and will become productive again. Now that I personally have an Alpha-Stim my quality of life is back in my hands. No more prescription drug stupor and spiraling negative side effects. I am blessed."

– Justin P.

The pain was off the scale. I barely left my bed for three months. I began using the Alpha-Stim three times a week for an hour each session. I went dancing for the first time in over a year. I am running two miles a day now. I felt like a miracle occurred. I was also angry that my doctor hadn't known about the Alpha-Stim. I could have lived the last year of my life in a lot less pain had he been up to date with Dr. Kirsch's technology."

- Nancy E.

"I experienced extreme pain daily. I have used the Alpha-Stim for the past three months. I am receiving a great deal of relief from its use. Some days I use it 2 or 3 times and other days I may not use it at all. I can then tolerate the pain and I am a much better person to be around. I would highly recommend the use of the Alpha-Stim to anyone. It has helped me to experience less pain and enjoy life everyday."

– Alan M.

"This equipment is extraordinary. I had surgery and the post-op pain was (a) agonizing and (b) not greatly helped by extremely strong pain meds. I used the Alpha-Stim – in 6 hours, my pain had all but vanished. I was blown away – this technology is transformative, and I had no need to return to painkiller drugs again. The surgeon was astounded. I ordered my own Alpha-Stim as soon as I could, and it has been an absolute godsend. This technology should be taken up by physicians everywhere."

– Gail M.

# What to Expect From Treatments

While Alpha-Stim technology is significantly effective when it is used correctly for 9 out of 10 people who use it, it will not work for everyone. If obvious pain relief is not achieved after several probe locations are attempted, consider treating the primary area of pain at a lower

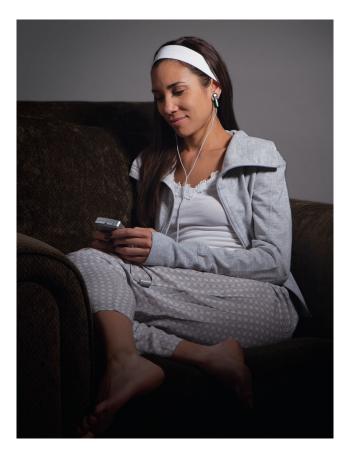


current setting of 1 - 2 (100 to 200 uA) with AS-Trode<sup>™</sup> electrodes for 60 minutes or more. If necessarv. it can be used all day. It may also be necessarv to treat all areas of pain anywhere on the body in order to get results.

If the Alpha-Stim is not working well for you, contact your healthcare practitioner, your local authorized Alpha-Stim distributor, or EPI for clinical support. We are here to help you.

Both pain control and 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 up to 4 weeks. While most people can use it at bedtime and when awakened during the night, some find they must conduct their 20 - 60 minute Alpha-Stim CES treatment at least 3 hours before going to bed because the CES treatment may interfere with sleep when used just before bedtime. It may also be used in the morning to promote better sleeping at night. Depression typically takes 3 weeks or more of daily treatment to experience significant improvement. After symptoms have improved, use of Alpha-Stim 2 - 3 times per week or less is usually sufficient to maintain good results.

No significant lasting side effects have been reported from millions of treatments in doctors offices and at home. Occasional headache, discomfort or skin irritation under the electrodes or lightheadedness may occur. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. These are all mild, self-limiting reactions.



### Electromedical Products International, Inc. A Dedicated Company You Can Trust



Electromedical Products International, Inc. (EPI) was founded in 1981 by Dr. Daniel L. Kirsch, a world-renowned neurobiologist, who developed a safe and effective solution for the treatment of pain, sleep and mood disorders with Alpha-

Stim technology. He was the recipient of the 2008 prestigious Richard S. Weiner Pain Educator of the Year Award from the American Academy of Pain Management. EPI was a recipient of the 2013 Best of Business Award in the Surgical and Medical Instruments

category by the Small Business Commerce Association (SBCA). EPI and its staff are dedicated to the pursuit of excellence in the treatment and diagnosis of medical and healthcare related issues.



In 2011, EPI won the prestigious American Institute of Stress Award for Distinction and Innovation based on the growing list of publications in peer reviewed journals demonstrating efficacy and safety of Alpha-Stim products.



EPI today is a global enterprise with representatives throughout the world. EPI is an FDA registered establishment with operations certified by an independent third party to the International Standards Organization (ISO) 13485:2003 standards for quality in medical devices. Alpha-Stim products earned and maintain the CE mark through compliance with the European Medical Device Directives.

# Alpha-Stim<sup>®</sup> Product Features

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

# Select the Alpha-Stim That's Right for You

Alpha-Stim technology is available in two

easy-to-use therapeutic devices for both home and clinical use. See Table above.

Alpha-Stim M provides both microcurrent electrical therapy (MET) that treats pain and cranial electrotherapy stimulation (CES) that treats anxiety, insomnia and depression.



### Alpha-Stim<sup>®</sup> M

For treating multiple pain areas, anxiety, insomnia and depression.

### Alpha-Stim<sup>®</sup> AID

For treating anxiety, insomnia and depression without pain.



Alpha- Stim M is the most complete and versatile product, and the only choice for those wanting to treat pain as well as anxiety, insomnia and depression. Alpha-Stim M comes complete with probes and self-adhesive AS-Trodes<sup>™</sup> for treating pain, and earclips for administering CES.

Alpha-Stim AID provides cranial electrotherapy stimulation (CES) for those suffering from anxiety, insomnia and/or depression without pain. Alpha-Stim AID comes complete with earclips for administering CES.



# How do I Get an Alpha-Stim?

1. In the USA, you must first ask your doctor if Alpha-Stim is right for you and obtain a prescription.\*

2. Go to www.alpha-stim.com or call (800) FOR-PAIN in the USA to order your Alpha-Stim or for a referral to your local distributor. Outside the USA, call +940.328.0788 or email info@epii.com.

# **5 Year Limited Warranty**

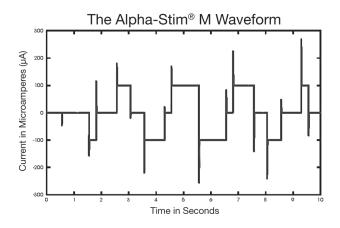
Each Alpha-Stim M is warranted to be free from defects in materials and workmanship under normal use for a period of five years from the date of purchase (not including batteries and accessories). See Owner's Manual for complete details.

# **Alpha-Stim M Technical Specifications**

### Electrical

Batteries	2 AA 1.5 volt (included).
Timer	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.
Current	0 to 600 microamperes (µA)
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 $\mu$ A and 0.5 Hz the charge per pulse varies between 150, 300, 450 and 600 microcoulombs ( $\mu$ 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 $100 \Omega$ to $10 K \Omega$ . 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 inter vals. The waveform is balanced to achieve 0 net current in either direction (see graphic on the next page).

<sup>\*</sup>Note: Alpha-Stim has regulatory clearance throughout most of the world. In the United States, it is cleared by the FDA for interstate marketing by or on the order of a licensed healthcare professional. Outside of the USA, it is available without a prescription.



### Mechanical

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

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

The Alpha-Stim M comes complete and ready to use with 1 set of Earclip electrodes, 1 15-ml bottle of Alpha Conducting Solution<sup>™</sup> (250 ml refill bottles available), 2 sets of lead wires for 4 electrodes, 2 Smart Probes, 4 silver AS-Trode<sup>™</sup> brand single person multiple use self-adhesive electrodes (good for approximately 2 weeks to 1 month of use), 100 Probe Electrode Pads (PEPS<sup>™</sup>), 256 Earclip Electrode Pads (EEPS), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AA Batteries. This is everything you need to begin using your new Alpha-Stim M. Replace Alpha Conducting Solution<sup>™</sup>, AS-Trode<sup>™</sup> brand electrodes, PEP<sup>™</sup> and EEP electrodes only with authorized Alpha-Stim and AS-Trode<sup>™</sup> brand products.

# **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.

### 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 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.

### **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 of the USA, it is available worldwide 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 Alpha-Stim AlD 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 affected 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 other implanted devices. Do not stimulate directly on the eyes, or press the 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 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, but are rare.

If Alpha-Stim does not begin to control your pain, anxiety, insomnia or depression within one month, consult your healthcare practitioner, authorized Alpha-Stim distributor, or EPI for advice.





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Type B Equipment. This stimulator is internally powered only.



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