

Practitioner's Guide to Using Alpha-Stim®

*How to Use Alpha-Stim® Technology
To Help Your Patients With Pain,
Anxiety, Depression and Insomnia.*

ALPHA-STIM®



Alpha-Stim® is the most researched medical device in its class with more than 55 completed independent research studies and published reports and several more underway. Research shows that 93% of patients reported significant relief from their pain, anxiety, depression and/or insomnia after 3 weeks of use.

9 out of 10 tough pain patients, who couldn't get relief with anything else, finally had relief with Alpha-Stim®. The effects of Alpha-Stim® are usually immediate, cumulative, and long lasting. Because of this, many practitioners integrate Alpha-Stim® treatment protocols into their office procedures, as well as prescribe or order Alpha-Stim® for their patients to use at home.

So Let's Look at the Concrete Facts About Using Alpha-Stim®

There are only four reasons why a licensed health care or mental health professional would recommend any intervention for a particular patient:

- 1) Safety**
- 2) Efficacy**
- 3) Cost-Effectiveness**
- 4) Reliability and Support**

Through this guide we will demonstrate how Alpha-Stim® meets all four criteria.

Alpha-Stim® can easily be incorporated into your practice resulting in more satisfied patients who refer friends and colleagues.

Now let's look at this in more detail.

Alpha-Stim® and Your Patients

Safety First!

With all the current and on-going publicity about the dangers of drugs like Oxycotin, Vioxx, Celebrex, and the SSRI's like Prozac, Zoloft and Paxil, patients are more concerned than ever about the risks they take when they seek help for their pain or mood disorders. Alpha-Stim® technology is not only safer than any drug, but it is even safer than most other devices because it only uses microamperes (millionths of an ampere) of electricity. The only side effects derived from studies with over 6,000 patients are headache, which

occurs in 1 of 506 patients, and skin irritation in 1 of 910 patients. Both of these problems are minor and self-limiting.

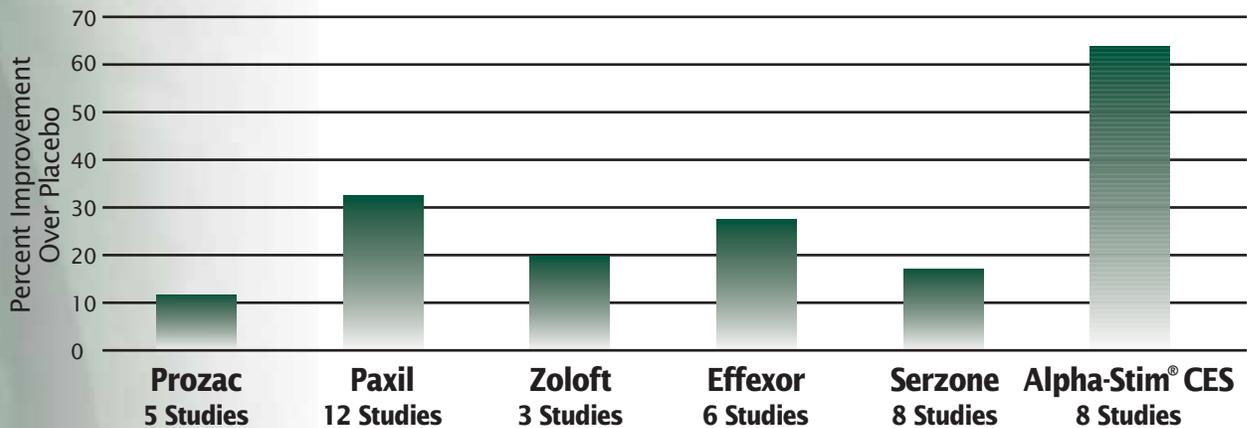
With Alpha-Stim® there is no chance of causing tardive dyskinesia, increased suicidal ideation, addiction, death, or hepatic failure, to name just a few of the risks of pharmaceutical intervention. The worst problem that has ever been documented with Alpha-Stim® was the rare occurrence of mild disorientation when a cranial electrotherapy stimulation (CES) session was prematurely interrupted. That problem is easily avoidable by completing the full treatment session, which generally takes only 20 minutes.

Proven Efficacy

More than 93% of pain patients achieve significant relief with Alpha-Stim®, even when conventional intervention has failed. So how can you trust this?

There are only three ways to prove efficacy: research, surveys and testimonials. Alpha-Stim® has all three in abundance. In fact, with 55 completed studies and many more underway, there is more research supporting Alpha-Stim® technology than there is for most drugs. An important fact about Alpha-Stim® research is that none of it is company-supported. Most of the studies are double blind placebo controlled and were conducted at major US universities. The US government has funded two major Alpha-Stim® studies. One is a NCI/NIH study for breast cancer patients undergoing chemotherapy and the other is a VA study for veterans with spinal cord injuries.

Efficacy of Antidepressants Beyond the Placebo Response



Kirsch I, Moore TJ, Scorbora A, and Nicholls SS. The Emperor's New Drugs: an Analysis of Antidepressant Medication Data submitted to the FDA. *Prevention and Treatment*. 2002;5:1-11.

Gilula ME, and Kirsch DL. Cranial Electrotherapy Stimulation Review: A Safer Alternative to Psychopharmaceuticals in the Treatment of Depression. *Journal of Neurotherapy*. 2005;9(2):7-26.

In addition to the prospective research, we have survey data from both doctors and patients. Forty-seven doctors reported their results on 500 patients in 22 diagnostic categories resulting in a 50-page analysis of that data published in the book *The Science Behind Cranial Electrotherapy Stimulation* by Dr. Daniel L. Kirsch (2nd Ed. Medical Scope Publishing, Alberta 2002). That data correlates well with a peer-reviewed outcome study of 2,500 patient's self reports published in the *American Journal of Pain Management*: 11(2):62-66, 2001. For most diagnostic categories, both doctors and patients reported that 9 out of 10 patients had significant results based on the drug standard of a minimum of 25% improvement. However, most Alpha-Stim® patients had at least 60% improvement in their symptoms. Furthermore, clinical research tells us the technology is effective if it achieves

a probability factor of at least $P < .05$. This means that if the study is repeated 20 times, the chances are that a similar outcome would be reproduced 19 times. While that is the benchmark for acceptable science, it is not of great value to a clinician. An advantage of comprehensive survey data over other kinds of research is that it helps us predict more specifically how well a patient in a specific diagnostic category might do with this treatment. For example, doctors tell us that in 286 pain patients they treated in their offices, 27% will achieve a 50 to 74% reduction in their pain. Of 1,947 pain patients who used Alpha-Stim® for at least 3 weeks at home, 38% reported that same 50 to 74% level of improvement. We have created convenient charts for clinicians to use this data to assist in prognosis which we call, "Alpha-Stim® Results at a Glance".

Finally, there are hundreds of endorsements on our Web site: www.alpha-stim.com



from physicians and other licensed health care professionals, sports teams and patients. Viewed on the foundation of our prospective research, these personal testimonials to the effectiveness of Alpha-Stim® technology in adults, children and animals fill in the fine details about the Alpha-Stim® experience that pure research reports omit.

Cost-Effectiveness

Forbes Magazine reported annual cost figures for the most popular drugs used to treat various conditions including anxiety and depression, chronic pain and insomnia (“Just Say No!”, November 29, 2004, pages 102-112).

For the customary, pharmaceutical treatment of depression or anxiety using the popular drug Zoloft, the annual cost per patient is \$850. However, it is well known that Zoloft may cause insomnia, and Alpha-Stim® CES is also FDA cleared to treat insomnia. Therefore, patients who use Alpha-Stim® CES to treat anxiety are simultaneously receiving an effective

treatment for insomnia and depression. Recent studies have acknowledged what has been empirically demonstrated and understood by clinicians for quite some time – that chronic pain is highly correlated with depression, anxiety and insomnia, and vice versa.

According to *Forbes*, the sum of the annual costs for the drug treatment of anxiety and insomnia is \$1,770 per patient. Adding chronic pain to the mix would result in an annual cost per patient of \$3,100.

A patient suffering from chronic pain, anxiety and insomnia, spending \$3,100 annually for Oxycontin, Ambien, and Zoloft would begin seeing a cost savings by using Alpha-Stim® CES at 1.91 or 3.46 months, depending on the Alpha-Stim® model. Put another way, against the combined costs of Oxycontin, Ambien, and Zoloft, Alpha-Stim® CES breaks even at about 2 to 3½ months, and lasts at least five years.

Over the 5 year warranty that covers every Alpha-Stim®, the savings can amount to as much as \$7,100 for the Alpha-Stim® SCS over Prozac alone. This product-to-product comparison assumes that drug prices will remain at current levels and the patient will take their drugs for five years without incurring any additional drug or doctor visit costs. Of course in real life the drugs and their associated costs would probably be some multiple of these figures. The Alpha-Stim® 100 will take a little longer to save money over drugs but it can replace a lot of drugs for both pain and associated depression so the savings still add up quickly.

Reliability and Support

Electromedical Products International, Inc. (EPI) has been in business since 1981. EPI takes care to ensure its operations meet the highest quality standards by maintaining a special certification for the medical device industry. This is accomplished by implementing a quality system for business operations in compliance with ISO 13485:2003, an internationally recognized quality control standard for the medical industry. EPI is inspected annually to insure its quality systems adhere to the stringent requirements of this ISO standard.

Further, Alpha-Stim® Technology is classified by Underwriters Laboratories Inc., an independent testing company in accordance with UL-2601-1 and CA/CSA C22.2 No 601.1.34VF.

Nothing is more important to our management and employees than customer service. We have a variety of resources to assist you and your patients including illustrated owner's manuals, illustrated specialized treatment protocols both in hard copy and on our Web site, and educational DVDs that explain and demonstrate our pain treatment protocols. We pride ourselves on providing the best ongoing support of any medical device company. When you buy or prescribe an Alpha-Stim®, you and your patients get access to the top experts in electromedicine at no additional cost. Our clinical support team fields questions on just about every topic, from how to do the simple 2 to 5 minute pain management



protocols, to more complex, difficult to treat cases like reflex sympathetic dystrophy, rheumatoid arthritis and fibromyalgia. We help you through your learning curve. No other comparable medical device company offers this much support.

Alpha-Stim® and Your Practice

Using Alpha-Stim® in a Clinical Environment

We have substantiated that Alpha-Stim® works on 9 out of 10 patients that have tried it. Now that we know it works for patients, let's look at how the Alpha-Stim® benefits the health care or mental health professional's practice. We'll first provide background, suggestions and examples for the practitioners who see pain patients, followed by the same for mental health professionals. Please note that Alpha-Stim® is a medical device regulated in the United States by the Food and Drug Administration (FDA). Accordingly, its use in the United States is by prescription or the order of licensed professionals, although it is available over-the-counter in the rest of the world. If you are a licensed practitioner and can see patients for a specific condition without a referral from another practitioner, you can order Alpha-Stim® for that patient's condition. Don't hesitate to call us for more information.



Alpha-Stim® for Managing Pain

There are as many variations for using Alpha-Stim® in a practice as there are types of practitioners. However, there is a common model that has emerged that can be emulated successfully. Most practitioners use Alpha-Stim® for immediate relief of acute and chronic pain using the probes and our proven treatment protocols right in their office. These procedures can be performed either by the practitioner, a nurse, or assistant in an examination or treatment room. No special tables or other devices are required.

Insurance usually pays for treatments in a practitioner's office using established CPT or DSM codes. It only takes about 2 to 5 minutes of active probe treatments using our simple proven protocols to substantially reduce or eliminate pain. You can view the pain protocols on our Web site.

For the best results, probe treatments should be followed by a 20-minute CES session wherein the patient relaxes in a comfortable chair with ear clip electrodes on. These sessions can be unattended. Accordingly, one assistant can comfortably treat 3 or 4 patients per hour. The CES part of the treatment can even be done on multiple patients at one time in a large room limited only by the number of chairs. Some practitioners do this to relax patients

while they are undergoing other procedures, such as dialysis.

Because the results of Alpha-Stim® are cumulative and long lasting, patients feel better immediately, with the results usually lasting for days before another treatment is necessary. Each treatment adds to the cumulative effect, making each treatment last longer than those preceding it. For chronic or persistent conditions, the patient can be taught to use the Alpha-Stim® at home between visits to your office, for check-ups and other interventions.

To ensure your best success, we offer everything from a 30 minute DVD version of the Owner's Manual (filmed at St. John's Regional Health Center in Springfield, Missouri) to an in-depth 6½ hour DVD set featuring eight prestigious speakers filmed at the American Academy of Pain Management's annual meeting in 2003. This can be used for comprehensive staff training, along with reprints of textbook chapters on our protocols and full color posters with examples. Questions beyond that are happily answered by our fully trained distributors or our clinical support specialists using our toll free 1-800-FOR-PAIN number. Using these resources you can be confident in achieving immediate results with Alpha-Stim®.

Alpha-Stim® for Anxiety, Insomnia and Depression

Mental health professionals often have to deal with drug problems, including tolerance, side effects, addiction,



overdosing and polypharmacy effects. Moreover, given the recent FDA mandated black box warnings, more patients

are concerned about every new emotion or sensation they experience.

With the side effects and safety issues of psychotropic drugs, it's a wonder that their use has become so prevalent in our society. Here's a list compiled from the safety warning sheets from several of the most popular antidepressants: gastrointestinal upset, sexual dysfunction, headache, restlessness, nervousness, insomnia, somnolence, discontinuation syndrome with sudden withdrawal of certain SSRIs, cardiovascular effects, nausea, dry mouth, dizziness, sedation, agitation, constipation, weight loss, weight gain, orthostatic hypotension, anticholinergic effects, reflex tachycardia, cholinergic rebound upon rapid discontinuation, possibility of severe hepatotoxicity, priapism, risk of elevated supine diastolic blood pressure, cardiac conduction abnormalities, possible lethality in overdose, routine use requires monitoring of serum drug levels when new meds are started or discontinued or in the case of suspected overdose or nonadherence or if severe adverse effects develop, and use with caution in patients with acute angle closure glaucoma, cardiovascular disease, cognitive impairment, or suicidal tendencies.

The incidence of side effects with Alpha-Stim® are: headache, 0.20%, and skin irritation, 0.11%. These are minor and self-limiting.

Even if your patient is not currently taking medication, research demon-

strates that Alpha-Stim® may help their condition. It simultaneously treats anxiety, depression and insomnia and allows the patient to focus on other therapies such as relaxation, biofeedback or cognitive behavioral therapies (CBT). Many mental health professionals use Alpha-Stim® during CBT because it helps the patient focus. Once proven effective for a particular patient in a clinical setting, Alpha-Stim® can be ordered for home use.

The most current review and meta-analyses on CES for anxiety, depression, insomnia, cognitive dysfunction and pain was published as a chapter by Kirsch et al. in the 2004 textbook, *Bioelectromagnetic Medicine* (Marcel Dekker, Inc., New York). You can view this chapter on our Web site. The r effect sizes from 25 studies of CES for depression involving 1,075 patients is .57 (which means 57% improvement where .10 is considered small, .30 medium and .50 high). Surveys of 500 anxiety patients detailed in this chapter found an overall effect size of $r = .62$, and 21 studies of CES for insomnia involving 940 patients also found a mean effect size of $r = .62$. (i.e., the mean improvement in the group was 62%).

Alpha-Stim® Provides Proof; Others Can't Even Come Close

Keep in mind that Alpha-Stim's® proven results are due to its proprietary technology and protocols that are not transferable. No other device has our technology, nor have any proven they

can achieve these results. Others may claim they have a similar technology, but look at it like this: all “five mg white pills” are not alike. Morphine and aspirin are both analgesics but of course they differ in many ways. Some companies would like you to believe that their device can equal Alpha-Stim® results just because it is in the same category. Yet, no other product has achieved marketing clearance by FDA for all four primary Alpha-Stim® applications. So another brand of so-called microcurrent stimulator or cranial electrotherapy stimulator would have to provide proof of efficacy for their specific technology. None provide as much proof of safety and efficacy as Alpha-Stim®. Surprisingly, most devices have no research at all. We have even seen several companies trying to use Alpha-Stim® studies to support their unfounded claims for their untested products. Also keep in mind that Electromedical Products International, Inc. offers the best support and longest warranty for any medical device.

Conclusions

Remember, Alpha-Stim® has been around since 1981. It has been proven effective by hundreds of thousands of patients and health care professionals, without significant side effects. While we have painstakingly labored away, accumulating research and endorsements from delighted patients and their doctors, we are now witnessing a fundamental shift in patient and practitioner attitudes. We firmly believe that the health care climate is changing and that informed patients are demanding safe and effective treatment from their

health care practitioner. Alpha-Stim® is prepared for this challenge, and is well positioned to help health care practitioners in many disciplines respond to the changing dynamics of health care delivery. Call us. Give Alpha-Stim® a try, and see if you and your patients don't agree.

Try It RISK FREE!

As a licensed health care or mental health practitioner, we are pleased to offer a no-cost, low-risk way to see for yourself how Alpha-Stim® can help your patients and your practice. Call our toll free number, 1-800-FOR-PAIN and choose Option 4 from our automated response unit. This will put you in touch with one of our experienced and knowledgeable clinical support specialists who will be happy to answer any further questions you might have. Then, we'll put you in touch with an authorized distributor in your area who can demonstrate Alpha-Stim® in your office and show you how to use it on your patients. Your distributor will be able to provide valuable insights and suggestions on how to effectively integrate Alpha-Stim into your practice and introduce it to your patients.

If there is no distributor in your area, Electromedical Products International, Inc. is your distributor.

We will loan you an Alpha-Stim® to try out absolutely free for 60 days. During and after your free trial our legendary customer service is at your fingertips. From clinical and technical support, to



insurance billing or financing for your patients, we'll be there for you.

So, call 1-800-FOR-PAIN
or email alpha-stim@epii.com
today for a free demonstration
or a 60 day free trial.

More Information On Our Website

Visit our website at www.alpha-stim.com
where a substantial amount of informa-
tion about the technology and products
is available.

Topics include:

- Results at a Glance
- Research Abstracts and Studies
- Video Clips of Alpha-Stim® in the News
- Frequently Asked Questions

Practitioner Comments:

Alpha-Stim® for Treating Pain and the Symptoms of Fibromyalgia

"There's been variable acceptance regarding the safety of using opioid analgesics to treat non-cancer pain. In fibromyalgia patients, the risk-benefit ratio becomes even more complicated. Given that Alpha-Stim® raises serotonin and norepinephrine levels, and has a neutralizing effect on somatic pain generators, I predict this therapy will become a mainstream modality for reducing medication reliance and enhancing function in patients with fibromyalgia."

Stephen E. Plotnick, MD
Board-certified rheumatologist. From an article
in *Advance For Directors In Rehabilitation*
("Finding Hope", May 2005, page 82)

Alpha-Stim® In Psychiatry; Treating Stress, Anxiety and Depression

"The Alpha-Stim® has had dramatic effects on my patients and on my practice.

I bought one to try on people with ADD and soon found that it is the most calming experience that I can offer my patients, or myself. My patients report that it has improved their responses to the medications that they take, or that it helps them without medication. Several bipolar teenagers are doing considerably better with it, as is a young autistic boy. Adults who are stressed and/or anxious usually respond within about 10 minutes. One boy with a tic disorder doesn't tic as long as he used the Alpha-Stim® in the AM and another, with severe OCD disorder who is on 300 mg a day of Zoloft without full benefit, has stopped his ritual praying and blessing (in the past year averaging about 2-3 times a minute). So it sounds too good to be true. I would not have believed that something as simple as this could be so effective unless I had seen it myself. Thank you for your bringing the Alpha-Stim® into my practice."

Henry Mann, MD
Connecticut

Alpha-Stim® For Treating Chronic and Acute Pain

"As director of the Pain Management Center at Grandview/Southview Hospitals, I specialize in treatment of both acute and chronic pain. The Pain Management Center has been in existence for approximately nine years. I was introduced to the Alpha-Stim® 100 early this year and have used it on a number of the patients that we see in the Pain Management Center. I have used it on patients with diagnosis of myofascial, fibromyalgia, arthritis, post-surgical incisions, cephalgia, leg pain, knee pain and reflex sympathetic dystrophy. We have had excellent results with the microcurrent approach along with the

treatments done at the pain center and pain relief has been excellent. I have also prescribed for several of my patients the purchase of the Alpha-Stim® 100 for use in the home.”

*B. Harker, DO
Ohio*

Alpha-Stim® for Rehabilitation

“I would like to thank you for introducing Alpha-Stim® therapy to my rehabilitation practice last year. Since that time, we have been applying it as “attended electrical stimulation”, as a part of our

patient’s physical therapy programs. The results have often been very good, and sometimes spectacular. It is especially rewarding to be able to offer this modality to chronic pain patients who have been unresponsive to all other therapies. We have many patients who have been able to reduce their dependence on pain medications and have realized increased functional capacity as a result of having an Alpha-Stim® at home.”

*Craig H. Lichtblau, MD
Pennsylvania*

How to Choose The Alpha-Stim® That’s Right for You and Your Patients

	Alpha-Stim® 100	Alpha-Stim® SCS	Alpha-Stim® PPM
Primary Indications	For treating multiple pain areas, and the anxiety, insomnia or depression often associated with chronic pain.	For treating anxiety, insomnia or depression without pain.	For treating simple pain problems on one or two areas of the body without attendant anxiety, insomnia or depression.
Pain	✓		✓
Anxiety	✓	✓	
Depression	✓	✓	
Insomnia	✓	✓	
Treatment Methods			
Probes for Pain	✓		
Electrodes for Pain	✓		✓
Ear Clips for CES	✓	✓	



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ALL RIGHTS RESERVED.
Alpha-Stim® is registered in the US Patent and Trademark Office and worldwide.

Prescribing Information

CE conformity Statement for Europe: Alpha-Stim® is a class IIa, Type B medical device. It has been independently tested by outside agencies in order 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 health care practitioner. Outside of the USA a prescription is not necessary, but consultation with a qualified health care professional is recommended.

Indications: Alpha-Stim® is an effective treatment with broad applications for a variety of syndromes involving pain, and for the management of anxiety, depression, and/or insomnia, or for the short term relief of the symptoms of pain, anxiety, depression and/or insomnia. In many cases, it is the sole therapeutic method required. Effective results in pain management have been seen 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.

Contraindications: Alpha-Stim® may effect the operation of cardiac pacemakers (particularly demand type pacemakers). Do not stimulate directly on the eyes, or over the carotid sinus (on the neck beside the larynx).

Precautions: For external use only. Do not allow children to use or handle this device without adult supervision. Do not operate potentially dangerous machinery or vehicles during, and in some cases, for several hours after treatment. Caution is advised in cases where other forms of analgesia 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 isolated reports of blood pressure being lowered by CES so care should be taken while using Alpha-Stim® with high blood pressure medication.

Adverse Effects: Adverse effects are usually mild and self-limiting. Adverse effects seen in approximately 4,541 patients in controlled, open, uncontrolled conditions, and by physician survey and reasonably associated with the use of CES are dizziness (6 cases, 0.13%), skin irritation/electrode burns (5 cases, 0.11%), and headaches (9 cases, 0.20%). Prolonged CES treatment at higher than necessary currents may cause dizziness or nausea that can last from hours to days. Paradoxical reactions such as hyperexcited states, increased anxiety, and sleep disturbances may occur.



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