

ALPHA-STIM[®] TECHNOLOGY

for the
Healthcare Professional



THE DRUG-FREE, CLINICALLY PROVEN TREATMENT FOR
ANXIETY, INSOMNIA, AND PAIN



Alpha-Stim® Technology for the Treatment of Anxiety, Insomnia, and Pain

Alpha-Stim is a non-invasive, non-drug prescription medical device that utilizes cranial electrotherapy stimulation (CES) and microcurrent electrical therapy (MET) for safe and effective treatment in the clinic or at home.

ALPHA-STIM® AT-A-GLANCE

- Clinically proven safe and effective with no lasting side effects
- Used worldwide by civilian healthcare professionals and practitioners within the Department of Defense (DOD) and Veterans Administration (VA) hospitals
- Cleared by the U.S. Food and Drug Administration for the treatment of anxiety and insomnia and relief of pain
- Proven to help 90% of patients*

* Based on physician and patient surveys

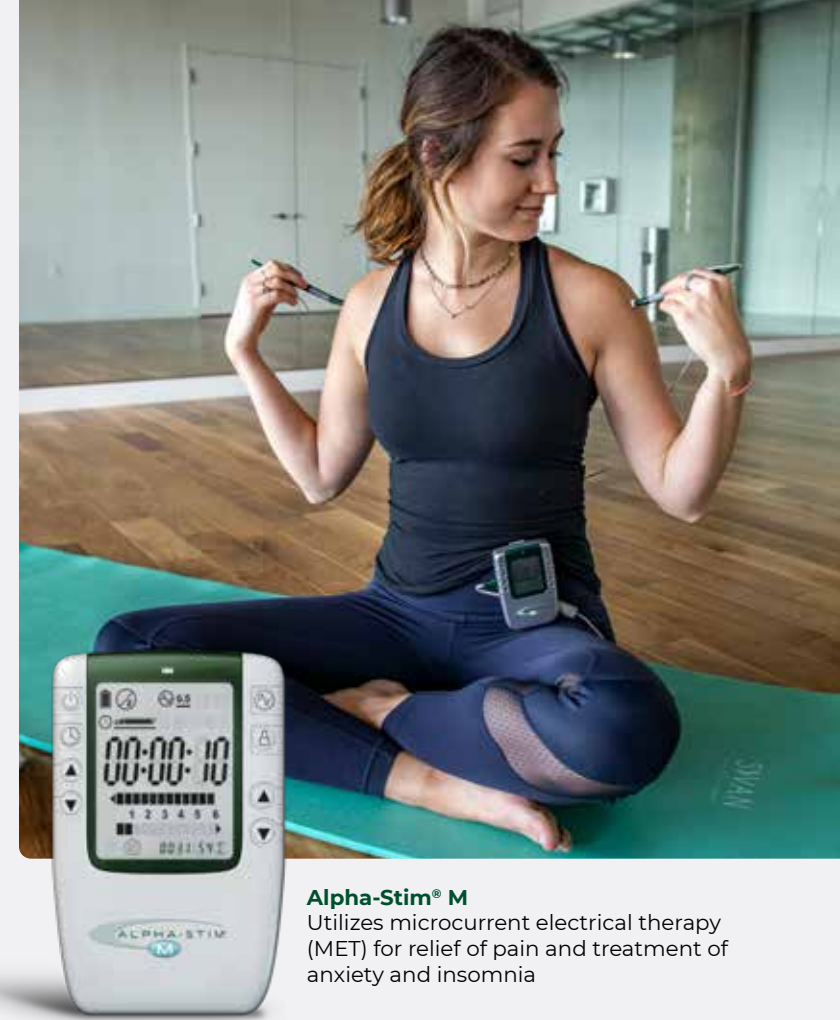


HOW ALPHA-STIM® WORKS

Alpha-Stim treats patients using two modalities: cranial electrotherapy stimulation (CES) and microcurrent electrical therapy (MET).



Alpha-Stim® AID
Utilizes cranial electrotherapy stimulation (CES) for treatment of anxiety and insomnia



Alpha-Stim® M
Utilizes microcurrent electrical therapy (MET) for relief of pain and treatment of anxiety and insomnia



CES

CES is a form of non-invasive brain stimulation that applies rhythmic, low amplitude current to the brain via earclip electrodes. Psychiatric disorders, such as anxiety and insomnia, are associated with alterations in electric activity in large-scale brain networks. Research suggests that Alpha-Stim® CES modulates large-scale brain network activity patterns in two synergistic ways:

- 1) **by stimulating cranial nerves including the vagus nerve, and**
- 2) **by directly modulating cortical oscillations in the temporal lobe, which is part of the default mode network.**

Ultimately, these two ways of stimulating the brain normalize the pathological signaling in the default mode network

observed in psychiatric disorders, providing rapid, effective, and lasting symptom relief without the side effects of medication.

MET

MET is the process of directing microcurrent through the body via Smart Probes or self-adhesive AS-Trodes™ to relieve pain. When applied peripherally, the rhythmic, low-amplitude current of Alpha-Stim MET modulates the peripheral signaling in pain circuits that emanate from the spinal cord, providing rapid, effective, and lasting pain relief with no risk of addiction or tolerance.

THE ALPHA-STIM® DIFFERENCE

Alpha-Stim delivers a proven, patented waveform that can be safely delivered at home and is better tolerated than more expensive and burdensome alternatives. It also increases treatment motivation and thereby augments treatment response as it offers the patient agency over their

recovery process by adjusting stimulation parameters.

Alpha-Stim can be performed at any time during a wide range of daily activities, allowing a patient to live an active and uninterrupted lifestyle.

Indications	Alpha-Stim® M	Alpha-Stim® AID
Pain	✓	
Anxiety	✓	✓
Insomnia	✓	✓

Proven Efficacy, Clinical Research

Alpha-Stim's effectiveness is backed by extensive, in-the-field, clinical experience as well as numerous clinical studies demonstrating safety and effectiveness in treating anxiety, insomnia, and pain.

The device is used in both civilian and military outpatient settings by more than 200 practitioners within the DoD and more than 130 VA hospitals.



SAFETY

Alpha-Stim provides lasting therapeutic results without the risks of dangerous side effects, tolerance, or addiction. In studies of more than 8,000 patients using Alpha-Stim, only minor, self-limiting side effects have been reported in less than 1% of patients. The two most common side effects were headaches and skin irritation at the electrode site.

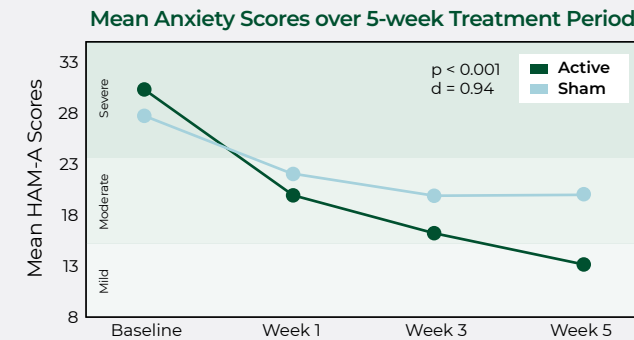
ANXIETY

Alpha-Stim outperforms sham stimulation for the treatment of anxiety in a double-blind, sham-controlled study.

Quick relief: From baseline to week 1, HAM-A scores decreased in the active group by 33% — more than 3 times the decrease for the sham group.¹

Clinically meaningful benefit: 83% of active Alpha-Stim group had a decrease of $\geq 50\%$ in anxiety scores on the HAM-A from baseline to endpoint of study.¹

Sustained Treatment Response: Improvements in anxiety were maintained for 12 weeks after treatment discontinuation.²



¹Barclay, T.H. & Barclay, R.D. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*. 2014, 164, 171-177.

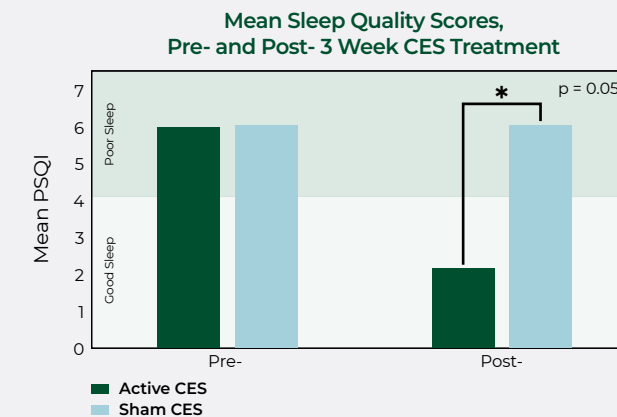
²Morris R., Xydopoulos, G., Craven, M., Price, L., & Fordham, R. Clinical effectiveness and cost minimization model of Alpha-Stim cranial electrotherapy stimulation in treatment seeking patients with moderate to severe generalized anxiety disorder. *Journal of Affective Disorders*. 2019, June; 253:426-437.

INSOMNIA

Alpha-Stim significantly outperformed sham stimulation for the treatment of insomnia in a controlled trial.³

Improved sleep quality: Post-treatment sleep quality (PSQI) improved by 64% in the active group compared to 1% in the sham group.

Increased sleep duration: On average, patients in the active Alpha-Stim group showed a trend of 2 additional hours of sleep post-treatment compared to pre-treatment. Patients in the sham group showed no improvement in sleep duration.



³Khyatee, S., Sarker, A., & Aggarwal, R. (2019). Impact of Cranial Electrotherapy Stimulation Based Analysis of Heart Rate Variability in Insomnia. In: Prateek, M., Sharma, D., Tiwari, R., Sharma, R., Kumar, K., Kumar, N. (eds) Next Generation Computing Technologies on Computational Intelligence. NGCT 2018. *Communications in Computer and Information Science*, Vol 922. Springer, Singapore.

PAIN

Alpha-Stim outperforms sham stimulation for the treatment of pain in a double-blind, sham-controlled study.⁴

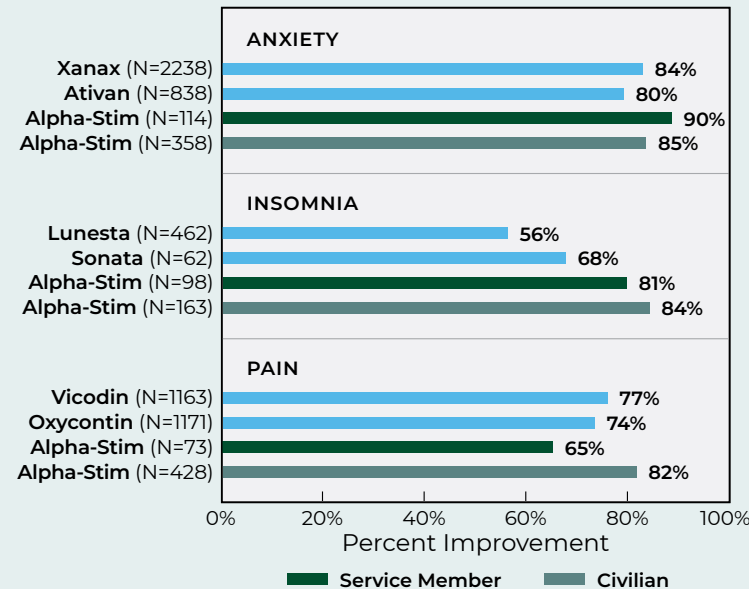
Significant improvement in pain severity: Post-treatment pain significantly improved over two-weeks as measured by the Numeric Rating Scale (-17.00 in active group vs 5.73 in sham group).

Easy to use: Preparation of the device and easiness of use were 9.87 and 9.97 respectively on a 10-point scale.

High patient satisfaction with treatment: Patients report a high level of treatment satisfaction with Alpha-Stim with an average of 28.37 (CSQ-8, range 8 – 32 where higher values indicate higher satisfaction).

⁴Ahn, H., Galle, K., Mathis, K., Miao, H., Montero-Hernandez, S., Jackson, N., Ju, H.-H., McCrackin, H., Goodwin, C., Hargraves, A., Jain, B., Dinh, H., Abdul-Mooti, S., Park, L., & Pollonini, L. Feasibility and efficacy of remotely supervised cranial electrical stimulation for pain in older adults with knee osteoarthritis: A randomized controlled pilot study. *Journal of Clinical Neuroscience*. 2020 Jul; 77: 128-133.

Patient Self Reports: Alpha-Stim® vs. Drugs



WHAT PATIENTS ARE SAYING

“

Lauren W.
EFFECTIVE RELIEF

From the very first time I used an Alpha-Stim AID in my therapist's office, I experienced relief from crippling anxiety. I'd been searching for relief from anxiety for a few years, and no other drug or therapy has been as effective as Alpha-Stim. ”

“

Linda S.
HEALTHY SLEEP

My doctor prescribed Alpha-Stim AID for my chronic insomnia. The first night I tried it, I went to sleep without any medication for the first time in years. ”

“

Justin P.
CHANGED MY LIFE

The Alpha-Stim M has changed my life. After a decade of debilitating chronic pain, I can walk, sleep and function again. No more prescription drug stupor and spiraling negative side effects. ”



CUSTOMER EXPERIENCE

Teams are dedicated to helping you seamlessly integrate Alpha-Stim into your treatment plans.

We offer a range of resources to both new and existing practitioners, including:

- Free live, comprehensive training webinars
- Illustrated owner's manuals
- How-to instructional videos
- Patient brochures for your office
- On-site and live virtual training



GET ALPHA-STIM® STARTED AT YOUR PRACTICE

Try it FREE for 60 days with our Practitioner Loan Program (available in most areas).

To speak directly with a dedicated member of our customer service team and/or enroll in the Practitioner Loan Program, call **(800) FOR-PAIN** in the U.S. or (940) 328-0788 outside of the U.S. You may also email us at alpha-stim@epii.com.





ALPHA-STIM® M

The Alpha-Stim M comes complete and ready to use with 1 set of Earclip Electrodes, 1 50 ml bottle of Alpha-Stim® Conducting Solution (250 ml refill bottles available), 2 sets of leadwires 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 50 ml bottle of Alpha-Stim® Conducting Solution (250 ml refill bottles available), 256 Earclip Electrode Pads (EEPS™), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AAA Batteries.

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 (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 (μ 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.

MECHANICAL

	ALPHA-STIM® M	ALPHA-STIM® AID
Height	11.0 cm	9.8 cm
Width	7.2 cm	6.3 cm
Depth	2.1 cm without belt clip	2.0 cm without belt clip
Weight	152 gm with batteries	101 gm with batteries

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 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.

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 and insomnia, or for the short-term relief of symptoms associated with these indications. In many cases, it is the sole therapeutic method required. Effective results in pain management have been achieved during and/or subsequent to stimulation over affected body parts, adjacent areas, and areas distant from those in pain. As with any therapeutic intervention, not all people will respond to the Alpha-Stim. 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.

Warnings and Precautions

- Safety of stimulation has not been established during pregnancy.
- Do not stimulate directly on the eyes or press the probes over the carotid sinus (on the neck near the larynx). Application of the electrodes near the thorax may increase the risk of cardiac fibrillation.
- Potential hazard from simultaneous connection of a patient to a high frequency surgical medical equipment and stimulator may result in burns and possible damage to the stimulator.
- Operation in close proximity (e.g. 1m) to a shortwave or microwave therapy medical equipment may produce instability in the stimulator output.
- Modification of your Alpha-Stim device or accessories is not allowed, it could result in injury.
- Do not place Alpha-Stim in direct contact with lint, dust, light (including sunlight).
- For external use only. Small parts, keep out of reach of children, avoid inhalation or swallowing. Do not allow children to use or handle this device without adult supervision.
- Do not operate potentially dangerous machinery or vehicles during treatment, and in some cases for several hours after treatment.
- Do not plug leadwires into wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether the leadwires are attached to the stimulator or not.
- 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 the USA it is available worldwide without a prescription but consultation with a qualified health care professional is recommended for difficult and unresponsive problems or when used with pharmaceuticals or other therapeutic intervention.

Contraindications

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

Adverse Effects

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

- dizziness
- skin irritation/electrode burns
- headaches



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