

ALPHA-STIM® AID

for the
Healthcare Professional



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



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

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

ALPHA-STIM® AT-A-GLANCE

- Utilizes a patented waveform that is clinically proven safe and effective with no lasting side effects
- Used by healthcare providers in private practice, the United States Department of Defense (DOD), and Veterans Administration (VA) medical facilities
- Easy-to-use, portable, and painless
- Fast acting, long-lasting, cumulative relief



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 and insomnia.

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.

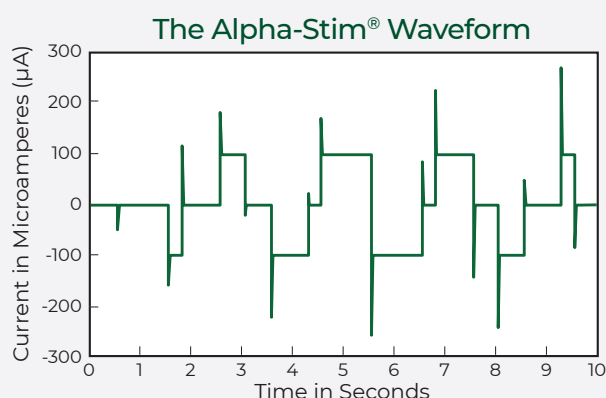


THE ALPHA-STIM® DIFFERENCE

Alpha-Stim can be safely delivered at home and is better tolerated than more expensive and burdensome alternatives.

Alpha-Stim also increases treatment motivation and thereby augments treatment response as it offers the patient agency over their recovery process by adjusting stimulation parameters.

The Alpha-Stim AID uses a patented waveform that is proven by more than 100 clinical studies to be both safe and effective. This patented waveform differentiates Alpha-Stim from any other device.



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.

TESTIMONIALS FROM THE UNITED KINGDOM

“

Lou

I was looking for alternatives, not wanting more pills, then I was introduced to Alpha-Stim. I researched, tried and tested it over a couple of months, I had nothing to lose. I wasn't ready for it to work or help, but I was so wrong, it's had a huge life changing impact, not just for me but others around me.

”

“

Dion

This innovative device has made a noticeable difference in my anxiety levels, allowing me to approach each day with greater ease and confidence. I incorporate it into my morning relaxation routine, and it works like a shield, helping me not to feel too overwhelmed by the day's challenges. It's a small but powerful tool that has helped me regain control and find moments of serenity, proving that sometimes, the most significant transformations come from the simplest of sources.

”

“

Sinead, NHS Healthworker

The positive results and feedback from the people who used Alpha-Stim AID surpassed my expectations. I had no idea that a piece of equipment the size of a phone, could have such a big impact on people's lives.

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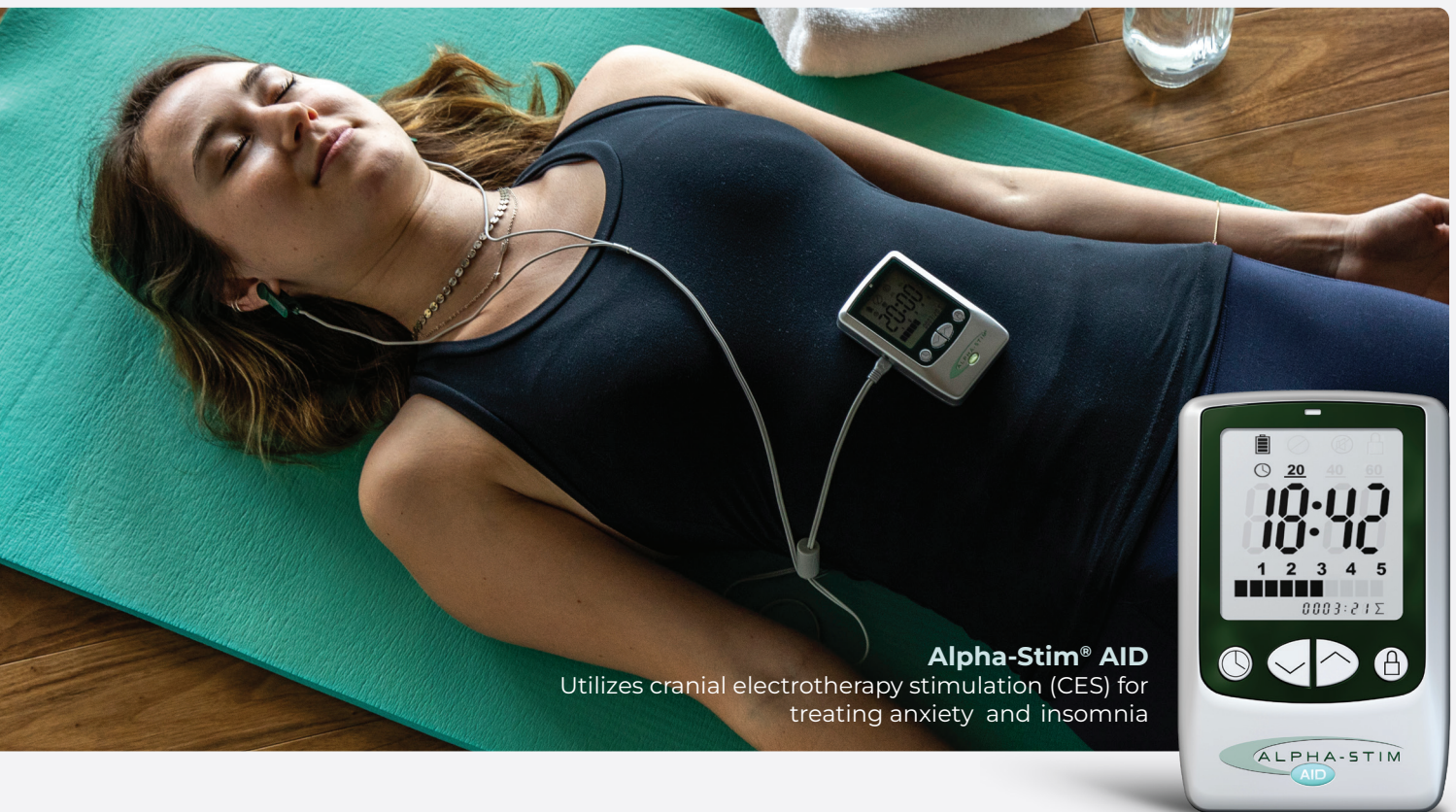
Hollie

I went to a session to try the Alpha-Stim and was really impressed with the difference it made. I could feel it straight away. After 30 minutes I felt a clarity of thought, an improved focus and a boost of resilience to get on with the rest of the day. I felt empowered to be able to take on any challenges that came my way that day. I use it daily and it enables me to think more clearly in a world that's chaotic and to juggle competing demands on my time and energy.

”

HOW ALPHA-STIM® WORKS

Alpha-Stim® treats patients using cranial electrotherapy stimulation (CES).



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

CRANIAL ELECTROTHERAPY STIMULATION (CES)

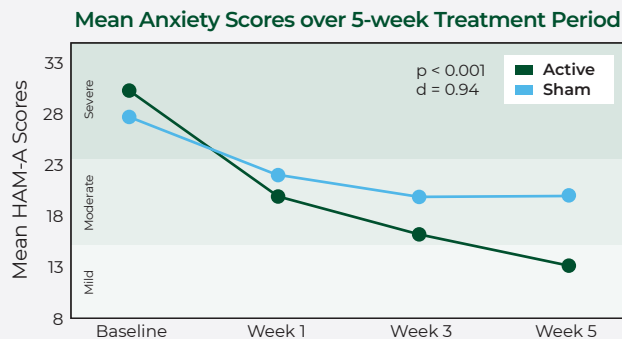
Alpha-Stim CES is a form of non-invasive brain stimulation that applies a patented, low-amplitude waveform to the brain via earclip electrodes. Psychiatric disorders, such as anxiety and insomnia are associated with alterations in electric activity in large-scale brain networks. Research suggests that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



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.

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 3% — 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:

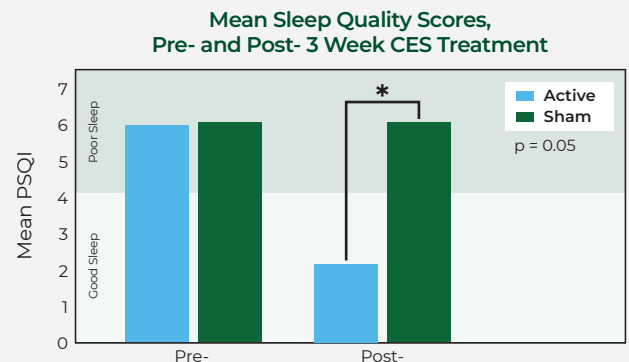
Improvements in anxiety were maintained for 12 weeks after treatment discontinuation.²

¹ Barclay, 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.

² Morriss 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

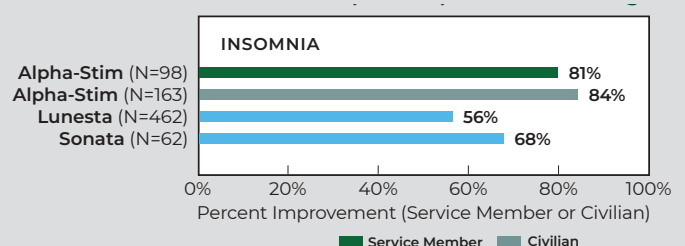
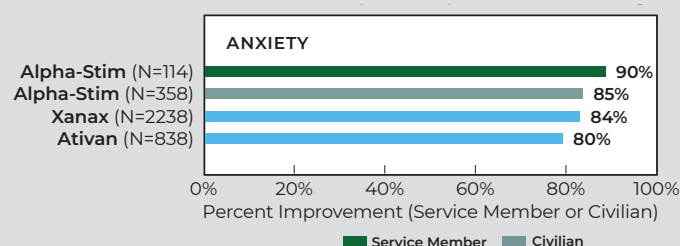


Improved sleep quality: Post-treatment sleep quality (PSQI) improved by 64% in the active group compared to 1% in the sham group.

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.

³ Khyatee, 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.

ALPHA-STIM® VS. DRUGS Patient Self Reports⁵



⁵ Kirsch, D.L., Price, L.R., Nichols, F., Marksberry, J.A., & Platoni, K.T. Military Service Member and Veteran Self-Reports of Efficacy of Cranial Electrotherapy Stimulation for Anxiety, PTSD, Insomnia, and Depression. *The Army Medical Department Journal*. 2014; 46-54.



HEALTHCARE PROVIDER AND CUSTOMER SERVICE

Technical, clinical and customer support are available to help healthcare providers and patients utilize Alpha-Stim in treatment.

- Support by email, phone and webmeetings
- Introduction, demonstration and training in webmeetings and on-site
- Training webinars
- Instructional videos
- Patient brochures
- Information available on www.alpha-stim.se, US website www.alpha-stim.com, or UK website www.alpha-stim.co.uk

Flexible solutions available for healthcare providers to offer Alpha-Stim treatment to patients.



GET STARTED WITH ALPHA-STIM®

Contact us at email kontakt@alpha-stim.se or phone 08-7097711 to discuss ways forward.

ALPHA-STIM® AID TECHNICAL SPECIFICATIONS

ELECTRICAL

Batteries	2 AAA 1.5 volt (included).
Timer	20, 40 or 60 minute countdown timers to auto-off.
Current	0 to 500 μ A adjustable in 50 μ A increments.
Frequency	Preset at 0.5 Hz.
Pulse Widths	Varying between 0.25, 0.5, 0.75, and 1 second at 0.5 Hz.
Charge	At 500 μ A and 0.5 Hz the charge per pulse varies between 125, 250, 375 and 500 microcoulombs (μ C). Every 10 seconds the total charge is 1.25 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.

MECHANICAL

Height	9.8 cm
Width	6.3 cm
Depth	2.0 cm without belt clip
Weight	101 gm with batteries



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.

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® AID is a precision medical device used for cranial electrotherapy stimulation in adults 22 years and above for the treatment of anxiety, insomnia, depression and pain..

Warnings and Precautions

- ~ Safety of stimulation has not been established during pregnancy.
- ~ 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 AID 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.

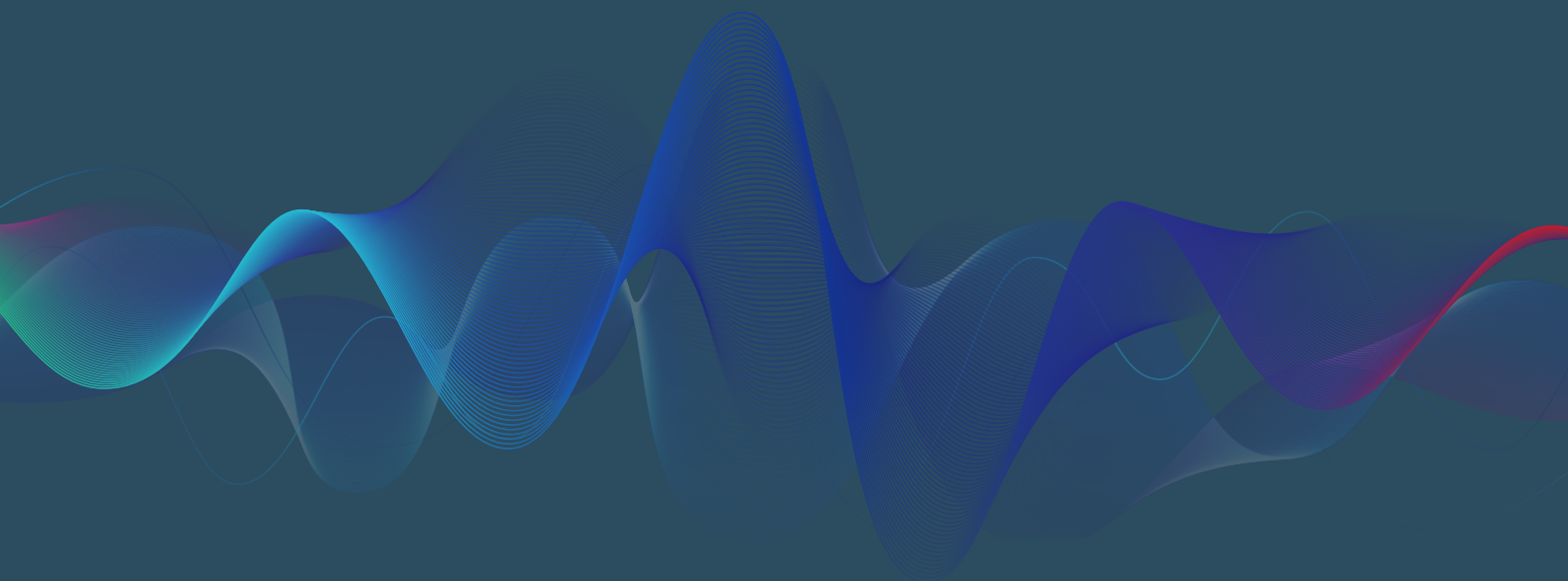
Contraindications

Use of an Alpha-Stim AID 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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