

ALPHA-STIM® M

The Alpha-Stim M comes complete and ready to use with 1 set of Earclip Electrodes, 150 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, 150 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 (µA) for the M and 0 to 500 µA for the AID adjustable in 50 µA 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 μA and 0.5 Hz the charge per pulse varies between 150, 300, 450 and 600 microcoulombs (μC). Every 10 seconds the total charge is 1.5 millicoulombs (mC) in each direction.	
Waveform	The impedance range within which the wave form parameters remain valid are from 100Ω to $10 \text{ K} \Omega$. 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	

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

current in either direction.

intervals. The waveform is balanced to achieve 0 net

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.

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

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

- dizziness
- · skin irritation/electrode burns
- headaches



Electromedical Products International. Inc.

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Are you tired of living with anxiety, insomnia or pain? YOUR QUEST FOR RELIEF ENDS HERE.



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.



Nancy E. **ACTIVE ONCE AGAIN**

pain was off the scale. I barely left my bed for three months. I began using the Alpha-Stim M 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.



HEALTHY SLEEP

Justin P.

CHANGED MY LIFE

spiraling negative side effects.

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

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.

Alpha-Stim is a non-invasive, non-drug medical device that is FDA cleared to safely and effectively treat anxiety, insomnia, and pain. It can be used in the comfort of your own home while doing normal, everyday activities.

USE ALPHA-STIM® M FOR:



- Pain
- Anxiety
- Insomnia

USE ALPHA-STIM® AID FOR:



- Anxiety
- Insomnia

SPEAKING THE LANGUAGE OF THE BRAIN

Pain, mood conditions like anxiety, and insomnia are caused by changes in the electric firing patterns of certain brain cells. Alpha-Stim uses safe, low amplitude (mild) electricity to target these impaired activity patterns, restoring physiologic brain activity and improving symptoms.

The device delivers cranial electrotherapy stimulation (CES) applied via clips on the earlobes or microcurrent electrical therapy (MET) using smart probes placed at the site of your pain.

Over 100 independent clinical studies have proven the safety and effectiveness of Alpha-Stim.

ANXIETY

- Relief during single treatment
- May last for hours or days
- · Relief after initial treatment
- · May take up to 4 weeks

• Immediate relief after 2-5-minute treatment

WHAT TO EXPECT

Alpha-Stim delivers fast, long-lasting and cumulative relief. Use daily until symptom reduction is noticeable. Then maintain your results with 2–3 treatments a week, or as needed.

CONDITION

TYPICAL RESULTS



- NSOMNIA

PAIN



