

# Prescribing Information for Alpha-Stim® Stimulators

**CE conformity statement for Europe:** The Alpha-Stim 100 and Alpha-Stim SCS are class IIa, Type B medical devices. They have been independently tested by outside agencies in order to provide assurance of conformity to applicable standards for medical equipment safety and electromagnetic compliance. The Alpha-Stim PPM is not yet approved for sale in Europe.

**Caution statement for United States:** Federal Law (USA only) restricts these devices to sale by, or on the order of a licensed health care practitioner. Outside of the USA they are available world wide without a prescription but consultation with a qualified health care professional is recommended for difficult and unresponsive problems.

**Indications:** Rx must specify the prescribed Alpha-Stim model, i.e. "Alpha-Stim 100", "Alpha-Stim SCS" or "Alpha-Stim PPM" (no substitutions; see model comparison below). Healthcare practitioners should include their degree and license number on the order form. No Rx required for shipments outside the USA.

	Alpha-Stim 100	Alpha-Stim SCS	Alpha-Stim PPM
	For treating multiple pain areas and anxiety, insomnia and depression often associated with chronic pain.	For treating anxiety, insomnia and depression <u>without</u> pain.	For treating <u>simple pain problems</u> on one or two areas of the body <u>without</u> attendant anxiety, insomnia and depression.
<b>Primary Indications</b>			
Pain	✓		✓
Anxiety	✓	✓	
Insomnia	✓	✓	
Depression	✓	✓	
<b>Treatment Method</b>			
Probes for Pain	✓		
Electrodes for Pain	✓		✓
Ear clips for CES	✓	✓	
<b>Five (5) Year Warranty</b>	✓	✓	✓
<b>Clinical and Technical Support</b>	✓	✓	✓

Alpha-Stim 100, Alpha-Stim SCS, and Alpha-Stim PPM microcurrent electrical therapy (MET) and cranial electrotherapy stimulation (CES) technology is continuously being subjected to rigorous study and evaluation by the international medical community. Findings to date indicate that the Alpha-Stim 100 and Alpha-Stim PPM (MET) are effective treatment with broad applications for a variety of syndromes involving pain, or for the short term relief of the symptoms of pain, and the Alpha-Stim 100 and Alpha-Stim SCS (CES) are effective treatment with broad applications for the management of anxiety, depression, and/or insomnia, or for the short term relief of the symptoms of 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 the Alpha-Stim 100, Alpha-Stim PPM or Alpha-Stim SCS. 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:** The Alpha-Stim 100, Alpha-Stim PPM or Alpha-Stim SCS may affect 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 these devices without adult supervision. Do not operate potentially dangerous machinery or vehicles during, and in some cases, for several hours after treatment with the Alpha-Stim 100 or Alpha-Stim SCS (CES). Caution is advised in cases where other forms of analgesia (pain control) 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 the Alpha-Stim 100 or Alpha-Stim SCS with high blood pressure medication.

**Adverse Effects (Alpha-Stim 100 and Alpha-Stim SCS):** 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. Treatment immediately prior to going to sleep may cause difficulty sleeping due to increased alertness. It is recommended that CES be used at least 3 hours before going to sleep. Paradoxical reactions such as hyperexcited states, increased anxiety, and sleep disturbances may occur, but are rare.



Type B Equipment.  
These stimulators  
are internally  
powered only.



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

**Manufactured and marketed by:**  
**Electromedical Products International, Inc.**  
2201 Garrett Morris Parkway  
Mineral Wells, Texas 76067-9484 USA

**Allevia Health, Inc.**  
Your Authorized Alpha-Stim® Distributor  
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