

Prescribing Information for Alpha-Stim® Stimulators

Conformity statement for Europe: The Alpha-Stim 100 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 it is available world wide without a prescription but consultation with a qualified health care professional is recommended for difficult and unresponsive problems or when used in conjunction with pharmaceuticals or other therapeutic intervention.

Indications: Prescription **must specify** the prescribed Alpha-Stim model, i.e. “Alpha-Stim 100”, “Alpha-Stim SCS” or “Alpha-Stim PPM” and **must state** “no substitutions”. See the model comparison below for information on the appropriate device to prescribe. Healthcare practitioners should include their degree and license number on the order form.

	Alpha-Stim® 100	Alpha-Stim® SCS	Alpha-Stim® PPM
Primary Indications			
Pain	X		X
Anxiety	X	X	
Insomnia	X	X	
Depression	X	X	
Treatment Methods			
Probes for Pain	X		
Electrodes for Pain	X		X
Ear Clips for CES	X	X	
Five (5) Year Warranty	X	X	X
Clinical and technical support	X	X	X
Treatment Description			
	For treating multiple pain areas, and the anxiety, insomnia and depression often associated with chronic pain.	For treating anxiety, insomnia and depression without pain.	For treating simple pain problems on one or two areas of the body without attendant anxiety, insomnia and depression.

Alpha-Stim 100 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 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 the Alpha-Stim 100. 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 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 (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 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. 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 hyper-excited states, increased anxiety, and sleep disturbances may occur.

The Proven Remedy

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