

OWNER'S MANUAL

Alpha-Stim® SCS

cranial electrotherapy stimulator

for control of anxiety, depression, and insomnia





Type B Equipment. This stimulator is internally powered only.



See Instructions for use.

Read this manual thoroughly before using. Do not plug lead wires into wall sockets or line cord receptacles under any circumstances. Doing so could result in severe shock or burns whether the lead wires are attached to the stimulator or not.



Medical Electrical Equipment classified by Underwriters Laboratories Inc.® with respect to electric shock, fire, mechanical and other specified hazards only in accordance with UL-2601-1 and CAN/CSA C22.2 No. 601.1. 34VF.



Conformity Statement for Europe:

The Alpha-Stim® SCS 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.

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Alpha-Stim® is registered in the US Patent and Trademark office and worldwide.

CONTENTS

Introduction.....	4
Description.....	4
Electromedical Therapeutics.....	5
How To Use The Alpha-Stim® SCS For Anxiety, Depression and/or Insomnia Control.....	5
Skin Care.....	6
What to Expect.....	6
Prescribing Information: Indications, Contraindications, Precautions, Adverse Effects.....	7
Technical Specifications.....	7
Storage and Cleaning.....	8
Trouble Shooting.....	8
Service.....	8
5 Year Limited Warranty.....	8

A NOTE TO DOCTORS

Thank you for recommending the Alpha-Stim® SCS. This manual is written for the person who will be using the Alpha-Stim® SCS, but your input will be invaluable to your patient. Alpha-Med is available to serve the needs of your patients, and to support you in doing so. New research is constantly available that may have a direct bearing on one of your patient's specific disorders. Feel free to write, call, fax, or email Alpha-Med for any reason at all.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® SCS cranial electrotherapy stimulator (CES). You have purchased a quality medical instrument. In so doing, you have already taken the first step to a more comfortable and rewarding life.

Alpha-Med was established with the aim of improving the quality of our Clients' lives and we are dedicated to help those who use our products. We have technical experts available to assure that you receive the best Possible support. Telephone consultations can be scheduled with you and your doctor, Sunday through Thursday, 10 a.m to 5 p.m. You may also communicate with us by mail, fax or email. We stand behind all our Alpha-Stim® Stimulators with the manufacturer's 5 year warranty as indicated in this manual.

The Alpha-Stim® SCS is a precision medical instrument used for the management of anxiety, depression, and/or insomnia. This treatment is non-invasive and drug-free. The Alpha-Stim® SCS provides a welcome alternative to drugs, especially in disorders that require long-term management. Unlike some drugs, the Alpha-Stim® SCS leaves the mind alert. The dangerous side effects of drugs are avoided, including accidental, intentional, and/or suicidal overdosing. After treatment, there are usually no physical limitations imposed so you can resume normal activities. The treatment is simple and can easily be self-administered at any time. People using the Alpha-Stim® SCS usually report a pleasant relaxed feeling of well-being.

The current is applied by ear clip electrodes. During a treatment you may experience a mild tingling sensation as a result of the stimulating current flow.

The Alpha-Stim® SCS is often the only means required to relieve anxiety, depression and/or insomnia. However, it may also be added to other therapy prescribed by your doctor. The Alpha-Stim® SCS will not interfere with most other treatments.

Once you understand the basic procedures, You will find the Alpha-Stim® SCS very easy to use. Please read this entire manual thoroughly before using it. Be sure to follow the general instructions given herein, and any specific directions from your doctor.

DESCRIPTION

The Alpha-Stim® SCS was developed through original research by Electromedical Products International, Inc., in Texas, USA. It is a precision technology which generates a modified square, bipolar waveform of 0.5 pulses per second (Hz), 10 to 500 millionths of an ampere (μ A), at a 50% duty cycle.

The Alpha-Stim® SCS is small, compact and light-weight. Its design lends itself well to treatment in a health practitioner's office, clinic or hospital as well as self-administered treatment at home.

The controls are simple and easy to operate. An automated timer assures the prescribed treatment time even if you are distracted or fall asleep. The amount of current can be easily modified for maximum comfort and effectiveness.

The Alpha-Stim® SCS is categorized as cranial electrotherapy stimulation, or CES, represented by the application of using ear clip electrodes for the control of anxiety, depression, and/or insomnia.

Results in electromedicine are based on the design of the waveform, the amount of current (intensity), and the amount of time it is used. The Alpha-Stim® SCS has 2 waveform generators that serve to add random factors to avoid accommodation by the nervous system. The Alpha-Stim® SCS is actually a microcomputer, incorporating the latest advances in solid state electronics. All components are of the highest quality available to assure the user the ultimate in reliable and trouble free performance. The output is accurate within 0.1% under all operating conditions. The instrument's design assures electrical safety to the user by the use of readily available 9 volt batteries. One battery will generally last for over 50 treatments.

One important feature incorporated into the Alpha-Stim® SCS is an electronic circuit which operates to maintain a nearly constant current flow to the electrodes, minimizing the effects of electrode resistance variations due to poor electrode-to-skin contact.

Alpha-Stim® SCS was developed by neurobiologist Dr. Daniel L. Kirsch and consultant engineers. Dr. Kirsch has been a leading pioneer in the field of electromedicine since 1972 He is board-certified in pain management by the American Academy of Pain Management and is a Fellow of the American Institute of Stress. Dr. Kirsch has served as Clinical Director of the Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center in New York City and the Sports Medicine Group in Santa Monica, California. He lectures frequently to physicians worldwide on pain and stress management. Only original Alpha-Stim® products meet Electromedical Products International, Inc.'s exacting specifications.

ELECTROMEDICAL THERAPEUTICS

The application of electromedical currents is not a new concept. Ancients recognized the therapeutic value of naturally occurring electrical phenomena long before William Gilbert defined electricity in 1600. Both Aristotle and Plato refer to the Black Torpedo (electric ray fish) prescribed in 46 AD by the physician Scribonius Largus for the relief of a variety of medical conditions from headaches to gout (head to foot). In the 1800's dentists reported excellent results using crude electrical devices for pain control.

Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Roux of France in 1902. Initially, this method was called electrosleep as it was thought to be able to induce sleep. Research on using what is now referred to as cranial electrotherapy stimulation (CES) for treatment of anxiety, depression and insomnia began in the Soviet Union during the 1950s and continues through this day.

One hundred years ago, electrical devices were in widespread use to manage pain and claimed to cure a variety of medical disorders. Because of the unrefined early electrical technologies and political clout of the pharmaceutical lobbies, this form of therapy fell into disrepute by the medical profession in the early part of the 20th century. As a result, medical colleges stopped teaching electrotherapeutics. Biophysics was virtually eliminated from medical practice leaving chemistry as the master science and with it the burden of responsibility for curing all of mankind's ills. Now, at the start of the 21st century, it is clear that chemistry as the sole explanatory model for medicine has not lived up to its promise, causing modern medicine to re-examine the role of biophysics.

Modern science has established that there are extensive electrical fields at work in the body. The nervous system, for example, has long been known to work through both electrochemical and purely electrical signals. In fact, all molecules are held together by electrical bonding at the atomic level. This knowledge has led medical scientists such as Dr. Robert Becker of the U.S.A. and Dr. Björn Nordenström of Sweden (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on bioelectrical control systems.

Over the past few decades, technology has surpassed chemical analysis for the diagnostic side of medicine. With Alpha-Stim® technology, therapeutic intervention based on the new biophysics is finally emerging as a viable alternative to pharmacological management and surgery. The original Alpha-Stim® Model 2000, a sophisticated clinical device, weighed 40 pounds and cost \$5,850 U.S. when it was first introduced in 1981. The Alpha-Stim® SCS cranial electrotherapy stimulator utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate anxiety, depression and/or insomnia, and experience long term and cumulative relief with as little as only a few minutes of treatment, every other day. When used properly, we trust your new Alpha-Stim® SCS will help to control your anxiety, depression and/or insomnia and improve the quality of your life.

HOW TO USE THE ALPHA-STIM SCS FOR ANXIETY, DEPRESSION AND/OR INSOMNIA CONTROL

1. Clean skin - Clean the skin of your ear lobes thoroughly and allow them to dry before applying electrodes. Use mild soap and water or baby wet wipes.

2. Connect ear clip electrodes to Alpha-Stim®SCS - Insert L-shaped plug from the ear clip electrodes into the output receptacle on the Alpha-Stim® SCS.

3. Attach earclip electrode pads to ear clips – First clean and dry the ends of the ear clips, then peel 4 self-adhesive earclip electrode pads off of their protective backing and attach them to the inside of each ear clip electrode (as originally packed). Replace earclip electrode pads after each treatment. If using the Alpha-Stim® SCS in a clinical setting, clean the clips thoroughly with alcohol prior to replacing the earclip electrode pads between patients.

4. Wet electrodes – Wet each of the 4 earclip electrode pads while attached to the ear clips with about 2 or 3 drops of Alpha Conducting Solution™ (ACS). Discard the ring around the ACS bottle after opening to seal it tightly and prevent leakage.

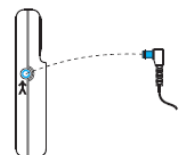
5. Place electrodes on ears - Clip electrodes on each ear lobe close to the jaw, and as high on the lobe as possible. You must always use both clip electrodes to complete the electrical circuit.

6. Set the current, turn power on and set the timer - Be certain the current control (wheel on side of device) is all the way down to 0. The LCD will start counting down as soon as the Alpha-Stim® is turned on by

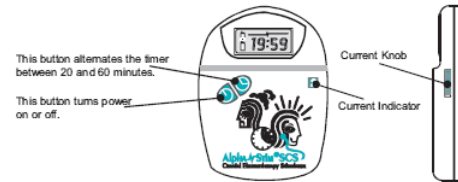


ONE BUTTON OPERATION

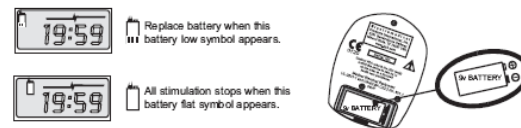
Read the following instructions carefully. Then you may simply moisten and place the clip electrodes on your ear lobes and turn the POWER button on for 20 or 60 minutes. That's all there is to it! If necessary, adjust the current up or down to a comfortable level at any time during treatment.



depressing the power button on the left. You adjust the timer between 20 and 60 minutes by pressing the button on the right while the Alpha-Stim® is on. 20 to 60 minutes is recommended unless otherwise specified by your physician. People who can only tolerate a current setting of 2 (200 microamperes) or less will generally need more than 20 minutes. Turn the current up slowly until a comfortable tingling feeling is felt (for some people it is normal not to feel anything). Immediately decrease the current if the tingling feeling becomes uncomfortable or if dizziness or nausea develops. Decreasing the current should immediately relieve any of these unpleasant feelings and they are not necessary for optimal effect. Some people experience a feeling of “heaviness” during the early part of treatment. If this occurs, treatment should be continued until at least 2 minutes after this feeling “lifts”, and a lighter feeling is experienced, even if it takes more than 60 minutes.



7. Check battery - Be sure you are using a good, fresh battery such as the one provided with the unit. Replace the battery when the display indicates "battery low" (as illustrated). Once the display indicates "battery flat" (as illustrated) the Alpha-Stim® SCS will discontinue stimulation until a new battery is installed. Do not use a rechargeable battery.



8. Relax - Sit or lie down and let the Alpha-Stim® SCS relax you.

9. Automatic Power off - At the end of the timed cycle the power will turn off automatically.

10. Disconnect and remove ear clip electrodes.

Use daily for the first 2 weeks, then 3 times per week or as directed by your physician.

SKIN CARE

1. Apply electrodes on dry, clean unbroken skin only.
2. Before applying and after removing electrodes, wash skin with mild soap and water or clean with baby wet wipes. Rinse and allow to dry completely.
3. Excess hair at the electrode site should be clipped, but not shaved.
4. If skin irritation develops discontinue use and consult your physician.

WHAT TO EXPECT

Anxiety reduction is usually experienced during a treatment, but may be felt hours later, or as late as 1 day after treatment. Depression and/or insomnia control is generally felt after 1 to 3 weeks of daily treatment. After the condition is under control, use of Alpha-Stim® 3 times per week is usually sufficient to maintain good results.

The Alpha-Stim® SCS leaves the user alert while inducing a relaxed state. One 20 minute session is usually all that is needed to effectively control anxiety, depression and/or insomnia for at least a day. It may also be used as an adjunct to medication and/or psychotherapy. For people who have difficulty falling asleep, Alpha-Stim® should be used at least 3 hours before going to bed or the increased alertness may interfere with sleep.

After treatment, there are usually no physical limitations imposed so most people can resume normal activities immediately. Some people may experience an euphoric feeling, or relaxation that may temporarily impair their mental and/or physical abilities for the performance of potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment.

At present, there are over 125 research studies on using cranial electrotherapy stimulation for anxiety, depression and/or insomnia related disorders in humans and 29 animal studies. No significant lasting side effects have been reported. Occasional self-limiting headache, discomfort or skin irritation under the electrodes, or lightheadedness may occur. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. Some people will see flashing lights due to stimulation of the optic nerve. Some may experience the metallic taste of dental fillings. Neither of these conditions are harmful.

PRESCRIBING INFORMATION

CE Conformity Statement for Europe: The Alpha-Stim® SCS is a Class IIa, Type B 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.

Caution Statement: Outside of the USA, this device 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: Alpha-Stim® SCS 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® SCS is an effective treatment with broad applications for a variety of anxiety disorders 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. As with any therapeutic intervention, not all people will respond to the Alpha-Stim® SCS. The degree of efficacy will vary with the nature of the problem being treated and the overall health of the person.

Contraindications: Alpha-Stim® SCS may affect the operation of cardiac pacemakers (particularly demand type pacemakers).

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. 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® SCS 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 for 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.

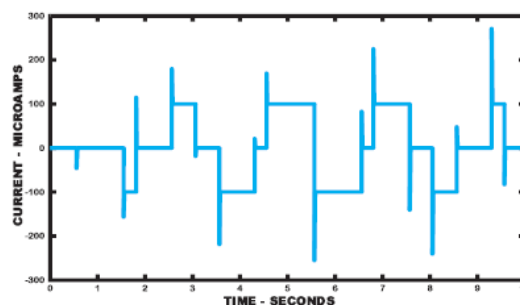
If the Alpha-Stim® SCS does not control your anxiety, depression and/or insomnia within 3 weeks, consult your physician.

TECHNICAL SPECIFICATIONS

Electrical

Power Source	One 9 volt battery (included). Replace with disposable batteries (alkaline preferred). Do not use rechargeable batteries.
Timer Settings	20 or 60 minutes
Current	10 to 500 μ A continuously adjustable
Frequency	0.5 Hz (pulses per second)
Waveform	Bipolar asymmetric rectangular waves, 50% duty cycle,
	0 net current (see graphic depiction below)

Alpha-Stim® SCS Waveform



Mechanical

Height	10.0 cm
Width	7.5 cm
Depth	2.3 cm
Weight	106 gm with battery

Accessories

The Alpha-Stim® SCS is packaged complete with one set of ear clip electrodes, 256 earclip electrode pads, a 15 ml bottle of Alpha Conducting Solution™, a 9 volt battery, carrying case, and illustrated Owner's Manual. This is everything necessary to begin to use the Alpha-Stim® SCS right away.

Replace the conducting solution and earclip electrode pads only with authorized Alpha-Stim® brand products.

STORAGE AND CLEANING

Remove the battery when storing the Alpha-Stim® SCS for an extended time (more than 1 month). Always use the carrying case to transport the Alpha-Stim® SCS. When not in use, the Alpha-Stim® SCS and all its accessories should be stored in the carrying case provided. The Alpha-Stim® SCS, and its accessories, should be stored and used within a temperature range between 0° and 36° C, with a relative humidity of 90% or less, at an atmospheric pressure between 0.9 - 1.1 atm. Clean the Alpha-Stim® SCS by periodically gently wiping the surface with a damp cloth when dirty. Use mild soap and water. Use of other cleaning solutions may damage the case. Never spray cleaners directly on to the device. 70% isopropyl alcohol may be used on the clip electrodes to disinfect them between treatments.

TROUBLE SHOOTING

PROBLEM

POSSIBLE SOLUTIONS

There is no sensation of current.....Note: This is normal for some people. Try turning up the current or wetting electrodes.
There is no output.....Change the battery if the "battery low" or "battery flat" icon appears in the display. Try turning up the current. Check electrodes: make sure electrode connection is firmly in place.
Earclip electrode pads do not stick well.....Replace ear clip electrode pads. Apply to a clean, dry surface.

SERVICE

The Alpha-Stim® SCS is not user serviceable.

To obtain service, first contact Alpha-Med -your authorized Alpha-Stim® distributor for advice or a return authorization number (RAN). Upon authorization by Alpha-Med, you may send the entire unit, with all accessories and packed in the original carrying case to Alpha-Med by registered mail or delivery, insured and freight prepaid. Please include a copy of your invoice and a note describing the problem. Please do not forget to include your return address, your phone number, and if available, your fax number and email address.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI"), the manufacturer of Alpha-Stim devices, the Alpha-Stim® SCS ("product") is generally effective in relieving anxiety, depression and/or insomnia, health care is not an exact science and individual results will vary. Accordingly, EPI makes no warranties as to the effectiveness of its products for a given individual.

Electromedical Products International, Inc. warrants to the original purchaser (and no one else) that each new Alpha-Stim® SCS is free of defects in workmanship and materials, under normal use, for a period of 5 years from original purchase date, except for accessories. The warranty registration card must be completed and returned to Alpha-Med in order to validate the warranty.

Accessories such as batteries and electrodes are excluded from the warranty and are sold "as is" because they may be easily damaged before or during use.

During the warranty period, EPI's sole obligation shall be, at EPI's option, to replace or repair the Alpha-Stim® SCS without charge. In order to recover under this warranty, purchaser must first contact Alpha-Med, your authorized Alpha-Stim distributor, by phone, mail, fax, or email for a return authorization number (RAN). Purchaser must have an original copy of the invoice to prove that the product is still covered by warranty. The authorized return may then be shipped to Alpha-Med, safely packaged with all accessories, packed in the original carrying case, by registered mail or delivery, insured and freight prepaid. Alpha-Med and EPI will not be responsible for damage due to improper packaging or shipment. If EPI determines there is a defect covered by this warranty, the repaired or replaced product will be shipped back, freight and insurance prepaid, as soon as reasonably possible. If EPI determines in its sole discretion that the product does not contain defective workmanship or materials, EPI will return the product and the return freight and insurance charges shall be the purchaser's responsibility.

This warranty is voided immediately if the product has been subjected to abuse, accidental damage, damage in transit, negligence, acts of nature, or damage resulting from failure to follow operating instructions, or alteration/disassembly by anyone other than by EPI.

Electromedical Products International, Inc. and Alpha-Med shall not be liable for any direct, indirect, special, incidental, or consequential damages, lost profits or medical expenses caused by any defect, failure, malfunction, or otherwise of the product, regardless of the form in which any legal or equitable action may be brought against EPI or Alpha-med (such as contract, negligence, or otherwise). In no event shall EPI's or Alpha-Med's liability under any cause of action relating to the product exceed the purchase price of the product.

Manufactured by:



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