Alpha-Stim® AID Owner's Manual

Cranial electrotherapy stimulator

ALPHA-STIM®

LET NOTHING STOP YOU™

ALPHA-STIM®

For a successful Alpha-Stim® treatment, follow these simple steps:

1. Scan QR code and watch videos on alpha-stim.com/training.

2. Do an Alpha-Stim® treatment.

3. Feel like yourself again!

Alpha-Stim® AID Owner's Manual

Cranial Electrotherapy Stimulator for the Treatment of Anxiety and Insomnia

Type BF Equipment. Internally powered.

Consult operating instructions. Read manual thoroughly before using the device.

Text consists of a warning or precaution relating to safety. Read the text carefully and use the equipment as instructed to ensure safety.

Reference Number.

Serial Number.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CE marking certifies that a product has met consumer safety, health or environmental requirements.

Date of Manufacture.

Manufacturer.

Medical device.

Non-sterile.

Authorized Representative in the European Community.

IP22

Protection against ingress of solid foreign objects >12.5 mm and dripping water when tilted at 15 degrees.

Single patient- multiple use.

Use-by-date.

Keep away from sunlight.

Do not use if package is opened or damaged.

Waste electrical and electronic equipment should not be discarded together with unseparated household waste but must be collected separately.

Lot Number.

Medical Electrical Equipment classified by Underwriters Laboratories Inc. with respect to electric shock, fire, mechanical and other specified hazards only in accordance with UL-60601-1 and CAN/CSA C22.2 No.601.1.

Unique Device Identifier.

IFU-CUS-002 VER. 3

CONTENTS

FEATURES

The Alpha-Stim® AID Device Package Contains:

- 1 set of Earclip Electrodes
- 1 50 ml bottle of Alpha-Stim® Conducting Solution
- 1 empty bottle for use with Alpha-Stim® Conducting Solution
- 256 Earclip Electrode Pads (EEPS™)
- Owner's Manual
- Lanyard
- Storage case
- 2 AAA 1.5 volt lithium batteries

The Alpha-Stim® AID Kit Comes Complete and Ready to use with:

- Alpha-Stim® AID device – The Alpha-Stim® AID device is a battery powered electrical device that produces low level electrical current to treat anxiety and insomnia. Device accessories connect to the Alpha-Stim® AID to facilitate treatment. Part# 500
- Earclip Electrodes – Earclip Electrodes are accessories to the Alpha-Stim® AID. The Earclip Electrodes transfer the current from the Alpha-Stim® AID device to the patient through the earlobes. Part# 501
- Alpha-Stim® Conducting Solution is an accessory to the Alpha-Stim® AID device. It is supplied as a liquid in a separate bottle. It is a proprietary mineral salt solution that facilitates an efficient transfer of the Alpha-Stim® AID current from the device to the electrodes and finally to the patient. Alpha-Stim® Conducting Solution is applied to the Electrode Pads to ensure the current is conducted properly. Part# SL50
- Electrode Pads – Earclip Electrode Pads (EEPS™) are also accessories for the Alpha-Stim® AID device. They are felt-like pads made from polyester that allow Alpha-Stim® Conducting Solution absorption to facilitate transfer of current. The pads have an adhesive backing allowing them to stick to the Earclip Electrodes. The adhesive does not contact the patient's skin. The pads are saturated with Alpha-Stim® Conducting Solution to ensure proper current flow from the Alpha-Stim® device through to the Earclip Electrodes and to the patient. Part# EEP
- Owner's manual – Describes what items come with the device and how to use it. Includes a symbol table along with contraindications, warnings and precautions. Device use is the same for the healthcare provider as it is for use directly by the patient. Part# 503CUS

- Lanyard – The lanyard is an optional accessory for the Alpha-Stim® AID device. It is a cloth cord to hold the Alpha-Stim® AID device around the neck when in use, if desired. Part# 502
- Storage Case(s) – Alpha-Stim® AID comes in a hard case. An optional soft case can be purchased separately. Part#s 504 & 505
- 2 AAA batteries – The Alpha-Stim® AID is powered by lithium batteries which are supplied in the initial order. They provide the energy source and are placed inside the Alpha-Stim® AID before use. Batteries can be replaced with off the shelf lithium batteries as needed. Part# 5300

Alpha-Stim® AID Features Include:

1. Full digital control for precision, consistency and reliability.
2. Earclip Electrodes.
3. Back lighting when any button is pressed.
4. Continuous circuit check when electrodes are in contact with skin.
5. Preset to 0.5 Hz.
6. 20, 40 or 60 minutes countdown cycles to auto-off.
7. Large timer display.
8. 0 – 500 microampere (μA) current control.
9. Current and treatment time may be locked to preset values throughout entire treatment session.
10. Mute option.
11. Cumulative timer.
12. 30 minute auto-off when not in use.
13. Lanyard so AID can be worn around the neck.
14. Able to withstand electrostatic discharges of up to 15,000 volts.
15. Automatically and permanently disables itself should a single fault develop within the device causing the current to exceed 700 μA.
16. Battery strength indicator.
17. Earclip Electrode Pads (EEPS™) require Alpha-Stim® Conducting Solution (included).
18. 5 year limited warranty.
19. Protection against ingress of solid foreign objects >12.5 mm and dripping water when tilted at 15 degrees.
20. Uses 2 AAA 1.5 volt batteries (included in the package but not installed).

Installation of Batteries

Inserting batteries

- Slide the cover of the battery case on the back side of the device in the arrow direction.
- Insert the enclosed batteries according to the symbols (+/-) into the base of the battery case.
- Close the battery case again and push the cover towards the device until it snaps into position.
- When changing the batteries, only use 2 AAA 1.5 volt lithium batteries.

Danger of chemical burns! Leaking battery acid may lead to chemical burns.

- Avoid contact between battery acid and skin, eyes and mucous membranes.
- If battery acid comes in contact with any of these parts, rinse the affected area with copious amounts of plain water immediately and seek medical attention if necessary. Keep batteries out of children's reach. If a battery has been swallowed seek medical attention immediately.
- Do not disassemble, recharge, short circuit batteries or dispose of them in fire. There is a risk of explosion.
- Remove batteries from the device if you do not use it for a prolonged period.
- Do not dispose of used batteries in the household garbage, instead dispose of them as special waste or at a battery collection point in a specialist outlet.

A Note to Healthcare Practitioners

Thank you for recommending the Alpha-Stim® AID. This manual is written for the person who will use the Alpha-Stim® AID, but your input will be invaluable to your patient.

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Electromedical Products International, Inc. is available to help serve the needs of your patients. New research is often available that may have a direct bearing on a patient's specific disorder. Feel free to write, call, fax, or email EPI for any reason at all. Also, check the website regularly for new information. We welcome your input in the form of testimonial letters or emails.

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CONTROL BUTTONS

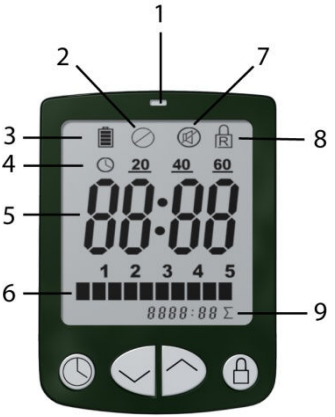
1. **On - Off**

2. **Timer**. Waveform cycle starts when electrodes touch skin. Countdown timers: select 20, 40 or 60 minutes.

3. **Lock**. Press 2 times within 5 seconds to lock or unlock settings during treatment if desired.

4. or **Current**. Increases or decreases current. Increases at 50 microamperes (µA) per second when held down. Decreases at 100 µA per second. When the device is turned on, the current defaults to 100 µA.

LCD Display



1. **Light Sensor** lights LCD screen for 10 seconds in a dark room when any button is pushed.

2. ⊘ **Test Circuit** symbol and an audio warning indicates device is not treating. The timer will stop and the device will turn off in 30 minutes if nothing else is done. Current must be set above 0 µA and moistened electrodes must be in contact with skin for Alpha-Stim® AID to work. An audible signal and resumption of the timer occurs the instant the integrity check circuitry determines everything is working properly.

3. **Battery Charge** indicator. Replace battery when only 1 bar remains at which time the device shall give out an audible low battery warning and repeat the warning every 10 minutes (unless mute function is on).

4. **Timer**. Select 20, 40 or 60 minutes countdown to auto-off.

5. **Time** setting indicator. Displays time remaining.

6. ■■■■■■■□□□ 0 - 500 microamperes (µA) of current.

7. **Mute** feature. To turn on or off press the key sequence: **Lock-Timer-Lock**.

8. **Lock** is on when display is lit.

9. **Σ Cumulative Timer** records total hours and minutes Alpha-Stim® AID has been in use.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® AID Cranial Electrotherapy Stimulation (CES) device. You have purchased a quality medical device. In so doing, you have already taken the first step to a more comfortable life.

Electromedical Products International, Inc. (EPI) is a leading innovator of the finest state-of-the-art medical technology available to improve the quality of your life. EPI and its distributors are dedicated to helping those who use our products. We have technical experts available to assure you receive the best possible results from treatment. Telephone consultations in English may be scheduled with you or your doctor Monday through Friday, 9 AM until 5 PM, Central Time (Texas, USA). You may also communicate with us by mail, fax, or email. The company stands behind all our medical devices with a 5 year limited warranty.

The Alpha-Stim® AID is a precision medical device used for the treatment of anxiety and insomnia. The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

After treatment, there are usually no physical limitations imposed so you can resume normal activities. The treatment is simple and easy to self-administer at any time. People using the Alpha-Stim® AID usually report a pleasant, relaxed feeling of well-being.

The current is applied by Earclip Electrodes for anxiety and insomnia. During a treatment you may experience a mild tingling sensation at the electrode sites. If the current is too high, you might experience dizziness and nausea which can both be alleviated by reducing the current.

Once you understand the basic product features and procedures you will find the Alpha-Stim® AID is 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 healthcare practitioner.

The Alpha-Stim® AID was developed by Dr. Daniel L. Kirsch, a neuroscientist, and Raymond Chan, an engineer. Dr. Kirsch has been a leading pioneer in the field of electromedicine since 1972. He was board-certified in pain management by the American Academy of Pain Management in 1990, and awarded the Richard S. Weiner Pain Educator of the Year Award by AAPM in 2008. He became a Fellow of the American Institute of Stress in 1997 where he was elected President in 2012. He was also the only American Member of InterPain, the organization for pain specialists in Germany and Switzerland. He was the Electromedical Department Editor of the journal, *Practical Pain Management* and Editor-in-Chief of *Contentment* and *Combat Stress Magazines*. 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 also served as an expert research and practice consultant to Veterans Affairs Medical Centers and the United States Army and Navy. He is an author of books and articles and lectured frequently to physicians and psychologists worldwide on pain and stress until his retirement in 2020.

DESCRIPTION

Results in electromedicine are based on the design of the waveform, the amount of current, the location of the electrodes, and the amount of time it is used. The Alpha-Stim® AID is a microcomputer incorporating the latest advances in solid state electronics. All components are of the highest quality available to assure the user reliable and trouble-free performance.

The design assures electrical safety by the use of readily available 1.5 volt AAA batteries.

The Alpha-Stim® AID was developed through original research by Electromedical Products International, Inc. It is a precision technology which generates a modified square, bipolar waveform of 0.5 Hz (pulses per second), at 50 to 500 microamperes (1 μA is one-millionth of an ampere), in a 50% duty cycle.

The Alpha-Stim® AID is small, compact and light-weight. It was designed to be versatile. It can be used in a healthcare practitioner's office, clinic or hospital, for portable and quick response needs such as emergency medical or military applications, as well as for self-administered treatment at home on a scheduled or as-needed basis.

The controls are fully digital for precision, consistency and reliability and at the same time simple and easy to operate. An adjustable timer and a locking option that freezes the treatment time and current settings assures the prescribed treatment waveform and dosage even if you are distracted or fall asleep. The amount of current can easily be increased to reduce treatment time or decreased when necessary to assure comfort.

One important feature of the Alpha-Stim® AID is an electronic circuit which operates to maintain a nearly constant current flow to the electrodes minimizing the effects of skin resistance variations. The Alpha-Stim® AID continuously performs self-diagnostics to assure that all aspects of the circuitry are always working properly, and the electrodes are making adequate contact with skin. Ergonomic and user-friendly features (such as the lock, auto-off timers and alarm that warns you if an electrode falls off) make the Alpha-Stim® AID reliable, easy, quick, and fun to use.

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 referred 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 1800s dentists reported pain reduction using early and somewhat crude electromedical devices.

By the late 1800s electrical devices were in widespread use to manage pain and claimed to cure a variety of medical disorders. The exuberant claims of early electrical technologies facilitated by the political clout of the pharmaceutical lobbies caused this form of therapy to fall 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 disease. Now, in the 21st century, it is clear that chemistry as the sole therapeutic model for medicine has not lived up to its promise, causing modern medicine to re-examine the potential of biophysics.

Experimentation with low intensity electrical stimulation of the brain was first reported by Drs. Leduc and Rouxeau 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 and insomnia began in Russia during the 1950s and first came to the USA in the 1960s.

All life is of an electrochemical nature. There are extensive electrical fields at work throughout the universe and 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. Basic science research into the nature of bioelectrical control systems in humans and animals led medical scientists such as Dr. Robert O. Becker of the USA[1] and Dr. Björn Nordenström of Sweden[2] (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on our latest understanding of biophysics.

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[1] Becker, Robert O. *The Body Electric*. New York: William Morrow and Co. 1985.

[2] Nordenström, Bjorn E.W. *Biologically Closed Electric Circuits*. Stockholm: Nordic Medical Publications, 1983.

Alpha-Stim® technology incorporates these theories and is proven more efficacious than most other treatments for the conditions it treats. The original Alpha-Stim® Model 2000 weighed 40 pounds and cost $5,850 when it was first introduced in 1981. The Alpha-Stim® AID utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate anxiety and insomnia, with far less current than used in previous technologies, and experience long-term and cumulative relief with as little as only 20 minutes of treatment every other day. When used properly, we trust your new Alpha-Stim® AID will improve the quality of your life.

USE THE ALPHA-STIM® AID WITH CONFIDENCE

Because the Alpha-Stim® AID uses such a low level of current, many people do not feel anything at all, even at the maximum current level. Do not be concerned if you can not feel the current; this is perfectly normal, and your perception of the current will not affect the results. The Alpha-Stim® AID is working unless the ⊘ **Test Circuit** symbol appears, or the low battery indicator is down to the last bar. Some people only achieve maximum benefits when using the Alpha-Stim® AID for hours every day. While this is rarely necessary it is also not harmful – so use the Alpha-Stim® AID with confidence knowing you have a safe and effective tool and LET NOTHING STOP YOU™.

Quick Guide

Read the following instructions carefully. Then, after you have used the Alpha-Stim® AID once you simply press the Power button, wet the Earclip Electrode Pads (EEPS™) on the Earclip Electrodes, place them on both ear lobes and adjust the current to a comfortable level. *That's all there is to it!* Adjust the current up or down to a comfortable level at any time during treatment if necessary.

Cranial Electrotherapy Stimulation (CES) to Treat Anxiety and/or Insomnia with Earclip Electrodes

1. Clean ear lobes with mild soap and water, alcohol pads or antibacterial wipes and allow skin to dry. Areas where skin oils or dirt have accumulated, or where cosmetics or hair spray have been used must be thoroughly cleaned to ensure adequate conductivity. Monitor skin condition prior to and after treatment. Skin irritation may develop in light skin. If skin burns are noted following treatment, discontinue use and apply an appropriate skin cream. Varying **Earclip Electrode** locations around the ear lobe may minimize irritation.
2. Plug dual connector end of **Earclip Electrode** wires into jack on left side of the Alpha-Stim® AID. **Figure 1**.
3. Remove and discard old **Earclip Electrode Pads (EEPS™)** if present. Remove old glue residue, clean and dry **Earclip Electrodes** and attach 4 new **EEPS™**. Note that **EEP™** case opens with label on bottom.
4. Saturate 4 new **Earclip Electrode Pads (EEPS™)** thoroughly with several drops of **Alpha-Stim® Conducting Solution** while on Earclip Electrodes.
5. Press **Power** on.
6. **Mute** the audio, if desired, with the key sequence: **Lock-Timer-Lock**. To reinstate the audio alerts, press the same key sequence again.

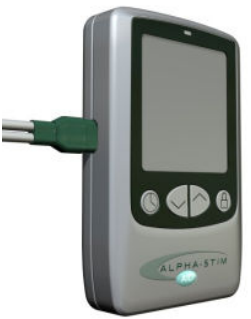


Figure 1

7. Set **Timer**. 20 minutes is usually enough time if the current is set to at least 250 µA. 40 minutes to 1 hour is recommended if the current is at or below 200 µA.
8. Squeeze **Earclip Electrodes** and apply one to each ear lobe. **Figure 2**.
9. **Current** defaults to 1 (100 µA) when the Alpha-Stim® AID is turned on. Increase **Current** slowly (5 is the highest setting) until a slight

vertigo is experienced (a dizzy feeling, similar to the sensation of rocking on a boat), then decrease *immediately* until the dizziness stops. Also decrease immediately if the normal tapping sensation felt on the ear lobes is uncomfortable. For people who have a history of experiencing vertigo such as motion sickness, treat at a subsensory current setting of 1 (100 µA) for one hour or more to prevent residual vertigo after treatment. The tolerable current level will be determined by the subjective feeling of vertigo which should subside immediately upon reducing the current. The current should always be reduced just below the level that causes vertigo.

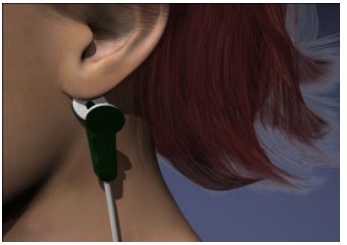


Figure 2

10. Press **Lock** twice to lock settings, if desired. Press **Lock** twice again to unlock and change settings, if necessary.
11. Relax, if possible, during the treatment. It is best to sit quietly or lie down although it is also possible to read, work at a desk or watch television during treatment. Do not attempt to drive or operate any dangerous tools or machinery during treatment.
12. **Power** will turn off automatically at the conclusion of the timed cycle.
13. **Always complete a CES session.** When the timed session ends, and a "heavy" feeling is still experienced, resume treatment until at least 2 minutes after the heaviness lifts and a light feeling develops. Failure to do this can result in disorientation that can last for hours to days. Some people benefit the most from several hours of treatment in a given treatment session.
14. Remove and discard **EEPS™**. Clean and dry **Earclip Electrodes** and replace 4 **EEPS™** for the next treatment, if desired. **EEP™** case opens with label on bottom.
15. Store Alpha-Stim® AID away from children.
16. CES may be used as often as necessary but for most people it is best to treat between once a day and twice a week. Results usually improve and last longer with additional treatments.

WHAT TO EXPECT

While the Alpha-Stim® AID is significantly effective when it is used correctly, it may not work for everyone. If the Alpha-Stim® AID is not working well for you contact your healthcare practitioner, your local authorized Alpha-Stim® distributor or EPI for technical support.

Anxiety reduction is usually experienced during a single treatment but may be experienced hours after treatment. Insomnia is usually improved after the initial treatment but may take 3 weeks. Most people can use it at bedtime and when awakened during the night. However, some people find they must conduct their 20 - 60 minute Alpha-Stim® CES treatment at least 3 hours before going to bed because a CES treatment may interfere with sleep. It may also be used in the morning to promote better sleeping at night. The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Following treatment, there are usually no physical limitations imposed so most users can resume normal activities immediately.

At present, there are over 100 research studies on using Cranial Electrotherapy Stimulation in humans and more than 30 animal studies. No significant lasting side effects have been reported. If a heavy feeling occurs, continue treatment until at least 2 minutes after it gives way to a light feeling. Any side effects which have occurred have all been mild, self-limiting reactions.

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® AID 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 for the treatment of anxiety and insomnia.

CES Devices for Insomnia and Anxiety:

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Warnings and Precautions

- Patients should be monitored by their physician for signs of worsening.
- If a patient experiences headaches while using the device, they should consult their physician prior to continued use of the device.
- 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.
- This device is intended to be used in individuals who are 18 years of age or older.
- Brain development continues beyond 18 years of age. The long-term effects of electrical stimulation from this device on the brain has not been studied.
- 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 healthcare practitioner. Outside the USA it is available worldwide without a prescription but consultation with a qualified healthcare 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

TECHNICAL SPECIFICATIONS

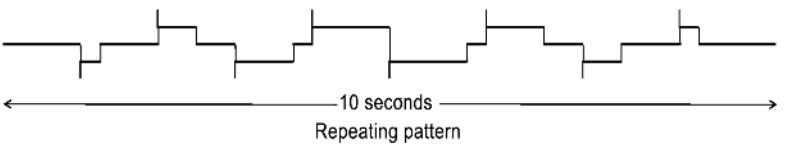
Electrical

Batteries	2 AAA 1.5 volt (included). Replace with disposable batteries. Do not use rechargeable batteries. Dispose of batteries safely in accordance with local government regulations.
Timer	20, 40 or 60 minute countdown timers.
Current	0 to 500 microamperes (μA), +/- 5%, adjustable in 50 μA increments. When load is 1KΩ, maximum output current is 525 μA (waveform amplitude is 525 mV) and minimum output current is 475 μA (waveform amplitude is 475 mV).
Frequency	0.5 Hz (pulses per second) combined with a constant 0.4 Hz. The average pulse repetition rate is 0.8 Hz.
Pulse Widths	Varying between 0.25, 0.5, 0.75 and 1 second.
Charge Per Pulse	At 500 μA the charge per pulse varies between 125, 250, 375 and 500 microcoulombs (μC). Every 10 seconds the total charge is 1.25 millicoulombs (mC) in each direction.
Waveform	The impedance range within which the waveform parameters remain valid are from 100 Ω to 10 KΩ. The waveform is composed of bipolar asymmetric rectangular waves at a 50% duty cycle repeating periodically at 10 second intervals. The waveform is balanced to achieve 0 net current in either direction (see graphic).

Device Dimensions

Height	9.8 cm
Width	6.3 cm
Depth	2.0 cm
Weight	101 gm with batteries

Characteristics of the Waveform



Alpha-Stim® 0.5 Hz Waveform

Alpha-Stim® AID output waveform parameters (Load resistance = 1000Ω)

Item	Parameter	Alpha-Stim® Waveform 0.5 Hz
1.	Average pulse repetition rate (pulses per second)	0.8
2.	Pulse width (seconds)	0.25 0.5 0.75 1
3.	Charge per pulse at 500 µA (µC)	125 250 375 500
4.	Period (seconds)	10
5.	Total charge in each direction in a period at 500 µA (mC)	1.25
6.	Duty cycle (%)	50
7.	Net current in either direction	0
8.	Output current	0 to 500 µA adjustable in 50 µA increments

STORAGE AND CLEANING

Storage

Remove the batteries when storing the Alpha-Stim® AID for an extended time of more than one month. Use the case to store and transport the Alpha-Stim® AID. The Alpha-Stim® AID and its accessories should be stored within a temperature range between -22^0 C and 55^0 C (-7^0 F and 131^0 F) and used within a temperature range between 5^0 C and 40^0 C (41^0 F and 104^0 F), with a relative humidity below 90%, at an atmospheric pressure between 912 to 1115 hPa.

Cleaning

Clean the Alpha-Stim® AID by gently wiping the surface of the case and screen with a damp cloth when dirty. Use mild soap and water if necessary. Use of other cleaning solutions may damage the case and screen. Never spray cleaners directly on the case and screen. Between treatments, the Earclip Electrode Pads (EEPS™) may be removed, and 70% isopropyl alcohol may be used on the Earclip Electrodes. New EEPS™ should be placed on the Earclip Electrodes prior to the next treatment.

TROUBLE SHOOTING

Problem	Possible Solutions
There is no sensation of current. *Note: This is normal for some people.*	Try increasing the current or wetting EEPS™ with more Alpha-Stim® Conducting Solution.
There are no results.	1. Treat more often or for a longer time at a lower current. 2. Some people require up to 3 weeks or more of treatment to begin to see an effect. 3. Consult your healthcare practitioner, authorized Alpha-Stim® distributor, or EPI for advice.
Earclip Electrode Pads (EEPS™) do not stick well.	Make sure the Earclip Electrodes are clean and dry before applying EEPS™.
The ⊘ symbol appears.	1. Make sure Earclip Electrodes are touching skin firmly. 2. Make sure the plug/jack connection is firmly in place. 3. Try wetting EEPS™ with more Alpha-Stim® Conducting Solution. 4. Change the batteries if they are low.

SERVICE

The Alpha-Stim® AID is not user serviceable.

To obtain service, first contact your authorized Alpha-Stim® distributor or Electromedical Products International, Inc. for advice. If necessary, send the entire device, with all accessories, packed in the original case, if available, to:

In the United States:
Electromedical Products International, Inc.
2201 Garrett Morris Parkway
Mineral Wells, TX 76067
USA

In Europe:
Electromedical Products International, Inc.
p.a. HealthLink Europe BV
Mechie Trommelenweg 8
5145 ND Waalwijk
THE NETHERLANDS

In Asia:
Electromedical Products International (Asia), Ltd.
Unit 8, 19/F Fook Yip Bldg.
53-57 Kwai Fung Crescent
Kwai Chung, Hong Kong

Send it insured, freight prepaid, and include a copy of your invoice and a note describing the problem. Please do not forget to include your return address, including country, and your phone number, and if you have them, fax and email.

NOTES ON DISPOSAL

Device recycling and disposal

This device may not be disposed in the household garbage.

Every consumer is required by law to dispose electric or electronic equipment, regardless whether or not they contain hazardous substances* at a collection point in his/her city or at the retail outlet so that they can be disposed of in an environmentally friendly manner without batteries.

* Lead is the only hazardous substance that is present in the batteries.

Battery recycling and disposal

End-users can remove the batteries before they dispose the unit. Do not dispose used batteries in the household garbage, instead dispose them as special waste or at a battery collection point in a specialist outlet. End-users can contact their local administration or vendor with respect to disposal. If you're curious about how to recycle batteries, the best place to start is by visiting web pages referring this subject in your country.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI") the Alpha-Stim® AID ("Product") is generally effective in relieving anxiety and insomnia, healthcare 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® AID is free of defects in workmanship and materials under normal use for a period of 5 years from the original purchase date, except for accessories.

The warranty registration must be completed to validate the warranty. Warranty registration can be completed online by going to www.alpha-stim.com/product-registration.

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® AID without charge. In order to recover under this warranty, purchaser must first contact EPI by phone, mail, fax, or email to obtain a Return Material Authorization number (RMA). Purchaser must have a copy of the original invoice and have completed the warranty registration process to prove that the Product is still covered by warranty. The authorized return may then be shipped to EPI safely packaged with

freight and insurance prepaid. 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 bill for the return freight and insurance charges.

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

Electromedical Products International, Inc. 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 (such as contract, negligence, or otherwise). In no event shall EPI's liability under any cause of action relating to the Product exceed the purchase price of the Product.

Reporting Device Issues

Please contact EPI if you have any concerns with the device: Call EPI at 1-800-367-7246 or email alpha-stim@epii.com. If you are located outside of the US, please call +1-940-328-0788.

You may also report any adverse events to the FDA using the following information:

MedWatch is the Food and Drug Administration's (FDA) program for reporting serious reactions, product quality problems, therapeutic inequivalence/failure, and product use errors with human medical products, including drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics.

If you think you or someone in your family has experienced a serious reaction to a medical product, you are encouraged to take the reporting form to your doctor. Your healthcare provider can provide clinical information based on your medical record that can help FDA evaluate your report.

However, we understand that for a variety of reasons, you may not wish to have the form filled out by your healthcare provider, or your healthcare provider may choose not to complete the form. Your healthcare provider is not required to report to the information. In these situations, you may complete the Online Reporting Form yourself.

You will receive an acknowledgement from FDA when your report is received. Reports are reviewed by FDA staff. You will be personally contacted only if we need additional information.

Submitting Adverse Event Reports to FDA

Use one of the methods below to submit voluntary adverse event reports to the FDA:

- Report Online at: www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home
- Consumer Reporting Form FDA 3500B. Follow the instructions on the form to either fax or mail it in for submission. For help filling out the form, see MedWatchLearn. The form is available at: www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
- Call FDA at 1-800-FDA-1088 to report by telephone.
- Reporting Form FDA 3500 is commonly used by health professionals. The form is available at: www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting

Clinical Literature Summary on CES Devices In General for Anxiety and Insomnia

Below is a literature summary of different types of CES devices that have been studied in the literature for anxiety and insomnia. This information is not specific to Alpha-Stim and is provided as a background for CES device types.

The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Cranial Electrotherapy Stimulation (CES) Safety and Effectiveness
January 1, 1970, to November 8, 2022

Introduction

According to the final reclassification order ("Final Order") published in the Federal Register on December 20, 2019 (84 FR 70003), CES devices have been determined by FDA to collectively demonstrate a "class effect" of CES for treating anxiety and/or insomnia. The historical indications for CES devices have mentioned "anxiety" and "insomnia," which are umbrella terms that encompass a variety of specific diagnoses, severities, etc. CES devices have been found to collectively demonstrate a class effect for treating "anxiety" and/or "insomnia." Evidence specific to the Alpha-Stim technology can be found in the "Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia" section of this Owner's Manual, which details the populations for which EPI has evidence. Individuals using this device should work with the prescribing healthcare practitioner to determine the best treatment settings to use.

Please see below for a summary of pertinent clinical literature that has been published using various combinations of CES devices, stimulation settings, and electrode positions. Please note that not all combinations of parameters provided below have been studied for safety and effectiveness; therefore, individuals using this device should work with the prescribing medical provider to determine the best treatment settings to use and should not apply electrodes to locations that are not indicated in the specific product's labeling.

Anxiety

As of November 2022, 33 studies investigated the impact of Cranial Electrotherapy Stimulation (CES) on anxiety (14 randomized controlled trials (RCTs), 13 observational studies, 2 meta-analysis, and 4 reviews). Of the RCTs that were evaluated, some trials reported superiority of CES treatment versus placebo (Rosenthal, SH, 1972; Philip et al., 1991; Lee et al., 2013; Sousa et al., 1975; Gibson et al., 1987; Ryan et al., 1976; Kim et al., 2021) or control (Kang et al., 2020; Park et al., 2022) in reducing anxiety symptoms, while other studies demonstrated no impact on anxiety (Levitt et al., 1975; Passini et al., 1976; Scallet et al., 1976; Hearst et al., 1974). One study noted transient improvement in symptoms (Feighner et al., 1973). The majority of observational studies reported a positive association between CES treatment and reduction in anxiety symptoms (Flemenbaum et al., 1974; Overcash, 1999; Rosenthal et al., 1970; Smith et al., 1999; Ryan et al., 1977; Morriss et al., 2019; Morriss et al., 2020; Bystritsky et al., 2008). One observational study reported that CES was as effective as usual care (Royal et al., 2022). Only 2 observational studies reported that CES did not have a significant impact on anxiety based on clinical assessment and standard inventories (Moore et al., 1975; Von Richthofen and Mellor, 1980). A meta-analysis of 10 studies evaluating the effectiveness of cranial stimulation in treating depression noted an effect on anxiety as a secondary study outcome compared to sham (Cheng et al., 2022). Another meta-analysis of 14 RCTs evaluating the effectiveness of cranial stimulation indicated that CES versus sham treatment was associated with significantly improved anxiety (Klawansky et al., 1975). Similar findings were reported in a review that examined 34 controlled trials involving a total of 767 patients receiving CES and an additional 867 patients serving as controls (De Felice et al., 1997). Twenty six (26) of 34 studies (77%) reported decreased anxiety after treatment with CES and the remaining 8 of 34 studies (24%) reported no such benefit. Two other reviews of trials using CES in patients with anxiety and depression concluded that CES may provide a modest benefit in the treatment of anxiety (Shekelle et al., 2018; Brunye et al., 2021). A fourth review found several

small studies reporting decreased anxiety with CES use in patients with various conditions, including 1 small study in individuals with anxiety disorder (Freire et al., 2020). In studies that reported improvement in anxiety with use of CES, the reported stimulation parameters, electrode placement, and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all CES devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

Insomnia

As of November 2022, there were a total of 23 studies that evaluated the effectiveness of CES on insomnia. Of the 11 RCTs, some reported greater reduction in insomnia symptoms in the CES group compared to placebo (Rosenthal, 1972; Philip et al., 1991; Feighner et al., 1973; Weiss et al., 1973; Heffernan et al., 1995), while others reported no significant differences in measures of insomnia symptoms between the 2 groups (Levitt et al., 1975; Scallet et al., 1976; Hearst et al., 1974; Coursey et al., 1980; Chang et al., 2022; Aseem et al., 2022). Among the 8 observational studies, CES treatment was associated with less frequent (Rosenthal and Wulfshon, 1970) and less intense (Matteson et al., 1986) sleep disturbances, improved soundness of sleep (39), less difficulty falling asleep (Nagata et al., 1981; Cartwritght and Weiss, 1975; Itil et al., 1972) and feeling more rested (Cartwright and Weiss, 1975) or improved mood (Nagata et al., 1981) in the morning. Several observational studies reported no impact of CES on insomnia (Empson, 1973; Frankel et al., 1973) or reported an effect that did not persist after the first week (Moore et al., 1975). A meta-analysis of 14 RCTs indicated that CES versus sham treatment had no impact on insomnia (Klawansky et al., 1995). Lastly, 3 reviews evaluated the effectiveness of CES on insomnia. One review found 23 studies, 6 of which were RCTs of which only 2 studied participants with insomnia (Aseem et al., 2019). Of these two RCTs, only 1 showed improved patient-reported sleep latency and objective changes in sleep, while the other did not show any change (Aseem et al., 2019). The other 2 reviews concluded that studies evaluating the effectiveness of CES on insomnia were inconclusive (Shekelle et al., 2018) or inconsistent (Brunye et al., 2021). In studies that reported improvement in insomnia with use of CES, the reported stimulation parameters, electrode placement, and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all CES devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

Clinical Literature Summary on Alpha-Stim for Anxiety and Insomnia

Below is a literature summary of clinical studies specific to the Alpha-Stim technology for anxiety and insomnia as well as the stimulation parameters studied.

Anxiety

In total, 27 studies investigated the impact of cranial electrotherapy stimulation (CES) delivered by the Alpha-Stim devices on anxiety (13 randomized controlled trials (RCTs), 2 surveys, 3 retrospective studies, 9 observational studies). Of the RCTs that were evaluated, 12 reported superiority of Alpha-Stim treatment versus placebo or control groups (Barclay et al., 2014; Cork et al., 2004; Gong et al., 2016; Hill et al., 2015; Kim et al., 2008; Koleoso et al., 2013; Lee et al., 2013; Lu and Hu, 2014; Mellen et al., 2008; Strentzsch et al., 2008; Voris et al., 1995; Winick et al., 1999) in reducing anxiety by a significant amount. One RCT demonstrated dramatic improvements in psychological factors including anxiety in patients receiving CES however the results were not found to be statistically significant likely due to a small sample size (Lichtbroun et al., 2001). Surveys showed that a majority of participants in both surveys reported having significant improvements in anxiety of greater 50% when compared to the baseline (Kirsch et al., 2014; Price et al., 2013). The majority of single arm studies reported a positive association between Alpha-Stim treatment and reduction in anxiety symptoms (Bystritsky et al., 2008; Kirsch et al., 2019; Mellen et al., 2016; Morriss et al., 2019; Platoni et al., 2019; Royal et al., 2022; Yennurajalingam et al., 2018). One study did not measure the effect of CES on anxiety but did determine that there was a significant decrease in subjective units of distress after Alpha-Stim treatment (Lande et al., 2018). The retrospective studies noted significant improvements in anxiety scores (Libretto et al., 2015; Morrow et al., 2019; Overcash et al., 1999).

In studies that reported improvement in anxiety with use of CES, the reported stimulation parameters and treatment schedule varied widely and were only evaluated in a small number of combinations. Please also note that not all Alpha-Stim devices are capable of providing the same stimulation parameters or combination of stimulation parameters.

Frequencies Studied:

- 0.5 Hz

Current Amplitudes Studied:

- 100 µA
- 100-500 µA
- 10-500 µA
- 200 µA
- 100-600 µA
- 50-500 µA
- 200-600 µA
- 300 µA

Treatment Schedules Studied:

- Daily for one hour (5 week study)
- Daily for one hour (6 weeks)
- 10-15 minutes once a day for 15 days, with a rest period of 2 days after every 5 days.
- 1 hour a day for 3 weeks.
- 30 minutes a day 5 times in a week, 10 times per course for a total of 3 courses.
- 1 hour for 1 session
- 20-60 minutes daily for 6 weeks.
- 45 minutes for each session for three days.
- 20 minutes the day before and the day prior to a surgery
- Daily for 3-8 weeks.
- 20 minutes daily from 3-15 days.
- 20 minutes for 20 daily sessions
- 20 minutes for 5 days daily.
- 60 minutes daily for 6 to 12 weeks
- 5 times a week for 2 weeks
- 1 hour daily for 3 weeks
- 1 hour per day for five days for three consecutive weeks
- 1 hour daily for eight weeks
- 20 minutes daily for 10 days.
- Over the course of a procedure
- 1 hour daily for four weeks

Please see below for a list of studies and patient population that have demonstrated improvements in anxiety with Alpha-Stim.

Randomized Control Studies:

- Barclay et al., 2014: Patients with anxiety disorder
- Voris et al., 1995: Patients diagnosed with anxiety
- Lu and Hu, 2014: Patients with anxiety disorders
- Strentzsch et al., 2008: Chronically mentally ill patients
- Cork et al., 2004: Patients diagnosed with fibromyalgia
- Gong et al., 2016: Patients with functional constipation
- Kim et al., 2008: Preoperative patients with anxiety
- Koleoso et al., 2013: Preoperative patients with dental anxiety
- Winick et al., 1999: Dental patients
- Lee et al., 2013: Preoperative female patients with anxiety
- Mellen & Mackey, 2008: Correctional and law enforcement personnel
- Hill et al., 2015: College students

Non-Randomized Studies:

- Kirsch et al., 2014: Service members and veterans
- Price et al., 2013: Civilian, service members, and veterans
- Bystritsky et al., 2008: Patients with General Anxiety Disorder
- Kirsch et al., 2019: Teachers
- Mellen et al., 2016: Victims of domestic violence
- Morriss et al., 2019: Patients with general anxiety disorder
- Platoni et al., 2019: First responders
- Royal et al., 2022: University students
- Yennurajalingam et al., 2018: Patients with advanced cancer
- Libretto et al., 2015: Active duty service members with PTSD
- Morrow et al., 2019: Veterans
- Overcash et al., 1999: Patients with acute anxiety disorders

Insomnia

A total of 9 studies investigated the impact of cranial electrotherapy stimulation (CES) delivered by Alpha-Stim devices on insomnia (3 RCTs, 2 surveys, 4 observational studies). Of the RCTs that were evaluated, 2 out of 3 reported superiority of Alpha-Stim treatment versus placebo or control/sham groups (Lande et al., 2013, Taylor et al., 2013) in improving the amount of time slept, quality of sleep decreasing the amount of sleep disturbances. One study could determine no significant effect of CES on sleep deficiency (Wagenseil et al., 2018). The two surveys showed that a majority of participants in both surveys reported having significant improvements in insomnia of greater 50% when compared to the baseline (Kirsch et al., 2014; Price et al., 2013). The majority of observational studies reported a positive association between Alpha-Stim treatment and reduction in insomnia symptoms (Kirsch et al., 2019; Morriss et al., 2019; Platoni et al., 2019; Yennurajalingam et al., 2018).

In studies that reported improvement in insomnia with use of CES, the reported stimulation parameters and treatment schedule varied widely. Please see below for details.

Frequencies Studied:

- 0.5 Hz

Current Amplitudes Studied:

- 100 – 600 μA
- 100 μA

Treatment Schedules Studied:

- 20-60 minutes daily for 6 weeks.
- 60 minutes daily for 5 days
- 60 minutes daily for 3 weeks
- 60 minutes daily for 6 – 12 weeks.
- 1 hour daily for 8 weeks
- 60 minutes daily for 4 weeks.

Please see below for a list of studies and patient population that have demonstrated improvements in anxiety with Alpha-Stim.

Randomized Control Studies:

- Lande et al., 2013: Service members
- Taylor et al., 2013: Patients with fibromyalgia

Non-Randomized Studies:

- Kirsch et al., 2014: Service members and veterans
- Price et al., 2013: Civilian, service members, and veterans
- Kirsch et al., 2019: Teachers
- Morriss et al., 2019: Patients with general anxiety disorder
- Platoni et al., 2019: First responders
- Yennurajalingam et al., 2018: Patients with advanced cancer

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