

Alpha-Stim® M

אלפא-סטים M

microcurrent & cranial
electrotherapy stimulator

מכשיר אלקטרוטרפיה באמצעות
מיקרו זרם וגירוי גולגולתי



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מדריך למשתמש



ENGLISH

Alpha-Stim® M

Microcurrent and Cranial Electrotherapy Stimulator
For Control of Anxiety, Insomnia, Depression and Pain

OWNER'S MANUAL



Type BF Equipment. This stimulator is internally powered only.



See instructions for use. Read this manual thoroughly before using the device. 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-60601-1 and CAN/CSA C22.2 No. 601.1. 34Vf.



Conformity Statement for Europe: Alpha-Stim® M is a Class IIa, Type BF 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.



When the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.

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.

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CONTENTS

Features	3
A Note to Health Care Practitioners	4
Control Buttons.....	5
LCD Display	6
Introduction.....	8
Description.....	9
Electromedical Therapeutics.....	10
Using the Alpha-Stim® M for Pain Control: Clean Skin, Evaluate Your Pain	13
Use the Alpha-Stim® M with Confidence.....	14
Quick Guide.....	14
Microcurrent Electrical Therapy (MET) To Treat Pain with Smart Probes.....	15
Smart Probe Treatment Strategy A	18
Smart Probe Treatment Strategy B.....	21
To Treat Pain with AS-Trode™ Electrodes.....	22
Cranial Electrotherapy Stimulation (CES) To Treat Anxiety, Insomnia or Depression with Earclip Electrodes	24
What to Expect	26
Prescribing Information: EPI is ISO Certified, Electromagnetic Interference, CE Conformity Statement for Europe, Caution Statement for United States, Indications	27
Prescribing Information Continued: Contraindications, Precautions, Adverse Effects	28
Technical Specifications	29
Storage and Cleaning	30
Trouble Shooting.....	30
Service	31
5 Year Limited Warranty.....	31

FEATURES

The Alpha-Stim® M (Part No. 400) comes complete and ready to use with 1 set of Earclip electrodes (Part No. 401), 1 15-ml bottle of Alpha Conducting Solution™ (Part No. ACS, 250-ml refill bottles available, Part No. ACSR), 2 sets of lead wires for 4 electrodes (Part No. 403), 2 Smart Probes (Part No. 402), 4 silver AS-Trode™ brand single person multiple use self-adhesive electrodes (Part No. AT, good for approximately 2 weeks to 1 month of use), 100 Probe Electrode Pads (Part No. PEP), 256 Earclip Electrode Pads (Part No. EEP), Illustrated Owner's Manual, Lanyard, Storage Case, and 2 AA batteries. This is everything you need to begin using your new Alpha-Stim® M. Replace Alpha Conducting Solution™, AS-Trode™ brand electrodes, Probe Electrode Pads (PEP™) and Earclip Electrode Pads (EEP) only with authorized Alpha-Stim® and AS-Trode™ brand products.

Alpha-Stim® M features include:

1. Full digital control for precision, consistency and reliability.
2. Choice of Earclip electrodes, Smart Probes, or AS-Trode™ electrodes.
3. Back lighting when any button is pressed.
4. Continuous circuit checks when electrodes are in contact with skin.
5. 3 frequency selections (0.5 Hz recommended).
6. 10 second Smart Probe cycle begins on contact with skin.
7. 10, 20, 40 or 60 minutes countdown cycles to auto-off.
8. Continuous time elapsed timer.
9. Large timer display.
10. 2 independent channel controls providing 0 - 600 microamperes (μA) of current.
11. Frequency, current and treatment time may be locked to preset values throughout entire treatment session.
12. Mute option for all functions (except Smart Probe).
13. Cumulative timer.

14. Choice of belt clip or lanyard so the Alpha-Stim® M can be worn around the neck.
15. 30 minute auto-off when not in use.
16. Able to withstand electrostatic discharges of up to 6,000 volts.
17. Automatically and permanently disables itself should a single fault develop within the device causing the current to exceed 700 µA.
18. Uses 2 AA 1.5 volt batteries (included).
19. Battery strength indicator.
20. Probe Electrode Pads (PEPS™) and Earclip Electrode Pads (EEPS) requires Alpha Conducting Solution™ (included).
21. 5 year limited warranty.

A NOTE TO HEALTH CARE PRACTITIONERS

Thank you for recommending the Alpha-Stim® M. This manual is written for the person who will use the Alpha-Stim® M, but your input will be invaluable to your patient. One way to help is to explain to your patient exactly where his or her problem is located. You might also suggest specific electrode locations where a particular pain may be originating from. Alpha-Med, your authorized distributor of Alpha-Stim®, 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 Alpha-Med 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 and participation in the forums on our website.

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CONTROL BUTTONS

1.  **On - Off**

2.  **Frequency.** 0.5 Hz is the strongest frequency setting and the one most people will achieve the best results with for all applications (Earclips, Smart Probes and AS-Trode™ electrodes).

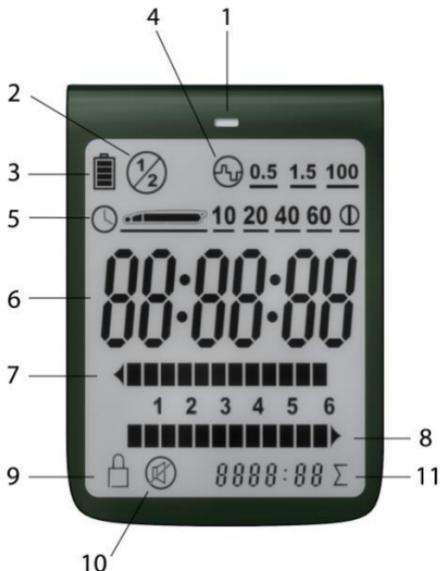
3.  **Timer.** Smart Probe 10 second waveform cycle starts when electrodes touch skin. Countdown timers: select **10, 20, 40 or 60 minutes.**
 **Continuous time elapsed timer.**

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

5.  or  **Current.** Increases or decreases current for each channel. 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 except on  Smart Probe setting which defaults to current setting from previous use.



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 for one or both channels (the number of the Channel that is not working will appear). The timer will stop and shut down in 30 minutes if nothing else is done. Current must be set above 0 μ A and moistened electrodes must be in contact with skin for Alpha-Stim[®] M to work. An audible signal and resumption of the timer occurs the instant the integrity check circuit 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 the mute function is on).

4.  **Frequency** setting indicator. 0.5, 1.5, or 100 Hz for both Channels.
5.  **Timer** setting indicator. Select  Smart Probe 10 second cycle begins on contact with skin, 10, 20, 40 or 60 minutes countdown to auto-off or  Continuous count forward timer.
6. **Time** remaining on all settings except  Continuous which shows time elapsed.
7.  0 - 600 microamperes (μA) of current for **Channel 1**.
8.  0 - 600 microamperes (μA) of current for **Channel 2**.
9.  **Lock** is on when display is lit.
10.  **Mute** feature for all settings except Smart Probe. To turn on or off press the key sequence: **Lock-Timer-Lock**.
11. **Σ Cumulative Timer** records total hours and minutes Alpha-Stim[®] M has been in use.

INTRODUCTION

Congratulations on your selection of the Alpha-Stim® M Microcurrent Electrical Therapy (MET) and 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 and rewarding life.

Electromedical Products International, Inc. (EPI), the manufacturer of Alpha-Stim®, is a leading innovator of the finest state-of-the-art medical technology available to improve the quality of your life. EPI and its distributor, Alpha-Med, 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 may be scheduled with you or your doctor Sunday through Thursday, 10 AM until 6 PM. 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® M is a precision medical device used for the management of anxiety, insomnia, depression and pain. Alpha-Stim® M provides a safe, effective and proven alternative to drugs especially in disorders that require long-term management. Potential side effects of drugs are avoided. After treatment, there are usually no physical limitations imposed so you can resume normal activities. The treatment is simple and easily self-administered at any time. People using the Alpha-Stim® M usually report a pleasant, relaxed feeling of well-being.

The current is applied by hand-held Smart Probes or self-adhesive AS-Trode™ electrodes for pain control, or by Earclip electrodes for anxiety, insomnia and depression. 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 be alleviated by reducing the current.

Once you understand the basic product features and procedures, you will find the Alpha-Stim® M 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 health care practitioner.

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® M 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 AA batteries.

The Alpha-Stim® M 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, 1.5, or 100 Hz (pulses per second), at 50 to 600 microamperes (1 μ A is one-millionth of an ampere), in a 50% duty cycle.

The Alpha-Stim® M is small, compact and light-weight. It was designed to be versatile. It can be used in a health care 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, frequency and current assures the prescribed treatment waveform and dosage even if you are distracted or fall asleep. The amount of current can easily be decreased to assure comfort or increased to reduce treatment time.

The Alpha-Stim® M may be categorized into two general categories. *Microcurrent Electrical Therapy*, or MET, is a generic term used to describe low level current used for pain control typically applied for 2 to 5 minutes through probes, or self-adhesive electrodes for longer applications. It is distinguished from previous forms of transcutaneous electrical nerve stimulation (TENS) in that MET uses far less current, but delivers the current in much longer pulses. Whereas TENS devices must be constantly worn because they offer virtually no residual effect, MET effects are long-lasting and cumulative. The second category, represented by the application using the Earclip electrodes to treat the brain for anxiety, insomnia and/or depression is known as *Cranial Electrotherapy Stimulation*, or CES.

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

The Alpha-Stim® M was developed by neurobiologist, Dr. Daniel L. Kirsch and engineer, Raymond Chan. 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 from 1990 - 2015, 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. He is also a Member of Inter-Pain, the organization for pain physicians in Germany and Switzerland. He is the Electromedical Department Editor of the journal, *Practical Pain Management* and a Consulting Editor for the *Journal of Neurotherapy*. 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 is an author of books and articles and lectures frequently to physicians and psychologists worldwide on pain and stress management and is an expert research and practice consultant to Veterans Affairs Medical Centers and the United States Army.

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, insomnia and depression began in Russia during the 1950s and first came to the USA in the 1960s.

In 1965 Drs. Ronald Melzack of Canada and Patrick Wall of the United Kingdom published a paper explaining a new comprehensive theory of how pain is processed by the nervous system. Their *Gate Control* theory also explained how electrical stimulation can influence the physiology of pain pathways. By 1967 electrical devices were surgically implanted to control severe low back pain. Surface electrical stimulation devices were used to test the person's response as a means of screening surgical candidates and to determine the most effective electrode site for implantation. It was soon discovered that electromedical treatment through the skin (transcutaneous) was equally effective and could be used for pain relief alone, avoiding surgery. Since then, these devices, known as transcutaneous electrical nerve stimulators (TENS), have become widely accepted by health care practitioners to control many forms of pain.

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 USA¹ and Dr. Björn Nordenström of Sweden² (who served as Chairman of the Nobel Assembly) to propose completely new theories of physiology based on our latest understanding of biophysics.

Alpha-Stim® technology incorporates these theories and is proven more efficacious than most other treatments for the conditions it treats. It is a viable alternative to traditional TENS, as well as an alternative or complementary treatment with pharmacological management, surgery and other interventions. The original Alpha-Stim® Model 2000 weighed 40 pounds and cost \$5,850 when it was first introduced in 1981. The Alpha-Stim® M microcurrent stimulator utilizes the most advanced technology available today. It is now possible, in most cases, to alleviate anxiety, insomnia, depression and pain with far less current than used in previous technologies, 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® M will improve the quality of your life.

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.

USING THE ALPHA-STIM[®] M FOR PAIN CONTROL

Clean Skin

Clean the skin around the treatment area before applying electrodes. Use 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 post treatment. Skin irritation may develop in light skin. If skin burns are noted following treatment, discontinue use and apply an appropriate skin cream. Varying electrode locations may minimize irritation.

Evaluate Your Pain

Evaluate your pain before and from time-to-time during and after each treatment. Your health care practitioner can give you guidelines to help you do a quick, simple evaluation. This may consist of simply moving into a position that causes you to be more aware of your pain, then noting the level of pain you are experiencing on a 0 (no pain) to 10 (maximum pain) scale at the beginning and end of each treatment. Moving the affected body part through its range-of-motion and observing the increased range along with the decreased pain after treatment are good indicators of progress. Because Alpha-Stim[®] works quickly for most people it is helpful to use these reference parameters to determine effectiveness throughout a single treatment session. Keeping a daily (or even as often as hourly) chart of changes in your pain locations and levels on a 0 to 10 scale will help track progress and may be useful in determining the best areas to treat. To help you understand this system, a description of pain levels follows (use odd numbers for between values, e.g., Level 1 would indicate a very slight pain that does not interfere with activities):

<u>Pain Level</u>	<u>Description</u>
0	No pain.
2	Mild pain; only aware of pain when focused on it. Considered nagging and annoying but only slightly interferes with activities of daily living (ADL).
4	Tolerable pain; can be ignored somewhat.
6	Distressful pain; interferes significantly with ADL.
8	Severe pain; can not concentrate or do anything but simple tasks.
10	Disabling pain; unable to perform ADL.

It may also be helpful to keep a diary of Alpha-Stim[®] treatment times, duration of each treatment, frequency (Hz) and current (μA) settings along with the electrode locations you use.

USE THE ALPHA-STIM® M WITH CONFIDENCE

Because the Alpha-Stim® M 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® M is working unless the  **Test Circuit** symbol appears displaying the number 1 or 2 for the Channel you are using or the low battery indicator is down to the last bar. Some people only achieve maximum relief when using the Alpha-Stim® M for hours every day, or even all the time. While this is rarely necessary it is also not harmful – so use the Alpha-Stim® M with confidence knowing you have a safe and effective tool to help you *experience life...AGAIN™*.

Quick Guide

Read the following instructions carefully. Then, after you have used the Alpha-Stim® M once you simply press the **Power** button, place the electrodes or **Earclips** in the appropriate place(s) and adjust the current to a comfortable level. The time and frequency parameters default to the previous settings until changed. *That's all there is to it!* Readjust the current up or down to a comfortable level at anytime during treatment, if

MICROCURRENT ELECTRICAL THERAPY (MET) TO TREAT PAIN WITH SMART PROBES

1. Plug dual connector end of wires into **Channel 1** or **Channel 2** jack and pin plugs into **Smart Probes**. **Figure 1**.
2. Apply **Probe Electrode Pads (PEPS™)** to Probes by placing clean Probe tip into **PEP™** in **PEP™** case. **PEP™** case opens with label on bottom. **Figure 2**.



Figure 1

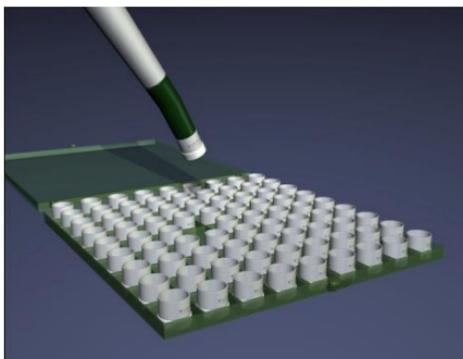


Figure 2

3. Press **Power** on.
4. Set **Frequency** to 0.5 Hz or desired setting. For joint problems (e.g., shoulders, elbows, wrists, fingers, hips, knees, ankles, toes) use 100 Hz for 10 - 20 seconds immediately followed by 0.5 Hz. Try 1.5 Hz if 0.5 Hz is not effective.
5. Set **Timer** to Probe setting.
6. Set **Current** on Channel in use to 6 (600 μ A). Decrease immediately if uncomfortable. When used on or near the head, immediately decrease the current if dizziness or nausea develops. This may happen initially or several minutes into treatment. Decreasing the current will immediately relieve these unpleasant feelings.

7. Saturate **PEPS™** thoroughly with several drops of **Alpha Conducting Solution™ (ACS)**. Repeat as necessary throughout treatment. **Figure 3**.
8. Note level of pain for all areas being treated and any limitations of movement in joints before, during, and at conclusion of treatment. It helps to keep a diary of pain levels where 0 is no pain and 10 is the worst the pain being treated has been, along with time of day, duration of treatment, frequency and current levels used, and the most effective electrode locations.



Figure 3

9. Apply **Smart Probes** to clean, dry skin. Cycle will start with 2 beeps on contact with skin and end with a single beep. Hold Probes firmly against skin for the entire 10 second cycle before moving to next treatment location. Lift Probe off skin and replace to repeat treatment at the same location. See **Smart Probe Treatment Strategies** for guidelines for Probe placements. **Figure 4**.

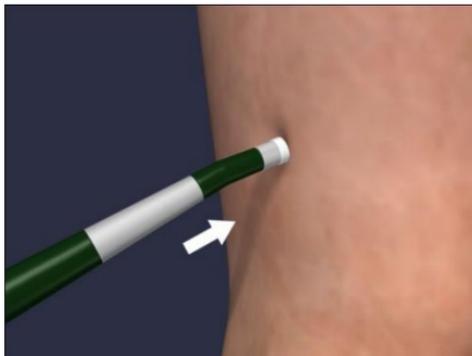


Figure 4

10. Always place the **Smart Probes** to direct the current between them through the area being treated. Two **Smart Probes** must always be used together to complete the electric circuit. **Figure 5**.

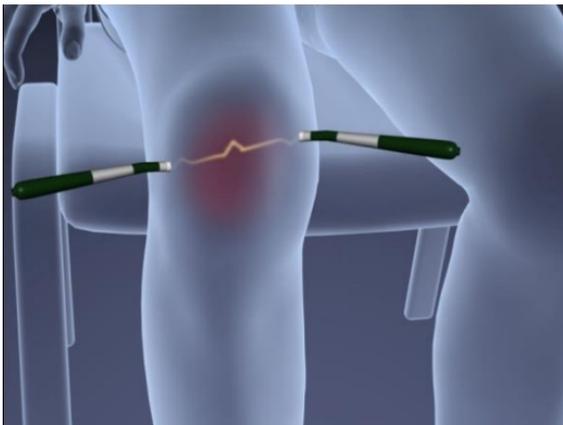


Figure 5

11. Continue treatment until pain is completely gone or maximum relief is achieved. There is usually an increased range of motion in treated areas. Sometimes treated areas of the body feel stiff or tight after the pain is gone. This will wear off over time.
12. Turn **Power** off.
13. Discard **PEPS™**.
14. Finish with **Cranial Electrotherapy Stimulation** (see directions on page 24).
15. Repeat as necessary. Results usually improve and last longer with additional treatments.
16. Store Alpha-Stim® M away from children.

SMART PROBE TREATMENT STRATEGY A



1. First treat beyond the treatment area (*e.g.*, the entire leg for knee pain) in at least 2 places directing the current between the Probes through the treatment area. **Figure 6.1.**
2. Treat closer in, around and through the area being treated for about 1 minute applying the Smart Probes at about 6 different angles of approach with the Probes always placed on opposite sides of the body (*e.g.*, front to back or side to side). **Figure 6.2.**
3. Treat the same body part on the opposite side of the body in at least 2 places (such as other knee, wrist, other side of back, etc.). **Figure 6.3.**
4. Connect the two sides by placing one Probe below the treatment area and the other in the same place on the opposite side of the body in a few places. For example, follow “a line” under and around each knee placing the Probes at intervals along the line. **Figure 6.4.** For back pain place probes in at least 3 places on both sides of the body at the level being treated and slightly above and below. This directs the current through the nerves and spinal cord. **Figure 7.**
5. Repeat as necessary, varying Smart Probe positions but always directing the current between the Probes through the area being treated.
6. Continue treatment until pain is completely gone or maximum relief is achieved.



Figure 6.1

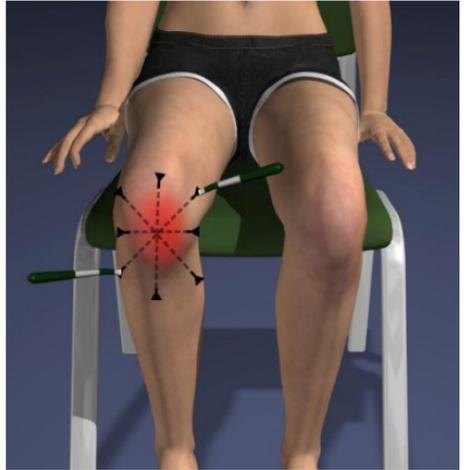


Figure 6.2



Figure 6.3



Figure 6.4

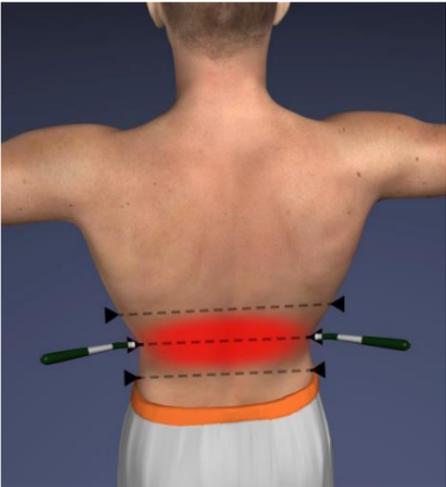
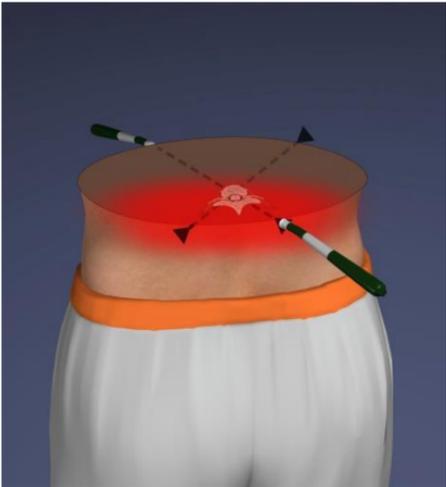
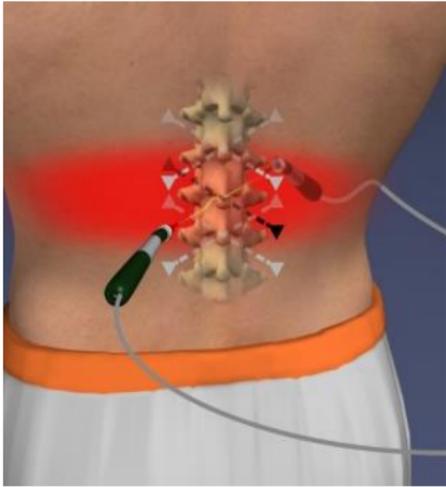


Figure 7

SMART PROBE TREATMENT STRATEGY B

1. To treat any problem in the neck and arms (e.g., fingers, hand, wrist, elbow, shoulders) connect the two sides by placing one Smart Probe on one finger tip and the other Smart Probe in the same place on the corresponding finger tip of the other hand for 10 – 20 seconds (i.e., thumb tip to thumb tip on other hand, index finger next, etc. for all 5 fingers). **Figure 8**. The same strategy applied to the toes may be used to treat any problem in the legs such as toes, feet, ankles and knees, but not hips. Hip pain requires local Probe treatment as described in Strategy A.
2. Repeat as necessary, varying Probe positions but always directing the current through the area being treated by placing the Smart Probes past that area, in a direction away from the spine.
3. Continue treatment until pain is completely gone or maximum relief is achieved.

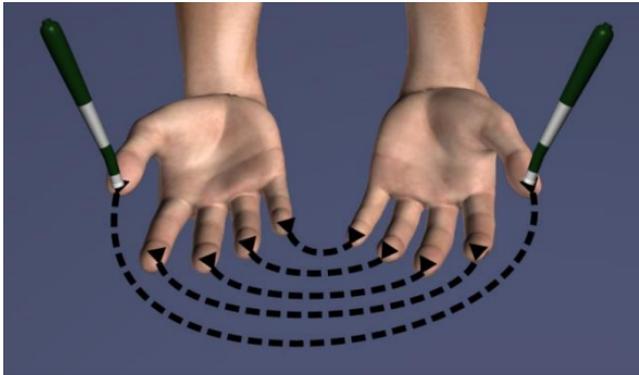


Figure 8

TO TREAT PAIN WITH AS-TRODE™ ELECTRODES

1. Plug dual connector end of wires into **Channel 1** and/or **Channel 2** jack and pin plug into **AS-Trodes™**. **Figure 1**.
2. Press **Power** on.
3. Mute the beeping if desired with the key sequence: **Lock-Timer-Lock**. To reinstate the audio alert press the same key sequence.
4. Set **Frequency** to 0.5 Hz or desired setting.
5. Set **Timer** to 10, 20, 40, 60 minutes or **Continuous**. This depends on the length of time necessary to effectively manage your pain. The cause and severity of the pain, your overall health, and any ongoing physical or psychological stress that might add to your condition are some of the factors determining length of treatment. Standard treatment time is 20 minutes to 1 hour per **AS-Trode™** location. Additional treatment time is usually not necessary. The Alpha-Stim® M may be used continuously all day for months or even years in severe cases but such usage is rarely necessary.
6. Set **Current** on the **Channel(s)** in use to desired setting. Use 6 (600 μ A) for maximum pain relief; decrease immediately if uncomfortable. Use 1 (100 μ A) when using **AS-Trodes™** for over 1 hour; increase as necessary to obtain relief, but reduce current to lowest possible effective level (but not less than 100 μ A) when used for long periods of time. This has shown to provide better results than when maintaining the maximum current level.
7. Press **Lock** button twice to lock settings if desired. Press **Lock** button twice again to unlock and change setting if necessary.
8. Note level of pain for all areas being treated and any limitation of movement in joints before, during, and at conclusion of treatment. It helps to keep a diary of pain levels where 0 is no pain and 10 is the worst that area of pain has been, along with time of day, duration of treatment, frequency and current levels used, and the most effective **AS-Trode™** locations.
9. Peel the self-adhesive **AS-Trodes™** off of the protective backing. Save the backing for storage of the **AS-Trodes™** after use. **Figure 9**. If the adhesive dries out and the electrodes do not stick well, you may wet them with a few drops of **Alpha Conducting Solution™ (ACS)** and lightly rub your finger over the electrode to spread the solution into the electrode gel. Be careful as too much **ACS™** will saturate the **AS-Trodes™** decreasing their ability to adhere to the skin.

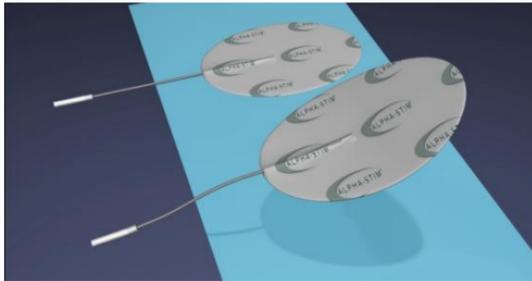


Figure 9

10. Apply **AS-Trodes™** to clean, dry skin. Always place the **AS-Trodes™** to direct the current between them through the area being treated. Two **AS-Trodes™** must always be used in pairs to complete the electrical circuit. **Figure 10.**

11. Move **AS-Trodes™** around as necessary to obtain the best results.
12. Continue treatment until pain is completely gone or maximum relief is achieved. There is usually an increased range of motion in treated areas. Sometimes areas of the body feel stiff or tight when the pain is alleviated, but this will wear off after a brief period of time.

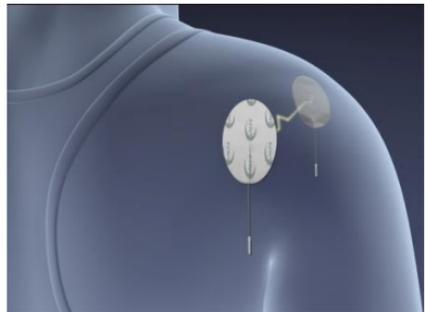


Figure 10

13. Replace **AS-Trodes™** in bag and seal bag. Discard and replace electrodes when adhesive has split or worn through to the conductive backing. Use only EPI **AS-Trode™** brand silver electrodes available through your authorized Alpha-Stim® distributor. Many electrodes are significantly less conductive and will not allow the Alpha-Stim® current to penetrate the electrical resistance of the skin.
14. Finish with **Cranial Electrotherapy Stimulation** (see directions on following page).
15. Repeat as necessary. Results usually improve and last longer with additional treatments.
16. Store Alpha-Stim® M away from children.

CRANIAL ELECTROTHERAPY STIMULATION (CES) TO TREAT ANXIETY, INSOMNIA OR DEPRESSION 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** locations around the ear lobe may minimize irritation.
2. Plug dual connector end of **Earclip** wires into **Channel 1** or **Channel 2** jack.
3. Remove and discard old **Earclip Electrode Pads (EEPS)** if present. Remove old glue residue, clean and dry **Earclips** 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 Conducting Solution™ (ACS)** 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.
7. Set **Frequency** to 0.5 Hz
8. 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 .
9. Squeeze **Earclips** and apply one to each ear lobe. **Figure 11**.
10. **Current** defaults to 1 (100 μA) when the Alpha-Stim® M is turned on. Increase



Figure 11

Current slowly (6 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 μ A) 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.

11. Press **Lock** twice to lock settings if desired. Press **Lock** twice again to unlock and change settings if necessary.
12. 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.
13. **Power** will turn off automatically at the conclusion of the timed cycle.
14. **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.
15. Remove and discard **EEPS**. Clean and dry **Earclips** and replace 4 **EEPS** for the next treatment session if desired. **EEP** case opens with label on bottom.
16. Store Alpha-Stim® M away from children.
17. 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® M is significantly effective when it is used correctly for 9 out of 10 people who use it, it will not work for everyone. If obvious pain relief is not achieved after several Smart Probe locations are attempted, consider treating the primary area of pain at a lower current setting of 1 - 2 (100 to 200 μ A) with AS-Trode™ electrodes for 60 minutes or more. If necessary, it can be used all day. 1.5 Hz may produce better results in some people when the 0.5 Hz fails, but this is rare. It may also be necessary to treat all areas of pain anywhere on the body in order to get results. If the Alpha-Stim® M is not working well for you, contact your health care practitioner, your local authorized Alpha-Stim® distributor, or EPI for technical support.

Both pain control and 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. Insomnia is controlled by the relaxation effect and most people 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 the increased alertness after a CES treatment may interfere with sleep. It may also be used in the morning to promote better sleeping at night.

Depression typically takes 3 weeks or more of daily treatment to experience significant improvement, but may take considerably longer. After the condition is under control, use of Alpha-Stim® 2 - 3 times per week or less is usually sufficient to maintain good results.

Following treatment, there are usually no physical limitations imposed so most users can resume normal activities immediately. Some users may have a response that may affect their ability to perform potentially hazardous tasks, such as operating a motor vehicle or heavy machinery for up to several hours after treatment.

At present, there are over 150 research studies on using Cranial Electrotherapy Stimulation in humans and more than 30 animal studies. No significant lasting side effects have been reported. Occasional 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. These are all mild and 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® M 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.

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 worldwide without a prescription but consultation with a qualified health care practitioner is recommended.

Indications

Alpha-Stim® M is an effective treatment with broad applications for a variety of syndromes involving pain, and for the management of anxiety, insomnia and depression, 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® M. 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.

Contraindications

The Alpha-Stim® M may affect the operation of implanted demand type cardiac pacemakers and implanted defibrillators. Do not stimulate directly on the eyes, or press the probes over the carotid sinus (on the neck near 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 treatment, and in some cases for several hours after treatment if the user experiences profound relaxation. 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.

Adverse Effects

Adverse effects are usually mild and self-limiting. Adverse effects from data on approximately 8,792 patients participating in 144 controlled studies, open clinical trials, and uncontrolled conditions, and by physician survey and reasonably associated with the use of CES are dizziness (6 cases, 0.07%), skin irritation/electrode burns (6 cases, 0.07%), and headaches (9 cases, 0.10%). Prolonged CES treatment at currents higher than necessary 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. Paradoxical reactions such as hyperexcited states, increased anxiety, and sleep disturbances may occur, but are rare.

If the Alpha-Stim® M does not begin to control your anxiety, insomnia, depression or pain within one month, consult your health care practitioner, Alpha-Med your authorized Alpha-Stim® distributor, or EPI.

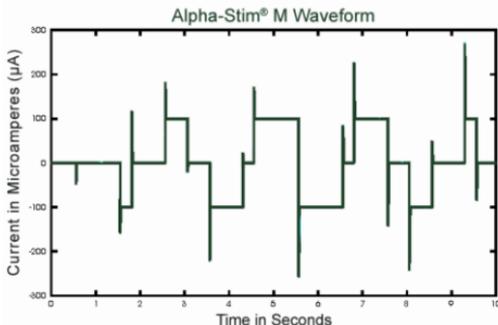
TECHNICAL SPECIFICATIONS

Electrical

Batteries	2 AA 1.5 volt (included). Replace with disposable batteries. Do not use rechargeable batteries. Dispose of batteries safely in accordance with local government regulations.
Timer	10 second Smart Probe activated by skin contact, 10, 20, 40, 60 minute countdown timers, and continuous time elapsed timer.
Current	0 to 600 microamperes (μA) adjustable in 50 μA increments.
Frequency	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.
Pulse Widths	Varying between 0.25, 0.5, 0.75, and 1 second at 0.5 Hz.
Charge Per Pulse	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 waveform parameters remain valid are from 100 Ω to 10 K Ω . 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 intervals. The waveform is balanced to achieve 0 net current in either direction (see graphic).

Mechanical

Height	11.0 cm
Width	7.2 cm
Depth	2.1 cm without belt clip
Weight	152 gm with batteries



STORAGE AND CLEANING

Remove the batteries when storing the Alpha-Stim® M for an extended time of more than one month. Use the case to store and transport the Alpha-Stim® M. The Alpha-Stim® M and its accessories should be stored and used within a temperature range between 0° and 36° C, with a relative humidity below 90%, at an atmospheric pressure between 912 to 1115 hPa. Clean the Alpha-Stim® M by gently wiping the surface with a damp cloth when dirty. Use mild soap and water if necessary. Use of other cleaning solutions may damage the case. Never spray cleaners directly on the device. 70% isopropyl alcohol may be used on the Smart Probes and Earclip electrodes to disinfect them between treatments.

TROUBLE SHOOTING

Problem	Possible Solutions
There is no sensation of current. <i>Note: This is normal for some people, especially with Probes.</i>	Try increasing the current or wetting electrodes with more Alpha Conducting Solution™ (ACS).
There are no results.	<ol style="list-style-type: none">1. Vary the electrode locations.2. Treat all other areas of pain.3. Try 1.5 Hz, or 100 Hz if 0.5 Hz is ineffective.4. Treat more often or for a longer time at a lower current.5. Some people require up to 3 weeks or more of treatment to begin to see an effect.6. Consult your health care practitioner, authorized Alpha-Stim® distributor, or EPI for advice.
Electrodes do not stick well.	<ol style="list-style-type: none">1. Wet AS-Trode™ electrodes with a few drops of ACS™, replace if they still do not stick well.2. Apply EEPS electrodes to a clean, dry surface.
Smart Probes do not conduct current.	<ol style="list-style-type: none">1. Use more ACS™.2. Try other lead wire to determine if it is a broken wire.
The $\frac{1}{2}$ symbol appears.	<ol style="list-style-type: none">1. Make sure electrodes are touching skin firmly.2. Make sure all plug/jack connections are firmly in place.3. Try wetting PEPS or EEPS with more ACS™.4. Change the batteries if the batteries are low.

SERVICE

The Alpha-Stim® M is not user serviceable.

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

**Alpha-Med
16 Shazar Zalman Street
Netanya 42493 Israel**

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.

5 YEAR LIMITED WARRANTY

While in the opinion of Electromedical Products International, Inc., ("EPI") the Alpha-Stim® M ("Product") is generally effective in relieving anxiety, insomnia and/or depression, 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® M 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 card must be completed and returned 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® M 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 to obtain a Return Material Authorization number (RMA). Purchaser must have a copy of the original invoice to prove that the Product is still covered by warranty. The authorized return may then be shipped to Alpha-Med, safely packaged with freight and insurance 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 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, or alteration/disassembly by anyone other than 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.



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