SAFE & EFFECTIVE RELIEF

AlleviaHealth
For healthy mind and body

2023 STATEMENT OF MEDICAL NECESSITY

To whom it may concern,

I am ordering the purchase or rental of an Alpha-Stim® electromedical device complete with accessories for the below named patient to use at home as a conservative method of treating anxiety, insomnia or pain. This technology is supported by successful outcomes documented by more than 140 published articles (Abstracts and PDFs of research articles are available at www.Alpha-Stim.com).

I want this patient to have the following Alpha-Stim® device (*do not substitute*):

☐ Alpha-Stim® M microcurrent stimulator for treatment of pain, anxiety and insomnia

☐ Alpha-Stim® AID cranial electrotherapy stimulator for treatment of anxiety and insomnia

Allevia Health, Inc. provides detailed printed instructions and follow-up support by phone for patients who purchase or rent an Alpha-Stim®. Alpha-Stim® devices come with a 5 year manufacturer's warranty.

PATIENT

Name_____

Address_____

_____

City_____State_____Zip_____

Home Phone (_____)_____

Cell Phone (_____)_____

Email_____

Date of Birth_____

FAX form to (888) 684-8414

or email it to: info@alleviahealth.com

or mail it to:
Allevia Health, Inc.
Authorized Distributor for OR & WA
20 E Airport Road, Suite 342
Lebanon, OR 97355

Questions? (800) 684-9343

www.AlleviaHealth.com

PRACTITIONER

Practitioner's Name_____

Practitioner's Signature_____

Degree_____State License #_____

NPI#_____

Office/Clinic_____

Street Address_____

City_____State_____Zip_____

Phone (_____)_____Fax (_____)_____

Date Ordered For Patient_____

The patient's current diagnoses applicable to the Alpha-Stim® treatments are:

1. _____ ICD10 Code_____

2. _____ ICD10 Code_____

3. _____ ICD10 Code_____

4. _____ ICD10 Code_____

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Ordering Information for Alpha-Stim®

Federal Law in the USA restricts Alpha-Stim® devices to sale by, or on the order of, a licensed health care practitioner.

Indications: Treatment Chart

	Alpha-Stim® M	Alpha-Stim® AID
Anxiety	•	•
Insomnia	•	•
Pain	•	

Indications Alpha-Stim M is an effective treatment with broad applications for a variety of syndromes involving pain, and both the M and Alpha-Stim AID are used for the management of anxiety and insomnia, or for the short term relief of symptoms associated with these indications. In many cases, Alpha-Stim 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.

Cautions U.S. Federal law restricts these devices to sale by or on the order of a licensed practitioner. Outside of the USA they are available worldwide without a prescription, but consultation with a qualified healthcare practitioner is recommended.

As with any therapeutic intervention, not all people will respond to Alpha-Stim. The degree of efficacy will vary with the nature of the problem being treated, the overall health of the person, and the method of treatment. As much as a one month initial trial may be required to see significant reductions in symptoms.

Contraindications Alpha-Stim may affect the operation of implanted demand-type cardiac pacemakers and implanted or wearable defibrillators. Do not stimulate directly on the eyes, or press the Alpha-Stim M probes over the carotid sinus (on the neck near the larynx).

Precautions For external use only. Do not allow children to use or handle these devices without adult supervision. Do not operate potentially dangerous machinery or vehicles during treatment, and in some cases for several hours after treatment. Caution is advised in cases where other forms of analgesia (pain control) would not be used, such as to retain the beneficial aspects of pain for diagnosis or in cases where people may overuse pain-controlled areas. Safety of stimulation during pregnancy has not been established.

Adverse Effects Adverse effects are usually mild and self-limiting. Adverse effects from data on approximately 8,800 patients participating in 144 controlled studies, open clinical trials, and uncontrolled conditions, and by physician survey and reasonably associated with the use of CES and MET, 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. Paradoxical reactions such as increased anxiety and sleep disturbances may occur, but are rare.

EPI is ISO Certified Electromedical Products International, Inc. is an International Standards Organization (ISO) certified establishment. ISO works 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.