

Increase **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. 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 the 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