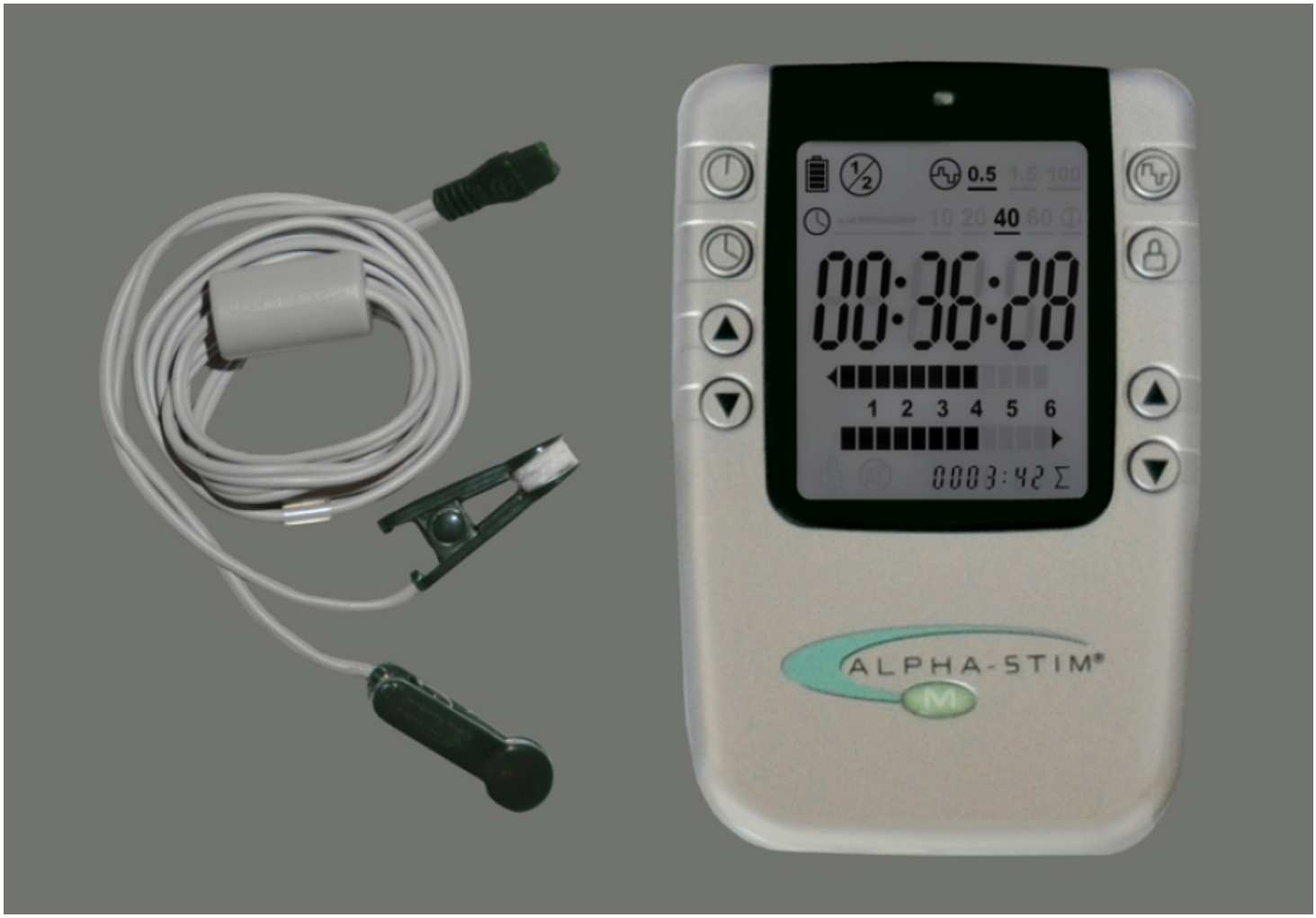
Promising PTSD treatment faces hurdle



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Devices such as Electromedical Products International's Alpha-Stim M are used to administer cranial electrotherapy stimulation treatment for troops suffering from PTSD.
COURTESY OF ELECTROMEDICAL PRODUCTS INTERNATIONAL, INC.

By WYATT OLSON (/reporters/2.1926?author=Wyatt_Olson) | STARS AND STRIPES

YOKOTA AIR BASE, Japan — For decades, Ed Gaumer's restless sleep was plagued with snippets of dreams arising from his three tours in Vietnam as a Marine in 1967-70. By day, he was hyper-alert to certain smells and sounds, any of which might leave him breathless and scanning for threats.

They were classic symptoms of post-traumatic stress disorder, and by 2005 the flashbacks were interfering with his civilian job for a Defense Department agency that provided logistical support for overseas operations.

Based at Wright-Patterson Air Force Base near Dayton, Ohio, Gaumer began seeing a psychologist who had experience treating soldiers in combat zones, who introduced him to cranial electrotherapy stimulation, or CES, a treatment she used on combat-stressed soldiers in Iraq.

"For 40 years I'd been kind of chasing the things in my flashbacks. I've finally been able to put them to rest so I can move on," Gaumer said, crediting CES.

While CES worked for Gaumer, others might not get the chance to see whether they respond to the treatment.

An FDA panel recommendation to change the classification of CES devices could take them off the market until lengthy and expensive testing is completed.

The possible delay comes at a time when there is no single magic-bullet therapy for the symptoms of PTSD — including anxiety, depression, insomnia — and a growing number of doctors are turning to alternative methods like CES to treat servicemembers and veterans.

Researchers found that CES activates and deactivates certain parts of the brain via micro-electrical current delivered by a device resembling a smartphone with ear buds.

Although the mechanisms of how CES works aren't fully understood, mental health professionals who advocate its use say that it is easily folded into any treatment regimen because there are no serious side effects or harmful interactions with prescription drugs and other therapies. Most devices cost between $500 and $1,500.

The owner of the largest producer, Texas-based Electromedical Products International, said the technology has been proven safe and effective on thousands of patients while on the market for 40 years. But now, a U.S. Food and Drug Administration panel has

ommended changing the classification of CES devices — a move that could take them off the market pending lengthy, expensive testing.

Col. Dallas C. Hack, director of the Army Combat Casualty Care Research Program at Fort Detrick, Md., told Stars and Stripes that the prevalence of CES treatment in the military is “moderately widespread,” but its use depends mainly on whether a particular practitioner has adopted it.

In January, Hack sent a letter to the FDA on behalf of the Army requesting expedited review of CES because “continued and uninterrupted availability of these devices for further study is in the best interest of patients.” The letter noted that a Veterans Affairs study found “limited efficacy of drugs in the treatment of depression in soldiers who are suffering from PTSD.”

An alternative to drugs

Sales of CES devices to the military have grown steadily since 2007.

EPI, whose Alpha-Stim brand dominates the industry, filled 3,000 prescriptions for the device for the Department of Defense, Tricare and the Veterans Administration from 2007 to mid-2011, according to company data submitted to the FDA.

The Army Office of the Surgeon General’s Pain Management Task Force in 2010 recommended CES for pain management.

CES is a key component of PTSD treatment in the Warrior Combat Stress Reset Program at the Darnall Army Medical Center in Fort Hood, Texas, according to a letter submitted to the FDA by program director Jerry E. Wesch. CES is particularly useful in suppressing hyper-arousal and improving sleep, Wesch wrote, noting his comments did not reflect Army policy.

The program also uses CES to treat pain and headaches, “a real boon for the many combat soldiers in our program who have chronic neck, back and joint pains.”

“I am reluctant to treat PTSD in our population without this tool in the mix,” he wrote, adding that about 80 percent of the 500 soldiers completing the program had opted to use CES in their follow-up plan.

Kathy Platoni, the Ohio clinical psychologist who treated Gaumer, is an Army Reserve colonel and a psychology consultant to the chief of the Medical Service Corps. She has used CES extensively during deployments in Iraq and Afghanistan.

devices were routinely used to lessen symptoms typically arising from PTSD: insomnia, irritability and outbursts of anger, lack of concentration and feeling "jumpy."

"Medications in many cases render soldiers mission incapable," she said. CES "allows soldiers to function without medications that might impair them."

Gaumer, who now lives in Akron, compares the immediate after effects of CES to the elation felt after intense exercise. "You feel good. You feel light on your feet," he said.

There is a slight tingling sensation at the connection points, which is on the earlobes for the model Gaumer uses. He said he knows the current is a notch too high if he feels pressure on his temples.

At first, he used it daily, often during his "talk therapy" sessions with Platoni. He began sleeping better and started understanding the origin and nature of his flashbacks.

"What happens is that these little flashes of memory are hidden in your mind," he said. "You're trying to figure out what's real and what's not. I did that for years."

CES, he said, "kind of opened up some of that so that I can finally start walking back in time and finding out why some things bother me more than others. That was part of the healing."

Most users feel the effects of CES after one use, but lasting benefits normally come only after repeated, regular use.

Studies on CES suggest that the microcurrent stimulates certain nerve cells in the brain stem that produce chemicals called serotonin and acetylcholine. Those chemicals act on the nerve cells throughout the brain and nervous system.

Various levels of CES micro-current have been found to alter alpha brain waves, sometimes activating areas, shutting down others. Those zones are apparently responsible for feelings of agitation, anxiety, depression and physical pain in some people.

Dr. Stephen Xenakis, a retired Army brigadier general and psychiatrist in Washington, has been prescribing CES for about two years.

"I like it for patients who've been on many drugs, and you don't want to give them another drug," said Xenakis, who sits on the medical advisory board for Fisher Wallace Laboratories, a maker of CES devices. He said he is not paid by the company and owns no stock in it.

xiety makes pain feel worse," he said. "And, of course, if you have pain, then you feel ...re anxious — or you feel depressed about it. All these things interact."

FDA steps in

The FDA began stringent regulation of medical devices in 1976, although many that were in use at the time were "grandfathered" in without broad testing. The Safe Medical Devices Act of 1990 required the FDA to re-examine those grandfathered devices to determine what classification they should carry — Class I, II or III. Class III devices are considered life-support or life-sustaining, such as pacemakers.

In February, an FDA panel proposed formally categorizing CES devices as Class III, which would require extensive trials for market approval. Although acknowledging the device posed no serious risks — some users have reported headaches, and it's advised that people with epilepsy not use it — the panel disregarded dozens of studies published in medical journals indicating varying levels of effectiveness.

"They threw out all our studies, which left us with no research," said Daniel L. Kirsch, chairman of EPI.

Explaining their elimination, the panel's report concluded: "The reviews that FDA has performed on the data have demonstrated that while there is an abundance of published literature on the use of CES for the treatment of anxiety, depression and insomnia, the studies have limitations that preclude favorable interpretations of the effectiveness results, even if those results are mostly positive."

The watchdog group Public Citizen submitted a letter to the FDA supporting its proposed reclassification. It urged the FDA to require "rigorous, well-designed, controlled, double-blind clinical trials" for all CES devices. The group wrote that the device's most serious risk was "a worsening of the condition being treated due to the ineffectiveness of the device."

Xenakis, like other CES proponents, said that no competent doctor would stick with a treatment that wasn't working when others were available. "In my practice I like to only make one or two changes in treatment at a time to figure out what's working or not working," he said.

In a letter to FDA Commissioner Margaret Hamburg, EPI complained that the review panel had not followed federal regulations that define valid scientific evidence as including "well-documented case histories conducted by qualified experts" and "reports of significant human experience with a marketed device."

akis questions the wisdom of the FDA taking any action that would remove a therapy option with so many servicemembers returning from Iraq and Afghanistan with PTSD and other emotional disorders.

“My feeling is, from the standpoint of the military, we’re facing what I’d say is an epidemic,” Xenakis said. “We’ve got hundreds of thousands of people with problems with alcohol and misconduct and suicide risk, all those kinds of things. We’ve got treatments that are safe that might work. We’ve got to jump on it.”

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