FDA clears CES for the treatment of Depression

Robert Ellsworth  Longevity Examiner
May 14, 2012

Although electro-medicine has been in existence for over a thousand years—in 46 AD, Roman physician Scribonius Largus recommended his patients stand on a live torpedo fish for the relief of a variety of medical conditions, including insomnia and headaches. Roman Emperor Claudius Galen (131 - 201 AD) attached electric eels or rays to his head to subdue headaches by electrically altering the pain aura--new developments in electronics has seen this technology grow at an accelerated rate.
Modern Cranio-Electro Stimulation (CES) started in Russia around the 1940s as a treatment for insomnia and heaps of research over the past 25 years has shown that CES not only helps with insomnia but it diminishes anxiety and enhances cognition and memory capacity and may even help recovering alcoholics and drug addicts. In fact, Pete Townsend of "The Who" swears by it for his former drug addiction.

For those who are conjuring up images scary doctors and straightjackets, don’t worry. This has nothing to do with Electroconvulsive therapy (ECT)—electroshock therapy, where medical professionals administer an electric shock to the brain like something in a 50’s shock film. Cranial electrotherapy stimulation is a very gentle treatment, with a minor pleasant buzz-like feeling, which you control, and which you can do yourself.

What’s even better is that you can now buy home CES machines at a very reasonable price. CES in the United States has received Food and Drug Administration marketing clearance for the treatment of anxiety, depression, and insomnia. CES devices are sold over the counter in Europe and other parts of the world. A few of my favorites are the CES-Ultra, BTPlus Av and the Fisher Wallace stimulator.

The CES-Ultra is a small device that you can use yourself to treat depression, anxiety and insomnia. It looks a bit like an iPod, so you can take it anywhere and use it whenever you. It sends micro-currents (similar to levels within the brain) through the brain at a variety of frequencies. This patented waveform normalizes the electrical activity of the nervous system producing a calming yet focused effect. Effects can be seen after a single treatment, and repeated treatments increase the strength and period of these effects. CES-Ultra technology can be beneficial to patients with pain, anxiety, depression and sleep disorders.

Approved by the FDA and backed by over twenty years of research, CES home therapy is an amazing new breakthrough. Effects tend to be cumulative in nature and gradually reveal themselves over a period of 1 to 4 weeks.

The micro-current produced by the Fisher Wallace stimulator provokes a natural extension of your brain’s electricity, affecting your brainwaves and providing a slight energy boost to your central nervous system. Therefore it increases the feel-good factor, and inhibits feelings of depression and anxiety. The Fisher Wallace stimulator is available to the public for home use (by prescription only), and the results of research into its efficacy and safety is easily obtainable. The many benefits of CES devises tend
to be cumulative in nature and gradually reveal themselves over a period of 1 to 3 weeks. Research demonstrates that CES produces a mild stimulation in the hypothalamic area of the brain, resulting in balancing neurotransmitter activity (in particular Beta Endorphin and Norepinephrine). The effects achieved are similar to that of a "runner's high."

**Over twenty years of research** have demonstrated numerous benefits from these instruments. What’s even better is you don’t have to worry about any negative pharmaceutical side effects. In fact, a review of hundreds of scientific studies with thousands of subjects reveals that a majority of users report long-term improvements after two to three weeks of use. Several studies have demonstrated exciting improvements in memory and I.Q. testing scores too!

References:

**Harvard University School of Public Health, Department of Health Policy and Management** found: “The meta-analysis of anxiety showed CES to be significantly more effective than sham (P<.05).” (Meta-analysis of randomized controlled trials of cranial electro stimulation: efficacy in treating selected psychological and physiological conditions by Dr. Sidney Klawansky et al. Journal of Nervous and Mental Disease, 183(7):478-485, 1995.

Soroush Zaghi et al. published an article in the journal The Neuroscientist, finding that CES increases the production of serotonin, GABA, and endorphins.[19] These neurochemical changes explain any positive effects that might be experienced from CES.


Adverse Events Reported to EPI 2007 - 2011

The following tables demonstrate the excellent safety profile of Alpha-Stim® CES over the five year period between 2007 and 2011. **A total of 58,030 Alpha-Stim® devices were sold in the USA.** There were 15 reported adverse events during this time frame. Every reported adverse effect was deemed **mild and self-limiting.** Adverse events from using Alpha-Stim® CES reported to EPI in 2007-2011 were < 1%. This is consistent with a review of 14 Alpha-Stim® CES studies where adverse events reported from using Alpha-Stim® CES were also < 1%. There were no Medical Device Reports (MDR’s) reported to FDA during this time.

<table>
<thead>
<tr>
<th>Adverse Events Summary 2007-2011</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin irritation at electrode site</td>
<td>11</td>
</tr>
<tr>
<td>Tinnitus</td>
<td>2</td>
</tr>
<tr>
<td>Panic attack</td>
<td>1</td>
</tr>
<tr>
<td>Black tongue¹</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>

Based on the last 5 years USA sales figure of 58,030 minus returns (there were 75 returns in 2011), an individual home Alpha-Stim® user survey² and an Alpha-Stim® practitioner survey,³ using a conservative estimate, during 2007-2011 there was a total of 8,248,920 Alpha-Stim® CES treatments (1,982,520 individual users treatments plus 6,266,400 in-office treatments by practitioners).

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¹ The tongue discoloration was later attributed to medication (Pepto Bismol).
² Individual home Alpha-Stim® CES user survey, August 2011, where patients used Alpha-Stim® for an average of 3 months, 3 times per week (36 treatments).
³ Practitioners in-office treatment survey, December 2011, where practitioners reported an average of 19.1 treatments per week for 48 weeks per year.

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**Psychology Today**

**Brain Stimulation Makes the ‘Impossible Problem’ Solvable**

"Thinking cap" makes a virtually impossible problem — possible.

Published on April 18, 2012 by Scott Barry Kaufman, Ph.D. in The School of Life

"The difficulty lies, not in the new ideas, but in escaping from the old ones, which roll heavily into every corner of our mind." — John Maynard Keynes

Try connecting all nine of those dots with just four straight lines without lifting your finger or retracing a line.

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**Problem**

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**CES Works**

In their prior research, Allan Snyder and his colleagues have found that zapping the brain leads to increased insight. Enter a recent study. Richard Chi and Allan Snyder wondered: would their electric thinking cap make more performance on a virtually unsolvable problem—the nine-dot problem—solvable? They gave 28 healthy right-handed participants (aged 18-65) the nine-dot problem to solve. Before brain stimulation, 0 out of 22 participants solved the problem. Then they used transcranial direct current stimulation (tDCS), which is a safe, non-invasive technique that can increase or decrease cortical excitability and spontaneous neuronal firing in targeted regions. Specifically, they simultaneously decreased excitability of the left anterior temporal lobe (ATL) while they increased the excitability of the right anterior temporal lobe (ATL).
FDA approves first migraine prevention device

MARCH 19, 2014

WASHINGTON, March 19 — The US Food and Drug Administration (FDA) has authorized the first nerve-stimulating device that can prevent the onset of migraines, according to a Wall Street Journal report.

“Cefaly provides an alternative to medication for migraine prevention,” said Christy Foreman, director of the Office of Device Evaluation at the FDA’s Centre for Devices and Radiological Health in a press release. “This may help patients who cannot tolerate current migraine medications for preventing migraines or treating attacks.”

A migraine episode is characterised by painful throbbing in a portion of the head. Symptoms, which also include nausea, vomiting, and heightened sensitivity to light and sound, can last from four hours to as long as three days.
The prescription device, known as Cefaly, is a battery-powered electric nerve stimulation headband worn across the forehead and atop the ears. Michael Solomita, vice president of the device’s North American distributor, Roxon Medi-Tech Ltd of Canada, said the device is currently sold at retail in Canada for roughly US$300.

Symptoms of a migraine include nausea, vomiting and heightened sensitivity to light and sound which can last from four hours to as long as three days. — Reuters pic

The technology reportedly has the ability to stave off migraine pains, which are transmitted by the trigeminal nerve from the scalp to the brain stem. The approved device emits low energy electric signals to the trigeminal nerve via an electrode placed on the forehead. These signals counteract pain signals travelling down the nerve.

The device maker suggests users suffering from migraines wear the headband 20 minutes daily, during which the FDA says patients will experience a slight tingling sensation on the forehead.

In a clinical trial held in Belgium that involved 67 migraine patients randomly assigned to treatment using the device or to take a placebo, patients using the headband experienced fewer days of migraines each month.

The treatment, however, was unable to completely alleviate migraines or reduce the intensity of migraine pains. — Reuters
Suffer from migraines? Device worn on the head may prevent them

By William Hudson, CNN

March 12, 2014 -- Updated 1309 GMT (2109 HKT)

STORY HIGHLIGHTS

- The Food and Drug Administration has approved a device called Cefaly
- It stimulates nerves beneath the forehead, creating a tingling sensation
- Study showed it prevented frequency -- but not severity -- of migraine attacks

(CNN) -- The Food and Drug Administration has approved the first medical device for preventing migraines. It's called Cefaly and works by stimulating nerves beneath the forehead. Shaped like a tiara, the battery-powered device's electrode is positioned just above the patients' eyes. It delivers an electric current, creating a tingling sensation.
In a 67-person randomized controlled trial published in the journal Neurology last month, Cefaly reduced chronic migraine attacks on average by two per month, and 38% of users had at least a 50% reduction in their number of migraine episodes. The device was not shown to reduce the severity of attacks in the study.

Patients are meant to wear the device for no more than 20 minutes per day. In contrast to migraine medications, Cefaly has no known side effects and might be combined with other drugs. "New therapies are needed in migraine, and further studies of neurostimulation using innovative study designs are warranted to explore the optimum way to create an acceptable evidence base for widespread use of this potentially valuable treatment," writes Dr. Eishi Asano, associate professor of pediatrics and neurology at Wayne State University in Detroit.

The manufacturer of the device is STX-Med, which is based in Belgium. The device is already sold in Canada, where it costs $250 on the Costco Wholesale website.
The U.S. Food and Drug Administration (FDA) on Tuesday approved the first medical device for preventing migraine headaches. The device, called Cefaly, works by stimulating nerves beneath the forehead that trigger migraine headaches. Made by a Belgian company, Cephaly Technology, Cefaly is a small, portable and battery powered nerve-stimulating device that looks like a plastic headband.

Just like a tiara, this prescription device is worn across the forehead and atop the ears. Cefaly is positioned in the center of the forehead with a self-adhesive electrode. This small electrode applies an electric current to stimulate the migraine-inducing trigeminal nerve.
The device uses the transcutaneous electrical nerve stimulation (TENS) technology to emit an electric impulse that is transmitted to the skin and underlying body tissues to stimulate branches of the trigeminal nerve. The technology triggers the pain center of the brain evoking it to produce more endorphins to relieve the migraine.

“Cefaly provides an alternative to medication for migraine prevention,” said Christy Foreman, director of the Office of Device Evaluation at the FDA’s Center for Devices and Radiological Health. “This may help patients who cannot tolerate current migraine medications for preventing migraines or treating attacks.”

The FDA’s approval for the device is based on a study of 67 people in Belgium and a patient satisfaction study of 2,313 Cefaly users in France and Belgium.

The 67-person study showed that those who previously suffered more than two migraine attacks a month reported significantly fewer days with migraines per month after using Cefaly compared to those who used a placebo. These patients also reported a reduced need for migraine medication compared to placebo group.

In the 2,313 - migraine patients study, about 53 percent of the patients said they were satisfied with the Cefaly headband and wanted to purchase it for future use.

However no serious adverse events took place during either study, some participants reported sleepiness while wearing the device and migraine pain and headaches after the treatment session.

The FDA, an American health watchdog within the U.S. Department of Health and Human Services, has indicated Cefaly for patients aged 18 years and older and to be used not more than for 20 minutes once a day.

Tags: Cefaly · FDA · featured · medical device · migraine attacks · migraine headaches · migraine pains · preventing migraines
FDA approves electric headband to prevent migraine

WASHINGTON (AP) – The Food and Drug Administration says it has approved a nerve-stimulating headband as the first medical device to prevent migraine headaches.

The Cefaly device is a battery-powered plastic band worn across the forehead that emits an electric current to stimulate nerves associated with migraine pain. The device is designed to be used no more than 20 minutes a day by patients 18 years and older.

A 67-person study reviewed by the FDA showed patients using the device experienced fewer migraines per month than patients using a placebo device. The Cefaly did not completely eliminate migraine headaches or reduce the intensity of migraines that occurred.

About 53 percent of 2,313 patients in a separate study said they were satisfied with the device and willing to purchase it for future use.
What Cause Migraines?

#1 Allergies and allergic reactions:
#2 Physical or emotional stress:
#3 Changes in sleep patterns or irregular:
#4 Smoking or exposure to smoke:
#5 Hormonal changes in women:
#6 Changes in routine:
#7 Tension headaches:
#8 The computer monitors:
#9 Lack of food:
#10 Teeth grinding:

There is extreme evidence and an ever growing stream of research showing how we can use electrical readings to understand the body and then use soft safe electrical stimulation to treat and correct functions. And this is what we at SCIO / Eductor Technology have been doing for over 30 years.
Safety and patients’ satisfaction of transcutaneous Supraorbital NeuroStimulation (tSNS) with the Cefaly® device in headache treatment: a survey of 2,313 headache sufferers in the general population

Delphine Magis*, Simona Sava, Tullia Sasso d’Ella, Roberta Baschi and Jean Schoenen

Abstract

Background: Transcutaneous supraorbital nerve stimulation (tSNS) with the Cefaly® device was recently found superior to sham stimulation for episodic migraine prevention in a randomized trial. Its safety and efficiency in larger cohorts of headache sufferers in the general population remain to be determined. The objective of this study was to assess the satisfaction with the Cefaly® device in 2,313 headache sufferers who rented the device for a 40-day trial period via internet.

Methods: Only subjects using specific anti-migraine drugs, and thus most likely suffering from migraine, were included in the survey. Adverse events (AEs) and willingness to continue tSNS were monitored via phone interviews after the trial period. A built-in software allowed monitoring the total duration of use and hence compliance in subjects who returned the device to the manufacturer after the trial period.

Results: After a testing period of 58.2 days on average, 46.6% of the 2,313 renters were not satisfied and returned the device, but the compliance check showed that they used it only for 48.6% of the recommended time. The remaining 54.4% of subjects were satisfied with the tSNS treatment and willing to purchase the device. Ninety-nine subjects out of the 2,313 (4.3%) reported one or more AEs, but none of them was serious. The most frequent AEs were local pain/intolerance to paresthesia (47 subjects, i.e. 2.03%), arousal changes (mostly sleepiness/fatigue, sometimes insomnia, 19 subjects, i.e. 0.82%), headache after the stimulation (12 subjects, i.e. 0.52%). A transient local skin allergy was seen in 2 subjects, i.e. 0.09%.

Conclusions: This survey of 2,313 headache sufferers in the general population confirms that tSNS with is a safe and well-tolerated treatment for migraine headaches that provides satisfaction to a majority of patients who tested it for 40 days. Only 4.3% of subjects reported AEs, all of them were minor and fully reversible.

Keywords: Transcutaneous peripheral nerve neurostimulation; Preventive migraine therapy; Cefaly®
The Educator
Starts with a Measure of the EEG-ECG
EMG-GSR TVEP and VARSOPE

Then it Treats the Body Electric with a Soft Safe Gentle Touch

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for autism

It is a scientific fact that when a low level voltage and micro-current pulse is applied to the body, osmosis, enzyme activity, and healing are increased. The SCIO will let the patient’s body electric autolocate a harmonic pulse to maximize this effect. This current applied to the cranium has been shown to help autism, attention deficit, and hyperactive children. It has been shown helpful for anxiety, addictions, emotional disturbances, and insomnia.

There is published research on these therapies. The new world of energetic medicine can help you.
Cranial electrotherapy stimulation and fibromyalgia

Marshall F. Gilula

Cranial electrotherapy stimulation (CES) is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients. CES is no panacea but, for some FM patients, the modality can be valuable. This article discusses aspects of both CES and FM and how they relate to the individual with the condition. FM frequently has many comorbidities such as anxiety, depression, insomnia and a great variety of different rheumatologic and neurological symptoms that often resemble multiple sclerosis, dysthyroidism, chronic fatigue syndrome and others. However, despite longstanding criteria from the American College of Rheumatology for FM, some physicians believe there is probably no single homogeneous condition that can be labeled as FM. Whether it is a disease, a syndrome or something else, sufferers feel like they are living one disaster after another. Active self-involvement in care usually enhances the therapeutic results of various treatments and also improves the patient’s sense of being in control of the condition. D-ribose supplementation may prove to significantly enhance energy, sleep, mental clarity, pain control and well-being in FM patients. A form of evoked potential biofeedback, the EPX, is a powerful stress reduction technique which assesses the chief stressors and risk factors for illness that can impede the FM patient's built-in healing abilities. Future healthcare will likely expand the diagnostic criteria of FM and/or illuminate a group of related conditions and the ways in which the conditions relate to each other. Future medicine for FM and related conditions may increasingly involve multimodality treatment that features CES as one significant part of the therapeutic regimen. Future medicine may also include CES as an invaluable, cost-effective add-on to many facets of clinical pharmacology and medical therapeutics.


Cranial electrotherapy stimulation (CES) with Alpha-Stim® is a well-documented neuroelectrical modality that has been proven effective in some good studies of fibromyalgia (FM) patients (Figures 1 & 2). This article discusses aspects of both CES and FM and how they relate to the individual with the condition. CES is the US FDA- and EU-recognized generic category for medical devices using microcurrent levels of electrical stimulation applied across the head via transcutaneous electrodes for the treatment of anxiety, insomnia and depression. Microcurrent (<1000 μA) stimulation usually means 1 mA or less, whereas transcutaneous electrical nerve stimulation (TENS) involves higher currents in the 60–100 mA range and with very different waveforms. CES treatment of anxiety and depression began in the USA in the early 1960s and is still being prescribed routinely by several dozens of physicians today, but has yet to achieve ubiquitous acceptance in medical practice. That is possibly because sufficient information has not been made available to practitioners regarding the safety and efficacy of CES as a treatment for the approved indications of anxiety, insomnia and depression. Using an electromedical device requires more of an additional learning curve for both practitioners and patients who are accustomed to the pharmaceutical model of intervention. Ingesting a capsule or a tablet does not always require the attention to detail that correct application of ear clip electrodes, for example, demands. We have been conditioned
USE EDUCTOR CES FOR FEAR, PHOBIAS AND PARANOIA

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Transcranial Direct Current Stimulation

Transcranial direct current stimulation (tDCS), is a non-invasive, painless brain stimulation treatment that uses direct electrical currents to stimulate specific parts of the brain. A constant, low intensity current is passed through two electrodes placed over the head which modulates neuronal activity. There are two types of stimulation with tDCS: anodal and cathodal stimulation. Anodal stimulation acts to excite neuronal activity while cathodal stimulation inhibits or reduces neuronal activity.

Although tDCS is still an experimental form of brain stimulation, it potentially has several advantages over other brain stimulation techniques. It is cheap, non-invasive, painless and safe. It is also easy to administer and the equipment is easily portable. The most common side effect of tDCS is a slight itching or tingling on the scalp.

Several studies suggest it may be a valuable tool for the treatment of neuropsychiatric conditions such as depression, anxiety, Parkinson’s disease, and chronic pain. Research has also demonstrated cognitive improvement in some patients undergoing tDCS. Currently, tDCS is not an FDA-approved treatment.

The Brain Stimulation Clinic

- Depression
- Neuropathy
- Fibromyalgia
  - CRPS
  - Migraine
- Neuro-enhancement
- Location
tDCS

Transcranial Direct Current Stimulation (tDCS) is a safe, new, non-invasive procedure which provides relief for treatment-resistant neurologic, psychiatric and chronic pain conditions.

Mission Statement

The mission of the Brain Stimulation Clinic is to provide transcranial direct current stimulation to relieve suffering and enhance quality of life.

Latest News

1. First report of tDCS treatment for autism
2. tDCS reduces relapse in alcohol dependence
3. Neuroplastic responses to anodal tDCS are delayed for mature adults

Medical Director of the Brain Stimulation Clinic

Dr. James Fugedy has treated patients for over 30 years. He graduated from the Creighton University School of Medicine, completed his Residency in Anesthesiology at the Yale-New Haven Hospital and was certified by the American Board of Anesthesiology.

Dr. Fugedy is an ardent advocate of universal healthcare. His vocation is to provide for the treatment-refractory patient.
Dr. Fugedy: “It is disheartening when treatment provides inadequate relief for the patient. Treatment-refractory chronic pain patients are compelled to search for doctors, clinics, protocols and procedures until improvement is achieved. This is an arduous, expensive and frustrating journey. Besides not providing improvement, successive treatment failures can be depressing, demoralizing and depersonalizing. Some may find the treatment-refractory frustrating to work with. I refer to them as my “special patients.” How can you not admire and be inspired by perseverance and endurance when dealing with this degree of adversity?

“For treatment-resistant conditions, listening to the patient is especially important. The most profound insights often come from the patient’s own words. Communication forms the foundation of the therapeutic relationship upon which healing occurs.

“When I read the initial studies utilizing transcranial direct current stimulation, I was very excited because here was a procedure for treatment-resistant patients which was effective, easy-to-do, inexpensive and without side effects. In 2006, I described tDCS to a fibromyalgia patient and my anticipation for its certification and availability. She agreed that tDCS demonstrated impressive results, but she needed it now, not in the future. I called the FDA that day. They verified that the “off-label” use of a direct current stimulator, certified for iontophoresis, could be used to provide tDCS. This is similar to the “off-label” use of pharmaceuticals, such as amitriptyline which is frequently prescribed for the relief of chronic pain and insomnia, for which it is effective, although it is certified only for use as an antidepressant. With completion of the tDCS protocol, the patient experienced a 40% reduction of her fibromyalgia pain. My excitement was second only to hers.

“After tDCS studies for depression were published, I was contacted by a patient who requested tDCS before undergoing a course of electroconvulsive therapy for treatment-resistant depression. He wanted to go back to work, but was afraid that the side effects of ECT might interfere with his memory. He experienced a significant reduction of depression symptoms and was able to return to work. After 4 months he needed to be retreated. He lived a long distance from the clinic. The 3 hour round trip drive produced no therapeutic benefit. Because of the ease of use and safety of tDCS, I proposed training and supervising him to do it himself at home. His results were as good as mine. When the effects wore off again after 4 months, he purchased his own stimulator. At that point his lifetime cost for tDCS ended.

“I did not invent tDCS. I did not develop tDCS. I simply want to make tDCS accessible for patients who would benefit. Treatment in the clinic is available, but for out-of-town patients, this may become an agonizing safari, as protocols are of 1 to 2 weeks duration or longer. My experience with home-use of tDCS has been consistently favorable. Competent patients can be instructed to safely administer tDCS, just as diabetic patients are taught to give themselves insulin injections. tDCS stimulators are inexpensive. Besides the obvious cost reduction, home-use eliminates the discomfort and inconvenience of travel, facilitates longer treatment protocols and makes tDCS more available.

“New tDCS studies are literally published weekly. Improvements in technique, understanding and application continue. I expect that future protocols will be even more effective. Although today’s tDCS treatment is not the final product, it is effective, safe and even at this point of development significantly beneficial for the treatment-refractory patient.
“Currently, I provide tDCS for treatment-resistant patients suffering from the chronic, central pain syndromes (migraine, complex regional pain syndrome, temporomandibular joint disorder, neuropathy, phantom limb syndrome, multiple sclerosis pain and fibromyalgia), depression, tinnitus and for stroke rehabilitation. This year I began using tDCS to improve learning, enhance cognitive function and augment memory. In the future, I envision tDCS benefiting ADHD, autism and PTSD.”
Establishment Registration Database

Establishment:
ECLOSION KFT.
Kalvaria Ter 2
Budapest, HUNGARY 1089
Registration Number: 3004444071
Operations: Remanufacturer
Status: Active
Date Of Registration Status: 2004

Owner/Operator:
ECLOSION KFT.
Kalvaria Ter 2
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Owner/Operator Number: 9061821

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Fax: 914-931-3462
Email: INFO@QXSUBSPACE.COM
The EPFX measures the Electrophysiologic Reactivity intensity of the patient to many QQC trivector voltammetry patterns. These are patterns of reactions to Sarcodes, Nosodes, Allensodes, Isodes, Nutritional, Herbs, Imponderable and Classic Homeopathics. The reaction patterns or profiles can relate disturbances of the patient. Therapies can then be arranged to develop harmonic reactions, desensitizations, biological resonance or rectification processes. All of these are applied and managed through biofeedback application. Biofeedback is the operation that allows for the cybernetic loop of systemic feedback. The only indicated use of this device and all claims related to this device are under biofeedback. The loop of measured reaction and bio-varied resonance response allow for a true feedback for self corrective Electrophysiologica1 therapy. Hence it is called the Electro Physiological Feedback Xrroid.

Excerpt from the 510k registration of 1989

<table>
<thead>
<tr>
<th>DEPARTMENT OF HEALTH &amp; HUMAN SERVICES</th>
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<tbody>
<tr>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>1000 Rockville Drive</td>
</tr>
<tr>
<td>Rockville, MD 20850</td>
</tr>
</tbody>
</table>

| Re: K892114A                           |
| Electro-Physio-Feedback-Xrroid* System |
| Dated: Undated                        |
| Received: July 18, 1989               |
| Regulatory Class: II                 |
EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM
(Annex II, excluding section 4, of the MDD 93/42/EEC on Medical Devices, as revised)
No. 44 DM 2.3

The certificate is granted to the manufacturer:
S.C. BIOFEEDBACK 2014 S.R.L.
B-dul Henri Coandă nr. 2, cam. 14, Satu Mare, judeţ Satu Mare, România

For the following medical device:
Universal electrophysiological biofeedback system, type EDUCTOR

OTDM CERTIFICARE hereby declares that an examination of the full quality assurance system has been carried out following the requirements of the annex II of the Directive 93/42/EEC on medical devices, with subsequent modifications, excluding section 4, and certifies that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

The certification is based on:
Audit report no. 44 – A2 – I / 08.08.2014

President of the Committee for Safeguarding Impartiality
Eng. Lazăr IORDACHE
14.08.2014
issue date

Director
Eng. Ioana ȚENE
13.08.2019
Valid until

The validity of the certificate will be in accordance with the provisions of MDD 93/42/EEC, Annex II, section 2 and of the Certification Contract no. 44DM 23.08.2014.
The CE mark, can be applied only for the medical devices spotted in this certificate.
It is a scientific fact that when a low level voltage and micro-current pulse is applied to the body osmosis, enzyme activity, and healing are increased. The SCIO will let the patient’s body electric autofocus a harmonic pulse to maximize this effect. This current applied to the cranium has been shown to stimulate the learning process and increase memory retention, and learning. There is published research on these therapies. The new world of energetic medicine can help you to learn twice as much in half the time comfortably and easily.

If you need more information on the SCIO and purchase details please get in touch with us

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