# EDUCTOR Biofeedback Clinical Evaluation Research Presentation

The post war Helsinki Accord made sure that any research must have ethical supervision and informed consent from subjects. Here is a 30 plus year history of our research with all studies having proper ethic committees or Institutional Review Boards, informed consent, medical supervision, regulatory device registration and medical peer review. First our device does a lifestyle inventory questionnaire of the behavioral risks to suppressing and obstructing the flow of health. Then our device measures EEG, EMG, ECG, GSR, VARHOPE and TVEP and applies EWH, MTENS, and CES at properly tested medical safe levels. Here is a review of the history of research publications.



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In this document we will present thru simple review peer reviewed studies, double blinds, regulatory registrations, safety registrations, certified medical textbooks, and governmental certificates of professional qualifications. All in all, this is a complete validation and verifications of safety and efficacy of our technology.

### Introduction

On December 9, 1946, an American military tribunal opened criminal proceedings against 23 leading German physicians and administrators for their willing participation in war crimes and crimes against humanity. During World War II, German physicians conducted medical experiments on thousands of concentration camp prisoners without their consent. They shot concentration camp prisoners to test blood clotting. They infected groups of inmates with viruses, then only treated part with the test vaccines, while they observed he course of the disease in the untreated inmates. They tested poison bullets to find more effective ways of killing; they tested prisoners to see how long they could remain alive under high altitude conditions of low air pressure and lack of oxygen.

The prosecution team submitted a memorandum outlining legitimate research to the Counsel for War Crimes, which was the basis for a section of the final verdict entitled "Permissible Medical Experiments." The ten points of the section have been subsequently referred to as "The Nuremberg Code."

In 1964, the World Medical Association established recommendations guiding medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki was revised in 1975, 1983, 1989 and 1996 and is the basis for Good Clinical Practices used today.

Issues addressed in the Declaration of Helsinki include:

- Research with humans should be based on laboratory and animal experimentation
- Research protocols should be reviewed by an independent committee
- Informed consent is necessary
- Research should be conducted by medically/scientifically qualified individuals
- Risks should not exceed benefits

Every study that we have ever done has been compliant with all aspects of the Declaration of Helsinki and regulatory requirements. With that in mind, we will move to presenting the research we have conducted all over the world, in countries like France, Germany, Italy, Switzerland, England, China, Mozambique, South Africa, and United States of America.

For over 100 years The FDA in America has controlled manufacturing quality and claims of Food, Drugs and Cosmetics. In 1976 America started the first registration of medical devices. Thus controlling all medical device quality control and sales claims. Other countries have all followed suit. Notified bodies as independent businesses do this in Europe outside of Governmental control.

More and more validation and verification of sales claims has become a constant trend. Good science, bench studies, case studies, double blinds, peer reviewed journal publications for recognized journals and medical textbook publication in medical universities are all needed to assure validation and verification.

Accredited Medical Universities dictate the practice of medicine. The regulators do not determine what is or is not medicine. The Teaching Medical Universities and Medical Hospitals do. And they perform and supervise most research. The legal requirements of performing research has been a changing and evolving process. A gradual tightening of restrictions has made this more and more difficult.

We will review now a 40 plus year history of clinical research done at the legal requirements, informed consent and proper ethical and professional supervision. We have a constant desire to clinically investigate and validate all of our processes. Our clinical evaluation starts in Ohio, USA at Youngstown State University In 1973.

## Early research

We will start this presentation by going back in time more than 30 years ago, to the 1970's, to discuss the significant study conducted at the Youngstown University by prof. William Nelson. In 1973, Prof. Nelson started studying the body electric on a group of subjects. The study was published in 1974 at the Post Graduate Department.



Prof. Nelson took 40 pairs of intimate friends (that is married people, couples going steady, very, very close friends). One of the pair was put into a dark room in a building in Youngstown State University. A stroboscope and a siren was placed into the dark room next to the ears and eyes of the person. At random times over the course of a two hour plus+ session, a one minute signal of stroboscopic burst and siren's scream would be initiated, subjecting the patient to a fluctuation that would initiate an evoked potential brain wave response. This would provide a startle to the system, a threat to the system that, although safe, would be interpreted by the patient as possibly life-threatening. This would produce a hormonal and nerval reaction and would it would be discernible by their friend.

The other person in the group was placed in a separate building at Youngstown state campus. The separate building was needed to make sure that there was no electrical artifact in the electric measures that could be detected. This person was hooked up to a polygraph device capable of measuring the brainwave, the heart rate, and the galvanic skin response. Thus we were measuring voltage, amperage and resistance (VAR). During the two hour plus session the person hooked to the polygraph was to make verbal guesses as to when they thought their friend was being subjected to the evoked potential shock. It is shown that the verbal guesses were less than chance. In other words there was no verbal ability to understand what was going on. However, there was always an electrophysiological voltammetric plus resistance reaction that could be discerned. Thus, the article could show that there was a type of psychic communication. It was seen to be isolated from verbal, conscious pathways and was more of an unconscious bio-electronic signal.

Prof. Desire' Dubounet has done very significant work with Nobel Prize Winners William Fowler, Roger Sperry, Albert Szent Gyorgy and Hans Selye, one of the most recognized medical doctors in the world of stress. Selye's work on accumulated stress as a cause of disease became a big part of Prof. Dubounet's work.

Going forward to the 1980', we will now take a look at the research conducted at the American Academy of Quantum Biofeedback Technology (AAQBT). The AAQBT, situated in Rio Rancho, New Mexico, U.S.A., has been the setting for a series of studies conducted over 4 years, from 1984 to 1988, on 935 patients, with the EPFX (Electro Physiological Feedback Xrroid System) device.

Conducted with proper IRB supervision, medical supervision, informed consent, these studies have been among the first ones to analyze the body electric and therefore represent groundbreaking scientific advances in the field of energetic medicine.

Over the 4 years, the following fields have researched:

- Alarm Response in this part of the study it has been shown through statistically significant results that a stimulus that might be too much for the body provokes an alarm response.
- Calibration it has been designed from EPR data to test the reaction speed of the patients
- Electro Acupuncture it showed that particular electrical signatures applied to unhealthy acu-points might cause them to improve
- Electro Physiological Reactivity (EPR) the study measured the subjects' reactivity patterns to nosodes, allersodes, isodes, sarcodes, and classic homeopathy and proven an accuracy of approximately 71% percent to known medical conditions
- Skin Capacitance the goal of this particular measurement was to further analyze the nature of the body electric by better understanding the basic skin capacity to store charges and other bio-electric measures
- Skin Conductance the study describes the EPFX method for measuring the skin conductance responses
- Skin Inductance this part of the study analyzed the skin's capacity to affect inductance transfer
- Trivector this review makes a comparison between skin conductance, capacitance and inductance (known as the Trivector) and SCIO Electro-Physiological-Feedback-Xrroid EPR reactivity
- Stress Reduction through Electro Stimulation this part of the study showed with significant results that the EPFX treatment reduces stress; 76% of the 935 subjects tested declared they had reduced levels of stress, 14% reported they felt no different, and 10% reported they felt more stress.

Out of the 935 subjects tested over a period of 4 years, there have been no adverse events reported, proving that the device was safe to use to the indications for use.

Below we present you with the abstracts of the study discussed above.

# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### Alarm Response

#### By William Nelson

ABSTRACT: Situated on a golf course in New Mexico the Land of Enchantment, in the City of Vision Rio Rancho the AAQBT made history. We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. We need to develop electrical profiles that indicate alarm reaction from the patient. The mathematical factor of Ohms law states the Volts=Amps times Resistance. It would be theoretically impossible for a contained system to have all three factors increase. When one rises such as volts amps would drop. For all three to increase would be difficult. But we found that when a patient reacts adversely to a stimulus then all three vectors can increase. This is part of a defense shield people have to stop electrical stimulation from upsetting body process. This is needed in a world of electrical stimulation or a small snap of an electric spark could be devastating. We found a statistical profile on the subjects to indicate an alarm response to a stimulus that might be too much for the body. A simultaneous increase of the VAR indicators of the extremities could be a measureable indictor for discontinuing a stimulus automatically. The Alarm response could be a valuable addition to our cyberneticloop.



# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### Calibration

#### By William Nelson

ABSTRACT: Situated on a golf course in New Mexico the Land of Enchantment, in the City of Vision Rio Rancho the AAQBT made history. We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. We need to develop electrical profiles that indicate reaction EPR time of the patient. The usual reactance speed of a person maximizes at the speed of ionization change or one hundredth of a second in the human body. But several conditions can change the speed of Electro-Physiological-Reactivity (EPR). To test the reactive speed a calibration process was designed from EPR data on our subjects. The test will start at one hundred and three of a second and test the patient's EPR to 22 vials/xrroid stimulation of distilled water (the least reactive substance measured and four vials stimulation of a highly reactive compound of mosquito venom + chemicals. If the patient EPR data can statistically show a reaction of the four reactive compounds then the speed of reactivity is set at 1/103 of a second. If the test fails 85% it is repeated at 103-1 or 102, and it keeps testing at reduced times till +85% accuracy is done, thus making the speed of calibration of the patient.



# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### Electro-Acupuncture

#### By William Nelson

ABSTRACT: Situated on a golf course in New Mexico the Land of Enchantment, in the City of Vision Rio Rancho the AAQBT made history. We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. This review report scrutinizes a comparison between skin conductance, inductance, and capacitance (collectively known as the Trivector), and acupuncture points. We surveyed the acupuncture points on the subjects with a wave form analyzer and a frequency counter. We found that each healthy acu-point had a particular signature profile. There was a discrete and different frequency band, wave form and signal intensity showing that each acu-point has its own particular electrical signature. When we supplied this signature to unhealthy points, the points can improve. This opens to door for an electro-acupuncture program to measure and treat acu-points and help the body.

## Published AADBT Press 1988



http://www.downloads.imune.net/medicalbooks/978-615-5169-24-3%20Electro-Acupuncture%20with%20Energetic%20Cybernetic%20Therapy.pdf

# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### Electro-Physiological-Reactivity (EPR)

By William Nelson

ABSTRACT: Situated on a golf course in New Mexico the Land of Enchantment, in the City of Vision Rio Rancho the AAQBT made history. We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. This review report scrutinizes a comparison between skin conductance, inductance, and capacitance (collectively known as the Trivector), and SCIO Electro-Physiological-Feedback-Xrroid EPR reactivity. We measured the 935 subject's reactivity patterns to nosodes, allersodes, isodes, Sarcodes, and classic homeopathy using the EPFX biofeedback system. Significant profiles revealed an accuracy of about 71% to known medical conditions. The reactance was a collective measure of change in resistance, change in capacitance, and change in inductance (the 3 vectors of the trivector) together referred to as the reactivity or in this case the EPR.





# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### SKIN CAPACITANCE

By William Nelson

ABSTRACT: Skin Capacitance is affected by polarization capacitance (where stored charges around an electrode appear in a near electrolytic medium). We tested 935 subjects in Denver and New Mexico to understand the basic skin capacity to store charges and other bio-electric measures to better understand the nature of the body electric. Skin capacitance was measured to range from .01 to .07 microFarads per centimeter squared. If the corneum thickness of 10 micrometers and a dielectric constant of 2.5 for biological membranes then the capacitance will be about 2 x microFarads per centimeter squared. Two equivalent electric current paths are measured: one crossing lipid-corneocyte medium and the other going thru skin appendages. The current-time response of the skin during the application of rectangular pulses of different voltage amplitudes demonstrates an insightful similarity with the same characteristics in model and plasma membrane electroporation. A significant (up to three orders of magnitude) drop of skin resistance happens due to electro-stimulation can be explained by electroporation of various substructures of stratum corneum. At relatively low voltages (U<30V) this drop of skin resistance can be ascribed to electroporation of the appendageal ducts. At higher voltages (U>30V), electroporation of the lipid-corneocyte matrix makes an extra drop of skin resistance.

## Published AADBT Press 1988



#### Electro-Physiological Measures of the Interstitial fluid

Thus, a DC current of 0.70 to 1.28V (below any rheobase) is applied across 10 electrodes placed symmetrically on the forehead, wrists and ankles. Carbon can accept or donate electrons equally.

Each carbonized electrode is alternately cathode then anode so that 22 volumes of the human body can be registered. These records of the conductivity of each volume are incorporated in a graph. The graph of 22 volumes is an electro-

# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### SKIN INDUCTANCE

By William Nelson

ABSTRACT: Skin effects Inductance transfer. We tested 935 subjects in Denver and New Mexico to understand the basic skin capacity to affect inductance transfer to better understand the nature of the body electric. The amount of inductance is reduced as the skin makes the current move away from the locus of the stimulation and move outward. Thus there are fewer lines of magnetic flux within the conductor that lowers the internal inductance. The skin makes the inductance decrease as the square root of the increase in frequency. This happens at the same rate where resistance increases as we change frequency. Inductors do not act the same as resistors. Whereas resistors simply oppose the flow of electrons through them (by dropping a voltage directly proportional to the current), inductors oppose changes in current through them, by dropping a voltage directly proportional to the *rate of change* of current. In accordance with *Lenz's Law*, this induced voltage is always of such a polarity as to try to maintain current at its present value. That is, if current is increasing in magnitude, the induced voltage will "push against" the electron flow; if current is decreasing, the polarity will reverse and "push with" the electron flow to oppose the decrease. This opposition to current change is called *reactance*, rather than resistance. These factors are used to develop the EPFX.

## Published AADBT Press 1988



# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### TRIVECTOR

#### By William Nelson

ABSTRACT: We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. This review report scrutinizes a comparison between skin conductance, inductance, and capacitance (collectively known as the Trivector), and SCIO Electro-Physiological-Feedback-Xrroid EPR reactivity. Electricity acts in three basic dimensions of conductance, inductance and capacitance. These events can be measured and a three dimensional trivector analysis can be derived. Events display that the Xrroid has a very high interdependence to culture results, and thus the Xrroid is very helpful in determining the electrical reactivity of the patient, and in determining the type of infection the patient might have. The overall correlation was approximately 91%. The existence of many so called false positives or infections that are subclinical makes reading difficult. The trivector field of a living organism is not static, it is reactive. A living being is interacting with the environment to be drawn towards nutrition, and repelled from toxins. Thus with the xrroid we measure which items the patient reacts to and how he reacts so we can see a profile that might help us learn more about our patient.



### Published AADBT Press 1988

# The American Academy of Quantum Biofeedback Technology

Located in Rio Rancho, New Mexico since 1988

#### Stress Reduction thru electro stimulation

#### By William Nelson

ABSTRACT: Situated on a golf course in New Mexico the Land of Enchantment, in the City of Vision Rio Rancho the AAQBT made history. We tested 935 subjects in Denver and New Mexico to understand the basic body electric measures to better understand the nature of the energetic medicine. This review report scrutinizes a comparison between skin conductance, inductance, and capacitance (collectively known as the Trivector), and electro-stimulation of the body electric in stress reduction. From the work of Hans Selve and others it has been shown that stress is "THE" concern of medicine. Collective stress can be additive and accumulate to weaken an organism and thus let in disease. In our study here the 935 subjects were asked if stress was reduced after their EPFX treatment. 76% of the subjects said there was less body stress, 14% said they felt no different, and 10% said they felt more stress. No adverse events were reported and the device was safe and effective in reducing stress.

## Published AADBT Press 1988

Clinical Review of Biofeedback Stress Therapy with the SCIO/ EPFX Biofeedback Device Two Decades of Stress Reduction

> Chief Edito Prof William Nelson M.D. IMUNE Consultant. International Ethics, Lebedei 58. Oradea, Romania John Keisey Phd, ND N.Z. Eng. Somlea Livia Romania Richard Atkinson MCSP, Physical Therapist, West Yorkshire England Developed and written By: Gage Tarrant LBT, C.H.T, USA, Mezei Josif MD. Romania Debbie Droke M.D. Canada William Cuningham CBT Deriver Colorado Igor Cetojevic MD, Cyprus

Matthias Heiliger M.D. Germany/Switzerland Anna Maria Cako M.D. Hungary

Bacean Aurel MD Romania

This study was performed in the field by practising Biofeedback technicians. Data was collected and the study supervised by the Ethics International, Ethics Cammittee of Romania. The Data analysis and study presentation is done By The Centro Ricerche, University of Venice + Padova, Italy

@ UMSH 2008

#### Abstract

This article reviews the clinical results and experiences of users of the SCIO/EPFX biofeedback device after almost two decades of use. The practice of biofeedback dates back to the fifties. The technique of using biofeedback devices to diagnose stress and treat stress is receiving more attention in our ever increasingly stressful world. In this article we review the positive results achieved from clinical experience treating patients on a day to day basis.

In over two hundred million patient visits the SCIO/EPPX was estimated at an 80% success rate in reducing stress.

Key Words: Biofeedback, stress, stress reduction

#### Introduction

In 1976 the World Health Organization announced to the world that stress was the major cause of disease in the world at that time, and any ways or means to reduce stress were encouraged.

Stress is the most incipient killer of people today. Stress is responsible for 70 to 80 percent of the disease in America. Stress reduction is a must in today's society for longevity, health and happiness. Stress awareness begins with recognition or awareness. As we become aware of stress, we can Stress awarehess begins with recognition or awareness. As we become event of stress, we can begin to deal with it. The "otrich" technique of stress reduction never works. Humans resist change. Whether change occurs in the body, mind, social, spirit or environment, most humans will resist. To learn to relax, we must learn to break our old habits of stress reaction and substitute more productive reactions such as clear thinking, calm headed and relaxed understanding. To change requires perseverance, positivity, proper goals and beneficial rewards. Whether changing eating habits, exercise routines, stress reactions or social skills, change requires work, but the rewards of a healthy body and mind for you and your family are worth

Although biofeedback is an effective clinical procedure, it is not used in isolation from other therapeutic techniques. Since many of its clinical applications focus on the reduction of anxiety or physiological arousal, relaxation procedures have been used with biofeedback to maximise or proceedings around, related in proceedings into been ded with doneeding to interact to interact the network this effect. The patient undergoing biofeedback treatment is often introduced to a relaxation technique prior to receiving biofeedback. Clinicians using biofeedback frequently develop their own individual relaxation procedures. Most of these modified techniques are based on the progressive relaxation method originally developed by Jacobson in 1958 .

Standardised relaxation techniques are effective for most patients. If the patient has difficulty, Statistication reactation techniques are energies on most patients, in the patient has building, the therapist must be certain that the patient's failure to relax is not due to a misconception or to therapeutic resistance. For example, some patients try to vigorously to relax, which results in increased tension. This may occur with Jacobson's technique because patients spend too much time tensing muscles and too little time relaxing. If a well-motivated patient, however, cannot adjust to the standard relaxation procedure, other methods are available. Biofeedback therapists must be familiar with alternative procedures when a standard technique fails to generate the desired response (i.e. Lowered arousal). We define arousal as it is commonly used in the field of psychology; i.e. an excess level of muscular tension and or hyperactivity to stress.

Gage Tarrant is a professional Biofeedback Therapist and Stress Consultant practising in the Los Angeles area of California , USA. She has been using the SCIO./EPFX device as her principle



# Situated on a golf course in the Land of Enchantment, in the City of Vision the AAQBT made history From 1984 to 1988 935 subjects were tested with EPFX

4248

WELCOME TO

**RIO RANCHO** 

AND STATI

CITY OF VISION

The home of AAQBT

With proper IRB supervision, informed consent, and medical doctor direction the AAQBT did a series of studies on the electro-physiology to validate the 1989 FDA registration of the EPFX

## 510(k) Registration of the EPFX of 1989

This body of research led to the EPFX FDA 510(k) registration obtained on October 13, 1989. Inside the 510(k) registration we have the first appearance of the Electro-Physiological Reactivity (EPR) and the VARHOPE. This registration is still valid and can be found on the FDA website. A copy of our 510(k) is included for your reference.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service CCT 13. Food and Drug Administration 1390 Giocard D Rockville, MD 20850 Re: K892114A Electro-Physio-Feedback-Xrroid\* Eclosion Corporation System Attn: Frank DiMauro 3936-A Niagara Street Dated: Undated Received: July 18, 1989 Regulatory Class: II Denver, Colorado 80207 Dear Mr. DiMauro: We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to Ma 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for annual registration, listing of devices; good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration. and adulteration. ! your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further amouncements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal laws or regulations. This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-Amendments device results in a classification for your device and permits your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you wire specific advice on the labeling for your device, please contact the pivision of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597. Sincerely yours, Local FOA: Lloy & Beaston Forge C Murray George C. Murray, Ph.D. Director Division of Anesthesiology, Neurology, and Radiology Devices Office of Device Evaluation Center for Devices and Radiological Health

The EPFX 510(k) registration was the first one in a long line of legal registrations obtained over the world.

The EPFX measures the Electrophysiologic Reactivity intensity of the patient to many QQC trivector voltammetry patterns. These are patterns of reactions to Sarcodes, Nosodes, Allersodes, Isodes Nutritional, Herbals, 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 Electrophysioloigcal therapy. Hence it is called the Electro Physiological Feedback Xrroid.

#### Excerpt from the 510k registration of 1989

Eclosion Corporation Atta: Frank DiMauro 3936-A Niagara Street Denver, Colorado 80207	OCT	13	Re:	K892114A Electro-Phys System Dated: Unda Received: J Regulatory C From the 19	Food and Drug Administr 1390 Piccard Drive Rockville. MD 20850 10-Feedback-Xrroid* ted uly 18, 1989 lass: II 189 510k documenting the regis
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on of the EPR Electrosodes, sorcodes, etc



Bere ev elli see numbers in front of the tetegories of sacordes, nessoes, isodes, silersoles, homespathy, nutriton, are gen, geopathic stress, the top 100, and electrical. The numbers next to these un SFORT SILETIONS will will us the average source in sami of these matrixes. By clicking on the SACORE button as now bring up all of the carrodes from top to botter that can be vareade in our someon. These alls can be maneavered up, down, loft and right by using the

FDA 510 (k) registration for the EPFX was obtained on October 13, 1989. The following is an excerpt from the original office 510(k) application:

The EPFX measures the <u>Electro-Physiologic Reactivit</u>y intensity of the patient to many QQC trivector voltammetry patterns. These are patterns of reactions to <u>Sarcades, Nosodes, Allersodes, Isodes</u>, Nutritional, Herbals, 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 manage through biofeedback application. Biofeedback is the operation that allows for the cybernetic loop to 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 Electro-Physiological therapy. Hence it is called the Electro Physiological Feedback Xrroid."

**FDA Registration of EPFX** Electro-Physiological-Reactivity = EPR

# The Long Term Pathological Findings of the Camelford Aluminum Toxicity Group

A study done in Camelford, England on aluminum toxicity in 1992 has been reproduced in Budapest, Hungary in 2012.

#### Title

The Long-term Pathological Findings of the Camelford Toxicity group. 1990

#### Subtitle

The Premature Ageing Effects of a Toxic Water Syndrome Case.

By

Dr. William Nelson LPCC, Peter Smith LCH

#### ABSTRACT:

In July 1988, a toxic water spill in the Camelford water district by South West Water, the public water utility, in Cornwall England resulted in some 20,000 people being exposed to a toxic cocktail of chemicals in their drinking water. This produced a host of different physiological diseases. It also resulted in a homoeopathic practitioner, together with other colleagues, launching into long-term 7 year study of the effects of this toxicity on the population

Besides extensive case notes on 200 people, hair and nail samples, several different electrical measures, chemical measures, and psychological interventions have yielded a understanding of these patients' discase profile. Various lengthy papers have been prepared by the North Cornwall Homoeopathic Project and the Lowermoor Support Group. A book is in preparation.

One of the key factors that have been observed in this population is that of premature aging. This is discussed within this article.





\* = > 2 Standard Deviations SS = Statistically significant

http://www.downloads.imune.net/journals/1997%201%20Electro%20Physiological%20Reactivity,%2 0%20the%20Xrroid%20Effect,%20Vol.%20I/







# Kiev Institute of Oncology home of the Cancer Research on the EPFX and Natual Medicine



In Kiev we did research on cancer + energetic medicine and presented it in Paris, Oncology congress.

http://www.downloads.imune.net/journals/1997%202%20Cancer%20Studies/

"All truth passes through three stages. First, it is ridiculed, second it is violently opposed, and third, it is accepted as self-evident."
- Arthur Schopenhauer German philosopher, 1788-1860.

## Hippocampus Research

Preceding the existence of the companies (Eclosion Kft., Maitreya Kft. and Mandelay Kft.), but post ceding the 510(k) FDA registration, the Hippocampus Egészségügyi Kereskedelmi es Szolgáltató BT was the location for several research projects on the SCIO, in 1995-1996, under the medical supervision of D. Istvan Bandics, who was following the work of Dr. Albert Szent-Gyorgy.

We present you a list of abstracts of the aforementioned studies:

# Electro-Physiological Stimulation of Body Charge Potentials

3400 Mezokövesd

Szent László tér 11. IV/5.

Tel.: 49 / 311-026

#### HIPPOCAMPUS

Egézségügyi Kereskedelmi- és Szolgáltató BT.

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OTP BANK Rt.; 650-010787-9

RENDELO és IRODA

Budapest III.

Nánási út 67 . I.em.

Tel.: 1-188-68-65

06-20-342-662

Supervizing researcher: Dr Istvan Bandics MD Licensed Hungarian Medical doctor. This study was done at the Hippocampus clinic in Budapest on 73 patients attending the clinic in 1994. Studies done with the supervision of a local ethics committee and all subjects gave informed consent to participate as part of their intake form.

#### Abstract

In this study we took 73 patient/subjects from the medical clinic and tested their global Voltage, Amperage, Resistance, Hydration and Oxidation body electrical parameters in per and post fashion. Each subject was treated with the EPFX device for one week after pre and before post testing. The patients had significant increases in their post electrical measures. These factors are called the VARHO.

http://www.downloads.imune.net/journals/1997%201%20Electro%20Physiological%20Reactivity,%2 0%20the%20Xrroid%20Effect,%20Vol.%20I/

## NEW TECHNIQUES OF HOMEOPATHIC TREATMENT OF FUNGAL INFECTIONS

Chief Editor: N. Vilmos, M.D.; Independent Medical Editor; Budapest, Hungary Edited and Validated By: Istvan Bandics, M.D.; Budapest, Hungary Gylila Panszki, M.D.; Budapest, Hungary Illya Brenner, M.D.; Institute of Oncology, Kiev, Ukraine Peter Smith, LCH; Cornwall, England Dima Sakharov, Ph.D.; Kiev, Ukraine

Developed By: The staff of Maitreya; Limerick, Ireland William Nelson, L.P.C.C.; Denver, Colorado; USA

This article was presented at the Pharma Expo in Budapest, Hungary; an international pharmacy exposition presented on November 10 - 13, 1994.

#### ABSTRACT

In this study there are two major investigative reports that we explain. One is a forty-five-patient study of female yeast problems, in which a complex homeopathic treatment was proven to be effective. We first present a twenty-patient study of various effects on overall fungus population. The overall fungus was measured through culture analysis of patients' hair, urine, sputum, and other physiological samples.

Three treatment groups were organized: that of a candida-only diet, that of a homeopathic singular of Candida albicans only, and that of a complex homeopathic for full-range treatment of fungal disorders. In the study we show the dramatic superiority of the complex homeopathic, how it worked on a wide variety of fungal disorders, and how the Candida albicans homeopathic only worked on Candida albicans. The diet proved to have little or no effect.

The study reviews the process of the immune system's defense against fungal intrusion and fungal overgrowth. Also, there is the proposed mechanism for the homeopathic action, in that it appears to be stimulatory of the immune system.

http://www.downloads.imune.net/medicalbooks/Lung%20Fungus%20+%20MycoBacteria.pdf



## HOMEOPATHIC TREATMENT OF EPSTEIN-BARR VIRUS INFECTIONS

Nosodal Therapy for Viral Chronic Fatique Chief Editor: N Vilmos, M.D.; Independent Medical Editor; Budapest, Hungary

Edited and Validated By: Istvan Bandics, M.D.; Budapest, Hungary Illya Brenner, M.D.; Institute of Oncology, Kiev, Ukraine Peter Smith, LCH; Comwall, England Dima Sakharov, Ph.D.; Kiev, Ukraine Tony Hughes, D.A.C.; Dublin, Ireland Peter Bartlett, D.O.; London, England Attila Kiss, M.D.; Gyor, Hungary Richard Atkinson. MCSP, State-registered Physical Therapist; West Yorkshire, England Christopher Hammond, MB. BS. LCH; Nottinghamshire, England Michael Gerber, M.D.; Reno, Nevada; U.S.A. Developed By: The staff of Maitreya; Limerick, Ireland

This study was performed in 1987 at the Survival Center Clinic in Ravenna, Ohio, U. S.A. Revalidation and further clinical testing are currently being performed by medical doctors at the Clinic in Budapest, Hungary, and by the doctors listed above.

#### ABSTRACT

Homeopathy has been proven effective historically in many different viral conditions. Recent experimental evidence has shown homeopathy to-be effective for flu, measles, AIDS, and other viral conditions. In this article we review some of this literature and research, and we explore homeopathic treatment of Epstein barr and mononucleosis conditions.

#### http://www.downloads.imune.net/medicalbooks/Prepare%20for%20Ebola%20or%20any%20new%2 0Virus%20new.pdf



## STIMULATION OF MOTILITY FACTORS IN NEUTROPHILS

#### Chief Editor: N. Vilmos, M.D.; Independent Medical Editor; Budapest, Hungary

Edited and Validated By: Istvan Bandics, M.D.; Budapest, Hungary Gylila Panszki, M.D.; Budapest, Hungary Illya Brenner, M.D.; Institute of Oncology, Kiev, Ukraine Peter Smith, LCH; Cornwall, England Dima Sakharov, Ph.D.; Kiev, Ukraine Tony Hughes, D.A.c.; Dublin, Ireland Peter Bartlett, D.O.; London, England Attila Kiss, M.D.; Győr, Hungary Richard Atkinson, MCSP, State-registered Physical Therapist; West Yorkshire, England Christopher Hammond, MB. BS. LCH; Nottinghamshire, England Dr. Michael Gerber; Reno, Nevada; USA Developed By: The staff of Maitreya; Limerick, Ireland William Nelson L.P.C.C.

This study was performed in 1994 at the Homeopathic Research Facility in Budapest, Hungary. Revalidation and further clinical testing are currently being performed by medical doctors at the Homeopathic Clinic in Budapest, Hungary, and by the doctors listed above. This article was presented at the Pharma Expo in Budapest, Hungary; an international pharmacy exposition presented on November 10 - 13, 1994.

#### ABSTRACT

In 1987 a department of scientific research in Germany published the first part of this study [Studies: 5]. In this study a sample of patients' blood was taken by finger prick, and put onto an inverted slide. The inverted slide allowed for motility of the white blood cell underneath the cover slip. When viewing blood normally, using a noninverted slide, the cover slip would produce pressure on the white blood cell and restrict its movement.

A sample of various bacteria was put into the blood sample, comprised of streptococcus. The mobility and motility of the white blood cell was then studied under the microscope. This was done using a dark field at 1500x to minimize the effects of excess infrared radiation. However, the temperature of the blood was always maintained within one degree of body temperature (98.62 F., 37.58 C..).

The speed of the white blood cell was then measured in seconds per 10 Em, as well as the ability of the white blood cell to produce phagocytosis around the bacteria. The baseline was thus established by observing multiple white blood cells in the patients. One group of patients was then given a placebo of water and alcohol (ten drops) orally, and another group was given a sample of a complex homeopathic designed to stimulate the white blood cell towards bacteria. Blood was taken thirty minutes after administration of the placebo or homeopathic.

In the treatment group there was virtually no change from the initial pre-test. In the homeopathic group there was an increase. In the homeopathic treatment group there was a thirty-five percent increase in the motility and mobility factors of the leukocytes.

This initial American study of 1987 has been duplicated using an additional ten subjects with fungus instead of bacteria, and fifteen subjects have recently been added to the study population from Hungary. This makes a sum total of thirty-five subjects who participated in our study.

### Full Spectrum Micronutrient Treatment of Bacteria (Homeopathic Treatment of Bacterial Infections)

Chief Editor:

Judith Nagy, M.D.; Independent Medical Editor; Budapest, Hungary

Edited and Validated By: Istvan Bandics, M.D.; Budapest, Hungary Gylila Panszki, M.D.; Budapest, Hungary Illya Brenner, M.D.; Institute of Oncology, Kiev, Ukraine Peter Smith, LCH; Cornwall, England Dima Sakharov, Ph.D.; Kiev, Ukraine Tony Hughes, D.A.c.; Dublin, Ireland Peter Bartlett, D.O.; London, England

#### Consultant: Dr. Simon Gutl, M.D.; Hanover, Germany

- 340

13.00

### Abstract

Two studies involving homeopathic or micronutrient treatment of bacteria are reported which indicate a natural, safe alternative to antibiotics. Both studies involve patients aged twenty-five to fifty. In the first study we take pin-prick blood samples from ten healthy patients, bring them on an inverted side, and then measure the speed and motility factors of the white blood cell. The patients are then given (in double-blind fashion) either water and alcohol or a homeopathic for bacterial stimulation. On evaluation under the microscope, the speed of the white blood cell is increased in the treatment group; the placebo group shows no change.

In the second study patients are evaluated for urinary bacteria from culture.

They are then prescribed the complex homeopathic, and reevaluated. The study shows that the complex homeopathic can indeed help the patients to deal with their bacterial infections.

The proposed mechanism is discussed, along with this short study.

#### Keywords

Bacteria, complex homeopathic, micronutrient, motility factor, phagocytosis

This article was presented at the Pharma Expo in Budapest, Hungary; an international pharmacy exposition presented on November 10 - 13, 1994.

# Bio-electronic Increase of Power Lifting Performance Clinic Details

#### TELEPHELY

3400 Mezokövesd Szent László tér 11. IV/5. Tel.: 49 / 311-026

#### **HIPPOCAMPUS**

Egézségügyi Kereskedelmiés Szolgáltató BT. Adószám: 21284823-2-05 OTP BANK Rt.; 650-010787-9

#### RENDELO és IRODA

Budapest III. Nánási út 67 . I.em. Tel.:1-188-68-65 06-20-342-662

Supervising researcher: Dr Istvan Bandics MD Licensed Hungarian Medical doctor. This study was done at the Hippocampus office in Budapest in January 1994. Studies done with the supervision of a local ethics committee and all subjects gave informed consent to participate.

#### Abstract

This study took 18 members of a Hungarian Power lifting team and measured their performance before and after an EPFX therapy and some sport oxygen formula. Their personal best are a matter of record. Each had two sessions on the EPFX over two days and they were asked to do their best in Squats and Bench press. By comparing to the personal bests most of these athletes had increases in performance after two sessions on the EPFX.

> http://www.downloads.imune.net/medicalbooks/978-615-5169-13-7%20Injury%20and%20Sport%20Medicine.pdf



## Electro-Physiological Stimulation of Body Charge Potentials

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3400 Mezokövesd

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#### Abstract

In this study we took 73 patient/subjects from the medical clinic and tested their global Voltage, Amperage, Resistance, Hydration and Oxidation body electrical parameters in per and post fashion. Each subject was treated with the EPFX device for one week after pre and before post testing. The patients had significant increases in their post electrical measures. These factors are called the VARHO.

## HOMEOPATHIC STIMULATION OF WHITE BLOOD CELL MOTILITY AS ANALYSED UNDER THE MICROSCOPE

#### (A Proposed Mechanism of Homeopathic Immuno-Stimulation)

Chief Editor: N. Vilmos, M.D.; Independent Medical Editor; Budapest, Hungary. Developed By: The staff of Maitreya; Limerick, Ireland William Nelson L.P.C.C.

This article was presented at the Pharma Expo in Budapest, Hungary; an international pharmacy exposition presented on November 10 - 13, 1994. Revalidation and further clinical testing are currently being performed by medical doctors at the Homeopathy Clinic in Budapest, Hungary, and by the doctors listed above.

#### ABSTRACT

The dynamic factors of life seem to be dependent on photons. This has been developed through quantum electrodynamics, which has been applied to biology by many researchers. In this study we microscopically analyzed the white blood cell's recognition and motility factors for bacteria and fungi. By then observing how the white blood cell moves towards the bacteria and fungi we are able to analyze one factor of immunity.

A key question in biology must be: How do the white blood cell and the immune system find and isolate the microorganism intruder?

A thermodynamic and/or chemical mechanism is not a complete avalysis. In this paper we bring gorth the treatise that the white blood cell has some photon receptors and a type of vision which allows it to find these intruders and thereby destroy them.

In this study we then gave the patients a treatment of water and alcohol, and/or a homeopathic of various microorganisms. This was performed in a double-blind fashion. In the placebo group there was virtually no change from the baseline reading in the motility recognition factors. However, there was a thirty-five percent increase in recognition and motility of the white blood cells in the blood samples of the patients receiving the homeopathic treatment.

The conclusions of this study are drawn through a dynamic, quantum, photon system of understanding of biology, which then helps us to understand some possible mechanisms of homeopathy. In the conclusions of the study we further show that homeopathy not only is a safe but also an effective and natural process of not defeating the organism directly, but stimulating the immune system to do its job better in defeating the microorganism intruder. Thus homeopathy offers a more natural way to stimulate the immune system of the host rather than a way to defeat the intruder directly, as in antibiotic treatment. In 1995, at the Szent Janos Hospital in Budapest, Prof. Dubounet has done work on cataract patients, showing significant results in TVEP patterns that can be helpful in detecting disease patterns.

## Abstract During the course of a one year period the 1834 patients in our clinic were all asked in their intake form to participate in a study. All patients were treated with the EPFX device. The types of disease trends these patients presented were evaluated by one of the medical doctors on staff. The EPR reactivity profile was checked by the EPFX device. A comparison of the EPR reactivity patterns yielded a Risk probability profile. The results of this profile are reported here. At the Szent Janos hospital in 1995 Budapest a TVEP study was done on cataract patients. Both of these studies proved TVEP reactions patterns to be helpful and significant in detection of disease patterns. see XRROID reactivity patterns in Cataract patients, IJMSH 1997 volume1/ 4 ISSN 1417 0876 The following reactants are statistically significant at alpha levels .05 for the cataract patient. SUCTOSE SUCTASE glucuronidase glucose glucogen glucose dehydrogenase aspartase myleoperoxidase cataract nosode pancreatin pancrease sarcode glutathione

http://www.downloads.imune.net/journals/1993%20Updated%20-%20Nosodes-%20Using%20Microorganism%20Endotoxins%20Selye%20and%20Bertok%20on%20Immunology/pdf

In 1995, Semmelweis University Budapest was the location for a study that investigated the Zap capabilities of the QXCI/EPFX on Human Papilloma Virus. The results showed that overall, the therapy applied was more than 60% successful in treating papilloma virus.

#### Zapping the Human Papilloma Virus

#### By William Nelson LPCC

At the Semmilvise Hospital in Budapest 1994

#### Abstract

We know of no good evidence for Dr. Krugers zap therapy. The Zap technology of the QXCI/EPFX has some tested capabilities. In this study 25 women showed signs of papilloma virus spots. The papilloma virus HPV spots fluoresce in UV light if they are exposed to vinegar. A vinegar swab showed spots on all 25 with an average of 12 spots per person. The women were given three 30 min QXCI Zap therapies over the course of one week. In 2 of the subjects there was no change. All of the others had lessening of their spots in size and number. In five subjects there was complete removal of the spots. The rest had approximately 60% reduction in the number of spots. The overall average therapy was 60% effective in treating papilloma.

#### A SHORT STUDY OF COMPARISON FACTORS OF COPROLITH VERSUS QXCI DETECTION OF INTESTINAL PARASITES

- Chief Editor: William Nelson, N. M.D.; Independent Medical Editor; Budapest, Hungary
- Edited and Validated By: Istvan Bandics, M.D; Budapest, Hungary Gylila Panszki, M.D; Budapest, Hungary, Attila Kiss, M.D; Győr, Hungary
- Consultant: Dr. Simon Gutl, M.D; Hanover, Germany
- Developed By: The staff of Maitreya; Limerick, Ireland

This study was performed in 1984 at the King Health Center in Lowellville, Ohio, USA Revalidation and further clinical testing and has been repeated by medical doctors at the Homeopathy Clinic in Budapest, Hungary and by the doctors listed above.

William Nelson1995.

This work was presented at the Singapore World Congress on Sexually Transmitted Diseases. This Body of Research has led to the first registration of the QXCI in 1997. The QXCI is a follow on the original EPFX.



TO THE HUNGARIAN AIDS RESEARCH HOSPITAL

FROM: William Nelson MD and Nagy Karoly MD

DATE: SEPTEMBER 20, 1994

RE: ANALYSIS OF XRROID REACTIVITY READINGS OF AIDS PATIENTS IN BUDAPEST

#### ABSTRACT

Twenty-two ambulatory AIDs patients in Budapest were studied for xiroid electrical reactivity readings. The electrical reactivity patterns and reactive substances that were in the highest faction of reactivity. In other words, those reactants that were statistically significant are compared in the groups of the AIDs patients taking the AZT as well as the AIDS patients that were treated with homeopathic and nutritional items. The purpose of the study was to analysis similarities and consistencies in their electrical reactivity patterns over the course of four measurements. This took place during the 4th, 5th, 6th and 7th month of 1994. During these months there was also a homeopathic and nutritional intervention done on several of these patients to see the effect on blood chemistry profiles denoting aids sisks and the homeopathic and nutritional intervention are described in the article known as the comparative results.



# Singapore Raffles Place of the 1995 World congress on AIDS with Dr Nelson's Historic presentation

TO: THE HUNGARIAN AIDS RESEARCH HOSPITAL

FROM: William Nelson + Nagy Karoly

DATE: SEPTEMBER 20, 1994

RE: ANALYSIS OF XRROID REACTIVITY READINGS OF AIDS PATIENTS IN BUDAPEST

The science of electrical reactivity in the body has been documented in several articles. Two such papers were recently submitted at an international medical diagnostic symposium in Pecs Hungary in September 1994. Copies of these articles are attached. Also included is the article that totally describes the electrical reactivity factors in medication testing.



http://www.downloads.imune.net/journals/1997%201%20Electro%20Physiological%20Reactivity,%2 0%20the%20Xrroid%20Effect,%20Vol.%20I/pdf/

http://www.downloads.imune.net/journals/1993%20Updated%20-%20Nosodes-%20Using%20Microorganism%20Endotoxins%20Selye%20and%20Bertok%20on%20Immunology/pdf

# Royal Society of Medicine + EPFX



In 1992, Dr. Nelson/Desire' Dubounet was invited to the Royal Society of Medicine, where a group of 6 doctors lectured on this technology.

http://www.downloads.imune.net/journals/1998%204%20Royal%20Society%20Of%20Medicine/

# ISBN # 978-615-5169-32-8 Int Library #

This is a transcript of the proceedings of the Alternative medicine Conference on Homeopathy And Energetic Medicine at the ROYAL SOCIETY OF MEDICINE London, Eng. 1992



Presented by AAQBT and the International Medical University

Dr Nelson was the keynote speaker



Dr Julian Kenyon is an integrated medicine physician and Medical Director of the Dove Clinic for Integrated Medicine, Winchester and London. He has written approximately 20 books and has had many academic papers published in peer review journals and has several patents to his name. He graduated from the University of Liverpool with a Bachelor of Medicine and Surgery and subsequently with a research degree, Doctor of Medicine. In 1972, he was appointed a Primary Fellow of the Royal College of Surgeons, Edinburgh..

Fröehlich basically said is that inside the body there is communication that would make an enzyme come to a substrate. This would, in the first instance, be a coherent electromagnetic oscillation. The reason for that is that within the body there's so much going on all the time. There is such a range of biological processes that you've got a signal-to-noise ratio problem

We have achieved a viable hypothesis after six or seven years of hard work. In two of those years we were able to employ two physicists and electronic engineers, and a biologist and immunologist full time. We researched the EPFX and found it to be the best energetic medicine device. And the EPFX has a scalar component.

Now, scalar fields are actually quantum fields. They are basically quantum interference patterns between electrons. Electromagnetic fields are derived from quantum fields. Maxwell's equations for the derivation of electromagnetic fields actually do contain a scalar expression. So they are derived from that. They are, therefore, more fundamental than electromagnetic fields.

Electromagnetic fields act as carriers for scalar information. That's very important, because you can piggyback one on top of the other. When I use the Eclosion EPFX system, I'm basically piggybacking the scalar information on top of electromagnetic information. That's why it's easier to do. That's why, for example, if I have to dowse out all these patients (I'm not ashamed of saying I do dowsing, I'm a fairly average dowser), I could probably dowse out about four patients a day. By that time I'm absolutely tired. With any equipment where I use an electromagnetic field as a carrier, I can cope with probably thirty or forty patients a day without any problem at all. I'm making use of what seems to be a fact, that the scalar information is piggy-backed on the electromagnetic information.

For example, in electro-acupuncture, if you want to use an electro-acupuncture stimulation device, the waveforms that work best are square waves, in which the rise time is very high, and the fall time is very, very steep. Biological systems respond best to that. Bill Nelson will tell you is that the information carriers are the photons, and I'm sure he's right, because that's what makes the interference pattern



Richard Gerber, MD, is the author of the 1988 book, **Vibrational Medicine: New Choices for Healing Ourselves**, a publication that has been reviewed as 'landmark' and 'encyclopedic', and in many ways bridges the gap between science and esoteric healing. **Vibrational Medicine** cites hundreds of scientific studies that support the energy model of health and healing and presents the theoretical foundation for such therapies as homeopathy and acupuncture.

Is there any type of research that substantiates the existence of this organizing energy field? We need to look no further than the work of Dr. Harold Saxton Bur, who in the early 1940s was a neuro-anatomist at Yale University. He was very much interested in the electrical field characteristics of living objects; plants and animals. He found some rather unusual things about animals and plants. He decided to study salamanders, because their electrical field characteristics were fairly easy to map. You could actually trace the outline of the field around the salamander. It seemed to have an electrical orientation along a central axis, which mapped along the nervous system and spinal cord. And he wondered when this electrical axis in the organism first formed, so he started looking at earlier and earlier stages of embryological development of salamanders trying to draw the electrical field around this earlier and earlier living form. What he found was actually an electrical axis at the level of the unfertilized egg. He wondered if this was the same electrical axis as the one in the adult organism.

It is the necessity of developing this type of sensitive technology to measure things happening at the subtle energy level that will really be important in finding out not only how subtle energy medicine therapies work, but some of the unseen side effects of accepted medical therapy; surgical therapies we are really not aware of. We take for granted that the body heals up just fine, and it doesn't matter that there's some scar tissue over here.

It turns out that it is very important. You do develop energy blockages in the body with surgery, and there are unseen side effects with drugs that happen at the subtle energetic level.

I want to move on from this into this phenomenon of acupuncture. Acupuncture is also an energy system that is very ancient. It is a model that describes energy circuitry throughout the body, yet it is thousands of years old, or older. This particular statue [visual reference] is a teaching statue that is several hundred years old. It shows these different acupuncture points on the body. It's a more contemporary model, used for teaching acupuncture students.


Dr. Bill Wolfe graduated from Baylor University College of Dentistry in Texas in 1972. He practiced dentistry in Austin, Texas from 1972 until 1978; and in Albuquerque, New Mexico from 1978 to the present day. Dr. Wolfe also has a doctorate degree in naturopathic medicine. He is a member of several organizations including the American Dental Association, the Holistic Dental Association, the American Association of Biological Dentists, the American Association of Health Practitioners, and the Environmental Dental Association, of which he is a director.

This is important in the United States right now: informed consent. In many areas of medicine, it is quite usual that the patient must be informed of what the procedure their going to be receiving involves. Yet, we have a material that has been used, in the United States at least, since the 1820s. We've been fighting about it for that long. We've called it silver fillings. Now, by the FDA labeling laws, you are supposed to put the ingredient with the highest content first. So if you had a mixture of mercury which is fifty percent, silver which is thirty percent, and then zinc, tin and copper, what would you call it? A mercury filling. This demonstrates the level of denial of the American Dental Association to call it a silver filling instead of a mercury filling, with fifty percent mercury.

Now, what happens is that once the mercury is mixed into the sludge of metals, the mercury does vaporize. I was the first dentist in the United States to purchase a mercury vapor detector, which is like a Geiger counter. It was originally developed for mining geological surveys, because wherever they find mercury vapor in a cave or mine, there is usually gold associated with it. That's why I don't feel that a dentist should put gold and mercury in the same mouth; they're very attractive to each other, and create a battery effect.

The US Navy found out about this machine, that it can detect mercury vapor, and purchased two hundred of them for their submarines, because in electrical switches, gauges, etcetera there's a lot of mercury used, and they didn't want vapor leaks in a closed, pressurized container under the ocean. So they purchased the vapor detectors, and started using them in their industry. OSHA in the United States, which controls work environment, has testing methods where if they come into your industry with a mercury vapor detector, and find more than .05 milligrams of mercury per cubic meter of air, they can fine you ten thousand dollars, and close your plant down. Yet, there are many of you in this room who have that much mercury vapor coming out of one tooth.



Dr. Will Corell is a cum laude graduate of Yale College, 1970 and Stanford University School of Medicine, 1974. He completed five years of postgraduate training including Internal medicine, Ear, Nose and Throat, General Surgery, and Family Medicine.

He was board certified by the American Academy of Family Practice in 1979 with recertification in 1986, 1993, 2000 and 2007. He has been in practice in the Spokane area since 1979, where he blends aspects of traditional medicine with his primarily holisticoriented medical practice.

Thank you, Dr Nelson for inviting me here. Thank you all for having me here. It's a great honor to be talking in the Royal Society of Medicine here in London.

I'd like to address my talk today on some of the more practical applications of some of the bio-medicine techniques we've been talking about today. For the purpose of the talk, I'd like to address a syndrome we call **CHRONIC FATIGUE SYNDROME** in America. I understand that here it's called myalgic encephalomyelitis. If you don't mind, for my untrained American tongue, I prefer to call it chronic fatigue syndrome, or **CFS**, or more appropriately, chronic fatigue immune deficiency syndrome.

First off, the criteria. A patient must have both major criteria to be identified as having chronic fatigue syndrome; again, for purposes of research. The primary onset of fatigue, persistent or relapsing; or easy fatiguability with the conditions you will see described.

The second factor under major criteria-- and here is where we may have some disagreement-- there is an exclusion of other conditions that produce similar symptoms. I would look specifically at letters C or D, especially chronic or sub-acute bacterial, fungal or parasitic disease. As Dr. Nelson mentioned, the degree of vigor with which we look for parasitic disease will often determine our success at finding it. So when my colleagues typically say they've done a routine investigation for parasitic disease and found the workup negative, I think we need to take that with a small to moderate-sized grain of salt. As we've all discussed, I think parasitic disease is much more common than traditionally reported.

I've been measuring patients for ten years now with my mercury vapor detector, and very rarely do I find a filling that doesn't have mercury vaporizing from the filling, no matter how old it is. That's why it's called chronic micro-mercurialism; low-dose mercury exposure over a long period of time. This is why it may take years before the chronic exposure to mercury is noticed. When you're eighteen or twenty-five, the adaptive capacity of your immune system to deal with these mercury fillings is much greater. But maybe you're forty now, and with the pesticides, pollutants, preservatives, stress, plus the mercury vapor leakage affecting your teeth, then it does begin to catch up with you.



Dr. LaValley is a member of the American Medical Association (AMA), the Texas Medical Association (TMA), the Travis County Medical Society (TCMS) in Austin Texas, the Canadian Medical Association (CMA) and Doctors Nova Scotia. He has also served as the Chairperson of the Complementary Medicine Section of the Nova Scotia division of the CMA since 1994.

Thank you. I feel that it's a great honor to be here, it's a very exciting moment, I think, in the history of this field, because we're here at the Royal Society of Medicine. I want to thank Dr. Nelson and the Royal Society of Medicine for having me here to speak on what I feel is an important and long-controversial subject. In order for clarity, I'm going to read what I have written rather than speak extemporaneously, because there are so many specific points I want to make, and tie together at the end.

My intention is to discuss a scientifically accountable framework, model or paradigm that can begin to give us as scientists and medical practitioners reasonable and logical access to the underlying mechanism of action of homeopathy and homeopathic effect. I must acknowledge the vast number of scientists and practitioners who before me have generated research, knowledge and effort that have made available all the facts and observations drawn upon for this discussion. This discussion will bring into consideration many general facets of science: chemistry, physics, mathematics and homeopathy, in order to build a consistent, coherent model of scientific accountability in this vast area. Concepts will be brought forth in succession, and then tied together in a testable hypothetical picture or model that acts to include these various schools of thought in a svnergistic understanding for all of us to consider, to critique, to investigate, and to explore.

Dr. Nelson, now known as Desire' Dubounet, has been nominated for the Nobel Prize, and in 2000 was invited to speak at the Nobel Prize Hospital in Stockholm, Sweden.





#### Dr William Nelson Inventor of the Electro-Physiological Feedback Xrroid Interface EPFX



Born and raised in Ohio, Bill Nelson was identified as a genius from an early age. As a young man, his interest in quantum physics and electronic engineering led to his work on the navigation system for the Apollo space project. He turned his genius to the field of medicine and health after the birth of his first-born, a son. His son retreated into the world of autism-a result of an anti-nausea drug his wife took while pregnant. After devouring the information offered by a medical world, he turned to the world of alternative health. With natural remedies, he was successful in reversing many of the

symptoms of his son's autism. During his research, he was intrigued by

During his research, he was intrigued by a number of bio-electric devices being used in Germany-the Vega machine, the Voll, and the Mora unit-as well as biofeedback and cranial electrical stimulation (CES) units in the US. These units either measure the body's electrical response to help diagnose problems in the body or they emit frequencies to treat problems. He also studied the body's subtle energy systems-acupuncture meridians, chakra energy, applied kinesiology or muscle testing, etc. The body's subtle energy system is an early warning system. Imbalances in the body's subtle energies show up much earlier than disease symptoms. Bill Nelson decided to apply his genius to design an all-inclusive system-a computerized system that would both test and balance the body at the subtle energy level. The EPFX was born.

Dr Nelson has been Nominated for the Nobel Prize in Medicine many times, In 2000 he was invited to lecture in the Nobel Prize Hospital In Stockholm Sweden

His lecture was a Revolution in Medicine



The Nobel Prize Hospital In Sweden Place of Desire' Dubounet's lecture in 2000



# International Journal of the Medical Science of Homeopathy, Naturopathy and Energetic Medicine

A group of doctors from the Szent Janos Hospital and Semmelweis University in Budapest have gotten together and created the International Journal of the Medical Science of Homeopathy in 1997. This journal has been unchallenged and recognized for over 16 years. Over a hundred volumes have been published with over 1,000 studies.

The International Journal of the Medical Science of Homeopathy, Naturopathy and Energetic Medicine has been a reputable, well established, publically accessible and professional medical peer reviewed journal since its conception in 1997. The original international peer reviewed library registration number was ISSN 1417-0876, and currently it is ISSN 2041-4293. The first medical doctor that supervised the peer review process as a director was a Hungarian doctor, Judith Nagy M.D. After her retirement, she was replaced by Dr. Hilf Klára, M.D., who is still the supervisor and director of the medical peer review process.

This journal has been credentialed and recognized by over 20 respected and recognized medical doctors, all very well acknowledged and respected in their field of application. Below we present some of the doctors, professionals and lay people that have been involved with the International Journal of the Medical Science of Homeopathy, Naturopathy and Energetic Medicine over the years:

Dr. Debbie Drake, M.D., Canada Dr. Sarca Ovidiu, M.D., Romania Mezei Iosif, Romania Dr. Czako Annamaria, M.D., Hungary Gage Tarrant, Canada Richard Atkinson, Canada Gulyas Kinga, Hungary Dr. Radu Stefan, M.D., Romania Bill Cunningham, United States of America John Kelsey, England Dr. Christopher Hammond, M.D., United States of America Dr. Michael Gerber, M.D., United States of America Dave Cowan, United States of America Dr. Bandics, M.D., Hungary Penny Fox, England Dr. Danis Gyorgy, M.D., Hungary Dr. Hilf Klara, M.D., Hungary

- Dr. Igor Cetojevic, M.D., Cyprus
- Dr. Pauline Wills, M.D., United States of America
- Dr. Matthias Heiliger, M.D., Switzerland
- Dr. Aurel Bacean, M.D., Romania
- Dr. Oana Bacean, M.D., Romania
- Dr. Theron Francois, M.D., South Africa
- Turako Yuy, Homeopath, Japan

Max Yang, China

Dr. Ho, M.D., China

The International Journal of the Medical Science of Homeopathy, Naturopathy and Energetic has operated without a single challenge to its credibility for over 15 years. It has published hundreds of articles, double blind studies, case studies, and clinical data on various topics focused on natural, energetic and alternative medicine.





Maitreya Kft. 1089 Budapest, Kálvária tér 2. Fax:2109-93-40

Budapest, 1997.08.07.

Értesítjük Őnöket, hogy a Homeo-Diagnostica Academy Press által kiadott/közreadott

The international journal of the medical science of homeopathy mint egyenrangúan felülvizsgált orvosi újság

című időszaki kiadvány (periodikum/sorozat) részére a Magyar ISSN Nemzeti Központ 1997 április 15-I kelettel az alábbi nemzetközi azonosító számot állapította meg:

#### ISSN 1417-0876

A fenti azonosító szám a kiadvány változatlan címen történő megjelenéséig érvényben marad.

Kérjük Önöket, hogy ezen értesítésünket követően szíveskedjenek kiadványunkban, annak a jövöben megjelenő minden részegységében (számában, kötetében) az itt közölt ISSN számot feltüntetni. Amennyiben kiadványukat nemzetközi forgalmazásra szánják, az azonosító szám kiegészíthető a Magyarországra utaló kóddal az alábbi formában:

#### HU ISSN 1417-0876

Az időszaki kiadványok nemzetközi azonosító számozásával kapcsolatban részletes tájékoztatás található a Magyar ISSN Nemzeti Központ web-oldalain, melyek az OSZK honlapjáról a "Helyi szolgáltatások" menüpont alatt, az azonosítószámokat választva érhetők el.

#### http://www.oszk.hu/index\_hu.htm

A dokumentumazonosítókra vonatkozó minden további kérdésben szívesen állunk rendelkezésükre.

#### Koosisne' Sections Marianna



Országos Széchényi Könyvtár Magyar ISSN Nemzeti Központ H 1827 Budapest, Budavári Palota "F" épület

Kocsisné Szakács Marianna Magyar ISSN Nemzeti Központ Gyűjteményfejlesztési és Feldolgozási Igazgatóság Országos Szécényi Könyvtár H 1827 Budapest, Budavári Palota "F" épület Tel: 22 43 842 Fax: 22 43 754 Ügyintézés (e-mail): <u>issn@oszk.hu</u>

1827 BUDAPEST Budavári Palota F épület, 411., 413. szoba Telephone: administrator (Ms. Erika Szabó): 22 43 754, group head (Mrs. Elizabeth Gazdag): 22 43 842, department head (Mrs. Aniko Nagy): 22 43 763 Fax: 22 43 754, 20 20 804, E-mail: <u>issn@oszk.hu; eszabo@oszk.hu; liza@oszk.hu</u>

### The journals can be accessed online at http://ijmshnem4u.com/



# The International Journal of the Medical Science of



Evidence Based Literature to Protect and Explore Natural Medicine since 1996 ISSN # 1417-0876, 2041-4293 http://ijmshnem.com/

IJMSHNEM Ethics Supervisor & Institutional Director: Dr. of Sociology Brad Victor Johnson, Dean of the International Medical University of Natural Education – IMUNE

Editorial Consultant: Alejandro Arregui Henk, Argentina,

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Welcome to our first journal of 2015. The company Biofeedback srl has been accepted by a new ethics committee as indicated by the next letter. The studies published in this journal have all been under the scrutiny and supervision of this ethics committee. All of the studies in this journal have had ethics supervision of institutional review boards or the like. And we welcome this new ethics review board to our team of research associates.

This journal will have articles about GSRtDCs electro stimulation to help insight, hormone, erection, chess ability, memory, focus, learning among others. Stories and details of Alzheimer's are also contained. Please see, read, review and consider the call for papers in the back of this journal. We wish to broaden our knowledge of natural and energetic medicine.

Brad Victor Johnson 2015

# Large Scale SCIO Study

970,000+ Study of the Safety and Efficacy of the TVEP families in the SCIO Device

Chief Editor:

Dr Danis IMUNE

The Centro Ricerche, University of Venice + Padova, Italy

Edited and Validated By IMUNE Medical Staff:

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Matthias Heiliger M.D. Germany/Switzerland

Klara Hilf M.D. Hungary

Anna Maria Cako M.D. Hungary

Debbie Drake M.D. Canada

Bacean Aurel MD Romania

Consultant:

International Ethics, Lebedei 58,

Oradea, Romania

John Kelsey Phd, ND N.Z. Eng,

Gage Tarrant LBT, C.H.T, USA, Somlea Livia Romania

Richard Atkinson MCSP, Physical Therapist, West Yorkshire England

Developed By:

The Centro Ricerche University of Venice + Padova, Italy

This study was performed in the field by practicing Biofeedback technicians. Data was collected

and the study supervised by the Ethics International Institutional Review Board of Romania. The

Data analysis and study presentation is done By the The Centro Ricerche, University of Venice,

Padova, Italy; © Ethics International, 2006.

http://www.downloads.imune.net/journals/2008%201%202%203%204%20The%20Large%20Scale% 20Study%20of%20the%20Scio/ To: Richard Lloyd Maitreya Kft. Kalvaria ter 2,

1089 Budapest Hungary

#### International Ethics SRL

Municipiul Oradea, Str. Moldovel, Nr. 17, Bloc AN50, Ap. 20, Judetul Bibot



Cod unie de Inregistrare 18880090 din data 06/07/2006 Numar de ordine in registrol comertului J05/1809/2006

## **Certificate of Cooperation**

Title of Study: Large Scale Study of the use of the SCIO Therapists are to be enrolled from all over the world including N. America, Europe, Africa, Asia, and S. America. They were trained in the aspects of the study and how to attain informed consent and transmit the results to the ethics committee. The therapists are to be trained and supervised by medical staff. They were to perform the SCIO therapy and pre-analysis. They will report any medical suspected or confirmed diagnosis. Then the therapist is to inquire on any reported post changes during the meeting and on follow-ups any measured variations.

Int Ethics code:	12-2006
Sponsor:	Maitreya Kft
Date of agreement:	10-12-2006

We have reviewed your study proposal and we are happy to work with you to assure ethical execution of the protocol. We can receive the data and compile the results as an independent ethical review committee. We have determined this study to be of no substantial risk but we insist on recorded informed consent from all participants. There is no risk of radiation damage, and no risk of electrical pollution from this study.

We request yearly reports of progress and we will provide a yearly report of our data collection. It will be up to you to refine and define the data into your publication, but we will supervise data collection.

We welcome your cooperation and we approve of your study protocol as ethical and safe.

Somlea Livia Director of Operations

Signed: 5 11 /2

Date: 12-12-2006

A global and momentous research project was developed over the period of 2005 – 2008. The SCIO device is a Universal Electro-Physiological device used for stress reduction and patient treatment. Over 2,200 qualified biofeedback therapists joined our Ethics Committee study to evaluate how stress reduction using the SCIO device could help a wide variety of diseases. The device and thus the study has insignificant risk. There was a staff of medical doctors who designed and supervised the study.

Over 100,000 patients gave informed consent and participated in the study. The study would conclusively prove safety and efficacy of the SCIO Device. With over 60% of these patients having multiple visits. There were over 300,000 patient visits and over 225 diseases investigated. With a total record of the SCIO patient information, therapy parameters and reactivity data. No names of patients were recorded for confidentiality.

Two of the 2,200 plus therapists were given blank devices that were completely visually the same but were none functional. These two blind therapists were then given 35 patients each. This was to evaluate the double blind component of the placebo effect as compared to the device. Thus the studied groups were a placebo group, a subspace group, and an attached harness group.

This is just the first study in a long task of analysis in truly break down the data totally. This study verifies the safety and efficacy of the SCIO device as well as the validity of the TVEP family reactivity. There were small effects seen in the placebo group, larger effects in the subspace, and astounding effects in the real harness group. Below is a list of the study topics that were published out of this large scale study. Each of these diseases (and a few more) were studied and reported in the scope of this study. This is one of the largest studies ever done.

# Vol.XXIII.1. - IJMSHNE – 2008- The Large Scale Study of the SCIO--ISSN 2041-4293

## LIST OF DISEASES STUDIED with SCIO

ACNE VULGARIS, ACROPARESTHESIA, ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS and HIV positive), ALCOHOLISM, Allergy, ALZHEIMER'S DISEASE, ANEMIA, ANXIETY UNSPECIFIED, ASTHMA, BACTERIA INFECTION, **BRAIN FATIGUE UNSPECIFIED, CANCER, CARDIAC ARRHYTHMIA, CIRCULATION** DISORDERS, CROHN'S DISEASE, COMMON COLD, DEPRESSION + SEASONAL AFFECTIVE DISORDER, DIGESTIVE DISORDERS, ENDOMETRIOSIS, **ENTEROCOLITIS, ESOPHAGITIS aka GASTRIC REFLUX, PREMENSTRUAL STRESS** OR TENSION, FLEXIBILITY Restricted Range of Motion, FRACTURES, HIATAL HERNIA, HAY FEVER ALLERGIC RHINITIS, HEADACHE, HERNIATED DISK, LUMBAR | L1, L2, L3, L4, L5 ], High Blood Pressure, HYPOADRENIA, HYPOGLYCEMIA, HYPOTHYROID, HYPERTHYROID, HYSTERIA, IMPOTENCE, INDIGESTION, INFECTION UNSPECIFIED, INJURED and DISEASED TISSUE, **INSOMNIA, IRRITABLE BOWEL SYNDROME, ITCHING UNSPECIFIED, KIDNEY** DISORDERS, LEUKEMIA, LIVER PROBLEMS UNSPECIFIED, LOW BACK PAIN, MALABSORPTION SYNDROME, STRESS unspecified, METACARPAL TUNNEL, MYASTHENIA GRAVIS, OSTEOPOROSIS, OTITIS MEDIA, PAIN UNSPECIFIED, POLYCYSTIC OVARIES, PROSTATITIS-PROSTATIC HYPERTROPHY, SINUSITIS, **TENDON CALCIFICATION, THYMUS DISORDERS, TRANSIENT ISCHEMIC ATTACK** - STROKE, PANCREATITIS, DEEP VEIN THROMBOSIS, WEIGHT LOSS

http://www.downloads.imune.net/journals/2008%201%202%203%204%20The%20Large%20Scale%20Study% 200f%20the%20Scio/



#### MINISTERUL JUSTIŢIEI

OFICIUL REGISTRULUI COMERȚULUI DE PE LÂNGĂ TRIBUNALUL

BÍHOR Str. Şiefan Zweig nr. 11, Oradea Tel : 0259/43.50.17; Fax :0259/43.50.17 orcbh@bh.onrc.ro

#### CERTIFICAT CONSTATATOR

emis in temeiul art. 1<sup>1</sup>alin. (1) lit.b) din Legea nr. 359/2004 privind simplificarea formalităților la înregistrarea persoanelor fizice, asociațiilor familiale și persoanelor juridice, înregistrarea fiscală a acestora, precum și la autorizarea funcționării persoanelor juridice, cu modificările și completările ulterioare, eliberat în baza declarației pe propria răspundere înregistrată sub nr. 46073 din 30/11/2006

Firma : INTERNATIONAL ETHIC SRL. Sediu social : MUNICIPIUL ORADEA, Str. MOLDOVEI, Nr. 17, Bloc AN50, Ap. 20, Judetul Bihor. Cod unic de înregistrare 18830090 din data 06/07/2006. Număr de ordine în registrul comerțului J05/ 1399/2006 din data 06/07/2006.

Prezentul certificat constatator atestă că s-a înregistrat declarația pe propria răspundere conform căreia firma îndeplinește condițiile de funcționare, specifice pentru fiecare autoritate publică, pentru activitățile declarate, încadrate în clasa CAEN: 7210 Consultanță în domeniul echipamentelor de calcul (hardware);

7230 Prelucrarea informatică a datelor;

7240 Activități legate de bazele de date;

8042 Alte forme de învățământ;

la sediul secundar din MUNICIPIUL ORADEA, Str. LEBEDEI, Nr. 58/A, biroul nr.4., Ap. biroul 4, Judetul Bihor (CENTRU DE PREGĂTIRE I.M.U.N.E.).

Valabilitate: până la modificarea condițiilor de funcționare sau activităților pentru care s-a dat declarația pe propria răspundere.

#### DIRECTOR, CORNELIA LUCIA GLIGOR

Emis la data : 05/12/2006 0 5. DEC. 2006 Eliberat la data :

ROMÂNIA MINISTERUL JUSTIȚIEI		OFICIUL NATION. OFICIUL R DE PELANGĂ TRI	AL AL REGISTRULUI CO EGISTRULUI COMERTUI RUNALUL BIHOR	MERTULUI
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Sediul social: Municip Activitatea principala	siul Oradea, Str. Moldovel, Nr. Prelucrarea informatică a dat prelucrarea din data d	17, Bloc AN50, Ap. 20, Jud ielor - 7230	qut Bihor	2  265  275
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Seria B Nr. UB	96514 RC		And and	155

# Registrations

This massive body of research has gotten registrations all over the world: Europe, United States of America, China, Mexico, Canada. All of our research has been conducted according to the regulatory requirements, everything has been done to the letter of the law, and all of our paperwork submitted to the notified bodies has always followed the most recent standards and requirements. Staff in our office has had more than 500 hours of training in regulatory standards and procedures.

#### In 2008 our company obtained the United Kingdom Intertek CE certificate:



Certificate Number 846 CE

Initial Certification Date 20 November 2008

Certificate Issue Date 23 January 2009

Certificate Expiry Date 19 November 2013

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

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# **EC** Certificate

FULL QUALITY ASSURANCE SYSTEM Directive 93/42/EEC for Medical Devices, Annex II (3)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

#### Organization:

## MAITREYA HUNGARY KFT

Kalvaria ter 2, 1089 Budapest, Hungary

Universal electrophysiological system for the detection of stress and reduction of stress, and the treatment of muscular reeducation from injury, muscle weakness, or dystonia and electrophysiological reactivity

R. NASH

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AMTAC Certification Services Limited, Milton Keynes, UK

In 2009, the Korean registration was obtained:

수허 09-1306 호	
3	의료기기 수입품목 허가증
	입허가번호 : 제1895 호 구 분 : 수입
제품명(품목명 및 형영)	의료용바이오피드백장치(SCIO) 분류번호(동급) A30080.01(
형상 및 구조	State of the state
원자재 또는 성분 및 분량	
제조방법	28
성능 및 사용목적	
조작방법 또는 사용방법	
사용 시 주의사항	
포장단위	1 Set
저장방법 및 사용기관	별첨, 해당사항 없음
시험규력	별형
제조원(수입 또는 제초공정 전부 위탁의 경우)	PENTAVOX KFT., 27F2I.Dugonics utca 11. 1043 Budapest
허가조건	Ha A
「의료기기법」 제1	4조 및 같은 법 시행규칙 제18조제3황에 따라 위와 같이 허가합니다 2009년 12월 16일 식품의약품안전청장 (인



KFDA Documentation Number 0261-3552-1933-2908

No. 1895 Imported Medical Device License Permit

Company Name – Quantum Health Korea Inc. Address – Seoul Gangnam-gu Nonhyun-dong 277-21 Mirae building 6fl. Representative – Jung Won Jung Date of Birth – Oct, 10<sup>th</sup> 1973 Permit Condition –

[Medical Device Legislation] Permits granted by Article 14 and 17

2009 Dec. 16th

Korean FDA

Documentation Number 09-1306

Medical Device License Permit

Permit Number : 1895 Classification: Imported Device

Name of Device(Line Item) Biofeedback Device(SCIO) Division Number(Class) A30080.01(2) Shape and Structure Attached Component, Quantity Attached Manufacturing Method Attached Performance and Purpose Attached Operation Method Attached Cautious Attached Cautious Attached Terms of Packing 1 set Storage and Use-By Date Attached, none Device test standards Attached Manufacturer PENTAVOX KFT., Hungary, Dugonics utca 11. 1043 Budapest Licensing Condition Attached

[Medical Device Legislation] Permit granted by Article 14 and 18 - 3

2009 Dec. 16th

Korean FDA

In 2010 we obtained the Mexican registration:



#### SECRETARÍA DE SALUD

COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS COMISIÓN DE AUTORIZACIÓN SANITARIA DIRECCIÓN EJECUTIVA DE AUTORIZACIÓN DE PRODUCTOS Y ESTABLECIMIENTOS SUBDIRECCIÓN EJECUTIVA DE SERVICIOS DE SALUD Y DISPOSITIVOS MÉDICOS

> PRÓRROGA DEL REGISTRO SANITARIO No. 1009E2005 SSA No. DE SOLICITUD 103300CT081650 No. DE SOLICITUD ANTERIOR 103300421C1816

Con fundamento en los artículos 4° párralo tercero, 8, 14 y 16 de la Constitución Política de los Estados Unidos Mexicanos; 2 fracción I, 14, 17, 26, 39 fracciones XXI y XXIV de la Ley Orgánica de la Administración Pública Federal; Artículo 1, 3 fracciones XXV y XXX, 4 fracción III, 13 inciso A fracción IX, X 17 bis fracción IV, 194 fracción III, 194 bis, 197, 204, 262, 371, 376, 376 bis fracción II, 378, 380 y 393 primer párrafo de la Ley General de Salud; 1, 2, 3, 15 y 16 fracción IV de la Ley Federal e Procedimiento Administrativo; 1, 2 inciso c fracción X, 15, 36 y 37 del Reglamento Interior de la Secretaría de Salud; 1, 3 fracción 1 inciso b y fracción VII, 4 fracción II inciso c y 14 fracción I del Reglamento de la Comisión Federal para la Protección contra Riesgos Sanitanos; 1, 2, fracción XI, 82, 83, 153, 157, 190 bis 3, 190 bis 4 y 190 bis 6 y Tercero Transitorio fracción I, II, IV, V y VI del Reglamento de Insumos para la Salud; así como los relativos y aplicables del Acuerdo por el que se dan a conocer los trámites y servicios, así como los formatos que aplica la Secretaría de Salud; a través de la Comisión Federal para la Protección contra Riesgos Sanitanos, inscritos en el Registro Federal de Trámites y Servicios de la Comisión Federal de Mejora Regulatoria; publicado el 19 de junio de 2009, en el Diario Oficial de la Federación; se prorroga el presente bajo las siguientes condiciones:

Titular del registro:	Subspace, S.A. de C.V.	
Domicilio:	Nicolás San Juan No. 1507, Colonia Del Valle, Delegación Benito Juárez, C.P. 03100, Distrito F México.	ederal,
R.F.C.	SUB 040826GV1	

#### CARACTERÍSTICAS DEL PRODUCTO

_ Denominación Distinitiva:	Cardiotocografo Ambulatorio con Sensor Pasivo, Sistema
	Electrofisiológico Universal "SCIO"
Denominación Genérica:	Equipo Médico Auxiliar para la Reducción del Estrés
Tipo de Insumo para la Salud Art. 262 LGS:	Equipo Médico
Clasificación del Insumo para la Salud Art. 83 RIS:	Clase I
Fabricado por:	Pentavox KFT
Domicilio:	Dugonics U. 11, 1043 Budapest, Hungria.

#### COF 017542

36.7%

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Nicolás Can Juan Ma. 1507. Colonia Del Valle, Delegación R.	-
C.P. 03100, Distrito Federal, México.	any obdiez,
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Modelo SCIO	
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Profesionales de la salud.	
	Subspace, S.A. de C.V. Nicolás San Juan No. 1507, Colonia Del Valle, Delegación Bo C.P. 03100, Distrito Federal, México. El SCIO es un sistema auxiliar de biofeedback para prediagnóstico y lerapias de regulació que mide los cambios en voltaje, amperaje y resistencia de un organismo al aplicar mice eléctricas. Es un sistema que actúa motivando el potencial evocado del organism microfrecuencias eléctricas. Sus dimensiones son 201 x 80 x 175 mm y su peso aproximado es de 790 g. El equipo está integrado por: 1 electrodo de cabeza, 1 electrodo de extremidades, 1 cable oc a USB, 1. caja de interfase, DVD & CO, de software y 1 manual de uso, su alimentación el través del puerto USB conectado al ordenador. Cuenta con una entrada nominal eléctricas de 4 a 5 volts (dependiendo del ordenador) y nominal máxima a través de electrodos de 4 a 10 miliamperios. El electrodo de cabeza pesa 200 g y sus medidas son 1.75 m de cable y 780 x 51 mm de electrodo entra en contacto con la piel al ser aplicado alrededor de las muñecas y tobil cos electrodos de extremidades pesan 180 g y miden 25 m de cable y 19 x 370 x 2 mm de electrodo entra en contacto directo con la piel al ser aplicado alrededor de las muñecas y tobil cos delectrodos de extremidades pesan 180 g y miden 25 m de cable y 19 x 370 x 2 mm de electrodo entra en contacto directo con la piel al ser aplicado alrededor de las muñecas y tobil cos delectrodos de extremidades pesan 180 g y miden 25 m de cable y 19 x 370 x 2 mm de electrodo entra en contacto directo con la piel al ser aplicado alrededor de las muñecas y tobil

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# **COF** 017543

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On 29 August 2012 SFDA has approved the SCIO to be marketed in the Chinese market after a successful review process of our application.

中华人民共和国 PEOPLE'S REPUBLIC OF CHINA 疗器械注册证 REGISTRATION CERTIFICATE FOR MEDICAL DEVICE 国食药监械(进)字2012第2213148号 注册号: REG.NO.: SFDA (I) 20122213148 匈牙利 MAITREYA KFT.: 你单位生产的生物反馈仪,经审查,符合医疗 器械产品市场准入规定,准许注册。自批准之日起 有效期至二零一六年八月二十八日。 特此证明。 MAITREYA KFT.: This is to certify that the medical product Biofeedback Device manufactured by your company has been inspected by our office and is permitted to register on the Chinese market. This registration certificate is valid till August 28, 2016. 国家食品药品监督管理局 State Food and Drug Administration 2012年8月29日 医疗器械产品注册登记表 件, ATTACHMENT: MEDICAL DEVICE REGISTRATION RECORD No. 120692

Our latest European CE Certificate was obtained with TÜV Rheinalnd InterCert Kft on 23 February 2012.

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	TÜVBhaialand
	APPROVAL
EC Di	rective 93/42/EEC; Annex II without Article 4
	Full Quality Assurance System
	Medical Devices
Registration No.:	OH 69241773 0001
Report No.:	28208466 004
Manufacturen	Mandalay K#
manulacturer:	ÁTI-SZIGET IPARI PARK 11. ép.
	H - 2310 Szigetszentmiklós, Hungary
Covered site	Kálvária tér 2
	H - 1089 Budapest, Hungary
Scope:	Design/Development and Manufacturing of Universal Electrophysiological Biofeedback System
	Product: SCIO
	Replaces approval with registration number: M23 69240068 0001
Date of expiry:	2015-02-22
The Notified Body hereb company mentioned abo met. This approval is aforementioned EC Direc Conformity.	by authorizes the quality management system established and applied by the twe. The requirements of Annex II (without Article 4) of the directive have been subject to periodic surveillance, defined by Annex II, Article 5 of the stive, and can be used by the company with the manufacturer's Declaration of
	And Real And
Budapest, 2012-02-23	F TÜVRheinland <sup>a</sup> Hale Bulas
Page: 1 / 1	Notified Body (No Certifier
TÜV RH Tel.: (+36/1) 461-110	neinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B )0, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/
	Notified under No. 1008 to the EC Commission.



# Certificate

The Certification Body of **TUV Rheinland InterCert Kft.** 

hereby certifies that the company

Mandelay Kft. ÁTI-SZIGET IPARI PARK 11. ép. H - 2310 Szigetszentmiklós, Hungary

Site: Kálvária tér 2., H - 1089 Budapest, Hungary

has established and maintains a quality management system for medical devices for the following scope:

#### Design/Development, manufacturing, distribution and servicing of Universal Electrophysiological Biofeedback System

Proof has been furnished that the requirements of

## EN ISO 13485:2003+AC:2009

are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No .: OX 69241776 0001 Audit report No .: This certificate is valid:

28208466 004 from 2012-02-23 to 2015-02-22

inland In

2012-02-23 Date of issue

TÜVRheinland Balázs Bozsik 5 ed Body 10 Certifier

18/020 7.95Q

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B Tel.: (+36/1) 461-1100, Fax: (+36/1) 461-1199, e-mail: medical@hu.tuv.com, http://www.tuv.com/hun/ In the United States the Eductor/Educator have been successfully registered in 2014 with the FDA:



Australian Register of Therapeutic Goods Certificate 2015



#### Australian Government

Department of Health Therapeutic Goods Administration

#### Australian Register of Therapeutic Goods Certificate

#### Issued to

#### Quantum World Pty Ltd

for approval to supply

#### Quantum World Pty Ltd - EDUCTOR 1 - Biofeedback system

ADTC Identifier	224777
ARTOIdenuner	234111

ARTG Start date 11/03/2015

Product Category Medical Device Included Class IIa

GMDN 10396

GMDN Term

#### Biofeedback system Stress detection. Stress Relief and Management, Muscle Re-Education

Manufacturer Details	Address	Certificate number(s)
Biofeedback 2014 SRL	2 Henri Coanda Street Room 14 , Satu Mare, Romania	DV-2015-MC-01981-1

#### ARTG Standard Conditions

The above Medical Device Included Class IIa has been entered on the Register subject to the following conditions:

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.,

 The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

 Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device the distribution records shall be retained for a minimum period of 5 years.

device, the distribution records shall be retained for a minimum period of 5 years.,
The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.,

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG. Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.,

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products Covered by This Entry

#### 1. EDUCTOR 1 - Biofeedback system

Product Specific Conditions

\* The inclusion of medical devices under this ARTG entry is only limited to one device of the kind. This device of the kind is the medical device identified by the manufacturer as EDUCTOR 1.,\* Other devices of the kind must not be included and/or supplied under this ARTG entry until and unless an application to vary the entry is submitted and approved by the TGA.

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia Phone: 1800 020 653 Email: info@tga.gov.au ARTG Identifier: 234777 ARTG Start Date: 11/03/2015

# **Chinese Olympics**

Helping us to get the Chinese registration was the research done on the 2008 Chinese Olympic Team. The Beijing 2008 Olympic project was unbelievably successful project where, over a three month period, more than 200 Chinese Olympic athletes were tested and 60 athletes were worked with closely in therapeutic trials in over 1200 sessions with the SCIO/EPFX System. All of this was under the supervision of Doctor Li Guo Ping, head of Sports Medicine China), as well as 20 doctors and nurses through the Federal Hospital Sports.

The people involved in the Chinese Olympics project were (QX China), Victor Ke, George Fang, Jeff Sutton, Dr.Jiao Li Ping and Yin Lin.

# Voltammetry Stimulation of Testosterone in Gold medal Athletes in the China Olympics

Taken from Adam Mandel's lecture in 2011 Budapest at the congress on SCIO about work done at the 2008 Olympics



Adam Mandel was sent to China to work on the Chinese Athletes with the SCIO in 2007 till 2008. He presented his work for the first time in the 2011 International conference on the SCIO held in Budapest. Titled "The Greatest Story Never Told" he showed the audience incredible awe inspiring details of wondrous results with the SCIO. This is a brief summary of his 3 part lecture now available from IMUNE.

Adam talked about testosterone boosting by voltammetry streaming therapy of the SCIO. The SCIO is a

http://www.downloads.imune.net/medicalbooks/978-615-5169-13-7%20Injury%20and%20Sport%20Medicine.pdf

<u>https://www.youtube.com/watch?v=C7\_gf-fWAvM</u> Adam Mandal on china work part 1 <u>https://www.youtube.com/watch?v=nDAAEhM6p7k</u> Adam Mandal on china part 2 <u>https://www.youtube.com/watch?v=3flhGNBoV\_8</u> part 3

# 国家体育总局运动医学研究所

August 10, 2008

Dear Professor Nelson,

First of all, I am pleased to inform you that it was a very successful project accomplished by the Beijing Sports Medicine Hospital and the team lead by Mr. Victor Ke in the period from May to August, 2008. We have achieved an outstanding result beyond our expectation in the health management of Chinese Olympic Athletes.

In the mean time, I would like to express my personal appreciation for your wisdom and contributions in the area of health management.

I would like to take this opportunity to invite you to visit Beijing at your convenience.

Professor Li Guo Ping

President of Beijing Sports Medicine Hospital General Director of National Institute of Sports Medicine (NISM) Chief Medical Officer of Chinese Olympic Committee (COC) President of Chinese Association of Sports Medicine (CASM) Vice President of Asian Federation of Sports Medicine (AFSM) Executive Committee Member of International Federation of Sports Medicine (FIMS) Chief Editor of Chinese Journal of Sports Medicine (CJSM)

# 中华人民共和国

PEOPLE'S REPUBLIC OF CHINA 医疗器械注册证 REGISTRATION CERTIFICATE FOR MEDICAL DEVICE

注册号: 国食药监械(进)字2012第2213148号 REG.NO.: SFDA(1)20122213148

匈牙利 MAITREYA KFT.:

你单位生产的生物反馈仪,经审查,符合医疗 器械产品市场准入规定,准许注册。自批准之日起 有效期至二零一六年八月二十八日。 特出证明

特此证明。

### MAITREYA KFT.:

This is to certify that the medical product **Biofeedback Device** manufactured by your company has been inspected by our office and is permitted to register on the Chinese market. This registration certificate is valid till August 28, 2016.

## 国家食品药品监督管理局

State Food and Drug Administration

2012年8月29日

No. 1206926

附 件: 医疗器械产品注册登记表

ATTACHMENT: MEDICAL DEVICE REGISTRATION RECORD

# **Project Nahinga**

There have been a host of different other studies conducted on this technology, including Project Nahinga, in Mozambique and South Africa.

http://www.downloads.imune.net/journals/2008%20The%20NaHinga%20Project/

Nahinga – Immuno Compromised Protocol

#### NaHinga IMMUNO COMPROMISED PROTOCOL

First Avoid All White Processed Sugar This means all dextrose sugar products including candy, cola, doughnuts, etc. You can have all of the levulose fructose products you want, this means any fruit of fruit sugar

Second Avoid all Foods Boiled or Fried in Oil. Use at least three tablespoons a day of uncooked natural cold processed oil such as olive oil, safflower, sunflower, soybean oil. Have some five servings a day of fresh and raw fruits or vegetables.

Third Reduce Stress and Enjoy Life Do at least fifteen minutes twice a day of quiet meditation using affirmations, and imagery of your immune system working.

Exercise for twenty minutes at least four times a week work to a sweat and breathe deeply, use the thymus tap

Take the Hemo-A twice a day with other supplements Hemo-A has Yerba Santa, Phytolacca, Chinese Cucumis Sativa, Trifolium, herring sperm and other sarcodes of Thymus adenoids tonsils and appendix use 500 mg Vitamin C, 15, mg Zinc, 4 pills of Oxygen Stimulator at bed use Golden Seal, Aloe Vera, Lentil, Mustard, Tumeric, Curry, Paprika Sesame seeds, and use Sambuca

> AVOID ANTI-BIOTICS use Probiotics Actimel, Activa, etc Twice a day



### ELECTRICAL REACTIVITY AS A PRESCREEN OF HIV INFECTION PATIENTS

By: Nagy K., Nelson W., Barabas E., Balazs E. Varkonyi V., Horvath A Study Site National Institute of Dermato-Venereology, Budapest, Hungary 1994

## ABSTRACT

Twenty-two ambulatory AIDs patients in Budapest were studied for xrroid electrical reactivity readings. The electrical reactivity patterns and reactive substances that were in the highest faction of reactivity. In other words, those reactants that were statistically significant are compared in the groups of the AIDs patients taking the AZT as well as the AIDS patients that were treated with homeopathic and nutritional items. The purpose of the study was to analysis similarities and consistencies in their electrical reactivity patterns over the course of four measurements. This took place during the 4th, 5th, 6th and 7th month of 1994. During these months there was also a homeopathic and nutritional intervention done on several of these patients to see the effect on blood chemistry profiles denoting aids risks and the homeopathic and nutritional intervention are described in the article known as the comparative results.



# IMMUNOLOGICAL AND ELECTROPHYSIOLOGICAL REACTIVITY OF PATIENTS WITH HIV INFECTION

By: Nagy K., Nelson W., Barabas E., Balazs E. Varkonyi V., Horvath A. National Institute of Dermato-Venereology, Budapest, Hungary 1994

#### ABSTRACT

The diagnostic and prognostic value of electrophysiological reactivity patterns of HIV infected subjects were compared to complex immunological and virological laboratory markers.

Electrical responsiveness of 22 asymptomatic HIV infected patients were monitored monthly for a 4 month period by Quanta Med 4000, a sensitive multichannel diagnostic biofeedback machine, capable of measuring slight fluctuation of patients' brain waves and skin resistance, whilst the patients are sequentially exposed to a battery of numerous homeopathic nosodes and isodes. This process known as the Xrroid process.

Immunological and virological analysis included determination of CD cell count, HIV, HCV and CMV antibodies, HbsAG, and serum Beta 2-microglobulin (B2M) and Neopterin levels.

In the study - 4000 substances (items) were tested to determine which of these the patient had the most reaction to. The reactivity scores were than analyzed statistically. As a result a profile of electro-reaction is suggested, which considered characteristic of HIV disease in contrast to that of the normal subjects.

After initial evaluation a treatment protocol was designed. Half of the patients received a fatty acid blend and homeopathic medicaments throughout the test. Subjects were instructed to use the products daily and compliance was evaluated in the monthly interview. Reevaluation of electrophysiological reactivity and immunological tests were repeated every month.

H2M level was found decreased in 88 percent of those who received homeopathic treatment and in 50 percent it was found < 3 mg/L, compared to 27 percent of those untreated. Antibody level to CM was also found decreased in consequence of treatment. No changes, however could be detected in CD count and HbsAg and HBC antibody level.

The electrophysiological reactivity test provided information, which suggest that it can be used as a pre-diagnostic method, which might complete laboratory analysis. Complex homeopathy and individual nosode treatment shows some positive intervention.



# ANTIBIOTICS AS A PRIMARY CO-FACTOR IN AIDS PROGRESSION

By: William C. Nelson L.P.C.C. M.D. and Eva Toth M.D. Homeodiagnostica, Budapest, Hungary, Vörösmarty tér 3.

Presented at the 1st International Conference of the Mor Kaposi Research Foundation, Convergence of AIDS and Cancer Research, Budapest, Hungary August, 27, 1996

"If a Man sees a Wrong and does not Correct it, He is NOT a Man"

#### ABSTACT

The world has now recognized the demise of antibiotics. latrogenic damage, resistant strains, immunosuppression and dependency have now challenged the core of one of the prides of modern medicine. The vast marketing of antibiotics has left medicine with a severe crisis. Reductionistic research and philosophy has been used for financial reward of the chemical companies. These antibiotics have been shown to have a wide variety of deleterious side effects, including effects on the bowel flora. We also theorize about how this disruption of the bowel flora, could be a contributing cofactor to the AIDS epidemic.

The populations with the greatest antibiotic use are the highest risk for development of AIDS. A balanced bowel flora could be essential in defense against the virus propagation into the deadly disease. The antibiotics might then increase the progression of risk in the disease. This hypothesis, because of its' non Reductionistic complexity is difficult to challenge in a single study. Funding of such a study would also be extremely difficult, in light of the challenge to synthetic chemistry. This brief article is but an introduction to the concept. For further information please refer to the collection of studies in the Journal of the Medical Science of Homeopathy, special issue on AIDS and vituses.

Dr. Kofi Ghartey of Project Nahinga



We have seen six patient data files from Ghana where patients who had HIV in Blood test were cured and the tests have come back negative for HIV after the Nahinga protocol

In Budapest, Africa, and eleswhere we have seen several reports of cures and viral irradiction. This begs for further study and confirmation of results. But the research from project Nahinga seems interesting at least. We are continuing the search for more funds to do better studies and better controls, but till then we still seek to study and treat patients with this future orientated medicine. Dr. Amanda Velloen – Update on Project Nahinga

# Dr Amanda Velloen ~ Budapest Conference 2009 Update on Project Nahinga



Project Nahinga (bantu for the Angel that comes from the heavens to help us, the bantu name for Desire') has been spreading and many extreme success stories have shown fantastic results.

### PROGRESS

- Results in PHASE 1 -
- Up to 100% feeling better
- Average 65% improving in Critical Measures of HI V progression
- No side effects reported
- Symptom free
- No secondary infections
- Improved quality of life

**Critical Measures** 

- Subjects tested positive for HI Virus
- CD4 count
- Elisa test if available
- Viral Load test

Schedule for 2009

- Father John Mugaga in Kwa-Zulu Natal 1st Satellite
- October 2009 AIDS Children's homes
- November 2009 Brazzaville Congo, DRC, Angola, Nigeria
- November 2009 Kenya, Zimbabwe, Mozambique
- December 2009 Lesotho, Swaziland

After Desire has donated over 2 million dollars of equipment for our research we have shown saftey and efficacy and there appears to be a natural cure for this horrible disease on the future horizon

	DEPARTMENT OF	HEALTH		
Ö	Directorate: Radiation Control Private Bag X62 BELLVILLE 7535 Web: https://sites.google.com/s	Tel:(021) Fax:(021) site/radiationcon	9486162 9461589 troldoh/	
MEG-ANI PO Box 4 QUEENS 4070	N 5 <mark>762 SERVICES CC</mark> 0015 BURGH	Enquiries: Reference Date:	X-Ray devices: Other devices: 600/8851 30 January 2015	Ms N.P. de Koker Mr J.F. Uys Mr S. G. Diedericks
Attention	: Marianne Lilian Van Rooyen			
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- in agreement with the intended purpose of the device as reflected in the manufacturer's labelling and instructions for use (i.e. documentation required in terms of the certification process according to EC Directive 93/42/EEC or 90/385/EEC, whichever is applicable).
- The licence for each model remains valid only while the EC compliance documentation is valid.
- The safety and performance of all the licensed models remain the responsibility of the licence holder.
- Inspections may be performed to ascertain whether the licence conditions are being adhered to.

Yours faithfully

forDIRECTOR-GENERAL: HEALTH
# **Other Journal publications**



#### CONTENTS

Evidence for efficacy of CES in the treatment of FM Role of the patient in FM treatment Role of D-ribose in FM treatment Stress reduction in FM treatment with the EPF X Conclusion Expert commentary Five-year view Information resources Key issues References Affiliation

Lite Energies Research Institute. 25 10 Inages Arenue, Manut, FL 33133, USA Tat.: +1 305 402 1475/ +1 305 720 0501 Fax: +1 305 854 8954 migliola# mizedanting.com

Keywordos Alpha Stim<sup>®</sup>, cranial electrotheragy silimidation, D-ribose, EFPX, fibromyalgia, mechanism of CES, neuroclastic modallias, meumatology

# 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 multiplesclerosis, dysautonomias, 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 EPFX, 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.

#### Expert Rev. Med. Devices 4(4), 489-495 (2007)

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 (HCURES 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 hundreds 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

Advancing the development, dissemination and utilization of knowledge about applied psychophysiology and biofeedback to improve health and the quality of life through research, education and practice.

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Ausgabe 09/07

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Genehmigung

nachfolgende Artikel ist mit freundlicher

Dr. med. Rainer Mutschler und Dr. Andreas Kött

# Bioenergetische Diagnose und Therapie mit umweltmedizinischem Potenzial

Anwendungsmöglichkeiten des computergestützten Bioresonanzsystems SCIO

Seit zwei Jahren macht auch in Deutschland ein bieenergetische Hightech-System (SCIO) mehr und mehr von sich reden. Seine Attraktivität liegt in der Möglichkeit begründet, nicht nur die energetischen Störungen des Patienten zu diagnostizieren, sondern mit ihm gleichzeltig die meisten energetischen Therapien durchführen zu können. Dieser Beitrag befasst sich mit der Fragestellung, welche Optionen dieses System bietet, funktionelle Störungen, die durch Schadstoffe der Umwelt hervorgerufen werden, zu analysieren und zu behandeln. Zum besseren Verständnis wird zunächst in die Funktionsprinzipien dieses bieenergetischen Verfahrens eingeführt.



Abb. 1: Über das homotoxikologische Diagnosepigiramm lassen sich auch gezielt umwelttoxische Belgstungen des Patienten ermitteln.

SCIO ist ein hochkomplexes bioenergetisches Verfahren, dass wie ein Scanner energetische Muster eines Organismus erfasst und auf Grund vieler tausend registrierter Daten entsprechende Therapieansätze aufzeigt, die dann auch direkt durch das System angewandt werden können. Es vereinigt in sich viele Prinzipien der energetischen Medizin, weshalb es dem Therapeuten ein weites Spektrum an Diagnose- und Behandlungsmöglichkeiten bietet.

#### Biophysikalische Steuerung des Organismus

Das System macht sich das Grundprinzip der Quantenphysik zunutze, nach dem zu jedem Materieteilchen ein elektromagnetisches Feld gehört, also auch zu jeder Zelle, zu jedem Organ und zu jedem Erreger. Gestörte Schwingungsmuster deuten auf ein zunehmendes Krankheitsrisiko hin, das sich zu einem akuten oder auch chronischen Leiden auswachsen kann.

Mit dem System werden die energetische Reaktivität des Körpers, wie sich diese Reaktivität ändert, wenn der Körper Frequenzen von außen ausgesetzt wird, und mit welchem Resonanzvolumen der Organismus auf die Störung seines energetischen Netzwerks antwortet gemessen. Dieser Wirkungsmechanismus lässt sich mit einem Hai verdeutlichen, dem ein hochsensibles elektrisches Ortungssystem zur Verfügung steht, mit dem er Beute auf mehrere Kilometer Entfernung ausfindig machen kann, obwohl er diese weder sehen noch riechen oder hören kann. Aber wenn ein Fisch schwimmt, bewegt er sich im Wasser und verändert dadurch seine elektrischen Koordinaten, und diese Veränderung kann der Hai mittels seines Ortungssystems wahrnehmen.

Die Reaktivität eines Organismus wird in der Varhope-Analyse mit den Parametern Spannung (Volt, V), Stromstärke (Ampère, AI, Widerstand (Ohm, R), Oxidation und Hydratation (Sättigungsgrad freier Ionen mit Wasserstoffbzw. Sauerstoffatomen) bestimmt.

Insgesamt registriert das bioenergetische System die Reaktivität des Körpers über zwölf Elektroden, acht am Kopf und vier an Händen und Füßen. Da die gemessenen Werte auch in Beziehung zueinander gestellt werden, erhält man auf diese Weise 55 elektronische Funktionen, die den energetischen Zustand des Organismus beschreiben.

#### Resonanz-Test

In der Elektroakupunktur wird die bioenergetische Information einer Substanz auf die eindimensionale Bestimmung einer Frequenz reduziert und die Reaktivität des Organismus nur über den Hautwirderstandswert ermittelt. Indem bei der SCIO-Analyse die drei elektrischen Parameter (Spannung, Stromstärke und Widerstand) in Beziehungen gestellt und algorithmisch berechnet werden, erhält man eine dreidimensionale Darstellung des Frequenzmusters einer Substanz, was letztlich den Trivektoren entspricht, die die Substanzinformation in Wassermolekülen speichert. Folglich ist das hier vorgestellte System zum Teil technologisch umgesetzte Homöopathie.

Mit Hilfe die ser Technik wurden Frequenzmuster und Energielevel von rund 10 500 hom öopathisch aufbereiteter Substanzen inklusive Nosoden, Allersoden, Isoden, Sarkoden (Organpräparate), klassische und kombinierte Homöopathika digital erfasst. Unter ihnen befinden sich mehrere hundert Substanzen, die umwelttoxikologisch relevant sind: die so genannten "Isoden". Dieses sind industriell hergestellte Substanzen, z. B. Formaldehyd, Insektizide, Pestizide und PCB, die homöopathisch aufbereitet wurden. Durch die große Vielzahl der digital erfassten Frequenzmuster können allgemeine, aber auch spezifische Informationen getestet, Bereiche von energetischen Schwerpunkten bestimmt, die Reaktionen von Muskeln und anderen Organen und Organsystemen aufgezeichnet oder allergi-

Der

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#### Electrical stimulation in wound care





Electrical stimulation therapy in wounds involves the use of an externally applied current to create an electrical flow through the tissues. In recent years, there has been a renewed interest in using this as a treatment where wound healing is delayed and a range of sophisticated products have been developed to provide electrical flow through the tissues, although the exact mechanism for some of these effects is not known. This supplement explores the use of electrical stimulation in chronic wounds.



Page 75 of 269



# How Electric Brain Stimulation Relieves Depression

By <u>TRACI PEDERSEN</u> Associate News Editor Reviewed by John M. Grohol. Psv.D. on May 8, 2013





For many people who don't respond to standard <u>antidepressant</u> treatment, electric brain stimulation — known as <u>vacus</u> nerve stimulation — has been shown to effectively relieve severe symptoms of <u>depression</u>. But how exactly does it work?

Researchers at Washington University School of Medicine in St. Louis are beginning to discover how implanting these electronic stimulators lessens depression.

Their findings, published in the journal *Brain Stimulation*, reveal that <u>vagus</u> nerve stimulation causes changes in brain metabolism weeks or even months before patients feel relief from symptoms.

"Previous studies involving large numbers of people have demonstrated that many with treatment-resistant depression improve with <u>vagus</u> nerve stimulation," said first author Charles R. Conway, M.D., associate professor of psychiatry.

"But little is known about how this stimulation works to relieve depression. We focused on specific brain regions known to be connected to depression."

The study involved 13 people with treatment-resistant depression. Their symptoms had not improved after several months of treatment with as many as five different antidepressant <u>medications</u>. Most had been depressed for at least two years, but some had been clinically depressed for more than 20 years.

All of the patients underwent surgery to have a device inserted that would electronically stimulate the left <u>vagus</u> nerve, which runs down the side of the body from the brainstem to

# Research Shows Music Improves Brain Function



For most people music is an enjoyable, although momentary, form of entertainment. But for those who seriously practiced a musical instrument when they were young, perhaps when they played in a school orchestra or even a rock band, the musical experience can be something more. Recent research shows that a strong correlation exists between musical training for children and certain other mental abilities.





### Pain Control Feature Article

Reid Laurence Winick, DDS

#### Abstract

A double-blind placebo-controlled study was performed on 33 randomly selected dental patients to evaluate whether cranial electroblerapy stimulation (CES) is reliable procedure for reducing anxiety during routine dental procedures. The active CES treatment group was significantly less anxious than the placebo group at the conclusion of various dental procedures.

Received: October 13, 1998 Last Revisions: February 13, 1998 Accepted: April 14, 1998



# Cranial electrotherapy stimulation (CES): A safe and effective low cost means of anxiety control in a dental practice

Reducing patient anxiety always has been a concern in the practice of dentistry Today, dentists have a variety of modalities available to reduce patients' anxiety Typical examples include medication. electronic anesthesia, acupuncture, hypnosis, air-abrasion dental handpieces, and nitrous oxide Each has its advantages and disadvantages Concerning disadvantages, some are too expensive, some are too time-consuming, and some have a long learning curve. Others are limited by patients' medical conditions, or have lingering side effects after treatment

A popular dental anxiolytic is nitrous oxide, a gas of low anesthetic potency that is incapable of inducing deep levels of anesthesia if an adequate oxygen concentration is maintained ' Nitrous oxide induces a state of behavioral disinhibition, analgesia, and euphoria Physicians and dentists have long considered nitrous oxide to be a safe pharmacological agent Nevertheless there is some evidence that its excessive or prolonged use can damage the bone marrow and nervous system by interfering with the action of vitamin B

There have been reports of immunological and reproductive disturbances in health care professionals who are chronically exposed to nitrous oxide.<sup>1</sup> An elevated risk of spontaneous abortion has been seen among women who worked with nitrous oxide for three or more hours per week in offices not using scavenging equipment (relative risk = 2.6, 95 percent confidence interval 1.3-5.0. adjusted for age, smoking, and number of amalgams prepared per week), but not among those using nitrous oxide in offices with scavenging equipment.<sup>4</sup>

It has been known for some time that electrical stimulation effects physiological changes. In the 1800s dentists reported excellent results using crude electrical devices for pain control By the turn of this century, electrical devices were in widespread use to manage pain and to cure everything from cancer to impotency. The unrefined early electrical technologies and financial strength of the young pharmaceutical industry caused this form of therapy to fall into disrepute in the medical and dental profes-This left chemistry the sions. "master science" and, as such, fully responsible for treating all of mankind's ills.

Now that we are approaching the turn of another century, armed with a new foundation of scientific data about the potential role of biophysics, scientists and practitioners are reexamining the use of electromedical modalities <sup>6</sup> One of the results is that over the past 30 years, transcutaneous electrical nerve stimulation has become widely accepted by physicians and dentists as a means to control many forms of pain.

Alpha-Stim (Electromedical Products International Inc. Mineral Wells, TX) cranial electrotherapy stimulation (CES) technology appears to offer an easy to use. safe, and cost-effective treatment to reduce situational anxiety. Stanley et al. showed that CES

50 GENERAL DENTISTRY/JANUARY-FEBRUARY 1999

CURRENT THERAPEUTIC RESEARCH VOL. 51, NO. 2, FEDRUARY 1992

#### THE USE OF CRANIAL ELECTROTHERAPY STIMULATION TO BLOCK FEAR PERCEPTION IN PHOBIC PATIENTS

#### RAY B. SMITHI AND FRANK N. SHIROMOTO<sup>2</sup>

<sup>1</sup>Life Balance International, Draper, Utah and <sup>2</sup>Private Practice Consultant, Huntington Beach, California

#### ABSTRACT

Cranial electrotherapy stimulation (CES) involves small pulses of electrical current (1.5 mA or less) across the head. It is a known treatment for depression, anxiety, and insomnia. Chance clinical observations suggested that CES might be effective in reducing fear perception in phobic patients. This study was designed to investigate this possible effect. Thirty-one persons responded to public media announcements requesting subjects for a phobia treatment project. They were asked to imagine themselves in their worst phobic situation, then rate their fear on a scale from no fear to extreme fear. They were then given 30 minutes of CES, after which they were asked to frighten themselves again and to rate the fear as before. The patients were successful in generating a fear response, which, in turn, appeared to be mitigated by CES.

#### INTRODUCTION





Among the approaches for the treatment of fear in phobic patients, varied success has been claimed for biofeedback,<sup>1,2</sup> desensitization,<sup>3,4</sup> aversion relief,<sup>5</sup> and combinations of behavior and/or cognitive therapies,<sup>6</sup> including relaxation therapy.<sup>7</sup> All of these are time consuming and require great attention to detail by the patient and therapist alike.

The treatment of phobic patients can be a long and taxing process for the physician or other therapist. Among pharmaceutical approaches, antidepressant drugs are said to be of particular benefit,<sup>8</sup> as is at least one cardiovascular medication.<sup>9</sup> However, even the newer tricyclic antidepressants are not without their risk to the patient, requiring the physician to be conscientious in the regulation of dosage and alert to the numerous possible negative side effects.<sup>10</sup> They may also take days or weeks to begin to be effective.

Recently, the authors serendipitously observed that cranial electro-

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Address correspondence to: Ray B. Smith, Ph.D., Life Balance International, P.O. Box 672, Draper, Utah 84020. Received for publication on September 3, 1991. Printed in the U.S.A.



# Amping Up Brain Function: Trans-cranial Stimulation Shows Promise in Speeding up Learning: Scientific American

#### Posted on August 20, 2012 by John

Another group of researchers hot on the trail how tDCS might be used to enhance brain function is the (non-profit) Mind Research Network of Albuquerque, NM. A lot of their work is funded by NiH, but what I've seen around their tDCS research pertains to increasing soldier's ability to detect danger, and is funded by DOA (2010 Research Report pdf) Unfortunately I was not able to find a full version of the paper not behind a pay wall. The abstract is here and from a Scientific America article...

Subjects definitely register the stimulation, but it is not unpleasant. "It feels like a mild tickling or slight burning," says undergraduate student Lauren Bullard, who was one of the subjects in another study on TDCS and learning reported at the meeting, along with her mentors Jung and Michael Weisend and colleagues of the Mind Research Network in Albuquerque. "Afterward I feel more alert," she says.

Bullard and her co-authors sought to determine if they could measure any tangible changes in the brain after TDCS, which could explain how the treatment accelerates learning. The researchers looked for both functional changes in the brain (altered brain-wave activity) and physical changes (by examining MRI brain scans) after TDCS.

They used magnetoencephalography (MEG) to record magnetic fields (brain waves) produced by sensory stimulation (sound, touch and light, for example), while test subjects received TDCS. The researchers reported that TDCS gave a <u>six-times</u> baseline boost to the amplitude of a brain wave generated in response to stimulating a sensory nerve in the arm. The boost was not seen when mock TDCS was used, which produced a similar sensation on the scalp, but was ineffective in exciting brain tissue. The effect also persisted long after TDCS was stopped. The sensory-evoked brain wave remained 2.5 times greater than normal 50 minutes after TDCS. These results suggest that TDCS increases cerebral cortex excitability, thereby heightening arousal, increasing responses to sensory input, and accelerating information processing in cortical circuits.

Remarkably, MRI brain scans revealed clear structural changes in the brain as soon as five days after TDCS. Neurons in the cerebral cortex connect with one another to form circuits via massive bundles of nerve fibers (axons) buried deep below the brain's surface in "white matter tracts." The fiber bundles were found to be more robust and more highly organized after TDCS. No changes were seen on the opposite side of the brain that was not stimulated by the scalp electrodes.









### Clinical commentary

Epileptic Disord 2011; 13 (4): 435-40

# Mirth and laughter elicited during brain stimulation

#### Guadalupe Fernández-Baca Vaca<sup>1</sup>, Hans O Lüders<sup>1</sup>, Maysaa Merhi Basha<sup>2</sup>, Jonathan P Miller<sup>3</sup>

<sup>1</sup> Department of Neurology University Hospitals Case Medical Center, Case Western Reserve University, Cleveland

Department of Neurology Harper University Hospital, Wayne State University, Detroit <sup>3</sup> Department of Neurosurgery University Hospitals Case Medical Center, Case Western Reserve University, Cleveland, USA

ABSTRACT - There are few reports of laughter and/or mirth evoked by electrical stimulation of the brain. In this study, we present a patient with intractable epilepsy in whom mirth and laughter was consistently produced during stimulation of the left inferior frontal gyrus (opercular part) using stereotactically placed depth electrodes. A review of the literature shows that cortical sites that produce mirth when stimulated are located in the dominant hemisphere close to language areas or cortical negative motor

Key words: brain stimulation, cortical mapping, mirth, laughter, language

Received May 30, 2011; Accepted November 30, 2011

areas, negative motor areas, gelastic seizures

Arroyo et al. (1993) suggested that

the motor program of laughter and

the experience of mirth are dissoci-

ated. Based on their results, it was

concluded that laughter is repre-

sented in the anterior cingulate

gyrus and that mirth is a func-

Page 82 of 269

areas.

brain.



#### (pics inserted)

- Correspondence:
- Guadalupe Fernandez-Baca Vaca Epilepsy Center,
- Department of Neurology,
- University Hospital Case Medical Center, 11100 Euclid Ave,
- Lakeside 3200,
- Cleveland Ohio 44106, USA
- <guadalupe.fernandezbacavaca2 @uhhospitals.org>

Epileptic Disord, Vol. 13, No. 4, December 2011

Electrical stimulation in epileptic tion of the temporal lobe. This was later supported by results published patients undergoing pre-surgical evaluation with intracranial elecby Satow et al. (2003) and Sperli trodes is routinely performed to et al. (2006). Other reported data (Fried et al., 1998; Krolak-Salmon determine the location of eloquent cortical areas. This provides et al., 2006; Schmitt et al., 2006) showed that laughter with and witha unique opportunity to study the functional anatomy of the human out mirth can be provoked by stimulation of the frontal cortex; in the pre-supplementary sensorimo-Laughter and mirth have been stutor area (pre-SSMA), immediately died by researchers for centuries anterior to face and hand repreyet their neuronal correlates still remain poorly defined (Wild et al., sentation in the rostral part of the 2003). There are few reports of supplementary sensorimotor area (SSMA), and the superior frontal laughter and mirth provoked by electrical stimulation of the brain. gyrus.

In this manuscript, we present evidence that electrical stimulation of the left inferior frontal gyrus (opercular part) consistently elicited mirth and laughter in a patient with sterotactically placed depth electrodes for intractable epilepsy.

# FEKI – freiburger etik kommision -- Ethics Committee

In 2009 we received approval from feki, freiburger etik kommision, for a body of research that was conducted in Italy, Germany, Romania, Switzerland, France and United States of America.

feki was the ethics committee for the following clinical studies:

- VARHOPE Improvements in a Clinical Setting
- VARHOPE Large scale study Correction of aberrant body electric profiles such as voltage, amperage, resistance impedance, proton + electron pressure
- Verbal report of stress reduction A double-blind placebo-controlled study of the application of Eclosion EPFX/SCIO therapy for stress reduction
- A double-blind placebo-controlled study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session
- Double Blind Study of Sport Performance with the SCIO device versus Placebo control 2013 USA
- Trauma Sport Pain Electro Healing With SCIO-2013 USA
- MCES and Addiction Control a Dbl Blind Clinical Study -2013 USA
- SCIO's Effect on Body Osmosis2013 -USA
- Stimulating Eye Hand Coordination With SCIOVARHOPE Update 2013
- SCIO Effects on Oxidation/Oxygenation 2013
- TVEP reactivity scores to Allersode compounds measured 2013 USA
- TVEP reactivity scores to compounds measured update 2013 USA
- Voltammetric Sarcode Hormone Streaming of TestosteroneUpdate 2013 USA
- VARHOPE and EPR Validation Of the SCIO technology -2013 USA

TUV inspected and approved our research, including our feki approval obtained in 2009, and gave us our ce mark in 2010. We were also given medical device approval at the time.

### Need for Clinical Investigations

The following guidance documents were referenced regarding the Clinical Investigations Route:

 NB-MED/2.1/R1 "Guidance for the Application of: The Council Directive 90/385/EEC on Active Implantable Medical Devices [and] The Council Directive 93/42/EEC on Medical Devices" Section V "Devices intended for Clinical Investigations."

### Conduct of Clinical Investigations

The clinical study, in addition to being conducted under the above guidance, was also conducted in following these guidance documents and regulations:

- a) MDD 93/42/EEC Annex X Clinical Evaluation
- b) NB-MED/2.7/Rec3 Evaluation of Clinical Data
- c) ISO 14155 Clinical Investigations of Medical Devices for Human Subjects
- d) ICH 6 Guidance for Industry: Good Clinical Practice: Consolidated Guideline
- e) ICH 8 Guidance for Industry: General Considerations for Clinical Trials

f) ICH 9 Guidance for Industry: Statistical Principles for Clinical Trials

### Requirements

- i. Identification of Relevant Documents:
  - a. Copy of the letter of "no objection" (Approval Granted letter) and opinions/comments from the Ethics Committee. Note: This was the first submission to the Ethics Committee and this protocol has never been rejected.
  - b. Copy of the signed and dated Final Report.
  - c. Copy of letter of no objection from a European Competent Authority. The Romanian Competent Authority have received the application and have permitted the study.
- ii. Information to be checked
  - a. The determination of the device as non-significant risk (NSR) was approved on 16 November 2009 by the Freiburger Ethics Committee (feki).
  - b. Clinical Investigation Plan (CIP): the CIP used for the Clinical Study is the same that was submitted for approvals. Evidence of this is the Case Notes stored in the Office of the Regulatory Manager at the Sponsor are the same as the Clinical Study Protocol which was approved by the Freiburger Ethics Committee (feki).
    - i. The number of patients entered were: 151 TOTAL from the following testing sites (Seattle, Washington (USA), Paris (France), Speyer (Germany), Timisoara (Romania).
    - ii. Objectives of Investigation (in particular which Essential Requirements are being addressed):
      - ✓ (1) The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety;
      - (2) The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherently safe design and construction),
- where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated,
- inform users of the residual risks due to any shortcomings of the protection measures adopted,
- ✓ (3) The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such

a way that they are suitable for one or more of the functions referred to in Article 1 (2)(a), as specified by the manufacturer.

- ✓ (6) Any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.
- ✓ (10.1) Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.
- The Duration of the Investigation, per the approved protocol, was one 45minute Treatment with immediate follow-up within 3 hours after treatment. This was completed on all 150 patients and documented in the Case Notes.
- The end points in terms of diagnostic tools and patient assessment are stated in the approved Protocol under "Expected Results."
- The Inclusion and Exclusion criteria, as stated in the approved protocol, were all met so that the total 150 subjects all met the inclusion criteria.
- All parameters were followed as set up in the approved, original CIP.
- There were no changes to the parameters as set up in the approved, original CIP.
- One testing site (Seattle, Washington, USA) was outside the EU and the population, as shown in the inclusion/exclusion criteria, is equivalent to those for which the device will be used within the EU and other parts of the world were regulatory status is sought.





Maitreya Kft. Attn.: Richard Lloyd Kalvaria ter 2

1089 Budapest Hungary

Freiburg, December 15, 2009 FECI Code: 09/2120

# freiburger ethik-kommission\_ international



freiburger ethik-kommission international Mozartstr. 21 D-79104 Freiburg (Germany)

tel +49-(0) 761 - 3 20 07 fox +49-(0) 761 - 2 33 13

e-mail: graf@feki.com Internet: http://www.feki.com

Steuer-Nr.: 06424-43242 ID-Nr. DE 175296617

working according to -Rev. Decl. Helsinki -EG-SCP-Note for Guidance -ICH Guidelines for GCP -EN ISO 14155 -FDA Regulations (USA)

Dear Mr. Lloyd,

please find enclosed the original version of the following documents for the a.m. study without an invoice:

Grants Approval (x2)

Amendment # 1 (x1)

The feci wish the study great susses and thank you for the confidence you have shown us.

Yours sincerely,

Karin-A. Graf

Freiburger Ethik-Kommission GmbH Geschäftsführer: Karln A. Graf Amtsgericht Freiburg I.Br. HRB 5010

Founder Prof. Dr. med. Dr. rer. nat. Hans Peter Graf Radiologist and Physicist Master of advanced studies in applied ethics ( MAE )



# freiburger ethik-kommission international

IRB/IEC

International Mozartstr. 21

(Germany)

D-79104 Freiburg

freiburger ethik-kommission

tel +49-(0) 761 - 3 20 07 fax +49-(0) 761 - 2 33 13

Steuer-Nr.: 06424-43242 ID-Nr. DE 175296617

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e-mail: graf@fekl.com Internet: http://www.fekl.com

#### CERTIFICATE

Study Title:

A Double-Blind Placebo Controlled Study of the application of the SCIO Universal Electrophysiological Biofeedback System for Statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session Clinical Study Protocol Final Version Maitreya Kft. Revision 2.0 19 August 2009 CT-103-01

Study Code: CT-103-01

feci Code: 09/2120

Sponsor: Maitreya Kft.

Date of meeting: August 24, 2009 grants conditional approval

Place of meeting:

Mozartstrasse 21, 79104 Freiburg, Germany The proposed clinical study was reviewed on August 24th, 2009 with conditional approval. The freiburg ethics commission international (feci) has completed a careful review of the study protocol, the informed consent and other submitted documentation (see Review Request Form Documents page 2), in particular from ethical and legal points of view and

with impartial expertise. The regulations of the German Medical Device Law (MPG) § 20 Abs. 8 (MPG § 23) are reviewed and the bylaw about protection against damages caused by X-rays or radioactive material/ ionizing rays (§ 28g RöV and § 92 StrlSchV) have also been reviewed. (The sum insured stated in the documents fulfils the demands of risk assessment according to MPG).

The feci requests the submission of an interim report after one year (should the study last longer than one year) and a brief final report upon completion of the study.

In your letter (E-Mail) dated November 6th, 2009 you substantiate that all conditions have been fulfilled.

With regard to proposed clinical study, the feci hereby

💢 grants approval Prof. Hans-Peter Graf, Md PhD

Freiburg, November 16, 2009

Freiburger Ethik-Kommission GmbH Geschäftsführer: Karln A. Graf Amtsgericht Freiburg 1.8r. HRB 5010

Founder Prof. Dr. med. Dr. rer. nat. Hans Peter Graf Radiologist and Physicist Master of advanced studies in applied ethics ( MAE )



# freiburger ethik-kommission international

#### CERTIFICATE

Study Title: A Double-Blind Placebo Controlled Study of the application of the SCIO Universal Electrophysiological Biofeedback System for Statistical evaluation of the (Germany) SCIO's ability to increase Body Wellness after one 45-minute session Clinical Study Protocol **Final Version** Maitreya Kft. Revision 2.0 19 August 2009 CT-103-01 Study Code: CT-103-01 feci Code: 09/2120 Sponsor: Maitreya Kft. Date of meeting: August 24, 2009 grants conditional approval Mozartstrasse 21, 79104 Freiburg, Germany Place of meeting:

IRB/IEC itional Review Board/ rendent Ethics Committee

freiburger ethik-kommission international Mozartstr. 21 D-79104 Freiburg

tel +49-(0) 761 - 3 20 07 fax +49-(0) 761 - 2 33 13

e-mail: graf@feki.com internet: http://www.feki.com

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In your letter (E-Mail) dated November 6th, 2009 you substantiate that all conditions have been fulfilled.

With regard to proposed clinical study, the feci hereby

grants approval Prof. Hans-Peter Graf, Md PhD

Freiburg, November 16, 2009

Freiburger Ethik-Kommission CmbH Geschäftsführer: Kalin A. Graf Amtsgericht Freiburg I.Br. HRB 5010

Founder Prof. Dr. med. Dr. rer. nat. Hans Peter Graf Radiologist and Physicist Master of advanced studies in applied ethics ( MAE )



## freiburger ethik-kommission\_ international

#### CERTIFICATE

to an Amendment 1 of the clinical study

Study Title:

e: A Double-Blind Placebo Controlled Study of the application of the SCIO Universal Electrophysiological Biofeedback System for Statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session Clinical Study Protocol Final Version Maitreya Kft. Revision 2.0 19 August 2009 CT-103-01

Study Code:

feci Code: 09/2120

Sponsor: Maitreya Kft.

Date of meeting: August 24, 2009 grants conditional approval November 16, 2009 grants approval November 16, 2009 amendment 1

CT-103-01

Place of meeting: Mozartstrasse 21, 79104 Freiburg, Germany

The freiburg ethics commission international (feci) has reviewed the protocol amendment # 1 – Clinical Study Protocol Revision 2.2, dated October, 2009 (Patient Informed Consent Form English included) – under consideration of the relevant protocol and accompanying documentation according to ethical, legal and medical-scientific points of view, and with impartial expertise. The regulations of the German Medical Device Law (MPG) § 20 Abs. 8 (MPG § 23) and the bylaw about protection against damages caused by X-rays or radioactive material/ionizing rays (§ 28g RöV and § 92 StrlSchV) have also been reviewed. (The sum insured stated in the documents fulfils the demands of risk assessment according to MPG).

With regard to proposed amendment, the feci hereby

grants approval Prof. Hans-Peter Graf MD PhD Freiburger Ethik-Kommission Grubh Geschäftsführer: Karin A/Gro Amtsgericht Freiburg 1,8/. HRB 5010

Freiburg, November 16, 2009

Founder Prof. Dr. med. Dr. rer. nat. Hans Peter Graf Radiologist and Physicist Master of advanced studies in applied ethics ( MAE )

#### IRB/IEC Institutional Review Board/ Independent Ethics Committee

freiburger ethik-kommission International Mozartstr. 21 D-79104 Freiburg (Germany)

tel +49-(0) 761 - 3 20 07 fax +49-(0) 761 - 2 33 13

e-mall: graf@feki.com Internet: http://www.feki.com

Steuer-Nr.: 06424-43242 ID-Nr. DE 175296617

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# VARHOPE (Voltage, Amperage, Resistance, Oxidation, Hydration, Proton and Electron pressure, the body electric's vital signs) Clinical Journal

#### http://www.downloads.imune.net/journals/2010%20VARHOPE%20and%20Stress/pdf/

The VARHOPE Clinical Journal (ISSN 2041-4293) published a series of studies sponsored by Maitreya Kft./Mandelay Kft. on various topics concerning charging the human battery, charged stability, stress reduction with the SCIO System.

# **VARHOPE** Improvements in a Clinical Setting

The first study we are going to discuss has taken place in Toronto, Canada, where the investigator, Jonathan Sargent, a SCIO therapist, did an evaluation of 100 patients of before and after VARHOPE readings. The results (published in this journal) showed significant changes after a two week therapy session.

This study shows three cases and an overview of one hundred cases.

# VARHOPE Improvements in a Clinical Setting

By Jonathan Sargent

ABSTRACT: We are made up of atoms that are mostly electrons and protons. The outer electrons of any atom or molecule never touch. The outer electrons of any atom or molecule never touch another set of electrons. The entire interaction is through electro-magnetic-static, quantic, or other interactive fields.

There is Electrical energy in the human body. The most simple factors of anything electrical are the volts amps and resistance. This makes up Ohms law of electronics, where Volts = Amps times Resistance. This is a correlation not an exact law. Oscillations of the volts and amps give us the frequency of a current. Fluctuations of these calculations can be used in virtual or mathematical ways to calculate other biological factors. There are norms of the body electric variables relative to age and lifestyle.

Thus the key Bio-electric factors of Volts Amps Resistance Hydration Oxidation and Proton versus Electron charge stability are measurable with the SCIO. Then device then using a cybernetic biofeedback loop can help to stabilize the VARHOPE of a client.

In thus study we assay the VARHOPE scores of several clients. In all cases there is a significant improvement in the bio-electric after a simple SCIO therapist lead session.

This study shows three cases and an overview of one hundred cases.

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A student coming through the beginner program brought this client to me. The student was living two hours north of the patient and was not comfortable working with his situation. the patient was diagnosed with HIV (Human Immunodeficiency Virus) in late 2004. When the patient came to me, it was mid March and he was exhibiting and feeling many symptoms.

The symptoms were ranging from skin lesions, skin discolouration, yellow eyes, and chronic fatigue. the patient was taking an AIDS (Aquired Immune Deficiency Syndrome) prescription drug, prescribed by his doctor, as well as seeing a nutritionist and having colonic sessions, 1-2 times a week. He was not feeling any results and felt that he was on his death bed. He was therefore in a fragile emotional state, which needed to be balanced immediately. As we were talking and unraveling the deep emotional core issues, the patient made a decision that his mother's lack of love for him was the strongest negative resonance. He believed that the tension was created due to his choice in sexual orientation and belief.

On February, 23<sup>rd</sup> 2006 the patient's HIV count was 327,021 copies/mL.

(data collected by his doctor). Demographic Male Born – 1960 Age - 46 Diagnosed with HIV and AIDS Prescription drug for AIDS Lifestyle – altered and healthy Water consumption – fair Employment – High school teacher Case

With this particular client it was a life and death situation right from the beginning. the patient's digestive system was compromised due to years of unhealthy eating, without the use of digestive enzymes. On our first session together, we helped each other to balance the emotional issues and help to build the immune system. Through stress management and organ stimulation, we worked with the lymphatic system, adenoids, appendix, tonsils, thymus, liver and spleen. These organs were gently stimulated through biofeedback therapy and the spiritual healing was balanced. NLP (Neuro Linguistic Programming) techniques were used to work with guilt and self esteem issues and in

addition, I added Auto zaps for AIDS and "feel good". I told the patient that if I were in his situation I would take a "detox bath", containing baking soda, Epsom salts, and hydrogen peroxide 3%, to help detox the skin. After a bath I would take a shower and rub my skin with coconut oil, to help bring back the moisture and oils to my skin.

He saw the benefit this would have for him. the patient mentioned that he was getting colonics done 1-2 times a week, but I noticed that he was neglecting to replace to vital digestive enzymes (probiotics) that his body was desperately searching for, this information was concluded from the extreme mal absorption issues appearing on the device. From the beginning of his first session it was clear there was an issue with blood, environmental, immune, inflammation, liver, and fungus.

It was determined at that time that we would have a 2 hour session once a week and if there was a concern of any kind, he could call and be seen right away. What I noticed after the first session with the patient is that his skin colour returned and he had a look in his eye of confidence, as if he found his path to wellness.

#### Continuing

the patient returned once a week for 7 months. Over this time we worked through the layers of stressors on the body and helped supply the proper nutrients needed. I had the patient bring several types of supplements from his nutritionist and checked the resonance according to his meridian flow and reaction. It was not long after the first session that the patient's skin began to clear up and he could return to work. His digestion and bowel movements improved greatly. This was a great relief to him, for the goal seemed to be in sight! As we proceeded through the process his body was now ready to start detoxing. At first I told him in this situation, I would do a lymphatic cleanse for 2 weeks, and then begin a liver cleanse that was supplied from a Hulda Clark website. Over 100 stones were released within his stool and lots of internal bowel congestion, that was blocking his main detox outlet.

Throughout this entire time I noticed that his VARHOPE scores were improving greatly per session, with the odd slip. The more we worked together the longer the varhopes would stay in tune. This whole process was very exciting for both of us, since at the outset of our meeting he had been sent home by his doctor to die. This alone was a traumatic event. It was a coaching and confidence building conversation, which was critical throughout the entire process.

Since I am not a doctor, I was strongly recommending that he see his doctor for check ups and routine blood checks. During this time his doctor would "forget to get his blood test done" and would not disclose his information. We couldent figure it out. Then the patient became angered by this and demanded that another blood test be taken and reported to him immediately. This alone was a feat of emotional confidence that was not the same the patient I first met, frail and scared of the unknown and what the future held. Two weeks passed and the patient arives in my office with a giant smile on his face. I ask him what he was so happy about. He handed me his blood test, not only from the recent blood test but also the "lost" blood results.

It read:

HIV count -

327,021 copies/mL, T-cell count 30 February, 2006 200,000 copies/mL, T-cell count 120 May, 2006 70,000 copies/mL, T-cell count 449 July, 2006

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This was a very exciting time for both of us since the marker for HIV activity is 50,000.

It meant that we have almost reached our goal! We then continued throughout the next couple months with more biofeedback sessions.

### Review

In reviewing this case I feel very confident in the direction of the therapy sessions. Other than the minor setbacks, which is natural in the healing process. The body needs time to heal and to detox as well. Over the 7 months that I was working with the patient, I saw a great improvement in his spiritual, physical and emotional state. This was a great joy to see that we can help with such a fatal dis-ease.

I watch as his confidence and feeling of self worth improved. This was a very good thing, since now he was able to enjoy life to the fullest. I am looking forward to seeing the patient again in the future and see if there is any decline in overall state.

My advice to all new practitioners coming into the field of biofeedback is that we must listen to the body and not the "standard protocols". In my experience it is relevant that balancing the person instead of the dis-ease. This alone causes for less therapy sessions and more productive results. We must understand that every individual is different and special in there own way and it would be unfair to treat every person the same as the last.

Our job and duty as biofeedback therapist is to assist the body in balancing stressors, in turn making it easier for the body to heal its self. We make suggestions of lifestyle changes and coach them through their emotional issues, so that they can make their own decisions. I find it much easier to work with clients when you have them create their own conclusions and help them to learn about themselves on an even deeper level. We need to educate, so that when our clients leave us, they are able to maintain a state of health and not fall back into their previous lifestyle that brough them to us.



March 22, 2006

March 25, 2006



April 3, 2006











April 22, 2006



2000









May 10, 2006



Chart

May 15, 2006



Chart

May 17, 2006



May 29, 2006















June 26, 2006



July 20, 2006







July 28, 2006



August 8, 2006









August 15, 2006





August 25, 2006





2000

September 1, 2006





# The patient

This particular client was sent by a past client that found very good results working with me and the system. The patient was diagnosed with lung cancer at the age of 74.

He had decided that chemo therapy and radiation were not the answer for him. Over the course of five months we only saw the patient five times. This is not a lot of sessions, but this was the only time that the patient could fit into his very busy schedule.

the patient was very hard to communicate with due to his small understanding of the English language. He was always accompanied by his daughter, who translated everything in to his native tongue. (Italian)

# Demographics

Born – 1931 Male Diagnosed with lung cancer Six different Prescription drugs Water Consumption – fair Employment – Retired

### Case

As I looked into the patient's case, it was prevalent that virus, fungus and parasite activity was high within his body. One of the first things I noticed with the patient besides the large amount of pathogens present, was his Ph levels were acidic. Making it a perfect home for all pathogens to mutate and duplicate. These pathogens were highly concentrated within the lungs and bowels of the client. This is also where he was diagnosed with cancer. Was it possible the parasites were mistaken for tumors? Very possible, I then decided to work with this concern because cancer was not in high levels, compared to pathogen activity.

the patient's organs were also highly under stress due to his age and lack of previous care to his body. Degeneration was present, and he had a high reactance speed. His high reactance speed was telling me that his body did not recognize the pathogens as a threat; another good sign there was a possible wrong diagnoses.

# Continuing

Over the five months that I saw the patient I worked with what his body needed for that day, balancing all stresses one by one. In turn this would allow his body to heal itself much quicker, and understand what was happening. The sessions were also mostly centered around Rife therapy and zapping for pathogens.

Since there were a lot of emotional issues coming to the surface, it was clear that there were some things that need to be balanced within the NLP program as well. It was very exciting to see as the weeks and months pass, the patient responding very well and balanced on all levels.

Near the end of month five the patient went missing. I didn't hear from him for at least three (3) to four (4) weeks. It was making me worried, I decided to call his daughter and see what was happening. I was hoping for the best.

The answer was, "we didn't tell you?" my father went to get some radiation done and before the treatment they did another MRI scan. The "cancer" was gone! Gone!

### Review

To sum it all up, the patient was pleased with the sessions he received. It was amazing to see the traumatic things that were told to this particular client from his medical doctor without the proper research being gathered. Maybe if the medical world would be more accepting of biofeedback we could put an end to this "medicate or operate" system.

With a few lifestyle changes and a coaching process to deal with unspoken emotions, the results are amazing a significant. This technology of biofeedback is truly a leap towards a more productive medical system.

A few weeks after seeing the patient last, I decided to call his daughter. She had a tear in her eye and a frog in her throat. Her father went to the hospital for radiation. Before they perform the treatment it is standard protocol to administer another MRI, to find... THE TUMOR WAS GONE! How exciting is that! I was very impressed. Another person helped from biofeedback.



November 2<sup>nd</sup>, 2005










November 11<sup>th</sup>, 2005





March 3<sup>rd</sup>, 2006



# The patient

The patient was recommended to me by his brother. His bother found us on the internet. The patient had been diagnosed with Parkinson disease. He had experienced troubles with gambling and money management due to the side effects from the medications that he was currently taking and he had "the shakes".

When I first met the patient, he was in a very negative state. He could not hold still. Kicking and hand twitches were common. He was on three (3) different medications and was emotionally stressed. the patient is a retired hardware store owner, and had work very hard with several highly toxic chemicals on a regular basis

# Demographics

the patient Male Born – 1942 Age - 65 Diagnosed with Parkinson's Prescription drug for Parkinson's Lifestyle – fragile Water consumption – fair Employment – retired hardware store owner

# Case

The patient had been diagnosed with Parkinson's when I first met him. Sent to me by his brother, the patient did not know what to expect on his first visit. His thoughts were scattered and his emotions were high.

I did my best to guide the patient through the initial process in explaining what biofeedback was and how it works. the patient seemed to catch on quickly, and he was ready to try it out.

There was a high amount of heavy metals present, which told me that the nerves would be damaged and the myelin sheath would be gone for the most part. Chemical toxins were also high with in his blood. On the first session I always like to go through what the body is trying to say, nutrition, spinal, NLP, nelson report, all charts and patient super conscious reduction. This gives me a good idea of what is causing the most stress within the body and what the body is ready to deal with first.

Once I had my information it was very easy to find the path to wellness and the thread to dis-ease. With the patient it was all about the toxins running everywhere in his body. The homotoxicology screen was filled with red and endless supplies of toxins were present.

# Continuing

With this information I asked the patient how often his bowels movements were and if there was any pain. Once I had that information it was evident that his bowels needed to be detoxed before any toxins were released.

Most sessions were centered on detoxing the body, repairing the nerves and bringing back mental clarity, although every session was different then the last. After our first session with the patient, he held out his hands. Which were not shaking! He then said "I haven't been able to do this in 20 years"! I was amazed.

With more talking and coaching it was obvious the 30 years of working with toxic materials was the cause of his diagnosis of Parkinson's. And the side effects of his medications were the cause of his gambling addiction. Working with his doctor, the patient was able to come completely off his medications and the nutrition profile allowed the patient to have a nutritious lifestyle. Increasing the amount of water in his diet and using a cilantro pesto for heavy metal detox was essential to the patient regaining health and reversing the aging process.

# Review

In conclusion I would like to say that over 6 months and 11 sessions that the patient had we reached our goal! the patient was able to return back to the things he loved most. His sense of humor was back and he was able to play golf again with his brother. It was amazing to see the patient start as an individual sent home by his doctor to be a vegetable, into a strong willed, funny, and loving husband and brother. the patient was truly blessed to have come in contact with biofeedback and to receive the results he did. The patient is currently living out his retirement as he should, playing golf, laughing lots and loving life even more. His self-confidence has returned and his gambling has stopped.



November 3<sup>rd</sup>, 2005





November 11<sup>th</sup>, 2005



Chart

November 15<sup>th</sup>, 2005



November 22<sup>nd</sup>, 2005





December 16<sup>th</sup>, 2005









January 10<sup>th</sup>, 2005

January 23rd, 2006



February 7<sup>th</sup>, 2006



Chart

# Discussion

The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. We have seen hundreds of clients in our Clinic. this report shows 3 cases intimately. But in the other cases there is almost always some improvement in the VARHOPE indices are even one therapy. Of our clients visits, some 50 plus % show very low electro-physiological factors, some all below 30% normal. The cybernetic electro-physiological feedback loop is used to help the client reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (posttest) versus the pretest. The average improvement in electro-physiological VARHOPE factors is 5% per session. These clients report stress reduction and improved well-being as well.

Norms of patient voltage, amperage, resistance, capacitance, inductance, reactance, impedance, and proton electron balance, have all been established.

When we intake air and breathe we oxidate. This produces a shift up and down of our amperage. Oxidation is measured as the average shift in amperage over a measured set of time. Hydration is the shift of voltage over a set of time.

Proton pressure versus electron pressure is the measure of which is more plentiful in the body. Excess protons means an acid condition, excess electrons means alkainity. By measuring the electrical imbalance from the various electrodes of the SCIO we can measure the proton versus

electron pressure. A balance form is reported at 70 where there are equal numbers of electrons and protons. Below 70 is excess protons, above excess electrons. A variation of the ph scale.

The SCIO software will allow the Central Nervous System (CNS) of the patient to guide to stabilize electrical and vibrational divergence in your body. This is the cybernetic loop or biofeedback component of the system.

#### Important Note (This study had the following contributors:

Institution : International Medical University NE

**Ethics Committee Int IRB : Ethics International** 

#### Medical staff has supervised the overall study

Peer review committee for the International Journal of the Medical Science of Homeopathy has reviewed and accepted this study for publication.

The purpose of this study was to assay the safety and efficacy of a visit to a trained SCIO therapist, exacting statistics are not assayed beyond the simple questions of reported success. Thus this study points to further scientific studies of more refined statistics.)



# VARHOPE Large scale study – Correction of aberrant body electric profiles such as voltage, amperage, resistance impedance, proton + electron pressure

http://www.downloads.imune.net/journals/2010%20VARHOPE%20and%20Stress/pdf/

## http://www.downloads.imune.net/journals/2008%201%202%203%204%20The%20Large%20Scale% 20Study%20of%20the%20Scio/

This study demonstrates the safety and effective qualities of the SCIO device used in a large scale study. A large scale study of over 97,000 patients with over 320,000 patient visits reported their diseases. The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. Of the patient visits listed some 50 plus % (55,921) showed very low electro-physiological factors, below 30% normal. The cybernetic electro-physiological feedback loop was then used to help the patient reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (post-test) versus the pre-test. The average improvement in electro-physiological VARHOPE factors is 5%. These patients reported stress reduction and improved well-being as well.

### This study has been Edited and Validated By:

Mezei Iosif, Sarca Ovidiu Somlea Livia Consultant:

International Ethics, Lebedei 58,

Oradea, Romania

**Developed By:** 

## The Centro Ricerche of Prof. William Nelson University of Venice + Padova, Italy

This study was performed in the field by practicing Biofeedback technicians. Data was collected and the study supervised by the Ethics International Institutional Review Board of Romania. The Data analysis and study presentation is done By the The Centro Ricerche, University of Venice + Padova, Italy © Ethics International, 2007.

Correction of aberrant body electric profiles such as voltage, amperage, resistance impedance, proton + electron pressure,

Part of the Following:

#### Large Scale Study of the Safety and Efficacy of the SCIO Device

#### **Chief Editor:**

## Prof N. Vilmos

#### **Edited and Validated By:**

#### Page 119 of 269

#### Mezei Iosif, Sarca Ovidiu

#### Somlea Livia

#### **Consultant:**

#### International Ethics, Lebedei 58,

#### Oradea, Romania

Developed By:

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(This article is translated into English and Hungarian from the original Romanian)

#### Abstract

This study demonstrates the safety and effective qualities of the SCIO device used in a large scale study. A large scale study of over 97,000 patients with over 320,000 patient visits reported their diseases. The SCIO measures global electrical measures of the body. When there are abnormal measures of the electro-physiological factors, the device allows a feedback loop between the Central Nervous System (CNS) of the patient and the device. Of the patient visits listed some 50 plus % showed very low electro-physiological factors, below 30% normal. The cybernetic electro physiological feedback loop was then used to help the patient reduce stress and thus improve the electro-physiological factors. There was improvement in over 95% of the electro-physiological measures at the end of the session (posttest) versus the pretest. The average improvement in electro-physiological VARHOPE factors is 5%. These patients reported stress reduction and improved well-being as well.

#### Introduction

#### Overview

This Large scale research was designed to produce a extensive study of people with a wide variety of diseases to see who gets or feels better while using the SCIO for stress reduction and patient monitoring. The SCIO is a biofeedback Universal Electro-Physiological Medical apparatus. The device is registered in Europe, America, Canada, S Africa, Australia, S. America, Mexico and elsewhere.

The traditional software is fully registered. Some additional functions where determined by the manufacturer to be worthy of evaluation. Thus a study was necessary to determine safety and efficacy. (As a result of these studies these additional functions are now registered within the EC)An European ethics committee was officially registered and governmental permission attained to do the insignificant risk study. Qualified registered and or licensed Biofeedback therapists where enlisted to perform the study. Therapists were enrolled from all over the world including N. America, Europe, Africa, Australia, Asia, and S. America. They were trained in the aspects of the study and how to

attain informed consent and transmit the results to the ethics committee or IRB (Institutional Review Board).

2,569 therapists enlisted in the study. There were 98,760 patients. 69% had more than one visit. 43% had over two visits. There were over 320,000 patient visits recorded. The therapists were trained and supervised by medical staff. They were to perform the SCIO therapy and analysis. They were to report any medical suspected or confirmed diagnosis. Therapists personnel are not to diagnose outside of the realm of their scope of practice. Then the therapist is to inquire on any reported changes during the meeting and on follow-ups any measured variations. It must be pointed out that the Therapists were free to do any additional therapies they wish such as homeopathy, nutrition, exercise, etc. Therapists were told to not recommend synthetic drugs.

Thus the evaluation was not reduced to just the device but to the total effect of seeing a SCIO therapist.

• Part 1. The emphasis was on substantiating safety followed by efficacy of the SCIO.

• Part 2. Proving the efficacy of the SCIO on normalizing the electro-physiological factors Methods and Materials:

### **SCIO Device:**

The SCIO is an evoked potential Universal Electro-Physiological Medical device that measures how a person reacts to items. It is designed to measure electro-physiological factors. Biofeedback is used for stress reduction and muscular re-education.

The SCIO measure global electrical measures of the body. Norms of measurement can only be assayed on an individual piece of equipment. The nature of the electrodes, the size or surface area of measurement, age and personal demographics, the reading mechanism etc. The SCIO has been registered in many countries and has been legally sold for over two decades. After thousands of patients tested with this device in the late 1980s, norms of the electrical parameters have been set. Norms of patient voltage, amperage, resistance, capacitance, inductance, reactance, impedance, and proton electron balance, have all been established.

When we intake air and breathe we oxidate. This produces a shift up and down of our amperage.

Oxidation is measured as the average shift in amperage over a measured set of time. Hydration is the shift of voltage over a set of time.

Proton pressure versus electron pressure is the measure of which is more plentiful in the body. Excess protons means an acid condition, excess electrons means alkainity. By measuring the electrical imbalance from the various electrodes of the SCIO we can measure the proton versus electron pressure. A balance form is reported at 70 where there are equal numbers of electrons and protons. Below 70 is excess protons, above excess electrons. A variation of the ph scale. The SCIO software will allow the Central Nervous System (CNS) of the patient to guide to stabilize electrical and vibrational divergence in your body. This is the cybernetic loop or biofeedback component of the system. For complete functional details and pictures, see appendix.

**Basic Software Design:** The SCIO software is designed for electro-physiological connection to the patient to allow electro-physiological and rectification of subtle aberrance of the body electric. The feedback loop is established by measuring the electro-physiological factors, feeding them back to the CNS and re-measuring the changes, feeding them back to the CNS, and on and on till a satisfied result is attained for the day.

#### **VARHOPE Scores**

As previously described, there are norms set for the Body electro-physiological measures. Since these measure are relative to age, sex, and other demographics, a percentage of the norm is used on the report. There is a degree of inaccuracy as well. norms are reported loosely as above 80%. In this series of tests when the percentages of the global VARHOPE are all below 30%, the device patient records were used to report the posttest or after therapy results.

#### SOC Index (Library Function stressor questionnaire):

The SCIO interview opens with a behavioral medicine interview. This is called the SOC Index. Named after the work of Samuel Hahnemann the father of homeopathy, he said that the body heals itself with it's innate knowledge. But the patient can suppress or obstruct the healing process with some behavior. Hahnemann said that the worst way to interfere with the healing natural process was allopathy or synthetic drugs. Theses upset the natural healing process by unnatural intervention and regulation disturbance. Other ways to Suppress or Obstruct the Cure are smoking, mercury amalgams, stress, lack of water, exercise and many others. This behavioral survey then gives an index of SOC.

The scores relate to the risk of Suppression and Obstruction to the natural Cure. The higher the scores the more the Suppression and or Obstruction. The scores of 100 or lower are ideal. A copy of the SOC index questions appear in the appendix.

#### **Study Technicians:**

The study technicians were educated and supervised by medical officers. The study technicians were to execute the SCIO therapy and analysis. All were trained to the standards of the International Medical University of Natural Education. Therapists from all over the world including N. America, Europe, Africa, Australia, Asia, S. America and elsewhere were enlisted to perform the study according to the 1951 Helsinki study ethics regulations, since modified several times.

They were to chronicle any medical suspected or confirmed diagnosis. Therapists personnel are not to diagnose outside of the realm of their scope of practice. Then the study technician is to inquire on any disclosed observations during the test and on follow-ups report any measured changes.

To test the device as subspace against the placebo effect, two of the 2,500+ therapists were given placebo SCIO devices that were totally outwardly the same but were not functional. These two blind therapists were then assigned 35 patients each (only 63 showed). This was to assess the double blind factor of the placebo effect as compared to the device. Thus the studied groups were

A. Placebo group, and B SCIO group.

Cross placebo group manipulation was used to further evaluate the effect.

Important Questions : these are the key questions of the study

- 1. Define Diseases or Patient Concerns
- 2. Percentage of Improvement in Symptoms
- 3. Percentage of Improvement in Feeling Better
- 4. Percentage of Improvement Measured

- 5. Percentage of Improvement in Stress Reduction
- 6. Percentage of Improvement in SOC Behavior
- 7. What Measured+How (relevant measures to the patient's health situation)

8. If Patient worsened please describe in detail involving SOC\_

After the patient visit is was complete the data was e-mailed to the Ethics Committee or IRB for storage and then analysis. This maneuver minimized the risk of data loss or tampering. Case studies were reported separately in the disease analysis.

Results:

Before we review the direct disease improvement profiles, we need to review the overall results.

The first most basic of question in the results is the basic feedback of the generic patient conditions.

- 1. Percentage of Improvement in Symptoms
- 2. Percentage of Improvement in Feeling Better
- 3. Percentage of Improvement Measured
- 4. Percentage of Improvement in Stress Reduction
- 5. Percentage of Improvement in SOC Behavior

The SOC index gives us great insight to this study. Each disease has a different cut off where the ability of the SCIO to help was compromised. As a general index scores of 200 + where much less successful.

The electro-physiological aberrant group total number of patients was 55,921

SCIO Harness Patients, 55,921 Patients

#### OVERALL ASSESSMENT

A. Placebo Group- 63 cases with a Dbl Blind System and no Treatment

There were no cases of patients who reported a negative Improvement.

There were

- 19 cases reporting no improvement of Symptoms, 30% of group
- 12 cases reporting no improvement in feeling better, 19% of group
- 13 cases reporting no improvement in stress reduction 20% of group
- 12%--- Percentage of Improvement in Symptoms
- 15%--- Percentage of Improvement in Feeling Better
- 2%---. Percentage of Improvement Measured
- 12%-- Percentage of Improvement in Stress Reduction
- 3%---- Percentage of Improvement in SOC Behavior

#### B. SCIO Treatment 163,870 patient visits

There were 658 cases of patients who reported a negative Improvement.

There were

- 512 cases reporting no improvement of Symptoms, .003% of group
- 759 cases reporting no improvement in feeling better, .004% of group
- 460 cases reporting no improvement in stress reduction .002% of group
- 65%--- Percentage of Improvement in Symptoms
- 56%--- Percentage of Improvement in Feeling Better
- 24%----.Percentage of Improvement Measured
- 53%-- Percentage of Improvement in Stress Reduction
- 20%----Percentage of Improvement in SOC Behavior

There was an overall 43% average improvement in the VARHOPE score from the therapy on each visit. There was an additional improvement on pursuing visits.



http://www.downloads.imune.net/medicalbooks/978-615-5169-17-5%20VARHOPE%20(Voltage,%20Amperage,%20Resistance,%20Oxidation,%20Hydration,%20Proton %20and%20Electron%20pressure,%20the%20body%20electric's%20vital%20signs).pdf

# Pre and Post SCIO Therapy Electro-Physiological percentages

#### SCIO Treatment 163,870 patient visits

	Pre	Post
Voltage	25	33
Amperage	21	27
Resistance	10	15
Hydration	27	36
Oxidation	28	35
SCIO Treatment 100,834 patient visits		
Below		
Proton vs Electron	50	57
SCIO Treatment 63,036 patient visits		
above		
Proton vs Electron	79	77

# Discussion

The results show significant improvement in symptoms and feeling better. The Collective results show a dramatic benefit to the SCIO therapist visit.

The Electro-physiological factors were slightly improved during the SCIO therapy. This is reported by most of our therapists. The Cybernetic Feedback loop of the SCIO to the CNS seems to be helpful in stabilizing the VARHOPE.

There is much more to the body electric than resistance. It is impossible to measure a frequency with a resistance device such as the Listen, Voll, Vega or other simple resistance devices. This makes for a very complicated fractal system that can be difficult to analyze. With a computer a vast amount of electrical data can be collected and analyzed. This can then allow for the beginning of a true energetic medicine. Below is an abbreviated list of electrical variables and their corresponding components that our SCIO can analyze in the short space of minutes in a clinical setting. The time of ionic exchange is approximately one hundredths of a sec. Thus it would be impossible for a person who wants to test a patient with a manual device.

#### \*articles in Promorpheus

As we pointed out in the Promorpheus, electricity as an electrical entity travels in the direction of, for example, your right thumb. Then for conduction of the electron, there is a magnetic field produced at 90°, and a static field will be produced at another 90°. This electromagnetic and electrostatic

combination and its effect on conductance and from conductance is the basis for understanding electrical phenomena.

The factors of the electrolyte in the body greatly affect the electrical nature of the body. The amount of minerals, liquids, oxygen, amino acids, fatty acids and others effect the nature of the electrolyte. So our total energetic medicine (beyond simple resistance variables) can offer us great insights into many factors of health. Since so much of energetic medicine is fixated in one channel resistance point probe techniques it is time for a quantum leap in the technology. In this article we will outline some basic aspects of energetic medicine for electroencephalographs electro cardiology and energetic medicine.

This article will outline the electron and its action. The photon link is outlined in the Promorpheus. French physicist Coulomb laid out a law, which states: "The force of attraction or repulsion between two charged bodies is directly proportional to the product of the charges and inversely proportional to the square of the distance between them."

Thus the force can be allowed in the following equation

F ~=~ {Q sub 1 ~TIMES~ Q sub 2} over D sup 2

The inverse square law is a dictum of four-dimensional physics. Our ten-dimensional model questions its pervasiveness.

Here Q represents the force of the charges, D is the distance, and F is the force in dynes. A coulomb of charge, C, is nearly 3 times 109 esu. The strength of an electrical field will have the equation

E ~=~ {9 ~TIMES~ 10 sup 9 ~TIMES~ q} over {R sup 2}

This is called the electrical potential. The potential at a point is equal to the work needed to bring one coulomb charge to the point from an infinite distance away. Biology will need to monitor this effect very closely.

An electric potential is thus work per unit of charge. Kinetic energy, which is equivalent to work, is measured in a relationship of force to distance. A gram that is moved at one centimeter per second of velocity is an erg. A kilogram that is moved at one meter per second is known as a joule.

When we have a joule per coulomb, this is known as a volt. One volt equals one joule divided by one coulomb. The volt is often a measure of potential energy. It is the difference between two points, between positive and negative charge; thus a six-volt battery with a potential difference of 6 joules or coulombs that can flow from one terminal to the other. Potential difference, thus, is an integral measurement of profound importance in biology and medicine.

If the surface of an item has a charge that is stored as potential energy, the ratio of charge to potential is called the capacitance of the body. The basic unit of capacitance is known as the farad, which is one coulomb per volt. If one coulomb of charge added to a body gives it potential of one volt, it has the capacitance of one farad. In a capacitor current is proportional to the rate of change of voltage.

Thus capacitance can be measured as a fluctuation in voltage (DV) over a qualitative time.

1~ Farad~ =~ {1~ Coulomb} over {1~ Volt}~~~~~ BOLD {Capacitance~ {dV} over {dT} ~=~ Amps}

The farad is a very large unit, measuring a lot of potential. Often in electronics we use micro-farads, or even pico-farads; a micro-farad being 10-6 farads and a pico-farad being 10-12 farads. By having

two sheets of a high conductor, such as metal, with an insulating material between them, we can produce a condenser or capacitor. In biology cellular forces will invoke pico-farads. Organismic forces must relate to and control micro-farads.

The capacitance of the capacitor is the amount of the electrical charge on its plate divided by the potential difference between its plates. This depends on several factors, such as the area of the plates. If the plates are made larger, greater charge can be put on them. The thickness of the insulating layer is important. The closer the plates are to one another, the greater the amount of charge that is held. It is the strength of the electric fields of the electric plates as they are brought closer together. In biology organs, cells, organ systems, and organisms must store charge to deal with metabolism and growth.

The material between the plates will have an influence on the capacitor. These insulators, or nonconductors between the plates, are also known as dielectrics. Biology is filled with membranes that act as storage entities. We have only to review neuronal axon transfer to see biocapacitance at work.

The dielectric constant of an insulating material is a relationship between the effect of the material and that of a vacuum between the plates. The dielectric constant of water is 80; the dielectric constant of air is 1.001, as compared to a vacuum. The dielectric constant of rubber is 2.5.

Water has such an enormous dielectric constant because the water molecule is already polarized, even if it is not in an electric field. One end of the water molecule is positive and the other negative, because of the dipole magnetic effect. Biology uses this concept of water to store and use energy.

The molecules can now rotate easily in the liquid state, and in response to the electric forces on them can readily produce strong layers of induced charge on its surfaces. Capacitance action is of extreme importance to biology.

When we move one coulomb of charge per second, this is known as an ampere. An amp is movement or quantity of charge. Movement of charge, amps, is the most important criteria of biology. This correlates to life force and indolamine production.

1~ Amp ~=~ 1~ Coulomb~ per~ second #phantom x #

Volts ~=~ Inductance~ @~ {d~ Amps} over {d~ Time} #phantom x #

Amps<sup>~</sup> = Capacitance<sup>~</sup> @<sup>~</sup> {d<sup>~</sup> Volts} over {d<sup>~</sup> Time}

Dr. Ohm, a German physicist, found that electric current in a conductor is directly proportional to the potential difference between its ends. Thus he generated Ohm's law, finding that the resistance of one ohm is generated in a conductor if the potential difference of one volt between its ends will cause a current of one ampere to flow through it. Thus we have generated and found

Ohm's law, which is

Amperes~ =~ Volts~ DIV~ Ohms #phantom x #

\or~ Volts~ =~ Amps~ TIMES~ Resistance

Ohm's law is not strictly adhered to in electrolytes, discharge of gasses, and semiconductors; nor is it followed perfectly applicable to biology, for there are many different factors that can affect it. Changing potentials over time causes instability in Ohm's law for biology. But in knowing an electrical system we must know the amperage, the voltage, and the resistance in order to be able to calculate variables more accurately. Ohm's law, when involved in quantic systems, is not precise, but still

shows the tendencies of electromotive force. For biology Ohm's law offers an invaluable systemic measuring system for easy bio force analysis.

Now let us look at some of the basic components and relationships of magnetic fields.

When strongly polarized molecules align, they induce stronger and stronger magnetic poles. An electric current flowing through a wire will also generate a magnetic field of 90 (right-hand rule).

The strength of the magnetic field created by a current is directly proportional to the strength of the current and inversely proportional to the distance from the wire. The formula for this will show that

Magnetic~ Fields~ left ( {Amp} over {2 pi d} right )

Thus a magnetic field strength can be measured in units of amperes per meter. Inductance is the factor measured for biological significance. Magnetic and paramagnetic forces can have strong implications in the long- and short-range forces of biology (see PROMORPHEUS).

A magnet near a stationary electric charge will not have an effect on it. If there is movement, then they have a natural influence on each other. Biology will need to be dynamic, and move constantly to use magnetic properties. The force of this influence is at right angles to both the velocity of the charge and the direction of the field. Stagnation is a magnet's enemy.

The magnitude of this force is

Force = Charge in Coulombs x Velocity in meters per second and Magnetic Force of Amperes per meter x the Permeability Factor through which the Magnetic Field permeates.

This permeability factor times the magnetic factor, which is amperes per meter, is known as the magnetic flux density, or the magnetic induction, and is expressed in Webers per square meter. In an inductor the voltage is proportional to the rate of change in the current.

Inductance~ TIMES~ {d~ Amps} over {d~ Time}~ =~ Volts #phantom x #

1~ Henry~ =~ 1~ Volt/~ (1~ Amp/1~ Sec) ~=~ 1~ Volt~ Second/Amp

These permeability factors are rated between that of the material and that of permeability of a vacuum. Materials that are high-ratio (that increase the flux density) are called ferro-magnetic; such as iron, cobalt, and nickel. Substances that are close to the ratio of 1, or other substances (which are very near to the relationship of the vacuum) are para-magnetic, and will contribute weakly, such as aluminum. There are substances like bismuth that are actually detrimental to the magnetic field. These are called diamagnetic, and their ratio is actually less than 1. Items which are non-magnetic will have no influence, and thus have a ratio of 1. Bismuth will have a place in biology, and is used in several homeopathics for energetic stability. Magnetic induction can be measured by changes in amperage over a qualitative analysis, such as the QXCI\* machine test.

This might be used to infer magnetic interaction, and thus, involvement of geopathic stress.

Thus we have outlined the concept of magnetic, static, and conductive forces, which are used to our understanding of the electrical nature of our homeopathic pharmaceuticals. By measuring the inductance, the dielectric constant and the conductance relationship, we can find an electrical profile for these various substances. This makes up an electrical fingerprint that allows us to calculate and plot its electrical nature. The trivector analysis is born. The long-range implications on energetic medicine are profound.

By charting the resistance, inductance, and dielectric constant of various homeopathic items we can get a trivector analysis of their electromagnetic fields. This trivector analysis gives us three vectors, which we will be able to apply to a three-dimensional space. Thus a variety of homeopathics have been analyzed for their trivector analysis. The dimension of time gives us a four-dimensional relation that with some superb mathematics we can extrapolate the six virtual dimensions using a trinary logic system.\*\*

Here we can see some of the effects that sarcodes, nosodes, allersodes and classic herbals have in their relationship to each other. This trivector analysis gives us a quality control factor for the electric field of a homeopathic item. In analyzing patients we can analyze serum in blood or personal field in a similar fashion. We can measure body pH from urine, blood, breath, etc., as well as redox capacity and body fluid resistance. Skin resistance readings can be taken at several points and easily averaged. Body voltage can be easily measured by dissimilar metals creating potential across the electrolyte capacity of the body, just as in a battery. Most proficient instruments choose to use silver and zinc (zinc because of its equi-potential for giving or receiving electrons, silver because of its great medicine history). Amperage is a correlate of voltage and resistance by placing similar metals in contact with the body (two silver probes contacting the frontal eminences). We can get an amperage reading. For our device Carbon electrodes where chosen for their ability to accept and donate electrons. Capacitance is measured by changes in voltage during a scheduled interview. Inductance can be calculated through changes in amperage over the same interview.

Resonant frequencies of the body can be calculated from the equation

Resonance~ Freq.~ =~ 10 sup 6 over sqrt {1~ -~ (` (\CAP) sup 2 ~+~ (IND) sup 2)}

From these readings we can now calculate a true metabolism chart to define a patient's overall health and energetic well-being.

The preliminary work has shown that where patients have valleys, or dips, in their fields, homeopathic peaks will be helpful. Work on this is just starting; more work, funding and time will be needed before we can find out if this is a viable technique for quality control and/or for homeopathic utilization. Now, with the help of the computer, matching remedies is high-tech and easy.

Another factor that we can use with this trivector analysis is that once we know the first three vectors, and the vector of time, we might be able to extrapolate the other six virtual dimensions.

If we know the four factors of conductance, capacitance, inductance and time, we might be able to extrapolate other dimensional effects from this four-dimensional type of field.

Biology needs to not only look into quantum physics but also needs to embrace an energetic philosophy as well. This seems complicated at first, but is easy with today's tools. Applying our right-hand rule and Ohm's Law to energetic medicine represents a dramatic quantum leap in energetic medicine which is significant to the field.

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First sent to the Library of Congress 1982

When English Homeopathy was challenged in the early 90's Dr. Nelson addressed the Parliament to help save Homeopathy

# Verbal report of stress reduction - A double-blind placebocontrolled study of the application of Eclosion EPFX/SCIO therapy for stress reduction clinical study protocol

#### http://www.downloads.imune.net/journals/2012%20Contemporary%20Research/pdf/

As we reported in the introduction, many people over value and over rate the verbal mind. They might even think that it is all. At any rate a second test was designed to evaluate stress reduction over a three month period by using a verbal assay of the stress of the patient. The verbal mind is only aware of very little of the body's activities and is easily confused and prone to suggestion.

A study of 240 patients, over a three month period started with a verbal questionnaire using the Beck's Stress inventory. A placebo group was designed and the test sites of Speyer, Germany and 5 test sites in Italy were chosen. Under medical doctor supervision the intervention was a series of treatments with the SCIO or the placebo device.

This study had two main flaws. 1. There was no on site study supervisor to properly determine that the placebo device was fully disabled from the active software. Later analysis determines that there was confusion and perhaps no placebo was used. 2. The study used only verbal subjective measures and was not properly designed to measure electro-physiological or medical data.

The study results showed no difference from placebo group to treatment group. There was 62.5 percent improvement in both groups. This is a significant improvement over no intervention. Most people do not improve such after 3 months of stress therapy. So there were results. But since there was no guarantee of an established placebo group a fourth study was conducted.

# A double-blind placebo-controlled study of the application of Eclosion EPFX/SCIO therapy for stress reduction clinical study protocol

Dr. Gianfranco Amaduzzi

Bologna, Italy			
Luigi Maselli			
Bari, Italy			
Rossella IanTorno			
Milano, Italy			
Giuseppe Mauger			
Catanid, Italy			
Dr. Rainer Mutschler			
Germany			
Kathrin Sollner,			
Germany			
2008 Ethics International			

#### PURPOSE OF STUDY

The purpose of this clinical study is to determine the efficacy of the ECLOSION Electro Physiological Feedback Xrroid (EPFX)/Scientific Consciousness Interface Operations System (SCIO) device, manufactured by ECLOSION KFT (the Company), in stress reduction by introducing low-level electromagnetic frequencies into an individual's body through electrodes attached to the person's wrists, ankles, and forehead to balance or harmonize and return to normal the optimal frequencies at which the body's cells and organs should resonate. This enables the body to strengthen, heal and expel the pathogens that propagate stress and its associated 'unwellness', consequently reducing stress and improving general health and function.

#### **EXPECTED RESULTS**

Following completion of the treatment phase with the ECLOSION EPFX/SCIO, it is anticipated that the subjects in the test group, relative to subjects in the control group, will show, where applicable:

• a reduction in systolic and/or diastolic blood pressure reading at rest.

•decreased resting heart rate (fewer beats per minute)

• a decreased score on the Perceived Stress Scale (PSS), implying a reduced level of overall stress.

•decreased scores on one or more of the six mood factors of the Profile of Mood States (POMS)

Standard questionnaire, implying improved mood states.

•decreased scores on the State and/or Trait Anxiety scales on the Spielberger's State-Trait

Anxiety Inventory (STAI), implying reduced anxiety levels and/or improved reactions to anxiety.

•a decreased score on the Beck Depression Inventory-II<sup>®</sup> (BDI-II<sup>®</sup>) implying reduced levels of depression.

•some degree of satisfaction with the overall study outcome.

•maintenance in improved outcome measure ratings at the one-month post-treatment phase measurement time point.

For subjects in the control group, it is expected that there will likely be some improvement in measured variables. That is, subjects in the control group will likely report some of the positive changes listed above for test group subjects. However, on average, any positive change in post-treatment measures for control subjects is expected to occur to a significantly lesser degree than for subjects in the test group.

This study will be a double-blind, placebo-controlled, randomized clinical trial designed to demonstrate safety and effectiveness of the Eclosion EPFX/SCIO.

#### TREATMENT GROUPS

There will be two subject groups in this clinical study, with as close as possible to an equal number of subjects assigned to each of the two groups, as follows:

Test group:

Subjects in the test group will receive the actual study treatment with an active, operational harness.

Control group:

Subjects in the control group will receive a 'fake' study treatment with a placebo harness that does not contain any active electrodes.

Apart from the distinction of whether or not the subject receives the study treatment with the true or placebo harness attached to the Eclosion EPFX/SCIO device, all subjects will adhere to all phases of the entire protocol design.

### BLINDING

This clinical study will be a double-blind design, such that neither the subject nor the investigator will be aware of to which group a subject has been assigned (test or placebo) until after the clinical study is complete.

Subjects will be randomly assigned to either Group A or to Group B, by the independent study Monitor. Subjects assigned to Group A will be treated with the EPFX/SCIO device A using Harness A and subjects assigned to Group B will be treated with the EPFX/SCIO device B using Harness B. Only the study Sponsor will know which label ('A' or 'B') corresponds to the actual (test) device and harness and which label corresponds to the sham (placebo) device and harness until the study is complete. The Sponsor will ensure this information is stored and maintained confidentially at the Sponsor's work site. This knowledge will not be shared with the investigators, subjects, or study Monitor until the final subject data file of the study has been completed and submitted for analysis.

The sham (placebo) equipment will be designed to have the same external physical appearance as the actual equipment. The difference is that the placebo harness will not be equipped internally with functional electrodes and the programming for the placebo device will output only blank matrices. Neither the actual (test) nor the sham (placebo) harness produces any detectable noise, heat, light or other sensation output, so this also won't be a distinguishing factor for subjects or the investigator between the test and placebo devices.

## STUDY PROCEDURE - STUDY QUALIFICATION EVALUATION

#### SIGNING OF INFORMED CONSENT FORM

The investigator will start by presenting and reviewing in detail the items in the informed consent form with the individual and answer any questions he or she may have. To proceed further in the study, the individual must willingly sign the informed consent form at this time.

## INCLUSION/EXCLUSION CRITERIA EVALUATION

After voluntarily signing the informed consent form, the subject will undergo the study qualification inclusion/exclusion criteria evaluation as follows.

#### **INCLUSION CRITERIA**

To be considered eligible for participation in this clinical study, a subject must satisfy each of the following "Inclusive Conditions" criteria.

Population: Individuals with Elevated Levels of Perceived Stress

Individuals in this study will be males and females who present with elevated levels of perceived stress as indicated by a total score of 25 or greater on the Perceived Stress Scale.

The Perceived Stress Scale (PSS) is a global measure of perceived stress that assesses the degree to which situations in an individual's life are appraised as stressful. The subject is asked to indicate how

often he or she felt or thought a certain way regarding14 items, following a 5-point Likert scale from 0 to 4, as follows: 0=never, 1=almost never, 2=sometimes, 3=fairly often, 4=very often.

The PSS total score is obtained by reversing the scores on seven positive items and then summing across all 14 items, for a possible total of 56.

The PSS was designed for use with samples with at least a junior high school education. The items are easy to understand and the response alternatives are simple to grasp. The questions are general in nature such that they are relatively free of content specific to any sub-population group.

Validation data for the 14-item PSS was collected from three samples: two groups of college students and one group of individuals enrolled in a smoking-cessation program. Mean scores on the PSS complete samples ranged from 23.18 to 25.0. There was no statistically significant difference in mean PSS score between males and females, and age was found to be unrelated to

PSS in all three samples.

Statistical evaluations found the PSS to have adequate internal and test-retest reliability and to be correlated in the expected manner with a range of self-report and behavioral criteria.

Additional information, including the complete PSS tool, can be found in Appendix C of this clinical study protocol. This includes the original article evaluating the scales, as follows: "Cohen, S., Kamarck, T., and Mermelstein, R. A Global Measure of Perceived Stress. Journal of Health and Social Behavior, 1983, Vol. 24 (December): 385-396."

•Able and willing to maintain regular and consistent diet, exercise and lifestyle regimens throughout the study.

•Able and willing to maintain current medication regimes throughout the study.

•Able and willing to abstain from partaking in treatments – conventional or alternative (such as hypnotherapy, acupuncture, massage therapy, etc.) - or over-the-counter or prescription medications, including herbal remedies, designed to reduce stress throughout the study, other than the EPFX/SCIO treatment that is part of this study.

•Between 18 and 65 years of age.

•Male or female.

•Females on adequate birth control or not of child-bearing years.

#### **EXCLUSION CRITERIA**

A subject will be considered ineligible for participation in this clinical study if he or she satisfies any one or more of the following exclusive conditions criteria.

•Total score of less than 25 on the Perceived Stress Scale.

•Stage 2 Hypertension (elevated blood pressure), defined by a systolic blood pressure level of 160 mmHg (millimeters of mercury) or higher OR a diastolic blood pressure level of 100 mmHg or higher, measured using a sphygmomanometer and averaged across three seated (resting) blood pressure readings taken at 10-minute intervals. The first measurement will be recorded after the subject has been at rest (seated) for about 10 minutes. The source for the Stage 2 Hypertension criteria is the Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High

Blood Pressure, American Heart Association Subjects taking antihypertensive (blood pressure lowering) drugs.

•Tachycardia, Bradycardia or Irregular Resting Heart Rate, defined as follows:

•Tachycardia: rapid or increased resting heart rate of greater than 100 beats per minute.

•Bradycardia: abnormally slow resting heart rate of less than 60 beats per minute.

•Irregular Resting Heart Rate: Irregular pattern of beats wherein beats are consistently missed across a 60-second period.

Resting Heart Rate - the number of times the heart beats per minute - will be measured at the wrist (radial artery), using the manual palpation method to feel the pulse - the rhythmic expansion and contraction (or throbbing) of an artery as blood is forced through it by the regular contractions of the heart. It is a measure of how hard the heart is working.

Heart rate through measurement of the pulse at the wrist will occur as follows:

1. The palm side of the subject's right hand is faced upwards.

2. The investigator places his or her index and middle fingers on the wrist, approximately ½-1 inch below the base of the hand.

3. The investigator presses his or her fingers down in the grove between the middle tendons and the outside bone until a throbbing sensation - the radial pulse – is felt.

4. The investigator counts the number of beats that occur in 60 seconds, using a watch with a second hand or digital second counter for accuracy.

Resting Heart Rate will be taken after the subject has been seated for 10 minutes. The subject's final recorded pre-treatment heart rate will be the average of three consecutive measurements, each taken about 5 minutes apart.

•Generalized Obesity, defined by a Body Mass Index (BMI) of 30 kg/m<sup>2</sup> or greater, according to the World Health Organization (WHO) and Center for Disease Control (CDC) criteria.

•Significant major stressful life events in the past 3 months likely to impact not only emotional but also physical health and wellness, defined by a score of 200 or greater on the Life Events Questionnaire (LEQ). The LEQ is contained in Appendix D.

•Significant major stressful life events known or anticipated to occur during the course of the study (i.e. the upcoming 3 months), defined by a score of 200 or greater on the Life Events Questionnaire, answered for known upcoming events such as a wedding, retirement, home move, etc.

•Type 1 diabetes.

•Any known heart condition(s), such as cardiac arrhythmias, congestive heart failure disease, myocardial infarction.

• Prior cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.

•Seizure disorder or family history of seizure disorder.

•Serious medical illness or condition: cancer; HIV, anorexia/bulimia.

•Serious head trauma

• Pregnant, breast feeding, or planning pregnancy prior to the end of study participation.

•Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in past two years.

• Excessive use of any illicit drug or alcohol on a regular basis.

•Infection or wound or any other external trauma in the areas to which the electrode bands of the EPFX device are to be attached.

•Developmental disability or cognitive impairment that would make it difficult for the subject to partake in the clinical study, including adequate comprehension of the informed consent form and ability to record the necessary measurements.

•Involvement in litigation and/or a worker's compensation claim and/or receiving disability benefits because of a stress-related or involved condition.

• Participation in a clinical study or other type of research in the past 30 days

### TREATMENT PROTOCOL ADMINISTRATION PROCEDURE

#### **PRE-TREATMENT PHASE**

The purpose of the pre-treatment phase is to record baseline measures against which post-treatment changes will be assessed, and to record demographic subject variables.

#### The following measures will be recorded during the pre-treatment administration phase:

#### **Physiological Measures**

1. Blood Pressure: Systolic and diastolic blood pressure will be measured in millimeters of mercury (mm Hg) using a sphygmomanometer. If the pre-treatment phase occurs on the same day as the study qualification evaluation phase, then blood pressure does not need to be measured again.

If the pre-treatment phase occurs on a different day to the study qualification evaluation phase, then the subject's blood pressure will be measured again at this time, three consecutive seated measurements, each ten minutes apart (as during the study qualification evaluation phase). Also as during the study qualification evaluation phase criteria, if the subject's three-measurement blood pressure average falls into the category of Stage 2 elevated high blood pressure (defined by a systolic blood pressure level of 160 mmHg or higher OR diastolic blood pressure of 100 mmHg or higher), then the subject shall be disqualified from further participation in the study at this time.

Else, the subject's blood pressure reading will be classified as follows:

Category	Systolic (mm Hg)		Diastolic (mm Hg)	
Normal	less than 120	and	less than 80	
Prehypertension	120–139	or	80–89	
Hypertension				
Stage1	140–159	or	90–99	

Source: The Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, American Heart Association

N.B.: When a person's systolic and diastolic pressures fall into Different categories, the higher category is used to classify the blood pressure status.

2. Resting Heart Rate: Resting heart rate - the number of times your heart beats per minute - will be measured at the wrist (radial artery), using the manual palpation method to feel the pulse. The precise methodology is detailed in the study qualification evaluation section.

If the pre-treatment phase occurs on the same day as the study qualification evaluation phase, then Resting Heart Rate does not need to be measured again.

If the pre-treatment phase occurs on a different day to the study qualification evaluation phase, then the subject's Resting Heart Rate will be measured again at this time, three consecutive seated measurements, each five minutes apart, with the first measurement occurring after the subject has been seated at rest for about 10 minutes (as during the study qualification evaluation phase). Also as during the study qualification evaluation phase criteria, if the subject's three-measurement Resting Heart Rate average falls into the bradycardia, tachycardia or irregular categories, then the subject shall be disqualified from further participation in the study at this time. Else, the subject's Resting Heart Rate will be recorded as the number of beats per minute. A Resting Heart Rate in the range of 60 - 90 beats per minute is considered in the normal range. The average Resting Heart Rate for a male is 70 beats per minute, and for a female is 75 beats per minute.

#### **Quality of Life Assessment Measures**

1. The Perceived Stress Scale (PSS): The 14-item PSS questionnaire will be administered during the pre-treatment assessment phase ONLY IF the study qualification evaluation phase has occurred on a different day. Else, the PSS score attained during the study qualification evaluation administration will hold at this time. If the PSS is re-administered during the pre-treatment assessment phase, also as per the study qualification evaluation phase criteria, if the subject's PSS total score is 25 or greater, indicative of excessively elevated levels of perceived stress, then the subject shall be disqualified from further participation in the study at this time.

Additional information about the PSS can be found in the study qualification evaluation section as well as in Appendix C of this clinical study protocol.

2. The Profile of Mood States (POMS) Standard: The POMS Standard is a factor-analytically derived inventory that measures six identifiable mood or affective states. The POMS is easy and quick to administer and score.

The POMS Standard is a self-report inventory that contains 65 items and takes about 10 minutes to complete. The items pertain to a series of mood states and the subject responds to each item based on how well each item describes his or her mood at the present time (right now). Each item is rated on a 5-point scale ranging from 'Not at all' to 'Extremely.' The complete POMS inventory is contained in Appendix E of this clinical study protocol document.

#### The POMS measures six identified mood factors:

- •Tension-Anxiety
- •Depression-Dejection
- Anger-Hostility
- •Vigor-Activity

### •Fatigue-Inertia

## •Confusion-Bewilderment

The POMS Standard includes psychiatric norms derived from a sample of 100 individuals, college student norms derived from 856 undergraduates, adult norms derived from a group of 400 volunteers aged 18-94, stratified by age, gender and race according to the 1990 U.S. census.

Since 1971, many research studies have provided evidence for the predictive and construct validity of the POMS Standard. Alpha coefficient and other studies have found the POMS Standard to exhibit a high satisfactory level of internal consistency, while product-moment correlations indicate a reasonable level of test-retest reliability. Factor analytic replications provide evidence of the factorial validity of the 6 mood factors, and an examination of the individual items defining each mood state supporting the content validity of the factor scores. Many recent studies continue to add to and affirm the validity of POMS normative sample. A bibliography of published research of almost 3000 research studies from 1964-2002 utilizing the POMS adds to and affirms the validity of the POMS normative sample.

## 3. Spielberger's State-Trait Anxiety Inventory (STAI):

The State-Trait Anxiety Inventory (STAI) provides a reliable measure of both temporary and dispositional anxiety in adults. First developed by Charles D. Spielberger in the 1960s, the STAI was later revised in 1983. The revised STAI is typically referred to as the STAI-Y. The STAI is a self-administered test and it is the most widely used measure of anxiety worldwide, used in both clinical and research settings. It is suitable for adults at a 6th grade reading level or above.

The STAI consists of 40 items divided into two subscales or domains: State Anxiety and Trait

Anxiety: State Anxiety assesses an individual's current level of anxiety – a more temporary state. The 20 items measuring State Anxiety ask subjects how they feel "right now, at this moment," and reflects situational factors that may influence anxiety levels. Subjects rate their feelings about each statement on a four-point intensity scale of 1=Not at all, 2=Somewhat, 3=Moderately So, and 4=Very Much So.

Trait Anxiety assesses an individual's anxiety proneness – a more general and long-standing quality of how an individual typically responds to stress. The 20 items measuring Trait Anxiety ask subjects how they "generally" feel. Subjects rate themselves on a four-point frequency scale of 1=Almost Never, 2=Sometimes, 3=Moderately So, and 4=Very Much So). Examples of items Trait

Anxiety scale items are "I feel at ease;" "I feel upset;" "I lack self-confidence."

Scoring: State and trait anxiety are scored separately. Each item is scored from 1-4, for a total inventory score range of 20 to 80, where 20 equals 'not feeling like that at all (state anxiety) or ever (trait anxiety)' and 80 equals 'feeling like that very much (state anxiety) or always (trait anxiety).' Essentially, the higher the score, the greater the level of anxiety.

Both percentile ranks and standard (T) scores are available for male and female working adults and stratified by age.

#### Statistical data:

Statistical analysis was conducted on a sample of almost 5,000 adults. For the Trait-anxiety scale, reliability coefficients ranged from .65 to .86, whereas the range for the State-anxiety scale was .16 to .62. This low level of stability for the State-anxiety scale is expected since responses to the items

on this scale are thought to reflect the influence of whatever transient situational factors exist at the time of testing.

Regarding validity, correlations between the STAI and other common measures of trait-anxiety are as follows: the Taylor Manifest Anxiety Scale: .80; the IPAT Anxiety Scale: .75; and the Multiple

Affect Adjective Check List: .52.

The STAI is contained in Appendix F of this clinical study protocol document. The STAI Manual is available upon request.

#### 4. Beck Depression Inventory®—II (BDI®–II):

Aaron T. Beck, Robert A. Steer, Gregory K. Brown

The Beck Depression Inventory<sup>®</sup>—II (BDI<sup>®</sup>–II) is in line with the depression criteria of the Diagnostic and Statistical Manual of Mental Health Disorders—Fourth Edition (DSM–IV). This new edition of the Beck Depression Inventory<sup>®</sup> is the most widely used instrument for detecting depression.

It takes about five minutes to complete and is demonstrated to be highly clinically sensitive to measurement and change.

The BDI–II consists of 21 items that assess the intensity of depression in clinical and normal patients. Each item is a list of four statements arranged in increasing severity about a particular symptom of depression, evaluated over the period of the past two weeks. It has been validated for samples aged13-80 years.

Reliability: Internal consistency (Cronbach's alpha) is .92 for clinical patients and .93 for non-clinical individuals. Test-retest reliability is .93.

Validity: Concurrent validity: two comparisons between BDI-II and its previous version resulted in correlations of .93 and .84, the latter using the take-home form. Other tests found BDI-II to be correlated with the Beck Hopelessness Scale (.68), Scale for Suicide Ideation (.37), Beck Anxiety Inventory (.60), Hamilton Psychiatric Rating Scale for Depression-Revised (.71), and Hamilton Rating Scale for Anxiety - Revised (.47).

Scoring: Most items on the BDI-II are rated on a 4-point scale ranging from 0 to 3. Several items have seven response options to discern differences in behavior or motivation. The BDI-II is scored by adding the ratings for the 21 items. The maximum total score is 63.

Clinical interpretation of total scores uses the following guidelines: 0 to 13 (minimal depression), 14 to 19 (mild depression), 20 to 28 (moderate depression), and 29 to 63 (severe depression). The BDI-II is contained in Appendix G of this clinical study protocol document.

#### TREATMENT PHASE MEASUREMENTS

The following measurements, using the tools and protocols established during the study qualification evaluation and pre-treatment assessment phases of the study, will occur at each of the following specified time points during the treatment course of the study.

There will be three during-study assessment time points, as follows:

- End of Month 1 (after the 8th study treatment)
- End of Month 2 (after the 12th study treatment)

• End of Month 3 (after the 14th study treatment)

At end of Months 1 and 2 assessment time points, the following measures will be recorded:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)

At end of Month 3 assessment time point, all of the measures recorded during the pre-treatment phase will again be recorded, as follows:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)
- Profile of Mood States (POMS) Standard
- Spielberger's State-Trait Anxiety Inventory (STAI)
- Beck Depression Inventory-II (BDI-II)
- Analyzing Stress in the Body Subject Questionnaire
- Revision of applicable drug, treatment and food/exercise behavior and history variables

• Satisfaction with overall study outcome rating: The subject will be asked to indicate how satisfied he or she is with any overall change in perceived level of stress attained following the treatment administration period with the ECLOSION EPFX/SCIO, using the following five-point scale:

- Very Satisfied
- Somewhat Satisfied
- Neither Satisfied nor Dissatisfied
- Not Very Satisfied
- Not at All Satisfied

• Subject perceived group assignment: The subject will indicate whether he or she believes to have been assigned to the treatment or placebo group, and why.

• Investigator perceived group assignment: The investigator will indicate whether he or she believes the subject to have been assigned to the treatment or placebo group, and why.

At any time that is warranted:

At any time that is warranted during the course of the study treatment administration phase, the subject and/or investigator may record the following:

•Adverse Reactions and Events: Any belief or perception that the subject may have experienced an adverse reaction or event as a result of the treatment with the ECLOSION EPFX/SCIO device.

A subject adverse reactions and events sheet will be completed by the Principal Investigator. Any necessary action will be taken. More detailed information on this process can be found in the section below titled: "REPORTING OF ADVERSE REACTIONS AND EVENTS."

•Additional Comments: A subject or investigator may record any comments related to study participation at any time, as desired.

#### **POST-TREATMENT PHASE**

The post-treatment phase will occur two weeks (14 days) following the final treatment administration with the ECLOSION EPFX/SCIO at the end of month three.

The purpose of the post-treatment assessment phase is to gain a sense of duration of treatment effect beyond the cessation of the treatment administration period. At the end of the two-week follow-up period, the following measures will be recorded:

- Blood pressure: three-reading average
- Resting Heart Rate: three-reading average
- Perceived Stress Scale (PSS)
- Profile of Mood States (POMS) Standard
- Spielberger's State-Trait Anxiety Inventory (STAI)
- Beck Depression Inventory (BDI-II)
- Analyzing Stress in the Body Subject Questionnaire



# A double-blind placebo-controlled study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45minute session

#### http://www.downloads.imune.net/journals/2010%20VARHOPE%20and%20Stress/pdf/

# Gage Tarrant, Bart Keough, Jane Summers, Jill Caravalho, Gene Helton, Lynn Smith and Julie Craker in Seattle, U.S.A.;

Jacqueline Jacques, Jean-Pierre Turblin, Adrian Muresan and Anne Préau in Paris, France;

Dr. Codruta Bacean and Dr. Onut Bacean in Timisoara, Romania;

#### Dr. Rainer Mutschler and Kathrin Sollner in Speyer, Germany.

#### Dr. Danis in Budapest, Hungary

In this study there were conclusive results of electro-physiological improvement. This study was conducted at five sites of approximately 40 subjects in each.

Under medical supervision the study was conducted in Budapest, Hungary, Timisoara, Romania, Seattle Washington, Speyer Germany, and Paris, France. Thus there were over 200 patients in this medical study.

A host of wellness tests and electro-physiological tests were performed. The results showed significant results with the electro-physiological factors of the VARHOPE. Thus the SCIO was proven to have significant action in improving the electro-physiological field of a patient.

In a review of the results. Patients with dysfunctional wellness of flexibility, blood pressure, and other factors can be improved with just one session. This was a tendency that was not statistically shown at a 5 alpha level, but was seen in the data.

So after this series of experimental tests and evaluation we can conclusively conclude that the SCIO is

- 1. Safe (no report of any significant risk)
- 2. Effective at long term stress reduction
- 3. Effective at short term electro-physiological, charge stability and stress reduction
- 4. Effective at making short term wellness changes

#### 5 August 2009 - 27 November 2009.

# Introduction

### BACKGROUND:

Stress is known to have many negative effects on multiple aspects of an individual's life. Stress can affect an individual's physical, cognitive, emotional and social well-being. We hypothesized that within one 45 minute biofeedback session, a measurable improvement in Body Wellness indicators can be achieved.

#### **OBJECTIVE:**

To evaluate whether a 45 minute session with the SCIO biofeedback device affects an individual's Body Wellness.

DESIGN: Randomized, double-blind, placebo controlled trial.

**SETTING AND PATIENTS**: 192 individuals with awareness of levels of perceived stress as well as injuries/pain, between 18 and 65 years of age, male or female, randomized into placebo and SCIO test groups, at private clinics at multi centered sites.

#### **INTERVENTION:**

Subjects were randomized to the test group (a 45 minute SCIO biofeedback system session) or placebo (SCIO, Maitreya Kft. www.qxsubspace.com)

#### **MEASURES:**

Pre and post measures as follows: Quality of Life Questionnaire, Energy Index Factor (systolic blood pressure left arm sitting x pulse), Grip Strength Test (measured in kilograms), Oxygenation Test, Flexibility Test (measured in inches in The USA and centimeters everywhere else), Memory Test, pH Test, VARHOPE scores (electrical measures within the device, as follows: voltage (V), amperage (A), resistance (R), hydration (H), oxygenation (O), proton pressure (P) and electron pressure (E)).

#### **RESULTS:**

Patients in SCIO group had greater VARHOPE scores than those in placebo group (p<0.005). The other indicators of Body Wellness were not statistically significant, but there are trends in the improvement levels between the Test and Control (Placebo) groups.

#### **CONCLUSIONS:**

The electrical parameters of VARHOPE can be improved by a 45 minute SCIO biofeedback session. However, it may require more SCIO biofeedback sessions for the other Body Wellness Indicators to be increased. Further studies are suggested.

Stress is known to have many negative effects on multiple aspects of an individual's life. Stress can affect an individual's physical, cognitive, emotional and social well-being. Different applications of biofeedback have been shown to be effective on stress management and health. Biofeedback is usually combined with a relaxation technique, applied before, during or after the biofeedback training. Studies have evaluated the effectiveness of biofeedback combined with a relaxation technique, EEG Biofeedback, EMG Biofeedback, and HRV Biofeedback and found them to have

positive results on reducing the stress burden and alleviating the conditions. In the fifth grade we learned that our bodies are made of atoms. And atoms are made mostly of protons, neutrons and electrons. There are great spaces between these electrons and protons and other atoms. Our bodies are made up mostly of electrons and their electromagnetic fields.

Things don't fall through other things because they are levitating on an energetic electrostatic fields. When you sit on a chair, you are not really touching it. You see, every atom is surrounded by a shell of electrons. This electron cloud presents a rather negative face to the world. Remember that like charges repel each other. When two atoms approach each other, their electron shells push back at each other, despite the fact that each atom's net charge is 0.

When two atoms come together and have empty spaces in their electron quantum shells, they will share electrons to fill in the spaces in both of their shells. The electrons really do go back and forth between atoms and they do so pretty fast. Outer Electrons tend to be kind of mobile, which is also a very nice feature of nature, since without it your walkman would not work or you would not be alive. It is the free electrons and protons in the body that allow life. Once both atoms' outer shells are full due to this electron sharing, they go back to their usual repulsive behavior. This, by the way, is how we get molecules, hormones, enzymes etc and the secret to understanding Chemistry, Biology, Medicine, Physiology etc. It's all about the electrons and protons, charged particles and vibration.

The electrons and atoms of our complex Fractal body obey quantum, QED, photonic, electromagnetic-static laws. This is a mouthful so we abbreviate and since these are all energy let's say ENERGETIC.

There is undeniably a body electric and there is indeed an Energetic Medicine. Only a presumptive fool would assume otherwise. There is pressure from the chemical companies and their vast wealth and pervasive influence to view the body as a set of chemicals. But these chemicals are all made of energetic fields and they obey energetic laws like quantum, electro-magnetic, static, quantum electro-dynamic photonic laws.

This study was designed for a biofeedback device (SCIO) that combines all known applications of Biofeedback and a unique protocol that addresses specific Body Wellness Indicators.

The SCIO is designed to correct the manifestation of stress and/or electro-stress patterns within the individual at the most primal of physiological levels. The device works on the theory that stress disrupts the inherent electromagnetic frequencies at which the body's cells, organs, etc. resonate and that by returning these frequencies to their natural state, the stress and any subsequent illness that occurred because of the disruption can be corrected.

The objective of the study was to determine if one 45-minute treatment with the SCIO would show a change, and hopefully an improvement, on a person's Body Wellness indicators.
### Methods

### •Study design

The study was designed as a randomized, double blind, placebo controlled study. The goal of the study was to analyze the changes in Body Wellness Indicators after one 45-minute SCIO session, so there was no follow up necessary days or weeks after the treatment.

All study personnel and participants were blinded to treatment assignment for the duration of the study. Only the study statisticians and the data monitoring committee saw unblinded data after the study sites are completed, but none had any contact with study participants, nor will they ever have contact with future participants.

Randomization was assured at each testing site by the one person organizing the subject scheduling prior to the study. As people called to schedule their appointments based on the Subjects availability, the Scheduler would randomly assign the subject to one group or the other depending on which room was available. None of the staff members involved in the clinical trial process were aware of what group/device was placebo and what group/device was real. Each testing site was given two pieces of equipment - placebo equipment and actual equipment. Testing sites were chosen on the basis that the staff was knowledgeable of the functions of the device and are well trained and supervised to conduct the study. Either the Clinical Investigator or an Independent Monitor supervised the study.

Subjects assigned to Testing Group A were treated with the SCIO device A using Harness A and subjects assigned to Testing Group B were treated with the SCIO device B using Harness B. Only the study Sponsor knew which label ('A' or 'B') corresponded to the actual (test) device and harness and which label corresponded to the placebo device and harness.

The placebo equipment was designed to have the same external physical appearance as the actual equipment. The software operating the placebo devices is designed to look exactly as the one operating the real device, with no distinguishing differences. The difference is that the placebo harness was not equipped internally with functional electrodes and the programming for the placebo device output only blank matrices. Neither the actual (test) nor the placebo harness produced any detectable noise, heat, light or other sensation output, so this also wasn't a distinguishing factor for subjects or the investigator between the actual (test) and placebo devices.

To evaluate blinding, at the end of the session, both subject and investigator were asked to indicate which group they believed the subject to be assigned to (SCIO Test, placebo) and what led to that belief.

The study was completed in five testing sites on the following dates: Budapest, Hungary, 5-10 August 2009, Timisoara, Romania from 2-4 September 2009, Seattle, Washington, from 23 – 25 October 2009, Paris, France from 17-20 November 2009 and Speyer, Germany from 23 – 27 November 2009.

The investigation was initiated on the 2nd of September 2009, in Timisoara, Romania, and completed on the 27th of November 2009 in Speyer, Germany.

### • Patients

A sample size of 40 patients per site was calculated. The sample size of 45 subjects per group (test and control, separately) has been determined using Table A.3. Sample sizes per group for a twotailed test on proportions. P1=.20, on page 266 of the textbook, Statistical Methods for Rates and Proportions, Second Edition, Joseph L. Fleiss, Division of Biostatistics, School of Public Health, Columbia University, 1981, John Wiley & Sons, Inc. Publishers, New York, NY. To apply the values in this table to a one-tailed test, the alpha value of 2\*alpha (0.05) was used.

From here, it was anticipated that about one-twelfth of subjects overall may withdraw from the study prior to completion for various reasons, including the length of the treatment period.

Final sample size = sample size X 1/(1-d); where d = # expected dropouts/# subjects enrolled.

Final sample size =  $45 \times 1/(1-0.089)$ ; where d = 4/45

Final sample size = 45 X 1/0.911 = 45 X 1.098 = 49 subjects per group.

Therefore, a minimum starting sample size of 49 subjects in each treatment group was needed to insure that a sufficient number remains at the end of the trial (40 subjects per group) for any significant differences found between groups to be considered statistically valid and representative of the general population being sampled. For ease of division between the test sites, the number has been rounded up to 50 subjects per treatment group.

Patients were locally recruited in Speyer, Seattle, Paris, and Timisoara, from the pool of potentially suitable patients who normally attend the test sites for various services or form nearby consenting and suitable medical offices and other such suitable locations. Respondents were invited to the session. After giving written Informed Consent forms, patients were screened by investigators.

Inclusion criteria were perceived levels of high stress, injury and/or pain (based on a Quality of Lifestyle Questionnaire), age between 18 and 65. Exclusion criteria included extremely sick patients on more than 5 prescribed drugs, crippled and handicapped patients, diagnosed heart conditions, prior head traumas, pregnancy, breastfeeding or planning pregnancy, pacemaker use, serious mental illnesses, prior cardiac surgeries, seizure disorders, developmental disability or cognitive impairment, participation in other medical research in the past 30 days. At some sites,

Inclusion/Exclusion Criteria were evaluation via email or phone in advance.

Participants deemed eligible based on baseline assessment were randomly assigned to either the test (SCIO) group or the control (placebo) group. Subjects in the test group received the actualstudy treatment with an active, operational harness, and those in the control group received a 'fake' study treatment with a placebo harness that does not contain any active electrodes. The investigators follows the same protocol for all subjects. None of the participants could discern if they were in one group or the other as the devices and equipment looked and felt the same.

Levels of stress were assessed by self-report questionnaires. Body Wellness Indicators were evaluated through physiological measurements and electrical device measurements.

The potential for adverse reactions were monitored at each test site according to the Freiburger Ethics Committee International, Germany, which approved the study protocol. However, no adverse reactions were reported during the study or after the study.

### •Outcome measures

The study was designed to determine the device's efficacy by recording baseline measures in the pretreatment phase, against which post-treatment changes were assessed. There were 8 types of tests performed pre- and post – treatment, for both test group and placebo group. First, the levels of stress and pain/injury were assessed using a self-report Quality of Life Questionnaire. The questionnaire had 10 questions to be answered on a scale from 1 to 10 (the higher the stress, the higher the value).

Then physiological measurements were taken for the assessment of Body Wellness Indicators, defined as follows: Energy Index Factor, Strength Test, Oxidation Test, Flexibility Test, Memory Test, pH Test, VARHOPE test.

Energy Index Factor was calculated using the formula:

Systolic BP left arm sitting + the diastolic BP left arm sitting x pulse = energy index factor.

The Energy Index Factor indicates parasympathetic control below 9,000, balance at 14,000 and sympathetic nerval control at 18,000+.

The strength test was performed using a hand-held Dynamometer. Subject held the Dynamometer in one hand, gave one big squeeze with one hand on the Dynamometer while the investigator documented how many kilograms of strength the patient was able to exert.

The same procedure was repeated for the other hand.

For the anaerobic oxidation test, the patients started in a seated position, relaxed and breathed at a normal breath rate for 1 minute. The subject took a deep breath at the same time that the investigator started a stop-watch counting minutes, seconds and tenths-of-a-second. Subject stood up at a normal speed and sat down again at a normal speed while still holding their breath as long as possible. As soon as the subject stopped holding breath and took a new breath then investigator stopped the stop-watch. Investigator documented the length of time that the subject held breath during Anaerobic Oxygenation Test

To evaluate flexibility, there were three types of flexibility tests performed. Low back flexibility was measured with the subject sitting down on the floor with legs stretched out in front, heels approximately 20.32 cm (8 inches) apart. The subject extended both hands, outstretched fingers towards their heels keeping legs straight. Subjects were asked to do a maximum stretch and touch the floor as far as they can, even going past the heels, if they could. The distance in centimeters (or inches in The USA) from where their fingers touched the floor to the heels, with Zero at the heels, positive if they can extend past the heels, minus if they are before the heels. Normal scores are anywhere from -7.62 centimeters (-3 inches) to 0 centimeters (0 inches), scores below -7.62 centimeters (-3 inches) to 0 score should be 17.78 centimeters (7 inches) past the heels.

Side to Side Flexibility was measured with subject standing on their knees without bending forward or backward at the waste, and leaning to the left side, trying to touch their left palm to the floor.

Normal readings are touching fingers or knuckles to floor. An advanced subject would be able to touch their palm. If they cannot touch their fingers it indicates a lack of flexibility. A protractor was used to determine the angle of flexibility.

Neck flexibility is measured with the subject trying to touch their ear to their shoulder without raising their shoulder to their ear. A protractor was used to determine the angle of flexibility.

The suggested method for the memory test was to choose a first set of 5 random numbers. If the subject remembered these numbers in the proper sequence (either forward or backward depending

on the memory test), then the investigator added 2 to the existing digit and one more digit to the end to increase the sequence by one digit. This method was continued until the end.

The investigators recorded the number of memorized digits (forward and backward).

An Over-The-Counter pH (acidity-alkalinity) Test Kit was purchased and used for pre-test and post-test measurements of pH.

VARHOPE is an acronym coined by the manufacturer in which V = Voltage, A = Amperage, R =

Resistance, H = Hydration, O = Oxygenation, P = Protons and E = electrons.

The VARHOPE numbers are measured by the biofeedback device, during a 1,5 minute Calibration process and they are measured again at the end of the session.

The VARHOPE numbers are separated into two (2) categories where VARHO is one category and PE and the second category. The VARHO readings are set on a scale, determined by the manufacturer, from 0-110. Changes in the readings are shown on the scale where an increase in number shows in improvement.

The PE readings are set on a scale, determined by the manufacturer, where the closer the P reading to 75 the more the client's state of wellness has stabilized, and the closer the E reading to 65 the more the client's state of wellness has stabilized. This scale was chosen to make it easier for the layperson to accept readings on a simpler scale rather than electrical readings.

Voltage is derived directly from the skin electro-potential amplitude. Amperage is the amount of charged particles flowing and Voltage is the pressure behind the flow. All biofeedback instruments measure voltage which is the electro-potential of the skin underneath the electrode. Amplitude disorders in EEC or ECG, refer to the voltage vector.

Amperage is calculated from the volume of current over a short period of time coming off of the body. Knowing the skin's electro-potential and impedance using Ohm law of  $V = A \times R$  (Voltage equals Amperage times Resistance), the current or amperage at a transcutaneously measured point can be calculated. This is referred to in the industry as a virtual measured variable. Using simple collective mathematics global measures of our patient's Voltage, Amperage and Resistance can now be established. Amperage is the amount of charged particles flowing and Voltage is the pressure behind the flow.

Resistance is a measure of how a substance resists current flow. In a complex situation of multiple liquids acting as electrolytes and multiple membranes, there are induction and capacitance enhancements to the flow (magnetic and capacitance). Resistance is measured in Ohms.

### Hydration

The active stability of water concerning the amount of free water and its ability to permeate osmotic membranes. The electrical pulse of the SCIO stimulates osmosis. It is measured as the range of voltage scores over a period with the aberrant signals and cardio-signals filtered out give us a Hydration index. Voltage changes observed during the Calibration process give us a Hydration index (based on the free proton effect).

Oxygenation is given through the range of amperage scores over a period of time, with the aberrant signals and cardio-signals, which, when filtered out give an Oxygenation index. The range of scores, between maximum and minimum, reflects oxygenation giving an Oxygenation index. As the changing Voltage and Amperage is measured we get inductance and capacitance virtual scores and this allows

us to find a Hydration and Oxygenation index. As Amperage changes slightly with each breath, we get an Oxygenation index from comparing maximum and minimum values. We need to observe several normal breaths to establish an Oxygenation index during the Calibration procedure.

Proton balance (in relation to Electron balance) The polarity of the signal and the collective global readings give us a proton-electron balance. Thus the system has an index which can be compared to established norms of patients based on age, stress, metal implants in teeth, smoking and behavior. Proton and Electron balance (or the charge stability of the client) affects the polarity and the resting potential. The slight changes in these electrical profiles can be measured. This is measured globally.

Improvements in the VARHOPE Scores show improvements in the body's natural electrical functions.

For the purpose of this clinical study, the VARHOPE measurements were taken at the beginning of the test session with the SCIO and then again towards the end of the test session with the SCIO.

### Intervention

The SCIO biofeedback session was 45 minute in length. The SCIO device utilizes transcutaneous voltammetric evoked potential biofeedback technology, which consists of both hardware and software. The hardware consists of a digital interface box attached to the computer with electrodes attached to the wrists, ankles, and 8 on the forehead of the person (making up 12 transcutaneous carbon impregnated rubber electrode contact points). The software is a PC-based platform consisting of mathematical calculations and high-end graphics. The placebo equipment was designed to have the same external physical appearance as the actual equipment. The difference is that the placebo harness was not equipped internally with functional electrodes and the programming for the placebo device outputted only blank matrices. Neither the actual (test) nor the placebo harness produced any detectable noise, heat, light or other sensation output, so this also wasn't a distinguishing factor for subjects or the investigator between the actual (test) and placebo devices.

After the pre measurements were taken, patients were invited to a quiet room, seated comfortably in a chair, connected to the device via harnesses and advised to be as relaxed as they can. The session protocol included relaxation treatments, Neuro Linguistic Programming treatments, electro-acupuncture, and biofeedback treatments.

After the 45 minute session, the subjects were ready for the post-treatment phase, were the measurements were repeated and recorded.

### •Statistical analysis

Independent statisticians were hired to analyze the data and determine statistical significance. Success of the study was determined by simple calculation of the percentage of subjects in each treatment group who met the individual subject success criteria. If these percentages showed that the overall study success criteria are met, the study will be considered to have had a successful outcome.

In addition, the primary efficacy outcome measure was evaluated. A one-tailed z-test of proportions was conducted to assess for a statistically significant difference in the average post-treatment Body Wellness scores for test versus control group subjects. Using the paired t-test, the percentage differences between the mean differences in final post-treatment Body Wellness score minus pre-treatment Body Wellness score for subjects in the test group versus subjects in the control group was evaluated.

For the primary outcome measure, an intent-to-treat analysis (including all randomized patients), and a per-protocol analysis (subjects without major protocol deviations, incompletes excluded) were performed.

Handling of missing data in the per-protocol analysis was according to the multiple imputation method.

For the evaluation of the secondary efficacy outcome measures an ANOVA was used to evaluate the change in total Body Wellness score across the measurement time points of pre-treatment and post-treatment, comparing test and control group subjects. It was expected that more test group subjects will demonstrate an improvement in Body Wellness in one or more tests from pre-treatment to treatment to post-treatment than will control group subjects. There were made correlations between scores on the various inventories and a z-test was used to evaluate differences in outcome satisfaction ratings between test and placebo group subjects. Changes recorded on the VARHOPE readings during treatment and comments provided by subjects were also evaluated. A safety outcome evaluation of any reported adverse events and reactions was performed.



The study flow chart, based on the Consolidated Standards of Reporting Trials recommendations, is shown in Figure 1. Subjects were recruited through local contacts on a voluntary basis. Some were screened beforehand via phone or e-mail and others were screened upon arrival. Potential candidates were excluded or deemed ineligible for the following reasons: a) did not meet inclusion criteria (n=3), b) scheduling problems (n=2), c) missed appointments (n=7). 151 subjects were enrolled and randomly assigned to either the SCIO Test Group (n=86) or Placebo Group (n=65). The subjects not included in analysis were those from whom no pre and/or post measurements were recorded at the end of the session. Reasons for not obtaining data were scheduling problems.



Figure 1. Flowchart of the study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session

Results are shown in Figure 2. There was no statistical difference between groups in the following outcomes: Quality of Life Questionnaire, Energy Index Factor, Strength Test, Flexibility, Memory and pH.

Demographics	for Patient		This	softwar	e is designed	For EDUCTOR/USA rev 14.04.2014					
Demographics	Report set up	Patient Data	Help	Close	Halt system	Focus on Symptoms not Diagnosis	Ethics Co.	Access fo	or Informed consent		
Testee Name					Pregnant	🗌 Inherited Disc	order	<u>C</u> lose	Visit #-000 🗌	Top Cl	ass Athlete
						Amount of negati	ivity 1-10	Ar	nount of kg. overwei	ght Dr. 🛛	opinion
		0	Male	🔘 Геп	nale 🔘 Bot	h		Str	ess + Detox Type (re	do on e	ach visit)
	-SOC Ind	ex						Inte	rpersonal stress	0	
	Numbe	er of organs	remov	ed		Personal stress 0-10 10 max		Job	or School stress	0	
NEE	No.Synt	hetic drugs	used a	urrent	У	No. of Sugar type products / da include soft drinks,ice cream (	ay etc	Str	uggle- self or money	0	
	Amount (No.	of times you of cigaretts,	ı smol , cigar	ce / day s etc)		No. of exercise sessions /wk 20 minutes or more, Not work		Str	ess from sickness	0	
and the second distance of the second distanc	Number used	of steroid ty in the last y	ype dri ear	ugs		No. of alcoholic drinks / day on average		Far	nily stress 0	ings to	he different
	No. of m	retal amalga or present d	m filli uring	ngs last ve		No. of cups of coffee,tea / day or any caffiene product			0 10	s extre	me disease
	Number	of street dr	ugs us	ed/ ma	in.	No.Extreme toxic exposures/y radiation.insecticide.chemicals	vr.	Pi Pi	oblem with bowels oblem with sweat	0 0	
	Numbe	er of all know	vn alle	rgies		Number of major injuries in pa	ist		Problem with urine	0	
	No. of	unresolved	menta	l factor	s	Number of major infections		Pr	oblem with mucous	0	
	I am Re 0 mi	esponsible f nimum-10 m	or my aximu	Body m	10	Number of glasses of water or natural fruit juice per day		Pr	oblem with menses	0 0	More Input
	Amount Includ	of Fat in diet e Processed	,as pe 1 foods	rcent/1 s	0	How many kilos overweight 2.2lb=1kilogram, seen by patie	ent	F	Problem with skin	0	Close
E	Ratient D	ata (Load N	ew or l	reviou	us Patient)			F	Problem with sleep	0	
SOC INDEX 1	to be	Tested			,			How	w many Times a day editate or use stress hniques?	do you reducti	on O
Device User:		Jesi the best						Nu	mber of Root Canal 1	reatme	nts 0
What part of y	/our body(if	any) do you	ı dislil	e mos	t:						
How would ye	our life char	ige if your d	isease	was g	one?						

SCIO Treatment group (Test group)						
	Mean	Ν	Std.	Std. Error of	Range	
			Deviation	Mean		
x Quality of life	0,5412	85	0,92005	0,09979	5,00	
Questionnaire						
1						
x Quality of life	0,2353	85	0,66632	0,07227	4,00	
Questionnaire						
2						
x Energy Index	871,3294	85	2 309,45944	250,49605	12 770,00	
Factor						
x Left Hand	0,4118	85	3,89839	0,42284	29,00	
Strength (Kg)						
x Right Hand	-0,8235	85	5,06664	0,54955	48,00	
Strength (Kg)						
x Oxygenation	-1,1786	84	3,87193	0,42246	32,00	
	1 2712	05	6 10205	0.67162	60.00	
X FIEXIDIIITY	-1,2712	65	0,19203	0,07102	00,00	
	0.6599	05	7 07540	0 86506	55.00	
X Flexibility	-0,0388	65	7,97349	0,80500	55,00	
	0.9706	05	11 22697	1 21772	78.00	
X Flexibility	0,8700	65	11,22087	1,21772	78,00	
Neck	0.2706	05	1 21202	0 14240	6.00	
x iviemory lest	-0,2700 V		1,51205	0,14240	0,00	
	0 1624	QE	1 21027	0 14200	8.00	
	-0,1024	65	1,31927	0,14309	6,00	
(васкwага)	0.6012		6 62828	0 72421	62.20	
x pH level	0,6012	84	0,03838	0,72431	62,20	

x Voltage	-14,4286	84	8,98632	0,98049	40,00
x Amperage	-15,8333	84	9,78791	1,06795	58,00
x Resistance	-16,9167	84	11,80383	1,28790	62,00
x Hydration	-16,6071	84	9,84949	1,07467	45,00
x Oxygenation	-18,7381	84	12,49879	1,36373	72,00
x Proton pressure	-2,3214	84	4,09572	0,44688	27,00
x Electron pressure	3,6548	84	3,89159	0,42461	28,00

### Table 1. Summary results for the SCIO Treatment (Test) group

Placebo group (Control group)						
	Mean	N	Std.	Std. Error of	Range	
			Deviation	Mean		
x Quality of	0,4462	65	1,17301	0,14549	8,00	
life						
Questionnaire						
1						
x Quality of	0,2000	65	0,75416	0,09354	5,00	
life						
Questionnaire						
2						
x Energy Index	885,7077	65	2 404,62943	298,25757	13 076,00	
Factor						
x Left Hand	-0,0615	65	4,19776	0,52067	27,00	
Strength (Kg)						
x Right Hand	0,0769	65	3,24185	0,40210	17,00	
Strength (Kg)						
x Oxygenation	-1,2500	64	2,05480	0,25685	12,00	
x Flexibility	-2,0580	65	5,06185	0,62785	30,00	
Low Back						
x Flexibility	1,5846	65	10,99132	1,36331	60,00	
Side to Side						
x Flexibility	2,0615	65	9,58657	1,18907	55,00	
Neck						
x Memory	-0,1846	65	0,89952	0,11157	5,00	
Test (Forward)						
x Memory	-0,4923	65	1,14732	0,14231	6,00	
Test						
(Backward)						
x pH level	-0,1246	65	0,37292	0,04626	2,20	

x Voltage	0,6923	65	7,74379	0,96050	72,00
x Amperage	-0,9077	65	5,51057	0,68350	44,00
x Resistance	-0,3538	65	1,71784	0,21307	12,00
x Hydration	-1,4769	65	12,45631	1,54501	106,00
x Oxygenation	-0,8462	65	7,23540	0,89744	70,00
x Proton pressure	0,5231	65	4,15372	0,51521	34,00
x Electron pressure	-0,2154	65	1,51547	0,18797	13,00

90875 CPT CODE 90875 Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient) e.g. insight oriented, behavior modifying, lifestyle education, stress reduction modalities) approximately 20-30 minutes.

CPT CODE

For

SOC Index

Table 2. Summary results for the Placebo (Control) group



# Figure 2. Outcomes of 146 subjects analyzed in the study of the application of the SCIO Universal Electrophysiological Biofeedback System for statistical evaluation of the SCIO's ability to increase Body Wellness after one 45-minute session.

There was significant difference between groups in the VARHOPE measures (p < 0.005). The results were as follows:

- a. 86.90% of subjects had a V improvement of more than 5%,
- b. 90.47% of subjects had an A improvement of more than 5%,
- c. 88.09% of subjects had an R improvement of more than 5%,
- d. 88.09% of subjects had an H improvement of more than 5%,
- e. 89.28% of subjects had an O improvement of more than 5%,
- f. 47.61% of subjects had a P improvement of more than 5%,
- g. 48.80% of subjects had an E improvement of more than 5%.

### There were no adverse events reported during or following the study.

### • Discussion

We conducted a double blind, randomized study with a placebo controlled design to evaluate an intervention comprising a 45 minute SCIO Biofeedback session. We looked at the impact of this session on electrical scores (VARHOPE), perceived levels of stress and pain/injury, blood pressure, strength, memory, flexibility and pH in subjects with high levels of stress. Significant effects associated with the intervention were observed in VARHOPE scores. The biofeedback session had no risks associated; compliance to study protocol was maintained during the study.

The body is an electrical process requiring volts and amps which conduct through resistance circuits to operate. All muscles are turned on by electrical impulse. Muscles themselves are magnetic using volts and amps for their operation. The brain is a massive collection of cells that have electrical activity that can be measured via the EEG. The heart itself is the largest electro-magnetic engine and uses electrical impulses to influence the muscles of the heart to circulate blood. Most EEG, ECG and EMG measures are only concerned with oscillatory properties and not so concerned with the volume or basic amperage of the circuit. The collective baseline of the circuit of EEG, ECG, EMG and GSR measurements can give us a rating of the global body voltage, body amperage and skin resistance (V, A, and R respectively). There are norms of the V, A and R and certain people, due to stress or other factors, can have low V, A and/or R.

The collective inductance and capacitance changes in the body are a reflection of redox potential and can reflect hydration (H) and oxygenation (O) indexes.

Irregularities in EEG, EMG, ECG and GSR can be corrected through guided electro-stimulation. The V and A are also greatly affected by the charge stability of the free protons and electrons, (negative charges and positive charges in the body), which collectively make up the proton pressure (P) and electron pressure (E). The acidity-alkalinity balance is an electrical measure of the amount of positive versus negative charged particles. This can be measured by the carbon based electrodes of the SCIO through electro-stimulation biofeedback.

This Clinical Study was developed in the context of substantiating the Indication for Use for the SCIO biofeedback device of rectifying charge stability imbalance and rectifying redox potential, two of the factors that influence Body Wellness. One study objectives was to determine if one 45-minute treatment with the SCIO would show a change on a person's Body Wellness indicators as defined by the study hypothesis, which is now proven valid.

The other indicators of Body Wellness (Quality of Life Questionnaire, Energy Index Factor, Strength, Anaerobic Oxygenation Test, Flexibility, Memory and pH) were not statistically significant. This does not mean that the results are not valuable. A closer analysis shows that there are trends in the improvement levels between the Test and Control (Placebo) group. As per the hypothesis defined in the Clinical Study protocol it was expected that any positive change in post-treatment measures for control subjects is expected to occur to a significantly lesser degree than for subjects in the test group.

The subjects were not equally assigned to the placebo versus test group, but as follows:

Timisoara, Romania Control Group n=17

Treatment Group n=21

Seattle, Washington, U.S.A.

Control Group n=20

Treatment Group n=20

Paris, France

Control Group n=20

Treatment Group n=20

Speyer, Germany

Control Group n=8

Treatment Group n=25

Because the test/placebo assigned ratio was not equal, in order to determine trends of improvement per the study hypothesis, we have analyzed subjects from Seattle, USA and Paris, France (40 subjects in test group, 40 subjects in placebo group).

Strength test results analysis showed that 60% of the subjects in the test group had a 5% or more improvement in left hand strength, as opposed to only 35% of the placebo group which had a 5% or more improvement. In the case of the right hand strength, difference is smaller, however, 47% of the test group subjects improved more than 5%, and 37,5% of the placebo group improved more than 5%. The results show that there is definitely a possibility of improving strength with the SCIO biofeedback device, the question that remains is how many SCIO sessions would have a statistically significant result. Also, another thing to consider while analyzing the results is that the protocol followed included mostly general stress reduction therapies, as opposed to using specific muscle strengthening treatments, which could have a greater impact on strength.

It is interesting how the anaerobic oxygenation test had a greater improvement for the placebo group (68,42%). Test group had an 55,26% of subjects that had a 5% or more improvement. The question that rises is whether the improvement occurred because the subjects had a chance to relax during the 45 minute protocol or because of the biofeedback session. The anaerobic oxygenation test requires a clear mind and a rested body. So whether the results are due to the relaxing 45 minute session or not is unclear.

Analysis of flexibility back shows that 60% of the subjects in test group had a 5% or more improvement versus 55% of the placebo group that showed a 5% or more improvement. 10% more of the subjects in the test group had a 5% or more improvement of flexibility side versus subjects in placebo group. In Seattle, side to side flexibility showed statistically significant improvement. Even though the overall analysis does not support these findings, it is a strong basis for future studies. Also, evaluating pathological versus non-pathological data revealed that, for one site (Paris) subjects with pathological reactions to the low back flexibility test had non-pathological reactions after the biofeedback session.

Flexibility of the neck has again quite similar results. 25% of the test group and 27,5% of the placebo group had a 5% or more improvement. It would be interesting to find out whether flexibility would be significantly improved by specific muscle therapies with the SCIO device. Considering the relaxation therapies that were applied in this study, it is definitely worth finding out how many specific SCIO treatments would have a considerable effect of flexibility measurements.

Memory test din not suggest any trends, improvement of more than 5% being observed at an exactly the same percent of the test group subjects as the placebo group subjects.

Energy Index Factor, a variable based on blood pressure measurements did not show statistical significance. However, a study that evaluated the effects of GSR Biofeedback and Progressive Muscle Relaxation showed that PMR inducted a significant decrease in blood pressure whereas GSR biofeedback training showed a decrease in respiratory rate<sup>1</sup>. The GSR treatment was administered for 20 minutes daily, for 10 consecutive days. This provides a strong basis for a further analysis of the SCIO device sessions and the effects they might have on blood pressure.

This study has limitations, primary among them the lack of follow-up. Nevertheless, the results obtained after one session provided valuable data on feasibility and plausibility. Another limitation was the short duration of the study. An alternative design would provide data obtained over a significantly longer period of time, which may also influence the results of the study and offer better understanding of the efficacy of a sequence of session with the SCIO device.

### • Conclusions

The SCIO device appears to be a valuable tool in improving Body Wellness. One 45 minute session had significant results in improving the natural electrical parameters of the body. The results also showed trends of improvement in other body variables, therefore providing a basis for future studies. The fact that there were no adverse events reported shows device safety.

### Acknowledgements

<sup>&</sup>lt;sup>1</sup> Khanna A, Paul M, Sandhu JS., Indian Journal of Physiology and Pharmacology, 2007 Jul-Sep;51(3):296-300. A study to Compare the Effectiveness of GSR Biofeedback Training and Progressive Muscle Relaxation Training

The study was funded by Maitreya Ltd., manufacturer of the SCIO Universal Electrophysiological Biofeedback System. Maitreya Ltd. was involved in the design and conduct of the study and provided logistical support during the trial. Employees of the sponsor worked with the investigators, but the analyses were performed by two independent statisticians. The manuscript was prepared by Dr Mutschler. Maitreya Ltd. was permitted to review the manuscript and suggest changes, but the final decision on content was exclusively retained by the authors.

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# 2013 USA new studies Validating the SCIO auto focusing Cybernetic loop

STUDY INFORMATION:

SUPERVISING RESEARCHERS: Dr. Danis György, MD,

Dr. Hilf Klara

MD, Jozsef Mezei MD

**MEDICAL CONSULTANT :** 

Dr. Pauline Willis, USA, Dr.

Gebhard Gehring MD Bavaria, Germany

DATE and PLACE: 2008 –2013 Arizona, USA

**SPONSORS:** 

SCIO International / Maitreya Kft.

#### INSTITUTIONAL MONITOR:

IMUNE / University of Timisoara (Victor Babes University of Medicine) Dr. Bacean Aurel MD

USA IRB-Freiburger Ethik-Kommission International (FEKI)

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http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# Double Blind Study of Sport Performance with the SCIO device versus Placebo control 2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

This study took 46 healthy athletic subjects over a period from 2007 to 2012 and measured their strength power performance before and after a SCIOtherapy and compared to Placebo control group.

This study showed an increase in strength performance in the treatment SCIO group versus the control group in most patients.

# Trauma Sport Pain Electro Healing With SCIO/Eductor-2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In this study 27 fit healthy subjects in Arizona USA were hit with a sport injury of the same strength on each leg one at a time. The one leg would get real SCIO therapy the other leg would get Placebo. After the SCIO or control treatment the athletes rated the pain in 10 min intervals till pain recovery was stable. The SCIO showed ability to lower pain after a slight sport injury and promote flexibility recovery quicker than placebo treatment. It is proposed that the increase in osmosis and the autofocused injury treatment pulse increases the body's natural ability to deal with pain and heal. Transcutaneous Electro-Nerval Stimulation for pain and Electro Wound Healing for injury have been well documented in the literature. This study has shown conclusively that the SCIO technology is significantly safe and effective in treating sport pain and minor injuries.

# http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# MCES and Addiction Control a Dbl Blind Clinical Study -2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

This study was done in a medical doctor supervised clinical setting in Arizona USA from 2008 through 2013. 37patients with tobacco addiction and 21patients with alcohol addiction diagnosis were given SCIO MCES treatments or Placebo treatments for three to ten sessions. There was three report of headache logged and no report of any significant risks. Patients were asked to rate their desire or cravings as scalar numbers from one to ten rating. There was significant evidence of the SCIO MCES reducing craving versus the Placebo control group. The literature discussion proves that there is a wealth of evidence for MCES ability to reduce addiction cravings. The Autofocused Cybernetic Stimulation of the SCIO technology has an improved ability tohelp stabilize emotional and reduce aberrant addictive impulses. The literature shows MCES has positive results to lower addiction craving and to stabilize emotional depression. The significant evidence of the SCIO technology's ability to make this claimis now firmly established. Discussion will show a statistically significant positive effect on addiction and emotions using MCES and trans-cranial-cutaneous electrodes.

# http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# SCIO's Effect on Body Osmosis2013 -USA

#### Written by Darwin Davidson Doctor of Quantum Biofeedback

In this study 41subjects were hooked to the SCIO with the SCIO off and a line drawn firmly on their forearm with a finger nail. Then we count the seconds it takes before the line turns red.

This is an indication of osmosis as that the traumatized tissue will have histamine rush in the s traumatized tissue of the forearm. The time it takes indicates the osmosis ability. Norms are 8 to 10 sec. Then the SCIO is turned on and the line drawn on the forearm again of the subject. In the control group there was an average of 12 seconds and 4did not have the line appear after the 20 secdeadline. The SCIO group had an average of 9 seconds and all were under the deadline. This improvement of treatment group over control demonstrates the SCIO's ability to increase osmosis thru its auto-focused electrical pulsation. This verifies the SCIO ability to enhance osmosis.

# Stimulating Eye Hand Coordination With SCIO-Eductor VARHOPE Update 2013

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In this 53 subject study we review the history of the SCIO sport medicine use with an eye on eye hand coordination 21 athletic males from 13 to 43 were asked to shoot basketball free throws in a double blind fashion after being on the SCIO or after a placebo treatment in 2009 -2013.

In July 2009 15 athletes were give the same double blind test with very similar results. In Arizona, USA 18 subjects were tested with darts accuracy to determine the ability of the SCIO to increaseeye hand coordination. The SCIO treatment was proven effective in safely and reliably increasing eye hand coordination. So in total 53 people participated in a double blind study with reversal patterns that prove the ability of the SCIO autofocused stimulation to improve eye hand coordination. Significant results will show that increase in VARHOPE from the treatment group correlate to increased performance of eye hand coordination needed for free throws, darts and other coordination challenges.

# http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# SCIO-Eductor Effects on Oxidation/Oxygenation 2013

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In our test of the VARHOP index in Arizona 2009 we saw significant ability of the SCIO to improve the VARHOP Profile (Voltage, Amperage, Resistance, Hydration, Oxidation and Proton pressure). Here we saw an increase in the Oxidation index. There was also a strong trend of increase in our double blind stand-ups sit-downs while holding the breath test. This was a testof the anaerobic strength of the

body or the ability of the subjects to do a physical task while in a deprived oxygen condition. Our hypothesis is that the increase of Oxidation and osmosis proven before would be able to increase oxygenation and endurance. Much experiential study has shown the benefits of SCIO on athletes. We thought that a double blind direct measure of time of holding the breath would be easier to measure and make less opportunity for interference. So in Arizona USA 32 volunteers had thestimulation of the SCIO with pre and post measures of the time they can hold their breath. On certain random sampled volunteers Placebo control was performed. The results show a significant increase in breath retention and thus endurance. The SCIO autofocused cybernetic pulse increase osmosis as well as the VARHOP index. So an increase in body voltage and amperage coupled with an increase with oxidation produces a distinct improvement in oxygenation and endurance.

# http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# TVEP reactivity scores to Allersode compounds measured 2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In this continuing study started in Arizona, USA 2007, we have tested 53 males and 78 females with known allergies using the Transcutaneous Voltammetric Evoked Potential (TVEP) electrical reactivity in theSCIO. The SCIO readings to the allersodes of the know allergies of the subjects was compared to TVEP xrroid scores of the non-allergic trivector readings. The reactivity scores of the known allergies were significantly higher than the non-allergic items.

This research adds to the continuing steam of evidence that proves the TVEP reactivity reaction of the SCIO. The SCIO technology is able to test and display allergy reactions.

# TVEP reactivity scores to compounds measured update 2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In this study we tested 65subjects Transcutaneous Voltammetric Evoked Potential

(TVEP) electrical reactivity to five compounds given internally. One was diluted orange juice to act as a placebo and the next four were safe weak dilution of common herbal poisons. Atropine, Convallariana, Aconite and Podophyllum were used because of their toxicity but safety in a 4 x dose. The subjects had a very significant reaction to homeopathic compounds containing the herbals detox and other detox compounds. They also had a no measurable reaction to placebo orange juice after testing. The placebo test showed no reaction to the sensitive compounds were as the treatment group had significant reactions. This points to the efficacy of the TVEP method.

# Voltammetric Sarcode Hormone Streaming of TestosteroneUpdate 2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In our study 28men (ages 13 to 60) were told to lie down and use their mind to turn themselves on and get an erect penis. They are not allowed to touch or move to do this but only in the mind. The men were connected to the SCIO device and told it would help. The SCIO device was set on placebo for the first round and the SCIO was then operative on visit 2. The time it takes to get an erect penis is an indication of availabletestosterone. Testosterone is richer in young men and in the morning hours when you get anearly morning erection. All tests were done after 12AMto minimize circadian effects. Thus there was a single blind test of testosterone streaming. In the control measure there was an average of 13.5minutes and several could not do it within the 15 minute allowed time. The second time with the SCIO on testosterone streaming the time was nearly half with an average of 7.8 minutes and all achieved erections within the15 allowed period.

Thus is appears that hormone streaming works and the body builders success is real from hormone streaming.

# http://www.downloads.imune.net/journals/2013%20United%20St ates%20of%20America%20Research/

# VARHOPE and EPR Validation Of the SCIO technology -2013 USA

### Written by Darwin Davidson Doctor of Quantum Biofeedback

In 1989 the American FDA registered the EPFX (Electro-Physiological-Feedback-Xrroid) as medical equipment based on research done by the AAQBT and on an equivalency 510k application.

Massive research has been done to further validate the EPFX device. The basic design is still the same since 1989 even though the device has had other names like QXCI, SCIO, Indigo, Eductor, Indigo Pro.

Most recently a series of research projects were done in Europe and America over the last five years. It is well documented that slight oscillating electro stimulation will increase osmosis. We suppose that a harmonious stimulation from an autofocusing cybernetic loop will help to perfect this process, and thus all physiological processes will be improved.

We did simultaneously studies on Sport Performance on performance, breath retention, osmosis, eye hand coordination, addiction urge control, VARHOPE changes, injury repair and EPR (Electro-Physiological-Reactivity which is now called TVEP—Transcutaneous-Voltammetric-Evoked-Potential). We used the same exact protocols in our America study and thus we shared wiring format as well in our presentation.

Working with the American approved IRB of the sponsor and under strict medical supervision we did our studies from 2008 till 2013 in similar fashion to the studies done in Europe. We got similar results showing the SCIO technology valid in these areas.

# **Romanian Sports Studies**

# http://www.downloads.imune.net/journals/2013 Romanian Study of the Stimulation of Sports Ability/

Ethical Supervision for the following studies has been done by Ethics International Romania, University of Timisoara and the Pshycology Faculty of the University of Bucuresti.

The following sports studies have been conducted under the ethic supervision of the foreamentioned ethics committees, and have been published in peer reviewed medical journals.

- SKIN SCRATCH
- BASKETBALL FREETHROWS EYE HAND COORDINATION
- LOW BACK FLEXIBILITY TEST
- HOLD BREATH TEST
- FOOTBALL KICK ACCURACY TEST EYE FOOT COORDINATION
- HANDBALL THROW ACCURACY EYE HAND BODY COORDINATION
- DARTS THROW ACCURACY EYE HAND COORDINATION
- VARHOP MEASURE



historic Lecture on VARHOPE techniques with SCIO

# 2013 Romanian Study of the Eductor Stimulation of Sports Ability

Co Authored by Professor of Medicine Desire' Dubounet and Hilf Klara MD STUDY INFORMATION: SUPERVISING RESEARCHERS: Dr. Danis György MD, Dr. Hilf Klara MD Licensed Hungarian Medical Doctors DATE and PLACE: May, 2013, Saut Marie, Romania SPONSOR: Sterling Srl / Mandalay Kft. INSTITUTIONAL MONITOR:

IMUNE / University of Timisoara (Victor Babes University of Medicine) Dr. Bacean Aurel MD

### ABSTRACT:

Our previous European and American research has fully shown how the Indigo Plus/Indigo Pro device can increase osmosis with an autofocused micro-current stimulation. Then using a trickle charge system that measures VARHOP (Voltage, Amperage, Resistance, Oxidation and Ph) and can slightly correct aberrations of the body electric. We have shown in previous studies how this has helped a normal population to improve skills in holding breath, eye hand coordination, strength and addiction reduction. This study is designed to test a professional / semi-professional group of athletes for direct sport improvement among base wellness measures. 81 professional / semi-professional athletes age 12 to 45 were tested. 33 basketball players, 28 handball players, and 20 footballers. These athletes were measured for skin osmosis, holding breath, low back flexibility, ability to throw darts, shoot baskets, handball and football skills as well as VARHOP improvement.

And 83 tests results showed a significant improvement versus placebo control measures. Our discussion has shown that these studies have more than proven the claim that the autofocused VARHOP test and intervention is real and enhances sport performance.

### INTRODUCTION:

When we apply a micro charge electro-pulse through a biological membrane process, Osmosis increases. Everything in the body depends on osmosis. When Osmosis increases enzymes work better, hormones work better, detox works better, nutrition works better, all cellular functions works better.

**Osmosis** is the movement of <u>solvent</u> molecules through a selectively <u>permeable</u> membrane into a region of higher <u>solute</u> concentration, aiming to equalize the solute concentrations on the two sides.<sup>[1][2][3]</sup> It may also be used to describe a physical process in which any solvent moves, without input of energy,<sup>[4]</sup> across a semipermeable membrane (permeable to the <u>solvent</u>, but not the solute) separating two solutions of different concentrations.<sup>[5]</sup> Although osmosis does not create energy, it does release kinetic energy <sup>[6]</sup> and can be made to do work,<sup>[7]</sup> but is a passive process, like <u>diffusion</u>. Everything is made of atoms that never touch each other because of the charge of the outer electrons. The charge of the outer electrons allows for osmosis to occur. When we apply a micro charge electro-pulse through a process, Osmosis increases. This helps explain the tremendous results the INDIGO patients get on all types of diseases. There is a universal stimulation of osmosis. The INDIGO measures the body level of Voltage, Amperage, Resistance, Hydration, Oxidation and Ph (VARHOP). By stimulating an autofocusing cybernetic harmonic frequency to the body the INDIGO can maximize the osmosis increasing effect without doing any damage. Since it is through Osmosis that the cells bring nutrition and remove toxins, all of life's processes are improved. Injury improves from the Electrical field stimulation of the INDIGO.

This trickle charge can have maximum benefits in a simple 45 min session. The total change is limited to the body factors of free ions, free minerals, free fatty acids pools, and specifically the membrane potentials of the body.

### SUBJECT AND INVESTIGATOR PROFILE:

The study took place in Satu Mare, Romania, at the Satu Mare Sports High school. Subjects were 60% male and 40% female, aged between 12 and 45 years old semi-professional and professional athletes.

The Romanian Competent Authority granted permission to do studies in Romania, and the Hungarian Ethics Committee has allowed Hilf Klara to do studies in Hungary. (See Appendix)

Our Ethic committee, And written informed consent was approved by all participants.

Medical supervisor: Dr. Hilf Klára, MD Placebo officer: Calin Pap Taflan Andreea, Regulatory Site Manager. Dates: 20-22 May 2013 There were 4 therapists performing the tests: Dr. Hilf Klára Tavman Gabriella- IMUNE Certified Biofeedback Therapist Pop Gheorghe- IMUNE Certified Biofeedback Therapist Ruff Krisztian- IMUNE Certified Biofeedback Therapist

http://www.downloads.imune.net/journals/2013 Romanian Study of the Stimulation of Sports Ability/

### METHOD:

#### SKIN SCRATCH

In this study subjects were hooked to the INDIGO with the INDIGO off and a line drawn firmly on their forearm with a finger nail. Then we count the seconds it takes before the line turns red. This is an indication of osmosis as that the traumatized tissue will have histamine rush in the s traumatized tissue of the forearm.



The time it takes indicates the osmosis ability. Norms are 8 to 10 sec. Then the INDIGO is turned on and the line drawn on the forearm again of the subject. In the control group there was an average of 12 seconds and 2 did not have the line appear after the 20 sec deadline. The INDIGO group had an average of 9 seconds and all were under the deadline. This improvement of treatment group over control demonstrates the INDIGO's ability to increase osmosis thru its auto-focused electrical pulsation. Pre and post tests indicate a possible effect versus placebo group results.

### **BASKETBALL FREETHROWS - EYE HAND COORDINATION**

to test this effect in professional patient blind fashion we got 23 atheltic players to do 10 freethrows as a baseline and then 10 more after a 20 min INDIGO treatment and 10 after a placebo treatment. The subjects were blinded as to when the placebo versus therapy happened. VARHOPE measures were also calculated and compared for improvements.



The subject was told to shoot free throws. The measure was of success of free throws out of ten.

Pre and post tests indicate a possible effect versus placebo group results.

#### LOW BACK FLEXIBILITY TEST



Subjects sat on the ground with feet out stretched and knees straight. They reach for their heels and see if they can go past the heels with both hands touching the ground at the longest extension. If they reach their heels they get a zero. If they cannot reach to their heels we use the number of cm shy of the heels as a negative number. If they reach past the heels they get a positive number reflecting the cm they can extend past their heels. Pre and post tests indicate a possible effect versus placebo group results.

#### HOLD BREATH TEST

Simple measure of how long the subjects can hold their breath in minutes and seconds, pre and post.

Pre and post tests indicate a possible effect versus placebo group results.



#### FOOTBALL KICK ACCURACY TEST - EYE FOOT COORDINATION

The kicker was told to aim at the vertical post from the penalty kick. The measure was of success of hitting the post how many times out of ten.

Pre and post tests indicate a possible effect versus placebo group results.



### HANDBALL THROW ACCURACY - EYE HAND BODY COORDINATION

The thrower was told to aim at the vertical post from the penalty kick. The measure was of success of hitting the post how many times out of ten.

Pre and post tests indicate a possible effect versus placebo group results.



### DARTS THROW ACCURACY - EYE HAND COORDINATION

The subject was told to aim at the bull's eye and counted the points from the board. The measure was of success of hitting the bull's eye and or accumulated points.

Pre and post tests indicate a possible effect versus placebo group results.

### VARHOP MEASURE

The SCIO/Eductor electrically measures the body voltage, amperage, hydration, oxidation index, and Ph. The pre and post scores are made as part of the test.

The VARHOPE Scale is made up of the following terms:

V = Voltage where normal is 80-100, below 50 is chronic and from 100-110 is above normal. Voltage is derived directly from the skin electro-potential amplitude.

A = Amperage where normal is 80-100, below 50 is chronic and from 100-110 is above normal. Amperage is calculated from the volume of current over a short period of time coming off of the body.

R = Resistance where normal is 80-100, below 50 is chronic and from 100-110 is above normal. Resistance shows the body's reaction to the electrical input from the INDIGO.

H = Hydration where normal is 80-100, below 50 is chronic and from 100-110 is above normal. Voltage changes observed during the Calibration process give us a Hydration index.

O = Oxidation where normal is 80-100, below 50 is chronic and from 100-110 is above normal. We get an Oxidation index from comparing maximum and minimum values of changing Amperage.

P = Proton Pressure (commonly interchanged with Proton Balance and refers to pH) where 75 is normal for humans (much like neutral pH is 7.0 and above is more alkaline and below is more acidic.) Changes toward our established norm show an improvement. Proton and Electron pressure (or the charge stability of the system) affects the polarity and the resting potential.

### **RESULTS:**

### **Treatment Group 58**

Test type	Pre treatment	Post treatment	Improvement Percentage
Skin scratch (seconds):	8	10	-25%
Low back extension (cm):	4	5	25%
Hold Breath (seconds)	25	30	20%
Darts (how many points out of 3)	38	30	-21%
Basketball (how many out of 10)	3	4	33%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Improvement percentage
Skin scratch (seconds):	11	10	9%
Low back extension (cm):	10	15	50%
Hold Breath (seconds)	10	13	30%
Darts (how many points out of 3)	14	51	264%
Basketball (how many out of 10)	4	4	0%
Handball (how many out of 10)			
Football (how many out of 10)			

### Subject 3

Test type	Pre treatment	Post treatment	Improvmeent percentage
Skin scratch (seconds):	11	8	27%
Low back extension (cm):	7	9	29%
Hold Breath (seconds)	32	50	56%
Darts (how many points out of 3)	33	33	0%
Basketball (how many out of 10)	3	5	67%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of
			improvement

Skin scratch (seconds):	8	13	-63%
Low back extension (cm):	15	15	0%
Hold Breath (seconds)	32	73	306%
Darts (how many points out of 3)	32	49	53%
Basketball (how many out of 10)			
Handball (how many out of 10)	5	9	200%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	12	-50%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	39	42	8%
Darts (how many points out of 3)	42	10	-76%
Basketball (how many out of 10)			
Handball (how many out of 10)	10	9	-10%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	8	0%
Low back extension	20	25	25%

(cm):			
Hold Breath (seconds)	39	46	18%
Darts (how many points out of 3)	59	4	-93%
Basketball (how many out of 10)			
Handball (how many out of 10)	6	4	-33%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of
			improvement
Skin scratch (seconds):	9	5	44%
Low back extension (cm):	5	8	60%
Hold Breath (seconds)	39	37	-5%
Darts (how many points out of 3)	42	28	-33%
Basketball (how many out of 10)			
Handball (how many out of 10)	10	7	-30%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	4	56%
Low back extension (cm):	4	5	25%

Hold Breath (seconds)	20	31	55%
Darts (how many points out of 3)	43	26	-40%
Basketball (how many out of 10)			
Handball (how many out of 10)	9	10	11%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	26	20	23%
Low back extension (cm):	0	10	100%
Hold Breath (seconds)	34	36	6%
Darts (how many points out of 3)	20	42	10%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	10	10	0%
Low back extension (cm):	0	8	100%
Hold Breath (seconds)	53	41	-23%
Darts (how man y	19	52	174%

points out of 3)			
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	63	14	78%
Low back extension (cm):	0	7	100%
Hold Breath (seco nds)	40	24	-40%
Darts (how many points out of 3)	32	34	6%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	8	0%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	17	22	29%
Low back extension (cm):	6	10	67%
Hold Breath (seconds)	34	41	21%
Darts (how many points out of 3)	19	9	-53%
Basketball (how many			

out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	9	10	11%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	12	-50%
Low back extension (cm):	5	5	0%
Hold Breath (seconds)	42	44	5%
Darts (how many points out of 3)	54	17	-69%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	11	-22%
Low back extension (cm):	18	18	0%
Hold Breath (seconds)	22	29	32%
Darts (how many points out of 3)	45	39	-39%
Basketball (how many out of 10)			
Handball (how many out	7	7	0%

of 10)		
Football (how many out of 10)		

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	11	12	-9%
Low back extension (cm):	5	5	0%
Hold Breath (seconds)	18	20	11%
Darts (how many points out of 3)	23	29	26%
Basketball (how many out of 10)			
Handball (how many out of 10)	10	16	60%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	15	11	27%
Low back extension (cm):	15	15	0%
Hold Breath (seconds)	31	39	26%
Darts (how many points out of 3)	36	39	8%
Basketball (how many out of 10)			
Handball (how many out of 10)	8	10	25%
Football (how many out			

of 10)
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Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	10	25%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	27	29	7%
Darts (how many points out of 3)	8	23	188%
Basketball (how many out of 10)			
Handball (how many out of 10)	7	10	43%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	7	46%
Low back extension (cm):	-5	-2	60%
Hold Breath (seconds)	22	25	14%
Darts (how many points out of 3)	47	78	66%
Basketball (how many out of 10)			
Handball ( how many out of 10)	9	9	0%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	10	13	-30%
Low back extension (cm):	4	4	0%
Hold Breath (seconds)	35	32	-9%
Darts (how many points out of 3)	25	43	72%
Basketball (how many out of 10)			
Handball (how many out of 10)	8	9	13%
Football (how many out of 10)			

### Subject 21

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	16	8	50%
Low back extension (cm):	20	20	0%
Hold Breath (seconds)	29	34	17%
Darts (how many points out of 3)	23	28	22%
Basketball (how many out of 10)			
Handball (how many out of 10)	9	10	11%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of
			improvement
Skin scratch (seconds):	18	13	28%
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w back extension (cm):	8	10	25%
Hold Breath (seconds)	37	37	0%
Darts (how many points out of 3)	29	22	-24%
Basketball ( how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	25	15	40%
Low back extension (cm):	15	20	33%
Hold Breath (seconds)	45	35	-22%
Darts (how many points out of 3)	46	72	57%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	7	8	14%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	8	11%
Low back extension (cm):	10	10	0%

Hold Breath (seconds)	33	33	0%
Darts (how many points out of 3)	76	31	-59%
Basketball (how many out of 10)			
Handball (how many out of 10)	8	9	13%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	9	0%
Low back extension (cm):	18	18	0%
Hold Breath (seconds)	46	53	15%
Darts (how many points out of 3)	32	40	25%
Basketball (how many out of 10)			
Handball (how many out of 10)	3	9	200%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	7	10	43%
Low back extension (cm):	6	7	17%
Hold Breath (seconds)	31	32	3%
Darts (how many points	54	12	-78%

out of 3)			
Basketball (how many out of 10)			
H andball (how many out of 10)	9	10	11%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	12	8	33%
Low back extension (cm):	5	8	60%
Hold Breath (seconds)	32	28	-13%
Darts (how many points out of 3)	19	18	-5%
Basketball (how many out of 10)			
Handb all (how many out of 10)	7	9	29%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	14	34	143%
Low back extension (cm):	0	5	100%
Hold Breath (seconds)	36	73	103%
Darts (how many points out of 3)	14	36	157%
Basketball (how many			

out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	9	10	11%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	15	34	127%
Low back extension (cm):	9	6	-33%
Hold Breath (seconds)	37	60	62%
Darts (how many points out of 3)	45	30	-33%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	7	8	14%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	19	14	26%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	96	67	-30%
Darts (how many points out of 3)	9	33	267%
Basketball (how many out of 10)			
Handball (how many out			

of 10)			
Football (how many out of 10)	8	8	0%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	25	40	-60%
Low back extension (cm):	17	6	-65%
Hold Breath (seconds)	79	98	24%
Darts (how many points out of 3)	34	27	-21%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	6	10	67%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	7	22%
Low back extension (cm):	4.5	7	56%
Hold Breath (seconds)	30	39	30%
Darts (how many points out of 3)	30	28	-7%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out	8	10	25%

of 10)
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Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	24	16	33%
Low back extension (cm):	0	10	100%
Hold Breath (seconds)	56	57	2%
Darts (how many points out of 3)	17	80	371%
Basketball (how many out of 10)			
Handbal I (how many out of 10)			
Football (how many out of 10)	10	9	-10%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	28	14	50%
Low back extension (cm):	0	5	100%
Hold Breath (seconds)	41	42	2%
Darts (how many points out of 3)	20	66	230%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	35	8	77%
Low back extension (cm):	0	9	100%
Hold Breath (seconds)	62	41	-34%
Darts (how many points out of 3)	11	53	382%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	9	9	0%

### Subject 36

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	11	11	0%
Low back extension (cm):	0	5	100%
Hold Breath (seconds)	26	27	4%
Darts (how many points out of 3)	28	26	-7%
Basketball (how many out of 10)			
Handball (how many out of 10)			
Football (how many out of 10)	8	9	13%

Test type	Pre treatment	Post treatment	Percentage of
rest type			improvement

Skin scratch (seconds):	10	12	-20%
Low back extension (cm):	2	4	100%
Hold Breath (seconds)	27	17	-37%
Darts (how many points out of 3)	19	23	21%
Basketball (how many out of 10)			
Handball (how many out of 10)	5	9	80%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	13	-44%
Low back extension (cm):	15	15	0%
Hold Breath (seconds)	34	36	6%
Darts (how many points out of 3)	35	6	-83%
Basketball (how many out of 10)			
Handball (how many out of 10)	9	10	11%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	11	5	55%
Low back extension	4	5	25%

(cm):			
Hold Breath (seconds)	28	28	0%
Darts (how many points out of 3)	52	72	38%
Basketball (how many out of 10)			
Handball (how m any out of 10)	9	10	11%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	12	-8%
Low back extension (cm):	-5	-3	40%
Hold Breath (seconds)	35	40	14%
Darts (how many points out of 3)	24	20	-17%
Basketball (how many out of 10)			
Handball (how many out of 10)	7	9	29%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	12	14	17%
Low back extension (cm):	20	20	0%
Hold Breath (seconds)	30	32	7%

Darts (how many points out of 3)	22	80	264%
Basketball (how many out of 10)			
Handball (how many out of 10)	7	9	29%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	12	50%
Low back extension (cm):	5	5	0%
Hold Breath (seconds)	31	35	13%
Darts (how many points out of 3)	24	37	54%
Basketball (how many out of 10)			
Handball (how many out of 10)	8	9	13%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	14	-8%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	21	22	5%
Darts (how many points out of 3)	18	5	-72%

Basketball (how many out of 10)			
Handball (how many out of 10)	8	9	13%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	12	14	17%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	35	37	6%
Darts (how many points out of 3)	8	20	150%
Basketball (how many out of 10)			
Handball (how many out of 10)	10	10	0%
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	14	12	14%
Low back extension (cm):	11	14	27%
Hold Breath (seconds)	33	50	52%
Darts (how many points out of 3)	53	36	-32%
Basketball (how many out of 10)	1	3	200%

Handball (how many out of 10)		
Football (how many out of 10)		

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	7	4	43%
Low back extension (cm):	5	6	20%
Hold Breath (seconds)	30	29	-3%
Darts (how many points out of 3)	15	30	100%
Basketball (how many out of 10)	2	2	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Ski n scratch (seconds):	8	7	13%
Low back extension (cm):	2	3	50%
Hold Breath (seconds)	42	43	2%
Darts (how many points out of 3)	30	25	-17%
Basketball (how many out of 10)	0	3	100%
Handball (how many out of 10)			

Football (how many out of 10)		
,		

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	6	5	17%
Low back extension (cm):	7	7	0%
Hold Breath (seconds)	21	33	57%
Darts (how many points out of 3)	23	39	70%
Basketball (how many out of 10)	2	2	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	12	11	8%
Low back extension (cm):	17	17	0%
Hold Breath (seconds)	53	42	-21%
Darts (how many points out of 3)	31	21	-21%
Basketball (how many out of 10)	2	2	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	22	31	41%
Low back extension (cm):	2	3	50%
Hold Breath (seconds)	22	28	27%
Darts (how many points out of 3)	18	24	33%
Basketball (how many out of 10)	2	4	100%
Handball (how many out of 10)			
Football (how many out of 10)			

### Subject 51

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	6	7	-17%
Low back extension (cm):	1	4.5	350%
Hold Breath (seconds)	52	62	19%
Darts (how many points out of 3)	36	38	6%
Basketball (how many out of 10)	3	3	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of
rest type			improvement

Skin scratch (seconds):	5	9	-80%
Low back extension (cm):	1	3	200%
Hold Breath (seconds)	120	234	95%
Darts (how many points out of 3)	32	32	0%
Basketball (how many out of 10)	3	4	33%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	6	11	-83%
Low back extension (cm):	4	4	0%
Hold Breath (seconds)	42	42	0%
Darts (how many points out of 3)	55	15	-73%
Basketball (how many out of 10)	0	2	100%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	6	9	-50%
Low back extension (cm):	0	0	0%

Hold Breath (seconds)	23	33	43%
Darts (how many points out of 3)	73	60	-18%
Basketball (how many out of 10)	1	3	200%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	8	38%
Low back extension (cm):	8	11	38%
Hold Breath (seconds)	47	49	4%
Darts (how many points out of 3)	31	32	3%
Basketball (how many out of 10)	2	3	50%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	8	9	-13%
Low back extension (cm):	10	15	50%
Hold Breath (seconds)	20	24	20%
Darts (how many points	23	24	4%

out of 3)			
Basketball (how many out of 10)	3	4	33%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	10	8	20%
Low back extension (cm):	10	13	30%
Hold Breath (seconds)	30	34	13%
Darts (how many points out of 3)	49	29	-41%
Basketball (how many out of 10)	2	4	100%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	7	8	-14%
Low back extension (cm):	1	2	100%
Hold Breath (seconds)	14	15	7%
Darts (how many points out of 3)	4	22	450%
Basketball (how many	5	3	-40%

out of 10)		
Handball (how many out of 10)		
Football (how many out of 10)		

# PLACEBO Group 15

# Subject 1

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	5	6	-20%
Low back extension (cm):	4	4	0%
Hold Breath (seconds)	45	34	-24%
Darts (how many points out of 3)	24	20	-17%
Basketball (how many out of 10)	5	4	-20%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	4	4	0%
Low back extension (cm):	3	3	0%
Hold Breath (seconds)	42	40	-5%
Darts (how many points out of 3)	36	21	-42%
Basketball (how many	7	6	-14%

out of 10)		
Handball (how many out of 10)		
Football (how many out of 10)		

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	11	14	-27%
Low back extension (cm):	6	6	0%
Hold Breath (seconds)	58	40	-31%
Darts (how many points out of 3)	36	30	-17%
Basketball (how many out of 10)	8	7	-13%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	16	-23%
Low back extension (cm):	15	16	7%
Hold Breath (seconds)	62	57	-8%
Darts (how many points out of 3)	37	26	-30 %
Basketball (how many out of 10)	6	5	-17%
Handball (how many out			

of 10)		
Football (how many out of 10)		

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	13	16	-23%
Low back extension (cm):	10	10	0%
Hold Breath (seconds)	35	32	-9%
Darts (how many points out of 3)	56	12	-79%
Basketball (how many out of 10)	6	6	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	18	20	-11%
Low back extension (cm):	14	12	-14%
Hold Breath (seconds)	27	28	4%
Darts (how many points out of 3)	6	10	67%
Basketball (how many out of 10)	8	6	-25%
Handball (how many out of 10)			
Football (how many out			

of 10)	

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	34	39	-15%
Low back extension (cm):	13	12	-8%
Hold Breath (seconds)	47	40	-15%
Darts (how many points out of 3)	78	23	-71%
Basketball (how many out of 10)	5	5	0%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	7	7	0%
Low back extension (cm):	12	13	8%
Hold Breath (seconds)	47	45	-4%
Darts (how many points out of 3)	45	32	-29%
Basketball (how many out of 10)	6	5	-17%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	14	12	14%
Low back extension (cm):	4	3	-25%
Hold Breath (seconds)	47	34	-28%
Darts (how many points out of 3)	55	24	-56%
Basketball (how many out of 10)	8	7	-13%
Handball (how many out of 10)			
Football (how many out of 10)			

# Subject 10

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	12	14	-17%
Low back extension (cm):	10	8	-20%
Hold Breath (seconds)	57	42	-26%
Darts (how many points out of 3)	26	21	-19%
Basketball (how many out of 10)	5	4	-20%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	7	6	14%
Low back extension (cm):	12	11	-8%
Hold Breath (seconds)	43	35	-19%
Darts (how many points out of 3)	51	49	-4%
Basketball (how many out of 10)	7	6	-14%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	17	19	-12%
Low back extension (cm):	13	12	-8%
Hold Breath (seconds)	56	48	-14%
Darts (how many points out of 3)	34	21	-38%
Basketball (how many out of 10)	6	5	-17%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of
rest type			improvement

Skin scratch (seconds):	8	10	-25%
Low back extension (cm):	16	11	-31%
Hold Breath (seconds)	51	35	-31%
Darts (how many points out of 3)	34	28	-18%
Basketball (how many out of 10)	8	6	-25%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	14	-56%
Low back extension (cm):	10	7	-30%
Hold Breath (seconds)	38	33	-13%
Darts (how many points out of 3)	29	28	-3%
Basketball (how many out of 10)	9	6	-33%
Handball (how many out of 10)			
Football (how many out of 10)			

Test type	Pre treatment	Post treatment	Percentage of improvement
Skin scratch (seconds):	9	8	-11%

Low back extension (cm):	6	7	-17%
Hold Breath (seconds)	25	23	-8%
Darts (how many points out of 3)	15	1	-93%
Basketball (how many out of 10)	6	6	0%
Handball (how many out of 10)			
Football (how many out of 10)			

#### Treatment 58

#### Placebo 15

Treatment group all tests improvement:	+35,23%
Placebo Group all test improvement:	-19.88%
Skin scratch (real):	+13.85%
Skin scratch (placebo):	-15,88%
Low back extension (real):	+41,32%
Low back extension (placebo):	-9,12%
Hold Breath (real):	+18,39%
Hold Breath (placebo):	-14,43%
Darts (real)	+45,23%
Darts (placebo)	-28,06%
Basketball (real)	+34,19
Basketball (placebo)	-14,25%

#### **Treatment 58**

#### Placebo 15

Treatment group all tests improvement:		+35,23%
Placebo Group all test improvement:		-19.88%
Skin scratch (real):		+13.85%
Skin scratch (placebo)	-15,88%	
Low back extension (re	+41,32%	
Low back extension (p	-9,12%	
Hold Breath (real):	+18,39%	
Hold Breath (placebo)	-14,43%	
Darts (real)	+45,23%	
Darts (placebo)		-28,06%
Basketball (real) 17 people		+55,05%
Basketball (placebo) 16 people		-17,32%
Handball (real) 24 people		30,91%
Handball (placebo)	4 people	0%
Football (real) 16 people		25,25%
Football (placebo)	4 people	0%

#### Treatment 58

Ы	a	ce	bo	15

Treatment group all tests improvement:	+35,23%
Placebo Group all test improvement:	-19.88%
Skin scratch (real):	+13.85%
Skin scratch (placebo):	-15,88%
Low back extension (real):	+41,32%
Low back extension (placebo):	-9,12%
Hold Breath (real):	+18,39%
Hold Breath (placebo):	-14,43%
Darts (real)	+45,23%
Darts (placebo)	-28,06%
Basketball (real) 17 people	+55,05%
Basketball (placebo) 15 people	-17,32%

Handball (real) 24 people		30,91%
Handball (placebo)	4 people	0%
Football (real) 16 people		25,25%
Football (placebo)	4 people	0%

#### VARHOP PRE POST MEASURES

#### VARHOPE TREATMENT GROUP IMPROVEMENT:

V 14,07%

A 19,23%

R 15,36%

H 21,44%

0 18,24%

P 4,56%

#### VARHOPE PLACEBO IMPROVEMENT:

V 0,01%

A 0,01%

R 0,10%

H -0,03%

0 -0,10%

P -0,20%

#### **DISCUSSION:**

After selling over 35,000 equivalent such devices without any cases of any significant risks, we can unequivocally say that this device is safe. Our safety risk analysis and the ISO safety tests show there is insignificant risk at best from the SCIO/Eductor.

This study along with our 2012 European and 2013 American research has fully shown how the Indigo Plus/Indigo Pro device can increase osmosis with an autofocused micro-current stimulation. Then by using a trickle charge system that measures VARHOP (Voltage, Amperage, Resistance, Oxidation and Ph) and can slightly correct aberrations of the body electric. We have shown in this study how this has helped a normal population to improve skills in holding breath, eye hand coordination, strength and addiction reduction versus a placebo group. The professional / semi-professional group of athletes demonstrated direct sport improvement among base wellness measures.

Results showed a significant improvement versus placebo control measures. Our discussion has shown that these studies have more than proven the claim that the autofocused VARHOP test and intervention is real and enhances sport performance.

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APPENDIX:

### MINISTERUL SĂNĂTĂŢII

DIRECȚIA PENTRU INFRASTRUCTURĂ SANITARĂ, LOGISTICĂ, ACHIZIȚII ȘI DISPOZITIVE MEDICALE COMPARTIMENT DISPOZITIVE MEDICALE Str. Cristian Popișteanu Nr. 1-3, Sector 1, 010024, BUCUREȘTI Telefon: 021 307 25 82; Fax: 021 307 25 85; E-mail: apmed@ms.ro

Nr. 20474/31.03.2010

Referitor la solicitarea dumneavoastră transmisă prin e-mail și înregistrată la Ministerul Sănătății cu nr. 20474/23.03.2010 vă comunicăm următoarele:

- investigația clinică pentru dispozitive medicale este reglementată de Hotărârea Guvernului nr.54/2009 privind condițiile introducerii pe piață

a dispozitivelor medicale, publicată în Monitorul Oficial nr. 94 din 17 februarie 2009 și Ordinul ministrului sănătății nr. 792/2006 privind

desfășurarea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale, publicat în Monitorul

Oficial Nr. 595 din 10 Iulie 2006;

- cererea pentru emiterea autorizației privind desfășurarea procedurii de investigație clinică trebuie însoțită de documentele prevăzute în anexa nr. 2,

din OMS nr 792/2006 și aceste documente se depun la registratura Ministerului Sănătății din str. Cristian Popișteanu nr.1-3, sector 1, 010024, București;

 Ministerul Sănătății nu percepe taxe pentru emiterea autorizației menționată mai sus;
 potrivit HG 54/2009 se va prezenta punctul de vedere al comitetului de etică implicat. Cu stimă,

DIRECTOR,

#### Ing. Alexandru STERIU

Ref.Specialitate Margareta Mihalache

### ORDIN Nr. 792 din 29 iunie 2006

privind desfășurarea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale

*Text în vigoare începând cu data de 22 aprilie 2009* 

REALIZATOR: COMPANIA DE INFORMATICĂ NEAMŢ

Text actualizat prin produsul informatic legislativ LEX EXPERT în baza actelor normative modificatoare, publicate în Monitorul Oficial al României, Partea I, până la 22 aprilie 2009. **Act de bază** 

**#B**: Ordinul ministrului sănătății publice nr. 792/2006

### Acte modificatoare

**#M1**: Ordinul ministrului sănătății nr. 465/2009

Modificările și completările efectuate prin actul modificator sunt scrise cu font italic. În fața fiecărei modificări sau completări este indicat actul normativ care a efectuat modificarea sau completarea respectivă, în forma **#M1**.

#### #B

Având în vedere prevederile art. 9 și 11 din Legea nr. 176/2000 privind dispozitivele medicale, republicată, ale art. 35 din Hotărârea Guvernului nr. 911/2005 privind stabilirea condițiilor de introducere pe piață și de punere în funcțiune a dispozitivelor medicale, ale art. 19 din Hotărârea Guvernului nr. 798/2003 privind stabilirea condițiilor de introducere pe piață și de utilizare a dispozitivelor medicale pentru diagnostic in vitro și ale art. 23 din Hotărârea Guvernului nr. 344/2004 privind stabilirea condițiilor de introducere pe piață și/sau de punere în funcțiune a dispozitivelor medicale implantabile active, cu modificările ulterioare,

văzând Referatul de aprobare al Direcției generale farmaceutice și aparatură medicală nr. E.N. 1.290/2006,

în temeiul Hotărârii Guvernului nr. 168/2005 privind organizarea și funcționarea Ministerului Sănătății, cu modificările și completările ulterioare,

ministrul sănătății publice emite următorul ordin:

### ART. 1

(1) Prezentul ordin stabilește condițiile și modul de desfășurare a procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale.

(2) Prevederile prezentului ordin se aplică dispozitivelor medicale, dispozitivelor medicale implantabile active și dispozitivelor medicale pentru diagnostic in vitro, denumite în continuare dispozitive medicale.

#### ART. 2

În prezentul ordin sunt aplicabile definițiile și procedurile stipulate în Hotărârea Guvernului nr. 911/2005 privind stabilirea condițiilor de introducere pe piață și de punere în funcțiune a dispozitivelor medicale, în Hotărârea Guvernului nr. 798/2003 privind stabilirea condițiilor de introducere pe piață și de utilizare a dispozitivelor medicale pentru diagnostic in vitro și în Hotărârea Guvernului nr. 344/2004 privind stabilirea condițiilor de introducere pe piață și/sau de punere în funcțiune a dispozitivelor medicale implantabile active, cu modificările ulterioare. ART. 3 Autorizația pentru desfășurarea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale este eliberată de structura de specialitate din cadrul Ministerului Sănătății Publice, cu avizul comisiilor de specialitate ale Ministerului Sănătății Publice.

ART. 4

Producătorii sau reprezentanții lor autorizați care vor să desfășoare procedura de investigație clinică sau procedura de evaluare a performanței pentru dispozitivele medicale în România trebuie să notifice în scris structura de specialitate din cadrul Ministerului Sănătății Publice. ART. 5

(1) Pentru aprobarea desfășurării procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale, producătorul sau reprezentantul său autorizat înaintează o cerere la structura de specialitate din cadrul Ministerului Sănătății Publice, al cărei model este prevăzut în anexa nr. 1.

(2) Cererea prevăzută la alin. (1) va fi însoțită de documentele prevăzute în anexa nr. 2, după caz. ART. 6

(1) În baza cererii și a documentelor prevăzute la art. 5 alin. (2), structura de specialitate din cadrul Ministerului Sănătății Publice autorizează:

a) începerea investigației clinice, potrivit prevederilor art. 36 și 37 din Hotărârea Guvernului nr. 911/2005 sau ale art. 24 din Hotărârea Guvernului nr. 344/2004;

b) începerea evaluării performanţei, potrivit art. 19 din Hotărârea Guvernului nr. 798/2003.
(2) Pentru începerea procedurii de investigaţie clinică şi a procedurii de evaluare a performanţei pentru dispozitivele medicale, structura de specialitate din cadrul Ministerului Sănătăţii Publice eliberează autorizaţia al cărei model este prevăzut în anexa nr. 3, respectiv în anexa nr. 4, după caz.

ART. 7

Investigațiile clinice trebuie să se desfășoare în concordanță cu prevederile anexei nr. 10 la Hotărârea Guvernului nr. 911/2005 sau ale anexei nr. 7 la Hotărârea Guvernului nr. 344/2004, iar evaluarea performanței, potrivit prevederilor anexei nr. 8 la Hotărârea Guvernului nr. 798/2003. ART. 8

Producătorul sau reprezentantul său autorizat trebuie să păstreze la dispoziția Ministerului Sănătății Publice raportul privind investigația clinică prevăzut la pct. 2 subpct. 2.3.7 din anexa nr. 10 la Hotărârea Guvernului nr. 911/2005 sau raportul prevăzut la subpct. 2.3.7 din anexa nr. 7 la Hotărârea Guvernului nr. 344/2004, respectiv raportul privind evaluarea performanței prevăzut la pct. 3 din anexa nr. 8 la Hotărârea Guvernului nr. 798/2003.

ART. 9

Potrivit art. 56 lit. b) și d) din Hotărârea Guvernului nr. 911/2005, nerespectarea prevederilor art. 4, 5, 7 și 8 din prezentul ordin constituie contravenție și se sancționează cu amendă de la 2.500 lei (RON) la 5.000 lei (RON).

### #M1

ART. 10 \*\*\* Abrogat

### #B

ART. 11

Anexele nr. 1 - 4 fac parte integrantă din prezentul ordin.

ART. 12

Structura de specialitate din cadrul Ministerului Sănătății Publice, direcțiile cu atribuții în activitatea de asistență medicală din Ministerul Sănătății Publice, comisiile de specialitate ale Ministerului Sănătății Publice, precum și toate unitățile sanitare vor aduce la îndeplinire prevederile prezentului ordin.

ART. 13

Prezentul ordin va fi publicat în Monitorul Oficial al României, Partea I.

ANEXA 1

CERERE

pentru eliberarea autorizației de desfășurare a procedurii de investigație clinică sau a procedurii de evaluare a performanței pentru dispozitivele medicale

Nr. ..... din .....

Către Ministerul Sănătății Publice

Structura de specialitate în domeniul dispozitivelor medicale

Producătorul/Reprezentantul autorizat de dispozitive medicale ....., cu

sediul în ....., telefon ....., fax ...., e-mail ...., reprezentat de

....., solicit autorizarea desfășurării procedurii de investigație clinică sau a procedurii de evaluare a performanței pentru dispozitivele medicale:

.....

Anexez documentele prevăzute în lista verificărilor din anexa nr. 2.

Data ...... Semnătura .....

ANEXA 2

INVESTIGAȚIA CLINICĂ/EVALUAREA PERFORMANȚEI

LISTA VERIFICĂRILOR

1. INFORMAŢII GENERALE

1.1. Numele producătorului/reprezentantului autorizat, adresa, telefonul, date pentru contactare în vederea comunicării

1.2. Dacă este prima cerere pentru investigație/evaluare sau resolicitare

1.3. Dacă este resolicitare legată de același dispozitiv, numărul referinței sau referințelor și datele anterioare rezultate din cele mai recente investigații

1.4. Alte țări membre participante la investigația clinică/evaluarea performanței ca parte a studiului multinațional/în multicentre

1.5. Declarație semnată din care să rezulte că dispozitivul în cauză este conform cu cerințele esențiale, cu excepția acelor aspecte care fac obiectul investigației și în conformitate cu care au fost luate toate măsurile pentru protejarea siguranței și sănătății pacientului.

2. DATE CARE PERMIT IDENTIFICAREA DISPOZITIVULUI

2.1. Numele comercial al dispozitivului

2.2. Numele generic al dispozitivului

2.3. Numele de model al dispozitivului

2.4. Numărul modelului, dacă există.

3. ALTE DETALII PRIVIND DISPOZITIVUL

3.1. Clasificare

3.2. Descriere completă a dispozitivului, inclusiv o listă a accesoriilor, principiile de operare şi desenele de ansamblu şi ale componentelor de bază, împreună cu o scurtă descriere a dispozitivelor destinate să fie folosite în combinație, în scopul investigației/evaluării
3.3. Identificarea oricăror caracteristici de proiectare care sunt diferite față de cele ale produsului similar introdus anterior pe piață

3.4. Detalii privind caracteristicile dispozitivelor noi sau netestate anterior, care să prevadă, unde este posibil, funcția și principiile de operare

3.5. Rezumat al experiențelor cu orice dispozitiv asemănător, făcut de același producător, care să conțină data când a fost introdus pe piață și o prezentare a problemelor legate de performanțe, incidente și măsurile luate pentru rezolvarea acestora

3.6. Analizele beneficiu-risc, care să cuprindă identificarea hazardului și estimarea riscurilor legate de fabricație (inclusiv cele referitoare la alegerea dispozitivului, a materialelor și a softului) și de utilizare a dispozitivului, precum și descrierea măsurilor care trebuie să fie luate pentru minimalizarea sau eliminarea riscurilor identificate

3.7. Rezumat și analize ale testelor preclinice și ale datelor experimentale, care să cuprindă rezultatele calculelor de proiectare, testelor mecanice, testelor electrice, testelor de validare a softului, verificarea siguranței în funcționare și orice performanță sau teste de siguranță efectuate pe animale

3.8. Descrierea materialelor care vin în contact cu organismul uman, motivul pentru care au fost alese astfel de materiale și standardul aplicabil, dacă este relevant

3.9. Descrierea biocompatibilității și siguranței biologice și modul în care a fost abordată astfel încât să cuprindă și identificarea riscurilor și hazardului legat de utilizarea dispozitivului

3.10. Identificarea oricăror componente farmacologice ale dispozitivului, cu descrierea scopului propus și experiența anterioară în utilizarea acestor substanțe

3.11. Principiul de proiectare și diagramele de funcționare, inclusiv materiale și biomateriale, însoțite de descrierea și explicațiile necesare pentru a înțelege proiectul

3.12. Descrierea softului, logica și condițiile de utilizare, dacă este cazul

3.13. Metoda de sterilizare și validare (metode, justificare)

3.14. Identificarea oricăror țesuturi de origine animală încorporate în dispozitiv și informații privind sursa și colectarea țesuturilor înainte de fabricație; detalii privind validarea procedurilor de fabricație utilizate pentru reducerea sau inactivarea agenților neconvenționali

3.15. Identificarea oricăror condiții speciale de fabricație ca cerințe speciale și modul în care trebuie să fie îndeplinite aceste cerințe

3.16. Lista standardelor armonizate aplicabile în întregime sau parțial ori descrierea soluțiilor adoptate pentru îndeplinirea cerințelor esențiale ale directivei, dacă standardele de referință nu sunt aplicabile în întregime

3.17. Instrucțiuni de utilizare

3.18. Ce măsuri au fost luate de producător - dacă există - pentru reconstruirea (reproiectarea) dispozitivului (aplicabilă în cazul dispozitivelor implantabile, dispozitivelor cu utilizări multiple) și prevenirea ulterioară a unei utilizări neautorizate.

4. PLANUL INVESTIGAŢIEI CLINICE/EVALUĂRII PERFORMANŢEI

Informații generale

4.1. Numele, calificările, funcția profesională, adresele investigatorilor clinici, ale investigatorului coordonator, dacă este cazul, din multicentrele de investigație clinică

4.2. Precizări privind experiența și calificarea necesare pentru utilizarea dispozitivului investigat

4.3. Numele, adresele și instituțiile în care se vor desfășura investigațiile

4.4. Copie de pe opinia Comitetului de etică, cuprinzând informații cu privire la faptul dacă documentele de studiu au fost aprobate parțial sau total sau aprobate cu unele condiții, dacă este cazul

4.5. Copie de pe consimțământul avizat al pacientului

4.6. Copie de pe documentul privind modul de despăgubire a pacientului în cazul deteriorării stării lui de sănătate în urma investigației clinice

4.7. Sumarul literaturii științifice de referință care a stat la baza studiului, cu analiză și bibliografie, dacă este cazul.

5. PLANUL INVESTIGAȚIEI CLINICE/EVALUĂRII PERFORMANȚEI

Planul și parametrii investigației

5.1. Scopul și obiectivele investigației

5.2. Planul investigației, de exemplu dacă este prevăzută utilizarea unui grup controlat de pacienți - cu motivația corespunzătoare; dacă s-a luat în considerare concomitent tendința datorată evoluției naturale a bolii față de efectele tratamentului

5.3. Numărul de pacienți - justificare

5.4. Durata studiului, cu precizarea datelor de început și sfârșit și perioada de urmărire a realizării finale a investigației - justificare

5.5. Populația studiată

5.6. Criterii de selecție a pacienților

5.7. Criterii de includere și excludere

5.8. Criterii pentru retragerea din studiu

5.9. Descrierea și justificarea incidentelor cauzate de procedurile invazive care nu sunt de natură medicală

5.10. Descrierea metodelor generale de diagnostic sau a condiției medicale de tratament pentru care a fost propusă investigația.

6. PLANUL INVESTIGAȚIEI CLINICE/EVALUĂRII PERFORMANȚEI

Colectarea datelor/Analize/Statistici

6.1. Descrierea rezultatelor finale pentru a demonstra performanţa şi siguranţa utilizării dispozitivului şi datele înregistrate pentru realizarea scopului final, metoda de urmărire a pacienţilor, evaluarea şi monitorizarea în timpul investigaţiei

6.2. Descrierea procedurilor și detalii privind înregistrarea și raportarea incidentelor, inclusiv detalii ale incidentelor deosebite care trebuie să fie raportate autorității competente

6.3. Descrierea și justificarea datelor statistice, metodei și procedurilor analitice.

7. ALTE PREVEDERI

Compensație în cazul agravării stării de sănătate a pacienților

ANEXA 3

ROMÂNIA

MINISTERUL SĂNĂTĂŢII PUBLICE

Structura de specialitate în domeniul dispozitivelor medicale

AUTORIZAŢIE PENTRU INVESTIGAŢIA CLINICĂ

a dispozitivelor medicale

Nr. ..... din .....
În conformitate cu prevederile Hotărârii Guvernului nr. 168/2005 privind organizarea și funcționarea Ministerului Sănătății, cu modificările și completările ulterioare, ale Hotărârii Guvernului nr. 911/2005 privind stabilirea condițiilor de introducere pe piață și de punere în funcțiune a dispozitivelor medicale, ale Hotărârii Guvernului nr. 344/2004 privind stabilirea condițiilor de introducere pe piață și/sau de punere în funcțiune a dispozitivelor medicale implantabile active, cu modificările ulterioare, și în baza documentației înaintate, Ministerul Sănătății Publice autorizează desfășurarea investigației clinice pentru dispozitivul medical:

..... ..... ..... ..... ..... ..... ..... ..... (denumirea, tipul) Producător: ..... ..... ..... Orice modificare a condițiilor stabilite prin reglementările Ministerului Sănătății Publice, care au stat la baza autorizării, atrage anularea prezentului document. Director, ..... ANEXA 4 ROMÂNIA MINISTERUL SĂNĂTĂŢII PUBLICE Structura de specialitate în domeniul dispozitivelor medicale AUTORIZAȚIE PENTRU EVALUAREA PERFORMANȚEI dispozitivelor medicale Nr. .... din ..... În conformitate cu prevederile Hotărârii Guvernului nr. 168/2005 privind organizarea și funcționarea Ministerului Sănătății, cu modificările și completările ulterioare, ale Hotărârii Guvernului nr. 798/2003 privind stabilirea condițiilor de introducere pe piață și de punere în funcțiune a dispozitivelor medicale pentru diagnostic in vitro și în baza documentației înaintate, Ministerul Sănătății Publice autorizează evaluarea performanței pentru dispozitivul medical: ..... ..... ..... ..... ..... ..... .....

(denumirea, tipul) Producător: .....

Orice modificare a condițiilor stabilite prin reglementările Ministerului Sănătății Publice, care au stat la baza autorizării, atrage anularea prezentului document. Director,

.....

Magyar Tanulmányi javaslat

Nagyrápolti Szent-Györgyi Albert (élt: szeptember 16, 1893 - október 22, 1986 között) egy magyar fiziológus, aki elnyerte a az 1937-es élettani-orvosi Nobel-díjat.

1932 őszén letesztelte a paprika C-vitamin tartalmát. Bebizonyosodott, hogy a paprika egy nagyon gazdag forrása a C-vitaminnak, és a kínálat nem volt gond - Szeged volt a Magyarország paprika fővárosa. Szent-Györgyi azonnal mozgósította a munkatársait, és megkezdték a paprika nagyszabású C-vitaminkitermelését. Egy héten belül több mint három font tiszta kristályos anyagot, C-vitamint készítettek.

Szent-Györgyöt kutatásai az izomszövet légzésével kapcsolatban, arra a kérdésre vezette, hogy hogyan mozog az izom. 1939-ben a kutatók arról számoltak be, hogy az izom fehérjéi kölcsönhatásba léphetnek és megoszthatják az ATP-t. Bár 1929-ben fedezték fel ATP-t, még nem azonosították fő energiaforrásként a sejtekben (hatalmas energia szabadul fel, amikor a foszfát, kötésekre van felosztva). Szent-Györgyi indoklása szerint a miozin-ATP kölcsönhatás megmagyarázhatja az izom mozgását.

Szent-Györgyi izomműködésről írt munkáját rövid, elegánsan írt sorozatú könyvekben összegzi.

Szent-Györgyi András, Albert fiatalabb unokatestvére, és felesége Éva, felfedezték a miozin alegységeit ("meromyosin-okat"), és elkezdték az izomfehérjék működésének elemzését több elektronikus szinten. Szent-Györgyi és más kollégák úttörő munkát végeztek az izomszövet elektronikus szinten való elemzésével kapcsolatban. Legtöbb termés a paprikából Magyarországon volt, javasoljuk, hogy tanulmányozza a paprika hatását, és az elektro-stimulációt az izomnövekedésben. A testépítők izomtömeg teljesítménye mérhető elektromos izom aktivitással, a szokásos EMG készülékkel, és négy témában.

- 1. Izom növelése diéta allat
- 2. Paprika a diétában és az Elektromágneses stim (szabványos TENS készülékkel)
- 3. TENS készülék önmagában
- 4. Kontroll csoport

5 és 10 témára számítunk minden csoportban. És, egy egy hónapos időszakot vennénk figyelembe a fejlődés során.

Előtte és utána mérések: vér, hormon szint, tesztoszteron, humán növekedési hormon, kortizol, lélegzet visszatartás, szem és kéz koordináció, fájdalom tolerancia, az érzelmi állapot összpontosítása az ingerlékenységre, fogyás, az erő és izom tömege.

Ezzel a tanulmánnyal, szeretnénk felkelteni az érdeklődést C-vitaminnal kapcsolatban, és javítani a magyar paprika exporton.

Szent-Györgyi kiadványok

Az oxidáció, erjesztés, vitaminok, egészség, és a betegség (1940) Bioenergetika (1957) Bevezetés egy szubmolekuláris biológiába (1960) Az izommal kapcsolatos tanulmányok az Orvostudományi Vegyészeti Intézettől

Referenciák.

- 1. ^ Kyle, R. A., sampon, M. A. (2000). "Nobel díjas Szent-Györgyi Albert". Mayo Klinika eljárása. Mayo Klinika 75 (7): 722. PMID 10907388. szerkeszt
- 2. ^ Dr.Czeizel, E.: Családfa, 148 oldal, Kossuth Könyvkiadó, 1992.
- 3. ^ Dr. Czeizel E. : Az érték még mindig bennünk van, 172 oldal, Akadémiai kiadó, Budapest

### University of Timisoara

The essential contribution of knowledge to scientific progress and social welfare is now widely recognized. Such recognition has increased the attention to the role of universities in the production and dissemination of knowledge. Universities are no longer seen as self-indulgent "people factories," but as valuable idea generators with vast influence and the potential to manifest technologies and concepts that can change lives. So who determines what is or is not an art? It is not the

governmental bodies, not the notified bodies, but the unversity who teaches it, implements it, develops it and makes it part of the state-of-the art current science.

IMUNE's medical text books are a part of the curriculum of the 'Victor Babes' Medical University in Timisoara, Romania, and have been for the last 5 years, since 2009.

As a general rule, a medical device study cannot be n a university approved medical text book until it has been in a peer reviewed medical journal for at least 5 years. Our studies have been in peer reviewed medical journals for more than 7 years thus our studies are included in the following medical text books of the University of Timisoara:

- Energetic Medicine Science over Convention
- VARHOPE (Voltage, Amperage, Resistance, Oxidation, Hydration, Proton and Electron pressure, the body electric's vital signs)
- TVEP and Medication Testing (the research)
- Stress as THE Medical Concern
- Electro-Physiology-Feedback Measures of Interstitial Fluids
- Medical Research Validation of the SCIO
- SOC Index and the Evidence for Lifestyle Medicine
- The Body Electric Simplified
- To Be a Professional Biofeedback and Energetic Medicine Therapist
- Today's Modern Research in Electro Stim and the Eductor
- VASO-VAGAL Reaction what you need to know to operate the SCIO

Since 2009, University of Timisoara has been the host of a 4 module Postgraduate Study on Neuroanatomy, Neuroelectrophysiology and Biofeedback, on the SCIO device. The professors involved with the postgraduate study, together with SCIO International Romania, are:

Dr. Aurel I. Bacean (Romania)

Dr. Igor Cetojevic (Cyprus)

Dr. Matthias Heiliger (Switzerland)

Stephanie Heiliger (Switzerland)

- Dr. Codruta Bacean
- Dr. Onut Bacean

This is the first international postgraduate study on biofeedback credited by the Romanian College of Physicians with CME (Continuous Medical Education) credits with an internationally recognized certificate.

This is a picture of Dr. Igor's (Novak Djokovic's doctor) Romanian license professional qualification a Neuro-Physiologist-Bio-Feedback-Bio-Resonance SCIO therapist.

MANUL HUNDER, ULING AND SI INC. MAN Seria H Nr. - 0003572 ROMÂNIA MINISTERUL EDUCATIEI, CERCETĂRII ȘI INOVĂRII UNIVERSITATEA DE MEDICINĂ ȘI FARMACIE VICTOR BABES" DIN TIMIŞOARA ECTORGERTIFICAT DE ABSOLVIRE Domnul IGOR CETOJEVIC ETAPI născut ... în anul 1962 luna martie ziua 6 in localitatea judetul ..... tara BOSNIA ȘI HERZEGOVINA a absolvit cursurile postuniversitare de perfecționare cu durata de \_\_\_\_apr.2010-feb.2011 (4 module) în specializarea Neuroanatomie, neuroelectrofiziologie și biofeedback, Aparatul SCIO - placa turnantă a biorezonanței și a susținut colocviul la data de 12.02.2011 Tindarularmeestui certificat i se acordă toate drepturile legale. RECTOR, DECAN RECSORATZ ann SECREPAR SEF. 15.03.2011 e insoțit de foata matricolă Semnătura titularului ILLINY T



Neuro-Anatomy, Neuro-Electro-Physiologist in Biofeedback SCIO Therapist with Bio-Resonance



Medical University of Timsoara Romania Place of Desire' Dubounet historic Lecture on VARHOPE techniques with SCIO

Medical regulators do not decide what is or is not medicine. Medical Universities decide what is or is not medicine. When the Unversity of Timisoara allowed medical text books to include our publications, which have been in peer reviewed journals for mor than 5 years, this became undeniably a medical art. And beyond that, when the Governemt of Romania has issued a professional work qualification for this device, we have achieved complete compliance, validtion and verification.

# Dr. Hilf Klara's research

In 2012 Dr. Klara Hilf has made an application to the Hungarian Ethic Committee for a study based on Albert Szent Gyorgy's work. She has received one request from the EEKH for additional information, and after submission, after the passing of the 60 days, the study has been started.

On the 31<sup>st</sup> of January 2013, Andreea Taflan and Edit Barota have attended a course organized by SAASCO Kft. on Medical Device technical File. As a part of the presentation, was a section on Clinical Evaluations and Clinical Investigations with Fodor Eszter from Pharmahungary. Mrs. Fodor has stated that after the passing of 60 days without a response from the Ethics Committee, the study is considered approved and can be initiated.

Thus Dr. Hilf Klara has received approval from the Hungarian Ethics Committee to conduct research when they have not refused her after the passing of 60 days from her submission. In addition, the Ethics Committee of the Psychology Faculty of the University of Bucuresti has further approved Dr. Hilf Klara's work and research.

In her office, with researcher's help, Dr. Hilf Klara has duplicated the study conducted in 1973 initially by Prof. Desire' Dubounet. This has brought us back to the start. After 40 years of research, validation, verification, we have proven that this device is safe and effective to the indications for use.

# Quantum Entwinement as a Principal of Human Communication Eductor- 2014

### http://www.downloads.imune.net/journals/2013%204%20Quantum%20Ent winement%20as%20a%20Principal%20of%20Human%20Communication/

### Abstract:

A research study first done in 1973 is being redone forty years later in 2013-2014. Volunteer subject teams were chose for their intimacy relationships. Mothers and child, marital partners, and close friends each in a pair are chosen. One member is isolated in a dark room with a stroboscope in front of their face. The other is hooked to an EEG device (the Eductor). The Eductor measures their Brain wave, heart electrical pattern, skin resistance and the VARHOPE of their body electric. At random intervals the strobe light in the room with the remote subject will flash for 30 sec. this will make a subtle shock to the system of the person and induce an ocular evoked potential. In the original experiment in 1973 the system shock to the one member of the pair provoked a similar evoked potential to the other.

In our 2013-2014 study we had 33 teams. In twenty eight of the subjects there was an evoked potential at a distance detected in the VARHOPE of the receiver on the first stimulation. On the second strobe stimulation there was a reduced but measurable evoked potential. Verbal mind guesses were inaccurate but a bioelectric response was demonstrated.

This can be explained thru a type on quantum entwinement/entanglement principle of the body electric. But since this process is beneath the reticular activating system and thus not connected to the word area. Over emphasis of the word area in science has prevented us from truly accepting the

ability of telepathy. Over 20 different research scientists have validated this incredible result in independent medical supervised studies.

There is a distinct dichotomy of the brain in a word area (left hemispheric logic) versus a Intuitive body electric a global Gestalt systemically wired Holistic nonverbal mind. The word area's logic has dominated over the last few centuries. New developments in Insight Creativity have shown it occurs elsewhere in a nonverbal mind.

As we can see, there are basic barriers to acceptance of ESP. most of these barriers are intellectual and come from the verbal mind. First is a lack of a logical plausible explanation for the word area of the minds of limited thinking scientists to comfort. The basic idea of Quantum Entwinement/Entanglement has now offered us such a plausible explanation. But the word area of limited verbal minded scientist struggle with this. Einstein struggled with this and called it "Spooky Action at a Distance". And indeed most all things beneath verbal minded analysis are spooky indeed. But most of our societies and their inhabitants have held fast to their beliefs in spooky action at a distance. Who does not have a story of a thought or communication from someone at a distance? More than 75% of the people believe in ESP communication. Studies have shown its effect but not its reliability or at least its verbal reliability.

We did this study in 1973 at Youngstown State University, and hence printed it in the graduate department publication. Forty years of further research into the components in the face of incredible resistance has led to a complete analysis of the concerning factors. Now with the advent of a new technology we have repeated the experiment. And now that modern science of Quantum Electro Dynamics has caught up with us a scientific explanation is apparent. And the belief of the masses has been verified. In fact with quantum entwinement/entanglement the ability of close people to communicate nonverbally at a distance is expected.

### Strobe Stimulation:

One member of each subject team is isolated in a dark room with a stroboscope in front of their face. The strobe stimulation room is placed in a different building, to remove the electrical interference effect. At random intervals over an hour the strobe light in the room with the remote subject will flash for 30 sec. Hypothetically this will make a subtle shock to the system of the person and induce an ocular evoked potential. Verbal guesses had no results.

The other member of the study team is hooked to an EEG device (the Eductor). The Eductor measures their Brain wave, heart electrical pattern, skin resistance and the VARHOPE of their body electric. In the original experiment in 1973 the system shock to the one member of the pair provoked a similar evoked potential to the other.

**Result processes:** measures of attention were the moments of stimulus beginning and discontinuation, 1-2 seconds, in the measured subjects' EEGs. An affirmative relationship was hypothesized to appear between the collective modifications of the stimulated subjects' EEGs versus a strobe stimulated subjects. Control data using the same equipment and test conditions, but normal subjects tested, was collected to see if there was equipment and systematic artifacts.

**Results:** The placebo test resulted in a correlation of r 5 20.05, p 5 0.61; the experimental test resulted in r 5 0.25, p 5 0.0005.

Twenty eight (28) of the 33 pairs of participants showed independently significant correlations. Five (5) of the 33 pairs of participants showed no significant reactions.

Inspection of the stimulated subjects' event-related evoked potentials showed that the stronger their responses in the theta band.

The analytical procedure was as followed:

1. Determine for each S period *j* the maximum value from the onset or offset of each stimulus up to one second post partner stimulus; call these maximum values *max*.

2. Identify those S period where max values were larger than a maximum threshold value selected to identify at least 50 such periods; call this subset of periods {max}.

3. Find the peak value of the R ensemble variance array v, that is, variance across all Rs, from each stimulus up to 1 second afterwards; call the time where this peak occurred p and the associated variance value vp.

4. Determine the R ensemble variance array v for the subset of  $\{max\}$  periods identified

Brainwave frequencies drifting towards the theta band were found. And a slight change in volt potential max reading was displayed.

**Conclusion**: Under certain conditions, the EEG of a sensorial isolated human subject can influence event-related evoked potentials of their meaningful other at a distant. Showing a quantum entwinement of people at a distance.

### Discussion:

In this study we reproduced the 1973 results showing that there was indeed spooky action at a distance between intimate pairs. Things once so joined maintain a level of communication regardless of distance.

### Eductor research

The Eductor device is substantially equivalent to the SCIO, EPFX, QXCI devices. The Eductor device is today's technology, today's design, but operating within the same specs, only with a higher range of efficacy. We now present research done on the Eductor, echoing research done on the SCIO, EPFX and QXCI to show completely that our device is valid, verified and compliant with all the regulatory requirements and standards.



Page **226** of **269** 

# GSRtDCs Biofeedback Stimulation Increases Math, Insight and Language Memory Eductor 2014

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

### Supervising Researchers: Dr Klara Hilf, Dr Danish Biofeedback Research Technician: Neményi Rita Permission of the Hungarian Ethics Committee and the Ethic Committee of the University of Bucharest Faculty of Psychology Institution: International Medical University Sponsor: Mandalay kft

### Dates: September 2014 Place: Budapest, Hungary

### Abstract:

93 subjects male and female were measured for basic Math skills, Insight and Language Memory.

Three GSR Cybernetic systems were compared to a placebo group. The Indigo, SCIO, Eductor 2014 with single signal generator and double signal generator setting were compared to placebo control testing. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the effect.

We analyzed speed, accuracy and stress during math problem solving and learning new words in a new language. Once a base-line was established, the trans-cranial GSR Biofeedback cybernetic operation was turned on. After stimulation there was a significant noticeable increase in accuracy and speed of the math and word skills. The second wave form generator performed better in the test.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's by Desire' and first clinically proven in 2002. And proven again in several studies over the last two decades.

The technology has used a single wave form generator for CES since first registered with the US FDA in 1989. After over 35,000 such devices with not one reported significant risk, safety is obvious. Hundreds of studies have shown this technology to be effective, and now a second wave form generator will be tested.

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IT IS OUR BASIC HYPOTHESIS THAT A SMALL DC PULSED MICRO-CURRENT APPLIED TO THE CRANIUM CAN STIMULATE OSMOSIS AND THUS IMPROVE SYNAPTIC ACTION, MEMORY AND LEARNING. THIS EFFECT CAN BE MAXIMIZED WITH AN AUTOFOCUSED CYBERNETIC PULSE. THIS HAS BEEN PROVEN WITH THE EPFX, QXCI, SCIO AND A HOST OF OTHER RESEARCHERS HAVE MADE SUCH TECHNOLOGY. NOW WE ARE TESTING THE NEWEST ADVANCE THE EDUCTOR WHICH HAS AN EXTRA TWO SIGNAL GENERATORS.

WE FIRST USE THE EDUCTOR DEVICE TO MEASURE THE BODY ELECTRIC FOR VOLTAGE, AMPERAGE, RESISTANCE, HYDRATION, OXIDATION AND ACID ALKALINE BALANCE PLUS OUTPUT OF DISSIMILAR CONDUCTION MATERIALS. AND ONCE WE KNOW THE BODY ELECTRIC FACTORS WE CAN APPLY AN APPROPRIATE TAILORED ELECTRO-POTENTIAL SIMILAR SIGNAL TO THE BODY. THEN WE MEASURE THE ELECTRO RESPONSE AND USE IT TO MAKE THE NEXT STIMULATION. THIS MAKES AN AUTO FOCUSED CYBERNETIC LOOP WHERE THE BODY ELECTRIC CAN GUIDE THE DEVELOPMENT OF THE STIMULATION OF THE SYNAPTIC FUNCTION. THIS HAS BEEN SHOWN TO BE ABLE TO INCREASE MENTAL ACUITY.

### Brief History:

Micro-current Cranial Electro Stimulation MCES is a new advance in Cranial Electro Stimulation CES and energetic medicine. "Electrotherapy" has been in use for over 2000 years, as shown by the clinical literature of the early <u>Roman physician</u>, <u>Scribonius Largus</u>, who wrote in the *Compositiones Medicae* of 46 AD that his patients should stand on a live black <u>torpedo fish</u> for the relief of a variety of medical conditions, including gout and headaches. <u>Claudius Galen</u> (131 - 201 AD) also suggested using the shocks from the electrical fish for medical therapies. There is evidence of electro-therapy in ancient Babylon and Egypt. The body works on electro signals and electro stimulation of low current helps homeostatsis.

Low intensity electrical stimulation is believed to have originated in the studies of galvanic currents in humans and animals as conducted by <u>Giovanni Aldini</u>, <u>Alessandro Volta</u> and others in the 18th century, Aldini had experimented with galvanic head current as early as 1794 (upon himself) and reported the successful treatment of patients suffering from melancholia depression using direct low-intensity currents in 1804.

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In the 1960s and 1970s, it was common for physicians and researchers to place electrodes on the eyes, thinking that any other electrode site would not be able to penetrate the <u>cranium</u>. It was later found that placing electrodes on the forehead was far more convenient, and quite effective.

CES was initially studied for insomnia and called **electro-sleep therapy**; it is also known as **Cranial-Electro Stimulation** and **Transcranial Electrotherapy**.

One of the mechanism of action for CES is that the pulses of electric current increase the ability of neural cells to produce serotonin, dopamine DHEA endorphins and other neurotransmitters stabilizing the neurohormonal system. Since a slight stimulation of a pulsed milliamp current increases osmosis it is shown that neurhormones work better from the increased osmosis.

It has been demonstrated that through CES, an <u>electric current</u> is engrossed upon the <u>hypothalamic</u> <u>region</u>; during this process, CES electrodes are placed near to the face with the ground at the lower body.

Current research shows an increase of the brain's levels of <u>serotonin</u>, <u>norepinephrine</u>, and <u>dopamine</u>, and a decrease in its level of <u>cortisol</u>. After a MCES treatment, users are in an "alert, yet relaxed" state, characterized by increased alpha and decreased <u>delta brain waves</u> as seen on EEG.

In 1972, a specific form of addiction release CES was developed by Dr. Margaret Patterson, providing small pulses of electric current across the head to ameliorate the effects of acute and chronic withdrawal from addictive substances. She named her treatment "**NeuroElectric Therapy (NET)**".

I worked with Margaret and treated rock star Pete Townsend for drug addiction. This is why the SCIO system has had the MCES capacity built in.

The SCIO is a descendent of the EPFX system US FDA registered in 1989 still in registered for sale in America. Since 1989 we have sold over 31,000 such systems under the registered name of EPFX, QXCI, and SCIO. There have been well over 500,000,000 patient visits with all getting some MCES, and not one reported case of any significant risk. Over 200 studies and articles have been written and published on these systems and no report of any risk. It has passed all safety tests since 1989 and all risk analysis has proved it to be insignificant risk.

The systems outlined have a potential of 0-4 volts which is beneath the human threshold of perception, and 0-7 milliamps which makes it safe and for most subtle and undetectable.

For over 26 years reports of stress reduction, relaxation, anxiety reduction, emotional balance, addiction release, insomnia reduction and sleep induction have been reported from the users and doctors.

The Eductor has a second wave form generator that can further intensify the CES effect. All this was done with a cybernetic loop technology guided by the patient body electric reactions to the stimuli. Thus we can further intensify the CES effect over older antiquated non-cybernetic technology.

### Method:

All subjects are volunteers who gave informed consent in writing. We used ages from 17 To 72 Male and female. Subjects with extreme disease were excluded.

We first established a control reference group of ten subject reactions by asking them to solve the math problems or remember the words with no device. We observed practice effect and just how much time and effort normal subjects used to solve the problems.

Then the same researcher asked the questions to the subjects. The subjects were read an example, then asked to solve with no stimulation, then with a single generator and then with two signal generators.

### There are samples of the questions used:

Two numbers added together make <u>A</u> and Multiplied by each other make <u>B</u>

В	Answer
4	2-2
3	3-1
re Test	
12	3-3
12	2-6
36	6-6
48	4-12
	B 4 3 re Test 12 12 36 48

15 56 7-8

Start stimulation tell them to relax with eyes closed wait one minute while getting one channel of CES

9	20	4-5
11	30	6-5
10	21	3-7
18	81	9-9
12	35	5-7
11	10	10-1
22	121	11-11
9	18	3-6

Next we tell them to relax with eyes closed wait one minute while getting two channels of CES

10	2-5
99	11-9
16	2-8
42	6-7
27	3-9
15	3-5
25	5-5
45	9-5
	10 99 16 42 27 15 25 45

ten

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### Part two word memory retention

one	ichi	どうして? (doushite?) = Why?
two	ni	なに? (nani) = What?
three	san	時間 (jikan) = Time
four	yon	だれ (dare) = Who.
five	go	いつ (itsu) = When.
six	roku	人 (hito) = Person.
seven	nana	(doko) = Where.
eight	hachi	(mnon) sapan.
nine	kyuu	



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### Results of the math studies:











### Results of the "words" studies:

















### Word Test results After Second Wave







In the test there were no reported significant risks. Two small headaches were reported on treatment that passed after several minutes. Of the 93 test subjects 90% had improvement in the word memory performance and the same in mathematical performance. The comparison to our placebo control group shows the effect of stimulation of the mental cognition similar effect to recently quoted research in the literature. Our hypothesis has been confirmed in this research.

This has resulted in a p-value of 0.038 proving significance in our study. The GSRtDCs is safe + effective.



In comparison to normal practice effect control group, the single wave form generator had a 15% increase in performance



control Single WFG Double WFG

The second Wave Form Generator (WFG) had an additional effect of 23% over the control. 8% over the single Wave Form Generator

### Discussion:

There were no reported risks during the study. The study showed clearly that the CES can stimulate math ability and memory retention. The history of micro-current CES positive effects on learning dates back decades. There have been no safety issues in the literature. There has been subtle but positive effects demonstrated on thousands of research documentation. This research shows the extra boost of positive effects of the second wave form generator only in the Eductor.





Brain stimulation promises 'long-lasting'

maths boost



### Effects of GSRtDCs Math Stimulation can Last 6 Months

The brain stimulation technique nou dire picalidear who chargels with arthmetic, day researchers

Applying high-frequency electrical noise to the brain can boost maths skills up to six months later, say Oxford University researchers.

A small study in Current Biology suggests the taker standard technique makes neurons for characteristic efficiently if could help those suffering with neurodegenerative, dress, state or learning difficulties. An expert sold the technique sould have "real, applied impact," transcranial and on mose stimulation (TRNS) involves spalying random electrical rose to bargetel steas of the brain by placing electrodes on the surface of the scalp. It is a relatively new method of brain stimulation which is pantiess and non-ancesive.

Our neuro-imaging results suggested that TRNS increases the efficiency with which stimulated brain areas use their supplies of oxygen and nutrients."

Dr Roi Cohen Kudash University of Oxford

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### GSRtDCs Biofeedback Stimulation Increases Math, Insight and Language Memory Eductor 2014

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

### Supervising Researchers: Dr Klara Hilf, Dr Danish

### Therapist: Andrea Fantan

### Permission of the Ethic Committee of the Univ of Bucharest Faculty of Psych Institution: International Medical University Sponsor: Mandalay kft

### Dates: October 2014 Place: Saut Marie Romania

### Abstract:

75 subjects male and female ages 17 to 61 and 15 extra subjects were measured for basic Math skills, Insight and Language Memory. They were asked to report any changes in focus and confidence after the therapy.

The Eductor was compared to a placebo group. The Eductor 2014 with single signal generator and double signal generator setting were compared to placebo control testing. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the effect.

There was a measurable performance increase in the treatment group. There was a dramatic 77% increase in confidence and focus. Confidence and focus is key for children in school.

We analyzed speed, accuracy and stress during math problem solving and learning new words in a new language. Once a base-line was established, the trans-cranial GSR Biofeedback cybernetic operation was turned on. After stimulation there was a significant noticeable increase in accuracy and speed of the math and word skills. The second wave form generator performed better in the test.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's by Desire' and first clinically proven in 2002. And proven again in several studies over the last two decades.

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We first established a control reference group of ten subject reactions by asking them to solve the math problems or remember the words with no device. We observed practice effect and just how much time and effort normal subjects used to solve the problems and we also asked them to report if there were changes in their confidence and focus.

Then the same researcher asked the questions to the subjects. The subjects were read an example, then asked to solve with no stimulation, then with a single generator and then with two signal generators.

### **Pre Questions:**

Do you like Mathematics???

Do you have confidence while doing Math???

Can you Focus while doing Math???

### There are samples of the questions used:

Two numbers added together make <u>A</u> and Multiplied by each other make <u>B</u>

Α	В	Answer
Examples - giv	e answers	
2	4	2-2
4	3	3-1
Start control P	Pre Test - Now d	o not give answers
7	12	3-3
8	12	2-6
12	36	6-6
16	48	4-12
15	56	7-8
Start stimulati CES	on tell them to	relax with eyes closed wait one minute while getting one channel of
9	20	4-5
11	30	6-5
10	21	3-7
18	81	9-9
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11	10	10-1
22	121	11-11
9	18	3-6

### Post Questions after single wave generator:

Do you now have more confidence while doing Math??? Can you now Focus better while doing Math??? Does your ability to think seem clearer???? Anything else you feel.

7	10	2-5
20	99	11-9
10	16	2-8
9	8	8-1
13	42	6-7
12	27	3-9
8	15	3-5
10	25	5-5
14	45	9-5

#### Post Questions after single wave generator:

Do you now have any more confidence while doing Math???

Can you now Focus any better while doing Math???

Does your ability to think seem any clearer????

Anything else you feel.

#### **Results:**

In the placebo group 4 of the 15 increased performance which was 27%. 5 out of the 15 reported noticeable increases in focus and confidence.

Next we tell them to relax with eyes closed wait one minute while getting two channels of CES

In the Eductor treatment group first wave form generator there was a noticeable increase in performance in %, confidence %, and focus %.

In the Eductor treatment group 2nd wave form generator there was a noticeable increase in performance in %, confidence %, and focus %.

	Performance	Confidence	Focus	all as increase over baseline
Placebo	27%	33%		27%
1 <sup>st</sup> WFG	67%	65%	64%	
2 <sup>nd</sup> WFG	76%	77%	76%	

This shows a dramatic increase in performance, confidence and focus over placebo control.

The GSRtDCs part of the program works to stimulate the brain for math performance and confidence as well.

### **BBC** NEWS

Brain stimulation promises 'long-lasting'

maths boost



The brain stimulation technique could help califors who mergels with antimatic, any researchers. Applying high-frequency electrical noise to the brain can boost maths skills up to six months later, say Oxford University researchers.

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Our neuro-imaging results suggested that TRNS increases the efficiency with which stimulated brain areas use their supplies of oxygen and nutrients."



Dr Rei Conen Kubbal University of Oxford

Normal Brain map

1 2

-2 -1 0

severe ADHD

1 Eductor session

3 -2 -1 0 1 2 3 3 GSRtDCs 5 GSRtDCs



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Evenimente	
PUBLICATII	Centrul Doctoral de Cercetare Interdisciplinară, Inovare și Dezvoltare Durabilă (CCIIDD) este o structură
Domeniul Psihologie	instituțională în cadrul Universității din București care își propune să stimuleze excelența în domeniul cercetari-dezvoltări- Inovări în pshologie și în științele educației. Scopul fundamental al CCIIDD este consolidarea capacitti instituționale a școli
Domeniul Stiintele Educatiei	doctoraleincurajandinovarea în domeniul cercetării ștințifice și al programelor de studii specifice.
ORAR	Inițierea CCIIDD a fost susținută logistic cu echipamente de cercetare, platformă de comunicare virtuaă, tehnologi asistive achiziționate în cadrul Proiectului "Inovarea și dezvoltarea curriculei doctorale din perspectiva formari și evaluarii
Proiecte	competentelor de cercetare; corelati cu mecanisme de asigurare a calitati scolii doctorale" (POSDRU/21/1.5/G/36046) dezvoltat de către Școala Doctorală din Facultatea de Pshologie și Ștințele Educației în perioada 2009-2011.
Admitere și taxe	Principalele objective ale activitati CCIIDD sunt:
Legislație	Consolidarea capacități instituționale a școli doctorale și a cercetării fundamentale și aplicative în domeniul pshologiei și al distalar aducației
AVIZIER	<ul> <li>analiza, evaluarea și dezvoltarea de politici și programe corelate cu cele mai reprezentative experiențe și tendințe avansate de cercetare în domeniu;</li> </ul>
Revista "Studia Doctoralia"	Stimularea competitivități ștințifice în randul cercetătorilor, cadrelor didactice din școala doctorală; dezvoltarea abilităților acestora de cercetare ștințifică avansată, în vederea perfecționării continue, ca și competență transversală;
CCHDD	Proiectarea și derularea unor cercetări aplicate care să sprijine îmbunătățirea practicilor, luarea decizilor și valorificarea experiențelor relevante din domeniu;
Contact	<ul> <li>Valorizarea competentelor stintifice ale personalului scoli doctorale pentru a răspunde nevolor de dezvoltare-inovare din cadrul centrelor de cercetare apartmand diferitelor institute si organisme de cercetare (academi, agenti ecceentri, agenti de dezvoltare insursc)</li> </ul>
Acces Platforma Studenti	<ul> <li>economici, agentii de dezvoltare-inovare).</li> <li>Implicares în rețelele profesionale internaționale de cercetare-dezvoltare și consultanță în proiecte de cercetare interdisciplinară în domenu;</li> <li>Îmbunătățirea perceptiei pe termen lung asupra caltăți și performanțelor în cadrul sistemului romanesc de cercetare; creşterea vizibilității cercetării interdisciplinare în domenille psihologie și științele educației în spatiul național și internațional.</li> </ul>

# **GSRTDCs** INCREASES SPORT PERFORMANCE

Studies show increases of : Strength 3 to 5 % Stamina 3 to 7% Eye Hand Coordination 5%






2014

#### CERTIFICAT

Denumirea studiului:

Un studiu dublu orb, controlat placebo, referitor la folosirea ,SCIO/EDUCTOR Universal Electrophysiological Biofeedback System' pentru evaluarea statistica a abilitatii SCIO/EDUCTOR de a imbunatati starea de Wellness a organismului uman ca urmare o unei sedinte de 45 de minute.

Identificatorul studiului: CT-103-01

Sponsor: Sterling S.R.L.

Descriere:

Cercetarea cu sistemul SCIO/EDUCTOR are ca scop evaluarea subiectilor cu o varietate de conditii pentru determinarea modului in care sistemul imbunatateste starea de wellness. Teoria de baza este ca aparatul SCIO/EDUCTOR imbunatateste starea de Wellness a organismului si parametrii "corpului electric" in cantitati masurabile intr-o singura sedinta.

Dintre parametrii masurati inainte si dupa sedinta cu dispozitivul se numara urmatoarele: Chestionar de calitate a vietii, teste de forta, memorie, flexibilitate, coordinare, oxigenare, pH, si scorurile VARHOP (masuratori interne ale dispoztivului).

Organizatia noastra a evaluat cu atentie si impartial protocolul investigatiei medicale propuse, acordul de participare prezentat subiectilor, impreuna cu restul documetatiei prezentate, concentrandu-ne in special asupra aspectelor etice si legale.

In urma analizei, organizatia noastra:

(x) aproba inceperea studiului propus.

Manager Horia LAZARESC

Semnatura:

Page 1 of 1

## <u>GSRtDCs Biofeedback Stimulation Increases Math,</u> <u>Insight, Confidence, Focus and Language Memory in</u> Students - Eductor 2015

Supervising Researchers and Medical Review: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante, Dr. Hobian Veronica and Dr. Maria Baicu

Therapist: Andreea Fanatan, IMUNE Qualified GSRtDCs Research Technician

Permission of the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

> Institution: International Medical University Sponsor: Mandalay kft

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Massage	Electro-Stress
Naturopathy	Chiropractic
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Dates: January, 7, 2015 Place: Saut Marie Romania

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

#### Abstract:

75 subjects male and female ages 17 to 61 and 15 extra subjects were measured for basic Math skills, Insight and Language Memory. They were asked to report any changes in focus and confidence after the therapy.

The Eductor was compared to a placebo group. The Eductor 2014 with single signal generator and double signal generator setting were compared to placebo control testing. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the effect.

There was a measurable performance increase in the treatment group. There was a dramatic 77% increase in confidence and focus. Confidence and focus is key for children in school.

We analyzed speed, accuracy and stress during math problem solving and learning new words in a new language. Once a base-line was established, the trans-cranial GSR Biofeedback cybernetic operation was turned on. After stimulation there was a significant noticeable increase in accuracy and speed of the math and word skills. The second wave form generator performed better in the test.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's by Desire' and first clinically proven in 2002 and proven again in several studies over the last two decades.

The technology has used a single wave form generator for CES since first registered with the US FDA in 1989. After over 35,000 such devices with not one reported significant risk, safety is obvious. Hundreds of studies have shown this technology to be effective, and now a second wave form generator will be tested.

## <u>GSRtDCs Biofeedback Cortical Excitation Stimulation</u> <u>Increases Spontaneous Neuronal Firing to Enhance</u> Chess Skill – with Eductor 2015

Supervising Researchers and Medical Review Staff: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante, Dr. Hobian Veronica and Dr. Maria Baicu

Therapist: Rita Nemenyi, IMUNE Qualified GSRtDCs Research Technician

Permission of the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

#### Institution: International Medical University Sponsor: Biofeedback Srl

Dates: Feb, 27, 2015 Place: Budapest, Hungary

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

#### Abstract:

22 subjects male and female ages 17 to 61 were asked to compete in 15 different chess games with another subject. Each player was hooked to a harness, one harness was active to the Eductor, and the other was a placebo control. No one knew which was which, so we have a perfect double blind study. They were asked to report any changes in focus and confidence after the therapy.

6 of the subjects were asked to play in 2 games and 2 subjects played in 3 games. In our games the player receiving the Eductor stimulus won each time. Even after losing the first time the player receiving the stimulus in the second game won when they got the stimulus. 2 subjects played 3 games. They lost when they got the placebo treatment and won when they got the treatment. The stimulation group reported increasing insight, play expertise, board vision, ability to see moves ahead and chess skills.

The Eductor 2015 with single signal generator and double signal generator setting were compared to placebo control testing. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the effect.

There was a measurable chess performance increase in the treatment group. We asked the subjects to report focus, perception, creativity and confidence after the treatment. There was a dramatic 80% increase in confidence and focus.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's by IMUNE and first clinically proven in 2002 and proven again in several studies over the last two decades.

The technology has used a single wave form generator for CES since first registered with the US FDA in 1989. After over 35,000 such devices with not one reported significant risk, safety is obvious. Hundreds of studies have shown this technology to be effective, and now a second wave form generator will be tested.



## <u>GSRtDCs Biofeedback Cortical Excitation Stimulation</u> <u>Increases Insight in Students – with Eductor 2015</u>

Supervising Researchers and Medical Review Staff: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante, Dr. Hobian Veronica and Dr. Maria Baicu

Therapist: Rita Nemenyi, IMUNE Qualified GSRtDCs Research Technician

#### Permission of the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

#### Institution: International Medical University Sponsor: Biofeedback Srl

Dates: Feb, 27, 2015 Place: Budapest, Hungary

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

#### Abstract:

28 subjects, male and female ages 16 to 63, were asked to use Insight to solve a mental puzzle. They were also asked to report any changes in focus, perception, creativity and confidence after the therapy.

The subjects were asked to solve the nine dot problem to cover each of the nine points with four connected lines. The points of the problem are shown here on the left and the solution on the right. To solve this problem one must develop the insight to go outside the box of the lines.



The 28 subjects were shown the problem and give 5 minutes to solve it. 3 solved it with no stimulation and they were thus removed from the study. 25 could not and were thus entered into the study. The subjects were then given 5 minutes of single channel and the 10 minutes of the 2<sup>nd</sup> wave form generator (WFG) making a total of 15 minutes of stimulation with the Eductor. 5 solved it in the first 5 min. and 13 did it with the 2<sup>nd</sup> WFG. 18 total of the subjects could solve the puzzle in the 15 minutes all subjects were asked to rate their focus, perception, creativity and confidence.

The Eductor 2015 with single signal generator and double signal generator setting were compared. The lack of signal stimulation at the start of the test was used as a control. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the insight effect.

There was a measurable performance increase in the treatment group. There was a dramatic 77% increase in confidence and focus. Confidence and focus is key for children in school.

We analyzed speed, accuracy and stress during insight problem solving. Once a base-line was established, the trans-cranial GSR Biofeedback cybernetic operation was turned on. After stimulation there was a significant noticeable increase in accuracy and speed of the insight problem solving. The second wave form generator performed better in the test.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's and first clinically proven in 2002 and proven again in several studies over the last two decades.

The technology has used a single wave form generator for CES since first registered with the US FDA in 1989. After over 35,000 such devices with not one reported significant risk, safety is obvious. Hundreds of studies have shown this technology to be effective, and now a second wave form generator will be tested.



## GSRtDCs Biofeedback Stimulation Increases Math, Insight and Language Memory Eductor 2015 update

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

#### Supervising Researchers and Medical Review: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante and Dr. Hobian Veronica GSRtDCs Biofeedback Research Technician: Neményi Rita, IMUNE Qualified Permission of the Hungarian Ethics Committee and the Ethic Committee of the University of Bucharest Faculty of Psychology Institution: International Medical University Sponsor: Mandalay kft

Dates: January 2015 Place: Budapest, Hungary

#### Abstract:

96 subjects male and female were measured for basic Math skills, Insight and Language Memory.

Three GSR Cybernetic systems were compared to a placebo group. The Indigo, SCIO, Eductor 2014 with single signal generator and double signal generator setting were compared to placebo control testing. Cybernetic autofocusing of micro-current stimulation and biofeedback correction is used to maximize the effect.

We analyzed speed, accuracy and stress during math problem solving and learning new words in a new language. Once a base-line was established, the trans-cranial GSR Biofeedback cybernetic operation was turned on. After stimulation there was a significant noticeable increase in accuracy and speed of the math and word skills. The second wave form generator performed better in the test.

Many new studies have shown the safety and efficacy of GSR trans-cranial stimulation inducing improved performance in mental acuity. These devices showed superior effect largely due to the autofocused cybernetic loop technology first developed in the 1980's by Desire' and first clinically proven in 2002. And proven again in several studies over the last two decades.

The technology has used a single wave form generator for CES since first registered with the US FDA in 1989. After over 35,000 such devices with not one reported significant risk, safety is obvious. Hundreds of studies have shown this technology to be effective, and now a second wave form generator will be tested.

## Quantum Strength and Muscle Enhancement with the Eductor

#### Written by IMUNE Staff

STUDY INFORMATION:

SUPERVISING RESEARCHERS + MEDICAL REVIEW STAFF: Dr. Marco Antonio Rodriguez Infante, MD, Dr. Hobian Veronica, and Dr. Hilf Klara MD Licensed Hungarian, Mexican and Romanian Medical Doctors Therapists: Rob Wright, Rita Nemenyi Permission of the Hungarian Ethics Committee, and the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

> Institutional Monitor: International Medical University Sponsor: Biofeedback Srl

> > DATES: March 2015

#### Abstract:

Nobel Laureate Hungarian born **Albert Szent-Györgyi** was one of the first researchers to look into the Quantum Electro Physiological nature of Biology. **Albert Szent-Györgyi's** 1957 book on '<u>Bio-Energetics</u>" was one of the first to look into the electrical nature, and quantum nature of the electro-chemical process of life. I worked with **Albert Szent-Györgyi** in America before his death. Albert was truly one of the great minds with vision in all of humanity. I have followed up on his work ever since being with him.



In a series of studies we wanted to test the hypothesis that a CE mark registered Bio-Energetic device could measure the body electric of patients and through energetic intervention we could affect the biology in a positive way. We have tested such things as Chess playing, Insight, Math skills, Memory, Blood, Telepathy, Strength, Stamina, eye-handfoot coordination among others were tested and found positive.

In this study we have tested body builders before and after Bio-Energetic therapy to see effects on power, stamina, and blood hormone level. In a series of different test we found complete safety and a surprising efficacy from the Bio-Energetic therapy.

## <u>GSRtDCs Biofeedback Cortical Excitation Stimulation</u> <u>Increases Insight in Students – with Eductor 2015</u>

Supervising Researchers and Medical Review Staff: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante, Dr. Hobian Veronica and Dr. Maria Baicu

Therapist: Rita Nemenyi, IMUNE Qualified GSRtDCs Research Technician

Permission of the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

> Institution: International Medical University Sponsor: Biofeedback Srl



Dates: Feb, 27, 2015 Place: Budapest, Hungary

http://www.downloads.imune.net/journals/2015%20GSRtDCs%20issue%201/

#### Abstract:

As we have shown everything is an energetic collection of fields that hold atoms in their places. These fields that make us up are reactive with the environment. We must decide what is appropriate to eat and what to avoid. This education starts at the earliest of ages. Most of our current biological electro detection of what is good or bad for us takes place in the nasal-pharynx between smell and taste. The shape receptors of the smell and taste buds are electronic voltammetric field detectors. They sense a proper voltammetric fields that says it is good for nutrition or what is bad. The taste receptors do not absorb or metabolize the nutrient they only test it for intake by measuring the shape of the fields with the shape receptors of the tongue. Voltammetry is the science of analysis of the electrical fields of a substance.

We have shown the patent for the process of the QQC voltammetric analyzer. This device has been designed to work like the human tongue and to recognize the voltammetric signatures of items. These signatures are maintained as a 22x22x22 matrix of 10,648 separate shape vectors that constitute one signature. Since these fields reflect shapes they have a 3 Dimensional component and are referred to as the trivector voltammetric signatures. These complex signatures can be amplified and inputted into the body as part of the Xrroid process in the EPFX, SCIO, Indigo, or what is now known as the Eductor.

The Xrroid analysis is where the SCIO device measures the reaction of the body to over 10,000 substances at the calibrated speed of the body reaction. During the calibration of the SCIO device to the subject the device will measure the voltammetric field of the patient and then send in the QQC. Then the voltammetric signature of what is generally known as the weakest reactive substance (distilled water) is sent in over 20 times and the highest known reactive substance combination is sent in 4 times. The starting speed is 103<sup>rd</sup> of a second. If the subject does not react significantly to the reactive substance versus the non-reactive distilled water the speed is reset minus one to 102<sup>nd</sup> of a second. The speed drops in this increment till the subject has a significant reaction to the reactive substances and it is repeatable. This then gives us a measure of the speed the subject reacts to items. Research in the 1980s showed that patients on morphine reacted much slower to norm patients. Then a variety of reactive speeds was shown thus making a speed of reactivity calibration need for proper testing.

There are several factors that can interfere with the testing of reactivity. If we test and test an item over and over there is adaptation. An aberrant movement, electrical wave form, or a brain wave surge can affect a reading. So we have seen that the reading of reactivity to a single item is not as significant as we would like. Till we could put a subject into a Faraday cage and perfectly control mental aberrations it is not likely. But we have seen that if we measure family reactions we can get some good insight into the reactivity fields of a subject. Research has shown that these families that we use to develop risk profiles are worth medical attention. In this review over one hundred thousand subject studies have verified the TVEP reactive families and the risk profiles have resulted from this work.

In this study over one hundred subjects were measured for Xrroid analysis on either a normal setting or a placebo setting. This was done to validate the TVEP validity and show that on normal setting there would be much more replication of data.

Proper Ethics committee and IRB were used and informed consent from subjects. The study took place in Europe and in America. Subjects were asked to do several measures of their wellness and they were measured for their Xrroid reactivity profiles before and after the test. Repeated items were counted in placebo versus real testing.

### **TVEP Explanation on one page**

 We are all made of atoms with electrons on the outside. The electrons and the atoms never touch each other they repel. The atoms are held in place by energetic fields. We are 99.9999999% energetic fields.
Every molecules of a substance have a specific signature energetic field which can be measured with Voltammetry

 Every living creature has a reactive field that is seeking nutrition and repelling toxins. The global field of the body maintains a changing field of Voltage, Amperage, Resistance, Hydration, Oxidation and Ph variables. This reactive field reacts to stimulation.
By measuring the Voltammetric field of a substance and amplifying the field we can send the field into the body and measure its reactance to the stimulation.
We use over the skin thus Transcutaneous electodes. We send in a known Voltammetric
Research has shown that the TVEP reactions are interesting not diagnostic. The family trends of reactivity are of more interest but still not accurate enough to be diagnostic. Thus a disclaimer of these patterns needs to be displayed.

## **QQC<sup>®</sup> Electronic Trivector Tongue**



QQC Electronic Tongue Detects the Shape and the SCIO Eductor sends the Shape into the Body and the system Measures the Electro Physiological Reactivity EPR / TVEP







Café

Coffea Arabica

The QQC Trivector Electronic Tongue Technology has been Reviewed and Published in PEER Reviewed Medical Journals and printed in Medical University Textbooks



Tested, Reviewed, + Recognized technology used throughout the world today.

# **Over 25 yrs Registerd Techology**

Please Read: <u>http://qqc-electronic-tongue.com/</u>

http://indavideo.hu/video/Clinical\_Evaluation\_of\_the\_QQC\_Electronic\_Tongue

<u>http://indavideo.hu/video/Medication\_Testing\_for\_Dummies</u> <u>http://qqc-electronic-</u> <u>tongue.com/useruploads/files/an\_electronic\_tongue\_based\_on\_voltammetry\_review\_of\_articles.</u> pdf

## <u>TVEP and Electro-Physiological-Reactivity</u> <u>– with Eductor 2015</u>

#### http://www.downloads.imune.net/journals/2015%20TVEP%20issue/

Supervising Researchers and Medical Review Staff: Dr Klara Hilf, Dr. Marco, Antonio, Rodriguez Infante, Dr. Hobian Veronica and Dr. Maria Baicu

Therapist: Rita Nemenyi, IMUNE Qualified GSRtDCs Research Technician

Permission of the Ethic Committee of the National Institute of Recovery Physical Medicine and Balneo-Climatology, Bucharest, Romania

> Institution: International Medical University Sponsor: Biofeedback Srl

#### Dates: Feb, 27, 2015 Place: Budapest, Hungary

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As we have shown everything is an energetic collection of fields that hold atoms in their places. These fields that make us up are reactive with the environment. We must decide what is appropriate to eat and what to avoid. This education starts at the earliest of ages. Most of our current biological electro detection of what is good or bad for us takes place in the nasal-pharynx between smell and taste. The shape receptors of the smell and taste buds are electronic voltammetric field detectors. They sense a proper voltammetric fields that says it is good for nutrition or what is bad. The taste receptors do not absorb or metabolize the nutrient they only test it for intake by measuring the shape of the fields with the shape receptors of the tongue. Voltammetry is the science of analysis of the electrical fields of a substance.

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Proper Ethics committee and IRB were used and informed consent from subjects. The study took place in Europe and in America. Subjects were asked to do several measures of their wellness and they were measured for their Xrroid reactivity profiles before and after the test. Repeated items were counted in placebo versus real testing.



Following are some of the important certified medical university textbooks that review our clinical research:



**TVEP** - The Clinical Experience



Edited by Professor Emeritus Desire' Dubounet, IMUNE

http://www.downloads.imune.net/medicalbooks/978-615-5169-19-9%20TVEP%20and%20Medication%20Testing%20(the%20research).pdf

http://www.downloads.imune.net/medicalbooks/TVEP%20The%20Clinical%20Experience%20reduced.pdf





edited by Professor Emeritus Desire' Dubounet, IMUNE ISED: 978-415-5169-18-2

http://www.downloads.imune.net/medicalbooks/978-615-5169-01-4%20The%20Body%20Electric%20Simplified%20(warning).pdf

http://www.downloads.imune.net/medicalbooks/Voltammetry.pdf



http://www.downloads.imune.net/medicalbooks/978-615-5169-55-7%20Stress%20as%20THE%20Medical%20Concern.pdf

http://www.downloads.imune.net/medicalbooks/Electro-Physiology-Feedback%20-%20Measures%20of%20Interstitial%20Fluids.pdf



http://www.downloads.imune.net/medicalbooks/Symptom%20Operationalization%20(Repertory)% 20For%20Homeopaths,%20Nurses%20and%20Scio%20Biofeedback%20Therapists.pdf

http://www.downloads.imune.net/medicalbooks/Clinical%20Evaluation%20of%20the%20QQC%20El ectronic%20tongue%20tech.pdf

#### Conclusion

After all this research conducted to the letter of the law, in the entire Europe (Spain, Germany, Romania, Hungary, Italy, France, England), Switzerland, United states of America, Mexico, China, Mozambique, South Africa, Canada, now we present to you complete evidence of validation, verification, safety and efficacy of our technology.

As we see from the World Health Products Ratings Service, the Eductor gets the highest validation and verification rating of 11. With full ratings, medical university textbooks, and even governmental registration of professional education the Eductor is well proven safe and effective.

