Clinical Evaluation Research Presentation

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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 the 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 blings, 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 neural reaction and 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. There was over 90% correlation to a type of electrophysiological (VAR) reaction that could be determined. 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 bioelectronic 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.
AAQBT

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 Ohm's 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 spark 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 measurable indicator for discontinuing a stimulus automatically. The Alarm response could be a valuable addition to our cybernetic loop.
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 933 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/irroid 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 8% 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.
AAQBT

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 the door for an electro-acupuncture program to measure and treat acu-points and help the body.

Published AAQBT Press 1988
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-Kroid 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 reactivity 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.

Published AAQBT Press 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 micro Farads 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 AAQBT Press 1988
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 AAQBT Press 1988
ABSTRACT: We tested 935 subjects in Denver and New Mexico to understand the basic body electric measure 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.
AAQBT
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 Selye 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 AAQBT Press 1988

510(k) Registration of the EPFX
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.
The EPFX 510(k) registration was the first one in a long line of legal registrations obtained over the world.
Re: K892114A
Electro-Physio-Feedback-Xroid System
Dated: Undated
Received: July 18, 1989
Regulatory Class: II

Eclosion Corporation
Attn: Frank DiMauro
3936-A Niagara Street
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 Mar. 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.

If 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 announcements 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 to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFD-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,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology, and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological Health
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 May 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.

If 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 announcements 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.

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Sincerely yours,

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology, and Radiology Devices
Office of Device Evaluation
Center for Devices and Radiological Health
7. Has been consulted concerning the use of biofeedback Eclosion to
Eclosion.

8. Software is validated. The software is

In my discussion with Mr. DiMauro he explained that the biofeedback system is composed of: a computer, terminal, keyboard, printer, software and the GSR, EMG, skin temperature monitoring components.

Stephen M. Hinckley
MEMORANDUM OF TELEPHONE CONVERSATION

Between: Frank DiMauro & Bill Schlining
Eclosion Corp.
3960-A Niagara St.
Denver, CO 80207
(303) 322-8978

And: Stephen M. Hinckley, Physiologist,
DARPD, HP-430

Date: 29 September, 1989

Subject: Premarket Notification KB92114

I called Mr. DiMauro to discuss the addendum he submitted to this file. He referred me to Mr. Schlining for any information or discussion concerning this file. Prior to completing our conversation he said that:

Mr. Schlining and I discussed this file. During our conversation he made the following comments:

1. The labeling for this device has been redrafted and does not include any reference to the use of this device for treating any medical condition. The labeling also only includes instructions for monitoring only those physiological parameters the device is capable of, i.e. GSR, ENG and skin temperature. There is no reference to using this device to monitor ECG, blood pressure or any other physiological phenomenon.

2. The firm only intends to sell this device to clinicians; they do not intend to sell it as an OTC device.

3. The electrodes for monitoring GSR and ENG are [redacted] electrodes.

4. The physiological parameter monitoring components of this device [redacted] a switching box which allows the clinician to switch from one monitoring location on the body to the next without disconnecting the patient. The patient is [redacted] isolated from the amplifier the computer and any other source of AC current.

5. The electrode gel supplied with the device is [redacted] manufactured by [redacted]

6. The list of reference material included in the addendum is not going to be included in the labeling for the device. It was only included in the file as reference material for the FDA.
510(K) REVIEW

EB92114/A

COMPANY NAME: Eclosion Corporation

DEVICE NAME: Electro-Physio-Feedback-Xrroid System

1. Life-supporting or life-sustaining: No
2. Implant (short-term or long-term): No
3. Software-driven: Yes Moderate level of concern

4. Device(s) to which equivalence is claimed and manufacturer:
   Professional Series Model 421/Self Regulation Systems

5. Submission provides comparative specifications:
   Technical Specifications
   Instructions for use
   comparative in vitro data: No
   summary of animal testing: No
   summary of clinical testing: No

6. Description of device and similarities and differences between device and
   pre-existing/predicate device(s), including indication for use, new
   technology and new kinds of safety issues:
   1. Performs EMG, GSR and skin temperature biofeedback.
   2. Four channels; 2 temperatures, 1 GSR, 1 EMG.
   3. GSR range, 0-100 Kohms; EMG, 0-10 millivolts, bandpass 100-200 Hz or 15-1000
      Hz; temperature range, 60°-100° F.
   4. Eclosion Corp. manufactures biofeedback components, the computer, the printer,
      the keyboard, software and the switching box. Eclosion manufactures and provides a switching box which allows the user to switch
      from monitoring at one position on the body to another without disconnecting
      the subject.
   5. isolation is used to isolate the subject from any line voltage. Firm
      indicates the biofeedback monitoring system meets UL 544.
   6. Through software the user is capable of storing data, performing statistical
      evaluation of data, change monitoring ranges, change feedback displays or
      tones.
   7. Firm states that the labeling will not contain any reference to the use of
      this equipment for treating any medical condition and will only provide
      instructions for use which relate to the capabilities of the device, i.e.
   8. Software validation procedures are followed.

7. RECOMMENDATION:

   I believe that this device is equivalent to:

   Classification should be brought out: 882.5050 Biofeedback Device
   Section Number and Device Name
   Class: Class II

   Stephen M. Hinckley
   Date 10/4/89

BEST COPY AVAILABLE
ATTACHMENT IV

Use Description

The sole purpose of the E.P.F.X. System is to provide the patient with insight into the subtle changes in the temperature, skin resistance (sweat), and muscle voltage. No claims are made by the Eclosion Corporation for the ability of biofeedback to treat any medical condition. Even claims for stress reduction are not without critics or criticism.

What we do claim is that the system measures subtle body electrical and thermal changes in the patient and feeds them back to the patient via audio or video signals. These signals give the patient awareness of the electrical and thermal changes and thus allows them to better relax.
Eclosion Corporation introduces a new biofeedback system, the Electro-Physio-Feedback-Xrroid (a Xrroid is our coined word for our computer interfacing biofeedback system)

The Newest in Biofeedback Analysis with Capabilities for:
- 6 to 8 position thermography
- 8 point galvanic skin resistance readings
- 9 point EMG system for muscle tension

This system can analyze two or three modality changes for mixed variable feedback. Software allows for display of variables in multiple fashion such as barograph, kaleidoscope, multiple circles, or various games such as Egg Catching, River Rafting, etc. Patient awareness can be increased with the new E.P.F.X. System.

Contact your nearest Eclosion salesperson or phone 1-800-950-8551 for more information. In Colorado, phone 322-8978.
The submitter requests under 21 C.F.R. §807.95:

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code – Panel and class:

Additional Product Code(s) w Panel (optional):

REVIEW: __________________________ (BRANCH CHIEF)  1/2/87 (DATE)

FINAL REVIEW: _____________________ (DIVISION DIRECTOR)  1/2/87 (DATE)

BEST COPY AVAILABLE
ELECTRO-PHYSIO-FEEDBACK-XRROID® SYSTEM

510 K NOTIFICATION

March 15, 1989

From: Eclosion Corporation, NDC# 172-1698
3960-A Niagara St.
Denver, CO 80207
(303) 322-8978

Contact Person: Frank DiMauro

Physio feedback-Xrroid (E.P.F.X.)

E.P.F.X. System is a simple biofeedback with computer graphics. Eclosion Corporation wishes to apply for equivalency to devices sold before marketing the E.P.F.X. System. The Eclosion Corporation also wishes to have this application and any FDA response kept confidential.

XRroid is a potential trademark term of Eclosion Corporation for computer biofeedback connection.
March 15, 1989

Food and Drug Administration
Center for Devices and Radiologic Health
Document Mail Center (HFZ-401)
8757 Georgia Ave.
Silver Spring, Maryland 20910

Attention: Document Control Clerk

Re: 510 K

Dear Sir Madam:

The Eclosion Corporation wishes to request marketing clearance for its computerized biofeedback system (Class II). The pre-market notification information required is as follows:

A. Classification Name: Computerized biofeedback system (feeds back skin impedance, point milli-voltage, and temperature).

B. Preregistration: The establishment registration number is 172-1698.

C. Classification: Skin impedance instrument measuring galvanic skin resistance is FDA number 84GZO; Electromyograph, 84HCC; and temperature feedback is FDA number 80FLL.

D. Eclosion Federal I.D. number is 84-1108034.

E. Performance Standards: September 5, 1980, the FDA set general safety guidelines (45FR58970) for electromedical devices. We are aware of no other performance standards for biofeedback devices. Eclosion corporation has provided ground fault protector attachment to all wall plug units. Micro-circuit breakers (50 milliamps) are attached to all probes and wires attached to the patient. Absolute safety is assured the patient. (See electrical diagram.) The test in transcutaneous (skin contact) only and is not invasive.
F. Labeling Promotional Material: Labeling specimen and draft copies of promotional literature are enclosed.

G. Substantial Equivalence: The E.P.F.X. System is a simple biofeedback machine for stress reduction use only. It measures skin resistance, dermal voltage, and skin temperature. This is equivalent to the autogenic system, the davanon system, and several other pre-amendment systems pre-1976.

Sincerely,

ECLOSION CORP.

Frank DiMauro
President

FD ld

Attachments
### ATTACHMENTS

<table>
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<tr>
<th>Attachment</th>
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<td>I</td>
<td>Software Description and Operators Manual</td>
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<tr>
<td>VI</td>
<td>Label Sample</td>
</tr>
</tbody>
</table>
PRECAUTIONS OF USING E.P.F.K. MACHINE

A. Do not use on small infants or children under 3 years of age.
B. Do not use on pregnant women.
C. Do not use over irritated, inflamed, red, or broken skin.
D. Do not use on patients with electrical sensitivity.
E. Do not use on patients who are under the influence of alcohol or drugs.
F. Do not use on patients with a history of epilepsy.
G. Use caution with psychotic or patients with histories of electro-shock.
H. The E.P.F.K. is for biofeedback use only.
A Message

from the president of Davicon:

As a health care professional, you want to provide the best care you can for your patients. In clinical biofeedback, that starts with using the best tools. I believe Davicon makes the best instruments and systems for biofeedback and here are some of the product advances pioneered by Davicon:

* Automation of every major protocol for biofeedback
* Comprehensive stress profiling using both self-report and psychophysiology assessment
* Use of photoplethysmography (PPG) for heart rate and real-time vascular monitoring
* Implementation of an advanced systems approach to EMG that includes an sensors, extended bandwidth and enhanced artifact rejection

These are not "paper-specs." Each one of these advances has real clinical utility. Davicon was the first company to introduce these advances to biofeedback. And our extensive experience and aggressive product development have established us as the continued leader in these and many other areas of clinical technology.

We are justifiedly proud of our product development team. But we're not the only ones who appreciate their work. You may have noticed that many of our product "firsts" are being imitated by other manufacturers. Also, Davicon was recently awarded a grant by the National Institute of Health to develop improved means for assessing stress. The bottom line is that when you buy a Davicon product, you know that you are getting the most advanced clinical technology available.

But we know that no matter how good the product is, our job doesn't end when we hand you a box. We are committed to service. We have the most complete customer support services in the industry. You can talk to our customer service staff by calling our toll-free Service Hot-line: 1-800-DAVICON. (How many other manufacturers offer this?) And we service everything we sell, including Apple* and IBM* equipment. Davicon has the most complete line of biofeedback products and the people to support you in using them.

Biofeedback is our only business. I have personally made my career in biofeedback since 1972, when I was president of Autogenic Systems. And every member of the Davicon team is equally committed to advancing biofeedback. You can count on us to be here when you need us and to deliver what we promise.

Sincerely,

[Signature]

Kevin M. Connolly
President
Clinically Proven Products for Biofeedback

Precise instruments. Excellent reliability and ease of operation. I am also very happy with the original signal amplifiers and the fact that measurements are instantly available. The true dual display in the MEDAC EMG is essential for determining pain distribution and the true Active Electrode is exceptional for exceptional movement feedback and the most, the immediate needs of the patient.

L. Libo, Ph.D., Director
Aquapacque Biofeedback Center

A complete system for biofeedback and stress profiling. Clinically proven and easy to use.

"MEDAC has been very reliable and I am particularly happy with the dual display. It is very useful in the treatment of patients for headaches and patients who have had muscle pain. I have found the MEDAC to be very helpful and service and phone service support.

F. Spatzendorf, M.D.
Rhode Island Hospital

State-of-the-art biofeedback instruments. For stand-alone use or as part of a computer system.

"No trouble experienced with the computer feedback displays. Accurate, durable and easy to use. For routine clinical work or home training.

"I am very pleased with the high-quality of the instruments. The visual and audio feedback are very helpful. I have been totally satisfied.

P. Remmes, M.S., Therapist
St. Luke's Hosp., Mesa, AZ
Reasons to Choose the MEDAC System

The MEDAC System is a proven performer whose reliability and clinical utility have been demonstrated in years of use. Its integrated software is designed by clinicians for clinicians. You don’t have to be a programmer or an engineer to run MEDAC. It works the way you do.

There are no “hidden costs” to MEDAC. Complete systems include all necessary instrumentation for up to eight channels of physiological monitoring, software, and the best in user-friendly computer equipment.

MEDAC is the easiest system for biofeedback, with hospital-grade instrumentation and more clinical programs than any other integrated software. Standard types of biofeedback programs include: single and dual channel EEG, arterial pulse, heart rate, heart rate variability, skin conductance, skin temperature, and multi-channel for up to seven channels simultaneously.

MEDAC is also a powerful tool for prescriptive diagnosis. MEDAC is the only system to have comprehensive stress profiling, with programs that make it possible to quantify individual stress responses. Stress profiling can add a new dimension to the practice of clinical biofeedback.

MEDAC software is the best of both worlds, its standard mode makes MEDAC the easiest system to use. Programs use clinically proven protocols for biofeedback and collect data automatically. But you can modify standard protocols and even create and save your own protocols in a software “library” (MEDAC 3000 only). This means that not only is MEDAC easy enough for you to use immediately, it is flexible enough for you to use for years to come!

MEDAC automatically keeps biofeedback session records, scores and graphs questionnaires, and performs data acquisition for physiological monitoring. Each patient has an individual desk on which all MEDAC data are kept. And you can print any portion of a patient’s record at any time. Reports are suitable for referral sources or insurance companies.

MEDAC has always embodied the most advanced signal analysis and electrode systems. Now MEDAC has been re-designed, based on new technology and Daviscus’s extensive experience with computerized instrumentation. New MEDAC instruments feature significantly enhanced skin conductance, photoplethysmography, temperature, and a long-life Gel-cell battery system. In addition, a new interface card provides high-quality audio feedback with more flexibility than any other system, plus allows use of an optional Remote Control Box.

MEDAC is now available for use with the new IBM Personal System/2 Model 60, as well as the IBM PS/XT, IBM AT®, or compatible. MEDAC takes full advantage of the power of the new IBM computers with high resolution (EISA) color displays and constant 14-bit resolution. This allows fully auto-ranging instrumentation for “hands-off” operation while maintaining the highest sensitivity in the industry, including resolution of 1mV/TF and 0.01μV EEG activity!
MEDAC is now available for Apple's new high-performance LEXI computer, as well as the dependable and familiar Apple IIe.

MEDAC is a versatile system that pays for itself in numerous ways:
- By providing several distinct and valuable packages, including the P5A, Stan's 4.1, and Electrode Quantameter, as well as biofeedback.
- By producing quality for third party manufacturers and research facilities.
- With operations simplicity that minimizes training costs for new personnel.

Finally, don't forget that your computer is not dedicated to MEDAC. You can still use it for word processing, spreadsheet, and office billing programs.

Let's talk money. MEDAC is fairly priced, but it is not the least expensive system. So consider leasing. With leasing, you pay almost no money down and payments can come from cash-flow. And if you compare the monthly payments for various systems, you might be surprised to see how little it costs to buy the best.

Davivc's offers the most complete customer support services in the industry. This support begins with the MEDAC System itself. MEDAC is self-documenting and easy to use. MEDAC is also extremely reliable, but if it should ever require repair, it is designed for convenient field service. Instructions and software have built in Diagnosis. These tools will virtually allow us to isolate any problems over the phone. And because hardware is modular you can easily be exchanged for new.

Support is always available by calling our full-time Service hotline:
1-800-DAVIDCO. We have found that most problems can be actually solved over the phone. And cannot MEDAC users how they find about dealing with us. We are committed to supporting you.

Davivc's continuous policy has been to upgrade systems as needed or as fast. Whenever possible, changes to improve performance and reliability are utilized to MEDAC users.

"I am still impressed with your equipment after 5 years and a half of use. It is well designed and it works. It is the best system available for my purposes. Excellent features include that Arter Electrode, fully zero-based system, and upgrades to software."

- J. Zunick, Ph.D., St. Vincent, M.D.

"I love my system and I'd have gotten good support."

- D. Wells, Ph.D., Marshall Univ., Huntington, WV

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The Monitor Series

"No frills" instruments

The Monitor Series are "no frills" instruments that are highly accurate and have exceptional feedback displays. Instruments are available in each of the three most commonly used modalities: EMG, EDR, and skin temperature. Despite their low cost, their accuracy makes them appropriate for routine clinical work. Their durability and ease of use also make them particularly well suited for use by patients at home trainers.

M4 EMG
Features flexible thresholding and the Active Electrode, the most accurate and flexible EMG sensor available with a built-in preamp that virtually eliminates artifact. The Active Electrode can be used dry for muscle scanning or wet with standard disposable electrodes. Audio feedback includes a fully adjustable thresholding and raw EMG sound.

C2 EDR
Features two sensitivity ranges and two display modes for measuring skin conductance. NORM for most relaxation therapies, and DERIV for a highly responsive mode useful for psychological monitoring. Also either a continuous or pulsed tone. Uses dry, gold-plated sensors.

T3 or T3H TEMP
Features exceptional resolution of temperature changes and the fastest responding sensors in the industry. In its Derivative mode, the T3H tracks only the changes in temperature and resets displays after each change, allowing hands-off operation. Optional sensor allows automatic multi-site averaging. Available in °C or °F.

Ordering Information:
Each Monitor Series unit has everything necessary for clinical installation. It is a single self-contained package, including rechargeable batteries, a built-in speaker, and a combination transducer/measurement. Also comes with a recharge sensor, and operating manual. The bid also includes AE-128 tape units.
More Specs

C2 EDR
Sensor: Gold-plated brass, Effective area 0.5 cm², Single-ended.
Excitation: Constant voltage 0.5 VDC.
Conductance Range: Calibrated 0.66 ± 0.30 μS/m at 25°C.
Audio Timer: 1 pulse/sec normal.
Display: 15 element, 3 color LED bargraph zero-center type. Measures the percentage change from baseline.
Options: Baseline, power on/off, volume sensitivity, audio type, display mode.

84x EIMG
Sensor: Active Esophageal low-pass pre-amplifier integral to esophageal assembly.
Range: 0-2000 μV.
Input Bias Current: Less than 20 picoamperes.
Differential Input Impedance: Greater than 100,000 Megohms.
Audio Reaction: 90 dB.
Bandwidth: 35-250 Hz.
Voice: Less than 0.05 mV at 60 Hz.
Detector: Logarithmic power detector.
255-Volt constant.
Display: 15 element, 3 color LED bargraph zero-center type. Measures all indexes of baseline.
EIMG: Same as dB change. 25% increments per LED. 500% range full scale.
Controls: Baseline, power on/off, volume sensitivity, audio type, display mode.

The Stress Audit

Paper and pencil version

The Stress Audit presents a quick and comprehensive summary of stress-relevant data that can be used to identify intervention and treatment planning. The Stress Audit is a 238 item Likert scale instrument that samples the magnitude and type of stress experienced or expected by the respondents and assesses cumulative stress over time. The Stress Audit yields a profile that reflects these facets of stress:

- Situational stress items, divided into six scales.
- Stress symptoms items, organized into seven physiological symptom scales, and
- Voluntary/voluntary scales.

administration includes a summary with a profile sheet for scoring in cumulative versus. A comprehensive manual aids in interpretation of the profile. Scans from this brochure may also be entered into the MEDAC System for a comprehensive interpretation.

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MEDAC MEDAC System, PSS, Physiological Stress Analysis, Active Esophageal Map Processor and Device are trademarks of Davidson, Inc. Stress Audit is a registered trademark of Davidson Associates. Apple and Apple logo are registered trademarks of Apple Computer Inc. Appli and AppliCare are trademarks of Appli Computer Inc. IBM and IBM AT are registered trademarks of International Business Machines Corporation. IBM PC/XT IBM Personal System/2 and IBM Personal System are trademarks of International Business Machines Corporation.
Memorandum

REVIEWER(S) - NAME(S) K822114

510(k) NOTIFICATION

THE RECOMMENDATION

It is my recommendation that the subject 510(k) Notification:

(A) Is substantially equivalent to marketed devices.

(B) Requires premarket approval. NOT substantially equivalent to marketed devices.

(C) Requires more data.

(D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

The submitter requests: Class Code w/Panel:

No Confidentiality

Confidentiality for 90 days

Continued Confidentiality exceeding 90 days

REVIEW: (BRANCH CHIEF) 6.26.17

FINAL REVIEW: (DIVISION DIRECTOR) (DATE)

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BioLab System Information

The BioLab's modular design allows unparalleled flexibility. Standard "mount" systems are available for applications in clinical biofeedback, psychophysiological research and rehabilitation medicine. Or, special systems can be easily configured to meet your unique clinical or research needs. One of our Ph.D. psychologists would be happy to discuss your requirements with you.

BioLab Modules

The BioLab offers a variety of physiological monitoring modules for applications in clinical biofeedback and psychophysiological research.

The BioLab will accept up to eight of the following modules:
- Physiological Biopotential Physiological Monitoring
- EEG: Electroencephalography
- EMG: Electromyography
- ECG: Electrocardiography
- EOG: Electrencephalography and Oculography
- EKG: Electrocardiography
- HRV: Heart Rate Variability
- NIBP: Non-Invasive Blood Pressure

Special monitoring or data acquisition requirements can be accommodated by the BioLab's Isolated Instrument Interface Module. This module accepts the voltage output (±10 volt range) from virtually any type of free-standing clinical or laboratory instrument.

BioLab Software

BioText, the BioLab's powerful operating software, is the heart of the BioLab system. It is an easy-to-use program to run training, therapy, or research sessions. Summary statistics are automatically calculated and recorded for each session by BioText.

Demonstration Disks

Convince yourself the new IBM and Apple compatible BioLab is the superior choice for clinical biofeedback or research by ordering the BioText software demonstration disk.

Additional Information:

Please send complete detailed information and prices on BioLab components and software.

Please send demo disk ($15.00) circle one: Apple IBM

Please have representative phone to discuss any needs.

Name ____________________________

Title or Department ____________________________

Organization ____________________________

Address ____________________________________________

City __________________ State __________ Zip ____________

Telephone No. (_________ ) ____________________________

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Autogenic Systems
820 West Ave
Wood Dale, Illinois 60191 USA
Phone: (312) 652-9700
Fax: (312) 652-8715
Clinical Biofeedback

Ease of Operation
Combined with Superior Performance

Why Computerize Your Biofeedback Practice?
The BioLab streamlines the complex and time-consuming aspects of your practice and greatly increases the effectiveness of each session.

Imagine telling a patient to warm the palms of the human figure on the monitor and they do so by warming their own. Or telling them to lower the heart rate of the human figure on the monitor, and they do so by lowering their own. Or perhaps, for audio feedback, have them close their eyes and listen to melodies, relaxing tones specifically designed to deepen relaxation. Then, imagine being free of record keeping and statistical analysis, allowing more time for interaction with your patient. And you'll begin to understand the power and purpose of the BioLab.

Patient Motivating Visual Feedback

Patients relate easily to BioLab displays, becoming enthusiastic participants in the therapeutic process.

Among the BioLab's proprietary visual feedback displays are:

Analogue Biofeedback Display: This display provides a selection of generic male and female, adult and adolescent human figures. Changes in the patient's EMG activity, skin temperature and heart rate are reflected back to the patient by these 'analog' on the BioLab's monitor. Analogue biofeedback lets the patient 'see' the improvement occurring in his or her body.

Composite Biofeedback greatly simplifies biofeedback training. When more than one site or type of physiological activity is monitored, it displays from two to eight channels of activity as a single, undivided display.

The BioLab's colour-coded Line Graph plots up to four physiological measures on a single large graph or, alternatively, one measure each on its own graph in a quadrant of the monitor screen.

The BioLab's Illar displays simultaneously displays up to four physiological measurements as color coded bars.

The Mainndata Slitdisplay is an ever-changing kaleidoscope pattern that feeds back the patient's psychological signal as proportional changes in the patterns.

These and other BioLab displays ensure you and your patients of the most interesting and efficacious visual feedback in biofeedback.

Superior Audio Feedback

The BioLab's new audio module utilizes a Yamaha, eight-channel music synthesizer for the finest audio in biofeedback.

The module has four modes of operation: proportional audio feedback, background audio, reinforcement audio and auditory stimulus presentation.

Standard music selections are provided for each type of audio. Significantly, the module also allows the clinician or researcher complete control to create their own totally new audio feedback.

Proportional Audio Feedback provides audio feedback directly or inversely proportional to the patient's physiological activity.

The Background Audio feature provides a selection of those background audio, ranging from meditative Tibetan Bells to the sound of the ocean surf (white noise).

Reinforcement Audio allows the option of playing a song or music for reinforcement upon goal achievement.

Stimulation Audio allows the triggering of an auditory stimulus at a specified time or event.

Clinical Applications

Hundreds of BioLabs are in clinical use in relaxation training, neurovascular re-education and in the treatment of essential hypertension, tension/migraine headaches, micturition, and many other physiological disorders.

BioLab features especially useful to the clinician are:

- Easily understood audio and visual feedback designed to stimulate and maintain patient interest.
- Automated record keeping, including patient history and session notes.
- Session trials can be recalled, displayed and overlapped, dramatically demonstrating progress and providing positive reinforcement for patients.
- For muscle re-education, waveform of desired muscle movements (from an unaffected limb) can be recorded and displayed for patients to match.
- Exclusive Blood Pressure Module: facilitates biofeedback training for non-pharmacological control of hypertension.
- The BioLab's Audio and Visual Feedback are excellent with children as well as adults.
- Tape recorders, VCR's or other equipment can be activated at, before or after goal attainment by the BioLab.

Optional Patient Stress Profiling Software

 Optional software is available for computerized psychophysiological stress profiling of your patients. The BioLab's Stress Vector Analysis Test features automated scoring of the profile and computer-generated narrative reports. The test areas are based on well-known, widely accepted and research proven instruments.
27.11 If an insulating material is used for the enclosure or part of the enclosure, the leakage current is to be measured using a metal foil with an area not exceeding 10 by 20 centimeters in contact with accessible surfaces of the insulating material. Where the accessible surface of insulating material is less than 10 by 20 centimeters the metal foil shall be the same size as the surface. The accessible parts shall be tested individually, collectively, and from one part to another. Parts are considered accessible unless guarded by an enclosure as defined in paragraphs 4.27-4.30.

27.12 A sample of the appliance shall be tested for leakage current as indicated in paragraph 27.1. Starting with the as-received condition, the as-received condition being without prior energization except as may occur as part of production line testing, the test sequence, with reference to the measurement circuit in Figure 27.1, shall be as follows. Nonpatient equipment is tested in accordance with items A, B, and C below. Patient care equipment is tested in accordance with items B and C.

A. With switch S1 open, the appliance shall be connected to the measurement circuit. Leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

B. With switch S1 closed to energize the appliance, leakage current shall be determined using both positions of switch S2, with the appliance switching devices and variable controls in all their normal operating positions, and with switch S3 in both the open and closed positions.

C. Leakage current shall be monitored at sufficient intervals to determine the maximum leakage current from the time of the previous measurement to the conditions under which the normal temperature test would be terminated. Both positions of switch S2 shall be used in determining this measurement.

Note 1: Separated and used as clip when measuring voltages (currents) from one part of appliance to another.

Note 2: Prober with shielded lead.
Patient Care Equipment

27.13 The measurement circuit for leakage current on patient care equipment is to be as follows:

A. Normally the measuring circuit is to have a resistive input impedance (R) of 1000 ohms. If, in the preliminary analysis and review mentioned in paragraph 27.9, an appliance circuit is found to have a low source impedance, it will be evaluated using a 500 ohm resistance.

B. The meter is to be average-responding and indicate rms value of a pure sine wave within an overall measuring circuit error of not more than 5 percent at indications of 10, 50, 100 and 500 microamperes (10, 50, 100 and 500 millivolts, respectively) when using a 1000 ohm resistor at frequencies from 10 hertz to 100 kilohertz.

C. Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the resistor and meter are to be connected between the accessible parts and the grounded supply conductor.

D. The supply voltage is to be adjusted to the test voltage as specified in paragraph 24.3.

Non-patient Equipment

27.14 The measurement circuit for leakage current from non-patient equipment is to be as follows. The ideal measurement instrument is defined in items A–C. The meter which is actually used for a measurement need only indicate the same numerical value for a particular measurement as would the ideal instrument. The meter used need not have all of the attributes of the ideal instrument.

A. The measuring circuit is to have an input impedance (Z) of 1500 ohms resistive shunted by a capacitance of 0.15 microfarad.

B. The meter is to indicate 1.11 times the average of the full-wave rectified composite waveform of voltage across the resistor or current through the resistor.

C. Over a frequency range of 0–100 kilohertz, the measurement circuitry is to have a frequency response (ratio of indicated to actual value of current) that is equal to the ratio of the impedance of a 1500 ohm resistor shunted by a 0.15 microfarad capacitor to 1500 ohms. As an indication of 0.5 milliamperes the measurement is to have an error of not more than 5 percent at any frequency within the range of 0–100 kilohertz.

D. Unless the measuring circuit is being used to measure leakage current from one part of the appliance to another, the impedance and meter are to be connected between the accessible parts and the grounded supply conductor.

E. The supply voltage is to be adjusted to the test voltage as specified in paragraph 24.3.

27.15 Generally, a peak reading voltmeter having an input impedance of one megohm or greater is to be employed in measuring the open circuit voltage between the parts in question. However, where the voltage is sinusoidal, the peak voltage can be computed from the rms or average voltage.

28. Applied Patient Current

28.1 The available applied patient current shall be measured for an appliance which involves the application of an electric potential to a patient (see paragraph 2.14). If the available current measured exceeds the leakage current value in Table 27.1, the appliance shall be marked in accordance with paragraph 56.1.

28.2 In making the measurement required in paragraph 28.1, the circuit is to be as described in paragraph 27.13 except that the 1000 ohm input impedance may be increased or lowered (but not less than 500 ohms) if it can be shown that maximum output would be obtained at some different level of measuring circuit input impedance.
F6, and then press the SPACE BAR. Press ALT A, and then press the SPACE BAR.

There are two exceptions to the SPACE BAR rule: if you are at the METERS or F3 DISPLAY screens, the SPACE BAR will have no effect.

2.3.16 EXIT PROGRAM, ALT N: (13) Press ALT N to exit the program. This procedure will take you back to C or A prompt. If you have entered changes in the system, you will be reminded to save these changes if you have not already done so. For most instances, you will probably not elect to save the changes.

2.3.1 DEFINITION, SIGNAL SELECTION KEYS

SELECTION keys are used for activating, deactivating, moving, swapping, copying, and removing signals from DISPLAY screens (F1, F2, and F3). These keys include:

1, 2, 3, 4, TAB, ALT S, ALT N, ALT M (ALT D), ALT M (ALT N), ALT N (ALT C), and ALT N (ALT S).

2.3.2 SIGNAL IDENTIFICATION: The temperature signal you observe upon activating the UF program comprises the TEMPERATURE SETUP. SETUPS consist of specific configurations of signals, special features which have been assigned to signals (e.g., audio feedback), and DISPLAY OPTIONS which have been assigned to them. All SETUP signals appear on the METERS screen and on the two DISPLAY OPTION screens (F2 and F3).

All DISPLAY OPTIONS let the active signals which are visually presented in the display. Press ALT S for the SETUP LIBRARY and press the "NUMBER" key for the MA SETUP. Notice that the BASIC SETUP signals appear at the bottom of the FULL SIZE GRAPH option.
June 23, 1989

ECLOSION CORP.
ATTN: FRANK DIMARCO
3960-A NIAGARA ST.
DENVER, CO 80207

D.C. Number: KB92114
Product: ELECTRO-PHYSIO-
SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-8162.

Sincerely yours,

Robert L. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Best Copy Available
APRIL 10, 1989

ECLOSION CORP.
ATTN: FRANK DIMAURPO
1960-A NIAGARA ST.
DENVER, CO 80207

D.C. Number : K89C0114
Received : 03-30-89
Product : ELECTRO-PHYSIO-
FEEDBACK-XRPROID-
SYSTEM

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the receipt date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center HFC-401
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number 800-638-2041 or me at (301) 427-8162.

Sincerely yours,

Robert I. Chissier
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and Radiological Health

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Clinical Solutions

Using MEDAC

MEDAC is firmly grounded in the real-world needs of clinical practice. MEDAC software has been used in clinical practice for over five years, with thousands of patients. And it has been extensively updated as a result of input from users in the field. Representative users and their work include:

**Professionals Medicine**
- PTSD (Post-traumatic stress disorder) - VA Medical Ctr, Gainesville, FL
- Stress profiling - Dartmouth Medical School, Hanover, NH
- Myofascial pain - Tufts School of Dental Medicine, Boston, MA
- Private practice, psychological - D. Pelosi, PhD, Winston-Salem, NC
- Private practice, psychiatric - R. T. Kramer, M.D., Torrington, CT
- Clinic - Pinehurst Psychiatric Clinic, Pinehurst, NC
- Out-patient psychiatric - Beth Israel Hosp, Boston, MA
- In-patient psychiatric - University Hosp, Boston, MA
- Health Maintenance Organization - Harvard Univ Health. Care, MA

**Physical Medicine and Rehabilitation**
- Neuro-structural realignment - Salem Hosp, Salem, MA
- Pain management - Scripps Memorial Hosp, La Jolla, CA
- Cardiac rehab - T. Wood, MD, LINK, Portland, ME
- Stress tolerance assessment for head injury rehab - Rhode Island Hosp

**Experimental Applications**
- Athlete performance enhancement - L. Zarchansky, Ph.D., Boston Univ
- Psychophysiological assessment - G. Schwartz, Ph.D., Yale Univ

**BEST COPY AVAILABLE**
The new MEDAC System

A complete system for biofeedback and stress profiling

"MEDAC is very easy to use. Allows you to spend more time with your patients. Has received outstanding support from the company. Enjoy not only working with the MEDAC System, but also the entire relationship with Daviscom."

R. Poli, B.A.
St. Helens Hosp., Deer Park, CA

The MEDAC System is a proven performer whose reliability and clinical utility have been demonstrated in years of use. Now MEDAC features new, enhanced instrumentation. And it is available for use with the new IBM Personal System/2™ model 30 and the Apple Lisa™. The new MEDAC System provides increased capability and higher performance, but has the same excellent support that MEDAC users are accustomed to.

Choose MEDAC if you're looking for a powerful "turn-key" system with a full range of capabilities for stress management and rehabilitation. MEDAC's integrated software was designed by clinicians. For clinicians, it makes the way you do what you need biofeedback or stress profiling, you'll find MEDAC logical and easy to use.

BEST COPY AVAILABLE
Integrated Software

For biofeedback, stress profiling, and report generation

MEDAC utilizes a biosensory approach to stress management. Software integrates programs for stress profiling and other diagnostics, as well as clinically proven biofeedback, and full report generation. And since software is integrated, commands and procedures are consistent. This makes MEDAC easy to learn.

Unsupervised biofeedback

MEDAC is the sensor system for biofeedback, with hospital-grade instrumentation and more clinical programs than any other integrated software. Standard types of biofeedback programs include:
- Arterial pulse
- Skin conductance
- Heart rate
- EMG

MEDAC biofeedback software provides the best of both worlds. A standard node makes operation very simple. Programs use clinically proven protocols for biofeedback and collect data automatically. But, prompted by on-screen instructions, we can easily modify standard protocols. You can even create and save your own protocols in a software "library." This means that MEDAC is easy enough for you to use immediately, and flexible enough for you to use for years to come.

Data for all biofeedback session records are kept automatically, including mean, standard deviation, maximum, and minimum values, as well as baseline, threshold level, and percent success.

Unique stress profiling

MEDAC is also a powerful tool for prescriptive diagnosis. It is the only system to have full stress profiling, with programs that make it possible to quantify individual stress responses. MEDAC uses a combination of self-report and physiological monitoring to assess stress responses.

Stress Audit: The Stress Audit is a 238 item Likert scale instrument that samples the magnitude and types of stress experienced or expected by the respondent and assesses relative vulnerability to stress. It yields a profile that reflects three facets of stress: 1) Situational stress items, divided into six scales, 2) Stress symptom items, organized into seven physiological scales, and 3) Vulnerability items.

Physiological Stress Analysis (PSA): These programs can detect which physiological systems are most reactive to stressors, as well as analyze over-all patterns in stress responses. Up to eight instrument channels are monitored simultaneously.

A standard protocol provides: (1) an initial or baseline period, (2) a period for the introduction of a stressor; and (3) a recovery period. This protocol is based on the assumption that abnormal responses to stress are characterized by a high level of reactivity, and/or the length of time required to recover to baseline levels. You can easily customize this protocol to meet virtually any requirement.

Headache Questionnaire: Provides administration and scoring of a self-report diagnostic instrument. It surveys symptoms, breaking them down into seven categories, and noting specific responses that may be significant.

Automated record-keeping and reports

MEDAC automatically keeps biofeedback session records, scores and graphs questionnaires, and performs data acquisition for physiological stress profiling. Each session has an individual desk upon which all MEDAC data and identifying personal information are kept. You can enter comments for any session, marking or unmarking simple and convenient. And you can print any portion of a patient's record at any time. Reports are suitable for referring physicians and insurance companies.
Using MEDAC

In your practice

How can I use stress profiling in my practice?

A stress part of your patient’s problem? Stress profiling can help you tell! And only MEDAC provides a complete stress profile with a combination of self-report and physiological monitoring to assess stress responses.

Profiling can help you discriminate those conditions in which stress is a causative or contributing factor from those of other etiology.

How else can you use stress profiling in clinical biofeedback? Here are some ways: Patients are using MEDAC stress profiling:

- Screening patients for biofeedback: Use the Stress Audit and PSA to help select those patients most appropriate for biofeedback training.
- Determining the optimal type of biofeedback for each patient: Use the PSA and Questionnaires before beginning training. For instance, in the case of headache, use them to evaluate the relative involvement of muscular and vascular responses.
- Establishing therapeutic milestones: Use the PSA and Questionnaires during the course of treatment to help set clear goals and mark progress.
- Assessing the effectiveness of training: Compare stress profiling data before, during, and after the course of biofeedback training or other stress reduction therapies.

Experimental uses of stress profiling include screening psychophysiological reactivity, particularly cardiovascular reactivity, as a predictor of pathology.

Why is stress profiling important?

Because your time is important, MEDAC is easier to operate than any other system. This means that you can concentrate on your patient, not your equipment.

This operational simplicity has proven particularly important for hospitals and clinics. Since MEDAC requires very little training to get started, new staff members can come up to speed quickly. Also, any level of clinical personnel can operate MEDAC.

Every system claims to be easy to use. But MEDAC is self-documenting and so “user-friendly” that you can sit down and begin using it immediately, without help. If you think that is possible with any other system, try it!

Outlining information:

- Computer MEDAC System includes a necessary computer equipment. For those who already have a computer of one wish to purchase and maintain their own computer equipment, Danver also offers MEDAC “unboxed.” MEDAC 3000 for IBM PCs and MEDAC 2000 for Apple II series computers include all instrumentation interfacing and software from the MEDAC System specifically.

- Instrument Control: Standard measures:
  - Channels: Heart rate (PPG), Pulse (PPG), etc.
  - Channels: Temperature (PPG), Conduction: ECG, 2 channels: Electroceutical (ECG, EMG)
  - 2 channels: Electroencephalogram (EEG)

- Installation Guide: Use the installation guide and stress audit unit.


Surfaces capabilities vary nonuniformly, depending on test computer. System components may differ from photo. Consult current Price List for exact system configurations. See Specifications for more details.

The PSA program provides patients with a simple method of quantifying complex data regarding a patient’s physiological pain or stress profile. These data are used for:

- 1. Design treatments
- 2. Help patients understand their own symptoms
- 3. Motivate patients to comply with treatment
- 4. Measure treatment gains
- 5. Substance treatment programs: referring physicians, attorneys, and insurance companies

S. Lande, Ph.D.
Bala Cynwyd, PA
JULY 19, 1989

ECLOSION CORP.
ATTN: FRANK DIMAIORE
3960-A NIAGARA ST
DENVER, CO 80207

D.C. Number : KB92114
Received : 07-16-89
90th Day : 10-16-89
Product : ELECTRO-PHYSIO-
FEEDBACK-XRROID®
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intent to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you do not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted as considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST COPY AVAILABLE
To: Robert Chissler  
Premarket Notification Coordinator  
Office of Device Evaluation  
Center for Device and Radiologic Health  
FDA 510k application  
D.C. number K892114  
co: Steve Hinckley  
Re: Additional requested material basic Manual  
requested for 510k Application for 510k equivalency  
From: William Nelson and William Schliening  
Eclosion corp of Commerce City, Colorado  
3970 Monaco drive  
EPFX Biofeedback system  
7/10/1989

Electro Physioloical Feedback Xrroid System

Design for Biofeedback EPFX Device use for stress detection and stress reduction  
For Professional Biofeedback Use Only

DISCLAIMER:

Electro Physiological Feedback Xrroid System EPFX
This system is to be used as a Biofeedback multimedia system. It is designed for stress detection and stress reduction. The device does not diagnose any disease other than stress. Stress can come from many sources, this system uses many multimedia treatments to treat stress. This device also measures patients electrophysiological reactivity, which is another representation of stress.

Only a licensed practitioner can diagnose a patient.
This system is calibrated to measure the very fine and subtle electrical and subspace reactions to a group of biological and medical substances. The sensitivity is set so fine so as to pick up the earliest sign of disease and distress. Thus the results might be below the client recognition. The readings should be evaluated by trained staff. Use additional tests or referrals for further clarity.

No claims other that Biofeedback Stress detection and treatment are made of the system or results.

System Basic Design Intentions
This system measures Electro-Physiological Reactions of the patient to applied varied electro stimulations. This is a type of
Biofeedback. This device catalogues and tabulates the complex electrophysiological reactions of your patient. This is the EPR pattern. The accuracy of the EPR pattern is limited, and as such the results can not be treated as completely diagnostic. This device is not diagnostic of anything other than stress, the readings are meant as prediagnostic.

The doctor or practitioner then should use this data wisely and challenge the results with more standard medical measures for more accurate diagnosis within the scope of practice of the therapist. The EPFX is a computer operated energetic medicine interface that is so sophisticated most of its' functions are automatic. The autofocus system uses a link of therapy to test that is self correcting and self adjusting. The system can make corrections at speeds over one hundredth of a second. The hardest part is learning to operate the computer. It doesn't take long. In ten or so patients you will be somewhat proficient. We expect that no-one would be so presumptive as to try to treat patients the first time they use any new system. However so often new owners have all of their tough cases lined up for the first day therapy. No good results and then the system must be at fault. Any new therapy takes some time to get used to.

The Electro-Physiological-Feedback-Xrroid is a biofeedback system. The definition of biofeedback is measuring a physiological response and feeding it back to the patient. Most of the devices feedback the information primarily to the conscious and thus then to the unconscious of the patient. The EPFX-SCIO system differs in that it feeds back the information or signal to the unconscious primarily and conscious secondarily. The unconscious can then direct these autonomic processes. So our device focuses on repairing the unconscious link of mind body directly.

Feedback of electro physiological processes are given as relaxation signals to the patient. The EPFX system measures a combination of the following physiological functions, voltage potential, current potential, skin resistance, Electro Physiological Reactance, Electro Physiological Susceptance, skin temperature and Frequency. These are the raw readings made at the extremities and the head harness. (see Diagram). The EPFX system applies a variant set of signals and then measures changes in the readings. The changes determine resonance, reactivity and coherency.

The QQC is a proprietary process that does an analysis of the Polographic or voltametric three dimensional electrical pattern of a substance. This produces a substance electronic signature field. The Fields of these substances are sent into the patient via the harness. These variant patterns are of 0 Hz to 25,000 Hz and of variant wave forms. The total current is never over 5 milliamps. The patient is evaluated before and after stimulation to measure any EPR
changes that show patient reactivity. The type intensity and style of reactivity EPR offers insight into the patient health. Types of item reacting can be a link to therapy or deeper diagnosis.

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 Electrophysiological therapy. Hence it is called the Electro Physiological Feedback Xrroid.

The work of Dr. Nelson in his landmark treatise ‘The PROMORPHEUS’, has broken down the science to its basic form, consciousness. The extra-Dimensional theories were tested and proven by Nelson to develop a living system model. The trivector voltammetry system measures the voltage, amperage, resistance, frequencies, etc to calculate the inductance, capacitance, resonance and conductance of the reactive system of the body over time. All done in the strict confines of biofeedback. Thus we can calculate and model the mind body connection from these multi dimensional factors. The quantic nature of the biological system allows for the interface of the digital computer.

The scientific theories behind this device are contained in the 1250 pages of the PROMORPHEUS, written in 1982.

The word doctor comes from the Latin word "EDUCTOR" or teacher. A doctor should be a teacher, thus education is a must for medicine. True medicine should be holistic medicine. Medicine is based in responsibility. Separation from a cause of disease is the responsibility of the diseased patient. If there is a cause of disease in your environment you can choose to change or reduce the cause, move to a new environment, or accept the conditions. Responsibility for healing is with the patient.

Many of the causes of disease that approach us are beneath our conscious awareness. Our unconscious is much more aware of the
disease causing factors that come at us. Our unconscious reacts with subtle energetic changes in electrical bodies. The EPFX device is the first energetic medicine device to test reactions where the patient and doctor both do not know what is being tested. Thus the unconscious of the patient causes the reactions. The reactions are not picked by the computer, not picked by the unconscious of the doctor as with point probes or kinesiology, but the results are picked by the unconscious of the patient.

**WHAT IS HEALTH**

Health is ease of flow.

Health is a flow of items into and out of the body. We intake nutrients, air, water, minerals, amino acids, fats, carbohydrates, thoughts, ideas, friendship, love, respect, mental stimulation, spiritual stimulation, and a host of other nutrients. We detox and excrete urine, breath exhale, stool, mucus, sweat, menses, bad feelings, fixations, addictions, Coercions, intimidations, fetishes, manias, compulsions, spiritual doubts and a host of excretions. Life is a cycle of intake, chew, absorb or reject, assimilate, produce toxins, detox, and start anew. This is the need to survive. Add to this the need to reproduce and now enters our sexual needs. All of this results in a very complex flow of energies in and out, in cycles.

The levels of the person are the body, mind, spirit, social, and environmental. It is impossible to separate these or to know where one starts and another stops. Thus these parts can not be reduced or analyzed separately. When there is ease of flow of things in these levels the person is in health. Health is ease of flow.

**FLOW OF DISEASE**

Disease starts when a stressor or intrusion causes a disruption in the flow. The ease is now dis-ease. Hans Selye outlined a medical system were disease comes into the body as some sort of stressor. This produces an ALARM reaction phase as that the body is trying to deal with the incoming stress. Thus the symptom is a sign of the ALARM reaction. If we fight the symptom not the cause we stop healing. So when our child is exposed to a stress (like a bacteria from another child) a symptom presents, such as a sore throat. The symptom is sign of a disease in flow. The immune system needs help. To fight the symptom is what allopathy does. The allopathic medical doctor fights the symptom by trying to block some other flow. He uses an anti-pyretic for fever, MAO inhibitors for depression, Serotonin uptake blocker for despair, calcium blackens for heart problems, antibiotic to attack the bacteria thus weakening the immune system etc.

So our child with the sore throat might have a toxin or
nutritional deficiency as the deeper cause of the sore throat. The body is attempting to detox and stimulate the immune system with the symptom. The body is trying to cure itself and everything would be alright but, via a unfortunate twist of fate, this child is taken to an allopath. He spots the symptom right off, and prescribes an antibiotic and an anti-inflammatory. The body own attempts for healing and detox are thwarted. The disease is driven deeper. The symptom goes away but the cause lingers and another disease, more insidious than the first continues to develop. This requires another allopathic remedy, and another, till the life force and the body natural can not adapt and fight on its own. Now degenerative disease clicks in, the downward spiral disease, symptom drug, disease symptom drug continues till death stops it. The average seventy year old is on 8 drugs, the average eighty year old 10.

As the stress continues the body acclimates and goes into the ADAPTATION phase. Here the symptom goes away from familiarization. But the disease progresses deeper. We now come to an ultra important conclusion that must change medicine forever. BEING SYMPTOM FREE IS NOT A SIGN OF HEALTH. In fact you can be symptom free and quite sick. Allopathy is for crisis intervention only.

If the stressor continues the body now progresses from the ADAPTATION phase to the EXHAUSTION phase. Here organs weaken. The first form is the FUNCTIONAL phase where organs dysfunction. They make less or excess hormones, enzymes, or others. After a while they slip into the ORGANIC phase, where here the organs or organ will shrink (atrophy) or grow(hypertrophy). There now is a physical disease. If the stressor continues the last phase results which is DEATH. Cellular death, organ death, organ system death, organism death. The next diagram relates the flow of disease.

HEALTH
STRESSOR (TOXIN ETC)----->>---------->>
    ADAPTATION
    EXHAUSTION
    FUNCTIONAL
    ORGANIC
    DEATH

The causes of disease or possible stressors are:
LACK OF AWARENESS  TOXICITY
STRESS            TRAUMA    INJURY
HEREDITY          PATHOGENS
ALLERGY           PERVERSE ENERGY
MENTAL FACTORS                  DEFICIENCY OR EXCESS OF
NUTRIENTS

When these enter the body they disrupt the ease of flow. This produces the Alarm symptom. Then the body adapts, symptoms go away, but if the cause continues the disease continues. BEING SYMPTOM FREE IS NOT A SIGN OF HEALTH. The ability to restore or heal the body is based on how much life force the body has. This has an electrical component. The life force can be suppressed or obstructed. This is the SOC index in the EPFX software.

1. Reduce or remove the cause of disease reduce the SOC index
get the patient to take responsibility for their disease and their bodies, minds and spirits.
2. Try to repair the damaged organs resulting from the disease
3. Unblock the blockages to flow of energy in the body.
Chiropractic, Acupuncture, and other medical arts are dedicated to unblocking unbalances of flow.
4. Reduce the symptoms with natural methods and naturopathy
5. Deal with the constitutional make up or tendencies of the patient.

This flow sheet can be set as your wallpaper by setting it from your install disk.

The EPFX medical device is a Biofeedback device. Thus it is designed to stimulate conscious awareness of our unconscious processes.
Our unconscious is aware of the initial interference in flow. And as such we all need to start our healing process with an interface with our unconscious awareness. This is the reason for the design of the EPFX.

Finally the system can help in finding ways to reduce stress thru other naturopathic means.
So the primary goal of our system is to stimulate the body to heal itself. Symptom reduction is the third priority. We try to prevent the disease from slipping further. We want true healing and long term symptom reduction.
Some patients are more aware of their unconscious. These patients are likely to feel the difference the EPFX device make and recognize the reaction patterns more easily. Others will take more time, but after several visits they will become more aware of their unconscious and feel the effects more.

Philosophy of Medicine:
The word doctor comes from the Latin word EDUCTOR which means
teacher. A doctor should be a teacher, thus education is a must for medicine. The word science is from the Latin word scio which is "to Know". A scientist seeks to know. So he must reduce variables from their natural complexity. In the real world of fractal complexity there is no way to know. This is the realization of recent science, it is a shock to science but it is true. In complex fractal situations we can not know exact results of interventions. A healer seeks to heal and thus it is secondary to know. A true healer is satisfied to heal even if he does not know how or why. A scientist wants to know more than he wants to heal. Many of our youth have grown up seeing scientist make advances in technology and they want to be like the scientists. These frustrated scientist find there is little money in science, and thus become doctors because they think that being a doctor as a form of science. When they seek to know more than they seek to heal they are not good doctors. It is important for scientist to develop and test products before they are used on patients, but then science should take a back seat to healing and education which is true healing. Healing and knowing are not the same. Healing most often takes place without conscious knowing. Healing is an unconscious process. Healing in our own bodies is maximized if we do not seek to intellectually force it.

The rules of a fractal or complex interaction such as the body human start with four simple truths,
1. Things never repeat
2. Small events can have large effects.
3. The whole is more than a sum of its' parts.
4. Analysis of the whole can be intuited or felt but not by analysis of the parts

RULES FOR THE HARNESS

1. DO NOT apply over broken skin
2. DO NOT use on patients with pacemakers
3. DO NOT use on patients with extreme electrical allergy
4. BE CAUTIOUS with patients who have had electroshock therapy
5. Wipe and clean the harness after each use (especially if contagion is suspected)
6. DO NOT try to open or tamper with the box on your harness tampering will destroy the warranty.
7. Black lead to left ankle, blue to right ankle, red to right wrist, yellow to left wrist, and head harness to forehead, or over any part of the body.

Attempting to open the box will interfere with the operation and voids any guarantees on your device.
SOFTWARE

Many energetic medicine diagnostic systems are currently on the market. There are also many therapeutic systems using energetic medicine or bio-resonance therapy. This is the first device of its kind to apply both in simultaneous operation. This allows for autofocusing of stress therapy and stress diagnosis.

Client Waiver

EPFX WELLNESS BIOFEEDBACK CONSULTATION WAIVER

1. I fully understand that the attending therapists are not allopathic doctors (M.D.'s) and do not pretend to be, but are nutritional, wellness consultants and are biofeedback specialists.

2. I fully understand the difference between the practice of allopathic medicine, nutritional wellness consulting, and Biofeedback.

3. I fully understand that the services provided by the attending therapists are not allopathic, but are nutritional, behavioral or biofeedback in nature.

4. I fully understand that the attending therapists perform their services within the parameters of a natural health care and wellness system using biofeedback and stress reduction.

5. I fully understand that the attending therapists do not offer allopathic drugs, surgery or chemical stimulants or radiation therapy. I understand that illness is not being diagnosed nor treated and that my wellness and stress are being measured.

6. I have solicited the attending, biofeedback therapists services in good faith, exercising my free will and following the dictates of my own conscience which allows me to select what I understand is most beneficial to my health.

7. I agree to consult my family medical doctor for a consultation of any risk or contraindications from biofeedback. If a medical doctor is not available, a referral for such services can be arranged.

8. I presently seek counsel, advice, opinions, biofeedback or points of view and/or programs within the scope of the attending therapists wellness and stress reduction practice.

I am aware and release the biofeedback technician to do biofeedback tests and treatments.
9. I fully understand that the services provided by the attending
therapists are not generally accepted and/or recommended by
allopathic doctors or other conventional health professionals.
I realize that insurance payment is possible but unlikely.
Signature of patient or guardian

________________________________________

date________________

Your Family or personal Doctor:

________________________________________

DEMOGRAPHICS OF PATIENT

Now you will see that several other buttons are enabled with
the words in dark letters. HELP will take you to the complete help
manual in Computers format.

But on some Computers computers the format might not be right
so this manual might be all you can get.

You can go to the therapy program, the insurance and billing
program, information if accessible, or demographics. In the normal
patient program you should now go to the Demographics button and
click. The cursor starts in the patient name box and you must enter
a name to proceed. The name is important for the subspace operation.

You should now enter the patient name in the upper edit box.
The cursor should appear in the edit box of the name when the program
is started. If not, click into the box with the arrow if the cursor
is not already in the edit box, and then type the correct patient
name. Tabbing twice more will put you into the SOC questions.

SUPPRESSION AND OBSTRUCTION TO CURE

SOC Index:

The SCIO interview opens with a behavioral medicine interview.
This is called the SOC Index. Named after the work of Samuel Hahneman
the father of homeopathy, he said that the body heals itself with
its innate knowledge. But the patient can suppress or obstruct the
healing process with some behavior. Hahneman 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. The SOC index questions are: mostly based on a scanine (1-10) answer. Some answers can be more. These questions include:
1. Number of organs removed:
2. Number of Synthetic drugs taken currently:
3. Number of cigarettes you smoke a day
4. Number of metal or amalgam fillings in the teeth during the last year:
5. Number of street drugs used per month:
6. Number of known allergies:
7. Number of unresolved mental factors:
8. Are you responsible for your body and the diseases you have:
9. Amount of fat in diet as a percent:
10. Personal stress 0-10 10 being max. Numbers can be larger than 10.
11. Number of sugar servings per day:
12. Number of exercise sessions 20 min or more per week:
13. Number of alcoholic drinks per day average:
14. Number of cups of coffee or any caffeine product:
15. Number of extreme toxic exposures last year:
16. Number of major injuries in past:
17. Number of major infections in past:
18. Number of glasses of water or natural fruit juice per day:
19. Number of pounds over weight:
20. Interpersonal stress 0-10 10 being max. Numbers can be larger than 10.
21. Job-school stress 0-10 10 being max. Numbers can be larger than 10.
22. Money stress 0-10 10 being max. Numbers can be larger than 10.
23. Sickness stress 0-10 10 being max. Numbers can be larger than 10.
24. Family stress 0-10 10 being max. Numbers can be larger than 10.
25. Desire stress 0-10 10 being max. Numbers can be larger than 10.
26. Bowel detox stress 0-10 10 being max. Numbers can be larger than 10.
27. Sweat detox stress 0-10 10 being max. Numbers can be larger than 10.
28. Urine detox stress 0-10 10 being max. Numbers can be larger than 10.
29. Mucous detox stress 0-10 10 being max. Numbers can be larger than 10.
30. Skin detox stress 0-10 10 being max. Numbers can be larger than 10.
31. Sleep stress 0-10 10 being max. Numbers can be larger than 10.
32. Number of Root canals:
Each of these questions relates a behavioral burden on the body that can create a suppression or obstruction to the curative process. Scores below 50 are very good and show little risk of suppression or obstruction. Scores above 50 and below 100 are good and show some chance of suppression or obstruction to cure. Numbers above 100 are of risk.

If the SOC has changed from the last visit, you must change it on the Demographics page. Use the "Modify Patient" button on the Patient Data screen return.

Proper placement of the electrodes
Place electrodes on dry skin, loosely and gently. Thin hose can be under electrodes.

---

**Head electrode**

Wipe Clean harness with 20% alcohol solution

---

**EPFX**

- **Limb**
- **Head**

**Function Print**

---

**Computer Printer**

for external test trays or honey combs, red out, black in

**DC input 6 to 10 V 250 mA**
and save the new info. We hope the patient has taken responsibility and changed their behavior positively. This is reinforcing for the patient and helps the report menu.

Next we can calculate the Suppression and Obstruction to Cure Index, which can tell us the amount of available life force the patient has to recover from their disease. The computer screen has several questions on their medical history. Such as organs removed, drugs taken etc. Click onto the first edit box after the organs removed question. A none entry is equivalent to a zero. You can tab from one box to another and enter only a number. If you make a mistake and backspace the computer will give an error message. To avoid this enter the correct number after the mistake and then click in front of the correct number and backspace to remove the mistake. This will assure that there is always a number in the box once a number is inserted.

There is an impairment rating system in the report. Input any amputation, or other impairments into the report.

For body fat percentage we need to input some anthropomorphic data. Height, weight, abdomen and thigh circumference are essential. Also fat layer thickness on abdomen, and under arm tricep area are helpful. This data and the electrical harness data will allow a fat percentage rating.

If the patient is pregnant the click the pregnant box. This will allow testing of the baby in the test screen.

PREPARE NEW PATIENT OR RETRIEVE OLD PATIENT REPORT

This file allows you to start a new patient report or to find an old patients demographics file. The demographics file you have saved on a patient can be retrieved with this screen.

After you have inputted the patient name, sex, and Suppression and Obstruction to Cure (SOC Index) in the Demographics file, you can add additional information such as birth date, address, phone, etc. on this screen.

If the patient you are working on is new then go to the start new file after pulling down from the File access. Then insert the birth date in the same fashion as the date is presented. You must use the date format that your Computers uses. This is different in Europe from America. Then insert any other information you want on the insert edit boxes. When you are through with entering data then save the file by clicking the 'Save Current' button. If you wish to exit without saving click the 'Cancel' button. If you want to get an old patient demographic file the click the 'Load Old patient' button. Use Modify to change old data especially the SOC index. This will allow you to search the hard drive for an old record. The scroll bars allow you to view the records. When done use close to
BIOFEEDBACK

This program contains several programs designed to induce stress reduction and unconscious awareness of the body. The stress reduction button will start a series of relaxing images to provide a stress reducing environment.

There are guided imagery programs under the Relaxation Methods. Once selected these imagery programs will appear at the top of the screen when you click the Start Biofeedback button. This activates the system and the energetic results are displayed on the chart. On the yellow panel are relaxation numbers that indicate harmonic relaxation. Tell the patient to try to reduce these numbers.

The EPFX system measures over 10 channels every centisecond. Showing these numbers could be over-reductionistic, this is what normal traditional biofeedback does. Our idea of biofeedback differs. The goal is to help the patient. Conscious awareness might not be needed for it is most often over-reductionistic and thereby not wholistic. Rather we use an unconscious biofeedback system where we interact with the unconscious not the conscious to give the patient natural control.

There is a biofeedback game using two colored balls. If the harness is on then click the turn on game balls button and enter any of the above programs. The balls will move to the left as the patient's unconscious reduces harmonic stress. To turn off the game effect use the turn off game balls button.

Under the Biofeedback name on top of the page is also a list of other therapies. These are for a variety of issues. There is a series of treatments for the Oriental Medical concern of excess cold, heat, wind, dryness, and dampness. The EPFX will treat these deficiencies while the screen will show a multimedia program and image. The patient should sit in front of the screen for as long as you want to treat. To stop the program click on the image.

Awareness After Testing

The EPFX interface is set at natural biological electrical levels. So the therapy is most often not felt directly. But the effects are none the less dramatic even though they are below conscious perception. Still the unconscious will perceive the healing effects. This most often results in a positive change in the mood and awareness. Sensations of warmth tingling and euphoria are most often perceive. Sometimes the conscious fights the change and limits conscious perception of the healing. Increase in memory, compassion, and positivity can be demonstrated by asking questions of the patient in these areas. And realize that sometimes the conscious will
recognize these effects later that day. Some conscious minds will struggle with natural intervention and they need time to feel the effects. The goal of this medical device is to promote healing not perception of change. So be patient with such patients.

The patient should not feel the device but should feel the effects. If the water is the same temperature as the skin the person does not feel the bath but afterwards the person should feel clean. This simple awareness needs to be cultivated in our patients as they increase in self awareness and self healing.

**TESTING PROCEDURE OR THE XRROID PROCESS**

The "Prepare test" button allows for computer calibration. Click 't' to start. It is best to proceed with the test as soon as entering. Push the 't' key or click on the Test button once. Tell the patient to be still but not stiff. They should not talk or move and be in the same position and state of mind. The interrupt for testing will test over 1,000 items at approximately one hundredths of a second each, with a pause in between testing. There will be a click during the test and a gong at the end. If you are sensitive to noises then use your sound access on your Computers system to mute the sounds. If the patient is pregnant you can test the baby by going to the treatment button on top then to the test baby button. This can activate a filter for measuring the baby reaction patterns. If the computer can not properly filter the signals for a very young fetus it will tell you. For the fetus under 2 month there is sometimes difficulty.

Computers does not operate in real time. So to measure our patient’s reactivity we will need to interrupt Computers. The mouse will not work during this interrupt. The computer shifts to assembly language and then completes the test or therapy and when it returns it brings the data into Computers for us to review.

The total time of the test should be under 2 minutes. The mathematical calculation will start, taking about 5 to 20 seconds. During the calculation the patient can talk and move.

The SOC index is in the upper left side, on the lower part there is the voltage, amperage, resistance, oxidation and hydration scores. These scores reflect results from the demographics and calibration screens. Now we can start our analysis of the patient.

Xrroid is a word for rapid testing of thousands of substances in the test kit on your harness to the electrophysiological reactivity of the patient. There are over twelve real measures of reactance variables performed on each substance. Since the reaction is an ionic reactance the test reaction take place in small time intervals allowing for the rapid test procedure called the XRROID.

The lowest scores will now appear on the top. The highest
reaction score on the top. The scores on the first screen are somewhat significant, look at them. But the most significant scores are the highest ones. To see the highest scores click on the arrow pointing to the right above the scores matrix. This takes you to the high scores. The higher the number the higher the reaction, scores above 95 are significant. The computer will shade the significant numbers in purple or red. This is not an absolute but the best mathematical estimate. The red scores are three standard deviations from the mean, purple are two SD from the mean, Yellow, one. The blue scores are in order of reactivity.

The other buttons have functions such as:

<table>
<thead>
<tr>
<th>BUTTON</th>
<th>FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programs</td>
<td>Accesses most of the programs</td>
</tr>
<tr>
<td>Aging</td>
<td>By adapting the work of Becker, Priori, Beardall and others, Nelson has developed a computerized system that can develop a tiny DC potential multi signal to time reverse cells. Use of techniques such as differentiation and redifferentiation into a massive set of multi signal fractals. The nonlinear analysis then can develop multi signals for deep tissue interface. This can be used to stimulate immune function, destroy pathogens, detoxify free radicals antiaging, rejuvenation.</td>
</tr>
<tr>
<td>Calibrate</td>
<td>For recalibrating</td>
</tr>
<tr>
<td>Homotoxicology</td>
<td>accesses detox and tissue stage analysis</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Access nutrition and Constitutional homeopathy programs</td>
</tr>
<tr>
<td>Patient Demographics</td>
<td>For patient SOC and behavioral analysis</td>
</tr>
<tr>
<td>Risks</td>
<td>For assaying the EPR Tendencies</td>
</tr>
<tr>
<td>Adjust Anomalies</td>
<td>For adjusting the computer interface</td>
</tr>
<tr>
<td>Spinal Sarcodes</td>
<td>For testing the spine and the sarcodes</td>
</tr>
<tr>
<td>Therapy</td>
<td>Accesses many different therapy programs</td>
</tr>
<tr>
<td>Wellness</td>
<td>Use to evaluate external measures of wellness</td>
</tr>
<tr>
<td>Homeopathic Activation</td>
<td>Allows for seeing homeopathic reactivity and making homeopathic replicas</td>
</tr>
<tr>
<td>Notes</td>
<td>For keeping notes on the patient for adding to the report</td>
</tr>
</tbody>
</table>

Music therapy and SUPERLEARNING
Biofeedback access

Body and Face scan for younger looking skin from stress reduction Biofeedback

Info relative risk of mental, physical, spiritual, social, or environmental problem, this program can be added to by double clicking on any item in the screen it is added to the info report, go to value order if you wish to add top items
Erase Info This will erase the info screen.

Report goes to the report screen

Notes This allows you to compile a note file on your patient to add to your report.

Test resets all reactions to zero and tests all items

Retest retains values of previous tests and tests all items

Virtual Only Tests without harness uses subspace link

Risk Profile Calculates general risks of 40 different areas

Set Value Order puts all substances in order of reaction

Substance Order Puts all substances in order of appearance

Go to No. goes to the exact product number entered in the edit box below

Show Referrals shows the panel with 12 ways for health(double click on it to remove) another panel shows access points for various items in the table, use the go to function to find in substance order.

Load Program Any item added to the report with the double click will be added together for testing or treatment.

Hold: Items are held for all tests of items (to challenge a disease, type it into the hold file and hit 'Indiv Reaction' after 10 sec the top reaction hint will appear in the goto edit. Click 'Go to' to see your hint.

Patients Unconscious Reaction Panel: This panel asks the
patients' unconsciousnessto electrically pick a cause, cure, palliation, mental fixation, and bifurcation of health points
A report of the reaction can be added with 'Make Report' button. Double clicking on an item will allow you to check or treat the item that presents.

Retest VARHOPE: This function is to retest the Voltage, Amperage, and etc after the test. An estimate of improvement is calculated this is all automatically added to the report.

Edit Empty lines: This allows the user to add items to the list by emptying the lines.

Print table: This allows the user to print part or all of the list of remedies.

Test and Treat Alarm Reaction This will test an alarm reaction and correct it if possible.

More Research This allows library access to the Disease Dictionary, Medical Research, and Nelson method of medicine.

When you click on an item in the table it will become highlighted. If you accidentally strike a key it might erase. Alt backspace can return the message. If you proceed to far only reinstalling the disc can reload the lost items.

When you leave the Test screen the computer remembers the last patients data. It will not erase them till the next patient is done. If you wish to edit or data to the database you may but it should only be done in the substance order of products mode. Doing an edit with the value order is dangerous to the data base. Also Please close Computers properly.

INDIVIDUAL REACTION TEST
This checks the reactance response of the patient to an item with multiple channels and multiple vectors.
If the patient develops a headache or pain response terminate use. Individual Reaction Test just one item whatever is marked This function has been improved over the past and can also turn on an EMG, EPR, or EPR function. Since we know the proper vibration levels of the muscle we can work a EMG or other without reconnecting the harness. The coherence of the wave form connection is also rated by the computer. A long list of reaction scores is now shown but this is still only one thousandths or less of the total mathematics used. This is not meant to confuse but should improve your analysis of the reactivity. This program now is improved and compensates for entropic
variance. There is still a massive amount of mathematics used, like it takes many many signals to make a tv picture which we reductionistically call a tree. This program takes many signals to get a reactance. Some of the electrical vectors are shown in the first 18 values. The total reactance value is the old reductionistic value, it shows the total reactance.

**E.P.F.X Software Instructions**

**INTRODUCTION**

The Eclosion E.P.F.X Software system is a state of the art mouse driven biofeedback software system. If you do not have a mouse you may still run this software from the keyboard. When using a mouse just 'Point and Shoot' on any statement on the screen. You will notice one letter in every statement is red, this is-called the accelerator key. To drop a menu down press <ALT> + the red accelerator key for the menu you want. Once in a menu you may access any item on that menu by pressing a accelerator key for that item. You may also move the green highlight bar to that item and press <ENTER>. To exit this software press <ALT>--<X> from the menu system.

**DEMOGRAPHICS**

When you enter the demographics entry screen the date will automatically be entered on the first line for you. If this date needs to be changed you may do so at this time. To move to the next field use the <TAB> key, previous field use <SHIFT>--<TAB>. You may also use the mouse by pointing to each data area and pressing the mouse button. Move form field to field typing in the data required for each field. You do not have to enter all the information but you at least must enter the first and last name. When you are finished entering all the data press <ENTER> or click on the OK button, the data will be saved. If you press <ALT>--<C> or click on the Clear Demographics you will clear all the demographic information. If you press <ESCAPE> or click on the Cancel button you will exit the demographics but you will not save the data.

**BIOFEEDBACK SYSTEM MENU**

The GSR,EMG,ECG selection will take you to the main menu of the biofeedback system. These choices will take you to general biofeedback screens with that channel active. The GSR selection will have the GSR channel active. The EMG selection will have the D.C. Amplifier active. The ECG will have the D.0 Amplifier active but more sensitive.

A. Temperature Biofeedback
The Temperature Biofeedback system will record the temperature of the body at its extremities. First put the harness on the person, headband on the head, wrist bands with temperature probes on the wrist. The computer will instruct you to put the input selector in the 'harness' position. The computer will record the temperature of the head. You will then be prompted to turn the input selector to the 'left wrist' position. The computer will record the temperature of the left wrist. You will then be prompted to turn the input selector to the 'right wrist' position. The computer will record the temperature of the right wrist. You will now be instructed to remove the wrist bands from the wrist and put them on the ankles. The computer will tell you to put the input selector in the 'left wrist' position and press <INSERT>. The computer will now record the temperature of the left ankle. You will now be instructed to turn the input selector to the 'right wrist' position and press <INSERT>. The computer will now record the temperature of the right ankle. Now that the test is finished you will be asked to choose a name from the list of names given to you. Use the arrow keys to move to the name of the person you are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

B. Voltage Biofeedback

The Voltage Biofeedback system will record the voltage and resistance of the body at selected body locations. This test is preformed using the auxiliary harness and the finger wraps. Clip the two white connections of the harness to the finger wraps. Wrap the finger wraps around your fingers with the the silver-chloride contacts away from your fingers. The computer will instruct you to put the input selector in the auxiliary position, do this now. You will be touching locations on muscles. These muscles are: Tricep, Bicep, Forearm, Thigh, Hamstring and Calve. You will start on the right side and move to the left side. The computer will prompt which muscle is to be touched. When the name of the muscle appears on the screen touch that muscle. You will have about 5 seconds to get a reading. You will then see the name of the next muscle. Touch that muscle so the device can get a reading. Continue through all the muscles the computer prompts you to touch. When finished the computer will instruct you to put the wrist wraps on the ankles and instruct you to put the input selector in the 'Harness' position. Press <INSERT> to start the test. This will take resistance readings from the ankles. Now that the test is finished you will be asked to choose a name from the list of names given to you. Use the arrow keys to move to the name of the person you are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk
for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

C. Spinal Biofeedback

The Spinal Biofeedback System will record the temperature, resistance and voltage of the back. This test is performed using the back probe. Plug the back probe into the calibration box and plug the calibration box into the device. Calibrate the back probe following the back probe calibration instructions. Put the input selector in the auxiliary position. Apply a layer of electro-dermal gel to the area to be tested. It is a good idea to warm up the temperature probes built into the spinal probes to body temperature by holding them against the person for about 30 seconds before you begin the test. Make sure you have enough cable to test the full range of the person. When the test starts the standard Biofeedback screen will appear. Note the REC-ON. You are given one 10 second screen sweep to get ready before the test taking the readings for C 1. At the top of the Biofeedback screen notice the C 1 indicator. At the end of the screen sweep the system will "BEEP" to let you know that you must move the probes to position C 2, then C3, and so forth all the way down the persons back. The last screen sweep will be labeled SAC (top row of the Biofeedback test screen). Testing is finished at the end of this screen. The system will automatically proceed the "SAVE CURRENT SESSION TO DISK" screen to store the readings that were recorded from the procedure. Now that the test is finished you will be asked to choose a name from the list of names given to you. Use the arrow keys to move to the name of the person your are testing and press <ENTER>. The computer may now ask you if you want to change the signal labels. If so press <2> meaning use current labels. The computer will ask you if the labels are ok press <Y>. The data will be saved to disk for later viewing. You will now be prompted to press <ALT>-<X> to exit, doing so will end the test and return you to the menu system.

D. Dual EMG Biofeedback

The Dual EMG Biofeedback system records the same data as the spinal biofeedback system. This test requires you to follow the same directions as the spinal biofeedback system except you will make two passes down the back on both sides of the spine. When this test is finished follow the previous directions for saving the data.

DISPLAY MENU

A. Temperature Display
The temperature display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the temperatures will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the menu system.

B. Voltage Display
The voltage display will appear when the selection is made from the menu. To get the temperature readings also you must have looked at the temperature display first.

C. Spinal Display

The spinal display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the spine and its data will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the spinal display menu, type <0> and <ENTER> to exit this menu.

C. Dual EMG Display

The dual EMG display menu will appear showing the name of the person tested with a number next to it. Type that number and press <ENTER>. The graphical display of the spine and its data will appear. This screen may be printed by pressing the <PRINT-SCREEN> key. When you are finished viewing the display press <ENTER>. You will be returned to the dual EMG display menu, type <0> and <ENTER> to exit this menu.

Eclosion EPFX Mark II Manual

INTRODUCTION

This is the manual for the EPFX Mark II system using windows. Manufactured by Eclosion Corporation. This system is mouse operated and operates in the windows environment. Windows all rights reserved.
From the windows screen there are several different systems that can be manipulated and utilized for calculations for point analysis, for reports, and for data base.
1. Calculation System
2. Database Display
3. Point System
4. Report System
5. Biofeedback System
If you double click onto any icon with the mouse, you can go into any of these systems.

1. CALCULATION SYSTEM

Here on the calculation system main screen we see some of the following:
Current Client - Name of the patient that the computer is prepared to do.
Calculation selection - You may select all items or selected items.
All items: All items in the entire data base which then constitutes the Xrroid.
'Selected items: Only the items highlighted on the matrix list.
Status - 1. No data available
2. Data ready for calculation
3. Calculation complete
Tells whether we have done a calculation or not.

Matrixes list - (far right of screen) All Matrixes that can be tested. Top 100 of all can only be obtained after doing a scan and having data which then tells us the top 100 readings of all of the items that were done.

Other categories that are in the data base are:
All of the amino acids, bacteria, DNA, enzymes, food reactants, fungus, homeopathics, herbals and tonics, heavy metals, hormones, inhalant reactants, lipids, minerals, dental nosodes, medical nosodes, parasites, phenols, pollutants, sarcodes, supplements, vibrations, viruses, vitamins, and xenobiotics.

At the bottom of the screen there are five different boxes that can be activated:

A. ABOUT - Contains copyright information and other references to the software.
B. DEMOGRAPHICS - Allows us to go into the adding of the name and putting in the basic demographics of the patient.
C. TEST - Allows us to activate the testing capacities. D. CALCULATE - Allows the computer to calculate the procedures. E. CANCEL - Allows us to cancel the program and go back to our

window icon menu:

B. DEMOGRAPHICS
If we go down and click on the DEMOGRAPHICS button, (a single click will do) then the DEMOGRAPHICS box will appear. We can see that the first name appears which will be in blue and by just simply typing now, we can type in the first name of our patient. When we are done with the first name, by hitting TAB we then move to the last name. Type in the last name, when we are done, by hitting TAB we then move to the age of our patient, hitting TAB we then move to sex and the up and down arrows can move it back and forth to female and male. When we are done with the demographics we then use a single click on OK or ENTER when done. Only press ENTER when all of the demographics data is correct.

C. Test

Now when we come back to the CALCULATION SYSTEM screen we will see that the name has changed to the name that we have entered under Current Client. We will also see under STATUS that it says no data available. Our calculation selection should be moved to all items if we are going to do the total Xrroid. If we are going to SELECTED ITEM, we can go to the screen, click on whatever matrix we want or a combination of matrixes by putting our arrow on matrixes, holding the left mouse button down, then moving it down. This will allow the
blue bar to bring in multiple matrixes, or we can hold on CONTROL and hit the left mouse button which allows us to select any combination of matrixes for testing. Then we need to move to the CALCULATION SYSTEM and hit SELECTED ITEMS to do just a partial test on whatever it is that we wish. If we want to the entire Xrroid we need the black ball to be on all items for CALCULATION SELECTION. The next step is to go to TEST box, click on TEST which brings us into the BIOFEEDBACK DISPLAY screen. From the BIOFEEDBACK DISPLAY screen we next need to notice that the test label at the top of the screen underneath biofeedback display says Xrroid test. From this screen we can also see the time of day at the far upper left. In the RECORD STATUS window at the far upper right. We currently see that the record is OFF. To start recording data for the test we can turn the record ON by clicking onto the record on switch on the bottom. When we do so, the computer will start to flash different items from the test tray and also from the Hololinguistics screen that is being displayed at the top panel next to the RECORD STATUS window. This changing environment tells us just which items are being tested at the super Xrroid speed. In the middle we see that the number will be changing from 1 - 24 which will tell us just how many of the matrixes it has tested as the test proceeds. When the test is done, a box will appear that will be titled FILE SAVE AS. Here we can see the file name and under here should appear an abbreviated form of the patient's name followed by ".BIO". This is in blue. We see DIRECTORY LABELS and DIRECTORIES, all we need to know is that we press on OK with the arrow or we hit ENTER which then allow the computer to save the mathematical data that it has encountered on the patient. We will see on the top screen that it says 'Saving Data...' which tells us what the computer is doing. We also see that the arrow has turned to an hour glass and this prohibits us from being able to operate other buttons while the saving data screen is going on. After a couple of seconds the data saving will be done, this will maneuver us back to the screen known as CALCULATION SYSTEM.

D. Calculate

Here under CLIENT, we will see the same name of the patient. We will see under STATUS that it says data ready to calculate. Now by moving the arrow to CALCULATE and clicking, the computer will now start calculating the data ant making the mathematical analysis. The arrow has changed to an hour glass to prohibit us from activating other buttons. The computer will say LOADING BIOFEEDBACK DATA, PLEASE WAIT. A calculation status a pie chart will tell us how much time is left in the operation as it goes through its calculation. This pie chart will appear twice as it is reading data in a separate function. At the end of the second pie chart, we will see 100 percent will come up. Under STATUS we will see calculation complete, under CURRENT CLIENT we will see the name of the patient that we have been working on. Under the CALCULATION SYSTEM the results of our test cannot be viewed. We will now need to go down to the CANCEL BOX with our arrow and click which brings us back to the ICON MENU.
Here we have our other systems where we can look at the results. We can look at results under report system, point system, or data base display. Let's go to DATA BASE display first.

2. DATABASE DISPLAY

Clicking into DATABASE display we go into the display program. Here we will see a list of the items, the top 10 of the products, and all the other facets of the data base. By going into the DATABASE screen and clicking our arrow at the top of READ THE TOP 100 box, the operation comes up, says it is reading the data and then proceeds and gives us numbers of the items tested in their top 100 form starting at the top and going down to the lower. These will appear in the LIST BOX towards the left side of the screen. We can maneuver the LIST BOX screen up and down by using the scroll bar on the left side of the LIST BOX. You can maneuver the LIST BOX left and right by using the scroll bar on the bottom of the LIST BOX. This type of click allows us to read the entire top 100 screen. To maneuver to another list we only have to go to the LIST BOX on the right side which tells us all of the different matrixes.
On this screen there are many buttons that can be activated:

A. About
B. Top 100
C. Numerical & Alphabetical
D. + and -
E. Include
F. Print

By clicking on any of those matrixes, we can bring up the scores of our test and see just what was the mathematical scores of electrical reactivity that was obtained from each item.

A. ABOUT

At the top of our screen is another ABOUT button to the far upper right which tells us about the different types of copyrights and references on our software. If we hit OK, we can get rid of that screen and then come back to the DATA BASE DISPLAY.

B. Top 10

If we click our button on the TOP 10 box, the computer will take a little bit of time and it will generate the top 10 lists of each item in each matrixes. We will not have a rating of the score but we can see the top 10 enzymes, amino acids, bacteria, DNA, or all matrixes will be contained. By using the scroll bar, we can maneuver through this list and see the top 10 matrixes on the entire report. To EXIT, we have to click on the EXIT button.

C. Numerical & Alphabetical

The system is already programmed to be able to make it's initial presentation in numerical fashion. Down at the bottom we will see two boxes; one for NUMERICAL, one for ALPHABETICAL. By clicking on the ALPHABETICAL box, the organization of the data will be presented in alphabetical form from A - Z. By clicking on the NUMERICAL box, it will be presented from the highest number down to the lowest.

D. + and -

To change the scores on any of the items in the matrixes, we have to highlight them by moving the arrow to the item, clicking on the blue bar, holding the button down to go into order, or by hitting CONTROL and the mouse button, allowing us to bring other things into the item by hitting CONTROL and by hitting the button on our mouse while any item is selected. Those highlighted items in blue can have 10 points added to the numbers by hitting the POSITIVE box next to
SCORE or subtracting ten points from them by hitting the NEGATIVE box next to SCORE. When we hit those, it will change the amount of numerical rating in front of the item. This allows the doctor to intervene with the system and to increase or decrease the numerical value of an item, whatever he feels is clinically worth while in his judgement. By continuing to click on the POSITIVE or continuing to click on the NEGATIVE we can bring any of the item's numerical rating value up or down and this allows the doctor to intervene from his own experience and to possibly correct some of the data that has been presented by the Xrroid.

It is our conclusion that the Xrroid is not always correct and that there is a statistical limitation to its data base. The correction of the system seems to be about 80%. That means that still 1 out of 5 items might be inappropriate. Here the doctor can use his technical expertise to change those scores.

E.' Include

Anything that is also highlighted can also be included into our biofeedback EDITOR by hitting the word INCLUDE. When we tap on the word INCLUDE by bringing the arrow to it and hitting the mouse button, anything that is in blue will be added to the biofeedback EDITOR.

E. PRINT

The entire item list may be printed by hitting PRINT which will then bring up the PRINT window which then tells us what type of printer we are connected to. If we hit PRINT and click OK, the print function is turned on and the items are sent to the printer. To get out of the DATA BASE DISPLAY menu, we need to move the button down to CANCEL and click out the CANCEL system.

3. REPORT SYSTEM
To go into the REPORT system from our ICON MENU. If you double click on REPORT which allows a CALCULATION STATUS box to appear, tells us about the operation in progress, and the finally brings us to the DATA REPORT system.
Here we will see numbers in front of the categories of sarcodes, nosodes, isodes, allersodes, homeopathy, nutrition, amalgam, geopathic stress, the top 100, and electrical. The numbers next to these on REPORT SELECTIONS will tell us the average score in each of these matrixes. By clicking on the SARCODE button we now bring up all of the sarcodes from top to bottom that can be viewed in our screen. These also can be maneuvered up, down, left and right by using the scroll bar on the arrow keys in the windows environment. If we move down to the ELECTRICAL box and click on it, we get a reading of our electrical parameters which include oxidation index, hydration index, resistance, amperage, voltage, watts, capacitance, inductance, and resonant frequency.
For the interpretation of the electrical parameters we need to point the doctor towards the New Biology book which describes each of these electrical functions of the body. To leave the electrical parameter screen, we need to move our arrow down to OK, click on the OK box. In our DATA REPORT SYSTEMS screen we also have NUTRITION which is a collection of all the amino acids, vitamins, lipids, minerals, and supplements screen will allow us to chart out just the complete nutritional needs of the patient. GEOPATHIC tells us about all the different vibrations in possible geopathic stress. HOMEOPATHY, we have a list of all the different homeopathics, (combination and singulars), ALLERSODE has food and inhalant allergies, ISODES has all different types of pollutants and environmental problems, NOSODES contains all different nosodes of dental, medical, origin, virus, bacteria, and parasites, and under SARCODES we see all of the different healthy tissues of the body. Thus we can look at these quickly and easily in our DATA REPORT screen. To print the information in the DATA REPORT screen, look for the PRINT box at the bottom so that we can be able to print out our data reports generated from the patient. To leave the DATA REPORT system, we click on the CANCEL box which pulls us out.

Now we can also review our results under POINT system. 4.
By going into the POINT system we can also see the scores in any of our matrixes and maneuver through the data looking at the top 100. The operation of this system is identical to the operation of the Database System. We still have a button for the TOP 10, we also have a button for READ TOP 100, PRINT functions, PRINT SETUP, an ABOUT box which tells us about the copyrights, NUMERICAL readings, ALPHABETICAL readings on the bottom, INCLUDE function which allows us to include anything that is highlighted in the blue bar, SCORE box with plus and minus allowing us to change the items up and down in proportion, and a CANCEL screen. The beauty of the POINT system program allows us to test the patient actively in harness. To test a patient we need to maneuver the arrow to a list of items such as the TOP 100 OF ALL, ENZYMES, FOOD REACTANCE, or whatever. Put the arrow on the very top upper right arrow going up which now brings the BIOFEEDBACK DISPLAY program up on three quarters of the screen. To our right, we will see a list of the products that we are about to test and by pressing down with the mouse and moving the arrow downwards we can include any batch of items to be tested either in singular fashion or in group fashion or by pressing CONTROL and the mouse button we can bring in items that are not together and highlight them. To activate the test kit and to bring those into contact with the patient we now bring our arrow down to the box marked REACTIVITY. When go to REACTIVITY, the screen will now test the patient's initial reaction to entering those items into their electrical field. The results will appear in a couple of seconds just to the right of the REACTIVITY screen which will tell us their maximum electrical reactivity, their minimum electrical reactivity, their mean or average electrical reactivity during the test, their rise and their fall. Meaning the rise from their previous position and the total fall. The higher the numbers under reactivity, the more reaction the patient is having. The higher the rise, the more positive reaction the patient is having. The more the fall, the more negative reaction the patient is having. This allows us now to test those items and to tell if the patient is reactive. When we hit on the REACTIVITY screen, our list of products disappears and the window is turned off. To review those after testing the reactivity we have to hit ALT-T which brings back our product menu. When the product menu comes back we will see the items that we have tested. If those items are good and need to be included in the patient's profile and printshop, we move our arrow down to the small four boxes underneath the products where we see an I in one box. This allows us to click on that I and that allows the computer to include everything that is highlighted into the print screen. If we hit the minus button just above the I,
we will subtract 10 points from all of the items that are highlighted. If we hit the plus button we will add 10 points to anything that is highlighted. Thus we can add, subtract, or include the different items to be able to maneuver through the screen and determine an entire printout function for the patient. After we've added all of the information in the patient, we can bring up PRINT or PRINT SETUP function or we can hit the EDITOR from the biofeedback test screen. If we hit BIOFEEDBACK DISPLAY, with the point system matrix being done after we've included data, we click on EDITOR. This brings up the EDITOR function and allows us to look at the patient record, the date, the name of the patient, the sex and a list of all the items that we have included in the report. We can view this report by hitting the UP, DOWN, LEFT, or RIGHT arrow keys or by using the scroll bar to look at the entire data report. To print this report, we only have to click on PRINT MENU which allows us to have PRINT SETUP or PRINT FUNCTION. In PRINT FUNCTION we go into the print box and allows us to print the item if the printer is turned on. Once the printer has been turned off, the items will be returned to the screen. Thus by maneuvering through the data with the blue bar and our print function we can determine the reactivity of the patient to any different individual item and then increase or decrease the numbers and finally end at a workable homeopathic program consisting of possible nosodes, sarcodes, nutritional supplements, isodes, allersodes, and the like for patient therapeutics. With a little bit of practice, moving through the windows environment is quite easy and fun and a patient can be fully Xrroided and reactivity tested and a full therapeutic program can be charted out in 10 - 15 minutes. The purpose of the DATA BASE display, is to allow us to look at the items without being able to test them and to look at each individual matrix. This differs from the REPORT screen which allows us to look at all allersodes, nosodes, isodes, sarcodes, and nutritional items. This also differs from the POINT system which allows us to go in and test reactivity. The EPFX system also has the ability to work with an individual stylist or point probe which can also give us a system analysis.

CANNOT BE UNDONE. So you must be careful when using the CLEAR ALL function. The next selection on the menu bar is the PRINT MENU. Under that we have PRINTER SETUP and PRINT. If you click on the PRINTER SETUP, you will be shown your default printer. If you would like to see more, you would press the little down arrow to the right of the name of that printer and it will show you all of the printers that have been installed during your windows installation. There are three buttons below this: OK, SETUP, and CANCEL. OK is if you like that printer. CANCEL will remove you from this box without making any of the changes saved. If you press SETUP, this allows you to change the printer resolution, it's orientation, it's paper size or paper
source. Also under the PRINT menu is the PRINT FUNCTION. This will show you, first of all the printer you have selected and the print range. At this time if you have more than one page, you can select which pages you would like to print. You can also, at the bottom, select how many copies you would like to print. There is a CANCEL, OK, and SETUP. Pressing SETUP brings you to the regular printer setup window. OK actually makes the print come to the printer. The default is IBM Graphics, the print range all copies one. If you press OK, one copy of all the pages will be printed. EXIT, of course, takes you back to the main biofeedback system.

### BATTERY MAINTENANCE

The EPFX Mark II Device operates with 4 AA Nicad Batteries placed permanently inside. These batteries should provide a minimum of 2 years of service with normal usage. Your batteries should last many years without problems. When your equipment arrives, please charge the batteries for 8 hours prior to use.

We recommend recharging after each 20 hours of normal use. For best maintenance, disconnect harness from device and turn off power when not in use.

• **WARNING•**: If patient connections are touching, batteries will drain faster.

**To charge batteries:**

1. Use device 20 hours or if battery test reads below 50% of charge.
2. Plug charger into charger input located at the back of the device.
3. Plug charger into wall outlet.
4. Allow to charge for 8 hours.
5. 'Power switch must be in the "OFF" position to charge batteries.

Unplug charger from device and wall outlet when charger is not in use.

**To test batteries:**

Click pointer on battery test button. The battery test screen will appear. Unplug all probes. Click on test button. Percent of battery charge is shown for each of the 4 batteries. If any battery charge is below 70%, proceed to battery charge procedure.
Probe Impedance - Point probe resistance only (Green Signal)
Probe Voltage - Point probe voltage only (Green Signal)
Harness Impedance - Wrist to wrist Resistance (Red Signal)
  Ankle to ankle Resistance [Yellow Signal]
  Finger to finger Resistance (Blue Signal)
  Voltage from head (Green Signal)

Harness Voltage - Wrist to wrist Voltage (Red Signal)
  Ankle to ankle Voltage (Yellow Signal)
  Finger to Finger Voltage (Blue Signal)
  Voltage form Head (Green Signal)

Auxiliary - Only used for battery test.
**The power switch must be On (Pushed In) for resistance reading**

The biofeedback system at the top has the name of the system which is BIOFEEDBACK DISPLAY. The next line down there are five items. There is time in the upper left hand corner, the title of test
that you are performing at the time in middle of the screen, there
is the number of trials that are going to be tested and the current
trial that is being tested. They are displayed in 0 of 0 and if
you were doing 10 trials it would be 0 of 10 and it would count
from 1 to 10 on the first number, with the second number always
staying 10. The next field over is a virtual field and usually
used for the Hololinguistic placing. The next field over is the
recording state and it will either read REC.ON or REC.OFF. Below
that is the actual biofeedback data screen. It is a black screen
with the biofeedback lines moving from left to right across it.
On both sides of the biofeedback data display area there is a
scale. On the right hand side, the scale shows four places
including a decimal point. On the left hand side the scale only
shows two places. The next area on the screen are the signals
themselves. There are four buttons, each with an outline of the color
of the signal that they are referred to. There also are four boxes
with the same colored outline showing you the actual data recorded
for each signal. Remember that the signals are color coordinated and
the data inside the color outlined box corresponds to that colored
line. Below that, there is a section on reactivity. There is a
reactivity button all the way to the left. This prepares the
biofeedback device to give a reactivity report. There must be one
full screen of data recorded. Then not only will you see the
reactivity data, which is constantly recorded next to the reactivity
button, but the maximum, minimum, mean, rise and fall of that entire
screen sweep will be displayed. In this area there is also an ABOUT
button that gives you some information about copyright and versions.
Next to that is the BATTERY TEST button. Then, we have a line that
sections off the screen. In the left hand side of this next area there
is memory, this is a scale from 0 - 100% showing you how much of the
computer's memory is still left for you to record in. When there is
no data recorded the memory is at 100%. As the data is recorded into
memory the memory bar will drop to 0. 'If the memory gets below 10%,
it will prompt you that the memory is full and ask you to save the
data. Also in this area there is a TIMING button which activates the
timing screen, an EDITOR button which activates the editor, a RECORD
ON button that turns on the record state, a RECORD OFF button which
turns off the record state, and an EXIT button. Next, we'll go into
explaining what some of these buttons mean. On the SIGNAL
IDENTIFICATION buttons are the names of each of the four signals,
these are seen by a grey box with a colored outline. The name in the
center of each of the boxes is the signal name. If you go onto this
button and push it, a signal control box will pop up for that signal.

HOW LONG, HOW OFTEN

The most asked question on the EPFX is how long and how often
to treat. This is most often a question that requires a specific
and individual response not a generic one. But let me respond with
some ideas.

First and foremost is the question of the SOC index. how much
life force is left for the patient to heal themselves. Here is where many of the doctors look at their shoes in embarrassment. It seems that many persons by the EPFX device so that they need not have any patient contact. Perhaps they made a wrong career choice, there are several job opportunities in the food service and housecleaning field. But to be in the health field there is a sacred unspoken oath to try to help as much as possible without doing any harm. Education and responsibility are important and necessary parts of the healing process. Sometimes a patient can't talk or relate such as with pets, but still try to take the one or two minutes it takes to input the SOC data as much as you know.

The higher the SOC the less life force the patient will have to cure themselves and they will need more therapy for longer times. Under fifty SOC will not take much time and usually is asked to come see me once or twice a month. SOC up to 100 the same unless the disease has had dramatic organ destruction. Cases of moderate to extreme organ destruction will take weekly visits. Nerve based and sensory organs are harder and need more therapy. Use the timed therapies in sarcodes. This supplies needed organ energy and awakens cellular repair.

The danger is that the device could take over regulatory functions in the patient's body. The device is designed to increase awareness and to stimulate the body to heal itself. Too much and the body can get lazy and let the system do the work. So be careful, your end goal is helping the patient to help and balance themselves.

Another factor to consider is compliance. Does the patient like the treatment, did they feel the effects of the device. They should not feel the device but should feel the difference the device makes. If they feel nothing the awareness level is probably low, another session is helpful after a week or two. So many of my patients feel nothing for three or four treatments but have incredible cures, so feeling the device is not essential. Thus it should not be the goal. The short term goals are responsibility and some light symptoms. The long term goals are cure and self dependency of self awareness and self fulfillment.

To get to these goals we should try to get an agreement with our patient to a course of therapies. For simple conditions I often agree to perhaps three visits once a month. I will terminate the need for number three if total cure is achieved on number two. A very chronic or life threatening disease will require more therapy. I ask for weekly session for 8 weeks. Twice a week if crucial.

So to summarize there are many factors to consider in setting a course of action. Let the patient and you discuss and operationalize changes and responsibility. Please do not call me if you do not have the SOC.
HOMOTOXICOLOGY

This program is very sophisticated and takes some skill in interpreting and using. In the basic philosophy of Homotoxicology there is the insight of how the body needs to detoxify. In an ever toxic society, our bodies need to detox more and more. Detox of stool, sinus, menses, urine, sweat, etc. Excess Detox can be seen as a symptom. Diarrhea, excess sweat, smelly urine, excess menses, sinusitis, skin rash, etc can result from excess toxicity. An if the patient is taken to an allopath the symptom can be treated. This will drive the toxin in deeper. So the field of Homotoxicology was founded. But how to know what toxin or pathogen is involved has always been the problem. Now with the EPFX device Homotoxicology is easy to learn and easier to do.

We need to know the phase of the illness, and the likely tissue it has affected. The phase is clicked on the top of the screen and the tissue types run down the page. Click on the tissue type. A green panel will appear that will have an edit box for you to input more specific tissue of an organ of concern for testing. Click the test button and the system will then test and provide two panels with information on the nature of the toxicity(isodes), the problem of pathogens(nosodes), and behaviors that interfere with detox. To treat these problems directly click on the name of the item you want to treat.

Homotoxicology has never been easier or more accurate. The patients unconscious will react to the items needed to treat. Most of the toxins in the body are free radicals. As such they have an electrical charge. The “Detox” button will provide a magnetic electrical impulse that will shake the free radicals and increase detox. As you enter the program the system will guess what the disease state is. As you leave the panel the system will give hints, if the show hints button has not been pushed.

Also on the page is access to the lie detector, miasms, mental factors, love versus frustration from a swift Fourier analysis of the heart beat, and other functions as well.

The Homotoxicology page is perhaps the finest achievement of the EPFX system. Use it wisely.

A new set of homeopathic remedies of over two thousand has been added with the trivector voltammetry signal for each. They are tested in the big test and added to the remedy list and can be viewed by clicking the load Homeopathic Remedy list. There is a repertory report access which can improve the retesting of remedies. This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions
in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head. DO NOT ASK is there a pain in your head? Or any direct reference to a possible symptom.

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box. After completion

Click the Load button then click the Scan button on the next panel. The computer will now scan the electrical and repertory compatibility in the homeopathic matrix, the top items will have values above 400 and appear at the bottom of the grid. Most patients are sick because they can not properly feel, express, or understand their own sensations. Patients often lie, twist or cover up some data when asked to verbally describe their sensations. The verbal area of the brain is very small and is restricted in access to the rest of the body. This makes verbal interactions weak in their ability to get to the truth of the patient’s health. The EPFX device interacts with the unconscious for a deeper and truer picture. The device will now look for compatibility and allow the unconscious of the patient to choose homeopathics for their own body.

Scan Potency This program will search the patient’s reaction to potencies of a single homeopathic. First make sure he patient name is in the top edit panel. Type in the name of the homeopathic to be tested.

Start the scan. The scan will take from 1 minute to five minutes. The primary reaction or peak reaction will be displayed in the spin edit boxes. There are many other reactions that are significant. These are the harmonics of the main potency. To treat and check this potency click the 'treat' button.

Energy from Test Tray

This will allow you to make a remedy from the test tray. Put the item on the tray and click this button after loaded take the item off and the put the item to be energized on the tray, and then click start. The item energized will have the energy added to it of the item in the tray. This works equivalent to the Dermatron from Germany.

Repertory

This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head. DO NOT ASK is there a pain in your head? Or any direct reference to a possible symptom.

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present
sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box.

After completion Click the Load button then click the Scan button on the next panel.

The computer will now scan the electrical and repertory compatibility in the homeopathic matrix. The top items will have values above 400 and appear at the bottom of the grid. Most patients are sick because they can not properly feel, express, or understand their own sensations. Patients often lie, twist or cover up some data when asked to verbally describe their sensations. The verbal area of the brain is very small and is restricted in access to the rest of the body. This makes verbal interactions weak in their ability to get to the truth of the patient's health. The EPFX device interacts with the unconscious for a deeper and truer picture. the device will now look for compatibility and allow the unconscious of the patient to chose homeopathics for their own body.

**RISK PROFILE**

In the risk profile panel we can calculate the average risk of certain risk states. In the large test we can see individual reactions to individual items, where in the risk panel we average 20 items that say reflect immunity. The risk scores are then insightful for disease pattern recognition. The values that appear are the last patient's.

To set the current values you must first click on the 'Load Current Patient' button This is a mathematical estimate. If there are too many red items then hit 'add 1' repeatedly till there are fewer red items this can be done till the most significant items remain. Reset will return to the beginning.

There are 40 categories. Twenty below and twenty above. Press the Information button and we also have Amino acids, Minerals, Oriental Herb, Electromagnetic static Hertzian reactions, combinations and also a switch board to our other panels. Click on calculate or hit 'u' to present the risks. The bottom 20 of 40 will appear. The top can be seen by striking the 'p' or top button. Double click on the name of a risk area and the system will put homeopathic products into the report file.

**THERAPY**

**ENERGETIC AND ELECTRO-INTERACTIVE THERAPY WITH BIORESONANCE**

The next important program is the Therapy program. Click on this button to go to the Therapy screen. As it appears there will be a suggested primary therapy mode if the computer has chosen one. This is written on the top of the screen. As that most of the primary
Therapies are autofocusing the most you need to know is often how to just hit start. The autofocus system will do the rest.

There are several types of energetic therapy available and several ways to deliver them. The upper right box allows you the choice of delivery. Remove the harness for Virtual treatment. These therapies involve subspace treatments and active energetic frequencies of voltage and amperage oscillations through the parallel port through the harness. Read the harness rules in the front of this manual. The best choice is the default choice of 'Activate All'.

The power double switch on the button will activate a double signal for any function. The system will then put two wave forms together to get a double power and gain. This will still satisfy any safety levels but produces a more penetrating signal. Use when you have deep stubborn disease.

For the doctors and therapists with little experience or we have provided several automatic treatments. Since this system is interactive an automatic system is a last possible. Now the device can do BIORESONANCE therapy and evaluate the progress. It can terminate the program when the therapy has accomplished the goals and prolong or in EPR Biofeedback the therapy if required. In essence this system can make midcourse corrections in the therapy treatment. It can sense and make the required changes most compatible for the patient. Most of these autofocusing systems are so easy to operate. Just hit start. The computer does the rest. Don't complain because it is too easy. Make it look hard for your patients sake, so they respect the process.

The Panels and instructions will guide you.

The Automatic therapies are:

<table>
<thead>
<tr>
<th>THERAPY</th>
<th>GOALS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto Freq</td>
<td>Automatically treats with Rife frequencies the organs and the polarity disturbances of the patient.</td>
</tr>
<tr>
<td>AutoColor</td>
<td>Automatically treats the patient with color therapy and finally chooses the best healing color for the patient.</td>
</tr>
<tr>
<td>Auto Trivector</td>
<td>Voltammetry Automatically filters like the Bicom and Mora devices but with this cybernetic interface this system can adjust the treatment program to the best treatment capacities for maximum results. double click on the book for DNA therapy.</td>
</tr>
<tr>
<td>Scaler</td>
<td>Treats the Chakras of the patient. This program can only be seen with the Autocolor screen activated. This system can develop maximum voltage, be careful with this program.</td>
</tr>
</tbody>
</table>
Mental NLP  This program allows for energetic reprogramming of mental energy follow the directions and insert the answers in the edit boxes. The device can detect personality superimposition and will alert if present. The Warning panel will allow for correction of the superimposition of personalities if detected.

Spinal  This program allows for energetic correction and detection of energetic imbalances in the spinal vertebrae. Follow instructions on screen. Sarcode, chackra, and organ reactivity is also revealed Double click on any sarcode to treat it. An Allersode test of allergy families is also provided. Difficult and reapearing concerns will need more correction and sometimes show miasmatic or inherited tendencies.

Homotoxicology  This program reveals Homotoxicology disturbances, Xenobiotics, Miasms, and mental reactions. This screen allows for a brief glimpse of the key notes or polycrests of German Homotoxicology. There are info panels on Isodes, Nosodes, Miasms, Mental factors.

Nutrition  This screen allows glimpses of nutritional disturbances and classical Homeopathy from EPR scores

Auto Frequency Modulation  This screen offers us the functions of EPR, GSR, trivector voltammetry

Auto VARHOPE  Will activate a program that will attempt electrical repair of any energetic terrain disturbance detected in the test screen. You can only use the button once. The same is activated with other programs so you can repeat.

NOTES

On every page there is notes access. This will allow you to make a special record of any observation, note, or message to put into the patient record. The first time you access this note file a warning will appear that will require you to allow the file to be created. The note file is destroyed after each patient and thus needs to be recreated with each patient. Type in any data for your report.

On the 'Report Screen' there is an 'Add Simple Notes' to add your note file to your patient report. Or use the 'Just Notes' button to see just your note file.

REPORT DATA

This will allow you to put your personal clinic data on the top of your patient reports. To access this function go to the Report screen and select the pull down Report Access menu. Click on the Report Data button. Specify your own clinic data, font
select an icon for your heading, and then save your choices. This will be the heading for your patient reports.

REPORT

The pull down menu on the top can be used to activate the report screen. We can make a report, save it for future reference and or print it for our records or for the patient to take home. The basic report starts with the patient name and demographics from the patient data screen. Then we add info to the report on the 'Information' button on the Test screen. Also we can take notes and add information on any screen by going to the 'Notes' button. When we first go to the 'Notes' file the computer will ask if we want to construct the notes file. Say yes because it will need to be constructed new with each new patient. Once constructed the 'Notes' file can take notes as you proceed through the total procedure. The note file can sometimes not go past 32K however. Once you have accumulated the Demographics, the Info, and the Notes, then you are ready to complete the report. Word Pad can do more.

Start the Procedure of recording a new patient visit with the New Examination Report button.

This loads the current patient data. The doctor in the Report Data will be the default doctor selection if you wish to change this then click on the Doctor or Therapist name edit box.

If you want to see an old record then click on the name in the upper middle panel to see your old records. You can select the order of their appearance with the order by selection.

The 'Report Access' on the pull down menu will have several choices for use. We can open the current file on our current patient or go to a past report for information. These are our Open choices. The current will allow us to construct our current report.

The 'Add Information' on the pull down menu will allow us to add some extra data to our report. The 'Natural Switch' has diet and health suggestions. The 'Affirmations' has some suggested affirmations. The 'Rules for taking Homeopathics' can be added. Or we can add our notes file That we have been developing during the client visit. We can also save some notes to the hard drive file that will not be added to the print function. If we want to make a note that will not be seen by the patient on his hard copy report, use the 'Add data to Hard drive not print' function.

The 'Edit Main Text File' function on the pull down menu allows us to change the style of the first lines of our reports. The Clinic heading and basic practitioner information can be changed and remembered on the 'Edit Clinic Data' function. The basic preliminary information on your report can be changed with the 'Main Text File'
function. This is the template used in the beginning page of each report. What you type here will be inserted at the front of each of your reports. If this file is blank then nothing will appear in front of your reports. A sample choice is included to begin with. It can be erased permanently if you wish, by going to the 'Edit Starting Report' Button and erase the info in the file.

The 'Report Access' on the pull down menu will have several choices for saving your report. To save the report to the hard drive click that function. To save to a floppy you must go to the print preview and use the floppy icon at eh top of the print preview page. To exit without saving anything use the appropriate function.

IF YOU WANT TO SAVE THE TOP ITEMS IN YOUR REPORT. Go to the Wellness screen, accessible from your Test screen pull down menu called 'Programs'. In Wellness then click the 'Save Significant Data to The Info File Report' button. This will add the purple items on your report or the top 250 items (which ever is smaller) to the report INFO file. They will then appear on the Info file when you load it next. You can only load the top items once per patient.

Print and Print preview can allow you to make a hard copy of your report. These are typical of Computers functions. Be sure to remember you can cut and copy from any file to your report. Be careful when saving your text files in the notepad to not lose your master templates.

IF YOU TRY TO SAVE A REPORT WITHOUT A PATIENT NAME YOU WILL GET AN ERROR OF KEY VIOLATION. Try to always have a patients' file to save to report or use save cancel to not save report. So there are the facets of making a report and saving it. Use your word processor to prepare other styles and practice with the system. After a short time you will be abased at how well it works on the 10th time. Good Luck.

If you are having a hard time printing your reports through the EPFX device, You might need to get a Parallel port switch for the printer and device. Some printers have difficulty with complex systems like the EPFX. Purchase a parallel port switch from your local computer shop and connect it to the computer and then to the EPFX device and then to the printer. Switch to the desired setting, device for testing and printer for printing.

**HOMEOPATHIC REPERTORY**

This program is on the homeopathic activation screen. This program will look for an electrical compatibility to classic repertory symptoms. Input the sensations into the edit boxes. Try not to lead the patient, ask for patient responses to the questions in the edit boxes. Get the answers in simple terms and type them into the boxes in English. Ask a question like please tell me what sensations you feel in the head. DO NOT ASK is there a pain in your head? or any direct reference
to a possible symptom

If the answer is that the area is normal then type normal. If the only answer is I am not sure then ask for the immediate or present sensations. If the patient can not talk or converse to you type N/A (for not applicable) into the edit boxes or leave all untouched. You can type 256 characters in each box.

After completion Click the Load button then click the Scan button on the next panel. The computer will now scan the electrical and repertory compatibility in the homeopathic matrix. The top items will have values above 400 and appear at the bottom of the grid.

Most patient are sick because they can not properly feel, express, or understand their own sensations. Patients often lie, twist or cover up some data when asked to verbally describe their sensations. The verbal area of the brain is very small and is restricted in access to the rest of the body. This makes verbal interactions weak in their ability to get to the truth of the patient's health. The EPFX device interacts with the unconscious for a deeper and truer picture. the device will look for compatibility and allow the unconscious of the patient to chose homeopathics for their own body.

**SPINAL EPR AND SARCODES**

On this panel there is access to functions of spinal analysis, allergy testing, and sarcode or organ strength. The “test and treat Trivector Voltammetry Energy Flow” this will test and treat each vertrabrae. It measures the reactivity of the system to sarcode of the vertrabrae while testing the flow of electrical energy thru the system. If there is a flow disturbance the computer will identify it by telling us it is not corrected, difficult (meaning chronic), or other message. The individual vertrabrae can be treated or the whole system can be treated multiple times.

The button “Show Sarcodes” will show us many organs and show resonant they were with the patient. The higher the number the more problem there is in the organ. An inflamed or degenerate organ will show high numbers the therapist will have to decide what was the difficulty. Healthy tissue will tend to have moderate numbers like 50 to 80. Higher numbers represent risks in the organ. The “mental foci” button will turn the organ most related to the current mental state of the patient white.

The “timed treatments” button allows us to activate therapy suggestions for specific organs or organ functions. You can set the time up to forty minutes. At the right there is activation for selections of 1. Inflamation 2. Metabolic disorder, 3. Injury, 4. Infection 5. degeneration. If you know these are present in the organ you wish to treat then click. If you are not aware then do not click these boxes. You can chose several of these check boxes but only one radio button or organ therapy at a time. The help with question will allow you to ask the patient questions to access more data. These
questions are also asked in the demographics panel under the “acu symptom profile”, so if you have answered them on the demographic page you do not need to enter them here they will already be in the computer. This will make high risk organs be red on the sarcode panel. Click on the name of the organ to treat it for a short time. Resonance and rectified will appear on the lower right. Continue the treatments till rectified is above 90.

Response-Reinforcing Stimulus Mechanisms in Biofeedback Training: Operant Behavior

Neurological thinking has been largely governed by Sherringtonian principles of stimulus-response (S-R) mechanisms underlying motor activity and therefore behavior. There now can be added to our neurological thinking the concept that a "response-stimulus" mechanism plays a role in underlying motor activity. This phrase "response-stimulus" may at first sound nonsensical to the classical neurologist. It can, however, be made clear by adding the qualifying adjective "reinforcing" to the word stimulus and by rephrasing the idea as "activity-reinforcing stimulus." It will be better understood by envisaging an actual situation. For example, a person yawns; the activity of yawning stretches the muscle spindles around the temporomandibular joint and this acts as a reinforcing stimulus for a further yawn. If the subject merely opens the mouth, letting the jaw fall passively with gravity, there is usually insufficient stretch stimulus to cause a second yawn. The subject has to inspire (draw in a breath) as he opens his mouth in order to evoke adequate reinforcing stimulus to produce the next yawn. Such inspiration is termed operative because it leads to or enforces the subsequent activity (the second yawn). In other words, it has operated a piece of motor activity. It is causal behavior. In another example, a person touches a button, and the music begins to play; the auditory stimulus of the music acts as the reinforcing stimulus for the subject to push the button again. This, of course, is more complex or indirect "activity-reinforcing stimulus" situation because there is no choice or latitude in that, if the music does not please the listener, he may not press the button again. In similar way, however, the subject also has the choice (albeit more limited) of not responding to the reinforcing stimulus
of the jaw by a further yawn. Whether or not the initial behavior is repeated after receiving reinforcement by the stimulus depends upon a number of variables. It is with these variables that biofeedback is concerned. It is also concerned with causing motor activity after reinforcing stimuli. Behavior which is followed by a positively reinforcing stimulus or terminates (reduces) a noxious reinforcing stimulus is termed operant behavior.

Biofeedback sometimes deals with "initial stimulus-response" mechanisms in the Sherringtonian sense, tracing the afferent-efferent pathways through the brain. On the other hand, however, it often deals with the "response-reinforcing stimulus" mechanism (or "activity-reinforcing stimulus" mechanism). In this latter type, the subject performs an action (for example, contracting a weak, partially paralyzed muscle); this causes a sound from the biofeedback instrument and the patient responds by contracting a second time in order to receive the pleasure of hearing the sound (which is sweet music to his ears because it indicates that the muscle is functioning). The fact that the muscle contracts causes summation of action potentials, and with both spatial and temporal summation more muscle fibers contract on the next occasion. This is the kind of "positive" muscle contraction mechanism used for muscle rehabilitation biofeedback when there is insufficient motor activity. Another example of the "response-reinforcing stimulus" situation is when the patient has pain from performing an action (over contracting the back muscles). This causes a high-pitched grating sound from the biofeedback instrument, and the patient responds by relaxing the muscle so that the intensity of sound goes down and at the same time the pain is less because fewer of the "Type C" fibers which carry pain sensations to the parietal cortex are stimulated. The excitatory neuronal mechanisms. In the actual practice of motor control, however, the patient does not have to be aware of the exact mechanism whereby the desired effect has been achieved. For example, an individual is not aware of the exact curling movements performed by the tongue when he speaks, until he has a neurological lesion which destroys part of the mechanism of articulation. He then has to become aware of the exact movements of the tongue in order to volitionally direct the operation. Behavior then becomes, in part, operant behavior.

There is a difference between "body-memory" or somatic memory which is not conscious and appears or rely heavily on peripheral
mechanisms, and cerebral memory which can be verbalized and is more purely central. This may be illustrated by an example of complex motor movements (complex behavior). The child prodigy violinist produced musical sounds on the violin with greater facility than the "average" child. He is not aware of the exact mechanism whereby the fingers operate on the instrument. Later in life, he may change, and for a number of reasons connected with his "psychological" status, (meaning the internal stimuli which in part caused the original motor behavior of operating the violin), he loses some of the motor skills involved with using his fingers. When he asks himself, "How did I do it?," he is only able to answer partially and incompletely. He then has to use the "response-reinforcing stimulus" mechanisms to relearn. He plays; he watches the fingers both directly and in a mirror; and when the sound is correct to his ears, he "memorizes" both in his consciousness and in his fingers (body-memory, or kinesthetic joint memory) the feeling (meaning the afferent stimulus) which leads to that particular motor response. For all these mechanisms to work, there has to be a "reward" or pleasurable sensation: and clearly the more "conscious" the subject, or in other words, the more aware of the significance of the reward to himself, the quicker will the linkage be established between the reinforcing stimulus and the response. It is in this light that one may look at behavior as a chain reaction composed of an initiating stimulus leading to a response, leading to a reinforcing-stimulus leading to a response and so on sequentially. In this way, peripheral neuronal activity is linked to cortical neuronal activity, leading to further peripheral activity and repeated again in sequence.

An analogy may be drawn regarding behavior in an interdisciplinary approach. The psychiatrist and the analyst are examining the factors operating at the "initiating stimulus" end, meaning that they study the patterns of sensation, emotion, and behavior laid down early in the organism's neurological development. The neurologist observes the present ongoing behavior, and in classical tradition the neurologist has frequently regarded the nervous system in terms of exteroceptive or interoceptive stimuli causing responses. There may now be added the dimension of the operant-orientated psychologist who examines a segment of behavior (which the patient finds sufficiently distressing to cause him to seek advice), but who disregards the cause in the distant past for that behavior. By having repetitive reinforcing stimuli linked in the
biofeedback technique to the opposite of that particular piece of motor activity, the patient comes to learn a different behavior. This new segment of motor activity is likely to cause new sensations which acquire feeling-tone, and the patient may then view himself or view the world through himself differently.

As a related neuropsychological theme, one may examine the meaning of "control-of-self" being at the basis of, or synonymous with, self-control. From the neurological point of view, it appears that subjects with poor impulse control are in some respects lacking good inhibitory mechanisms in the limbic system and, in particular, in the hypothalamus.

Thorndike (1898), who described the law of readiness also emphasized the mechanisms of stimulus-response activity. This response activity can be termed respondent activity. Under specific experimental circumstances, it can be seen as respondent conditioning. It is of interest that with special DC recording of the brain waves, the contingent negative variation or expectancy wave Grey Walter can be observed to give the electrical component of activity just prior to the operant response in classical conditioning experiments.

The whole field dealing with the role of reinforcement in the explanation of behavior id highly complex and this brief description must be regarded as an introduction to more detailed texts on reinforcement.

ALTERED STATE THERAPY AND BIOFEEDBACK

Relaxation Techniques: Hypnosis, Meditation, and Imagery

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 maximize this effect. The patient undergoing biofeedback treatment is often introduced to a relaxation technique
prior to receiving biofeedback (Fair 1979). 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 (1958).

Standardized relaxation techniques are effective for most patients. If the patient has difficulty, 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 too 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 hyperactivity to stress. Current relaxation methods differ in a number of ways. Four types will be examined: hypnosis, meditation, progressive muscle relaxation, and imagery. Each of these techniques will be discussed.

**Hypnosis**

**Historical Development**

The emergence of hypnotic techniques as a recognized form of psychological therapy has paralleled the growth of biofeedback techniques in the last two decades. Although formal hypnosis predates biofeedback by about two hundred years, it has until recently, had a checkered past. The unscientific image of hypnosis has been intensified by the activities of stage hypnotists and the portrayal of hypnosis in fiction and the cinema. However, hypnosis has been extensively and scientifically studied and has become an accepted treatment procedure in certain well-defined therapeutic approaches.

The concept of animal magnetism was created by Van Helmont (1577-1644) based on Paracelus (1493-1541) theory of magnetic forces. An 18th century Viennese physician, Frenz Mesmer, used the concept of animal magnetism to develop a treatment technique based on the idea that illness was caused by an imbalance in an invisible,
magnetic fluids. Mesmer and, later, hypnosis came to be regarded as quackery and both were banned in several European countries. However, naive and unusual his theory and appears today, Mesmer contributed to the development of modern clinical hypnosis because of his use of trance induction (Boring, 1950).

Mesmer's controversial theories and practices caused medical practitioners and others, to form negative opinion about hypnosis. The use of hypnentic techniques, however, by physicians such as Charcot, Liebault, and Bernheim helped maintain its importance in the mainstream of scientific inquiry (Boring, 1950).

Eventually, professional associations (such as the American Society for Clinical Hypnosis and the Society for Clinical and Experimental Hypnosis) established standards for its clinical practice. Professional training programs were developed to insure that hypnosis was used ethically and responsibly. Clinical hypnosis achieved a new level of acceptance in 1956, when an American Medical Association statement described it as a "Hypnosis is a valuable therapeutic adjunct for the medical doctor" (Goleman, 1977).

**Theory**

Everyone has a level of conditioning that is accumulated from their past. A person might be conditioned to respond to the smell of chocolate with craving. Another might see a person light up a cigarette and want one. In fact hypnosis when it is best is a deconditioning therapy that sets one free to respond openly and independent of conditioning. Hypnosis is often used to replace a conditioned response with a safer response. But deconditioning of response and freedom of response is our goal. This type of freedom of response or deconditioning hypnosis was pioneered by William Nelson in his early work.

There are several theories to account for the clinical effectiveness of hypnosis. Controversy still exists, however, over whether or not hypnosis is a special trance state. For many years it was believed that subjects under hypnosis went into a special state or trance. This is the "state" theory of practitioners such as Milton Erickson (Goleman, 1977).

An alternative, and more recent, concept is referred to as the
"nonstate" theory (T X Barber 1975). Barber believes that hypnosis is not a specifically different state of consciousness, although consciousness may be somewhat altered in the process. He has demonstrated empirically that anything a subject does under a "hypnotic trance" may be duplicated by those who are not in a trance. Even theorists who believe that hypnosis produces a special trance state cannot agree on what actually occurs. Measurements of physiological changes in subjects undergoing hypnosis have had mixed results but have generally supported the theory that the neurological status of the subject is not altered qualitatively. There have been no consistent findings of altered EEG rhythms, eye movements, pulse rate, or galvanic skin response (Barber 1975). Although hypnosis is a well-established clinical technique basic research is still needed to investigate the process (Kroger and Felzer 1976).

A thorough review of the therapeutic use of hypnosis, or hypnotherapy, is beyond the scope of this book. Researchers and therapists, who are well-versed in this technique, consider the reallocation which results from hypnosis as only one of many desirable effects of this procedure. In this chapter, only the relaxation effects of hypnosis will be discussed.

**Hypnotic Relaxation**

A variety of hypnotherapy techniques currently exist. These, however, have in common the induction of a condition (or state) where the subject becomes hyper suggestible. This allows the hypnotherapist to have significant influence over the subject's attitudes and/or behavior.

Kroger and Felzer (1976) summarize the hypnotherapeutic process which they have developed, involving what is described as a "double-bind" induction technique, based on the assumption that the subject will become automatically hypnotised. The term "double-bind" means that the subject cannot easily avoid being hypnotised. The phrase originated in the field of family therapy describing the situation of a child with schizophrenic parents, e.g. the child is given conflicting communication which causes him to be punished no matter what he does. Kroger and Fezer's induction technique involves the presentation of suggestions regarding sensations such as "warmth" or "heaviness." The subject is also given the suggestion
that he can choose to control these sensations if he wishes. One result of this induction procedure is to make the subject believe that the hypnotherapist is responsible for these sensations, instead of realizing that they are self-produced.

In addition to a standard induction techniques, patients are also "placed" into deeper states of relaxation through the use of "scene visualization," which is technique common to many types of hypnotherapy. A narration is given to the subject describing relaxing scenes with vivid, sensory experiences and colorful, elaborate visual images.

A useful technique developed by Vogt (Kroger and Felzer 1976) in the last century, is often employed to deepen the hypnotic state of relaxation. This is referred to as "fractionation" and, according to Kroger and Felzer, it involves the hypnotic presentation of sensations and images which the subject reported during previous hypnotic experiences.

After the first few sessions of hypnosis the subject is gradually introduced to "auto-hypnosis" (self-hypnosis). He learns to place himself into a deep state of relaxation through means of a conditioning process. Most therapeutic uses of hypnosis rely heavily on self-hypnosis. Indeed some theorists (e.g. Barber 1975) argue that all hypnosis is self-hypnosis since the hypnotised subject ultimately can control the situation even though he may be convinced that he cannot.

Hypnotic induction (regardless of how it is accomplished) can result in a deep state of relaxation when employed by an experienced hypnotherapist.

Although biofeedback and hypnosis are frequently applied to treat the same disorders, few studies have been undertaken which compare their relative effectiveness. Some authors suggest that hypnotherapy is more effective than biofeedback but offer little evidence to support their claim (Kroger and Felzer 1976).

Ian Wickramasekera (1976a) has conducted several experiments exploring the relationship between biofeedback and hypnosis. For example, he found the EMG training resulted in increased hypnotic susceptibility in young college males. Melzack and Perry (1976) combined alpha biofeedback training and hypnosis to teach patients control of chronic pain. They concluded that alpha biofeedback produced a marked reduction in pain only when accompanied with hypnosis and placebo effect (i.e. distraction and suggestion).
Wickramasekera (1976b) also hypothesized that biofeedback, behavior therapy techniques and hypnosis share many common elements. All three techniques arose from experimental laboratory studies, and in all three, various treatment components are specified in order that the therapist can control and predict the specific behavior of each patient. Biofeedback, behavior therapy and hypnosis all tend to focus on specific symptoms, to manipulate cognitive functioning, to focus on physiological consequences of verbal-motor events, emphasize informational feedback and reinforcement and expand the possibility of an individual to regulate his internal environment. Wickramasekera concludes that the important common element among these three types of treatment is that they strengthen the placebo response. In addition Wickramasekera believes that patients who are good candidates for biofeedback treatment.

Several biofeedback techniques have qualities similar to standard hypnotherapy, although they are not hypnotic procedures in the strict sense. One of these, "autogenic training," has become associated with biofeedback training in conjunction with thermal biofeedback in the treatment of migraine.

A German physician Johann Schultz developed autogenic training, which he considered a form of self-hypnosis. His student, Wolfgang Luthe, refined the procedure and developed a therapeutic system based on it. The technique is most often used in a simpler form when employed in biofeedback training (Schultz and Luthe, 1969).

The procedure involves the presentation of psychophysiological statements such as: "my hands feel heavy and warm" during a state of passive concentration. Although, at first, the therapist presents these statements to the subject, the latter is to practice the technique after memorizing the appropriate sequence, with frequently repeated sensory statements such as "warm" and "heavy". The repetition of such statements results in deep relaxation which often leads to peripheral vasodilatation. It is, therefore, successful treatment for vasoconstrictive disorders such as migraine and Raynaud's disease (Green and Green, 1979). Many clinicians have developed autogenic feedback techniques based on Green's original study. These can be used in conjunction with thermal training (Green and Green, 1979). After each autogenic statement the subject's average skin temperature is measured and recorded, so that the effect can be observed immediately. The measurements also allow the therapist to determine which statements best promote vasodilatation.
The patient can then use these particular phrases to control vasoconstruction in situations when he cannot go through the entire procedure, for example, when working or engaged in daily activities.

In some ways this procedure is similar to Vogt's fractionation method. In autogenic feedback, however, the subject does not verbalize what he experiences; it is indicated by the electrothermal instrument. Besides being more immediate, such information is more objective and reliable than the subject's verbal report under hypnosis.

For further information, readers are referred to Hypnosis and behavior Modification (Kroger and Felzer, 1976) and Hypnotic realities (Erickson, Rossi, and Rossi, 1976).

**Meditation**

Meditative techniques have been adopted by many biofeedback therapists to elicit deep states of relaxation.

Meditation, especially that associated with the Eastern religions, such as Zen Buddhism, has been indirectly influential in the development of biofeedback in this country. The physiological effects of various forms of meditation accomplished under empirical conditions, such as Swami Rama's demonstration of bradycardia with cardiac asystole and restitution of heartbeat as reported by Green and Green (1977), stimulated research in the conscious control of physiologic events. It became clear, however, that few people could achieve similar results, though many individuals from diverse populations can be trained in physiologic control of autonomic events (although of a less dramatic nature) through the use of biofeedback.

**Historical Development**

Although medication is often associated with the religions of the East, Christian ascetics in the West practises a form of meditation in the 4th century. These meditation techniques involved in the repetition of a single phrase from the Bible. This was later known as "Hesychasm," after a 5th century religious teacher named Hesychius.

The most popular of these techniques was the "Jesus Prayer," consisting of repeating the phrase "Lord Jesus Christ, Son of God,
have mercy on us," in the Latin "Kyrie elesion," (as such it is one of the introductory responses of the Latin Mass). Other religions developed their own forms of meditation, including the Moslem "Sufism" and the Judaic "Kabbolah".

"Transcendental Meditation" (TM) was currently popularized by Maharishi Mehesh Yogi (Benson 1975). As in every form of meditation, TM involves the use of repetitive thought which leads to a deep state of relaxation and peace of mind. This repeated thought or "mantra" apparently is derived from the Sanskrit of the Hindu religion. Many members of the Western culture have become increasingly aware of other Eastern forms of meditation such as Yoga and Zen meditation or "Zazen".

Zazen has been studied extensively by Japanese researches, who discovered that Buddhist monks can generate an unusually "high concentration of EEG alpha rhythms" (Kasamatsu and Hirai, 1966). Interest in biofeedback in that country is keen and research on the psychophysiological correlates of Zen meditation is being conducted in Japan. At an international symposium on biofeedback in Kyoto in 1977 the results of numerous investigations of Zazen were presented and an attempt was made to synthesise the Eastern tradition of Zen meditation with the Western technique of biofeedback.

Theory

When examining theoretical explanations for the effectiveness of meditation, it is difficult to separate theory from religious beliefs. Meditation is commonly seen as a method where by the practitioner can achieve a closer relationship with a being or transcending experience. Altered states of consciousness are also thought to cause the physiological changes which accompany meditation.

Research on the effects of TM demonstrated that it results in "positive" changes in physiological responsiveness; positive in the sense that it lowers arousal. Herbert Benson (1975), a Harvard psychiatrist, reported that TM resulted in 10-20% lower oxygen consumption than in the normal waking state. (This decrease is greater than usually observed in sleeping subjects). Marked decreases were also observed in serum lactate levels (where as high concentrations of serum lactate have been reported in chronically anxious subjects). The most significant physiological changes with TM involved reductions in systolic and diastolic blood pressure of
individuals who regularly practises meditation (Benson, 1975).

**Meditative Relaxation**

Various meditative techniques have been developed but all involve the same factors. Benson delineated four factors: a quiet environment, concentration, a comfortable bodily position, and a passive mental attitude.

Although hypnosis and other forms of relaxation also involve the first three factors, passivity is not stressed. On the contrary, in hypnosis, the subject actively listens to the suggestions of the hypnotist and is very much aware of bodily events. This differs from meditation, where the subject is not supposed to be actively concentrating on anything. The repetition of a certain sound or single thought prevents the individual from actively engaging in distracting thought or imagery during meditation.

Benson developed a form of meditation (described in his book *The Relaxation Response*) as an efficient and economical alternative to TM. His procedure is straightforward and easy to learn; the subject is given the following six instructions:

1. Sit quietly in a comfortable position.
2. Close your eyes.
3. Deeply relax all your muscles beginning at your feet and progressing up to your face. Keep them relaxed.
4. Breathe through your nose. Become aware of your breathing. As you breathe out, say the word "ONE," silently to yourself. For example, breath IN......OUT, "ONE," IN....OUT,"ONE," etc. Breathe easily and naturally.
5. Continue for 10 to 20 minutes. You may open your eyes to check the time, but do not use an alarm. When you finish sit quietly for several minutes, at first with your eyes closed and later with your eyes opened. Do not stand up for a few minutes.
6. Do not worry about whether or not you are successful in achieving a deep level of relaxation. Maintain a passive attitude and permit relaxation to occur at its own pace. When distracting thoughts occur, try to ignore them by not dwelling on them and return to repeating "ONE." With practice the response should come with little effort, Practice this technique once or twice daily, but not within two hours.
after any meal, since the digestive process seems to interfere with
the elicitation of the Relaxation Response (Benson 1975).

Patients can learn this technique prior to biofeedback treatment.
Since TM has many adherents it is not unusual that a TM advocate
may be referred for biofeedback treatment. It has been the authors'
experience that teaching such individuals a different form of
meditation or relaxation technique is counterproductive and may
alienate them. Although TM may not have been effective in eliminating
a specific disorder, therefore, it appears to be an adequate
relaxation procedure and can be combined with biofeedback under these
circumstances.

The only modification necessary is that concentration on the
biofeedback signal may replace the mantra or be combined with it
during the biofeedback training. Although TM purists may not favor
this suggestion or insist that this antithesis of what they are
attempting to achieve, many TM patients have been treated
successfully using TM and biofeedback in a combined fashion.

**Progressive relaxation**

**Historical Development**

Although both hypnosis and meditation result in states of deep
relaxation, that is not their primary function. Relaxation is
actually a secondary effect in both techniques. Other methods have
been developed specifically to foster a relaxation response, however.

Edmund Jacobson is regarded as the originator of progressive
relaxation. In 1908, Jacobson began his research at Harvard on the
muscular correlates of anxiety and tension. He observed that tension
can be defined, physiologically, as the inappropriate contraction
of muscle fibers. From this, he developed the concept that complete
relaxation of all muscles may eliminate anxiety. He noted that
individuals can learn to relax their muscles deeply through a process
of alternately contracting and relaxing major muscle groups. This
procedure was termed progressive muscle relaxation (Jacobson 1958).

His procedure consisted of approximately 50 sessions of
relaxation training involving 15 muscle groups. These muscles were
systematically relaxed; complete relaxation had to be accomplished
in one muscle group before the subject was permitted to concentrate on another group.

Jacobson's methods became popular in the 1950s when a variation of his technique was employed by Joseph Wolpe (1973), a psychiatrist noted for his development of "systematic desensitization".

Wolpe modified Jacobson's technique to make it more practicable; instead of the subject going through the procedure over a long period, Wolpe streamlined the method so that progressive muscle relaxation could be accomplished in one session. All of the major muscle groups were relaxed systematically in less than an hour. Although this modification does not produce all of the physiological changes described by Jacobson, it results in a relatively deep state of relaxation.

Since then, variations of Wolpe's modification have been developed, and therapists have refined the technique to meet specific therapeutic demands. Many biofeedback therapists use a version of Wolpe's method to relax subjects prior to feedback training, and a familiar one was developed by Bernstein and Borkovec (1973).

Theory

The theory of progressive muscle relaxation is that it counteracts the physiological effects of tension. Since a muscle cannot contract and relax simultaneously, total muscle relaxation theoretically results in complete absence of bodily tension. Since bodily tension (i.e. inappropriate excess muscle contraction) and mental states of anxiety are closely related, muscle relaxation should eventually result in the reduction of anxiety. The patient acquires this skill by learning to differentiate between sensations associated with excess muscle contraction and those associated with relaxation. This is accomplished by having the subject carefully observe physiological changes as he alternates between states of contraction and relaxation in each major muscle group.

The efficacy of progressive relaxation was documented by Gordon Paul (1969) a psychologist, at the University of Illinois, with significant decreases in heart rate, respiration rate, muscular tension and reports of anxiety in subjects undergoing relaxation. Similar results were reported earlier for Wolpe's technique and Jacobson's original method (Wolpe 1973).
Technique

The technique of progressive muscle relaxation involves the systematic contraction and relaxation of major muscle groups (usually 15 groups are used initially). As the subject learns how to relax, these groups can be combined and the entire procedure shortened. Eventually the patient should be able to relax individual muscle groups which do not have to be contracted in order to engage in certain activities.

Through a process of conditioning the patient also learns to associate physiological sensations with various words or phrases used by the therapist. After the patient has gone through the entire procedure, the therapist may ask him to sit quietly and maintain the relaxed state by repeating the word "calm". Eventually, words such as "relax" or "calm" will be associated with a deep state of relaxation and can, therefore, be used to elicit the entire relaxation effect. As was discussed in Chapter 1 with reference to Pavlov's experiment, however, a conditioned response differs in degree from the unconditioned response. Therefore, the relaxation produced by a cue word (conditioned response) would not be as deep as that produced by the entire relaxation procedure (unconditioned response).

Relaxation procedures are further described in recent texts (Basmajian 1979; Bernstein and Borkovec 1973).

After the patient has mastered the basic relaxation technique he can be introduced to the procedure of "differential relaxation." He learns to relax all muscles which do not have to be contracted in order to perform ongoing activity. For example, if he feels tense while driving a car, he can progressively relax all nonessential muscle groups such as the forehead, neck, chest, and back while allowing essential muscles such as the arms and legs to remain contracted. This procedure takes time to learn and, obviously, may be dangerous if a person cannot maintain necessary tension in task related muscles (Bernstein and Borkovec 1978).

Several taped relaxation exercises, currently available, have been developed specifically for use with biofeedback (Budzynski 1977).
Imagery

Historical Development

Compared with other relaxation methods, imagery techniques have not developed as systematically. The use of imagery for inducing relaxation training for the last century, however. Before then, imagery experiences (often artificially induced by drugs) played an important role in primitive religious rites. Artists have also used subjective imagery experiences to enhance their expression: e.g. the visual hallucinations experienced by Blake, Milton and Poe with images of heaven, hell and the supernatural.

Vivid imagery experiences have been associated with the development of many scientific hypotheses; for example, Kekule, a Belgian chemist, reportedly had a dream concerning the molecular structure of benzene. Similar imagery experiences were reported to have occurred to Descartes and Poincare (Hilgard and Atkinson 1967).

Many theorists believe that imagery experiences are influenced by activities of the right cerebral hemisphere, while mathematical and verbal concept are more dependent on left hemisphere functioning. Highly creative individuals are thought to use imagery more than others, who may be more technically or verbally orientated.

Although most patients are able to produce images, they may have difficulty maintaining them over time. Many patients are unable to produce vivid, life-like images on demand. Individuals differ in their imagery ability; some people have very few imagery experiences or perhaps, none at all. Certain patients may need training in imagery production prior to being presented with imagery therapy.

Singer (1974) recently reviewed and summarized the major therapeutic uses of imagery. Many of these techniques so far beyond the elicitation of relaxation and, therefore will not be discussed further in this chapter. Imagery techniques have been used to treat a number of disorders although they are rarely used alone. Most often imagery is combined with hypnosis or biofeedback techniques.

Theory

There are several theories concerning how imagery
facilitates memory and learning, but the mechanism whereby mental images are produced, and the reason why the production of certain images may result in deep relaxation is little understood. Concentration is a key factor in imagery, however, just as it is in hypnosis and meditation, and restful mental images produce beneficial physiological changes in many individuals.

If a patient is able to picture a tranquil scene, he will become gradually more calm and able to reduce physiological arousal. The physiologically disturbing effect of frightening images e.g. nightmares, is familiar to everyone. The goal of imagery therapy is to increase production of beneficial mental images to modify emotions and, ultimately, behavior patterns.

**Imagery Relaxation: Technique**

One technique used to produce relaxation is "scene visualization," a method often employed in hypnosis. Recollection of certain pleasant scenes can elicit relaxation; however, individuals differ in their evaluation of the pleasurable quality of images. Self-report questionnaires assist therapist in selecting the most appropriate scenes.

For example, the Reinforcement Survey Schedule (RSS) created by Tondo and Cautela (1974) contains descriptions of many images which can be developed into pleasing scenes. In taking the RSS, the patient rates those images which are most pleasurable, thereby insuring that the scene narrated by the therapist will actually please the patient.

The following episode illustrates the importance of individual differences in imagery experiences during therapy. A patient undergoing biofeedback treatment was taught to relax. She was presented with a visual image of herself lying on a beautiful white beach on a warm sunny day. Less than two minutes into this imagery experience, however, the EMG instrument registered a significant increase in frontalis muscle tension. On questioning she indicated that the scene had turned into a frightening image when she suddenly visualised the fin of a great white shark circling just off shore.

The therapist must be sensitive to changes in the patient's behavior
of physiological responses (if biofeedback is used) so as to prevent distressing imagery experiences.

In scene visualization, the therapist asks the patient to sit back comfortably, close his eyes, and concentrate on imaging the scene narrated by the therapist. Such narration is a detailed technique which depends on the style and creativity of the therapist. Colorful references to sensory experiences are stressed to make the image as life-like as possible. Whenever possible, all five senses should be involved. For example, the patient, described above, not only sees herself lying on the sandy beach, but feels the spray of the surf and the warmth of the sun, smells the ocean breeze, hears the seagulls and the gentle roar of the surf and tastes the ocean salt from the spray. Some therapists however, may feel uncomfortable with narration and, therefore, might employ a more structured relaxation technique, such as the progressive relaxation procedure presented earlier in this chapter.

**Focused Imagery**

A relaxation technique, recently developed, combines elements of all four of the major relaxation procedures discussed in this chapter (Nigl and Fischer-Williams 1980). Termed focused imagery, it is used in the treatment of psychological disorders ranging from muscle contraction (tension) headache to low back strain.

This technique involves the patient's imagining the appearance of each of the major muscle groups of the body and how they feel. Then the patient is asked to Visualised the site of tension. He is then asked to Visualised each muscle relaxing and to see and feel the tension slowly disappearing. The process starts with the forehead and systematically moves down to the feet. In addition, autogenic phrases are incorporated into the suggestions; emphasizing feelings of warmth and heaviness in the limbs. After the progressive relaxation is completed, the subject is asked to concentrate on the breathing process and allow it to occur as naturally as possible. Finally, meditation is used to enhance the relaxation effect using a cue word such as "calm" or "relax"; repeated subvocally with each expiration. The entire technique takes approximately 40 minutes.

In summary, relaxation techniques are important adjuncts which enhance the effect of biofeedback. It is difficult to train an
individual to reduce feedback signals without employing one or more of the techniques discussed. Certain authors have criticized biofeedback techniques because they are no often effective when used alone. For example, Orne (1975) states, "This is another instance where a new technique is introduced and found to be wanting, by itself, so it is combined with older, proved therapies." It is not uncommon in medicine and clinical psychology, however, to treat disorders with more than one technique. The fact that the two procedures (relaxation and biofeedback) may be additive increases the probability of successful treatment. Indeed, these two procedures may be synergistic, for example, EMG biofeedback combined with relaxation is more effective in treating muscle contraction headaches than either used alone (Budgynski 1978).

In summary, many techniques exist which can help individuals learn to relax, and most of these are compatible with biofeedback procedures. It is unusual for biofeedback therapists to treat patients without employing one or more of these relaxation exercises as part of the total treatment procedure. Patients must be able to reduce their physiologic arousal in order to alter the feedback signal, and without the use of one of the techniques outlined in this chapter, this would be difficult. Therefore, biofeedback therapists should be as familiar with relaxation techniques as they are with electronic instrumentation and other aspects of the biofeedback method.
--- BIBLIOGRAPHY ---

BOOKS


The Long Term Pathological Findings of the Camelford 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 homeopathic practitioner, together with other colleagues, launching into a long-term 7 year study of the effects of this toxicity on the population.

Besides extensive case notes on 250 people, hair and nail samples, several different electrical, chemical, and psychological interventions have yielded a understanding of these patients' disease profile. Various lengthy papers have been prepared by the North Cornwall Homeopathic 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.
Hungarian XRROID analysis of the people exposed to the Aluminum Toxicity showed extremely sensitive to the same compounds as the Camelford England Aluminum accident 15 years earlier.

Proving the Meta-Analysis of the Xrroid technology

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* = > 2 Standard Deviations
SS = Statistically significant
Hippocampus Research

Preceding the existence of the companies (Eclosion Kft., Maitrea Kft. and Mandelay Kft.), but postceding 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

TELEPHELY
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Tel.: 49 / 311-026

HIPPOCAMPUS
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RENDELETSZÉN ÉS IRODA
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Tel.: 1-198-68-65
06-20-342-662

Supervising researcher: Dr. István 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 the 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 EPPX device for one week after pra and before post testing. The patients had significant increases in their post electrical measures. These factors are called the VARHO.
NEW TECHNIQUES OF HOMEOPATHIC TREATMENT OF FUNGAL INFECTIONS

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.; 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.
HOMEOPATHIC TREATMENT OF EPSTEIN-BARR VIRUS INFECTIONS

Nodal Therapy for Viral Chronic Fatigue
Chief Editor: N Wilner, M.D.; Independent Medical Editor; Budapest, Hungary

Developed By: The staff of Maltreyes, 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.
NEW TECHNIQUES OF HOMEOPATHIC TREATMENT OF FUNGAL INFECTIONS

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 homoeopathic 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.
STIMULATION OF MOTILITY FACTORS IN NEUTROPHILS

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 non-inverted 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 (98.6°F, 37.5°C).

The speed of the white blood cell was then measured in seconds per 10 film, 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
Gyilla 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

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

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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.
Electro-Physiological Stimulation of Body Charge Potentials

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HIPPOCAMPUS
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Adószám: 21284823-2-05
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06-20-342-662

Supervising researcher: Dr. István 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.
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 Mairay; Limarick, 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 than 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 analysis. In this paper we bring forth 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, JMSH 1997 volume1/ 4 ISSN 1417 0876

The following reactants are statistically significant at alpha levels .15 for the cataract patient:

- sucrose
- sucrase
- glucuronidase
- glucose
- glucogen
- glucose dehydrogenase
- aspartase
- myeloperoxidase
- cataract nosode
- pancreatin
- pancrease seccode
- glutathione
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 Semmelweis Hospital in Budapest 1994

Abstract

We know of no good evidence for Dr. Kruger's 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 Gyilis Pans2ki, M.D; Budapest, Hungary, Attila Kiss, M.D; Győr, Hungary
- Consultant: Dr. Simon Guti, 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.


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.

Royal Society of Medicine

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

Presents the EPFX World Congress of 1992
Freihlich 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 Edosion 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 dowsing out all these patients (I’m not ashamed of saying I do dowsing. I’m a fairly average dowser), I could probably douse 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 Burr, 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 therapies, 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. LaVolley 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 synergistic understanding for all of us to consider, to critique, to investigate, and to explore.

Dr. Nelson, now known as Desire’ Dubouneet, has been nominated for the Nobel prize, and in 2000 was invited to speak at the Nobel Prize Hospital in Stockholm, Sweden.
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
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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.
This is to inform you that the Homeo Diagnostical Academy Press has published

The International Journal of the Medical Science of Homeopathy

as a peer reviewed medical journal

under from Hungarian ISSN National Center 1997 apr. 15-4 and has awarded the international identification number:

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This number will remain unchanged for the lifetime of this publication.

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Large scale SCIO Study

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

Chief Editor:

Prof William Nelson M.D. IMUNE

The Centro Ricerche, University of Venice + Padova, Italy

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Richard Atkinson MCSP, Physical Therapist, West Yorkshire England

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, 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.

Reference:

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

emis in temeiul art. 1\al. (1) lit,b) din Legea nr. 359/2004
privind simplificarea formalităților la înregistrarea persoanelor fizice,
associațiilor 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. 460/3 din 30/11/2006

Firma: INTERNATIONAL ETHIC SRL-
Sediul social: MUNICIPIUL ORADEA, Str. MOLDOVEI, Nr. 17, Bloc AN50, Ap. 20, Judetul Bihor.
Cod unic de înregistrare 1883090 din data 06/07/2006.

Prezentul certificat conстатator ațestă că s-a înregistrat declarația pe propria răspundere conform căreia firma îndeplinește condițiile de funcționare specific specific pentru fiecare autoritate publică, pentru activitățile declarate, încadrate în clasă CAEN: 7210 Consultanță în domeniul echipamentelor de calcul (hardware);
7230 Preluarea informatică a datelor;
7240 Activități legate de bazele de date;
8242 Alte forme de învățământ;
la sediul scindar din MUNICIPIUL ORADEA, Str. LEBEDEI, Nr. 58/A, biroul nr.4, Ap. biroul 4, Judetul Bihor

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
Eliberat la data: ........................
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 have had more than 500 hours of training in regulatory standards and procedures.
In 2008 our company obtained the United Kingdom Intertek CE certificate:

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 exception 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 re-education from injury, muscle weakness, or dystonia and electrophysiological reactivity

Authorized Signatory
R. Nash

AMTAC Certification Services Limited, Milton Keynes, UK
In 2009, the Korean registration was obtained:

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식품의약품안전청장 (인)

2009년 12월 16일

본 침용제는 인터넷으로 얻을 수 있으며 식품의약품안전청(http://www.fda.go.kr/) 통해 확인할 수 있습니다.
의료기기 수입업 허가증

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KFDA
Documentation Number 0261-3552-1933-2908

No. 1895
Imported Medical Device License Permit

Company Name – Quantum Health Korea Inc.
Address – Seoul Gangnam-gu Nonghyun-dong 277-21 Mirae building 6FL
Representative – Jung Won Jung
Date of Birth – Oct. 10th 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
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:
Indicaciones de uso: El SCIO es un sistema auxiliar de biofeedback para prediagnóstico y terapias de regulación del estrés que mide los cambios en voltaje, amperaje y resistencia de un organismo al aplicar microcorrientes eléctricas.

Descripción: Es un sistema que actúa motivando el potencial evocado del organismo mediante 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 conector USB a USB, 1 caja de interfase, DVD & CD de software y 1 manual de uso, su alimentación eléctrica es a través del puerto USB conectado al ordenador.

Cuenta con una entrada nominal eléctrica de 4 a 5 voltas (dependiendo del ordenador) y una salida nominal máxima a través de electrodos de 4 a 10 milliamperios.

El electrodo de cabeza pesa 200 g y sus medidas son 1.75 m de cable y 780 x 51 mm de goma. Este electrodo entre en contacto con la piel al ser aplicado alrededor de la cabeza.

Los electrodo de extremidades pesan 180 g y miden 25 m de cable y 19 x 370 x 2 mm de goma, el electrodo entra en contacto directo con la piel al ser aplicado alrededor de las muñecas y tobillos.

Presentaciones: Empaque con un equipo.

Modelo SCIO

Publicidad dirigida a: Profesionales de la salud.
On 29 August 2012 SFDA has approved the SCIO to be marketed in the Chinese market after a successful review process of our application.
Our latest European CE Certificate was obtained with TÜV Rheinland InterCert Kft on 23 February 2012.
Certificate

The Certification Body of TÜV 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


are fulfilled. The certification is subject to periodic surveillance.

Certificate Registration No.: OX 69241776 0001
Audit report No.: 28208466 004
This certificate is valid: from 2012-02-23 to 2015-02-22

2012-02-23
Date of issue

Balázs Bozsik
Certifier

TÜV Rheinland InterCert Kft. – H-1132 Budapest, Váci út 48/A-B
Tel.: (+36/1) 461-1199, Fax: (+36/1) 461-1189, 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:

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

Project Nahinga

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

**NaHinga**

**IMMUNO COMPROMISED PROTOCOL**

First Avoid All White Processed Sugar
- This means all dextrose sugar products including candy, cola, doughnut, 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 oils 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 Cucumber Salvia, Trifolium, herring sperm
  and other sarcodes of thymus adenoids tonsils and appendix
- Use 500 mg Vitamin C, 15 mg Zinc, 4 pills of Oxygen Stimulation at bed
- Use Golden Seal, Aloe Vera, Lentil, Mustard, Turmeric, Curry, Paprika, Sesame seeds, and use Sambuca

**AVOID ANTI-BIOTICS**
- Use Probiotics Actimel, Activia, etc Twice a day

---

Electrical Reactivity as a Prescreen of HIV Infection Patients

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

By Nagy K, Nelson W., Janos E., Bela E., Varkonyi V., Honvath A Study Site National Institute of Dermato-
Venereology, Budapest, Hungary 1994

**ABSTRACT**

Twenty-two ambulatory AIDS patients in Budapest were studied for xerox 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
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 urological 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 Xroid process.

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

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"

ABSTRACT

The world has now recognized the demise of antibiotics. Iatrogenic 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 viruses.
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 elsewhere we have seen several reports of cures and viral irradiation. 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 - 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 HIV 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 safety and efficacy and there appears to be a natural cure for this horrible disease on the future horizon
FEKI – freiburger etik kommision

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:


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
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 45-minute 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.
Freiburg, December 15, 2009
FECI Code: 09/2120

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 success and thank you for the confidence you have shown us.

Yours sincerely,

Karin-A. Graf
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 StPrSchV) have also been reviewed. (The sum insured stated in the documents fulfills 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

[Signature]

Prof. Hans-Peter Graf, Md PhD

Freiburg, November 16, 2009
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
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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

X grants approval

Prof. Hans-Peter Graf, M.d. PhD
Freiburg, November 16, 2009

Freiburger Ethik-Kommission G.m.b.H
Geschäftsführer: Kolit A. Graf
Amtsgericht Freiburg LB: 489 0010

IRB/EC
Institutional Review Board/Independent Ethics Committee

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CERTIFICATE

to an
Amendment 1
of the clinical study

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
November 16, 2009 grants approval
November 16, 2009 amendment 1

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 RÜV and § 92 StrSchV) have also been reviewed. (The sum insured stated in the documents fulfills the demands of risk assessment according to MPG).

With regard to proposed amendment, the feci hereby

X

grants approval

Prof. Hans-Peter Graf  MD PhD  Freiburg, November 16, 2009
VARHOPE (Voltage, Amperage, Resistance, Oxidation, Hydration, Proton and Electron pressure, the body electric's vital signs) Clinical Journal

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 this 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.

Table of Contents:

Case Study 1

Charts for Case Study 1

Case Study 2

Charts for Case Study 2
Case Study 3

Charts for Case Study 3

Discussion

the patient

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 (Acquired 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, 23rd 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 couldn't 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 arrives 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

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 set backs, 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 brought them to us.

March 22, 2006
March 25, 2006

April 3, 2006
June 24, 2006

Before

After

Voltage

Amperage

Resistance

Hydration

Oxygen

Reactance

Speed

Percent

Improvement

June 26, 2006

Before

Voltage

Amperage

Resistance

Hydration

Oxygen

Proton

Electron

Reactance

Speed

2000
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 2nd, 2005

November 7th, 2005
November 11th, 2005

January 19th, 2006

Chart

Chart
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\textsuperscript{rd}, 2005

![Chart of improvement](image-url)
January 3rd, 2006

January 10th, 2005
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 (post test) versus the pre test. 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

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
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 (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.

Introduction
Overview

This large-scale research was designed to produce an 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 were 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 were 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 measures 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 post test 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 Hahneman 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. Hahneman 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 aberant 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 persuing visits.

Pre and Post SCIO Therapy Electro-Physiolgical percentages

<table>
<thead>
<tr>
<th>SCIO Treatment 163,870 patient visits</th>
<th>Pre</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voltage</td>
<td>25</td>
<td>33</td>
</tr>
<tr>
<td>Amperage</td>
<td>21</td>
<td>27</td>
</tr>
<tr>
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<td>10</td>
<td>15</td>
</tr>
<tr>
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<td>27</td>
<td>36</td>
</tr>
<tr>
<td>Oxidation</td>
<td>28</td>
<td>35</td>
</tr>
</tbody>
</table>

SCIO Treatment 100,834 patient visits
Below
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 analyse. 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 probetecniques 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

\[ F \sim \frac{Q_1 \times Q_2}{D^2} \]

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 $3 \times 10^9$ esu. The strength of an electrical field will have the equation

$$E \approx \frac{9 \times 10^9 \times q}{R^2}$$

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.

$$1\text{ Farad} = \frac{1\text{ Coulomb}}{1\text{ Volt}}$$

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 non-conductors 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.

\[ 1\text{ Amp} = 1\text{ Coulomb per second} \]
\[ 1\text{ Volt} = \text{Inductance} \times \frac{\text{d Amps}}{\text{d Time}} \]
\[ \text{Amps} = \text{Capacitance} \times \frac{\text{d Volts}}{\text{d Time}} \]

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

\[ \text{Amperes} = \text{Volts} \div \text{Ohms} \]
\[ \text{or} \quad \text{Volts} = \text{Amps} \times \text{Resistance} \]

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 an 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

\[ \text{Magnetic Fields} = \left( \frac{\text{Amp}}{2 \pi \text{d}} \right) \]

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

\[ \text{Force} = \text{Charge in Coulombs} \times \text{Velocity in meters per second} \times \text{Magnetic Force of Amperes per meter} \times \text{The Permeability Factor through which the Magnetic Field permeates.} \]

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.

\[ \text{Inductance} \times \text{d Amps over d Time} = \text{Volts} \]

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

\[ \text{Resonance~ Freq.~} = 10^6 \frac{1}{\sqrt{1 - (\text{CAP})^2 + (\text{IND})^2}} \]

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.

Bibliography

Books


Articles and studies

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

As we reported in the introduction, many people overvalue and overrate 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

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Bologna, Italy
Luigi Maselli
Bari, Italy
Rossella IanTorno
Milano, Italy
Giuseppe Mauger
Catania, Italy
Dr. Rainer Mutschler
Germany
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® (BDI-II®) 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 regarding 14 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/m² 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:

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic (mm Hg)</th>
<th>Diastolic (mm Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>less than 120</td>
<td>and</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120–139</td>
<td>or</td>
</tr>
<tr>
<td>Hypertension</td>
<td>140–159</td>
<td>or</td>
</tr>
<tr>
<td>Stage 1</td>
<td>140–159</td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>90–99</td>
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</tbody>
</table>
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 and is available upon request.

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®—II (BDI®–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® 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 aged 13-80 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 45-minute session

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


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 + the diastolic 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.

In Hydrogen if the protons are like marbles, the electron is over a kilometer away the next atom’s electron is over 2 kilometers away, the next proton is over 4 kilometers away. So there is more than 99.9999999999999999% empty space. This space is filled with energetic fields. The electrons never touch each other so what we are made of is interacting electromagnetic fields.

Atoms are 99.999999999999% empty space and the empty space between atoms is just as or emptier 99.999999999999999999999999%. Electrons repel of course so the atoms with outer electrons repel each other. Why don’t things pass right through things?

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 two-tailed 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 X 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 actual study
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 pre-treatment 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:

\[
\text{Systolic BP left arm sitting + the diastolic BP left arm sitting x pulse} = \text{energy index factor.}
\]

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) indicate low back difficulty. Ideal 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 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 x 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 device 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.
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.

<table>
<thead>
<tr>
<th>SCIO Treatment group (Test group)</th>
<th>Mean</th>
<th>N</th>
<th>Std. Deviation</th>
<th>Std. Error of Mean</th>
<th>Range</th>
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<td>Quality of life Questionnaire</td>
<td>0,5412</td>
<td>85</td>
<td>0,92005</td>
<td>0,09979</td>
<td>5,00</td>
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<tr>
<td></td>
<td>Mean</td>
<td>N</td>
<td>Std. Deviation</td>
<td>Std. Error of Mean</td>
<td>Range</td>
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<td>Quality of life Questionnaire 1</td>
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<td>1,17301</td>
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<td>Quality of life Questionnaire 2</td>
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<td>Energy Index Factor</td>
<td>871,3294</td>
<td>85</td>
<td>2 309,45944</td>
<td>250,49605</td>
<td>12 770,00</td>
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<tr>
<td>Left Hand Strength (Kg)</td>
<td>0,4118</td>
<td>85</td>
<td>3,89839</td>
<td>0,42284</td>
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<tr>
<td>Right Hand Strength (Kg)</td>
<td>-0,8235</td>
<td>85</td>
<td>5,06664</td>
<td>0,54955</td>
<td>48,00</td>
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<tr>
<td>Oxyegnation</td>
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<td>84</td>
<td>3,87193</td>
<td>0,42246</td>
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<tr>
<td>Flexibility Low Back</td>
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<td>85</td>
<td>6,19205</td>
<td>0,67162</td>
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<td>Flexibility Side to Side</td>
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<td>85</td>
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<td>11,22687</td>
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<td>Memory Test (Backward)</td>
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<td>pH level</td>
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<td>Proton pressure</td>
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<td>4,09572</td>
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<td>Electron pressure</td>
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<td>84</td>
<td>3,89159</td>
<td>0,42461</td>
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Table 1. Summary results for the SCIO Treatment (Test) group
<table>
<thead>
<tr>
<th></th>
<th>Placebo (Control) group</th>
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<tbody>
<tr>
<td><strong>x Energy Index Factor</strong></td>
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<tr>
<td><strong>x Left Hand Strength (Kg)</strong></td>
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</tr>
<tr>
<td><strong>x Right Hand Strength (Kg)</strong></td>
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<tr>
<td><strong>x Oxygenation</strong></td>
<td>-1,2500</td>
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<tr>
<td><strong>x Flexibility Low Back</strong></td>
<td>-2,0580</td>
</tr>
<tr>
<td><strong>x Flexibility Side to Side</strong></td>
<td>1,5846</td>
</tr>
<tr>
<td><strong>x Flexibility Neck</strong></td>
<td>2,0615</td>
</tr>
<tr>
<td><strong>x Memory Test (Forward)</strong></td>
<td>-0,1846</td>
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<tr>
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<td><strong>x pH level</strong></td>
<td>-0,1246</td>
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<td><strong>x Voltage</strong></td>
<td>0,6923</td>
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<td><strong>x Amperage</strong></td>
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<td><strong>x Resistance</strong></td>
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<td><strong>x Proton pressure</strong></td>
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<tr>
<td><strong>x Electron pressure</strong></td>
<td>-0,2154</td>
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</table>

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 did 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 induced a significant decrease in blood pressure whereas GSR biofeedback training showed a decrease in respiratory rate\(^1\). 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.

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.

References


2013 USA new studies Validating the SCIO auto focusing Cybernetic loop

STUDY INFORMATION:
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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)
Registered at Amtsgericht Freiburg i.Br. HRB 5010,
Registered according to § 20 Abs. 7 MPG at Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) under Reg. No.: GS 4.1-A 1871 2375/95

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-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.

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. 37 patients with tobacco addiction and 21 patients 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 to help 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 claim is now firmly established. Discussion will show a statistically significant positive effect on addiction and emotions using MCES and trans-cranial-cutaneous electrodes.

**SCIO’s Effect on Body Osmosis 2013 - USA**

Written by Darwin Davidson Doctor of Quantum Biofeedback

In this study, 41 subjects 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 the traumatized tissue will have histamine rush in the 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 4 did not have the line appear after the 20 sec deadline. 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 SCIOVARHOPE 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 given 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 increase eye 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.

**SCIO 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 test of 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 the stimulation 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.

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 the SCIO. The SCIO readings to the allersodes of the know allergies of the subjects was compared to TVEP xroid 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 65 subjects 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 herals 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 Testosterone Update 2013 USA
Written by Darwin Davidson Doctor of Quantum Biofeedback

In our study 28 men (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 available testosterone. Testosterone is richer in young men and in the morning hours when you get an early morning erection. All tests were done after 12AM to minimize circadian effects. Thus there was a single blind test of testosterone streaming. In the control measure there was an average of 13.5 minutes 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 the 15 allowed period.
Thus it appears that hormone streaming works and the body builder's success is real from hormone streaming.

**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**

Ethical Supervision for the following studies has been done by Ethics International Romania, University of Timisoara and the Psychology Faculty of the University of Bucharest.

The following sports studies have been conducted under the ethic supervision of the aforementioned 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
2013 Romanian Study of the Indigo Plus
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 aberations 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 atheltes for direct sport improvement among base wellness measures. 81 professional / semi-professional atheltes age 12 to 45 were tested. 33 basketball players, 28 handball players, and 20 footballers. These atheltes 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 solvent molecules through a selectively permeable membrane into a region of higher solute concentration, aiming to equalize the solute concentrations on the two sides.\[1\][2][3] It may also be used to describe a physical process in which any solvent moves, without input of energy,\[4\] across a semipermeable membrane (permeable to the solvent, but not the solute) separating two solutions of different concentrations.\[5\] Although osmosis does not create energy, it does release kinetic energy\[6\] and can be made to do work,\[7\] but is a passive process, like diffusion. 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 Highschool. 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
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 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 freethrows. The measure was of success of freethrows 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 bullseye and counted the points from the board. The measure was of success of hitting the bullseye and or accumulated points.

Pre and post tests indicate a possible effect versus placebo group results.

**VARHOP MEASURE**

The INDIGO/Indigo Pro 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

Subject 1

<table>
<thead>
<tr>
<th>Test type</th>
<th>Pre treatment</th>
<th>Post treatment</th>
<th>Improvement Percentage</th>
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<td>25%</td>
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### Subject 5

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<td>Post treatment</td>
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Subject 7

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<tr>
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<td>Pre treatment</td>
<td>Post treatment</td>
<td>Percentage of improvement</td>
</tr>
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<td>60%</td>
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<td>39</td>
<td>37</td>
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<td>Darts (how many points out of 3)</td>
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<td>-33%</td>
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Subject 9

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<tr>
<td>Test type</td>
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<td>Post treatment</td>
<td>Percentage of improvement</td>
</tr>
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<tr>
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**Subject 10**

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<td>100%</td>
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<td>10%</td>
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<tr>
<td>Basketball (how many out of 10)</td>
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<td>Handball (how many out of 10)</td>
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<td>Football (how many out of 10)</td>
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<td>13%</td>
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**Subject 11**

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### Subject 12

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<td>Basketball (how many out of 10)</td>
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<td>Handball (how many out of 10)</td>
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<td>Football (how many out of 10)</td>
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### Subject 13

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<td>Post treatment</td>
<td>Percentage of improvement</td>
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<td>Post Treatment</td>
<td>Percentage of Improvement</td>
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<td>Post treatment</td>
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Subject 25

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Subject 26

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**Subject 27**

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**Subject 28**

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### Subject 36

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### Subject 37

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**Subject 38**

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<td>Football (how many out of 10)</td>
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**Subject 39**

<table>
<thead>
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<tr>
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<td>35</td>
<td>40</td>
<td>14%</td>
</tr>
<tr>
<td>Darts (how many points out of 3)</td>
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**Subject 41**

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<td>Post treatment</td>
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Subject 42

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Subject 43

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<td>10</td>
<td>0%</td>
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<td>5%</td>
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<td>Post treatment</td>
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<td>9</td>
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**Subject 44**

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<td>0%</td>
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**Subject 45**

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### Subject 46

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<td>100%</td>
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<td>2</td>
<td>0%</td>
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<tr>
<td>Handball (how many out of 10)</td>
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### Subject 47

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<td>50%</td>
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<tr>
<td>Hold Breath (seconds)</td>
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<td>43</td>
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<td>25</td>
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<td>100%</td>
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<td>Pre treatment</td>
<td>Post treatment</td>
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</tr>
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Subject 49

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<td>-21%</td>
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<td>0%</td>
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<tr>
<td>Handball (how many out of 10)</td>
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<td>Post treatment</td>
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<td>50%</td>
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<td>Handball (how many out of 10)</td>
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<td>Football (how many out of 10)</td>
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Subject 53

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Subject 54

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Subject 55

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<td>Handball (how many out of 10)</td>
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Subject 56

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Subject 58

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<td>100%</td>
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<td>Pre treatment</td>
<td>Post treatment</td>
<td>Percentage of improvement</td>
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<td>Football (how many out of 10)</td>
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**PLACEBO Group 15**

**Subject 1**

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**Subject 4**

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<td>Pre treatment</td>
<td>Post treatment</td>
<td>Percentage of improvement</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------------</td>
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<td>---------------------------</td>
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<td>Handball (how many out of 10)</td>
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**Subject 6**

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### Subject 7

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<td>Hold Breath (seconds)</td>
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</tr>
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### Subject 8

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<td>8%</td>
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<td>Hold Breath (seconds)</td>
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<td>45</td>
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<td>-29%</td>
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<td>-17%</td>
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Subject 9

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<th>Post treatment</th>
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<td>Low back extension (cm)</td>
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<td>3</td>
<td>-25%</td>
</tr>
<tr>
<td>Hold Breath (seconds)</td>
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<td>34</td>
<td>-28%</td>
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<td>Darts (how many points out of 3)</td>
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<td>Basketball (how many out of 10)</td>
<td>8</td>
<td>7</td>
<td>-13%</td>
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<tr>
<td>Handball (how many out of 10)</td>
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<td></td>
<td></td>
</tr>
<tr>
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Subject 10

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<tr>
<td>Skin scratch (seconds)</td>
<td>12</td>
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<tr>
<td>Low back extension (cm)</td>
<td>10</td>
<td>8</td>
<td>-20%</td>
</tr>
<tr>
<td>Hold Breath (seconds)</td>
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<td>42</td>
<td>-26%</td>
</tr>
<tr>
<td>Darts (how many points out of 3)</td>
<td>26</td>
<td>21</td>
<td>-19%</td>
</tr>
<tr>
<td>Basketball (how many out of 10)</td>
<td>5</td>
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<td>-20%</td>
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<td>Skin scratch (seconds)</td>
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<td>6</td>
<td>14%</td>
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<tr>
<td>Low back extension (cm)</td>
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<td>11</td>
<td>-8%</td>
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<tr>
<td>Hold Breath (seconds)</td>
<td>43</td>
<td>35</td>
<td>-19%</td>
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<td>-4%</td>
</tr>
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<td>Basketball (how many out of 10)</td>
<td>7</td>
<td>6</td>
<td>-14%</td>
</tr>
<tr>
<td>Handball (how many out of 10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Football (how many out of 10)</td>
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## Subject 12

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<td>Skin scratch (seconds)</td>
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<td>-12%</td>
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<td>Low back extension (cm)</td>
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<td>12</td>
<td>-8%</td>
</tr>
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<td>Hold Breath (seconds)</td>
<td>56</td>
<td>48</td>
<td>-14%</td>
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<td>34</td>
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<td>-38%</td>
</tr>
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<td>Basketball (how many out of 10)</td>
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<td>5</td>
<td>-17%</td>
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## Subject 13

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<td>-25%</td>
</tr>
<tr>
<td>Low back extension (cm)</td>
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<td>-31%</td>
</tr>
<tr>
<td>Hold Breath (seconds)</td>
<td>51</td>
<td>35</td>
<td>-31%</td>
</tr>
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<td>Darts (how many points out of 3)</td>
<td>34</td>
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<td>-18%</td>
</tr>
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<td>Basketball (how many out of 10)</td>
<td>8</td>
<td>6</td>
<td>-25%</td>
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## Subject 14

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<td>14</td>
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<td>Low back extension (cm)</td>
<td>10</td>
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<td>-30%</td>
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<td>Hold Breath (seconds)</td>
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<td>Basketball (how many out of 10)</td>
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Football (how many out of 10)
Subject 15

<table>
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<td>-11%</td>
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<tr>
<td>Low back extension (cm):</td>
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<td>7</td>
<td>-17%</td>
</tr>
<tr>
<td>Hold Breath (seconds)</td>
<td>25</td>
<td>23</td>
<td>-8%</td>
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<td>Darts (how many points out of 3)</td>
<td>15</td>
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<td>-93%</td>
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<tr>
<td>Basketball (how many out of 10)</td>
<td>6</td>
<td>6</td>
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<tr>
<td>Handball (how many out of 10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Football (how many out of 10)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

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 (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) 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%
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<th>Improvement</th>
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<td></td>
<td>-14.43%</td>
</tr>
<tr>
<td>Darts (real)</td>
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<td></td>
<td>+45.23%</td>
</tr>
<tr>
<td>Darts (placebo)</td>
<td></td>
<td></td>
<td>-28.06%</td>
</tr>
<tr>
<td>Basketball</td>
<td>real</td>
<td>17</td>
<td>+55.05%</td>
</tr>
<tr>
<td></td>
<td>placebo</td>
<td>15</td>
<td>-17.32%</td>
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<tr>
<td>Handball</td>
<td>real</td>
<td>24</td>
<td>30.91%</td>
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<tr>
<td></td>
<td>placebo</td>
<td>4</td>
<td>0%</td>
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<tr>
<td>Football</td>
<td>real</td>
<td>16</td>
<td>25.25%</td>
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<tr>
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<td>4</td>
<td>0%</td>
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**VARHOP PRE POST MEASURES**

**VARHOPE TREATMENT GROUP IMPROVEMENT:**

- V 14.07%
- A 19.23%
- R 15.36%
- H 21.44%
- O 18.24%
- P 4.56%

**VARHOPE PLACEBO IMPROVEMENT:**

- V 0.01%
- A 0.01%
- R 0.10%
- H -0.03%
- O -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 INDIGO/Indigo Pro.

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 aberations 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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6. INDIGO’s ability to increase Body Wellness, Vol.XXV.1. 2010 VARHOPE and Stress ISSN 2041-4293

7. VARHOPE Large scale study, Vol.XXV.1. 2010 VARHOPE and Stress ISSN 2041-4293

8. Varhope Improvements in a Clinical Setting, Vol.XXV.1. 2010 VARHOPE and Stress ISSN 2041-4293

9. Large Scale Studies of the INDIGO, Vol.XXIII.1. - 2008 The Large Scale Study of the INDIGO ISSN 2041-4293
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 desfăşurarea procedurii de investigaţie clinică şi a procedurii de evaluare a performanţei 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 sănătăţii publice nr. 792/2006
Acte modificatoare
#M1: Ordinul ministrului sănătăţii nr. 465/2009
Modificările şi completările efectuate prin actul modifier sunt scrise cu font italic. În faţa 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 şi 11 din Legea nr. 176/2000 privind dispozitivele medicale, republicată, ale art. 35 din Hotărârea Guvernului nr. 911/2005 privind stabilirea condiţiilor de introducere pe piaţă şi de punere în funcţiune a dispozitivelor medicale, ale art. 19 din Hotărârea Guvernului nr. 798/2003 privind stabilirea condiţiilor de introducere pe piaţă şi de utilizare a dispozitivelor medicale pentru diagnostic in vitro şi ale art. 23 din Hotărârea Guvernului nr. 344/2004 privind stabilirea condiţiilor de introducere pe piaţă şi/sau de punere în funcţiune a dispozitivelor medicale implantabile active, cu modificările ulterioare, văzând Referatul de aprobare al Direcţiei generale farmaceutice şi aparatură medicală nr. E.N. 1.290/2006,
in temeiul Hotărârii Guvernului nr. 168/2005 privind organizarea şi funcţionarea Ministerului Sănătăţii, cu modificările şi completările ulterioare, ministrul sănătăţii publice emite următorul ordin:
ART. 1
(1) Prezentul ordin stabileşte condiţiile şi modul de desfăşurare a procedurii de investigaţie clinică şi a procedurii de evaluare a performanţei pentru dispozitivele medicale.
(2) Prevederile prezentului ordin se aplică dispozitivelor medicale, dispozitivelor medicale implantabile active şi dispozitivelor medicale pentru diagnostic in vitro, denumite în continuare dispozitive medicale.
ART. 2
În prezentul ordin sunt aplicabile definiţiile şi procedurile stipulate în Hotărârea Guvernului nr. 911/2005 privind stabilirea condiţiilor de introducere pe piaţă şi de punere în funcţiune a dispozitivelor medicale, în Hotărârea Guvernului nr. 798/2003 privind stabilirea condiţiilor de introducere pe piaţă şi de utilizare a dispozitivelor medicale pentru diagnostic in vitro şi în Hotărârea Guvernului nr. 344/2004 privind stabilirea condiţiilor de introducere pe piaţă şi/sau de punere în funcţiune 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 performanței, potrivit art. 19 din Hotărârea Guvernului nr. 798/2003.
(2) Pentru începerea procedurii de investigație clinică și a procedurii de evaluare a performanței pentru dispozitivele medicale, structura de specialitate din cadrul Ministerului Sănătății Publice eliberează autorizația 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 dispozitive 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 .........., solicitează autorizarea desfășurării procedurii de investigație clinică sau a procedurii de evaluare a performanței pentru dispozitive medicale:
..........................................................................
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...................................................................

Anexez documentele prevăzute în lista verificărilor din anexa nr. 2.
Data ........... Semnătura ............... 

ANEXA 2
INVESTIGAȚIA CLINICĂ/EVALUAREA PERFORMANȚEI
LISTA VERIFICĂRILOR
1. INFORMAȚII 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/in 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 PERMITE 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 accesorioarelor, principiile de operare și desenele de ansamblu și 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, logică 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 INVESTIGAȚIEI CLINICE/EVALUĂRII PERFORMANȚEI

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 parametrul 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 performanța și siguranța utilizării
dispozitivului și datele înregistrate pentru realizarea scopului final, metoda de urmărire a
pacienților, evaluarea și monitorizarea în timpul investigației
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 SĂNĂȚĂȚII PUBLICE
Structura de specialitate în domeniul dispozitivelor medicale
AUTORIZAȚIE PENTRU INVESTIGAȚIA 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:

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(denumirea, tipul)
Producător: .....................................
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.................................................
Orică modificare a condițiilor stabilite prin reglementările Ministerului Sănătății Publice, care au stat la baza autorizării, atrage anularea prezentului document.

Director,

ANEXA 4
ROMÂNIA
MINISTERUL SĂNĂTĂȚII 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:

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1932 őszén letestelte 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 megkezdtek a paprika nagyszabású C-vitamintermelését. Egy héten belül több mint három font tiszta kristályos anyagot, C-vitamin készítettek.

Szent-Györgyi 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 a testesítőként azonosították fő energiaforrásként a sejtekben (hatalmas energia szabadul fel, amikor a foszfát, kötésekre van felosztva).

Szent-Györgyi érdeklődése szerint a miozin-ATP kölcsönhatás megmagyarázhatja az izom mozgását.

Szent-Györgyi András, Albert fiatalabb unokatestvére, és felesége Éva, felfedezték a miozin alegységeit ("meromyosin-okat"), és elkezdtek 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 izomtömege teljesítménye mérhető elektromos izom aktivitással, a szokásos EMG készülékkel, és négy témában.

1. Izom növelése diéta állat
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.

3. ^ Dr. Czeizel E.: Az értékteljes, 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 university 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.
ROMÂNIA
MINISTERUL EDUCAȚIEI, CERCETĂRII ȘI INOVĂRII
UNIVERSITATEA DE MEDICINĂ ȘI FARMACIE
"VICTOR BABES" DIN TIMIȘOARA

CERTIFICAT DE ABSOLVIRE

Nume: IRGOR CEPOJTEVIC

N. 0003372

Data de naștere: 1962
Luna: ianuarie
Ziua: 6
Locația: Bosnia și Herțegovina
Județul: 

A absolvit cursurile postuniversitare de perfecționare cu durata de 03.06.2010 - 03.08.2011 (4 module)
în specialitatea Neuroanatomie, neuroelectrofiziologie și biofeedback
Aparat SCIO - placă tumatică a hronozană

S-a susținut conecțiul la data de 12.02.2011

Timbru această certificat s-a acordă toate drepturile legale.

Rector

(Ștâpânit de foaia notarului)

Secrețar STF

Semnatarul
"The SCIO turned around my career"

Novak Djokovic

Neuro-Anatomy, Neuro-Electro-Physiologist in Biofeedback SCIO Therapist with Bio-Resonance
Medical regulators do not decide what is and is not medicine. Medical Universities decide what is and is not medicine. When the University of Timisoara allowed medical text books to include our publications, which have been in peer reviewed journals for more than 5 years, this became undeniably a medical art. And beyond that, when the Government of Romania has issued a professional work qualification for this device, we have achieved complete compliance, validation 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 31st of January 2013, AndreeaTaflan 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’ Duboune. 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 2014

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 \( r = 0.05, p = 0.61 \); the experimental test resulted in \( r = 0.25, p < 0.0005 \).

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 \( \text{max} \).

2. Identify those S period where \( \text{max} \) values were larger than a maximum threshold value selected to identify at least 50 such periods; call this subset of periods \( \{ \text{max} \} \).
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 $v_p$.

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.

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**Trans-cranial GSR Biofeedback Stimulation**
**Increases Math, Insight and Language Memory**
**2014**

**Supervising Researchers:** Dr Klara Hilf, Prof of Medicine Desire’ Dubounet
**Biofeedback Research Technician:** Neményi Rita
**Permission of the Hungarian Ethics committee**
**Institution:** International Medical University
**Sponsor:** Mandalay kft

**Dates:** February thru June 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.

Introduction:

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 AUTOFOCUSED 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 Roman physician, Scribonius Largus, who wrote in the Compositiones Medicæ of 46 AD that his patients should stand on a live black torpedo fish for the relief of a variety of medical conditions, including gout and headaches. Claudius Galen (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 homeostatis.

Low intensity electrical stimulation is believed to have originated in the studies of galvanic currents in humans and animals as conducted by Giovanni Aldini, Alessandro Volta 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.

Modern research into low intensity electrical stimulation of the brain was begun by Leduc and Roux in France (1902). In 1949, the Soviet Union expanded research of CES to include the treatment of anxiety as well as sleeping disorders.

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 cranium. 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 mechanisms 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 electric current is engrossed upon the hypothalamic region; 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 serotonin, norepinephrine, and dopamine, and a decrease in its level of cortisol. After a MCES treatment, users are in an "alert, yet relaxed" state, characterized by increased alpha and decreased delta brain waves 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 _A_ and Multiplied by each other make _B_

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>4</td>
<td>2-2</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>3-1</td>
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Start control Pre Test

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>7</td>
<td>12</td>
<td>3-3</td>
</tr>
<tr>
<td>8</td>
<td>12</td>
<td>2-6</td>
</tr>
<tr>
<td>12</td>
<td>36</td>
<td>6-6</td>
</tr>
<tr>
<td>16</td>
<td>48</td>
<td>4-12</td>
</tr>
<tr>
<td>15</td>
<td>56</td>
<td>7-8</td>
</tr>
</tbody>
</table>

Start stimulation tell them to relax with eyes closed wait one minute while getting one channel of CES

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<tbody>
<tr>
<td>9</td>
<td>20</td>
<td>4-5</td>
</tr>
<tr>
<td>11</td>
<td>30</td>
<td>6-5</td>
</tr>
<tr>
<td>10</td>
<td>21</td>
<td>3-7</td>
</tr>
<tr>
<td>18</td>
<td>81</td>
<td>9-9</td>
</tr>
<tr>
<td>12</td>
<td>35</td>
<td>5-7</td>
</tr>
<tr>
<td>11</td>
<td>10</td>
<td>10-1</td>
</tr>
<tr>
<td>22</td>
<td>121</td>
<td>11-11</td>
</tr>
<tr>
<td>9</td>
<td>18</td>
<td>3-6</td>
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</tbody>
</table>

Next we tell them to relax with eyes closed wait one minute while getting two channels of CES
<p>| | | |</p>
<table>
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<tbody>
<tr>
<td>7</td>
<td>10</td>
<td>2.5</td>
</tr>
<tr>
<td>20</td>
<td>99</td>
<td>11.9</td>
</tr>
<tr>
<td>10</td>
<td>16</td>
<td>2.8</td>
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<td>13</td>
<td>42</td>
<td>6.7</td>
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<tr>
<td>12</td>
<td>27</td>
<td>3.9</td>
</tr>
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<td>8</td>
<td>15</td>
<td>3.5</td>
</tr>
<tr>
<td>10</td>
<td>25</td>
<td>5.5</td>
</tr>
<tr>
<td>14</td>
<td>45</td>
<td>9.5</td>
</tr>
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</table>
**Part two word memory retention**

<table>
<thead>
<tr>
<th>English</th>
<th>Japanese</th>
<th>Translation</th>
</tr>
</thead>
<tbody>
<tr>
<td>one</td>
<td>ichi</td>
<td>どうして？ (doushite?) = Why?</td>
</tr>
<tr>
<td>two</td>
<td>ni</td>
<td>なに？ (nani) = What?</td>
</tr>
<tr>
<td>three</td>
<td>san</td>
<td>時間 (jikan) = Time</td>
</tr>
<tr>
<td>four</td>
<td>yon</td>
<td>だれ (dare) = Who.</td>
</tr>
<tr>
<td>five</td>
<td>go</td>
<td>いつ (itsu) = When.</td>
</tr>
<tr>
<td>six</td>
<td>roku</td>
<td>人 (hito) = Person.</td>
</tr>
<tr>
<td>seven</td>
<td>nana</td>
<td>(doko) = Where.</td>
</tr>
<tr>
<td>eight</td>
<td>hachi</td>
<td>(nihon) = Japan.</td>
</tr>
<tr>
<td>nine</td>
<td>kyuuu</td>
<td></td>
</tr>
<tr>
<td>ten</td>
<td>juu</td>
<td></td>
</tr>
</tbody>
</table>
Results of the math studies:
Results of the "words" studies:

- Much better result with machine:
- Better result:
- Same result:
- Worse result:

![Chart showing results of the "words" studies]
Much better result with machine:
Better result:
Same result:
Worse result:
Math Test Results After Second Wave
Word Test results After Second Wave

- Much better result with machine: 6%
- Worse result: 0%
- Same result: 38%
- Better result: 56%

- Pre-Test
- With Machine
- 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 91 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.
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.

References:

1. ^a b 21CFR882.5800, Part 882 ("Neurological Devices")
2. ^a b Smith RB, Cranial Electrotherapy Stimulation: Its First Fifty Years


29. ^Smith R et al. The use of transcranial electrical stimulation in the treatment of cocaine and/or polysubstance abuse, 2002

30. ^FDA medical device classifications


**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.