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

ECLOSION KFT.

Version 1

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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) a reduction in systolic and/or diastolic blood pressure reading at rest.
b) decreased resting heart rate (fewer beats per minute)
c) a decreased score on the Perceived Stress Scale (PSS), implying a reduced level of overall stress.
d) decreased scores on one or more of the six mood factors of the Profile of Mood States (POMS) Standard questionnaire, implying improved mood states.
e) 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.
f) a decreased score on the Beck Depression Inventory-II® (BDI-II®) implying reduced levels of depression.
g) some degree of satisfaction with the overall study outcome.
h) 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.

DEVICE INFORMATION AND MECHANISM OF OPERATION

DEVICE DESCRIPTION, THEORY AND OPERATION

ELECTRO PHYSIOLOGICAL FEEDBACK XRROID (EPFX – usb port)/
SCIENTIFIC CONSCIOUSNESS INTERFACE OPERATIONS SYSTEM (SCIO)

The Electro Physiological Feedback Xrroid (EPFX) and the Scientific Consciousness Interface Operations System (SCIO) are two different names for the same device.

The EPFX/SCIO is an automatic, computer-operated non-invasive device that combines bioresonance and biofeedback fields for body analysis and energy balancing. It is a subconscious stress detection and reduction system that measures electro physiological reactions and patterns through a 'harness' of electro-magnetic electrodes attached to the head, ankles and wrists, which are catalogued, tabulated and fed back to the individual without he or she being aware of any effect or sensation. This 'reverse feedback' sends signals back into the individual's body to create an environment that is uncomfortable for parasites and viruses etc., and that boosts the body's own resources so that the body can speed up the healing process.

Research in the field of energetic medicine began in the 1930s when scientist Royal Rife discovered that all forms of life resonate or vibrate at particular frequencies that are measurable. Later, Dr. Rheinhold Voll discovered that changes in resistance could be detected at acupuncture points on the body when a person was subjected to differing compounds. This 'electro reactivity' could indicate if an item (such as a toxic compound or allergen) produced a negative reaction or was beneficial (such as a nutrient). This information led to the development of a range of energetic testing devices to measure human electrical resistance.

Over the last twenty years, research conducted in the field of bio-energetics by researchers such as scientist Hans Jenny and Dr Peter Manners has shown that the body is electric and can be measured by more than resistance alone but also in impedance, amperage, voltage, capacitance, inductance and frequency. The theory of electro magnetic resonance is that they are fragile and can be altered or cancelled out by setting up an equal and opposite wave (based on Newton's original wave theory).

As a result of the past near century of research, many different forms of bioresonance therapy exist today that primarily involve the application of certain frequencies or magnetic fields to the body. These devices and treatments are based on the general underlying theory that all matter has a resonant frequency and that every cell in the body resonates at a particular frequency, and that electromagnetic fields and groups of cells in an organ or system have multiple frequency patterns that are unique such that the whole body has a complex frequency make up which can change or become distorted when affected by illness. When a pathogen interacts with cells, the subtle cellular frequencies become distorted or even blocked. Such pathogens can include toxins, bacteria, viruses, allergens, fungi, toxic metals, stress, or other internal or external influences. Based on this notion that the body's cells are controlled by subtle electromagnetic fields whose optimal frequencies can be disrupted by illness, it follows that introducing healthy frequencies to the body can re-balance the cells and consequently the whole body to ultimately provide an environment where the body cures itself. When the cells are in good health, the electro-magnetic frequencies emitted by the body's cells, tissues, organs, and systems will resonate freely and easily with other cells.This is in line with the principles of acupuncture and homeopathy that rely on energy flow and imprinting of

frequencies on aqueous solutions.

Janos Seyle, a Hungarian medical scientist first coined the word 'stress'. His theory was that stress is the start of all disease. When stress first appears it produces an alarm reaction, which is the 'symptom'. This is the alarm stage. If the stress persists, then the disease goes deeper while the symptom disappears. This is known as the adaptation stage. If the stress continues, eventually the organism will exhaust and the exhaustion stage of deep incurable disease takes place. Therefore, Seyle theorizes that early stress detection and reduction, as well as ongoing stress management, is crucial to an individual's general and overall well-being, as it can take much longer to bring the stress back from exhaustion stage.

By adapting the above and other similar theories, scientist Bill Nelson developed the EPFX/SCIO computerized bioresonance and biofeedback system to read the signals of stress and convert the information into a non-linear analysis. This information is than compared to an extensive database of 'normal' values and 'corrective' frequencies are then fed back to the individual. This is based on the theory of *Electro-Acupuncture Meridian Therapy*, a well known system that operates on automatically balancing the acupuncture meridians by adjusting them with harmonic frequency techniques to bring the individual 'in tune with' the natural low frequency field that permeates the world, called the Schuman field after its discoverer.

The basis of bio-electrical medicine is in the combination of voltage, amperage and resistance. The only things that can truly be measured electrically are voltage and amperage. Everything else is a mathematical variation of voltage and amperage. The EPFX/ SCIO device starts by measuring multiple channels of this information so that variations in the electrical potential and flow of the whole body can be observed. This direct measurement is of four channels of voltage, four of amperage, and four of resistance. These are received by a computer via the device, with the computer acting as a frequency counter for receiving this data. This makes an active twelve-channel measuring device. Other calculations are made mathematically. Resistance can not be measured directly; it must be calculated from an amperage or voltage meter. In the same way a capacitance meter can not directly measure capacitance it must perform a mathematical adjustment of voltage and amperage flow. These calculations are referred to as 'virtual' or 'mathematical' measures, so even the single-channel resistance devices of electroacupuncture devices such as Listen (BEST), Voll, Phasix, Bicom, Mora and a host of others use virtual measurement. The EPFX/SCIO measures over 40 virtual dimensions. The variations of amperage and voltage flow allow measurement of capacitance and inductance. These are the reflections of static and magnetic effects of bio-electricity. Variations in amperage and voltage allow measurement of frequency. Changes in voltage, amperage, and resistance together make up the reactance and susceptance of the electrical system. Complete electrical reactance is the best measure of biological reactance, but multiple channels are needed to measure total reactivity.

The EPFX/SCIO measures 55 different electrical factors of the body through the sensors attached to the forehead, wrists and ankles. The EPFX/SCIO has a database of the trivector resonant frequencies of over 12,000 substances (trivector is a mathematical calculation of the relationship between voltage, amperage and resistance) and these are compared to the trivector resonant frequencies of the individual during testing. The results of testing are then listed and color coded to indicate where the higher 'abnormal' reactions have occurred at one, two or three standard deviations from the norm. Each individual test reaction score is a hint or possibility of significance. Where there is a recurring theme in the significant test scores then the possibility becomes probability. Therapy is then delivered through digital frequency

corrections. The energy fed back to the individual is direct currents of less than 8-10 micro amperes.

The system is a safe, powerful autonomous bio-feedback device designed for diagnosis and powerful healing, scanning for individual reactions to different compounds ranging from homeopathic remedies to nutritional deficiencies to individual risk profiles. The device focuses on frequency balancing for stress reduction and provides information on the possible origins of imbalances throughout the body. Once an imbalance has been diagnosed, the system utilizes the comprehensive suite of therapeutic programs in the software to return the individual's system to 'balance'.

DEVICE DETAILS

The EPFX/SCIO device utilizes 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 head of the person. The software is a PC-based platform consisting of high-end graphics.

The EPFX/SCIO measures voltage and current potential as well as skin resistance. To measure transcutaneous skin resistance, a medically safe, variant micro-current is applied to the body. The changes in voltage, amperage, and resistance produce reactivity profiles that determine the Xrroid.

Specifically, the device measures sixteen (16) standard electrical parameters of the body, as follows:

- ✓ Measurement of electro-magnetic reactivity in the body via six different responses: impedance, amperage, voltage, capacitance, inductance, and frequencies – resulting in 16 different electrical parameters.

- ✓ Comparison of the tri-vector resonant frequencies – a complex mathematical calculation relating voltage, amperage, and resistance – of the body with over 12,000 known compounds.

- ✓ Feedback: a patient-directed Xrroid auto-focusing Galvanic Skin Resistance (GSR) signal that allows a variant micro-current EDS challenge for measuring electro-potential and GSR.

The EPFX/SCIO:

- ✓ is an entirely non-invasive, painless device, with five comfortable straps attached to the person's wrists, ankles, and forehead on the one end, which feeds through a digital interface box on the other end controlled by PC-based measurement and feedback software.

- ✓ measures, compares, and provides feedback on over 12,000 compounds stored in the PC database.

- ✓ is entirely independent of user error, personal bias, or machine malfunction.

- ✓ establishes a tri-vector relationship between the body being tested and the compound database, offering a 3-dimensional view of the body's health.
- ✓ maintains a hand-shake with the body, for nano-second bio-response testing – meaning that the EPFX/SCIO samples the body many times every second.
- ✓ has built-in auto-focus therapies, meaning it cannot cause harm, ensuring that pathogens cannot mutate and resonate at a different frequency.
- ✓ works on the physical, mental, and emotional levels because all three react in the body electro-magnetically and can be accurately measured.
- ✓ is portable.

The EPFX/SCIO provides information about the energetic state of the body and the direction in which the body is focusing its energy. After measuring the body's frequencies, the EPFX/SCIO feeds back its own frequencies to redress or neutralize the 'out-of-sync' wave patterns. This may involve adding frequencies in some instances and in others, reversing them to either enhance or counteract the body's own resonances.

APPROVALS AND CERTIFICATIONS

- **U.S. FDA:** The EPFX has FDA market clearance under 510(k) # K892114.
- EPFX/SCIO has been certified by the **UL544, CE, and European Standard tests** that control industry standards of safety.
- **Yamamoto,** an international acupuncture testing organization have tested and then certified the electro acupuncture, EEG and ECG aspects of the EPFX/SCIO as being both accurate and therapeutic.
- The **Occupational Standards Council for Bio-resonance Medicine and Complex Homeopathy in England** has done extensive field tests of the accuracy of the Electro Physiological Reactivity tests. They have also certified bio-resonance therapy as valid.
- The **International Medical Education Accreditation Service** with Head Quarters in Geneva, Switzerland reviewed the studies and certified the overall performance of the EPFX/SCIO as a Medical device for allergy reactivity testing and bioresonance therapy.
- The **International Journal of the Medical Science of Homeopathy** published a dedicated journal to the use of the EPFX/SCIO. The peer review staff reviewed 7 articles that validate the diagnostic value of the reactivity tests and the therapeutic value of the bioresonance auto-focus therapies.
- The **Royal College of Homeopathy of Japan** validated the clinical use of the device as a tool for Homeopaths.

DETERMINATION OF DEVICE SAFETY

The EPFX/SCIO is a biofeedback device that delivers to the individual a total power of 30 mWatts (3 Volts – 10 milliAmps). The input voltage is 6VDC via a USB cable connection to a personal computer. The personal computer is isolated by a medical safety surge protector (or in the case of a laptop, may be run on battery power). The patient harness has an optocoupler isolation to box with shared ground. Please refer to the Application for Non-significant Risk Determination in **Appendix A** and the Risk Analysis Report in **Appendix B**.

STUDY RATIONALE & BACKGROUND ABSTRACTS

STUDY INDICATION RATIONALE: STRESS REDUCTION

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.

Over-stressed individuals will typically feel overwhelmed and unable to cope with or manage their usual workload and responsibilities. They may often feel anxious, angry, irritable or tense, and experience difficulty with concentration, focus, productivity and memory. Individuals suffering from stress may feel more tired or have less energy than usual and may lack interest in activities that would normally be of interest and enjoyment, and begin to feel alone or isolated from people around them. Oversleeping or inability to sleep may occur as well as overeating or lack of appetite.

Physically, over-stressed individuals may get headaches or stiffness/tension in the muscles, jaw or back. They may experience frequent upset stomachs, skin rashes, racing heartbeat or sweaty palms. Even more significantly, those with untreated stress can develop high blood pressure, irregular heart rhythms, damage to arteries and higher cholesterol levels. Eventually, these symptoms may extend to the development and progression of coronary artery disease (atherosclerosis) and even a weakened immune system.

Worsening many of these direct physical ailments is the fact that individuals who are stressed often turn to harmful habits to reduce their stress, such as cigarette smoking, overeating, use of drugs or over-use of alcohol. All of these factors put the person at additional risk for physical impairment, including heart disease and stroke.

The Benefits of Stress Reduction are in their simplest form, a reduction, and often even reversal, of the individual's physical, cognitive, emotional and social symptoms that result from being overstressed. Reducing stress can even take an individual one step further toward improved overall mental and physical health and well-being.

THE EPFX/SCIO AND STRESS REDUCTION

The EPFX/SCIO is designed to reverse the manifestation of stress 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 reversed. Studies have shown that people who are over-stressed produce different patterns of brain waves than do people who are not over-stressed, and that reversal of that stress, in particular through techniques such as biofeedback training that employ the individual in controlling their return to stress-free living, can result in the abnormal patterns becoming normal.

The EPFX/SCIO tunes into an individual's body's physiological stress levels so that this information can be used to control the physiology, and consequently affect a decrease in those stress levels, resulting in improved physical and emotional health.

BACKGROUND INFORMATION ON THE BIORESONANCE TECHNIQUE

Edmund Jacobson first developed the progressive muscle relaxation technique. Although most of his research on the conditioning of muscle relaxation was conducted 50 years ago, it remains relevant today. For example, most therapeutic applications of biofeedback include the use of a systematic relaxation technique. Although Jacobson's system has been modified over time, his ideas and research methods have much to offer clinicians and researchers. Based on an interview reported by McGuigan, he may have been the first researcher to use medical instrumentation to provide feedback about physiological responses (Jacobson and McGuigan, 1978). His procedure, employing a prototype of modern biofeedback instrumentation, involved an individual observing an oscilloscope to determine the level of tension in his forearm extensor muscle. Later, Wolpe modified Jacobson's technique and popularized it as part of the systematic desensitization procedure.

In 1958, Kamiya began to study the changes in consciousness that accompanied variations in EEG alpha rhythm of human subjects. He developed a discrimination conditioning task in which a bell was rung periodically and the subject was requested to indicate if he had been generating EEG alpha just prior to the auditory stimulus. Many subjects were able to learn this task and this led to further research of alpha rhythm control. Kamiya and his associates later discovered that subjects could suppress alpha when given auditory feedback concerning its presence or absence.

One of the intriguing areas of investigation concerns the search for empirical validation of visceral or smooth-muscle operant conditioning. Neal Miller and his colleagues most notably, the late Leo DiCara, have been involved in research on instrumental autonomic conditioning in animals for a number of years. In 1968, DiCara and Miller observed that curarized rats could learn to avoid a shock by lowering their heart rate. Other investigators showed that visceral conditioning, through the use of feedback techniques, could be demonstrated in humans (Miller and Dworkin, 1974).

Although less well known, H D Kimmel (1960) spent years investigating instrumental conditioning off the autonomic nervous system (ANS) in man. Stimulated by results of earlier experiments in conditioning of the galvanic skin response (GSR), Kimmel and his students found that subjects' GSR's could be conditioned using pleasant odors. Kimmel (1974) summarized the research up to 1967, including 16 studies of GSR, five of heart rate and three of the vasomotor response. Results of all these studies supported the contention that the ANS could be modified through operant conditioning.

Subsequently biofeedback procedures were applied to clinical problems. In 1973, two innovative treatment procedures were developed which are widely used today, with certain technical refinements. Elmer and Alyce Green (1977) developed a clinical protocol for thermal feedback training. They used peripheral skin temperature as a measure of vasodilatation and combined skin temperature feedback with Schultz and Luthe's (1969) "Autogenic Training". Sargent, Green and Walters (1972) applied temperature biofeedback training to treat migraine. Patients were taught to increase the warmth in their fingers (vasodilatation) while decreasing the temperature of their foreheads (vasoconstriction). They found that almost 75 percent of the subjects were able to decrease both the duration and intensity of migraine attacks. Later studies have confirmed these results.

While the Green's were developing their treatment technique for migraine, Thomas Budzynski (1973) and his associates at the University of Colorado developed a feedback technique to treat

muscle contraction (tension) headaches. They used EMG training to teach patients to reduce the tension in their frontalis (forehead) muscles. Their results showed that average muscle tension levels dropped from 10 to 3.5 (microvolts) and headaches intensity was reduced over the 16-week training period. Two control groups of headache patients were employed in the experimental design; one group received "false" or pseudofeedback and the other group received no feedback at all. Neither of these groups improved as much as the EMG treatment group.

The clinical research which has been reviewed thus far has involved procedures where feedback is used to reduce muscle and blood vessel contraction ("physiological arousal"); however, a technique to increase muscle contraction (a form of EMG biofeedback training) has existed for almost 25 years. John Basmajian's early research, first published in 1963, indicated that patients can increase the functioning of single motor units through the use of EMG biofeedback. Even earlier, Marinacci and Horande (1960) demonstrated that EMG feedback could be applied to improve neuromuscular functioning in several disorders. Basmajian and his colleagues have designed specially constructed biofeedback instruments for use in rehabilitation, e.g., a miniature EMG feedback device. They have applied such instrumentation to various disorders including paralytic foot-drop. There is significant difference between the EMG units used in rehabilitation and those adapted for use with psychophysiological disorders. The biofeedback units employed in rehabilitation are designed to transmit information about single motor units or the functioning of a specific muscle. Most of the EMG units used to enhance relaxation, however, summate the bioelectrical information of a particular muscle group. The resulting feedback is somewhat less specific.

Prior to 1970, relatively few studies were conducted using biofeedback techniques. Since then, however, hundreds of investigations have been done and the accumulation of data has been impressive. For this reason, BSA task forces were developed to survey the current literature and summarize the current status of biofeedback as a therapeutic technique in a number of areas including: psychophysiological disorders (Fotopoulos and Sunderland, 1978), gastrointestinal disease (Whitehead, 1978), vasoconstrictive disorders (Taub and Stroebel, 1978), muscle tension headache (Budzynski, 1978) and others.

In 1989, Bill Nelson proposed and proved that biofeedback technique need not involve just a conscious or verbal process, but could work just as effectively at the subconscious level. The EPFX/SCIO was designed to provide feedback to the individual’s subconscious.

SUPPORTING ABSTRACT MATERIALS

Support for the Effects of Stress Reduction on Overall Health

1) Impact of a Workplace Stress Reduction Program on Blood Pressure and Emotional Health in Hypertensive Employees
The Journal of Alternative and Complementary Medicine. Jun 2003, Vol. 9, No. 3: 355 -369
Rollin McCraty, PhD, Mike Atkinson, Dana Tomasino, BA.
HeartMath Research Center, Institute of HeartMath, Boulder Creek, CA.

Objectives: This study examined the impact of a workplace-based stress management program on blood pressure (BP), emotional health, and workplace-related measures in hypertensive employees of a global information technology company.
Design: Thirty-eight (38) employees with hypertension were randomly assigned to a treatment group that received the stress-reduction intervention or a waiting control group that received no intervention during the study period. The treatment group participated in a 16-hour program, which included instruction in positive emotion refocusing and emotional restructuring techniques intended to reduce sympathetic nervous system arousal, stress, and negative affect, increase positive affect, and improve performance. Learning and practice of the techniques was enhanced by heart rate variability feedback, which helped participants learn to self-generate *physiological coherence*, a beneficial physiologic mode associated with increased heart rhythm coherence, physiologic entrainment, parasympathetic activity, and vascular resonance. BP, emotional health, and workplace-related measures were assessed before and 3 months after the program.
Results: Three months post-intervention, the treatment group exhibited a mean adjusted reduction of 10.6 mm Hg in systolic BP and of 6.3 mm Hg in diastolic BP. The reduction in systolic BP was significant in relation to the control group. The treatment group also demonstrated improvements in emotional health, including significant reductions in stress symptoms, depression, and global psychological distress and significant increases in peacefulness and positive outlook. Reduced systolic BP was correlated with reduced stress symptoms. Furthermore, the trained employees demonstrated significant increases in the work-related scales of workplace satisfaction and value of contribution.
Conclusions**:** Results suggest that a brief workplace stress management intervention can produce clinically significant reductions in BP and improve emotional health among hypertensive employees. Implications are that such interventions may produce a healthier and more productive workforce, enhancing performance and reducing losses to the organization resulting from cognitive decline, illness, and premature mortality.

2) Effects of Mindfulness-Based Stress Reduction on Medical and Premedical
Journal of Behavioral Medicine; Volume 21, Number 6 / December, 1998: 581-599
Shauna L. Shapiro, Gary E. Schwartz and Ginny Bonner

The inability to cope successfully with the enormous stress of medical education may lead to a cascade of consequences at both a personal and professional level. The present study examined the short-term effects of an 8-week meditation-based stress reduction intervention on premedical and medical students using a well-controlled statistical design. **Findings indicate that participation in the intervention can effectively (1) reduce self-reported state and trait anxiety, (2) reduce reports of overall psychological distress including depression, (3) increase scores on overall empathy levels, and (4) increase scores on a measure of spiritual experiences assessed at termination of intervention.** These results (5) replicated

in the wait-list control group, (6) held across different experiments, and (7) were observed during the exam period.

3) A Controlled Pilot Study of Stress Management Training of Elderly Patients With Congestive Heart Failure
Preventive Cardiology 2002;5(4):168-172, 176.
Frederic Luskin, PhD, Megan Reitz, BA, Kathryn Newell, MA, Thomas Gregory Quinn, MD, William Haskell, PhD

The purpose of this study was to evaluate the effect of stress management training on quality of life, functional capacity, and heart rate variability in elderly patients with New York Heart Association class I-III congestive heart failure (CHF). While substantial research exists on stress management training for patients with coronary heart disease, there are few data on the value of psychosocial training on patients with CHF. Thirty-three multiethnic patients (mean age, 66±9 years) were assigned through incomplete randomization to one of two treatment groups or a wait-listed control group. The 14 participants who completed the treatment attended eight training sessions during a 10-week period. The training consisted of 75-minute sessions adapted from the Freeze-Frame stress management program developed by the Institute of HeartMath. Subjects were assessed at baseline and again at the completion of the training. Depression, stress management, optimism, anxiety, emotional distress, and functional capacity were evaluated, as well as heart rate variability. **Significant improvements ($p<0.05$) were noted in perceived stress, emotional distress, 6-minute walk, and depression, and positive trends were noted in each of the other psychosocial measures.** The 24-hour heart rate variability showed no significant changes in autonomic tone. The authors noted that CHF patients were willing study participants and their emotional coping and functional capacity were enhanced. This program offers a simple and cost-effective way to augment medical management of CHF. Given the incompleteness of CHF medical management and the exploding interest in complementary medical intervention, it seems imperative that further work in psychosocial treatment be undertaken.

4) The Effects of Different Emotional States and a New Stress Management Intervention on Autonomic Regulation of the Heart.
Cardiovascular Health: Coming Together for the 21st Century, Proceedings, San Francisco CA, 1998. R. McCraty

Emotional stress directly impacts autonomic nervous system function and is a significant risk factor for cardiovascular disease. This study examined the effects of a new stress management intervention, 'Freeze-Frame,' on autonomic regulation of the heart and sympathovagal balance, assessed by power spectral analysis of heart rate variability (HRV), in a laboratory setting and in the workplace. In the laboratory, 20 subjects first experienced self-induced anger and then used the Freeze-Frame technique to self-generate a focused state of appreciation. In the workplace, Holter monitoring was used to assess the effects of Freeze-Frame used in response to real-life stress. Distinct shifts in autonomic activity and balance correlated with anger and appreciation. Anger produced a disordered HRV waveform and a sympathetically-dominated power spectrum, while appreciation, induced via the Freeze-Frame technique, produced a spectral shift towards increased parasympathetic activity and increased order in the HRV waveform. Through Freeze-Frame, subjects were able to enter and maintain a state of 'entrainment,'in which other physiological systems frequency-lock to the primary HRV rhythm of ~0.1 Hz. These data suggest that **stress management techniques that induce positive emotional shifts are a practical, effective approach to promoting a more cardioprotective autonomic profile, which may benefit patients with heart failure, coronary artery disease and hypertension.**

Support for the Beneficial Effects of Biofeedback Therapy

1) Comparative efficacy of biofeedback and stress inoculation for stress reduction.
J Clin Psychol. 1983 Mar;39(2):191-7.
Lustman PJ, Sowa CJ.

This study evaluated the comparative effectiveness of frontalis electromyographic (EMG) biofeedback, a primarily somatic intervention, and stress inoculation, a self-instructional form of cognitive-behavior therapy. Both treatments were compared with a waiting list control group on systolic and diastolic blood pressure, the Taylor Manifest Anxiety Scale, and the Teaching Anxiety Scale (N = 24). Multivariate assessment on all four dependent measures indicated that both the frontalis feedback and stress inoculation groups improved significantly more than the no treatment control, but did not differ overall from one another. The stress inoculation group showed more improvement in self-reported anxiety than the EMG group, while the EMG group tended to do better than the stress inoculation group on blood pressure measures. The untreated control group regressed somewhat across all measures. It was proposed that each treatment may have specific effects that might suggest which treatment would be indicated for a particular client.

2) A comparison of EMG feedback and alternative anxiety treatment programs.
Biofeedback Self Regul. 1981 Dec;6(4):501-16.
Hiebert BA, Fitzsimmons G.

Four cohorts of 40 subjects each were randomly assigned to 1 of 10 treatment conditions utilizing EMG feedback, cognitive monitoring training, systematic desensitization, high expectancy discussion group, or waiting list controls either in isolation or in various combinations. A three-way ANOVA for repeated measures indicated that significant anxiety reductions were experienced in all noncontrol treatment conditions.**Treatment groups employing EMG feedback demonstrated significantly greater anxiety decrements on Cattell's IPAT Self-Analysis Form, and baseline frontalis EMG**. Adding desensitization or cognitive monitoring to EMG feedback did not produce a more powerful effect than using EMG feedback alone. Sex and age differences were also observed. Some implications are discussed.

3) Low-resolution electromagnetic tomography neurofeedback.
IEEE Trans Neural Syst Rehabil Eng. 2004 Dec;12(4):387-97.
Congedo M, Lubar JF, Joffe D.
Department of Psychology of the University of Tennessee, Knoxville, TN 37996-0900, USA.
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Through continuous feedback of the electroencephalogram (EEG) humans can learn how to shape their brain electrical activity in a desired direction. The technique is known as EEG biofeedback, or neurofeedback, and has been used since the late 1960s in research and clinical applications. A major limitation of neurofeedback relates to the limited information provided by a single or small number of electrodes placed on the scalp. We establish a method for extracting and feeding back intracranial current density and we carry out an experimental study to ascertain the ability of the participants to drive their own EEG power in a desired direction. To derive current density within the brain volume, we used the low-resolution electromagnetic tomography (LORETA). Six undergraduate students (three males, three females) underwent tomographic neurofeedback (based on 19 electrodes placed according to the 10-20 system) to enhance the current density power ratio between the frequency bands beta (16-20 Hz) and alpha (8-10 Hz). According to LORETA modeling, the region of interest corresponded to the

Anterior Cingulate (cognitive division). The protocol was designed to improve the performance of the subjects on the dimension of sustained attention. Two hypotheses were tested: 1) that the beta/alpha current density power ratio increased over sessions and 2) that by the end of the training subjects acquired the ability of increasing that ratio at will. Both hypotheses received substantial experimental support in this study. This is the first application of an EEG inverse solution to neurofeedback. Possible applications of the technique include the treatment of epileptic foci, the rehabilitation of specific brain regions damaged as a consequence of traumatic brain injury and, in general, the training of any spatial specific cortical electrical activity. These findings may also have relevant consequences for the development of brain-computer interfaces.

STUDY DESIGN

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.

RANDOMIZATION

Each qualifying subject will be randomized to either treatment group A or B, using the computer-generated program on the web site: http://www.randomization.com. Randomization will occur on blocks of 2, 4 and 6.

Concealment of study treatment group assignment from both the subject and the investigator will be assured as follows:

(i) Each computer generated randomization sequence is unique and will therefore not be able to be replicated.
(ii) Randomization to treatment group will occur to either 'Group A' or to 'Group B' rather than to a test or placebo group, and only the study sponsor will know which group (A or B) corresponds to the true harness and which corresponds to the placebo harness. The sponsor will not reveal this information to any source (investigators, subjects, or study monitor) until the final subject in the study has completed his or her one-month follow-up phase of participation.

SUBJECTS

Sample size

There will be 100 subjects enrolled in this clinical study:

- 50 subjects in the test group
- 50 subjects in the control group

Testing will be done at eight different sites – two in the United States, four in Italy and two in Germany. Each European test site will enroll 5-6 subjects (for a total of 30-36 subjects). The remaining 64-70 subjects will be enrolled at United States test sites. Within each test site, subjects will be randomized to test or to placebo treatment group (Group A or Group B).

Rationale for sample size

Based on the following parameters established for the purposes of assessing efficacy of the Eclosion EPFX/SCIO in this clinical study …:

- ✓ overall study success criteria of at least a 30% difference between groups, comparing the proportion of individual successes in each group.
- ✓ Individual subject success criteria is defined as a decrease in total PSS score of 5 or more from pre-treatment to after the 6-month treatment period. It is anticipated that about 50% of subjects in the test group and about 20% of subjects in the control group will meet the individual success criteria, and
- ✓ intended application of a one-sided test for results analysis with an alpha value of 0.025 and Power of 0.8.

…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 is 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. Therefore, the following formula is used to determine the final needed starting sample size for each group:

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 is needed to insure that a sufficient number remains at the end of the trial (45 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.

Compensation of Subjects

A subject will not be offered money or any other form of compensation to participate in the study; however, he or she will also not be charged for the cost of the treatments with the Eclosion EPFX/SCIO or for the cost of any other directly-related evaluations or measurements that occur as part of his or her participation in the study.

A subject will remain financially responsible for any part of any session in which the clinical protocol is being carried out that is not a part of the clinical protocol, but a separate patient activity as determined appropriate and necessary by the investigator. Whenever possible, the study investigator will schedule a separate appointment outside of the study visit to take care of the subject's other needs. Only if this is not possible will the investigator take care of the subject's needs outside the scope of the study protocol at the end of a study session.

Subject Recruitment

Subjects will be recruited from one or more of the following sources:

- The pool of potentially suitable patients who normally attend the test sites for various services for an appointment they have self-scheduled. If the patient's previously recorded profile appears to fit that of the targeted study population, the possibility of taking part in the study will be presented to the patient. If the patient expresses interest and is willing, a study-related appointment will be scheduled to review the study informed consent form, and then, if the subject willingly signs the informed consent form, to proceed with the study qualification evaluation phase to confirm the individual's suitability to participate in the study.

- Nearby consenting and suitable medical offices and other such suitable locations, through use of the following flyer to alert potential subjects to the study.

The intended flyer is shown on the following page:

WANTED

PEOPLE AGED 18 TO 65 YEARS WHO FEEL THEY HAVE A LOT OF STRESS IN THEIR LIFE, FOR A CLINICAL STUDY OF THE EFFECTS OF BIORESONANCE THERAPY ON STRESS LEVELS.

THIS STUDY INVOLVES TWENTY ONE-HOUR TREATMENTS WITH THE ECLOSION EPFX/SCIO BIORESONANCE DEVICE OVER SIX MONTHS.

THERE IS ONE FOLLOW-UP VISIT TO THE TEST CLINIC ONE MONTH AFTER THE EPFX/SCIO TREATMENTS ARE FINISHED.

FOR MORE INFORMATION PLEASE CONTACT:

<Investigator Name>
<Test Site Name>
<phone number>

STUDY PROCEDURE

STUDY QUALIFICATION EVALUATION

SIGNING OF INFORMED CONSENT FORM

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

INCLUSION/EXCLUSION CRITERIA EVALUATION

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

INCLUSION CRITERIA

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

- **Population: Individuals with Elevated Levels of Perceived Stress**

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

The Perceived Stress Scale (PSS) is a global measure of perceived stress that assesses the degree to which situations in an individual's life are appraised as stressful. The subject is asked to indicate how often he or she felt or thought a certain way regarding14 items, following a 5-point Likert scale from 0 to 4, as follows: 0=never, 1=almost never, 2=sometimes, 3=fairly often, 4=very often. The PSS total score is obtained by reversing the scores on seven positive items and then summing across all 14 items, for a possible total of 56.

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

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

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

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

- Able and willing to maintain regular and consistent diet, exercise and lifestyle regimens throughout the study.
- Able and willing to maintain current medication regimes throughout the study.
- Able and willing to abstain from partaking in treatments – conventional or alternative (such as hypnotherapy, acupuncture, massage therapy, etc.) - or over-the-counter or prescription medications, including herbal remedies, designed to reduce stress throughout the study, other than the EPFX/SCIO treatment that is part of this study.
- Between 18 and 65 years of age.
- Male or female.
- Females on adequate birth control or not of child-bearing years.

EXCLUSION CRITERIA

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

- Total score of less than 25 on the Perceived Stress Scale.
- Stage 2 Hypertension (elevated blood pressure), defined by a systolic blood pressure level of 160 mmHg (millimeters of mercury) or higher OR a diastolic blood pressure level of 100 mmHg or higher, measured using a sphygmomanometer and averaged across three seated (resting) blood pressure readings taken at 10-minute intervals. The first measurement will be recorded after the subject has been at rest (seated) for about 10 minutes. *The source for the Stage 2 Hypertension criteria is the Seventh Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure, American Heart Association.*
- Subjects taking antihypertensive (blood pressure lowering) drugs.
- Tachycardia, Bradycardia or Irregular Resting Heart Rate, defined as follows:

  - ✓ *Tachycardia*: rapid or increased resting heart rate of greater than 100 beats per minute.
  - ✓ *Bradycardia*: abnormally slow resting heart rate of less than 60 beats per minute.
  - ✓ *Irregular Resting Heart Rate*: Irregular pattern of beats wherein beats are consistently missed across a 60-second period.

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

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

  1. The palm side of the subject's right hand is faced upwards.
  2. The investigator places his or her index and middle fingers on the wrist, approximately ½-1 inch below the base of the hand.
  3. The investigator presses his or her fingers down in the grove between the middle tendons and the outside bone until a throbbing sensation - the radial pulse – is felt.
  4. The investigator counts the number of beats that occur in 60 seconds, using a watch with a second hand or digital second counter for accuracy.

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

- Generalized Obesity, defined by a Body Mass Index (BMI) of 30 kg/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 6 months), defined by a score of 200 or greater on the Life Events Questionnaire, answered for known upcoming events such as a wedding, retirement, home move, etc.
- Type 1 diabetes.
- Any known heart condition(s), such as cardiac arrhythmias, congestive heart failure disease, myocardial infarction.
- Prior cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.
- Seizure disorder or family history of seizure disorder.
- Serious medical illness or condition: cancer; HIV, anorexia/bulimia.
- Serious head trauma.
- Pregnant, breast feeding, or planning pregnancy prior to the end of study participation.
- Serious mental health illness such as dementia or schizophrenia; psychiatric hospitalization in past two years.
- Excessive use of any illicit drug or alcohol on a regular basis.
- Infection or wound or any other external trauma in the areas to which the electrode bands of the EPFX device are to be attached.
- Developmental disability or cognitive impairment that would make it difficult for the subject to partake in the clinical study, including adequate comprehension of the informed consent form and ability to record the necessary measurements.
- Involvement in litigation and/or a worker's compensation claim and/or receiving disability benefits because of a stress-related or involved condition.
- Participation in a clinical study or other type of research in the past 30 days.

TREATMENT PROTOCOL ADMINISTRATION PROCEDURE

PRE-TREATMENT PHASE

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

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

Physiological Measures

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

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

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

Category	Systolic (mm Hg)		Diastolic (mm Hg)
Normal	less than 120	and	less than 80
Prehypertension	120–139	or	80–89
Hypertension			
Stage 1	140–159	or	90–99

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

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

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

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

If the pre-treatment phase occurs on a different day to the study qualification evaluation phase, then the subject's Resting Heart Rate will be measured again at this time, three consecutive seated measurements, each five minutes apart, with the first measurement occurring after the subject has been seated at rest for about 10 minutes (as during the study qualification evaluation phase). Also as during the study qualification evaluation phase criteria, if the subject's three-measurement Resting Heart Rate average falls into the bradycardia, tachycardia or irregular categories, then the subject shall be disqualified from further participation in the study at this time.

Else, the subject's Resting Heart Rate will be recorded as the number of beats per minute.

A Resting Heart Rate in the range of 60 - 90 beats per minute is considered in the normal range. The average Resting Heart Rate for a male is 70 beats per minute, and for a female is 75 beats per minute.

Quality of Life Assessment Measures

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

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

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

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

   The POMS measures six identified mood factors:

   - ✓ Tension-Anxiety
   - ✓ Depression-Dejection
   - ✓ Anger-Hostility
   - ✓ Vigor-Activity
   - ✓ Fatigue-Inertia
   - ✓ Confusion-Bewilderment

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

Since 1971, many research studies have provided evidence for the predictive and construct validity of the POMS Standard. Alpha coefficient and other studies have found the POMS Standard to exhibit a high satisfactory level of internal consistency, while product-moment correlations indicate a reasonable level of test-retest reliability. Factor analytic replications provide evidence of the factorial validity of the 6 mood factors, and an examination of the individual items defining each mood state supporting the content validity of the factor scores. Many recent studies continue to add to and affirm the validity of POMS normative sample. A bibliography of published research of almost 3000 research studies from 1964-2002 utilizing the POMS adds to and affirms the validity of the POMS normative sample 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 aged13-80 years.

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

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

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

Clinical interpretation of total scores uses the following guidelines: 0 to 13 (minimal depression), 14 to 19 (mild depression), 20 to 28 (moderate depression), and 29 to 63 (severe depression).

The BDI-II is contained in **Appendix G** of this clinical study protocol document.

Demographic Variables

The following demographic variables will be recorded at the pre-treatment phase:

(i) Age
(ii) Gender
(iii) Race
- ✓ Caucasian
- ✓ Hispanic
- ✓ Asian/Pacific Islander
- ✓ Middle Eastern
- ✓ Other

(iv) Education Level
- ✓ Less than high school
- ✓ High school
- ✓ Some college
- ✓ Undergraduate
- ✓ Graduate
- ✓ Post-graduate

Drug, Treatment and Food/Exercise Behavior and History

The following drug and treatment history variables will be recorded at the pre-treatment phase:

(i) Current medications – over-the-counter and prescription – that the subject is taking, including dosage schedule where possible.
(ii) Non-current medications – over-the-counter and prescription – that the subject has taken during the past 6 months.
(iii) Any herbs and dietary supplements that the subject is currently taken or has taken over the past 6 months.
(iv) All treatments in which the subject is currently engaged for any purpose. This includes conventional and alternative treatments and therapies. Alternative treatments and therapies include acupuncture, chiropractic, massage, etc. Any current treatment for the purpose of stress reduction will disqualify a subject from continued participation in the study and should have been screened during the study qualification evaluation phase.
(v) All treatments – conventional and alternative - in which the subject has partaken over the past 12 months for the purpose of stress reduction or relaxation.
(vi) Food/General Diet: Subject's general diet composition, such as typical average caloric intake, fat intake, vegetarian/non-vegetarian, etc.
(vii) Non-Alcoholic Drinks: General drink composition: number of glasses of water per day, fruit drinks, soda, milk, etc.
(viii) Alcoholic Drinks: Typical weekly alcohol consumption type and pattern, e.g. wine, beer, liquor, 2 glasses on a Saturday, one glass per day, none at all, etc.
(ix) Smoking: Yes or no; if yes, average number of cigarettes smoked daily.
(x) Exercise: existent or not; type and general frequency.

N.B.: Subjects are required, as outlined during the study qualification evaluation phase, to maintain their typical pre-study pattern of food and drink intake and exercise regimen throughout the course of participation in the study.

N.B.: Excessive alcohol consumption is a study qualification exclusion criteria.

Subject self-evaluation of disease status
The subject will complete the *Analyzing Stress in the Body Subject Questionnaire* that asks the subject to record various aspects of their general health and well-being, their disease history and self-perception of their health. This questionnaire is contained in **Appendix H** of this clinical study protocol document.

SUBJECT GROUP ASSIGNMENT
Subjects will be randomly assigned to treatment group A or treatment group B, as outlined in the **STUDY DESIGN** section above.

TREATMENT PHASE

The treatment phase of the study will start within three days of completion of the pre-treatment phase.

The study treatment phase will last six months and encompass two alternating treatment protocols – Protocol 1 and Protocol 2 – for a total of 20 treatments with the Eclosion EPFX/SCIO. Each of the 20 study treatment visits will last about 1 to 1¼ hours.

The treatment phase treatment schedule is as follows:

		Protocol 1	Protocol 2
Month 1**	Week 1	✕	✕
	Week 2	✕	✕
	Week3	✕	✕
	Week4	✕	✕
Month 2	Week 5	✕	
	Week 6		✕
	Week 7	✕	
	Week 8		✕
Month 3	Week 9	✕	
	Week 10		
	Week 11		✕
	Week 12		
Month 4	Week 13	✕	
	Week 14		
	Week 15		✕
	Week 16		
Month 5	Week 17	✕	
	Week 18		
	Week 19		✕
	Week 20		
Month 6	Week 21	✕	
	Week 22		
	Week 23		✕
	Week 24		

**During Week 1, Protocols 1 and 2 are administered at 2 separate visits, each visit 3 or 4 days apart.

TREATMENT ADMINISTRATION PROTOCOL

Each treatment administration protocol will proceed as follows:

1. The subject is seated on a non-metal chair in the treatment room.
2. The subject is connected to the EPFX/SCIO harness system A or B according to group assignment, with each electrode fixed to bare skin, as follows:

    a. Red harness on right wrist.
    b. Yellow harness on left wrist.
    c. Blue harness on right ankle.
    d. Black harness on left ankle.
    e. Head harness on forehead with cord on right.

3. The investigator sets the EPFX/SCIO device programming for Protocol 1 or Protocol 2, as applicable for the particular test session.

    Details of the programming process and parameters are contained in **Appendix I** of this clinical study protocol document.

4. The subject remains seated and restful while the treatment protocol is administered.
5. When the protocol is completed, the investigator unhooks the harness from the subject.
6. The subject's treatment administration for that session is complete.

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 four during-treatment 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 4 (after the 16th study treatment)
- End of Month 6 (after the 20th and final study treatment)

End of Months 1, 2 and 4: At each of these three during-treatment phase assessment time points, the following measures will be recorded:

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

End of Month 6: At the final during-treatment phase 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 one month (30 days) following the final treatment administration with the ECLOSION EPFX/SCIO at the end of month six.

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 one-month 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

TABLE OF SUBJECT EVENTS

The following table provides a progressive summary of subject events throughout the duration of the clinical study.

STUDY QUALIFICATION EVALUATION

1) A potentially well-suited and interested candidate for participation in the study attends the investigator's office.

2) The investigator reviews and discusses in detail the informed consent form with the candidate.

3) If the candidate continues to be interested and voluntarily signs the informed consent form, the study qualification evaluation phase of the study is performed to determine if the subject is suitable for participation in the study.

PRE-TREATMENT PHASE

1) The following physiological measures are repeated if the pre-treatment phase occurs on a different day than the study qualification evaluation phase:

- ✓ Blood pressure
- ✓ Resting Heart Rate

If these measures are repeated, then the results must comply with the study qualification criteria for the subject to continue.

2) The following Quality of Life measures are recorded:

- ✓ Perceived Stress Scale (PSS): repeated if the pre-treatment phase occurs on a different day than the study qualification evaluation phase; the results must comply with the study qualification criteria for the subject to continue.
- ✓ The 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

3) The following demographic variables will be recorded:

- ✓ Age
- ✓ Gender
- ✓ Race
- ✓ Education Level

4) The following drug, treatment and food/exercise behavior and history items will be recorded:

- ✓ Current medication use.
- ✓ Non-current medication use.
- ✓ Use of herbs and dietary supplements.
- ✓ Current treatments.
- ✓ Treatments in past 12 months.
- ✓ Food/general diet: typical intake and composition.
- ✓ Non-alcoholic drink consumption
- ✓ Alcoholic drink consumption.
- ✓ Smoking
- ✓ Exercise

TREATMENT PHASE

1) All subjects will undergo 20 treatments with the EPFX over a 6-month period with 2 alternating treatment protocols. There will be 2 treatment sessions per week for the first month, one treatment session per week for month 2 and one treatment session every two weeks for months 3, 4, 5 and 6. Each treatment session will last approximately 1 to 1¼ hours. All subjects, regardless of treatment group randomization, will undergo the entire treatment protocol regimen.

2) At the end of treatment months 1, 2 and 4, the following measures will be recorded:

- ✓ Blood pressure
- ✓ Resting Heart Rate
- ✓ Perceived Stress Scale (PSS)

3) At the end of treatment month 6, the following measures will be recorded:

- ✓ Blood pressure
- ✓ Resting Heart Rate
- ✓ 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
- ✓ Revision of drug, treatment and food/exercise behavior and history variables
- ✓ Subject satisfaction with overall study outcome rating
- ✓ Subject perceived group assignment, and why
- ✓ Investigator perceived group assignment, and why

4) At any time that is necessary, the following will be recorded:

- ✓ Occurrence of an adverse reaction or event
- ✓ Additional comments by the subject or investigator.

POST-TREATMENT MEASUREMENTS

One month after the final treatment administration at the end of treatment month 6, the following measures will be recorded:

- ✓ Blood pressure
- ✓ Resting Heart Rate
- ✓ 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

REPORTING OF ADVERSE EVENTS AND REACTIONS

At each evaluation point throughout the study, and at any other time during the clinical trial that is necessary, any and all potential adverse events and/or reactions will be recorded on the case report form, and subsequently evaluated by the Principal Investigator for its relation to the study treatment and whether or not any corrective action needs to be taken.

It is unlikely and not expected that any adverse events and/or reactions will result from implementation of this clinical study protocol. However, any and all adverse reactions and/or events that may occur to any participating subject will be recorded on the case report forms, and the investigator will report any and all adverse reactions and/or events that do occur to any participating subject as a result of this clinical study procedure to the governing IRB.

PRIVACY AND CONFIDENTIALITY

Records for each subject in the clinical study will be maintained in separate files in a locked filing cabinet at the test sites. The Principal Investigator at each site will be responsible for ensuring that all records for a subject are stored in that subject's file at all times other than when information is being recorded on them.

Once a subject's participation in the clinical study is complete, copies of the subject's files will be made and supplied to the study Sponsor who will then store them in a locked filing cabinet. Copies of subjects' case report forms will also be sent to Regulatory Insight, Inc. for the purposes of monitoring the data collection process and analysis of results. Regulatory Insight, Inc. will also maintain these copies in a separate clinical study file that is kept in a locked filing cabinet. The original records will be maintained at the respective test sites upon completion of the study in their original files and stored in a locked filing cabinet.

Subjects' identities will be kept confidential by assigning each subject a unique ID upon acceptance into the study. The subject ID will comprise the investigator's first and last name initials followed by a three-digit number determined according to the subject's order of entry into the clinical study. Each test site will be assigned a range of numbers for that test site. Test site #1 will be assigned numbers 001 to 100. Test site #2 will be assigned numbers 101 to 200. Test site #3 will be assigned numbers 201 to 300. Test site #4 will be assigned numbers 301 to 400. For example, the eighth subject to be enrolled at test site #2 with Principal Investigator John Black would have a subject ID of JB108. Neither the study Sponsor nor Regulatory Insight, Inc.

will receive any additional identifying information about a subject and will therefore have no way of linking a subject ID to a particular subject and his or her results.

MONITORING OF THE CLINICAL STUDY

The Monitor will assure that each test site and investigator is executing the protocol exactly as outlined and intended. This includes insuring that a signed informed consent form has been attained from each subject prior to commencing the protocol, that the treatment protocol is administered as specified, and that all pre- and post-procedure evaluations and measurements are taken using the specified methods and correctly and fully recorded on the appropriate clinical case report forms.

STATISTICAL ANALYSIS

PRIMARY EFFICACY OUTCOME MEASURE: CHANGE IN TOTAL SCORE ON THE PERCEIVED STRESS SCALE (PSS)

Primary efficacy outcome measure for this clinical study will be a statistically significant difference in the proportion of subjects who demonstrate a change in total score on the Perceived Stress Scale (PSS) of 5 or more points between treatment and control group subjects, in favor of treatment group subjects.

The measure will be evaluated in the following way:

Subjects meeting Individual Success Criteria
The individual subject success criteria is defined as a decrease of 5 or more on the total Perceived Stress Scale (PSS) score from pre-treatment to end of Month 6 measurement.

Overall Study Success Criteria.
Overall study success criteria is defined as at least a 30% difference between groups, comparing the proportion of individual successes in each group. It is anticipated that about 50% of subjects in the test group will meet the individual success criteria, and about 20% of subjects in the control group will meet the individual success criteria.

Evaluation Time Points
The evaluation time point at which study success will be analyzed is determined as the end of treatment Month 6 evaluation time point following the 20th and final treatment administration with the ECLOSION EPFX.

Null and Alternative Hypotheses
For this clinical study:

Null Treatment Hypothesis: There will be no statistically significant difference in the percentage of subjects who attain a decrease of 5 or more on the PSS following the 6-month treatment protocol with the EPFX/SCIO between subjects in the test and control groups.

Alternative Treatment Hypothesis: There will be a statistically significant difference in the percentage of subjects who attain a decrease of 5 or more on the PSS following the 6-month treatment protocol with the EPFX/SCIO between subjects in the test and control groups, in favor of test group subjects.

Statistical Procedures

Success of the study will be determined by simple calculation of the percentage of subjects in each treatment group who met the individual subject success criteria. If these percentages show that the overall study success criteria is met, the study will be considered to have had a successful outcome.

In addition, the primary efficacy outcome measure will be evaluated in the following two ways:

(i) ***Independent-Samples One-Tailed Z-Test of Proportions*** : This statistical procedure compares means for two groups of cases where the subjects have been randomly assigned to

one of the two groups, so that any difference in response is due to the treatment (or lack of treatment) and not to other factors.

A one-tailed z-test of proportions will be conducted to assess for a statistically significant difference in the average post-treatment PSS scores for test versus control group subjects.

(ii) ***Paired Samples T-Test***: This procedure is a statistical test of the null hypothesis that two population means are equal. It is used when the observations for the two groups can be paired in some way, such as in this clinical study, when the same subject is observed before (pre treatment administration) and after (post treatment administration) a treatment. Pairing is used to make the two groups as similar as possible. Observed differences between the groups can then be attributed more readily to the variable of interest.

Using the paired t-test, the percentage differences between the mean differences in final post-treatment PSS score minus pre-treatment PSS score for subjects in the test group versus subjects in the control group will be evaluated.

For the primary outcome measure, two analyses will be performed:

- Intent-to-treat analysis (including all randomized patients), and
- Per-protocol analysis (subjects without major protocol deviations, incompletes excluded)

Handling of missing data in the per-protocol analysis will be according to the multiple imputation method.

SECONDARY EFFICACY OUTCOME MEASURES

The following secondary efficacy outcome measures will be evaluated using appropriate statistical techniques:

a) An ANOVA will be used to evaluate the change in total PSS score across the measurement time points of pre-treatment, end of months 1, 2, 4 and 6, and one-month post evaluation, comparing test and control group subjects.
b) An ANOVA will be used to evaluate the change in average systolic and diastolic blood pressure readings across the measurement time points of pre-treatment, end of months 1, 2, 4 and 6, and one-month post evaluation, comparing test and control group subjects.
c) The percentage of subjects who decrease one or more categories of blood pressure reading between and across the pre-treatment, end of treatment weeks 1, 2, 4 and 6, and one-month post-treatment assessment points will be assessed comparing test and control groups. It is expected that significantly more test group subjects will demonstrate a decrease in one or more categories from pre-treatment to treatment to post-treatment than will control group subjects.
d) An ANOVA will be used to evaluate the change in average resting heart rate across the measurement time points of pre-treatment, end of months 1, 2, 4 and 6, and one-month post evaluation, comparing test and control group subjects.
e) An ANOVA will be used to evaluate the change in scores on the POMS Standard scales across the three time points of pre-treatment, end of treatment month 6 and one-month post-treatment, comparing test and control group subjects.
f) An ANOVA will be used to evaluate the change in scores on the STAI across the three time points of pre-treatment, end of treatment month 6 and one-month post-treatment, comparing test and control group subjects.

g) An ANOVA will be used to evaluate the change in scores on the HAM-D across the three time points of pre-treatment, end of treatment month 6 and one-month post-treatment, comparing test and control group subjects.
h) The percentage of subjects who decrease one or two categories on the HAM-D (indicating a decrease in depression level) between and across the measurement time points will be assessed comparing test and control groups. It is expected that significantly more test group subjects will demonstrate a decrease in one or more categories from pre-treatment to treatment to post-treatment than will control group subjects. Similar analyses will be performed for changes in subjects' overall scores on the inventory.
i) Correlations between scores on the various inventories will be made.
j) A z-test will be used to evaluate differences in outcome satisfaction ratings between test and placebo group subjects.
k) Evaluation of changes recorded on the 'Analyzing Stress in the Body Subject Questionnaire' will be made.
l) Evaluation of comments provided by subjects will be made.
m) Correlations between perceived and actual group assignments for both subjects and investigators will be made.
n) Safety outcome evaluation of any reported adverse events and reactions will be performed.

Analysis of results will be performed by individual test site and pooled across test sties. Application of a balanced test-control group study design incorporating a block by test site randomization procedure will contribute to statistical justification of pooling data across the different test sites.

COVARIATES

The baseline covariates of age, gender and pre-treatment PSS score will be adjusted for in the analysis through use of an ANCOVA analysis.

INFORMED CONSENT

- Informed consent will be an agreement between the investigator and each subject, having the capacity to understand and make an informed decision. Consent will be obtained prior to each potential subject's participation in this clinical study.
- Each subject participating in this clinical study will be made aware of the fact that his or her participation involves research and the intent of the research, the expected duration of his or her participation and a description of the procedures that will be followed.
- Each subject will be made aware of the reasonably expected benefits he or she might receive, as well as any risks or potential discomfort that are involved.
- Each subject will also be made aware of alternative treatments available to him or her.
- Each subject will be made aware that his or her records will remain confidential, but that the FDA and the governing IRB has the right to inspect his or her records.
- Each subject will be told that his or her participation in the clinical study is voluntary, without force or influence from the investigator or sponsor.
- Each subject will be given the name and method of contacting the appropriate person(s) to answer any questions about the research and in the event of a research-related injury.

Please refer to a copy of the consent form in **Appendix J**.

CASE REPORT FORMS

The case report forms used record the study data and measures can be found in **Appendix K**.

APPENDIX A:
APPLICATION FOR NONSIGNIFICANT RISK DETERMINATION

Application for Nonsignificant Risk Determination

1. Name of the device: Electro Physiological Feedback Xrroid (EPFX)/ Scientific Consciousness Interface Operations System (SCIO).

2. 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.

3. Description of the device: The EPFX/SCIO is an automatic, computer-operated non-invasive device that combines bioresonance and biofeedback fields for body analysis and energy balancing. It is a subconscious stress detection and reduction system that measures electro physiological reactions and patterns through a 'harness' of electro-magnetic electrodes attached to the head, ankles and wrists, which are catalogued, tabulated and fed back to the individual without he or she being aware of any effect or sensation. This 'reverse feedback' sends signals back into the individual's body to create an environment that is uncomfortable for parasites and viruses etc., and that boosts the body's own resources so that the body can speed up the healing process.

   The EPFX/SCIO device utilizes 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 head of the person. The software is a PC-based platform consisting of high-end graphics.

   The EPFX/SCIO measures voltage and current potential as well as skin resistance. To measure transcutaneous skin resistance, a medically safe, variant micro-current is applied to the body. The changes in voltage, amperage, and resistance produce reactivity profiles that determine the Xrroid.

   Specifically, the device measures sixteen (16) standard electrical parameters of the body, as follows:

   - ✓ Measurement of electro-magnetic reactivity in the body via six different responses: impedance, amperage, voltage, capacitance, inductance, and frequencies – resulting in 16 different electrical parameters.

   - ✓ Comparison of the tri-vector resonant frequencies – a complex mathematical calculation relating voltage, amperage, and resistance – of the body with over 12,000 known compounds.

- ✓ Feedback: a patient-directed Xrroid auto-focusing Galvanic Skin Resistance (GSR) signal that allows a variant micro-current EDS challenge for measuring electro-potential and GSR.

The EPFX/SCIO:

- ✓ is an entirely non-invasive, painless device, with five comfortable straps attached to the person's wrists, ankles, and forehead on the one end, which feeds through a digital interface box on the other end controlled by PC-based measurement and feedback software.
- ✓ measures, compares, and provides feedback on over 12,000 compounds stored in the PC database.
- ✓ is entirely independent of user error, personal bias, or machine malfunction.
- ✓ establishes a tri-vector relationship between the body being tested and the compound database, offering a 3-dimensional view of the body's health.
- ✓ maintains a hand-shake with the body, for nano-second bio-response testing – meaning that the EPFX/SCIO samples the body many times every second.
- ✓ has built-in auto-focus therapies, meaning it cannot cause harm, ensuring that pathogens cannot mutate and resonate at a different frequency.
- ✓ works on the physical, mental, and emotional levels because all three react in the body electro-magnetically and can be accurately measured.
- ✓ is portable.

The EPFX/SCIO provides information about the energetic state of the body and the direction in which the body is focusing its energy. After measuring the body's frequencies, the EPFX/SCIO feeds back its own frequencies to redress or neutralize the 'out-of-sync' wave patterns. This may involve adding frequencies in some instances and in others, reversing them to either enhance or counteract the body's own resonances.

4. Labeling: The devices used in this clinical study shall be labeled with the following statement:

   "CAUTION – Investigational device. Limited by United States law to Investigational use."

5. Risk analysis: Please refer to the formal risk analysis performed by Eclosion Kft. contained in **Appendix B**.

Summary
Through the application of design controls it is virtually impossible for hazard to occur; either in the absence of a failure, in a single-fault condition, or in a multiple-fault condition. This fact has been substantiated through an Engineering analysis. Our analysis has shown that the probability of hazard is incredibly remote.

6. Do you contend that this device as used in this protocol is an NSR device?
   _✓_ Yes ___No

7. Has another IRB decided this device is SR?
   ___ Yes _✓_ No

8. Does this type of device appear as SR on the FDA Information Sheet?
   ___ Yes _✓_ No

_____ _____
Signed Date

APPENDIX B:
RISK ANALYSIS

EPFX-USB/CSIO Risk Analysis

Rev 2

Updated 30 May 2007

Potential Hazard	Potential Cause	Initial Risk				Risk Mitigation	Required	Residual Risk				Eclosion Kft. Approval
		Severity	Probability	Risk Index 1-25	Risk Index Code			Severity	Probability	Risk Index 1-25	Risk Index Code	
Skin irritation	**Energy is applied via electrodes over irritated, inflamed, red, or broken skin**	**2**	**3**	**6**	A	**There already exists in the Warnings section of the installation manual the statement, "DO NOT apply over irritated, inflamed, red or broken skin." No further risk mitigation is required.**						
Skin irritation	**Customers with electrical sensitivity or allergies may experience bruises, sores or blisters if the metal part of the limb harnesses comes in direct contact with the skin**	**2**	**2**	**4**	A	**Additional warning added to the EPFX Operator Manual and EPFX Installation Manual to state "Do not allow the metal part of the limb harnesses to directly touch the skin."**						

Potential Hazard	Potential Cause	Initial Risk				Risk Mitigation	Required	Residual Risk				Eclosion Kft. Approval
		Severity	Probability	Risk Index 1-25	Risk Index Code			Severity	Probability	Risk Index 1-25	Risk Index Code	
Cardiac arrhythmia leading to death	**Pacemaker patient could experience the pacemaker shutting off due to the EPFX output creating the same mathematical pattern that is used to turn off the pacemaker.**	**5**	**1**	**5**	A	**The chance of this occurring has been determined to be 1 in 10 trillion; therefore, it is extremely unlikely to occur. Additionally, there already exists in the Warnings section of the installation manual as well as the box label the statement, "DO NOT use on patients with pacemakers." No further risk mitigation is required.**						
Allergic reaction to EPFX treatment	**Use on patient with extreme electrical sensitivity.**	**2**	**2**	**4**	A	**The injury would be considered minor and the chance of using this on someone with an extreme electrical sensitivity is remote. Additionally, there already exists in the Warnings section of the installation manual the statement, "DO NOT use on patients with electrical sensitivity." No further risk mitigation is required.**						

Potential Hazard	Potential Cause	Initial Risk				Risk Mitigation	Required	Residual Risk				Eclosion Kft. Approval
		Severity	Probability	Risk Index 1-25	Risk Index Code			Severity	Probability	Risk Index 1-25	Risk Index Code	
Violent reflex action	**Use on patient who has had electroshock therapy causing violent memories.**	**2**	**2**	**4**	A	**The injury would be considered minor and the chance of using this on someone who has previously had electroshock therapy is remote. Additionally, there already exists in the Warnings section of the installation manual the statement, "Use caution with psychotic patients or patients with histories of electro-shock." No further risk mitigation is required.**						
Skin burn	**Lightning surge crossing over a shared ground when surge protector is not being used.**	**3**	**2**	**6**	A	**There is an optocoupler and a flash resistor in the device to protect the patient from a lethal dose of electricity. Additionally, there already exists in the Warnings section of the installation manual the statement, "Use this device with a computer on battery mode free from wall current or with a medically safe surge protector. " No further risk mitigation is required.**						

Potential Hazard	Potential Cause	Initial Risk				Risk Mitigation	Required	Residual Risk				Eclosion Kft. Approval
		Severity	Probability	Risk Index 1-25	Risk Index Code			Severity	Probability	Risk Index 1-25	Risk Index Code	
Harness would not maintain good contact and therefore might not provide accurate readings.	**Device is used on child under 3 years of age.**	**1**	**2**	**2**	A	**The severity is considered to be a nuisance only because it will cause no harm to the child. There already exists in the Caution section of the installation manual the statement, "Do not use on children under 3 years of age." No further risk mitigation is required.**						
Device falsely indicates that patient is under a state of stress.	**Device is used on pregnant woman.**	**1**	**3**	**3**	A	**The severity is considered to be a nuisance only because it will cause no harm to the patient. There already exists in the Caution section of the installation manual the statement, "Do not use on pregnant women." No further risk mitigation is required.**						
Patient is in an altered state of consciousness, which might not provide accurate readings.	**Device is used on patient who is under the influence of alcohol or drugs.**	**1**	**3**	**3**	A	**The severity is considered to be a nuisance only because it will cause no harm to the patient. There already exists in the Caution section of the installation manual the statement, "Do not use on patients who are under the influence of alcohol or drugs." No further risk mitigation is required.**						

Potential Hazard	Potential Cause	Initial Risk				Risk Mitigation	Required	Residual Risk				Eclosion Kft. Approval
		Severity	Probability	Risk Index 1-25	Risk Index Code			Severity	Probability	Risk Index 1-25	Risk Index Code	
Device triggers anf epileptic seizure.	**Device is used on a patient with a history of epilepsy.**	**3**	**2**	**6**	A	**The triggering of an epileptic seizure would prevent the continuation of the sessions. There already exists in the Warnings section of the installation manual the statement, "Do not use on patients with a history of epilepsy." No further risk mitigation is required.**						

APPENDIX C:

PERCEIVED STRESS SCALE: LITERATURE AND ASSESSMENT TOOL

[Insert PSS Journal Article here – PSS journal article.pdf]

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts over the past month. In each case, you will be asked to indicate *how* often you felt or thought a certain way. Although some of the questions are similar, there are differences between them and you should treat each one as a separate question. The best approach is to answer each question fairly quickly. That is, don't try to count up the number of times you felt a particular way, but rather indicate the alternative that seems like a reasonable estimate.

For each question choose from the following alternatives:

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

1. In the last month, how often have you been upset because of something that happened unexpectedly?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

2. In the last month, how often have you felt that you were unable to control the important things in your life?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

3. In the last month, how often have you felt nervous and "stressed"?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

4. In the last month, how often have you dealt successfully with irritating life hassles?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

5. In the last month, how often have you felt that you were effectively coping with important changes that were occurring in your life?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

6. In the last month, how often have you felt confident about your ability to handle your personal problems?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

7. In the last month, how often have you felt that things were going your way?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

8. In the last month, how often have you found that you could not cope with all the things that you had to do?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

9. In the last month, how often have you been able to control irritations in your life?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

10. In the last month, how often have you felt that you were on top of things?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

11. In the last month, how often have you been angered because of things that happened that were outside of your control?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

12. In the last month, how often have you found yourself thinking about things that you have to accomplish?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

13. In the last month, how often have you been able to control the way you spend your time?

4	never
3	almost never
2	sometimes
1	fairly often
0	very often

14. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?

0	never
1	almost never
2	sometimes
3	fairly often
4	very often

APPENDIX D:

LIFE EVENTS QUESTIONNAIRE (LEQ)

Life Events Questionnaire: Past 3 Months

Subject ID: _____Date: _____

Instructions: Place a check mark in the column labeled "Happened" for those events that occurred in the **past 3 months**. Then record your score with the event value for each. Total the score.

Event Rank	Event Value	Happened	Your Score	Life Event
1	100	☐		Death of a spouse
2	73	☐		Divorce
3	65	☐		Marital separation
4	63	☐		Detention in jail or other institution
5	63	☐		Death of close family member
6	53	☐		Major personal injury or illness
7	50	☐		Marriage
8	47	☐		Being fired at work
9	45	☐		Marital reconciliation
10	45	☐		Retirement from work
11	44	☐		Major change in the health or behavior of a family member
12	40	☐		Pregnancy
13	40	☐		Sex difficulty
14	39	☐		Gaining a new family member through birth, adoption or remarriage
15	39	☐		Major business readjustments
16	38	☐		Major change in financial state
17	37	☐		Death of close friend
18	36	☐		Change to a different line of work
19	35	☐		Major increase in the number of arguments with spouse
20	31	☐		Taking on a mortgage
21	30	☐		Foreclosure on a mortgage or loan
22	29	☐		Major change in responsibilities at work (promotion, demotion, transfer)
23	29	☐		Son or daughter leaving home

24	29	☐		In-laws trouble
25	28	☐		Outstanding personal achievement
26	26	☐		Spouse beginning or ceasing work outside the home
27	26	☐		Going back to school
28	25	☐		Major change in living condition (building, remodeling or deterioration of home
29	24	☐		Revision of personal habits
30	23	☐		Troubles with supervisor, boss, or superiors
31	20	☐		Major change in working hours or conditions
32	20	☐		Change in residence
33	20	☐		Change to a new school
34	19	☐		Major change in type or amount of recreation
35	19	☐		Major change in church activities
36	18	☐		Major change in social activities
37	17	☐		Purchase of a car or other big purchase
38	16	☐		Major change in sleeping habits
39	15	☐		Major change in the number of family get-togethers
40	15	☐		Major change in eating habits
41	13	☐		Vacation
42	12	☐		Christmas or holiday observances
43	11	☐		Minor violations of the law (traffic tickets)

Total Score: _____

Life Events Questionnaire: Upcoming 6 Months

Subject ID: _____Date: _____

Instructions: Place a check mark in the column labeled "Will Happen" for those events that you know will happen over the **upcoming 6 months**.

Event Rank	Event Value	Will Happen	Your Score	Life Event
1	100	☐		Death of a spouse
2	73	☐		Divorce
3	65	☐		Marital separation
4	63	☐		Detention in jail or other institution
5	63	☐		Death of close family member
6	53	☐		Major personal injury or illness
7	50	☐		Marriage
8	47	☐		Being fired at work
9	45	☐		Marital reconciliation
10	45	☐		Retirement from work
11	44	☐		Major change in the health or behavior of a family member
12	40	☐		Pregnancy
13	40	☐		Sex difficulty
14	39	☐		Gaining a new family member through birth, adoption or remarriage
15	39	☐		Major business readjustments
16	38	☐		Major change in financial state
17	37	☐		Death of close friend
18	36	☐		Change to a different line of work
19	35	☐		Major increase in the number of arguments with spouse
20	31	☐		Taking on a mortgage
21	30	☐		Foreclosure on a mortgage or loan
22	29	☐		Major change in responsibilities at work (promotion, demotion, transfer)

23	29	☐		Son or daughter leaving home
24	29	☐		In-laws trouble
25	28	☐		Outstanding personal achievement
26	26	☐		Spouse beginning or ceasing work outside the home
27	26	☐		Going back to school
28	25	☐		Major change in living condition (building, remodeling or deterioration of home
29	24	☐		Revision of personal habits
30	23	☐		Troubles with supervisor, boss, or superiors
31	20	☐		Major change in working hours or conditions
32	20	☐		Change in residence
33	20	☐		Change to a new school
34	19	☐		Major change in type or amount of recreation
35	19	☐		Major change in church activities
36	18	☐		Major change in social activities
37	17	☐		Purchase of a car or other big purchase
38	16	☐		Major change in sleeping habits
39	15	☐		Major change in the number of family get-togethers
40	15	☐		Major change in eating habits
41	13	☐		Vacation
42	12	☐		Christmas or holiday observances
43	11	☐		Minor violations of the law (traffic tickets)

Total Score: _____

APPENDIX E:

PROFILE OF MOOD STATES (POMS) STANDARD

Profile of Mood States

Subject ID: _____Date: _____
Evaluation Session: _____

Instructions: Describe how you **FEEL RIGHT NOW** by circling one response for each of the words listed below.

FEELING	Not at All	A Little	Moderately	Quite a bit	Extremely
Friendly	1	2	3	4	5
Tense	1	2	3	4	5
Angry	1	2	3	4	5
Worn out	1	2	3	4	5
Unhappy	1	2	3	4	5
Clear-headed	1	2	3	4	5
Lively	1	2	3	4	5
Confused	1	2	3	4	5
Sorry for things done	1	2	3	4	5
Shaky	1	2	3	4	5
Listless	1	2	3	4	5
Peeved	1	2	3	4	5
Considerate	1	2	3	4	5
Sad	1	2	3	4	5
Active	1	2	3	4	5
On edge	1	2	3	4	5
Grouchy	1	2	3	4	5
Blue	1	2	3	4	5
Energetic	1	2	3	4	5
Panicky	1	2	3	4	5
Hopeless	1	2	3	4	5
Relaxed	1	2	3	4	5
Unworthy	1	2	3	4	5
Spiteful	1	2	3	4	5
Sympathetic	1	2	3	4	5
Uneasy	1	2	3	4	5
Restless	1	2	3	4	5
Unable to concentrate	1	2	3	4	5
Fatigued	1	2	3	4	5
Helpful	1	2	3	4	5
Annoyed	1	2	3	4	5
Discouraged	1	2	3	4	5
Resentful	1	2	3	4	5
Nervous	1	2	3	4	5
Lonely	1	2	3	4	5
Miserable	1	2	3	4	5
Muddled	1	2	3	4	5
Cheerful	1	2	3	4	5
Bitter	1	2	3	4	5

Exhausted	1	2	3	4	5
Anxious	1	2	3	4	5
Ready to fight	1	2	3	4	5
Good-natured	1	2	3	4	5
Gloomy	1	2	3	4	5
Desperate	1	2	3	4	5
Sluggish	1	2	3	4	5
Rebellious	1	2	3	4	5
Helpless	1	2	3	4	5
Weary	1	2	3	4	5
Bewildered	1	2	3	4	5
Alert	1	2	3	4	5
Deceived	1	2	3	4	5
Furious	1	2	3	4	5
Effacious	1	2	3	4	5
Trusting	1	2	3	4	5
Full of pep	1	2	3	4	5
Bad-tempered	1	2	3	4	5
Worthless	1	2	3	4	5
Forgetful	1	2	3	4	5
Carefree	1	2	3	4	5
Terrified	1	2	3	4	5
Guilty	1	2	3	4	5
Vigorous	1	2	3	4	5
Uncertain about things	1	2	3	4	5
bushed	1	2	3	4	5

APPENDIX F:

STATE TRAIT ANXIETY INVENTORY (STAI)

State-Trait Anxiety Inventory for Adults
Self-Evaluation Questionnaire

STAI Form Y-1

Subject ID: _____ Date: _____

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate response to the right of the statement to indicate how you feel *right* now, that is, *at this moment*. There are no right or wrong answers. Do not spend too much time on any one statement, but give the answer which seems to describe your present feelings best.

	Not at All	**Somewhat**	**Moderately**	**Very Much So**
1. I feel calm	1	2	3	4
2. I feel secure	1	2	3	4
3. I am tense	1	2	3	4
4. I feel strained	1	2	3	4
5. I feel at ease	1	2	3	4
6. I feel upset	1	2	3	4
7. I am presently worrying over possible misfortunes	1	2	3	4
8. I feel satisfied	1	2	3	4
9. I feel frightened	1	2	3	4
10. I feel comfortable	1	2	3	4
11. I feel self-confident	1	2	3	4
12. I feel nervous	1	2	3	4
13. I am jittery	1	2	3	4
14. I feel indecisive	1	2	3	4
15. I am relaxed	1	2	3	4
16. I feel content	1	2	3	4
17. I am worried	1	2	3	4
18. I feel confused	1	2	3	4
19. I feel steady	1	2	3	4
20. I feel pleasant	1	2	3	4

State-Trait Anxiety Inventory for Adults
Self-Evaluation Questionnaire

STAI Form Y-2

Directions: A number of statements which people have used to describe themselves are given below. Read each statement and then circle the appropriate response to the right of the statement to indicate how you *generally* feel.

	Almost Never	**Sometimes**	**Often**	**Almost Always**
21. I feel pleasant	1	2	3	4
22. I feel nervous and restless	1	2	3	4
23. I feel satisfied with myself	1	2	3	4
24. I wish I could be as happy as others seem to be	1	2	3	4
25. I feel like a failure	1	2	3	4
26. I feel rested	1	2	3	4
27. I am “calm, cool, and collected”	1	2	3	4
28. I feel that difficulties are piling up so that I cannot overcome them	1	2	3	4
29. I worry too much over something that really doesn’t matter	1	2	3	4
30. I am happy	1	2	3	4
31. I have disturbing thoughts	1	2	3	4
32. I lack self-confidence	1	2	3	4
33. I feel secure	1	2	3	4
34. I make decisions easily	1	2	3	4
35. I feel inadequate	1	2	3	4
36. I am content	1	2	3	4
37. Some unimportant thought runs through my mind and bothers me	1	2	3	4
38. I take disappointments so keenly that I can’t put them out of my mind	1	2	3	4
39. I am a steady person	1	2	3	4
40. I get in a state of tension or turmoil as I think over my recent concerns and interests	1	2	3	4

APPENDIX G:

BECK DEPRESSION INVENTORY-II (BDI-II)

Formatiert: Überschrift 6, Links, Abstand Vor: 0 pt, Nach: 0 pt

BECK DEPRESSION INVENTORY-II (BDI-II)

Subject ID: _____ Date: _____ Assessment time point:: _____

Instructions: This questionnaire has 21 groups of statements. Please read each group of statements carefully, and then pick the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number next to the statement you have picked. If more than one statement in the group seems to fit, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

0	I do not feel sad.
1	I feel sad much of the time.
2	I am sad all the time.
3	I am so sad or unhappy that I can't stand it.

2. Pessimism

0	I am not discouraged about my future.
1	I feel more discouraged about my future than I used to be.
2	I do not expect things to work out for me.
3	I feel my future is hopeless and will only get worse.

3. Past Failure

0	I do not feel like a failure.
1	I have failed more than I should have.
2	As I look back, I see a lot of failures.
3	I feel I am a total failure as a person.

4. Loss of Pleasure

0	I get as much pleasure as I ever did from the things I enjoy.
1	I don't enjoy things as much as I used to.
2	I get very little pleasure from the things I used to enjoy.
3	I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0	I don't feel particularly guilty.
1	I feel guilty over many things I have done or should have done.
2	I feel quite guilty most of the time.
3	I feel guilty all of the time.

6. Punishment Feelings

0	I don't feel I am being punished.
1	I feel I may be punished.
2	I expect to be punished.
3	I feel I am being punished.

7. Self-Dislike

0	I feel the same about myself as ever.
1	I have lost confidence in myself.
2	I am disappointed in myself.
3	I dislike myself.

8. Self-Criticalness

0	I don't criticize or blame myself more than usual.
1	I am more critical of myself than I used to be.
2	I criticize myself for all of my faults.
3	I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0	I don't have any thoughts of killing myself.
1	I have thoughts of killing myself, but I would not carry them out.
2	I would like to kill myself.
3	I would kill myself if I had the chance.

10. Crying

0	I don't cry anymore than I used to.
1	I cry more than I used to.
2	I cry over every little thing.
3	I feel like crying, but I can't.

11. Agitation

0	I am no more restless or wound up than usual.
1	I feel more restless or wound up than usual.
2	I am so restless or agitated that it's hard to stay still.
3	I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0	I have not lost interest in other people or activities.
1	I am less interested in other people or things than before.
2	I have lost most of my interest in other people or things.
3	It's hard to get interested in anything.

13. Indecisiveness

0	I make decisions about as well as ever.
1	I find it more difficult to make decisions than usual.
2	I have much greater difficulty in making decisions than I used to.
3	I have trouble making any decisions.

14. Worthlessness

0	I do not feel I am worthless.
1	I don't consider myself as worthwhile and useful as I used to.
2	I feel more worthless as compared to other people.
3	I feel utterly worthless.

15. Loss of Energy

0	I have as much energy as ever.
1	I have less energy than I used to have.
2	I don't have enough energy to do very much.
3	I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0	I have not experienced any change in my sleeping pattern.
1a	I sleep somewhat more than usual.
1b	I sleep somewhat less than usual
2a	I sleep a lot more than usual.
2b	I sleep a lot less than usual
3a	I sleep most of the day.
3b	I wake up 1-2 hours early and can't get back to sleep.

17. Irritability

0	I am no more irritable than usual.
1	I am more irritable than usual.
2	I am much more irritable than usual.
3	I am irritable all the time.

18. Changes in Appetite

0	I have not experienced any change in my appetite.
1a	My appetite is somewhat less than usual.
1b	My appetite is somewhat greater than usual.
2a	My appetite is much less than usual.
2b	My appetite is much greater than usual.
3a	I have no appetite at all.
3b	I crave food all the time.

19. Concentration Difficulty

0	I can concentrate as well as ever.
1	I can't concentrate as well as usual.
2	It's hard to keep my mind on anything for very long.
3	I find I can't concentrate on anything.

20. Tiredness or Fatigue

0	I am no more tired or fatigued than usual.
1	I get more tired or fatigued more easily than usual.
2	I am too tired or fatigued to do a lot of the things I used to do.
3	I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0	I have not noticed any recent change in my interest in sex.
1	I am less interested in sex than I used to be.
2	I am much less interested in sex now.
3	I have lost interest in sex completely.

APPENDIX H:

ANALYZING STRESS IN THE BODY SUBJECT QUESTIONNAIRE

EPFX/SCIO STRESS REDUCTION STUDY
ANALYZING STRESS IN THE BODY SUBJECT QUESTIONARE

SUBJECT ID: _____

BIRTHDATE: _____

DATE: _____

VISIT: PRE-TREATMENT / FINAL POST-TREATMENT (circle one)

1. ORGANS REMOVED (INCLUDING TEETH): _____

_____

_____

_____

_____

2. PLEASE LIST ANY PARTICULAR AREAS OF CONCERN/COMPLAINTS:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

3. WRITE ANY COMMENTS YOU WOULD LIKE:

_____

_____

_____

_____

_____

_____

_____

_____

_____

SUPPRESSION AND OBSTRUCTION TO CURE INDEX (SOC)

Please answer all that apply to you with the appropriate number.

____ Number of organs removed
____ Number of synthetic drugs used
____ Number of times you smoke or chew tobacco per day
____ Number of steroid type drugs used in the past
____ Current number of dental fillings that are NOT porcelain (including any removed within the past year)
____ Number of street drugs used per month
____ Number of all known allergies
____ Number of unresolved mental factors
____ Responsibility for your disease on a scale of 0 (min) to 10 (max)
____ Amount of fat in your diet as a % of total calories (national average is 40%)
____ Personal stress level 0 (min) to 10 (max)
____ Number of sugar type products consumed per day (Including soft drinks, ice cream, etc.)
____ Number of exercise sessions per week, at 20 minutes or more per session (not work)
____ Number of alcoholic drinks consumed per day, on average
____ Number of cups of coffee, tea or caffeine products (including chocolate) consumed per day
____ Number of extreme toxic exposures per year (radiation, insecticide, chemicals, chemotherapy, etc.)
____ Number of major injuries and surgeries (incl. emotional traumas) from past
____ Number of major infections
____ Number of water or natural fruit juice drinks per day
____ Number of pounds that you think you are overweight

List all types of stress you think you have in your life right now (job, family, home, relatives, emotions, etc.)

_____
_____
_____
_____
_____

List any inherited disorders

_____
_____
_____
_____
_____
_____

Please check any of the following that apply to you

____ Vascular or circulatory disease, cold extremities, artery or vein problems
____ Current Infection or history of infections
____ Neoplasm, possibility of cancer, tumor, or degenerative disease
____ Dietary problems, possible addiction to drugs or toxic exposure
____ Intoxication or possible addiction to alcohol
____ Congenital disorder, hereditary or from birth
____ Allergy tendency or prevalence of allergic symptoms in history
____ Endocrine disturbance, hormonal, glandular, or regulatory problems
____ Emotional problems
____ High stress levels
____ Sensory (eyes, ears, taste, feeling, smell) problems
____ Adverse reaction to excess humidity, heat, cold, dryness, wind, or radiation

Exposure to toxins:

____ Beauty shop toxins or similar
____ Asbestos from shipping, industry, insulation, etc.
____ Insecticides, herbicides, industrial farm chemicals
____ Heavy metals
____ Food additives
____ Radiation
____ Chorine or fluoride sensitivity
____ Environmental toxins of water and air pollution
____ Exposure to infections

APPENDIX I:

ECLOSION EPFX/SCIO TREATMENT PROGRAMMING PROCESS AND PARAMETERS

TREATMENT PROGRAMMING PROCESS AND PARAMETERS

Be sure to have this document open on your computer before you start your day so you can access the codes and affirmation at the bottom of the document.

These protocols will take approximately 1 hour to 1 1/4 hour (Allow 1 ½ hours until the technician becomes more use to the protocol and proficient) on the first visit of the week. Second visit will take 50 min to 1 hr 5 min (up to 1 hr 30 min until the technician becomes proficient). Variation in speed depends on clients' ability to accept frequencies.

Protocol 1

1. Greet client and bring them into your office
2. Have client sit on a non-metal chair
3. Hook up client to harnesses with straps directly on bare skin
    a. Red on right wrist
    b. Yellow on left wrist
    c. Blue on right ankle
    d. Black on left ankle
    e. Head harness on forehead with cord on right
4. Click on Clasp 32 Hands for entry to EPFX-usb/SCIO
    a. Close harness check box
5. Go to Password Enter 0210 and then click Ok
6. Go through Demographics quickly with the client, using intake form but questioning items, which may not have been understood. This step is only done on a first time client, try and keep this to a 5 min max. For return visit ask to see if any of the answers in Demographics may have changed if so you will need to do the steps in the 2nd weekly visit under Demographics.
7. Enter the button Enter Patient Data (Load New or Previous Patient)
8. Enter New Client
    a. Type in first time only:
        i. Place in Birth date
        ii. Type in chief complaints in white box,
        iii. Address for geographic information of IRB report
9. Enter Birth Time and Place and then Geographic information, first time only
10. Save Data and exit Client Data and Demographic pages
    a. If Demographics information has changed for past client you must do step 10 and then click Modify allowing you to go back to the demographics list and make changes. Repeat entry to Client Data and now click Save Current Patient and close to Main Page.
11. Enter Calibration Button
    a. Do the Computer Risk Field Neutralization
    b. Check Room For Geographic Stress and clear if needed
    c. Fast Track Calibration
    d. Close to Main Page
12. Open Shaping Function – type Gaba, Serotonin, 39 behind the current word Love (double space between each leaving off the comma)
    a. Reward Sample
    b. Engage

    c. Close to main page
13. Enter Test Matrix
14. Click Prepare Test and then Test
15. Record Varhope (if keeping paper record)
16. System Power Settings Click on Scalar Boost Active, Shield from remote viewing
17. Auto Zap for CoQ energies
18. While doing Auto Zap for CoQ Click on Activate Bodyviewer in the AFE box to open the bottom buttons for Bodyviewer and Irid
19. While doing Auto Zap go to Irid button at bottom of screen: Click on the following
    a. Ear & Etc
        i. Kidney then activate piggyback
        ii. Liver then activate piggyback
        iii. Large Intestine then activate piggyback
        iv. Small Intestine then activate piggyback
        v. Stomach then activate piggyback
        vi. Endocrine then activate piggyback
        vii. Spleen then activate piggyback
        viii. Lymph then activate piggyback
        ix. Lungs then activate piggyback
        x. Top 2 Extra (for brain) then activate piggyback
    b. Iridology: Misc Rx
        i. Skin then activate piggyback
    c. Iridology: Facial & Eye Gums Diagnosis
        i. Both Brain Scans on that page, then activate piggyback then activate piggyback
        ii. Minimize the page
    d. Go back to Test matrix
20. Programs click on Risk Profile to open
    a. Click Please Load New Info Report (large gray bar) do no therapy
    b. Ok
    c. Ok
    d. Double click the highest red number
    e. Click the BOTTOM Close returns you to Test Matrix
21. Auto Zap Emotions
22. While Auto Zap is running open Bodyviewer
    a. Bodyviewer: Click on Organ and then click on each of the following
    b. Brain Frontal, Parietal, Temporal, Occipital, Limbic, Medulla, Cerebellum
    c. Program Start
    d. Click Load Unconscious Choice, Start movie
    e. Minimize the page
23. Research & Reports dropdown
    a. Orgone Generator
        i. Paste affirmation saying listed after protocol in white box
        ii. Bio-Growth
        iii. Interactive
        iv. 200 meters
        v. Activate Orgone Field
        vi. Close to Timed Therapies Music & Superlearning
24. Timed Therapies Music and Superlearning
    a. Timed Treatment, Enable, Set timer to 2 minutes

    b. Add Additional Therapy (use the line-by-line codes at the end of the document and cut and paste them in for each category)
    c. Click Metabolic error on Add additional treatment to therapy
        i. Metabolic Repair
        ii. Feel good
        iii. Close back to Test Matrix
25. Auto Zap Miasms
26. Go back to Bodyviewer
    a. Click Programs Start
    b. Pathway to all past trauma and minimize the page
27. Immune Stimulation – Disease Dictionary
    a. Acquired Imune Deficiency Syndrome – Electroacupuncture & BioResonance
    b. Ok-Reveal Text,
    c. Set Magnetic Method to 5,
    d. Time of therapy in Minutes 35,
    d. Add to Therapy: Cut and paste items from the large listing of test matrix numbers following this protocol into one of the lines and it will put it into the text (not the line itself)
    e. Load (this should bring up a confirmation box, if it does click Ok, if it does not then you need to right click on the Disease Lexicon bottom ruler button to force the confirmation box to appear.)
    f. Auto Treat,
    g. Minimize picture (requires using the – sign 2 times) this allows the therapy to work while doing the other therapies to follow
28. Programs to Activate Frequency Modulation Program to Autonomic Nerval System
    a. Click Sympathetic Nerval System 2 times
    b. Click Parasympathetic balance 1 time
    c. Close to therapy page
29. Add Shuman Wave
30. Primary Disease: Stress
31. Organ Relation: Adrenal
32. Emotional box: Put in, Shame Guilt Anger Fear Grief (double space between each)
33. Rife Generator 24 – 2,400,000
34. Set Rife at 1 min and Start
35. Expand to Energetic link click both at bottom left of page to access Activate Spiritual Healing
    a. Set for 1 min
    b. Activate Spiritual Healing
    c. Click Multi Media (at top of the page) opens Manfly picture watch for large picture to close automatically
    d. Minimize (if the program does not allow this, possible glitch) reopen and close it.
36. Trivector Energy Flow
    a. Start (1 time)
    b. Enter DNA
    c. Click on Telimere
    d. Minimize
    e. Close DNA
    f. Close Trivector
37. Spinal Button
38. Spinal Energy Flow - Test & Treat Trivector Energy Flow 2 times (if messages come up close them)

39. Neuro Emotional Complex NEC –Test and Treat Emotions with phase stabilization 1 time
40. While running Spine and later:
    a. Open Bodyviewer every 15 min. to
    b. Program Start
    c. Load Program, Start Info Exchange
    d. Minimize
41. NLP – Relaxation Pulse 3 times
42. NLP -Stress Reduction place 5 in each of the options of yellow and blue leave timer 1 min for Start and 1 min for Treat
43. NLP
    a. Neural Net Stabilization
    b. Neuro–Peptide balance
44. Cranial Sacral – SomatoEmotion
45. Spinal – Sports – Sport SuperConscious Report – Repair All 2 times
46. Nutrition Profile, Click Calculate Strike this key first and Ok
    a. Stress and Cortisol – Adrenal Balance (do you wish to answer questions answer No) – Adrenal 1 time
    b. General Digestion – Nutrienergy Balance 1 time
    c. Close Digestion
    d. Close Spinal Page
47. Close back to Main Therapy Page
48. Info top Ruler bar
    a. Info view
    b. Save SOC
    c. Add top 200 to Significant Data
    d. Report
        i. Current Exam Report
        ii. Okay
        iii. Save Examination
        iv. Close back to Main Screen
49. Check current Rectification
    a. Correct All Till Maximum
    b. Close to Panel (do not close out of program)
50. Tools & Data Transfer
    a. Answer Type of condition
    b. Save
    c. Save to Transfer File into C drive or travel drive for IRB study
51. Close program
52. Unhook client
53. Clean Straps

Protocol 2

Repeat steps starting in Demographics entry directly to Client list choose repeat person and Previous Patient then Close to Calibration. Add on the following (time should allow since questions in Demographic have already been done.) Do all before step 53 and then continue to ending.

1. Greet client and bring them into your office
2. Have client sit on a non-metal chair or massage table
3. Hook up client to harnesses with straps directly on bare skin
    b. Red on right wrist
    c. Yellow on left wrist
    d. Blue on right ankle
    e. Black on left ankle
    f. Head harness on forehead with cord on right
4. Click on Clasp 32 Hands for entry to EPFX-usb/SCIO
    a. Close harness check box
    b. Continue
    c. Password
    d. Enter 0210
    e. Ok
5. Go to Demographics
6. Enter Patient Data (Load New or Previous Patient)
7. Click on persons name who is repeating visit
8. Click on Previous Patient
9. If Demographics information has changed for past client you must do Modify and close make the changes on Demographics and reenter Patient Data bar, click Modify again and close.
10. Save Data and exit Client Data and Demographic pages
11. Enter Calibration Button
12. Do the Computer Risk Field Neutralization
13. Check Room For Geographic Stress and clear if needed
14. Fast Track Calibration
    a. Close to Main Page
15. Open Shaping Function – behind the current word Love type in: Gaba Serotonin 39 (double space between each leaving off the comma)
    a. Reward Sample
    b. Engage
    c. Close to main page
16. Enter Test Matrix
17. Click Prepare Test and then Test
18. Please Load New Info Report (if red Varhope panel remains up click close, if Blue Info box is still open click Remove Info)
19. Record Varhope (if keeping paper record)
20. System Power Settings
    a. Click on Scalar Boost Active,
    b. Shield from remote viewing
21. Auto Zap for CoQ energies
22. While doing Auto Zap for CoQ Click on Activate Bodyviewer in the AFE box to open the bottom buttons for Bodyviewer and Irid
    a. Ear & Etc (top ruler bar)

i. Kidney then activate piggyback
ii. Liver then activate piggyback
iii. Large Intestine then activate piggyback
iv. Small Intestine then activate piggyback
v. Stomach then activate piggyback
vi. Endocrine then activate piggyback
vii. Spleen then activate piggyback
viii. Lymph then activate piggyback
ix. Lungs then activate piggyback
x. Top 2 Extra (for brain) then activate piggyback

b. Iridology: Misc Rx
    i. Skin then activate piggyback
c. Iridology: Facial & Eye Gums Diagnosis
    i. Both Brain Scans on that page, then activate piggyback then activate piggyback
    ii. Minimize the page
d. Go back to Test matrix

23. Programs click on Risk Profile to open
    a. Click Please Load New Info Report (large gray bar) do no therapy
    b. Ok
    c. Ok
    d. Double click the highest red number
    e. Click the BOTTOM Close returns you to Test Matrix
24. Auto Zap Emotions
25. While Auto Zap is running open Bodyviewer
    a. Bodyviewer: Click on Organ and then click on each of the following
    b. Brain Frontal, Parietal, Temporal, Occipital, Limbic, Medulla, Cerebellum
    c. Program Start
    d. Click Load Unconscious Choice, Start movie
    e. Minimize the page
26. Research & Reports dropdown
    a. Orgone Generator
        i. Paste affirmation saying listed next page in white box
        ii. Spiritual Harmony
        iii. Interactive
        iv. 200 meters
        v. Activate Orgone Field
        vi. Close to Timed Therapies Music & Superlearning
27. Timed Therapies Music & Superlearning, Enable
    a. Set time at 2 min
    b. Add Additional Therapy (use the line-by-line codes at the end of the document and cut and paste them in for each category)
    c. Click Metabolic error on Add additional treatment to therapy
    d. Hormonal Treatment
    e. Auto Digestive System
    f. Additional (top Ruler bar) Balance Life Force 1 time
    g. Close Timed Treatments box & purple box
28. Nutrition
    a. Click Calculate Strike this key first
    b. Ok
    c. Stress and Cortisol

        i. Adrenal Balance
        ii. Do you wish to answer questions
        iii. Answer No – Adrenal 2 time
    d. General Digestion – Nutrienergy Balance 1 time
    e. Close Digestion
    f. Close Spinal Page
29. Auto Zap Feel Good Therapy
30. Go back to Bodyviewer
    a. Click Programs Start
    b. Pathway to all past trauma and minimize the page
31. Immune Stimulation – Disease Dictionary
    a. Acquired Imune Deficiency Syndrome – Electroacupuncture & BioResonance
    b. Ok-Reveal Text,
    c. Set Magnetic Method to 5,
    d. Time of therapy in Minutes 35,
    e. Add to Therapy: Cut and paste items from the large listing of test matrix numbers following this protocol into one of the lines and it will put it into the text (not the line itself)
    f. Load (this should bring up a confirmation box, if it does click Ok, if it does not then you need to right click on the Disease Lexicon bottom ruler button to force the confirmation box to appear.)
    g. Auto Treat,
    h. Minimize picture (requires using the – sign 2 times) this allows the therapy to work while doing the other therapies to follow
32. Programs to Therapy
33. Expand to Energetic link (click both at bottom left of page)
    a. Set for 1 min
    b. Activate Spiritual Healing
    c. Click Multi Media (at top of that panel) opens Manfly picture, wait until the large picture closes automatically.
    d. Minimize the Manfly picture (if the program does not allow this, possible glitch) reopen and close it.
34. Activate Frequency Modulation Program
    a. Autonomic Nerval System
        i. Click Sympathetic Nerval System 2 times
        ii. Click Parasympathetic balance 1 time
        iii. Close to therapy page
    b. Brain Wave Therapy
        i. Start
        ii. Click Alpha, Treats Stress
        iii. Treat clicked items, Stim Brain with Wave Form Clicked, 2 min.
        iv. Close back to Test Matrix
35. Add Shuman Wave
    a. Primary Disease: Stress
    b. Organ Relation: Adrenal
    c. Emotional box: Put in, Shame Guilt Anger Fear Grief (double space between each)
36. Rife Generator 24 – 2,400,000
    a. Set Rife at 1 min
    b. Start
37. Trivector Energy Flow

    a. Start (1 time)
    b. Enter DNA
    c. Click on Telimere
    d. Minimize
    e. Close DNA
    f. Close Trivector
38. Spinal button
39. Spinal Energy Flow - Test & Treat Trivector Energy Flow 2 times
40. Neuro Emotional Complex NEC –Test and Treat Emotions with phase stabilization 1 time
41. While running Spine
    a. Open Bodyviewer (to update the computer of what is done)
    b. Program Start
    c. Load Program, Start Info Exchange
    d. Minimize
42. Close back to Test Matrix
43. Body Scan and Face Therapy
    a. Skin Rejuvenation
    b. Set time to 2 min.
    c. Divine Light to Pineal Gland
    d. Close on the face picture
    e. Scan All
        i. Treat Foci 5 times
        ii. Close back to Test Matrix
44. Homotoxicology
    a. Click Info First
    b. Bio terrain
    c. Therapy
    d. Close Therapy
    e. Close Homotoxicology back to Test Matrix

    Note: If you have a glitch here and your computer crashes, replace this step with Auto Varhope, it is shorter but similar therapy
45. Auto Scalar
    a. Treat All
    b. Close back to Test Matrix (you will also be closing Auto Color in this step)
46. Info top Ruler bar
    a. Info view
    b. Save SOC
    c. Add top 200 to Significant Data
    d. Report
        i. Current Exam Report
        ii. Okay
        iii. Save Examination
        iv. Close back to Main Screen
47. Check current Rectification
    a. Correct All Till Maximum
    b. Close to Panel (do not close out of program)
48. Tools & Data Transfer
    a. Answer Type of condition
    b. Save
    c. Save to Transfer File into C drive or travel drive for IRB study

49. Close program
50. Unhook client
51. Clean Straps

* * * * * * * * * * * * *

2469 3097 1393 2546 6224 6336 9150 567 2476 2526 2532 2536 2546 2673 5404
6242 7227 1524 1580 1663 1686 1714 1719 1724 1770 1801 1838 5474 5963
4356 5491 5646 5735 5765 6113 7524 567 1831 1838 5605 5734 5742 6247 1714
1715 1717 1719 1720 1723 1724 1728 275 8536 8548 8551 8552 8554 8560 2773
2779 2780 2792 4771 4922 7460 469 2493 3437 3725 4666 4701 4903 4914 2793
2794 2795 2796 3844 5110 5902 4506 4530 4779 4838 4840 4929 4935 4511
4515 4554 4616 4671 4777 4900

Nosodes:	2469 3097 1393 2546 6224 6336 9150
Isode:	567 2476 2526 2532 2536 2546 2673 5404 6242 7227
Allersode:	1524 1580 1663 1686
Sarcode (Organ)	1714 1719 1724 1770 1801 1838 5474 5963
Symptoms:	4356 5491 5646 5735 5765 6113 7524
Emotional Concern:	2773 2779 2780 2792 4771 4922 7460
Spiritual Concern:	4511 4515 4554 4616 4671 4777 4900
Social Concern:	469 2493 3437 3725 4666 4701 4903 4914
Psychological Concern:	4506 4530 4779 4838 4840 4929 4935
Blockages:	1714 1715 1717 1719 1720 1723 1724 1728
Constitutional:	275 8536 8548 8551 8552 8554 8560
Possible Causes:	567 1831 1838 5605 5734 5742 6247
Environmental Concern:	2793 2794 2795 2796 3844 5110 5902

APPENDIX J:

INFORMED CONSENT FORM

CONSENT TO PARTICIPATE IN MEDICAL RESEARCH

PROJECT TITLE: An Evaluation of the Effects of Biofeedback with the ECLOSION Electro Physiological Feedback Xrroid (EPFX)/Scientific Consciousness Interface Operations System (SCIO) on Stress Reduction

PRINCIPAL INVESTIGATOR: _____

SPONSOR: ECLOSION, KFT.

You are being invited to be told about a research study before being fully evaluated to see if you qualify to take part in it. The study will use an investigational therapy. Before agreeing to be in any study you should take your time, ask questions, and think about participation.

BACKGROUND AND PURPOSE

Stress can affect a person's physical, mental, emotional and social well-being. Reducing stress can reverse many of these problems and improve a person's overall health and wellness.

In this project, the company and investigators are studying the use of a bioresonance device called the ECLOSION EPFX/SCIO and how it affects stress and stress-related problems. It is an investigational device that has not been cleared for market by the Food and Drug Administration (FDA) for this purpose.

The EPFX/SCIO is a bioresonance and biofeedback stress detection and reduction system. It sends low level electromagnetic waves into the body through electrodes at the head, wrists and ankles to fine tune the cells and organs of the body to bring the body back into harmony that reduces stress levels.

You are being invited to see if you qualify to take part in this study because you believe you have high levels of stress in your life.

THE STUDY

This study is a randomized trial. About 100 subjects will take part in the study at several test sites in Europe and the United States. About 50 subjects will be assigned to the test group and about 50 subjects will be assigned to the control group. The assignment is random (like a roll-of-the-dice) and neither you nor we will be selecting the group.

Regardless of to which group you are assigned, you will take part in all stages of the study. The only difference is that if you are assigned to the test treatment group, you will get the actual treatment with the EPFX/SCIO and if you are assigned to the control treatment group, you will receive a fake treatment with the EPFX/SCIO.

PROCEDURE

If you decide to be evaluated to see if you qualify for the study, your total study time commitment will be 7 months. **During this period, you will need to visit the test site a total of 22 times.**

The process you will go through is the following:

Screening: This first visit at the test site with the investigator will take about **45**

minutes and will be to see if you qualify to take part in this study.

At this visit, the investigator will ask some questions about your physical and emotional health and medication use. He or she will measure your height and weight and take three readings of your blood pressure and resting heart rate (pulse). You will also need to fill out a questionnaire about the level of stress in your life and another questionnaire that asks about specific stressful life events.

Pre-Treatment Phase: If you pass the screening process, you will move to the pre-treatment phase of the study that lasts about **30 minutes.**

The Pre-Treatment Phase may occur right after the study qualification evaluation or on a different day.

If the Pre-Treatment Phase occurs on a different day to the study qualification, the investigator will again measure your blood pressure and resting heart rate and you will again need to complete the questionnaire about the level of stress in your life. If the two phases occur on the same day, you will not have to repeat these measures.

Then, you will need to fill out three other questionnaires: one that asks about your moods, one that asks about your anxiety levels and responses and one that assesses if you are depressed.

The investigator will also record information on your age, race and education level. He or she will ask questions about medications and dietary supplements you are using or have recently used, treatments you have tried to reduce stress, and your food, drinking, smoking and exercise habits.

IMPORTANT: You will be asked to keep the same food, drink and exercise pattern during the course of the study as you are doing right now. You will be asked to not start taking any new medications or take part in any new treatments for stress reduction while you are taking part in this study.

Treatment Phase:

(i) Treatment Administration
The treatment phase of the study will last **6 months**. During that time, you will need to come to the test site **20 times** to receive treatments with the EFPX/SCIO. **Each treatment will take about one hour.**

The treatment visit schedule is as follows:

- *Month 1*: Two visits each week for a total of eight visits.
- *Month 2*: One visit each week for a total of four visits.
- *Months 3, 4, 5 & 6*: One visit every two weeks for a total of eight visits.

For each treatment, you will sit in a chair. Electrodes will be attached to your skin at the wrists, ankles and forehead. You just need to relax during the treatment. You will not feel any sensation during the treatment.

(ii) Treatment Phase Measurements

At the **end of Month 1, Month 2, Month 4 & Month 6,** the investigator will measure your blood pressure and resting heart rate, and you will need to fill in the questionnaire about the stress level in your life.

Also, at the **end of Month 6**, you will need to again fill in the questionnaires about your moods, and anxiety and depression levels.

Post-Treatment Phase: One month after your last treatment with the EPFX/SCIO,

you will need to go to the test site to again have your blood pressure and resting heart rate recorded, as well as to fill in the questionnaires about stress levels in your life, about your moods, and your anxiety and depression levels.

POTENTIAL RISKS AND BENEFITS

There are presently no known risks from use of bioresonance therapy like that used by the ECLOSION EPFX/SCIO device.

Some medical conditions may present a risk, and if you are found to have any of those conditions, you will not qualify to take part in this study.

Although there are no expected risks from bioresonance therapy as it is to be applied in this study, there may be side effects that are not known at this time.

This research may not help you personally. There is a chance that you will not reduce your stress at all.

The results of this study may help the study Sponsor and investigator to learn how bioresonance therapy may help to lower stress levels.

ALTERNATIVES TO PARTICIPATION:

You do not have to take part in this study. You can discuss other options with your doctor for reducing your stress.

CONFIDENTIALITY:

All information obtained from you during this study will remain as confidential as possible. A study number will be used as an identifier on tests and other materials collected during this study.

Regulatory agencies, as well as the administrators of this study and their representatives, and the governing Ethics Committee may inspect all study records as a part of their oversight of this study.

Your identity will not be released if any results from this study are used for publication in medical journals, presentations at meetings, or for educational purposes.

FINANCIAL CONSIDERATIONS:

The cost of all measurements, tests and other materials used as part of this study will be covered.

The treatment with the ECLOSION EPFX/SCIO device will be provided to you at no charge.

You will not receive any compensation for your participation in this study.

If you are injured as a result of your part in this study, immediate medical treatment will be provided. The clinic has professional liability coverage and will be responsible for any injury if it is caused by their negligence. Financial compensation for such things as lost wages, disability, or discomfort due to the injury is not routinely available. The sponsor is not providing any coverage for costs from injuries. You are not giving up any legal rights by signing this.

OBTAINING ADDITIONAL INFORMATION:

You are encouraged to ask questions at any time during this study. The investigator, <>, or his assistant will discuss the information on this form with you and answer your questions. If you have questions later, you may call the investigator or one of the study coordinators at <>.

You can also contact Richard Lloyd at ECLOSION KFT (the manufacturer of the ECLOSION EPFX/SCIO device) at 36-1-303-6043.

You will be informed promptly if information becomes available that could affect your decision to stay in the study.

RIGHTS:

Your participation in this study should be voluntary. You can refuse to take part or stop taking part at any time without penalty or loss of benefits to which you are otherwise entitled. You are free to ask questions, or to stop taking part in the study, at any time. Your withdrawal will involve no loss of benefits to which you are otherwise entitled.

	J. Subject Consent	K. Person obtaining consent
	I have read this form and have had an opportunity and time to ask questions. All of my questions have been answered to my satisfaction. I am giving my informed consent to take part in the study. I will be given a signed copy of this consent form for my records	I have discussed this form with the subject. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.
Signature		
Printed name		
Date and Time		

APPENDIX K:

CASE REPORT FORMS

ECLOSION STRESS REDUCTION CLINICAL STUDY

STUDY QUALIFICATION EVALUATION: Inclusive/Exclusive Conditions Criteria

Subject ID:	Investigator initials:	Date:

Mark each box that applies:

☐	Signed informed consent form.
☐	18 to 65 years of age.
☐	Females on adequate birth control or not of child-bearing years.
☐	Not taking antihypertensive (blood pressure lowering) medication.
☐	Does not have Type 1 Diabetes.
☐	No known heart condition(s), such as cardiac arrhythmias, congestive heart failure, myocardial infarction.
☐	No prior cardiac surgeries such as cardiac bypass, heart transplant surgery, pacemakers.
☐	No seizure disorder or family history of seizure disorder.
☐	No serious medical illness or condition: cancer, HIV, anorexia/bulimia, etc.
☐	No serious head trauma.
☐	Not pregnant or lactating, or planning pregnancy prior to the end of study participation.
☐	No infection/wound/other external trauma to the areas to be fixed with the electrodes.
☐	No serious mental health illness or psychiatric hospitalization in the past 2 years.
☐	No developmental disability/cognitive impairment that impacts study participation ability.
☐	No excessive use of any illicit drug or alcohol on a regular basis.
☐	Not involved in litigation/worker's compensation claim/receiving disability benefits because of stress or a stress-related condition.
☐	No participation in research in the past 90 days.
☐	Able and willing to maintain regular and consistent diet, exercise and lifestyle regimens.
☐	Able and willing to maintain current medication regimes.
☐	Able and willing to abstain from non-study stress-reduction treatments and medications.

Mark the appropriate box:

☐	All of the above boxes are checked **=> continue with the qualification evaluation.**
☐	One or more of the above boxes is checked **=> end the subject's participation.**

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Mark the appropriate box based on the Three-Reading Average values:

☐	Average Systolic blood pressure is 160 mmHg or higher => Stage 2 Hypertension**=> end the subject's participation.**
☐	Average Diastolic blood pressure is 100 mmHg or higher => Stage 2 Hypertension**=> end the subject's participation.**
☐	Average Systolic blood pressure is less than 160 mmHg AND Average Diastolic blood pressure is less than 100 mmHg **=> continue with the qualification evaluation.**

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #1	beats per minute
Resting Heart Rate #1	beats per minute
Average Resting Heart Rate	**beats per minute**

Mark the appropriate box based on the Three-Reading Average values:

☐	Average Resting Heart Rate is greater than 100 beats per minute => Tachycardia**=> end the subject's participation.**
☐	Average Resting Heart Rate is less than 60 beats per minute => Bradycardia**=> end the subject's participation.**
☐	Average Resting Heart Rate is irregular, with beats consistently missed across the 60-second period => Irregular Resting Heart Rate**=> end the subject's participation.**
☐	Average Resting Heart Rate is between 60 and 100 beats per minute**=> continue with the qualification evaluation.**

BODY MASS INDEX

weight (in kg)	
height (in meters)	
BMI (kg/m²)	

Mark the appropriate box based on the BMI measure:

☐	BMI is 30 kg/m² or greater => Generalized Obesity **=> end the subject's participation.**
☐	BMI is less than 30 kg/m² **=> continue with the qualification evaluation.**

LIFE EVENTS QUESTIONNAIRE (LEQ)

LEQ score for past 3 months	
LEQ score for upcoming 6 months	

Mark the appropriate box based on the LEQ score:

☐	LEQ score for either past 3 months or upcoming 6 months is 200 or more => Significant past/anticipated stressful life events **=> end the subject's participation.**
☐	LEQ score for either past 3 months or upcoming 6 months is less than 200 **=> continue with the qualification evaluation.**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

Mark the appropriate box based on the PSS score:

☐	The total PSS score is 25 or more **=> continue with the qualification evaluation.**
☐	The total PSS score is less than 25 **=> end the subject's participation.**

STUDY CONTINUATION DETERMINATION

Mark the appropriate box based on the above recorded information:

☐	The subject has satisfied all of the study qualification criteria **=> the subject may progress to the pre-treatment study phase.**
☐	The subject has not satisfied one or more of the study qualification criteria **=> end the subject's participation in the study.**

ECLOSION STRESS REDUCTION CLINICAL STUDY

PRE-TREATMENT PHASE

Subject ID:	Investigator initials:	Date:

PHYSIOLOGICAL MEASURES

BLOOD PRESSURE: Please record the following information for the subject.

N.B. IF THE PRE-TREATMENT PHASE OCCURS ON THE SAME DAY AS THE STUDY QUALIFICATION PHASE, BLOOD PRESSURE DOES NOT NEED TO BE REPEATED. JUST ENTER THE THREE-READING AVERAGE FROM THE STUDY QUALIFICATION PHASE .

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Mark the appropriate box based on the Three-Reading Average values:

☐	Average Systolic blood pressure is 160 mmHg or higher **AND/OR** Average Diastolic blood pressure is 100 mmHg or higher => Stage 2 Hypertension **=> end the subject's participation.**
☐	Average Systolic blood pressure is less than 160 mmHg AND Average Diastolic blood pressure is less than 100 mmHg **=> continue with the pre-treatment phase.**

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	Systolic (mm Hg)		Diastolic (mm Hg)
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99

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.*

RESTING HEART RATE: Please record the following information for the subject.

N.B. IF THE PRE-TREATMENT PHASE OCCURS ON THE SAME DAY AS THE STUDY QUALIFICATION PHASE, RESTING HEART RATE DOES NOT NEED TO BE REPEATED. JUST ENTER THE AVERAGE RESTING HEART RATE FROM THE STUDY QUALIFICATION PHASE.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

Mark the appropriate box based on the Average Resting Heart Rate value:

☐	Average Resting Heart Rate is greater than 100 beats per minute => Tachycardia **=> end the subject's participation.**
☐	Average Resting Heart Rate is less than 60 beats per minute => Bradycardia **=> end the subject's participation.**
☐	Average Resting Heart Rate is irregular, with beats consistently missed across the 60-second period => Irregular Resting Heart Rate **=> end the subject's participation.**
☐	Average Resting Heart Rate is between 60 and 100 beats per minute **=> continue with the qualification evaluation.**

QUALITY OF LIFE ASSESSMENT MEASURES

PERCEIVED STRESS SCALE (PSS)

N.B. IF THE PRE-TREATMENT PHASE OCCURS ON THE SAME DAY AS THE STUDY QUALIFICATION PHASE, THE PSS DOES NOT NEED TO BE REPEATED. JUST ENTER THE TOTAL PSS SCORE FROM THE STUDY QUALIFICATION PHASE.

Total PSS score	

Mark the appropriate box based on the PSS score:

☐	The total PSS score is 25 or more **=> continue with the qualification evaluation.**
☐	The total PSS score is less than 25 **=> end the subject's participation.**

THE PROFILE OF MOOD STATES (POMS) STANDARD

Record the following scores from the POMS:

Tension-Anxiety score	
Depression-Dejection score	
Anger-Hostility score	
Vigor-Activity score	
Fatigue-Inertia score	
Confusion-Bewilderment score	
TOTAL POMS SCORE	

SPIELBERGER'S STATE-TRAIT ANXIETY INVENTORY (STAI)

Record the following scores from the STAI:

State Anxiety score	/80
Trait Anxiety score	/80

BECK DEPRESSION INVENTORY-II (BDI-II)

Record the following for the BDI-II:

BDI-II Total Score:	

ANALYZING STRESS IN THE BODY SUBJECT QUESTIONNAIRE

☐	Analyzing Stress in the Body Subject Questionnaire completed **=> continue with the qualification evaluation.**

DEMOGRAPHIC VARIABLES

AGE: Please record the age of the subject.

☐	18-25 years	☐	36-49 years
☐	26-35 years	☐	50-65 years

GENDER: Record the subject's gender

☐	male	☐	female

RACE: Please record the race of the subject.

☐	Caucasian	☐	Hispanic	☐	Middle Eastern
☐	Asian/Pacific Islander	☐	Other: _____		

EDUCATION LEVEL: Please record the highest attained education level of the subject.

☐	Less than high school	☐	Undergraduate
☐	High school	☐	Graduate
☐	Some college	☐	Post-graduate

DRUG, TREATMENT AND FOOD/EXERCISE BEHAVIOR AND HISTORY

CURRENT MEDICATIONS: List all of the over-the-counter and prescription medications that the subject is currently taking, including dosage schedule where possible.

Over-the-counter medications

Prescription medications

NON-CURRENT MEDICATIONS: List all of the over-the-counter and prescription medications that the subject has taken during the past 6 months.

Over-the-counter medications

Prescription medications

HERBS AND DIETARY SUPPLEMENTS: List all of the herbs and dietary supplements that the subject is currently taking or has taken during the past 6 months.

CURRENT TREATMENTS: List all of the treatments in which the subject is currently engaged for any reason. Include conventional and alternative therapies

NON-CURRENT TREATMENTS: List all of the treatments in which the subject has taken part in for stress reduction or relaxation over the past 12 months. Include conventional and alternative therapies.

FOOD/GENERAL DIET: Record information about the subject's general diet composition, including:

- Typical average caloric intake:
- Typical average daily fat intake:
- Vegetarian/non-vegetarian:
- Typical types of food consumed:
- Additional information:

NON-ALCOHOLIC DRINKS: Record information about the subject's general drink composition, including:

- Average number of glasses of water consumed daily:
- Average daily fruit drink consumption:
- Average daily soda drink consumption – caffeinated/non-caffeinated :
- Average daily milk consumption:
- Average daily coffee/tea consumption:
- Other daily drinks:

ALCOHOLIC DRINKS: Record information about the subject's typical weekly alcohol consumption type and pattern, including wine, beer, liquor, etc.

SMOKING: If the subject smokes, record the average number of cigarettes smoked dally.

EXERCISE: Record the types of exercise, if any, in which the subject partakes, and the frequency with which the subject engages in each exercise type.

Mark the following box once applicable:

☐	The subject has been reminded and continues to agree to maintain his or her typical pre-study pattern or food and drink intake and exercise regimen throughout the study.

ECLOSION STRESS REDUCTION CLINICAL STUDY

PRE-TREATMENT PHASE

SUBJECT GROUP ASSIGNMENT

Subject ID:	Investigator initials:	Date:

Record to which group the subject has been assigned.

☐	Group A
☐	Group B

ECLOSION STRESS REDUCTION CLINICAL STUDY

TREATMENT PHASE: TREATMENT ADMINISTRATION VISIT SCHEDULE

Subject ID:	Investigator initials:	Date:

In the table below, enter the date for which a treatment protocol administration is scheduled and check the adjacent box when that a treatment is administered.

		Protocol 1	Protocol 2
Month 1	Week 1	☐ _____/_____/_____ (dd/mm/yy)	☐ _____/_____/_____ (dd/mm/yy)
	Week 2	☐ _____/_____/_____ (dd/mm/yy)	☐ _____/_____/_____ (dd/mm/yy)
	Week3	☐ _____/_____/_____ (dd/mm/yy)	☐ _____/_____/_____ (dd/mm/yy)
	Week4	☐ _____/_____/_____ (dd/mm/yy)	☐ _____/_____/_____ (dd/mm/yy)
Month 2	Week 5	☐ _____/_____/_____ (dd/mm/yy)	
	Week 6		☐ _____/_____/_____ (dd/mm/yy)
	Week 7	☐ _____/_____/_____ (dd/mm/yy)	
	Week 8		☐ _____/_____/_____ (dd/mm/yy)
Month 3	Week 9	☐ _____/_____/_____ (dd/mm/yy)	
	Week 10		
	Week 11		☐ _____/_____/_____ (dd/mm/yy)
	Week 12		
Month 4	Week 13	☐ _____/_____/_____ (dd/mm/yy)	
	Week 14		
	Week 15		☐ _____/_____/_____ (dd/mm/yy)
	Week 16		
Month 5	Week 17	☐ _____/_____/_____ (dd/mm/yy)	
	Week 18		
	Week 19		☐ _____/_____/_____ (dd/mm/yy)
	Week 20		
Month 6	Week 21	☐ _____/_____/_____ (dd/mm/yy)	
	Week 22		
	Week 23		☐ _____/_____/_____ (dd/mm/yy)
	Week 24		

ECLOSION STRESS REDUCTION CLINICAL STUDY

TREATMENT PHASE: TREATMENT PHASE MEASUREMENTS

TREATMENT MEASUREMENT TIME POINT #1: END OF MONTH 1

Subject ID:	Investigator initials:	Date:

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	Systolic (mm Hg)		Diastolic (mm Hg)
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99
☐	Stage 2	160+	or	100+

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.*

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

ADVERSE EVENTS AND REACTIONS: Do you think you have experienced any adverse events and/or reactions from the treatments you have done using the Electro Physiological Feedback Xrroid?

☐	yes
☐	no

IF YOU MARKED "YES", PLEASE CONTACT THE STUDY INVESTIGATOR AS SOON AS POSSIBLE.

STUDY INVESTIGATOR, COMPLETE THE INVESTIGATOR ADVERSE EVENTS AND REACTIONS FORM AND TAKE ANY NECESSARY ACTION RIGHT AWAY.

ADDITIONAL COMMENTS: Please write any additional comments you may have about your participation in this clinical study in the space provided below.

ECLOSION STRESS REDUCTION CLINICAL STUDY

TREATMENT PHASE: TREATMENT PHASE MEASUREMENTS

TREATMENT MEASUREMENT TIME POINT #2: END OF MONTH 2

Subject ID:	Investigator initials:	Date:

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	Systolic (mm Hg)		Diastolic (mm Hg)
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99
☐	Stage 2	160+	or	100+

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.*

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

ADVERSE EVENTS AND REACTIONS: Do you think you have experienced any adverse events and/or reactions from the treatments you have done using the EPFX/SCIO?

☐	yes
☐	no

IF YOU MARKED "YES", PLEASE CONTACT THE STUDY INVESTIGATOR AS SOON AS POSSIBLE.

STUDY INVESTIGATOR, COMPLETE THE INVESTIGATOR ADVERSE EVENTS AND REACTIONS FORM AND TAKE ANY NECESSARY ACTION RIGHT AWAY.

ADDITIONAL COMMENTS: Please write any additional comments you may have about your participation in this clinical study in the space provided below.

ECLOSION STRESS REDUCTION CLINICAL STUDY

TREATMENT PHASE: TREATMENT PHASE MEASUREMENTS

TREATMENT MEASUREMENT TIME POINT #3: END OF MONTH 4

Subject ID:	Investigator initials:	Date:

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	Systolic (mm Hg)		Diastolic (mm Hg)
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99
☐	Stage 2	160+	or	100+

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.*

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

ADVERSE EVENTS AND REACTIONS: Do you think you have experienced any adverse events and/or reactions from the treatments you have done using the EPFX/SCIO?

☐	yes
☐	no

IF YOU MARKED "YES", PLEASE CONTACT THE STUDY INVESTIGATOR AS SOON AS POSSIBLE.

STUDY INVESTIGATOR, COMPLETE THE INVESTIGATOR ADVERSE EVENTS AND REACTIONS FORM AND TAKE ANY NECESSARY ACTION RIGHT AWAY.

ADDITIONAL COMMENTS: Please write any additional comments you may have about your participation in this clinical study in the space provided below.

ECLOSION STRESS REDUCTION CLINICAL STUDY

TREATMENT PHASE: TREATMENT PHASE MEASUREMENTS

TREATMENT MEASUREMENT TIME POINT #4: END OF MONTH 6

Subject ID:	Investigator initials:	Date:

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	Reading #2	Reading #3
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	Systolic (mm Hg)		Diastolic (mm Hg)
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99
☐	Stage 2	160+	or	100+

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.*

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

THE PROFILE OF MOOD STATES (POMS) STANDARD

Record the following scores from the POMS:

Tension-Anxiety score	
Depression-Dejection score	
Anger-Hostility score	
Vigor-Activity score	
Fatigue-Inertia score	
Confusion-Bewilderment score	
TOTAL POMS SCORE	

SPIELBERGER'S STATE-TRAIT ANXIETY INVENTORY (STAI)

Record the following scores from the STAI:

State Anxiety score	/80
Trait Anxiety score	/80

BECK DEPRESSION INVENTORY-II (BDI-II)

Record the following for the BDI-II:

BDI-II Total Score:	

☐	Analyzing Stress in the Body Subject Questionnaire completed.

SATISFACTION RATING: Using the scale below, please mark the category that best shows how satisfied the subject is with any overall perceived change in stress levels believed to be because of the treatment with the EPFX/SCIO. (Please note: Only one box should be marked)

☐	Very satisfied
☐	Somewhat satisfied
☐	Neither satisfied nor dissatisfied
☐	Not very satisfied
☐	Not at all satisfied

SUBJECT PERCEIVED GROUP ASSIGNMENT

Does the subject believe that he or she had been assigned to the treatment group, using the actual EPFX/SCIO or to the control group using a fake EPFX/SCIO?

☐	Test group
☐	Control group

Why does the subject feel this way?

INVESTIGATOR PERCEIVED GROUP ASSIGNMENT

Does the investigator believe that the subject had been assigned to the treatment group, using the actual EPFX/SCIO or to the control group using a fake EPFX/SCIO?

☐	Test group
☐	Control group

Why does the investigator feel this way?

ADVERSE EVENTS AND REACTIONS: Do you think you have experienced any adverse events and/or reactions from the treatments you have done using the EPFX/SCIO?

☐	yes
☐	no

IF YOU MARKED "YES", PLEASE CONTACT THE STUDY INVESTIGATOR AS SOON AS POSSIBLE.

STUDY INVESTIGATOR, COMPLETE THE INVESTIGATOR ADVERSE EVENTS AND REACTIONS FORM AND TAKE ANY NECESSARY ACTION RIGHT AWAY.

ADDITIONAL COMMENTS: Please write any additional comments you may have about your participation in this clinical study in the space provided below.

DRUG, TREATMENT AND FOOD/EXERCISE BEHAVIOR AND HISTORY

CURRENT MEDICATIONS: List all of the over-the-counter and prescription medications that the subject is currently taking, including dosage schedule where possible.

Over-the-counter medications

Prescription medications

NON-CURRENT MEDICATIONS: List all of the over-the-counter and prescription medications that the subject has taken during the past 6 months.

Over-the-counter medications

Prescription medications

HERBS AND DIETARY SUPPLEMENTS: List all of the herbs and dietary supplements that the subject is currently taking or has taken during the past 6 months.

CURRENT TREATMENTS: List all of the treatments in which the subject is currently engaged for any reason. Include conventional and alternative therapies

FOOD/GENERAL DIET: Record information about the subject's general current diet composition, including:

- Typical average daily caloric intake:
- Typical average daily fat intake:
- Vegetarian/non-vegetarian:
- Typical types of food consumed:
- Additional information:

NON-ALCOHOLIC DRINKS: Record information about the subject's current general drink composition, including:

- Average number of glasses of water consumed daily:
- Average daily fruit drink consumption:
- Average daily soda drink consumption – caffeinated/non-caffeinated :
- Average daily milk consumption:
- Average daily coffee/tea consumption:
- Other daily drinks:

ALCOHOLIC DRINKS: Record information about the subject's typical current weekly alcohol consumption type and pattern, including wine, beer, liquor, etc.

SMOKING: If the subject smokes, record the average number of cigarettes smoked dally.

EXERCISE: Record the types of exercise, if any, in which the subject currently partakes, and the frequency with which the subject engages in each exercise type.

ECLOSION STRESS REDUCTION CLINICAL STUDY

POST-TREATMENT PHASE: ONE MONTH POST-TREATMENT

Subject ID:	Investigator initials:	Date:

BLOOD PRESSURE: Please record the following information for the subject.

	Reading #1	**Reading #2**	**Reading #3**
Systolic blood pressure	mmHg	mmHg	mmHg
Diastolic blood pressure	mmHg	mmHg	mmHg

Three-Reading Average

Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg

Based on the subject's three-reading average blood pressure, mark the appropriate box below:

	Category	**Systolic (mm Hg)**		**Diastolic (mm Hg)**
☐	Normal	less than 120	and	less than 80
☐	Prehypertension	120–139	or	80–89
	Hypertension			
☐	Stage 1	140–159	or	90–99
☐	Stage 2	160+	or	100+

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.*

RESTING HEART RATE: Please record the following information for the subject.

Resting Heart Rate #1	beats per minute
Resting Heart Rate #2	beats per minute
Resting Heart Rate #3	beats per minute
Average Resting Heart Rate	**beats per minute**

PERCEIVED STRESS SCALE (PSS)

Total PSS score	

THE PROFILE OF MOOD STATES (POMS) STANDARD

Record the following scores from the POMS:

Tension-Anxiety score	
Depression-Dejection score	
Anger-Hostility score	
Vigor-Activity score	
Fatigue-Inertia score	
Confusion-Bewilderment score	
TOTAL POMS SCORE	

SPIELBERGER'S STATE-TRAIT ANXIETY INVENTORY (STAI)

Record the following scores from the STAI:

State Anxiety score	/80
Trait Anxiety score	/80

BECK DEPRESSION INVENTORY (BDI-II)

Record the following for the BDI-II:

BDI-II Total Score:	

ANALYZING STRESS IN THE BODY SUBJECT QUESTIONNAIRE

☐	Analyzing Stress in the Body Subject Questionnaire completed

ADVERSE EVENTS AND REACTIONS: Do you think you have experienced any adverse events and/or reactions from the treatments you have done using the EPFX/SCIO? ☐ yes ☐ no	**IF YOU MARKED "YES", PLEASE CONTACT THE STUDY INVESTIGATOR AS SOON AS POSSIBLE.** **STUDY INVESTIGATOR, COMPLETE THE INVESTIGATOR ADVERSE EVENTS AND REACTIONS FORM AND TAKE ANY NECESSARY ACTION RIGHT AWAY.**

ADDITIONAL COMMENTS: Please write any additional comments you may have about your participation in this clinical study in the space provided below.

ECLOSION STRESS REDUCTION CLINICAL STUDY

INVESTIGATOR'S ADVERSE EVENTS AND/OR REACTIONS RECORD SHEET

Subject ID:	Investigator initials:	Date:

Please record the following information for any adverse event(s) and/or reaction(s) that the subject believes he or she may be experiencing because of the treatment that he or she received with the ECLOSION EPFX/SCIO device.

Date:

Time that the subject reported starting to experience the event:

Please describe the event or reaction in detail in your words:

Would you say that the event or reaction the subject is experiencing is:

☐	Mild
☐	Moderate
☐	Severe

Please explain why you believe that the event or reaction <u>is or is not</u> a result of the treatment that with the ECLOSION EPFX/SCIO device.

Please describe the action that you have taken to resolve the event or reaction. If no action is taken, please explain why not.

When do you anticipate that the event/reaction will resolve?

Please describe any follow-up treatment that you may be recommending as result of the event/reaction.