IRB- Investigational Review Board of Peer Reviewed Medical Journal Operations Manual

Historical Background

In 1992 a group of medical doctors taking advanced courses at Semmelveis Medical University decided that a medical journal needed to be formed to allow studies on natural and energetic medicine to be better represented. There was too much bias against arts like homeopathy, electro-acupuncture and naturopathy. A professional journal to allow quality studies in these arts to be published was essential. They designed a peer reviewed medical board to review such studies and the journal achieved it ISSN library number in 1996. It continued quarterly publication till it changed its structure in 2010. It still publishes quarterly journals dedicated to validating natural and energetic medicine.

Now we have changed the name of the journal to ***The International Journal of the Medical Science of Homeopathy, Naturopathy and Energetic Medicine*** . This Journal is designed to look for validation, verification of claims and ideas. We are dedicated to searching for the evidence based ideas beyond the limits of SINthetic chemistry and surgery. We wish to protect an industry of medical doctors and therapists who believe in Natural Medicine from the SINthetic chemical cartel and from the charlatans operating in alternative medicine.

We are open to discussion and to positive criticism. We are open to new ideas. In fact we are open to a broader form of evidence than most journals, but we must cling to an evidence based philosophy and a dedication to the pursuit of validation to protect for safety and efficacy.

Here are some of our rules and guidelines, but we insist on maintaining a large degree of flexibility in running or journal to help you find evidence and to protect the world from the forces of greed, anger, prejudice and delusion.

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Foreword.

In this time of ever clouded issues and falsification of facts, we here at IMUNE endeavor to present the facts the way they should be presented. Our goal is to assist you in your chose profession of biofeedback, naturopathy, homeopathy or energetic medicine. These fields are ever growing and expanding and encompassing more complex ways in which to help us live healthier, cleaner and more natural existences. It is necessary that any information that will assist us in this area be presented in a timely fashion and that it be reviewed by professionals for its validity and accuracy. That is what we at the IRB Peer Review intend to do. All the articles and studies presented here have been reviewed by our panel of doctors selected specifically to help guide you to the best possible alternatives and options available to you for your practice. We will always maintain the standard of excellence and accuracy that we started with and which has been our platform. IRB Peer Reviews are designed to present excellence in concepts, studies and understandings in our field of biofeedback and naturopathy thus enabling us to continuing with the development process necessary allowing us to raise the bar on the standards, treatment and care that we provide.

Preface.

The Peer review will focus on presenting material that will be helpful to all professionals in the Biofeedback and Naturopathy fields. The studies, case reviews and articles presented here are from accredited physicians and therapists whose goal is contribute to the validity, verifiability and accuracy necessary in both of the aforementioned fields. Enough cannot be said on the necessity of these measures to ensure proper application and therapy administration.

1. Introduction.

The purpose of peer review is to assure the reader that the quality of the articles published here are professionally reviewed by accredited peers who are dedicated to raising the quality and standards of our field and who will review each submission with the intent of bolstering that support and eliminating substandard methods.

2. The peer review process how to get going.

Invited articles undergo peer-review to reinforce the quality and integrity of the content. Peer-reviewers are asked to complete their reports with a checklist of points to consider; additional comments may also be included in the report. Frank comments about the scientific and medical content of submitted manuscripts are strongly encouraged.

Peer-reviewers accept conditions of confidentiality when agreeing to peer-review a manuscript. Details are included in the Confidentiality policy.

All contributions that are selected for peer-review are sent to at least one, but usually two or more, independent reviewers, selected by the editors. Authors are welcome to suggest suitable independent peer-reviewers and may also request that Nature Clinical Practice excludes one or two (but no more) individuals or institutions if there is a specific, declared competing interest. Nature Clinical Practice sympathetically considers such requests, but the editor's decision on the choice of peer-reviewers is final.

Nature Clinical Practice editors may seek advice about submitted papers not only from technical peer-reviewers but also on any aspect of a paper that raises concerns. These may include, for example, ethical issues or issues of data or materials access. Very occasionally, concerns may also relate to the societal implications of publishing a paper. In such circumstances, advice will usually be sought simultaneously with the technical peer-reviewing process. As in all publishing decisions, the ultimate decision on whether to publish is the responsibility of the editor of the journal concerned.

Corresponding authors are notified of acceptance, rejection or request for revision within 6 weeks from submission of initial revisions whenever possible. Revised manuscripts should be returned within 3 weeks, together with a covering letter detailing responses to every point made by editors and peer-reviewers.

The following types of contribution are peer-reviewed: Viewpoints, Practice Points, Reviews, Case Studies, and any supplementary files associated with these articles. Supplements to the journals are also peer-reviewed.

The following types of contribution are not usually peer-reviewed: Editorials, Book Reviews, Research Highlights, Article Responses, Errata and Corrigenda. Nevertheless, contributions of these types may be peer-reviewed at the discretion of the Editor.

The people involved in running the peer review process now as of 2013 are Brad Vee Johnson PhD in Sociology and his staff. He can be contacted at dean@imune.net. He will act as liaison to all peer review staff.

3. Manuscript submission and initial checks on completeness and suitability.

Submission guidance to authors. We are here to assist all authors in guidance with regards to their submissions in any way possible. Submissions should follow a certain format and consist of material that follows the criteria of IRB Peer Review. All manuscripts submitted will be logged and checked for authenticity and substance. All manuscripts submitted will be forwarded to the editor who will then assess them for suitability and who also has the right to reject any submissions without external reviewing . Manuscripts written in another language other than English must be translated before being submitted since it is not the IRB Peer Review's job to translate submitted material.

4. The full review process.

The review process is a complete system which first consists of identifying and locating appropriate reviewers. Afterwards forwarding the manuscripts and material for review to the review board and continually monitoring their progress. After each reviewer has reviewed a submission and sent it back to the editorial staff, each review is then checked for validity. Manuscripts can be sent

to each reviewer back to back in order to assure that each IRB Peer Review Journal contains sufficient material to be released. The IRB editorial staff also answer any and all enquiries as to the review status of a manuscript by authors.

5. The decision making process for reviewed manuscripts.

The decision making process is one that is carefully undertaken. The organizational structure of the decision making process is determined by the IRB Peer Review editorial staff. The decision making process is as follows:

1. All material and submissions will be thoroughly checked before communicating any decisions to the authors.
2. The communication process with the authors to conducted by editorial staff and handled in a professional and timely manner.
3. Rebuttals and appeals by authors whose submissions have been rejected by the board is also the responsibility of the editorial staff and to be administered in a professional and courteous manner.
4. All revisions to submitted material will be the responsibility of the editorial staff.
5. Any material that has been rejected can be re-submitted after an appropriate "grace" period.
6. Accepted material will be announced by letter from the editorial staff.
7. The decision making proceed will take into consider the standards and guidelines set out by the IRB Peer Review assuring that all material submitted follows the parameters set out for all material plus the editorial staff will ensure that there will be enough material submitted for each Journal release for continuity.
8. Submitted material will be scrutinized for dual usage of research in submissions and the also the possible misuse of information.

7.

To be considered as a reviewer for our journal is indeed an honor. Your input by reviewing papers, articles and material submissions allows for us the IRB Peer Review to present information to our readers of the highest quality and accuracy and helping them in their development. Our gratitude for our reviewer's contribution is of the highest level and caliber. We have an extensive training curriculum which our reviewers must go through and we strive to create a strong bond between the journal and our reviewers because their work allows for us to produce a product which is recognized and revered as a source of information for all to be able to use in the biofeedback and naturopathy fields.

8. The obligations and responsibilities of the people involved in peer review.

As an author for the peer review, your obligations are sacred. You are charged with providing material that is fact based, educational, useful and entertaining to our readers. It your responsibility to make sure that everything that you submit is indeed factual, has proven trial studies to support it and that it indeed is something with will prove to be beneficial to our readers. As an author you are further charged with the responsibility of making sure that the work you submit is your own and not plagiarized.

As peer review reviewer your obligations and responsibilities are equally as stringent as are the authors submitting material for review. Your job is to assess, evaluate, correct, guide and subsequently approve any and all material that is submitted for review and ensure that all said material meets the standards and criteria as set out in the IRB Peer Review guidelines.

As editor of the peer review, the Dean of IMUNE and his staff have the solemn responsibility to

checking that all articles submitted for review are indeed viable and are of educational value plus have merit to be included in the peer review. The editorial staff further ensures that the content of all material appearing in the IRB Peer Review is pertinent, up-to-date, professionally presented and has entertainment value thus following the format of the peer review.

Authors cannot be Reviewers and vice versa. This is considered a "conflict of interest" and is strictly prohibited by the IRB Peer Review. Moral dilemmas fall under the same category. The IRB Peer Review will not be affiliated with political, religious, off colored humor, racial and/or gender biased material which has no scientific, medical and educational value to our readers.

9. Misconduct in scientific research and publishing what it is and how to deal with it.
Submissions turned in by authors which are plagiarized, falsified and created to coerce or encourage illegal activities or experimentation are deemed "issues of misconduct" and will not be tolerated by the IRB Peer Review. Cases such as these will be dealt with to the fullest extent of the law allowable. Sanctions imposed upon those who engage in misconduct with regards to the IRB Peer Review will be barred for submitting material for indefinite period time and also may be subject to fines and incarceration.

Appendix I The Golden Rules and the Peer Review Good Practice Checklist.
Appendix II Examples of checklists, forms, guidance for reviewers and editorial letters.
Appendix III Useful websites.
Appendix IV Alternative models of peer review.

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GENERAL INFORMATION

The IJMSHNEM journals review developments in each medical area and keep practicing physicians up to date with recent research and opinion. By synthesizing the wealth of information available and providing it in an accessible format, the time needed to stay informed decreases – a benefit to both physician and patient. Content is generally invited, but proposals for articles can be suggested through the online submission system on each journal's website.

RELATIONSHIP BETWEEN IJMSHNEM JOURNALS

The IJMSHNEM journals are editorially independent, and the editors make their own decisions, independent of the other *IJMSHNEM* journal editors. The editor of each journal has full responsibility for the content, but is advised by the journal's Editor-in-Chief and Advisory Board. The Editor-in-Chief of IJMSHNEM Publications, Brad Vee Johnson, is ultimately responsible for the quality of all publications bearing the name *IJMSHNEM* in their titles.

Most papers published in the *IJMSHNEM* journals are submitted to them directly; therefore, each *IJMSHNEM* journal has to decline many papers of very high quality but insufficient interest to their specific readership. An editor may suggest that a paper declined for editorial (not technical) reasons might be suitable for submission to another *IJMSHNEM* journal, including IJMSHNEM, if the article is appropriate to its scope.

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If part of a contribution has appeared or will appear elsewhere, the author must specify the details in the covering letter accompanying the IJMSHNEM submission. Consideration by IJMSHNEM is possible if the main result, conclusion, or implications are not apparent from the other work. Other exceptions can apply at the editor's discretion, for example if the other work is not published in English, or if it is published on a recognized preprint server for review by other scientists in the field before formal submission to a journal.

This information will be considered confidential and will be used to ensure, as far as possible, that duplicate publication does not take place. This might mean delaying publication of a IJMSHNEM article until after the original research it mentions has been published elsewhere.

If in doubt, please contact the editors for advice.

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A shortened form of the declaration is published as part of the printed article, with a more detailed version, if appropriate, as part of the article online.

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PEER-REVIEW

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If an author of a published paper subsequently becomes aware of a significant error in it, a paragraph of correction should be sent to the journal by using the article response link within the published article online. The Authorship policy also applies to corrections.

If a reader believes that an article in an IJMSHNEM journal contains an important error, he or she should submit this information by using the article response link within the published article online. The journal will consider these responses if they include verification to substantiate the information, and the case is made using reasoned language.

Published clarifications can take a variety of formats, not necessarily in the form of a publication by the person who sent the initial comment to the journal. IJMSHNEM's decisions about clarifications are made in the interests of maximum clarity for readers, succinctness, fairness, and maintenance of the integrity of the published record.

Further general enquiries about corrections should be sent by email to the relevant journal.

Next a SAMPLE of a Study Protocol

IMUNE must disclaim this sample and maintain that although we have worked with the following device people and their efforts for validation, IMUNE is independent of these companies and our decisions are based on evidence and professionalism

QXCI/EPFX/SCIO/Indigo/Eductor ongoing Large Scale Study

SAMPLE

Contents

Summary

Europe: the system is known as the EPFX, QXCI/EPFX/SCIO/INDIGO/EDUCTOR or SCIO/EDUCTOR and carries
a CE and FDA Classification.

USA: special requirements apply and QX have been diligent in conforming to these. There are two primary aspects.

1. Eclosion kft have held a registration for the EPFX (precursor to the QXCI_SCIO/EDUCTOR) which covers some of the program facilities. The EPFX can be considered the core software element.

2. The full program contains additional software not covered by the original registration and referred to by QXCI/EPFX/SCIO/INDIGO/EDUCTOR system. It is legal, within certain client notification and record keeping procedures, to use this fully facilitated program in the USA. This is tagged (IRB) in the full program.

The appointed person within QX related to QXCI/EPFX/SCIO/Indigo/Eductor sponsor is Andreea Taflan. Any queries should be made initially via your provider. This will ensure consistency and is a requirement of the registration process for the USA. Details are provided below. Peer reviewed staff relate to "Brad Vee Johnson" Dean of IMUNE brad@sensevents.com

Current Situation

1. The EPFX device registration owner has been the Eclosion Corporation since 1989 and this has been maintained. In 2004 the Eclosion Corporation registered address moved to Hungary.
2. The EPFX system included some elements but not all of the current programmes. Within the test screen under programmes drop down programmes that are registered EPFX software are annotated (REG). The programmes so annotated and forming part of the original EPFX software are:
   - Audio test
   - Auscult cardiogram
   - Biface hemispheric programme
   - Biofeedback
   - SOC Index- lifestyle assessment
   - Calibrate
   - EEG ECG FREQ

Risk profile
Spinal and sarcodes
Test
Aspects of nutrition

Thus all equipment and software labeled EPFX (this includes the EPFX version of the QXCI/EPFX/SCIO/INDIGO/EDUCTOR and the EPFX version of the SCIO/Eductor) are registered and the hardware interface (EPFX/QXCI/SCIO/EDUCTOR box) ***cannot*** be confiscated by the FDA.

3. The combination of testing and therapy is registered within Europe. Consequently the previous FDA restriction (which did not permit a combination of testing and therapy in the same device) no longer stands. Due to the acceptance of registration in Europe and the consequent legalities automatically applying for equipment manufactured in Europe and exported to the USA, the availability of testing and therapy within a single device automatically must be accepted by the FDA.

EPFX (both in terms of hardware and software) is the USA system. In respect of this there are two aspects:

Aspect 1: EPFX hardware-this is either a QXCI/EPFX/SCIO/INDIGO/EDUCTOR derivative labeled EPFX or a SCIO/Eductor derivative labeled EPFX.

Aspect 2: software- all supplies into the USA will be EPFX software. There are effectively 2 software variants.

Variant 1: EPFX software for the USA, FDA compliant.
Variant 2: Clasp software for outside the USA e.g. Europe, Far East etc.

The EPFX and IRB

The EPFX device and its EPFX software is registered in the USA as a biofeedback medical device. The Eclosion Company of Hungary reg no. 3004444071, owner operator no. 9061821. It is also registered in Europe, S Africa, Mexico, Australia, Romania, etc.

EPFX stands for Electro Physiological Feedback Xrroid. Xrroid is a coined term meaning rapid computer testing of patient's reactions to remedies. This is registered as a function under Biofeedback known as Provocative or Evoked Potential Biofeedback.

The QXCI/EPFX/SCIO/INDIGO/EDUCTOR software uses biofeedback instruments such as the EPFX to use the Xrroid process for several medical aspects that are revolutionary. The USA law allows for studies of such software to be used in on people. To comply with the guidelines we first need an Institutional Review Board or IRB. This is a group of independent professionals who will review the completed research of the device. If the IRB is out of America it must be properly registered with the government authorities where it is located. Our IRB is registered in Italy and Romania.

An Investigational Device Exemption is achieved by virtue of the insignificant risk the EPFX device has. The EPFX is tested safe and insignificant risk and its safety is registered with the European Community the CE mark is attached.
QX ltd has an office in Str. Lebedei #58/A Oradea, Romania. This office handles the IRB software collection and distribution. It operates independently from the Eclosion Company.

The next step of a qualified study is the informed consent. A patient who participates in the study must be allowed to decide on his participation. Participation is not mandatory, but voluntary. There are 8 different criteria of informed consent. Since this software offers insignificant risk a verbal yes can be accepted as consent but we recommend a written and signed consent form. A section detailing this and a possible informed consent form is included later in this document.

The next step is a protocol for the study and a procedure to collect the data, collate the data, analyze the data, write the study, review the data, and publish the results.

Application Requirements for Informed Consent

In terms of the USA there is no requirement for informed consent if the system is being used purely for self and family use. There is probably no requirement if no charge is being made.

However if you are charging, are a registered/certified biofeedback technician etc. then you **MUST** use informed consent.

The consequence is that the FDA, in the course of their monitoring, may check out your use of the system and if you cannot demonstrate informed consent then there is a possibility of confiscation of the software. Please note that the hardware cannot be FDA confiscated.

IRB: Making Full Facilities Available to the Practitioner

All programmes registered in the original EPFX software are tagged (REG) within the programmes drop down list in the test screen.

In respect of FDA regulation all other functions are deemed experimental and are tagged (IRB).

In order to be experimental there needs to be several aspects in place:

1. An institutional review board (IRB) to assess the experimental information. This has been established as IRB (Research Centre), University Padua, Venice, Italy under the auspices of Dr Nelson. This is established.
2. The client must give informed consent as regulatory criteria for participating in the research study. Informed consent is available in several places.

IRB Study Philosophy

QX ltd WELLNESS STUDY

The major criteria of this study are to determine if the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software can help people deal with and reduce personal stress. We want to analyze wellness in context of the Selye system of Stress.

Biofeedback is designed for stress detection and stress therapy. All disease involves stress. The body has an undeniable electrical nature. Biofeedback can give us insight into the body electric. The EPFX device is registered to due biofeedback and evoked potential and reactivity scores. But several of the rather new QX software functions will be experimental. So we need to set up a simple study for evaluating the Nelson Method and the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software.

Simply put we first will establish that the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software is effective in making patients feel better. Next we wish to study if it can help improve health with any measurable criteria. With over 14,000 devices in the field around the world it will be easy for us to
get large quantities of data on many different types of factors. There are currently over 25 different studies on specific diseases in process now. Studies on nervous function, adipose loss, face rejuvenation, and many other therapies. So this large open natured study allows us to address the experimental world easily and effectively.

It must be apparent that true Wellness is not just lack of symptoms. Wellness has more to do with oxygenation, attitude, strength, flexibility, cardiovascular conditioning, balance and others. Many patients think that Wellness is freedom from symptoms. This is an allopathic major misconception.

Being Symptom Free is not an Indicator of Health

With this in mind this Wellness test was designed to measure our Wellness, measure our stress, measure the medical changes and to give us a method of observing our health. We can then change and improve our Wellness. The purpose of this study is to see the relationship of stress to health.

Selye taught us a new medicine based on just how stress causes disease and how stress reduction can be helpful to all. Selye points out that stress enters the body in many ways, toxicity, trauma, heredity, perverse energy, cold, heat, damp, X-ray, pathogens, lack of awareness, allergies, dietary deficiencies or excess, social tension, job pressure, uncertainty, poverty, mental factors, etc.

When these first enter the body there is an ALARM reaction. This is a symptom such as a cough, fever, pain, itch and all other symptoms. The alarm is to notify us of the start of the disease process.

If the Stress continues, the body will adjust and conform slipping into the next stage of ADAPTATION. The body adapts and acclimatizes to the symptom. The symptom goes away. The disease progresses. A symptomatic medicine is illogical and invalid. Allopathy is a symptomatic medicine.

Being Symptom Free is not an Indicator of Health

If the Stress continues the disease progresses to the next stage of EXHAUSTION. Here the disease advances and the organism falls into chronic disease.

The EXHAUSTION stage has two parts. First the FUNCTIONAL stage decay of the organs where they start to dysfunction, and later the ORGANIC stage where the organs start to physically deform.

If there is progression and no stress reduction the next stage of DEATH occurs. Cellular death, organ death, organ system death, and finally organism death.

This system of medicine is developed to deal with the first stage and reduce the starts of disease. Stress reduction and release of all stress factors is the basis of medicine.

Being Symptom Free is not an Indicator of Health

The Nelson method of disease therapy is as follows.
1. Reduce the Causes of disease
2. Restore Healthy functions to the damaged organs
3. Unblock the Blockages of flow of life's cyclic components, air, blood, prana, acupuncture energy, chiropractic energy of the nerves, social dynamics, psychological, etc
4. Treat symptoms naturally, not sinthetically
5. Treat Metabolic or Constitutional trends

IRB Study Objective

The major criteria of this study are to determine if the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software can help people deal with and reduce personal stress.

The first basic proposal is simplicity in its design. After a therapist sees a client or patient, he should proceed to the TOOLS function. This is designed to make data assembly and transfer easy to perform. The computer system knows which functions

were used during the test. The system knows which products were selected and which therapies were used. The therapist has merely to tell the system how much improvement was displayed in the patient. And some class of diagnosis.
Three categories of improvement are suggested.

1. Does the patient feel better after the last therapy?
2. What was measured in improvement? Is there any measurement that can be made?
3. Does the patient feel better now after the test? How much in percent

The relative feel good factor is not to be ignored. If there is negative results please report using a negative score.

Measurement

If there is any measurement made by the therapist or the patient or other doctors to show improvement please report it on the TOOLS screen. If not use any of the WELLNESS test scores or if you do not have time just use the feel good score. Pain rating, hours of sleep, memory tests or recall, range of motion of limbs etc, vision hearing and many many others can be used as measurement criteria. The major criteria of this study is to determine if the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software can help people deal with and reduce personal stress. So stress rating before and after is most important.

Wellness Test

The major criteria of this study are to determine if the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software can help people deal with and reduce personal stress. So stress rating before and after is most important.

1. First we can measure the *blood pressure*. Blood pressure is not the same throughout the body. Several diseases or disorders can create imbalances in the flow or pressure of the flow. The computer is programmed to give us warnings on a report screen if there are such diseases. Simply use a large blood pressure cuff to measure both of the arms and legs. We then measure the standing pressure within 2 sec. of standing from a sitting position. We only need to input the systolic reading on standing.
   In some states unlicenced persons can not take blood pressure.

2. Next we measure the *relative strength* of the patient. How many push-ups, chin-ups, leg-lifts, toe raises is measured in the time limits outlined by the computer.
3. The *stand-ups* while holding your breath is accomplished by first telling the patient to relax sitting in a chair. They will then hold a normal (not forced) breath. While holding the breath the patient will stand up and sit down as many times as they can. When the brain can no longer deal with the aerobic loss the patient will quit. The counts of the times they can stand up tell us the *anaerobic capacity* of the brain. The computer will give us a ranking in the report.
4. The *cardiovascular challenge* is a variation of the Harvard Step test.
   Here we must get the base line heart rate and respirations per minute. Measure for 10 sec and multiply by 6. Then the patient undertakes a met of exercise (heavy exercise)

for two minutes. Then we take the heart rate and respirations per min immediately. Then we wait one minute and re-measure to get a cool down measure. These calculations will give us an expert insight into the cardiovascular strength of our patient.

5. Next is the *balance beam test*. Here we use an eight foot two by four, where the patient first walks across the board. Then the patient walks backwards, next the patient tries the same two maneuvers with a blind fold. We record the best performance.

6. Next we measure the *self-rating of the patient*. The patient rates themselves in several areas. Such as ability to be still, relax, stress, all around health. We use 10 being extreme and 0 being no ability and the patient rates themselves.

   Next we measure the flexibility of the patient with measures of multiple areas of flexibility.

7. The *low back flex* is measured by sitting on the floor extend legs. Reach as far as you can towards the heels with both hands. If you can place the two extended fingers at the heels then record zero. If you can go past the heels then record each inch past the heels. If you cannot get to the heels then record the number of inches as negative numbers.
8. The *side to side measure* is performed while on the knees you reach to the side if you can place the palm of the hand on the floor then score 100%. If you can reach the first knuckle score 75%, second knuckle 50%, only the tip of the fingers 25%.
9. The rotation score is 100% if you can twist to the side far enough to get your shoulders at 180 degrees to your hips. if the patient cannot perform this difficult feat then rate the attempt in percent.
10. The *neck flexibility* is a rating of how far towards the shoulders you can extend your ears. if you can touch the ear to the shoulder rate 100%. if not rate the attempt.
11. Last we use *anthropromorphic measures* such as height, weight, waist diameter, thigh diameter. The fat thickness is a measure of the adipose tissue around the abdomen and the under the arm in the triceps. The waist to thigh ratio was found to be the most significant bit of data for estimating the risk of heart attack.

    This and other calculations are performed in the computer and generated into an easy report. Wellness is not just freedom from symptoms. It is much more. Just this philosophy can be healing.

Diagnosis

If you are licensed to diagnose then list your diagnosis. If not use all of the diagnosis of other therapist or licensed doctors has made. If none is clear list the symptoms and use stress as your diagnosis. List the disease type as best you can. This will let us analyze the data better.

HOW TO TRANSMIT THE DATA

After you have done the QXCI/EPFX/SCIO/INDIGO/EDUCTOR therapy and any of its' functions, go to the TOOLS button on the main screen. Choose a disease type if there is no choice, and click on the

Operationalize Button. Rate improvement or list any measure of health known. Save the data to the hard drive to send later, or transmit the data directly to us via the net. We will store, collate, analyze, and save the data so you don't have to. The data sent to us will not have the patient's name. It is confidential. You have no data management worries.

If there is any measurement made by the therapist or the patient or other doctors to show improvement please report it on the TOOLS screen. If not use any of the WELLNESS tests scores or if you do not have time just use the feel good score. Pain rating, hours of sleep, memory tests or recall, range of motion of limbs etc, vision hearing and many, many others can be used as measurement criteria. The major criteria of this study are to determine if the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software can help people deal with and reduce personal stress. So stress rating before and after is most important.

For help with all of this see our research video or send questions to question@irbqxci.net

SUMMARY

For a more in depth description see the Wellness book, or watch the videos in the Wellness Test on the Test Screen under the Programs pull down.
Good luck: if you need more info send questions to www.irbqxci.net.
(question@irbqxci.net)

Operating the IRB

All programmes registered in the original EPFX software are tagged (REG) within the programmes drop down list in the test screen.

In respect of FDA regulation all other functions are deemed experimental and are tagged (IRB).

In order to be experimental there needs to be several aspects in place:

1. An institutional review board (IRB) to assess the experimental information. This has been established as IRB (Research Centre), University Padua, Venice, Italy under the auspices of Dr Nelson. This is established.
2. The client must give informed consent as regulatory criteria for participating in the research study. Informed consent is available in several places.

After you have done the QXCI/EPFX/SCIO/INDIGO/EDUCTOR therapy and any of it's' functions, go to the TOOLS button on the main screen. Choose a disease type if there is no choice, and click on the Operationalize Button. Rate improvement or list any measure of health known. Save the data to the hard drive to send later, or transmit the data directly to us via the net. We will store, collate, analyze, and save the data so you don't have to. The data sent to us will not

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For help with all of this see our research video or send question
info@imune.net

Detailed Operation

The message will display when returning from Patient data to Demographics.

Test>information>informed consent: this is a complete informed consent document and it is recommended that if the user proposes to employ other than the (REG) functions that copies of this are printed out from the programme and signed and kept by the practitioner.

Main Screen>Tools>Informed consent: this is a secondary aspect whereby the client is asked for permission for transmission of information elected during use of the programme to be forwarded to the IRB. Please note that this information is confidential and the client remains anonymous. No client name is transmitted. It is most secure if the previously mentioned consent form is signed by the client. In the absence of this verbal or even nod of the head acknowledgement can be interpreted as permission: however this is not robust upon examination.

Confidential Statistics Science Programme

This programme implemented to satisfy the data collection and forwarding aspect of the experimental (IRB) aspect of the software for USA usage.

1. Obtain informed consent (Test>information>informed consent).
2. Access tools (main button screen).
3. Select the disease type or types and make additional finding remarks.
4. Operationalize research access: this will display a screen for data entry. The white edit boxes are optional, with the most critical information being in the grey boxes on the lower part of the screen.
5. Percentage improvement in symptoms: this relates to client perception of improvement within the session.
6. Percentage of improvement measured: this is only applicable if a physiological measurement e.g. blood pressure, swelling etc. is physically measured.

7. Percentage of improvement in feeling better: this is again from the client perspective.

If there is an improvement in symptoms or in feeling better when the client next visits then this information can be entered.

What measured and how is optional for additional information.

Save to confidential report will bring up the Save As window where the destination drive (floppy, memory stick, hard drive etc.) can be selected as well as a file established for the storage of this information. The file name is automatically coded and is confidential.

Alternatively the data can be transmitted on line to the data base facility maintained for the experimental information analysis.

At the completion of these stages close the screens.

USA and non-USA Software

The EPFX software is specifically designed to accommodate American regulations. The European software is broader since the regulatory constraints are less stringent than in the USA. It is the policy of QX Ltd to not supply non-EPFX software to the USA.

There is however a free world market and similarly to other software availability the manufacturer has no control over USA based users obtaining European software. This is at the discretion and the sole responsibility of the user and QX Ltd can accept no liability in any respect for failure to comply with the requirements of use of non (REG) software elements or non EPFX software.

Disclaimer

The above has been prepared independently by Dr John Kelsey PhD, resident in Europe and is correct to the best of his belief and knowledge. It is provided for information purposes and no liability can be ascribed to the writer for the provision of this information.

Note that closing the disease type window will automatically bring up the operationalise resurge access screen.

Informed Consent

Information

The EPFX Biofeedback Medical device is registered in the USA, Europe, S Africa, Mexico, Australia etc. It is a evoked potential Biofeedback device that measures how a person reacts to items. It is designed to measure reactions for allergy, homeopathy,

nutrition, sarcodes, nosodes, vitamins, minerals, enzymes and many more items. Biofeedback is used for pre-diagnostic or therapy. These functions are registered in all of the above regions. Eclosion and Maitreya manufacture the hardware. Eclosion distributes the EPFX software.

At QX Ltd., we have written software that uses the EPFX data in more avant-garde ways. This software offers no risk and is completely safe. We recognize that this new type of system needs to be tested experimentally. The USA allows us to develop an Institutional Review Board and operate an Investigational Device Exemption for this software. To use this software in the USA we need to get informed consent from the patients or persons who are tested. Informed consent must be signed, implied, or understood.

The registered EPFX software and hardware uses a micro current medically safe pulse applied to the wrists, ankles and forehead. We safely measure some of the electrical aspects of the body. A variant micro current is then adapted to the patient to feedback the signal. The QXCI/EPFX/SCIO/INDIGO/EDUCTOR software will use the same medically safe standards to develop a wider range of variant wave forms to the body. The patient will choose and direct the therapy by their unconscious electrical reactions. The QXCI/EPFX/SCIO/INDIGO/EDUCTOR will also use a subspace system or Prayer wheel if there are no biological signals present. The system will show the patient reactions to homeopathic or nutritional items. This will help the therapist and the patient choose items that might be helpful. These choices are voluntary suggestions. The patient can greatly benefit from help with these choices. No items of significant risk are possible. These items are not part of the study and purchase of them is the patient's responsibility.

There is insignificant risk and the only discomfort is sitting still for the 30 or 40 min evaluation. The patient name will be held confidential in the study. Participation is always purely voluntary. There is no penalty for withdraws. The other facts of the case are e-mailed to QX ltd IRB. The FDA of America reserves the right to inspect records. But confidentiality is always guaranteed.

The results of the studies are to be published on the International Journal of the Medical Science of Homeopathy. These results are available in 2006 on the internet or through your therapist. Over 35 studies on the device have already been published.

Since there are over 35,000 EPFX machines around the world, and all have access to the QXCI/EPFX/SCIO/INDIGO/EDUCTOR software, assuming 10 patient visits a week there might be over 400,000 data streams per month. We fully expect over a million bits of data in the first year alone. We will analyze all types of diseases - all types of clients - in one of the world's largest studies of its kind. We welcome your participation.

The clinical therapist is responsible for ensuring that informed consent is obtained from each research subject before that subject participates in the research study. FDA does not require the therapist to personally conduct the consent interview. The therapist remains ultimately responsible, even when delegating the task of obtaining informed consent to another individual knowledgeable about the research.

Informed Consent

I am informed of the experiment on the QXCI/EPFX/SCIO/Indigo/Eductor software. I willingly give my consent to participate in the study. I give my consent for any children under my supervision or custody. I am to be guaranteed confidentiality of the data. I will be allowed to see the results of the publication in roughly one year. I recognize that there is no firm diagnosis resulting from the software. We are diagnosing and treating only Stress via Biofeedback.
I give my full and informed consent to partake in this research.

SIGNATURE_____

DATE_____

THERAPIST OR WITNESS_____

In short

1. The QXCI/EPFX/SCIO/INDIGO/EDUCTOR software research is to study millions of people with a wide variety of diseases to see who gets or feels better.
2. The QXCI/EPFX/SCIO/INDIGO/EDUCTOR software will allow the unconscious of the patient to guide to repair electrical and vibrational aberrations in your body.
3. The device and the study are always voluntary, confidential and safe.
4. There are a wide amount of benefits already displayed by the thousands of users and millions of patients. A millions of people have already been helped.
5. Results of the study and answers to your questions are available.