

IRB- Investigational Review Board

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Disclaimer

This 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.

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Summary

Europe: the system is known as the QXCI or SCIO and carries a CE Classification. No special measures are currently required to conform to regulations, although in the coming years there will be considerations.

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

1. QX have held a registration for the EPFX (precursor to the QXCI_SCIO) which covers some of the program facilities. These are tagged (Reg). It is legal to import the system with this (EPFX) software into the USA. 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 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 is Richard Lloyd. Any queries should be made initially via your provider and NOT Richard Lloyd or John Kelsey. This will ensure consistency and is a requirement of the registration process for the USA. Details are provided below.

Historical Background

In 1989 Dr Nelson saw a resistance style (Voll EAV) device. Based upon his electronic background and our 3 dimensional world he postulated that measuring voltage and amperage (to complete the shape picture energetically) would provide a more appropriate interaction with an organism. Variations in voltage and amperage give rise to wave forms or oscillations. The initial review in 1980 focused on how fast it was necessary to test and the organism response to a stimulus was determined at around the 100th of a second mark. In 1982 the first software was developed and in 1985 the QQS (3D shape characterisation of substances) was developed.

In 1989 the EPFX testing function was registered with the FDA. In 1990 a therapy device system was registered. A proposal to register an integrated testing and therapy device was in the same year rejected by the FDA with no reasons given (this they are entitled to do!)

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
- Calibrate
- EEG ECG FREQ
- Risk profile
- Spinal and sarcodes
- Test
- Aspects of nutrition

Thus all equipment and software labelled EPFX (this includes the EPFX version of the QXCI and the EPFX version of the Scio) are registered and the hardware interface (EPFX/SCIO box) **can not** 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 derivative labelled EPFX or a Scio derivative labelled 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 it's EPFX software is registered in the USA as a biofeedback medical device. The Ecllosion 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 patients reactions to remedies. This is registered as a function under Biofeedback known as Provocative or Evoked Potential Biofeedback.

The QXCI software uses biofeedback instruments such as the EPFX to use the Xrroid process for several medical aspects that are revolutionary. And as such the QX ltd company sees these functions as experimental. 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.

IRB = Centro Ricerche of Prof. William Nelson, University of Venice + Padova, Itally www.irbqxc.net

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. An 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 EPMX 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 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 software.

Simply put we first will establish that the QXCI 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 a 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 a 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 a 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 synthetically
5. Treat Metabolic or Constitutional trends

IRB Study Objective

The major criteria of this study are to determine if the QXCI 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 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 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 unlicensed 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 manoeuvres 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 can not 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 can not 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 *anthropomorphic 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 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 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@irbqxi.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.irbqxc.net.
(question@irbqxc.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.

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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. Operationalise 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

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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. Ecllosion and Maitreya manufacture the hardware. Ecllosion 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 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 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 10,000 EPFX machines around the world, and all have access to the QXCI 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.

The Centro Ricerche of Prof. William Nelson University of Venice + Padova, Italy Is the headquarters for the study IRB. There are researchers in over 25 different countries. If you have questions or comments please ask your therapist or send them in writing to www.irbqxci.net.

Informed Consent

I am informed of the experiment on the QXCI 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 software research is to study millions of people with a wide variety of diseases to see who gets or feels better.
2. The QXCI 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.

A Conversation with the FDA- Registration and FDA.

At Eclosion we are FDA and CE registered and we are required by law to report any one who might be stealing or fraudulently using or registration numbers. We must do this it is the law. I reported a possible pretender to a medical device investigator yesterday. The following is a transcript of that conversation joined mid course.

Medical Device Investigator = (MDI)

Bill = (BD)

(BD)-“ we must report any one who might be using our registration numbers”

(MDI)-“ yes it is illegal to fraudulently use someone else’s registration numbers, we have checked your registration at Eclosion and it is fine, your device has been tested safe to UL standards for biofeedback devices. Your registration and safety qualifications date back for over a decade, but some one has tried to use your number on an imported “xxxx” system device”

(BD)-“ yes, the “xxxx” system is using our numbers, and we think that the “yyyy” people are also using our numbers”

(MDI)-“ there is no registration for the “xxxx” system or “yyyy”. No record of standard UL safety tests. None that we can find anywhere, not in America, Europe, or anywhere. *But the fact that it is not registered in America makes it illegal for use in America, Europe is for some one else to handle*”

(BD)-“ in regard to “xxxx” systems, they are rumored to be forming an IRB to cover the old sales that they made”

(MDI)-“ if they sold a device without a proper IRB in the past, then that is a violation. Trying to cover the past with an IRB with some type of post dating is another serious violation, How many devices have they sold?”

(BD)-“ I don’t know maybe a hundred”

(MDI)-“How many sales people do they have”

(BD)-“ I have no idea”

(MDI)-“ *the law is rather strict on this, a proper IRB investigation has rigid rules. it is not to be used for marketing, it is for doing an experiment. If an experiment is not being done it is a problem. On the “xxxx” systems device we expropriated today there is no “Investigational Use Only” warning. In fact, there is no manufacturer listed. this is another serious violation*”

(BD)-“ Really, it appears to be a secret where the manufacturer is”

(MDI)-“ how could the customers and sales people have been so stupid as to not question the lack of a manufacturer label, this is a must on everything, even toothpaste puts on the manufacturer label “

(BD)-“ Nobody seemed to mind, some people have no ability to ascertain legal things, you know naive”

(MDI)-“ they must be very stupid to not figure this one Out “

(BD)-“ they were blinded by greed I think, they did not question

things properly. What will happen to the “xxxx” systems?”

(MDI)-“ use or sale of a “xxxx” system is unlawful, it will become a banded listing and prohibited from registration or experimentation. You can not start your business by violating the law. The law of registration or exemption must be adhered to from the start. If there is a series of violations then it voids consideration. This incompetent and illegitimate action will prevent them from getting registration or an IRB”

(BD)-“ What if they start an IRB now?”

(MDI)-“ *an IRB device can not make a profit, no one can make a profit from an experiment on the American people, no sales commissions, no excess return. Only base expenses. Informed consent is a must from sale to use. Any buyer must be aware of his risk any user must be aware of the experiment, and all experiments have a time line.If an IRB is formed after the fact and thus rules are not adhered to, members of that IRB might be committing a crime.*”

(BD)-“ We have discussed our IRB”

(MDI)-“ Yes I have checked your system, your EPFX is registered and has past UL safety equivalence, you are allowed to do an experiment with a registered safe system, you are charging nothing for the IRB software so no profit is made, your IRB is properly sanctioned, your informed consent forms are compliant, Your QXCI IRB seems to be OK.

I am not aware of an IRB for “xxxx” systems, but the fact that the original box is not labeled as such and the lack of a manufacturer on the label has them already in trouble. an IRB now is just going to get more people in trouble. “

(BD)-“ there are a lot of really gullible people I hope nobody gets hurt, so many have been hurt by “xxxx” systems already, what can be done for the innocent buyers” “

(MDI)-“If some one has innocently believed them they can ask to return their system and get their money back”

(BD)-“ but won't the company and the officers just go bankrupt”

(MDI)-“ Probably, but there is in all likelihood some money or some resources to sue for and it will be first come first serve. They can sue the manufacturer, the directors, or the salespeople as well. There is often some resources there for people to recover in civil court”

(BD)-“ and is there criminal action”

(MDI)-“ from all evidence especially the attempt to hide the manufacturer, it appears to be lots of criminal intent. This tell me someone plotted the fraud. phone calls across state lines might involve racketeering charges. If a sales person profited or was part of committing a fraud to pretend there was registration and they knew there was not, then they might be included as well..... Ignorance of the law is not a defense, It might weaken a sentence or fine, but if they knew it was not registered and were actively committing a

fraud the consequences will be severe”

(BD)-“ what can I tell some of these innocent duped people?”

(MDI)-“ tell them to stop selling and using unregistered equipment and cooperate with authorities when asked. If they start a law suit to recover funds or to get civil action it would appear that they are part of the solution of stopping this fraud. Such a law suit would show some due diligence, late but due diligence”

(BD)-“ when will this escalate?”

(MDI)-“my investigation is not yet complete, we have no idea how large this problem is. we have already been in contact with other countries.

This is possibly an Interpol extensive operation. But it appears that in the next some months actions against “xxxx” system will start, believe me we are taking this one serious”(BD)-“and what about us?”

(MDI)-“ everyone is always under investigation, but it appears that your are in compliance, you have registration, audit release, clean experiment, proper advertisement, proper labeling. the “xxxx” system has none of these, the fact that you reported this possible violation speaks well for you. but our investigation started before and “yyyy” is being looked as well”

The conversation continues but is not relevant

Well now users:

Let me help you, there is only one question- here is the question to ask

“Is the “xxxx” System Registered?”

when they say “NO”.

Wake up smell the Gurana, and realize the problem. Hang up the phone

Sincerely Yours in the Struggle

Bill