

Regulation, Registration, Legalities

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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.

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!)

General

There are a number of primary aspects relating to the use of devices in therapeutic practices. These include:

- *The device must be safe in its use.* It must not harm or entail risk. In Europe this is covered by the CE Classification which has specific investigation processes for determining safety, e.g. is it flammable, will it electrocute, etc. Other countries have similar criteria within their own right (e.g. Therapeutic Goods Association, TGA in Australia) although these bodies do have a degree of cross accreditation and may accept devices that have undergone safety audits in other countries. In Europe in particular the CE is universal across Europe and is also generally accepted by countries who are either provisional or even not members of the European Community. However in certain countries the use of the device, even though it has a CE, may be restricted in medical operation (e.g.. Norway).
- *Medical or therapeutic application:* this is where there is a more rigorous requirement. It is an area that varies considerably between countries and involves both the device and practitioner regulations. Integral with this is the claims situation.

Unless there are case or clinical studies which have been submitted to a regulatory authority then in general no claims can be made for a device.

There are devices, e.g. TENS units that are either approved by or registered with regulatory authorities for pain. This type of claim of success in a particular treatment area is generally reflected in the specific classification of device and the category of classification. For example, there are Class 1, Class 2, etc devices both within the CE Regulations and the FDA Regulations. Generally when it comes to making medical claims (and pain reduction is a medical claim along with most other health restoration issues, with the major exception of stress identification and reduction) there is a medical classification. Even here, whilst the CE Class 2 medical classification of a device can be accepted in most of Europe there may be separate additional regulations applying in specific countries, e.g. Norway, which requires specific trials and proving to be undertaken in that country. A prime example of this is the unacceptability of Russian clinical trials in the UK and USA, although these are accepted in a number of Far East countries.

Claims

The upshot of this is specifically in terms of making claims:

- It is not legal to make claims of a device unless it carries a registration/approval for a particular disease or issue.
- Thus to say that a device was responsible for a health improvement or resolution is not appropriate or legal.
- An approach or a technique involves three elements:
 1. A device.
 2. A practitioner.
 3. A method of working, i.e. procedure.

Techniques are generally neither licensed nor registered and as such it is in principle possible to make a claim for a technique, e.g. biofeedback can be effective in stress reduction. There are however limits and whilst it may in principle be legal to claim that the technique of biofeedback is effective in treating cancer this will draw attention and is in many ways inappropriate since you are treating the whole person rather than a specific disease. Essentially to be safe claims should be soft.

Practitioner Regulation

In a number of countries, e.g. Europe the primary requirement is that the device carries a safety approval, i.e. CE. In most European countries there are bodies like the FDA who regulate quality control of the manufacturing and all claims made for devices. In the UK this is the MDA (Medical Devices Agency) and in Australia the TGA (Therapeutic

Goods Act). In the USA and Australia a device must be registered with these regulatory authorities whereas currently in the UK this is not necessary.

In many countries device safety/registration is sufficient to enable a practitioner to use it provided they do not make claims for the device or their activities as a practitioner (e.g. they should not claim that they cure a disease).

It is particularly important to note that practitioners are not regulated by device authorities (e.g. CE, FDA, TGA) but by other professional bodies. For example in the UK doctors are only allowed to practise by law if they are registered with the British Medical Association who is empowered by an Act of Parliament to authorities medical doctors to practise. There are similar Board i.e. state by state licensing arrangements in the USA. The subject of practitioner licensing and certification in the USA is the subject of a separate document. However, in many countries of the world practitioners are able to use devices provided they are registered with the appropriate regulatory authority.

The key point in respect of practitioners is that they should be able to get professional indemnity insurance: this is generally not difficult for low risk devices such as biofeedback but most insurance companies require proof of the device registration and of the practitioner training in its safe use.

Summary- Practitioner & Device Regulation

There are regulatory authorities, e.g. FDA, TGA, CE, MDA that regulate devices i.e. manufacturers (quality control assessment), claims for devices, and in some instances what qualification of practitioner can use them. However these regulatory authorities' remit is for the device and not the practitioners. In general provided a device is registered there will be no interference with the practitioner as long as they do not make claims for the device.

There are bodies in various countries that regulate practitioners, and the regulation process (self regulation, statutory regulation) varies between countries. Practitioner regulation bodies are completely separate and not related in any way to the bodies that regulate devices. In terms of claims practitioners are not empowered by the regulatory bodies to make claims on the cure of diseases. Depending on their regulation body they may be able to use terminology such as diagnosis, disease treatment, cure, etc. In general only licensed medical doctors can make the claim to diagnose and cure. In addition depending on the country there are certain conditions that only licensed medical practitioners can claim to treat, e.g. in the UK cancer, diabetes, epilepsy, amongst others.

In essence it is very smart to be very general and to focus on:

- Offering education to a client, i.e. making information available that is supportable by reputable information within the public domain (and not just your opinion) about the health process.

- Focus, in terms of the EPFX-SCIO-QXCI device on stress identification and reduction and as one (and not the only) element of a session with the client. This view comes from the country in the world, i.e. USA where the device has a registration with a medical devices control agency, i.e. FDA. There its registration is under biofeedback and the definition of biofeedback in terms of the FDA website is associated with stress. Whilst this restriction does not apply in many other countries (since the device does not need to be legally registered with the equivalent of the FDA in these countries) it is still sensible to avoid any potential confrontations with any regulatory authorities (device or practitioner regulating) by focusing on stress reduction. Unfortunately the rest of the world is likely to follow the USA model over the next 5-10 years. This provides ample scope and can be validated according to the effects of stress on the organism as outlined by Hans Seyle.

Hardware and Software- IRB

A TENS device is essentially a hardware device and if this is not registered or if claims are made for it which are not within the scope of the registration then the device can be confiscated by the regulatory authority.

The EPFX-SCIO-QXCI is more a system comprising the elements of:

1. Hardware
2. Software

There are thus two elements to consider. The hardware is effectively an interface and on its own i.e. without software does nothing. Provided it conforms to safety, conforms to the specification that it was registered with (and the manufacturing quality control process of the device is rigorous and is audited by regulatory authorities as a matter of course) then the device cannot be confiscated by the regulatory authorities. If the manufacturer makes claims for a device that is outside its registration then the device can be confiscated. If a practitioner makes claims for a device outside its registration then the practitioner and not the device is responsible and thus legally liable for the claims.

In respect of the software there are specific requirements that apply to the USA (FDA) registration and similar in Canada. This is believed not to generally apply in other countries of the world but probably will in due course. Thus to apply the same diligence worldwide as is required to conform to the FDA requirements is sensible.

The original software is known as EPFX software, and the software supplied into the USA references only EPFX. This is software that is deemed to be appropriate within the original regulation remit i.e. biofeedback-stress reduction. Advanced software is available and within the FDA regulations there is a process for using what is classed as experimental software (and devices). This requires something known as an investigational device exemption (IDE) (based upon submissions that the device/system

is insignificant risk to safety and health) and with a requirement that the results of such experimental work by practitioners is provided to a body set up by the manufacturer known as Institutional Review Board (IRB). This enables the aspects of the programme that were not under the original registration to be used.

Aspects of the programme that were under the original registration are tagged – Reg.

Aspects that are purely informational are tagged – Library.

Aspects that are experimental are tagged – IRB.

If a practitioner in the USA/Canada (and any other countries that are FDA regulated) uses the advanced (CLASP) software then they will be assumed to be using the experimental software facilities tagged IRB and if they cannot prove, if visited, to the regulatory authority (FDA) that they are conforming with the requirements to submit the experimental data then the software can be confiscated. It is highly unlikely that the device interface (hardware) would be confiscated.

This highlights the emphasis placed by QX on users within the USA in submitting the IRB.

Whilst there is not a current regulatory requirement in many parts of the world to conform with the IRB it is the very strong request of QX/Eclon that this information is provided. It is a requirement for trainers that they follow the IRB in their practice. It is easy and a process is set out both in a document and within the programme for this purpose. This is one of the primary events that practitioners can contribute to that will help not only the survival but the forward progress of device based energetic medicine.

Essentially this process is mandatory in the USA for your own protection and is very highly commended elsewhere.

Approval, Registration, Licensing and Certification

No regulatory body approves the use of a device or technique for diagnosis or treatment.

Device regulatory bodies register devices into a classification according to their risk. They apply assessment criteria both in terms of intrinsic electrical/mechanical etc safety and in terms of safety in application according to the risk class. Thus to obtain a medical device classification (available within the CE) a very much more rigorous assessment is undertaken which includes submission of clinical data.

The regulatory authorities also require that the manufacturer operates and maintains a quality control system on both hardware and software and they have the right to audit this. This is covered within Europe by ISO procedures (e.g. ISO 9000, 9001, 9002) and similarly by the FDA and Health Canada. Many countries accept CE, FDA or ISO registrations. Some countries with their own framework e.g. TGA in Australia and

Department of Health (Radiation Control) in South Africa have specific requirements but in the main reference CE certification.

Specifically the device is registered in the following countries:

USA – FDA

South Africa – South African Health Department

Australasia – TGA

Canada – Health Canada registration in process

It is important to recognise that device registration:

- Does not mean it is a medical device.
- Means that it is only a medical device if it is specifically registered under that classification.
- Is a not therapeutic validation of a device.
- It does mean that it is intrinsically not harmful when used in accordance with the manufacturer's instructions.
- Is not a licence for diagnosis.
- Is not a licence for therapy.
- Is not a stand alone diagnostic system.

FDA

FDA General

Budapest, 30th July 2004

Dear friends & holistic practitioners,

I am writing this letter to advise you of a developing problem and how we can all address it and correct it. We manufacture, promote and sell biofeedback equipment. Hungary venerates the work of it's own researchers: the Nobel Prize winning Szent Georgii Albert, Selye Janos, James Issacs (and William C. Nelson). Hans Selye as you might know was a medical genius who devised a new way of working with patients. Selye coined the word 'stress'. Issacs developed the original Quantum Biology. All of these special men worked in Hungary and Canada. I have based my work on the research and findings of these three geniuses to develop a philosophy of medicine and several devices which allow easy and detailed capacities to detect electrical health aberrations and remedy them. Hungary and Canada allow alternative medicine. The United States of America is, as always, a problem.

Selye's theory was that stress is the start of all disease. When stress first appears it produces an 'alarm' reaction that 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. Early Stress detection and reduction is a primary form of medicine with expansive results as our studies show.

The undeniable truth of medicine is that since the symptoms can disappear through adaptation, basing medicine on symptoms is illogical. Since we live in a toxic environment we will have greater detoxification. Detoxification through excretions, but excess excretions is seen as symptoms and is suppressed with medications by some modern medical doctors. We call that ‘Allopathy’ where the symptom is the enemy. The neuro-psychological link is more a part of medicine every day. A study I saw the other day on ‘SKY News’, relates that the pain from exercise is not so much in the muscles as in the mind. The role of the mind in medicine is ever expanding all over the world. Biofeedback is just a tool for access.

We, however, see the symptoms past and present as the messengers or pointers for us. The Allopathic statistical approach is not all that we do here in Europe. Drugless therapies don’t scare us, they interest us. Thus stress reduction takes a much larger picture of medicine in our philosophy. We use ‘Allopathy’ as well in our country but we are also much freer to use alternative philosophies than in your country. We are registered with the ‘EEC’ here in Hungary where we enjoy more freedom to express our treatment options. Biofeedback is seen as a comprehensive tool in medicine.

Now the problem at hand: ***The ‘QXCI’ device or the ‘SCIO’ device is a biofeedback device full stop.*** The use of the device is to measure electro physiological responses and feed them back to the patients unconscious. When assertions are made about the device it can involve the ‘FDA’. The ‘FDA’ is very sensitive to claims, and over sensitive to claims made by alternative people. Some of our people have been tormented by this.

The ultimate truth is that the ‘FDA’ does not control the practice of medicine. This is a myth. The ‘FDA’ controls devices, medication, and claims for such. The practice of medicine is a state issue. Every state allows biofeedback to operate without regulation as long as it does not transcend stress related diseases, uses safe registered devices, and operates with a disclaimer. A disclaimer announces that disease diagnosis and disease treatment are not happening past stress. Unless a medical referral is used. Our problem is that overzealous officials are paranoid and looking into the claims. So there is a simple solution to our problem we must all implement immediately. The claims can’t be made for the device but for the therapist.

Since all of the users are trained to some extent, they must all be trained in some simple biofeedback use with a special name: ‘Nelson Biofeedback’, ‘Quantum Biofeedback’, ‘Evoked Potential Biofeedback’, ‘Nouveau Biofeedback’, ‘Modern Biofeedback’, ‘Computer Biofeedback’, and ‘Cybernetic Biofeedback’ are some simple examples we might choose. These are names for a philosophy not a device. The ‘FDA’ cannot interfere in freedom of speech or philosophy. We all must stop using claims for the devices. If we make claims for the philosophy only, the ‘FDA’ will be neutralized. This is not a ploy but the truth. The device does not work on its’ own, it needs an operator who is trained in a

certain philosophy. It is the philosophy that really does the most good. Claims made for the philosophy are not of 'FDA' concern.

As an example you might go to a Doctor for angioplasty. You do not go into the office for 'Bob's balloon appliance', this is a device. You do not see the Doctor advertising the device, you see him advertising the philosophy, the procedure, or the therapist. This gets him out of the 'FDA' control loop. Harry's scalpel is not advertised for gall bladder surgery, 'ABC' blood pressure cuffs do not appear on the Doctor's brochure, the Doctor's philosophy, procedures and credentials do. Please stop making claims for the device as if it works by itself.

If the claim "The QXCI device can cure headaches" is changed to "Modern Biofeedback Philosophy can cure headaches", then the claims are not made of a device. The 'FDA' is neutralized. The state medical board can be involved if an unlicensed practitioner is involved. A licensed (not just certified) biofeedback practitioner could say "Modern Biofeedback Philosophy can help stress and therefore benefit people with headaches" then the state medical board will be content. Case studies or testimonials about the results of "Modern Biofeedback Philosophy" are freedom of speech and are not approachable. The same claims involving a device is suspect to concern. A certified biofeedback practitioner should consider a license. 'IMUNE' offers a license in biofeedback.

So if the credit for results can be transferred to the philosophy and the developers not the devices, it will benefit us all. We have something special but it transcends the devices. What is truly special is the work of Selye, Szent Georgi, James Issacs, and me. The device works only with a trained therapist. Europe has much more freedom than its unenlightened restrictive and fearful partner America. We must be more patient with our primitive and backward partners. America and its addiction to money are fearful of therapies that do not involve synthetic drugs. More of this later, but first we must shift claims and assertions from the devices to the developers or to the philosophy. I know that when someone spends so much money on a device they want to talk about it to gratify the expenditure, but simply transfer the enthusiasm to the correct address.

These changes must be implemented universally immediately. Please give us some feedback.

Bill Nelson

FDA Registration General

The following response is from Bill Nelson to an email

Let me first tell you that it is extremely difficult to get registration with the FDA and Europe. Especially a Class 2B registration like we have in Europe. It is extremely difficult to keep such registration. We have to constantly read and re-read the laws, go to

seminars, schedule audits and investigations. It is a massive effort. It is an effort that we do and we do well. It is an effort that we MUST do well to protect you.

We are not afraid of investigations because we are on top of the law and on top of compliance. The FDA is not allowed to confront people about practicing medicine without a license. That is not a Federal concern. Practicing medicine without a license is always a state issue. It involves an irregularity of the person - not the device. We have talked to FDA Regulators and everything is fine and we are still in compliance. Everybody is on the radar and I mean EVERYBODY in the Health Care Profession from blood pressure cuffs, microscopes, CAT Scans, etc., etc. We all must be prepared to defend ourselves. We have nothing to fear. We have a deep degree of professionalism and legality.

The FDA was designed by a homeopath to protect the citizens of the United States from illegitimate, fraudulent claims that do not comply with proper quality control. Many see the FDA as the enemy, but the FDA is needed because only the FDA can stop 'bait and switch' cons or other unsanctioned and improper company claims.

The FDA is not our enemy. We must work with these people. They do have good intentions. It is a constant fight and struggle for natural medicine. It is never easy, as I can tell you from over 30 years of experience. We work within the law. We work within the FDA compliance. We work within the concepts of Natural Medicine.

Bill Nelson

Current Situation

1. The EPFX device registration owner has been the Ecllosion Corporation since 1989 and this has been maintained. In 2004 the Ecllosion 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.

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.

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 3 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 a regulatory criteria for participating in the research study. Informed consent is available in several places.

See IRB Document for full details