

Bio Energy Partnership

Supporting Quantum Users

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The following information is for presentation to an Insurance Company.

Information for Insurance of the QXCI Biofeedback Device

The QXCI & SCIO Devices

The QXCI carries a CE Classification and Certification as a Class 1 Biofeedback Device. It is manufactured in Hungary.

The SCIO carries a CE Classification and Certification as a Class 2 Device. It is manufactured in Hungary.

The primary functions are stress detection and stress reduction. This is achieved by a biofeedback loop using a computer interface. It is not a diagnostic medical device. No therapeutic claims are made for the system.

The definition of Biofeedback is “measuring a physiological response and feeding it back to the patient”. Evoked Potential Biofeedback is Transcutaneous (on the skin) Electro Nerval Stimulation. This system measures evoked potential reactions of the patient to applied stimulations. This is evoked potential Biofeedback. This device catalogues and tabulates the complex evoked potential electro physiological reactions of a client. This is the EPR pattern. The accuracy of the EPR pattern is limited as such the results can be treated only as pre-diagnostic.

It is used for safety purposes and for conformity with CE rules either on battery power or mains powered via a surge/spike protector and an Earth Leakage Breaker (ELB).

Training and Certification

A Certificate of Competence has been established during 2001 to meet the requirements of UK Insurers. It is issued by a trainer certified by the manufacturer’s educational organisation. This specifically relates to safe use of the device. Users are able to apply by submission of a record of training and a safety oriented questionnaire.

This approach was originally requested by Sun Alliance via Shephards Insurers and has been accepted.

Technical Documentation

Due to EC legislation which has come into effect on 1st June 2001 Medical Device Equipment manufactured, CE Certified and Registered in Hungary no longer needs registration with the MDA (Medical Devices Agency). The specific protocol is the Hungarian PECA.

The relevant considerations that still apply are that:

1. The Device has an EC Declaration of Conformity (Issued 25th December 1999)
2. The CE certificate and prescribed manufacturer contact details are shown on the equipment.
3. The device and Manufacturer are registered with a Competent Authority (See Quality Certificate issued 1997.04.10, ORKI- National Institute for Hospital and Medical Engineering).

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