

Update to device label and Installation Manual for all devices, all countries

Dear All:

The following procedure has been reviewed and it has been decided that the term "medical professional" will be replaced by the term "HEALTH CARE professional."

This change will be reflected on the label on the bottom of the biofeedback box as well as in the Installation Manuals that are shipped with the devices.

Richard

Richard Lloyd <lloydqxc@yahoo.com> wrote:

Dear All:

Pursuant to FDA requirements, our devices will have a new label affixed to the bottom effective December 1, 2005. This information will also be listed in the EPFX Installation Manual, SCIO Installation Manual, and the QXCI Installation Manual on the DISCLAIMER page. The label will be on all devices irregardless of country.

The label and Disclaimer page will say the following:

"This device is to be used as a BIOFEEDBACK and STRESS REDUCTION system only. Use this device with a computer on battery mode free from wall current or with a medically safe surge protector. **Do not use this device with a pacemaker.**

Caution: Federal Law (USA) restricts this device to sale in the United States by or on the order of a medical professional."

These steps bring us closer to FDA Compliance. Failure to have this information as a label on our device and on the Disclaimer in our Installation Manual may be determined by an FDA Compliance Officer to be a violation of the original 510k of our device.

You should be aware that a Risk Analysis was completed per FDA requirements to determine if a patient with a pacemaker may experience electrical conflict if attached to the device. The FDA Risk Analysis has determined this situation to have a severity level of 5 meaning "death", but a probability level of 1 meaning "improbable." The FDA Risk Analysis procedure recommends that we inform our customers with a label of the potential risks of using the device with a pacemaker. By phrasing it with such intensity as "**Do not use this device with a pacemaker**" then we are putting the responsibility in the hands of the user and patient if they decide to use the device.

For those customers in the United States, there is going to be some difficulties with the Federal Law requirement. This statement, again, is required per the original 510k for the device. The phrase "medical professional" leaves it open for a doctor, dentist, chiropractor, nurse, medically certified/licensed massage therapist, etc. We are willing to listen to feedback from the North American Brokers to see what they think

about this requirement. If someone on your staff or in your chain or Networkers is a medical professional, then a letter from them ordering the sale should be sufficient.

If you have any questions on any of these items, please feel free to contact me.

Best regards,

Richard Lloyd