

The Laws Governing All Clinical Biofeedback Devices

What is a clinical biofeedback device?

All biofeedback devices operated in the USA, Canada, North, South and Central America, the European Union, British Commonwealth and most of Europe are clinical biofeedback devices by law. The government has the right to allow or to deny any manufacturer to manufacture market or sell any biofeedback device in their state, province or country.

The key things to remember about the laws pertaining to biofeedback and neurofeedback equipment as you proceed with this correspondence course, and the Coaching Skills Workshop for Biofeedback Professionals, are:

1. Biofeedback devices are medical devices in North, Central and South America, the European Union and some other countries in Europe, India, China, Australia, New Zealand, South Africa and other British Commonwealth countries.
2. If your country isn't listed, you need to check with your government to see if biofeedback devices are classified as medical devices or not. If they are, then the rest of these important points apply to you. If not, they don't.
3. The intended use for all biofeedback equipment in these countries is "relaxation and muscle re-education to manage stress and pain and improve the quality of life." These are the only claims that may legally be made about biofeedback devices in all of the countries listed.
4. Licensed chiropractors, counselors, dentists, medical doctors, homeopathic medical doctors, naturopathic medical doctors, oriental medical doctors, osteopaths, psychologists, psychotherapists and veterinarians may use biofeedback for any purpose under the scope of practice allowed by their license.
5. Biofeedback professionals who are not licensed in one of these professions must be certified in biofeedback or neurotherapy as a therapist or specialist by an accredited and approved certification board. (Currently that includes only BCIA and NTCB.) There are no exceptions to this law other than the licensing laws mentioned above.
6. All other biofeedback professionals must be supervised by a health care professional licensed in one of the above professions or certified by an accredited and approved certification board. It is a felony in most

jurisdictions for an unlicensed, uncertified biofeedback professional to provide services for a fee or donation to the public if not properly supervised.

7. Any person or persons who use biofeedback for their own personal purposes only may be exempt from the requirement to be licensed or certified under either of two conditions. These exceptions apply if the person or persons: 1) have a prescription for the device from a licensed or certified professional as defined above, or 2) purchase a commercially available retail consumer biofeedback device classified as a game or entertainment device.

Where can I find a biofeedback device?

Consumer biofeedback devices are commercially available through retail stores, over the Internet and by mail order. If you have any questions about whether operating any biofeedback device without a license, certification or prescription is legal, ask the manufacturer for a letter explaining why it is legal. If the manufacturer refuses, report that manufacturer to the regulatory agency for biofeedback in your country. In the USA that agency is the FDA (800-332-1088). In Canada call Health Canada at (613-957-0368). In the European Community call the EC medical devices representative listed in the directory for your country. In the rest of the world, identify the name of the regulatory agency and obtain their number from your medical licensing agency.

Clinical biofeedback devices are available through distributors and manufacturers directly or over the Internet. You can search the Internet for specific medical topics that interest you or for "biofeedback devices." A better way may be to join on-line discussion groups and ask what other people are using, or to speak with local biofeedback professionals. Health fairs are usually a good place to find biofeedback practitioners willing to help you.