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The firm of Swankin & Turner has reviewed the Quantum Clarity Reactivity Report template produced by, Quantum Clarity, for compliance with United States Food and Drug Administration regulatory requirements and has concluded that, when used as directed by Quantum Clarity Reactivity Report template complies with United States federal regulatory requirements.

The directions for use for the report make clear that nothing in the report is intended to in any way change the conditions of use that govern the use of any SCIO or INDIGO device. Specifically, a SCIO or INDIGO biofeedback device is to be used for relaxation training and muscle reeducation. All of the claims and uses of the device must be for relaxation training and muscle reeducation for use for patients with stress. A practitioner may use the information obtained in this way in conjunction with the scope of practice authorized by their license or certification.

The purpose of the biofeedback system with which the Quantum Clarity Reactivity Report is designed to work is to provide the patient with insight into the subtle changes in their temperature, skin resistance (sweat), and muscle voltage. No claims are to be made for the ability of biofeedback to treat any medical condition. Proper use of the Quantum Clarity Reactivity Report as directed by Quantum Clarity does not conflict with this requirement.

The SCIO or INDIGO systems do measure subtle body electric and thermal changes in the patient and feed them back to the patient via audio or video signals. These signals give the patient awareness of the electrical and thermal changes and thus allow them to better relax. Quantum Clarity Reactivity Report adds precision to these observations but does not change in any way the nature of the claims that can be made for the systems themselves.

As a matter of freedom of speech, anyone is free to state their praise for any product and they are free to tell anyone. However, if firms or clinicians use such testimonials they are considered to be labeling, since they are promoting the device, or making claims for the device. Claims outside of the indications for use indicated above made by a therapist are inappropriate and could trigger regulatory action against the practitioner.

The Quantum Clarity Reactivity Report is the product of a software tool designed for use with SCIO and INDIGO Biofeedback Systems. The systems the report is intended to work with are designed to simultaneously detect and record information about the various stress reactions of individual users. The Reactivity Report software is designed to extract results from the SCIO and INDIGO tests, organize and structure the test results into an easy to understand report template and to store the information.

The information contained in the Quantum Clarity Reactivity Report carefully presents the biofeedback information obtained by the software in a manner that meets the requirements of United States federal law concerning devices that are not intended to treat, diagnose, prevent, cure or mitigate disease. The information contained in the Quantum Clarity Reactivity Report is intended to record various stress reactions and is in compliance with recognition accorded the SCIO and INDIGO systems by the United States Food and Drug Administration.

The reports as designed and the instructions for use of the reports are presented to make clear that the reports are

not intended to be used to treat, diagnose, prevent, cure or mitigate any disease. All users of the reports are instructed not to use the reports to treat, diagnose, prevent, cure or mitigate any disease. The statements of intended use in the language of the reports comply with the US Food and Drug Administration's regulatory requirements for the SCIO and INDIGO biofeedback systems.

Details of Biofeedback device usage compliance

The following statements set forth more detailed guidance for practitioners on the use of biofeedback devices:

- Voltammetric signatures have been clearly established as an acceptable term in Biofeedback
- Voltammetric signatures have been accepted as established measures of Isode, Nosode, Sarcode, Imponderables

To avoid adulteration[1] and misbranding[2] claims or classification as a medical device[3], biofeedback devices should conform to the following:

- Unless the specific model of the device has been recognized by the FDA to do otherwise, neither the label nor any promotional materials for the device may claim, either expressly or impliedly, that the device cures, diagnoses, mitigates, prevents, or treats disease. SCIO and INDIGO devices have not been so recognized; The Quantum Clarity Reactivity Report in no way changes this fact;
- The label and any promotional materials for the device may not state any new indications for use beyond those uses allowed by the FDA under the clearances provided by the FDA under Section 510(k) of the Food, Drug and Cosmetic Act. SCIO and INDIGO devices are limited by the statement above. The Quantum Clarity Reactivity Report in no way changes this fact;

Additionally, biofeedback practitioners should ensure that they do the following:

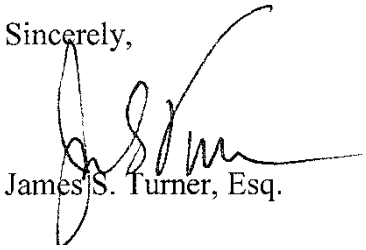
- Provide the client with a written statement that a biofeedback report generated on any given day only reflects the reactivity for that particular day, and that reactivity may vary from day to day
- Inform the client that analysis of biofeedback reports may vary depending on the practitioner's scope of practice
- Inform the client that the biofeedback report provides information that may be used to track the client's reactivity from session to session, thus allowing for identification and analysis of possible stress patterns
- Inform the client that the biofeedback report, in and of itself, should not be construed as recommending any course of action by the client
- Inform the client that the biofeedback report should not be construed as recommending the use of any drugs or dietary supplements by the client
- Inform the client that contraindications for biofeedback may include:

[1] 21 U.S.C. § 351(f)(l)(B)
[2] 21 U.S.C. § 352(o)
[3] 21 U.S.C. § 360c.

- Unevaluated symptoms -- biofeedback may provide relief from various symptoms, and this relief of symptoms may mask underlying medical problems; therefore, clients should not use biofeedback treatments in the place of appropriate medical evaluation and treatment
- Severe hypertension
- Psychosis and acute psychiatric disorders
- Cognitive impairments that interfere with an understanding of the biofeedback process.

Apprehension of the biofeedback process

Sincerely,



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