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Fact Sheet for Biofeedback

Warnings and Contraindications

The following contraindication have been listed by the manufacturer of our biofeedback device in their user manual.

Part 5.2 Warnings

The following warnings have been established based on our risk analysis and must be implemented in your use of the device.

1. DO NOT use this device if the client/patient has a pacemaker.
2. DO NOT use on clients/patients with epilepsy.
3. DO NOT use on clients/patients with electrical hyper reactivity.
4. DO NOT connect the harnesses over irritated, inflamed, red or broken skin.
5. DO NOT use on pregnant women.
6. DO NOT use on children under 3 years of age.
7. DO NOT use on clients/patients who are under the influence of drugs or alcohol.

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Part 5.4 Undesirable side effects:

Post Market surveillance shows that some clients have experienced these undesirable side effects:

- A slight feeling of lightheadedness after a session. Please note that this may be due to the client's own health such as high blood pressure, or the sudden standing up after being in a relaxed, reclined position during a session. If this feeling feels in any way abnormal or of a concern, then the client should see their primary healthcare practitioner.
- Through biofeedback transcutaneous interaction with the Central Nervous System the SCIO may induce an Autonomic Nervous System Cascade that can lead to a vasovagal crisis. The client might sweat excessively, report nausea, and dizziness. If this occurs, place a cool, wet rag over the eyes gently with light pressure, tell the client to relax, breathe deeply, and wait about 5 to 10 minutes for the vasovagal storm to pass. In extreme cases there might be a syncope (fainting).
- Some clients are highly sensitive to certain plastics, rubbers, or metals. These are usually people who do not wear a lot of jewelry and who do not use a lot of lotions or perfumes. Some clients have noted a slight redness of skin where the harnesses were connected to the client. If this is of concern, then the client should consider not returning for another session until they see their primary healthcare practitioner.

I have read and understand what I have read:

Signature _____ Date _____