New IEEE Draft Standard Developed by Collaborative Working Group

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How can purchasers and users of neurofeedback equipment be sure what they are getting? Do they know the working principles, design elements, and performance details of their equipment? Is there a uniform standard that can be used to ensure uniformity of expectations and outcomes? Dr. John Nash, while president of the ISNR in 2009, asked these questions, and came up with an unfortunate "no." In response to this need, he chartered a group to look toward establishing an industry standard that could pave the way to create uniform standards and recommendations for neurofeedback systems design, documentation, and training. The result of this effort has now been approved by the Institute for Electrical and Electronics Engineers (IEEE) in the form of a draft standard. In much the same way that standards ensure that your television or cable device works correctly, or that an MRI machine meets relevant requirements, this standard sets out criteria and recommendations for neurofeedback systems. It is intended for systems that comply with this standard to meet a minimum level of performance and understandability and that this will help to ensure uniform clinical experiences and outcomes.

A working group of the Institute for Electrical and Electronics Engineers (IEEE) has drafted a Recommended Practice Standard for Neurofeedback Systems, published in June of 2012. The standard was created based upon the initial efforts of John Nash, while president of the ISNR. John saw the need for a standard that could guide neurofeedback systems developers, as well as users, in ensuring the validity, quality, and understandability of neurofeedback devices and software, amid an ever-changing world of technology and methods. The committee was formed in 2010, and consisted of Chair Tom Collura representing BrainMaster Technologies Inc., Vice-Chair Howard Lightstone representing EEG Software, Marc Saab representing Thought Technology, Cynthia Kerson and Nancy Wigton representing the ISNR, Alan Pope from NASA representing the AAPB, Klaus Schellhorn from neuroConn, and Sara Aguel and Michael Hoffman representing the US FDA. This standard was developed following the IEEE's established procedures, and has been approved by the IEEE Standards Association as a recommended practice. The majority of the drafting work was done by Howard Lightstone and Marc Saab, but all group members contributed their time and expertise.

This standard includes nine sections describing recommended design, testing, and documentation. The major areas covered are general (regulatory, training, and marketing), system components, electrodes and sensors, data acquisition, software, computers, and user documentation. The standard includes a detailed conformance statement that providers can fill out, to describe and document their compliance with the standard. A provider who follows this standard will be providing equipment, software, and documentation that meet industry-wide expectations for how the system is designed and functions, so that it meets the needs of the neurofeedback community. Providers will have to be clear about how they are processing data, presenting feedback, and how the performance of the system can be traced to the system design and specifications. This standard is not intended to limit or shackle any developers or manufacturers; rather, by providing a standard of clarity and documentation, it will help providers ensure that users understand and use their equipment to best advantage. It will also help to ensure the repeatability and consistency of neurofeedback results, based upon objective standards.

This standard does not dictate exactly how systems are designed. It defines the four major components and delineates how they should be described and documented, to ensure that users know what they are using. The electrode/sensor component should use standard nomenclature, and should define the usage and lifetime expectations of the sensors. Stability and related factors should also be stated. This is increasingly significant as neurofeedback moves from the traditional 1–30 Hz operation into low-frequency work below 1 Hz, and into high-frequency work, including Gamma at 40 Hz, 60 Hz, or beyond. One provision of the standard is that frequency response including corner frequencies, rolloff, attenuation, and other parameters be clearly stated, and supported by testing. Of particular importance is the issue referred to as "shaping," which includes how artifacts and/or key EEG values are detected and rewarded, how controls such as sustained reward conditions or refractory periods are used, and how baseline or historical data are used in the system processing algorithms.

With regard to software, the standard states that transformations such as digital filtering, characterization and shaping of EEG data, and response characteristics be described and validated. This will help to ensure that practitioners have confidence that their equipment and software are performing as expected, and that all performance claims are supported by proper evidence and data.

Major Sections of IEEE P2010 Recommended Practice for Neurofeedback Systems

1. Overview: scope, purpose, conformance
2. Definitions
3. General: information, regulatory, training, marketing
4. System components, system-level specifications
5. Electrode/sensor nomenclature, specifications, cleaning, maintenance, application
6. Acquisition: amplifier, frequency response, analog-to-digital conversion
7. Software: general, timing, transformations, user controls, data, post-session data
8. Computer: specifications, display
9. User documentation: operator, installation, technical manuals
10. Annex A: implementation conformance statement
11. Annex B: bibliography

Critical user-interface issues are also addressed, such as the uniform use of color, the ability to change colors if required, the availability of impedance and signal quality data, and information support displays. Systems should have adequate flexibility for selecting and viewing information in real time, and selecting which bands or components are to be displayed or used for feedback. Also, times and dates, as well as changes in settings, should be stored along with data, to facilitate quality evaluation and ensuring that parameters can be verified in conjunction with data or statistical reviews. Data formats, and HIPAA conformance are also addressed. While the details of an implementation are not dictated, systems should be able to package data in suitably portable formats, and it should be possible to operate a system in a HIPAA-compliant manner, even if the system does not specifically support HIPAA-related features. Playback, analysis, review, and user documentation are also described, with minimum requirements specified for a basic system.

An important issue raised by this new standard is how it will be validated, and by whom, for each provider. Providers can complete the Implementation Conformance Statement that is built into this standard, but some type of third-party verification will likely be desired. We anticipate that a competent evaluating body, such as are now used for compliance with other specifications, can be brought into this effort to provide auditing and certification services. The IEEE has a Conformity Assessment Program (ICAP) that is working with this group to establish the procedures and guidelines. It is possible, although not certain, that the FDA or other regulatory bodies may look for compliance with this standard as part of achieving certification to 510(K), exempt status, or other approvals.