

IEEE Recommended Practice for Neurofeedback Systems

IEEE Engineering in Medicine and Biology Society

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of the
IEEE Engineering in Medicine and Biology Society

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Abstract: A detailed set of documentation requirements is proposed. The detailed requirements for the documentation of neurofeedback instruments and software to provide quality and availability of information to users are specified.

Keywords: biofeedback, biofeedback assessment, biofeedback equipment, biofeedback instrumentation, biofeedback software, biofeedback training, IEEE 2010, neurofeedback, neurofeedback assessment, neurofeedback equipment, neurofeedback instrumentation, neurofeedback software, neurofeedback training

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Participants

At the time this recommended practice was completed, the Neurofeedback (EEG Biofeedback) Systems Working Group had the following membership:

Thomas Collura, *Chair*
Howard Lightstone, *Vice Chair*

Sara Aguel
Michael Hoffman

Cynthia Kerson
Alan Pope
Marc Saab

Klaus Schellhorn
Nancy Wigton

The following members of the entity balloting committee voted on this recommended practice. Balloters may have voted for approval, disapproval, or abstention.

Association for Applied
Psychophysiology and
Biofeedback (AAPB)
BrainMaster Technologies, Inc.
EEG Education & Research, Inc.

International Society for
Neurofeedback & Research
(ISNR)
K-micro (Kawasaki
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SanDisk Corporation
Thought Technology, Ltd
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Administration (FDA)

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John Kulick, *Vice Chair*
Robert M. Grow, *Past Chair*

Satish Aggarwal
Masayuki Ariyoshi
Peter Balma
William Bartley
Ted Burse
Clint Chaplin
Wael Diab
Jean-Philippe Faure

Alexander Gelman
Paul Houz e
Jim Hughes
Joseph L. Koepfinger*
David J. Law
Thomas Lee
Hung Ling
Oleg Logvinov

Ted Olsen
Gary Robinson
Jon Walter Rosdahl
Sam Sciacca
Mike Seavey
Yatin Trivedi
Phil Winston
Don Wright

*Member Emeritus

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Richard DeBlasio, *DOE Representative*
Michael Janezic, *NIST Representative*

Don Messina
IEEE Standards Program Manager, Document Development

Kathryn Bennett
IEEE Standards Program Manager, Technical Program Development

Matthew Ceglia
Client Services Manager

Introduction

This introduction is not part of IEEE Std 2010-2012, IEEE Recommended Practice for Neurofeedback Systems.

There is considerable variation in the marketplace for electroencephalography (EEG) biofeedback (neurofeedback) equipment, software, and user training. There is no stated set of minimum documentation requirements under which systems provide effective and meaningful feedback and that system operators can understand and interpret results. This recommended practice is intended to put forth minimum guidelines for the documentation of neurofeedback instruments and software.

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1. Overview

1.1 General

Neurofeedback (NFB), also called electroencephalography (EEG) biofeedback, is a type of biofeedback that uses real-time electroencephalography to illustrate brain activity with a goal of modifying EEG activity. Sensors are used to capture neuronal activity at the surface of the scalp and electronic equipment is used to transmit that activity to a computer for processing and multimedia display to the user.

1.2 Scope

This recommended practice describes electroencephalography (EEG) biofeedback (neurofeedback) systems and software to optimize the quality and availability of information available to device users.

1.3 Purpose

This recommended practice describes the minimum standards sufficient to verify that conforming EEG biofeedback systems provide quality biofeedback results and information that is clear.

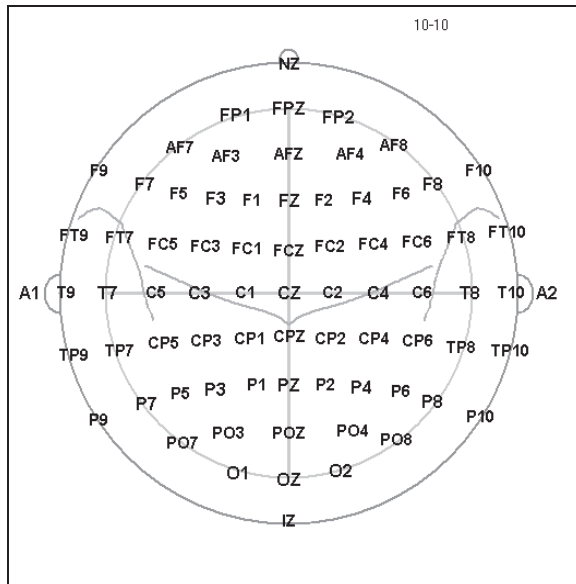
1.4 Conformance

A correctly filled-in implementation conformance statement (Annex A) documents compliance with this recommended practice.

2. Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.¹

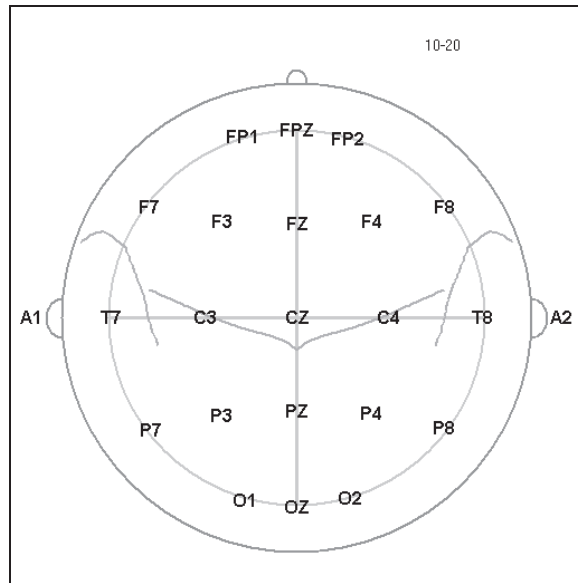
10-10 electrode system²: A system of electrode placements for acquisition of scalp electroencephalography. The “10-10” title means that the placements are every 10% around the circumference of the head (like a hat measurement) and every 10% of the distance from nasion (front) toinion (back) over the top of the head (ACNS [B1] and Jasper [B9]). It is defined by the placement shown in the following figure.



¹ *IEEE Standards Dictionary Online* subscription is available at: http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.

² The standard placements used are derived from American Clinical Neurophysiology Society, Guideline 5: Guidelines for Standard Electrode Position Nomenclature. Available online: www.acns.org/pdfs/ACFDD46.pdf. Copyright © 2006 by American Clinical Neurophysiology Society, and generally used throughout the EEG world. ACNS is a member society of the International Federation of Societies for Electroencephalography and Clinical Neurophysiology. Also, see Jasper, H. H. “The ten-twenty electrode system of the International Federation.” *Electroencephalography and Clinical Neurophysiology* 10, no. 2 (1958): 371–75. <http://www.ncbi.nlm.nih.gov/pubmed/10590970>.

10-20 electrode system of the International Federation: Most widely used electrode placement for acquisition of scalp electroencephalography (ACNS [B1] and Jasper [B9]). It is defined by the placement shown in the following figure.



activation: Excitation/inhibition; referring to operant conditioning process.

amplifier: A device that draws power from a source other than the input signal and produces as an output an enlarged reproduction of the essential features of its input (Graf [B5]).

analog to digital converter (A/D): A device that changes an analog signal to a digital signal of corresponding magnitude through discretization (Laplante [B11]).

artifact: Any distortion of the electroencephalography signal from any physiologic source other than the brain or any non-physiologic source that may interfere with the interpretation of the signal.

average value (P-P): The “average value” traditionally used in neurofeedback is actually the “equivalent peak-to-peak” voltage value assuming that the signal being measured is a sine wave. The normal method of calculation is to sum the absolute voltage values of each signal sample, divide by the number of samples, and $2 \times \sqrt{2}$ to get the peak-to-peak equivalent.

baseline: Status of brain activity when not engaged in a feedback/operant conditioning process.

characterization: The extraction of significant features from the EEG waveforms.

client: Person who is receiving neurofeedback (i.e., is connected to a neurofeedback system); person from whom electroencephalography signal is being acquired.

clinician: Person responsible for ordering (prescribing) as well as interpreting and making clinical decisions about neurofeedback; oversees the neurofeedback session. This person is also responsible for the technician.

coherence: Measure of phase relation of two processes at a specific frequency band (ACNS [B1]).

common mode rejection ratio (CMRR): A measure of amplifier quality with differential inputs, defined as the ratio between the common-mode gain and the differential gain (Laplante [B11]).

component: A major element of a neurofeedback system (acquisition, software, etc.).

corner frequency: Frequency designating the meeting between the transition band and passband; frequency at which gain crosses -3dB (typically) (Graf [B5]).

digital filter: A linear computation or algorithm performed on a selected series in the form of an input signal that produces a new series as output (Graf [B5]).

EEG activity/frequency bands (alpha, theta, delta, sensorimotor rhythm, beta, gamma, etc.): There are many definitions for naming electroencephalography data bands. Typical names/ranges (from Fisch [B4]) are:

DC-EEG: < 0.1 Hz

delta: 0.1 to < 4 Hz

theta: 4 to < 8 Hz

alpha: 8 to 13 Hz

beta: > 13 to 30 Hz

SMR (sensorimotor rhythm): rhythm seen in signals over the sensorimotor cortex; usually considered in the range 12 to 15 Hz

gamma: > 30 Hz (particularly 36 to 44 Hz)

electroencephalograph (EEG): Instrument for recording the electrical potentials produced by the brain by the use of electrodes.

event related potential (ERP): Evoked activity of the brain related to a sensory stimulus; derived by averaging electroencephalographic activity with respect to stimulus onset.

fast Fourier transform (FFT): Computational technique that reduces the number of mathematical operations in the evaluation of the discrete Fourier transform (DFT) to $N \log_2 N$ (Laplante [B11]); where DFT is a transform for Fourier analysis of finite-domain discrete-time function; used to convert the input signal from time domain to frequency domain.

finite impulse response (FIR) filter: A FIR filter is a non-recursive method for extracting frequency information from a time-sampled input. FIR filters typically have good phase accuracy but poor amplitude fidelity. FIR accuracy is a function of the number of samples used.

frequency response: (A) The portion of the frequency spectrum that can be sensed by a device within the specified limits of amplitude error (Graf [B5]). (B) The range of frequencies over which an amplifier responds within the defined limits of amplification or signal output (Graf [B5]). (C) Range or band of frequencies to which a unit of electronic equipment will offer essentially the same characteristics (Graf [B5]).

haptic: Of, or pertaining to, a sense of touch; tactile.

IIR (infinite impulse response) filter: An IIR filter is a recursive method for extracting frequency information from a time-sampled input. IIR filters typical have poor phase accuracy but good amplitude fidelity.

joint time frequency analysis (JTFA) filter: JTFA filters analyze data in both time and frequency domains simultaneously; this is done by segmentation of the time series into shorter epochs, the determination of the amplitude of the frequency of interest in each epoch, and the analysis of the time course of modulation of the amplitude of the frequency of interest (ACNS [B1]).

operant conditioning: A form of learning or modifying behavior during which individuals modify their own behavior due to the consequences of that behavior. Neurofeedback uses responses based on electroencephalography data as the stimulus for the desirable rewards (positive consequences).

passband: Range of frequencies, or frequency band, for which a filter passes the frequency components of the input signal (Laplante [B11]).

peak-peak voltage: The peak-peak voltage is twice the amplitude of the voltage being sensed/measured. For simple sine waves, the value is easily determined. For complex electroencephalographic waves, an average value is computed and the peak-peak voltage is inferred from that result.

phase: Angular relationship between two waveforms.

product: The component(s) sold or provided by a manufacturer.

quantitative electroencephalography (QEEG): Mathematical analysis of electroencephalograph waveforms used to extract discrete data and output specified parameters. The electroencephalography data can be algorithmically analyzed by the size, frequency, and/or the locality of the electrical activity. These datasets can be reported either absolutely or relative to some other dataset. The data is typically presented in tabular form or as topographic maps.

rolloff: Transition region between passband and stopband; usually reported as a function of logarithmic frequency in decibels per decade or decibels per octave.

session: Single administration of neurofeedback to the client by the clinician or by the technician but overseen by the clinician. There may be multiple electrode placements and/or shaping actions within a single session. A neurofeedback regimen may necessitate multiple sessions.

shaping: The use of significant features of the electroencephalograph (EEG) waveform in the operant conditioning process to alter the EEG waveform. Shaping implies control over which elements of the transformed waveform are used and how they are applied in producing the operant conditioning stimulus.

slow cortical potentials (SCP): A feedback signal generated from lowpass filtering of artifact-corrected electroencephalograph using a sliding averaging window. The frequency range is usually considered 0 to 2 Hz (Hinterberger [B6], ACNS [B1]).

stopband: Range of frequencies attenuated by a filter with some specified attenuation.

technician: Operator of neurofeedback system while the client is connected to a neurofeedback system.

threshold: Term used to describe the setting of a point at which a transformed value is acted upon (such as artifact detection).

wavelet filters: Wavelet filters use a computation method based on harmonic analysis rather than the Fourier transforms used by traditional filter methods. Wavelet filters can contain either finite impulse response or infinite impulse response filter banks.

3. General

3.1 Availability of information

The information outlined in this standard shall be made available to the user in the documentation delivered with the product, in the marketing, in the training literature, or upon request. This should include but not be limited to the following:

- a) Detailed descriptions of the technology, functionality, and features
- b) Detailed instructions about installation, configuration, usage, and methodology
- c) Specifications of each component of the system
- d) Descriptive diagrams, images, and software screen captures where applicable to complement the instructions
- e) Description of the hardware and software components as well as the use of the system, as a whole
- f) Information to aid in the detection of failures and understanding of the consequences of failures or misuse

The details of each of the above points are contained within the subsequent sections of this standard. Guidelines for adequate user documentation are provided in Clause 9.

3.2 Regulatory requirements

3.2.1 Safety

The manufacturer shall document the system adherence to the IEC 60601-1 Safety and Essential Performance standard [B7].³ Certification documentation of adherence to IEC 60601-1 (as recognized by the regulatory body within the country of sale) should be made available on request by the user.

3.2.2 Intended use

The intended use of the system should be disclosed and should be consistent with the regulatory laws governing medical devices within the country of sale. This implies that the system should be sold as a “medical device,” and thus should adhere to the medical device regulations within the country of sale.

3.2.3 Efficacy claims

Any claims as to the efficacy of the intended use should conform to applicable regulatory requirements in the country of sale.

³ IEC publications are available from the International Electrotechnical Commission (<http://www.iec.ch/>). IEC publications are also available in the United States from the American National Standards Institute (<http://www.ansi.org/>).

3.3 Training

Training should be made available to the user such that all topics covered by the documentation described above are also available as instructions to the user. Training can be delivered in person, via webinar or online course, or prerecorded and available on the internet or electronic media.

3.4 Marketing

All claims made shall not exceed the boundaries of the intended use listed in the medical device registration or applicable required documentation of the product within the country of sale.

4. System

A product is considered a system when it includes two or more components operating together to achieve the desired output. When describing a system, in addition to the specifications of each component outlined in 3.1, the manufacturer shall also make available system-level specifications which indicate the performance of the components operating together. These are described in 3.2.

4.1 Components

The following information should be categorized by component and made available in the documentation accompanying the system.

- a) *Electrode/sensor component*: This includes electrodes or other sensors, retention accessories, skin preparation gel, conductive paste or other electrolyte, and other accessories (as outlined in Clause 5).
- b) *Acquisition component*: A system component which captures the raw signal for transmission to the feedback mechanism. May include the feedback mechanism presented to the operator (as outlined in Clause 6).
- c) *Software component*: A computer program that takes as input a raw signal from the acquisition component, processes it, and outputs it (as outlined in Clause 7).
- d) *Computer component*: The computer and display hardware. This contains the acquisition component interface and executes the software component (as outlined in Clause 8).

4.2 System-level specifications

The following system-level specifications shall be made available in the documentation accompanying the system:

- a) *Acquisition component/computer interface*. The method of communication between the measuring device and the computer should be described in detail, including the technology and version number.
- b) *Overall system latency*. An estimate of system latency shall be provided. This should include three cases: a best case, a worst case, and a most likely case (describing the scenario in which the majority of users would find themselves the majority of the time). In the event of several common

usage scenarios each of which elicits different performance from the system, an estimate should be provided for each usage scenario. Estimates will vary based on the following factors:

- 1) Computer minimum requirements and overall performance specifications
- 2) Computer operating system (versions) and background software
- 3) Acquisition component/computer interface specifications
- 4) Features of the neurofeedback software, on-screen or otherwise, activated/deactivated
- 5) Number of simultaneous input signals
- 6) Use of third-party technology

5. Electrode/sensor component

5.1 Electrode nomenclature

5.1.1 Standard usage

Standard nomenclature for electrode sites is shown in Clause 2. The latest standards for electrode nomenclature should be used (ACNS [B1] and Jasper [B9]).

5.1.2 Non-standard usage

Non-standard site locations should be clearly documented.

5.2 Electrode specifications

The specifications of electrode systems provided, or of the third-party electrode systems supported, shall be provided. For cases in which this varies according to application, performance characteristics for each application should be described. These include:

- a) *Electrode lifetime*: The maximum usage time during which the electrode performs within the specifications listed. This may be reported in duty cycle or overall usage time (e.g., the electrode lifetime is approximately 250 applications or 950 hours).
- b) *Electrode performance/noise over the system bandwidth of operation*: This may be reported in sections of bandwidth according to usage scenarios and various applications (e.g., for dc recordings, low frequency performance in the bandwidth of 0 to 0.1 Hz may be reported).
- c) *Polarization rate*: This should be reported in conjunction with the electrolyte recommended for use with the electrodes for the given application. A different rate may be reported for different electrodes and electrolyte combinations.
- d) *Long-term stability*: This should be reported as the maximum single usage time during which performance is maintained. The level of performance should also be reported (e.g., noise level below 0.1 μV for 3.5 hours).

5.3 Electrode cleaning and maintenance

Detailed cleaning and maintenance instructions shall be provided for reusable electrode systems, including:

- a) *Cleaning*: Instructions should recommend regular and careful cleaning with specific guidelines to provide proper performance (e.g., rinse with lukewarm water and hang dry, do not soak).
- b) *Supplies*: Adequate cleaning and maintenance supplies should be recommended. Products to be avoided should be explicitly listed (e.g., 70% ethanol-based alcohol is recommended instead of 99% isopropyl alcohol).
- c) *Wear*: Recommendations for identifying and protecting against performance degradation from wear should be included.
- d) *Sterilization*: If applicable, guidelines for sterilization in a clinical setting should be provided.

5.4 Biocompatibility

This includes biocompatibility of the electrode material, electrode retention system, and any accessory that is in contact with the skin during use.

- a) *Biocompatibility requirement*: All elements of the electrode system shall be biocompatible and tested appropriately for conditions of use (e.g., limited skin contact less than 24 hours) in accordance with ISO 10993.⁴
- b) Biocompatibility certification should be provided to the user upon request.

5.5 Electrode application

5.5.1 Preparation

Instructions for adequate scalp preparation and fixing of the electrodes on the scalp (can vary depending on the type of electrode) should be provided.

5.5.2 Placement

Detailed instructions for placement including reference to the international 10-20 system (and/or 10-10 and/or others as documented) or another method of providing placement repeatability taking into account inter-patient variability should be provided.

5.5.3 Cautions and warnings

Usage notes designed to avoid commonly made errors which lead to performance degradation should be included (e.g., mismatched electrode materials).

⁴ ISO publications are available from the ISO Central Secretariat (<http://www.iso.org/>). ISO publications are also available in the United States from the American National Standards Institute (<http://www.ansi.org/>).

5.5.4 Impedance checking

Impedance checking functionality should be included in the system. If not, a third-party device for impedance checking shall be made available for purchase with the system and recommended for purchase by the system manufacturer (e.g., resale of commercially available impedance meter). In this case, the electrode system should allow for access to individual electrodes and interface with a third-party device (e.g., 1.5 mm standard DIN connector).

6. Acquisition component

6.1 Amplification

The following amplifier specifications shall be included:

- a) Input impedance
- b) DC/AC coupling (and time constant if ac coupled)
- c) Noise/sensitivity
 - 1) Root means square and/or peak to peak voltage
 - 2) For given bandwidth, given application, or bothOR
 - 3) Provide noise spectrum (e.g., white noise + peaks)
- d) Signal input range
- e) Signal output range
- f) Ground type (active or not): or make direct reference to line noise interference
- g) Common mode rejection ratio (CMRR): or make direct reference to line noise interference
- h) Gain
- i) Bandwidth
- j) Supply voltage/current consumption
- k) Impedance checking specifications (stimulus, measurement time/duration, absolute accuracy, relative accuracy)

6.2 Frequency response

The frequency response of the passband shall be provided, displayed graphically and/or numerically. The following specifications should be included:

- a) Magnitude response
- b) Phase response
- c) Corner frequency(ies). Tolerance(s) should be provided if corner frequency is relatively close to bandwidth of operation. This can be mode and/or application based.
- d) Decay and rolloff
- e) dB attenuation in the stopband

6.3 Analog to digital conversion

The following specifications shall be included:

- a) Number of bits
- b) Sampling rate
- c) Anti-aliasing filter specifications
- d) Resolution, quantization error, and/or least-significant-bit size
- e) A/D technique including phase jitter between channels (uncertainty due to sampling)

7. Software component

7.1 General requirements

The general sequence of operations for neurofeedback consists of sampling EEG signals, transforming the EEG signals into some informational state, and presentation about state information with the goal of influencing EEG activity.

7.1.1 General control requirements

There should be controls over the transformation and presentation operations.

7.1.2 General documentation requirements

7.1.2.1 Contents

The software documentation shall provide clear description of filter characteristics, transformations, user controls, feedback outputs, and analysis results.

7.1.2.2 Nomenclature

The documentation shall define any unusual terms and any definitions not present in the definitions section of this standard such as EEG frequency bands, etc. The source of these definitions shall be documented.

7.1.2.3 Other

Other specific documentation requirements are described in 7.2, 7.3, 7.4, 7.5, and 7.6.

7.2 Timing

7.2.1 Discussion

The overall timing requirement is composed of many factors, among them the refresh rate of the visual display, the aural cueing, wave shape, computational timing, and transmission delays.

NOTE—Lags of more than 100 ms from a haptic input to a visual response are perceptible⁵ (Laplante [B11]) and can impede or complicate operant conditioning. Aural responses may be processed more quickly than visual changes.

7.2.2 Overall timing

System timing from receipt of data from the hardware to visual and/or aural representation should be less than 100 ms. Slow cortical potentials (SCP) timing may involve longer times.

7.2.3 Responsiveness

The data may be smoothed over longer periods of time but the ability to respond to input events within the specified time should be maintained. This has implications in the transmittal timing and graphical/visual update rates.

7.3 Transformations

7.3.1 General

Transformations involve the filtering, processing, characterization, and shaping of the EEG data. The documentation shall describe these processes in sufficient detail to differentiate the effects of the transformations.

7.3.2 Filter characteristics

The filter choices available shall describe (for each filter) at least the following elements:

- a) Filter type (moving average, FIR, IIR, JTFA, wavelet, etc.)
- b) Number of stages (filter order)
- c) Rolloff (frequency) characteristics
- d) Measurement points (edge, corner, 50%, etc.)
- e) Ripple
- f) Impulse/step (transient) response
- g) Phase accuracy
- h) Delay
- i) Other significant information as necessary

⁵ Among other sources, AFHRI-TP-83-45 references Queijo, M. J. and D. R. Riley, *Fixed-Base Simulator Study of the Effect of Time Delays in Visual Cues on Pilot Tracking Performance*, NASA TN D-8001. Hampton, VA: NASA Langley Research Center, 1975.

7.3.3 Processing

7.3.3.1 Processing delays

The documentation shall describe the maximum and nominal processing delays of the neurofeedback software from receipt of the data by the transformation processes to the feedback presentation. The documentation should also describe the maximum and nominal transmission delay involved in moving the data from the transformation source(s) to the output of the transformation elements.

7.3.3.2 Client presentation delays

Visual/audible timing and delays in client presentation should be documented.

7.3.3.3 Frequency processing

Typically, certain frequency bands of the EEG signal are of interest in the determination of appropriate feedback. There are several display requirements:

- a) There shall be provision for display of the raw EEG signal.
- b) If the software contains selections for different frequency bands of interest, there should be a method of selecting the band or bands to be used.
- c) If selectable bands are provided, there should be a minimum of two frequency bands selectable for processing. The upper and lower frequency limits should be controllable by the operator and changeable during a session. The limits may be preselected.

7.3.3.4 Special processing

Processing of data by third-party applications should be described and documentation accessible. Use of the data provided by third-party applications by the software shall be described sufficiently to determine the applicability, usage, and limitations of the data.

7.3.3.5 Characterization

Characterization of the data is the process by which information is extracted, compared, and used. The documentation should describe the characterizations performed sufficiently to differentiate the computations and resulting values. The types of data extracted may include (but not limited to):

- a) Amplitude or power values
- b) Ratios
- c) Deviations/deviation rates
- d) Coherence values
- e) Phase/phase changes
- f) Other

Typically, the data is used to shape the feedback responses.

7.3.3.6 Shaping

Shaping is the method by which the characterized data is used to provide (or not provide) operant conditioning stimulus in support of the neurofeedback process.

7.3.3.6.1 Shaping controls

The software should provide controls over the shaping process or processes to be used. The software should provide controls during the real-time process.

7.3.3.6.2 Shaping process

The shaping process may include one or more of the following (but not be limited to):

- a) Artifact determination
- b) Value changes/rate of value changes
- c) Reward rates
- d) State maintenance
- e) Comparison with various baseline values
- f) Other

7.3.3.6.3 Shaping exclusions

A mechanism should be provided that permits exclusion of artifact-generated events from influencing any shaping modes in a positive manner. For example, a satisfactory method could include frequency of artifacts over a period of time blocking any positive feedback for some period of time.

7.4 User controls and output

7.4.1 Presentation

The presentation of information to the clinician (and, if needed, to the client) should be clearly readable and consistent.

General guidelines for the layout include:

- a) Use title-style capitalization for titles and sentence-style capitalization for all other elements.
- b) Use bold sparingly.
- c) Color/coloration should be used consistently.
- d) Match foreground colors with their associated background colors for textual information. Foreground colors may only be legible against their associated background colors.
- e) Use consistent terminology for labels and features.

- f) Avoid using modes that lock into one operation and prevent working on anything else until that operation is completed. If an application uses modes, there should be a clear visual indicator of the current mode, and it should be very easy for users to get into and out of the mode.
- g) Do not create interfaces that rely solely on color coding to convey important information. There may be users with color or visual difficulties trying to use the system.
- h) If coloration is used, there should be user controls to allow changing the colors or color theme.
- i) Minimize the number of alignment points in your layout. An alignment point is an imaginary vertical or horizontal line through your layout that touches the edge of one or more labels or fields in the layout.
- j) Align fields in the layout exactly. The eye is very sensitive to aligned and unaligned objects. If nothing lines up with anything else in a window, it will be very hard for users to scan the contents and find the information they want. Two things that almost line up, but not quite, are equally distracting.
- k) Leave some spacing between objects in the layout to provide separation, usually in a common size (typically, six-pixel increments).

7.4.2 Clinician displays

7.4.2.1 Layout

The clinician display layouts and layout elements should be described in the system documentation. An aesthetically-pleasing layout provides the clearest information and the most optimal presentation of information.

7.4.2.2 Data display

The software shall be able to display the raw EEG data during a real-time session. If selectable frequency bands of data are provided, the software should be able to display each of the selected bands of data and the current settings for those bands.

7.4.2.3 Impedance display

If the acquisition component provides impedance information, the impedance data should be displayable.

7.4.3 Information support displays

There should be available a display of average peak-peak voltage for the raw EEG signal(s) and any provided selectable frequency bands of the EEG data. The characterized data values used for shaping should be displayable in real-time.

7.4.4 Client feedback output

7.4.4.1 Documentation

Client feedback outputs can be visual, aural, and/or tactile. All client feedback output and display presentation options should be described in the system documentation.

7.4.4.2 Multiple displays

Multiple display presentation modes should be provided to support different requirements.

7.4.4.3 Enable/disable

The clinician should be able to enable/disable any individual outputs to the client.

7.4.4.4 Feature effects

The documentation should describe which features of the EEG signal that alter the display, aural, and tactile outputs.

7.5 Data

7.5.1 Raw data

Raw data is defined as the original record of sampled and quantized information obtained when a digital recorder converts an analog signal into digital form. This information may be made available in binary, octal, hexadecimal, or decimal form. The correction of the output for offset to give a zero-based record is permitted, as is multiplying the record by a constant scale factor; records processed in this way are still classed as raw data.

7.5.1.1 Raw data recording requirements

Raw data shall be recorded for later analysis and reporting requirements. The data storage format definition should be part of the documentation. Software should record automatically (or make provisions for manual entry) of at least the following elements:

- a) Time of day at the start of a session.
- b) Filter settings at the start of a session.
- c) Electrode placement at the start of a session and at any change of placement.
- d) Frequency band or filter changes as they occur.
- e) Processing mode changes as they occur.
- f) Other technical amplifier control settings if there is any effect on the signal.

7.5.1.2 Raw data recording recommendations

If impedance values are provided by the acquisition component, the software should record them or make provision for manual entry.

7.5.2 Derived data

Any derived data pertinent to training or assessment should be recorded. This should be saved as it occurs to report the actual process of the session with frequency band changes, mode changes, feedback timing changes, etc. Values saved typically include (but are not limited to):

- Average (P-P) value of raw signal(s) and each frequency band
- Training measures
- Trend data
- Deviation data
- Artifact determinations

7.5.3 Secondary data

Any observational changes during a session should be recorded with the data at the time they are made. These include, but are not limited to:

- Eyes open/closed status
- Observation of drowsy status
- Symptoms of seizure

Free text comments should be able to be entered and stored with the EEG data.

7.5.4 Data import/export

7.5.4.1 Data export

All recorded data shall be exportable into at least one binary and one textual standard format. The documentation for each format shall be accessible.

Binary formats include raw native format, EDF⁶ [B10], BDF⁷, and other documented formats.

Textual formats include ASCII comma-separated-value formatted data.

⁶ EDF and EDF+ format are documented at <http://edfplus.info>. EDF was originally published in 1992 by Bob Kemp, Alpo Varri, Agostinho C. Rosa, Kim D. Nielsen, and John Gade as “A Simple Format for Exchange of Digitized Polygraphic Recordings,” *Electroencephalography and Clinical Neurophysiology* 82 (1992): 391–393.

⁷ BDF is the Biosemi Data Format, an extension of EDF to support 24-bit data. Documented at http://www.biosemi.com/faq/file_format.htm.

7.5.4.2 Data import

The software may have the ability to input certain data and convert it to internal format suitable for further analysis or for playback/review.

7.5.4.3 Data transfer

The software should have the ability to package session data for transfer to another system from the same manufacturer. The software should have the ability to un-package data and make it available for playback/review.

7.5.4.4 HIPAA conformance

This standard does not define data transfer methodology.

This standard does not define data storage requirements.

The software should provide a method(s) of protecting the displayed identification of a client.

7.6 Post-session support

7.6.1 Playback

The software should be able to replay the recorded session data. Playback systems should be able to display recorded electrode placement labels, filter settings, and derived data, along with the raw or transformed EEG data and time stamp information. Playback systems should allow selectable filtering and characterization to be applied to the raw EEG data for review and analysis.

7.6.2 Analysis

The software should provide human-readable results for each session and selectable groups of sessions.

Those results should include relevant training and assessment values. The documentation shall include an explanation of each of the values in sufficient detail to allow interpretation.

7.6.3 Review

Review systems should be able to display the raw, derived data, and secondary data acquired during a session. Annotations or analysis results should be appendable to the recorded session results. Recorded session data shall not be modifiable after the session is terminated.

8. Computer component

The computer can be delivered as part of a neurofeedback system or procured to match the specified requirements of the computer system.

8.1 Computer specifications

8.1.1 Computer capability

The processing speed and memory requirements should be documented.

8.1.2 Operating system

The operating system requirements should be documented.

8.2 Display specifications

The display requirements should be documented.

9. User documentation

9.1 User qualification documentation

The level of user training and experience required should be documented and supported by the system manufacturer or its assignees.

9.2 Operator's manual

The operator's manual should display detailed, step-by-step instructions with adequate screen captures and descriptive graphics to support the understanding of the steps required for each operations described. The operator's manual should also contain:

- a) Any needed safety warnings
- b) Description of all user-configurable options and controls
- c) Description of test procedures used to verify correct operation of the software and hardware
- d) Description of controls and effects of the characterization and shaping mechanisms
- e) Instructions for performing the tasks required for a neurofeedback session
- f) Description of the content of the post-session analysis output
- g) List of all normal messages presented to the operator
- h) List of all unexpected error messages and known issues

9.3 Installation manual

The installation manual should provide clear and concise instructions on installation of the software. Where applicable, system requirements should be clearly stated. The installation process should include an initial testing procedure to verify correct installation and operation of the system. The manual should display

detailed, step-by-step instructions with adequate screen captures and descriptive graphics to support the understanding of the steps required.

9.4 Technical manual

This manual should contain the specifications of the system and the detailed descriptions of all characterizing and shaping operations.

Annex A

(normative)

Implementation conformance statement

This form is a statement by the manufacturer showing conformance to this recommended practice.

Implementation identification

Supplier	
Contact point for ICS	
Implementation name(s) and version(s)	
Other information necessary for full identification, e.g., name(s) and version(s) of the machines and/or operating systems(s), system names	

Status values:

- F Fully compliant
- D Compliant but some documentation missing
- P Partially compliant (some functionality missing)
- N Not compliant
- N/A Not applicable (when documenting individual components rather than a system)

Implementation conformance statement (continued)

Item	Description	References	Status
1	Availability of information: Detailed descriptions	3.1a)	
2	Availability of information: Detailed instructions	3.1b)	
3	Availability of information: Specifications	3.1c)	
4	Availability of information: Supporting diagrams	3.1d)	
5	Availability of information: System description	3.1e)	
6	Availability of information: Failure/misuse detection/consequences	3.1f)	
7	Safety	3.2.1	
8	Intended use	3.2.2	
9	Efficacy claims	3.2.3	
10	Training available	3.3	
11	Marketing claims comply with requirements	3.4	
12	System specifications: Acquisition component/computer interface	4.2a)	
13	System specifications: Overall system latency	4.2b)	
14	Electrodes: Standard nomenclature usage	5.1.1	
15	Electrodes: Non-standard nomenclature usage	5.1.2	
16	Electrodes: Supported/provided specifications	5.2	
17	Electrodes: Lifetime	5.2a)	
18	Electrodes: Performance/noise	5.2b)	
19	Electrodes: Polarization rate	5.2c)	
20	Electrodes: Long-term stability	5.2d)	
21	Electrodes: Cleaning	5.3	
22	Electrodes: Biocompatibility requirement	5.4a)	
23	Electrodes: Biocompatibility certification	5.4b)	
24	Electrodes: Preparation	5.5.1	
25	Electrodes: Placement	5.5.2	
26	Electrodes: Cautions and warnings	5.5.3	
27	Electrodes: Impedance checking	5.5.4	
28	Acquisition: Amplification specifications provided	6.1	
29	Acquisition: Frequency response	6.2	
30	Acquisition: A/D conversion	6.3	
31	Software: General control requirements	7.1.1	
32	Software: General documentation requirements: Contents	7.1.2.1	
33	Software: General documentation requirements: Nomenclature	7.1.2.2	

Implementation conformance statement (continued)

Item	Description	References	Status
34	Software: Overall timing	7.2.2	
35	Software: Responsiveness	7.2.3	
36	Software: Transformations, general	7.3.1	
37	Software: Filter characteristics	7.3.2	
38	Software: Processing delays	7.3.3.1	
39	Software: Client presentation delays	7.3.3.2	
40	Software: Raw EEG display	7.3.3.3a)	
41	Software: Bands of interest	7.3.3.3b)	
42	Software: Multiple bands	7.3.3.3c)	
43	Software: Special processing (third-party applications)	7.3.3.4	
44	Software: Characterization, amplitude/power	7.3.3.5a)	
45	Software: Characterization, ratios	7.3.3.5b)	
46	Software: Characterization, deviations	7.3.3.5c)	
47	Software: Characterization, coherence	7.3.3.5d)	
48	Software: Characterization, phase	7.3.3.5e)	
49	Software: Characterization, other (describe)	7.3.3.5f)	
50	Software: Shaping, artifact	7.3.3.6.2a)	
51	Software: Shaping, value changes	7.3.3.6.2b)	
52	Software: Shaping, reward rates	7.3.3.6.2c)	
53	Software: Shaping, state maintenance	7.3.3.6.2d)	
54	Software: Shaping, other (describe)	7.3.3.6.2e)	
55	Software: Shaping exclusions	7.3.3.6.3	
56	Software: Presentation	7.4.1	
57	Software: Display layout	7.4.2.1	
58	Software: Data display	7.4.2.2	
59	Software: Impedance display	7.4.2.3	
60	Software: Information support display	7.4.3	
61	Software: Client feedback output, documentation	7.4.4.1	
62	Software: Client feedback output, multiple displays	7.4.4.2	
63	Software: Client feedback output, enable/disable	7.4.4.3	
64	Software: Client feedback output, feature effects	7.4.4.4	
65	Software: Data recording requirements	7.5.1.1	
66	Software: Data recording recommendations	7.5.1.2	
67	Software: Derived data	7.5.2	

Implementation conformance statement (continued)

Item	Description	References	Status
68	Software: Secondary data recording	7.5.3	
69	Software: Data export	7.5.4.1	
70	Software: Data import	7.5.4.2	
71	Software: Data transfer	7.5.4.3	
72	Software: HIPAA compliance	7.5.4.4	
73	Software: Playback	7.6.1	
74	Software: Analysis	7.6.2	
75	Software: Review	7.6.3	
76	Computer: Capability	8.1.1	
77	Computer: Operating system	8.1.2	
78	Computer: Displays	8.2	
79	User qualification documentation	9.1	
80	Operator's manual	9.2	
81	Installation manual	9.3	
82	Technical manual	9.4	

Annex B

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

[B1] American Clinical Neurophysiology Society, Guideline 5: Guidelines for Standard Electrode Position Nomenclature. Available online: www.acns.org/pdfs/ACFDD46.pdf. [ACNS is a member society of the International Federation of Societies for Electroencephalography and Clinical Neurophysiology.]

[B2] Birbaumer, N., Rockstroh, B., Elbert, T. et al., “Biofeedback of Slow Cortical Potentials in Epilepsy.” In *Clinical Applied Psychology*, edited by Carlson J. G., 29–42. New York: Plenum Press, 1994.

[B3] Cacioppo, J. T., L. G. Tassinary, and G. G. Berntson. *Handbook of Psychophysiology*. Cambridge, UK: Cambridge University Press, 2007.

[B4] Fisch, Bruce J., *Spehlmann’s EEG Primer*, 2nd ed. Amsterdam: Elsevier, 1991.

[B5] Graf, R. F. *Modern Dictionary of Electronics*. Woburn, MA: Newnes, 1999.

[B6] Hinterberger, Y., J. M. Hootkooper, and B. Kotchoubey. “Effects of Feedback Control on Slow Cortical Potentials and Random Events,” in *Proceedings of Presented Papers: The Parapsychological Association 47th Annual Convention*, 39–50. Vienna, Austria, 2004.

[B7] IEC 60601-1 is a family of medical electrical equipment safety standards published by the International Electrotechnical Commission.⁸

[B8] ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process.⁹

[B9] Jasper, H. H. “The Ten-Twenty Electrode System of International Federation,” *Electroencephalography and Clinical Neurophysiology* 10 (1958): 371–75.

[B10] Kemp, B., A. Varri, A. C. Rosa, K. D. Nielsen, and J. Gade. “A Simple Format for Exchange of Digitized Polygraphic Recordings,” *Electroencephalography and Clinical Neurophysiology* 82 (1992): 391–93.

[B11] Laplante, P. A. *Comprehensive Dictionary of Electrical Engineering*. Boca Raton, FL: CRC Press / Heidelberg, Germany: Springer, 1999.

[B12] Summers, R. H., *Nondestructive Inspection: Improved Capabilities of Technicians*, AFHRL-TP-83-63. Lowry Air Force Base, CO: Air Force Human Resources Laboratory, 1984.

[B13] Queijo, M. J. and D. R. Riley, *Fixed-Base Simulator Study of the Effect of Time Delays in Visual Cues on Pilot Tracking Performance*, NASA TN D-8001. Hampton, VA: NASA Langley Research Center, 1975.

⁸ IEC publications are available from the International Electrotechnical Commission (<http://www.iec.ch/>). IEC publications are also available in the United States from the American National Standards Institute (<http://www.ansi.org/>).

⁹ ISO publications are available from the ISO Central Secretariat (<http://www.iso.org/>). ISO publications are also available in the United States from the American National Standards Institute (<http://www.ansi.org/>).