

## Implementation Conformance Statement

In July 2012, the IEEE Standards Association published a new document titled “IEEE Recommended Practice for Neurofeedback Systems” (IEEE Std 2010-2012). This document describes the recommended documentation for a neurofeedback system.

This standard is not currently part of FDA conformance documents.

Herein is the Implementation Conformance Statement as specified in the IEEE document.

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Implementation Name(s) and Version(s)	EEGer4 Neurofeedback Software 4.3.0b
Other	

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 (ICS)**

#	Description	Ref	Status	Location/Notes
1	Availability of information: Detailed descriptions	3.1a	F	Operator Manual, Technical Manual
2	Availability of information: Detailed instructions	3.1b	F	Operator Manual, Installation Manual
3	Availability of information: Specifications	3.1c	F	Software specifications only; Operator Manual, Technical Manual, Installation Manual
4	Availability of information: Supporting diagrams	3.1d	F	Operator Manual
5	Availability of information: System description	3.1e	F	Operator Manual
6	Availability of information: Failure/Misuse detection/ consequences	3.1f	F	Operator Manual
7	Safety	3.2.1	F	Operator Manual
8	Intended use	3.2.2	F	Operator Manual
9	Efficacy claims	3.2.3	F	Operator Manual
10	Training available	3.3	F	Through EEG Education & Research Inc.
11	Marketing claims comply with requirements	3.4	F	Operator Manual
12	System specifications: Acquisition component/computer interface	4.2a	F	Installation Manual, Technical manual
13	System Specifications: Overall system latency	4.2b	F	Technical Manual
14	Electrodes: standard nomenclature usage	5.1.1	F	Operator Manual
15	Electrodes: non-standard nomenclature usage	5.1.2	F	Operator Manual
16	Electrodes: supported/provided specifications	5.2	N/A	
17	Electrodes: lifetime	5.2a	N/A	
18	Electrodes: performance/noise	5.2b	N/A	
19	Electrodes: Polarization rate	5.2c	N/A	
20	Electrodes: Long term stability	5.2d	N/A	
21	Electrodes: cleaning	5.3		
22	Electrodes: Biocompatibility requirement	5.4a	N/A	
23	Electrodes: Biocompatibility certification	5.4b	N/A	

#	Description	Ref	Status	Location/Notes
24	Electrodes: Preparation	5.5.1	N/A	
25	Electrodes: Placement	5.5.2	F	Operator Manual
26	Electrodes: Cautions and Warnings	5.5.3	F	Operator Manual
27	Electrodes: Impedance checking	5.5.4	F	As supported by acquisition component or external device. Operator Manual
28	Acquisition: Amplification specifications provided	6.1	N/A	
29	Acquisition: Frequency response	6.2	N/A	
30	Acquisition: A/D conversion	6.3	N/A	
31	Software: general control requirements	7.1.1	F	Operator Manual
32	Software: general documentation requirements-contents	7.1.2.1	F	Operator Manual
33	Software: general documentation requirements - nomenclature	7.1.2.2	F	Operator Manual
34	Software: overall timing	7.2.2	F	Technical manual
35	Software: responsiveness	7.2.3	F	Technical manual
36	Software: Transformations, general	7.3.1	F	Operator Manual, Technical Manual
37	Software: Filter characteristics	7.3.2	F	Technical manual
38	Software: Processing delays	7.3.3.1	F	Technical manual
39	Software: client presentation delays	7.3.3.2	F	Technical manual
40	Software: Raw EEG display	7.3.3.3 a	F	Operator Manual
41	Software: Bands of interest	7.3.3.3 b	F	Operator Manual
42	Software: Multiple bands	7.3.3.3 c	F	Operator Manual
43	Software: special processing (3 <sup>rd</sup> party applications)	7.3.3.4	F	Operator Manual
44	Software: characterization, amplitude/power	7.3.3.5 a	F	Operator Manual
45	Software: characterization, ratios	7.3.3.5 b	F	Operator Manual
46	Software: characterization, deviations	7.3.3.5 c	F	Operator Manual
47	Software: characterization, coherence	7.3.3.5 d	F	Operator Manual
48	Software: characterization, phase	7.3.3.5 e	F	Operator Manual
49	Software: characterization, other	7.3.3.5f	F	Operator Manual
50	Software: shaping , Artifact	7.3.3.6. 2a	F	Operator Manual
51	Software: shaping , value changes	7.3.3.6. 2b	F	Operator Manual

#	Description	Ref	Status	Location/Notes
52	Software: shaping , Reward rates	7.3.3.6.2c	F	Operator Manual
53	Software: shaping , State maintenance	7.3.3.6.2d	F	Operator Manual
54	Software: shaping ,other	7.3.3.6.2e	F	Operator Manual
55	Software: shaping exclusions	7.3.3.6.3	F	Operator Manual
56	Software: Presentation	7.4.1	F	Operator Manual
57	Software: display layout	7.4.2.1	F	Operator Manual
58	Software: data display	7.4.2.2	F	Operator Manual
59	Software: Impedance display	7.4.2.3	F	Operator Manual
60	Software: Information support display	7.4.3	F	Operator Manual
61	Software: client feedback documentation	7.4.4.1	F	Operator Manual
62	Software: client feedback output-multiple displays	7.4.4.2	F	Operator Manual
63	Software: client feedback output-enable/disable	7.4.4.3	F	Operator Manual
64	Software: client feedback output-EEG feature effects	7.4.4.4	F	Operator Manual
65	Software: data recording requirements	7.5.1.1	F	Operator Manual
66	Software: data recording recommendations	7.5.1.2	F	Operator Manual
67	Software: derived data	7.5.2	F	Operator Manual
68	Software: secondary data recording	7.5.3	F	Operator Manual
69	Software: Data export	7.5.4.1	F	Operator Manual, Technical Manual
70	Software: Data import	7.5.4.2	F	Operator Manual
71	Software: data transfer	7.5.4.3	F	Operator Manual
72	Software: HIPAA compliance	7.5.4.4	F	Operator Manual
73	Software: Playback	7.6.1	F	Operator Manual
74	Software: Analysis	7.6.2	F	Operator Manual
75	Software: Review	7.6.3	F	Operator Manual
76	Computer: capability	8.1.1	F	Installation Manual, Technical Manual
77	Computer: operating system	8.1.2	F	Installation Manual, Technical Manual
78	Computer: displays	8.2	F	Installation Manual, Technical Manual
79	User qualification documentation	9.1	F	Operator Manual
80	Operator's Manual	9.2	F	
81	Installation Manual	9.3	F	
82	Technical Manual	9.4	F	