Electroencephalograph Devices
Guidance for 510(k) Content
Draft Document
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Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

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INTRODUCTION

This document supplements the Division of Cardiovascular, Respiratory, and Neurological Devices "Draft Guidance for Format and Content for Premarket Notifications 510(k)," which provides guidance for preparing a "510(k)" premarket notification. This "Guidance for Electroencephalograph (EEG) 510(k) Content" provides more specific guidance for 510(k)s that claim substantial equivalence to EEG devices. Both clinical diagnostic devices and monitoring devices are within the scope of this document. However, certain sections of this document may not apply to Anesthesia monitors and devices which are combinational devices of EEG with electrical stimulators, biofeedback components, etc. **This guidance represents the agency's current thinking on EEG devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.**

I. BASIC DEVICE DESCRIPTION

The manufacturer (or importer) should provide a complete description of the device including, but not limited to, the means for gathering, storing, and displaying data. A picture of the device should be provided which clearly shows all controls, connections, accessories, and labels. This should include an explanation of the purpose of each control, connection, and accessory and how they are intended to be used. The application should contain a complete and precise product comparison (see II. DEVICE SPECIFICATIONS below) of the devices to which substantial equivalence is made and the device under review. Included in this description should be the source of information concerning the comparison devices; e.g., the number of a prior 510(k) or published data for pre-Amendments devices.

II. DEVICE SPECIFICATIONS

A. Hardware Specifications

1. Head-box. The head-box (lead plug-in box) is the means whereby the electrodes, attached to the head, are connected to the EEG machine. The manufacturer should provide a complete description of the head-box including testing conducted that demonstrates that an adequate conductive path is obtained for each electrode.

2. Switching. A description of the switching system that is used to connect the various pairs of electrodes to the different channels (usually a minimum of sixteen) of the machine should be provided. Switching systems are needed because, to obtain an adequate coverage of the electrical activity from various parts of the brain for clinical diagnostic purposes, it is necessary to record from more combinations than can typically be displayed at one time.

3. Amplifiers. The amplifiers should be completely described, including documentation that they provide the same distortionless output over the entire EEG frequency spectrum. A distortionless system has a flat frequency response over the frequency spectrum of interest (0.1 Hz to 100 Hz). (See Ref. 1)

4. Filters. The high and low frequency cutoff points of the low-pass and high-pass filters, respectively should be specified. These define the bandwidth of the amplifier. The manufacturer should specify whether a 60 Hz "notch" filter is used in the design to reduce the artifact due to the presence of power lines or transformers in the vicinity of the patient. (See Ref. 2) The application should indicate how the device design considers the fact that the electrical activity of skin and of the muscle falls, respectively, in the low and high ends of the frequency spectrum.

5. Common-Mode Rejection Ratio. The manufacturer should specify the common-mode rejection ratio (CMRR) that has been assured and compare the value with a predicate device. CMRR is a measure of how well common-mode voltages are rejected by a differential amplifier incorporated in the device. Testing should demonstrate, for example, that 60 Hz artifacts are processed as common mode signals.

6. Input Circuit. In order to realize the CMRR quoted in the specifications of a particular amplifier, it is essential for the input circuit of the amplifier to be balanced. The manufacturer should demonstrate that the impedances of both leads in the pair are essentially the same. This is important because if the input circuit becomes unbalanced, the common-mode rejection capabilities of the amplifier would be significantly degraded.

7. Noise. The manufacturer should specify the power amplifier noise. This noise can be determined by connecting the inputs of the amplifier together or "short-circuiting" the input of the amplifier and measuring the output of the amplifier. Typical values are on the order of 1 microvolt peak-to-peak.

8. Input Impedance. To accurately measure the voltage appearing at the scalp, the input impedance of the amplifier should be six orders of magnitude higher than the impedance of the electrodes at the skin/electrode interface. The manufacturer should provide this input impedance value where typical values are on the order of Megohms.

9. Frequency Response. The file should describe the amplifier in terms of frequency response (Hz), as described in number 3 above, and amplitudes of the recorded signals (microvolt).

10. Impedance Checking. If the device has the capability of performing an electrode impedance check, the manufacturer should specify the amount of current amplitude and

waveform values used to measure impedance. Typical values of impedance are less than 5 kOhms. The operating instructions should caution the user if the impedance is too high for adequate recording.

11. Calibration. The device should provide the capability of user calibration. Diagnostic EEGs have a built-in calibration feature that allows the gain to be verified at any time. Preferably, the calibration signal should be injected into the front end of the first amplification stage so that the function of all channels is assured. The operating instructions should specify the correct output amplitude and waveform to be obtained with the calibration signal.

B. Software

1. The file should include documentation that identifies the various software components comprising the software (system functions), the undesirable events (hazards) that may occur if a failure should occur, the risk to the patient, corrective actions, and level of concern. This material should be provided for a "minor" level of concern, for the entire device, as specified in the Reviewer Guidance Document for Computer Controlled Medical Devices (See Ref. 3). This information can be provided in tabular form.

2. The file should include a discussion of the safety features implemented as a result of the hazard analysis. The manufacturer should provide documentation that the safety measures address both environmental influences and random software component failures. Also, the file should contain a software structure chart depicting the partitioning of the system into functional units, the hierarchy and organization of those units, and the communication interfaces, including a written description.

C. Safe Electrical Design Criteria

1. Leakage Current. Specify measured patient to ground and chassis to ground leakage current

of the device. How does it compare with industry standards (e.g., IEC 601-1, or UL 2601)? (See Ref. 4)

2. Safety Standard. Indicate the extent to which the device conforms to any industry standard (i.e, UL 2601 or any other electrical safety standard).

3. Isolation. The manufacturer should specify the means by which isolation from commercial power and power line ground (return) is achieved. This may be achieved by:

   (a) labeling that claims that the device meets UL 2601, or some other appropriate industry standard.
   (b) employing battery operation. (Provide assurance that device cannot be operated with a line-powered battery charger.)
   (c) the use of an isolation transformer, or equivalent techniques, that provide fault protection by redundant insulation. (UL 2601 specifies several acceptable transformer designs for patient isolation).

4. EEG Standards. Specify the extent to which the device conforms to any particular standard for EEG devices (e.g., IEC 601-2-26 or American Electroencephalographic Society guidelines).

D. Environmental Testing

Discuss the Electromagnetic Compatibility or Electromagnetic Interference (EMI) testing done on the device. If testing has been conducted, provide complete performance data, including a description of equipment used, protocol, and results of testing. Indicate the extent to which the device conforms to any industry standard (i.e, IEC-601-1-2). Labeling in the user's manual should reflect the results of testing and summarize the adverse effects, if any that might be caused by EMI. If the device has not been tested, labeling should caution that the device has not been tested for EMI for specific

environments, identify the environment to which the device is restricted, and the potential impact of device failure or malfunction.

III. ACCESSORIES, ELECTRODES, AND CONDUCTIVE MEDIA (GEL)

1. Detailed data should be provided which describes all of the accessories to be shipped with the device. This should include the name and the dimensions of the electrodes and a complete description of gels provided with the device. If possible, identify the 510(k) number under which these accessories were introduced to the market, or otherwise explain how you have assured these accessories have been legally marketed. If electrodes (or gels) have not been the subject of a previous 510(k), provide a complete description and data that demonstrates that these products are substantially equivalent to a legally marketed device with the same intended use.

2. Electrode lead wires should be designed to preclude any accidental contact with a dangerous power source such as an AC power outlet. The manufacturer should describe the design features intended to assure that the lead wires do not jeopardize patient safety. (See Ref. 5).

IV. LABELING

The file should include copies of all proposed labeling and advertisements. If this material has not been developed, drafts of the text should be provided which are sufficient to describe the intended use for which the device will be promoted and to provide adequate directions for use.

1. Indications. Pre-Amendment EEG devices were used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head. For some devices, this claim has been extended to include aiding the physician in diagnosing epilepsy. Any other intended use, including diagnostic claims that the manufacturer makes about the device's capabilities, should be supported by clinical data.

2. Instructions for Use. The instructions for use should explain include all information needed by the operator to operate the device according to its intended use. These instructions should explain the purpose and function of all displays, controls, connections, and accessories as well as how they are intended to be used. Calibration instructions should be included.

3. Cautions. A list of cautions should be included in the product labeling. This may include, but is not limited to, a caution to the operator not to remove the cover to reduce the risk of electric shock. The manual should refer the operator to the manufacturer for assistance by qualified service personnel.

4. Warnings. A list of warnings should be included in the product labeling. This may include, but is not limited to, a warning that grounding reliability can only be achieved when the equipment is connected to a hospital grade plug. Advise the user if all patient electrodes should be disconnected before switching the device off.

References

1. J.G. Webster, Medical Instrumentation Application and Design, Second Edition, pp 194-214 and p 320-324, 1992.

2. F.H. Lopes da Silva, W. Storm van Leeuwen, A. Remond, Handbook of Electroencephalography and Clinical Neurophysiology Revised Series, Vol. 2, pp. 15-24, 1986.

3. "Reviewer Guidance Document for Computer Controlled Medical Devices," Center for Devices and Radiological Health, August 29, 1991*. (revision in progress)

4. Medical Electrical Equipment, Part 1: General Requirements for Safety, IEC 601-1, International Electrotechnical Commission, 1901 North Fort Meyer Drive, Suite 602, Arlington, Virginia 22209.

5. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used with Medical Devices, D. Bruce Burlington, M.D., FDA/CDRH Director, December 28, 1993.

* It may be obtained from the Division of Small Manufacturers Assistance at (800) 638-2041 or at their internet address DSMA@CDRH.FDA.GOV.