BME 400

Product Design Specification

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Section 302

Affordable Diagnostic EEG System for Viral-induced Epilepsy

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Function

Epilepsy is a common chronic neurological disease characterized by abiding recurrent seizures [1]. The most recent WHO report cites 50 million people affected worldwide, whose risk of premature death is up to three times that of the general population [2]. Electroencephalogram (EEG) is the most widely used detection and analysis procedure for epilepsy, which records cortical electrical activity. Identifying EEG patterns and seizure foci is critical for the diagnosis of specific epilepsy syndromes and, consequently, the selection of appropriate therapy [3]. However, 80% of epilepsy patients live in low- and middle-income countries, the majority of which do not have access to EEG systems or treatments [2]. Therefore, affordable EEG systems that can be rapidly and broadly deployed are in critical need.

Client requirements

- A single-channel sampling rate of at least 1 kHz.
- 12- to 16-bit analog-to-digital converter resolution.
- Periodic reading of electrode impedance to detect improper electrode contact.
- Total system cost at or below $100.
- 10-channel analog frontend.
- Driven by wall-plugged power supply.

Design requirements

Physical and Operational Characteristics

Performance requirements

The devices will be used for 20 to 40 minutes per patient per procedure [4]. The frequency of usage is dependent on the medical facility.

Safety

The device must be sanitized between uses, and the skin contact electrodes must be replaced. Since the device involves prolonged skin contact, irritation, discomfort, and allergic reactions are possible. The device consists of active electrical components and wires; thus, it must be carefully handled and not be tampered with while powered on. Furthermore, the device's temperature during operation must not exceed 40 ℃.

Accuracy and Reliability

The system should have a sampling rate of at least 1 kHz per client's requirement. The analog-to-digital converter (ADC) should encode with at least a 12-bit resolution to capture finer details of the EEG waveform. Low impedance, e.g., 5 k**Ω** electrodes, should be used to enhance signal clarity. To improve ease of use, the device should detect improperly connected electrodes.

Additionally, signal filtering is required to reduce capacitive coupling effects from power lines and electromyogram interference. Typically, the reliability of a diagnostic system is measured by its positive predictive value; however, the accuracy of epilepsy classification is critically dependent on monitoring duration and is unrealistic to calculate within the scope of this project [5].

Life in Service

The system must remain operational for 3-4 years with proper daily usage, ensuring durability and consistent performance. It should function effectively within a temperature range of 0-40°C without any drop-off in EEG signal amplitude, as higher temperatures are observed to negatively affect signal quality in existing EEG systems [6]. Additionally, the system must be easy to clean between uses, as it will be exposed to various cleaning products. The head cap should remain functional for 3-4 years with daily cleaning.

Shelf Life

The product should maintain its integrity and functionality in storage for at least ten years at room temperature. It must withstand transportation without any wear or damage and be designed to endure harsh conditions during transit. The product should tolerate storage temperatures ranging from -20°C to 100°C, as it may encounter extreme environments during transportation.

Operating Environment

The EEG cap must ensure consistent and secure contact between the electrodes and the scalp to accurately capture brain signals while maintaining user comfort over extended periods. The materials should be soft, lightweight, and non-invasive, providing a secure yet non-irritating fit. The EEG system should also function reliably in various temperatures typical of indoor and controlled outdoor environments, e.g., 0-40°C. The cap and circuit board should resist sweat, moisture, and mild physical impacts, ensuring long-term durability and accurate signal collection.

Ergonomics

The system should be accurate and fit users with a maximum horizontal head circumference between 50 to 64 cm, similar to other commercially available EEG electrode caps [7, 8]. The system should be effective for users of any hair volume and texture between bald and hair type 1 to 4d [9].

Figure 1. *Examples of hair types*

Size

The entire system should be portable and easy to carry. The cap and electrodes should be able to fit on most children and adults.

Weight

The system should weigh less than 1 lb and cause no neck strain while wearing.

Materials

There are no printed circuit board (PCB) materials restrictions as the device is not intended to operate in extreme environments. Operating temperatures, coefficient of thermal expansion, and electrical characteristics are non-critical factors. Dry electrodes are preferred, typically composed of conductive silicone or gold-plated electrodes, as requested by the client [10]. The head cap should resist cleaning solutions, e.g., ethyl or isopropyl alcohol and chlorine-releasing agents.

Aesthetics, Appearance, and Finish

The cap's design will ensure the patient feels comfortable in the environment. All wires should be as enclosed as the system allows. The circuit board will have a cover to shield the view from the patient. The appearance will be sleek and neutral to avoid any strong aversions. The appearance of the electrodes and the board will be professional in portraying the device's safety.

Production Characteristics

Quantity

One unit is needed for the scope of this project. This unit should be created to be reproducible on a large scale.

Target Product Cost

For one unit, the entire system costs at or below $100.

Miscellaneous

Standards and Specifications

The Code of Federal Regulations Title 21, Volume 8 Chapter 1 Part 882: Neurological Devices provides specific standards concerning electroencephalograms (EEGs) and other commercially distributed neurological devices intended for humans. Sec. 882.1400 states that EEGs are used to measure and record the brain's electrical activity and are classified as a class II medical device [11]. This means they have to follow general regulatory control and special controls, including performance standards, special labeling requirements, and post-market surveillance [12]. They must also go through the 510(k), a premarket submission process that proves the device is similar to one currently operating and showcases that it is safe [13]. To be considered within this classification, the EEG can have recording hardware, monitor, and basic software; however, this does not include electrodes, a complex software analysis system (to either auto-detect or analyze events), or a system with more than 16 electrodes. Additionally, this device is not allowed to be used in sleep studies. EEG electrode/lead tester is a device used to test the impedance of electrodes. It is classified as a Class I device, along with an EEG signal spectrum analyzer and an EEG test signal generator. Cutaneous electrodes are applied directly to the skin to record or apply electrical stimulation and are classified as a Class II medical device.

In addition to FDA standards, IEEE recommended practice for EEG Neurofeedback Systems details practices that should be abided by [14]. The system must adhere to the IEC 60601-1 Safety and Essential Performance standard to follow safety procedures. The EEG should be sold as a medical device, where the user is trained to operate the equipment properly. System software shall be available to allow all parts of the system to be analyzed as needed. This includes electrodes, which should have an expected lifetime, performance, polarization rate, and long-term stability. Cleaning techniques, application, and impedance checking should accompany these electrodes. Several different specifications should be included for the primary component, as listed in Table 1.

Along with these documents, several ISO and IEC standards are applicable. IEC standard 80601-2-26:2019 details the particular requirements for EEGs' basic safety and performance [15]. ISO standard 22077-5:2021 specifies the format of waveforms created during EEG to support one recording session [16].

Table 1*: Specifications that must be listed, as stated by IEEE Recommended Practice for EEG [14]*

Amplifier Specifications	**Frequency specifications**	**Analog to Digital Conversion**
Input impedance	Magnitude response	Number of bits, number of channels, and type input/output channel
DC/AC coupling (time constant if ac coupled)	Phase response	Sampling rate
Noise/sensitivity (RMS and/or peak-peak voltage, given bandwidth or application, noise spectrum)	Corner frequency / frequencies	Anti-aliasing filter specification
Signal input range	Decay and rolloff	Resolution, quantization error, and/or least-sig bit size (eg performance over temperature, hysteresis, etc.)
Signal output range	Decibel (dB) attenuation in stopband	ADC technique
Ground type (active/not) or direct reference line noise		Channel-to-channel isolation and digital channel
CMRR		
Gain		
Bandwidth		
Supply voltage/current consumption		
Impedance checking specifications (stimulus, measurement time/duration, absolute accuracy, relative accuracy)		
Amplification		

Customer

The device is tailored for medical clinics in underdeveloped areas; thus, its cost and durability are prioritized. Borth criteria are detailed in this document above. Additionally, the device should be intuitive to use and include detailed instructions in various languages.

Patient-related concerns

Four main patient-related concerns will be addressed:

- **Patient Comfort & Skin Irritation**: Long-term EEG monitoring may cause discomfort or skin irritation, especially due to the electrodes' contact with the scalp. Proper cap design, skin preparation, and using hypoallergenic materials are essential to reduce discomfort and prevent rashes or sores.
- **Movement Restrictions**: Patients must remain relatively still during EEG recording to avoid artifacts from muscle movements. This can be challenging, especially for pediatric or uncooperative patients, leading to inaccurate readings.

- **Infection Risk & Hygiene**: Reusing EEG caps and electrodes poses a risk of infection if they are not properly sanitized between uses. Ensuring strict hygiene protocols and using disposable components when necessary can mitigate this risk.
- **Psychological Stress or Anxiety** Some patients, particularly children or those with certain neurological conditions, may experience anxiety or discomfort during the EEG process due to unfamiliar equipment or the need to remain still for extended periods. Clear communication and a calming environment can help alleviate these concerns.

Competition

Most EEG systems are intended for medical use and are inaccessible to consumers and medical facilities in underdeveloped countries. Although consumer EEG systems with relatively low costs exist, none of the multi-channel systems cost close to the $100 threshold (Table 2). Commercialized products like Neurosky, Muse, and Emotiv often feature non-essential Bluetooth functionalities and auxiliary sensors that contribute to their cost. Their channel count and sampling rate also fall short of the client's requirements. Open EEG's modular EEG system offers the most competitive pricing for its performance. However, its ATmega8 employs a 10-bit ADC with six channels that fail to meet the performance requirements.

***Table 2**: Summary of Existing Consumer EEG Devices*

Product	**Channel Count**	**Sampling Rate (Hz)**	**Bit Depth**	**Wireless**	**Cost (USD)**
Neurosky MindWave	1	512	12	Yes	130
Muse2	4	256	12	Yes	300
Emotiv MN8	2	128	14	Yes	400
Emotiv Insight	5	128	16	Yes	500
Emotiv EPOC X	14	256	14-16	Yes	1000
Emotiv Flex Saline	32	256	16	Yes	2000
Open BCI Complete Kit	16	125	24	No	2500
Open EEG	2-6	Up to 15.4k	10	No	200-400

Reference

[1] E. Beghi, “The epidemiology of Epilepsy,” Neuroepidemiology, vol. 54, no. 2, pp. 185–191, Dec. 2019. doi:10.1159/000503831
[2] Epilepsy: A Public Health Imperative. Geneva: World Health Organization, 2019.
[3] S. Noachtar and J. Rémi, “The role of EEG in epilepsy: A critical review,” Epilepsy & Behavior, vol. 15, no. 1, pp. 22–33, May 2009. doi:10.1016/j.yebeh.2009.02.035

[4] S. C. Schachter, “EEG procedure,” Epilepsy Foundation, https://www.epilepsy.com/diagnosis/eeg/procedure (accessed Sep. 19, 2024).
[5] G. S. Drenthen et al., “Predictive value of functional MRI and EEG in epilepsy diagnosis after a first seizure,” Epilepsy & Behavior, vol. 115, p. 107651, Feb. 2021. doi:10.1016/j.yebeh.2020.107651
[6] C. de Labra, J. L. Pardo-Vazquez, J. Cudeiro, and C. Rivadulla, “Hyperthermia-induced changes in EEG of anesthetized mice subjected to passive heat exposure,” Frontiers in Systems Neuroscience, vol. 15, Sep. 2021. doi:10.3389/fnsys.2021.709337
[7] NEUROSPEC, “EasyCap Standard EEG Cap (with Holders).” Accessed: Sep. 18, 2024. [Online]. Available: https://shop.neurospec.com/easycap-standard-eeg-cap-with-holders?___store=en_US&___from_store=x_default
[8] OPENBCI, “EEG Electrode Cap Kit.” Accessed: Sep. 18, 2024. [Online]. Available: https://shop.openbci.com/products/openbci-eeg-electrocap
[9] S. N. Moody et al., “Impact of hair type, hair sample weight, external hair exposures, and race on cumulative hair cortisol,” Psychoneuroendocrinology, vol. 142, p. 105805, Aug. 2022, doi: 10.1016/j.psyneuen.2022.105805.
[10] G. Di Flumeri et al., “The dry revolution: Evaluation of three different EEG dry electrode types in terms of signal spectral features, mental states classification and usability,” Sensors, vol. 19, no. 6, p. 1365, Mar. 2019. doi:10.3390/s19061365
[11] 21 CFR § 882.1400, Code of Federal Regulations, U.S. Government Publishing Office, 2014
[12] Center for Devices and Radiological Health, “Regulatory controls,” U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls#:~:text=Special%20controls%20are%20regulatory%20requirements,Guidelines (accessed Sep. 19, 2024).
[13] Center for Devices and Radiological Health, “Learn if a medical device has been cleared by FDA for marketing,” U.S. Food and Drug Administration, https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing#:~:text=Section%20510(k)%20of%20the,manufacturer%20can%20market%20the%20device (accessed Sep. 19, 2024).
[14] IEEE recommended practice for electroencephalography (EEG) neurofeedback systems. doi:10.1109/ieeestd.2023.10186304
[15] Medical electrical equipment – Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs, IEC 80601-2-26, International Electrotechnical Commission, 2019.
[16] Health informatics — Medical waveform format — Part 5: Encoder for SCP-ECG, ISO/TS 22077-5, International Organization for Standardization, Geneva, Switzerland, 2021.