Portable EEG Device and Machine Learning Analysis of Spectrographic Data for Biomarker Identification for Patient Use Using EEG Data for Epilepsy Support.

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Introduction/background

Epilepsy impacts millions, with unpredictable seizures affecting quality of life. Real-time monitoring is crucial for safety, but current methods lack accuracy, speed, and ease of use. Our project introduces a portable, EEG-based device for real-time seizure detection, offering continuous, reliable monitoring to support early intervention and provide valuable data, ultimately enhancing epilepsy management and patient care

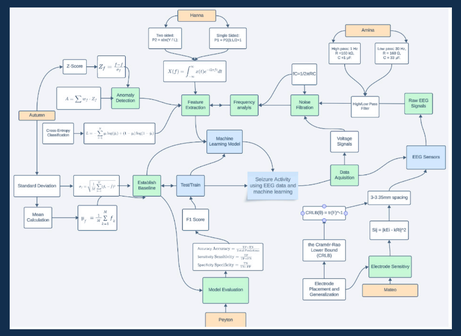
Mission statement

Our mission is to develop an innovative, wearable EEG device that provides real-time seizure detection, providing epilepsy patients and healthcare providers with reliable, immediate insights to enhance safety and quality of life.

Customer needs

- **Accurate Seizure Detection**: Minimize false positives and negatives to ensure patient safety and clinician trust.
- **Real-Time Monitoring:** Enable timely intervention with real-time data processing and alerts.
- **Comfortable Wearable Design**: Lightweight and discreet for prolonged, daily use.
- **User-Friendly Interface:** Simple access and interpretation of data for patients and clinicians.
- **Data Privacy and Security:** Ensure HIPAA compliance and secure handling of patient data.

Product architecture



Design for manufacturing

Key Manufacturing Design Elements:

- **Standardized Components:** Off-the-shelf electrodes, microcontrollers, and casings lower costs and simplify the supply chain.
- **Modular Design:** Separate units for sensors, processing, and battery simplify assembly and upgrades.
- **Material Selection:** Lightweight, medical-grade silicone ensures comfort and durability.
- **Automated Assembly:** Compatible with automated processes to reduce labor costs and increase speed

Manufacturing costs

Component	Description	Estimated Cost per Unit (USD)
EEG Electrodes	Standardized, medical-grade	$10.00
Microcontroller	For processing and data handling	$15.00
Noise Filtering Components	High-pass and low-pass filter circuits	$5.00
Battery	Rechargeable lithium-ion battery	$8.00
Casing	Medical-grade silicone housing	$7.00
Data Transmission Module	Bluetooth module for data relay	$10.00
Assembly and Testing	Labor and machine costs	$12.00
Packaging and Accessories	Packaging, user manual, charger	$5.00
Total Estimated Cost		**$72.00**

Project planning/timeline

Task	Assigned To	Progress	Start Date	End Date
Needs and Metrics	Team	100%	9/10/24	9/10/24
Competitive Benchmarking	Team	100%	9/10/24	9/10/24
Lab Notebook	Individual	100%	9/10/24	9/10/24
Due Diligence	Individual	100%	9/10/24	9/10/24
Time Log	Individual	100%	9/10/24	10/3/24
Ethical Issue	Team	100%	9/10/24	10/3/24
DHF	Team	100%	9/10/24	10/3/24
Gantt Chart	Team	100%	9/10/24	10/3/24
Executive Summary	Team	100%	9/10/24	10/3/24
Formal Design Review	Individual	100%	10/3/24	10/17/24
Generating Design Solutions	Team	100%	10/3/24	10/17/24
Continue Benchmarking	Team	100%	10/3/24	10/17/24
Concept Iteration	Team	100%	10/3/24	10/17/24
Intellectual Property Doc	Team	100%	10/3/24	10/17/24
Preliminary Business Model	Team	100%	10/3/24	10/17/24
Prior Art Search	Team	100%	10/3/24	10/17/24
Lab Notebook	Individual	100%	10/3/24	10/17/24
Due Diligence	Individual	100%	10/3/24	10/17/24
Time Log	Individual	100%	10/3/24	10/17/24
Ethical Issue	Team	100%	10/3/24	10/17/24
DHF	Team	100%	10/3/24	10/17/24
Gantt Chart	Team	100%	10/3/24	10/17/24
Executive Summary	Team	100%	10/3/24	10/17/24

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Final product Design Metrics

- **Detection Accuracy:** ≥ 95% to ensure seizure identification.
- **Battery Life:** ≥ 24-hour life with 1.5-hour USB-C charging
- Size: 8 cm x 5cm x 1.5cm
- **Data Transmission Delay:** ≤ 10 seconds for real-time alerting
- **Device Weight:** ≤ 100 grams to enhance comfort
- **Signal Quality (SNR):** ≥ 20 dB to maintain noise reduction and clear EEG signals.
- **Data Processing:** Real-time microcontroller, BLE for ≤ 10s transmission delay, 48-hour local storage.
- **EEG Sensitivity:** ≥ 98% sensitivity to capture brainwave activity.
- **Wearability (Head Adjustability):** ± 2 cm adjustment for various head sizes.
- **Interface Customizability:** iOS/Android app with alerts and data visualization.
- **Encryption Level:** AES-256 encryption, HIPAA-compliant
- **Electrodes:** 3-3.35 mm spacing, medical-grade, adjustable fit.
- **Durability:** IPX4 water-resistant, 0°C to 40°C range, shock-resistant.

Device concept and design

Our device is a wearable, EEG-based seizure detection system designed to provide continuous, real-time monitoring of brainwave activity in patients with epilepsy. By detecting seizure-related patterns in EEG data, the device enables timely intervention, enhances patient safety, and assists healthcare providers in managing epilepsy more effectively.

Current Design Status

The EEG-based seizure detection device is in the prototype testing phase, with functional subsystems for signal acquisition, filtering, anomaly detection, and machine learning integration. Preliminary tests show promising accuracy, sensitivity, and specificity.

Future work

Extended testing to validate accuracy and minimize false detections in real-world settings, optimizing the machine learning model with diverse datasets for greater reliability, and enhancing battery efficiency for longer monitoring. User interface improvements will focus on customizable alerts and data views, while regulatory preparation aims for FDA/CE certifications and HIPAA compliance. Finally, pilot production and design adjustments will support efficient large-scale manufacturing.

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