Epilog: A Rapid-Application EEG Headband for At-Home Monitoring of Non-Convulsive Status Epilepticus

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Abstract

Status epilepticus (SE) is a medical emergency defined as an enduring seizure or a series of rapidly recurring seizures and stands as the most prevalent pediatric neurological emergency. The transition to SE is characterized by a decrease in outward movement without a return to baseline neurological activity, and it is easily confused with the unresponsiveness associated with the comedown of a convulsive seizure. This often impedes timely medical intervention, leading to a mortality rate of nearly 30%. To address this need, our team developed Epilog—a rapid-application electroencephalography (EEG) headband to detect non-convulsive SE. Current seizure detection technologies are primarily based on motion or full-head EEG, rendering them ineffective or impractical for at-home detection of SE in emergency scenarios. Epilog is designed to be rapidly applied by a caregiver, collect and filter EEG data, and alert caregivers if the child remains in a state of SE using our proprietary machine learning algorithm. Epilog features eight electrodes with adjustable positions and a custom case to simultaneously gel electrodes in under ten seconds. Epilog's data acquisition system can capture and clean EEG signals, transmitting them via Bluetooth. This signal is processed in real-time by our detection algorithm, which can be fine-tuned to individual patients and has a specificity of 0.88, sensitivity of 0.95, and detection of SE in under 15 seconds. These decisions are available on a smartphone application (iOS/Android). We will continue conducting human factors testing and clinical validation to ensure that Epilog empowers caregivers to make informed, life-saving decisions.

Background

Though extensive research efforts have been dedicated to detecting the onset of seizure activity in the brain, very little attention has been given to determining when a seizure has ended – yet this question carries serious, life-threatening consequences. There are approximately 11 million children with epilepsy worldwide who experience seizures throughout their daily lives [1], and as many as 7% of these children are projected at some point to experience a medical emergency known as status epilepticus (SE) [2]: a prolonged episode of seizure activity exceeding 5 minutes [3], and the most prevalent neurological emergency during childhood according to the NIH with a mortality rate of 30% [4]. Whereas the beginning of a seizure is usually noticeable due to convulsions and movements of the body, these outward signs can disappear by the time a seizure evolves into SE due to fatigue. The only way SE is detected in the context of daily life is based on a caretaker's instinct and personal risk assessment: if, and only if, they suspect their child is exhibiting irregular behavior minutes after a seizure first begins, they can call their child's neurologist, describe the situation, and ask if a trip to the hospital is needed for an electroencephalogram (EEG) test to quantitatively examine their child's brain signal and verify that they are still seizing. The time window before severe brain damage is incurred after the onset of SE is approximately thirty minutes to one hour [2]. Caretakers are left distressed and paranoid that with every seizure that appears to have ended, their child could still be seizing without anyone knowing. The mission of our device, Epilog, is to bring the quantitative EEG test from the hospital to patients' homes, providing a data-driven approach that can inform caregivers of their child's brain state in the moment and offer greater insight as to whether a trip to the hospital is needed.

The need for rapid SE detection is a global problem, rooted in deep inequities in medical accessibility. Epileptic seizures are experienced daily by millions of children on a global scale, who have varying – and often limited – access to hospitals and seizure-ending medications, which are highly expensive and imperfect [2]. Caretakers currently have no way to quantitatively assess whether their child is in SE at home, and many cannot afford to repeatedly take drastic measures such as rushing their child to the hospital every time a seizure occurs. Furthermore, not only is this need a matter of life-threatening emergency, but also of constant, serious distress for children with epilepsy and their caregivers, who are left worrying indefinitely that a seizure can unknowingly result in death at any given moment.

Current seizure detection devices on the market, outlined and compared in Table 1, are largely designed to detect the onset of seizures, with little to no emphasis dedicated to seizure termination. Motion-based devices, such as accelerometer-based bracelets and wristwatches, provide no insight into seizure activity once outward movements have ceased, rendering them useless during cases of SE [6]. Current EEG-based devices, such as helmets and caps, either require trained hospital technicians for placement or involve a full-head system that are uncomfortable and inconvenient for rapid application during the seizure comedown period. Recently developed seizure monitoring devices, such as Ceribell, offer rapid application EEG but are only suited for use in hospitals, and all of these existing devices are intended for continuous seizure monitoring and long term wear. These shortcomings inhibit the rapid recognition of SE, which is critical for successful treatment.

Table 1: Differentiation of Epilog from Existing Technologies

	Empatica Embrace 2 Seizure Alert Wristwatch [5]	**Ceribell Rapid Response EEG System [6]**	**CortiCare CortiCal EEG Electrode Set [7]**	**Epilog**
EEG-based Seizure Monitoring	☒	☑	☑	☑
Rapid Application (< 45 sec)	☑	☑	☒	☑
Home-Use	☑	☒	☒	☑
Comfortable Design	☑	☑	☒	☑
Reduced Montage	–	☑	☒	☑
Reusable	☑	☑	☒	☑
Accessible Cost (< $800)	☑	☒	☒	☑
Reliable Alert System (Specificity > 0.9, Sensitivity > 0.85)	☒	☑	☒	☑

Epilog stands out in the EEG monitoring market as the only device that can rapidly detect NCSE in an at-home setting, with considerations for all needs specifications required to have an impact in the pediatric medical device space (Table 2).

Table 2. Needs Specifications for Epilog

Category	Specification	Quantification	Justification
Physical Design	Rapid Application	< 45 seconds	A decision regarding next steps in medical care typically needs to occur within 3 minutes post convulsive seizure [2]. Rapid application streamlines the data driven decision making process, and allows caregivers to act within the recommended window.
	Reduced Electrode Montage	≤ 10 electrodes	An 8 working electrode system with 2 electrodes for ground and reference was chosen based on both design criteria and preliminary algorithmic performance. 8 working channels was shown to be the least before compromising accurate detection. Additionally, this will be more comfortable and easier to place on the user.
	Low Cost	< $800	To be standardized for at-home use, Epilog must be significantly cheaper than the multi-thousand dollar clinical EEG devices.
	Adjustable	N/A	An adjustable design is essential to accommodate a child's growth, eliminating the need for frequent replacements and making it a cost-effective, long-term solution. This adjustability ensures the headband remains comfortable and effective as the child grows from infancy through adolescence.

Algorithmic Performance	Computation Time	< 5 seconds	Our algorithm makes a decision every second regarding the state of seizure. Computation time includes the processing time and the transmission of this decision to the user interface.
	High Sensitivity and Specificity	> 0.9 sensitivity > 0.85 specificity	A recent study done with a reduced number of EEG channels achieved a 70% sensitivity and 96% specificity [8]. For the purpose of this device, it is important that the false negative rate is extremely low. If the seizure is in fact continuing, but the device says it is over, that is potentially fatal to the user. For ease of mind and reliable use of the product, the false alarm rate must be minimized.

<u>Project Overview</u>

Objectives and Design Goals

Epilog's main objective is to reduce the subjectivity in the detection of non-convulsive SE detection in pediatric epilepsy patients by providing a reliable at-home EEG monitoring solution that can be easily applied by caregivers. Epilog features a design that allows for quick and easy application by caregivers, who often have minimal medical training. This rapid deployment of less than 15 seconds is crucial during seizure events, ensuring that the EEG can begin monitoring brain activity without delay. Epilog analyzes EEG data in real-time and alerts caregivers immediately if a child is in a state of SE, through integration with a custom machine-learning algorithm that has achieved a sensitivity and specificity of 0.95 and 0.88, respectively. This enables prompt action to manage the seizure, potentially preventing further complications. With consideration that the end users are children who will grow over time, the headband is adjustable to fit a range of sizes and shapes, ensuring comfort and maintaining accuracy as the child grows. Furthermore, high-quality, hospital-grade gel electrodes are used to ensure the best possible signal quality for precise EEG readings, supporting the reliability of the device in detecting non-convulsive SE.

Table 3. Product Specifications

Category	**Specification**	**Final Product**
Physical Design	Rapid Application	Gel and Headband Application Time: < 15 seconds
	Reduced Electrode Montage	10 total electrodes
	Low Cost	< $400 (cost of production)
	Adjustable	Adjustable electrode placements and size
Algorithmic Performance	Responsivity	Computation Time: < 3 seconds Latency for 10 seconds of 100% Accuracy: < 1 minute
	Accuracy	Sensitivity: 0.95 Specificity: 0.88 ROC: 0.95

The primary end users of the Epilog EEG headband are caregivers of children with epilepsy. These caregivers need a solution that fits seamlessly into their home environment and daily routines without requiring significant medical knowledge or disrupting existing care practices. Because of this, Epilog is designed to be integrated into the home setting without the need for professional setup, making it an extension of the care already provided by families. By providing granular alerts on if a child is in a state of SE, Epilog modifies the current workflow of SE management, which typically involves uncertain observation and possibly delayed hospital visits. Now, caregivers can receive immediate, actionable information, reducing the need for emergency interventions and frequent hospital visits. With minimal training and adjustment by the patient's neurologist, caretakers can use Epilog effectively in an at-home setting significantly enhancing the quality of life and safety for both the children affected and their caregivers.

Epilog is used once the visual signs of a seizure have stopped, wherein the Epilog headband electrodes are simultaneously gelled using the gel case, where then the headband is secured onto a child's head (Fig. 1).

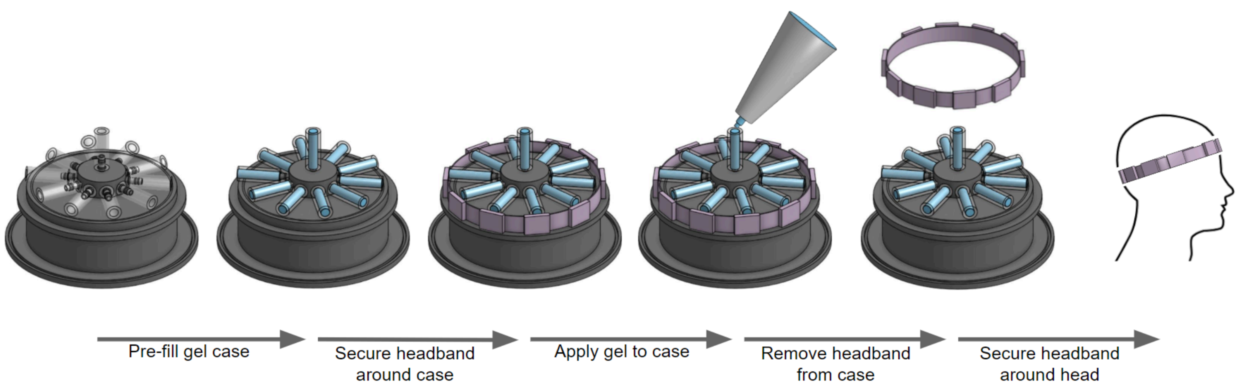

Figure 1. Workflow diagram of the rapid-gelling

Eight channels of EEG data immediately begin being recorded, and the signal is fed into a fully personalized machine learning model for extraction of relevant features for diagnosis of SE. The caregiver is then alerted if the child is in a state of SE through our user-friendly application available on both iOS and android (Fig. 2) .

Figure 2. Epilog Use Flow Diagram

Project Schematics

Figure 3: Complete Assembly of Epilog

Our full product includes a rapid-application gel case, a customizable EEG headband, a full EEG data acquisition system, a machine-learning algorithm for the detection of seizure activity, and a user-friendly mobile app. Detailed schematics and descriptions of each element of Epilog are described in Figures 4-7.

Gel Case Design

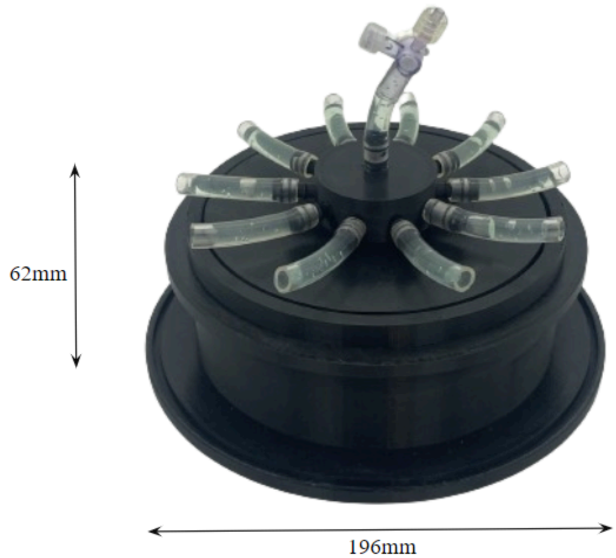

Figure 4: Gel Case Specifications

We designed the gel case to facilitate rapid gelling of all 10 electrodes on the EEG headband. The cylindrical design allows for even distribution of gel, as well as compact storage when not in use (Fig. 3).

Headband Design

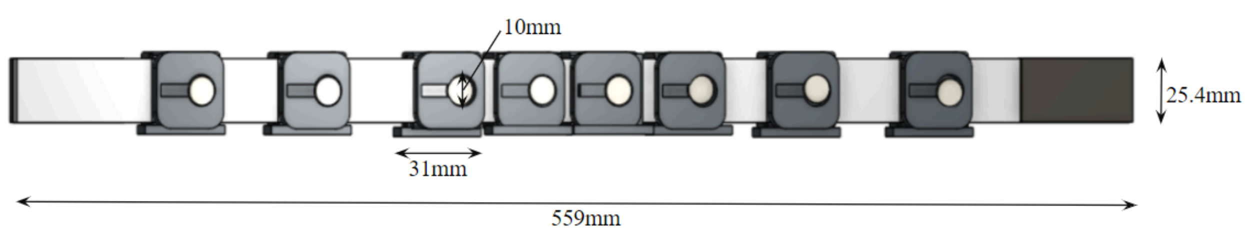

Figure 5: Epilog headband specifications

The headband is made of a dual layered elastic band which secures around the patients head with an adjustable hook. The eight working electrodes are attached to 3D-printed brackets which can be slid along the band and locked into place in order to align the placement of the electrodes to standard electrode placements for each patient's head (Fig. 4). The adjustability of the brackets also allows for modification of electrode placements as a patient's head grows over time. The electrode wires extrude from the left end of the headband and connect to the circuit enclosure.

Algorithm

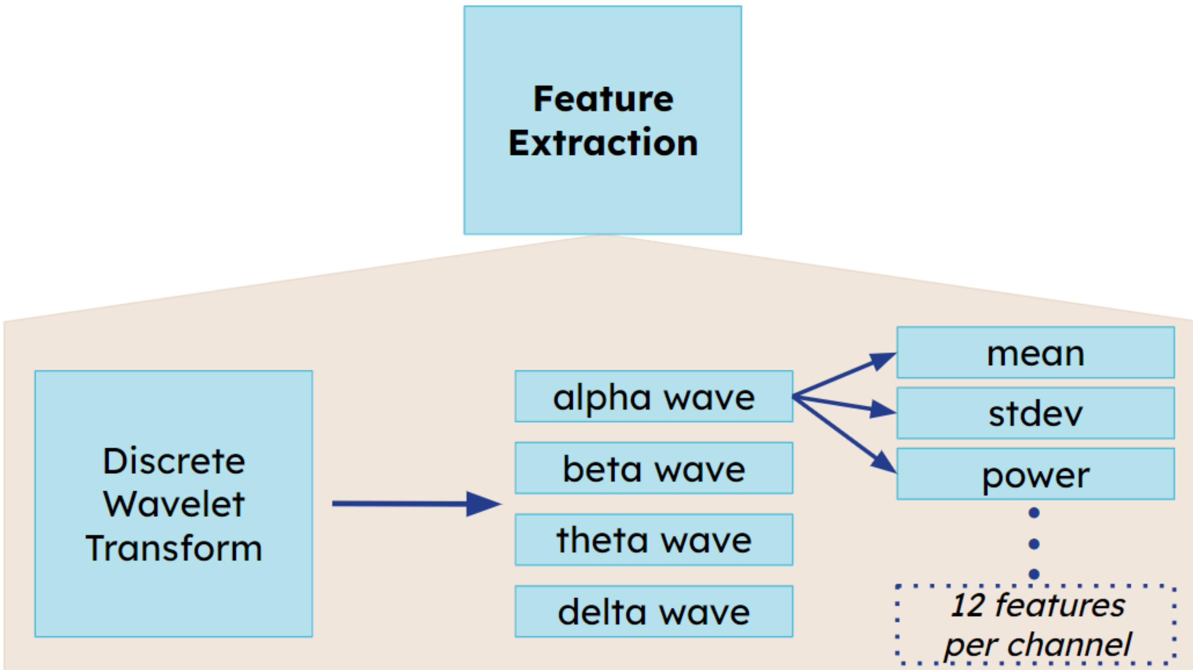

Figure 6: Feature Extraction Algorithm

To use the signal collected from our EEG headband, we first extracted relevant features. We use a discrete wavelet transform, a cousin of the Fourier transform, to convert the data into the wavelet domain and obtain the coefficients of key physiological frequencies: the alpha, beta, delta, and theta bands. We can calculate the mean, standard deviation, and power of each of these frequency bands, giving us 12 features per channel, calculated every second (Fig. 5).

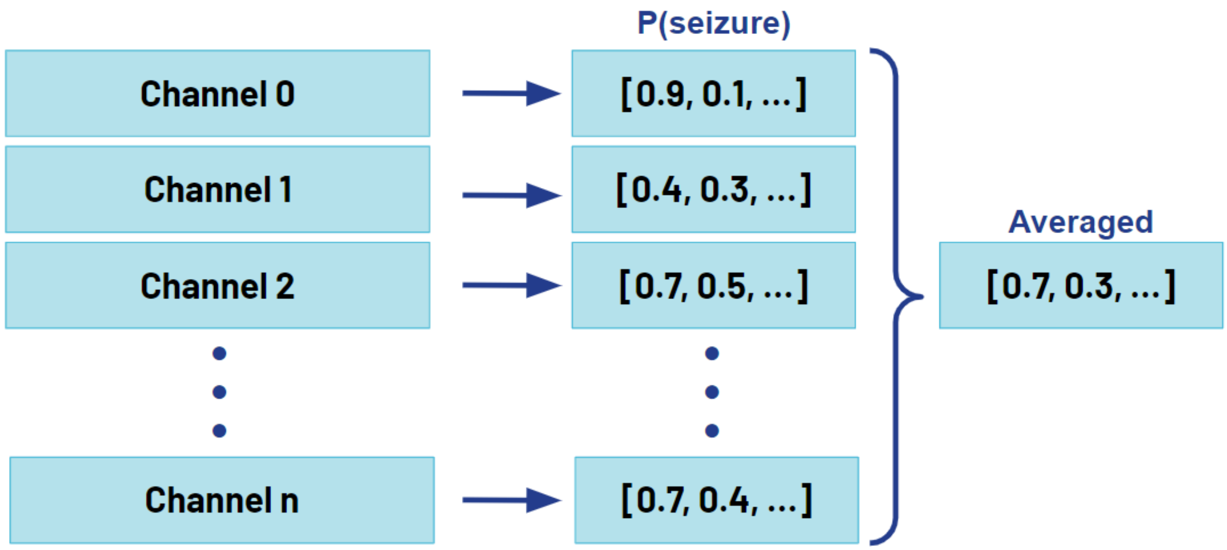

Figure 7: BalancedRandomForest Algorithm

These features are fed into a BalancedRandomForest classifier, which has class imbalance baked into the model, key for clinical datasets like ours. Each channel is analyzed separately to find the probability of a seizure at every given second. The results are then averaged across all 8 channels and thresholded for a final decision (Fig. 6).

Impact

With these features in mind, Epilog provides caregivers of pediatric epilepsy patients much needed peace of mind, knowing that this device would allow them to accurately determine if their child was in SE. In a broader context, Epilog allows for increased accessibility to EEG monitoring devices which would contribute to a safer environment for children with epilepsy and facilitate better integration of children with epilepsy into mainstream educational settings. Caregivers in educational settings would be better equipped to manage and respond to seizures, promoting a more inclusive learning environment. Increased accessibility to EEG monitoring devices, including Epilog, could help reduce healthcare disparities, particularly in regions with limited resources. Remote monitoring capabilities could bring diagnostic and monitoring tools to areas where specialized healthcare facilities are scarce. Additionally, a broader usage of Epilog monitoring devices could generate a wealth of data for research purposes. This data, with privacy considerations taken into account, could be used to enhance our understanding of epilepsy, improve treatment strategies, and contribute to public health efforts aimed at reducing the global burden of epilepsy. Early detection and monitoring through Epilog could also potentially reduce healthcare costs associated with emergency room visits and hospitalizations due to uncontrolled seizures. It may also lead to more cost-effective long-term management strategies. As Epilog is designed to be reusable, it addresses environmental concerns of electronic waste, as the metal electrodes used in our design are treated as single-use in hospital contexts and discarded after each EEG recording. Since our product is intended for use for only one patient, reusing the electrodes in the headband is a feasible and environmentally friendly option.

Design Limitations

A tradeoff associated with the reduced montage of our design is that our minimal number of electrodes used, while allowing for computational efficiency, will inherently never achieve the same accuracy as a configuration of 20+ electrodes used in hospitals. Additionally, while our device allows for easy at-home use, there will always be a risk that user error could contribute to incorrect reading of EEG and thus determination of seizure state. We would anticipate that all caregivers who plan to use Epilog would participate in training, likely provided by the patient's neurologist to ensure consistent application and proper interpretation for the next steps in providing care for their child.

Standards and Regulations

Our device must adhere to the standards detailed by certain national and international regulatory bodies, including the Food and Drug Administration (FDA), International Organization for Standardization (ISO), and Institute of Electrical and Electronics Engineers (IEEE) Standards Association. The Food and Drug Administration (FDA) is a national agency that curates standards which our medical device would be required to adhere to. The FDA stipulates that any EEG recording device should be fully characterized and tested for electrical, mechanical, and thermal safety, as well as biocompatibility and electromagnetic compatibility. In addition, software design specifications must be clearly documented for the device, and any algorithms must be evaluated for validation, verification, and hazard analysis for FDA approval to be considered. The device must also include precautionary safeguards that prevent users from relying on it as a stand-alone diagnostic device, such as a warning label. Reproducibility would need to be analyzed using inter-class correlation coefficients and depicted in a scatter plot. The device label must also explicitly name the intended user population and environment [9]. In terms of quality assessment, the device must be evaluated for precision, accuracy, reproducibility, sensitivity, specificity, and positive and negative predictive value in a clinical setting to be considered for FDA approval, and these specifications must be explicitly written on a label for the device. These parameters should be assessed using a quality management system such as the one stipulated in ISO 13485 (specifically for medical devices) [10]. The specific standards for EEG recording devices are detailed in ISO 60601-2-26 [11]. Risk assessment must also be evaluated in accordance with ISO 14971 [12]. To ensure that an EEG device can interface with other electronic systems (such as computers for data processing), it must satisfy the medical devices communication standards outlined in ISO/IEEE 11073 [13]. Software validation and verification for seizure detection should be evaluated according to the criteria specified in IEEE 1012 [14].

Testing and Evaluation

Signal Quality: Signal to Noise Ratios

To calculate the signal to noise ratio (SNR) of the EEG signal collected from the Epilog headband, it was essential to establish a notion of the "true signal." This was achieved by calculating the mean amplitude of a 500ms window centered on a blink artifact spike, which was observed consistently across 20 trials. This mean value represented our "true signal," reflecting the primary EEG response we intended to analyze (Fig. 8).

Next, we defined the "noise" as the deviation of the individual signals from this true signal. Specifically, for each trial, the standard deviation of the EEG readings within the same 500ms window was computed. This measurement reflects the variability or noise around the mean spike, not attributable to the blink artifact itself. The SNR was then calculated using the following formula:

$$SNR = 10log_{10}(P_{signal} / P_{noise})$$

This ratio provides a quantitative measure of the signal clarity against the background noise, indicating the strength of the blink signal in relation to the variability of the EEG readings within the targeted window. The higher the SNR, the clearer and more distinguishable the true signal is from the noise, thus facilitating a more accurate analysis of the EEG data.

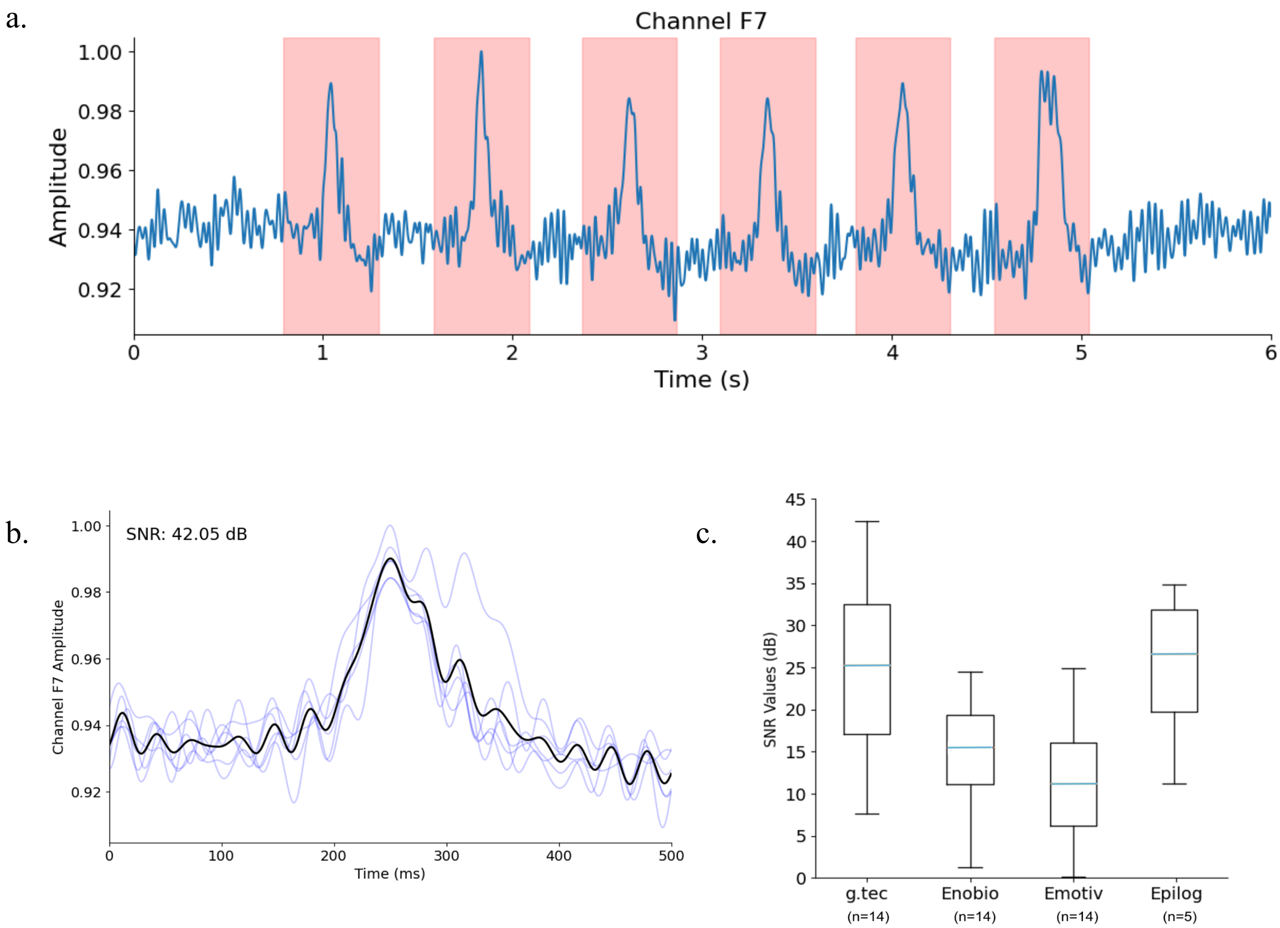

Figure 8. (a) Representative image of windows centered on each blink spike. (b) Visual representation of the mean spike and signal noise. (c) Box-and-whisker plot comparing the SNR of current devices compared to Epilog.

As shown in Figure 8c, the SNR of Epilog is comparable to other EEG devices on the market, calculated using an equivalent method, meeting our needs specification of accurate EEG data acquisition [15]. The biggest limitation in this testing was the number of participants available to validate the signal. For future validation tests, Epilog will be tested on a greater number of participants to increase the reliability of this SNR metric.

Signal Quality: Presence of Blink Artifacts

The identification and rejection of eye-related artifacts are critical in the interpretation of clinical EEG [16]. Our signal processing methodology effectively removes these artifacts prior to analysis by the detection algorithm. However, to ensure that our device was sensitive to small changes in brain activity, we monitored the EEG responses to various eye movement stimuli. The experimental protocol involved participants, wearing our EEG headband, executing these specific behaviors in repetition: five eye blinks spaced one second apart, five seconds with eyes closed, and five seconds of rapid eye flutters. These movements were anticipated to generate EEG signals of significant magnitude relative to baseline brain activity (Fig. 9). By qualitatively comparing these signals to expected patterns, we confirmed the reliability and responsiveness of our data acquisition system. Throughout the development process, these tests were conducted frequently as part of a continuous validation strategy. Our final validation tests involved ten trials across five users, to ensure comprehensive verification of our system's capabilities. These tests contribute to the validation of our needs specification of acquiring a clean, live EEG signal using our device. For a qualitative test, we are confident with our conclusions drawn from the number of trials and replicates we had.

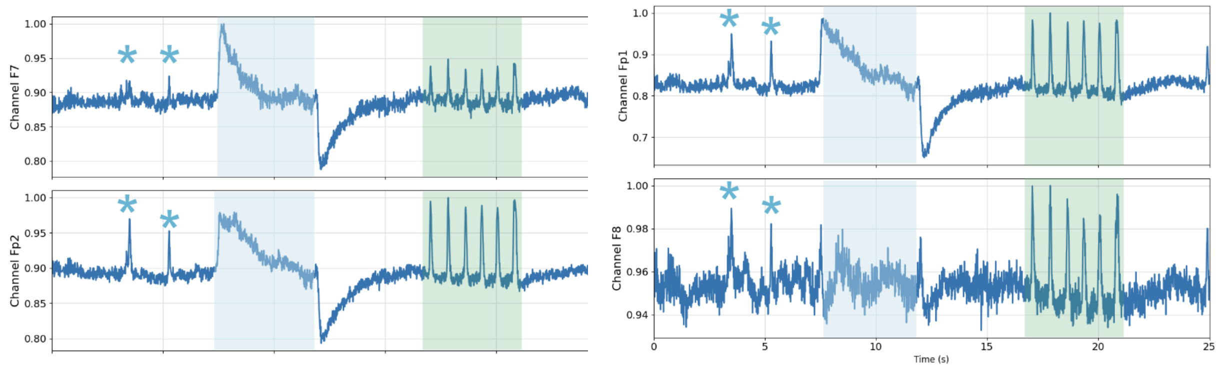

Figure 9 . EEG response to eye movements from four forehead channels. Asterisks represent eye blinks, shaded blue areas are periods of eyes closed, and shaded green areas are rapid eye flutters.

Signal Quality: Spectral Signal to Noise Ratio

The presence of blink artifacts in our recorded signals confirmed whether our data acquisition system could read, clean, and amplify signals of the same magnitude as EEG. However, we needed to verify whether these signals were truly from the brain and not simply from other kinds of electrophysiologic signals that can also originate from the scalp, such as electromyographic (EMG) signals from nearby muscle groups.

To accomplish this, we tested whether we could observe the Berger Effect in our system's collected data. The Berger Effect is a neurophysiologic phenomenon observed in the alpha band (8-12 Hz) of recorded EEG signals [17]. The spectral amplitude of this particular frequency band, which represents the relative amount of signal that oscillates within these frequencies, behaves differently when the eyes are closed and when the eyes are opened: when the eyes are closed, the spectral amplitude of the alpha band increases, and when the eyes are opened, the alpha amplitude decreases. The most plausible hypothesis behind this behavior is that specialized neurons, which are usually dedicated to recording different aspects of environmental stimuli such as color, motion, shape, and brightness, synchronize once the eyes are closed, due to the lack of variation in what the eyes are seeing. This synchronization causes the signals from individual neurons to add up across neuron populations, which leads to the greater spectral amplitude observed once the eyes are closed, and this effect is best observed in the alpha band [18].

To test whether we could observe the Berger Effect using our own system, the alpha amplitude was calculated in the signals recorded from each of the four forehead electrodes (F1, Fp1, F2, Fp2) during a five-second interval of eyes closed, and again during a five-second interval of eyes opened. The alpha amplitudes of the four electrodes during eyes closed were then averaged with each other, and the same was done for the eyes-opened state. This was then repeated over another five seconds of eyes closed and five seconds of eyes opened, and the mean alpha amplitudes of each five-second clip were then averaged with each other, within each state. The end result of this testing was the grand average of the alpha amplitude across four forehead electrodes during ten seconds of eyes closed, compared to the grand average of the alpha amplitude across the same four electrodes during ten seconds of eyes opened. These grand averages were plotted and compared as shown in Fig. 10, and the spectral signal-to-noise ratio between the eyes closed and eyes opened states, also displayed on Fig. 10, was calculated using the following formula:

$$SNR_{spectral} = \alpha_{eyes\ closed} / \alpha_{eyes\ opened}$$

where α represents alpha amplitude [18].

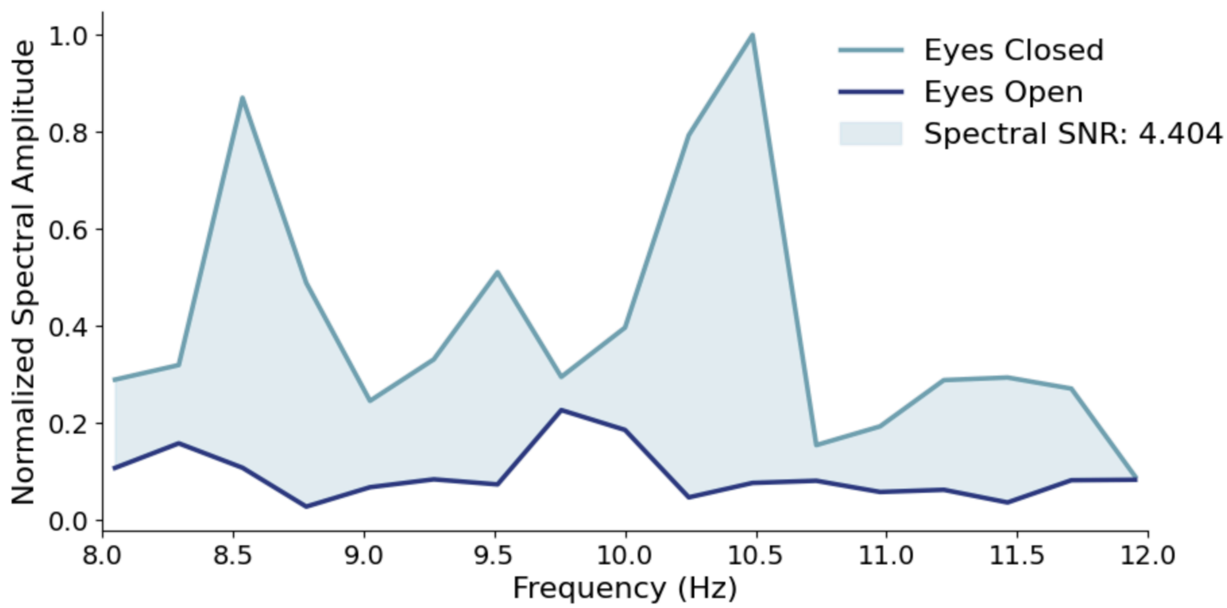

Figure 10. Observation of the Berger Effect in signal acquired by the Epilog system, quantified using spectral SNR of the alpha frequency band.

The Berger Effect is most pronounced in the frontal lobe, responsible for cognition, and the occipital lobe, responsible for visual processing. Our headband does not record EEG from the occipital lobe, so we focused on the four forehead channels on the frontal lobe when analyzing the Berger Effect. [18]

Compared to 12 EEG devices tested in a study conducted by Bussalb et al., which averaged a spectral SNR of 1.813 ± 0.191 [17], our spectral SNR of 4.404 matched expectations that the alpha amplitude indeed increases in the eyes-closed state. The two most probable explanations for why our spectral SNR was significantly higher than the twelve EEG devices tested in this study are the number of participants (the study had n=19 while we had n=5) and the types of electrodes tested. The study surveyed a wide array of electrode types, including gelled and dry, while ours were strictly gelled. Gelled electrodes typically have much higher signal quality than dry electrodes [19], which could explain why our device's spectral SNR was much higher than the average of twelve mixed EEG devices. For future validation tests, more trials of Epilog will be conducted on a greater number of participants.

Signal Quality: Clinical Professional Verification

As a final verification metric, we presented a sample of signal collected from our headband as well as the culmination of our signal verification results to Dr. Dennis Dlugos, Director of Pediatric Epilepsy Program and Clinical Neurophysiology at the Children's Hospital of Philadelphia. Dr. Dlugos demonstrated enthusiasm in our results and offered a preliminary endorsement of the Epilog's ability to collect and transmit EEG signals with quality on par to that of devices currently on the market. He emphasized the importance of further clinical trials to fully establish the device's efficacy and reliability in a real-world setting.

Algorithmic Performance

Our model was trained on 70% of randomly selected patients from the CHB-MIT dataset [20], hyperparameters were tuned on 15% of the patients, and the remaining 15% were our testing dataset. They were randomly selected using a pseudorandom number generator.

The algorithm can output the probability of a seizure occurring at every given second. This can be used to calculate the likelihood of false positives and false negatives at varying thresholds (a threshold of 0 means all false positives, 1 for all false negatives). This can be used to construct a receiver operating characteristic curve, or ROC. Our ROC score was 0.95 for the testing dataset (Fig. 11). With a threshold of 0.5, we can also calculate how many true positives, true negatives, false positives, and false negatives resulted from our analysis. This can be used to calculate the specificity (TN / (TN + FP)) and sensitivity (TP / (TP + FN)), which are inversely related to the false positive rate and false negative rate, respectively. For our testing dataset, we reached a specificity of 0.883 and a sensitivity of 0.946. Note that our sensitivity is higher, which indicates a preference for avoiding false negatives, which is a child in status that is detected as normal (and more harmful than false positives). This met our criteria of a specificity over 0.85 and a sensitivity over 0.9, which is in-line with products currently on the market and in the literature, as can be seen in Table 4.

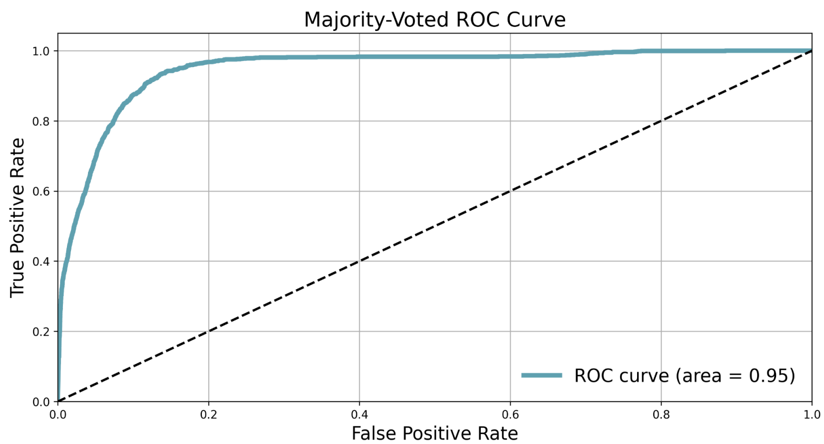

Figure 11. The receiver operating characteristic (ROC) curve for the test dataset. The resultant probabilities are the result of averaging across all channels, which are independently trained and tested.

Table 4. Comparison of algorithmic metrics from key papers analyzing the CHB-MIT dataset. Epilog is able to reach a performance level similar, if not better than, these seminal papers.

Author	**Score**	**Metric**
Shoeb and Guttag (2010) [21]	96	Sensitivity
Logesparan et al (2015) [22]	52	ROC
Ahmad et al (2014) [23]	94.8	Average Accuracy
Gill et al (2015) [24]	87.58	Average Accuracy
Orelanna and Cerqueira (2016) [25]	97.12, 99.29	Sensitivity, Specificity
Birjandtalab et al (2017) [26]	80.87, 47.45	Sensitivity, Precision
Epilog	**94.6, 88.3**	**Sensitivity, Specificity**

While these statistics provide a holistic view of the data, the most important aspect for caregivers is how long the algorithm takes to correctly detect status epilepticus or lack thereof after a seizure event. By calculating how long it takes for the algorithm to correctly detect 10 consecutive seconds of non-seizure activity after convulsions, we can quantify the expected value of time before a firm answer is received. This time for 10 consecutive seconds of 100% correct detection is 26.77 seconds. Our goal was to have detection in under 1 minute, and with an average latency of < 1 second and a detection time < 27 seconds, this was easily met.

Note that experimentation was done to address the needs of those with irregular EEG baselines. The baselines (lack of seizure activity) were measured for different patients over the course of 10 seconds. This data was artificially upsampled by replicating 1000 times with Gaussian noise and added to the training set to retrain the algorithm. The resultant performance showed a marginal improvement in detection accuracy, specificity, and sensitivity.

Physical Design: Application Time

The required time to gel all ten electrodes included in our design was calculated based on the average across twenty trials. Each trial mimicked the expected use scenario. Prior to timing each trial, the gel case was pre-filled with salt- and chloride-free electrode gel, and the headband was secured around the case with the electrodes aligning with the positions of the gelling tubes. Each timed trial included a single user applying additional gel through the vertical application tube, examining for successful gelling of the electrodes, removing the headband from the case, and securing it around a model head (Fig. 1). The average time to complete said tasks across the twenty trials was 10.64 seconds with a standard deviation of 1.15 seconds (Table 5).

Table 5. Timing rapid application trials. The average time to completion was 10.64 s ± 1.15 s.

Trial Number	Application Time (s)
1	12.16
2	10.5
3	11.2
4	12.74
5	12.29
6	8.82
7	11.17
8	8.83
9	9.88
10	10.51
11	10.19
12	11.78
13	10.94
14	10.16
15	10.55
16	10.42
17	11.83
18	9.76
19	10.39
20	8.71
MEAN	10.64
STDEV	1.15

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Appendices: Table of Contents

Appendix A: Bill of Materials

Category	Vendor	Web Link	Catalog #	Item	Quantity	Cost/piece
Physical Design	Amazon	Link	B0869KZ9CT	1” Width Woven Elastic	2 pcs, 1”x24”	$5.49
Physical Design	Amazon	Link	B0CJ8RZW4D	Detachable Clasps	1 pcs, 1”x0.25”	$5.99
Physical Design	The Electrode Store	Link	SH-48S	10mm Die-Cast Ag EEG Electrodes	10 pcs	$18.50
Physical Design	Amazon	Link	B07YNBTVMC	Flexible Comb	1 pc, 1”x12” (cut to size)	$5.61
Physical Design	-	-	-	Electrode Casing, PLA	8 pcs	-
Circuit Design	Texas Instruments	Link	EAR99	LM741	24 pcs	$0.75
Circuit Design	Digikey	Link	3132-ST-PROTO-2-3-ND	Solderable Breadboard	8 pcs	$4.99
Circuit Design	Amazon	Link	B07HGT77R5	Wire	1 pcs	4.99
Circuit Design	Digikey	Link	13-CFR-25JR-52-2KTR-ND	2kΩ Resistors	24 pcs	$0.10
Circuit Design	Digikey	Link	13-MFR-25FTF52-100KCT-ND	100kΩ Resistors	8 pcs	$0.10
Circuit Design	Mouser Electronics	Link	603-CFR-25JR-52-750R	750kΩ Resistors	16 pcs	0.10

Circuit Design	Adafruit	Link	1831	100k Potentiometer	8 pcs	$0.95
Circuit Design	Amazon	Link	B00MH4QM1S	9V Rechargeable Batteries	3 pcs	$1.57
Circuit/Software integration	Digikey	Link	1050-ABX00063-ND	Arduino GIGA R1 WiFi	1 pcs	$72.82

Appendix B: Build Procedure

This build procedure outlines the step-by-step process for assembling the EPILOG system, a cutting-edge electroencephalogram (EEG) headband designed for rapid seizure detection. The construction of EPILOG involves several key stages, starting with the preparation of the EEG electrodes and headband, followed by the assembly of the data acquisition (DAQ) circuitry. It also includes instructions for setting up the wireless communication module for data transmission and configuring the software for seizure detection. The guide is structured to first address the fabrication of the dual-layered polychloroprene headband integrated with EEG electrodes, followed by the assembly of the electrical components, including the DAQ system. Subsequently, it details the process for embedding the wireless communication module, specifically designed for seamless data transfer. The final section covers software setup, calibration, and testing to ensure accurate and efficient operation.

<u>Fabrication of the EEG Headband</u>

Physical Design

3D Printed Components and Combs

1. Using Onshape Modelling or other desired modeling software, design the electrode casing according to Figure 1 and the below instructions
    a. Sketch a 1.2” by 1.2” square
    b. Extrude ⅛”
    c. Sketch a 0.4” circle
    d. Boolean Extrude ⅛” to create inset for electrode to sit

e. Sketch ⅜" by 1/10" rectangles

f. Merge Extrude 1.2" and connect to front wall at top and bottom

g. Sketch a 1.2" by 1.2" square

h. Merge Extrude ⅛" to top and bottom pieces to form full piece to surround the elastic and encase the electrode

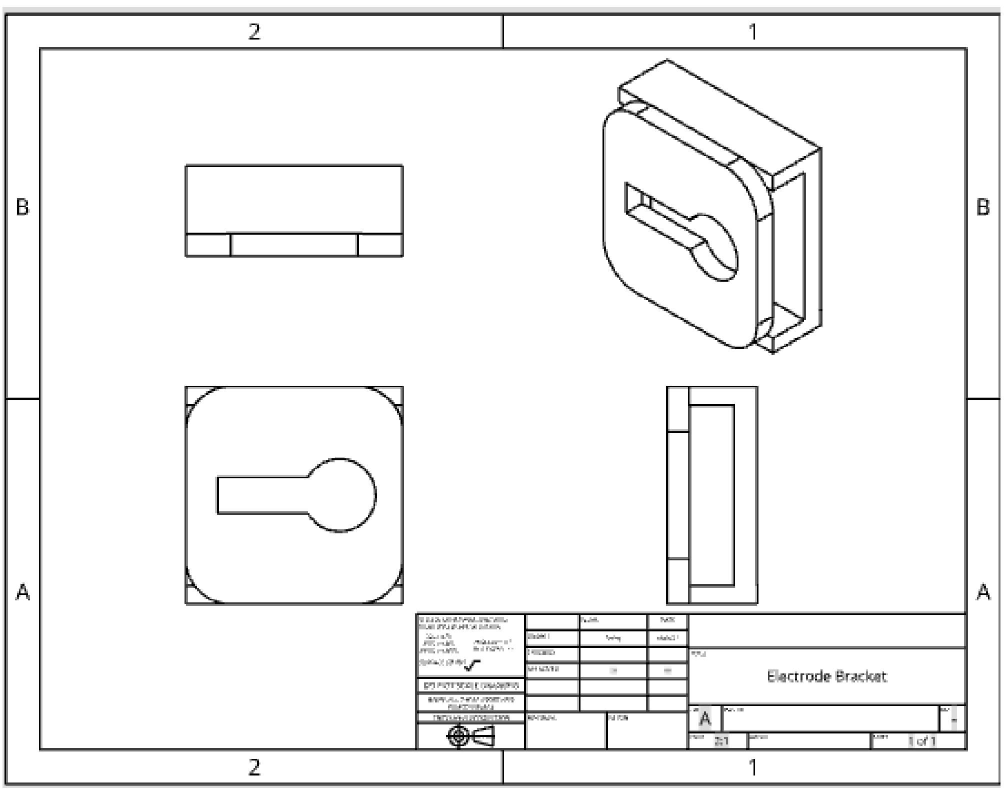

Figure S1: Drawing of Electrode Bracket

2. Affix using glue small combs around the electrode hole on 4 pieces
3. Using Onshape Modelling or other desired modeling software, design the circuit housing

   a. 3D print a press fit box with dimensions of 3" by 5" by 2"

a. Leave a 1” by 0.5” by 0.5” opening to thread electrode wires through
b. Leave a 0.5” by 0.5” by 0.5” opening to place the on/off switch

Sewing the Band

1. Two pieces of 1.5” wide elastic strip is cut 18” long
2. The two pieces of elastic are sewn to each other around the perimeter to create a dual layer elastic
3. Two velcro (one being the hook velcro, and the other being the loop velcro) pieces are cut into 2.5” long and 1.5” wide strips.
4. The loop and hook velcro are sewn in on opposite surfaces of the band.
5. 8 slits (⅛” wide) are cut 1.5” apart along the length of the elastic band
6. 10 electrodes are thread through the band from one end
7. Each electrode should go through exactly one slit
8. Affix the 3D printed pieces over the elastic band, lining them up with the slits and electrodes
    a. Ensure the pieces with affixed combs are on the 4 back of the head electrodes
9. Press the electrode into the piece until locked into place
10. Lay the band flat and ensure all components lay flat and electrodes are all facing the same direction to ensure proper alignment and contact once the headband is applied
11. Connect electrode wires to the rest of the circuit, and bundle wires to make more compact
12. Place wires and circuit into circuit housing

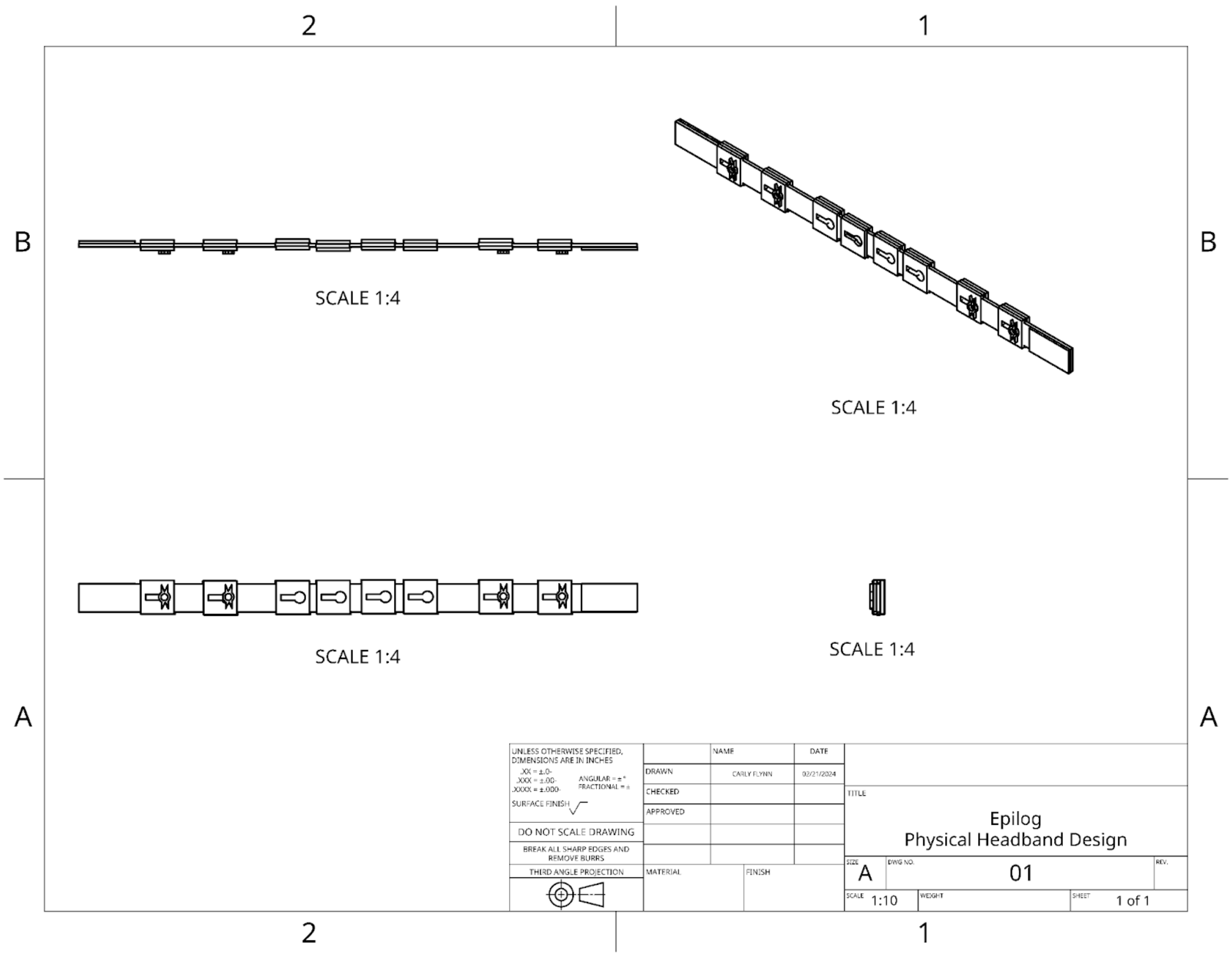

Figure S2: Drawing of Headband Design

Figure S3: Construction of Headband with Elastic and Electrodes

Electronics Assembly

Shown below is a circuit diagram outlining the electrical schematic of the device:

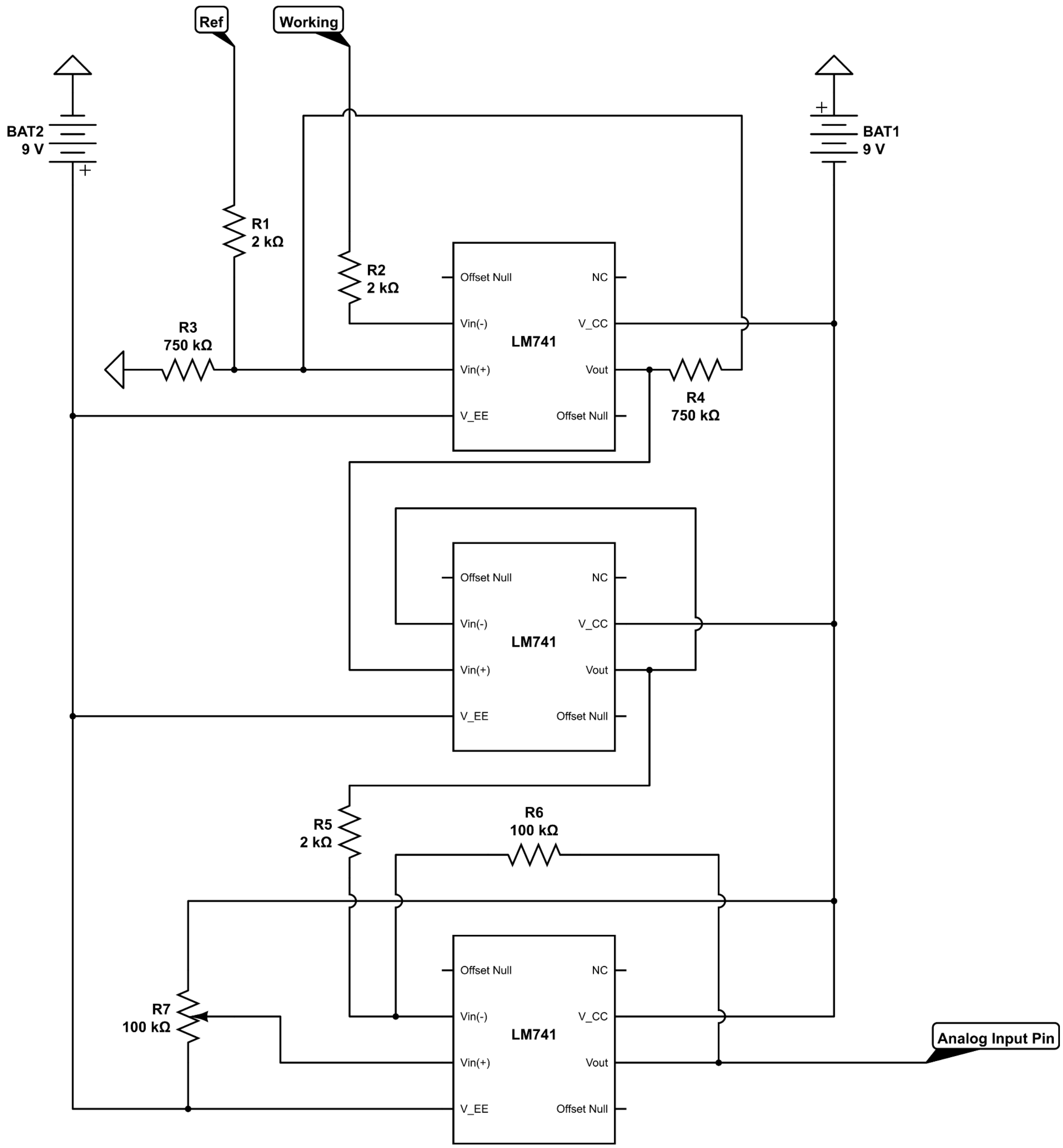

Figure S4: Circuit Diagram for a Single Electrode Channel

1. Solder eight copies of the circuit diagram outlined above on a solderable breadboard.
2. Solder the end of the working electrodes to the appropriately labeled node.
3. Solder the reference electrode to the appropriately labeled node.
4. Solder the ground electrode to the ground rail.
5. Solder wires from the final output pin to the analog pins of the Arduino GIGA R1 WiFi (see diagram below).

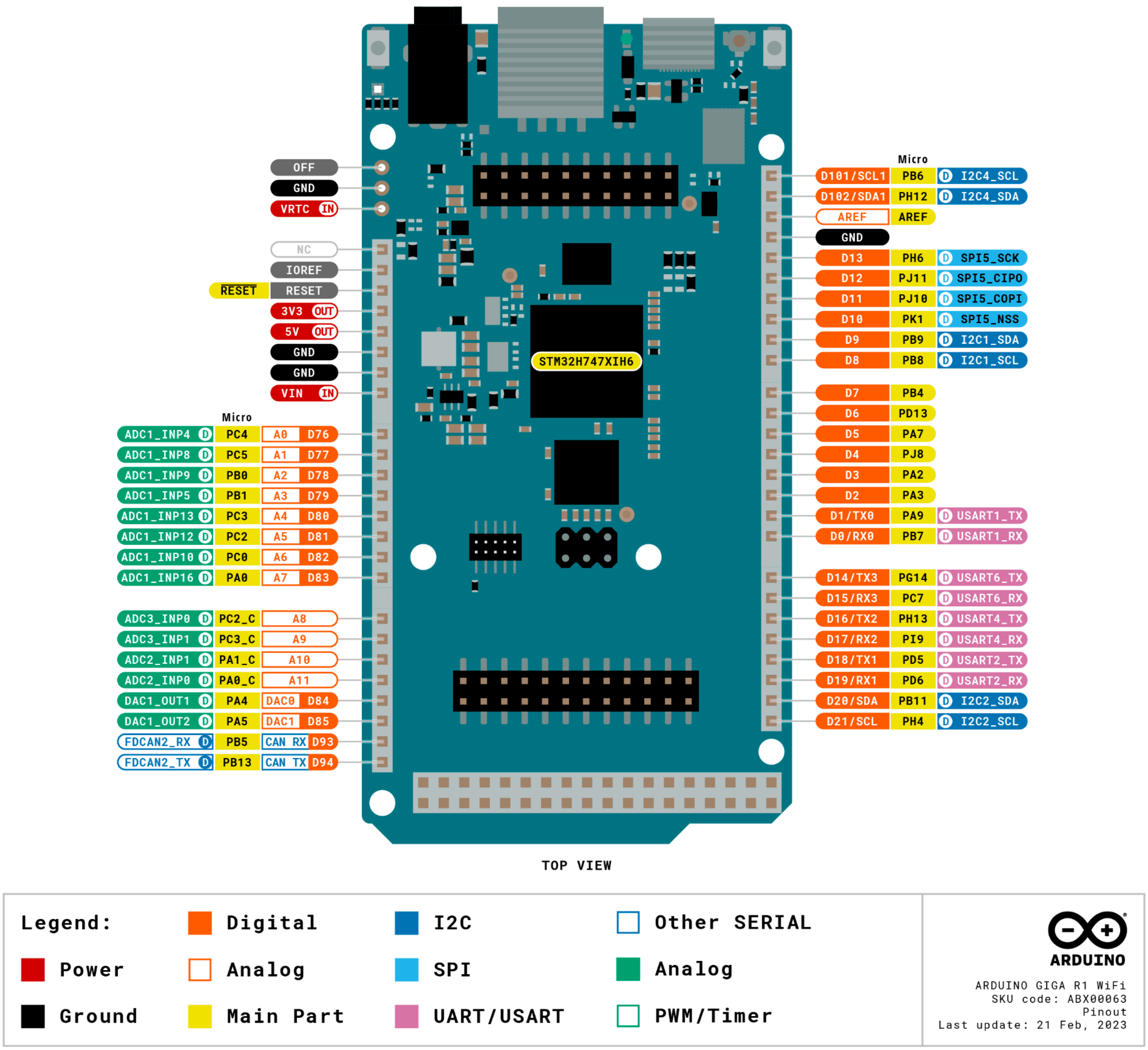

Figure S5: Pinout Diagram for the Arduino GIGA R1 WiFi

6. Secure the final breadboards together so they are with the appropriate hardware.

7. At this point, you should have:

   a. A fully assembled circuit board

   b. Long output wires soldered securely and inserted into the Arduino GIGA R1 WiFi input pins

c. 10 electrode wires (8 working electrodes, 1 ground electrode, and 1 reference electrode) soldered securely and attached to EPILOG headpiece

Integration of Bluetooth Communication Module

- The microcontroller interfaced with the DAQ circuitry is the Arduino GIGA R1 WiFi, which has a Bluetooth module that enables wireless data transmission to a local device, such as a mobile phone or laptop.
- Using the Bluetooth Low Energy (BLE) software from the ArduinoBLE library, configure the Arduino to sample at a rate of 500 Hz, transmitting data packets of 30 samples at a time.
- Embed a Bluetooth module into the circuitry, ensuring it is correctly interfaced with the microcontroller for efficient data transmission.
- Implement security measures for encrypted data transfer to protect patient information during wireless communication.

Software Setup and Calibration

1. Install the necessary software on a personal computer or a cloud platform for real-time seizure detection analysis.
2. Program the microcontroller with firmware to manage EEG data acquisition, signal processing, and transmission.
3. Conduct initial calibration of the system using standard EEG signals to fine-tune the detection algorithms and ensure accurate seizure detection.

Appendix C: User Manual

Device Description: Epilog is an electroencephalogram (EEG) headband designed to be rapidly secured around a child's head during the seizure comedown period, after outward movements have ended. This device will provide a convenient, comfortable, at-home solution for caretakers to determine if their child is in a state of status epilepticus (SE), leading to greater peace of mind and providing necessary urgency in emergency situations.

Intended Use Case: Epilog is specifically designed as an informational tool to aid caretakers of pediatric epilepsy patients in monitoring and managing seizure activities. Its primary function is to be utilized during the seizure comedown period, after the cessation of visible convulsions, to determine if the child is experiencing SE, a condition where seizures follow one another without recovery of consciousness between them. To ensure the accurate and effective use of Epilog, comprehensive training will be provided by the patient's neurologist or a qualified healthcare professional, who will instruct the caretaker on how to properly secure the headband, interpret the readings, and act on the information provided by the device. Given the tailored nature of seizure detection and the variability in seizure manifestations among individuals, the Epilog headband may require initial fitting and periodic adjustments by a neurologist. This customization is crucial for optimizing the device's sensitivity and specificity to the child's specific needs.

Elements Needed for Device to Function:

Hardware requirements

- Device connected to WiFi
- Rechargeable 9V batteries (included)

- Conductive electrode gel

Software requirements

- Epilog Android or IOS app

Safety Considerations and Caution Statements:

- Epilog is intended to be used as an informational tool and should not replace professional medical advice or emergency medical services. Always follow the guidance of a healthcare professional regarding its use.
- Ensure that all caretakers using Epilog have received proper training from a qualified healthcare professional, as incorrect use may lead to inaccurate readings or potential discomfort for the user.
- Before using the headband, check the skin in the area where the electrodes will be placed for any signs of sensitivity, irritation, or injury. Avoid using the device on broken or irritated skin.
- Use only the recommended conductive gel to prevent skin irritation and ensure accurate readings. If skin irritation occurs, discontinue use immediately and consult a healthcare professional.
- Ensure the headband is fitted securely but comfortably. An overly tight fit may cause discomfort or pressure marks, while a loose fit may result in inaccurate data collection.
- Epilog may be susceptible to interference from other electronic devices. Avoid using it near strong electromagnetic fields, such as those produced by MRI machines, to prevent inaccurate readings.

- The device is not waterproof. Protect it from water and moisture to avoid damage to electronic components.
- Follow the manufacturer's instructions for charging and storage.
- Do not attempt to modify or repair the Epilog headband yourself. Unauthorized modifications could compromise the safety and functionality of the device.
- Dispose of the device, batteries, and any other components according to local regulations regarding electronic waste. Improper disposal may harm the environment or pose a health risk.
- Epilog is not a life-saving device. In the event of a medical emergency, contact emergency services immediately.
- Be mindful of privacy and data security when using the app associated with Epilog. Ensure that personal health information is protected according to privacy laws and regulations.

User Directions:

Mechanical Design Setup:

1. With the user's neurologist, carefully remove the Epilog headband and accessories from the packaging. Ensure you have the headband, gel case, and any circuitry housing laid out. A neurologist should adjust the electrode placements on the headband, which are marked according to standard EEG placement (Fig. S6).

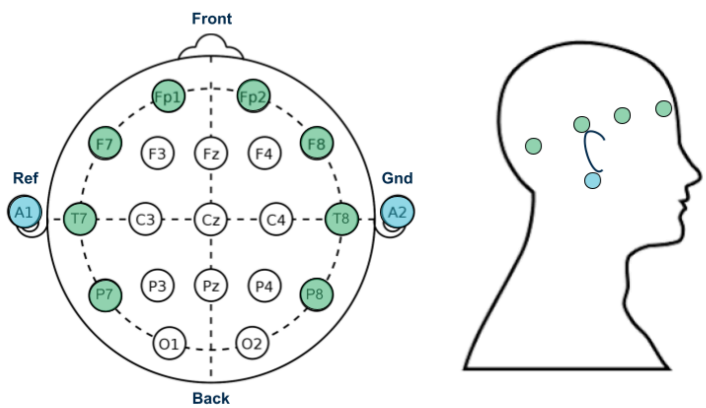

Figure S6. Standard EEG Placements Aligned with Epilog Headband

2. The Epilog headband is designed with adjustable sizing to securely fit around a child's head. Before initial use, find the appropriate hook strap to ensure a snug but comfortable fit, without exerting excessive pressure.
3. When a child begins seizing, use the gel case to apply a thin layer of conductive gel to each electrode (Fig. S7). The gel enhances the conductivity between the electrodes and

the scalp, ensuring high-quality signal acquisition.

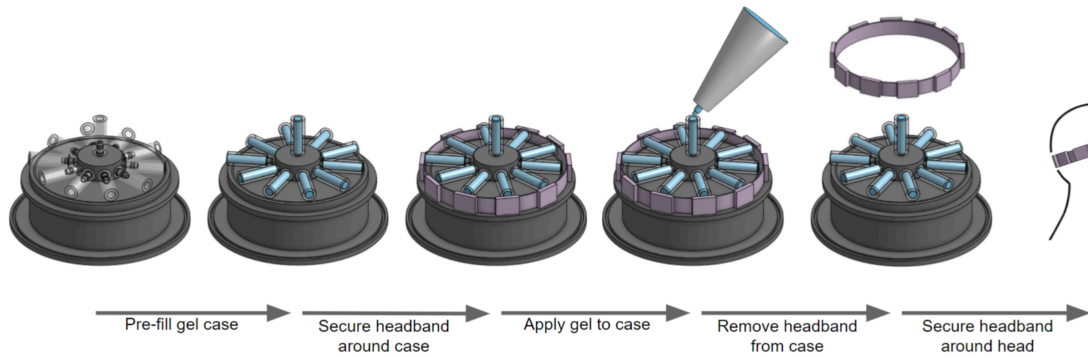

Figure S7. Workflow diagram of the rapid-gelling

4. Once the gel has been applied, place the headband on the child's head, aligning the electrodes with the previously identified positions. Secure the headband using the hook tabs, ensuring a firm fit that prevents slippage but does not cause discomfort.
5. Once the headband is secured, turn on all switches located on the circuitry housing (Fig. S8). You will see an indicator light signaling that the device is powered on. EEG data will now be sent to the Epilog app via bluetooth.

Figure S8: CAD of Circuitry Housing

UI Setup:

1. Download the Epilog app on your smartphone. Open the app and pair the Epilog headband to your device via Bluetooth.
2. Create a patient profile for the child, including necessary medical information and any specific instructions from the neurologist.
3. Familiarize yourself with the app's dashboard, where you can view real-time risk of SE, conduct the initial calibration, and set up alerts for specific seizure indicators (Fig. S9).

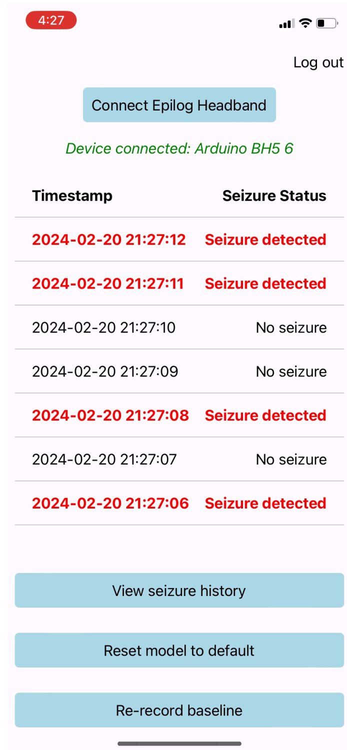

Figure S9. Connect Epilog Headband to Bluetooth Using App

4. Upon the first use, and whenever advised by a healthcare professional, perform a calibration of the Epilog headband. This involves recording a short period of EEG data while the child is at rest to establish a baseline for normal brain activity. Calibration ensures that the device accurately captures and interprets EEG signals based on the child's unique physiological characteristics (Fig. S10).

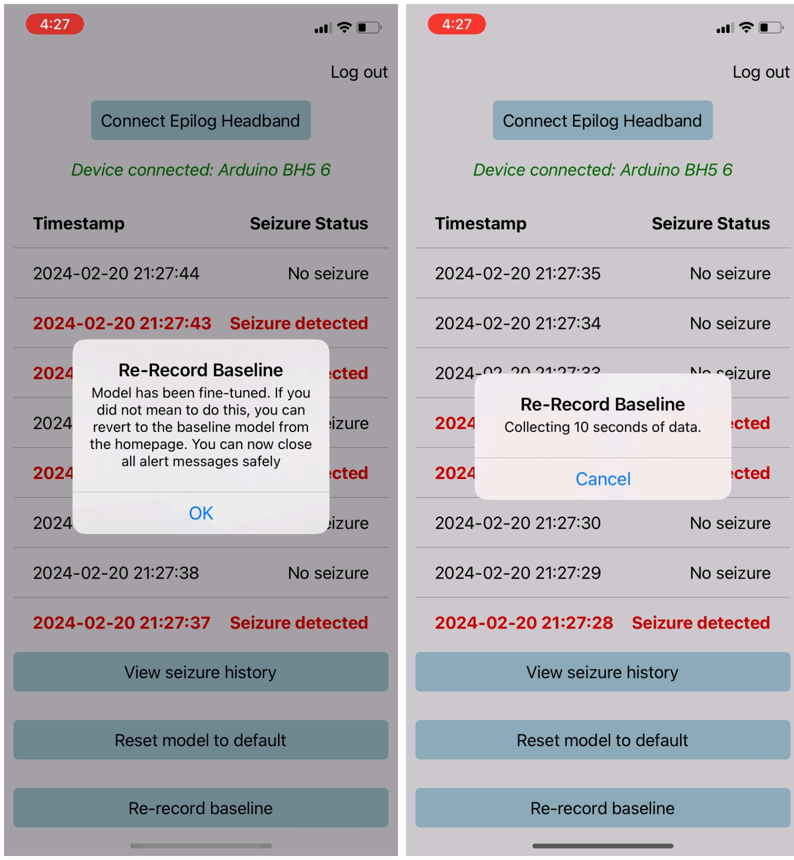

Figure S10. Calibration

5. Once baseline has been recorded, which the app will confirm via a pop-up notification as seen in Figure S10, the app will automatically switch to monitoring EEG signal for seizure activity.
6. If deemed appropriate, reset the model to baseline (Fig. S11).

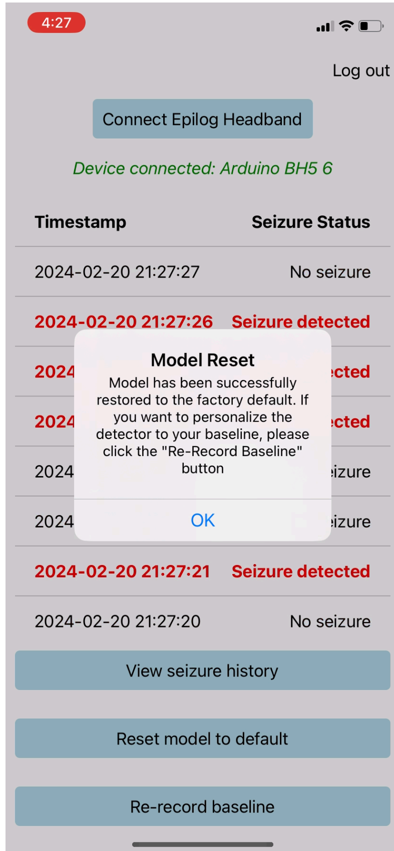

Figure S11. Reset Model

Troubleshooting Tips:

If the device won't turn on…

- Check if the battery is properly installed and charged. Replace or recharge the battery as necessary.
- Ensure that all switches are turned on.

If there is poor signal quality…

- Confirm that the electrodes are correctly positioned on the head and making good contact with the scalp. Adjust the headband if necessary.

- Check for and remove any hair or debris that might be obstructing the electrodes.
- Ensure that a sufficient amount of conductive gel has been applied to each electrode to improve conductivity.

If there are bluetooth connection issues…

- Ensure the headband is within the Bluetooth range of the device it's supposed to connect with.
- Restart the Bluetooth connection on both the headband and the smartphone/tablet. Sometimes turning Bluetooth off and then back on can resolve connectivity issues.
- Check if the app is up-to-date. Outdated apps may have compatibility issues.

If the app is not displaying algorithm results…

- Confirm that the headband is properly connected to the app via Bluetooth.
- Check if the headband is turned on and properly fitted to the user's head.
- Restart the app or your mobile device to reset the connection.

If the device is uncomfortable or causes irritation…

- Adjust the headband to ensure it's not too tight or too loose. The headband should fit snugly but comfortably.
- If irritation occurs at the electrode sites, consider using a different conductive gel recommended for sensitive skin, and consult a healthcare professional.

If the battery drains quickly:

- Check if the headband is being turned off properly after use. Accidentally leaving the device on can drain the battery.

- If rechargeable, ensure the battery is being charged correctly according to the manufacturer's instructions.

If there are inaccurate seizure detection alerts…

- Recalibrate the device according to the instructions in the user manual. Calibration ensures the device is accurately interpreting the EEG signals.
- Consult with a healthcare professional to verify the device is correctly adjusted for the user's specific condition.

If the headband slips off during use…

- Re-adjust the headband's size for a better fit. Make sure the headband is not positioned over hair or a slippery surface on the scalp.
- Consider using a non-slip accessory or adjusting hair placement to improve headband stability.

Product Care:

- After each use, gently wipe the electrodes and the surface of the headband with a damp cloth with isopropanol to remove any gel residue and oils from the skin.
- Ensure that any gel used is compatible with the electrodes to prevent damage. After use, remove any remaining gel from the electrodes to prevent buildup, which can affect signal quality.
- Regularly inspect the electrodes for signs of wear or damage. If an electrode appears damaged or worn out, contact customer service for replacements or advice on proper care.

- When not in use, store the headband in a cool, dry place away from direct sunlight. Avoid folding the electrodes sharply or storing under heavy objects to prevent damage.
- If you plan not to use the headband for an extended period, ensure it is clean and dry before storing. Remove any batteries if applicable to prevent leakage. Store in a protective case if provided.
- Charge the device using the provided charger or as directed in the user manual. Do not overcharge or leave the battery connected to the charger for extended periods beyond the recommended charging time.
- Use only the recommended battery type for replacements. Dispose of old batteries properly according to local regulations.
- Keep the device's firmware and associated app updated to ensure you have the latest features and security patches. Updates may also include improvements in signal processing and user interface enhancements.
- Avoid dropping the headband or subjecting it to severe shocks, as this could damage the electronic components or the structural integrity of the headband.
- The headband is not waterproof. Protect it from rain, splashes, and submersion in water.
- Besides home care, it may be beneficial to have the device checked by a professional periodically, especially if you notice any changes in performance. This can ensure that any potential issues are identified and addressed promptly.

Appendix D: Circuit Diagrams

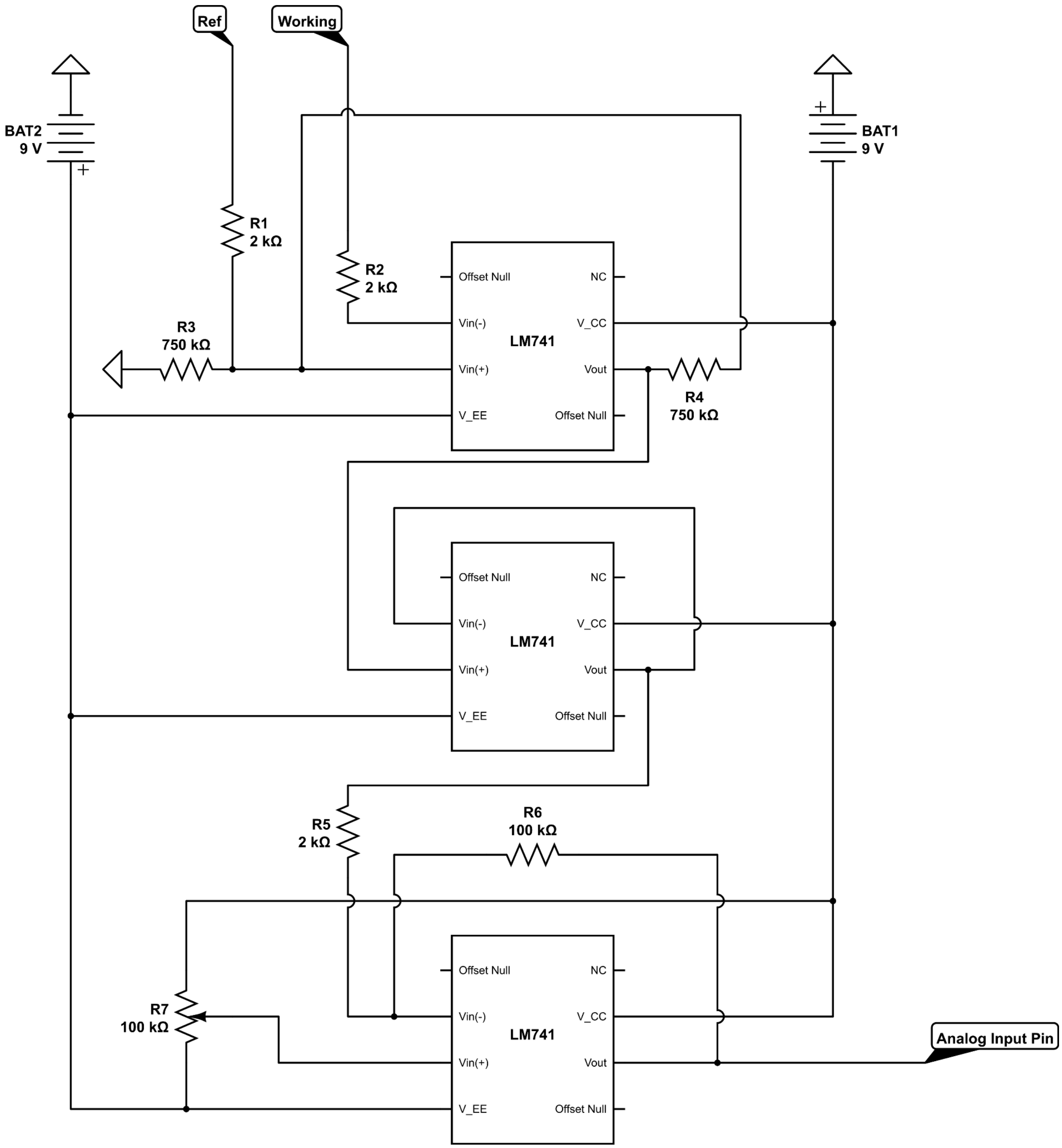

Figure S12: Circuit Diagram for a Single Electrode Channel

Appendix E: SEAS Competition Video

Link to Youtube Video: SEAS Competition 2024 - Epilog

Appendix F: Words of Wisdom

Team X's most important words of wisdom are LAB NOTEBOOK. Make a lab notebook!!! Share it with your whole team. Keep everything in there. It will make your life so much easier after long days in the lab when you can't even remember what you were doing 3 hours ago. It also helps when you're asking for help and you can show exactly what you've already tried. Some things you can list in it are:

- Missions for the day
- Failed missions from the previous day carried over to today
- 500 pages of copy-pasted code (half of which will be comments)
- Michael's words of wisdom
- Texts/messages to your group members outside of the text group chat y'all already have
- Prop bets (over-unders, most likely to's)
- Circuit diagrams
- Screenshots from datasheets (chip pins) so you don't have to go back to the full BE inventory a thousand times a day
- Brain thoughts
- A hundred different errors and what they look like (janky signal, Arduino errors)

We started ours second semester and she's 143 pages long. You can do better! Beat us

Our secret debugging procedure when everything stops working on your computer/bluetooth stops connecting/code won't run:

1. Restart computer
2. Pray
3. Blast Kesha
    a. We recommend "Your Love is My Drug"

good luck, you got this!!! <3

P.S. You are much, much more capable than you think you are. We all went into this project with feedback that it would be impossible, that it wouldn't work, that it was too complicated – do *not* let the haters bring you down. You can do it!!

Figure X.