

An Unobtrusive and Lightweight Ear-worn System for Continuous Epileptic Seizure Detection

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Epilepsy is one of the most common neurological diseases globally (around 50 million people worldwide). Fortunately, up to 70% of people with epilepsy could live seizure-free if properly diagnosed and treated, and a reliable technique to monitor the onset of seizures could improve the quality of life of patients who are constantly facing the fear of random seizure attacks. The scalp-based EEG test, despite being the gold standard for diagnosing epilepsy, is costly, necessitates hospitalization, demands skilled professionals for operation, and is discomforting for users. In this paper, we propose *EarSD*, a novel lightweight, unobtrusive, and socially acceptable ear-worn system to detect epileptic seizure onsets by measuring the physiological signals from behind the user's ears. *EarSD* includes an integrated custom-built sensing-computing-communication PCB to collect and amplify the signals of interest, remove the noises caused by motion artifacts and environmental impacts, and stream the data wirelessly to the computer/mobile phone nearby, where data are uploaded to the host computer for further processing. We conducted both in-lab and in-hospital experiments with epileptic seizure patients who were hospitalized for seizure studies.

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The preliminary results confirm that *EarSD* can detect seizures with up to 95.3% accuracy by just using classical machine learning algorithms.

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1 INTRODUCTION

Epileptic seizures are one of the most prevalent neurological disorders affecting approximately 50 million people worldwide, with an estimated 5 million new cases diagnosed every year [1]. Seizures can occur suddenly and unpredictably, leading to severe accidents or even death [2]. This makes it critical to have an accurate and reliable way to identify and forecast seizures. A substantial challenge in the clinical management of epilepsy is the dearth of precise and reliable data that is accessible to physicians when diagnosing and treating seizures. Current methods rely predominantly on patients self-reporting through seizure diaries, but studies have shown that seizure records collected this way are accurate only for about 50% of patients [3]. In hospitals, video EEG (vEEG) is the primary method of diagnosing seizures. Given the infrequent nature of seizure events, patients are often required to spend several days in a hospital for a vEEG test. During the test, they wear a headset with over 20 wired electrodes to monitor electrical activity in the brain. They are under constant video surveillance so doctors can review the recordings to identify events that might have triggered a seizure.

Over the last 50 years [4], there has been continuous research to develop automated seizure detection tools to improve the reliability of EEG-based seizure monitoring. Most efforts have been devoted to developing robust seizure detection algorithms using signal processing, feature extraction, and machine learning techniques [5, 6] based on the collected vEEG data. While these works have demonstrated seizure classification accuracy of over 90%, vEEG setup is uncomfortable for users and needs to be set up and operated by trained technicians. Moreover, the study is costly, making long-term data collection unfeasible.

To fill the gap, one active research direction is to develop mobile, at-home monitoring solutions leveraging miniaturized sensors and electronics, wireless data transmission, and rechargeable batteries. Several approaches and commercialized products have also emerged using signals from alternative sources such as Electrocardiography (ECG) and Photoplethysmography (PPG) [7–10], Electromyography (EMG) [11–13] or even Electrodermal Activity (EDA) [14–16] in a range of form factors. However, the usability and practicality of these devices have been confirmed. Other wearable devices that can capture brain signals, such as Earable.AI, Emotiv, NeuroSky MindWave, BrainLink Pro, Muse, Kokoon, Versus, Neuroon Open, Naptime, etc., were designed to capture brain activities at slow frequencies such as sleep, meditation [17], etc., their abilities to capture low amplitude and complex patterns of epileptic seizure signals are unknown.

In this paper, we explore a novel and robust sensing system integrated into one of the most well-accepted wearable form factors – *the everyday earbuds* – for epileptic seizure detection, as illustrated in Fig. 1. Our proposed device, namely *EarSD*, collects physiological signals of EEG, EMG, and EOG from behind the ear and fetches them into machine learning models to accurately and rapidly detect seizure onsets. Thanks to the social acceptance of earbuds/earphones, *EarSD* could be worn in all environments, making it an ideal solution for continuous patient monitoring. *EarSD* has the potential to revolutionize the field of epilepsy management and significantly improve the quality of life for those affected by the condition. First, timely detection of epilepsy is critical for prompt intervention and mitigating potential risks and complications. Second, *EarSD* can enable real-time detection for early warnings and facilitate swift medical care. Third, the inconspicuous nature of an ear-worn wearable enhances patient compliance and encourages long-term usage, leading to more comprehensive data collection. Fourth, such unobtrusive devices will empower individuals to live their lives more freely, with the confidence

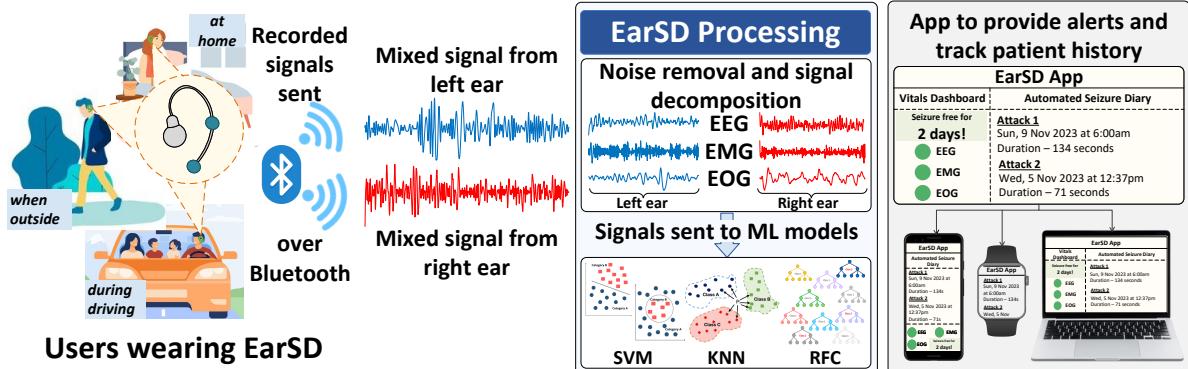


Fig. 1. The vision of *EarSD*, a socially acceptable wearable that supports real-time epileptic seizure detection. *EarSD* will be worn by epileptic seizure patients pre- and post-hospitalization. *EarSD* can be used as a standalone device or combined with video EEG to allow caregivers to design an effective treatment plan.

of timely seizure detection and improved seizure management. Last but not least, by collecting long-term data using *EarSD*, we can contribute to a deeper understanding of epilepsy and facilitate personalized treatment plans.

Besides epileptic seizure monitoring, if successful, *EarSD* system can be considered as a reference design for many other brain disorders monitoring systems, including. Neuromuscular Diseases [18], Autism and Neurodevelopment [19], dementia [20], pain [21], movement disorders [22], and others.

However, realizing *EarSD* is difficult due to the following challenges. First, the relationship between the signals from around the ear and epileptic seizure onset has not been thoroughly analyzed in the literature and needs to be better studied. Second, the signals recorded around the ear are weaker and have more noise than those collected at well-understood locations in vEEG settings. Creating a sensitive hardware setup capable of accurately capturing head-based signals in a compact design is challenging. A critical obstacle is devising a resilient method that can effectively eliminate the influence of human-generated disturbances on the monitored signals. For instance, while brain (EEG), muscle (EMG), and eye (EOG) signals typically range from microvolts (μ V) to a few millivolts (mV), bodily movements like head motion, walking, or talking can significantly overshadow the sensor data, causing noise levels to spike up to several volts. Third, running signal processing and machine learning algorithms on resource-constrained wearable devices is a demanding task limiting their usefulness for timely and effective seizure management. Efficient frameworks are needed to support real-time data acquisition, signal analysis, and inference while still operating within the limitations of the hardware. Last but not least, unlike common wearable devices designed for healthy individuals, *EarSD* is designed as a medical diagnosis tool. Its accuracy, efficiency, and robustness must be evaluated in clinical settings. Developing an end-to-end research prototype, which utilizes cost-of-the-shelf hardware and software front ends, requires a comprehensive analysis and thorough engineering efforts and skills in order to approach clinical settings accurately, which is currently only obtained by a tens of thousands of dollars system.

This project aims to make fundamental contributions to low-power, low-cost, unobtrusive, high-fidelity, and robust ear-based sensing systems for physiological signal monitoring. In this project, we take a holistic approach from form factor fabrication, sensing circuit design, and implementation to algorithm development to build and deploy the first ear-based epileptic seizure systems in clinical settings. We first design a sophisticated hardware and firmware pipeline to reduce the noise and then extract the mixed physiological signals collected around the ear into EEG, EMG, and EOG. We then explored multiple signal separation techniques, including ICA, PCA,

EMD, and NNMF, and found that the NNMF technique is the most suitable approach. We evaluate the proposed solution on epileptic patients in a hospital to confirm the approach's feasibility, usability, and practicality. We approach this clinical accuracy (up to 95.3% accuracy) using only two electrodes behind the ear instead of the hospital vEEG [23], with more than 20 electrodes placed on the scalp.

To summarize, the main contributions of this paper are:

- **Designing and developing a high fidelity, noise-resilient, and socially acceptable long-term EEG ear-based physiological monitoring method.** We developed an ear-worn system that can be safely worn behind the ear and make the device socially acceptable so the patient can wear it continuously, enabling long-term EEG monitoring.
- **Monitoring human physiological signals using just two electrodes.** While state-of-the-art epileptic seizure detection relies on at least 4 physiological channels sensing [24], to the best of our knowledge, *EarSD* is the first work to confirm the feasibility of detecting seizure with only two sensing channels.
- **Building high-fidelity ear-based signal acquisition and separation algorithms to extract the signal of interest from the noisy collected data.** We derived sensing techniques to capture the important physiological signals from around the ear and deployed a biosignal separation algorithm.
- **Building machine learning model techniques based on data collected in clinical settings.** We confirm the accuracy, usability, and practicality of *EarSD* through thorough clinical experiments in the Epilepsy Monitoring Unit at the University of Texas Southwestern Medical Center in Dallas, Texas, USA. The preliminary results confirm that *EarSD* is able to detect seizure with up to 93.5% accuracy on 33 patients.
- **Conducting a user study with patients, medical doctors, and caregivers in the hospital to verify the usability of *EarSD*.** We conducted a user study on 33 patients and 9 medical doctors and caregivers. Most users found the system to be socially acceptable and easy to use, and doctors have also verified the reliability of our device. This encourages us to continue with an ongoing study on a larger scale.

2 BACKGROUND AND RELATED WORK

In this section, we present the current practice of epileptic seizure monitoring in clinical and off-site settings.

2.1 Clinical-based Studies

Patients diagnosed with seizures are admitted into the Epilepsy Monitoring Unit in the hospitals, where they are monitored continuously 24/7 for up to a week using vEEG system. During the test, the patients wear EEG head caps containing electrodes connected to the patient's scalp. A standard setup includes between 21 to 32 electrodes positioned at specific locations across the scalp following the International 10-20 system as illustrated in Fig. 2. The electrodes are connected to an EEG reader which amplifies these signals, records the brain's electrical activity, and displays them on a screen as a series of waves or patterns. This setup is often supported by video monitoring allowing the medical team to correlate the recorded brain activity with observable physical or behavioral changes, aiding in the diagnosis and identification of specific seizure types. At the end of the test, neurologists interpret these recordings to diagnose conditions like epilepsy, tumors, or sleep disorders and formulate a treatment plan or further diagnostic investigations. To simplify this tedious task and reduce patient expenses, epileptic seizure detection has been an active

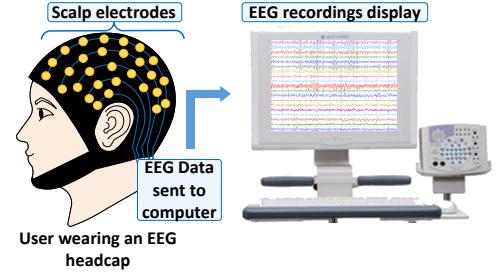


Fig. 2. Hospital-based video-EEG (vEEG) setup. Scalp electrodes capture EEG signals which are then recorded and displayed in the EEG machine for analysis by doctors.

research area since the early 1970s [4, 25]. Over the last few decades, there has been significant advancement in the field of automated epilepsy detection primarily using data from vEEG systems in hospitals. In addition to hospital-based studies, there have been efforts to develop wearable devices for home settings. These portable and user-friendly devices offer continuous and long-term monitoring outside clinical environments. We discuss some of the methods used in the literature in this section.

Improving the accuracy of physiological-based seizure detection algorithms. Persyst's [24] algorithms for seizure detection have been widely used as a suggestion tool to medical doctors and caregivers, while it is known to have a high false positive rate [26], posing challenges for adoption in practical applications.

Multiple research groups proposed various deep learning techniques for epileptic seizure detection leveraging collected video-EEG data [27]. Asif et al. [28] employed a deep learning framework, utilizing an ensemble architecture, to learn multi-spectral feature embeddings for cross-patient seizure type classification and classify seizures with 94%. However, a major challenge of deep learning models is the limited availability of clinical data. Most works such as [29–32], rely on the TUSZ open seizure dataset [33].

The analysis of EEG signals is inherently complex due to the presence of noise requiring extensive preprocessing to remove unwanted artifacts. Joshi et al. [34] applied a Butterworth bandpass filter to preprocess the CHB-MIT dataset [35], another public seizure-based dataset. They performed preprocessing in both the time and frequency domains, segmenting the data into seizure and non-seizure images and processing the resultant dataset through a CNN to achieve an accuracy of 98.21%. Madhavan et al. [36] proposed an automated classification method using synchro squeezing transform (SST) and deep CNN. They transformed the one-dimensional EEG signals into two-dimensional time-frequency matrices using Fourier SST (FSST) and wavelet SST (WSST) techniques. The processed signals were then fed into a two-dimensional (2D) CNN, resulting in an accuracy of 99.94% when classifying EEG signals into focal and non-focal events. This highlights that signal processing steps to remove noise improve the results of seizure detection algorithms.

Combining multiple physiological signals such as EMG, ECG, EOG, motion, as well as audio/video recordings, also boosts the accuracy of seizure detection [37]. Szabó et al. [38] utilized electromyography (EMG) to detect seizures, achieving high sensitivity and specificity. The works done in [39, 40] utilized electrocardiography (ECG) and heart rate variability (HRV) analysis, respectively, to successfully detect seizure events.

Reducing computational costs. Feature selection methods play a vital role in reducing computational complexity, improving computing times, and enhancing accuracy. Savadkoohi et al. used T-test and Sequential Forward Floating Selection (SFFS) to select significant features from EEG signals, achieving a classification accuracy exceeding 99.5% [41]. Tran et al. employed the discrete wavelet transform and a binary particle swarm optimizer to reduce data dimensionality by 75% while achieving an accuracy of 98.4% and reducing the computational time by 47% [42]. Atal et al. combined a modified Blackman bandpass filter-greedy particle swarm optimization (MBBF-GPSO) and CNN to achieve a seizure classification accuracy of 99.65% [43]. Through proper data analysis techniques, it is possible to extract relevant features from the EEG signals which can significantly reduce computational costs for a more optimized detection method.

While promising results have been demonstrated in the studies mentioned, further testing with a more diverse set of patients and for longer periods is necessary for comprehensive conclusions which is not feasible with just hospital-based tests. Continuous monitoring through wearable devices has emerged as a potential solution to address this limitation.

2.2 Wearable-based Approaches

Wearable EEG devices are key to extending seizure studies beyond the hospital settings [44, 45]. Researchers have developed wearable EEG recording devices that can be paired with smartphones to continuously monitor a

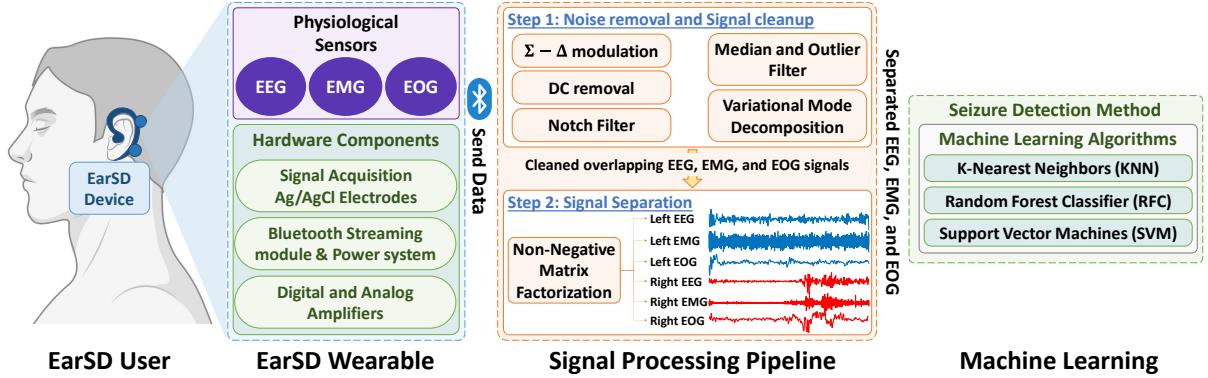


Fig. 3. *EarSD*'s system overview. The electrodes capture EEG, EMG, and EOG signals, wirelessly transmitting data to a host computer for noise filtering and signal separation. The decomposed signals are then analyzed by machine learning algorithms for automated seizure detection.

patient's EEG signals for later evaluation by doctors [46, 47]. However, the lack of convenience with existing designs highlights the need for smaller and less cumbersome mobile EEG systems [48, 49]. Several companies are also exploring the feasibility of developing wearable systems as alternatives to clinical setups [50–52]. However, wearables like Empatica Embrace 2 [16] are unable to reliably capture signals for seizure detection due to their placement away from the brain. Conversely, head-worn devices such as [53, 54] are either too unwieldy or obtrusive for regular use while limitations such as battery life also restrict their continuous use. Discreetly worn EMG devices have also been explored [55], but limitations such as battery life restrict their continuous use. Finally, most of the current devices primarily focus on detecting one type of seizure, and including other seizure types lowers sensitivity and raises false detection rates [56]. The lack of convenience with existing designs highlights the need for smaller and less cumbersome mobile EEG systems.

Can We Develop An Ear-Worn Seizure Detection System? Ear-worn devices offer a promising alternative to traditional EEG systems for seizure detection, offering several advantages over scalp EEG and other wearable types. Wireless, ear-worn devices are less cumbersome and more socially acceptable, increasing patient compliance for long-term monitoring. The absence of wires in wireless systems reduces noise degradation due to electrode wire movement [57]. They also enable easier and less intrusive data collection, making monitoring in non-clinical environments feasible. In this regard, studies comparing EEG signals from around the ears and scalp EEG indicate they can reliably capture brain activity [58–62]. However, despite these advantages, challenges such as bulkiness, discomfort, and high false detection rates persist in current wearable devices.

3 PROPOSED APPROACH

We propose *EarSD*, a low-cost, unobtrusive, and comfortable ear-worn system designed to continuously monitor critical physiological signals associated with epileptic seizure onset. *EarSD* utilizes a non-invasive approach by capturing data from the upper and lower areas of the ears. The signals are wirelessly transmitted via Bluetooth to a host computer for further processing and analysis to detect if the user is experiencing a seizure. The core components of the *EarSD* include (1) an ear-worn sensing device, (2) a sophisticated signal processing pipeline, and (3) lightweight machine-learning algorithms for seizure detection as showed in Fig. 3.

Ear-Worn Device. The developed ear-worn device includes a signal acquisition front-end connected to four Ag/AgCl electrodes facilitating cross-ear sensing. Each electrode is strategically placed, with two positioned

symmetrically on the upper left and right ears while the other two serve as reference and bias electrodes located on the bottom of the left and right ears, respectively (Figure 4). The electrodes are placed close to the eyes, facial muscles, and regions of the brain, facilitating the recording of eye movements (EOG), muscle contractions (EMG), and mid-brain activity (EEG). Since EEG, EOG, and EMG are biopotential signals, they can be captured using the same electrodes. Further details are provided in Section 4.

Advanced Signal Processing Pipeline. EarSD includes a sophisticated signal processing pipeline that processes the noisy data before passing them to the ML model for seizure detection. The collected signal is a mixture of EEG, EMG, and EOG, which have overlapping frequency and amplitude. Moreover, since our signals are recorded from around the ear, they are weaker than traditional scalp-based signals and more susceptible to noise. So, removing these unwanted artifacts and enhancing signal quality is important before any machine learning is done. Our proposed pipeline, elaborated in Section 5, involves applying essential noise filtering through bandpass filters, data segmentation, and utilizing an adaptive signal separation method to decompose the mixed signals.

EarSD’s Seizure Detection Algorithm. EarSD equips lightweight machine learning algorithms to perform automated seizure analysis. The signal processing step outputs six values (three signals for EEG, EMG, and EOG from each ear), and we evaluate three main machine learning algorithms, including SVM, kNN, and Random Forest Classifier (RFC). Note that we intended to constrain the algorithm’s design choices to lightweight options to make them more friendly with embedded system architectures. More sophisticated machine learning algorithms will definitely result in higher accuracy but add significant computational overheads and energy consumption. The multimodal data enhances the algorithm’s ability to distinguish between genuine seizure signals and normal fluctuations due to daily activities (e.g., drinking, eating, talking, and motion artifacts), reducing the likelihood of false positives and contributing to a more reliable and accurate seizure detection system. The algorithms were trained on 1,782 epochs (10 seconds each) and evaluated with leave-one-out testing (Sections 6 and 7).

4 EARSD DEVICE

4.1 EarSD Hardware and Firmware

Our proposed device includes two modules: sensing hardware and data acquisition software.

Sensing Hardware. The sensing hardware consists of two primary components: a brain-computer interface (BCI) and a pair of biosensor stickers (the wearable device). The first component, the BCI, featuring an ultra-low noise analog front-end (TI ADS1299) and an energy-efficient ARM Cortex-M4 microcontroller (TI MSP432P401), utilizes ultra-low noise amplifiers and a 24-bit ADC chip for signal digitization. The first-order analog filters remove high-frequency noise from the environment before passing it to the low-noise differential amplifiers of the ADC. The ADS1299 also contains an integrated second-order $\Sigma - \Delta$ modulator that samples the input at 1.024 MHz and shapes noise across the Nyquist bandwidth (i.e. 0-512 kHz). A third-order low-pass sinc filter then removes most of the noise at high frequency before decimation to 250 Hz for Bluetooth streaming to the host computer. The main processing unit, the MSP432 microcontroller, is responsible for controlling the analog front end, dynamically adjusting amplifier gain, and streaming data to the host device.

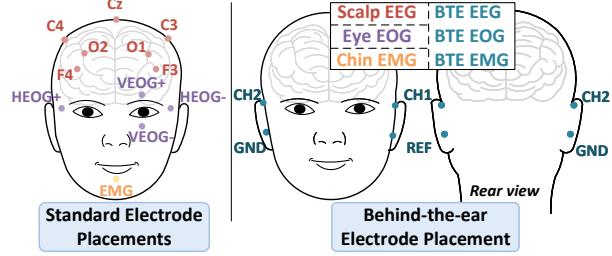


Fig. 4. EarSD has only 2 electrodes placed behind each ear whereas the standard placement has over 20 electrodes placed all over the head, eyes, and chin.

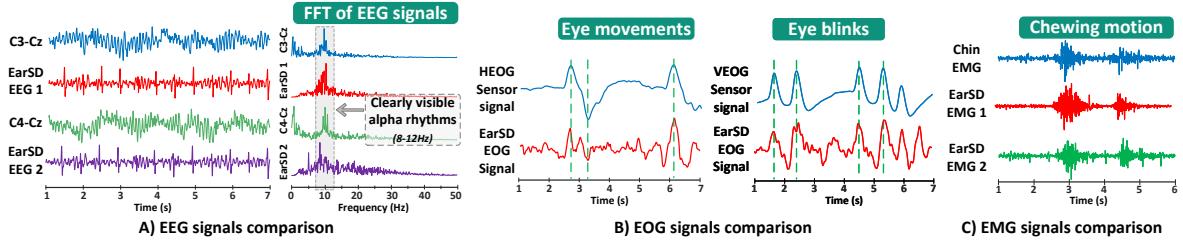


Fig. 5. *EarSD* EEG, EOG, and EMG signals compared to signals captured by dedicated sensors. The outputs show strong similarity between the dedicated sensors and the *EarSD* sensors for all three modalities validating the reliability of the signals recorded by *EarSD*.

The second component is the biosensor stickers, designed with two pairs of electrodes embedded on a pair of stickers that are fixed to the skin using disposable, double-sided adhesives behind the left and right ear. Each electrode is equipped with sensors that capture EEG, EMG, and EOG signals. This design allows unobtrusive, continuous monitoring of the patient’s bioelectrical signals without requiring an invasive or extensive setup. We use Ag/AgCl electrodes in our device as it is less prone to oxidation than other types of electrodes and thus ensure better accuracy and reliability of the captured signals. The electrode contact quality was regularly monitored so that we could detect and remove noisy signals created by loose electrodes. We also minimized electrical noise from the connecting wires by shielding them with two layers of aluminum and plastic. They are further shielded inside the stickers when connected to the electrodes, ensuring the subject’s safety and preventing direct contact with the connections on their skin.

Real-time Acquisition Software. The real-time data acquisition firmware controls the operations and collects the physiological data measured from behind the ears through Bluetooth. It can be deployed on a laptop or a smartphone. The system produces low electrical risks as the electricity supplied to the sensing hardware is from a 3.7V rechargeable Lithium-Polymer battery. The receiver and batteries are enclosed in an electrically inert cover and casing. The sensing hardware and the battery power supply are enclosed in a small and lightweight plastic box to increase the subject’s safety while using the system during the study.

4.2 Preliminary Results with in-lab Validation

We conducted experiments to verify *EarSD*’s ability to capture EEG, EMG, and EOG signals from behind-the-ear electrodes. Measurements were compared against ground-truth sensors positioned on the scalp, chin, and eye as per the standard International 10-20 system as illustrated in Figure 4. The ground truth EEG, EOG, and EMG signals were acquired using an FDA-approved Lifeline Trackit Mark III device. Data was acquired for one hour with the subject seated and the resultant signals obtained from both *EarSD* and the ground-truth sensors are visualized in Figure 5. Figure 5a represents the Alpha (α) rhythms seen on both ear electrodes for EEG when the eyes are closed. α -rhythms are prominent electrical oscillations in the frequency range of 8 to 12 Hz. Their presence indicates the sensor’s ability to detect the subtle electrical activities of the brain and proves that *EarSD* can discern specific frequency bands of different brain states which are needed for capturing EEG patterns. Similarly, Figures 5b and c show similar EOG and EMG outputs between the dedicated sensors and *EarSD* for actions such as eye blinks, left-right eye movements, and chewing motion. Thus this confirms that *EarSD* is able to capture the important EEG, EMG, and EOG signals for seizure detection.

5 SIGNAL PROCESSING

As a mobile-first device designed for daily use, our proposed *EarSD* will be more susceptible to motion artifacts than ambulatory devices. We found noise to be a consistent feature in our recordings even under the controlled environment of a hospital. This problem will only be exacerbated when the device is deployed in the real world. Hence, having robust noise removal techniques is necessary to minimize their impact on the seizure detection algorithm. We found motion artifacts to span all frequencies of interest with high unpredictability, making their removal challenging through filtering or Independent Component Analysis (ICA) [63]. While Active Electrodes (AE) have been proposed to mitigate motion artifacts [64], conventional designs do not consider behind-the-ear signals which are weak, overlapping, and constrained by limited space. Therefore, we implement customized measures to address noise in *EarSD*.

5.1 *EarSD*'s On-Board Motion Removal

The ADS1299 ADC provides an integrated second-order $\Sigma - \Delta$ *modulator* which we use to ensure signal fidelity during quantization. This modulation technique reduces quantization noise through oversampling, noise shaping, digital filtering, and decimation. In the quantization process, the quantization error (ϵ) for an ADC with a resolution of b bits and a full signal scale (FS) is modeled as a stationary random process [65], with constant quantization noise power. The quantization noise is uniformly distributed across the Nyquist spectrum, resulting in a constant power spectral density ($S_e(f)$). If we oversample this by a factor of K , we can expand the bandwidth, effectively reducing quantization noise energy within the spectrum of interest, according to the following equation $S_e(f) = \frac{\sigma_e^2}{Kf_s}$ where f_s is the sampling frequency. To further attenuate noise within this range, the signal undergoes processing by $\Sigma - \Delta$ *modulator*'s noise shaping function. By transforming the noise transfer function (NTF) into the frequency domain using trigonometric identities, $NTF^2(f) = 4\sin^2\left(\frac{\pi f}{f_s}\right)$. Consequently, the adjusted power spectral density becomes:

$$S_e(f) = \frac{\sigma_e^2}{Kf_s} \times |NTF(f)|^2$$

i.e., the energy of the noise signals is moved to higher frequencies in the spectrum, which a digital filter can then attenuate, effectively removing any noise that is outside the spectrum of interest. The resultant signal is then decimated to the requisite sampling rate.

5.2 *EarSD* Software-based Motion Removal.

All sensor data is passed through a notch filter to eliminate power line interference at 50/60 Hz. Linear trends are removed to prevent DC drift effects, and an outlier filter is applied to exclude transient spikes and ripples. We then use Variational Mode Decomposition (VMD) [66] to ensure only denoised signals are passed on to the signal decomposition step before machine learning.

Variational Mode Decomposition (VMD).. We employed VMD to decompose the physiological signal into various components called Intrinsic Mode Functions (IMFs) [67]. IMFs are Amplitude Modulated-Frequency Modulated (AM-FM) signals $u_k(t) = A_k(t)\cos(\phi_k(t))$ where $\phi_k(t)$ is the phase (non-decreasing function) and $A_k(t)$ is the non-negative envelope. The VMD process produces IMFs with distinct correlation patterns to IMU signals, facilitating selective reconstruction. Then, using data gathered concurrently from the Inertial Measurement Unit (IMU) of the device, the acceleration amplitude is calculated and compared with the motion artifacts. Subsequent analysis of IMU data revealed that the amplitude of acceleration correlates with motion artifacts. The VMD process yields several IMFs with distinct correlation patterns to the IMU signals, allowing for selective reconstruction of the physiological signal. By computing correlations between physiological IMFs and IMU data,

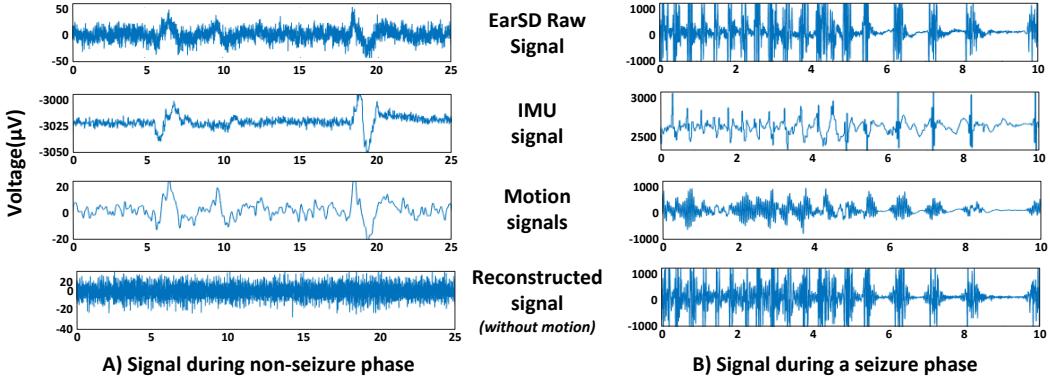


Fig. 6. VMD yields IMFs with distinct correlation patterns to the IMU data. Selectively reconstructing using IMFs uncorrelated with motion data filters motion artifacts removing noise while retaining critical seizure waveforms.

we can identify motion-related components for selective reconstruction, excluding any distortions due to noise. The reconstructed signal post-VMD showcasing the mitigation of motion artifacts is illustrated by Figure 6a. As can be seen from the figure, most of the motion-related events are removed from the signal. The same technique can be applied to remove most of the motion artifacts caused during a seizure (Figure 6b). We can see VMD can retain seizure-characteristic information while excluding motion-induced distortions.

5.3 Decomposing the Denoised Signals into EEG, EMG, and EOG Constituents

Combining EEG, EMG, and EOG in the algorithm helps reduce false positives in seizure detection algorithms by providing a more complete picture of neurological activity. The ML algorithms can learn to distinguish seizure *signatures* spanning the modalities that are distinct from normal traits present in each signal. Further, training on multidimensional input can better discriminate artifacts from neurological phenomena, and separating the signals is an important step in the process. Table 1 shows the frequency and amplitude ranges of the key biosignals acquired by *EarSD*, specifically 3-25 Hz/1mV for EEG, 0.3-10 Hz/0.001-0.3mV for EOG, and 10-100 Hz/100mV for EMG. However, it is challenging to separate the low-amplitude EEG and EOG signals overlapped with high-amplitude EMG signals. To overcome this, we investigated various signal decomposition techniques commonly utilized in seizure detection applications. Standard EEG data analysis often uses filtering methods [68, 69], which have limited efficacy when signals overlap. Alternative approaches such as Independent Component Analysis (ICA) [70, 71] and Principal Component Analysis (PCA) [72, 73], typically presuppose signal independence which is not always met by physiological signals. Through our analysis, we determined that Empirical Mode Decomposition (EMD) effectively separates the composite signal into distinct components with unique frequency resolutions. These components, when properly combined, facilitate the accurate reconstruction of the original signals. Additionally, we evaluated Non-Negative Matrix Factorization (NNMF), which leverages pre-trained frequency templates for signal differentiation. EMD and NNMF were chosen due to their advanced capability in signal separation tasks.

Physiological signal	Frequency	Amplitude
EEG	Delta (δ)	<3 Hz
	Theta (θ)	3-8 Hz
	Alpha (α)	8-12 Hz
	Beta (β)	12-25 Hz
	Gamma (γ)	>25 Hz
EOG	0.3-10 Hz	0.001-0.3 mV
EMG	10-100 Hz	<100 mV

Table 1. Characteristics of physiological signals

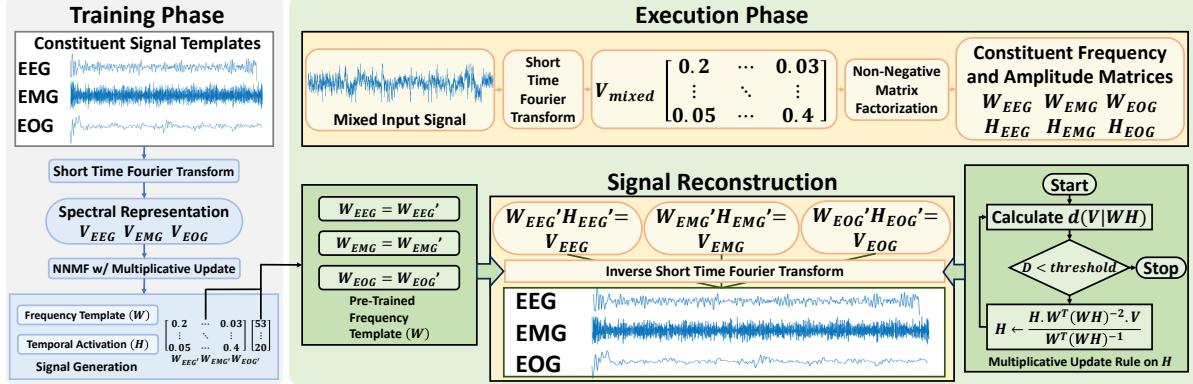


Fig. 8. Overview of supervised NNMF signal separation algorithm, Using templates of known EEG, EOG, and EMG signals in the training phase, NNMF can decompose a mixed physiological signal through an iterative process that minimizes divergence between the original and generated signals for accurate reconstruction in the execution phase.

5.3.1 Empirical Mode Decomposition (EMD).

EMD is a robust technique for analyzing non-linear and non-stationary data by decomposing a signal into its Intrinsic Mode Functions (IMFs). This facilitates detailed time-frequency analysis while retaining the data in the time domain [74, 75]. IMFs exhibit three key properties. (1) Each IMF represents a single frequency at any given time, enabling multiresolution decomposition of the composite signal. (2) The average value of the oscillatory components within each IMF is zero. (3) The IMFs are mathematically orthogonal to one another.

By correlating IMF frequencies with known EEG, EOG, and EMG ranges across two separate data segments of the same patient, we observed that IMFs 1 and 2 typically capture EMG activity, while IMF 3 aligns with EEG, and IMFs 4, 5, and 6 with EOG. However, as Figure 7 shows, the assignment of IMF 2 to EMG is not consistent, as the range of an IMF is contingent upon the frequency content present in the mixed signal. Through our analysis, we determined that assigning IMF 1 for EMG, IMF 3 for EEG, and IMFs 4 to 6 for EOG yielded more accurate results.

5.3.2 Non-Negative Matrix Factorization. Non-Negative Matrix Factorization (NNMF) factors a non-negative matrix into two lower-dimension matrices through multiplication [76]. The equation is given by $V = W * H$ where V is the original non-negative matrix, W is the frequency template matrix, and H is the activation matrix. NNMF has various applications, including dimension reduction [77, 78], feature extraction [79, 80], and blind source separation [81, 82] making it suitable for our purpose. In signal processing, NNMF is particularly useful for disentangling one-dimensional signals by leveraging the non-negative properties of their spectral representations [83–85]. If V is a spectral representation of a signal, its factorization W would be considered as the frequency template and H is the temporal activation of the signal. That is to say, W will represent for the frequency inside the signal and will not change for EOG, EEG, and EMG and we can decompose and reconstruct the signal

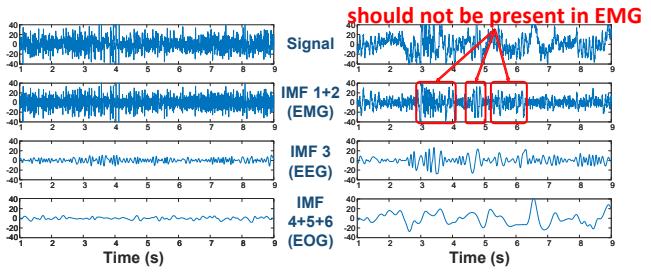


Fig. 7. EMD IMFs 1 and 2 typically capture EMG activity, IMF 3 aligns with EEG, and IMFs 4-6 show EOG, but IMF 2 for EMG is inconsistent, sometimes including EEG artifacts due to the overlapping nature.

accordingly if we know the frequency template of EOG, EEG, and EMG. Supervised NNMF-based separation algorithm utilizes known physiological signals to train the model, then applies that model to signal separation and reconstruction [86]. Figure 8 shows the overview of our supervised NNMF approach.

Training Phase. During training, signal-specific templates are extracted from channels known to be dominated by each modality to derive the frequency basis matrix W . EEG segments are extracted from the C3-P3 and C4-P4 channels. EMG artifacts are typically pronounced in channels P7-TP9 and P8-TP10, so this is chosen as the EMG template, and channels FP9 and FT10, known for capturing EOG artifacts like blinks and saccades, are used to obtain EOG templates. We also used signals during well-studied seizure events for each of the three modalities to ensure that our signal templates included traces from both seizure and non-seizure periods.

Once the EEG, EMG, and EOG templates are acquired, NNMF with multiplicative updates is applied to construct the frequency template W . The updates progressively refine W and the activation matrix H through an iterative process, minimizing the divergence between matrices [87]. The error in the factorization process necessitates a metric for the distance between two matrices. One well-established measure is the β divergence [88] with three common variations defined as:

$$d_\beta(X|Y) = \begin{cases} \frac{1}{\beta(\beta-1)}(X^\beta + (\beta-1)Y^\beta - \beta XY^{\beta-1}) & \beta \in \mathbb{R}\{0, 1\} \\ X \log \frac{X}{Y} + (Y - X) & \beta = 1 \\ \frac{X}{Y} - \log \frac{X}{Y} - 1 & \beta = 0 \end{cases}$$

The β divergence includes three commonly utilized variations [89]:

- Euclidean divergence ($\beta = 2$) : $d_{EUC}(X, Y) = \sqrt{\sum_{i,j} (X_{i,j} - Y_{i,j})^2}$
- Kullback-Leibler divergence ($\beta = 1$) : $d_{KL}(X, Y) = \sum_{i,j} (X_{i,j} \log \frac{X_{i,j}}{Y_{i,j}} - X_{i,j} + Y_{i,j})$
- Itakura-Saito divergence ($\beta = 0$) : $d_{IS}(X, Y) = \frac{X}{Y} - \log(\frac{X}{Y}) - 1$

One important characteristic that affects our approach is their scale invariance properties:

- $d_{EUC}(\lambda X | \lambda Y) = \lambda^2 d_{EUC}(X | Y)$
- $d_{KL}(\lambda X | \lambda Y) = \lambda d_{KL}(X | Y)$
- $d_{IS}(\lambda X | \lambda Y) = d_{IS}(X | Y)$

The Itakura-Saito divergence (d_{IS}), due to its scale-invariance, is particularly suitable for representing data with significant dynamic ranges, such as physiological signal spectra. NNMF with a multiplicative update rule for d_{IS} divergence is then applied in the training phase.

$$H \leftarrow H \cdot \frac{W^T (WH)^{-2} \cdot V}{W^T (WH)^{-1}}; W \leftarrow W \cdot \frac{((WH)^{-2} \cdot V) H^T}{(WH)^{-1} H^T}$$

By leveraging known EEG, EMG, and EOG patterns containing both normal and epileptic traits, supervised NNMF can effectively decompose the composite ear signal for selective reconstruction of each modality.

Execution Phase. In the execution phase, mixed signals obtained from *EarSD* are separated using the frequency template W derived in the training phase. Since the frequency template remains unchanged for each signal, we apply an STFT to each data segment to acquire its spectral form. The multiplicative update rule is subsequently employed on matrix H to extract temporal activation of individual signal components within the mixed data. This process strives to minimize the distance between the reconstructed and the original signals, hence reducing

the error inherent in the factorization. The final reconstructed signal is obtained by inverse STFT using the component matrices W and H once divergence is sufficiently minimized.

6 SEIZURE DETECTION USING *EarSD*: A REAL-WORLD STUDY

6.1 Study Protocol

To evaluate the effectiveness of the proposed *EarSD* device in seizure detection, we conducted a clinical study at the Epileptic Monitoring Unit (EMU) of a hospital. Our study aimed to demonstrate that *EarSD*'s performance is comparable to the "gold standard" of video EEG monitoring in hospitals. We required patients to wear both the *EarSD* device and standard 21-channel scalp-EEG with video recording simultaneously to ensure that both devices were collecting the same data from the same patient for the same times (Figure 9). This allowed us to compare the results and verify if the same events were detected by both.

Patient Recruitments. Through our collaboration with the hospital, we gained access to patients admitted to the EMU for long-term vEEG monitoring. To be eligible for our study, individuals had to be at least 18 years old at the time of enrollment and willing to wear the *EarSD* device. Patients wearing any other ear device, such as hearing aids, or intracranial electrodes, were excluded from the experiment. Anyone unable or unwilling to provide informed consent was also excluded. Following these rules, we were able to recruit 33 patients aged between 19 and 74, with 17 biological males and 16 biological females represented in the sample over 09 months. To evaluate the effectiveness of the proposed *EarSD* device in seizure detection, we conducted a clinical study at the Epilepsy Monitoring Unit (EMU) of UTSW Medical Campus hospital.

Data Collection Procedure. At the start of the study, before the device placement, the area behind each ear was examined for any pre-existing skin condition that might have hampered the skin-electrode contact. After obtaining formal written consent, the subject wore *EarSD* and the standard 21-channel scalp-EEG with video recording (Natus NeuroWorks EEG Software [90]) simultaneously. The *EarSD* board, was placed around the patient's neck using a detachable lanyard, and the sticker electrodes were attached behind the patient's ears using collodion glue to ensure firm contact between the skin and the electrode. Once the electrodes were placed comfortably over each ear, the sensing circuit was paired via Bluetooth to a tablet for real-time data storage and viewing. The participants were encouraged to wear our device for as long as they felt comfortable during their EMU stay, including during sleep. As per standard clinical protocol, they were then monitored in their rooms for the duration of their stay in the hospital. On average, *EarSD* was worn for 41 hours across patients. At the end of the test, all information that was gathered was deidentified, except for the patient's study identification number. The data was then stored on an encrypted and password-protected laptop for processing before being uploaded to the REDCap (Research Electronic Data Capture) Database. Local data on the laptop was destroyed after uploading to REDCap. The data collected from subjects is unidentifiable and was only shared between the researchers participating in this study.

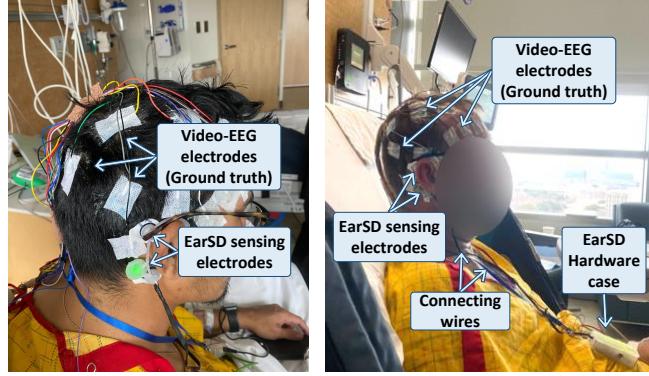


Fig. 9. A patient in the hospital wore the standard vEEG electrode and the *EarSD* wearable behind the ears at the same time for data collection.

6.2 Dataset Preparation and Clinical Verification

After the data was processed using the signal processing method described in Section 5, experts from our collaborating hospital examined the outputs from our experimental setup which contained the recordings from both the video-EEG setup and the *EarSD* device to mark the onset and offset times of each seizure as shown in Figure 10. This provided us with a labeled dataset to train the supervised machine learning algorithms. The dataset comprised a total of 22 minutes and 35 seconds (1,355 seconds) of seizure data and we extracted an equivalent amount of non-seizure data from both pre and post-seizure stages. We also added 40% data from activities such as eating and talking to better simulate the regular day of a person. Per American Clinical Neurophysiology Society guidelines, an abnormal event is considered a seizure if it lasts for at least 10 seconds [91]. Thus, we segmented the events into 10-second chunks for analysis. A chunk entirely within the labeled seizure onset time was labeled as a seizure, while chunks partially overlapping or out of seizure onset and offset times were labeled as non-seizure. A subset of the dataset is provided in Table 2.

6.3 *EarSD*'s Seizure Detection Algorithms

We examine three classical Machine Learning algorithms, including Support Vector Machine (SVM), K-Nearest Neighbor (KNN), and Random Forest Classifiers (RFC). If these three algorithms perform well with these three ML approaches, accuracy can be further optimized with more sophisticated algorithms, such as neural network-based approaches. To evaluate the generalizability of our machine learning approach, we utilized a leave-one-patient-out cross-validation strategy. The model was trained on all samples from the full dataset except one held-out patient in each fold.

All data from this patient was kept separate from the test set and only used to test the model performance. We obtained a rigorous estimate of the model's ability to generalize to new patients by iterating through folds where each patient serves as the test set once. This strategy helps verify that the machine learning model is not overfitting to a particular patient in the training data.

7 PERFORMANCE EVALUATION

7.1 Sensitivity Analysis

7.1.1 Noise Removal. To demonstrate the effectiveness of the developed EMD-based and NNMF-based signal separation algorithms, we performed a thorough validation using data captured from the *EarSD* device in a clinical setting. For each patient, we extracted 2-hours of data - one hour during the daytime (between 1 p.m. to 3

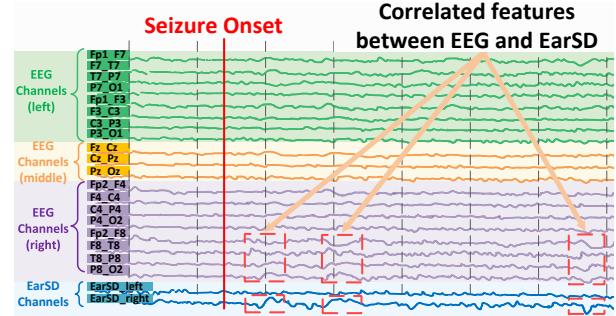


Fig. 10. Seizure event onset marked by the doctors shows a strong correlation between the vEEG and the *EarSD* channels. The spikes can be seen on the right channels of both devices allowing *EarSD* to classify seizures as well.

Figure 10 shows a multi-channel EEG and EarSD signal plot. The plot is divided into three sections: EEG Channels (left), EEG Channels (middle), and EEG Channels (right). The EarSD Channels section at the bottom shows two channels: EarSD_left and EarSD_right. A vertical red line marks the 'Seizure Onset'. Orange arrows point from the EEG channels to the EarSD channels, indicating 'Correlated features between EEG and EarSD'. Red dashed boxes highlight specific activity on the EarSD channels during the seizure onset.

Patient ID	Start Time	End Time	Type
SD_004	21:42:56	21:43:21	Focal Right
SD_005	01:01:01	01:01:58	Generalized
SD_016	15:01:49	15:02:55	Focal Left
SD_017	22:55:36	22:56:53	Focal Left
SD_020	14:37:08	14:38:04	Focal Left
...

Table 2. Seizure log labeled by doctors

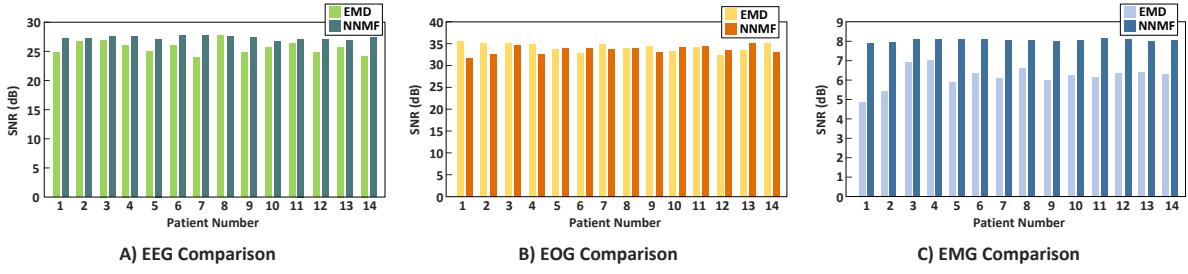


Fig. 11. Signal-to-Noise Ratio (SNR) between EMD and NNMF. The NNMF algorithm demonstrated superior EEG and EMG signal quality compared to EMD, with average SNR improvements of 1.64dB and 1.84dB respectively. For EOG signals, both NNMF and EMD yielded approximately equivalent SNRs.

p.m.) and one hour during the night (between 10 p.m. to 4 a.m.). The two-hour (7,200 seconds) recordings are segmented into 720 10-second epochs to enhance computational efficiency.

Signal-to-noise ratio (SNR) is a well-known metric in digital signal processing, quantifying the target signal strength relative to noise. We estimated SNR based on the known frequency ranges of EEG, EOG, and EMG components. SNR for a signal within the frequency range $[a b]$ Hz was calculated as $SNR_{[a b]} = \frac{P_{[a b]}}{P_{other}}$ where $P_{[a b]}$ is the mean power of the signal in the frequency band of $[a b]$ Hz and P_{other} is the mean power outside this band. After computing SNRs for each epoch, we determined the average SNR per patient shown in Figure 11. We can see that compared to the EMD-based algorithm, the NNMF-based algorithm demonstrated better performance in EEG and EMG signal quality, with comparable outcomes for EOG signals. Specifically, as can be seen in Figure 11a, the average SNR values for EEG signals using the EMD-based algorithm ranged from 24.20dB to 27.66dB, with a mean of 25.69dB, while the NNMF-based algorithm ranged between 26.84dB and 27.77dB with a mean of 27.33dB. For the EOG signals, both algorithms yielded nearly equivalent average SNRs, 33.94dB for EMD and 33.77dB for NNMF as shown in Figure 11b. Figure 11c shows the results for the EMG with an EMD average SNR of 6.23dB, while NNMF averaged 8.07dB. So, we can conclude, that the NNMF approach provided an SNR enhancement of 1.64dB for EEG and 1.84dB for EMG signals over the EMD approach.

7.1.2 Energy Consumption. We measured the power consumption of the *EarSD* device using a Monsoon Power Monitor with a sampling rate of 5 kHz. Each measurement lasted 180s, resulting in 900,000 data points to get stable results. Under conditions of 250°C and a nominal battery voltage of 3.7V, the average power usage of our device was (1) Active state (sensing physiological signals, recording, and streaming via Bluetooth) consumed 241.5mW, (2) Idle state (MCU active with other components and streaming turned off) consumed 51.60mW. With a 500mAh Li-Po battery, the *EarSD* device can operate for approximately 7.7 hours in the active state and 35.9 hours in the idle state. We also conducted component-level measurements during the active state by individually turning off each component and repeating the measurements. The sensing components (amplifiers and external ADCs) and the Bluetooth communication module were the primary power consumers, with an average power consumption of 93.5mW and 85.2mW, respectively, while the processing unit (MSP432) consumed only 62.8mW. These power

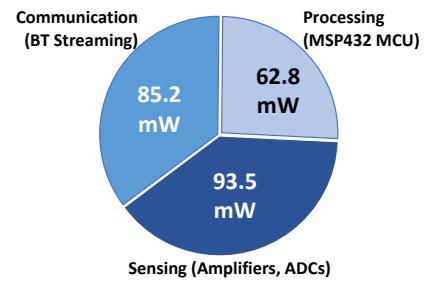


Fig. 12. Power Consumption of *EarSD*

consumption figures demonstrate the *EarSD* device's capability to monitor a user for extended periods. The current high energy consumption is due to engineering limitations, as direct power from the earbuds is not feasible and so requires a separate power source. However, optimization and implementation on a System-on-Chip (SoC) can enable power supply from the earbuds. By reducing the number of sensing components, optimizing Bluetooth transmission, and leveraging the MCU's deep power-saving modes, power consumption can be further reduced.

7.2 System Performance

The performance of the detection algorithms is evaluated over the dataset collected from our study at the hospital which contained all events from the patients who experienced seizures during our study. We test the performance of the machine learning algorithms (SVM, KNN, and RFC) through a leave-one-out strategy where we trained on all samples from the full dataset except one held-out patient which was used for testing. We also rotated the test sample so that all patients were tested in successive iterations. This approach showed the performance of the algorithms over specific events from each of our patients and can simulate the algorithm's performance in a real-world setting with unknown events.

7.2.1 Impact of Sliding Windows on Seizure Detection.

We augmented our dataset using sliding windows.

To evaluate the impact of sliding windows on the algorithm performance, we extracted the data with different overlapping windows. We varied it from 1 to 9 seconds to find the best configuration. With a 1-second sliding window, we slid the window 1 second forward which kept a 9-second overlap between the successive windows. Similarly, with a 2-second sliding window, the window was moved 2 seconds forward, which means there was an 8-second overlap between the two windows and so on. Using sliding windows also enabled us to capture spatial information and feed co-dependent data from earlier windows to the next window, helping the machine learning models improve their accuracy. It is evident from Figure 13a that all three algorithms show an accuracy of over 70% indicating their reliability in seizure detection using only data recorded from our *EarSD* device. We can see that when the stride size is set to 1, the results get vastly better, exceeding 90% accuracy for all three algorithms, with SVM achieving the best accuracy of 94.5%. In this configuration, there is maximum overlap between consecutive windows resulting in better training of the algorithms.

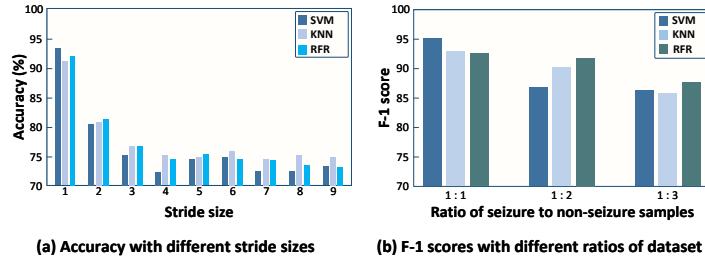


Fig. 13. All three algorithms show the best performance when there is maximum overlap between successive sliding windows and the dataset contains a 1:1 ratio between seizure and non-seizure samples.

7.2.2 Impact of the Number of Seizure and Non-seizure Samples in the Dataset. To investigate the impact of dataset bias, we calculated the F-1 scores by examining various ratios of seizure to non-seizure samples in the dataset. An imbalanced dataset leads to a decline in accuracy as the machine learning model becomes biased towards the majority class as we see in various other works [92, 93]. This disproportionality results in the algorithm producing false negatives making them unreliable. Our experimental results are depicted in Figure 13b which illustrates the F-1 scores achieved by the three algorithms when the ratio of seizure to non-seizure samples in the dataset are 1:1, 1:2, and 1:3. Even though all three algorithms attain high F-1 scores (exceeding 85%) indicating

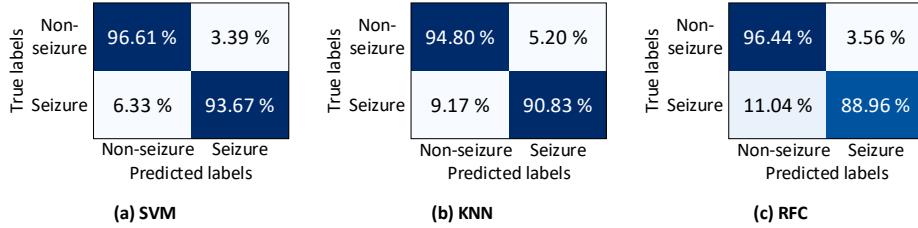


Fig. 14. Results of the seizure detection task. All three algorithms show accuracies of over 90% at seizure detection. SVM performs the best with an average accuracy of 95.3% at distinguishing between seizure and non-seizure events.

their capability in detecting seizures, the best results are obtained when there is an equal number of seizure samples to non-seizure samples with SVM showing the best F1-score of 95% in this case as well.

Based on the conclusions drawn from these experiments, we perform our seizure detection task using a 1-second sliding window and keeping a 1:1 ratio between seizure and non-seizure samples in the dataset. In this configuration, we obtained a total of 1,782 samples from our dataset which we used to train the machine learning models.

7.2.3 Seizure Onset Detection Accuracy. The confusion matrices of Figure 14 show the performance of the ML algorithms by comparing the predicted labels with the actual labels. From this, we can assess the model’s ability to correctly classify both positive (seizure) and negative (non-seizure) instances and evaluate its overall performance. From Figure 14a, we can see that the SVM algorithm is able to correctly detect seizures 93.67% of the time and non-seizures 96.61% of the time indicating its ability to correctly distinguish between seizure and non-seizure events. Similarly, Figure 14b, shows that the KNN algorithm achieves a seizure detection rate of 90.83% and a non-seizure detection rate of 94.80%. RFC also shows good performance in Figure 14c. We can see that it correctly detects seizures 88.96% of the time and non-seizures 96.44% of the time. We can thus conclude that SVM outperforms the other two algorithms showing the best overall results.

In summary, the results show that with just two electrodes placed behind the ear, we are able to capture signals that can be used to reliably identify seizure events proving the effectiveness of our device. These promising results were achieved using our *EarSD* device, which captures EEG, EMG, and EOG data from two electrodes placed behind the ear, demonstrating the feasibility and effectiveness of our wearable device for continuous, non-invasive seizure monitoring. It should be noted that although *EarSD* has only been tested on a small number of patients due to limitations of funding, such high accuracy of detection is encouraging and approaches the standard of accuracy needed for medical devices to receive approval from regulatory bodies [94, 95].

7.3 User Study & Focused Group Discussion

Upon patient discharge, an anonymous, 14-question survey was given to the patients to gather feedback about their experience with *EarSD*. The survey included questions on the users’ perspective of *EarSD*’s comfort, ease of use, sleep disruption, social acceptability, and willingness to use such a device. In addition to the anonymous patient survey, a one-hour focus group discussion (FGD) with nine epileptologists was held at the hospital to obtain their opinion on portable seizure detection devices. Conducting such end-user studies allows us to gather insights from experts and patients alike which will help lay the foundations for future improvements. We discuss the results of the survey and the FGD here.

7.3.1 Survey Results. Out of the 33 participants who participated in our experiment, 30 (91%) completed the post-survey. Figure 15 presents the questions that we asked our participants to find their opinions and experiences.

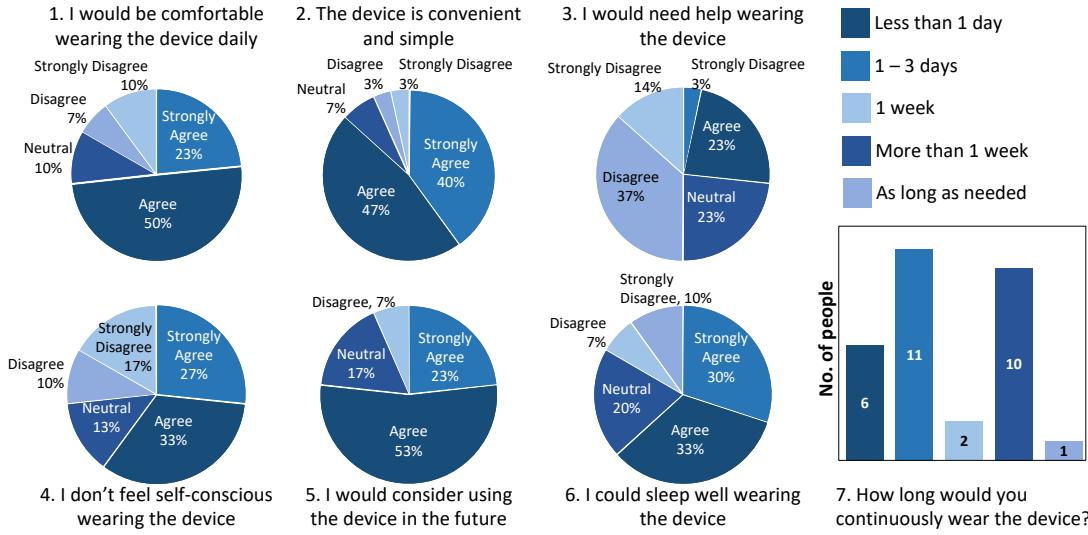


Fig. 15. Responses to User Study Questionnaire showing overwhelmingly positive perception about *EarSD* among the users in our study. This emphasizes the need for an inexpensive, comfortable, and convenient wearable device among patients suffering from epileptic seizures. Devices like *EarSD* can significantly improve the quality of life for such patients.

The results show that 73% found *EarSD* comfortable, while 17% reported discomfort due to pressure and the adhesive glue. An interesting insight that we found was that discomfort was more prevalent among users wearing eyeglasses, likely because both items rely on the ear as a support point. Nevertheless, an overwhelming 87% agreed it was far simpler than conventional hospital EEG setups. A particularly important result was that 80% of the participants indicated that they would be willing to continuously wear the device for prolonged periods (between 3 days to 1 week) and 60% thought the device would be socially acceptable. Finally, 67% of the respondents said it did not hamper their sleep.

In addition to answering the questions in our survey, users provided qualitative feedback on desired features and areas for improvement. Many expressed interest in a user-friendly, self-applicable design to facilitate independent use and enhance comfort and control. Patients were also interested in monitoring their signals through an app, which would provide a summary explanation of their measurements so that they could be more informed about their condition.

7.3.2 FGD Results. The purpose of the FGD session was to find out epileptologists' and medical professionals' perspectives on a seizure detection device. Nine epileptologists were invited to a one-hour, recorded focus group to determine the preferences of epileptologists regarding a wearable, EEG-based seizure-detection device. The participants expressed considerable enthusiasm regarding the potential of an EEG-based seizure-detection device like *EarSD*. They acknowledged the immense value of recorded EEG data for their practice, emphasizing that it offers a more dependable source of information compared to patient-reported data. However, the epileptologists did express some reservations and concerns offering valuable suggestions regarding wearable EEG devices. The reliability of the device emerged as a main issue with particular emphasis on the fact that *EarSD* operates as a 2-channel EEG system. Epileptologists stressed the need to maximize the sensitivity and specificity of the device

prior to any commercial use as false positives could lead to unnecessary anxiety and possible overmedication for patients.

8 LIMITATIONS AND FUTURE DIRECTIONS

8.1 Limitations

As a preliminary proof-of-concept study, our results are somewhat limited in terms of our sample size. The strong positive outcome shown by our proposed *EarSD* warrants further investigation through expanded trials to provide a better understanding of the device’s generalizability. We had a sample size of only 33 patients and 1,782 epochs in total. Larger studies will be needed in the future to better understand the device’s generalizability. In addition, while our results have shown promising outputs in detecting seizures, In addition, our testing was conducted in controlled hospital settings. It is important to assess real-world factors including external wearables like jewelry and hearing aids, physical conditions such as perspiration, and environmental conditions such as rain all of which may impact signal quality and electrode contact. Robustness to such potential interferences will be critical for reliable performance outside of clinical settings. Finally, the device was applied using collodion glue to ensure reliable skin contact during this proof-of-concept study which is an impractical method for home use. This method is unsuitable for practical deployment as we cannot expect users to use glue every time they use the device at home.

8.2 Future Directions

Future iterations of *EarSD* will incorporate the recommendations made by users and epileptologists, especially when it comes to device comfort and ease of use. Further technical improvement is also needed to make the data collection more reliable and feasible in the real world. For example, it is important to have electrodes that can be applied without adhesives like collodion glue and still obtain strong skin-electrode contact to obtain reliable signals. We also plan to improve overall performance and battery life through on-device machine learning, eliminating the need for constant wireless connectivity. A larger, multi-center study will be needed to gather more patient data and minimize sample selection bias. Furthermore, improving the traditional machine learning approaches is difficult since these algorithms depend heavily on feature engineering. The quality of the selected features greatly impacts their performance and identifying the most relevant features for the model can be time-consuming and may require domain expertise. Also, as the dataset increases, training and inference times may become impractically long. Therefore, applying deep learning models could make the system more scalable and adaptable to complex patterns with their automated feature extraction capabilities. They can also scale much better with larger datasets which can improve detection accuracy and generalization. We also aim to integrate additional capabilities such as classifying seizure types and predicting seizures for proactive interventions. Lastly, the form factor requires continued refinement to improve comfort, aesthetics, and discreetness for easier long-term use. Once optimized, home studies will reveal the strengths and limitations of real-world performance across diverse environments and lifestyles.

While the results of this work are promising and prove the reliability of a low-cost, low-burden, ear-worn sensing system for seizure detection, there is still room for improvement. If these limitations can be successfully addressed, *EarSD* has great potential to become a practical, reliable, and acceptable option for long-term seizure monitoring at home. We will continue to focus on optimizing the system and expanding its capabilities to make it suitable for real-world deployment.

9 CONCLUSION

In this work, we present *EarSD*, a wearable device designed to enhance the lives of epilepsy patients by providing continuous and at-home monitoring for the detection of seizures. The device contains only two electrodes, worn

behind each ear, and records vital physiological signals of EEG, EMG, and EOG, analyzing them to detect seizures and eliminate the need for unnecessary hospital visits. Through our collaboration with a hospital, we were able to test our proposed device on real-world patients and compare it with the *gold-standard* scalp EEG test. Our study involved 33 patients who simultaneously wore the hospital vEEG setup and our *EarSD* device to ensure both devices captured the same events. The recorded signals were preprocessed using our signal processing algorithm to remove noise and extract features. The processed signals were then analyzed using machine learning algorithms of SVM, KNN, and RFC. We obtained a seizure detection accuracy of 95.3% with SVM using just the recordings of *EarSD* from behind each ear. We also conducted a user study and a focus group discussion with patients and epileptologists to learn the limitations of *EarSD* and receive feedback to further improve the system for future studies. Their responses provide clear directions on the key priorities of end users and lay the foundation for future development. Overall, this work provides substantial evidence that our proposed *EarSD* can reliably capture seizures and contribute to a more effective management of the disease.

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