Feasibility Report
EEG based communication system for paralysed patients

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1 Introduction

This report covers the process of finding a solution to the previously identified problem. We go through the steps of ideation and concept screening as specified in the book [?].

2 Need Statement

"ML-driven communication system for paralyzed patients utilizing EEG signals"

Patients who are paralyzed, especially those with severe conditions like locked-in syndrome or quadriplegia, often experience an inability to communicate verbally or physically with the outside world. Traditional communication methods such as eye-tracking systems or specialized keyboards may be slow or unreliable depending on the severity of their paralysis.

A more effective solution is needed to bridge this communication gap. EEG (Electroencephalography) signals, which capture brain activity, offer a promising avenue for enabling non-invasive communication. However, the challenge lies in the complexity of interpreting these signals into meaningful commands in real time.

3 Initial Concept Selection

The proposed solution is a Machine Learning (ML) driven communication system that leverages EEG signals to enable paralyzed patients to communicate with the outside world. The system will utilize non-invasive EEG headsets to capture the patient's brain activity. These signals will be processed using advanced ML algorithms to classify and translate the brainwaves into specific commands or language constructs.

Steps involved:

- **EEG Signal Acquisition**: Non-invasive EEG sensors will be placed on the scalp of the patient to measure brain activity. These signals are often noisy and require pre-processing to filter out irrelevant data.
- **Feature Extraction and Pre-processing**: The raw EEG data will be pre-processed to remove noise and artifacts (like eye blinks or muscle movements). Feature extraction techniques will be applied to identify the relevant features that correspond to different mental states, thoughts, or intentions.

- **ML Model**: A machine learning model, such as a neural network, will be trained to recognize patterns in the EEG data that correlate with specific intentions, thoughts, or commands. The model will be continuously refined using training data collected from the patient or other individuals, making it increasingly accurate in understanding and translating brainwaves.

- **Command Translation and Output**: The classified signals will be translated into predefined commands (e.g., selecting letters to form words, moving a cursor on a screen, controlling a device, or activating a voice synthesis system). The system will provide feedback to the patient, helping them refine their thoughts and improve communication accuracy over time.

- **User Interface (UI)**: A user-friendly interface will be developed that allows patients to communicate through a display of symbols, letters, or words, controlled entirely by their brain signals. The system can be adapted to suit individual patient needs, allowing flexibility in how they interact with their environment.

- **Personalization**: Over time, the system will learn and adapt to the specific brainwave patterns of the user, enhancing accuracy and speed. This allows for a highly personalized communication experience

This solution will enable paralyzed patients to regain some degree of autonomy by allowing them to communicate effectively, improving their quality of life and enabling deeper interactions with caregivers and loved ones.

Initial concept was selected after the brainstorm session which was held on 19th August 2024.Here is a summary of that session.

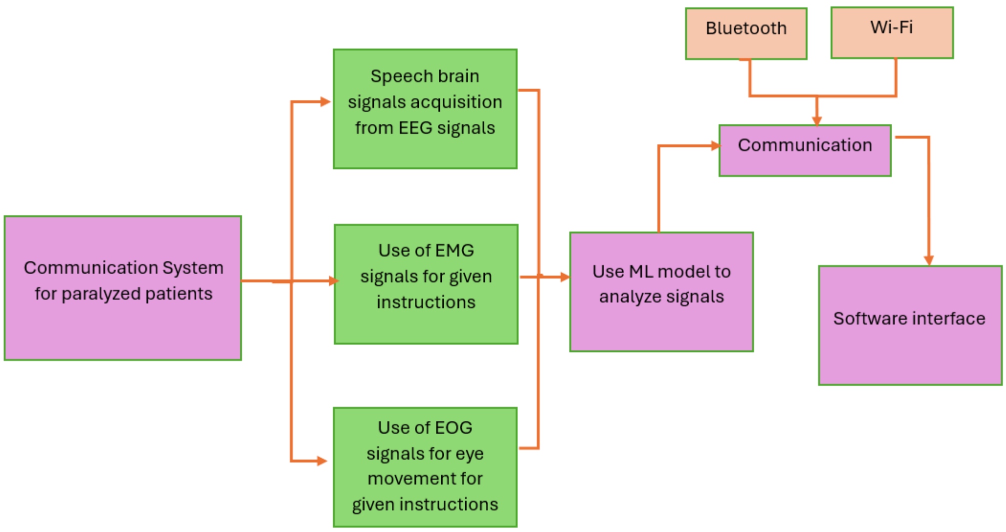

Figure 1: Brainstorming session

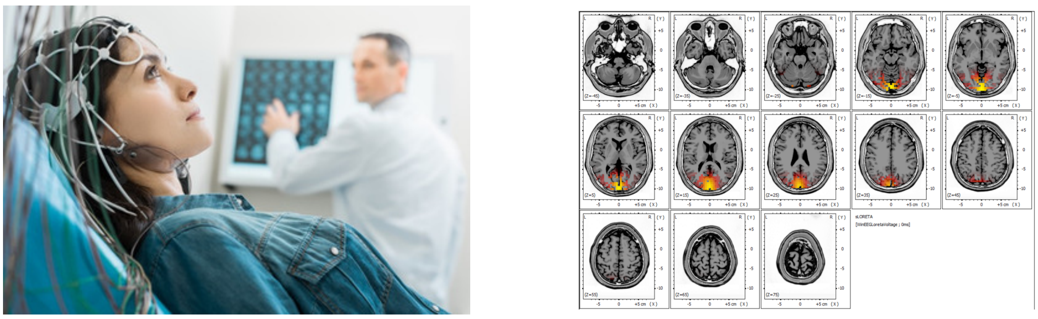

Figure 2: EEG Scanning.

4 Concept Screening

4.1 Intellectual Property

- **Patents**: File patents to protect our novel specific methods, algorithms, or system designs
- **Licensing**: When using third-party EEG hardware, open-source software libraries, or pre-trained machine learning models, verify the licensing agreements to avoid conflicts.

- **Trademarks**: Secure trademarks for the branding of your communication system, as this will protect the name and logo of your product or system.
- **Software IP**: Protect the source codes and the models of the ML Models or signal processing algorithms

4.2 Regulations

In Sri Lanka, medical devices are regulated by the National Medicines Regulatory Authority (NMRA), which oversees the safety, efficacy, and quality of medical products. To ensure the EEG-based communication system complies with Sri Lankan laws, the following regulatory aspects must be considered:

4.2.1 Medical Device Classification

- NMRA Approval

The EEG-based communication system would likely be classified as a medical device because it is designed to improve the quality of life for paralyzed patients.

- Clinical Testing

In Sri Lanka, devices classified under higher risk categories require clinical trials and validation before approval. We will conduct clinical trials in collaboration with local hospitals or research institutions to demonstrate the device's effectiveness in facilitating communication for paralyzed patients.

4.2.2 Ethical and Data Privacy Considerations

- Sri Lankan Data Protection Laws

Handling patient EEG data means that the system must comply with local data protection laws. The Personal Data Protection Act (PDPA) of Sri Lanka, enacted in 2022, outlines the standards for data collection, storage, and processing.

- Patient Rights

Under Sri Lankan law, patients have the right to access and control their personal data. The communication system will allow patients to view, modify, or delete their data, ensuring full compliance with PDPA regulations.

4.2.3 AI and Algorithmic Transparency

- Algorithmic Accountability

While Sri Lanka does not yet have specific AI regulations, it is crucial to ensure transparency and accountability for the machine learning algorithms used in the communication system.

- Real Time Signal Processing

To meet regulatory standards, we will need to demonstrate that the system can interpret EEG signals and translate them into meaningful commands or language constructs in real time, without significant delays. The NMRA will likely require proof that the system's performance is consistent, safe, and effective.

4.2.4 Clinical Trials and Testing

Before the system can be approved for use in Sri Lankan healthcare settings, it must undergo clinical trials to validate its safety and effectiveness. These trials will involve testing the system with real patients, ensuring it meets the needs of individuals with severe paralysis or locked-in syndrome.

In collaboration with hospitals or research institutions, we will collect data on the system's usability, accuracy, and impact on patients' quality of life. This data will be submitted to the NMRA as part of the regulatory approval process.

5 Business Model

5.1 Direct Sales Model

- Overview: Sell the system directly to hospitals, clinics, and individuals.
- Revenue: One-time purchase of the device by institutions or patients.
- Advantages: Immediate revenue and easier control over distribution.
- Challenges: High initial cost may be a barrier for patients.

5.2 Subscription Model

- Overview: Offer the system under a subscription plan where users pay a recurring fee.
- Revenue: Monthly or yearly subscription fees covering hardware, software updates, and support.
- Advantages: Lower initial cost for users, ensuring steady cash flow.
- Challenges: Requires ongoing support and regular updates to keep users subscribed.

5.3 Leasing Model

- Overview: Lease the device to healthcare institutions or patients for a specified period.
- Revenue: Monthly or yearly leasing fees.
- Advantages: Lowers the upfront cost, making the device accessible to more users.
- Challenges: Requires a system for device returns, maintenance, and upgrades.

5.4 Partnership with Healthcare Providers and Insurance

- Overview: Partner with insurance companies and healthcare providers to cover the cost of the system.
- Revenue: Insurance reimbursements or bulk purchases by healthcare providers.
- Advantages: Makes the device more affordable for patients.
- Challenges: Navigating the complex insurance approval process and securing partnerships can take time.

5.5 Freemium Model (Software Focused)

- Overview: Provide the basic version of the system for free or at low cost, with premium features available for an additional fee.
- Revenue: Premium upgrades for advanced features such as enhanced EEG interpretation or customization.
- Advantages: Expands user base with a free version while generating revenue from premium features.
- Challenges: Balancing the free and premium features to ensure enough value to encourage upgrades.

6 Prototyping and Testing Plan

To test the feasibility of our EEG-based communication system for paralyzed patients, we start with a basic prototype. This involves placing gold cup EEG electrodes with use of electrolytic gel on the patient's scalp to capture brainwave activity. Since language-based EEG signals are difficult to interpret, we rely on asking the patient to try to open and close their eyes to answer questions with limited vocabulary. For signal acquisition 7 electrodes will be used. This includes one reference electrode, one ground electrode and 5 active electrodes, 2 placed on occipital lobe, 2 placed on Parietal lobe and one placed on central midline.

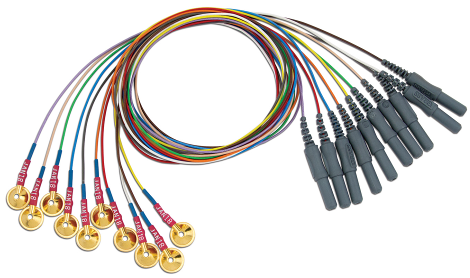

Figure 3: EEG Electrodes.

Signals will be processed using the TGAM board with the help of a multiplexer, which will filter out noise and prepare the data for analysis. Filtered EEG signals will be directly fed to a computer via bluetooth. We'll then create a simple software interface that displays the patient's response in real-time, based on the EEG signals. Recorded EEG data is then run through a machine learning model to determine what the patient response was.

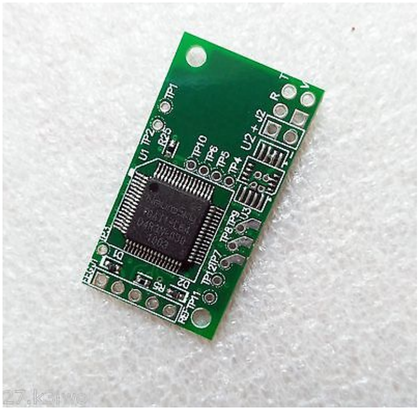

Figure 4: TGAM Board

The prototype will be tested on a small group of participants, where each person will be asked simple yes/no questions while the system records their brain activity. Multiple trials will allow us to collect enough data to fine-tune the signal interpretation. If necessary, adjustments will be made to improve accuracy and reliability.

Prototyping Steps:

- Place electrodes (5 active, 1 reference, 1 ground) on the scalp.
- Process signals using the TGAM board.
- Create a basic software interface to interpret signals.
- Test the system by asking yes/no questions.
- Analyze and fine-tune the system as needed.

7 Final Concept Selection: Risks and Selection Matrix

Key risks include signal noise, patient comfort, and accuracy. We will mitigate these risks by carefully selecting and testing the final design.

Major Risks:

- Signal noise from muscle activity.
- Patient comfort for long-term wear.
- Accuracy of signal interpretation.
- Processing speed to avoid delays.

Selection Matrix:

Criteria	**Design 1**	**Design 2**	**Design 3**
Signal Accuracy	8	7	9
Comfort	6	8	7
Ease of Setup	7	6	8
Total Score	21	21	24

8 References

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