Final Report for BM2210
EEG based communication system for paralysed patients

May 23, 2025

- Dulsara G.M.L. 220146A
- Perera P.L.P 220472T
- Wijayarathna K.K.B.C 220705M

Contents

1 Introduction

In this project, we have developed an EEG-based communication system that incorporates signal acquisition, amplification, filtering, and classification processes. The primary objective is to create a dependable and accessible communication solution for paralyzed patients, enabling them to connect with caregivers, family members, and their environment.

This report outlines the end-to-end development of the system. By leveraging modern technologies, this project aims to bridge the communication barrier faced by individuals with severe physical disabilities, providing them with greater autonomy and an enhanced quality of life.

2 Problem Statement

"User friendly 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 Proposed Solution

Our proposed solution is an **EEG-based communication system** designed to provide a reliable and efficient means of communication for paralyzed patients who lack the ability to speak or move. The system utilizes **electroencephalography (EEG)** to capture brainwave signals, which are processed to classify the patient's intent into a binary response—**"Yes"** or **"No"**—that is then displayed through an intuitive user interface.

The solution is built on a structured pipeline that includes the following key components:

1. **Signal Acquisition:** EEG signals are captured non-invasively using electrodes placed on the patient's scalp, ensuring comfort and safety during the process.

2. **Amplification and Filtering:** The acquired signals, which are typically low in amplitude and contain noise, are amplified and filtered to extract the relevant brainwave components for further analysis.

3. **Classification:** A machine learning model processes the cleaned EEG signals and classifies them into one of two responses, **"Yes"** or **"No"**, based on predefined patterns associated with patient intent.

4. **User Interface (UI):** The classified output is displayed on a user-friendly interface, which features a **Start/Stop** button to control the process. This interface ensures accessibility and ease of use for caregivers and medical professionals.

The proposed system offers a **non-invasive, affordable, and scalable solution** that empowers paralyzed patients to communicate effectively. By leveraging EEG technology and machine learning algorithms, this solution bridges the communication gap, enabling patients to express their needs, interact with their surroundings, and achieve a greater sense of independence.

4 Device details and methodology

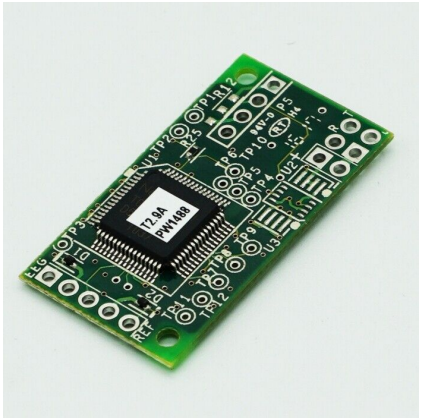
4.1 Component Selection

- **Gold Cup Electrodes**: Chosen for their high signal fidelity and patient comfort, ensuring effective EEG signal acquisition.

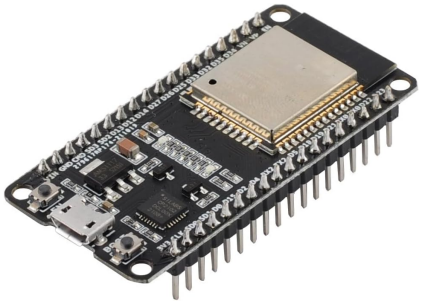
- **ADG408 Multiplexer**: Enables sequential switching between multiple active electrode channels, minimizing hardware complexity and improving efficiency.

- **MT3608 Booster Module**: Converts 5V from a USB connection to a stable 12V output, providing reliable power to the multiplexer and ensuring the system can operate solely on USB power.

- **NeuroSky ThinkGear ASIC Module**: Specially designed for EEG applications, this module handles signal amplification and filtering, delivering high signal-to-noise ratio (SNR) and effective noise reduction.



- **ESP 32**: Manages the multiplexer, processes signals from the ThinkGear module, and interfaces with the machine learning classification algorithm.



4.2 Capturing the signal

- **Electrode Placement**:
  - Two electrodes on the left and right forehead.
  - Two electrodes in front of the left and right ears to cover the temporal lobes.
  - One ground electrode on the forehead.
  - One reference electrode on the bone behind the ear.
- **Signal Acquisition Process**: The electrodes capture EEG signals non-invasively from the patient's scalp. These signals are fed into the ADG408 multiplexer, which sequentially selects active channels and sends the signals to the ThinkGear module for further processing.

- **Power Supply**: The MT3608 booster module converts 5V USB power to 12V, ensuring stable operation of the multiplexer without requiring external power sources.

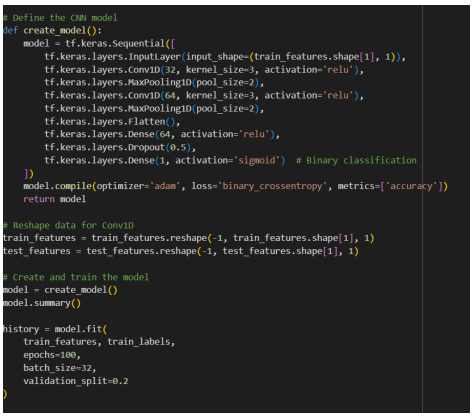
4.3 Classification through ML Integration

- **Amplification and Filtering**: The ThinkGear ASIC module amplifies the low-amplitude EEG signals and filters out noise caused by muscular artifacts and external electrical interference. Relevant EEG frequency bands (e.g., alpha, beta, theta) are extracted for analysis.

- **Machine Learning Model**:

  This model implements a 1D **Convolutional Neural Network (CNN) for binary classification**, designed to process sequential data. It uses two Conv1D layers, each with 32 and 64 filters and ReLU activation, followed by MaxPooling1D layers for downsampling. A fully connected Dense layer with 64 units and a dropout rate of 0.5 helps prevent overfitting, while the final Dense layer with a sigmoid activation outputs the binary classification. The model is trained using the Adam optimizer and binary cross-entropy loss, and its performance is evaluated with accuracy as the metric.

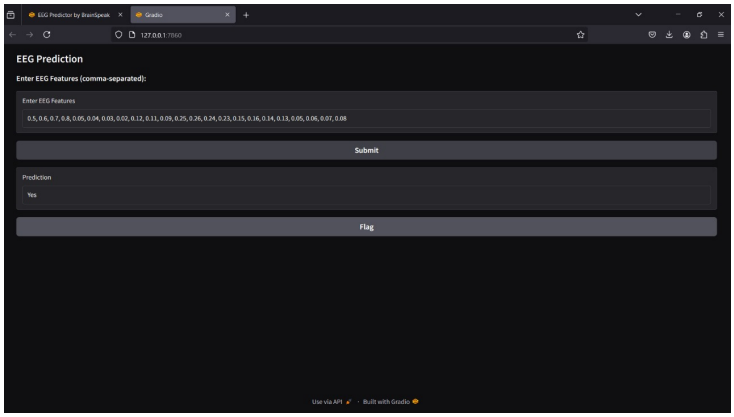
  – To train our model, a dataset for motor imagery available on Kaggle was reshaped.Dataset was trained using the model for 100 epochs of 32 batches. The dataset can be found at Kaggle Dataset.



```
# Define the CNN model
def create_model():
    model = tf.keras.Sequential([
        tf.keras.layers.InputLayer(input_shape=(train_features.shape[1], 1)),
        tf.keras.layers.Conv1D(32, kernel_size=3, activation='relu'),
        tf.keras.layers.MaxPooling1D(pool_size=2),
        tf.keras.layers.Conv1D(64, kernel_size=3, activation='relu'),
        tf.keras.layers.MaxPooling1D(pool_size=2),
        tf.keras.layers.Flatten(),
        tf.keras.layers.Dense(64, activation='relu'),
        tf.keras.layers.Dropout(0.5),
        tf.keras.layers.Dense(1, activation='sigmoid')  # Binary classification
    ])
    model.compile(optimizer='adam', loss='binary_crossentropy', metrics=['accuracy'])
    return model

# Reshape data for Conv1D
train_features = train_features.reshape(-1, train_features.shape[1], 1)
test_features = test_features.reshape(-1, test_features.shape[1], 1)

# Create and train the model
model = create_model()
model.summary()

history = model.fit(
    train_features, train_labels,
    epochs=100,
    batch_size=32,
    validation_split=0.2
)
```

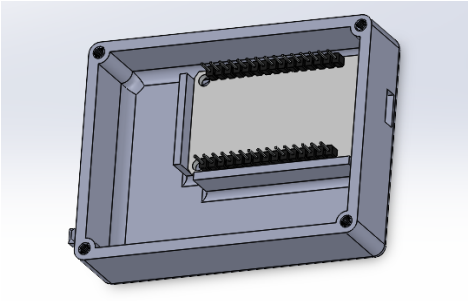
4.4 The User Interface

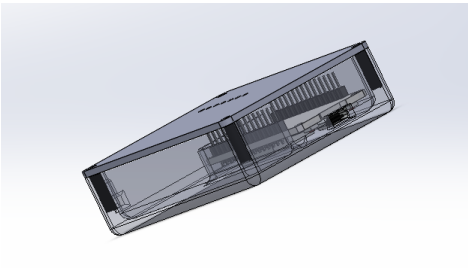
- **Output Display**: The classified results from the machine learning model are displayed as binary responses ("Yes" or "No") on an intuitive interface.
- **System Control**: The microcontroller integrates the classification results with the user interface for seamless operation, ensuring accessibility for medical professionals and caregivers.

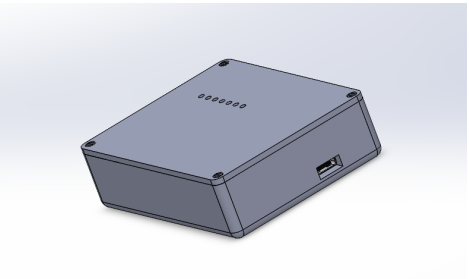


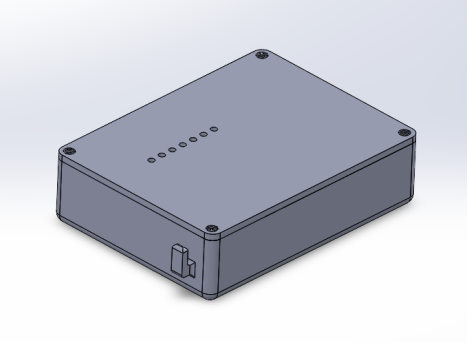
4.5 Enclosure

The enclosure for device was designed using SolidWorks to ensure precision and functionality. Leveraging SolidWorks' advanced modeling and simulation tools, ensuring that all components fit together seamlessly and meet high-quality standards.





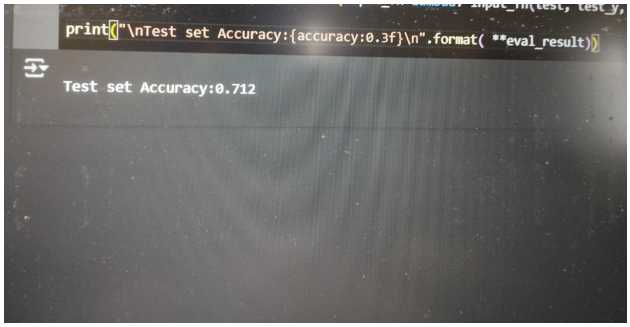




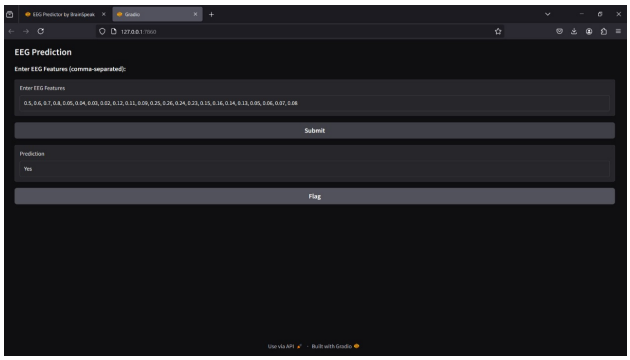
5 Simulation and Test Results

1. Our 1D CNN model reached about 70% accuracy in binary classification. We tested it by changing things like the number of epochs, batch size, and dropout rate to see how it performed. The results show the model works fairly well, but there's still room to make it better. We could improve it by tweaking the design, adding more data, or trying other techniques.

2. The current dataset we are using will have to be replaced by our own dataset. The current data is skewed and does not specify our task.



(a) Model Accuracy



(b) UI for manual testing of the model

6 Possible Regulatory Pathway

For the successful implementation and deployment of our EEG-based communication system, adherence to relevant regulatory pathways is essential to ensure **safety, efficacy, and compliance** with industry standards. These pathways involve approvals from medical device regulatory bodies, certifications for data privacy and safety, and adherence to ethical guidelines. The following regulatory aspects are key considerations:

1. **Medical Device Classification:** Depending on the jurisdiction, the EEG-based system is likely to be classified as a *medical device*. For example:

    - In the **United States**, the system would require clearance under the **FDA (Food and Drug Administration)**. Based on its risk level, the device may fall under Class I (low risk) or Class II (moderate risk) medical devices. A *510(k) premarket notification* or a *De Novo pathway* may be required to demonstrate substantial equivalence to existing technologies.

- In the **European Union**, compliance with the **Medical Device Regulation (MDR)** would be required. The device will need to earn a *CE marking* to confirm safety and performance standards.

2. **Safety and Electrical Standards:** Since the device involves electrical components (EEG acquisition hardware), it must comply with international safety standards such as:

   - **IEC 60601**: Standards for the safety and performance of medical electrical equipment.
   - **ISO 14971**: Risk management for medical devices to identify, assess, and mitigate risks throughout the device lifecycle.

3. **Data Privacy and Security Regulations:** Ensuring the confidentiality and security of EEG data is critical, particularly when dealing with sensitive patient information. Compliance with data privacy laws such as:

   - **HIPAA (Health Insurance Portability and Accountability Act)** in the United States, which governs the use and protection of medical data.
   - **GDPR (General Data Protection Regulation)** in the European Union, which enforces strict guidelines on the collection, storage, and processing of personal data.

4. **Clinical Trials and Validation:** Prior to regulatory approval, the system may require *clinical trials* to validate its effectiveness and safety in real-world settings. Trials must be conducted under ethical standards such as:

   - **Good Clinical Practice (GCP)**: Ensures integrity, safety, and transparency in clinical research.
   - Approval from an **Institutional Review Board (IRB)** or **Ethics Committee** to ensure the protection of patient rights during testing.

5. **Post-Market Surveillance and Maintenance:** Once approved and deployed, the device must adhere to post-market surveillance regulations. This involves:

   - Monitoring the system's performance in real-world use cases.
   - Reporting any adverse events to regulatory authorities.

- Ensuring periodic updates and maintenance to address any hardware or software issues.

Conclusion: By navigating these regulatory pathways, our EEG-based communication system can achieve **regulatory compliance, safety assurance, and widespread acceptance** within healthcare settings. Proper adherence to these pathways not only guarantees patient safety and trust but also facilitates the integration of our solution into clinical practice, thereby improving the lives of paralyzed patients.

7 Future Improvements

We plan to expand this system into a comprehensive communication solution, moving beyond binary Yes/No responses. The ultimate goal is to develop it into a fully functional communication system as part of our final year project, enabling paralyzed patients to express a wider range of responses and interact more effectively with their surroundings.

8 Task Allocation

Name	Task
DULSARA G.M.L.	Enclosure Design, User Interface and Component Selection
Perera P.L.P	Machine Learning Model, Component Selection and Debugging
Wijayarathna K.K.B.C	EEG signal Capturing, Assembling and Component Selection