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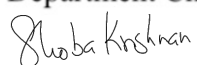
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NeuroGen: EEG and Near-Infrared Light Stimulation Control System

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NeuroGen: EEG and Near-Infrared Light Stimulation Control System

By

Arnold Nieto, Jaylinn Solis, Matthew Tamanaha

SENIOR DESIGN PROJECT REPORT

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Department of Electrical Engineering
Santa Clara University
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ABSTRACT

Light stimulation or transcranial photobiomodulation (tPBM) therapy has been shown to be effective when treating patients suffering neurodegenerative diseases such as Alzheimer's and Parkinson's disease. While there is currently no cure, light stimulation can help alleviate symptoms for those patient's suffering from these diseases. With this in mind, the senior design team from last year began a prototype hybrid electroencephalography (EEG) and tPBM device. They implemented a specific wavelength of 810 nanometer (nm) near-infrared (NIR) light emitting diodes (LEDs), with a 16 channel EEG headset from OpenBCI. The device was intended to serve as a potential research tool, with a closed loop system between the EEG and light stimulation system; this means, changing the light stimulation therapy based on the patient's EEG measurements.

The goal of this year's senior design team was to expand and improve the hybrid EEG and tPBM head-device. Last year's senior design team was able to implement the EEG and LEDs in the same system, however, they were unable to finish closing the loop between the two subsystems. Also, last year's group was only able to work with 810 nm LEDs, but this year we were lucky enough to receive 1070 nm LEDs from the Quiet Mind Foundation. These LEDs are shown to be more effective in stimulation than that of the 810 nm; this is due to the fact that the 1070 nm wavelength is better absorbed by tissue than the 810 nm, and can penetrate deeper from a further range. There is also evidence that light sensitive ion channels in neurons are tuned to 1070 nm and not 810. However, 1070 nm LEDs are considerably more expensive than the 810 nm, as well

as difficult to access. These trade-offs were important to consider when designing our device, as we wanted to reach specific benefits and functional criteria. We worked together as an interdisciplinary team, both bioengineers and electrical, in order to progress towards a fully closed loop system, enhance the user interface, and implement these newly received diodes.

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Chapter 1: Project Introduction

1.1 Project Rationale

Neurodegenerative diseases such as Alzheimer's and Parkinson's are diseases caused by the loss of function and death of nerve cells in the brain and peripheral system [1]. These diseases progress over the lifetime of the person and in many cases, the brain continues to deteriorate and completely debilitates the individual. Alzheimer's and Parkinson's aren't the only things causing damage to brain nerve cells. Stroke and head trauma survivors also suffer from loss of brain neurons, so the term dementia is most typically used to describe this condition. Currently, more than 55 million people are living with dementia worldwide, and nearly 10 million new cases are reported every year [2]. Alzheimer's disease alone affects about 6 million people in the United States, and this is projected to increase to about 13 million people by 2050 [3].

The rise in concern for neurodegenerative disease patients comes from the fact that age is the primary risk factor for developing diseases like Alzheimer's and Parkinson's [4]. Other risk factors include genetics and environmental triggers [5]. Considering the current global birth rates, which have decreased by half compared to the 1960s according to the World Bank, it is projected that the older population, specifically individuals aged 65 and above, will surpass the younger generation over the next forty years. This demographic shift poses significant challenges to our capacity as a society to effectively respond to the needs of the elderly. This poses an issue since the demand for direct care workers (in roles such as nurse aides and home health aides) is projected to grow by more than 40% between 2016 and 2026, while their availability is expected to decline [3],[6]. Because of that, 80% of the help provided to individuals with Alzheimer's disease (AD) comes from family, friends, and unpaid workers [3]. Additionally, there is no cure for neurodegenerative diseases so far, and no current explanation as to what exactly causes neurons to die which makes coming up with a treatment plan much harder [7].

New research suggests that transcranial light stimulation therapy, also known as transcranial photobiomodulation (tPBM), can be used to treat neurodegenerative diseases, brain trauma injury, and psychiatric disorders [8]. Clinical trials have shown an overall positive effect on PBM treatment subjects in their executive control which includes: clock drawing tests, immediate

recall, practical memory, visual attention, and task switching [9]. PBM stimulation devices currently exist in the market today but lack monitoring and processing components, and assessment relies on acquiring electroencephalography readings (EEG) to process the information before and after PBM stimulation. Because of this, there is little to no data on how the brain reacts to photobiomodulation during the treatment nor is there a way for people to modulate the protocol based on the brain's dynamic response during the treatment.

An interdisciplinary team focused on continuing the prototype research device built during the 2021-2022 academic year as well as designing a new prototype with LEDs of different wavelengths. The team consists of both electrical and bioengineers working together with the goal of creating a closed-loop system that would provide a wide range of control options and real-time analysis capability to adapt the PBM stimulation protocol according to EEG readings.

1.2 Background

The NeuroGen is a multifunctional device that combines the principles of light stimulation and electroencephalography (EEG) to address specific needs in the field of neurodegenerative monitoring. Building upon previous research, our team undertook a comprehensive review of relevant literature and emerging technologies to enhance the capabilities of the NeuroGen. This project aimed to tackle key aspects such as stimulation control, real-time recording, response analysis, and the development of an effective control strategy. By integrating these elements, the NeuroGen aimed to provide advanced monitoring and therapeutic solutions for people with neurodegenerative conditions.

1.2.1 Transcranial Photobiomodulation

Light has been established to have an important role in biological systems which can be observed in the way our body bases sleep, wakefulness, and cardiac cycles on the presence of light.

Photobiomodulation (PBM) is the result of researchers exploring using lasers as sources of amplified, stimulated emission of radiation. Transcranial photobiomodulation (tPBM) therapy utilizes near-infrared (NIR) light-emitting diodes (660 - 1100 nm wavelength range) to penetrate the skull and interact with the human brain parenchyma.

PBM has been observed to have many different effects on the human body such as numerous instances of regeneration and healing. NIR light has been observed to reduce inflammation and pain, raise ATP production and improve regional cerebral blood flow and oxygen levels. As illustrated in Figure 1.1, NIR produced by 810 nm LEDs is absorbed by cytochrome c oxidase in the mitochondria which creates a proton gradient causing influx of Ca^{2+} and enacts ATP production. In contrast, 1070 nm wavelength NIR stimulation targets light sensitive ion channels on the mitochondria, allowing Ca^{2+} to enter the cell and enact ATP production. The rise in ATP production leads to improved cerebral blood flow, oxygen availability and consumption which leads to stimulating, healing and enhancing cell functions. Mitochondrial dysfunction has been shown to be linked to aging and diseases related to aging such as AD. Therefore targeting the mitochondria is a crucial first step towards developing treatment for neurodegenerative diseases.

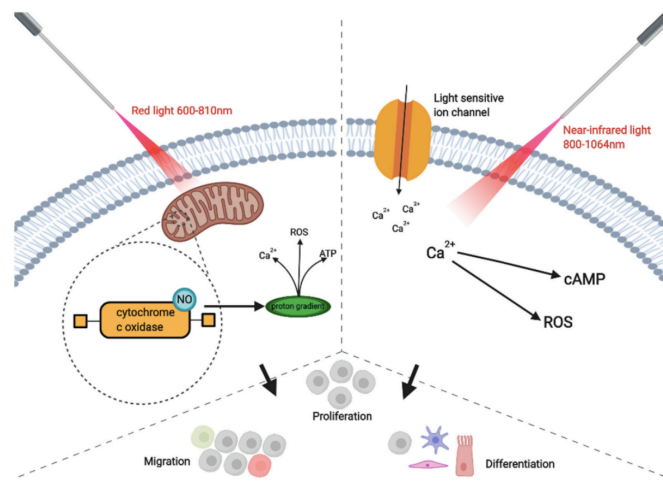


Figure 1.1: PBM Mechanism in Action [10]

1.2.2 Photobiomodulation Clinical Trials

There have been a number of tPBM conducted targeting a range of neurological conditions, one of the larger study groups has been the treatment of dementia using tPBM. PBM has been effective in studies, where they were able to conclude the importance of stimulation time, meaning that more time was more effective [10]. A study that was conducted was able to see a positive effect in subjects with dementia through various tests such as a Mini Mental State Exam

(MMSE), clock drawing tests, and Trail Making tests, two of which are shown in Figure 1.2 below [9].

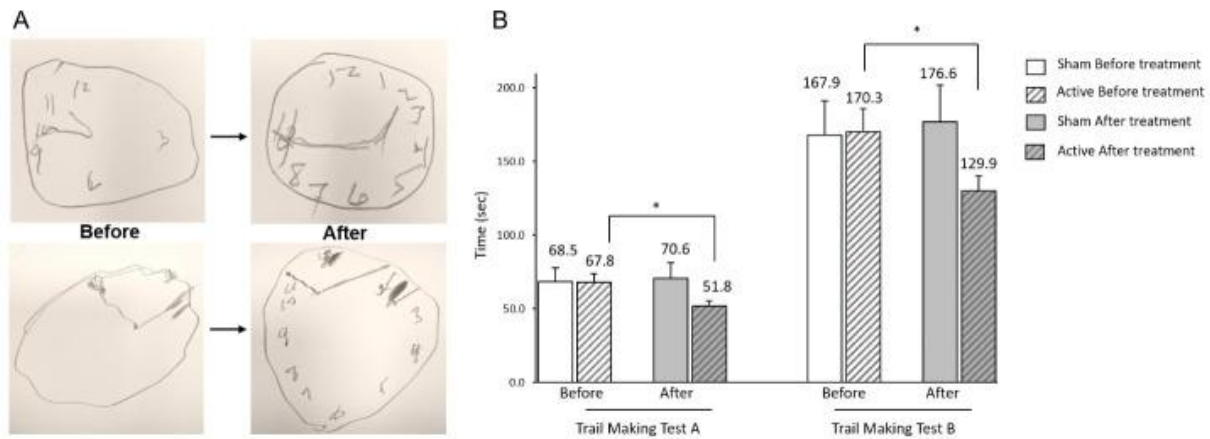


Figure 1.2: Clock Drawing Test (A) and Trail Making Test (B) after 1060-1080 nm PBM treatment. The * symbol in the figure stands for statistical significant result with $p < 0.05$.

For these tests, the patients were instructed to follow a stimulation protocol of at least 6 minutes, twice a day, for eight consecutive weeks. The control group was given a “sham treatment” that did not include near-infrared stimulation. The Clock Drawing test (A) involved having patients draw a clock from memory before and after the eight weeks of stimulation. The figure shows two separate subjects that were tested and both showed massive improvement after the stimulation protocol. The Trail Making tests (B) involves a test where the subject is instructed to connect a set of 25 numbered dots as quickly as possible in ascending order. There was an overall decrease in time and improvement in drawings in the patients that went through treatment compared to the control group that had a sham treatment [9].

1.2.3 Electroencephalography (EEG)

An electroencephalogram (EEG) is a recording of the brain’s electrical activity through the use of electrodes placed on the scalp. This raw data can be used to evaluate how different parts of the brain are affected by viewing the electrical impulses that occur [11]. EEG is a valuable tool due to its ability to analyze cognitive processes, its high temporal resolution, and its additional advantages of being noninvasive and cost-effective. These recording devices are also portable

and lightweight and can view the activity at different areas in the brain at different moments. Through the use of PBM and EEG it is possible to provide neurofeedback, which is important because it provides the parameters for viewing specific patterns that are seen in different neurological disorders that can be altered through operant conditioning when the prototype is in open loop [12]. In the final version of the prototype, the user will not be given feedback and instead the change would automatically occur due to the nature of having a closed-loop device

Through the EEG recordings we will be able to capture brain activity in the form of brain waves. Brain waves are dependent on different states of the brain. The 5 frequency bands that are widely used are Delta (1-4 Hz), Theta (4-8 Hz), Alpha (8-12 Hz), Beta (12-25 Hz), and Gamma (above 30 Hz). Gamma waves have the highest frequencies of the brain waves and are associated with high levels of concentration and high levels of cognitive function. Alpha waves are most notable during meditative moments and focused attention meaning that there is an increase during creativity and learning.

The EEG being implemented into the control system would allow for real-time recording of brain activity and this feedback would be displayed into a user interface and an LED controller that would then allow the tPBM stimulation to be personalized to each user of the device [13]. With an EEG in our design, we will be able to receive feedback during PBM stimulation as well as being able to have the closed-loop control system be used to show the effectiveness of the PBM stimulation past a benchtop test. The prototype built by last year's senior design team was able to process EEG signals from raw data of the electrodes.

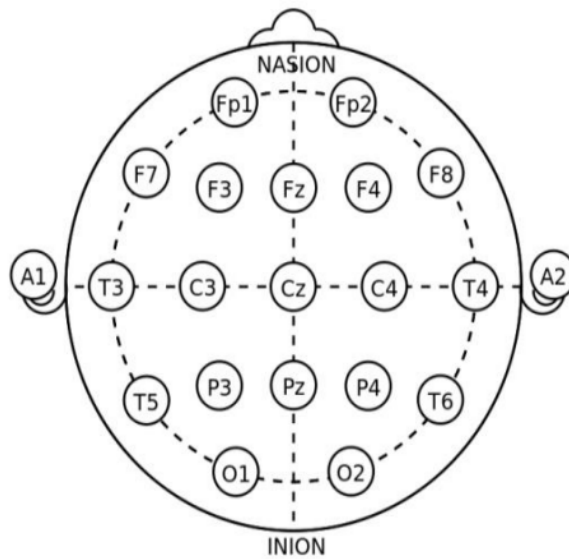


Figure 1.3: Arrangement of 10-20 Electrode System

EEG electrodes are placed in a 10 - 20 international electrode system. This system is used as a guide for optimal electrode placement with a conventional naming system to be understood. As discussed further we will be choosing placement of our electrodes based on this system. Figure 1.3 shows this arrangement based on the 20 electrodes. The points A1 and A2 are integral in EEG recordings as those are the grounding clips that are connected to the earlobes of the subject. With this system we are able to visualize the placement before beginning the prototyping of the electrodes on the device.

1.2.4 Neural Entrainment

As we have mentioned above the alpha frequency is within the range 8-12Hz. The brain oscillations within this frequency range are correlated with performing perceptual tasks. These frequencies can go through training known as frequency entrainment. Frequency entrainment is the act of training brain waves by matching frequencies to a desired outcome. The process occurs when a stimuli is oscillated at the same phase and frequency as a brainwave frequency [14]. Entrainment phenomenon is when these two oscillations become synchronized and match. This entrainment of brainwave has been observed specifically within the alpha range in studies for increased learning in making perceptual decisions [15]

A study observing the effects of flicker-induced stimulation allows us to better see what it means to have frequency entrainment. In this study a high contrast square was flickered on a screen in 15 cycles of flashes and 3 groups were exposed to either peak matching phase, trough matching phase, and trough non-matching phase. The results were analyzed using Matlab through an FFT and the learning rates of the subjects were observed through comparing the performance of trials.

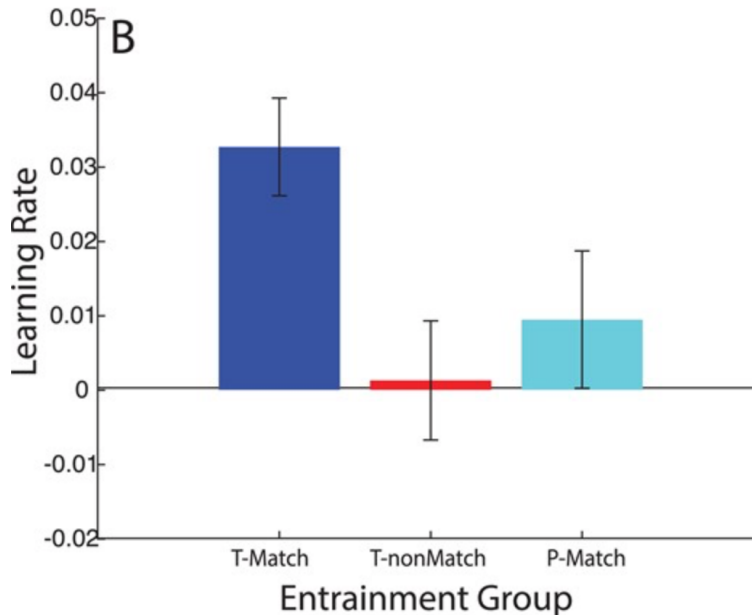


Figure 1.4: Learning rate of frequency entrainment [15]

As can be seen in Figure 1.4 when the flicker-induced entrainment was at a trough with a matching phase there was a higher learning rate observed during the performance tasks. This result is important because it shows how the entrainment at the frequency of brain waves, with stimulation, has observable effects in behavioral tasks. Using EEG as an analysis tool will allow us to see the effects of entrainment through reading the actual frequency in the alpha range to observe the 10 Hz frequency matching. If the recordings are at a lower alpha frequency, the stimulation can be set to a frequency that will be matched by the natural brain waves. In this case, we want to get to 10Hz so we would stimulate at 10Hz. Successful entrainment would be observed by focusing on the alpha band and an increase in power relative to the original state [16].

1.2.5 Closed Loop System

Our team's goal is to develop a closed-loop system in a technology that currently exists in an open-loop. When a person is prescribed a photobiomodulation protocol as treatment, the patient must follow a predetermined treatment plan and later return to their clinician to modulate their treatment plan [17]. The open-loop aspect of this situation is how there is a need to interrupt treatment protocols and manually adjust the stimulation dosage. As pictured in Figure 1.5, the open-loop system requires a medical professional to evaluate and program the new stimulation protocol after stimulation occurs, traditionally through the use of diagnostic EEG. A closed-loop system enables automated treatment and adjustment of stimulation protocols based on the patient's neurochemical biomarkers [18],[19]. This innovative approach facilitates personalized treatment and ensures continuous modifications to treatment protocols. This aspect holds significant importance due to various factors, including skin tone, hair color, and hair density, which can influence the level of stimulation received by each individual. As a result, photobiomodulation protocols cannot rely on traditional "cookie-cutter" prescriptions provided by physicians, necessitating a more tailored and adaptable approach.

As explained earlier, our project's biomarkers are brainwaves collected through the use of electrodes. The evaluation aspect is the EEG analysis, the programmer is the real time adjustment based on EEG data, and the stimulation comes from the near-infrared LED panels.

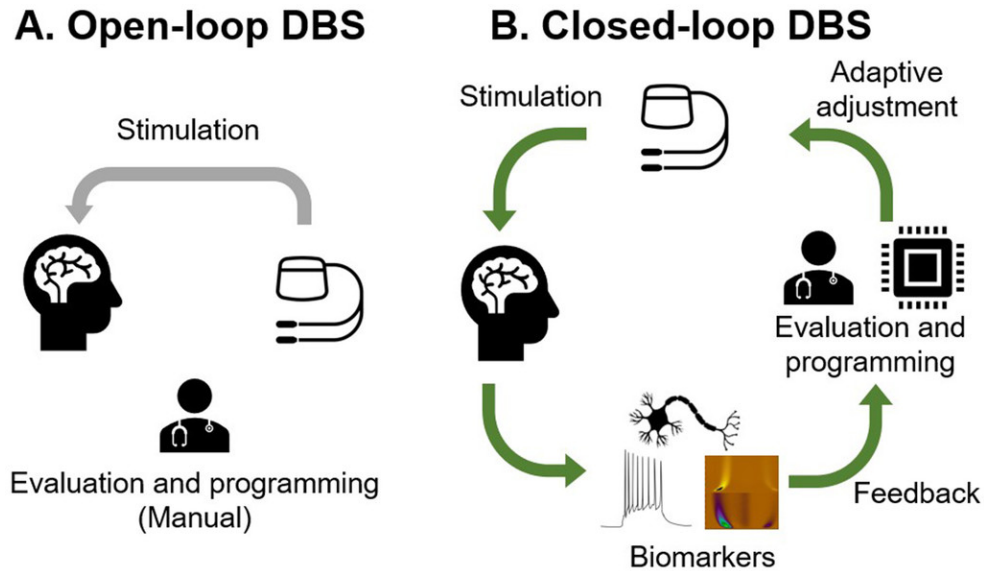


Figure 1.5: Open-Loop vs Closed-Loop Deep Brain Stimulation [20]

1.2.6 Existing Technologies

Near-infrared photobiomodulation has been observed on the market in the form of only light therapy, meaning that there is no diagnostic component in the device. The devices on the market require an input from doctors in the form of prescription on the dosage of the light stimulation. This means that patients wanting to receive treatment with this device would need to go in to get recordings of brain activity to view the effects of the stimulation. Devices only include the stimulation aspect and not the feedback or observation aspect.

One such device is the Neuradiant 1070 with a total of 256 LEDs [21]. This device contains an interface that allows for full control over 4 quadrants of the device. The control over these quadrants includes being able to change aspects such as pulse rate, duration and light intensity to those quadrants. The Neuradiant 1070 device is pictured in Figure 1.6, where it can be seen that the device has the ability to have full coverage of the top of the head and also uses 1070 nm wavelength NIR light.



Figure 1.6: Neuradiant 1070 device [21]

In contrast to the Neuradiant 1070 device, there is the Vielight Neuro which is a device that uses 810 nm wavelength LEDs [22]. This device is a transcranial-intranasal device which means that there is a nasal connection point along with the transcranial LEDs. The intranasal technology is for the connection of the olfactory bulb to the prefrontal cortex. The use of this technology is non-invasive with the added benefit of having controlled stimulation protocols. This device offers the ability to have targeted stimulation depending on what is the prescribed dosage and desired effect. The two focus areas are in the gamma frequency and the alpha frequency, the gamma frequency relating to problem-solving, energization and focus, while the alpha frequency is correlated with mental relaxation. The Vielight device pictured in Figure 1.7 is one of the devices available by the Vielight company. As is the case with this device and others found on the website, these don't offer full coverage of the head with the LEDs.



Figure 1.7: Vielight Neuro 3 [22]

There are also many clinical studies that are ongoing to investigate the effects of photobiomodulation on patients. Among these are studies that revolve around having active devices and sham devices. A sham device, in the context of these studies, refers to a control device that mimics the physical characteristics of the active device but does not deliver the therapeutic intervention. Instead, it serves as a placebo or reference point for comparison. The devices in these clinical trials range from the creation of their own devices and the use of already existing devices to perform these tests. A few of these include low level laser therapy and BIOFLEX DUO + which is another device using near-infrared light. One thing that is important to note is that these devices all have different LED wavelengths ranging from 800 nm - 1100 nm. The other important distinction between these devices and what we are trying to achieve with our prototypes is that there is no method of closed monitoring found on the technology that currently exists. The devices do not include a way to monitor changes in real-time, unlike our device that includes the EEG recording subsystem which means that it is possible to observe the alpha power band for viewing the neural entrainment that occurs during photobiomodulation protocols.

1.3 Project Goals

1.3.1 State of the Project

The team this year began with a prototype prepared by the two teams in 2021-2022. These two teams had students from the General, Mechanical, Electrical, and Bioengineering department to develop the primary prototype. Our team consisted of two bioengineering and two electrical engineering students to continue the development of the previous team and new control capability. We built our project on their prototype that contained: four 810 nm wavelength LED panels, each with 96 810 nm diodes, a Mark IV 3D printed head frame, a bluetooth enabled amplifier, 16 electrodes, an active cooling system that consisted of two DC powered motorized fans, and strategically placed heat sinks that acted as an active cooling system. The device had only gone through benchtop testing and was verified to have control of the LED arrays, and also show that the electrodes were able to pick up EEG signals although they also had significant problems with noise and signals from its surroundings. The device is shown in Figure 1.8.

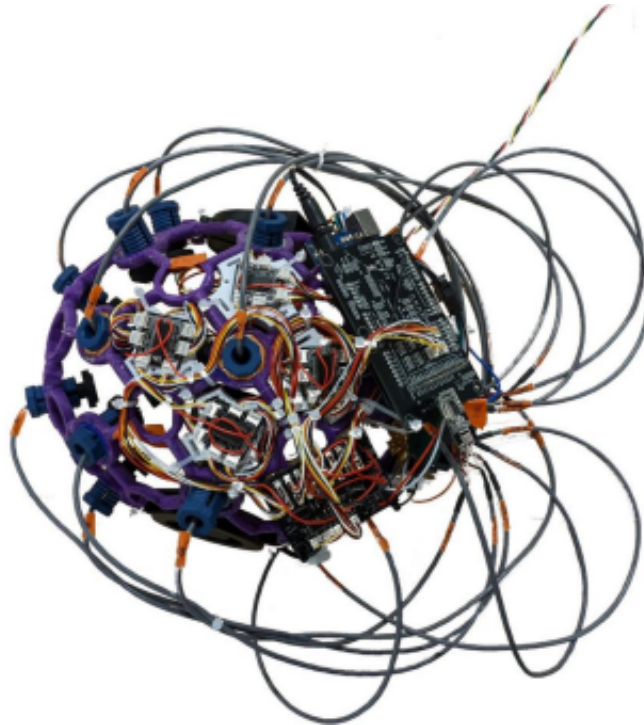


Figure 1.8: 2021-2022 Completed Hardware Component

1.3.2 Team Objectives

The objective of our project is to develop a system of customizable photobiomodulation protocols. We worked with the current physical prototype to further develop it into defining methods for a closed loop system that utilizes metrics gathered from EEG readings and adjusts the PBM program accordingly. With the new closed-loop system we wanted to analyze the effects of light stimulation therapy with 810 nm LEDs and compare them to a new 1070 nm LED headpiece our team planned to build. The motivation of this project is to create a more effective light stimulation therapy by making it more personalized to the individual. Improvements in sleep, cognitive function, and memory have been observed in patients that have undergone photobiomodulation therapy in many different studies and we hope to provide the capability to improve these results with a more personalized treatment plan. [9]

1.3.3 Hardware and Software Objectives

The goals for the function of this device remain the same as last year: (1) LED modules deliver light stimulation treatment, (2) EEG detects and records brain activity, (3) control system analyzes real-time changes, and (4) user interface adjusts the intensity and frequency of the light therapy. Our team worked to continue development of a closed loop system and a separate prototype using 1070 nm LEDs. However, a full closed loop system was outside the scope of our project this year so instead we focused on making sure that messages could be sent between OpenBCI, our signal processing software, and the PBM stimulation protocol. A new headset frame was made for this separate prototype and our team needed to split our total electrodes between the two systems and match electrode configurations in each device to focus on measuring alpha waves with 8 electrodes each instead of the original 16. [23]

As mentioned earlier, this year we started a separate head-device, with new 1070 nm LEDs. These new LEDs were gifted to use by the Quietmind Foundation, where they use the same LEDs in their model of a tPBM head device which uses 256 diodes. The first task of utilizing these LEDs was to determine if they could be used with the existing panels from last year's design, however, there was a clear size difference between the 1070 and the previous 810 nm LEDs. The casing on the 1070 nm LEDs were much larger than the 810 nm LEDs, which led us

to designing new PCBs to properly house the LEDs. While the control signals and power supply used by the previous group can still be utilized, having less LEDs could potentially mean using a simpler power system, as well as a different plan for controlling the localization of the LEDs.

Additionally, we planned to address an issue last year's team had with the heating of the device. Their LED arrays in the 810 nm prototype generated more heat than is permitted in wearable medical device standards and therefore needed the DC fans as active cooling agents to lower the device to a safe temperature. However, because the motorized fans ended up interfering with the EEG data collection we planned to strategize a new way to approach this heating problem by changing the mechanical design of the LED panels.

Chapter 2: NeuroGen: EEG and Near-Infrared Light Stimulation

2.1 System Overview

The complete system requires three subsystems to work together. The different subsystems here would be the EEG subsystem, the light stimulation subsystem, and the control system of the device. This year, we did not focus on the headset system due since no changes were made to the design or build other than omitting the use of the motorized fans.

The subsystems in our prototype work together through the use of three separate softwares working together. In the EEG subsystem, we work with the OpenBCI interface which functions as our user interface where EEG data is calculated and displayed. [24] Its great adaptability and customization allows it to communicate to the rest of the system. The Arduino software is used to control the light stimulation protocol in each LED panel. Our prototype is able to wirelessly receive Arduino code to enact stimulation modification. Lastly, the Processing GUI allows for customized code to be displayed in the OpenBCI interface which is used to form the communication between the two systems.

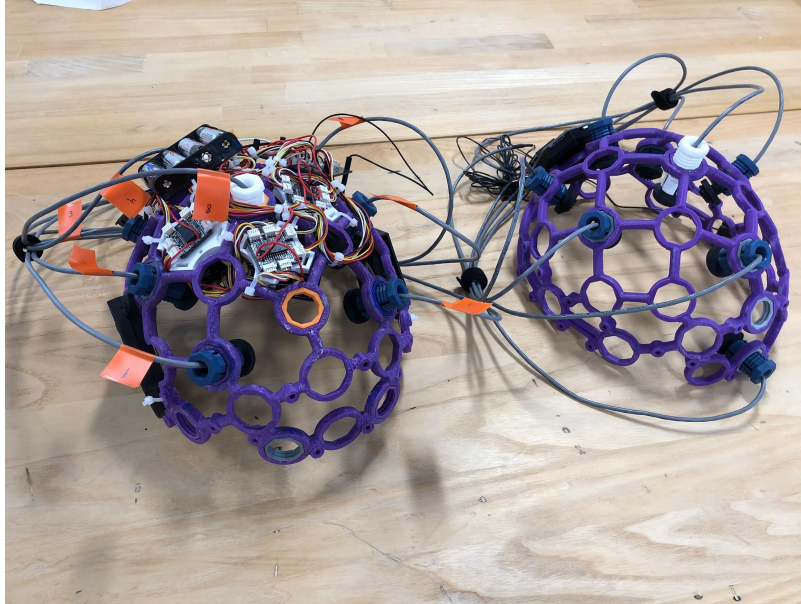


Figure 2.1: Two prototypes; 810 nm Device (Left) and 1070 nm Device Frame (Right)

2.1.1 EEG Subsystem

As this is a continuation of a project from the year before, we decided to keep a few of the design choices such as using the Ultracortex Mark IV headset from the OpenBCI shop for the frame of the device as well as two Thinkpulse Active Electrode [25] kit containing 6 spiky electrodes for through-hair locations and 2 flat electrodes each, as well as an upgrade kit that would add two more spiky electrodes as well as longer dry comb electrodes. This allows us to split each headset to have seven spiky electrodes and one flat electrode. Additionally, each device must include a set of ear clip electrodes that allows for stable grounding signal while recording EEG data. The electrodes are connected to a Cyton Amplifier (Figure 2.1) [26],[27] that acts as the communicator to the OpenBCI software.

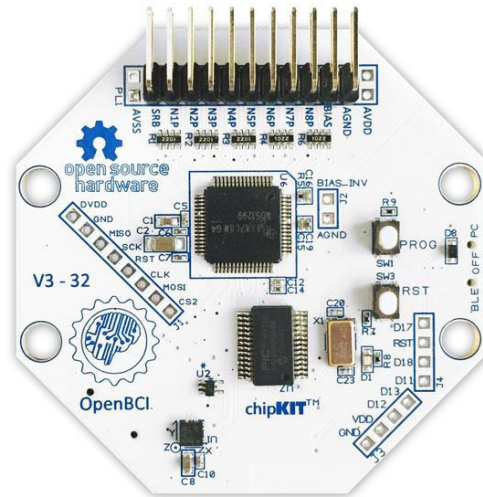


Figure 2.2: OpenBCI Shop Components. Cyton Amplifier (Top), Thinkpulse electrodes (Left), Grounding Ear Clips Electrodes (Right)

To move past benchtop testing, the team needed to ensure that EEG data was clean and without noise. The Cyton Amplifier is responsible for adjusting the gain values to have either 1x, 4x, 6x, 8x, or 64x. The gain settings are inputted manually and a trial and error method and are used to control the amplitude of signals in each electrode channel reading. If the gain is too high, the system will experience railing channels, which means the channel is out of the reading range of 0 -1000 μV and is disabled and omitted from appearing in any other features in the OpenBCI GUI.



Figure 2.3: OpenBCI Gain Settings and Railing Channels

This year, we expected to move past benchtop testing and testing the EEG system on people. With the removal of the motorized fans in the new design, it's expected that less noise is observed in EEG recordings. Other sources of error and railing in the EEG could be caused by faulty contact between the electrodes. Unfortunately, we were unable to do testing on a large population. Instead, the testing we did was on our own team members and we were able to see a benefit of removing the fans as they were a large source of error

2.1.2 Light Stimulation Subsystem

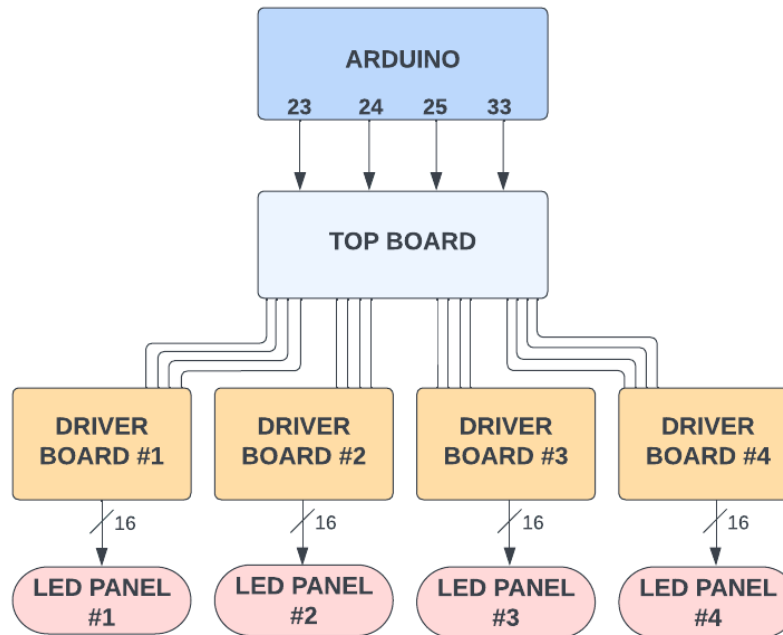


Figure 2.4: Arduino to LED Panel Communication

The light stimulation system is made up of an array of boards that are wired together and intended to relay a message inputted by the user or the feedback controller to the LED panels on the head-device. First, the Arduino takes the instruction from the user and then sends it to the mid-adapter board via four pin connectors. These connectors link the mid-adapter board to the top board on the head-device which relays the signals to the LED drivers. The LED drivers are designed to be able to communicate to one LED panel, each of which has 96 LEDs. However, one panel receives four, four pin connections from the drivers, which enables them to individually control each of 16 groups of six LEDs individually. The current voltage necessary for the LEDs is 12 volts, whereas the new boards with fewer LEDs in a group will only require five volts.

The system designed by the previous group had a total of four LED panels, meaning four total drivers attached to it. The current code for the system can only pulse the entire LED panel at a

set frequency, however as mentioned above, the drivers can enable each group of LEDs which can greatly improve treatment later on.

The major change for the project this year was receiving the new 1070 nm LEDs, which are researched to be more effective for stimulation. The new LEDs did not fit the same as the previous group's LEDs, however, when changing the design for the panels, we found that it was not necessary to change the control signals or drivers later on.

2.1.3 Control System

The control system portion of our project involves the communication between the light stimulation subsystem and the EEG subsystem. This is done through the OpenBCI interface as it contains features that can be modified through Processing. The previous group was working on Processing version 3 while this year, due to updates, we have been able to switch to Processing version 4. In order for the closed loop to be implemented it is important to look at the control system portion of our project.

One of the requirements for our system is the need for us to run the OpenBCI program through Processing rather than opening the OpenBCI GUI. In order to make changes to the OpenBCI GUI, the code for the GUI must be opened with Processing4. This allows us to view and edit each subsection, variables and libraries involved in making the OpenBCI GUI possible.

The previous group left off on creating a sample of the control interface for the control system using Processing 3 and the control CP5 libraries. These libraries give the ability for features like dropdown menus, text boxes, and sliders to be added and drawn out. With this we are also able to transfer and add these features to the OpenBCI GUI. The other portion that was added last year was the code for turning on the LEDs through a preset setting, this code was shown to pulse the LEDs and was written for the Arduino controller. There was no communication between the arduino controller and the OpenBCI interface. The user interface was also not implemented on the OpenBCI interface and was only displayed on the Processing interface.

2.2 Customer Needs and System Level Requirements

For our device to perform appropriately, here are the requirements for each subsystem.

Table 1: System Level Requirements	
Subsystem	Requirement
Light Stimulation	Design and Build 1070 nm LED Panels
EEG	Able to do a clean brain recording
Control System	Able to communicate to Arduino with OpenBCI

2.3 Functional Analysis

With these systems in place, we can form an idea of how they work together. In Figure 2.5, each component is represented by the color of the block— red signifies the hardware components and yellow represents the software components.

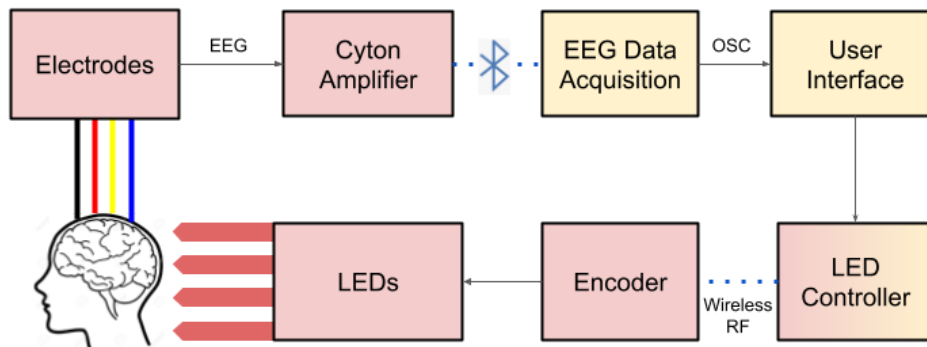


Figure 2.5: 2021-2022 Functional Block Diagram

2.4 System Issues/ Tradeoffs

2.4.1 Hardware Issues

While testing last year’s head-device, it became apparent that many wire connections from the original design had been broken, and due to a lack of documentation, only photos with the

specific boards could be used to rewire the broken connections. Unfortunately, one of the power wires was incorrectly connected to the boards, leading to the drivers being supplied the wrong amount of voltage, hence destroying at least three out of the four drivers. Fortunately, there are more PCBs and ICs to replace these drivers, so in the future, this could be accomplished.

Another issue was encountered when receiving the new 1070 nm wavelength LEDs gifted to use by the Quietmind foundation. Last year's head-device was specifically designed to house 96 810 nm wavelength LEDs in 16 groups of six. However, when trying to implement the newly gifted LEDs, we found that due to a larger casing, the 1070 nm LEDs could not be installed onto last year's PCB design. Because of this, it became necessary to create new designs for PCBs that would properly house the new 32 LEDs, without changing the overall design of the head-device.

2.4.2 Software Issues

There were various issues that we had to work around when it came to the software aspect of the project. The software components that we had to troubleshoot were the use of the OpenBCI GUI since this is the main program we are using for our analysis of EEG and the communication to the board. Another important component is being able to have control over the LED panels in a way that we are able to control with as much specificity as possible. For this function we are using an Arduino Controller, which allowed the previous group to write code that would turn on the LED panels. The challenges faced with these software components include the limited accessibility to Arduino code used last year to control the LED panels and the OpenBCI platform becoming compatible with processing version 4 therefore requiring the update from processing 3 to processing version 4. In order to address these issues there was communication required specifically, reaching out to the previous senior design group, and reworking how processing is used to load OpenBCI.

The use of Processing 3 to open the OpenBCI GUI became a problem during the end of the fall quarter. Processing 3 was used to run the OpenBCI GUI when the team worked on it last year and we were unable to make the change to Processing 4 until the OpenBCI GUI was compatible with the updated version of processing. This update happened with no announcement made on

the documentation leading us to believe that there were underlying issues in the OpenBCI GUI code. After searching for a solution to error messages, it became evident that a switch to version 4 would be necessary in order to continue working with the OpenBCI GUI. The solution of this software issue was to delete all current instances of the OpenBCI GUI found on the lab PC. After this was completed, it was important to download the necessary libraries as there were updates that needed to be made when it came to these libraries. The other component of this solution was to make sure that these were found in the administrator folders on the PC. Administrator access would allow for us to save the changes done to OpenBCI and would provide for more control of how the program is run as it would be able to permanently save changes.

In terms of the software side of the ELEN team one of the important components is the control of the LEDs. This was performed last year using Arduino code written and commented by the previous team. When it came time to test these LED panels, the code that was found in our records did not actually provide anything and did not function for turning on the panels. This is because this code was for the control interface portion of the light stimulation. This software issue was a simple solution but it did give us setbacks as the team needed to decipher how the code would function before they could use it to turn the panels on. We soon discovered that the code made available to us would not be able to perform the function we needed so we had to reach out to the previous group in order to obtain the correct code. This required time for response and for action which further set our timeline back. After receiving the code to turn the panels on, it was hard to visualize if the NIR diodes were actually on because the light is not visible to the human visual system. A way to visualize NIR is through a phone camera which responds to NIR light and shows it in a viewable image. There were a few problems that arose when trying to visualize and the code that we received from the previous group also did not provide the functionality that we required from the LEDs. The ELEN team had to analyze the code and find a way to make the LEDs turn on for the prototype.

These software issues were setbacks in both the BIOE and ELEN teams and did require looking into code to solve the issues. Both of these aspects of the project are important for the functionality as we use OpenBCI for the EEG and feature calculation with the ultimate end goal

being to have the control interface on the OpenBCI GUI, the other aspect of Neurogen is the photobiomodulation so being able to turn the panels on is a necessary components. It was necessary to address these issues in the quickest way possible to prevent any further delays in the work timeline. These allowed us to see how important it is to have all of our work documented especially when it comes to a project that has the intent of having more than one year's worth of work. We were able to continue to document all the work we have done, including instructions on how to update to new versions of processing as software updates occur, and commenting code to explain the important features and why certain decisions were made when writing the code. This will allow for an easier transition and better understanding of the work completed for the setbacks to be as minimal as possible.

2.5 Team and Project Management

2.5.1 Project Challenges

One of the challenges that we faced was the lack of documentation and understanding from the previous senior design group. As we have discussed in the software issues, one of the setbacks that we encountered was that there was not a lot of documentation to show where the group left off last year except for their thesis. This was hard because we did not know what aspects of the project were completed and which ones we had to complete this year. This lack of communication also led to problems such as being able to pick up where the previous team had left off.

Given the interdisciplinary nature of our project, one of the challenges we faced was coordinating focused work sessions that accommodated the availability of all team members. To address this challenge, we adopted the practice of updating and sharing our Google Calendars with each other. This enabled us to effectively identify and select optimal lab times that worked well for everyone involved. By using this approach, we were able to streamline our scheduling process and ensure productive and collaborative work sessions.

During the initial stages of our project, our team encountered a learning curve that involved familiarizing ourselves with the existing work carried out by the previous team. Our objective

was to grasp all the knowledge and insights accumulated by the previous team while conducting our own extensive research. Furthermore, we had to adapt to a new programming language, first to understand its fundamentals and syntax and how to effectively apply it to our project within the given timeframe of this year.

2.5.2 Budgeting

This year, we had a lot of leftover materials to work with and therefore only requested a small amount of funds from the School of Engineering. In total, we received \$235.21 to purchase additional batteries, adhesives, wires, and other electrical components. We were able to split our available electrodes into two 8 electrode systems and also reprint any printable parts purchased last year to cut down on costs. Additionally, our advisor Dr. Julia Scott had an extra Cyton Biosense board and we received a thousand 1070 nm NIR LEDs as a donation from the Quiet Mind Foundation for our new device.

2.5.3 Timeline of project

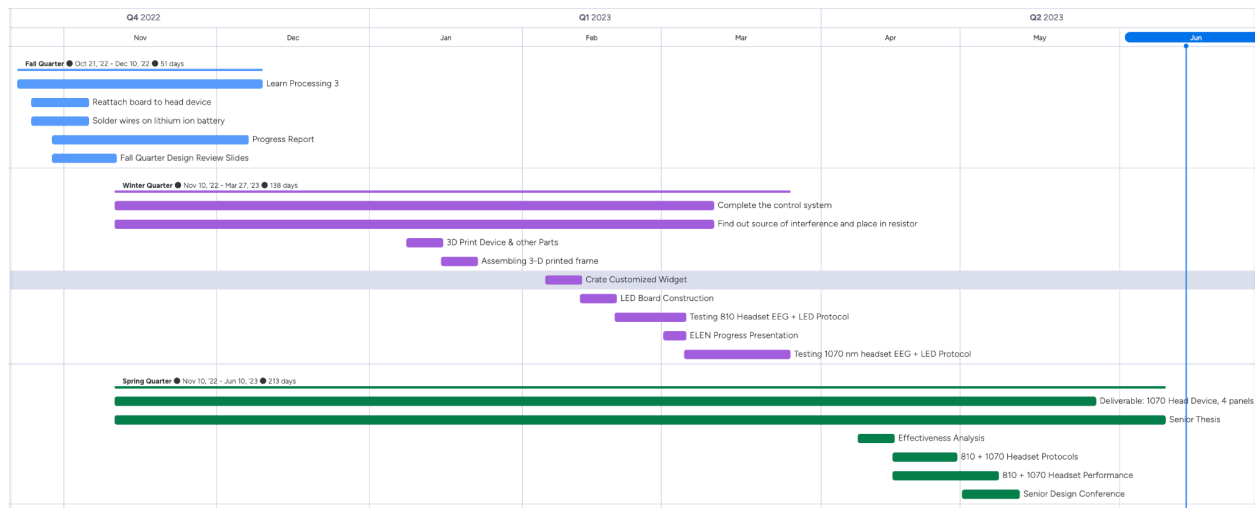


Figure 2.6: Gantt Chart For Project

2.5.4 Design Process

The Design of our project began when we first got access to 1070 nm LEDs thanks to a donation

by the Quiet Mind Foundation. Each LED is worth \$2.00 and they are the same LEDs used in the Neuradiant 1070 product. Initially, our team aimed high and hoped to complete another headset prototype with the 1070 nm LEDs this time to run a comparative analysis between the 810 nm design and the newer 1070 nm design. But first we had to move the prototypes out of the benchtop testing phase to begin comparing them. However, once we received the 1070 LEDs, we noticed that their packaging size was much bigger than the 810 nm LEDs and did not fit as desired in the previous printed circuit boards (PCB) designed for the 810nm LED panels.

2.5.5 Project Risks and Mitigations

The risks that surround this project primarily concerns the level of research that has been done, as well as that is still needed regarding photobiomodulation. To begin with, there is the risk that the data received from the EEG is not accurate enough in order to adapt the light stimulation, which could end up leading to the wrong kind of treatment for the patient. On top of this, it is also not entirely clear when the collection of data should begin after the light stimulation; meaning that if we run the stimulation for say, five minutes, should we collect data immediately after, or wait longer for a better response? This also is considering the brightness levels of the panels, as given the range, we may not be able to determine which brightness level has the best impact. For instance, changing the brightness by one percent could have a large impact, or 80 percent could have no impact, so how can we adjust the brightness more efficiently? The answer to these questions are still currently unknown.

2.5.6 Team management

Due to the composition of our team, which includes both BIOE and ELEN students, we were able to effectively allocate tasks based on disciplinary expertise. The ELEN students primarily concentrated on the LED design aspect, dedicating their efforts to its development and implementation. Meanwhile, the BIOE students focused on EEG testing and analysis, ensuring comprehensive examination and interpretation of the acquired data.

Collaboration between the two disciplines was crucial when working on the control system. During this phase, the BIOE students took the lead in addressing OpenBCI-related challenges

and focused on developing a control interface for the device. On the other hand, the ELEN students focused on addressing Arduino-related issues and primarily worked on the direct control of the LED panels. Additional delegation of tasks were made as comments in Google Docs when working on deliverables.

At the beginning of our project, effective communication posed a significant challenge for our team. We needed to identify a communication platform that not only suited the students but also allowed us to keep our advisors informed. After exploring options such as Slack, Monday, and Discord, we discovered that the most successful communication methods for us were email and Google Calendar invites. Email provided a reliable and comprehensive way to share updates, project information, and important announcements with both team members and advisors. Google Calendar invites helped us coordinate meetings, work sessions, and deadlines efficiently. Within the student team, iMessage proved useful for quick exchanges of ideas, sharing findings, and staying updated on assignments. By utilizing these communication tools, we established clear channels for information sharing, collaborated effectively, and ensured our advisors were kept in the loop throughout the project.

Chapter 3: Subsystem 1: EEG Subsystem

3.1 Overview of Subsystem

The EEG Subsystem is critical for proving any concepts in our design. The EEG is important for both open-loop and closed-loop systems to be used as a diagnostic tool for monitoring our biomarker. In the case of our design, the EEG subsystem is responsible for detecting any changes in the alpha frequency band, which is between 8-13 Hz and is indicative of changes in a person's cognitive functions. Using the concept of entrainment, we expect to see a change at 10 Hz after stimulating the brain with light at a 10 Hz pulse rate.

3.2 Design Choice

For the second prototype of our headset, it was necessary to divide the available electrodes between two devices. After careful consideration, we finalized the configuration illustrated in Figure 3.1. In this configuration, seven out of the eight electrodes are positioned on the top of the

head, coinciding with the placement of the LED panels in the headset design. This deliberate arrangement allows us to concentrate our data collection on the stimulated area. The rationale behind this approach is that feedback obtained from data points in close proximity to the stimulation areas should carry greater significance compared to those located farther away. Similar to the previous year's senior design team, we opted for dry electrodes in this project to minimize the risk of interference from LED signals and to enhance user comfort. Additionally, we continued to utilize Thinkpulse dry electrodes instead of comb electrodes due to the larger surface area they provide.

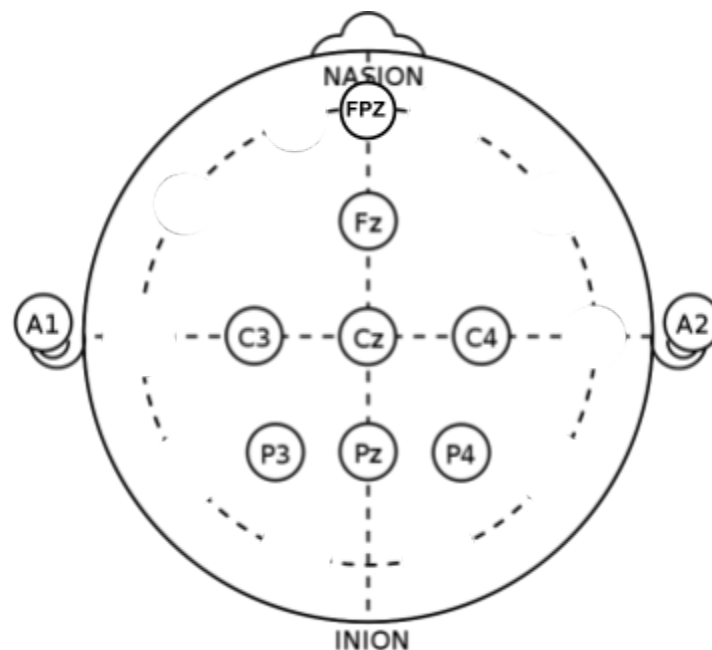


Figure 3.1: Final EEG Electrode Map

In the provided figure, the electrodes FPZ, Fz, C3, Cz, C4, P3, Pz, and P4 have been selected from the initial 10-20 Electrode system. It is worth mentioning that FPZ is an additional electrode not found in the traditional 10-12 system. The decision to include FPZ was driven by the presence of a flat electrode that could not make direct contact with the scalp due to the presence of hair. Therefore, a design incorporating forehead contact was necessary to ensure effective electrode placement.

Moreover, it is crucial to acknowledge that each electrode is assigned a numerical label based on its channel number and the specific pin number to which it is connected on the Cyton amplifier.

This numerical labeling system ensures precise identification and proper electrode connection within the system. Additionally, this electrode mapping is useful for examining the system in an open-loop.

1070nm EEG Mapping		A1 and A2 are reserved for Ear Clips for Grounding.
Electrode	Pin	N*P Pins belong to their Corresponding Channel
FPz	N1P	
Fz	N2P	
C4	N3P	
P4	N4P	
Pz	N5P	
P3	N6P	
C3	N7P	
Cz	N8P	
A1	BIAS	
A2	SRB	

Figure 3.2: Pin and Channel Numbers

3.3 OpenBCI

OpenBCI is a widely used open-source software that facilitates EEG analysis. To enable real-time EEG data streaming, the platform requires the acquisition of an OpenBCI board. In our specific case, we have access to the Cyton Biosensing board, which supports real-time data streaming for eight EEG channels.

Alternatively, OpenBCI offers several other board options to cater to different needs. For instance, the Ganglion board allows for 4-channel streaming, while the Cyton Daisy board supports 16-channel streaming. Additionally, there is a synthetic board option available for algorithmic data simulations, as well as a data playback option for loading previously saved data stream files. By providing this array of board options, OpenBCI enables flexibility and customization in EEG data acquisition. EEG data recorded in OpenBCI is stored in the form of text documents as the raw EEG data in the time series. In this format, the data could be loaded

into OpenBCI as a playback file, allowing for review and reassessment of data that couldn't be done in real time and apply any filters offered on OpenBCI. Additionally, the text file has the ability to be imported into outside analysis software such as Matlab, Neuromore, OpenVibe, Lab Streaming Layer (LSL), BrainBay, BioEra, and VirtualBox for any offline analysis.

As mentioned before the OpenBCI interface is highly customizable to which of its “widgets” can be displayed at a time. The interface allows the display of EEG data in Time Series, FFT Plot, and Band power. As well as giving access to Impedance testing and Networking to other devices.

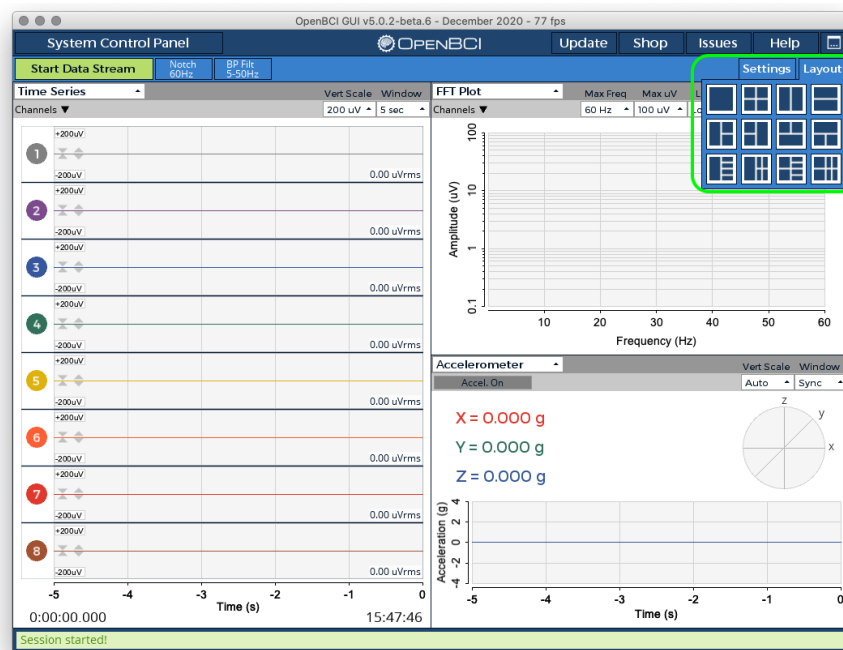


Figure 3.3: OpenBCI Interface

3.3.1 Time Series

The time series display is the first step in the process of the EEG subsystem as it is sent to OpenBCI. The raw EEG data is collected by the electrodes in a format that must be filtered in order to focus on the specific frequencies of brain waves. These are outputted on the interface in the time series display. The time series display gives a visual representation of the brain waves being recorded and as can be seen in the image below show all 8 channels that we are using for the EEG analysis. This time series allows for features that allow to change the gain settings, the time window for display and scaling for more effective visualization. One of the other features is

the ability to isolate channels for more localized recordings. The time series gives the ability to visualize in real time the changes in brain wave frequencies, for example a peak will show up with eye blinks and because of the real time analysis it is possible to view which channels are actually in contact and are gathering electrical signals.

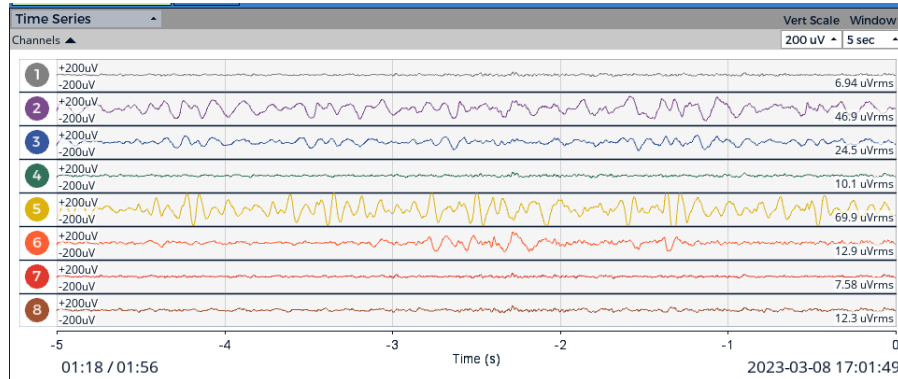


Figure 3.4: OpenBCI Time Series Widget

3.3.2 Fast Fourier Transform (FFT)

The fast Fourier transform (FFT) is a widely utilized algorithm in signal processing, playing a crucial role in converting the raw EEG signal from the time domain into the frequency domain. By employing the FFT, we can effectively isolate and determine the respective amplitudes of individual frequencies within the data. This capability, present within the OpenBCI GUI, proves valuable as it allows for the segregation of frequency ranges and facilitates visualization of information across different frequency bands.

In the context of our design, our specific biomarker of interest lies within the alpha frequency band. Thus, if our devices prove successful in stimulating the brain at a pulse frequency of 10 Hz, we anticipate observing a discernible change in amplitude within the 10 Hz frequency range. This analysis and observation within the alpha frequency band serve as significant indicators of the impact and effectiveness of our brain stimulation devices. Figure 3.5 shows a peak in 12 Hz which is also often observable when the person being observed has their eyes closed.

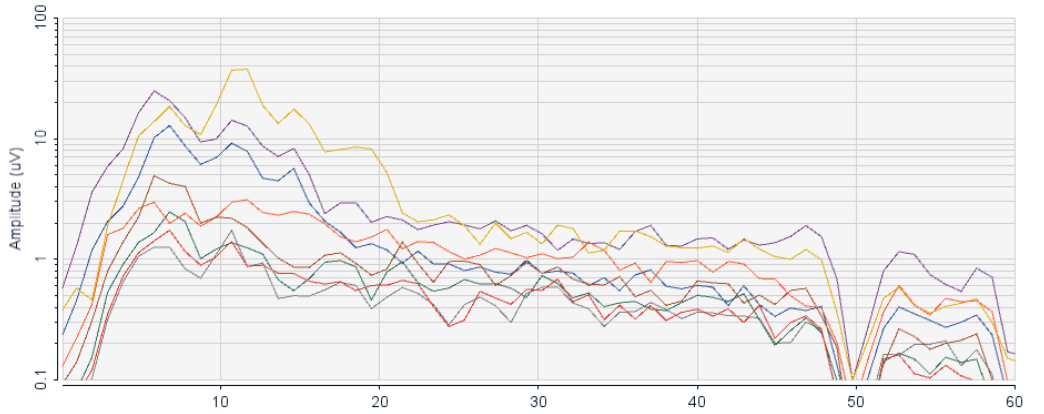


Figure 3.5: OpenBCI FFT Widget

3.3.3 Band Power/Focus

The Band Power and Focus widgets are two widgets that involve estimating power spectral density within specific frequency bands. The Band Power widget, depicted in Figure 3.6, provides a concise overview of power values associated with each band. Power values within each frequency band are typically estimated using techniques such as the periodogram, Welch's method, or multitaper method, which involve segmenting the signal, applying window functions, and calculating the average power spectrum. These estimation techniques take into account the squared amplitudes at various frequencies to determine the power values within each band.

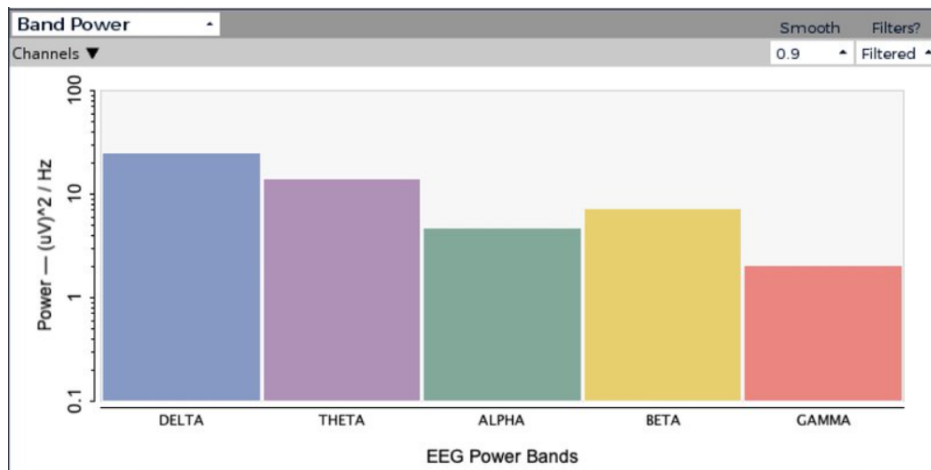


Figure 3.6: Band Power Widget

The Focus widget is an integrated feature that provides a 2 by 6 chart displaying normalized band power values. It leverages the BrainFlow library and BrainFlow metrics to process band power information and generate the desired Metric Value. In Figure 3.7, located in the top right corner, the Focus widget enables the selection of two metrics: "Relaxation" and "Concentration."

The "Relaxation" metric primarily examines FFT values associated with lower frequencies, including Delta, Theta, and Alpha brainwaves. On the other hand, the "Concentration" metric focuses on Beta and Gamma brainwaves. Typically, achieving relaxation involves a meditative state with closed eyes, while concentration is attained through intense focus with eyes open.

The computations for BrainFlow Metrics take place in the backend of the imported BrainFlow libraries, utilizing the chosen classifier, such as Regression, KNN, SVM, or LDA. These calculations utilize the available band power data and selected classifier to derive the Metric Value for relaxation or concentration assessment. If the Metric Value is above the selected Threshold value from the top right dropdown, the metric value is displayed as a binary value and is communicated as such to the rest of the OpenBCI GUI.

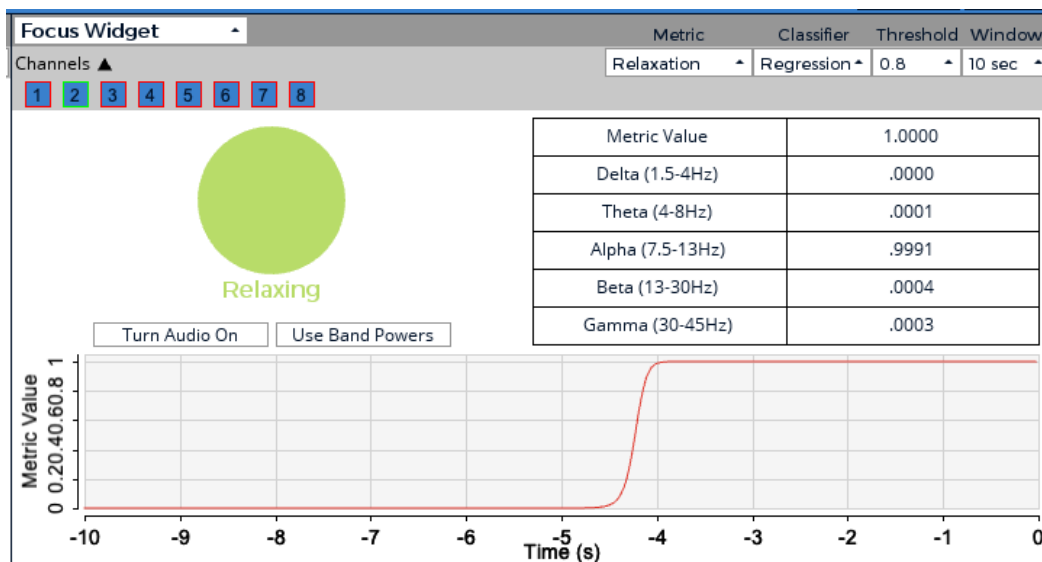


Figure 3.7: Focus Widget

3.3.4 Cyton Signal

The Cyton Signal widget offers a convenient feature that allows users to perform an impedance test on each channel. This step is crucial in ensuring the quality of the EEG signal, as it provides the most accurate assessment of signal integrity. If the impedance value is excessively high, it indicates insufficient contact between the electrodes and the user's scalp. Therefore, it is recommended to initiate a recording session by checking the impedance of each electrode. This practice increases the likelihood of capturing valuable information right from the beginning, eliminating the need for unnecessary test files.

Additionally, the Cyton Signal widget includes a device headplot displayed on the right-hand side. However, it is important to note that the headplot image shown is currently a placeholder image. OpenBCI has not yet implemented a feature that allows edits to the headplot within the Cyton Signal widget. Therefore, the headplot serves as a visual representation without the ability to make modifications directly within the widget.

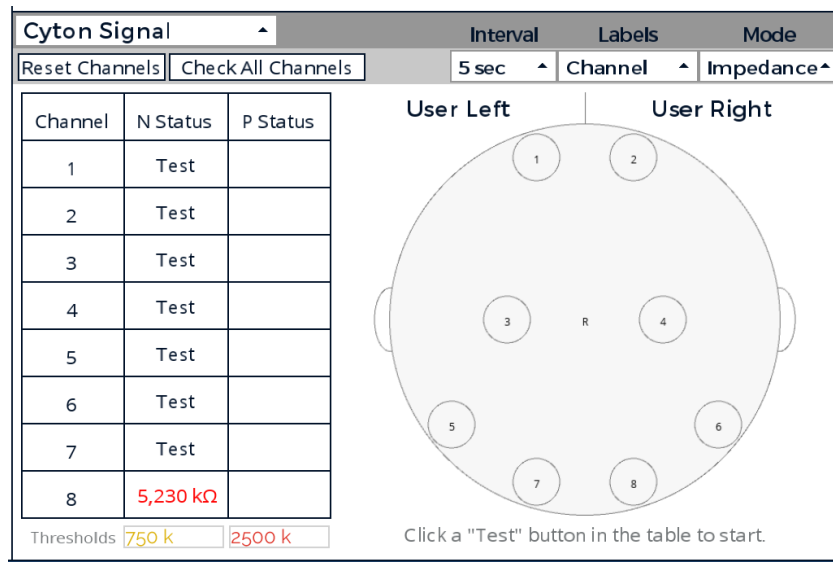


Figure 3.8: Cyton Signal Widget

3.3.5 Networking

The Networking Widget serves as the primary interface for communication between the OpenBCI GUI and external programs. It offers various data streaming options, including Serial, UDP, OSC, and LSL data types. Serial communication, in particular, is the main networking protocol used when integrating OpenBCI with Arduino. It facilitates bit-by-bit data streaming, ensuring precise and reliable data communication.

In contrast to the usage of OSC by the previous team in the 2021-2022 period, the adoption of Serial communication allows for more accurate data transmission. This is especially important when sending BandPower data, which comprises channel numbers followed by five floating-point values displayed with three decimal points. The data is comma-separated and enclosed in brackets, enabling a standardized and structured format for reliable communication and processing. However, both OSC and Serial communication only send “0” and “1” values for the Focus data type which makes the Focus data type less favorable.

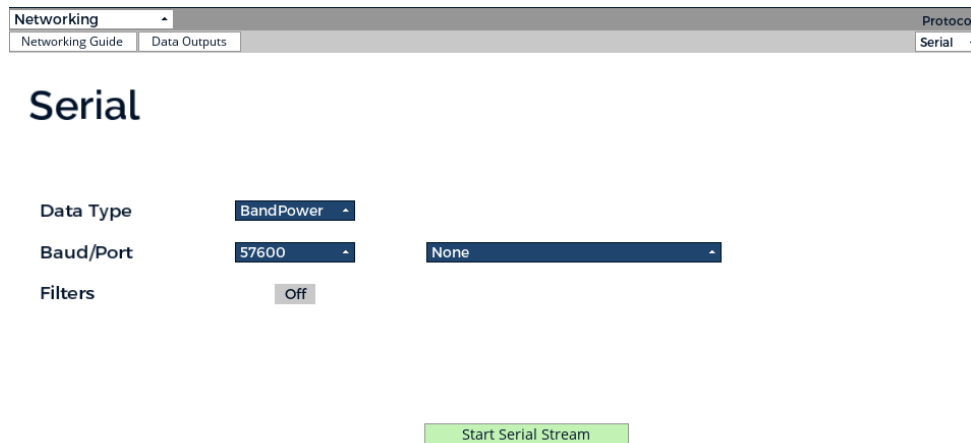


Figure 3.9: Networking Widget

Chapter 4: Subsystem 2: Light Stimulation

4.1 Overview of Subsystem

The light stimulation comes from the LEDs mounted on panels that flash at a specific frequency and brightness level. The panels holding the LEDs can be controlled independently in order to apply stimulation at certain areas of the scalp, which is important for accessing specific regions of the brain. The current head-device with 810 nm LEDs has 96 LEDs divided into 16 groups of 6, where each group can be accessed individually. In order to stimulate at an entrainment frequency, f_0 , the LEDs are turned on and off with a 50% duty cycle at full illumination; meaning all 16 groups of the LEDs turned on. In Figure 4.1 below, a timing diagram for this entrainment frequency with its corresponding cycles underneath is shown. Each square pulse represents one cycle (N) at the given entrainment frequency.

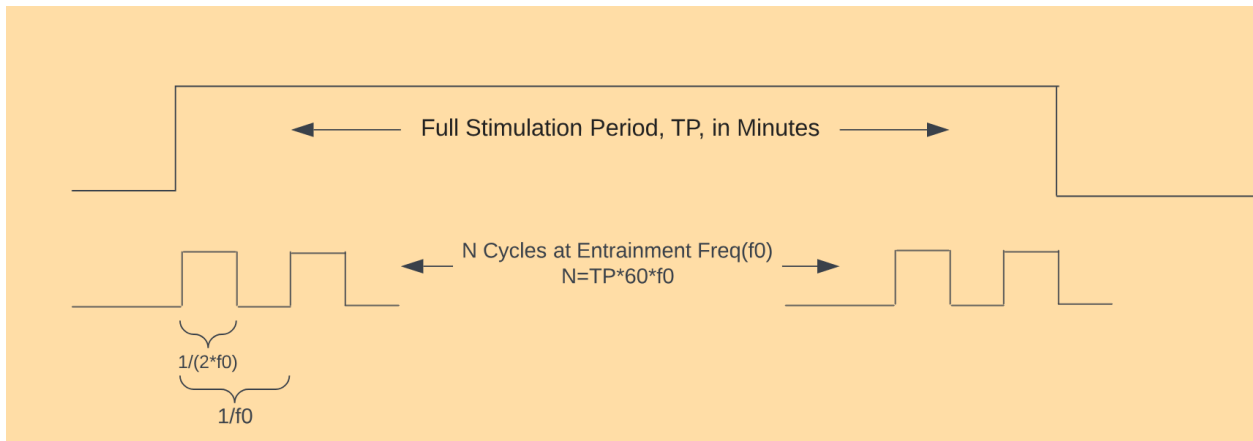


Figure 4.1: Timing Diagram for Entrainment

In order to control the pulse-width modulation (PWM), which controls the brightness by controlling the percentage of the time during one cycle when the LEDs are on, the hierarchy of boards shown earlier in Figure 2.4 was used to communicate an instruction from the user to the LED panels. This instruction sets parameters for frequency and brightness for the LED panels. To give a general overview of the hierarchy of the boards, the user input is first sent to an arduino with a mounted PCB called “mid-adapter board,” which then passes the instruction to the “top board,” a PCB mounted on the head-device. From here, the top board sends the message to the “LED drivers,” which then finally relays the message to the LED panels. Each driver communicates with one corresponding LED panel, and can also access each individual group of

the 16 groups of LEDs. This feature will be slightly different later on, as the panels no longer house as many groups of LEDs.

The mid adapter board, shown in Figure 4.2, is physically mounted on top of the Arduino, and is responsible for receiving the user input from the computer, and relaying the message to the top board on the head-device. The mid-adapter board achieves this through wiring the digital input and output pins (set in the code) to four pin connectors that then connect to the top board.

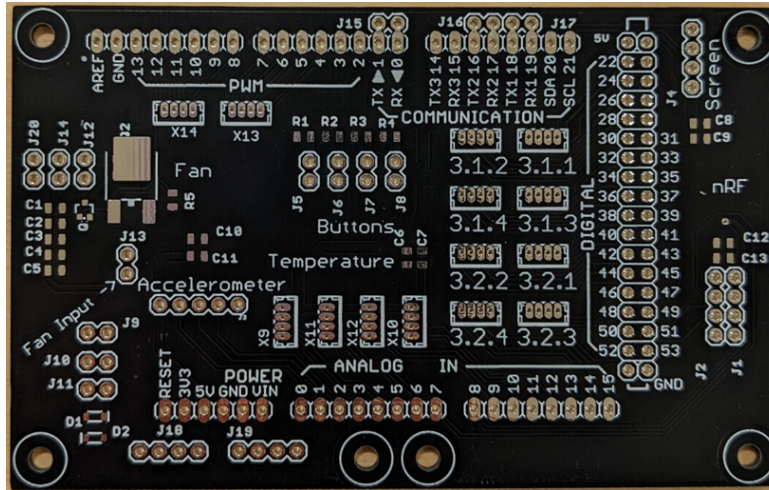


Figure 4.2: Mid-adapter Board

Following the mid-adapter board, the top-board (Figure 4.3a) receives and relays the message sent from the Arduino and relays the message to the driver board. The top-board (Figure 4.3a) achieves this through three integrated circuits (ICs): two AND gates and one Texas Instruments (TI) 12 channel, constant-current sink pulse-width modulation (PWM) driver (TLC59711) (see specifications in Appendix A) . Once the message is received and processed through the ICs, the top board then delivers the message via four pin connectors to the LED drivers.

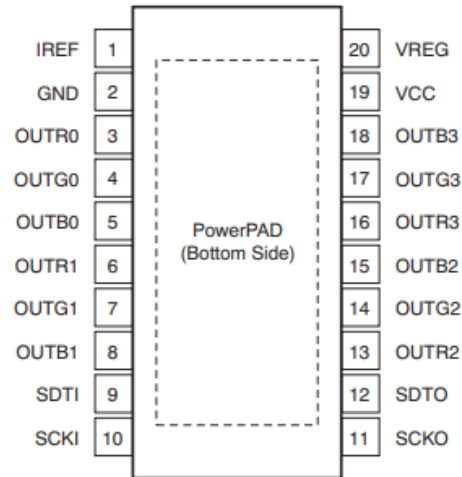
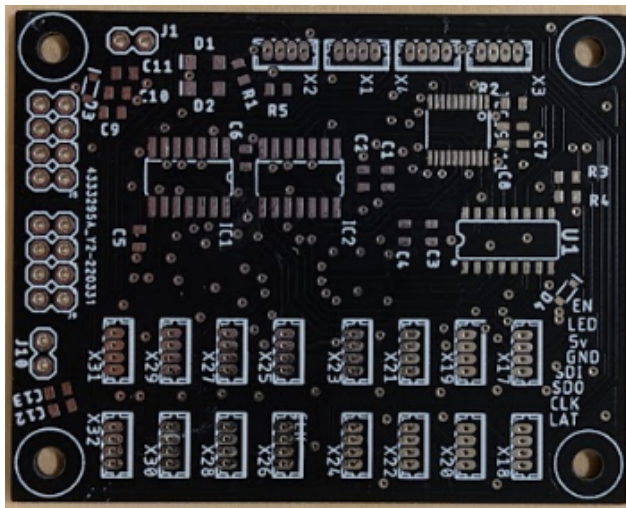


Figure 4.3a (left), Figure (4.3b): Top Board & TLC59711 Pin Layout

The LED driver is responsible for powering specific LEDs on or off on the panels. The driver is designed to deliver switchable constant current to 16 channels (Figure 4.4), which each correspond to 6 diodes in series on the LED panels. The inputs for this board are the control signals for the LED panels to follow and the power for the LEDs, hence the driver outputs to the panels instructions from the top board and power for one panel. Another IC we use on the LED driver is by STMicroelectronics(STP16DPP05) (see specification in Appendix A.). The device contains a 16-bit shift register and data latches, which converts serial input data into parallel output format. The brightness of the LEDs is determined by the serial data received from the top board and the OE pin can change the level from 0% through 100%. The IC has 16 output channels that each correspond to the subgrids on the LED panel. This allows arbitrary patterns of utilization of different sets of 6 LEDs of the 96 LEDs on each of the panels, which allows control of brightness in addition to changing the duty cycle of the LEDs.



Figure 4.4: LED Driver

4.2 Design Choice

As mentioned earlier, the new system uses 1070 nm LEDs rather than the 810 nm LEDs used previously. The old printed circuit board (PCB) design was intended to house 96 LEDs with 16 groups of 6 LEDs. Due to a larger profile, there are less 1070 nm LEDs per panel compared to that of last year's senior design, and clearly there is a need for a new PCB design. This year, we designed a panel that maintained the 16 channels that deliver constant current, with 8 subgroups of 4 LEDs per group, resulting in a total of 32 LEDs. Although this reduces the number of LEDs compared to last year by a third, the surface area covered remains the same with the new PCB boards. This design improvement allows us to compare favorably with the only other 1070 nm head-device available on the market, the Neuradiant 1070, which has a total of 240 LEDs covering the entire scalp surface.

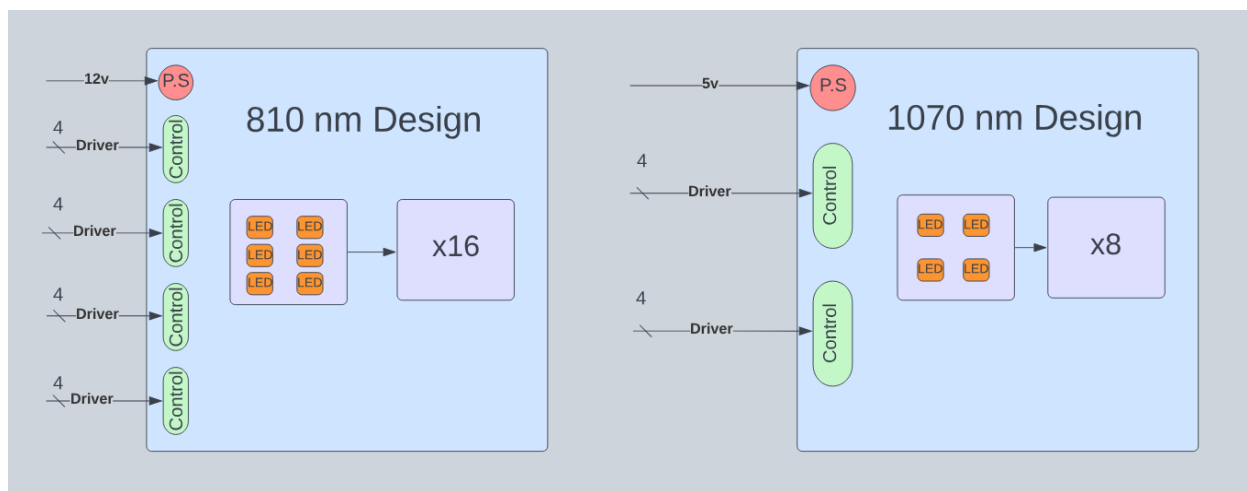


Figure 4.5: Block Diagram of Previous LED Panel (left) and New Design (right)

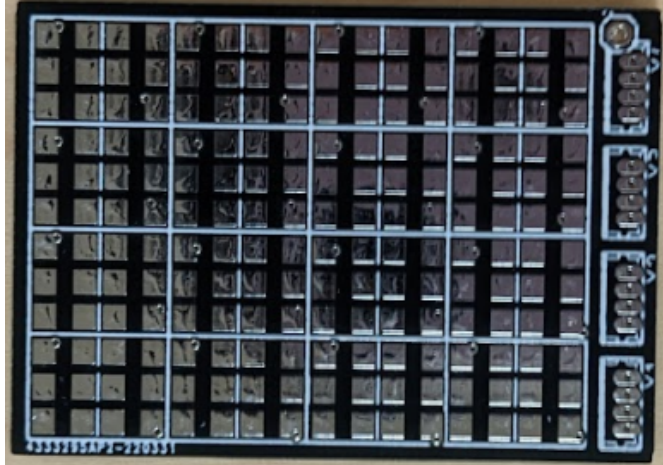


Figure 4.6: Previous LED Panel Design; 16 x 6 LED Array

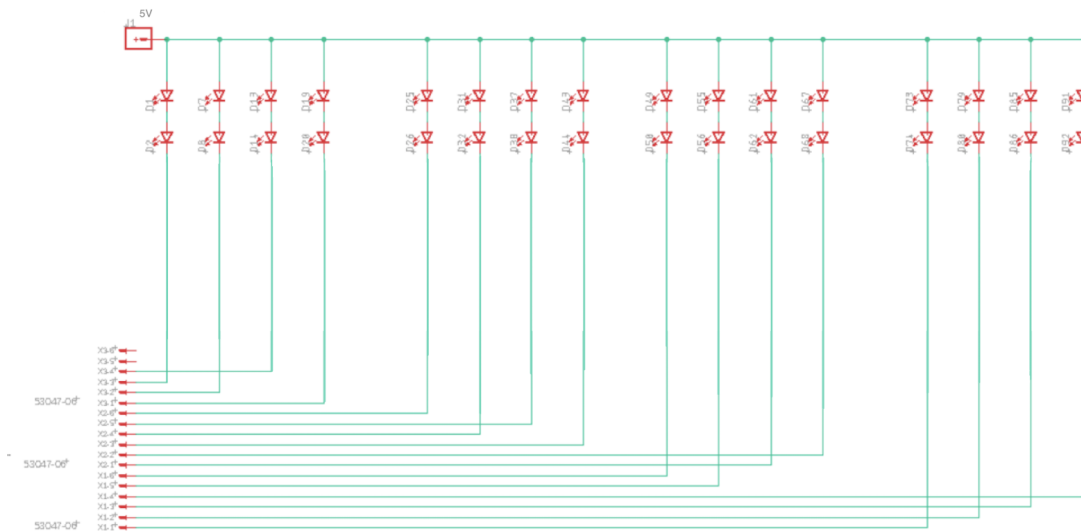


Figure 4.7: 1070 nm LED Panel Schematic

The new LEDs will be physically distributed differently but the control signals being sent down the boards will not have to change, and we may even be able to use one power supply, instead of the two we currently use. As mentioned above, we will be cutting the amount of groups in half as well as reducing the amount of LEDs per group, resulting in eight groups of four LEDs for a total of 32 LEDs, as shown in Figure 4.7. The panel size will likely remain the same, as the panels must fit properly on the head-device to be as close to the patient's head as possible. Also, with the amount of LEDs being reduced by a third, it also may be possible to power the LEDs

with the same 5v supply being used to power the hierarchy of boards. This way, we can avoid having two different supplies which would simplify the power system of the head-device.

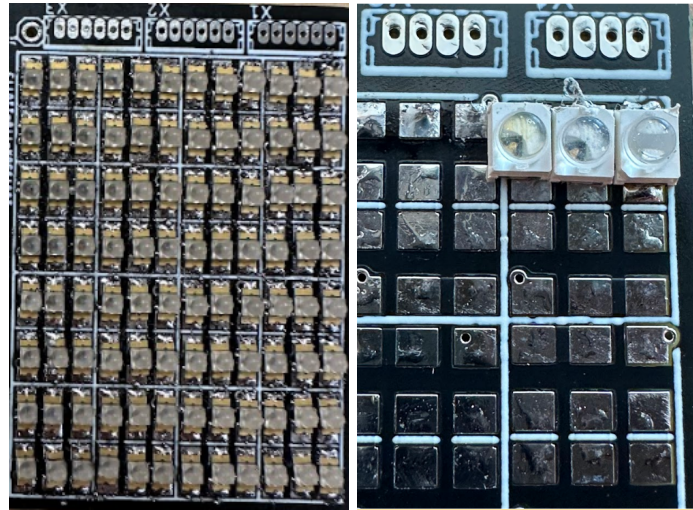


Figure 4.8: Old design with 810 nm LEDs(Left) & Attempted Installation of 1070 nm LEDs (Right)

Chapter 5: Subsystem 3: Control System

5.1 Overview of Subsystem

The control system portion of the project uses the specification of the parameters for the therapy session to specify and implement the sequencing of the on/off waveforms for all the LEDs. The input to the control system can come from an overall specification for the complete therapy session or from an interactive adaptive system that updates the specifications after short observation intervals. The global specification parameters are frequency and duration and the local LED group parameters are brightness and localization.

The control subsystem provides the connection between the software and hardware components of the prototype. As shown in Figure 5.1, the adaptive part of the control subsystem consists of the processing of raw EEG signals, feature extraction of the EEG signals, and specifying short term control parameters. The control interface connects communication of the LED panels to the arduino controller. We have discussed the EEG Subsystem and the light stimulation subsystems and the important next subsystem is the control subsystem as discussed previously has the ability

to specify the parameters of the stimulation. The control system gives control over these features through the control protocol panel depending on the EEG recordings. The end goal is to achieve a fully functional closed-loop system through the analysis of the EEG recordings along with the adjustment of duty cycle, intensity and frequency, and as mentioned in Chapter 4, having control of the individual panels found on the 1070 nm and 810 nm devices.

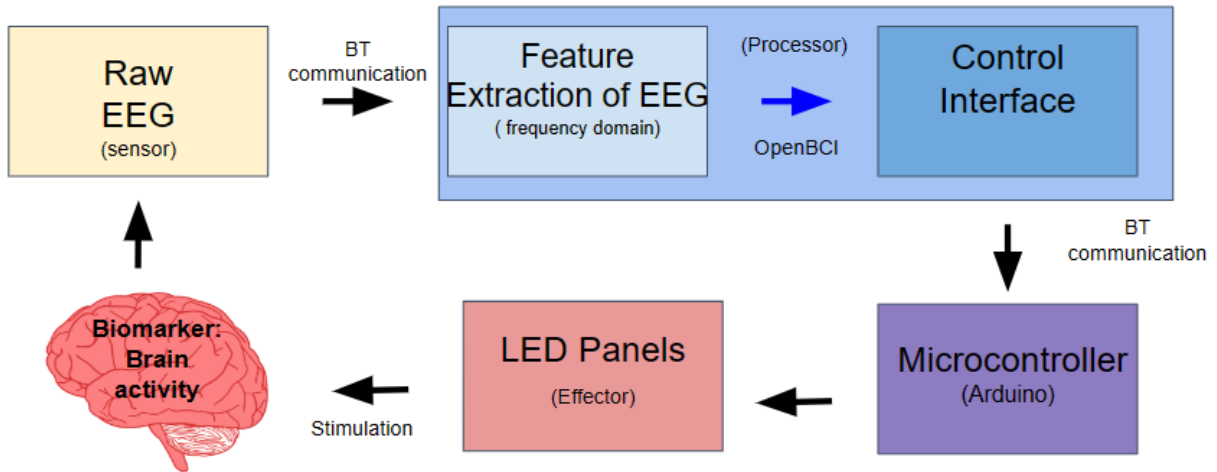


Figure 5.1: Closed-loop control system

Figure 5.1 depicts the closed-loop control system that Neurogen aims to achieve. As a quick overview the depiction of brain activity is collected using the electrode techniques described in Chapter 3. These raw recordings are sent to the OpenBCI Gui for analysis as they then go through analysis. In figure 5.1 the control system are the blue boxes titled “Feature Extraction of EEG” and “Control Interface”, both of which are necessary for the closed loop system. The feature extraction can be seen in Chapter 3 where it is mentioned that alpha band power is extracted from the raw EEG. After this is extracted on OpenBCI the goal is to display it on the control interface where it will be viewable for the current state of the power band. After this the control interface gives the ability to edit the light stimulation accordingly and for the changes to be sent to the Arduino Microcontroller.

5.2 Software Data Flow

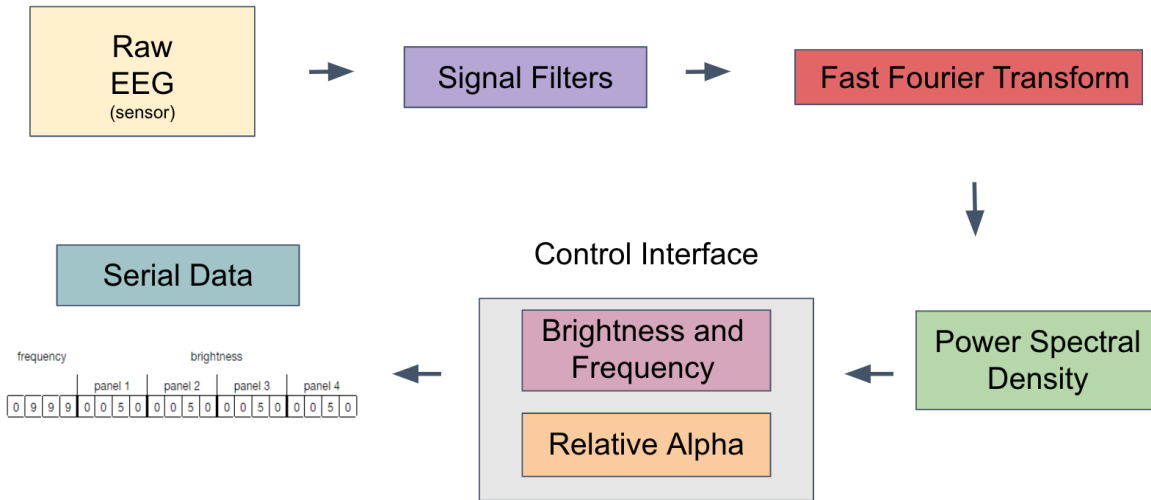


Figure 5.2: Software Data Flow

5.2.1 Preprocessing Filtration

Figure 5.2 shows the in depth data flow of the control system, the first section of the data flow is the collection and removal of noise from the raw EEG signals. Preprocessing is a crucial step in removing noise from artifacts such as blinking eyes and muscle movements that may interfere with viewing weaker brain waves. [28] These filters include the bandpass and notch filters. Bandpass and notch filters are those that allow only specific frequencies within a range and they reject any frequencies outside this range. They attenuate any signals within a specific frequency therefore allowing for artifact removal. The filtered data is input to an FFT for frequency domain analyses.

5.2.2 Power Spectral Density

The power spectral density is a measure of the power, over a sampling window, for each channel in specific biological frequency ranges. Relative alpha power is a measurement of the power relative to other frequencies. The calculation is performed by comparing the amplitude of alpha to the amplitude of the other brain waves.[29] For our project, we are focusing on the frequency range of alpha waves, as our performance metric relies on measuring the relative alpha power within the 8-12 Hz frequency range. This evaluation is conducted within the default time

window of 10 seconds provided by OpenBCI. Through the stimulation, this will increase in amplitude if the PBM pulsed at 10 Hz effectively stimulates the neurons. Another reason we selected alpha as the performance metric is that a decrease in alpha band power can be observed in patients with early stages of developing Alzheimer's disease. Thus this performance metric may serve as a clinical biomarker in future studies. With this analysis we are able to take the specific power band in the alpha frequency band.

5.2.3 Control Interface

The control interface portion of the OpenBCI pipeline is created using Processing 4 which is the program that we use to run the OpenBCI GUI, this control interface is the front end portion of the control system that allows the user to specify the parameters the light stimulation should be set to. The user interface is created with the ControlP5 GUI[30] libraries which contain features such as drop down menus, text boxes, and sliders. This allows more refined control of the features of the lights such as frequency, duration and intensity. The ControlP5 GUI libraries are compatible with Processing software and because we are using Processing to run OpenBCI it allows us to use these features on the OpenBCI GUI.

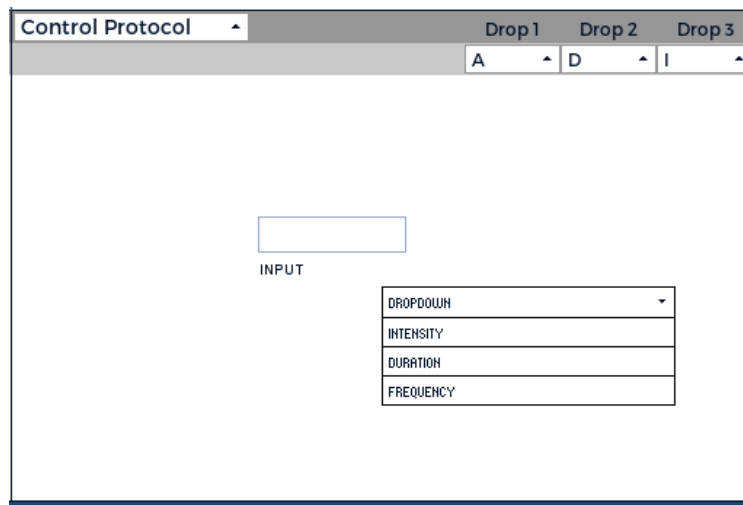


Figure 5.3: Rough Control Protocol

In Figure 5.3 we can see the Control protocol being implemented on the OpenBCI GUI. This gives the ability to send data to a networking feature on OpenBCI to communicate with the arduino controller on the board for control of the LEDs.

After this calculation is performed on OpenBCI it is displayed on the control interface, where we are able to have control over features such intensity and frequency. In the case of our project, we are stimulating at a pulse frequency of 10 Hz. If stimulation is effective, in the alpha frequency range, we would observe an increase in power due to the entrainment seen during neural stimulation. This change in alpha is our measure of how effective the stimulation is. The relative alpha values will be outputted on the control interface where there will be a panel selection feature. If the relative alpha values displayed are too low, there will be the ability to control the panel, the intensity, duration, and frequency. An example of the display can be seen in figure 5.3 where the “input” will be four boxes for the four panel control. As this relative alpha is being the message for changing any aspect of the stimulation will be sent as the stimulation is occurring. This message for change in the duty cycle is then passed on to the Arduino Controller through serial port in the data format found in 5.2.4 Data Transmission. We want to change the association between the feature of relative Alpha and the changes in the duty cycle. The decision to change the duty cycle is based on the observed Alpha power, or a derived feature of relative Alpha. The association between the Alpha power levels and the necessary adjustments to the duty cycle will allow us to dynamically adapt the stimulation parameters based on real-time measurements. An example of the format for change can be seen in figure 5.4. The figure shows the duty cycle (“brightness”) per panel is to be at 0050 this indicates that it is at a 50% duty cycle.

5.2.4 Data Transmission

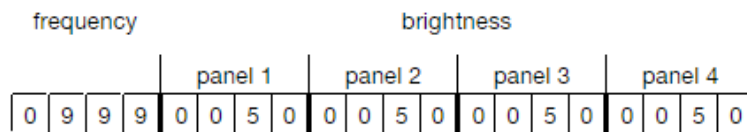


Figure 5.4: LED Panel Serial Communication

The data sent through the chain of boards from the Arduino to the LED panels is sent using serial communication, or more specifically the serial peripheral interface. The instruction sent to the

LED panels is intended to be able to control frequency and brightness over a certain duration. Currently the code can only turn on panels at a set frequency and brightness, which is achieved by using the TLC59711 PWM driver. Eventually, the goal would be to simultaneously change these parameters while the EEG takes measurements from the patient, as this will result in the best customized treatment for the patient.

It is important to note however, that even though a new LED panel design is required, this does not necessarily mean that the control signals we send downstream will have to change as well. Currently, the drivers are meant to output the message via four, four pin connectors, which can each individually access four groups of LEDs each, resulting in the total of 16 groups of LEDs being activated. In the new panel design, if we cut the amount of groups in half, then each panel would only require two, four pin connectors. This way, we can still utilize the code from last year to send the same control signals, as well as output these signals to a wider array of LED panels.

5.3 Implementation

Currently, the head-device operates using an open loop system, meaning that the user inputs the parameters for frequency, brightness, and duration, with the LED panels only responding when the user changes the instructions. As shown in the code above, the panels are turned on in the main loop, first setting the frequency to high (a preset value), then running the “on1” function which shifts bytes one bit at a time. This shifting is necessary to utilize the TLC59711 driver mentioned earlier. From this, we adjusted the byte values and drew out expected control signals which are shown in the diagrams below. As you can see, the data pin waveform is expected to match the bytes being shifted out.

```

void on1(void)
{
    digitalWrite(latchPin1, LOW);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);

    shiftOut(dataPin1, clockPin1, LSBFIRST, B00000000);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B00000000);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B00000000);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B00000000);
    digitalWrite(latchPin1, HIGH);
    delay(1);
}

```

Figure 5.6: Adjusted Byte Values

The new implementation of the closed loop system will still use the same parameters, but instead of the user inputting the instruction each time, the system will adapt based on the data received from the EEG. Despite the closed loop still being able to use the same parameters as the old implementation, it is important to note that the intervals for entrainment will inherently be shorter due to the device constantly updating itself. Again, the advantage of this will be that the treatment for the patient will be entirely customized based on their own EEG measurements.

Chapter 6: Testing

6.1 EEG Testing

6.1.1 Experimental Design Setup

We first tested the function of the EEG systems with standard protocols that produce reliable effects in the frequency domain. This ensures that our signal quality is good prior to any interference by additional components and for the ability to model the effects of the stimulation. We conducted tests using 3 different conditions for both before and after stimulation. Before recordings took place there were a few instructions that needed to be followed to receive clean EEG recordings:

The person would need to have the prototype fitted on their head and would need to clip the ear clip electrodes to their ear lobes. Each electrode position must be adjusted to optimize contact

with the scalp to prevent railing issues or inaccurate recordings.

The subject would also be required to stay seated with both feet planted on the ground and there was to be minimal to no movement during the recordings to prevent the possibility of noise.

Our recordings consisted of an eyes closed test, in which the subject would close their eyes and the EEG was recorded for 30 seconds making sure that there was relaxation. The next procedure is the eyes open test which requires the subject to remain with their eyes open for a total of 30 seconds. They were of course allowed to blink and look ahead without entirely concentrating on anything in specific. This was harder to control due to the nature of getting distracted within the lab. The last test performed was a reading test. The reading consisted of an article of medium difficulty reading that the subject would read as they simultaneously would be getting EEG recordings. This was also performed for a total of 30 seconds.

To reiterate, our pre and post stimulation data recordings will follow this format:

Table 2: Pre And Post Stimulation Testing Plan	
Test	Duration in Seconds
Eyes Closed	30
Eyes Open	30
Reading Medium Difficulty Text	30

For preliminary recordings, we decided to utilize the Neuradiant 1070 device which contains 1070 nm LEDs and is the commercial version of our prototypes without the feedback implementation of electrodes. With this device, we decided to work within the clinical protocol settings of this device. It has been previously shown that 6 minutes of exposure at a 10 Hz pulse rate allows one to actually view any results occurring with the photobiomodulation [9]. The protocol settings that we used were a 75 % duty cycle with a 10 Hz pulse rate. The device could either select full head coverage or only partial. We decided to select full coverage of the LEDs to

test the function of our EEG. The time of exposure selected for the trial was 6 minutes and during this time, the subject would need to keep the device on to receive this dosage.

After the stimulation, there was a delay of about 2 minutes between exposure to the stimulation and the recordings being taken. It is not clear if this delay would affect the recordings as it has not been specified how long the effects of the photobiomodulation last. For post-stimulation, the same three tests as above were performed. These are 30 seconds of eyes closed, 30 seconds of eyes open, and 30 seconds of reading.

6.1.2 EEG Results

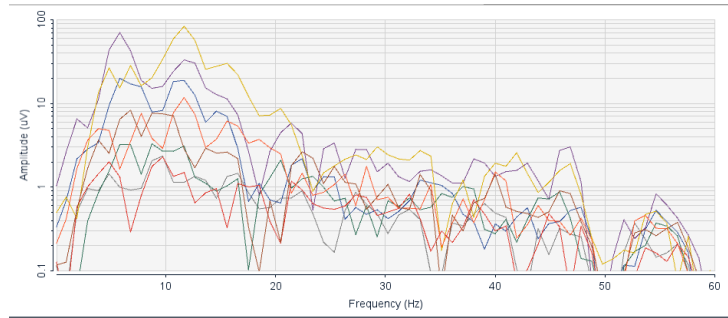


Figure 6.1: Post Stimulation EC FFT

Figure 6.1 is an example of a real time screenshot of how the FFT data looked after stimulation had occurred, we see peaks at 10 Hz for many of the channels but we also see high amplitudes at other frequencies as well. Overall, the EEG data exhibits very scattered and inconsistent patterns between each channel. For this reason, we believe that this could be because of poor contact between EEG electrodes and the scalp while using the Mark IV head set. To further investigate this issue we decided to run another experiment with just a single electrode on the 1070 nm device. As of now, the device only has the EEG installed and theoretically should not have other sources for noise or interference.

Figure 6.2 illustrates the FFT plot obtained using the second prototype, which also occurred after 6 minutes of stimulation from the Neuradiant 1070. This new setup allowed us to move beyond the benchtop stage and capture a live EEG recording. The recording displayed higher amplitudes at lower frequencies, gradually decreasing as frequencies increased, resembling a typical EEG

pattern. However, during the testing of the 1070 nm device, we encountered a significant challenge with "railing" in the EEG channels, despite adjusting the gain settings. Consequently, only one channel is displayed in the figure.

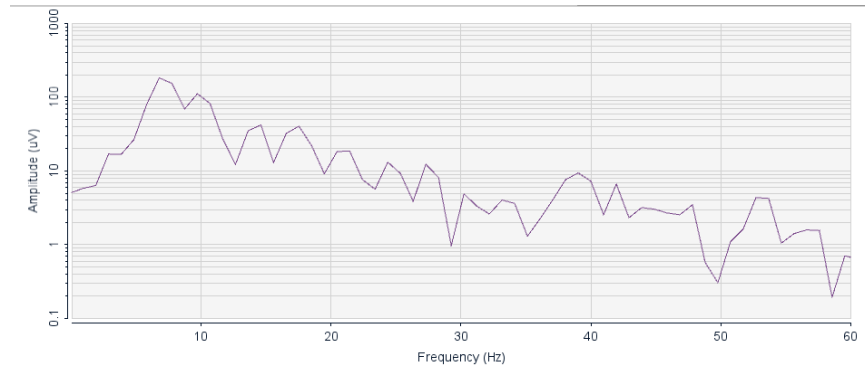


Figure 6.2: Single EEG Test Post Stimulation

6.1.3 Offline Analysis

After acquiring EEG data using OpenBCI, we can employ external analysis software to further investigate and interpret the data. One such software is EEGLAB, an interactive program available within the Matlab toolbox. With the EEGLAB GUI, users can access a range of features for processing continuous and event-related EEG, MEG, and other electrophysiological data. These features include independent component analysis (ICA), time/frequency analysis, artifact rejection, event-related statistics, and various visualization modes. By utilizing EEGLAB, we can visualize the FFT graphs similar to those observed in OpenBCI and perform further analysis, such as power spectral density (PSD) analysis.

The process of EEGLab Analysis involves importing the EEG data as a numeric array and appropriately transposing it to meet the required data format. Subsequently, the channel locations for each dataset are specified, and this information can be saved as a .ced file for future use. Channel locations are crucial for spectral map analysis and accurate labeling. Following that, the data needs to have its baseline drift removed for cleaner data and be filtered within a bandpass range of 0.5 Hz to 50 Hz to eliminate electrical interference occurring at 50-60 Hz, which originates from the alternating current (AC) present in electrical devices.

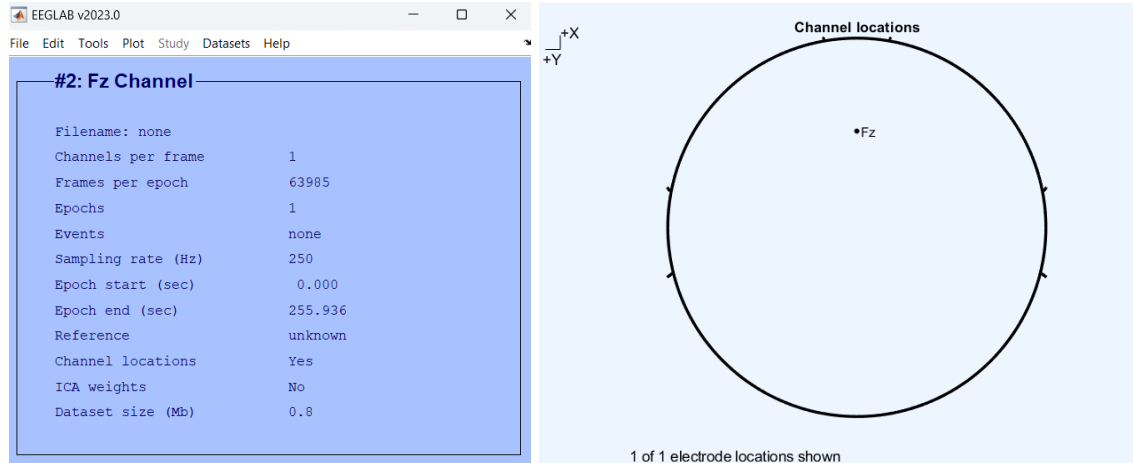


Figure 6.3: EEG Lab Setup

In Figure 6.3, we present the EEGLAB GUI along with the channel location set used for the single EEG test conducted previously, this test captured EEG data from the Fz channel. Although the dataset collected spans 255 seconds, the analysis can be performed on any desired time segment. After applying filtering techniques and removing the baseline artifacts from the data, we proceeded to analyze the average Log Power Spectral density over a 50-second interval, as depicted in Figure 6.4.

Upon analyzing the results, we observed that the data did not exhibit peaks exactly at 10 Hz, as initially anticipated. Instead, the peaks appeared around 8 Hz, which aligns with the findings from the FFT plot displayed in Figure 6.2. It is important to note that these observed peaks still fall within the frequency range associated with the Alpha band, typically spanning from 8 Hz to 12 Hz.

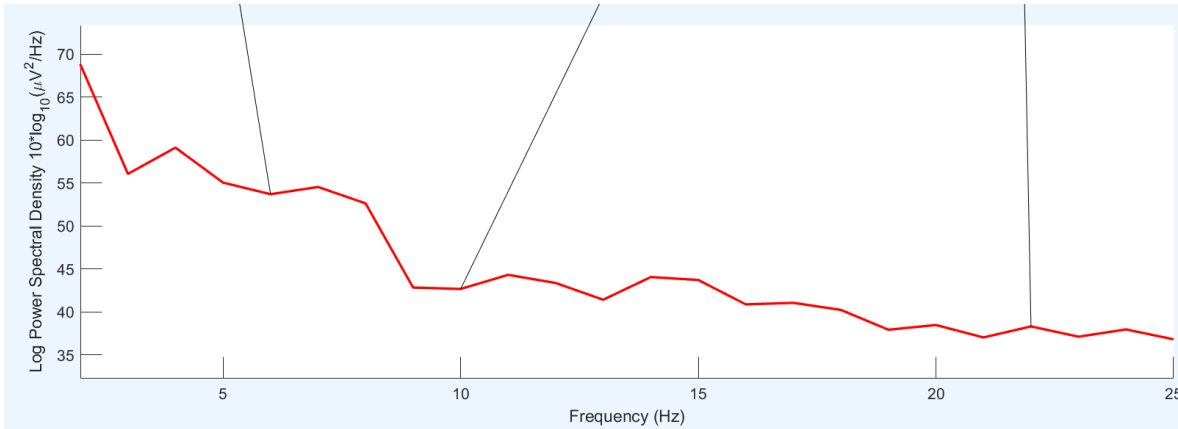


Figure 6.4: Log Power Spectral Density of Single EEG Test

6.2 LED Testing

In order to verify the signals being sent from the Arduino to the top board, oscilloscope readings were taken to observe the waveforms generated by the code.

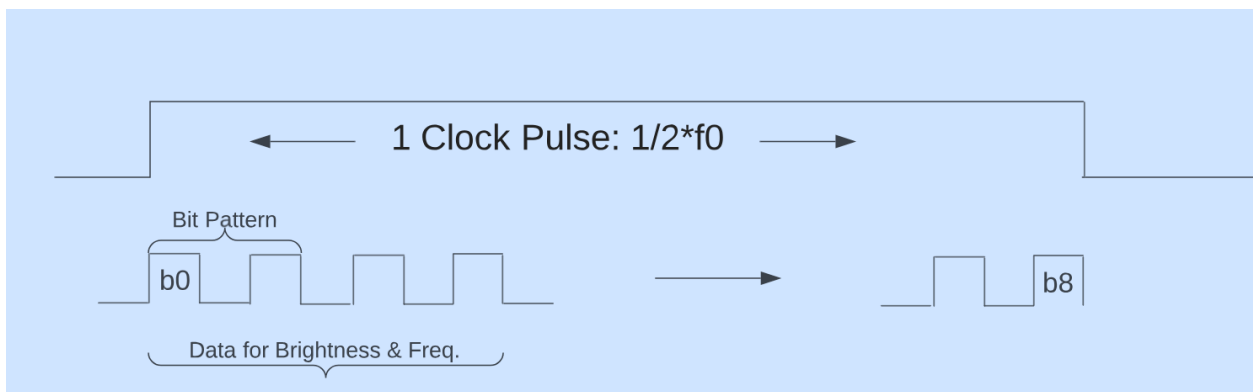


Figure 6.5: Expected Data Pattern Waveform Example

The “on” function in the code turns on the LEDs by writing to the pulse pin (responsible for the frequency parameter), which is either set to high or low, but later on can hopefully be changed more dynamically. Then the function uses the “shiftout” command in order to shift out 8 bytes with the hex values of B11111111. In Figure 6.5 above, the expected data pattern during the clock signal is shown. The code then runs this function until updated to do otherwise. For the purpose of oscilloscope testing, we adjusted the byte values in order to see a defined pattern in the waveform, and after the data values were sent out, we set the pulse pin to low in order to see when the bytes finished shifting out.

```

void on1(void)
{
    digitalWrite(latchPin1, LOW);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);

    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    shiftOut(dataPin1, clockPin1, LSBFIRST, B11111111);
    digitalWrite(latchPin1, HIGH);
    delay(1);
}

```

Figure 6.6: Original Code for Instructions Sent to Arduino

The trigger on the oscilloscope was set to the rising edge of the pulse pin, which is the first yellow waveform shown at the top of the screen. The time scale is at 200 picoseconds per division. We expected to see a range of eight values over the time it takes the pulse pin to go from high to low. Hence, the most important waveform to observe was the blue line, which represented the data pin from the code, which shifts out eight bits. The green signal is the latch pin which is set to low before all bits are shifted out, and then set to high once all eight bits are shifted out. Following that, the red pin represents the clock pin which is toggled each time the bit is set to the correct values. With this we were able to confirm that the message being sent aligned with what was written in the code, however, we did notice that there is a slight microsecond delay, which can be found more specifically through the use of the `micros` command in the Arduino libraries.



Figure 6.7a (left), Figure 6.7b (right): Unadjusted Code Waveforms & Adjusted Code Waveform

Additionally, testing further downstream for the purpose of continuing this project will prove useful for verifying the control signals being sent across the boards. That is, after the arduino sends the message to the top board, we should expect to see a message being passed from the top board to the LED drivers. In order to test this, specific wires from the four pin connectors that bridge the top board to the drivers will have to be spliced and observed through the oscilloscope.

6.3 Summary of Results

Figures 6.1 and 6.4 both revealed that we were able to successfully capture quality EEG data from at least one channel. The data shows peaks in amplitude and PSD at 8 Hz, which still falls within the 8-12 Hz alpha frequency range. The reason we might see the peak at 8 Hz is because of variability within users, some might have peaks at 8 Hz and others might have it at 13 Hz. It was important for us to observe some peak at that frequency to show that we were able to get good EEG data in the new device.

The offline analysis of EEG data in Figure 6.4 revealed issues related to calibration or accuracy of the EEG readings seen in the railing of the other seven electrodes. We suspect that these data inaccuracies stem from poor contact between the electrodes and the scalp, possibly due to the ill-fitting frame of the Mark IV device on the subject's head. When attaching the electrodes, it is necessary to tighten them until contact is established. However, if one electrode is tightened too

much, it can displace the other electrodes, making the fitting process challenging. Therefore, it may be necessary to consider redesigning the head frame of the device to address this issue.

Additionally, other potential sources of error include electrical interference from the environment, inadequate signal amplification and filtering, errors in data analysis, or potential calibration issues with the equipment.

From the oscilloscope readings, we can see that the signals being sent out are indeed matching what is written in the code, the only problem being the microsecond delay. The signals however, are not as important as the new PCB design, where we are choosing to use 32, 1070 nm LEDs instead of the original 96. This will still yield a higher amount of LEDs than that of the Neuradiant 1070, as it uses 240 total LEDs, but our design will eventually have at least 320, with a minimum of 10 panels on the device.

Chapter 7: Cost Analysis

As outlined in Chapter 2, a budget of \$235.21 was allocated to the project for the current year. However, the total cost of the prototypes exceeded the initially requested budget. This includes significant expenses incurred in the previous year, such as the acquisition of Cyton Boards, while a substantial portion of this year's budget was allocated towards additional wires and electrical components. The comprehensive cost of the two prototypes amounts to \$8,784.92, as detailed in Appendix C. It is important to note that this cost encompasses all the parts utilized in the current design, excluding any purchases for fans and any LEDs that were not incorporated into the design.

Additionally, this sum includes the cost of purchasing a Neuradiant 1070 PLUS which was used for testing and possibly future senior design projects and normally costs \$4,999.00 however, it was discounted to about \$4,000 without the 3 month consultation. Regarding the LED count, even though one thousand 810 nm LEDs were purchased and one thousand 1070 nm LEDs were donated, only 384 and 128 LEDs, respectively, were accounted for in the final design. This discrepancy arises from the actual number of LEDs integrated into the prototypes.

Thanks to the resources allocated by Santa Clara University, expenses regarding 3-D printing, acquiring project space, and tools needed for the project were covered and were at no additional cost.

7.1 Budget Constraints

Regrettably, the need for additional materials was not adequately accounted for, resulting in the complete utilization of the budget provided by the School of Engineering. Initially, the team mistakenly assumed that each ThinkPulse™ Active Electrode Kit would include a pair of electrode clips. Consequently, emergency funds were used to separately purchase these clips. Furthermore, there was an erroneous belief that additional spiky electrode ends were available, enabling each prototype to have an electrode configuration of 8 spiky electrodes centered on the top of the head at F3 and F4, rather than Fz and Fzp. Lastly, the team did not have the option of ordering more printed circuit boards as doing so would have exceeded our allocated budget. This is significant because it means that our team was only able to design the new 1070 nm LED panel but not able to order it.

Chapter 8: Professional Engineering Standards and Realistic Constraints

8.1 Health And Safety Concerns

Neurogen involves components such as EEG analysis and near-infrared light stimulation which are both methods of non-invasive analysis and simulation. With this comes the need for an analysis of the health and safety of the device. There are potential issues and concerns for neural modulation, heat safety of the device, and component invasiveness. These concerns are important to address as they relate to the effectiveness and safety of the device, especially during the prototyping phase.

The use of an EEG for recording has been proven to be fairly safe in terms of usage as they do not produce any sort of energy and are only used to capture electrical activity. [30] The dry comb electrodes provide us with the ability to non-surgically and non-invasively read electrical brain activity. They can easily pass through the hair and make contact with the scalp, eliminating the

need for a more invasive procedure and minimizing any discomfort associated with it. There are other methods of EEG that are not at surface level and require the insertion of electrodes through surgical procedures. The comb electrodes are surface level and give a good analysis of the brain activity through the contact on the scalp.

Photobiomodulation is a therapy that has been used for treatment of various diseases and conditions. The use of light for therapy has been explored before [9] and this offers a rather safe alternative to more invasive methods used for neurodegenerative disorders. One of these is the use of deep brain stimulation devices which are highly invasive and produce electrical impulses to control the abnormal brain activity[32]. These devices require a surgical procedure which increases the risk of infection and complications. Comparing this device to PBM methods, a considerable difference and why PBM would be a safer alternative is that these invasive methods stimulate using irreversible stimuli, electrical stimulation, while PBM functions by causing metabolic changes through neuron excitability

8.2 Ethics of Brainwave storage

OpenBCI is an open source platform which in the case of our project is used to capture, record, and analyze the brainwaves of the subjects that have used NeuroGen for the analysis of the brainwave activity. The storage of this brain activity is on the device being used for the EEG analysis. Although this is stored on a PC found in the Healthcare Innovation and Design with access limited to the users, it is important to note that if the device were to be used for clinical trials it would require a device with password encryption among other methods of security to ensure the safety and privacy of the users. Brain activity is health related data and must be privately and securely stored especially since the brain activity is also captured using wireless connection. [33]

According to The Belmont Report, there is a guide to ethical considerations when it comes to conducting biomedical or behavioral research. The summary of this is the three basic principles of ethics: the respect of persons, beneficence, and justice. [34] Respect of persons is when the person in the study is treated as a being with the ability to govern themselves and that those with

limited autonomy are entitled to protection. The second is beneficence which is making sure to not harm, and if there is to be some harm done make sure the benefits are maximized and the harm done is as minimized as possible. The last is justice which is related to picking subjects based on their relation to the research and not just because of their position or easy manipulation.

Using these three basic principles, we can see how the ethical standards of brainwave and neuromodulation follow these and provide a good sense of ethical considerations. Following the five neurorights it is possible to adhere to the respect of persons as the neurorights provide guidelines to allow subjects to have autonomy over their brain health. Beneficence is an ethical consideration that is important as PBM therapies and EEG recordings do not cause significant harm that must be outweighed, the benefits of studies in this area are far greater than the harm produced. The subject pool for this device is specific in the sense that it is targeted for individuals with neurodegenerative diseases, picking subjects should be randomized from the group that meets the specific criteria.

Considering how photobiomodulation is a relatively new technology, there are safety concerns of the device as it is considered a class II device which means that this device must be within regulation to be approved by the FDA. Most PBM devices are already FDA approved but transcranial PBM has not yet reached FDA approval. There's also the concern of privacy, and where EEG data would be stored during treatment and whether this is shared to outside data servers. It is important to discuss these ethical considerations for the device as it is a technology that uses health data and neural modulation.

8.2.1 Neurorights

Neurorights [35] are a new topic concerning the individual's rights to their own brain wave data output and control of any modulating input. They are a set of rules and guidelines to protect human rights as the use of neurotechnology is emerging and there needs to be a way of protecting human brain activity. This campaign is fairly recent and is an important one as the emergence of neurotechnology keeps increasing. NeuroGen uses neural modulation and the collection of brain activity to perform the necessary tasks therefore it is important to look into the

five neurorights that have been established. The five neurorights are: neural privacy, personal identity, free will, fair access to mental augmentation, and protection from bias.

Neural privacy is how the storage of brain recordings is handled. This can be from how safe the network in which the recordings are collected is and how easy it is for the subject to request the information to be deleted. The storage of brain recordings on a computer at school may need to have added security. If this device is used in clinical settings there should be access to an encrypted network for the storage of these brain waves. Brain recordings are personal and count as health data meaning that HIPAA laws must be followed in order to get permission to use and share this data. An important consideration when it comes to clinical trials is how it is possible to use brain activity and not have it be traceable for an anonymous study.

Personal identity is the importance of separation between the self and the technology. What is meant by this is that there must be boundaries in place so that the neurotechnology does not interfere with the sense of self of the person who is using the technology. A closed-loop device with a self-adjusting protocol would make this separation harder as there would be a heavy reliance on the device for duty cycle changes. The automated changes would be regulated by the ability to add a control interface portion of the control system. This means that the subject would have the ability to change the features of light stimulation without having to solely rely on the device to self regulate. Personal identity and free will work hand in hand in our case because Neurogen plans on having a closed loop system that would mean the input of an outer modulation would be eliminated. This is why free will is another important neuroright relating to our project because this concept means that the individual should have access to their own decision-making without the input of neurotechnology. The patient should have full control over any sort of neural technology, this goes hand in hand with the neuroright of personal identity. The addition of a user interface guided by the EEG recordings could allow for this to occur as mentioned previously. In our case, a closed loop system would push out the consumer from making decisions in their treatment plan if it is automatically modulated by a closed loop system. Additionally, it is important to note that the target consumer of this product would be persons

with neurodegenerative conditions that might not be capable of making these decisions themselves.

The fair access to mental augmentation means that there should be guidelines relating to technology that mentally alters. The access to this technology must be available for all and cannot be exclusive. This means that the device end goal should be that it can be used and accessed by the intended population. Photobiomodulation technologies should be available for access and should not be for only a select few. The regulations necessary for this technology are that this device should be affordable and that clinical trials be with the group that is needed with subjects picked at random. The fifth neuroright is protection from bias which is important especially to keeping a fairly accessible device and a just subject pool. Protection from bias discusses the importance of when using algorithms there should be guidelines to make sure biases do not interfere with performance. We aren't using an algorithm as of right now, so this is not as relevant but it is important to keep in mind for future iterations or advances.

8.2.2 Lack of Ethical Language

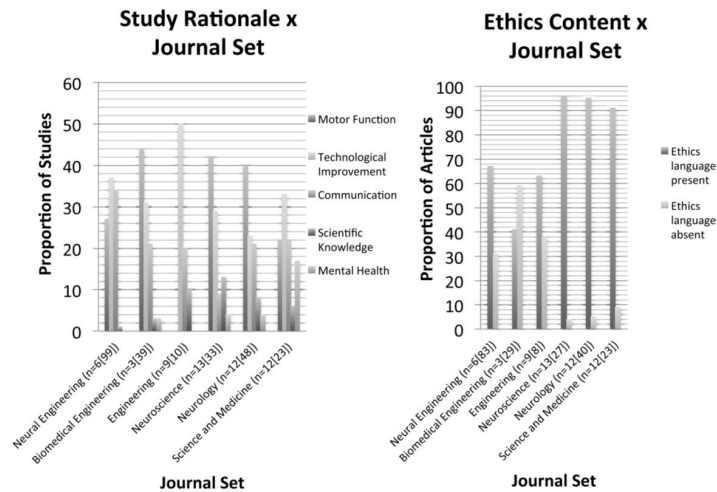


Figure 8.1: Analysis of Journals and the Use of Ethics

Figure 8.1 displays the use of ethics in academic reports when comparing fields such as engineering to neuroscience. When it comes to studies within biomedical engineering,

engineering, and neural engineering there is a significant lack of ethics language in these fields, with more articles not containing ethics language than those that have language present in biomedical engineering [36]. The lack of ethics language in academia has posed an issue due to the fact that this can lead to not enough analysis of the technology. Articles that talk of neural engineering and its advancements only briefly state how ethics plays a role in the technology but even fewer go in depth when it comes to ethics in BCI applications. A lack of exposure can lead into future advancements not having any knowledge of the ethics and then not working towards a better more ethical approach. Lack of ethical discussion makes it difficult to have an indepth analysis of neurotechnology and it's potential dangers.

8.3 Civic Engagement and Compliance

In the United States, medical devices are regulated by the Food and Drug Administration (FDA) to ensure all devices meet the necessary regulatory requirements to guarantee safety and effectiveness to the public. The FDA classifies these medical devices into different classes based on their level of risk. As most PBM devices, our headpiece would be classified as a Class II medical device, a category reserved for devices that pose low to moderate levels of risk. In order to attain this clearance, our device would require a 510(k) submission to the FDA. [37] This submission is a premarket notification that would demonstrate our device's substantial equivalence to an already legally marketed device that has already attained FDA clearance.

Should future iterations of this device seek FDA approval, it is important to prioritize compliance with regulatory standards and familiarity with the FDA's 510(k) submission process. This entails compiling a comprehensive application with detailed information about the device's intended use, technical specifications, performance data, and supporting clinical studies or literature. Further, it would be beneficial to engage with industry experts such as healthcare professionals and other regulatory bodies to gather feedback, address concerns, and ensure adequate device performance as it is the manufacturer's responsibility to understand and fulfill all regulatory requirements.

It is worth noting that regulations and requirements may vary in different countries, so marketing

this device outside the U.S. would require additional understanding and compliance with the specific regulations of each target market.

8.4 Sustainability as a Constraint

In line with the growing emphasis on sustainable biotechnology, sustainable technologies such as bio-wearables, paper assays, and microfluidics are gaining favor among sustainability advocates. However, it is important to acknowledge that our device, while aiming for reusability, incorporates materials that are not sustainable, including 3D-printed plastics. During the device manufacturing process, waste is generated when 3D printing orders fail or when obsolete plastic prints, as well as associated bases and supports, are discarded. Additionally, waste was generated when attempting to solder 1070 nm LEDs onto the 810 nm panels before deciding to design new panels, resulting in unused LEDs. Furthermore, the power consumption of the device raises concerns regarding its energy efficiency, particularly with active EEG electrodes and four panels of LEDs operating simultaneously.

In efforts to make our design more sustainable, we made the following changes: First we use PLA instead of ABS and HIPS as our 3-D print material. PLA (polylactic acid) is a 3-D print material available at the SCU MakerLab that is biodegradable and compostable thermoplastic derived from renewable resources such as corn starch or sugarcane. Second, we lowered the power efficiency of the device by using less LEDs in the new 1070 nm design and opting not to use DC fans.

8.5 Usability

It is important to consider the user-friendliness of the device, especially since our intended clients are individuals with neurodegenerative conditions. Currently, there are several challenges in this regard. For instance, the process of tightening the electrodes onto the user's head can be difficult to do independently. Moreover, the current user interface (UI) of the system lacks robustness and requires technical knowledge of the device to effectively operate it in its open-loop stage. Additionally, utilizing the EEG functionality necessitates access to a computer with the OpenBCI program and a reliable processor, which may not be readily available or easily

set up by every user. Although there is a need to automate many of the software components, certain setup steps and software requirements for EEG would remain unchanged. To address these challenges, it may be beneficial to explore the possibility of designing a new headset subsystem that simplifies the fitting process of the device, thereby enhancing its usability.

Chapter 9: Summary and Conclusions

9.1 Summary of Project

Neurogen is a hybrid EEG-PBM device that has the ability to be continued for future years. The device consists of three different subsystems discussed in the previous sections: EEG subsystem, light stimulation subsystem, and control subsystem. These subsystems work together to provide a functioning device for the target audience, those with neurodegenerative diseases. PBM has been used to treat neurodegenerative diseases with different mechanisms depending on the wavelength of near-infrared light. It is important to note that the team was able to collect EEG recordings from both the 810 nm and 1070 nm devices over extended periods of time. The team has also come up with a feature calculation to extract the alpha power band as is needed for the closed-loop system. There has also been progress on the addition of the control interface as this was not added on the OpenBCI GUI last year. Neurogen's end goal is to use EEG and PBM as a source of a closed-loop system for clinical analysis.

This year, we were also able to design a new LED panel for the 1070 nm LEDs, while maintaining the same software structure last year intended for the control system. With the new panel design, we can also potentially have a simpler power system, as the current supply is difficult to constantly keep attached to the head-device. The software structure is being kept, however, the code to adjust frequency and to access specific groups on the LED panels must be written in order to maximize the efficiency of the closed loop system. We were able to take measurements on the control signals being passed through the hierarchy of boards for the current code, but when new instructions are written these tests may be necessary once more.

9.2 Future Steps

With the progression of this year's team it is important to continue to work on NeuroGen as it is a device that would expand clinical trial analysis. Receiving the 1070 nm donation also allowed us to further expand on the device by allowing us to start the 1070 nm prototype which as discussed before provides a deeper stimulation that can be observed on the OpenBCI interface.

Eventually, we would like to implement an easy way to communicate from the PC to the headset, using the nRF24L01+ module. This module would allow us to use radio communication from the PC to the headset; meaning the instruction being sent downstream can be sent without plugging into the Arduino on the head-device each time. This would require another Arduino attached to the PC, as there needs to be two radio modules in order to communicate wirelessly. Eventually, this would allow us to send back information from the Arduino to the PC, where the information would contain EEG measurements. These measurements would then be equivalent to some updated set of instructions for the LED panels, closing the loop between the EEG and light stimulation.

Along with this, we were given one thousand 1070 nm LEDs this year, which unfortunately were not implemented this year, due to the PCB design not being able to properly hold the LEDs. The new intended PCB design will be necessary to create next year, in order to research the most effective wavelength for light stimulation. On top of creating new panels, adjusting the code to change the frequency and localization parameters for these panels will be necessary, as the current code can only turn all LEDs on.

9.3 Lessons Learned

The most important lesson learned from working on the project this year was communication between team members as well as documentation for future work on the project. Communication between team members was difficult at times, however, the obstacles and struggles throughout this project have taught us valuable lessons for our future when working on a team with professionals. The documentation issue we encountered made it difficult to progress as much as

we would have wanted to, but it taught us this year to document all progress, no matter how small or insignificant the information seems.

Throughout this project we also learned valuable skills working with OpenBCI, Processing, and various Arduino libraries. We have learned how to change the user interface with processing, and how to access specific drivers and ICs on the hierarchy of boards for the light stimulation system. We also learned when struggling with developing these skills, there are lots of great forums and tutorials easily accessible for us to take advantage of when needing assistance.

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Appendix A IC Specifications

“STP16CPC26.” *STP16CPC26 Low Voltage 16-Bit Constant Current LED Sink Driver*,
https://drive.google.com/file/d/1pMeahK6Vbql2inx-Q3KNhGFhCBQhfrf/view?usp=drive_link

“STP16DPP05.” *STP16DPP05 Low voltage 16-bit constant current LED sink driver with output error detection*, www.st.com/en/power-management/stp16dpp05.html.

https://drive.google.com/file/d/1myCAnGKm2Vu3ddiCKnYuNLhyDJCTjO0S/view?usp=drive_link

“TLC5971.” *TLC5971 Data Sheet, Product Information and Support | TI.Com*,
www.ti.com/product/TLC5971.

https://drive.google.com/file/d/1gmQrKV3SL0MvuDgRMmC0eMFH68F2UYC/view?usp=drive_link

Appendix B LED Specifications

810 nm specifications:

https://drive.google.com/file/d/1upo146cSQTtY1DDKSf0bODKPemL6s5Lk/view?usp=drive_link

1070 nm specifications:

https://drive.google.com/file/d/1lzTeko3wYcXTcKrvkU81EVWR4Cqpd3Vy/view?usp=drive_link

Appendix C Project Cost Breakdown

Total Project Cost				
Item	Number of Items	Manufacturer	Cost Per Item	Cost (+Tax & Shipping*)
12-Channel 16-bit PWM LED Driver	3	Adafruit	\$7.50	\$30.43
1.25mm Pitch 4-pin Cable	70	Adafruit	\$0.86	\$65.62
lipo battery	2	Adafruit	\$12.50	\$27.25
USB Lilon/LiPoly charger - v2	1	Adafruit	\$5.95	\$6.49
Heatsink Set	1	Amazon	\$14.99	\$16.34
M3x6mm screw	1	Amazon	\$7.99	\$8.71
Female Press in Thread 3M	1	Amazon	\$7.99	\$8.71
Allen Key 2mm	1	Amazon	\$5.99	\$6.53
SML-S13RTT86	384	DigiKey	\$0.32	\$139.67
Hair dresser waist belt	1	Amazon	\$13.49	\$14.70
Portable Charger 3880mAh	1	Amazon	\$28.75	\$31.34
TalentCell Rechargeable 12V	1	Amazon	\$27.99	\$30.51
XINGYHENG 30Pin Wire	1	Amazon	\$13.99	\$15.25
Hook up Wire Kit 26 Gauge	2	Amazon	\$15.88	\$34.62
Gorilla Epoxy Glue	1	Amazon	\$14.39	\$15.69
Ultracortex "Mark IV" EEG Headset	1	OpenBCI	\$499.99	\$554.98
Circuit Boards	1	Custom	\$120.00	\$130.80
LED driver STP16DP05PTR	10	DigiKey	\$2.18	\$30.75
LED driver STP16DPP05MTR	15	DigiKey	\$2.31	\$37.77
AND Gate 74LVC08AS14-13	20	DigiKey	\$0.31	\$6.78
Shift Register74HCT595S16-13	20	DigiKey	\$0.37	\$8.04
4pin 1.25mm WM1733-ND	70	DigiKey	\$0.28	\$20.98
4pin 1.25mm WM1744-ND	60	DigiKey	\$0.39	\$25.18
Cyton Biosensing Boards	2	OpenBCI	\$999.00	\$2,187.81
Earclip Electrode	2	OpenBCI	\$64.99	\$151.67
ThinkPulse™ Active Electrode Kit	2	OpenBCI	\$349.99	\$762.98
ThinkPulse™ Active Upgrade Kit	1	OpenBCI	\$69.99	\$76.29
Octabolt - White, Long	1	Shapeways	\$48.39	\$52.75
Octabolt - White, Small	1	Shapeways	\$27.80	\$30.30
1070 nm NIR LED	128	Quiet Mind	\$2.00	\$256.00
Neuradiant 1070 PLUS -Consultation	1	Quiet Mind	\$4,000.00	\$4,000.00
*Items bought in Bulk, Shipping is counted once		Total Cost		\$8,784.92










Signature for Inter Thesis- NeuroGen: EEG and Near-Infrared Light Stimulation Control System

Final Audit Report

2023-06-20

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By:	Jean Tsai (ctsai2@scu.edu)
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Transaction ID:	CBJCHBCAABAA73e_TysDFiuE9aGka8N780MQxQGpmuKq

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-  Signer ukim@scu.edu entered name at signing as Unyoung Kim
2023-06-20 - 10:03:57 PM GMT
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-  Agreement completed.
2023-06-20 - 10:03:59 PM GMT