SANTA CLARA UNIVERSITY

DEPARTMENT OF BIOENGINEERING

DEPARTMENT OF ELECTRICAL ENGINEERING

I HEREBY RECOMMEND THAT THE THESIS PREPARED
UNDER MY SUPERVISION BY

Karina Sanchez, Sruthi Sakthivel, Michael Bose, and Evan Jennings

ENTITLED

NeuroGen: EEG and Near-Infrared Light Stimulation Control System

BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE OF

BACHELOR OF SCIENCE

IN

BIOENGINEERING

ELECTRICAL ENGINEERING

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NeuroGen: EEG and Near-Infrared Light Stimulation Control System

By

Karina Sanchez, Sruthi Sakthivel, Michael Bose, and Evan Jennings

SENIOR DESIGN PROJECT REPORT

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NeuroGen: EEG and Near-Infrared Light Stimulation Control System

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ABSTRACT

Neurodegenerative diseases, such as Alzheimer's disease and Parkinson's disease are widespread, affecting millions of people worldwide. These diseases occur when neurons in the brain or peripheral nervous system progressively lose function and deteriorate. Current pharmacological treatments manage some of the neurological symptoms, but there is no cure yet. Interventions that mitigate or restore loss of function can fill the void until that goal is met. Light stimulation, or transcranial photobiomodulation (tPBM) therapy, can help treat people with neurodegenerative diseases, as it has been shown to improve sleep, attention, memory, and cognitive function.

The objective of this project is to develop a hybrid electroencephalogram (EEG) and near-infrared light stimulation device with a real-time, dynamic closed-loop control system. The device is designed as a research tool to study the effects of light stimulation therapy on the brain because the associated mechanism by which the effects occur is not well understood. Simultaneous stimulation of the brain and measurement of brain activity is required to answer these questions.

We worked closely with an interdisciplinary team to design a helmet-like device and software program with integrated electrode arrays, LED arrays, cooling system, and dynamic light stimulation and EEG signal control interface for effective and comfortable delivery of light therapy. The device and control system enable the functionality to design experiments that test the assumptions of light therapy mechanisms. These types of findings will improve light therapy protocol design by providing direct evidence of the acute and long term effects of the

intervention. The clinical implications for patients with neurodegenerative diseases are that light therapy may be more effectively designed and thereby improve quality of life for those suffering.

Acknowledgments

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List of Figures

Page

List of Tables

Page

Table of Contents

Chapter 1: Project Introduction

1.1 Project Rationale

Neurodegenerative diseases such as Alzheimer’s disease and Parkinson’s disease affect millions of people worldwide[1], [2]. As of 2021, NIH reports that the Alzheimer's Disease Association estimates that approximately 6.2 million Americans are living with Alzheimer’s disease[2]. Furthermore, almost 1.2 million Americans could be living with Parkinson’s disease by 2030[1].

Neurodegenerative diseases occur when neurons in the brain or peripheral nervous system progressively lose function and end up dying[1]. Current treatments help with managing some of the physical and mental symptoms that are associated with neurodegenerative diseases[1]. However, there currently is no way to surely slow the progression of the disease, and there are no known cures yet[1].

Age is the primary risk factor for developing neurodegenerative diseases[1]. As our average life span continues to increase, more people are bound to be affected by different neurodegenerative diseases in the coming decades[1]. This situation creates an urgent and critical need to develop new approaches for treatment and prevention.

Transcranial light stimulation therapy, also known as transcranial photobiomodulation (tPBM), can be used to treat neurodegenerative diseases, brain trauma injury, and psychiatric disorders. Transcranial near-infrared (tNIR) light-emitting diodes (LED) generate light that penetrates the skull and reaches the brain parenchyma[3]. tNIR light can therapeutically improve the physiological condition and maintain a healthy brain state of patients with neurodegenerative diseases.

Clinical trials have shown positive results of transcranial light stimulation therapy. These results include increased memory, lowered anxiety, and better recall[4]. There are many transcranial light stimulation devices on the market today. However, the performance of these devices can still be improved upon. These devices currently evaluate the performance of the light stimulation with pre- and post- electroencephalography (EEG) recordings. Monitoring EEG during light stimulation to adapt the stimulation parameters can lead to improvement. This Senior Design

Project focuses on how a closed-loop system can make transcranial light stimulation therapy more effective and personalized for each individual patient.

In collaboration with the Bioinnovation and Design Lab, two interdisciplinary teams worked together to develop the first-generation prototype of the NeuroGen: EEG and Near-Infrared Light Stimulation Device and Control System. The Mechanical/General Engineering (MECH) team designed and built the physical headset of the NeuroGen device. The Bioengineering/Electrical Engineering (BIOE/ELEN) team designed the closed-loop control system of the device.

1.2: Background

For the first generation of the NeuroGen prototype, it was very important to conduct a literature review on transcranial photobiomodulation (tPBM), electroencephalography, and closed-loop control system. The design choice of the prototype and control system is based on this research.

1.2.1: Transcranial photobiomodulation (tPBM)

Transcranial photobiomodulation (tPBM) is a near-infrared light therapy, also known as low-level laser light therapy (LLLT), used for tissue regeneration and enhancing cell function[5]. Lasers and diodes can emit light in the near-infrared range (660-1100nm). tPBM can be used to treat people with neurodegenerative diseases, trauma injury, and psychiatric disorders. This light therapy reduces inflammation, provides pain relief, and has been shown to improve sleep, cognitive functions, and memory in patients with dementia[3].

The effectiveness of tPBM is dependent on the light parameters, such as light source, wavelength, energy density, light pulse structure, and the duration of the laser application[6]. Red light or near-infrared (NIR) light are commonly used for tPBM. Their wavelengths range from 600-1100 nm. As shown in Figure 1.1, red light (600-800nm) is absorbed by the enzyme cytochrome c oxidase, a chromophore that absorbs photons. This enzyme is located in the unit IV respiratory chain of the mitochondria. PBM stimulates electrons in chromophores creating a proton gradient that enacts ATP production[5]. Figure 1.1 also shows that near-infrared light (800-1064nm) activates light-sensitive ion channels, and increases the levels of Ca^{2+}, ROS, and cyclic AMP (cAMP). These activities increase cell differentiation, proliferation, and migration, among other things[5]. The rise in ATP production improves the regional cerebral blood flow, oxygen availability, and consumption, which then leads to stimulating, healing, regenerating tissue, and enhancing cell function.

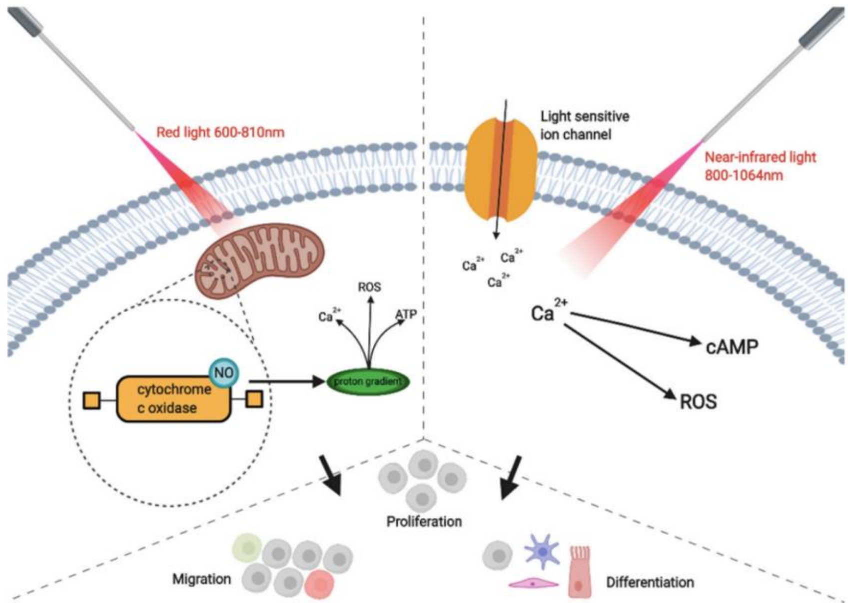


Figure 1.1 Effect of photobiomodulation on human cells[5]

1.2.2: Electroencephalography (EEG)

Electroencephalography (EEG) is a non-invasive method to record the brain's electrical activity through electrodes placed on the scalp of the head[7]. During various tasks or behaviors, neurons are activated, and the resulting electrical activity generated by the synchronized activity of thousands of neurons is detected by the electrodes placed on the head of the patient[8]. Therefore, the EEG can detect various kinds of brain frequencies and their respective locations.

The different brain rhythms that can be observed through EEG are the delta wave (1-4 Hz; linked to deep sleep), theta wave (4-7 Hz; linked to high cognitive workload), alpha wave (8-12 Hz; linked to relaxed wakefulness), beta wave (12-30 Hz; linked to the execution of bodily movements), and gamma wave (>30 Hz; linked to peak attentive focus)[8].

The 10-20 system is a de facto standard EEG electrode placement and correlates external skull locations to underlying cortical areas[9]. It is used internationally, especially for EEG tests as it ensures the reproducibility of the experiments. As seen in Figure 1.2 below, the “10” and “20” refer to the distance between adjacent electrodes that are 10% or 20% of the total front-back or right-left distance of the skull[10].

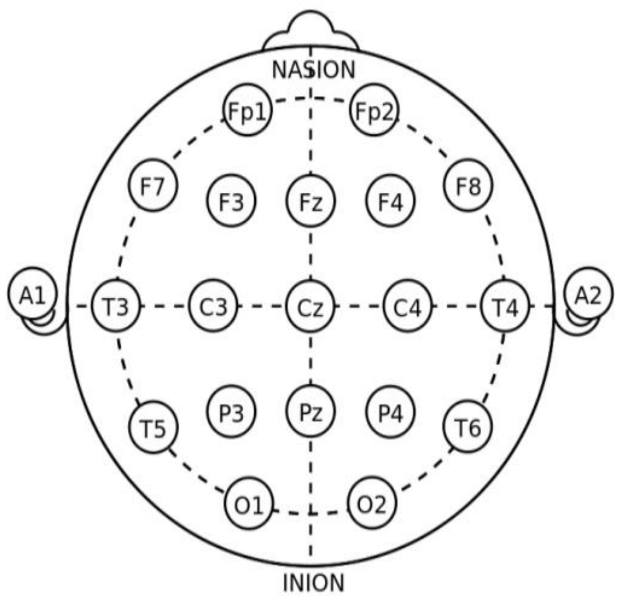


Figure 1.2 Arrangement of 10-20 Electrode System

Raw EEG data represents a complex combination of signal sources in the brain, muscle movement, and noise artifacts (due to electromagnetic interference and impedance quality). Raw data must be preprocessed to isolate clean brain activity data for further analysis. Preprocessing steps include different types of filtering, including FIR, bandpass, notch, and smoothing filters. This allows us to produce clean data that gets rid of background interference and data that may not be biological activity. The data will also be processed using artifact rejection to filter out waveforms caused by head or muscle movement. After such pre-processing steps, we can perform feature extraction by doing Fast Fourier transform (FFT) analysis and a power spectral density analysis.

1.2.3: Closed-System Control System

Our devices focus on developing a closed-loop control system over an open-loop system. In an open-loop system, a specific treatment plan is chosen with a predefined stimulation protocol, and changes to the stimulation are only made when there is a manual adjustment of stimulation parameters as depicted in Figure 1.3a. The dotted line refers to an offline data analysis comparing the pre-stimulation and post-stimulation levels of a selected neurochemical biomarker. However, a closed-loop control system uses a patient's own physiological activity to selectively adjust stimulation when selected neurochemical biomarkers significantly deviate from target levels [11]. A sensor continuously tracks changes in the selected biomarkers. Based on the changes in the biomarkers in comparison to their target levels, the control system is able to adjust the stimulation protocol in real-time in order to restore biomarkers back to the target levels as depicted in Figure 1.3b. The solid blue line refers to real-time changes in the stimulation protocol.

Specifically, in our project, the sensor in Figure 1.3b refers to the EEG. The processing unit is real-time EEG analysis. The programmer is the real-time control system that has the additional input of the desired EEG characteristics. The stimulator is the LED arrays for light stimulation therapy.

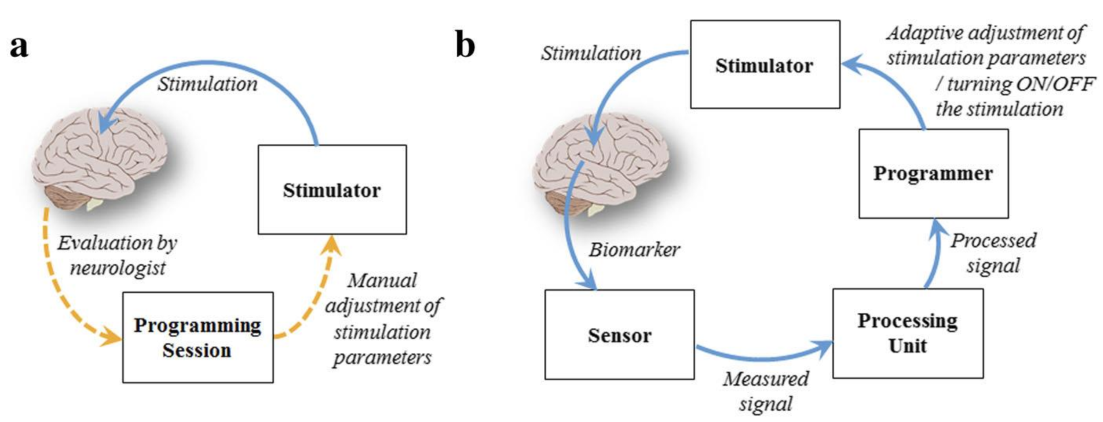


Figure 1.3: Open-loop (a) and closed-loop (b) system overview comparison [12]

1.2.4: Default Mode Network (DMN)

The default mode network (DMN) is a collection of brain regions including the bilateral mesial prefrontal cortex, precuneus/posterior cingulate cortex, angular gyrus, and hippocampus. The DMN is associated with a resting brain state [13]. Disruptions in the DMN can be observed in patients with neurodegenerative diseases experiencing cognitive decline, and the clearest changes can be seen in the alpha frequency band [14].

In a healthy brain, we can observe a reduction in the alpha band power from the eyes-closed (EC) to eyes-open (EO) state in the DMN as shown in Figure 1.4. This is the system that is disrupted in patients with neurodegenerative diseases [14].

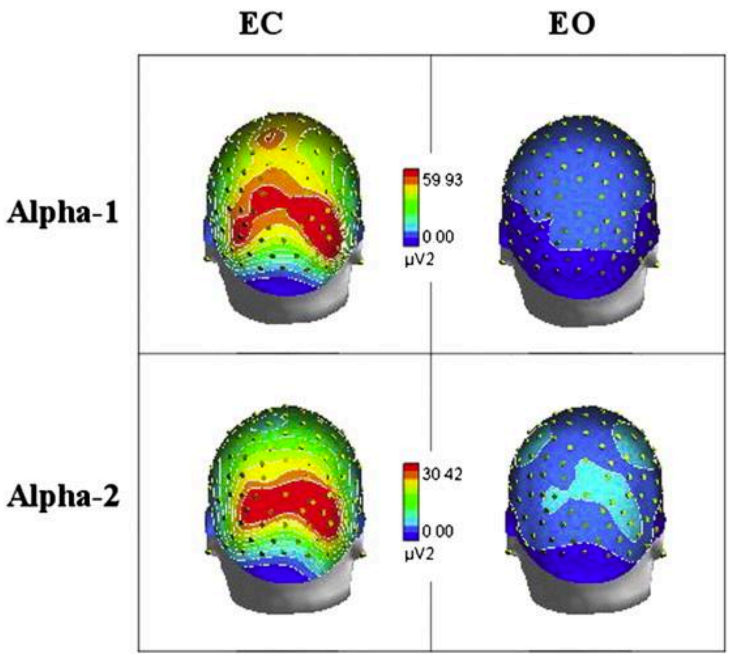


Figure 1.4: Reduction in the alpha band power from eyes-closed (EC) to eyes-open (EO) state in the DMN [14]

1.2.5: Existing tPBM Devices

Photobiomdulation is becoming a more common therapeutic tool, especially for neurodegenerative diseases. Transcranial photobiomodulation can slow down or stop the progression of neuronal degradation[15]. Although research on the effects of tPBM is still being researched, there is currently a market for tPBM devices. These devices are safe, user-friendly, and adjustable.

The Vielight Neuro Gamma 3 (Brain) is a portable, wearable, low-level light delivery device that emits near-infrared light to the brain transcranial and intra-nasally. As shown in Figure 1.5, the device consists of a controller, a nasal applicator, and a headset with four light-emitting diodes (LED) modules. This device's LEDs are at 810 nm wavelength and pulsed at 40 Hz with a 50% duty cycle[16]. The 40 Hz frequency correlates with gamma wave oscillations in the brain. Gamma waves are associated with memory, perception, cognition, and creativity[16]. Users using this product should expect to optimize the outcome of their tPBM therapy with features like different pulse frequencies, brain networks, and synchronization.

Figure 1.5: Vielight Neuro Gamma 3 (Brain)[16]

The Weber Medical LED infrared helmet is another transcranial photobiomodulation device. This device also uses a wavelength of 810 nm. It uses 320 diodes, power at 50 mW/diode, and total power at 16 W[17]. The treatment time can be from 1-30 minutes and the intensity levels are set at 25 - 50 - 75 - 100%. The frequency ranges from 1 to 20kHz. Users using this device can adjust the tPBM therapy by adjusting the duration, frequency, and intensity.

Figure 1.6: Weber LED Helmet[17]

While both aforementioned devices are very successful products in the market, they both focus only on transcranial photobiomodulation therapy to improve the patient's cognitive function. Overall, tPBM and EEG devices exist separately in the market. The NeuroGen: EEG and Near-Infrared Light Stimulation device aims to integrate tPBM and EEG devices together to improve usability and efficacy of patient assessment and improvement of cognitive function.

1.2.6: Open Loop Block Diagram

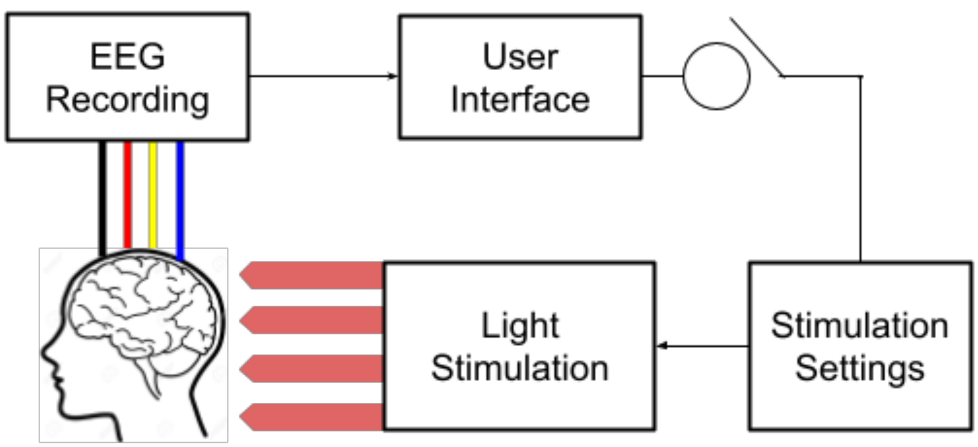


Figure 1.7: General Open Loop Block Diagram

The functionality of the existing devices can be described with the block diagram in Figure 1.7, with the discontinuity created by having separated headsets for the EEG and light stimulation. This connection is only closed off temporarily with a clinician making a judgment from the EEG on how to adjust the light stimulation going forward.

The novel approach in this project comes with connecting these two blocks and closing the loop. Connecting the two would allow for an automated, adaptive element that does not require active user control. This would allow for a more optimized light stimulation treatment without having a clinician present to monitor the inputs, particularly beneficial for patients who are scheduled to undergo daily light stimulation therapy in their own homes. Additionally, researchers could use such a device to better answer questions such as how long it takes for a light stimulation to change the EEG, and how the different regions of the brain respond in real time.

1.4 Project Goal

1.4.1: Team Objectives

The objective of our project is to develop a research device with an integrated transcranial photobiomodulation and electroencephalography system. With this research device, we want to analyze the effects of a closed-loop system on light stimulation therapy with prototype testing, and eventually, conduct tests with a healthy group as proof of concept of the device. The motivation of the project is to make progress toward personalized and more effective light stimulation treatment for patients with Neurodegenerative diseases. Photobiomodulation therapy can improve sleep, cognitive functions, and memory in these patients[5].

The BIOE/ELEN team was responsible for developing the control system of the device. The control system includes LED modules for the tPBM therapy, EEG that detects brain activity during the tPBM therapy, OpenBCI which is a signal processing platform, and the controller that sends signals to the LED modules to adjust the light intensity setting for the tPBM therapy. For the first-generation prototype, it is the team’s responsibility to conduct an extensive literature review, make design choices, implement and test the design and lay a foundation for future improvements.

The MECH team was responsible for creating the helmet shell and cooling system for the device. They closely collaborated with our team, specifically on the placements of the LED modules and electrodes.

Overall, our project goal is to develop a research device in which we can record brain activity to see real-time changes in the brain, and from this data, we can adjust the intensity of the light therapy. With this research device, we hope to pave the way for future devices that make light stimulation therapy more personalized and effective for each individual patient. Our motivation is to help create and sustain a world in which those that suffer from these diseases are given more time to live a happy, healthy, and memorable life with loved ones.

1.4.2: Device Objectives and Requirements

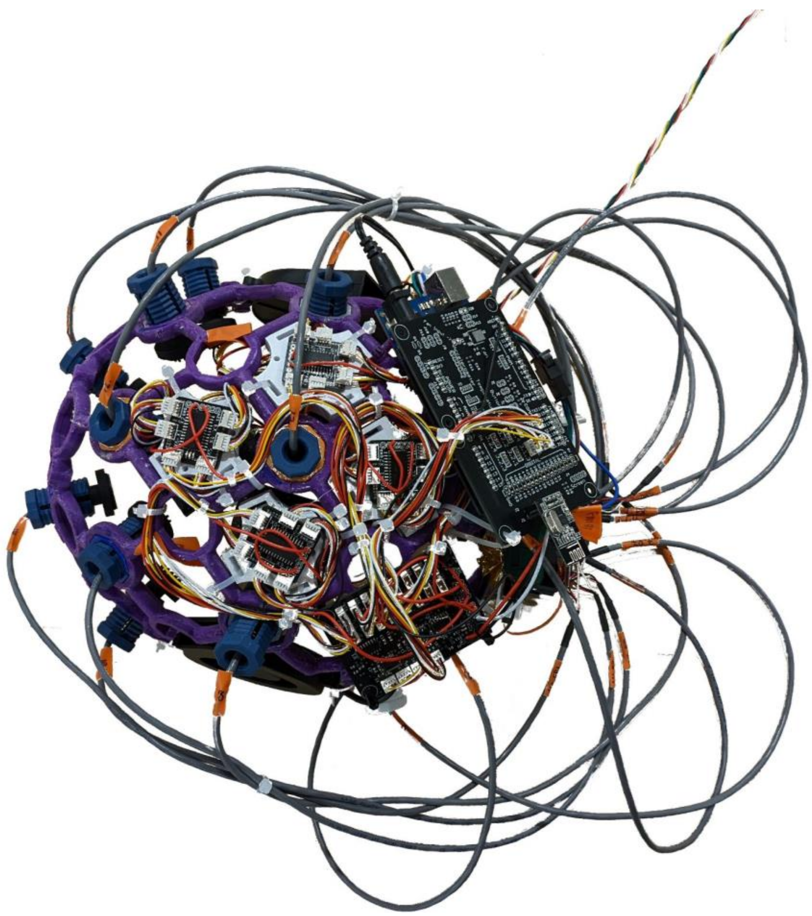
The NeuroGen: EEG and Near-infrared Light Stimulation Control System must perform these four main functions: (1) LED modules deliver light stimulation treatment, (2) EEG detects and records brain activity, (3) control system analyzes real-time changes, and (4) User Interface adjusts the intensity of the light therapy.

For the device to perform the functions listed above, our device requirements are to develop an EEG and LED montage for a prototype, to build controllable LED modules that emit light in the near-infrared range of 600 to 1100 nm, and to design a closed-loop protocol that uses real-time EEG readings from at least 16 electrodes to adjust light therapy through manual or automatic control.

Chapter 2: The NeuroGen EEG and Near-Infrared Device

2.1: System Overview

The complete system comprises both the headset (placed on a patient) and the software on a nearby computer. In addition to the LED boards of a PBM system and the electrodes of an EEG system, the headset utilizes an Arduino which receives instructions to control the stimulation. This control can be done both manually, through the user input, as well as automatically, using metrics derived from the EEG recording to adjust the parameters of the LEDs.



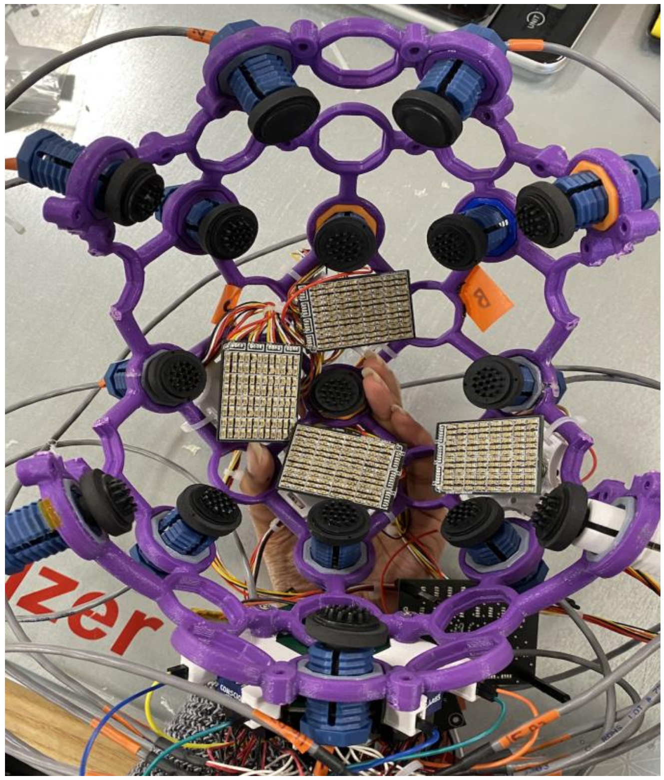
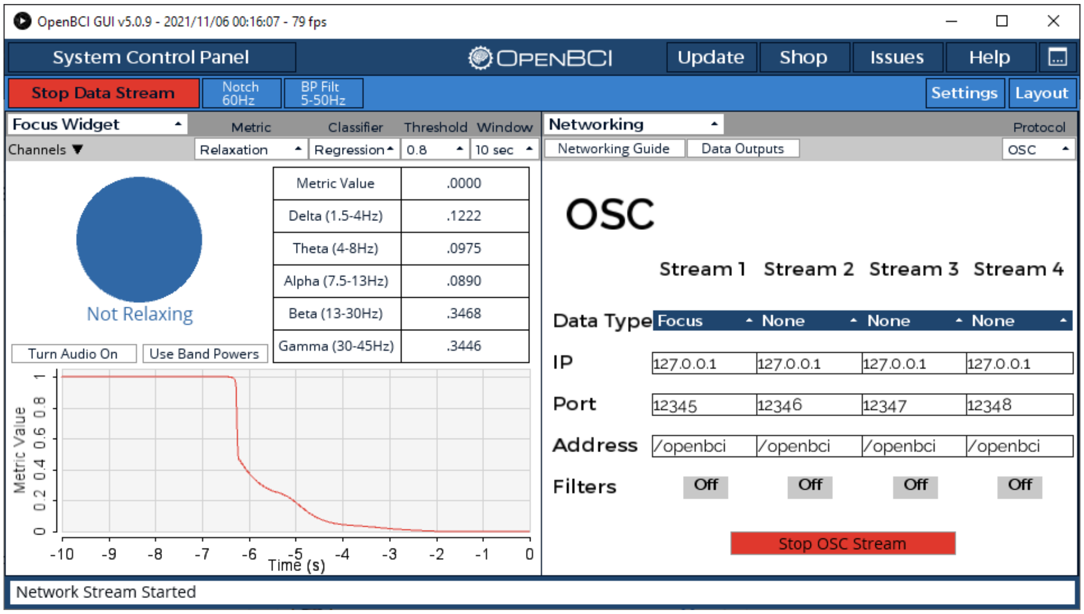


Figure 2.1: Completed hardware components of the system (Top View and Bottom View)

There are three components to the software system: The OpenBCI GUI is provided by the organization and intended for their devices, but the platform is also adaptable and customizable for one's own project. The Processing GUI and Arduino codes are written by our team for control over the LED arrays. Figure 2.1 shows the LED modules and electrodes from the outside/top and inside/bottom of the headset. Figure 2.2 shows all the software platforms used for the control system: OpenBCI, Processing, Arduino IDE.


OpenBCI GUI v5.0.9 - 2021/11/06 00:16:07 - 79 fps
System Control Panel
OPENBCI
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Shop
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Help
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Metric Value .0000
Delta (1.5-4Hz) .1222
Theta (4-8Hz) .0975
Alpha (7.5-13Hz) .0890
Beta (13-30Hz) .3468
Gamma (30-45Hz) .3446
Not Relaxing
Turn Audio On
Use Band Powers
Metric Value
Time (s)
Networking
Protocol
Networking Guide
Data Outputs
OSC
Stream 1 Stream 2 Stream 3 Stream 4
Data Type Focus None None None
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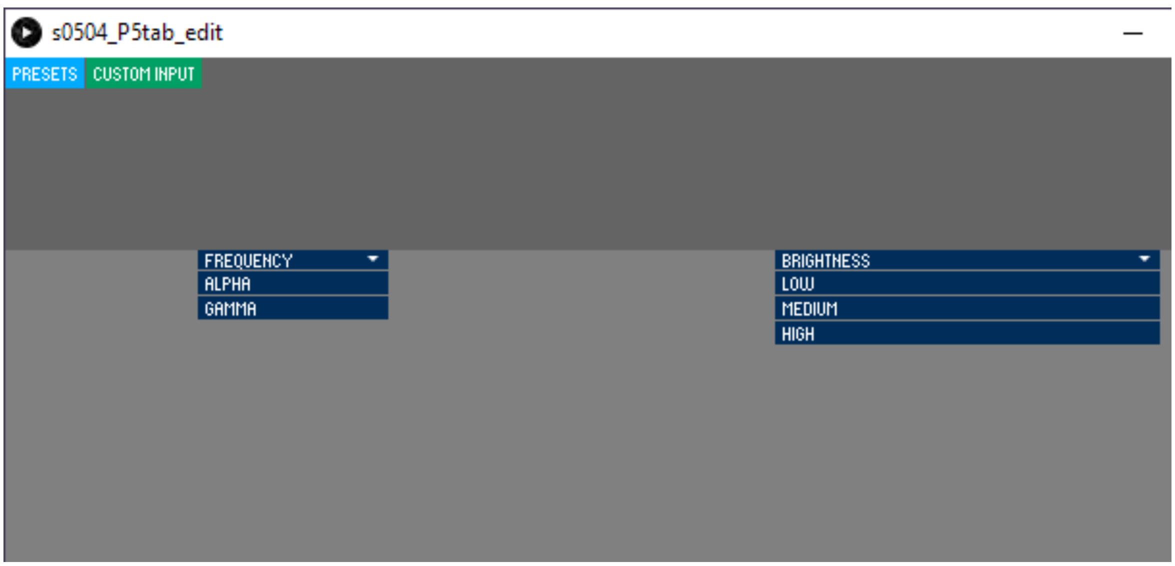
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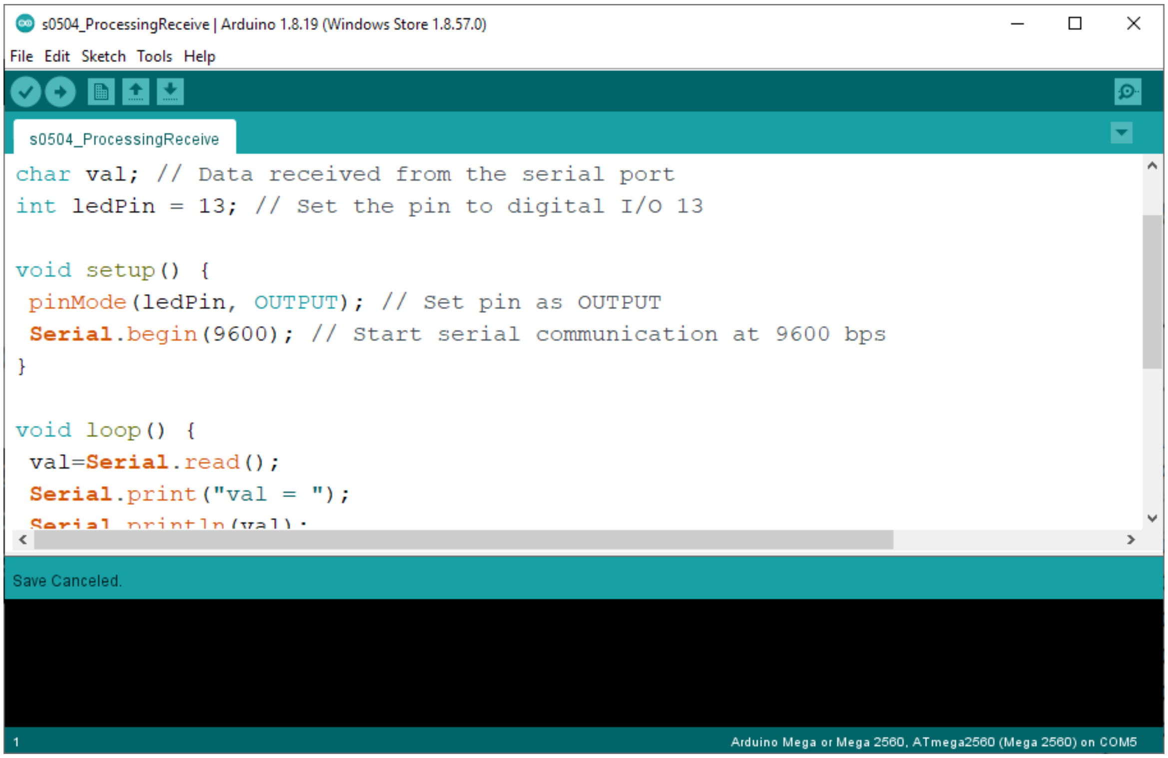


Figure 2.2: Main interfaces for the software. From top to bottom: OpenBCI, Processing, Arduino IDE

2.1.1: The Headset Subsystem

The headset is built upon the skeleton of the Ultracortex Mark IV headset by OpenBCI. The CAD file of the headset was purchased from OpenBCI. We purchased the headset in the size medium as it was the standard size that would best fit all our teammates. As shown in Figure 2.3, the helmet skeleton is designed with electrode placements.

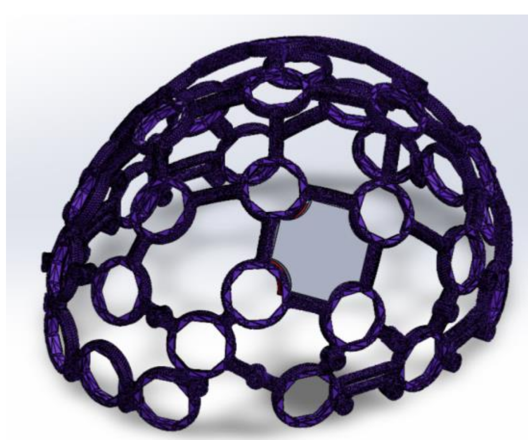


Figure 2.3: CAD of Headset[18]

Figure 2.4 below shows the OpenBCI Ultracortex Mark IV Headset with the electrodes installed. The MECH team 3D printed the headset from the Maker Lab/Innovation Zone at Santa Clara University. Only minor modifications of the headset structure were allowed to be edited with the provided CAD file. Therefore, when collaborating with the MECH team, we decided to design LED modules that fit the open gap areas of the headset. This constraint limited the number of diodes per module.

Figure 2.4: OpenBCI Headset with electrodes[18]

In addition to the electrodes and LED modules on the headset, the MECH team installed two fans (one on each side of the headset) for their cooling system. The LEDs are emitting heat and dissipating energy that can negatively affect the temperature of the scalp and also disrupts the signals. This is why a cooling system is necessary to ensure the safety and function of the device.

2.1.2: The EEG Subsystem

The electrodes in this kit are both dry and active, meaning that they do not require a liquid dielectric and are powered by an amplifier, respectively.

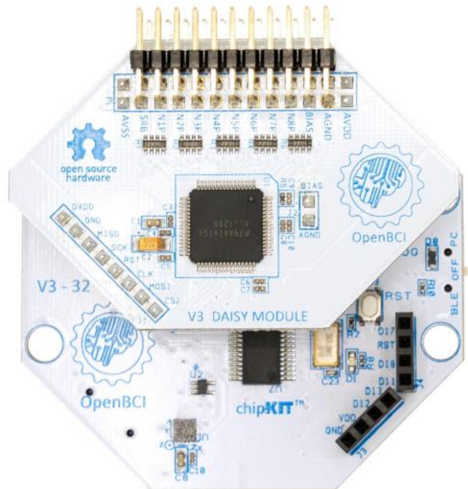


Figure 2.5: Cyton + Daisy Amplifier[19]

The kit includes the Cyton + Daisy amplifier, which is also responsible for transmitting the data to the computer via Bluetooth. This amplifier also includes multiple gain settings: 1x (no amplification), 4x, 8x, and 24x. The gain is determined by testing them all and choosing the one that gives a not railed reading.

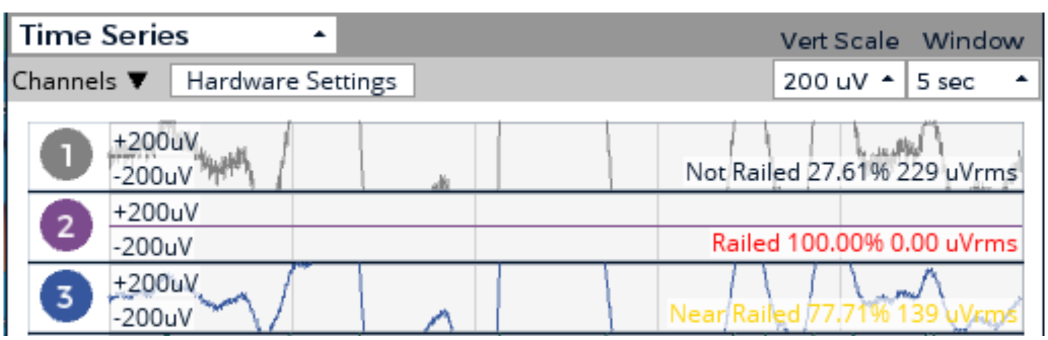


Figure 2.6: Non-railing and Railing Electrodes

When live streaming data, the OpenBCI GUI will indicate whether an electrode is railing, as shown in FIgure 2.6. Railing indicates measured values beyond the displayable range of -10000uV to 10000uV, meaning the data is clipping. If only some of the electrodes are railing, then this is usually a fitment issue with the contact of those particular electrodes and the scalp. However, if most of the electrodes are railing then it is more likely with the gain settings amplifying the data out of range. As of now, the gain values are set by trial and error, with the default value of 8x being used and then decreased in the presence of railing.

We originally planned to use dry comb electrodes (shown in Figure 2.7) that were included with the kit, because the long combs could reach the scalp through one's hair. Instead, we opted to use the ThinkPulse Electrode (shown in Figure 2.7) which had shorter combs but larger surface area. This yielded a better electrode connection, and therefore, we will receive more consistent EEG recordings.

Figure 2.7: Packaged Dry Comb Electrodes (left)[20] and ThinkPulse Electrodes (right)[21]

2.1.3: The Light Stimulation Subsystem

tPBM effectiveness is dependent on light source, wavelength, energy density, light pulse structure, and the duration of the LED application. Based on these parameters, we designed the light stimulation protocol (Table 2.2). Based on our literature review, we know that wavelengths from 600-1100 nm can be absorbed by the chromophore cytochrome c oxidase. Due to time and our financial budget (Table 2.1), we purchased infrared LEDs at 850 nm, which is well within the range of wavelengths that are proven to be absorbed in neuronal cells.

Table 2.1: LED Options

LED Order	Cost	Factors
EOLS-1070-844 (Infrared, 1070nm) EPIGAP	$1,067.00	*Pro:* High Wavelength *Cons:* Expensive, 8-week lead time (International, Supply Chain Issues, No Credit Card)
SML-S13RTT86 (Infrared, 850nm) Newark	$160.00	*Pro:* High Wavelength *Cons:* August 2022 Delivery (Supply Chain Issues)
SML-S13RTT86 (Infrared, 850nm) Digi-Key	$220.00	*Pro:* High Wavelength, March 2022 Delivery

Because the intensity of light waves decreases with an inverse square relationship with distance, they need to be as close as possible to minimize power loss. The design goal was a distance of 2-4mm from the scalp, having the LEDs close while still being at a safe physical distance as to not cause harm. Based on in vitro studies, the baseline value for the energy density is 4 J/cm^2 [6]. This is the minimum amount for light stimulation to work. The energy density is the light intensity parameter that the user interface will adjust in the early stages of our prototype. The pulse frequency of stimulation to the brain (regardless of mode of stimulation) causes entrainment. A 10 Hz stimulation will promote 10 Hz oscillation in the brain originating from the source of the pulse stimulation. The pulse at 10 Hz is shown to have a peak response in cortical neuronal cells because alpha waves are from 8-13 Hz. Alpha waves are associated with the DMN, so the pulse at 10 Hz will strengthen the DMN. Our energy density and power density are dependent on exposure time, which we set to 600 seconds or 10 minutes. Using equation 2.1, at 10 minutes, the power density is 5 mW and the energy density is at 4.2 J/cm^2, which is the baseline value that will be adjusted with the closed loop control system.

$$Energy\ Density\ = \frac{output\ power\ in\ watts\ [W] * Exposure\ \ Time\ (s)}{irradiated\ area\ in\ cm^{2}\ [\pi r^{2}]} J/cm^{2} \quad \textbf{(2.1)}$$

Table 2.2: Proposed Irradiation Parameters

Irradiation Parameter	Proposed
Light Source/Wavelength	Infrared LED, 850nm
Distance	2-4mm from scalp
Power Density (Irradiance)	5 mW
Energy Density (Fluence)	4.2 J/cm^2
Pulse	10 Hz
Duration	600s

For the original design goal, the team wanted to fit a large number of diodes to ensure the effectiveness and flexibility of the light stimulation therapy, and thus tested the board dimensions in Figure 2.8 to compare physical fitment between the electrodes.

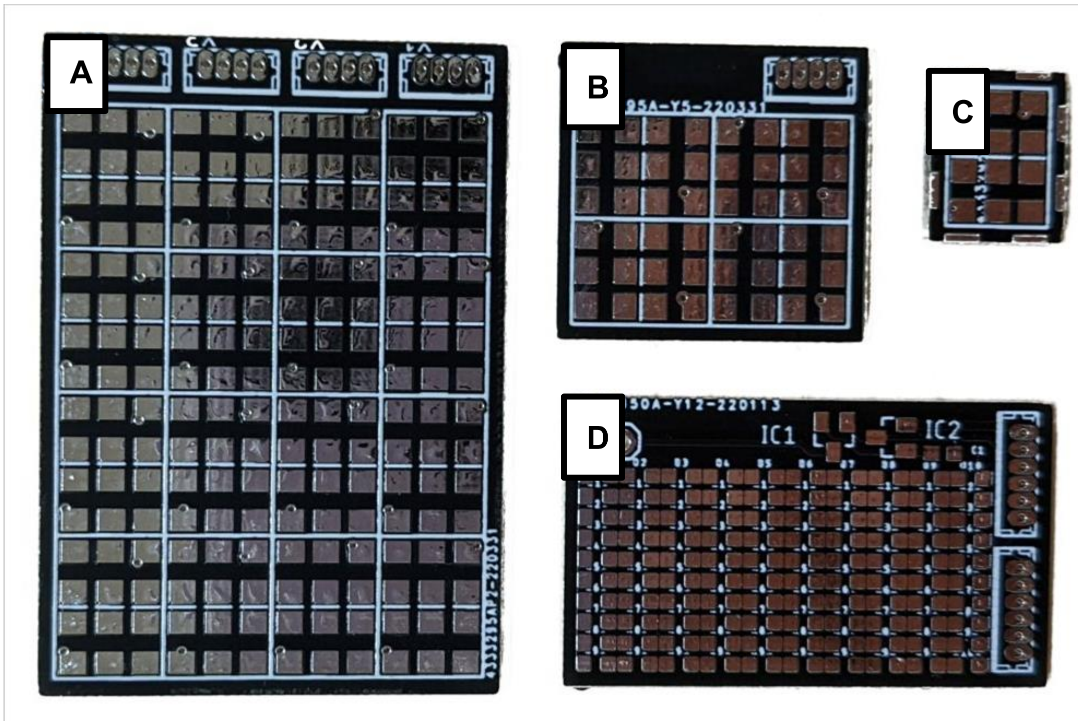
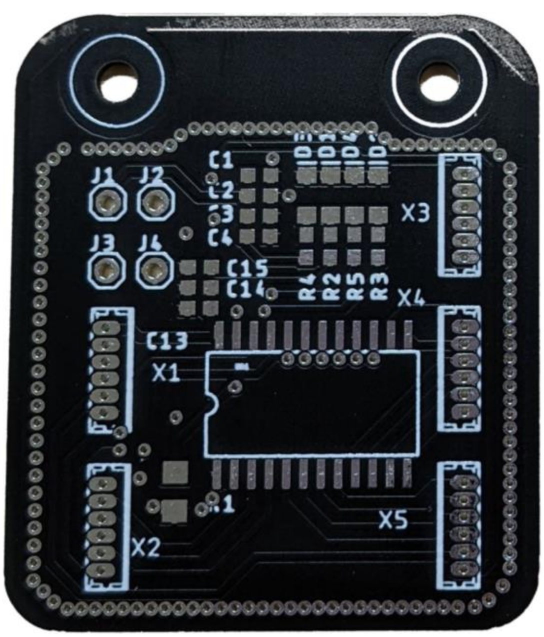


Figure 2.8: Tested Board Dimensions (Chosen board: A)

With the spatial constraint set by the electrode locations, the final LED boards are 25.6 mm x 19.2 mm, allowing for a 8x12 grid of standard 1206 diodes. This size can be placed in between electrodes while also being large enough to be physically stable.



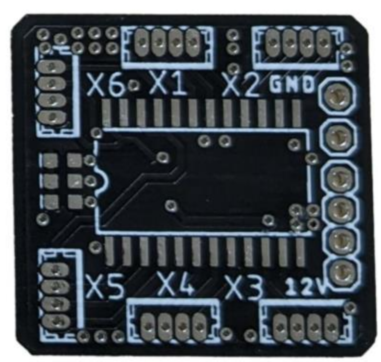


Figure 2.9: Control boards, which deliver power to multiple LED panels

One of the objectives for this device is the spatial adjustment of LEDs, such as having those around a certain region of the head have a higher intensity than those in other regions. To implement this feature, there are control boards between the LED panels, shown in Figure 2.9, as well as Arduinos from the control system. These control boards can use hardware logic to distribute different signals to a set of LED boards.

With the headset, EEG, and light stimulation subsystems, this development stage of the device can be described with the following block diagram in Figure 2.10.

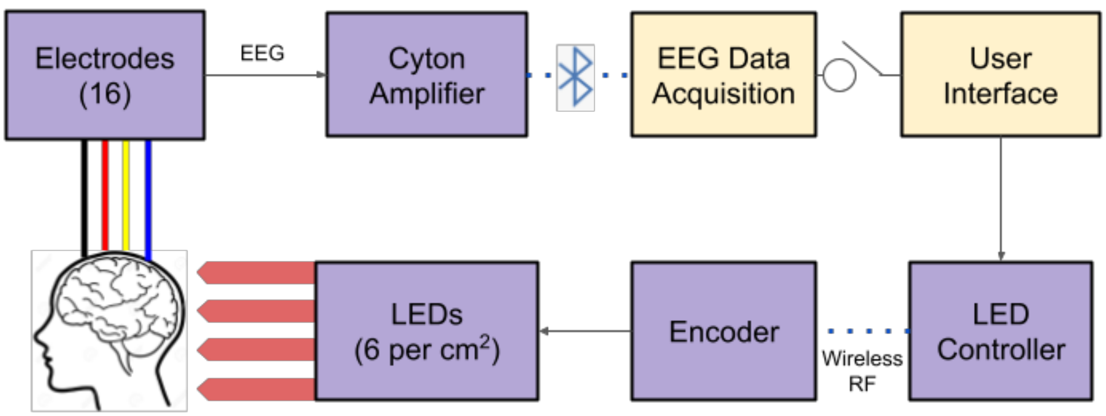


Figure 2.10: Open Loop Data Pipeline Block Diagram

Here, the functionalities of the EEG and light stimulation systems operate independently from each other. The labeling here indicates in purple which pieces are directly connected to the headset, while the yellow blocks are on the computer and also house most of the software. The light stimulation system has the LEDs feeding into the head, while the EEG measures the activity from the head.

2.1.4: The Control System

The next development stage is to create the control system, which interlinks the EEG and light stimulation such that they influence the other. This is first achieved with the hybrid design of the headset, which contains both electrodes and LED boards, removing the discontinuity from needing separate devices. Next, software data flow is created to define how a metric from the EEG should influence a PBM instruction output. For this project, we are using a physiological measurement of 10 Hz because of its association with alpha waves and the DMN. We want to use entrainment and keep alpha frequency band power above a baseline in order to stabilize the DMN. A low alpha band power would necessitate increasing the intensity of the light stimulation by a fixed value until a high alpha band power is detected for a set amount of time. The control system will analyze the alpha band power and send instructions for the light intensity based on this data.

2.2: Integration of Subsystems

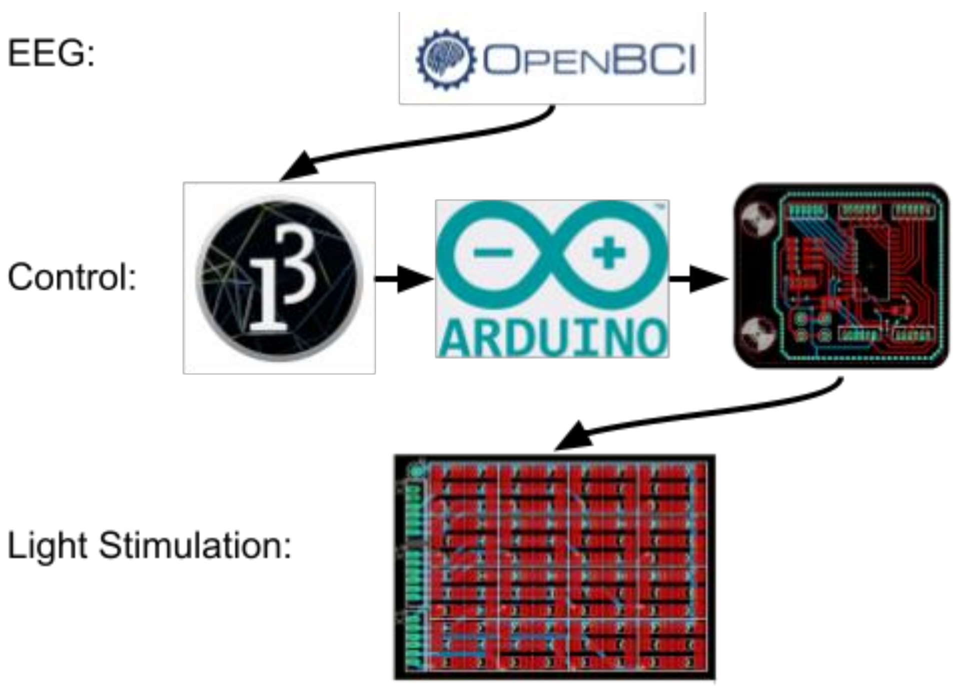


Figure 2.11: Simplified Representation of Subsystems

In this diagram (Figure 2.11), the middle portion represents the new components that have to be added, which include both software from Processing 3 and the Arduinos and hardware control boards. All together, the control system maps output from OpenBCI to changes at the LED panels.

2.3: Closed Loop Block Diagram

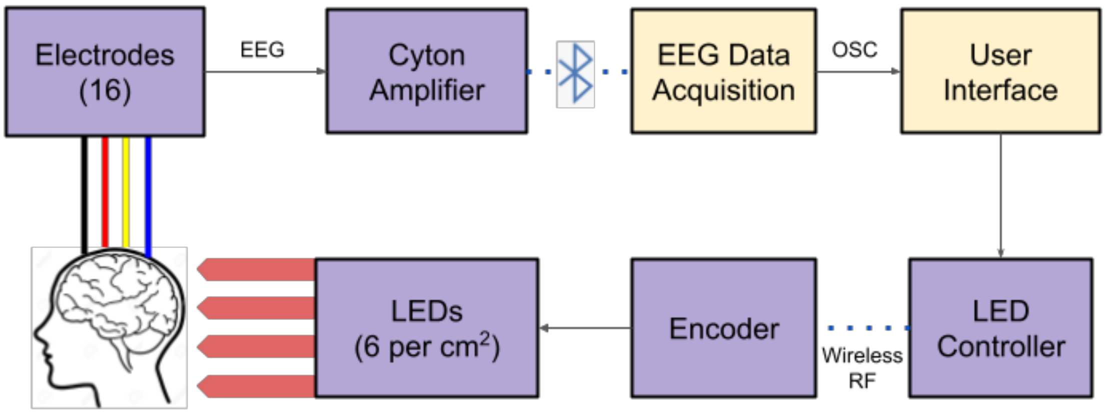


Figure 2.12: Closed-Loop Block Diagram

With all of the subsystems in place, the final system, represented in Figure 2.12, contains the same physical components but closes the loop with the software on the control system.

Chapter 3: Subsystem 1: The Headset

3.1: Overview of Subsystem

The subsystem of the headset refers to the physical shell of our device. This subsystem provided the structure to integrate the EEG subsystem and light stimulation subsystem.

3.2: Design Choice

We chose ThinkPulse dry electrodes paired with the Ultracortex Mark IV headset for clean set up, comfort, adjustability, and modifiable design reasons. We choose the dry electrode system over the wet electrode system (shown in Figure 3.1) because the dry electrodes are preferable for testing with multiple people. Unlike the wet electrodes, there is no liquid dielectric that needs to be applied and cleaned up after each use. Wet electrodes would also present an electrical issue with the LED boards that would surround each electrode. Since wet electrodes are enmeshed into a cap, we would have had to place the LED boards on an outer shell, which would increase the distance of the LEDs from the scalp and consequently reduce the efficacy of the light stimulation protocol. A specific advantage of the Ultracortex Mark IV is the wireframe structure that allows us to move around the electrodes as we see fit. Furthermore, the spaces in between the electrodes allowed for the ideal placement of the LED boards close to the scalp without disturbing the placement of the dry electrodes.

Figure 3.1: Wet (left) vs. Dry (right) Electrode System[22][18]

Chapter 4: Subsystem 2: EEG

4.1: Overview of Subsystem

The EEG subsystem is a key component of the NeuroGen device. The EEG functions as the sensor that measures changes in the selected biomarker, the alpha band power, in this closed-loop system. The electrode placement was guided by the anatomical regions of the default mode network (DMN). The number of electrodes were limited to 16, the maximum amount of inputs available on the Cyton + Daisy amplifier system.

4.2: Design Choice

In order to most effectively measure the changes in the alpha band power in the DMN, we chose to move forward with 16 electrodes, the maximum that can be supported with the compatible Cyton + Daisy amplifier system by OpenBCI. The electrodes were chosen within the neurofeedback clinical standard of 19 electrodes [22]. As seen in Figure 4.1 below, the 16 electrodes that were chosen for the final EEG montage for the device to symmetrically maximize the scalp coverage are circled in red. The channels that are crossed out are those within the 19 channel standard, but were excluded. The chosen electrodes include Fp1, Fp2, F3, F4, F7, F8, Fz, C5, C6, Cz, P7, P8, PO3, PO4, Pz, and Oz.

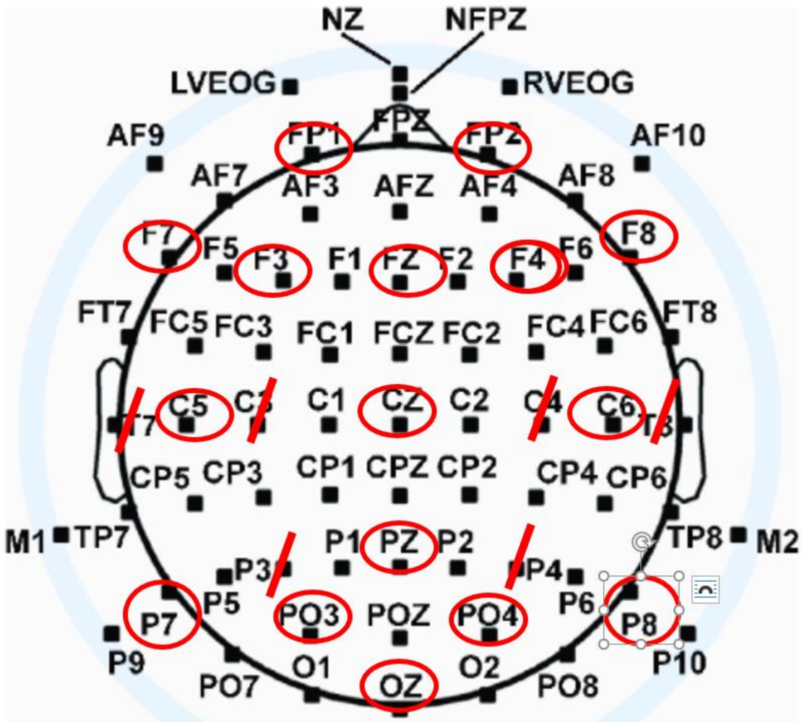


Figure 4.1: Final EEG montage

ThinkPulse electrodes by Conscious Labs were used for each channel. These are active, dry electrodes. “Active” in this context means that they have shielding built into the electrode rather than filtering of electrical noise in the pre-amplifier. Each electrode is grounded and powered independently. This enables a high input impedance and low output impedance. “Dry” means not requiring some “wet” electrical conductivity gel. [21]

It is important to have the electrode number mapped out on a 10-20 EEG system. This can help determine if the noise issue is targeting specific electrodes in areas near the fans and/or LED modules or if the issue is global. Figure 4.2 shows the electrode numbering for our testing.

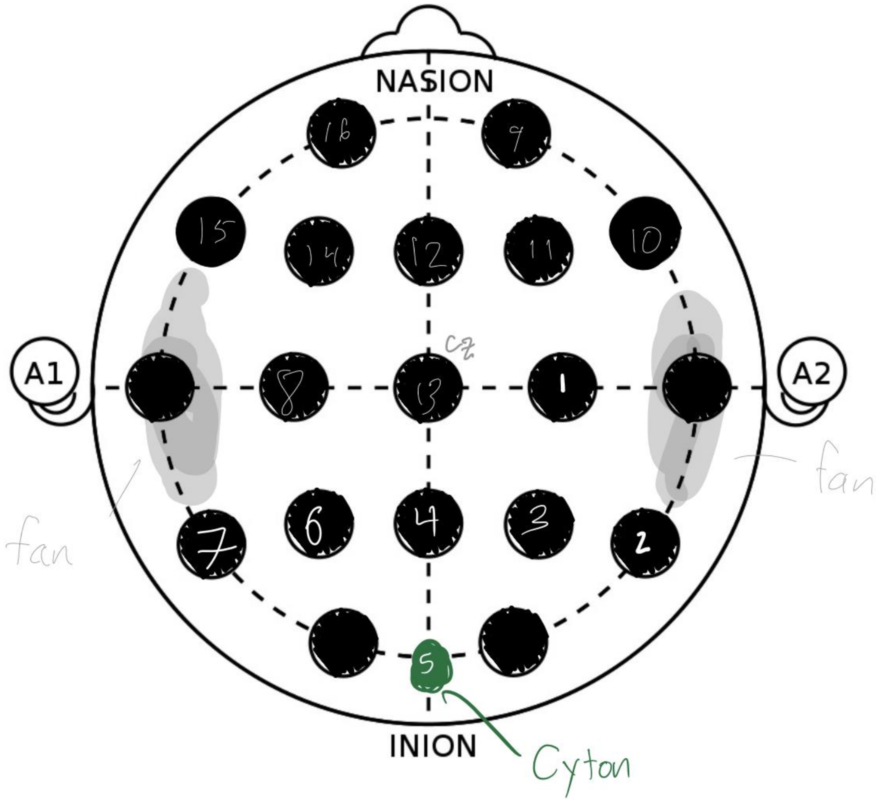


Figure 4.2: Electrode Mapping for Testing

4.3: OpenBCI

OpenBCI is an open-source EEG analysis platform with an active forum. We decided to work with the OpenBCI because it is an open-source platform that provided a great amount of guidance on setting up the electrodes on the headset and amplifier, information on how to analyze electrical brain activity on the software OpenBCI GUI, and lastly, freedom to adjust settings and add features that would benefit our project.

In the OpenBCI GUI (Figure 4.2), there are multiple data filtration options. One option is a notch filter, which can be turned on and set to 50 or 60 Hz to target the AC frequency of Europe or the U.S. respectively. There are bandpass filters: None, 5-50 Hz, 7-13 Hz, 15-50 Hz, 1-50 Hz, and 1-100 Hz. We chose to keep the bandpass filter from 1-50 Hz, because we wanted to focus on analyzing the alpha wave (8-13 Hz) and gamma wave frequencies from 38-42 Hz.

One important thing to note about these data processing settings is that they only affect the data stream, and not the file that is automatically saved after a recording session on OpenBCI. We can verify this by plotting the same text file data into MATLAB without implementing any of these filters ourselves. Furthermore, when replaying a text file, we can continue to experiment with either the settings that were used at the time or with our own results. This is immensely helpful because the original information is retained even if we choose to only look at a subset of it at the given moment.

In addition to using the notch and bandpass filters, we used four widgets for our data processing and analysis. These widgets include Time Series, FFT Plot, Band Power, and Focus.

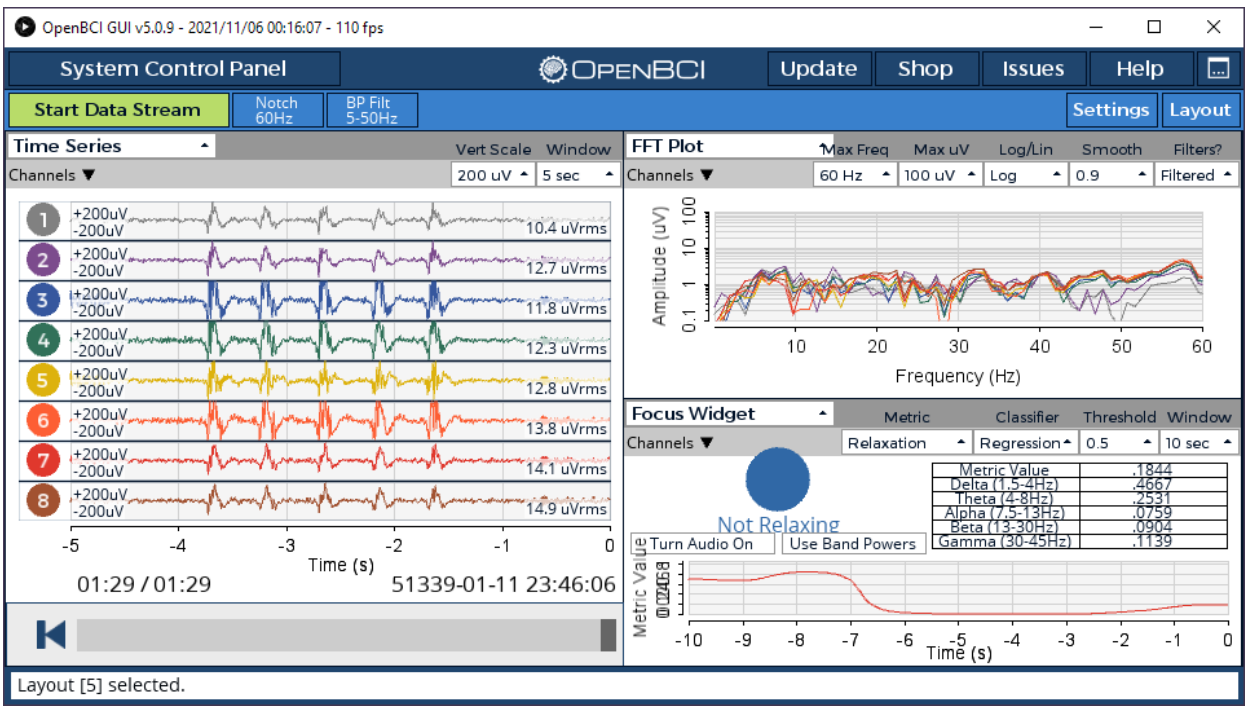


Figure 4.3: OpenBCI GUI for Signal Processing and Data Analysis

4.3.1: Time Series

The EEG records the electrical activity of the brain as a function of time, hence the name “Time Series”. This is also the waveform that is being referred to when mentioning the “raw data”. In OpenBCI, however, what we see under the visualization is not usually the raw data as there are filters that we usually apply. Though inaccurate, we still sometimes use the term raw data because it is closer to the original form than other transformations, such as the further types of FFT and the Focus Widget. While these types are preferred for drawing inferences from the brain activity, the time series is an invaluable tool for our data analysis because we can use it to determine if the electrodes are detecting real brain activity or noise. If there is too much noise, there will appear to be multiple high peaks and/or the widget will state that it is “railing.” Based on this indication, we can troubleshoot the EEG testing. Some issues we have encountered are loose contact of the electrodes to the scalp or loose connection of the electrodes to the Cyton + Daisy amplifier. Figure 4.4 is a good example of raw data of real brain activity.

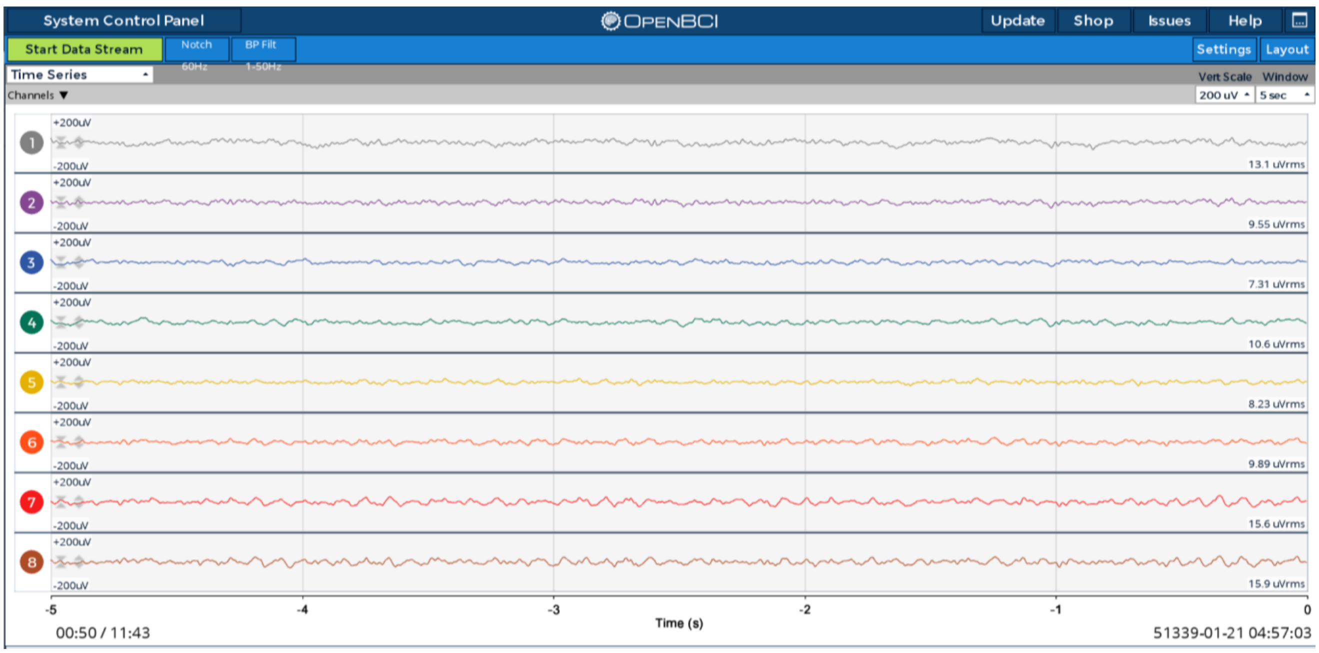


Figure 4.4: Time Series Widget

4.3.2: FFT Plot

Simply put, the Fast Fourier Transform, or FFT, receives a signal and decomposes it into its individual frequency components and their respective amplitudes. The x-axis displays various frequencies, and the y-axis shows each frequency’s respective amplitudes in µV. This widget is very useful because it readily visualizes fluctuations in the alpha band,which we hope to achieve with the eyes closed/open testing protocol. When the DMN is upregulated, absolute alpha power increases over associated channels. When the light stimulation therapy is on, we can detect how the brain reacts to tPBM by analyzing the change of alpha amplitude. Figure 4.5 shows a peak at 12 Hz for a single channel, which is within the alpha range.

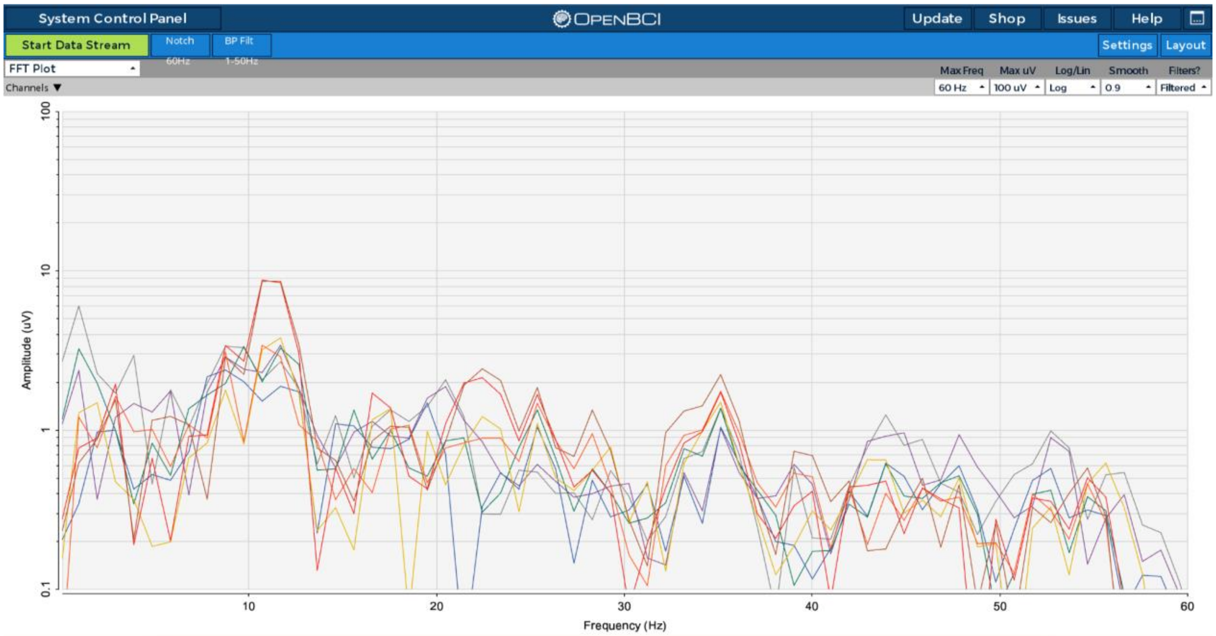


Figure 4.5: FFT Plot Widget

4.3.3: Band Power

Band power is a further extension of FFT. The band power used the power spectral density (PSD) analysis, which is an average over selected channels. Here, the frequency components are grouped into their brain wave frequency groups of alpha, beta, gamma, theta, and delta. These are transformed into power values to compare with the activity of each of the frequencies over time. As mentioned already, disruptions in the DMN, as indicated by decreased alpha power, can be seen in patients with neurodegenerative diseases experiencing cognitive decline. The objective of the light stimulation protocol is to entrain the DMN at 10 Hz. We want an alpha wave with a high band power when doing the light stimulation therapy at 10 Hz. Figure 4.6 shows the band power widget when the alpha band power is high.

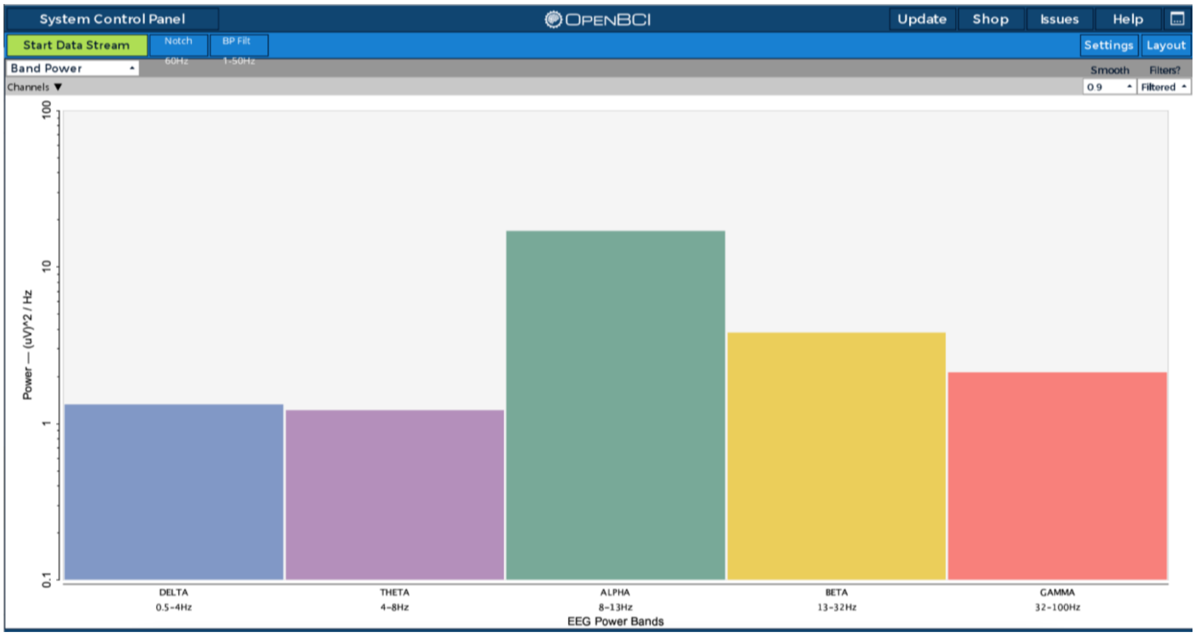


Figure 4.6: Band Power Widget

4.3.4: Focus Widget

The focus widget uses the BrainFlow Metric feature to detect Relaxation or Concentration. Note that these are the semantic labels given to the classification of an objective EEG feature based on relative band power. In the present usage, mental state is not being inferred.

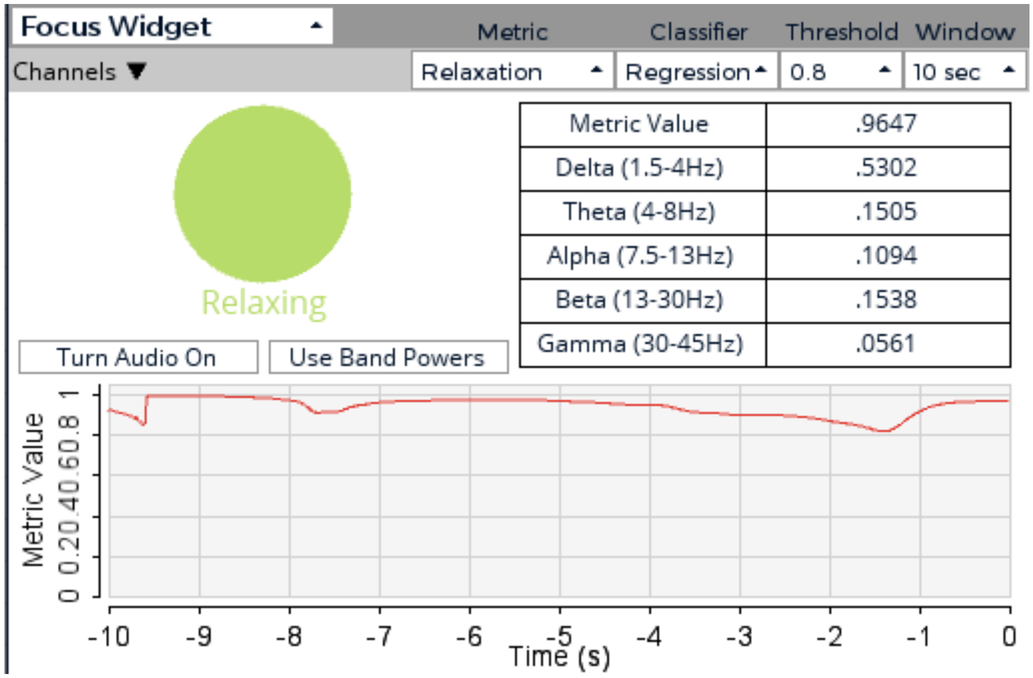


Figure 4.7: Focus Widget

The settings for this widget reside in the top right corner of Figure 4.7. The OpenBCI website describes that "'Relaxation' is associated with Delta, Theta and Alpha bands, while 'Concentration' is associated with Beta and Gamma bands."[23]. The metric values are normalized (scaled from 0 to 1) to compare the relative intensity of each frequency band. The threshold for the metric is used to determine if the state is relaxation and concentration. For example if the threshold is 0.8 with the relaxation metric selected, the corresponding frequency (delta, theta, and alpha) bands need metric values above 0.8 to determine a relaxation state.

The metric value is not the immediate measurement, but rather is calculated with measurements from the selected time window. The calculation is determined by the classifier, with "regression" performing the simple moving average, whereas other options undergo more complicated calculations, such as K-nearest neighbors (KNN), which can be thought of as grouping adjacent measurement values.

The output of this focus widget is a binary value (0 when below or 1 when above) that is sent to the controller, the goal of which is to have no modifications of the light parameters when the alpha wave is high and to increase the power of light intensity when the alpha wave is low over a given time.

4.3.5: Networking Widget

Using this data in real time with another program requires the networking widget, which allows multiple options for data transfer protocols. This project used OSC, an IP-based networking protocol that is specialized for real-time communication between software programs. This setup is depicted in Figure 4.8, where the localhost IP address of 127.0.0.1 means that the data is sent back to the computer.

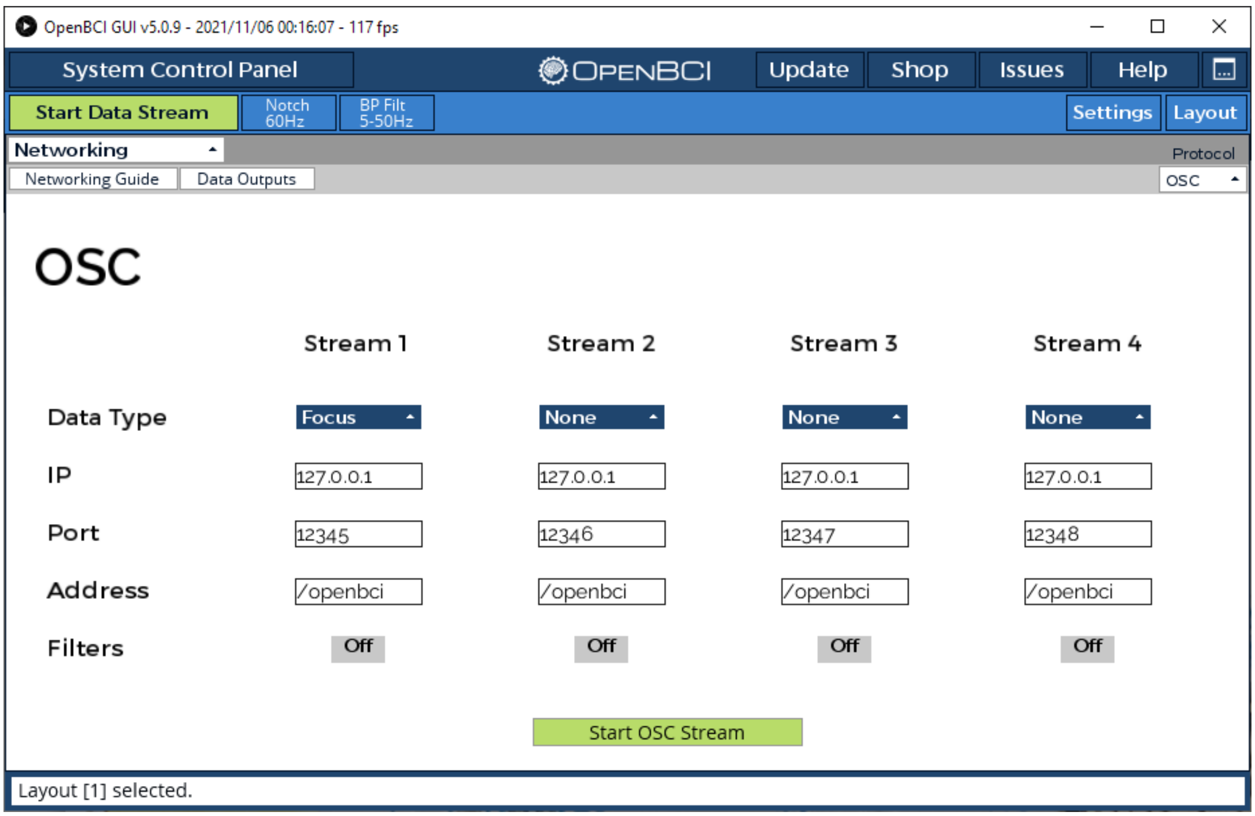


Figure 4.8: The Networking Widget, with OSC and the Focus Widget output selected

Chapter 5: Subsystem 3: Light Stimulation

5.1: Overview of Subsystem

For light stimulation, there needed to be features for both variable intensity adjustments for the LEDs as well as addressable LED subgrids for localized control, meaning that, in addition to LED panels and drivers, there also needed to be controllers. Moreover, these components must fit inside or be otherwise attached to the headset, placing bounds on their physical dimensions. The electrical layouts were chosen to implement these needs. These layouts were then manufactured by JLCPCB as printed circuit boards.

The first design problem was to implement LEDs variable intensities. Since LEDs need a constant voltage to operate efficiently, the intensity cannot be adjusted by changing the voltage. Instead, to allow the different brightness levels in Figure 5.1, the LEDs are turned on and off at a fast enough frequency such that the human eye only perceives the average of the two states. Over a fixed time period the on time of the LEDs are adjusted as a percentage of the total period. This percentage is called the duty cycle.

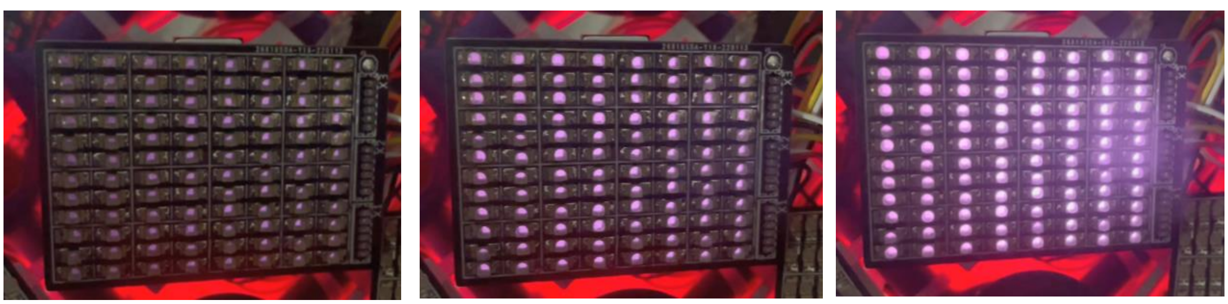


Figure 5.1. Verifying the low, medium, and high brightness settings

The next design problem was to address individual blocks of LEDs, turning them on and off independently of another as is depicted in Figure 5.2. To accomplish this, a shift register was used to take in serial data from a microcontroller and provide parallel outputs, in this case meaning that each of these blocks receives power at the same time.

Figure 5.2: Addressable subgrids at the LED panels

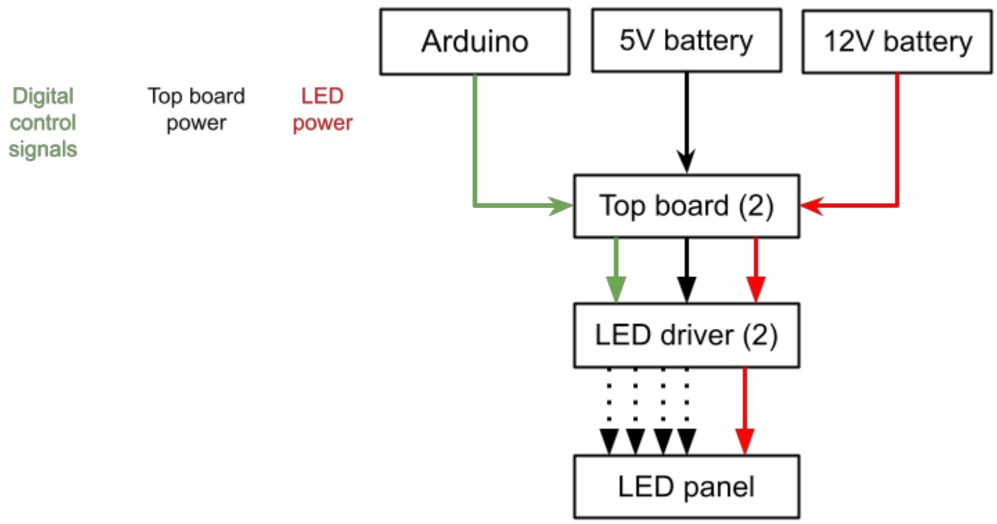


Figure 5.3: High level block diagram of hardware

The hierarchy of power and control signals can be seen in Figure 5.3. In parentheses are the number of each type, meaning that the Arduino and batteries feed into 2 top boards which each have 2 LED drivers, for a total of 4 LED panels. The LED driver uses hardware logic, to “merge” the control signals and board power.

5.2: LED Panel

In the beginning stages of the project, the goal was to house 900 diodes inside the headset. Since some of the headset space is occupied with electrodes, the LED Panel was designed to have as many LEDs as physically possible, with a small footprint so that it can be placed inside the headset (Figures 5.4). This LED density was first increased by having the panel not perform any hardware logic, instead delegating this task to the driver. As a result, the panel only needs to mount the LEDs and receive their electrical power.

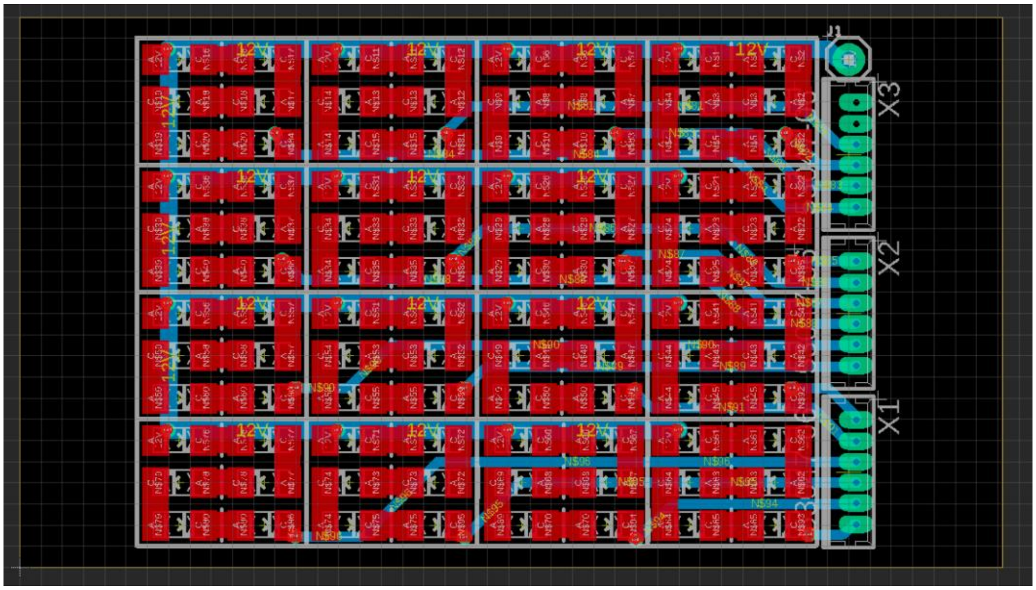


Figure 5.4: LED panel circuit

Figure 5.5: Assembled LED panel

The final board dimension was 25.6 mm x 19.2 mm, resulting in an 8 x 12 grid of LEDs. These are further divided into another 2 x 3 subgrid, for a total of 16 subgrids (Figure 5.5).

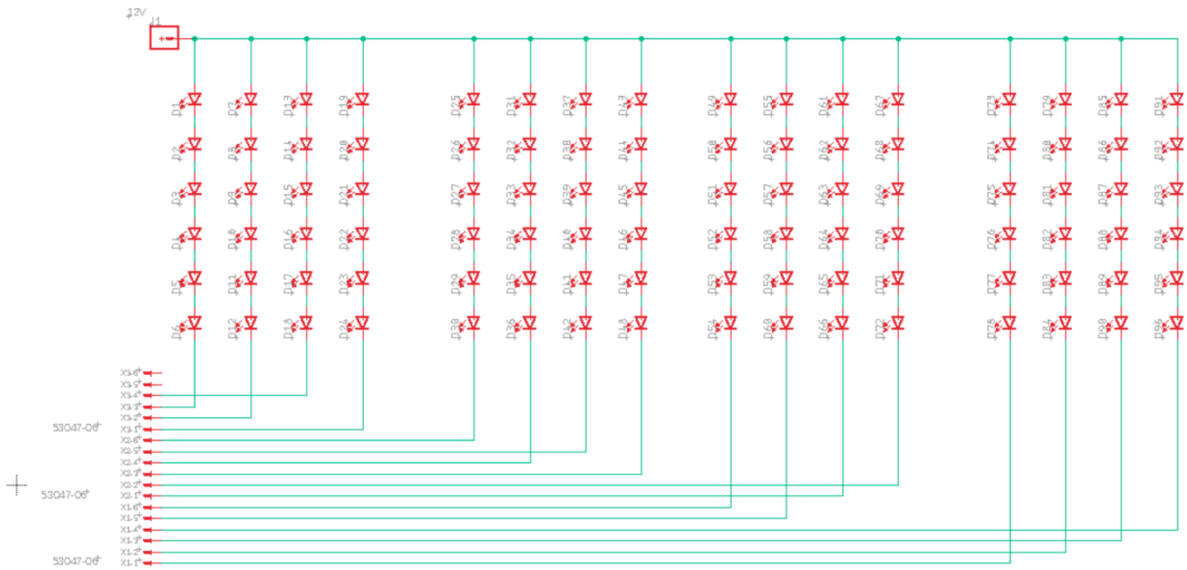


Figure 5.6: LED panel schematic

The LED panel receives 12V and splits it in parallel to 16 power lines, each corresponding to a subgrid and containing 6 LEDs in series (Figure 5.6). With a voltage drop of 1.3V each, there is a total 7.8V drop at every power line, and the 4.2V remaining voltage could support 3 more LEDs in each subgrid. If this were implemented in a 3x3 subgrid array for the 9 LEDs, it would have a physical dimension of 9.6mm x 4.8mm.

The panel is powered with 12 V which is delivered through a single through hole connection. In the future this may be replaced by some connector type. The LED cathode pins (12 V return) are connected through four 1.25 4 pin connectors. The board is routed in two layers with a large ground plane on the back for heat distribution. The back side of the panel is clear to allow for maximum surface area for heat sink placement.

5.3: Hardware

5.3.1: LED Driver

Since the LED panels only serve to distribute power, the LED driver is responsible for setting which LEDs are on or off. The LED driver was designed to deliver constant current to 16 channels, OUT0-OUT15 in Figure 5.7. Each of these corresponds to a channel of 6 diodes on the LED boards.

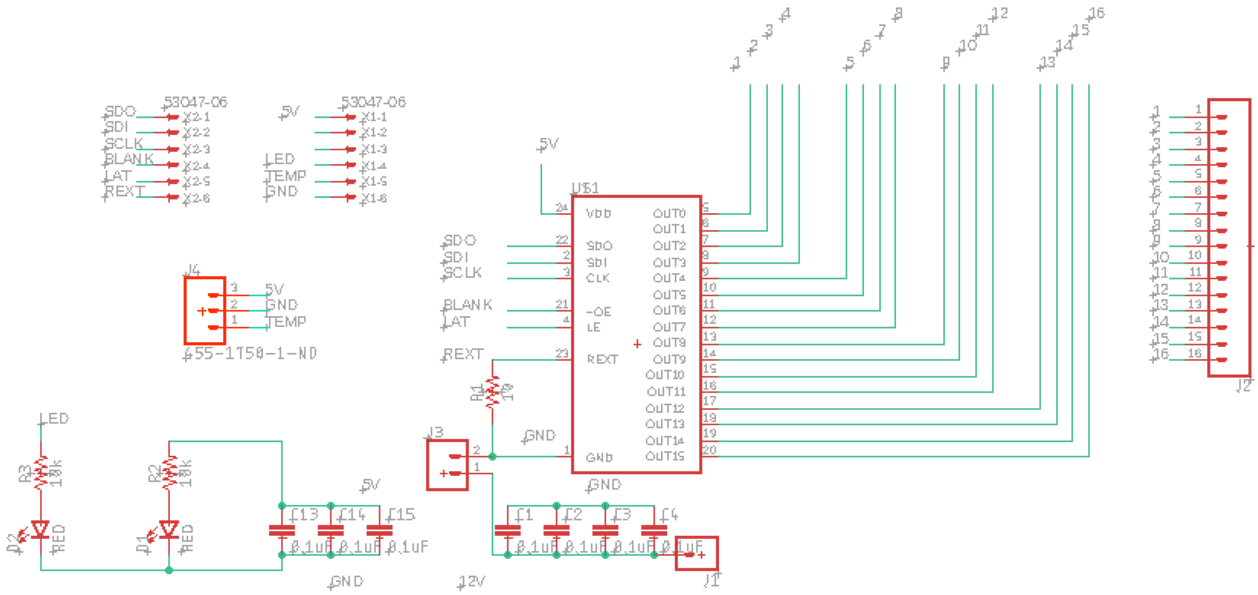


Figure 5.7: LED driver schematic

The physical layout of the LED driver, shown in Figure 5.8, was chosen to fit between the electrodes, resulting in a dimension of 50.6mm x 50.6mm.

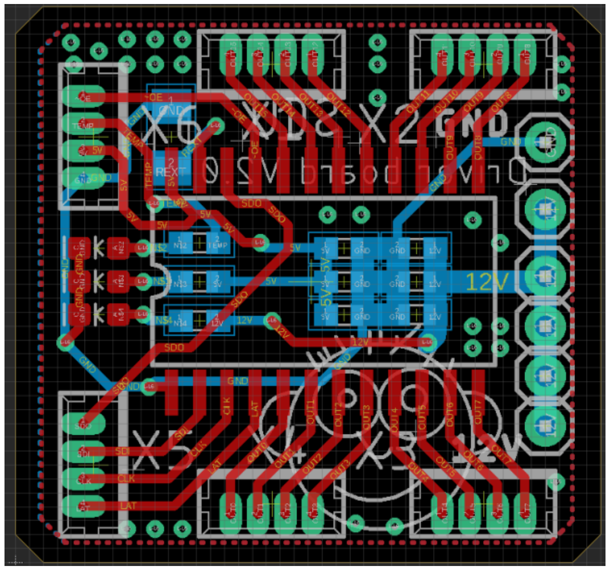


Figure 5.8: LED driver layout

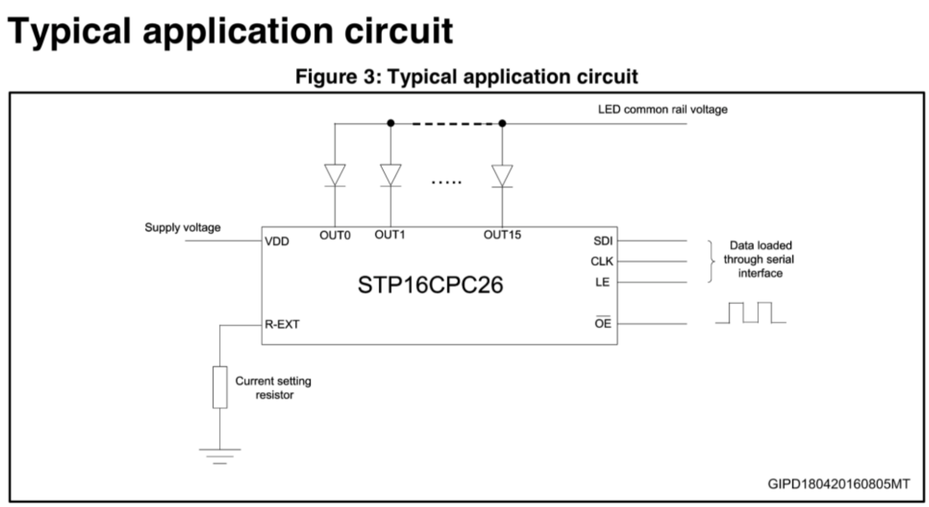


Figure 5.9: 16 channel shift register LED driver

The integrated circuit (IC) that was used, shown in Figure 5.9, was selected from a family of 16 bit shift register LED drivers that are somewhat standardized across the industry. Due to the ongoing chip shortage it was difficult to find parts that meet the project specification. As of now the part that was used for this project is no longer available so if more drivers need to be made in the future a new IC will need to be chosen that is available in the necessary quantity and fits the project specifications.

5.3: Top Board

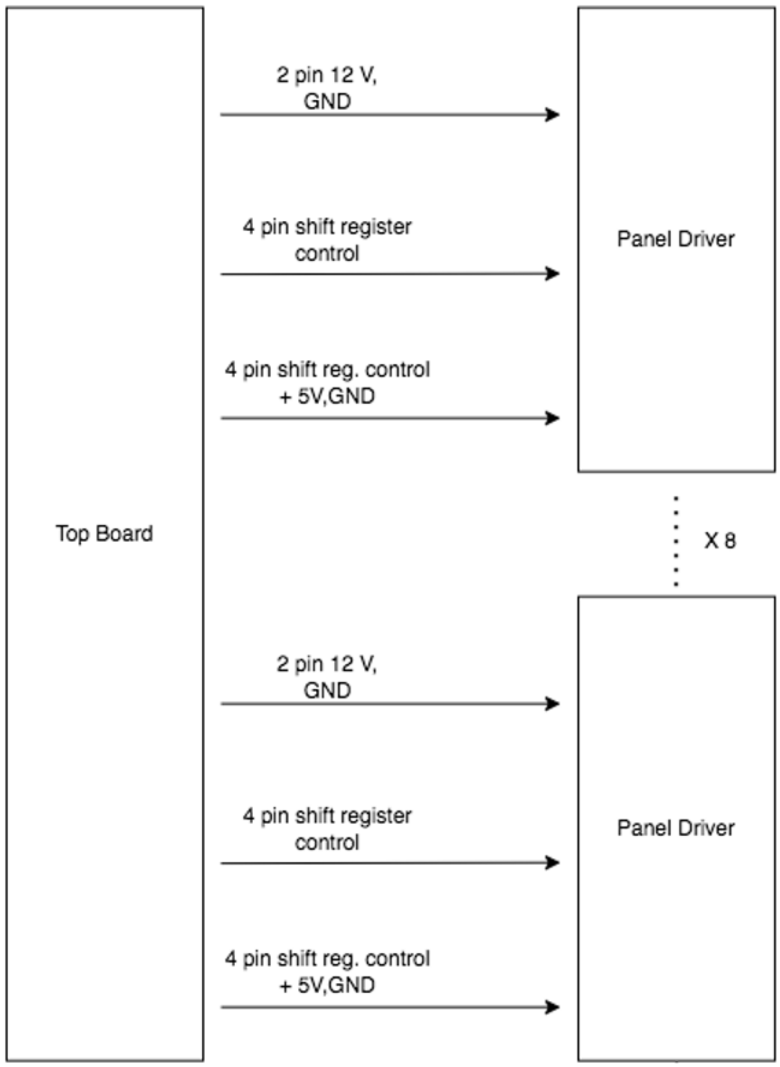


Figure 5.10: Board to panel connections

Due to the limited number of voltage output pins on the Arduino, they are not connected directly to the drivers, but rather to two top boards, each of which can then distribute power to eight drivers, as is implied in Figure 5.10. The top board has connections for 5 V, ground and the shift register signal pins (Figure 5.11). The brightness is set through an SPI protocol to control onboard PWM signal generation.

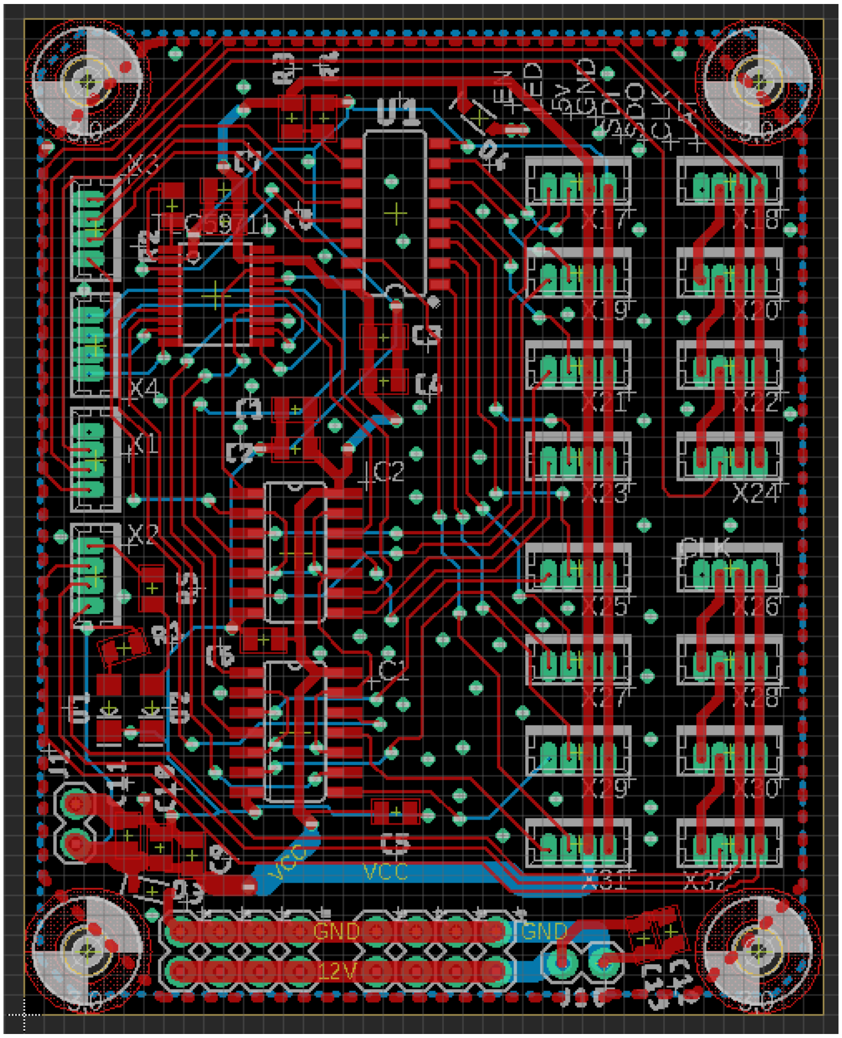


Figure 5.11: Top board layout

Chapter 6: Subsystem 4: Control System

6.1: Overview of Subsystem

At a general level, a control system tries to make a measurement match a desired value. Here, the measurement comes from the Focus Widget's relaxation metric, extracted from the EEG. The goal is to maintain the metric above a specified value.

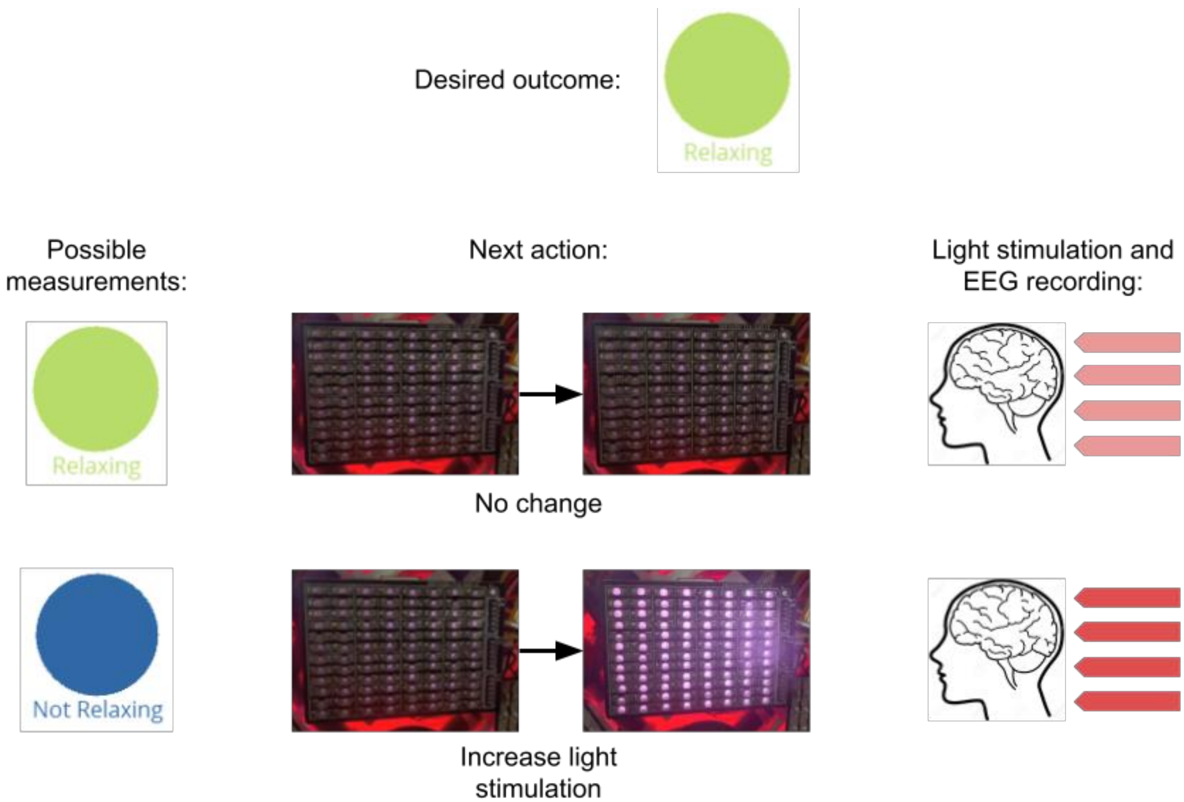


Figure 6.1: Subsystem Diagram

The task of this control system is to both decide and implement the next action needed to accomplish this state. From collecting data from the Focus Widget to adjusting the light stimulation, the control system includes the Processing sketchbook, the LED boards, and all intermediate components. Figure 6.1 illustrates how this would be applied to the light stimulation control system.

6.2: Software Data Flow

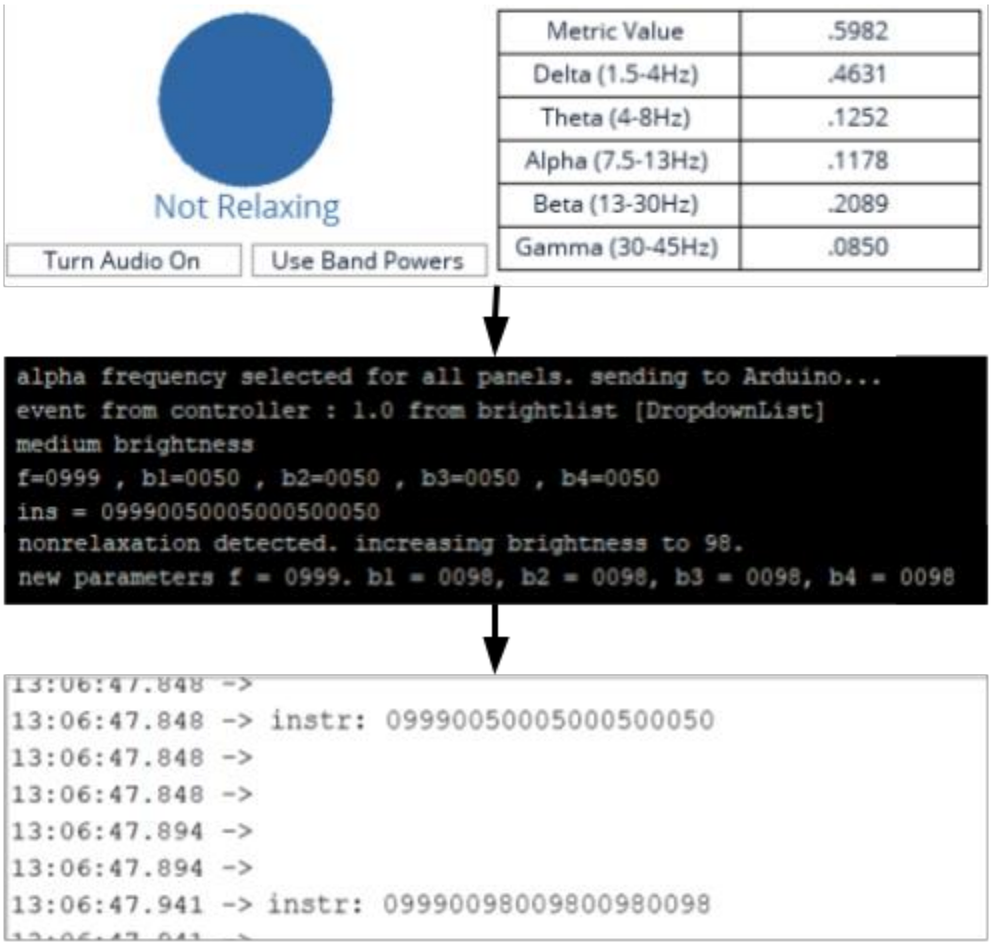


Figure 6.2: Data flow from OpenBCI, Processing, and the Arduino on headset

To take input from the Focus Widget, create the user input with an adaptive element, and send the light stimulation instructions to the headset, there are multiple programs involved, hence a "software data flow" (Figure 6.2).

At the start of the device operation, the intensity of the light stimulated is selected by the user. Once the EEG is processed to the biomarker metric, the initial stimulation intensity is overwritten with a higher value (98%), with the intention that this greater stimulation intensity will lead to alpha entrainment measured by increased absolute alpha power across electrodes.

6.2.1: EEG Processing to Light Stimulation Settings

In OpenBCI, there are choices for both the type of data to transfer as well as with the networking protocol to use. This information is published as it is needed so that the matching data type can be specified in code. The data format varies according to the type of data being transferred as well as the capabilities of the networking protocol, as depicted in Table 6.1. For instance, sending out FFT over OSC uses a datatype of an array of 125 float values for each channel. On the other hand, the Serial communication protocol cannot transmit FFT due to data limitations.

Data Type	Output by Protocol Mode			
	OSC	**UDP**	**LSL**	**Serial**
Time Series (Filtered & Unfiltered) One float for each channel	Data as floats for each channel, sent all at once	{“type”:”eeg”,“data”:[DATA]}\r\n	Data as floats for each channel	Data as floats to 3 decimal places surrounded by brackets
	0. 1. 2. 3.	{“type”:”eeg”, “data”:[0.0,1.0,2.0,3.0]}\r\n	0. 1. 2. 3.	[0.000,1.000,2.000,3.000]
FFT 125 floats, one for each bin, per channel For now, each bin represents a frequency band. Ex.: Bin 0 = 0-.9765625Hz	Channel Number followed by floats for each data bin (125 bins total), sent sequentially	Type “fft” with 125 floats for each channel surrounded by brackets and comma separated	125 floats, one for each bin, per channel	***Disabled***. If you select FFT while using Serial, it will auto-switch to use Band Power instead. It’s too much data for Serial.
	1 0. 1. 2. … 124.	{“type”:”fft”, “data”:[[ch1 bins],[ch2 bins],[etc. bins]]}\r\n	0. … 124. 0. … 124. etc.	[1,0.000,etc.,124.000][2,0.000,etc.,124.000]...
Focus One float or integer, varies by data type	0 - not focused, 1 - focused	Type “focus”, 0.0 - not focused, 1.0 - focused	One float, 0.0 - not focused, 1.0 - focused	String output ending in newline character
	1	{"type":"focus","data":0.0]}	1	1\n or 0\n

Table 6.1. OpenBCI Networking Outputs[24]

For this project, the Focus Widget was selected, utilizing the OpenBCI GUI’s EEG analysis. As shown in Table 6.1, the output of Focus Widget sent via OSC sends in an integer value of 0 or 1, and this binary value is directly used in a conditional statement to activate the adaptive element. Specifically, a value of 0 indicates a below threshold relative alpha power for the given time frame, prompting the increased intensity of light stimulation, the effects of which should be measurable after 5 minutes. After this time, the Focus Widget output is observed again to evaluate whether this new intensity is sufficient or needs to be further increased.

6.2.2: Light Stimulation Settings to Computer Arduino

Processing 3 connects the results of the OpenBCI Focus Widget at alpha frequencies to the next frequency and intensity parameters for the light stimulation, which is first picked up by the transmitting Arduino connected to the computer. The instructions can also be decided by the user in the GUI, with either selectable preset values or text options for a granular range. These are sent through the Serial protocol, which can communicate a single byte or an array of bytes in the form of a string or buffer. As a whole, these instructions need to assign a frequency value and brightnesses for each of the panels. Although these are consolidated into one message, the individual instructions are kept separate from each other in the format which will be discussed in section 6.2.4.

6.2.3: Computer Arduino to Headset Arduino

Since the instructions have already been composed in Processing 3, these Arduinos are mainly responsible for sending the instructions to the headset. As shown in Figure 6.1, the Arduino connected to the computer, RF-Tx, makes no changes to the message, while the Arduino connected to the headset, RF-Rx, parses this data, converts it into integers, and splits these integer values into the corresponding driver board (Figure 6.3).

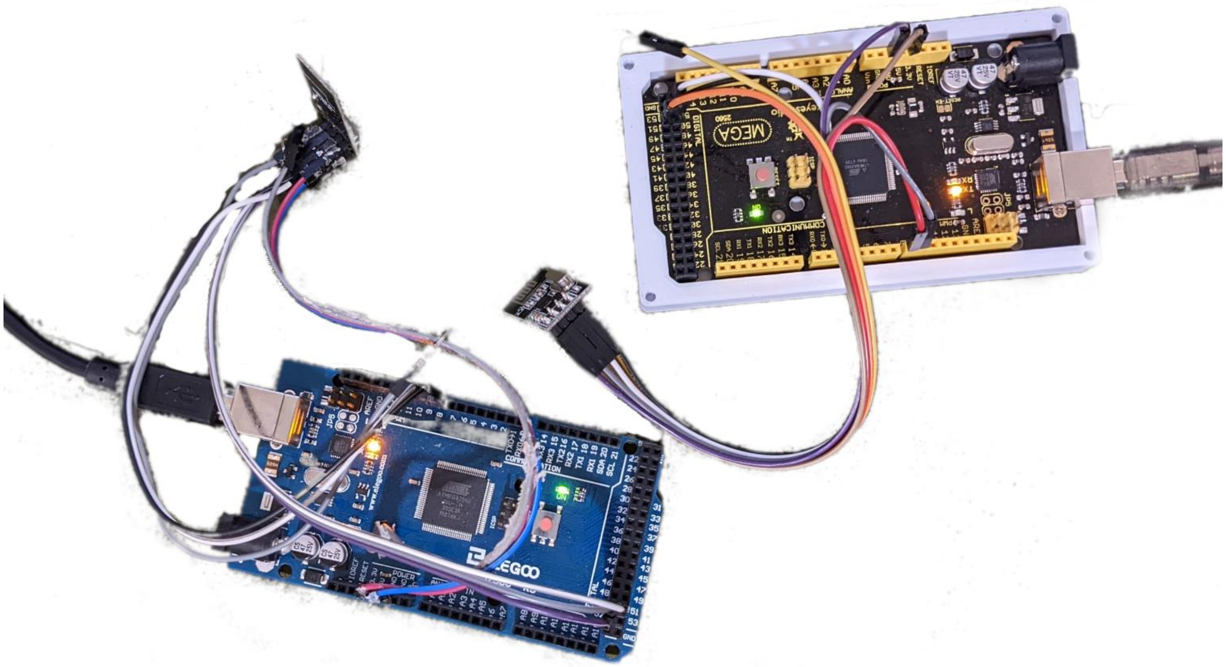


Figure 6.3: Tx and Rx Arduinos, both with nrf2401 modules connected. Outside of the frame, they are connected to the computer and headset

6.2.4: Driver Message

Although the changes across the PBM do not have to occur synchronously, sending the instructions in a combined message would reduce timing issues. Additionally, one message would be simpler to verify and understand across the data pipeline mentioned from 6.2.1.-6.2.3.

Figure 6.4: 10 Hz, 50% brightness

In Processing 3, the manual text input prompts the user to enter in a float data type for frequency values of 0.1-100 Hz, with increments as small as 0.1 Hz. This range is mapped to 0-9999 by multiplying the value by 10 and subtracting by 0.1, meaning that 100 Hz is encoded into “9999”. The decimal point is also removed in the conversion.

For each parameter, this format allocates a character for each of the 4 digits of a decimal, creating up to 10,000 unique values. This instruction is packaged as an array of characters, using a character to represent each digit. In memory, a character occupies 1 byte, and with 20 characters, the entire instruction uses 21 bytes, with an additional byte for the terminating null character of a string. An example message is shown in Figure 6.4.

The maximum transmittable instruction length using the RF modules between Arduinos is stated as 32 bytes in the RF24 documentation, and verified by sending a long string. This means that up to 32 characters could be transmitted, which would allow for at most 8 brightness adjustments with this format.

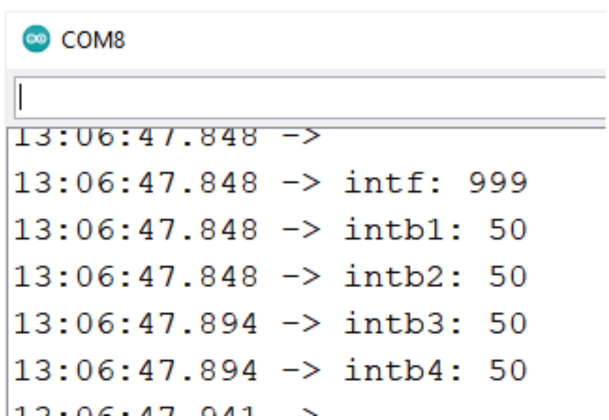


Figure 6.5: Instructions Parsed at the Rx Arduino

Because the Serial port at the RF-Rx is unused, the serial monitor can display the information as it is received or what is sent to each of the drivers, shown in Figure 6.5. With the long data pipeline, this serves an important debugging feature in determining whether an unintended light stimulation pattern is the result of data transmission or hardware connections.

Chapter 7: Testing

7.1: Benchtop Testing

For the first-generation prototype of the NeuroGen: EEG and Near-Infrared Light Stimulation device, the team conducted preliminary testing of the functional requirements. To support the design assumptions, the device must complete the four main functions listed in our Device Objectives and Requirements section. These simultaneous functions are: (1) LED modules deliver light stimulation treatment, (2) EEG detects and records brain activity, (3) the control system analyzes real-time changes, and (4) the User Interface adjusts the intensity of the light therapy.

Recording of EEG with the OpenBCI system for 16 channels produced unreliable data streams across channels. First, channels are frequently railed due to pin instability or poor contact with the scalp. The pins of all 16 channels are located on the back of the headset, causing stress on the wires that connect with the pins. We optimized the arrangement of the wires so that the farthest wires connected to pins on the top of the amplifier and the closet wires connected to the pins on the bottom. This resulted in less stress on the wires and more pin stability. We were able to get clean (not railed) recordings for a number of channels. The processing and analysis led to reproducible metrics in the focus widget.

While these functions successfully perform on their own, the integration of the LED modules, cooling system, and EEG resulted in unexpected noise issues. For this reason, we had to shift our testing from proof to concept to determining the source of noise activity. We focused on benchtop testing, operating the electronics on the headset without being placed on a human subject. With this method, we were able to troubleshoot the cause of the noise without the variability of real brain activity. The main goal of this testing was to find the source of the noise so that the integration of the subsystems can be resolved in the future and the proof of concept can be achieved.

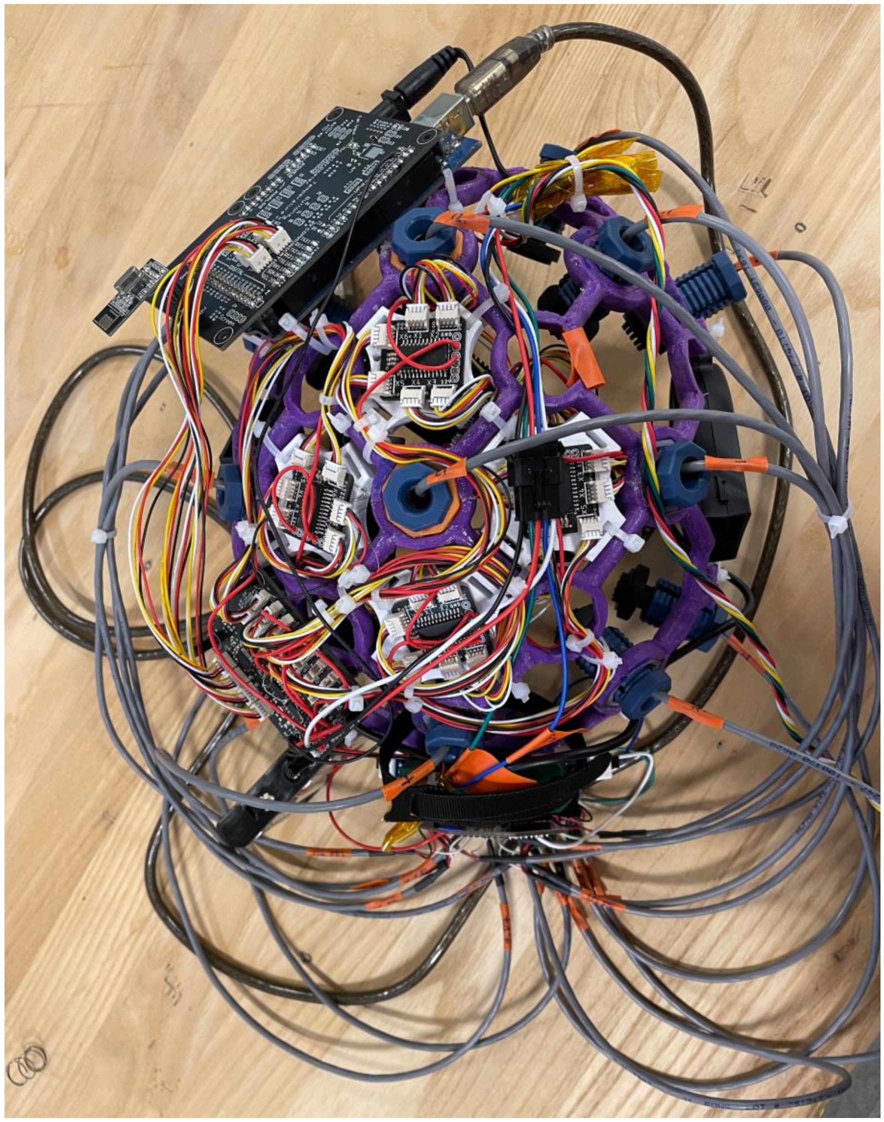


Figure 7.1: Device with Arduino Controller Attached

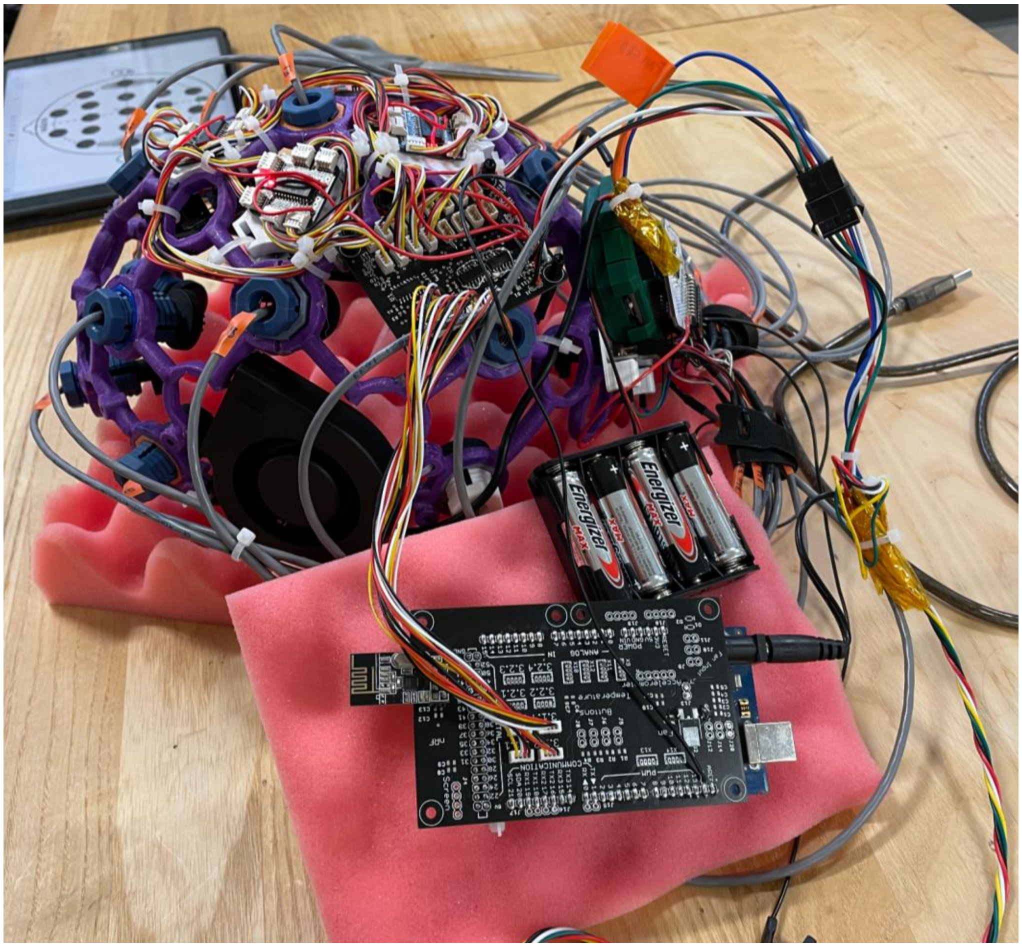


Figure 7.2: Device with Arduino Controller Detached

Before testing, the team identified these possible causes of the noise:

- The close proximity of the helmet and/or the fans to the Arduino controller, whose on-board circuitry and RF module could have electromagnetic radiation
- The LED driver, which could be dissipating power that interferes with the signal detection of the electrodes
- The vibration of the fans, which could shake the parts inside the electrode, leading to incorrect data collection

To determine which of these led to noise, we isolated these components and ran benchtop tests for 6 different conditions: (1) EEG ON, (2) EEG + Fans ON, (3) EEG + LED Power (Arduino

Attached) ON, (4) EEG + Fans + LED Power (Arduino Attached) ON, (5) EEG + LED Power (Arduino Detached) ON, and (6) EEG + Fans + LED Power (Arduino Attached) ON.

7.1.1: Test #1 EEG ON

The first test is to have the EEG system on, the LED power off, and the fans off. Because the electrodes are not placed on a human subject, the expected outcome is that there is only low-frequency electrical activity picked up. The time series widget should show flat lines and/or lines with minimal peaks for each electrode. As shown in Figure 7.3, the outcome of our experiment shows no harmonic interference, and therefore, it can be used for baseline comparisons of other tests. Each electrode had a flat or almost flat line. As shown in the time series, most of the electrodes are "Not Railed" which means that the output signal is not clipped. Railing often indicates that the signal is high voltage noise. Our experiment with the not-railing signals indicates that there is no issue with the electrodes or signal processing itself. It is likely disrupted when the fans, LED power, or both are on.

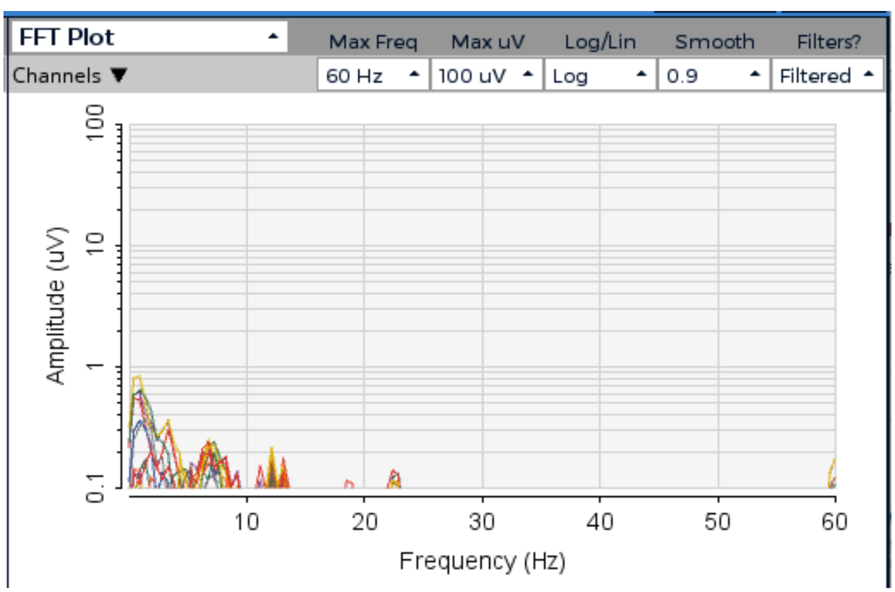


Figure 7.3: Results of EEG ON

7.1.2: Test #2 EEG + Fans ON

The second test is to have the EEG and Fans on. From this test, we saw some electrodes railing on the time series widget. As shown in Figure 7.4, the FFT plot shows peaks at 27 Hz and 48 Hz. There is a clear disruption in the electrode signal detection due to the fans. The issue appears to be global as the electrodes that are railing are in random areas on the headset, likely caused by the magnet of the motor of the fans. This railing can be resolved by reducing the electrode amplifier gain. For the current iteration of the project, this noise does not interfere with the frequencies of interest, the alpha band of 8-13 Hz, and the noise can be filtered out. However, if this headset would be used to analyze gamma frequencies from 38 Hz to 42 Hz, then the noise can not as easily be filtered out, thus needing a different cooling configuration.

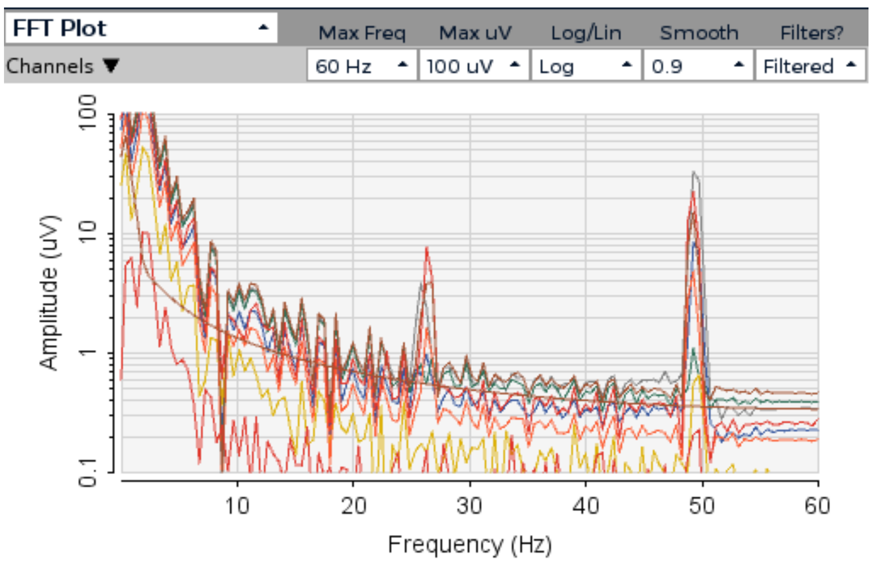


Figure 7.4: Results of EEG + Fans ON

With the source of the 24 Hz harmonic found, the next step was to determine the cause of the 10 Hz harmonic. The initial hypothesis for the was that it was radiated from the Arduino, and therefore should be eliminated by detaching the Arduino from the headset.

7.1.3: Test #3 EEG + LED Power (Attached) ON

The third test is the EEG and LED power (attached) is on. There is a 10 Hz interval of peaks, unrelated to the 10 Hz stimulation frequency of the LEDs (turned off). The primary wave is in-phase and the secondary wave appears summative.

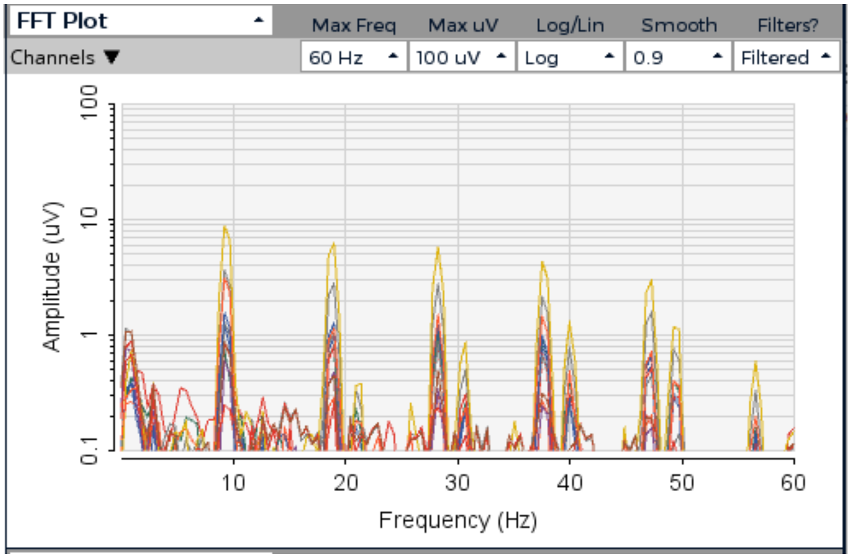


Figure 7.5: Results of EEG + LED Power (Attached) ON

7.1.4: Test #4 EEG + Fans + LED Power (Attached) ON

The fourth test is when the EEG, Fans, and LED Power (attached) are on. Figure 7.6 shows the combination of fan and panel power noise, confirming that these peaks are independent of each other.

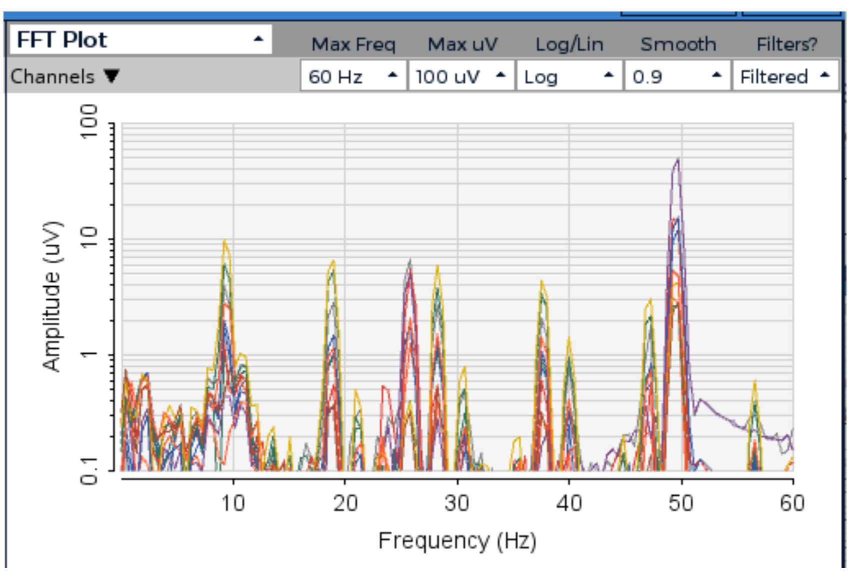


Figure 7.6: Results of EEG + Fans + LED Power (Attached) ON

7.1.5: Test #5 EEG + LED Power (Detached) ON

For the fifth test, we tested with the EEG and LED Power on, and the Arduino controller detached from the headset. The 10 Hz noise still occurred, ruling out the theory that it came from nearby electromagnetic radiation and meaning that it had to do with the power that was passing through the Arduino. However, it was uncertain whether the noise was caused by the Arduino or any of the other items in the electrical path, and we began considering that it may be caused by the 12V, 5V, or both power supplies. Figure 7.7 is with a 12V power supply on.

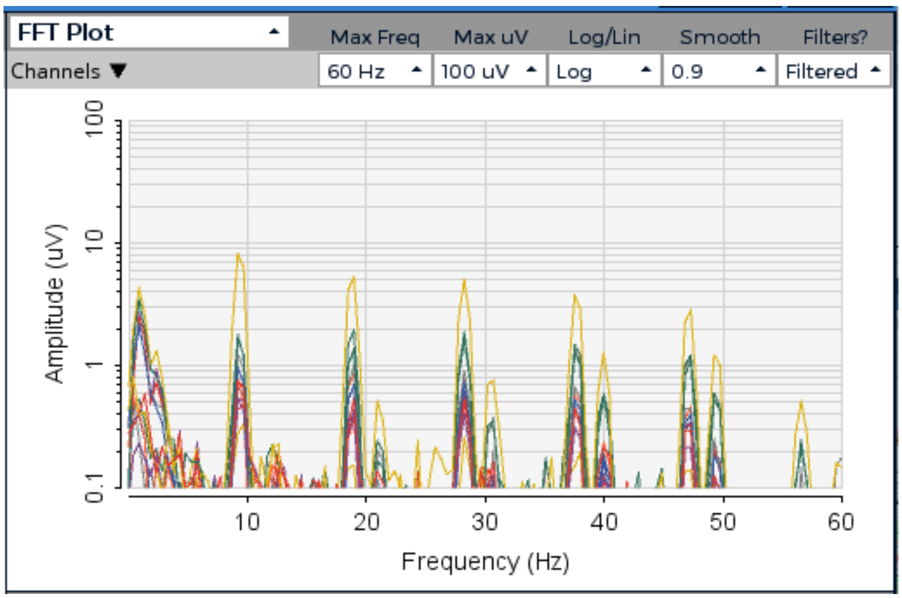


Figure 7.7: Results of EEG + LED Power (Detached) ON (12V)

Figure 7.8 is with a 5V power supply on. There appears to be a 10Hz interval of peaks, primary in phase, and secondary appears summative for testing with a 5V power supply.

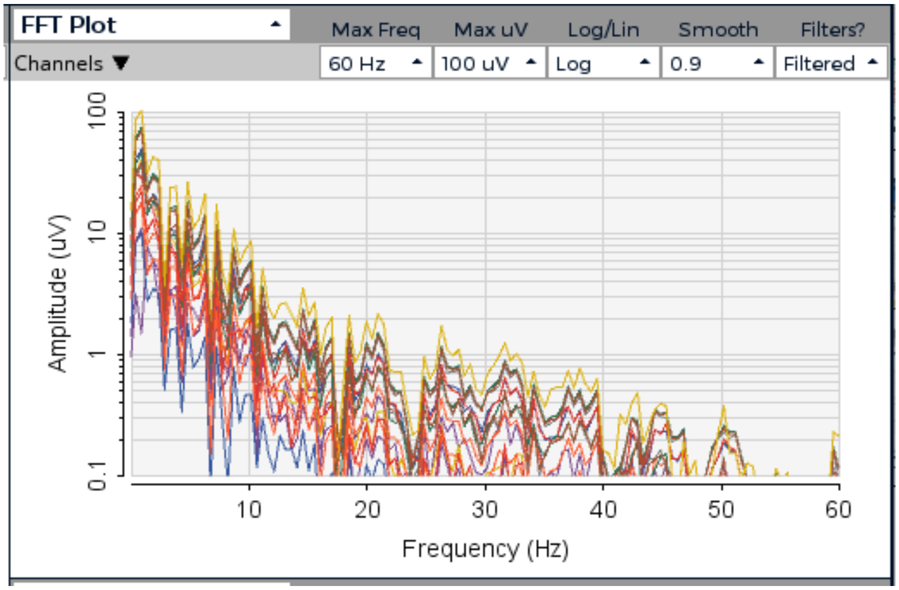


Figure 7.8: Results of EEG + LED Power (Detached) ON (5V)

7.1.6 Test #6 EEG + Fans + LED Power (Detached) ON

The sixth test, we tested with the EEG, Fans, and LED Power on and the Arduino controller detached. The 48 Hz peak is present. Figure 7.9 shows that the 24 Hz and 48 Hz are caused by the fans.

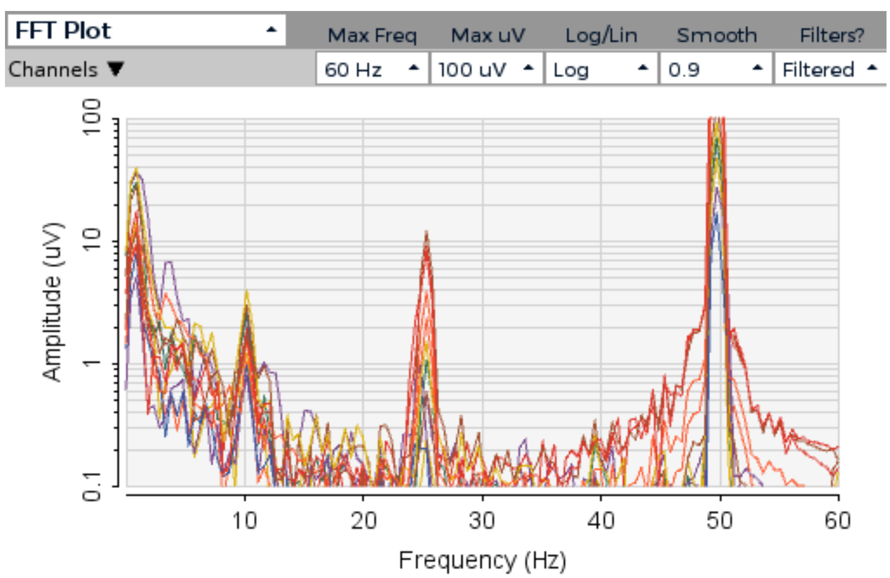


Figure 7.9: Results of EEG + Fans + LED Power (Detached) ON

7.2: Summary of Results

Equipment						
LED Power Source					Noise	
12V	5V	AC outlet	Arduino	Fans	10Hz	24Hz
.	.	.	.	.	.	.
✓	.	.	.	✓	.	✓
✓	✓	.	✓	.	✓	.
✓	✓	.	✓	✓	✓	✓
✓	.	.	✓	.	✓	.
.	✓	.	.	.	.	.
✓	.	.	.	✓	.	✓

Table 7.1: First Test Results

Benchtop testing of the fully powered, integrated system revealed interference between the electronics and the EEG recording. After arranging these test results into Table 7.1, we confirmed that the fans were responsible for the 24 Hz harmonic noise and that the 10 Hz noise can be attributed to the Arduino.

The concern about the battery packs prompted the second phase of testing, where we tested whether harmonics at 10 Hz and 24 Hz can be eliminated using different power sources while keeping the Arduino and fans powered on.

The 12 V battery pack and the 5 V battery pack were replaced with a wall AC outlet and laptop USB power source, respectively. The tests with the battery packs were also repeated, leading to the following conditions: (1) 12V off + Arduino unplugged + 5V to drivers turned on, (2) 12V off + Arduino on (USB connected to 5V) + 5V to drivers on, (3) 12V from the battery pack + 5V to drivers on, (4) 12V from wall outlet + 5V to drivers on, (5) 12V from the battery pack, (6) 12V from the wall outlet, (7) 12V from wall outlet + Arduino on (USB connected to 5V).

Equipment					
Battery Packs		New Power Sources			Noise
12V	5V	12V AC outlet	5V Laptop USB	Arduino	10Hz
.	✓	.	.	.	.
.	✓	.	✓	✓	✓
✓	✓	.	.	.	.
.	✓	✓	.	.	.
✓	.	.	.	.	.
.	.	✓	.	.	.
.	.	✓	✓	✓	✓

Table 7.2: Second Test Results

Since the 5V powers normally power both the Arduino and LED drivers, tests were done with each of these. Using the same procedure and compiling these results into Table 7.2, it was confirmed that the 10Hz noise came from the Arduino, and not any of the power supplies. Next, the team investigated the circuitry in the Arduino and discovered that there is a 10 Hz cutoff fuse in the Arduino, which activates when drawing more than 500mA of current.

7.3: Possible Explanation for Testing Errors

Noise could be caused by hysteresis feedback from the current limiting fuse on the Arduino. When too much current is drawn the fuse opens up causing a voltage spike and shutting down the system. When the system is off the current is zero so the fuse resets and the system turns on again. This process repeats continuously at a constant frequency. Harmonics can be seen at 12 Hz, 25 Hz, and 50 Hz. The frequency is set by the delay time of the fuse, the current draw of the system, and the temperature. The fans are also a potential source of noise, as they contain metallic coils which can act as inductors in the presence of electromagnetic waves.

Since the cutoff fuse is a known feature of the Arduino, the unexpected portion had to do with how this noise fed through the control and LED boards, as the Arduino did not supply the power for these boards, but rather provided signals to determine which of the LEDs would turn on, and by how much. Looking at the circuit diagram for the control boards, it was found that the wires for signal and power were directly connected, so the Arduino actually ended up supplying power and drawing enough current to activate the cutoff fuse. For a future revision of this project, a resistor would need to be placed between these signal and wire connections to prevent this power draw.

This project looked at alpha frequencies at 8-12 Hz, meaning that the Arduino noise would lead to interference while the fan noise at 24 Hz would not, and can be filtered out. However, if this project were to continue and look at beta frequencies at 12-30 Hz, then a revised cooling system would be needed, either using fans with a different noise frequency or an alternative cooling method entirely.

Chapter 8: Professional Engineering Standards and Realistic Constraints

8.1: The Ethical Justifications of Light Stimulation and Personal Data Collection

Light stimulation or tPBM is a noninvasive therapeutic tool that can help improve memory, sleep, and cognitive functions of patients, especially patients with neurodegenerative diseases. tPBM has been described as “brain modulation” which seems intimidating and may deter people from using our device. Our device does not negatively affect the brain, it restores tissue regeneration and enhances cell function. It is non-invasive and the personalization of the device ensures that the therapy serves the user in the best way it can.

Although we have not collected personal data, we have planned out how we would collect private health information. Brain activity data cannot be tied back to the participant. The data will be stored on the private Google Drive that will be encrypted with password protection. Only project team students and faculty will have access to the Drive. The data will be used in Senior Design reports and theses and scientific publications in aggregate form only. Consent forms will be signed by all participants before they begin the study.

8.2: Health and Safety Implications

When functioning as expected, this device has no risk to safety but may have some level of discomfort. There is no significant risk because all the devices and procedures used may be operated within safety requirements. Both EEG and PBM are class II exempt medical devices by FDA classifications. We sourced our headset design and EEG system from OpenBCI. Discomfort may be experienced by the user when having the device mounted on the head for a prolonged period of time. The contact of the electrodes of the device can be adjusted for each person to maximize comfort. There could be some heat discomfort from the tPBM therapy, but it can be controlled and reduced. Safe stimulation for wavelengths 800 to 900 nm has a power density of less than 750 mW/cm^2[6]. There is a heat risk with the current design. If the fans are not used, then the surface temperature exceeds the safety limits for medical devices. The limit is 43 degrees Celsius and the heat sinks alone only bring it down to 47 degrees Celsius.

8.3: Sustainability as a Constraint

Sustainability is a constraint for the building of our device. Our device relied heavily on 3D printed components. For example, our wireframe headset, the shell covering, and the cover for the amplifier were all 3D printed. The biggest challenges with 3D printing were the plastic waste, such as failed and obsolete prints and support material. This is a challenge that could be overcome by using more sustainable and environmentally friendly materials to 3D print our components. Other components of our design also produced some waste. When creating the LED arrays, incorrect amplification caused LEDs to become unviable.

One way we were environmentally conscious was we used epoxy to attach our headset components together. Epoxy is environmentally friendly because it is made of organic materials.

8.4: Civic Engagement and Compliance with Regulations

The medical device industry is heavily regulated and medical devices must be compliant with those regulations in order to reach patients. Brain photobiomodulation devices like Vielight are not FDA approved because the FDA classified these devices as low-risk general wellness devices, per “General Wellness: Policy for Low Risk Devices” on the FDA website [25]. EEG devices are classified as Class II devices because they have a moderate risk. Our device would be classified as a Class II device, which will require clinical testing, unless it is approved under 510(k) review. 510(k) reviews are for new devices that are substantially equivalent to an existing device. However, our project is the first-generation prototype, it is not intended to be used by patients yet. We hope with the continuation of research from this project will produce an efficient and effective form of therapy for patients with neurodegenerative diseases. Which then a device can be marketed and undergo the process of FDA approval.

8.5: Manufacturability

The manufacturability of this device is something that could be improved. Currently, our device is quite complex with multiple subsystems, each with its own specifications for components. Since each subsystem is connected to produce our prototype, supply chain issues with any of the components could pose a challenge to the manufacturability of this device. Furthermore, multiple components of the device including the wiring of the electrodes to the amplifier and the attachment of components to the wireframe headset is best done manually to avoid the damage of other components on the device. Having to attach components of the device manually makes it difficult to automate the manufacturing processes and decreases the efficiency of manufacturability.

8.6: Budget Constraints

Our Senior Design team and the MECH team collectively received funding from Santa Clara University Undergraduate Programs Senior Design Grants and the Bioinnovation and Design Lab. We were awarded $2,500 from the Bioinnovation and Design Lab. And we were awarded $3,500 from the Undergraduate Programs Senior Design Grants. In total, we received $6,000 and spent $3,041.09. Thankfully, we did not experience budget constraints. More details are listed in Appendix A.

8.7: Time Constraints

The main time constraint was with the global supply chain issues, particularly the semiconductor shortage. The original goal for this project included a diode specification of a 1070nm frequency, which would have been manufactured and shipped internationally from EpiGap GmbH in Germany. We decided to cancel this order because of process challenges with wire transfers, 8-week production lead time, and international shipping intervals. We decided to go with another vendor, but with an order sent out in January 2022. In February 2022, we discovered these were expected in August 2022 and canceled the order. We resolved this order issue by purchasing the current 850nm diodes from Digi Key, which were readily available locally. The change in the diode model did not make us expect a reduction in performance, but rather a need to modify light intensity parameters based on the 850 nm wavelength.

Chapter 9: Summary and Conclusion

9.1: Summary of the Project

At the end of this school year, our interdisciplinary team was able to complete a prototype of our NeuroGen: EEG and near-infrared light stimulation device. We built and are able to control over 4 operational LED panels for light stimulation therapy. We have also built a data pipeline from the OpenBCI platform over to the helmet. Lastly, we have obtained EEG recordings for 16 channels successfully.

9.2: Future Work

Our team made tremendous progress working on this project over the past 9 months. However, there is still more work to be done.

A main short-term goal for future work is to continue testing the device and the control system. While performing the tests, it would be beneficial to look at the effects of the fans and LED arrays on the EEG signal. Another short-term goal is to make the control system more complex with further parameter control. An example of this is localized LED array adjustment in relation to the EEG heatmap. Another short-term goal is that we can add bidirectional communication to relay circuit error messages to the computer. Lastly, another short-term goal is to develop a custom widget that can be coded on the OpenBCI platform for visual outputs of the control system for ease of use.

A main long-term goal for future work for this project is to find an amplifier with 19 or more channel support. This would allow us to compare the device to standard EEG devices and utilize a normative database. Another long-term goal would be to reuse our design and replace the 850 nm diodes with 1070 nm diodes, which is our primary wavelength of interest. Lastly, another long-term goal would be to test an entrainment protocol to make sure the light stimulation therapy is actually reaching the scalp and producing changes in brain activity that would be reflected on the EEG signal.

9.3: Lessons Learned

Working on this Senior Design project was truly a rewarding experience. Our team learned about the benefits and challenges of working on a large, interdisciplinary team. We encountered difficulties with project management and effective communication among team members and all of our sub-teams. However, it was invaluable to be able to work with engineers from different disciplines to troubleshoot through roadblocks in the project. Everyone brought different expertise to the project, and we could not have made this much progress without everyone's time and effort.

Through this project, we gained so many skills that we can take away with us in our lives post-graduation. We learned how to code using Processing to modify the OpenBCI platform. We found that the brain-computer interface community is large and that forums are a great way to get answers to questions and roadblocks that may come up during a project.

Lastly, we also learned a lot about the growing field of brain-computer interfaces. Working on this project was the first time that many of us encountered light stimulation therapy, electroencephalography, OpenBCI, and closed-loop control systems. We had a large learning curve, but with a focused literature review, in-depth reading of many articles, and discussions with our project manager and faculty advisors, we became well-versed with the majority of the background needed to work on this project.

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