WEARABLE NEAR-INFRARED SPECTROSCOPY DEVICE FOR ACUTE ORTHOPEDIC TRAUMA

A Major Qualifying Project
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ABSTRACT

Acute Compartment Syndrome (ACS) is a musculoskeletal disorder characterized by abnormally high levels of pressure within a muscle compartment, leading to a critical disruption of the local blood circulation. Although the current methods are effective at diagnosing ACS, they have limitations such as invasiveness, time consumption, and high cost. As an alternative, near-infrared spectroscopy (NIRS) has emerged as a noninvasive technique to quantify blood oxygen levels by detecting light-intensity changes through tissue. This project aimed to develop a wearable NIRS device for detecting ACS. The final design consisted of a Raspberry Pi and a PCB with LED emitters and detectors to measure real-time hemodynamic changes, which led to information for identifying abnormal muscle pressure. Design verification proved that NIRS is a viable alternative technique to detect changes in muscular pressure and has application for ACS.

ACKNOWLEDGMENTS

The team would like to thank Professor Yihao Zheng and Ge Zhu for their support and guidance in this project. The team would also like to extend our gratitude to Barbara Furhman and Lisa Wall for their assistance in purchasing for this project. Lastly, the team thanks the Mechanical Engineering Department, the Biomedical Engineering Department, the Robotics Engineering Department, and Worcester Polytechnic Institute for their help throughout the project and during the team's undergraduate education.

TABLE OF CONTENTS

List of Figures

List of Tables

AUTHORSHIP

All project members contributed equitably to this report's writing, editing, and formatting. The team split chapters into sections and subsections for individuals to write and then edited collaboratively. All members also contributed to designing the physical device and conducting experiments to validate the device's functions and objectives.

EXECUTIVE SUMMARY

Acute Compartment Syndrome (ACS) has emerged as a significant concern, prominently affecting individuals in high-stress environments. Considered a medical emergency, ACS is a musculoskeletal disorder characterized by a sudden reduction in blood flow or a restriction to the heart's blood supply, specifically occurring within the compartments of muscles. This condition arises when the pressure within the compartment reaches abnormally high levels, leading to a critical disruption of the local blood circulation. Without treatment, ACS can lead to several complications, such as contractures, rhabdomyolysis, nerve damage, renal failure, ischemia, and eventually necrosis. Despite existing preventive and diagnostic methods, limitations pose challenges for patients, such as invasiveness, comfortability, and cost [1].

This project aims to develop a wearable, noninvasive optical technology leveraging near-infrared spectroscopy. This technology aims to prevent the onset of ACS by enabling real-time monitoring of muscle compartment conditions based on blood oxygen levels, providing a promising alternative to existing methods.

Acute Compartment Syndrome usually occurs in traumatic experiences and would require immediate medical intervention to prevent irreversible tissue damage. Compartments within the body are inelastic, meaning they cannot quickly expand to accommodate an increase in volume, such as swelling or bleeding. The increased swelling within the compartment leads to compression of the neurovascular bundles, which leads to a rapid rise in pressure that can affect blood flow and tissue health. High-pressure development for extended periods can reduce the blood flow to the tissues, leading to a deprivation of oxygen and nutrients and, therefore, cell necrosis or tissue death.

NIRS uses near-infrared light to pass through biological tissues, typically from light-emitting diodes (LEDs) or laser diodes. Oxygenated and deoxygenated hemoglobin have distinct absorption spectra in the near-infrared range. NIRS for hemodynamics uses wavelengths around 740 nm and 850 nm to detect deoxyhemoglobin (HHb) and oxyhemoglobin (HbO_2). NIRS device requires a modified Beer-Lambert law to account for the scatter of light in biological tissues.

$$A = log_{10}\left(\frac{I_0}{I}\right) = \varepsilon cl$$

The modified Beer-Lambert law considers the path length (l) of light that travels through the tissue, which not only passes through but also scatters light in various directions [2]. By analyzing the changes in light absorption at different wavelengths, the NIRS device can calculate the relative changes in oxygenated and deoxygenated hemoglobin concentrations within the tissue. Additionally, these concentrations can lead to calculating local tissue oxygen saturation StO_2 using the equation below.

$$StO_2 = \frac{HbO_2}{HbO_2 + HHb}$$

Initially, the team found a research article where engineers from Vanderbilt University developed a low-cost, wearable, functional near-infrared spectroscopy headband that produced oxygenation levels of the head [3]. The team began to replicate this device for the lower extremities for ACS. While the team spent a significant amount of time and effort to reproduce this device, the gaps in information and knowledge in the article proved too substantial to move forward. The team then agreed to shift directions to prototype a device from the ground up. The team continued using the basic principles of near-infrared spectroscopy to design a unique device using a breadboard. The team then developed a PCB to interact with a Raspberry Pi and a 3D-printed housing to be wearable.

The device's final design consists of a PCB with two emitter LEDS, two bandpass filters, and two detectors to measure oxy- and deoxyhemoglobin levels. The PCB is connected to a Raspberry Pi Zero to collect and process data and to a portable power bank. A 3D-printed case protects all electrical components, where a Velcro strap secures the device onto a limb.

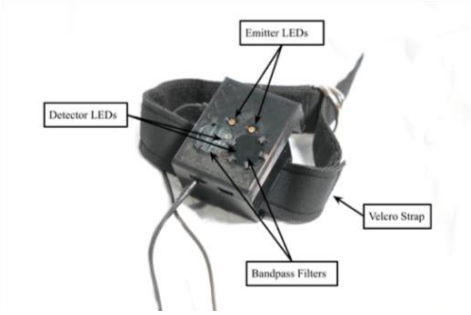

FIGURE 1: PROTOTYPE OF NIRS DEVICE

To verify if the device can detect changes in blood oxygen levels, the team used a pressure cuff in conjunction with the device on the right lower leg of a team member. By varying the pressure cuff's pressure between 0 to 40mmHg, the team tested the changes in oxyhemoglobin, deoxyhemoglobin, and tissue oxygen saturation (StO_2).

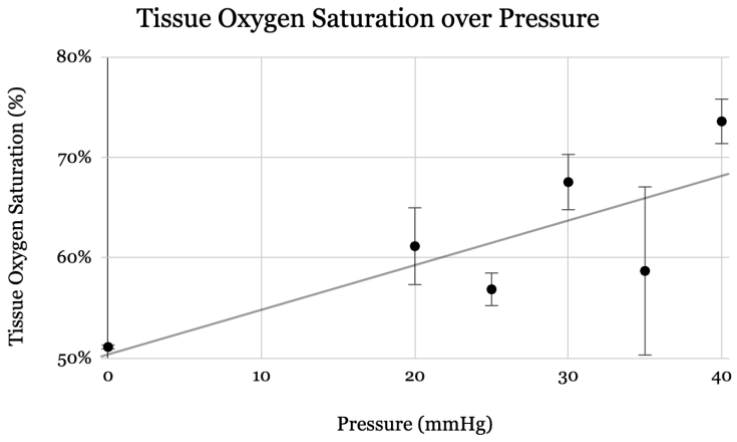

FIGURE 2: INFLUENCE OF COMPRESSION PRESSURE ON STO2

The graph above shows a positive relationship between tissue oxygen saturation and compression pressure, from 51% at no pressure to 74% at 40 mmHg.

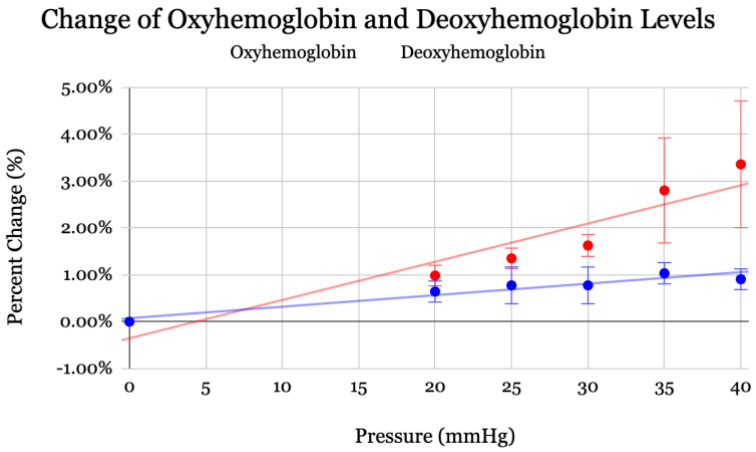

FIGURE 3: HEMOGLOBIN LEVELS OVER PRESSURE

Figure 3 shows the levels of hemoglobin, where both oxyhemoglobin and deoxyhemoglobin increase with compression pressure.

These results correlate with previous research, in which a greater blood flow rate induced higher StO2. Additionally, compression of the lower limbs increases venous return, therefore increasing StO_2 [4].

Our results show that our device can successfully measure changes in StO_2 based on changes in compression pressure. This detection can lead to the device detecting the abnormal compartment pressure from ACS based on the correlating StO_2 levels.

Although the device successfully detected changes in StO_2, the sensitivity of the device can improve. The team believes using an optimal distance between the emitter and detector could aid in this discrepancy and the use of operational amplifiers for greater precision. Another future recommendation for the device is to use multi-distance detectors to account for superficial layers between the LEDs and the muscle compartments. Adding a second pair of detectors at a closer distance eliminates the refraction of light due to layers such as the epidermis, resulting in a greater accuracy in data.

This project showcases that a NIRS device can be a viable alternative to current high-cost and invasive methods for measuring tissue oxygen saturation, particularly in the lower extremities. While our data reproduced similar trends to past research, further testing is needed to develop an optimized device for detecting ACS.

CHAPTER 1. INTRODUCTION

Acute Compartment Syndrome (ACS) has emerged as a significant concern, prominently affecting individuals in high-stress environments, such as the military. ACS is a musculoskeletal disorder and is considered a surgical emergency, characterized by a sudden reduction in blood flow or a restriction to the heart's blood supply, specifically occurring within the osteofascial compartments of muscles. This condition arises when the pressure within the compartment reaches abnormally high levels, leading to a critical disruption of the local blood circulation. [1]

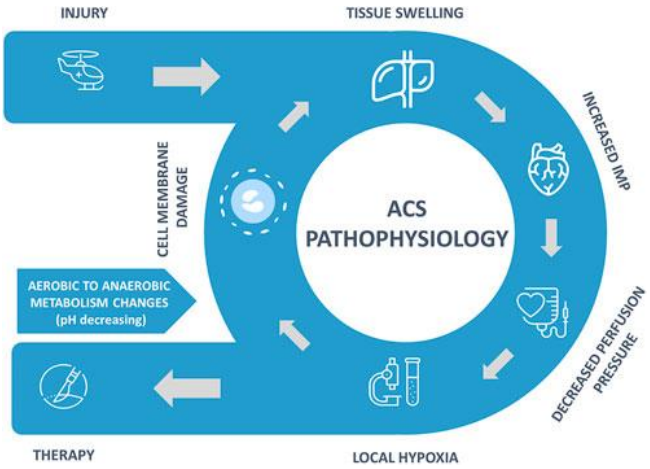

FIGURE 4: ACS PATHOPHYSIOLOGY [5]

ACS is most associated with bone fractures and can lead to severe complications, including muscle damage and nerve injury, potentially resulting in long-term disability. Statistics reveal that 75% of ACS cases are related to bone fractures, with tibial shaft fractures being a frequent cause [5]. Notably, the incidence rate of ACS in high-stress environments, such as those encountered by military personnel, is a pressing concern, with an incident rate of 5.69 per 1000 individuals, according to data from the Defense Health Agency database [1]. Without treatment, ACS can lead to several complications, such as contractures, rhabdomyolysis, nerve damage, renal failure, ischemia, and eventually necrosis.

Despite existing preventive and diagnostic methods, limitations pose challenges for patients. For instance, using an intramuscular pressure needle, while effective, is invasive and carries risks of discomfort and infection. This technique is also labor intensive, providing only a snapshot of the compartment pressure. Similarly, although capable of diagnosing ACS, magnetic resonance imaging (MRI) is hindered by its high cost and time inefficiency [5].

Presenting an innovative approach, this chapter introduces a project dedicated to addressing the critical concerns of ACS. The team developed a wearable, noninvasive optical technology leveraging near-infrared spectroscopy. This technology aims to prevent the onset of ACS by enabling real-time monitoring of muscle compartment conditions, providing a promising alternative to existing methods.

CHAPTER 2. BACKGROUND

2.1 WHAT IS ACS

To understand ACS, we must first understand compartment syndrome. Compartment syndrome occurs when increased pressure within a compartment compromises the circulation and function of tissues within that area. This condition occurs when the pressure within a compartment increases, typically due to swelling or bleeding after an injury. The body is divided into various compartments in the arms, legs, hands, and feet, which are delineated by thick layers of fascia—connective tissues that envelop the muscles and nerves. These compartments within the body are inelastic, meaning they cannot quickly expand to accommodate an increase in volume, such as swelling or bleeding. The increased swelling within the compartment leads to compression of the neurovascular bundles and a rapid rise in pressure that can affect blood flow and tissue health. Having a high development in pressure for extended periods can reduce the blood flow to the tissues, leading to a deprivation of oxygen and nutrients. In extreme cases, ACS can cause cell necrosis or tissue death.

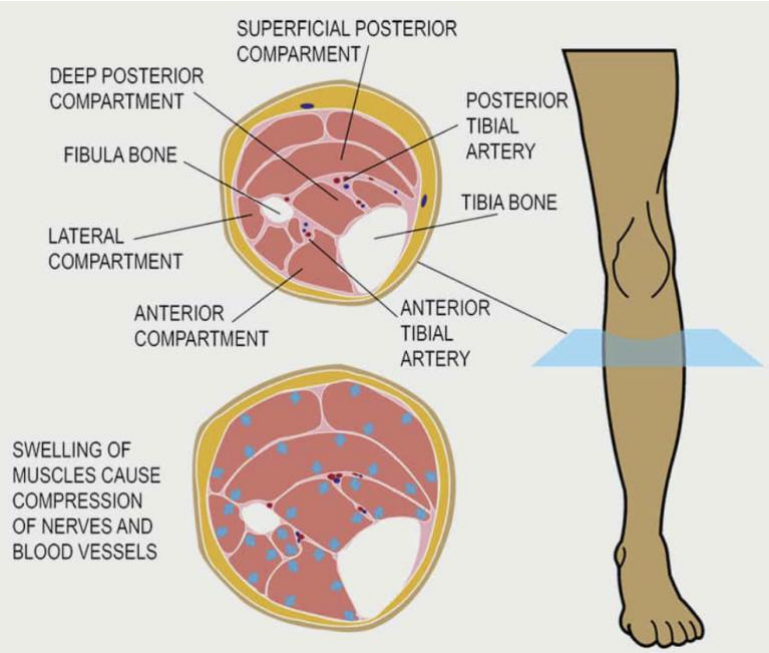

FIGURE 5: ACUTE COMPARTMENT SYNDROME DIAGRAM [10]

There can be two types of compartment syndrome: acute or chronic. Acute compartment syndrome typically results during traumatic experiences. These experiences include fractures and severe bruises, which would cause bleeding and rapid swelling to occur in that area. This condition would be considered a medical emergency due to the increased pressure and the decreased blood flow to compartments. The symptoms are more severe and sudden than chronic compartment syndrome due to the instantaneous decrease of blood flow. Chronic compartment syndrome is exercise-induced and occurs during extensive use of a muscle. It is gradual and curable with rest and commonly affects athletes or people who may engage in repetitive activities such as biking or running.

2.2 Clinical Presentation and Diagnosis of ACS

Commonly, medical professionals diagnose ACS through physically invasive methods or costly and time-consuming image testing. For example, imaging tools such as X-rays and MRIs help look at where the source of the pressure could be coming from. These imaging techniques provide detailed views of tissue, assisting physicians to pinpoint areas for potential concern. Compartment pressure testing is also typically used by most physicians to diagnose ACS. This procedure involves injecting a local anesthetic into the affected compartment to minimize discomfort, followed by inserting a needle connected to a pressure monitor. The handheld device is attached to a needle in the muscle compartment to measure the pressure. The compartment pressure tests reveal whether the symptoms are acute or chronic compartment syndrome.

2.3 How does NIRS work

Although there are many methods of monitoring muscle oxygenation, near-infrared spectroscopy (NIRS) has gained significant attention for this purpose as a portable, noninvasive monitoring technique. NIRS uses infrared light to pass through biological tissues, typically from light-emitting diodes (LEDs) or laser diodes. The differences in reflection and absorption of various chromophores then scatter the light.

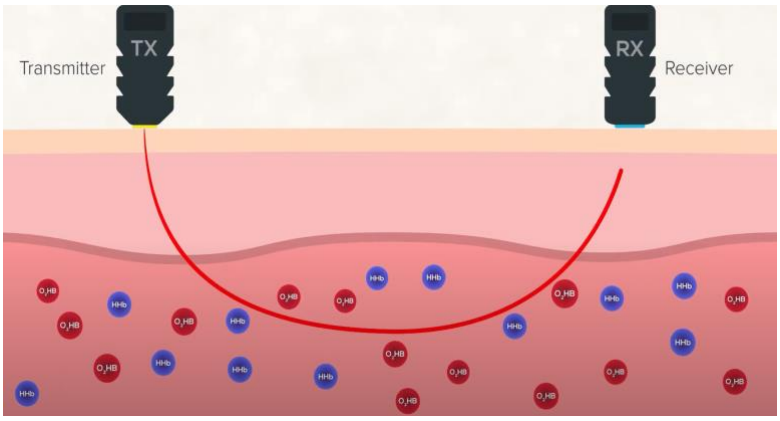

FIGURE 6: NEAR-INFRARED SPECTROSCOPY DIAGRAM [11]

Oxygenated and deoxygenated hemoglobin have distinct absorption spectra in the near-infrared range. Oxygenated hemoglobin absorbs more light at specific wavelengths, while deoxygenated hemoglobin absorbs more light at others. In particular, NIRS for hemodynamics applications wavelengths of around 740 nm and 850 nm to detect deoxyhemoglobin (HHb) and oxyhemoglobin (HbO_2), respectively. This light is then detected using photodetectors placed a certain distance away from the LEDs or laser diodes. The amount and distribution of the detected light depends on the concentration and oxygenation state of hemoglobin in the tissue. If more light is absorbed, the signals detect less scattered light, and vice versa. The detected signals are then analyzed using a modified Beer-Lambert Law, which relates light absorption to the concentration of the absorbing substance. The Beer-Lambert Law provides information for analyzing the concentration of a particular substance in a solution based on how much light it absorbs at a specific wavelength. NIRS device requires a modified version of this law to account for the scatter of light in biological tissues. The modified Beer-Lambert Law considers the pathlength or distance light travels through the sample because, in tissues, light not only passes through but also scatters in various directions. By analyzing the changes in light absorption at

different wavelengths, the NIRS device can calculate the relative changes in oxygenated and deoxygenated hemoglobin concentrations within the tissue.

This technology detects real-time changes in oxygen levels with high reliability. Continuous wave (CW) NIRS assumes the degree of scattering by using a continuous light source. CW-NIRS equipment makes it possible to obtain the changes in HbO_2 and HHb concentrations to find the tissue oxygen saturation (StO_2 %) [3].

Although many studies have concluded this technique can reliably assess muscle performance during exercise, "noise" is still present due to the contribution of superficial layers and motion within the measurements. As research in NIRS has expanded, employing multi-distance placements identifies such components. By including multiple sets of light sources and detectors at shorter separations to the source and detector, the "noise" can be subtracted from the long separation measurements, leading to improved accuracy of NIRS evaluation.

CHAPTER 3. PROJECT STRATEGY

3.1 INITIAL CLIENT STATEMENT

The initial client statement serves to identify the needs of the project. This statement also directed team members and client Dr. Yihao Zheng through the iteration and design process. The team created the following initial client statement:

> *"Design and develop a wearable near-infrared spectroscopy (NIRS) device as a means of diagnosing pressure buildup in the compartments of lower appendages."*

3.2 DEFINING THE STAKEHOLDERS

The initial stakeholder for this project is Dr. Yihao Zheng, who has provided insight and expectations for the design. The team directly took feedback from this stakeholder and designed a final prototype that satisfied their goal for this project. The end user of this project is also a stakeholder. The team designed and tested the device with the consideration of the end user, who will be the one wearing and benefiting from the product. Medical professionals are also stakeholders in the design, as they will operate this equipment. The team developed the product with the understanding of all stakeholders and adjusted the client statement and the design through iterations.

3.3 DEVELOPED OBJECTIVES AND DESIGN CONSTRAINTS

Based on a discussion with Dr. Yihao Zheng, the team considered certain design specifications and objectives when designing this device. The team created these objectives with the clients and end users in mind. Each objective has a sub-objective to explain the criteria further. The main objectives the team focused on were ease of use, biometric accuracy, comfort, and affordability. These objectives and their descriptions can be seen below in Table 1.

TABLE 1: DESIGN OBJECTIVES AND DESCRIPTIONS

Objective	Description
1. Ease of use	
User Interface	The user interface includes simple, easy-to-read displays with straightforward controls allowing simple data acquisition.
Effortless design	Putting on the device requires minimal physical activity and features an easily secured, adjustable strap.
2. Biometric Accuracy	
Accurate results	Accurately detect changes in muscle pressure from hemoglobin and tissue oxygen saturation levels (StO_2)
Noise reduction	Minimize interference from external light and superficial layers of skin, ensuring consistent and accurate data.

Real-time analysis	Provide data that is processed immediately without significant delay. The device provides continuous updates on oxygen levels over time.
3. Comfort	
Adjustable	Use a convenient strap for individuals of different sizes to adjust to their tightness.
Lightweight	Use lightweight materials and ergonomic shapes to ensure the user's comfort during extended wear. Small housing compartments for electronics do not interfere with users.
4. Affordability	
Low-cost	The device does not exceed a high cost; others can replicate this design using a low-cost method.

Table 2 below showcases the design constraints the device must meet to succeed. These constraints were determined by the team, client, and university.

TABLE 2: DESIGN CONSTRAINTS

Constraint	Description
Have hemoglobin levels be responsive to changing levels of induced pressure	- Client Constraint
Able to detect tissue oxygen saturation values within the known range of 46 – 95%	- Client Constraint
Must cost less than $1000	- Must be completed before WPI's project deadline and graduation
Must be achievable by April 2023	- Must be completed before WPI's project deadline and graduation

3.4 Revised Client Statement

Using the objectives and constraints described above, the team altered the client statement to create the finalized client statement, as seen below.

> *"Design and develop a low-cost, wearable near-infrared spectroscopy (NIRS) device to accurately measure tissue oxygen saturation to detect abnormally high pressure in muscle tissue for conditions such as Acute Compartment Syndrome."*

CHAPTER 4. DESIGN

4.1 DESIGN PROCESS

Near-infrared spectroscopy is broad and has many applications but has not yet been developed for ACS. Because of this, the team started by conducting a literature review of near-infrared spectroscopy as well as acute compartment syndrome to grasp all aspects of these areas. The literature review targeted the electrical circuitry of NIRS and the mathematical quantification of ACS pressure buildup through oxygenation levels, as seen in Chapter 2. Subsequently, the team directed attention to a research article where engineers from Vanderbilt University developed a low-cost, wearable, functional near-infrared spectroscopy headband that produced oxygenation levels of the head [3]. The team began to replicate this device for the lower extremities for ACS. While the team spent a significant amount of time and effort to reproduce this device, the gaps in information and knowledge in the article proved too substantial to move forward. The team then agreed to shift directions to prototype a device from the ground up.

4.1.1 INITIAL DESIGN

Inspired by the Vanderbilt design, the team applied their design process when shifting design concepts. Keeping most of the conceptual design aspects for a NIRS device, the team first prototyped our design using a Raspberry Pi 4 and hardware components on a prototyping breadboard. This initial design consisted of two LED laser diodes at 750nm and 850nm, respectively. The breadboard also features two photodiode receptors, which were connected to the Raspberry Pi 4 through an analog-to-digital converter to obtain an output of voltage for our data.

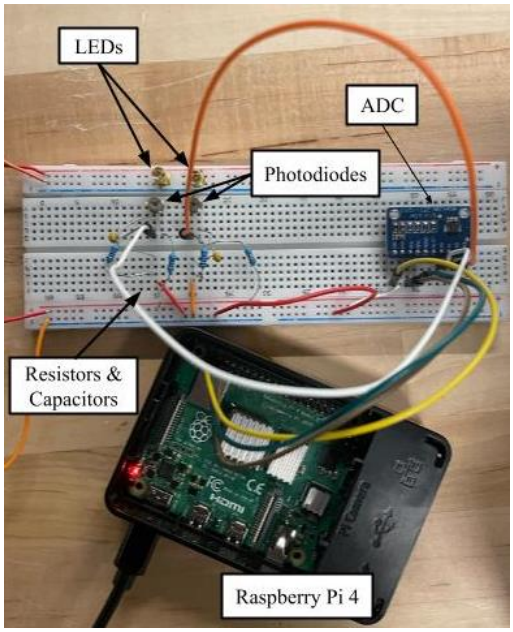

FIGURE 7: INITIAL DEVICE DESIGN

An initial housing design to protect the hardware components was created in SolidWorks and printed using PLA material. This design utilized a Velcro strap through the side openings to secure onto the lower leg. Cuts along the back side of the housing allowed easy access to the power switch on a PCB and wires connected to the Raspberry Pi while the participant was wearing the device. The Raspberry Pi fits inside the housing first, and, separated by a thin layer of black electrical tape, the PCB was layered on top. Figure 8 below is a SolidWorks Drawing of the team's initial housing design CAD model with millimeter units.

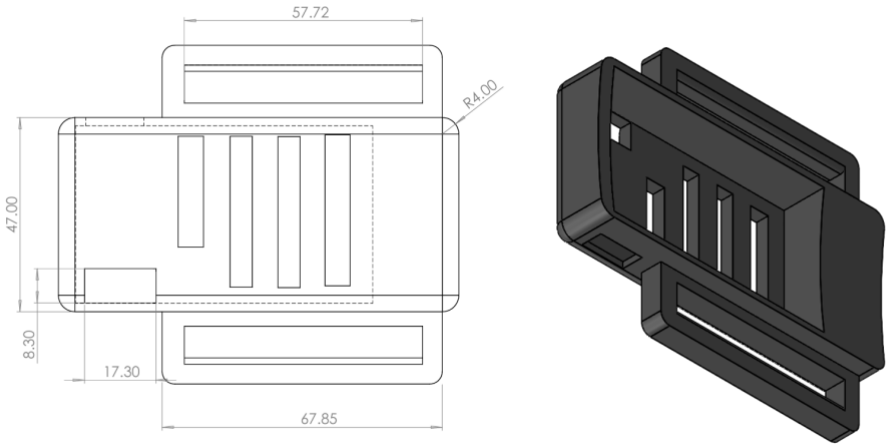

FIGURE 8: INITIAL HOUSING CAD MODEL

Both the Velcro strap and the housing were chosen to be black to help keep external light from entering the housing. In addition, a top layer of black TPU rested on top of the PCB closest to the skin, having cuts that only allowed for the LEDs and photodiodes to be in contact with the skin. The team did encounter issues in this initial design, one of which was that the device heated up near the LED and needed more TPU support. The other concern was that there was no way for both photodiodes to receive specific wavelengths; instead, they read both 750nm and 850nm. The team addressed these concerns in the final design.

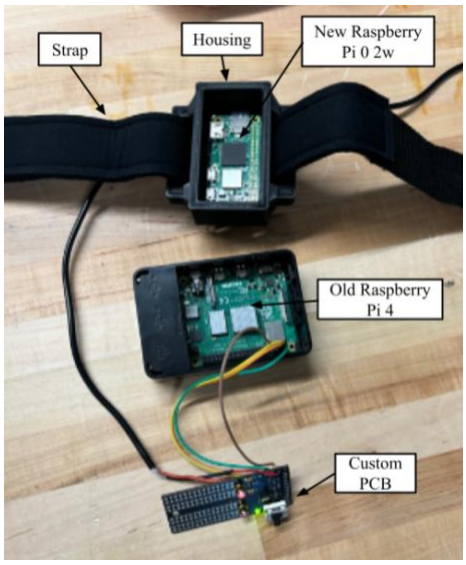

FIGURE 9: INITIAL COMPONENTS OF DEVICE

4.2 Final Design

Through extensive prototyping, the team decided to move forward with the final device design. This final design consisted of a custom PCB with the same hardware components as the initial prototype. A Raspberry Pi 0 2w was used instead of a Raspberry Pi 4 to decrease the device's size and allow for better wearability. In addition, the team created an improved housing model in Fusion in this design. A final image of our device is seen below in Figure 10.

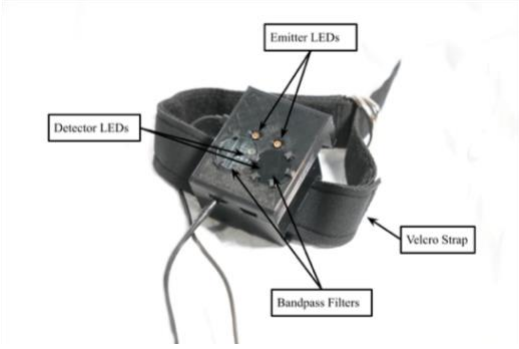

FIGURE 10: IMAGE OF DEVICE

4.2.1 NIRS Hardware

The team built a custom PCB designed specifically for a wearable NIRS application. This PCB consisted of two main components: LEDs at 750nm for deoxygenated hemoglobin and 850nm for oxygenated hemoglobin and photodiode receptors. Capacitors and resistors also provided bias voltage to amplify the signal, and an analog-to-digital converter connected the photodiode signals to the Raspberry Pi 0 2w to receive an output of voltage in the data. A schematic showcasing the connections within the PCB is shown in Figure 11.

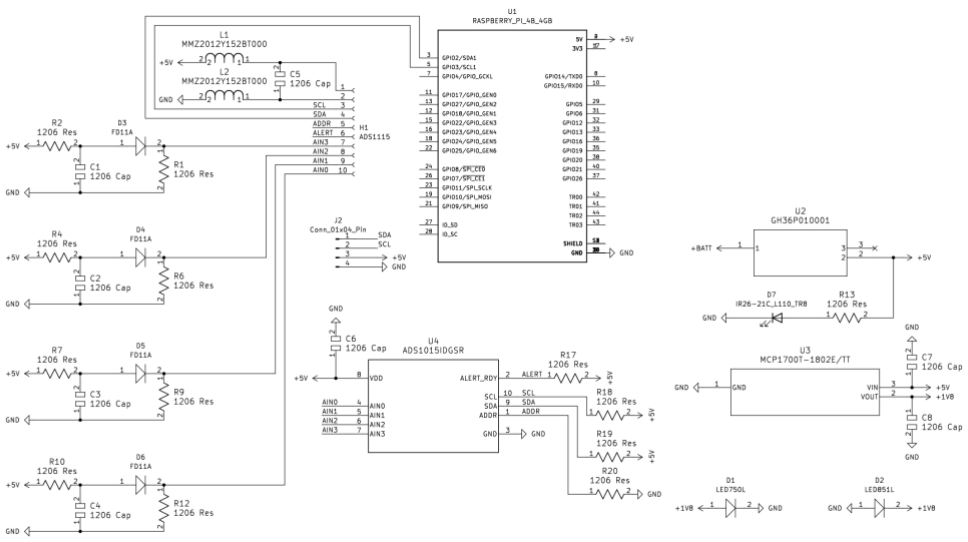

FIGURE 11: PCB SCHEMATIC

A manual switch button is also on the PCB, allowing easy access to turn the device off and on, where a green light signifies when the device is on. Bandpass filters separate the two photodiode channels when receiving specific wavelengths. The team printed the PCB in black to minimize the external light that could affect the data collection. Thinking forward, the team designed the PCB with multiple slots for the photodiodes to move, giving the capability to test different distances between the LED and photodiodes and the effect on the quality of data collected. During experiments, the team placed the photodiodes 13 centimeters away from the LEDs. Lastly, a 5V power bank powered the PCB and the Raspberry Pi.

4.2.2 Wearable Housing

Using Fusion CAD software, the team created a final design of the PLA housing. Due to safety concerns, the team wanted a layer to separate the Raspberry Pi 0 2w and the PCB. To achieve this, the team designed a portion of the housing that allowed the Raspberry Pi to connect to the bottom and the PCB on top. This section of the housing slid onto the next portion of the housing, which allowed for easy accessibility in case the team needed to change aspects of the hardware in the future. A top layer of TPU was designed with correct tolerancing to fit snugly onto the bottom housing print. The layer of TPU helps the two bandpass filters directly over the photodiode detectors and makes the top of the LEDs meet the skin. Cuts within the housing allowed Micro USB and HDMI connections to the Raspberry Pi and exposed the power switch. Rather than two handles for the Velcro strap to go through, as seen in our initial design, this iteration has a single sleek hole in the back for the strap. This housing was designed efficiently and enabled the team to access all design components quickly. In the end, the final dimensions of the device were 80mm in length, 60.8mm in width, and 45.6mm in depth. An exploded view of how the final housing design fits our hardware components is shown in Figure 12.

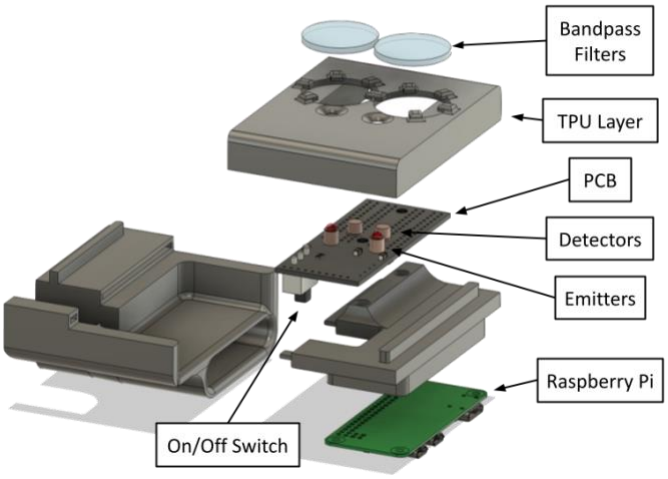

FIGURE 12: EXPLODED VIEW OF FINAL DEVICE

4.2.3 NIRS SOFTWARE

The device was configured using a Raspberry Pi 0 2w and Python as the software language. Using a Raspberry Pi allowed the device to run remotely on a computer. With this code, the team could collect and process data efficiently. One of the main tasks of the Python code is to receive the voltage data outputs from the ADC. The team preprocessed this data, which included adding a threshold and averaging the voltage values to omit noise and outliers within the data. The team could directly convert these voltage outputs from the ADC to values of oxyhemoglobin and deoxyhemoglobin by using Equation I, a modified Beer-Lamberts Law equation, and Equation II, an equation for StO_2.

$$\text{(I)} \qquad A = log_{10}\left(\frac{I_0}{I}\right) = \varepsilon c l$$

$$\text{(II)} \qquad StO_2 = \frac{HbO_2}{HbO_2 + HHb}$$

The team used Equation I to find concentration (c) by taking the log of the input voltage (I_0) over the output voltage (I) and dividing this by the molar extinction coefficient (ε) times the path length (l). The team was able to calculate real-time concentrations of hemoglobin in the calf. Using equation II, the team calculated StO_2 for the calf as well. These concentrations were recorded every 0.1 seconds at an ADS gain of 16 as the device ran. The code then printed values for each photodiode and their averages over time. The complete Python code can be found in Appendix A. The team saved their trial runs as .csv files to post-process the data and imported them into Microsoft Excel.

CHAPTER 5. DESIGN VERIFICATION

5.1 PRESSURE TESTING

The team conducted several tests with a pressure cuff to verify that our device can accurately detect changes in pressure through changes in tissue oxygen saturation (StO_2). The team collected changes in StO_2 based on different compression pressures, ranging from 0 mmHg to 40 mmHg. The team conducted three trials at each pressure, and each trial included one minute of quiet rest before two minutes under the specified pressure, followed by a minute of quiet rest with the pressure released.

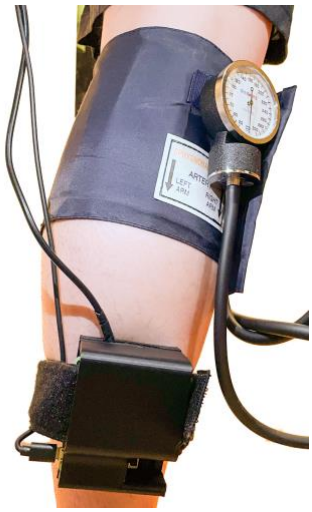

FIGURE 13: EXPERIMENTAL SETUP ON LOWER LEG

Initially, the team conducted tests on the forearm due to the ease of use with the pressure cuff and the shallow penetration depth for the forearm. Figure 14 shows the relationship between StO_2 and pressure. They have a positive relationship where StO_2 increases as pressure increases. StO_2 is 51% at no pressure, which increases to an average of 72% at 40 mmHg.

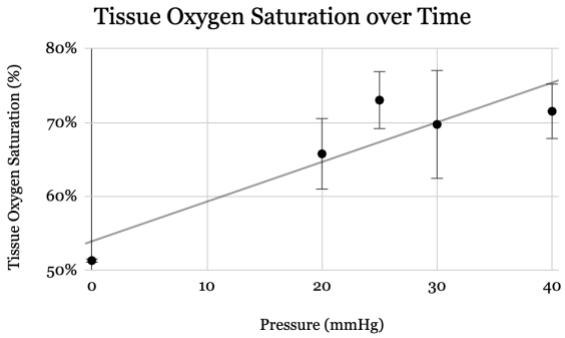

FIGURE 14: STO2 OVER PRESSURE OF FOREARM

Figure 15 shows the hemoglobin levels of the tests on the forearm. Both oxyhemoglobin and deoxyhemoglobin show an increase. Oxyhemoglobin changes at a greater rate, where the percent change is about 3%, whereas deoxyhemoglobin increases to about 1.25% at 40 mmHg.

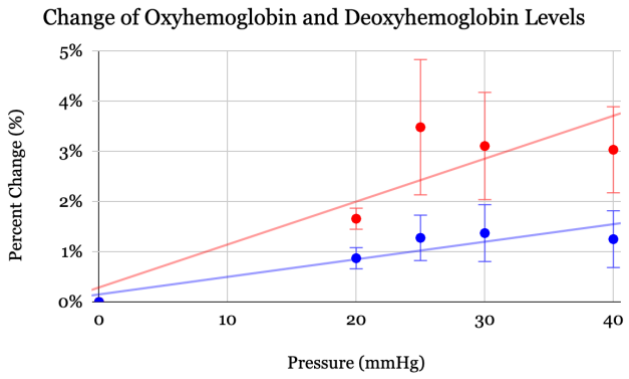

FIGURE 15: FOREARM OXYHEMOGLOBIN (RED) & DEOXYHEMOGLOBIN (BLUE) LEVELS OVER PRESSURE

Following these tests, the team transitioned to the calf to simulate ACS with the pressure cuff and the same test parameters. After collection and post-processing, the data showed inaccurate changes with changes in compression pressure with significant variance, as seen in Figures 16 and 17. The team then inferred that the device was strapped to the calf too tightly, where the LED emitter did not have the optimal optical penetration, thus leading to inaccurate reception and high variance by the photodiode detectors.

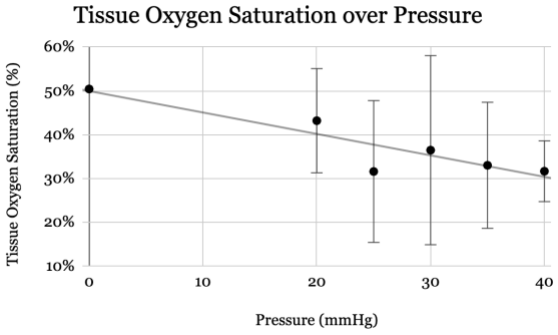

FIGURE 16: STO2 OVER PRESSURE OF CALF

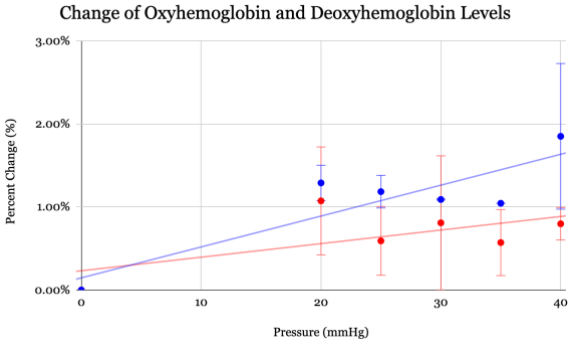

FIGURE 17: OXYHEMOGLOBIN (RED) & DEOXYHEMOGLOBIN (BLUE) LEVELS OVER PRESSURE OF CALF

The team then repeated these tests with the device attached to the calf more loosely and with little force between the device and the calf. These tests showed a positive relationship between StO_2 and compression pressure, as seen in Figure 18. Tissue oxygen saturation rose from 51% at no pressure to 74% at 40 mmHg. Most trials showed relatively low variation except for trials at 35 mmHg.

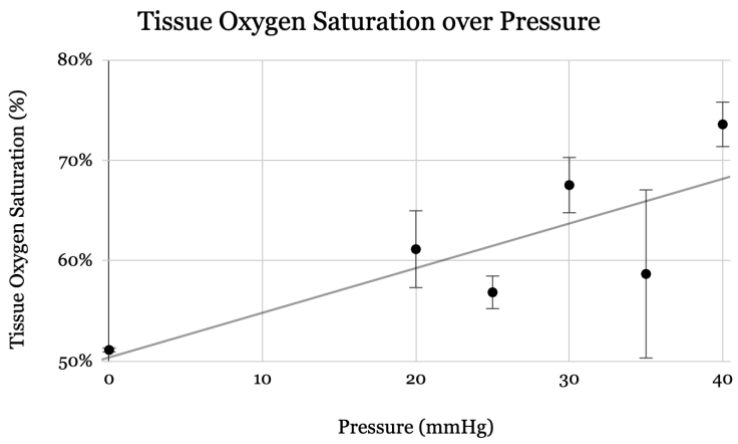

FIGURE 18: RETEST OF STO2 OVER PRESSURE OF CALF

In addition, changes in oxyhemoglobin and deoxyhemoglobin levels are seen in Figure 19. Both oxyhemoglobin and deoxyhemoglobin levels rose from no pressure to an average of 3.35% and 0.90% at 40 mmHg, respectively. Oxyhemoglobin showed a more significant change based on the pressure and more variance as pressure increased.

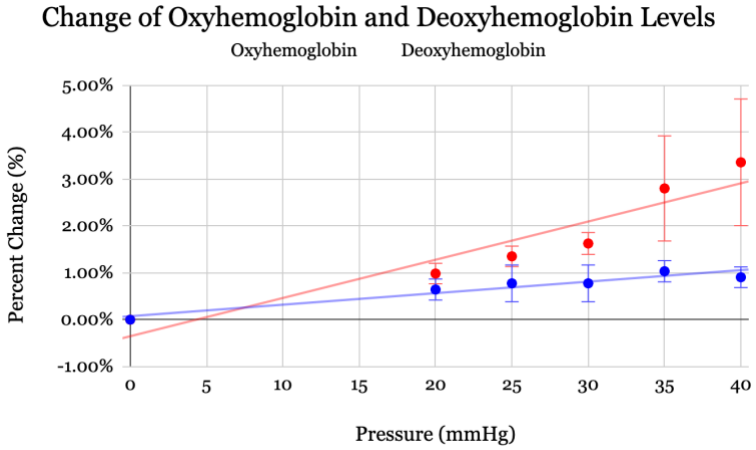

FIGURE 19: CALF OXYHEMOGLOBIN (RED) & DEOXYHEMOGLOBIN (BLUE) LEVELS OVER PRESSURE

5.2 Cost Evaluation

In addition to function, the team valued designing the device with cost in mind. A bill of materials can be seen in Appendix B, where the total cost of the device is $255.35. Current NIRS devices can cost upwards of $40,000 [8]. In addition, hospital charges associated with ACS can range from $34,000 to $79,000 based on the length of stay [9].

5.3 WEARABILITY

All team members wore the device and tested the comfortability. All team members felt no discomfort due to the padded Velcro strap and the TPU top layer. The Velcro strap allowed for the adjustable size and shape of appendages, and the 3-D printed housing proved light enough not to pose any discomfort or affect wearability. Lastly, the portable power bank allowed for movement and ease of testing.

CHAPTER 6. DISCUSSION AND CONCLUSIONS

6.1 DISCUSSION

The results from the initial testing showed insights into the relationships between tissue oxygen and saturation levels with applied external pressure. The positive correlation observed between the StO_2 and the compression pressure across different tests aligns with previous literature, indicating the devices' reliability in detecting changes in pressure [12]. In addition, the increase in oxyhemoglobin and deoxyhemoglobin levels is supported by an article that showed similar results using a compression stocking [13]. The tests on the forearm showed a relationship between increased compression pressure and StO2, with values rising from 51% at no pressure to 72% at 40 mmHg. This increase could show that the forearm is a possible device calibration and testing model. However, the forearm does not fully replicate a more complex muscular tissue like the calf. The variance and inaccuracies observed could have been caused by the improper strapping of the device to the user's leg. This would affect the optical penetration that an LED emitter might have on the skin, affecting the photodiode detectors' data. Furthermore, the calf's complex structure, which has larger muscle mass and deeper tissue layers compared to that of a forearm, likely contributed to the initial inaccuracies. However, it was seen that the adjustments to the device helped improve data consistency and restoration of the positive StO2 relationship, such as loosely fitting it.

Along with the device's functionality, the team achieved a low-cost design. The device itself is much less expensive than current NIRS devices. In addition, hospital charges increase the cost by double. This device has the capability to substantially lower this expense by diagnosing ACS rapidly.

6.2 CONCLUSIONS

The NIRS device presents a promising alternative to other current methods for detecting ACS. Traditional approaches rely heavily on invasive techniques, which could pose a risk of complications and be impractical due to high costs. However, this device still requires further testing and verification despite the potential advantages. The primary challenges faced are accurately calibrating the device to account for different distances, scattering coefficients, and differential path length factors (DPF) used in the modified Beer-Lamber Law.

6.3 FUTURE WORK

The development of the NIRS devices hinges on their accuracy and reliability in measuring oxygen saturation. Three critical aspects of the NIRS device could significantly influence its effectiveness: the difference distances between the photodiodes and receivers, shorter separation channels, and integration of operational amplifiers.

The varying distances between photodiodes and emitters play a critical role in tissue penetration depth. The device can capture data from different tissue depths by varying the distances. Increasing the emitter-detector distance allows the near-infrared light to penetrate deeper into the tissue. Finding the optimal distance configuration could allow for more accuracy in assessing changes in

muscle compartments. Furthermore, if the distances were changed to be shorter, it would be more helpful to monitor changes closer to the skin layer.

The team suggests the implementation of short separation channels with another pair of photodiode receivers at a shorter distance from the light emitters on the NIRS device. By minimizing the distance light travels through the tissue, shorter separation channels will only collect hemodynamic data of shallow layers of tissue. The short separation channels can reduce the impact of superficial layers such as skin. By omitting the unwanted data from the original photodiodes at a farther distance, the levels of hemoglobin and StO_2 can improve in accuracy.

Integrating operational amplifiers into NIRS systems can also improve the reliability of the signal readings. These amplifiers will increase the amplitude of the NIR signals received by the detectors, allowing for the detection of changes in tissue oxygenation that might otherwise be difficult to detect. Additionally, operational amplifiers contribute to noise reduction by improving the signal-to-noise ratio, ensuring that the readings are more robust, more precise, and more reliable. Furthermore, they expand the device's dynamic range, enabling it to effectively capture and process signals across a broad spectrum of intensities. This capability is especially valuable in diverse clinical environments and under varying patient conditions, where precise and adaptable measurement tools are essential for accurate diagnostics and monitoring.

Lastly, the team suggests conferring with medical professionals as this device advances to gain a medical perspective and insight into concerns, areas of improvement, and overall competency of the project.

Chapter 7. Broader Impacts and Ethical Implications

The team observed and satisfied the Engineering Code of Ethics throughout this project to protect public health, safety, and welfare. This project aimed to design and develop a wearable near-infrared spectroscopy (NIRS) device to diagnose pressure buildup in the compartments of lower appendages. As this directly pertains to improving health technology, the team realized the priority of safety in health applications. The team engaged in research and development under the principles of ethical conduct to develop the resulting prototype. Each team member conducted research within their competence and in an objective and truthful manner, avoiding deceptive acts. In addition, the team conducted a literature review to attain extensive knowledge of the project's subject matter. The team cited all prior research in this report and gave credit for engineering work to those to whom credit is due, recognizing the proprietary interests of others. Furthermore, the team explored the broader impacts of our research on society, the economy, the environment, and the world.

7.1 Social Impact

While our device detected changes in oxygenation of the muscles in the lower limb, there were physiological differences that the team could not account for due to the time constraints and the participants of our tests. Due to the team being only young male adults, no females nor other age groups tested the prototype. Although ACS occurs up to 10 times more often in males than females [5], the lack of diversity may skew the data as well as the capabilities of the device. In addition, skin pigmentation and the amount of hair follicles in patients can cause inconsistencies in data. Unfortunately, the team did not test for these variables, which can cause discrepancies in target demographics. On the other hand, the NIRS device has supported the versatility of using near-infrared light for advanced technology. This project can develop knowledge of near-infrared spectroscopy, especially among students and within the educational system.

7.2 Economic Impact

The team prioritized a low cost for the device throughout the project, ensuring it remains accessible to people of all economic backgrounds. Each component was chosen to balance quality and affordability, guaranteeing functionality and durability. Through innovative design and resourceful material sourcing, the team achieved a solution to overcome financial barriers, making it available to everyone. This approach reflects a commitment to inclusivity and economic responsibility, ensuring that technological advancements benefit all, regardless of financial status.

7.3 Environmental Impact

The team does not foresee any environmental impacts of this project. However, if mass-produced, manufacturing the device's components would consequently add to the carbon emissions, thus harming the environment. In particular, the team used PLA to 3D print the housing of the electrical components. PLA can be recycled, but there is no official collection of post-

consumer waste from 3D printing. The device also includes a battery for wearability, but it can harm ecosystems if disposed of incorrectly. With all this in mind, the team agreed that the beneficial health impacts of the device outweigh the environmental complications of manufacturing.

7.4 Global Impact

Acute compartment syndrome, a severe condition where increased pressure within a muscle compartment impairs blood flow, often requires prompt diagnosis and treatment to prevent tissue damage or loss. Early detection of acute compartment syndrome becomes more feasible by making a cost-effective spectroscopy device available, especially in regions with limited healthcare resources. This could lead to timely interventions, reducing the risk of long-term complications and potentially saving lives. With this noninvasive monitoring method, patients may experience less discomfort, leading to higher patient compliance and better outcomes overall. Moreover, this research could extend to other sectors of medical intervention and advance interdisciplinary collaboration in innovation and research of near-infrared spectroscopy, thus advancing knowledge for the betterment of society.

WORKS CITED

[1] Torlincasi AM, Lopez RA, Waseem M. Acute Compartment Syndrome. [Updated 2023 Jan 16]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448124/

[2]Barker T, Midwinter M, Porter K. The diagnosis of acute lower limb compartment syndrome: Applications of near infrared spectroscopy. Trauma. 2011;13(2):125-136. doi:10.1177/1460408610388700

[3] Tsow, F., Kumar, A., Hosseini, S. H., & Bowden, A. (2021). A low-cost, wearable, do-it-yourself functional near-infrared spectroscopy (DIY-FNIRS) headband. *HardwareX*, *10*. https://doi.org/10.1016/j.ohx.2021.e00204

[4] Dermont, T & Morizot, Laury & Bouhaddi, Malika & Menetrier, A.. (2015). Changes in Tissue Oxygen Saturation in Response to Different Calf Compression Sleeves. Journal of sports medicine (Hindawi Publishing Corporation). 2015. 857904. 10.1155/2015/857904.

[5] Novak M, Penhaker M, Raska P, Pleva L, Schmidt M. Extremity compartment syndrome: A review with a focus on noninvasive methods of diagnosis. [Updated 2022 Jun 27]. In: Frontiers [Internet]. Available from: https://www.frontiersin.org/articles/10.3389/fbioe.2022.801586/full

[6] Torlincasi AM. Acute Compartment Syndrome. [Updated 2023 Jan 16]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK448124/#:~:text=The%20anterior%20compartment%20of%20the,nerve%2C%20and%20the%20tibial%20artery

[7] Waterman BR, Gun B, Bader JO, Orr JD, Belmont PJ. Epidemiology of lower extremity stress fractures in the United States military. [Published 2016 Oct 1]. In: OUP Academic [Internet]. Available from: https://academic.oup.com/milmed/article/181/10/1308/4159734

[8] The Hamlyn Centre for Robotic Surgery. Use of near-infrared spectroscopy and implantable doppler... : Plastic and reconstructive surgery – global open. In: LWW [Internet]. Available from: https://journals.lww.com/prsgo/fulltext/2019/10000/use_of_near_infrared_spectroscopy_and_implantable.19.aspx

[9] Fuglestad MA, Hernandez H, Gao Y, Ybay H, Schieber MN, Brunette KE, Myers SA, Casale GP, Pipinos II. A low-cost, wireless near-infrared spectroscopy device detects the presence of lower extremity atherosclerosis as measured by computed tomographic angiography and characterizes walking impairment in peripheral artery disease. [Published 2020 Mar]. In: Journal of Vascular Surgery [Internet]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7501596/

[10] *Compartment syndrome*. MOTUS Physical Therapy. (2022, October 19). https://motusspt.com/compartment-syndrome/

[11] YouTube. (2022, October 13). *Nirs explained: Absorbance & Transmittance (part 2/2)*. YouTube. https://www.youtube.com/watch?v=iguDN69m6do

[12] T. Dermont, L. Morizot, M. Bouhaddi, A. Ménétrier, "Changes in Tissue Oxygen Saturation in Response to Different Calf Compression Sleeves", *Journal of Sports Medicine*, vol. 2015, Article ID 857904, 5 pages, 2015. https://doi.org/10.1155/2015/857904

[13] Kinoshita, Misato, Yuko Kurosawa, Sayuri Fuse, Riki Tanaka, Nobuko Tano, Ryota Kobayashi, Ryotaro Kime, and Takafumi Hamaoka. 2019. "Compression Stockings Suppressed Reduced Muscle Blood Volume and Oxygenation Levels Induced by Persistent Sitting" *Applied Sciences* 9, no. 9: 1800. https://doi.org/10.3390/app9091800

APPENDIX

APPENDIX A. RASPBERRY PI SOURCE CODE

```
import time
import board
import busio
import adafruit_ads1x15.ads1115 as ADS
from adafruit_ads1x15.analog_in import AnalogIn
import RPi.GPIO as GPIO
import csv
from datetime import datetime
import math

# Create the I2C bus
i2c = busio.I2C(board.SCL, board.SDA)

# Create the ADC object using the I2C bus
ads = ADS.ADS1115(i2c)

# Set the gain
ads.gain = 16

# Create single-ended input on channels
chan1 = AnalogIn(ads, ADS.P1)
chan3 = AnalogIn(ads, ADS.P2)

interval = 0.1
offset = 0.0

max_reading = 5
readings2 = [0 for i in range(max_reading)]
readings4 = [0 for i in range(max_reading)]
current_reading = 0
total2 = 0
total4 = 0
avg2 = 0.00000001
avg4 = 0.00000001
value2 = avg2
value4 = avg4
oldV2 = 0.0001
oldV4 = 0.0001

with open('CalfRaisesAlexTrial1.csv', mode='a', newline='') as file:
    writer = csv.writer(file)
    writer.writerow(["Timestamp", "D2", "D4"])

    while True:
        now = datetime.now().strftime("%H:%M:%S:%f")[:-3]

        value2 = (chan1.voltage)
        value4 = (chan3.voltage+offset)

        if (value2 <= 0.0):
            value2 = oldV2
```

```
        else :
            oldV2 = value2

        if (value4 <= 0.0):
            value4 = oldV4
        else :
            oldV4 = value4


#       print(str(value2)+", "+str(value4))
        oxy = math.log10(1.8/value2)
        oxy = oxy/1058/1.2/64500
        deoxy = math.log10(1.8/value4)
        deoxy = deoxy/1405.24/1.2/64500

        total2 += value2
        total2-= readings2[current_reading]
        readings2[current_reading] = value2

        total4 += value4
        total4-= readings4[current_reading]
        readings4[current_reading] = value4

        current_reading += 1

        if(current_reading >= max_reading):
            current_reading = 0
        avg2 = total2/max_reading
        avg4 = total4/max_reading

        sto2 = oxy/(oxy+deoxy)*100
#       print(f"Diode2: {avg2} Diode4: {avg4}")
        writer.writerow([now, value2, value4, avg2, avg4, oxy, deoxy, sto2])
        time.sleep(interval)
```

APPENDIX B. BILL OF MATERIALS

MODEL OR PART #	ITEM DESCRIPTION	QTY	UNIT PRICE	TOTAL PRICE
https://www.amazon.com/AWG-Stranded-Wire-Kit-Pre-Tinned/dp/B087TJNJZS/ref=sr_1_1_sspa?crid=RF8RKB4W84YY&dib=eyJ2IjoiMSJ9.96JBXGUxxRyiC96qWLsf1pAj8i0xiBcXk7lGptVP9xG7q_i-hjZZrSTQVPuQIQAd1FMjHLpw9iVih2zvn6TWML8Kn3zNttWxYuS3M9TyPB1yuQQHpGqWST-927emqvtf4q6n504DExqpWhr1lk1vlMV9zNEuhkwiBfHZApoaiDZ-gBA6ba-328cjBMqMl0YUFZfMbXttOGI6oKTF7hVkumicHz_EFDbqcbbtG72YZ1pS7KmPvrXf9ubBgYVj4MZG_t6iXLbTDZq8GuJ5IaRRJ4dhSGCqmhiONrWDstptv8g.SbuAswhqJrqm_NBOd1DUtpNY1Qww2-ZpjZYtuKKfHPw&dib_tag=se&keywords=wire&qid=1713472189&sprefix=wire%2Caps%2C89&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1	24 AWG Stranded Wire Kit	1	$12.99	$12.99
https://www.amazon.com/Amazon-Basics-microSDXC-Memory-Adapter/dp/B08TJRVWV1/ref=sr_1_1_ffob_sspa?crid=1IEA1ND3N9I07&keywords=micro%2Bsd%2Bcard&qid=1707429576&s=electronics&sprefix=micro%2Bsd%2Bcard%2Celectronics%2C87&sr=1-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&th=1	Amazon Basics Micro SDXC Memory Card 128GB	1	$12.92	$12.92
399-C1206C104K5RAC7210CT-ND	CAP CER 0.1UF 50V X7R 1206	4	$0.07	$0.27
399-C1206C105K3RACTUCT-ND	CAP CER 1UF 25V X7R 1206	4	$0.16	$0.63
https://www.amazon.com/DURAMIC-3D-Filament-Flexible-Dimensional/dp/B095HRG913/ref=sr_1_3_pp?crid=14WOZK1E3S33T&dib=eyJ2IjoiMSJ9.Kf2R4WEQgpErBBYTQ_BvcG356mpQks9R6tOiJDR2A-8vdUvsAg7B_3iF0gEmORzftua8Zg05slT3vPYxwdbXyl-5qSOnomioZjROr7dJqeVY-e-ywoSnGsvxIS5WfGB6NrYORfwm8pHRlhOCrVJHMgGvDe9nYsjM806KSArlfuDVXGEYgK3Iuobd9KmY-xkvUagqh7_Tc6_jmQREMM6O7Ixj0MhWOq06G2Ba1iAqoOg.g6R8-21Xv9IGkV2p-rBFLNn0cHapv6_I8uoWahE27do&dib_tag=se&keywords=tpu%2Bfilament&qid=1713471168&sprefix=tpu%2Bfilament%2Caps%2C109&sr=8-3&th=1	DURAMIC 3D TPU Filament 1.75mm Black	0.05	$26.99	$1.35
https://www.thorlabs.com/thorproduct.cfm?partnumber=FD11A	FD11A - Si Photodiode, 400 ns Rise Time, 320 - 1100 nm, 1.1 mm x 1.1 mm Active Area	4	$16.00	$64.00
445-MMZ2012Y152BT000CT-ND	FERRITE BEAD 1.5K OHM 0805 1LN	2	$0.10	$0.20
FGL830	FGL830 - Ø25 mm RG830 Colored Glass Filter, 830 nm Longpass	1	$31.06	$31.06
FGS550	FGS550 - Ø25 mm KG2 Colored Glass Bandpass Filter, 304 - 785 nm	1	$32.13	$32.13

160-1456-1-ND	Green 571nm LED Indication - Discrete 2V 1206 (3216 Metric)	1	$0.31	$0.31
296-41185-1-ND	IC ADC 12BIT SIGMA-DELTA 10VSSOP	1	$2.94	$2.94
MCP1700T1802ETTCT-ND	IC REG LINEAR 1.8V 200MA SOT23-3	1	$0.50	$0.50
https://www.thorlabs.com/thorproduct.cfm?partnumber=LED750L	LED750L - 750 nm LED with a Glass Lens, 18 mW, TO-18	1	$10.61	$10.61
https://www.thorlabs.com/thorproduct.cfm?partnumber=LED851L	LED851L - 850 nm LED with a Glass Lens, 13 mW, TO-18	1	$16.52	$16.52
https://www.amazon.com/Charging-Android-Charger-Samsung-Devices/dp/B0BLL6M29N/ref=sr_1_3?crid=1LJJJYAU77OAZ&dib=eyJ2IjoiMSJ9.QWjmsQQqpyXKoa6oR2LrjriDRJPcN-9wByokUCYERoy2W1e0mSYkA4A_UEi_q7sY-xvE75vTH9tltdb_1gfZ3OnqH4U2wo6x_51sfraIxKj8Pwv6Px1etJETAJuLe6b-8Kys_580sqPBF2YlqiCB9HN2DgJCZkllI3myFpdiWKjB4Jf2MpaxKLZMms7C0HzGsKiMuI9kbKvwd1vTpg3t8TVbqdqA4jBC2S8MTXN7_RQ.Icsm3KPMq_Haw7UVY-T665PhOiQPjWLTsUdtT4aMA3Q&dib_tag=se&keywords=micro%2Busb%2Bcable%2B5ft&qid=1710880408&sprefix=micro%2Busb%2Bcable%2B5ft%2Caps%2C80&sr=8-3&th=1	Micro USB Cable 5 Feet	2	$4.49	$8.98
https://www.amazon.com/OVERTURE-Filament-Consumables-Dimensional-Accuracy/dp/B07PGY2JP1/ref=sr_1_1_sspa?crid=3M5RFZN62LIAH&dib=eyJ2IjoiMSJ9.N3CoWT0Yay-Z6cEggqI3zg9IU8ZxVnT6rBIdfG3FZ0S2ftG7Al9K3EzP9XR6G4y4oQMX5j6uECM1tbZBhis3-p-IcrKya3aw2eLufJyxMfMF9gRlT-UW3jOBZc2ibEFUh_tXppW2IV3fO1Zf_uzj3gTeh_cY8HKyJASFD0SyzzNV5N_SMQZwbTZ4UX57CZDhAcTFjqNkxnNorozzD2ionbaQeKgVMPYEI_O-7hzbXn0.YIGR2OiMXNcXEgNt6vTKyEd8tal0WcXoAoiEIP7rTTg&dib_tag=se&keywords=pla+filament&qid=1713472107&sprefix=pla+filament%2Caps%2C141&sr=8-1-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9hdGY&psc=1	OVERTURE PLA Filament 1.75mm PLA 3D Printer Filament	0.1	$16.19	$1.62
PCB	Pi Header Board PCB	1	$3.23	$3.23
https://www.amazon.com/10400mAh-Portable-Charger-External-Compatible/dp/B07JYYRT7T/ref=sr_1_7_sspa?crid=3XID5A8L92VT&dib=eyJ2IjoiMSJ9.30Wgg7Wn1eQ1wvDU9Adan4c-adq5ym6rMX3iIQGiviR6mL20KF3WstToFfwSD9-HppyZ-EmDrpzmRButEL9s6z9G6nAfrYEQBmxrIAuHPdcwydQGfM5SBBENidGM0HOLIisqv3MM5ufpzgTSh1AN8kfQgQd4_9gT5Ef7MgQn2FILG8rxWhPlF5TGPX8stIOXsbSKfKa8N7sBNIwBf4xwuBfRKXgRHBNG-rPQjAR9Ci0.8Jgy8lSd0OnKRpH5uEn_FUZikm8Ng7BhEKJDCrSuqSM&dib_tag=se&keywords=usb%2Bpower%2Bbank&qid=1710880146&sprefix=usb%2Bpower%2Bbank%2Caps%2C82&sr=8-7-spons&sp_csd=d2lkZ2V0TmFtZT1zcF9tdGY&th=1	Portable Charger, USB C Battery Pack	1	$13.99	$13.99
https://www.amazon.com/Raspberry-Zero-Bluetooth-RPi-2W/dp/B09LH5SBPS	Raspberry Pi Zero 2 W	1	$27.49	$27.49
RMCF1206FT10K0CT-ND	RES 10K OHM 1% 1/4W 1206	4	$0.02	$0.10

RMCF1206FT1K00CT-ND	RES 1K OHM 1% 1/4W 1206	4	$0.02	$0.10
RMCF1206FT2K00CT-ND	RES 2K OHM 1% 1/4W 1206	4	$0.02	$0.10
P150BCCT-ND	RES SMD 150 OHM 0.1% 1/4W 1206	1	$0.37	$0.37
679-1877-ND	SWITCH SLIDE SPDT 3A 30V	1	$5.97	$5.97
https://www.amazon.com/JKJF-Cycling-Trousers-Adjustable-Fastening/dp/B07WZ86RF1/ref=sr_1_1?crid=16HYHSOQZKT36&dib=eyJ2IjoiMSJ9.hhIsSHfFYdSYCk5f8o63bdtYbRE_xkgrENxQX2F7f520-p9lYGoUpGX6UPygVg-C0yAoVTG3EATn1uIAb2lH-bxMaqNZJw2UeBVypjhwWOIJIF5fzRdt4677lLs0iiuj0w9BxZgmzLwYqaqENS59CyR8wtR-89JOHv7MqeN7Zt7LZcSYLlD8Dh7-TW3EeU2rJen9uAQyFEw4M52gIzNTWEeZHB2VUprAwcwBdd-TXS6YaxEyqne2l0gFvIf9wfEmcjH4tSe0qjLrJgK9K7opsLuOTY2DpvZJXEw6jWptY1s.I2a9Lvan5xlgObtrd2j9CUFsVMbwEHc7EpQesV_Yfw0&dib_tag=se&keywords=leg+velcro+strap&qid=1713473979&sprefix=leg+velcro+strap%2Caps%2C108&sr=8-1	Cycling Safety Bind Pant Leg Bands Clip Strap	1	$6.99	$6.99
			Total	$255.35

APPENDIX C. DEVICE CAD MODEL

Link to device CAD model: https://a360.co/4cGNYVX