Adhesive Capsulitis Shoulder Assist Device (The ACS Assist)

Senior Project II (BME/ECE 496)

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Adhesive Capsulitis Heating Assist Device

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ABSTRACT

Adhesive capsulitis is a musculoskeletal condition that primarily affects the shoulder joint capsule through inflammation and scar tissue formation. It results in debilitating conditions such as limited range of motion (ROM), joint stiffness, and pain during arm movement. Approximately 20% of the diabetic population and 4% of the general population who have experienced shoulder trauma are affected by this condition. Physical therapy is a common treatment option. The focus of this project is to develop a home-use device to aid the physical therapy process by monitoring and assisting with shoulder ROM during exercise while simultaneously using heat therapy to help reduce joint stiffness and muscle fatigue. The device will track and record ROM data to allow for bidirectional therapy feedback and oversight between the medical professional and patient through software applications. Design requirements and specifications address the shoulder ROM monitoring, therapeutic heating system, device fit/comfortability, phone/web applications, and cloud database functionality.

The device is designed to be easily worn by patients without interfering with their therapy. It is expected to provide support through heating and ROM monitoring that will aid in performing prescribed exercises with reduced pain. The design will implement ROM tracking and heating functionalities through a microcontroller unit that collects and communicates data to the patient and supervising medical professional. Preliminary testing was conducted to determine component functionality and an initial design was developed in SolidWorks.

The device's plans were finalized and prototyping materials were purchased. Verification and validation protocols for testing the prototype were written. An IRB approval was obtained for testing the prototype on human subjects. Due to COVID-19, the prototype was left partially incomplete. This resulted in a lack of final testing data for the device.

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CHAPTER 1: INTRODUCTION

Written by Shruthi Radhakrishnan

Adhesive capsulitis is a pathological shoulder condition that affects approximately 20% of the diabetic population and 4% of shoulder trauma patients[1]. It is characterized by an onset of joint stiffness that progressively worsens and results in excruciating pain during shoulder movement. Typically, the treatment options available to patients can be classified as either operative or nonoperative techniques. The operative method involves arthroscopic shoulder capsule release surgery that allows surgeons to release the inflamed scar tissue formed around the shoulder joint capsule. The non-invasive methods include nonsteroidal anti-inflammatory drugs, intra-articular corticosteroid injections, and physical therapy. Although multiple treatment options are available, the most common method that is prescribed to patients is physical therapy. Rehabilitative exercises are performed by patients under the discretion of the medical professional.

In physical therapy, the medical professional typically uses household items, such as a towel, cane, and wall to assist the patient during manual stretching exercises[2,3]. After the stretching exercise regimen is performed for a few months, the medical professional uses resistance bands and weights to help improve the strength of the muscles that were lost during limited movement[4]. Typically, after the manual stretching and strengthening exercises, the patient is prescribed a home therapy program to further improve mobility and reduce pain[4]. Although simple household items are available for the patients to use during exercises, there are no commercially available devices that can record shoulder use during exercise and provide assistive measures such as heating and patient/medical professional feedback. The focus of the project is to address Adhesive Capsulitis in patients seeking physical therapy, by monitoring and assisting with their shoulder range of motion while performing exercises outside a clinical environment. Although patients and therapeutic endpoints will not be utilized as a part of this project, the goal of this project is to create a working device prototype that gives a patient the ability to monitor the progress of their physical therapy and provide assistance as they perform their exercises, and to also implement a means by which a physical therapist can check upon their patient's progress and provide feedback.

Team Roles

This project encompasses a number of distinct technical components that must be successfully integrated to complete the final device. Thus, the following roles have been assigned to each team member:

Shruthi Radhakrishnan: Shruthi is responsible for the thermal component of the device, including the heating source and control system, temperature sensor selection and integration, and thermal analysis modeling. She is managerially assigned Team Leader.

Ryan DesRochers: Ryan is responsible for the mechanical structure design and physical modeling of the device. He is managerially assigned as Secretary.

Geoffrey Bartner: Geoff is responsible for device battery selection and power consumption analysis as well as environmental shielding of the device.

Daniel Hanna: Daniel is responsible for microcontroller selection as well as range of motion tracking component selection and integration. Also responsible for android application development. He is managerially assigned as Webmaster.

Javier Thomas: Javier is responsible for the backend storage and management of user data, as well as web app development. He is managerially assigned as Timeline Master.

CHAPTER 2: BACKGROUND

Written by: Shruthi Radhakrishnan

Adhesive Capsulitis is a musculoskeletal condition that involves inflammation and scar tissue formation of the synovial shoulder capsule[5] (Figure 1). The condition presents in three stages: the painful, frozen/adhesive, and thawing/regression[6]. In the first stage, patients experience an onset of shoulder pain while moving their arm, which eventually leads to progressive joint stiffness[6]. The next phase involves gradual reduction in shoulder range-of-motion (ROM) in all anatomical planes[6]. The last stage is described as a regression period where the patient's ROM is slowly improving; however, it is never restored to the original ROM. It is a painful disorder that results in stiffness and discomfort in the shoulder joint, as well as limited range of motion with respect to arm movement[7].

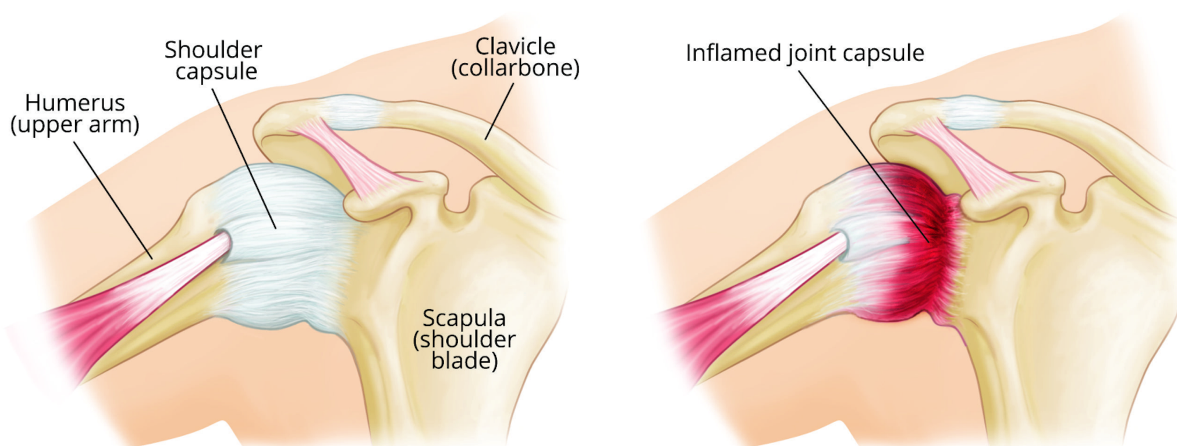


Figure 1. Average Human Shoulder Capsule (LEFT) Inflamed Capsule found in Adhesive Capsulitis patients (RIGHT)

[8] "Thawing." Frozen Shoulder, OrthoInfo, orthoinfo.aaos.org/en/diseases--conditions/frozen-shoulder/.

Although invasive treatment options such as arthroscopic capsular release and manipulation under anesthesia are available, patients typically prefer a more conservative approach such as physical therapy to improve shoulder range of motion. In the therapy sessions, the medical professional focus on both passive and active motion exercises. Passive exercises are movements that are performed on the patient by the medical professional[3]. These exercises include passive arm elevation and external rotation, which are typically executed in the coronal and transverse planes[4,9] (Figure 2). Physical therapists generally begin with passive ROM exercises as pre-workout exercises to reduce the initial stiffness experienced by the patient[3].

Afterwards, patients perform active motion exercises under the supervision of the medical professional. The active motion exercises include pendulum, wall climb, and back stretch exercises which address flexion, extension, and rotation movements[4,10]. In the pendulum (flexion) exercise, the patient is asked to bend over so that the arm is at a relaxed position on the side and is expected to swing the arm back and forth or in a circular motion for about 2-3 minutes[10](Figure 3). The wall climb stretch focuses on vertical extension where the patient is asked to place a hand on the wall and is expected to move the hand upwards while stretching the arm for approximately 15 seconds[10] (Figure 4). Lastly, in the internal rotation back stretch exercise, the patient is asked to place the frozen shoulder arm behind their back and stretch the arm up towards the shoulder blade for approximately 15 seconds[10](Figure 5). This exercise can be performed with another hand or towel for external support.

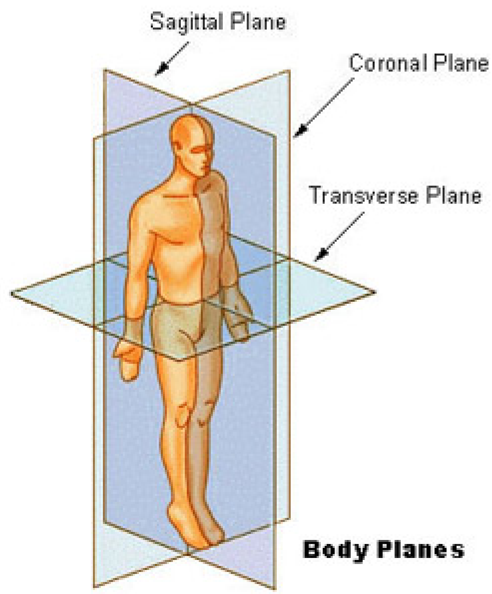


Figure 2. Representation of the Anatomical Planes[9]

[9] "Body Planes." Anatomical Terminology, U. S. National Institutes of Health, National Cancer Institute, https://training.seer.cancer.gov/anatomy/body/terminology.html

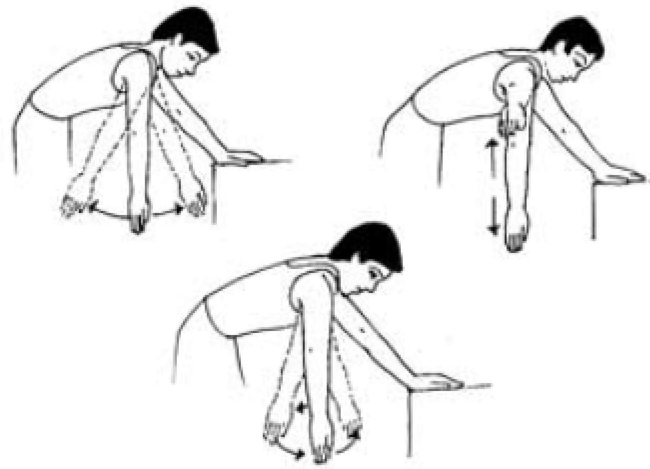


Figure 3. Pendulum Exercises that address Flexion[11]

[11] "Shoulder Exercises." Arthritis, www.arthritis-india.com/shoulder-exercises.html.

Figure 4. Wall Climbing Exercises that address Extension[10]

[10] Sanders, Brett. "Frozen Shoulder – Adhesive Capsulitis", Massachusetts General Hospital Sports Medicine Service.

Figure 5. Back Stretch Exercises that address Internal Rotation[10]

[10] Sanders, Brett. "Frozen Shoulder – Adhesive Capsulitis", Massachusetts General Hospital Sports Medicine Service.

Although these exercises are performed by the patient with the assistance of the medical professional, joint pain and stiffness tend to persist. Therefore, heating packs or wraps are used to provide heat to the target regions for relief. Superficial heating is a common technique used during physical therapy to help improve mobility and reduce joint pain experienced during rehabilitation exercises. The application of heat can modify the viscoelastic properties of the inflamed shoulder capsule by improving muscle extensibility in patients with this condition[4]. From a physiological standpoint, the heat will help improve perfusion in the muscle tissue, increase metabolism and elasticity of the shoulder connective tissue[12]. Typically, heat is applied to the subscapularis and infraspinatus muscles (rotator cuff muscles). The heating regimen is 10 minutes prior to exercise and 15 minutes during exercise for therapeutic effect[3] (Figure 6) . The optimal temperature range to attain therapeutic benefit is between 40 - 43 °C[13].

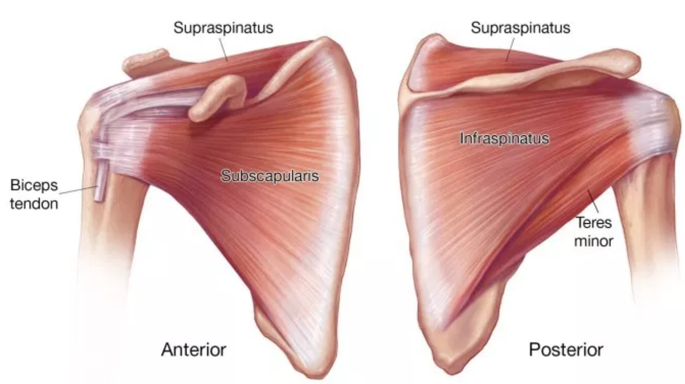


Figure 6. Anatomical diagram of targeted shoulder muscles (subscapularis and infraspinatus) for heat therapy[14]

[14] "Tears of the Subscapularis: Hidden and Forgotten, No More!" Shoulder & Elbow, 9 Aug. 2018, shoulderelbow.org/2018/08/08/subscapularis-rotator-cuff-tears/.

The focus of the project is to design and build a prototype that addresses adhesive capsulitis in physical therapy patients. The functions of the device are to provide rehabilitative assistance for adhesive capsulitis patients by applying heat to the shoulder joint during physical therapy exercises and allow shoulder ROM monitoring by both patient and medical professionals. The assistive monitoring can prevent patients from over-exceeding their prescribed ROM while exercising at home. The device will communicate the temperature and angle data in a bidirectional manner between the patient and medical professional so that feedback and oversight can be given accordingly. The targeted populations of this device are 20% of diabetic patients and 4% of shoulder trauma patients who develop adhesive capsulitis[1]. On average, these patients are between the ages of 40 and 60 years[1]. The project will primarily impact patients who are performing physical therapy exercises at home. According to a Voice of Customer obtained from the physical therapist, patients typically fail to use proper therapy techniques while doing the exercises without supervision[3]. Therefore, this device will be a way for both the patient and medical professional to monitor therapy progress[3].

CHAPTER 3: BROADER IMPACT OF DESIGN

Written by: Ryan, Shruthi, and Geoff

Adhesive Capsulitis is an exceedingly prevalent condition where the shoulder joint capsule becomes inflamed. This results in significant scar tissue formation, causing limited shoulder range of motion, overall joint stiffness, as well as pain in the movement of the arm. Approximately 4% of shoulder trauma patients are affected by this condition. Physical therapy is the most common treatment plan due to its non-invasive nature. This device is designed to aid these physical therapy patients by monitoring and improving the quality of the patients' physical therapy regimens in order to reduce joint stiffness. This is implemented through the use of a heating component as well as a range of motion monitoring system which is overseen remotely by the supervising physical therapist[1]. As a result of the increase in adhesive capsulitis patients, it is significant to examine the potential impact of the device design from social, global, and economic standpoints.

An incidence of 3-5% in the general population means adhesive capsulitis is one of the most common orthopedic issues. This issue often presents long term effects for up to 10 years. As a result, many individuals involved in physical work struggle to maintain their lifestyle with this condition. While this condition has a smaller impact on those involved in office jobs, the condition can still result in an altered lifestyle of these individuals. With a broad implementation of this device across physical therapy offices, the overall convenience of the physical therapy regimen for treatment will be vastly improved. As a result, the users who may not have had the ability to take the time to seek clinical treatment due to work or other commitments may have the time to complete the physical therapy regimen. This can result in workers not only missing less work time, but also fully recovering much more quickly so that they can contribute to the workforce at their greatest capacity[5].

The majority of patients who are impacted by this condition are within the ages of 40-60 years old1 which means that on average, these people will not qualify for Medicare since they are not over the age of 65 years. However, it does not put the patients at a disadvantage because Medicaid is available for people who have limited financial capabilities who are unable to pay the out-of-pocket expenses after insurance[15]. Furthermore, there are also private insurance companies like Aetna that provide financial help and will pay approximately $1,500 for assistive devices like the ACS Assist to cover for the financial strain experienced by people who have low incomes[15].

Another aspect of this device is that it's intended to be powered by a rechargeable lithium ion battery pack. This is advantageous since lithium ion batteries can also be safely recycled in processing plants across the country once they have corroded causing less damage to the environment. Users recycling these worn out batteries will allow them to not contribute to the staggering 180,000 tons of battery waste dumped by Americans each year which leads to the waste runoff into the environment. Recycling batteries also allows rare resources to be reused, cutting down on the need to excavate and process more from the Earth[16].

Since the device has the added feature of providing heating to the subscapular and surrounding tissue it is a more costly option compared to conventional shoulder rehabilitation devices which range from $50 to $150. Yet the ACS device has a greater return on investment since the heat it provides will assist the users, helping them to recover quicker by providing exercise data and therapeutic heating. As previously mentioned this allows them to return to work sooner which benefits themselves and their company. A quicker turnaround results in more productivity the user can achieve at work, as well as more patients the physical therapist can treat. The rechargeable lithium ion battery also removes the need for purchasing disposable batteries. The ACS device is more expensive than conventional rehab devices but its extra features allow its users to recover from shoulder trauma quicker and resume productivity sooner.

CHAPTER 4: DESIGN INPUTS

The design process is modeled after the FDA Design Control framework (21 CFR 820.30). Design inputs were developed based on the physical and performance needs of the device and are categorized as requirements and specifications. Design requirements are formulated based on the user needs and target functionalities. Specifications are the quantitative measures that correspond to the requirements to which the device must conform. The design inputs were used to develop prototype sketches. Verification and validation testing are performed to confirm that the design requirements and specifications are fulfilled by the prototype. The design inputs listed below address the device need and intended functionalities of the prototype.

Requirement 1: The device must fit the average female and male human shoulder dimensions. -Ryan

The device needs to fit users with different body types and shapes in the target population.
Specification 1.1: The device needs to be wearable by men and women who have an average shoulder breadth range of between 35.6 and 53.2 cm[17].
Specification 1.2: The device needs to be wearable by men and women who have an average bicep circumference range between 21.8 and 36.9 cm[17].
Specification 1.3: The device needs to be wearable by the 5th percentile of women to the 95th percentile of men who have a shoulder-elbow length between 30-39 $\pm$ 0.6 cm[18].

Requirement 2: The device weight must not prevent the patient from performing the exercise. -Ryan

This requirement is essential to the proper function of the device, which is intended for the patient to use to perform physical therapy. The patient must be able to correctly perform the exercises outside the clinical environment without the device hindering them.
Specification 2: The device must not exceed a weight of 4.1 kg. This is equivalent to 10% of the weight of the 5th percentile of women, the smallest intended users of the device. According to Son et. al., this weight can be beared by the shoulders without significantly affecting the movement of the individual[19].

Requirement 3: The device must support movement in vertical flexion.
-Ryan

The device is intended for users to safely move their shoulders in vertical flexion during the recovery process.
Specification 3: The device must support movement in vertical flexion. The device will allow the arm to be raised along the sagittal plane for 180° ± 9° from resting position at the side (0°)[20].

Requirement 4: The device must support shoulder movement in vertical extension.
-Ryan

The device is intended for users to safely move their shoulders in vertical extension during the recovery process.
Specification 4: The device will allow the arm to be raised along the sagittal plane for 60° ± 3° from resting position at the side (0°)[20].

Requirement 5: The device must support shoulder movement in rotation.
-Ryan

The device is intended for users to safely move their shoulders in rotation during the recovery process.
Specification 5: The device needs to move with the arm for 68° ± 3.5° in external rotation and 109° ± 5.5° in internal rotation with the shoulder complex at 90° of abduction[20].

Requirement 6: The device must continuously deliver superficial heat to the shoulder before and during exercise.
-Shruthi

The device is intended to provide user with therapeutic relief while performing exercises according to the physical therapist's prescribed regimen. The heat can modify the viscoelastic properties of the tissue located at the shoulder muscles and reduce joint stiffness to improve mobility.

<u>Specification 6.1:</u> The device's heating element needs to heat to 40-43°C for therapeutic effect[13].
<u>Specification 6.2:</u> The device's heating element needs to apply heat from the subscapularis muscle around the armpit region to the infraspinatus muscles (rotator cuff muscles)[3].
<u>Specification 6.3:</u> The device's heating element needs to heat the shoulder 10 minutes before the exercise and heat for 15 minutes during the exercise[3].

<u>Requirement 7:</u> The device's heating element must shut off before an unsafe temperature is reached.
-Shruthi

The shoulder temperature needs to be monitored so that the device does not overheat the region and cause burns/injury during therapeutic heating regimen. The shut-off mechanism will help to avoid any safety hazards and injuries that can result from device malfunction.
<u>Specification 7.1:</u> The device's heating element will shut off when device temperature exceeds 43°C[21].
<u>Specification 7.2:</u> The device will have a physical and software shut-off mechanism in accordance with ISO/TS 19218-1[22].

<u>Requirement 8:</u> The device must record positional data during exercise.
-Daniel

The device is intended to enable a wearer to view the progress of their exercise in real time and to also allow for a physical therapist to comment on such progress. In order to do this, the device will need to record angle data for the different ROMs and device temperature as a function of time in an algorithm so that viable data can be available for viewing by the device users.
<u>Specification 8:</u> The metrics that are recorded must include flexion/extension/rotation angles as well as temperature and must be within 5% accuracy.

<u>Requirement 9:</u> Data that are stored from the device must be electronically protected.
-Daniel

These data involve personal medical information of the device wearer; hence, this data must be electronically protected such that unauthorized persons do not have immediate access to it.

Specification 9: The data are Advanced Encryption Standard (AES) encrypted in accordance to National Institute of Standards and Technology (NIST) recommendations[23].

Requirement 10: The device must send collected data to a database containing previous measurements.
-Daniel, Javier

In order to allow a medical professional to review the recorded data without having direct access to the device, the data must be available in a database that can be accessed remotely. This is done through the dual connection of a cloud database, which will allow access to the data at all times. Thus, wireless connectivity must be established to allow for the sending of data.
Specification 10: The device will have wireless capability via Bluetooth.

Requirement 11: The device's partnered software must allow medical professionals to review performance data.
- Javier

The data must be interpreted by a physical therapist/clinician so that they can monitor user progress and update regimen if necessary. Because of this, the raw data will not be sufficient in its base form.
Specification 11.1: The accessible metrics include flexion/extension/rotation angles and temperature.
Specification 11.2: There will be use of external software to display data.

Requirement 12: The device and software components must be user-friendly outside a clinical environment.
- Shruthi

Patients who are in a non-clinical environment are going to be using the device, and as a result they need to understand the system they are using since the device is not only for english-speaking people.

Specification 12: The symbols on the medical device and its documentation should be used in accordance to ISO 15223-1 standard[24].

<u>Requirement 13:</u> The device must alert the user if the clinical range of motion is exceeded.
-Shruthi

The device is intended to deter re-injury due to overextension in any anatomical plane during recovery exercises. The alert will be used as an alternative to physical lockouts (barriers) that can hinder the user's mobility (Requirement 2).
<u>Specification 13.1:</u> The physical therapist needs to be able to set the clinically prescribed ROM for each individual.
<u>Specification 13.2:</u> The device should have a progressive alarm system that alerts user via visual and tactile (vibration) cues.
<u>Specification 13.3:</u> There will be a visual gradient displayed on the user's mobile device app throughout the duration of the exercise.

<u>Requirement 14:</u> The electric components of the device must be shielded from external moisture and contaminants.
-Shruthi

The electric components must be shielded from external moisture such as sweat during exercise so that electrical hazards can be prevented. These ANSI/IEC standards specify safe operating and storage conditions that must be met for the electrical enclosures.
<u>Specification 14.1:</u> The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11[25].
<u>Specification 14.2:</u> The electric components should be made in accordance to ANSI/IEC 60529 (IP Code regulations for electric enclosures)[26].

<u>Requirement 15:</u> The user must be able to put on the device without assistance.
-Geoff

The users of this device would not have full mobility in one of their arms, so they should be able to put on the device using one arm without external assistance. This requirement will be confirmed through validation tests and surveys.

Requirement 16: The battery of the device must last for the duration of physical therapy exercise. -Geoff

The device is intended to record prevalent data for the physical therapist throughout the entire exercise as well as apply therapeutic heat to the user.
Specification 16: The device needs to be powered for at least 25 minutes during the exercise session[3].

CHAPTER 5: HEATING

Written by Shruthi Radhakrishnan

Heating Source Element Selection

Heating elements are available in different sizes and can produce a large range of temperatures. However, the targeted regions of the device are the shoulder joint and surrounding muscles; hence, thermal sources were considered such that heat could be provided to the specified area without restricting shoulder movement. Since the device is intended to perform multiple functionalities that involve electrical sources, the heating elements that were examined involved converting electric energy to heat energy (thermoelectric). Therefore, the possible options were carbon fiber heater tape, polyimide heater sheets, an AdaFruit Heating Pad, and a Peltier System. These options were analyzed using decision matrices that evaluated each source based on a set of criteria.

Flexibility is an important criterion that was considered because the Voice of Customer (Specification 6.2) provided by the physical therapist specified that the targeted regions for therapy are the subscapularis muscles located on the anterior plane of the body, the underarm region, and the infraspinatus muscles located at the back of the shoulder[3](Figure 6).Another major criterion was the temperature range provided by the heating element. Based on the heating element specification, the produced heat needs to reach the therapeutic range of 40-43°C[13](Specification 6.1). The heat sources were also evaluated based on thermal conductivity values. Thermal conductivity is a quantitative measure that describes the rate of heat transfer that occurs by conduction through the length of the material. Another factor that was considered was the mechanism of heating, because it is crucial for the heat to diffuse throughout the targeted muscles instead of accumulating in one stagnant region. Lastly, the estimated power consumption was also analyzed for each option so that the power can be supplied adequately without a bulky battery supply that can potentially hinder the user from performing the exercises. Therefore, the criteria used to select the heating element were flexibility, output temperature range, heating mechanism, power draw (W) or power density (W/cm^2), thermal conductivity (W/mK), and cost.

All the heat sources were evaluated based on a level of acceptance indicated for each decision criterion. In the decision matrix, a criterion is either fully, partially, or not satisfied and is indicated in green, yellow, or red colors, respectively (Table 1). For flexibility, the criterion is fully satisfied if it allows shoulder movement when attached to the device. The acceptance range for the temperature category is between 40-43C[13](Specification 6.1). Heat mechanism was also important and this criterion is fulfilled if the heat can be diffused through the source without a heat sink. While considering thermoelectric heaters, it is crucial to estimate the expected power draw from the source so that an appropriate battery could be selected. Therefore, the power draw acceptance criteria are heat sources that drew less than 15 W. This value is determined based on the other electric components of the device which were also factored into the power draw estimates. Furthermore, the acceptance criteria for the thermal conductivity category are heaters with conductivities (K) greater than 0.2 W/mK. Lastly, the cost category is satisfied for heat sources that cost less than ten dollars. The level of acceptance for each of these categories are indicated in Table 1 for each heat source.

Initially, the peltier heater system was evaluated based on the listed criteria. It was determined that the peltier lacked flexibility since it has a square configuration which would make it difficult for patients to move the arm easily when the element is attached to them. Also, a peltier system is a thermoelectric source that is intended to provide both heating and cooling by functioning as a heat pump[27]. Heat is transferred from one electric junction to another in the direction of current flow when a specified voltage is applied[27]. Hence, a heat sink was needed to dissipate the heat evenly throughout the shoulder muscles because the peltier was not heat diffusive[27] (Table 1). The peltier module did have the potential to meet the heating needs for the device, because it covers the expected temperature range which is between 40-43 °C, according to design specification 6.1. Furthermore, factors such as estimated power draw and cost made the peltier a less effective option for the device (Table 1).

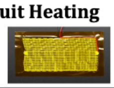
The polyimide heater sheet was the next source that was evaluated. Polyimide sheets have foil elements embedded between the polyimide film which help distribute the heat evenly[28]. Although the polyimide sheets were flexible and had a wide temperature range, it was not the most effective option for this project because it lacked thermal conductivity relative to the other options with K = 0.17 W/mK at 100°C[28]. Thermal conductivity is a significant criterion that was used to evaluate the components, because it quantifies a material's ability to conduct and transfer heat. The source needs to have the capacity to transfer the heat to the specified shoulder muscles. Thus, the polyimide sheets were not selected as a component to be used for the device.

The next component that was investigated was the Adafruit Electric Heating Pad. This electric heater is manufactured with metal-polymer fiber conductive threads in a rectangular configuration[29]. It is voltage-powered and has a heat diffusive mechanism through the conductive thread mesh which allows for heat distribution. It has good flexibility and yields a low estimated power draw ranging from 2.5 to 3.8 W[23] (Table 1). However, it is a moderate heat conductor because it has a small thermal conductivity of 0.2 W/mK[29]. Hence, the Adafruit heating pad was not selected as the device's heating element.

The final option evaluated in this decision matrix was the carbon fiber heater tape. Carbon fiber has high thermal conductivity values and strong tensile properties due to its metal-composite fiber structure[30]. Additionally, the tape is also thin and flexible which makes it a viable option to wrap around the patient's shoulder muscles to increase the surface area for heat to dissipate evenly. Lastly, the carbon fiber tape is within the expected temperature range and is relatively low in cost, $4.40/ft[31]. The one criterion that was slightly concerning was the estimated power draw values because the tape has a very wide range (Table 1), which could indicate that more power would be necessary to reach the therapeutic temperature range of

40-43°C. Power calculations and tape testing were performed to obtain an accurate power draw estimate and can be found in Chapter 7. The carbon fiber heater tape was selected as the heating element because it satisfied most of the criteria relative to the other options.

Table 1. Decision Matrix for Heat Source Component Selection. The cells are indicated as green,yellow, or red to signify the level of acceptance. Green cells indicate the criterion is satisfied. Yellow cells indicate that criterion was partially satisfied. Red cells indicate that the criterion was not satisfied.

	Flexibility	Temperature Range (°C)	Heating Mechanism	Estimated Power (W) or Power Density (W/cm^2)	Estimated Thermal Conductivity (W/m·K)	Unit Price ($)
Carbon Fiber Heater Tape 	Yes	-20 to 400	Heat Diffusive	1.1 to 28.6 W	0.5 to 3	4.40/ft
Polyimide Heater Sheets 	Yes	-195 to 200	Heat Diffusive	0.8 to 7.8 W/cm^2	0.17 (100°C)	5 to 20
AdaFruit Heating Pad 	Yes	40 to 130	Heat Diffusive	2.5 to 3.8 W	0.2	3.95
Peltier System 	No	Δ T-max: 50 to 123	Heat Pump; Needs Heatsink	2 to 133 W	0.025 to 1.5	13 to 60

Carbon Fiber Heater Tape Testing

After selecting the carbon fiber tape as the heating element, initial testing was performed to determine if the temperature of the tape can be modulated within the therapeutic range. The tape was prepared for testing by crimping each end with a brass conductive metal sheet (Figure 7). Then, wires were attached to the brass sheet on each side of the tape . Afterwards, the red and black metal clips were connected to the brass ends of the tape in order to pass current from a DC power supply. While the current was passed through the tape, the temperature was measured using a thermocouple thermometer probe that was calibrated to 25°C (ambient air temperature) prior to testing.

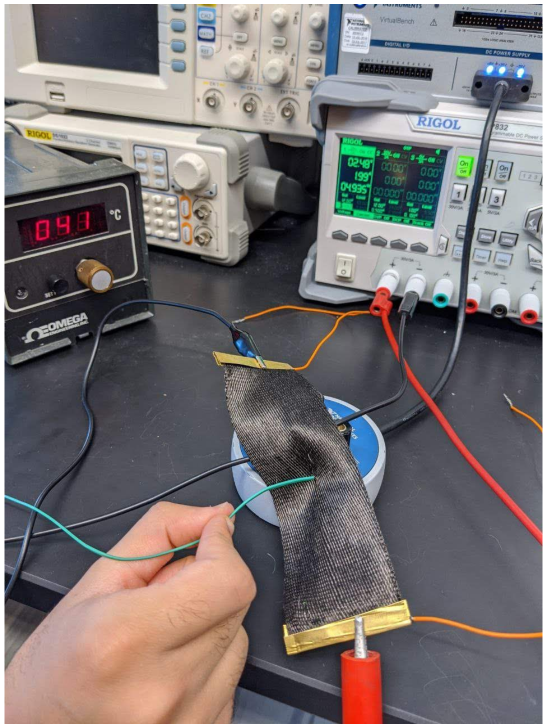


Figure 7. Carbon Fiber Tape testing setup using DC Power Supply to supply voltage and current. A thermocouple temperature probe was calibrated and used to record the tape temperature.

The input voltage that was tested was at 9V according to the estimated voltage range listed in the manufacturer's temperature data sheets[32]. The DC power supply was adjusted to these voltages and held constant. Five trials were completed while varying the current and keeping the voltage constant. Voltage, current, and resistance share a linear relationship according to Ohm's Law (Equation 1). Therefore, the input voltage was held constant while the current was varied as it was passed through the tape. The current was linearly proportional to the voltage and inversely proportional to the internal resistance of the carbon fiber tape.Temperature data were recorded from the testing to calculate the expected power draw of the tape (Equation 2, Appendix N). The power quantifies the rate of electric energy that is consumed per unit time from the electric circuit.

(1) $V = IR$ **(2)** $P = IV$

The current and temperature data were plotted for each current value tested between 1.2 and 2 A. (Figure 8). The overall trend was a progressive increase in temperature as the current was increased (Figure 8).

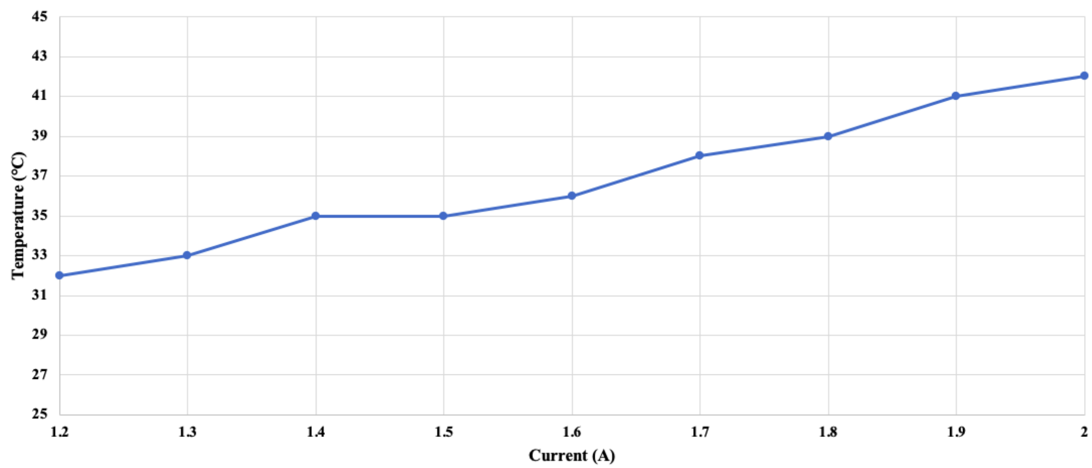


Figure 8. Current and Temperature Data plotted for 9 volts source.

Furthermore, temperature and current data were used to compute a relationship between power (W) and temperature for 9 V source. The purpose of this testing is to determine the estimated power draw necessary to heat the carbon fiber heater tape. The results plotted temperature as a function of power (Figure 9). Based on the results, it is inferred that the therapeutic temperature range 40 - 43°C can be attained with 14 to 17 watts. Further calculations were conducted in order to precisely estimate the expected power draw for the carbon heater tape included in Chapter 7.

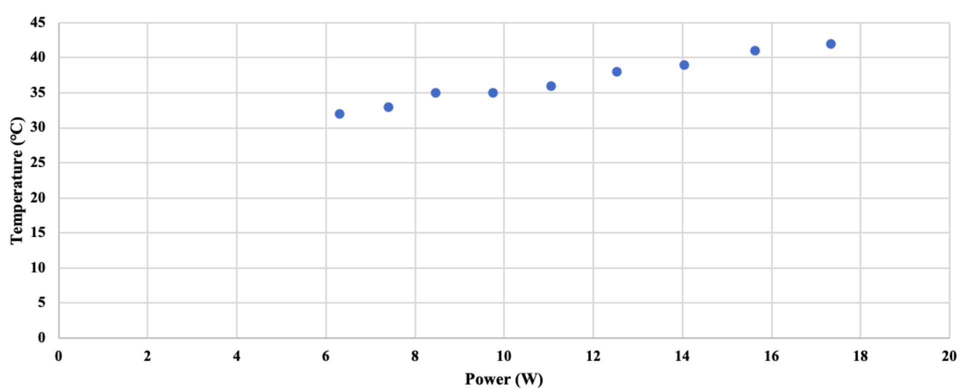


Figure 9. Temperature plotted as a function of power for 9 volts source.

Temperature Sensor Options

The next part of the heating system that was addressed were temperature sensors that would be used to detect the device temperature. Sensors are devices that convert physical parameters to electrical signals. Temperature sensors are crucial for the device so that surface temperatures can be recognized and converted to electric signals to sense temperatures that deviate from the therapeutic range to modulate the heating control system. The options that were considered were the Negative-Temperature Coefficient (NTC) thermistors, Resistance Temperature Detectors (RTD), and Digital I^2C sensors (Table 2). The factors that were used to evaluate each of these components were temperature range (°C), sensor accuracy, need for an analog to digital signal converter (ADC), sensor response time, and cost.

Similar to the heat source decision matrix, the temperature sensors were also rated based on a level of acceptance. In the decision matrix, a criterion is either fully, partially, or not satisfied and is indicated in green, yellow, or red colors, respectively (Table 2). For temperature range, the criterion is satisfied if the sensor can detect a wide temperature of at least 100°C. In terms of accuracy, it is vital that the sensor has a higher degree of precision so that the slightest temperature change can be detected. Therefore, the accuracy should be within ±0.5°C. Since the temperature sensor is interfaced with the outside environment and heating element. The temperature is modulated with a control system implemented with a microcontroller. In order to detect any signals through the microcontroller, the signal needs to be digitized. Therefore, the analog value initially obtained by the temperature sensor would be converted using a AD converter making it another category in the decision matrix. This category is fully satisfied if there is no need for an external AD converter, otherwise it's only partially satisfied if the temperature signal needs to be manipulated. Furthermore, the response time of the temperature sensor was also analyzed. The acceptance criteria for this category are response times less than 10 seconds. Lastly, the sensor cost was another factor that was considered. The sensor satisfies this criterion if the cost is less than 10 dollars.

Initially, the RTD was considered as a sensor option and evaluated based on the criteria mentioned above. RTDs are sensitive to temperature changes and can detect a wide range of temperatures. However, the RTD was not the optimal choice for this project because it had a slow response time relative to the other two options, making it more difficult for the sensor to quickly detect any slight deviations in device temperature. Furthermore, the RTD also had a decent accuracy range between ±0.1 to 1°C[33]. Sensor accuracy is imperative for this component because the therapeutic range is very small and narrow (40-43°C), so it would be necessary for the sensor to precisely detect any temperature changes at a higher resolution to avoid the chances of overheating. Additionally, RTDs were quite expensive with prices ranging from $13 to $75, which was not suitable for the listed budget[34]. Based on these factors, the RTD was not selected because it lacked in response time, sensor accuracy, and cost.

The second temperature sensor that was examined was the digital I^2C sensor. Unlike the other two options, this sensor is not analog so it does not need an ADC converter to digitize the physical signal. It also has a large temperature range; however, it has poor accuracy and slow response time similar to the RTD (Table 2). Furthermore, it is also slightly expensive relative to the other options, so the I^2C sensor was not selected for the heating component.

The last temperature sensor that was considered was the NTC thermistor. The trend that is observed in these thermistors is an inversely proportional relationship between resistance and temperature, where an increase in temperature will decrease electrical resistance. This sensor satisfied most of the criteria which include the temperature range, accuracy, response time, and unit price (Table 2). The only drawback is that it needs an AD converter to digitize the analog signal, which is expected to be performed through the analog pins of the microcontroller unit. The NTC thermistor was selected as the temperature sensor for the device as it satisfied most of the listed criteria.

Table 2. Decision Matrix for Temperature Sensor Selection. The cells are indicated as green,yellow, or red to signify the level of acceptance. Green cells indicate the criterion is satisfied. Yellow cells indicate that criterion was partially satisfied. Red cells indicate that the criterion was not satisfied.

	Temperature Range (°C)	Accuracy (°C)	AD Converter	Response Time (seconds)	Unit Price ($)
NTC Thermistor 	-100 to 325	± 0.05 to 1.5	Yes	0.12 to 10	0.40 to 3.60
RTD 	-200 to 650	± 0.1 to 1	Yes	1 to 50	13 to 75
Digital I2C 	-55 to 125	± 0.1 to 2	No	5	2 to 15

Thermal Analysis Model Setup / Heat Calculations

Thermal analysis modeling was performed on ANSYS Workbench to analyze the temperature gradient as heat travels from the surface of the skin through fat to the shoulder muscle tissue. The shoulder skin, fat, and muscles were simplified to a three layer slab model. The slab was modeled under transient, semi-infinite conditions for the full duration of physical therapy which is 25 minutes[4]. The boundary conditions of this model are skin surface temperature (T_s) at z = 0 which was set at a value between the therapeutic range of 40-43 °C as indicated in the model diagram (Figure 10). The model was initially sketched as a 10cm by 5cm slab and extruded to the thickness of skin, fat, and muscle layers. As a three-layer slab model, each layer was differentiated based on isotropic thermal conductivity, density, and specific heat values that were distinct to human skin, fat, and muscle. According to literature, the human skin is approximately 0.254 cm thick with an isotropic thermal conductivity of 0.442 W/mK[35]. Human fat and muscle were approximated to 0.30 and 0.50 cm in thickness, respectively, with corresponding isotropic thermal conductivity values equivalent to 0.21 W/mK and 0.42 W/mK, respectively[36],[37]. The muscle thickness values were obtained using the average thicknesses of the subscapularis and infraspinatus muscles. In order to perform the transient analysis, the density and specific heat values for each layer were approximated based on literature findings. Skin has a density of 1109 kg/m^3 and specific heat of 3391 J/kg/K[37]. The subcutaneous fat beneath the skin has a density of 911 kg/m^3 and specific heat of 2127 J/kg/K[37]. Lastly, the muscle layer has a density of 1090 kg/m^3 and specific heat of 3421 J/kg/K[37]. These thermal properties were inputted into ANSYS Workbench, and the geometry was meshed for finite-element analysis (Figure 11). The mesh quality was set to fine and applied across the entire geometry.

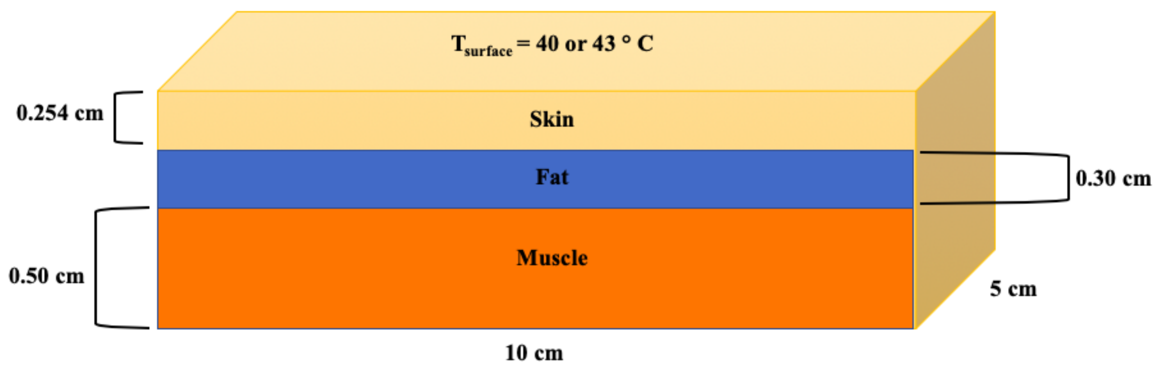


Figure 10. Three layer, semi-infinite slab model that separates the shoulder region into skin, fat, and muscle layers. The thickness of each layer is scaled according to literature values. The surface temperatures of $T_{surface}$ = 40 and 43 °C were used to run two simulations in transient analysis.

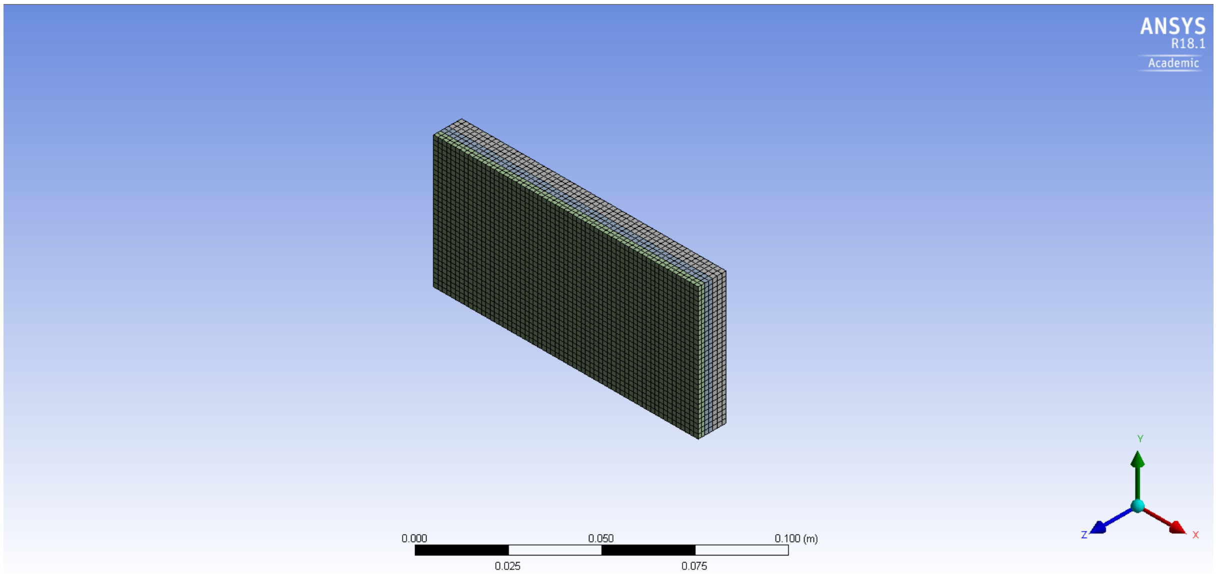


Figure 11. The slab geometry with a fine mesh applied to all surfaces for finite element transient analysis

Afterwards, the transient thermal simulation settings were configured for initial temperature and thermal conduction. The initial temperature of the slab was set to average body temperature, 37 °C. Heat conduction was modeled using surface temperatures of either 40°C or 43°C assigned to the top face of the skin layer. The thermal conduction gradient was modeled through the layers as three resistances arranged in series. Two simulations were performed to obtain temperature profiles for the lower (T = 40°C) and upper bound (T = 43°C) in the therapeutic temperature range. The time steps were modulated in analysis settings to model the simulation for the entire duration of physical therapy, 1500 seconds (25 minutes).

Thermal Simulation Results & Future Development

The results from the simulations converged and temperature profiles were obtained for $T_{surface}$ = 40 and 43°C. The overall trend that is observed in the 40°C simulation is a slow increase to 39°C from the initial body temperature of 37°C (Figure 12). Similarly for the 43°C surface temperature simulation, the temperature profile gradually increases from 37°C to 42°C in the layers where it can be assumed that the model reaches steady state around 42°C over the course of 25 minutes (Figure 12). The temperature gradient as it travels through the three layers is visualized as a thermal map for 40 °C and 43 °C (Figures 9 and 10). Overall, the simulation results show that the therapeutic range can be attained during a single physical therapy session that lasts for about 25 minutes (1500 seconds). Based on the profile, it is important to have a pre-heating phase in the device of 10 minutes to have enough time to heat the skin surface and allow it to progress through the fat and muscle layers. In the 40°C simulation, the temperature gradient slowly decreases from the surface to the muscle layer as the heat travels through the skin, fat, and muscle until it reaches a steady state temperature of 39.82 °C in the muscle (Figure 13). Likewise, in the 43°C simulation, the physiological resistance of the layers prevents the muscles from reaching 43 °C and only heats it to ~ 42.64 °C (Figure 14). Although the temperature profiles fit the expected trend where the surface temperature reaches the muscle layer over a period of 1500 seconds, further analyses were performed to validate the thermal analysis models.

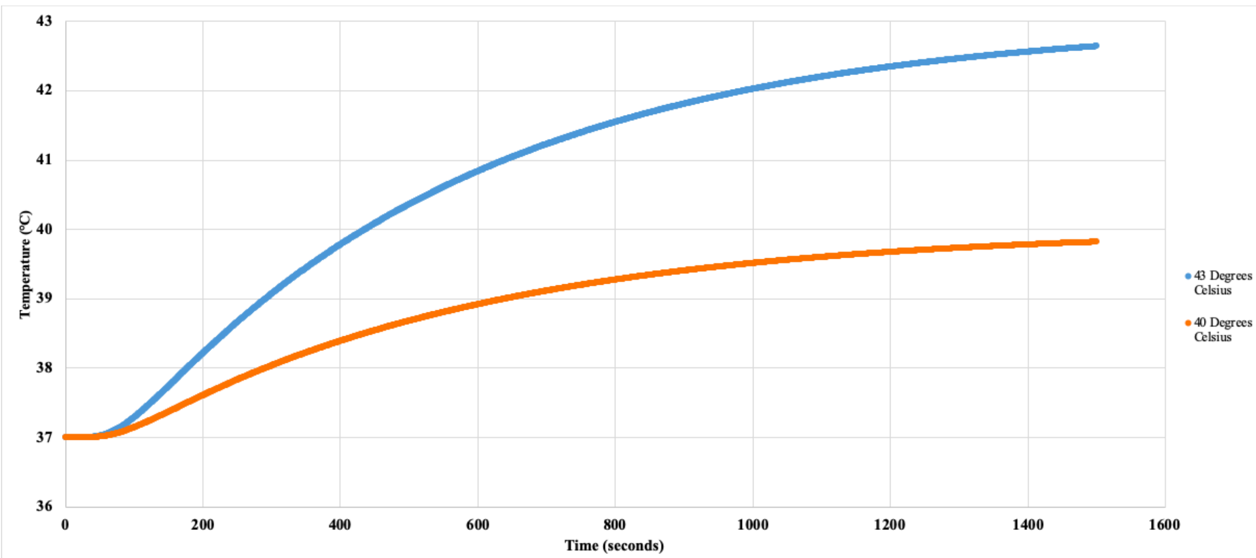


Figure 12. The temperature profiles of the 40°C and 43°C simulations as a function of time over 1500 second time intervals.

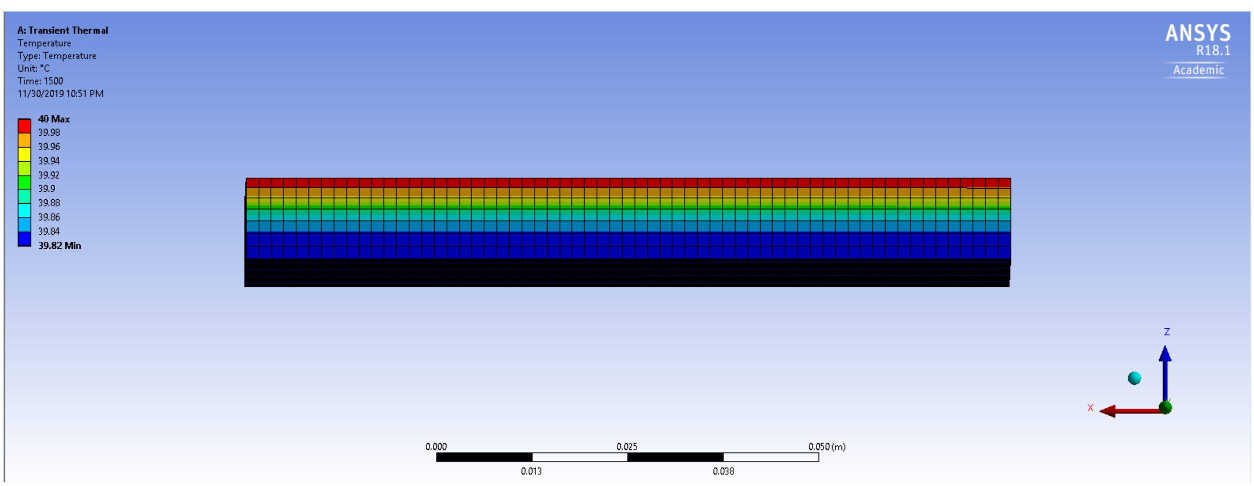


Figure 13. The thermal map that displays the temperature gradient as the surface temperature of 40 °C travels from the skin to fat to muscle layers

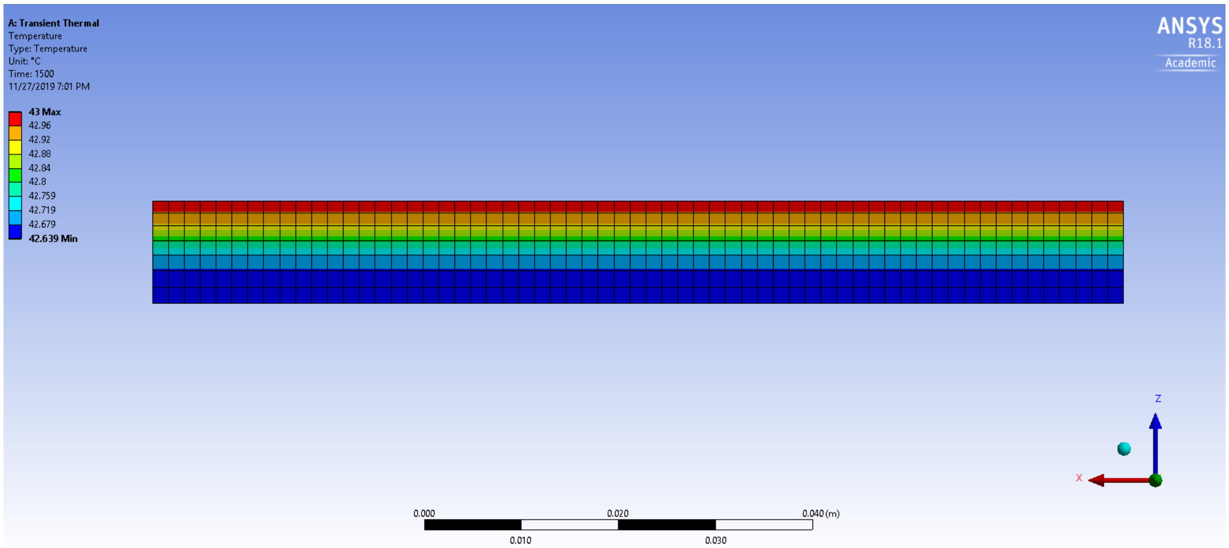


Figure 14. The thermal map that displays the temperature gradient as the surface temperature of 43 °C travels from the skin to fat to muscle layers

Heating Control System Overview

The heating element will need to be modulated to prevent the shoulder from overheating; therefore, a control system is needed to monitor any temperature deviations and rectify them in the system. There are several temperature controllers that are available. These include a simple (binary) ON/OFF, proportional, proportional integral (PI), and Proportional Integral Derivative (PID) Controllers. The binary controller would not be a viable option because it only activates the heating element if the setpoint temperature is not reached and turns off the element when the setpoint is surpassed without precise control. Also, the on/off controller can potentially damage the heating element because it constantly cycles back and forth between turning the element on and off. Furthermore, a proportional controller was also analyzed. This type of controller uses the error detected between the output and setpoint temperature values and produces a response that is proportional to this difference. Although this controller is a good option to obtain a quick response, it can potentially lead to overshoots and oscillations depending on the difference that is detected. Therefore, a proportional controller is not an optimal option. Furthermore, PI and PID controllers were considered. A PI controller incorporates both proportional and integral gain values to fine tune the system. The integral control is used to reduce the error between the actual temperature and steady state value. The combination of proportional and integral control helps to reach the therapeutic temperature in a quick manner with no steady state error. Lastly, a PID controller builds on the PI controller with a derivative gain that is used to stabilize the system and prevent amplification of high frequency noise. The noise is reduced using a low-pass filter that is attached to the derivative portion of the control loop. Therefore, the expected control system will incorporate either a PI or PID controller so that the heating cycles can be quick and stable between each exercise. The anticipated heating control system will incorporate a PID controller that would interface with a microcontroller and thermistor (Figure 15). The intended schematic of the system will begin with the thermistor sensing the device temperature which would be converted to a digital signal through the analog pins in the microcontroller (see below) . The digitized signal will then be passed through the controller that is configured using Arduino code. The gain values would be fine-tuned in order to ensure that the temperature stays within 40-43°C such that heating remains at its optimal level. Afterwards, the output of the PID controller will undergo pulse-width modulation to convert the digital signal back to analog so that it can interface with the heating element (actuator) and device. Lastly, the actual temperature reading will change as the heating system responds to the controller input. The new resulting temperature will be utilized in a negative feedback mechanism such that the controller may continue to drive the heating system throughout the therapy session. The PID controller will continue to modulate the rate of heating until the setpoint and actual temperatures are matched resulting in zero error found by the negative feedback loop. At that point, the controller would drive the system such that the setpoint temperature is maintained until another mismatch between the readings is detected.

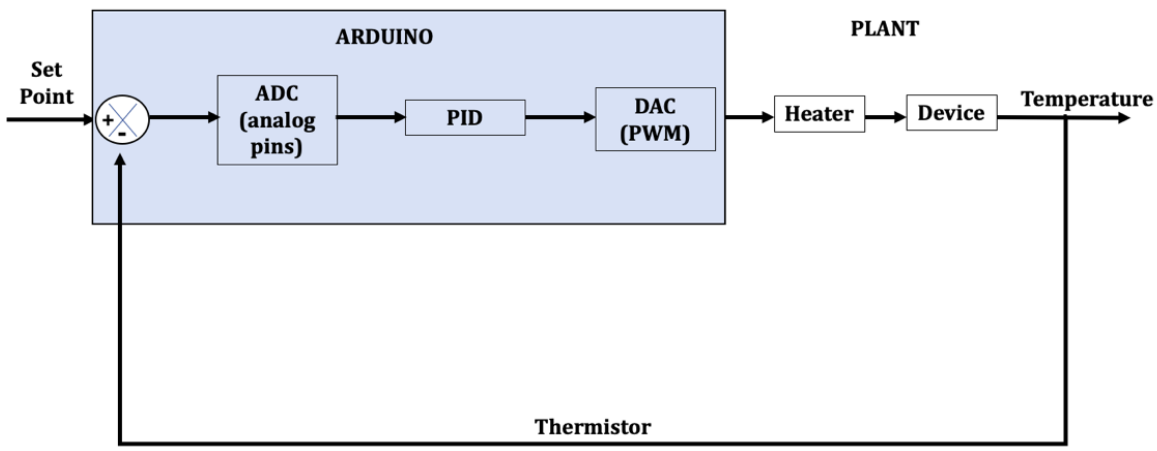


Figure 15. Anticipated schematic of the heating system with a PID controller. The heating system module interfaces with a microcontroller to fine tune the PID system to obtain the desired temperature output based on the setpoint value.

Thermal Modeling Validation in MATLAB

In order to further validate the ANSYS thermal simulations, finite element analysis was performed again on a three layer composite slab in MATLAB using the partial differential equation (PDE) toolbox. The geometry was created as a 10 cm x 5 cm slab with varying thicknesses for the skin, fat, and muscle layers using the ‘multicuboid’ function (Figures 16 and 17). A mesh was applied to the geometry using the ‘generateMesh’ and ‘pdeMesh’ functions with the maximum edge length set to 0.004 m and mesh growth rate set to 1.9 (Figures 16 and 18). Afterwards, thermal conductivity, density, and specific heat values were applied to the skin, fat, and muscle layers to better represent the targeted region. A boundary condition of 43°C was applied to the top face of the slab configuration to represent the carbon heater tape interfacing with the physiology. Since simulation involves transient modeling, an initial condition of 37°C (average body temperature) was applied to each layer. The simulation was performed for 2000 seconds in 0.5 second time steps. This time frame was chosen to demonstrate that the device can reach a steady state temperature.

```
%Thermal transient modeling
model = createpde('thermal','transient')

%Build geometry in meters
gm = multicuboid(0.05,0.1,[0.005 0.008 0.01254], 'Zoffset', [0 0.005, 0.013])
model.Geometry = gm
pdegplot(model,'Celllabels','on','FaceAlpha',0.5)
hold on
pdegplot(model,'Facelabels','on')
hold on
pdegplot(model,'EdgeLabels', 'on')

%Mesh the geometry
msh = generateMesh(model,'Hmax',0.004,'Hgrad',1.9);
pdemesh(model)

%Thermal Conductivities
thermalProperties(model,'Cell',1, 'ThermalConductivity',0.42,'MassDensity',1090,'SpecificHeat',3421);
thermalProperties(model,'Cell',2,'ThermalConductivity',0.21,'MassDensity',911,'SpecificHeat',2127);
thermalProperties(model,'Cell',3,'ThermalConductivity',0.442,'MassDensity',1109,'SpecificHeat',3391);

%Thermal BC
thermalBC(model,'Face',12,'Temperature',42);

%ThermalIC
thermalIC(model,37);
```

Figure 16. Transient modeling functions in the PDE toolbox that helped create the geometry, mesh, and assign thermal properties to the composite slab.

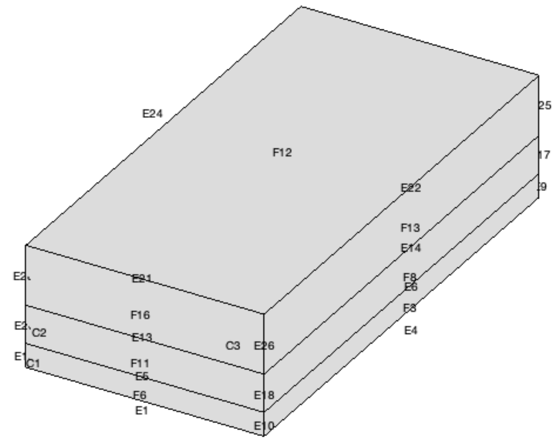


Figure 17. Three-layer composite slab geometry created in MATLAB.

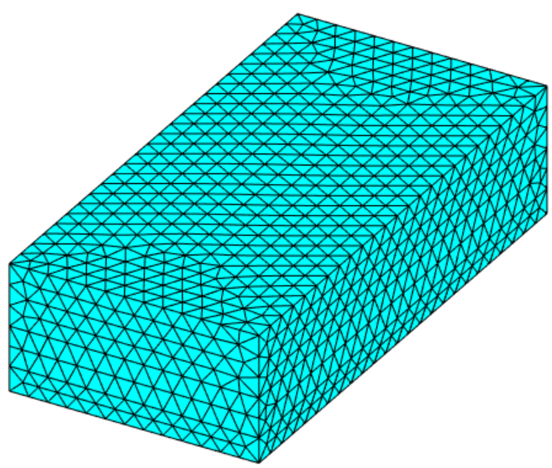


Figure 18. Finite Element Mesh was applied to the entire geometry.

After the simulation was completed, a thermal map (Figure 19) and temperature profile was obtained for the composite slab. The 'interpolateTemperature' function was used to monitor the temperature gradient as a function of the z thickness (Figure 20). Overall, the results obtained in this validation study are similar to the ANSYS transient simulation model which show that the surface temperature applied to the skin does reach the shoulder muscle capsule over time.

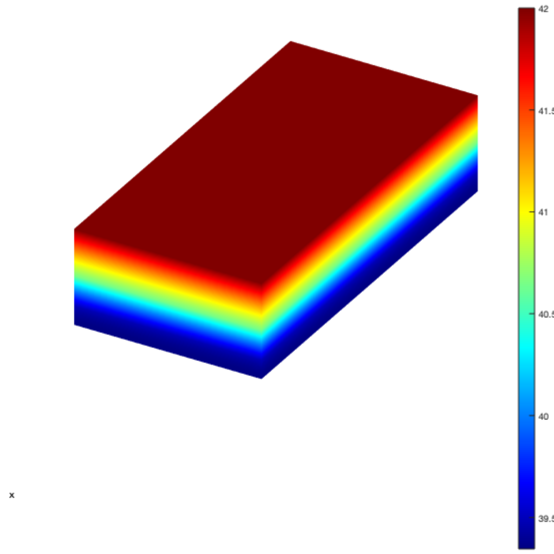


Figure 19. Thermal map that shows the temperature gradient as it goes from 43°C from the skin to the muscle layers.

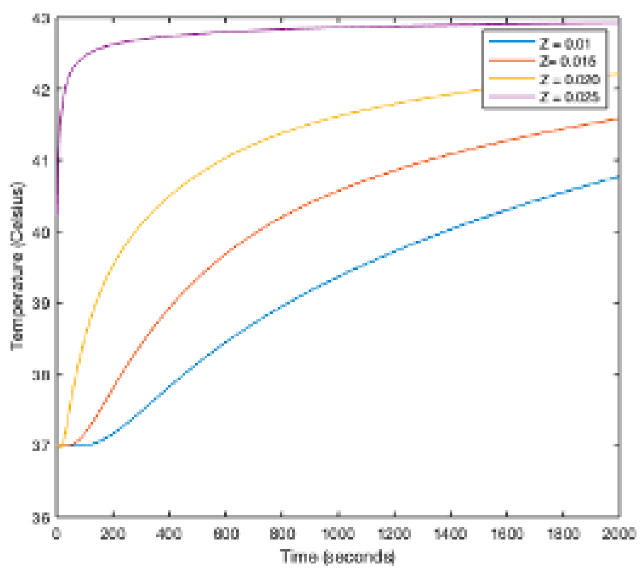


Figure 20. Temperature profile for a 43°C simulation as a function of time and depth (z-value) in MATLAB.

Thermistor Loop Development

The heating element as mentioned earlier was modulated by a PI controller implemented in the Arduino Nano BLE. Prior to creating the control system algorithm, the Arduino code had a thermistor loop that read the analog value sensed by the thermistor using a 10k resistor arranged in series with the 10k resistor (R_0). The loop starts by reading an analog value from the voltage divider connected to the A1 pin of the Arduino. It converts it to a voltage using a ADC conversion factor of (3.33/1023.00) that uses the maximum operating voltage of an Arduino Nano BLE, 3.33 V. This voltage is subtracted from the initial battery voltage to obtain a value for the thermistor voltage. The thermistor voltage was used to compute the thermistor resistance (Figure 21). Next, the thermistor value was ready through another analog pin which converted the reading into a digital value. Lastly, the NTC thermistor temperature formula uses the thermistor's beta value (provided by manufacturer), thermistor and resistor resistance values , and initial temperature value to compute the final temperature (Equation 3). The initial temperature test readings and corresponding thermistor resistances are displayed in Figure 22.

$$T_f = \frac{\beta}{\ln(\frac{R_{thermistor}}{R_0 \times e^{\frac{-\beta}{T_0}}})} \qquad \textbf{(3)}$$

```
voltageUnit = analogRead(A1);
voltageThermistor = (3.33/1023.00) * voltageUnit;//Convert the analog value (0-1023 volts/unit) to a voltage (0-3.33V) using conversion factor
//voltageNew = InputVoltage - voltageThermistor;
voltageNew = initialBatteryVoltage - voltageThermistor;
newThermistorResistance = voltageThermistor / (voltageNew / Resistor);
thermistorReading = analogRead(thermistorPin);
thermistorReading = (1023/thermistorReading) - 1;
thermistorReading = Resistor / thermistorReading;
lnRTR0 = log(newThermistorResistance / initialThermistorResistance);
tempFinal = (1 / ((lnRTR0 / BetaValue) + (1 / tempInitial))); //Temperature from thermistor using beta value
tempFinal = (tempFinal - 273.15); //Conversion to Celsius
```

Figure 21. Thermistor Loop in Arduino Code.

```
Temperature = 22.19C        Thermistor Resistance =  4740.63
Temperature = 22.11C        Thermistor Resistance =  4740.63
Temperature = 22.11C        Thermistor Resistance =  4740.63
Temperature = 22.11C        Thermistor Resistance =  4740.63
Temperature = 21.97C        Thermistor Resistance =  4761.90
Temperature = 22.11C        Thermistor Resistance =  4761.90
Temperature = 22.11C        Thermistor Resistance =  4740.63
Temperature = 21.97C        Thermistor Resistance =  4740.63
Temperature = 21.97C        Thermistor Resistance =  4740.63
Temperature = 21.97C        Thermistor Resistance =  4761.90
```

Figure 22. Temperature and Resistance (Ω) of the Thermistor

Battery Loop Development

In order to activate the heating element to the optimal temperature range (40°C - 43°C), an external battery supply was necessary. The battery was connected to the circuitry using voltage dividers to ensure that the Arduino Nano BLE does not exceed the optimal operating voltage which is 3.3V. The voltage divider consisted of a 10kΩ resistor and 2kΩ resistor in series (Figure 23). This allowed the battery voltage input to the Arduino to be any value below 12V. A battery reader loop was also implemented in Arduino code to read the current voltage readings as the control system modulated the heating unit (Figure 24). The battery voltage readings along with the temperature were displayed while testing the heating system when it was connected to a 9 V external battery supply (Figure 25).

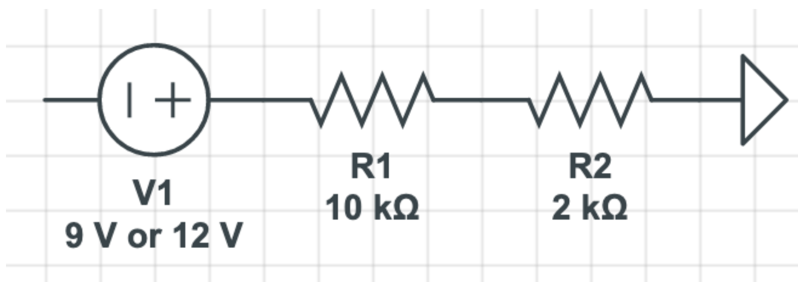


Figure 23. Voltage divider used in carbon heater tape circuitry

```
void loop()
{
    analogReading = analogRead(A2); //Reading the power supply
    initialBatteryVoltage = analogReading * (3.33/1023.00);
    voltageRatio = 6.00;
    finalBatteryVoltage = initialBatteryVoltage * voltageRatio;
```

Figure 24. Battery Reader Loop

```
Analog Read = 618.00        Voltage = 9.06        Temperature = 22.25C
Analog Read = 618.00        Voltage = 9.06        Temperature = 22.11C
Analog Read = 619.00        Voltage = 9.08        Temperature = 22.33C
Analog Read = 618.00        Voltage = 9.06        Temperature = 22.11C
Analog Read = 618.00        Voltage = 9.06        Temperature = 22.11C
```

Figure 25. Battery Voltage Readings when a 9.06V was supplied to the circuit

Carbon Fiber Tape Testing Data

The carbon fiber heater tape was tested to estimate the control system's transfer function. A 9 volt source was connected to the tape which drew approximately 1.8 A of current. The temperature was recorded for a total of 8 trials as the output current was varied. The time to reach the therapeutic temperature range was also recorded and stopped after the tape exceeded 43°C. These trials helped obtain a time-temperature profile for the carbon heater tape that served as the plant in the control system (Figure 26).

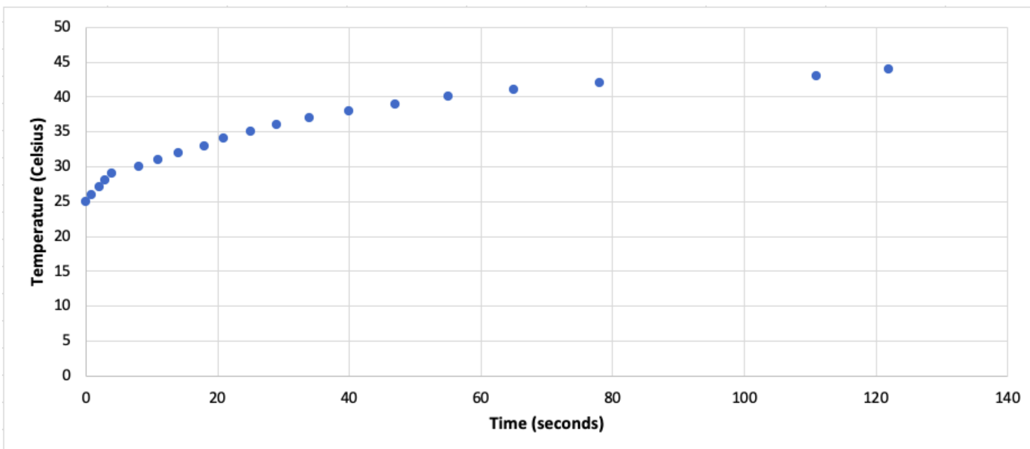


Figure 26. Graphical Representation of Testing Data for Given Input of 9V drawing 1.8 A

The resulting data made it possible to calculate the transfer function of the plant by finding the time constant, which is equivalent to the time value that corresponds to 63% of the maximum amplitude value (Equation 4). Afterwards, the transfer function was used in Simulink to model the uncontrolled and PI controlled response with a step temperature input of 43°C (Figure 27). The Simulink model was used to better visualize the effects of tuning the control system using the proportional (Kp) and integral (Ki) gains.

$$G_p(s) = \frac{21.5}{s + 0.5} \quad \textbf{(4)}$$

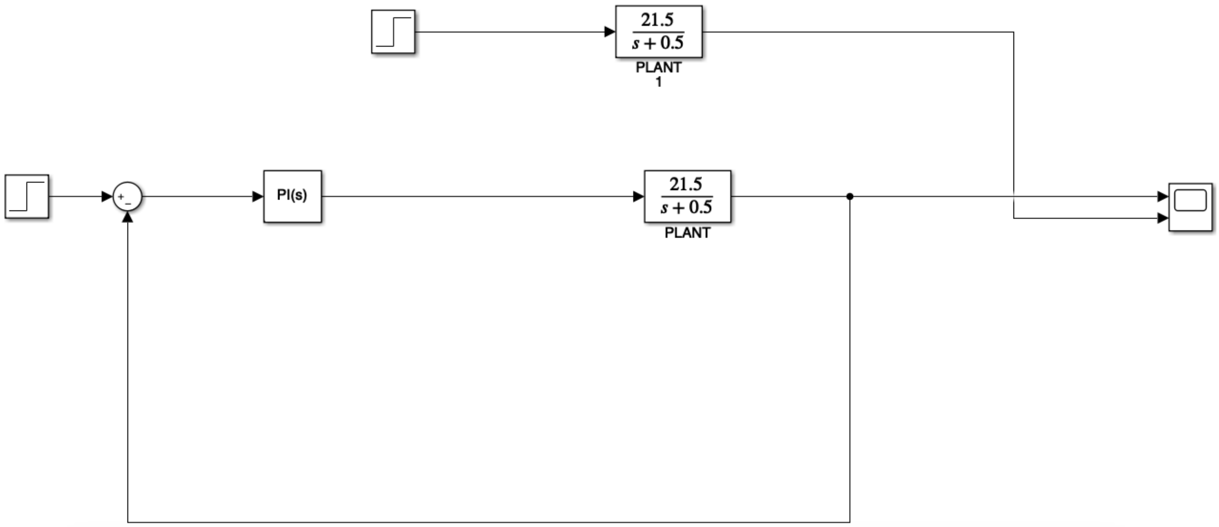


Figure 27. Simulink model of the PI controller in MATLAB

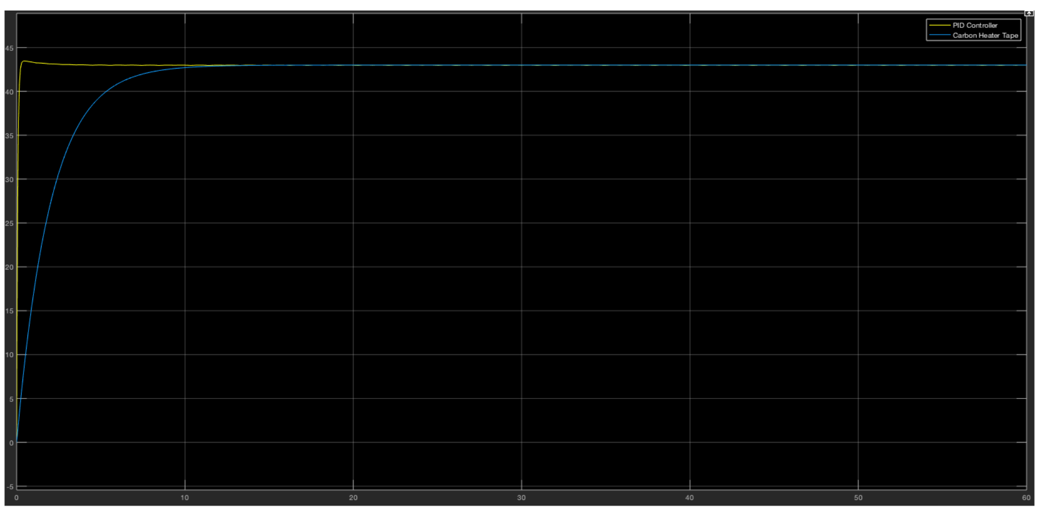


Figure 28. Plant Transfer Function and controlled in MATLAB and plotted as Time vs Temperature (Celsius)

Arduino PI Controller Implementation

The transfer function obtained from the plant's step response helped to tune the PI controller for the system. From the Simulink model, the Kp value was 2 and Ki value was 0.6 which is used in the arduino along with pulse width modulation to control the amount of current supplied to the carbon heater tape from the battery source (Figure 29). The voltage divider for the thermistor reading (10k resistor with 10k thermistor) was connected to the A0 pin of the Arduino. The battery voltage divider along with the mosfet was connected to the D2 pin of the

Arduino to help control the amount of current supplied to the carbon heater tape using Pulse Width Modulation (PWM) as described in the PI controller code (Figure 30). The mosfet unit in the circuit served as a heatsink to dissipate any heat received from the microcontroller and battery unit. All of these pins helped to supply heat to the carbon fiber heater tape and activated the heating element (Figure 30) .

```
int kp = 2;
int ki = 0.6;
void setup()
{
  Serial.begin(9600);         //Baud Rate at 9600 bits/second (serial communication)
  tempInitial = 273.15 + 25; //Converting Ambient Temperature to Kelvin for the Beta Formula
  pinMode(PWM_pin,OUTPUT);
}
void loop ()
{
  float PI_control = PILoop ()
  float thermistor = thermistorLoop ()
}

void PILoop()
{
if(controller_On==0)
{
  // First we read the real value of temperature
  readTemp = readThermistor();

  //PI calculations
  PIError = setPoint - readTemp;
  PI_p = 0.01*Kp * PIError;
  PI_i = 0.01*PI_i + (Ki * PIError);

  //Final total PI value
  PIFinal = PI_p + PI_i

  //Define Pulse Width Modulation range between 0 and 255
  if(PIFinal < 0)
  {    PIFinal = 0;    }
   if(PIFinal > 255)
  {    PIFinal = 255;  }
//Write the PI final value to pulse width modulation pin connected to MOSFET
  analogWrite(PWM_pin,255-PIFinal);
  previousError = PIError;
```

Figure 29. PI Controller code for Arduino Circuit

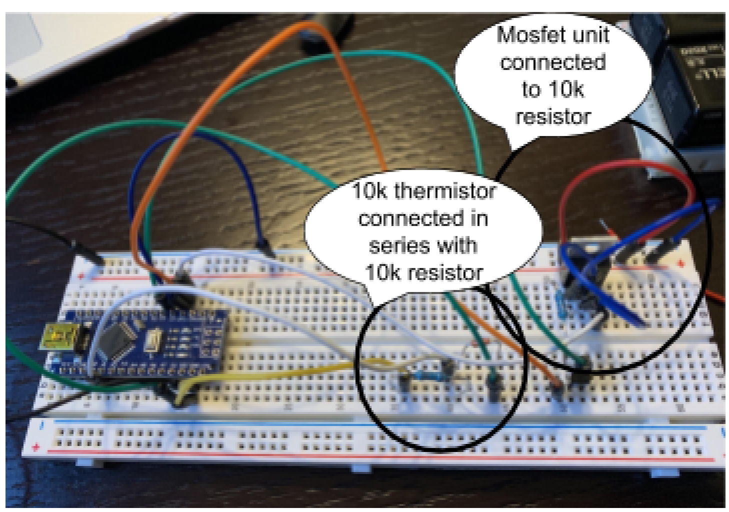


Figure 30. Arduino circuit with 10k thermistor, 10k resistor, and MOSFET

Future Development

Although the heating element was not completely built for this semester due to the current pandemic situation, a considerable amount of progress has been made with regards to the thermal analysis modeling and the initial control system implementation using the Arduino platform. The temperature sensor (thermistor) and battery components were integrated into the control system algorithm and the initial proportional and integral gains were selected. However the battery was not finalized, so the carbon fiber heater tape was unable to heat to its full potential for the entire 25 minutes since there was not enough battery power. Several future improvements can be made for this project in terms of completing the control system circuit to ensure that the heating element can last the entire 25 minutes physical therapy cycle. Verification and validation testing should be performed to test if the specifications and requirements for the heating element are met.

CHAPTER 6: MICROCONTROLLER & IMU

Written by Daniel Hanna

Need, Overview, and Benefits

The shoulder assist device needs to enable the monitoring and recording of positional data during exercise, allow for connectivity to send such recording to a database, enable heating of the shoulder, and provide auditory alerts and sensory feedback to the wearer. As a result, it would be ideal to have a central point from which all of these functionalities can be implemented.

A microcontroller is a small computer capable of providing specific operations in an embedded system. Data received from a microcontroller's input and output ports can be interpreted via the central processor, thus allowing for implementation of a device's sub-function. Thus, a microcontroller will be utilized as a primary component from which the aforementioned functionalities can be implemented.

Microcontroller Unit Options

Microcontrollers are available in a wide array of sizes and features. Since this device is intended to be wirelessly worn by a patient, a small form factored microcontroller is the first aspect of consideration towards selecting an appropriate unit. Further criteria, such as processing power, estimated current draw, pin availability, sensor availability, and connectivity are also considered (Table 3).

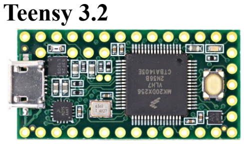
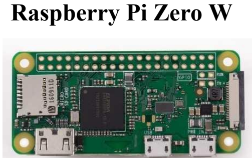
The first board considered is the Teensy 3.2[38]. It is a board that contains a very small physical footprint and will thus reduce overall bulk of the completed device. While the processing rate and generous analog and digital pin availability are strong points for the intent of the project, a lack of built-in sensors, and no wireless connectivity make this board not ideal for implementation. Poor documentation availability makes it difficult to estimate a current draw, which increases difficulty with regards to future battery selection. Although it is possible to obtain desired features such as bluetooth and sensors via breakout boards, doing so will add unnecessary procedures that would not need to be performed when compared to other available boards that already have these features built in. Thus, the Teensy 3.2 was not selected as a component to be used for the device.

The Raspberry Pi Zero W is the second microcontroller that was considered[39]. Although it is the largest board in terms of dimensions, it is the strongest board available in terms of processing power. However, although the board contains a large number of available pins, only digital input is accepted. This adds a limit in regards to the potential sensors that can be added to the board which can lead to later complications in the project's development. The Pi Zero W also includes built in WiFi and Bluetooth, which address the wireless capability needs of the device. However, this board reflects an unusually high estimated current draw given its size. This concern in addition with the lack of available built in sensors also make the Raspberry Pi Zero W not ideal for selection.

The final board to be considered is the Arduino Nano 33 BLE[40]. The Arduino addresses those features that were not available in the other boards that were considered. Although not the smallest in dimensions, the board remains small enough to be applicable for future integration with the overall device. While pin availability is lower than that of other boards, the digital and analog capability are suitable for any potential input/output component integrations. Bluetooth availability is also built into this board, which will be useful in future app integration. The 33 BLE also holds the lowest estimated current draw, which will be beneficial for extending overall device battery life and power consumption. The most notable feature is the built in inertial measurement unit, which will aid in keeping track of the patient's range of motion as they perform their exercises.

The below table depicts the decision matrix that was utilized in selecting the appropriate microprocessor. The Arduino Nano 33 BLE was ultimately chosen.

Table 3. Overview of microcontroller options. Current Draw is estimated assuming that device is idle, bluetooth is on, and the IMU is on (if applicable). The cells are indicated as green,yellow, or red to signify the level of acceptance. Green cells indicate the criterion is satisfied. Yellow cells indicate that criterion was partially satisfied. Red cells indicate that the criterion was not satisfied.

	Dimensions (mm)	**Processor & Rate**	**Estimated Typical Current Draw* (mA)**	**Available Pins**	**Connectivity**	**IMU Included**
Teensy 3.2 	36 X 18	Cortex M4 72 MHz	Unknown	34 Digital 21 Analog	None	No
Raspberry Pi Zero W 	65 X 30	Broadcom 1 GHz	160	40 GPIO (Digital)	WiFi Bluetooth	No
Arduino Nano 33 BLE 	45 X 18	Cortex M4 64 MHz	34.8	16 Digital 9 Analog	Bluetooth	Yes Gyro Out: 104 Hz Accel Out: 104 Hz

Inertial Measurement Unit

An inertial measurement unit (IMU) is an electronic device that measures force, angular rate, and orientation through the use of gyroscopes, accelerometers, and magnetometers. Utilizing an IMU's accelerometer and gyroscope outputs will allow for calculation and outputting of roll, pitch, and yaw angles as a source of positional data regarding the wearer's range of motion with respect to the transverse, sagittal, and coronal planes (Figure 31).

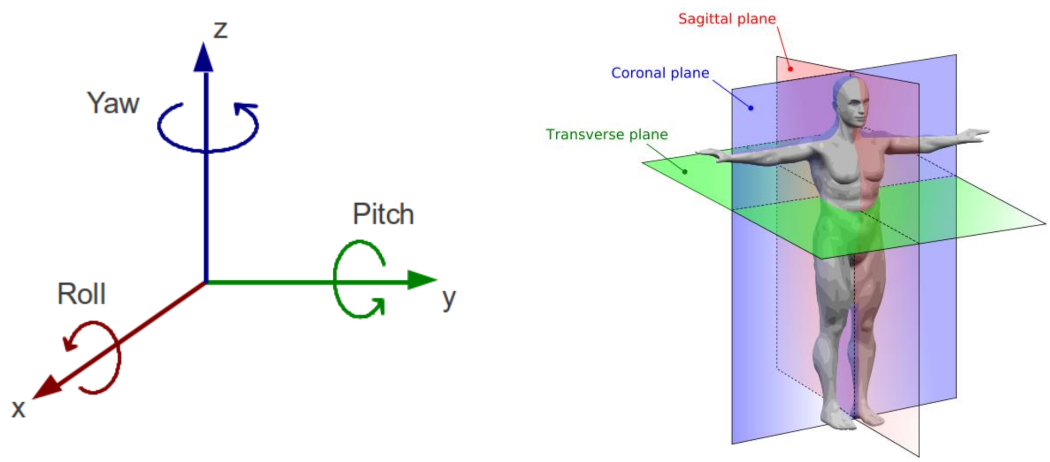


Figure 31. Roll, Pitch, and Yaw in Correlation with the Transverse, Coronal, and Sagittal Planes

The IMU that is integrated as a part of the selected Arduino Nano 33 BLE is a LSM9DS1 chip[41] (Table 4). It is a 9-Axis unit that includes one gyroscope, accelerometer, and magnetometer. The 3-Axis gyroscope maintains angular rate sensitivity modes of ±245, 500, and 2000°/s. The 3-Axis accelerometer maintains linear acceleration sensitivity modes of ±2, 4, 8, and 16g. A breakout IMU board is estimated to hold a current draw of 4.6mA; however, the impact of this power consumption with respect to the overall device is unknown, and will only be of concern if additional IMUs are desired to be utilized in addition to the built in IMU of the Adruino.

Arduino Company features a library built for the LSM9DS1 that streamlines the process involved in reading the data outputted from this IMU. The library sets the accelerometer range and gyroscope range to ±4g and ±2000°/s, respectively. The library also sets data output rates for each of these components to 104 Hz, which translates to one measurement per ~9.6 milliseconds[42]. Similar research done regarding motion tracking through the use of IMU devices has found that a minimum data output rate of 50Hz will lead to effective recording of device orientation over time, thus confirming the appropriateness of the IMU specifications given the desired resulting functionality of the device[43].

Table 4. Overview of the LSM9DS1's areas of interest. The cells are indicated as green,yellow, or red to signify the level of acceptance. Green cells indicate the criterion is satisfied. Yellow cells indicate that criterion was partially satisfied. Red cells indicate that the criterion was not satisfied.

	Gyroscope	Accelerometer	Total DOF	Typical Current Draw (mA)	Notable Benefits	Price ($)
LSM9DS1	Yes, 3-Axis ± 245, 500, 2000 °/s	Yes, 3-Axis ±2, 4, 8, 16 g	9-Axis	4.6	Included on Nano 33 BLE	22.61

Testing

Before purchasing the microprocessor, initial testing was performed by utilizing materials loaned to the team by the TCNJ Robotics Club. An Arduino Nano was utilized in conjunction with an ADXL345 accelerometer by connecting the SCL and SDA pins of each board as well as 5V to the accelerometer through the microprocessor's 5V pin (Figure 32). The Nano maintains the same processing power as the Nano 33 BLE, but does not include a built in IMU or Bluetooth[44]. Concurrently, the ADXL 345 3-axis accelerometer match the same specifications as that of the LSM9DS1 accelerometer output[45].

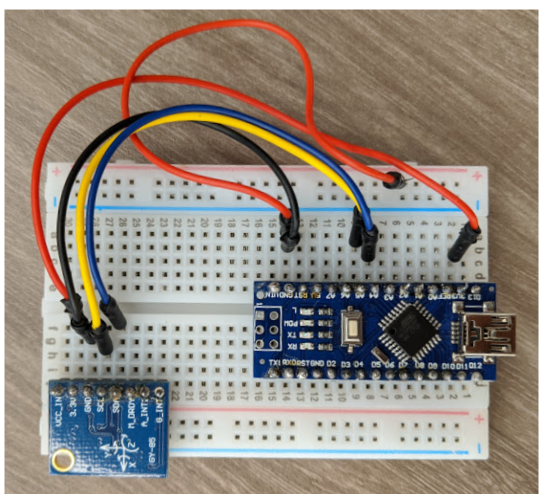


Figure 32. Connection Setup Between the Arduino Nano and ADXL345 Accelerometer

When accessing the six registers containing the measurements for the X, Y, and Z axes, default g-force measurements could be noted. Calibration can be performed by setting the sensor down on a level surface and observing the outputs for the three cartesian axes and consequently writing the appropriate values to the calibration offset registers such that an output of zero for each axis can be seen.

In the absence of linear acceleration, an accelerometer will output a measurement of the rotated gravitational field vector, which can then be utilized to calculate the pitch and roll orientation angles[46]. Algebraic expressions can be used to compute the accelerometer tilt given accelerometer readings, such that:

$$Roll = \frac{180}{\pi} tan^{-1}\left(\frac{Y}{\sqrt{X^2+Z^2}}\right)$$

$$Pitch = \frac{180}{\pi} tan^{-1}\left(\frac{-X}{\sqrt{Y^2+Z^2}}\right)$$

where X, Y, and Z represent the numerical outputs for each axis. A low-pass filter is then applied through code:

$$Roll_o = 0.94 * Roll_p + 0.06 * Roll_c$$

$$Pitch_o = 0.94 * Pitch_p + 0.06 * Pitch_c$$

where in 94% of the previous state (denoted with subscript *p*) is added to 6% of the current state (denoted with subscript *c*) to output the resulting angle (denoted with subscript *o*). Performing such filtering will enable a smoother data output, wherein the computed angle will not drastically vary with slight movements of the device. Implementing such calculations in code results in the output shown in Figure 33.

Figure 33. Roll and Pitch Angle Output as Seen Through a Serial Monitor

It should be noted that yaw angle can not be calculated without the use of an additional component such as a gyroscope or magnetometer. The Z axis lies perpendicular to gravitational force, and thus any changes applied to yaw with no change in roll and pitch cannot be measured via an accelerometer alone.

Arm movement recording was simulated by holding the accelerometer directly outward and steadily moving the device such that it would point toward the ceiling, and pointing the device back down to return to the initial state. Performing such action resulted in the following data output (Figure 34), which has been graphed to visually represent the recordings over the 4.5 second timeframe in which the action was executed.

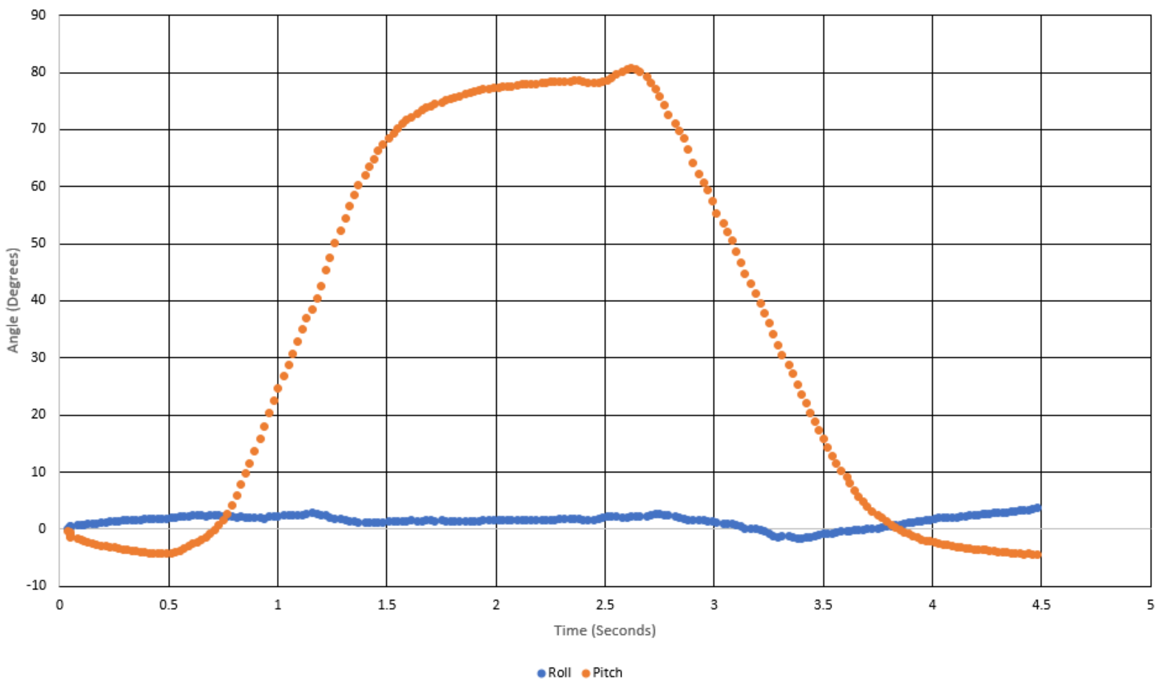


Figure 34. Roll and Pitch Angles Plotted Over a 4.5 Second Movement via ADXL345

The outputted data demonstrated the suitability of the components that are considered for implementation. As a result, the Arduino Nano 33 BLE was purchased. Implementing the previous calculations onto the new board was efficiently performed by accessing the IMU library's *readAcceleration(x,y,z)* function. Similar data output (Figure 35) is demonstrated with the new board.

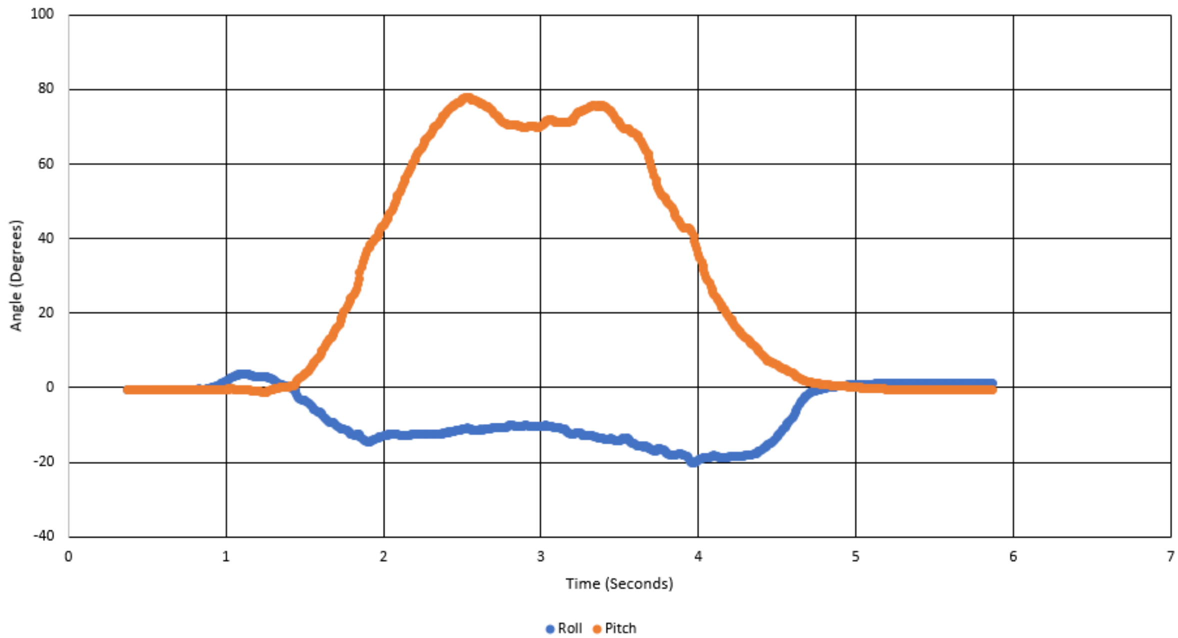


Figure 35. Roll and Pitch Angles Plotted Over a 6 Second Movement via LSM9DS1

Future Development

Although promising results have been achieved thus far with the microprocessor, further development is needed to achieve full integration with the remaining components of the project. This includes improving calculations and filtering methods utilized for roll pitch, and yaw angles. Temperature, vibration, and auditory sensors need to be connected with the Arduino, as well as integration of a heating control to allow for the management of the heating component of the device; these components are not expected to pose an issue with integration, since the decision matrix utilized in selecting the Arduino Nano 33 BLE has accounted for sufficient input/output ports as well as processing capability and speed.

CHAPTER 7: BATTERY AND SHIELDING

Written by Geoff Bartner

Power Consumption Analysis

Power consumption analysis is necessary in order to determine which battery can power the device over the entire duration of the physical therapy exercise. The total power consumption of the device is split into the sum of consumption of the controller parts ($P_{controller}$) and heating parts ($P_{heating}$). A part's power (P) can be calculated by its voltage (V) and current (I) using the following equation:

$$P = V * I$$

$P_{controller}$ consists of the power consumption of the device's controller parts. These consist of the microcontroller unit (Arduino Nano 33 BLE)[40], the alert system (vibration motor/ RS PRO 3V ac PCB Mount Buzzer), the inertial measurement unit (LSM9DSI)[41], and the heating element (carbon fiber tape). The power load was calculated from the range of voltages and currents, V_{avg} and I_{avg}, which the component can function properly (Table 5). These values were found in datasheets published by the manufacturer about the specifications for each specific part. $P_{controller}$ and initial testing which was found to equal about 24,000 mW or 24 W.

Table 5. Power consumption calculation of parts based on values published by manufacturers

		Normal Volts (V)		Normal Current (mA)		Normal Load (mW)	
		Min	Max	Min	Max	Min	Max
Arduino Nano 33 BLE							
nRF 52840 microcontroller		1.7	3.6	3.83	16.4	0.006511	0.05904
NiNA B306 Bluetooth		1.7	3.6	4.8	14.1	0.00816	0.05076
LSM9DSI :	Accelerometer	1.9	3.6	0	0.3	0	0.00108
	Gyroscope	1.9	3.6	0	4	0	0.0144
Alert System							
Vibration Motor		2.3	3.6	0	60	0	0.216
RS PRO 3V ac PCB Mount Buzzer		1	3	0	15	0	0.045
IMU							
LSM9DSI:	Accelerometer	1.9	3.6	0	0.3	0	0.00108
	Gyroscope	1.9	3.6	0	4	0	0.0144
Heating							
Carbon fiber tape		-	12	-	2000	-	24000

Initially a Peltier device was considered to be used for heating, but due to factors such as high power consumption carbon fiber tape was chosen instead. Preliminary testing on the carbon fiber tape showed that the most optimized battery to reach the therapeutic range is 12 volts at 2000mA (2A).

Battery Selection

The carbon fiber tape testing found that the power needed to reach the therapeutic temperature range of 40-43°C was 24 W. Based on the power needed for the device to function the RS Pro 1449413 lithium-ion battery pack was chosen for our device (Figure 36). This battery has 11.1 volts at 2.6 amp/hours, thus a total load 28.86 watts/hour which reaches and even exceeds our power needed. Also the device is only being powered for 25 minutes, the length of the typical physical therapy exercise, the battery will last for about an hour and fifteen minutes before needing to be recharged again, although it is recommended users recharge it after its use. A series regulator would be used to safely supply the Arduino Nano with power as well as a DC power supply AC adapter and male and female barrel jacks to make the battery rechargeable.

Figure 36. RS Pro 1449413 lithium-ion battery pack

Shielding

Heat sealable coated nylon taffeta was going to be ordered to shield the battery and other electrical components from water and other contaminants. This material is lightweight and strong but its most important factor is that it has water resistant properties that will protect the electrical components from corroding. The protection offered by the taffeta will increase the longevity of the device by blocking debris and moisture from damaging the electronics. The shielding must also protect the user from leakage current since it is an inherent risk while the battery provides power to the device.

CHAPTER 8: PHYSICAL DESIGN

Written by Ryan DesRochers

Physical Design Options

Initially, two major design solutions were investigated to satisfy the design requirements (Table 6). The first of these options is a physical shoulder brace. This brace is intended to provide mechanical aid to the shoulder in order to prevent the user from overextending their arm during recovery exercises.The advantage of this device is hard mechanical stops which would ensure the user did not reinjure themselves during their exercise regimen. After drawing initial sketches of this design, it became clear that a device of this design had some distinct disadvantages. First, the device would require a significant size and heft in order to firmly brace the shoulder. This had the potential to fail design requirement 2, as the heft of the device could prevent the user from being adequately able to move their shoulder normally. A second disadvantage of this device is that it would be difficult to adjust the range of motion stops as the wearer progressed through therapy.

This led to the second major design solution, in which a digital monitor and warning system would be implemented in order to warn the user of overextension during their therapy (Table 6). This option provided the advantage of minimal weight on the arm, where the bulk of this device was a heating system wrapped around the shoulder. Vibratory and auditory alerts serve to prevent the user from overextension, as the movement of the arm relative to the shoulder is tracked through an inertial measurement unit placed on a small band around the bicep. This design has the added benefit of easily adjustable range of motion stops, as they are software based. Additionally, the device is closest as possible to allow complete, uninhibited shoulder movement when desired. The decision matrix outlining these two major design solutions is shown below.

Table 6. Decision matrix for the two major design solutions.

	Weight	ROM limitation	Adjustment	Exercise inhibition
Physical Brace with ROM lockouts	Larger device, would add weight to the arm	Mechanical stops ensure user does not overextend	More difficult to set range of motion stops	Components will add a slight amount of resistance
Digital monitor and warning system	Minimal weight on the arm	Vibratory and auditory feedback prevents overextension	Easy for PT to adjust ROM limits	Allows for complete, uninhibited shoulder movement when desired

Moving forward with the digital monitor and warning system, two further iterative solutions were proposed. The first was a sleeve which would slide up the arm (Figure 37). This had the advantage of comfort and security in terms of the sensors on the arm, but lacked a level of adjustability, requiring several sizes to be designed in order to satisfy requirement 1 and achieve fitment for a broad array of users. A sketch of this design is shown below.

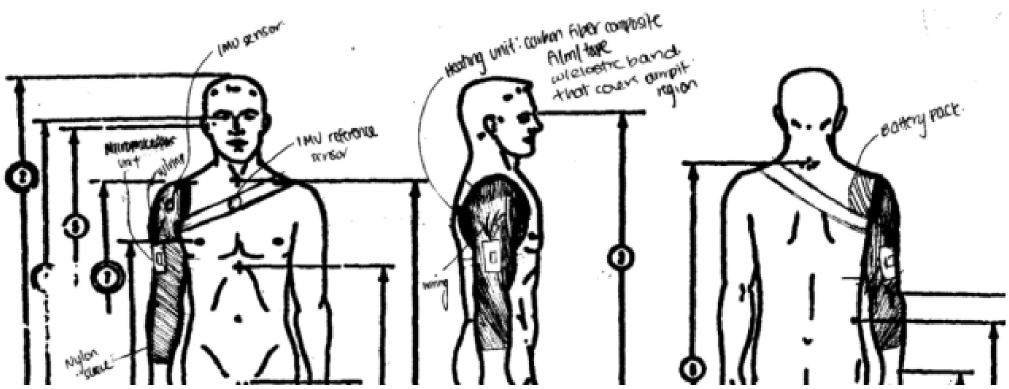


Figure 37. Sleeve design sketch.

Alternatively, a holster design was chosen, which secured the heating module around the shoulder and including a separate arm band containing the important sensors that are needed to track the user's range of motion (Figure 38). This design offers a high level of adjustability through various straps, and provides the absolute minimum shoulder movement inhibition during exercise. The decision matrix outlining the decision to move forward with this holster design is shown below, following a sketch of the holster design (Table 7).

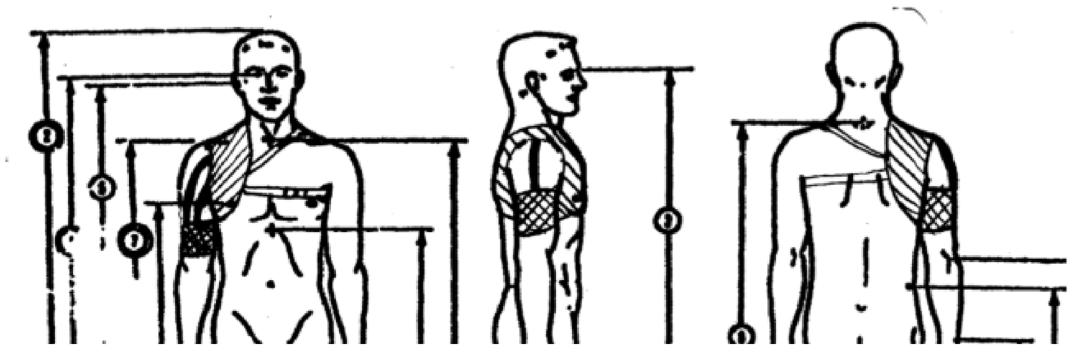


Figure 38. Initial holster design sketch.

Table 7. Final physical design decision matrix.

	Adjustability	Sizing	Fit	Other
Sleeve	Less adjustable	More sizes necessary for proper fitment	Secure on the arm	More material required
Holster with separate arm band	Great adjustability	One size fits most	Heating component well-secured	Minimum shoulder movement inhibition

Textile Selection

Once the holster design was chosen, a selection of textile materials for its construction had to be selected. The requirements for the chosen textiles were a level of strength and durability, light weight, ease of cleaning, and cost within the project budget (Table 8). Additionally, it was determined that the electronics should be shielded within a waterproof shell in order to prevent premature corrosion and proper cleaning of the device between uses. Polyester ripstock of 200 denier weight was chosen for its durability and strength. This material will be used for the outer shell of the device, which will contact the user directly. Next, polypropylene straps were chosen to secure the device to the user. These two materials will form the outer shell of the device, which will be removable and machine washable. Finally, heat-sealable coated nylon was chosen to form the waterproof enclosure for the electronics, including the heating module. This material provides the flexibility of a normal fabric with the addition of waterproofing so that the electronic components do not corrode prematurely. Additionally, this housing will be easy to wipe down after each use. The textile selection matrix is shown below.

Table 8. Textile decision matrix.

	Cost	Weight	Ease of Cleaning	Other
Polyester Ripstock 200 Denier (Per Yard)	3.95 per yard^2	6.6 oz per yard^2	Machine Washable	
Heat-Sealable Coated Nylon Taffeta (Per Yard)	\$14.95 per yard^2	4.3 oz per yard^2	Machine Washable	Waterproof after heat-sealing
Polypropylene 1 inch Strap	\$0.20 per foot	.23 oz per foot	Machine Washable	300lb working load

CHAPTER 9: SOFTWARE AND DATABASING

Written by Daniel Hanna and Javier Thomas

Software Purpose

Written by Daniel Hanna

Developing software that complements the physical device will address the feedback and assistive measures previously outlined. The physical therapist who served as the Voice of Customer identified statistics, data, and software capabilities which would be useful for integration with the physical device. Several aspects of the therapy can also be controlled from an external source such as a phone application or web app.

Bluetooth Implementation

Written by Daniel Hanna

In order to utilize Bluetooth, Generic Attribute Profiles (GATTs) are utilized. These profiles enable the use of either predefined or custom services and characteristics to be created for Bluetooth communication between two devices, and simplifies the overhead required for data transmission.

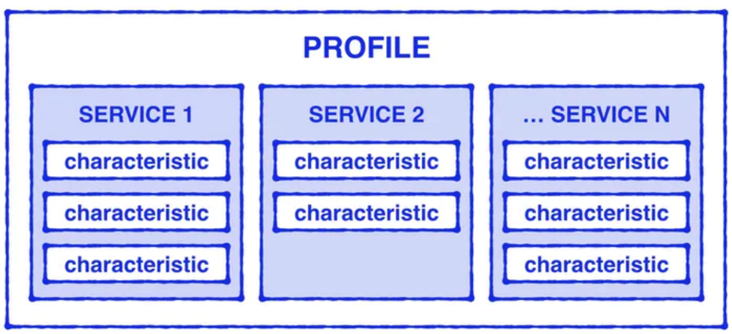


Figure 39. Diagrammatic overview of Bluetooth GATT Structure[47]

These GATT services and characteristics are defined through the ArduinoBLE library. A Universally Unique Identifier (UUID) of 0x1826 was used for the service declaration, which indicates the device to be a Fitness Machine device in accordance with the Bluetooth standard[48]. Custom UUIDs were created to hold the recorded measurements of roll, pitch, yaw, and temperature.

```
BLEService angleService("1826");
BLEStringCharacteristic pitchBLE("78c5307a-6715-4040-bd50-d64db33e2e9e", BLERead | BLENotify, 20);
BLEStringCharacteristic rollBLE("78c5307b-6715-4040-bd50-d64db33e2e9e", BLERead | BLENotify, 20);
BLEStringCharacteristic yawBLE("78c5307c-6715-4040-bd50-d64db33e2e9e", BLERead | BLENotify, 20);
BLEStringCharacteristic temperature("78c5307d-6715-4040-bd50-d64db33e2e9e", BLERead | BLENotify, 20);
```

Figure 40. Generic and Custom-Defined UUIDs

Once the characteristics were added to the service, the service was advertised, making it possible to establish a single Bluetooth connection between the Arduino, which acts as the server, and the Android device, acting as the client. Further explanation of this connection is discussed in the following sections.

Database and Encryption

Written by Javier Thomas and Daniel Hanna

The database used for this application is Firebase by Google. This was decided as it was compared to other options such as AWS. After a decision matrix was made, the selection of Firebase was made primarily due to the price. The full decision matrix can be seen in Table 9.

Table 9. Database decision matrix.

	Storage capacity	Accessibility	Ease of use	Cost ($)	Additional benefit
AWS	Over 10gb	Cloud	High	Under 10 per month	Nice connection to data analytics, user authentication
Firebase	Over 10gb	Cloud	High	Free under 10gb storage usage	User authentication
SD card	64 gb	Local	Medium	5	None

For both the web app and Android app, the database is accessed via a database instance and can be called using a simple call API. The database instance is only made possible by downloading and importing a unique configuration setup into the Android and web applications' root contents. This configuration setup includes a custom client ID value for authentication along with a unique API key which ensures that no unauthorized programs or persons can access this data.

Accessing the database via this method will enable a secure connection for retrieving and posting whatever data is needed from and to the database for any metric. By default, direct database access is completed in a web browser over secure HTTPS, and all login information as well as data written to the database is 256-bit AES encrypted by default. Further details of implementation are discussed in the following *Android Application* and *Web Application* sections.

Android Application: Overview
Written by Daniel Hanna

The Android application enables the wearer to see an overview of their recovery path via data recording and reviewing of exercises as they are performed with the physical device being worn. Additionally, the application implements bidirectionality of the device by allowing the wearer to directly communicate to their physician, such that communication between the two parties may be streamlined and direct.

Physician input has helped determine the design of the application. Consequently, the application has been developed around five main pages: the *Home* page, the *Begin Exercise* page, the *View History* page, the *Chat* page, and the *Settings* page.

Each page serves a specific use for the patient. The *Home* page allows an overview of the last exercise performed. The *Begin Exercise* page allows for selection from a list of exercises that are desired to be performed, and consequently guides the patient through the steps required for exercise completion. This page also enables the user to view real time feedback of the progress they are making towards completing their exercise session. The *View History* page enables the user to see a history of past exercises recorded and the data recorded for each exercise. The *Chat* page enables text-based communication between the patient and physical therapist. Lastly, the *Settings* page provides the user with the ability to modify app related settings, which may include options such as enabling dark mode, submitting a problem report, and viewing additional experiences such as the project website.

Android Application: Setup & Bluetooth Connection
Written by Daniel Hanna

The Android application development has progressed via the use of Android Studio, wherein a new project was created with an empty activity as the template. Additionally, the selected project language was Java. The project's minimum Application Programming Interface (API) level was 19, which is representative of Android 4.4 KitKat (Figure 41). Selecting such an API level enables the resulting application to run on approximately 95.3% Android devices that are currently online.

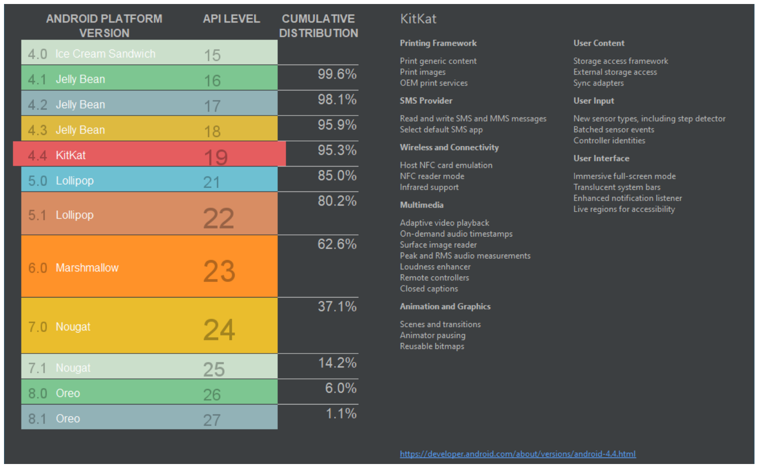


Figure 41. Cumulative Distribution of Android Platform Versions and Respective API Levels

The project's *MainActiviy.java* holds the logistics required in creating the menu that allows for application navigation (Figure 42). It should be noted that this means of implementation has been selected such that the different application pages may be affected through the use of Fragments. Consequently, the Main Activity's *activity_main.xml* holds the layout elements required to complete the navigation menu design. An application toolbar has also been implemented to allow for icon-based navigation as well as custom titling of pages. Each navigation item fragment defines each page of the application.

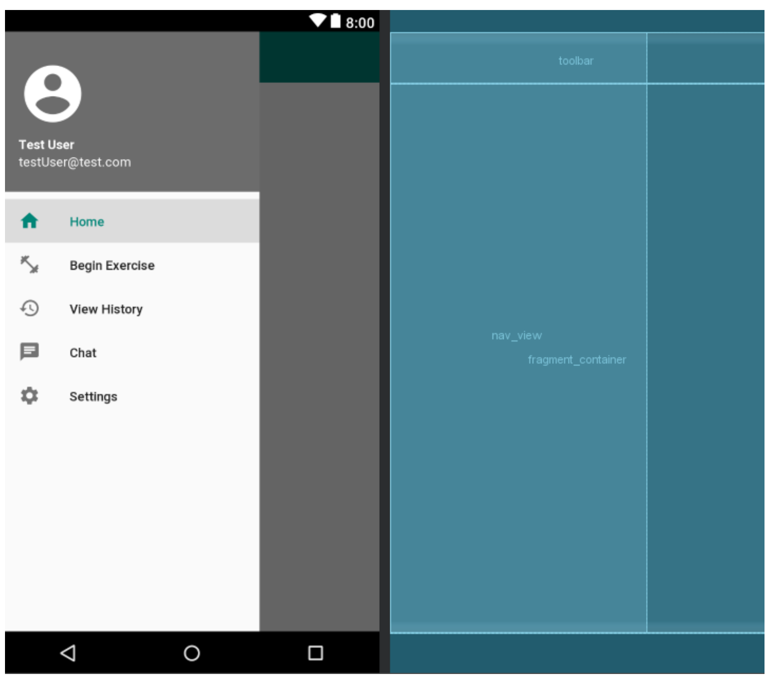


Figure 42. The ACS Assist App Navigation Menu and Layout

The *Begin Exercise* page is the center point from which connection is established between the Android application and the Arduino, and enables the user to perform their therapeutic exercises. Upon navigation to the *Begin Exercise* page, an object reference to the Android device's bluetooth adapter is obtained, along with a reference to the Arduino via the Arduino's MAC address (Figure 43). This address serves as a unique ID that does not match that of any other device.

```
BluetoothAdapter bluetoothAdapter = BluetoothAdapter.getDefaultAdapter();
BluetoothDevice arduino = bluetoothAdapter.getRemoteDevice("E5:A5:53:32:BD:7C");
Boolean showMeasurements = false;
```

Figure 43. Bluetooth Adapter and Arduino References

After performing the appropriate checks to ensure a bluetooth capable device is being used and that the appropriate permissions are granted, a connection is established with reference to the Bluetooth GATT callback (Figure 44). Since the Arduino is advertising Bluetooth and accepting connections, the connection will be established.

```
switch (newState) {
                case BluetoothProfile.STATE_CONNECTED:
                    instructionText.setText("Connected. Select Exercise");
                    gatt.discoverServices();
                    break;

                case BluetoothProfile.STATE_DISCONNECTED:
                    getView().findViewById(R.id.rollLabel).setVisibility(View.INVISIBLE);
                    getView().findViewById(R.id.pitchLabel).setVisibility(View.INVISIBLE);
                    getView().findViewById(R.id.yawLabel).setVisibility(View.INVISIBLE);
                    instructionText.setText("acsAssist Disconnected ");
                    break;

                case BluetoothProfile.STATE_CONNECTING:
                    instructionText.setText("Connecting to acsAssist...");
                    break;

                default:
                    instructionText.setText("acsAssist Disconnected");
            }
```

Figure 44. Notifying of Connection Status

Once a connection is established, service discovery must be initiated to allow for detection and monitoring of data written to the Arduino's bluetooth characteristics. In order to be notified of every data change, a specific UUID value of 0x2902 was written[49] to the characteristics' descriptors. It should be noted that writing this value occurs asynchronously through the Android framework. As a result, a custom function was implemented to ensure that this descriptor is written to all of the bluetooth characteristics (Figure 45).

```
public void onServicesDiscovered(BluetoothGatt gatt, int status) {
    if (status == BluetoothGatt.GATT_SUCCESS) {
        for (BluetoothGattCharacteristic characteristic: gatt.getService(UUID.fromString("00001826-0000-1000-8000-00805f9b34fb")).getCharacteristics()) {
            chars.add(characteristic);
        }
        subscribeToCharacteristics(gatt);
    }
}

private void subscribeToCharacteristics(BluetoothGatt gatt) {
    if(chars.size() == 0) return;
    BluetoothGattCharacteristic characteristic = chars.get(0);
    gatt.setCharacteristicNotification(characteristic, true);
    BluetoothGattDescriptor descriptor = characteristic.getDescriptor(UUID.fromString("00002902-0000-1000-8000-00805f9b34fb"));
    if(descriptor != null) {
        descriptor.setValue(BluetoothGattDescriptor.ENABLE_NOTIFICATION_VALUE);
        gatt.writeDescriptor(descriptor);
    }
}
```

Figure 45. Forcing Synchronous Characteristic Notification

Although there is a significant amount of setup and logistics required for Bluetooth implementation, the end result is a seamless experience for the user to connect to the device without having to perform any manual setup (Figure 46).

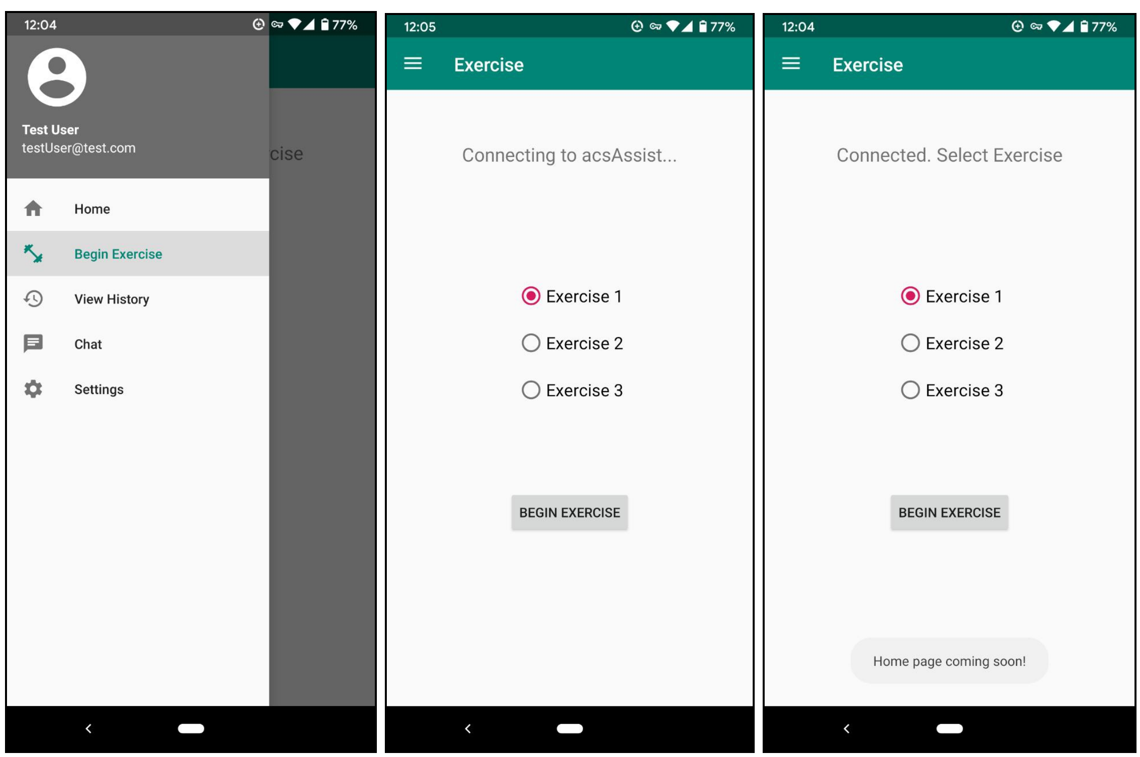


Figure 46. Procedure for establishing device connection

Android Application: Data Monitoring & Communication

As data values for each characteristic were changed, the text views displayed on the screen were updated, and the data were added to the database via a previously defined database instance (Figure 47).

```
public void onCharacteristicChanged(BluetoothGatt gatt, BluetoothGattCharacteristic characteristic) {
            super.onCharacteristicChanged(gatt, characteristic);
            FirebaseFirestore db = FirebaseFirestore.getInstance();
            TextView pitchText = getView().findViewById(R.id.pitchLabel);
            TextView rollText = getView().findViewById(R.id.rollLabel);
            TextView yawText = getView().findViewById(R.id.yawLabel);
            TextView temp = getView().findViewById(R.id.tempLabel);
            if(showMeasurements) {
                if(characteristic.getUuid().equals(pitchUUID)) {
                    pitchText.setText("Pitch\n" + characteristic.getStringValue(0));
                    Map<String, Object> angleData = new HashMap<>();
                    angleData.put("pitch", characteristic.getStringValue(0));
                    db.collection("Patient Data").document("testUser").set(angleData);
                }
```

Figure 47. Example of Updating Pitch Angle Value

Posting to the database enables the web application to pull the data and allows the therapist to view progress. Additional data, such as heating temperature and elapsed time, can also be posted as needed (Figure 48).

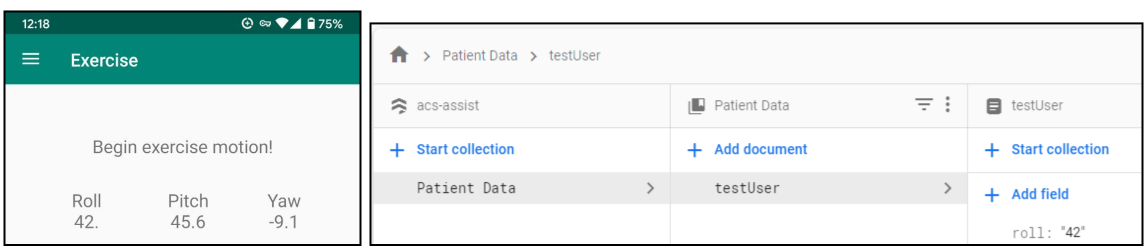


Figure 48. Monitoring measurements in app (Left). Example of posting roll angle data to database (Right)

The Android application's *Home* serves as the page from which overall therapeutic progress is monitored. While average values are calculated based on all recorded data, the overall progress is set by the therapist (Figure 49).

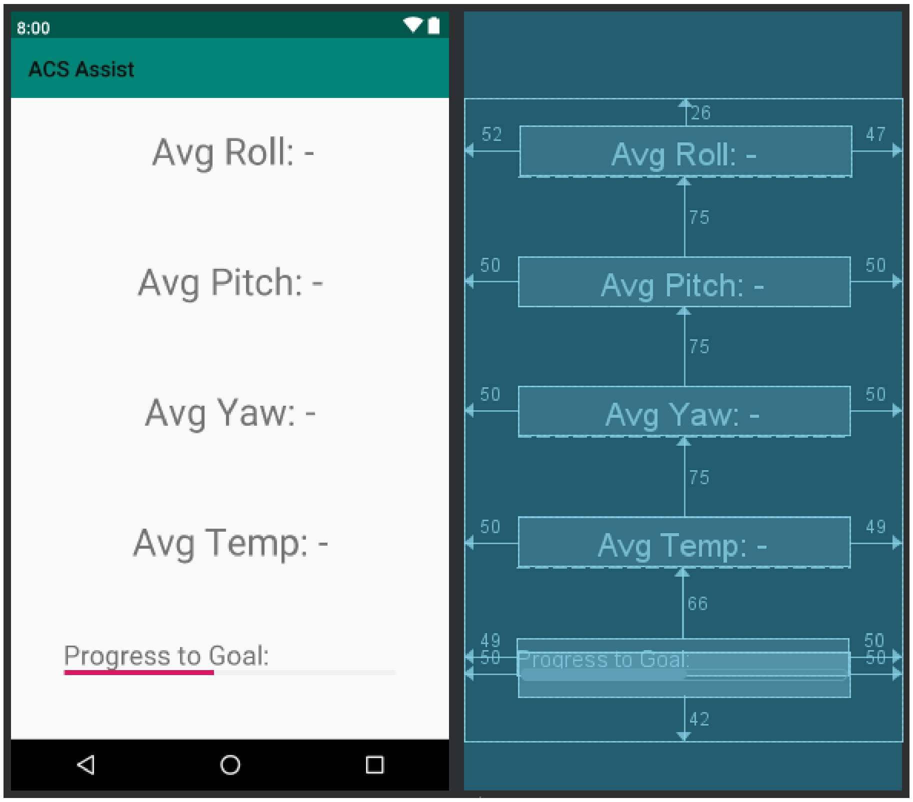


Figure 49. Home page layout which includes monitoring of therapy progress

Direct message communication between patient and therapist is also possible via the *Chat* page (Figure 50). Each message sent is posted to the android database, and the database is also monitored to see if any messages have been posted from the other member.

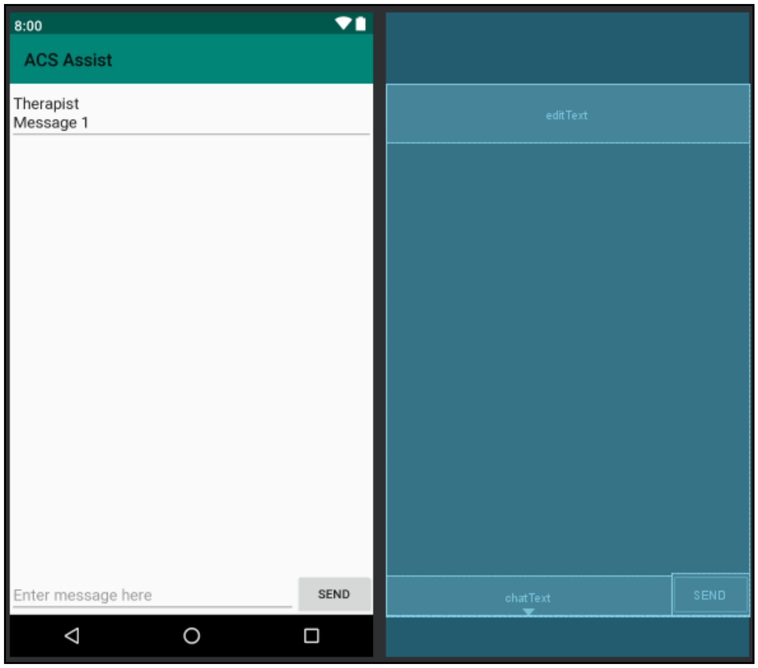


Figure 50. Example of Chat page with messaging

Android Application: Exercise History

The *History* page enables the user to view a list of all exercises previously performed. Selecting an exercise will result in a page similar to the *Home* page, where average values for the selected exercise and progress at that time are displayed (Figure 51).

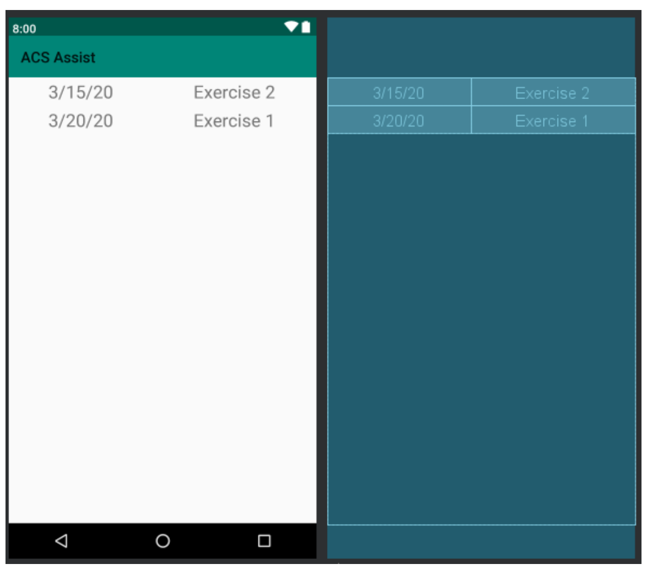


Figure 51. Example of History page

Android Application: Accessibility

Accessibility considerations should be made throughout the development of the software for this project, particularly in regards to color selection and icon design. All icons utilized in the application have been obtained from Android Studio's icon palette and have been selected to clearly demonstrate the functionality of each element. Additionally, color choices have been centrally defined via a resource value XML file (Figure 52). The colors currently being utilized by the application are subject to change given future user feedback.

```
<resources>
    <color name="colorPrimary">#008577</color>
    <color name="colorPrimaryDark">#00574B</color
>   <color name="white">#ffffff</color>
    <color name="darkGray">#6c6c6c</color>
    <color name="colorAccent">#D81B60</color>
</resources>
```

Figure 52. Current Color Selection

Additionally, a dark mode option has been added as an option in the settings page of the application (Figure 53). Upon initial application activity creation, the dark mode toggle value is checked, and the *AppCompatDelegate.setDefaultNightMode()* is utilized to enable the built in dark-theme palette that is included in the Android Operating System. An additional menu element is added that allows the user to easily navigate to the project website.

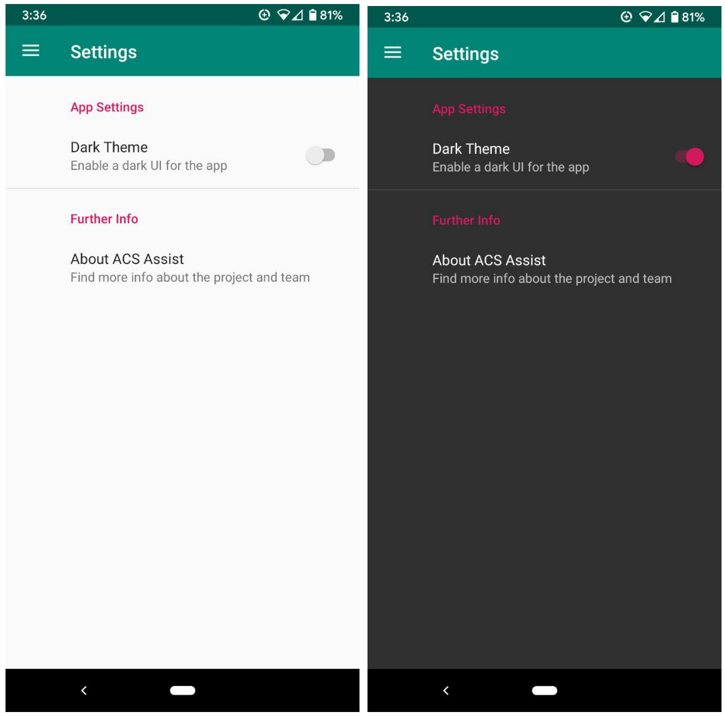


Figure 53. Dark Theme Enabling in the Settings Page

Android Application: Future Development
Written by Daniel Hanna

Although the Android application has been developed sufficiently for the device, future improvements are always possible to better fit the user's needs. This may include more precise measurements of angle and temperature, real time feedback and guidance during therapy exercises, and a refactored database that can more easily account for new users to be added.

Web Application: Django Web Framework
Written by Javier Thomas

Django Web Framework[50] was chosen to model the web app due to its flexibility. It allows for seamless integration with the cloud database and proved to be fully functioning with its ability to do simple graphical analysis through Pandas. The goal with this framework is to show proof of concept regarding a web app which will satisfy design requirements 11 and 12. These being that the devices partnered software must allow a medical professional to review performance data, and that the device and software components must be user-friendly outside a clinical environment. The purpose of having a functioning application along with the physical device is to add another layer of assistance. Based on physician input, the team identified base statistics which could be recorded during the therapy which would be useful for viewing and analysis. Along with this there are several aspects of the therapy which could be controlled from an external source such as a widget or web app.

The design of the application was based on design requirements as well as the input of the physician. The team decided on a base format as follows: Home page, Exercise page, Statistics page, History page, Chat page, and Settings page.

These will each lead to their own resources and have a specific use for both the physician and the user. The homepage will allow an overview of their current recovery path, their last exercise, a graph of their exercise average ROM, and the chat log between the user and physician. Over time, these may be adjusted with further research into what should be most important for the user. The exercise page will have a list of exercises for the user to perform as well as the recommended therapy prescribed by the physician. This may change over time and can be adjusted from the physicians point of view. The statistics page will feature the following statistics; average ROM over time, average ROM during the last exercise, history of reports of pain, time with use of heating pad, and average ROM over time after therapy visits.

The history page will consist of their exercise history and the option to get statistics for each individual session. There is some blending of this page along with the statistics page, and overtime they may be adjusted. The chat page will allow the user to contact their physician in the app and see the recommendations the physician may make. The nature of this chat will assist the patient and physician communication and status to allow for a better experience. Finally the settings page will have control of the user login, the dark mode, problem report, and any additional experience features that may be added.

The goal would be to have the web app view designed for the physician. In this way, the physician can do all the admin work on the same pages if needed and the user would not need to worry about interfacing with it. Each view will be created by hiding the control features from a base user and only allowing view to the admin.

So far, a local host has been launched in which the application pages will be built on. This is the admin page in which the physician will sign on to.

The admin page[51] (Figures 54 and 55) would give the physician the ability to manipulate variables that the user will see. Any element that is added to the website will be adjustable from this view.

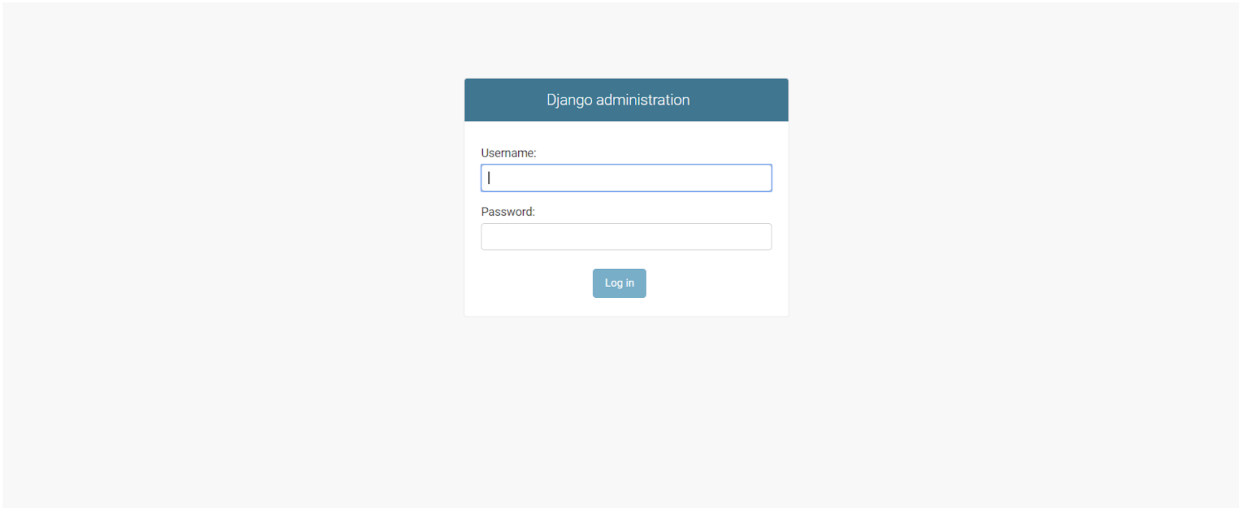


Figure 54. Log-in page for physicians to securely view patient data

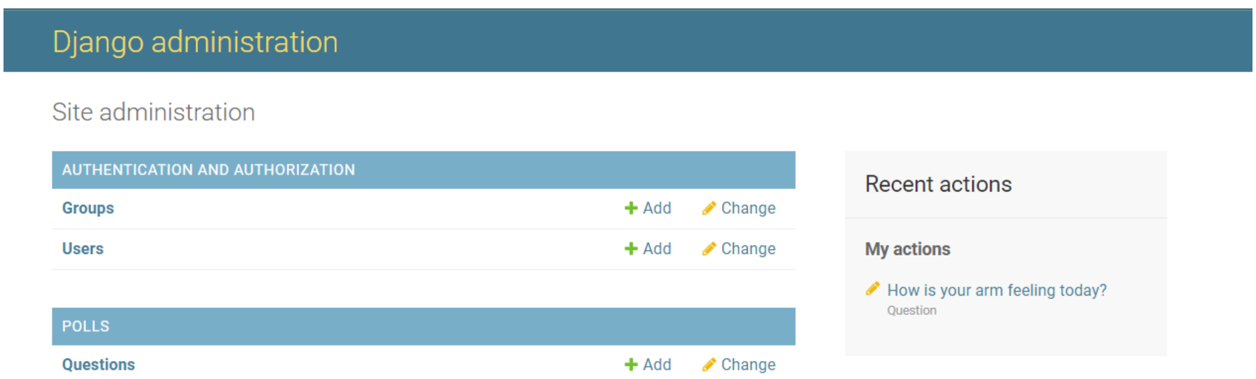


Figure 55. Homepage where physician could provide feedback, set ROM, view statistics, etc.

The foundation of the app continued development with the homepage and additional support pages. This can be seen in the git repository. In addition, progress was made with the display of the data using Dash. This will be covered in more depth in the next section.

Web Application: Views and Statistics
Written by Javier Thomas

Voice of Customer has aided in addressing what views would be the most important. In most cases, the statistical view which will be featured is that of average ROM in each rotation method as a function of time. This will be done by averaging out the ROM per exercise and making a timeline as the user completes more exercise. In this way, the user will see into their progress and how overtime their ROM increases and to what speed. This statistic will also allow the physician to notice trends and make recommendations as to the course of the recovery process.

The main statistics that will be included are as follows: Mean ROM per exercise as a function of time, Mean ROM as a function of time, Max ROM per exercise as a function of time, Max ROM as a function of time, and Comfort range ROM max as a function of time. Development of these equations will be the next step, and implementing them into Dash by Ploty[52], a built in python library.

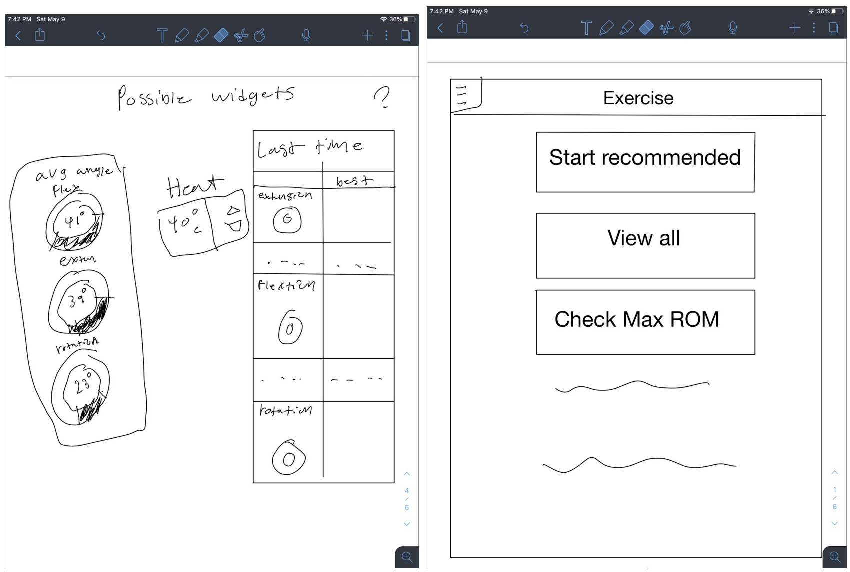
Figure 56. Homepage where physician could provide feedback, set ROM, view statistics, etc.

The barchart above (Figure 56) represents data that may be presented to the physician. It shows the month summary of average ROM per specific page. This view can be adjusted to show per day, per week, and per month, as well as showing highs and lows as opposed to averages. In addition, it would also potentially have a drill down option to make those edits easier. This is still being configured and will be a special feature if time permits. The main goal would be to develop the view's required for the patient to do their job.

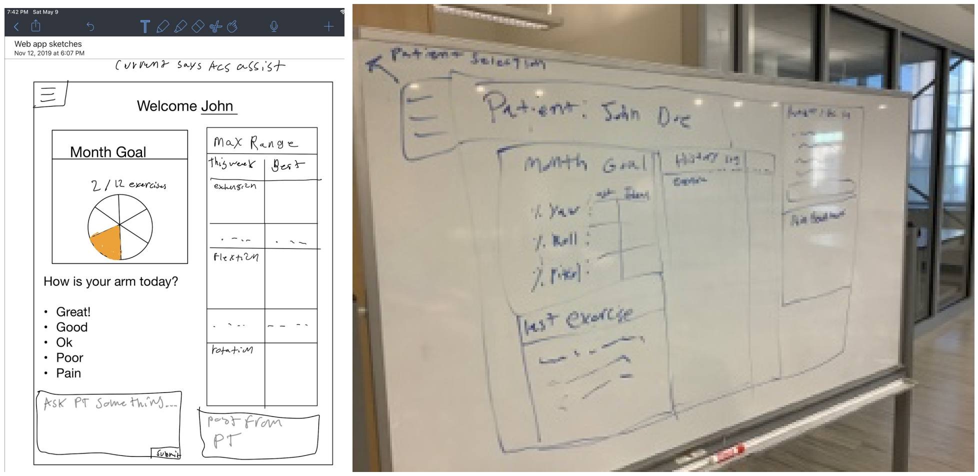
This being the main functionality, the remaining pages are simply the display of all the patients the doctor has, and a page to modify and suggest exercises. This brought the team to focusing on getting the functionality of the web app to a better place whence from when the communication between the two could be established.

Web Application: Future Development
Written by Javier Thomas

With the completion of the admin page, the remaining build will be slightly simpler. Each of the discussed pages will have its own link and look designed through an HTML format. Once this is done, the tweaking of the substance can begin and the final design can be made. Preliminary sketches of the website (Figure 57, 58, 59, 60) were made to prevent any rehashing of the design template. Once they were completed, the database connection was made and testing would be the next step.



Figures 57 & 58. Exercise page and possible widget sketches.



Figures 59 & 60. Homepage for user (left) and physician (right)

With future development in this project, experience says just do it simple and get functionality out of the way. Many times with the development of things on the website side, a priority was put into aesthetic and design as opposed to getting functionality working. This delayed the process tremendously. The team would suggest to future teams to focus primarily on the simple framework of function as opposed to an all encompassing scope.

CHAPTER 10: ALERT SYSTEMS

Written by Javier Thomas

As per requirement 13, which states that the device must alert the user if the clinical range of motion is exceeded, the device will be equipped with an auditory and tactile alert system. This will complement the real time app feedback as mentioned in Chapter 9. This alert system will provide further guidance during exercise, and will be accomplished through the use of a mini speaker, vibration motor, and attached LED. These units will be powered and operated by the Arduino[53], [541]. The locations of these will be determined based on the layout of the design and positioned in a way that will optimize their use.

The method of design of the controller for the speaker is as follows. There will be an internal controller programmed into the arduino which will monitor each ROM angle. The set range for the max value will be an adjusted value set by the physician. There will be a for loop constantly running to check if any of these ranges have been reached. If a range is reached, the speaker will output a series of beeps at a specific frequency indicating that the user reached the threshold. If the user surpasses the threshold by more than two degrees, the frequency will rise and the rate of beeps will also increase.

The vibration motor will have a similar control. As it only operates when the output pin is set to high, the vibration will occur once the user has surpassed their ROM threshold by one degree. This is checked for with the same technique as for the speaker, with a constant for loop checking on the ROM.

The LED will be attached on the armband in a location that is visible to the user. It will indicate when the threshold value is reached and light up. The purpose of this is to add a final assurance to the alert system as well as adapt for those who may have trouble hearing and feeling the speaker and vibrator respectively. Power to this LED will be supplied through the board since it operates on a very low power consumption.

```
    //InitializeSetPoint
    //Setpoint to 120 degrees
    Setpoint = 42;
    Input=0;
    Output=0;

    analogReference(EXTERNAL);
    Serial.println("Temperature PID ");
    delay(4000);

}

void loop(void) {

     uint8_t i;
     float average;

     if(Serial.available() > 0)
    {
      val = Serial.parseInt();
      Serial.println(val);
      if(val != 0)
      {
        analogWrite(10,val);
        digitalWrite(13,HIGH);
      }else{
        analogWrite(10,val);
        digitalWrite(13,LOW);
      }
    }
```

Figure 61. Implementation of the PI with alert system beta.

The goal of the PI was to regulate the temperature and know when to trigger the alert system. The basic triggering would operate with set limits to determine when to use the high and low voltages. These in turn activate the alert and notify the user with the vibration motor and mini speaker. The temperature would then drop, and the alerts would reside.

CHAPTER 11: DESIGN INTEGRATION

Written by Ryan DesRochers and Shruthi Radhakrishnan

The final proposed design will fulfill all design requirements. The device is comprised of two main components. The first component is the armband which will be secured to the user's arm around their bicep. The armband will be secured using velcro straps. Housed within the armband will be the inertial measurement unit onboard the Arduino Nano microprocessor. This location will allow the microprocessor to record data concerning the arms location throughout the exercises. This component will be attached to the main device by a tube containing the wiring necessary to power this component. A solidworks rendering of this component is shown below (Figure 62).

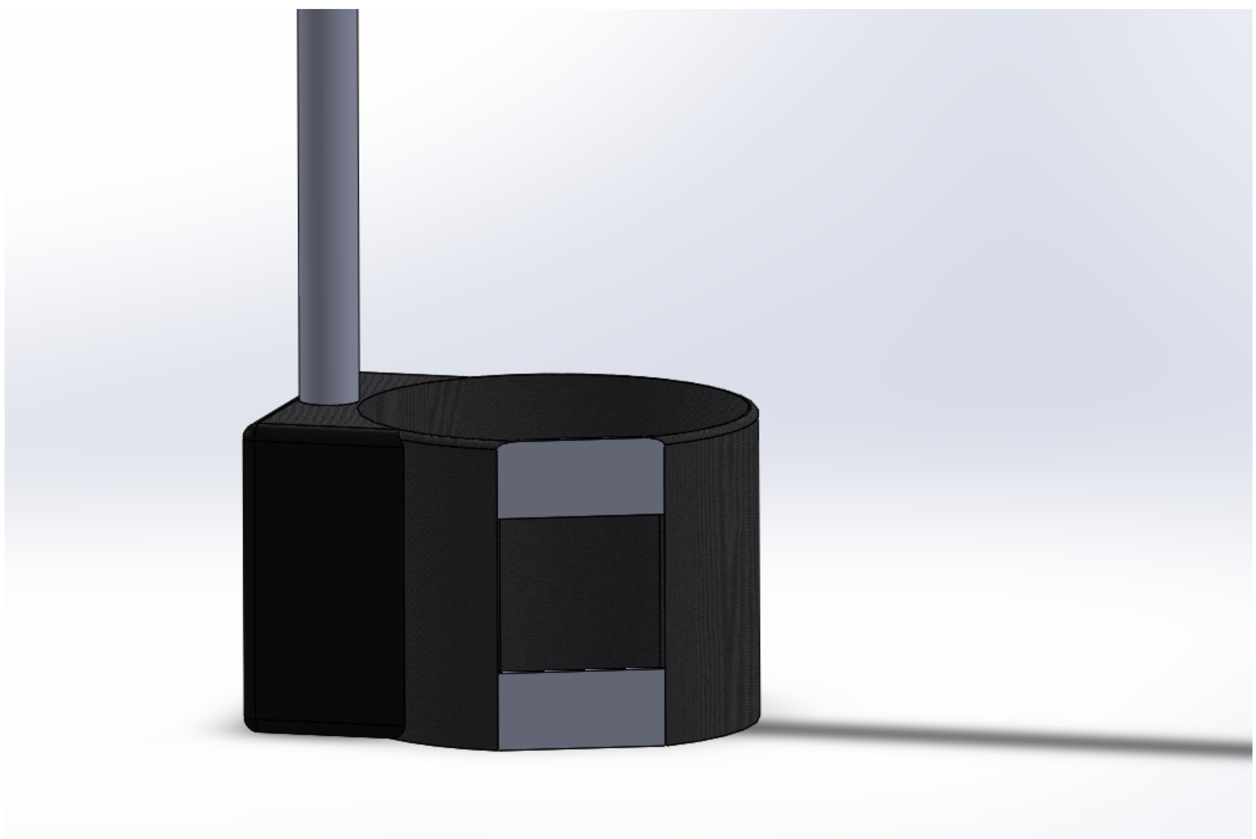


Figure 62. Armband Solidworks rendering.

The second component contains the heating system. This section is a wrap covering the rear of the shoulder and underneath the armpit. This will allow for heat to be delivered to the shoulder joint. This will be adjusted to fit users of varying size through a series of adjustable straps reaching over the opposite shoulder and around the front of the wrap. The heating system will be modulated by a PI control system that interfaces with the physical device through the Arduino Nano circuitry. Two or three thermistors will be placed sparsely along the shoulder joint and muscle area to detect and record the temperature readings into the device. On the back of the device, the battery pack will be housed. This placement will ensure that the device does not inhibit the shoulder's range of motion. This component is shown below (Figure 63), followed by a solidworks rendering of the complete device (Figure 64).

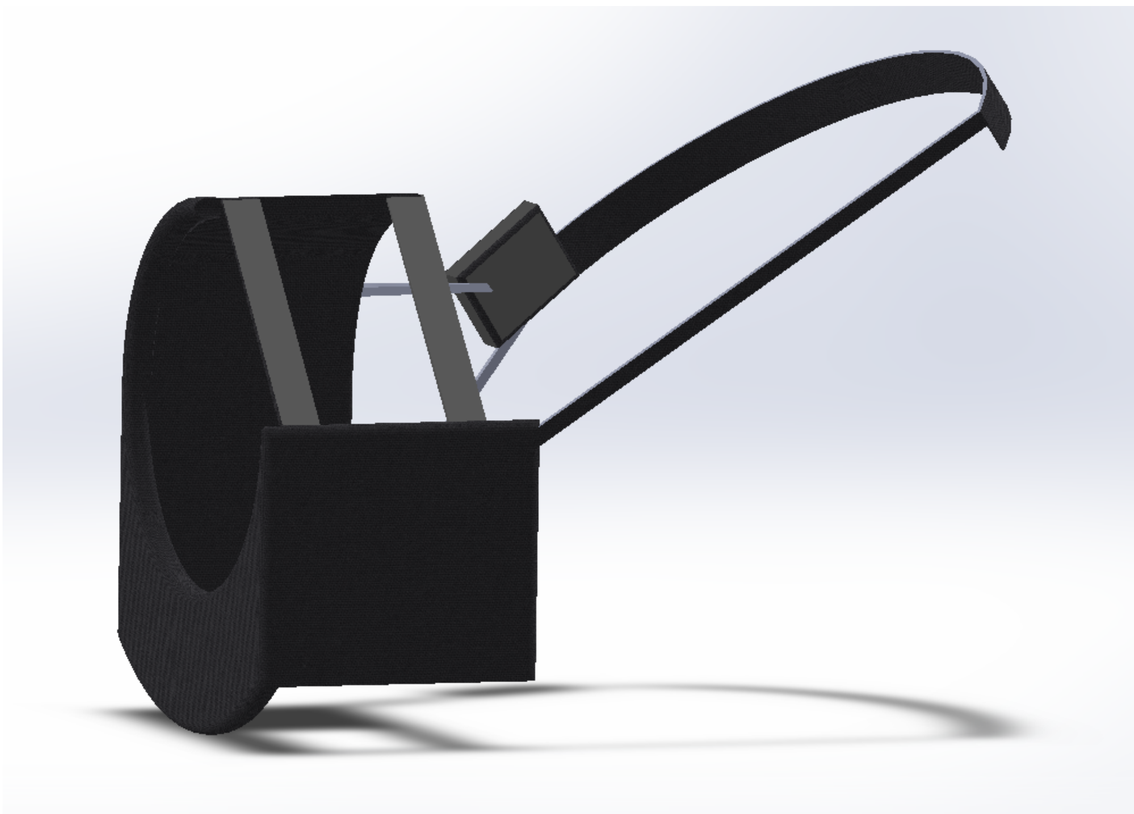


Figure 63. Heating holster Solidworks rendering.

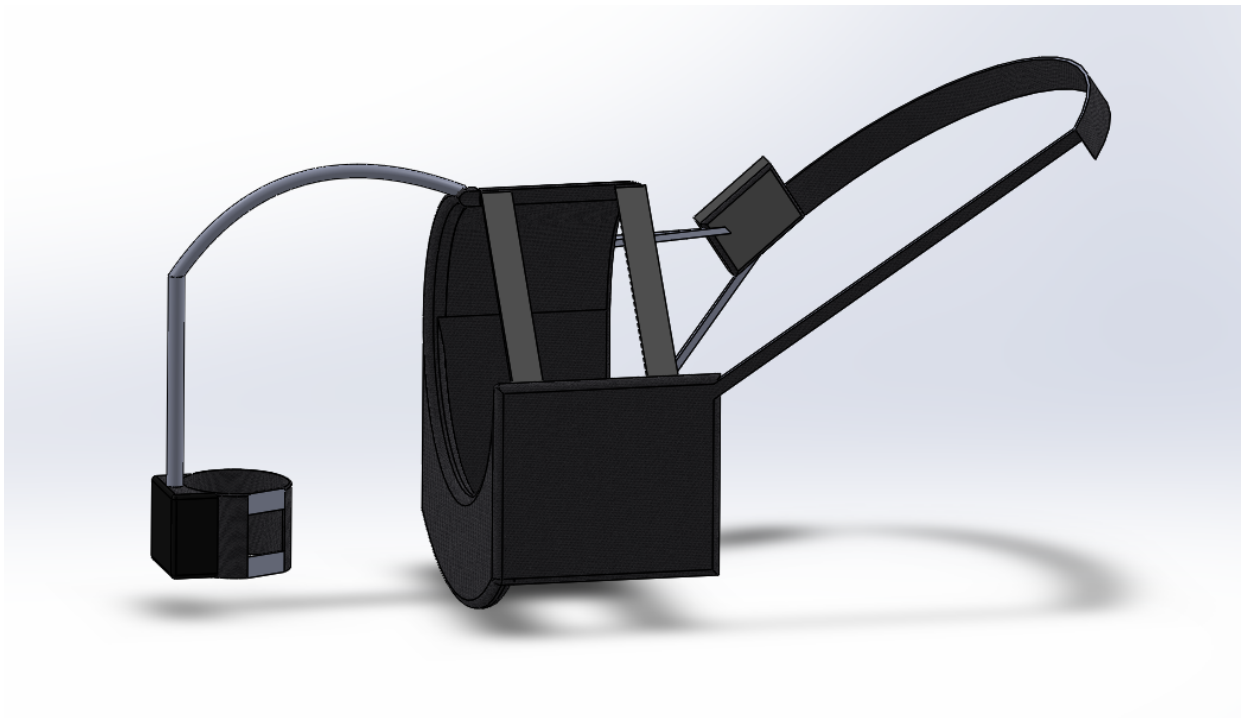


Figure 64. Final Design drafted in SolidWorks.

This physical design is expected to communicate the locally stored data to the user application and database that is viewable by the medical professional. The anticipated data flow from the device to the patient and medical professional is described in Figure 65. The flow diagram starts with the device input which is the patient performing the physical therapy exercise. The thermistor and angle sensors embedded in the device will detect the temperature and angle data, respectively. The data that is recorded is locally stored in the device and transmitted to the user application and cloud database. These two applications will be used so that the user can instantly view their ROM progress and communicate with the physical therapist if necessary. Meanwhile, the physical therapist would be able to separately view the ROM and temperature data to monitor the patient's progress and set limits for ROM if needed. These two components address the bidirectional feedback feature of the device where the device can communicate data to the user and medical professional while still being able to receive any input/comments from the physical therapist as well (Figure 65) .

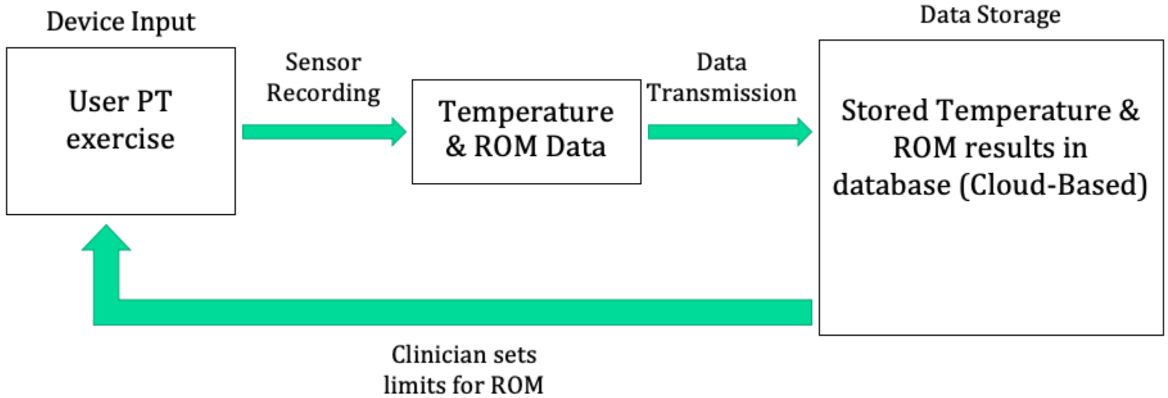


Figure 65. Data flow during device use.

Prototyping

Written by Ryan DesRochers

While the prototype was never completed, several important developments and considerations will be detailed from the process. In terms of building the design, the sleeve was constructed using polyester fabric. The polypropylene straps were adjustable with the intention of making it highly adjustable. This outer sleeve was built to close with velcro around the edges, for easy removal of the inner heating module so that the sleeve could be easily washed. Although the device had a buckle for release of the shoulder strap, it was designed so that it could easily be donned by simply slipping the strap over the head and across the shoulder with the healthy arm.

Figure 66. Prototype on user.

The inner enclosure was not constructed, but was to be built with heat-sealable nylon surrounding the heater tape. The heater tape, wired at the ends with brass crimping for a strong electrical connection, would be water-sealed to reduce corrosion from sweat during the use of the device. The wires from this system led to the battery pack, which was to be included mounted on the back strap of the device. The wires throughout the device were to be connected using quick-release electrical attachments. Additionally, at each connection, approximately 20% of extra wire was to be wrapped and included inside the enclosures to relieve excessive strain on the wires.

Figure 67. Prototype on user, with bicep band in the foreground.

For the bicep band, a cloth portion of the device was assembled resembling a blood pressure cuff. This was stiffened for some rigidity using interfacing fabric. The cuff was wrapped in velcro to allow for a high level of adjustability. The outside of the cuff was to have a plastic box mounted which housed the Arduino and IMU.

CHAPTER 12: DEVICE USE RISK ASSESSMENT

Written by Geoff Bartner

Risk assessment is the use of available information to properly identify and eliminate any possible hazards while using the device. In order to accurately assess a risk the hazards must be determined by their severity and probability. These two factors were measured on a scale from negligible to major and rare to likely, respectively. This scale was then quantified by assigning numbers to the scale. For example, a negligible severity received a score of one while a major severity received a four. Risk could then be determined by multiplying severity and probability as seen in Table 10. A risk score below or equal to three was deemed low risk, a score from four to six was deemed medium risk, and if the score was greater than six it was deemed a high risk. The goal of this assessment was to identify any areas of high risk and to develop solutions to mitigate and lower said risk. Once a hazard could be measured for risk accurately it was possible to identify the device's hazards.

Table 10. Table used to determine the level of risk.

		Probability			
		Rare (1)	Unlikely (2)	Possible (3)	Likely (4)
Severity	Negligible (1)	Low (1)	Low (2)	Low (3)	Medium (4)
	Minor (2)	Low (2)	Medium (4)	Medium (6)	High (8)
	Serious (3)	Low (3)	Medium (6)	High (9)	High (12)
	Major (4)	Medium (4)	High (8)	High (12)	High (16)

The first hazard considered was if the device's heating element exceeded the 40-43 °C. It is possible for this to occur if the thermistors fail to read temperature due to disconnected circuitry or if the software fails to set a temperature cap because it may not be connected to bluetooth. In either case, the physical shut off must also fail in order for the user to be burned. If the device is left on for too long it could result in serious burns. The severity is serious but since so many safeguards have to fail the probability was considered unlikely, thus receiving a medium risk (Table 10). The design solution for this hazard is to ensure that the device can be removed easily if the user is feeling any discomfort, before any burning can occur.

The next area of concern was if the user continuously exceeded the clinically set ROM which would cause the user to possibly re-injure their shoulder. This ROM could be exceeded if the sensory alert is not working because it has been disconnected from the device, or if the software fails to set the clinical ROM due to a software failure. These would both be failures of the device so their severity was considered minor and their probability unlikely. These conditions were evaluated to be a medium risk (Table 10). Yet the user could also intentionally ignore the set ROM which could lead to serious consequences, although it is unlikely that a user would do so. To combat any of these possibilities an emergency shutoff should be programmed into the device if the ROM is ignored for long enough to deter injury. This condition was evaluated to be a medium risk but with these design solutions it should lower the occurrence, thus decreasing the risk to low.

As mentioned beforehand, the device is powered by a battery so there is the potential hazard of leakage current, or an electric current in an unwanted conductive path. This could occur if the circuitry is exposed allowing for runoff, or if the user's sweat seeps into the device allowing for another conductive path although it is unlikely. If this were to happen the device would shock the user resulting in major harm, thus resulting in a high risk. In order to protect the user the circuitry will be enclosed in a water resistant seal and insulated material. This would ideally decrease the probability of leakage current happening.The residual risk from using insulation would lower the risk to medium.

Another possible hazard is that the clasp on the device may pinch the finger of the user when they are adjusting it to fit. At most this hazard can only cause mild discomfort and slight injury and likely that it could happen so the risk was determined to be low (Table 10). To minimize the harm caused by the clasps they should not be sharp so they cannot cause serious harm and keep the risk factor low.

The last hazard identified was if the battery or microprocessing unit began to overheat and similar to the heating pads this overheating could lead to burning the user. This could occur if either of these components short circuit. This could lead to a serious injury but it is unlikely that such a failure would happen, resulting in a medium risk. Again similar to the heating pad design solution the device should be easy to remove before the user can feel discomfort decreasing the chance of a burn, making the risk of a possible burn low.

Table 11. Risk assessment table

Potential Hazard	Hazard Event	Harm	Severity level	Probability	Risk
Heating pads exceeds 43°C	-The thermistors can't sense temperature -Software doesn't set temperature range -Physical shut off does not work	Device burns user	Serious	Unlikely	Medium
Clinical ROM is exceeded	Sensory alert doesn't alert user if they exceed clinical ROM	Possibly re-injure shoulder joint	Minor	Unlikely	Medium
	Device software fails to set clinical ROM		Minor	Unlikely	Medium
	User ignores ROM alert		Serious	Unlikely	Medium
Leakage current from device	Circuitry allows current runoff through device material User's sweat allows for a leakage current	Device shocks user	Major	Unlikely	High
Device clasp pinches skin	Finger gets stuck in clasp while user puts on device	Mild discomfort and slight injury	Negligible	Possible	Low
Battery and Microprocessor Unit Overheating	The battery unit becomes overheated due to electric short	Device Burns User	Serious	Unlikely	Medium

CHAPTER 13: REGULATORY CONSIDERATIONS

Written by Geoff Bartner

The risk analysis performed in Chapter 12 showed that there was a moderate risk for the patient while using the ACS Assist Device. Based on this analysis the ACS Assist Device would be classified as a Class II medical device and would be expected to follow a premarket notification 510(k) pathway using substantial equivalence from a Physical Medical Device (21 CFR 890) that has previously been approved. A 510(k) pathway was determined to be the most optimal because the ACS Assist Device combines key principles of two other previously approved predicate devices. One device is PT-Pac Portable Heating Pad (K963887) which implements a powered heating pad similar to the ACS Assist Device. The carbon fiber heating tape in our device employs the same redundancy in safety circuits and utilizes the same low voltage DC power source, so there is no new safety or effectiveness issue posed by this inclusion. The other device is the Dynatron 360 Range of Motion Testing Device (K897178) that utilizes an internal motor unit to track ROM which would be equivalent to the goniometer used in the ACS Assist Device. The inertial motor unit is a similar electronic device which has similar power and connectivity as a goniometer, again ensuring there is no additional safety or effectiveness issue. The entire 510(k) pathway and substantial equivalence information can be found in Appendix Q.

CHAPTER 14: TESTING (VERIFICATION & VALIDATION)

Verification Protocol for Specifications 1.1-1.3, 2-5
Written by Ryan and Shruthi

Study Objective

This study will verify that the device is capable of meeting the shoulder range-of -motion specifications:

Specification 1.1: The device needs to be wearable by men and women who have an average shoulder breadth range of between 35.6 and 53.2 cm[17].
Specification 1.2: The device needs to be wearable by men and women who have an average bicep circumference range between 21.8 and 36.9 cm[17].
Specification 1.3: The device needs to be wearable by the 5th percentile of women to the 95th percentile of men who have a shoulder-elbow length between 30-39 $\pm$0.6 cm[18].

Specification 2: The device must not exceed a weight of 4.1 kg. This is equivalent to 10% of the weight of the 5th percentile of women, the smallest intended users of the device. According to Son et. al., this weight can be beared by the shoulders without significantly affecting the movement of the individual[19].

Specification 3: The device must support movement in vertical flexion. The device will allow the arm to be raised along the sagittal plane for 180° $\pm$ 9° from resting position at the side (0°)[20].

Specification 4: The device will allow the arm to be raised along the sagittal plane for 60° $\pm$ 3° from resting position at the side (0°)[20].

Specification 5: The device needs to move with the arm for 68° $\pm$ 3.5° in external rotation and 109° $\pm$ 5.5° in internal rotation with the shoulder complex at 90° of abduction[20].

Materials/Equipment

- Surrogate Arm-Shoulder Device
- Protractor
- Weighing Scale (Acculab VA-8000 Industrial Bench Scale)
- Tape Measure

Methods

Estimated sample size (n): 15

Setup of Weighing scale:

1. Turn ON the device, press and hold F1 button
2. Press and hold the 'TARE' button
3. Place a calibration weight of 1 kg and turn off the scale.
4. The weighing scale is calibrated if the it reads 1 kg
5. Turn ON the device and press 'TARE' to zero the scale before weighing the object.

Testing

1. The device and materials will be gathered in STEM 218 for this study.
2. The device will be positioned onto the surrogate arm-shoulder device as it would be positioned on a user.
3. The surrogate arm will be extended in vertical flexion directly over the head. A protractor will be used to measure the change in this angle from the side of the surrogate body to the position directly overhead.
4. The surrogate arm will be raised along the sagittal plane from the side. A protractor will be used to measure the change in angle of the arm between these two positions.
5. The surrogate arm will be positioned in 90º of abduction. The surrogate arm will then be externally rotated, and the change in angle will be measured with a protractor.
6. The surrogate arm will be positioned in 90º of abduction. The surrogate arm will then be internally rotated, and the change in angle will be measured with a protractor.
7. The device will be removed from the surrogate shoulder device. The device will be placed on a calibrated scale and its weight will be recorded.
8. The device's straps will be fully extended. The maximum dimensions in terms of shoulder breadth, bicep circumference, and shoulder-to-elbow length will be measured with a tape measure.
9. The device's straps will be fully retracted. The minimum dimensions in terms of shoulder breadth, bicep circumference, and shoulder-to-elbow length will be measured with a tape measure.

Calculations/Statistical Methods

Fit Verification Data Collection:

The mean values will be calculated from the collected data for the three fit measurements (n = 15) from steps 8 and 9. Afterwards, a two tailed t-test will be performed to compare the actual readings to means of shoulder breadth, bicep circumference, and shoulder-elbow length measurements based on the ranges listed in the specifications.

Weight Verification Data Collection:

The weight measurement readings will be analyzed using a one-tail, one-sample t-test to determine if there is a significant difference between the recorded weight measurements and the specified weight limit.

ROM Data Collection:

The mean ROM measurement readings will be calculated from the test subjects and analyzed using three one-tail t-tests to determine if the values are significantly different for the given flexion (180°), extension (60°), internal and external rotation (68° and 109°) angle measurements.

Acceptance Criteria

Device Fit Data: (alpha should be 0.025 at each tail)

The measurements of the breadth range, bicep circumference, and shoulder elbow length should have critical values that do not fall in the lower and upper tails. The acceptance criteria will be set at $\boldsymbol{\alpha} = 0.05$ level, where it's 0.025 at both tails and the p-value should not exceed 0.05.

Weight Data:

The acceptance criteria will be set at $\boldsymbol{\alpha} = 0.05$ level and the three weight readings should not exceed 4.1 kg[3].

ROM Data:

The p-value obtained from each of the three t-tests should be less than 0.05 in order to support that the flexion, extension, and rotation angle specifications are met.

Verification Protocol for Specifications 6.1-6.3, 7.1-7.2
Written by Shruthi and Ryan

Study Objective

This study will verify that the device is capable of meeting the following the heating specifications:

<u>*Specification 6.1:*</u> The device's heating element needs to heat to 40-43°C for therapeutic effect[13]
<u>*Specification 6.2:*</u> The device's heating element needs to apply heat from the subscapularis muscle around the armpit region to the infraspinatus muscles (rotator cuff muscles)[3].
<u>*Specification 6.3:*</u> The device's heating element needs to heat the shoulder 10 minutes before the exercise and heat for 15 minutes during the exercise[3].

<u>*Specification 7.1:*</u> The device's heating element will shut off when device temperature exceeds 43°C[21].
<u>*Specification 7.2:*</u> The device will have a physical and software shut-off mechanism in accordance with ISO/TS 19218-1[22].

Materials/Equipment

- ACS Assist Device
- Surrogate Arm-Shoulder Device
- Thermistor
- Laser Thermometer
- Timer

Methods

Estimated sample size (n): 15

The variability of this study is unknown; thus, power analysis could not be done and an accurate sample size could not be calculated. For this reason, the total number of participants would have been in a range from 10 to 15 people. Once the study is complete an accurate power analysis would be conducted.

Testing

1. The device and materials will be gathered in STEM 218 for this study.
1. The device will be positioned onto the surrogate arm-shoulder device as it would be positioned on a user.
2. The surrogate arm will be positioned at rest with the arm on the side.
3. Through the device's bluetooth connected application, the device's normal programmed heating regimen will be started which includes 10 minutes pre-heating and 15 minutes heating during exercise.
4. The device's temperature will be checked at two points along the back, one point under the arm, and two points in the front using the thermistor. This is repeated every 2 minutes throughout a 25 minute cycle.
5. The thermistor will detect the temperature for the full duration of the exercise session (25 minutes) .
6. The temperature readings outputted by the thermistor will be checked using a laser thermometer for accuracy and also recorded.
7. Based on the recorded temperature data, the control system's input voltage will be increased in order to modulate the current to a point such that the device temperature exceeds 43°C. The device will be monitored to ensure that a software shutdown occurs when the temperature exceeds the maximum limit of 43°C.
8. The heating element will be turned on again and activated until heating reaches the therapeutic range. The physical shut off will be triggered to check if the heating system turns off.

Calculations/Statistical Methods

Continuous Heating Data Collection:

The mean values from all temperatures collected for the 25 minute cycle will be calculated. The data will be checked for any values above 43°C.

Heating Element Shut off Data Collection:

The data will be analyzed for any temperature readings above 43°C.

Acceptance Criteria

Continuous Heating Data Collection:

The recorded temperature readings must be between 40-43°C ± 0.5°C with an acceptance criteria of $\boldsymbol{\alpha} = 0.05$.

Heating Element Shut off Data Collection:

No temperature reading may be above 43°C.

Verification Protocol for Specifications 8, 9, 13.1-13.3, 16
Written by Daniel and Shruthi

Study Objective

This study will verify that the device is capable of meeting the following data, alert, and power specifications.

Specification 8: The metrics that are recorded must include flexion/extension/rotation angles as well as temperature and must be within 5% accuracy.

Specification 9: The data are AES encrypted in accordance to NIST recommendations[23].

Specification 13.1: The physical therapist needs to be able to set the clinically prescribed ROM for each individual.

Specification 13.2: The device should have a progressive alarm system that alerts the user via visual and tactile (vibration) cues.

Specification 13.3: There will be a visual gradient displayed on the user's mobile device app throughout the duration of the exercise.

Specification 16: The device needs to be powered for at least 25 minutes during the exercise session[3].

Materials/Equipment

- Surrogate Arm
- ACS Assist Physical Device
- Smartphone with Android application
- Protractor
- Laser Thermometer
- Computer with access to Firebase and the Web Application
- Timer

Methods

Estimated sample size (n): 15

The variability of this study was unknown; thus, power analysis could not be done and an accurate sample size could not be calculated. For this reason, the total number of participants would have been in a range from 10 to 15 people. Once the study is complete an accurate power analysis would be conducted so that the sample size (n) can be adjusted, accordingly.

Testing

1. The device and materials will be gathered in STEM 218 for this study.
2. The device will be positioned onto the surrogate arm-shoulder device as it would be positioned on a user.
3. The smartphone application will be loaded to the ‘Begin Exercise” page and the ‘Begin Exercise’ button will be selected to activate the range-of-motion and preheating phase of the device.
4. The android application will be checked to see if the temperature data are displayed.
5. Firebase will be checked on the computer to ensure that the temperature data displayed on the android application is being securely recorded to the database.
6. The temperature data will then be checked for accuracy by using a laser thermometer under the surrogate arm.
7. The surrogate arm will move in the three planes of motion (flexion, extension, and rotation) while the android application is checked to see if angle data are displayed and a visual gradient is shown.
8. Firebase will be checked on the computer to ensure that the angle data displayed on the android application is being securely recorded to the database.
9. The angle data will then be checked for accuracy by using a protractor, where 0° for flexion, extension, and rotation is read by having the surrogate arm extended outwards, parallel to the ground.

10. Range of motion limits will be entered via the web application. Firebase will be checked to ensure that the limit is securely recorded. The surrogate arm will be intentionally moved past the prescribed limit to confirm the auditory and vibratory alerts are functioning.
11. Exercises will be performed on the surrogate arm for 25 minutes and the device will be checked for power thereafter to ensure that power was sufficient for the session.

Calculations/Statistical Methods

Positional Data Collection:

Angle values will be measured for 15 points via both the device and protractor. Each value obtained from the protractor measurements will be compared to the device value.

Temperature Data Collection:

Temperature values will be measured for 15 points via both the device and laser thermometer. Each value obtained from the protractor measurements will be compared to the device value using a t-test to determine any significant difference between the device and thermometer ($\boldsymbol{\alpha}$ = 0.05.).

Acceptance Criteria

Positional Data:

The device and protractor measurements should have p-values less 0.05.

Temperature Data:

The device and thermometer values should have p-values less than 0.05.

Verification Protocol for Specification 10
Written by Daniel

Study Objective

This study will verify that the device is capable of meeting the following connectivity specifications:

<u>*Specification 10:*</u> The device will have wireless capability via Bluetooth.

Materials/Equipment

- ACS Assist Device
- 3 Android devices with Bluetooth capability and mobile application
- Stopwatch

Methods

Estimated sample size (n): 3

The variability of this study is unknown; thus, power analysis could not be done and an accurate sample size could not be calculated. For this reason, the total number of trials would be 3, where each trial uses a different smartphone with Bluetooth and the time to connect is recorded. Once the study is completed an accurate power analysis would be conducted so that the sample size (n) can be adjusted, accordingly.

Testing

1. The android application will be opened up to the ‘Begin Exercise’ page.
2. A stopwatch will be started.
3. It will be confirmed that the application connects to the device when the screen displays “Connected. Select Exercise”.
4. The stopwatch will be stopped.
5. This test will be repeated two more times on different smartphones.

Acceptance Criteria

Bluetooth Connection:

The android application should connect to the device within 60 seconds of launching.

Verification Protocol for Specification 11
Written by Javier

Study Objective

This study will verify that the device is capable of meeting the following connectivity specifications:

Specification 11.1: The accessible metrics include flexion/extension/rotation angles and temperature.
Specification 11.2: There will be use of external software to display data.

Materials/Equipment

- ACS Assist Device
- Computer with Web application

Methods

Data will streamline to the app from the device using the database and then use that data to project the findings.

Testing

1. The web app will be opened to the display page for a specified user.
2. It will be confirmed that the data appears present and will include angle and temperature measurements over the specified time period.
3. Data points will be manually added to the database.
4. It will be confirmed that the web app displays the updated data.

Acceptance Criteria

Web application:

Flexion, extension, and rotation angles as well as temperature data is retrieved through the web application after powering down the ACS Assist Device.

Verification Protocol for Specification 14
Written by Geoff

Study Objective

This study will verify that the device's electrical components are protected and enclosed so that it meets the following leakage current specifications:

Specification 14: The device's max leakage current must be less than 10-500 µA

Materials/Equipment

- ACS Assist Device
- Spray bottle filled with water

- DC Power Supplier

Methods:

Estimated sample size (n): 5

The variability of this study is unknown; thus, power analysis could not be done and an accurate sample size could not be calculated. For this reason, the total number of trials would be 5 Once the study was completed an accurate power analysis would be conducted so that a more accurate sample size could be determined.

Testing

1. The ACS Assist device will be connected and powered through a DC Power Supplier.
2. Input values of 9V and 2A will be supplied to the prototype. The leakage of the device will be determined through getting the difference between the input and the output currents.
3. The heating area will be sprayed with 50ml of water every three minutes for fifthteen minutes to simulate a user sweating during the duration of the physical therapy exercise.

Acceptable Criteria

Leakage Current

The device cannot exceed the 10-500µA range throughout the entire study.

Validation Protocol for Requirements 1-7, 13, 15
Written by Shruthi and Ryan

Study Objective

These requirements are to be validated by conducting tests on human subjects, so it had to be done through an IRB approved study. This study was going to be conducted on a subject population of healthy males and females ages 18-23 with no prior shoulder trauma and they were to be recruited through flyers posted on campus. The data being obtained is the subject's feedback about the prototype's accessibility, heating, and hindrance. The focus of this study is to validate requirements 1-7, 13, and 15:

Requirement 1: The device must fit the average female and male human shoulder dimensions.
Requirement 2: The device weight must not prevent the patient from performing the exercise.
Requirements 3: The device must support movement in vertical flexion.

Requirement 6: The device must continuously deliver superficial heat to the shoulder before and during exercise.
Requirement 7: The device's heating element must shut off before an unsafe temperature is reached.
Requirement 13: The device must alert the user if the clinical range of motion is exceeded.
Requirement 15: The user must be able to put on the device without assistance.

Subjects should be able to put on the prototype without assistance since the intended users of the device will have a limited ROM on one shoulder. After the study is completed, the subjects would answer a questionnaire asking them to rank the prototype's accessibility, heating control, and motion-hindrance on a likert scale from 1 to 5 in order to determine if the requirements were validated.

Materials/Equipment

- ACS prototype device

Methods

Estimated sample size: n = 15

The variability of this study was unknown; thus, power analysis could not be done and an accurate sample size could not be calculated. For this reason, the total number of participants would have been in a range from 10 to 15. Once the study was complete an accurate power analysis would be conducted.

Testing:

1. Subjects would go to STEM 218, where the testing would occur
2. The investigators would obtain consent from the subjects through an Adult Consent form
3. Once subjects sign the consent form, they would be assigned a subject identification number that would act as an anonymous identifier for the subject's questionnaire.
4. The subjects would then put on the device with one arm without assistance.
5. The subjects would turn on the device and begin a 10 minute warm-up period.
6. Once the warming period is completed, they would perform the pendulum exercises (flexion) for five minutes.
7. Next they would perform the wall climbing stretch (extension) for five minutes.
8. Next they would perform the back stretch (rotation) for five minutes.
9. As the subjects perform the exercises, the ROM alert system would be checked to see if it warns the subject when they exceed their ROM limits.

10. Once the exercise period is completed the subjects would shut off the device and remove it with one arm without assistance.

Calculations/Statistical Methods

Device Fit, Heating, and Hindrance Data Collection:
The test subjects would be asked to complete an anonymous questionnaire (pending IRB approval) asking them to grade the prototype's accessibility, heating, and hindrance from one to five.

A Wilcoxon statistical test would be performed to determine the difference between the ranked survey responses to the mean value of 3 on the grading scale. After calculating the difference of each observation and ranking it, a one-sided p-value would be obtained from a table of critical values ($\alpha = 0.05$).

Acceptance Criteria

Device Fit Data:
The acceptance criteria will be set at $\alpha = 0.05$ level in order to support that the device fit requirements are met.

Validation Protocol for Requirements 10 and 11
Written by Daniel and Shruthi

Study Objective

These requirements will be validated through medical professionals who use the web application to view the patient's therapy progress. This study will be conducted with a group of medical professionals who will be asked to use a web application that displays the data stored in Firebase. The focus of this study is to validate requirements 10 and 11:

Requirement 10: The device must send collected data to a database containing previous measurements.

Requirement 11: The devices partnered software must allow medical professionals to review performance data.

Materials/Equipment

- ACS prototype device

- Computer with access to web application

Methods

Estimated sample size: n = 3

The sample size includes three medical professionals in physical therapy.They would be given a questionnaire that inquires about the accessibility of patient data in the web application.

Testing

1. The device will be activated and an exercise will be initialized and performed.
2. Firebase will be checked to ensure that the data from the exercise has been recorded and added to the database containing previous exercises.
3. The investigators would obtain consent from the medical professionals through an Adult Consent form.
4. Once professionals sign the consent form, they would be assigned a subject identification number that would act as an anonymous identifier for the subject's questionnaire.
5. The medical professional will be given access to the web application. They will confirm in their questionnaire whether or not they were able to view performance data as well as rate the data's relevancy towards therapeutic input and progress.

Calculations/Statistical Methods

Medical Professional Data Accessibility:

The test subjects would be asked to complete an anonymous questionnaire (pending IRB approval) asking them to rate the data relevance towards patient therapeutic input and progress on a likert scale from one to five.

A Wilcoxon statistical test would be performed to determine the difference between the ranked survey responses to the mean value of 3 on the grading scale. After calculating the difference of each observation and ranking it, a one-sided p-value would be obtained from a table of critical values ($\alpha = 0.05$).

Acceptance Criteria

Medical Professional Data Accessibility:

The acceptance criteria will be set at $\alpha = 0.05$ level in order to support that the data accessibility requirements are met.

CHAPTER 15: BUDGET/COST ESTIMATE

Written by Geoff Bartner

The budget allocated to each team is $100 per team member. Since this senior project group has five members the total budget is subsequently $500. Before anything was considered to be purchased the team agreed upon that 20% of the budget, or $100, should only be used in case of emergencies. This way if extra parts need to be ordered, or shipping costs are too high, the team would still have available funds to complete the order. During the design phase of the project some parts such as the microcontroller, IMU, and material were already chosen and needed to be ordered for the device to function as intended. These part's total costs were recorded in the initial budget table where members could view a rough estimate of how much the total project was going to cost and how much of the remaining budget was available to afford additional unforeseen parts. The initial budget was just an estimate of what the project is believed to cost as prices, additional parts, and shipping costs were subject to change. The initial budget of the project was calculated using the following three equations:

$$Part\ Total\ Cost\ =\ (Quantity\ *\ Unit\ Cost)\ + Shipping\ Cost\ +\ Special\ Handling$$

$$Project\ Total\ Cost\ =\ \sum Part\ Total\ Cost$$

$$Difference\ =\ Budget\ -\ Project\ Total\ Cost$$

Utilizing these equations the team could monitor how much the project was going to cost when parts were added and if there was enough money left in the budget to afford a specific component. The initial budget could be seen in Table .

Table 12. Budgeting table.

Item	Company	Quantity	Part #/Stock #	Unit Cost ($)	Shipping Cost ($)	Special handling (eg hazards)	Total Cost ($)	Purchase Date	Expected Delivery Date	Actual Delivery Date	Company Website	Notes
Carbon heater tape 10 ft length x 1.73 in width	CarbonHeater	1	CT44	44.00	4.99		48.99				https://www.amazon.com/Carbon-heater-tape-length-width/dp/B077CBFVLB/ref=sr_1_5?gclid=EAIaIQobChMI8ebe1NCy5QIVkovICh2aAQoIEAAYAiAAEgIbufD_BwE&hvadid=295268902466&hvdev=c&hvlocphy=9003964&hvnetw=g&hvpos=1t2&hvqmt=e&hvrand=9690366112974871368&hvtargid=kwd-300416211526&hydadcr=954_9642223&keywords=carbon+heater+tape&qid=1571842248&sr=8-5	
Polyester Ripstock 200 Denier (Per Yard)	Ottertex	2	DWR	3.95	6.99		14.89				https://www.fabricwholesaledirect.com/products/polyester-ripstop-fabric?variant=1634355970060&gclid=CjwKCAjw5_DsBRBPEiwAIEDRW7KPR-XZWhwPwjLtzwmSx0gA-jKwBH7OMX4a19xBSiZWk6Dyc-g6uRoCUXcQAvD_BwE	
Heat-Sealable Coated Nylon Taffeta (Per Yard)	Seattle Fabrics	2	FHST	14.95	18.20		48.10				https://www.seattlefabrics.com/60-Heat-Sealable-Coated-Nylon-Taffeta-1495-linear-yard_p_31.html	
Side Release Buckle-1 inch Black	Strapworks	2		0.85	4.56		6.26				https://www.strapworks.com/ProductDetails.asp?ProductCode=SRBSA&CartID=1	
Heavyweight Polypropylene 1 inch	Strapworks	10		0.20	4.99		6.99				https://www.strapworks.com/ProductDetails.asp?ProductCode=HWP1&CartID=2	
Heavy Duty Z46 And Nylon Thread	Seattle Fabrics	1	T-46Z-BLACK	5.49	4.06	4.00	13.55				https://www.seattlefabrics.com/Heavy-Duty-Z46-and-Z69-Nylon-Thread_p_861.html	
ARDUINO NANO	Arduino	1	33 BLE	19.00	6.76		25.76				https://store.arduino.cc/usa/nano-33-ble	
IMU	Sparkfun	1	LSM9DS1	15.95	6.66		22.61				https://www.digikey.com/catalog/en/partgroup/lsm9ds1/50138?utm_adgroup=xGeneral&slid=&gclid=EAIaIQobChMI9_aX0JKh5QIVk4vICh06Eg-mEAAYASAAEgIfpPD_BwE	
NTCLE101E3103JB0 NTC Thermistor	Digikey	3	BC3403-ND	0.99	8.99		11.96				https://www.digikey.com/product-detail/en/NTCLE101E3103JB0/BC3403-ND/7101800/?itemSeq=306607657	
Polymer Lithium-ion Battery	Adafruit industries	1	785060	14.95	9.00		23.95				https://www.alliedelec.com/product/adafruit-industries/328/70928240/?gclid=EAIaIQobChMIvanItPqc5QIVAniGCh0rMQRaEAQYECABEgKRvvD_BwE&gclsrc=aw.ds	
TSYS01-1 Digital IC Temperature Sensor	Digikey	2	G-NICO-018	4.59	8.99		18.17				https://www.digikey.com/product-detail/en/G-NICO-018/223-1134-ND/3736309/?itemSeq=306578815	
Vibration Motor	Sparkfun	1	ROB-08449	2.15	6.66		8.81				https://www.sparkfun.com	
Mini Speaker	Sparkfun	1	COM-07950	1.95	6.66		8.61				https://www.sparkfun.com	
Total for Project							258.65					
											Budget:	500
											Total Cost:	$258.65
											Difference:	$241.35

As shown in the initial budget the Project Total Cost came out to $258.65 leaving a Difference of $241.35. This shows that the project was expected to be well within budget and if any complications arose along the building process the funds were available to purchase extra parts and/or ship parts to TCNJ quicker. The initial budget was used as a guiding instrument as it still lacked an accurate battery since the specifications were still unknown at the time, and several other components the team didn't realize needed to be ordered. These unknown parts were accounted for in the leftover difference since it was assumed they would not cause the project to go over budget. Based on this initial budget the team had begun ordering parts for construction and these purchased parts were compiled into a separate purchased parts budgeting table. This was done in order to keep track of actual part cost, delivery time, and the team's remaining budget. This actual budget is shown in Table .

Table 13. Purchased parts cost table.

Who ordered it?	Advisor	Item	Company	Quantity	Unit Cost ($)	Shipping Cost ($)	Total Cost ($)	Purchase Date	Expected Delivery Date	Actual Delivery Date	Item Link
Danny	Adegbege	Arduino Nano 33 BLE	Arduino	1	19	4.32	23.32	10/31/2019	11/1 - 11/8	11/15	https://store.arduino.cc/usa/nano-33-ble
Javier	Adegbege	Vibration Motor	Sparkfun	1	2.15	6.66	8.81	10/31/2019	11/4 - 11/14	11/15	https://www.sparkfun.com/products/7950
Javier	Adegbege	Mini Speaker	Sparkfun	1	1.95	0	1.95	10/31/2019	11/4 - 11/14	11/15	
Shruthi	Wagner	Carbon Heater Tape	CarbonHeater	1	44	4.99	48.99	1/28/2020	2/26-3/17		https://www.amazon.com/Carbon-heater-tape-length-width/dp/B077CBFVLB/ref=sr_1_3?keywords=carbon+heater+tape&qid=1580259764&s=industrial&sr=1-3
Geoff	Wagner	(5 pairs) DC Power Pigtail Male & Female Barrel Jack 6-Inch Wire 5.5mm x 2.1mm	JacobsParts	1	6.55	0	6.55	3/10/2020			https://www.amazon.com/JacobsParts-Pigtail-Security-Voltage-Applications/dp/B07N8GCH6S/ref=asc_df_B00R1XZ09K/?tag=hyprod-20&linkCode=df0&hvadid=216499414469&hvpos=&hvnetw=g&hvrand=3089111179321700628&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9003964&hvtargid=pla-350998796055&th=1
Geoff	Wagner	Battery Lithium-Ion	Allied	1	30.29	9	39.29	3/10/2020			https://assets.alliedelec.com/v1556359324/Datasheets/66d0133dc05d5f961ff64ee2fdbd0204.pdf
Geoff	Wagner	DC Power Supply AC Adapter	Parts Express	1	6.97	9.54	16.51	3/10/2020			https://www.parts-express.com/12v-25a-dc-power-supply-ac-adapter-with-21-x-55mm-center-(-)-positive-plug--129-058
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
Total Amount for Project							145.42				
										Budget	$500
										Total Cost	145.42
										Amount Remaining	$355

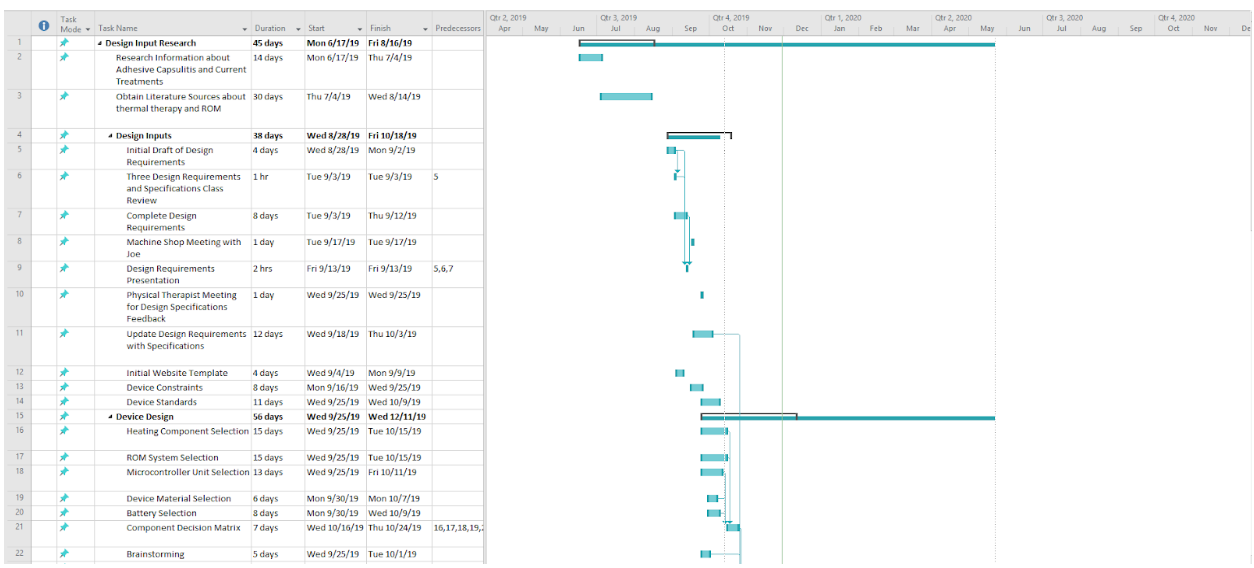
This table was continuously updated with components the team bought in accordance with the initial budget and the team's needs. If the team had the opportunity to order more parts it is expected to have followed the initial budget and beyond. The total project cost had been about $258.65 as outlined in the initial budget, but it was expected the actual total cost would have been higher since additional parts were going to be ordered throughout the semester. That being said the project was still never expected to go over budget and the leftover funds would have been used only in case of an emergency.

CHAPTER 16: PROJECT SCHEDULE

Written by Daniel Hanna and Shruthi Radhakrishnan

During the first semester, the design inputs were developed, components were tested, and the final design solution was evolved from iterative designs. The design inputs include requirements, specifications, and justifications for device need which stemmed from published literature as well as physical therapist voice of customer. These inputs were used to brainstorm alternative design solutions based on integral functionalities such as ROM monitoring, heat therapy, microcontroller/IMU implementation, and software development. After these solutions were designed, components were analyzed for each functionality and selected based on decision matrix criteria. Ultimately, a final design solution was created and drafted in SolidWorks. Figure 64 outlines the project Gantt chart, beginning from the project's inception and continuing throughout the remainder of the academic year.

In the second semester, a considerable amount of the building phase was completed. The building involved implementing a physical control system for the heating unit, creating a prototype of the mechanical design, and further improvements for the Android application and the database components. Unfortunately, the building was halted in mid-March due to a pandemic which prevented the team from completing the project. Therefore, the prototype was not fully built so verification and validation studies were unable to be conducted. This unexpected turn of events unfortunately changed the course of the project; however, in the future the Gantt chart could be modified to improve the projected timeline of the project.



	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1		**Design Input Research**	**45 days**	**Mon 6/17/19**	**Fri 8/16/19**	
2		Research Information about Adhesive Capsulitis and Current Treatments	14 days	Mon 6/17/19	Thu 7/4/19	
3		Obtain Literature Sources about thermal therapy and ROM	30 days	Thu 7/4/19	Wed 8/14/19	
4		**Design Inputs**	**38 days**	**Wed 8/28/19**	**Fri 10/18/19**	
5		Initial Draft of Design Requirements	4 days	Wed 8/28/19	Mon 9/2/19	
6		Three Design Requirements and Specifications Class Review	1 hr	Tue 9/3/19	Tue 9/3/19	5
7		Complete Design Requirements	8 days	Tue 9/3/19	Thu 9/12/19	
8		Machine Shop Meeting with Joe	1 day	Tue 9/17/19	Tue 9/17/19	
9		Design Requirements Presentation	2 hrs	Fri 9/13/19	Fri 9/13/19	5,6,7
10		Physical Therapist Meeting for Design Specifications Feedback	1 day	Wed 9/25/19	Wed 9/25/19	
11		Update Design Requirements with Specifications	12 days	Wed 9/18/19	Thu 10/3/19	
12		Initial Website Template	4 days	Wed 9/4/19	Mon 9/9/19	
13		Device Constraints	8 days	Mon 9/16/19	Wed 9/25/19	
14		Device Standards	11 days	Wed 9/25/19	Wed 10/9/19	
15		**Device Design**	**56 days**	**Wed 9/25/19**	**Wed 12/11/19**	
16		Heating Component Selection	15 days	Wed 9/25/19	Tue 10/15/19	
17		ROM System Selection	15 days	Wed 9/25/19	Tue 10/15/19	
18		Microcontroller Unit Selection	13 days	Wed 9/25/19	Fri 10/11/19	
19		Device Material Selection	6 days	Mon 9/30/19	Mon 10/7/19	
20		Battery Selection	8 days	Mon 9/30/19	Wed 10/9/19	
21		Component Decision Matrix	7 days	Wed 10/16/19	Thu 10/24/19	16,17,18,19,[illegible]
22		Brainstorming	5 days	Wed 9/25/19	Tue 10/1/19	

	Task Mode	Task Name	Duration	Start	Finish	Predecessors
23		Create Preliminary Anthropometric Sketches	6 days	Wed 10/2/19	Wed 10/9/19	
24		Calculate Initial Budget	11 days	Wed 10/2/19	Wed 10/16/19	
25		Select three device designs	2 days	Thu 10/24/19	Fri 10/25/19	
26		Interim Design Review	3 hrs	Mon 10/28/19	Mon 10/28/19	11,21,22,24,
27		Safety Training & Survey	11 days	Wed 10/23/19	Wed 11/6/19	
28		Select possible components to order for pre-testing	20 days	Wed 10/16/19	Tue 11/12/19	
29		Complete Component Material List	15 days	Wed 10/30/19	Tue 11/19/19	
30		Draft Verification Testing Protocols	8 days	Mon 11/4/19	Wed 11/13/19	
31		Create SolidWorks Sketches	8 days	Tue 11/5/19	Thu 11/14/19	
32		Determine Final Design	3 days	Thu 11/14/19	Mon 11/18/19	
33		Submit Project Abstract	8 days	Fri 11/15/19	Tue 11/26/19	
34		Submit Final Report Draft	5 days	Mon 11/25/19	Fri 11/29/19	
35		SP I Final Presentations	3 hrs	Wed 11/20/19	Wed 11/20/19	29,31,32
36		Final Report	8 days	Mon 12/2/19	Wed 12/11/19	32,33,34,35
37		**Build Prototype**	**84 days**	**Tue 11/5/19**	**Fri 2/28/20**	
38		Order Initial Materials to Start Building	40 days	Tue 11/5/19	Mon 12/30/19	
39		Build Thermal Therapy System	45 days	Mon 12/30/19	Fri 2/28/20	
40		Build ROM system	45 days	Mon 12/30/19	Fri 2/28/20	
41		Build phone application	40 days	Mon 12/30/19	Fri 2/21/20	
42		Develop Software Database	40 days	Mon 12/30/19	Fri 2/21/20	
43		Integrate Software Components with Device using Microcontroller Unit	35 days	Mon 1/6/20	Fri 2/21/20	
44		Integrate Device Wrap/Sleeve Material with components	20 days	Mon 3/2/20	Fri 3/27/20	39,40,43
45		**Prototype Testing**	**60 days**	**Mon 3/2/20**	**Fri 5/22/20**	
46		Finalize Verification and Validation Testing Protocols	10 days	Mon 3/2/20	Fri 3/13/20	
47		Device Temperature Testing	8 days	Mon 3/16/20	Wed 3/25/20	
48		ROM Angle Verification Testing in Flexion, Extension, Rotation	8 days	Mon 3/30/20	Wed 4/8/20	
49		Software Algorithm Verification Testing	5 days	Mon 3/30/20	Fri 4/3/20	
50		Material Testing	8 days	Mon 4/6/20	Wed 4/15/20	
51		Validation Testing	7 days	Thu 4/16/20	Fri 4/24/20	
52		Data Analysis	10 days	Thu 4/16/20	Wed 4/29/20	
53		SP II Final Presentation	7 days	Thu 4/30/20	Fri 5/8/20	47,48,49,50,
54		Submit Final Report for SP II	6 days	Fri 5/8/20	Fri 5/15/20	
55		Create Final Poster for COSA	2 days	Wed 5/13/20	Thu 5/14/20	
56		Commencement	2 days	Mon 5/18/20	Tue 5/19/20	53,54,55

Figure 67. Gantt chart projected schedule.

CHAPTER 17: CONCLUSION

Written by Ryan DesRochers and Javier Thomas

The goal of this project is to design and build a working prototype which offers the patient a system to monitor their physical therapy regimen, provide aid during the exercise through heating the body, and allow for patient and physical therapist feedback. The essential device design is complete at this point. Due to the Covid-19 pandemic cutting short the project time, the final prototype was never assembled. If the project is to be continued, the device prototype will be assembled, and final decisions in terms of part selection will be made in terms of the device's power supply. Testing will then commence to confirm that the prototype fulfills the requirements set for this project. Through extensive verification and validation testing, the design of this device will be proven effective in accomplishing these three main project goals.

Additional benefits that may be gained from the project include the pattern data that may be learned from the device after a period of use. It may also shed light as to the effectiveness of a more precise passive therapy and the benefits of adjusting the routine of therapy over time.

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APPENDIX

A: Biographies

Shruthi Radhakrishnan is a senior Biomedical Engineering student and team leader for this project. She is responsible for the thermal therapy component of the device and heating control system design. Her undergraduate research includes neural engineering and finite-element computational modeling. After graduation, she aspires to enter into the medical device industry or related field, where she can create medical devices that will help people in need.

Ryan DesRochers is a senior Biomedical Engineering student and the team secretary for this project. He is responsible for the mechanical structure design and physical modeling of the device. After graduation, he will train to become a physician, aspiring to improve medical devices used in patient care.

Geoffrey Bartner is a senior Biomedical Engineering student and treasurer for this project. He is responsible for device battery selection, power consumption analysis as well as environmental shielding of the device and risk assessment. After graduation he aspires to enter the biomedical industry

Daniel Hanna is a senior Computer Engineering student and team webmaster for this project. He has worked extensively with the software and hardware components, which involved the android app development, and microcontroller/IMU implementation. His background involves working on several software projects in languages such as Python, Java, Javascript, C++, and Ruby. Some of his hobbies include reading, playing basketball, and following tech news! After graduation, he aspires to enter industry as a software developer.

Javier Thomas is a senior Computer Engineering student and timeline master for this project. He worked with many software aspects of this project, most notably with the web app and data analysis. He has worked with many different coding languages such as Python, Java, C++, as well as different cloud services including AWS and Google Firebase. He plans on working in the industry as an innovator and hopes to go into data science and programming.

B: Design Matrix

Design Inputs			
	Requirements	**Specifications**	**Justifications**
1	The device must fit the average female and male human shoulder dimensions	1.1 The device needs to be wearable by men and women who have an average shoulder breadth range of between 35.6 and 53.2 cm[1] 1.2 The device needs to be wearable by men and women who have an average bicep circumference range between 21.8 and 36.9 cm[1] 1.3 The device needs to be wearable by the 5th percentile to the 95th percentile of men who have a shoulder-elbow length between 30-39 $\pm$ 0.6 cm [2]	The device needs to fit users with different body types and shapes in the target population
2	The device weight must not hinder the patient from performing the exercise	The device must not exceed a weight of 4.1 kg (10% weight of 5th percentile of women)[3]	The device is intended for the patient to use to perform physical therapy exercises correctly outside the clinical environment without letting it hinder them
3	The device must support shoulder movement in vertical flexion	The device will allow the arm to be raised along the sagittal plane for 180° $\pm$ 9° from resting position at	The device is intended for users to safely move their shoulders in vertical

		the side (0°)[4]	flexion during the recovery process
4	The device must support shoulder movement in vertical extension	The device will allow the arm to be raised along the sagittal plane for 60° ± 3° from resting position at the side (0°)[4]	The device is intended for users to safely move their shoulders in abduction during the recovery process
5	The device must support shoulder movement in rotation	The device needs to move with the arm for 68° ± 3.5° in external rotation and 109° ± 5.5° in internal rotation with the shoulder complex at 90° of abduction[4]	The device is intended for users to safely move their shoulders in rotation during the recovery process
6	The device must continuously deliver superficial heat to the shoulder before and during exercise	6.1 The device's heating element needs to heat to 40-43°C for therapeutic effect[5] 6.2 The device's heating element needs to apply heat from the subscapularis muscle around the armpit region to the infraspinatus muscles (rotator cuff muscles)[6] 6.3 The device's heating element needs to heat the shoulder 10 minutes before the exercise and heat for 15 minutes during the exercise [6]	The device is intended to provide user with therapeutic relief while performing exercises. The heat could modify the viscoelastic properties of the tissue located at the shoulder muscles and reduce joint stiffness to improve mobility
7	The device's heating element must shut off before an unsafe temperature is reached	7.1 The device's heating element will shut off when device temperature exceeds 43°C[7] 7.2 The device will have a physical and software shut-off mechanism in accordance with ISO/TS 19218-1[8]	The shoulder temperature needs to be monitored so that the device does not overheat the region and cause burns/injury during therapeutic heating regimen The shut-off mechanism

			will help to avoid any safety hazards and injuries that can result from device malfunction
8	The device must record positional data during exercise	The metrics that are recorded should include: - Flexion/Extension/Rotation Angles - Temperature	The device needs to record angle data for the different ROMs and device temperature as a function of time in an algorithm
9	Data that are stored from the device must be electronically protected	The data are AES encrypted in accordance to NIST recommendations[9]	These data involve personal medical information; hence, must be managed in a secure way
10	The device must send collected data to database containing previous measurements	The device will have wireless capability via Bluetooth	The device needs to send data to a software database when connected wirelessly
11	The devices partnered software must allow medical professional to review performance data	10.1 The accessible metrics include: - Flexion/Extension/Rotation Angles - Temperature 10.2 There will be use of external software to display data	The data need to be interpreted by a physical therapist/clinician so that they can monitor user progress and update regimen if necessary
12	The device and software components must be user-friendly outside a clinical environment	The symbols on the medical device and its documentation should be used in accordance to ISO 15223-1 standard[10]	The device and software need to adhere to the ISO standard so that it can be used safely and effectively by anyone who has this medical condition

13	The device must alert the user if the clinical range of motion is exceeded	13.1 The physical therapist needs to be able to set the clinically prescribed ROM for each individual 13.2 The device should have a progressive alarm system that alerts user via visual and tactile (vibration) cues 13.3 There will be a visual gradient displayed on the user's mobile device app throughout the duration of the exercise	The device is intended to deter re-injury due to overextension in any plane of motion during recovery exercises
14	The electric components of the device must be shielded from external moisture and contaminants	14.1 The electric components of the device should be used in accordance to ANSI/AAMI HA60601-1-11[11] 14.2The electric components should be made in accordance to ANSI/IEC 60529 (IP Code regulations for electric enclosures)[12]	The device will be used to ensure that the electric components of the device would be safely used outside clinical environments, without harming the user. These standards specify safe operating and storage conditions that must be met.
15	The user must be able to put on the device without assistance	The requirement will be confirmed through validation tests and surveys	The users of this device would not have full mobility in one of their arms, so they should be able to wear the device using one arm without external assistance
16	The battery of the device	The device needs to be powered for	The device is intended to

	must last for the duration of physical therapy exercise	at least 25 minutes during the exercise session[6]	record prevalent data for the physical therapist throughout the entire exercise as well as apply therapeutic heat to the user

Design Matrix References

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C: Constraints

Constraint Categories	Constraint	Justification	Requirement	Specification
Global	The device needs to be available for both domestic and international (Outside USA) populations	The target population are 40-60 year old frozen shoulder patients who are in physical therapy, which is not limited to the United States	The device must be available in domestic and international medical device markets for the target population	Frozen shoulder affects x % of population internationally
Economic	The device needs to be affordable to users with low income	The target population include people who could have low to high incomes depending on their social status and occupation	The device must be affordable for the target population with low incomes	In a conducted study of frozen shoulder demographics, it is found that 41% of frozen shoulder patients were unemployed, 20.8% patients were laborers, 20.1% office workers, and 18.1% patients were uncategorized[1]
Economic	The device needs to be updated through the mobile app	The device has a software/app component where the user would be able to track their ROM and adjust heating temperature during physical therapy over a period of time	The user must have access to a smartphone to connect to the device	The ROM collected on the device would be displayed on the app for the user to view overall progress according to therapist input
Health & Safety	The electronic components of the device need to be protected from	The functionality of the electronic components should not be impacted by	The electronic components of the device must be shielded from	The device must comply with IEC 60601 standard for medical device

	moisture and contamination	the moisture (sweat) and external contamination	moisture and contamination	electronics safety
Health & Safety	The device electronic components need to be insulated from the user	The device electronic components should not malfunction (electric shock) and harm the user	The device electronic components must not harm the user while device is in use	The device ROM and heating components would be programmed to specific range of values to deliver safe and effective therapy to user
Health & Safety	The device's heating element should not damage the device	The thermal component of the device should not damage the device's material and impact functionality of device	The device material must withstand the amount of heat administered from thermal component	The device material needs to safely withstand the therapeutic range of temperatures between 40-43 °C[2]
Social	The device needs to be compact and portable to carry by targeted population	The device should be easy to carry with just one arm because the frozen shoulder condition could affect the mobility of the other arm. So, it must not be too heavy and hard to carry for patients who want to perform physical therapy exercises outside a clinical environment	The device must be portable to carry by targeted population	The device weight should not hinder the patient's physical therapy performance The device must be y% of the user's weight

Ethical	The device must go through the appropriate IRB approval process before human testing	All human medical device testing must be approved by the IRB	The device must be safely tested by people in order to verify its effectiveness	Human testing will verify that the device allows the user to safely accomplish their physical therapy routine. Additionally, it will verify that the device is able to heat the shoulder appropriately during the exercises
Environmental	The device's manufacture and use should not result in extensive hazardous waste	Certain materials, including batteries, leak harmful chemicals into the environment after their disposal	The device's batteries must be rechargeable to reduce the number of batteries that are disposed during use	Batteries pose a significant threat to the environment
Manufacturability	The device has to be manufactured according to the available TCNJ resources	The TCNJ machine shop, prototyping lab, and woodshop are available as resources to prototype the project	The device must be manufactured using equipment available through TCNJ or for purchase within the budget	Equipment needing to be purchased for manufacture will quickly exceed the available budget
Sustainability	The device needs to survive daily use without extensive wear	Extensive wear will result in an extensive amount of waste from the product as parts need to be replaced	The device's materials must be resistant to wear	Fabric for the brace should be durable and washable so that the device can be used by the user for a long service life

Sustainability	The battery needs to last long enough for the entire physical therapy session	The user should be able to use the device continuously during a session without changing through multiple batteries	The batteries must last for the duration of the physical therapy session	The device’s battery must be able to provide z-hours of functionality including heating the shoulder and alerting the user of over-extended ROM during physical therapy session
Regulatory	The device should be designed within the FDA’s guidelines	All medical devices sold in the U.S. must be approved by the FDA	The device must be designed and documented according to the FDA protocol in order to obtain FDA approval	The device cannot be sold or distributed without FDA approval

Other Categories:

Political: This category was considered while developing the constraints, but it does not seem too relevant to the project because the targeted population is not specific to a political sector/party. The device design would also not be a controversial topic that would lead to any product/manufacturing process political debate/argument.

Constraints References

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D: Engineering Standards

Medical Data Encryption

NIST Advanced Encryption Standard (AES) (Federal Information Processing Standard (FIPS) PUB 197)
https://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.197.pdf

This standard specifies a cryptographic algorithm that can be used to protect confidential electronic data. The algorithm can be applied to both software and hardware components of the device.

- It provides pseudo code and general syntax requirements that should be used to encrypt the collected user data
- This standard is used as a specification to ensure that the data is electronically protected in the device phone application and software database
- It can also be used for testing as a verification activity to see if the device software code outputs the cipher examples and vectors listed in the standard

Electric Components Safety
ANSI/AAMI HA60601-1-11:2015
Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance
https://my.aami.org/aamiresources/previewfiles/HA6060101011_1508_preview.pdf

ANSI/IEC 60529-2004
Degrees of Protection Provided by Enclosures (IP Code for electrical enclosures)
https://www.nema.org/Standards/ComplimentaryDocuments/ANSI-IEC-60529.pdf

These standards will be used to ensure that the electrical components of the device would be safely used outside clinical environments, without harming the user. They specify safe operating and storage conditions that must be met. They will be used as specifications to ensure that the electric components are shielded from moisture and external contaminants. They outline testing requirements, power source specifications, and environmental testing guidelines.

- These standards will be used as specifications to ensure that the electrical components of the device are safe in home environments and protected against moisture and contaminants
- The general testing requirements could also be used to validate safe electric performance of the device

Device Sterilization
ANSI/AAMI ISO 13409-1:2008(R2011)
Aseptic Processing of Health Care Products

https://my.aami.org/aamiresources/previewfiles/1340801_wA_Preview.pdf

This standard outlines the process for building a device aseptically. This is important for the design of the device, as it must be able to be manufactured in a way that does not put users at risk of infection.

- This standard can be used for verification and validation testing protocols to determine if the device design aligns with the standard's sterilization requirements

AAMI TIR17:2008
Compatibility of Materials Subject to Sterilization
https://my.aami.org/aamiresources/previewfiles/TIR170808_preview.pdf

This standard outlines the specific materials to be used when building a sterilizable device. This is essential to the device being designed, as it will be worn by many different individuals.

- This standard will help validate the materials on the device, which can be sterilized between uses

Heating Component Safety
ISO/TS 19218-1:2011
Medical Devices-Hierarchical Coding Structure for Adverse Events
https://www.iso.org/obp/ui/#iso:std:55589:en

This standard outlines an adverse event reporting structure for medical devices that helps to avoid any safety hazards and injuries that can result from device malfunction.

- This standard lists testing requirements that can be used to verify the heating component shut off mechanism (physical and software shut-off switches) once the device temperature exceeds the therapeutic temperature range. This shut off helps to prevent injuries and adverse events that can result from overheating the user's shoulder.

Medical Device Quality Management
ISO 13485: 2016
Medical Devices- Quality Management Systems-Requirements for Regulatory Purposes
https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/iso_13485_medical_devices_2016.pdf

This standard specifies the requirements for a quality management system that allows organizations to show that it can manufacture medical devices that meet customer and regulatory requirements.

- This standard would be needed to market the device and to show that it can operate under safe, working conditions
- It can be used during validation testing to determine if the device meets the requirements to be listed in local and global medical device markets

Medical Device Symbology (User Friendly)
ISO 15223-1: 2016
Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied
https://www.sis.se/api/document/preview/921104

This standard outlines the symbology used in medical devices for safe and effective operation by users who have different language requirements. It can also be useful for healthcare providers who are learning how to navigate through the device. The standard specifies a list of symbols that can be used on the device, its packaging, and documentation associated with it.

- This standard applies to the user-friendly requirement because it specifies the symbols that are allowed on the device and instructions, so that users can utilize it in non-clinical environments
- This standard can also be used for validation testing to see whether or not the symbols on the device and its documents (device instructions manual) correlate with the symbology outlined in the standard

E: Engineering Tools Employed

ANSYS Workbench- Used to model the shoulder skin, fat, and muscle layers as a three slab model in transient thermal analysis. These layers were distinguished by the thermal conductivity, density, and specific heat values found in literature. Multiple simulations were performed using the slab model over the course of 25 minutes (1500 seconds) - the full duration of physical therapy for a variation of surface temperatures between 40-43°C. The temperature profiles and thermal maps were recorded for these simulations to describe the temperature gradient between the three layers.

SolidWorks - Used to develop the final physical design solution. The sketch was rendered using the 3D feature to create surfaces in order to visually display each component. The components include an armband that houses the microcontroller/IMU unit, along with straps and buckles for support. Additionally, there is a wrap for the thermal component that will go under the arms and around the shoulder for therapeutic heating. Lastly, the battery pack will be housed in a holder in the back of the device to ensure that it does not inhibit the user's ROM during exercise.

F: Life-long Learning

Essay 1, Written by Shruthi:

During the ACS Assist senior project, I learned the significance of the design control process (21 CFR 820) which helped me further strengthen my engineering and technical skills with regards to medical device design. Although I didn't understand the importance of defining design requirements and specifications in the beginning of the project, now I realize that it was critical to follow that methodology to ensure that the device can be designed in an efficacious manner. This process helped me recognize the device need and functionalities prior to formulating different design ideas.

In terms of engineering skills, I gained more knowledge using ANSYS Workbench, MATLAB/Simulink, and Arduino for thermal analysis modeling and heating control system implementation. In order to verify that the device temperature can be approximated as the therapeutic temperature for the shoulder, I had to model the shoulder as a 3 layer composite slab and use transient modeling in ANSYS. During this process, I understood the step-by-step method to run finite element models which involved geometry creation, mesh generation, and boundary/initial condition application for transient analysis.

Furthermore, I also gained a better understanding of Simulink in MATLAB when I tried to plot the uncontrolled and PI controlled responses of the system. Before the senior project, I was familiar with MATLAB as a mathematical software; however, I did not know about the SIMULINK tools which really helped me visualize how quickly the heating system can reach the desired temperature.

Lastly, I also became familiar coding in Arduino since I had to implement the control system using coding software. In this platform, I had to understand how to incorporate the analog temperature sensors (thermistors) and read the temperature value at a given time. Furthermore, I had to learn how to read the external battery voltage and supply it to the microcontroller without exceeding the operating voltage limits. I found it logical to learn these components individually, and then group them together for the PI controller loop so that I understand how one part of the code affects the other when it's changed.

Overall, I was really looking forward to completing this project at the end of the semester. Unfortunately, the team and I were unable to achieve that. But, I found this senior project experience to be truly valuable because it not only showed me how to apply my engineering/technical skills, but it also helped me gain leadership skills through my team leader position. Like with any team, we also had obstacles to overcome in order to function efficiently. Ultimately, we were able to put aside our differences as we worked together to finish this project as much as possible.

Essay 2, Written by Ryan:

The ACS Assist senior project gave me tremendous insight into the importance and life of an engineer. The designing of the device refined many technical skills. Additionally, the design process and instruction on the FDA design control framework will be incredibly valuable to my career. Finally, I learned more about working as a team for an extended period of time and the management that goes into that.

In terms of technical skills, I refined my use of solidworks. Additionally, I gained a greater understanding of what these CAD engineering drawings are used for. Moving forward, I learned basic methods of ANSYS modeling, especially in terms of thermal modeling. I also expanded my knowledge of MATLAB, learning just how expandable its applications are and its value to so many parts of any engineering problem.

I also learned how to identify medical needs in terms of an impacted population and understanding the problems they specifically face as a result. This project taught me how to think of novel ways to solve people's medical problems, thinking about the user and their safety first. This ties into learning about the FDA's design control framework for developing new medical devices.

As with any team, it is important to understand one's strengths and weaknesses. Even more important, though, is to understand how to deal with varying personalities. I think it is important to put in thought and effort to understand each individual on a team, so that everyone is able to contribute to their fullest. Moving forward, this will be extremely important in my medical career, as nearly everything is accomplished as a team. I am certain that this project will have a lasting effect on my future as a physician, as I am confident I will be able to identify and respond to the needs of a community in novel ways.

Essay 3, Written by Geoff

Working on the ACS Assist Device senior project was a great opportunity that I will never forget and helped me realize what many engineers experience everyday in industry. Over the course of the project I learned many new skills such as acclimating to a new work environment and fabrication of a surrogate device. Although one of the most important I learned is the knowledge of how imperative the user's safety is to the process of medical device design.

Until June of 2019 I was a part of an entirely different senior project group. Although a good deal of work had already been completed, and we were ready to start designing the next semester, unforeseen problems caused the group to be disbanded and redistributed among other groups. This sudden change taught me to acclimate to a different work environment to meet new expectations and requirements. Similar to engineers in industry it is not possible to work with your best friends on every project, and that a project you believe in will not always be able to be created. This experience will benefit me once I enter the workforce.

Another skill I learned is how to fabricate a model. I oversaw the manufacturing of a surrogate arm that would be used to verify several aspects of the ACS Assist Device. Firstly, I began designing a way to model the human shoulder as effectively and cheaply as possible. Once design and purchasing were completed, I had a great deal of enjoyment constructing the actual model. Seeing the model slowly come to life from the design process to a physical, working model was very fulfilling. This skill was something I could not wait to use to construct the ACS Assist Device and will hopefully use more once I enter industry.

The most important knowledge I learned was how crucial the safety of the users is and how engineers must build around it. I learned this while writing the study we planned on conducting to be approved by the International Review Board. The ACS Assist device had to meet several ISO and ANSI standards before its primary functions could be validated in a safe, controlled study. Engineers in industry today must confirm that their products are safe for consumers to use and their safety must be a guiding factor when designing any medical device. This emphasis on user safety will be carried with me throughout my career as an engineer.

Essay 4, Written by Daniel:

This senior project enabled me to learn how to work with others to create a device that required a lot of thought, effort, and teamwork. I acquired skills regarding microcontrollers, software development, and the medical device creation and development process. Each task that I encountered involved a significant investment in time to build up my knowledge set sufficiently such that I could complete what is required of me.

The first major knowledge area that I gained helped me complete this project was learning how to develop an Android application. This included learning about Android Studio, the Java programming language, and understanding concepts such as fragments and activities. I was also able to learn about Material Design Guidelines and development techniques that streamline the process and help in creating an application that works fluidly and that is easy to use.

The second major gain in knowledge involved learning about microcontrollers and the benefits that each model available on the market brings. I was able to learn about Arduino and how to program that microcontroller in the C language, as well as how to utilize its components such as Bluetooth and sensors. I also learned a lot about Inertial Measurement Units, and the different kinds that exist and the benefits of each. I learned how to interact with a component such as this that is included on the Arduino, as well as how to convert those sensor readings into data that is meaningful to the user.

The third major knowledge area involved learning about the Bluetooth specification, and how to use Bluetooth to communicate between the previously coded Android application and the programmed Arduino Nano microcontroller. I learned about Generic Attribute Profiles, and how they are defined in the Bluetooth specification. I was able to figure out how to create and implement my own profiles and services so that I could create a system that has quick and cohesive communication between devices.

In addition to these three major gains I was able to learn many smaller things, such as how to use a cloud database service, enable the monitoring and control over a heating element, and implement external sensors and components to work with an Arduino. I was also able to learn smaller but equally important tasks, such as communicating with advisors and obtaining user input. I even learned how to make and manage a website using WordPress. I am thankful for this project, as I would most likely have never learned how to do any of these things.

Essay 5, Written by Javier:

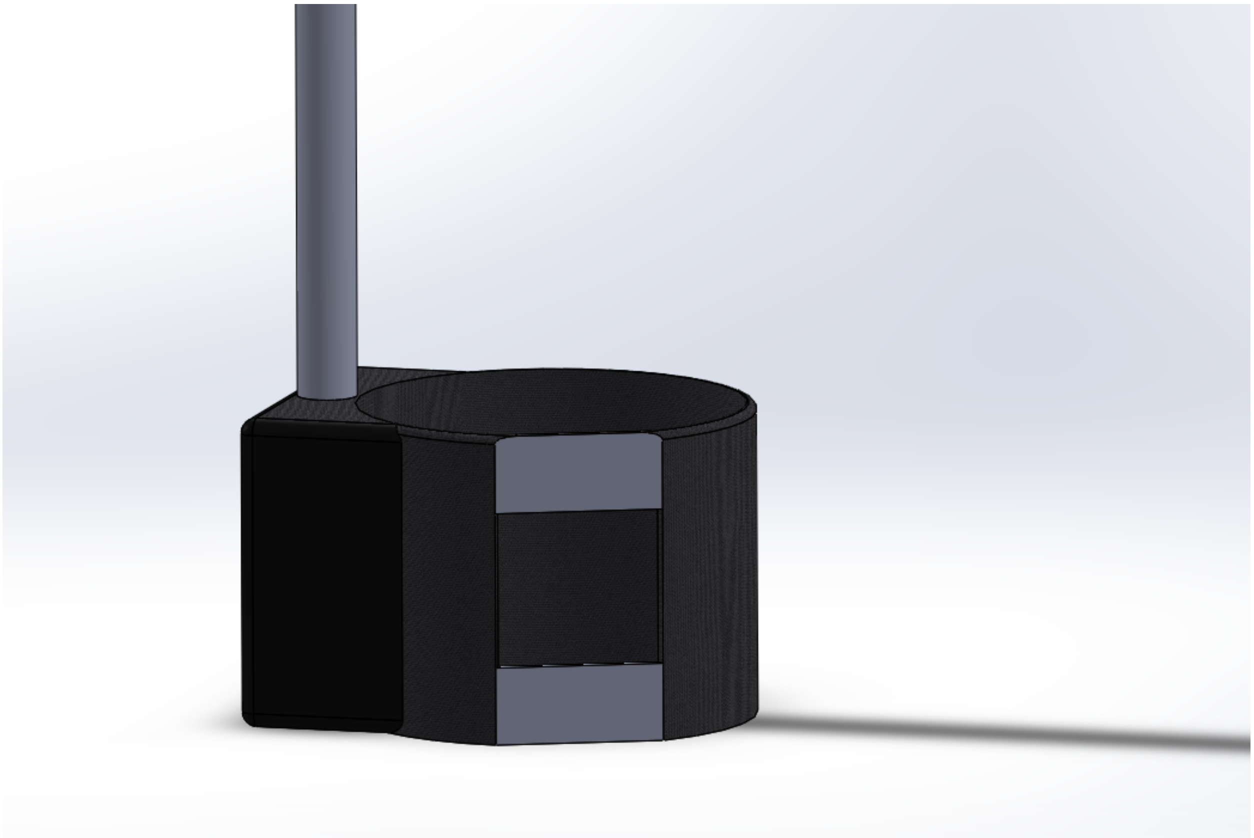
After working through the Senior Project Program, I can say with certainty that it provided one of the highlights of my undergraduate education. Over the course of these two semesters, I learned many valuable lessons in teamwork, responsibility, and engineering. Needless to say this project came with new and unexpected challenges, as it was primarily a BME project. Being part of the ECE department, I was unaware of the rigorous steps taken in BME to secure the ability to even begin building a biomedical device. I will always remember the intense security and planning that was put in up front, as I believe this brings an insurmountable amount of value to any project.

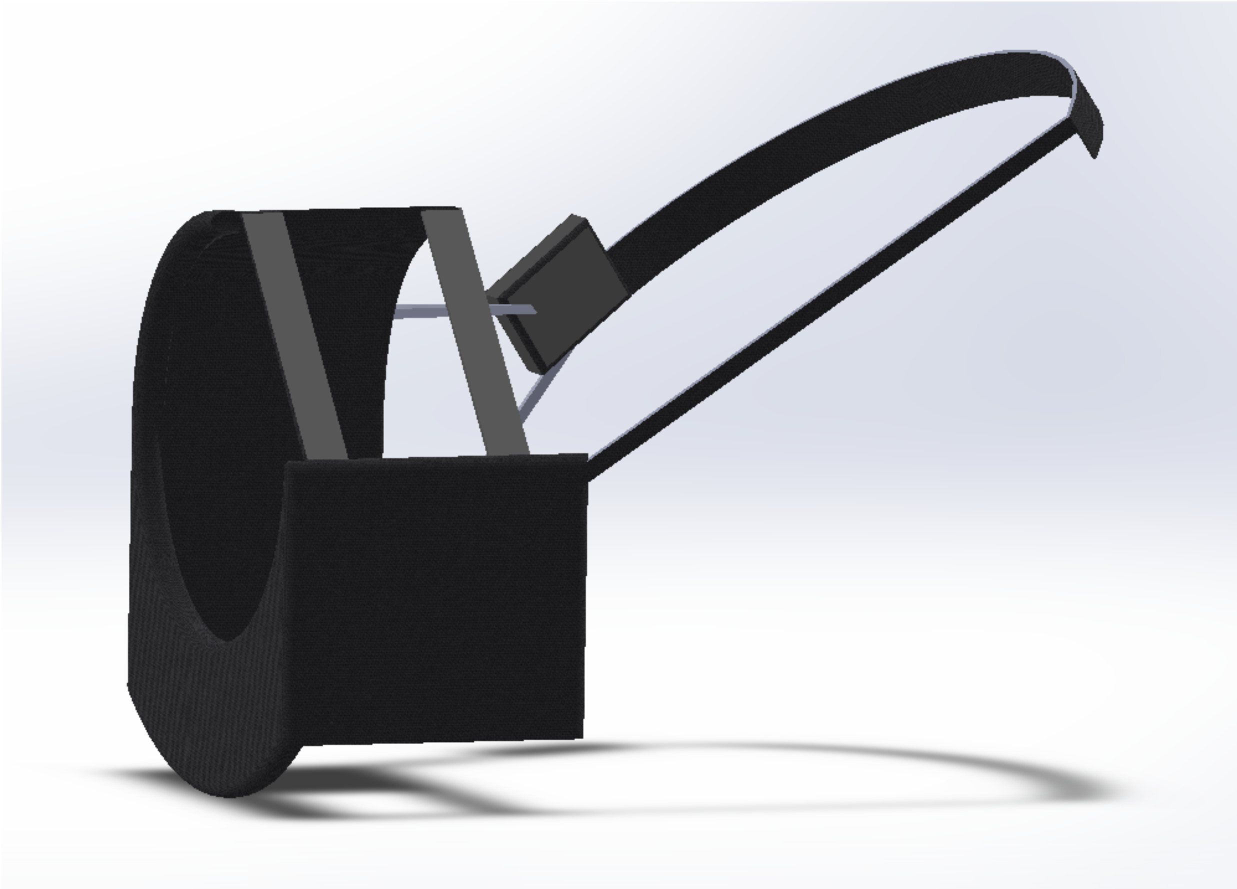
During the course of this device, our team faced many different tasks and challenges. I personally was tasked with learning a software that I was not familiar with, along with bringing elements of my engineering practices into each element I worked on. One of the most memorable challenges was bringing the database connection to the app. This experience was specifically memorable because it was a situation where teamwork proved best. By working on this with another member of our team, we were able to bounce ideas and comments off each other in a productive way. This led to a solution being found quickly and efficiently with a greater understanding.

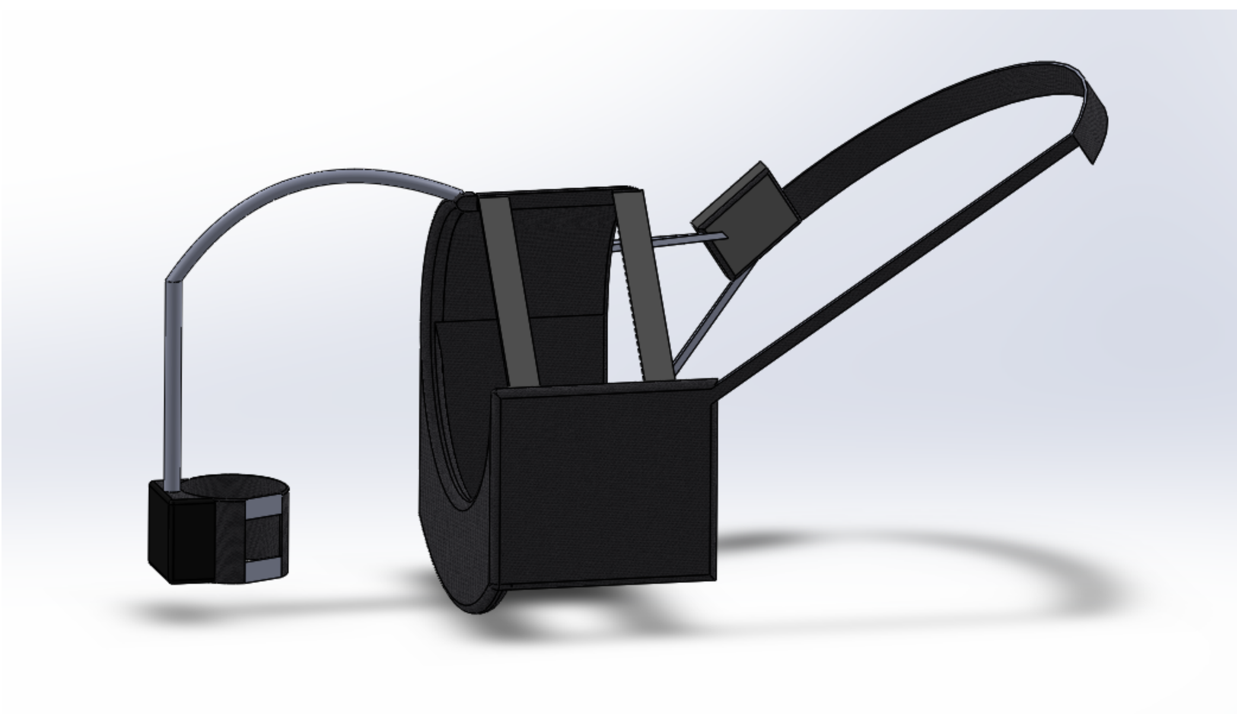
One of the big takeaways from this project for me was that it is important to prioritize properly. By understanding what elements are most important and fundamental to the design, a set of priorities can be made that will best suit the project. By understanding which components are most essential, the project can move along quickly in a manner that complements other areas of design. I am grateful to have worked with this team that has taught me valuable lessons in teamwork and project management. From this experience, I feel more confident in moving into a future career, having these valuable lessons under my belt.

G: 3D Drawings

The following are the CAD drawings of the prototype device.







H: Computer/Modeling/Microcontroller Codes

The following blocks outline the code that was written to form the Android application thus far. Further development of this code will be performed in order to integrate the application with the bluetooth capabilities of the microcontroller, as well as to further evolve the main views that are relevant to the application and that were discussed previously in this report.

MainActivity.java

```java
package com.seniorproject.acsAssistApp;

import android.content.SharedPreferences;
import android.os.Bundle;
import android.view.MenuItem;

import androidx.appcompat.app.ActionBarDrawerToggle;
import androidx.appcompat.app.AppCompatActivity;
import androidx.appcompat.app.AppCompatDelegate;
import androidx.appcompat.widget.Toolbar;
import androidx.core.view.GravityCompat;
import androidx.drawerlayout.widget.DrawerLayout;
import androidx.preference.PreferenceManager;

import com.google.android.material.navigation.NavigationView;

public class MainActivity extends AppCompatActivity implements
NavigationView.OnNavigationItemSelectedListener {
   private DrawerLayout drawer;

   @Override
   protected void onCreate(Bundle savedInstanceState) {
       super.onCreate(savedInstanceState);

       SharedPreferences sharedPreferences =
PreferenceManager.getDefaultSharedPreferences(MainActivity.this);
       boolean darkToggle = sharedPreferences.getBoolean("dark_toggle", false);
// Utilize the toggle from the settings page to handle themeing
       if (darkToggle) {
           AppCompatDelegate.setDefaultNightMode(AppCompatDelegate.MODE_NIGHT_YES);
// Enable android night mode when toggle set
       }
```

```
        else {
            AppCompatDelegate.setDefaultNightMode(AppCompatDelegate.MODE_NIGHT_NO);
        }
        setContentView(R.layout.activity_main);
// The content view is based on activity_main.xml
        Toolbar toolbar = findViewById(R.id.toolbar);
        setSupportActionBar(toolbar);

        drawer = findViewById(R.id.drawer);
// Finding the drawer (defined in activity_main.xml)
        NavigationView navigationView = findViewById(R.id.nav_view);
// Finding the navigation view (defined in activity_main.xml)
        navigationView.setNavigationItemSelectedListener(this);
// Setting a listener for the navigation view
        ActionBarDrawerToggle toggle = new ActionBarDrawerToggle(this, drawer,
toolbar, R.string.open, R.string.close);         // Setting the toggle & adding a
listener
        drawer.addDrawerListener(toggle);
        toggle.syncState();
// Sync the hamburger icon with the drawer status
        setTitle("Home");
// Manually set the title to "Home" bc of dark theme toggle bug

        if (savedInstanceState == null) {
// Upon initial setup, home page should be shown

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                   new Home()).commit();
            navigationView.setCheckedItem(R.id.home);
            setTitle("Home");
        }
    }

    @Override
    public boolean onNavigationItemSelected(MenuItem item) {
        switch (item.getItemId()) {
// Create a new fragment for each menu item selected
            case R.id.home: {

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                       new Home()).commit();
                setTitle("Home");
                break;
```

```
            }

            case R.id.beginExercise: {

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                        new BeginExercise()).commit();
                setTitle("Exercise");
                break;
            }

            case R.id.viewHistory: {

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                        new ViewHistory()).commit();
                setTitle("View History");
                break;
            }

            case R.id.chat: {

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                        new Chat()).commit();
                setTitle("Chat");
                break;
            }

            case R.id.settings: {

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                        new Settings()).commit();
                setTitle("Settings");
                break;
            }

            default:

getSupportFragmentManager().beginTransaction().replace(R.id.fragment_container,
                        new Home()).commit();
                setTitle("Home");
                break;
        }
        drawer.closeDrawer(GravityCompat.START);
        return true;
```

```
    }

    @Override
    public void onBackPressed() {
// Close the drawer if the back icon is pressed
        if (drawer.isDrawerOpen(GravityCompat.START)) {
            drawer.closeDrawer(GravityCompat.START);
        } else {
            super.onBackPressed();
        }
    }
}
```

activity_main.xml

```
<?xml version="1.0" encoding="utf-8"?>
<androidx.drawerlayout.widget.DrawerLayout
    xmlns:android="http://schemas.android.com/apk/res/android"
    xmlns:app="http://schemas.android.com/apk/res-auto"
    xmlns:tools="http://schemas.android.com/tools"
    android:id="@+id/drawer"
    android:layout_width="match_parent"
    android:layout_height="match_parent"
    android:fitsSystemWindows="true"
    tools:context="com.seniorproject.acsAssistApp.MainActivity"
    tools:openDrawer="start">

    <LinearLayout
        android:orientation="vertical"
        android:layout_width="match_parent"
        android:layout_height="match_parent">

        <androidx.appcompat.widget.Toolbar
            android:id="@+id/toolbar"
            android:layout_width="match_parent"
            android:layout_height="?attr/actionBarSize"
            android:background="@color/colorPrimary"
            android:theme="@style/ThemeOverlay.AppCompat.Dark.ActionBar"
            app:popupTheme="@style/ThemeOverlay.AppCompat.Light"
            />

        <FrameLayout
            android:id="@+id/fragment_container"
```

```
            android:layout_width="match_parent"
            android:layout_height="match_parent" />

    </LinearLayout>

    <com.google.android.material.navigation.NavigationView
        android:id="@+id/nav_view"
        android:layout_width="wrap_content"
        android:layout_height="match_parent"
        android:layout_gravity="start"
        app:headerLayout="@layout/header"
        app:menu="@menu/drawermenu" />

</androidx.drawerlayout.widget.DrawerLayout>
```

header.xml

```
<?xml version="1.0" encoding="utf-8"?>
<LinearLayout xmlns:android="http://schemas.android.com/apk/res/android"
    android:layout_width="match_parent"
    android:layout_height="176dp"
    android:background="@color/darkGray"
    android:padding="16dp"
    android:gravity="bottom"
    android:orientation="vertical"
    android:theme="@style/ThemeOverlay.AppCompat.Dark">

    <!-- Creating the profile picture placeholder -->
    <ImageView
        android:layout_width="75dp"
        android:layout_height="75dp"
        android:layout_marginTop="15dp"
        android:src="@drawable/ic_account_circle_white_24dp" />

    <!-- Creating the user name placeholder -->
    <TextView
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginTop="8dp"
        android:text="Test User"
        android:textColor="@color/white"
        android:textStyle="bold" />

    <!-- Creating the user email placeholder -->
    <TextView
        android:layout_width="wrap_content"
        android:layout_height="match_parent"
        android:text="testUser@test.com"
        android:textColor="@color/white"
         />

</LinearLayout>
```

drawermenu.xml

```
<?xml version="1.0" encoding="utf-8"?>

<!--  To Do: Change menu items to appropriate items based on user feedback -->
<menu xmlns:android="http://schemas.android.com/apk/res/android"
android:id="@+id/drawerList">
   <group
       android:checkableBehavior="single">
       <item android:id="@+id/home" android:title="Home"
android:icon="@drawable/ic_home_black_24dp" android:checked="true"/>
       <item android:id="@+id/beginExercise" android:title="Begin Exercise"
android:icon="@drawable/ic_fitness_center_black_24dp"/>
       <item android:id="@+id/viewHistory" android:title="View History"
android:icon="@drawable/ic_history_black_24dp"/>
       <item android:id="@+id/chat" android:title="Chat"
android:icon="@drawable/ic_chat_black_24dp"/>
       <item android:id="@+id/settings" android:title="Settings"
android:icon="@drawable/ic_settings_black_24dp"/>
   </group>

</menu>
```

Home.java

```
package com.seniorproject.acsAssistApp;

import android.os.Bundle;
import android.view.LayoutInflater;
import android.view.View;
import android.view.ViewGroup;
import android.widget.Toast;

import androidx.fragment.app.Fragment;

public class Home extends Fragment {
    @Override
    public void onCreate(Bundle savedInstanceState) {
        Toast toast = Toast.makeText(getActivity(),
                "Home page coming soon!",
                Toast.LENGTH_LONG);
        toast.show();
        super.onCreate(savedInstanceState);
    }

    @Override
    public View onCreateView(LayoutInflater inflater, ViewGroup container,
                             Bundle savedInstanceState) {
        // Inflate the layout for this fragment
        return inflater.inflate(R.layout.fragment_home, container, false);
    }

}
```

fragment_home.xml

```
<?xml version="1.0" encoding="utf-8"?>
<FrameLayout xmlns:android="http://schemas.android.com/apk/res/android"
    xmlns:tools="http://schemas.android.com/tools"
    android:layout_width="match_parent"
    android:layout_height="match_parent"
```

```
    tools:context=".Home">

    <!-- TODO: Update blank fragment layout -->
    <TextView
        android:layout_width="match_parent"
        android:layout_height="match_parent"
        android:text=""
        android:textAlignment="center" />

</FrameLayout>
```

BeginExercise.java

```
package com.seniorproject.acsAssistApp;


//acsAssist MAC:          E5:A5:53:32:BD:7C
//angle service:          00001826-0000-1000-8000-00805f9b34fb
//roll characteristic:    78c5307b-6715-4040-bd50-d64db33e2e9e
//pitch characteristic:   78c5307a-6715-4040-bd50-d64db33e2e9e


import android.Manifest;
import android.bluetooth.BluetoothAdapter;
import android.bluetooth.BluetoothDevice;
import android.bluetooth.BluetoothGatt;
import android.bluetooth.BluetoothGattCallback;
import android.bluetooth.BluetoothGattCharacteristic;
import android.bluetooth.BluetoothGattDescriptor;
import android.bluetooth.BluetoothProfile;
import android.content.Intent;
import android.os.Build;
import android.os.Bundle;
import android.os.CountDownTimer;
import android.util.Log;
import android.view.LayoutInflater;
import android.view.View;
import android.view.ViewGroup;
import android.widget.Button;
import android.widget.RadioButton;
import android.widget.RadioGroup;
import android.widget.TextView;
import android.widget.Toast;


import androidx.annotation.Nullable;
import androidx.core.content.ContextCompat;
import androidx.fragment.app.Fragment;
```

```
import com.google.firebase.firestore.FirebaseFirestore;

import java.text.SimpleDateFormat;
import java.util.ArrayList;
import java.util.Date;
import java.util.HashMap;
import java.util.List;
import java.util.Map;
import java.util.UUID;

public class BeginExercise extends Fragment {
   BluetoothAdapter bluetoothAdapter = BluetoothAdapter.getDefaultAdapter();
   BluetoothDevice arduino = bluetoothAdapter.getRemoteDevice("E5:A5:53:32:BD:7C");
   Boolean showMeasurements = false;



   @Nullable
   @Override
   public View onCreateView(final LayoutInflater inflater, ViewGroup container,
Bundle savedInstanceState) {
       final View currentView = inflater.inflate(R.layout.fragment_begin_exercise,
container, false);
       final TextView instructionText =
currentView.findViewById(R.id.instructionText);
       final RadioGroup exerciseButtons =
currentView.findViewById(R.id.exerciseButtons);
       final Button emergencyButton =
currentView.findViewById(R.id.emergencyButton);
       Button beginExercise = currentView.findViewById(R.id.beginExercise);
       emergencyButton.setVisibility(View.INVISIBLE);
       currentView.findViewById(R.id.rollLabel).setVisibility(View.INVISIBLE);
       currentView.findViewById(R.id.pitchLabel).setVisibility(View.INVISIBLE);
       currentView.findViewById(R.id.yawLabel).setVisibility(View.INVISIBLE);
       currentView.findViewById(R.id.tempLabel).setVisibility(View.INVISIBLE);

       Map<String, Object> angleData = new HashMap<>();

//
//
//         db.collection("Patient Data").document("testUser").set(angleData);
//         Log.i("DATABASE", String.valueOf(db));
```

```
        if (bluetoothAdapter == null) {                          // Bluetooth not
supported
            Toast.makeText(getActivity(), "This device does not support Bluetooth!
Use a Bluetooth enabled device.", Toast.LENGTH_LONG).show();
        }

        if (!bluetoothAdapter.isEnabled()) {                     // If adapter is not
enabled, request to enable it from within the app
            Intent enableBtIntent = new
Intent(BluetoothAdapter.ACTION_REQUEST_ENABLE);
            startActivityForResult(enableBtIntent, 1);
        }

        if (bluetoothAdapter.isDiscovering()) {
            bluetoothAdapter.cancelDiscovery();
        }

        if(Build.VERSION.SDK_INT > Build.VERSION_CODES.LOLLIPOP) {
            int permissionCheck = ContextCompat.checkSelfPermission(getActivity(),
Manifest.permission.ACCESS_FINE_LOCATION);
            permissionCheck += ContextCompat.checkSelfPermission(getActivity(),
Manifest.permission.ACCESS_COARSE_LOCATION);
            if (permissionCheck != 0) {
                this.requestPermissions(new
String[]{Manifest.permission.ACCESS_FINE_LOCATION,
Manifest.permission.ACCESS_COARSE_LOCATION}, 1001); //Any number
            }
        }

        arduino.connectGatt(this.getActivity(), true, gattCallback);

        beginExercise.setOnClickListener(new View.OnClickListener(){
            @Override
            public void onClick(View v) {
                int selectedExerciseID = exerciseButtons.getCheckedRadioButtonId();
                RadioButton selectedExercise =
currentView.findViewById(selectedExerciseID);
                Log.i("DESCRIPTOR", String.valueOf(selectedExercise));


currentView.findViewById(R.id.exerciseButtons).setVisibility(View.INVISIBLE);

currentView.findViewById(R.id.beginExercise).setVisibility(View.INVISIBLE);
```

```java
currentView.findViewById(R.id.emergencyButton).setVisibility(View.VISIBLE);

currentView.findViewById(R.id.emergencyButton).setBackgroundColor(0xFFFF0000);


                final CountDownTimer cTimer = new CountDownTimer(3000, 1000) {
                    @Override
                    public void onTick(long l) {
                        instructionText.setText("Now Heating \n" + new
SimpleDateFormat("mm:ss").format(new Date(l)));

currentView.findViewById(R.id.yawLabel).setVisibility(View.VISIBLE);
                    }

                    @Override
                    public void onFinish() {
                        showMeasurements = true;
                        instructionText.setText("Begin exercise motion!");

currentView.findViewById(R.id.emergencyButton).setVisibility(View.INVISIBLE);

currentView.findViewById(R.id.rollLabel).setVisibility(View.VISIBLE);

currentView.findViewById(R.id.pitchLabel).setVisibility(View.VISIBLE);

currentView.findViewById(R.id.yawLabel).setVisibility(View.VISIBLE);

currentView.findViewById(R.id.tempLabel).setVisibility(View.VISIBLE);
                    }
                };
                cTimer.start();

                currentView.findViewById(R.id.emergencyButton).setOnClickListener(new
View.OnClickListener() {
                    public void onClick (View v) {
                        instructionText.setText("Exercise Canceled");

currentView.findViewById(R.id.emergencyButton).setVisibility(View.INVISIBLE);
                        cTimer.cancel();
                    }
                });
            }
```

```
        });

        return currentView;
    }

    private final BluetoothGattCallback gattCallback = new BluetoothGattCallback() {
        List<BluetoothGattCharacteristic> chars = new ArrayList<>();
        UUID pitchUUID = UUID.fromString("78c5307a-6715-4040-bd50-d64db33e2e9e");
        UUID rollUUID = UUID.fromString("78c5307b-6715-4040-bd50-d64db33e2e9e");
        UUID yawUUID = UUID.fromString("78c5307c-6715-4040-bd50-d64db33e2e9e");
        UUID temperature = UUID.fromString("78c5307d-6715-4040-bd50-d64db33e2e9e");

        @Override
        public void onConnectionStateChange(BluetoothGatt gatt, int status, int
newState) {
            final TextView instructionText =
getView().findViewById(R.id.instructionText);
            switch (newState) {
                case BluetoothProfile.STATE_CONNECTED:
                    instructionText.setText("Connected. Select Exercise");
                    gatt.discoverServices();
                    break;

                case BluetoothProfile.STATE_DISCONNECTED:

getView().findViewById(R.id.rollLabel).setVisibility(View.INVISIBLE);

getView().findViewById(R.id.pitchLabel).setVisibility(View.INVISIBLE);

getView().findViewById(R.id.yawLabel).setVisibility(View.INVISIBLE);
                    instructionText.setText("acsAssist Disconnected ");
                    break;

                case BluetoothProfile.STATE_CONNECTING:
                    instructionText.setText("Connecting to acsAssist...");
                    break;

                default:
                    instructionText.setText("acsAssist Disconnected");
            }
        }

        @Override
```

```
        public void onServicesDiscovered(BluetoothGatt gatt, int status) {
            if (status == BluetoothGatt.GATT_SUCCESS) {
                for (BluetoothGattCharacteristic characteristic:
gatt.getService(UUID.fromString("00001826-0000-1000-8000-00805f9b34fb")).getCharacte
ristics()) {
                    chars.add(characteristic);
                }
                subscribeToCharacteristics(gatt);
            }
        }

        private void subscribeToCharacteristics(BluetoothGatt gatt) {
            if(chars.size() == 0) return;
            BluetoothGattCharacteristic characteristic = chars.get(0);
            gatt.setCharacteristicNotification(characteristic, true);
            BluetoothGattDescriptor descriptor =
characteristic.getDescriptor(UUID.fromString("00002902-0000-1000-8000-00805f9b34fb")
);
            if(descriptor != null) {

descriptor.setValue(BluetoothGattDescriptor.ENABLE_NOTIFICATION_VALUE);
                gatt.writeDescriptor(descriptor);
            }
        }

        @Override
        public void onDescriptorWrite(BluetoothGatt gatt, BluetoothGattDescriptor
descriptor, int status) {
            Log.i("DESCRIPTOR", "WROTE DESCRIPTOR FOR CHARACTERISTIC");
            super.onDescriptorWrite(gatt, descriptor, status);
            chars.remove(0);
            subscribeToCharacteristics(gatt);
        }

        @Override
        public void onCharacteristicChanged(BluetoothGatt gatt,
BluetoothGattCharacteristic characteristic) {
            super.onCharacteristicChanged(gatt, characteristic);
            FirebaseFirestore db = FirebaseFirestore.getInstance();
            TextView pitchText = getView().findViewById(R.id.pitchLabel);
            TextView rollText = getView().findViewById(R.id.rollLabel);
            TextView yawText = getView().findViewById(R.id.yawLabel);
            TextView temp = getView().findViewById(R.id.tempLabel);
```

```
            if(showMeasurements) {
                if(characteristic.getUuid().equals(pitchUUID)) {
                    pitchText.setText("Pitch\n" + characteristic.getStringValue(0));
                    Map<String, Object> angleData = new HashMap<>();
                    angleData.put("pitch", characteristic.getStringValue(0));
                    db.collection("Patient
Data").document("testUser").set(angleData);
                }
                if(characteristic.getUuid().equals(rollUUID)) {
                    rollText.setText("Roll\n" + characteristic.getStringValue(0));
                    Map<String, Object> angleData = new HashMap<>();
                    angleData.put("roll", characteristic.getStringValue(0));
                    db.collection("Patient
Data").document("testUser").set(angleData);
                }
                if(characteristic.getUuid().equals(yawUUID)) {
                    yawText.setText("Yaw\n" + characteristic.getStringValue(0));
                    Map<String, Object> angleData = new HashMap<>();
                    angleData.put("yaw", characteristic.getStringValue(0));
                    db.collection("Patient
Data").document("testUser").set(angleData);
                }
                if(characteristic.getUuid().equals(temperature)) {
                    temp.setText("Temperature\n" + characteristic.getStringValue(0));
                    Map<String, Object> tempData = new HashMap<>();
                    tempData.put("temp", characteristic.getStringValue(0));
                    db.collection("Patient Data").document("testUser").set(tempData);
                }
            }
        }
    };
}
```

fragment_begin_exercise.xml

```
<?xml version="1.0" encoding="utf-8"?>
<FrameLayout xmlns:android="http://schemas.android.com/apk/res/android"
   xmlns:app="http://schemas.android.com/apk/res-auto"
   xmlns:tools="http://schemas.android.com/tools"
   android:layout_width="match_parent"
   android:layout_height="match_parent"
   tools:context=".BeginExercise">
```

```xml
<androidx.constraintlayout.widget.ConstraintLayout
    android:id="@+id/relativeLayout"
    android:layout_width="match_parent"
    android:layout_height="match_parent">

    <TextView
        android:id="@+id/instructionText"
        android:layout_width="match_parent"
        android:layout_height="wrap_content"
        android:paddingTop="55dp"
        android:text="Connecting to acsAssist..."
        android:textAlignment="center"
        android:textSize="20sp"
        app:layout_constraintEnd_toEndOf="parent"
        app:layout_constraintStart_toStartOf="parent"
        app:layout_constraintTop_toTopOf="parent" />

    <TextView
        android:id="@+id/rollLabel"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginTop="60dp"
        android:paddingTop="55dp"
        android:text="Roll\n-"
        android:textAlignment="center"
        android:textSize="20sp"
        app:layout_constraintEnd_toStartOf="@+id/pitchLabel"
        app:layout_constraintStart_toStartOf="parent"
        app:layout_constraintTop_toTopOf="parent" />

    <TextView
        android:id="@+id/pitchLabel"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginStart="180dp"
        android:layout_marginTop="60dp"
        android:paddingTop="55dp"
        android:text="Pitch\n-"
        android:textAlignment="center"
        android:textSize="20sp"
        app:layout_constraintStart_toStartOf="parent"
        app:layout_constraintTop_toTopOf="@+id/instructionText" />
```

```
    <TextView
        android:id="@+id/yawLabel"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginTop="60dp"
        android:paddingTop="55dp"
        android:text="Yaw\n-"
        android:textAlignment="center"
        android:textSize="20sp"
        app:layout_constraintEnd_toEndOf="parent"
        app:layout_constraintStart_toEndOf="@+id/pitchLabel"
        app:layout_constraintTop_toTopOf="parent" />

    <TextView
        android:id="@+id/tempLabel"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginTop="-20dp"
        android:paddingTop="55dp"
        android:text="Temperature\n-"
        android:textAlignment="center"
        android:textSize="20sp"
        app:layout_constraintBottom_toTopOf="@+id/beginExercise"
        app:layout_constraintEnd_toEndOf="parent"
        app:layout_constraintStart_toStartOf="parent"
        app:layout_constraintTop_toBottomOf="@+id/exerciseButtons" />

    <RadioGroup
        android:id="@+id/exerciseButtons"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:layout_marginBottom="200dp"
        app:layout_constraintBottom_toBottomOf="parent"
        app:layout_constraintEnd_toEndOf="parent"
        app:layout_constraintStart_toStartOf="parent"
        app:layout_constraintTop_toBottomOf="@+id/instructionText">

        <RadioButton
            android:id="@+id/exercise_1"
            android:layout_width="match_parent"
            android:layout_height="50dp"
            android:checked="true"
            android:text="Exercise 1"
```

```xml
            android:textSize="18sp"
            app:layout_constraintEnd_toEndOf="parent"
            app:layout_constraintStart_toStartOf="parent"
            app:layout_constraintTop_toTopOf="parent" />

        <RadioButton
            android:id="@+id/exercise_3"
            android:layout_width="wrap_content"
            android:layout_height="50dp"
            android:text="Exercise 3"
            android:textSize="18sp"
            app:layout_constraintEnd_toEndOf="parent"
            app:layout_constraintStart_toStartOf="parent"
            app:layout_constraintTop_toTopOf="parent" />

        <RadioButton
            android:id="@+id/exercise_2"
            android:layout_width="wrap_content"
            android:layout_height="50dp"
            android:text="Exercise 2"
            android:textSize="18sp"
            app:layout_constraintEnd_toEndOf="parent"
            app:layout_constraintStart_toStartOf="parent"
            app:layout_constraintTop_toTopOf="parent" />

    </RadioGroup>


    <Button
        android:id="@+id/beginExercise"
        android:layout_width="wrap_content"
        android:layout_height="wrap_content"
        android:text="BEGIN EXERCISE"
        android:textAlignment="center"
        app:layout_constraintBottom_toBottomOf="parent"
        app:layout_constraintEnd_toEndOf="@+id/instructionText"
        app:layout_constraintHorizontal_bias="0.53"
        app:layout_constraintStart_toStartOf="@+id/instructionText"
        app:layout_constraintTop_toBottomOf="@+id/exerciseButtons"
        app:layout_constraintVertical_bias="0.445" />

    <Button
        android:id="@+id/emergencyButton"
```

```xml
            android:layout_width="wrap_content"
            android:layout_height="wrap_content"
            android:text="STOP"
            android:textAlignment="center"
            app:layout_constraintBottom_toBottomOf="parent"
            app:layout_constraintEnd_toEndOf="@+id/instructionText"
            app:layout_constraintHorizontal_bias="0.501"
            app:layout_constraintStart_toStartOf="@+id/instructionText"
            app:layout_constraintTop_toBottomOf="@+id/beginExercise" />
    </androidx.constraintlayout.widget.ConstraintLayout>



</FrameLayout>
```

ViewHistory.java

```java
package com.seniorproject.acsAssistApp;

import android.os.Bundle;
import android.view.LayoutInflater;
import android.view.View;
import android.view.ViewGroup;

import androidx.fragment.app.Fragment;

public class ViewHistory extends Fragment {

    @Override
    public View onCreateView(LayoutInflater inflater, ViewGroup container,
                             Bundle savedInstanceState) {
        // Inflate the layout for this fragment
        return inflater.inflate(R.layout.fragment_view_history, container, false);
    }

}
```

fragment_view_history.xml

```xml
<?xml version="1.0" encoding="utf-8"?>
<TableLayout xmlns:android="http://schemas.android.com/apk/res/android"
    android:layout_width="match_parent"
    android:layout_height="match_parent"
    android:stretchColumns="1">
    <TableRow>


        <TextView
            android:layout_width="150dp"
            android:padding="3dip"
            android:text="3/15/20"
            android:textAlignment="center"
```

```
            android:textSize="24sp" />

        <TextView
            android:layout_width="33dp"
            android:gravity="right"
            android:padding="3dip"
            android:text="Exercise 2"
            android:textAlignment="center"
            android:textSize="24sp" />

    </TableRow>

    <TableRow>

        <TextView
            android:id="@+id/textView3"
            android:layout_width="192dp"
            android:layout_height="wrap_content"
            android:padding="3dip"
            android:text="3/20/20"
            android:textAlignment="center"
            android:textSize="24sp" />

        <TextView
            android:id="@+id/textView6"
            android:layout_width="wrap_content"
            android:layout_height="wrap_content"
            android:gravity="right"
            android:padding="3dip"
            android:text="Exercise 1"
            android:textAlignment="center"
            android:textSize="24sp" />

    </TableRow>
</TableLayout>
```

Chat.java

```
package com.seniorproject.acsAssistApp;

import android.content.Context;
import android.net.Uri;
import android.os.Bundle;
import android.view.LayoutInflater;
import android.view.View;
import android.view.ViewGroup;
```

```java
import androidx.fragment.app.Fragment;

/**
 * A simple {@link Fragment} subclass.
 * Activities that contain this fragment must implement the
 * {@link Chat.OnFragmentInteractionListener} interface
 * to handle interaction events.
 * Use the {@link Chat#newInstance} factory method to
 * create an instance of this fragment.
 */
public class Chat extends Fragment {
    // TODO: Rename parameter arguments, choose names that match
    // the fragment initialization parameters, e.g. ARG_ITEM_NUMBER
    private static final String ARG_PARAM1 = "param1";
    private static final String ARG_PARAM2 = "param2";

    // TODO: Rename and change types of parameters
    private String mParam1;
    private String mParam2;

    private OnFragmentInteractionListener mListener;

    public Chat() {
        // Required empty public constructor
    }

    /**
     * Use this factory method to create a new instance of
     * this fragment using the provided parameters.
     *
     * @param param1 Parameter 1.
     * @param param2 Parameter 2.
     * @return A new instance of fragment Chat.
     */
    // TODO: Rename and change types and number of parameters
    public static Chat newInstance(String param1, String param2) {
        Chat fragment = new Chat();
        Bundle args = new Bundle();
        args.putString(ARG_PARAM1, param1);
        args.putString(ARG_PARAM2, param2);
        fragment.setArguments(args);
        return fragment;
    }

    @Override
    public void onCreate(Bundle savedInstanceState) {
        super.onCreate(savedInstanceState);
        if (getArguments() != null) {
            mParam1 = getArguments().getString(ARG_PARAM1);
            mParam2 = getArguments().getString(ARG_PARAM2);
        }
    }

    @Override
    public View onCreateView(LayoutInflater inflater, ViewGroup container,
                             Bundle savedInstanceState) {
        // Inflate the layout for this fragment
        return inflater.inflate(R.layout.fragment_chat, container, false);
    }
```

```
    // TODO: Rename method, update argument and hook method into UI event
    public void onButtonPressed(Uri uri) {
        if (mListener != null) {
            mListener.onFragmentInteraction(uri);
        }
    }

    @Override
    public void onAttach(Context context) {
        super.onAttach(context);
    }

    @Override
    public void onDetach() {
        super.onDetach();
        mListener = null;
    }

    /**
     * This interface must be implemented by activities that contain this
     * fragment to allow an interaction in this fragment to be communicated
     * to the activity and potentially other fragments contained in that
     * activity.
     * <p>
     * See the Android Training lesson <a href=
     * "http://developer.android.com/training/basics/fragments/communicating.html"
     * >Communicating with Other Fragments</a> for more information.
     */
    public interface OnFragmentInteractionListener {
        // TODO: Update argument type and name
        void onFragmentInteraction(Uri uri);
    }
}
```

fragment_chat.xml

```
<RelativeLayout xmlns:android="http://schemas.android.com/apk/res/android"
   xmlns:app="http://schemas.android.com/apk/res-auto"
   xmlns:tools="http://schemas.android.com/tools"
   android:layout_width="fill_parent"
   android:layout_height="fill_parent"
   android:orientation="vertical" >


   <EditText
       android:id="@+id/editText"
       android:layout_width="match_parent"
       android:layout_height="wrap_content"
       android:ems="10"
       android:inputType="textMultiLine"
       android:text="Therapist\nMessage 1" />


   <RelativeLayout
       android:id="@+id/form"
```

```
        android:layout_width="match_parent"
        android:layout_height="wrap_content"
        android:layout_alignParentLeft="true"
        android:layout_alignParentBottom="true"
        android:orientation="vertical">

        <EditText
            android:id="@+id/chatText"
            android:layout_width="306dp"
            android:layout_height="wrap_content"
            android:layout_alignParentStart="true"
            android:layout_alignParentLeft="true"
            android:layout_alignParentBottom="true"
            android:layout_toLeftOf="@+id/buttonSend"
            android:ems="10"
            android:hint="Enter message here"
            android:inputType="textMultiLine"
            tools:layout_editor_absoluteX="109dp"
            tools:layout_editor_absoluteY="555dp" />

        <Button
            android:id="@+id/buttonSend"
            android:layout_width="wrap_content"
            android:layout_height="wrap_content"
            android:layout_alignBottom="@+id/chatText"
            android:layout_alignParentEnd="true"
            android:layout_alignParentRight="true"
            android:text="Send" />
    </RelativeLayout>


</RelativeLayout>
```

Settings.java

```
package com.seniorproject.acsAssistApp;

import android.content.Intent;
import android.net.Uri;
import android.os.Bundle;
import android.widget.Toast;
import androidx.preference.Preference;
import androidx.preference.PreferenceFragmentCompat;
import androidx.preference.SwitchPreference;

public class Settings extends PreferenceFragmentCompat {
    public SwitchPreference darkToggle;
    public Preference webLink;
```

```java
    @Override
    public void onCreate(Bundle savedInstanceState) {
        super.onCreate(savedInstanceState);

        darkToggle = findPreference("dark_toggle");
        darkToggle.setOnPreferenceChangeListener(new
Preference.OnPreferenceChangeListener() {          // Set a listener for when toggle
changes
            @Override
            public boolean onPreferenceChange(Preference preference, Object o) {
                if (darkToggle.isChecked()) {
// Let the user know that changes have been registered
                    Toast.makeText(getActivity(),"Light Theme will be applied on app
restart",Toast.LENGTH_LONG).show();
                    darkToggle.setChecked(false);
                }
                else {
                    Toast.makeText(getActivity(),"Dark Theme will be applied on app
restart",Toast.LENGTH_LONG).show();
                    darkToggle.setChecked(true);
                }
                return true;
            }
        });

        webLink = findPreference("website_link");
        webLink.setOnPreferenceClickListener(new
Preference.OnPreferenceClickListener() {
           @Override
           public boolean onPreferenceClick(Preference preference) {
               Intent intent = new Intent(Intent.ACTION_VIEW);

intent.setData(Uri.parse("https://engprojects.tcnj.edu/acs-assist-20/"));
// navigate to senior project page through the intent
               startActivity(intent);
               return true;
           }
        });
    }

    @Override
    public void onCreatePreferences(Bundle savedInstanceState, String rootKey) {
        setPreferencesFromResource(R.xml.preferences, rootKey);
// the settings options are defined in preferences
    }
}
```

preferences.xml

```xml
<PreferenceScreen
    xmlns:android="http://schemas.android.com/apk/res/android">

    <PreferenceCategory
        android:title="App Settings">

        <SwitchPreference
            android:key="dark_toggle"
            android:defaultValue="false"
            android:title="Dark Theme"
            android:summary="Enable a dark UI for the app" />
```

```xml
    </PreferenceCategory>


    <PreferenceCategory
        android:title="Further Info">

        <Preference
            android:key="website_link"
            android:title="About ACS Assist"
            android:summary="Find more info about the project and team" />
    </PreferenceCategory>

</PreferenceScreen>
```

colors.xml

```xml
<?xml version="1.0" encoding="utf-8"?>

<!-- To Do: User Feedback to change app colors  -->
<resources>
    <color name="colorPrimary">#008577</color>
    <color name="colorPrimaryDark">#00574B</color>
    <color name="white">#ffffff</color>
    <color name="darkGray">#6c6c6c</color>
    <color name="colorAccent">#D81B60</color>
</resources>
```

strings.xml

```xml
<resources>
    <string name="app_name">ACS Assist</string>

    <!-- open and close are needed for MainActivity.java (to create the
ActionBarToggle) -->
    <string name="open">Open</string>
    <string name="close">Close</string>

    <!-- TODO: Remove or change this placeholder text -->
    <string name="hello_blank_fragment">Hello blank fragment</string>

</resources>
```

build.gradle

```
apply plugin: 'com.android.application'

android {
    compileSdkVersion 29
    buildToolsVersion "29.0.1"
    defaultConfig {
        applicationId "com.seniorproject.acsAssistApp"
        minSdkVersion 19
        targetSdkVersion 29
        versionCode 1
        versionName "1.0"
        testInstrumentationRunner "androidx.test.runner.AndroidJUnitRunner"
    }
    buildTypes {
        release {
            minifyEnabled false
            proguardFiles getDefaultProguardFile('proguard-android-optimize.txt'),
'proguard-rules.pro'
```

```
        }
    }
}

dependencies {
    implementation fileTree(dir: 'libs', include: ['*.jar'])
    implementation 'androidx.appcompat:appcompat:1.1.0'
    implementation 'androidx.constraintlayout:constraintlayout:1.1.3'
    implementation 'androidx.legacy:legacy-support-v4:1.0.0'
    testImplementation 'junit:junit:4.12'
    androidTestImplementation 'androidx.test.ext:junit:1.1.1'
    androidTestImplementation 'androidx.test.espresso:espresso-core:3.2.0'
    implementation 'com.android.support:design:28.0.0'
    implementation 'androidx.preference:preference:1.1.0'
}
```

The following blocks outline the code that was written for the Arduino Nano 33 BLE. This code was written so that the processing measurement capabilities of the Nano may be tested and analyzed.

imuOutputADXL345.ino

```
//The following sketch is applicable for the ADXL345 Accelerometer

#include <Wire.h>  // Wire library

int ADXL345 = 0x53; // The ADXL345 sensor I2C address
float X_out, Y_out, Z_out;  // Will hold the X, Y, Z Outputs
float roll,pitch,rollF=0,pitchF=0; // Will hold the calculated roll and pitch angles
as well as filtered calculation

void setup() {
  Serial.begin(9600);                   // Initiate serial communication (for serial
output for now)

  Wire.begin();                         // Initiate the Wire library

  Wire.beginTransmission(ADXL345);      // Start communicating with the device
  Wire.write(0x2D);                     //  Power on chip via POWER_CTL

  Wire.write(8);                        // Bit D3 High for measuring enable (8dec ->
0000 1000 binary)
  Wire.endTransmission();
  delay(10);

  //Off-set Calibration (+14, +7, +279) initially vs (0, 0, 256)

  //X-axis
  Wire.beginTransmission(ADXL345);
  Wire.write(0x1E);
  Wire.write(-4);
  Wire.endTransmission();
  delay(10);

  //Y-axis
  Wire.beginTransmission(ADXL345);
  Wire.write(0x1F);
  Wire.write(-2);
  Wire.endTransmission();
  delay(10);
```

```
  //Z-axis
  Wire.beginTransmission(ADXL345);
  Wire.write(0x20);
  Wire.write(-6);
  Wire.endTransmission();
  delay(10);

}
void loop() {
  // === Read acceleromter data === //
  Wire.beginTransmission(ADXL345);
  Wire.write(0x32); // Start with register 0x32 (ACCEL_XOUT_H)
  Wire.endTransmission(false);
  Wire.requestFrom(ADXL345, 6, true); // Read 6 registers total, each axis value is
stored in 2 registers
  X_out = ( Wire.read() | Wire.read() << 8); // X-axis value

  X_out = X_out / 256; //For a range of +-2g, we need to divide the raw values by
256, according to the datasheet
  Serial.print("X is ");
  Serial.println(X_out);
  Y_out = ( Wire.read() | Wire.read() << 8); // Y-axis value
  Y_out = Y_out / 256;
  Serial.print("Y is ");
  Serial.println(Y_out);
  Z_out = ( Wire.read() | Wire.read() << 8); // Z-axis value
  Z_out = Z_out / 256;
  Serial.print("Z is ");
  Serial.println(Z_out);
  Serial.println("");
  // Calculate Roll and Pitch (rotation around X-axis, rotation around Y-axis)
  roll = atan(Y_out / sqrt(pow(X_out, 2) + pow(Z_out, 2))) * 180 / PI;
  pitch = atan(-1 * X_out / sqrt(pow(Y_out, 2) + pow(Z_out, 2))) * 180 / PI;
  // Low-pass filter
  rollF = 0.941 * rollF + 0.06 * roll;
  pitchF = 0.941 * pitchF + 0.06 * pitch;
//  Serial.print(millis()/1000.0);
//  Serial.print(", ");
//  Serial.print(rollF);
//  Serial.print(", ");
//  Serial.print(pitchF);
//  Serial.println("");
}
```

imuOutputLSM9DS1.ino

```
    #include <Arduino_LSM9DS1.h>
#include <ArduinoBLE.h>
#include <BLECharacteristic.h>
#include <BLEDescriptor.h>
#include <BLEDevice.h>
#include <BLEProperty.h>
#include <BLEService.h>
#include <BLETypedCharacteristic.h>
#include <BLETypedCharacteristics.h>
#include <String.h>
#include <PID_v1.h>
```

```
#define initialThermistorResistance 10000 //Thermistor Resistance = 10k ohms
#define BetaValue 3950              // Beta Value of Thermistor 3950 K
#define Resistor 10000       // 10k Resistor for Voltage Divider
#define thermistorPin A0

float accelX, accelY, accelZ;
float magX, magY, magZ, mag_x, mag_y;
float gyroX, gyroY, gyroZ;
float roll, pitch, yaw, rollF = 0, pitchF = 0, yawF = 0, posiRoll, posiPitch,
posiYaw;

//Battery (Power Supply) Variables
float analogReading;
float initialBatteryVoltage;
float voltageRatio;
float finalBatteryVoltage;

//Declare Variables as Floats
float newThermistorResistance;
float voltageUnit;
float voltageThermistor;
float thermistorReading;
float voltageNew;
float lnRTR0;
float tempInitial;
float tempFinal;
float convertedReading;


BLEService angleService("1826");
BLEStringCharacteristic pitchBLE("78c5307a-6715-4040-bd50-d64db33e2e9e", BLERead |
BLENotify, 20);
BLEStringCharacteristic rollBLE("78c5307b-6715-4040-bd50-d64db33e2e9e", BLERead |
BLENotify, 20);
BLEStringCharacteristic yawBLE("78c5307c-6715-4040-bd50-d64db33e2e9e", BLERead |
BLENotify, 20);
BLEStringCharacteristic temperature("78c5307d-6715-4040-bd50-d64db33e2e9e", BLERead
| BLENotify, 20);

void setup()
{
 tempInitial = 273.15 + 25;
 if (!IMU.begin())
```

```
 {
   Serial.println("Failed to initialize IMU!");
   exit(1);
 }

 if (!BLE.begin())
 {
   Serial.println("starting BLE failed!");
   while (1)
     ;
 }

 BLE.setLocalName("acsAssist");
 BLE.setAdvertisedService(angleService);
 angleService.addCharacteristic(pitchBLE);
 angleService.addCharacteristic(rollBLE);
 angleService.addCharacteristic(yawBLE);
 angleService.addCharacteristic(temperature);
 BLE.addService(angleService);
 rollBLE.writeValue("0");
 pitchBLE.writeValue("0");
 yawBLE.writeValue("0");
 BLE.advertise();
}

void loop()
{
 BLEDevice central = BLE.central();

 if (central)
 {

   while (central.connected())
   {

     if (IMU.accelerationAvailable() && IMU.magneticFieldAvailable() &&
IMU.gyroscopeAvailable())
     {
       IMU.readAcceleration(accelX, accelY, accelZ);
       IMU.readMagneticField(magX, magY, magZ);
       IMU.readGyroscope(gyroX, gyroY, gyroZ);

       roll = atan(accelY / sqrt(pow(accelX, 2) + pow(accelZ, 2))) * 180 / PI;
```

```
        rollF = 0.94 * rollF + 0.06 * roll;

        pitch = atan(-1 * accelX / sqrt(pow(accelY, 2) + pow(accelZ, 2))) * 180 / PI;
        pitchF = 0.94 * pitchF + 0.06 * pitch;

        yaw = yaw + gyroZ * 0.01;
        yawF = 0.94 * yawF + 0.06 * yaw;
        // yaw = 180 * atan2(-mag_y,mag_x)/M_PI;

        posiRoll = rollF * -1;
        posiPitch = pitchF * -1;
        posiYaw = yawF * -1;
        rollBLE.writeValue(String(posiRoll));
        pitchBLE.writeValue(String(posiPitch));
        yawBLE.writeValue(String(posiYaw));

        analogReading = analogRead(A2); //Reading the power supply
        initialBatteryVoltage = analogReading * (3.33/1023.00);
        voltageRatio = 6.00;
        finalBatteryVoltage = initialBatteryVoltage * voltageRatio;
        voltageUnit = analogRead(A0);
        voltageThermistor = (3.33/1023.00) * voltageUnit; //Convert the analog value
(0-1023 volts/unit) to a voltage (0-5V) using conversion factor
        //voltageNew = InputVoltage - voltageThermistor;
        voltageNew = initialBatteryVoltage - voltageThermistor;
        newThermistorResistance = voltageThermistor / (voltageNew / Resistor);
        thermistorReading = analogRead(thermistorPin);
        thermistorReading = (1023/thermistorReading) - 1;
        thermistorReading = Resistor / thermistorReading;
        lnRTR0 = log(newThermistorResistance / initialThermistorResistance);
        tempFinal = (1 / ((lnRTR0 / BetaValue) + (1 / tempInitial))); //Temperature
from thermistor using beta value
        tempFinal = (tempFinal - 273.15); //Conversion to Celsius
        temperature.writeValue(String(tempFinal));
      }
    }
  }
}
```

The following blocks outline the code that was written to validate ANSYS thermal model using MATLAB.

```
%Thermal transient modeling
model = createpde('thermal','transient')

%Build geometry in meters
gm = multicuboid(0.05,0.1,[0.005 0.008 0.01254], 'Zoffset', [0 0.005,
0.013])
model.Geometry = gm
pdegplot(model,'Celllabels','on','FaceAlpha',0.5)
hold on
pdegplot(model,'Facelabels','on')
hold on
pdegplot(model,'EdgeLabels', 'on')

%Mesh the geometry
msh = generateMesh(model,'Hmax',0.004,'Hgrad',1.9);
pdemesh(model)

%Thermal Conductivities
thermalProperties(model,'Cell',1,
'ThermalConductivity',0.42,'MassDensity',1090,'SpecificHeat',3421);
thermalProperties(model,'Cell',2,'ThermalConductivity',0.21,'MassDensi
ty',911,'SpecificHeat',2127);
thermalProperties(model,'Cell',3,'ThermalConductivity',0.442,'MassDens
ity',1109,'SpecificHeat',3391);

%Thermal BC
thermalBC(model,'Face',12,'Temperature',42);

%ThermalIC
thermalIC(model,37);
```

```
tfinal = 2000; %2000 seconds in order to show it reaches steady state
around 1500 s
tlist = 1:0.5:tfinal;

%Solve the model
result = solve(model,tlist);
T = result.Temperature;

%Color Map
figure
pdeplot3D(model,'ColorMapData',T(:,length(tlist)))

% %Temperature Profile as a function of time
[X,Y,Z] = meshgrid(0,0,0.01:0.005:0.02554);
Tintrp = interpolateTemperature(result,X,Y,Z,1:length(tlist));
figure
plot(tlist,Tintrp)
% ylim([37 43])
xlabel('Time (seconds)')
ylabel('Temperature (Celsius)')
legend('Z = 0.01','Z= 0.015','Z = 0.020','Z = 0.025')
% X = ones(size(Z));
```

The following blocks outline the code that was written to implement the heating control system thus far. Future improvements could be made to the code depending on the external battery supply that is attached to the carbon fiber heater tape.

```
#include <PID_v1.h>
#define initialThermistorResistance 10000 //Thermistor Resistance = 10k ohms
#define BetaValue 3950           // Beta Value of Thermistor 3950 K
#define Resistor 10000      // 10k Resistor for Voltage Divider
```

```
#define thermistorPin A0

//Define PWM pin
int PWM_pin = 5;  //Pin for PWM signal to the MOSFET

//Battery (Power Supply) Variables
float analogReading;
float initialBatteryVoltage;
float voltageRatio;
float finalBatteryVoltage;

//Declare Variables as Floats
float newThermistorResistance;
float voltageUnit;
float voltageThermistor;
float thermistorReading;
float voltageNew;
float lnRTR0;
float tempInitial;
float tempFinal;
float convertedReading;


//PI Variables
float setPoint = 42;            //Default temperature setpoint. Leave it 0 and control it with rotary
encoder
float readTemp = 0
float PIError = 0;
float PIFinal= 0;
int controller_On;
float previousTemperature = 0;
float previousError = 0;
float elapsedTime, Time, timePrev;

int PI_p = 0;
int PI_i = 0;

float previousKp = 0;
float previousKi = 0;
float last_kd = 0;

int PID_values_fixed =0;
```

```
int kp = 2;
int ki = 0.6;
void setup()
{
  Serial.begin(9600);        //Baud Rate at 9600 bits/second (serial communication)
  tempInitial = 273.15 + 25; //Converting Ambient Temperature to Kelvin for the Beta Formula
  pinMode(PWM_pin,OUTPUT);

}

void loop ()
{
  float PI_control = PILoop ()
  float thermistor = thermistorLoop ()
}

void PILoop()
{
if(controller_On==0)
{
  // First we read the real value of temperature
  readTemp = readThermistor();

  //PI calculations
  PIError = setPoint - readTemp;
  PI_p = 0.01*Kp * PIError;
  PI_i = 0.01*PI_i + (Ki * PIError);

  //Final total PI value
  PIFinal = PI_p + PI_i

  //Define Pulse Width Modulation range between 0 and 255
  if(PIFinal < 0)

  {   PIFinal = 0;   }
  if(PIFinal > 255)

  {   PIFinal = 255;  }

//Write the PI final value to pulse width modulation pin connected to MOSFET
  analogWrite(PWM_pin,255-PIFinal);
  previousError = PIError;
  delay(500);
```

```
}

  void thermistorLoop ()
  {
   analogReading = analogRead(A2); //Reading the power supply
    initialBatteryVoltage = analogReading * (3.33/1023.00);
    voltageRatio = 6.00;
    finalBatteryVoltage = initialBatteryVoltage * voltageRatio;



    voltageUnit = analogRead(A1);
    voltageThermistor = (3.33/1023.00) * voltageUnit;//Convert the analog value (0-1023 
volts/unit) to a voltage (0-3.33V) using conversion factor
    //voltageNew = InputVoltage - voltageThermistor;
    voltageNew = initialBatteryVoltage - voltageThermistor;
    newThermistorResistance = voltageThermistor / (voltageNew / Resistor);
    thermistorReading = analogRead(thermistorPin);
    thermistorReading = (1023/thermistorReading) - 1;
    thermistorReading = Resistor / thermistorReading;
    lnRTR0 = log(newThermistorResistance / initialThermistorResistance);
    tempFinal = (1 / ((lnRTR0 / BetaValue) + (1 / tempInitial))); //Temperature from thermistor 
using beta value
    tempFinal = (tempFinal - 273.15); //Conversion to Celsius


  Serial.print("Analog Read = ");
  Serial.print(analogReading);
  Serial.print("\t\t");
  Serial.print("Voltage = ");
  Serial.print(finalBatteryVoltage);
  Serial.print("\t\t");
  Serial.print("Temperature = ");
  Serial.print(tempFinal);
  Serial.print("C");
  Serial.print("\t\t");
  Serial.print("Thermistor Resistance =  ");
  Serial.print(thermistorReading);
  Serial.print("\n\n");
  delay(2500);
  }
```

The following blocks outline the code that was written to form the web application thus far, which will be utilized by a physician in order to address the bidirectionality feature that is to be implemented in this project.

settings.py

```
"""
Django settings for mysite project.

Generated by 'django-admin startproject' using Django 2.2.7.

For more information on this file, see
https://docs.djangoproject.com/en/2.2/topics/settings/

For the full list of settings and their values, see
https://docs.djangoproject.com/en/2.2/ref/settings/
"""

import os

# Build paths inside the project like this: os.path.join(BASE_DIR, ...)
BASE_DIR = os.path.dirname(os.path.dirname(os.path.abspath(__file__)))


# Quick-start development settings - unsuitable for production
# See https://docs.djangoproject.com/en/2.2/howto/deployment/checklist/

# SECURITY WARNING: keep the secret key used in production secret!
SECRET_KEY = 'x1aoj*x*u8aw#=r52=gs-52!i+cyb8p8hvb7!a(@p%a8mbi)84'

# SECURITY WARNING: don't run with debug turned on in production!
DEBUG = True

ALLOWED_HOSTS = []


# Application definition

```

```python
INSTALLED_APPS = [
    'polls.apps.PollsConfig',
    'django.contrib.admin',
    'django.contrib.auth',
    'django.contrib.contenttypes',
    'django.contrib.sessions',
    'django.contrib.messages',
    'django.contrib.staticfiles',
]

MIDDLEWARE = [
    'django.middleware.security.SecurityMiddleware',
    'django.contrib.sessions.middleware.SessionMiddleware',
    'django.middleware.common.CommonMiddleware',
    'django.middleware.csrf.CsrfViewMiddleware',
    'django.contrib.auth.middleware.AuthenticationMiddleware',
    'django.contrib.messages.middleware.MessageMiddleware',
    'django.middleware.clickjacking.XFrameOptionsMiddleware',
]

ROOT_URLCONF = 'mysite.urls'

TEMPLATES = [
    {
        'BACKEND': 'django.template.backends.django.DjangoTemplates',
        'DIRS': [],
        'APP_DIRS': True,
        'OPTIONS': {
            'context_processors': [
                'django.template.context_processors.debug',
                'django.template.context_processors.request',
                'django.contrib.auth.context_processors.auth',
                'django.contrib.messages.context_processors.messages',
            ],
        },
    },
```

```
]

WSGI_APPLICATION = 'mysite.wsgi.application'


# Database
# https://docs.djangoproject.com/en/2.2/ref/settings/#databases

DATABASES = {
    'default': {
        'ENGINE': 'django.db.backends.sqlite3',
        'NAME': os.path.join(BASE_DIR, 'db.sqlite3'),
    }
}


# Password validation
#
https://docs.djangoproject.com/en/2.2/ref/settings/#auth-password-valida
tors

AUTH_PASSWORD_VALIDATORS = [
    {
        'NAME':
'django.contrib.auth.password_validation.UserAttributeSimilarityValidato
r',
    },
    {
        'NAME':
'django.contrib.auth.password_validation.MinimumLengthValidator',
    },
    {
        'NAME':
'django.contrib.auth.password_validation.CommonPasswordValidator',
    },
    {
```

```
        'NAME':
'django.contrib.auth.password_validation.NumericPasswordValidator',
    },
]

# Internationalization
# https://docs.djangoproject.com/en/2.2/topics/i18n/

LANGUAGE_CODE = 'en-us'

TIME_ZONE = 'America/New_York'

USE_I18N = True

USE_L10N = True

USE_TZ = True

# Static files (CSS, JavaScript, Images)
# https://docs.djangoproject.com/en/2.2/howto/static-files/

STATIC_URL = '/static/'
```

urls1.py

```
from django.urls import path

from . import views

app_name = 'polls'
urlpatterns = [
    # ex: /polls/
    path('', views.index, name='index'),
    # ex: /polls/5/
    path('<int:question_id>/', views.detail, name='detail'),
    # ex: /polls/5/results/
    path('<int:question_id>/results/', views.results, name='results'),
```

```
    # ex: /polls/5/vote/
    path('<int:question_id>/vote/', views.vote, name='vote'),
]
```

details.html

```
<h1>{{ question.question_text }}</h1>
<ul>
{% for choice in question.choice_set.all %}
    <li>{{ choice.choice_text }}</li>
{% endfor %}
</ul>
```

Index.html

```
{% if latest_question_list %}
   <ul>
   {% for question in latest_question_list %}
      <li><a href="{% url 'polls:detail' question.id %}">{{ question.question_text }}</a></li>
   {% endfor %}
   </ul>
{% else %}
   <p>No polls are available.</p>
{% endif %}
```

models.py

```
import datetime

from django.db import models
from django.utils import timezone

class Question(models.Model):
    question_text = models.CharField(max_length=200)
    pub_date = models.DateTimeField('date published')

    def __str__(self):
        return self.question_text
```

```
    def was_published_recently(self):
        return self.pub_date >= timezone.now() -
datetime.timedelta(days=1)

class Choice(models.Model):
    question = models.ForeignKey(Question, on_delete=models.CASCADE)
    choice_text = models.CharField(max_length=200)
    votes = models.IntegerField(default=0)

    def __str__(self):
        return self.choice_text
```

urls2.py

```
"""mysite URL Configuration

The `urlpatterns` list routes URLs to views. For more information please
see:
    https://docs.djangoproject.com/en/2.2/topics/http/urls/
Examples:
Function views
    1. Add an import:  from my_app import views
    2. Add a URL to urlpatterns:  path('', views.home, name='home')
Class-based views
    1. Add an import:  from other_app.views import Home
    2. Add a URL to urlpatterns:  path('', Home.as_view(), name='home')
Including another URLconf
    1. Import the include() function: from django.urls import include,
path
    2. Add a URL to urlpatterns:  path('blog/', include('blog.urls'))
"""
from django.contrib import admin
from django.urls import include, path

urlpatterns = [
    path('polls/', include('polls.urls')),
```

```
    path('admin/', admin.site.urls),
]
```

views.py

```
from django.shortcuts import render, get_object_or_404
from django.http import HttpResponse, Http404

from .models import Question

def index(request):
    latest_question_list = Question.objects.order_by('-pub_date')[:5]
    context = {
        'latest_question_list': latest_question_list,
    }
    return render(request, 'polls/index.html', context)

# Create your views here.
def detail(request, question_id):
    question = get_object_or_404(Question, pk=question_id)
    return render(request, 'polls/detail.html', {'question': question})

def results(request, question_id):
    response = "You're looking at the results of the question %s."
    return HttpResponse(response % question_id)

def vote(request, question_id):
    return HttpResponse("You're voting on question %s." % question_id)
```

app.py

```
# -*- coding: utf-8 -*-
import dash
import dash_core_components as dcc
```

```
import dash_html_components as html

external_stylesheets = ['https://codepen.io/chriddyp/pen/bWLwgP.css']

app = dash.Dash(__name__, external_stylesheets=external_stylesheets)

app.layout = html.Div(children=[
    html.H1(children='Welcome DR.'),

    html.Div(children='''
        Patient Name: John Doe.
    '''),

    dcc.Graph(
        id='example-graph',
        figure={
            'data': [
                {'x': [1, 2, 3], 'y': [44, 43, 46], 'type': 'bar',
'name': 'Pitch'},
                {'x': [1, 2, 3], 'y': [37, 40, 39], 'type': 'bar',
'name': 'Yaw'},
                {'x': [1, 2, 3], 'y': [45, 45, 47], 'type': 'bar',
'name': 'Roll'},
            ],
            'layout': {
                'title': 'Jan to March overlook'
            }
        }
    )
])

if __name__ == '__main__':
    app.run_server(debug=True)
```

I: Ethical Consideration

IRB Application:

General Information:

What is the full title of your study?

Adhesive Capsulitis Shoulder Assist Device

Who is the Principal Investigator for the study?

Christopher T Wagner

Are there any additional Research Staff?

- Bartner, Geoffrey T
- Desrochers, Ryan
- Hanna, Daniel
- Radhakrishnan, Shruthi
- Thomas Piraneque, Javier E

Research Description:

Provide an abstract of the proposed research or teaching in language that can be understood by a non-scientist. The abstract should summarize the objectives of this project and the procedures to be used, with an emphasis on what will happen to the subjects. (Maximum 250 words)

Adhesive Capsulitis is a musculoskeletal condition that primarily affects the shoulder joint capsule through inflammation and scar tissue formation. It can result in debilitating capabilities such as limited range of motion (ROM), joint stiffness, and pain during arm movement. The Adhesive Capsulitis Shoulder Assist Device prototype aims to address this condition by monitoring shoulder ROM during physical therapy exercises and help reduce joint stiffness and muscle fatigue with the use of heat therapy.

The focus of this study is to validate that a subject can put on the prototype without assistance, the prototype delivers adequate heating to the subject, and that the prototype does not hinder the subject while performing physical therapy exercises. Subjects would be instructed to put the device on and perform physical therapy exercises over the duration of twenty-five minutes, ten minutes of pre-heating and three five-minute periods of performing pendulum, wall climbing, and back stretches respectively. After the exercise is completed the subjects will then answer a questionnaire asking them to grade the prototype's accessibility, heating, and hindrance on a scale from one to five and statistically determine if the specification can be validated.

List the specific research objectives. (Maximum 250 words)

The objectives of this research are to validate that:

- Subjects can put on the prototype without assistance since the intended users of the device will have a limited ROM in one shoulder
- Subjects can feel the heating element of the prototype to assist them during physical therapy exercises
- The device does not hinder the subject while performing physical therapy exercises, which would be counterintuitive to their recovery process

Describe the specific research procedures. Include the data to be collected, and how it will be collected. Include data sheets as needed.

The investigators will gather specified subjects by asking them orally if they would participate in the study. Once the investigators obtain consent from the subjects the study can begin. The subjects will then put on the device with one arm. Once the device is securely on the subject will turn on the device and begin a twenty-five-minute exercise, consisting of a 10-minute warm up period, and a 15-minute stretching period. Once the warming period is completed, they will perform the pendulum exercises for five minutes, the wall climbing stretch for five minutes, and the back stretch for five minutes. After the twenty-five-minute exercise is complete they will shut off the device and remove it with one hand. They will then be given a questionnaire asking them to grade several aspects of the device from one to five. The answers for each question will be averaged together to determine if the device meets the Investigators standards to validate specifications stated in the objectives.

The data being obtained is the subject's feedback about the prototype's accessibility, heating, and hindrance. The subjects will be given an anonymous questionnaire which asks them to grade these factors on a scale from one to five.

Identify any equipment needed. If the equipment is classified as a medical device, specify if it is approved or if a valid IDE exists.

The ACS Assist Device prototype will be used in this study.

Subject Population:

Describe the subject population to be included in this research.

The subject population to be included in this research are healthy males and females ages 18-23 with no prior shoulder trauma.

How many subjects will be used and why?

The variability of this study is unknown; thus, power analysis cannot be done and an accurate sample size cannot be calculated. For this reason, the total number of participants will be in a range from ten to fifth teen.

Do the subject population include protected individuals? If yes, explain.

No

Identify inclusion and exclusion criteria for the subjects.

Any subjects that self-reported prior or existing bilateral shoulder injury.

How will subjects be recruited? Identify methods of advertising, compensation, and any other activities/circumstances that would affect the recruitment process.

Subjects will be recruited using flyers posted on campus. Classmates and peers will see the flyers and if they meet the requirements, healthy 18-23 years old with no shoulder trauma, they can participate in the study.

Risk and Benefits:

Identify the level of risk to the subjects (minimal, greater than minimal, significant, unknown) and explain.

The risk to subjects would be minimal. The Adhesive Capsulitis Shoulder Assist device prototype parts will be tested and verified to meet several safety standards before they will be assembled and used in the study. The only risk possibly presented to the subjects during the study would be discomfort from the heating element of the device. If this were to occur the subject could shut off the device and/or remove the device before any injury can occur.

What precautions have been taken to minimize risks and what is their likely effectiveness?

Heating risk will be minimized by running a series of tests on the heating element used in the device to verify that it is operating within a safe therapeutic range of 40-43 degrees Celsius. Doing this will greatly decrease the chance of a subject being injured due to the heating aspect of the device.

Describe other alternative and accepted procedures, if any, that were considered and why they will not be used.

None.

Describe how the research will be monitored to ensure subject safety.

The investigators will be present in the room during the testing to ensure the subjects' safety. If there is any risk posed to the subject the Investigators will be present to assist them.

Assess the potential benefits to science and/or society which may accrue as a result of this research. Identify any specific benefits to the subject.

Based on the results of this research the Adhesive Capsulitis Shoulder Assist Device prototype can be validated to meet the objectives stated earlier. This enables the Adhesive Capsulitis Shoulder Assist Device to be submitted to the Food and Drug Administration for future testing.

Privacy and Confidentiality:

Explain provisions to protect privacy interests of subjects. This refers to how investigators will contact subjects and/or access private information from or about subjects during and after their involvement in the research (e.g. time, place, etc. of research procedures).

Subjects will contact the investigators via the email or phone number posted on the flyers. Once subjects sign the consent form, they will be assigned a subject number that will act as an anonymous identifier for the subject's questionnaire. These consent forms and questionnaires will be locked away in the principal investigator's office to ensure only the investigators have access to them.

Will the data collected in the course of the study be considered sensitive data (e.g. mental health, HIV status, SS#, etc.)?

No.

Could any of this data, if disclosed, have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation?

No because the subjects will be assigned an anonymous subject number to protect their identity so no damage can come to them if the data is disclosed. Furthermore, the study will only ask questions regarding their experience during the study so that if any of the data is disclosed it will not have any adverse consequences for the subjects.

What specific safeguards will be employed to protect confidentiality of data (e.g., coding or removal of identifiers as soon as possible, limitation of access to data, use of locked file cabinets, protection of computer-based data systems, etc.)?

Subjects will be given an anonymous subject number to remove any identifier from the questionnaire after completing the exercises to protect their identity. These questionnaires will be locked in the principal investigator's office with access only to the investigators to prevent the data from tampered with or stolen.

Informed Consent:

Describe how you will obtain informed consent. How will required information be presented?

The subjects will be presented an adult consent form that will display all aspects of what they will be doing in the study. If they agree to participate, they will sign the form giving consent. The subjects will be presented this adult consent form to participate in the study before the study starts in STEM 218.

Who will obtain consent? Describe their experience in obtaining consent from subjects.

The investigators will obtain consent by getting the subjects to sign the consent forms to participate in the study.

J: Meeting Minutes

Adviser Meeting Minutes:

9/4/19

Danny and Javier will most likely be presenting with the BME department

Electrical requirements must be justified as well

Task-tracking sheets- danny and javier can use as well

Goal of semester: have design, parts ordered

Presentation in 2 weeks- refresher to the faculty of the project; what does PT do? Present basic requirements and specs

Dr. Wagner found a paper for us to look at- share Drive folder
-use reference manager- Mendeley

Needs to be some overlap in technical roles

Danny and Javier can push forward with more of the backend, computer-based stuff; do not have to wait for BME spec's to be completed

Javier will apply for Cloud storage programs (free)

How does FDA regulate cloud servers- dealing with patient safety; talk about what would need to be done to make the device safe for patients and privacy should it go to market.

We will not be able to test therapeutic benefit.

Dr. Wagner has our URL; if we log into Wordpress with our TCNJ login, we should have access.
- can put requirements of the device but should not put specifications

Goal for next week- refine complete requirements and specs (Critical requirements)

Cyclic or constant heating

The device must transmit the data to an external location for PT review.

On board capacity---rate to--cloud storage (per use/user)--PT

Part decision Matrix- list options and justify choices for their capabilities

PT as reference for specification- voice of customer

Can also justify through testing

Requirements review

Part 11 Compliance is an essential requirement/spec---- difficult to verify completely, but offer examples as to how its done

What is the device regulatory number?

Title 21 8 30.1
FDA.gov under medical devices, product classification tool

Ansys is not pertinent to specific tests- use it to test specific inputs; ansys supports the test

Check Wagner's musculoskeletal guide

Check populations for percentiles

Could have family of devices (different sizes, but prototype one)- could also make modular

Use PT resource- don't overload them with data- determine what is essential

- We need to discuss with them soon

Be careful of "and" requirements--- make 11.1 / 11.2

Specs can be a standard- international symbology- standard for words on medical devices

Look up standard language for medical devices, ISO, FDA

Some specs cannot be verified

must= requirement

Motion, safety, and software, electronic computer hardware; 90% of requirements

Also biocompatibility ISO 1345, and comfort- spec could be materials used- no verification, just validate by having someone put it on, take survey

For presentation- motion, heat, at least 1 ece requirement

Most critical stuff

Reference PT- Personal Contact, PT so and so

Talk about different heating variations

Peltier systems, TAPE, liquid, etc.

Cyclic heating versus constant- cyclic can be an issue due to time frame

9/11/19:

Requirements review

Part 11 Compliance is an essential requirement/spec---- difficult to verify completely, but offer examples as to how its done

What is the device regulatory number?

Title 21 8 30.1
FDA.gov under medical devices, product classification tool

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Most critical stuff

Reference PT- Personal Contact, PT so and so

Talk about different heating variations
Peltier systems, TAPE, liquid, etc.

Cyclic heating versus constant- cyclic can be an issue due to time frame

9/25/19 Meeting Agenda:

- Talk about modified requirements and specifications
- Talk about design constraints
- Mention that PT Appt at 1:45 pm today to finalize the reqs and specs
- Talk about possible design and materials that could be used
- Meeting with Mr.Zanetti last Tuesday
- Meeting with Brian today
- Ask about electric components requirement
- Ask if we can purchase shoulder heat wrap and look at the material that is used
    - Currently, thinking carbon fiber tape
    - Also maybe neoprene; but not really good, so don't know…
- Where to do the heating?
    - Allowed to ask PT?

Notes:

- Think about as many different ways to do things as possible
- Global Constraints about access to healthcare?
    - Think about how the international market is restricted possibly?
- Consider social stigma for social constraint
- Spec would be numbers in terms of cost for economic
- Possible there is no social constraint
- Regulatory is currently specific to the US
- Could say device is being made for the US market initially, will investigate global market later

- Building off of existing shoulder braces is a possibility
    - Talk to PT, what do they use for patients
- Where do PT's apply heat? Specification can be based off of what they say
- A material to distribute the heat, thermal gel for example, high thermal conductivity
- Can start Gantt chart
- Can start hand-drawn sketches

Goal for Next Meeting: Few Hand-Drawn Sketches, Finalized Reqs & Specs, and Material Comparison Chart for Device

10/2/19

Meeting Agenda:

- Talk about PT Feedback/Input
- Show Preliminary Designs
- Present Potential Materials for Different Components
- Ask if it is possible to view previous projects (in terms of materials that they used, etc).

10/9/19

- More analysis in regards to data and sampling rates- how much data are we actually getting
    - 16 bit → How much data is transferable?
    - Number of readings per second
    - Don't present specs for things we are using- like magnetometer
        - Could be reference, or smooth out noise
- Be cautious using copied code- must understand what code is doing
- If analog input on the arduino, wont have to worry about separate ADC
- Thermistor— must look into sensitivity within the actual range of interest for our project
    - Increasing gain increases the noise
    - Probably don't want to push into the nonlinear region for the thermistor
- Read particular value and then specify in the code
- Possibility to test a thermistor and a digital sensor
- Factors to consider
    - Sensitivity of interest
    - Ease of Implementation
    - Sampling rate
    - Cost

- Show an actual decision tree/table
- Conduction in series for different fabrics
- Look at current supplied by batteries, amp hours
    - Not just voltage
    - Heating elements are going to draw a large bit of power
- Heating elements draw more on startup
- Assume an hour for each use
    - Possibly lithium ion pack
- Possibility to make the heating pad cup under the arm
- Alternative designs
    - Talk about a physically constraining process and why we moved on from this idea into our current concept with free range mobility within a monitored and well defined zone (Voice of Customer)
- Show thought process
- On average, relative to shoulder height, where do we have to start being concerned about breasts and fit of the device
- Need to have more complete object designs before incorporating solid works drawings
- How will we represent multiple layers
- Flexible peltier?
- Need to insulate outside of peltier cold side, adding fins, etc.
    - Size of the unit and dissipation across surface area
- Look into peltier systems

10/29/19

Notes on Presentation:

- Think about how to present the intro slides (slides 1 and 2)

- Needs statement
    - Remove 'Shoulder Trauma' from the statement
    - Facilitating PT to regain ROM
    - Remove reinjury

- Target the design inputs that are currently being addressed
    - Don't need to talk about the others
    - Slide: Device Fit → Verification by drawing (Measure distances with tape measure)
    - Slide: Device weight

- Device will be weighed

- Slide: ROM
    - Measure the angles on a surrogate arm
    - Either protractor or goniometer, not both

- Slide: Heating System
    - Change verification
    - Measure the heating element to make sure it applies the temperature
    - Set Temperature on device and check deviation for 25 minutes

- Slide: Heating System Contd
    - Software validation script
        - Trigger output
        - Force the thing to happen
    - Verification of 7.2: It needs to have a physical shutoff

- Slide: Data Collection & Storage
    - Accuracy is missing
    - Verification: Presence of all the metrics within the file
    - Set-Points
        - ????
    - Think about accuracy
    - It's ok to say that you're working with PT
    - Not sure how to verification for Req 9, Software piece
    - Think about SD card, do we really need it?

- Slide: Data Collection & Storage
    - Get rid of "containing previous measurements"
    - "Verification" should be software validation
        - No verification activity: it's really about the presence of the wireless transmitter

- Slide: Software & Database
    - More validation than verification
        - Does it actually function the way we wanted to?
        - Device validation
            - Asking PT if it meets their needs

- So, make a list of the requirements at the end and say that these are other things that we considered but they're not relevant to the design
- Clarify that the "anticipated design flow"
    - Flow of Data
    - Talk about visual feedback
    - Description (verbal): Putting all this together, person is using the device while performing the exercise, and they'll get immediate feedback
    - Physical Build
    - Data
- Sketches (Design Iterations)
        - 3 slides
        - Started here → Evolved to other thing …
        - Laser Point (circles/point to areas)
        - SCAN FOR IMPROVEMENT
- Move the design slides down
- Textile Matrix
    - Talk primarily about the cleaning
        - Sanitary purposes because it's going to be around the armpit region
- Physical Design Matrix
    - Think about the security
- Heating Element Matrix
    - Don't spend a lot of time
    - Not sure about power, b/c we need battery choices
      Didn't do the power analysis
      Heat under the arm and the back
- Temperature Sensor Matrix
    - Don't talk numbers, Put pictures in the same place as the table
- Microprocessor Selection Matrix
    - Get through it quickly
    - Put the pictures with the matrix
    - IMU Included is the critical thing, don't spend time on the other factors
- IMU
    - Important to sync up communication; why we need to have it on-board

- IMU Matrix
    - Put the LSM9DS1 on the previous slide
    - Remove the MPU 9250
- Battery slides
    - Still working through the process of actual energy needs
        - Looking at some of these options
- Don't include the battery matrix
    - Don't have enough information to make a decision yet
- Database Slide
    - Decide if you have time before including it
- Database Matrix Slide
    - Don't include SD card row
    - Get rid of additional benefits
    - Save da money
- Remove the References Slide

11/6/19

Meeting Agenda:

- Discuss carbon tape testing
    - Set the voltage at 20 V; 2 amps of current
        - Was not able to go past about 2.6 V
    - Possibly will need a higher wire gauge
        - Maybe strip it better
    - Metal Sheets → Is it brass?
    - Weave pattern of the tape
        - Plain vs Twill?

- Need to hold current constant and play with voltage because Ohm's Law (duh we're stupid)
- Wants a closed loop control
    - Feedback mechanisms
- Heat control systems
    - Temperature simulations
- Can start GUI/software stuff now
- Need to follow up with Brian about the orders we placed
- Think about keeping the heating system separate
- Think about an outline

  - Chapter by Chapter
  - Draft done a week before the presentations which is 12/4
- Cannot specify voltage and current
  - Can only specify one
- Probably tested incorrectly
- Changing length changes resistance
- Will need a calibration curve as created
  - Length will be different than as tested
- Voltage will be control for temperature
- Probably test temperatures from 34C-45C
- Temperature calculation to determine what temperature we need the heating component to reach
- Changing wire changes calibration
- Dr. Wagner's last group were able to achieve 15 minute heating cycles with the carbon tape
- Closed control system for heater
  - Will maximize efficiency in terms of power draw from battery
- Touch base with Brian about orders
- Investigation on controllers
- Apps can be done
- Get into physical device construction
  - Strain relief
  - Ensure user is not pulling things apart
- Solidworks
  - Geometry works?
    - Better for curvilinear surfaces
  - Body as a separate part
  - Station 1 or 16?
    - Closest to joe's office
  - Look at the way a shirt is constructed
  - For report
    - Work on outline first and get to Wagner and adegbege asap
    - Final presentation dec. 4th
      - Draft done sometime the week before
      - After presentation, get comments on the draft
      - Final paper due during finals
      - Abstract will be due Nov. 26th

11/19/19

Meeting Agenda:

- Discuss carbon tape testing
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11/20/19

- Battery packs in parallel should be close to sufficient voltage for the heating tape
- Could use resistor to drive down current
    - Feedback control will still be necessary
- Fea analysis
    - Mesh optimization
        - If mesh is small enough to see difference without requiring too large computational power
    - Timestep needs to be small enough as well
    - Try a few different mesh sizes to demonstrate answers are not changing
- Draw on the body
    - Save as a part
    - Then bring part together with body
    - Don't reference against the body
        - Constraints for the drawing- constraint-free relative to the body

    - Then delete the parts you don't need eg body
- Nano
    - Came in, pitch and roll are working, yaw is next
    - Android app is started
        - Image of what GUI will look like in presentation
        - Will have to adjust colors and things for accessibility
- Describe what it looks like to use the device
    - Explain to the audience from a user standpoint
    - Eventually will show video of someone using with real-time feedback
- Javier has tester nano
    - Will get breadboard to test vibration motor and speaker
- Dr. Wagner will try to assign locks next week in STEM 218
- IRB
    - Can have different surveys for the same test and application
    - Think about the protocol and how it will be run, because this is needed to apply for IRB
    - "Just the facts"
- Testing among class is okay for most things since we are not testing therapeutic benefit
- Abstract to Dr. Wagner by slightly before due on 26… nov 25?
    - Speak at a level everyone can understand
    - Not necessarily the same one as in paper
        - Part of packet for senior project presentations
    - Current state of the project, basics of what we've done
- Paper
    - DI
    - Chapters
        - material / part selection--- these don't all have to be separate chapters-- can just be sub-sectioned to fewer chapters with multiple parts
            - Individual chapters tying every component back to design inputs
                - Heating
                - Feedback controls
                    - Thermal sensor
                    - IMU
                - User warnings
                    - Motor and audible
                - Break these chapters down individually by how we are selecting our parts
                - fabrics/water protection

                    - Power analysis/ battery selection-- to the degree that we can
                        - Still may have work to do- test other parts we have
                - Design integration chapter
                    - Puts it all together
                    - Design iterations
                - Data flow/processing
                - User Interface
                - PT connection
                    - Their flow, changing settings, seeing data, changing patient warnings, etc.
                - Fully developed map- how it all works
                - “However it makes sense to you”
            - Then verification
            - Validation
        - There is not right way, we can go a different route, just tell the story
            - Balance between feeding things to slowly and too fast
            - Err on the more wordy side for now
        - Summary analyses for data obtained
        - Integrate assignments into design process
        - For draft
            - Reviewed for basic ideas and flow
                - Read each other’s sections
            - There can be future things included
        - Not concerned with breaking down chapters by person
            - Whoever is the responsible engineer for that decision report writes that section---label by person
    - Design presentation will not be hugely different from our last
        - Dr Wagner would like it by that Sunday, early enough for him
        - We could meet on Monday, Dec. 2
            - 12:30 PM

Meeting with Dr. Adebege

- Danny showed the application
    - Next big thing is figuring out yaw with Nano
- In terms of structure for chapter
    - Can do it this way outlined by wagner
    - Or by submodules of the project
- Will email him abstract as well
- Along with final report draft

- Abstract is our selling point, or advertisement, high level
    - How many people impacted, reasons for project
    - He would like it by Sunday
- Heating control system
    - Simulink
        - Put equation for voltage to heat
            - Arrow into PI block
            - Loops back
            - Gain for proportional
                - Tune this first
            - Gain for integral
        - Model gives starting point for tuning
- See if Dr. Wagner can meet a little later and then we can meet with Adebege in the afternoon
    - Try to start at 1:30 or so and then meet around 2 with Adebege

<u>Team Meeting Minutes:</u>

8/29/19

Established general team meeting times on Wednesdays after team advisor meetings starting at 11am.

Planned to meet with Mr. Zanetti on a Wednesday afternoon if possible.

Discussed potential role for Geoff- adding range of motion tracking system to his roles

Javier and Danny are trying to solidify their goals for this project, agreed to talk to Dr. Adegbege during our meeting next week to determine if their roles are sufficient/feasible. We want to ensure that it is still computer engineering and not just computer science.

Potential to implement audible warnings when range of motion is being exceeded/pushed too far.

The website has been created, we just didn't have it sent to us yet. Gave Wordpress resources to Danny.

Discussed upcoming requirements for Computer Engineering students' senior design class- very similar to BME- presentation, Gantt chart.

Explained Requirements and Specifications to Danny and Javier.

Requirements by 9/3

10/9/19

Website by 9/11

- Have budget and Grant chart by next week
- Peltier system- pretty efficient, should be more than powerful enough
  - Very cheap, should probably get both to test
  - Need better heat distributor
- Still need to find a good conductive material to distribute heat
  - Composite films
  - Potential to use these films to spread peltier's heat
- Arduino Nano BLEsense
  - Should have adequate data transfer speeds and built-in sensor sampling rates
- Heat-sealed fabrics
  - Waterproof housing for the system- easily cleaned
  - Removable outer shell washable
- Thermistor is likely temperature sensor
  - Sampling rate shouldn't be too important
  - Digital sensors could be easier to implement into the circuit
  - Analog would require an ADC
- All IMU data is 16 bits resolution
- Add to components alert system components
- Main parts of power calculation- finalize processor and heating components to estimate power draw

10/16/19

- Javier showed a piezotransducer for auditory alert that he would like to propose to Dr. Wagner to order
- Danny demonstrated working code with the arduino which tracked pitch and roll through an accelerometer sensor
- Pitch and yaw are likely to be most important senses of device
- Going to ask advisors if we can move forward and order the arduino nano 33 BLE, chosen vibratory motor, speaker, and IMU
- Firebase- Google cloud-based database cloud storage

    - Authentication of users
    - May or may not use firebase to translate the data
        - Need to decide if we want raw data and/or processed data uploaded to cloud
    - 5Gb free
- Schedule an appointment with the PT (& Javier) and ask if they want to see the data in real-time or no?
- Processing of the data the phone?
- Next step: processing data so that we can see some sort of simplified graphical display of the device's location
- Javier will start working on the database
    - Create users
    - Create basic analytics
    - Uploading data, and pulling from the cloud to our analytics
    - Should be do-able by the next time we meet
    - Make new email for the database
- Peltier vs carbon tape
    - Peltier could have greater warmup time due to more conductive material between the heaters and skin
        - Peltier modules are more easily disrupted by external conditions on the cool side
    - New carbon tape source site
- PT did not want physical constraints- but good alternative design for presentation
- LSM IMU not other one
- SQL vs Pandas
- Thermistor- how to connect and interface with nano

10/23/19

- Reviewed presentation needs
    - Add decision matrices, 3 sketches, combine requirements by category
- Danny showed decision matrices for processors and IMU
- Ryan showed carbon tape research, expecting roughly 18W of power consumption on a 1m strip for device
- Ryan will add textile decision matrix
- Danny plans to show Dr. Wagner progress with arduino and IMU and present decision matrices to buy parts
- Javier found that Firebase cannot do the data analytics, the database will simply store the data

- Textile matrix: include cost, ease of sewing, strength

11/13/19

- Danny
    - Building his own app drawers- not using built-in
        - Home
        - Begin routine
            - Has exercise selections
            - Can show angle based on exercise
            - Going to use a placeholder until we decide on specific exercises
            - Review page after exercise routine?
                - Showing maximum ranges of motion
- Javier
    - Showed sketches for app interface
        - Page to show average range of motion
- Need to get controller for heating system
    - Heating should start
    - Probably no menu to adjust temperature… small effective range for therapeutic heating
- Home would show most recent exercise
    - History
- Settings
    - Leave as a placeholder for now in case something comes up later
- Chat
- Android library for visibility
    - Seems to line up with requirements
- Database purpose: house raw data, that's it
- Web-app will display analytics for PT
- Carbon tape
    - Higher voltage was more efficient
        - Probably 8 volts or more
- Closed-loop control system for heating component
    - Research what is needed
    - Need schematic for report and presentation

2/3/2020

Ryan showed mockup of heating pad outer shell

- Ordered nylon fabric
- Velcro around the edge of outer shell to make inner portion easily removable
- Danny changed app so that it will ask to turn on the user's bluetooth for them

        - Still working on communicating with the arduino to get desired codes
- Javier
    - Ready to start building pages on Django- for doc
        - Front page to choose patient, eventually
        - Home
            - Monthly goals-can be linked to app home page
                - Doctor sets
            - patient/doctor log--aka the chat
            - Pain feedback
            - History log
            - Last exercise
- Shruthi talked to Dr. Adebege about analyzing leakage current
    - Finding leakage current of carbon fiber tape as it relates to our system
        - Circuit with resistance of tape, skin, nylon, polyester
        - 1.2 A and 5V
        - Seeking less than 100 micro amps
    - Heating control system
        - Thermistors typically 10kohm
            - May not need one that high
        - Going to do a calculation to find beta value for temperature range of 25 to 45 C, which will allow us to choose correct thermistor
            - Still need to find resistance of the tape at 45 C
- Geoff
    - Working on IRB procedure
        - Confirmed stretches we are testing
        - Need power analysis
            - To confirm number of subjects necessary
        - Fit, can you feel heat, can you put on with one arm, can they perform the exercises
- For verification protocol
    - Use template online
    - Doing the ranges of motion

2/10/2020

- Shruthi showed thermistor in action with working arduino code
    - Code should be able to be easily added to Danny's Arduino code
- We may need multiple thermistors
    - Could be warmer under the arm than on the back
- Javier and Shruthi are going to work on the PID control for the heat together
- Need to check status of nylon and carbon fiber tape

    - Want to build heating pad, and then holster structure will follow
- Javier will help connect database to web app
- Geoff is trying to figure out the power analysis for the IRB
    - Also working on putting together a battery box
- Wire covering from inside PCs

2/17/2020

- After tape testing, we decided we need to run 9V and 2A through the tape pieces at the desired length for the right temperature
    - 12V power supply should be adequate
        - Need to do calculations based on power supplies to ensure lasts long enough
- Need to get metal for the crimps
    - From amazon (thin sheets)
- Controls
    - Loops for battery control
    - Temperature from thermistor
- Arduinos are having problems over which type of cable you use- some just don't work
- Possibly four thermistors
- Hoping to build physical device this weekend if nylon comes in
- Geoff is going to meet with Wagner tomorrow to try to get approval for our IRB
    - Looked into surrogate arm
        - Using PVC pipe?
- Need to do abstract for NEBEC-- due Wednesday
- Danny successfully transmitted data to the phone from Arduino
    - Data is coming in as a weird format by the phone
        - Just need to figure out how to convert it to something usable

2/24/2020

- Danny showed angles taken real time from the arduino to the phone wirelessly
- Ryan showed outer casing and straps for device
- Javier figured out how to build the pages for the web app, still trying to understand how to enter data into the page
- Geoff found a good battery
    - Said minimal risk for IRB
    - Also has all the pieces for the surrogate arm, just need to piece together
- Have to ask Dr. Wagner about the NEBEC
- Power supply module for arduino to draw power from battery

3/2/2020

- Shruthi found a time constant and transfer function for the heating tape.
    - Modulating current through the tape at a set voltage

    - Got values for PI controller through MATLAB
        - rise time is very short which is ideal for quickly heating the tape
- Going to try to control tape heating through a digital potentiometer, which will alter the total resistance of the tape system in order to vary the current through the system and the level of heating
- Geoff built a surrogate arm out of PVC pipe
- Javier made progress in the web app pages
- Going to order brass sheets for carbon tape crimp connections

3/9/2020

- Danny and Javier connected the database to the app
    - Can transmit data between
- Talked to PT
    - Got zero points for angles for exercises
    - Can work with a reasonable error in terms of an angle
- Shruthi started working with a MOSFET and her control system
- Thermistor data was transmitted through bluetooth
- Geoff finalized power consumption estimation
    - Picked our battery
- PT wants to see average of peaks

<u>Physical Therapist Meeting Minutes:</u>

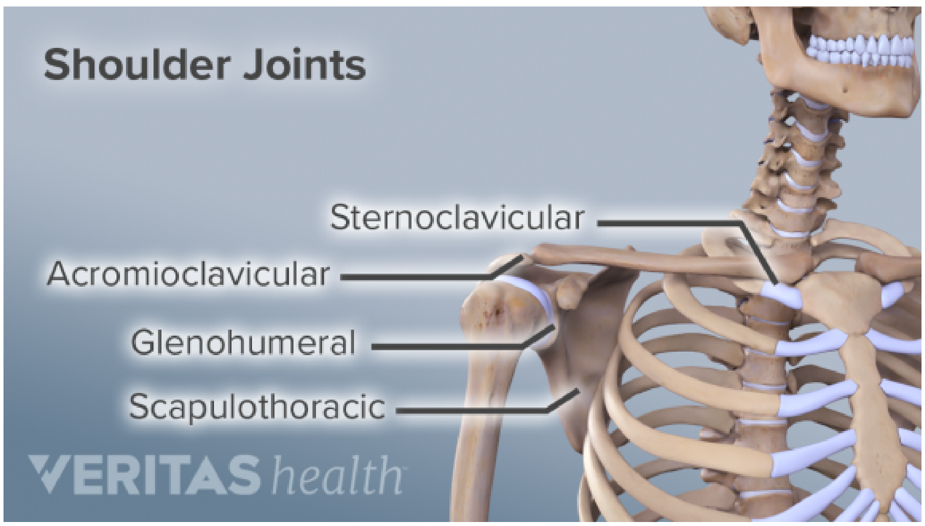
9/25/19

Physical Therapist: Brett Ostasiewski, PT, DPT
Location: Princeton Orthopaedics (Ewing Branch)
Preferred Mode of Contact: To email him at: bostasiewski@poamd.com
Otherwise Contact via Phone: (609)-924-8131 x5401

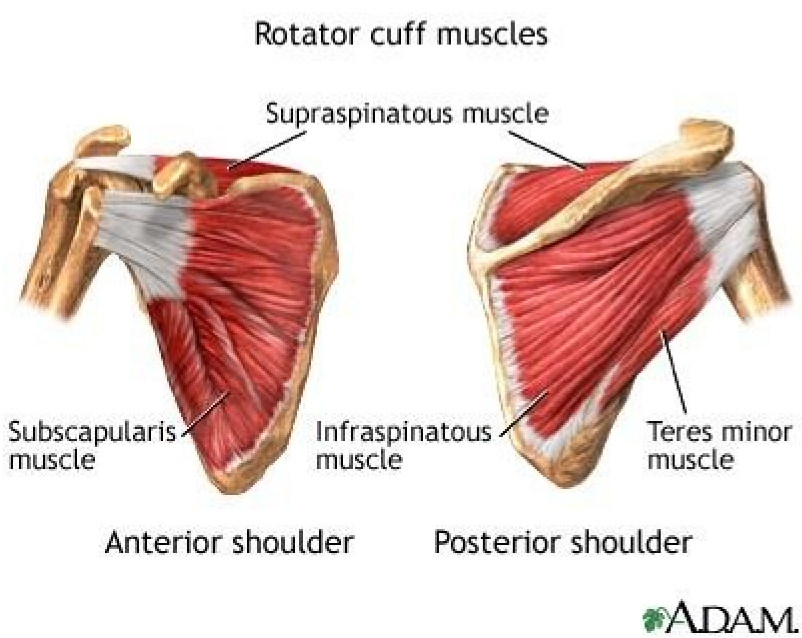
PT Questions:

1. What types of exercise do you suggest for Frozen Shoulder Patients for extension, abduction, and internal/external rotation?
    a. Abduction and External Rotation
        i. Cane Pushing Exercise while laying down (external rotation) or sitting up (abduction); primarily focuses on external rotation and abduction
        ii. Internal Rotation: Towel behind the back exercise
2. What types of data would you like to see?
    a. ROM Data (Active vs Passive); Unaided vs Aided

    b. Temperature Data (PT wants to know that the heat doesn't cause burns/injuries)
    c. It would be great to measure the separation between the scapulothoracic joint and glenohumeral joint, because these joints move together for frozen shoulder patients, instead of separately
3. When is heating used during the PT session?
    a. The heating is performed 10 minutes before the exercise (active)
    b. He likes the idea of having a heating component during the exercise as well ~15 minutes
4. Where is the heat applied?
    a. Usually a heat pack is wrapped around the shoulder blade and scapulothoracic joint targeting the rotator cuff muscles (See picture below for anatomy)



    b. The subscapularis muscle (front side of shoulder (anterior)) (rotator cuff muscles) is always the tightest; the heat is used to relieve the tension that is experienced in the muscles surrounding the shoulder joint (See picture below for anatomy) Also, mentioned that heat is applied around the infraspinatus muscle (back (posterior) of the shoulder)

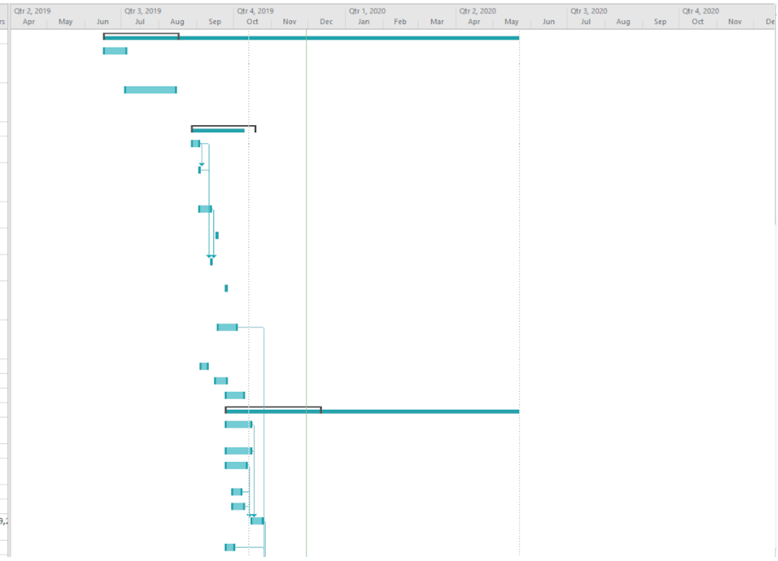


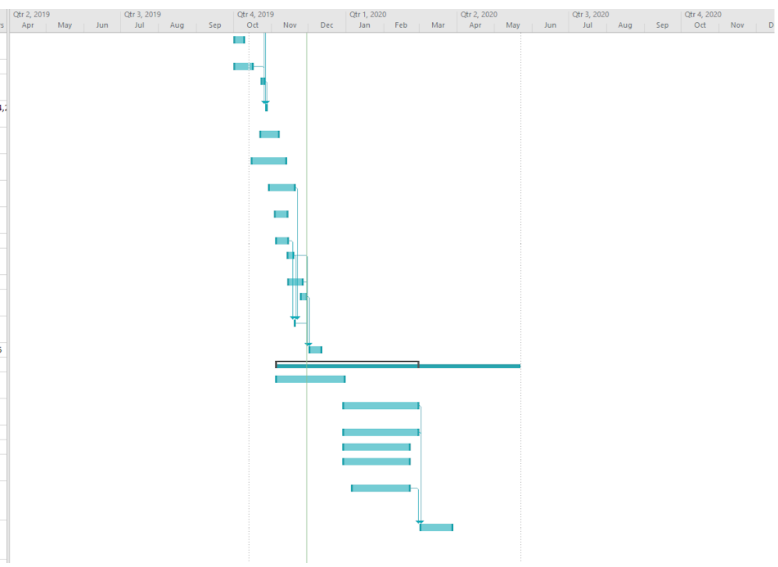
c. PT suggested to apply heat underneath the joint, around the armpit region
d. Also, suggested that he heats the neck muscles; probably not possible for us

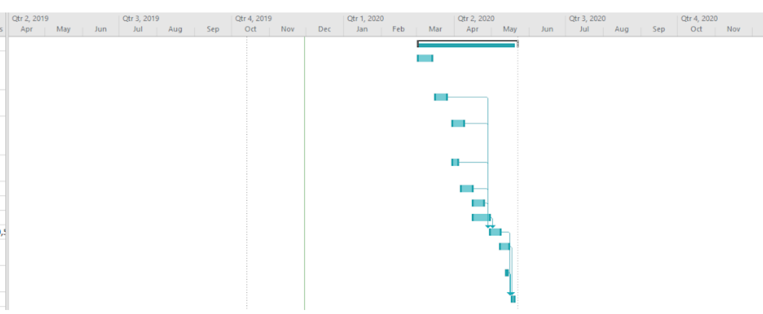
5. How often will the patient do therapy to optimize its effects?
   a. Frozen shoulder really never goes away
   b. Suggest 4 weeks of physical therapy (with instructions), either 3 times/week or 2 times/week
   c. Afterwards, encourages patient to enroll in a home-based exercise program

K: Gantt Chart

	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1		**Design Input Research**	**45 days**	**Mon 6/17/19**	**Fri 8/16/19**	
2		Research Information about Adhesive Capsulitis and Current Treatments	14 days	Mon 6/17/19	Thu 7/4/19	
3		Obtain Literature Sources about thermal therapy and ROM	30 days	Thu 7/4/19	Wed 8/14/19	
4		**Design Inputs**	**38 days**	**Wed 8/28/19**	**Fri 10/18/19**	
5		Initial Draft of Design Requirements	4 days	Wed 8/28/19	Mon 9/2/19	
6		Three Design Requirements and Specifications Class Review	1 hr	Tue 9/3/19	Tue 9/3/19	5
7		Complete Design Requirements	8 days	Tue 9/3/19	Thu 9/12/19	
8		Machine Shop Meeting with Joe	1 day	Tue 9/17/19	Tue 9/17/19	
9		Design Requirements Presentation	2 hrs	Fri 9/13/19	Fri 9/13/19	5,6,7
10		Physical Therapist Meeting for Design Specifications Feedback	1 day	Wed 9/25/19	Wed 9/25/19	
11		Update Design Requirements with Specifications	12 days	Wed 9/18/19	Thu 10/3/19	
12		Initial Website Template	4 days	Wed 9/4/19	Mon 9/9/19	
13		Device Constraints	8 days	Mon 9/16/19	Wed 9/25/19	
14		Device Standards	11 days	Wed 9/25/19	Wed 10/9/19	
15		**Device Design**	**56 days**	**Wed 9/25/19**	**Wed 12/11/19**	
16		Heating Component Selection	15 days	Wed 9/25/19	Tue 10/15/19	
17		ROM System Selection	15 days	Wed 9/25/19	Tue 10/15/19	
18		Microcontroller Unit Selection	13 days	Wed 9/25/19	Fri 10/11/19	
19		Device Material Selection	6 days	Mon 9/30/19	Mon 10/7/19	
20		Battery Selection	8 days	Mon 9/30/19	Wed 10/9/19	
21		Component Decision Matrix	7 days	Wed 10/16/19	Thu 10/24/19	16,17,18,19,2
22		Brainstorming	5 days	Wed 9/25/19	Tue 10/1/19	
23		Create Preliminary Anthropometric Sketches	6 days	Wed 10/2/19	Wed 10/9/19	
24		Calculate Initial Budget	11 days	Wed 10/2/19	Wed 10/16/19	
25		Select three device designs	2 days	Thu 10/24/19	Fri 10/25/19	
26		Interim Design Review	3 hrs	Mon 10/28/19	Mon 10/28/19	11,21,22,24,2
27		Safety Training & Survey	11 days	Wed 10/23/19	Wed 11/6/19	
28		Select possible components to order for pre-testing	20 days	Wed 10/16/19	Tue 11/12/19	
29		Complete Component Material List	15 days	Wed 10/30/19	Tue 11/19/19	
30		Draft Verification Testing Protocols	8 days	Mon 11/4/19	Wed 11/13/19	
31		Create SolidWorks Sketches	8 days	Tue 11/5/19	Thu 11/14/19	
32		Determine Final Design	3 days	Thu 11/14/19	Mon 11/18/19	
33		Submit Project Abstract	8 days	Fri 11/15/19	Tue 11/26/19	
34		Submit Final Report Draft	5 days	Mon 11/25/19	Fri 11/29/19	
35		SP I Final Presentations	3 hrs	Wed 11/20/19	Wed 11/20/19	29,31,32
36		Final Report	8 days	Mon 12/2/19	Wed 12/11/19	32,33,34,35
37		**Build Prototype**	**84 days**	**Tue 11/5/19**	**Fri 2/28/20**	
38		Order Initial Materials to Start Building	40 days	Tue 11/5/19	Mon 12/30/19	
39		Build Thermal Therapy System	45 days	Mon 12/30/19	Fri 2/28/20	
40		Build ROM system	45 days	Mon 12/30/19	Fri 2/28/20	
41		Build phone application	40 days	Mon 12/30/19	Fri 2/21/20	
42		Develop Software Database	40 days	Mon 12/30/19	Fri 2/21/20	
43		Integrate Software Components with Device using Microcontroller Unit	35 days	Mon 1/6/20	Fri 2/21/20	
44		Integrate Device Wrap/Sleeve Material with components	20 days	Mon 3/2/20	Fri 3/27/20	39,40,43
45		**Prototype Testing**	**60 days**	**Mon 3/2/20**	**Fri 5/22/20**	
46		Finalize Verification and Validation Testing Protocols	10 days	Mon 3/2/20	Fri 3/13/20	
47		Device Temperature Testing	8 days	Mon 3/16/20	Wed 3/25/20	
48		ROM Angle Verification Testing in Flexion, Extension, Rotation	8 days	Mon 3/30/20	Wed 4/8/20	
49		Software Algorithm Verification Testing	5 days	Mon 3/30/20	Fri 4/3/20	
50		Material Testing	8 days	Mon 4/6/20	Wed 4/15/20	
51		Validation Testing	7 days	Thu 4/16/20	Fri 4/24/20	
52		Data Analysis	10 days	Thu 4/16/20	Wed 4/29/20	
53		SP II Final Presentation	7 days	Thu 4/30/20	Fri 5/8/20	47,48,49,50,5
54		Submit Final Report for SP II	6 days	Fri 5/8/20	Fri 5/15/20	
55		Create Final Poster for COSA	2 days	Wed 5/13/20	Thu 5/14/20	
56		Commencement	2 days	Mon 5/18/20	Tue 5/19/20	53,54,55

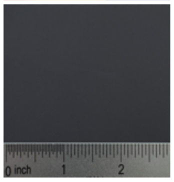






L: Material List/Decision Matrices

Textile Selection Matrix



	Cost	Weight	Ease of Cleaning	Other
Polyester Ripstock 200 Denier (Per Yard)	3.95 per yard^2	6.6 oz per yard^2	Machine Washable	
Heat-Sealable Coated Nylon Taffeta (Per Yard)	$14.95 per yard^2	4.3 oz per yard^2	Machine Washable	Waterproof after heat-sealing
Polypropylene 1 inch Strap	$0.20 per foot	.23 oz per foot	Machine Washable	300lb working load

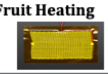
Physical Design Matrix

	Adjustability	Sizing	Fit	Other
Sleeve	Less adjustable	More sizes necessary for proper fitment	Secure on the arm	More material required
Holster with separate arm band	Great adjustability	One size fits most	Heating component well-secured	Minimum shoulder movement inhibition

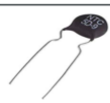
Physical Design Matrix

	Weight	ROM limitation	Adjustment	Exercise inhibition
Physical Brace with ROM lockouts	Larger device, would add weight to the arm	Mechanical stops ensure user does not overextend	More difficult to set range of motion stops	Components will add a slight amount of resistance
Digital monitor and warning system	Minimal weight on the arm	Vibratory and auditory feedback prevents overextension	Easy for PT to adjust ROM limits	Allows for complete, uninhibited shoulder movement when desired

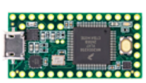
Heating Element Selection Matrix - Carbon Fiber (Optimal)

	Flexibility	Temperature Range (°C)	Heating Mechanism	Estimated Power (W) or Power Density (W/cm^2)	Estimated Thermal Conductivity (W/m·K)	Unit Price ($)
Carbon Fiber Heater Tape 	Yes	-20 to 400	Heat Diffusive	1.1 to 28.6 W	0.5 to 3	4.40/ft
Polyimide Heater Sheets 	Yes	-195 to 200	Heat Diffusive	0.8 to 7.8 W/cm^2	0.17 (100°C)	5 to 20
AdaFruit Heating Pad 	Yes	40 to 130	Heat Diffusive	2.5 to 3.8 W	0.2	3.95
Peltier System 	No	Δ T-max: 50 to 123	Heat Pump; Needs Heatsink	2 to 133 W	0.025 to 1.5	13 to 60

Temperature Sensor Matrix - Thermistor (Optimal)

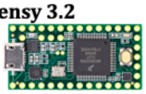
	Temperature Range (°C)	Accuracy (°C)	AD Converter	Response Time (seconds)	Unit Price ($)
NTC Thermistor 	-100 to 325	± 0.05 to 1.5	Yes	0.12 to 10	0.40 to 3.60
RTD 	-200 to 650	± 0.1 to 1	Yes	1 to 50	13 to 75
Digital I2C 	-55 to 125	± 0.1 to 2	No	5	2 to 15

Microprocessor Selection Matrix - Nano (Optimal)

	Dimensions (mm)	Process or & Rate	Estimated Current Draw* (mA)	Available Pins	Communication Support
Teensy 3.2 	36 X 18	Cortex M4 72 MHz	Unknown	34 Digital 21 Analog	I2C SPI
Raspberry Pi Zero W 	65 X 30	Broadcom 1 GHz	160	40 GPIO (Digital)	I2C SPI
Arduino Nano 33 BLE 	45 X 18	Cortex M4 64 MHz	34.8	16 Digital 9 Analog	I2C (+ Fast Mode) SPI

*Current Draw is estimated assuming that device is idle, bluetooth is on, and the IMU is on (if applicable)

Microprocessor Selection Matrix (cont'd)

	IMU Included	Connectivity	Documentation Availability	Total Price ($)
Teensy 3.2 	No	None	Poor	23.63
Raspberry Pi Zero W 	No	WiFi Bluetooth	Good	19.52
Arduino Nano 33 BLE 	Yes Gyro Out: 104 Hz Accel Out: 104 Hz	Bluetooth	Good	25.76

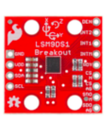
Database Selection Matrix - Firebase (Optimal)

	Storage capacity	Accessibility	Ease of use	Cost ($)
AWS	Over 10gb	Cloud	High	Under 10 per month
Firebase	Over 10gb	Cloud	High	Free under 10gb storage usage

IMU Overview - LSM9DS1

IMU - An electronic device that measures force, angular rate, and orientation through the use of gyroscope(s), accelerometer(s), and magnetometer(s).

Device onboard the MPU → Easier syncing of communication

	Gyroscope	Accelerometer	Total DOF	Current Draw (mA)	Notable Benefits	Price ($)
LSM9DS1 	Yes, 3-Axis ± 245, 500, 2000 °/s	Yes, 3-Axis ±2, 4, 8, 16 g	9-Axis	4.6	Included on Nano 33 BLE	38.56

M: Financial Budget

Item	Company	Quantity	Part #/Stock #	Unit Cost ($)	Shipping Cost ($)	Special handling (eg hazards)	Total Cost ($)	Purchase Date	Expected Delivery Date	Actual Delivery Date	Company Website	Notes
Carbon heater tape 10 ft length x 1.73 in width	CarbonHeater	1	CT44	44.00	4.99		48.99				https://www.amazon.com/Carbon-heater-tape-length-width/dp/B077CBFVLB/ref=sr_1_5?gclid=EAIaIQobChMI8ebe1NCy5QIVkovICh2aAQoIEAAYAiAAEgIbufD_BwE&hvadid=295268902466&hvdev=c&hvlocphy=9003964&hvnetw=g&hvpos=1t2&hvqmt=e&hvrand=9690366112974871368&hvtargid=kwd-300416211526&hydadcr=954_9642223&keywords=carbon+heater+tape&qid=1571842248&sr=8-5	
Polyester Ripstock 200 Denier (Per Yard)	Ottertex	2	DWR	3.95	6.99		14.89				https://www.fabricwholesaledirect.com/products/polyester-ripstop-fabric?variant=1634355970060&gclid=CjwKCAjw5_DsBRBPEiwAIEDRW7KPR-XZWhwPwjLtzwmSx0gA-jKwBH7OMX4a19xBSiZWk6Dyc-g6uRoCUXcQAvD_BwE	
Heat-Sealable Coated Nylon Taffeta (Per Yard)	Seattle Fabrics	2	FHST	14.95	18.20		48.10				https://www.seattlefabrics.com/60-Heat-Sealable-Coated-Nylon-Taffeta-1495-linear-yard_p_31.html	
Side Release Buckle-1 inch Black	Strapworks	2		0.85	4.56		6.26				https://www.strapworks.com/ProductDetails.asp?ProductCode=SRBSA&CartID=1	
Heavyweight Polypropylene 1 inch	Strapworks	10		0.20	4.99		6.99				https://www.strapworks.com/ProductDetails.asp?ProductCode=HWP1&CartID=2	
Heavy Duty Z46 And Nylon Thread	Seattle Fabrics	1	T-46Z-BLACK	5.49	4.06	4.00	13.55				https://www.seattlefabrics.com/Heavy-Duty-Z46-and-Z69-Nylon-Thread_p_861.html	
ARDUINO NANO	Arduino	1	33 BLE	19.00	6.76		25.76				https://store.arduino.cc/usa/nano-33-ble	
IMU	Sparkfun	1	LSM9DS1	15.95	6.66		22.61				https://www.digikey.com/catalog/en/partgroup/lsm9ds1/50138?utm_adgroup=xGeneral&slid=&gclid=EAIaIQobChMI9_aX0JKh5QIVk4vICh06Eg-mEAAYASAAEgIfpPD_BwE	
NTCLE101E3103JB0 NTC Thermistor	Digikey	3	BC3403-ND	0.99	8.99		11.96				https://www.digikey.com/product-detail/en/NTCLE101E3103JB0/BC3403-ND/7101800/?itemSeq=306607657	
Polymer Lithium-ion Battery	Adafruit industries	1	785060	14.95	9.00		23.95				https://www.alliedelec.com/product/adafruit-industries/328/70928240/?gclid=EAIaIQobChMIvanltPqc5QIVAniGCh0rMQRaEAQYECABEgKRvvD_BwE&gclsrc=aw.ds	
TSYS01-1 Digital IC Temperature Sensor	Digikey	2	G-NICO-018	4.59	8.99		18.17				https://www.digikey.com/product-detail/en/G-NICO-018/223-1134-ND/3736309/?itemSeq=306578815	
Vibration Motor	Sparkfun	1	ROB-08449	2.15	6.66		8.81				https://www.sparkfun.com	
Mini Speaker	Sparkfun	1	COM-07950	1.95	6.66		8.61				https://www.sparkfun.com	
Total for Project							258.65					

Budget:	500
Total Cost:	$258.65
Difference:	$241.35

Who ordered it?	Advisor	Item	Company	Quantity	Unit Cost ($)	Shipping Cost ($)	Total Cost ($)	Purchase Date	Expected Delivery Date	Actual Delivery Date	Item Link
Danny	Adegbege	Arduino Nano 33 BLE	Arduino	1	19	4.32	23.32	10/31/2019	11/1 - 11/8	11/15	https://store.arduino.cc/usa/nano-33-ble
Javier	Adegbege	Vibration Motor	Sparkfun	1	2.15	6.66	8.81	10/31/2019	11/4 - 11/14	11/15	https://www.sparkfun.com/products/7950
Javier	Adegbege	Mini Speaker	Sparkfun	1	1.95	0	1.95	10/31/2019	11/4 - 11/14	11/15	
Shruthi	Wagner	Carbon Heater Tape	CarbonHeater	1	44	4.99	48.99	1/28/2020	2/26-3/17		https://www.amazon.com/Carbon-heater-tape-length-width/dp/B077CBFVLB/ref=sr_1_3?keywords=carbon+heater+tape&qid=1580259764&s=industrial&sr=1-3
Geoff	Wagner	(5 pairs) DC Power Pigtail Male & Female Barrel Jack 6-Inch Wire 5.5mm x 2.1mm	JacobsParts	1	6.55	0	6.55	3/10/2020			https://www.amazon.com/JacobsParts-Pigtail-Security-Voltage-Applications/dp/B07N8GCH6S/ref=asc_df_B00R1XZ09K/?tag=hyprod-20&linkCode=df0&hvadid=216499414469&hvpos=&hvnetw=g&hvrand=308911179321700628&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9003964&hvtargid=pla-350998796055&th=1
Geoff	Wagner	Battery Lithium-Ion	Allied	1	30.29	9	39.29	3/10/2020			https://assets.alliedelec.com/v1556359324/Datasheets/66d0133dc05d5f961ff64ee2fdbd0204.pdf
Geoff	Wagner	DC Power Supply AC Adapter	Parts Express	1	6.97	9.54	16.51	3/10/2020			https://www.parts-express.com/12v-25a-dc-power-supply-ac-adapter-with-21-x-55mm-center-(-)-positive-plug--129-058
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
							0				
Total Amount for Project							145.42				

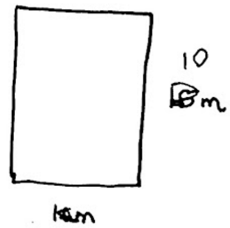
Budget	$500
Total Cost	145.42
Amount Remaining	$355

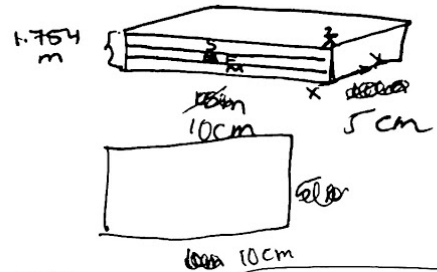
N: Thermal Analysis Calculations

Homogeneous, Isotropic, Slab configuration

Ansys WorkBench
Semi-inf Thermal Analysis
(Transient)
t=25mins

xy plane :





Skin layer : 2.54mm => 0.254 cm

Ti = 37°C @ t=0
(Initial condition)

ρ = 1109 kg/m³

Isotropic K: 0.442 W/mK

Specific Heat: 3391 J/kgK

Fat: 3mm => 0.3cm

Ti = 37°C @ t=0
(Initial condition)

ρ = 911 kg/m³

K = 0.21 W/mK

Cp = 2127 J/kgK

Muscle: 5mm => 0.5cm

ρ = 1090 kg/m³

K = 0.42 W/mK

Cp = 3421 J/kgK

O: Carbon Fiber Tape Testing Raw Data

Set Voltage = 3 V

Voltage (V)	Current (A)	Temperature (C)	Output Voltage (V)	Power (W)
3	1	28	1.38	1.38
3	1.5	31	2.07	3.105
3	2	39	2.58	5.16
3	2.5	41	3	7.5
3	3	53	3	9

Set Voltage = 8 V

Voltage (V)	Current (A)	Temperature	Output Voltage (V)	Power (W)
8	1	32	1.35	1.35
8	1.5	37	2.01	3.015
8	2	46	2.6	5.2
8	2.5	44	3.14	7.85
8	3	54	3.66	10.98

Set Voltage = 12 V

Voltage (V)	Current (A)	Temperature	Output Voltage (V)	Power (W)

12	1	32	1.33	1.33
12	1.5	35	1.98	2.97
12	2	43	2.59	5.18
12	2.5	50	3.12	7.8
12	3	61	3.61	10.83

P: IMU (LSM9DS1) CSV Raw Data

Time	Roll	Pitch
0.37	-0.45	-0.53
0.38	-0.46	-0.53
0.39	-0.47	-0.53
0.4	-0.47	-0.52
0.41	-0.48	-0.51
0.42	-0.49	-0.5
0.43	-0.49	-0.49
0.44	-0.49	-0.48
0.44	-0.49	-0.47
0.45	-0.48	-0.46
0.46	-0.47	-0.46
0.47	-0.47	-0.45
0.48	-0.47	-0.45
0.49	-0.47	-0.46
0.5	-0.46	-0.46

0.5	-0.46	-0.47
0.51	-0.46	-0.48
0.52	-0.45	-0.49
0.53	-0.45	-0.51
0.54	-0.44	-0.52
0.55	-0.44	-0.52
0.56	-0.44	-0.53
0.56	-0.43	-0.54
0.57	-0.43	-0.55
0.58	-0.44	-0.55
0.59	-0.44	-0.54
0.6	-0.45	-0.53
0.61	-0.46	-0.52
0.61	-0.46	-0.51
0.62	-0.47	-0.49
0.63	-0.47	-0.48
0.64	-0.46	-0.47
0.65	-0.46	-0.46
0.66	-0.46	-0.45
0.67	-0.45	-0.44
0.67	-0.45	-0.44
0.68	-0.44	-0.44
0.69	-0.44	-0.44

0.7	-0.43	-0.44
0.71	-0.43	-0.45
0.72	-0.44	-0.46
0.73	-0.43	-0.48
0.73	-0.43	-0.49
0.74	-0.43	-0.5
0.75	-0.43	-0.51
0.76	-0.42	-0.53
0.77	-0.42	-0.53
0.78	-0.42	-0.53
0.79	-0.43	-0.53
0.79	-0.43	-0.53
0.8	-0.45	-0.52
0.81	-0.42	-0.52
0.82	-0.39	-0.51
0.83	-0.35	-0.49
0.84	-0.65	-0.56
0.85	-0.53	-0.57
0.85	-0.42	-0.56
0.86	-0.4	-0.54
0.87	-0.38	-0.51
0.88	-0.31	-0.5
0.89	-0.2	-0.46

0.9	-0.11	-0.46
0.91	0.04	-0.46
0.91	0.12	-0.47
0.92	0.11	-0.44
0.93	0.21	-0.4
0.94	0.37	-0.42
0.95	0.63	-0.45
0.96	0.86	-0.53
0.97	1.17	-0.61
0.97	1.12	-0.54
0.98	1.28	-0.47
0.99	1.49	-0.38
1	1.79	-0.37
1.01	2	-0.35
1.02	2.29	-0.36
1.03	2.56	-0.3
1.03	2.72	-0.33
1.04	2.85	-0.34
1.05	3.05	-0.38
1.06	3.23	-0.42
1.07	3.37	-0.44
1.08	3.4	-0.43
1.08	3.56	-0.45

1.09	3.59	-0.43
1.1	3.62	-0.41
1.11	3.67	-0.46
1.12	3.7	-0.51
1.13	3.62	-0.51
1.14	3.51	-0.52
1.14	3.51	-0.57
1.15	3.46	-0.61
1.16	3.45	-0.72
1.17	3.37	-0.81
1.18	3.01	-0.79
1.19	2.97	-0.91
1.2	3.08	-1
1.2	3.05	-0.96
1.21	3.05	-1.02
1.22	3.06	-1.05
1.23	3.03	-1.1
1.24	3.12	-1.19
1.25	3.05	-1.16
1.26	2.94	-1.06
1.26	2.85	-0.93
1.27	2.69	-0.83
1.28	2.47	-0.64

1.29	2.23	-0.46
1.3	2.09	-0.36
1.31	2.01	-0.34
1.31	1.86	-0.31
1.32	1.67	-0.25
1.33	1.33	-0.09
1.34	1.04	0.05
1.35	0.94	0.06
1.36	0.73	0.16
1.37	0.57	0.21
1.38	0.4	0.27
1.38	0.29	0.3
1.39	0.2	0.31
1.4	0.09	0.34
1.41	0.06	0.37
1.42	-0.06	0.46
1.43	-0.32	0.63
1.44	-0.65	0.81
1.44	-1.32	1.31
1.45	-1.98	1.8
1.46	-2.52	2.31
1.47	-2.93	2.73
1.48	-3.21	3.07

1.49	-3.37	3.34
1.5	-3.47	3.55
1.5	-3.43	3.74
1.51	-3.56	4.03
1.52	-3.87	4.43
1.53	-4.26	4.9
1.54	-4.72	5.4
1.55	-5.21	5.94
1.56	-5.63	6.44
1.56	-5.94	6.9
1.57	-6.21	7.35
1.58	-6.36	7.82
1.59	-6.49	8.27
1.6	-6.56	8.72
1.61	-6.8	9.24
1.61	-7.19	9.89
1.62	-7.71	10.58
1.63	-8.19	11.25
1.64	-8.65	11.93
1.65	-8.96	12.52
1.66	-9.15	13.07
1.67	-9.28	13.59
1.68	-9.36	14.1

1.68	-9.42	14.6
1.69	-9.59	15.16
1.7	-9.92	15.8
1.71	-10.41	16.41
1.72	-10.71	17.12
1.73	-11.06	17.98
1.73	-10.96	18.76
1.74	-11.06	19.5
1.75	-11.05	20.32
1.76	-11.22	21.13
1.77	-11.44	21.74
1.78	-11.79	22.66
1.79	-12.04	23.21
1.79	-12.3	23.83
1.8	-12.6	24.43
1.81	-12.82	24.95
1.82	-12.79	25.6
1.83	-12.6	26.47
1.84	-12.55	27.73
1.85	-12.58	29.38
1.85	-12.98	31.01
1.86	-13.38	32.53
1.87	-13.69	33.83

1.88	-14.16	34.97
1.89	-14.24	35.94
1.9	-14.36	36.82
1.91	-14.43	37.57
1.91	-14.47	38.13
1.92	-14.33	38.58
1.93	-14.2	39
1.94	-13.96	39.46
1.95	-13.7	39.98
1.96	-13.52	40.54
1.97	-13.32	41.16
1.97	-13.14	41.86
1.98	-13.1	42.48
1.99	-13.05	43.03
2	-12.91	43.6
2.01	-12.78	44.22
2.02	-12.72	44.81
2.03	-12.65	45.42
2.03	-12.57	46.1
2.04	-12.46	46.75
2.05	-12.39	47.47
2.06	-12.32	48.25
2.07	-12.28	49.1

2.08	-12.35	49.91
2.09	-12.41	50.73
2.09	-12.5	51.57
2.1	-12.63	52.4
2.11	-12.75	53.13
2.12	-12.78	53.97
2.13	-12.88	54.79
2.14	-12.92	55.55
2.14	-12.85	56.3
2.15	-12.76	57.19
2.16	-12.71	57.93
2.17	-12.61	58.6
2.18	-12.51	59.4
2.19	-12.48	60.19
2.2	-12.43	60.94
2.2	-12.43	61.71
2.21	-12.44	62.47
2.22	-12.44	63.1
2.23	-12.41	63.64
2.24	-12.34	64.29
2.25	-12.31	64.99
2.26	-12.33	65.58
2.26	-12.39	66.15

2.27	-12.47	66.67
2.28	-12.47	67.14
2.29	-12.48	67.6
2.3	-12.43	68.21
2.31	-12.35	68.81
2.32	-12.27	69.41
2.32	-12.26	69.96
2.33	-12.39	70.29
2.34	-12.48	70.6
2.35	-12.44	70.99
2.36	-12.48	71.39
2.37	-12.42	71.88
2.38	-12.27	72.45
2.38	-12.15	72.97
2.39	-12.05	73.44
2.4	-11.94	73.87
2.41	-11.9	74.25
2.42	-11.95	74.52
2.43	-11.88	74.88
2.44	-11.74	75.29
2.44	-11.69	75.57
2.45	-11.6	75.9
2.46	-11.49	76.22

2.47	-11.46	76.38
2.48	-11.42	76.59
2.49	-11.27	76.92
2.5	-11.11	77.18
2.5	-11.07	77.32
2.51	-10.96	77.55
2.52	-10.87	77.69
2.53	-10.85	77.72
2.54	-10.92	77.73
2.55	-11.03	77.71
2.56	-11.15	77.54
2.56	-11.31	77.28
2.57	-11.44	77.1
2.58	-11.38	77.03
2.59	-11.29	76.86
2.6	-11.32	76.65
2.61	-11.25	76.51
2.62	-11.17	76.33
2.62	-11.23	76.13
2.63	-11.21	75.98
2.64	-11.15	75.8
2.65	-11.16	75.51
2.66	-11.16	75.38

2.67	-11.06	75.27
2.67	-10.93	74.93
2.68	-10.86	74.55
2.69	-10.78	74.2
2.7	-10.66	73.8
2.71	-10.59	73.32
2.72	-10.65	72.88
2.73	-10.71	72.59
2.73	-10.75	72.23
2.74	-10.77	71.81
2.75	-10.78	71.5
2.76	-10.76	71.21
2.77	-10.73	70.94
2.78	-10.69	70.72
2.79	-10.48	70.65
2.79	-10.25	70.47
2.8	-10.08	70.44
2.81	-10.06	70.49
2.82	-10.1	70.56
2.83	-10.18	70.56
2.84	-10.26	70.53
2.85	-10.3	70.46
2.85	-10.31	70.35

2.86	-10.28	70.22
2.87	-10.25	70.07
2.88	-10.24	69.89
2.89	-10.23	69.84
2.9	-10.15	69.82
2.91	-10.08	69.82
2.91	-10.1	69.95
2.92	-10.22	70.09
2.93	-10.3	70.12
2.94	-10.32	70.09
2.95	-10.35	70.06
2.96	-10.37	70.05
2.97	-10.4	69.94
2.97	-10.42	69.85
2.98	-10.46	69.72
2.99	-10.5	69.79
3	-10.43	70.06
3.01	-10.31	70.36
3.02	-10.16	70.7
3.03	-10.1	71.06
3.03	-10.13	71.38
3.04	-10.17	71.66
3.05	-10.24	71.81

3.06	-10.36	71.9
3.07	-10.47	71.89
3.08	-10.51	71.69
3.09	-10.65	71.43
3.09	-10.75	71.32
3.1	-10.72	71.24
3.11	-10.65	71.07
3.12	-10.74	71.02
3.13	-10.88	71.13
3.14	-11.05	71.21
3.15	-11.19	71.23
3.15	-11.39	71.28
3.16	-11.67	71.36
3.17	-11.92	71.35
3.18	-12.16	71.36
3.19	-12.39	71.44
3.2	-12.49	71.7
3.2	-12.41	72.13
3.21	-12.3	72.58
3.22	-12.2	73.06
3.23	-12.12	73.51
3.24	-12.06	73.91
3.25	-12.17	74.13

3.26	-12.4	74.2
3.26	-12.67	74.21
3.27	-12.8	74.35
3.28	-12.85	74.55
3.29	-12.82	74.76
3.3	-12.74	74.99
3.31	-12.67	75.25
3.31	-12.69	75.38
3.32	-12.75	75.49
3.33	-12.86	75.58
3.34	-13.02	75.59
3.35	-13.2	75.56
3.36	-13.33	75.59
3.37	-13.52	75.54
3.38	-13.64	75.5
3.38	-13.59	75.62
3.39	-13.56	75.72
3.4	-13.69	75.54
3.41	-13.76	75.3
3.42	-13.71	75.09
3.43	-13.77	74.83
3.44	-13.63	74.49
3.44	-13.69	73.96

3.45	-13.7	73.54
3.46	-13.89	73.15
3.47	-14.13	72.52
3.48	-14.23	71.89
3.49	-14.29	71.4
3.5	-14.32	70.89
3.5	-14.05	70.35
3.51	-13.86	69.97
3.52	-13.64	69.76
3.53	-13.66	69.54
3.54	-13.54	69.4
3.55	-13.61	69.37
3.56	-13.85	69.34
3.56	-14.28	68.99
3.57	-14.64	68.63
3.58	-14.89	68.46
3.59	-15.05	68.42
3.6	-15.25	68.19
3.61	-15.41	67.83
3.62	-15.56	67.53
3.62	-15.64	67
3.63	-15.69	66.4
3.64	-15.74	65.76

3.65	-15.77	65.05
3.66	-15.7	64.25
3.67	-15.72	63.47
3.68	-15.97	62.64
3.68	-16.18	61.63
3.69	-16.31	60.57
3.7	-16.6	59.3
3.71	-16.76	58.1
3.72	-16.83	56.89
3.73	-16.81	55.79
3.73	-16.64	54.73
3.74	-16.31	53.8
3.75	-16.12	53.11
3.76	-16.25	52.42
3.77	-16.47	51.77
3.78	-16.72	51.26
3.79	-16.99	50.81
3.79	-17.22	50.38
3.8	-17.55	49.97
3.81	-17.85	49.59
3.82	-18.1	49.11
3.83	-18.16	48.53
3.84	-18.12	47.88

3.85	-18.13	47.18
3.85	-18.17	46.44
3.86	-18.06	45.63
3.87	-17.85	44.91
3.88	-17.82	44.2
3.89	-17.81	43.63
3.9	-17.93	43.2
3.91	-18.03	42.96
3.91	-18.19	42.84
3.92	-18.4	42.82
3.93	-18.54	42.96
3.94	-18.96	43.01
3.95	-19.63	42.59
3.96	-20	41.75
3.97	-20.02	40.66
3.97	-20	39.48
3.98	-19.92	38.3
3.99	-19.75	37.09
4	-19.49	35.91
4.01	-19.22	34.75
4.02	-18.99	33.61
4.03	-18.84	32.54
4.03	-18.71	31.51

4.04	-18.64	30.59
4.05	-18.69	29.71
4.06	-18.77	28.9
4.07	-18.66	28.03
4.08	-18.5	27.2
4.09	-18.36	26.37
4.09	-18.25	25.61
4.1	-18.19	24.92
4.11	-18.23	24.29
4.12	-18.4	23.75
4.13	-18.56	23.2
4.14	-18.68	22.68
4.15	-18.78	22.15
4.15	-18.75	21.59
4.16	-18.73	21.02
4.17	-18.7	20.45
4.18	-18.69	19.91
4.19	-18.72	19.36
4.2	-18.52	18.78
4.21	-18.4	18.19
4.21	-18.32	17.64
4.22	-18.31	17.18
4.23	-18.3	16.73

4.24	-18.28	16.27
4.25	-18.28	15.81
4.26	-18.24	15.34
4.26	-18.25	14.89
4.27	-18.43	14.53
4.28	-18.5	14.19
4.29	-18.36	13.8
4.3	-18.06	13.35
4.31	-17.99	13.05
4.32	-18.02	12.79
4.33	-18.06	12.5
4.33	-18.06	12.19
4.34	-17.93	11.79
4.35	-17.78	11.37
4.36	-17.65	10.97
4.37	-17.58	10.64
4.38	-17.37	10.29
4.38	-17.15	9.94
4.39	-16.84	9.51
4.4	-16.58	9.02
4.41	-16.32	8.52
4.42	-16.01	8.05
4.43	-15.85	7.71

4.44	-15.44	7.43
4.44	-15.22	7.24
4.45	-14.96	7.03
4.46	-14.76	6.9
4.47	-14.48	6.77
4.48	-14.16	6.61
4.49	-13.75	6.41
4.5	-13.3	6.18
4.5	-12.88	5.96
4.51	-12.48	5.74
4.52	-12.1	5.51
4.53	-11.58	5.28
4.54	-11.06	5.07
4.55	-10.57	4.9
4.56	-10.06	4.75
4.56	-9.65	4.6
4.57	-9.26	4.47
4.58	-8.79	4.28
4.59	-8.27	4.08
4.6	-7.75	3.86
4.61	-7.25	3.62
4.62	-6.64	3.34
4.62	-6.14	3.12

4.63	-5.27	2.88
4.64	-4.47	2.63
4.65	-3.79	2.38
4.66	-3.34	2.21
4.67	-2.95	2.06
4.68	-2.61	1.94
4.68	-2.28	1.82
4.69	-1.94	1.71
4.7	-1.64	1.61
4.71	-1.4	1.52
4.72	-1.18	1.44
4.73	-0.96	1.35
4.74	-0.82	1.27
4.74	-0.72	1.21
4.75	-0.62	1.16
4.76	-0.53	1.1
4.77	-0.45	1.05
4.78	-0.36	0.99
4.79	-0.29	0.94
4.8	-0.21	0.88
4.8	-0.14	0.83
4.81	-0.07	0.79
4.82	0	0.74

4.83	0.07	0.7
4.84	0.13	0.66
4.85	0.18	0.62
4.86	0.23	0.58
4.86	0.28	0.55
4.87	0.33	0.52
4.88	0.38	0.49
4.89	0.43	0.47
4.9	0.47	0.45
4.91	0.51	0.43
4.91	0.55	0.41
4.92	0.6	0.39
4.93	0.64	0.37
4.94	0.68	0.35
4.95	0.71	0.33
4.96	0.74	0.31
4.97	0.76	0.29
4.97	0.78	0.26
4.98	0.81	0.23
4.99	0.85	0.19
5	0.88	0.15
5.01	0.9	0.12
5.02	0.92	0.08

5.03	0.95	0.03
5.03	0.99	-0.02
5.04	1	-0.06
5.05	1	-0.1
5.06	1.01	-0.13
5.07	1.02	-0.16
5.08	1.03	-0.19
5.09	1.03	-0.2
5.09	1.04	-0.21
5.1	1.04	-0.22
5.11	1.03	-0.24
5.12	1.06	-0.24
5.13	1.08	-0.25
5.14	1.09	-0.27
5.15	1.1	-0.28
5.15	1.11	-0.29
5.16	1.11	-0.3
5.17	1.11	-0.31
5.18	1.11	-0.33
5.19	1.11	-0.36
5.2	1.1	-0.39
5.21	1.09	-0.41
5.21	1.11	-0.44

5.22	1.12	-0.46
5.23	1.14	-0.48
5.24	1.15	-0.5
5.25	1.15	-0.52
5.26	1.16	-0.53
5.27	1.15	-0.53
5.27	1.14	-0.54
5.28	1.13	-0.53
5.29	1.13	-0.52
5.3	1.12	-0.52
5.31	1.12	-0.51
5.32	1.12	-0.5
5.32	1.13	-0.49
5.33	1.13	-0.48
5.34	1.13	-0.47
5.35	1.13	-0.47
5.36	1.12	-0.47
5.37	1.12	-0.47
5.38	1.11	-0.48
5.38	1.11	-0.49
5.39	1.12	-0.5
5.4	1.13	-0.52
5.41	1.14	-0.53

5.42	1.15	-0.55
5.43	1.16	-0.57
5.44	1.16	-0.58
5.44	1.16	-0.59
5.45	1.15	-0.6
5.46	1.14	-0.61
5.47	1.13	-0.61
5.48	1.11	-0.61
5.49	1.11	-0.6
5.5	1.1	-0.58
5.5	1.1	-0.57
5.51	1.1	-0.56
5.52	1.11	-0.54
5.53	1.11	-0.53
5.54	1.11	-0.52
5.55	1.11	-0.51
5.56	1.12	-0.51
5.56	1.12	-0.5
5.57	1.12	-0.5
5.58	1.12	-0.5
5.59	1.12	-0.51
5.6	1.12	-0.53
5.61	1.12	-0.54

5.62	1.12	-0.55
5.62	1.13	-0.57
5.63	1.13	-0.58
5.64	1.13	-0.6
5.65	1.13	-0.61
5.66	1.13	-0.61
5.67	1.12	-0.61
5.68	1.11	-0.6
5.68	1.1	-0.59
5.69	1.1	-0.58
5.7	1.09	-0.56
5.71	1.09	-0.55
5.72	1.08	-0.54
5.73	1.08	-0.53
5.74	1.08	-0.52
5.74	1.09	-0.51
5.75	1.09	-0.5
5.76	1.1	-0.5
5.77	1.1	-0.49
5.78	1.11	-0.5
5.79	1.11	-0.51
5.8	1.11	-0.51
5.8	1.11	-0.53

5.81	1.11	-0.55
5.82	1.11	-0.56
5.83	1.12	-0.58
5.84	1.12	-0.59
5.85	1.12	-0.6
5.86	1.12	-0.61
5.86	1.12	-0.61
5.87	1.12	-0.62

Q: 510(k) Decision Pathway

REVISED:3/14/95

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

K

Reviewer:_

Division/Branch:

Device Name:

Product To Which Compared (510(K) Number If Known):_K963887 K897178

		YES	NO	
1.	Is Product A Device	Yes		If NO = Stop
2.	Is Device Subject To 510(k)?	Yes		If NO = Stop
3.	Same Indication Statement?		NO	If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		NO	If YES = Stop NE
5.	Same Technological Characteristics?		NO	If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?		NO	If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?	YES		If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?			If NO = Request Data
11.	Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use: The ACS Assist Device is intended to be used by patients in physical therapy for shoulder pain. The device provides heat to the afflicted area before and during the user's exercise regimen. Additionally, the device tracks the range of motion of the individuals arm and records the data in order to ensure the proper range of motion is achieved.

2. Device Description: The ACS Assist Device

This device contacts the skin through a biocompatible (100% cotton) cover which is washed between uses. It provides sustained electrical heat to the afflicted area through use of electric power. It accomplishes this using carbon fiber heating tape in the temperature range of predicate devices, as controlled by a microprocessor. Safety shutoff circuits ensure operation in the appropriate temperature range. An inertial motor unit is included to track the motion of the user's arm in combination with an application run by a Bluetooth-connected Android device.

See Review Memorandum

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

This device combines the two principles of the predicate device. It offers the same heating potential and use as the PT-Pac, while also offering the range of motion tracking similar to the Dynatron 360 Range of Motion Testing Device.

4. Explain why there is or is not a new effect or safety or effectiveness issue:

There is no new safety issue because this device

5. Describe the new technological characteristics:

This device utilizes a heating pad design, similar to that used in the PT-Pac (K963887). The only difference between these devices is the use of carbon fiber heating tape in place of thermoelectric tiles. It offers the same redundancy in terms of safety circuits and power supplies.

This device also utilizes a range of motion tracking system similar to that of the Dynatron 360 Range of Motion Testing Device (K897178). The difference between these devices is that this device utilizes an inertial motor unit to track the range of motion rather than a goniometer.

6. Explain how new characteristics could or could not affect safety or effectiveness:

The carbon fiber heating tape employs the same redundancy in safety circuits and utilizes the same low voltage DC power source, so there is no new safety or effectiveness issue posed by this inclusion.

The inertial motor unit is a similar electronic device which has similar power and connectivity as a goniometer, again ensuring there is no additional safety or effectiveness issue.

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

R: IRB Adult Consent Form

School of Engineering
Voice: 609-771-2081___

ADULT CONSENT FORM

Please read below with care. You can ask questions at any time, now or later. You can talk to other people before you sign this form.

Title: Adhesive Capsulitis Shoulder Assist Device
Study Number: (This you will find in your IRB Submission, i.e. FY-18-19-___)

Why is this study being done?
This study is being done to validate that:
- Subjects can put on the prototype without assistance since the intended users of the device will have a limited range of motion in one shoulder
- Subjects can feel the heating element of the prototype to assist them during physical therapy exercises
- The device does not hinder the subject while performing physical therapy exercises

What will happen while you are in the study?
- The investigators obtain consent from you so the study can begin.
- You will then put on the device prototype using one arm.
- You will turn on the device prototype and begin a 10-minute warm up period.
- You will begin a 15-minute stretching period consisting of pendulum exercises for five minutes, wall climbing stretch for five minutes, and back stretch for five minutes.
- After stretching is complete you will shut off the device prototype.
- You will remove the device prototype with one hand.
- You will be given a questionnaire asking you to grade several aspects of the device prototype.

Time: This study will take about 30 minutes.

Risks: You may feel discomfort in your shoulder due to the heating element of the device prototype.

Benefits: If this device prototype passes it validation it can be submitted through the Food and Drug Administration for further testing where it could possibly benefit physical therapy patients in our society.

Who will know that you are in this study? You will not be linked to any presentations. We will keep who you are confidential and anonymous.

You should know that New Jersey requires that any person having reasonable cause to believe that a child has been subjected to child abuse or acts of child abuse shall report the same immediately to the Division of Youth and Family Services.

Do you have to be in the study?
You do not have to be in this study. You are a volunteer! It is okay if you want to stop at any time and not be included in the study. You do not have to answer any questions you do not want to answer.

Your grade for the course will not be affected by your participation or non-participation in this study.

School of Engineering
Voice: 609-771-2081___

<u>Do you have any questions about this study?</u> Phone or email the Principal Investigator, Christopher Wagner, at 609-771-2081 or wagnerc@tcnj.edu.

<u>Do you have any questions about your rights as a research participant?</u> Phone or email the IRB Chair, Dr. Sandy Gibson, at 609-771-2136 or irbchair@tcnj.edu.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used of distributed for future research studies.

One copy of this consent form is for you to keep.

Statement of Consent
I have read this form and decided that I will participate in the project described above and have no past or present shoulder trauma that would otherwise interfere with the results of this study. Its general purposes, the particulars of involvement, and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time. My signature also indicates that I am 18 years of age or older and have received a copy of this consent form.

______________________	______________________	__________
Print your name here	Sign your name here	Date
______________________	______________________	__________
Name of Principal Investigator	Signature	Date

S: IRB Flyer Advertisement

Are you a healthy adult with no shoulder injuries?

Research Participants wanted.

- We are looking at how well a device prototype assists with physical therapy exercises.
- This study will take 30 minutes, during one session, at the STEM Building room 218 on the TCNJ Campus.
- Participants will perform pendulum, wall, and back stretches while wearing the device and be asked questions about their experience.

Shruthi Radhakrishnan, Daniel Hanna, Javier Piraneque, Ryan Desrochers, and Geoff Bartner, of the Adhesive Capsulitis Shoulder Assist Device Senior Project team are conducting this study. If you are interested in participating or have more questions, please contact them at (609) 771-XXXX or audiologystudy@tcnj.edu

This study has been approved by The College of New Jersey Institutional Review Board, TCNJ IRB #FY_________________

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