Gait Analysis Device for Elderly Fall Prediction

Sponsor: Apple Health Technologies

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Executive Summary

This document serves to outline the design process and final design for our project to address elderly independent living in collaboration with Apple. Included in this document is necessary academic literature of current fall risk assessments and descriptions of the current market of wearable gait analysis devices. Based on this research and data, we then outline a plan for design, manufacturing, prototyping, and testing a device to fulfill the original prompt given by our sponsors: create a device that will increase the ability of an aging loved one to live at home safely. This device is a wearable that collects gait data of elderly people and uses that data to predict their risk of falling. Key customer requirements include increasing elder independence, predicting fall risk, and detecting changes in gait and balance. This led to a number of engineering specifications, the most important of which being time of supervision of the elderly person, displacement of device with movement, and the reliability of the sensors to accurately measure metrics associated with gait. In order to achieve these targets, we developed a workflow to span the next two quarters.

We created morphology sketches based on four different functions we decided were necessary for our device to function and created three different concepts based off those functions. All three concepts were analyzed against engineering metrics, and a single concept was chosen: a shoe with built in ultrasonic sensors and an IMU for foot height and gait analysis. Concept sketches were designed to model how this concept would function using SolidWorks, and failure mode and effects analysis was performed to find potential failures before we finalized the device design in order to prevent them from being designed into the product. We also conducted failure mode and effects analysis in order to detect possible problems that could be designed into the device unintentionally and took steps to eliminate the possible risks.

We then created a detailed design that lists exactly what our prototype contains along with how it functions and looks. A prototype was built based on the revised manufacturing plan, circuit diagrams, and design parameters. This prototype was evaluated based on the detailed test plans that include sample sizes, test protocols and expected results. The purpose of these tests was to verify that our device functions in the way that is expected and to validate that the data we are collecting is accurate. Correlation coefficients were determined to be higher than 0.4 for acceleration data of the device IMU when compared to the iPhone IMU, meaning they are strongly correlated with each other and suggesting any algorithms used with the iPhone may also be used for our device. Correlation coefficients were even higher for angular velocity collection, being 0.7 and higher, leading to a very strong correlation between the two IMUs and furthers the algorithm suggestion. Additional tests were to ensure the safety of the user at all times. Data collection was analyzed and then statistical analysis was performed to determine whether the prototype fulfilled the goals presented by our sponsor. Analysis tests determined that IMU acceleration and angular velocity were capable of detecting changes in gait, but ultrasonic sensors were not able to do so.

We conclude with a discussion of learnings from the prototyping process and suggested future steps with a focus on development of a more substantial data analysis algorithm.

Introduction

Around 36 million elderly people fall each year in the United States, and of those, about 32,000 of them die [1]. Because of this phenomenon, many children and caregivers of these elderly people want them to be in a safe environment that will prevent this from occurring, which can include putting their elders in a retirement home or having to hire an expensive in-home caretaker. This is not preferable, as elderly people prefer to remain independent and in control of their own lives and want to see their families and friends as much as possible. We want to improve the quality of life of these individuals by creating a device that will allow them to function more independently at home. This will be done by warning them and their caregivers when they may be at risk of falling and potentially injuring themselves. For this device, our stakeholders are elderly people aged 65 and older, their caregivers and families, and our company sponsor for this project, Apple. This statement of work will present our overall research, objectives, and further plans on making this idea a reality.

The background will discuss a summary of our general observations, research, and interviews conducted relating to the project. It shall review current similar designs, relevant patents, and technical literature. It will also give a list of applicable industry codes, standards, and regulations. Our objectives include our original prompt from Apple as well as our interpretation of the problem statement and boundary definition. It will have our indications for use, customer requirements, quality function deployment, engineering specifications table, specification measurement techniques, and a discussion of high-risk specifications. Project management will explain our expected design process, present our key deliverables and project timeline, and discuss special testing we plan on performing. It will also include our Gantt chart and critical path, as well as the next steps we plan on taking to move the project forward.

The concept generation section will include our morphology, Pugh matrix, a model of our front runner design concept, and a FMEA analysis. The morphology is an overview of the brainstorming process for solutions to meet each required function of our device. The Pugh matrix is an evaluation and comparison of three different potential designs against a current leading product. The best design was chosen and modeled in SOLIDWORKS for our concept design and analyzing the failure modes of this leading model is done in the FMEA section.

We will present our detailed design, which is very similar to our concept design, but with more accurate proportions of the midsole of the shoe and showcasing the precise location of our sensors, data collection, and battery placement. We will describe the steps necessary in order for a manufacturer to build our prototype from the base components. We will also give a summary of the different test plans we intend to conduct on our prototype that will make sure that the engineering specifications we noted in our House of Quality are met to our satisfaction.

In order to test our shoe, we will outline a series of tests to characterize, verify and validate our sensors and the performance integrity of our device. This involves two wear tests, a consumer-focused assembly test, various bench-top evaluations to characterize forces, weights and dimensions of the prototype, and software tests to validate the Arduino code.

We will then perform a variety of statistical tests in order to validate our data collection. This will assist us in determining whether our prototype fulfills the engineering specifications we have determined. Finally, we will showcase the instructions for use of our device and how it would be used in a household as well as a discussion that will determine whether we have properly met our specifications and how this device might be used as a proof of concept in the future.

Background

<u>Summary of Observations and Customer Interviews</u>

From initial meetings with our Apple collaborators, it was clear that we needed to better understand what the daily, mundane issues are that elderly people face. To better understand our target population of elderly people, we drew on personal experience and conversations with our own elderly relatives and the things that are barriers to their independence. In combination with that, we used our own experience of what would give us peace of mind when thinking of our elderly loved ones living at home, independently. It was clear that mobility is an issue that elderly people struggle with; more specifically, the event and fear of falling. The event and fear of falling seems to not stem from running into obstacles or tripping over object, but instead is a general lack of stability and coordination when walking. A simple transition from tile to carpet or a slope in a sidewalk was enough change to trigger instability or a fall; and some falls occurred seemingly with no outside factors, the elderly person just lost stability while walking. We supplemented these personal perspectives with published research detailed the risk of falling that elderly people face in daily life, which is discussed later in this section.

In addition to exploring fall risk, one of the main ideas that came out of our initial interviews was the need for elderly to live independently. Both conversations with our Apple collaborators and with our elderly relatives centered on a need to not only empower the elderly person to feel safe and comfortable on their own, but also give their family members and caregivers the confidence that the elderly person would be able to live on their own with a minimal risk of falling. In order to fulfill this need, our device would need to be easily worn and used by the elderly person and collect data that was accurate enough to inspire confidence in caregivers and family members. Our identification of the need for both accessibility and accuracy are not new and has been discussed in published literature.

<u>Summary of Current Literature</u>

The assessment of fall risk and prediction is a strong area of interest in the medical field. The fields of occupational and physical therapy in particular have focused on developing reliable ways to assess patents' risk of falling. This includes the use of many different metrics such as the Morse Fall Scale, the Fall Risk Assessment and Screening Tool (FRAST) and the Tinetti scale [2] [3] [4]. These tests are usually performed in a clinical setting, with the therapist using many different balance, mobility and movement tests as indicators of overall fall risk. This kind of intense assessment is not feasible for all elderly people, all the time. However, research has shown that trends in gait parameters correspond to trends in Tinetti scores [4], and that gait parameters can be used as independent predictors of fall risk [5].

In terms of devices that are available to analyze gait, there are multitudes of commercial products and research prototypes that have had varying degrees of success. From our research, the majority of the commercial products are not targeted towards the elderly and are instead indicated for use by athletes and sports professionals (see **Table 1**). However, despite not being significant in a commercial aspect, various devices have been used to do gait analysis on our target demographics of elderly people and those at risk of falling. Many clinical research settings have made on-off prototype devices to conduct gait and balance studies. Involved combinations of accelerometers attached to the subject on the foot, ankle, shank, waist, chest, sternum, lower back, or a combination of multiple locations [6].

The combination of gait analysis devices with fall risk is the gap we hope to fill. There is promising data that supports the idea and consistent daily gait evaluation is more beneficial at predicting fall risk compared to occasional clinical assessments [7]. However, there is a challenge in validation when it comes to the accuracy and repeatability of data collected from wearables. The main conclusion from many studies was that the exploration of fall risk predictions is in a developmental phase and requires more study to validate [7] [6].

Summary of Current Devices and Patents

As discussed previously, wearable consumer devices that collect gait analysis data are not unprecedented. Some are worn on the legs, feet, or lower back; however, that is not always the case as some smart phones now can track steps and gather gait data. Additionally, one contrast between gait research devices and consumer devices is that academic researchers almost exclusively used accelerometers [6], while consumer devices tend to use a combination of sensing devices like pressure sensors and distance measurements in combination with accelerometers.

Table 1 shows various products that are currently available for researchers and consumers to access gait data. Most of these are targeted towards athletes, coaches and sports scientists, leaving the elderly consumers underserved in the realm of gait and motion analysis outside of a clinical setting. The Apple iPhone uses accelerometer data to calculate gait parameters while the phone is in the user's pocket or held in the hand. It is the only comparable device that is not an insole system. For consumer insoles there are the NURVV Insole, and the SALTED Insole, which are inserted into shoes and used for specific sport applications. The XSensor, pedar system and Kinesis GAIT system are all used in research settings and are therefore more accurate than the consumer systems, but usually less portable. For example, the pedar system requires the user to wear a data collection device like a backpack and is not rated for strenuous activity because the sensors are extremely sensitive. While these devices cover a wide range of data collection and sports uses, none of them are designed with the elderly in mind and could be improved to serve that population.

Table 1: Summary of Existing Devices.

Product	**Description**	**Target Users**
Apple iPhone	-calculates walking speed, stride length, double support time and walking asymmetry [gait document]	All consumers
XSensor	-force sensing insoles for high performance athletes and biomechanics research	Professional coaches and sports scientists
Pedar System – Novel	-force and pressure mapping technology for	Biomechanics researchers
NURVV Insole	-smart wearable insole for tracking running data when paired with phone (GPS)	Runners
SALTED Insole	-insole that tracks weight shifts	Golfers
Kinesis GAIT	-pair of sensors that tracks velocity, angles and distance to calculate gait statistics	Medical clinicians (Therapy and Rehab)

In addition to commercially available products, there are multitudes of patents that have been filed in the space regarding pressure sensing, custom insoles, distance measurements, and other methods of gait analysis. Examples of patents found that exhibit these traits are presented in **Table 2.**

Table 2: Summary of Existing Patents.

Patent Number	**Title**	**Description**
US 20220273193	Estimation Device, Estimation Method and Program	Calculates stride length and height by using angular relationships between toes and ankle
US 20220054926 A1	Physical Balance Training System Using Foot Sensors, Real-Time Feedback, Artificial Intelligence and Optionally Other Body Sensors	Uses combination of foot sensors to collect gait data, analyzes it with an AI framework and then gives the user haptic real-time feedback in order to correct gait abnormalities.
US 220220252470 A1	Pressure Sensing Device and Method	A novel pressure sensor using capacitance of non-metal materials to detect changes in force
US 20220265153 A1	Biological Information Gathering System and Wearable Device	A device that used the feet of the wearer to transmit electrical signals to a data collector
US 20220280329	Pad Comprising a Pressure Element	A pad attached to the floor that tracked how a person was walking and where they were putting pressure on their feet

<u>Regulatory Considerations</u>

In addition to being aware of previous devices in our space, it is important to be aware of the regulatory guidelines set. Current FDA guidance (as of September 2019) indicates that a wearable device like ours would be classified as a general wellness device. This device is not intended to treat or diagnose a disease and can therefore be included in this classification. Because of this, our device would not need to complete any specific pathways for FDA clearance or approval. Due to this, no industry codes in the NACIS Code 33911, Medical Equipment and Supplies, apply to our specific device. SIC 3613, Switchgear and Switchboard Apparatus, would likely need to be adhered to, as well as SIC 3643, Current-Carrying Wiring Devices.

Our device will continuously be collecting data from its users, which raises questions about protecting user data to prevent HIPPA violations. Current guidelines do not require consumer wearables to comply with HIPPA guidelines, however the FTC recently notified developers that collect health data that they are required to notify consumers if any health data has been breached.

Objectives

When first introduced to this project, the given prompt was to "develop and test a prototype device that will help an aging loved one live at home more safely". We interpreted this statement as, "identify a problem that is a limiting factor for aging loved ones to continue living at home independently and design a testable prototype to help mitigate this problem". The prompt allowed for creativity in selecting a problem to design a device around, and as a team we decided to focus on falling. Our project scope was then narrowed to have the prototype device detect an increase in fall risk. This project will involve the creation of a device to collect data related to fall risk. It will not set out with an aim to decrease fall risk or detect a fall.

Indications for Use

Our device is indicated for use by skeletally mature adults, primarily aged 65 years and older while walking on flat terrain, primarily indoors. The device will be temporarily worn externally and used to sense gait and balance abnormalities. The device will then alert the user or their caregiver of a potential increase in fall risk. This device is not intended to be used on rough terrain or in environments with water.

Development of Engineering Specifications

To determine the critical aspects of the device did literature research (outlined in a previous section), but also decided there was a need to get first-hand information from elderly people about the issues they had and the kinds of devices they were likely to use. To do this, we drew upon personal experience with our elderly relatives and were able to have causal conversations in order to get a general understanding of their daily lives. From these experiences we were able to confirm the importance of preventing falling for elderly people, as well as get a better understanding of the experience that elderly relatives have gone through before, during and after a fall. In addition to elderly people being important sources of input for our device, we looked to our sponsors at Apple for guidance about what kinds of products would be marketable and how they would hypothetically integrate with the existing line of Apple products.

From literature, family conversations and brainstorming with our sponsor, customer requirements were compiled and linked to engineering requirements using a House of Quality (HOQ). The full list of HOQ customer requirements can be seen in **Appendix 1**, but the most important and highest weighted requirements are: increasing elder independence, predicting fall risk, and detecting changes in balance and gait. These requirements are important to all consumers: sponsors, elders and caregivers.

Our customer requirements were unspecific and tended to be more qualitative in nature. In order to proceed with the design process, we created a list of engineering specifications, in **Table 3,** that transformed the customer requirements into quantitative metrics that we can use to guide the design of our device. The requirements will be validated by test (T), analysis (A), inspection (I) or similarity (S) to a preexisting device. One of the critical customer requirements was the increase in independence of the elderly person. To quantify this, we thought it was important to decrease the amount of time to set up the device, decrease the number of adjustments that are needed when the device is worn, and decrease the amount of time that the elderly person needs to be supervise or taught how to use the device. In addition to reducing theses time metrics, we thought it was important to increase battery life in order to reduce the amount of time that the elderly person might be without the monitoring of the device, and to decrease the amount of time needed to disassemble the device for charging.

The prediction of falls and detecting changes in balance and gait are more related to the sensors themselves. These types of specifications lead to specific engineering metrics that deal with the sensor type and sensitivity. These types of engineering metrics are calibration time and sensor density and sampling rate. These metrics are also tied together in the fact that sensors that are highly sensitive may require more calibration time but would ultimately give us more accurate data.

Table 3: Engineering Specifications.

Spec Number	Specification	Units	Risk	Target	Tolerance	Compliance
1	Time of Supervision	Hours/week	High	7	±7	A, I
2	Displacement with movement	mm	High	1	± 1	T, A, I
3	Production Cost	Dollars	Low	70	±30	A
4	Battery life	hours	Low	30	±18	T
5	Weight	g/shoe	High	400	±50	A
6	Number of parts	Number	Low	2	±1	I
7	Size range	Number of sizes	High	10	Min	I
8	Adjustments needed	Number/hour	High	1	Max	T, A
9	Force required for assembly	Newtons	Low	100	±50	T, A
10	Compression force	Kilograms	High	80	Max	T
11	Ground clearance	cm	Low	2	±0.5	I
12	Reliability of US on variable surfaces	cm	Low	1	±0.5	T,A
13	Correlation of Arduino IMU to iPhone data	none	Low	0.4	Min	T,A,S

After these specifications were developed, we created reasonable estimates of the tolerances for the corresponding values for the engineering metrics. In addition to tolerances, we ranked each specification based on how risky it was if the tolerances were not met. For more specific information on how each engineering specification was measured, see **Table 4.**

Table 4: Measurement of Each Engineering Specification.

Time of Supervision	This spec refers to the amount of time an elder needs to be looked after by a caregiver per week. This number can be estimated from caregiver experiences.
Displacement with movement	This is a very important spec referring to how much the device and sensors move out of place during regular use. Not only does this displacement have the ability to interfere with data collection, but a change in device fit or function may effect the safety of the user. This will be measured by analyzing any displacements after regular use during testing.
Production Cost	Reducing cost is valuable to all customers who will be using the device. This will be estimated using the material costs from each device.
Battery life	Reducing the need to charge the device will allow for easier general use, as well as limit data losses from an uncharged battery.
Weight	Adding excess weight is uncomfortable and can potentially be dangerous. This will be a test of the functional prototype's weight.
Number of parts	Simplifying the device is helpful for all customers, so the number of parts will try to be limited.
Size range	Number of sizes compatible will allow for the most appropriate and safe fit for the most users. This limits any safety hazards that a loose wearable device may cause.
Adjustments needed	Limiting how often the device needs to be adjusted will help the consumers be comfortable and will aid in accurate data collection. This will be a counted measurement during prototype testing
Force required for assembly	Elders should have the ability to assemble this device on their own, so no strenuous or excessive force should be needed to operate the device. The maximum force required during assembly will be measured and limited for this device.
Compression force	All critical components of the device, including the Arduino protection case and the US sensors, should be able to withstand the weight specified in order to not be crushed when the shoes are worn. This will be tested using compression machine.
Ground clearance	The US sensors need to have ground clearance in order to stay within the working distance and to reduce the likely-hood of damage when contacting the ground. The US sensors will be recessed as far into the midsole as possible to avoid this.
Reliability of US on variable surfaces	Because the device is indicated for use indoors, the US sensors need to work on a variety of surface types, like tile and carpets. The reliability of the data should be consistent across surfaces.
Correlation of Arduino IMU to iPhone	In order to ensure accurate data collection, the IMU of the Arduino should be calibrated to a known accurate source. In this case we will calibrate the iPhone.

The specifications that include the largest risk are the specifications that may affect a user's ability to walk comfortably and safely. These include displacement with movement, size ranges, weight, the adjustments needed and the compression force. If the device adds additional difficulties to walking because of bulk, shifting or moving parts, or subpar fitting, users wearing or testing the device could be under less safe walking conditions. Because of consumer testing restraints, tests will only be able to be performed on classmate peers, limiting the potential risks to users.

Project Management

Design Phase

Our design process was the focus of the fall quarter of 2022, with key deliverables of the morphology and concept sketches of our device and using those to create a conceptual model. Before the model was created, we used the process of a Pugh matrix to compare sensor types (like pressure, ultra-sonic and laser) and device types (an insole, shoe or external sensor attachment). Once a final idea was solidified, it was implemented into a 3D model. The modeling of this device was done using CAD in SOLIDWORKS. The modeling step was critical to our device because of the limited amount of space that is available in the sole of the shoe. However, it is important to note that our model was an estimation of the design for the device. One critical factor that could not be addressed until the build phase was the structure and properties of the foam of the shoe. Shoe foam is a closely guarded trade secret and we were unsure how our sensor placement would affect the overall stability of the shoe. The model was presented as a conceptual design review and followed by a critical design review report. This critical design was used to move forward with our prototyping and testing phases.

Key Deliverables

Throughout the design, build and test processes, there are certain deliverables that must be created to ensure that the project is on track. These deliverables are listed in **Table 5.** The timeline for accomplishing these deliverables is detailed in the following section where the Gantt Chart is discussed.

Table 5: Key Deliverables and Due Dates.

Due Date	**Deliverable**
09/28/2022	Background Research
	Indications for Use
10/03/2022	House of Quality
10/05/2022	Gantt Chart
	Budget Proposal
	Patent Search
10/10/2022	Statement of Work
10/17/2022	Morphology
10/19/2022	Pugh Chart
10/26/2022	Conceptual Model
	FMEA
10/31/2022	Conceptual Design Report
11/14/2022	Hazard and Risk Assessment
11/28/2022	Critical Design Report
02/02/2023	Test Plan Report and Presentation
02/14/2023	Ethics Analysis and Reflections
03/14/2022	Final Report and Presentation

Gantt Chart

Our project Gantt chart is split up into five main sections: plan, design, build, test, and present, which can be seen in **Appendix 2**. The planning phase included background research, interviews, objective identification, indications for use, customer requirements, and specification development. The design phase consists of our development of morphology and concept sketches, a conceptual model, a Pugh chart, and a conceptual design review. Following that, the milestones within the design phase were our critical design review report and presentation at the end of fall quarter, and the completion of our design notebooks for fall quarter. Once our design was finalized, ordered materials in order to have them before they were needed for building. Our build and test sections began at the same time, at the beginning of winter quarter. The building phase included both functional prototyping and material acquisition, while the testing phase declared our test plan, a variety of tests we intend to perform including fit, comfort, sensor, and fatigue testing of our prototype. Finally, our present phase included our creation of an expo poster draft, the final expo poster, and our last milestone of the project is our final report write up and poster expo itself.

The critical path of this project overall begins with our background research, which then leads to our morphology and concept sketches as well as our conceptual model. It then continues to our functional prototype, and into fit and comfort testing specifically. The last deliverable is our expo poster final draft, and our presentation at the poster expo.

Following our Gantt chart and critical path, our next steps for this project were creating our project planning meeting slides, working on our morphology and concept sketches, and our conceptual model. These took place over the following weeks and allowed us to start to work on our conceptional design and review. These concepts allowed us to envision what our final design might look like by brainstorming any and all ideas that we might have to solve our given problem of elder independence related to fall risk assessment and prevention. By coming up with as many ideas as possible, we gave ourselves the freedom to pick and choose the more achievable and specific concepts that will lead to an overall more creative and effective device.

Concept Generation

Morphology and Concept Sketches

When creating the concept morphology, we identified the main functions of our project to be data collection, data storage, an alert system, and the fit of the sensors in the overall device. For gathering gait and balance data, we researched ultrasonic, pressure, accelerometer, IMU and laser sensors. Ultrasonic and laser sensors would be used to gather foot height data, pressure sensors would be used to sense balance abnormalities, and accelerometer and IMU sensors could be used in conjunction with other sensors to gather more gait data. Our product then needed to be able to store data for analysis and having a built-in Arduino that could be accessed for extracting data was one of our possibilities, as well as transmitting data live to another device using Bluetooth. We recognized that creating a physical alert system for our device was likely going to fall outside the scope of this project, but in a finalized product this is a very crucial function. We identified haptics, auditory, visual, and phone notifications as possible ways of alerting users of increased fall risk. Finally, we needed to decide how our sensors were going to fit and interact with our users. We determined that insoles, socks, attachments on the front or back of the shoe, or building sensors into the sole of the shoe were potential options for our device. All these morphologies are shown in **Table 6**.

Table 6: Morphology Table with Sketches.

Morphology

Product: Fall Risk Prevention | Organization Name : Apple

Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Data Collection	Pressure	Accelerometer	IMU	Ultra-Sonic	ToF	Laser
Data Storage	Arduino USB	Bluetooth				
Alert System	Haptics	Auditory	Visual	Phone alert		
Fit	Insole	Attach front shoe	Built into shoe	Sock	Attach back shoe	

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The Mechanical Design Process

Designed by Professor David G. Ullman
Form # 15.0

With our morphologies completed, we individually designed concepts in which we attempted to find viable ways to combine all different types of concepts sketches into a device that fulfilled all functions. Concept 1 was an insole with pressure and accelerometer sensors that use an Arduino for data storage and a phone alert system. Concept 2 was an attachment for the front of a shoe with IMU and laser sensors that had a haptic alert system and use an Arduino for storage. Concept 3 used an IMU and ultrasonic sensors built into the sole of the shoe that used an Arduino for storage with an auditory alert system. We will be referring to them as Concepts 1, 2, and 3 as the report continues. Sketches of all three concepts are shown in **Figure 1**.

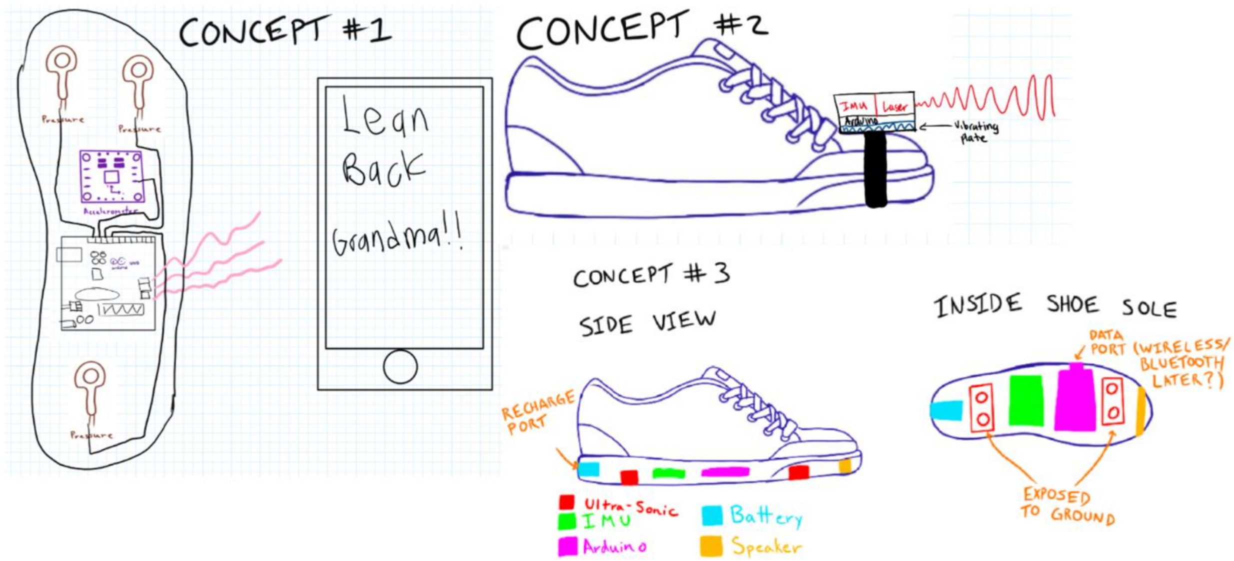

Figure 1: Sketches of Concepts 1, 2, & 3.

<u>Pugh Chart</u>

A Pugh chart evaluation was used to discover which of our three concepts would determine the front runner. We used a variety of metrics to analyze the different concepts, mostly taken from our House of Quality. Some of the metrics we rated weighted heavily include the number of adjustments needed, the time of supervision required by outside caregivers, and sensor sampling rate. These were weighted the highest in correlation with our customer requirements. The more important the requirement, the higher we weighted the criteria. For example, adjustments needed, and time of supervision were all very important to the independence of the elderly loved one, so those two were the most heavily weighted. We created a datum to compare each concept against as a baseline, this datum being the pedar system, which has been referred to as a similar data collection footwear device. We each individually created our Pugh charts, shown in **Appendix 3**, and then came together and discussed why we had made each our choices to come to a consensus on which concept fulfilled the most needs. The consensus Pugh chart is shown in **Table 7**. After looking at our weighted totals, the determined front runner of our analysis was Concept 3, the built-in option.

Table 7: Pugh Chart of Concepts 1, 2, & 3.

Issue: Choose a fall risk prevention design		Baseline - Pedar System	Concept #1	Concept #2	Concept #3
Set up Time	6	Datum	1	1	1
Time of Supervision	12		1	1	1
Sensor Sampling Rate	11		-1	-1	-1
Displacement with Movement	9		0	-1	1
Calibration Time	6		1	1	1
Production Cost	5		1	1	1
Battery Life	7		-1	-1	-1
Weight	6		1	1	1
Number of Parts	6		1	1	1
Size Range	7		0	1	-1
Adjustments Needed	13		0	-1	1
Force Needed to Assemble	5		-1	0	1
Sensor Density	7		-1	-1	-1
	Total		2	2	5
	Weighed Total		11	1	36

Concept Design

Our Pugh chart led us to decide that building ultrasonic and IMU sensors powered by an Arduino into the sole of the shoe would be our best course of action. The sole of the shoe provides natural protection for the sensors and makes this design stand out. This concept was modeled in SOLIDWORKS as seen in **Figures 2, 3, and 4** below. Ultrasonic sensors are placed in the toe and heel of the shoe to measure foot height data. The Arduino in this model is an Arduino UNO WiFi REV 2, which can transmit data via WiFi to a user's computer. This Arduino model also has a built-in IMU to obtain acceleration and foot angle data. The Arduino needed to be protected in a case to prevent bending. The Arduino is powered by a rechargeable 9V battery which then powers each sensor. The area surrounding the arch of the foot is left intentionally empty as that is where we expect the most bending in the shoe to occur.

Most analysis performed on the model was in relation to spacial relationships between different shoes and different parts. Through this, we decided that the Hoka Bondi 8 shoe was the closest to what we wanted, with a midsole going up to 40 mm. This would comfortably fit all our components within the housing of the foam.

We had thorough discussions about placement of our sensors and components. We decided that two ultrasonic sensors at the heel and the front of the foot would give us enough data to accurately determine fall risk increase. When thinking about placement we also avoided areas that tend to have high bending, like the forefoot. We also needed to fit in the battery and the Arduino within the sole, which required some dimensioning and rearrangement in order to get a good configuration. During our final concept generation, we determined that the battery could not feasibly be housed within the sole due to lack of space as well as risk of bending, so it was later moved to be attached to the laces on the top of the shoe.

We discussed among ourselves the distance sensors, and what would be required to get good data. The sensors we picked have a minimum distance sensor of 2 cm, which was potentially shorter than the actual distance to the ground from the sensor when the foot is on the ground. However, we decided that if the calibration of the shoe by the consumer had the baseline at a measurable level, we would be able to flag when the distance went below a determined percentage of the baseline height. If the distance sensors didn't trigger a change, that would likely be considered a flagged height, which would still produce the data we need for our shoe to help predict fall or tripping risk. This was based on the assumption that our ultrasonic sensors would be able to consistently receive and send accurate data to the Arduino, and then to the data collection webpage.

One of our main challenges with development and analysis was trying to make decisions based on estimated values. Because we do not have the shoes or the sensors on hand, we did our best to estimate how they would fit together based on dimensions we found online. One concern that came up was if the sensors would fit in the toe of the shoe (it curves up). The dimensions given for shoe midsole width are given as the max thickness and the drop from heel to mid-foot. There is no data on how much the toe curves up. This made us concerned that the data from the toe sensor may not be as accurate as the data from the heel sensor. This spurred a discussion as to whether we should change our design to ensure accuracy in the data collection. However, this change would make the shoe into more of a “platform” and less of a wearable walking shoe. The platform shoe would give us more area to place the sensors, but would be completely impractical to walk in. We discussed the pros and cons of better data collection versus practicality and wearability and decided that based on our past rankings the practicality was more important. We learned of the importance of going back to past documents to determine which requirements we have ranked as the most important.

This model will inform further development by giving us a starting point for sensor placement within the shoe. However, this could change due to the structural properties of the foam of the shoe. We did not know if this was a valid model until we received the shoes and were able to cut into them and see if our cuts compromised the structural integrity of the foam. The reason for this is because the shoe foam industry is very secretive about their foam properties, so while we could make educated guesses about various properties of it, we didn’t know for certain how it would behave with the sensors imbedded.

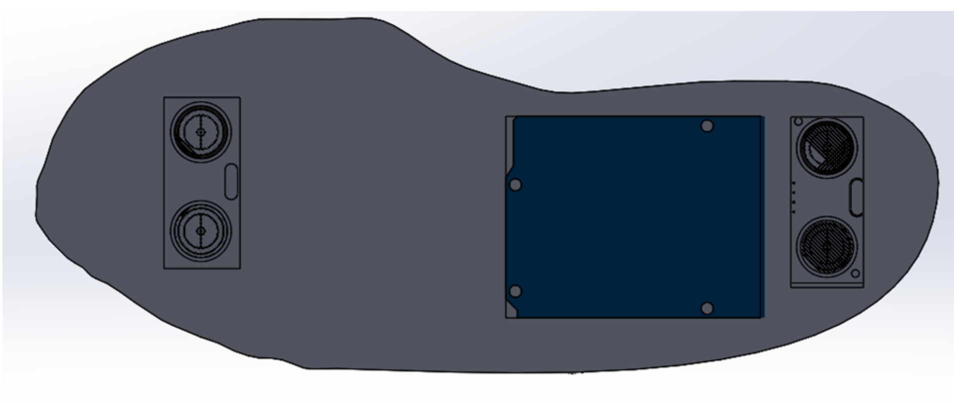

Figure 2: Image of the underside of the shoe sole.

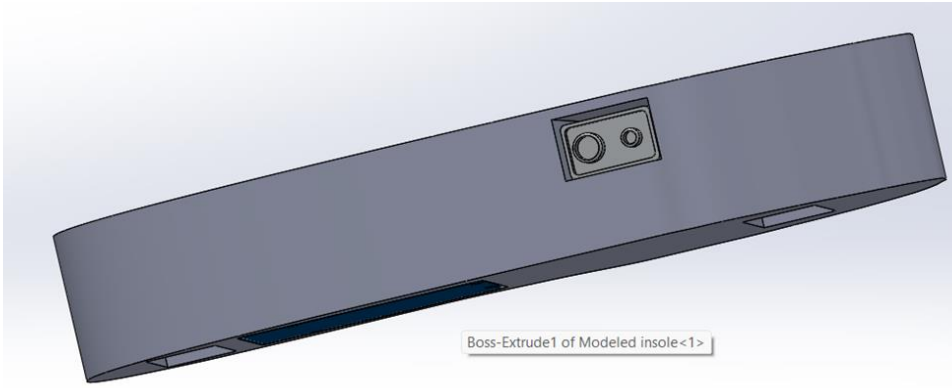

Figure 3: Image of the profile of the midsole.

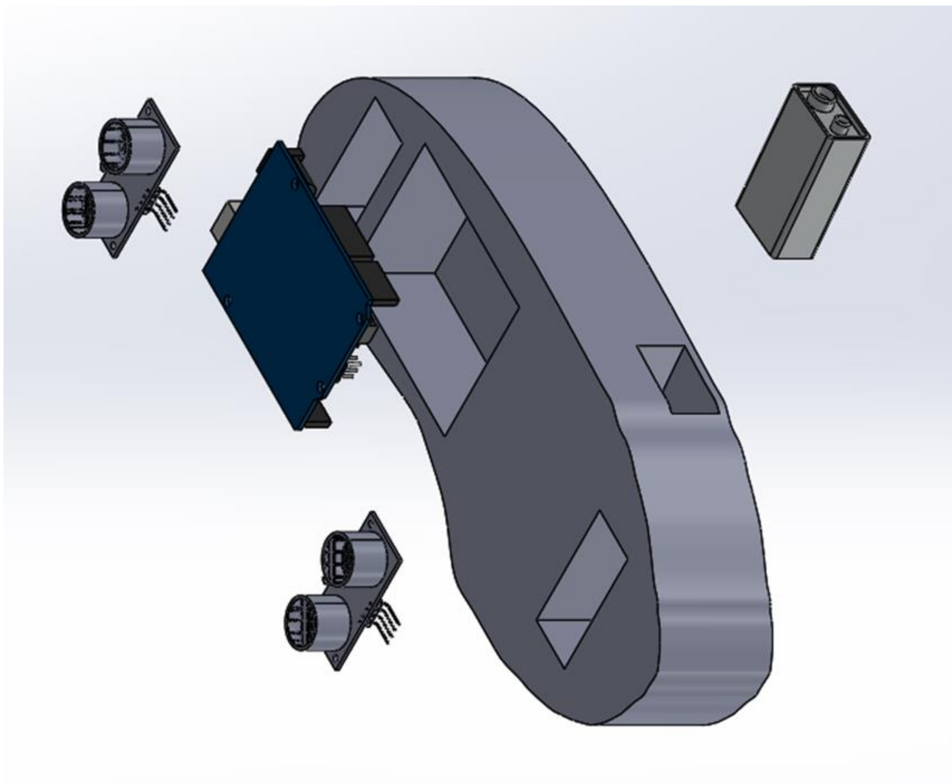

Figure 4: Exploded view of conceptual model.

<u>FMEA</u>

We created our failure modes and effects analysis (FMEA), shown in **Table 8**, based on a variety of problems we brainstormed. The main function failures were data collection, sensor protection, and wearability. We then identified potential failure modes, the effects of those failures, the cause of failure, and recommended actions. We also calculated risk priority numbers by rating the failure on a scale of 1 to 10 for occurrence, detection, and severity, and multiplied those together to get the risk priority number.

Within data collection, we thought that the failure modes were likely to be no power going to the sensor, the sensor being electronically overloaded, and the sensor being obstructed. Of these, the sensor being obstructed had the highest risk priority number due to it having a high occurrence and severity. Our recommended action for this was to make sure that the cover we used for the sensor was not able to be blocked or obstructed by debris from the ground or damaged by contact with the ground.

For sensor protection, failure modes to look out for include the sensor breaking or loosening. All of these would lead to a lack of or inaccurate data collection. The sensor breaking was the highest risk priority due to it having high severity and a middling detection rate. The recommended action for this was to make sure that the sensor is well protected within the shoe using a custom case and general protection in order to prevent too much force being applied to the sensor, whether that be from the ground or from the force exerted by the foot.

Wearability was also something we thought important, as our device must be worn for it to even work. We needed to make sure that the sensors didn't loosen and trip the wearer, or exposed parts from the inside didn't wear through the sole and damage the foot. Of these, foot damage scored the highest risk priority number, due to its high severity, and we decided that to prevent this we would design the shoe so there was no contact with the foot, and possibly add an extra insole for protection. In the final design, we decided to keep the wires running along the outside of the midsole in order to prevent both injuring the user through foot damage as well as prevention of wire breakage due to the fatigue of being continuously exposed to the pressure exerted by walking. Something we also considered was the necessity for sweat proofing and water proofing, as we want to make sure the sensitive components did not encounter moisture of any sort. Our solutions to this would be to use materials that are waterproof like plastic to protect our components and keep our sensors as far away from the ground as possible to prevent potential contact with water that may be present on the ground.

Table 8: Failure Mode & Effects Analysis (FMEA) of Fall Risk Prevention Device

FMEA

	Function Affected	Potential Failure Mode	Potential Effects of Faileure	OCC	DET	SEV	RPN	Cause of Failure	Recommended Actions	Responsible Person	Taken Actions
1	Data collection	No power to sensor	Sensor cannot collect data	5	3	8	120	Loose wire connection	Ensure secture connections, protect wires and reduce wire bending	EY	
2		Sensor is electronically overloaded	Break sensor, no data collected	3	3	8	72	Too much current	Add current limiters	EY	
3		Sensor is obstructed	Inaccurate data or no data collected	9	3	8	216	Dirty or scratched sensor or window	Do not use "skratchable" window material	EY	
4	Sensor Protection	Sensor is broken	No data collection	6	4	8	192	Too much force applied to sensor	Ensure sensor protection, within shoe or custom case	RH	
5		Sensor loosens	Inaccurate data collection	3	8	7	168	Too much force applied	Ensure sensor is secure within shoe or custom case	CM	
6		Sensor loosens	Inaccurate data collection	3	4	7	84	Improper attachment (glue failure)	Choose glue that has high factor of safety	CM	
7	Wearablity	Sensor loosens	Tripping	2	1	10	20	Too much force, glue failure	Choose glue with high factor of safety	CM	
8		Exposed wires	Skin damage	3	1	9	27	Improper connection, wire casing breakdown	Design wire to avoid direct foot contact.	RH	

Concept Refinement & Manufacturing

Detailed Design

The final design was very similar to the concept design chosen by our design matrix and Pugh chart. The components needed to measure and store foot height data were cut into the sole of our shoe. This included two ultrasonic sensors and an Arduino Uno. These components were powered with a 9 Volt battery which was previously going to be built into the shoe midsole along with the other components, but after the final SOLIDWORKS model it was made clear that there was not enough space to safely store a battery without placing it in an area with significant bending during walking, which led to the attachment of the battery to the laces of the shoe. This model drawings can be seen below in **Figures 5, 6, & 7** is the detailed design model. This model has accurate midsole curvature, and better approximates the total volume of the midsole. SOLIDWORKS force simulations done on the model show that the removed foam will not cause the shoe to fail, but depending on the foam Poisson's ratio, there could have been significant displacement, particularly in the large cutout for the Arduino Uno. For this reason, a protective casing around the Arduino will be a part of the final design, to help protect the Arduino as well as to provide additional support to this potentially structurally unsound area of the midsole.

The majority of the parts and materials needed for this device were purchased from outside vendors and modified to meet the needs of the project. The materials, part numbers, vendors, quantities and prices are shown in **Table 9** below. The only part that will not be purchased is the protective case for the Arduino. This case will be 3D-printed using the manufacturing steps outlined in the manufacturing section described later in the document.

Table 9: Bill of Materials for Externally Purchased Products

Item	Product Code Number	Vendor	Price	Count	Total
Hoka Bondi 8 Women's Size 9	304637538938	ebay	$ 124.99	1	$ 124.99
Arduino UNO WiFi REV2 [ABX00021]	B07MK598QV	Amazon	$ 58.00	2	$ 116.00
HC-SR04 Ultrasonic Sensor	B07YXX52SC	Amazon	$ 12.99	1	$ 12.99
1/4" Speaker/Filter Foam - 30 PPI - 36"x48"	N/A	The Foam Factory	$ 6.99	1	$ 6.99
Permatex 25905 Contact Cement, 1.5 oz	B000ALDYPM	Amazon	$ 20.34	1	$ 20.34
Gorilla Clear Glue, 5.75 oz	B07GQ1CT47	Amazon	$ 14.79	1	$ 14.79
Smraza Basic Starter Kit for Arduino, Breadboard...	B01HRR7EBG	Amazon	$ 15.99	1	$ 15.99
EBL 9V Li-ion Rechargable Batteries & Charger	B079G37Y61	Amazon	$ 22.99	1	$ 22.99
Yes4All Foam Exercise Pad, XL	B06Y24V4K8	Amazon	$ 24.98	1	$ 24.98
9V Battery Connector	B08SL9X2YC	Amazon	$ 5.38	1	$ 5.38
DC Power Connector 5.5mm x 2.1mm	B07C61434H	Amazon	$ 8.09	1	$ 8.09
				Total Cost	$ 373.53

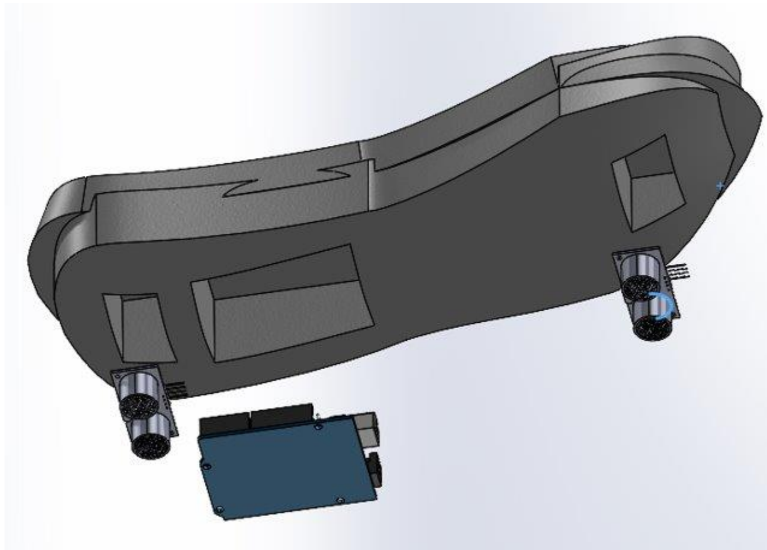

Figure 5: Detailed design assembly model.

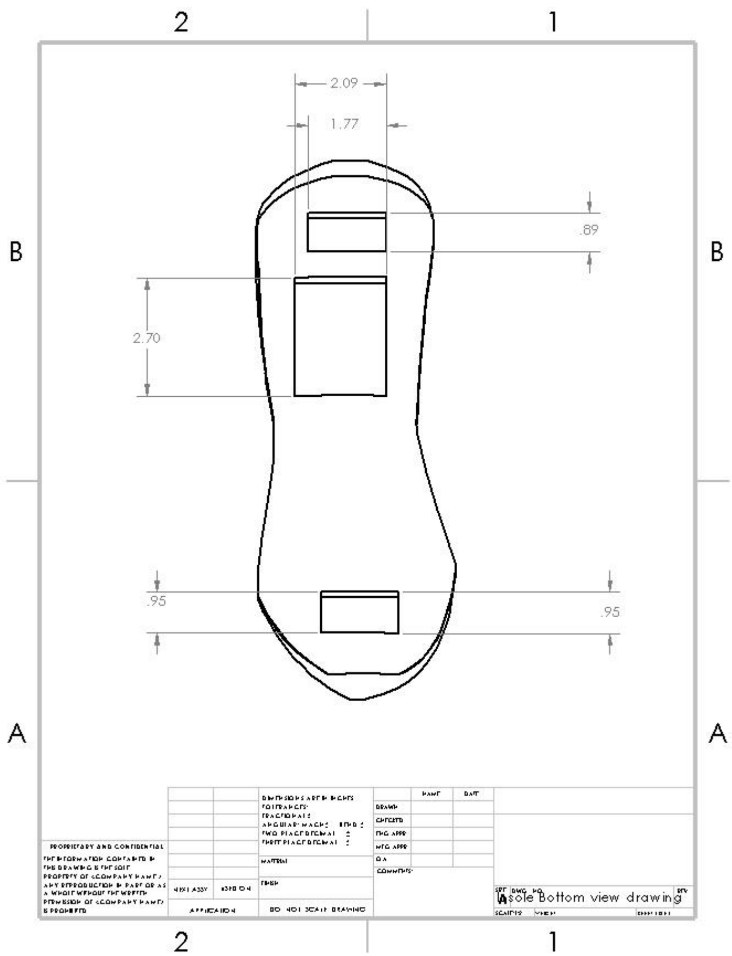

Figure 6: Dimensioned bottom view drawing of SOLIDWORKS Model.

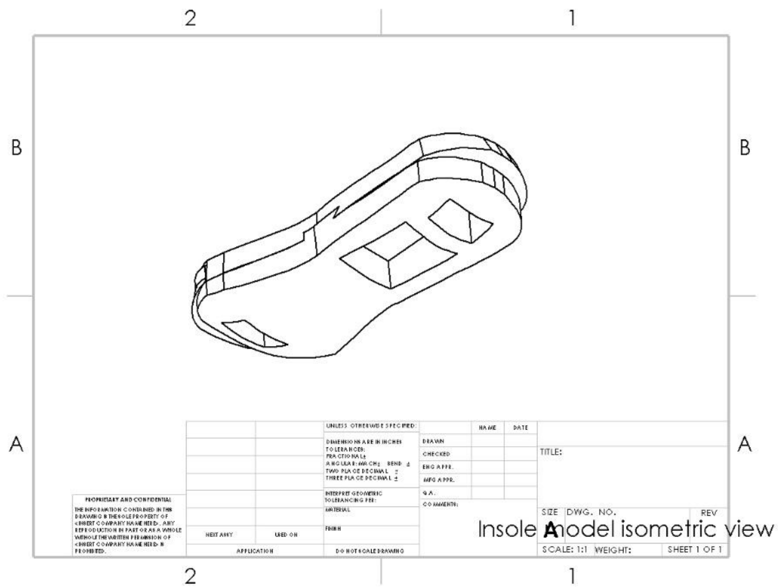

Figure 7: Dimensioned isometric drawing of SOLIDWORKS Model.

The protective case of the Arduino will be 3D printed using PETG and modeled using the dimensions shown in **Figures 8, 9 & 10** below. This case will serve to protect the Arduino from foot pressure and reinforce the shoe after the foam has been removed from the midsole. **Figure 11** shows the circuit layout of the Arduino, which was kept in mind when designing the box due to the necessity of accessing the pins needed to design the protective case.

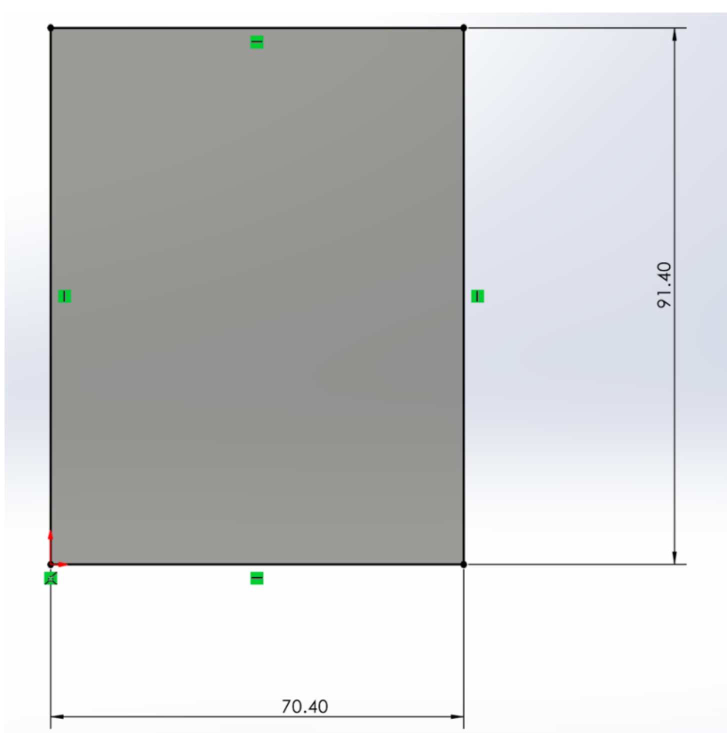

Figure 8: Overall dimensions for Arduino case.

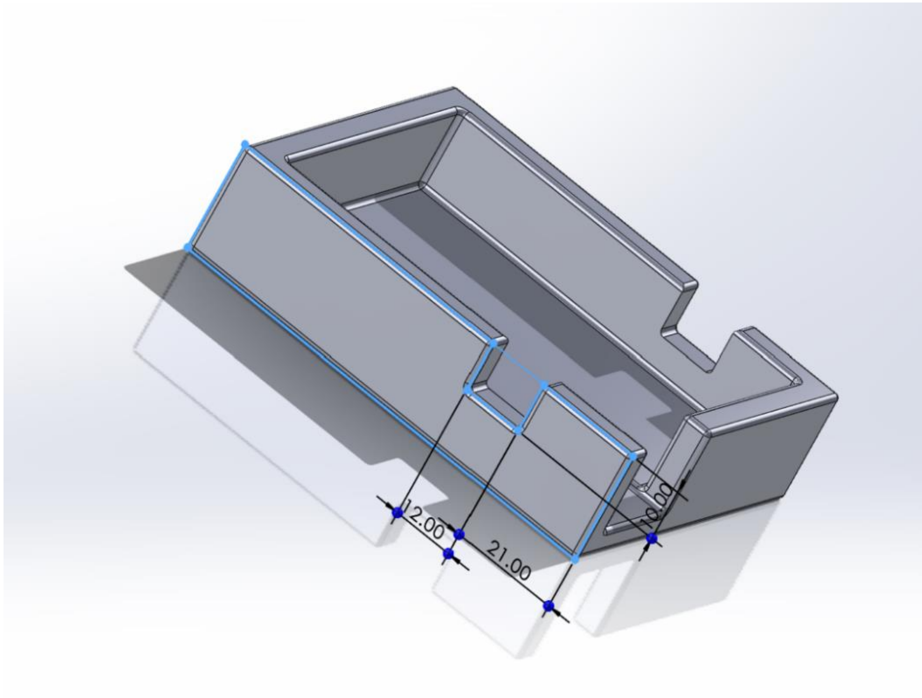

Figure 9: Model and critical dimensions for wire port of Arduino case.

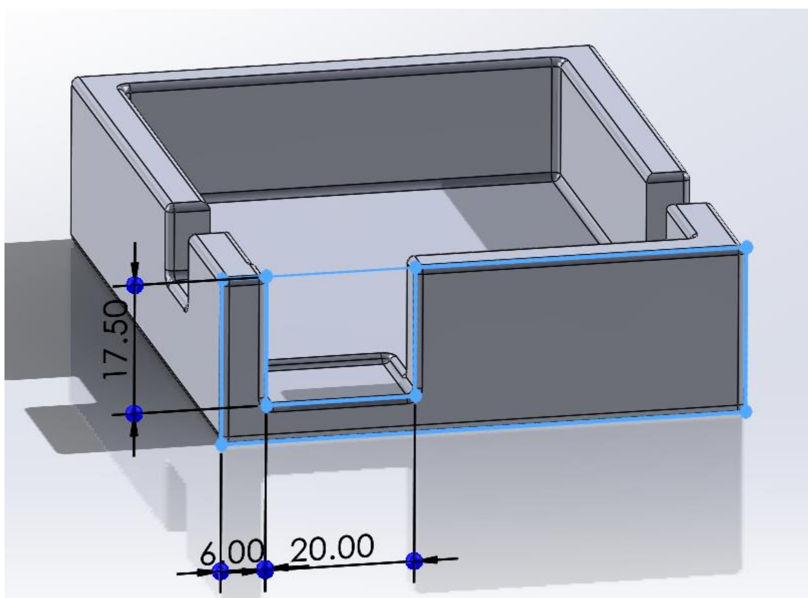

Figure 10: Critical dimensions of Arduino case opening.

Figure 11 shows the circuit diagram of the prototypes. Each ultrasonic sensor has 4 pins that need to be connected to the Arduino. These are pins for input power (VCC), ground (GND), echo (ECHO), and trigger (TRIG) pins. The input power pins are connected to the 5V pin of the Arduino, grounds are grounded, and Echo/Trig were coded to correspond to pins 2 and 4 respectively for each toe ultrasonic sensors, and 8 and 10 respectively for the heel ultrasonic sensors.

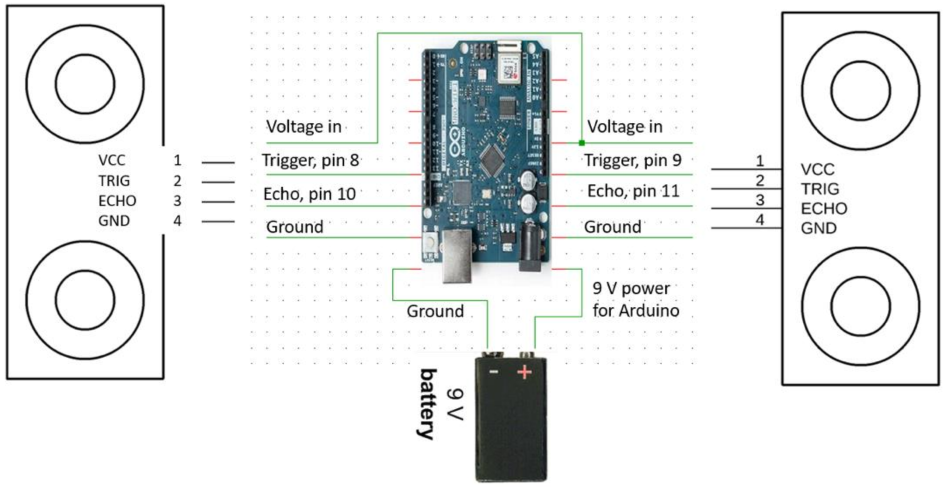

Figure 11: Circuit Diagram of Arduino used to Design Protective Case.

<u>Manufacturing Plan</u>

The manufacturing of the device was split into two parallel processes that were paired together during a final assembly. One manufacturing process involved the shoe and housing and the other process involved the electronics.

<u>Arduino Housing Manufacturing</u>

Step 1: Using the dimensions from **Appendix 5** create a slt file and import it into the Cura slicing software.
Step 2: In the Cura software, specify the print parameters for PETG. These may differ depending on the printer used. The settings used for the prototype print are listed in **Table 10** below. Any parameters not listed in the table were left on the default setting. Slice the model and export to the 3D printer.

Table 10: 3D Print Parameters.

Print Parameter	**Value**
Layer Height	0.2 mm
Wall Thickness	2.0 mm
Infill Density	25%
Infill Pattern	Cubic
Print Temperature	245 F
Build Plate Temperature	85 F
Print Speed	45.0 mm/s
Build Plate Adhesion	Raft

Step 3: Ensure that the build plate is clean and level, then ensure the PETG filament can feed freely into the nozzle. Preheat the nozzle and build plate and start the print.
Step 4: When the print is finished remove it from the build plate and remove the raft from the Arduino case. The raft can be discarded.

<u>Shoe Manufacturing</u>

Step 1: Using the dimensions and datums outlined in the *Detailed Design* section, trace an outline of the holes on the bottom of each shoe using a permanent marker.

Step 2: Using a blade and scissors, remove any of the rubber tread that is inside of the trace of the holes to be cut. This cannot be cut by the CNC mill and must be removed by hand.
Step 3: Using the same dimensions outlined in Step 1, create hole models in your CNC software with 1mm of tolerance in all directions.
Step 4: Place the shoe on a shoehorn and lace as tight as possible to prevent movement. Attach shoehorn to mount in CNC machine. Additionally, clamp sides of shoe in vice in the CNC machine.
Step 5: Align CNC datum with datum specified in figures above.
Step 6: Attach foam bit to mill.
Step 7: Run CNC program created in Step 3.
Repeat steps 3-7 for each of the three holes: heel US sensor hole, center Arduino hole and toe US sensor hole.
Step 8: Use a Dremel to remove any excess foam and smooth the walls of the holes to the Arduino case will slide into the middle hole, and the US Sensors will fit in their respective positions.
Step 9: Place the Arduino case into the center hole, and use a blade to slice the side of the shoe where the wire exit holes are, so the wires can exit the box and run along the outside of the shoe.
Step 11: Create slit from US sensor hole to outside of shoe, one from the heel compartment and one from the toe compartment.
Step 10: When placement is finalized, glue the Arduino protective case into the center hole of the shoe. (Final configuration is shown in **Figure 12** below)

Figure 12: Final layout of shoe manufacturing with holes cut and case secured.

Electronics Manufacturing

Step 1: Solder 2 branches of wire (20 cm) to the short arm of an L-shape pin. The pin will be placed in the Arduino in the 5 Volt in of the Arduino.

Step 2: Solder 2 branches of wire (20 cm) to the short arm of an L-shape pin. The pin will be placed in the ground in of the Arduino.
Step 3: In 2 separate pins, solder wire to connect to the echo pin of each ultrasonic sensor.
Step 4: In 2 separate pins, solder wire to connect to the trigger pin of each ultrasonic
Step 5: The wires need to connect each pin of the Arduino to the corresponding pins on the ultrasonic sensors. This will also be done using solder.
Step 6: Wires will be fed through the Arduino housing and along the side of the shoe to both ultrasonic sensor cutouts. There should be 4 wires per sensor.
Step 7: Wire extensions on the 9V battery clip need to be added using solder, and the output of these wires will connect to a universal barrel jack connector to power the Arduino.

Final Assembly
Step 1: Glue the Arduino to the lid of the housing.
Step 2: Place the Arduino + lid into the housing on the bottom of the shoe
Step 3: Gently run wires through the precut slits in the side of the shoe and align with grooves on sides of midsole
Step 4: Place US sensors in their respective compartments, and slide wires into precut slits, running from the sensor, along the grooves in the side of the shoe and into the slits with the Arduino.
Step 5: Once placement is secure, glue the US sensors into their compartments using the Gorilla Glue. Allow to dry and be secure before moving to the next step (approx. 2 hours for stability and 24 hours for full curing)
Step 6: Glue the wires to the grooves along the side of the shoe using hot glue. **Figure 13** shows the final configuration with wires glued down and sensors inserted.

Figure 13: Final configuration of sensors, and wiring glued to sole of shoe.

Step 7: Feed excess wiring into the Arduino housing and place the Arduino + lid in the case. Use Gorilla glue to secure the lid to the case.
Step 8: After all the electrical components are in place, use contact cement to seal all the wiring slits that were cut in the foam.
Step 9: Allow whole assembly to dry/cure for 48 hours before placing any strain on the foam or other components.

Testing

Test Plans

To ensure that all specifications are met, we executed a series of tests on our prototype throughout the manufacturing process and after the completion of building the prototype. Our tests focused on two main areas: the functionality of the sensors and the performance of the shoe itself. With feedback from the Apple team, we have designed tests to with the goals of characterization, verification and validation for our sensors. In addition to these tests, we designed tests to address each of our engineering specifications (**Table 11**) and FMEA/safety considerations (**Table 12)**. **Table 11** shows a general description of what the tests were looking for, and following it will be a more in depth look at each of them. For many tests, power analysis in order to confirm their functionality is somewhere in the hundreds or even thousands. We used our best judgement when determining sample sizes as that many repetitions is unrealistic for this project. Sample sizes range from 3 to 10, depending on how variable the test is likely to be.

Table 11: Test Plan for Engineering Specifications.

Test Title	Engineering Specifications Fulfilled	General Description
Wear Test	Time of Supervision, Displacement with Movement, Adjustments Needed, Sensor Loosening, Glue Failure	Wearing the shoes, walking around for a period of time, with all components in place
Zero Tests	Ultrasonic Sensor Sampling Rate, IMU Sensor Sampling Rate, Open Cell Foam Transparency	Ensure both the ultrasound and IMU sensors are functioning properly and to test their sampling rate
Battery Test	Battery Life	Ensure battery life is sufficient for sensors to function for average time of elderly wearing a shoe
Weight Measurement	Weight	Ensure device weight is not much larger than weight of the average shoe
Force Tests	Force Required for Assembly, Arduino Protection Box, US Durability	Testing general compressibility of both the Arduino protection box and US sensors, as well as how much strength is required to assemble device
Empty Wear Test	Too much force on sensors	Examine how much force is placed on sensors, ensure no damage
Gait Detection Test	Ultrasonic sensor data analysis, IMU sensor data analysis	Ensure that data gathered shows significant differences that are detectable when gait changes

Wear Test

Step 1: Place completed device onto user's feet, tie laces securely.

Step 2: Ensure all components are properly attached to shoe, including Arduino box, wires, ultrasonic sensors, and battery.
Step 3: Instruct user to walk around for 30 minutes. Observe for full time to determine movement of device or any adjustments needed and note the number of occurrences.
Step 4: Remove device from both feet and examine closely for displacement of any components and note any deviations.
Step 5: Repeat Steps 1-4 twice more, for a total of 3 data sets.
Step 6: Calculate average number of adjustments needed, if any components displaced with movement, and if both the sensors and glue are properly in place.
Step 7: Determine if test failed or not. Failure occurs when the number of adjustments exceeds 5 and/or any sensors or glue have displaced or loosened. Expected outcome is for device to have fewer than 5 adjustments over a period of 30 minutes with no sensor movement or loosening.

- This test has a sample size of 3, each a repetition of the same movements. It was completed using a timer, a user (Claudia), and two observers (Evan and Ryan) with a completed prototype. This test was completed over the course of two separate days, March 7th and March 10th.

Zero Tests

Ultrasonic Sensors Validation Test

Step 1: Connect ultrasonic sensors and Arduino to computer using a cable and breadboard and ensure that data is being collected.
Step 2: Place ruler on table where ultrasonic sensors are placed perpendicular to the table top using a breadboard to get an accurate measure of distance from the sensors.
Step 3: Place tile sample 1.5 cm from the ultrasonic sensor and record data for 10 seconds. Repeat 2 more times.
Step 4: Move tile sample to be 5 cm from the ultrasonic sensor and record data for 10 seconds. Repeat 2 more times.
Step 5: Move tile sample to be 10 cm from the ultrasonic sensor and record data for 10 seconds. Repeat 2 more times.
Step 6: Repeat Steps 3-5 with short carpet sample, medium carpet sample, and long carpet sample.
Step 7: Compare all carpet tests to tile test to determine whether the sensors can accurately determine distance on carpet when compared to tile. This test fails if there is a statistically significant difference between tile and carpet distances.

- This test has a sample size of 3, each a repetition of the same movements. It was completed using an Arduino, two ultrasonic sensors, a tile sample, a short length carpet sample, a medium length carpet sample, a long length carpet sample, a ruler, a computer, and one test conductor. This test was completed by Ryan on February 15th.

Open Cell Foam Test

Step 1: Connect ultrasonic sensors and Arduino to computer using a cable and ensure that data is being collected.
Step 2: Place ruler on table where ultrasonic sensors are placed perpendicular to the table top using a breadboard to get an accurate measure of distance from the sensors.

Step 3: Place tile sample 5 cm away from the ultrasonic sensors at a fixed location.
Step 4: Place open cell foam sample up against ultrasonic sensors, fixed in place between tile sample.
Step 5: Collect data to see if open cell foam interferes with distance measurement of the tile sample.
Step 6: Repeat Steps 3-5 four more times, for a total of 5 tests.
Step 7: Examine data to determine if ultrasonic sensor measurement was accurate. This test will fail if the distance displayed differs from the true distance by more than 1 cm. The baseline that this test is comparing to is the distance determined in the Ultrasonic Sensor Validation Test, with the tile sample placed 5 cm from the sensor.

- This test has a sample size of 5, each a repetition of the same movements. It was completed using an Arduino, two ultrasonic sensors, a tile sample, an open cell foam sample, a ruler, a computer, and one test conductor. This test was completed by Ryan on February 15th.

IMU Sensor Validation Testing
Step 1: Connect Arduino to computer with cable and open new data read out file.
Step 2: Align iPhone IMU coordinates with Arduino coordinates.
Step 3: Secure Arduino to iPhone with tape.
Step 4: Hold phone in a vertical position.
Step 5: Begin Arduino data collection and iPhone IMU data collection on MATLAB app at the same time.
Step 6: Move iPhone side to side to collect data 4 times.
Step 7: Stop collection.
Step 8: Repeat Steps 5-7 two more times.
Step 9: Repeat Steps 5-8 with iPhone held in horizontal position.
Step 10: Repeat Steps 5-8 with iPhone held face down.
Step 11: Hold phone in vertical position.
Step 12: Begin Arduino data collection and iPhone IMU data collection on MATLAB app at the same time.
Step 13: Rotate about x-axis to collect data 4 times.
Step 14: Stop collection.
Step 15: Repeat Steps 11-14 two more times.
Step 16: Repeat Steps 11-15 while rotating about y-axis.
Step 17: Repeat Steps 11-15 while rotating about z-axis.
Step 18: Repeat Steps 1-17 with second Arduino.
Step 19: Compare all data sets to determine if iPhone and Arduino data is correlated. Failure is achieved if correlation coefficients are below 0.4, which indicates that the two data sets are not strongly correlated. The expected outcome is for the IMUs to be at least strongly correlated with each other.

- This test has a sample size of 2, each Arduino being a sample. However, repetitions for each data collection ensure accuracy of data collected. It was completed using two Arduinos, a computer, an iPhone with MATLAB installed, and two test conductors: one to control the Arduino and one to control the iPhone. This test was completed by Evan and Ryan on February 13th, 17th, and 21st.

Battery Test
Step 1: Charge 2 9V batteries overnight to ensure full charge.
Step 2: Connect batteries to two completed circuits with Arduinos and ultrasonic sensors, fully functioning.
Step 3: Connect both Arduinos to Wi-Fi and assure data is being collected.
Step 4: Start timer.
Step 5: Allow both to run until the batteries die.
Step 6: Stop timer and record time. Failure is reached if batteries are unable to continuously collect data for at least 5 hours. The expected outcome is for the batteries to last at least 5 hours.

- The sample size is two, with the experimental group being 2 rechargeable batteries. Materials required for this test include 2 rechargeable 9V batteries, 2 completed sensor circuits, a computer, a timer, and an observer. This test was completed by Ryan on February 23rd.

Weight Measurement Test
Step 1: Obtain fully carved shoe and all necessary components.
Step 2: Weigh on scale to determine overall device weight.
Step 3: Record overall weight.
Step 4: Determine if weight is appropriate for device. Failure is achieved if device weighs over 400 grams, the average weight of a running shoe. The expected outcome is the device weighs less than 400 grams.

- The sample size is 1 and the experimental group is a carved shoe with all components. Materials required for this test include one carved shoe, two ultrasonic sensors, one Arduino, one protective case and lid, two small pieces of open cell foam, one battery, 10 wires, and one scale, with two observers. This test was completed by Evan and Claudia on February 7th.

Force Tests
Force Pull On Test
Step 1: Obtain 1 normal running shoe and 1 device shoe.
Step 2: Place toe into normal shoe without it being fully pulled on.
Step 3: Attach force gauge to heel pull on loop.
Step 4: Pull shoe onto foot fully using force gauge.
Step 5: Record maximum force applied to pull on shoe.
Step 6: Repeat Steps 2-5 four more times.
Step 7: Repeat Steps 2-6 with device.
Step 8: Determine whether force to pull on device is significantly more or less than force required to pull on normal running shoe. Failure is achieved if force required to pull on device is higher on average than the force required to pull on running shoe. The expected outcome is that the device will require the same or less force than the running shoe.

- The sample size is 1, with the experiment being repeated 5 times for more accuracy, and the experimental group is the device. The baseline to be compared to is a normal running shoe. Materials required for this test include one device shoe, one normal shoe, a force gauge, and two participants, one to pull on the shoe and one to observe the force gauge. This test was completed by Evan and Claudia on February 21st and 23rd.

Arduino Protection Box Compression Test
Step 1: Ensure proper protocol is followed for compression machine, including machine operator.
Step 2: Place protection box in compression area.
Step 3: Lower compression die to top of box.
Step 4: Apply 80 kg of pressure to top of box using compression machine.
Step 5: Examine box for damage and record results.
Step 6: Repeat Steps 2-5 four more times.
Step 7: Examine data to determine if box structure was damaged. Failure is achieved if structural integrity is compromised. Expected outcome is for the box to remain structurally intact.

- The sample size is 1, with the experiment being repeated 5 times for more accuracy, and the experimental group is the protection box. Materials required for this test include 3D printed box, compression machine, machine operator, and one observer. This test was completed by Evan on February 17th.

Ultrasonic Sensor Compression Test
Step 1: Ensure proper protocol is followed for compression machine, including machine operator.
Step 2: Place ultrasonic sensor in compression area.
Step 3: Lower compression die to top of sensor.
Step 4: Apply pressure until ultrasonic sensor is significantly deformed.
Step 5: Identify when sensor began to deform and record.
Step 6: Determine if sensor significantly deformed at an unacceptable weight. Failure is achieved if sensor deforms before 80 kg of force is applied. Expected outcome is that the ultrasonic sensor is able to withstand 80 kg of force.

- The sample size is 1 and the experimental group is one ultrasonic sensor. Materials required for this test include one ultrasonic sensor, compression machine, machine operator, and one observer. This test was completed by Evan on February 17th.

<u>*Empty Wear Test*</u>
Step 1: Hot glue two ultrasonic sensors into their respective carved cubbies of one shoe.
Step 2: Lay down paper towel on floor.
Step 3: Place device on one foot.
Step 4: Color each sensor in a different color (toe red and heel blue) with a dry erase marker.
Step 5: Step onto paper towel while ink is still wet to determine if sensors touch the floor.
Step 6: Record if any color transferred to paper towel.
Step 7: Repeat Steps 4-6 four more times.
Step 8: Determine if sensors touch the ground. Failure occurs if any sensors touch the ground, indicated by marker transfer. If failure is achieved, enact contingency test *Ultrasonic Sensor Compression Test*. Expected outcome is that the ultrasonic sensors do not touch the ground,

- The sample size is 1, repeated 5 times for accuracy, with the experimental group being the device with inserted ultrasonic sensors in the heel and toe. Materials required for this test include two ultrasonic sensors, one carved shoe, hot glue, two different colored dry erase markers, one paper towel, and two participants, one to wear the shoe and one to observe. This test was completed by Evan and Claudia on February 16th.

Gait Detection Test

Step 1: Place completed device on both feet of subject.
Step 2: Attach power supply to both shoes and ensure Arduinos are connected to Wi-Fi.
Step 3: Open fresh recording sheet on computer for IMU data collection.
Step 4: Begin data collection as subject begins to walk normally.
Step 5: When data is retrieved, stop data collection and instruct subject to stop walking. Record data to sheet and refresh page.
Step 6: Detach power supply to reset Arduino.
Step 7: Repeat Steps 2-6 two more times.
Step 8: Repeat Steps 2-7 with a shuffling gait.
Step 9: Repeat Steps 2-8, this time recording data from the ultrasonic sensors.
Step 10: Perform analysis on average acceleration, average angular velocity, and angular velocity variability in all dimensions and compare normal gait to shuffling gait. Failure is achieved if it is not possible to determine the difference between a normal gait and a shuffling gait. Expected outcome is that there will be a difference between a normal gait and a shuffling gait.

- The sample size is 2, with 3 repetitions to gather a more accurate data collection, with the experimental group being the shuffling gait and the baseline being a normal gait. Materials required for this test are two completed devices, one for each foot, a computer, and three participants, one to wear the device and two to observe. This test was completed by Evan, Claudia, and Ryan on March 7th, 9th, and 10th.

In addition to testing to ensure fulfillment of engineering requirements, we also know it is necessary to test the failure modes of our shoe to protect the safety of the user. In order to do this, we designed a test plan to address certain failures predicted in the FMEA. These can be seen in **Table 12**. Most of these failure modes can be evaluated using the Wear test that is previously described. The only additional test is the Empty Wear test, which will be performed before the sensors are placed into the shoes. The holes will be cut out of the midsole of the shoe and the shoe will be worn in the same way as the Wear test. After the test, the structural integrity of the foam will be visually evaluated to ensure there are no collapses or tears in foam caused by the creation of the compartments.

Table 12: Test Plan for FMEA and Safety.

Failure	**Test**	**Expected Result**
Loose wire connection	Wear Test	Wires should remain in place within the shoe and remain connected to the Arduino after the wear test is complete.
Too much force to sensors	Empty Wear Test	After the empty wear test, the foam of the shoe should remain intact and the compartments for the sensors should remain structurally sound.
Sensor loosening	Wear Test	The sensors should remain in place, shift less than 1 mm after an hour of wear.
Glue Failure	Wear Test	The glue bond should be intact after the wear test.

A third set of tests was needed in order to validate the software and data collection aspects of the Arduino coding and configuration. Once the Arduino software and hardware were set up for initial use, the Zero test was used to verify that the sensors and code were working. If the test is run, and the data collected is not zero, then root cause analysis would have been needed to be performed in order to identify the problem in the code or in the sensor configuration. No problems were identified, so we then moved onto the Analysis test to determine whether our prototype was able to identify the difference between a normal gait and a shuffling gait.

Risk Identification and Mitigation

There were inherent risks associated with the various steps of both the manufacturing and testing procedure. We identified these risks and took the necessary steps ensure that all test subjects and manufacturers are safe. During the manufacturing process there were hazards and risks associated with tools used to manufacture the device, the materials used and electrical hazards present. First, the risks associated with the various tools. The blades used to cut the foam needed to be sharp to cut the foam, and could have cut the person using them. By using proper technique, this risk can be eliminated. Using a Dremel has multiple hazards including operator injury from the bit and the creation of airborne foam particles. By using careful techniques and wearing a mask and safety goggles, these risks were mitigated. Additionally the use of a CNC machine has risks, but because a trained operator was using it, with proper PPE these risks were mitigated. Another dangerous tool needed for this manufacturing process was a soldering iron and solder. These tools posed a danger to burn the user and the fumes can be dangerous. These risk factors were addressed by getting proper safety training, wearing safety goggles, and only using the soldering iron in a well ventilated area. Solder also contains lead, which should not be left in contact with the skin, so operators made sure to wash their hands after use.

There are few material hazards in this manufacturing process, but the main hazard was the fumes from the glue and contact cement. This was easily be addressed by performing the gluing steps in a ventilated space or outside.

Lastly, if done improperly, there was a risk of electrical shock when assembling the device. However, the power source for the device was not be connected to the device until all other components are in place, so there was very low probability of shock occurring.

The testing protocols also had some risk associated with them because of the test fixtures being used and the prototype nature of the device. First, using a compression testing device poses the hazard of crushing a body part if the user is not properly trained. Additionally, if the case or sensor broke under compression, the pieces could have caused harm. However, calculations have predicted that the case will not break under the amount of force that is prescribed in the test protocol. When performing the compression tests, a safety Plexiglas was placed between the users and the component being compressed. A specially trained guide was also present for the compression testing, guaranteeing that the device was used safely and properly. There was also a slight risk of electrical shock, as there is with any electrical components. However, this was very low risk to the test subject during the wear tests because in the design, none of the electrical components are in contact with the test subject.

Testing Data and Analysis

Durability Testing

Durability testing was done to give a reasonable assurance that the device would not break during normal wear. These tests included testing for both the Arduino protection case and the compression test for the US sensor. These two tests correlated with the compression force specification. These tests did not require statistical analysis because they were pass/fail tests. The Arduino protection case passed all 5 of the compression trials, and the US sensor surpassed the benchmark when compressed to failure. The full results of these tests can be seen in **Appendix 7 & 8.**

Verification Testing

The goal of verification testing was to confirm that our Arduino IMU sensors were collecting data that was equivalent to previously verified IMU sensors. This fulfilled the correlation of Arduino IMU to iPhone IMU spec, which it passed. In our testing, the iPhone IMU data was used as a standard to compare to the Arduino data. For analysis, data from both sensors was overlayed on a single graph to visually identify any variations in the data collected.
The results for the correlation of acceleration data are shown in **Figures 14 & 15** below.

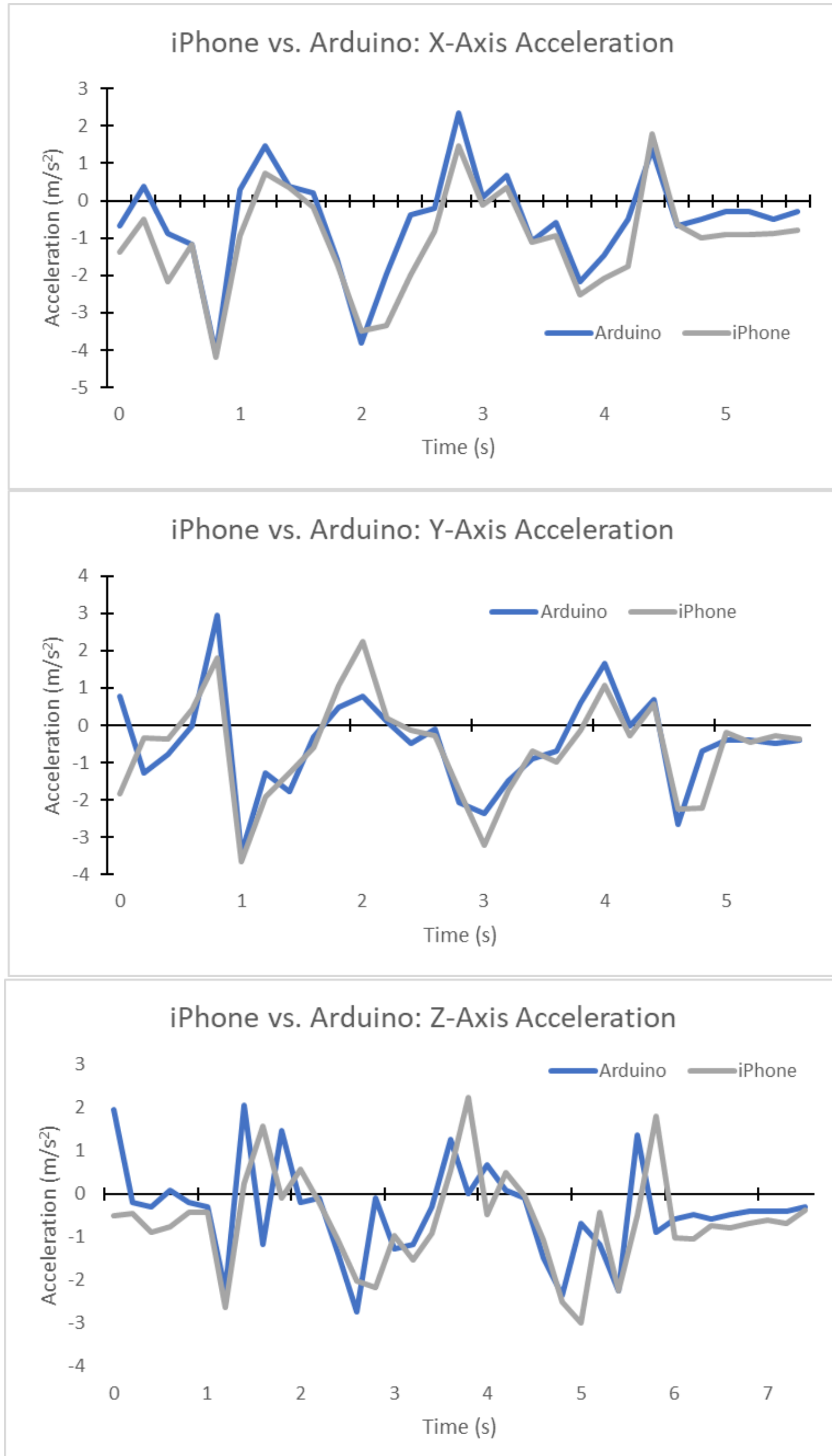

Figure 14: Verification testing in the x, y, and z -axis directions for the accelerometers of the Arduino IMU compared to an iPhone IMU.

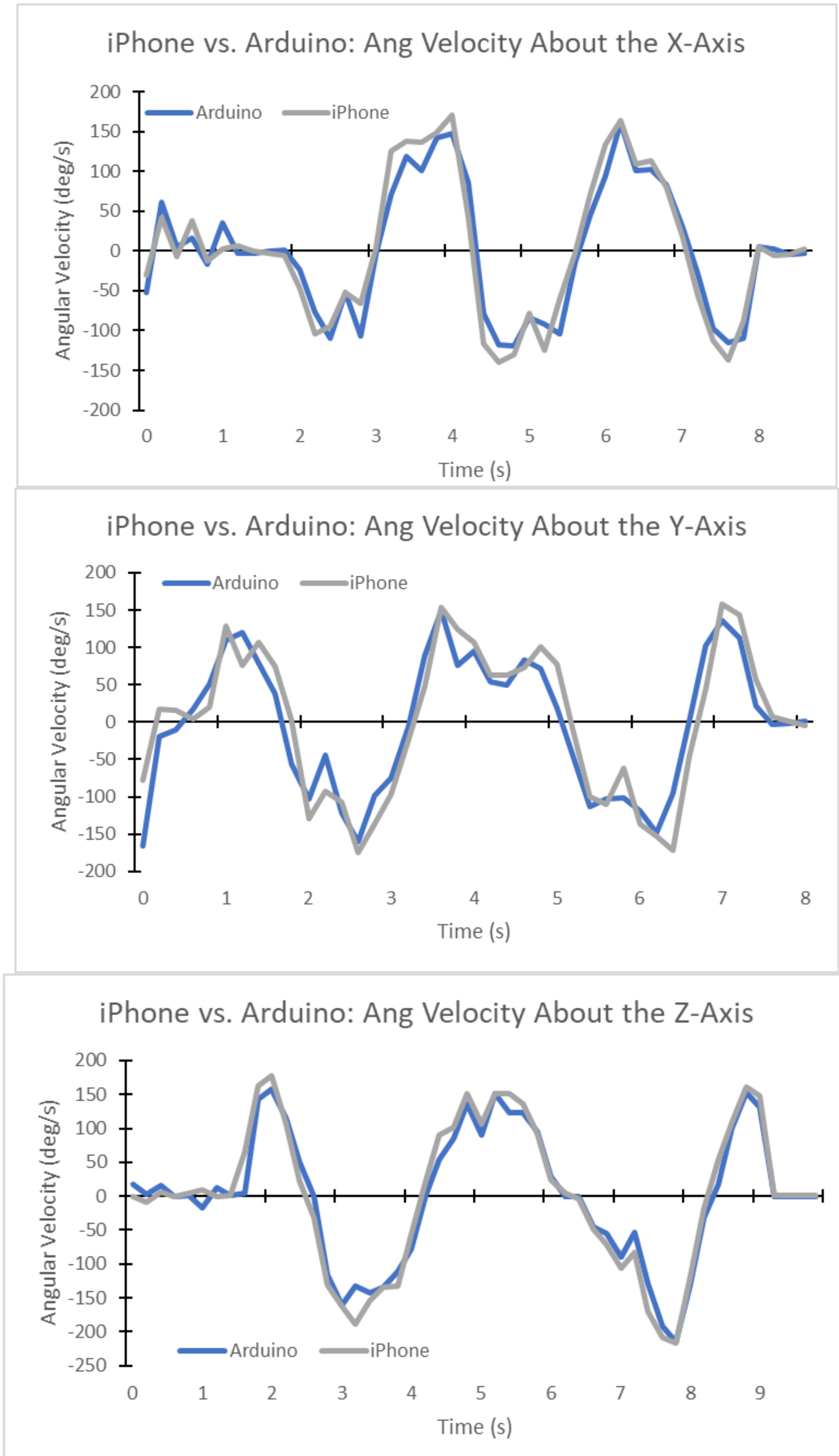

Figure 15: Verification testing in the x, y, and z -axis directions for the gyroscopes of the Arduino IMU compared to an iPhone IMU.

In addition to the visual confirmation that the IMU sensors were performing up to standard, the correlation coefficient was calculated between the two data sets. A correlation coefficient of > 0.7 indicated a very strong correlation, while a coefficient of > 0.4 indicates a strong correlation. The correlation coefficients for the verification testing are shown in **Figure 16** below. One important note is that the data from the X-axis acceleration in the first trial was not usable, and this was not discovered until testing had been completed. Statistical analysis was adjusted to account for the slightly smaller sample size.

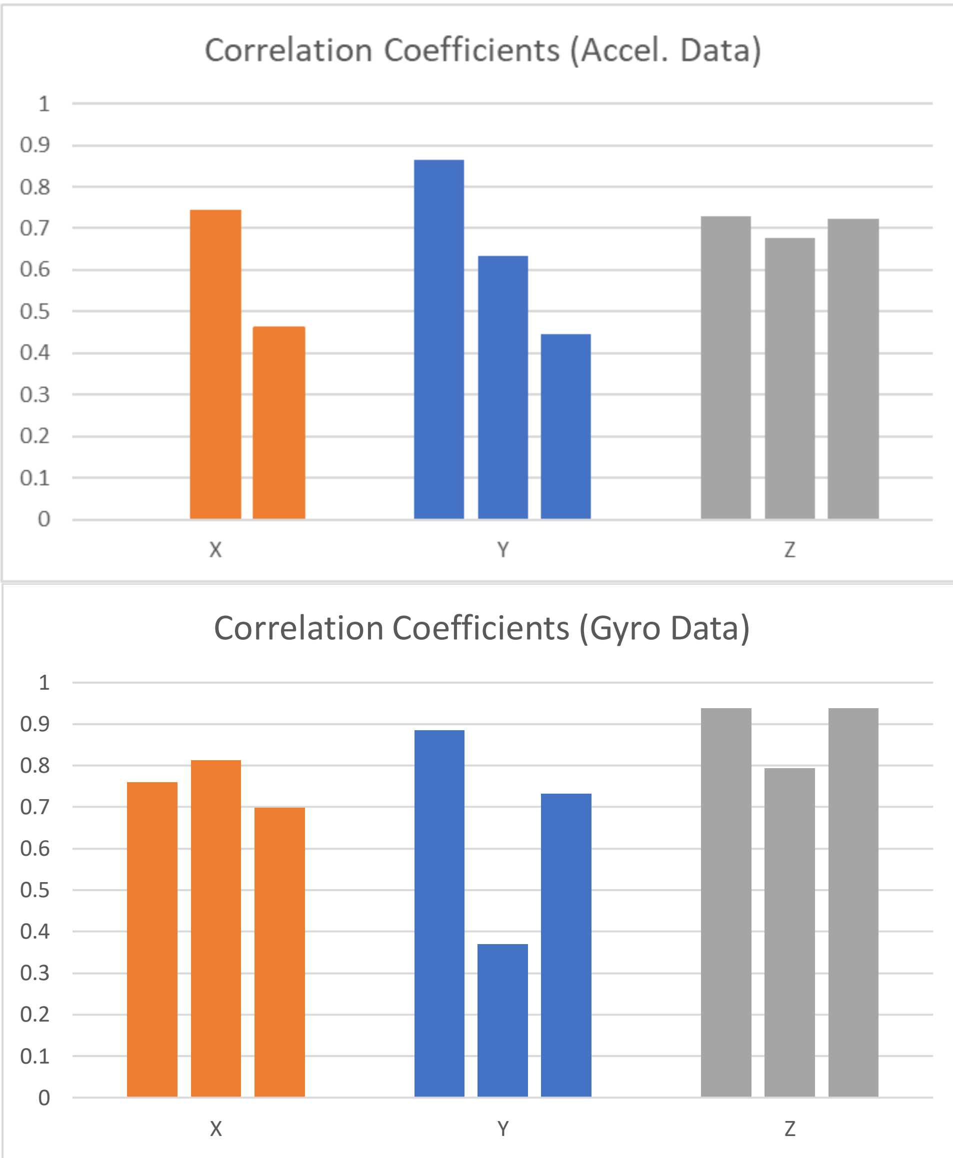

Figure 16: Correlation coefficients comparing Arduino and iPhone data collection for acceleration and gyroscopic angular velocity data.

In addition to conducting validation testing on the Arduino, we also verified that the US sensors would work on various surface types. This included tile, short carpet, medium length carpet and long carpet. This fulfilled the spec reliability of US on variable surfaces, which it passed.The US sensor was consistent on tile, but there was variation in the distance measurements on the various carpet lengths, with no obvious trends as in the data relating to the carpet material. The averages of the distance measured on a surface after three recordings are shown in **Figure 17** below.

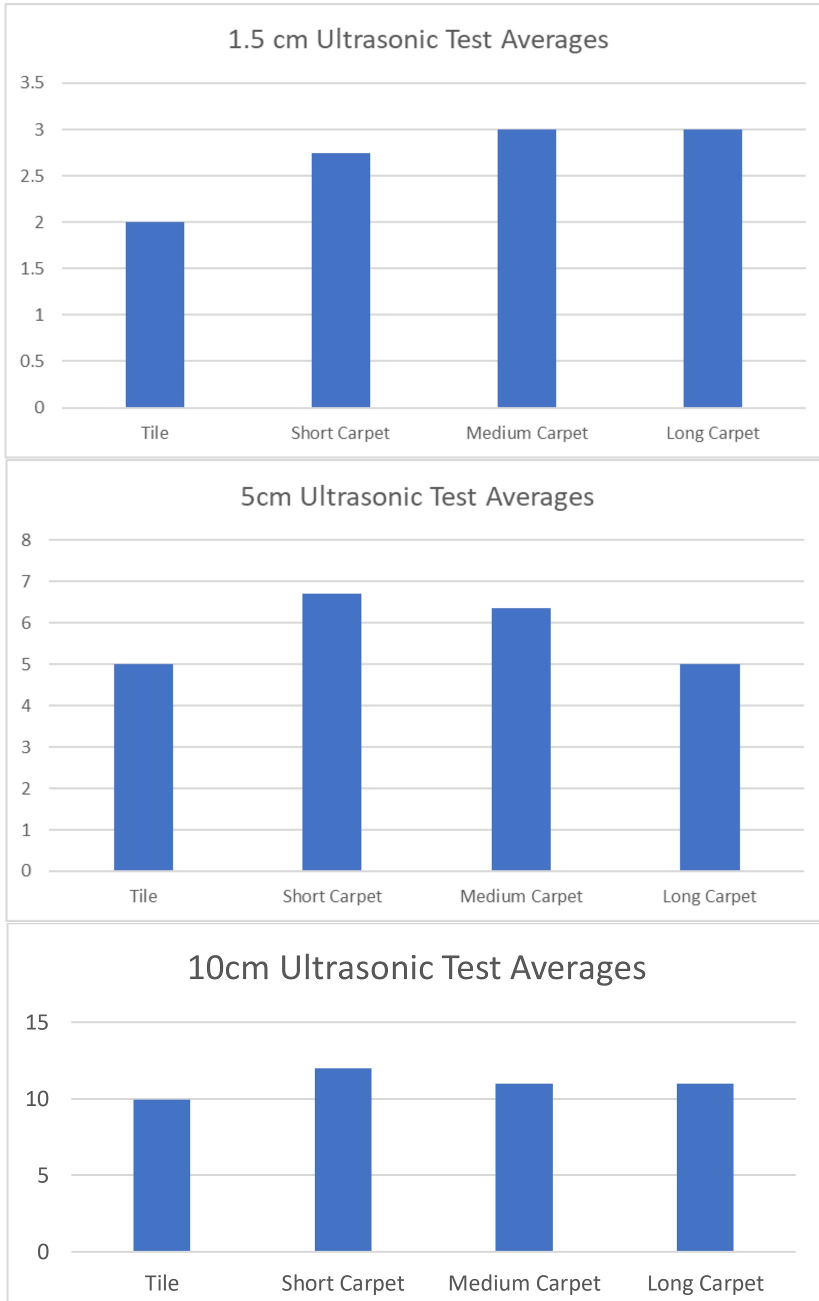

Figure 17: Average US sensors readings for tile, short carpet, medium carpet and long carpet at 1.5 cm, 5 cm and 10 cm.

<u>Validation Testing</u>

Validation testing occurred after the completion of both prototypes. Comparisons were to be made between a normal walking gait and a simulated shuffle gait. Test subjects were instructed to walk normally, and three random 20-second measurements were recorded. The process was repeated with a shuffle gait. Sensors collected data at 5 Hz. Samples of acceleration data for each gait are shown below in **Figures 18 & 19.**

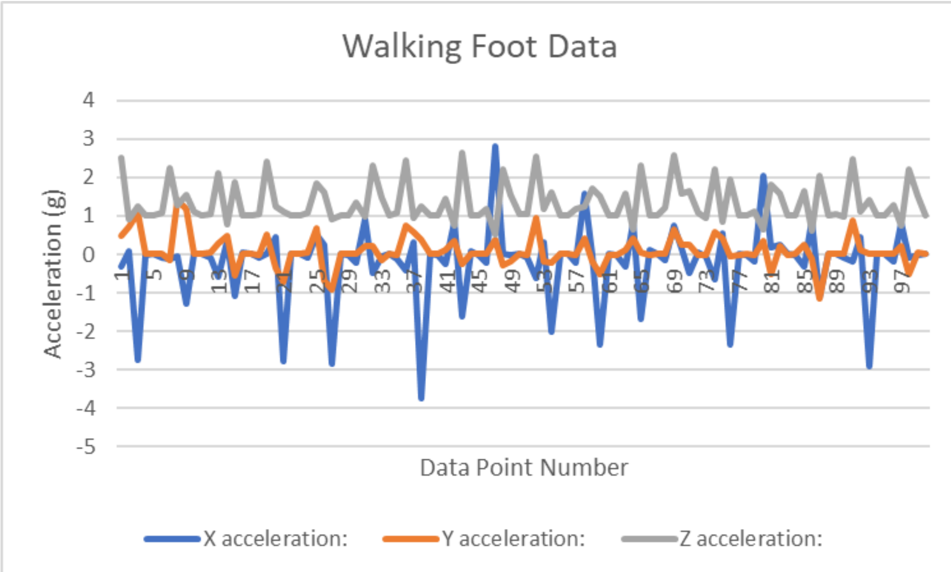

Figure 18: Normal walking X, Y, and Z acceleration.

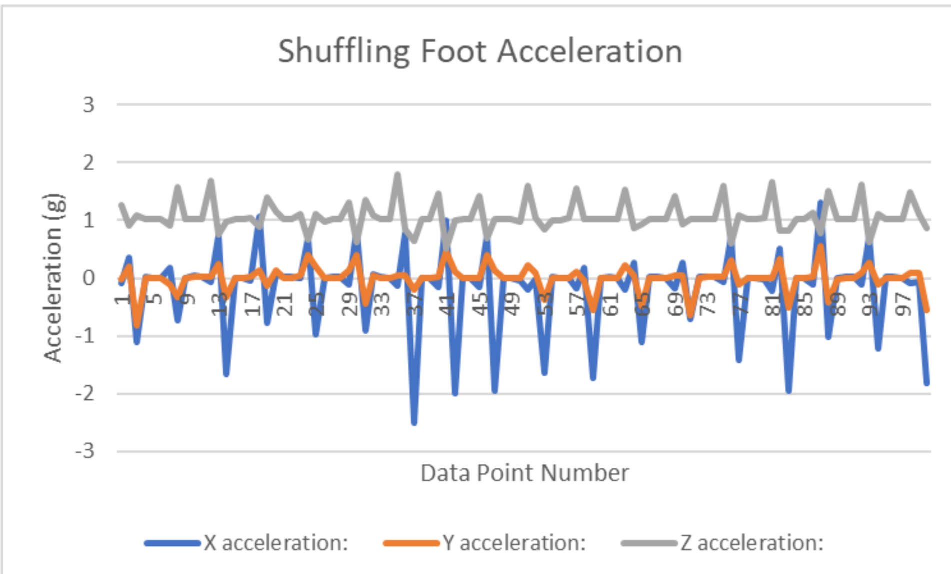

Figure 19: Shuffle X, Y, and Z acceleration.

Each trial was compiled into the data below in **Table 13**. Maximum accelerations in each direction were averaged and are shown under XA, YA, and ZA columns below. Averages for maximum angular velocity were also averaged, and the standard deviation of angular velocity was also calculated. Angular velocity values are labeled with G in the table below. Table 13 was then plotted in a histogram format for visualization purposes in **Figure 20**.

Table 13: Maximum acceleration and angular velocity averages for walking and shuffling.

	XA	YA	ZA	XG	YG	ZG
Walking averages	2.52	1.07	2.8067	162.11	364.89	148.5367
				SD XG	SD YG	SD ZG
				62.553	165.548	54.368

	XA	YA	ZA	XG	YG	ZG
Shuffling Averages	1.4767	0.6	1.7067	65	225.79	103.797
				SD XG	SD YG	SD ZG
				27.759	92.2103	28.367

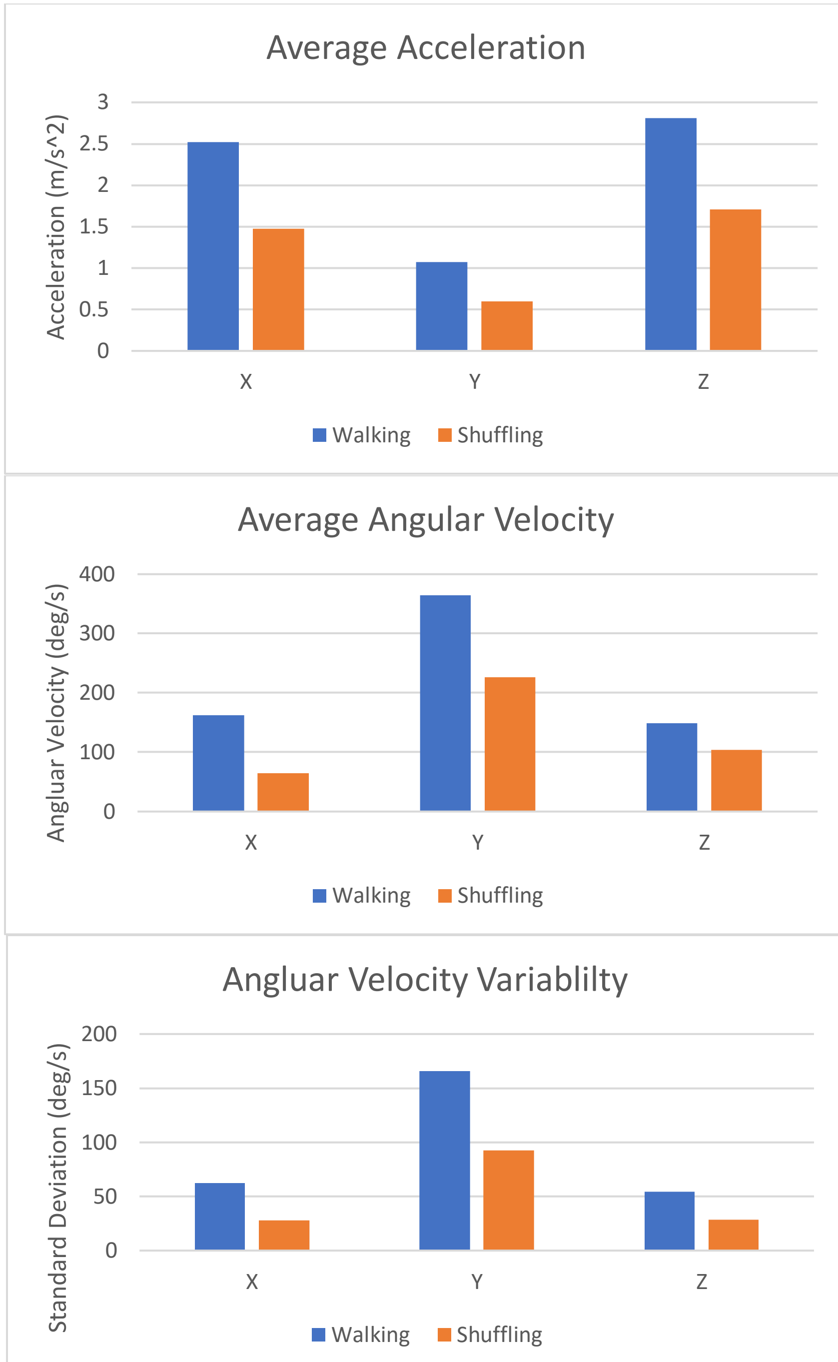

Figure 20: Average acceleration, angular velocity, and angular velocity variability compared between walking and shuffling gait examples.

Below in **Figure 21** is the data collected for heel ultrasonic sensors when walking vs shuffling. Data did not wirelessly upload reliably so very few data sets were able to be collected. This graph of one sample is an accurate representation of collected data.

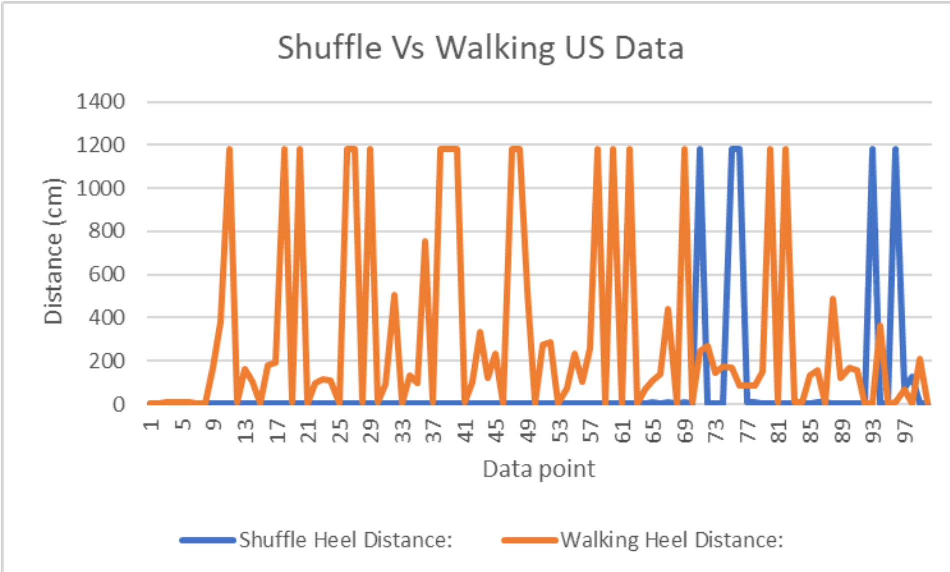

Figure 21: Heel ultrasonic data for a walking and shuffling trial.

Instructions for Use

Step 1: Sit down on a stable surface in order to assure proper balance while putting the device onto feet.
Step 2: Put on socks that are appropriate for wear with the device.
Step 3: Untie laces of right shoe.
Step 4: Place right foot into right shoe.
Step 5: Tie laces of right shoe securely.
Step 6: Repeat Steps 3-5 with the left shoe.
Step 7: Switch device on for both shoes.
Step 8: Stand and walk around to ensure device is properly secured to feet. If required, return to a sitting position to readjust device if at all uncomfortable or improperly secured.
Step 9: Ensure that device is connected to internet via corresponding phone app or watch to guarantee data collection.
Step 10: Go about your day as normal.
Step 11: If abnormal gait is detected, appropriate warning will be displayed on smart phone or smart watch. Contact a caregiver to assist in fall risk prevention.

Discussion

Our goal was to address the engineering specs outlined in the previous sections. We met the specs of time of supervision, displacement with movement, production cost, weight, number of parts, size range, adjustments needed, force required for assembly, compression force, reliability of US on variable surfaces, and correlation of Arduino IMU to iPhone data. We failed the specs of battery life and ground clearance. In order to address these failures in the future, we would use a different battery type that has a longer lifespan and would either use smaller ultrasonic sensors or design our shoe foam mold to provide enough clearance.

Based on the data analysis seen in **Figure 20,** it is clear that our device can detect changes in gait between walking and a simulated shuffling pattern. When the subject goes from walking to shuffling, there is a clear decrease in the acceleration of the foot, and the angular velocity of the foot and ankle. This makes sense from a physiological perspective, as the shuffling gait tends to be slower and involves less ankle flexion. Additionally, the variability in angular velocity decreases when the subject is shuffling vs. walking. This indicated that the angle of the foot is less variable and more static. In the case of gait analysis, the decrease in overall angular velocity and decrease of variability of angular velocity indicates to us that in the shuffling gait pattern, the foot is more flat and the toe and heel do not lift as much. This could be a potential indicator of an increase in fall risk; as we know from talking to elderly family members, falls tend to happen when the toe "catches" on the floor when it is not lifted properly. More data collection and research are needed to correlate our data with actual fall risk. However, we see this data collection as a success in the fact that our device was able to detect definite difference between instances of normal walking and shuffling.

In addition to the learning and conclusions from our gait analysis, the development of this prototype device allowed us to gain engineering insights into the sensors used, the configuration of them and other design aspects. These insights came from problems that were discovered throughout the build process. Some of these problems were able to be addressed with this prototype; however, some issues were not addressed with this iteration. For those issues, we will outline possible future solutions and ideas of how to move forward from our device.

One of the initial challenges that we faced was the placement of the sensors in the device. The proprietary nature of the shoe means we could not get accurate dimensions of the midsole in order to design to fit the specs of the US sensors. This caused issue with the working distance of the US sensors and the high incidence of the US sensors striking the ground when the subject walks. The working distance of the US sensors lead to data that was so unreliable that it was unusable for any meaningful gait analysis conclusions, see **Figure 21**. We also hypothesize that the US sensor struggled to get reliable data because of the angle of the sensor relative to the floor when the subject was moving. The US sensor collected reliable data when the device was stationary. For these reasons, we suggest not using these US sensors in future iterations. They were relatively cheap, which was the motivation for using them in the first place, but could have contributed to the low quality of the data that they collected. In the future, we suggest using a different sensor type, or higher quality US sensors.

Another challenge that we learned from was the excavation of the foam compartments to place our data collection devices. The foam had high energy return (because of the nature of the running shoe) and was difficult to cut out the excess foam to implant the sensors. Additionally once the foam was removed from the midsole of the shoe, the large space for the Arduino cause the midsole to be slightly unstable. We were able to mostly address this with the PETG protective case that served to house the Arduino and support the shoe. In future iterations, we would recommend that a foam mold be created to house the sensors, rather than carving the foam out from a pre-existing midsole. Additionally, any reduction in Arduino size would be beneficial to the stability of the midsole of the shoe.

After concluding data collection and testing, we believe that one of the most important aspects of future iterations of this device would be development of the analysis software and WiFi connectivity. One of the major limitations to our device in its current state is the lack of ability to collect large amounts of data for long periods of time. This is due to the nature of the Arduino we are using. It cannot store large amounts of data, and our data export method through WiFi is very unreliable, with the Arduino disconnecting regularly. Future versions of the device should focus on establishing a reliable WiFi connection and collecting data from longer sections of time. This could be done by including more memory on the Arduino, or using a different code for WiFi connectivity when programming the Arduino. A possibly valuable work-around for the storage issue on the Arduino might also be to have the Arduino store no data at all, and automatically upload all data as soon as it is collected; which would be possible if a reliable WiFi connection could be established.

It is important to acknowledge the future directions of our device because we think that this device serves more as an initial proof-of-concept, rather than a functioning prototype. The device that we set out to make is possible to create; however, we were not able to fully develop the idea into a device that would be usable by a consumer. Despite this, many valuable steps were made during this project in order to come closer to developing a wearable device that would predict an increase in fall risk to help elderly people live at home more safely. We think that this is a critical problem to address and that future work on this device is a valuable project to pursue in the future.

Conclusion

This document gave a general overview of the background of our project including objectives we intended to meet, our planning, detailed design, and manufacturing plan. We showed the history of how dangerous elderly falling can be and how the problem has been addressed in the past, including devices and strategies that are currently on the market. Our general objectives included our problem statement and different ways we can address it. They also included what is required of our device to function as intended, and how we will be measuring metrics that will confirm that the device will perform to our specifications. We laid out our plans on how this project progressed, including special tests we must perform, milestones, and a critical path that led to a functional prototype by March of 2023.

We completed our morphology and concept sketches that helped us to build our conceptual model. These, along with our Pugh chart, provided us with a leading design idea and a path forward in preparing for prototyping. Building our sensors and data collection into the midsole limited the number of moving parts and provide protection for each component. Along with the benefits our design offers, the FMEA showed potential failures that may come along with each of our specific design choices, which reassured us that the integrated shoe design is the best path forward.

We dimensioned out our model into our detailed design, with more accurate measurements for the midsole and locations for each of our components. We gave our manufacturing plan for our prototype, which helped us to build our prototype once we received all the parts necessary for our device. This plan was revised as the build process was completed so we had a robust manufacturing process in place. The risks of these manufacturing process were been identified and mitigation plans were also outlined.

Detailed test plans were created to ensure that engineering specifications were met by our device. We outlined specific DOE's and protocols for both mechanical and electrical testing to make sure that our device is safe and collects the data that we are looking for. We showcased testing data that we collected and identified if our experiments passed or failed our various criteria with strenuous data collection and statistical analyses. We created an ideal instructions for use of an iteration of our device that would be available for commercial use. Finally, we discussed the outcomes of this project as a whole, where we believe certain aspects of the prototype failed, and what next steps might be taken to further the creation of this assistance device.

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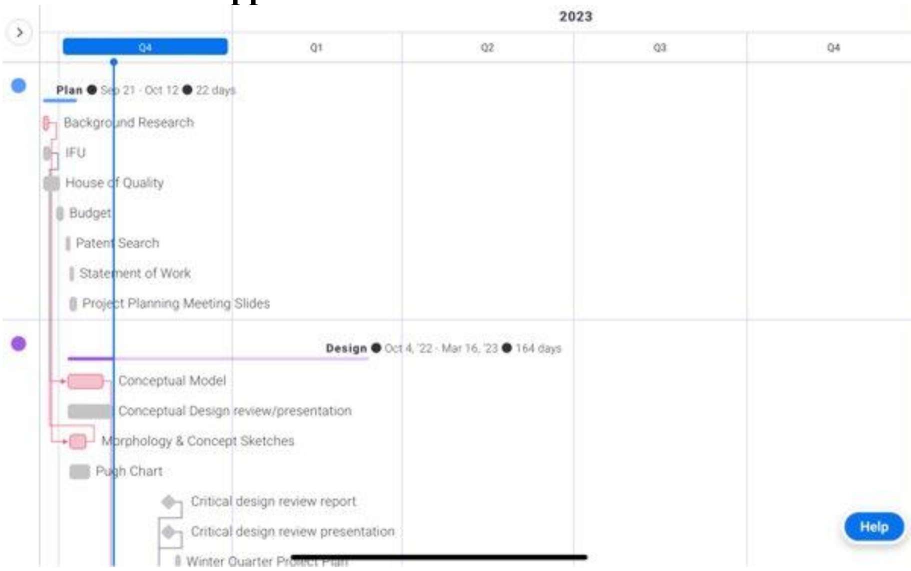
Appendices

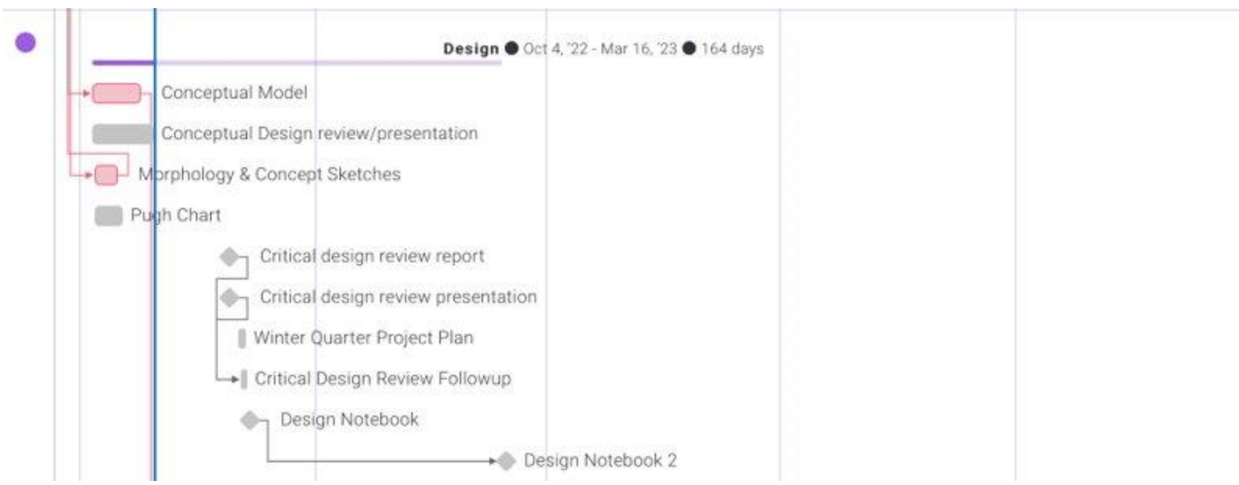
Appendix 1: Complete set of customer requirements and weights from HOQ.

Apple	Caregiver	Elder	Customer Requirements (Explicit and Implicit)
			Units
25	19	20	Increase independence
17.5	24	18	Predict fall risk
12.5	7.1	5	Detect changes in balance
12.5	7.1	5	Detect changes in gait
5	12	12	Reasonable cost
5	4.5	15	Comfortable
5	12	10	Easy to put on / take off
7.5	2.4	2	Wearable
5	7.1	5	Reusable
5	4.5	8	Small/ portable

Appendix 2: Overview of Gantt Chart.



Appendix 2a: Gantt Chart Plan & Design.



Appendix 2b: Gantt Chart Design.

Appendix 2c: Gantt Chart Build, Test, & Present.

Appendix 3: Individual Pugh Matrices by Each Member.

Issue: Choose a fall risk prevention design		Baseline - Pedar System	Concept #1	Concept #2	Concept #3
Set up Time	6		1	1	1
Time of Supervision	12		0	0	0
Sensor Sampling Rate	11		-1	-1	-1
Displacement with Movement	9		0	-1	1
Calibration Time	6		1	1	1
Production Cost	5		1	1	1
Battery Life	7	Datum	-1	-1	-1
Weight	6		1	1	1
Number of Parts	6		1	1	1
Size Range	7		0	0	0
Adjustments Needed	13		0	-1	1
Force Needed to Assemble	5		1	0	1
Sensor Density	7		-1	-1	-1
	Total		3	0	5
	Weighed Total		9	-18	31

Appendix 3a: Pugh Matrix by Evan.

Issue: Choose a fall risk prevention design		Baseline - Pedar System	Concept #1	Concept #2	Concept #3
Set up Time	6		-1	0	-1
Time of Supervision	12		1	1	1
Sensor Sampling Rate	11		-1	-1	-1
Displacement with Movement	9		0	0	0
Calibration Time	6		0	0	0
Production Cost	5		1	1	1
Battery Life	7	Datum	0	0	0
Weight	6		1	1	1
Number of Parts	6		1	1	1
Size Range	7		0	1	0
Adjustments Needed	13		0	0	0
Force Needed to Assemble	5		0	0	0
Sensor Density	7		-1	-1	-1
	Unweighted Total		1	3	1
	Weighted Total		5	18	5

Appendix 3b: Pugh Matrix by Ryan.

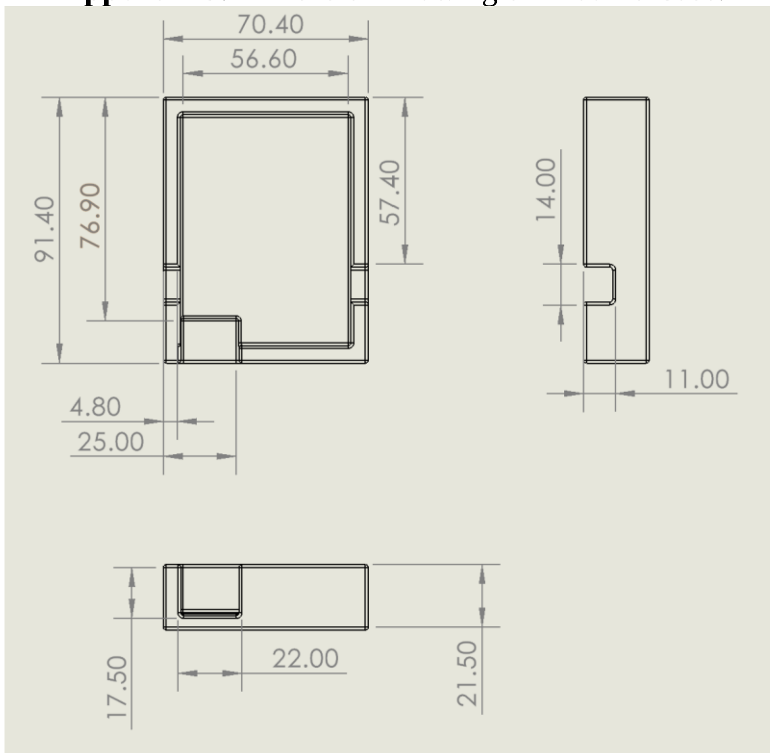
Issue: Choose a fall risk prevention design		Baseline - Pedar System	Concept #1	Concept #2	Concept #3
Set up Time	6	Datum	1	1	1
Time of Supervision	12		1	1	1
Sensor Sampling Rate	11		-1	0	0
Displacement with Movement	9		1	-1	1
Calibration Time	6		1	1	1
Production Cost	5		1	1	1
Battery Life	7		-1	-1	-1
Weight	6		1	1	1
Number of Parts	6		1	1	1
Size Range	7		0	1	-1
Adjustments Needed	13		1	-1	1
Force Needed to Assemble	5		-1	0	1
Sensor Density	7		-1	-1	-1
	Total		4	3	6
	Weighed Total		33	12	47

Appendix 3c: Pugh Matrix by Claudia.

Appendix 4: Original Manufacturing Plan.

Start at the heel of the Hoka Bandi 8 shoe. The contact points when resting on the ground along with the furthest back heel point are used as the datums for all measurements. For all cuts, a foam blade or X-acto knife should be used. The cutout of the heel ultrasonic sensor should start 30mm from the back of the shoe, with dimensions of 23mm by 45mm, seen in **Figure 6**. This cutout is centered in the heel portion of the shoe, with 28mm on either side of the cutout measured from the posterior end of the cutout. The depth of the cut will go through the entirety of the midsole of the shoe. The cut for the Arduino uno should be made second, and dimensions can be seen in **Figure 7**. There needs to be 15mm of space between the heel ultrasonic cutout and the Arduino cutout, as well as 15 mm on each side of the cutout. The dimensions of the Arduino cutout are 68mm length by 53mm width by 23mm depth. Save the foam from the Arduino cutout, as it may be used as a plug later. The final cutout is for the toe ultrasonic sensor, specifications seen in **Figure 8**. Start the cutout 112mm from the anterior end of the Arduino cutout. The dimensions are again 23mm by 45mm, all the way through the midsole in depth. To center this cutout, leave 35mm on either side of the cutout measured at the posterior end of the cutout. Wiring holes need to be made starting from the heel of the midsole. Using a needle or 1mm drill bit, make 2 wire holes that reach each of the 3 cutouts. Both ultrasonic sensors should be put in place from the top of the midsole to allow for as much space between the sensor and the ground as possible. The Arduino, in its protective case with wires already attached, must be inserted from the bottom of the shoe. The wires can then be fed through the holes to each of the other component cutouts.

Appendix 5: Dimension Drawing of Arduino Case.



All dimensions are in mm.

Appendix 6: Original Test Plan.

Test Plans

To ensure that all specifications are met, we will execute a series of tests on our prototype at throughout the manufacturing process and after the completion of building the prototype. Our tests will focus on two main areas: the functionality of the sensors and the performance of the shoe itself. With feedback from the Apple team, we have designed tests to with the goals of characterization, verification and validation for our sensors. In addition to these tests, we will design tests to address each of our engineering specifications (**Table 9**) and FMEA/safety considerations (**Table 10)**.

When reading **Table 10** it is important to note the various kinds of tests listed in the second column. Some metrics can be characterized at the same time and will save time and labor when combining multiple metrics into the same test. The Assembly Test will be asking volunteers to set up the device with our instructions and little/no background knowledge. This assembly test will be timed in order to measure speed of assembly. No special fixtures or measurement devices will be needed for this test. The Wear Test will involve the shoe being worn by a user for an hour. During this time, the user will engage in normal walking activities on flat, indoor surfaces. Throughout the wear test, the number of adjustments will be counted and after the test, the displacement of any of the sensors will be measured. The Zero test is for calibration and verification of our sensors. We will put the shoes in a scenario where we expect to see zero change in displacement and acceleration and verify that is what the sensors are picking up. This will also give us the opportunity to verify the sampling rate of the sensors. The Battery test will be more mathematical in nature. After the electronics on the device are configured, the amount of power usage will be calculated using a voltmeter and with the output of the battery being known, the battery life can be calculated. The Compression test involves putting the shoe into the compression testing devices and evaluating how much force it takes to put the shoe on.

There are also sections of **Table 10** that are listed as N/A for testing because they are values that have been calculated or addressed during the design phase. Additionally, sensor density is no longer a consideration because of design constraints. Sensory density will not be adjustable so there is no reason to design tests to evaluate variations in sensor density.

Table 10: Test Plan for Engineering Specifications

Engineering Specification	**Test**	**Expected Result**
Set Up time	Assembly Test	
Time of Supervision	Wear Test	It is not possible to directly measure the time of supervision, but when worn for an hour, the elderly person should not need supervision while wearing the device. This means any adjustments should be made easily and quickly.
Sensor sampling rate	Zero Test	The sensors sampling rate should be approx. 1 Hz but may need to be adjusted based on software and situation.
Displacement with movement	Wear Test	After wearing the shoe for an hour, we expect that the shoe does not displace, and the sensors displace less than 1 mm in any direction.

Calibration time	Assembly Test	When setting up the device, the software must also be started, and the sensors calibrated. This should take 5 mins or less.
Production Cost	N/A	
Battery life	Battery Test	At least 24 hours of use time.
Weight	Weight Measurement	The device should weigh less than 200 g.
Number of parts	N/A	
Size range	N/A	
Adjustments needed	Wear Test	When worn for an hour, we would expect less than 5 adjustments to be needed.
Force required for assembly	Compression Test	When placed on the machine any parts that need to be assembled should snap into place at less than 100 N.
~~Sensor density~~		

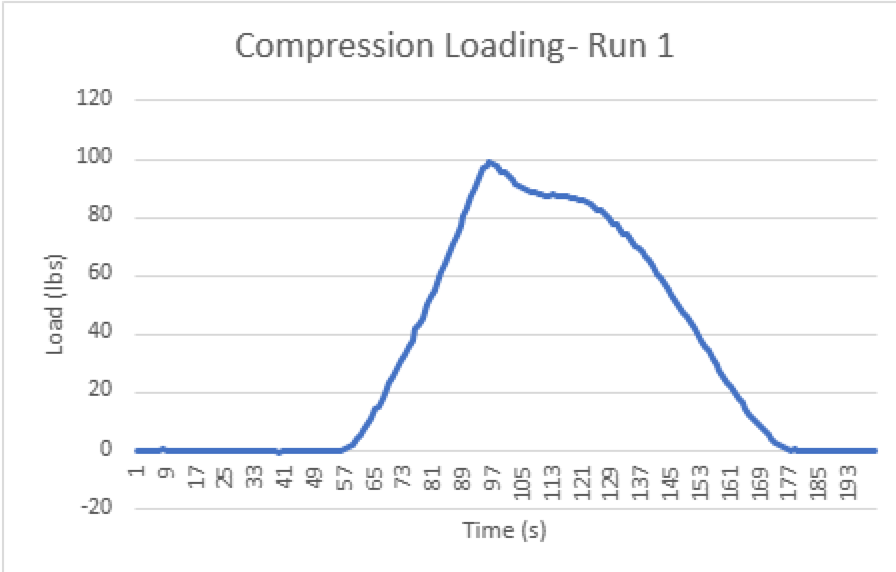
In addition to testing to ensure fulfillment of engineering requirements, we also know it is necessary to test the failure modes of our shoe to protect the safety of the user. In order to do this, we designed a test plan to address certain failures predicted in the FMEA. These can be seen in **Table 11**. Most of these failure modes can be evaluated using the Wear test that is previously described. The only additional test is the Empty Wear test, which will be performed before the sensors are placed into the shoes. The holes will be cut out of the midsole of the shoe and the shoe will be worn in the same way as the Wear test. After the test, the structural integrity of the foam will be visually evaluated to ensure there are no collapses or tears in foam caused by the creation of the compartments.

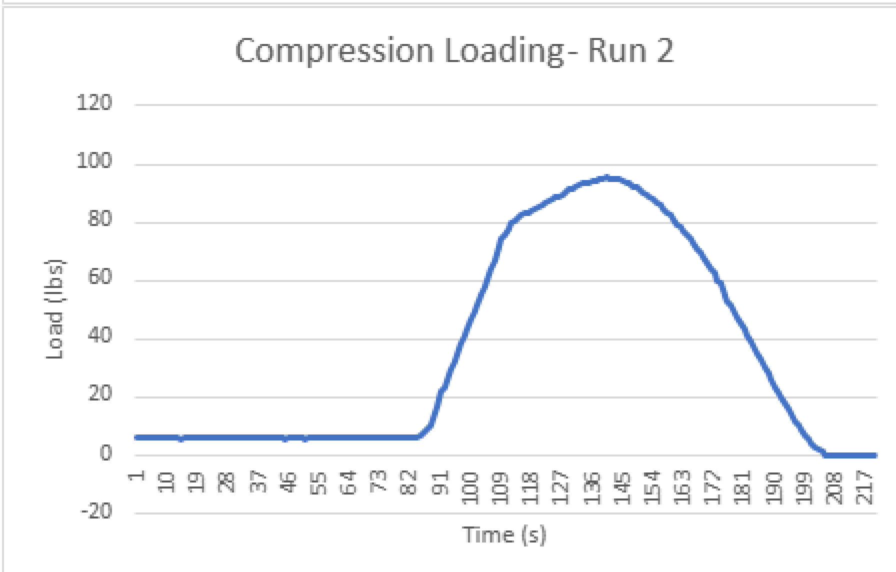
Table 11: Test Plan for FMEA and Safety

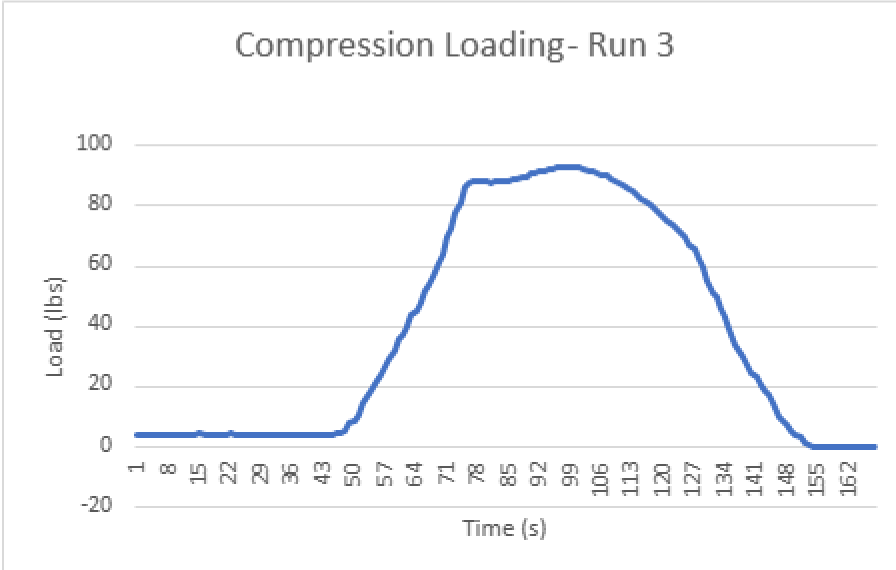
Failure	**Test**	**Expected Result**
Loose wire connection	Wear Test	Wires should remain in place within the shoe and remain connected to the Arduino after the wear test is complete.
Too much force to sensors	Empty Wear Test	After the empty wear test, the foam of the shoe should remain intact and the compartments for the sensors should remain structurally sound.
Sensor loosening	Wear Test	The sensors should remain in place, shift less than 1 mm after an hour of wear.
Glue Failure	Wear Test	The glue bond should be intact after the wear test.

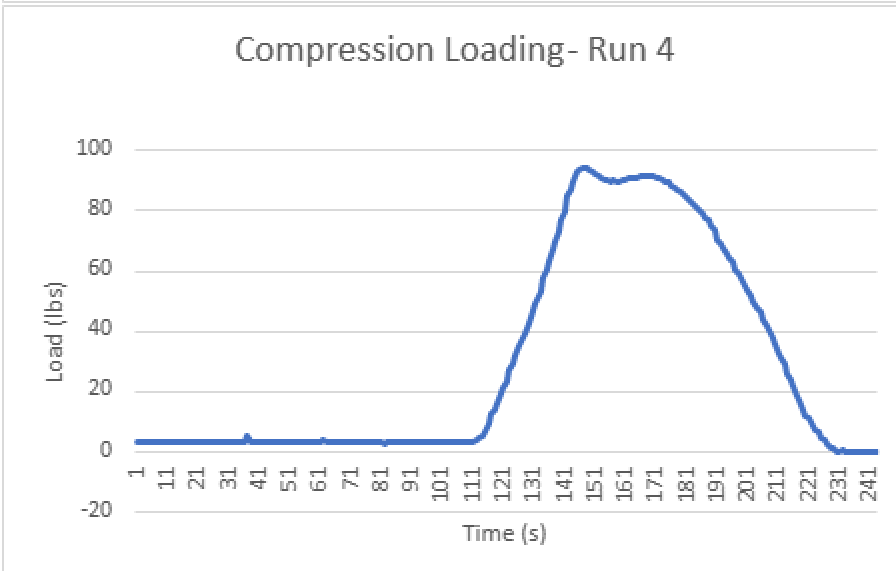
A third set of tests will be needed in order to validate the software and data collection aspects of the Arduino coding and configuration. Once the Arduino software and hardware are set up for initial use, the Zero test will be used to verify that the sensors and code are working. If the test is run, and the data collected is not zero, then root cause analysis will need to be performed in order to identify the problem in the code or in the sensor configuration. This type of testing will be iterative until we can reliably get the expected results of zero values when the shoe is not in use.

Appendix 7: Results of compression durability testing for Arduino protective case.






Compression Loading- Run 3
Load (lbs)
100
80
60
40
20
0
-20
1
8
15
22
29
36
43
50
57
64
71
78
85
92
99
106
113
120
127
134
141
148
155
162
Time (s)


Compression Loading- Run 4
Load (lbs)
100
80
60
40
20
0
-20
1
11
21
31
41
51
61
71
81
91
101
111
121
131
141
151
161
171
181
191
201
211
221
231
241
Time (s)

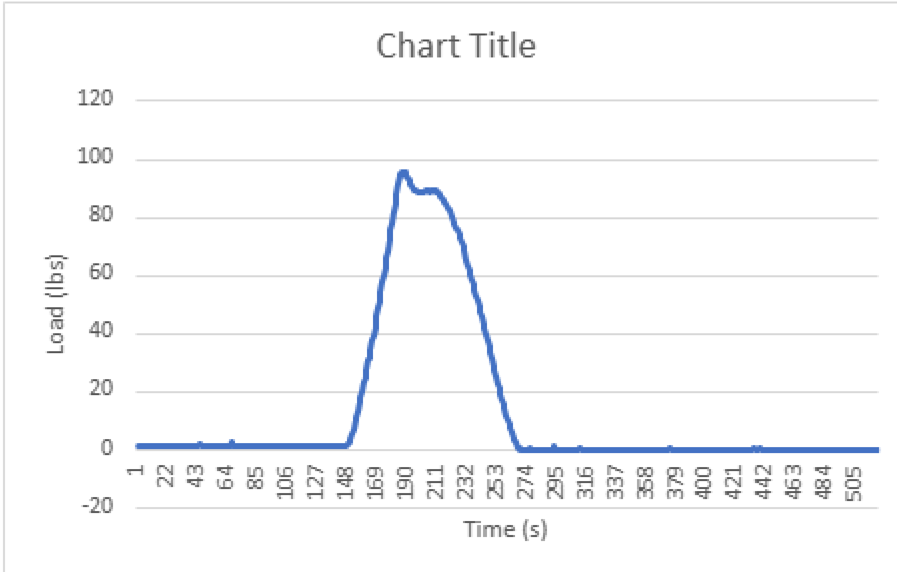


Chart Title
120
100
80
60
40
20
0
-20
Load (lbs)
1
22
43
64
85
106
127
148
169
190
211
232
253
274
295
316
337
358
379
400
421
442
463
484
505
Time (s)

Appendix 8: Results of compression to failure test of US sensor.