Project 34: Final Report

Providing Tactile Feedback During Gait Training for Adults with Disabilities During Inpatient Rehabilitation in Low-Resource Settings

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Abstract
This project aims to address the issue of impaired ability to walk in individuals suffering from strokes and partial spinal cord injuries. With millions affected globally, we aim to develop an affordable real-time feedback device for gait training in low-resource regions, reducing the heavy burden on therapists and improving independent patient training.

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Executive Summary

Our design problem looks to aid the Poovanthi Institute of Rehabilitation in Southeast India. This facility houses a high percentage of patients who have suffered from stroke or spinal cord injuries. These patients have partially lost their ability to walk, leading to gait impairments. To correct these impairments, gait training is used, where therapists will walk side by side with patients, and give them verbal and tactile cues to correct certain aspects of their walking, or gait, pattern. Since the number of therapists then puts a limit on the number of patients who can participate in gait training daily, our project looks to construct a device that can replace the therapists in this exercise. Thus, we look to create a design that will also provide real-time feedback to these patients, based on the impairments that it senses in their gait.

The requirements and engineering specifications that we have considered in delivering this project take into account the contextual factors that stroke and spinal cord injury patients suffer from and look to best correct them within the context of our rehabilitation clinic. The most critical of these requirements include: Detect relevant gait parameters, provide feedback to the user, be price efficient, be safe, be able to be used without power boxes, and function without fail in the local climate. The specifications for each of these requirements, and several others of slightly lower priority, have been determined through literature research, stakeholder interviews, and sponsor feedback.

Some challenges that we have encountered include assessing the engineering specifications for designing a system for post-stroke and spinal cord injury patients. These challenges encompass the contextual factors mentioned in our requirements and specifications, which are industrial, socio-cultural, infrastructure, geographical/environmental, institutional, economic, public health, and technological factors. Through research, interviews with stakeholders, and engineering analysis, we have developed potential solutions for tackling them, via both expert consultation and experimentation.

Throughout our design process, we have learned that a ready-for-use product may not be viable in one semester, but we were able to configure several existing products to form a cohesive device that can sense and analyze gait parameters in real-time. With research and development, we were able to develop a prototype that could meet each of our requirements. Our project plan for the semester was to go from simply the sensing aspect of our prototype to data processing and ultimately feedback in as real-time as possible, which was accomplished. We also looked to conduct several tests to analyze each subsystem's ability to meet our requirements. To do this we consulted with relevant experts and focused our research on the mechatronic, processing, and feedback side of things. As a result, we were able to develop a prototype for each subsystem of our final design that was capable of meeting our requirements. In the future, this prototype can be used to implement a cohesive final product for use by our sponsors.

Project Introduction, Background, and Information Sources

The ability to walk and move independently is often taken for granted by many people; this ability allows a person to easily integrate with society and achieve a certain quality of life [1]. One measure for assessing one's mobility is through their gait. Gait looks to analyze the way that someone walks, measuring several different factors such as stride length, stance width, and cadence among other factors. Some of these gait parameters are displayed in **Figure 1** below.

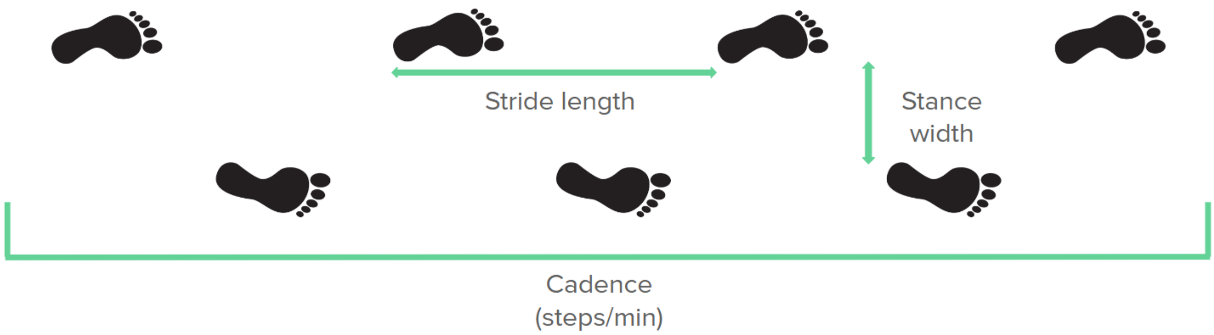


Figure 1. Overview of Standard Gait Parameters

For those who have difficulty walking, an analysis of these gait parameters seen in the previous figure can be used to help them understand their progress toward recovery. Our project has a key focus on gait improvement for people suffering from debilitating illnesses. One of these debilitating illnesses is a stroke, which can result from a blockage of blood supply to the brain or a bursting of a brain blood vessel. Strokes result in the damage or death of brain tissues, and the damage of these tissues can influence one's thoughts, emotions, and motor function [2]. Partial spinal cord injuries are also a debilitating illness that is the result of damage to neural elements in the spinal canal and can result in temporary or permanent sensory and motor dysfunction [3]. Annually 15 million people worldwide suffer from stroke [4], while 400,000 suffer from partial spinal cord injuries [5]. Additionally, 80% of stroke and spinal cord injury patients develop walking problems, due to sensory and motor dysfunction from their illnesses [6][7]. With stroke victims, the walking problems are related to hemiplegia, a one-sided muscle paralysis or weakness, where a victim exhibits slower walking speed, asymmetrical and decreased step length, decreased stance, and general gait asymmetry [6]. Partial spinal cord injuries cause damage to the nerves in the lower extremities that can result in reduced sensation and weakness in the arms and legs, making walking difficult. Complete rehabilitation walking devices that are used in the United States can cost more than $300,000 [8]. Although complete rehabilitation devices are effective, their cost can create a barrier to entry in low-income settings. Low resource settings, such as the ones we aim to address in our project, can suffer from increased logistical barriers, limited infrastructure, scarcity of advanced medical equipment, and shortages of trained medical professionals [9]. Current methods in low-income settings include techniques like coaching and supervision from therapists following behind patients, and making corrections to legs and feet manually to improve the patient's gait [10].

Our project (number 34), is titled "Providing tactile feedback during gait training for adults with disabilities during inpatient rehabilitation in low-resource settings". The sponsors for this project are the University of Michigan Department of Mechanical Engineering, and the Poovanthi Institute of Rehabilitation and Elder Care.

Increasing the mobility of patients is the motivator for the project. People with disabilities are more likely to earn less money, more likely to be unemployed, more likely to have additional living expenses resulting from their disability[1], and twice as likely to be at risk of developing depression [11]. Mobility is important; it allows for a person to integrate within their community and achieve a certain quality of life.

One facility that has a high number of these stroke and partial spinal injury patients with gait impairments is the Poovanthi Institute of Rehabilitation in Southern India. This therapy facility houses 86 patients who have gait deficits as a result of stroke and spinal cord injuries. However, the facility does not have access to complete rehabilitation walking devices due to cost limitations. In this center, therapists need to constantly supervise patients, giving them real-time verbal and tactile cues. However, this time commitment can prove difficult for the therapists, as there is a 12:1 patient-to-therapist ratio. Gait training requires the therapist's constant attention and a limited number of therapists limits individual patient training time[10]. Therefore, there is a need to develop a gait training system that provides feedback to patients; such a device would improve independent gait training and reduce the load on therapists.

Based on the design context and desires from stakeholders, a more defined scope for the project and the existing problem is a need for a device that provides multimodal, semi-real-time feedback for gait deviation patients in low resource settings. A successful project outcome would be the development of a device fitting the aforementioned scope that meets specified engineering requirements and specifications relayed by stakeholders. A complete list with priority ranking and justification can be found in the "User Requirements and Engineering Specifications" section of this report **(**pages 11-16**)**. For example, a rough explanation of some of the most critical requirements that should be met for the device to be successful include the device meeting price requirements, the ability for the device to detect relevant gait parameters, and ensuring the device operates safely and as intended. These are explained in depth in later sections. If the device was to successfully detect gait parameters and provide feedback to the patient, the device would enable more total patient training time and information without the need of a therapist leading to more positive recovery outcomes. Altogether such a device would enable the patient to integrate better with society and achieve a higher quality of life.

There are a variety of devices in the market that may address components of the design problem. In **Figure 2** below is a process flow of existing solutions in the market. They are capable of sensing motion, analyzing the gathered information, and then providing feedback. Sensing can be accomplished in a variety of ways such as using inertial measurement units or IMUs, pressure sensors, electromyography or EMGs, and image processing and camera tools. Information that is analyzed can consist of relevant gait parameters such as stride length, step width, and cadence. Other information that sensors may gather include muscle activation, joint range of motion, and foot pressure [51]. Feedback that is then provided to patients can be in the form of auditory, haptic or visual feedback.

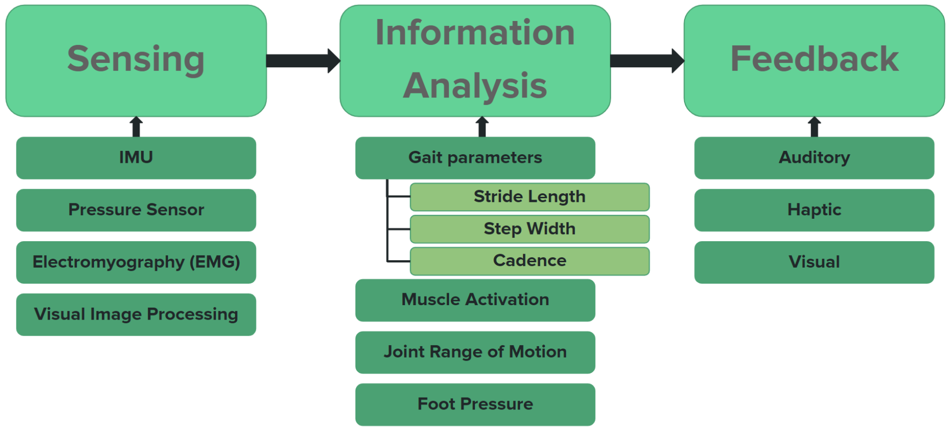


Figure 2. A Process Flow of Existing Solutions in the Market

Some of the specific solutions that are available are provided in **Table 1** below. This table provides benchmarking across different solutions. The majority of these solutions differ greatly in the sensing method used such as IMUs, pressure sensors, or camera based systems, but have similar feedback modes (mostly visual based on an external computer). Many existing devices are tailored for more of a delayed feedback mode, and cannot prompt the user in real-time to adjust their gait.

Table 1. Benchmarking of Existing Gait Measurement / Sensor Devices

Considerations	GAITRite Mat [12]	ProtoKinetics Zero Mat [13]	Hocoma Lokomat [14]	XSENSOR Clinical Insoles [15]	Camera-Based Systems* [16]	Cometa IMU Wearables [17]
Cost	~$10,000 - $30,000	~$10,000 - $30,000	~$300,000	N/A	N/A	~$10,000+
Data Collected	Stride Length, Stance Width, Cadence, Foot Pressure	Stride Length, Stance Width, Cadence, Foot Pressure	Stride Length, Stance Width, Cadence, Muscle Activation, Joint Range, Foot Pressure	Foot Pressure, Cadence	Stride Length, Stance Width, Cadence, Joint Range	Cadence
Information Analysis (Y/N)	Y (requires external computer)	Y (requires external computer)	Y	Y (requires external smartphone)	Y (requires external computer)	Y (requires external computer)
Feedback Modes	Visual (requires external computer)	Visual (requires external computer)	Visual, Auditory, Physical Correction	Visual (requires external smartphone)	Visual (requires external computer)	Visual (requires external computer)
Real Time Feedback (Y/N)	N	N	Y	N	N	N
Mechanical Support (Y/N)	N	N	Y	N	N	N
Involuntary Correction (Y/N)	N	N	Y	N	N	N

*These concept devices may not have a commercially available product

This is a very niche market, and so there are not many concepts on the market and not many of these are commercialized. The GAITRite and ProtoKinetics Zero mats are examples of gait mats that use pressure pads that measure gait features. The Hocoma Lokomat is an electromechanical holistic solution to gait related issues that utilizes treadmills and an exoskeleton. The XSENSOR Clinical insole is a variant of a pressure pad that is worn inside the shoe. The fifth column is an example of a camera based system concept to measure stride length, width, and cadence. Camera based systems are traditionally utilized in gait labs, and not necessarily in a busy clinical rehabilitation setting. Cometa wearables are an example of an IMU wearable system that can be used to measure gait parameters. Most of the concepts in the table above only record gait parameters, and there is still a need for a device that provides live feedback.

There are a few solutions for holistic gait analysis and gait correction, but there is a market gap for a device that is inexpensive and provides basic analysis and gait correction feedback that is relayed to the patient in real-time. Solutions such as the Hocoma Lokomat completely fulfill the functional needs of stakeholders, but fall well outside stakeholder price ranges [18].

Current benchmarked devices shown in **Table 1** are not necessarily designed with real-time feedback for a patient to interpret and learn to improve their gait without a therapist. There must be a consideration of feedback modes tailored for real-time patient use specifically. Current rehabilitation feedback modes in the facility are a combination of tactile and verbal cues from therapists themselves. In **Table 2**, there is a comparison of advantages and disadvantages between available feedback modes for this purpose.

Table 2. Comparison of Available Feedback Modes

Feedback Mode	**Real-Time Usability** (High, Medium, Low)	**Considerations**
Auditory	High	• Auditory feedback can pose issues for people with vestibular loss who may also have issues hearing [19]. • Patient does not need to be facing the feedback display to clearly receive feedback. • Can quickly and clearly deliver information. • Can be difficult to understand geometric feedback (as opposed to visual feedback methods). • Can be difficult to interpret in noisy settings.
Vibrotactile	High	• Can be difficult for partial spinal injury patients to detect and interpret feedback if they have partial numbness/lack of feeling [18]. • Unmistakable, clear sensation to receive feedback. • Feedback cannot convey large amounts of information.
Visual	High	• Offers good recognition but may be problematic with head movements [19]. • Patients must face visual elements at all times to receive and interpret feedback. • Can clearly and quickly communicate large amounts of information. • Can communicate geometric information effectively [20].

Multimodal feedback, in the combination of auditory and visual elements, is most common for gait rehabilitation [20]. Real-time feedback provides the best short-term results while delayed feedback provides better results long-term. Detailed feedback can make the task more complicated for the patient to understand or process other sensory information [20]. Additionally, the presence of feedback in the short term could result in dependence instead of learning [20]. Feedback can be descriptive (stating the error) or prescriptive (explaining how to correct the error). All of these are important considerations when selecting appropriate feedback modes and styles for the device.

As stated previously, the current solution for the Poovanthi rehabilitation facility is the use of a therapist to monitor and coach patients. However, this time commitment can prove difficult for the therapists, as there is a 12:1 patient-to-therapist ratio [18]. Gait training requires the therapist's constant attention and a limited number of therapists limits individual patient training time. There is existing gait training technology at the center, but it lacks the ability to provide sensory analysis and real-time- feedback to patients without a therapist [18].

Information sources consist of various interviews, patents, journal articles, studies, and standards. Interviews have been conducted with different stakeholders such as Dr. Shibu, the Chief Medical Officer (CMO) of the Poovanthi rehabilitation facility, stakeholders within the University of Michigan Global Health Design Initiative, and other professionals such as Dr. Ojeda, an expert in motion tracking for gait analysis at the University of Michigan or Danny Shin, a Master of Occupational Therapy. Patents have also been used as sources of information, found through locations such as Espace.net's patent search database. Journal articles and studies have also been plentiful sources of information in databases like the National Institute of Health, and the use of Medical Subject Headings (MeSH terms) aided in locating specific data. Relevant standards include the Central Drugs Standard Control Organization (CDSCO), India's regulatory body for medical devices, as well as proxy organizations within the United States such as the Food and Drug Administration (FDA). An exhaustive current list of sources can be found in the references section at the end of this document.

Design Process

This semester we utilized a combined stage-based and activity-based design process model. We saw this as the best method, compared to solely stage-based or solely activity-based, which we had also considered following. We determined that this is the best process for us to follow because it would allow us to continuously iterate well-structured activities upon our design throughout the entirety of our work. This has been helpful as we move from one stage to the next because we would oftentimes need to revisit previous stages, and going back over these stages as we simultaneously go over each activity allowed us to develop a more concrete understanding of our problem and potential solution.

The design process introduced during the lecture on the first day of class chronologically includes need identification, problem definition, concept exploration, solution development, and realization. Need identification involves accessing user needs; problem definition involves framing the problem; concept exploration involves generating concepts, developing them further with focus, and narrowing down to one concept; solution development involves CAD, analysis, and detailed designs that meet requirements; and realization involves verifying and validating the design. Our design process has heavily resemble the problem definition, concept exploration and solution development phases. These three phases provided a useful guideline for us to follow in terms of helping us to realize the complexity of our design in social and environmental contexts and generating a high-quality, novel concept. On the other hand, our design process has differed from the solution development phase given that need identification is already done for us before we received the project, and for the limited time given in this semester, we were not be able to perform validation on the effectiveness of our design. We have verified that our design meets stakeholder needs, requirements and specifications, but we will not be validating whether the customers are satisfied, the clinical trials are passing, nor the solution is working in a real environment.

From the beginning of the project to now, there have not been any significant changes to our design process plan. Instead, we have moved through the plan, out of the problem definition phase, and into concept exploration and solution development phases. Although validation of a final prototype was not feasible for this project this semester, subsystems within the final prototype could still pass safety, and functionality testing.

Design Context

Stakeholder Analysis

There are many different groups of people that can be impacted by the way we choose to go about our design process; these people are our stakeholders. **Figure 3** below shows a brief map of some of these people. We see the type of stakeholder color-coded on the left, with each stakeholder and their given affinity within the concentric circles.

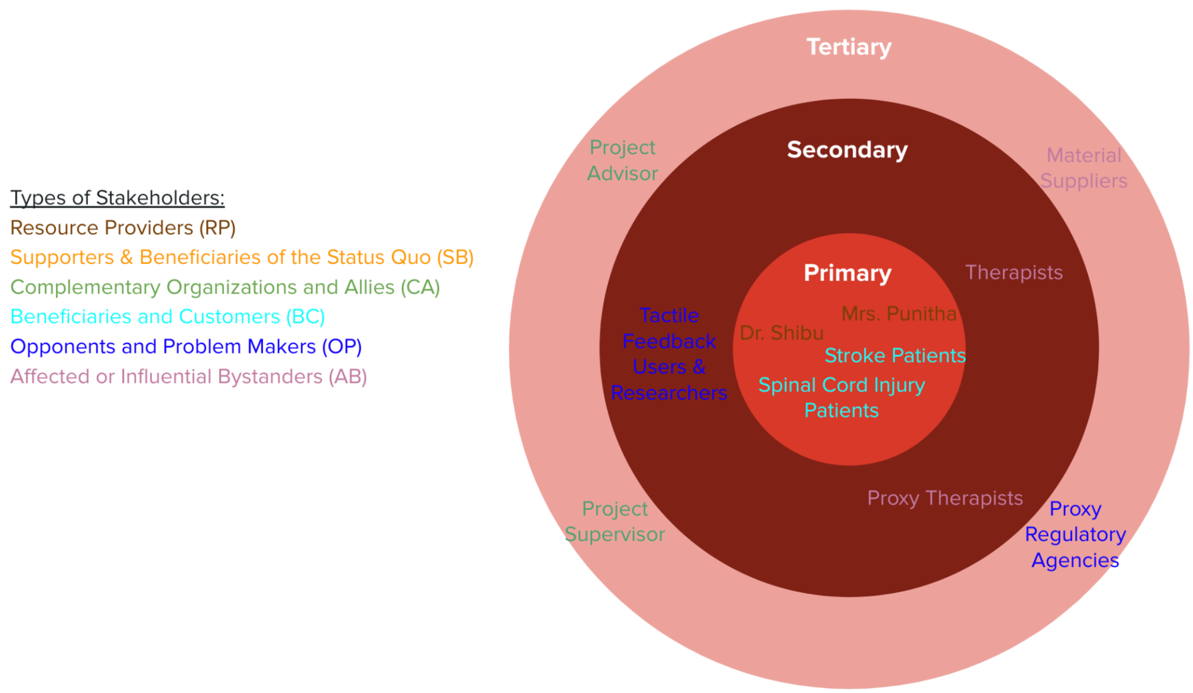


Figure 3. Stakeholder Map

Within the primary stakeholder group, we see Dr. Shibu and Mrs. Punitha, as well as stroke and spinal cord injury patients. These are the main stakeholders that we want our design to positively benefit the most, as making life easier at the facility for these people is our main goal. We then go to our secondary stakeholders, who are tactile feedback users & researchers and therapists & proxy therapists. We hope that our product is able to aid these individuals by giving them better insight into how to understand real-time feedback associated with gait training. It is worth noting that from a broader sense, there could be a negative impact on therapists, as ideally, our project no longer requires the active help of therapists during gait training. We then come to the outer edge of our circle with our project advisor & supervisor, material suppliers, and proxy regulatory agencies. Each of these stakeholders is not directly adjacent to our design project, however, can have an impact on it by limiting the exact direction we are able to go in. In **Table 3**, we then see an analysis of our stakeholder map, where each stakeholder and their contribution to the project is elaborated in greater detail.

Table 3. Stakeholder analysis map. Note that we use the same color coding scheme for the type of stakeholder in this table as seen in the previous figure.

Stakeholder name	Impact	Influence	What is important to the Stakeholder	How could the stakeholder contribute to the project	How could the stakeholder block the project	Strategy for engaging the stakeholder
Chief Medical Officer (Dr. Shibu)	High	High	Ensuring patients receive sufficient care, therapists are not overwhelmed	Provide expertise and help to set product requirements	Will determine if product is viable for use at facility	Frequent meetings and correspondence based on availability
Clinical Manager (Mrs. Punitha)	High	Medium	Ensuring patients receive sufficient care	Provide overview of scope of desired solution	Critique product effectiveness	Frequent meetings and correspondence based on availability
Therapists	High	Low	Improving patient recovery and wellbeing	Give insight on gait training corrections	Critique product effectiveness, learn new technology	Receive info through meetings with Dr. Shibu
Stroke Patients	High	Low	Recovery from disability	Insight on product comfort, effectiveness, and ease of use	Complexity and willingness to learn new technology	Receive info through meetings with Dr. Shibu, gather info from similar cases
Spine & Other Patients	High	Low	Recovery from disability	Insight on product comfort, effectiveness, and ease of use	Complexity and willingness to learn new technology	Same as above
Project Advisor & Supervisor	Low	Med	Creation and delivery of project for student learning	Communicate and bridge different stakeholders, Provide guidance	Lack of availability and communications	Set up meetings and proactively communicate
Material Suppliers	low	low	Increased product orders	They would be able to transport the product	If the tech can't be shipped then it wouldn't work	Researching shipping in India
Tactile Feedback Producers	medium	medium	Developing tactile feedback technology	Their work could be used to inspire an idea	Their patents could restrict us from using their ideas	Use existing tech to develop an alternative product
Tactile feedback researchers	medium	medium	Researching tactile feedback	Their research could be used to develop ideas	They could have proprietary research that cannot be cited	Research public sources and use info to develop designs

We can see clearly from the variety of stakeholders that there is a much broader societal impact of our project. There currently is no affordable real-time gait-specific feedback technology, and keeping our stakeholders in mind throughout the design process was the most beneficial aspect to both our sponsors and ourselves. This was our number one priority in our design and is important to both us and our sponsors. We hope that from a societal point of view we can positively help many patients with gait training, both at the Poovanthi Institute within our project and at many therapy practices around the world with a broader scope.

Project Impact and Key Factors

Another important thing to note when analyzing stakeholders is the intellectual property (IP) of the project. Our project has IP to the University of Michigan Global Health Design Initiative. This did not have much of an impact on our design, it simply meant that we could strive to meet our design requirements as effectively as possible and feel confident that the work would potentially be continued in good hands in the future. Furthermore, we needed to be aware of existing patents that are similar to our eventual solution, and ensure that our final product did not infringe upon them.

The individuals who stand to benefit the most are the stroke patients at our sponsor's hospital. The ones most likely to bear the costs are the sponsors themselves, having to pay for the technology in order to be able to supply their patients with it. Additionally, in the long run, the end product is likely to be cost sustainable due to the fact that it reduces costs to the sponsors. While the upfront material costs can be expensive when looking short term, over an extended period of time it will decrease the amount of time that therapists need to spend with patients, thus reducing costs and allowing them to expand easily to more patients not solely focused on gait training.

From an environmental standpoint, there is very little to worry about with our project, given that even in an idealized case there will only be a few units produced. Even in the case where more units are manufactured, the small demand and potential for pollutants is very low. However, in the long run, we must be aware of the specific materials used throughout the manufacturing process, as from a high-scale perspective it is important to utilize recyclable materials. If our product is eventually going to be mass manufactured, we must also be aware of the availability of each material, as we should ensure to use less finite materials and aim to reduce the levelized cost of energy throughout the process. One consequence of using recyclable materials that emit less pollutants however is cost, as oftentimes more sustainable materials may be more expensive. Additionally, these materials may not be available through our material suppliers in India, and if we want to focus on appealing to our primary stakeholders then sustainability in the long run may be less important.

One future important ethical dilemma is our testing and validation. We must ensure that our device is safe and efficient, however without extensive clinical trials this information may not be confirmed until the end of future design processes. With this in mind we must ensure to stress whatever safety assumption we have made, and develop a thorough plan for testing and validation. Another important ethical dilemma we faced is cultural sensitivity. We had to ensure that our device was culturally appropriate, respects local customs and beliefs, and could be utilized the same way across cultures.

We believe that our personal ethics closely align with those of the University of Michigan. However, if we look through the lens of a future employer as it pertains to our project, certain companies may be more likely to hold a higher emphasis on profit as opposed to end users. It is important that throughout our design process we stray away from this, and focus on helping users as opposed to helping potential shareholders increase profit.

One power dynamic that we faced in the design of our project was our hidden power over the end users. We were designing our project through research and communication with our sponsors and others associated with the project. However, we did not plan to speak directly with patients at the Poovanthi Institute. This means that while we strived to design our project for these end users, we likely did not necessarily perfectly interpret all their needs. As a team we strive to all hold no power dynamics over each other, and hope to do our best to minimize the power dynamics between us, our sponsor, and end users.

Lastly, it is important that we ensured our design was inclusive to all users, regardless of culture, sex, age, etc. This means that our research focused on patients of all sizes, and as we learned more about gait we must do it through an open lens, encompassing patients of each sex, of varying ages, and of multiple cultures. We also ensured that our device could be easily assembled, used, and interpreted through a language and cognitive ability barrier.

As we have gained a deeper understanding for our project and the deliverables that we needed to meet this semester, it has become apparent that a fully-fledged, ready for market product was not necessarily viable. This means that there is less of a concern on our end for the large scale implications that our project may have on public health, safety, and welfare. We do recognize that these implications are important, and still believe that the previously listed factors are important to consider, however this may be something more important for future work on this design project. Additionally, we maintained an objective of meeting our design requirements for the correct user, and holding the same global, cultural, social, and environmental contexts within our design space.

User Requirements and Engineering Specifications

A series of interviews was conducted with the client in order to determine the user requirements [18]. We then conducted research relating to each requirement to define each respective engineering specification. For example, we referred to existing, related, or competing systems and their specifications relevant to our requirements to formulate our own specification. We also incorporated appropriate standards, codes, and laws in defining our specifications.

Furthermore, the framework for holistic contextual design for low-resource settings shown below (**Figure 4**) [21] was employed along with the contextual factors for the medical facility [10] identified by the project advisor. A summary of the contextual factors we considered are listed below in **Table 4.**

Table 4. Table summarizing contextual factors applicable to the design project [10] and their description.

Contextual factor	Description
Socio-cultural	End users use Tamil language. End users wear T-shirts, shorts, and sandals (often barefoot).
Geographical	Climate is hot and humid, the temperature going up to 55°C and 100% humidity. The facility does not have air conditioning.
Geographical	Our facility is located in the rural part of Southern India.
Technological	Power outages are common and last a few hours.
Technological	The wall has 230V outlets and plugs are type C,D, and M.
Public Health	Power boxes are used to reduce the number of cords (trip hazard risk).
Environmental	Environmental consequences due to resource use, emission during manufacturing, transport, operation, and disposal are shared with the global population.

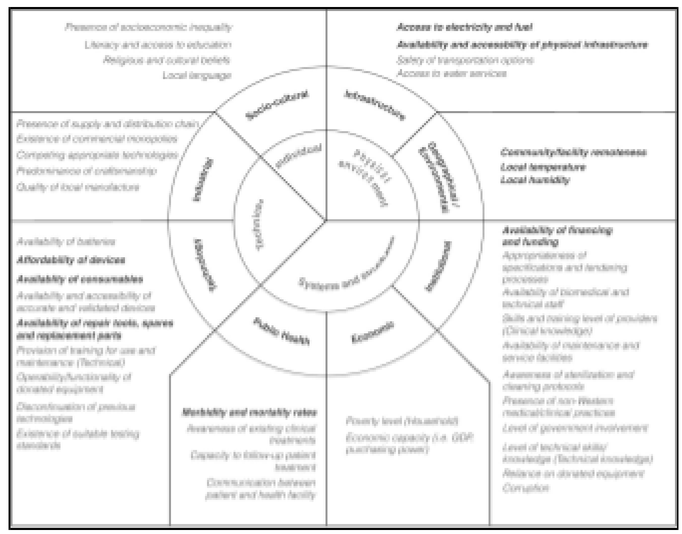


Fig. 4 A visual figure showing 8 different categories of contextual factors applicable for designing for low-resource settings.

The specifications were designed to be as quantifiable and measurable as possible in order to use them to rate the success of our final solution. However, it is noteworthy that certain requirements cannot be transcribed into fully quantifiable specifications. All of the current requirements and specifications our team is considering are depicted on the next page (**Table 5**). The list of resources that we incorporated while defining the requirements and specifications are included in the table. Furthermore, the rationales behind how each specification was defined in relation to the resources and why it was included are described below the table. As mentioned previously, our design process is an iterative process, hence the content of the table can and will be altered in the future to better suit the problem at hand.

Each requirement was categorized in terms of their importance to the success of the design solution. High priority requirements are those that are mandatory, while medium priority requirements are requirements beneficial to the solution's success. Low priority requirements are those that are helpful to have, but not at all crucial to the product's success. Any requirement the client has directly requested as a must-have has been categorized as high priority. In addition, requirements and specifications related to safety and compatibility with the facility environment, and legal codes, regulations, and standards that need to be met in order for our device to even be implemented have been categorized as high priority. Similarly, requirements that do not stop our device from being implemented if not fulfilled, but those that are still needed for the longevity, efficiency, and ease of use of the product were identified as medium priority. Other requirements that are simply nice to have have been defined as low priority.

Likewise, each row of the table was categorized based on our team's confidence to fulfill them. Green indicates we are confident, yellow means we are unsure at this moment, and red shows that we are concerned and not confident. Requirements and specifications that are fully defined and therefore are able to be used to evaluate the success of our final solution were shaded green (confident). Specifications that are incomplete or missing numerical values were classified as yellow (unsure). Lastly, those that are causing immediate concern were shaded red (worried).

Table 5. A table summarizing all of the current requirements and specifications our team has defined. Justification for each specification and the sources used in the process are also included.

Number	Priority	Requirements	Specifications	Sources	Confident to complete?
1	High	Detects relevant gait parameters	**The device must measure stride length ranging from 0 to 1.50m (inclusive).** **Measure cadence 0 - 120 steps/min (inclusive).** **The measured values must have total error ≤ ±3cm for stride length and ≤ ±5% for cadence.**	CMO [18] Review article on effect of cueing on stride length for stroke patients [22] Journal article on typical cadence for moderate and vigorous intensity activities [23] Research articles on accuracy of different commercial pedometers and their acceptability [24] Research articles on sensor accuracy requirements for medical uses [25] [26]	
2	High	Provide feedback to the user	The feedback must be provided every 2-4 steps for all gait parameters simultaneously. The device needs to have two or more means of providing feedback.	CMO [18] Project supervisor [27] Research article on real-time gait training to reduce knee adduction moment	

				[28]	
3	High	Be price efficient	The device must be ≤ $8,000 in final product acquisition price to stakeholder	CMO [18]	
4	High	Be safe	The device must be classified as class A (low risk) or B (low moderate risk) per CDSCO . The device must not have more than one cord to reduce the risk of trip hazard. The device must score 0 on Magnusson and Kligman scale for skin sensitization.	CDSCO standard [29] ISO standard for medical device biocompatibility [30]	
5	High	Be hygienic	The surface of the device must not be composed of materials (PMMA, Polyurethane coated Polyester, or Velvet Polyester) that are incompatible with conventional disinfectant products (composed of chlorine bleach or quaternary ammonium compounds). The surface of the device must have surface roughness value ≤ 0.8µm.	CMO [18] Disinfectant wipe material compatibility [31] Report on hygienic surface selection for food applications [32]	
6	High	Be able to be used with the power boxes	The device must function with 230V outlet The device must have type C, D, and M plug.	Project advisor [10]	
7	High	Function without faults at local climate	The device must be fully functional in environments up to 55°C and 100% humidity.	Local weather databases [33] [34] Academic article on effect of humidity on electronic devices [35]	
8	Medium	Be easy to set up	The device must take ≤ 5 minutes to set up by an untrained individual.	Project supervisor [27]	
9	Medium	Be durable	The device must be able to operate successfully for a minimum of 4 hours a day every day for ≥ 5 years.	CMO [18]	
10	Medium	Be able to be used during 6 minute walk test (6MWT)	The device must include a stopwatch to measure 6 minutes. The device must be able to measure and record up to 50 laps of 12 meter walks.	CMO [18] Project advisor [10] Rehabilitation measurements databases [36] Clinical review article [37]	
11	Medium	Be able to interact with the user in a comprehensible manner.	The device must have instructions and feedback provided in the form of universally understood visuals or the Tamil language.	Social Context Learning Block Project advisor	
12	Low	Be able to function during power outages	The device must be able to fully function for more than _ hours using battery power.	Project advisor [10]	
13	Low	Be comfortable	The degree of comfort while using the device must be ≥ 4/5 on the Likert scale from the	Research articles on comfort scales	

			questionnaires derived from the Wheelchair Seating Discomfort Assessment Tool.	[38][39] Wheelchair Seating Discomfort Assessment Tool [40]	
14	Low	Be sustainable	The device must score ≥ 5 on the Product Sustainability Index (ProdSI).	Social Context Learning Block Holistic Contextual Design Article [21] Product Sustainability Index [41]	

Justifications of the Requirements and Specifications

High Priority

1. Detects relevant gait parameters

The client explicitly requested for our device to be able to measure stride length and cadence [18]. Normal gait patterns involve stride length up to 1.5m, and for vigorous intensities, cadence up to 120 steps per minute [22] [23]. The device must therefore be able to detect up to those values. Measured values need to be accurate in order to elicit positive change to the patient's gait. Typical stride length and cadence measurement error were obtained by reviewing sources cited [24] [25] and [26] and incorporated into the specification.

2. Provide feedback to the user

Upon interviewing the client [18] and the project supervisor [27], our device needs to cue patients to make concurrent changes to their gait while walking. An example step amount value of 8-10 steps for real-time gait feedback was obtained from the source [28], but the client updated [42] that the more frequent the feedback the better. This led us to choose a range that is realistic (consider both feet), but at the same time as frequent as possible, settling at 2-4 steps. The mode of feedback is important to consider as well, given our device will be used in crowded therapy halls based on CMO interview, and the end users are stroke and spinal injury patients who may have lessened sensation to certain modes of feedback. Therefore, the feedback must be multi-modal.

3. Be price efficient

Client specified the price ceiling of $8,000 USD [18]. This price ceiling is considerably more price efficient than the typical price of the most commercially available existing solution with the price $10,000 [12].

4. Be safe

Our device being a medical device, it is required that it abides by medical safety standards set out by various public health administrations (CDSCO for the case of India) [29]. In a more practical sense, our device must not increase the risk of fall hazards. Therefore, we set a goal to ensure our device has no more than one power cord, to minimize the risk of trip hazard as much as possible while utilizing the wall outlets for charging, operation, and more. Lastly, the surface of our device must not cause skin sensitization, hence we must select a surface material which scores no more than 0 on the Magnusson and Kligman scale for skin sensitization [30].

5. Be hygienic

According to our client, the existing system at the facility is used by multiple patients everyday. With the COVID-19 pandemic in mind which caused a large amount of casualties worldwide, our device must minimize transmission of germs through surface contamination. Through research, we were able to identify surface materials that are incompatible with commercial disinfectants (chlorine bleach or quaternary ammonium compounds) [31]. These materials must not be selected to allow cleaning. We must also ensure bodily fluids are not absorbed into the device to make sure surface cleaning is effective in preventing transmission of germs [32]. A conventional metric of surface hygiene is surface roughness (R_a), and a standard for food grade hygiene is 8μm [32]. We expect our device to also have R_a below that standard value.

6. Be able to be used with the power boxes

The device must be able to function with the power boxes which have 230V outlets. They also work only with type C, D, and M plugs, hence our device must meet these specifications for it to function.

7. Function without faults at local climate

The device must be able to function at the facility, which includes functioning under high temperature and humidity conditions, along with the absence of air conditioning [33] [34] [10]. We discovered high humidity alone can lead to damages in electronic devices [35]. Highest temperature and humidity values recorded at the location were sourced from local weather databases and set as the maximum working environment for our device.

Medium Priority

8. Be easy to set up

Our device is intended for patients to use for gait training even when a therapist is unavailable. Thus, even an end-user with no medical or technological background must be able to set up the device quickly. This would also indicate the ease of use of our device.

9. Be durable

According to our client, the existing system at the facility is used for up to 4 hours everyday [18]. With the expansion of the facility to allow more than 100 patients in the near future [18], the patient to therapist ratio is expected to rise even more. This would therefore mean that our device will have to operate for 4 hours or more, and at the same time, be able to function for more than 5 years.

10. Be able to be used during 6 minute walk test (6MWT)

Based on the interview with the project advisor, we also decided to require our device to be useful during the 6 minute walk test. This test is a standard test used to gauge the ability of a patient's ability to walk, by measuring the number of laps the patient completes in the span of 6 minutes [36]. Its results are an effective indicator of a person's ability to walk and complete day to day activities [37]. Due to its effectiveness, we have agreed with the advisor to have the 6MWT as the best case scenario for the patients [10]. Therefore we set the specification such that it can measure the 6 minutes, as well as counting the number of laps recorded.

11. Interactions with the user must be comprehensible for the user

The end users speak the Tamil language [10] as discussed in **Table 4**, and therefore our device must provide all interactions in modes that are understandable by any and every patient. This includes instruction manual, feedback, and any labels on the device.

Low Priority

12. Be able to function during power outages

The facility often experiences power outages lasting a few hours according to our source. It is important that patients can receive continuous monitoring and support. However, inability to use the device during outages does not cause a significant safety issue. This requirement is therefore a low priority requirement.

13. Be comfortable

The discomfort during use can be a factor that deters the users from continually utilizing the device. We therefore require our device to score a 4/5 rating on Likert scale for the assessment we will derive based on a similar tool for measuring comfort of a medical device, such as the Wheelchair Seating Discomfort Assessment Tool [40].

14. Be sustainable

We acknowledge that the global population is also a tertiary stakeholder, as environmental consequences caused during the device's manufacturing, transport, operation, and disposal can affect them. We want our device to have a long product life while utilizing less finite resources available to us, and also be disposed of in a responsible manner. These components as well as many other sustainability related factors are considered and weighed in a measurable manner by the product sustainability index (ProdSI). We expect our device to score higher than 5 out of 10 (10 meaning perfectly sustainable) [41].

Concept Generation.

In order to generate concepts for our project, the project itself was able to be divided into three different subfunctions: sensing, processing, and feedback components. This is because every design that would meet requirements and specifications for our project include these three categories. In **Figure 2**, a process flow of existing solutions in the market. Existing solutions are capable of sensing motion, analyzing the gathered information, and then providing feedback. Sensing can be accomplished in a variety of ways, such as using inertial measurement units (IMUs), pressure sensors, electromyography (EMGs), or image processing and camera tools. Information that is analyzed can consist of relevant gait parameters such as stride length, step width, and cadence and may be processed using specialized microcontrollers, laptops, or stationary computers. Other information that sensors may gather include muscle activation, joint range of motion, and foot pressure. Feedback that is then provided to patients can be in the form of auditory, haptic and / or visual feedback.

To generate concepts, our team individually brainstormed concepts that would incorporate the three sub functions for the design. Through the completion of the learning block exercises on concept generation, each team member independently generated 20 different concepts using a brainstorming approach where an idea was written down regardless of quality or feasibility. After each team member generated the 20 concepts, each team member independently again generated 20 additional concepts that were modified variants of the original concept. To do this, design heuristics were used to consider new possibilities for the design. One example of a design heuristic that was used in our process is below in **Figure 5**.

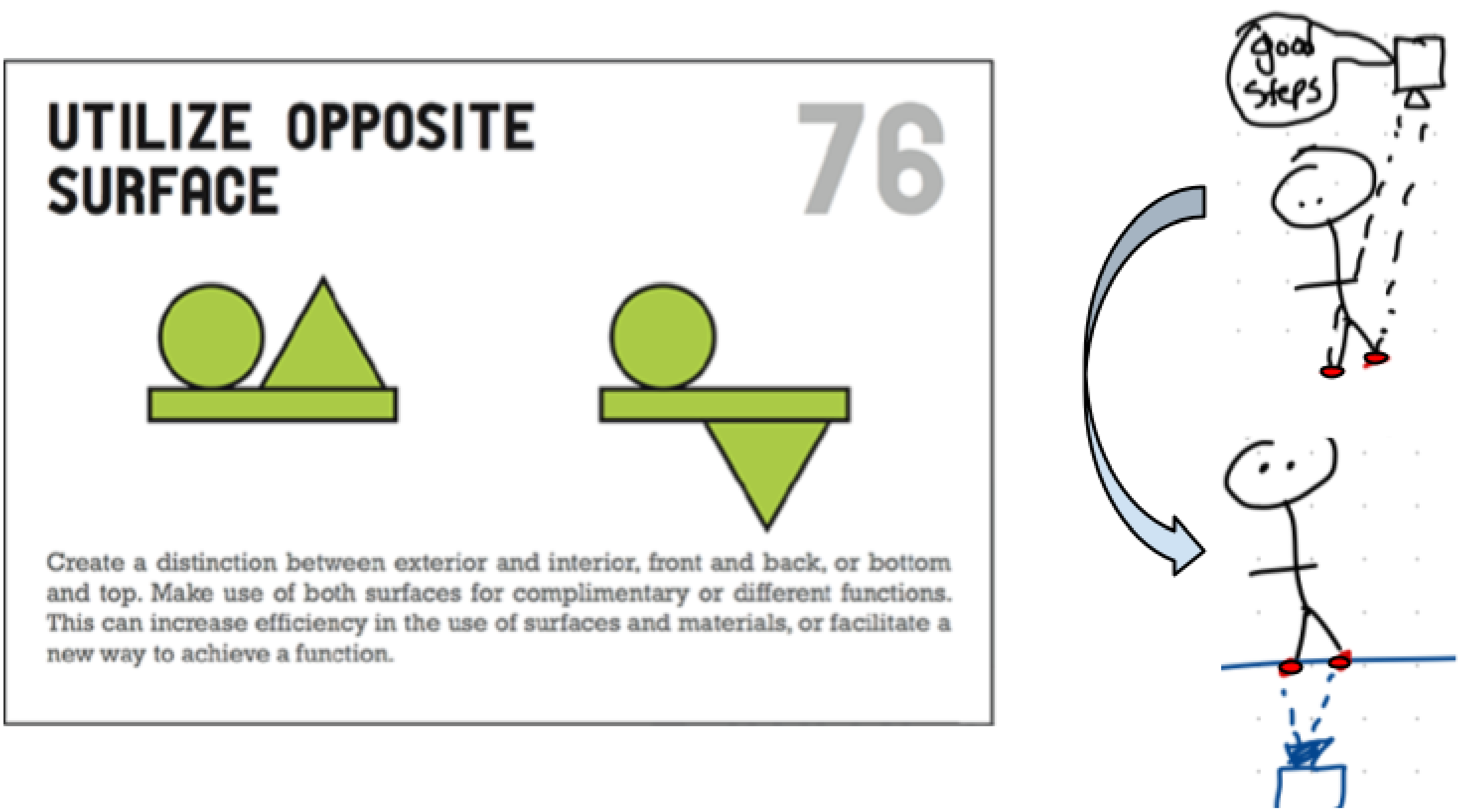


Figure 5. Example of design heuristic used to generate variants of existing concepts. A variant was created for an idea through the design heuristic "Utilize Opposite Surface" to change the location of a video camera element in the design between the two original brainstorming sketches on the left.

Each member of the team eventually generated a total of 40 different designs independently, meaning there were 160 total. The benefits of this independent idea generation was to fully flesh out ideas and prevent any single person or idea from dominating the brainstorming session and providing bias to move in that direction. The team then had a meeting together to discuss all generated designs and allow for cross-pollination.

When meeting, the team had to make the important decision of evaluating whether the design space had been fully explored, or if there were other ideas out there that could be viable solutions to the design problem. Evaluating whether or not our team had fully explored the design space was done in two manners: design sorting, and the creation of a morphological chart. Design sorting was accomplished by the group through filtering and sorting ideas by sensor type (more information on this is found in the "Concept Selection Process" section).

Once ideas were sorted, they could then be compared to a generated morphological chart for the design problem. Any theoretical combination of concepts that were present in the morphological chart and were not present in the sorted list of generated ideas were added to the sorted list. The combination of these sorting and morphology tools in addition to the generated concepts is how the team, with a reasonable degree of confidence, can claim that the design space was fully explored to the extent and scope reasonable for this ME450 project. The morphological chart used can be found below in **Table 6**.

Table 6. Morphological chart used to ensure complete examination of design space. Contains key parameters and variations of parameters. Combinations of variations of each parameter result in different generated designs.

	Variation 1	**Variation 2**	**Variation 3**	**Variation 4**	**Variation 5**	**Variation 6**	**Variation 7**	**Variation 8**
Feedback form	Audio -based	Visual based (lights)	Visual-based (monitor/ screen)	Vibro-tactile	Multiple	-	-	-
Location of sensor	Exterior	Feet	Ankles	Knees	Hips	Multiple	-	-
Information gathered	Distance between feet	Foot pressure	Foot acceleration/ velocity	Cadence	Foot pattern/ geometry	Range of motion	Muscle activation	Multiple
Form of sensing technology	IMU	Camera -based	Pressure Mat	Exo-skeleton	String-extension / encoder	Analog/ no sensor	EMG	Multiple
Attachment / support method	Elastic material/ harness (wearable)	Cane/ walker	Sticker/ pad	External moving device	Floor/ ceiling mounted	None	Multiple	-
Power Source	On board (battery)	Plug in	None		-	-	-	-

When looking over our generated concepts, lots of the concepts overlapped between the four team members, and so a sorting process was necessary to eliminate duplicates. Many designs featured the same selection of key elements (sensing, processing, and feedback forms) and needed processing. This sorting and selection process is covered in detail in the “Concept Selection and Sorting” section but the complete list of unsorted ideas is displayed in “Appendix A: Generated Concepts” and is arranged by group member.

After our filtering and sorting process, we had a total of 26 feasible design ideas, four of which stood out as attractive solutions for the team (see “Concept Selection Process” section for process). Those four solutions are explained below in detail. The first of the four robust concepts was the stationary camera system. Our design would use a mounted camera and markers on a patient, externally mounted speakers, an external laptop, and an external power source to analyze and provide gait corrections. It is pictured below in **Figure 6**.

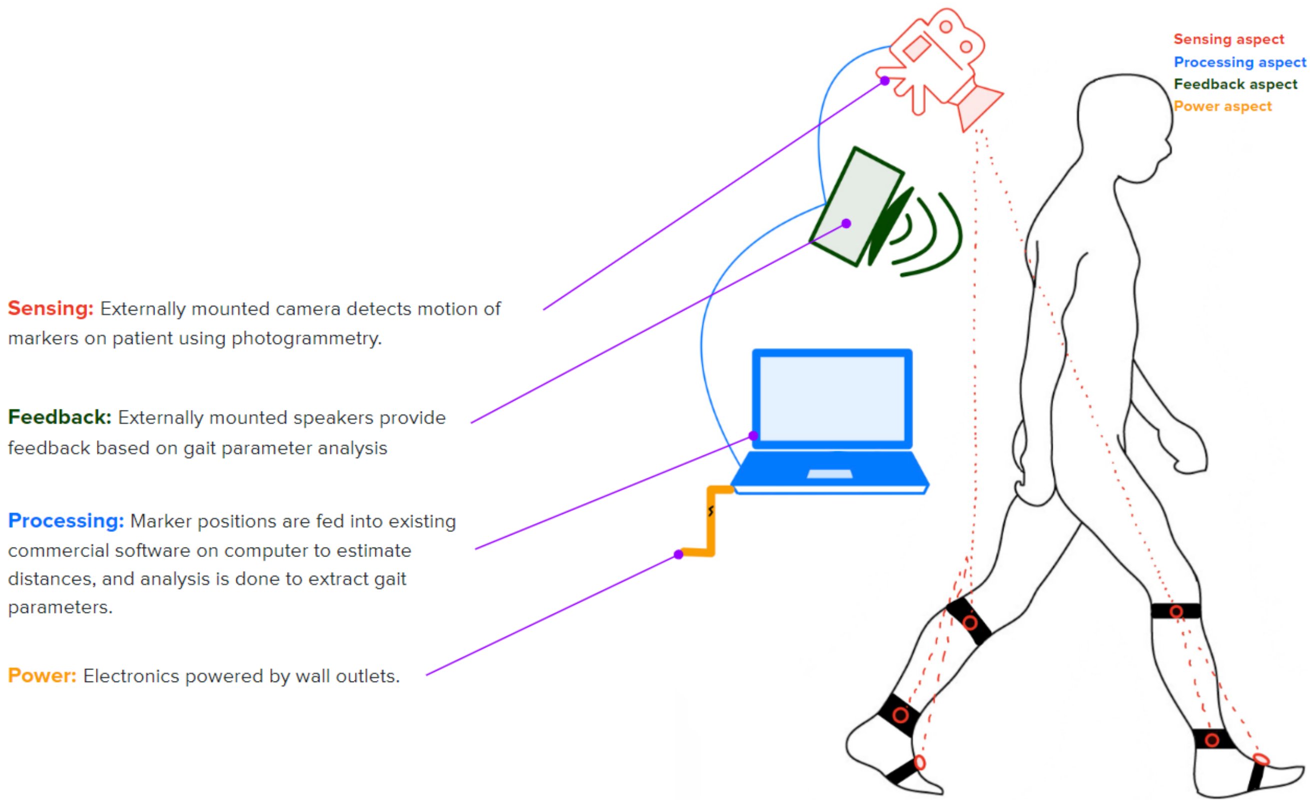


Figure 6. Overview of robust concept 1: Stationary Camera System.

Sensing technology used for obtaining data are an externally mounted camera and markers on a patient. Using photogrammetry, marker positions can be fed into existing commercial software to estimate distances and angles between markers. Analysis can then be performed to extract gait parameters like stride length, range of motion, or cadence. With this device, feedback is accomplished via externally mounted speakers, and power is provided to a laptop via wall outlet.

The second of the four robust concepts was the foot-attached IMU based system. Our design would use wireless IMU sensors, a single board microprocessor, and haptic feedback, all powered by portable battery to analyze and provide gait corrections. It is pictured below in **Figure 7**.

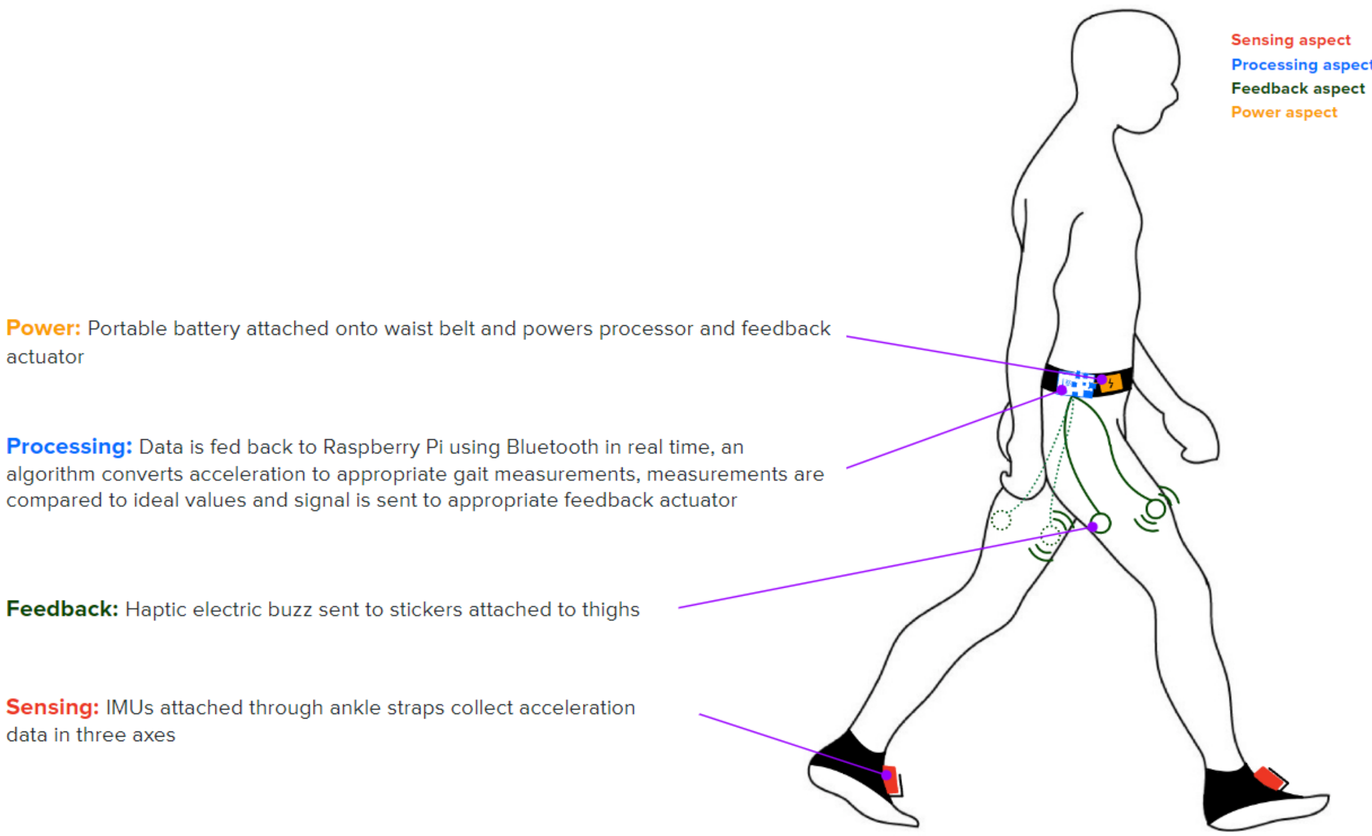


Figure 7. Overview of robust concept 2: Foot-Attached IMU based system.

Sensing technology used for obtaining data are a pair of Inertial Measurement Units, or IMUs worn on the feet of the patient. IMUs record accelerations in three axes, and this can be integrated along with a few assumptions to obtain distance measurements between steps. These distance measurements can be fed into software to extract gait parameters like stride length, step width, or cadence. With this device, feedback is accomplished via haptic actuators, and power is provided to the microprocessor and feedback system using a portable battery worn on the waist.

The third of the four robust concepts was the time of flight (ToF) based system. Our design would use two time of flight sensors, two arduino processors, and auditory feedback all powered by portable battery on ankle straps to analyze and provide gait corrections. It is pictured below in **Figure 8**.

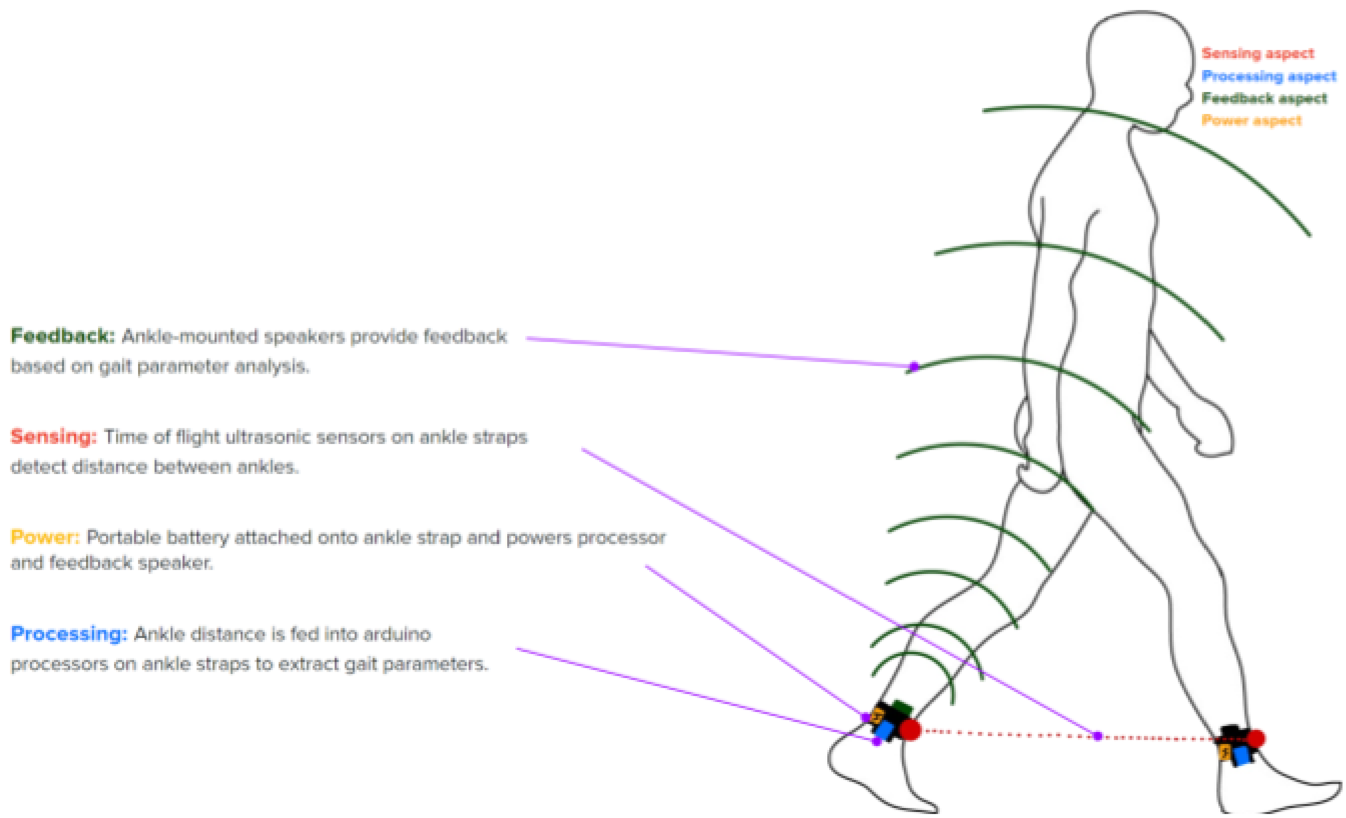


Figure 8. Overview of robust concept 3: Time of Flight based system.

Sensing technology used for obtaining data are a pair of time of flight sensors worn on the ankles of the patient. Time of flight sensors record time taken for an ultrasonic signal to travel from one sensor to another, and then back to the original sensor. This time can be converted to distance given the speed of sound to provide real-time data for distances between ankles. These distance measurements can be fed into software to extract gait parameters like stride length, step width, or cadence. With this device, feedback is accomplished via speakers, and power is provided to the microprocessors and feedback system using portable batteries worn on the ankles.

The last of the four robust concepts was the pressure mat based system. Our design would use an array of pressure sensors, a desktop PC, and visual feedback on a monitor, all powered by wall outlets. It is pictured below in **Figure 9**.

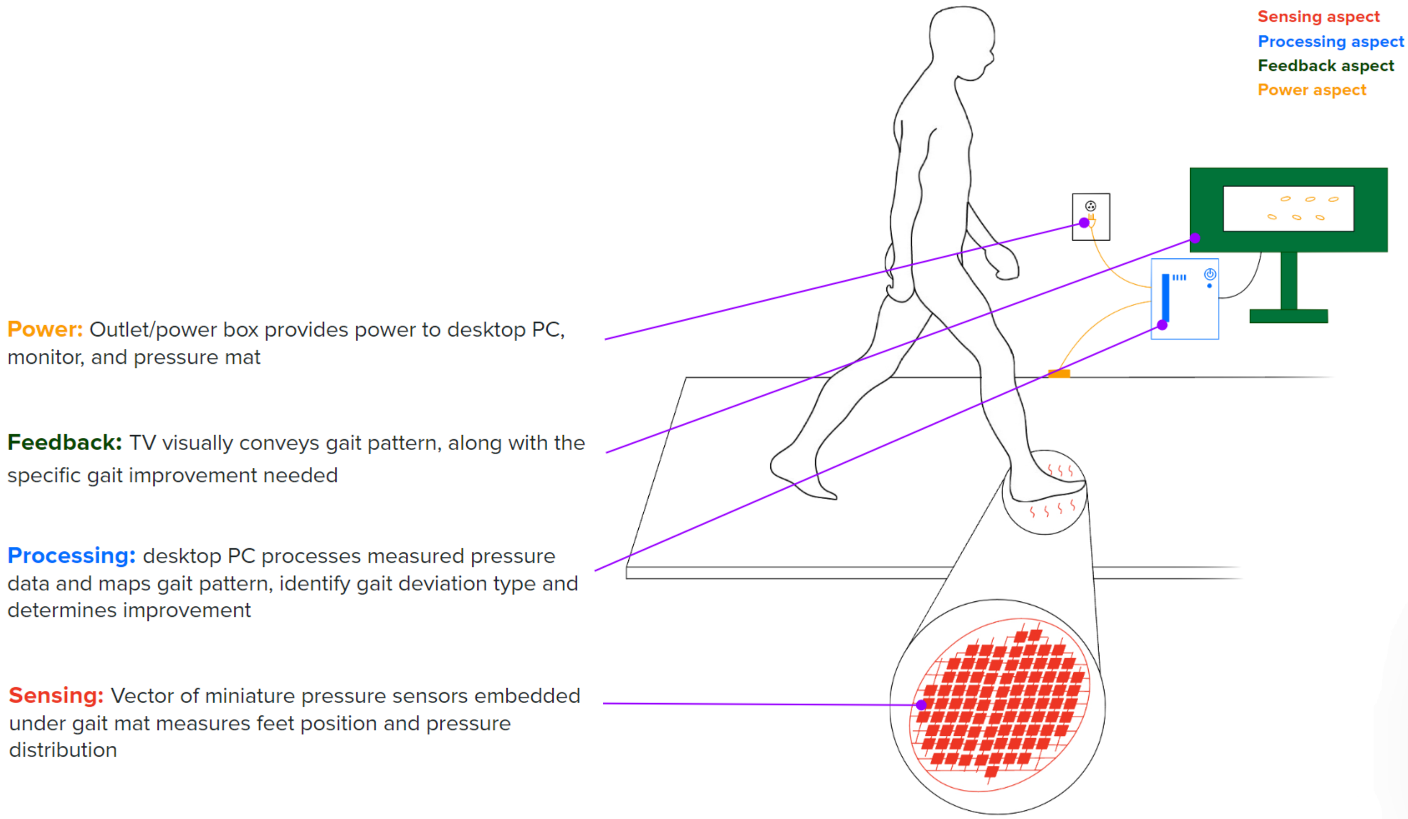


Figure 9. Overview of robust concept 4: Pressure Mat based system.

The sensing technology used for obtaining data is an array of miniature pressure sensors embedded inside a mat that detect the placement of a patient's feet during steps. This foot location can be converted to distance between feet, and these distance measurements can be fed into software to extract gait parameters like stride length, step width, or cadence. With this device, feedback is accomplished visually via a TV, and power is provided to the desktop PC, TV, and pressure mat via wall outlets.

Concept Selection Process

In concept generation, each team member individually brainstormed 40 ideas. Thus, at the end of concept generation, there were a total of 160 ideas. To come down to the ultimate selected concept, or "alpha design", our team devised several methods over a few different steps. **Figure 10** below shows the process flow from concept generation to selection.

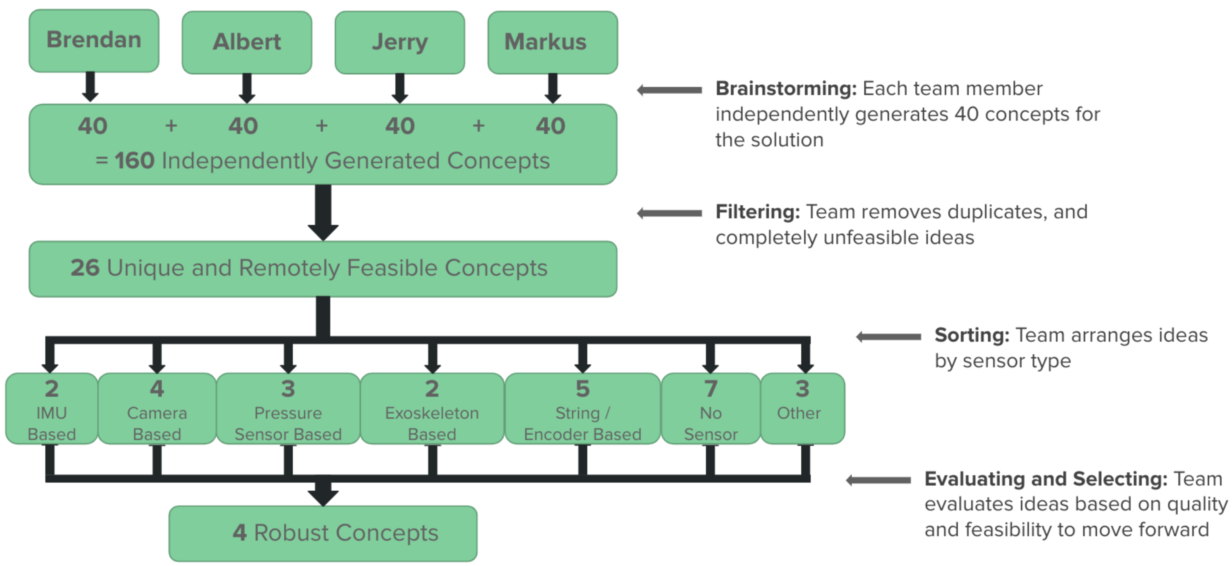


Figure 10. A process flow of concept generation and selection process.

Initial Filtering

In the first step, which is the initial screening, we filtered out duplicates and completely unfeasible ideas. We define duplicates by ideas that although might have different implementations, feature the same core components. For instance, **Figure 11** below demonstrates three generated concepts- Markus's 6th, Jerry's 10th, and Albert's 16th concept- that are considered duplicates of one another. Although implementation wise, these three ideas are different considering Markus's idea features a camera that tracks on a patient's footprints, Jerry's idea features a camera that tracks stickers on patient's body, and Albert's idea features multiple cameras forming a camera system, these three concepts all feature the use of stationary camera(s). Thus, we consider these three ideas as duplicates of one another and group them together.

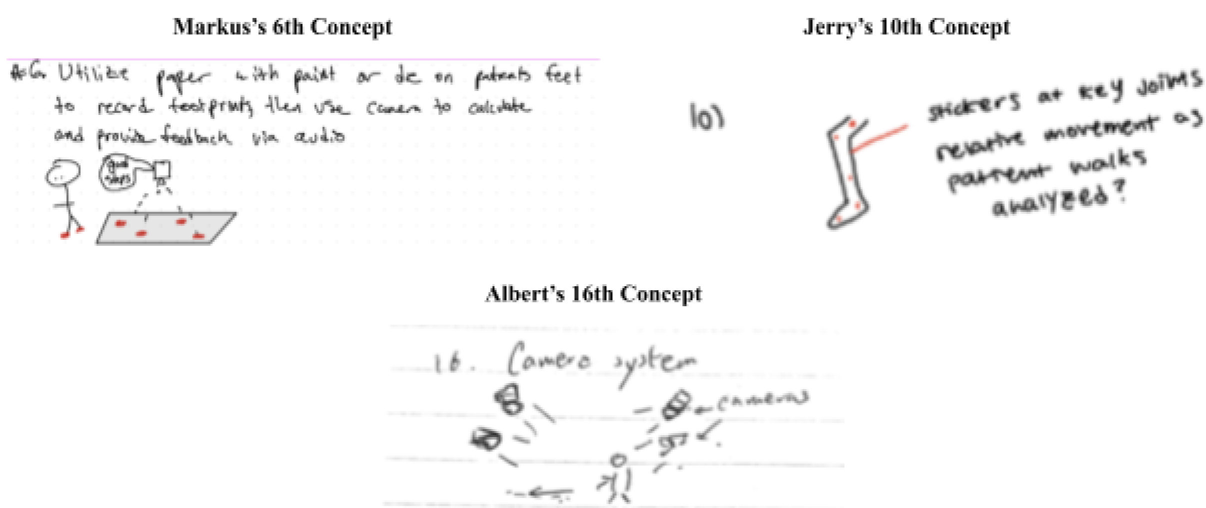
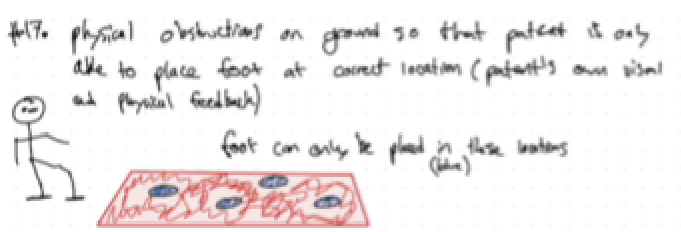


Figure 11. An example of concepts with different implementations but similar core components being considered duplicate of one another.

On the other hand, we also filtered out completely unfeasible ideas. We define an unfeasible idea as one that cannot be realistically achieved due to it having too much complexity, not being able to pass regulatory hurdles, or etc. To completely explore the solution space, we were encouraged to explore wild ideas and not limit ourselves; therefore, there existed some completely unfeasible ideas. Two examples of completely unfeasible ideas- both Markus and Jerry's 17th concepts- are shown in **Figure 12** below. Markus's 17th concept features physical obstacles on the ground to ensure that patients can only place their foot at ideal locations; however, if implemented, this idea can become a safety hazard to patients in rehabilitation. Jerry's 17th concept features the use of an underwater treadmill and pressure mat. However, it is impossible to implement this idea because an underwater treadmill does not currently exist in where our client is located, and to obtaining one would be outside our project's budget constraints.

Markus's 17th Concept



Jerry's 17th Concept

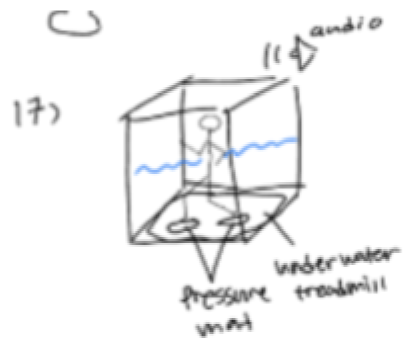


Figure 12. An example of concepts that were determined to be completely unfeasible ideas.

Filtering ideas by combining duplicates and removing completely unfeasible ones helped us to come down to a number of ideas that we can work with. This initial step is justified because it would be extremely time-consuming to go through a total of 160 ideas, and this step helped to create better efficiency and allow us to focus our efforts on the more promising concepts and options. After filtering through 160 ideas, our team came down with 26 unique and remotely feasible ideas. Then, we sorted the 26 ideas into the types of sensor technologies involved. Of the 26 ideas, 2 were IMU based, 4 were camera based, 3 were pressure sensor based, 2 were exoskeleton based, 5 were string/ encoder based, 7 were analog devices, or 3 did not belong to either group. Grouping ideas together based on their sensor types made it easier for us to weigh the ideas against each other.

Secondary Evaluation and Selection

From here on, we performed secondary evaluation and selection, in which we discussed and ranked the feasibility, cost, and quality of the remaining 26 concepts on a scale of 1 to 5, with a higher score denoting more feasibility, less cost and higher quality. We define feasibility as the extent to which the concept can be successfully implemented, cost as the monetary expenditure or resource investment required to complete the project or produce the product, and quality as the degree of which the concept can satisfy the functional requirements and specifications. Each group member individually ranked the feasibility, cost and quality of the remaining 26 concepts, and the average of the scores were taken and compiled into tables. We collected scores from each team member instead of working together to decide on a score for each concept to reduce group bias, as sometimes group discussions can be influenced by dominant groupthink, and it is important to reduce the impact of these biases so we can evaluate each idea on its own merits. **Table 7** below shows the feasibility, cost and quality scores of camera based systems.

Table 7. The average feasibility, cost, and quality scores of the three camera based systems evaluated individually by each member. The sum of the feasibility, cost, and quality scores greater than 11 are colored in green.

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
Stationary camera (M6, M8, B11, J10, A16)	3.75	3.25	4.25	• Would address all gait parameters • Equipment and space needed • Calibration needed
Walker with Camera (M10, J6, J14, A2)	1.50	3.00	4.00	• Allows user to walk around without getting out of sight from camera • Would need to derive user movement from subtracting walker movement
Treadmill with Camera (M10, A16)	3.00	2.75	2.75	• Less space needed, but more complex equipment • Would have to account user's ability to walk on treadmill

Eventually, after compiling scores for the remaining 26 concepts, we came down to 9 ideas with a total score of ten or above out of fifteen, 4 ideas with a score of eleven or above out of fifteen, and 0 ideas with a score of 12 or above out of fifteen. See appendix for the rest of the 26 concepts outside camera based systems. We decided to place the cut off at a score of eleven or above because ideally we would like to thoroughly evaluate just three to five concepts in the final step of process selection and evaluation to spend more time and effort on each concept, so a cut off score of 11 is justifiable.

Final Selection

Our top four concepts are discussed in greater detail in the concept generation section. To summarize, they are respectively a stationary camera system, IMUs attached on foot, time of flight sensors, and a gait pressure mat. Each of the top four systems each have a different sensing subsystem, and a few possibilities of processing and feedback subsystems that could be applied. An ideal alpha design would contain the best sensing, processing and feedback subsystem; thus, we decided to individually discuss and weigh these subsystems against each other. Since these subsystems work independent of one another in a process flow rather than in harmony, they can be combined into a complete system in the end. The only thing that requires more thought is the compatibility of the subsystems with one another, but other than that, breaking down the system into subsystems works.

Keep in mind that the first concept that came to the team was a gait mat, since three of the four members put a gait mat as their first design in concept generation. We are fully aware of our bias, and we plan to use decision-making matrices to evaluate whether requirements and specifications are met to reduce our bias. In addition, there does not seem to be an early fixation on this idea as well since our group is considering many other ideas too.

To make a strong argument on why the final alpha design that we would eventually choose is the best with respect to the requirements and engineering specifications, we used Pugh Charts to weigh each subsystem against one another. First, we evaluate the sensing subsystem. The decision-making matrix for the sensing subsystem is provided in **Table 8** below.

Table 8. Decision-making matrix for the sensing subsystem of the final design.

Criteria	Weight (1-3)	Stationary Camera	IMU Attached on Foot	Time of Flight Sensors	Gait Pressure Mat
Detect relevant gait parameters	3	0	+1	0	0
Be price efficient	2	0	+1	+1	-1
Be safe	2	0	0	0	0
Be easy to set up	2	0	+1	+1	+1
Be durable	2	0	-1	-1	-1
Can be used in 6 minute walk test	1	0	+1	+1	0
Be able to function during power outages	1	0	0	0	-1
Total		**0**	**+6**	**+3**	**-3**

In **Table 8**, several criteria were used to evaluate sensor subsystems along with their weight on a scale from 1-3, with a higher value denoting heavier weight and importance. These criteria came directly from user requirements, and their weights were also assigned based on the priority levels in our requirements and specifications table. This is to ensure that the sensor subsystem of our final designs is the best option with respect to requirements and specifications. In the case shown in the table, a stationary camera is used as the datum for comparison and subsystems that fulfill specific criteria better or worse would be given a score of +1 or -1. In the end, the scores of +1 and -1 for each criterion for each subsystem option were multiplied by the weight of the respective criterion and the total score for each subsystem was calculated.

Of all the sensing subsystem options, IMU attached on foot scored a total of +6 points, which was higher than stationary camera (+0), time of flight sensors (+3) and gait pressure mat (-3). IMU attached on foot and time of flight sensors scored similarly in many criteria. For instance, compared to the stationary camera, they are both more price efficient, easier to set up, less durable, and can be used better in a 6 minute walk test. What differentiates the two was IMU attached on foot scored better at the criterion "detect relevant gait parameters". We were able to test out IMUs presently available at the Sienko Research Lab at Michigan Engineering, and it yielded more accurate data on spatial acceleration of feet, which we can then use to obtain distance of feet. Although we have not tested the time of flight sensors, we do not believe it can yield results that are as accurate because they only measure relative distance between two sensors instead of distance in the x-y-z plane. Thus, it would be less accurate when accounting for relevant parameters such as stride lengths, since the height and width a foot follows can affect measurements. Thus, for this reason, IMU attached on foot scores a higher total than time of flight sensors and the rest, and we select the concept of IMU attached on foot as the sensing subsystem of our final design to best fulfill the requirements and specifications.

For the processing subsystem, a Pugh Chart is also used to weigh options against one another to determine the option that best fulfills the requirements and specifications. Different criteria were used this time but similarly they still come from the requirements and specifications. **Table 9** below shows the decision-making matrix for the processing subsystem.

Table 9. Decision-making matrix for the processing subsystem of the final design.

Criteria	Weight (1-3)	Laptop	Arduino/ Raspberry Pi	Desktop
Portability	3	0	+1	-1
Processing capability	2	0	-1	+1
Safety	2	0	0	0
Cost	2	0	+1	0
Durability	1	0	0	0
Total		**0**	**+3**	**-1**

Of all the processing subsystem options, Arduino/ Raspberry Pi has a score of +3, which is the highest, compared to laptop (+0) and desktop (-1). The “processing capability” criterion came from the “provide feedback to user/ feedback must be provided at least every 8-10 steps” user requirement and engineering specification. It would be ideal that our final design is able to process real-time data without noticeable delay, and this depends highly on the processing power of our sensing subsystem. In this criterion, Arduino/ Raspberry Pi scored lower than laptop and desktop because it has less processing power. However, we believe it still has sufficient capability to process real-time data and generate feedback. There could be a small lag, but it should not be long enough to cause failure to meet requirements and specifications. What puts Arduino/ Raspberry Pi atop of laptop and desktop is its portability. Portability is highly important because our product should not constrain the movements of the user. Laptop and desktop are more or less difficult to be moved to wherever the user goes compared to microprocessors like Arduino and Raspberry Pi. In addition, Arduino/ Raspberry Pi are less expensive than laptop and desktop; therefore, the ability to fulfill the cost criterion also contributed to Arduino/ Raspberry Pi having a higher score than laptops and desktops. Ultimately, we select Arduino/ Raspberry Pi as the processing subsystem of our final design to best fulfill the requirements and specifications.

For the feedback subsystem, a Pugh Chart is used again to weigh options against one another, and again the criteria was pulled from requirements and specifications and their weight from the priority of the respective requirements and specifications. Since these feedback options are not mutually exclusive and that implementing two in our final design would likely work better than just having one, we pick the highest two scoring feedback subsystems to construct a multimodal feedback subsystem. **Table 10** below shows the decision-making matrix for the feedback subsystem.

Table 10. Decision-making matrix for the feedback subsystem of the final design.

Criteria	Weight (1-3)	Haptic	Visual	Auditory
Be effective to the user base	3	0	+1	+1
Be perceptible in surroundings	3	0	-1	-1
Be safe	3	0	-1	+1
Be easy to set up	2	0	+1	+1
Be price efficient	1	0	-1	0
Be durable	1	0	0	0
Total		0	-2	+5

Of all the feedback subsystem options, auditory feedback form (+5) and haptic feedback form (+0) have the highest scores, while visual feedback form (-2) has the lowest score. Specifically, visual feedback form is marked down on the safety criterion. We were concerned that if patients occupy their eyes on a screen instead of their surroundings, there would be potential safety hazards. In addition, haptic actuators and speakers or headphones used in haptic and auditory feedback systems are also cheaper than the implementation of a screen display. Therefore, visual feedback is also marked down in price efficiency. A concern about haptic feedback is that sometimes users with spinal cord injuries cannot sense signals from a haptic actuator that well; however, this should not be a critical problem since with our multimodal feedback system design, they can still obtain from the other feedback mode. On the other hand, a concern with auditory feedback is its ability to "be perceptible in the surroundings." Often when the rehabilitation center gets crowded, it gets loud too and this in turn could hinder the users' ability to hear feedback. However, this also should not be a critical problem after implementing a multimodal feedback system. In a similar manner, the use of headphones specifically may reduce the end user's perception of the surroundings, for example other patients, therapists, and their voices warning them of potential sources of collision, trip hazard, and more. This can be easily avoided by implementing speakers instead of headphones. Overall, since haptic and auditory feedback are best in fulfilling the requirements and specifications, we select the two to be implemented in our final design.

There is no evidence of an early fixation of our original concept, which is the gait mat, since our selected design, which features IMU on foot, is very different from a gait mat. The same can be said about the feedback subsystem- we did not have a partiality early on over any feedback system ideas or existing solutions in the market, so early fixation should not be an issue.

Lastly, after selecting IMUs attached on foot as sensing subsystem, Arduino/ Raspberry Pi as processing subsystem, and speakers and haptic actuators as feedback subsystem, there is a need to determine a way to attach the following systems to the users' body. To obtain accurate data on gait parameters such as stride length and cadence, IMUs must be attached either on the user's foot or around the ankle. The haptic actuator could be attached anywhere to the body but preferably the user's legs since this would make the signal clearer. The user would have to carry the Arduino/ Raspberry Pi connected to speakers around too. Thus, to determine the best attachment forms, our group performed benchmarking on the existing solutions on the market. **Table 11** below shows the benchmarking of the existing solutions on the market for ankle and hip attachment methods.

Table 11. Benchmarking on the existing solutions for ankle and hip attachment.

Consideration	Heel Strap [43]	Ankle/Foot Straps [44]	Ankle Brace [45]	Ankle Band [46]	Belt [47]	Waist Pack [48]
Can used with sandals or on local clothing	N	N	Y	Y	N	Y
Comfort	Y	N	Y	Y	Y	Y
Safety	N (potential trip hazard)	N (potential trip hazard)	N (potential trip hazard)	Y	Y	Y
Free motion	Y	Y	N (ankle support)	Y	Y	Y
Secured fixation	Y	Y	Y	Y/N	Y	Y

All the considerations we used to evaluate the existing market products were from the requirements and specifications to ensure the requirements and specifications were fulfilled. For the ankle attachment form, we choose to use an ankle band, as it fulfills almost every consideration. The only potential concern associated with the ankle band is associated with whether it can be fully secure- while the ankle band should be secured from moving around the user's ankle, if it catches onto something in the user's way or is contacted by the user's other foot, it can rotate around the users' ankle, which can affect the accuracy of measurements at the time of contact and beyond. It is something that requires more thought and consideration in the future. However, currently, it serves as the best solution, since heel straps, ankle/ foot straps cannot be used barefoot or with sandals, an ankle brace might provide resistance to the user's ankle flexion, and all three other foot or ankle attachment forms have components under the foot, which can lead to potential trip hazards if not used carefully or properly.

On the other hand, for the hip attachment, the waist pack would work best since it not only fulfills every consideration but can also house Arduino/ Raspberry Pi, as well as speakers and the haptic actuator connections. The belt might not be able to be attached that well to local clothing, which might not always have belt loops. The two attachment forms will be discussed in greater detail in the following section on the selected concept description.

First Selected Concept: Alpha Design

Alpha Design Description

After going through the entirety of the concept selection process, we have come to a final alpha design concept, see in **Figure 13** below. This design utilizes each subsystem that scored highest in the Pugh charts through the concept selection process. This design is similar to the robust concept #2, however, differs slightly with the incorporation of multimodal feedback through the added portable speaker. Reiterating this concept 2 robust design with its new additions, we start with IMUs attached to the ankles for the sensing technology, to detect acceleration. We then see a Raspberry Pi processor attached to a belt on the hip, extracting relevant gait parameters from the IMU data, such as stride length or cadence. We then see both haptic and auditory feedback supplied to the user through four haptic actuators attached to the front and back of each thigh, and a portable speaker housed inside the belt along with the processing unit. We finally see a portable battery attached to this waist pack as well, to supply power to the processor and speaker. Each of these subsystems was selected based on the scores from the aforementioned Pugh charts.

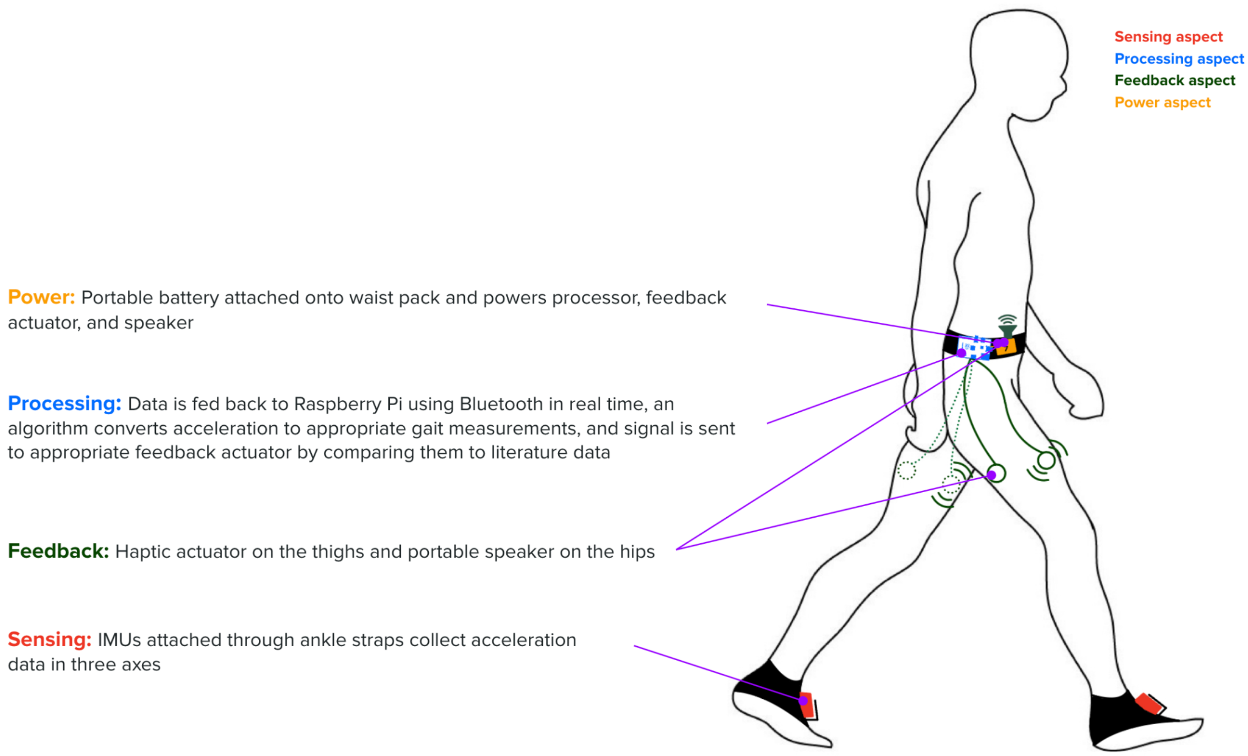


Figure 13. Final Selected Alpha Design Concept Drawing.

As we can see from the description of each subsystem, this design utilizes a portable battery for power, a Raspberry Pi for data processing, a haptic actuator and portable speakers for feedback, and Movella DOT IMU attached to the ankles for sensing. These specific attachments are additionally highlighted in more detail below in **Figure 14**.

Alpha Design Attachment

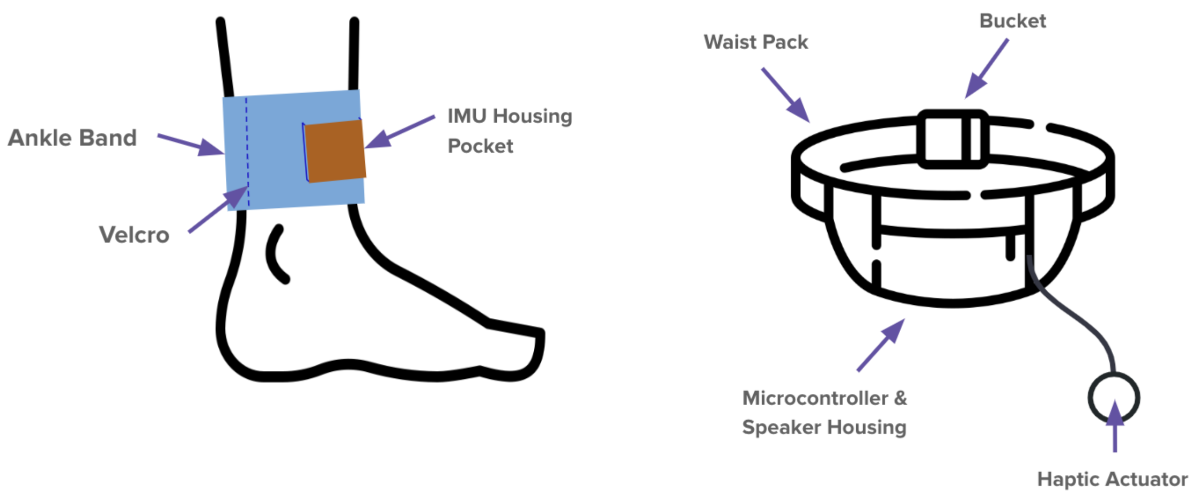


Figure 14. Attachments for Alpha Design Concept.

For the ankle attachment seen above, we plan to use a velcro ankle band to attach the IMU rigidly to the user's ankle. This attachment allows for optimal safety, comfort, and compatibility for the user. The IMU is then housed inside a mesh pocket on the front of the ankle. For the belt seen above, we have a fanny-pack-like waist pack, which will securely hold the microcontroller and speaker. These items will be rigidly attached to the pocket and will be protected on each side by the housing. The belt will additionally be adjusted using the bucket, and the haptic actuators will extend from the housing pocket to be placed on the user's thighs. At the moment we plan to extend four haptic actuators from the belt, each independently attached to the front and back of each leg, indicating whether to increase or decrease stride length for that given leg. In the future, more design and benchmarking will be necessary to determine the best method for attaching actuators to the user.

It is important to note that each of these subsystems, and their configurations within the overall design, were selected based upon their ability to meet the requirements and specifications. This ability was assessed and weighted using the Pugh charts in the previous section, where the weighting was based upon requirement priority, determined by stakeholder influence and background research. It is also important to note that a more objective selection process may have influenced the design. For example, if multimodal feedback was not a high priority to the stakeholders, or if IMUs weren't readily available for us to test and determine feasibility, then our final design concept could look very different. However, in the concept selection stage, our group truly did not know what direction we would take the project in. We decided to go through each Pugh chart without discussion beforehand, in order to come to an honest and unbiased decision for the final selected design and its components.

At the moment, the selected design still needs to be built on further in order to be rigorously analyzed using engineering analysis. This means that we first need to find a broad spectrum of reliable gait data for healthy patients, and then compare that to our sensor data using several tests, in order to determine the accuracy of the sensors in measuring gait parameters. We also need to elaborate more on the specific dimensions of the attachments, so that we can create realistic models for the device. We finally need to conduct more research on how exactly the microprocessor will work in quickly analyzing the data from the IMU, and how exactly to send a signal to the haptic actuator and speaker to convey appropriate feedback.

In general, this project is not necessarily difficult when looking at each component as a whole. It is simple enough to say that we will essentially take four different subsystems and combine them through an overarching attachment. We have a broad idea of how each subsystem works, and how they interact with each. However, the project becomes more difficult when looking at each subsystem individually. At the moment we are using existing products for each subsystem, and looking to combine them in the most simple yet effective way possible to fit the scope constraints of ME 450. Where the complexity increases is through both the fact that our proposed design is a makeshift assortment of existing products, and through the lack of current knowledge on how to effectively allow each of these products to communicate in application.

Alpha Design Processing Algorithm Description and Initial Engineering Analysis

Although further development must be done to the alpha design to rigorously perform engineering analysis, we can utilize initial preliminary engineering analysis to assess if the chosen design has potential to satisfy the requirements and specifications set out. Therefore, we decided to assess if our alpha design can satisfy the most essential high priority engineering requirements. Out of the high priority requirements, the most essential requirement is the ability to "Detects relevant gait parameters," as the feedback mechanism depends on the ability of the device to measure. Therefore, a preliminary engineering analysis was completed using computation and kinetic analysis on this aspect.

For the preliminary engineering analysis, we used Movella DOT IMUs which were available on campus. Two Movella DOTs were attached onto the feet of our team member and were synchronized together using the manufacturer's own Movella DOT application as shown below in **Figure 15**. Then, acceleration across the three axes were measured over 14 steps (7 on each foot). The sample IMU data output is shown below in **Figure 16**.

Figure 15. Illustration showing the Movella DOT software and IMUs (left), and the interface of the software which allows synchronization and real time data collection (right)

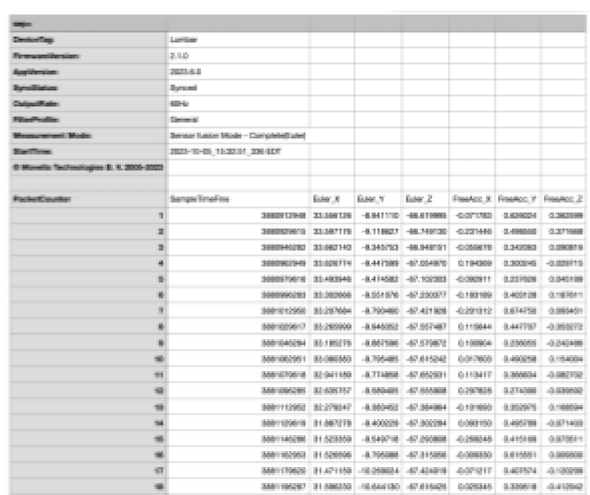


Figure 16. Example IMU data output; the three right columns are the acceleration in each of the three axes of the IMU. The sampling rate of this IMU is 60Hz, so this value was utilized to determine the time data points.

For the purpose of determining the stride length of the preliminary test walk, we analyzed the left foot only. The acceleration in the three defined axes were plotted against time for demonstration. These acceleration data were integrated with respect to time, and vector-summed to obtain the total magnitude of the velocity of the foot, shown below in **Figure 17**.

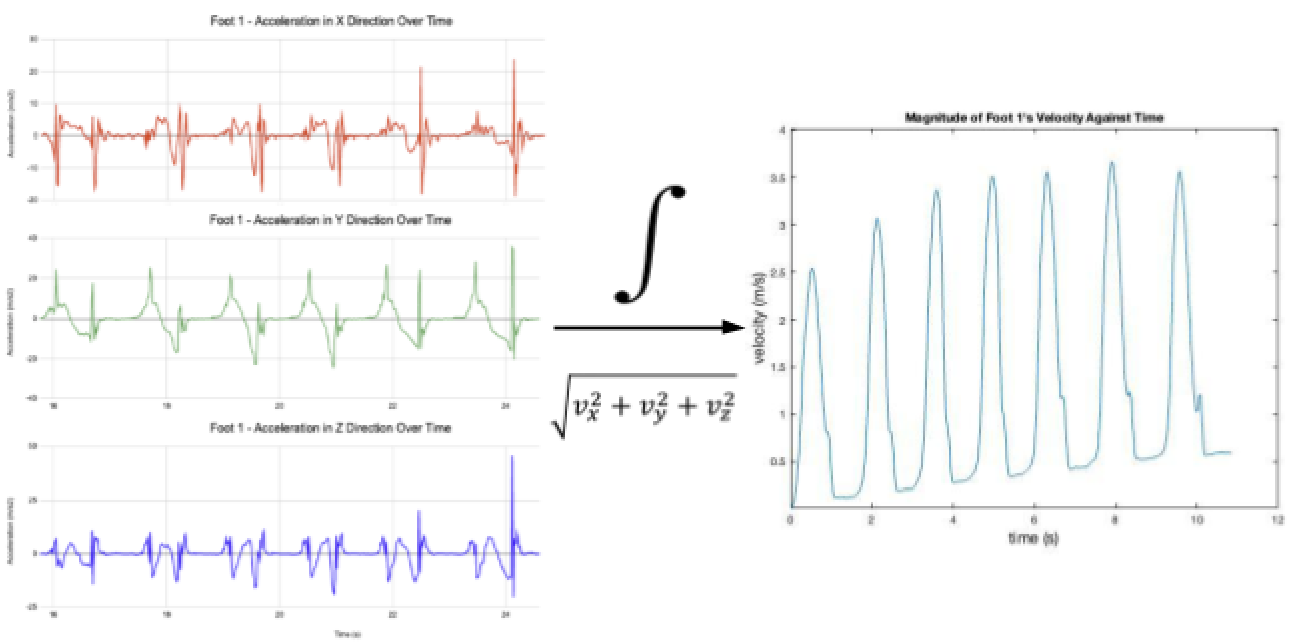


Figure 17. Illustration showing the process of obtaining the total magnitude of velocity of one foot using the raw X, Y, Z acceleration data.

Based on the plot in the above figure, we notice that each step (peaks and troughs of the velocity plot) were increasing in speed, but also are not coming to rest as the foot comes in contact with the floor. We therefore enforced this condition to combat the sensor drift, shown below in **Figure 18**.

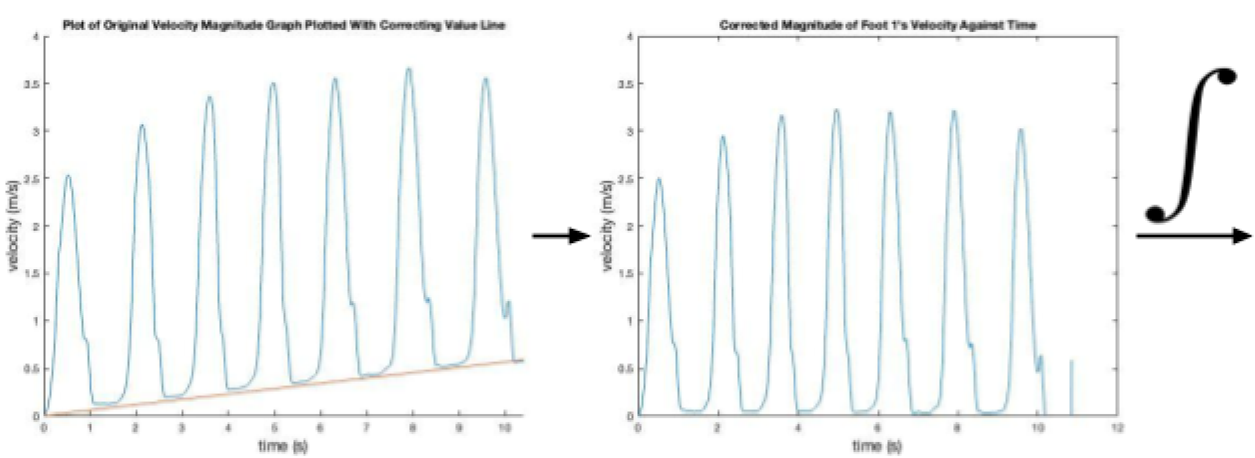


Figure 18. Illustration showing the process of correcting the sensor drift that is common for IMUs by using the boundary condition where the speed of the foot comes to a rest when it comes into contact with the floor.

Performing integration with respect to time again, we arrive at the displacement of the foot over time (**Figure 19**), where the vertical jumps (in displacement) are analogous to the stride length of each consecutive step. The final value of the stride length for the test subject was compared to average stride length values for people of his age, gender, and height to complete the preliminary engineering analysis of the alpha design. In conclusion, the measured value of 1.26 m fell within the range of normal values for the similar demographic of 1.25 - 1.85 m [49]. This suggests the alpha design can successfully fulfill the gait parameter detection requirement.

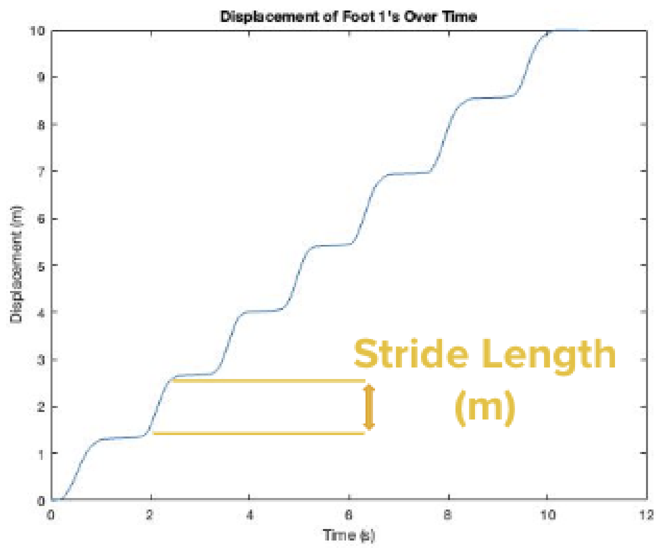


Figure 19. Displacement plot of the left foot of the preliminary test gait measurement, where the vertical jumps in displacements are analogous to the distance between two consecutive steps with the same foot (stride length).

Alpha Design Problem Analysis and Iteration.

In the previous section, we performed preliminary engineering analysis of our alpha design. We deemed this analysis as the most straightforward way to determine if our alpha design can meet one of the most crucial specifications. However, this analysis is merely a first step towards evaluating the alpha design. There are other aspects that need to be analyzed such as the degree of accuracy and error of the measurement result, the ability to process such data in real-time in order to provide feedback every 2-4 steps, as well as many other specifications that are critical to the success of our design.

As mentioned previously, due to the nature of the deliverable, the selected concept (alpha design) or at least a prototype must be built in order to thoroughly perform engineering analysis with respect to the requirements and specifications. As the prototype is not yet ready, we first planned engineering analysis that can be completed in the future.

Future Plans for Engineering Analysis of Alpha Design with Respect to Requirements

The requirements and specifications defined previously were re-visited to evaluate which specifications need to be considered for engineering analysis, that are both critical to the success of the alpha design, as well as those that are engineering related. Then, we assessed what field of engineering it pertains to, as well as the analysis and testing method that could be used to assess how the alpha design satisfies the requirements and specifications. **Table 12** illustrated below shows the list of requirements and specifications that were selected for engineering analysis, the justification behind their selection, the relevant scientific field specific for the specification and the planned engineering analysis/testing method.

By our definition of priority, the high priority requirements are those that are the most critical to the basic functionality of our design, the safety of the user, and the proper functioning of our design at the client's facility. We then screened out non-technical requirements and specifications, to arrive at the list of requirements shown in the below table.

Table 12. A table summarizing the selected requirements and specifications that must be considered when assessing the alpha design. Justification for selection, relevant scientific field and planned analysis or testing method are also included.

High Priority Requirements	Specifications	Justification of selection	Relevant Scientific Field	Planned Analysis/Testing Method	Interpretation of Analysis/Testing Result
Detects relevant gait parameters	The device must measure stride length ≤ 1.50 m. Measure cadence ≤ 120 steps/min. The measured values must have total error ≤ ±3cm for stride length and ≤ ±5% for cadence.	Gathering gait parameters of the user accurately and measuring those values for numerous end users with varying anatomy are primary functionality of our device that the client requested. Furthermore, without the success in the requirement, the device will not be able to provide any feedback (another primary functionality of the product).	Kinetics, Mechanical Engineering - General	Empirical testing with a prototype of the alpha design. A test subject could wear the prototype and take 20 uniform steps of the same stride length, with the help of distance indication on the floor. The same testing can be repeated for stride length ranging from 0 to 1.6m with a 0.1 m increment. The test will be repeated with other test subjects with different height, age, and gender. The resulting measurements can be compared to the correct stride length and the extent of error can be computed. Similar empirical testing can be completed with cadence varying from 0-120 steps/min in 10 step/min increments where the test subject gets auditory tempo cues of the cadence value being tested.	The processed gait data can be compared with ground truth (for example, the stride length selected within 0 - 1.6m in 0.1m increment). The deviations from this value can be compared with total error set out (±3cm for stride length and ±5% for cadence). Furthermore, if the calculated gait parameters have low accuracy but high precision, a multiplication factor can be obtained, applied to the processing code, and the testing can be repeated for validation.
Provide feedback to the user	The feedback must be provided at least every 2-4 steps. The device needs to have two or more means of providing feedback.	The client explicitly requested the feedback to be as often as possible, to maximize the effect it has on fixing gait deviation in patients. Furthermore, if data cannot be gathered, processed, and feedback cannot be provided within a short time period within the	Mechanical Engineering - Controls	Computational analysis could be completed where we calculate the total latency involved in collecting, processing, and determining and providing feedback using aspects of controls. The reaction time of typical adults wearing vibrotactile cueing devices [50] and step initiation time data for typical young adults will also be included in the computation. We can then compare the final value with durations of steps in order to determine if the design can physically meet the real-time feedback duration of 2-4 steps	If the total latency between actual walking (data collection) and feedback exceeds the time taken to complete those steps, modifications could be made to the code to reduce execution time and optimize computation speed, or physical changes can be made to the prototype by implementing wired communication instead of wireless communication like

		physical steps, then the gait feedback and cues provided will not be specific to the current action of the end user. This could reduce the effectiveness of the device.			bluetooth. Raspberry PI can also be upgraded to one that has higher processing power.
Function without faults at local climate	The device must be fully functional in environments up to 55°C and 100% humidity.	Extreme temperature and humidity may negatively influence the function of sensitive electronic components **[35]**. Components such as speakers, actuators, the Raspberry Pi, and the IMU all rely on PCBs or other sensitive electronic components to function correctly.	Mechanical Engineering - General	Prototype can be built and it can be left in a sauna in similar conditions as described in specifications for 1 hour. The prototype can be then used for measuring 20 steps with each uniform stride length (0.1-1.6m in 0.1m increment) for any fluctuation in performance. This can be repeated for up to 4 times (cycle testing) to see variation with usage in the harsh environment. Furthermore, product specification sheets for Movella DOT IMUs, Raspberry PI, and feedback actuators can be verified to see if they function at 55°C and 100% humidity.	If device performance varies drastically with extreme condition exposure (or cycles of it), then active cooling methods could be implemented on components susceptible to the high temperature and humidity. Movella DOT IMUs are IP68 water proofed, and can function from 0 - 50°C. Although this is slightly short of specification temperature, this number most likely includes a safety factor to it. Therefore, most focus will be put on the microprocessor (Raspberry pie), feedback mechanisms, and portable battery.

Validation of the Alpha Design as a Whole System with Respect to Requirements

In the above plans, we discuss how we will approach verification – evaluating our design output on whether we have successfully met the requirements and specifications. However, it is essential that we also look at our design and ask the question on whether we designed a device that can meet the client's needs and intended use. This involves *validating* the whole system in a holistic way, instead of verifying if each subsystem achieves the requirements and specifications we previously set out. Therefore, we formulated the plan to utilize the camera-based motion tracking system present in Sienko Research Group's gait laboratory, proxy therapists, and proxy stroke patients on campus to assess if our system not only functions properly, but also as the client requested, and whether if it is truly helpful for the patient as well as the therapist. Our plan is to attach our device and the tracking device necessary for the camera system onto the proxy patient. The patient will perform 3 rounds of supervised 20 step walk. The resulting gait measurements will be compared with that of the camera system, and the feedback provided by our device will be compared with the feedback provided by the therapist to evaluate if our device functions as requested by the client. The therapist can also aid in determining if our device is indeed safe.

Build Design/Final Design Description

Final Design

Based on our initial alpha design concept and our engineering analysis methods outlined in the previous section, we have come to the final design-build seen in **Figure 20** below. We start with IMUs attached to the ankles for the sensing technology, to detect acceleration. We then see a Raspberry Pi processor attached to a belt on the hip, extracting relevant gait parameters from the IMU data, such as stride length or cadence. We then see both haptic and auditory feedback supplied to the user through haptic actuators attached to the front and back of each thigh, and a portable speaker housed inside the belt along with the processing unit. We finally see a portable battery attached to this waist pack as well, to supply power to the processor and speaker.

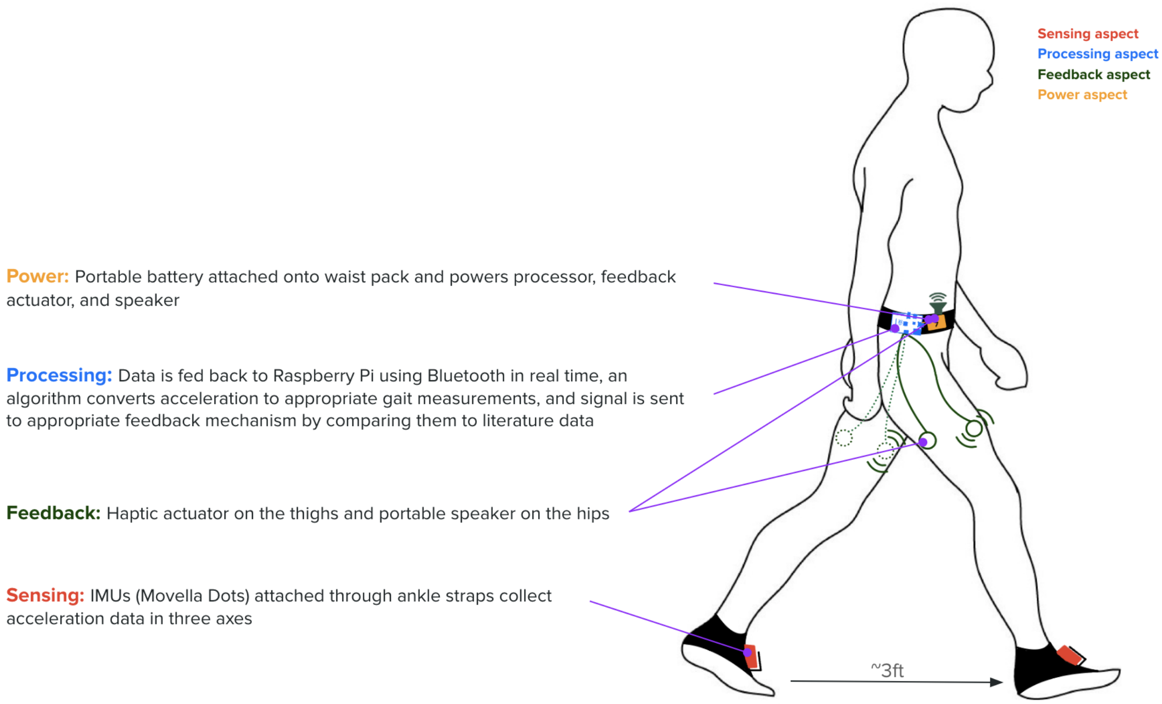


Figure 20. Final Design Drawing

As we can see from the above diagram, this final design utilizes Bluetooth IMU sensors, a single-board microprocessor, and haptic & auditory feedback powered by a portable battery. Additionally and not shown in this drawing is the addition of a user interface on a PC for inputting baseline parameters. The specific attachments for the ankles and waist pack have remained the same from the initial design, and are shown again below in **Figure 21**.

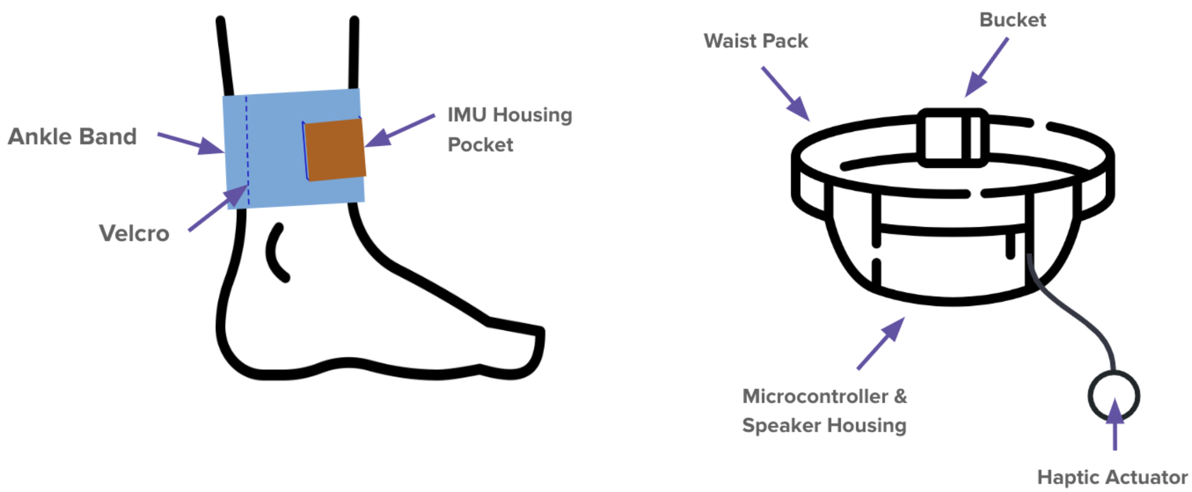


Figure 21. Attachments for Final Design Concept.

For the ankle attachment seen above, we plan to use a velcro ankle band to attach the IMU rigidly to the user's ankle. This attachment allows for optimal safety, comfort, and compatibility for the user. The IMU is then housed inside a mesh pocket on the front of the ankle. For the belt seen above, we have a fanny-pack-like waist pack, which will securely hold the microcontroller and speaker. These items will be rigidly attached to the pocket and will be protected on each side by the housing. The belt will additionally be adjusted using the bucket, and the haptic actuators will extend from the housing pocket to be placed on the user's thighs.

Going into each subsystem of our final design a little bit deeper, we begin with the sensing component. Our final design utilizes XSens Movella Dots to accurately measure the acceleration of the user's feet. For the processing final selection, we have specifically chosen a Raspberry Pi (4 Model 2019 Quad Core 64 Bit Wifi Bluetooth 2GB). This device has power delivery of 3.3 V and 5V and has processing capabilities that we have proven can meet our needs. For our haptic feedback final selection, we have chosen Solarbotics VPM 2 Coin Motors. These motors have 3.3 V capability, 120 mA start current, 80 mA load current, and 32 Ohm resistance. We have not identified a specific speaker for our final auditory feedback design, given that there are several available options, however any with 3.3 V capability, 8 Ohm resistance, and 500-20k kHz frequency response will be sufficient. Each of the aforementioned frequency, current, resistance, and voltage parameters were chosen based on compatibility with the Raspberry Pi, and any speaker will be acceptable so long as it has similar parameters. For the final attachment, our 450 build will utilize foot straps within the Sienko Lab and a commercially available fanny pack, however, any similar attachment will be sufficient so long as they are tightly secured. For our final user interface, which we will discuss further in the next section, we have chosen a PC for inputting user baseline parameters. **Table 13** below summarizes each component and our selection and gives our reasoning for making these selections.

Table 13. Reasoning for Final Design Elements

Component	Selection	Reasoning
Sensing	Movella Dot IMUs	Capable of accurate, real time collection of data that can determine stride length & cadence (see analysis)
Processing	Raspberry Pi	Portable, easily integrated with actuators, can communicate via bluetooth to speaker (see verification)
Feedback	Solarbotics VPM 2 Coin Motor & Speaker	Can vibrate within acceptable ranges & can easily connect to Raspberry Pi (from shopping cart analysis)
Attachment	Ankle band & Fanny Pack	Can securely hold compartments without increasing risk of falling (concept generation analysis)
User Interface	PC	Capable of connecting Movella Dots to Raspberry Pi Can easily input user metrics

Current Changes to Final Design

1. *PC as the Data Processor*

Most design elements have remained the same compared to the initial design, however, the most substantial change to the final design has been the inclusion of a PC.Due to issues connecting the Movella DOTs directly to the Raspberry Pi (refer to **Real-Time Data Streaming** engineering analysis section), a PC must be used as a middleman for connection. The PC will work by first steaming raw data from the IMU, translating it into XYZ acceleration, and processing it into stride length and cadence. The PC then compares these values to an acceptable range based on the user input, and the Raspberry Pi then gives feedback based on these ranges. Due to the difficulty that the team faced in implementing software for direct communication for these two devices, this change allowed for seamless integration. However, in the future, it is worth noting that the PC may not need to serve this purpose, as more skilled software developers could potentially figure out how to ensure that the Raspberry Pi and Movella DOTs communicate directly. One important thing to note is that this is viable to be implemented in the Poovanthi Institute, as they do have access to PCs.

2. *PC Graphical User Interface for Baseline Information*

While the integration of a PC as a middleman may not need to be included in the final design to the stakeholders with further development, a PC is also included as a means for inputting user parameters. Since the feedback will need to understand what a typical value for stride length or cadence will be for the user based on their height, age, and sex, the PC will be utilized for inputting these parameters and comparing them to standard ranges.

The following figure (**Figure 22**) demonstrates an example PC graphical interface that the end user will be interacting with the device in chronological order during device usage. The first image on the left is where the user information such as height, age, and gender is inputted so that the baseline gait parameters for comparison can be obtained. The second image shows the calculated baseline stride length and cadence information based on the information entered previously. These values can be modified by the user if they know their gait parameters before injury. The third image shows the interface while calibration of the sensors is occuring. Finally, the last image shows the graphical interface while the gait analysis is taking place. There are deliberately no user interactions on the last two images, as the user will only interact with the feedback actuators away from the PC.

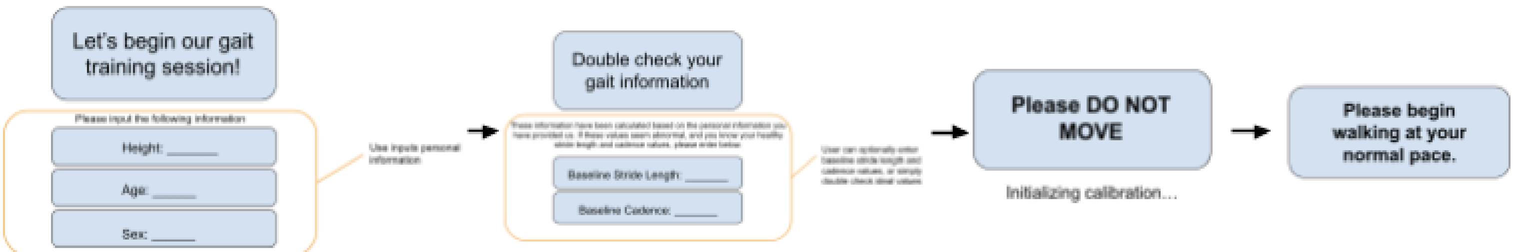


Figure 22. Example of the graphical interface used on PC to obtain patient's anatomical information in order to derive baseline stride length and cadence values for comparison with measurements.

Differences in Stakeholder Design vs ME 450 Design

Most components of our final design are the same for both our stakeholders vs our ME 450 design. The materials required for our design, which have more specifically been mentioned earlier in this section, include Movella Dot IMUs, Raspberry Pi processors, Solarbotics tactors, any speaker and battery with the aforementioned compatibility requirements, any PC, and any secure ankle & waist attachments. All of these items, with the exception of Movella DOTs, are accessible via Amazon India, and can be easily purchased by our stakeholders for use. Additionally, the Movella DOTs are commercially available for shipping to India, so this also should not be an issue.

One important difference between our ME 450 build and our final design is that our final ME 450 build will consist of simply inputting given user parameters on a Command Line Interface (CLI) like terminal (**Figure 23**), however, our final design to our stakeholders differs with the inclusion of a Graphical User Interface (GUI), similar to the one seen below in **Figure 24**, which displays prompts for the user to easily input their height, age, and sex.

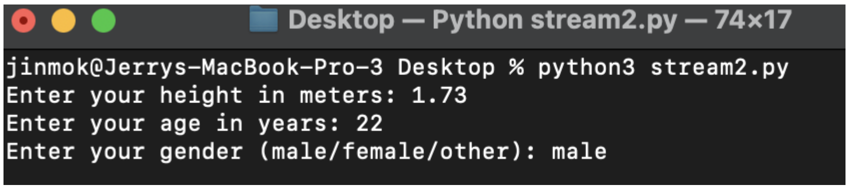


Figure 23. Example User Interface

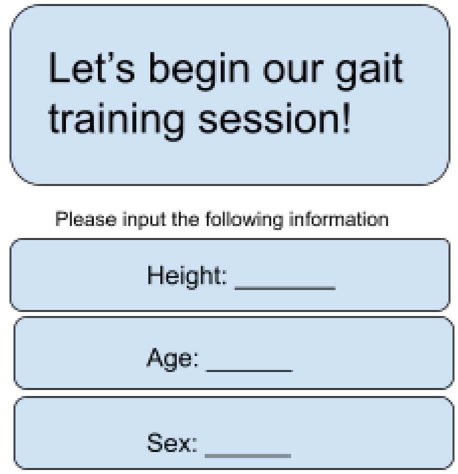


Figure 24. Example User Interface

One final important difference between our ME 450 build and stakeholder design is the separation of each subsystem. This semester we plan for our final prototype to consist of sensors, processors, and feedback all operating separately, while our final design intends for each to operate simultaneously. By proving that each component works on its own, and showing how to easily integrate them, we will have effective proof of concept for our final design, however, we do not yet plan to integrate them simultaneously at this time to allow for safe and mobile use.

Design Questions and Concerns

In the preceding alpha design section, we delved into the different subsystems of our gait feedback device, outlining key features, functionalities as well as how these subsystems work together to fulfill the client's needs. However, it's crucial to acknowledge that the alpha design represents merely the initial conceptualization and configuration of our product. As a result, we identified specific design concerns and uncertainties inherent to the alpha design. Evaluating these concerns serves as a strategic step in refining and optimizing the design before progressing into subsequent phases of development.

Table 14 below is the list of design concerns we derived based on the alpha design. Each concern was evaluated based on whether or not fulfilling them is absolutely critical or make or break to the success of our device. The concerns were then organized from highest to lowest priority. It is noteworthy that concerns deemed critical share equal priority and must all be thoroughly addressed and investigated, even under time constraints. In contrast, non-critical concerns exhibit varying degrees of importance. Our team plans to prioritize the investigation of those with higher significance whenever feasible.

Table 14. Summary of design concerns we formulated based on our alpha design, and whether the concern is a make or break aspect of the design. The justifications are also included.

Design Concern	Critical?	Justification
Accuracy of measured gait parameters	✓	Gait parameter measurements must be accurate in order to yield helpful feedback and ultimately make a positive contribution to improving the end user's gait deviation.
Implementation of real-time data processing on Raspberry Pi	✓	By definition, our device must be able to provide gait correction feedback in real time, hence it is absolutely essential that gait data must be processed in real-time.
Complexity of haptic actuator operation and communication with the processing medium	✓	Being able to realize haptic feedback is required to provide feedback to end users who may be in loud environments or have difficulty hearing, hence this concern is a critical one.
Perceivability of haptic actuators	✓	The perceivability of haptic cues is essential for user awareness and responsiveness. If haptic feedback is not easily perceivable, users may miss important cues, diminishing the device's impact on gait correction. Ensuring clear and distinguishable haptic signals is crucial for user engagement.
Establishing baseline gait parameter to compare recorded gait parameters with	✓	Establishing a baseline is required in order to provide any form of feedback for improvements based on the gait measurement data.
Safety	✓	Presence of wires, straps, or pouches interfering with gait of patient. With target users having limited mobility, any kind of fall hazard must be mitigated. Additionally, safe use of electronics must be considered.
Haptic actuator attachment	✖	The attachment mechanism for haptic actuators directly affects user comfort and the device's stability during use. A secure and comfortable attachment ensures that the haptic actuators remain in the correct position, optimizing their effectiveness. The concern was listed above the below concerns because the attachment of the actuators can impact perceivability of the vibrations, which is a more critical requirement than comfort.
The size and longevity of battery	✖	The size and longevity of the battery influence the device's portability and comfort during use. However, good portability and comfort are simply nice to have properties rather than a critical requirement
Dimensions of attachment belt	✖	The attachment belt's dimensions impact user comfort and device stability, however the device can still be helpful even if the attachment is not comfortable.

Engineering Analysis

With the alpha design concept and the design concerns in place, we decided to perform different analyses to address the design concerns, and evaluate if our design concept functions as initially imagined, and whether we need to make changes to the design moving forward. In the following sections, we discuss the details of the engineering analyses we completed, which design concern the analysis answers, as well as the rationale behind why we chose the specific analysis method.

Gait measurement range and accuracy

The first design concern we analyzed was the accuracy of the measurement of the gait parameters. We can divide this design concern into two aspects:

1. The device can measure the full range of typical stride length and cadence.
2. The measurements have small errors and deviations from the ground truth.

The empirical testing method was selected for evaluating the accuracy of gait parameters because it provides a direct and real-world assessment of the device's performance. Furthermore, we decided to predetermine the test subject's stride length and cadence values and use them as comparison values to evaluate device accuracy. We opted for predetermining the test subject's stride length and cadence values for comparison, deeming this approach less complex and resource-intensive than comparing measurements from a high-precision motion tracking system. However, this method also has limitations in that the predetermined values used for comparison may also be inaccurate as there is no guarantee that the test subject walks perfectly as determined by these values. Nonetheless, we believe that even with the limitation, the test will provide sufficient information on measurement accuracy while taking minimal time and resources.

Figure 25.1 and **25.2** below demonstrate the testing setup. The test on the left evaluates if our IMU sensors and processing algorithm can measure the full range of stride length and cadence (0 to 1.50m for stride length, 0 to 120 steps/min for cadence) by testing the edge values. The test on the right evaluates if the measurements are accurate, falling within total error ≤ ±3cm for stride length and ≤ ±5% for cadence.

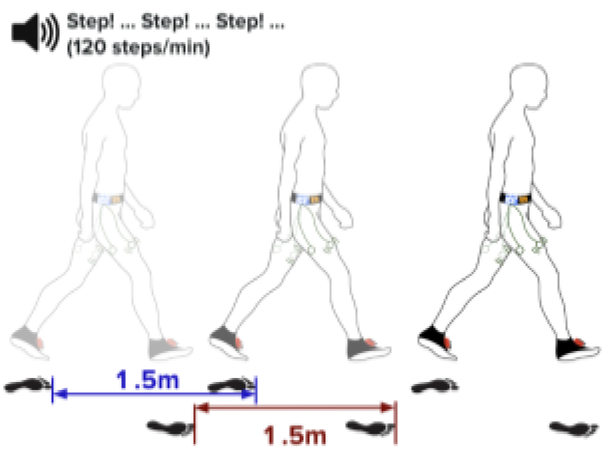


Figure 25.1. Stride length visual cue of 1.5 m, auditory cadence cue of 120 steps/min provided for the test subject for edge value measurement testing. IMUs were attached onto the ankles of the subject and gait analysis was performed.

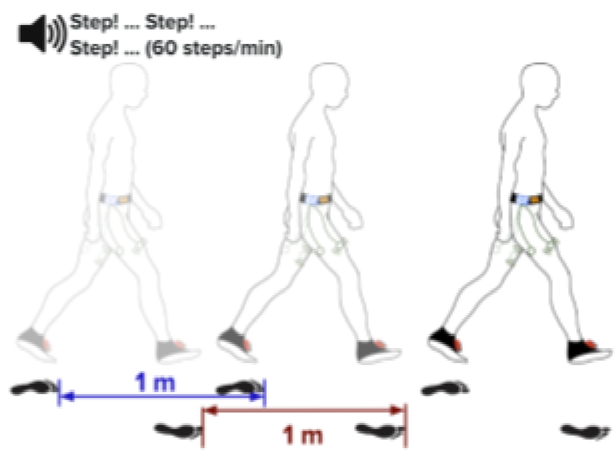


Figure 25.2. Stride length visual cue of 1 m, auditory cue cadence cue of 60 steps/min provided for the test subject for accuracy testing. IMUs were attached onto the ankles of the subject onto the ankles of the subject and gait analysis was performed. 60 steps/min was used so that the subject could make more accurate steps onto the visual markings on the floor.

For both tests, the raw acceleration values obtained from the IMUs were processed as shown below in **Figure 26,** in the same manner as **Figure 17**, **18**, and **19**. **Figure 26** only shows the velocity magnitude and distance plots for the measurement accuracy test.

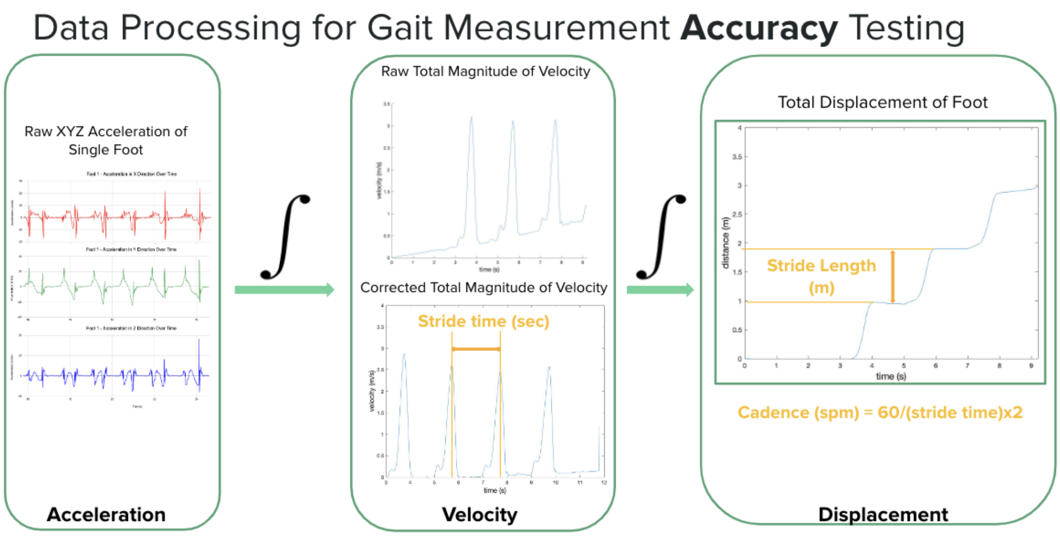


Figure 26. Data processing workflow for the gait measurement accuracy testing.

The cadence and stride length values measured at the end of processing are shown below for both tests (**Figures 27.1 and 27.2**). The results from **Figure 27.1** were 128.57 steps/min compared to the auditory cue of 120 steps per minute. Likewise, the stride length measured was 1.46 m, also hovering around the proximity of the provided visual cue of 1.5 m. This suggests that stride length and cadence can be detected, measured, and processed by our sensors and processing algorithm even at extreme values.

Even more, the results from **Figure 27.2** were 60.33 steps/min, only exceeding the 60 steps/min auditory cue by a small margin of 0.33 steps/min (0.56% error). Similarly, the stride length measured was 0.99 m, deviating only by the margin of error of 0.0085 m from the provided visual cue of 1 m. These deviations were then compared to the total error specification our team set up earlier in the project using accuracies of similar measurement devices used in research studies (refer to requirements and specifications section). The 0.56% error of cadence fell within ±5%, and the 0.0085 m error for stride length also was under ±3cm for stride length. In conclusion, this test demonstrates the IMU sensors and processing logic are highly accurate, fulfilling our specification and alleviating our design concern for measurement accuracy.

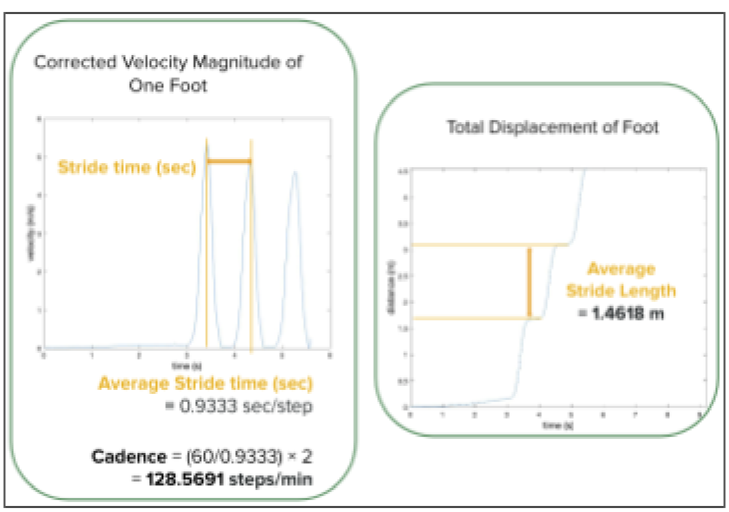


Figure 27.1. Average cadence and stride length measurements (128.5691 steps/min and 1.4618 m respectively) obtained from the "gait measurement end value" testing. The distance between two velocity magnitude peaks, the stride time, were used to determine how many steps were taken in a minute. The vertical jumps in displacement of foot were used to determine stride length.

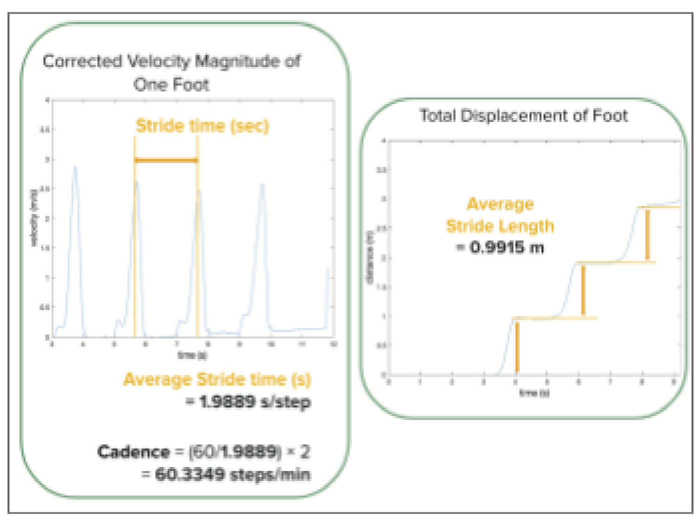


Figure 28.2. Average cadence and stride length measurements (60.3349 steps/min and 0.9915 m respectively) obtained from the "gait measurement accuracy" testing. The distance between two velocity magnitude peaks, the stride time, were used to determine how many steps were taken in a minute. The vertical jumps in displacement of foot were used to determine stride length.

Real-Time Data Streaming
The next design concern we investigated was the implementation of real-time data streaming on Raspberry Pi. Currently, Raspberry PI is used for communicating with the two feedback mechanisms to output the gait improvement cues. Being able to also implement real time processing on raspberry pi allows the data processing and feedback provision to happen on the same device. This allows the quickest feedback compared to passing through multiple devices, facilitating real-time feedback every 2-4 steps (refer to requirements and specs). Until now, we utilized history data analysis that reads in CSV files of raw gait data and calculates stride length and cadence values on Matlab to prove our processing algorithm functions as intended, and the outputs are accurate. By addressing the real-time data streaming concern by performing this analysis, we can not only alleviate our concern but also provide a foundation for us to develop a *real-time processing* algorithm.

Therefore, we planned to complete our analysis of real time streaming by completing the installation steps of Movella DOTs streaming software on the github community, and empirically collecting data by syncing up two IMU sensors after installation to verify real time streaming capability. We decided on this method as Movella's other IMU products state that real time data collection capability had issues collecting data real time, while the github community has a large number of users and contributors who verified real time streaming capabilities with the method of installation. **Figure 28** below demonstrates the method we adopted to install the software on our Raspberry Pi.

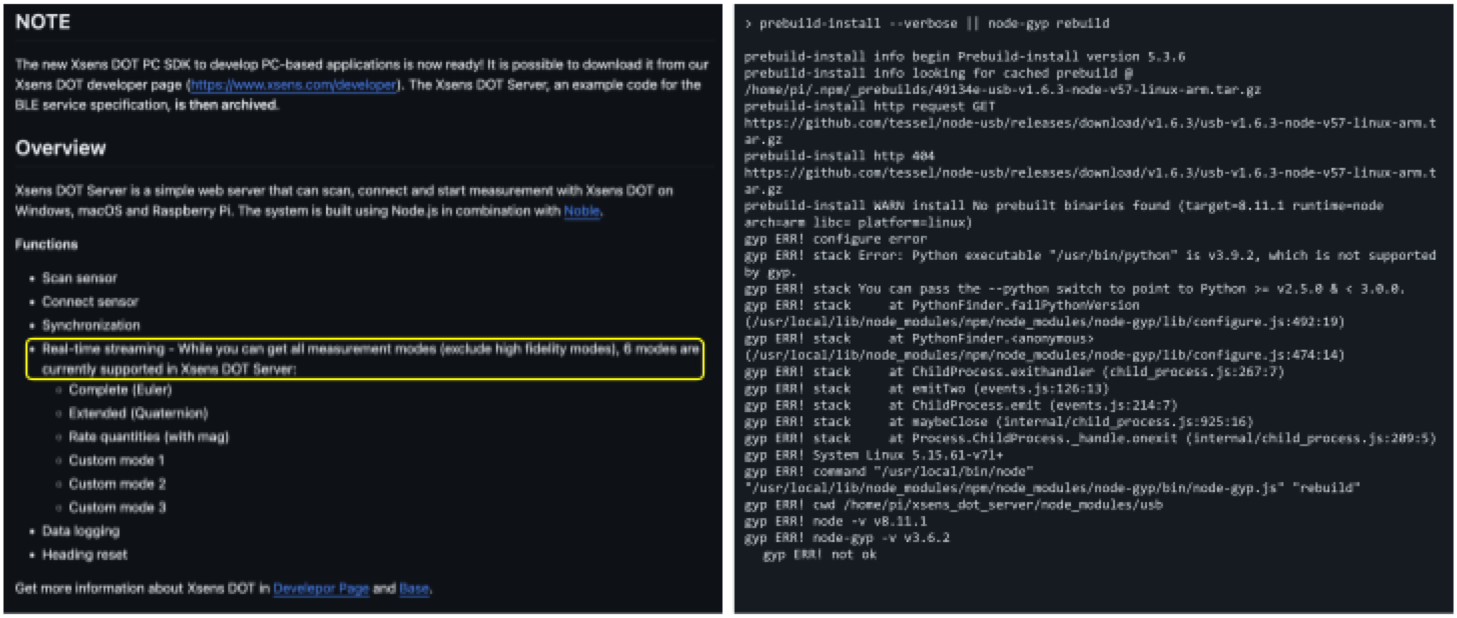


Figure 28. The github page of installation process of Movella DOT server which handles real time data streaming onto Raspberry Pi as highlighted on the figure, and the error message our team encountered. After scrutiny, we discovered this issue is common for other users on the github page since late 2022, and the issue has not been resolved due to Movella DOT discontinuing direct Raspberry Pi support.

Unfortunately, the github community's installation code was not kept up to date with the outdated requirements of Movella's official software. This led to difficulty completing this engineering analysis. Thus, we changed our final proof of concept to include a PC for real time data streaming and processing instead of utilizing a Raspberry Pi. **Figure 29** below shows how we developed a python algorithm that establishes connection to the IMUs and performs real time data collection. **Figure 30** demonstrates the actual measurement data read out. Finally, **Figure 31** shows examples of acceleration-time, velocity magnitude-time plots we constructed after the completion of 20 seconds of real time data collection that affirms the data collected in real time are valid data that are both similar in magnitude and shape as the plots we obtained during history data analysis on Matlab in the previous sections.

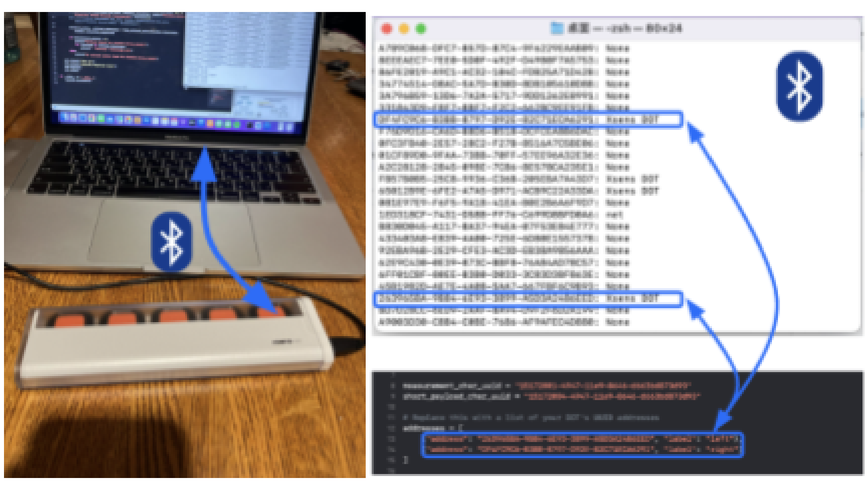
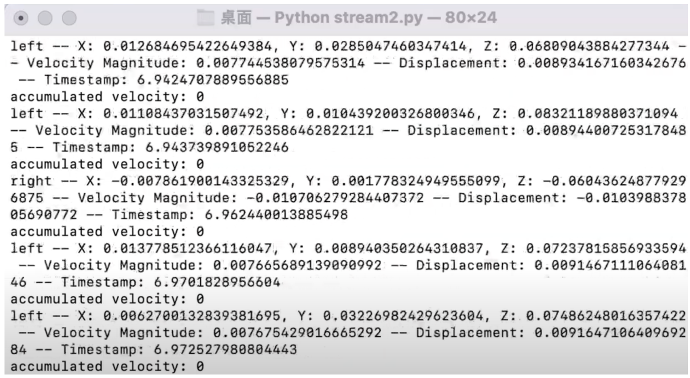


Figure 29. Figure showing the setup of the engineering analysis to test real-time streaming of data on a PC. IMUs are wirelessly connected to the PC by inputting the individual identification code of the sensors onto our python code. Refer to **Appendix C** for the Python Algorithm we developed.



```
桌面 — Python stream2.py — 80×24
left -- X: 0.012684695422649384, Y: 0.0285047460347414, Z: 0.06809043884277344 -
- Velocity Magnitude: 0.007744538079575314 -- Displacement: 0.008934167160342676
 -- Timestamp: 6.9424707889556885
accumulated velocity: 0
left -- X: 0.01108437031507492, Y: 0.010439200326800346, Z: 0.08321189880371094
-- Velocity Magnitude: 0.007753586462822121 -- Displacement: 0.008944007253178485
5 -- Timestamp: 6.943739891052246
accumulated velocity: 0
right -- X: -0.007861900143325329, Y: 0.001778324949555099, Z: -0.06043624877929
6875 -- Velocity Magnitude: -0.010706279284407372 -- Displacement: -0.0103988378
05690772 -- Timestamp: 6.962440013885498
accumulated velocity: 0
left -- X: 0.013778512366116047, Y: 0.008940350264310837, Z: 0.07237815856933594
 -- Velocity Magnitude: 0.007665689139090992 -- Displacement: 0.0091467111064081
46 -- Timestamp: 6.9701828956604
accumulated velocity: 0
left -- X: 0.0062700132839381695, Y: 0.03226982429623604, Z: 0.07486248016357422
 -- Velocity Magnitude: 0.007675429016665292 -- Displacement: 0.0091647106409692
84 -- Timestamp: 6.97252798080443
accumulated velocity: 0
```

Figure 30. Output data stream of the two IMU sensors in real time. The X, Y, Z values indicate the acceleration values in each axis. The code can be modified to only output the stride length and cadence instead of the data stream like above, but for testing and development purposes we are printing the acceleration, velocity magnitude, and displacement values.

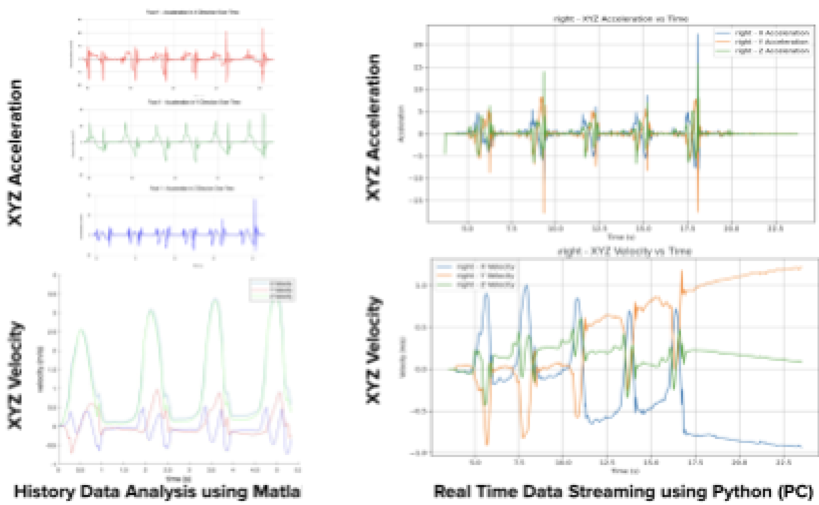


Figure 31. Comparison of the acceleration-time and velocity-time plots obtained from history data analysis on Matlab and real time data streaming on PC. The magnitude and shape of the plots are equivalent and therefore we are confident in our device's ability to perform real time measurement as well as processing.

In conclusion, after adopting a PC instead for data processing, we discovered not only that real-time measurement data streaming is possible for 20 seconds, but also the data we obtain from this method is valid. We also experimented with processing of these data to get to the displacement, but we noticed a more significant drift. This can be attributed to the high sampling rate (600 times a second) which exacerbates noise in the data, which in turn worsens integration error after the two integration processes. Moving forward, we would like to make changes to the sampling rate and the calibration algorithm to ensure the accuracy of the measurements before using the camera based motion tracking system for accuracy verification.We also plan to perform the engineering analysis for an extended period of time (6 minutes) to complete the verification of the device's ability to be used during the 6 Minute Walk Test (refer to **verification** section).

Vibrotactile Actuator Selection and Operation

Two more design concerns that were investigated were the perceivability of haptic actuators and their operation with the processing mode as listed in the design concerns table above. Being able to realize haptic feedback is required to provide feedback to end users who may be in loud environments or have difficulty hearing. The perceivability of haptic cues is essential for user awareness and responsiveness. If haptic feedback is not easily perceivable, users may miss important cues, diminishing the device's impact on gait correction. Ensuring clear and distinguishable haptic signals is crucial for user engagement.

Our established design would include haptic actuators that would notify the user via haptic signals to change their gait. These haptic actuators, as detailed by the alpha design, would be powered and have signals sent through them via Raspberry PI GPIO (General Purpose Input Output) pins. Due to the need for electrical connections, generated code, and considerations about signal perceivability, the team designated the haptic actuator related design concerns as critical. Prior to any engineering testing, a review of the Raspberry PI specifications sheet provided information as to the operating conditions that the GPIO pins would be able to produce for an actuator. An overview of the Raspberry Pi and GPIO pins are shown in **Figure 32** below:

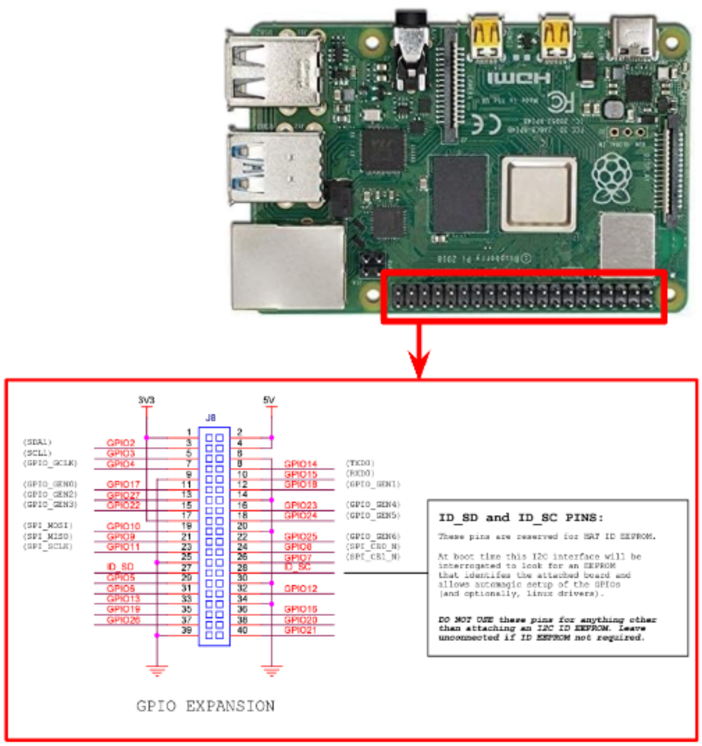


Figure 32. Overview of the Raspberry Pi with the GPIO expansion highlighted by a red box. The Raspberry Pi can provide 3.3V or 5V through the dedicated GPIO pins and a ground pin also found within the GPIO expansion.

A shopping cart analysis was then completed using the voltage information. From our design requirements, the haptic actuators should be small, inexpensive, and be able to be powered by the Raspberry Pi's 3.3V GPIO pin. Additionally, after conducting research on vibrotactile feedback, the actuator should achieve around 250 Hz to produce the most perceivable signal possible [51]. Solarbotics VPM 2 Coin Motors were sourced from the Sienko Research Group's labs for use as haptic actuators that met these required specifications. **Figure 33** below shows the coin motors:

Figure 33. Solarbotics VPM 2 Coin Motor. Achieves 200Hz using 3V power supply. 120mA start, 80mA load current. 32 Ohm Resistance.

After sourcing the haptic actuators, empirical testing was conducted to guarantee the compatibility of the haptic actuators with the Raspberry Pi, and to ensure that the design was feasible. Our team decided to connect one of the haptic actuators to the Raspberry Pi and first simply activate it. This testing method was selected because it would closely mirror the final design and on paper seemed feasible and easy to set up. The testing setup is shown below in **Figure 34**:

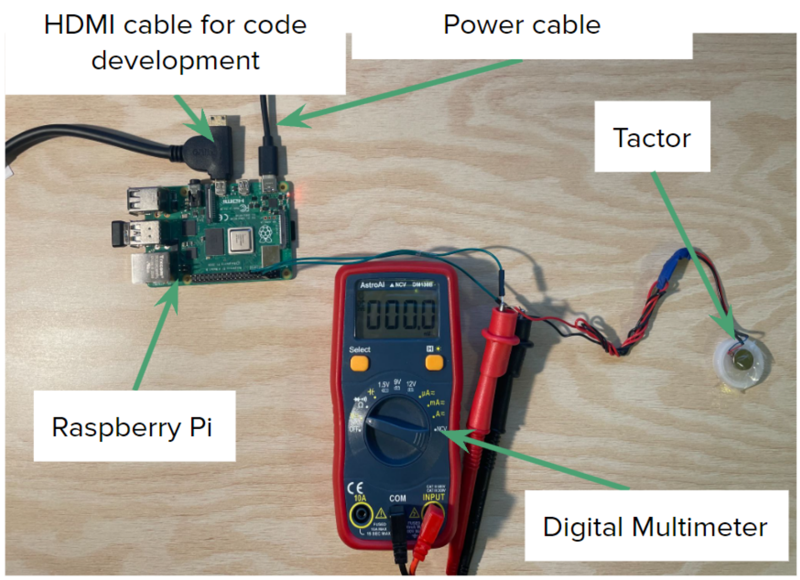


Figure 34. Overview of testing setup. The Raspberry Pi is connected to an external monitor via HDMI cable and mouse and keyboard for code development. Power is supplied via 5V USB-C. The haptic actuator is connected to GPIO pin #17 and ground. To read voltage that is supplied to the haptic actuator, a digital multimeter is placed in parallel with the haptic actuator.

After setting up the testing setup, a python script had to be created to inform the Raspberry Pi to send voltage over the GPIO #17 pin as desired. When this script was run, voltage was sent through the GPIO pin and was detected on the multimeter as shown in **Figure 35** below:

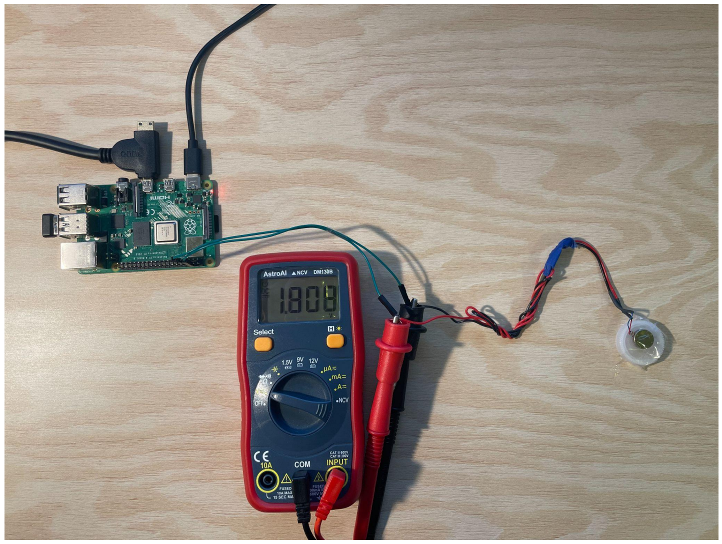


Figure 35. Overview of testing setup with voltage sent over GPIO pin. Although not visible from the picture, the haptic actuator vibrates and generates a loud buzzing noise.

Once the actuation of the haptic actuator was confirmed, further testing was performed to develop two perceivable signals for use with the haptic actuators. These signals were developed using the python script below in **Figure 36**:

```python
import RPi.GPIO as GPIO
import time

GPIO.setmode(GPIO.BCM)
GPIO.setup(17, GPIO.OUT)


for i in range (6):
    GPIO.output(17, GPIO.HIGH)
    time.sleep(0.2)
    GPIO.output(17, GPIO.LOW)
    time.sleep(0.1)

time.sleep(2)

for i in range (2):
    GPIO.output(17, GPIO.HIGH)
    time.sleep(0.6)
    GPIO.output(17, GPIO.LOW)
    time.sleep(1)

GPIO.cleanup()
```

Figure 36. Python script used to enable signaling on haptic actuators. After the GPIO pin is initialized, a “high” and a “low” signal are played.

In order to convey information to the user, we have decided on two signals to send through different haptic actuators: a high signal and a low signal. Ideally, high signals should be very perceptible and hard to ignore, and can be used to inform the user of too short of stride length. Low signals could seem less critical, and would be good to use to inform users of too long of stride length. These signals, in combination with audio cues and instructions for use can inform the user of gait corrections. After conducting empirical testing where different signals were tested on the leg of a team member, high and low signal information was established. The high signal consisted of 6 cycles where the coin motor was powered for 0.2 seconds and unpowered for 0.1 second. On the user, this signal felt fast, clear, and demanding of attention. The low signal consisted of 2 cycles where the coin motor was powered for 0.6 seconds and unpowered for 1 second. On the user, the low signal felt slow, clear, and far less demanding of attention compared with the high signal.

In conclusion, after conducting a shopping cart analysis, setting up and running a haptic actuator, and creating and optimizing signals, our team is confident with the feasibility of the haptic actuator based feedback system. Through this testing, we have been able to send signals through a haptic actuator to a user, and have empirical tests that guarantee the perceivability of the system, therefore addressing the relevant design concerns stated above.

Looking forward, the creation of a feedback system composed of several actuators would be trivial. The Raspberry Pi has several GPIO pins that can be used, and there would be minimal complexities involved in the python script to account for multiple pins. With this being said, there are voltage limitations involved with the power source (the Raspberry Pi is only supplied 5V, and so there would be a limit as to the number of haptic actuators that can be active at a single time).

Failure Mode & Effect Analysis

An additional design concern that was investigated was the idea of safety relating to the device. With target users having limited mobility, any kind of fall hazard must be mitigated. The presence of wires, straps, or pouches posed the risk of interfering with the gait of the patient. Additionally, the safe use of electronics must be considered. Since complete prototypes are not yet available for empirical testing relating to safety, an effective tool that is currently available would be the use of a failure mode and effect analysis (FMEA) to better understand potential safety threats of the device. The **Table 15** below shows this safety-focused FMEA:

Table 15. Safety-focused FMEA. Risk Priority Number is calculated by multiplying severity, occurrence and detection ratings. Low = 1, Moderate = 2, High = 3.

System	*Potential Failure Mode*	*Potential Effect on User*	*Severity Rating*	*Potential Causes*	*Occurrence Rating*	*Detection Rating*	*Risk Priority Number*	*Recommended Actions*
Vibrotactile Feedback System	Actuator Malfunction	Loss of Awareness of Gait Parameters	Moderate	Mechanical Wear, Electrical Failure	Moderate	Moderate	8	Ensure actuators are functional and responsive, implement redundant actuators for continuous feedback
	Actuator Electrocution	Physical Pain, potential for falling	Moderate	Improper assembly, Lack of Insulation	High	Low	6	Ensure wiring is covered using insulation, ensure no electronics have skin contact
Auditory Feedback System	Speaker Malfunction	Loss of Auditory Cues for Gait Parameters	Moderate	Manufacturing Defect, Connectivity Issues	Low	High	6	Thoroughly inspect and test speakers, connectivity testing to ensure uninterrupted auditory feedback
Raspberry Pi Processor	Data Processing Failure	Incorrect Feedback on Gait Parameters	High	Software Bugs, Hardware Malfunction	Low	Moderate	6	Ensure the processor is operating with latest software, redundancy in processing to prevent incorrect feedback
	Snagging of Power / Data Cord	Potential for falling	High	Improper assembly, Lack of Cable Management	High	Low	9	Ensure wiring is covered using insulation, ensure no electronics have skin contact
Power Source (portable battery)	Battery Overheating	Risk of Burns or Fire	High	High Ambient Temperature, Overcharging, Physical Damage	High	Low	9	Monitor battery temperature, charge management system to prevent overheating and ensure user safety
IMU	IMU Calibration Error	Inaccurate Gait Data	High	Calibration Drift	Moderate	Low	6	Maintain accurate gait data, alignment checks for precise sensor function, ensuring user safety in movement
	IMU Ankle Band Obstruction	Tripping of user, causing additional injury	High	Improper Donning, Obstructed surroundings	High	Low	9	Provide instruction to wear device, ensure walkway is clear of obstructions

This analysis provided our team with an idea of some of the largest risk safety issues with the device, and enabled us to plan for mitigating them. As seen in the table, IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns. Additional testing can be done for **verification** to ensure that IMU ankle bands do not interfere with the patient's walking, and subject matter experts can be consulted to ensure that the handling and use of the portable battery is done safely.

Summary of Engineering Analysis

In **Table 16** below we present a summary of all of the engineering analyses we have completed, their results, and implication of the results in relation to the design concerns.

Table 16. Summary of the Key engineering analyses completed, their results, and the implications/significance of the results.

Engineering Analysis	Results	Implication of the results
Gait measurement range and accuracy	The device can measure the normal range of stride length and cadence up to 1.5 m and 120 steps/min respectively with small errors that fall within the acceptable range defined in the specification (≤ ±3cm for stride length and ≤ ±5% for cadence).	These results are extremely promising, however our testing methodology involves potential sources of inaccuracy as mentioned above. We will be utilizing a more involved and more accurate camera based motion tracking system for comparison in the verification section to further confirm device measurement accuracy.
Real time data streaming	Real time data streaming on Raspberry Pi could not be accomplished due to the lack of technical support from IMU manufacturers. However, with the newly adopted PC as a middle man for processing the gait measurements before signaling feedback on the Pi, our device was able to stream raw acceleration data up to 600 times a second for each IMU on each foot.	With the limited time, we plan to change our final proof of concept to include a PC for real time data streaming and processing instead of sticking with the Raspberry Pi. Therefore, we plan on completing an engineering analysis to test the communication between the PC and the Raspberry Pi that will be attached onto the end user's hip for feedback actuator controls. Furthermore, we observed after the analysis that the high sampling rate (and the introduction of more noise), and the real time double integration on the PC can lead to large errors in the final displacement measurement we use to determine stride length. We therefore plan to make changes to the sampling rate and the calibration algorithm to ensure the accuracy of the measurements before using the camera based motion tracking system for accuracy verification. We also plan to perform the engineering analysis for an extended period of time (6 minutes) to complete the verification of the device's ability to be used during the 6 Minute Walk Test (refer to verification section).
Vibrotactile actuator selection and operation	Through this testing, we have been able to send signals through a haptic actuator to a user, and have empirical tests that guarantee the perceivability of the system, therefore addressing the relevant design concerns stated above.	After conducting a shopping cart analysis, setting up and running a haptic actuator, and creating and optimizing signals, our team is confident with the feasibility of the haptic actuator based feedback system, and will be using this testing to aid in the creation of the final envisioned feedback system.
Failure Mode & Effect	As seen in the table, IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns.	This analysis provided our team with an idea of some of the largest risk safety issues with the device, and enabled us to plan for mitigating them. Additional testing can be done during verification to ensure that IMU ankle bands do not interfere with the patient's walking, and subject matter experts can be consulted to ensure that the handling and use of the portable battery is done safely.

Verification and Validation Plans

The objective of verification is to test whether the product meets specified requirements, functions as intended, and is free from defects. On the other hand, the purpose of validation is to ensure the product tackles the design problem it is meant to address, which in our case is to aid the Poovanthi Institute of Rehabilitation in Southeast India in reducing the therapists load and developing a real-time feedback system gait deviation patients can use to train on. The following subsections outline the verification and validation approaches our team plans to take.

Verification Plans

It is important to ensure that the final build satisfies all the high priority design requirements and engineering specifications that were set in the early stages of the design cycle. **Table 17** below provides a brief summary of each high priority specification that requires verification, our verification methods for each specification, and our interpretation of the results.

Table 17. A summary of every requirement and their respective specification to be verified, verification methods, and interpretation of results.

Requirement	Specifications	Verification Method
Detects relevant gait parameters	The device must measure stride length ≤ 1.50 m. Measure cadence ≤ 120 steps/min. The measured values must have total error ≤ ±3cm for stride length and ≤ ±5% for cadence.	The specification is verified by comparing the design against an analog motion tracking system that can provide high accuracy stride length and cadence measurements.
Provides feedback to the user	The feedback must be provided at least every 2-4 steps. The device needs to have two or more means of providing feedback.	The first specification is verified by experimentally calculating the total latency involved in collecting, processing, and determining/providing feedback while using our device. Then, we incorporate the reaction time of typical adults wearing vibrotactile cueing devices [50] and step initiation time data for typical young adults into the computation. We then compare the latency value with the cadence of patients with varying degrees of gait deviations.
Be price efficient	The device must be ≤ USD$8,000 in final product acquisition price to stakeholder	The specification is verified by performing price analysis with supplier quotations, where we obtain quotations for each system component from local suppliers and negotiate for the best possible price.
Functions without faults at local climate	The device must be fully functional in environments up to 55°C and 100% humidity.	This specification is verified by checking product specification sheets for IMUs, Raspberry Pi, and feedback actuators. An additional verification test would be to conduct a sauna exposure test, where we leave the prototype in a sauna for 1 hour under conditions described in specifications, measure device performance after exposure, and repeat cycle testing up to 4 times.
Be safe	The device must be classified as class A (low risk) or B (low moderate risk) per CDSCO . The device must not have more than one cord to reduce the risk of trip hazard. The device must score 0 on Magnusson and Kligman scale for skin sensitization	The team used FMEA analysis to get an idea of safety related concerns, and the results of IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns. This specification can be verified by conducting controlled beta testing experiments with patients at different capability levels to simulate various rehabilitation scenarios, with gait rails being used to ensure patients do not injure themselves during the testing. Multiple therapists can supervise the testing for additional safety and identify any potential safety risks or hazards associated with the device's use. We can then collect this information based on surveys made with the Likert scale or interviews. Appropriate CDSCO regulation and Magnusson and Kligman testing methodologies can be adopted.
Be hygienic	The surface of the device must not be composed of materials (PMMA,	This specification can be verified by a material compatibility test using conventional disinfectant products containing chlorine bleach or

	Polyurethane coated Polyester, or Velvet Polyester) that are incompatible with conventional disinfectant products (composed of chlorine bleach or quaternary ammonium compounds). The surface of the device must have surface roughness value ≤ 0.8µm.	quaternary ammonium compounds, with the device's surface, composed of PMMA, Polyurethane coated Polyester, or Velvet Polyester, being exposed to these disinfectants to ensure that no adverse reactions or material degradation occurs. Additionally, a surface roughness test can be performed to measure and confirm that the surface of the device maintains a roughness value of ≤ 0.8µm. This dual-pronged approach should ensure that the device not only withstands routine disinfection procedures but also adheres to the specified surface roughness requirements, promoting an environment conducive to hygienic practices.the team hFMEA analysis to get an idea of safety related concerns, and the results of IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns.
Be able to be used during 6 minute walk test (6MWT)	The device must include a stopwatch to measure 6 minutes. The device must be able to measure and record up to 50 laps of 12 meter walks.	We validate the specifications by conducting a 6-minute walk test, during which we will assess the accuracy and precision of the collected data. We plan to move the IMU sensors 0.8 meters every 10 seconds.

For the requirement to detect relevant gait parameters and the specifications associated with it, we verified the specifications by comparing the design against analog measurements that provide decent accuracy in stride length and cadence measurements. This is documented in the Engineering Analysis section, and this is the best method due to its convenience and low resource consumption in data collection. An assumption we made was that this method yields accurate stride length and cadence. The limitations of this method mostly stemmed from our test subject's ability to take each stride based on distance markers and metronome- the bigger the error the person makes in taking equal stride length and cadence, the more difficult we are able to produce values for the error of our own device. However, this analog measurement test still provided decent accuracy in stride length and cadence measurements, and the results we obtained showed that the IMU sensors meet the accuracy requirements.

For the requirement to provide feedback to the user and the specifications associated with it, we verified the specification by calculating the total latency involved in collecting, processing, and providing feedback through conducting an experiment that involves the use of our device. Then, we incorporated the reaction time of typical adults wearing vibrotactile cueing devices [50] and step initiation time data for typical adults into the computation. This holistic approach ensures that all relevant components contributing to the overall system response time, which are data collection, processing, and feedback provision tests, are taken into account. Nonetheless, the effectiveness of the method hinges on the assumption that the reaction time of typical adults is the same as that of post-stroke or spinal cord injury patients. To mitigate this concern, we added a safety factor to the reaction time of typical adults. The results we obtained indicate that the latency and reaction time, 350 milliseconds and 300 milliseconds each at maximum, which amounts to a total of 750 milliseconds, and 900 milliseconds if we add a safety factor of 1.2, is far less than the time it takes to take the next 2-4 steps. Thus, at this stage, we do not plan to implement any optimizations for shorter run time nor hardware upgrades for improved processing speed.

For the requirement to be price efficient and the specifications associated with it, we verified the specifications by determining every material our actual stakeholder design contains and obtaining price listings for each system component per local suppliers, such as Amazon India and other local suppliers. The price listings are listed in the BOM section in Appendix G. Obtaining quotations from local suppliers is practical and direct and gives us more accurate pricing information around each component in the design. Nonetheless, few assumptions are made on this price analysis that might hinder its credibility: certain components such as the IMUs must be sourced internationally, and the shipping costs are difficult to calculate. In addition, we attempt to seek components for the stakeholder design that have already demonstrated success in our ME450 design; however, there are also certain elements that cannot be sourced such as the haptic actuator, and we have to find alternatives, which possess potential risks of cheaper local components not meeting the standards our product requires. Thus, when doing the price analysis, instead of going for the cheapest products, we try to strike a balance between cost efficiency and its reliability and performance ratings. The price analysis indicates that our estimated material costs, which is around USD$1,300, is well within the budget constraints of USD$8,000.

For the requirement to function without faults at local climates and the specifications associated with it, we checked product specification sheets for IMUs, Raspberry Pi, and feedback actuators. The rationale is that since this is a requirement that can simply be verified by checking if it is met by design, this simple method would save us valuable time and resources. However, some of the specification sheets did not provide information on the temperature and humidity that the electronic components can operate in. Thus, a future plan would be to conduct a sauna exposure test, where we leave the prototype in a sauna for 1 hour under conditions described in specifications, measure device performance after exposure, and repeat cycle testing up to 3 times. This approach is the best strategy because it provides us with the extremes of a real-world environment and should guarantee our product's functionality if it passes the test. There is, however, a limitation on sauna test replicability, as factors such as variations in sauna conditions and potential wear and tear on the prototype can all affect the results of this approach. Nevertheless, this is still a good approach as the limitations have little effect on the make or break nature of the results. With that, if the device breaks or fails to reach the specifications, we should consider implementing active cooling or waterproof features for components susceptible to high temperature and humidity, and repeat the test until the specification is fulfilled.

To ensure the safety requirements and associated specifications are met, our planned strategy involves executing controlled beta testing experiments with patients at various capability levels, thereby simulating a range of rehabilitation scenarios. Gait rails will be implemented during testing to prevent potential injuries to patients, guaranteeing a secure environment. To further enhance safety measures, multiple therapists will supervise the testing process too. Their oversight is crucial for identifying any potential safety risks or hazards related to the device's usage. In alignment with regulatory standards, we plan to adhere to the appropriate CDSCO regulations and implement Magnusson and Kligman testing methodologies. This approach not only ensures compliance with regulatory guidelines but also adds an additional layer of scrutiny to comprehensively assess the safety aspects of the device. By combining controlled testing conditions, therapist supervision, and regulatory adherence, our validation plan aims to address safety concerns thoroughly and systematically throughout the testing phase. The chosen verification method is considered optimal for its comprehensive evaluation approach. When it comes to user safety, we decided to conduct a more involved test, reducing the possibility of neglecting a safety risk. The assumption is that the simulated scenarios adequately mirror the challenges of real-world rehabilitation, ensuring a thorough assessment. However, a limitation arises from the setting of the experiment, which might not fully replicate the complexity of real-world settings. Despite this limitation, this method is still a robust approach in identifying potential safety hazards. If a safety risk is identified, then we should diagnose the root cause of the risk, and then proceed to change the design accordingly. Additionally, the FMEA analysis provided our team with some safety concerns and recommendations. As seen in the FMEA table, IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns. Additional testing can be done to ensure that IMU ankle bands do not interfere with the patient's walking, and subject matter experts can be consulted to ensure that the handling and use of the portable battery is done safely.

To ensure the hygienic requirements and associated specifications are met, our strategy involves a two-step assessment to guarantee the material compatibility and surface integrity of the device under routine disinfection procedures. We will conduct a material compatibility test using conventional disinfectant products containing chlorine bleach or quaternary ammonium compounds. This test aims to expose the device's surface, composed of PMMA, Polyurethane coated Polyester, or Velvet Polyester, to these disinfectants, ensuring that no adverse reactions or material degradation occurs. Simultaneously, a surface roughness test will be performed to measure and confirm that the device's surface maintains a roughness value of $\leq 0.8\mu m$. This approach is optimal as it not only ensures the device withstands disinfection but also verifies its adherence to specific surface roughness requirements, creating an environment conducive to hygienic practices. An assumption is made that the chosen disinfectants, containing chlorine bleach or quaternary ammonium compounds, are representative of those commonly used in healthcare settings in south India. However, a potential limitation lies in the diversity of disinfectants employed in south India, which may not be fully captured by our selected products. Once we interpret the results, if the material compatibility or surface roughness test yields unsatisfactory results, we should investigate the specific disinfectant-component interactions leading to the failure. This may involve reassessing the disinfection protocol, considering alternative materials, or modifying the device's surface composition.

Lastly, for the requirement to be able to be used during the 6 minute walk test and its associated specifications, the plan is to run the device for 6 minutes, moving the IMUs by 80 cm every 10 seconds, and measure the accuracy and precision of the data during the time. By running the device continuously and examining data precision at regular intervals, this test provides a straight-forward evaluation of the device accuracy and reliability. One potential limitation, however, arises in the inability of this method to encompass all potential variables encountered during the 6-minute walk test, such as longer walking distances and diverse user behaviors. A user could be moving continuously; however, choosing to move the IMUs by only every 10 seconds provides data with more clarity for analysis- hence why we will not simulate continuous movements in this test. Despite that, the test plan is still a robust means of validating the device's accuracy through time. In the actual test, three trials were conducted, and all three output similar results. **Figure 37** below illustrates the results of one of the trials.

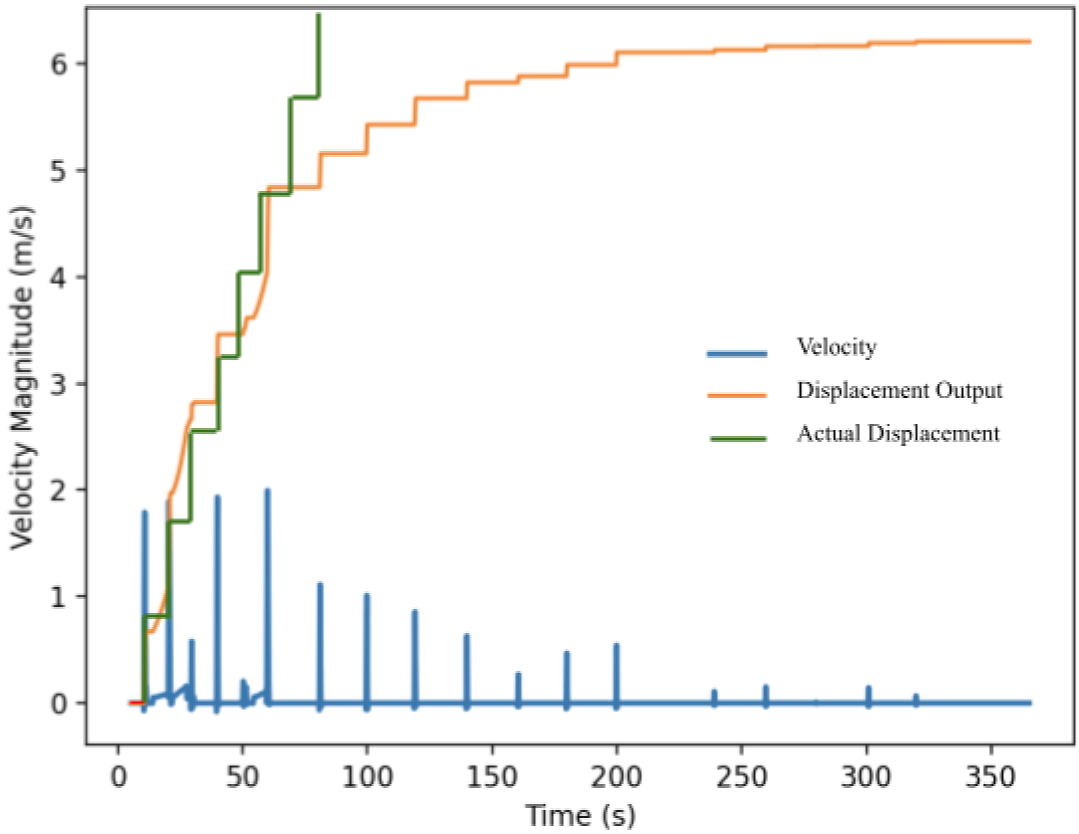


Figure 37. The displacement output generated by IMU sensors through the implemented algorithm for the six minute walk test. The expected output is represented by the green line, while the yellow line illustrates the actual output.

From this trial, the device produces some accurate results for the first 60 seconds, then the displacement output begins to dwindle exponentially. To fix this, one can either change the real-time data streaming algorithm to reset values at every minute mark, or add an exponential curve to subset the exponentially decreasing increase of stride length. The latter would be more difficult to implement than the former, but both methods should work to reduce sensor error due to sensor drift in real-time.

This comprehensive verification plan should cover all the critical specifications that need to be tested. There are some lower priority requirements and specifications that will not be validated via testing or experimentation due to time and resource constraints. These requirements include being easy to set up, being able to interact with the user in a comprehensible manner, being comfortable, and being sustainable. The requirement of being able to interact with users in a comprehensive manner will be accounted for in validation plans, elaborated in the following subsection. For the other specifications, the decision to exclude them from formal testing is not arbitrary; rather, it is a strategic choice based on prioritization- we choose to allocate our time and resources wisely, prioritizing the most crucial elements. Stakeholders can feel confident in our devices' ability to fulfill those specifications, however. Even though the team is not testing everything, the team is still considering the importance of these lower-priority aspects in a thoughtful way.

Validation Plans

The validation plan for our system encompasses thorough testing protocols to ensure its efficacy in real world settings, its user-friendliness, and ultimately its ability to tackle the design problem. **Table 18** below provides a brief summary of the design aspects we plan to validate and our plan to validate them.

Table 18. Summary of the design aspects to be validated and the approach to validation.

Design Aspect	Validation Plan
Individual Feedback Systems (Unit testing)	We plan to validate the vibrotactile feedback system by conducting beta testing with proxy patients. This test should assess patients' ability to distinguish between vibration patterns during gait training and determine if users can comprehend variations and make real-time gait changes. We plan to validate the auditory feedback validation by performing consultation and verbal validation with our clients. Taking into consideration language and cultural variations, this test aims to ensure clarity and pronunciation of auditory cues and confirm the comprehensibility for end-users during gait training.
Cohesive Feedback System (Integration Testing)	We plan to extend the validation plan for individual feedback systems to validate how the feedback systems (vibrotactile and auditory) work together in a cohesive manner. This test aims to ensure that the two feedback systems together improve the patient's perception of feedback rather than causing additional confusion.
Comfort and Ease of Use	We plan to validate comfort and ease of use by performing usability tests on proxy patients with varying degrees of gait deviations. The patients should perform activities such as rehabilitation exercises and tasks with the device and then be surveyed on comfort and ease of use based on Likert scale questionnaires derived from established medical device comfort scales (e.g. Wheelchair Seating Discomfort Assessment Tool). This test aims to gather user feedback on comfort during device use, ease of interaction in device setup and operation, and seamless user experience during rehabilitation.
Long-term Use	We plan to conduct a long-term usability study with end-users. This extended evaluation can capture insights into how users adapt to the device over an extended period, as well as valuable information on the durability of the device and potential issues that may arise with prolonged use.
End-user Diversity (Inclusive Usability Testing)	We plan to test our device on a pool of diverse demographics, taking into consideration factors such as age, gender, height. The usability and effectiveness of the device on patients with different injury types, for instance post-stroke, spinal cord, and etc., and on patients with different severity of gait deviation is another aspect we plan to study. This ensures that the device is inclusive and caters to the needs of a broad user population.

The unit testing on vibrotactile feedback, conducted through beta testing with proxy patients, focuses on assessing patients' ability to distinguish between vibration patterns during gait training. The primary goal of this test is to determine if users can comprehend variations in vibrotactile feedback and make real-time gait changes. This step is crucial in refining the device's feedback system to enhance its effectiveness in aiding rehabilitation. Simultaneously, the unit testing on auditory feedback involves consultation and verbal validation with the client. The objective here is to ensure the clarity and pronunciation of auditory cues, taking into consideration language and cultural variations. By conducting validation with the client, we aim to confirm the comprehensibility of auditory feedback during gait training, which is vital for its successful integration into rehabilitation practices.

During integration testing, the focus is on evaluating the seamless collaboration of both vibrotactile and auditory feedback systems to ensure they work cohesively in real-world rehabilitation scenarios. This entails assessing the synchronization and effectiveness of the combined feedback, considering potential challenges such as overlapping cues. By conducting integration testing, we aim to verify that the device provides a harmonized and effective multimodal feedback experience, minimizing potential conflicts between vibrotactile and auditory stimuli. This phase is instrumental in refining the device's overall feedback system, ensuring its successful integration and optimum support for rehabilitation practices.

For unit testing and integration testing, real-world simulation scenarios should be implemented to mimic the diverse environments and conditions users may encounter during rehabilitation. This could include variations in noise level, lighting conditions, and potential distractions to assess the device's performance in realistic settings, contributing to the robustness and reliability of the feedback systems during actual use.

Another critical aspect of the validation plan is comfort and ease of use. Usability testing and surveys will be conducted with proxy patients exhibiting varying degrees of gait deviations. Rehabilitation exercises and tasks will be performed with the device, and Likert scale questionnaires, derived from established medical device comfort scales, are employed to assess comfort and ease of use. The ultimate goal is to validate that the device offers a seamless user experience during rehabilitation, ensuring both proxy patients and end-users find it comfortable and easy to use. This comprehensive approach to validation should assist us in developing a device that not only meets technical specifications but also prioritizes the user's experience and rehabilitation outcomes in real-world scenarios.

To comprehensively assess the device's performance over an extended period, we plan to conduct a long-term usability study with end-users. This study aims to capture valuable insights into how users adapt to the device over time and understand any potential issues that may arise with prolonged use. The extended evaluation will provide essential information on the durability of the device and its ability to maintain optimal functionality throughout an extended rehabilitation period. By monitoring user experiences, feedback, and any potential wear and tear, this long-term study will contribute to refining the device's design and ensuring its sustained effectiveness in real-world applications.

Recognizing the importance of inclusivity, we have incorporated an inclusive usability testing phase to ensure our device caters to a diverse range of end-users. This involves testing the device on a pool of individuals representing various demographics, such as age, gender, and height. Additionally, we will assess the usability and effectiveness of the device on patients with different injury types, such as post-stroke and spinal cord injuries, and varying severity of gait deviation. This approach guarantees that our device meets the needs of a broad user population, considering the unique challenges and requirements of individuals with diverse backgrounds and medical conditions. By conducting inclusive usability testing, we aim to validate that the device is accessible, effective, and user-friendly for a wide range of potential users.

Discussion

During this semester, our defined problem scope for this project was “a need for a device that provides multimodal, semi-real time feedback for gait deviation patients in low resource settings”. If our device were to successfully detect gait parameters and provide feedback to the patient, the device would enable more total patient training time and information without the need of a therapist leading to more positive recovery outcomes. Altogether such a device would enable the patient to integrate better with society and achieve a higher quality of life.

If more time and resources were available to collect data and better define the problem for patients, there would be a variety of questions that would be asked to different stakeholders. Most importantly, interviews would be conducted with key stakeholders who were not a part of the design process during our semester. These key stakeholders would be local therapy patients at the Poovanthi Institute of Rehabilitation as well as therapists working with them. Interviews with these stakeholders is important so that the final design provides more utility to them. Additionally, if more time and resources were available, the overall scope of the project could be more specifically tailored to specific variations of gait, and how the device would aid a multitude of different users with different circumstances, be it stroke recovery patients or partial spinal cord injury patients.

Reflecting on the strengths of our design, the use of an IMU based system has several inherent advantages over other systems. Firstly, gait parameters can be accurately extracted from walking data. As demonstrated in our empirical testing, the accuracy of our cadence and step length measurements in our engineering analysis testing are very good. Additionally, the price point of our proposed system is very inexpensive relative to other existing systems, with the total estimated cost being about $925. The majority of this number comes from the purchasing of IMUs (about 700$). This final price for the system is still far under the $8,000 target system price, and so the rehabilitation center can benefit from multiple devices or increased savings. Furthermore, the proposed system has a very small footprint. Within busy therapy halls, space may be limited for large systems, especially those that take up large amounts of floor space. The proposed system would not have any item external to the user; the IMUs, processor, feedback system, and battery all are wearable items that do not restrict the user’s movement or limit space within the therapy hall.

Reflecting on the weaknesses of our design, the use of an IMU based system and our application of it have some inherent limitations. Using only IMUs to detect gait parameters makes it difficult to detect step width of users. Although this was not seen as a priority among different gait parameters, it would provide benefits to users if this detection was possible. Additionally, our concept requires user calibration for height, age, and sex, as well as calibration of the IMUs that must be done by remaining stationary for some time prior to testing. These requirements as well as software issues required the use of a PC interface to enable calibration as well as processing for sensor data. This increased complexity, cost, and infrastructure requirements for the system. With added complexity, there is added concern about usability, especially for those using it independently with limited mobility, and exposure to the system.

Looking into the future, there are a variety of modifications that can be made to improve the functionality of our system. Within the feedback subsystem, local language inclusion must be investigated and included for the audio feedback modes, along with instructions for use of the device. Additionally, the use of a backup power system should be considered for at least the PC components so that calibration and data processing can occur seamlessly regardless of electrical grid status. Moreover, validation testing as described in the validation sections of the report must be conducted, and testing would be useful if feedback would be able to be provided by local users of the device. As a final consideration, the repositioning of the ankle band that carries the IMU to the top of the foot should be an item worth considering. The ankle was chosen due to it being close to the foot for kinematic data, yet easily able to hold a commercially available strap without hindering local footwear norms and minimally impacting hygiene. Unfortunately, the ankle location for IMU systems provides more sensor noise as compared to positioning of the IMU on the top of the foot due to ankle joint movement that is not able to be considered in the processing algorithms.

There were a variety of challenges that our team had to overcome in the design process. These challenges encompass the contextual factors mentioned in user requirements and specifications section, which are industrial, socio-cultural, infrastructure, geographical/environmental, institutional, economic, public health, and technology. An analysis of the these challenges, along with suggested solutions are listed in **Table 19** below:

Table 19. A summary of the challenges in the current phase of the project with their corresponding contextual factors in parenthesis, their potential solutions and key considerations of special equipment, knowledge, experience, technical assistance, or logistics that might be required to tackle each challenge.

Challenge	Solution(s)	Consideration(s)
Selecting and sourcing effective sensing elements to be used in design to demonstrate proof of concept (technology)	● Explore existing sensing elements in the Michigan Engineering facilities ● Discuss with experts in motion tracking on current technologies and options of sensors that are both effective and low cost	● Collaborations with Michigan Engineering labs and professors, including Dr. Lauro Ojeda ● Review articles on current motion tracking technologies
Lack of direct communication with therapists and patients at the Poovanthi (infrastructure)	● Conduct remote surveys and interview with Chief Medical Officer ● Involve proxy therapists and patients in the design process	● Collaborations with proxy therapists at Michigan Engineering, including postdoc Danny Shin
Efficacy of product on gait sensing (technology)	● Conduct usability testing with target users	● Collaborations with local rehabilitation centers
Ease of use by patients without therapist support and feedback perceptibility for patients (socio-cultural)	● Design customizable feedback modes for patients with sensory, visual or hearing loss ● Involve proxy therapists and patients in the design process ● Involve human factor experts	● Medical journals on providing feedback perceivable to sensory impairments ● Collaboration with proxy therapists and patients ● Review articles on user-centered designs
Price justification (economic)	● Collect data on therapists time saved and patient outcomes to conduct price effectiveness studies	● Collaborations with local rehabilitation centers
Passing regulatory requirements (public health)	● Consult with regulatory experts ● Ensure compliance with safety standards of India ● Conduct risk assessment	● Standards from CDSCO (India's national regulatory body for medical devices) ● Consultation with William Davidson Institute at the University of Michigan
Contextual challenges including environmental factors and clothing interference (geographical/environmental)	● Select durable sensors that produce accurate data in local Indian climate conditions ● Design minimally intrusive wearables and work around local clothing	● Consultation with wearable design experts ● Information sources on local Indian clothing
PC Data Processing Algorithm	● Consult with experts in the Mechanical Engineering department	● Drift has accuracy concerns ● Sample rates on PC are high and creates noise
User Calibration	● Discuss user interface with local shareholders to ensure it is intuitive	● Must be intuitive for user, fast to use, and in local language
PC to Raspberry Pi Communication	● Conduct engineering testing, and consult with experts if necessary.	● Bluetooth connection has pending engineering work not sure if there will be software support

Lack of specialized knowledge about microcontrollers and power delivery	• Consult with experts in mechanical and electrical engineering departments	• Try to wire / assemble electronic components with supervision and / or guided steps.

Information gaps existed in various areas within our team, including sensor technology, user environment and habits, regulatory requirements, and device effectiveness. These gaps were addressed through conducting research and literature reviews and consulting technical experts, therapists and patients. More specifically, our team had a lack of specialized knowledge in bluetooth communications, mechatronic systems, and power delivery and wiring to microcontrollers. These knowledge gaps were addressed so that assembly / manufacturing of the mechatronic device could take place. Solutions for these gaps in knowledge were found by consulting with experts in the mechanical and electrical engineering departments and by purchasing mechatronic elements primarily used for prototyping such as arduino UNOs and Raspberry PIs.

Risks to primary users of the product were comprehensively covered in an FMEA analysis in the engineering analysis section of the report. This analysis provided our team with an idea of some of the largest risk safety issues with the device, and enabled us to plan for mitigating them. As seen in the FMEA table, IMU ankle band obstructions, wires snagging, and battery overheating were seen as some of the most prominent safety concerns. Additional testing can be done for verification to ensure that IMU ankle bands do not interfere with the patient's walking, and subject matter experts can be consulted to ensure that the handling and use of the portable battery is done safely.

Reflection

In the beginning stages of our design process, we sought to consider the global and societal impacts of our project. Now that we have concluded this process, we seek to reflect back on our initial perspectives, and then discuss how our perspectives have changed or stayed the same over the course of our project. **Table 20** below addresses several factors regarding our project, and discusses why or why not each factor is relevant to our final project.

Table 20. Relevancy of factors to final product

Factor	Relevancy to Final Project
Public health, safety, & welfare	Very relevant to final design. This factor was crucial throughout the entirety of our design process, as we needed to ensure that our design was safe for the end users in clinical rehabilitation settings.
Global Context	This factor was relevant in the grand scheme of things, however had less emphasis for our specific design. We sought to cater our solution solely to our sponsor, and less so on associated needs of a global marketplace for future developments.
Societal impacts with manufacture, use, and disposal	This factor again was relevant in the grand scheme of things, however had less of an impact on our specific design. Since we knew that we did not plan on manufacturing our final product, and it was only to be used on a small scale by the Poovanthi Institute, this was less important than functionality.
Economic impacts with manufacture, use, and disposal	The small-scale economic impacts were very relevant to our final design. We have sought to meet a low-cost requirement throughout the entirety of our design process, as we sought to cater our design for low-income settings.
Basic tools used	Basic tools, such as stakeholder/ecosystem maps and life cycle costing were very relevant to our final product. These tools were used throughout our design process as we sought to constantly remind ourselves of our goals, and ensure that our design was catered towards our stakeholders and life cycle costs.

We also must address the relevant differences in cultural, privilege, identity, and stylistic similarities between both team members and between our team and sponsor in regards to our final design. These differences were not much of a barrier in regards to approaches amongst team members, as the constant communication and overall cultural similarities allowed for very smooth and seamless communication and interaction. We ensured throughout the semester that everyone was always on the same page, and that members were comfortable to speak up whenever a problem arose .This allowed us to go through our design process together, and made it so any differences did not matter. However, there were significant differences between our sponsor and our team. While we did our best to ensure that our final design was culturally appropriate, given that we were unable to get feedback from end users, we do not know how effective we were in completing this objective. Furthermore, it was very difficult to communicate constantly and get feedback from our sponsor given the time difference. We did meet several times throughout the semester, however, when we did so it had to be very early in the morning. This led to less sponsor communication and delayed responses that made it more difficult to complete our design process.

One power dynamic that we faced in the design of our project was our hidden power over the end users. We were designing our project through research and communication with our sponsors and others associated with the project. However, we did not plan to speak directly with patients at the Poovanthi Institute. This means that while we strived to design our project for these end users, we likely did not necessarily perfectly interpret all their needs. As a team we strived to all hold no power dynamics over each other, and hoped to do our best to minimize the power dynamics between us, our sponsor, and end users.

In the case of our project, our identity and experience significantly shaped our perspective as compared to end users of our project. Given that none of us have ever utilized gait training before, we did not have the first hand experience to give insight on what cues were and were not helpful during real time gait training. Compared to other team members our identities and experience served a role in the technical analysis, as some members had more experience with MATLAB & Python than others, and were more equipped to deal with this side of the project.

Our approach for including diverse viewpoints of stakeholders typically consisted of consultations with our project advisor, who was able to provide valuable insight on University faculty and PhD students who could help for a given problem. For including diverse viewpoints of team members, we sought to develop an open-minded environment, where no one would be judged or criticized for any idea they brought to the table. To balance whose ideas, whether between stakeholders or team members, were selected to inform the project, we typically would discuss in a group meeting until the group could come to a unanimous decision. Fortunately, we were able to make these unanimous decisions for each important decision due to our open-minded dialogue and mutual respect.

While there were clear-cut cultural differences seen within our team members this semester given that half of the group were international students, this did not seem to play much of a role, if at all, on our approach to this project. Each team member was very hard working and accountable, and everyone was capable of getting tasks done on time and in a high-quality manner despite any cultural differences. Cultural differences with our sponsor did, however, certainly influence our design process. We ensured that our design was appropriate across cultures by frequently meeting with our sponsors to check in on this. One example is that we had to fit into our design that patients at the facility would wear very light clothing, given the humidity, and also that they would most commonly wear sandals or be barefoot.

Recommendations

This section offers practical recommendations to address the identified shortcomings in our gait feedback device's final design. The recommendations, spanning system-level improvements and detailed adjustments, aim to enhance user experience, simplify calibration processes, include local language options, ensure power backup, and optimize sensor positioning. Each suggestion is formulated to overcome challenges discussed earlier and pave the way for a more user-friendly, effective, and efficient gait feedback system. These proposed changes reflect a practical and forward-thinking approach, considering both immediate enhancements and future modifications to optimize the system's overall performance. **Table 21** below displays the list of system-level improvement recommendations, the weakness the recommendations address, the justifications of their selection and estimates of how complex applying these improvements are expected to be. It is worth noting that the complexity column on the very right was color coded where red denotes high, orange indicates medium, and green means low complexity. Similarly, **Table 22** lists the detailed-level recommendations.

Table 21. List of system level improvement recommendations, the weaknesses they address, justifications of their importance, and their respective complexity of applying the recommendations.

Recommendation	Addresses which weakness/supplements which strength?	Justification	Expected Complexity & reasoning
Utilize additional time of flight (ToF) sensors along with the IMUs to measure step width	Difficulty in detecting step width using IMUs	Incorporating Time-of-Flight (ToF) sensors facilitates step width measurement by providing additional depth information. ToF sensors emit light pulses and measure their travel time, offering precise distance calculations between two sensors. Integrating ToF sensors alongside IMUs by attaching the sensors around the IMUs facing each other will help measure step width.	Involves exploring additional sensor technologies and algorithm modifications. Wiring may become a problem if wireless ToF sensors cannot be sourced. However, there are a plethora of ToF sensor options that work with raspberry Pi, so options are plenty.
Adopt camera based motion tracking system which works alongside the IMUs	Difficulty in detecting step width using IMUs Complexity and user dependency in the current calibration process. Accuracy of gait measurements	Integrating a camera-based motion tracking system alongside IMUs can improve the calibration process. Cameras offer precise spatial information, aiding in the alignment of height, age, and sex calibration parameters. The motion tracking system can also double as another source of gait measurement during actual walking, providing a means of detecting step width, joint ranges of motion, and other gait related data, while further improving accuracy of IMU measurements. This approach enhances the calibration accuracy and user-friendliness, potentially reducing the need for prolonged stationary calibration.	Incorporating a camera-based system for calibration requires synchronization with IMUs, algorithm adjustments, and potential hardware additions that may be costly.
Develop processing algorithm on Raspberry Pi	Dependence on PC Interface. Need a backup power system (if a PC is used).	Developing a processing algorithm on the Raspberry Pi enhances the device's autonomy, and reduces the number of "middlemen" devices lowering device latency. This change also alleviates the need for a backup power system for a PC. Using a Raspberry Pi is also more price efficient, as an expensive PC does not have to be purchased for integration.	Involves algorithm development, optimization, and integration with existing Raspberry Pi capabilities.

Table 22. List of detailed-level improvement recommendations, the weaknesses they address, justifications of their importance, and their respective complexity of applying the recommendations.

Recommendation	Addresses which weakness/supplements which strength?	Justification	Expected Complexity & reasoning
Reposition IMU from Ankle Band to Top of the Foot	Increased sensor noise due to ankle joint movement affecting IMU accuracy	Considering the impact of ankle joint movement on sensor noise, relocating the IMU to the top of the foot provides a more stable platform for kinematic data. This adjustment aims to minimize noise, enhance sensor accuracy, and reduce calibration time to improve the overall effectiveness of the device.	Involves redesigning the attachment mechanism such as a new sandal design considering the contextual factors. However, little to no modifications are needed algorithm-wise.
Local Language Integration for Feedback Modes	Limited inclusivity of audio feedback modes due to language barriers	Introducing local language integration for feedback modes enhances the device's accessibility and user engagement. Providing instructions and feedback cues in the user's native language ensures clearer communication, fostering a more inclusive and effective user experience.	Involves software adjustments to incorporate multilingual support, potentially requiring collaboration with language experts for accurate translations.

Conclusion

Our objective in this project is to provide tactile feedback for gait training in low resource settings. Our work directly impacts the Poovanthi Institute of Rehabilitation in Southern India, where a high patient-to-therapist ratio necessitates a device that offers multimodal, semi-real-time feedback for gait training of post-stroke and spinal injury patients. The device should be price effective within price constraints, capable of detecting gait deviation parameters, and ensure safe and effective operation.

The project involves various stakeholders, including primary ones like Dr. Shibu, therapists, and patients. The user requirements and engineering specifications were determined through in depth literature review, client interviews and existing system benchmarking. The user requirements involved various factors: contextual aspects such as the location climate, technological aspects such as voltage and plug types, and socio-cultural factors such as language and clothing. The specifications were designed to be quantifiable and categorized by priority and confidence level for successful implementation.

Some high-priority requirements include the need to detect relevant gait parameters, provide user feedback, maintain cost-efficiency, ensure safety, ensure hygiene, and be compatible with local conditions. Medium-priority requirements emphasize ease of setup, durability, usability during the 6-minute walk test, comprehensible user interactions, and easy maintenance. Low-priority requirements include functioning during power outages, user comfort, and sustainability.

Over the span of the course, the project's more attainable objective is to create a functional prototype rather than full-scale implementation in India. Over the semester, we analyzed the design problem, generated concepts for gait detection and feedback subsystems, consulted with experts like Dr. Ojeda and Safa on motion tracking systems, created functional sensory and feedback systems, and carried out engineering testing. Major accomplished milestones include verifying the accuracy of sensing subsystems, proving real time data acquisition and processing is possible, and sending haptic signals via Raspberry Pi.

Although our team has recently struggled with software issues enabling PC to Raspberry Pi bluetooth connection that would allow for a fully integrated system, our team has provided proof of concept for key subsystems within our design, providing every indication of a successful and quality solution for the user.

Acknowledgments
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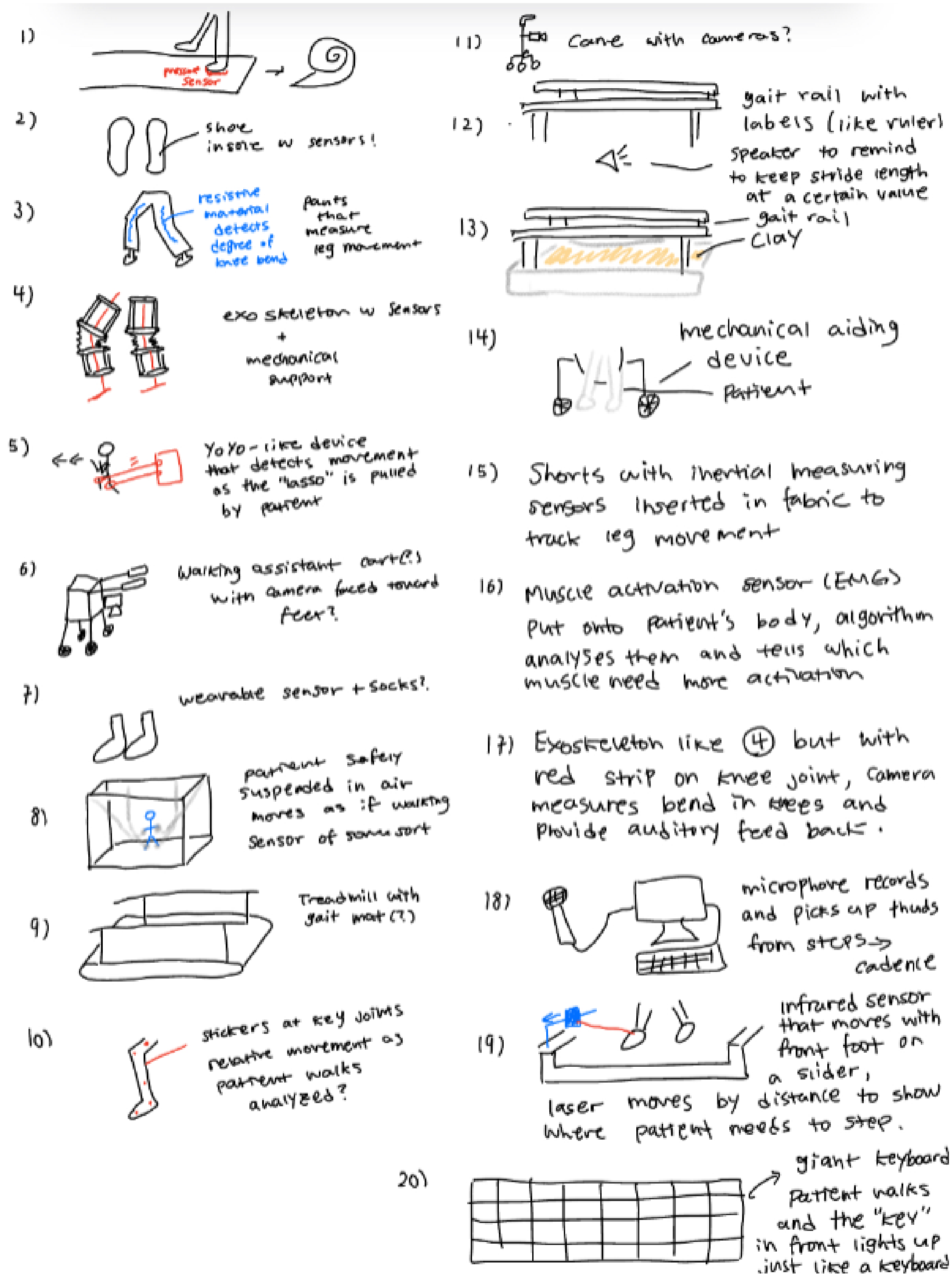
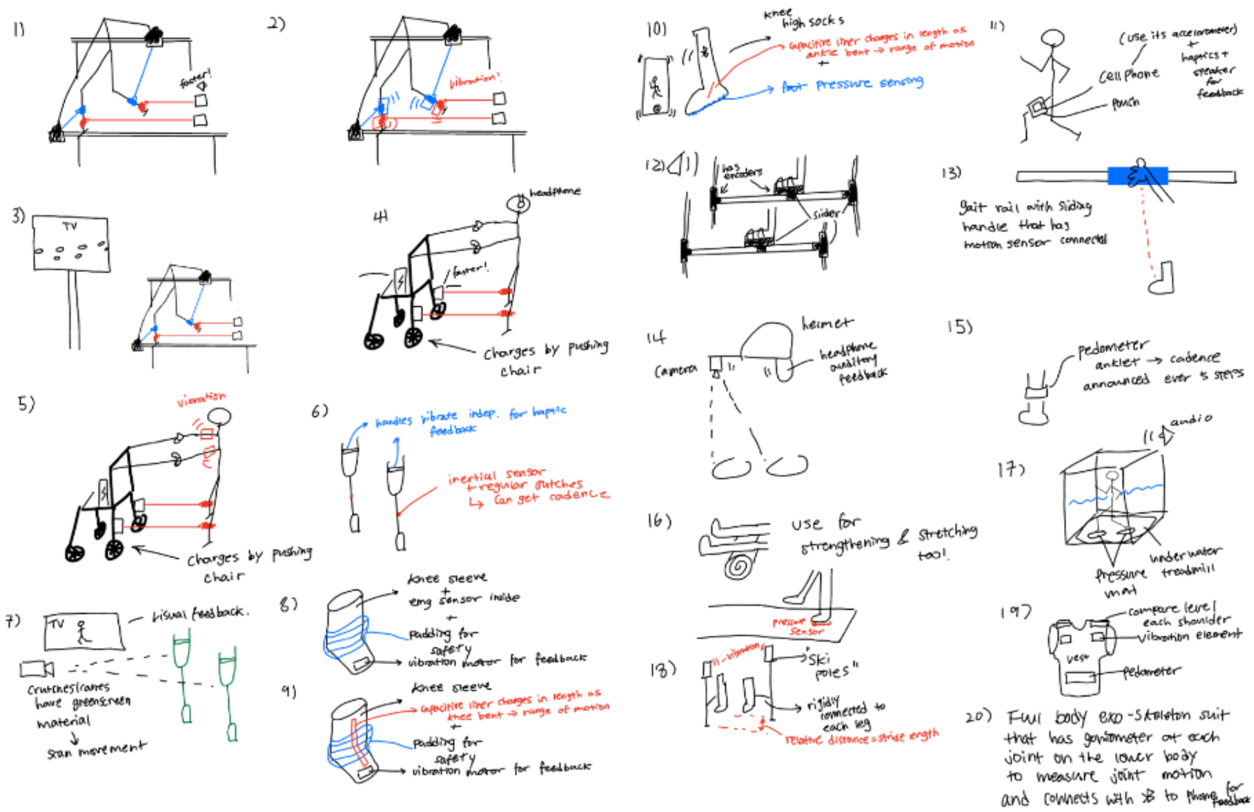
Appendix A: Generated Concepts

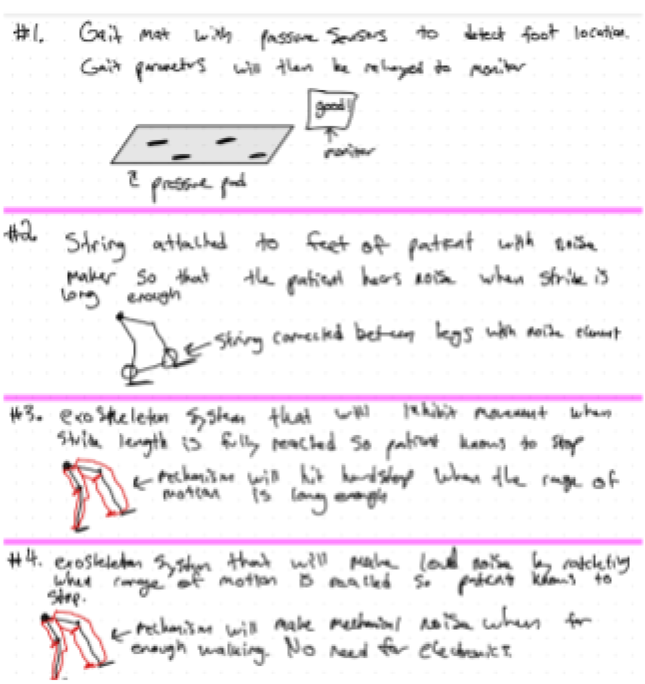
Concepts are listed by team members who generated them. These are original brainstorming notes for ideas. For each team member, concepts 0-20 are original generations, and concepts 21-40 are iterations on previous concepts.

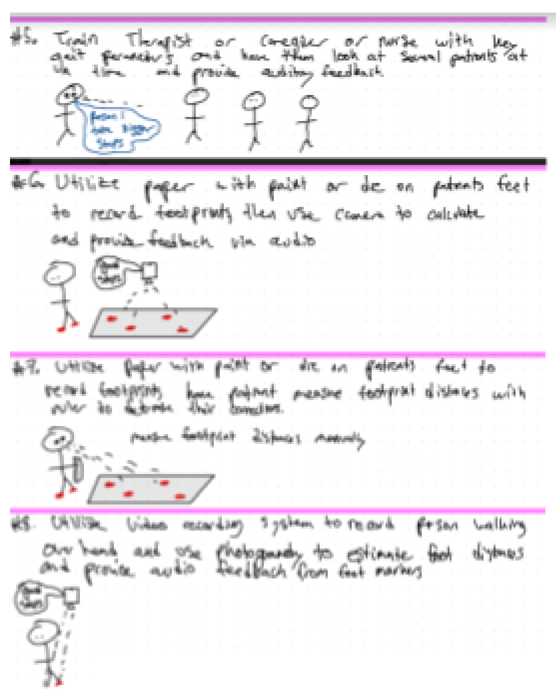
<u>Jerry's Generated Concepts</u>

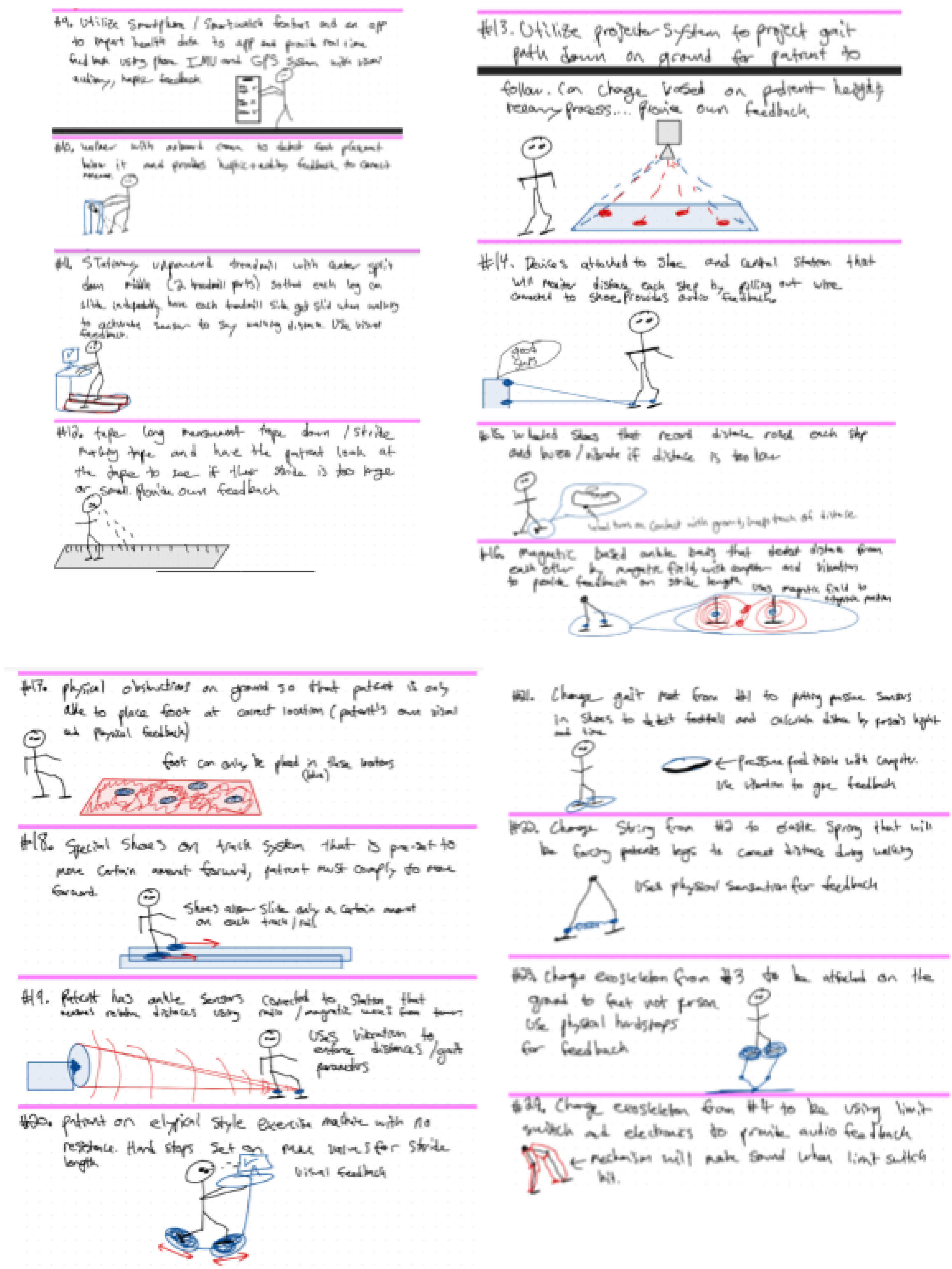




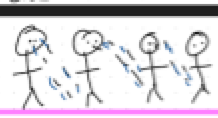
Markus's Generated Concepts





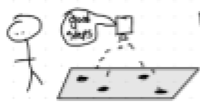

#13. Utilize projector system to project gait path down on ground for patient to follow. Can change based on patient height recovery process... Provide own feedback.
#14. Devices attached to shoe and central station that will monitor distance each step by pulling out wire connected to shoe. Provides audio feedback.
good
#15. Wheeled shoes that record distance rolled each step and buzz / vibrate if distance is too low
#16. Magnetic based ankle bands that detect distance from each other by magnetic field with computer and vibration to provide feedback on stride length.
#12. tape long measurement tape down / stride marking tape and have the patient look at the tape to see if their stride is too large or small. Provide own feedback
#17. physical obstructions on ground so that patient is only able to place foot at correct location (patient's own visual and physical feedback)
foot can only be placed in these locations (blue)
#18. Special shoes on track system that is pre-set to move certain amount forward, patient must comply to move forward.
Shoes allow slide only a certain amount on each track / rail
#19. Patient has ankle sensors connected to station that
Uses vibration to enforce distances / gait parameters
#20. patient on eliptical style exercise machine with no resistance. Hard stops set on max values for stride length.
visual feedback
#21. Change gait mat from #1 to putting pressure sensors in shoes to detect footfall and calculate distance by person's height and time
← Pressure pad insole with computer. Use vibration to give feedback
#22. Change string from #2 to elastic spring that will be forcing patient's legs to correct distance during walking
Uses physical sensation for feedback
#23. Change exoskeleton from #3 to be attached on the ground to feet not person. Use physical hardstops for feedback
#24. Change exoskeleton from #4 to be using limit switch and electronics to provide audio feedback
← mechanism will make sound when limit switch hit.

#25. Change therapist or care giver to patients examining gait for #5. Have patients walk in line and comment on patient in front of them.



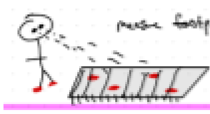
Patient behind will provide audio feedback to patient in front

#26. Change paint and die from #6 to graphite paper to record footprints to eliminate mess.



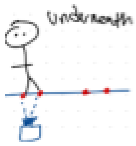
Use camera to measure and provide feedback

#27. Change mat from #7 to include distance markers so a ruler is not needed to actually measure.



measure footprint distances manually

#28. Utilize camera video recording from #8 but from underneath a glass plate. Use audio feedback

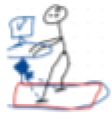


#29. Utilize smartphone app from #9 but use mount to strap to shoe or ankle to get better readings from IMU.

phone/watch attachment on ankle

#30. Use camera system from #10 but replace walker unit with treadmill system (not split treadmill)

Use visual feedback

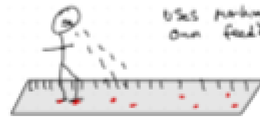


#31. Use treadmill from #11 but use distance string sensors from #17 to determine distances of strides

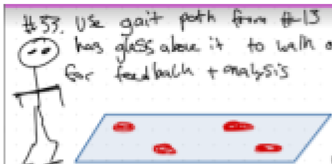
wires are retractable and measure distance of each stride

#32. Use measuring tape from #12 but include marker on shoes to see step distances.

uses markings and distance to provide own feedback

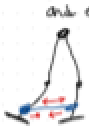


#33. Use gait path from #13 but use a screen that has glass above it to walk on + pressure sensors for feedback + analysis



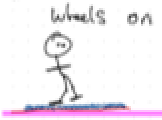
Screen can be walked on and responds to walking on

#34. Use devices from #14 but change to make devices attached between ankles so they retract and expand between ankles



no external control system like #14

#35. Same wheeled system like #15 but use wheels on the floor instead of the shoe



Use many wheels that sense when rolled

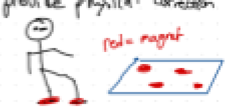
#36. Use magnets like #16 but have magnet on shoe and magnetically coupled to potentiometer hidden in track in floor.

magnet

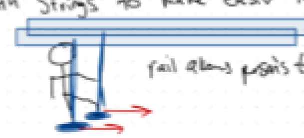
floor

Smooth floor with potentiometer + magnet on rail underneath

#37 Use same location idea as before #19 but use magnets under floor and on shoe to provide physical correction and confirmation of step distance



#38. Use same track system as #18 but mount overhead with strings to make easier to walk freely



rail allows person's foot to move a certain amount

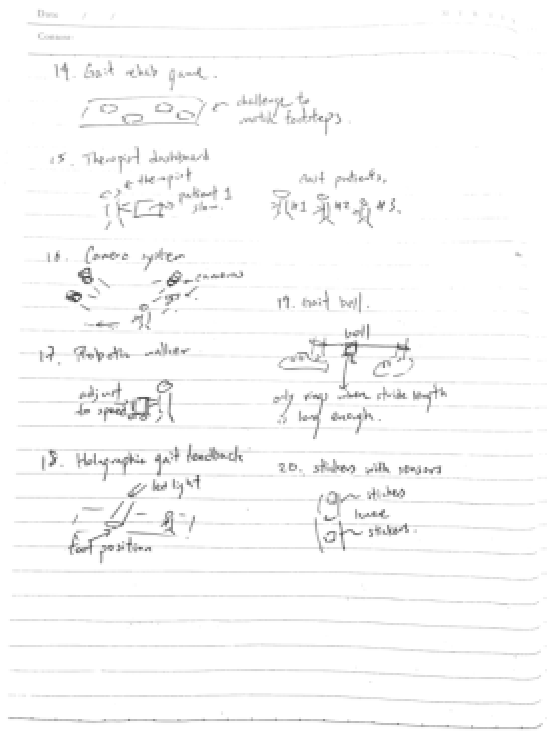
#39. Use same magnetic or radio wave sensing as #19 but put center unit on each ankle and have communication between ankles

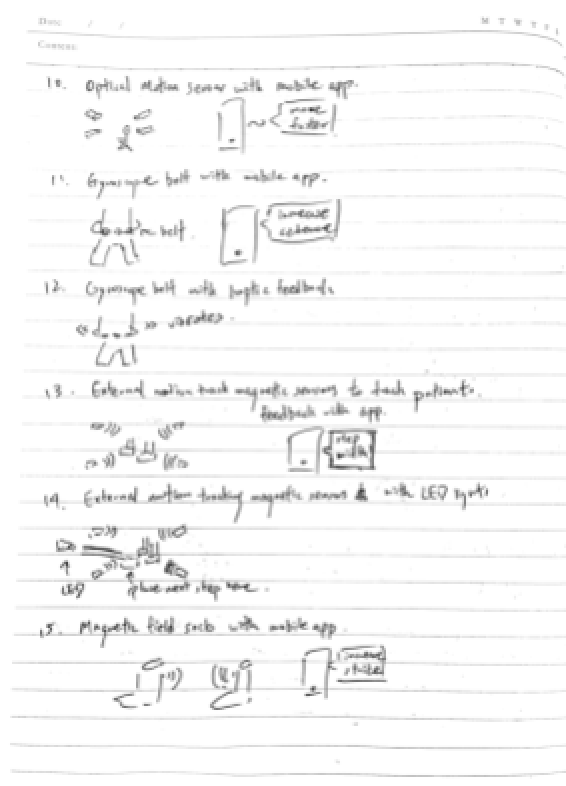
radio waves or magnetic field measures ankle distance

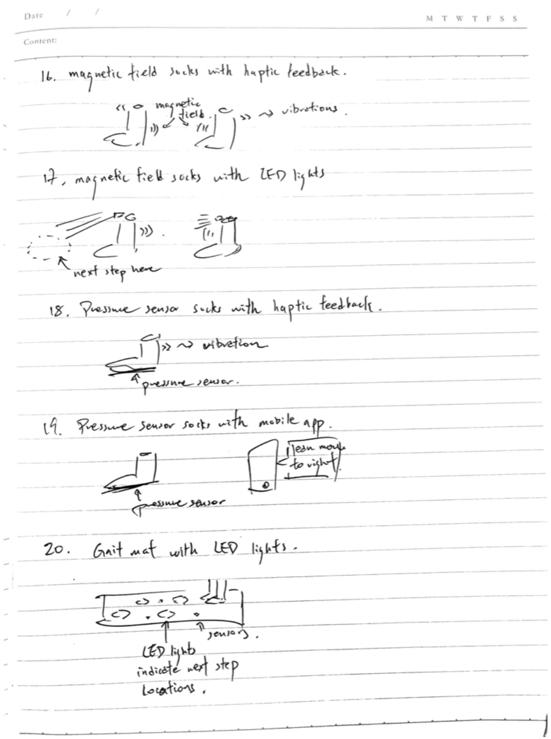
#40. Use elyptical style exercise machine like #20 but have it ceiling mounted instead of floor mounted

Can be folded up to ceiling when not in use

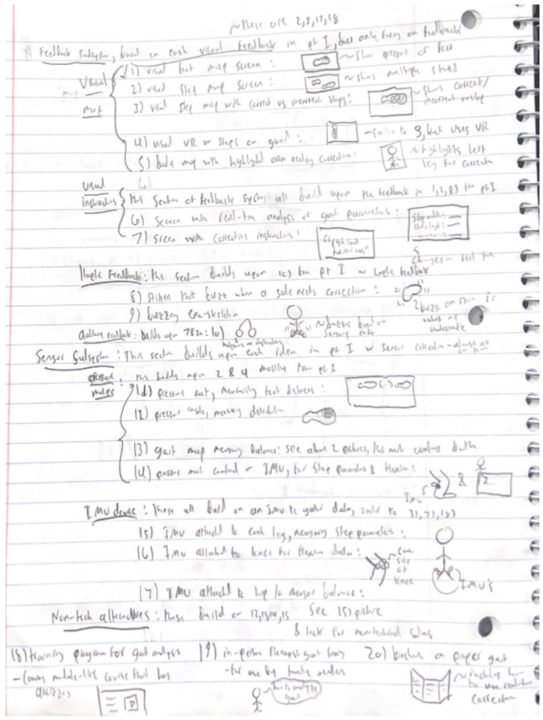
Albert's Generated Concepts







<u>Brendan's Generated Concepts</u>



Appendix B: Filtered Concepts

Robust concepts with high feasibility, cost, and quality score sums were highlighted in green.

IMU based:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
Smartphone app (M9, B19, 20, J11, A4, A10)	4.50	4.00	2.00	• Concerns with real-time aspect • Concerns with Indoor use • Concerns with sensor accuracy
IMU attached on leg (B3, B7, B10, J15, A1)	4.25	3.75	3.50	• Concerns with calibration • Concerns with cost

Camera based:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
Stationary camera (M6, M8, B11, J10, A16)	3.75	3.25	4.25	• Would address all gait parameters • Equipment and space needed • Calibration needed
Walker with Camera (M10, J6, J14, A2)	1.50	3.00	4.00	• Allows user to walk around without getting out of sight from camera • Would need to derive user movement from subtracting walker movement
Treadmill with Camera (M10,	3.00	2.75	2.75	• Less space needed, but more complex equipment

A16)				• Would have to account user's ability to walk on treadmill
VR based (B17)	2.75	3.00	3.75	• Safety concerns in surroundings • Easy feedback integration • Good gait parameter tracking • Engaging

Pressure sensor based:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
Gait mat (M1, B1, J1, A8)	3.75	3.25	4.00	• Technology already exists for most part • Interface with api • Resolution concerns
Shoe Inserts (M21, B2,8, J2, A3, A9, A12)	2.50	4.00	2.25	• Only able to give cadence • Foot pressure not really needed • Shoes are not really worn in this setting
Gait mat with LEDs (A40)	3.50	3.00	4.00	• Technology already exists for most part • Interface with api • Resolution concerns • Higher price concerns • Helpful for training

Exoskeleton based:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
2 DoF exoskeleton, no actuator (M3, M4, A11)	4.50	3.25	1.75	• Only gets range of motion • Safety concerns • Adjustability concerns
Digital exoskeleton, no actuator (M24, B6, J4)	3.00	2.75	4.00	• Range of motion • Effective feedback • Maybe able to calculate gait parameters

String extension/encoder based:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
String between legs (M2)	5.00	4.00	1.00	• String attached between legs only (analog) • Simple • Not safe (trip hazard) • Not lots of useful info
Spring between legs with no digital sensing element (M22)	5.00	4.00	1.00	• Spring attached between legs only (analog) • Simple, no digital sensors nor feedback medium needed • Not safe (trip hazard) • Only provides step width information

				• Spring tension alters end user gait pattern
String extension device with treadmill (M31)	4.00	3.75	2.00	• Safety concerns • Amplified safety concerns with treadmill • Lots of gait parameters, and more accurately than without treadmill • Complicated to provide feedback in real-time manner as information is sensed from various sensors.
Dual string extension encoder (M14, M34, J5)	4.00	3.50	2.00	• Safety concerns • No relation between feet
Wheeled encoder walker	3.00	3.75	2.25	• Use spurts of distance to estimate stride length • Only get single parameter

Analog / no sensor:

Concept	**Feasibility (1-5)**	**Cost (1-5)**	**Quality (1-5)**	**Comments**
Train Caregiver/ other patients (M5, B12, B13, B14)	4.00	2.75	3.00	• Person cannot practice completely by themselves
Paper and Die / Marker (M7)	4.50	4.75	1.00	• Feedback is not real-time, patient must do it themselves • Not good if patient is not mobile
Footpath Projector (M13, B4)	5.00	3.00	1.50	• Not able to provide feedback (patient does it themselves) • Adjustable • Cost effective • Novel
Paper board / twister	5.00	3.00	1.50	• Not able to provide feedback (patient does it themselves) • Not adjustable • Very cost effective • Novel
Footpath projector on shoe	2.00	4.25	2.00	• Not able to provide feedback (patient does it themselves) • Adjustable • Cost effective • Novel
LEDs on Floor or mat	5.00	4.50	1.25	• Not able to provide feedback (patient does it themselves) • Adjustable • Cost effective • Novel
Stopwatch with app	5.00	4.50	1.00	• No real-time feedback • No step distance • Only cadence

Other:

Concept	Feasibility (1-5)	Cost (1-5)	Quality (1-5)	Comments
Time of Flight sensor (M16, 19, 39, A21)	4.00	3.50	4.00	● Gives lots of needed gait parameters ● Safe ● Real-time
Wearable strain gauge knee sleeve (J3, J28, J29)	5.00	4.00	1.25	● Gives only one gait parameter (ROM) ● Requires fitting ● Hard to correlate resistivity values to range of motion, which is even harder to correlate to distances ● Uses relatively cheap, straight forward strain gauge sensor (team members have experience using)
EMG sensor	3.00	2.25	1.75	● Not possible to correlate muscle activation to gait parameters

Appendix C: IMU Connection Bluetooth Scanner Code

Our team developed the following code in Python to scan nearby bluetooth adaptors for IMUs.

```python
import asyncio
from bleak import BleakScanner

async def main():
    devices = await BleakScanner.discover()
    for device in devices:
        print(device)

asyncio.run(main())

```

Appendix D: Real-time Data Processing Algorithm

Our team developed the following code in Python to stream both left and right foot sensor information in real-time to the terminal. Further processing is also handled by this algorithm to determine stride length and cadence.

```
import numpy as np
import asyncio
import time
import matplotlib.pyplot as plt
from bleak import BleakClient
from scipy.signal import savgol_filter, argrelextrema

measurement_char_uuid = "15172001-4947-11e9-8646-d663bd873d93"
short_payload_char_uuid = "15172004-4947-11e9-8646-d663bd873d93"

addresses = [
    {"address": "263965BA-9B84-6E93-3899-A5D3A2486EED", "label": "left"},
    #{"address": "DF4FC9C6-B3BB-8797-D92E-82C71ECA6291", "label": "right"}
]

class CalibrationHandler:
    def __init__(self, device_info, start_time):
        self.device_label = device_info["label"]
        self.timestamps = []
        self.accelerations = {'x': [], 'y': [], 'z': []}
        self.velocities = {'x': [], 'y': [], 'z': []}
        self.velocities_magnitude = []
        self.start_time = start_time

    def callback(self, sender, data):
        formatted_data = encode_free_acceleration(data)[0]
        timestamp = time.time() - self.start_time
        x, y, z = formatted_data['x'], formatted_data['y'], formatted_data['z']
        adjusted_timestamp = timestamp
        self.timestamps.append(adjusted_timestamp)
        self.accelerations['x'].append(x)
        self.accelerations['y'].append(y)
        self.accelerations['z'].append(z)
        if len(self.timestamps) > 1:
            dt = self.timestamps[-1] - self.timestamps[-2]
            vx = self.velocities['x'][-1] + x * dt
            vy = self.velocities['y'][-1] + y * dt
            vz = self.velocities['z'][-1] + z * dt
```

```
        else:
            vx, vy, vz = 0, 0, 0
        self.velocities['x'].append(vx)
        self.velocities['y'].append(vy)
        self.velocities['z'].append(vz)
        vel_mag = np.sqrt(vx**2 + vy**2)
        self.velocities_magnitude.append(vel_mag)
        print(f"{self.device_label} -- X: {x}, Y: {y}, Z: {z} -- Velocity Magnitude: {vel_mag} \
            -- Timestamp: {adjusted_timestamp}")

class NotificationHandler:
    def __init__(self, device_info, start_time, cali_gradient):
        self.device_label = device_info["label"]
        self.timestamps = []
        self.accelerations = {'x': [], 'y': [], 'z': []}
        self.velocities = {'x': [], 'y': [], 'z': []}
        self.velocities_magnitude = []
        self.displacements = []
        self.start_time = start_time
        self.current_critical_points = [[], [], []]
        if self.device_label == "left":
            self.gradient = cali_gradient[0]
        elif self.device_label == "right":
            self.gradient = cali_gradient[1]
        self.accumulated_velocity = 0
        self.buffer = 0
        self.counter = 0
        self.left_step_timestamps = []
        self.right_step_timestamps = []

    def callback(self, sender, data):
        formatted_data = encode_free_acceleration(data)[0]
        timestamp = time.time() - self.start_time  # Use real-time timestamp
        x, y, z = formatted_data['x'], formatted_data['y'], formatted_data['z']
        adjusted_timestamp = timestamp
        self.timestamps.append(adjusted_timestamp)
        self.accelerations['x'].append(x)
```

```
        self.accelerations['y'].append(y)
        self.accelerations['z'].append(z)
        if len(self.timestamps) > 1:
            dt = self.timestamps[-1] - self.timestamps[-2]
            vx = self.velocities['x'][-1] + x * dt
            vy = self.velocities['y'][-1] + y * dt
            vz = self.velocities['z'][-1] + z * dt
        else:
            vx, vy, vz = 0, 0, 0
        self.velocities['x'].append(vx)
        self.velocities['y'].append(vy)
        self.velocities['z'].append(vz)
        if self.buffer == 0:
            critical_points, critical_timestamps, critical_velocities = \
                find_critical_points(self.timestamps, self.velocities_magnitude)
            if len(critical_velocities) > self.counter:
                self.accumulated_velocity += critical_velocities[-1]
                self.counter += 1
                self.buffer += 1
        elif self.buffer < 20:
            self.buffer += 1
        else:
            self.buffer = 0
        vel_mag = np.sqrt(vx**2 + vy**2) - (self.gradient * (adjusted_timestamp - self.timestamps[0]))\
            - self.accumulated_velocity
        if vel_mag < 0.05:
            vel_mag = 0
        self.velocities_magnitude.append(vel_mag)
        if len(self.timestamps) > 1:
            displacement = self.displacements[-1] + vel_mag * dt
        else:
            displacement = 0
        self.displacements.append(displacement)
        print(f"{self.device_label} -- X: {x}, Y: {y}, Z: {z} -- Velocity Magnitude: {vel_mag} -- \
            Displacement: {displacement} -- Timestamp: {adjusted_timestamp}")
```

```python
def encode_free_acceleration(bytes_):
    data_segments = np.dtype([
        ('timestamp', np.uint32),
        ('x', np.float32),
        ('y', np.float32),
        ('z', np.float32),
        ('zero_padding', np.uint32)
    ])
    formatted_data = np.frombuffer(bytes_, dtype=data_segments)
    return formatted_data

async def connect(device_info, handler, start_time, cali_flag):
    address = device_info["address"]
    async with BleakClient(address) as client:
        print(f"Client connection to `{client.address}: {client.is_connected}")
        await client.start_notify(short_payload_char_uuid, handler.callback)
        binary_message = b"\x01\x01\x06"
        await client.write_gatt_char(measurement_char_uuid, binary_message, response=True)
        if cali_flag:
            await asyncio.sleep(10)
            return calculate_calibration_gradient(handler)
        else:
            await asyncio.sleep(360)
        return None

def calculate_calibration_gradient(handler):
    timestamps = np.array(handler.timestamps)
    velocities_magnitude = np.array(handler.velocities_magnitude)
    slope, intercept = np.polyfit(timestamps, velocities_magnitude, 1)
    return slope

def find_critical_points(timestamps, velocities_magnitude, window_size=30, polyorder=2,
    peak_threshold=0.15):
    if len(velocities_magnitude) > window_size:
        smoothed_velocities = savgol_filter(velocities_magnitude, window_size, polyorder)
        peaks = argrelextrema(smoothed_velocities, np.greater, order=12)[0]
        significant_peaks = [peak for peak in peaks if smoothed_velocities[peak] > peak_threshold]
        valley_indices = argrelextrema(smoothed_velocities, np.less, order=18)[0]
        valleys_after_significant_peaks = [valley_index for valley_index in valley_indices\
            if any(valley_index > peak_index for peak_index in significant_peaks)]
```

```
        if len(valleys_after_significant_peaks) > 0:
            critical_timestamps = np.array(timestamps)[valleys_after_significant_peaks]
            critical_velocities = np.array(velocities_magnitude)[valleys_after_significant_peaks]
            return valleys_after_significant_peaks, critical_timestamps, critical_velocities
    return [], [], []

def identify_step_heights(timestamps, displacements, velocities_magnitude, threshold=0.1):
    step_indices = []
    step_heights = []
    for i in range(1, len(velocities_magnitude) - 1):
        if velocities_magnitude[i] > velocities_magnitude[i - 1] and velocities_magnitude[i] > \
            velocities_magnitude[i + 1] and velocities_magnitude[i] > threshold:
            step_indices.append(i)
    for i in range(1, len(step_indices)):
        step_height = displacements[step_indices[i]] - displacements[step_indices[i - 1]]
        step_heights.append(step_height)
    return step_indices, step_heights

async def main():
    current_time = time.time()
    sleep_duration = 1 - (current_time % 1)
    await asyncio.sleep(sleep_duration)
    calibration_start_time = time.time()
    print("Calibrating, Do Not Move")
    calibration_gradients = []
    calibration_handlers = [CalibrationHandler(device_info, calibration_start_time) for device_info in
        addresses]
    for device_info, handler in zip(addresses, calibration_handlers):
        calibration_gradient = await connect(device_info, handler, calibration_start_time, True)
        if calibration_gradient is not None:
            calibration_gradients.append(calibration_gradient)
    print("Calibration Done, Begin Walking")
    streaming_start_time = time.time()
    handlers = [NotificationHandler(device_info, streaming_start_time, calibration_gradients) for
        device_info in addresses]
    tasks = [connect(device_info, handler, streaming_start_time, False) for device_info, handler in
        zip(addresses, handlers)]
    connect_tasks = asyncio.gather(*tasks)
    await asyncio.gather(connect_tasks)
```

```python
    left_step_indices_all = []
    left_step_heights_all = []
    right_step_indices_all = []
    right_step_heights_all = []
    for handler in handlers:
        min_len = min(len(handler.timestamps), len(handler.displacements))
        smoothed_velocities = savgol_filter(handler.velocities_magnitude[:min_len], 30, 2)
        step_indices, step_heights = identify_step_heights(handler.timestamps[:min_len], \
            handler.displacements[:min_len], smoothed_velocities)
        if handler.device_label == "left":
            left_step_indices_all.extend(step_indices)
            left_step_heights_all.extend(step_heights)
        elif handler.device_label == "right":
            right_step_indices_all.extend(step_indices)
            right_step_heights_all.extend(step_heights)
        plt.plot(handler.timestamps[:min_len], smoothed_velocities, label=f"{handler.device_label} - Velocity", linewidth=2)
        plt.plot(handler.timestamps[:min_len], handler.displacements[:min_len],
            label=f"{handler.device_label} - Displacement")
    if left_step_heights_all:
        average_left_step_height = np.mean(left_step_heights_all)
        print(f"Average Step Length (Left): {average_left_step_height} meters")
    if right_step_heights_all:
        average_right_step_height = np.mean(right_step_heights_all)
        print(f"Average Step Length (Right): {average_right_step_height} meters")
    plt.xlabel('Time (s)')
    plt.ylabel('Velocity Magnitude (m/s)')
    plt.legend()
    plt.show()

if __name__ == "__main__":
    asyncio.run(main())
```

Appendix E: End of Semester Project Plan

Project Plan

The objective of the project is to design a device that provides multimodal, semi-real-time feedback for gait deviation patients in low resource settings. However, rather than implementing the device into commercial or non commercial use in India, a more reasonable scope for this semester would be to demonstrate proof of concept instead. The aim is to create a functional prototype and to document the process, and the plan is to use sensor technologies and simple motion tracking systems sourced through local American suppliers or Michigan Engineering lab facilities to demonstrate the core functionality of the design. Design domain and deliverables are clearly defined in the "Updated Domain Analysis and Reflection" section. In the time frame given, there will not be actual testing on the clinical efficacy of the device with proxy or actual patients and therapists, nor will there be an actual implementation in India. Note that the final prototype created in this project and the ultimate implementation in India will most likely differ in the technologies that are applied, given that our project will be using cheaper alternatives for each sensing and feedback elements due to budget constraints.

Prior to this design review, the team has outlined the problem statement, benchmarking, stakeholder analysis, and preliminary requirements and specifications. The team has also gone through concept generation, selection, engineering analysis, and planned verification and validation steps. Developing concepts of the gait detecting subsystem and feedback subsystem was also a critical task that had a huge influence over the project outcome. With major constraints such as cost, personnel, knowledge, and time in place, it was a challenge to create a design that excels in every single aspect of the requirements and specifications; therefore, the process of concept development was crucial. Each design had its limitations, and it is necessary that we not only chose the design concept with the least amount of limitations but also further developed the design concept to enhance its ability to fulfill our design requirements. Last but not least, after these initial tasks, we sorted, filtered and eventually decided on a single concept.

Some other critical tasks that have been accomplished so far include meeting with Dr. Ojeda to discuss motion tracking systems and developing concepts of the gait detecting subsystem and the feedback subsystem. Dr. Ojeda is an expert in motion capturing systems, and he was able to give us an overview on the current motion tracking technologies, the pros and cons of implementing them, and recommendations on a system that we can realistically implement throughout the course of this semester with our knowledge and experience. Additionally, Safa, a PhD student researching gait analysis was helpful to talk to in order to experiment with the IMU devices. The processing of the IMU data from testing has been a huge milestone for the team to demonstrate the feasibility of IMUs for use in obtaining gait parameters. As mentioned in the Problem Domain Analysis and Reflection section, a main challenge the team has is tackling the knowledge gap of sensor technologies. Each of us have few experiences working with sensors or motion capture systems; therefore, it was highly important that we reduced this information and knowledge gap by doing research and consulting with experts.

Some more recent critical tasks that the team has accomplished include engineering analysis for gait measurement range & accuracy, real-time data streaming, vibrotactile actuator operation, and FMEA. Furthermore, the team has outlined important verification and validation plans. A realistic schedule for completion of the project has been set up. The next steps of the project, prior to the final design report, and the person assigned to complete each tasks are labeled in **Figure 38** below:

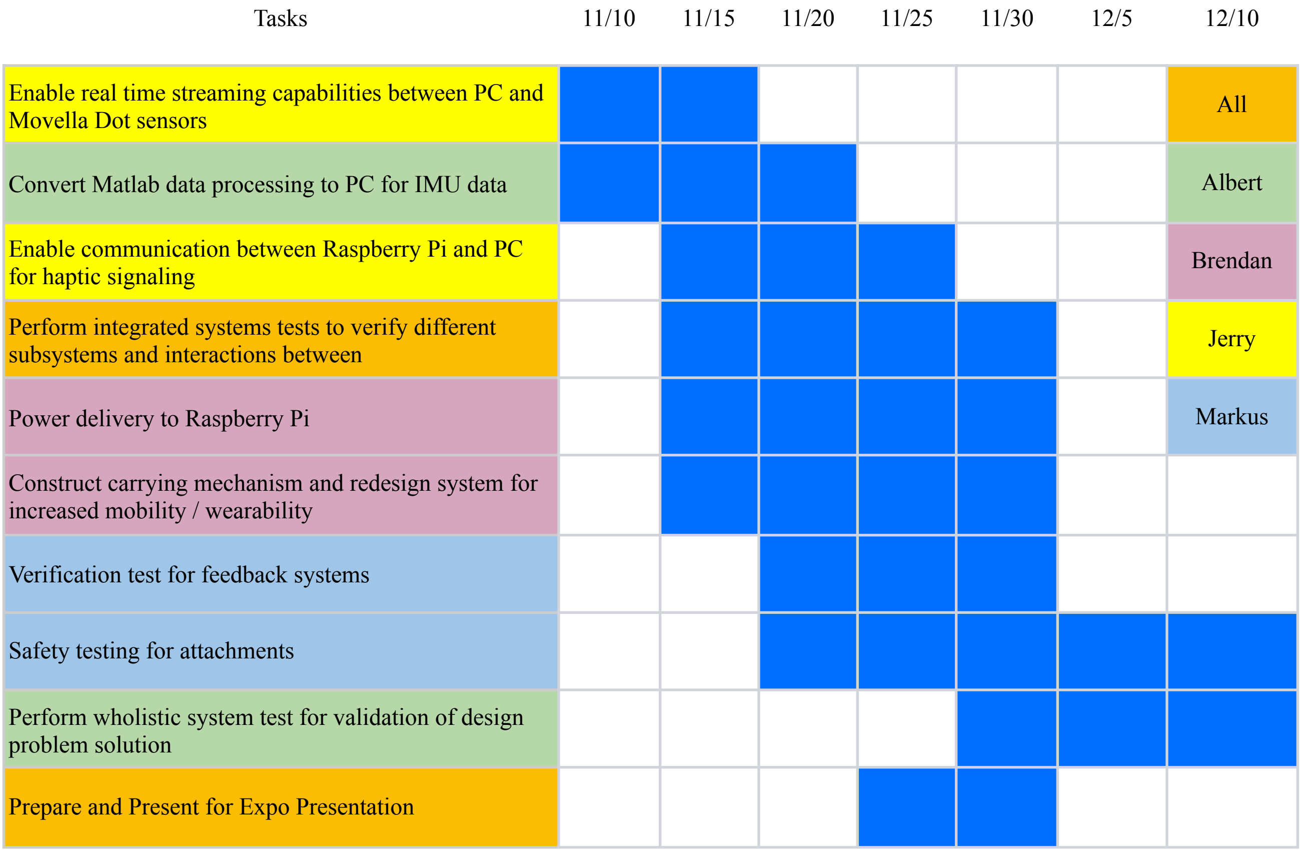


Figure 38. Gantt Chart illustrating project tasks to be completed before Final Report, the deadlines assigned to each task, and the person/people assigned to complete each task.

At the present moment, we are working on fully enabling real time streaming capabilities between the IMUs and the PC system. Once this is complete, we will ensure that the data processing algorithm is complete and functioning correctly after its conversion from Matlab to Python. After this, our team will work on power delivery, wearability / mobility, verification testing, and safety testing until our team is comfortable with the result. All of this will be working towards performing holistic system tests for validation of our design problem's solution and preparing and presenting our work.

Appendix F: Team Bios

Jerry (Jin Mo) Ku

I am a senior Mechanical Engineering student from South Korea. I came to the US in 2019 for college but took a one-year break during the COVID-19 pandemic, and therefore graduating at the end of this semester. I found my interest in Mechanical Engineering as I grew up in a family of engineers. I fell in love with Mechanical Engineering because of how broad the discipline is.

Within Mechanical Engineering, my interests lie in the automotive industry. I have previously worked at a carbon capture truck startup and Hyundai's automotive parts manufacturer, both in Michigan. After graduation, however, I have to fulfill my military duty back home. I have applied for alternative service, which allows me to work in the defense sector, specifically in the aerospace industry. I plan to use this time to further my career as a Mechanical Engineer. After completing my two-year duty, I intend to return to the United States as a Master's student.

Outside of academics and career, I am an avid gym-goer. I plan to compete in a competition before I return to Korea. As a result of this hobby, I have gained a deep understanding of human anatomy and kinesiology. I also suffered a lateral meniscus tear in my left knee and had to go through surgery and rehabilitation. The injury has left many imbalances in my body, and I spend many hours every week researching biomechanics to prevent any future injuries and improve my knee's condition. Although I am not an expert in biomechanics by any means, I believe I can utilize these experiences to make a valuable contribution to solving the design problem at hand.

Markus Isaacson

I am a senior Mechanical Engineering student, born in Houston, Texas. My family works in the energy industry and this has led me to grow up in different places like Anchorage Alaska, Doha Qatar, and Jakarta Indonesia. I have always been interested in engineering, especially the hands-on aspects. In the winter of 2022, I spent time researching as a student in the Smart Materials and Structures Lab at the University of Michigan doing work on tiled inflatable systems as ME390 credit. I have also been active in the Tau Beta Pi engineering honor society.

I will be graduating in the winter of 2024. After graduation, I will be working in Houston, Texas for bp as a drilling engineer for their deepwater subsea fields. I had two internships in the past with bp, one in the summer of 2022 at the Chicago Whiting refinery as a unit maintenance engineer, and one in the summer of 2023 in Houston as a wells engineer. I also spent the summer of 2021 as a maintenance service worker for SLB / Schlumberger in Prudhoe Bay Alaska.

Outside of school I spend a lot of time outdoors, with my family currently living in Alaska it is very easy to get somewhere beautiful outside. I do a lot of hiking, skiing, backpacking, climbing, and biking with my family. During the school year, I spend a lot of time going to the gym with friends.

Albert Wang

I am a senior Mechanical Engineering student with a minor in Computer Science from Taipei, Taiwan. I came to the US in 2020 to study at the University of Michigan and plan to pursue graduate studies in 2024 through the Sequential Undergraduate/Graduate Studies program. My interest in mechanical engineering stems from my interest in the physical world- physics, my strongest subject, combined with my interest in problem solving, made a degree in mechanical engineering a natural choice to me.

I am interested in automation and designing products that positively affect the people, communities, and environment around me. I have previously worked at the Dasgupta Research Lab at the University of Michigan, where I worked to create a robotic arm that is used to transfer solar panel cells down an assembly line, removing the need for manual operators to transfer parts over a 4-hour span per manufacturing session. I am also currently a project lead at BLUELab Sa'Nima', where my team designs and manufactures washing machines for local communities in Guatemala. Seeing my work positively impact the lives of the people is one of my main motivations at work, and my goal as an engineer is to create engineering solutions that have high societal impact.

Outside of academics, I enjoy staying active outdoors and cooking. I played various sports growing up, including baseball, swimming, basketball, cycling and hiking. In junior year of high school, I accomplished a 12-day, 700-mile cycling trip around the coasts of Taiwan. Currently, I play in a flag football league every weekend. One of my aspirations in life is to travel the world on my feet. I am hoping to explore all the national parks in the United States one day and visit as many natural wonders in the world as I can.

Brendan Rindfusz
I am a senior studying mechanical engineering engineering with a minor in math, from Arlington, VA. I'll be graduating this semester and plan on starting grad school in mechanical engineering right after through the SUGS mechanical engineering program. Math had always been my favorite subject in school prior to starting college, and after taking physics in high school I chose to explore engineering my freshman year after being fascinated by the hands-on problem-solving approaches. I chose to study mechanical engineering after my freshman year and have had a great time learning about the way things work.

Within mechanical engineering, I have developed a strong interest in dynamic modeling and controls. I worked in the Pentagon this past summer doing building automation system controls, however I plan to pursue more autonomous physical systems in the future. Outside of the classroom, I have enjoyed working on systems like these through the Medlaunch project team and the CORE Lab Research Group. I plan to focus on controls in grad school and hope that I can develop more skills that are applicable to any autonomous system - be it in the automotive, aerospace, robotic, or another applicable sector.

Outside of the classroom, I enjoy doing anything I can to stay active. Currently, some of these interests include playing in a pickup basketball league at my fraternity house, IM soccer, and going to the gym as frequently as possible.

Appendix G: Build Design Bill of Materials
In this section, two Bill of Materials (BOMs) are presented: one listing the components used in the ME450 design and the other listing the components required for the construction of the stakeholder design. The ME450 design BOM includes items such as Movella DOT sensors, a Raspberry Pi and a personal computer, specifying quantities, costs, and suppliers that are local to Michigan. On the other hand, the stakeholder design BOM encompasses additional components like waistpack, ankle band and battery, and it lists suppliers local in India. In the ME450 design, a personal computer was used in parallel with Raspberry Pi to run the real-time gait sensing program for convenience, but in the stakeholder design, as Raspberry Pi supports Python programming itself, the real-time gait sensing algorithm will be integrated into and ran by Raspberry Pi, which eliminates not only the need for a personal computer but also the concern of bluetooth connection going out of range, which is approximately 25 meters. However, a portable Raspberry Pi introduces the need for a portable power source and carrier on the user. Thus, a battery will replace power cables from the ME450 design, and a waist pack will be used. Moreover, since suppliers that are local to India are listed, the costs are listed in both Indian Rupees and US Dollars, and the conversion rate of December 9th, 2023 that is 0.012:1 is used. **Table 23** lists the BOM for ME450 design, and **Table 24** lists the BOM for the actual stakeholder design.

Table 23. Bill of materials per one build for ME450 design

#	Item Name	Description	Quantity	Cost/ Item	Supplier
1	Movella DOT Set	● Movella DOT sensor ● Charger and micro-USB cable ● Software Development Kit	2	USD$132.00	Movella [52]
2	Raspberry Pi	● Raspberry Pi 4 Model B ● Quad core 64 bit, 2 GB RAM ● Wifi and Bluetooth	1	USD$130.00	Amazon US [53]
3	MicroSD card	● 32 GB ● Primary storage medium for Raspberry Pi operating system and user data	1	USD$14.00	Walmart
4	Monitor	● Display device for the user interface of operating system on Raspberry Pi	1	USD$70.00	Best Buy [54]
5	Micro HDMI to HDMI Adapter	● Connects Micro HDMI devices (Raspberry Pi) to an HDMI-enabled monitor	1	USD$12.88	Walmart
6	Keyboard	● Used with a Raspberry Pi to provide a means of input for interacting with the device	1	USD$35.00	Best Buy [55]
7	Personal Computer	● MacBook Pro	1	USD$1,600.00	Apple [56]
8	Speaker	● 3.3V compatible speaker with 8 Ohm resistance	2	USD$11.00	Amazon US [57]
9	Haptic Actuator	● Solarbotics VPM 2 Coin Motors	4	USD$4.00	Solarbotics [58]
10	Plastic Bottle Caps	● From used plastic bottles	4	—	—
11	Power Adapter	● Provides constant 5V voltage to power Raspberry Pi	1	USD$21.88	Walmart

Table 24. Bill of materials per one build for actual stakeholder design

#	Item Name	Description	Quantity	Cost/ Item	Supplier
1	Movella DOT Set	● 5 Movella DOT sensors ● Charger and micro-USB cable ● Software Development Kit	1	USD$750.00	Movella* [52]
2	Raspberry Pi	● Raspberry Pi 4 Model B ● Quad core 64 bit, 2 GB RAM ● Wifi and Bluetooth	1	INR₹25,000 (USD$300.00)	Amazon India [59]
3	MicroSD card	● 32 GB	1	INR₹700	SanDisk [60]

		• Primary storage medium for Raspberry Pi operating system and user data		(USD$8.40)	
4	Monitor	• Display device for the user interface of operating system on Raspberry Pi	1	INR₹6,200 (USD$74.40)	Amazon India [61]
5	Micro HDMI to HDMI Adapter	• Connects Micro HDMI devices (Raspberry Pi) to an HDMI-enabled monitor	1	INR₹400 (USD$4.80)	Amazon India [62]
6	Keyboard	• Used with a Raspberry Pi to provide a means of input for interacting with the device	1	INR₹650 (USD$7.80)	Amazon India [63]
7	Waistpack	• Used for Raspberry Pi housing and • Comfortable and easy-to-adjust strap • 41cm L X 10cm W X 15cm H	1	INR₹1,400 (USD$16.80)	Nike India [64]
8	Speaker	• 3.3V compatible speaker with 8 Ohm resistance	2	INR₹3,300 (USD$39.60)	Amazon India [65]
9	Haptic Actuator	• Solarbotics VPM 2 Coin Motors	4	INR₹90 (USD$1.08)	MathaElectronics [66]
10	Plastic Bottle Caps	• From used plastic bottles	4	—	—
11	Medical Leukotape	• Used for attaching haptic actuator onto user's thighs	1	INR₹250 (USD$3.00)	Amazon India [67]
12	Ankle brace band	• Adjustable fit, breathable elastic material	1	INR₹300 (USD$3.60)	Boldfit on Amazon India [68]
13	Clothing fabric	• Used to make housing pockets for Movella DOT sensors on foot arch bands • 9 cm L x 4 cm W	1	INR₹20 (USD$0.24)	Local fabric supplier [69]
14	Velcro	• 5m Hook + 5m Loop (Width-25mm) Tape Roll Strips	1	INR₹400 (USD$4.80)	Amazon India [70]
15	Battery	• Uninterruptible power supply • Uses two 18650 batteries	1	INR₹5,130 (USD$61.56)	Amazon India [71]

If there is an asterisk (*) behind a supplier, it indicates that the supplier is a non local one and that either the product will likely need to be shipped from US to India or be replaced with an alternative component that can not only be sourced locally but also achieve the same or better effect.

Appendix H: Manufacturing Plan

1. Ankle Attachment:
    - Materials: ankle brace band, velcro, clothing fabric
    - Manufacturing Steps:
        1. Sew velcro along a 10 cm stretch at the end of the ankle brace band situated nearer to the toes.
        2. Fold the 9 cm L x 4 cm W clothing fabric in half lengthwise, sew two open ends together to form a pocket, then sew velcro onto one outer surface.
        3. Ensure proper placement and secure attachment of IMUs inside the mesh pocket.
        4. Test the ankle attachment for safety, comfort, and compatibility.
2. Waist Pack:
    - Materials: Waist pack, Raspberry Pi, Speaker, Haptic Actuators
    - Manufacturing Steps:
        1. Rigorously attach battery, speaker and haptic actuators onto Raspberry Pi.
        2. Place the Raspberry Pi, battery, and speakers into the waist pack.
        3. Ensure that haptic actuators can be securely extended from the housing pocket to the user's thighs.
        4. Test the belt for proper functionality, fitting, and durability.
3. Raspberry Pi Setup:
    - Materials: Raspberry Pi, MicroSD card, Monitor, Micro HDMI to HDMI Adapter, Keyboard, Battery or Power Adapter
    - Manufacturing Steps:
        1. Follow the instructions per the official Raspberry Pi setup guide [72] to set up Raspberry Pi.
        2. Once setup is complete, download the Movella DOT PC SDK [73], available for Linux, onto the Raspberry Pi OS from the Movella software and documentation page.
        3. Install Bleak and NumPy Python libraries to run Bluetooth connection
        4. Download the IMU Connection Bluetooth Scanner Code in Appendix C and the Real-time Data Processing Algorithm in Appendix D
        5. Write additional code that takes the following input: user gender, height, age, and the output of Real-time Data Processing Algorithm on stride lengths, and outputs feedback to the user through haptic feedback actuators and speaker control.
4. Haptic Feedback (Solarbotics VPM 2 Coin Motors):
    - Materials: Haptic Actuators, plastic bottle caps, medical Leukotape
    - Manufacturing Steps:
        1. Tape the plastic bottle caps onto the haptic actuators.
        2. Connect haptic actuators to the Raspberry Pi for feedback control.
        3. Secure haptic actuators around user’s thighs, one in front and one behind for both legs using medical Leukotape
        4. Test for functionality and evaluate user experience.
5. Auditory Feedback (Speaker):
    - Materials: 3.3V compatible speaker with 8 Ohm resistance, and 500-20k kHz frequency response
    - Manufacturing Steps:
        1. Connect the speaker to the Raspberry Pi for auditory feedback.
        2. Test the auditory feedback system for clarity and compatibility.

Appendix I: User Instructions

1. Fasten the ankle attachment by wrapping it securely around the user's ankle, ensuring the velcro is snug but not too tight.
2. Position the IMUs comfortably inside the fabric pocket, making sure they are securely placed.
3. Wear the waist pack around the user 's waist, adjusting the belt for a comfortable and secure fit.
4. Ensure the Raspberry Pi, battery, and speakers are correctly placed in the waist pack.
5. Turn on the wearable device by connecting the power source to the Raspberry Pi.
6. Connect Raspberry Pi to Monitor and keyboard and wait for the system to boot up and establish a connection with the IMUs.
7. Once the system is booted up, input user gender, height, and age into the system for personalized feedback.
8. Unplug monitor from Raspberry Pi, place Raspberry Pi attached to battery, speakers, and haptic actuators into waistpack.
9. Confirm that the haptic actuators are securely attached to the user's thighs using the provided medical Leukotape.
10. Run the gait feedback program and begin walking after calibration.