Objective Gait Analysis System for Low-Resource Settings: Magnetogait

MECHENG 450, Fall 2024

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Sponsors: Global Health Design Initiative at the University of Michigan and Poovanthi Institute of Rehabilitation and Elder Care

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EXECUTIVE SUMMARY

We have been tasked with developing an instrumental gait analysis system for the Poovanthi Institute of Rehabilitation and Elder Care. This device will provide data-driven insights through key gait parameters such as stride length, step width, cadence, time, and distance to help monitor patients with gait deficiencies.

Quantitative gait analysis involves measuring spatiotemporal gait parameters with various technologies to provide a data-driven assessment of gait. Current systems being used in the clinical setting typically fall into three categories: floor sensors, Inertial Measurement Units (IMUs), and motion capture systems. Benchmarking analysis reveals that the biggest gaps in the market are getting accurate spatiotemporal measurements at a relatively low price.

Our design process includes thorough stakeholder analysis, sociocultural considerations, sustainability, and ethics. Our primary stakeholders are the project sponsors Dr. Shibu and Mrs. Punita, Poovanthi's Chief Medical Officer and Clinical Manager, and Lucy Spicher, the project mentor and a design ethnographer of this design context. Culturally, we are considering resources available in Madurai, India as well as the environment. Ethically, we are considering medical device regulations from the government of India as well as ensuring an inclusive and user-centered design.

Through thorough analysis, we developed a list of unique requirements and specifications for our project. Our high-priority general device requirements include it being low-price, accurately able to measure stride length, width, step cadence, distance, and time, and having data interpretation capabilities. Our high-priority operator-specific requirements include being durable, sanitary, and having adequate UX. On the patient side, our high-priority requirements include the system being adjustable to a large range of the Indian population, and being safe to use.

Initially, the Alpha design concept of a pressure mat and IMU system was too expensive. Therefore, after Beta concept generation, selection, and further engineering analysis, we pivoted to a magnetic mat that a patient will walk on with magnets on their soles. IMUs will be used to collect temporal parameters, and a camera will be used to collect spatial parameters. Post-processing will display gait parameters for the end user. This solution has been analyzed and verification tests are both in progress and planned for the future to meet our specifications.

As the semester comes to a close, we have a few recommendations. On a systems level, IMUs can be set aside as a second source of analysis. The gait reset mechanism should also be electromagnetically automated as to further improve efficacy. On a detail level, viscous liquid within the mat must be optimized along with the magnets that will attract the iron filings. Multiple cameras should also be used to capture the mat after trials. These are the top recommendations needed towards a complete solution worthy of the Poovanthi Institute.

ABSTRACT

We are developing an instrumental gait analysis system for the Poovanthi Institute of Rehabilitation and Elder Care. Existing solutions are either expensive or lack accuracy. Our device needs to measure stride length, step width, step cadence, distance, and time accurately. It should also be durable and have data interpretation capabilities. Our final design consists of a magnetophoretic mat paired with IMUs to capture key gait parameters. Patients will walk on the mat to produce an image of their gait which will be captured and processed on a computer that runs Python to determine spatial gait parameters and IMUs will be used to determine temporal parameters. An operator will interface with the computer to capture the image and produce results that will be stored on the cloud. A build design has been created to aid in the verification of the mat. Currently, our design meets the majority of our specifications. On top of continuing the verification and validation process, our recommendations for future work on this design is to create a full system that encompasses the mat and IMUs separately, finish testing for detailed components of the mat, and finalize the camera system used for image capture.

INTRODUCTION

This design report will define and communicate the design problem of this project. The report will contain comprehensive information regarding project background, design process and design context. It will then define user requirements and engineering specifications based on the background and contextual information presented. There will be a problem analysis discussed, and finally, a project plan presented for project-specific tasks moving forward.

Project Context

Mobility is the foundation for living a healthy and independent life (*Mobility*, n.d.). Gait, a person's manner or pattern of walking, is a fundamental aspect of gauging mobility. Gait can be impacted by neurologic, metabolic, and psychiatric problems. 65% of people above the age of 80 have a gait disorder (Tasseel-Ponche et al., 2022). 60% of patients admitted to a neurological hospital have gait disorders, and 70% of patients experience a gait disorder-related fall within one year post-stroke (Stolze et al., 2005). These numbers show the high prevalence of gait disorders, and the goal of this project is to not only address a way to quantify these gait disorders but to also provide a solution that can lead to patients improving their gait in shorter periods of time in order to minimize further health issues and maximize quality of life. Quantifying gait is essential for expediting progress in gait improvement, as it will enable early and accurate diagnoses which allow identification and application of the most effective treatments for long-term benefits.

The prevalence of gait disorders is even more heightened in low and middle income countries, where there is minimal access to low-price solutions to quantify gait disorders, therefore restricting the ability to diagnose and treat disorders accurately. According to Ladha**,** “while validated commercial wearable gait systems exist, they remain expensive” (Ladha et al., 2016)**.**

Unfortunately, while current solutions based in first-world countries utilize high-tech approaches with low-price technology, this research and the various design solutions do not translate across borders (Godfrey et al., 2020). Therefore, there is a critical need for a gait-quantifying system to be implemented at low-price, specifically with low and low-middle income countries in mind.

This project is being done in conjunction with the University of Michigan Global Health Design Initiative for the Poovanthi Institute of Rehabilitation and Elder Care, located in Madurai, Tamil Nadu, India. The Poovanthi Institute of Rehabilitation and Elder Care lacks equipment that gives physical therapists the ability to measure and record key gait parameters such as stride length, step width, cadence, time and distance. Having this system would allow them to provide data-driven assessments and improve the management of gait disorders. We have been tasked with developing an instrumental gait analysis system that can provide data-driven assessments and management of patients with gait deficiencies. This device will provide patients and therapists with data-driven results to better identify progress in the recovery process. The project mentors are Lucy Spicher, a graduate student at the University of Michigan, Dr. Shibu, Poovanthi's Chief Medical officer, and Mrs. Punita, Poovanthi's Clinical Manager.

Technical Background

Gait may seem like a simple part of our everyday life, but it is actually a complex function of our lower limbs which utilizes the neuromuscular system to turn internal and external inputs into coordinated movements (Mirelman et al., 2018). In the Poovanthi Center, most patients with gait abnormalities have suffered from stroke or spinal cord infarction (Lucy Spicher, Meeting, September 12, 2023). Stroke is a disease which causes damage in the brain therefore impacting many daily activities and brain function. For more than 80% of stroke survivors, walking dysfunction is a direct impact of their stroke (Sheng Li, 2018). Spinal cord infarction is a stroke specifically within the spinal cord (*Spinal Cord Infarction*, n.d.). Since basic gait functions heavily rely on the neural control systems in the brain, when a stroke does damage to these neural pathways within the brain and spinal cord it causes a decrease in motor control throughout the body. This typically leads towards stroke victims having abnormal stride throughout their gait cycle which can also lead towards muscle weakness further increasing a person's risk of falling and injuring themselves (Sheng Li, 2018).

Gait is characterized the moment you first begin to move out of a standing posture into a steady state walk, this is called gait initiation. Initiating gait is a complex system of muscle activity and balance and is crucial in stabilizing your body as you make that transition from being static into your full speed gait. On the opposite side of gait initiation you have gait termination which is the movement from steady state gait back into that static standing posture. This also requires highly complex motor functions but focuses more on maintaining that balance and stability as you return to standing still (D et al., 2013). However once you reach your steady state walking speed in between gait initiation and termination, gait is simplified into the gait cycle which starts when the heel of one foot strikes the ground and ends when the same foot heel strikes the ground

again. One whole gait cycle can then be broken down into two phases, the stance phase and the swing phase. The stance phase occurs when the foot is in contact with the ground, which represents 60% of the entire gait cycle. The swing phase, when the foot is in the air, accounts for 40% of the entire gait cycle (Silva & Stergiou, 2020). To allow for a more detailed diagnosis of gait disorders, the gait cycle is further broken down into subphases as shown in Figure 1 below.

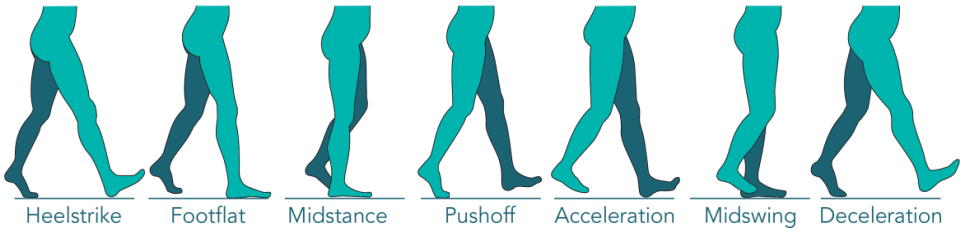


Figure 1: The phases of a normal gait cycle that are considered when quantifying and diagnosing abnormal gait (Speight et al., 2023a)

The ability to characterize gait is crucial in diagnosing gait disorders and can be done either qualitatively or quantitatively (Marín, Javier, 2020). Qualitative gait analysis is a simple and low-price solution that involves a physical therapist analyzing gait through visual observation. Quantitative gait analysis involves measuring spatiotemporal gait parameters with various technologies to provide a data-driven assessment of a gait disorder. Spatial parameters are used to characterize different distance measurements of the gait cycle including step length, step width, and stride length. Temporal parameters are used to deal with time-based measurements, the main ones including cadence, step time, stride time, stance duration, and swing duration. Figure 2 below shows a visualization of these gait parameters and how they are defined.

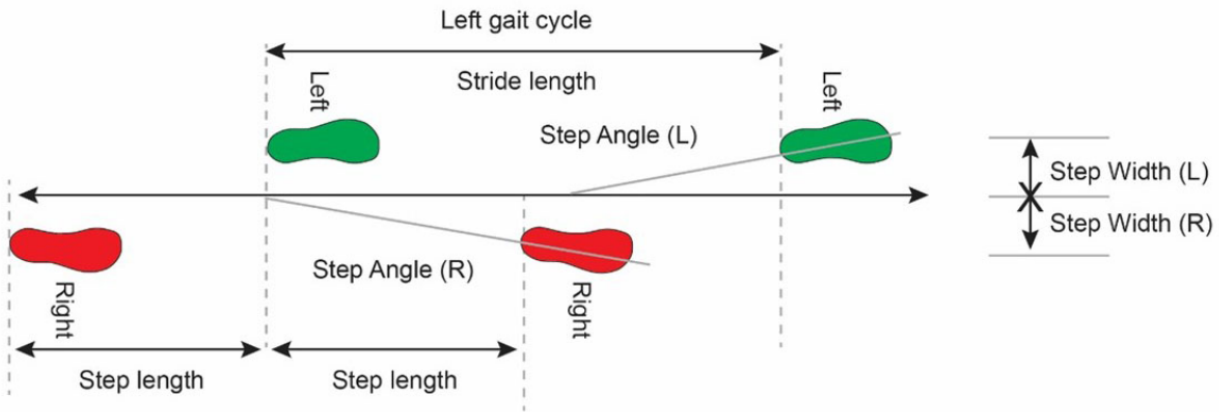


Figure 2: Visualization of gait parameters, most importantly including stride length, step width, and step length (*The Gait Cycle: Phases, Parameters to Evaluate & Technology*, 2023)

The parameters that are the most important to our primary stakeholders for our system are stride length, step width, and cadence (Dr. Shibu, Meeting, September 11, 2023). Stride length is the distance between the back of one foot in a full gait cycle, step length is the distance between two

feet in one step of the gait cycle, and step width is the distance between the midpoint and the middle of each foot. Step cadence is the amount of steps in a time period, typically given in steps per minute. All of these parameters are measured during the steady state gait phase when the patient is in between the gait initiation and termination phases.

Benchmarking Analysis

Quantitative gait analysis systems currently being used in the clinical setting to assess gait disorders typically fall into three categories: floor sensors, inertial measurement units (IMUs), and motion capture systems (Marín, Javier, 2020). The system we are designing for the Poovanthi Institute is constrained to be low-price, wearable, able to accurately measure the necessary spatiotemporal parameters, can interpret data, and works in a crowded setting. When starting our benchmarking, we considered each type of gait analysis technology to see how they meet the necessary constraints of our system. We recorded our observations in Table 1 to find the gaps in current solutions and to see how we can use this data to approach our concept generation.

Table 1. Summary of benchmarking analysis for various existing technologies

Technology		Floor sensors		IMUs		Motion capture	
	Visual observation	Pressure mat	Pressure insole	Full body IMUs	IMU insole	Infrared markers	Marker less
Low-price	✔	✖	✔	✖	✔	✖	✔
Wearable	✖	✖	✔	✔	✔	✖	✖
Accurate spatio-temporal measurements	✖	✔	✖	✔*	✔*	✔	✖
Data interpretation capabilities	✖	✔	✔	✔	✔	✔	✔
Useable in a crowded setting	✔	✖	✔	✔	✔	✖	✔

*lacks the ability to measure step width

Visual Observation

The current method being used in the facility is visual observation. As described by Dr. Shibu, this is typically conducted with a physical therapist following a patient around and taking notes of gait observations. Tests such as the 240 m six-minute walk test are conducted with a

stop-watch. Visual observation allows for real-time assessment, is low-price, and is very easy for physical therapists to perform, but lacks the ability to obtain quantitative data (Mobbs et al., 2022)**.**

Floor Sensors

Floor sensor systems include instrumented walkways and insoles lined with sensors that collect data by having patients walk on top of them. There are two types of floor sensors used in gait analysis: force sensors and pressure sensors (Mirelman et al., 2018). For our benchmarking purposes, we looked at pressure sensor products due to their ability to measure the spatiotemporal parameters necessary for our design. The most common pressure sensor device is a pressure mat. These are walkways instrumented with a high-pressure sensor resolution (1- 4 sensors/cm^2) which offers a detailed data analysis of various gait parameters (Klöpfer-Krämer et al., 2020). While some pressure sensor products have limited sensor areas, limiting the patient to only being able to take steps on certain areas of the mat, products like GAITRite shown in Figure 3 offer fully instrumented walkways that collect 100+ measurement parameters necessary for an accurate gait analysis (Speight et al., 2023a). Although these solutions produce very accurate data, their high sensor resolution causes them to be high-cost. Additionally, this is not a feasible solution as they take up space that is not available in the crowded center.

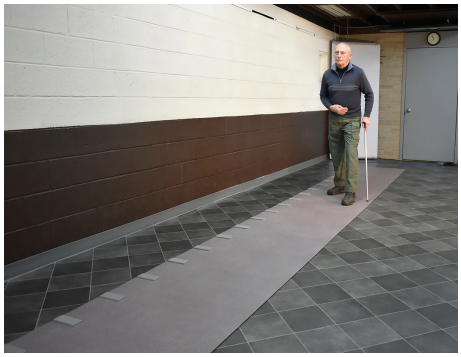


Figure 3: The GAITRite walkway systems are porTable pressure sensitive walkways used to measure spatiotemporal gait parameters to identify gait disorders (*GAITRite Gait Analysis | GAITRite Walkways*, n.d.).

Inertial Measurement Units (IMUs)

IMUs are electronic devices that utilize accelerometers, gyroscopes, and magnetometers to collect data related to velocity, acceleration, orientation, and gravitational forces (Muro-de-la-Herran et al., 2014)**.** As emerging wearable technologies for gait analysis continue to allow for low-price solutions, IMUs are the go-to device in the clinical setting. By taking the raw data collected by the basic sensors in the IMUs, algorithms can then be used to extrapolate gait parameters that are needed for analysis (Muro-de-la-Herran et al., 2014). Due to these complex algorithms, the data collected by IMUs are very accurate and can be used in very crowded environments. But, since there is no communication between the sensors, they are

unable to measure step width (Bäcklund et al., 2020). Current market solutions include Xsens MVN, as shown in Figure 4, which has put wireless IMUs into adjustable straps that can be placed on the body strategically to measure specific spatiotemporal parameters. With the measurements gained from the IMUs across the body, Xsens then uses a cloud-based motion capture system which allows for easy data analysis (Konrath et al., 2021).

Figure 4: The Xsens MVN is a wearable system containing 17 IMUs placed along the body to track six degrees of freedom ((Muro-de-la-Herran et al., 2014)).

Instrumented Insoles

Both pressure mats and IMUs have systems available on the market that are capable of collecting every parameter necessary for accurate gait analysis, but for someone looking to only measure a few parameters at a lower cost, a typical solution comes in the form of an instrumented insole. Instrumented insoles offer the portability and agility that the other technologies lack. However, due to the downsizing of the technology, the data accuracy also decreases (Klöpfer-Krämer et al., 2020). Two insoles on the marker that act as potential low-price solutions are the F-scan pressure insole and the PodoSmart insole, as shown in Figure 5. F-scan is an insole on the market that is fixed with pressure sensors. Even though it has similar sensors to the GaitRite mat, it is not capable of measuring spatiotemporal parameters, and only measures pressure parameters (Speight et al., 2023b). PodoSmart is an IMU-based insole that is capable of measuring spatiotemporal parameters with wireless sensors using Bluetooth to display data on a graphical screen (Ziagkas et al., 2021). Both of these products are able to do what the more expensive versions can do but with lower accuracy and at a lower cost.

Figure 5: F-scan pressure insoles on the left measure pressure and temporal parameters (*F-Scan GO System* n.d.). PODOSmart insoles on the right measure spatiotemporal and kinetic parameters (Ziagkas et al., 2021).

Motion Capture Systems

The final technology of our benchmarking analysis is video motion capture. Infrared marker-based motion capture systems are considered the "gold standard" of the industry due to their ability to quantitatively capture gait parameters with the highest accuracy on the market (Ziagkas et al., 2021). The most common system is the Vicon system as seen in Figure 6**.** These systems require markers to be placed on the body and multiple cameras placed around a room to record the markers' movement. They then use complex algorithms to translate data into usable gait data. These systems are very time-consuming to use and require trained staff to be able to analyze the post-test data that gets collected (Moro et al., 2022)**.** A cheaper alternative to this "gold standard" is markerless gait analysis based on RGB video acquisition. This method of video motion capture relies on deep-learning algorithms that require less expertise from operators, are easier to set up, and are easier to use in different environments. A problem that this system runs into is the need for a high-resolution camera to allow for accurate data collection – the data being collected with this method tends to be less accurate than the "gold standard" (Moro et al., 2022).

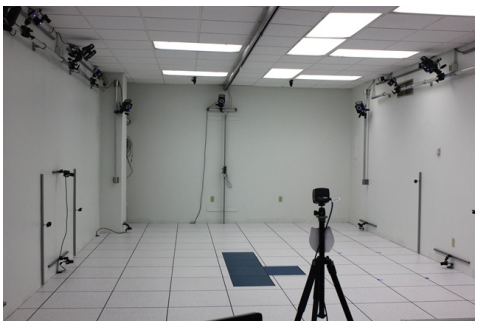


Figure 6: The Vicon infrared marker motion capture system is one of the most popular systems used in laboratory gait analysis (*Mizzou Vicon System*, n.d.).

DESIGN PROCESS

Following a design process is the best way to produce a high-quality design in the most efficient manner. However, there are numerous models which can be used. We considered stage-based versus activity-based models, as well as problem-oriented versus solution-oriented models. Specifically, the French model was impressive as a framework of reference. We also referenced the ME Capstone Design Process, and are leveraging aspects of each model for the greater goal of the project.

We first considered the French Model, a slightly more detailed stage-based model than others shown in Figure 7 below (Wynn, 2005). The process begins with the establishment of a need. Through problem analysis, this need then becomes a problem statement. This should include

defining the specifications and requirements through stakeholder interviews, benchmarking solutions, and further research and systems thinking. During the conceptual design stage, designers will select schemes and move onto creating a more detailed assessment of the schemes. The triple arrows indicate the need to select and analyze multiple schemes in this process. Then, the chosen concept is detailed, which shows up in working and drawings. There is feedback throughout this process, indicating the need to iterate through solutions and ideas. Although more complex processes are available, given the scope of the project, the French Model provides sufficient detail for guidance and feasible methodologies to be applied as the project progresses. Currently, we are at the embodiment of schemes stage of the French Model. We are utilizing the feedback loop of this model to consider how we might need to conduct further analysis of the problem based on how our selected scheme fits our needs and requirements.

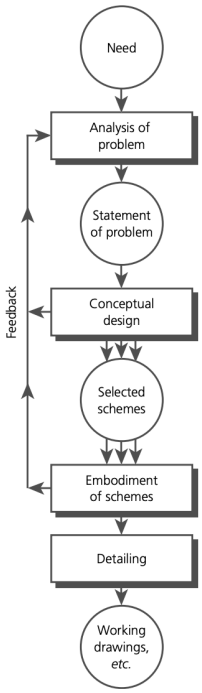


Figure 7: The French Model – a somewhat linear, slightly more detailed, stage-based model (Wynn, 2005).

Meanwhile, the more catered model is the design process model presented in ME450, shown in Figure 8 below (Skerlos, Steve, n.d.). This model, while containing stages like the previous stage-based models, also contains activity-based components. The stages of this model include need identification, problem definition, concept exploration, solution development & verification, and realization. Within these stages are backwards and forwards arrows, indicating that the process can move in either direction at each and every stage of the process, unlike the previous model. Additionally, the two feedback loops indicate multiple phases of iteration within the stages. The ribbons below the stages presented in this model include activities like literature review, design best practices, application of core engineering principles, context assessment, and decision-making. These activities are incredibly relevant to the tools we learn within the ME450 course, making it much more applicable to the work we are doing right now in developing our

selected concept. The stages and activities presented in this model include more detail than the French model, making it easier to use as a guide as we address our design problem.

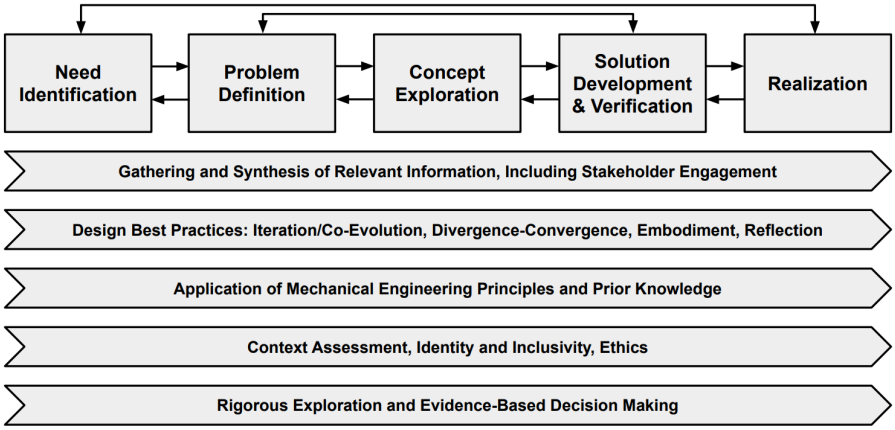


Figure 8: The ME450 Design Process Model – our chosen model which includes a stage-based and activity-based component (Skerlos, 2023).

Ultimately, our decision to first rely on the ME450 design process was due to its detail in the activity-based component which correlates to the structure of the project within the class, and its focus on detailed iteration between stages. Granted, the French Model does a good job by dividing the design process into more specific stages. However, the ME450 model offers much more guidance and structure than the French Model when it comes to activities, which is especially helpful in our first large, sponsored design project. Additionally, both models offer guidance in how to iterate on our selected solution. Now that we have completed engineering analysis and are moving forward into the verification process, we have realized that our design process requires multiple feedback loops. Our Alpha solution did not pass engineering analysis, but components of the solution were brought forward into the Beta design. This iteration also included stepping back into the concept generation phase. From our realizations during this project, we have realized the importance of iteration and the backwards arrows presented in the ME450 design process model, making it clear that this is the process we have been following throughout the project.

DESIGN CONTEXT

In this section, we will dive deeper into the design context of the presented design problem. Primarily, we will be discussing the stakeholders of this project, as well as social and cultural impacts, sustainability and ethics, and the involvement of intellectual property.

Stakeholder Analysis

We organized our stakeholder analysis into three main sections: primary, secondary, and tertiary. Our primary stakeholders are those whose lives and work are directly impacted by the problem and solution. Secondary stakeholders, while they might not experience the problem or be directly impacted by the establishment of a solution, are also part of the problem context. Tertiary

stakeholders are outside of the problem context, but could influence the success of a solution. For even more detailed categorization, we broke up our stakeholders into six categories: resource providers, supporters & beneficiaries of the status quo, complementary organizations and allies, beneficiaries and customers, opponents and problem makers, and affected or influential bystanders. These categories allow us to develop specific stakeholder engagement plans based on how they play a role in our project. Figure 9 below displays how we organized our stakeholders.

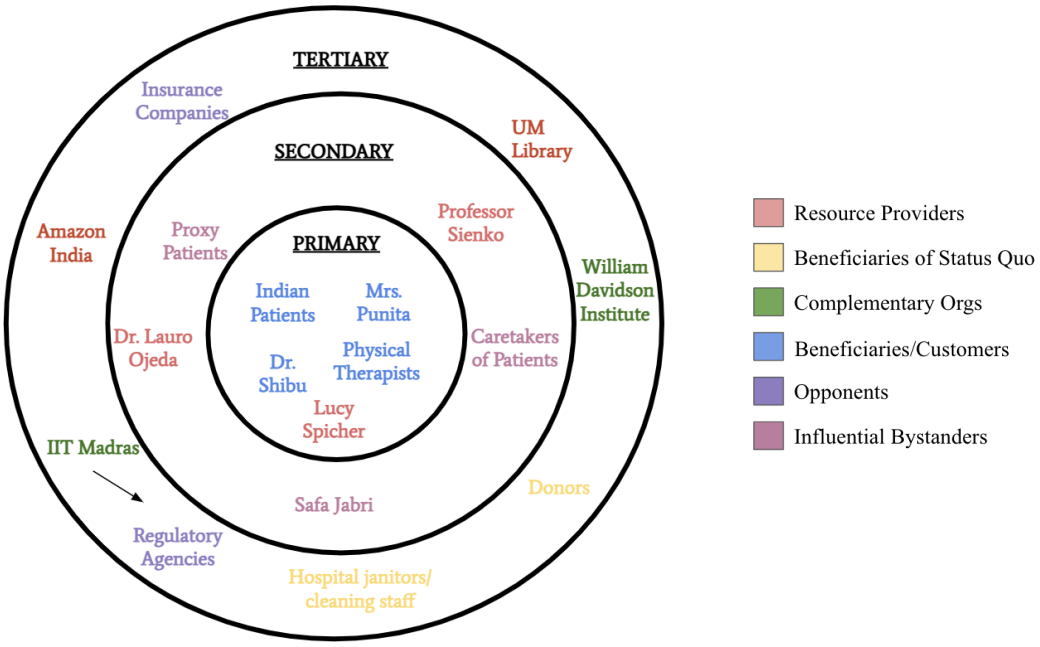


Figure 9: Stakeholder map for the Objective Gait Analysis System project, categorized by type and level of stakeholder.

Stakeholders such as Dr. Shibu, Mrs. Punita, and the physical therapists and Indian patients in the lab will be directly positively impacted by the implementation of this device. Lucy Spicher, our graduate student mentor, is a critical resource provider for us, as she has spent months in the Poovanthi Center as a design ethnographer. From Lucy, we are able to get observational information that we otherwise would not get from direct stakeholder interviews. On the secondary side, we will be utilizing proxy patients as not only testing subjects for our project this semester but as people with similar disorders who may also be able to weigh in on the impact of our solution. Caretakers of patients also may be positively impacted by the implementation of this device, since quantifying gait can help physical therapists correct disorders quicker, therefore allowing patients to improve at a faster rate. Another secondary stakeholder we wanted to take into account is Dr. Lauro Ojeda, a professor at the University of Michigan whose research revolves around gait analysis. He not only has resources to provide us, but also has years of expertise to share with us as we address our design problem. We may also be able to share

important findings with him that he may not have done extensive research on yet. Currently, we have had multiple meetings with him to discuss our work and gain insights from his experience. He has shown interest in our design solution and is helping us further develop it. We have also been in contact with Safa Jabri who is assisting in our preliminary engineering analysis. Safa Jabri has helped us learn how to utilize technology for our design solution. She has also provided assistance in our initial verification process. Our tertiary stakeholders include a range of various organizations, companies, and broad research options. IIT Madras, the university which also poses as the regulatory agency for this project, is outside of the direct problem context but plays a role in health regulation as a whole. Amazon India will be a major resource provider for our project, as it will be a basis for us to discover what materials are available for use in India, and what resources we might have to source elsewhere. We also included the William Davidson Institute, a complementary organization which does similar work to ours. Ultimately, we found it critical to address all types of stakeholders – from opponents to customers – to predict exactly how stakeholders will respond to our solution. Considering stakeholders more broadly that may be negatively impacted like regulatory agencies and insurance companies, as well as the cleaning staff in the center who may benefit more from the status quo, will allow us to figure out a way to create a solution that everyone will agree with.

Social and Cultural Impacts

In this project, social and cultural impacts are intertwined. Since our system is being implemented in Tamil Nadu, India, there are many cultural considerations to take into account. In order to be comprehensive in how we address the cultural context of our project, we considered Aranda-Jan's overview of contextual categories (Aranda-Jan et al., 2016). Currently, we believe we have addressed 8/8 of the contextual categories presented in this article. From a socio-cultural lens, we have considered local language and started developing ideas for how our UX design will incorporate either the Tamil language or globally understood symbols. In terms of infrastructure, we have considered power accessibility, and the physical infrastructure we are working under. Geographically, we have considered the high temperatures and humidity in India. We have also begun to question how we will ensure our device will be safe during monsoon season, since the center is not closed space. Institutionally, we have considered how easy our device will be to use for untrained staff and providers. We have also considered the maintenance and cleaning protocols that may or may not be followed in the center. Since this is a medical device, it is important to ensure sanitary standards will be followed. Under the technology category, we have started to consider the availability of batteries and electronics that may need to be replaced for the function of our system. From an industrial lens, we are considering how local manufacture will impact our design and how easy it will be to transport the device to this center. We have also considered public health, including regulatory guidelines and existing clinical treatments. Lastly, we have considered the economic capacity and poverty levels in this area, ensuring that we keep in mind how low-resource this area is and that we are being mindful of costs. While we have considered all of these cultural factors and more, like the clothing worn by

patients and the frequent power outages that occur in the center, there are still gaps to fill that we will address by more direct conversations with stakeholders based out of India, Lucy, and benchmarking.

On a broader note, the social aspect of the problem driving this work is the need for mobility within India. From conversations with Dr. Shibu, we recognize that the busy roads and challenging streets to navigate in villages in this area make gait disorders even more challenging to deal with independently (Dr. Shibu, Meeting, September 11, 2023)**.** While there is easy access to caretakers in the US and the EU, this is not the case within the context of Tamil Nadu, India. Therefore, it is important for patients to gain back their gait function before navigating daily life again. Dr. Shibu emphasized the importance of the six minute 240 meter walk test, a test to gauge patients' improvement which is meant to simulate the ability to cross busy roads in a timely manner when the patients leave and are on their own post-rehabilitation. From this, we can tell that social impact is incredibly important to the leaders in the center. Because of our sponsor's focus on social impact, we are aiming to design with positive social impact in mind, prioritizing impact to the patient and physical therapist experience over other priorities.

Furthermore, in terms of public health, safety, and welfare, in our design process it is critical to continuously consider how the product will impact the end user population and society as a whole. For example, considering how this product might be able to be implemented beyond the scope of the Poovanthi Center could allow us to show more commitment to the overall well-being and quality of life of communities everywhere who suffer from a lack of objective gait analysis. Ultimately, our goal is to provide a product that takes into consideration the prevention of risks for end users, the positive impact it can make on society as a whole, the ability for it to adhere to regulatory agencies, and the larger impact it may have.

Sustainability and Ethics

In terms of sustainability, our biggest concern is sourcing materials which will not only be low-price and durable, but also recyclable. According to the Air Quality Life Index, pollution is a large threat to the Indian population (*Country Spotlight: India*, n.d.)**.** In 2019, India launched a program aiming to reduce particulate pollution by 20-30% nationally relative to 2017 levels by 2024. Given the government's interest in minimizing pollution, we believe it is important to take into account sustainability, especially since our system will be produced in India. We are aiming to find a happy medium between a high-technology system at a low-price utilizing sustainable practices.

It is critical to ensure we are making ethical decisions since we are creating a medical device which people will be directly interfacing with in a low-resource setting. While it may be challenging to gain concept approval and ensure we are following all regulations thoroughly, we will have to invest our time in this in order to stay ethical in our design process. Additionally, we will have to keep inclusivity in mind in order to create a solution which includes all possible

users of the device. Firstly, we are ensuring we are complying with CDSCO regulations. CDSCO is the Central Drugs Standard Control Organization under the government of India, which oversees and implements regulatory control over drugs and medical devices in India. From an ethical standpoint, following these regulations for the implementation of our device in the Poovanthi Center is critical in ensuring safety of our patients and physical therapists. Secondly, we will be considering the ethics of how to properly store patients' objective gait data. Because this is a medical device that collects information about a patient's health, it is critical that we make ethical decisions in how we store patients' data, even if this makes our design and development process more challenging. Data privacy and security is critical not only in complying with laws and regulations, but also in ensuring patients are comforTable and feel protected when using the device. Another aspect in which ethics plays a role in design is in making user-centered decisions and ensuring inclusivity in design. When we make decisions on how we will approach any design problem we face, it is critical for us to see the issue from the perspective of the end-user to make the most ethical decision. Our ethics are meant to guide us in our design, and ensure a responsible and considerate outcome for all stakeholders. Considering perspectives beyond our own is critical in making sure we do not make decisions solely based on our research and backgrounds, but also the possible backgrounds and needs of end-users and more. Inclusivity is critical, especially in a medical design project, to ensure a diverse range of people will be able to benefit from the end product. It would be unethical to not consider this range of potential users and stakeholders simply for the ease of design – ethical design must consider everyone. Our social responsibility is to consider how this product will impact the Poovanthi Center and society as a whole, and focusing on this mindset as we move through the design process will ensure an ethical solution is created. Lastly, ethics in our own design decisions also include being honest to our analysis and testing, and sharing the truth rather than making up information to adhere to requirements or stakeholders' needs. It is critical to be honest to ensure we do not dive into a deep hole where we are conveying false information and results which are untrue. Especially in medical device design, this would be a very dangerous practice as it would cause the developed device to be inaccurate and potentially lead to harmful impacts for patients and end users involved.

Intellectual Property

Our team signed a nonexclusive license, with a right to sublicense, to the Regents of the University of Michigan. In doing so, we recognize that our work reflects the Global Health Initiative and furthers the Global Health Mission. While our work may be distributed and reproduced even once the scope of our project is over by Michigan, we also recognize our ownership rights to the Project Inventions in joint measure. Moving forward, we will be working with Dr. Kathleen Sienko to sign an invention disclosure, allowing her team to safely move forward with the design.

USER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

The user requirements and engineering specifications for this project were determined based on critical stakeholder interviews, an extensive literature review, and the benchmarking analysis presented on page 5**.** The user requirements are written in the language of the stakeholder and consider the needs and wants presented by the stakeholders. The engineering specifications, written in the language of the engineers, are based on user requirements, including target values and parameters for testing.

Although an entire list of requirements and specifications can be provided for reference, each one is pertinent to different stakeholders. Therefore, to better understand the requirements, they are categorized into three sections. Firstly, general device requirements pertain to what the gait device should do regardless of the user. This fundamentally addresses the problem statement that allows it to successfully function within its environment before users are considered. Secondly, operator-specific requirements cater towards the physical therapists who will be interacting and applying the device to patients, who are on the other end of the user experience. Thirdly, patient-specific requirements cater towards the conditions and considerations that allow for successful patient interactions with the gait device. In the following Tables, our benchmarks are numbered as sources which are numbered in our references section.

General Device Requirements

Fundamentally, our design needs to meet the functional requirements associated with stakeholders' expectations as well as standards and conventions within the gait analysis industry. There are basics such as the parameters it should be able to measure – accuracy and latency being two categories of consideration. Meanwhile, functionality also stems from the environment the device will be working in. This includes the financial, weather, and other demands the device needs to operate on. Table 2 demonstrates these requirements and specifications.

Table 2: General device requirements for the gait analysis device. These pertain to the functions of the solution and less so the user experience.

Priority	General Requirements	Engineering Specifications	Sources & Information
High	Accurately measures stride length	≤ ± 5% error	Benchmark[4] Benchmark[5]
High	Accurately measures step width	≤ ± 4.4 [cm]	Benchmark[3]
High	Accurately measures step	≤ ± 10 error	Benchmark[5]

	cadence		
High	Accurately measures traversed distance	≤ ± 2% error Must be able to measure ≥ 240 meters	Dr. Shibu Benchmark[4]
High	Accurately measures time	≤ 6.7 seconds from actual time of trial Must be able to measure ≥ six minutes	Dr. Shibu Benchmark[3]
High	Low-price	The total implementation of the device must be < 30 lakh indian rupees	Dr. Shibu
High	Data interpretation capabilities	Displays results post-trial within five minutes	Benchmark[14]
High	Functions in India's climate	Fully functions ≥ 10 ℃ & ≤ 43 ℃ at ≤ 100% humidity	Resource Provider[9] & Lucy Spicher
High	Functions on power available in India	Will work in power outages and be powered by 230 V	Lucy Spicher Resource Provider[8]
High	Adaptable to environment	Work within a space of 82 x 66 x 368 [cm] and work within crowded hallways	Lucy Spicher & Dr. Shibu
Medium	Sufficient battery life	Continuous use for > 7 hours	Lucy Spicher & Dr. Shibu

Accurate Measurements (stride length, step width, cadence, and traversed distance & time)
These specific metrics were included because they were requested by Dr. Shibu as part of the system's quantifiable gait metrics (Dr. Shibu, Meeting, September 11, 2023). Our specification targets were selected based on clinical products. The *DynaPort Minimod* was used to determine our walking time and traversed distance allowable errors ((Mobbs et al., 2022). The Sensorize® IMU was used in order to determine the upper bound error for the stride length as well as to validate the error we are allowing over the traversed distance and cadence (Mobbs et al., 2022). A total of 5 benchmarks were used in order to determine all spatiotemporal errors we are allowing. To find these values as well as the sources collected from, refer to the Figure in Appendix A (Marín, Javier, 2020). Specifically, we used the minimum and maximum of various benchmark methods. Although there is only one source for some metrics in Table 2, within the sources there are multiple benchmarks referenced. We prioritized this as high because it is the primary goal for our project, these metrics are what will be the main focus and drive the design process, and there is no low-price highly-accurate system currently available.

Low Price: The total implementation of the device must be < 30 lakh indian rupees

This requirement was strongly emphasized by Dr. Shibu, since current solutions do not suit this low-resource area (Dr. Shibu, Meeting, September 11, 2023). The conversion to USD is about $36,500.00. This may seem high, however, this value represents the overall implementation of the system, not just a singular product. The priority of this requirement is high because our goal is to make an affordable alternative to equipment that is currently available.

Data interpretation capabilities: Displays results post trial within five minutes
We are still in the process of defining this requirement. Initially, we were targeting real-time data processing. However, using independent sensors or cameras creates variability within our processing capabilities based on data type and timing (Zumel, 2022). To mitigate this issue, we have altered the specification so that our method will display the measured metrics within a reasonable time post-trial, based on benchmarking ("Gait Analysis Systems Compared » ProtoKinetics," n.d.). Additionally, Dr. Shibu recently confirmed that knowledge of results is sufficient for this device. To clarify, knowledge of results is information related to the performance outcome – the goal of performing a certain task – as a means for both the physical therapist and patient to validate their expected performance but also motivate them to do better (Sharma et al., 2016). We plan on establishing a specific time range by analyzing benchmarks, now that we know Dr. Shibu is looking for knowledge of results. This is of high priority because we want the data to be usable within a reasonable time. We currently believe our goal should be to allow explanation of the metrics within the two-hour long therapy session.

Functions in India's climate: Fully Functions ≤ 43 ℃ and at 100% humidity
Functions on power available in India: Will work in power outages and be powered by 230 V
Locally Sourced: Must be available available via Amazon India or shipping costs ≤ 15% of the components cost
After discussing with Lucy, we found it important to consider the environmental, industrial, and technological contextual factors (Lucy Spicher, Meeting ,September 12, 2023). Our driving force for these specifications was to acknowledge that just because a method is suitable in America or at the University of Michigan laboratories doesn't mean it will be suitable in India. Our requirements regarding India's climate and power sources are of high priority because if our device cannot work in these contexts it will be of no use. The requirement pertaining to the easily transporTable materials is of medium priority because of the context of our project. Our project scope is to prove that the conceptual method is feasible, not to create a final, completed product. We acknowledge that these specifications may be difficult to assess considering the time we have with this project.

Adaptable to environment: Work within a space of 82 x 66 x 368 [cm] and work within crowded hallways
Our conversation with Lucy also led us to a requirement referring to adaptability. She explained how the institution uses support beams of the minimum target dimensions specified in order to assist the patient (Lucy Spicher, Meeting, September 12, 2023). Our specification ensures our method will work within the smallest defined space. It also must work in the hallways because

the therapy sessions can extend into the hallway (Lucy Spicher, Meeting, September 12, 2023). We do not want noise from the environment to interfere with the measurements. To test these specifications, we plan on simulating both environments within the University of Michigan Laboratories. This is of high priority because it is necessary our method works within these constraints for it to be a viable solution.

Sufficient battery life: Continuous use for > 7 hours
During our discussion with Lucy, we also found it was important for the device to have a sufficient battery life, as there are power outages daily that can last for a few minutes (Lucy Spicher, Meeting, September 12, 2023). Our target set for this specification is based on the schedule of the therapy sessions. There are three therapy sessions throughout the day, each lasting two hours with a one hour break in between two of the sessions. This totals to be 7 hours (Lucy Spicher, Meeting, September 12, 2023). This requirement is of medium priority because of the short break between sessions. Although it is ideal for continuous usage through the entirety of the day, it is not a high-priority focus within the project.

Operator-Specific Requirements
Even if the general device can function perfectly, it would still be unsuccessful if the needs of operators are not considered. Physical therapists will be present in applying the gait analysis tool to measure the performance results of their patients. Their user experience is key to introducing the technological improvements to the Poovanthi Institute of Rehabilitation and Elder Care. Table 3 below provides such requirements and specifications.

Table 3: Operator-Specific requirements for the gait analysis device. The following pertains specifically to the Operator.

Priority	Operator-Specific Requirements	Engineering Specifications	Sources & Information
High	Durable	Can be used by 15 patients per day for 10 years	Lucy Spicher Dr. Shibu
High	Sanitary	Complies with the CDSCO (Medical Device Division) Class B Standard under Section 7.5. See *APPENDIX B.1.*	Benchmark[6] Benchmark[13]
High	Adequate UX	< 10 basic elements within the software. Font size ≥ 1/150th the viewing distance. < 3 levels deep in a menu hierarchy to reach main content. See *APPENDIX B.2*.	Resource Provider[10]

High	Maintainable	Must recalibrate without user inputs ≥ half of the sensing components in inventory as spares	Benchmark[4] Benchmark[14]
High	Ease of Use/Usable	Median score between 47.5 and 63.8 on System Usability Scale (n=10 questions; 5-point Likert scale, score out of 100)	Benchmark[2]
High	Provides understandable output data	Output the mean value of stride length, step width, & cadence	Benchmark[3]

Durable: Can be used by X patients per day for 7 - 10 years

It is important that our solution is also durable – repeated use and drops all compromise the lifetime of the product. To quantify this, we are going to discuss with Dr. Shibu the number of patients he intends to use this device with per day. Initially, we were reviewing benchmarks in order to set our target value, however we pivoted our thought process to the stakeholder to ensure we are acknowledging their specific request. We have not been able to discuss the target value with Dr. Shibu due to challenges in time differences, but have plans to in the near future. The priority for durability is high because we want this product to be long lasting. It was also specified by Dr. Shibu that the product be low-price (Dr. Shibu, Meeting, September 11, 2023). If the product continuously breaks, it would not be a successful method. We acknowledge this specification will be difficult to test. However, if we are able to develop a final product we will be able to assess the validity of our specification.

Sanitary: Complies with the CDSCO (Medical Device Division) Class B Standard under Section 7.5. See APPENDIX B.1.

We have included sanitary in our requirements to address the public health contextual factor. It is important that our method complies with an industry standard for public health. To ensure this we have referenced the CDSCO Class B medical Device Standard Section 7.5 which gives detailed descriptions on how to ensure the device is sanitary. Post COVID-19, this is of high priority for us and in all aspects of society, especially the medical industry.

Adequate UX: < 10 basic elements within the software, Font size ≥ 1/150th the viewing distance, < 3 levels deep in a menu hierarchy to reach main content.

An adequate user experience was a requirement we considered after a meeting with Dr. Sienko where we discussed the importance of addressing the user experience (Dr. Sienko, Meeting, September 11, 2023). Our target for the specification is based on the *Handbook of Human Factors in Medical Device Design* (Weinger et al., 2011). We will use the book to guide our user interface and display results so that it fits within the clinical standards. This is of high priority because we want the user experience to be seamless, and ensure there is no data that is unable to

be interpreted by the operator. In order to assess the streamline and how adequate our UX is, we plan on conducting usability testing of our final product. Our most important specifications state that there must be less than 10 basic elements within the software, to ensure complexity is as minimal as possible (Malkin & Keane, 2010). The font size must be greater than or equal to 1/150th the viewing distance so that it is of the standard size for reading critical information (Malkin & Keane, 2010). Lastly, there must be fewer than 3 levels deep in a menu hierarchy to reach main content, this is to ensure the user interface is not so complex it is inoperable (Malkin & Keane, 2010). Refer to *APPENDIX B.1* to see more details on each guideline as well as other guidelines we are taking into consideration.

Maintainable: Must recalibrate without user inputs and have ≥ half of each sensing component in inventory as spares

After literature review, we discovered differences with various benchmarks. Some are able to recalibrate simply by the press of a button or automatically, while others involve user manuals and long processes (Mobbs et al., 2022). Considering the institution has a staff to patient ratio of 1:12, we believe the recalibration being an efficient and simple process is high priority. To test this specification, we will be addressing multiple recalibration methods and finding a suitable solution. To further specify the requirement of maintainability will we be ensuring that at least half of each sensing component be in storage. For example, if we were to use four cameras to measure the patient's gait parameters, we would require that 2 cameras be in inventory as spares. The reason for having spare parts is that it is one of the most commonly cited reasons that equipment in low resource-poor settings go out-of-service. (Malkin & Keane, 2010).

Ease of use: Median score between 47.5 and 63.8 on System Usability Scale (n=10 questions; 5-point Likert scale, score out of 100)

Considering that there are 12 patients for each physical therapist, it is integral that use of the gait analysis device be easy and efficient. This is to enable the operator, or physical therapist, to move quickly between tasks without being bogged down by a complex device. To determine the ease of use of our device, the Systems Usability Scale (SUS) has ten equations, including questions on the complexity and ease of use of a device. During our literature review we found a Likert scale survey being used for medical devices being attached to different body parts. We felt this would be an appropriate use since our method is also considered a medical device (Keogh et al., 2020). Using a 5 point Likert scale and scaling the SUS score out of 100, we should expect our device’s usability to score between a median low of 47.5 and 63.8. This was a range of scores for a wide range of devices that were surveyed (Keogh et al., 2020). Since our concept could be any form of wearable device, it would be reasonable to fit the ease of use within the range, obviously shooting for the higher end of the spectrum.

Provides understandable output data: Output the mean value of stride length, step width, & cadence

To find our target data type we reviewed multiple benchmarks. Although there was some variation between the type of data, we continuously found that the average was displayed (Marín, Javier, 2020). Similar to the user experience, we have this requirement as high priority because we want to provide useful data to the physical therapists. At this point, we do not have a clear defining way to test this requirement. We plan to address this by consulting Dr. Lauro Ojeda at the University of Michigan.

Patient-Specific Requirements

Stakeholders who are just as important as the operators are the patients who will have their gaits analyzed. Not only should their safety be prioritized, but the device should not hinder their daily activities in any way. From both a comfortability standpoint on the patient's side and a data collection perspective, the device should work in a natural environment without altering variables for concern and error. Requirements and specifications are listed in Table 4.

Table 4: Patient-specific requirements for the gait analysis device. The following pertains specifically to the operator.

Priority	Patient- Specific Requirements	Engineering Specifications	Sources & Information
High	Safe	Complies with the CDSCO (Medical Device Division) Class B Standard utilizing a pilot and pivotal investigation. See *Appendix B.5*. The device should not impede the gait of the person	Benchmark[7]
High	Adjustable	Compatible with 5th percentile (female) to 95th percentile (male) of the Indian Population. ***See Appendix B***.	Article[11]
Medium	Comfortable	Average > 4 on the Likert Acceptability questionnaire by Jacucci	Benchmark[2]
Medium	Usable with rehab facility attire	T-shirt, Barefoot & Shorts	Dr. Shibu & Lucy Spicher

Safe: Complies with the CDSCO (Medical Device Division) Class B Standard utilizing a pilot and pivotal investigation. See Appendix B.5. The device should not impede the gait of the person

A dangerous device would only bring harm to the patients of the hospital. Patients are rehabilitating to heal, not hurt. Knowing that many standards come with the creation of medical devices, we followed India's Central Drugs Standard Control Organisation requirements for medical devices – which should be held up to a Class B Standard (Somani, n.d.). This should be done with high priority to ensure the number one priority is the safety of our patient

stakeholders. It is of highest priority that the measuring device not cause any harm or affect the gait of the rehabilitation center patients. We will use testing in order to ensure the mobility of the patient not be affected. The pilot and pivotal test will be used to identify potential dangers within the device before being released for clinical use.

Adjustable

According to Lucy and Dr. Shibu, patients of the Poovanthi Institute of Rehabilitation and Elder Care vary from 18 to 93 in age. Such a large range of ages imply major variabilities of body type. So, to be able to analyze the gait of all patients, the device must be adaptable to all body morphologies. In order to understand the types of bodies we must cater towards, Indian Anthropometric data was collected and used as our specifications. To be adjustable means that we should at most make our device compatible with the 5th percentile (female) to 95th percentile (male) of the Indian Population (Luthra, 2018). From weight to height to body depth, all the dimensions can be found in the *Appendix A*. The 5th percentile (female) to 95th percentile (male) reasonably covers the smallest stature to the largest. This data should be most representative of the hospital patients as it takes into account cultural and contextual differences, and is of high priority in order for the device to be usable in this context.

Comfortable

One medium-priority aspect of user experience is comfortability. It is essential for patients' acceptance of a new technology that we will be introducing to the center. However, to maintain natural gait, it would also be beneficial for our patients to be as comforTable as possible without compromising their walking stature. Using Dr. Jacucci's Likert scale questionnaire for wearable medical sensors, (Keogh et al., 2020), our device should score greater than 4 on such a comfortability scale.

Usable with rehab facility attire

When speaking to Lucy and Dr. Shibu, it was also brought to our attention that patients in the center wear a t-shirt, shorts, and sandals (similar to Teva). Our device must abide by patients' garments. Since this device will only be used within the context of the rehabilitation center, we deemed it as medium-priority, and have not yet had to take into account other cultural clothing worn outside the center.

After multiple iterations of our requirements and specifications, we are confident that we have come very close to a full list of requirements. Based on our requirements, we feel we have addressed 8/8 of the contextual factors discussed in the Aranda-Jan article previously mentioned.

As mentioned, two main methods were used to determine our engineering specifications. One method was through the use of stakeholder engagement. It was important for us to ensure we understood the project goals and got any specifications about the contextual factors that we could. The second method that we used was benchmarking. In order to ensure we meet the industry standard with our device, we have conducted a literature review on various clinically

used devices in which we utilized the data. All of our targets for specifications were ultimately based on either benchmarking, guidelines, stakeholder engagement, or standards from regulations. After creating this list of requirements and specifications, we rarely updated or iterated on our requirements and specifications. Since these were all solution-neutral, we ensured our designs met as many of these as possible. In the Beta verification section, we will address requirements which were not met in our design process, and explain our rationale for this.

ALPHA CONCEPT GENERATION AND SELECTION

The concept generation process can be broken down into distinct phases that follow a diverging to converging path. In order to fully explore the design space, we individually generated 40 concepts, totalling 160 concepts to begin with. We then utilized a filtration system to converge to a select set of concepts. Once we narrowed down to through our first and second filters, we diverged by creating a morphological chart to determine the six sub-functions of our design and exhaust design options.

Individual Concept Development

Initially, each member of our team developed 40 concepts individually in order to collect diverse concepts. There were no constraints put in place for the individual concept development in order to encourage diverse divergent thinking. Figure 10 and Figure 11 below showcase two significantly different concepts developed within the individual concept development stage. Each individual team member used various methods for generating methods such as morphological charts, design heuristics, and the SCAMPER method. Some members found morphological charts easier to use to create full systems for our design, while some preferred creating systems with a more vague structure like SCAMPER. Most members also individually incorporated design heuristics to make improvements to designs they had already created. This combination of methods were used purely based on individuals' preferences.

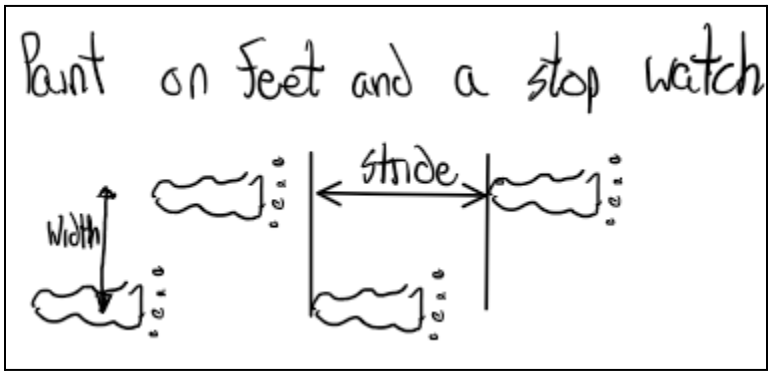


Figure 10: A concept generated utilizing paint on the feet in order to measure stride length, step width, cadence, and traversed distance, as well as a stopwatch to measure the time.

This concept was developed using brainstorming with an emphasis on constraining the problem to minimal costs under $10. The problem was also broken down into sub-functions in which each

metric to be measured was considered a sub-problem. The concept was classified as our lowest cost concept because it does not utilize any significant technology. It also exemplifies that in order to solve the problem of measuring gait metrics, advanced technology may not be needed.

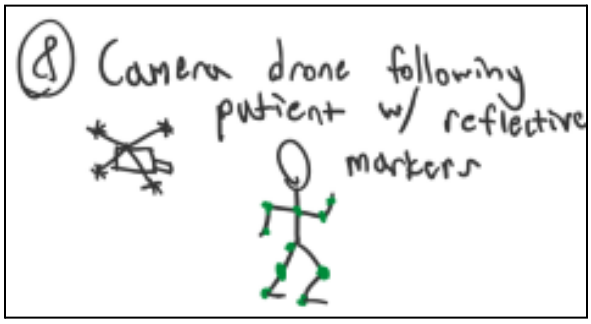


Figure 11: A concept generated considering attaching reflective markers to the patient and utilizing an autonomous drone that tracks the markers in order to measure stride length, step width, cadence, and traversed distance.

This concept was developed using the radical framing tool introduced in ME 457 (Daly, 2023). Specifically, there was no budget considered, no constraints, and it was unexpected. This concept was classified not only as one of the most abstract of our ideas but also presented many faults, one being that it would be extremely expensive and difficult to source materials for. The variation in the two examples shown in Figure 10 and 11 signify how vastly we explored the design space. Additionally, each member's unique way of thinking and design background allowed for drastically different concepts.

While it is challenging to definitively say we explored the entirety of the design solution space, we used a structured assessment to determine the exhaustiveness of our exploration of the design space. The factors we considered are as follows: diverse range of concepts, inclusion of information from a diverse range of stakeholders, a variety of constraint considerations, and the range of incremental to radical thinking considered. As shown in the examples above, our 160 concepts collectively were incredibly diverse. We also had many concepts that took into consideration what not only our primary stakeholders had told us, but also what we found from resource providers and other higher-level stakeholders. This included concepts considering materials available in India as well as concepts that adhered to the specifics of the Poovanthi Center. Putting no constraints on our individual concept development process ultimately allowed us to consider a larger range of possible constraints, including none at all. While some of our concepts were out of our budget and technical ability, some also considered these factors more. Because of this, we also had a wide range of incremental to radical design solutions. Some members focused on making slight improvements to concepts and systems currently on the market from our benchmarking work, while some created completely brand new system ideas. Ultimately, while there may be solutions we did not consider in our individual generation process, assessing these factors allowed us to determine we had exhausted the design solution space to our fullest extent in the time we had.

Collinear Concept Generation and Selection

Following the individual concept development, we decided to use a unique collinear approach, which added onto our concept generation while simultaneously conducting our selection process.

After individual concept generation, we realized that many of our generated concepts had overlapping components and approaches to solving the design problem. Therefore, we determined the most appropriate approach for our team and project would be to build upon our concept generation together while simultaneously converging towards our design solution by assessing the concepts developed. Additionally, since our Alpha solution largely seemed to require a combination of current technologies to create a new system, converging in subsystem selection while diverging in the overall system concept made the most sense in terms of efficient use of time and resources. Figure 12 below shows how we simultaneously conducted concept generation and concept selection.

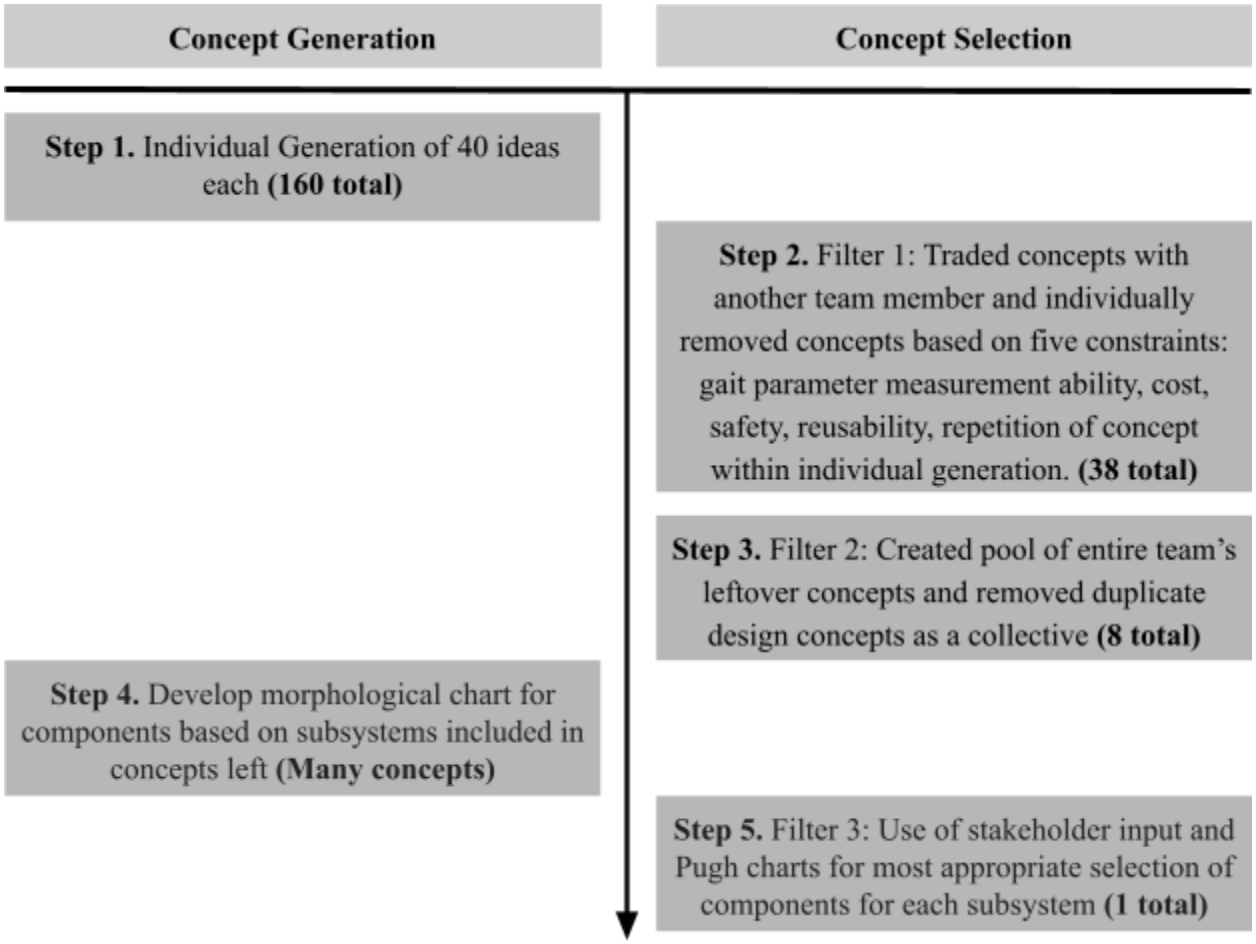


Figure 12: A representation of the process we have used to generate and select our concepts we have generated. Process is shown through five distinct steps and categorized by concept generation or selection. The concept selection steps are labeled as filters 1, 2, and 3

The first step involved in the concept selection process, Filter 1, we exchanged our 40 distinct ideas with one other person on our team to guarantee the absence of any personal biases when filtering based on the selected constraints. The filter consisted of five constraints, four of which were based on the need to meet our highest priority requirements and specifications. The first constraint was that our device must be capable of outputting the five parameters from our general requirements: stride length, step width, cadence, traversed distance, and time. Our second constraint ensured that the product would fit within our low-price specification. To assess this, we used benchmarking and knowledge of the devices stated. Our third constraint was to ensure the product was safe. To assess this constraint, we deemed any components that could pose harm or hinder the walking of a patient as unsafe. The last constraint was used to get rid of the repeated components and ideas that each team member came up with individually – this only considered repetition within one member's ideas, not between multiple members' ideas. Figure 13 below serves as an example of a concept that did not pass the first selection filter.

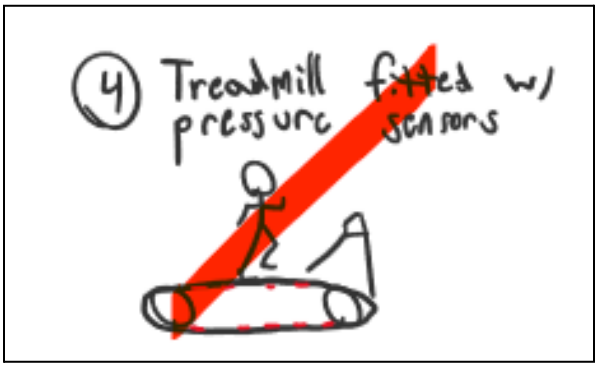


Figure 13: A sketch of a concept which depicts a patient walking on a treadmill consisting of pressure sensors. This design concept did not pass through the first filter.

The sketch depicted in Figure 13 did not pass the first concept selection filter because a team member deemed it unsafe. It is important to acknowledge that even though it was able to measure all the parameters, was reusable, and low-price, it still did not pass because all constraints must be satisfied. It was deemed unsafe because patients, especially with gait disorders, may fall on a moving treadmill. It was deemed costly based on benchmarking we had done.

Following step two, the first concept selection filter, we had a total of 38 concepts. The second concept selection filter was very straightforward and similar to our fifth constraint from the first concept selection step. The difference was that now we were comparing the total 38 concepts as opposed to individually generated concepts. Figure 14 below shows two concepts that were generated by different team members. Both of the concepts had many similarities to one another, so only the concept that we felt best suited with our constraints from filter one passed the second filter.

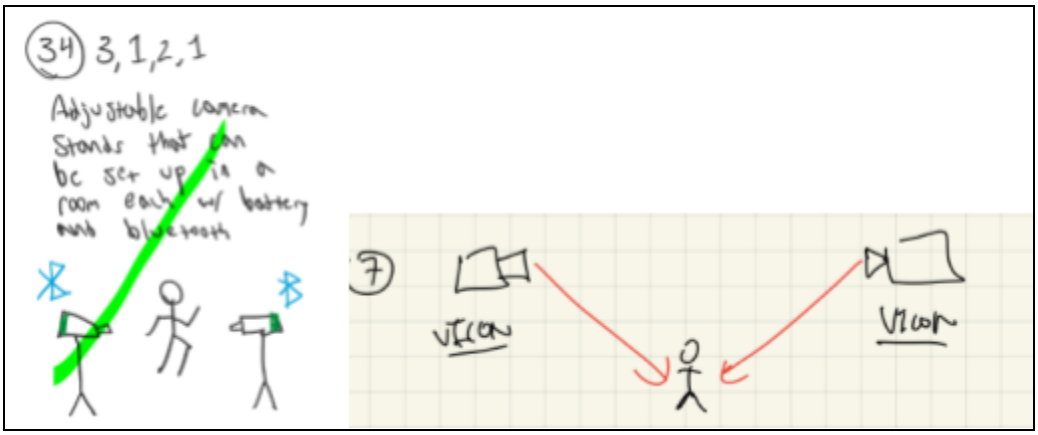


Figure 14: Two concepts generated from two different members of our team. Both concepts make use of high definition cameras to measure the selected gait parameters.

As a team, we decided the sketch on the left side of Figure 14 would best suit the constraints within the first filter. We also decided to go with this concept because it presented other components not represented in the concept on the right. Our thought process was that since the left sketch encompasses all aspects and components of the right concept, we will use it since it introduces the new data transmission component. Throughout this filter we had similar conversations for all of the other similar concepts.

After the second selection process, we had a total of eight concepts left. At this point, we decided to cross the plane and enter the concept generation space again. This was due to our collective realization that our concepts were not a singular device but rather systems of multiple components or sub-functions. Because of this realization, we were unsure we had fully explored every possible solution in the design solution space through our initial concept generation process. We decided it was critical to build upon our concept generation to keep fully exploring the solution space, and ensure no combination of sub-functions was missed. As a team, we decided that the use of a morphological chart that broke down each function presented in our eight concepts would be the best way to generate new complete concepts from each sub-function. This also allowed us to diverge and fully exhaust design options we may not have previously considered through assessing new combinations. Table 5 below is the morphological chart that we generated based on the final eight concepts we had left.

Table 5: Morphological Chart with six sub-functions listed in the first column along with the corresponding components in each row. All sub-functions and components were developed from our concepts and requirements.

Sensing	IMUs	Pressure insoles	Camera System	Measure by hand	Pressure mat
Display type	Graph	3D-model	Numerical		
Data transfer	Bluetooth	Hardwire	Wi-fi		

Data Processor	Raspberry Pi	Available Desktop	Ipad/Iphone
Attachment to patient	Velcro	Non-wearable	Straps
Data storage	Handwritten	Hard Drive	Cloud-based
Power source	Battery pack	Plugged in	

Table 5 consists of six sub-functions that we found were relevant in each of our concepts or deemed to be necessary based on our requirements and specifications. Sensing corresponds to the technology that we will be using to measure our five parameters. Each of these components can be referenced in Table 1 and throughout the benchmarking analysis. Display type represents the way in which data will be presented to the user of our system, either the physical therapist or patient at the Poovanthi Institute. From our concepts, we came up with three data representations: graphical, in which each of the metrics can be derived from using a graphical representation; numerical, in which values of each metric will be displayed, such as, averages, maximums, minimums and standard deviations; and 3D-models that can fully model the manner in which a patient is walking as well as the five parameters from our requirements. Data transfer is the means in which our data will be transferred from one component to a display monitor. We derived three components from our concepts: bluetooth, in which no wires will be attached from the patient to the monitor; hardwire, such that the component measuring the five parameters is directly connected to the display monitor; and Wi-Fi, in which the whole system is connected via the Wi-Fi provided by the Poovanthi Institute. Power source is the way in which our components will be powered. For this sub-function we came up with the possibilities of using a battery or having the device be directly plugged into the wall at the Poovanthi Institute during use. Attachment to the patient is the way in which our measuring component will interact with the patient. This sub-function contains three concepts: velcro pants, in which the patient will wear velcro lined leggings and the sensing components can be attached to this suit; non-wearable, pertaining to sensing components that we feel would be best used not attached to the patient; and straps that will connect to the patient and sensing component. Finally, data storage is how we will be storing the raw data and parameters. We have derived three forms of storage from our concepts: handwritten, hard drive, and cloud based.

Following our second concept generation step, we believed it would be best to consider input and information from two of our primary stakeholders, Dr. Shibu and Lucy Spicher, to establish our third concept selection filter. The input they offered us covered three sub-functions for our alpha design: the power source being used to operate our system, the data storage system that would be used, and the display of the data for our end users. For the power source, Lucy stated that there are frequent power outages in the Poovanthi Institute, and there are minimal outlet sources readily accessible everywhere due to the crowded nature of the center and large open space

(Lucy Spicher, personal communication, September 12, 2023)). Thus, we determined it would be critical for the device to be battery-powered as well have the ability to plug into an outlet when possible. For data storage, Dr. Shibu mentioned that the current system being used to keep patients' data is a paper-based system, but specified that the institute is looking to make a shift away from the paper system to a cloud-based one to allow for better collection and storage of patient data. We agree with this consideration, as cloud-based technology will allow for long-term ease of use, especially since patients may come back to the center down the line and need access to their past information (Dr. Shibu, personal communication, September 11, 2023)**.** Lastly, Dr. Shibu mentioned that graphical data is better for the display, but average numerical scores should not be ignored. We were also able to back up this stakeholder preference by benchmarking. Most of the devices we had benchmarked also contain data outputs in multiple formats, or allow end users to select among formats. Beyond this input, we required further analysis utilizing Pugh charts to ensure we were making the correct design decisions based on more than just stakeholder preference.

Pugh Charts for Sub-function Selection

The stakeholder input used for our third filter was only able to account for three out of the six sub-functions laid out in our morphological chart and only allowed us to make definitive design decisions for the power source and data storage sub-functions. For the display type sub-function, since it is a crucial function of our system and will involve a lot of back-end work, we wanted to further analyze this in order to confirm what our stakeholder preferred was actually the best option. For display type and the rest of the sub-functions not covered in our stakeholder input, we then created Pugh charts to decide on the specific component that would be selected for each sub-function. This was part of the last step in our concept generation and selection process. The criteria that we used for each Pugh chart was then weighed so we could compare each solution for every sub-function to a reference solution. The weights were a scale from 1-5, and the weight of each criteria was determined from referring back to our prioritized requirements and specifications, benchmarking on what is currently available, and stakeholder input in terms of what stakeholders prioritize.

Sensing

We began with the sensing sub-function. Each of the possible solutions as decided in the morphological chart were compared to its ability to meet the necessary weight criteria as shown in Table 6 below.

Table 6: Pugh chart of sensing sub-function

Criteria	Weight of criteria	Measurements by hand	IMUs	Pressure sensor insoles	Camera motion capture	Pressure sensor mat

Step Width	5	0	-1	-1	+1	+1
Stride Length	5	0	+1	-1	+1	+1
Cadence	5	0	+1	+1	+1	+1
Distance	2	0	+1	-1	-1	-1
Time	3	0	+1	+1	-1	-1
Works in crowds	4	0	+1	+1	-1	+1
TOTAL:		**0**	**14**	**0**	**6**	**14**

The criteria that we used to weigh each type of solution against the reference solution, measurements by hand, mainly deal with the ability to accurately measure the gait parameters as provided in our requirements and specifications. The spatial parameters in the criteria include step width, stride length, and distance. Step width is the most challenging parameter to measure from our benchmarking research, and a critical parameter for gait analysis (Bäcklund et al., 2020). Step length is also a critical parameter to measure for gait analysis for a given population. Temporal parameters, such as cadence and time, are also critical parameters for gait analysis (Prasanth et al., 2021). The last criteria, works in crowds, is a direct result from the *adaptable to environment* requirement as discussed by Lucy Spicher (Lucy Spicher, Meeting, September 12, 2023). We decided to assign a slightly lower weight to this factor compared to the gait parameters under consideration. This is because the device's failure to function effectively in crowded spaces would not render our device useless the way that not measuring the gait parameters would.

Out of all five solutions being compared, IMUs and the pressure sensor mat were tied with the same total score after being compared to measurements by hand. IMUs almost met all the criteria necessary for our solution to our sub-function, but did not meet being able to measure step width (Bäcklund et al., 2020). Pressure sensor mats performed very well, but lacked the ability to measure distance and time because it is stationary and cannot measure a six minute 240 meter walk test. Since both the IMUs and pressure sensor mat scored well on the Pugh chart, we determined combining both solutions would be a possibility, and by doing that we would be able to meet all of the necessary criteria in the chart as well as our requirements and specifications.

Data Transmission

Our system will have a device that will be collecting data which will be transmitted to a display. As shown in Table 7 below, we compared three different solutions for this sub-function: hardwiring to computers, bluetooth communication, and Wi-Fi communication.

Table 7: Pugh chart of data transmission sub-function

Criteria	Weight of Criteria	Hardwire	Bluetooth	Wi-fi
Low Noise	3	0	+1	+1
Safe	3	0	+1	+1
Ease of use	2	0	+1	0
Low price	2	0	0	-1
TOTAL:		**0**	**8**	**2**

The ability to transmit the data with low noise is the most crucial criteria in this Pugh chart because this will affect the ability to display accurate data so we can meet our requirement and specification to provide understandable output data for the physical therapist. The next criteria is that this sub-function be safe for the patient using our system because data transmission solutions can potentially add a lot of wiring that would need to be placed on the patient – we cannot have a trip hazard that would put the patient at risk. The lower weighted criteria are ease of use and low price, which correspond with our requirements and specifications. We need this sub-function to meet our ease of use specification because it will be used by the physical therapists who will need to set up connections to collect data. Some data transmission solutions are high cost, so we believe this plays a large role in the selection of this component more than for other sub-functions.

After weighing all possible solutions to the criteria, we determined that bluetooth is the best solution to meet our data transmission sub-function needs. Bluetooth is an easy to implement solution that will provide low noise data for easy data interpretation capabilities, does not have wiring that will cause trip hazards, and will be easy to implement in the institute at a low price (Chang et al., 2023).

Attachment to Patient

Since we will likely be using a wearable solution, we need to somehow attach the device to the patient in order to be able to accurately collect the data while a patient is walking. As seen in

Table 8 below, we compare the solutions of velcro pants and straps to a solution that is non-wearable.

Table 8: Pugh chart of attachment to patient sub-function

Criteria	Weight of Criteria	Non-Wearable	Velcro pants	Straps
AdjusTable	4	0	0	+1
Easy to Put On	2	0	-1	+1
No effect on Current Gait	4	0	0	+1
Sanitary	3	0	-1	+1
TOTAL:		**0**	**-5**	**13**

The two criteria that have the highest weights in this Pugh chart are the ability to be adjustable and for it to have no effect on the current gait of the patient. The criteria to be adjustable is important because there is a wide range of patients at the institute, and we need to make sure that our product can be worn by anyone who needs it, so we need to make sure that the attachments are in line with our adjustable requirement. It is also important that our attachments onto the patients do not affect the current gait of the patient, because this will lead towards an inaccurate diagnosis of gait disorders. The sanitary criteria is in line with our sanitary requirement and specification and is necessary because this device could be used by 10-15 patients per day, and it is important to be ethical by choosing a design which provides safety in terms of cleanliness for the patient.

After comparing all possible solutions we had for this sub-function of our system, we determined that straps are the best choice. Velcro pants are a unique solution idea we had which would allow for adjustable placement of IMUs, but it would lack the ability to be adjustable to a wide variety of patients, be challenging to put on in the large rehabilitation halls, and would provide a wide variety of sanitary problems. By using straps, we would be able to attach IMUs or other wearable devices to a wide variety of patients without affecting their gait, and with the low amount of surface area that will be in contact with the patient, it will be easy to clean to meet our sanitary requirement and specification.

Data Display

It was recommended from our stakeholder engagement that we should use a combination of numerical and graphical data in our display. Even though this was the stakeholder's recommendation, we needed to confirm that this was the best route beyond just being Dr. Shibu's preference, so we compared it to another possible solution, 3D modeling, as shown in Table 9 below.

Table 9: Pugh chart of display type sub-function

Criteria	Weight of criteria	Numerical	Graphical	3D modeling
Easy user interpretation	4	0	+1	-1
Efficient data interpretation	3	0	-1	-1
Low price	2	0	-1	-1
Offers continuous data	1	0	+1	+1
TOTAL:		**0**	**0**	**-8**

There were only three criteria that were relevant to determining the type of data display as shown in the Table above. The criteria with the largest weight was *easy to interpret* since the need for the physical therapist to be able to read the data to be able to provide a data-driven assessment of gait is the most crucial part to our problem. Next, it needs to be efficient at data interpretation to meet our *data interpretation* requirement. This was weighted at a 3, slightly less than the easy to interpret criteria, because the ability to identify what is going on with gait is the most crucial part of our project. Since some display types could take a lot of time and money to develop, the cost of creating the functions of the display is considered.

When weighing the possible solutions of the sub-function, it came out that the numerical and graphical solutions were both viable and out-performed the 3D modeling solution.The 3D modeling solution did have the potential to provide the physical therapists an extra tool to analyze the gait of patients, but it comes with a lot of data interpretation and calculation work that wouldn't be feasible in the environment with which our system will be used. A graphical display of the data will be easier for the physical therapist diagnosing the gait disorders to

interpret and will be able to provide them with continuous data that will allow them to analyze a full test. This Pugh chart analysis aligns with our stakeholder input, showing that numerical and graphical data will both be effective at providing the necessary data display capabilities to allow for the physical therapists at the institute to provide accurate data-driven assessments of gait disorders.

ALPHA DESIGN SOLUTION

Based on our concept selection process, we developed an alpha design solution that combines the best selected options from our sub-functions in order to create a system which meets our requirements and specifications. Figure 15 below shows our initial sketch of our solution.

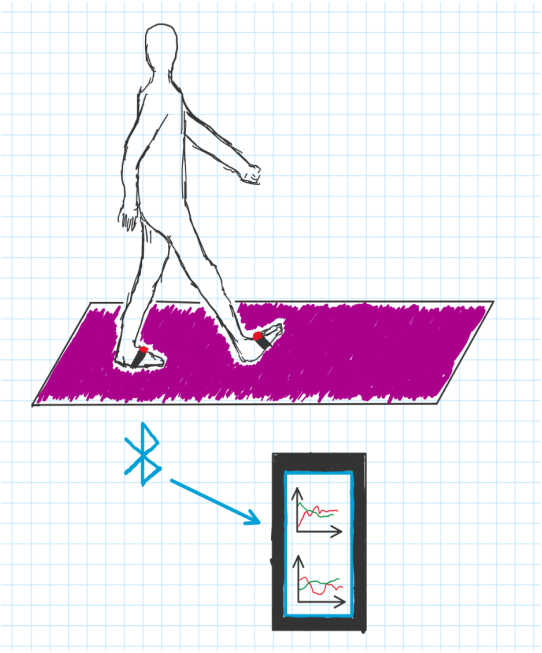


Figure 15: Alpha design solution. This sketch displays a patient with IMUs strapped to their feet walking on a pressure mat. The technology is battery-operated with bluetooth to transmit the data to a graphical and numerical display. The data is then stored in a cloud-based system.

Our system includes IMUs as well as a pressure mat in order to collect all spatiotemporal parameters from our requirements: stride length, step width, step cadence, distance, and time. Since IMUs are unable to record step width, the pressure mat will primarily be used for this parameter, and the IMUs will be utilized for the other parameters. While the pressure mat will be placed on the floor rather than attached to the patient, the IMUs will be attached using straps, which we determined is the best method of attachment from our design selection process as well as from our conversation from Safa Jabri (Safa Jabri, Meeting, October 5, 2023)**.** The power source for our design will be a battery, and data transmission to the display will occur utilizing bluetooth technology. The display will contain graphical and numerical components, and the data will be stored through the cloud.

IMU Selection

The first step in further developing our design solution was selecting IMUs to use. The IMU will contain 9-axes, which means it must contain an accelerometer in order to accurately measure acceleration, a gyroscope to accurately measure the angular rate and orientation, and a magnetometer to ground itself to the Earth's magnetic field (Safa Jabri, Meeting, October 5, 2023**)**. The use of the magnetometer will allow the IMU to recalibrate itself without user input which helps satisfy our specification regarding maintainability. From research, the average gait frequency is 2.7 Hz (Cavagna & Franzetti, 1986)**.** Using a safety factor of two, we obtain an average gait frequency of 5.4 Hz. This safety factor is critical in ensuring if a patient is walking at a higher frequency, their data can still be collected. We then used Nyquist's Theorem, which states that a signal can be exactly reproduced if its sample frequency is twice the maximum frequency in the signal ("Nyquist Theorem," 2021). Based on this theorem, we determined the sample frequency must be 10.4 Hz. Our initial research on IMUs which match these parameters as well as discussion with Safa Jabri brought up two readily available IMU systems which contain data outputs that would meet our requirements in terms of our ability to extract the necessary parameters. Notably, these IMUs came with software libraries that help calibrate the devices and process gait parameters such that our team did not need to build processing logic from scratch with something like an Adafruit IMU, especially for gait. These IMUs are the Movella DOT Set (*Movella DOT*, n.d.) and the Witmotion BWT901CL (*WitMotion Bluetooth 2.0 Multi-Connect BWT901CL 9 Axis IMU*, n.d.). Table 10 below compares the specifications of these two IMUs.

Table 10: IMU selection Table considering two applicable IMUs' specifications

	Movella DOT Set	**Witmotion BWT901CL**
Unit price (USD)	150.00	45.99
Data frequency (Hz)	1-120	0.2-200
Internal battery life (hrs)	8	10
Resolution Acc(g)/Gyro(°/s)/Mag(bits)	.031/.1/16	.005/.61/16
Bluetooth	Yes	Yes

Based on the specifications in Table 10, our initial consideration is to use the Witmotion BWT901CL. In terms of unit price, this IMU is much cheaper. The data frequency for both will work for our purposes. Regarding internal battery life, our specification was for it to survive through a 7-hour day, and both adhere to this specification. Both also include bluetooth capabilities. Lastly, in terms of resolution, we need to conduct more research on exactly what resolution might be required to obtain the level of accuracy we included in our specifications for each gait parameter. This analysis will require us to determine how much error we might get through the data analysis required to determine the parameters from the IMU's raw data and consider the resolutions provided in the specifications. This will be our next step in design solution analysis. It must be noted that we recognize these IMUs are sourced in America. Further research and analysis will be conducted to consider available IMU options in India or surrounding countries for better sourced options near the Poovanthi Institute.

IMU Straps Material & Design

As previously mentioned, our IMUs will be attached to the patient utilizing straps. This will ensure minimal noise in data collection, since IMUs are highly sensitive to movement. From our discussion with Safa Jabri, we determined two IMUs placed on the patient's feet will be sufficient for our data needs (S. Jabri, personal communication, October 5, 2023)**.** This placement will not only minimize noise, but it will also not inhibit the patients' gait and it will work with our requirement of working with rehabilitation center attire, which is either barefoot or sandals.

In determining the actual strap we will use, we utilized inclusive design practices by deciding to build our own IMU strap that can fit with a variety of foot sizes. Our current research was based on American sizes, however, these will be translated into Indian sizes and metrics once we determine what might be best to use based on what could be locally sourced. We have currently considered a US shoe size range of 4 (female) to 12 (male) in order to encompass the majority of adult foot sizes. We also considered gusset circumferences, which is the maximum circumference around the foot of a human, to be 28 centimeters as it is the largest circumference found for a size 12 (male) foot (*1inch X20 Ft Self Gripping*, n.d.)**.** This is to ensure that we are able to use our device on all patients. Ultimately, we determined a hook & loop strap would work the best as it is adjustable for a wide range of sizes. Our initial thought is that this will also be a comforTable choice for patients, however, we need to conduct more design ethnography research and a potential usability test to determine if this is definitely a comforTable option. Figure 16 below shows our initial CAD drawing of what this strap might look like.

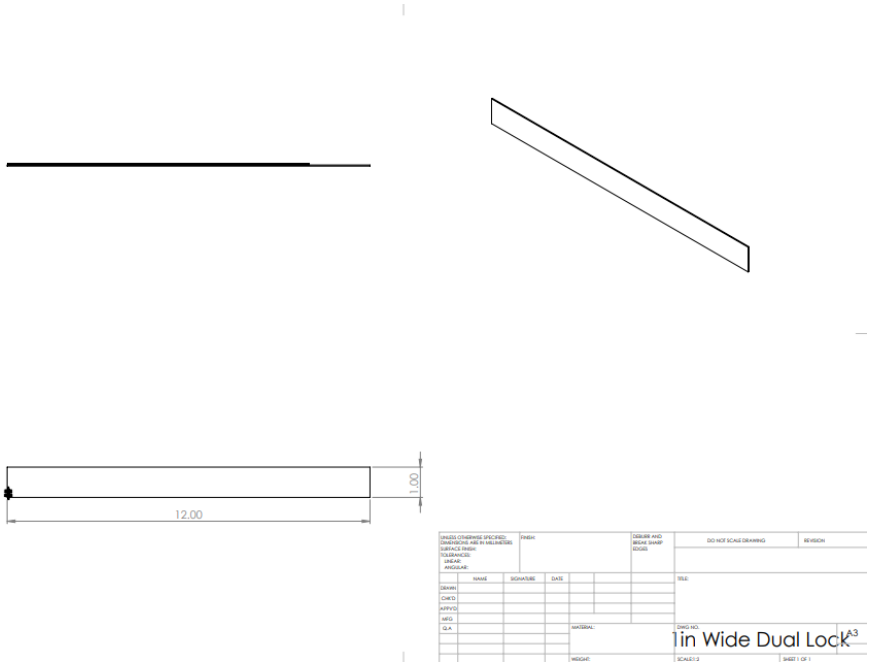


Figure 16: Our CAD drawing of the hook-and-loop strap for the IMUs

Another need for the IMU is a casing to ensure security of the IMUs and safety for the patients and physical therapists. Our selected IMUs under consideration come with plastic casings, however, we also considered the possible need of 3D printing our own casing. Upon discussion with Safa Jabri as well as research on the current casings that come with IMUs, we determined that for durability and ease of manufacturing, utilizing the cases that come with IMUs would be a better option. This would ensure durability, compatibility with the IMU, and long-term use. Figure 17 below is an example of what our IMU casing will look like.

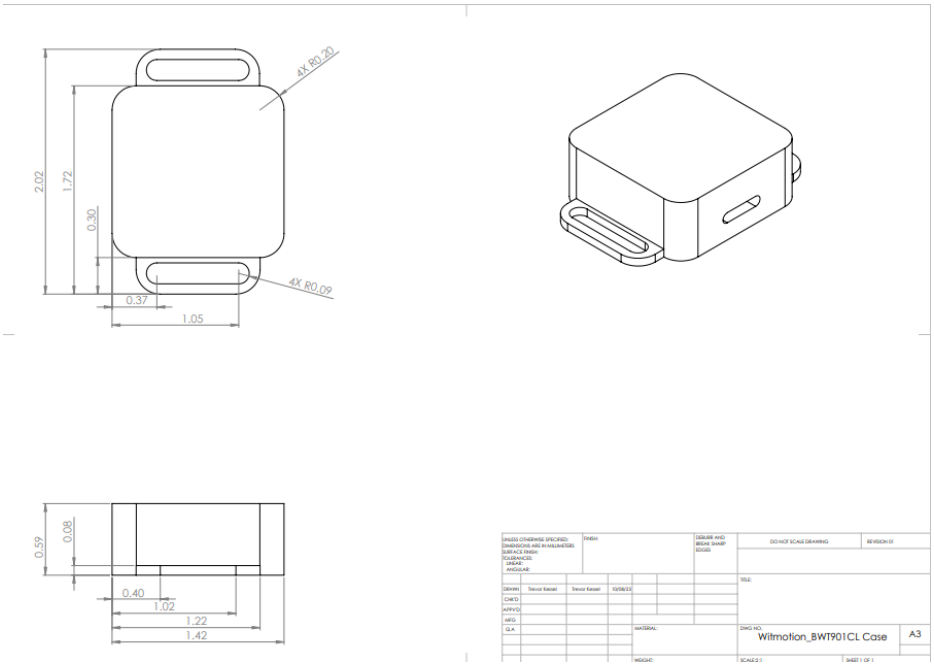


Figure 17: Our CAD drawings of the potential IMU casing we can use to secure the IMUs and attach them to the straps

This casing will contain loops for the straps as well as a box for the actual IMU. Currently, all IMUs under consideration come with casings that would fit with our hook-and-loop strap design.

Pressure Sensor Selection

Current pressure mat solutions use an array of pressure sensors that provide electrical signal outputs that are proportional to an applied pressure and they tend to be either capacitance, force resistive, piezoelectric, or piezoresistive sensors (Abdul Razak et al., 2012). All four of these sensors are used in various products across the market today but some perform better than others when trying to measure certain aspects of gait. For our purposes we will be using the pressure mat to primarily measure step width, a spatial parameter, of a patient so its ability to measure accurate pressure parameters is not necessary and the ability to be able to identify which sensors are being triggered is more useful. To determine which type of sensor will best suit our needs we created a Pugh chart as shown in Table 11.

Table 11: Pugh chart of pressure sensor selection

Criteria	Weight of Criteria	Capacitive	Force Resistive	Piezoresistive	Piezoelectric

Low-Price	3	0	+1	-1	-1
Accurate Spatial measurements	3	0	0	0	-1
Durable	2	0	+1	+1	0
TOTAL:		**0**	**+5**	**-1**	**-6**

Low price is a crucial aspect of the pressure sensor selection because in order to create the pressure mat with the sensor resolution to meet our accuracy requirements we will need a sensor that is effective but cheap. Since the pressure sensors are the most costly aspect of our design, this is an important requirement to consider in pressure sensor selection. Accurate measurements are equally important, as we are hoping to have minimal tradeoffs between cost and accuracy in order to create the best, low-price system. While durability is another critical aspect of our pressure sensor selection, we considered it to be slightly less critical than the first two parameters, as from our research and discussion with stakeholders on the frequency of usage of this pressure mat, it will not be put under extensive pressure as frequently as we initially expected.

From this Pugh chart, we determined force resistive pressure sensors to be the best option for our purposes. Piezoresistive and piezoelectric sensors are both costly when being used in bulk, and specialize in measuring plantar pressure distribution and are not as capable of specializing in taking measurements on spatial parameters of gait (Zhang et al., 2022). Force resistive sensors have the lowest cost out of all the possible sensors and specialize in taking measurements of spatial and temporal parameters when instrumented into a stationary object like a mat (Prasanth et al., 2021)

Pressure Mat Material Selection & Configuration

Our pressure sensors will be integrated into a mat to create a pressure matrix which can be stepped on to determine step width, the parameter which IMUs struggle to determine. To determine our sensor resolution and size of the mat we first conducted research on current pressure mats to determine configurations and sizes currently on the market (*GAITRite Gait Analysis | GAITRite Walkways*, n.d.). From this research, we determined the gold-standard on the market for pressure mats is 4 sensors per cm^2. While this configuration allows for very high accuracy, it is not a low-price option. However, we recognize that these pressure mats determine many parameters which ours is not required to. Therefore, we considered a one sensor per cm^2 layout. Even with this configuration, based on the average step width and stride length for determination of the necessary length and width of the math, this would become a high-cost solution (Kate Webster, 2005). From initial benchmarking, research, and stakeholder

conversations, we determined a more feasible option may be an alternating sensor per cm^2 layout. Figure 18 below shows these three possible layouts.

Figure 18: Each visualization represents 5x5 cm^2 configuration. On the left is the 4 sensor per cm^2 configuration which is the gold standard on the market today and the middle configuration is the 1 sensor per cm^2 configuration that produces not as accurate data but is still suitable for a lot of uses. Finally on the right is the alternating sensor configuration that would cut our costs in half and provide sufficient data to measure step width.

Currently, we are leaning towards an alternating sensor per cm^2 layout based on benchmarking, but future work is necessary to consider the resolution and accuracy of our selected pressure sensor and consider what the minimum amount of sensors necessary is to produce measurements matching up with the accuracy in our specifications for step width. With regards to the size of the pressure mat, our initial research and analysis allowed us to determine that our mat would only need to be able to measure one full stride length to get a minimum of two step width calculations to provide to the user analyzing the data. From this, we found that a mat with a length of 2 meters would cover the patients' stride lengths which would allow for data to be collected accurately and holistically through a whole stride without them having to adjust their gait during testing on the mat (Hollman et al., 2011). As for the width of the mat we will initially plan on making it 0.75 meters wide which is based on the benchmarking of current solutions on the market (Kate Webster, 2005). We are confident that the 2 x 0.75 meter mat will provide us with a sufficient area to allow for accurate measurements of step width. We will further confirm this initial design of our pressure mat dimensions through prototyping and testing.

In terms of the pressure mat material, we did research to determine what would function the best in a hot, open-air wet climate with electrical components. We considered the need for it to be durable to adhere to our general device requirements, as well as the need for it to be slip-resistant for our patient safety requirement. We also considered what materials were more widely available, and concluded that rubber would be a strong selection for our initial design solution (Brian Bond, 2021) (*Rubber in the World*, n.d.) (*What Rubber Materials Can Withstand High Heat*, 2020)**.**

ALPHA ENGINEERING ANALYSIS

After determining specifics of our Alpha solution, we developed a list of design worries to tackle through initial engineering analysis: the ability to calculate step width from the pressure mat, the ability for IMUs to collect and output accurate gait parameter data, and the overall price of our system fitting within our specification. Our device's ability to provide accurate parameters of stride length, step width, cadence and distance was ultimately our main concern. Therefore, we began our engineering analysis with theoretical and experimental analysis on the IMU and pressure mat systems available to us. This is the area of expertise we felt the most uncomforTable with, so sorting out challenges associated with computational and electrical components of the solution was prioritized as preliminary tests. The bulk of the testing conducted has focused on data processing for both the pressure mat and IMU. This was based on the assumption of mostly seamless data collection and transmission. Because our solution contains advanced technology sensors, we also had a concern and overall design worry on implementing the solution within the price specified by the Poovanthi Center. The following engineering analyses were ultimately chosen based on the design worries we had.

Pressure Mat Theoretical Analysis

We began our engineering analysis based on the design worry of being able to get accurate step width data from the pressure mat component of our Alpha solution. The vision for the pressure mat, as mentioned previously, includes a configuration that would contain Force Sensitive Resistors (FSRs) laid out in a grid. Because FSRs provide resistance values that correlate to varying forces (*Force Sensitive Resistor (FSR)*, n.d.), a pressure mat allows a layout of FSR coordinates that we can map into a matrix and provide a gradient of force values that form a shape of a foot as visualized in Figure 19 below through Python code (see Appendix D for hypothetical pressuremat code).

We determined that Python would be a valid preliminary coding to use as it can not only numerically analyze data through Numpy, but also conveniently display data through Matplotlib. Since display and numerical results are expected in stakeholder requirements, Python as a coding language is also tested in its efficacy in data processing and display as part of the solution albeit its backended-ness as a user interface. It was also adopted because of its availability in microprocessors such as the RaspberryPi.

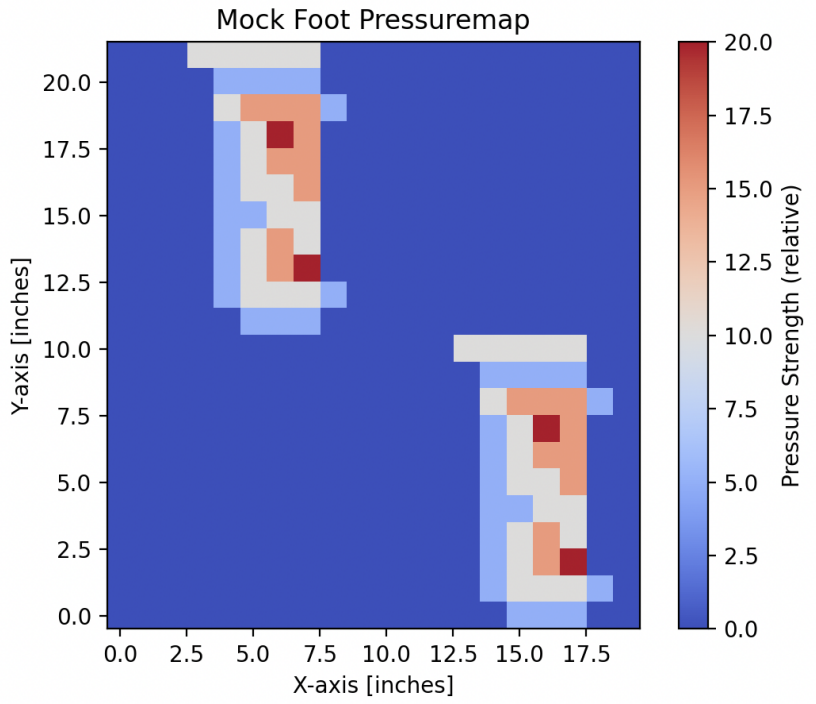


Figure 19. Hypothetical pressure gradient display coded in Python using Matplotlib.pyplot. To find step width, one should find the highest pressure point in the heels and the difference in horizontal distance.

With the imprints of the left and right feet visualized through pressure values, step width, as defined as the mediolateral distance between the heels (Skiadopoulos et al., 2020), can be determined by finding the highest pressure point in the heels of both feet and then subtracting the x-axis distance. In the Figure 19 example, the hypothetical step width would be 25.4 [cm]. Preliminary resolution calculations were quickly done as the grid can be treated as a two dimensional ruler in the x and y directions. Since the uncertainty of a ruler is half of its resolution by convention, treating our pressure matrix in similar fashions would provide us with a resolution two times that of the accuracy of step width (found in the specifications and requirements): 8.8 [cm] for the dimensions of each grid where a sensor should be placed.

Despite the initial preliminary theoretical trial, further testing needs to be conducted on other uncertainties with the pressure mat. Firstly, in order to meet the expectation of accepTable accuracy as defined in the requirements and specifications, continuation of resolution calculations and empirical testing is needed. Some ideas to improve resolution beyond adding more grids and FSRs is being able to triangulate and predict the center of the heel through surrounding pressure values as collected on the microprocessor. Secondly, being able to identify when both feet are fully on the ground during data collection will also be integral to displaying accurate data – having a foot slightly down might skew the actual step width measurements. These future tests are expected to be tested with a model pressure mat that is in the process of being built and iterated upon based on findings from data collection and analysis.

Ultimately, while we need to continue testing and mitigating bugs in our pressure mat design, our pressure mat theoretical analysis allowed us to mitigate our design worry of being able to utilize a pressure mat to obtain step width, so we believe we can move forward with this design.

IMU Mock Trial

A more realistic empirical test was conducted for the IMUs of our system in order to determine the feasibility of obtaining gait parameter data from the IMUs, which was another design worry of ours. Specifically, working with Safa Jabri, the Movella Dot IMU sensors were tested for a 30 second duration on Trevor Kessel. The sensors were attached to both his feet and shins as demonstrated by Figure 20a and 20b, respectively. Data from the foot IMUs were collected since our parameters heavily focus on where the foot is located. In terms of comfortability, Trevor confirmed that these did not hinder his gait during trial – which correlates well with our design requirement of not altering a patient's gait if a real set of IMUs were used as our final solution. This allowed us to determine the effectiveness of where the two IMUs can be placed for our design. While formative usability tests must be conducted to validate this, as a preliminary test, Trevor's experience is promising.

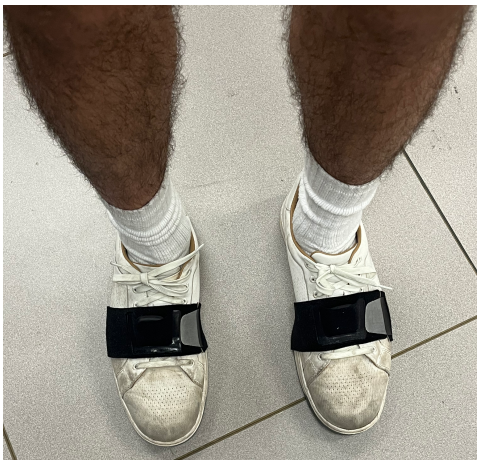


Figure 20a. Movella DOT sensors attached to "patient's" shoes.

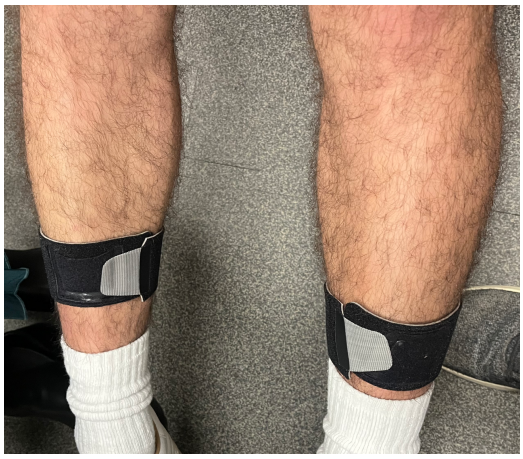


Figure 20b. Movella DOT sensor attached to "patient's" shins.

From the Movella Dot sensors on the foot, accelerometer data was collected for both the left and right feet. By connecting the IMUs through bluetooth, the data came in a comma separated value file that the team's Python code (see Appendix E for IMU Python code) was able to process. Acceleration data over time for Trevor's left foot is shown below in Figure 21a and the integrated velocity over time in Figure 21b.

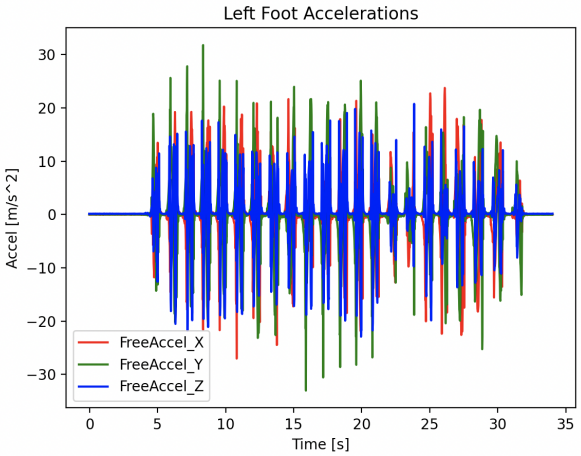


Figure 21a. Left foot accelerations

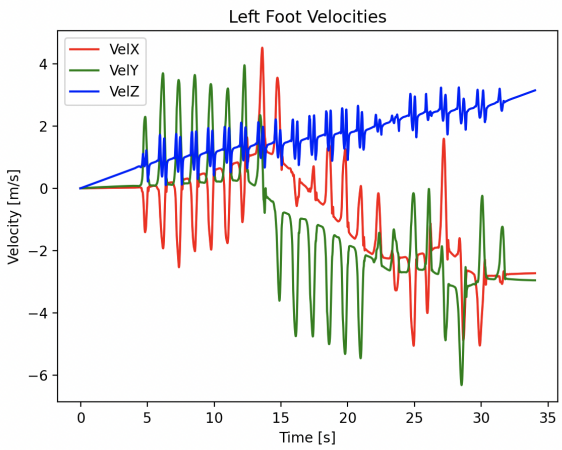


Figure 21b. Left foot velocities

The simplest parameter that can be determined from the acceleration graph without any manipulation is the step cadence. To determine such a parameter, one can look at the periodic fluctuations in accelerations as visualized through the stripes in the graph. These periodic stripes can be counted over its duration and divided by the duration to determine the cadence. For Trevor's left foot, it is approximately .84 steps per second. By adding that with his right foot over the same interval of time, his step cadence can be determined. Further coding tests must be performed to determine the accuracy of such a method through longer tests and cross-examinations with a pedometer and stopwatch.

Being able to manipulate the data from the IMU was the first step to determining the remaining gait parameters, including stride length and distance. For stride length, the integrated velocity needs to be further cleaned from integration drift (errors from integration) and integrated again to find position and thus distance. Moreover, the program should be able to identify the distance that changes the position during periodic time intervals of gait as the stride length.

Considering that distance lies only in the horizontal/2D plane of the ground, only the x and y accelerations need to be considered to double integrate and find positions and then, through the Pythagorean Theorem, triangulate both stride length and step distance. However, this is easier said than done, as accuracy decreases as one integrates over noisy data. This is the next hurdle in testing we must tackle to be able to measure all parameters as accurately as possible. We will be consulting Safa Jabri on the mathematical algorithms that can help us overcome this processing challenge in the upcoming days. Additionally, Dr. Ojeda will be available to us as a resource for tackling our post-processing challenges.

Beyond the data processing, we will also begin testing Bluetooth functionalities with the RaspberryPi in order to automate the data collection process with our own IMUs. Bluetooth Low Energy is one mechanism that will be tested with both the IMUs and pressuremat when built. We

have to determine whether or not the microcontroller will be able to handle the streaming of data coming from both the pressure mat and IMUs – depending on the answer, separate walking sessions for either the pressuremat or IMU might be recommended. Meanwhile, display functionalities for the physical therapists will also be a source for further testing. Theoretically, the RaspberryPi has the power to display performance metrics using Python as our code did onto a monitor as connected through HDMI. This semester, we will be creating a build design solely utilizing Python on a laptop screen, but our final design which would be the final implementation at the Poovanthi Center would utilize a RaspberryPi. However, this needs to be built out and validated as a function.

Ultimately, our IMU mock trial engineering analysis allowed us to mitigate our design worry of being able to utilize IMUs to obtain accurate gait parameter measurements, so we believe we can move forward with this aspect of our solution.

Cost Analysis

Our third engineering analysis consisted of a basic cost analysis due to our design worry that the device was stretching above our low-price specification of 30 lakh Indian rupees. While the selected IMUs were chosen to be low-cost, we had to analyze the total number of FSRs as well as the cost per FSR to determine how expensive implementing the pressure mat would be. For the basic materials, such as the Raspberry Pi, transceiver, and breadboard, the total cost adds up to ₹11,103 (see Appendix F for details).

For the FSRs in the pressure mat, after our analysis determining the need for alternating FSR's every 1 [cm^2] for a 5x1 [m^2] mat, we found that we would require a total of 20,500 pressure sensors. Based on a shopping cart analysis from Amazon India, the average force resistive sensor costs ₹815. This totals to 16.7 lakh solely for the cost of the force resistive centers for the pressure mat.

While a single implementation of our solution fits under the 30 lakh budget, simply implementing one device would not be sufficient for the needs of the Poovanthi Center and the amount of patients that would need to use the device per therapy session each day. Therefore, our cost analysis has failed, and we need to reassess our design solution.

ALPHA PROBLEM ANALYSIS, CHALLENGES, AND REFLECTION

After conducting our Alpha solution engineering analysis, we were not left confident that our solution would be feasible for the design problem. We reflected on the challenges we might face with this solution in order to determine if we should move forward with the design.

Eliminating Data Error: Increasing Accuracy in Analysis

From mock data analysis trials, a major challenge which the team is unfamiliar with is the reduction of error in both the pressuremat and IMU measurements. Firstly, as mentioned in the pressuremat engineering analysis, the concerns for error come from the resolution from the coordinate grid of sensors. Resolution scales with the increase in grid size. The specification of the mat that still needs to be answered is the resolution that is necessary to maintain accuracy across all morphological feet sizes. Although we can calculate the best resolution for one foot, a smaller foot might compromise the accuracy of the pressure gradients in determining the center of the heel where the medial lateral difference provides the step width. Finding the minimum foot size from Indian morphological data is necessary to calculate the resolution of the pressuremat, which is a standout technical challenge we anticipate. Both first principles and empirical testing will be conducted to validate the research/benchmarking done for the pressure mat specifications section above.

For the IMUs, the looming challenge is dealing with integration drift (*How Do I Calculate Position and/or Velocity from Acceleration and How about Integration Drift?*, n.d.). This is another mathematical concern as it heavily compromises the accuracy of positional inferences from double integration of the acceleration data. Because the team is unfamiliar with methods to reduce such errors, this anticipated challenge is top of mind to resolve in the engineering analysis process.

Uncertainties about Data Transmission for Analysis and Display

Theoretical data processing has been conducted through analysis through a mock pressure matrix as well as trial IMU data using the Movella DOT set. However, these were completed on the assumption that transmission is seamless and readily available. Once the testing and prototyping moves onto transmission, our lack of expertise will hinder us from quickly understanding the challenges that come with transmission from the numerous sensors from both the mat and IMUs. Qualities of transmission that we feel uncomforTable with include latency and load. Latency could compromise the accuracy of data, especially those that are time dependent – mathematical integrations over time for distance and stride length as well as a direct dependence on time for cadence. Our processor must also be able to retrieve data without being overloaded with information. If the transmission is sending an intense amount of data, how will our processor be able to handle it and not miss valuable information? Another large concern is determining how to link 20,500 pressure sensors and transfer that amount of data to a display. This would require very challenging and messy wiring, and could pose a threat to the time it would take to process data and send it to the display for the end user.

Low-Price Requirement

While eliminating errors in data analysis and uncertainties about data transmission were big challenges we determined from our engineering analysis, the main design problem we realized

we had was based on the sheer amount of FSRs our design solution requires. Not only would 20,500 sensors be a challenge to wire and link, but this would also be an incredibly high-cost system at over 16 lakh.

Ultimately, while our initial engineering analysis allowed us to determine the feasibility of obtaining gait parameters from this system, the high unit cost per force resistive sensor, large amount of sensors required, and challenges linking a large number of pressure sensors are high risk for our solution. Therefore, while the IMUs are still a feasible option, we have decided to not move forward with the pressure mat component of our Alpha solution.

BETA CONCEPT GENERATION

After determining our Alpha design solution would not be feasible to move forward with, we went back to the drawing board and began concept generation for our Beta design. Since our initial Alpha engineering analysis showed us the feasibility of using IMUs to collect temporal data, this process began by focusing on the spatial parameters with the need to create a solution that does not require the use of pressure sensors. Therefore, we shifted our thinking to create a less technologically-focused design.

We began the Beta concept generation process by utilizing analogical thinking to find various ways to detect footprints. The *Crayola Toddler Touch Light* was the first analogical object that was brought to our attention and was the basis of our thinking while moving through the concept generation (Crayola, n.d.). After discussion with Dr. Sienko of our design pivot based on our worries, she brought our attention to this toy that she had purchased for her children. We then began creating a list of ten analogies to our design problem, and consulted our MECHENG 450 class section in a brainstorming activity to add to our list, shown below.

1. My First Crayola gel toy
2. Heat sensitive paper/thermochromic surfaces
3. Foam mattress
4. Playdough
5. 3D pin art board
6. Magnet drawing toy
7. Liquid crystal display
8. Paint and paper
9. Dusty surfaces
10. Styrofoam

These analogies guided our concept generation for our Beta design, as we considered the full-scale feasibility of each one for our design problem.

After utilizing analogical thinking, we had to find a structured method to build on the analogical concepts we determined. We utilized brainwriting starting with the analogical concepts and

passing around our ideas to flesh them out and turn them into entire concepts rather than parts of full systems. An example of this process was when one member created an idea of using the foot imprints that would be created by a person walking on a foam mattress. Other team members built on this concept by adding camera processing methods and details on what would be worn on the foot to deform the mattress. Ultimately, using brainwriting allowed us to analyze the feasibility of using the analogical concepts in our full-scale design to measure the spatial parameters of a patient.

BETA CONCEPT SELECTION

In order to converge on a final Beta design, we started by filtering our analogies based on the following: full-scale feasibility, the design's ability to hold footprints, resolution of the footprints, and how easy it would be to walk on without impacting gait. Our first step in concept selection was to choose the type of mat we would use, then we were able to decide on the other subfunctions related towards our selected mat concept.

Mat Concept

Based on the parameters above, we determined the top three mat concept analogies: gel display, magnetic display, and liquid crystal display (LCD) screen. As shown in Figure 22, all three concepts stemmed from kids' toys that use different methods to allow for a user to display an image through unconventional drawing methods.

Figure 22: From left to right Crayola Toddler Touch Light, MagnaDoodle Magnetic Drawing Board, and Boogie Board LCD writing Tablet.

The *Crayola Toddler Touch Light* is a kids toy with a display containing gel enclosed by a plastic substrate which covers a brightly colored background, this toy is what inspired the gel display concept (Crayola, n.d.). When the user maneuvers the gel around in the display, they uncover the brightly colored background and a low resolution image can then be displayed. To better understand the product and its ability to produce high resolution footprints we purchased the product. Following our testing we found multiple issues with using this technology for our final design. First, the gel under the film did not move simply from pressure but seemed to be displayed by the friction generated when dragging a finger across the film. Also, when trying to create imprints we found that the resolution was not at the degree necessary to make accurate

measurements and the imprints disappeared at a rate that would be too quick for us to make any measurements using software.

The *Magna Doodle Magnetic Drawing Board* was the inspiration for our magnetic display concept (Magna Doodle, n.d.). The magnetic drawing board consists of a magnetophoretic display and a magnetic stylus to produce an image from iron filings within the display. The board is filled with a viscous fluid containing magnetic particles which are drawn to the top of the fluid by the stylus and can display an image from behind a clear plastic substrate. The magnetic particles are then able to stay on top of the white liquid due to its viscosity. To reset the display, an eraser magnet on the other side pulls the particles back down from the top of the liquid.

The final concept that we decided to weigh was an LCD display and the *Boogie Board LCD Writing Tablet* is what inspired this concept (Boogie Board, n.d.). The writing Tablet utilizes pressure sensitive screens that produce an electrical current when a stylus is pressed down upon it. When the electric charge is applied, the molecules in the screen realign to give way for a brightly colored background to display an image (Montbach et al., 2016).

Table 12 below weighs all three of these concepts against the following: safe to walk on, its ability to be reused, the resolution it has to display footprints of the user, and how durable it is. When weighing these options, we considered how the concept would function as a full-scale mat.

Table 12: Pugh chart of mat concepts

Criteria	Weight of criteria	Gel Display	Magnetophoretic Display	LCD Screen
Safe to walk on	5	0	+1	+1
Reusable	4	0	0	+1
Resolution	4	0	+1	-1
Durable	4	0	+1	+1
TOTAL:		**0**	**+13**	**+9**

Since safety is our top priority and the most critical of our weighted criteria, this was weighed the highest. Since our patient population have gait disorders and are stroke victims, their fall risk is already high and it is important we do not heighten this risk with our device. Reusability refers to the ability and ease of performing multiple trials in a quick and effective manner. While this is important for our design, it is not as critical as safety, and was therefore weighed slightly less. The resolution ability of the display was also weighted the same, since the display must accurately show the patients footprints, but there is wiggle room in that our image processing

technology can be developed to remove noise and error. Lastly, durability is of the same importance, as it is important for the mat to be feasible for a long-term clinical setting, but replacements for components are also possible along with maintenance occurring overtime.

After weighing all three concepts using the gel display as the control, we concluded that the magnetophoretic display is the best option to move forward with for our final Beta design. This display concept performed the best due to its thin and rigid base which will not impede gait, high resolution due to the size of the magnetic particles, and durable material. While its ability to be reused is not as effective as the LCD screen, we will find a more feasible erasing method in order to improve its reusability.

Shoe Attachment

Our next concept selection after deciding to move forward with the use of a magnetic mat was to determine how we would attach magnets to the patients' feet, similar to how the stylus is used on the magnetic display toy. Based on a conversation with Lucy Spicher, we determined three possible concepts: magnetic soles, straps, and adhesive (Lucy Spicher, personal communication, November 9, 2023). Magnetic shoe soles would have magnets embedded in them. For our purposes, an entire custom set of sandals made for the Poovanthi Center with shoe sizes ranging from the 5th to 95th percentile of both male and female would be required. Magnetic straps would be adjustable attachments to the foot with the magnets placed on the bottom of the patient's shoe or foot. Finally, magnetic adhesive is magnetized rubber with an adhesive backing that can be cut to size of the shape needed. Table 13 below shows the three possible solutions weighted on their ability to be safe to walk on, reusability, and resolution.

Table 13: Pugh chart of shoe attachment concepts

Criteria	Weight of criteria	Soles	Straps	Adhesive
Safe to walk on	5	0	-1	+1
Reusable	4	0	+1	0
Resolution	4	0	0	+1
TOTAL:		0	-1	**+9**

Weighting our criteria similarly to their weights for the mat concept selection Pugh chart, we determined the best method to attach the magnets to the patient would be through adhesive. This option, while not reusable, would be safest to walk on and provide the most accurate resolution

on the mat. Additionally, since adhesive magnetized rubber is not too expensive, we decided the lack of reusability would not pose a problem for our solution as a whole.

Eraser Method

After determining the mat concept and how magnets would be attached to the patients, we needed to determine a method to reset, or erase, the mat. This would be critical in establishing its reusability in the clinical setting. The two concepts that we analyzed as possible solutions were a sliding magnet on the backside of the mat and an electromagnetic current that would be sent through the mat to produce a magnetic field on the backside of the mat. The sliding mechanism is the method used on the initial kids toy concept we based our Beta solution off of, and it is a magnet the width of the display placed on a track that can be slid on the backside of the display. The other method that was looked at comes from the LCD writing device. It has a conductive film layered behind the display screen, and the press of a button sends an electric current through the film to create a magnetic field (Montbach et al., 2016). Table 14 below shows both of the possible erasing solutions weighted against the criteria of their full-scale erasing ability, reusability, and overall full-scale feasibility.

Table 14: Pugh chart for mat eraser method

Criteria	Weight of criteria	Slider	Electromagnet
Full-scale erasing ability	5	0	-1
Reusability	4	0	+1
Full-scale feasibility	3	0	-1
TOTAL:		**0**	-4

For this sub-function of our Beta design, full-scale erasing ability was the criteria weighted the highest because of the sub-function critical need of being able to fully erase and reset the mat prior to each trial conducted with a patient in order to gather accurate data. Next up, reusability was weighted next because the mat will be used multiple times a day in the rehabilitation center and it must be easy for a physical therapist to use the eraser method after every trial. However, it is not as critical as the first need. The final criteria was full-scale feasibility. Full-scale feasibility relates to the ability to implement this technology on a large enough scale to be effective on the size of the mat we plan on making. This was weighted last given that we could explore options for making a concept more feasible on a large-scale rather than completely eliminating it as a possible solution.

After analyzing both the slider and electromagnetic concepts, we determined that the sliding eraser mechanism best suits our needs. Even though the electromagnetic system would be very easy to use for a physical therapist when it comes to the reusability criteria, there is not enough research or similar benchmarks with which we could base our analysis off of to determine how to implement this technology. This would be another novel solution that would be very difficult to implement at the large full-scale size of our mat. Therefore, the sliding eraser mechanism is what we decided to move forward with for our final Beta design.

BETA DESIGN FINAL SOLUTION

After thorough analysis for our Beta concept selection process, we decided on our final Beta design which comprises a novel solution towards identifying the footprints of a patient which then provides data on gait parameters through image processing. Figure 23 shows an illustration of our Beta design concept. It should be noted that the IMU technology from our Alpha design solution will be utilized in our Beta design as well.

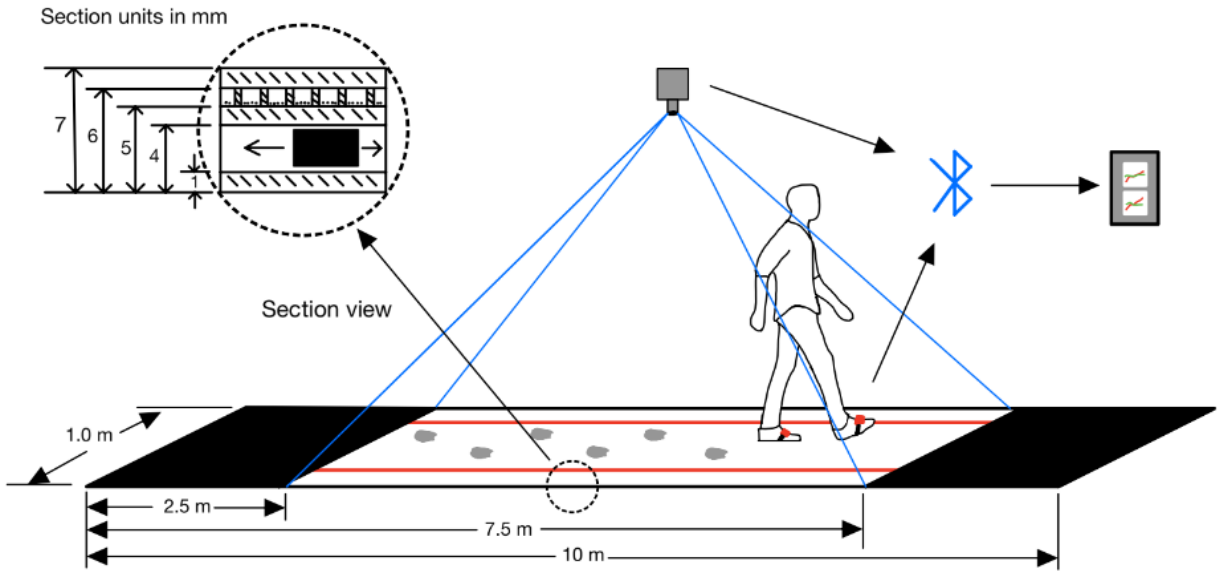


Figure 23: Beta Design Solution. Consists of a magnetic mat with gait initiation areas and cameras for data analysis. The camera imaging of the mat is paired with IMUs and both data is transmitted via bluetooth to a display. The section few shows the dimensions in mm of the slot for the sliding eraser mechanism underneath the magnetic mat.

Our Beta design consists of a magnetic mat with two gait initiation areas on either side. Cameras will be positioned above the mat to capture images, which will be used to process data on the patient's gait parameters. Via bluetooth technology, the data will be transmitted to a Tablet for the physical therapist to analyze and determine the patient's challenges in regards to their gait. The IMUs, which were selected with our Alpha design concept, will also be paired with this system to collect temporal gait parameters and allow for data to be collected off of the mat when necessary. On top of the magnetic mat, there will be two red lines parallel to the edges to show

the patient using the mat where they should be stepping to avoid a fall risk. If they step over the red lines, their footsteps will still be recorded but they will be much more safe from stepping over the edge of the mat.

Magnetic Display

Our magnetic mat features a magnetophoretic display, which functions on the principle of magnetophoresis—a process where particles move through a medium in response to a magnetic force (Munaz et al., 2018). Comprising two key components, a rigid structure and a viscous liquid with magnetic particles, a magnetophoretic display balances the viscosity of the liquid and resolution of the structure to produce a clear image. As shown in Figure 24 below, the magnetophoretic display works when a magnet is applied to the top of the display, producing a magnetic field strong enough to pull the magnetic particles from under the viscous liquid to the top of the display. The dyed-white viscous liquid enhances contrast and, due to its viscosity, prevents gravitational effects on the particles, maintaining them on the liquid's surface. In order to reset the display, another magnet is placed on the backside to pull the particles back through the liquid.

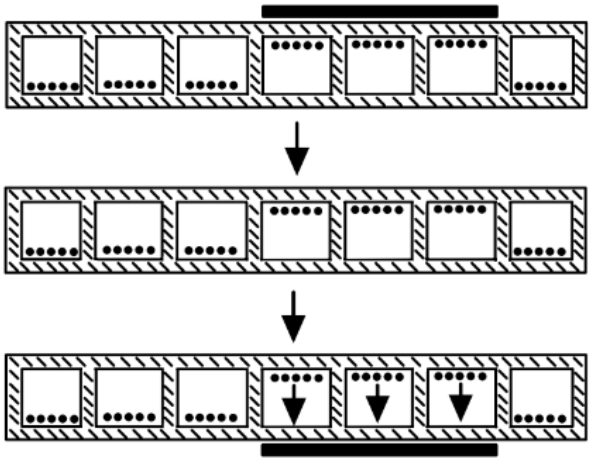


Figure 24: Magnetophoretic display. Magnets are applied to the top and bottom of the display to affect the magnetic particles in the viscous liquid.

The solid structure incorporates a cell-like pattern between two plastic substrates to maintain a consistent density of magnetic particles in the liquid. Within the viscous liquid – consisting of an oil base, thickener, and a colorant – the oil base is crucial to prevent the risk of rusting in the display since the magnetic particles, usually iron-based, require this specific formulation (Yan et al., 2023). The quantity of magnetic particles is measured by a weight ratio relative to the liquid to ensure uniform distribution across the display.

Magnetic Mat Dimensions

To determine the dimensions needed to obtain accurate gait data, we looked specifically to the GAITRite Mat from our benchmarking analysis, which has a length of about 4.6 [m] and a width of 0.9 [m] (*GAITRite Gait Analysis | GAITRite Walkways*, n.d.). Throughout our research as well as conversations with physical therapists, we also found the need for at least 2.5 [m] of space for both gait initiation and deceleration to ensure accurate data collection, which will be placed on either side of the magnetophoretic display portion of the mat (Lindemann et al., 2008). With this in mind, we decided that the length of our magnetophoretic display would be 5.2 [m] and the width of the mat would be 1 [m]. Additionally, we allocated an additional 0.2 [m] to accommodate the storage of our magnet beneath the display without interfering with the integrity of the footprints.

The overall thickness of the mat will be a total of 7 [mm], which includes 1 [mm] for the base, 3 [mm] for the space for the sliding eraser mechanism, 1 [mm] for the bottom substrate of the display, 1 [mm] for the displays cell structure, and 1 [mm] for the top substrate of the display. Further analysis will have to be done on these dimensions to ensure the structural integrity of the entire mat while maintaining the correct dimensions to maximize the resolution from the magnetic forces applied to it.

Image Processing Method

The purpose of the pivot was to explore more “simplistic” methods that could provide the same parameters of gait that we require. Fundamentally, by measuring the distances between footprints (say, painted feet on a paper mat) would allow us to retrieve meaning gait parameters at the cost of time. However, this measurement process can be automated through digital images. By snapping photos of the footprints, we can easily run the image through software to measure the parameters by translating pixels to distances. Rather than hand-measurement, digital image processing would reduce the feedback time by manyfold.

Thus, to create a seamless image processing environment, Python was used because of its established OpenCV library and established popularity as the most efficient coding language for image processing. With its easy syntax and accessibility, it is much more preferred over languages such as Matlab or C++. Although Matlab helps with the mathematical aspect of image processing, it is quite slow. On the other hand, C++ might be faster but its syntactic logic can be quite complex in application.

Magnetic Sandals

Custom sandals will have embedded magnets within the heels to pull the iron filings to the surface on our mat. We prioritized engineering a working magnetophoretic mat before developing the sandals since much more analysis goes into a functional mat. At this moment, the mat does not perform as we intended so we could not confirm a functional sandal. However, we

imagine that if the magnet within the sandal is strong enough, it yields similar results as running a magnet over our build design. Similar to how one heel strikes the ground, the magnet will impact the mat to imprint itself with the iron filings. Our expectation for the sandal is to produce a good footprint for the image processing code to pick up. Verification tests will demonstrate the feasibility of an embedded magnet-sandal.

User Interface: Operation and Results

Our display must cater towards both the patient and physical therapist. For the physical therapist, the user interface should be easy to use, providing only the necessary functions that will allow for the physical therapist to capture the image of the footsteps for both direct analysis and processing. Figure 25 below is a storyboard representation of how the interface will guide the physical therapist through the process.

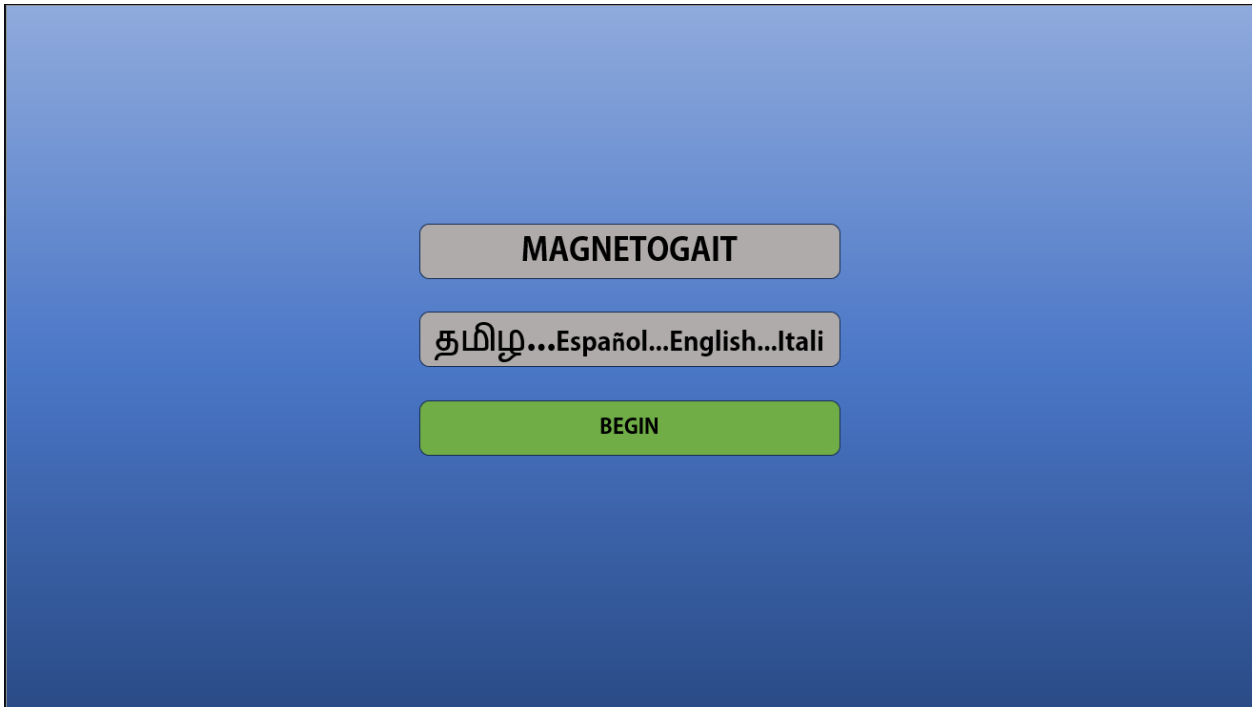


Figure 25a: Representation of the start screen. This includes the begin button as well as a button to change the language from English to Tamil as well as Telugu and Hindi, other languages that may be spoken in Madurai, India(*Languages Spoken in Madurai: A Complete Guide*, 2023). In order to make the interface globally accessible, we have included the option to shift through other large global languages.

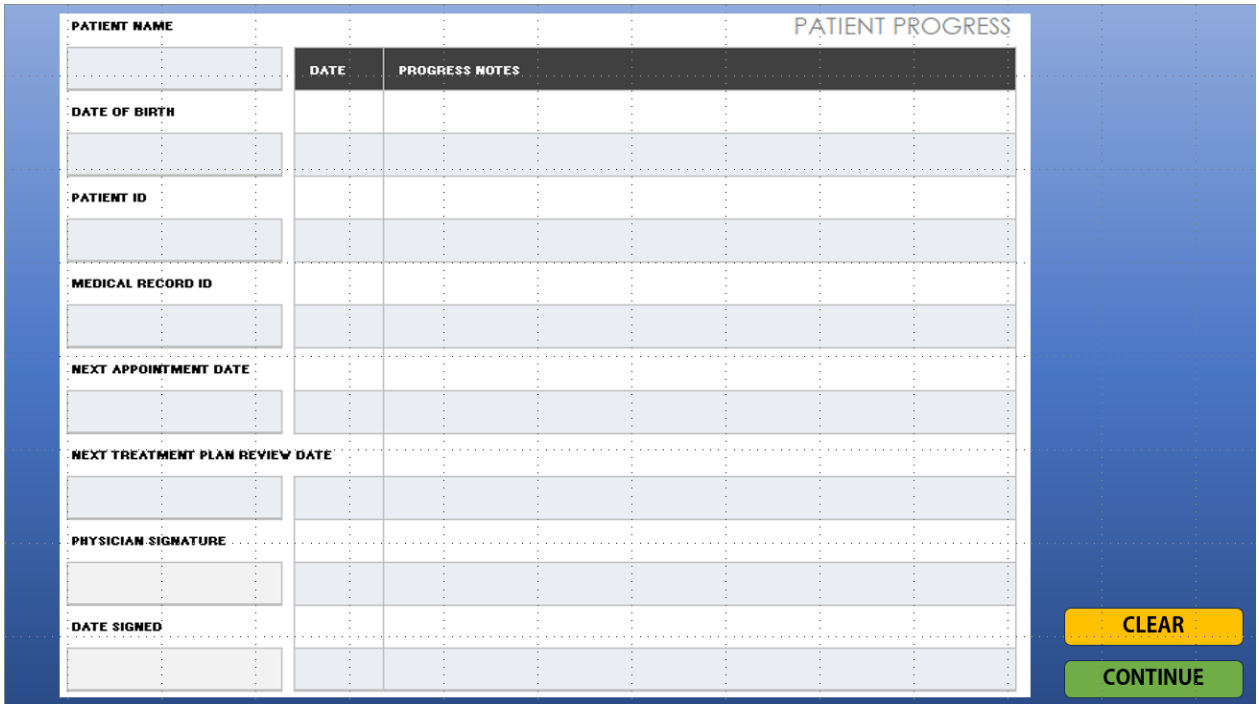


Figure 25b: Representation of the patient identification form and the progress notes.

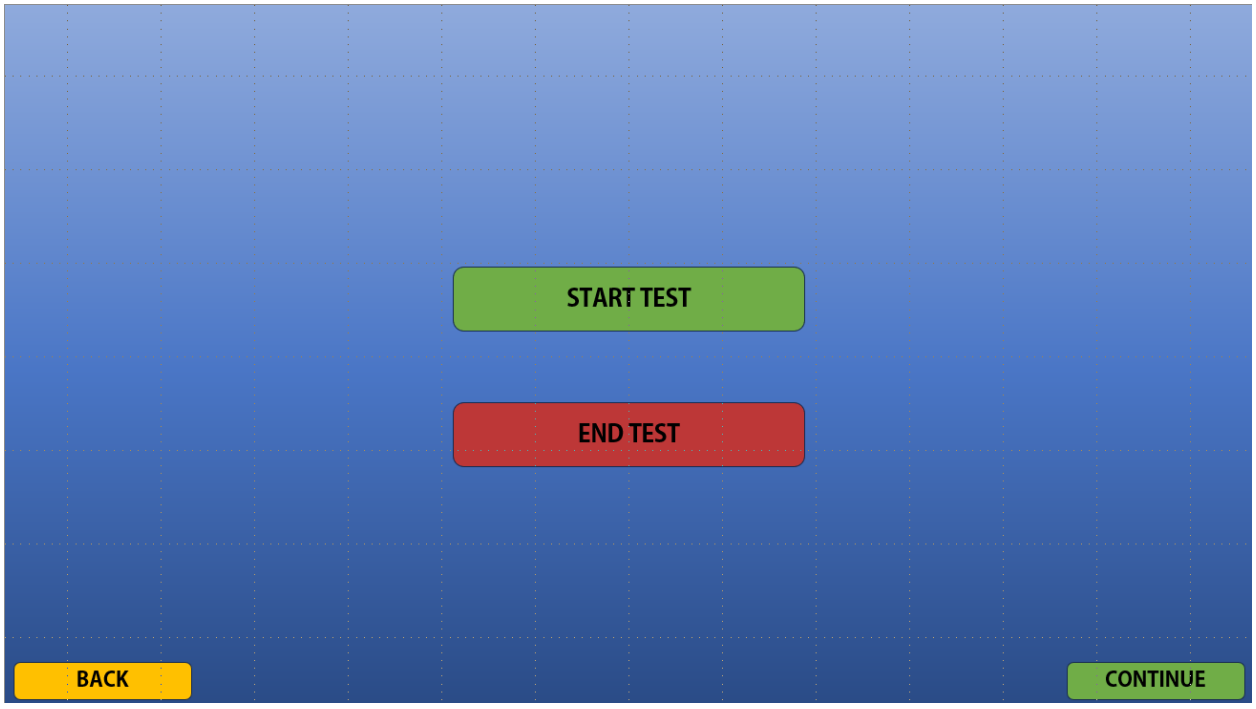


Figure 25c: Representation of the user interface for beginning the walking test on the gait mat. Physical therapist clicks “start test” when the patient is prepared to walk, and clicks “end test” when the patient is done walking.

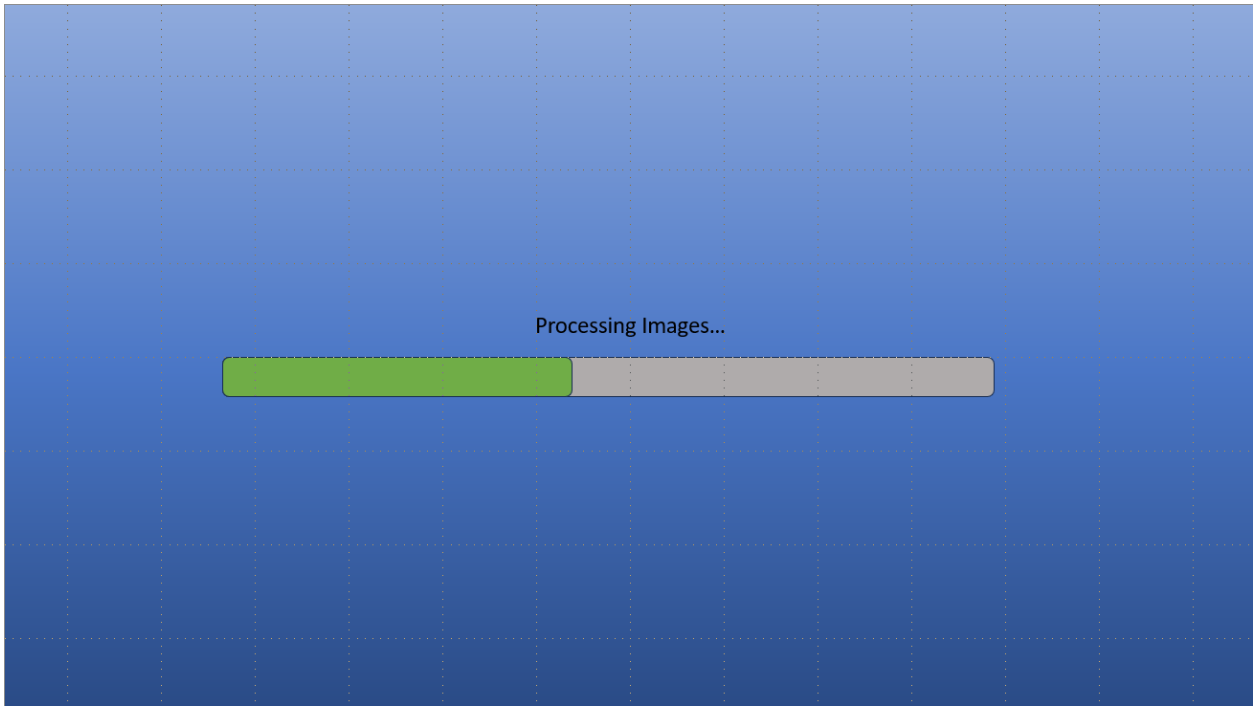


Figure 25d: Representation of the loading screen while camera is capturing images for post-processing.

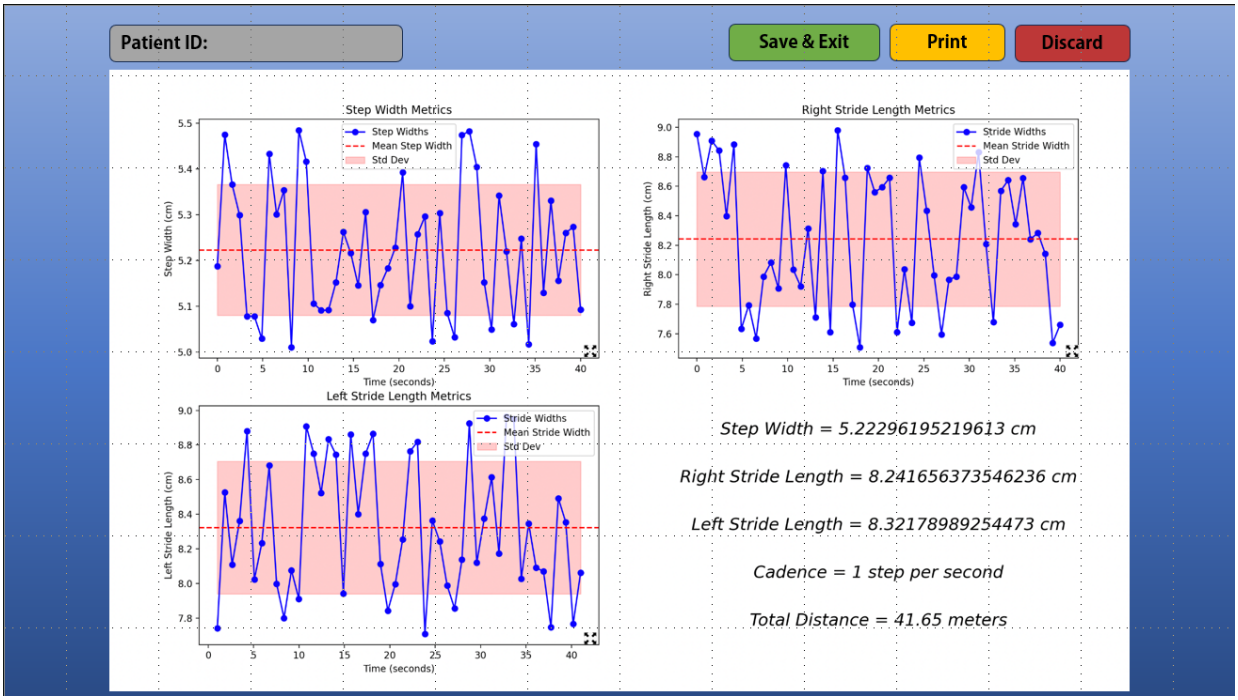


Figure 25e: Representation of the post-trial data screen. This is displayed once the image capturing and post-processing is complete. Physical therapists can print the screen to save data physically, save it & exit from the screen, or discard the trial.

The development of the user interface we will be implementing in our design was based on the Handbook of Human Factors in Medical Device Design (Weinger et al., 2011). The guidelines from the adequate UX section of this handbook can be found in Appendix B.2. Guideline 11.1.1.3 states the design must provide user guidance. Therefore, we followed the recommendation that there should be a clear operational sequence from the buttons that pop up on each screen. By having clear color-coded buttons for each direction in the sequence the user might navigate, we have provided adequate user guidance. Guideline 11.1.1.5 discusses the need to optimize interaction requirements. In order to create a user interface which allows physical therapists to spend less time interacting with the device and more time working directly with the patients, we developed screens which are brief and only contain the essential information needed to conduct a trial. This will ensure physical therapists can spend the majority of their time addressing patient needs and focusing on the patient's safety and interaction with the device. Guideline 11.1 suggests the number of elements that should be included in the display screen, stating that ten or fewer is recommended in order to create the simplest model possible for ease of use. Therefore, we created screens with minimal buttons to ensure the display is easy to follow for the physical therapists. Guideline 11.15 elaborates on the necessary text size to create adequate UX, recommending a character size of 1/150th viewing distance. It also states that a key parameter value on a patient monitor viewed from three feet away should be greater than or equal to a quarter of an inch. This is similar to the setup of our device in the Poovanthi Center, so this is what we are following.

Beyond following the Handbook of Human Factors in Medical Device Design, we also conducted a usability test as well as considered the cultural context of our design space in order to create a display screen tailored towards our design context. In our brief initial usability test, we showed our display mock-ups to five individuals of various backgrounds, considering them to be the physical therapists. One by one, we showed them the display and asked them to tell us how they would navigate through a trial, how they would restart a trial, and how they would collect the results from a trial. From this test, we determined the need for additional "back" and "continue" buttons to make it very clear how to navigate through the screens. In terms of cultural context, we considered the need for a language button, since the main language spoken in Madurai, India, is Tamil, however there may be patients or physical therapists who are more comfortable with other Indian languages. Since India has an incredibly diverse amount of languages, it was critical for us to address how understandable the interface would be to end users in our cultural context.

Manufacturing Considerations

At this point, since we have developed the details of our Beta solution late in the semester, we have yet to determine the most feasible manufacturing plans based on the details of our final design solution. Once the materials still under consideration are selected, such as the liquid being used, we recommend considering the best machinery and devices to create this design. While we do not have a specific manufacturing plan, we have considered manufacturability and broad issues associated with manufacturing throughout the design process. Some considerations are where the best location to manufacture the device is for efficient distribution, where we would be able to locate optimal materials for the device's design, and how we would manufacture safely to ensure no leakage from the liquid outside the mat components.

BETA ENGINEERING ANALYSIS FOR DESIGN WORRIES

After developing our Beta design concept, we wanted to identify design worries that would cause our Beta design to fail. This would allow us to determine which components of our design to conduct detailed engineering analyses on in order to feel convinced in the likelihood of success. This would also allow us to determine if we should move forward with the Beta design. Since our engineering analysis on our design worries previously failed our Alpha concept, we worked to be as specific and comprehensive as possible in our design worries for our Beta solution to ensure our engineering analysis would prove its feasibility. To assess this as a group, we identified any aspect that we felt would interfere with the success of our final design. We determined that if we are able to prove that the main design worries will not cause failure, we can continue moving forward with the design and consider verification and more complex testing. The following list shows eight major design worries that we considered may cause our Beta design to fail:

1. The thickness of the mat may cause tripping

2. There is not a strong enough material for the partitions
3. The image capturing device may have skewed results
4. We will not be able to measure the length and width of the footprints using algorithms
5. The mat will not be long enough to produce sufficient data
6. The magnets will not be strong enough to lift the iron filings
7. There is no sufficient pattern for withstanding forces while maintaining high fidelity of the foot
8. Are the selected materials suitable for the 3 [mm] deflection we are considering for the erasing mechanism

After reviewing the list we have identified the five design worries that we feel need further analysis and need to be prioritized. Ensuring these five worries are addressed would allow us to feel confident in moving forward with the design, as they are ultimately the main drivers of our design. The worries are listed as follows:

There is not a strong enough material for the partitions

Our worry was that we would not be able to find a suitable material that can withstand the forces or energy of a person running on the mat. This problem arose because the area of the partition will have walls of a certain thickness in millimeters that is much less than the space that is compartmented for the liquid.

There is no sufficient pattern for withstanding forces while maintaining high fidelity of the foot

Our worry was that we will not be able to find a suitable pattern and dimensions for the walls of the partition with the material we have selected while mitigating the resolution of our design.

The selected materials for the 3 [mm] deflection are not suitable for the eraser mechanism

Our worry was that the materials we have selected will not be able to deflect the 3 [mm] that we have accounted for in our full design. The deflection is due to there needing to be an erasing mechanism for resetting the iron filings. There is a 3 [mm] slotted hole so that a magnet can be put under the display and pull the magnets back down.

The magnets will not be strong enough to lift the iron filings

Our worry was that we will not have a strong enough magnet to lift the iron filings through the viscous material.

We will not be able to accurately measure the length and width of the footprints using algorithms

Our worry was that we will not be able to accurately measure the stride length and stride width of the footprints using algorithms. Since we have pivoted towards using images that will be read using algorithms, we must ensure that the data we collect produces accurate measurements.

Partitioning Material Analysis

The first design worry we identified was trying to find a material for the partition that would be able to withstand the pressure and impact energy of people walking or even running on the mat while maintaining the minimum heel area on the mat. In order to analyze this, we had to establish two extremes: the heaviest person and smallest heel area. The smallest heel area was based on the 5th percentile Indian women's length and width, which was 204.17 [mm] by 73.095 [mm] (Hajaghazadeh et al., 2018). Following this, we assumed the heel area to be one third the length and one half the width of the total foot size giving us a total heel area of 1243 [mm^2] (Luo et al., 2009). We asked Dr. Shibu about the heaviest weight we can expect, which turned out to be around 164 [kg] (Dr. Shibu, personal communication, September 11, 2023).

After establishing both of the extremes, we were able to explore which material would best suit our need for the partition. Initially, we were fixated on using ABS plastic for our partitioning design. It was not until stakeholder Lucy Spicher questioned this decision that we decided to look into other materials. After further considerations, we decided to also look into aluminum, which is known to be a very strong material. Table 15 shows the material properties that are most prevalent to our design worry and this engineering analysis.

Table 15: Material properties of Aluminum and ABS plastic needed to address our design worries. 1: (Haidar et al., 2016); 2: (Narayan & Rajeshkannan, 2017) 3: (MatWeb, n.d.) 4: (Ming-liang et al., 2018)

Material	Aluminum	ABS Plastic
Compressive Yield Strength (Mpa)	120[1]	65[3]
Impact Strength (kJm^{-2})	155[2]	41.2[4]

From the material compressive yield and impact strengths as well as our expected extremes for the patient, we were able to determine if one of these materials would be suitable for our design. Equation 1 was used to calculate the area that would be needed based on the maximum weight of a patient with respect to the yield strength of each material (Smith, 2022). *P* equals the maximum load experienced, *A* is the cross-sectional area of the force, and *F* is the compressive yield strength of the material. The results of this test can be found in Table 16.

$$A = \frac{P}{F} \quad (1)$$

After this, we determined the area necessary for the impact energy that we would expect the mat to experience. It was first necessary to identify the amount of energy we should expect from a

patient. We found that at a fast running speed of 4.4 [ms^{-1}], a 165 [kg] person's foot would release around 26.67 [J] of energy (Kelly et al., 2018). We decided to use such a high moving velocity as a safety measure. The impact energy did not vary significantly with respect to the speed that a person was moving. Equation 2 was used to determine the area that would be needed to account for the greatest impact energy that would be generated by a patient. A is the area needed, I_p is the impact energy from the patient, and I_s is the impact strength of the material. The results of this test can be found in Table 16.

$$A = \frac{I_p}{I_s} \tag{2}$$

Using these equations, we were then able to determine the percentage area of material needed under the heel area. Thus, allowing us to decide which material would best address our worry of the area needed for each material to accommodate both the compressive yield strength and impact strength. Table 16 below shows the values and results we have determined.

Table 16: Area needed to account for the expected force and impact energy of the patient

Material	Aluminum	ABS plastic
Area of material needed for Compressive Yield Strength (mm^2)	13.4	24.74
Area of material needed for Impact Energy (mm^2)	169	638
Greatest % area of heel needed	13.60	51.30

From Table 16, we have decided aluminum is the best material for our partitions, as it requires only 13.60% of the area under the heel as opposed to 51.30% of the area that ABS requires. We were also able to address our concern on not having a material that is suitable for the partition of our concept design.

We found that using theoretical calculations was the most appropriate method to address this design worry because of our timeline and budget constraints. Specifically, we do not have the ability to test lots of different materials, different partition wall widths and lengths, and different patterns. Also, this method is more efficient and less budget intensive than creating multiple prototypes. We chose this method by analyzing which aspects we might think cause issues with the structural integrity. We also did research to determine the most feasible materials for theoretical comparison. One advantage we have gotten from this method is that it is solution neutral. In other words, we only determined the area of material that is needed for both constraints. Therefore, we can conduct a more detailed analysis on the partition shape and design without having it impact the most feasible material. We feel confident in our results since our material properties come from ISO testing and our analysis was heavily research-based from similar theoretical analyses that have been done in other contexts. However, we did make

assumptions based on the area of the heel of the foot. To combat this, the most extreme cases that we expect we will encounter were used in analysis. Therefore, we feel confident with the results. As we determine the final design and create the build design, which will be presented this semester, we will consider further analysis through empirical testing. However, we feel this testing is most appropriate and sufficient to create a strong argument for the selected material.

Partition Design and Dimensions Analysis

Following our analysis of the selected material, we had to address our next worry which was the need for an effective pattern that will allow for high resolution of footprints while maintaining the structural integrity of the mat area. After doing research, we decided that a honeycomb pattern that utilizes hexagons would best suit our needs due to hexagons being one of the strongest known shapes (Kosmala & Kemmis, n.d.). Figure 26 gives a depiction of the honeycomb pattern under the area of the smallest heel we expect to see.

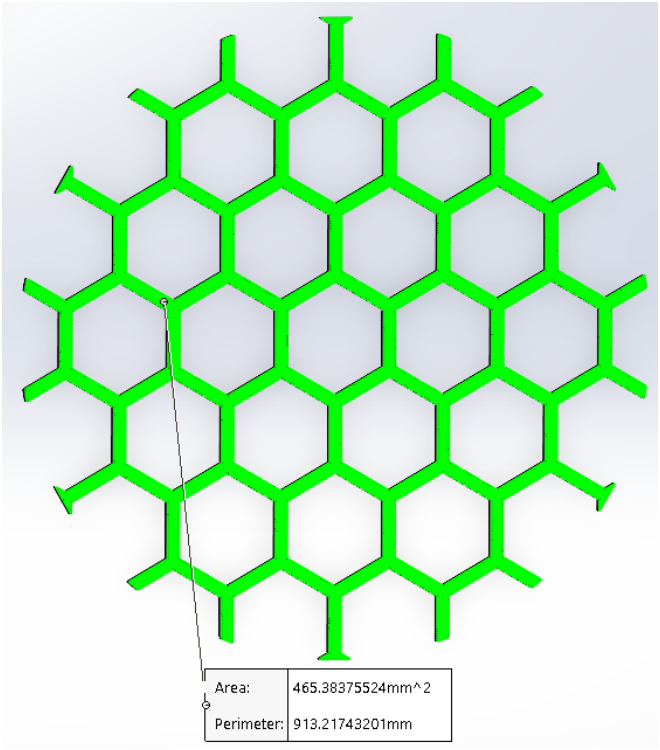


Figure 26: The area of the honeycomb pattern using a 5 [mm] long by 1 [mm] width by 1 [mm] thick hexagon. The area is approximately 465 [mm^2]

As shown in Figure 26, we found that 5x1x1 [mm] walls were best suited. This is because it gave us an area that has a safety factor of 2.75 when compared to the area we found in the material testing analysis (169 mm^2). This therefore ensures that our design is strong enough to withstand even more weight than what we expect it to receive, also therefore improving its durability over a long term.

The use of research and CAD modeling was the best method for deciding the partition patterns and design because it gave us the most quick and accurate results. We were able to use calculations that were previously made to build on our argument and expand it to a more detailed design of the partitions. Using Solidworks allowed us to get very detailed in calculating the area of aluminum that will be under the heel which instilled confidence in our results. Some limitations that we came across is that this information is all based on theoretical calculations. We now feel that further analysis should be done using a prototype with empirical testing. However, we are confident empirical testing will only confirm this determination. If we find that either this pattern is not able to withstand these forces or that it decreases the fidelity too much, we will re-evaluate our results and construct a different pattern or consider different materials.

Deflection of Display Area for Mat Reset Mechanism Analysis

Once we decided on the best suited material and pattern we needed to ensure that our final product would not break due to the slot created for resetting the mat, we needed to determine if the eraser mechanism we designed would be feasible. As explained earlier, we have created a 3 [mm] slot under the display so that we could use a magnet to reset the board easily. Our engineering analysis allowed us to determine this dimension to be feasible and feel confident in the ability for the design to function, therefore mitigating the design worry. We used the beam deflection method in which we calculated how much the beam would be able to deflect given the different material properties. Figure 27, is a diagram to help better portray our values for our calculations.

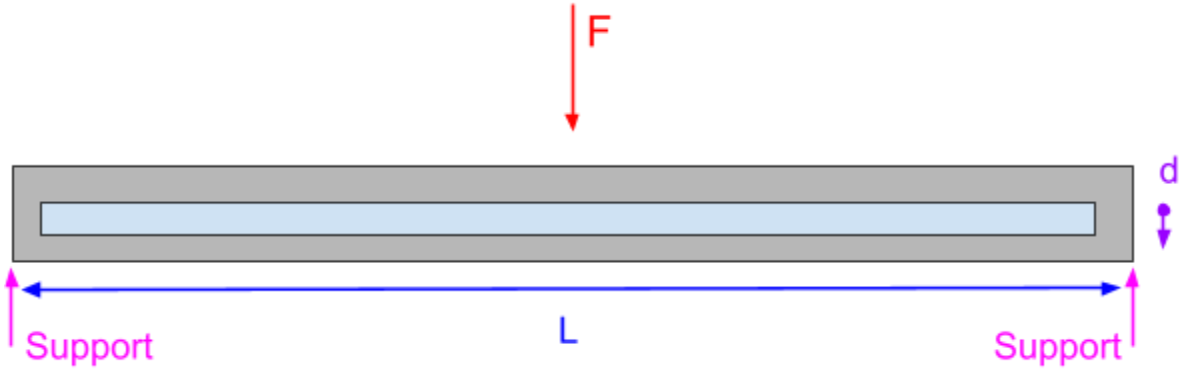


Figure 27: A depiction of the values used for our calculations

Equation 3 was used to calculate the allowable deflection for the aluminum partition as well as for the acrylic cover we will be using, where d is the deflection, L is the length of the beam, F is the force of the generated by a 164 [kg] person, I is the second moment of area, and E_{fllex} is the modulus of elasticity for either the aluminum or acrylic (Sherman, n.d.).

$$d = \frac{L^3 F}{48 I E_{flex}} \quad (3)$$

Following these calculations, we found that the acrylic sheet had a maximum allowable deflection of 14.88 [mm] and 44.56 [mm] for the aluminum. Since our slot is designed with a 3

[mm] deflection, it gives us a safety factor of about 4. Thus, helping to ensure the slot should not cause any structural issues in our final design.

We found a first principles analysis to be the best alternative to actual testing because we are not going to be able to create our full final design this semester, in which we will only be creating a build design. This gave us the confidence that our final design will be fully functional without requiring a high-fidelity prototype. One assumption that we have made is that there is no fatigue in this calculation. We made this assumption because we do not expect nor suggest people stand on the mat for long periods of time. Had we not had time and budget limitations, we would conduct empirical testing on a prototype to ensure that our design can withstand the deflections on a larger and more stress-inducing scale, but this testing can be done in the future. Further analysis that will have to be completed in the future is the effect that this design might have on the natural gait of a person. If the empirical testing fails, one alternative that we can look towards is the use of electromagnetic fields that can be created under the display to attract the iron filings.

Magnet Strength Analysis

Our fourth design worry was being able to find a magnet capable of showing the footprints of the foot. This became a design worry following our second round of prototype testing. Our goal was to prove that the ceramic rubber magnets were able to lift the iron filing through the 2 [mm] acrylic cover that is placed over the partitioned section. However, after testing we found that the acrylic cover was too thick to attract the filings. Following this test we realized we have two options: either buy and test magnets of different strength or find a different material that allows for the iron filings to be attracted. At this point, we are in the process of first testing different strengths of the magnet. Our plan is to look into three different types of magnets. The first magnet we have looked towards is the ferrite ceramic magnets. We are now looking into alnico and neodymium to see if a stronger magnetic field will prove better results. If this fails to produce better results, we will begin looking into other materials than acrylic for the cover of our design. In this analysis, we are also considering how the strength of the magnet might impact a patient’s gait.

Doing empirical testing on the ability of the magnet to attract the iron filing was the most appropriate testing method because it provides concrete results on the success. We chose this method because we already had all the materials for testing it – the kids toy and the magnets – and it was a simple but effective way to prove or disprove our hypothesis. Using the exact materials gave us great detail in our testing with few assumptions. The one assumption we made is that the viscous liquid and ferromagnetic material that is in the toy we purchased as an initial concept has the same properties as the components of our build and final designs, because we did not have our build design created at this point. Since we were not able to attract the iron filings using the ceramic magnets, further testing will be needed to test stronger magnets' ability to attract the filings. If the stronger magnets fail to create accurate footprints on the display, we will

look to change the acrylic cover thickness or material and conduct further testing. We will also take note of how the magnets impact the way a patient may step in this analysis.

Image Capturing and Data Analysis

Without the image capturing and analysis system, our design would not be able to provide the parameters in a timely manner. Thus, considering the use of an image capturing and analysis system, the design concern here is the accuracy of the measurements once the image is captured and processed. This concern derives from the fundamental uncertainties in scale and perspective. To fix the scale, one can provide a reference object that defines the dimensions of a single pixel, but with perspective distortion, these dimensions might not translate well to other objects that would be measured. Consider when the camera is pointed at an angle relative to the mat, rather than orthogonal, the angle would cause a project of the object at an angle that would distort its dimensions. To best fix these issues, Figure 28 demonstrates the use of a reference object with a camera that is orthogonal to the mat to fix both a scaling and perspective issue.

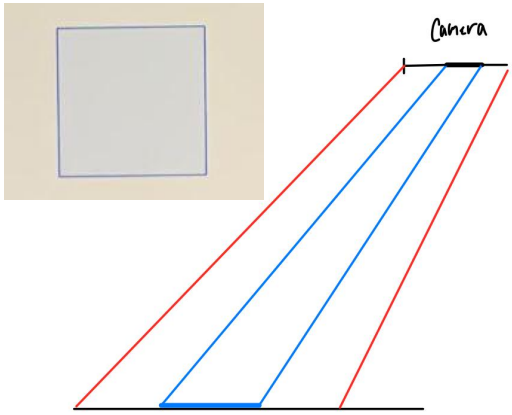


Figure 28a**.** Orthogonal camera perspective allows for accurate scaling of the relative distances between objects. The square remains a square

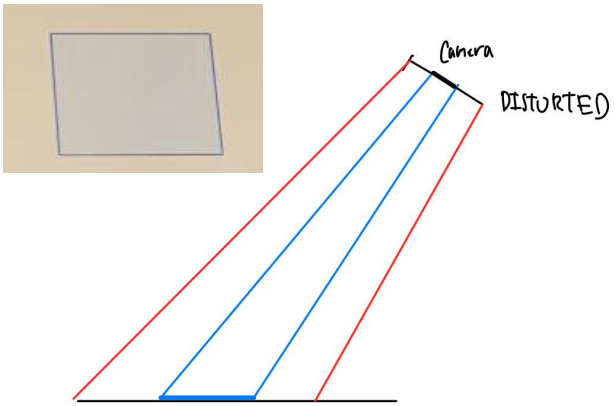


Figure 28b. An angled camera perspective distorts the shapes in an image. The original square becomes a rectangle, which can skew the digital measurements.

From the sub-figures, a simple empirical analysis on a drawn square reveals that an orthogonal camera will help maintain the relative distances between objects. Once the camera is calibrated correctly, these relative distances will scale correctly into the expected parameters that we hope to measure. An angled camera distorts objects by dramatically projecting what it sees and squeezing distances that are vertical from its perspective. However, it is noted that although empirical analysis was quick to support the theory, more quantitative analysis should be done to better understand the slight distortions that might arise on how the camera is engineered even though it has an orthogonal perspective. With more empirical testing on the build design mat, we can also code to compensate for errors if they arise.

Meanwhile, the data analysis was prototyped using OpenCV2 in the Python coding language. The algorithm first identifies the reference object, which has its dimensions provided in the input. This reference object establishes the distance a pixel represents in an image. Then, the algorithm will identify footstrikes through edge-detection and contouring, ordering them chronologically. Then, running through each foot in such an order, respective to every foot, the next chronologically closest foot will be opposite foot (left to right, or right to left) and the second chronologically closest foot will be the same foot. The algorithm can then measure stride width with the closest foot and the stride length with the second closest foot. To check the algorithm's viability, it was tested on a mock mat, with footprints drawn onto a piece of paper and a picture taken from an Iphone XR – as parallel to the paper as a hand would allow. The results are shown in the following Figure 29.

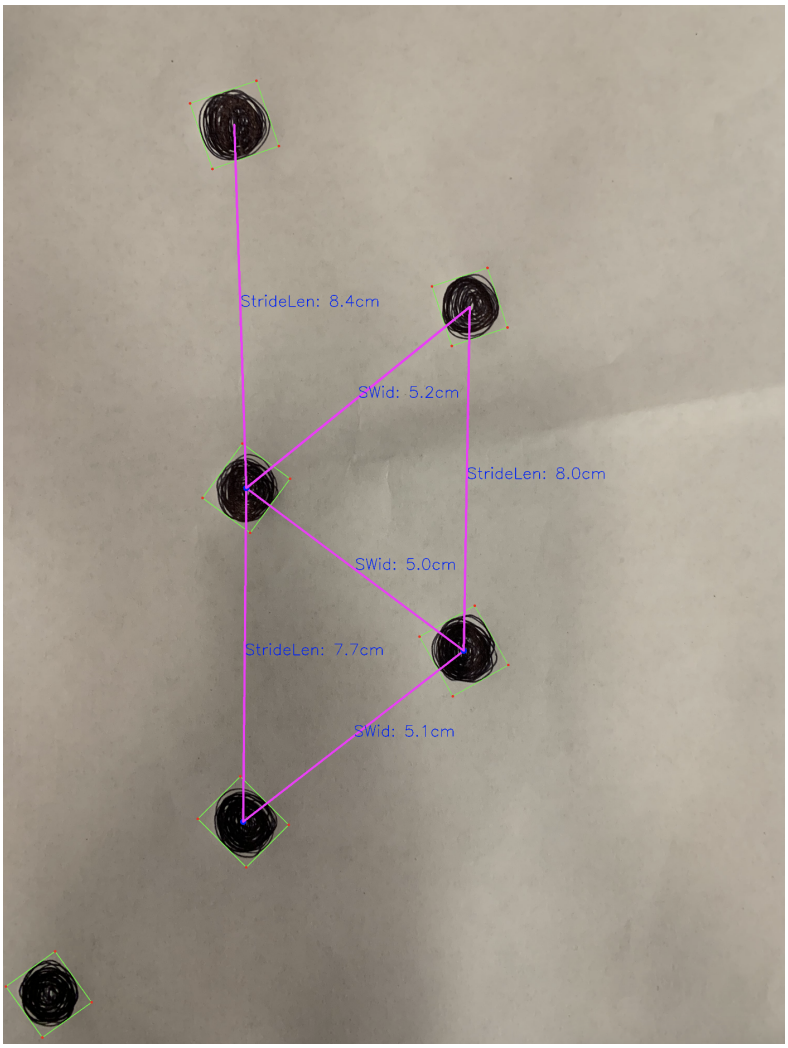


Figure 29. Mock gait image processing. A total of five "steps" were drawn and parameters extrapolated. Both stride widths and stride lengths were calculated using the processing algorithm described previously.

After running the processing code on a mock gait mat, we checked the parameter errors as opposed to ruler measurements.While the stride widths were measured perfectly, discrepancies

were apparent in the following step lengths. The sole right stride length between second and fourth step had an error of 2.4%. Meanwhile the stride length between the third and fifth step had an error of 5%, which was beyond the accuracy specification for it. However, this can be expected since the picture was taken by hand, meaning that an orthogonal view wasn't perfect, and the angle at which the picture was taken must have distorted the vertical distances, as demonstrated by the errors in stride length. Further testing with a parallel camera holder should be tested as well as further distances between the mat and the camera. Other edge cases such as odd gaits like shuffling and footsteps represented by a full foot instead of a circle for the heel can be considered through a more robust code and even machine learning. If time permits, we will be consulting machine learning experts from the university to aid us in identifying unconventional footprints.

After addressing all of our design worries we have instilled confidence that our final design will work. Although we have not been able to fully and successfully fulfill each design worry, we feel our contingency plans for each of our worries will provide us with alternative solutions that can easily be implemented into the design. Ultimately, our engineering analyses mitigated the majority of our design worries, and with further testing we can ensure additional feasibility of the concept. For the worries such as magnet strength, we will continue to iterate on concepts and conduct more analyses to improve this aspect of the design. However, there were no design worries that failed as much as they did in our Alpha solution. Therefore, we will be moving forward with our Beta design for our final product.

BETA SOLUTION CHALLENGES

Following our Beta design engineering analysis, we feel confident in the success of our concept, with a few challenges to further analyze. These challenges include:

1. Determining the best thickness for the magnetic display cover
2. Determining best materials for viscous fluid
3. Determining best angles for image processing
4. Creating manufacturing plans
5. Syncing up image capture data with IMU data

Determining the best thickness for the magnetic display cover
The main challenge regarding the thickness for the cover is that the cover has to be thick enough to provide enough structural support to the mat but also be thin enough so the magnets can effectively pull the magnetic particles to the surface. Further testing will have to be done to find the thickness that maximizes the performance of the top cover to meet these two needs. We have currently determined a solution that might not maximize performance, but definitely works. Along with this, we need to determine the magnet strength that will not impede a person's gait.

Determining best materials for viscous fluid

The current materials that have chosen to create the viscous fluid are off-the-shelf products, and the weight ratio of all the materials was determined through benchmarking. When we actually build our design, we will not be using off-the-shelf materials, so we will have to do more material analysis and testing to determine the best materials to use and the weight ratio that will give us the highest performing fluid for our purposes.

Determining best angles for image processing

The concern for the image processing is the software's sensitivity to noise. This sensitivity will be prone to circumstances such as an abnormal gait like shuffling or even highlighting the full sole instead of the heel. Also, the mat will be too large to capture all footprints in one image, therefore multiple cameras will have to be strategically placed at intervals to capture the image of the entire mat. This is our main concern on the data processing side of our system.

FINAL VERSUS BUILD DESIGN

While we've completed the detailed design phase, the project's tight timeline prevents us from delivering a fully functional full-scale final design. To evaluate various aspects of our design, we've opted to develop a prototype of smaller scale that will serve to verify and test different components of the design, called our build design. Figure 30 shows a CAD drawing of our build design.

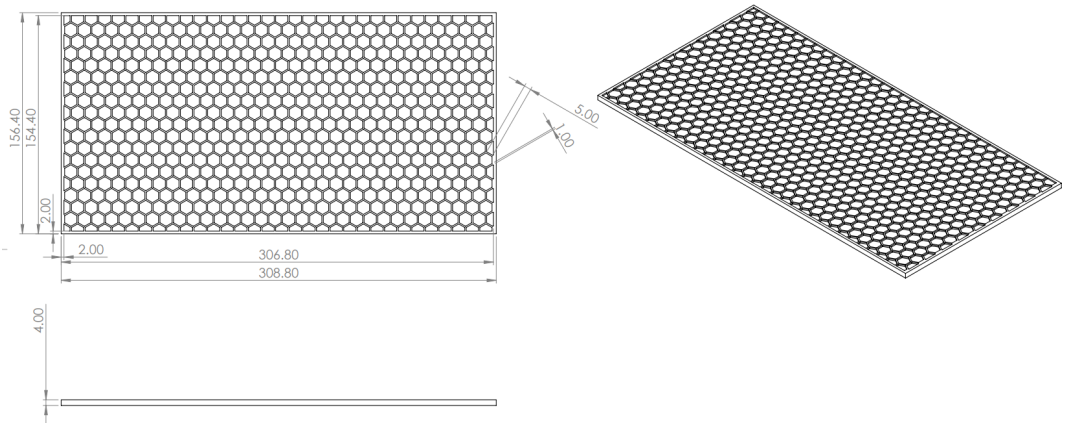


Figure 30: Engineering Drawing of our build design. All of the dimensions are in [mm].

The build design consists of a 3D-printed portion of our full-scale mat with the honeycomb cell structure we determined from our engineering analysis. With a length of 306.8 [mm] and a width of 156.4 [mm], the build design provides us with enough area to include one full footprint for testing purposes. The purpose of this build design is to provide us with the ability to test various viscous fluids, magnets of varying magnetic strengths, and top covers of varying thicknesses to determine the best combination of all three to produce the best resolution of a footprint while not impeding gait.

Beta Build Design Bill of Materials

As shown in Figure 30, the build design has a smaller length and width. However, we have chosen to keep the thickness the same as the final design. This is because our main concerns and needs in verification for the final design come from the thickness rather than the length and width of the mat. For a more detailed explanation of the build design we are creating this semester we have provided a bill of materials in Table 17 below.

Table 17: Bill of Materials for the Build Design

Part	Description	Provider	Quantity	Unit Cost	Total Cost
Acrylonitrile Butadiene Styrene (ABS)	3D-Printed base of mat design	Underground Fabrication Lab	1	$25.17	$25.17
Acrylic Sheet	2mm thick sheet	Michael's	0.67	$8.47	$5.65
Iron Filings	12-oz iron filings	Amazon	0.16	$9.97	$1.60
Mineral Oil	14 fl oz bottle of liquid	CVS	0.24	$5.99	$1.44
Talc Powder	4 oz bottle of talc powder	CVS	0.63	$2.99	$1.88
White Dye	18 ml bottle white dye	Michael's	0.1	$3.99	$0.40

The ABS plastic will be used to replace the aluminum partitions and base. We have decided to change this material for the build design so that we would be able to make the partitions clear for better analysis of any issues that we may come across while testing the movement of the iron filings through the viscous liquid. The acrylic sheet will be used to cover the display section of the build design while still allowing for a clear depiction of the footprints. However, as discussed earlier, this is subject to change because the ceramic magnets were unable to lift the iron filings through the viscous material. If we are unable to find a magnet that is strong enough to lift the iron filings, we will need to consider changing the materials.

The viscous liquid will be made using mineral oil as a base, talc powder as the thickener, and white dye as the colorant. Once the viscous liquid is made, iron filings will be mixed into the liquid to act as the magnetic particles being used in the display. The weight ratio being used to make the magnetic liquid is 25:35:40:1 of mineral oil, talc powder, iron filings, and white dye (Yan et al., 2023).

Our data processing for our build design will occur on a laptop in Python. The display will simply be the Python user's laptop screen. As previously mentioned, the final design will include a tablet screen to show more detailed parameters and include buttons to select different options. The data processing will also utilize more technology than a simple laptop with a Python application. Lastly, while a more high-technology camera system fixed above the mat will be used in our final design, our build design simply uses an iPhone camera. This is sufficient because our build design size can fit within the iPhone camera frame. Ultimately, we are able to test all aspects of the processing and display components with this build design. Therefore, this is the extent to which we will be developing our processing algorithms and display this semester.

Overall, our Beta build design differs in size, materials, and various processing components, however, it still allows us to test our major design worries through empirical engineering analysis, which will instill confidence in the functionality of our final design. Moving forward, we will use our build design to begin the verification process.

VERIFICATION & VALIDATION

Verification and validation are critical parts of the design process that can determine the need to iterate on a design solution. Verification is the process of evaluating a design's ability to meet its exact specifications. Validation is the process of assessing if the entire system fulfills the overall purpose and need of the product. We have determined both verification and validation plans for our product to determine its overall functionality, mitigate risks and concerns, and identify any areas of improvement.

Verification Plans

While we have only just begun the verification process due to recently establishing our Beta design solution, we have developed in-depth verification plans for each of our specifications. We have grouped these by the type of requirement each specification addresses: general device requirements, operator requirements, and patient requirements. We determined three possible categories of verification methods: experimental methods, met by design, and trivial analysis. Experimental methods may be used for more complex specifications which require additional testing to determine if they are met. Met by design refers to specifications which the design solution was created to meet, such as dimension or power needs. Trivial analysis refers to specifications that can be easily assessed to confirm whether they have been satisfied, such as price constraints. Table 18 below shows our verification methods for each of our general device design specifications.

Table 18: Verification plans for each general device specification, including current status of verification tests

Requirement	Specification	Verification Method	Status
Accurately measures stride length	≤ ± 5% error	Vicon Motion Capture test: Using paint & paper to mimic how our full-scale design will display footprints, we measured parameters using our developed image capture code as well as measured parameters with data from the Vicon Motion Capture system. We are now going to complete post-processing of the collected data to compare parameters between the two systems to determine our device's accuracy.	In progress
Accurately measures step width	≤ ± 4.4 [cm]	Vicon Motion Capture test (see above)	In progress
Accurately measures step cadence	≤ ± 10% error	Stopwatch and tape measure test: Use a stopwatch to manually measure step cadence (by counting steps over period of time), distance using a tape measure, and time, while also having the user wear IMUs. Compare results of step cadence, distance, and time from IMU post-processing with manually collected data to determine accuracy of data collected.	In progress
Accurately measures traversed distance	Must be able to measure ≥ 240 meters	Met by design	Met
	≤ ± 2% error	Stopwatch and tape measure test (see above)	Not started
Accurately measures time	≤ 6.7 seconds from actual time of trial	Stopwatch and tape measure test (see above)	Not started
	Must be able to measure ≥ six minutes	Met by design	Met
Low-price	The total	Bill of materials analysis: sum prices of	In

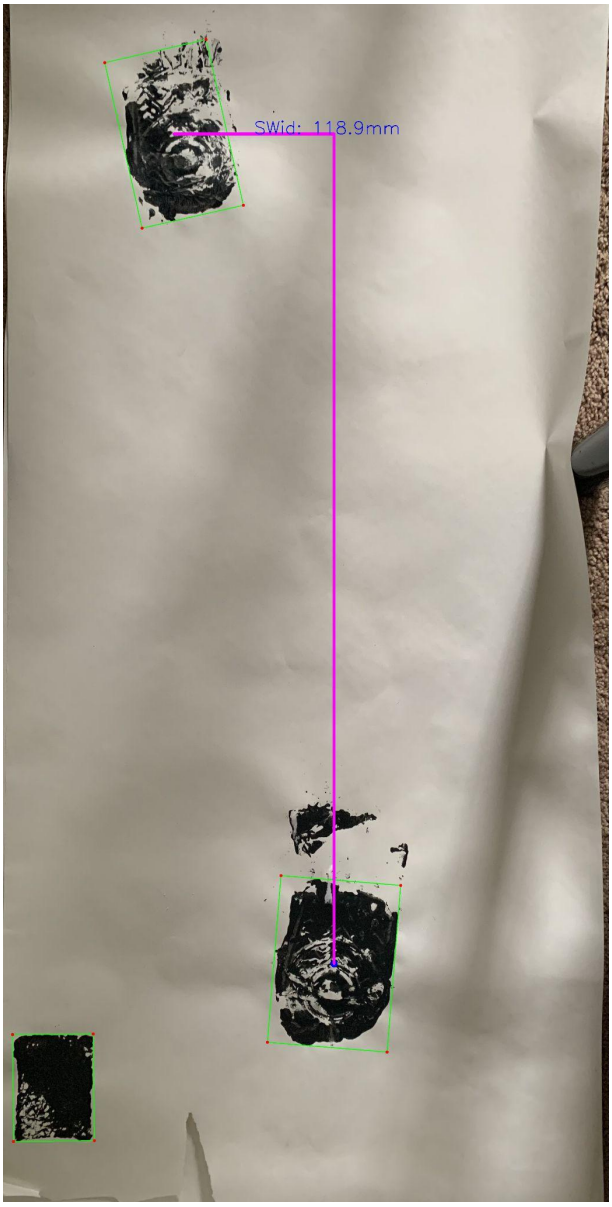
	implementation of the device must be < 30 lakh indian rupees	complete final design bill of materials	progress
		Life cycle cost analysis: utilize CES Edupack through CAEN to determine additional costs, such as manufacturing, transportation, and electricity use.	Not started
Data interpretation capabilities	Displays results post-trial within five minutes	Met by design	Met
Functions in India's climate	Fully functions ≥ 10 ℃ & ≤ 43 ℃ at ≤ 100% humidity	Environmental simulation: Simulate India's climate (given in specifications) in a lab environment (chamber). Use the device as planned.	Not started*
Functions on power available in India	Will work in power outages and be powered by 230 V	Met by design	Met
Adaptable to environment	Work within a space of 82 x 66 x 368 [cm] and work within crowded hallways	Not met by design	Not met
Sufficient battery life	Continuous use for > 7 hours	Met by design	Met

* Will not be completed this semester

Accurately measures stride length (≤ ± 5% error) & accurately measures step width (≤ ± 4.4 [cm]): Vicon Motion Capture test

To determine if our device meets the specifications for our requirements of accurately measuring stride length and step width, we are utilizing the Vicon Motion Capture system

to compare collected data on gait parameters with the post-processing data of our developed image capture system. We chose this method based on conversations with Dr. Kathleen Sienko and Safa Jabri, in which we developed an understanding for what systems are available in the Sienko Lab for us to use for verification. From there, we determined from our stakeholders that the Vicon Motion Capture system available in the lab would be the most accurate to compare our data with. This empirical testing method is very technical and detailed, which we believe is important since these are critical specifications our device needs to meet to function for its purpose in the Poovanthi Center. Based on our conversations with our stakeholders as well as benchmarking research conducted earlier in our design process, we are quite confident in the ability for this test to lead to accurate outcomes. The Vicon Motion Capture system is considered the "gold standard" on the market for gait analysis, so we believe the accuracy of these measurements will be a strong benchmark for us to compare our data outputs with. For this test, we are assuming that the Vicon Motion Capture system produces highly accurate gait parameter measurements. Since we have access to this system in the Sienko Lab as well as the assistance of Safa Jabri to use it and conduct post-data collection analysis, we believe there are no limitations on using this test this semester. We have already conducted the data collection with the system in the Sienko Lab, and now need to compare outputs to confirm if we have met these specifications or not. Unfortunately, we were unable to confidently ascertain the parameters for comparison within the time frame. So, we instead made hand measurements on the life size mat that tracked foot strikes with paint. One of our design worries is determining the camera angle required to use our image capture post-processing algorithm, so with the camera test, we made sure the camera was placed parallel one meter above the mat. The following figure demonstrates the verification done with the newly updated code (Appendix G) for the life-size mat. We focused on making sure step width was accurately measured as an initial verification test and plan continuing similar validation to both update our code for accuracy and better understand our camera placement in relation to the math we will be using to calculate the parameters.



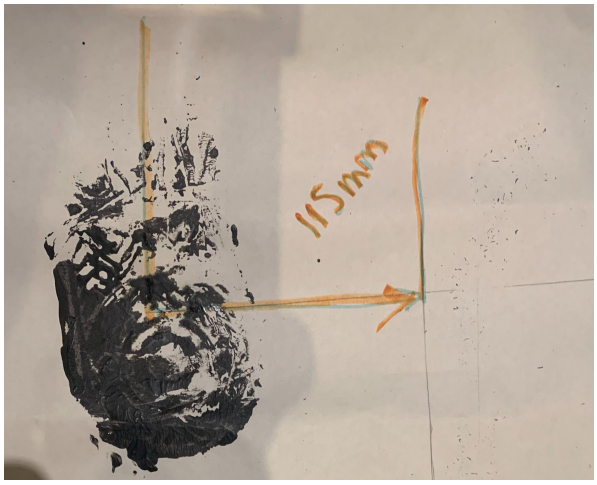


Figure 31a. Hand measurement of the stride width as it is the more difficult gait parameter to measure. By finding the horizontal intersection with the vertical vector of the first footstrike, we measured the stride width to be 115 millimeters.

Figure 31b. The newly updated code was run on a full-sized mat mimicking our magnetophoretic solution, focusing on step width. The software computed 118.9 millimeters, only 3.9mm in error with the hand-measured solution – well within error bounds. Next in verification would be step length as the team continues to resolve Vicon data.

Our analytical understanding of camera angle convinced us that parallel placement with the math gives us the least distortion that will properly give us greater accuracy when proportionally measuring our parameters. From just the step width, we verified that the 118.9 millimeters measurement from the code strayed only 3.9 millimeters from the 115 millimeter hand measurement, which is within the 4.4 millimeter error that is required. Moving forward, stride length will be verified in a similar way, as the updated code can now accurately identify footprints and measure them from a parallel perspective. That being said, the verification can also show us the height at which the camera can be placed as well as how spacing will work between cameras to capture the entirety of the mat. Although this can be hand measured, we hope that verification can move onto the Vicon system as a means to increase efficiency and automation.

Furthermore, we will be able to use this test to determine how much data we should include in our image post-processing. For example, determining how many steps we should remove as noise in our code to eliminate errors that may come from including non-steady state steps, like gait initiation steps, by comparing the Vicon data with our image post-processing code outputs.

Accurately measures step cadence (≤ ± 10 error), accurately measures traversed distance (≤ ± 2% error), & accurately measures time (≤ 6.7 seconds from actual time of trial): stopwatch and tape measure test

In order to test the specifications of accurately measuring step cadence, traversed distance, and time, we are utilizing a manual stopwatch test. Using a stopwatch and counting the number of steps taken in a certain period of time will allow us to manually calculate step cadence. A tape measure will allow us to measure the distance traveled, and the stopwatch will also allow us to measure the time walked for. This is a very accurate way which is currently being used in the Poovanthi Center to determine these parameters. We chose this method knowing how accurate it would be, and how simple it is to implement, since it does not require extensive manual work but provides highly accurate results. We will be comparing the data manually collected with the data produced by our IMU post-processing algorithm. We are confident in this method due to the accuracy of the data we are comparing our outputs with. Since we plan to do this test with only a couple of test patients and a few trials each, we are assuming that averaging the results, especially for step cadence, will be sufficient enough to determine if we meet this specification or not. There is the possibility of certain trials measuring out of our error range, however, since we are limited in time for conducting our verification tests this semester, we must trust in the accuracy of using a few trials. The results of this test will determine the accuracy of our IMU post-processing code, and will allow us to determine if there are any refinements that we need to make to the code to make it more accurate or account for any possible bugs that may occur in the trials. We will also utilize this verification test to understand how much data we should include in our post-processing. If the first few steps include gait initiation, including these in our code may cause inaccurate outputs. Playing around with our data based on the comparisons we can make to manually collected data will allow us to determine what level of data collected we should use in our post-processing code.

Accurately measures traversed distance (ust be able to measure ≥ 240 meters) & accurately measures time (must be able to measure ≥ six minutes): met by design

We have verified that our design can measure ≥ 240 meters and ≥ six minutes by creating a solution utilizing IMUs which have the ability to measure distance and time. We are confident that this parameter has been met from viewing the outputs from our IMU data.

Low-price (the total implementation of the device must be < 30 lakh Indian rupees): bill of materials analysis & life cycle cost analysis

In order to verify that the total implementation of the device is < 30 lakh Indian rupees, we will be conducting a trivial bill of materials analysis as well as a slightly more in-depth life cycle cost analysis utilizing software provided by the University of Michigan. For the bill of materials analysis, this is the best way to determine the total cost of a system by breaking it down into its parts. However, we decided to also utilize the life cycle cost analysis software because our primary stakeholder, Dr. Shibu, specified that this should be the maximum total price for the implementation of the device as a whole, and this requires further analysis on manufacturing, transportation, electricity, and additional costs. By combining these two methods, we will have in-depth analyses to provide to the Poovanthi Center to show how our device meets this low-price requirement, and does the job at a better price point than current options on the market. We are confident that this will account for all possible costs the device may incur over time, which will determine the overall price of implementation. While there may be some wiggle room in the costs we determine, we will provide a conservative and accurate estimate based on our research and knowledge to pitch to the Poovanthi Center. We will have to make assumptions when inputting data into the life cycle cost calculation tool, such as length of travel and location of manufacturing. However, we will base these assumptions off of additional research in order to create an argument for its accuracy. We hope to conduct this analysis this semester once we flesh out every last detail of our final design after addressing our last design worries in order to convince stakeholders to move forward with this design. The results of this analysis will allow us to determine if we need to find lower cost items or if we have additional wiggle room to improve the device functionality at all.

Data interpretation capabilities (displays results post-trial within five minutes): met by design

The device's data interpretation capability requirement of displaying results within five minutes after a trial is met by design. We have designed our post-processing algorithm to run efficiently in order to limit the time needed to output data. While our display for our build design is simply the computer which will be running the post-processing algorithm, the speed at which outputs will be displayed should not be much different for the final design. It is to be noted that currently, the software system prototype only contains the processing part, which runs in seconds. Based on our build design, which is our proof of concept, one still image would be needed, so processing time remains under the five minute specification we hope to achieve. We are confident that this will translate to our final design due to our experience and familiarity with data transmission and the algorithms we are using for this project.

Functions in India's climate (fully functions ≥ 10 ℃ & ≤ 43 ℃ at ≤ 100% humidity): environmental simulation

In order to test that the device can function in India's high temperature and high humidity climate, we are considering an environmental simulation in a chamber. It is possible for us to utilize a lab at the University of Michigan to simulate India's climate, and then simply use the device as normal in order to see how it functions in such an environment. Conducting an environmental simulation test may not be highly accurate, and since we are only creating a build design this semester, we are limited in our ability to test the full functionality of the final design. Therefore, we will not be able to conduct this test this semester. However, our design was built to function in the conditions of Madurai, India. Our analysis and material selection was based upon this specification, so we are confident in the product's ability to function in India. However, if this test was done, the results would confirm that the components are designed to work in India's climate as predicted. It is important to verify this if the project is continued beyond the scope of this semester since not meeting this specification would render our design useless, as it is being designed for this location specifically. If we run into issues with the way the design may function in this climate, we will need to iterate to determine better options to improve its functionality.

Functions on power available in India (will work in power outage and be powered by 230V): met by design

Since the IMUs are battery-operated, the mat does not require power, and only the display requires power, we designed our Beta solution to meet this specification. From conversations with Dr. Shibu and Lucy Spicher, we determined that while there are frequent power outages in the Poovanthi Center, they tend to last only a few minutes. Because of this, we are not worried about having to recharge any parts of our system. While power outages may occur, they will not be long enough to not allow our display mechanism to charge when needed.

Adaptable to environment (work within a space of 82 x 66 x 368 [cm] and work within crowded hallways): not met by design

Our design did not meet the criteria of working within the dimensions given by the rails in the Poovanthi Center. However, the ultimate decision to move forward with a design that did not meet these dimensions was due to our stakeholders confirming that patients will not have to walk between rails for the purpose of our product. For patients using our product to determine their gait improvement progress, they will be walking in the hallways as well as will have physical therapists as spotters. In order to not limit the design of our mat based on research on the dimensions needed to gain accurate measurement data, we chose to de-prioritize this need. Our most critical requirements include accurately measuring the parameters our stakeholders asked for, and by adhering

to this specification, we would have to risk not meeting those specifications. We ultimately made a decision based on the weight of the requirement and stakeholder input that this did not have to be prioritized in order to meet all high priority requirements.

Sufficient battery life (continuous use for > 7 hours): met by design

Since our mat does not require a battery, outlets are available for the displays, and the IMUs we have selected have sufficient battery life specifications, our design automatically meets the specification of the ability to be used for > 7 hours, or throughout the hours of therapy sessions during the day. We are confident that this will be achieved based on the work we have already done with the IMUs.

While we have not completed our general device requirements' verification tests, beyond the specifications met by design, we have collected data from the Vicon Motion Capture system and are currently working on comparing the Vicon outputs with the outputs from our image capture code. If all of these specifications are met, the device will function as it has been designed to in order to adhere to all stakeholder needs regarding the general device. If there are specifications that are not met, we will iterate on the design in order to improve the outcome and meet our specifications. However, these are not the only specifications we need to test in order to confirm our device adheres to all developed specifications. Table 19 below shows our verification plans for our operator-specific specifications.

Table 19: Verification plans for each operator-specific specification, including current status of verification tests

Requirement	Specification	Verification Method	Status
Durable	Can be used by 15 patients per day for 10 years	FEA test: Utilize Finite Element Analysis to simulate cyclic loading conditions to determine how patients' repetitive forces while walking on mat throughout the day will impact mat structure. Additionally, predict stress distributions and deformations over time.	Not started
		Magnet strength test: Consult with University of Michigan Materials Science staff specializing in magnetism to determine chosen magnet's long-term strength and ability to stay magnetized.	Not started

Sanitary	Complies with the CDSCO (Medical Device Division) Class B Standard under Section 7.5. See *APPENDIX B.1.*	Regulatory compliance test: looked at the CDSCO website to determine our device is class B. Once we submit an application to the CDSCO they will determine if this is the fitting class.	Met
Adequate UX	< 10 basic elements within the software.	Met by design	In progress
	Font size ≥ 1/150th the viewing distance.	Met by design	In progress
	< 3 levels deep in a menu hierarchy to reach main content. See *APPENDIX B.2*.	Met by design	In progress
Maintainable	Must recalibrate without user inputs ≥ half of the sensing components in inventory as spares	Not met by design	Not Met
Ease of Use/Usable	Median score between 47.5 and 63.8 on System Usability Scale (n=10 questions; 5-point Likert scale, score out of 100)	Usability/Likert test: see details outlined below.	Not started*
Provides understandable output data	Output the mean value of stride length, step width, & cadence	Met by design	Met

* Will not be completed this semester

Durable (can be used by 15 patients per day for 10 years): not started

We will conduct a finite element analysis (FEA) to determine the lifespan of our device to see if we meet the durability specification. Since FEA will be able to provide us with fatigue analysis and can simulate the use of at least 15 patients a day for 10 years, we will

be able to calculate the lifetime of our mat. We are confident that this is the best way to go about verifying this requirement because we are limited in empirical testing through our build design being our final prototype for the scope of this semester. Additionally, FEA is a very high-technology way of conducting the most accurate analyses without having physical testing done, so we are confident it will produce accurate results. For this test, we are assuming that the viscous liquid in the cells will not provide any support to the structure, and only the partitioned material will provide a support force. In order to conduct this test, we need to ensure we have the entire final Beta solution designed, including the exact material for the magnetophoretic display and the exact structure for the erasing mechanism. Since we have completed engineering analysis on these components, we should be able to complete this test this semester. After performing this test, we might have to look into changing the type of material being used as well as the dimensions of the structure to add more structural integrity. This would directly depend on the results of our verification test. Additionally, by making these changes, we may also have the consequence of needing to further analyze the performance of the magnets on the display.

To determine if the magnets we will be using with our magnetic mat will be durable enough to last 10 years, we will need to consult with University of Michigan Materials Science staff specializing in magnetism. We have little to no experience in materials analysis regarding magnetism, so we require more research and consultation with highly knowledgeable staff to determine the best way to conduct a magnet strength test. We are assuming that the properties of the magnets we move forward with will be constant, no matter where they are sourced from. This is something that can and will be done this semester in order to feel confident in our magnet selection. However, the results from this verification test are not high-risk because the magnets are an easily replaceable component of our design that will not impact the rest of the design.

Sanitary (Complies with the CDSCO (Medical Device Division) Class B Standard under Section 7.5. See APPENDIX B.1): met by design

Based on the CDSCO website, we have determined our device to fit under a Class B medical device, which poses a medium risk (Somani, n.d.). We determined this specification by performing a conservative analysis based on what the classes of other devices are and how the CDSCO defines the classes. We are confident that our design meets these standards, since we have designed based on complying with these CDSCO standards. Further analysis includes submitting an application to the CDSCO down the line, in which we would confirm which class our device falls under.

Adequate UX (< 10 basic elements within the software, font size ≥ 1/150th the viewing distance, & < 3 levels deep in a menu hierarchy to reach main content. See APPENDIX B.2): met by design

Our display, by design, will meet these specifications. We have based our display on the UX specifications from the handbook presented in Appendix B.2. We are confident that we are able to meet this specification because we have consulted with the displays of various products from our benchmarking, and even with a very intricate display design and user input needs, these guidelines will be met.

Maintainable (must recalibrate without user inputs ≥ half of the sensing components in inventory as spares): not met by design

Our Beta design does not meet this specification. The device requires an end user, or physical therapist, to "recalibrate" the mat, referring to resetting the mat via the erasing mechanism attached to the mat. This is considered an input for recalibration. However, it will be possible for over half of the sensing components, magnets, and IMUs be kept as spares to deal with any problems in regards to maintaining the device and its functionality. Even though we did not meet this requirement, we chose to continue forward with this design because all of the other potential solutions to recalibrating the mat required a more complex user input. The erasing mechanism has been designed for ease of use without complex components while still providing a robust solution to resetting the mat at each use.

Ease of use/usable (median score between 47.5 and 63.8 on System Usability Scale (n=10 questions; 5-point Likert scale, score out of 100))

To evaluate the usability of our final product, we will conduct usability tests that utilize the System Usability Scale. To initiate testing, we will have a set of participants, acting as patients, follow a set of instructions and then use the following questionnaire shown in Table 20 below to rate their experience. We have not thoroughly analyzed how many participants we will use for the purpose of this test, however, we will conduct benchmarking research to confirm how many participants will be necessary. Ideally, we would have a range of participants with and without gait disorders, as well as a range of experienced and inexperienced physical therapists. Prior to giving the participants this survey, we would have them use the mat. Specific instructions would include asking them to walk on it as if they are posing as proxy patients starting from various distances away. Additionally, for participants posing as physical therapists, we would ask them to reset the mat, click to find certain metrics on the display screen, and clean the mat. Ultimately, the goal would be to get an objective measurement of how easy the system is to use as a whole. This would allow us to determine if it is easy to use. If we do not meet this specification, we will further investigate through interviews with our participants to determine how we can improve the design to be more usable.

Table 20: The System Usability Scale (SUS) that we will be using to assess the usability of our final product (Bangor et al., 2008).

Question	Scale				
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in his system were well-integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

To convert to the SUS score we will be using the following method (Bangor et al., 2008):

1. For odd number questions (1, 3, 5…):
    - [User Rating] - 1 = [X points]
2. For even number questions (2, 4, 6…):
    - 5 - [User Rating] = [X points]
3. Add all points
    - [Q1: X Points] + [Q2: X Points] + … + [Q10: X Points] = [User points]
4. Multiply the total points by 2.5 to make the scale out of 100 points
    - 2.5 * [Users Points] = [User SUS Score]
5. Average all of the users scores together
    - ([User 1 SUS Score] + … + [User X SUS Score]) / [X # of Users] = [Total SUS Score]

As stated, our goal is to reach a median SUS score between 47.5 and 63.8. Meeting this specification would mean our device is straightforward and usable. This is important because if end users struggle to use the device appropriately, it may become obsolete. We

are assuming that the range of participants we use for this test will be sufficient in determining the overall score to confirm if this test is successful or not. We are limited in that we will not be completing a final design this semester, so this test cannot be done in the scope of this semester with the Build design. However, we could edit the test to implement with our Build design, and conduct a similar usability test based on a lower fidelity prototype.

Provides understandable output data (output the mean value of stride length, step width, & cadence): met by design

Our design meets this specification because we have created our post-processing algorithm to produce this data. Therefore, we have met this specification inherently in the design of our post-processing algorithm. A key component not included in this specification is that we will now also be outputting graphical information to further improve how understandable the output data is. This was based on feedback from our primary stakeholder, Dr. Shibu.

Based on the ability for our design to meet the operator-specific specifications through these verification tests, we will be able to determine how successful the device is from an operator standpoint, and make any corrections or improvements as necessary. Table 21 below shows the verification plans for our patient-specific specifications.

Table 21: Verification plans for each patient-specific specification, including current status of verification tests

Requirement	Specification	Verification Method	Status
Safe	Complies with the CDSCO (Medical Device Division) Class B Standard utilizing a pilot and pivotal investigation. See *Appendix B.5*.	Regulatory compliance test: looked at the CDSCO website to determine our device is class B. Once we submit an application to the CDSCO they will determine if this is the fitting class.	Met
	The device should not impede the gait of the person	Experimental usability test: We will conduct a usability test with a proxy patient. The objective will be to determine how the device impacts how the patient walks. We will take a baseline observational measurement and then implement the mat to see if our observations on the patient's walking pattern changes with the system in	Not started*

		place. Additionally, we will follow up with questions for the patient to determine how they felt it impacted their ability to walk.	
Adjustable	Compatible with 5th percentile (female) to 95th percentile (male) of the Indian Population. *See Appendix B.*	Met by design	Met
Comfortable	Average > 4 on the Likert Acceptability questionnaire by Jacucci	Usability/Likert test: see details outlined below.	Not started*
Usable with rehab facility attire	T-shirt, Barefoot & Shorts	Not met by design	Not met

Safe (Complies with the CDSCO (Medical Device Division) Class B Standard utilizing a pilot and pivotal investigation (see Appendix B.5) & The device should not impede the gait of the person): met by design

As previously mentioned in our sanitary requirement, we believe our device falls under the CDSCO Class B standard. Appendix B.5 highlights this compliance. We will determine if this is the appropriate class for our device after submitting an application to the CDSCO, which will be done further down the line. In terms of not impeding the gait of the patient, we have designed our product with this in mind. The selection of our magnets as well as the overall mat concept was based upon how much it would impact the person's gait, and we only selected options that would allow the patient to move freely as normal. However, this is assuming that our engineering analysis was accurate in terms of the mat and magnets' impact to the person's gait. Therefore, further analysis may be needed utilizing the build design to ensure gait is not impacted while walking on the mat with magnets on the user's feet. The results of this will allow us to be even more sure that we met this specification by design.

Adjustable (Compatible with 5th percentile (female) to 95th percentile (male) of the Indian Population. See Appendix B): met by design

Our Beta solution incorporates a design which will fit this specification. When designing the product, we based all our dimensions and components off of the anthropological data

presented in Appendix B. This includes the design of our IMU straps, the magnets on the patients' feet, and the mat itself.

Comfortable (Average > 4 on the Likert Acceptability questionnaire by Jacucci)

Through research when determining our specification for the comforTable requirement, we found the Jacucci questionnaire to be the best method to determine how comforTable the device is to use. Table 22 below shows the questionnaire we will use.

Table 22: 17 Question Likert Acceptability Questionnaire adapted from the original Questionnaire by Jacucci (Spagnolli et al., 2014).

Question	Scale				
1. The device would be incompatible with most aspects of my activity.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
2. The device limits the way in which I like to perform my activity.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
3. The device could help in reaching my objectives.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
4. The device could improve my performance.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
5. The device could improve the quality of my activity.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
6. It seems easy to learn how to use the device.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
7. It seems tiresome to use the device.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
8. If the device were available to me, I would use it.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
9. If it were launched on the market at an affordable price, I would likely purchase it.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
10. I think I would use the device only if I were forced to.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
11. I think that the device threatens my privacy	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
12. I think the device was pleasant.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

13. I think using the device was annoying.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
14. I think the device was boring.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
15. I think the device was comforTable.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
16. I think the device is well suited to my body.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
17. Wearing the components feels weird physically.	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree

To generate a score for the test we will be using the final method:

1. Multiply the numerical value of each sentiment (ie. Strongly agree = 5, Agree = 4 Neutral = 3…) by the number of respondents who picked that sentiment for each question
2. Add each sentimental value for that one question and divide by the number of participants.
3. Calculate the average score for all

Before conducting this questionnaire with a set of proxy patients and physical therapists, the specific number of patients to be determined after further analysis, we will bring them in for a usability test with instructions included. This would include similar instructions as previously mentioned with our usable requirement. We would ask them to walk on the device, use the device as normal, and put on and off device components. We would ask them to conduct multiple walking trials and trials of taking on and off components of the device. While further analysis is required to determine the exact correct instructions to include in this test, we are confident this will allow us to assess how the end users feel in terms of comfortability with the design. Since our final design will not be completed this semester, we can conduct a smaller scale test with our build design as well as the IMUs.

Usable with rehab facility attire (t-shirt, barefoot, & shorts): not met by design

Since our mat design includes placing magnets on patients' shoe soles, and placing these adhesive magnets would cause a feeling on their bare feet which could impact gait, we did not meet this specification. However, based on our conversation with Lucy Spicher, each patient, whether preferring to walk barefoot or in sandals, comes to the center with their own pair of shoes. Therefore, we will simply ask each patient who prefers to walk barefoot to walk with their shoes on in order to utilize the magnets as planned.

Validation Plans

While validation will not occur in the scope of this semester, we have determined two specific validation plans that should be conducted in the future to determine the validity of our solution. This will test how our design overall fits our needs and sets of requirements and specifications as a whole. For our project, we determined two specific validation tests that would provide us with an understanding of how well-received our device will be to address our design problem as a whole: clinical trials and a summative usability test. Table 23 below shows our validation plans.

Table 23: Validation objectives, questions, and methods

Objective/Question	Validation method	Status
Is the device safe and effective to use in the real world setting? Will we be able to obtain approval from the CDSCO? Will this product be beneficial to the medical industry on a larger scale?	Clinical Trials: multiple phases of trials with volunteers. See below for details.	To be completed later in the design process.
Is this product well-received by end users? Does the product meet the needs of the stakeholders? Is the product ready to be used in the Poovanthi Center?	Summative Usability Test: a specific, holistic usability test to determine overall feasibility of the device. See below for details	To be completed later in the design process.

Clinical Trials

A clinical trial includes volunteers evaluating the safety and efficacy of a medical product. The goal is to determine that the device is safe, performs effectively, and is well-received among the end user population. This will be done in a controlled environment with volunteers using the device, all while being watched in order to ensure ethical guidelines are met. This could be done in phases, which would expand on the volunteer population. *Phase I* would include a smaller volunteer population with specific objectives in mind for assessing the functionality and safety of the device. *Phase II* might include a larger population and collect more data. Similarly, this would go on for Phase *III* and *IV* to continue collecting data and an understanding of the device's functionality in the design setting as a whole. Key players involved would include the volunteer population, Dr. Shibu and the sponsors at the Poovanthi Center, a lead to conduct the trials, and the CDSCO as a regulatory authority. Below is our clinical trial plan and specifications as recommended by the FDA for medical devices (*Step 3: Clinical Research*, 2018, p. 3).

Phase I

Phase I will consist of a safety analysis using volunteers as participants. The volunteers will be healthy with no known gait abnormalities. An important aspect of this phase is that strict protocols and rules set by the FDA must be followed, to ensure the safety of participants is not put in jeopardy. During this phase researchers will gather information on how the participant has interacted with our device. It should be noted that the clinical trial will only be testing the mat and will have no input on the post data processing. One goal of this phase is to ensure that the mat is safe for use and on the market. As per the FDA this phase consists of 30 patients and should be done in a controlled environment. For our trial A second goal of this phase is to maximize the benefit of our device while minimizing any risks. Another recommendation provided by the FDA is that this phase should last for several months.

Phase II

Phase II will strengthen the findings from phase I in terms of safety but will now focus on the efficacy of the solution. That is, how will the device fare when actually analyzing a person's gait and providing digital feedback? During trials, we expect to test our device with 80 people to ensure a broad range of gaits will be measured and accurately recorded to validate basic functionality but also prove that edge cases such as abnormal gaits, shuffling, and other considerations can be accounted for on the software end of things – target patients will be tested. The difference between phase I and II is that accurately presenting results is a step beyond simply the experience of use. While we will look out for functionality during phase I, discrepancies in accuracy will not be prioritized if the device jeopardizes a patient's safety. Meanwhile, to mitigate the effects of unwanted factors that could affect functionality such as image processing, this phase will also test the protocols developed with our solution while a person uses our device. Such a protocol functions as both a safety precaution and a primer for optimal device use. With the expected use of the device to be much greater than phase I, the durability of our solution will also be tested in such a live scenario.

Phase III

The final phase of the clinical trial is to ensure that our device not only meets the industry standard but provides additional benefits. This phase may go on for years and will consist of about 1,000 volunteers. During this phase researchers will monitor the results of the system while stroke patients with abnormal gaits use them. Following, they will compare the results with an array of industry standard devices such as the Vicon and gaitrite mat.The key difference between phase II and III is that phase III is less intentional and controlled, but rather a simulation of everyday use of the device.

Summative Usability Test

A summative usability test tests the overall usability, effectiveness, and efficiency of a product. While our verification tests include formative usability testing in order to focus on the iteration of our design and the development of our final solution, this test will evaluate the final product

on a more holistic scale. The goal is to determine how it is received as well as if the device meets the collection of requirements and specifications we previously determined. We recommend combining aspects of the formative usability tests in our recommendations as well as the usability tests implemented in our verification section to create a summative usability test which allows us to determine the function of the device as a whole. This summative usability test would incorporate a wide range of questions from assessing the usability of walking across the mat while another participant conducts a trial to simply resetting the mat and re-orienting the cameras. Five participants would be used in this test to ensure the usability needs of each participant can be addressed, but a wide range of data can be obtained (Ellen Francik, 2015). We are confident that this method will allow us to validate the product's function as a whole for the Poovanthi Center. This validation test will ensure the product is ready for the market. Please refer to our recommended formative usability tests for more specifics on what types of questions our usability tests are addressing. The critical difference between this test and formative usability tests is the ability to obtain an understanding of the design's usability across all requirements, rather than having one test for one specific concern.

Failure Modes Effects Analysis (FMEA)

In order to further validate the safety of our device, we will conduct a Failure Modes Effects Analysis, or FMEA. This is a framework for us to consider hazards and failures in our device, as well as consider how we will mitigate them (*Risk & Safety: ME 450 Learning Blocks FA 2023*, n.d.). We will be comprehensive in addressing these risks to ensure all possible failure points are addressed in our design. While we will continue to flesh out possible failures of our device, below shows our initial FMEA analysis. The list below shows the FMEA steps.

1. Break down the system into components
2. Describe the function of each component or sub-system
3. List the potential failure modes of each component
4. Describe the effects of any of those potential failures
5. Determine the severity of each potential failure
6. Determine the probability each potential failure is likely to occur
7. Determine the detection rate of any potential failure
8. Assign a Risk Priority Number (RPN) to each potential failure
9. Take action to reduce the highest risk

The scales below from the MECHENG 450 Engineering Analysis learning block will be used for the FMEA analysis (*Risk & Safety: ME 450 Learning Blocks FA 2023*, n.d.).

Severity [S]
Possible 1-10 scale, with values representing:
1. No noticeable effect

2. Item operable, but with annoyance noticed by <25% of customers
3. Item operable, but with annoyance noticed by 50% of customers
4. Item operable, but with annoyance noticed by >75% of customers
5. Degradation of secondary function
6. Loss of secondary function
7. Degradation of primary function
8. Loss of primary function
9. Potential failure mode affects safe operation or regulatory requirements, with warning
10. Potential failure mode affects safe operation or regulatory requirements, without warning

Probability of Occurrence [O]

Possible 1-10 scale, with values representing:
1. Highly improbable
2-3. Low: relatively few failures
4-6. Moderate: occasional failures
7-8. High: repeated but unpredicTable failures
9-10. Very high: failure all but guaranteed

Failure Detection [D]

Possible 1-10 scale, with values representing:
1. Almost certain
2. High
3. Moderate: first noticed by a few customers
4-6. Moderate: first noticed by many customers
7-8. Low: highly likely customers will be the first to detect it
9-10. Almost no chance of detection prior to release to customers

[Risk Priority Number, RPN] = [severity, S] x [occurrence, O] x [detection, D]

To clearly show the results of our FMEA analysis, the steps are outlined and completed in Table 24 below.

Table 24: FMEA analysis, concluding in the determination of each failure mode's risk priority number

Component	Function	Failure mode	Effect	Severity	Probability	Detection rate	Risk Priority Number (RPN)
Magnetic mat	Show footprints of the user for collecting	Losing magnetism	Will no longer be able to collect	8	2	1	16

	data of spatial parameters		footprints				
		Eraser no longer functioning	Will not be able to reset mat	6	2	1	12
		Magnets not sticking to shoes	Will not be able to collect footprint data	6	5	1	30
IMUs	Collect data for temporal parameters	Collecting noisy data	Will cause challenges and inaccuracies in data analysis	3	3	4	36
		Losing battery	Will no longer be functional	8	2	1	16
Processing algorithm	Translate data from the mat and IMUs into understandable parameters	Lacking ability to be accurate	Will cause inaccuracies in data output	4	4	3	48
		Being slow	Will create delays in data outputs to display	2	3	2	12
Display	Show the end user what their gait parameters are, or what their patient's gait parameters are	Losing power	Will no longer be able to determine/see gait parameters	8	6	1	48
		Slow to display parameters	Will create delays in therapy sessions	3	5	2	30

Cameras	Collect the data from the mat to plug into the post-processing algorithm for analysis	Unclear images taken	Will cause challenges in post-processing data analysis	5	6	3	90

With the guidelines that RPN = 1 means failure is highly unlikely to occur, <30 is reasonable, and >100 failure is almost certain to occur, we can conclude that we have no certain failure points that are immediately critical to address. However, our camera failure mode had an RPN of 90, signifying that more analysis needs to be done to determine how to mitigate this risk. Additionally, our other failure modes with scores > 30 will require additional analysis and mitigation efforts. This will be done during this semester, prior to completing our build design and establishing a final ultimate solution for our Beta design as a whole.

DISCUSSION

Since this project is reaching an end point given the time frame of one semester, we will utilize this section to critique and analyze our design and design process as a whole. This will encompass an analysis of our problem definition, a detailed critique of our final Beta solution, and discuss risks of our solution. Mitigation steps to address these risks will be considered in the recommendations section of the report.

Problem Definition

While a significant role in our problem exploration included referencing design ethnography data shared by Lucy Spicher, conducting our own design ethnography would allow us to further develop the problem statement in order to better understand the gaps our solution is trying to fill and better define the constraints of our system. Additionally, further design ethnography work would allow us to develop our benchmarking analysis by incorporating a deeper understanding of where current systems lack in terms of usability and feasibility in low to low-middle income countries. Specific questions we would hope to explore with more time and resources include understanding how usable current systems are from both the patient and physical therapist perspective, how current systems perform, and what exact reasons are these systems not able to be implemented in low-resource settings. Additionally, it would be beneficial to understand exactly how a therapy session looks in the Poovanthi Center to better develop constraints.

The first method we could use to collect data is through observation, with permission for observation from patients and physical therapists involved. By setting up a video call over zoom with Dr. Shibu in the Poovanthi Center, we could observe a therapy session and better understand

what the center looks like, how the space is used, what activities are being done in the space, and how often gait observation is done. Another method we could use is a survey with physical therapists specializing in gait. Understanding how physical therapists from different areas perceive current solutions will allow us to better understand where the systems being used lack. Additionally, obtaining survey responses from physical therapists in the US as well as in low-resource areas and the Poovanthi center will allow us to better segment the stakeholders of our project, and consider what accessibility issues may exist based on differences in the data collected. After conducting a survey, an interview can be conducted with physical therapists in the Poovanthi center specifically to collect even more detailed data on what the current experience in the center looks like in regards to the problem at hand. Lastly, if given the resources, a usability test with current solutions on the market could allow us to further understand gaps that exist that end users and stakeholders might not recognize themselves. End users of objective gait systems may have compensatory behaviors that they don't recognize as flaws in the system itself. A usability test along with further observation would allow us to pinpoint compensatory behaviors and understand how our problem statement can be improved to address critical needs.

Design Critique

Through our verification process, we concluded that our design will meet a majority of our specifications. However, that does not necessarily mean our current design is final and flawless. There are several aspects of our design with strengths due to their thorough investigation and implementation. There are also aspects that lack in strength and will need to be re-evaluated in the future to further the development of our product. These weaknesses can be attributed to our pivot in design concepts which happened late in the design process, and if given more time and resources, we would aim to improve on these.

Design Strengths

The strongest overall aspect of our final design is the novelty of the technology being used to display the gait of patients for our image capture post processing algorithm. Current market solutions lack diversity and tend to be high-technology solutions that all use very similar techniques in diagnosing gait, such as pressure sensors. Our solution is based on magnetophoretic technology, which is comparatively cheap to current market solutions, and is a purely novel solution in the quantitative gait analysis space. Due to its novelty and minimal costs associated, the potential for our solution to address the needs of the Poovanthi Institute is a lot higher than if our solution was based on technologies currently being used. The design of the magnetophoretic display is another area of strength in our design. The hex pattern within the display to provide structural integrity and a high resolution was decided from a thorough analysis. The data provided from this analysis allowed us to determine we would meet our durability requirement so that this solution can meet the needs of the Poovanthi Institute. The ability for our design to be able to withstand multiple patients over a long period of time while

not requiring high-technology components or maintenance is a huge strength, given that this is a low-resource setting. Additionally, the dimensions of the mat were determined from thorough benchmarking and research, and prove to be a strength in obtaining accurate gait parameter measurements. The chosen dimensions provide a patient with ample space so that enough steady state steps can be displayed to provide physical therapists with enough data to make an accurate diagnosis. The initiation and deceleration areas on either side of the mat are essential so that the patient can reach steady state gait without impacting their walking, allowing for accurate measurements. Another component that provides a lot of strength to our design is the image capture post-processing algorithm, which will be used to provide accurate gait parameters to physical therapists. The integration of this algorithm with the user interface allows for a simple and efficient way to extract parameters. This algorithm is successful with the use of very simple cameras while still being highly accurate in calculating the key spatial gait parameters – a strength of our design that a solution like the Vicon system does not meet. The novel components of the magnetic display mat in combination with the highly accurate image capture post-processing provides us with a strong design that lays the foundation for success in the future, following verification and validation testing.

Design Weaknesses

Although our overall design concept is strong and our analysis has proven the ability for it to meet our needs, there are still numerous components and aspects that need to be further iterated upon in order to reach a final design that can be implemented within the Poovanthi Institute. One of the major design weaknesses we face is the use of IMUs in conjunction with the magnetic mat to provide temporal gait parameters. The IMUs were initially thought to be placed on the foot of the user, which is also where the sandals with embedded magnets will be to display the gait pattern on the mat. An issue we recently discovered is that magnets located near the IMUs can potentially affect their accuracy, leading to them being ineffective in providing accurate data. If the IMUs cannot provide accurate temporal data, then their use in combination with the mat would not be necessary. Another weakness of our design lies in our mat reset mechanism, which is a sliding magnet on the underside of the mat. Although a deflection analysis was done on the magnetic display above the gap needed for the sliding mechanism to confirm that our mat would be able to deflect and keep its shape for multiple uses, the deflection has the possibility of being a fall risk for users. It is also not confirmed whether this mechanism will be effective at resetting the display fully for multiple uses, and whether or not the continuous use of this mechanism will provide additional problems. Overall, the weaknesses in our design lie mostly in needing more research and testing to be done to understand full-scale functionality of the design. Through further iteration and testing, these design weaknesses can be improved to provide a fully functional final design for the Poovanthi Institute. We will further discuss our plans to mitigate these weaknesses in our recommendation section.

Design Process Critique

The design process we used was the ME450 Design Process Model due its focus on iteration between different design stages and providing us with activity-based components that fit in the structure of the class. Although we had an overall successful experience using this design process, it could have been more effective if we were more thorough in certain stages. As previously mentioned in the design process section, we continuously updated this process to incorporate the feedback loops we went through while iterating on our design. We were very effective as a team during initial phases of the process including need identification and problem definition, but once we got to concept exploration and solution development, we ran into some challenges. The major challenge we encountered during this process was the fixation we had on an initial Alpha design. Until we had almost completed Alpha engineering analysis, we did not realize that the design would not be feasible. By the time we realized that we would have to pivot to another design, it was already late in the timeline of the semester, and we had to rush to move to our new Beta design through the necessary design stages so we could start verification and create a feasible solution. If we were to complete this process again, we would spend more time in the concept exploration phase, fully exploring the solution space. Once we started to fixate on an idea based on the high-technology benchmarking we had done, we disregarded any novel solutions, which ultimately became the best type of concept for us to use. Conducting a more comprehensive analysis of the solution space as well as more analysis into a wider variety of concepts would have allowed us to potentially see and mitigate the challenges of our first design early on. Utilizing a wider variety of concept generation techniques early would have also been beneficial because the techniques we used during our initial concept generation were only able to scratch the surface of the solution space. When we used different techniques during our second round of concept generation, we were able to find a wider variety of concepts that could serve as potential solutions. Although we were not successful in the concept exploration phase at first, following the design process allowed us to identify the main design worry before it was too late to iterate and revisit that phase to pursue another design. This further confirmed to us that the design process is not linear, and iterations as well as feedback loops between stages are necessary for creating a successful design.

Future Modifications

Moving forward, multiple aspects of our design will require further testing and iterations to create a product that can be used successfully and meet the needs of the Poovanthi Institute. Specific areas that need to be improved upon are materials of the magnetic mat, mat reset mechanism, camera system and orientation, and form of capturing temporal gait parameters. Regarding the magnetic display, further testing will have to be done on the viscous liquid to find the right ratio of materials to provide the best performance. Further analysis, including FEA testing, must be done on the material of the top layer of the display to confirm its safety and overall structural integrity. Further material analysis along with empirical testing would allow us to better determine these materials. As for the mat reset mechanism, a future modification that

should be considered would be the use of an electric field to reset the mat for multiple uses rather than a manual mechanism. If further researched, it may be found that this is a feasible and less manual method to reset the mat. In order to implement this modification, initial research will have to be done in parallel with engineering analysis to determine how this technology could be implemented successfully. For the camera system, in order to capture an image of the entire mat, multiple cameras will have to be used. Since our build design only included one camera at an angle above the mat, there has been minimal testing done for the location and orientation of each camera. Determining specifics of the number, placement, and angle of the cameras will need to be done through empirical testing to determine how it can best be implemented. Finally, a future modification regarding obtaining temporal gait parameters would be to implement a timer along with the start/stop buttons on the user interface of the display to calculate cadence without having to worry about the problems that we could face using IMUs next to magnets. Therefore, we would potentially be able to remove the IMUs from our design as a whole. Due to the scope of the semester, we were not able to explore these potential future modifications, but we believe that all of these modifications would improve the performance of our design.

Risks

We encountered two types of risks and worries in our design process: hardware and software risks, as well as usability risks, taking into consideration how the final design could negatively impact the end users.

Hardware and Software Risks

We faced many challenges regarding hardware and software during our design process. Firstly, during our Alpha design analysis, we determined the risks of requiring lots of wiring for the initial pressure mat design as well as not being able to efficiently combine and transmit the data from all the sensors. Therefore, the goal of our Beta design was to mitigate these risks. We were more thorough with how we explored the design solution space during the Beta design iteration since we had previously failed our first design. Challenges we specifically faced during the Beta process included evaluating concepts which we were unsure would be feasible in terms of outputting all necessary gait parameters as well as considering exactly how the post-processing algorithm would work with minimal error. In order to minimize the adverse effects of these risks on our final design, we chose to create thorough methods for both idea selection as well as for engineering analysis. For idea selection, our Pugh charts as well as structured evaluation against our requirements and specifications allowed us to select the most viable concepts. By using these structured methods, we mitigated the risk of choosing a poor design once again and losing time evaluating a solution that would not work. In terms of the accuracy of the post-processing algorithm, we addressed the risk of choosing our Beta design solution in terms of its post-processing needs by meeting with stakeholders Safa Jabri and Lucy Spicher to determine the feasibility of extracting gait parameters from the design. By doing so, we learned how to minimize the error in our code that would impact the function of our final design. While we were

able to mitigate these risks from our design process itself, there are still risks to our final design, as presented in the design critique.

Usability Risks

While our hardware and software risks are critical to mitigate to improve our design, we also wanted to take into consideration the risks associated with the end-user of our final design to consider the design's overall usability. While our verification tests specifically test if we meet our specifications and our validation tests assess the overall functionality and feasibility of the design, we considered specific usability worries to establish needs for formative usability testing. Formative usability testing would be separate from our verification and validation tests, allowing us to address more specific usability questions we have regarding our design that are not addressed in our specifications. In order to determine and prioritize our usability worries, we first came up with a list of usability worries. We then ranked these from high to low priority, basing this ranking system off which worries would create the highest risk for our final design solution. This prioritized list is as follows, from high to low priority:

1. Slipping on the mat

   Our greatest priority is the safety of our patients. Because we have not finalized the materials that go into the mat and the custom sandals, the greatest worry we have is compromising the balance of the patient as they walk over the mat. This could lead to reinjury, the opposite of the purpose the mat intends to serve. Safety is the number one priority, and we must be certain through testing that patients can be confident in their foothold.

2. Difficulties resetting the mat

   Without being able to reset the mat, noise from previous footfalls will bring in unnecessary noise that will hinder accurate measurements from the image processing system. The inefficiencies revealed as difficulties in resetting the mat will become a bottleneck and prevent quick patient diagnoses and treatment. Our solution therefore would be no better than rolling out pieces of paper and having footprints stamped on by paint – an inefficient method as determined through concept elimination. To better understand mat rests and avoid these difficulties, we must ensure through testing that resets are quick and multiple rounds of gait tests can be conducted effectively.

3. User Interface Confusion

   Our final worry is expecting customers to competently operate the user interface (UI) to capture and process images and then save the results. Although the UI is simple, navigation can be considered a risk especially when understanding labels can be subjective. With manuals and protocols that will come with the solution, we hope our

instructions can clearly guide users, but it will ultimately come down to testing to see whether or not our solution is easily operable.

These usability concerns will be further addressed in the recommendations section.

REFLECTION

In order to be reflective practitioners and strive for continuous improvement, reflecting on our perspectives that may have influenced the final Beta solution and design process as a whole is necessary. In this section, we will discuss how social and contextual factors are relevant to our final Beta solution, referencing the design context established earlier in the report. We will also consider the influence of our identities as well as how inclusion, equity, and ethics played a role in the development of our final Beta design. In this section, we have all discussed these questions posed to us and come together as a group to create our responses.

Social, Global, and Contextual Factors

Especially since our design is a medical device that will be used in clinical settings, public health, safety, and welfare is incredibly relevant to our final product. Our device will be directly used to protect and improve the health of a vulnerable low-resource population, with the goal of ultimately improving quality of life and alleviating risks associated with compromised mobility. In our design process, we had to continuously assess how design decisions we were making would impact our end users, and how we could create the best design without compromising the safety and well-being of our end users. In order to keep this in mind, we used detailed and structured ranking systems and decision matrices with factors relating to public health, safety, and welfare to make well-informed decisions. Additionally, we referred directly to resources provided on the CDSCO web page in order to ensure we were meeting our safety and sanitation specifications, along with other critical requirements of Class B medical devices.

In terms of global context, the Poovanthi Center is just one of many rehabilitation centers focusing on gait improvement in a low-resource setting. Beyond the context of rehabilitation centers in India, for which our solution is the most catered towards, this solution will be incredibly valuable in other LMICs. Current solutions on the market are not only inaccessible in India, but also to LMICs as a whole, given their high-price and high-level technology that is challenging to implement in a low-resource setting. There are 137 countries in the LMIC categories. This represents 63% of countries which do not have easy access to a low-price objective gait analysis system (Raphael Lencucha, 2022). Therefore, this design has extreme promise for use beyond the context of India, both in other countries and even in low-resources areas in more developed countries.

Social and economic impacts associated with manufacture, use, and disposal of the design are also relevant to our project. In regards to manufacturing, the materials being used in our final design will not be recyclable. There will be an impact in energy consumption and emissions to

develop the design. However, since the lifetime of this solution should not require frequent disposal of materials or significant manufacturing, the effects should not be dire. Since only a few of this design will be needed to fully address the needs of all patients in the Poovanthi Center, the immediate environmental impact should be minimal. However, if produced on a mass level to distribute across other rehabilitation centers, there may be more significant effects to the environment. Given the use in low-resource settings where it would be challenging to also source the manufacturing of the product, the distribution itself could cause large emissions. Therefore, an iteration and analysis on the design to select more environmentally friendly materials and practices in manufacturing should be done in the future. One positive aspect of the manufacturing of this device is the ability for it to open up employment opportunities. Given the need for our final design manufacturing to include the development of high-technology algorithms to process and transmit data that our build design does not include, we could outsource the software development of the design, leading to employment opportunities. In this case, it would be critical for us to source this work ethically. Rather than targeting low-wage communities and outsourcing manufacturing and software development work to a population which might be more cost friendly to us, we would need to ensure we are following ethical practices and opening up opportunities for employment which do not take advantage of workers. In terms of the use of the system, the biggest social impact and goal of the product is to improve the health and safety of a vulnerable population in a low-resource community. As previously mentioned, this not only includes the Poovanthi Center but also other low-resource settings where access to gait analysis systems is a struggle. Beyond just improving the health and safety of patients, the product has been designed to be accessible and affordable, minimizing disparities in access to critical rehabilitation resources. In regards to the disposal of the system, as previously mentioned, there will be a long lifetime associated with the product. However, when it comes to disposal, there may be negative environmental impacts due to the lack of recyclable materials being used in the design and the potential lack of proper disposal infrastructure available in Madurai, India. Since pollution is a large issue in this area, considering the potential of improper disposal is important in order to ensure the device does not contribute significantly to negative environmental effects.

The tools we used to characterize the potential societal impacts of our design include a stakeholder map that was continuously updated throughout the design process, a scoping table to understand the context of our design on local and larger scales, as well as life cycle costing. These tools allowed us to further assess these factors in our design.

Culture, Privilege, and Identity

Cultural, privilege, identity, and stylistic similarities and differences between each team member played a large role in the approaches and decisions made throughout the project. With regards to culture from an ethnicity perspective, our experiences gave us all different perspectives which played a role in the design of our solution. For example, having a team member with family from Tamil Nadu allowed us to include cultural considerations we may not have otherwise considered

or understood. Additionally, having team members outside the Indian cultural perspective allowed us to make data-driven design decisions without solely basing decisions and approaches on personal experiences and cultural understanding. With regards to privilege, our team comes from privileged backgrounds. While some of us have traveled to low-resource communities or have family from low-resource areas, none of us have experienced living in low resource areas or struggling with accessibility in terms of rehabilitation and healthcare as a whole. While we conducted research and had insightful conversations with stakeholders to combat this single perspective, our similar levels of privilege may still have caused us to have a blind spot. This might have caused us to not fully explore the design solution space as well as not fully consider challenges less privileged communities face. With regards to our identities, we all come from similar upbringings and backgrounds. Our cultural differences are the most significant in terms of diversity of perspective. Three of our team members are male student athletes, an identity that played a role in how we approached the project and where our focus was throughout the process. As athletes, mobility is a huge issue. Having access to physical therapists and resources to improve our mobility as well as experience in rehabilitation settings impacted how we approached the design problem and where we could see gaps for low resource communities in current solutions. Additionally, having one female perspective and three male perspectives on the team allowed us to further consider design decisions. For example, we were able to recognize we would need to design the solution for the smallest possible female foot as well as the largest possible male foot. We also utilized our differences in gender to address how comfortable end users would be to use this solution, as well as how both male and female identities in the Indian cultural context would respond to the design. Throughout the process, we considered tools like the Designer Positionality Tool to ensure we were understanding how our own identities were impacting our design process.

There were also cultural, privilege, identity, and stylistic similarities and power differences with our sponsor that ultimately influenced our design process and final design. Dr. Shibu, located in India, has an understanding of Indian culture that our team lacks. With none of us having experience living in India, the cultural differences between ourselves and our sponsor may have influenced how well we incorporated discussions with him as our primary stakeholder into our design process. Additionally, with our sponsor being located in India, it was often challenging to have clear and direct communication. During moments in our design process under time pressures, we sometimes were unable to obtain feedback from Dr. Shibu in time to take the next step in the design process due to time differences. While these differences made it challenging to communicate efficiently sometimes, they also allowed us to make design decisions we may not have considered without his input. The final design includes components that were advised by Dr. Shibu, such as the content of the display and the parameters the device can measure. With regards to power differences, our identities as students working under Dr. Shibu as our sponsor may have influenced how receptive we were to his feedback. While we utilized decision matrices to ultimately make design decisions, we often took Dr. Shibu's word for design considerations, believing his experience and identity would inherently form the correct decisions. It was not until

later on in the process that we challenged his perspectives and ensured we were assessing his advice in a structured manner to make data-driven decisions.

Inclusion and Equity

A big emphasis during the early stages of our design process was identifying power dynamics and using strategy to include a diverse array of viewpoints. Between all four of our teammates there was little power dynamic, since all of us come from similar backgrounds with similar experiences in engineering. However, one of our group members is a computer science minor, giving him a much better understanding of the algorithms that would need to be used in order to measure our critical parameters. These created an expertise power dynamic in which the other three team members were not able to effectively work on this aspect of our project. When discussing the post-processing component of our final design, only one of our team members was able to fully iterate on this. Because of this, there may be ways to make our code more efficient or simply improve its accuracy that we did not address, since we only had one member with the ability to work on this aspect of the design. In terms of power dynamics existing between us and our stakeholders, we often considered our stakeholders to have a larger amount of knowledge and expertise, so we took their advice most of the time without testing it considerably. For example, Dr. Lauro Ojeda has an incredible amount of experience in this area, so his suggestions were taken into consideration with great weight. In terms of end users, we had minimal interactions with the patients and physical therapists, so this did not apply to us in our project. Our own identities and experiences definitely impacted our perspective on the project differently than the perspective of the end users. As students at a large research university with lots of resources and privileged backgrounds, we did not have much experience designing for or considering the needs of patients from lower-resource areas. By talking to Dr. Shibu as well as Lucy Spicher, we were able to gain more information about the context and backgrounds of the end users we were designing for, however, we were limited in our understanding of this context. Compared to other team members, we all had similar experiences. One member had more experience with the Indian context, however, with none of us having specifically experienced this design context, we all came from similar playing fields. In order to include diverse viewpoints of stakeholders and team members in our project work, we conducted as many interviews and meetings as possible, as well as ensured each of us shared our thoughts and ideas in each one of our team meetings and conversations. We created a list of expectations between team members at the beginning of the semester in order to have something to follow and to ensure an open space for the contribution of all team members.

In terms of balancing whose ideas were selected to inform the project, we consistently based our decisions off our stakeholders' interests while also backing up these interests by decision matrices and other structured decision-making tools. For example, Dr. Shibu suggested the display of data should be both graphical and numerical. Then, from a Pugh chart analysis, we determined that this would be the best way to convey information. Since Dr. Shibu was open to

our ideas and all considerations, we rarely felt as though we were constrained by his interests or ideas.

As mentioned previously, cultural similarities and differences between team members only mildly impacted the project. Since we all come from very similar backgrounds, we all approached the project with similar mindsets, simply contributing knowledge from our cultural backgrounds when applicable. However, this was always backed up with significant research and data in order to ensure all approaches were data-driven. Cultural differences between ourselves and our sponsor influenced how we responded to his advice and information – since we had minimal understanding of the cultural context we were designing for, we had to really take his advice into consideration to understand who we were building for. We believe that we created a globally accessible final product which contains components and considerations from our cultural backgrounds as well as Dr. Shibu's cultural background. For example, we considered Indian sizing and clothing while incorporating aspects of American toys into our Beta solution.

Ethics

From the beginning of our project, we knew ethical considerations would be critical in the success of our design. Designing a medical device for a low-resource community required us to be careful and make completely ethical decisions rather than make decisions based on our interests and goals. We had to consider the CDSCO's requirements to ensure we were meeting the ethical guidelines from this regulatory agency. While it was challenging to navigate the website, and it would have been easier to make assumptions on what was correct, we chose to make strong considerations based on the CDSCO to be as ethical as possible. We did not face many other ethical dilemmas. We did significant research and benchmarking at the beginning of our design process to ensure we fully understood the context we were designing for. This allowed us to be aware of the ethics of our design context, and made us more cognizant of how the decisions we made would impact our patient population. Understanding the struggles of patients and physical therapists in the Poovanthi Center allowed us to choose the ethical decision each time. If our product was to enter the marketplace, one major issue that might arise is the price of the product itself. We would have to decide if we could be a non-profit to minimize the costs to the low-resource communities we are designing for, or if we are for-profit, and would need to upcharge the price of the product to make a profit. We would also have to consider the ethics of how we approach iteration and improvement of the design. It would be easy to simply place the product on the market and assume its functionality post-validation, but it would be more ethical for us to create a structured method to check in on the settings in which the device is being implemented to ensure it is functioning correctly and being maintained well. While this might come at a cost for us, it is important for us to ensure the device is working well and being properly maintained, therefore still functioning as we have designed it to. Additionally, informed consent and data privacy and security is important for us to consider if putting the device on the market. Ensuring that the patients using the device understand what they are doing and where

their data is going is a huge ethical issue in the medical device industry, especially in low-resource communities. Lastly, if regulations change or the product is put on markets beyond India, it is important for us to consider improving the product to adhere to all regulations, not just the CDSCO regulations in place right now.

Our personal ethics and the professional ethics we are expected to uphold are very similar. While we were not aware of a lot of the ethical decisions engineers have to make prior to the 450 learning blocks, learning about these ethics and understanding the importance of ethical decision-making shifted our perspectives. We now realize just how important ethics are to consider in the design process, and we agree wholeheartedly with this importance.

RECOMMENDATIONS

The goal of this section is to provide all information relevant to our project at the time of our course ending. Specifically, we will be providing recommendations both on a system level as well as a detailed level, challenges we have not been able to solve, and areas we believe require further analysis. Using our experience with the project, we will also be providing usability questions in the form of formative and summative usability tests so the project can be taken over in the future, and the product can be verified and validated successfully.

System Level Recommendations

On the system level, we have recommendations in regards to IMU usage on the magnetic mat as well as further developing a met reset mechanism. Our recommendations would be to entirely remove the use of IMUs on the magnetic mat. IMUs are only used with the mat to measure temporal gait parameters such as cadence, and this parameter could instead be recorded manually. By putting a timer embedded in the start/stop button on the user interface, a physical therapist would be able to obtain cadence. This would also decrease the risk of affecting the accuracy of the IMUs through magnetic interference. However, we recognize the benefit of using IMUs, and recommend creating a larger system that uses both the magnetic mat and the IMUs. This system would be able to use one user interface, and a physical therapist would choose an option for the type of testing – IMU or magnetic mat – that they would want to do with a patient depending on the type of parameters they would want to collect. Since IMUs are widely available on the market, they would be easily implemented in the system and could be used for tests such as the six-minute walk test. IMUs will also be able to provide parameters such as step length and cadence during these tests. When a physical therapist wants to focus on obtaining spatial parameters, they would choose to use the magnetic mat due to its extreme accuracy. The mat is also capable of obtaining step width values of a patient's gait, which the IMUs are not able to do. We believe that this combination of tools would lead to a very effective system in providing physical therapists with the quantitative data they need to accurately diagnose gait disorders. The recommendation would be to not use them at the same time in order to eliminate risks of magnetic interference with IMUs.

For the mat reset mechanism, we recommend exploring a solution that uses an electric field to reset the mat because it would be able to reset the mat at the click of a button and eliminate the potential risks that we face with using the manual sliding magnet. Due to the scope of the semester, we were not able to explore this concept enough to finalize a useful design, but we believe that with the right expertise, it would be possible to implement. Further research into how this technology can be implemented and empirical testing with the magnetic mat will have to be performed in order to confirm that this would be a viable solution to resetting the magnetic mat display. It is important to note that implementing this solution would make the product reliant on electricity, a concern in the Poovanthi center. Due to the low power, we would recommend this implementation to be done using battery power, so it would function through power outages. We believe that these recommendations will improve the system we have designed to enable physical therapists in the Poovanthi Institute to provide data-driven assessments of patients gait.

Detail Level Recommendations

On the detail level of our design, we have recommendations to improve aspects of the magnetic mat and our camera system. For the magnetic mat, we recommend further analysis and testing be done on the viscous fluid in the mat, the top layer of the mat, and the magnets attached to the patients' foot in order to maximize the display of the patients' footprints on the mat. The viscous liquid has been tested, and we have found a combination of materials that provides us with our needs for our build design. However, in order to manufacture the final product, there will have to be further testing to determine the materials to use to ensure the performance of the mat is consistent with our durable and maintainable requirements. Since the viscous fluid comprises an oil base liquid, a thickener, magnetic particles, and a colorant, we recommend exploring different combinations of materials at different ratios to find the best solution. As for the top layer of the display, the material will need to be tested upon to determine the thickness of the mat that will provide enough structural integrity while maximizing the magnets ability to move the magnetic particles in the liquid. This optimization is critical for the overall success of our product. Finally, the type and size of magnets being used will have to be revisited to find the magnet that will perform best with the new thickness layer and viscous liquid. High magnetic strength does not necessarily contribute to the best performance, because the magnetic field of strong magnets may not fully pull all of the magnetic particles in the fluid to the surface. Therefore, empirical testing will have to be done on the viscous fluid, top layer of the mat, and magnet in order to determine the best performing combination of all three of those aspects. Additionally, we have determined the best method for attaching magnets to the patients' feet is to implement a set of personalized sandals in the center which match the foot sizes of patients. These sandals will have magnets embedded in them in order to show footprints on the mat. We recommend conducting further design work to ensure that it is possible to embed magnets in the soles of sandals that can create a visible footprint on our developed mat. We believe this will be more cost-effective and comfortable for the patients, instead of placing magnets on individuals' shoes. As for the camera

system, we recommend that multiple fixed cameras be used in order to capture the entirety of the magnetic display. The best way to go about this would be to do testing on the number of cameras and the distance and orientation with which they are placed in relation to the mat. The goal of this testing would be to minimize the number of cameras needed while maintaining the accuracy of the image capture post-processing algorithm. By addressing these detail-level recommendations, we fully believe that it would help establish a fully-developed solution capable of being used within the Poovanthi Institute.

On top of these recommendations, we recommend further implementing verification tests to determine how the device meets each specification. While the timeline of the semester did not allow us to complete verification testing, we believe this is the critical next step in determining feasibility of the design. We also recommend further addressing the risks previously posed in the discussion session after conducting further verification. While these recommendations are based on our design critique and the concerns we still have following our design process this semester, we believe there are more risks to address that would be developed throughout the verification process.

Formative Usability Tests

In order to mitigate the three critical risks stated previously in the section *Usability Risks,* we decided to create formative usability tests for each risk that we recommend implementing once the final design is further established. These would allow us to test more specific usability concerns outside of the verification and validation of the entire system. The details of this section are based on lectures from MECHENG 457: Front-End Design at the University of Michigan.

Slipping on the mat
Number of Participants: Eight
Participant Backgrounds*:* Various mobility levels and ages from 18-70
Methodology: Show participants the mat and instruct them on how to walk on it, starting from the initiation section.
Usability Instructions/Questions: Ask patients to walk forward on the mat. Ask patients to run on the mat. Ask patients how they feel while walking on the mat. Have patients repeat walking on the mat to see if there are any changes to their gait over time.

Difficulties resetting the mat
Number of Participants: Five
Participant Backgrounds*:* N/A – any participants are fine, no required background.
Methodology: Show participants how resetting the mat would work and instruct them to use the mechanism. Gauge how easy or challenging it is to use repetitively.
Usability Instructions/Questions: Have patients walk on the mat. Then, ask them to reset the mat. Show them an instruction manual on how to use the mat. Ask them to continuously slide the

mechanism back and forth to see how tedious the experience is. Ask participants how they feel about the sliding mechanism.

User interface confusion
Number of Participants: Ten
Participant Backgrounds*:* Various ages and understandings of technology
Methodology: Show participants the user interface (once developed). Have them utilize specific aspects of it to determine its ease of use.
Usability Instructions/Questions: Explain how the interface is used through an instruction manual. Ask participants to start and end a trial. Ask participants to restart the program. Ask participants to capture an image and print the data. Ask participants how they feel about the interface. Ask participants to move backwards in the interface.

CONCLUSION

The problem we are addressing is the need for a quantitative gait analysis system for rehabilitation use which can be implemented in a low-resource setting. Our stage and activity-based ME 450 design process is guiding our development of a solution. We utilized thorough benchmarking research, stakeholder analysis and engagement, and cultural context analysis to further define our problem context and develop our refined requirements and specifications, the most critical for a minimum viable product being accurate measurement of step width, stride length, step cadence, traversed distance, and time. Our concept generation process enabled us to create a morphological chart with the following sub-components: sensing, power source, attachment, display, data transmission, and data storage. After considering stakeholder input and conducting Pugh chart analysis for each sub-component, we selected strapped battery-operated IMUs with a pressure mat which use bluetooth technology to transmit data to a numerical and graphical display which will be stored in the cloud. After Alpha engineering analysis, we concluded that we needed to develop a lower cost solution. Therefore, we went through the design process to create our Beta solution. Ultimately, we decided on a magnetic mat with a magnetophoretic display containing an aluminum honeycomb cell structure for a viscous liquid and magnetic particles. The patient will have magnets on their soles for footprints to show up on the mat. Through IMUs and image processing, key gait parameters will be obtained. Recognizing time constraints for constructing a full-scale prototype this semester, we opted for a build design consisting of a 3D printed structure aligned with the dimensions determined from our engineering analysis to facilitate further testing of our design. The build design consists of a small-scale 3D printed structure that will allow us to further test our design and establish a proof of concept. In this report, we have also started our validation and verification process to determine whether or not our design meets our requirements and specifications and overall stakeholder needs. Along with verification and validation, a Failure Modes Effects Analysis was performed in order to validate the safety of our device and have determined there are no immediate critical safety concerns with our device. Finally, we have

proposed recommendations in regards to the system, design details, formative usability tests, as well as verification and validation plans for the continuation of the project following the end of the semester. Our design recommendations include creating a full system that uses IMUs and the magnetic mat separately, exploring new mat reset technologies, further analyzing components of the magnetophoretic display, and finding the most effective orientation of cameras for image capture.

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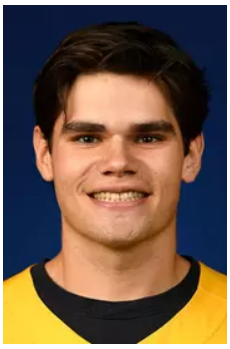
Shane Carr



Shane is a senior studying Mechanical Engineering at the University of Michigan. He grew up in Annapolis, MD where his interest in engineering sparked from working on his 1986 Ford Bronco that he drove in high school. By taking engineering classes offered at his high school he gained a deeper understanding of what it meant to be an engineer and decided to pursue a degree in it when he got to Michigan. This past summer, he interned with Ford in Dearborn, MI where he was a member of the BEV power calibration team and worked on the Mustang Maches calibrating the systems through conducting various tests. Post-graduation Shane hopes to return to the automotive industry but is open to any opportunities in mechanical design and hopes to create meaningful products for whatever company he may work for. Outside of academics, Shane is a member of the Men's Lacrosse team here at school where he plays goalie for them and enjoys balancing academic and athletic life.

Tianhao Wei

Tianhao "TH" Wei is a senior studying Mechanical Engineering and Computer Science at the University of Michigan. Born in Shanghai but raised in Los Angeles, TH grew up near the NASA Jet Propulsion Laboratory, where he was extensively exposed to engineering. So naturally, he excelled at mathematics in his youth, but he very much preferred participating in athletics growing up. He played soccer competitively before running track and field in high school and, now, for the University of Michigan. Here at the university, TH has been on UMich Solarcar as a member of the mechanical sub-team as well as a research intern working on M-Blue, an exoskeleton in the Locomotor Control Systems Laboratory. Before Michigan, TH studied Mechanical Engineering at Columbia University. Being in New York City, TH began listening to the Wall Street Journal daily and fell in love with business and economics along with his passions for engineering. This past summer, TH interned at UBS to better understand the financial industry. Recently, TH has had aspirations to become a quantitative analyst, design running shoes for Nike, or use his technical acumen for business ventures such as startups – all in the hopes of pursuing an MBA in the near future.

Anika Satish

Anika is a senior at the University of Michigan from Darien, Connecticut studying Mechanical Engineering with a minor in Business. Her interest in Mechanical Engineering began with an internship at ALPLA in India shadowing their product design process. She then became interested in healthcare and medical device design through her ENGR 100 section where she developed a design for a cochlear implant. She is on the mechanical sub-team of MHEAL Project Alivio where she is currently building a prototype of a hospital mattress to reduce the occurrence of pressure ulcers in a hospital in Guatemala. She continues to be involved in the engineering curriculum as discussion assistant for ENGR 110, enjoys being the outreach chair of Girl Up Michigan, and is a campus tour guide. Anika enjoys running and hiking in her free time. After graduation, Anika will be joining Boston Consulting Group as an Associate in Chicago, hoping to work in the healthcare practice. She hopes to one day work in medical device design.

Trevor Kessel

Trevor is a senior at the University of Michigan majoring in mechanical engineering and a minor in Business. He grew up in Long Island, NY where his grandfather and dad both work in the autobody industry. His interest in engineering was expressed through always wanting to Figure out how things worked. Entering college he had little exposure to engineering classes but quickly found interests. His first internship was at the Brookhaven National Lab where worked on systems within the Hazardous Waste Division. Last summer he interned with TRANE Technologies as a system sales intern. At the University of Michigan, Trevor is a member of the Men's Lacrosse team as a long stick middie. After graduation, Trevor will be working for TRANE Technologies as a systems sales associate, where he will continue to pursue his engineering passion.

APPENDIX A: Benchmarks

Benchmarks used to determine appropriate errors

	MDCs in the Literature						MDCs in This Study		
	[93]	[94]	[95]	[96]	[97]		[92]	MH-IMU	MH OPT
Spatio-temporal variables									
Step/Stride length [cm]	8.0	8.0	-	4.0	5.4	11.0	10.0	3.2	2.2
Step width [cm]	3.0	2.0	-	2.0	2.3	-	-	6.0*	1.7
Average of gait phases [%]	1.9	-	-	-	-	1.5	1.7	2.3*	0.8
Gait speed [cm/s]	17.0	12.0	-	9.0	15.0	12.0	7.0	6.5	0.7

Figure X The sources and minimum detecTable change values used in order to determine our stride length, step width, and cadence (Marín, Javier, 2020). To find more information visit the source listed.

APPENDIX B.1: CDSCO (Medical Device Division) Class B Standard under section 7.5

7.5 Sterilization:

(i) Where the device is supplied sterile, the dossier should contain the detailed information of the initial sterilization

validation including sterilizer qualification, bioburden testing, pyrogen testing, testing for sterilant residues (if

applicable) and packaging validation as per prescribed standards. Typically, the detailed validation information should include the method used, sterility assurance level attained, standards applied, the sterilization protocol developed in accordance with prescribed standards, and a summary of results.

(ii) Evidence of the ongoing revalidation of the process should also be provided. Typically this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.

APPENDIX B.2: *Handbook of human factors in medical device design - Adequate UX*

11.1.1.3 Provide User Guidance

Many caregivers favor user interfaces that provide step-by-step procedural instructions rather than leaving the user to infer the proper operational sequence from an array of options (Figure 11.5). Therefore, while providing instructions in the form of pop-ups or prompts might be perceived as an impediment to rapid task performance, it can be an appropriate and desirable means to ensure that people accomplish complex tasks correctly. Directions are also helpful to caregivers when they are learning to use a device. However, such procedural support can make users feel locked into one particular way of interacting with a device, and more experienced users might consider the interface inefficient and less satisfying. Therefore, designers should carefully consider the advantages and disadvantages of directed procedural support.

11.1.1.5 Optimize Interaction Requirements

Specific types of caregivers, such as interventional cardiologists and ultrasound technicians, spend hours every day operating specific equipment and, naturally, develop a high level of mastery. In contrast, many medical device users, including laypeople, are busy and usually lack the time or desire to master a software user interface. Most caregivers want to spend less time interacting with devices and more time interacting with patients. Work pressures mean that these caregivers cannot devote much time to learning to use a device. Designers must also appreciate that their device is not the only one that the caregiver must learn to use. Furthermore, caregivers might use dozens of complex devices, each of which has a unique user interface. Therefore, software interface designers should generally assume that they have the user's attention for only brief periods of time at best. This suggests bringing essential information and controls to the interface's top level. It also suggests designing software so that users receive essential information about important events, even if they are not attending to the device when such events occur.

Guideline 11.1: Number of Elements

As a general rule, it is easier to interact with software based on a conceptual model with a relatively small number of basic elements—perhaps 10 or fewer. Limiting the number of basic elements helps users form a simple mental model (i.e., big picture) of how the user interface is organized.

Guideline 11.15: Text Size

On-screen text should be sized to ensure reliable communication at the maximum expected viewing distance. For some applications, such as a digital thermometer, the expected viewing distance will be less than or equal to an arm's reach away from the face. For other applications, such as a heart rate monitor, the maximum expected viewing distance might be 25 feet or more, as one finds in some critical care environments. The recommended character size of critical information is 1/150th the viewing distance, suggesting that a key parameter value on a patient monitor viewed from 3 feet away should be greater than or equal to a quarter of an inch. The recommended character size of important, but noncritical information is 1/300th the viewing distance, suggesting that a key parameter value on a patient monitor viewed from 3 feet away should be greater than or equal to an eighth of an inch (a 9-point font, given that 1 point equals 1/72 inches). Viewed from a distance of 25 feet, critical and important information would be displayed using characters at least 2 inches tall.

APPENDIX B.3: System Usability Scale

System Usability Scale (SUS)

The System Usability Scale (SUS) provides a “quick and dirty”, reliable tool for measuring the usability. It consists of a 10 item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. Originally created by John Brooke in 1986, it allows you to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications.

Benefits of using a SUS

SUS has become an industry standard, with references in over 1300 articles and publications. The noted benefits of using SUS include that it:

- Is a very easy scale to administer to participants
- Can be used on small sample sizes with reliable results
- Is valid – it can effectively differentiate between usable and unusable systems

Considerations when using a SUS

If you are considering using a SUS, keep the following in mind:

- The scoring system is somewhat complex
- There is a temptation, when you look at the scores, since they are on a scale of 0-100, to interpret them as percentages, they are not
- The best way to interpret your results involves “normalizing” the scores to produce a percentile ranking
- SUS is not diagnostic - its use is in classifying the ease of use of the site, application or environment being tested

The System Usability Scale

When a SUS is used, participants are asked to score the following 10 items with one of five responses that range from Strongly Agree to Strongly disagree:

1. I think that I would like to use this system frequently.
2. I found the system unnecessarily complex.
3. I thought the system was easy to use.
4. I think that I would need the support of a technical person to be able to use this system.
5. I found the various functions in this system were well integrated.
6. I thought there was too much inconsistency in this system.
7. I would imagine that most people would learn to use this system very quickly.
8. I found the system very cumbersome to use.
9. I felt very confident using the system.
10. I needed to learn a lot of things before I could get going with this system.

The questionnaire and scoring are outlined in the System Usability Scale (SUS) Template.

Interpreting Scores

Interpreting scoring can be complex. The participant's scores for each question are converted to a new number, added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-100. Though the scores are 0-100, these are not percentages and should be considered only in terms of their percentile ranking.

Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average, however the best way to interpret your results involves "normalizing" the scores to produce a percentile ranking.

The references at the end of this page and the template provide more information in context about the process.

References

- SUS: A Quick and Dirty Usability Scale by John Brooke (read full text or download as a PDF, and download the proper citation)
- Measuring Usability with the System Usability Scale (SUS) by Jeff Sauro, PhD
- SUS: A Retrospective by John Brooke
- Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale by Aaron Bangor, PhD, CHFP, Philip Kortum, PhD, and James Miller, PhD

APPENDIX B.4: Indian anthropometric data

TABLE I
BRIEF DESCRIPTION OF PARAMETERS WHILE STANDING

S. No.	Criteria for standing posture	Brief description
1	Weight (kg)	Weight of a person without shoes
2	Height	Length from floor to top of the head
3	Depth (full body)	Distance from back to the front of the chest
4	Forward arm length	Length from spine to Arm stretched while standing in forward the direction
5	Forward arm height	Height from the floor to the arm stretched while standing in the forward direction
6	Both arms stretched outwards	Distance between tip of the fingers when both arms stretch fully in such a way that it is perpendicular to the spine
7	akimbo	Distance between tips of an elbow to the spine while in akimbo position
8	Sideway arm length	Length from spine to Arm stretched while standing in the sideway direction
9	Sideway arm height	Height from the floor to the arm stretched while standing in the forward direction
10	Forward step	Stepping in the forward direction
11	Sideway step	Stepping in sideway direction
12	Bending forward length	Length between spine and tip of the finger while bending in the forward direction
13	Bending forward height	Height between floor and tip of the finger while bending in the forward direction
14	Upper Leaning length	Length between spine and tip of the finger while leaning forward
15	Upper leaning height	Height between floor to tip of the finger while leaning forward
16	Body depth during movement	Distance from back to the front of the chest during free movement

TABLE II
BRIEF DESCRIPTION OF PARAMETERS WHILE SITTING

S. No.	Criteria for standing posture	Brief description
Cross-legged sitting		
1	Cross-legged width	Length from knee to knee while sitting cross-legged
2	Cross-legged sitting height (front)	Height from floor to top of the head while sitting cross-legged
3	Buttock knee length	Distance from butt to the knee while sitting cross-legged
Normal sitting		
4	Normal sitting	Sitting on a heightened plane, length from top of the head to sitting plane
5	Knee length	Height from the floor to knee while sitting normally
6	Straight sitting	Sitting with shoulder straight
7	Thigh height	Height from floor to thigh while sitting normally
8	Buttock-knee length	Length from buttock to knee during normal sitting.
9	Buttock-long leg	Length of buttock to leg while stretched forward
10	Buttock-full stretched leg	Length between buttock to the tip of the toe while Leg fully stretched while sitting
11	Buttock-mid stretched leg	Length between buttock to the tip of the toe while Leg mid stretched while sitting
12	Back Hip depth	Width of hip from the back while sitting
13	Relaxed depth	Distance between thigh to thigh while sitting normally in a relaxed position
14	Relaxed elbow	Distance between elbow to elbow while spreading arms
15	Closed leg	Knee to knee length while sitting with closed leg
16	sleeping	Length of Top of the head to the tip of the toe
17	Armchair length	Dimensioning armchair length

APPENDIX B.5: CDSCO description of the pilot and pivotal investigations

(6) Pilot Clinical Investigation

(i) Pilot clinical investigation is defined as those clinical investigations which are used to acquire specific essential information about a device before beginning the pivotal clinical investigation. Pilot clinical investigation is exploratory study which may be conducted in a few numbers of patients with the disease or condition being studied before moving to large population and scope that give insight into the performance and safety of a device but cannot provide definitive support for specific mechanistic or therapeutic claims.

(ii) The objectives of a pilot clinical investigation typically include assessing feasibility (e.g, preliminary device performance), exploring eligibility criteria and their practical application for pivotal controlled investigation, ascertaining potential harm (preliminary safety evaluations), studying device mechanism, validating a method for determining an outcome measure, using a defined device mechanism to validate a surrogate outcome measure, and evaluating the logistics of pivotal investigation for performance.

(iii) If the application is for conduct of clinical investigation as a part of multi-national clinical development of medical device, the number of sites and the patients as well as justification to conduct such clinical investigation in India shall be provided to the Central Licensing Authority.

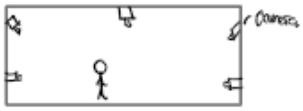
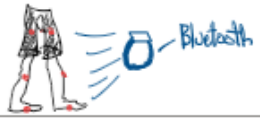
(7) Pivotal Clinical Investigation:

(i) The pivotal clinical investigation is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Pivotal clinical investigation is confirmatory study that may be conducted in large number of patients with disease or condition being studied and scope to provide the effectiveness and adverse effects.

(ii) For investigational medical device which does not have a predicate medical device but has been approved for sale or distribution in any country other than India, pivotal studies need to be carried out primarily to generate evidence of safety and effectiveness of the medical device in Indian patients when used as recommended in the prescribing information except in cases of investigational medical device classified under class A which shall be governed as per permission of para 6 above. Prior to conduct of pivotal clinical investigation in Indian subjects, the Central Licensing Authority may require making the pilot study data available to assess whether the pilot data is in conformity to the data already generated outside the country.

APPENDIX C: Concept generation methods and examples

Method 1: Morphological Chart

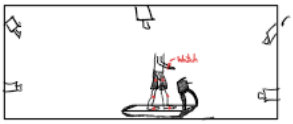
Modes of movement	Treadmill (13) 		Walking on ground (20) 
Measuring devices	Wearable Sensors (1) 	Camera System: (8) 	Mat with Pressure Sensors (4) 
Display	Watch (16) 	tablet (9) 	Computer (10) 

21) - Treadmill
- Wearable sensors
- Watch

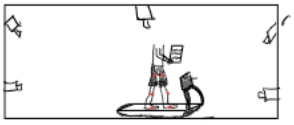
22) - Treadmill
- Wearable sensors
- Tablet

23) - Treadmill
- Wearable sensors
- Computer

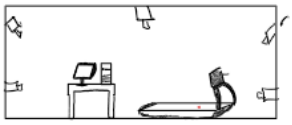
24) - Treadmill
- Camera System
- Watch



25) - Treadmill
- Camera System
- Tablet



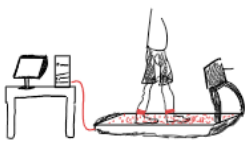
26) - Treadmill
- Camera System
- Computer



27) - Treadmill
- Mat w/ Pressure Sensors
- Watch

28) - Treadmill
- Mat w/ Pressure Sensors
- Tablet

29) - Treadmill
- Mat w/ Pressure Sensors
- Computer

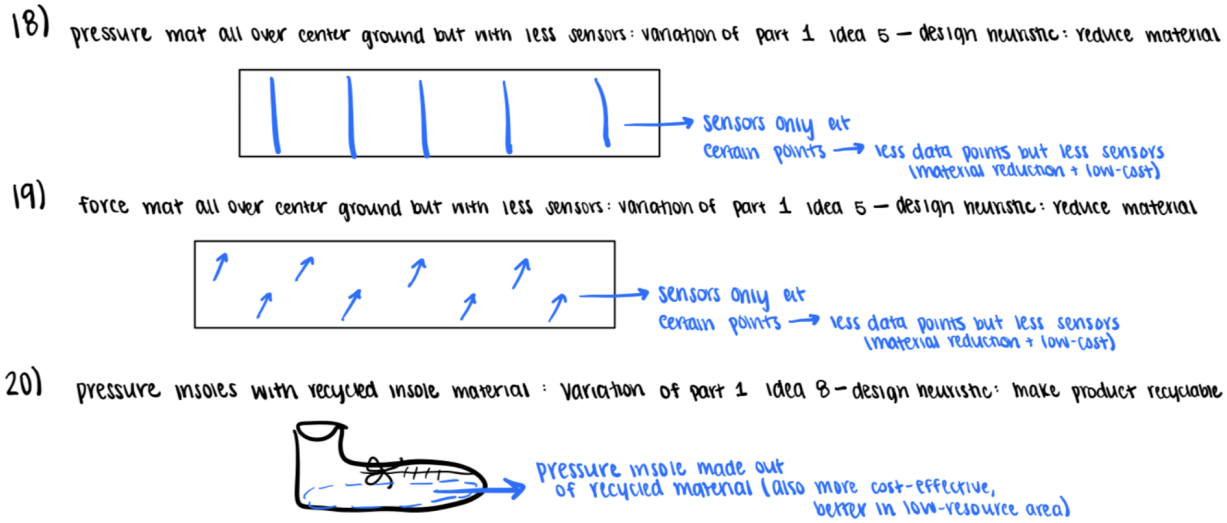


30) - Walking on ground
- Wearable sensors
- Watch

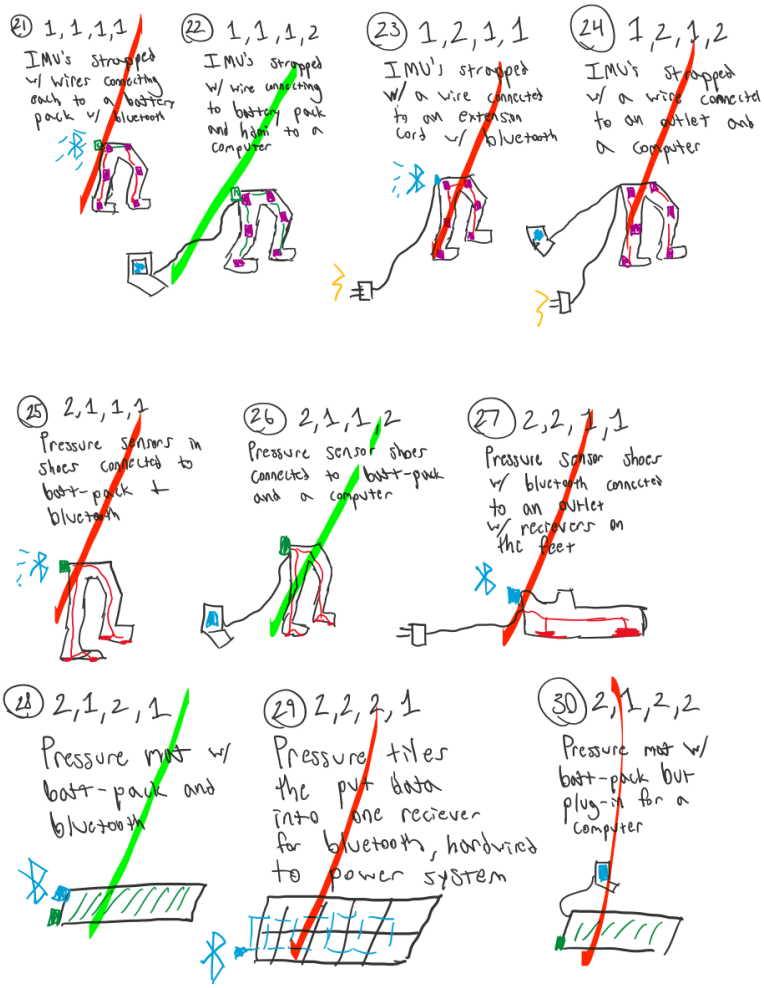
31) - Walking on ground
- Wearable sensors
- Tablet

32) - Walking on ground
- Wearable sensors
- Computer

Method 2: Design Heuristics

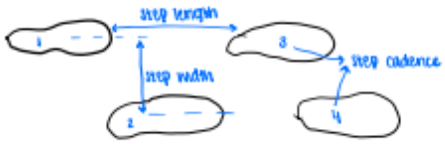


Filter 1: Parameter capability, Low-price, Safety, Reusability, Repetition



All Concepts Generated:

1) Ink foot stamp system: patient wears sandals with ink on the soles + walks – PT can then measure parameters from stamps



2) sensors on each foot – communicate through bluetooth

3) wearable IMUs all up legs – can pull out info

4) visual observation with camera iphone app: app that can visually interpret gait parameters through camera

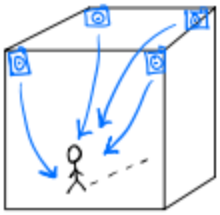
5) pressure mat all over center ground: patients can all walk on pressure mat to determine parameters

6) knee brace with sensor attachments (IMUs)

7) ankle brace with sensor attachments (IMUs)

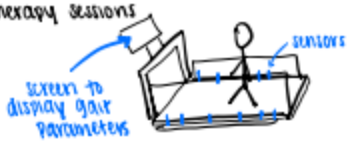
8) pressure insoles : inserts into shoes with a smaller version of pressure mat technology

9) high-tech motion capture system : similar to 4 but with cameras on walls of center to capture data

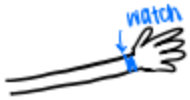


10) force plate mat on center ground : mat on center ground to measure forces from feet

11) treadmill with bluetooth-communicating sensors : bring multiple treadmills to the center for PTs to use during therapy sessions



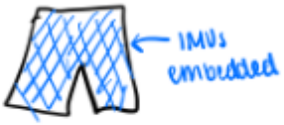
12) smartwatch : similar to an apple watch but only with the ability to measure gait parameters



13) ankle-watch : like a smartwatch but fits around the ankle like an anklet. picks up parameters similarly

14) measuring tape in real-time analysis: PT: use a measuring tape while patient walks - manual measurements

15) IMU Shorts: since patients at the center wear shorts, we can create shorts containing IMUs for measurement

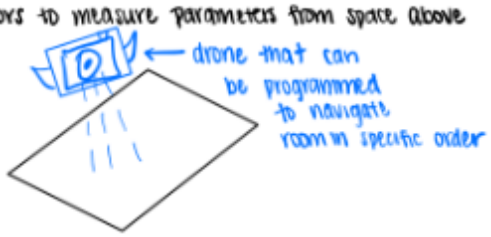


16) EMG sensors attached to patient: measures muscle electrical activity

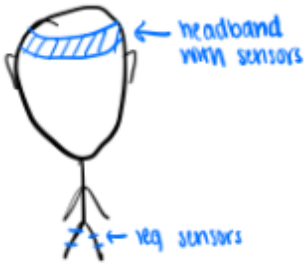
17) gait-measuring socks: socks that contain tiny embedded sensors that measure all pressure points + step force + also measure timing

18) sensor walking cane: walking cane with sensors which pick up gait data (IMUs)

19) drone containing sensors to measure parameters from space above



20) sensor headset to measure neurological activity: since most patients have gait disorders from stroke, this can assess their brain function in addition to sensors to measure gait



- determining sub-sections
- attach product to user
- reduce materials (sensors → low-cost)

morph chart:

sub-functions	solutions →								
wearable aspect	knee brace	ankle brace	anklet	watch	shorts	sandals	insoles	socks	sneaker
sensor technology	IMUs	pressure sensors	force plates/ sensors	EMG					
data capture/ display	drone w/ display	cameras w/ display	bluetooth w/ display	wires + screen display	app display				

← iterating through various combos of these

1) IMU insoles: variation of part 1 idea 8

- insoles containing IMU technology

2) IMU socks: variation of part 1 idea 17

- socks containing IMU technology

3) bluetooth powered IMU insoles: variation of part 1 ideas 2 + 8

- insoles containing IMUs + bluetooth technology for sensors to communicate to pick up step width data

4) pressure socks: variation for part 1 ideas 8 + 17

- socks with pressure sensors underneath

5) force-measuring socks: variation of part 1 ideas 8 + 10

- socks with embedded force plates

6) knee brace with wires attaching to EMG sensors: variation of part 1 ideas 6 + 16

- knee brace for wearability, measures muscle movement

7) ankle brace with wires attaching to EMG sensors: variation of part 1 ideas 7 + 16 + part 2 idea 6

- ankle brace for wearability, measures muscle movement

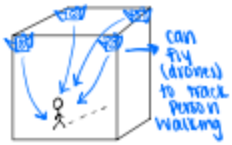
8) anklet with wires attaching to EMG sensors: variation of part 1 ideas 13 + 16 + part 2 idea 7

← small anklet w/ emgs attached – reduces material, easier to make adjustable

9) Automatic ink-measuring system: variation of part 1 idea 1

- ink on soles of patients feet but includes app with camera to automatically measure - no longer manual process

10) drone motion-capture system: variation of part 1 ideas 9 + 19



- motion-capturing drones attached to high-tech cameras to record data

11) pressure-detecting walking cane: variation of part 1 idea 18

- walking cane that detects pressure using small sensors for pressure detection

12) force-detecting walking cane: variation of part 1 idea 18

- walking cane that detects forces using small sensors for force detection

13) pressure sandal: variation of part 1 idea 8

- sandal with pressure mat technology

14) force sandal: variation of part 1 idea 10 + part 2 idea 13

- sandal with force plate technology

15) pressure sneaker: variation of part 1 idea 8

- sneaker with pressure mat technology on shoe itself

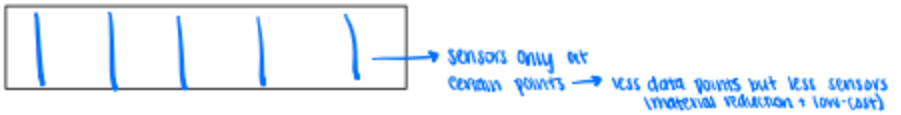
16) force sneaker: variation of part 1 idea 10

- sneaker with force plate technology on shoe itself

17) knee strap with IMU attachments: variation of part 1 idea 6 — design heuristic: reduce material

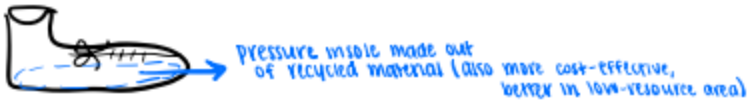
- single strap to reduce material

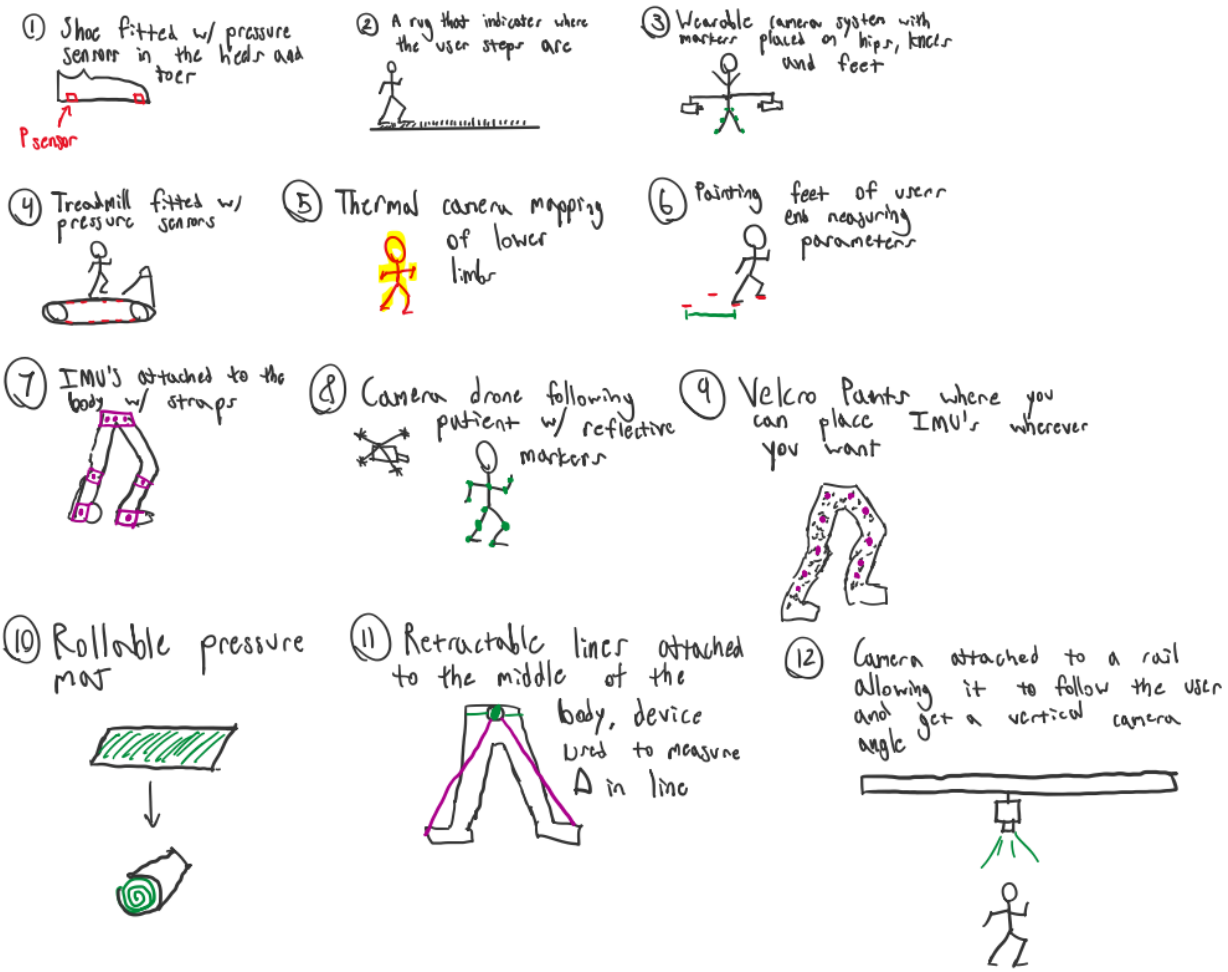
18) pressure mat all over center ground but with less sensors: variation of part 1 idea 5 — design heuristic: reduce material



19) force mat all over center ground but with less sensors: variation of part 1 idea 5 — design heuristic: reduce material

20) pressure insoles with recycled insole material: variation of part 1 idea 8 — design heuristic: make product recyclable



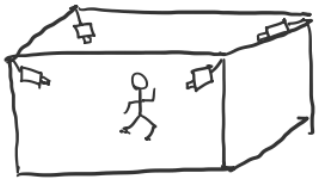

1 Shoe fitted w/ pressure sensors in the heels and toes
P sensor
2 A rug that indicates where the user steps are
3 Wearable camera system with markers placed on hips, knees and feet
4 Treadmill fitted w/ pressure sensors
5 Thermal camera mapping of lower limbs
6 Painting feet of users and measuring parameters
7 IMU's attached to the body w/ straps
8 Camera drone following patient w/ reflective markers
9 Velcro Pants where you can place IMU's wherever you want
10 Rollable pressure mat
11 Retractable liners attached to the middle of the body, device used to measure Δ in line
12 Camera attached to a rail allowing it to follow the user and get a vertical camera angle

(13) Pressure sensors that can be placed on the bottom of shoes

straps

(14) Sandbox where you can measure distance of steps

(15) Room full of motion capture cameras

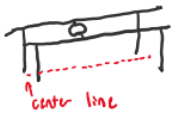


(16) Smartphone app + hip attachment. Uses phones accelleromeater

(17) Pressure Tiler instead of a floor

(18) IMU shoes

(19) Waist system that keeps patient on a straight line to measure step width



(20) Exoskeleton w/ sensors in the joints

Morphological chart 1 2 3

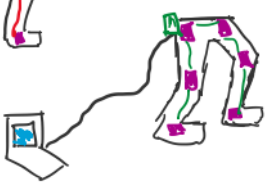
Measure Gait Parameters	IMU's	Pressure Sensors	Motion Capture
Must last 7 hours a day	Battery Powered	Plugged in with backup power	
Multiples Uses a day	Wearable	One thing in a room	
Collect Data	Bluetooth	Hard connection	

(21) 1, 1, 1, 1

IMU's strapped w/ wires connecting each to a battery pack w/ bluetooth

(22) 1, 1, 1, 2

IMU's strapped w/ wire connecting to battery pack and hdmi to a computer

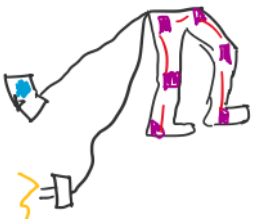


(23) 1, 2, 1, 1

IMU's strapped w/ a wire connected to an extension cord w/ bluetooth

(24) 1, 2, 1, 2

IMU's strapped w/ a wire connected to an outlet and a computer

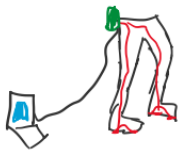


(25) 2,1,1,1

Pressure sensors in shoes connected to batt-pack + bluetooth

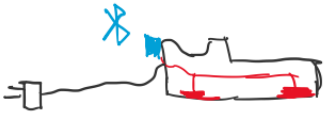
(26) 2,1,1,2

Pressure sensor shoes connected to batt-pack and a computer



(27) 2,2,1,1

Pressure sensor shoes w/ bluetooth connected to an outlet w/ recievers on the feet

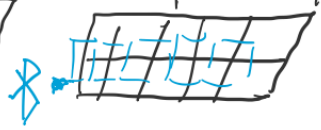


(28) 2,1,2,1

Pressure mat w/ batt-pack and bluetooth

(29) 2,2,2,1

Pressure tiles the put data into one reciever for bluetooth, hardwired to power system



(30) 2,1,2,2

Pressure mat w/ batt-pack but plug-in for a computer

(31) 3,1,1,1

Two wearable cameras that each have bluetooth and battery's

(32) 3,2,1,1

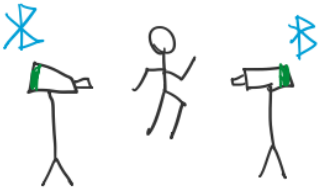
360° camera thats connected to an outlet w/ bluetooth

(33) 3,1,1,2

360° camera connected to a wearable tablet that uses a battery

(34) 3,1,2,1

Adjustable camera stands that can be set up in a room each w/ battery and bluetooth



(35) 3,2,2,1

Camera room with cameras mounted and connected to power, each w/ bluetooth

(36) 3,2,2,2

Camera room w/ mounted cameras with a stand to plug your computer into

SCAMPER

37 Combine:

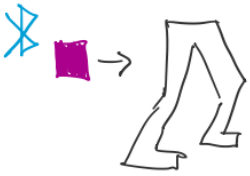
System that uses both IMU's on legs and pressure sensing shoes

38 Put to other uses:

Have sensors make an exoskeleton on the PT walk like the patient so they can give a good diagnosis.

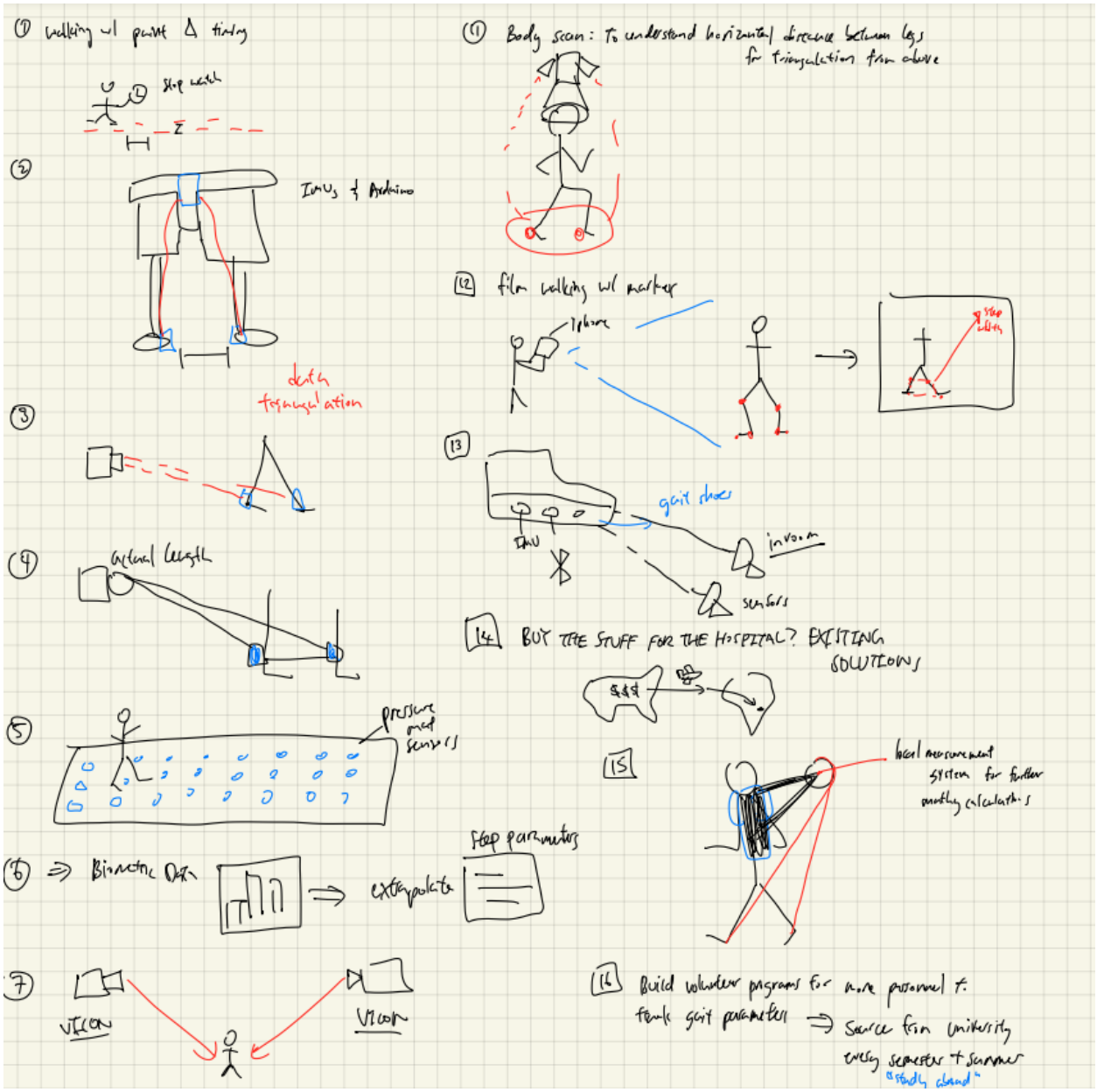
39 Eliminate:

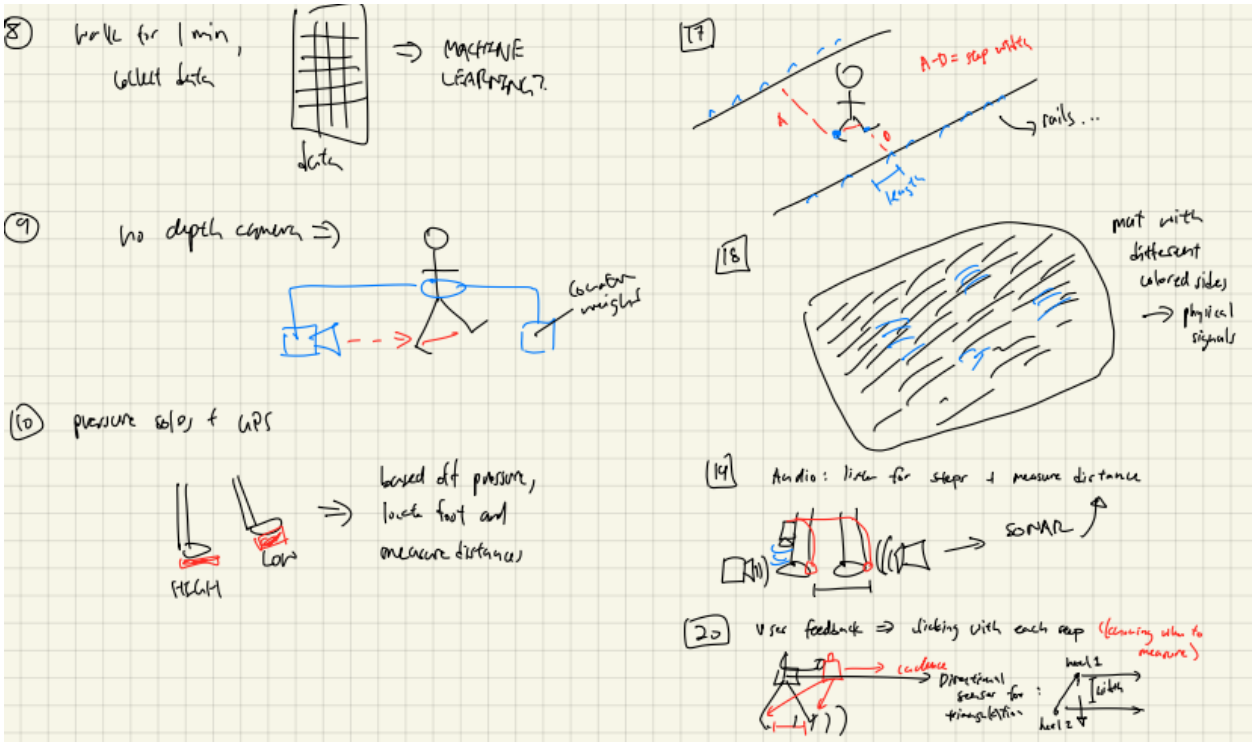
Sensors that communicate via bluetooth and are stuck on the body with some sort of adhesive

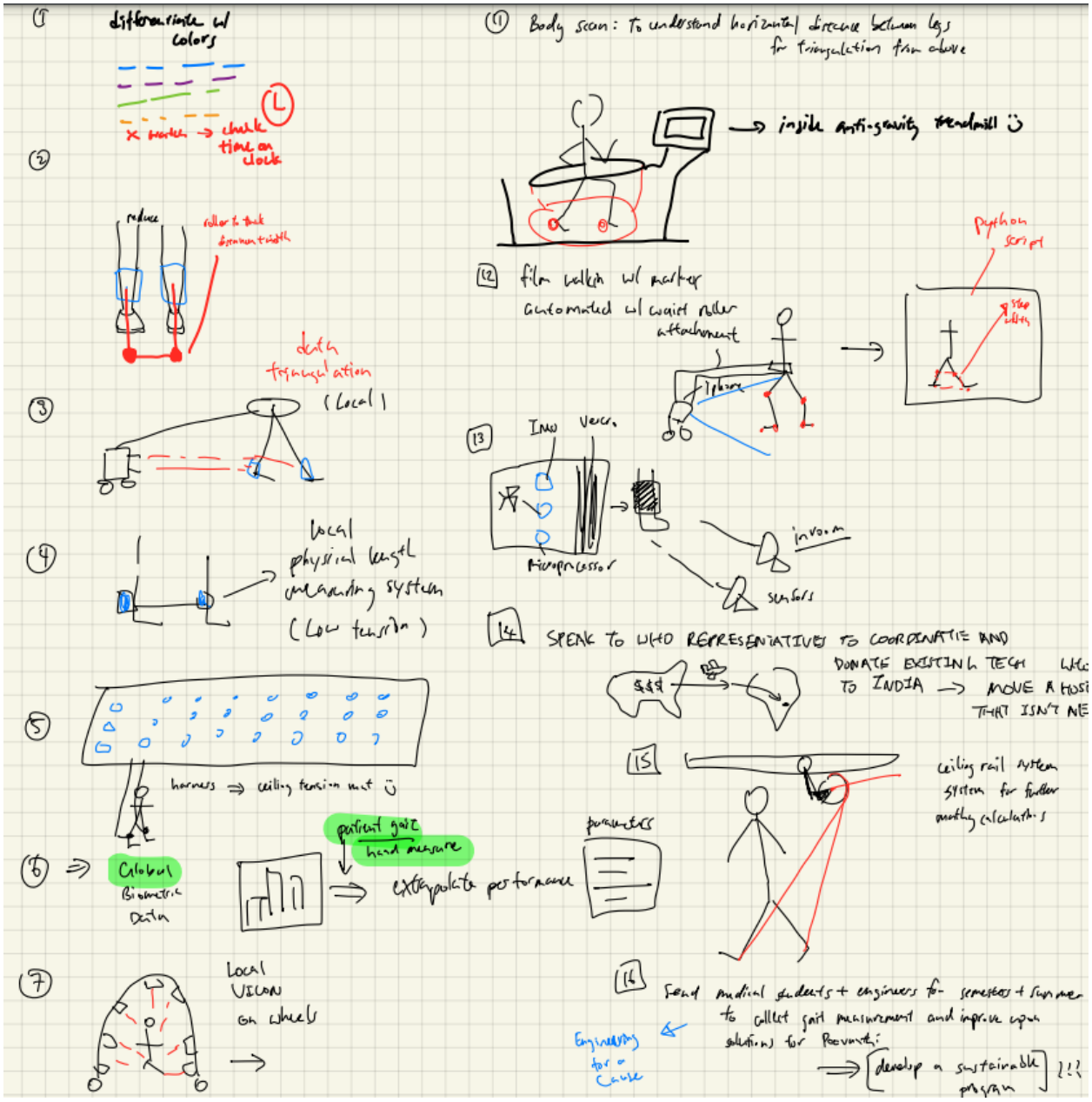


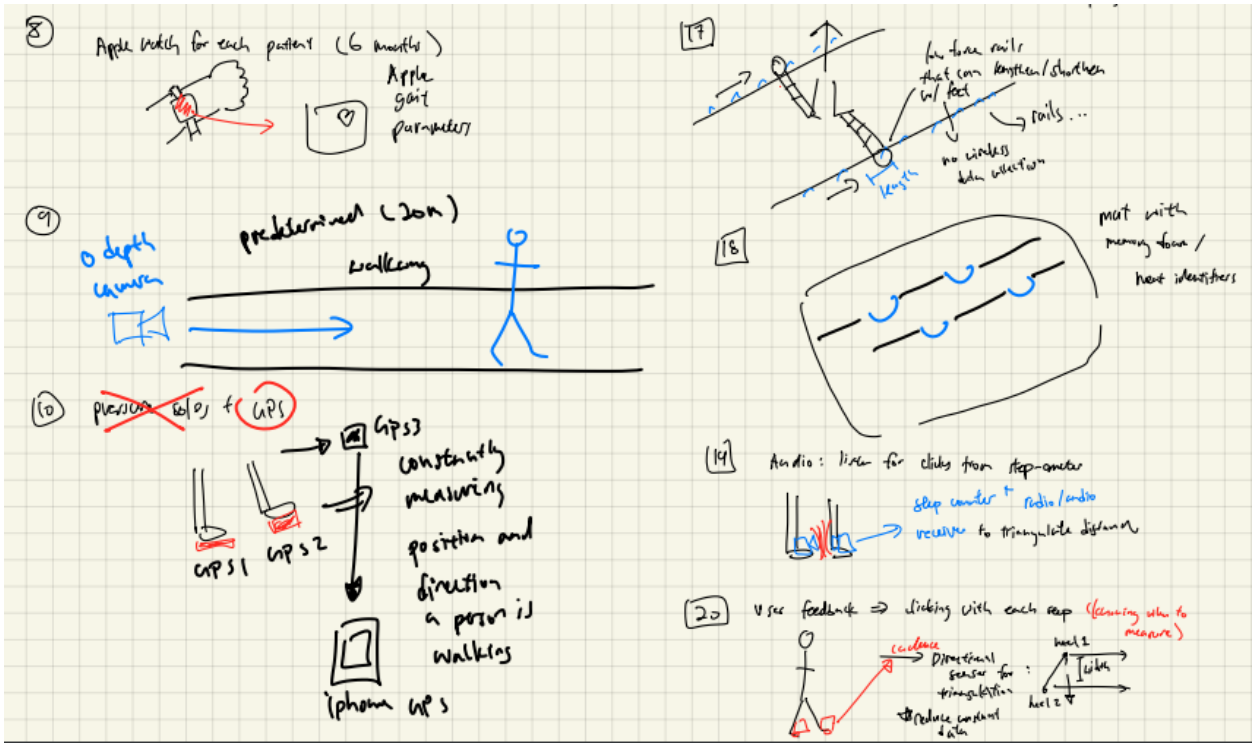
40 Rearrange:

A camera that follows the patient directly from behind to measure step width


① walking w/ pause Δ timing
step width
z
②
IMUs + Arduino
depth triangulation
③
④
external length
⑤
pressure mat sensors
⑥ ⇒ Biomech Dat
⇒ extrapolate
step parameters
⑦
VICON
VICON
⑪ Body scan: To understand horizontal distance between legs for triangulation from above
⑫ film walking w/ marker
iphone
step width
⑬
gait shoes
IMU
insoles
sensors
⑭ BUY THE STUFF FOR THE HOSPITAL? EXISTING SOLUTIONS
$$$
⑮
head measurement system for further marker calculations
⑯ Build volunteer programs for more personnel f. female gait parameter ⇒ Source from university every semester + Summer "study abroad"

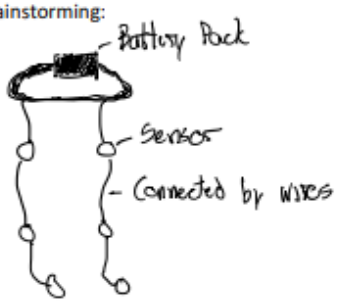

8
walk for 1 min,
collect data
data
⇒ MACHINE LEARNING?
9
no depth camera ⇒
counter weight
10
pressure soles + GPS
HIGH
LOW
⇒ based off pressure, locate foot and measure distance
17
A-D = step width
A
D
rails...
length
18
mat with different colored sides
→ physical signals
19
Audio: listen for steps + measure distance
SONAR
20
User feedback ⇒ clicking with each step (learning when to measure)
cadence
Directional sensor for triangulation
heel 1
heel 2
side


differentiate w/ colors
L
x marker → check time on clock
reduce
roller & back dynamic weight
data triangulation
(local)
local physical length measuring system
(low tension)
harness ⇒ ceiling tension mat ü
Global Biometric Data
patient gait hand measure
extrapolate performance
parameters
Local VICON on wheels
(11) Body scan: To understand horizontal distance between legs for triangulation from above
→ inside anti-gravity treadmill ü
(12) film walkin w/ marker
customized w/ waist roller attachment
Python script
step width
(13)
IMU
Vecs.
Microprocessor
sensors
in vivo
(14) SPEAK TO WHO REPRESENTATIVES TO COORDINATE AND
DONATE EXISTING TECH
TO INDIA → MOVE A HOSI
THAT ISN'T NE
$$$
(15)
ceiling rail system
system for further
(16)
Send medical students + engineers for semesters + summer
to collect gait measurement and improve upon
solutions for Peruvian
develop a sustainable
program
!!!
Engineering for a Cause

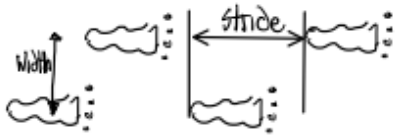

8
Apple watch for each patient (6 months)
Apple gait parameters
9
predetermined (20m)
walking
depth camera
10
GPS3
constantly measuring
position and direction a person is walking
GPS 1
GPS 2
iphone GPS
17
for those rails that can lengthen/shorten w/ feet
rails...
no wireless data collection
length
18
mat with memory foam / heat identifiers
19
Audio: listen for clicks from step-counter
step counter + radio/audio receiver to triangulate distance
20
User feedback ⇒ clicking with each step (knowing when to measure)
cadence
Directional sensor for triangulation
reduce constant data
heel 1
heel 2
width

2) Brainstorming:

1)



2) Pant on feet and a stop watch



3) Treadmill w/ sensor mat to measures metrics & time

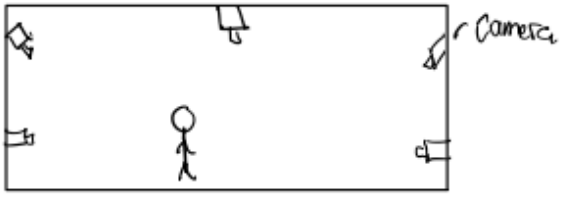
4) Mat with Pressure Sensors

5) Leg Sleeves with sensors in them to computer

6) Drone flying behind patient measuring metrics

7) Railings with sensors

8) Camera System:



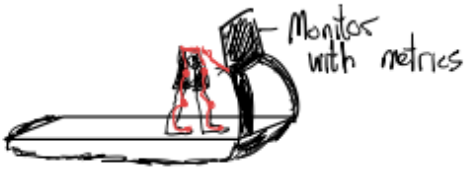
9) Sensor Attached w/ markers to tablet

10) Rover that follows behind Person

11) "Hoola Hoop Sensor"

12) Bubble wrap rolled out on floor and clock

13) Treadmill with sensors attached



14) Shoe with sensors that connect to monitor

15) Knee Brace w/ sensor

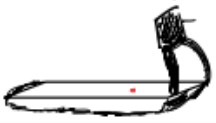
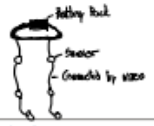
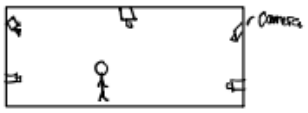
16) Watch that connects to sensors

17) Hat that has infared cameras

18) Pressure sensitive tiles

19) Full Body sensor suit

20) Ankle bracelet with sensor

Modes of movement	Treadmill (13) 		Walking on ground (20) 
Measuring devices	Wearable Sensors (9) 	Camera System: (8) 	Mat with Pressure Sensors (4) 
Display	Watch (16) 	tablet (9) 	Computer (10) 

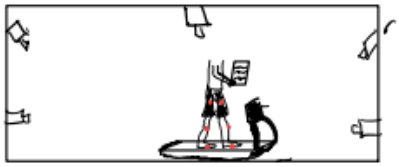
21) - Treadmill
- Wearable sensors
- Watch

22) - Treadmill
- Wearable sensors
- Tablet

23) - Treadmill
- Wearable sensors
- Computer

24) - Treadmill
- Camera System
- Watch

25) - Treadmill
- Camera System
- Tablet



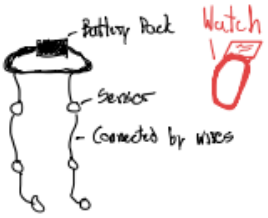
26) - Treadmill
- Camera System
- Computer

27) - Treadmill
- Mat w/ Pressure Sensors
- Watch

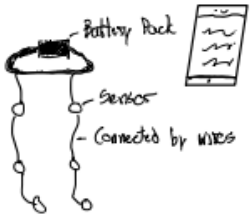
28) - Treadmill
- Mat w/ Pressure Sensors
- Tablet

29) - Treadmill
- Mat w/ Pressure Sensors
- Computer

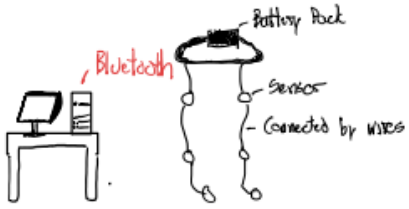
30) - Walking on ground
- Wearable sensors
- Watch



31) - Walking on ground
- Wearable sensors
- Tablet

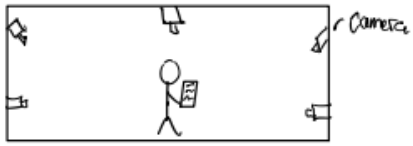


32) - Walking on ground
- Wearable sensors
- Computer

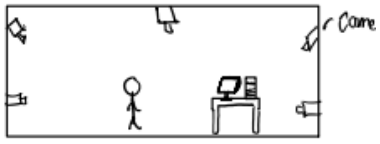


33) - Walking on ground
- Camera System
- Watch

34) - Walking on ground
- Camera System
- Tablet



35) - Walking on ground
- Camera System
- Computer



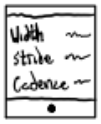
36) - Walking on ground
- Mat w/ Pressure Sensors
- Watch

37) - Walking on ground
- Mat w/ Pressure Sensors
- Tablet

38) - Walking on ground
- Mat w/ Pressure Sensors
- Computer

Method 2: Heuristics

- Offer optional Components (39)
  - ↳ Wearable sensors with a sensor map
    - ↳ That utilizes a tablet for Therapist



- Attach product to user (40)
  - ↳ Monitor on user with wearable sensors
    - ↳ So therapist can see progress

APPENDIX D: Pressuremat Theoretical Testing Code

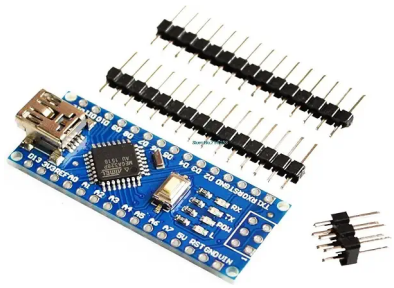
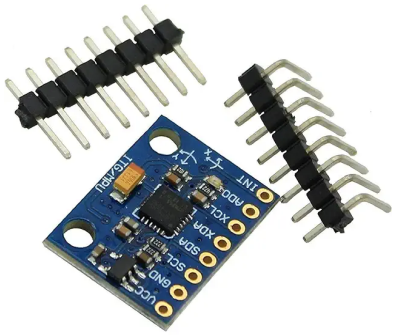
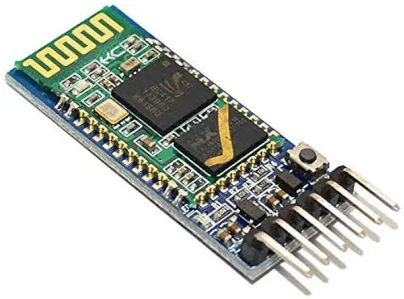
```
import numpy as np
import matplotlib.pyplot as plt

# Define the dimensions of the grid
grid_width = 10
grid_height = 10

# Generate mock pressure sensor data (values between 0 and 1)
pressure_data = [
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 0, 1, 1, 1, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 2, 2, 1, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 3, 4, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 3, 2, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 1, 2, 2, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 2, 3, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 3, 3, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 2, 4, 3, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 2, 3, 3, 3, 1, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 1, 1, 1, 1, 0, 0],
[0,0,0,0,0,0,0,0,0,0, 0, 0, 0, 0, 2, 2, 2, 2, 2, 0, 0],
[0, 0, 0, 0, 0, 1, 1, 1, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 2, 2, 2, 1, 0,0,0,0,0,0,0,0,0,0,0],
[ 0, 0, 0, 0, 1, 2, 3, 4, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 2, 3, 2, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 1, 2, 2, 0, 0,0,0,0,0,0,0,0,0,0,0],
[ 0, 0, 0, 0, 1, 2, 2, 3, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 2, 3, 3, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 2, 4, 3, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 2, 3, 3, 3, 1, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 0, 1, 1, 1, 1, 0, 0,0,0,0,0,0,0,0,0,0,0],
[0, 0, 0, 2, 2, 2, 2, 2, 0, 0,0,0,0,0,0,0,0,0,0,0],
]
for row in range(0, len(pressure_data)):
for col in range(0, len(pressure_data[row])):
pressure_data[row][col] = pressure_data[row][col] * 5

# Create a grid of colors based on the pressure data
plt.imshow(pressure_data, cmap='coolwarm', interpolation='nearest', origin='lower')
plt.colorbar(label='Pressure Strength (relative)')

# Add labels and title
plt.xlabel('X-axis [inches]')
plt.ylabel('Y-axis [inches]')
plt.title('Mock Foot Pressuremap')

# Display the grid
plt.show()
```

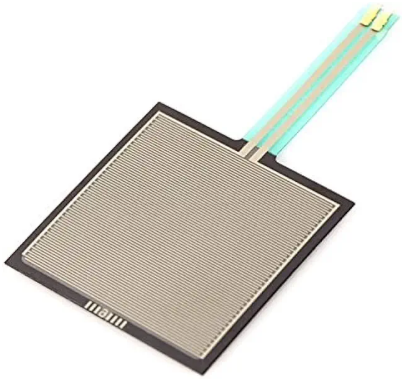
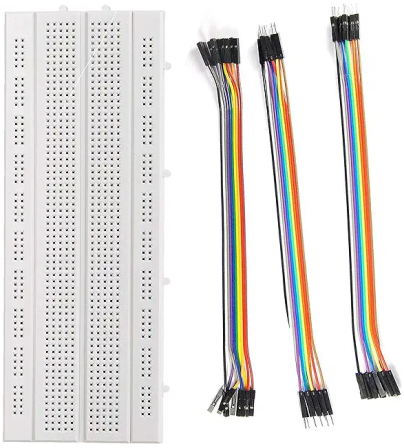
Appendix E: IMU Empirical Testing Code

```
import numpy as np
import matplotlib as mpl
import matplotlib.pyplot as plt
import math
import pandas as pd
from scipy.integrate import cumulative_trapezoid

# Read in the data for the time and X and Y velocities
Lfoot = pd.read_csv("Lthigh.csv", delimiter=",", skiprows=11)
Rfoot = pd.read_csv("Lumbar.csv", delimiter=",", skiprows=11)
Lfoot['SampleTimeFine'] = (Lfoot['SampleTimeFine'] - Lfoot.at[1,'SampleTimeFine']) * .000001
Rfoot['SampleTimeFine'] = (Rfoot['SampleTimeFine'] - Rfoot.at[1,'SampleTimeFine']) * .000001

plt.Figure(1)
plt.plot(Lfoot['SampleTimeFine'], Lfoot['FreeAcc_X'],color='r', label = 'FreeAccel_X')
plt.plot(Lfoot['SampleTimeFine'], Lfoot['FreeAcc_Y'],color='g', label = 'FreeAccel_Y')
plt.plot(Lfoot['SampleTimeFine'], Lfoot['FreeAcc_Z'],color='b', label = 'FreeAccel_Z')
plt.xlabel("Time [s]")
plt.ylabel("Accel [m/s^2]")
plt.title('Left Foot Accelerations')
plt.legend()

# plt.Figure(2)
# plt.plot(Rfoot['SampleTimeFine'], Rfoot['FreeAcc_X'],color='r', label = 'FreeAccel_X')
# plt.plot(Rfoot['SampleTimeFine'], Rfoot['FreeAcc_Y'],color='g', label = 'FreeAccel_Y')
# plt.plot(Rfoot['SampleTimeFine'], Rfoot['FreeAcc_Z'],color='b', label = 'FreeAccel_Z')
# plt.xlabel("Time [s]")
# plt.ylabel("Accel [m/s^2]")
# plt.title('Right Foot Accelerations')
# plt.legend()

# Integrate the velocities for x and y positions
LDictV = {'Time':[],'vel[1]':[],'vel[2]':[],'vel[3]':[]}
LfootVel = pd.DataFrame(LDictV)
RDictV = {'Time':[],'vel[1]':[],'vel[2]':[],'vel[3]':[]}
RfootVel = pd.DataFrame(RDictV)

LDictP = {'Time':[],'pos[1]':[],'pos[2]':[],'pos[3]':[]}
LfootPos = pd.DataFrame(LDictP)
RDictP = {'Time':[],'pos[1]':[],'pos[2]':[],'pos[3]':[]}
RfootPos = pd.DataFrame(RDictP)

lv1 = cumulative_trapezoid(Lfoot['FreeAcc_X'],Lfoot['SampleTimeFine'], initial=0)
lv2 = cumulative_trapezoid(Lfoot['FreeAcc_Y'],Lfoot['SampleTimeFine'], initial=0)
lv3 = cumulative_trapezoid(Lfoot['FreeAcc_Z'],Lfoot['SampleTimeFine'], initial=0)
LfootVel['Time'] = Lfoot['SampleTimeFine']
LfootVel['vel[1]'] = lv1
LfootVel['vel[2]'] = lv2
LfootVel['vel[3]'] = lv3

rv1 = cumulative_trapezoid(Rfoot['FreeAcc_X'],Rfoot['SampleTimeFine'], initial=0)
rv2 = cumulative_trapezoid(Rfoot['FreeAcc_Y'],Rfoot['SampleTimeFine'], initial=0)
rv3 = cumulative_trapezoid(Rfoot['FreeAcc_Z'],Rfoot['SampleTimeFine'], initial=0)
```

```
RfootVel['Time'] = Rfoot['SampleTimeFine']
RfootVel['vel[1]'] = rv1
RfootVel['vel[2]'] = rv2
RfootVel['vel[3]'] = rv3

plt.Figure(3)
plt.plot(LfootVel['Time'], lv1, color='r', label = 'VelX')
plt.plot(LfootVel['Time'], lv2, color='g', label = 'VelY')
plt.plot(LfootVel['Time'], lv3, color='b', label = 'VelZ')
plt.xlabel("Time [s]")
plt.ylabel("Velocity [m/s]")
plt.title('Left Foot Velocities')
plt.legend()

# plt.Figure(4)
# plt.plot(RfootVel['Time'], rv1, color='r', label = 'VelX')
# plt.plot(RfootVel['Time'], rv2, color='g', label = 'VelY')
# plt.plot(RfootVel['Time'], rv3, color='b', label = 'VelZ')
# plt.xlabel("Time [s]")
# plt.ylabel("Velocity [m/s]")
# plt.title('Right Foot Velocities')
# plt.legend()

plt.show()
```

Appendix F: Cost Analysis – Material Images and Sources

Material	Image	Link
Raspberry Pi 4 Model B		https://www.amazon.in/sspa/click?ie=UTF8&spc=MTo1NTk0MDE3MTM5MzA1NjU3OjE2OTc3NjQzMzg6c3BfYXRmOjMwMDAwMTM1MzI2MjYzMjo6MDo6&url=%2FRaspberry-64-bit-1-5GHz-Single-Computer%2Fdp%2FB0C6ZCP5XL%2Fref%3Dsr_1_1_sspa%3Fcrid%3D14RB0U6FX0JYZ%26keywords%3DRaspberry%2BPi%2B4%2BModel%2BB%26qid%3D1697764338%26sprefix%3Draspberry%2Bpi%2B4%2Bmodel%2Bb%252Caps%252C478%26sr%3D8-1-spons%26sp_csd%3Dd2lkZ2V0TmFtZT1zcF9hdGY%26psc%3D1
Arduino Nano V3		https://www.amazon.in/easy-electronics-Arduino-Nano-Cable/dp/B07C8G4N6X/ref=sr_1_3?crid=2TAG3F8I975MT&keywords=Arduino+Nano+V3&qid=1697764523&sprefix=arduino+nano+v3%2Caps%2C252&sr=8-3
REES52 GY-521 Mpu6050 Module+ 3 Accelerometer		https://www.amazon.in/REES52-GY-521-Mpu6050-Accelerometer-Arduino/dp/B008BOPN40/ref=sr_1_1?crid=ZR5RQCS5J27E&keywords=REES52+GY-521+Mpu6050+Module%2B+3+Accelerometer&qid=1697764563&sprefix=rees52+gy-521+mpu6050+module%2B+3+accelerometer%2Caps%2C264&sr=8-1
Wireless Bluetooth Rf Transceiver Module Serial		https://www.amazon.in/Robotly-Transceiver-Master-Slave-Integrated-Communication/dp/B092942CQJ/ref=sr_1_1?crid=2NHBIQI3P999P&keywords=Wireless+Bluetooth+Rf+Transceiver+Module+Serial&qid=1697764616&sprefix=wireless+bluetooth+rf+transceiver+module+serial%2Caps%2C149&sr=8-1

Kobo NBR Athletica Yoga Mat		https://www.amazon.in/Kobo-Athletica-Multi-use-Exercise-Anti-tear/dp/B07B9RXNZ2/ref=sr_1_5?crid=2SW2Z3JN4GMVP&keywords=Kobo+NBR+Athletica+Yoga+Mat&qid=1697764678&sprefix=kobo+nbr+athletica+yoga+mat%2Caps%2C309&sr=8-5
SunRobotics Force Sensitive Resistor		https://www.amazon.in/SunRobotics-Force-Sensitive-Resistor-Square/dp/B01GJYF1ZY/ref=sr_1_1?crid=2O8V6RCH881OH&keywords=SunRobotics+Force+Sensitive+Resistor&qid=1697764697&sprefix=sunrobotics+force+sensitive+resistor%2Caps%2C170&sr=8-1
Breadboard		https://www.amazon.in/ApTechDeals-Breadboard-point-jumper-wires/dp/B07PQS67BN/ref=sr_1_5?crid=1HA52H87L0E9J&keywords=breadboard&qid=1697764714&sprefix=breadboa%2Caps%2C161&sr=8-5

Appendix G: Beta Build Design Manufacturing Plan

Stage Number	Description	Required Resources, Parts, and Tools	Files and other relevant details
1	Developed CAD Model of base and partition.	SOLIDWORKS	https://drive.google.com/drive/folders/1W7gf2vj-LuV5mccKR-iT3BZFmSKXY8cl?usp=drive_link
2	Convert .SLDPRT file into .STL file	SOLIDWORKS	https://drive.google.com/drive/folders/1W7gf2vj-LuV5mccKR-iT3BZFmSKXY8cl?usp=drive_link
3	Fill out the 3D Print Quote Request located in the Duderstadt Library. To be printed using Digital ABS plus.	Stratasys Polyjet J750 White Filament	Request From: https://docs.google.com/forms/d/e/1FAIpQLSf1mCvneN7XLLAI29rPAzWCKU8O4DGTfGsgDiyMshtQoT95Qg/viewform Under Unit of Measure select [mm] Under Machine Select Stratasys Polyjet J750 Under Material Type select opaque Under Filament Color select write out white
4	Receive base		
5	Mix a ratio of 25 parts mineral oil, 35 parts talcum powder, 40 parts iron filings, and 1 part white coloring dye by mass in a bowl until a viscous yet fully liquid	- Mineral Oil - Talcum Powder - White coloring dye - Iron Filings - scale	

	substance (no chunks) is formed.	- mixing bowl - mixer - 3D base	
6	Use an eyedropper to fill each partition.	- Viscous substance - Eye Dropper - 3D base	
7	Use a flat edge to remove any access fluid from partitions, so the fluid flush to the top of the surface	- Flat edge - 3D base	
8	Cover one side of an acrylic sheet with clear glue and apply to the top of the 3D printed model. Keep sheet firmly pressed to base with a weight and wait until glue fully dries.	- Acrylic sheet - Clear glue - 3D model - Weight	

Appendix H: Mock Image Processing Code (Updated)

```
# import the necessary packages
from scipy.spatial import distance as dist
from scipy.stats import linregress
from imutils import perspective
from imutils import contours
import numpy as np
import pandas as pd
import argparse
import imutils
import cv2
def midpoint(ptA, ptB):
   return ((ptA[0] + ptB[0]) * 0.5, (ptA[1] + ptB[1]) * 0.5)
# construct the argument parse and parse the arguments
ap = argparse.ArgumentParser()
ap.add_argument("-i", "--image", required=True,
   help="path to the input image")
ap.add_argument("-w", "--width", type=float, required=True,
   help="width of the left-most object in the image (in inches)")
args = vars(ap.parse_args())

# load the image, convert it to grayscale, and blur it slightly
image = cv2.imread(args["image"])
height, width, _ = image.shape
gray = cv2.cvtColor(image, cv2.COLOR_BGR2GRAY)
gray = cv2.GaussianBlur(gray, (7, 7), 0)
# ksize = (50, 50)
# # Using cv2.blur() method
# gray = cv2.blur(gray, ksize)
# kernel = np.array([[-1,-1,-1],
#                    [-1, 9,-1],
#                    [-1,-1,-1]])
# gray = cv2.filter2D(gray,-1,kernel)
# cv2.imshow("Image", gray)
# cv2.waitKey(0)

# perform edge detection, then perform a dilation + erosion to
```

```
# close gaps in between object edges
edged = cv2.Canny(gray, 50, 100)
edged = cv2.dilate(edged, None, iterations=1)
edged = cv2.erode(edged, None, iterations=1)
# find contours in the edge map
cnts = cv2.findContours(edged.copy(), cv2.RETR_EXTERNAL,
   cv2.CHAIN_APPROX_SIMPLE)
cnts = imutils.grab_contours(cnts)
# sort the contours from left-to-right and initialize the
# 'pixels per metric' calibration variable
(cnts, _) = contours.sort_contours(cnts)
pixelsPerMetric = None

midpnts = []
midXs = []
midYs = []
orig = image.copy()

# loop over the contours individually
for c in cnts:
   # if the contour is not sufficiently large, ignore it
   area = cv2.contourArea(c)
   if cv2.contourArea(c) < 23200:
       continue
   # compute the rotated bounding box of the contour
   box = cv2.minAreaRect(c)
   box = cv2.cv.BoxPoints(box) if imutils.is_cv2() else cv2.boxPoints(box)
   box = np.array(box, dtype="int")
   # order the points in the contour such that they appear
   # in top-left, top-right, bottom-right, and bottom-left
   # order, then draw the outline of the rotated bounding
   # box
   box = perspective.order_points(box)
   cv2.drawContours(orig, [box.astype("int")], -1, (0, 255, 0), 2)
   # loop over the original points and draw them
   for (x, y) in box:
       cv2.circle(orig, (int(x), int(y)), 5, (0, 0, 255), -1)

   # unpack the ordered bounding box, then compute the midpoint
   # between the top-left and top-right coordinates, followed by
   # the midpoint between bottom-left and bottom-right coordinates
   (tl, tr, br, bl) = box
   (tltrX, tltrY) = midpoint(tl, tr)
   (blbrX, blbrY) = midpoint(bl, br)
   # compute the midpoint between the top-left and top-right points,
   # followed by the midpoint between the top-right and bottom-right
   (tlblX, tlblY) = midpoint(tl, bl)
   (trbrX, trbrY) = midpoint(tr, br)

   # compute the Euclidean distance between the midpoints
   dA = dist.euclidean((tltrX, tltrY), (blbrX, blbrY))
   dB = dist.euclidean((tlblX, tlblY), (trbrX, trbrY))
   # if the pixels per metric has not been initialized, then
   # compute it as the ratio of pixels to supplied metric
   # (in this case, inches)
   if pixelsPerMetric is None:
       pixelsPerMetric = dB / args["width"]
# compute the size of the object
   dimA = dA / pixelsPerMetric
   dimB = dB / pixelsPerMetric
   # draw the object sizes on the image

   (midX, midY) = midpoint(tl, br)
   midpnts.append([midX, midY])
   midXs.append(midX)
   midYs.append(midY)



midpnts.pop(0)
midXs.pop(0)
midYs.pop(0)
# midXs = np.array(midXs)
# midYs = np.array(midYs)
# slope, intercept, _, _, _ = linregress(midXs, midYs)
```

```
def mag(m,a = width/2,b = height):
  return (m[0]-a)*(m[0]-a) + (m[1]-b)*(m[1]-b)


ordered = sorted(midpnts,key = mag)
for m in range(len(ordered)-1):
  cv2.circle(orig, (int(ordered[m][0]), int(ordered[m][1])), 12, (255, 0, 0), -1)

  closestpt = None
  closest = float('inf')
  secondclosestpt = None
  secondclosest = float('inf')
  # d1 = dist.euclidean(ordered[m],ordered[m+2]) / pixelsPerMetric
  swid = abs(ordered[m][0] - ordered[m+1][0]) / pixelsPerMetric

  cv2.line(orig, (int(ordered[m][0]), int(ordered[m+1][1])), (int(ordered[m+1][0]), int(ordered[m+1][1])),
      (255, 0, 255), 10)
  cv2.line(orig, (int(ordered[m][0]), int(ordered[m][1])), (int(ordered[m][0]), int(ordered[m+1][1])),
      (255, 0, 255), 8)
  # x,y  = midpoint(ordered[m],ordered[m+2])
  # cv2.putText(orig, "StrideLen: {:.1f}cm".format(d1),
  #     (int(x),int(y)), cv2.FONT_HERSHEY_SIMPLEX,
  #     2, (255, 0, 0), 2)
  # cv2.line(orig, (int(ordered[m][0]), int(ordered[m][1])), (int(ordered[m+2][0]), int(ordered[m+2][1])),
  #     (255, 0, 255), 8)
  x,y  = (ordered[m][0] + ordered[m+1][0])/2, (ordered[m+1][1])
  cv2.putText(orig, "SWid: {:.1f}mm".format(swid),
      (int(x),int(y)), cv2.FONT_HERSHEY_SIMPLEX,
      2, (255, 0, 0), 2)
  cv2.imwrite("Verify.jpg", orig)
```