Smart Walker

Final Report

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BME 200/300

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Abstract

After sustaining neurological or physical injuries, many patients face a challenging journey in neurorehabilitation to re-learn walking amongst other skills in physical daily activities. Patients in the neurorehabilitation process often use walkers as assistive devices to support their mobility. Physical therapists aim to reduce patient dependence upon these assistive devices and track patient progress through various metrics including the pressure applied on the walker and gait speed. However, currently these measures are conducted manually or through visual observation and there is yet to be a clinically targeted "smart" walker that can deliver objective data on speed or pressure. To address this clinical challenge, in our final design and prototype we developed an attachment to a two wheeled/glider walker with integrated load cells in the feet to measure pressure and a magnetic speed measuring system with a hall effect sensor to detect the rotation of the wheel. An Arduino microcontroller delivers data to a Google Firebase server which is then relayed to an iOS smartphone app in realtime. In experimental trials compared to known weights and manually measured speeds, there was an average error of 7.97% for pressure measurements and 31% error for speed measurements. For future development, we aim to develop an adaptive calibration system that adjusts for pressure sensor drift and improves the frequency of magnetic sensing to increase the accuracy of measurements. As a whole, a sensorized smart walker represents a significant step forward in enhancing the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

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I. Introduction

Motivation

After a serious injury, be it physical or neurological, the long road to recovery often includes re-learning to walk. The neurorehabilitation process can be long and arduous and during this time, every second spent with professionals—doctors, physical therapists, clinicians—is valuable. Physical therapists need to evaluate and understand the unique needs of the patient as the demographic of individuals in need of neurorehabilitation is substantial, with stroke survivors, individuals with traumatic brain injuries, and those suffering from neurological disorders making up a significant portion.

Many of these individuals require walkers and assistive devices during their rehabilitation journey. However, there is a significant lack of commercially available smart walkers adapted to a clinical setting that can provide objective sensor data that tracks the motor independence of patients.

Extensive research indicates that technology-assisted interventions can improve gait, balance, and overall mobility and objective measurements can lead to better outcomes [1].A smart clinically tailored walker would be able to provide objective sensor data on the pressure, gait speed, balance, among other notable measurements[2].

Currently, the assessment of a patient's progress relies heavily on subjective observations by physical therapists. Objective data throughout the neurorehabilitation process would enable physical therapists to effectively monitor the progress of their patients, make more informed diagnostic decisions, and better tailor rehabilitation plans to the individual[3]. Objective progress tracking can also enhance patient care and independence where real time or instant feedback on their gait, balance, and motor control can significantly help a patient. Seeing tangible long term progress can boost the confidence and commitment of patients to the rehabilitation process. Beyond individual patient care, smart assistive devices can be employed by researchers to analyze and develop rehabilitation strategies, benefiting a wider range of patients.

As a whole, we are motivated to develop a smart walker tailored to clinical settings that can provide objective data that tracks a patient's dependence which can significantly help the diagnostic progress, improve rehabilitation/intervention strategies, and enhance the care of patients in their neurorehabilitation journey.

Competing and Current Designs

There are a few commercial smart walkers on the market along with attachable devices to sensorize a walker however each comes with their own unique disadvantages. First, the Camino Smart Walker is an electric powered walker device integrated with boosts and brakes. The walker uses artificial intelligence to track 22 different gait metrics and maintain the safety of the user while maximizing their efficiency. However, it has notable drawbacks, including its high 3000 dollar cost, which may be financially prohibitive for many patients and clinical settings. Many of its features are also redundant and unnecessary given the intended features and specifications requested by our client. Additionally, the lack of seamless clinical data recording limits its adaptability in a clinical setting [4].

The AmbuTrak Device is an installable device for a walker with a display that shows real time gait speed. The device attaches to the wheel to measure the RPM and has an LED display. Although the device can display data in realtime, it does not have the capability of uploading this information to a server. It also does not record the applied pressure distribution of the patient on the walker [5].

Another notable smart assistive device design is the Intelliwalker, a design published for patent approval in 2015, which is a walker equipped with various sensors to monitor the balance and movement of an individual then in turn help the user navigate their environment through a motorized system. Similar to the previous designs, the Intelliwalker is mainly for commercial use and not adapted to a clinical setting where sensor data can not be recorded and uploaded to a server for further analysis. Many of the features including a self propelling system along with the built in motors are redundant and unnecessary in the context of the neurorehabilitation process. Importantly the patent was abandoned in 2016, but the design can still serve as a useful reference [6].

Problem Statement

Patients with mobility impairments involved in the neurorehabilitation process often use walkers as transitional devices that can aid with their coordination and balance. Within the neurorehabilitation process, clinicians or physical therapists often aim to reduce a patient's dependency upon walkers as they regain motor control. However, there is yet to be a commercial smart walker that can track a patient's functional independence and deliver objective data for physical therapists and patients. The client, Mr. Danile Kutschera, a physical therapist at the UW Rehabilitation Hospital, requests a sensorized smart walker that can track in real time a patient's distance traveled, gait speed, and applied pressure distribution on the walker. In turn, the Smart Walker will be capable of tracking a patient's motor control through their dependency on the walker and provide objective data of improvement over time. The data can be utilized for motivational purposes for the client along with insurance/medicare reasons to evaluate the efficacy of intervention strategies. As a whole, a sensorized smart walker would enhance the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

II. Background

The demographic of patients in neurorehabilitation encompasses a wide range of individuals who have experienced various neurological disorders and injuries. Some of the most common neurological disorders and injuries can include stroke, traumatic brain or spinal cord injury, neurodegenerative diseases(ALS, Parkinsons, …), and musculoskeletal injuries [7]. There are an extensive number of unique ways in which different neurological disorders can lead to motor impairment and affect balance, coordination, and movement. Stroke and spinal cord injuries can lead to partial or complete paralysis rendering certain muscle groups unresponsive [8]. Peripheral neuropathy among other sensory impairment related disorders can lead to sensory deficits that make it difficult to maintain balance [9]. Other neurological disorders including Alzheimer's disease or traumatic brain injuries can affect a person's ability to plan and execute coordinated movements [10].

A number of rehabilitative strategies exist for individuals with physical impairments that are targeted to the individual. Strategies may include patients working on walking, transferring from a bed to a chair, walking along a predetermined path and other mobility-related tasks. Throughout the physical neurorehabilitation process, walkers and other assistive devices can be used to supplement the balance and coordination of patients. Physical therapists conduct regular assessments to monitor the patient's progress. This includes evaluating changes in strength, range of motion, pain levels, balance, and other relevant factors. Assessments can be objective(strength tests, range of motion exercises, gait analysis…) but are also largely subjective through open communication and feedback from the patient. The integration of objective data in combination with subjective analysis is an effective approach to improving patient outcomes in the rehabilitation process [3][10].

From a biomechanics perspective, walkers can enhance the mobility and balance of patients by providing a wider base of support and more points of contact with the ground. With a larger base of support a patient can distribute their weight and transfer some of the burden off their legs making the walking process physically less arduous and psychologically the walker can support the confidence of a patient. Distributing a patient's weight through their arms to the walker handles also allows a patient to more easily make adjustments to their center of pressure relative to their center of mass to maintain balance [3][10][11]. The pressure a patient places on the walker along with their capable gait speed can also be indicative of their reliance on the walker and functional independence. It is a common goal in the rehabilitation process to decrease one's dependence on these assistive devices. And in evaluating patient dependence, a physical therapist may employ manual measurement including using timers for measuring gait speed, or a subjective visual analysis of how much pressure they are exerting. However, there is notably not a common smart walker among clinical settings for physical neurorehabilitation with objective calibrated measurements that can directly determine the patient's reliance on the device [2].

Client Information

Mr. Daniel Kutschera is a physical therapist at the UW rehabilitation hospitals, where his responsibilities include helping his patient learn to walk again after serious injuries. Mr. Kutschera has identified areas for improvement in this process and has proposed a number of projects for BME students in order to address them, including the Smart Walker.

Product Design Specifications and Design Constraints

The client has provided a budget of $400 to produce one Smart Walker with the ability to measure speed, distance, and applied pressure. As this Smart Walker is being used for rehabilitation, it is very important that it does not add any obstacles for the patient. This means that any elements added to the structure of the walker should not intrude into the walking path of the patient or add more than 1.81kg to the overall weight of the walker, so that it can still be easily moved by patients. An average walker supports 136 kg, and this will remain true of the Smart Walker [12]. Additionally, the walker purchased for the project weighs 3.63 kg, so the final weight of the Smart Walker should not exceed 5.44 kg [12][13]. The use of the walker in for rehabilitation purposes also means that the walker will be used at a max of around 4.83 kph, so the sensors will need to be accurate to within 5% of true values to prevent accumulation of error at such slow speeds, as well as to be able to detect small changes during the rehabilitation process. The Smart Walker will remain in the clinic, and be used by many patients, so it will need to be adjustable so as to keep the grips at waist level for patients of varying heights. The purchased walker is flexible between heights of 1.65-1.93 meters, and our design should not change this [12][13]. Patients at different stages of recovery will apply different amounts of pressure to the walker, so the pressure sensors should be able to measure pressures up to the average weight of 70 kg.

Additionally, to be used safely by many patients the walker will need to be sanitized between uses, so our design should not be sensitive to sanitizing materials. Finally, as a medical device that records patient data, the Smart Walker will need to comply with safety and user privacy standards and regulations, such as ISO 14971 and Health Insurance Portability and Accountability Act (HIPAA) [14][15].

There are also some notable codes and standards that will be referenced in the development of the smart walker including ISO 14971 which provides further guidance on risk management and evaluation for in vitro diagnostic medical devices especially if physical therapists use the sensor data to diagnose the patient in any way or determine future treatments or interventions. IEC 60601 details standards and guidelines in building medical electrical equipment, and our device which will employ electronic sensors and be used in the context of neurorehabilitation for helping patients can be labeled as medical electrical equipment

III. Preliminary Speed/Distance Designs

Design #1 - Magnetic Sensor

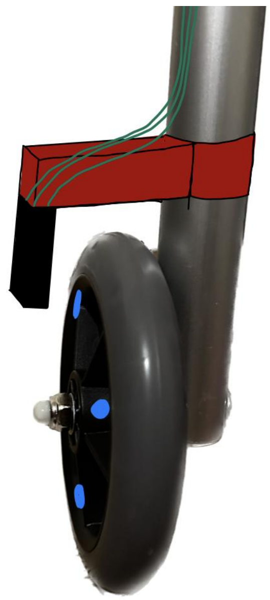


Figure 1: *The magnetic sensor design*

For the magnetic sensor design, magnets would be placed on each of the spokes of the wheels of the walker and a Hall effect sensor would be placed at an appropriate distance from the face of the wheel. The Hall effect sensor would be attached to the leg of the walker, so it does not move with the rotation of the wheel. The sensor acts as a closed circuit when it detects a magnetic field, so as the wheel rotates, and the magnets move in and out of the range of the sensor, the voltage spikes in the circuit can be recorded. The time between these voltage spikes can be used with the known distance between magnets to find both the speed and distance traveled of the walker. Hall effect sensors can be built to a variety of specifications, and there are some that are sensitive to magnetic fields as small as 2 mT, meaning low-cost magnets could be used [16].

Design #2 - Light Sensor

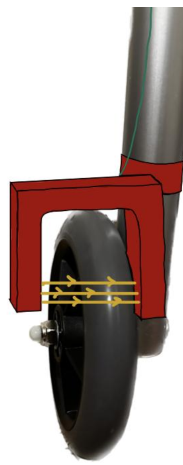


Figure 2: *The light sensor design*

The light sensor design uses a photogate sensor to track the rotation of the wheel. The photogate sensor sends an infrared light laser from one half of the sensor to the other and senses when the laser's connection is disrupted. As the wheel spins the spokes of the wheel disrupt the laser of the photogate sensor. Dividing the number of interruptions by the number of spokes on the wheel would provide the amount of rotations. Rotations per minute could be then calculated.

Design #3 - Distance Sensor

Figure 3: *The distance sensor*

The distance sensor would use an ultrasonic distance sensor. This sensor would send out an ultrasonic wave which bounces off of a surface and returns to the sensor which tracks the amount of distance traveled between sending and receiving the wave. The sensor would be mounted to the top bar of the walker which would make for easy integration into the existing walker. To account for some sense of turning a second distance sensor could be placed on the other end of the bar, so as the walker rotates the sensor would track the change of distance. This system would still have very questionable accuracy and would not be able to account for full turns.

IV. Preliminary Speed/Distance Design Evaluation

Speed/Distance Design Matrix

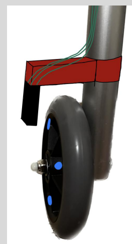
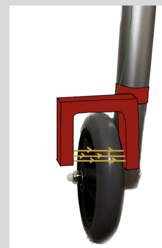
Criteria	Weight	Magnetic Sensor 		Light Sensor 		Distance Sensor 	
Accuracy/precision	25	4/5	20	4/5	20	3/5	15
Ease of Use	20	5/5	20	5/5	20	5/5	20
Safety	20	5/5	20	3/5	12	5/5	20
Durability	15	4/5	12	3/5	9	5/5	15
Ease of Fabrication/Integration	10	4/5	8	4/5	8	2/5	4
Cost	10	5/5	10	2/5	4	3/5	6
Total:	100	Sum	90	Sum	73	Sum	80

Table 1: *Speed/Distance design matrix*

The three preliminary speed and distance designs were evaluated using the 6 criteria depicted in the matrix above. The criteria and their corresponding weight were chosen based on the client's needs. Accuracy and precision were given the highest weight of 25 because it is important that the walker return accurate measurements for insurance requirements and to track patient rehabilitation. The magnetic sensor and light sensor both received ⅘ because they could accurately measure the rotation of the wheel which could be converted into overall speed using the radius of the wheel. The magnetic sensor and light sensor did not receive a perfect 5/5 because there will still be difficult calculating turns because the outside wheel will spin faster than the inside wheel on a turn. The distance sensor received a score of ⅗ for accuracy because it relies on a reference surface for the ultrasonic waves to bounce off of which would have to maintain constant during testing. Once the walker turns the reference surface would change giving inaccurate results.

The next criteria with the highest weight were ease of use and safety both with a weight of 20. Ease of use was weighted highly because neurorehabilitation is already cHallenging so the client and the team wanted to ensure that the additions to the walker would not make it harder to use the walker. All preliminary designs scored 5/5 because the team predicts that none of the sensors will make it more difficult to use the walker. This is because none of the sensors actively impinge on any parts of the walker the patient will have contact with.

Safety was also weighted at 20 because the patients are already in a vulnerable state so the walker needs to be as safe as possible to prevent further injury. Both the distance sensor and magnetic sensor scored a 5/5 because there is minimal interference with the walker and the sensors would be more compact. The light sensor received a ⅗ because it would be a larger sensor and could interfere with the patient.

The next criteria used for evaluation was durability. The durability of the product was given a weight of 15 because although the walker would only be used in a controlled environment in the client's clinic, it is important that the walker continually gives accurate feedback with little maintenance. The magnetic sensor received a ⅘ because of its simplicity and small size. The light sensor received a ⅗ because it is larger and more complicated make it more susceptible to damage. The distance sensor received a 5/5 because its location on the upper bar of the walker is a safer location for the sensor.

The fifth criteria was ease of fabrication which was given a weight of 10. Because this product would not need to be mass produced the fabrication process was not given a heavy weight. Both the light and magnet sensors received a ⅘ because they have similar structures and only one sensor would be needed. The distance sensor received a ⅖ because two sensors would be needed.

The final criteria used to evaluate the designs was cost. This was given a weight of 10 because only one walker would be produced so cost was not a very important factor. The magnetic sensor had the highest score of 5/5 because the magnetic sensor itself is inexpensive and only one would be needed. The distance sensor received a score of ⅗ because it would need 2 sensors. The light sensor received a score ⅖ because the light sensor would be the most expensive sensor of the three.

The scores of each design were summed and the highest scoring design was the magnetic sensor because it provided accurate data, was easy to use, safe, and cost effective.

V. Preliminary Pressure Designs

Various methods of pressure/force measurement were considered during the initial brainstorming including compression force sensors, hydraulics, and even pneumatics. Ultimately, force sensing resistors were chosen for the project due to their easy integration into the design and Arduino setup, inexpensive cost, and minimal size profile.

Design #1 - Handle Placement

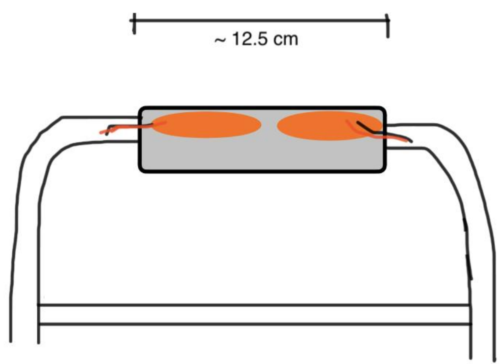


Figure 4: *Handle placement design*

The handle placement design would require the use of multiple force sensing resistors to cover the surface area of the handles, and would require routing of wires down the tubing to the centrally-located Arduino. Even more sensors could be incorporated into this design on the underside of each handle to get readings on the grip force of the patient while using the walker, which would provide even more data for the client.

Design #2 - Foot Placement

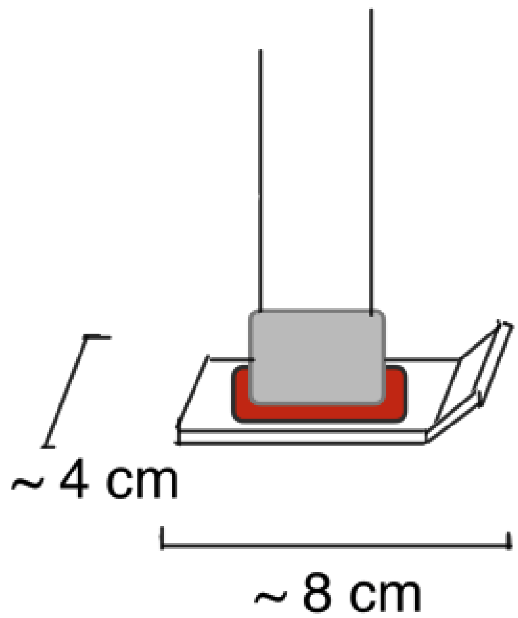


Figure 5: *Foot placement design*

This design would require using one load cell at each of the feet of the walker. The load cells would be placed in between the bottom of the foot of the walker and the glider. This would enable the sensor to get an accurate pressure reading while maintaining some durability by not placing the sensor in direct contact with the ground where it would likely be damaged.

Design #3 - Wheel Placement

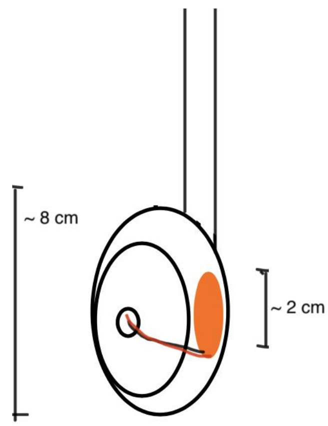


Figure 6: *Wheel placement design*

The wheel placement design would include placing a force sensing resistor on the outer circumference of the wheel, and would give a pressure reading at each rotation of the wheel when the pressure sensor makes contact with the ground. The fabrication of this design would be difficult as the wires from the sensor would need to be routed through the wheel axle in order to not get tangled during use. However, in theory, this design would also be able to provide speed and distance measurements as the pressure recording would indicate how quickly the wheel would be rotating.

VI. Preliminary Pressure Design Evaluation

Pressure Design Matrix

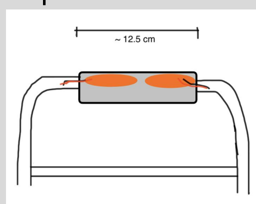
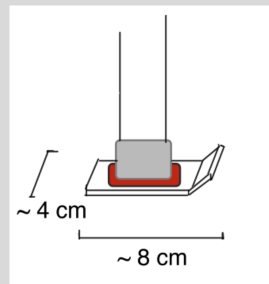
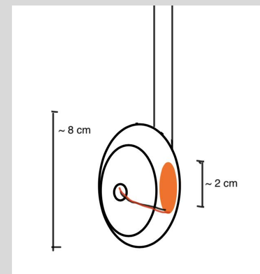
Criteria	Weight	Grip  		Foot  		Wheel  	
Accuracy/Precision	25	3/5	15	4/5	20	4/5	20
Ease of Use	20	5/5	20	5/5	20	5/5	20
Safety	20	5/5	20	5/5	20	3/5	12
Durability	15	4/5	12	1/5	3	3/5	9
Ease of Fabrication/Integration	10	5/5	10	3/5	6	2/5	4
Cost	10	3/5	6	5/5	10	5/5	10
Total:	100	Sum	83	Sum	79	Sum	65

Table 2: *Pressure design matrix*

The three placement options for the pressure designs were evaluated in the above design matrix based on six criteria.

The most important parameter was accuracy/precision due to the measurements' use for insurance reasons. Both the foot and wheel designs scored high in this category due to their simplistic incorporation of the pressure sensors. The handle design only received a ⅗ in the accuracy category due to the potential complications with the grip force of the patient playing a role in the pressure measurements. Although the grip force might alter the pressure readings negatively, the team believes that this extra measurement can be used productively to get further insight into how the patient uses the walker.

The second criteria used to evaluate the designs was ease of use because the recording components should not affect how the patient uses the walker. The handle design scored low in this category because it would fundamentally change how the patient interacts with the walker which might cause discomfort and lead to a less genuine experience. The feet and wheel designs however, scored well in this category because they did not significantly impact how the patient interacts with the walker.

Safety was the third most important criteria because patient safety is always a large concern in clinics, especially when working with rehabilitating patients. The handle and foot placement scored high in this category, but the wheel design lost a few points due to the potential danger of having rotating sensors and wires creating a bumpy experience that could lead to patient instability.

Durability was another concern when evaluating the designs because the walker will be used constantly throughout the rehabilitation clinic on a daily basis, so making sure the components are protected from wear and can give accurate measurements consistently was paramount. The durability of the handle placement was given high marks due to the absence of constant pressure and contact with the ground. The foot placement also received fairly high marks because the sensor would be protected from the friction of constantly rubbing against the ground. The wheel placement was perceived as less durable due to the constant contact of the sensor with the ground.

The fifth criteria used to evaluate the design was ease of fabrication/integration in which the handle placement scored very high due to the ease of placing the sensors on the handles and easy wire routing. The foot placement received a ⅖ score as it was seen to be somewhat difficult to place the sensor in between the foot and glider and route wires through the frame of the walker. The wheel placement also scored very low because of the need to route wires through the axle of the wheel, then up through the frame, which would be difficult.

The last criteria was cost, in which the foot and wheel placements scored high due the need for only two sensors, whereas the handle placement required the use of four or more sensors, which increased the cost of the design. The handle placement also would require a cover of sorts to prevent the patient from damaging the sensors on the handles during use.

After evaluating each design using the six criteria, the foot placement scored the highest with a score of 86/100 due to the high scores in accuracy, ease of use, safety, and durability. The handle and wheel placements scored 71/100 and 65/100 respectively. The design matrix final scores determined that the foot placement would be the best design to pursue based on the established criteria.

VII. Proposed Final Design

As decided in the speed and distance design matrix, the team will be moving forward with the magnetic sensor as the means for measuring the speed and distance traveled of the walker. The pressure design matrix determined the use of load cells integrated into the feet to be most effective, and therefore will use the feet placement to record pressure and force data. In combination, these two sensors will provide the clients requested data of gait speed, distance, and pressure. The sensors will be hardwired to an Arduino microcontroller which will record and relay the live data to the server which will be accessible from the client’s smartphone.

VIII. Fabrication/ Development Process

Materials

For the walker frame a two wheel walker was chosen because it was similar to the walker already used at the client's clinic. The walker also met the standards set in our product design specification. It was light weight and could withstand the required loads.

For the speed/distance sensing portion of the Smart Walker, a Hall effect sensor was used as well as five magnets. The Hall effect sensor was used because it was an affordable, reliable way of sensing magnetic fields. The magnets were used to provide the magnetic field that would trigger the Hall effect sensor.

For the pressure sensing portion of the Smart Walker, two load cells were used. In addition, to this walker two custom ski shaped feet that could accommodate the force sensors were printed to replace the existing ski shaped feet on the walker. These load cells had an internal strain gauge which outputs an electrical signal in the form of resistance when a force was applied. These load cells were chosen because they were easy to integrate, inexpensive, and more durable than force sensing resistors. Initially, force sensing resistors were considered, however, durability concerns and the inability to sense larger force loads ruled them out. Alongside the two load cells an hx711 amplifier board was used in the circuit. The amplifier board was used because the resistance signal sent by the load cells is very small and an amplifier is needed for the Arduino to read it. The hx711 board is standard for load cell circuits.

Two ski shaped walker feet were also used in the Smart Walker. The feet were built so the load cells could fit inside and still be triggered reliably. They were printed out of tough PLA for its durability as both the feet will see high wear in regular use. The front ends of both the feet were printed with a radius at the end, similar to the feet included with the walker, so the walker can handle more difficult terrain. The terrain, however, should not be too concerning because the walker will be used in a clinic.

To receive data from the walker, an Arduino MKR WiFi 1010 board was used in the Smart Walker. This microcontroller was used because it is able to connect to WiFi and is able to send the data it collects to a server for storage. The Arduino MKR WiFi 1010 also uses the Arduino IDE. The Arduino IDE has a great set of resources which makes it straightforward to find information on the code and the corresponding circuits.

Methods

For the speed and distance sensing circuit a Hall effect sensor was used in tandem with magnets glued on the wheel of the walker. The Hall effect circuit consisted of a Hall effect sensor with a 10k ohms of resistance across the voltage and output leads. The voltage lead of the Hall effect sensor was connected to the 5V output of the Arduino MKR WiFi 1010 via protoboard. The output lead of the sensor was connected to a digital pin of the Arduino (pin 3 on Fig. 7). The ground lead of the sensor was connected to the ground of the Arduino via a protoboard (Fig. 7). The leads of the sensor were soldered to solid core wires which were suitable to be soldered to the protoboard or plugged into the Arduino (Fig. 7). The length of wire was measured so it could reach from the wheels to the middle of the lower cross bar of the walker without putting tension on the connections. The Hall effect sensor itself was taped to the bottom of the leg of the walker nearest the wheel positioning its sensing side facing outwards towards the wheel. On the wheel, five magnets were glued at equal distances around the circumference of the wheel. The distance traveled was then found using the formula Distance = $N*\frac{circumference}{\#\ of\ Magnets}$ where N is the amount of times the magnet was sensed.

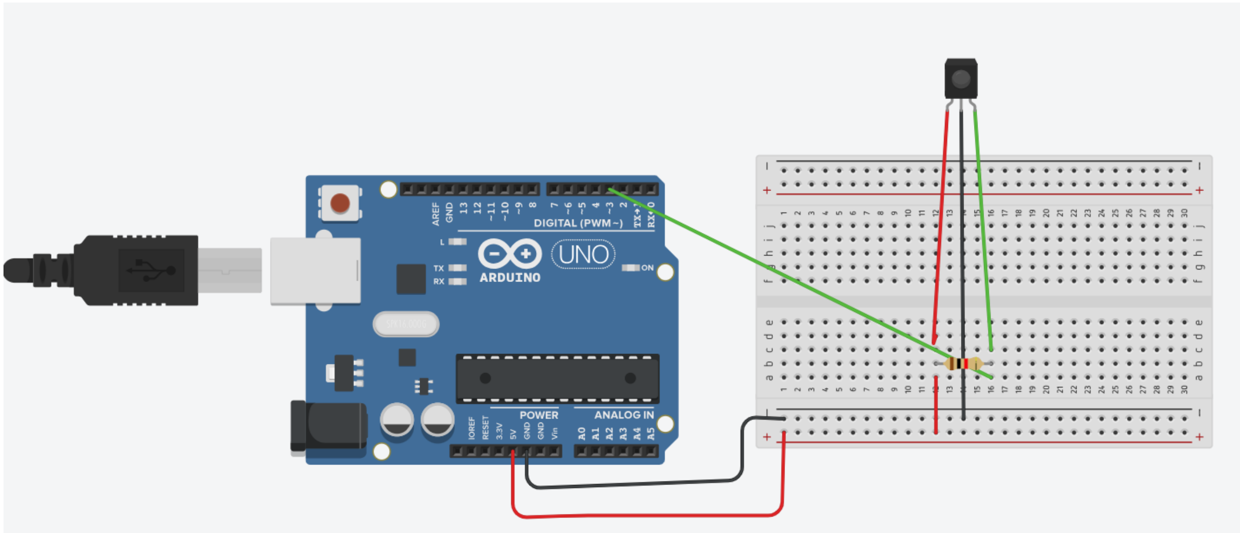


Figure 7: *Speed and Distance sensing circuit with Hall effect sensor*

The force sensing circuit used two load cells and an hx711 board. The force circuit went through several iterations of sensors and circuit configurations. Initially, four load cells were connected in a wheatstone bridge circuit. Two of the load cells would have variable resistance and be placed under the feet of the walker while the other two would act as constant resistors. After struggles with this circuit, a new refined circuit was designed using only two load cells depicted in figure 8. This circuit connected the positive leads of the load cells to the negative leads of the other load cell (depicted by the green and black wires in fig. 8). After connecting the positive and negative leads to each other they were run to the E+ and E- pins of the hx711 amplifier board. The red center tap wires of each load cell were connected to the A+ and A- pins of the hx711 board. The hx711 board amplified the resistance signal from the load cells and output the signal through the DT pin which was connected to a digital pin of the Arduino (pin 4 in the figure 8). The SCK serial clock pin of the amplifier was connected to a digital pin of the Arduino (pin 5 in figure 8). The VCC voltage pin was connected to the shared voltage line on the protoboard and the GND ground pin was connected to the shared ground line on the protoboard (fig. 9). It took several tries and hx711 boards before the connections were good and force was being sensed. One of the major problems was connecting the thin threaded wires of the load cells to the Arduino and to the other wires. Because of this the load cell wires were soldered to thicker solid core wires which were cut so they could extend from the feet of the walker to the center of the lower crossbar. The load cells were incorporated into the 3D printed feet of the walker and the wires ran up along the legs of the walker to the lower crossbar where the Arduino and protoboard were located. The force value was found by dividing the voltage signal from the hx711 amplifier by a calibration factor which was determined during testing. The calibration factor used for this circuit was 250.34.

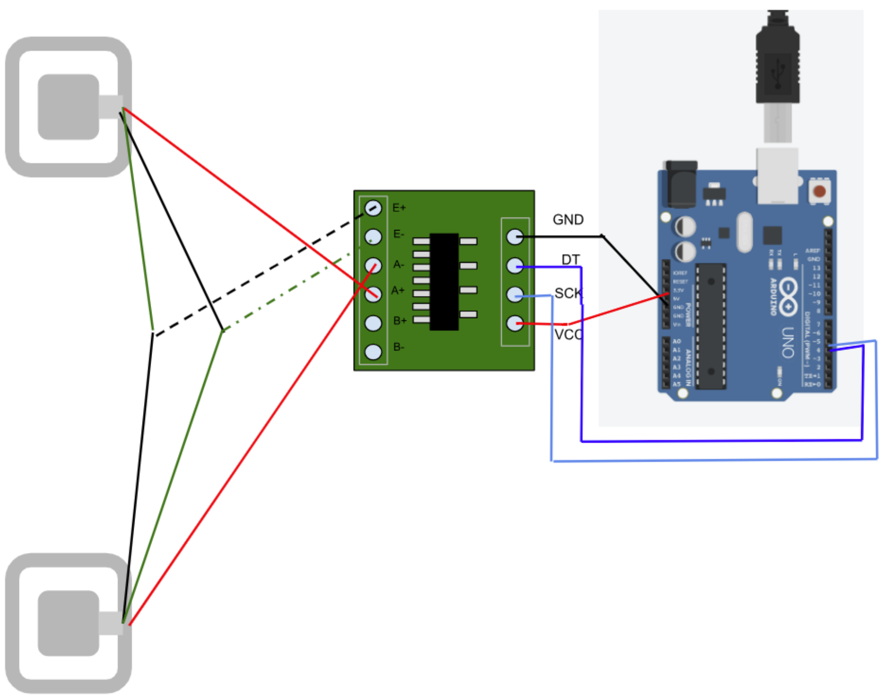


Figure 8: *Pressure Sensing Circuit with two Load Cells*

Finally the two circuits were combined to yield the final set of circuits using a shared 5V line and ground line. All of the wires going into the Arduino or being soldered to the protoboard were solid core wires to ensure good connections. The wires from the Hall effect sensor were run up one of the front legs while the load cell wires ran up the two rear legs to the lower crossbar where the Arduino and protoboard were located.

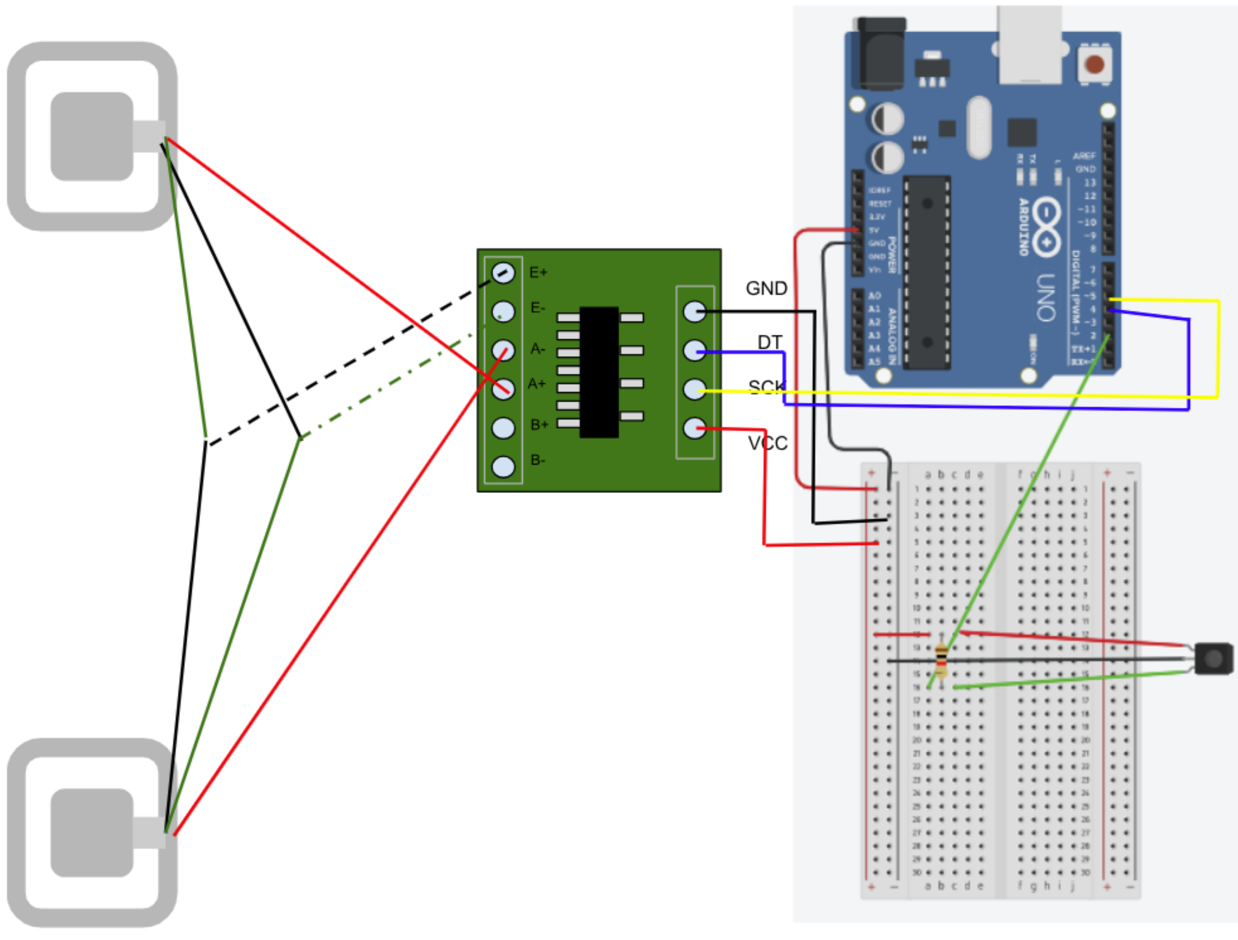


Figure 9: *Combined Speed/Distance and Pressure Circuits*

In order to integrate the load cell circuit into the walker, 3D-printed gliders capable of housing the load cells were modeled and printed. The process started by modeling new walker gliders based on the size and shape of the original gliders that came with the walker. The preliminary model featured a recess in which the load cell could sit with a second recess in the middle which allowed for the deflection of the strain gauge. The model allowed for the load cell wiring to run out of the back of the foot and up the legs. Additionally, the model incorporated a second piece that attached around the leg of the walker and aligned the center of the leg with the center of the load cell. Lastly, an end cap was printed to fit inside the hollow leg pipe. The model was designed to use four, 4mm-wide screws to fasten the upper and lower pieces together.

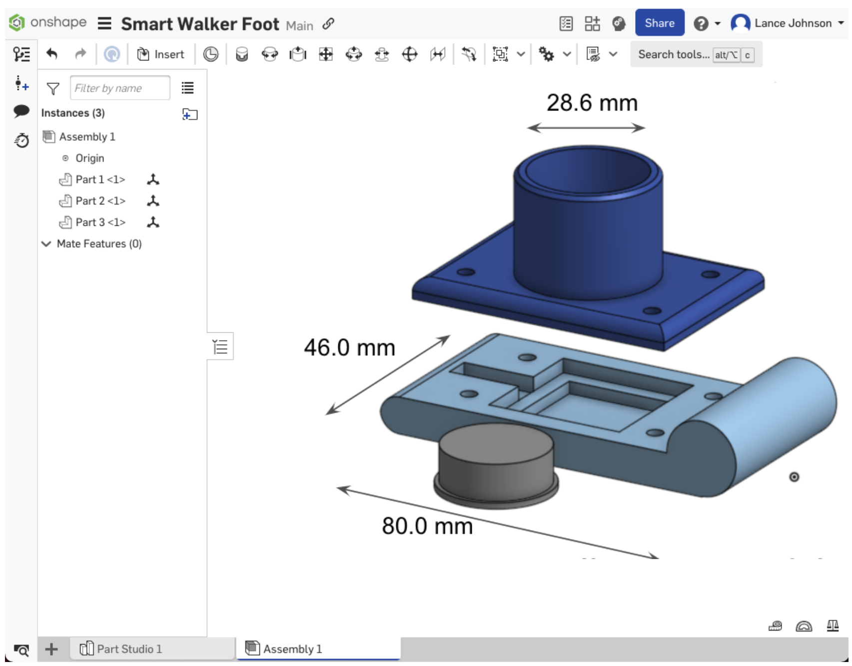


Figure 10: *Walker Foot Model in Onshape*

This initial prototype was printed out of PLA material with 20% infill in order to keep costs and printing time down. The initial prototype needed refining after printing, but the general concept seemed to work very well for the walker. Therefore, after necessary adjustments were made to the dimensions of the cuff radius, load cell recess, and screw holes, a second prototype was printed. This time, the infill was increased to 40% in order to provide a more robust piece that could withstand the forces of the walker and the friction against the ground. Once the second foot model was printed, the print supports were removed and the piece was sanded to fine tune the fit between the walker leg and the cuff. The foot was then assembled using a load cell, 4, 4-mm screws, and 4 nuts, using Allen wrenches to fully tighten the screws. Once the prototype was deemed functional and no further changes needed to be made, a second foot was printed for the other leg of the walker. This piece too was sanded and tested to ensure a proper fit. Once both feet were completed, the final prototype could be assembled.

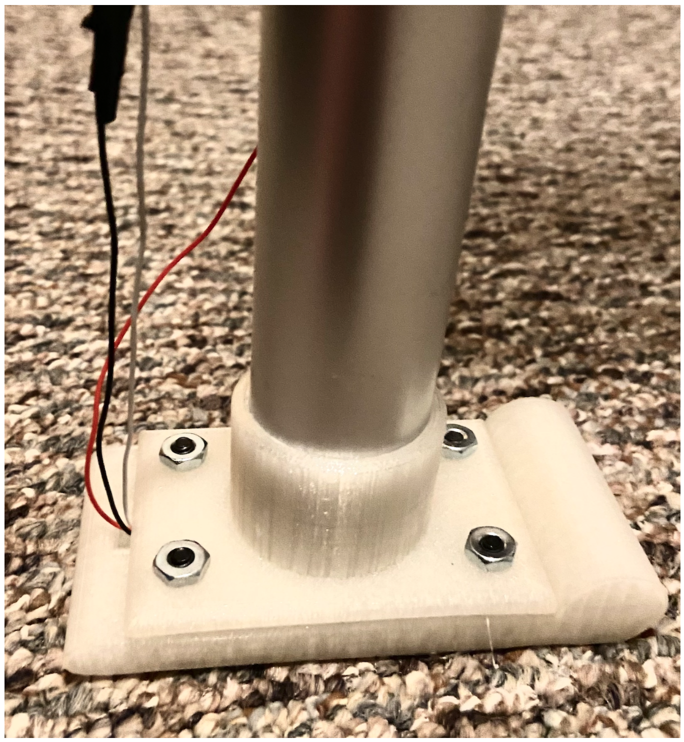


Figure 11: *Completed Walker Foot Prototype*

In order to house all the electrical components a 3D holder was created. Starting by finding the dimensions of all of the components that needed to go into the box. After the dimensions were found a first model of a 3D box was created to be large enough to house all the components. Additionally the box had to connect to the frame of the walker where all the components were located. The preliminary design of this box was to have 3 sides of a box extend for the box. And to connect the box to the frame, two holes were supposed to be drilled through the sides and through the frame of the walker where a screw with a nut could be put in place. This design did not work because the frame was not removable and a hard metal, so drilling a hole would become very difficult. Additionally the box could fit all the components, however the wiring would have to bend a lot to fit, which brings in the risk of them breaking.

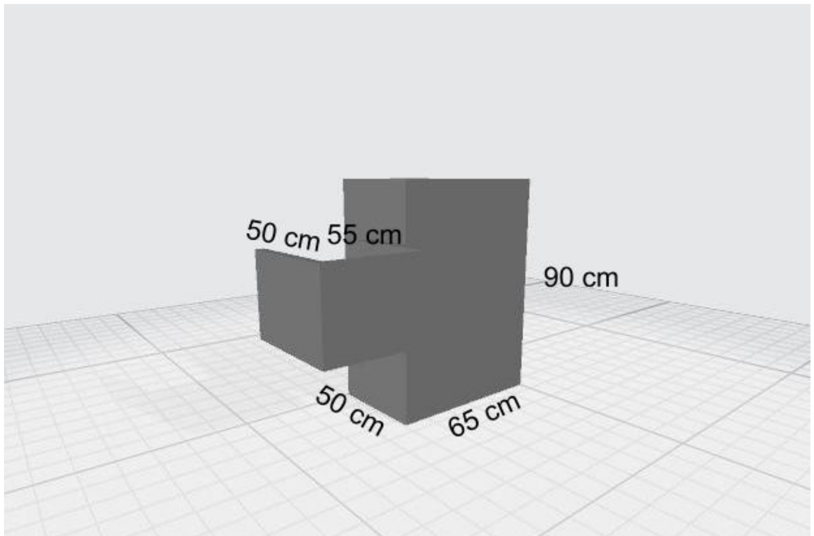


Figure 12: *Preliminary Box Design in AutoCad*

The next design created aimed to fix these problems that arose in the first design. The box width and length were increased, so that the components could fit inside without too much stress on the wiring. Additionally, because drilling through the frame was not possible a new design for connecting the box to the frame was created. The new design included a rectangular side extended from the box attached to this is a half empty cylinder. The radius of the half cylinder is 13.5 mm which is the radius of the frame of the leg. Then on the opposite side of the half cylinder another side is extended. The same structure of a side, half cylinder, and side was created separately and detached from the box. The sides of both bodies were drilled in, so that the screws (3.5 mm) can be put in to connect the full cylinder to the frame of the walker. The material used was PLA because it is strong and durable with a 30 % infill.

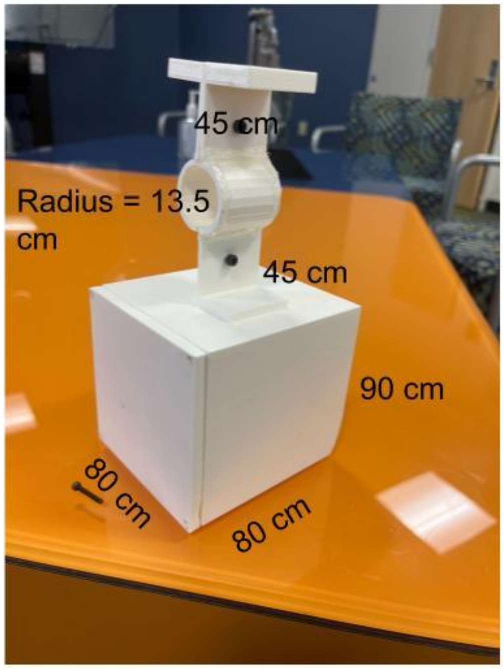


Figure 13: *Final 3D Printed Box Model*

Software Development

The software application frontend was coded in SwiftUI in the software program, Xcode, which is a programming language developed by Apple native for iOS application development. There are four main user interface(UI) components to the frontend software application being three separate UI components to display speed, distance traveled, and pressure in real time and another UI page to allow a physical therapist to create and select a patient.

The UI components programmed in SwiftUI are shown below separately. The code for all the UI components, and code further described in this section is linked to a private github repository in the appendix. No external libraries were used for the development of the UI. After developing each component individually, they were then integrated into a collective UI on one page as shown below.

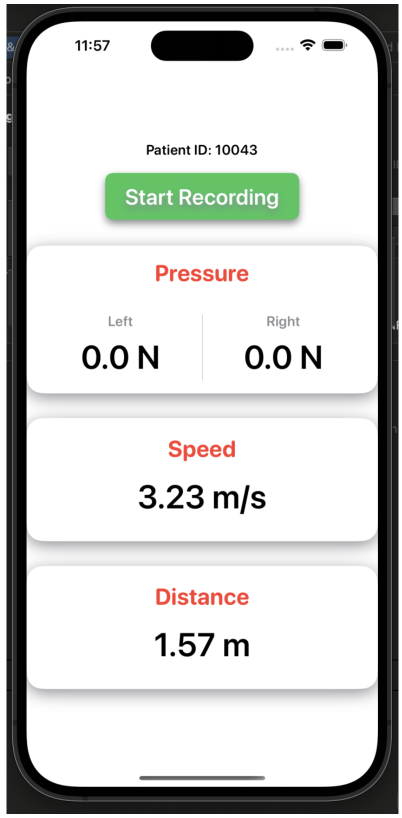


Figure 14: *Collective User interface with integrated components*

For the software app to display data from the sensors in real time, we used an Arduino MKR WiFi 1010 board to deliver data to a google Firebase server. Specifically, google Firebase is a user friendly backend that requires no backend code rather only code on the client/frontend side. Google Firebase offers various features such as app analytics, advertisement capabilities, and we mainly employed the Firebase Firestore feature which offers database capabilities with the ability for real time queries for data retrieval and storage to be made. Google Firebase was chosen not only due to the previous experience of teammates, but also because of its user-friendly interface where the client would be able to access the server at any time and easily navigate through the data.

Firebase Firestore stores data in a document collection hierarchy that is similar to JSON. Each document stores data in key value pairs, and collections store multiple documents. The Firebase firestore server stores various data variables including real time data on pressure, speed, and distance traveled. There is also a list of existing patients, the currently selected patient, and data on all the tests organized by patient. Each test will store data including the date and time of the test, and the average pressure, speed, and distance over the duration of the test. All of this data was organized in the Firebase document collection hierarchy as shown in the below images of the Firebase Firestore interface.

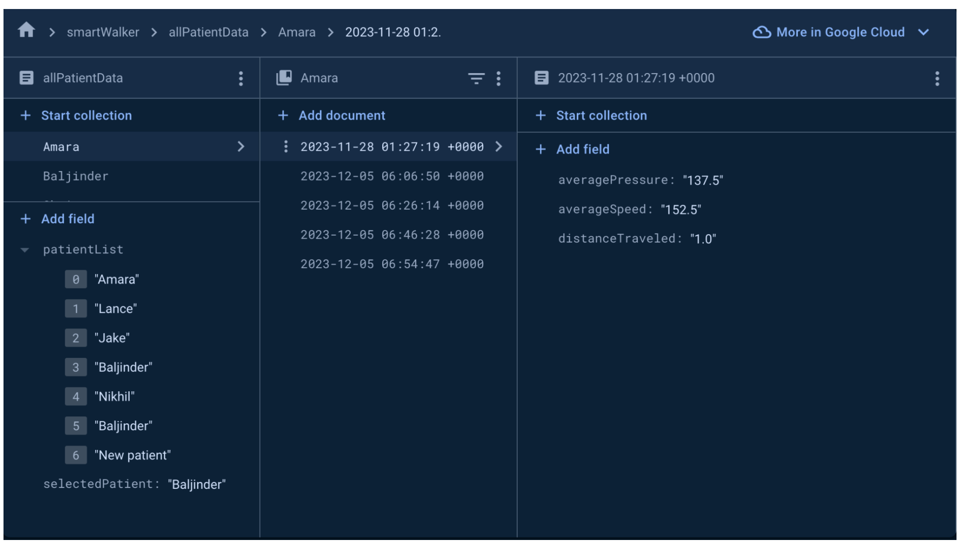


Figure 15: *Firebase patient data test structure*

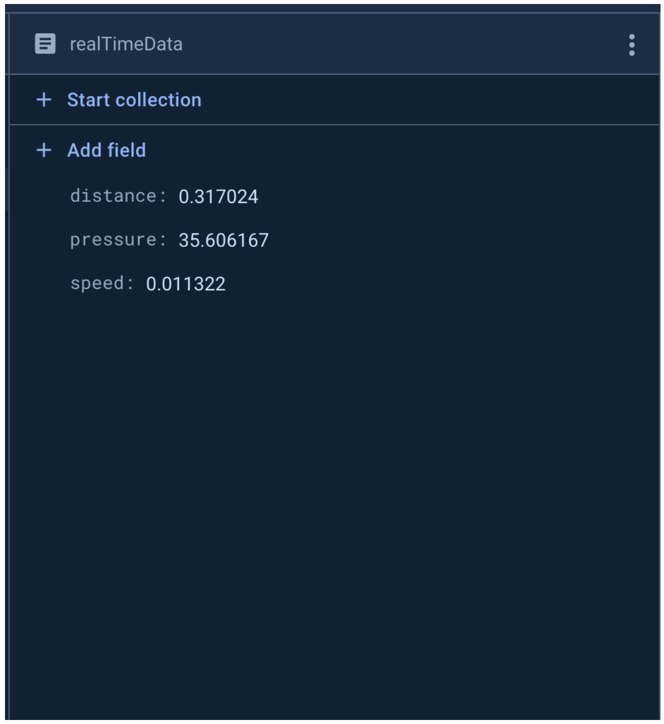


Figure 16: *Real time data firestore data structure*

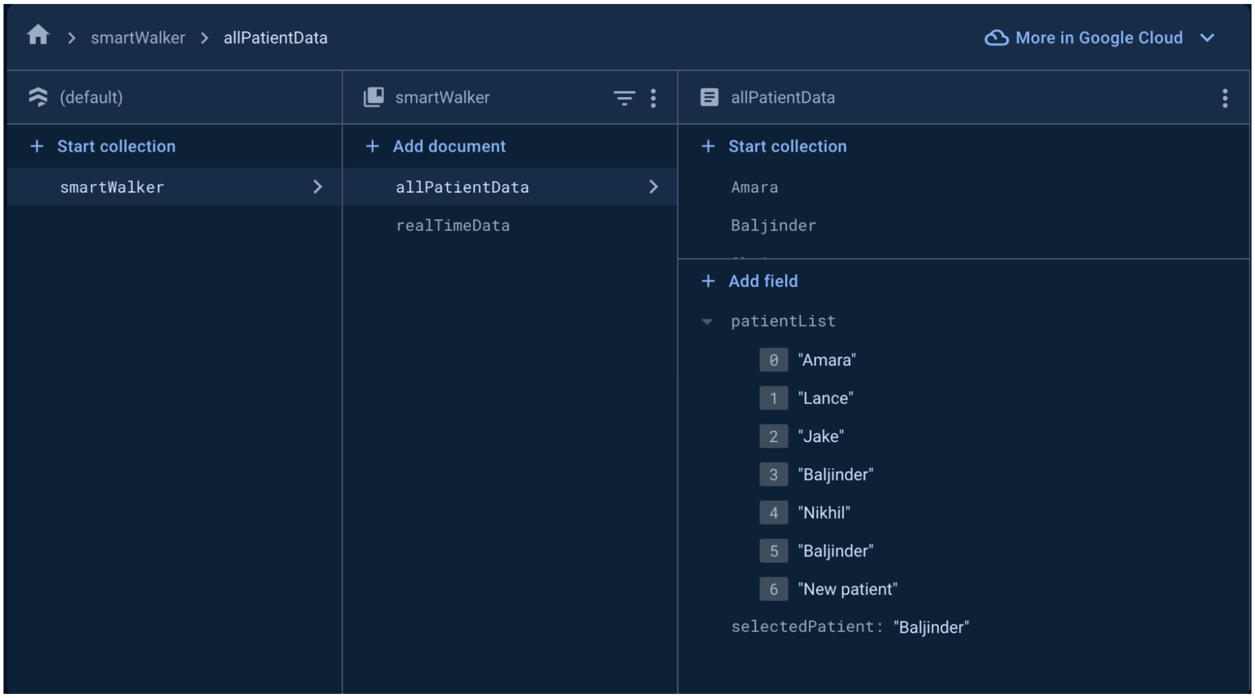


Figure 17: *Patient data firestore data organization*

Subsequently to organizing the firestore database structure and developing the software application UI, the Arduino MKR WiFi 1010 code was developed and integrated into the overall software flow and the client server communication code was developed for the Arduino and software app. This is generally outlined in the below software flowchart. Note that the calculation for the force and total distance traveled was previously described in the circuits section of the methods.

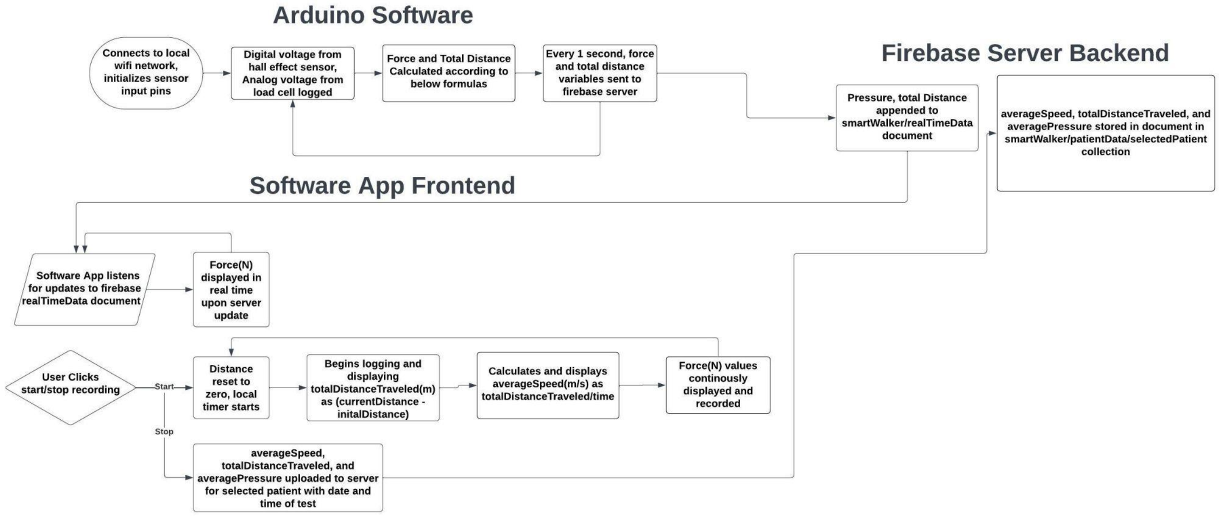


Figure 18: *Overall software flowchart describing relay of sensor data between Arduino, Firebase, and software app*

To further describe the Arduino MKR WiFi 1010 code, after initializing all the sensor pins using built in functions, the Arduino connected to a local WiFi network using a specific SSID and password and the external library [17]. After setup, in a loop the Arduino would calculate the force utilizing the voltage signal input from pin 3 and a previously determined calibration factor. The total distance also gets calculated by adding to a total distance variable initialized at zero and simply adding the distance between magnets each time a magnet is sensed. Using the built in millis() timer function in Arduino and the external library for communication between an Arduino and Firebase Firestore, every second that passed, the Arduino would send the total distance and and force data variables to firestore and store them in the real time data document [18].

In the software application algorithm, upon clicking start recording, the app will use a snapshot listener which is a part of the FirebaseFirestore library in order to continuously listen to updates to the real time data document [19]. When the document gets updated, the app will record the new pressure and total distance. Upon start, the total distance is reset to zero and a built in timer is started. The total distance is simply calculated as the difference between the distance in the real time document and the initial distance upon starting the recording, and the speed is simply the total distance over the time measured by the built in timer. The pressure values are continuously logged in an array, and upon clicking stop recording, the average pressure is calculated. The average pressure, the average speed, and the total distance are then stored in Firebase Firestore for the selected patient in a document titled by the current date and time.

Final Prototype

Figure 19: *Completed final prototype with sensors, feet, protoboard, and microcontroller*

The final prototype integrates the two sensor systems and a software app on the backend to record and analyze the data. The two load cells on the back two legs of the walker which are housed in 3D printed feet record the downward force exerted on the walker. These were integrated into the walker by modeling and 3D printing new walker gliders which facilitate smooth movement across the ground and house the load cells.

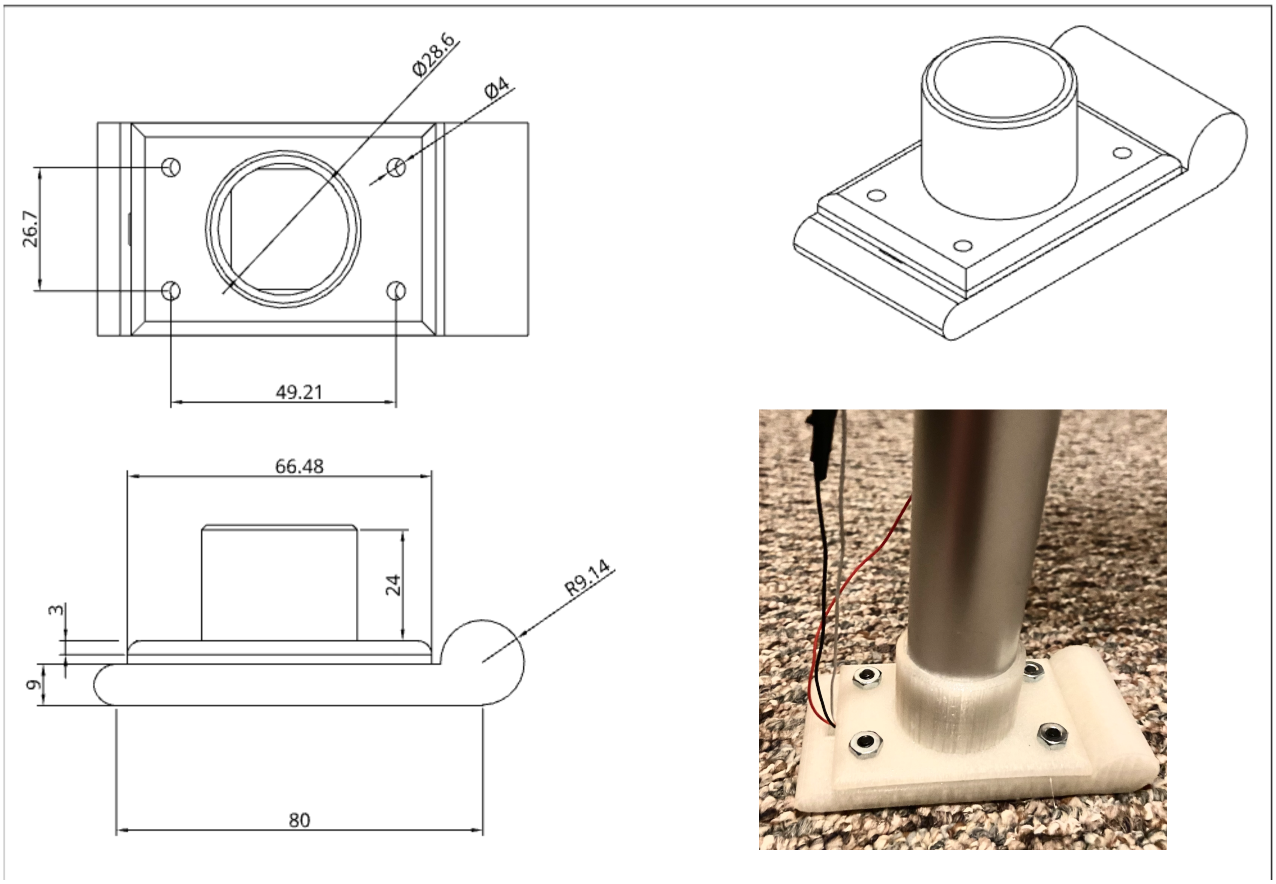


Figure 20: *Final foot prototype (measurements in mm)*

For our speed and distance circuit, a Hall effect sensor was attached to one of the forward legs with wheels and five magnets were fastened to the inside of the corresponding wheel. This setup allowed for the recording of the angular speed of the wheel based on how frequently the

Hall effect sensor detected a magnet, and when sent through the Firebase server and analyzed by the app, was outputted as average linear speed and distance.

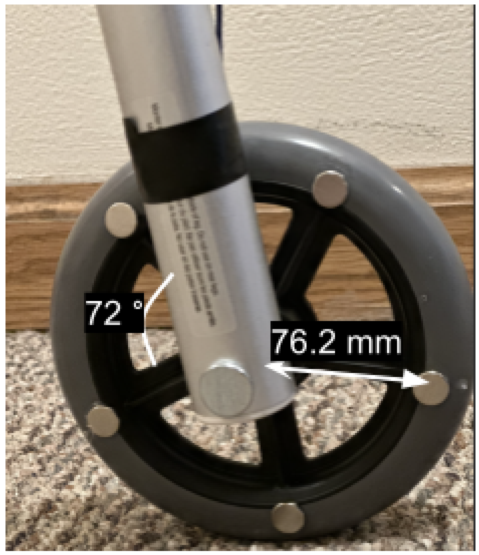


Figure 21: *Hall effect sensor & magnet setup*

The two sensor systems were hardwired to an Arduino, with the load cell circuit being wired through an amplifier board before connecting to the Arduino microcontroller. The data was then sent through a WiFi connection to the Firebase server, from which the software app drew live data, performed the calculations, and presented the data in a user interface. All together, the walker is used exactly the same as any other standard two-wheel walker, yet the embedded sensor systems serve to provide live data to the client's smartphone about the force exerted on the walker, speed of travel, and distance traveled.

Testing

Before the bulk of the testing was done, a short test was performed to find the calibration coefficient of the load cell circuit. To do this, an object's weight was measured using a bathroom scale, and then placed on the handles of the walker with the weight distributed equally. After inputting the known weight of the object into the calibration code, a calibration coefficient was output for use in the main code (Appendix C). The weight was removed and replaced 3 times to ensure that the coefficient remained constant. This coefficient was then put into the main code, and the rest of the testing was done.

To test the pressure, 3 objects were placed on the bathroom scale to measure their weights. After their weight was recorded, the objects were placed on the handles of the walker and the pressure values shown in the app were recorded after 5 seconds to allow for settling. 3 trials were performed at each weight, as well as 3 trials with no weight applied to the handles. It was observed that when the weight was removed, the pressure values shown in the app did not return to zero. To combat this, a zero button was created in the app and subsequent tests more accurately reflected the actual values.

To test the functionality of the speed and distance design, a measuring tape extended to 3.05 m was placed on ground. With the front of the walker wheels starting at one end of the measuring tape, the walker was pushed forwards along this 3.05 m path. The time it took for the front of the wheels to reach the other end of the measuring tape was recorded manually, so that the speed of the walker could be calculated. This method reflected the way that Mr. Kutschera currently runs tests with his patients. This was repeated for four trials, recording the speed and distance values shown in the app each time. As these tests were performed, the walker was also evaluated against other criteria such as path impedance, maximum support, and adjustability of the legs.

To analyze the data recorded during testing, a paired t-test was used and a confidence interval of 90% was found. A paired t-test is a statistical test used to determine if the mean difference between two sets of data is statistically different from zero. The confidence interval provides a range that the error between expected and actual values will fall in 90% of the time.

IX. Results

For each of 3 trials for 3 different known weights, the force (N) values shown in the app were recorded. The calibration factor used was 250.34. The average force of each group of 3 trials was calculated and converted into kilograms using:

$$Mass\ (kg) = \frac{Force\ (N)}{g} \qquad (1)$$

where g = 9.81. The distribution of scale weight vs average walker weight values can be seen in Figure 21.

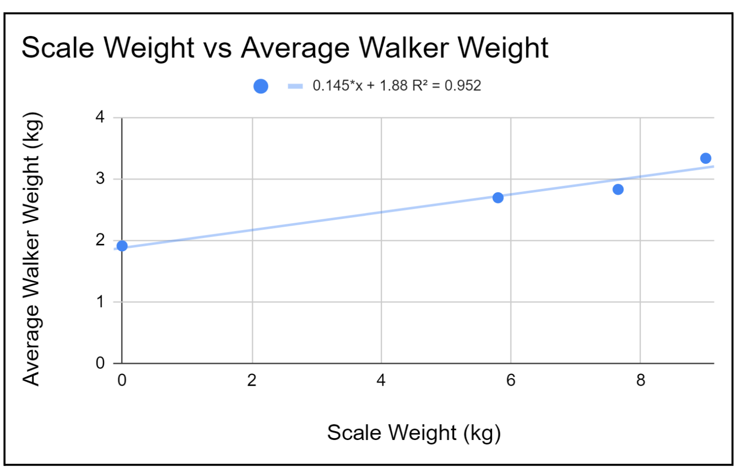


Figure 21: *Scale Weight vs Average Walker Weight*

The paired t-test was applied to the expected (scale) weights and the actual (walker) weights using the Google Sheets T.Test command, and a p-value of 0.42 was returned. This means that at 95% significance—when $\alpha = 0.05 < 0.418$—the expected and actual values are not statistically different. The error between each scale reading and average walker reading was calculated, and it was found that the average error was 7.97%. A confidence interval at 90% significance was determined in Google Sheets using the "TINV" command:

$$Confidence\ Interval\ (0.90) = TINV(0.05,\ 8) \times \frac{s}{\sqrt{n}} \qquad (2)$$

where standard deviation (s) = 0.04, and sample size (n) = 8. The confidence interval indicated with 90% confidence that the mean error between the measured and true pressure values would be between 3.47% and 12.47%.

Using the time and distance values recorded manually during speed testing, the speed of the walker during each of the 4 trials was calculated and compared to the speed values displayed in the app. The results can be seen in Figure 22.

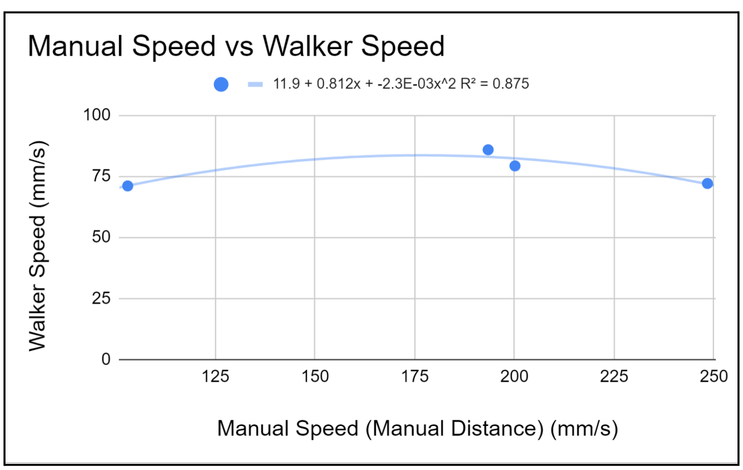


Figure 22: Manual Speed vs Walker Speed

The average error between the manually calculated speed and speed displayed by the walker was 31%, and increased with speed. This is far greater than the design specification of 5% accuracy. A paired t-test returned a p-value of 0.03, which is less than $\alpha = 0.05$ at 95% significance, so these two data sets are statistically different. It was observed that the speed read by the walker remained around 75 mm/s even as actual speed increased. A proposed explanation for this is due to the sensor delay caused by communication between the Arduino and Google Firebase. When the Arduino is sending data to the app, it is not reading the sensors. So at slower speeds, fewer magnets are sensed each time the Arduino communicates with the sensors, but there are more periods of sensing over the course of a distance. At higher speeds, the Arduino senses more magnets each time it communicates with the sensors, but there are fewer periods of sensing over the course of the same distance. This limits the ability of the design to accurately determine the speed of the walker.

During the testing of the speed, there was no impedance by the added electrical elements into the path of the walker user and the legs of the walker were adjusted between their shortest and longest lengths with no effect on the electrical elements. Additionally, there were no modifications made to the structural integrity of the walker itself and it was observed to safely support the entire body weight of a grown adult multiple times. These observations all satisfy design requirements.

X. Discussion

To comprehensively evaluate the prototype's key components, namely the load cell force sensors and the magnetic system for speed and distance measurement, we executed two experimental sets. These experiments were designed to benchmark the sensor outputs against known weights and manually recorded speed values. Regarding precision, the force and speed sensor systems demonstrated the ability to register measurements down to 0.1 N and 0.1 m/s, respectively. On the aspect of accuracy, the load cell system within the prototype showed a promising alignment with the actual force values, albeit with a slight deviation. The observed average error margin of 7.97% slightly overshoots the target of 5% set in the product design specifications. This discrepancy suggests a necessity for refining the sensor system. Potential sources of error in the force sensors could include sensor drift, as indicated by an increasing error margin over the duration of tests and a failure to reset to zero post-load removal. To rectify this, we plan to conduct further trials to map the drift pattern in sensor values and potentially implement a recalibration method or an adaptive zeroing system to adjust the sensor output dynamically. The problem may also be due to the physical housing of the load cells that may cause the applied pressure to persist even when a load on the walker is removed, and a redesign of the housing that can consistently dissipate energy upon removal of a load such as through the use of springs may more effectively minimize sensor drift.

In addition, the average error between the manually measured speed values and measured values was 31%, notably higher than the target of 5%, and thus significant refinement is needed to improve the accuracy of the magnetic speed measurement system. Various sources of error could have led to inaccurate speed measurements. Each time a magnet is not sensed by the Hall effect sensor, the distance traveled does not increase, and in turn the speed decreases as the time continues to increase. In turn, a more sensitive Hall effect sensor or stronger magnets could improve magnetic sensing. Further tests should be conducted to specifically evaluate the frequency at which magnets are not sensed by the Hall effect sensor, and it may be possible to in turn develop an experimental offset value to adjust the speed values accordingly in real time to be more accurate. Another major potential source of error could be the conflict between the Arduino's client server communication and the sensor readings, where when the Arduino is sending data it is unable to asynchronously also read sensor readings. Two separate Arduinos would be required to independently handle client server communication and real time sensor data processing.

Other major components of the product design specification tested related to the assembly of the walker. The added weight of the walker from the sensor systems, 3D printed gliders, and microcontroller was 0.23 kg which was successfully less than the 1.81 kg target ensuring that the walker is not heavy for the patient to move or for the physical therapist to move to storage. There were no bugs encountered with the software app throughout the duration of testing and it reliably continuously displayed real time force, speed and distance values as intended. From visual inspection, the wires and microcontroller do not conflict with the handles or inner center of the walker, however running the wires through the tubes of the walker and creating a housing for the electrons will further decrease potential interference of the assembly with the patient.

XI. Conclusions

Physical therapists often aim to reduce the dependency of patients involved in the physical neurorehabilitation process and currently manually determine or visually observe the patient's applied pressure on the walker, their speed, and distance traveled to assess progress. Throughout the project, a sensorized smart walker tailored to clinical settings was developed that would be able to provide real time objective sensor data on applied force, speed, and distance traveled. The data could be vital in the long term for diagnostic purposes, insurance evaluation, and patient motivation.

The final design of the walker encompassed two load cell sensors integrated into the gliders of the walkers with a magnetic speed sensing system including a Hall effect sensor to detect magnets equally spaced along the wheel to calculate angular rotation. An Arduino would store data every second in a Google Firebase server that would be retrieved and displayed on a software app in real time. The average error of the force and speed sensing systems was 7.97% and 31% respectively, indicating the need for further refinement of the calibration of the sensors to reach the 5% accuracy target. For future semesters, it would be necessary to develop an adaptive zeroing system and redesign the load cell housing to address the sensor drift of the load cell sensors being a major source of error. In improving the speed sensor system, the integration of stronger magnets, a more sensitive Hall effect sensor, and the inclusion of separate Arduino for client server communication would increase the frequency at which magnets are sensed when they pass by.

The software application successfully was able to display data in real time, and the server was effectively organized to store data during tests for analysis by the physical therapist in the long term. In addition it would be necessary to install the housing unit of the Arduino and ensure that its size is appropriate to effectively store all the electronics, and if not we will continue to refine the dimensions of the electronics box. We also plan to hide the wiring on the sides of the walker to decrease interference with the patient. It would be necessary to then continue to run tests in a clinical setting with the prototype and receive feedback from both patients and the physical therapists. Further down the line, with the development of a final product, we would then be able to investigate the potential for filing a patent or scaling development of the product. As a whole, a sensorized smart walker represents a significant step forward in enhancing the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

XII. References

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XIII. Appendix

Appendix A - Project Timeline

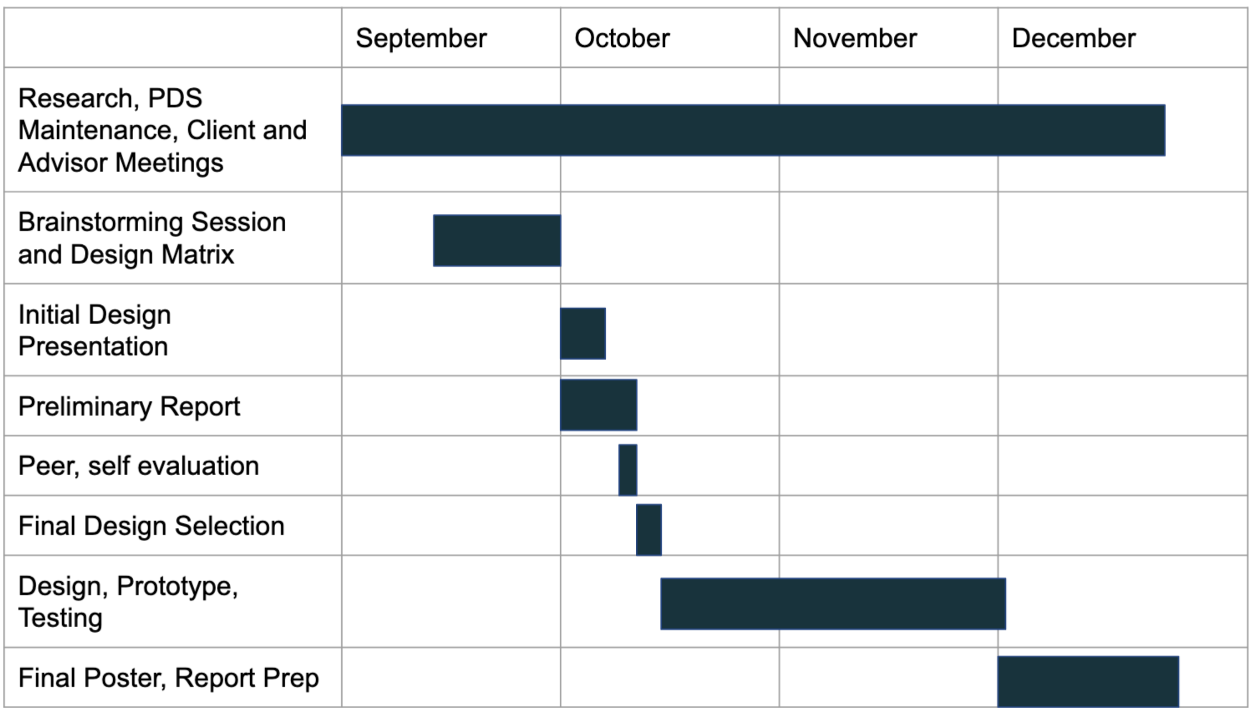

Table 3: *Project timeline*

Appendix B - Materials & Budget

Item	Price	Quantity	Total Price	Buying Location
Walker	$43.53	1	$43.53	Link (Amazon)
Gliders	$11.04	1	$11.04	Link (Amazon)
Apple Developer Account	$99.00	1	$99.00	Link (Apple)

ARDUINO				
Microcontrollers	$48.53	1	$48.53	Makerspace
Hall Effect Sensor	$1.00	1	$1.00	Makerspace
Load Cells (First Prototype)	$2.25	4	$9.00	Link (Amazon)
Load Cells (Second Prototype, first did not work)	$4.50	4	$18.00	Link (Sparkfun Electronics)
Amplifier Boards	$1.80	5	$8.98	Link (Amazon)
Hall Effect Sensors - Time Constraint	$1.10	2	$2.20	Makerspace
3D PRINT				
3D Printed Glider - PLA (Prototype)	$3.28	1	$3.28	Makerspace
3D Printed Gliders - PLA	$8.00	1	$8.00	Makerspace
3D Printed Box - PLA(Prototype)	$4.58	1	$4.58	Makerspace
MISC				
Screws	$0.03	9	$0.30	Makerspace
Nuts	$0.15	8	$1.20	Makerspace
Zipties	$0.05	10	$0.50	Makerspace
Big Magnets	$0.25	3	$0.75	Makerspace
Medium Magnets	$0.11	4	$0.44	Makerspace
Powerblock	$11.50	1	$11.50	Makerspace
Electric Tape	$3.50	1	$3.50	Makerspace
Super Glue	$1.15	1	$1.15	Makerspace

Total	**Remaining Budget**
$276.48	$123.52

Appendix C - Prototype Code

Github Link to all code: https://github.com/nikhilChandra1/smartWalker

Appendix D - Testing Data

Scale Weight (kg)	Walker Force (N)	Walker Force (N)	Walker Force (N)	Average Walker Weight (kg)
0	8.386429621	7.646195511	8.054926699	0.8184693113
5.8	16.59090712	17.55624288	17.15050859	1.743039708
7.65	20.96314037	17.68901246	18.48264526	1.94137948
9	26.41190643	28.78833515	26.88343491	2.789115749

Manual Times (s)	Manual Distance (m)	Manual Speed (mm/s)	Walker Speed (mm/s)
12.28	3.05	103.0753633	71.1
15.24	3.05	193.4051997	85.9
29.59	3.05	200.1312336	79.3
15.77	3.05	248.3713355	72.1

Appendix E - Product Design Specifications

Smart Walker
Product Design Specification (PDS)

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CONTENTS OF PDS

Function -

Patients with mobility impairments involved in the neurorehabilitation process often use walkers as transitional devices that can aid with their coordination and balance. Within the neurorehabilitation process, clinicians or physical therapists often aim to reduce a patient's dependency upon walkers as they regain motor control. However, there is yet to be a commercial smart walker that can track a patient's functional independence and deliver objective data for physical therapists and patients. The client, Mr. Danile Kutschera, a physical therapist at the UW Rehabilitation Hospital, requests a sensorized smart walker that can track in real time a patient's distance traveled, gait speed, and applied pressure distribution on the walker. In turn, the smart walker will be capable of tracking a patient's motor control through their dependency on the walker and provide objective data of improvement over time. The data can be utilized for motivational purposes for the client along with insurance/medicare reasons to evaluate the efficacy of intervention strategies. As a whole, a sensorized smart walker would enhance the neurorehabilitation process by providing vital data for progress monitoring of a patient's motor independence.

Client requirements -

- The product can be designed specifically for the walkers being used in the clinical setting of the UW Rehabilitation hospital and need not be versatile for all walker brands.
- The product should be durable for daily repeated use with minimal maintenance, and should not be sensitive to sanitizing wipes.
- The product must be produced within a budget of $400 including the purchase of the walker, electronics, and any other materials.
- A display or smartphone app to show data including gait speed, distance traveled, pressure, in real time is necessary for the patient and for monitoring by the therapist
- A start and stop button for recording data is necessary for conducting intervention tests in a

clinical setting.
- The raw time series data should be uploaded to a server in real time or stored locally for access and analysis by the clinician.
- The distance should be measured in meters, gait speed in meters/second,, and the pressure in $N/meters^2$. It would also be preferable that the walker senses a pressure distribution on the left and right side of the walker to better capture weight imbalances.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*:

The walker will be used for short distances of 3-5 meters, at low speeds of **983.5 mm/s**, and less than average body weight(70 kg) will be applied on the walker. The device will be used daily for multiple tests throughout a day, where each test can have a duration of an hour or more. The smart walker will need to provide consistently accurate measurements of the pressure that the patient is applying to the walker, the gait speed of the patient, and the distance traveled. The smart walker needs to be durable and of sound construction to prevent further injury to patients during rehab.

b. *Safety*:

Safety is an important consideration in the design of the walker because the primary users already have a neurological or physically related injury putting them in a compromised state. Standards govern all parts of the walker and must be followed to ensure a safe product.

Manufacturing standards around walkers exist to ensure that walkers can effectively and safely support the balance, coordination, movement, and weight of a patient. In turn, we need to sensorize a smart walker that does not compromise some of these essential standards that have been developed to minimize the potential risk for injury for users. Specific specifications include, the diameter of the walker tip must be at least 44 mm in diameter where it contacts the floor and the hole that the shaft of the walker fits into must be 35 mm deep. The shafts of the walker should be adjustable to ensure proper fit for all patients reducing risk of injury. The frame should be lightweight with the upper tube being at least 25.4 mm x 1.62 mm and the lower tube being at least 21.6 x 1.4 mm. The walker frame must withstand a load of at least 100 kg [1]. Ensuring that the sensorized smart walker does not deviate significantly(>5%) from the following manufacturing standards ensures that the walker will be safe for the patient to use and fall within insurance guidelines.

There are other more general safety standards for medical devices and user privacy including standards such as ISO 13485 (medical devices) and ISO 14971 (risk management) which will be essential to consider, and are elaborated further in the standards section.

Moreover in regards to material safety, durable hand grips resistant to perspiration and scuffing are important for maintaining a secure grip and preventing accidents. Water damage can pose electrical hazards and compromise the functionality of the sensors. The tips of the feet of the walker should also be non-slip and replaceable **such that the sensors stay functional.**

In regards to safety labels, there will be comprehensive labeling and indicators including an on or off LED or labels for multiple buttons. We will also prepare a guide that would include instructions on proper use, any weight limitations, and maintenance guidelines. A datasheet of expected values and ranges for speed, pressure, … etc can be prepared such that the clinician is aware when values fall outside of the range to evaluate if the sensors are faulty and need repair.

Additionally the electrical components of the sensors must be water resistant to prevent damage during routine cleaning and sanitation. They also must be compact enough and secure enough to not impede the patient while the walker is in use while again fitting the aforementioned manufacturing standards for walkers. We do not intend on using any chemical or thermal components in sensorizing the walker.

c. *Accuracy and Reliability*:

Because the walker will not be used over long distances(<5 meters at a time) and will be used at slow speeds**(<983.5 mm/s**) the sensors will have to have a high precision of +- 0.1 meters(distance), +- **10 mm/s**(speed) and +-10 **N**(pressure). The desired accuracy would be within 5% across all measurements. Due to the slow process of neurorehabilitation and the marginal gains over time, the device would require both high accuracy and high precision to be evaluated effective.

d. Life in Service:

The walker should be able to last a minimum of 5 years which is the estimated lifespan of most mobility aids [2]. However, our walker should be expected to have a much longer lifespan considering it is used in a controlled environment over shorter 1 hour periods of time with flat surfaces. But in order to ensure that the sensors are still accurate the walker should be serviced at least once **every 6 months**. The walker will need regular service to ensure that the batteries are charged and sensors still output values within the specified accuracy and precision tolerance.

e. Shelf Life:

The walker should be stored in a dry environment around room temperature. Alkaline batteries will likely be used to provide power to the walker. Alkaline batteries have an ideal storage temperature of **15**℃ and will store for ten years with only moderate capacity loss [3]. Assuming the use of an Arduino microcontroller, the smart walker will have a shelf life of 20-30 years if it is kept near room temperature [4]. Conditions for the shelf life of the product will be further refined as we understand more about the sensors and specific electronic or mechanical components involved in our final design and prototype.

f. Operating Environment:

The walker will be used in a clinical setting, so it will be exposed to a clean, room temperature (15-25℃) environment. As it will be used by multiple patients, it will need to be sanitized between uses and should not be sensitive to sanitizing materials. Due to varying patient weights and abilities, the walker will be subject to a range of pressures, and should be safe up to 136 kg of both continuous and intermittent pressure. Due to the clinical setting, no extreme conditions need to be considered, and the Smart Walker will be used under supervision so there should be no unforeseen hazards.

g. Ergonomics:

As the walker will be used by numerous patients, it will need to accommodate a variety of weights, and the handles should be adjustable to hip level for a variety of heights [5]. Like an average standing walker, the walker will have adjustable legs to be used comfortably in the range of **165mm to 198mm**, and will support up to 136 kg of weight [6]. As the patients will be re-learning to walk, the walker should move smoothly across the floor so as not to impede their movement, and should not have any sharp edges that could cause injury to the patient. The Smart Walker will be used under professional supervision, so it can be expected that the walker will be used properly, with a hand on each of the handles, but the walker should remain stable should the pressure on each handle be unequal. **There is no display on the walker to potentially distract the patient from keeping their focus, as all the real time data will be accessed by the physical therapist.**

h. Size:

The walker should be sized similarly to most walkers on the market, with a maximum width of 63.5cm so that it can pass easily through all standard doorways. The walker should be between 81.28cm and 101.6cm tall in order to accommodate patients with various heights ranging from **165mm and 198mm.** To aid in the versatility of the device to fit patients of all sizes, the device needs to maintain the ability to adjust the grip heights. Ideally, the device should be foldable in order to be easily transported and stored, however because it will only be used in a clinical setting, the strength and durability of the walker is more important. The device and its components should be easily maintained and accessible in the case of technical issues.

i. *Weight*:

A design constraint is that he walker needs to be of reasonable weight, ideally between 4.54kg and 9.07kg such that it can be easily moved both by patients during clinic sessions and by the client for storage purposes. The distribution of the weight of the components should also be monitored to provide the ideal walking experience. The device should be robust enough to support a maximum weight of 136kg in order to accommodate all patients in their recovery.

j. *Materials*:

A material that is commonly used in the frame of walkers that is both light and strong is aluminum tubing [14]. Additionally, the padding on the handles of the walkers is typically composed of vinyl. These materials have been tested for comfort, safety, and the integrity of the walker. **There is no intention of introducing new components that will be attached to the handles or can change the structural integrity of the walker, these same materials should be used**. There are a variety of materials that we should not use as they may be affected by sanitization, are absorbent to perspiration, or can be breeding grounds for bacteria, which may decrease the life in service or shelf time of the product and may not be most appropriate in a clinical setting. For example, wood, cloth or fabric, leather, and non slip rubber all can introduce sanitization, maintenance, or even safety issues [15].

k. *Aesthetics*, *Appearance, and Finish*:

The walker should have simple aesthetics because the most important part of the smart walker is that it aids in the recovery of a patient and that it is comfortable for them. The color can be as simple as the natural gray color of aluminum. The shape of the walker should allow it to be transported easily so it is accessible for the hospital and different patients. As mentioned previously a handle that is of vinyl material or resistant to perspiration should be used to ensure the texture of handles can allow the patient to have a good grip at all times.

2. Production Characteristics

a. *Quantity*:

The client has requested one Smart Walker unit be created. The unit can remain in the physical therapy room and be used as needed by multiple physical therapists.

b. *Target Product Cost*:

The client has provided a budget of $400. A walker to be modified could be provided by the client, or could be purchased for ~$40 [7]. All additional materials will be included in the budget.

d. Miscellaneous

a. *Standards and Specifications*:

There are a number of relevant standards and specifications to reference in the development of a smart walker device. IEC 60601 details standards and guidelines in building medical electrical equipment, and our device which will employ electronic sensors and be used in the context of neurorehabilitation for helping patients can be labeled as medical electrical equipment [8]. The Health Insurance Portability and Accountability Act (HIPAA) is also an important reference in regards to how to legally manage personal patient information and we will need to create appropriate security rules to ensure that only the patient and clinician involved have access to the server or local storage folder containing all the time series sensor data [9]. ISO 14971 provides further guidance on risk management and evaluation for in vitro diagnostic medical devices, a category that which our smart walker could potentially fall under if physical therapists use the sensor data to diagnose the patient in any way or determine future treatments or interventions. In addition, since the smart walker is intended for medical purposes and can deliver sensitive data to healthcare professionals for clinical decision making, the smart walker's development as a product and distribution to hospitals will likely require FDA approval [10].

b. *Customer*:

The client prefers a smartphone app to show statistics such as speed, **pressure**, and distance that would then be uploaded to a server and formatted automatically to be accessed at any time. **However this app should not be flashy, in which the patient nor the client are losing focus on their task. For this to work out, the app has to be simplistic so that it is easy to read and easy for the client to access the data locally by connecting the computer to the device**. Also preferred was a 24 hour battery life and a start and stop button.

c. *Patient-related concerns*:

The device will be subjected to constant use from patients throughout the clinic, so measures regarding sanitation will need to be taken to provide a product that is easily sanitized/sterilized in between patient uses. Additionally, because the device will be used by multiple patients and various sensitive data will be recorded and stored either on the device itself or on an external database, it will be important that patient confidentiality is preserved under HIPAA regulations. The HIPAA Privacy Rule establishes national standards to protect individuals' medical records and other identifiable health information [11]. Lastly, the device will be used by multiple patients so making sure the device is robust and safe to use to ensure the health and safety of the patient will be paramount, and previous ranges and conditions for weight, size, materials, … were selected to ensure the integrity of the walker and in turn the safety of the patient. Any other liability concerns should be discussed with the client.

d. Competition:

The Camino Smart Walker is an electronic walker that is meant to help the patients get to destinations more efficiently [12]. The walker uses artificial intelligence to track 22 different gait metrics and maintain the safety of the user while maximizing their efficiency. However this walker does come out to be expensive at $3000, and many of its features are redundant and unnecessary given the intended features and specifications requested by our client. In addition the walker is not adaptable to a clinical setting where the data can be seamlessly recorded for analysis by a clinician. Another item is the AmbuTrak Device, which is an attachment to the walker that records distance and speed [13]. The device attaches to the wheel to measure the RPM and has an LED display. Although the device can display data in realtime, it does not have the capability of uploading this information to a server. It also does not record the applied pressure distribution of the patient on the walker. Overall the main competition is mainly for commercial use and is not perfectly adaptable to the requested features by our client for a clinical setting.

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