SMART WALKR

Biomedical Engineering Design

Department of Biomedical Engineering

University of Wisconsin-Madison

October 6th, 2024

Client

Dan Kutschera

Advisor

Dr. Amit Nimunkar

Team

Nolan BlomWillis (Leader & Communicator)
Eva Schiltz (BSAC)
Jacob Parsons (BPAG)
James Waldenberger (BWIG)

Abstract

The rehabilitation process is ever evolving, now more than ever a data driven approach to rehabilitation is needed. Both the Physical Therapist and the patient would be beneficiaries of this data. The Smart Walker will bring an approach that tracks and displays measurements of speed, distance traveled, and pressure applied to the Smart Walker. This will allow the patient in real time to see the progress they have been making on each visit. This also allows the Physical Therapist to give the patient data driven goals on a recovery timeline. The previous team that worked on this project had the data stored in an app on a phone and did not show these measurements in pounds and mph. Our goal is to have a display that outputs values in pounds for force, mph for speed, and feet for distance traveled. The improvements for this group will be focused on the client's requests for a better clinical use for the walker.

Table of Contents

Introduction

Motivation

People enter neurorehabilitation under a variety of different circumstances. They are often recovering from traumatic brain injury, degenerative neurological diseases or strokes. One of their most common symptoms is gait impairment, a condition which greatly reduces quality of life and increases the risk of future falls [1]. Furthermore gait impairment can prevent reintegration back into society due to diminished walking speeds complicating everyday actions like crossing the street. In order to ensure these patients have regained functional mobility, physical therapists will use basic walking tests to assess characteristics such as speed and reliance on assistive devices. These tests offer insight into the effectiveness of the therapy but also act as motivational tools for those in treatment. Establishing benchmarks in training can encourage more engagement in and adherence to the rehabilitation process [2]. However these indicators are often estimated through observations by the physical therapist as opposed to being collected as objective data. A smart walker which could collect the speed and pressure applied by the user could become an important tool in neurorehabilitation. This device could facilitate the development of a more effective training plan and incentivize those in treatment, hastening their recovery and improving quality of life.

Existing Devices and Current Methods

There are currently patents and existing devices for walkers which include elements of the smart walker envisioned by the client. A Distance Measuring Walker Patent lays claims to walkers with distance and speed measuring sensors built into its wheels [3]. This data would then be displayed on a sensor attached to the frame of the walker. However this patent does not include any methods of measuring pressure through the walker and therefore does not fully encompass the needs of the client.

Another patent for an instrumented mobility assistance device uses sensors in the handles of the walker to measure the force transmitted through the user to the walker [4]. The peaks and valleys of the output force vs. time graph are correlated to parts of the users gait, and can be used to make calculations to infer about the users gait speed, travel distance, and stability/balance when using the walker. Though this design measures applied pressure and speed similar to the proposed smart walker, it also includes gait analysis which would increase the price and complexity of the device.

Finally, on the market there is a Camino Smart Walker which uses AI to perform gait analysis and measure 22 different gait parameters [5]. It also incorporates boosts and brakes, facilitating assisted transport. This added technology contributes to the steep price of the walker, each unit selling at $3000. This is far out of the price range for the client and diminishes the effectiveness of the walker as a simple rehabilitation aid.

Problem Statement

In the rehabilitation process of acute strokes or similar conditions it is necessary for the patient to be able to walk independently so they can safely return home. Physical therapists often gauge reliance on assistive walking devices through observational measures of speed and applied pressure on the walker. No current devices on the market offer these measurements while requiring minimal setup and employing a standard walker. For this reason, the team has been tasked with creating a smart walker which can record walking speed and pressure placed on the walker. The pressure measurements should track distribution in order to ensure symmetry while walking. This data will need to be recorded during individual walking tests, after which the average should be displayed on a monitor attached to the walker. This information will help guide physical therapists in shaping therapy goals as well as motivate patients to engage with the rehabilitation process. As a result the smart walker could improve the neurorehabilitation process and send patients home faster.

Background

Physiology and Biology

More than 795,000 people in America have a stroke annually [6]. Specifically, acute strokes, commonly known as “brain attacks”, are a major contributor to disability to those who were able to recover from the stroke in the first place [7]. While the chances for stroke increase with age, 38% of victims in 2014 were less than 65 years old according to the CDC [6], which means that the affected population is quite broad in terms of age and therefore other physical attributes as well. Because the project focuses on the physical rehabilitation aspect of acute stroke recovery, it is important to understand how the recovery process looks. There are a plethora of stroke symptoms that affect the digestive system to the mental state of the patient, but for the purposes of this report the physical symptoms are of greatest concern. These symptoms include weakness or paralysis on one or both sides of the body, numbness or strange sensations, and pain in the hands and feet [8]. As one can imagine, walking while experiencing these afflictions, even with a walker or other such assistive device, could be quite difficult and cumbersome. The possibility of heavy reliance on the Smart Walker during tests, and the wide range of potential users of the device mean that it is important that the Smart Walker be up to par with design specifications.

Design Specifications

A more detailed explanation of the design specifications for the Smart Walker can be found in *Appendix A.* at the end of the report. That being said, there are important specifications that are brought here to explicitly outline them, as they will guide the entire design for the most part. The Smart Walker will be used in a clinical setting with up to 10 different patients a day, each doing up to 5 trials with the walker to determine their recovery status. The aforementioned trials will be 10 meters of walking distance, and should take no longer than 30 minutes at the very maximum to complete. Due to the variety of potential users of the Smart Walker, it should be able to accommodate a variety of heights from 0.8-1.1 meters, widths of 0.64-0.74 meters, and weights of up to 140 kilograms. The patient's speed, distance traveled, and force/pressure data will be transmitted to a screen attached to the Smart Walker, and should display these metrics converted to imperial units. Sensor measurements are expected to be within 5% accuracy of the real value. The client has specified $350 as the budget for this project.

Client Information

Dan Kutschera is a physical therapist who works at an acute stroke clinic in Madison, Wisconsin. He is looking for a way to quantitatively assess the ability for his patients to walk using a walking aid, as he currently has no way to do so.

Preliminary Designs

Speed Sensor 1: Accelerometer

The first preliminary design for tracking the speed and distance of the walker is an accelerometer. An accelerometer will detect accelerations that occur in the x, y, and z axis and measure them in units of gravitational force, or g force. The accelerometer will output a voltage value proportional to the acceleration measured. This voltage value will be converted back to an acceleration and derived once to calculate the speed and again to calculate the distance.

The accelerometer can be placed anywhere on the walker since the walker is a rigid body. This means that the accelerations induced on the walker by the patient are also induced on the accelerometer. The accelerometer will need to have a high level of sensitivity to pick up on the accelerations of the patient walking.

Speed Sensor 2: Rotary Encoder

The second sensor for measuring the speed and distance of the walker is a rotary encoder. A rotary encoder converts the angular position of an axle into a voltage output. This sensor would measure the number of revolutions the wheels undergo during a trial. This amount of revolutions can then be multiplied by the circumference of the wheel to calculate the distance traveled. It would also require an internal clock to keep track of the amount of time that has passed, from this the speed can be calculated.

The rotary encoder would be located at both of the wheels. Fabrication of an axle that originates from the wheel would be necessary to drive the rotary encoder and evaluate the amount of revolutions that occur since clinical walker wheels do not have axles.

Speed Sensor 3: Hall Effect Sensor

The final potential sensor to be evaluated for measuring the speed and distance of the walker is a hall effect sensor. A hall effect sensor detects magnetic fields along an axis and once the measured field surpasses a threshold the sensor's output is turned on.

The hall effect sensor would be located at the wheel and would require small magnets to be attached at equal distances about the wheel. When the hall effect sensor outputs a voltage signifying that a magnet has passed, the arc length between these distances can be used to evaluate how far the walker has traveled. An internal clock keeping track of the time in the trial can then be used to calculate the speed of the walker.

Pressure Sensor 1: Load Cell

The load cell was the first pressure sensor considered for tracking pressure distribution on the smart walker. This sensor uses a strain gauge which detects changes in electrical resistance as pressure is applied and the strain gauge is stretched. The load cells would be integrated into the feet or legs of the walker. Building sensors into both sides of the walker would allow the sensors to detect if the user is applying asymmetric pressure to the walker.

Pressure Sensor 2: Piezoresistive Pad

A piezoresistive pad was the second pressure sensor considered for the smart walker. It also utilizes a strain gauge in a similar manner to the load cell. These pads are thinner with a greater surface area, allowing them to be integrated into the walker handles. In this way the pressure measured in these pads would be directly applied through the hands of the user.

Pressure Sensor 3: Capacitive Force Sensor

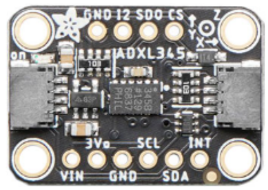
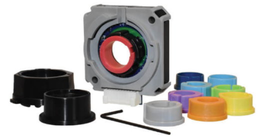
A capacitive sensor was the last type of pressure sensor evaluated for use with the smart walker. This sensor uses two metal plates with a dielectric medium in between. As pressure is applied to the sensor the distance between the plates decreases which causes a change in capacitance. This change is then calculated and converted into an electrical signal. The capacitive force sensors would also be integrated into the feet or legs of the walker.

Design Evaluations

Speed Sensor Design Matrix

Table 1: Design Matrix for Speed Sensor

Categories	**Accelerometer**	**Rotary Encoder**	**Hall Effect**

	 [9]		 [11]		 [12]	
Accuracy (30)	5/5	30	5/5	24	3/5	18
Ease-of-use (25)	5/5	25	5/5	25	4/5	20
Price (20)	4/5	16	2/5	8	5/5	20
Fabrication (15)	4/5	12	3/5	9	3/5	9
Reusability (10)	4/5	8	3/5	6	3/5	6
Total (100)	91		72		73	

Speed Sensor Design Criteria

Accuracy: This design criteria scored the highest since without a device that is able to accurately measure the distance and speed traveled by the patient on the walker, the sensor's function is useless. The sensor must measure values within 10% accuracy and 5% precision, these metrics are suitable for the client.

Ease of Use: This design criteria scored the second highest due to the fact that the product will be used multiple times a day for various patients and for multiple years (see Appendix A); therefore the walker must be easy to use for the patient and easy to set up and evaluate the metrics by the client.

Price: The Smart Walker project has a budget of $300, so maining a low cost for the electrical components is a must for the walker to stay within the budget.

Ease of Fabrication: There is a limited amount of time for fabrication and testing of the sensors, so it is necessary that it is easy to do so. If it is not, then the device will not be able to be fabricated to its complete potential and specifications.

Reusability: The Smart Walker will be used multiple times a day for various patients and for multiple years (see Appendix A). This means that it is necessary that the sensors use minimal power and are durable to withstand the use that it will undergo.

Speed Sensor Design Matrix Evaluations

Accelerometer

The accelerometer had the highest evaluation from the design matrix was a score of 91/100. This sensor scored highly across all design criteria, with 5/5 in both the accuracy and ease-of-use categories. This can be attributed to the high level of sensitivity of the accelerometer, specifically 3.9 mg/LSB (milli-g-force per least significant bit), which is less than 1% error [9]. This error and sensitivity is well within the necessary accuracy limits expressed in the Design Product Specifications (see Appendix A) of 10%. The accelerometer also scored highly in the ease-of-use criteria due to the fact that it requires no set up by the client and has no effect on the patient using the device. The accelerometer also scored the highest fabrication due to existing code and methods on how to use the device existing [10]. And finally it scored the highest in reusability due to the low power consumption of the accelerometer since it requires 3.3 V and 23 uA of supply [9].

Rotary Encoder

The rotary coder scored the lowest from the design matrix with an evaluation of 72/100. The sensor scored highly in its accuracy due to the incremental encoder's sensitivity being 0.2 degrees [11]. It also scored a 5/5 in the ease-of-use since it requires no setup for the client and does not obstruct the patient in any way. The device scored the worst in the price category due to each rotary encoder being $51.17, which is a large portion of the $300 budget. The sensor would also require additional fabrication of an axle that originates at the wheel, and additional support so both the axle and rotary encoder can withstand the forces applied from the user and the walker. This additional fabrication and concern of durability is what led to 3/5 scores for both the ease of fabrication and reusability criteria.

Hall Effect Sensor

Finally the hall effect sensor scored in the middle of the pack with a 73/100; though it nearly tied with the rotary encoder. The hall effect sensor scored a 3/5 in accuracy due to the potential for error since other magnetic fields could affect the ones induced by the magnets on the wheels. Along with this, the ease-of-use scored a 4/5 due to the added need for awareness of devices and objects that can hinder or enhance magnetic fields in the room or on the patient. The hall effect was the lowest cost out of all the products with the sensor being $0.62 each [12]. Similar to the rotary encoder, the hall effect scored a 3/5 in both the fabrication and reusability categories due to the added fabrication steps to have it function properly and the concerns of durability with the design.

Pressure Sensor Design Matrix

Table 2: Design Matrix for Pressure Sensor

Categories	**Load Cell**		**Piezoresistive Pad**		**Capacitive Force Sensor**	
Accuracy (30)	5/5	30	2/5	12	4/5	24
Ease-of-use (25)	3/5	15	4/5	20	3/5	15
Price (20)	4/5	16	3/5	12	2/5	8
Fabrication (15)	4/5	12	4/5	12	2/5	6
Reusability (10)	4/5	8	2/5	4	3/5	6
Total (100)	81		60		59	

Pressure Sensor Design Matrix Criteria

Accuracy: This design criteria scored the highest since without a device that is able to accurately measure the pressure applied by the patient on the walker, the sensor's function is useless. The sensor must measure values within 10% accuracy and 5% precision, these metrics are suitable for the client. The load cell scored the highest in this category compared to the piezoresistive pad and the capacitive force sensor due to its ability to accurately measure and withstand higher force loads, such as a human.

Ease-of-use: There isn't much set-up required for any of the sensors here, both in regards to the patient and the physiologist. Each of the sensors would need to be calibrated initially, to ensure that voltage readings coincide with the correct point on the calibration curve. That being said, both the load cell and capacitive force sensor would most likely need to be calibrated throughout the use of the walker (each day, perhaps), so the piezoresistive pad has the highest rating at 4/5.

Price: Sensor price often increases dramatically with improved accuracy. For this reason it was important to choose a sensor that would deliver accurate readings for a reasonable price. The piezoresistive pad was the most cost effective option giving it the highest rating of a 4/5. The capacitive force sensors tended to be priced higher to measure a similar weight range to the load cell and were therefore given the lowest rating.

Fabrication: The team has two semesters to complete the project; however, the project plan is to finalize the sensors of the device within the first semester. To do so, the sensor must be easily integrated into the device to meet this timeline. The load cell and piezoresistive pad both scored a 4/5 in this category. They scored the highest since it would be simple to integrate the sensor into the wheelchair, and the code required to gain meaning from the outputs of the sensors is easy to write and comprehend.

Reusability: Each of these options consume relatively little power, so there isn't a big discrepancy there. However, the load cell accels in this category because of its high durability compared to the other two sensors that struggle to pick up large weight signals, therefore the load cell has the highest in this category with a 4/5, given that it still has a fairly limited weight requirement.

Load Cell

The load cell scored the highest of the pressure sensors with a 81/100. This is largely due to its high accuracy (5/5) and affordable price (4/5). The Sparkfun load cell chosen by the team has a sensitivity of 1 +/- 0.1 mV/V which is more precise than either of the other sensors [13]. It also only costs $4.50 per unit making it easy to test and iterate off of. The load cell tied for the highest score in fabrication with a 4/5 as a result of its use in the previous semesters design for the smart walker. They 3D printed a component to integrate the load cell into the walker which the team still has access to. Lastly the load cell scored the highest in the reusability category with a 4/5 due to its low power consumption and overall durability.

Piezoresistive Pad

The piezoresistive pad had the next highest score of 60/100. It scored the highest in ease of use (4/5) as it would require less calibration between trials compared to the other two sensors. It also scored the highest in fabrication with a 4/5 as its placement on the handles of the walker would make it easy to integrate into the overall design. However, it scored the lowest in accuracy (2/5) due to it sensing only up to 50 lbs in weight. Also due to its placement in the handles, the user would need to place their hands carefully over the sensor to accurately transmit all of the forces through the pads. The piezoresistive pad also scored the lowest in reusability with a 2/5 due to its direct contact with the user diminishing the durability of the design.

Capacitive Force Sensor

The capacitive force sensor had the lowest overall score of 59/100. It had a relatively high score for accuracy (4/5) with a sensitivity of 2 +/- 0.2 mV/V. It also scored well for reusability (3/5) due to its low power consumption. However, it scored the lowest in price with a 2/5 due to its cost of $133 per unit. It also scored the lowest in fabrication (2/5) as its placement in the feet or legs of the walker would require more fabrication than the load cell or piezoresistive sensor.

Proposed Final Design

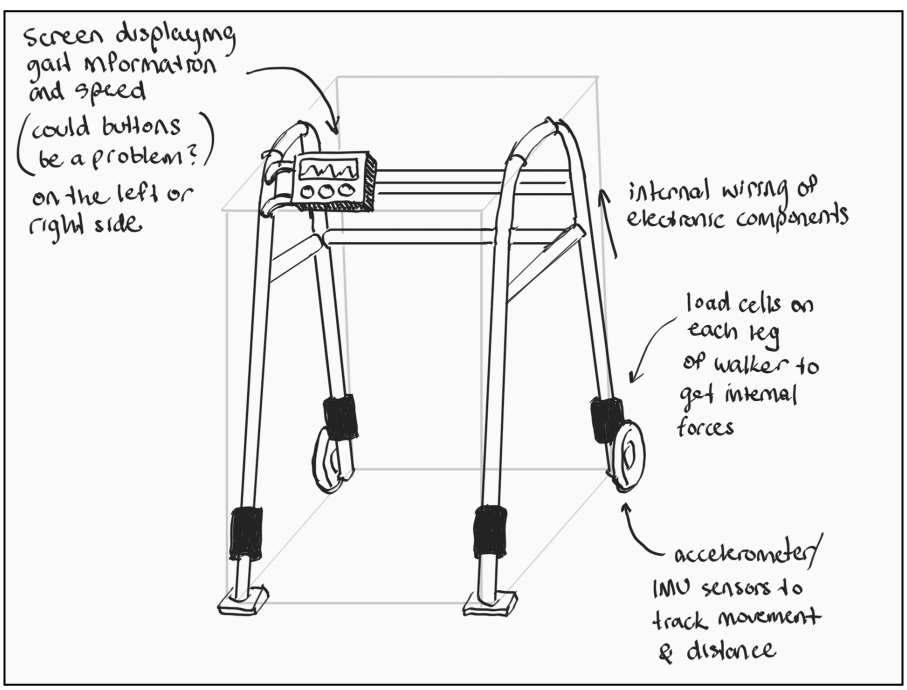


Figure 1: Sketch of proposed final design with load cells present in each leg and 1 accelerometer. As well as screen displaying the metrics measured.

The proposed final design will consist of a standard 2 wheeled clinical walker with load cells integrated into each of the legs. These load cells will be able to measure the total pressure applied to the walker and can provide information if the walker is being loaded unequally. There will be an accelerometer attached to the frame of the walker that will be used to calculate the speed and distance traveled by the walker. The walker will contain a main housing unit for the power supply, microcontroller, and OLED screen. The force applied, speed, and distance traveled by the walker will all be displayed so the client can evaluate how well the patient is recovering and provide extra motivation to the patients.

Fabrication and Development

Materials

The team has ordered an accelerometer, raspberry pi microcontroller, load cells, a hall effect sensor and magnets to conduct testing and fabrication (see Appendix B). The team also has reached out to the previous team on reimbursement for their design in hopes to use the previous team's Walker so the client does not have to be charged twice for one. The team intends to purchase an OLED board once the testing of the sensors has been completed and they have been integrated into the walker.

Fabrication Process

The fabrication of the final design will require multiple areas of focus. The first area of focus will be measuring the pressure applied to the sensor using the load cells. These load cells will be integrated into each of the 4 legs of the walker so the force can be measured from each one. This will require the team to cut out enough space and load the top part of the frame onto the sensor. The team will then connect the power supply and communication wires to each of the load cells. These wires will be run through the frame to the main housing chamber.

The housing chamber will be a 3D printed box that will hold the battery supply, accelerometer, microcontroller, and display screen. The accelerometer will be secured to the box, which is secured to the frame, and it will receive its voltage supply and be connected to the microcontroller for communication.

Finally, the team will fabricate the hall effect sensor set up exclusively for testing; however, if it performs better than the accelerometer, the team may opt to use it instead. The team will adhere 4 magnets at equal distances about the wheel and wire the hall effect from the base of the frame to the microcontroller and power supply (see Appendix C).

Testing

In order to determine whether or not the Smart Walker device is up to par with the previous design specifications, multiple tests are in order for each different type of specification.

First and foremost, the team must determine whether or not the Smart Walker fits with the static variables outlined in the design specifications. Specifically, whether the walker fits with the height, width, and max weight requirements, among other values. There will not be any calculation for this test, just a yes or no check to see if the device is as intended.

The accuracy of the sensing components of the Smart Walker is of utmost importance to the client, meaning that the load sensor, accelerometer, and hall effect must be tested with multiple trials to determine their efficacy.

- To test the load sensor the team will apply known weights ranging from 40-140 kg to the Smart Walker at multiple different configurations and check with the sensor output to see if it is accurate or not.
- To test the accelerometer the team will walk the walker at a known pace for multiple predetermined distances from 1-10 meters and check with the sensor output to see if it is accurate or not.
- To test the hall effect sensor the team will follow the same procedure for the accelerometer; a known pace will be taken for multiple predetermined distances from 1-10 meters and check with the sensor output to see if it is accurate or not.

Results

The expected outcomes from each test correspond to the product design specification value that the test is meant to determine. See *Appendix A* for specific values regarding the Smart Walker. The acceptable tolerance for measurement with the load sensor and accelerometer is ±5%.

Discussion

Ethical Considerations

The main ethical consideration of this project is ease-of-use for the patient and the client. The design should be easy to use and easy to set up, and should not take additional time to set up or track the metrics of the walker. If the device is unable to meet these standards, then it would be more helpful to not use the product.

Another ethical consideration is that the walker must be able to be used by any patient the client has. The walker should not impede the space that the patient would use to walk or require a higher level of dexterity to use. If either of these are the case, then the walker would need to be redesigned so it can cater more to the patient.

Sources of Error

No testing has been performed yet, but for the accelerometer there are a couple sources of error that the team must pay attention to in order to have the most accurate results. The largest concern is the processing time. The accelerometer measures accelerations and outputs an equivalent voltage. This means that in order to calculate speed and distance, the microcontroller will need to convert the voltage outputs to an acceleration, then integrate once to find the speed and integrate a second time to calculate the distance. These computations will take the microcontroller a bit of time and any errors that occur will be magnified. A second source of accelerometer error is that accelerations will be occurring in all 3 directions. The team will need to determine through testing whether ignoring all accelerations in directions non parallel with the path of the walker is sufficient data to accurately calculate the speed and distance.

Conclusion

This rendition of the Smart Walker aims to break away from the costly alternatives there are in the rehabilitation field so that moving forward there can be cost effective solutions for these patients. There is a striking need for our client to have a more efficient way of collecting data to use for his data driven approach to rehabilitation. Using the design matrices to decide which force sensor as well speed sensor the team is now able to move forward with the fabrication and testing of the Smart Walker. When this device is fully functional testing will be done for accuracy of the sensors as well as the accuracy of real time feedback for our patients in their rehabilitation.

References

[1] M. Bonanno et al., “Gait analysis in neurorehabilitation: From Research to Clinical Practice,” Bioengineering, vol. 10, no. 7, p. 785, Jun. 2023. doi:10.3390/bioengineering10070785

[2] R. Gangwani, A. Cain, A. Collins, and J. M. Cassidy, “Leveraging factors of self-efficacy and motivation to optimize stroke recovery,” Frontiers in Neurology, vol. 13, Feb. 2022. doi:10.3389/fneur.2022.823202

[3] “US7044361B2 - Walker Distance Measuring Device,” Google Patents, https://patents.google.com/patent/US7044361B2/en (accessed Sep. 12, 2024).

[4] “US7826983B2 - instrumented Mobility Assistance device,” Google Patents, https://patents.google.com/patent/US7826983B2/en?q=%28walker%2Bsensor%29&oq=walker%2Bwith%2Bsensor (accessed Oct. 9, 2024).

[5] Camino Mobility, https://caminomobility.com/ (accessed Oct. 3, 2024).

[6] CDC, “Stroke Facts,” Stroke. Accessed: Oct. 09, 2024. [Online]. Available: https://www.cdc.gov/stroke/data-research/facts-stats/index.html

[7] P. Tadi and F. Lui, “Acute Stroke,” in StatPearls [Internet], StatPearls Publishing, 2023. Accessed: Oct. 09, 2024. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK535369/

[8] CDC, “Treatment and Intervention for Stroke,” Stroke. Accessed: Oct. 09, 2024. [Online]. Available: https://www.cdc.gov/stroke/treatment/index.html

[9] “ADXL345 Accelerometer,” DigiKey Electronics, https://www.digikey.com/en/products/detail/adafruit-industries-llc/1231/4990764?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax+Shopping_Product_Low+ROAS+Categories&utm_term=&utm_content=&utm_id=go_cmp-20243063506_adg-_ad-__dev-c_ext-_prd-4990764_sig-Cj0KCQjwr9m3BhDHARIsANut04bPGPY5jbZcj8F7XtWGCQXBoB-frsDbSqwsqubekB6EU4K-cDJH8w8aAmDOEALw_wcB&g

ad_source=1&gclid=Cj0KCQjwr9m3BhDHARIsANut04bPGPY5jbZcj8F7XtWGCQXBoB-frsDbSqwsqubekB6EU4K-cDJH8w8aAmDOEALw_wcB (accessed Oct. 8, 2024).

[10] "ADXL345," ADXL345 Datasheet and Product Info | Analog Devices, https://www.analog.com/en/products/adxl345.html (accessed Oct. 8, 2024).

[11] "Amt132s-V," DigiKey Electronics, https://www.digikey.com/en/products/detail/same-sky/AMT132S-V/10269185 (accessed Oct. 8, 2024).

[12] "DRV5013ADQLPGM," DigiKey Electronics, https://www.digikey.com/en/products/detail/texas-instruments/DRV5013ADQLPGM/5181338?utm_adgroup=Texas+Instruments&utm_source=google&utm_medium=cpc&utm_campaign=PMax+Shopping_Supplier_Texas+Instruments&utm_term=&utm_content=Texas+Instruments&utm_id=go_cmp-17816159938_adg-_ad-__dev-c_ext-_prd-5181338_sig-Cj0KCQjwxsm3BhDrARIsAMtVz6PD_HDO_P0oGmSIo3DPesBpY68lwtmjRtrsTzsAPZ9u8hhuheGPcUUaAhr5EALw_wcB&gad_source=1&gclid=Cj0KCQjwxsm3BhDrARIsAMtVz6PD_HDO_P0oGmSIo3DPesBpY68lwtmjRtrsTzsAPZ9u8hhuheGPcUUaAhr5EALw_wcB (accessed Oct. 8, 2024).

[13] M. #905039 et al., "Load Sensor - 50kg (generic)," SEN-10245 - SparkFun Electronics, https://www.sparkfun.com/products/10245 (accessed Oct. 3, 2024)

Appendix

A. Product Design Specifications

Function

In the rehabilitation process of acute strokes or similar conditions, it is necessary for the patient to be able to walk well enough before returning home to ensure their safety. The client, Mr. Dan Kutschera, is a physical therapist that evaluates patients that come from an acute stroke clinic. He requests a device that will improve his evaluation process of the patients and is able to work in conjunction with a standard clinical walker. In order for the physical therapist to evaluate the patients' ability to walk, they must obtain various forms of data; such as the speed the patient goes, the distance they are able to travel, and the pressure applied to the walker from the patient. All of these sensors will be housed and powered on the walker, and after the metrics are taken, they will be displayed to a screen on the walker. The Smart Walker would enhance the ability of our client to evaluate the rehabilitation process of his patients.

Client requirements

- The device will be designed to enhance a standard physical therapy walker so it can be used in a clinical setting for the client
- The Smart Walker must be durable enough to withstand daily usage, year round with minimal maintenance.
- The device must be manufactured within the budget of $300, what will be purchased with this budget is a walker, electrical components, and other housing components.
- A display module attached to the walker will display measured data from the enhancements to the walker. Such data will be the pressure applied to the walker, the speed of the walker, and the distance traveled.
- An initiation and termination button for the walker will be implemented so the device is only measured during the trial period.
- All measurements will be in customary units so the patients have a better understanding of their performance.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**

The Smart Walker would be required to perform within distances of 10 meters and for time periods within 30 minutes. The Smart Walker would be an enhanced clinical walker and it will retain its standard functions of supporting the weight of the user, no more than 140 kg [1], whilst the user walks across the room. The enhanced performance of the walker will allow it to measure and display the pressure applied to the walker, the speed of the walker, and the distance traveled. The added enhancements of the walker should not make using it more difficult, such as not impeding the walking motion of the user nor adding additional weight to the walker.

b. **Safety**

Safety is a high priority concern for the Smart Walker, given that it is going to be used by patients who are in rehabilitation after an acute stroke, or acute stroke adjacent event. The Smart Walker should follow standard OSHA guidelines regarding clinical services in physical therapy. The Smart Walker should not be used near water and must have both the equipment and electrical components maintained properly to avoid mechanical failure or electrical exposure [2]. The physical therapist should also be properly trained to both handle the device and guide a patient through the use of it.

c. **Accuracy and Reliability**

The Smart Walker would need to measure values within an accuracy of 10% the true value. It would also need to be very reliable and vary from its measured value within 5%. These metrics of accuracy and reliability will need to be true for distances within 10 meters and for time periods within 30 minutes.

d. **Life in Service**

The Smart Walker will be required to be used every day in the lab for no more than 10 patients a day and for no more than 5 trials per patient. Each trial will take no longer than 30 minutes at a time. The Smart Walker should operate for 10 years without maintenance.

e. **Shelf Life**

In storage the Smart Walker should be kept in dry, room temperature conditions (16-26 deg C). The device should be folded while in storage to minimize the space it occupies and reduce the risk of unexpected forces. When lifted while in a folded state the walker should not unexpectedly unfold [3] . The alkaline batteries used for the Smart Walker have a shelf life of approximately 10 years while the Arduino should last much longer [4]. Given the shelf life of the individual parts the device should last about 10 years in storage before requiring replacement parts.

f. **Operating Environment**

The walker will be used in a neurorehabilitation center with a 16-26 °C ambient temperature and relatively flat surfaces. It should not be used outdoors and therefore should not be exposed to unexpected environmental conditions or loading conditions. The walker will need to be sanitized between users and therefore should be able to withstand repeated exposure to alkaline cleaning products. The Smart Walker will often be subjected to uneven force distribution and should be able to maintain stability despite up to 10 kgs pressure difference. The walker should also hold up to 140 kgs pressure for periods of up to 30 minutes [1]. Finally when engaged, the brakes on the walker should be able to withstand pushing forces of up to 6 kgs and pulling forces up to 4 kgs [3].

g. **Ergonomics**

The walker should have an adjustable height of 0.8 m to 1.1 m to accommodate a wide range of user heights. The width should be within 0.64 m and 0.74 m to accommodate users while still allowing room within doorways and hallways. The walker should withstand braking forces of 4-6 kgs and an applied weight of 140 kgs [3]. The Smart Walker display should only show speed and pressure measurements after recorded trials to avoid distracting users interacting with the device.

h. **Size**

The smart walker should have a maximum height of 1.1 m that can be lowered to 0.8 m depending on the user. It's maximum width should be 0.74 m to avoid taking up too much space within hallways and to allow it to easily pass through doorways. Finally for portability, the walker should fold and weigh between 2-4 kgs.

i. **Weight**

The smart walker should be roughly between 4.5 and 9 kilograms. This is so that it is easy to move and the attachments added do not add an unreasonably heavy weight to the walker. This way when used in trials, the walker is realistic. This smart walker should be able to support no more than a 140 kg patient which is what a normal walker will be able to do [1].

j. **Materials**

A typical walker is made of aluminum and the handles of vinyl. These are this way to be anti-perspirant and can withstand the pressures a patient exerts. There are certain materials that should not be used on the walker for health reasons and safety reasons. These include wood, cloth, leather, and other materials that can bring along more sanitization, maintenance, or safety issues. These do not want to be a worry for our client in a clinical setting.

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

The smart walker should look almost identical to a regular walker. This is so that it is not intimidating for the patient and they feel as though they are working with a walker that is not what they are used to seeing. The handles on the walker should be resistant to perspiration so that proper grip can be used at all times without a worry about the patient's grip being limited. Lastly, wires should be tucked away on the smart walker so that there are no wires dangling that the patient could get caught up on mentally or physically.

2. **Production Characteristics**
    a. **Quantity**

There should only be one Walker designed. The client has asked that there is only one walker to start and use in the clinical setting.

b. **Target Product Cost**

The target cost is between $250-$350 dollars for one of the walkers. There are competing designs that are roughly $2500 at times which the client does not want to spend.

3. **Miscellaneous**
    a. **Standards and Specifications**

While the Food & Drug Administration (FDA) allows custom medical devices to be exempt from pre-market approval and other such requirements [5], the Smart Walker, because it is intended to be used with multiple different patients as opposed to one particular person, will still be subject to regular FDA standards. Similar electronic mobility devices have been classified as a Class II medical device, meaning that this device will most likely also be classified as such, thus requiring compliance with the FDA's quality system regulation, basic and medical performance standards [6], and also a 510(k) premarket notification. Most generally, hazards associated with device use must be identified and controlled as per ISO 14971

[x3], and while the Smart Walker won't be particularly harmful to the user, nor will it be a life-sustaining device, it remains important to understand any possible faults that could cause bodily harm, especially in regards to the batteries/power-supply. These safety concerns are expounded upon by IEC standards numbered 60601-1 and 62366-1, who deal specifically with medical instrumentation [7][8].

b. **Customer**

Mr. Kutschera outlined a few important preferences that he had for the Smart Walker that fit his vision for the most effective version of the device. First of all, he envisioned the device being implemented into/onto an existing 2-wheel walker because most of his patients use something similar. He also believes that having live feedback given to the patient during their walking test with the walker will help boost enthusiasm for the therapy session; as such, some sort of screen is required near the handles of the walker to display metrics about speed, distance, and force to the patient as they are using the device. That being said, he also explicitly stated that these values must be in imperial units because metric units don't mean much to people outside of STEM careers. Finally, any batteries or wires must be fully encased within the walker or their own housing parts, as loose wiring could make the device unwieldy and/or dangerous in some cases.

c. **Patient-related concerns**

Because the Smart Walker is meant to be used by a variety of patients throughout the day, proper sanitization measurements must be taken between uses of this device by different patients. Furthermore, the differing users of this device give rise to concern about its stability, adjustability, and weight outlined in the *ergonomics* and *size* sections (1g & 1h). Finally, the UI for the Smart Walker must be accessible to (usually elderly) acute stroke patients, meaning that tactile buttons would be preferred over a touchscreen interface, as there has been a similar robotic walker by Frontiers in Neurorobotics that experienced difficulty with such a UI [9].

d. **Competition**

There are a few similar devices to the Smart Walker that are either on the market or used for research, but none of them have the exact use-case that Mr. Kutschera desires, plus most of them are egregiously expensive. One such device is called the Camino, which integrates multiple sensors in the walker to detect changes in terrain and drive a motor accordingly to make walking easier for the user. Similar to the Smart Walker, it is also able to track its user's gait, but the Camino incorporates AI to filter through the input data in order to do so [10]. The aforementioned walker by Frontiers in Neurorobotics, while mostly used to prevent the elderly from falling, has a spongy handle that senses changes in air pressure when being compressed [11]. Patents for other proof-of-concept devices also exist online, as seen in patents US20220211568A1 and US7826983B2 that each outline some application of sensors on a walking device, but these devices most likely never made it to fruition [12][13]. That being said, there really doesn't exist a device that works perfectly for Mr. Kutschera's needs, but there are such devices that can help guide the Smart Walker in the right direction.

Citations

[1] “What is the maximum weight capacity for a medical walker?,” TheMedSupplyGuide.com - Medical Supply Company Directory, https://www.themedsupplyguide.com/weight/#:~:text=Most%20have%20the%20ability%20to,often%20manufactured%20using%20welded%20steel. (accessed Sep. 19, 2024).

[2] “ETool : Hospitals - clinical services - physical therapy,” Occupational Safety and Health Administration, https://www.osha.gov/etools/hospitals/clinical-services/physical-therapy/ (accessed Sep. 19, 2024).

[3] “ISO 11199-3:2005,” ISO, https://www.iso.org/standard/41191.html (accessed Sep. 19, 2024).

[4] “Battery Storage, Shelf Life, Self-Discharge, and Expiration.” Microbattery, www.microbattery.com/battery-storage-discharge-expiration. Accessed 22 Sept. 2023.

[5] “Custom Device Exemption - Guidance for Industry and Food and Drug Administration Staff”.

[6] T. Lysechko, “Which standards apply to your medical device?,” StarFish Medical. Accessed: Sep. 19, 2024. [Online]. Available: https://starfishmedical.com/blog/which-standards-apply-to-your-medical-device/

[7] “Recognized Consensus Standards: Medical Devices.” Accessed: Sep. 19, 2024. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=41349

[8] “Recognized Consensus Standards: Medical Devices.” Accessed: Sep. 19, 2024. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=44029

[9] “Recognized Consensus Standards: Medical Devices.” Accessed: Sep. 19, 2024. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=41235

[10] X. Zhao et al., “A Smart Robotic Walker With Intelligent Close-Proximity Interaction Capabilities for Elderly Mobility Safety,” Front. Neurorobot., vol. 14, Oct. 2020, doi: 10.3389/fnbot.2020.575889.

[11] “Meet Camino,” Camino Mobility. Accessed: Sep. 19, 2024. [Online]. Available: https://caminomobility.com/pages/meet-camino

[12] A. AlGhazi and A. Hejazi, “Mobility assistance apparatus,” US20220211568A1, Jul. 07, 2022 Accessed: Sep. 19, 2024. [Online]. Available: https://patents.google.com/patent/US20220211568A1/en?q=(smart+walker)&oq=smart+walker

[13] M. Alwan, G. S. Wasson, P. N. Sheth, A. Ledoux, and C. Huang, “Instrumented mobility assistance device,” US7826983B2, Nov. 02, 2010 Accessed: Sep. 19, 2024. [Online]. Available: https://patents.google.com/patent/US7826983B2/en?q=(walker+sensor)&oq=walker+with+sensor

B. BPAG Expense Spreadsheet

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Electronics										
ADXL345	3-axis Accelerometer	Adafruit Industrie	1231	DigiKey	528-1015-ND	10/4/2024	1	$17.50	$17.50	DigiKey
DRV5013ADQLP(	Hall Effect Sensor	Texas Instrument	13ADQLPGM	DigiKey	-41077-1-ND	10/4/2024	1	$0.62	$0.62	DigiKey
SEN-10245	Load Cell	Sparkfun	SEN-10245	DigiKey	1568-1661-N	10/4/2024	4	$4.50	$18.00	Digikey
Raspberry Pi Pico	Microcontroller	Raspberry Pi	SC0915	DigiKey	2648-SC0915	10/4/2024	1	$4.00	$4.00	DigiKey
9049	Magnets	Radial Magnets	9049	DigiKey	469-1075-ND	10/4/2024	4	$0.82	$3.28	DigiKey
Housing Materials										
									$0.00	
									$0.00	
								TOTAL:	**$43.40**	

C. Functional Block Diagram