Smart Walker
Product Design Specification (PDS)

9/15/2023

Team Members:

Amara Monson - Co Leader
Nikhil Chandra - Co Leader
Joseph Koch - Communicator
Lance Johnson - BSAC
Baljinder Singh - BPAG
Jake Maisel - BWIG

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 1 m/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.

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(<3 m/s) the sensors will have to have a high precision of +- 0.1 meters(distance), +- 0.1 m/s(speed) and +-10 Pa(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 effectively

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 a year. 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 59°F 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 1.65m to 1.98m, 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. Any display on the walker should not distract the patient from keeping their focus safely ahead of them.

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 1.65m and 1.98m. 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:

The 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. If we intend on 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 customer prefers a smartphone display to show statistics such as speed, velocity, and distance that would then be uploaded to a server and formatted automatically to be accessed at any time. However this display should not be flashy, in which the patient is losing focus on the pathway. The alternative to each of these would be to use a digital electronic display and 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.

Citations:

[1] *Assistive Product Specification for Procurement*, World Health Organization, www.who.int/docs/default-source/assistive-technology-2/aps/mobility/aps22-walking-frames-oc-use.pdf?sfvrsn=49508707_2. Accessed 23 Sept. 2023.

[2] Marquis, Jeremiah. "How Long Do Mobility Scooters Last with Proper Care?" *Mobility Plus Colorado*, Mobility Plus Colorado, 20 Sept. 2023, www.mobilitypluscolorado.com/blog/how-long-do-mobility-scooters-last.

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

[4] gwn3000. "Arduino Circuit Lifespan?" *Arduino Forum*, 24 Jan. 2016, forum.arduino.cc/t/arduino-circuit-lifespan/360703/2.

[5] Using a Walker: Medlineplus Medical Encyclopedia." *MedlinePlus*, U.S. National Library of Medicine, medlineplus.gov/ency/patientinstructions/000342.htm. Accessed 22 Sept. 2023.

[6] "Walkers: Adult Walkers: Aluminum Walkers: Walkers Used after Surgery." *American Medical & Equipment Supply - Lift Chairs Recliners, Home Medical Supplies, Supports Canes and Crutches, Wound Care Supplies, Incontinence Supplies*, www.americanmedicalinc.com/store/p87/walkers.html. Accessed 22 Sept. 2023.

[7] *Medline Easy Care Two-Button Folding Walkers with 5" Wheels*, www.amazon.com/Medline-MDS86410W54BH-Two-Button-Folding-Walkers/dp/B013SBHHDK. Accessed 23 Sept. 2023.

[8] "IEC 60601-1-11:2015." *ISO*, 9 Sept. 2020, www.iso.org/standard/65529.html.

[9] (OCR), Office for Civil Rights. "Your Rights under HIPAA." *HHS.Gov*, 19 Jan. 2022, www.hhs.gov/hipaa/for-individuals/guidance-materials-for-consumers/index.html.

[10] Center for Devices and Radiological Health. "Medical Devices." *U.S. Food and Drug Administration*, FDA, www.fda.gov/medical-devices. Accessed 22 Sept. 2023.

[11] (OCR), Office for Civil Rights. "Privacy." *HHS.Gov*, 31 Mar. 2022, www.hhs.gov/hipaa/for-professionals/privacy/index.html#:~:text=The%20HIPAA%20Privacy%20Rule%20establishes,care%20providers%20that%20conduct%20certain.

[12] "Camino : The World's First Smart Walker." *Camino Mobility*, caminomobility.com/. Accessed 22 Sept. 2023.

[13] E. H. and D. F., "AmbuTrak digital/electronic distance tracker for Walkers & Rollators," Rehabmart.com, https://www.rehabmart.com/product/ambutrak-movement-tracker-for-rolling-walkers-47972.html (accessed Sep. 22, 2023).

[14] *Amazon.Com: Drive Medical 10210-1 2-Button Folding Walker with Wheels ...*, www.amazon.com/Drive-Medical-10210-1-Lightweight-Adjustable/dp/B001HOM4U2. Accessed 1 Oct. 2023.

[15] Straube, John. *BSD-138: Moisture and Materials*, buildingscience.com/documents/digests/bsd-138-moisture-and-materials. Accessed 30 Sept. 2023.