 doi:10.20944/preprints202110.0316.v1

Article

Engineering a Clinical Force Measuring Walker for Patients Recovering from Median Sternotomy

Ansel LaPier

Physical Therapy Department, Eastern Washington University, Spokane, Washington, USA
* Correspondence: Lapierlab233@gmail.com

Abstract: Patients often need the use of their arms to assist with functional activities, but after bone disruption, pushing is frequently limited to <10 lb (4.5 kg). No method exists to measure arm weight bearing objectively in clinical settings. This project aimed to design, construct, and test a walker for patients who need to limit arm force to prevent excessive bone stress during post-fracture (iatrogenic or traumatic) ossification. First, a qualitative study was conducted to obtain critiques of a Clinical Force Measuring (CFM) walker prototype from rehabilitation professionals. Key statements and phrases were coded that allowed "themes" to emerge from transcribed interviews, which guided device revisions. Next, a second CFM Walker prototype was designed based on the qualitative data and device criteria/constraints and finally tested. The result was fabrication of a new lightweight, streamlined, and cost-effective prototype walker with a simple visual display and auditory cue with upper limit alarms. Key features included attachments for medical equipment and thin film force-sensing resistors integrated into the walker handles that progressively activated 3 LEDs and a buzzer when UEWB force exceeded programmed thresholds. The innovative CFM Walker will help patients with restricted UEWB, especially elderly adults, recover safer and faster in the future.

Keywords: Bone fracture, Median sternotomy, Ossification, Rehabilitation, Functional mobility, Assistive device, Feedback training, Sternal precautions, Instrumented walker

1. Introduction

Patients recovering from bone disruption due to trauma or surgery need to limit use of their upper extremities during bone healing often to < 10 lb (4.5 kg) of pushing, pulling, or lifting [1-3]. This restriction is thought to minimize shear force and movement between the bone halves to protect callus formation and osteogenesis [1-5]. Common patient diagnoses that require post-fracture (iatrogenic or traumatic) bone ossification include cardiac surgery via median sternotomy, total shoulder arthroplasty, and upper extremity bone fractures [1-3,5]. For example, median sternotomy is commonly performed to access the heart during a variety of different surgeries such as coronary artery bypass, heart valve replacement, heart transplantation, and thoracic trauma repairs. The procedure entails sawing longitudinally from the sternal notch to the xiphoid process, separating the sternum with retractors, and wiring the sternal halves together after surgery completion [6,7]. Complications can occur when the bone halves do not heal correctly, including deep wound infection (osteomyelitis), bony nonunion/instability, and or bone dehiscence [1-4].

Restricting arm use often limits patient functional independence, contributing to longer hospital stays and greater need for care after hospitalization. It is difficult to function independently when upper body daily activities are limited, especially for older adults. Restricting arm use is particularly problematic for patients who need assistance sitting down or standing up from a chair and or need to use a walker for ambulation. Loss of functional independence can contribute to a greater need for assistance and rehabilitation after hospital discharge [8-11]. Therefore, appropriate arm use is essential for timely return to function.

Little is known about how much upper extremity weight bearing (UEWB) force occurs when older patients attempt to use < 10 lb; therefore, their ability to safely resume

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

activity and use of a walker is unknown [12-14]. Adams et al. found that force when using a single arm to assist with standing up from a bench was 27.5 lb (12.5 kg) [15]. Similarly, Swanson et al. found UEWB while moving from side lying to sitting in a bed was 22.2 lb (10.1 kg) [16]. Previously, we have shown that self-selected arm force when instructed to use less than 10 lb (4.5 kg) was 11.7-19.0 lb (5.3-8.6 kg) during ambulation with an assistive device and sit-stand transfers in a young (18-40 years old) cohort and that subjects used more than 12 lb (5.5 kg) of arm force during most trials (67%) [12]. This study also employed a feedback training protocol and demonstrated its efficacy for improving subjects' ability to modulate UEWB. We have also corroborated these findings in a cohort of older subjects (60-85 years) and identified metrics predictive of excessive UEWB during functional tasks, including handgrip strength, static and dynamic balance, health status, and body mass index [13,14]. Other researchers have found that patients are not good at limiting leg weight bearing and can improve accuracy with feedback training [17-19].

Therefore, a method to objectively measure UEWB while patients use a walker is needed. Currently, there are no walkers for use with patients to provide UEWB feedback. The device previously fabricated using handgrip dynamometers to measure UEWB was only appropriate for research purposes because it was bulky, had remote force displays, and was expensive. Other researchers have used bathroom scales, force plates/pressure sensing mats, or foot pressure sensors to measure extremity weight bearing [17-21]. Existing walkers instrumented to measure UEWB are only appropriate for research applications and have many limitations that preclude their use with patients in clinical settings, including they: 1) have complicated force displays positioned remotely from the walker [12-14,22], 2) use sensors placed in the walker's legs, not the handles [22-24], 3) do not display data for the patient and therefore cannot be used for feedback training [24,25], 4) are bulky, expensive, and not built on a clinical walker frame [26].

The ultimate goal or this project was to design and construct an instrumented walker for rehabilitation professionals to utilize with patients who need to restrict UEWB to safely perform functional mobility tasks using < 10 lb. We know from previous work that UEWB and pectoralis major muscle electromyography during functional mobility are greater in younger versus older subjects and improve (decrease) following feedback training [12-14]. This preliminary research established proof-of-concept, the need for an instrumented walker, and the efficacy of its use with feedback training. The purpose of the first part of this project (PART 1) was to systematically obtain qualitative critiques from hospital rehabilitation professionals regarding an initial Clinical Force Measuring (CFM) walker prototype (v1.0) to allow revisions and refinement of the mechanical device and user interface. The engineering goal for the second part (PART 2) of this project was to use the infomation obtained in PART 1 to design and construct a second CFM Walker prototype (v2.0)

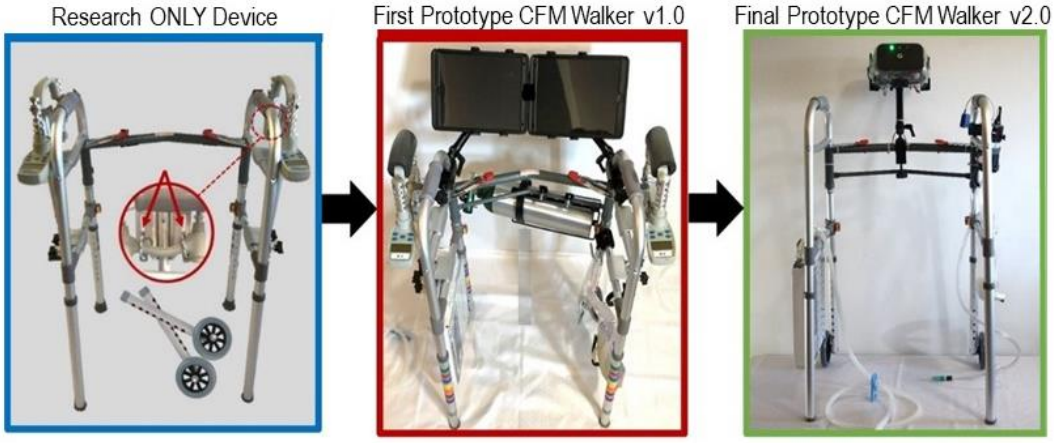


Figure 1. Evolution of the Clinical Force Measuring (CFM) Walker.

and to test its ability to meet essential criteria and constraints. The evolution of the CFM

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Walker v2.0 is illustrated in **Figure 1**, beginning with the laboratory instrumentation and then 2 CFM Walker prototypes.

2. Materials and Methods

2.1 Qualitative Research Study (Part 1)

First, a prototype was fabricated using biomedical device engineering and critical care equipment principles [27,28]. The CFM Walker v1.0 (see **Figure 2**) retained the externally mounted force transducers wirelessly connected to tablets. The tablets were housed in waterproof cases that could be disinfected and mounted directly to the walker with multi-planar adjustable mounting arms. A plate was attached below the left lateral support to suspend a chest tube reservoir tank with placement below the tube exit site to maintain gravity assist drainage of pleural secretions. Chest tubes exit the left lower chest wall after cardiac surgery and must have a water seal to maintain negative pressure within the pleural space. Walker legs were color-coded to facilitate adjustment for multiple patient use and included interchangeable front standard and 5" single plane wheeled legs. A portable oxygen tank mounting bracket was positioned on the lower front horizontal walker support and centered for optimal walker stability and symmetrical drag when using a front wheeled walker configuration. Ergonomic soft handle grips were added to improve patient ability to grip and patient comfort. A hook that rotated 90 degrees to suspend a urinary collection bag was mounted below the right lower lateral support to facilitate gravity assist drainage. The swivel hook allowed a urinary collection bag with a parallel or perpendicular oriented hook to hang parallel from the walker to keep it from obstructing a patient's gait. In addition, an S-shaped hook was attached directly to the right lower lateral support to tether a Foley Catheter (aka urinary catheter) in front of the patient's leg, so the tubing would not obstruct gait.

Figure 2. Clinical Force Measuring Walker v1.0 components: 1) Chest tube reservoir plate, 2) Color coded walker legs, 3) Oxygen tank mounting bracket, 4) Ergonomic soft handle grips, 5) Tablet adjustable mounting arms & waterproof cases, 6) Urinary collection bag swivel hook, 7) Foley Catheter S-hook.

This part of the study used a qualitative description methodology (phenomenology). Qualitative inquiry is appropriate when seeking to describe a topic in depth through insights from participants [29,30]. By using an interview process, participants' perspectives were explored using open and probing questions. A purposeful sampling strategy was employed to achieve sufficient variability and understanding of the concepts.

Study participants were rehabilitation professionals with experience working in critical care and or with post-surgical patients. Criteria for selection of subjects included: 1)

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

between the ages of 25-60 years, 2) rehabilitation professional (physical therapist, registered nurse, exercise physiologist, etc.), and 3) minimum of 6 months working in a hospital with critical care patients. This study was approved by the Eastern Washington University Institutional Review Board for Human Subjects (Protocol #HS-5953), and all subjects signed an informed consent prior to participation.

Data collection involved asking the study participants a number of open-ended questions to garner feedback on the instrumented walker prototype. Subject interviews were conducted via Zoom virtual meeting application to adhere with COVID-19 social distancing guidelines. The slides with component photographs and specific questions used during interviews are included in **Appendix 1**. The interviews were video-recorded so that the answers and comments could be transcribed for data analysis. The subject interviews began with an introduction and narrated video clips of the walker prototype from multiple angles. The interview questions were sequentially shown on a slide with close-up photographs of the specific walker parts/features from different angles.

Data analysis involved reviewing the transcribed interviews and identifying key statements and phrases that were significant within each category. Statements then were sorted into groups of similar statements that emerged as meaningful units or ''themes.'' Rich descriptions of participant perceptions corresponding with each theme were generated using their exact words and phrases. An iterative process of data analysis was used until saturation was achieved within each theme. Qualitative data were analyzed and triangulated before themes were named.

2.2 Engineering Design and Testing (Part 2)

Figure 3 shows the flow of steps used to design the final CFM walker prototype. Using data from the qualitative study and device testing, extensive revisions were made to the first walker prototype. The essential features that the CFM Walker needed to have were defined based on engineering design criteria and constraints, qualitative data, and published information [27,28]. Next, testing procedures for each of the essential design elements were developed. **Table 1** outlines the design elements, criteria, constraints, and testing protocols used to test both CFM Walker prototypes.

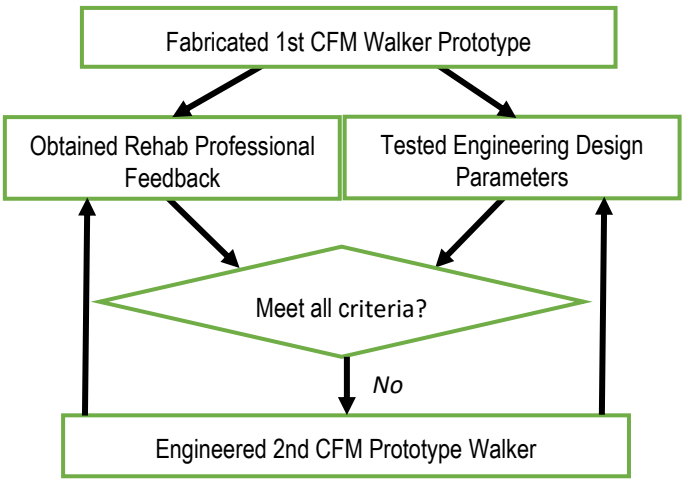


Figure 3. Engineering process flowchart.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Table 1. Engineering Design Elements, Criteria, Constraints, and Testing Plane

Design Elements	Criteria / Constraints	Design Testing Plan *3 Trials
Vertical force measuring capability	Measurement accuracy ≥ 90% in 1-20 lb (0.5-9.1 kg) range	Obtain readings using push dynamometer[1] on each handle within correct range: Green <7 lb, yellow 7-10 lb, red > 10 lb (30 trials)
Ergonomic handles	Handle diameter 3-6 cm	*Measure circumference of handles using tape with 1 mm increments and calculate diameter
Simple visual & auditory feedback with alarms	Display readable and buzzer audible from 1 m with upper limit alarm	*Measure distance in 50 cm increments up to 3 m that subjects ages 18-83 year old (n = 6) can: 1) see visual display screen and 2) hear auditory signal output.
Streamlined, stable, & maneuverable frame	Width < 66 cm Depth < 63 cm	*Measure using a caliper device and tape measure with 1 mm increments
Lightweight construction	Total weight < 6 kg	*Weigh walker with & without attachments using scientific scale[2]
Minimal drag	Horizontal push-pull resistance < 2 kg on solid surface	Measure horizontal resistance using a push-pull force dynamometer[1] over 155 cm with 4 front wheel types[3] (10 trials each)
Adjustable height handles	Appropriate for patients 1.6-1.8 m tall	*Measure top of handle height using a caliper device and tape measure with 1 mm increments
Ability to disinfect	All components nonporous; Electrical components covered / water resistant	Create checklist of component materials to categorize as nonporous vs porous; Assess functionality after spraying 100 cc of water
Affordable cost	Total cost of all components (parts and materials) < $500	Keep a detailed itemized list of all components and material costs

[1]*Mark-10 CG High capacity digital force gauge, 1,000 lb tensile or compressive force (Mark-10 Corporation, Copiague, NY)*
[2]*CAS SW-50 SW-1W Series Washdown Portion Control Bench Scale, 50 lb Capacity, 0.01 lb Readability (CAS Corporation, East Rutherford, NJ)*
[3]*Walker Wheels Swivel 5", Universal 3" (Drive Medical, Post Washington, NY), Lumex Swivel 3" (Graham Field, Atlanta, GA)*

3. Results

3.1 Qualitative Research Study (Part 1)

A detailed parts list of the components used to fabricate the CFM Walker v1.0 is included in **Appendix 2**. The total cost for the components of this prototype was $1,423. The bulk of this cost was for the force transducers and tablet displays. The total cost did not include the actual medical devices (portable oxygen tank, chest tube, chest tube reservoir, urinary collection bag, and Foley / urinary catheter).

Table 2 outlines the main themes for each walker components that emerged with data analysis. There were 5 overarching ideas that developed at the completion of data analysis.

1) The subjects (rehabilitation professionals) overwhelmingly expressed that a force measuring walker would be very useful with a variety of patients, particularly those recovering from open heart surgery.
2) Integrating the force measuring mechanism into the walker handles / structure would be optimal for arm biomechanics and the width of the device (to be maneuverable in narrow spaces).
3) Simplifying the force output display and adding upper limit visual and auditory alarms would be easier for patients and rehabilitation professionals to know when UEWB exceeds 10 lb.
4) The optimal leg combination was unanimously front 5" single plane wheels and back standard legs.
5) Subjects also identified revisions to improve the medical equipment attachments for the oxygen tank, Foley Catheter, and oximeter.

Direct quotes were extracted from the transcribed data to provide rich descriptions of the subjects' perceptions corresponding with each theme. A few examples for each walker component are provided here.

Chest Tube & Reservoir

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

- *I think it would protect it better than I do when I walk with them [hung on side or front walker bar].*
- *I like that the location is low so it shouldn't impede drainage.*

Walker Legs

- *I actually prefer that size of wheel [5" planar] vs the smaller circumference…swivel wheels just add another plane of movement [so not ideal].*
- *We are familiar with the button [mechanism to change height]. So, you don't need to [change it].*

Oxygen Tank

- *I don't know that you necessarily need the oxygen tank attached.*
- *…it's attached to other equipment like IV poles that I'm already taking with me.*

Force Transducers

- *It might be confusing for patients who are reaching up to grab the walker to have 2 sets of handles.*
- *So as it is right now, it might be difficult to fit say in and out of the bathroom doorway…*

Display Screen Mounts

- *…would be in the way as far as patients being able to see where they're going or looking for obstacles.*
- *[I] like that they have a lot of degrees of freedom.*

Display Interface

- *…having the screen flash if you went over the set amount would be really beneficial for that feedback.*
- *[Good] to have such an annoying buzzer just when they've gone over their mark- because they're pretty good at hearing annoying things.*

Urinary Collection Catheter and Bag

- *I think it would protect it better than I do when I walk with them.*
- *I like the hook because it can't slide.*
- *Looks fabulous!*

Overall Opinion

- *I would love to see the next generation of- when you upgrade this walker. This is already innovative. Very practical, but it's just a bit busy. -this is the right way to go forward. Advancing in terms of how we improve our patients' gait.*
- *I like the ability to measure force that the patients are using in their arms…I've never seen that before... and to have some built-in attachments.*
- *...it's beneficial across a broad range of patients.*
- *…you could tell how much of their body weight they were putting through their legs versus their arms. So, you know how much they were relying on the walker to assist with ambulation.*

3.2 Engineering Design and Testing (Part 2)

The components of the CFM Walker v2.0 are shown in **Figure 4.** Thin-film force resistors (1.8 x 1.8 cm) were placed under the original walker handgrips (**Figure 5.A**). Khodadadi et al found that force transducers incorporated into walker handles had easier installation and less error than those installed on circular vertical walker legs [25]. These were connected to the Arduino System with male-to-female breadboard jumper wires. A visual display with 3 different colored LEDs was designed to simplify the force feedback interface. The LEDs were triggered as follows: the green LED was always on, the yellow LED was activated when force was greater than or equal to 7 lb, and the red LED was activated when force was greater than or equal to 10 lb. An auditory alarm that triggered when force exceeds 10 lb was also included. The system was programmed to trigger the red LED and buzzer when the left or right force transducer measured greater than the

Table 2. Qualitative Data Themes for Each Walker Component

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Clinical Force Measuring Walker v1.0 Themes
Chest Tube & Reservoir • Good location - low for drainage, same location often used clinically • Tube adequately protected (not touching ground, kinked, tangled) • Essential features: no gait obstruction, protected adequately, user-friendly • May not work for all reservoir types (with different shapes, handles, hooks) • Improvements: higher or with adjustable height, block swinging inward
Walker Legs • Ideal combination: wheels only on front legs, commonly used clinically • Color-coding possibly helpful, not necessary (Healthcare professionals already familiar with this type of height adjustment mechanism) • Improvements: color-coding material needs to be nonporous for disinfecting, back leg “ski-type” gliders
Oxygen Tank • Not a good location – tendency to tip forward, cause asymmetrical drag • Essential features: no gait obstruction, protected adequately, user-friendly • Would not fit most common portable oxygen tanks used in hospitals • Improvements: remove bracket, transport tank separately / with other device (IV pole), better to have another person to assist with oxygen tank if needed
Force Transducers • Wider diameter grips better for patients • Transducer handles wider than normal - problematic for small patients, hard to fit through narrow spaces, change biomechanics of arm force • 2 sets of hand grips confusing for patients • Improvements: materials need to be nonporous for disinfecting, integrated transducers ideal to reduce width / weight and simplify build
Display Screen Mounts • Location Issues: possibly cause tipping forward, obstruct patient view while walking, hard for provider to see if patient is large • Essential features: good adjustability with multi-angle articulation and wireless connection, intuitive, easy to use • Improvements: single unit instead of 2, reduce weight and size
Display Interface • Good to have units in pounds for patient reference • Color-coded, graphical information helpful • Visual feedback display too complicated and small • Improvements: larger, simpler force output, upper limit signal warning lights (flashing lights, color LEDs) and auditory signal (buzzer)
Urinary Collection Catheter & Bag • Good location - low for drainage, same location often used clinically • Catheter adequately protected (not touching ground, kinked, tangled) • Essential features: no gait obstruction, protected adequately, user-friendly • Improvements- block swinging inward, remove hook for catheter
Overall Opinion • Force measuring walker with integrated handles clinically useful • Streamline attachments to reduce total weight and surface area • Some attachments helpful; remove oxygen tank, add oximeter • Simplify visual display and add auditory warning signal • Useful for a variety of patient populations (median sternotomy, arm fracture / surgery, critically ill…)

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

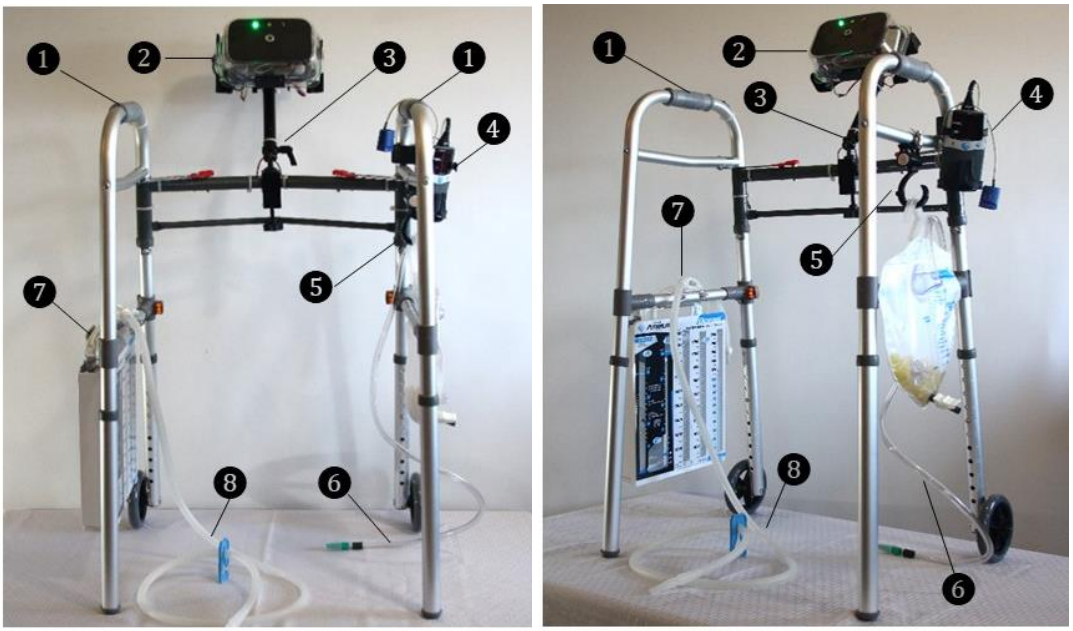


Figure 4. Clinical Force Measuring Walker v2.0 Components. 1) Integrated force Transducers, 2) Force output electronic components, 3) Mounting bracket, 4) Oximeter attachment, 5) Urinary collection bag attachment, 6) Foley Catheter, 7) Chest tube reservoir attachment, 8) Chest tube.

RIGHT	LED	LEFT	LED
1.0	G	2.0	G
1.2	G	2.2	G
1.6	G	2.6	G
2.0	G	3.2	G
2.2	G	4.0	G
2.4	G	4.4	G
3.0	G	4.6	G
3.4	G	5.0	G
3.6	G	5.0	G
4.2	G	5.6	G
4.4	G	6.2	G
4.8	G	7.0	G
5.0	G	**7.2**	**G**
5.8	G	7.6	Y
5.8	G	7.8	Y
6.2	G	8.4	Y
6.4	G	8.4	Y
7.0	**Y**	8.6	Y
8.0	Y	8.8	Y
9.2	Y	9.2	Y
9.2	Y	**9.6**	**R**
9.8	**R**	**9.8**	**R**
10.0	**Y**	10.4	R
10.6	R	10.8	R
11.6	R	12.4	R
11.8	R	14.0	R
13.2	R	15.6	R
15.4	R	16.2	R
17.4	R	17.6	R
23.8	R	20.0	R
Error%	**10.3%**		**10.3%**

Figure 6. Force accuracy testing results. G=green, Y=yellow , R=red, **Error**

preset 10 lb of force. The thin-film force resistors were calibrated with a force dynamometer in a 1-20 lb range. Force accuracy data are presented in **Figure 6**. An external power source was added to the system, and **Figure 5.C** illustrates the electrical schematic of the feedback system. The electrical components were housed in a clear acrylic waterproof case with exit holes for the 3 LEDs, speaker, and cord to the power source **(Figure 5.E).** The electrical component housing and external power source were positioned on the front of the walker using a multi-planar clamp mount. This position allows the patient and healthcare professional to see the LEDs but does not obstruct their view when walking forward.

A bracket was fabricated to hold a standard handheld oximeter and was clamped to the right upper vertical walker support. This position allowed a healthcare provider to maintain line-of-sight for continuous oxygen saturation and heart rate monitoring. In this position, the oximeter probe could remain attached to the patient's finger while using the walker. The oximeter holder can also be placed on the left side or other horizontal or vertical walker support. The bracket was designed to make the digital display visible and allow easy oximeter placement and access to the power switch **(Figure 5.D)**. A swivel hook was mounted to the upper right horizontal support using a metal hose clamp to suspend a urinary collection bag **(Figure 5.b)**. A 90 degree swivel hook was used so urinary collection bags with a parallel or perpendicular suspension hook could be attached to the walker and maintain bag orientation in the same plane as the right walker support frame. By moving this swivel hook to a higher location, the S-hook to tether the Foley Catheter was no longer needed. This higher attachment location ensured that the urinary collection bag

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

would not drag on the floor; it also could not swing inward, hitting the patient's foot because the lower right horizontal support blocked this motion. Even with this higher location, the urinary collection bag was still lower than the level of the bladder to maintain gravity assist drainage. The swivel hook was initially mounted using a Velcro strap, and replacing it with a hose clamp removed a porous component that would be difficult to disinfect.

A bracket to suspend the chest tube reservoir from the outside of the lower left horizontal walker support was fabricated **(Figure 5.F)**. The bracket was 7.7 cm wide to keep

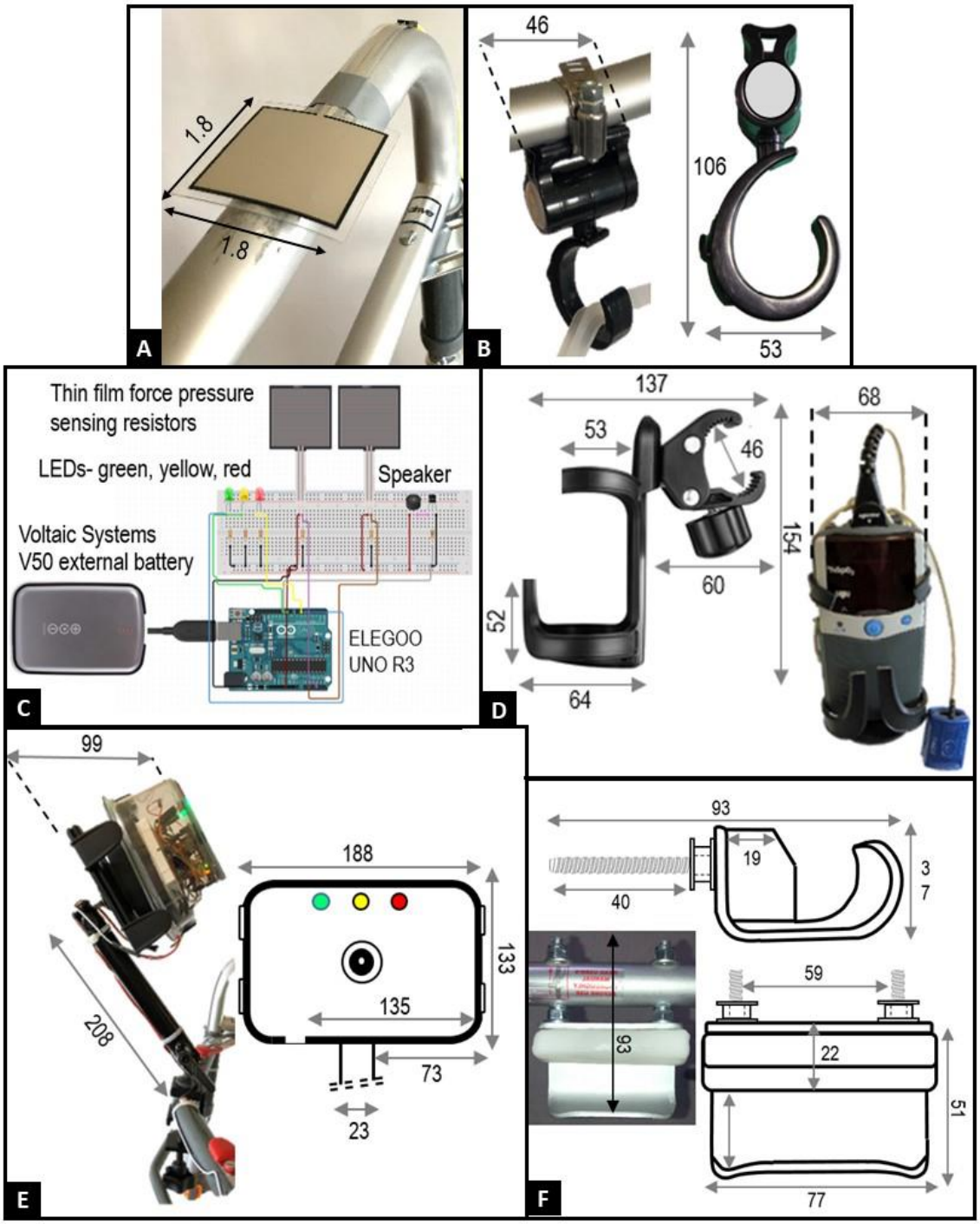


Figure 5. Components of the Clinical Force Measuring Walker v2.0. A) Thin film force resistors, B) Urinary collection bag hook, C) Arduino circuit components, E) Feedback console components, D) Oximeter holder, and F) Chest tube reservoir bracket. *All measurements in mm.*

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

the chest tube reservoir parallel to the walker side support and prevent front-to-back movement, which is important to preserve the water seal required to maintain negative pleural pressure and lung inflation. The bracket was 5.1 cm deep with a wedge-shaped spacer, so the chest tube reservoir handle would slide into the bracket and then be cradled tightly to prevent side-to-side movement. The CFM Walker v1.0 had a bracket mounted below the left lower horizontal support, which positioned the chest tube reservoir very close to the floor and front walker wheel. The new position not only moved the reservoir higher but to the outside rather than below it so any side-to-side movement would no longer interfere with a patient's gait.

Lastly, the walker's legs were modified slightly based on the qualitative data and engineering testing. The color-coding was removed because the rehabilitation professionals said it was not necessary (they are used to changing walker heights), and the tape was somewhat porous, so there were concerns about adequately disinfecting it. The study participants overwhelmingly preferred 5" single-plane wheels on the front with regular legs on the back of the walker. They stated that this configuration is what they use in clinical settings and prescribe for patients' home assistive devices. Walker drag was tested (**Table 3**) using 4 types of front wheels (5" single-plane, 5" swivel, 3" single-plane, and 3" swivel). Results showed that with 5" single-plane front wheels walker horizontal push-pull resistance was significantly less than with the other wheels both with and without medical equipment attached on smooth, solid surface flooring (similar to that found in a hospital). Three types of "ski-like" gliders on the back walker legs were tested with the 5" single-plane wheels, and results suggested that none significantly reduced walker drag and in many cases increased it.

Table 3. Horizontal Push-Pull Resistance for 4 Different Front Wheel Types. $P < 0.05$

	5" Planar Wheels		5" Swivel Wheels		3" Planar Wheels		3" Swivel Wheels	
Trial #	**Push**	**Pull**	**Push**	**Pull**	**Push**	**Pull**	**Push**	**Pull**
1	0.7	1.3	0.6	1.0	0.8	2.4	0.9	2.1
2	0.7	0.8	0.8	1.6	0.7	1.8	1.0	1.8
3	0.8	1.0	0.6	1.4	0.9	2.4	0.9	2.6
4	0.7	0.9	0.6	1.7	0.8	1.7	1.1	2.7
5	0.8	1.1	0.9	1.6	0.8	1.8	1.1	2.5
6	0.8	1.4	0.7	1.4	0.8	2.2	0.9	2.2
7	0.8	1.5	0.8	1.2	0.8	2.3	0.8	2.2
8	0.8	1.1	0.7	1.8	0.8	2.5	1.1	2.2
9	0.7	1.2	0.9	1.2	0.8	2.0	0.9	2.3
10	0.8	1.2	0.8	1.4	0.8	2.0	1.1	2.1
Mean	**0.76**	**1.15**	**0.74**	**1.43***	**0.80**	**2.11*†**	**0.98**	**2.27*†**
SD	*0.05*	*0.22*	*0.12*	*0.25*	*0.05*	*0.29*	*0.11*	*0.27*

**Significantly greater than push; †Significantly greater than 5" Wheel*

A detailed parts list of the components used to fabricate the CFM Walker v2.0 is included in **Appendix 2**. The total cost for the components of this prototype was $238. The total cost did not include the actual medical devices (portable oxygen tank, chest tube, chest tube reservoir, urinary collection bag, and Foley / urinary catheter). By removing the externally mounted force transducers and creating a simple force feedback interface using an Arduino system, the cost ($1,171 savings) and weight (4.5 kg reduction) of the CFM Walker v2.0 were substantially reduced. The CFM Walker v2.0 met all criteria/constraints, and the testing results are shown in **Table 4**. In addition, technical diagrams of the CFM Walker v2.0 are shown in **Appendix 3.**

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Table 6. Summary of Engineering Testing Results.

Design Elements	Criteria / Constraints	Testing Results
Vertical force measuring capability	Force accuracy ≥ 90% → MET	Force error rate = 10.3%
Ergonomic handles	Handle diameter 3-6 cm → MET	Handle diameter = 3.5 cm
Simple visual & auditory feedback with alarms	Visual & auditory alarms > 1 m distance → MET	1) Visual display > 3 m 2) Auditory signal > 3 m
Streamlined, stable, & maneuverable frame	Frame < 66 cm wide x < 63 deep → MET	Width = 63.0 cm Depth = 50.2 cm
Lightweight construction	Total weight < 6 kg → MET	Without medical equipment = 3.9 kg With medical equipment = 5.6 kg
Minimal drag	Horizontal push-pull resistance < 2 kg → MET	Without medical equipment = push 0.5 kg & pull 0.9 kg; With medical equipment = push 0.8 kg & pull 1.2 kg
Adjustable height handles	Handle Height for patients 1.6-1.8 m tall → MET	Shortest to tallest patient height = 1.49-1.95 m
Ability to disinfect	Components nonporous & water resistant → MET	1) Nonporous→ Yes 2) Water resistant→ Yes
Affordable cost	Cost < $500 → MET	Cost = $238.49

4. Discussion

The interview data obtained supported the overall clinical need for an assistive device with the ability to provide feedback regarding UEWB. This information was used to guide revisions of the CFM Walker v1.0 and engineering of the CFM Walker v2.0. Several specific alterations were made to the second walker prototype based on the qualitative data. Getting rid of the externally mounted force transducers and finding a force measuring mechanism that would be integrated and streamlined was a top priority. It was also necessary to design a force output display that was much simpler for patients to interpret and that had upper limit visual and auditory signals. Revisions to the medical equipment included removing the oxygen tank bracket and Foley Catheter S-hook. The only addition suggested was an attachment to hold a pulse oximeter. For the device to be easily disinfected, all components needed to be nonporous and water-resistant, so replacing some materials was needed.

Finally, follow-up qualitative interviews were conducted with the rehabilitation professionals. The CFM Walker v2.0 was taken to the study participants so they were able to use the walker and test the force measuring system and medical equipment attachments. They were provided a brief overview of the CFM Walker v1.0 revisions incorporated into the CFM Walker v2.0. Then they were asked these general questions –

What is your opinion of the:

- force transducers integrate into the walker handles?
- force feedback display and buzzer?
- electronic components housing and mounting arm?
- oximeter holder?
- urinary collection bag swivel hook?
- chest tube reservoir bracket?
- overall walker performance?

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

As described in PART 1, the interviews were again video recorded, transcribed, coded, and sorted into themes. The qualitative interviews were overwhelmingly positive, and the rehabilitation professionals indicated that the CFM Walker v2.0 could be used with hospitalized patients. They said the walker was lighter than expected. Study participants reaffirmed that a variety of patient populations could benefit from use of the CFM Walker v2.0. One study participant stated that an Intensive Care Unit telemetry monitor could be placed in the oximeter holder for patients using that technology in lieu of a handheld pulse oximeter. It was also noted that the oximeter holder could be mounted on the upper lateral walker supports, making it easier for tall rehabilitation professionals to see the display screen. Subjects recommended minor improvements to the electronic housing box and external power source to make it more streamlined.

5. Conclusions

In conclusion, previous research suggests that patients are not good at estimating arm force <10 lb and that feedback training is effective at reducing it [12-14,18,20,31]. Therefore using an instrumented walker and feedback training would be beneficial in clinical practice, especially with older patients. The qualitative data obtained from rehabilitation professionals (PART 1) indicated that a CFM walker with integrated handles would be clinically useful. Suggestions for the CFM Walker v1.0 led to modifications including, streamlining, modifying, removing, and adding components. Finally, engineering tests of the CFM Walker v2.0 demonstrated that it met essential criteria for making it feasible for patients who need to limit UEWB to prevent excessive bone stress during post-fracture ossification. **Table 5** compares the engineering features of each walker rendition. Ultimately the CFM Walker v2.0 could improve outcomes for patients recovering from heart surgery performed via median sternotomy and certain orthopedic conditions that are associated with upper body bone fracture (iatrogenic or traumatic) and subsequent osteogenesis.

Table 5. Comparison of Walker Versions' Design Criteria and Constraint Characteristics.

Design Elements	Research Device	CFM Walker v1.0	CFM Walker v2.0
Vertical force measuring capability	Accuracy = 82%	Accuracy = 82%	**Accuracy = 90%**
Ergonomic handles	Diameter = 2.2 cm	**Diameter = 5.2 cm**	**Diameter = 3.5 cm**
Simple visual & auditory feedback with alarms	Visual→ < 50 cm Auditory→ NONE	Visual→ < 50 cm Auditory→ NONE	**Visual display→ > 3 m** **Auditory signal→ > 3 m**
Streamlined, stable, & maneuverable frame	Width = 67.9 cm **Depth = 53.0 cm**	Width = 67.9 cm **Depth = 53.0 cm**	**Width = 63.0 cm** **Depth = 50.2 cm**
Lightweight construction	No MD = 7.2 kg	No MD = 8.4 kg With MD = 13.0 kg	**No MD = 3.9 kg** **With MD = 5.6 kg**
Minimal drag (Push-Pull)	No MD = 1.4 - 2.0 kg	No MD = 1.4 - 2.0 kg With MD = 1.4 - 2.0 kg	**No MD = 0.5 - 0.9 kg** **With MD = 0.8 - 1.2 kg**
Adjustable height handles	1.76 - 2.06 m	1.76 - 2.06 m	**1.49 - 1.95 m**
Ability to disinfect	**Nonporous→ Yes** **Water resistant→ Yes**	Nonporous→ No **Water resistant→ Yes**	**Nonporous→ Yes** **Water resistant→ Yes**
Affordable cost	$1,359	$1,409	**$238**

Bold *indicates the testing criteria set was met*

 doi:10.20944/preprints202110.0316.v1

Supplementary Materials: The following are available online at www.mdpi.com/xxx/s1, Figure S1: Slides of the First Force Measuring Walker Used During Qualitative Data Interviews; Table S1: Materials and Part List with Costs for the Clinical Force Measuring Walker v1.0 (A) and v2.0 (B).

Author Contributions: Conceptualization, A.L.; methodology, A.L.; software, A.L.; validation, A.L.; formal analysis, A.L.; investigation, A.L.; resources, A.L.; data curation, A.L.; writing—original draft preparation, A.L.; writing—review and editing, A.L.; project administration, A.L. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of Eastern Washington University (protocol code HS-5934 and November 17, 2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Transcripts and coding of the interview data can be obtained by request from the author.

Acknowledgments: Thanks to Dr. Kimberly Cleary for advice on obtaining and analyzing the qualitative data in this study.

Conflicts of Interest: The authors declare no conflict of interest.

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Appendix 1. Slides of the first Clinical Force Measuring Walker Used during Qualitative Data Interviews.

1) Chest Tube and Reservoir

a) What is your opinion of the location of the chest tube reservoir?
b) Would it obstruct the patient's gait pattern?
c) Would it adequately protect the device while a patient is ambulating?
d) Does the mounting device seem user-friendly? If not, what would you suggest?
e) Do you have any other comments or recommendations?



2) Walker Legs

a) What is your opinion of the walker legs?
b) Do you think that color coding the walker legs to facilitate adjustment for multiple patient use is helpful? Why or why not?
c) Would you recommend a different type of wheel for the walker?
d) What do you think is the optimal combination of walker legs: front wheeled and back standard, all wheeled, or all standard?
e) Would you recommend a different type of wheel for the walker?
f) Do you have any ideas on a different mechanism to be adjusted and or removed / replaced?



3) Oxygen Tank

a) What is your opinion of the location of the oxygen tank?
b) Would it obstruct the patient's gait pattern?
c) Would it alter weight distribution too drastically?
d) Does the mounting device seem user-friendly? If not, what would you suggest?
e) Do you have any other comments or recommendations?


4) Force Transducer Handgrips

a) What is your opinion of the force transducer handgrips?
b) Are they ergonomically friendly for the user?
c) Should they be integrated into the horizontal supports of the walker?
d) Do you anticipate any problems that a patient using the walker may have regarding the handgrips?
e) Do you have any other comments or recommendations?




5.1) Tablet Screen

a) What is your opinion of the location of the tablets / screens?
b) Would the healthcare professional and patient be able to adequately see the screen?
c) Would it alter weight distribution too drastically?
d) Does the mounting device seem user-friendly? If not, what would you suggest?
e) Do you have any other comments or recommendations?



5.2) Force Display Interface

a) What is your opinion of the force display interface?
b) How do you feel about the ease-of- use to display and store data?
c) What do you like and dislike about the current display function?
d) What minimum functions, both visual and auditory, do you think are necessary for feedback training with a patient?
e) Do you have any other comments or recommendations?

6) Urinary collect bag mount
7) Foley Catheter hook

a) What is your opinion of the location of the urinary collection bag?
b) Would it obstruct the patient's gait pattern?
c) Would it adequately protect the device while a patient is ambulating?
d) Does the mounting device seem user-friendly? If not, what would you suggest?
e) Do you have any other comments or recommendations?


8) Overall Opinion

a) Overall what is your opinion of the walker – what do you like and dislike?
b) Do you think the overall weight of this walker is an issue for patients recovering from median sternotomy? Why of why not?
c) Does having these built in features for the oxygen tank, chest tube reservoir, and urinary collection bag seem useful or would they work better mounted to a separate mobile stand?
d) Do you have any other comments or recommendations?
e) What type of patient populations and practice settings do you think a force measuring instrumented walker could be beneficial in clinical practice?

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

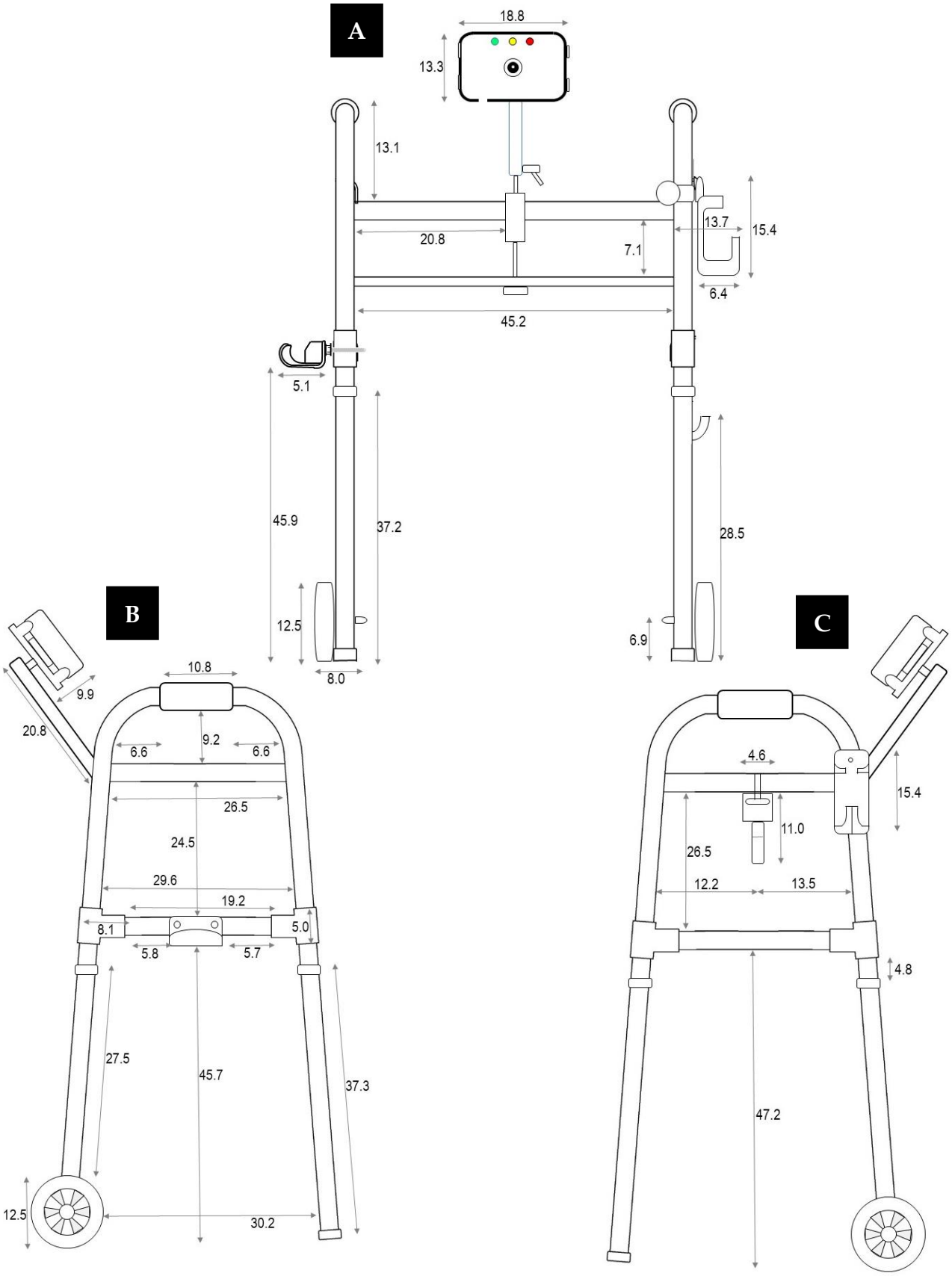
Appendix 2. Materials and Part List with Costs for the CFM Walker v1.0 (A) and CFM Walker v2.0 (B).

A. Component	Description	Unit	Qty	TOTAL
Dynamometer	Jamar Handgrip Smart Dynamometer, Performance Health, Chicago	$349.95	2	$699.90
Walker Frame	Deluxe Folding Walker, #10200-1, Drive Medical, Post Washington, NY	$32.99	1	$32.99
Walker Attachments	Platform Attachment, #101-105, Drive Medical, Post Washington, NY	$41.33	2	$82.66
Walker Wheels	Universal 5" Walker Wheels (set), Drive Medical, Post Washington, NY	$23.40	1	$23.40
Display Tablet	Fire HD 10 Tablet, 1080p Full HD, Amazon, Seattle, WA	$149.99	2	$299.98
Table Mount	Arkon Heavy Duty Tablet Clamp Mount, Arkon Mounts, Arcadia, CA	$68.63	2	$137.26
Tablet Water Proof Cover	360 Rotating Multi-Functional Grip Carry Cover with Built-in Screen Protector Amazon Fire HD 10, Fintie, Columus, OH	$39.99	2	$79.98
U-Bolts	Everbuilt Zinc-plated U-bolt 5.16 x 1 3/8 x 2 1/4", #320, Home Depot	$1.42	2	$2.84
Oxygen Tank Mount	E Cylinder Oxygen Tank Mount 15490 for Either D or E Oxygen Cylinders - Black, Rolyn Prest, San Francisco, CA	$37.26	1	$37.26
Handle Grips	Foam Pipe Insulation, 1", Home Depot	$2.55	1	$2.55
Urinary Collection Bag Hook	Swivel Multi-Purpose Hook - 2 Pack of Hooks / Hanger, BabyBubz, Vancouver, BC, Canada	$4.49	1	$4.49
Foley Catheter Hook	Jumbo Swirly Hook, Brushed Aluminum/Black, Think King, New York, NY	$9.99	2	$19.98
				TOTAL = $ 1,423.29

B. Component	Description	Unit	Qty	TOTAL
Electrical Interface Walker Mount	Arkon Heavy Duty Tablet Clamp Mount for iPad, Pro iPad, and Air iPad, Black; Arkon, Arcadia, CA	$57.90	1	$57.90
Circuit Board & Components	Arduino Board Kit ELEGOO UNO Project Super Starter Kit with Tutorial & UNO R3 Compatible with Arduino IDE	$36.99	1	$36.99
Force Transducers	Thin Film Pressure Sensor, Flex/Bend Sensor ZD10-100 500g Resistance-type Force Sensing Resistor, Walfront LLC, Lewes, DE	$10.59	2	$21.18
Power Source	V50 Always On External Battery Pack with Dual USB Ports - 12,800mAh, Voltaic Systems, Brooklyn, NY	$69.00	1	$69.00
Electrical Components' Waterproof Housing	Brilliance Storage 3.2-Cup Food Containers with Lids, BPA Free, Leak Proof, Clear (4-Pack) Newell Rubbermaid, Atlanta, GA	$34.66	0.25	$8.67
Front Wheeled Walker	Deluxe Two Button Folding Walker with 5-Inch Wheels, #10210-1, Drive Medical, Post Washington, NY	$31.64	1	$31.64
Urinary Collection Bag Hook	Swivel Multi-Purpose Hook (2 pack), BabyBubz, Vancouver, BC	$4.49	1	$4.49
Hose Clamp 4"	ISPINNER 304 Stainless Steel Adjustable 27-102mm Hose Clamps	$0.83	1	$0.83
Chest Tube Reservoir Hook	Custom, fabricated with aluminum bracket, bolts/nuts/washers, and heat moldable plastic sheets (Polly Plastics, Midland, MI)	$7.79	1	$8.79
				TOTAL = $238.49

Preprints (www.preprints.org) | NOT PEER-REVIEWED | Posted: 21 October 2021 doi:10.20944/preprints202110.0316.v1

Appendix 3. Schematic Diagrams of the Clinical Force Measuring Walker v2.0. A) Back view, B) Left side view, and C) Right side view. *All measurements in cm.*



References

1. Tuyl LJ, Mackney JH, Johnston CL. Management of sternal precautions following median sternotomy by physical therapists in Australia: a web-based survey. *Phys Ther* 2012, 92(1), 83-97.
2. Balachandran S, Lee A, Denehy L, et al. Risk factors for sternal complications after cardiac operations: a systematic review. *Ann Thorac Surg* 2016, 102(6), 2109-2117.
3. Brocki BC, Thorup CB, Andreasen JJ. Precautions related to midline sternotomy in cardiac surgery: a review of mechanical stress factors leading to sternal complications. *Eur J Cardiovasc Nurs* 2010, 9(2), 77-84.
4. Casha AR, Manche A, Gatt R, et al. Mechanism of median sternotomy dehiscence. *Interact Cardiovasc Thorac Surg* 2014, 19(4), 617-621.
5. Kostenuik P, Mirza FM. Fracture healing physiology and the quest for therapies for delayed healing and nonunion. *J Orthop Res* 35, 213–223, 2017
6. Zubair MH, Smith JM. Updates in minimally invasive cardiac surgery for general surgeons. *Surg Clin North Am* 2017, 97(4), 889-898.
7. Alhalawani AM, Towler MR. A review of sternal closure techniques. *J Biomater Appl* 2013, 28(4), 483-497.
8. Min L, Mazzurco L, Gure TR, et al. Longitudinal functional recovery after geriatric cardiac surgery. *J Surg Res* 2015, 194(1), 25-33.
9. Stocicea N, You T, Eiterman A, et al. Perspectives of post-acute transition of care for cardiac surgery patients. *Front Cardiovasc Med* 2017, 27(4), 70.
10. Edgerton JR, Herbert MA, Mahoney C, et al. Long-term fate of patients discharged to extended care facilities after cardiovascular surgery. *Ann Thorac Surg* 2013, 96(3), 871-877.
11. Graham A, Brown CH. Frailty, aging, and cardiovascular surgery. *Anesth Analg* 2011, 124(4), 1053-1060.
12. LaPier A, Cleary K. Feedback training improves accuracy of estimating upper extremity weight bearing during functional tasks – implications after open heart surgery. *Internat J Physiother Res* 2019, 7(4), 3163-3172. DOI: 10.16965/ijpr.2019.151
13. LaPier A, Cleary K. Feedback training improves compliance with sternal precaution guidelines during functional mobility: implications for optimizing recovery in older patients after median sternotomy. *Appl Bionics Biomech* 2021, Article ID 8889502:13 pages. doi.org/10.1155/2021/8889502
14. LaPier A, Cleary K. The influence of age and feedback training on ability to modulate upper extremity weight bearing force and pectoralis major muscle recruitment while following sternal precautions. *Phys Ther Rehabil* 2021, 8, 1. dx.doi.org/10.7243/2055-2386-8-1
15. Adams J, Cline MJ, Hubbard M, et al. A new paradigm for post-cardiac event resistance exercise guidelines. *Am J Cardiol* 2006, 97(2), 281-286.
16. Swanson LB, Kinney LaPier T. Upper extremity forces generated during activities of daily living. *J Acute Care Phys Ther* 2014, 5(2), 70-76.
17. Ruiz FK, Fu MC, Bohl DD, et al. Patient compliance with postoperative lower extremity touch down weight bearing orders at a level I trauma center. *Orthop* 2014, 37(6), e552-556.
18. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Effect of age on partial weight-bearing training. *Orthop* 2012, 35(7), e1061-1067.
19. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Is it possible to train patients to limit weight bearing on a lower extremity? *Orthop* 2012, 35(1), e31-37.
20. Hustedt JW, Blizzard DJ, Baumgaertner MR, Leslie MP, Grauer JN. Lower-extremity weight-bearing compliance is maintained over time after biofeedback training. *Orthop* 2012, 35(11), e1644-1648.
21. Uhl TL, Carver TJ, Mattacola CG, Mair SD, Nitz AJ. Shoulder musculature activation during upper extremity weight-bearing exercise. *J Orthop Sports Phys Ther* 2003, 33(3), 109-117.
22. Po-Chen Y, Cherng L. Using walker during walker: a pilot study for health elder. *Work* 2012, 41, 2081-2085.
23. Costamagna E, Thies SB, Kenneyet LPJ, et al. A generalizable method for the assessment of static stability of walking aid users. *Med Eng Physics* 2017, 46, 167-175.
24. Gill S, Scheme E. Design of a smart enabled walker or deployable activity and gait monitoring. *IEEE Life Sci Conference*, 2018. DOI:10.1109/LSC.2018.8572227
25. Khodadadi M, Baniasad MA, Arazpour M, Farahmand F, Zohoor H. Designing instrumented walker to measure upper-extremity's efforts: a case study. *Assist Tech* 2018, 26, 1-9.
26. Alwen M, Rajendran PJ, Ledoux A, Huang C, Wasson G, Shethet P. Stability margin monitoring in steering-controlled intelligent walkers for the elderly. *AAAI Fall Symposium: Caring Machines*, FS05-02-001, 2005. https://www.aaai.org/Papers/Symposia/Fall/2005/FS-05-02/FS05-02-001.pdf
27. Bonzino J, Peterson D. *Medical Devices and Human Engineering*. 4th Ed. CRC Press: Boca Raton, FL, USA, 2015.
28. Paz J, West. *Acute Care Handbook for Physical Therapists.* Elsevier: St. Louis, MO, USA, 2014.
29. Neergaard MA, Olesen F, Andersen RS, Sondergaard J. Qualitative description – The poor cousin of health research? *BMC Med Res Methodology* 2009, 9, 52.
30. Creswell J. *Qualitative Inquiry and Research Design*. Sage: Thousand Oaks, CA, USA, 1998.
31. Sawers A, Hahn ME, Kelly VE, Czerniecki JM, Kartin D. Beyond componentry: how principles of motor learning can enhance locomotor rehabilitation of individuals with lower limb loss – a review. *J Rehabil Res Dev* 2012, 49(10), 1431-1442.