BME Design-Spring 2024 - MARGO AMATUZIO
Complete Notebook

PDF Version generated by

RILEY TOTH

on

May 01, 2024 @10:37 PM CDT

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Team contact Information

RILEY TOTH - Feb 28, 2024, 9:51 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
Johnson	Russ	Advisor	russ.johnson@wisc.edu		ECB
Kutshera	Daniel	Client	kutshera@att.net		
Amatuzio	Margo	Leader	amatuzio@wisc.edu	218-590-0776	
Wille	Delani	Communicator	djwille@wisc.edu	651-408-3627	
Owens	Cameron	BSAC	cjowens2@wisc.edu	920-849-4520	
Toth	Riley	BWIG	rltoth@wisc.edu	443-875-5080	
Kreissler	Gracie	BPAG	gkreissler@wisc.edu	815-721-3789	

Project description

RILEY TOTH - Feb 21, 2024, 9:40 AM CST

Course Number: BME 400

Project Name: Stair Assist Bench

Project description/problem statement:

In the field of neuro-rehabilitation, physical therapists encounter a significant obstacle when assisting patients with weight-bearing restrictions to transition back to their homes. The primary challenge revolves around negotiating steps, which often proves to be an arduous task due to various constraints. Ramps, typically considered a solution, are frequently deemed impractical due to cost implications and compliance with rise-to-run criteria. As an alternative, patients are advised to use garden benches from hardware stores, which lack adjustability and medical design. This makeshift solution is frustrating for healthcare providers, as it is not purpose-built and poses issues with bench availability.

To address this gap in the next three months, there is a clear need for a specialized, medically designed bench tailored for step use, offering safety and adjustability to improve the mobility and independence of patients in neuro-rehabilitation.

About the client:

The client for the stair assist bench is Dan Kutschera, a physical therapist. The client will be using this product to reintegrate patients with weight-bearing restrictions to their homes after neurological and trauma rehabilitation.

2024/01/26 Meeting

MARGO AMATUZIO - Jan 30, 2024, 7:34 PM CST

Title: Meeting with Client to Discuss Patenting

Date: 01/30/2024

Content by: Margo Amatuzio

Present: Delani, Gracie, Riley, Margo, Dan Kutschera

Goals: Establish goals for this semester regarding patenting

Content:

- if we wanted to test this device in his clinic, what kind of safety forms would we need?
- very least, needs for own practice
    - wants to be involved with the patent
- worry regarding another group's device conflicting with ours for the patent
- chief facilities officer at their hospital to try prototype
- InCompass Health
    - Dan will follow up with safety protocol
- connect Dan with Russ

Conclusions/action items:

- Communicate with Dr. P about intellectual property

Delani Wille - Jan 31, 2024, 12:18 PM CST

Date: 01/30/2024

Content by: Delani

Present: Delani, Gracie, Riley, Margo, Dan Kutschera

Goals: Establish goals for this semester regarding patenting

Content:

-sees the market and the opportunity to help other people
- Understands how the push back may be from Iwalk
- want for own practice but would love to see it help other clinics
- Dan would like to continue with patent process
- stable design, older and frail pt 5’ - 5’5”
- stair negotiation - 2 devices
- spectrum of injuries
- budget $400 and continuation with however much money needed
- Ask the head of his hospital - has someone that would like to try
- Works for compass health with around 160 hospitals in the US
- make device about 3in shorter than leg height
- niche that can’t do Iwalk

-Viable for patients and clinicians

Conclusion: Discuss next steps with Dr. Puccinelli and Russ

2024/01/26 Meeting

MARGO AMATUZIO - Jan 26, 2024, 12:59 PM CST

Title: 01/26 Meeting

Date: 01/26/2024

Content by: Margo Amatuzio

Present: Team, Russ

Goals:

- Establish goals for semester

Content:

prelim. presentation 2/12 before 10:30am

invention disclosure — talk to Dr. P

start patent process

convo with client for commercialize vs personal use

- determine his intentions
  - his clinic and his customers? or entrepreneurial
- WARF patents UW-Madison
  - $40-50k
- need to determine who owns intellectual property of the project

final deliverable is a paper

product development

- FDA classification — Class 1
- risk analysis
  - start IRB
  - risk assessment of safety to yourself
- do we need an IRB to have people try it in general?
  - is there an informal way
  - internal IRB (talk to Dr. P)

$400 budget — clarify with Dan

- observing Dan's clients using the prototype
- need safety information
- intellectual property exposure

invention disclosure -> WARF -> provisional (have a year to tweak design) OR design patent or utility patent (independent or dependent claims)

Conclusions/action items:

- Schedule meaning with client

Delani Wille - Jan 29, 2024, 3:46 PM CST

Title: 01/26 Meeting

Date: 01/29/2024

Content by: Delani Wille

Present: Team, Russ

Content:

Notebooks are important - add everything to notebook, meetings, pictures
Final report is a journal report - where would this fit?

- Rehabilitation, biomechanics, physical therapy

Move preliminary presentation to feb 12th
Show and tell is providing feedback to juniors
Model now is frankenstein model
Does client want to patent this, commercialize this

- Invention disclosure, future of this product

Talk to Dr. Puccinelli about patent
Wisconsin Madison goes through Warf
Poster presentation at the end of April
Experimentation
Risk assessment, IRB for human trials (Dr. Puccinelli)
Mechanical model - CAD, FEA

End of semester goals: Invention disclosure, Patent,

1. Invention disclosure: WARF why is this novel
2. Provisional (gives you time) or Design or utility patent

Summary: Email Dan about patent and commercial and budget, Talk to Dr. P after get a response from Dan

2024/02/02 Meeting

MARGO AMATUZIO - Feb 02, 2024, 12:44 PM CST

Title: 02/02 Advisor Meeting

Date: 02/02/2024

Content by: Margo Amatuzio

Present: BME Team, Russ Johnson

Goals:

-

Content:

- resources on campus to help with patent
  - technology entrepreneurship office
  - ETP
- pursue through WARF
  - if Dan wants to use it he would have to license from them
- ownership of the patent? ask Dr. P
- don't need F10K
  - need design control
- Class 1 device -- less FDA burden

Device design

- look at how crutches are covered under insurance
  - FDA pathway
  - reimbursement process
- 8020 for prototyping
- pick a range that covers 90% of the population
  - make 3 inches shorter than tibia
  - 8 in for lowest and 18 for highest (not accounting for cushion)
- configuration for push scooters that we can borrow
- modify footplate?
  - make it more flexible
- hypothesis for adjustable bench
- want to know knee configuration
- how much does handle need to hold?
  - pick a good average handle height

Conclusions/action items:

- send email to Russ about what we should ask about the IRB
- purchase 8020
- Gracie adjust CAD

2024/02/07 Patent Meeting with Dr. Puccinelli

MARGO AMATUZIO - Feb 09, 2024, 8:11 AM CST

Title: Patent informational meeting

Date: 02/07/2024

Content by: Delani Wille, Margo Amatuzio

Present: Margo, Delani, Cam, Dr. Puccinelli

Goals: Understand the pathway to get patent for stair assist bench

Content:

(Delani)

- one year from December presentation date (2023 - 2024)

- WARF doesn't really do international patents, lost international patent when we presented to public in December

- Provisional patent gives another year to claim work before it becomes prior art

Pathway to patent

- WARF say yes to our device/patent venture

- This means warf pay for everything and write patent/ provisional patent, otherwise would need federal funding and entrepernural efforts

- WARF submit to US PTO

- $2000 fee split between inventors

When patent approved

- license the patent to buy patent from WARF

- inventors get 20% of gross revenue

- 20% goes to department for research

(Margo)

1 year from december to file for US patent

- 1 year after public presentation to file for patent

provisional - one extra year to file full utility patent

- not review, much scrutiny
- abbreviated version for filing utility patent

claim 1 — no longer have international patent rights by presenting rights

- WARF — patenting and listening arm of university
- rare they'll file for international patents

after 1 year it becomes "prior art" i.e., existing technology

- our language cannot be like their Claim I at all

WARF

- project not federally funded
- WARF writes patent and makes sure language is different
- U.S. PTO accepts it -> finders fee from WARF, $2000 to split between inventors
- WARF wants to license patent to get someone to buy it from them
- license agreement between other companies

- other company gives percent of profits to WARF or someone buys patent from WARF
- WARF gives 20% split of all gross licensing revenue from the patent to the inventors
- other 20% goes to department to research
- other 40% goes to costs
- other 20% goes to graduate school startup companies for research
- once given to WARF then we aren't involved

reach out to IRB office

copy iWalk testing protocols and literature

- send to IRB folks
- making modifications to an existing device

design idea -- torsion spring for the base so when no pressure the base "flips up" to avoid it catching on the lip of the stairs

Conclusions/action items:

Start working on IRB for testing and move forward with developing device before we approach WARF.

04/18/2024 Meeting

MARGO AMATUZIO - Apr 12, 2024, 12:25 PM CDT

Title: Weekly Advisor Meeting

Date: 04/18/2024

Content by: Margo Amatuzio

Present: BME Team, Russ Johnson

Goals:

- Establish weekly goals and update

Content:

- testing:
  - do we need smaller increments in the adjustable column
  - compare gait cycle for iWalk + boot, SAB + boot, crutch + boot
  - adjustability confined to population
  - qualitative -- biased
    - how are you going to progress the design?
      - yes/no? different handle? size of platform?
    - limit down what you want to test
      - keep it minimal as possible bc sample size and bias
  - quantitative
    - force plate analysis

Conclusions/action items:

-

2023/10/13 Initial Drawings for Design Matrix

CAMERON OWENS - Dec 11, 2023, 11:56 AM CST

Title: initial Drawings for Design Matrix

Date: 2023/10/13

Content by: Cameron Owens

Present: Group

Goals: To develop several viable designs to compare and eventually move forward on fabrication of one as a prototype. The designs were developed to meet a few design criteria such as weight capacity, accessibility, and ability to aid patients climbing stairs.

Content:

Three group members took on the responsibility of each drawing one potential design to serve as an option for our design matrix to come.

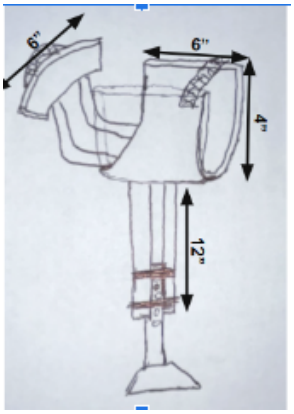
Gracie, Riley, and Cameron spent some time creating hand drawings of the potential designs which were later discussed at a group meeting to determine that they were each reasonable options. They drawings would be further elaborated on including dimensions and other critical perspective for finalizing a design matrix to come.

See below for design drawings:

Conclusions/action items:

The initial design brainstorming was crucial to creating a design matrix which will be used to select a design for fabrication.

CAMERON OWENS - Dec 11, 2023, 12:44 PM CST



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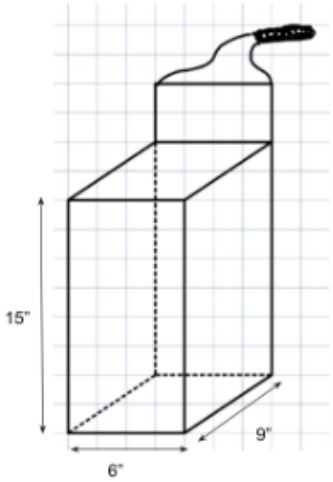
Screenshot_2023-12-11_at_12.38.19_PM.png (71.8 kB) Riley's Design Drawing

CAMERON OWENS - Dec 11, 2023, 12:44 PM CST



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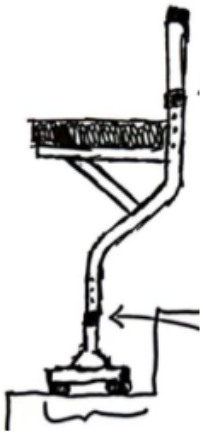
Screenshot_2023-12-11_at_12.38.42_PM.png (37.9 kB) Cameron's Design Drawing

CAMERON OWENS - Dec 11, 2023, 12:44 PM CST



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Screenshot_2023-12-11_at_12.39.53_PM.png (34.4 kB) Gracie's Design Drawing

2023/10/13 Design Matrix

CAMERON OWENS - Dec 12, 2023, 10:49 AM CST

Title: Design Matrix

Date: 10/13/2023

Content by: BME Team

Present: N/A

Goals:

- Determine preliminary design

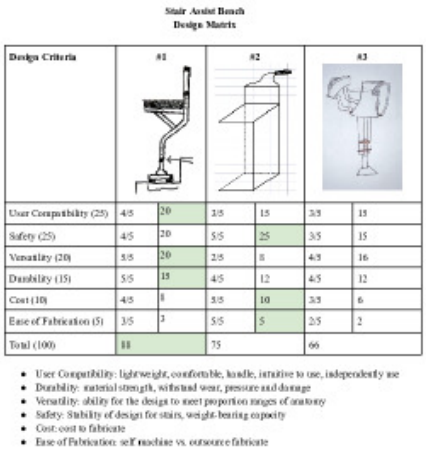
Content:

Attached PDF

Conclusions/action items:

- CAD preliminary design and make adjustments

MARGO AMATUZIO - Oct 11, 2023, 8:23 PM CDT



Stair Assist Bench
Design Matrix

Design Criteria	#1		#2		#3	
User Compatibility (25)	4/5	20	3/5	15	3/5	15
Safety (25)	4/5	20	5/5	25	3/5	15
Versatility (20)	5/5	20	2/5	8	4/5	16
Durability (15)	5/5	15	4/5	12	4/5	12
Cost (10)	4/5	8	5/5	10	3/5	6
Ease of Fabrication (5)	3/5	3	5/5	5	2/5	2
Total (100)	81		75		66	

- User Compatibility: lightweight, comfortable, handle, intuitive to use, independently use
- Durability: material strength, withstand wear, pressure and damage
- Versatility: ability for the design to meet proportion ranges of anatomy
- Safety: Stability of design for stairs, weight-bearing capacity
- Cost: cost to fabricate
- Ease of Fabrication: self machine vs. outsource fabricate

Download

Design_Matrix_-_stair_assist_bench.pdf (256 kB)

2023/10/20 SolidWorks Drawing - Prototype 1.1

CAMERON OWENS - Dec 11, 2023, 12:49 PM CST

Title: SolidWorks Drawing - Prototype 1.1

Date: 2023/10/20

Content by: Cameron Owens

Present: N/A

Goals:

Create a CAD of our first prototype iteration

Content:

Using SolidWorks the dimensions, material properties, and coupling components were included to exactly match those of our first prototype.

Conclusions/action items:

The CAD was an accurate representation of prototype and will be used in the future for computer simulations as well as graphics for presentation.

CAMERON OWENS - Dec 11, 2023, 12:52 PM CST

Download

Bench_proto_1_-_Copy.zip (7.2 MB)

2023/12/1 SolidWorks Drawing - Prototype 1.2

CAMERON OWENS - Dec 11, 2023, 12:59 PM CST

Title: SolidWorks Drawing - Prototype 1.2

Date: 2023/12/1

Content by: Cameron Owens

Present: N/A

Goals: Update CAD of the previous to prototype to reflect the changes made to the base.

Content:

The new CAD features the new base with accurate dimensions, connections, and material properties. Attached zip file includes updated component drawings with dimensions and material properties.

Conclusions/action items:

This CAD with facilitate new computer testing to support design change motivations such as increased stability and weight bearing capacity.

CAMERON OWENS - Dec 11, 2023, 12:58 PM CST

Download

Modified_Assembly-20231211T185704Z-001.zip (768 kB)

2023/12/13 - CAD of Final Assembly

GRACE KREISSLER - Dec 13, 2023, 10:45 PM CST

Title: CAD of the Final Assembly

Date: 12/13/2023

Content by: Gracie

Present: N/A

Goals: Provide CAD designs of the final prototype

Content:

- CAD is provided for both the original and new base

-CAD for the whole assembly is also provided

Conclusions/action items:

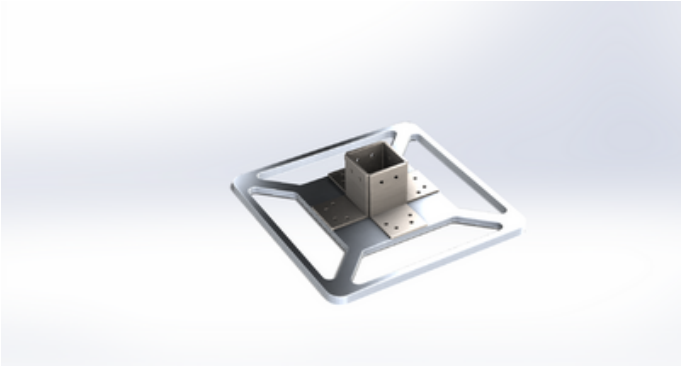
Gracie and Cam worked together to model the final prototype.

GRACE KREISSLER - Dec 13, 2023, 10:42 PM CST

Download

Bench_proto_1.PNG (330 kB)

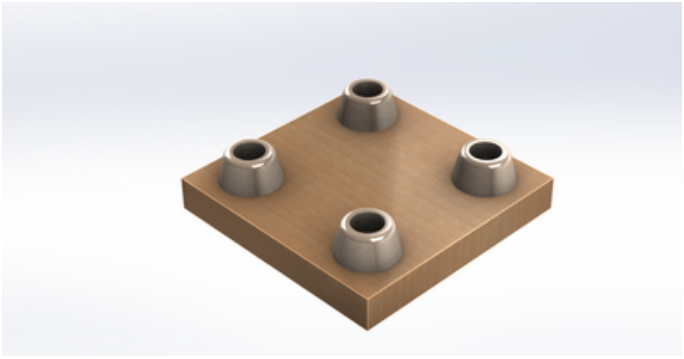
GRACE KREISSLER - Dec 13, 2023, 10:42 PM CST



Download

Base.PNG (379 kB)

GRACE KREISSLER - Dec 13, 2023, 10:42 PM CST



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OGBASE.PNG (968 kB)

2024/5/1 Materials and Expenses

GRACE KREISSLER - May 01, 2024, 6:12 PM CDT

Title: Expenses

Date: 2024/5/1

Content by: Gracie

Present: N/A

Goals: Itemize all expenses throughout the semester.

Content:

Materials and Expenses

Item	Description	Manufacturer	Vendor	Vendor Part #	Date	Total
CORNER BRACE	BRACE, CORNER_2"_GALV_4PK	Everbilt	Home Depot	030699152674	02/04/24	$6.97
BRACE, CORNER_5"_ZINC	BRACE, CORNER_5"_ZINC	Everbilt	Home Depot	030699152124	02/04/24	$5.94
CLEVIS PIN	TOWSMART 3/8" CLEVIS PIN	TowSmart	Home Depot	849278012038	02/04/24	$5.38
SQ TB1.25	PUNCHED SQUARE TUBE ZP 1-1/4 X 36	Everbilt	Home Depot	887480030471	02/04/24	$22.93
SQUARE TUBE	TUBE SQUARE ALUM 48X1X1/16	Everbilt	Home Depot	887480013078	02/04/24	$28.47
8 IN SHIMS	8" COMPOSITE SHIM (12 PC BDL)	Timberwolf	Home Depot	852981002098	02/04/24	$2.28
						$71.970

Conclusions/action items:

N/A

2024/01/05 Updated Materials & Expenses

GRACE KREISSLER - May 01, 2024, 6:16 PM CDT

Title: Updated Materials & Expenses

Date: 5/01/2024

Content by: Gracie

Present: N/A

Item	Description	Manufacturer	Mft Pt#	Vendor	Date	Total
CORNER BRACE	BRACE, CORNER_2"_GALV_4PK	Everbilt	030699152674	Home Depot	02/04/24	$6.97
BRACE, CORNER_5"_ZINC	BRACE, CORNER_5"_ZINC	Everbilt	030699152124	Home Depot	02/04/24	$5.94
CLEVIS PIN	TOWSMART 3/8" CLEVIS PIN	TowSmart	849278012038	Home Depot	02/04/24	$5.38
SQ TB1.25	PUNCHED SQ TUBE ZP 1-1/4X36	Everbilt	887480030471	Home Depot	02/04/24	$26.89
SQUARE TUBE	TUBE SQUARE ALUM 48X1X1/16	Everbilt	887480013078	Home Depot	02/04/24	$28.47
8 IN SHIMS	8" COMPOSITE SHIM (12 PC BDL)	Timberwolf	852981002098	Home Depot	02/04/24	$2.28
BLACK SPRAY PAINT	MATTE BLACK SPRAY PAINT	Krylon	724504055464	Micheals	2/19/24	$8.56
8’x8’x16’ REG CONCRETE BLOCK	Concrete cinder block	Home Depot	0000-938-076	Home Depot	7/16/24	$6.27
NEOPRENE RUBBER FOAM	Neoprene Sponge Foam Rubber Roll Adhesive, 15X60 Inches X 1/4" Thick	Duaplex		Amazon	7/16/24	$19.99
						$110.75

2023/10/30 Prototype 1.1

CAMERON OWENS - Dec 11, 2023, 3:12 PM CST

Title: Prototype 1.1 Fabrication

Date: 2023/10/30

Content by: Cameron Owens

Present: Entire Group

Goals: To detail the process and techniques used to fabricate the first version of our prototype.

Content:

Material Selection

Our first prototype is an all wood construction that has used cedar for handle, main support, and diagonal supports. Plywood was used to create base and the knee support of the prototype. The main goal of the prototype was design a low cost and lightweight visual of the potential product so we chose these materials for those properties. The last component was a cushion to soften the knee support for user comfortability, for this to stay consistent with criteria for material selection we chose a foam kneeling pad used for kneeling on hard surfaces which was lightweight and lost cost.

Assembly

To assemble the components we used 2 1/4" wood screws as well as some shorter 1" wood screws. Wood screws were chosen based the applied loads at the connects. Most of these connections experience tensile or compressive loads which based on common knowledge and literature screws are better at withstanding than the other common coupling technique (nails) who better withstand shear loads. The length of the screw was applied based on thickness of the components being coupled. If the two components could accommodate the longer screw without the screw protruding the on the other side of the piece it would be used. For example, when connecting the plywood knee support to the cedar diagonal supports the shorter screws need to be used in order to avoid aforementioned circumstance. Finally the foam cushion was applied to the knee support using super glue to fix it permanently to the knee support.

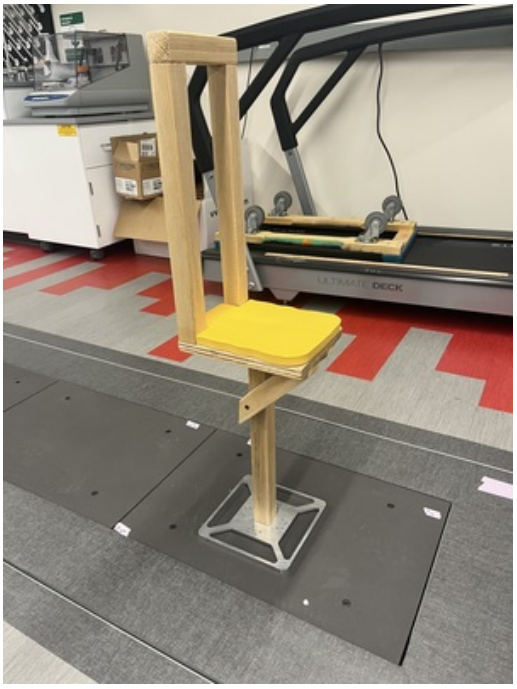
Fabrication

The cedar wood supports were cut to length using a Miter saw because of the precise angles need to create a balanced device. Based on limitations such as size the plywood base and knee support needed to be cut using a handheld circular saw. The foam cushion was cut to size using a utility knife.

Conclusions/action items:

The finished prototype is successful with consideration of weight and cost. Testing will be preformed on it to determine areas of improvements necessary for future iterations.

MARGO AMATUZIO - Dec 13, 2023, 10:23 PM CST



Download

IMG_0221.jpeg (4.36 MB)

2023/12/1 Prototype 1.2

CAMERON OWENS - Dec 11, 2023, 2:30 PM CST

Title: Prototype 1.2

Date: 2023/12/1

Content by: Cameron Owens

Present: N/A

Goals: To attach the new aluminum base to the existing wooden prototype.

Content:

The first step was remove the current wooden base that was attached via a 2 1/4" wood screw. The new base was fabricated to accommodate a wood screw from the bottom directly screwed into the existing hole in the cedar support as well as some steel supports which sat atop the base at a right angle with the second surface touching the wood. However, the dimensions of angle supports were meant to fit a 2" x 2" main support. Because wooden building material is often 1/2" smaller than common language used to describe them 1/4" shims needed to be cut from excess cedar material in order to fill the gap between the steel supports and main cedar support. This was accomplished using a handheld circular saw. Once cut one of the four shims would be positioned between each support and the corresponding side of the wood support. At this point the a 1 1/2" wood screw was used to secure the components together through predrilled holes in the steel supports.

Conclusions/action items:

The second iteration or prototype with an aluminum base was secure and we can now proceed with stability testing.

CAMERON OWENS - Dec 11, 2023, 2:31 PM CST

Download

Base_Shims.jpeg (3.81 MB)

CAMERON OWENS - Dec 11, 2023, 2:32 PM CST

Download

Close_up_Base_Shims.jpeg (3.5 MB)

2023/11/30 Aluminum Base for Prototype 1.2

CAMERON OWENS - Dec 11, 2023, 2:18 PM CST

Title: Aluminum Base for Prototype 1.2

Date: 2023/11/30

Content by: Cameron Owens

Present: N/A

Goals: Have a new base fabricated from the aluminum which is little weight and much stronger than wood which serves to increase the stability of the current prototype based on observations from previous design.

Content:

The aluminum base was a component that we had outsourced to a metal fabrication shop. The shop used specialized CNC techniques to create the new component. They were able to create the component based on dimensions and preferences the group gave them. We wanted the device to be 8"x8", have a favorable moment of inertia, as well as a bottom profile with was conducive to accommodating a variety of surfaces. They achieved this by reducing excess material on the interior portion of the square shape as seen in the photos below.

Conclusions/action items:

We were able to receive the initial component free of charge and we will couple it to the wooden prototype for testing and validation.

CAMERON OWENS - Dec 11, 2023, 2:19 PM CST

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IMG_20231130_141500_01.jpeg (273 kB)

2024/05/01 Final Prototype

MARGO AMATUZIO - May 01, 2024, 8:01 PM CDT

Title: Final Prototype

Date: 05/01/2024

Content by: Team

Present: Team

Goals: Fabricate final prototype.

Content:

- Final prototype with adjustable column, metal base, and l-brackets to support the bench.

Conclusions/action items:

- Include in final presentation.

MARGO AMATUZIO - May 01, 2024, 8:01 PM CDT

Download

IMG_1698.HEIC (1.53 MB)

2024/4/19 Testing Protocol

CAMERON OWENS - May 01, 2024, 10:28 AM CDT

Title: Testing Protocol

Date: 2024/4/19

Content by:

Present: n/a

Goals: Layout the testing so its repeatable

Content:

Testing Protocol

Interventions:
The first intervention is a fracture boot on the right leg to mimic a below the knee injury. The second intervention will be the assistive device for which its effectiveness will be investigated. The third intervention will be the iWalk for comparison to the assistive device.

Protocol:
The test subjects will be asked to wear a fracture boot to emulate a non-weight bearing injury that is distal to the knee. Two to three markers will be placed at each joint on the participants' body for motion capture analysis. Stairs will be placed in the center of the motion capture frame volume and equipped with portable force plates. Each subject will climb three steps with the six research conditions in a randomized order: 1) BOOT, 2) BOOT + BENCH, 3) NO BOOT + BENCH, 4) BOOT + iWALK, 5) NO BOOT + iWALK, 6) NONE. An OptiTrack motion capture system will synchronize with the Bertec force plates to obtain both kinematic and kinetic gait cycle measurements of each participant with the following interventions. After completion of the experiment, participants will be asked to fill out an activity-specific balance confidence (ABC) questionnaire and further feedback of the device.

Conclusion/Action Items:
Complete the testing.

2024/4/20 Matlab Code for Stair Ascension

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

Title: One-Step Stair Ascension MATLAB

Date: 2024/4/20

Content by: Margo Amatuzio

Present: N/A

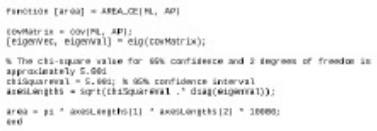
Goals: Analyze the data from testing

Content:

Conclusions/action items:

Finish analysis and prepare it for presenting.

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT



```
function [area] = AREA_CE(ML, AP)

covMatrix = cov(ML, AP);
[eigenVec, eigenVal] = eig(covMatrix);

% The chi-square value for 95% confidence and 2 degrees of freedom is
approximately 5.991
chiSquareVal = 5.991; % 95% confidence interval
axesLengths = sqrt(chiSquareVal .* diag(eigenVal));

area = pi * axesLengths(1) * axesLengths(2) * 10000;
end
```

Download

AREA_CE.m (347 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [swayAreaPerSecond] = AREA_SW(cop3_x_filt, cop3_y_filt)

% Calculate the differences between consecutive points for both dimensions
deltaML = diff(cop3_x_filt);
deltaAP = diff(cop3_y_filt);

% Calculate the Euclidean distances between consecutive points
distances = sqrt(deltaML.^2 + deltaAP.^2);

% Sum these distances to get the total path length
totalPathLength = sum(distances);

% Calculate the measurement time
Fs = 1000; % Sampling frequency in Hz
numPoints = length(cop3_x_filt); % Number of data points
measurementTime = numPoints / Fs; % Total measurement time in seconds

% Calculate the sway area per second
swayAreaPerSecond = (totalPathLength*100) / measurementTime;

end
```

Download

AREA_SW.m (694 B)

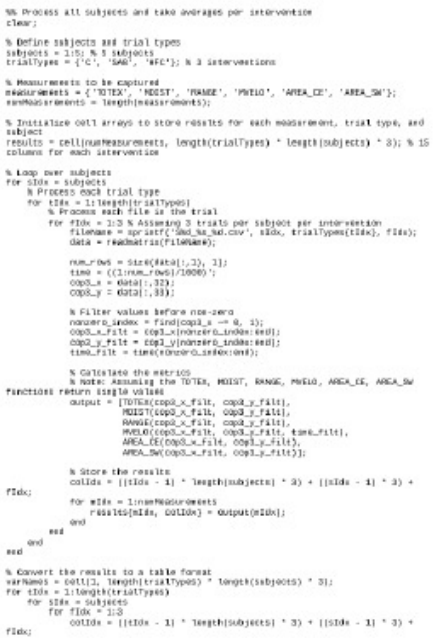
MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
clear;

% Load the data from the uploaded Excel file
filename = 'aggregate_results.xlsx'; % Update the path
data = readtable(filename, 'Sheet', 'Arrays');

% Measurements to be captured
measurements = {'TOTEX', 'MDIST', 'MVELO', 'RMSEE', 'AREA-CE', 'AREA-SW'};
numMeasurements = length(measurements);

interventions = {'Control', 'SAB', 'HFC'};

meanstd_output = cell(numMeasurements, length(interventions));

% Initialize matrices to store the means and standard deviations
means = zeros(numMeasurements, length(interventions));
stds = zeros(numMeasurements, length(interventions));

for i = 1:numMeasurements
    data_Control = data.Control(i);
    data_SAB = data.SAB(i);
    data_HFC = data.HFC(i);

    % Extract the string from the cell
    strControl = data_Control{1};
    C_array = str2double(strsplit(strControl, ', '));

    strSAB = data_SAB{1};
    SAB_array = str2double(strsplit(strSAB, ', '));

    strHFC = data_HFC{1};
    HFC_array = str2double(strsplit(strHFC, ', '));

    Control_mean = mean(C_array);
    Control_std = std(C_array);
    SAB_mean = mean(SAB_array);
    SAB_std = std(SAB_array);
    HFC_mean = mean(HFC_array);
    HFC_std = std(HFC_array);

    SAB_mean_norm = SAB_mean/Control_mean * 100;
    HFC_mean_norm = HFC_mean/Control_mean * 100;

    Control_percSet = 100; % Control is the baseline (100%)

    means_storm(i, :) = [Control_percSet, SAB_mean, HFC_mean];
    stds_storm(i, :) = [Control_std, SAB_std, HFC_std];

    % Store the mean and standard deviation in the matrices
    means(i, :) = [Control_perCent, SAB_mean_norm, HFC_mean_norm];
    stds(i, :) = [Control_std/Control_mean*100, SAB_std/SAB_mean*100,
HFC_std/HFC_mean*100];

end

resultsTable = cell2table(results, 'RowNames', measurements, 'VariableNames',
varNames);

% Display the table
disp(resultsTable);

%%
```

Download

COP_figures.m (2.58 kB)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT



```
%% Process all subjects and take averages per intervention
clear;

% Define subjects and trial types
subjects = 1:5; % 5 subjects
trialTypes = {'C', 'SAB', 'RFC'}; % 3 interventions

% Measurements to be captured
measurements = {'TOTEX', 'MOIST', 'RANGE', 'MVELO', 'AREA_CE', 'AREA_SW'};
numMeasurements = length(measurements);

% Initialize cell arrays to store results for each measurement, trial type, and
subject
results = cell(numMeasurements, length(trialTypes) * length(subjects) * 3); % 15
columns for each intervention

% Loop over subjects
for sIdx = subjects
    % Process each trial type
    for tIdx = 1:length(trialTypes)
        % Process each file in the trial
        for fIdx = 1:3 % Assuming 3 trials per subject per intervention
            filename = sprintf('SNd_%s_%d.csv', sIdx, trialTypes{tIdx}, fIdx);
            data = readmatrix(filename);

            num_rows = size(data(:,1), 1);
            time = ((1:num_rows)/1000)';
            cop3_x = data(:,32);
            cop3_y = data(:,33);

            % Filter values before non-zero
            nonzero_index = find(cop3_x ~= 0, 1);
            cop3_x_filt = cop3_x(nonzero_index:end);
            cop3_y_filt = cop3_y(nonzero_index:end);
            time_filt = time(nonzero_index:end);

            % Calculate the metrics
            % Note: Assuming the TOTEX, MOIST, RANGE, MVELO, AREA_CE, AREA_SW
functions return single values
            output = [TOTEX(cop3_x_filt, cop3_y_filt),
                      MOIST(cop3_x_filt, cop3_y_filt),
                      RANGE(cop3_x_filt, cop3_y_filt),
                      MVELO(cop3_x_filt, cop3_y_filt, time_filt),
                      AREA_CE(cop3_x_filt, cop3_y_filt),
                      AREA_SW(cop3_x_filt, cop3_y_filt)];

            % Store the results
            colIdx = ((tIdx - 1) * length(subjects) * 3) + ((sIdx - 1) * 3) +
fIdx;
            for mIdx = 1:numMeasurements
                results{mIdx, colIdx} = output(mIdx);
            end
        end
    end
end

% Convert the results to a table format
varNames = cell(1, length(trialTypes) * length(subjects) * 3);
for tIdx = 1:length(trialTypes)
    for sIdx = subjects
        for fIdx = 1:3
            colIdx = ((tIdx - 1) * length(subjects) * 3) + ((sIdx - 1) * 3) +
fIdx;
```

Download

COP_Measures.m (8.68 kB)

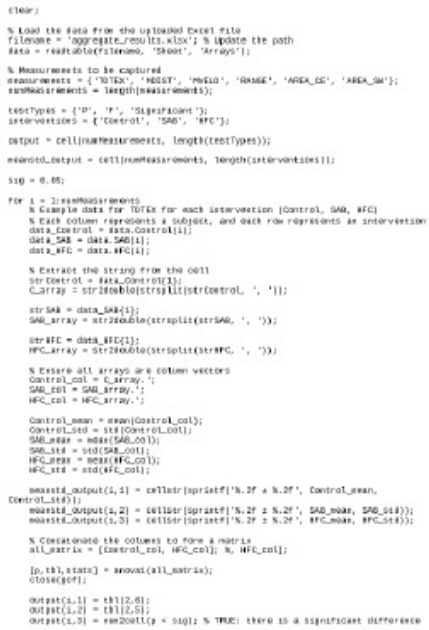
MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
% Stabilogram for one subject
%
C = "S1_C_1.csv";
SAB = "S1_SAB_2.csv";
RFC = "S1_RFC_1.csv";

files = {C, SAB, RFC};
colors = {'#007BFF', '#00CC33', '#CC0000'};

figure;
hold on

for fIdx = 1:length(files)
    filename = files{fIdx};
    data = readmatrix(filename);

    cop3_x = data(:,32);
    cop3_y = data(:,33);

    nonzero_index = find(cop3_x ~= 0, 1);
    cop3_x_filt = cop3_x(nonzero_index:end);
    cop3_y_filt = cop3_y(nonzero_index:end);

    plot(cop3_x_filt, cop3_y_filt, 'LineStyle', 'None', 'Marker', '*', 'Color',
colors{fIdx});


end
title('Stabilogram');
xlabel('Medio-Lateral (m)'); % If standing facing toward the Wii symbol or plate
ylabel('Anterior-Posterior (m)');
legend('C', 'SAB', 'RFC');
%axis equal;
hold off

%%
trialTypes = {'C', 'SAB', 'RFC'};

%for sIdx = 1:5
    for tIdx = 1:3
        for fIdx = 1:3
            filename = sprintf('SNd_%s_%d.csv', i, trialTypes{tIdx}, fIdx);
            data = readmatrix(filename);

            cop3_x = data(:,32);
            cop3_y = data(:,33);

            % Filter values before non-zero
            nonzero_index = find(cop3_x ~= 0, 1);
            cop3_x_filt = cop3_x(nonzero_index:end);
            cop3_y_filt = cop3_y(nonzero_index:end);

            figure;
            plot(cop3_x_filt, cop3_y_filt, 'Marker', '*', 'LineStyle', 'none');
            title(filename);
            xlabel("Mediolateral (m)");
            ylabel("Anterior-Posterior (m)")
            axis equal;

        end

    end
```

Download

COP_stabilogram.m (5.1 kB)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT



```
clear;

% Load the data from the uploaded Excel file
filename = 'aggregate_results.xlsx'; % Update the path
data = readtable(filename, 'Sheet', 'Arrays');

% Measurements to be captured
measurements = {'TOTEX', 'MDIST', 'MVELO', 'RANGE', 'AREA_SE', 'AREA_SW'};
numMeasurements = length(measurements);

testTypes = {'P', 'F', 'Significant'};
interventions = {'Control', 'SAB', 'AFC'};

output = cell(numMeasurements, length(testTypes));

meanstd_output = cell(numMeasurements, length(interventions));

sig = 0.05;

for i = 1:numMeasurements
    % Example data for TOTEX for each intervention (Control, SAB, AFC)
    % Each column represents a subject, and each row represents an intervention
    data_Control = data.Control(i);
    data_SAB = data.SAB(i);
    data_AFC = data.AFC(i);

    % Extract the string from the cell
    strControl = data_Control{1};
    C_array = str2double(strsplit(strControl, ', '));

    strSAB = data_SAB{1};
    SAB_array = str2double(strsplit(strSAB, ', '));

    strAFC = data_AFC{1};
    AFC_array = str2double(strsplit(strAFC, ', '));

    % Ensure all arrays are column vectors
    Control_col = C_array.';
    SAB_col = SAB_array.';
    AFC_col = AFC_array.';

    Control_mean = mean(Control_col);
    Control_std = std(Control_col);
    SAB_mean = mean(SAB_col);
    SAB_std = std(SAB_col);
    AFC_mean = mean(AFC_col);
    AFC_std = std(AFC_col);

    meanstd_output(i,1) = cellstr(sprintf('%.3f ± %.3f', Control_mean,
Control_std));
    meanstd_output(i,2) = cellstr(sprintf('%.3f ± %.3f', SAB_mean, SAB_std));
    meanstd_output(i,3) = cellstr(sprintf('%.3f ± %.3f', AFC_mean, AFC_std));

    % Concatenate the columns to form a matrix
    all_matrix = [Control_col, AFC_col]; %, AFC_col];

    [p,tbl,stats] = anova1(all_matrix);
    close(gcf);

    output(i,1) = tbl(2,6);
    output(i,2) = tbl(2,5);
    output(i,3) = num2str(p < sig); % TRUE: there is a significant difference
```

Download

COP_Statistics.m (2.35 kB)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [MDIST] = MDIST(cop_x, cop_y)

% Calculate the mean COP position
meanX = mean(cop_x);
meanY = mean(cop_y);

% Calculate the distance of each COP point from the mean COP
distances = sqrt((cop_x - meanX).^2 + (cop_y - meanY).^2);

% Find the average distance from the mean COP
MDIST = mean(distances)*100;

end
```

Download

MDIST.m (317 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function mean_frequency = MFREQ(COP_X, COP_Y, reference_X, reference_Y, time)
    % Calculate displacement of COP from reference point
    displacement = sqrt((COP_X - reference_X).^2 + (COP_Y - reference_Y).^2);

    % Calculate time intervals between consecutive COP measurements
    time_intervals = diff(time);

    % Compute the mean time interval
    mean_time_interval = mean(time_intervals);

    % Compute the mean frequency of COP displacement
    mean_frequency = 1 / mean_time_interval;
end
```

Download

MFREQ.m (514 B)

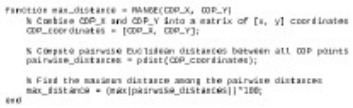
MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [MVELO] = MVELO(COP_X, COP_Y, time)
    % Calculate displacement in X and Y directions
    displacement_X = diff(COP_X);
    displacement_Y = diff(COP_Y);

    % Calculate time intervals
    time_intervals = diff(time);

    % Calculate velocity components in X and Y directions
    velocity_X = displacement_X ./ time_intervals;
    velocity_Y = displacement_Y ./ time_intervals;

    % Calculate magnitude of velocity vector
    velocity_magnitude = sqrt(velocity_X.^2 + velocity_Y.^2);

    % Calculate average velocity
    MVELO = mean(velocity_magnitude)*100;
end
```

Download

MVELO.m (593 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT



```
function max_distance = RANGE(COP_X, COP_Y)
    % Combine COP_X and COP_Y into a matrix of [x, y] coordinates
    COP_coordinates = [COP_X, COP_Y];

    % Compute pairwise Euclidean distances between all COP points
    pairwise_distances = pdist(COP_coordinates);

    % Find the maximum distance among the pairwise distances
    max_distance = (max(pairwise_distances))*100;
end
```

Download

RANGE.m (387 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [totalPathLength] = TOTEX_AP(cop_y)
    % Initialize path length
    pathLength = 0;

    % Calculate the number of points
    numPoints = length(cop_y);

    % Accumulate the absolute differences in successive cop_y values
    for i = 2:numPoints
        yLength = abs(cop_y(i) - cop_y(i-1));
        pathLength = pathLength + yLength;
    end

    % Scale the total path length as needed
    totalPathLength = pathLength * 100;
end
```

Download

TOTEX_AP.m (454 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [totalPathLength] = TOTEX_ML(cop_x)
    % Initialize path length
    pathLength = 0;

    % Calculate the number of points
    numPoints = length(cop_x);

    % Accumulate the absolute differences in successive cop_y values
    for i = 2:numPoints
        xLength = abs(cop_x(i) - cop_x(i-1));
        pathLength = pathLength + xLength;
    end

    % Scale the total path length as needed
    totalPathLength = pathLength * 100;
end
```

Download

TOTEX_ML.m (454 B)

MARGO AMATUZIO - May 01, 2024, 7:56 PM CDT

```
function [TOTEX] = TOTEX(cop_x, cop_y)

a = size(cop_x(:,1));
pathLength = 0;

for i = 2:a
xLength = cop_x(i) - cop_x(i-1);
yLength = cop_y(i) - cop_y(i-1);
dis = sqrt(xLength^2 + yLength^2);
pathLength = pathLength + dis;
end

TOTEX = pathLength*100;

end
```

Download

TOTEX.m (256 B)

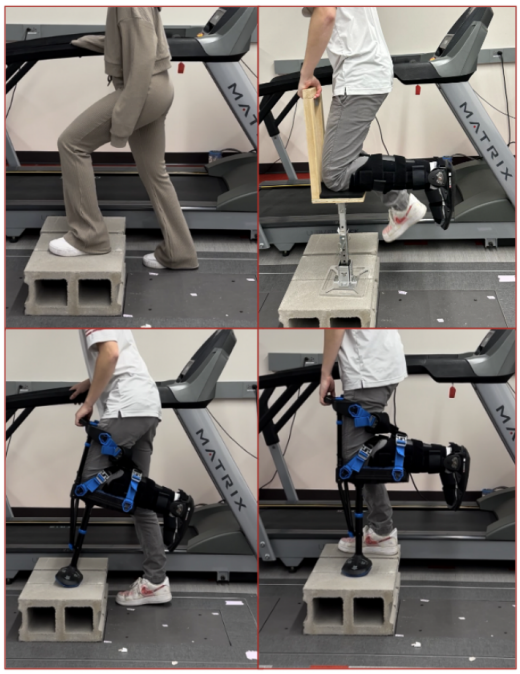
2024/5/1 Updated Testing Protocol

GRACE KREISSLER - May 01, 2024, 6:36 PM CDT

Date: 5/01/2024
Content By: Gracie
Present: N/A

Testing Protocol

Participants underwent a physical examination to obtain their weight and height to ensure they qualified for the study. The participants were asked to wear a fracture boot to emulate a non-weight bearing injury that is distal to the knee. Two cinder blocks were placed side by side on one force plate to account for the dimensions of a realistic stair step, and another cinder block was placed to the right, not in contact with the force plate for the other foot. Each participant ascended one step and descended one step with the three research conditions in the respective order: 1) NONE, 2) BOOT + SAB, 3) BOOT + HFC. After completion of the experiment, participants were asked to fill out a feedback form that included pain ratings, comfort scores, device preference, and further feedback of the device.



This is a picture of the one-step stair ascension experimental setup. Each participant performed three trials each for three conditions: Control (top left), Stair-Assist Bench (SAB) (top right), and the Hands-Free Crutch (HFC) (bottom). A force plate was used to collect center of pressure (COP) measurements to assess postural stability.

2024/4/24 Testing

CAMERON OWENS - May 01, 2024, 10:15 AM CDT

Title: Testing of final prototype

Date: 24/4/19

Content by: Team

Present: Team

Goals: Complete stair gait for analysis

Content:

Below

Conclusions/action items:

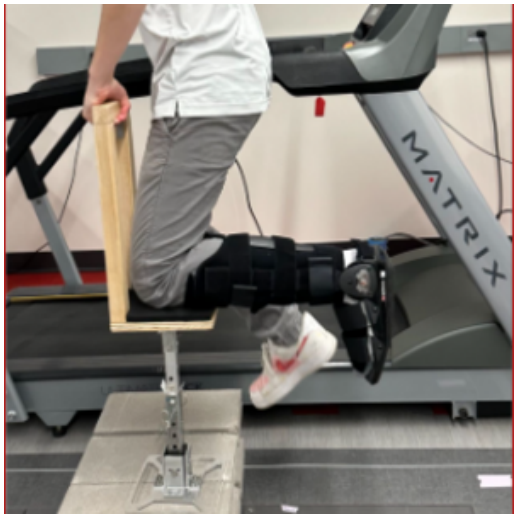
Analyze data for presentation.

CAMERON OWENS - May 01, 2024, 11:02 AM CDT

Download

Screenshot_2024-05-01_at_11.02.00_AM.png (170 kB)

CAMERON OWENS - May 01, 2024, 11:02 AM CDT



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Screenshot_2024-05-01_at_11.02.08_AM.png (192 kB)

CAMERON OWENS - May 01, 2024, 11:02 AM CDT

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Screenshot_2024-05-01_at_11.02.16_AM.png (188 kB)

CAMERON OWENS - May 01, 2024, 11:02 AM CDT

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Screenshot_2024-05-01_at_11.02.27_AM.png (188 kB)

2024/05/01 COP Testing Results

MARGO AMATUZIO - May 01, 2024, 8:11 PM CDT

Title: Final COP Measure Results

Date: 05/01/2024

Content by: Margo Amatuzio

Present: BME Team

Goals:

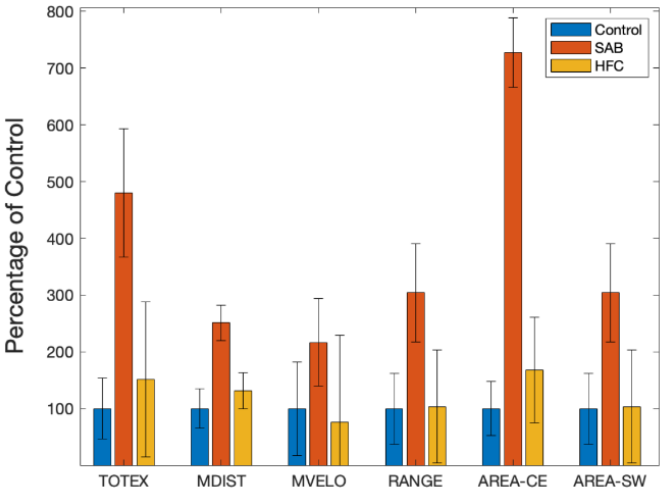
- Measures for COP tests to determine intervention stability

Content:

Mean ± standard deviations for COP measures across groups with statistical significance indicators.

	Control	SAB	HFC	SAB vs. Control	HFC vs. Control
TOTEX (cm)	261.65 ± 91.71	1256.71 ± 1166.99	396.89 ± 344.00	*	
MDIST (cm)	1.81 ± 0.47	4.54 ± 1.30	2.38 ± 0.67	***	*
MVELO (cm/s)	140.80 ± 65.15	428.44 ± 281.71	145.63 ± 89.54	*	
RANGE (cm)	43.77 ± 26.98	94.82 ± 38.94	33.41 ± 31.27	**	
AREA-CE (cm)	43.75 ± 14.79	318.06 ± 153.56	73.31 ± 43.43	***	
AREA-SW (cm_2/s)	140.72 ± 88.27	428.29 ± 369.36	145.57 ± 144.95	**	

Asterisks (*) indicate statistically significant differences (=p < 0.05, **=p<0.01, ***=p<0.001) compared to the control group, as determined by one-way ANOVA tests indicating a significant main group effect. SAB: stair-assist bench; HFC: hands-free crutch.*



Control, SAB, and HFC interventions for each COP measure. SAB and HFC normalized to percentage values based on the Control group.

Conclusions/action items:

- Include in final report

2024/05/01 Subject Feedback Results

MARGO AMATUZIO - May 01, 2024, 8:11 PM CDT

Title: Subject Feedback Results

Date: 05/01/2024

Content by: Margo Amatuzio

Present: BME Team

Goals:

- Assess subject feedback from the trials

Content:

Mean percentage of device preference, associated pain, and device comfort.

	SAB + BOOT %	HFC + BOOT %	SAB vs. HFC
Preference	100	0	*
Associated pain	44	48	
Device comfort	92	72	*

Asterisks (*) indicate statistically significant differences (=p < 0.05) of the SAB compared to the HFC, as determined by one-way ANOVA tests. SAB: stair-assist bench; HFC: hands-free crutch.*

Conclusions/action items:

- Include in final report

2024/05/1 Final Poster

CAMERON OWENS - May 01, 2024, 10:13 AM CDT

Title: Final Poster

Date: 24/4/26

Content by: Team

Present: Everyone

Goals: Create poster for presentation

Content:

Below

Conclusions/action items:

Present the poster

CAMERON OWENS - May 01, 2024, 10:13 AM CDT

Download

Final_Poster_402_-_stair_assist_bench_.pdf (1.32 MB)

2024/5/1 Final Report

CAMERON OWENS - May 01, 2024, 10:38 AM CDT

Title: Final Report

Date: 2024/5/1

Content by: Team

Present: n/a

Goals:

Content:

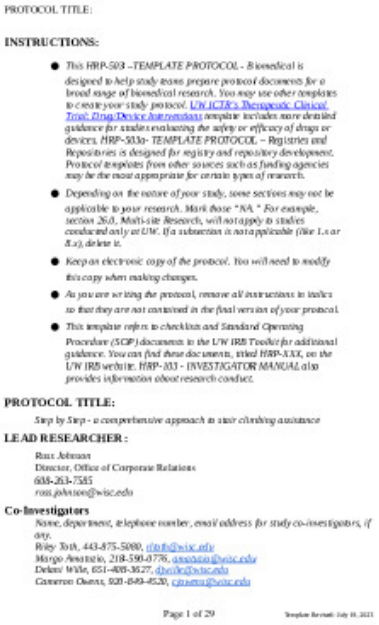
See Below

Conclusions/action items:

Submit deliverables.

2024/5/01 - Protocol

RILEY TOTH - May 01, 2024, 6:20 PM CDT



PROTOCOL TITLE:

INSTRUCTIONS:

- *This HRP-503 –TEMPLATE PROTOCOL - Biomedical is designed to help study teams prepare protocol documents for a broad range of biomedical research. You may use other templates to create your study protocol. UW ICTR's Therapeutic Clinical Trial, Drug/Device Intervention template includes more detailed guidance for studies evaluating the safety or efficacy of drugs or devices. HRP-503a- TEMPLATE PROTOCOL – Registries and Repositories is designed for registry and repository development. Protocol templates from other sources such as funding agencies may be the most appropriate for certain types of research.*
- *Depending on the nature of your study, some sections may not be applicable to your research. Mark those "NA." For example, section 26.0, Multi-site Research, will not apply to studies conducted only at UW. If a subsection is not applicable (like 1.1.a or 8.x), delete it.*
- *Keep an electronic copy of the protocol. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *This template refers to checklists and Standard Operating Procedure (SOP) documents in the UW IRB Toolkit for additional guidance. You can find these documents, titled HRP-XXX, on the UW IRB website. HRP-103 - INVESTIGATOR MANUAL also provides information about research conduct.*

PROTOCOL TITLE:

Step by Step - a comprehensive approach in stair climbing assistance

LEAD RESEARCHER:

Russ Johnson
Director, Office of Corporate Relations
608-263-7585
russ.johnson@wisc.edu

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Page 1 of 29 Template Revised: July 10, 2023

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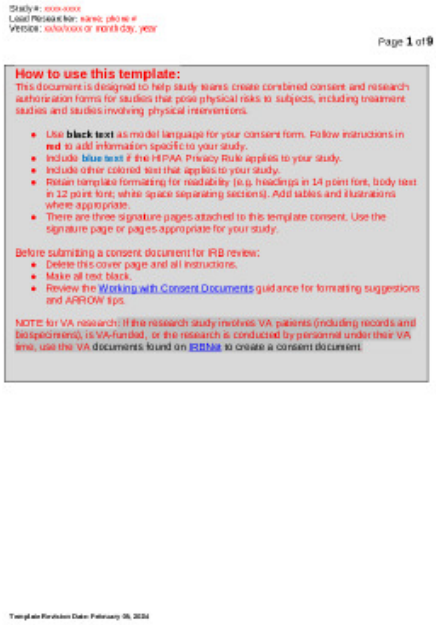
HRP-503_-_TEMPLATE_PROTOCOL_-_Biomedical_1_1_.docx (660 kB)

2024/5/01 - Consent Form

RILEY TOTH - May 01, 2024, 6:22 PM CDT



Study #: xxxx-xxxx
Lead Research Site: name, phone #
Version: xx/xx/xxxx or month-day, year

How to use this template:

This document is designed to help study teams create combined consent and research authorization forms for studies that pose physical risks to subjects, including treatment studies and studies involving physical interventions.

- Use **black text** as model language for your consent form. Follow instructions in **red** to add information specific to your study.
- Include **blue text** if the HIPAA Privacy Rule applies to your study.
- Include other colored text that applies to your study.
- Retain template formatting for readability (e.g. headings in 14 point font, body text in 12 point font; white space separating sections). Add tables and illustrations where appropriate.
- There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study.

Before submitting a consent document for IRB review:

- Delete this cover page and all instructions.
- Make all text black.
- Review the Working with Consent Documents guidance for formatting suggestions and ARROW tips.

NOTE for VA research: If the research study involves VA patients (including records and biospecimens), is VA-funded, or the research is conducted by personnel under their VA time, use the VA documents found on RISNet to create a consent document.

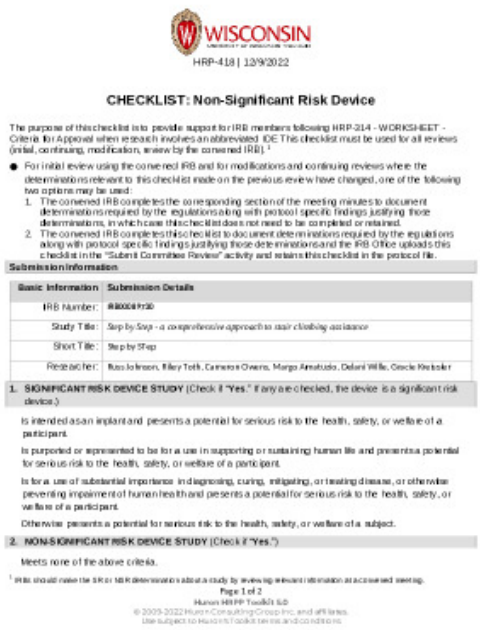
Template Revision Date: February 29, 2024

Download

HRP-502_-_TEMPLATE_CONSENT_DOCUMENT_1_1_.docx (425 kB)

2024/5/01 - Checklist

RILEY TOTH - May 01, 2024, 6:22 PM CDT



HRP-418 | 12/9/2022

CHECKLIST: Non-Significant Risk Device

The purpose of this checklist is to provide support for IRB members following HRP-314 - WORKSHEET - Criteria for Approval when research involves an abbreviated IDE. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB).[1]

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Submit Committee Review" activity and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	#####
Study Title:	*Step by Step - a comprehensive approach to stair climbing assistance*
Short Title:	Step by Step
Researcher:	Russ Johnson, Riley Toth, Cameron Owens, Margo Amatuzio, Delani Wille, Gracie Kreissler

1. SIGNIFICANT RISK DEVICE STUDY (Check if "Yes." If any are checked, the device is a significant risk device.)

Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a participant.

Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant.

Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a participant.

Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2. NON-SIGNIFICANT RISK DEVICE STUDY (Check if "Yes.")

Meets none of the above criteria.

[1] IRB should make the SR or NSR determination about a study by reviewing relevant information at a convened meeting.

Download

HRP-418_-_CHECKLIST_-_Non-Significant_Risk_Device_1_.docx (927 kB)

2024/5/01 - Status

RILEY TOTH - May 01, 2024, 6:33 PM CDT

Title: Current Status of ARROW Application

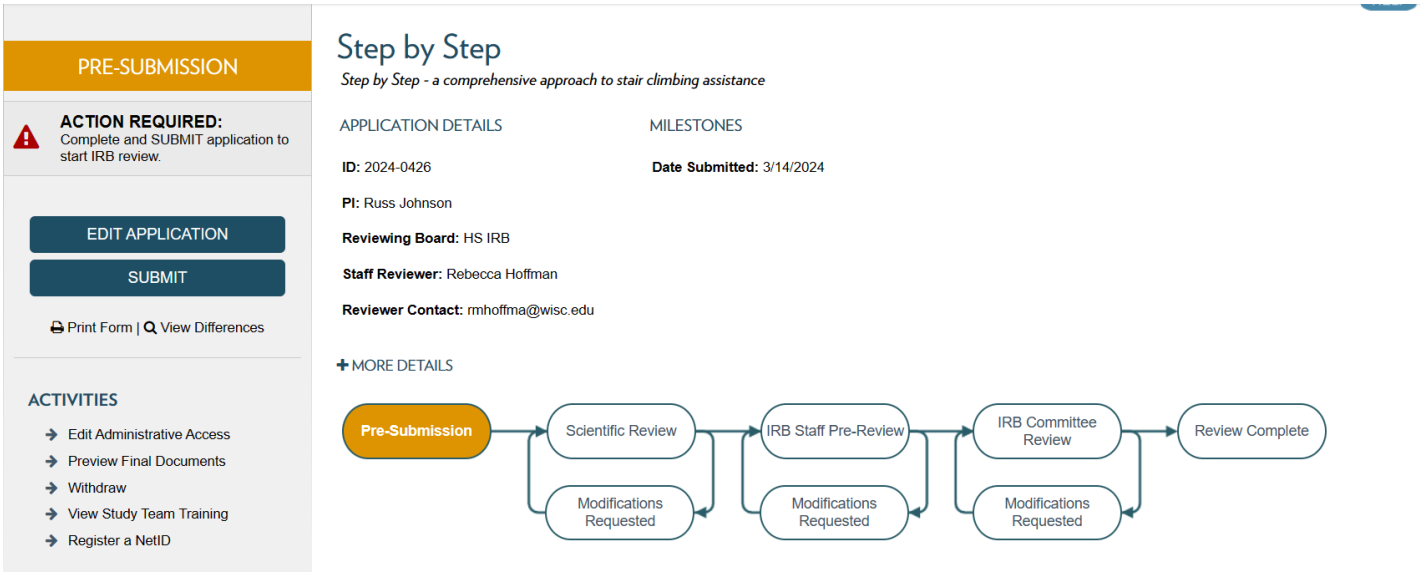
Date: 05/01/2024

Content by: Riley Toth

Present: Riley Toth

Goals: Relay the current location of the ARROW application

Content:



Conclusions/action items:

Rebecca Hoffman is the current reviewer of this application but Steph Metzger helped me fill everything out

Much is missing and needs to be done. It is a template as best but can change based on the test you choose to do. because our test kept on changing it was hard to make a complete application to the standards they wanted.

2023/02/09 iWalk Testing Protocol

Title: iWalk Testing Protocol

Date: 02/09/2024

Content by: Margo Amatuzio

Present: N/A

Goals:

- Examine iWalk testing protocol to build current experimentation

Source:

“iWalk Hands Free Crutch - Full Text View - ClinicalTrials.gov,” Clinicaltrials.gov, 2021. https://classic.clinicaltrials.gov/ct2/show/study/NCT04978363 (accessed Feb. 09, 2024).

Content:

Study Design:

- Intervention model:

All participants will complete all six testing conditions, including:

1. BOOT (walking boot)
2. HFC + BOOT (Hands Free Crutch with the walking boot)
3. SAC + BOOT (Standard Axillary Crutches with the walking boot)
4. NONE (no device/baseline)
5. HFC NO BOOT (Hands Free Crutch with no walking boot) and
6. SAC NO BOOT (Standard Axillary Crutches with no walking boot).

The order of the four primary conditions will be randomized using an online random number generator (1-4) with:

1=NONE, 2=BOOT only, 3=HFC+BOOT, and 4=SAC+BOOT.

- 21 participants
- motion capture data from infrared camera system with 12 mounted cameras surrounding a level walkway
- balance data through self-reported activity-specific balance confidence (ABC) questionnaire
- healthy individuals
- participants complete 5 total sessions
- participants complete pre-consent screening and consent paperwork
    - randomized to the four conditions
    - anthropometric data (height, weight/mass, leg length, shoe length and width) and demographic data
- data collected using 50 small reflective markers placed on the participants and the devices, computerized motion capture system and force plates on the floor
    - force plates for GRF and calc joint moments for interpretation of angular momentum data

Outcome measures

- **w**hole body angular momentum-sagittal plane
- ABC questionnaire
- numerical pain rating scale
- participant device comfort score
- participant device numerical score
- participant device preference

Eligibility

- 18 to 45 years
- male or female
- 5'2 and 6'6
- healthy individuals
- full active pain free ROM of bilateral upper and lower extremities

Exclusion

- weight greater than 270lb
- BMI greater than 35
- max thigh circumference at top of leg greater than 28"

Conclusions/action items:

- Use iWalk protocol to inform design of our device protocol

2024/02/28 ABC Questionnaire

MARGO AMATUZIO - Feb 28, 2024, 11:43 AM CST

Title: ABC Questionnaire (Draft)

Date: 02/28/2024

Content by: Margo Amatuzio

Present: N/A

Goals:

- Draft ABC questionnaire for the trials

Content:

The Activities-specific Balance Confidence (ABC) Scale for an assistive device designed to navigate stairs with a non-weight bearing limb involves assessing users' confidence in performing various activities without losing balance or experiencing fear of falling. This questionnaire is tailored to understand how the device impacts users' confidence levels in navigating stairs under specific conditions.

For each activity listed below, please rate your confidence by selecting a percentage that best describes your current level of confidence. The scale ranges from 0% (no confidence) to 100% (completely confident).

1. Ascending stairs without assistance
    - How confident are you in ascending stairs using the device without any assistance?
2. Descending stairs without assistance
    - How confident are you in descending stairs using the device without any assistance?
3. Ascending and descending stairs in various lighting conditions
    - How confident are you in using the device on stairs under poor lighting conditions?
4. Using the device on different types of stair materials (e.g., wood, carpet, metal)
    - How confident are you in using the device on stairs made of different materials?
5. Using the device during times of physical discomfort (e.g., fatigue, pain)
    - How confident are you in using the device when experiencing physical discomfort?
6. Using the device in emergency situations (e.g., need to quickly evacuate)
    - How confident are you in quickly and safely using the device in an emergency situation?
7. Using the device on stairs with varying step heights
    - How confident are you in using the device on stairs that have irregular step heights?
8. Transferring onto and off the device
    - How confident are you in safely transferring onto and off the device before and after navigating stairs?
9. Using the device on narrow stairs
    - Navigating narrow or crowded staircases with your non-weight bearing limb on the device bench and using the handrails for support.

Please provide your confidence level for each activity listed above. This information will be crucial in assessing the device's impact on your ability to navigate stairs safely and independently.

Conclusions/action items:

- Bring to team to adjust and modify for the trials

2024/02/28 3D-Printing Knee Cushion

MARGO AMATUZIO - Feb 28, 2024, 7:39 PM CST

Title: 3D-Printing Knee Cushion Materials and Software

Date: 02/28/2024

Content by: Margo Amatuzio

Present: N/A

Goals:

- Obtain materials and software for 3D printing options for the bench cushion

Source:
D.-R. Viziteu, A. Curteza, and M. Avadanei, "Prototyping Tutorial for Protective Knee Pad Design Using 3D Printing Technology," in Proc. 17th Int'l Scientific Conf. eLearning and Software for Education, Bucharest, Romania, Apr. 22-23, 2021, pp. 248. doi: 10.12753/2066-026X-21-172.

Content:

- Software Selection: Choose appropriate modeling software. The paper mentions Rhinoceros 3D and Grasshopper as tools that offer extensive capabilities for creating detailed models.
    - Rhinoceros 3D (Rhino): This is a highly versatile 3D modeling software that can handle tasks from drafting to intricate modeling. It is popular in various industries, including product design, architecture, and fashion, for its flexibility and wide range of capabilities. Rhino is particularly beneficial for designing complex shapes and surfaces due to its powerful NURBS (Non-Uniform Rational B-Splines) engine.
    - Grasshopper: This is a visual programming language and environment that runs within Rhino. Grasshopper allows designers to build generative algorithms to create complex models and automate repetitive processes without writing code in the traditional sense. It's particularly useful for exploring parametric designs, where you can adjust parameters to iterate designs quickly.
- Initial Design: Create the initial virtual model of the knee pad, taking into consideration the ergonomic requirements and intended functionality.
- Simulation Tools: Utilize the simulation tools available within the modelling software to evaluate the performance of the knee pad design under various conditions that mimic real-world stresses it might encounter.
- Material Selection: Choose appropriate materials. The paper suggests experimenting with plastics of varying degrees of rigidity to assess their fit with the needs of climbers.
    - TPU (Thermoplastic Polyurethane): TPU is known for its flexibility, durability, and resistance to abrasion and many chemicals. It's a popular choice for making protective gear due to its shock-absorbing properties and flexibility. TPU can simulate the softness and flexibility of rubber, making it suitable for protective knee pads that require a balance between protection and comfort.
    - PLA (Polylactic Acid) with Impact Modifiers: While standard PLA is known for its rigidity and might not be the first choice for protective equipment, certain modifications and blends make it more suitable. By incorporating impact modifiers, PLA's brittleness can be reduced, and its impact resistance can be enhanced, making it a potential material for parts of the knee pad that require structural integrity.
    - ABS (Acrylonitrile Butadiene Styrene): ABS is another thermoplastic with good mechanical properties, including toughness and impact resistance. It could be used for parts of the knee pad that require rigidity and strength. However, it's worth noting that ABS lacks the flexibility of TPU, making it more suitable for the outer shells rather than the parts that directly interact with the user's skin.
    - Flexible Filaments (Various Blends): There are many flexible filaments available on the market, designed specifically for 3D printing applications requiring elasticity and flexibility. These materials can range in flexibility, from semi-flexible, like certain PETG (Polyethylene Terephthalate Glycol) variants, to highly flexible, mimicking rubber or soft silicone. These materials are well-suited for areas of the knee pad that need to conform closely to the body and absorb impacts.
    - Composite Materials: Composite filaments are standard plastics (like PLA, ABS, PETG) that are mixed with other materials (such as carbon fiber, glass fiber, or even wood). These materials can enhance certain properties, like strength and durability, without significantly compromising weight or flexibility. For knee pads, a composite material could provide additional protection or durability in high-stress areas

Conclusions/action items:

- Consider options for 3D-printing and select a suitable material

2024/02/28 Adjustable Column Spring Pin

MARGO AMATUZIO - Feb 28, 2024, 11:29 AM CST

Title: Adjustable Column Spring Pin Design

Date: 02/28/2024

Content by: Margo Amatuzio

Present: N/A

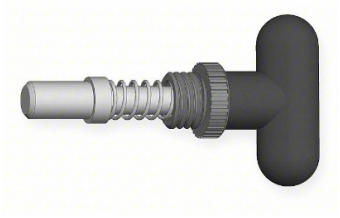
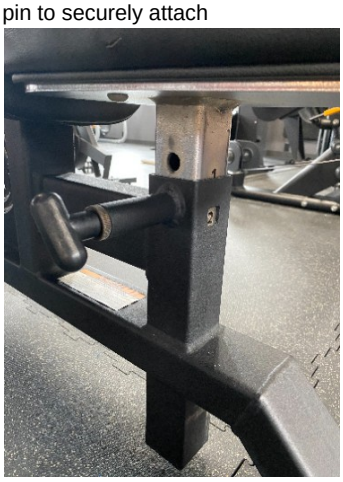
Source:

“Quick Release Pin: Rounded T-Knob, Steel, Zinc Finish,” *Grainger*, 2024. https://www.grainger.com/product/3CRP6?gucid=N:N:PS:Paid:GGL:CSM-2295:4P7A1P:20501231&gad_source=1&gclid=CjwKCAiA0PuuBhBsEiwAS7fsNVJu7D14pYO2pBR9OFyvcqQCQcItdyaAfsr81R7Gi0wEFOKqH73zjxoC-V8QAvD_BwE&gclsrc=aw.ds (accessed Feb. 28, 2024).

Goals:

- Design adjustable column for the device base

Content:

- quick release pin: rounded T-knob, steel, zinc finish
  - 
- two columns fit flush together with 1 inch increments
- spring pin to securely attach
  - 
  - above photo taken at the gym

Conclusions/action items:

- Implement design idea in prototyping adjustable column

Statistical Analysis

GRACE KREISSLER - Feb 28, 2024, 7:59 PM CST

Title: Statistical Analysis

Date: 2/27/2024

Content by: Gracie Kreissler

Present: N/A

Goals:

The goal of this research is to determine which statistical method would be best for our study and how the parameters we are measuring fit into the statistical parameters. From previous knowledge learned in my statistics course here at UW, I decided to focus on an ANOVA test. This research will prove that ANOVA is a good option for validating our results and will also provide some knowledge on how to sort our variables.

Content:

- ANOVA test analyzes the effects of different interventions within a study. For our case, it would compare how the fracture boot, assistive device, and iWalk affect gait biomechanics [1].
- The within-subject factor will be the six research conditions (BOOT, BOOT + BENCH, NO BOOT + BENCH, BOOT + iWALK, NO BOOT + iWALK, NONE) [1].
- The between-subject factor will be participant demographics (gender, age) [1]
- Post-hoc tests (pairwise comparisons using Bonferroni correction) are performed to identify significant differences between specific intervention conditions - (BOOT, BOOT + BENCH, NO BOOT + BENCH, BOOT + iWALK, NO BOOT + iWALK, NONE) [2].
- Correlation analyses examine the relationship between calculated results and participant-reported outcomes.

Conclusions/action items:

ANOVA is a good option for our data analysis. Next steps are to determine which correlation analysis test is the right fit for our testing.

References

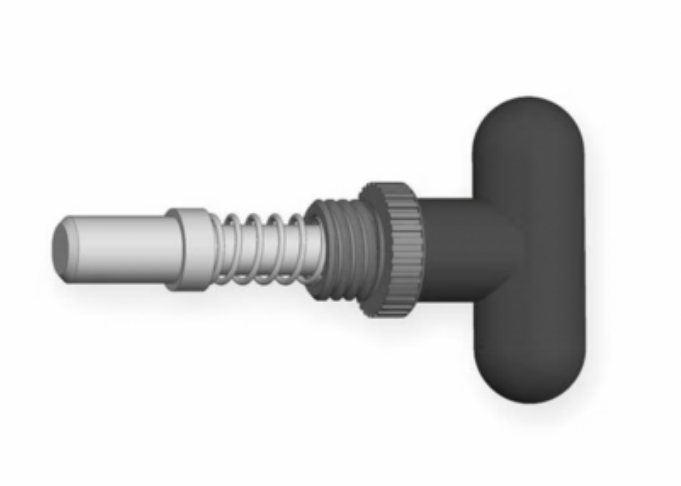
[1] How to perform a Mixed ANOVA in SPSS Statistics | Laerd Statistics. (n.d.). https://statistics.laerd.com/spss-tutorials/mixed-anova-using-spss-statistics.php

[2] Lee, S., & Lee, D. K. (2018). What is the proper way to apply the multiple comparison test? Korean Journal of Anesthesiology, 71(5), 353–360. https://doi.org/10.4097/kja.d.18.00242

[3] Faizi, N., & Alvi, Y. (2023). Correlation. In Elsevier eBooks (pp. 109–126). https://doi.org/10.1016/b978-0-443-18550-2.00002-5

Push Pin Design

GRACE KREISSLER - Feb 02, 2024, 11:03 AM CST



Download

Screen_Shot_2024-02-02_at_9.12.36_AM.png (463 kB)

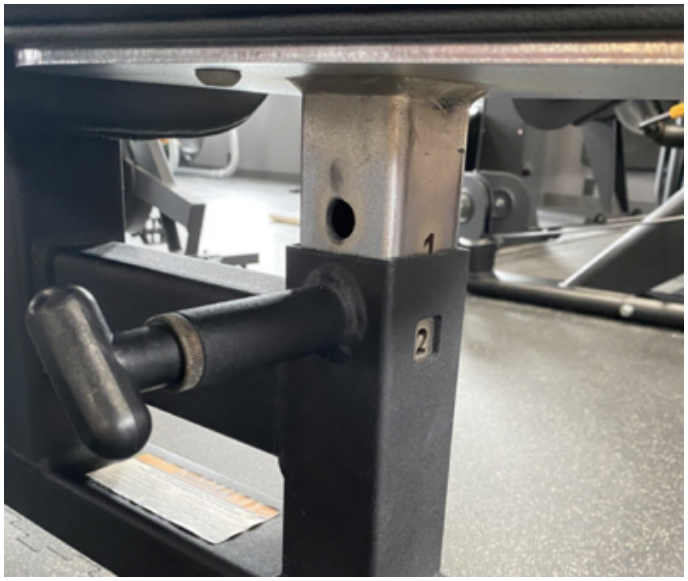
GRACE KREISSLER - Feb 02, 2024, 11:05 AM CST

Dimensions	
Thread Size	3/4"-10
Tip Dia.	3/8"
Barrel Dia.	1"
Barrel Height	1.50"
Tip Length	0.600"
Pin Dia.	3/8 in

Download

Screen_Shot_2024-02-02_at_9.12.52_AM.png (185 kB)

GRACE KREISSLER - Feb 02, 2024, 11:05 AM CST

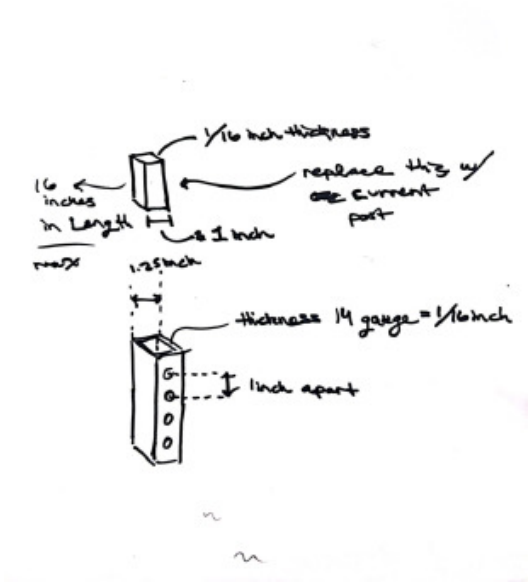


Download

Screen_Shot_2024-02-02_at_9.13.08_AM.png (672 kB)

Adjustable Design Rough Sketch

GRACE KREISSLER - Feb 28, 2024, 8:32 AM CST



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Adjustable_Design_Rough_Sketch.pdf (252 kB)

Adjustable Design CAD

GRACE KREISSLER - Feb 28, 2024, 8:49 AM CST

GRACE KREISSLER - Feb 28, 2024, 5:26 PM CST

Download

72902835102__38CA86A3-393E-42BC-9D51-5E38C182200D.HEIC (1.87 MB)

GRACE KREISSLER - Feb 28, 2024, 5:26 PM CST

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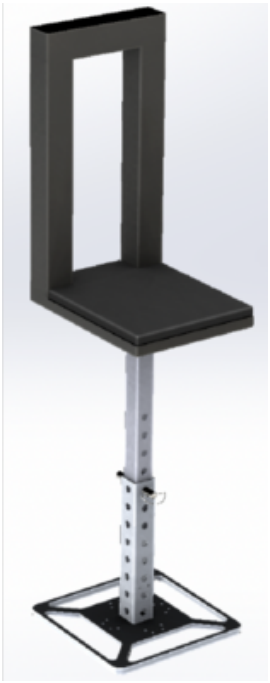
72903049096__1BEE1066-4D77-49B2-9255-88DF16C5B66D.HEIC (4.56 MB)

Final Prototype CAD

GRACE KREISSLER - May 01, 2024, 10:27 PM CDT



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Screen_Shot_2024-05-01_at_10.27.31_PM.png (209 kB)

GRACE KREISSLER - May 01, 2024, 10:28 PM CDT

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Screen_Shot_2024-05-01_at_10.28.03_PM.png (68.4 kB)

2024/2/15-Ground Reaction Force and Stability study

Delani Wille - Feb 28, 2024, 10:12 PM CST

Title: Ground Reaction Force Study

Date: 2/15/2024

Content by: Delani Wille

Present: N/a

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Link: https://www-sciencedirect-com.ezproxy.library.wisc.edu/science/article/pii/S096663620300198X?via%3Dihub

Cite: A. Stacoff, C. Diezi, G. Luder, E. Stüssi, and I. A. Kramers-de Quervain, “Ground reaction forces on stairs: effects of stair inclination and age,” *Gait Posture*, vol. 21, no. 1, pp. 24–38, Jan. 2005, doi: 10.1016/j.gaitpost.2003.11.003.

Content:

- Study Goals:
  - Compare vertical ground reaction force (GRF) data during level walking, stair ascent, and descent across different stair inclinations and age groups.
  - Test 20 healthy subjects from three age groups (young, middle, old) across seven test conditions with 8-10 repetitions.
- Data Collection:
  - Measure vertical forces during two consecutive steps using force plates embedded in walkway and staircase.
- Level Walking Findings:
  - Regular and repetitive vertical GRF curves with low variability and asymmetry.
- Stair Ambulation Findings:
  - Slight changes in vertical GRF pattern during stair ascent compared to level walking.
  - Considerable changes during stair descent, especially on steep stairs with increased load, variability, and asymmetry.
  - Steep stair descent deemed most demanding, showing least stable gait pattern.
- Impact of Age:
  - Young age group exhibited faster walking and larger vertical GRF maxima during level walking and stair ascent.
  - Differences between middle and old age group were minimal.
- Study Significance:
  - First to provide normative GRF data on gait variability and symmetry during level walking and stair ambulation.
  - Intended for comparison with patient data and informing further research on gait stability, especially on stairs.
- Introduction:
  - Stairs pose fall risks, especially for the elderly, yet research on stair ambulation and GRF measurements is limited.
- Gait Analysis Context:
  - Traditional focus on vertical GRF in level walking; less known about its characteristics during stair ascent and descent.
- Gap in Knowledge:
  - Lack of data on reproducibility and characteristics of vertical GRF during stair ambulation and its dependence on stair inclination and age.
- Methodological Considerations:
  - Description of first two steps as a transition phase; need for minimum five steps for steady-state analysis.
- Previous Studies' Limitations:
  - Many studies used inadequate test stairs, potentially affecting data quality.

Conclusions/action items: Use as background for testing GRF on stairs.

2024/1/30 - Complications of Crutches

Delani Wille - Feb 28, 2024, 10:18 PM CST

Title: Complications of Crutches

Date: 1/30/2024

Content by: Delani Wille

Present: N/a

Goals: Purpose of device and pitfalls of standard devices

link: https://www.ucl.ac.uk/civil-environmental-geomatic-engineering/sites/civil_environmental_geomatic_engineering/files/the_complications_of_crutches_-_a_summary_of_a_systematic_review_of_the_literature.pdf

Cite: N. Papadosifos, “The Complications of Crutches - A Summary of a Systematic Review of the Literature”.

Content:

Background
- Over 575,000 people annually receive crutch prescriptions in the USA.
- Limited data exists on complications associated with crutch use.
- Systematic review aims to provide comprehensive overview of crutch-related complications.

Aims & Objectives:
- Raise awareness among health professionals prescribing crutches.
- Encourage scientific exploration for improved crutch designs.

Methods:
- Online literature search conducted using Medline and PubMed.
- English language articles searched irrespective of publication year.
- Manual examination of bibliography and citation lists for additional articles.
- Manual search across UK and European libraries after exhausting electronic resources.

Key Findings:
- Lack of previous systematic reviews in this area.
- Crutch use is widespread without significant scientific attention to clinical practice or design modifications.
- Crutch design has remained largely unchanged over time.
- Complications can occur even with short-term use and may be underreported.
- Serious complications, such as arm or hand amputation, can occur.
- Axillary crutches are significantly associated with injury incidents.

Conclusions/action items: Use as background for study and market gap

2024/2/18 - IWalk IRB

Delani Wille - Feb 28, 2024, 10:00 PM CST

Title: iWalk IRB

Date: 2/18/2024

Content by: Delani Wille

Present: N/a

Goals: Compare IRB testing for device similar to our device

link: https://classic.clinicaltrials.gov/ct2/show/NCT04978363

Cite: J. Wilken, “Effects of a Hands Free Crutch on Walking Stability During Gait,” clinicaltrials.gov, Clinical trial registration NCT04978363, Apr. 2023. Accessed: Dec. 31, 2023. [Online]. Available: https://clinicaltrials.gov/study/NCT04978363

Content:

-Study Objective: To compare the effectiveness of Hands-Free Crutch (HFC) to Standard Axillary Crutches (SACs) with and without a walking boot regarding walking stability, balance confidence, patient preference, device comfort, and reported pain.
-Participant Profile: Healthy individuals wearing a walking boot to simulate a below knee injury or post-surgery condition, maintaining a non-weight bearing status.
- Research Conditions: Participants undergo four conditions in randomized order: BOOT, HFC + BOOT, SAC + BOOT, or NONE (without boot). Two additional conditions, HFC NO BOOT and SAC NO BOOT, are included to assess the effect of crutch use alone.
-Data Collection: Five sessions include pre-consent screening, anthropometric data collection, and biomechanics data collection sessions corresponding to each condition. Whole body angular momentum, balance confidence, device preference, and pain levels are measured using reflective markers, motion capture system, force plates, validated questionnaires, and numerical pain rating scale.
- Purpose of Research: Evaluate the impact of crutch and boot use on walking stability, balance confidence, and device preference to inform clinical prescription and application by physical therapists and providers.
- Study Design: Interventional clinical trial with 21 participants undergoing all six testing conditions in a crossover assignment. Randomization is used to determine the order of primary conditions. The study commenced on October 5, 2021, and concluded on January 27, 2022.

Conclusions/action items: iWalk clinical trial can be used to model our IRB study

2024/02/01 - Awarded iWalk patent

Delani Wille - Feb 28, 2024, 10:07 PM CST

Title: Iwalk Patent

Date: 2/1/2024

Content by: Delani wille

Present: n/a

Goals: Establish possible intellectual property based on competitive market

Content:

- Crutch Design Features:
  - Leg platform supports a portion of the user's leg.
  - Ground contact with weight supporting medial and lateral regions.
  - Optional strap for maintaining leg position.
  - Optional thigh saddle to prevent lateral movement.
  - Optional front-facing handle for user assistance.

- Claimed Crutch Characteristics:
  - Medial contact region positioned higher by at least 2 mm than lateral contact region.
  - Both regions touch surface at a minimum 2° angle off vertical.
  - Leg platform transitions from "U" shaped anterior portion to "V" shaped posterior portion.
  - Various fasteners for knee and lower leg support.
  - Upper leg restraint with flexible mechanism and laterally adjustable thigh member.

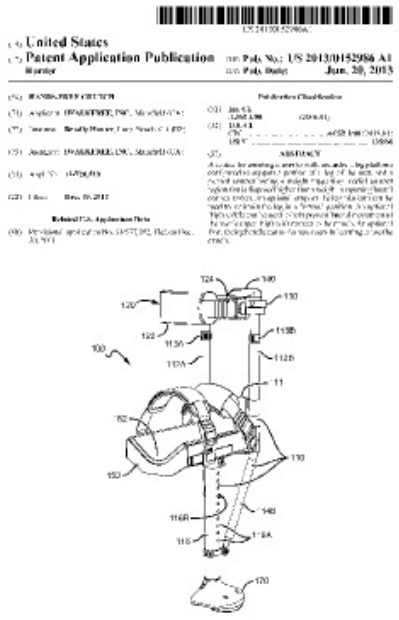
- Ground Contact and Frame Details:
  - Medial and lateral contact regions on sagitally oriented rockers.
  - Options for user-replaceable tread.
  - Frame includes handle positioned for user comfort and alignment.

- Additional Adjustments and Configurations:
  - Mechanisms for adjusting height difference between contact regions.
  - Frame with adjustable height.
  - Thigh member for alignment with user's leg.
  - Foot with medial ground contact portion elevated at least 1 mm relative to lateral portion.

- Variations in Handle Position:
  - Handle position relative to frame and leg platform.
  - Proximity of handle top to frame top.

Conclusions/action items: Review valid claims of device in comparison to our stair assist bench.

Delani Wille - Feb 28, 2024, 10:07 PM CST



United States
Patent Application Publication
Pub. No.: US 2013/0152986 A1
Pub. Date: Jun. 20, 2013

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US20130152986A1.pdf (1.09 MB)

2024/4/03- EZ Step climber

Delani Wille - May 01, 2024, 11:13 AM CDT

Title: EZ step climber

Date: 4/3/2024

Content by: Delani

Present: n/a

Goals:

link: https://ezstepclimber.com/

Cite: “EZ Step Climber,” EZ Step Climber. Accessed: May 01, 2024. [Online]. Available: https://ezstepclimber.com/

Content:

- Awarded patent to EZ step climber US 8302974 • US 9107503

- 4 leg chair/walker assistive device for stairs

1.Walking on Level Surfaces:Enables walking on flat surfaces without the need for assistance or crutches.
2. Ascending and Descending Ramps: Facilitates effortless movement up and down ramps without external aid.
3. Climbing Stairs:Allows for climbing stairs independently, eliminating the reliance on crutches or assistance.
4. Sitting Rest: Provides a comfortable sitting position on level ground, ramps, or stair steps, ensuring convenience and versatility.

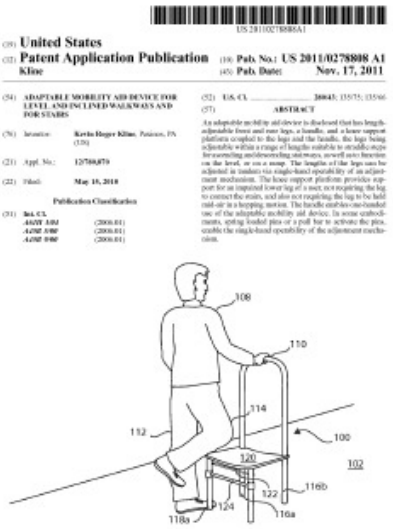
Using the EZ Step Climber is straightforward:

- Place your injured leg's good knee onto the device.
- Shift your weight onto the EZ Step Climber while taking a step with your uninjured leg.
- Transfer your weight back to your uninjured leg as the device is moved forward.
- Repeat this simple process for seamless mobility.

- The EZ Step Climber boasts user-friendly easy adjustment

Conclusions/action items: EZ Step climber is another main competitor in the space with design patents. Patent for Stair assist bench will need to work around existing patents.

Delani Wille - May 01, 2024, 11:13 AM CDT



(19) **United States**
(12) **Patent Application Publication** (10) **Pub. No.: US 2011/0278808 A1**
Kline (43) **Pub. Date: Nov. 17, 2011**

(54) **ADAPTABLE MOBILITY AID DEVICE FOR LEVEL AND INCLINED WALKWAYS AND FOR STAIRS**

(76) Inventor: **Kevin Roger Kline**, Paterson, PA (US)

(21) Appl. No.: **12/780,870**

(22) Filed: **May 15, 2010**

Publication Classification

(51) **Int. Cl.**
A63C 1/01 (2006.01)
A63C 5/00 (2006.01)
A63C 9/00 (2006.01)

(52) U.S. Cl. **280/43; 135/75; 135/66**

(57) **ABSTRACT**

An adaptable mobility aid device is disclosed that has length-adjustable front and rear legs, a handle, and a lower support platform coupled to the legs and the handle, the legs being adjustable within a range of lengths suitable to straddle steps for ascending and descending stairways, as well as to function on the level, or on a ramp. The lengths of the legs can be adjusted in tandem via single-hand operability of an adjustment mechanism. The lower support platform provides support for an impaired lower leg of a user, not requiring the leg to contact the stairs, and also not requiring the leg to be held mid-air in a hopping motion. The handle enables one-handed use of the adaptable mobility aid device. In some embodiments, spring loaded pins or a pull bar to activate the pins, enable the single-hand operability of the adjustment mechanism.

Download

ezclimber_patent.pdf (1.95 MB)

Delani Wille - May 01, 2024, 11:15 AM CDT

UNITED STATES PATENT AND TRADEMARK OFFICE

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Download

74209_12780870_04-26-2012_CTNF.PDF (392 kB) Claim rejections of EZ step

Delani Wille - May 01, 2024, 11:16 AM CDT

UNITED STATES PATENT AND TRADEMARK OFFICE

NOTICE OF ALLOWANCE AND FEE(S) DUE

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

Download

74209_12780870_08-02-2012_NOA.PDF (461 kB) Revised patent claims for EZ step, results in design patent instead of a utility patent

Delani Wille - May 01, 2024, 11:21 AM CDT

The Physical Therapy Department at the University of North Dakota conducted a comparative analysis examining muscle activity and range of motion (ROM) while ascending and descending a standard stairway versus the same stairway outfitted with the EZ-Step Stair Climbing Cane. The findings revealed a significant decrease in muscle activity necessary for both ascending and descending, alongside a noticeable reduction in required ROM when utilizing the EZ-Step equipped stairway.

Purpose of the Study:

- Compare lower extremity muscle activity and range of motion (ROM) during stair climbing with the Portable Quad-Step assistive device versus standard stair climbing.

- Participants: Twenty-nine volunteers aged 65 to 88 years.

Procedures:

- Two stair-climbing trials: Portable Quad-Step and standard steps without an assistive device.

- Participants used handrails for both trials, with the order randomized.

- Practice sessions were provided to ensure familiarity with the devices.

Results:

- EMG Activity:

  - Significant reduction in muscle activity with the Portable Quad-Step during stair climbing, compared to standard stairs.

- Range of Motion:

  - Hip: Reduced peak hip ROM during stair ascent with the Portable Quad-Step, but not during descent.

  - Knee: Reduced knee ROM for both ascent and descent with the Portable Quad-Step.

Discussion:

- Findings suggest reduced muscle activity and joint contact forces with the Portable Quad-Step, potentially beneficial for individuals with degenerative joint disorders or muscle weakness.

- Reduction in knee and hip ROM may contribute to decreased muscle activity and joint contact forces.

Conclusion:

- The Portable Quad-Step demonstrated lower muscle activity and reduced hip and knee ROM compared to standard stairs.

- This reduction in muscle activity and joint ROM may be advantageous for individuals with joint disorders or restricted ROM, potentially enhancing functional independence.

Cite:“University Study,” John Stocker. Accessed: May 01, 2024. [Online]. Available: http://www.ez-step.com/univ.-study.html

2024/4/15- Assistive devices Market

Delani Wille - May 01, 2024, 11:26 AM CDT

Title: Assistive devices Market

Date: 4/15/2024

Content by: Delani

Present: n/a

Goals: Understand the possible market for Stair Assist Bench

link: https://www.gminsights.com/industry-analysis/stair-lifts-and-climbing-devices-market

Cite: “Stair Lifts and Climbing Devices Market Share & Trends, 2032,” Global Market Insights Inc. Accessed: May 01, 2024. [Online]. Available: https://www.gminsights.com/industry-analysis/stair-lifts-and-climbing-devices-market

Content:

-Stair lifts and Climbing device market values ar 2 Billion in 2023, estimated to reach of 4.1 billion my 2032

- market increase due to increasing disability rates, aging population and government initiatives

- CAGR: 8.3%

Conclusions/action items: There is a large market for assistive mobility aids and even if our product captures a small amount of this market it will be profitable.

2024/2/06-FDA device guidance

Delani Wille - Feb 28, 2024, 10:24 PM CST

Title: FDA device class

Date: 2/6/2024

Content by: Delani Wille

Present: n/a

Goals: explore FDA pathway for different device classes

link: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing#:~:text=Class%20I%20%E2%80%93%20These%20devices%20present,exempt%20from%20the%20regulatory%20process.

cite: C. for D. and R. Health, “Learn if a Medical Device Has Been Cleared by FDA for Marketing,” *FDA*, Nov. 2018, Accessed: Feb. 28, 2024. [Online]. Available: https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing

Content:

Regulatory Classes of Medical Devices:
- Class I: Minimal potential for harm, simpler design, 95% exempt from regulatory process.
- Class II: Most medical devices, includes powered wheelchairs, 43% of devices.
- Class III: Sustain or support life, implanted, present unreasonable risk, includes pacemakers, 10% of devices.
- Exempt: Certain Class I devices exempt from premarket notification, but still require registration.

Premarket Notification (510(k)):
- Manufacturers notify FDA before marketing new devices.
- Must demonstrate substantial equivalence to a device already on the market.

Premarket Approval (PMA):
- Required for new products with new materials or differing design.
- Must provide scientific evidence from human clinical trials demonstrating safety and effectiveness.

-Investigational Device Exemption (IDE):
- Allows use of investigational devices in clinical studies.
- Required for devices needing clinical data to support FDA clearance.
- Limits distribution to specified sites identified in the IDE application.
- Clinical studies monitored by Institutional Review Boards (IRBs) to ensure ethical principles and patient protection.

IRB Functions:
- Determine risk level of device/clinical study (significant or non-significant).
- Oversee patient selection criteria and informed consent.
- IRB determines need for IDE application based on risk assessment.
- FDA can overrule IRB risk determinations.
- IDE application required if device/clinical study deemed significant risk by IRB.

Confidentiality of IDE Information:
- FDA does not disclose existence of IDE due to confidentiality reasons.

Conclusions/action items: Our device is class one and may have market exemptions.

2024/4/18- Neoprene

Delani Wille - May 01, 2024, 11:03 AM CDT

Title: Neoprene

Date: 4/18/2024

Content by: Delani

Present: n/a

Goals: Determine is Neoprene would be a good material for the knee cushion

link: https://www.foamorder.com/learning-center/foam-utility/30-products-made-with-neoprene#:~:text=Neoprene%20is%20often%20used%20in%20medical%20applications%20due%20to%20its,and%20support%20to%20injured%20limbs.

Cite: “30 Things You Didn’t Know Were Made of Neoprene Fabric.” Accessed: May 01, 2024. [Online]. Available: https://www.foamorder.com/learning-center/foam-utility/30-products-made-with-neoprene

Content:

- Neoprene, recognized for its synthetic rubber composition and renowned for its resistance to oil, heat, and water, stands as a versatile and durable material, widely adopted across diverse sectors including automotive, medical, industrial, and sporting goods.
- Its adaptability renders it a sought-after choice for an array of applications, including wetsuits, life jackets, sporting equipment handles, yoga mats, exercise equipment padding, prosthetics, splints, casts, and braces.
-For sporting goods, neoprene's flexibility and insulating properties make it ideal for crafting wetsuits and buoyancy aids, ensuring both lightweight comfort and dependable warmth, even in frigid waters. It is incorporated in handles for equipment like baseball bats, golf clubs, and fishing rods not only enhances resilience but also mitigates wear and tear, prolonging the lifespan of such items.
- In exercise equipment offers a blend of softness and sturdiness ideal for yoga mats and protective padding, ensuring both comfort during workouts and long-lasting durability, minimizing the need for frequent replacements.
- In the medical field, neoprene's sterilizability and resistance to bacterial growth make it a preferred choice for orthopedic braces, splints, casts, and prosthetics, facilitating conformity to body contours and providing essential compression and support for injured limbs, thereby aiding in the healing process.

Conclusions/action items: Neoprene can provide a soft but sturdy leg cushion for the bench and can be easily cleaned. We will be using adhesive neoprene for the leg cushion on the stair assist bench.

2024/2/9- Fabrication Sketch

Delani Wille - Feb 28, 2024, 9:54 PM CST

Title: Fabrication sketch of main post

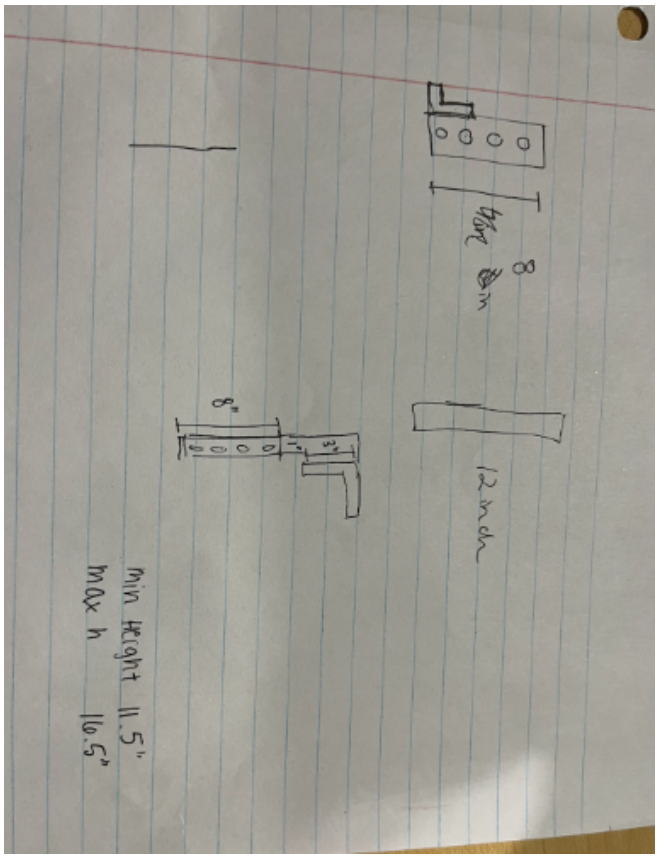
Date: 2/9/2024

Content by: Delani Wille

Present: Margo, Gracie, Cam, Riley

Goals: Determine maximum and minimum reach of main post for fabrication

Content:



Conclusions/action items: Design in CAD for true representation of main post.

2024/2/20 - Anti Catch Base design

Delani Wille - Feb 28, 2024, 9:51 PM CST

Title: Anti Catch Base Design

Date: 2/20/2024

Content by: Delani Wille

Present: N/a

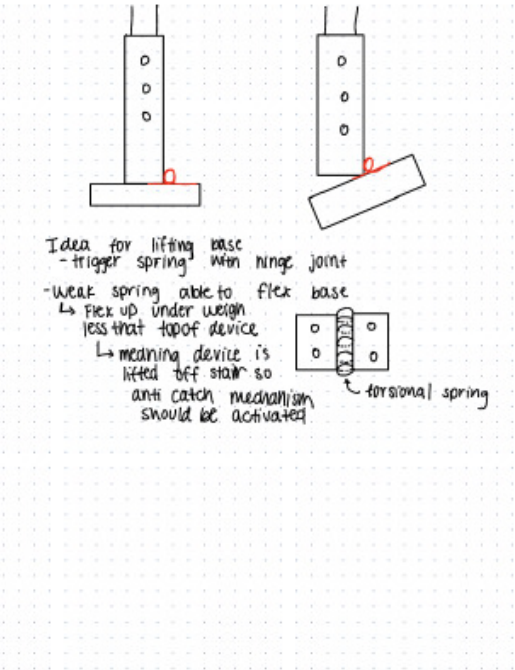
Goals: Design idea for base

Content:

PDF attached below

Conclusions/action items: Discuss design with team.

Delani Wille - Feb 28, 2024, 9:51 PM CST



Download

Anti_catch_mechanism.pdf (277 kB)

2024/04/18- Force Plate Stair design

Delani Wille - May 01, 2024, 10:35 AM CDT

Title: Force Plate Stair design

Date: 4/ 18/2024

Content by: Delani

Present: n/a

Goals: Design stairs to fabricate for force plate testing

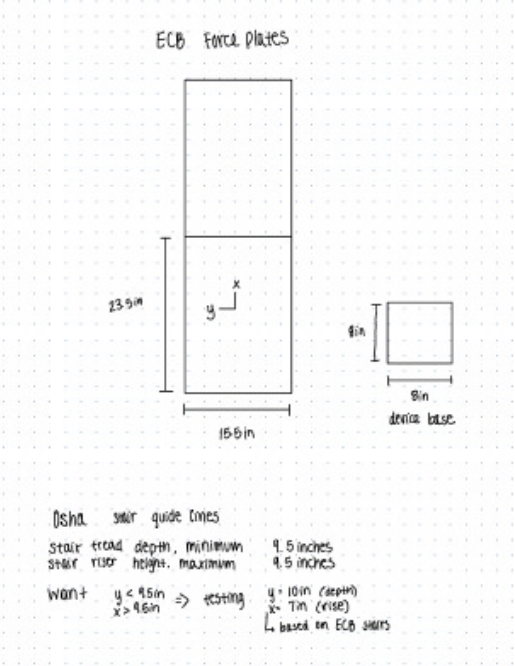
Content:

PDF attached

- images attached are of force plate measurements and stair heights in ECB.

Conclusions/action items: Go to home depot for wood supplies to fabricate

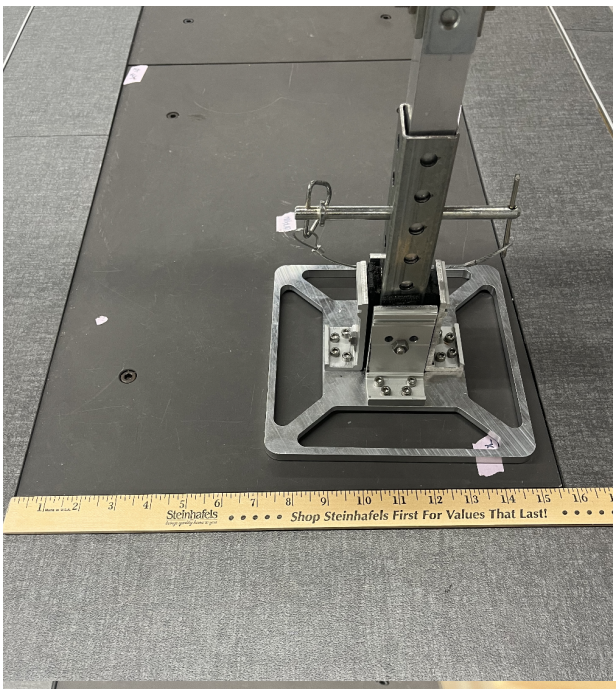
Delani Wille - May 01, 2024, 10:36 AM CDT

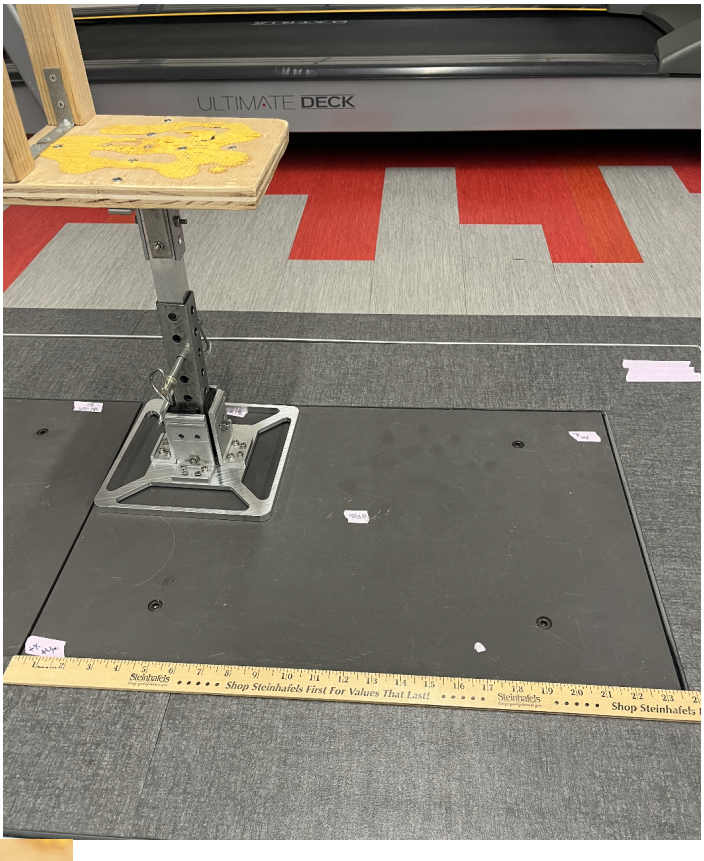


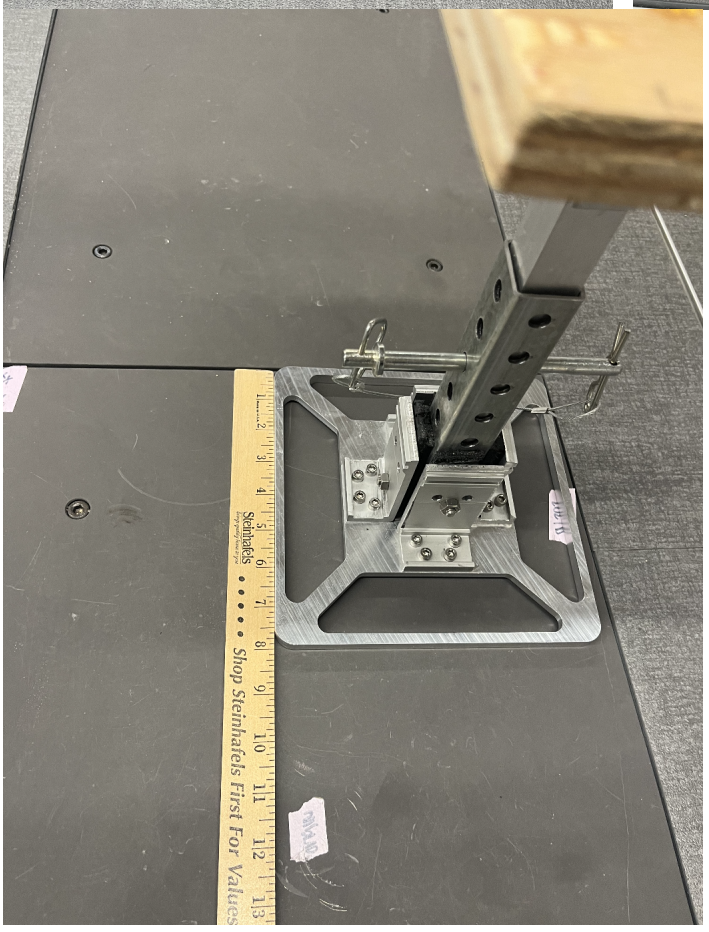
Download

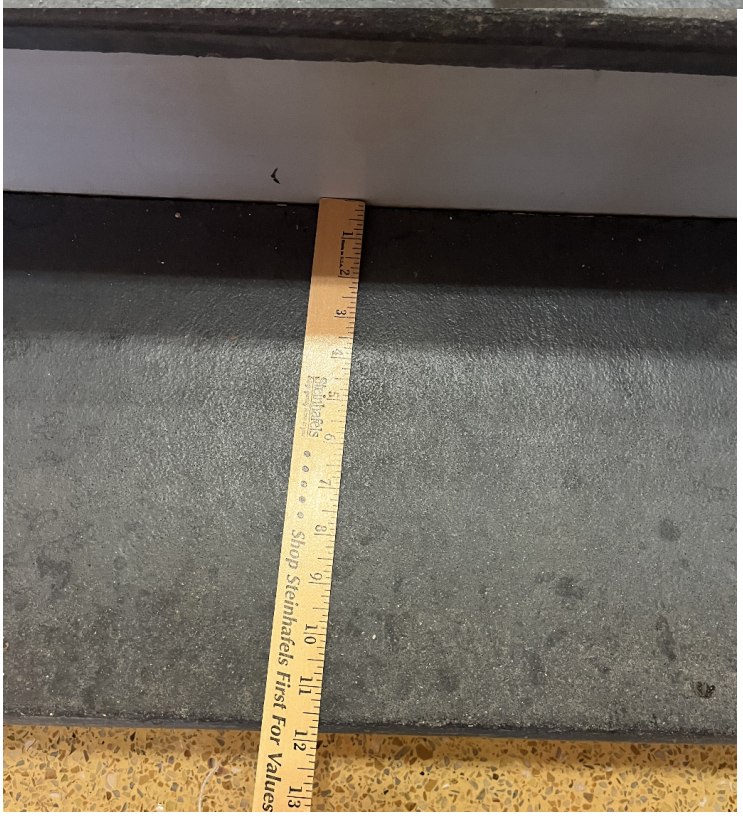
Stairs_fabrication_plan.pdf (868 kB)

Delani Wille - May 01, 2024, 10:39 AM CDT









Delani Wille - May 01, 2024, 10:42 AM CDT

After discussing with team stairs for force plate were made of cinderblocks from home depot as they matched stair riser height of 8 inches and were 15 1/2 inches wide to fit on force plate

2024/01/29 Red permit Documentation

Delani Wille - Jan 29, 2024, 3:43 PM CST

Title: Red Permit

Date: 01/29/24

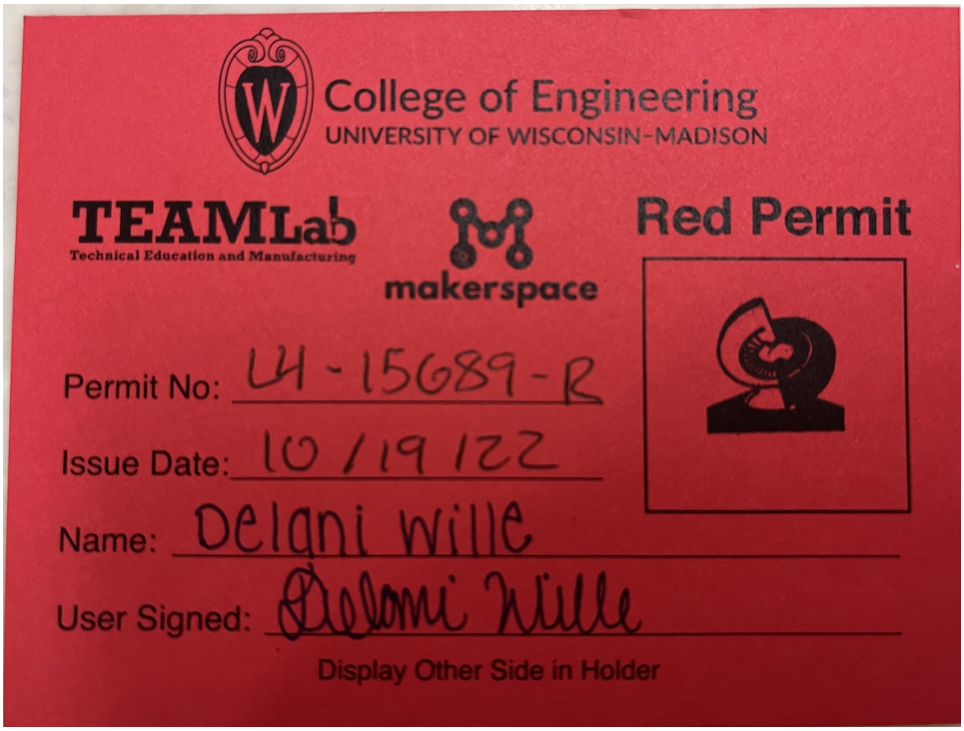
Content by: Delani Wille

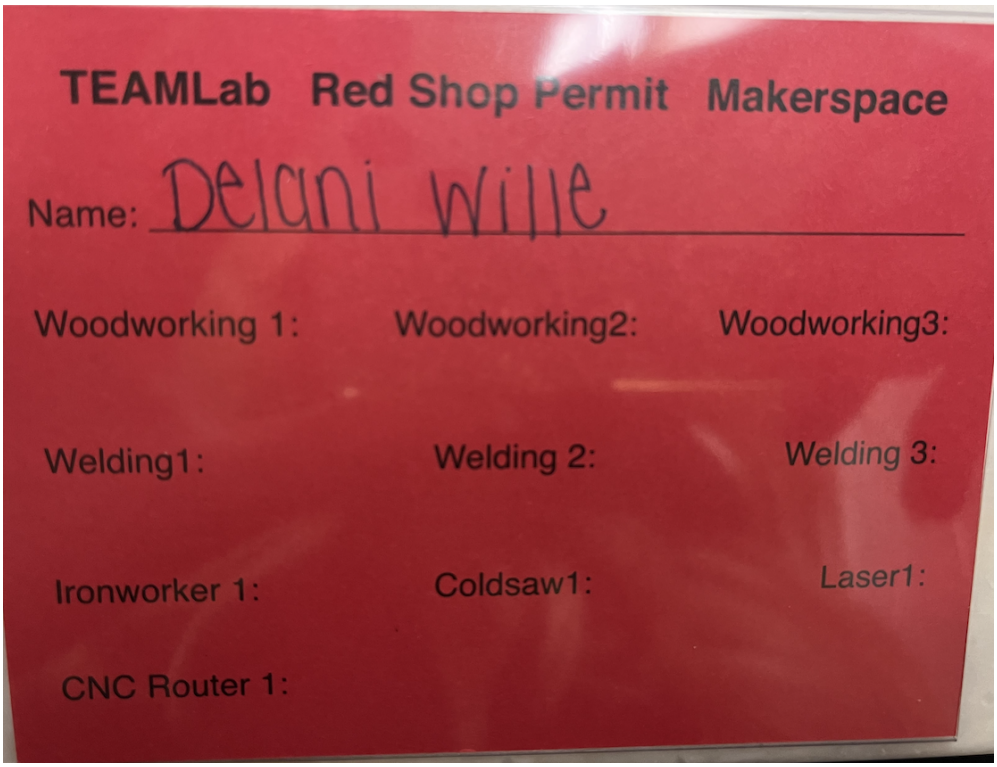
Present: n/a

Goals: Red permit

Content:

Red permit card





Conclusions/action items: Proof of red permit training. Now working on green permit.

2024/01/29 Green permit Documentation

Delani Wille - Jan 29, 2024, 3:44 PM CST

Title: Green Permit

Date: 01/29/2024

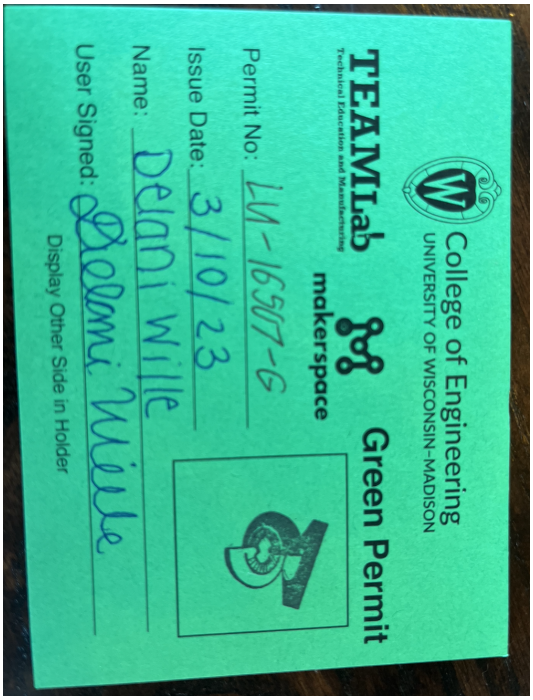
Content by: Delani Wille

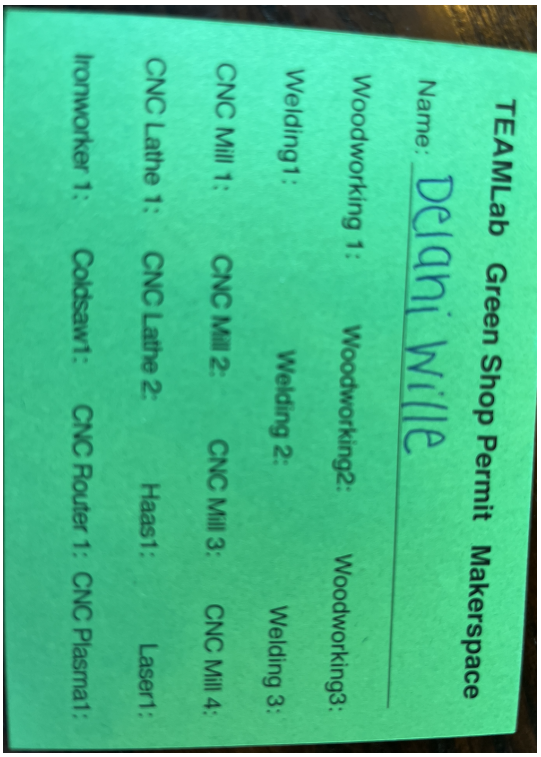
Present: n/a

Goals: Green Permit

Content:

Green permit card





Conclusions/action items: Proof of Green permit training. Training will be used in fabrication of design project.

2024/01/29 Biosafety and Chemical Safety training documentation

Delani Wille - Jan 29, 2024, 3:44 PM CST

Title: Biosafety and Chemical Safety Training Documentation

Date: 01/29/2024

Content by: Delani Wille

Present: n/a

Goals: Complete required training for biosafety and chemical safety

Content:

Image attached

Conclusions/action items: Completed required training. Training will be used in biomaterial and tissue engineering portion of lab.

Delani Wille - Mar 28, 2023, 12:31 PM CDT


WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

This certifies that Delani Wille has completed training for the following course(s):

Course	Assignment	Completion	Expiration
Biosafety Required Training	Biosafety Required Training Quiz 2023	3/10/2023	
Chemical Safety: The OSHA Lab Standard	Final Quiz	3/10/2023	

Download

201_trainings_Delani_Wille.pdf (110 kB) Screenshot of training completion

2024/03/15- Tong Lecture

Delani Wille - May 01, 2024, 10:06 AM CDT

Title: Tong Lecture

Date: 3/15/2024

Content by: Delani Wille

Present: n/a

Goals: Attend Tong Lecture

Content:

Elephas CEO Notes

Revitalizing Exact Sciences and Unveiling Cologuard - Maneesh Aries
- What's involved in crafting and bringing a product to market?

Success Factors:
- Demonstrating clinical effectiveness and healthcare utility
- Grasping the regulatory framework, reimbursement policies, and economic motivations
- Cultivating an adaptable team and fostering a resilient organizational culture

The Journey of Exact Sciences up to 2009
- Established in Boston in 1995
- Went public in 2002, pioneering innovative diagnostics for colon cancer screening
- Faced setbacks in 2004 with poor efficacy at 52% specificity
- Operated with just 4 employees from 2004 to 2008
- New leadership took the helm in 2009 to pursue enhancements.

Identifying a Clinical Challenge and a Lucrative Market Opportunity
- Addressing the invasive nature of current procedures, such as colonoscopies involving a camera and six feet of steel tubing
- Collaboration with Mayo Clinic researchers to explore solutions.

Business Considerations
- Navigating FDA and CMS approval processes, alongside the challenges posed by GI doctors.

The Turning Point: FDA and CMS Approval
- Exact Sciences soared following the green light from regulatory authorities.

Navigating Turbulence: From a $10 Billion Valuation to $2 Billion
- A turbulent journey, marked by a regulatory body's draft release causing a significant drop in company valuation.

The Triumph of Cologuard's Commercial Launch
- The release of the Cologuard commercial marked a turning point, bolstering the company's prospects.
- A subsequent humorous commercial, even becoming a hit on SNL, further boosted the company's profile.

Venturing into New Frontiers: Elephas and Cancer Research Development

Conclusions/action items: The Tong lecture was interesting to hear about Exact Sciences and Colonguard as it is a big company in Madison. Important concepts of Market and reimbursement pathways to think about for industry

2024/3/20 - Warf Invention Disclosure

Delani Wille - May 01, 2024, 10:55 AM CDT

Title: Warf invention disclosure

Date: 3/20/2024

Content by: Delani

Present: n/a

Goals: Write and submit an invention disclosure for WARF

Content:

PDF Attached

Conclusions/action items: Invention disclosure Submitted, now wait to schedule meeting with WARF to address possible patenting.

Delani Wille - May 01, 2024, 10:55 AM CDT

Innovation Disclosure P240311

Response ID: 13569
Submitted Date: 04/17/2024 03:43:01 PM
Completion Time: 2 hr. 11 min. 7 sec.

Who is your IP Manager at WARF?
At least one innovator must be affiliated with UW-Madison or the Morgridge Institute for Research

Innovators

First Name	Last Name	Email	Primary UW Department	Job Title
Delani	Wille	djwille@wisc.edu	Biomedical Engineering	

Innovators

First Name	Last Name	Email	Primary UW Department	Job Title
Riley	Toth	rltoth@wisc.edu	Biomedical Engineering	

Innovators

First Name	Last Name	Email	Primary UW Department	Job Title
Margo	Anastasio	anastasio@wisc.edu	Biomedical Engineering	

Innovators

First Name	Last Name	Email	Primary UW Department	Job Title
Cameron	Owens	cjowens2@wisc.edu	Biomedical Engineering	

Innovators

First Name	Last Name	Email	Primary UW Department	Job Title
Grace	Kreissler	gkreissler@wisc.edu	Biomedical Engineering	

Innovation Details

Title
Step-By-Step: Stair assist bench

Description
Step-By-Step is a stair assist bench that is used to ascend and descend stairs independently. This bench is designed for individuals with below the knee injuries and weight bearing restriction. Our device provides support to non weight bearing leg while climbing stairs. The bench has a foot plate, adjustable central column, leg platform, leg cushion, and handle. The adjustable support column allows for device to be set for different heights. Device is free standing and independently

Download

P240311_Wille_IDR.pdf (186 kB)

2024/04/20- Tong Executive summary

Delani Wille - May 01, 2024, 10:14 AM CDT

Title: Tong Executive summary

Date: 4/20/2024

Content by: Delani

Present: Delani and Margo

Goals: Tong executive summary for final poster presentations

Content:

PDF attached

Tong

- give market of device

- competitors in the space

- Possible IP for device

- Testing

Conclusions/action items: Wrote executive summary and presented Tong presentation at final poster presentations.

Delani Wille - May 01, 2024, 10:14 AM CDT

402 - Tong - 14 - stair_assist_bench - Executive Summary

From 2016 to 2020 hospitalization for lower extremity injuries increased from 130,000 to 150,000 patients accounting for 12% of all emergency department admissions (Albright et al., J Emerg Med, 2022). Most lower extremity patients require rehabilitation for injuries and a non-weight bearing period which lasts for 4 to 6 weeks or longer depending on the severity of the injury (Lynch et al., Curr Rev Musculoskelet Med, 2017). Medical professionals prescribe tools such as crutches, canes, scooters, and wheelchairs to assist with daily activities at home; however, there is a notable gap in suitable and safe mobility solutions for navigating stairs during the recovery process. Traditional devices are not specifically designed for stair use and may pose safety risks or discomfort for patients recovering from below-knee injuries.

A commercially available alternative to standard crutches that was recently launched is the iWalk™ hands-free crutch (HFC). This device provides support to the lower leg in a bent position while freeing the upper extremities for use during walking. iWalk was awarded a design patent US 10624810 B2 April 2020 and has international patents awarded in Brazil, China, Canada, Europe and Mexico (Patent Public Search, USPTO, 2024).

While the iWalk is noted for its benefits on level surfaces, it can be cumbersome and inconvenient to use when traversing stairs (Ketchum, 2021). This limitation opens up opportunities for the development of novel solutions to enhance mobility and safety for individuals with below-knee injuries during stair ascent and descent. The global market for stair lifts and climbing devices, valued at $2 billion in 2023, is projected to be $4.1 billion by 2032. Although it is difficult to predict the available market for a device at such an early stage, capturing as little as 1% of this market could represent over $20M of revenue.

Our design process focused on developing a safe, user-friendly, and lightweight mobility aid. The stair-assisting bench (SAB) features a central height-adjustable column to accommodate various users, a cushioned bench for resting non-weight bearing limbs, along with a fixed handle to facilitate bench movement between stairs. The central column is anchored to a custom designed aluminum footplate ensuring stability of the device. The SAB's innovative footplate design maximizes support and contact area, promoting weight-bearing stability and allowing the device to stand independently when not in use. The compact leg platform and cushion design offer comfort and versatile lower limb support without interfering with walking boots or casts.

The testing methodology involved 5 healthy participants undergoing trials with various interventions, including a fracture boot, SAB, and HFC. Participants ascended and descended stairs under different conditions while motion capture and force plate technology captured kinematic and kinetic data to verify that the SAB provided sufficient stability. Feedback forms, including pain ratings and comfort evaluations, were collected to assess balance, ease of use, and device preference. The testing aimed to compare the effects of different assistive devices on gait biomechanics and participant performance during stair climbing.

This new device addresses the needs of patients recovering from below-the-knee injuries who face challenges when navigating stairs. It was designed to improve the lives of patients, giving them a reliable tool to maintain independence and support at-home recovery. The key design requirements defined by our client included comfort for the user, sufficient load capacity, overall stability, and adjustability. It is believed that this new SAB will offer a practical solution for those with weight-bearing limitations, providing a means to safely navigate stairs at home, which is crucial during the rehabilitation period.

Download

402_-_Tong_-_14_-_stair_assist_bench_-_Executive_Summary.pdf (64.5 kB)

2024/2/1 - Testing Safety

RILEY TOTH - Feb 01, 2024, 12:36 PM CST

Title: Testing safety 1

Date: 2/1/2024

Content by: myself

Present: myself

Goals: understand more how to properly and safely test our device

Content:

How to Determine if Your Product is a Medical Device | FDA

It is a medical device

Understanding The Different Types Of Medical Device Testing | Cigniti

Defines different ways to test a device

Hi team,

If you are trying to see if design improvements need to be made, your classmates can try it out to give you their feedback.

However, if you are interested in systematically testing it and making generalizations about the device (like it is suitable for anyone under X weight) or if you want to publish your results, then you need an IRB.

https://irb.wisc.edu/

You should all start by doing your required training: https://irb.wisc.edu/education-training/training/

Prof. Block can help you through the process after that as well (or is your client UW affiliated)?

This process takes a long time, so starting it now is a good idea so that by spring you would be able to collect these results.

Let me know if you have any questions.

Wishing you well,
-Dr.P

Conclusions/action items: Go through and look at the IRB steps as I have already done the training

2024/2/26 - ARROW resources

RILEY TOTH - Feb 26, 2024, 10:37 AM CST

Title: Arrow Resources

Date: 2/26/2024

Content by: Stephanie Metzger and Myself

Present: Delani and myself

Goals: Understand how to properly fill out an Arrow application

Content:

The following is the email sent from Stephanie with links to helpful documents. This was sent directly after a meeting going through the Protocol Document

Hello Riley and Delani,

I am writing to follow up after our meeting this morning to discuss your IRB submission that is in progress (IRB00089730, PI Russ Johnson). The project is funded as a gift by a physical therapist who is not part of UW. Here are some of the issues we discussed, with links to guidance from the IRB or UW websites.

- You will be sharing data with the external therapist who is funding the study. Because he will be involved in the analysis, he will probably need IRB coverage. Please email irbreliance@wisc.edu to let them know you would like to have UW serve as the IRB of record for him. We talked about conducting research procedures at UW instead of at his clinic, to reduce the complexity of any reliance agreements.
    - The process for serving as IRB of record for one external personal is not super complicated. I think the main thing is that you will need to describe his role in the study, and he will need to complete UW human subjects research trainings.
- You could potentially recruit from UW-Madison rather than his clinic, by posting flyers or sending mass recruitment emails to faculty/staff/students via DoIT.
- Because you are evaluating a device, you will need to submit a letter requesting a Non-Significant Risk (NSR) determination for the device. In that letter, you will need to explain why the device does not meet the criteria for being a Significant Risk device. The criteria are listed in Section 1 of #418. This letter should include information about both devices you would be testing (the one that you're working on, and the one that is commercially available that you said you might also include). The letter should be uploaded on the Drug and Device Documents page in the ARROW application; one letter is sufficient for both devices.
- You will be obtaining informed consent as part of the study. There is an SOP for obtaining written informed consent. It's #091. Section 5 of SOP #091 will be the most relevant to you. There is also #090, which is an SOP for the consent process. #090 consent process is more focused on having the conversation with participants and answering their questions, and #091 is more focused on how to properly document that #090 was followed. There is also a video about how to obtain consent; if you look in the Consent section of the PREP Presentations, there is a video about How To Obtain Informed Consent. It's a few years old, but the principles will still apply. There are also some newer videos about the consent process.
    - You will need to use #502 as your consent template. There is some blue template text that is used for studies where HIPAA applies. If you include the external therapist, that *may* make HIPAA apply. If you include anyone from the UW-Madison Healthcare Component, HIPAA will apply. If HIPAA applies, you will need to use certain specific tools for storing and sharing data. If HIPAA does not apply, I think UW Box is ok for storing data.

I think that's everything for right now. Please let me know if you have any other questions. Thanks,

Steph

Conclusions/action items: We will have to go through the Consent document next, make the questionnaire, and format an email to send with information on the study.

2024/2/01 - Adjustable Base

Title: Adjustable Base design

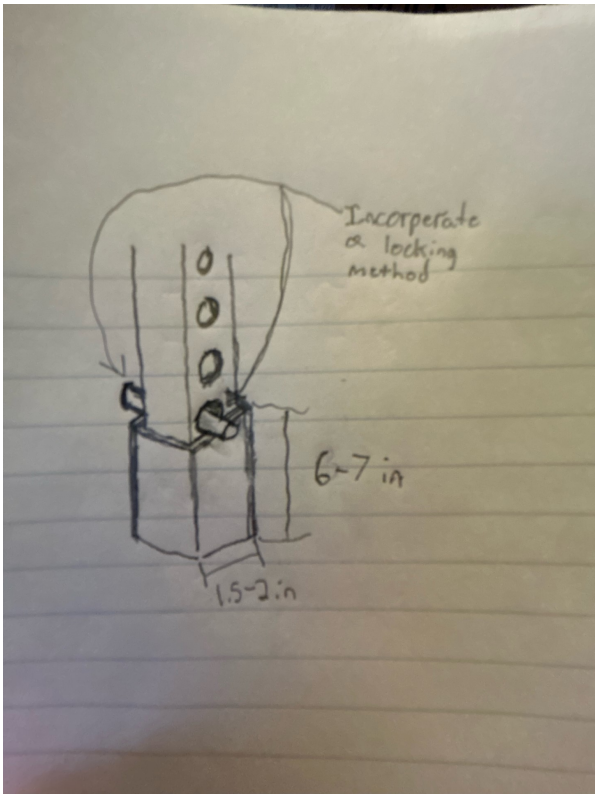
Date: 2/1/2024

Content by: Myself

Present: myself

Goals: develop a safer adjustability system

Content:



Put a rod through two holes. One side of the rod will have a pin inside to prevent movement and the other will be thicker to not go fully through

https://www.googleadservices.com/pagead/aclk?sa=L&ai=DChcSEwjP3tjB_YeEAxV2UkcBHdnQD1EYABAXGgJxdQ&ae=2&ohost=www.google.com&cid=CAESVuD2J17lqCPYEFq7URE6cCRE9Syy27Lr8LkjShieke_yc6-3Vz6bBP9Blw23aWEf1EQtFqQ0iYRbREUCOxYD&sig=AOD64_1lbj6CIdRI3j0JtdqfOQRaVPll9w&ctype=5&q=&ved=2ahUKEwjB09LB_YeEAxXLv4kEHVuV

https://www.googleadservices.com/pagead/aclk?sa=L&ai=DChcSEwjP3tjB_YeEAxV2UkcBHdnQD1EYABAIGgJxdQ&ae=2&sph=&ohost=www.google.com&cid=CAESVuD2J17lqCPYEFq7URE6cCRE9SyyLkjShieke_yc6-3Vz6bBP9Blw23aWEf1EQtFqQ0iYRbREUCOxYD&sig=AOD64_2QdV29DMByzs5zpdBO2KA5HlR0yg&ctype=5&q=&ved=2ahUKEwjB09LB_YeEAxXLv4kE

Conclusions/action items: This design is both safer than a crutch pole and it is easier to fabricate. I hope the team will listen to this idea as it cou

2022/03/28 - Green Pass

RILEY TOTH - Mar 28, 2022, 4:00 PM CDT

Title: Green Pass Certification

Date: 3/28/2022

Content by: myself

Present: whole class

Goals: Obtain the green pass as well as the red pass

Content:

Conclusions/action items: By getting the green pass this also shows that I have gotten the red pass. I can now use the mill and lathe in the Team Lab to help the team make the holder for the biomaterial in the bioreactor. I now also have the opportunity to do more training.

2023/10/25 - CITI study certificate

RILEY TOTH - Oct 25, 2023, 10:30 AM CDT

Title: Citi study certificate

Date: 10/25/2023

Content by: riley toth

Present: riley toth

Goals: complete modules to do human trials

Content: Below

Conclusions/action items: Step one to be able to do human trials on our device. more steps need to be taken to ensure safety to our test subjects.

RILEY TOTH - Oct 25, 2023, 10:29 AM CDT

Download

citiCompletionCertificate_12762853_59205863-RileyToth.pdf (77.3 kB)

2024/2/08 - Preliminary Presentation

Title: Preliminary presentation

Date: 2/8/2024

Content by: myself

Present: myself

Goals: complete my slides of the presentation

Content:

Final Prototype

Packaging

- Packaged in 2 pieces (Base & Support)
- Minimal internal box protection

Documentation

- User manual (Adjustability/Assembly)
  - Done by medical professional
  - Pictures and video link of usage
- Safety Cautions
  - Weight capacity
  - Height constraints
  - Do Not Use unless recommended by a healthcare professional
  - Approved by the FDA as class 1 low-risk medical device

Budgeting

Last Year	$23.58

This Year	$75.93
Budget Left for Prototyping	$300.49
Purchase of Device (On Market)	>$100

Conclusions/action items: Need to edit the approved by FDA as they do not approve but they give regulations to follow.

2023/10/07 - Injury from Mobility Aids

CAMERON OWENS - Oct 11, 2023, 1:27 PM CDT

Title: Injury from Mobility Aids

Date: 2023/10/07

Content by:

"Pediatric Mobility Aid-Related Injuries Treated in US Emergency Departments," Pediatrics (American Academy of Pediatrics), https://publications.aap.org/pediatrics/article/125/6/1200/72473/Pediatric-Mobility-Aid-Related-Injuries-Treated-in?autologincheck=redirected. Accessed: October 7, 2023.

Present: N/A

Goals: Understand dangers and likely hood of re injury.

Content:

An estimated 63 309 cases of children and adolescents who were aged ≤19 years were treated in US emergency departments for mobility aid–related injuries. Approximately 70% of mobility aid– related injuries occurred while patients were using wheelchairs. Children who were aged 2 to 10 years were more likely to sustain injuries while using walkers and wheelchairs, injure their heads, and sustain traumatic brain injuries. Children who were aged 11 to 19 years were more likely to sustain injuries while using crutches, injure their lower extremities, and sustain sprains and strains. Injuries involving wheelchairs were more likely to be traumatic brain injuries and result in hospitalization. Injuries involving crutches were more likely to involve misuse and be triggered by stairs or curbs

Conclusions/action items:

The document shows evidence that there is a significant need for a safer alternative to current practices of climbing stairs. The docuemtn supports this because it suggest most common cause of injury is the stairs.

2023/10/04 - Injury Statistics

CAMERON OWENS - Oct 11, 2023, 1:22 PM CDT

Title: Injury Statistics

Date: 2023/10/04

Content by:

E. R. Talsma et al., "Incidence and Epidemiology of New-Onset Diabetes Mellitus After Transplantation," Diabetes Spectrum, vol. 25, no. 3, pp. 195-206, 2012. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3237997/. [Accessed: October 4, 2023].

Present: N/A

Goals: Understand the need and size of effected population.

Content:

We used the National Electronic Injury Surveillance System (NEISS) to obtain a probability sample of all lower extremity injuries treated at emergency departments during 2009. A total of 119,815 patients who presented to emergency departments with lower extremity injuries in 2009 were entered in the NEISS database. Patient and injury characteristics were analyzed. Incidence rates for various regions, disease categories, injuries, and age groups were calculated using US census data.

Conclusions/action items:

In conclusion there are at least 120,000 recorded cases of lower limb injuries reported from the emergency room every year. This gives us insight into the client demographic and size of population.

2023/10/01 - Therapy Advice

CAMERON OWENS - Oct 11, 2023, 1:16 PM CDT

Title: Therapy Advice

Date: 2023/10/01

Content by:

"Therapy Advice When Non-Weight Bearing," Worcestershire Acute Hospitals NHS Trust, https://www.worcsacute.nhs.uk/patient-information-and-leaflets/documents/patient-information-leaflets-a-z/3014-therapy-advice-when-non-weight-bearing/file. Accessed: October 1, 2023.

Present: N/A

Goals: Determine current approaches being taught by PT.

Content:

Comment points -

Mobilizing non-weight bearing with an appropriate walking aid Teaching you exercises to maintain your movement and strength as appropriate Stairs practice (if required) Transferring off your bed/chair/toilet Discussing/practicing how you will manage your activities of daily living Providing certain pieces of equipment to support your discharge home following assessment of your needs. It is not always possible to supply all equipment insome instances e.g. wheelchairs, but we will provide you with information to help you access other useful equipment (further information can be found later in this leaflet)

Conclusions/action items:

Current practices include showing patients to use a walking canes/crutches where one hand opposite of your injured limb is holding the railing. The other use hand is holding the cane/crutch to support weight not being beared by the injured leg.

2023/10/05 - Knee Scooter

CAMERON OWENS - Oct 11, 2023, 1:37 PM CDT

Title: Knee Scooter

Date: 2023/10/05

Content by:

"Carex Knee Walker," Carex. [Online]. Available: carex.com/products/carex-knee-walker. Accessed: Oct. 5, 2023.

Present: N/A

Goals: Understand and gather information on other mobility aid devices.

Content:

- **Height adjustable knee pad and handles.** Having the proper height is essential. The knee walker scooter features a height-adjustable knee pad from 16" to 22.5". The handles can be adjusted from 31.75" to 40".
- **A more stable and comfortable crutch alternative.** Crutches can be uncomfortable and unstable. The Carex broken leg scooter is the perfect alternative. It's comfortable to use and dependable.
- **Large 7.5" rubber wheels with a tight turning radius.** The all-terrain knee scooter's large wheels allow it to roll smoothly on all surfaces. Its high turn radius makes it easy to navigate tight areas such as hallways.
- **Features a hand brake for safety.** Have full control of the mobility knee scooter with the hand brake. It enables users to stop easily and stay safe.
- **Holds up to 250 lbs.** The heavy-duty knee scooter features a durable aluminum frame. It's been built to last to provide dependable mobility assistance.

Conclusions/action items:

The knee scooter designs gives good insight into the design aspects that have already been incorporated into designs. The design aspects here translate well to what we are trying to achieve in areas of comfort, safety, and ergonomics.

2023/10/04 - Statistics on Mobility Devices.

CAMERON OWENS - Oct 11, 2023, 1:32 PM CDT

Title: Mobility Devices

Date: 2023/10/04

Content by:

"The Complications of Crutches - A Summary of a Systematic Review of the Literature," UCL Department of Civil, Environmental, and Geomatic Engineering, [Online]. Available: https://www.ucl.ac.uk/civil-environmental-geomatic-engineering/sites/civil_environmental_geomatic_engineering/files/the_complications_of_crutches_-_a_summary_of_a_systematic_review_of_the_literature.pdf. [Accessed: October 4, 2023].

Present: N/A

Goals: Understand what devices are being prescribed currently.

Content:

Over 575,000 people are prescribed crutches each year in the USA1, either axillary or forearm crutches (see figure 1). Each design has its problems however data is limited in terms of the complications their use can result in. This is a summary of a systematic review which provides a-comprehensive overview of all the published complications associated with crutch use, irrespective of type or duration of use.

Conclusions/action items:

This is one form of mobility aid but it shows there is a large market for aid mobility devices to levitate weight from a lower limb due to injury. Coupling this with prior research that suggests that crutches are unsafe and over used for stair use.

2024/2/27 Stair Accidents

CAMERON OWENS - Feb 27, 2024, 12:37 PM CST

Title: Stair Accidents

Date: 2024/2/27

Content by: Cameron

Present: N/A

Goals: Compile some values for incident rates and related demographics related to stair use.

Content:

-10% of fall related fatalities were confirmed to be caused by stairs

-The real number could be higher cause most reports didn't include location of fall

-2/3 of falls were among those aged 75 years or older.

-Article presents that declining musculoskeletal, vestibular, and visual systems in older adults can account for the increase incident rate among that demographic.

Startzell, J.K., Owens, D.A., Mulfinger, L.M. and Cavanagh, P.R. (2000), Stair Negotiation in Older People: A Review. Journal of the American Geriatrics Society, 48: 567-580. https://doi.org/10.1111/j.1532-5415.2000.tb05006.x

Conclusions/action items:

These can be used in reports to justify the need for our device.

2024/2/2 Aluminum Stock

CAMERON OWENS - Feb 07, 2024, 1:05 PM CST

Title: Aluminum Stock

Date: 2024/2/2

Content by: Cameron

Present: N/A

Goals: Understand the options for aluminum stock that fits design goals.

Content:

The goal is to get two pieces of square aluminum stock with one being smaller so it can slide into the inner void of the larger one. This will allow us to create a support leg that moves up and down and with the addition to a pin can be added to secure the structure in place.

The options most closely compatible with our current base is one piece of square stock aluminum with dimensions of 1.5" x 1.5" x 4' and another with the dimensions 1 3/8" x 1 3/8" x 4'. The two pieces can fit one inside the other with enough clearance to slide up and down. Each piece cost $20-25 depending on where they are sourced and the coating used.

Conclusions/action items:

The team will go to Home Depot to find the aluminum stock there.

2024/2/7 Spring loaded base

CAMERON OWENS - Feb 14, 2024, 2:55 PM CST

Title: Spring Loaded Base

Date: 2024/2/7

Content by: Cameron

Present: N/A

Goals: Design a potential option for a spring loaded base that creates clearance for moving up stairs.

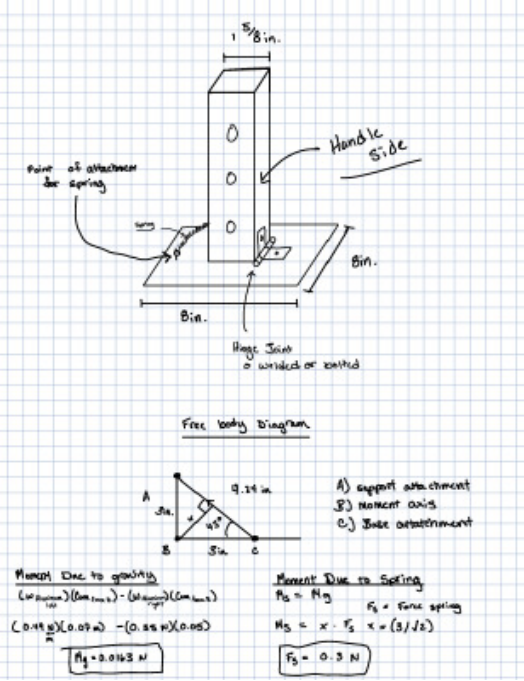
Content:

See Below for Diagram.

Conclusions/action items:

Discuss options with team and decide wether it's an appropriate addition.

CAMERON OWENS - Feb 14, 2024, 2:56 PM CST



Download

Note_Feb_14_2024.pdf (336 kB)

2024/5/20: Staircase

CAMERON OWENS - Apr 25, 2024, 5:10 PM CDT

Title: Staircase

Date: 2024/5/20

Content by: Cameron

Present: N/A

Goals: Ideas for potential testing staircase

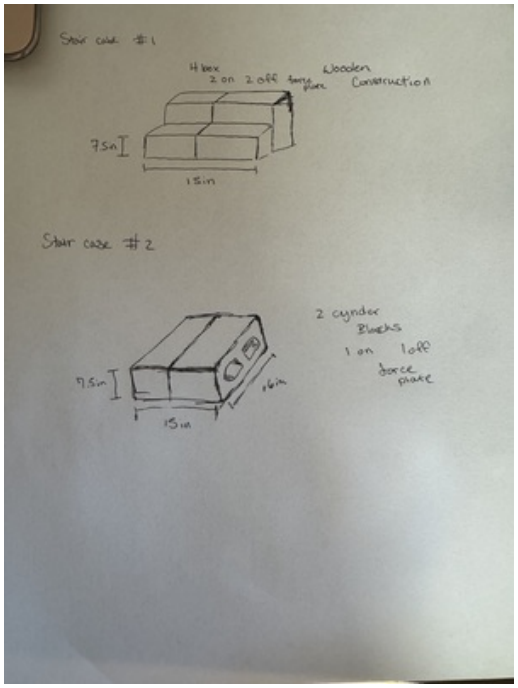
Content:

See below for designs

Conclusions/action items:

Cinder blocks were among ideas considered by group as a whole and was the final design solution.

CAMERON OWENS - Apr 25, 2024, 5:11 PM CDT



Download

IMG_0549.jpeg (1.74 MB)

Lab 3 SolidWorks II 2022/02/10

CAMERON OWENS - Mar 31, 2022, 1:36 PM CDT

Title: SolidWorks 2

Date: 2022/02/11

Content by: Cameron

Present: Group

Goals: To Develop SolidWorks knowledge and skills.

Content:

We designed three different parts using different features like revolve base, centerline, and reference plane.

Once we finished each we had to create drawings of them including isometric views showing hidden lines and cross sectional views of the parts.

Finally for our last part we needed to run a stress test on one of the parts we had created out of ASTM A36 steel. We had to load it in such a way that it was in tensile stress. From there we used it analyze the way it would fail.

My group and I did not have time to start on our design report for the bioreactor shelving but I was able to get a preliminary design started.

Conclusions/action items: Meet with group to discuss the design report due for next week's lab. Finish shelving design.

Lab 2 SolidWorks I 2022/02/03

CAMERON OWENS - Mar 31, 2022, 1:37 PM CDT

Title: Lab 2

Date: 2/3/2022

Content by: Cameron

Present: Group 2

Goals: Develop SolidWorks skills further

Content:

1. Design and build a part in the part section of solid works.

2. Take part into the assembly section of solid works and assemble two of the pieces.

3. Take original part into the drawing section of solid works and create a layout with at least 5 different views including: front, top, right, left, and isometric.

4. Preform a stress test on the part and note a few of the important figures it produces.

5. Play around on edrawing with the stressed part and submitted three different images.

6. Took the two post-lab assessment quizzes.

Conclusions/action items:

1. **Continue research on the bioreactor**
2. **Bring this and ideas to group meeting on Monday to start developing our PDS**
3. **PDS must be completed by Thursday's (2/10) Lab.**

CAMERON OWENS - Feb 03, 2022, 5:18 PM CST

Download

Edrawing1.eprt (3.17 MB)

CAMERON OWENS - Feb 03, 2022, 5:18 PM CST

Download

Edrawing2.eprt (3.18 MB)

CAMERON OWENS - Feb 03, 2022, 5:18 PM CST

Download

Edrawing3.eprt (3.17 MB)

CAMERON OWENS - Feb 03, 2022, 5:18 PM CST

Download

Lab2_firstpart.SLDPRT (186 kB)

Lab 12 Mechanical Testing 2022/04/21

Title: Mechanical Testing

Date: 2022/04/21

Content by: Cameron

Present: Group

Goals: Test our samples

Content:

1. While performing this part of the protocol, you should document your work in your design project folder of your notebook in LabArchives.

    1. Review - what is a standard and how to find them: https://researchguides.library.wisc.edu/c.php?g=177647&p=1167580

    2. ASTM International, known until 2001 as the American Society for Testing and Materials (ASTM), is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. Using the standards below note the testing conditions in which the test is performed. Comment on whether the test conditions are appropriate for physiological applications and how you would alter the standard for your application. Does your testing apparatus meet this standard? Do the sample sizes meet this standard? If not, what modification would you like to make (even if not possible) to meet this standard? **Document this research in your design notebook and briefly discuss it in your report.** Feel free to find several other ASTM tensile or compressive testing standards that are relevant for your testing protocol.

        ASTM F2150-19: Section 8 - Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Regenerative Medicine and Tissue-Engineered Medical Products
        (Use the link above → Click “View Online” → “View full text” → type, for example: ASTM F2150 into the search)

        ASTM F2902: Standard Guide for Assessment of Absorbable Polymeric Implants
        (Use the link above → Click “View Online” → “View full text” → type, for example: ASTM F2150 into the search)

    3.

        1. For testing your samples, put the following steps in the correct order assuming the machine has been turned on, the safety stops are set if needed, and it is ready to go (kill switch is not engaged). Write out a full testing protocol using these steps as a guide.
            1. Zero the meter for load
            2. Watch the load carefully so that it does not exceed your load cell capacity or fixture capacity
            3. Place your sample into the fixture
            4. Enter the appropriate parameters for your test on the “monitor” tab for diameter and test rate, etc.
            5. Make observations about your samples looking for defects, uneven surfaces, or other potential sources of error and make measurements with an accurate measuring tool such as a caliper for dimensions to obtain cross-sectional area and mass.
            6. Export your data
            7. Hit the emergency kill switch
            8. Press the “play” button to start your test
            9. Unlock the machine
            10. Preload your sample such that the load reads just above zero
            11. Power off the machine, return components, clean up your sample and leave the area cleaner than you found it!
            12. Zero the meter for load and the meter for crosshead / displacement

13. Stop your test or wait for break detection to occur (provided you have not exceeded the capacity)

2. One group at a time will test their samples (bioreactor samples and control samples). Document this testing.
3. Return the BME Department's materials back to their proper place.

Bioreactor Wrap Up

1. If you haven't already, make sure to get data (n >=5) comparing your bioreactor temperature to the actual temperature.
2. Save your EEPROM data by running eeprom_read and copying the text off of the serial monitor. Remember to note each stop and start time of your reaction
3. Make observations (of your samples and PBS color) and get pictures of your device and bioreactor
4. Use the stereoscope to take a picture of your samples if you haven't already done so
5. Return each component we gave you to the appropriate bin
6. Breathe - you successfully programmed a closed-loop microcontroller system!

Cross Sectional Area :

Ultimate Strength (stress in MPa) :

Maximum Load (force in N) :

Bioreactor Observations

1. The PBS stayed the same pink color throughout the testing process.
2. The samples turned into a paste consistency after only a few hours in the bioreactor and solution.
3. The temperature readout stayed within the desired range of 35 - 39 celsius.
4. PBS solution was at a pH of 8.93
5.

Conclusions/action items:

Red Permit

CAMERON OWENS - Mar 24, 2022, 1:53 PM CDT

Download

Screen_Shot_2022-03-24_at_1.52.55_PM.png (339 kB)

Green Pass

CAMERON OWENS - Mar 24, 2022, 1:51 PM CDT

Download

IMG_0023.HEIC (802 kB)

2024/2/20 BME Outreach

CAMERON OWENS - Feb 22, 2024, 10:33 AM CST

Title: Outreach

Date: 2024/2/20

Content by: Cameron

Present: N/A

Goals: Outline talking points for BME outreach podcast

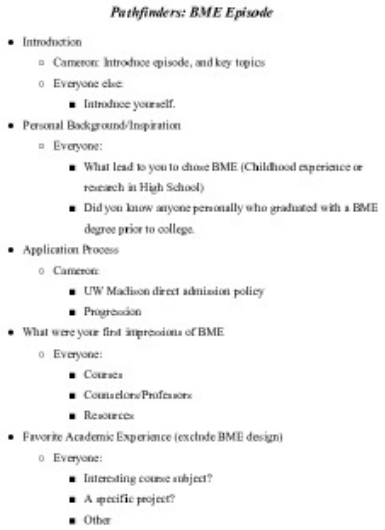
Content:

See Below.

Conclusions/action items:

Record Podcast

CAMERON OWENS - Feb 22, 2024, 10:50 AM CST



Pathfinders: BME Episode

- Introduction
  - Cameron: Introduce episode, and key topics
  - Everyone else:
    - Introduce yourself.
- Personal Background/Inspiration
  - Everyone:
    - What lead to you to chose BME (Childhood experience or research in High School)
    - Did you know anyone personally who graduated with a BME degree prior to college.
- Application Process
  - Cameron:
    - UW Madison direct admission policy
    - Progression
- What were your first impressions of BME
  - Everyone:
    - Courses
    - Counselors/Professors
    - Resources
- Favorite Academic Experience (exclude BME design)
  - Everyone:
    - Interesting course subject?
    - A specific project?
    - Other

Download

Pathfinders__BME_Episode.pdf (58.3 kB)

2024/5/11 Outreach

CAMERON OWENS - Apr 25, 2024, 5:16 PM CDT

Title: Outreach

Date: 2023/5/11

Content by: Cameron

Present: N/A

Goals: Final report, presentation instructions for BME outreach

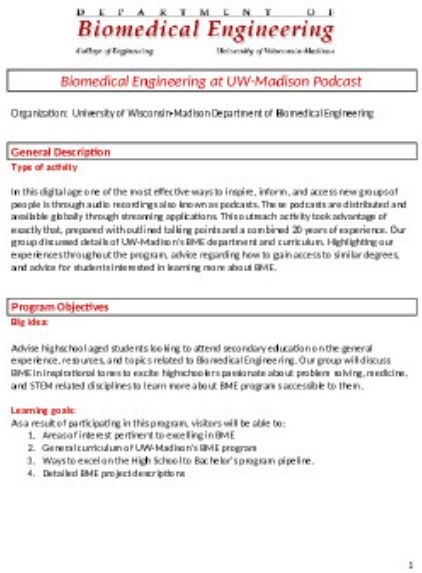
Content:

Attached below.

Conclusions/action items:

Submit to BME website.

CAMERON OWENS - Apr 25, 2024, 5:14 PM CDT



DEPARTMENT OF
Biomedical Engineering

Biomedical Engineering at UW-Madison Podcast

Organization: University of Wisconsin-Madison Department of Biomedical Engineering

General Description

Type of activity

In this digital age one of the most effective ways to inspire, inform, and access new groups of people is through audio recordings also known as podcasts. These podcasts are distributed and available globally through streaming applications. This outreach activity took advantage of exactly that, prepared with outlined talking points and a combined 20 years of experience. Our group discussed details of UW-Madison's BME department and curriculum. Highlighting our experiences throughout the program, advice regarding how to gain access to similar degrees, and advice for students interested in learning more about BME.

Program Objectives

Big idea:

Advise highschool aged students looking to attend secondary education on the general experience, resources, and topics related to Biomedical Engineering. Our group will discuss BME in inspirational tones to excite highschoolers passionate about problem solving, medicine, and STEM related disciplines to learn more about BME program accessible to them.

Learning goals:

As a result of participating in this program, visitors will be able to:

1. Areas of interest pertinent to excelling in BME
2. General curriculum of UW-Madison's BME program
3. Ways to excel on the High School to Bachelor's program pipeline.
4. Detailed BME project descriptions

1

Download

Final_Activity_Guide_Owens_Kreissler_Amatuzio_Wille_Toth.docx (246 kB)

CAMERON OWENS - Apr 25, 2024, 5:16 PM CDT

BME Outreach Overview

On March 21, 2024 our BME design group recorded a podcast discussing the ins and outs of Biomedical Engineering both at UW-Madison and in general. The audio was recorded in Ehall in an empty room with some of the groups personal audio recording equipment. Different from traditional outreach activities, ours doesn't involve having a physically present crowd to interact with. The podcast is a bit of a gamble because there is no guarantee that we will reach specific audience demographics, like you can do by going to a school where you know things about the age and interests of your audience.

However, the podcast format allows for the presentation of information to spread to much greater lengths. For example, Lex Fridman is one of the most popular podcasters on the planet with 2.6 million subscribers which are people who sign up to be notified when he releases an episode. Lex is important because much of his content focuses around STEM related topics and guests. Lex's success shows there is a large audience who may be interested in a podcast such as ours. An audience much larger than the 30 kids we could have reached through an in-person school event. The podcast will be uploaded to Spotify, a popular streaming service, most commonly used for music and podcasts. Spotify offers a free version which allows listeners to access most podcasts for free. Therefore, the only constraint inorder to be a part of our audience is a smart device that can download Spotify's software inorder to listen to our presentation. This will help limit any constraints on certain demographics to access the information.

Our podcast will not offer the same immediate feedback that you can expect from the traditional activities. However, unlike the traditional approach the viewership and effect is not finite, the podcast will be around indefinitely, gaining interactions and reaching new people for the foreseeable future. The content presented was gauged to inform highschool students searching for major or discipline to pursue in secondary education, that being said despite not having immediate feedback from an audience, we have shown our work to fellow BME students who have expressed that the content presented would have intrigued them to learn more about Biomedical engineering when they were in high school. I believe our content will inspire people who listen to do their own research on BME resulting in greater awareness of our major and UW-Madison's program.

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Report_Owens_Kreissler_Amatuzio_Wille_Toth.pdf (38.5 kB)

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity. subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

CAMERON OWENS - Feb 27, 2024, 12:32 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

BME 400 Fall 2023 Notebook

MARGO AMATUZIO - Feb 09, 2024, 8:48 AM CST

BME Design-Fall 2023 - MARGO AMATUZIO
Complete Notebook

PDF Version generated by
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Feb 09, 2024 @ 08:48 AM CST

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