BME Design-Fall 2024 - MATTHEW SHERIDAN
Complete Notebook

PDF Version generated by

Luke Rosner

on

Dec 13, 2024 @06:09 PM CST

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Team contact Information

Luke Rosner - Sep 24, 2024, 4:38 PM CDT

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Conners	Abi	BPAG	aconners2@wisc.edu		

Project description

Luke Rosner - Sep 24, 2024, 4:35 PM CDT

Course Number:

BME 200/300

Project Name:

Stair Chair

Short Name:

Stair Chair

Project description/problem statement:

Create a mechanical device that temporarily handicapped patients can use to ascend and descend 3-5 stairs. The device should be inexpensive to fabricate, as compared to competing powered stair lifts, and be easy to set up and take down, both inside and outside the patient's home.

About the client:

Mr. Kutschera is a physical therapist at Encompass Health Rehabilitation Hospital in Fitchburg, WI.

9/16 Initial Client Meeting

Cody Kryzer - Sep 16, 2024, 5:54 PM CDT

Title: Client Meeting

Date: 9/16/24

Content by: Cody

Present: Whole team and client

Goals: Get an understanding of the client's goals

Content:

Questions:

- What is our total budget for the project?
    - Preferred materials? (seat material?)
- Full scale vs model/drawing?
    - Max weight for the product?
    - Max patient weight/average patient height/weight
    - Strength required to move chair?
- Weather? Rain etc
- Previous work? 3D models, other designs
- Patents, standards, codes
- What do you want to see at poster pres?
- What should be the shelf life of the product?
    - Amount of uses? How long should it be usable?
- Safety requirements for the stair chair?
    - Straps? Buckle?
- Luggage/groceries? Wheelchair??
- Hospital visit? What date and time works best?

Answers:

- Encompassed hospital in Fitchburg
- Getting up and down 3-5 steps
- Methods
    - 12:1 for ramps - too long
    - Make em hop, not feasible
    - Use a shower bench, move bench, stand, sit, move bench …
    - https://bmedesign.engr.wisc.edu/projects/f23/stair_assist_bench/file/view/1f6b5ba0-7a47-4fcd-a26f-a2a697c621ee/Final%20Poster%20-%20stair_assist_bench%20.pdf

    - Sit and scooch

- Use the seat from the exercise bike, throw it on rails, push with leg, click their way up the step. Chair should swivel
- Getting down is the main problem (unsure if its a possibility)
- Stair lifts are too expensive for being temporary
- Cheap, uses patients own force
- Not 12 steps only 3-5

- Budget - up to five hundo
- Preferred materials - aluminum? Can't rust, seat doesn't have to be fancy/comfy (plastic is fine), have straps
- Patient weight limit - 250-300 or more if possible
- Chair weight limit - same thing?
- Everyone that this is for should be able to push themselves up. Have one good leg, no arm strength required
- Usually 80 years old, fractured ankle, non weight bearing 6 months?, 3-5 steps
- Careful with electronics in rain and snow
- Dan isn't looking to own this because of liability, just wants to see if it's possible
- Patients would rent this out for however long. Ideally reused by another patient
- In a perfect world, could just set the sucker down. Freestanding. Rail attachment limits use. We should keep the rail accessible with the device installed
- Patients don't have great housing/ stable rails
- Airplaneesque seatbelt

Hospital visit

- CEO says we can come out during business hours.
- Sign an NDA
- Could come after hours and Dan could show us around
- Vector system
- Get an idea of how someone would use it
-

Conclusions/action items:

Work on PDS which is due Thursday. Set up a time to visit the hospital sometime soon.

10/7 Hospital Visit

Cody Kryzer - Oct 09, 2024, 10:30 PM CDT

Title: Hospital Visit

Date: 10/7

Content by: Cody

Present: Whole team and Daniel Kutschera

Goals: Learn what facilities/resources are available for the client. See what we're working with

Content:

Hospital

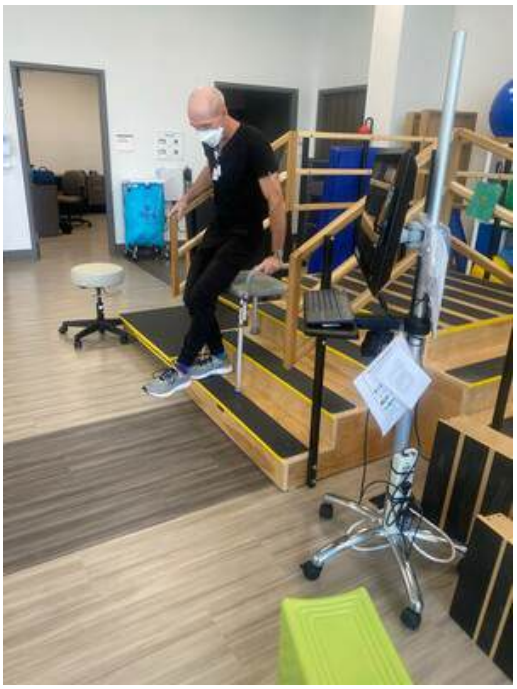
- Average stay is two weeks
- Biggest barrier is stairs
- Roof system- vector system 500000$
- trolley has a computer to monitor the rope on the x and y axes, how fast and force and distance.
- Patients wear a harness to get hooked up, computer can provide 10-220 pounds of support,
- fall prevention- four inches detects a fall, auto arrests.
- As patient walks the trolley moves with them.
- Arrest can be set for a certain force as well.
- Typically used on the stairs.
- Community discharge, patients go home or to assisted living at the end of the day, mostly home, get set up with all the equipment they need
- Stairs are six inches of rise. Ramp needs 12:1 run:rise
- Go to Amazon buy 30$ guard block.
- Use it to climb sit and stand sit and stand
- Bath bench, two different sized legs
- Using the block requires turning as well
- Ratchet catches on the way up but not the way down
- Exercise bike - NuStep, looks like it works really well
- Stroke patients very weak on one side of the body
- One step is no problem at all
- Bumping up in a wheelchair is for a sure a two person job
- Each patient gets three hours of pt a day in three disciplines, they get scored on many things, going up and down numbers of step, moving certain distances, getting in and out of cars, navigating uneven surfaces, navigating ramps and curbs. Patients hit all of these every day
- Single leg squat is too difficult for some
- Goal on commercial price??
    - Not any concern at the moment

- How many have wheelchairs??
    - Wheelchair is easy to move with nobody in it, could be reasonable to leave a wheelchair at top and bottom if they have two. Doesn't need to be right on the edge of stairs since most are walking. Wheelchairs aren't too expensive
- Not set on ratchets
- Set on just getting a human up and down stairs
- Could we design one that's not so safe just to use in the hospital?
    - Yeah to have one but not really useful
- Patients almost always have a second person with them
- They do home assessments
- How has grandma been getting up and down stairs???
- Try not to rely on railings
- 12-14 days of stay here
- Ramp in place in the time is tough
- Stairs are biggest obstacle
- Ideally no installation, just plop down. In a perfect world
- Perhaps Dan could install
- Home access form, family measures everything and sends pictures so Dan can know in a couple days what the situation is like
- Set of cubes on every step, like a second stair case but elevated, would solve the problem of getting up from the ground.
- Good leg would have to be on the inside but bad leg would just get dragged along
- Have a handle attached to each block
-
- Weight capacity will be an issue
- Patients could use a boat winch pretty easily
- Boat lift could maybe have issues being temporary
- Make sure it doesn't take up the whole stair case width wise

Conclusions/action items:

Kutschera is not set on the ratchet mechanism which means we are ok to explore other possibilities. I liked the idea of a block set of stairs that will go on top of the existing stairs. Although it likely would be hard to make adaptable. One of the big issues is that patients are unable to stand up from sitting on the ground.

Cody Kryzer - Oct 09, 2024, 10:25 PM CDT



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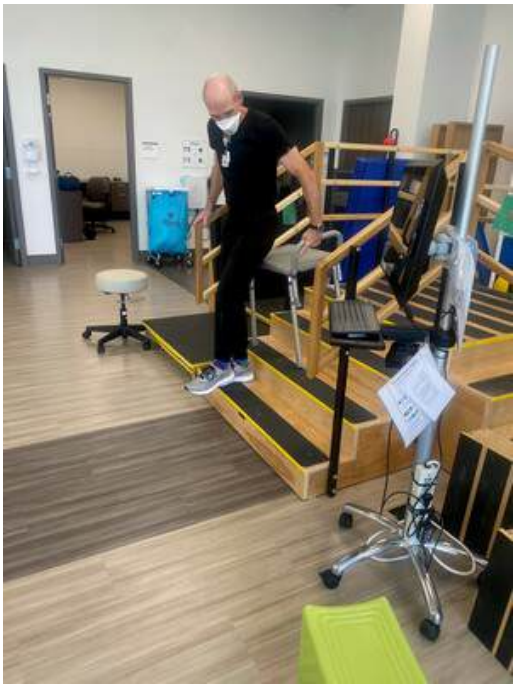
Kutschera_stair_1.jpg (668 kB)

Cody Kryzer - Oct 09, 2024, 10:25 PM CDT



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Kutschera_Stair_2.jpg (617 kB)

12/13 Project Recap

Cody Kryzer - Dec 13, 2024, 6:08 PM CST

Title: Project Recap

Date: 12/13/24

Content by: Cody Kryzer

Present: Cody, Luke, Dan, Matt, Daniel Kutschera

Goals: Meet with the client to show him our final design and go over results

Content:

- Gave Kutschera our poster presentation while screen sharing our poster
- It was hard to get a read on him, unsure if he genuinely liked it or not

Conclusions/action items:

We agreed to arrange something with Kutschera next semester to bring him the scale model and take some photos to help his company build a relationship with the university. The three of us taking BME 301 are uninterested in continuing the project, but it seemed like Kutschera would be interested in a group continuing our work and perhaps making a full scale model. He will communicate those details with Dr Puccinelli.

9/13/24 - Initial Advisor Meeting

MATTHEW SHERIDAN - Sep 18, 2024, 1:15 PM CDT

Title: Initial Advisor Meeting

Date: 9/13/2024

Content by: Matt Sheridan

Present: Matt, Luke, Dan, Abi, Cody

Goals: To get on the same page about goals for the semester.

Content:

Dr. Trevathan works on understanding safety of interfaces of neural engineering in the human body. The areas of interface between wires and the human body (electrons vs. ions) can be corrosive and dangerous.

This project should truly be about going through the design process and then communicating through that process with our advisor and client rather than just going through assignments and completing them. Shouldn't be about completing a rubric but designing.

Don't just focus on exactly what the client wants us to make, focus on the end goal that the client wants and figure out how to best go about solving this problem. We know more about the scope of this project and about engineering than the client, so we need to share and use this knowledge.

We should be completing the notebook with the goal of communicating our process to groups in the future, our client in the future, etc. It should be clean but full of information that has been entered throughout the semester. Don't just tick off boxes in the rubric but treat it as a design project and share all information effectively in the design notebook. Somebody should be able to follow our process and replicate it in the future.

Notebook checks are *technically* weekly, but as long as you are logging information and making progress throughout the semester, it should be sufficient. If you aren't making progress, you will get bad grades on the checks as a reminder.

For PDS, we won't know all information exactly, it should be malleable and be changed throughout the semester as you go through the design process. Put all important specifications on this document, and put general ideas for requirements that aren't known at the moment. Figure out specs for the product to be useful. Even if something isn't feasible in the scope of this semester (eg. some certain material that we don't have access to), still include it in the PDS and just state this at the end of the semester, saying if we were truly making this and taking it to market we would use that material, but are using 3-D print plastic.

Best thing to do is communicate our needs to Dr. Trevathan. Every group is different, so communicate these so he can best help us throughout the semester.

Conclusions/action items:

Throughout this semester, we need to communicate with Dr. Trevathan, and actively attempt to fill out the notebook with the end goal of sharing the process that we followed throughout the design project. The focus should be on doing our best to go through a good design process and journal this in our notebook.

9/20/24 - PDS Advisor Meeting

MATTHEW SHERIDAN - Sep 20, 2024, 12:33 PM CDT

Title: PDS and Initial Design Ideas Advisor Meeting

Date: 9/20/2024

Content by: Matt Sheridan

Present: Matt, Luke, Dan, Cody

Goals: To talk through our client meeting and our product design specs.

Content:

We want to define something that is feasible throughout this semester; a prototype that we can make, not necessarily anything near a final product. Figure out if the mechanism is even possible and then attempt to design this mechanism during the semester. Steer away from a full design that tests long term, but more so the mechanical advantage you can get on the device, forces that the patient would need to apply to move forward. For design specification on initial presentation, focus on the portion of the project that we will be able to look at during this semester. Also for design matrix/design ideas, just focus on the mechanism that we are looking at. Can maybe look at how ratcheting mechanism interacts with rails, but not the extension of the rails themselves. Also think about what we will be able to test when making the criteria for the design matrix.

Conclusions/action items:

This next week, we will need to go to the hospital and make some individual designs that look at the ratcheting mechanism and make a design matrix with valid design specs.

9/27/24 Advisor Meeting

Cody Kryzer - Sep 27, 2024, 12:34 PM CDT

Title: Advisor Meeting

Date: 9/27/24

Content by: Cody

Present: Team and Trevathan

Goals: Discuss design matrix and preliminary presentation

Content:

Focus on solving the problem the best way we can. Don't worry as much about how client wants us to do it. We can use the design matrix as a tool to communicate with the client our thinking.

When considering safety, make sure the mode of failure is something that would still be safe for the patient. Think a car intentionally crumpling

Linear force pistons to offset weight of chair. Fairly small and compact. Could be included in any of our designs really. Allows for two points of failure. Assistance on the way up and the way down. Linear force applied. Think of a car trunk, controlled ascent and descent. Pressure can be adjusted for weight.

^ https://www.iqsdirectory.com/articles/linear-actuator/linear-motion-products.html

Consider budget and scale. A full scale probably won't be possible with 500$. Use 3D prints and models/scale versions. Even a shortened version over a couple stairs. Just enough to demonstrate that it works.

Look for regulations and FDA approvals for other stair lifts and learn from that and apply it to our project. Use examples to explain our safety thought process.

Potentially use arms or legs to apply force.

Maybe procrastinate worrying about the weather.

Hydraulic ratcheting system?

Conclusions/action items:

Everyone should do some research. Finish the design matrix and prepare for the preliminary presentation. Don't forget about weekly progress reports

10/11/24 Advisor Meeting

MATTHEW SHERIDAN - Oct 11, 2024, 12:29 PM CDT

Title: Advisor Meeting

Date: 10/11/24

Content by: Matt

Present: Team and Trevathan

Goals: Discuss our team's plan moving forward

Content:

We should be making progress towards a prototype in this and coming weeks.

During this semester, we don't need to focus on our materials, manufacturing cost, etc. and can just work on making a working prototype. Focus on figuring out specification that we are trying to meet when it comes to gear ratio, mechanical advantage. Figure out these equations to figure out ideal values and then test for actual values.

Decide upon force that somebody will need to apply, reasonable time for the device to work in, and find the sweet spot between applied/output force and time. There will be losses due to things such as friction in the real world, we will need to either estimate that value or just account for it with a factor of safety. If the mechanics work correctly on a scale model, we will be able to know that it will scale to the real size accurately.

Is it at a weight it can be installed easily, is it easy to use ergonomically, does it get the user up in a good amount of time.

We can have cutoffs such as a certain weight so it can fit in the back of a truck; this doesn't need to be tested, just something to calculate by scaling up a scale model.

We can talk about equations governing the mechanism with Trevathan in a future meeting.

Conclusions/action items:

The team should start modeling/prototyping as soon as possible so we can figure out difficulties, needed materials, etc., and come to Trevathan with any questions about equations, models, and concerns.

10/18/24 Advisor Meeting

Cody Kryzer - Oct 18, 2024, 12:31 PM CDT

Title: Advisor Meeting

Date: 10/18

Content by: Cody

Present: Cody, Luke, Dan, Trevathan

Goals: Discuss where we go from here

Content:

- How can we make our proof of concept most useful
- When we scale up our model keep in mind that some things don't scale linearly
- Show and tell is mainly about getting feedback. Not so much what we bring. It shouldn't be a measure of progress. What do we want feedback on. A CAD model, a 3D print. If we need feedback how to build something, a CAD model is enough for people to get the idea.
- A CAD model would be fine for show and tell
- We should spend more time researching equations and materials rather than fabrication at this moment. Get numbers for show and tell.
- At show and tell get feedback on our plans for testing
- Consider the motion between pieces, constraining linear motion, friction, expenses
- Use relevant materials for scale model to get accurate forces
- Failure points may or may not be relevant for scale model
- Generally keep things simple for this class but make sure our decisions are well thought out

Conclusions/action items:

Come in next week with a plan on how to construct our device. Know what goals we want for scale model and why is it relevant.

10/25/24 Design Considerations Advisor Meeting

MATTHEW SHERIDAN - Oct 25, 2024, 12:36 PM CDT

Title: Design Considerations Advisor Meeting

Date: 10/25/24

Content by: Matt

Present: Cody, Luke, Dan, Matt, Abi, Trevathan

Goals: Discuss plans for designing the scale model

Content:

- What is the goal of the scale model?
  - Make sure the mechanisms work, get an idea of what it actually looks like and show it to Mr. Kutschera and get feedback; so both qualitative and quantitative
- What aspects of the lifting mechanism need to be tested (apart from the winch which has likely already been tested?
  - How the design will slide up and down; where the forces are going to be applied on the design; identifying failure points.
  - How do forces change if the users force is not directly pointed through the center of the platform.
    - This can be tested by looking at angle of twist of the platform, and also how the required force input changes with different locations of weight.
    - Also look at how the platform hinges during this process as well, how the ramp interacts with the top stair, as it must move along that top stair.
  - For ramp mechanics, we can model it both mathematically by hand or using SolidWorks to figure out appropriate deflection/failure values.
- We will need to send Kutschera an email with our shopping list, see if he wants to buy it or reimburse us for it.
- Important to figure out how to keep the platform stable; this will do a lot to decrease friction and allow for smooth motion up and down.
- Bearings likely have specifications for withstanding torque/torsion, we will have to look into that; important to use devices that have specification that allow for the use in this product.

Conclusions/action items:

Throughout this week we need to make sure to get all of our calculations and specific ideas for testing to bring to show and tell.

11/8/24 Advisor Meeting

Dan Altschuler (daltschuler2@wisc.edu) - Nov 20, 2024, 4:03 PM CST

Title: Advisor Meeting

Date: 11/8

Content by: Cody

Present: Cody Matt Trevathan and Luke

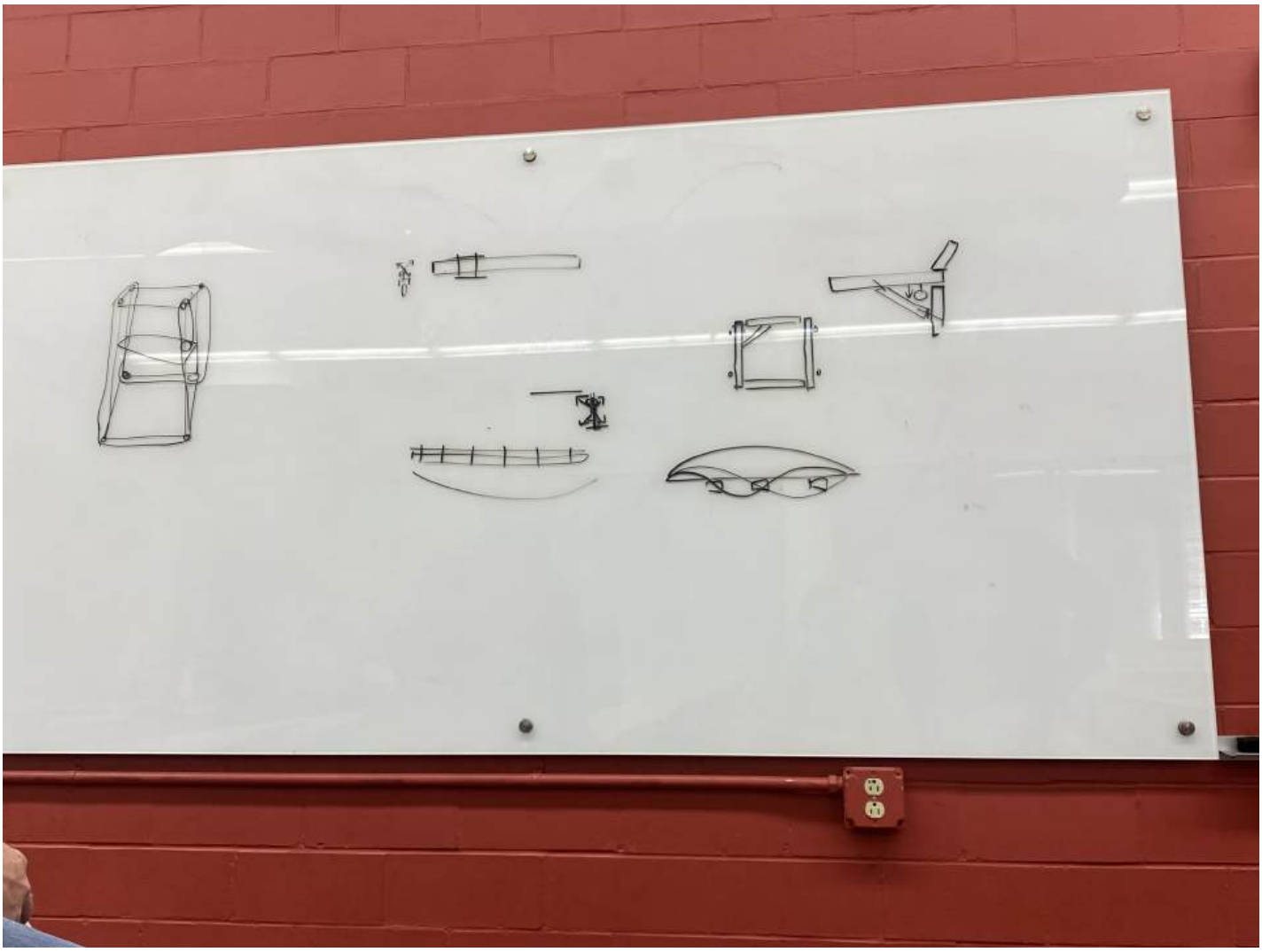
Goals: Get feedback and tips for fabrication

Content:

- Next week is Tong lecture - let Trevathan know if we want to set up a time to meet otherwise assume no meeting
- One more meeting before break - talk about testing at that one
- Use fasteners to put together framework - double check what we ordered or where we can order them from
- Identify where forces will be applied and place fasteners accordingly
- Fasteners can provide varying rigidity
- Could thread center hole and then put a bolt through neighboring beam - would be effective for tensile forces, not torsional forces
- Our design can withstand compression forces better than tensile forces
- Use T slot nuts for the framework on the bottom of the plates. Drill up through the plates. Use many weaker points of contact
- Make the platform feel safe, not just be barely safe.

Conclusions/action items:

Consider moving top pulleys to the underside of the beams - bolt through the beam to hang the pulley. Plan out fasteners and joint connections before we begin manufacturing. Start manufacturing tomorrow with the materials we have. 3D print stairs. Find rope and pulleys and something to wind the rope up in place of the winch.



11/22/24 Advisor Meeting

Luke Rosner - Nov 22, 2024, 12:28 PM CST

Title: Advisor Meeting

Date: 11/22/24

Content by: Luke

Present: Matt, Dan, Luke

Goals: Discuss plans for testing

Content: Plans for testing

Loading test - how does failure mode change in scale model vs full scale

Twisting test - x weight x cm from center of flatform. how does that affect the force required to lift

Overall function of device - look at PDS specifications - qualitative

Use spring scale to measure force - where to source? luggage scale?

Final deliverables - final report intro same as prelim report, final notebook should document design and thought process.

Statistics - don't always use t-test, mean & confidence interval sometimes relative, does doing statistics provide actual insight? -

twisting test - where can the maximum weight on platform be put on the platform before failure?

"If I had a full scale version of this, what would I test to verify this meets all specifications?"

Do relevant tests on scale model where possible and then explain what would be relevant on a full-scale model/future work

Conclusions/action items:

Less tests that actually tell information are better than a bunch of tests that don't give any relative information

9/25 Design Brainstorm

Cody Kryzer - Oct 09, 2024, 10:31 PM CDT

Title: Design brainstorm

Date: 9/25

Content by: Cody

Present: Whole team

Goals: Come up with designs for design matrix

Content:

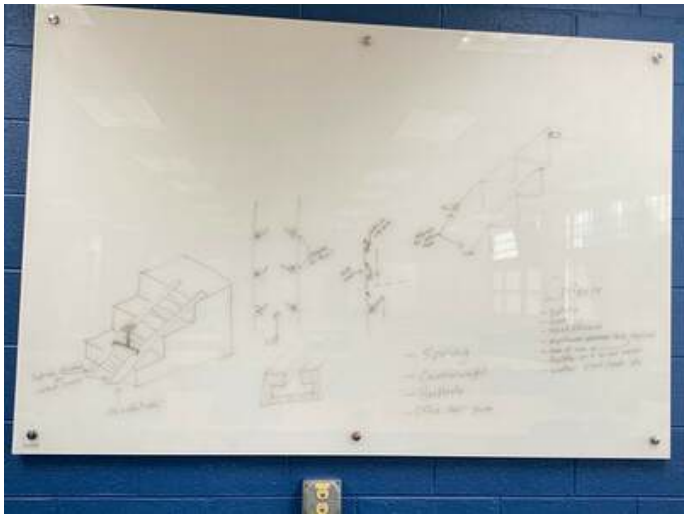
The team discussed potential designs for the design matrix

- Tried to figure out a two way ratchet mechanism
- Explored hydraulic lift systems, like a barber shop chair
- Explored counterweight systems
- Discussed criteria for design matrix

Conclusions/action items:

For the design matrix we will include a ratchet mechanism, a counterweight mechanism, and a hydraulic mechanism. Criteria will include cost, safety, weather, weight, and efficiency. (all subject to change).

Cody Kryzer - Oct 09, 2024, 10:20 PM CDT



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design_ideas.jpg (400 kB)

10/23/2024 Materials and Testing Brainstorm

Dan Altschuler (daltschuler2@wisc.edu) - Nov 15, 2024, 5:50 PM CST

Title: Materials and Testing

Date: 10/23/2024

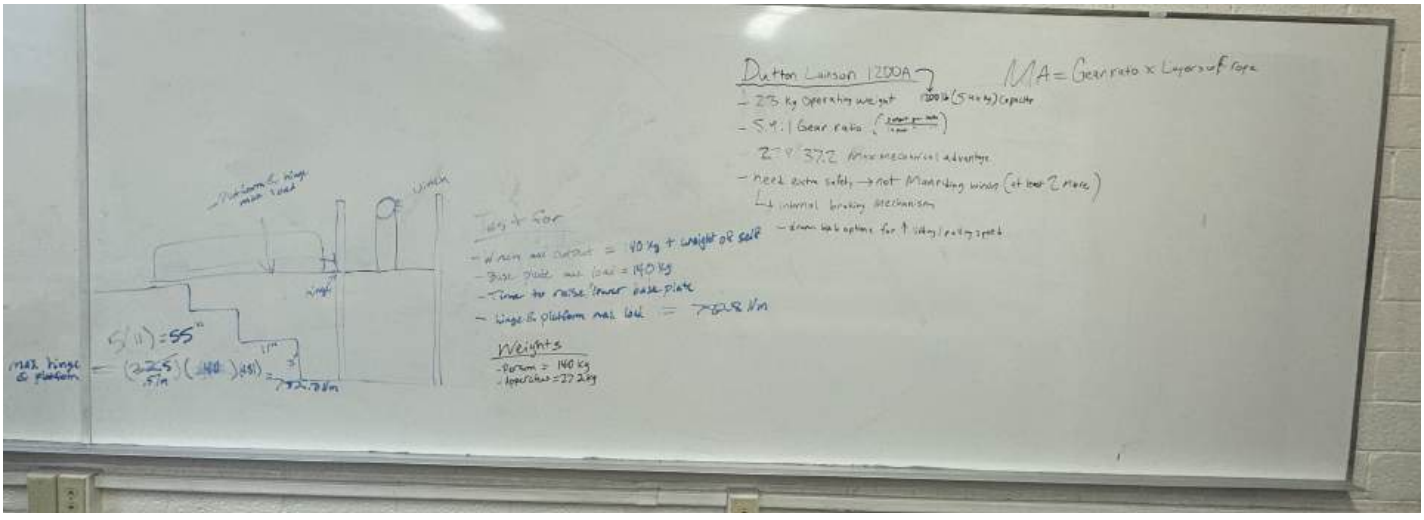
Content by: Dan

Present: team

Goals: Talk over materials and mechanical properties of our device

Content:

- A key part of the project will be making sure that our design would have enough points of safety to be usable within the FDA context
- The materials the team plans to use will help the team make these determinations after the design is testing
- The Dutton Lainson winch should be usable for the the design
    - it will have enough mechanical advantage for the weakest user as determined by the PDS
    - it also have a brake which can help with safety concerns
    - there are drum options for increasing the hoisting speed of the winch
- The other aluminum materials will be good to prevent rusting
- Extrusion is also very strong in compression which will be good to withstand the typical expected loads of the device outlined in the PDS
    - the weight of the person and the apparatus will be carried with ease by the extrusion that the team has decided on



Conclusions/action items:

After looking over these materials and moving forward with them, ordering and fabricating is what the team needs to do next.

10/16/24 Potential Materials

MATTHEW SHERIDAN - Oct 30, 2024, 4:24 PM CDT

Title: Potential Material Options

Date: 10/16/24

Content by: Luke Rosner

Present: Luke Rosner

Goals: To document potential materials for our final prototype.

Content:

Extrusion - https://8020.net/20-2040.html, https://8020.net/20-2020.html

Winch - https://www.amazon.com/TYT-Trailer-Anti-Slip-Portable-Backward/dp/B09MKGBQQC/ref=sr_1_8?s=hi&sr=1-8

Diamond Plate - https://www.metalsdepot.com/aluminum-products/aluminum-diamond-plate

Conclusion:

We will want to get the materials we need on order as soon as possible.

12/4/2024 Final Materials and Expenses

Dan Altschuler (daltschuler2@wisc.edu) - Dec 13, 2024, 5:27 PM CST

Title: Final Materials and Expenses

Date: 12/4/2024

Content by: Dan

Content:

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1										
Surface-Mount Hinge	Hinges for connection of base and ramp plates.	McMaster-Carr	1798A31	McMaster - Carr		11/1	2	$9.62	$19.24	https://www.mcmaster.com/products/hinges/
Pulley	Pulley for ropes to hoist design.	McMaster-Carr	3099T34	McMaster-Carr		11/1	8	$11.89	$95.12	https://www.mcmaster.com/products/pulleys/pulleys~/mounted-pulleys-for-wire-rope-for-lifting/
Silver Anodized Aluminum — Grooved Rail Texture	Extrusion for support and framework.	McMaster - Carr	47065T101	McMaster - Carr		11/1	4	$28.93	$115.72	https://www.mcmaster.com/47065T101-47065T413/
Diamond Tread Aluminum ⅛ inch Baseplate (1x1 and 1x2)	Material for base and ramp plates	Metals Depot	P418	Metals Depot		11/1	2	$18.92 (1x1) $32.84 (1x2)	$51.76	https://www.metalsdepot.com/aluminum-products/aluminum-diamond-plate
Hardware (screws, brackets, nuts)	Used to fabricate the final design	UW Makerspace		UW Makerspace		12/2		$16.78	$16.78	
HDF	Used to make the stairs for the final design	UW Makerspace		UW Makersapce		12/2		$4.48	$4.48	
								TOTAL:	**$303.02**	

11/20/2024 Fabrication Protocol

Dan Altschuler (daltschuler2@wisc.edu) - Nov 20, 2024, 5:28 PM CST

Title: Fabrication Protocol

Date: 11/20/2024

Content by: Dan

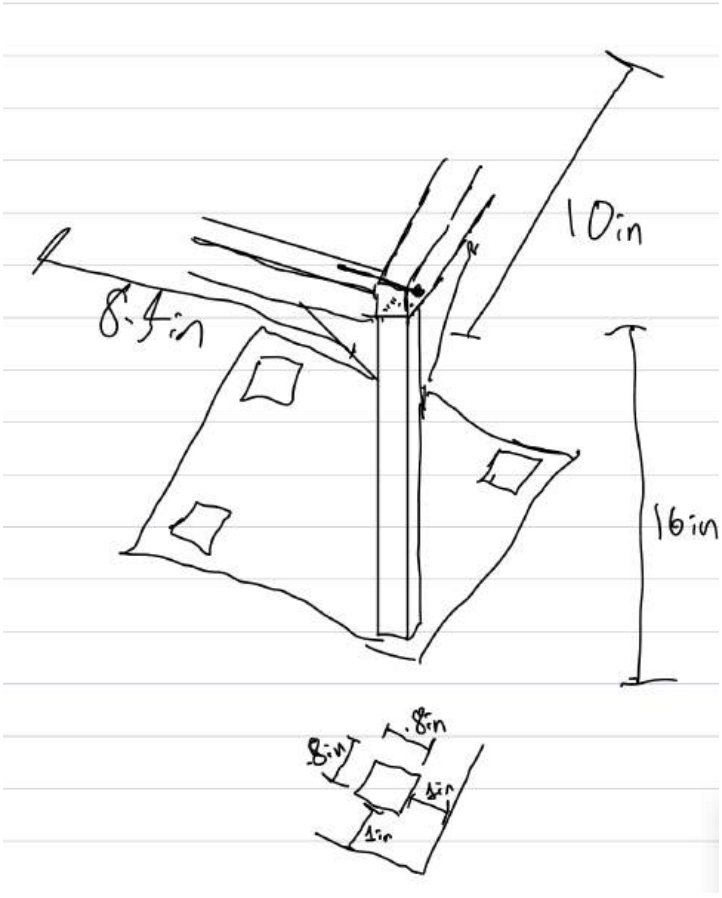
Present: Dan, Cody, Matt

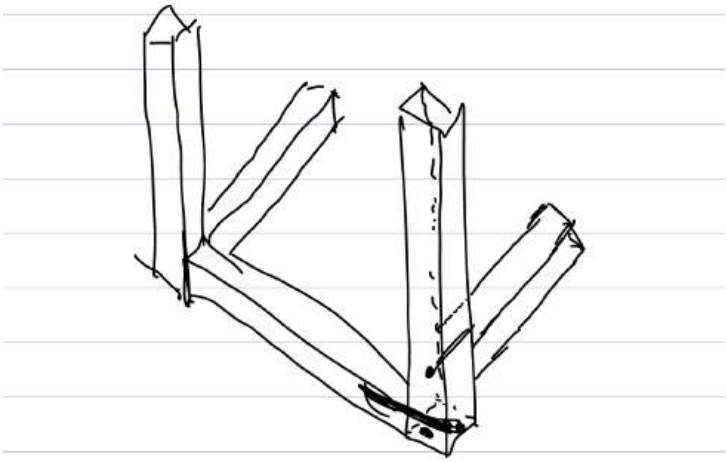
Goals: Get a fabrication protocol written for the final design

Content:

- The team is going to 3D print stairs for the final design, that file will be made soon and 3D printed during break
  - We have a determined height for that design and we can adjust based on our fabrication protocol here
- Pulley protocol
  - all 4 on the bottom will be drilled through the bottom of the plate and attached with a screw and a nut
  - the first two top pulleys will get two new holes on the base, both of which will go through the middle of the extrusion
  - the other two pulleys will hang off the side upside down

1. Cut the 20:20 aluminum extrusion to length (around 16 inches 4x for the height wise ones) (6x 8.4 inches, 2x 10 inches) (cut two to 18 inches for ramp plate)
2. Water-jet the aluminum base plates to create holes for the extrusion to run through (the cuts on the base plate should be 1 inch in from each side) (cuts will be about .8 inch side length squares)
3. Cut a notch into each side of the base plate to prevent the rope from rubbing on the metal
4. tap the extrusion holes for fasteners
5. fasten the extrusion together at the bottom with offset screws (see the figure below for details)
6. fasten the top plates across
7. attach 8 brackets (2 per piece of extrusion) for further stability
8. use the hinges to attach the two plates





Conclusions/action items:

Use this protocol to create our final design.

12/2/2024 Water Jetting

Luke Rosner - Dec 08, 2024, 2:06 PM CST

Title: Water Jetting Fabrication Protocol

Date: 12/2/24

Content by: Luke R

Present: Team

Goals: Create protocol for water jetting metal plates

Content:

Makerspace has a Omax Protomax water jet.

Waterjet is programmed with ProtoMAX MAKE software

We will use the water jet to cut the holes in the base plate for the extrusion and the slots for the pulleys

Protocol -

1. Download ProtoMax Make software

2. Program cuts into software

2a. The holes should be 1 inch inset from each corner and be 90x90mm

2b. The pulley slots should be 1 inch inset from the holes and go 1 inch in to the plate

3. Place plate into waterjet and secure with clamps

4. Fill waterjet until water just covers top of material

5. Run program.

Conclusions/action items:

This protocol should allow anyone to replicate building our design.

12/2/2024 Laser Cutting

Dan Altschuler (daltschuler2@wisc.edu) - Dec 02, 2024, 6:24 PM CST

Title: Laser Cutting Model Stairs

Date: 12/2

Content by: Cody and Dan

Present: Whole team

Goals: Create a model staircase using the laser cutter

Content:

Use this website to generate schematics for laser printed boxes https://boxes.hackerspace-bamberg.de/boxes.py/

To make the stairs, we will build 4 boxes and glue them together. I think this is the simplest way to do it, and they don't have to be anything fancy for the purposes of this project.

The dimensions for the four boxes are in millimeters as follows

x:88.9 y: 300 h:63.5

x:88.9 y:300 h:127

x:88.9 y:300 h:190.5

x:190.5 y:300 h:254

These are the OUTSIDE dimensions for the boxes since we haven't picked a material yet and have an unknown thickness

Protocol:

1. Use boxes.py to generate the boxes needed for the laser cutting files
2. Take the files generated from boxes.py and select the thickness of the material to ensure that the material will be cut through completely
3. Download these files as .dxf and move them adobe illustrator for final processing before putting the wood into the laser cutting machine
4. Set the scope to 255 on the red in RGB to ensure the corners are defined by the laser cutting software
5. Copy and paste these drawings into the laser cutting software and ensure the laser is on material for the entire size of the wood
6. Once the corners are established on the software, allow the process to run
7. Once the boxes are cut out of the wood, pull the small pieces off and use a mallet to attach the panels of wood together
8. Once all four boxes have been put together, use wood glue to attach the boxes to create the final stairs

Conclusions/action items:

Using these numbers and following this protocol, one can replicate the process of lasercutting the wood and creating the stairs.

12/2/2024 Metal Fabrication

Cody Kryzer - Dec 11, 2024, 12:44 AM CST

Title: Metal Fabrication

Date: 12/2/2024

Content by: Dan

Present: Team

Goals: Get the metal ready for fabrication

Content:

1. cut the extrusion using a chop saw into 6 8.4 inch pieces, 2 10 inch pieces, 2 22 inch pieces and 4 24 inch pieces
2. tap the holes in the 8.4 inch pieces of extrusion and in the 10 inch pieces of extrusion so they can be attached for the top and the bottom of the frame
3. screw the extrusion together to create the base, this will be made from connecting the 24 inch pieces and the 8.4 inch pieces
    1. attach two 8.4 pieces on opposing sides that are above the screw hole for the bottom to create the base
4. drill a hole through two of the pulleys to attach the t slotted fasteners and the screws
5. these pulleys will be the ones to hang off the sides and must be tight to the extrusion
6. attach the pulleys onto the bottom with holes drilled through the base plate (these pulleys will be close to the notches in the base plate)
7. drill through the ramp plate to attach the bottom pieces of extrusion that are meant for support (there will be three screws on each extrusion evenly spaced)
8. drill through the base plate to attach the hinges and use a nut on the end to make sure the screw is fully attached

Conclusions/action items:

Using this protocol, there should a path to follow to create the final design.

12/4/2024 Testing Protocols

Luke Rosner - Dec 10, 2024, 8:24 PM CST

Title: Testing Protocol

Date: 12/4

Content by: Luke Rosner

Present: Team

Goals: Document protocol for testing prototype

Content:

1. Place test weight on base plate and secure with tape

2. Place level on top of weight to record tilt angle

3. Pull rope using force meter

4. Record tilt and force at 1,3,5,7 & 9 in above bottom of plate

5. Repeat protocol for 0, 5, 10, and 15 lbs

Conclusions/action items:

This protocol should allow anyone to reproduce our testing protocol

12/4/2024 Testing Data

Luke Rosner - Dec 13, 2024, 5:37 PM CST

Title: Testing Data

Date: 12/4

Content by: Luke R

Present: Team

Goals: Record Testing Data

Content: Attached Doc

Conclusions/action items:

Overall, we are pleased with the function of the scale model. The data shows that the addition of the nylon to the base plate greatly improved the device, decreasing the amount of force required to lift it greatly.

Luke Rosner - Dec 10, 2024, 8:26 PM CST

Stair Chair Scale Model Testing

Distance From Center of Mass (in)	Weight (lbs)	Trial	Deflection of Platform (° from flat) Avg Force Required to Lift (kg) At Height Above Base (in)					
			0	1	3	5	7	9
0	0	1	0 0	8 1.7	8 1.8	8 1.4	7 1.0	7 0
0	0	2	0 0	8 1.9	8 1.5	8 1.3	7 1.1	7 0
0	0	3	0 0	8 1.8	8 1.6	8 1.2	7 1.0	7 0
0	5	1	0 0	9 2.9	8 2.4	8 2.3	7 1.8	7 0
0	5	2	0 0	8 3.1	8 2.7	7 2.1	7 1.5	7 0
0	5	3	0 0	6 3.0	7 2.8	6 2.4	6 1.7	5 0
1	5	DOES NOT LIFT						
1.5	5	1	0 0	7 6.4	7 5.3	-8 5.0	DOES NOT EXCEED 5 in	
.5	5	1	0 0	7 5.4	8 5.0	7 4.9	8 5	7 2.4
0	10	1	0 0	6 3.4	7 2.6	6 1.5	8 1.3	5 1.1
0	10	2	0 0	8 3.5	8 3.2	8 2.2	7 1.6	7 1.3
0	10	3	0 0	7 3.1	7 3.0	6 2.0	6 1.3	8 .9

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Scale_Model_Testing_.pdf (134 kB)

Product Design Specifications

Cody Kryzer - Oct 09, 2024, 10:06 PM CDT

Stair Chair

Product Design Specifications (PDS)

BME 200/300 Section 307

September 19, 2024

Client

Mr. Daniel Kutschera

Advisor

Dr. James Treichler

Team

Matt Sheridan	mjsheridan2@wisc.edu
Cody Kryzer	ckryzer@wisc.edu
Daniel Altschuler	daltschuler2@wisc.edu
Abi Conners	aconners2@wisc.edu
Luke Rosner	lrosner2@wisc.edu

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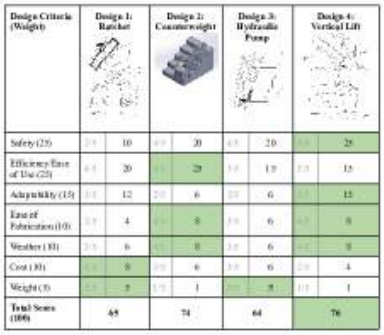
Stair_Chair_-_Product_Design_Specification_PDS_.pdf (292 kB)

Design Matrix

Cody Kryzer - Oct 09, 2024, 10:07 PM CDT



Design Criteria (Weight)	Design 1: Ratchet		Design 2: Counterweight		Design 3: Hydraulic Pump		Design 4: Vertical Lift	
Safety (25)	2.5	10	4.5	20	4.5	20	4.5	20
Efficiency/Ease of Use (25)	4.5	20	4	20	3.5	13	2.5	12
Adaptability (15)	3.5	12	2.5	6	2.5	6	4	15
Ease of Fabrication (10)	2.5	4	4.5	8	3.5	6	4.5	8
Weather (10)	2.5	6	4.5	8	3.5	6	4.5	8
Cost (10)	4.5	8	2.5	6	3.5	6	2.5	4
Weight (5)	4.5	5	1.5	1	4.5	5	1.5	1
Total Score (100)		65		74		64		78

Safety:
The safety category refers to the risk of injury for a user while operating the stair chair. This category also considers the risk of worsening injuries through accidental mechanical output from the user's wounded lower extremity, either through slipping while operating the device, or total mechanical failure. Given the wide range of patients that the stair chair is hoped to be usable for, and the risks of mechanical failure, the team decided to weigh the safety category highest at 25. The bi-lift design won this safety category because the user never needs to move up and down an incline, which contributes to user safety. It also will have attached railings so that individuals will not roll off the lifter it raises.

Speed/Efficiency:
The efficiency/ease of use category refers to how quickly the user can get from the bottom to the top of the stairs and how easily the chair is mounted and dismounted by the user. The team recognizes that an inefficient and slow device will not be worth using and that a device that involves significant mechanical output could limit the kind of patients who can operate the

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Stair_Chair_Design_Matrix.pdf (500 kB)

Preliminary Report

Dan Altschuler (daltschuler2@wisc.edu) - Oct 25, 2024, 12:16 PM CDT

BME Design

Stair Chair

Preliminary Report

BME 200/300 Section 307
October 9, 2024

Client

Mr. Daniel Kutschera

Adviser

Dr. James Tretsfan

Team

Matt Sheridan	mjsheridan2@wisc.edu
Cody Kryzer	ckryzer@wisc.edu
Daniel Altschuler	daltschuler2@wisc.edu
Abi Connors	aconnors2@wisc.edu
Luke Rosner	lrosner2@wisc.edu

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Stair_Chair_Preliminary_Report.pdf (1.27 MB)

Final Report

Dan Altschuler (daltschuler2@wisc.edu) - Dec 13, 2024, 6:06 PM CST

Stair Chair

Product Design Specifications (PDS)

BME 200/300 Section 307

Client

Advisor

Team

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Stair_Chair_Final_Report.pdf (4 MB)

Final Poster

Dan Altschuler (daltschuler2@wisc.edu) - Dec 13, 2024, 6:07 PM CST

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Stair_Chair_Final_Poster_2_.pdf (2.59 MB)

9/25/2024 Meeting with Luke's Dad

Dan Altschuler (daltschuler2@wisc.edu) - Oct 18, 2024, 12:29 PM CDT

Title: Meeting with Luke's Dad/Design Matrix

Date: 9/25/2024

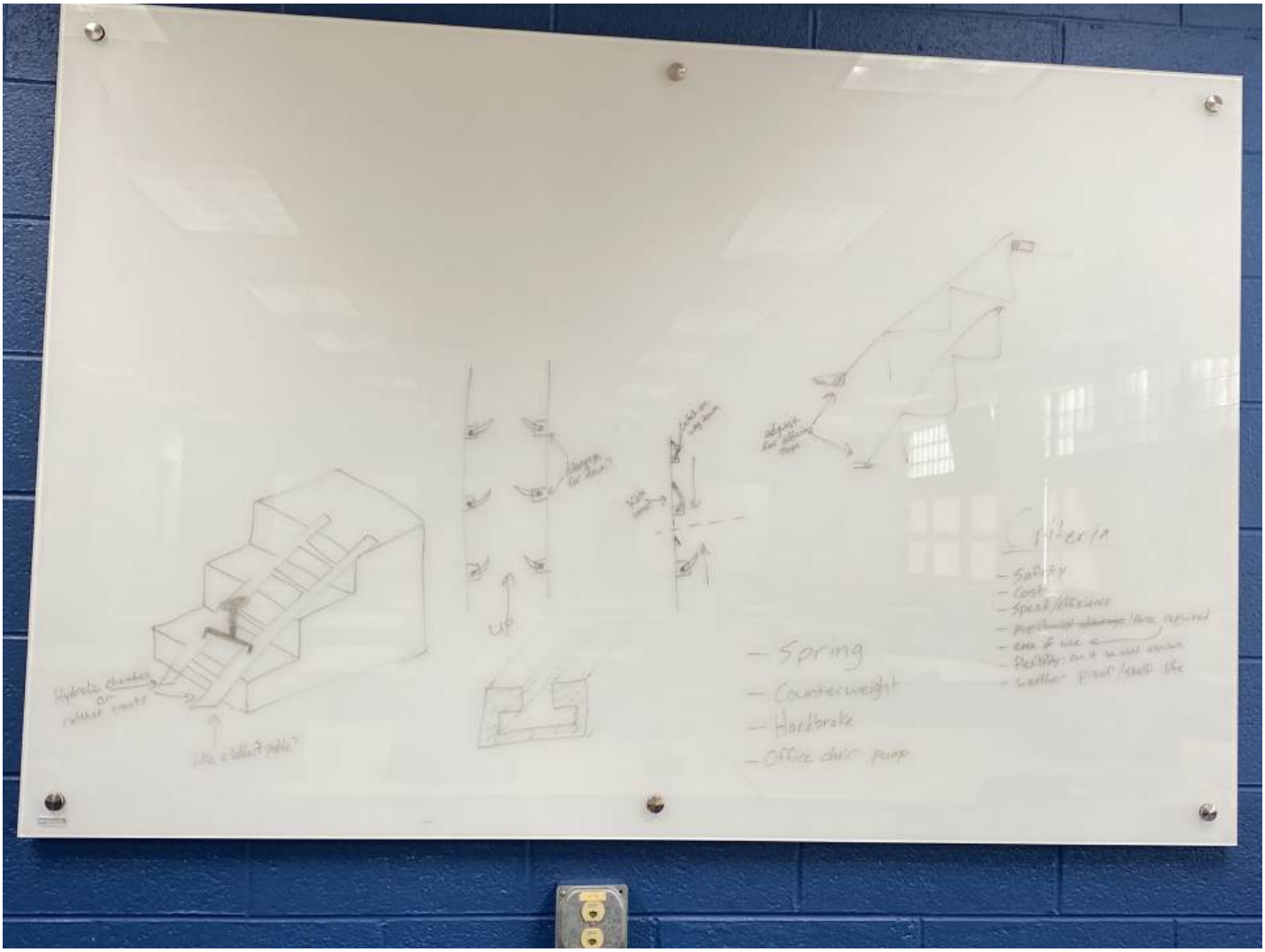
Content by: Dan Altschuler

Present: Luke, Matt, Cody, Dan

Goals: Get some ideas for the design matrix

Content:

- could use a linear guide that could have a chair attached to ride up the incline
- design considerations for skinny staircase could involve making the smallest contraption that is possible so that the stairs are not blocked
- good to write down all the assumptions and all the constraints involved with the designs
- could use a torsional spring on the bottom, tuned to the weight of those that use
    - can load the spring with the accurate weight for the person involved
    - energy must be stored somehow - a string is the cheapest way to store energy
- rotary spring like a tape measure
- counterweight could help you up and also control the descent
    - counterweight would be hard to include while also keeping the design small
    - pulley system that goes up a little higher than the device would need to be used
- gravity hydraulic system with water
- pump something like a barber's chair
    - hydraulic jack
    - release valve that controls the descent
- must also consider how cheap we can make the device so that people are able to afford it and not just try to make do during the time they are non-weight-bearing
- bicycle contraption that can pull you up a ramp
    - can attach to the wheelchair and hoist up the chair
    - can only feed at x inches per second to control the descent
- **Criteria for our designs**
    - ease of use - mounting, dismounting, chair swivel, who can use it
    - ease of assembly
    - usable by any age and ability to push
    - mechanical advantage
    - safety
    - cost



Conclusions/action items:

The team will now shift it's focus to creating our design matrix and rating our designs.

10/3/2024 Preliminary Presentation Meeting

Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 5:12 PM CST

Title: Preliminary Presentation Meeting

Date: 10/3/2024

Content by: Dan

Present: Team

Goals: Prepare for the preliminary presentation

Content:

- First thing to address is to assign certain parts of the presentation to people
- It makes sense for Luke to talk about the final design and the boat lift design since he created these designs in Solidworks
    - We also need to make drawings for the designs so that we can display these on the presentation
    - Cody and Matt are handling these right now so that they will be ready
- Dan is going to handle the intro and a lot of the preliminary part of the presentation
    - This includes the background research and the motivation since he did a lot of this research
- We are going to do a run through of the presentation for the sake of timing and being comfortable talking with each other
- After the first run through we are going to go again just for the sake of timing since we took way too long at first

Conclusions/action items:

Now that we have practiced our presentation and the document is created and finished, we are ready to go for the preliminary presentation.

10/23/2024 Team Meeting

MATTHEW SHERIDAN - Nov 15, 2024, 5:46 PM CST

Title: Team Meeting

Date: 10/23/2024

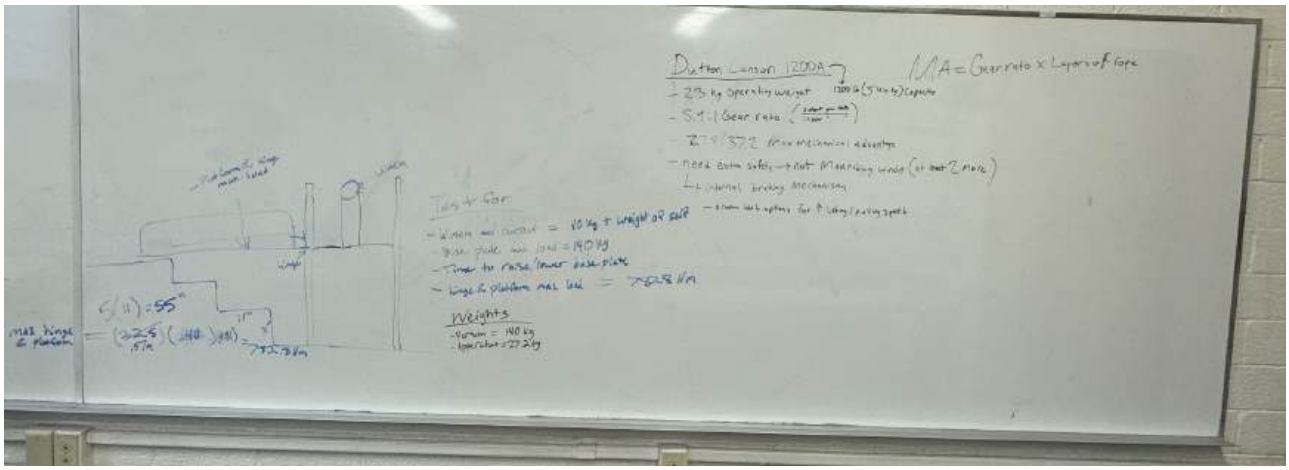
Content by: Dan

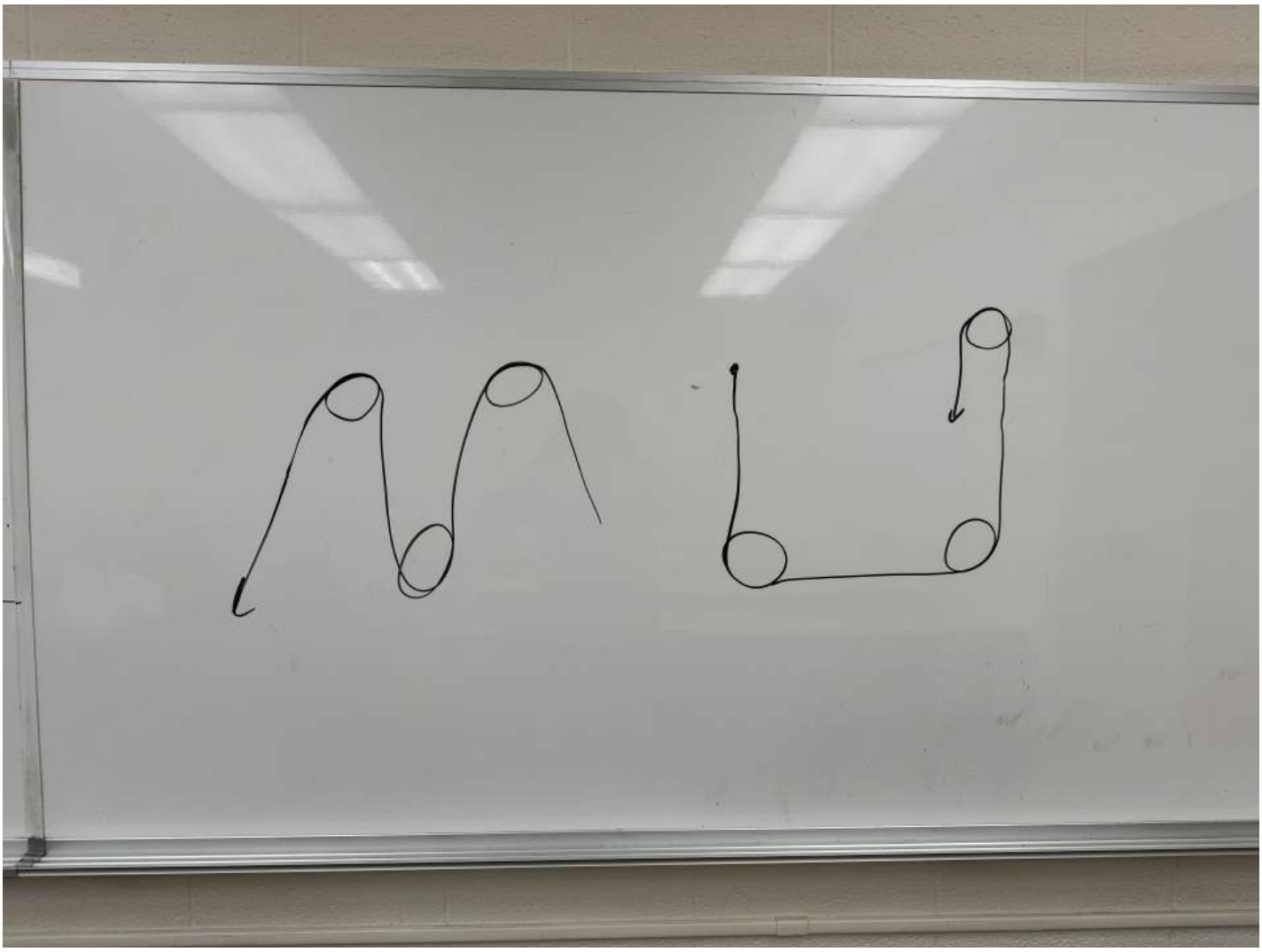
Present: Luke, Abi, Matt, Cody, and Dan

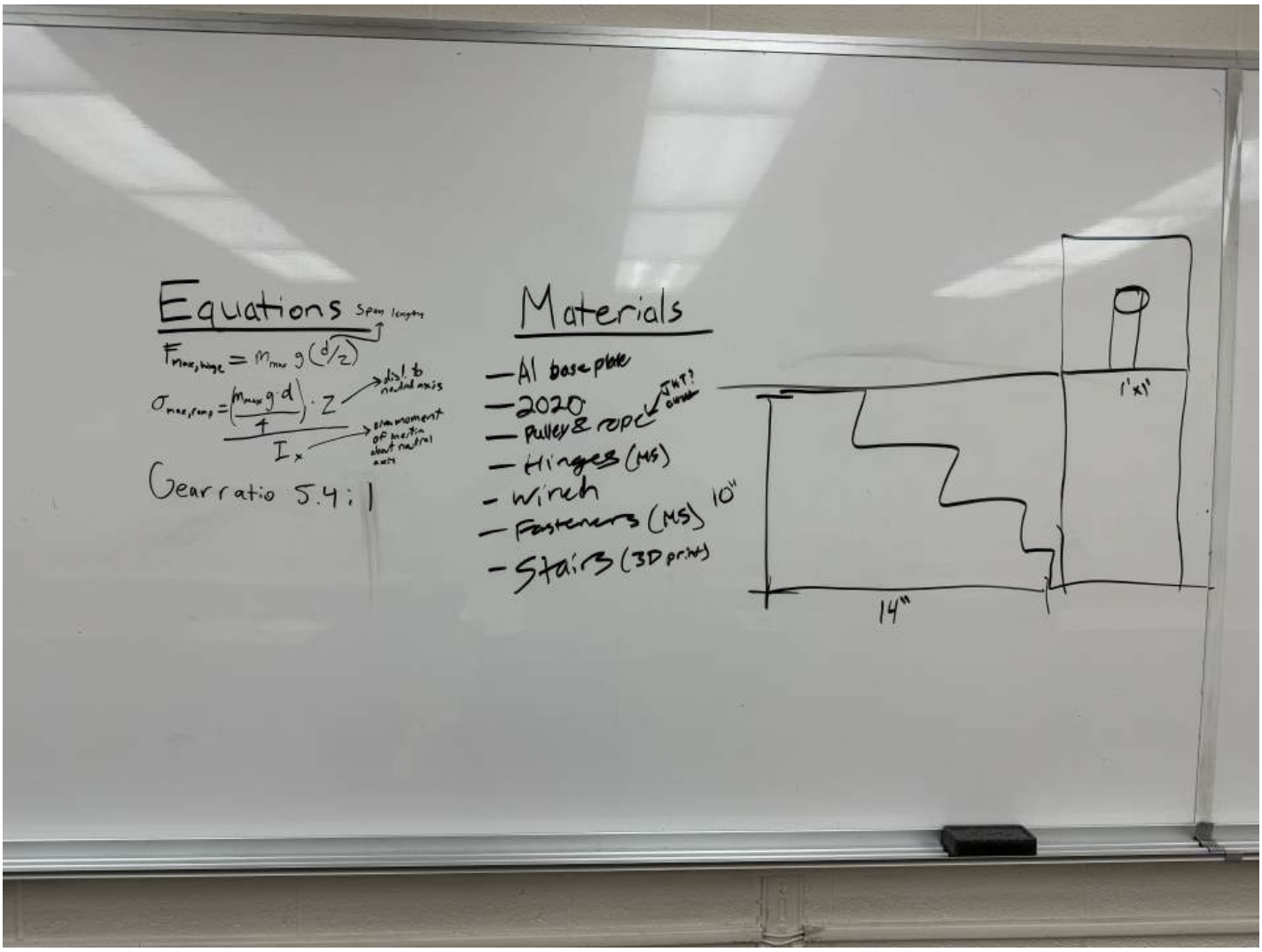
Goals: Talk over equations in an attempt to quantify our methods before the next advisor meeting/also look at materials to order

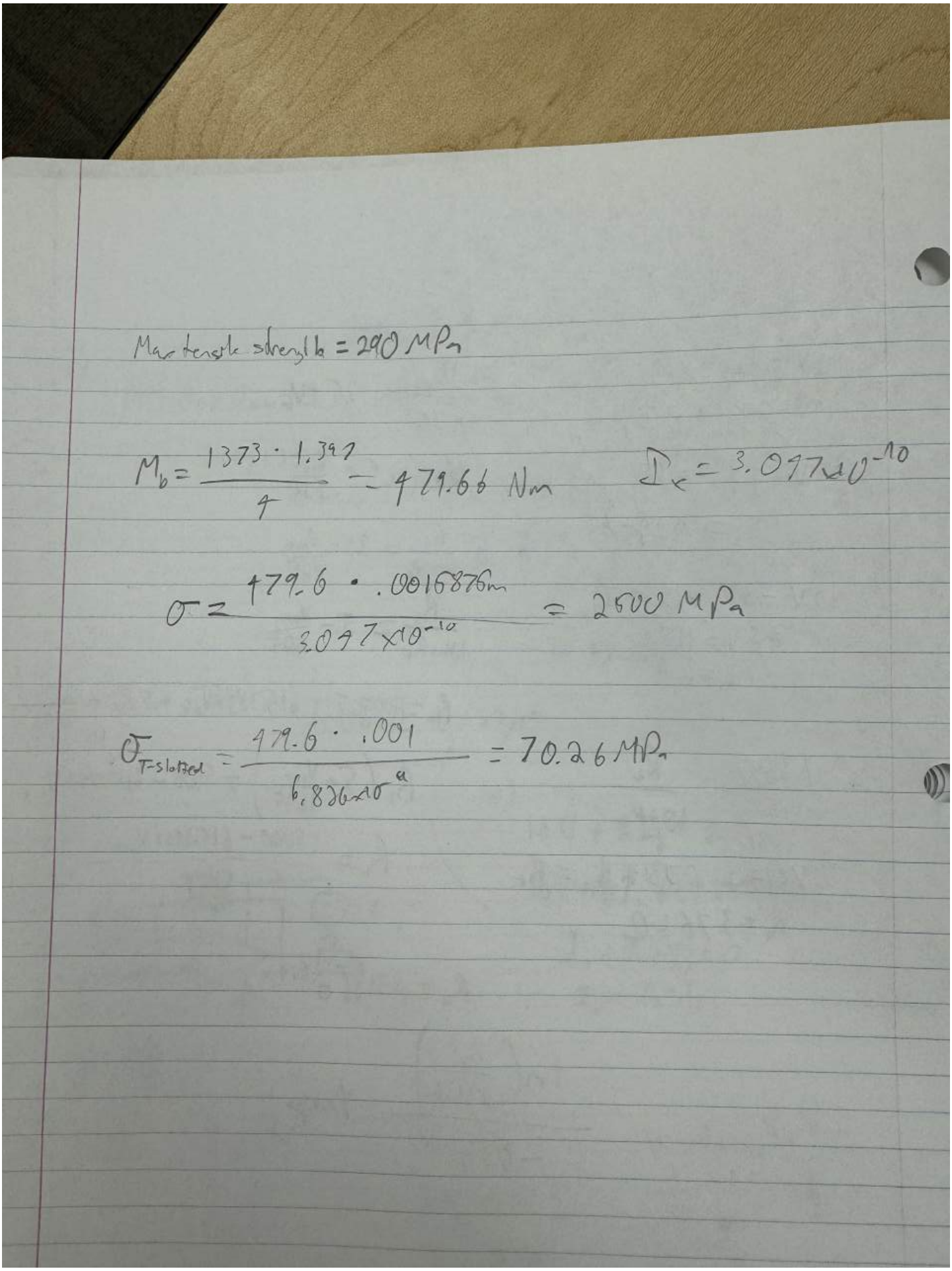
Content:

- The team needs to determine what we want to bring to show and tell and also what type of feedback we want to get from the groups
    - We could use a CAD model or we could some piece of the full scale model, depends on time and what we think will get us the best feedback
- We also need to determine what we are testing for
    - winch max output?
    - base plate max load?
    - time to raise it?
- The team also needs to consider equations for the mechanical advantage of the device, and the gear ratio associated with the winch
    - these can be found on the Dutton-Lainson website for the 1200A brake winch we were considering using
- The team is considering 3D printing the stairs for ease of creation
- Could test the winch using a forcemeter or by hoisting something






Equations
Span length
$F_{max,hinge} = m_{max} g (d/2)$
$\sigma_{max,ramp} = \left(\frac{m_{max} g d}{I_x}\right) \cdot z$
dist. to neutral axis
area moment of inertia about neutral axis
Gear ratio 5.4 : 1
Materials
- Al base plate
- 2020
- Pulley & rope
- Hinges (MS)
- Winch
- Fasteners (MS)
- Stairs (3D print)
10"
14"
1'x1'



Conclusions/action items:

The team is now ready for the fabrication meeting, and will look to order the materials as soon as possible.

10/30/2024 Show and Tell/Materials Meeting

Dan Altschuler (daltschuler2@wisc.edu) - Oct 30, 2024, 5:07 PM CDT

Title: Show and Tell/Materials Meeting

Date: 10/30/2024

Content by: Dan

Present: Dan, Matt, Luke, Cody

Goals: Determine what we want to get out of show and tell and also draft an email with the materials we would like to purchase

Content:

- We want to start off with the broad scope of our project and then narrow into what we are hoping to accomplish this semester
    - This includes mentioning the problem, the proposed solution, and then our final solution
    - We should get feedback on the ratchet mechanism, but look for more feedback on the CAD model
        - we could also maybe get feedback on the materials we are gonna use and the actual scale of our model
        - we should really get feedback on our testing and maybe scale of the model
    - We also need to know what we are doing about our materials
        - do we need to invoice our client
        - do we have to buy all the things and then he will reimburse us
- Order Form
    - 1 1x1 1/8 inch thick aluminum diamond tread and 1 1x2 of the same https://www.metalsdepot.com/aluminum-products/aluminum-diamond-plate
    - 20 linear ft 20/20 aluminum extrusion https://www.mcmaster.com/products/2020-t-slotted-framing/
    - Chrome-Plated Zinc—Dull hinges (2x) https://www.mcmaster.com/products/hinges/hinges-2~/surface-mount-hinges-with-holes/
    - Single-Groove Without Bearing 600 lb capacity pulley (8x) https://www.mcmaster.com/products/pulleys/pulleys~/mounted-pulleys-for-wire-rope-for-lifting/

Conclusions/action items:

Get these materials ordered or at least sent to Kutschera so that we can get them in time to put together the final design.

11/1/2024 Show and Tell Notes

Dan Altschuler (daltschuler2@wisc.edu) - Nov 01, 2024, 1:43 PM CDT

Title: Show and Tell Notes

Date: 11/1/2024

Content by: Dan

Present: team

Goals: Learn about testing for our model

Content:

- How do we scale the weight and the winch to work well together?
    - do the testing on the small device, find some weight ratio between the scaled model and the full sized model
    - should we get foldable supports? could wedge them into the stairs? meant for fairly specific use cases?
    - could test the max weight before it bends - calculate some bending ratio for the device that can apply
- Don't want to spend all the money
- Can use some sort of lattice on the bottom, triangle metal on the bottom side on the plate
- larger feet for greater contact area on the bottom to prevent swaying or breaking down of materials
- Testing
- Use variety of materials?
- Bolt framework to the plates
- What weight will make the different components collapse/fail?
- time to lift
- vertical distance per rotation
- test with different materials
- slippage on the ramp
- test hinge strength
- Garden hose wind up for scale model if we dont' get a whole winch - would be more similar than pulling the rope with our hands
- use lubricant to prevent tipping
- Let the platform tip a bit but prevent the tipping from applying friction
- Simulate a person standing/walking at different points
- Have a seat on the platform to keep weight distribution predictable

Conclusions/action items:

After learning all of this from Show and Tell, the team will try to implement these ideas during fabrication.

11/22/2024 Fabrication Meeting

MATTHEW SHERIDAN - Nov 25, 2024, 12:54 PM CST

Title: Fabrication Meeting

Date: 11/22/2024

Content by: Dan and Matt

Present: Team

Goals: Fabricate the final design

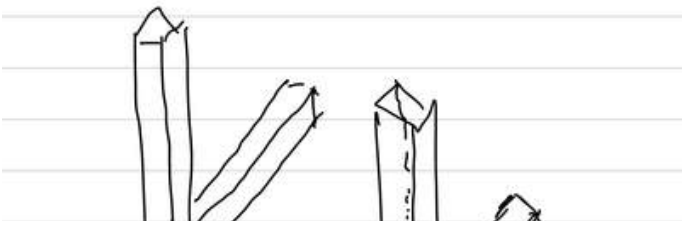
Content:

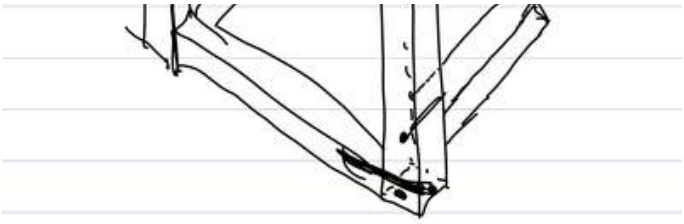
- The first order of business for the team is waterjetting the 1/8 inch aluminum base plates 1 inch from each corner and with a square side length of .8 inches to give the 20:20 extrusion a place to fit into the base plate
    - this waterjetting will happen on Monday with Matt and Luke because they are all reserved for today but they will be in Madison still
- Next the team needs to cut the aluminum extrusion to make best use of the material
    - Dan has come up with two different plans to cut the extrusion for ease of use and also to save the most amount of material
    - we are likely going to have a lot of extrusion leftover, which will be fine, as it can be used for future work or if we need more extrusion after putting together our design
    - After a small change to the design, there will not be as much extrusion left over as we have raised the length of the heightwise extrusion to 24 inches
- Attaching the hinges to the base plate
    - these hinges will be place on the bottom of the base plates, facing up
    - the team plans to drill through the hinges and have them clamped so that the holes are directly aligned for fabrication
- The team just cut the extrusion using a chop saw into 6 8.4 inch pieces, 2 10 inch pieces, 2 22 inch pieces and 4 24 inch pieces
    - We then tapped the holes on all 6 of the 8.4 inch pieces to allow for fastening
    - Next we will need to drill holes where needed into the other extrusions and attach everything together.
- the extrusion on the bottom of the base plate is going to be fastened with screws drilled through the baseplate and nuts on the end of each of these screws
- m5 fasteners for hinges and the extrusion; m4 for the pulleys

Conclusions/action items:

The team must acquire all the fasteners this weekend so that the final device is ready to be fabricated for the Monday after break. This will give us time to test the device before the final poster session.

Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:28 PM CST





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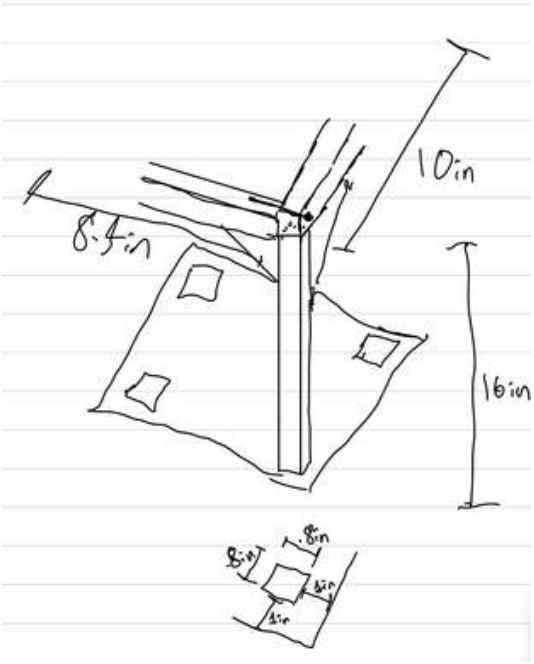
Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:29 PM CST



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12/2/2024 Fabrication Meeting

Dan Altschuler (daltschuler2@wisc.edu) - Dec 02, 2024, 6:19 PM CST

Title: Fabrication Meeting

Date: 12/2/2024

Content by: Dan

Present: Team

Goals: Build the final design

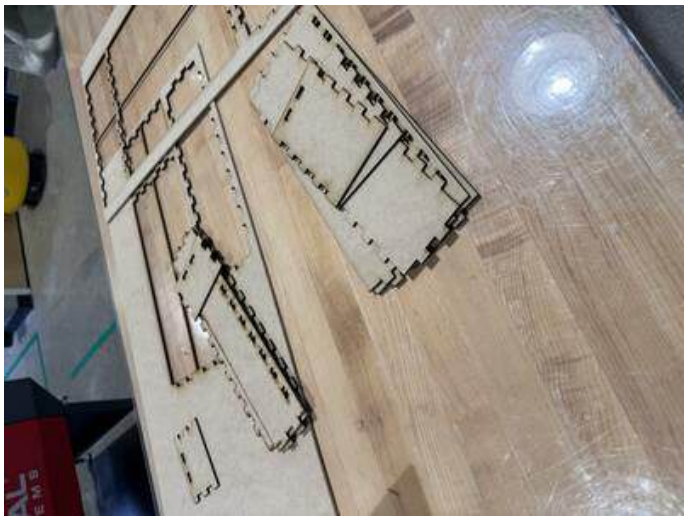
Content:

- The first thing the team did is create the files for the lasercutting to create the stairs
  - We took these files from boxes.py and then converted them to dxf files in Adobe Illustrator
  - By taking MDF from the scrap bin, the team put this in the laser cutter and created the the stairs
  - We then used wood glue to put the stairs together and they are officially finished
- While the stairs were being lasercut, the aluminum base plate needed to be fixed on the waterjet as the holes for the extrusion were not big enough
  - This fix was done by Matt and then the base plate is being drilled through to add the pulleys
  - The pulleys are going to be added to the bottom
- We also need to add the hinges onto the baseplate so there will be more cuts made to add the place for the hinges onto both plates
- The frame made out of the aluminum extrusion was screwed together and is ready to be used for the design.

Conclusions/action items:

The team will finish the design tonight with the goal of testing on Wednesday.

Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:32 PM CST



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Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:32 PM CST

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Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:32 PM CST

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Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:32 PM CST

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IMG_8674.jpg (1.61 MB)

12/4/2024 Testing and Final Design Meeting

Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:22 PM CST

Title: Testing and Final Design Meeting

Date: 12/4/2024

Content by: Dan

Present: Team

Goals: The team is looking to complete testing on the final design and also make some needed additions to the final design to help the metal sliding on metal

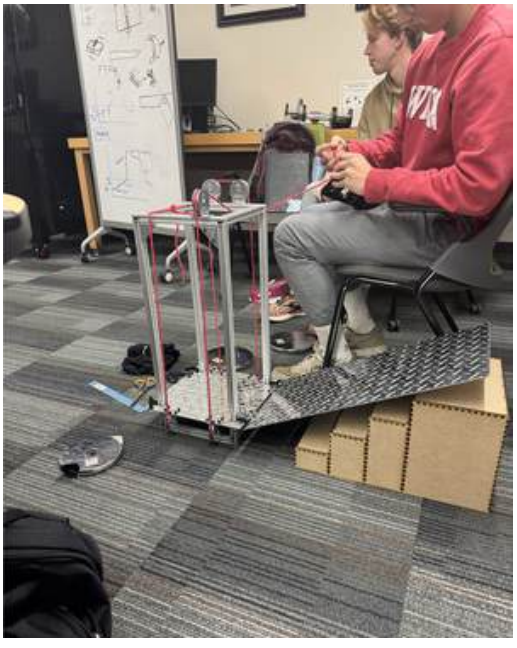
Content:

- The team has acquired some nylon to add into the slots where the extrusion slides with the base plate, which has helped the cranking of the device a lot
    - The nylon has prevented the screeching of the metal, and has also made the tipping of the base plate less significant which is important for the demonstration of the final design
- The team did testing on the design by adding weights found in the green room of the ECB
- We conducted testing and measured the deflection at heights of 0, 1, 3, 5, 7, 9 inches for varying weights
- We also did testing to find the force needed to move
- The team also did testing with and without the nylon added to measure the different deflections
- With the testing complete and the final design completely fabricated, the team will turn its focus to completing the poster and preparing for the final presentation on Friday
- The team hopes to meet with Dr. Trevathan tomorrow to get feedback on our poster and to also go over strategies for presenting

Conclusions/action items:

With all of this done, it is time to do the final poster presentation to show all of our work.

Dan Altschuler (daltschuler2@wisc.edu) - Dec 04, 2024, 4:33 PM CST



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2024/10/02 - Counterweight Design Idea

MATTHEW SHERIDAN - Oct 09, 2024, 10:51 PM CDT

Title: Counterweight Design Idea

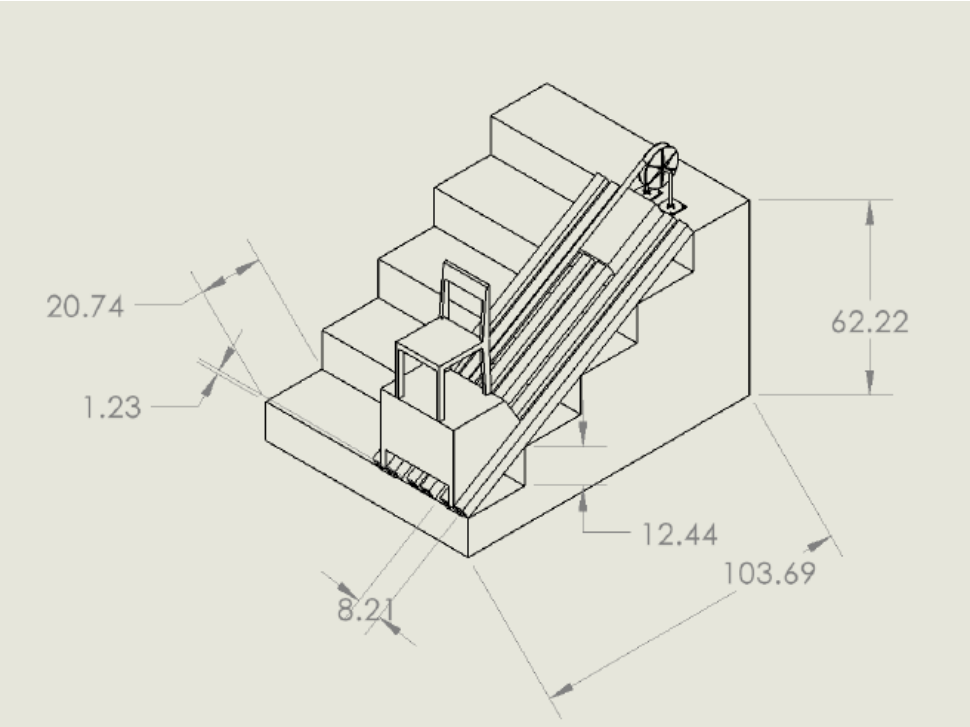
Date: 10/2/24

Content by: Matt Sheridan

Present: Matt Sheridan

Goals: To document my counterweight design idea.

Content:



This design utilizes a counterweight to aid in both the ascent and descent of the stairs. The design also includes a swiveling seat to allow for easy entry and exit from the device and a lap belt for safety on the ascent and descent. Additionally, the seat is moving up and down on two tracks, with a third in the middle housing the counterweight. The seat and the counterweight are connected via a pulley system, and the counterweight would be adjusted in weight based on the user's weight. On the way up, the counterweight would be lowered, meaning less force would be required to move up the stairs. The user could either push themselves up with their working leg or use the railing to pull themselves up. On the way down, the counterweight would be raised, slowing the descent to make it both safe and quick.

Conclusions/action items:

This design will be included in the team's design matrix.

2024/10/23 - Stair Lift Constraining Equations

MATTHEW SHERIDAN - Nov 15, 2024, 5:56 PM CST

Title: Stair Lift Plate Constraining Equations

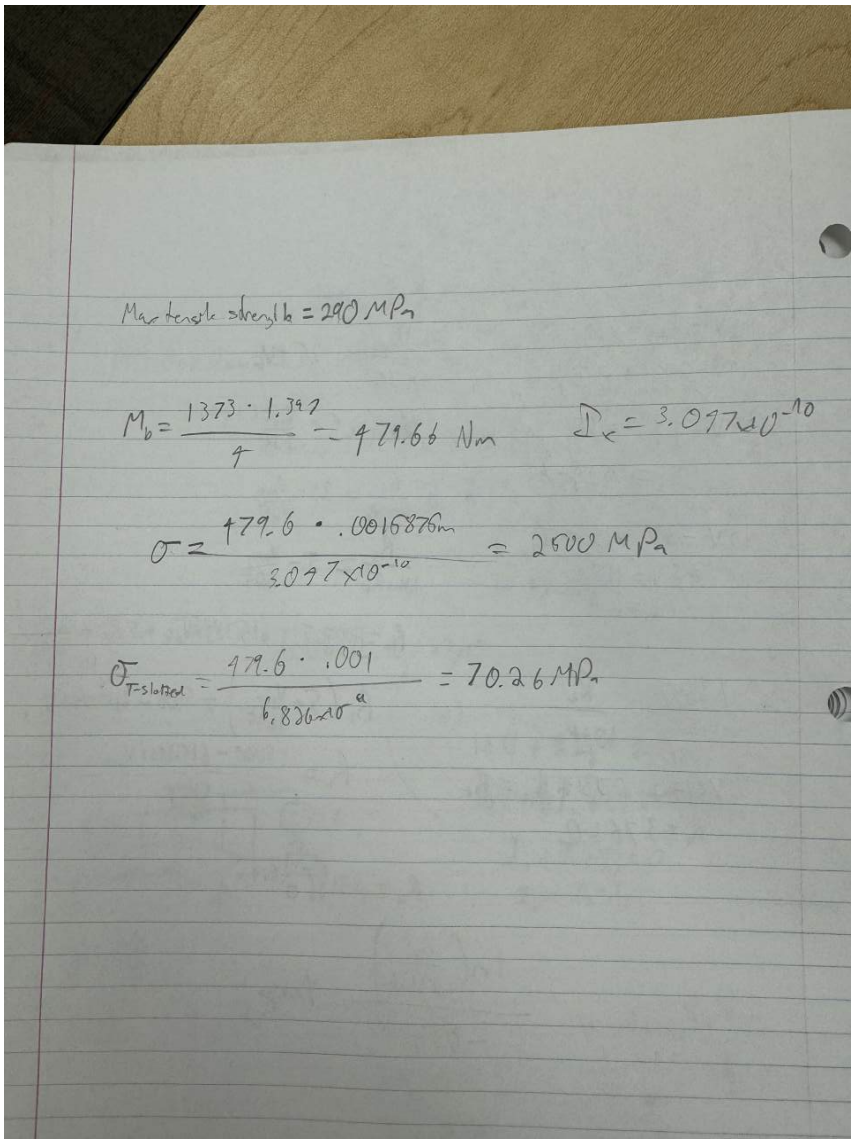
Date: 10/23/24

Content by: Matt Sheridan

Present: Matt Sheridan

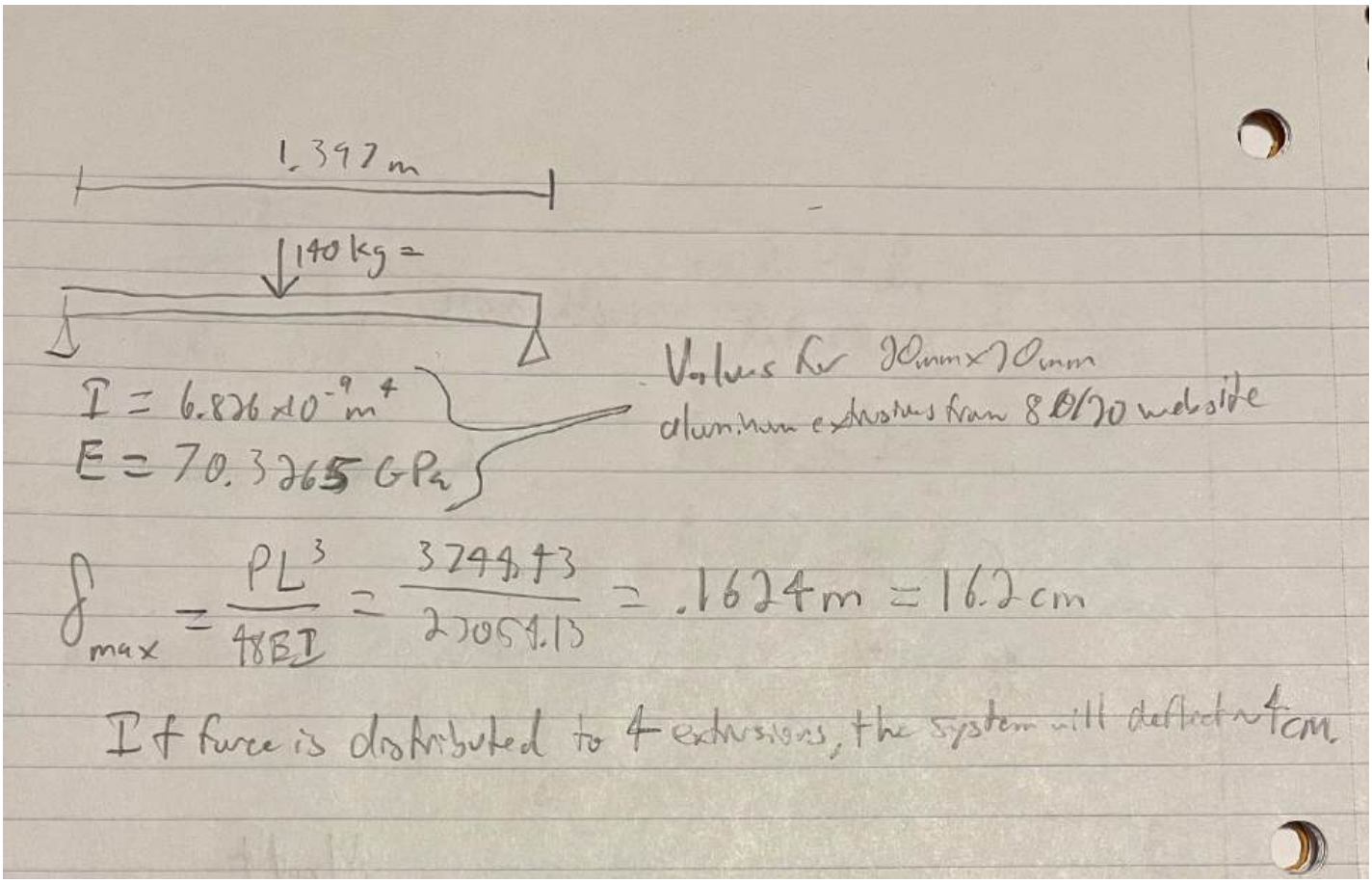
Goals: To map out the various equations constraining our design that will be used to choose components and perform tests on.

Content:



Working from a maximum tensile strength of 290 MPa for the diamond tread aluminum plate, I found the maximum stress that would be encountered by this plate if an individual weighing 140kg were standing in the middle of the plate to be roughly 2500 MPa, which is an order of magnitude higher than the plate alone would be able to withstand. Our group then thought about enforcing this plate with aluminum extrusions that would be used to build the general

structure of our design. With these included, the plate would be able to withstand the weight of the individual. The other concern with regards to this plate is the deflection that may come from somebody in the middle of the plate.



From this work here, using data from the 80/20 website (whom we ordered the aluminum extrusions from), if four 2020 extrusions are used to enforce the plate, the maximum deflection by the aluminum plate will be roughly 4 centimeters, or 1.5 inches. This is an acceptable value, as (we believe) it would not feel unstable for the individual using it. As we test, this may need to be changed.

Conclusions/action items:

Once we put together our initial scaled prototype, we will need to do tests regarding both failure and deflection to see how the actual components interact with one another and withstand stress.

2024/09/11 - Lecture 1: Career Fair

MATTHEW SHERIDAN - Sep 11, 2024, 2:37 PM CDT

Title: Lecture 1

Date: 9/11/2024

Content by: Matt Sheridan

Present: N/A

Goals: Learn about career fair and job searching

Content:

- Job Search Tips
  - Keep track of what you do (ECS tracking sheet)
    - https://ecs.wisc.edu/resources/
  - Connect before being a candidate
  - Applying is only beginning, need to follow up in 2-3 weeks
  - Focus on skills/exposure, not just title
- Resume Tips
  - Tailor resume to specific position you are applying to
  - Create balance - show everything you do
  - MS Word (works better with applicant tracking systems)
  - No columns, charts, colors
  - Include design projects (without years or semester)
  - Include technical skills and coursework
- Career Fair Advice
  - Identify purpose (more than just internship)
  - Look at the overlap that you have with other disciplines
  - Research the employer
  - BME looks different at every university, figure out "value added" statement - why you?
  - Looking to move in the right direction, not find the perfect position
- Fall Career Fair
  - Sept 16-Sept 19
  - 11-5
  - Different employers every day
  - Look for BME, ME, and EE on the grid to find potential employers

Conclusions/action items:

Throughout this week, I will need to work on finding potential employers at the career fair and write a resume.

2024/09/18 - Lecture 2: Leadership Styles

MATTHEW SHERIDAN - Sep 18, 2024, 2:02 PM CDT

Title: Lecture 2

Date: 9/18/2024

Content by: Matt Sheridan

Present: N/A

Goals: Learn about leadership style and how to find yours

Content:

- Important qualities in a leader
  - Communication, respect, understanding, initiative, leading by example
- Anatomy of a good leader
  - Self-awareness (understand strengths+weaknesses)
  - Vision (provide direction and purpose)
  - Transparency (clear processes, open to feedback)
  - Communication
  - Decision-making
  - Empathy
- Leadership Styles
  - Power Model (Leadership = Power)
    - Hierarchical, authoritative
    - Great Man Theory - Idea that only certain people are born to lead
  - Servant (Leadership = Mutual Service)
    - Needs of my followers is most important
    - Service to others, sharing power, listening and understanding
  - Authentic
    - By being my genuine self, I will gain and build trust
    - Building self esteem and self-awareness
    - Emotional intelligence, creating authentic relationships
- Consider how your individual strengths fit a certain leadership style
  - People-oriented leader
    - Glue that holds team together, get to know individuals
  - Process-oriented leader
    - Set the pace for the team, work alongside all
  - Thought-oriented leader
    - Sees big picture, anticipates future
  - Impact-oriented leader
    - Set bar high, push for excellent performance
- Leadership doesn't require a particular job title, can be developed regardless of position
- Leading others starts with leading yourself
- Explore how you want to lead
  - Self-assess motivations, strengths, weaknesses, and values
  - Observe and Reflect, what gives you a sense of accomplishment, where do you show up well
  - Seek out feedback from others who can identify strengths and areas for growth that you can't see yourself.
- Goal setting
  - Team goal: I would like our design team to function as a group of friends who want to show up for each other. To do this, I can actively reach out to team members and create these relationships. Additionally, if I complete tasks on and ahead of time, this can be a good example for everyone to follow, and shows respect between all members of the team
  - Self goal: I would like to work on my ability to both stay focused during group meetings and do my best to help all members accomplish what they need to as well as doing my job 100% of the time as to be a reliable team member that can be trusted.

Conclusions/action items:

We learned a lot about different leadership styles today, and I will do my best to implement some of these techniques throughout the semester to help our group be at the best place possible by the end of the design project.

2024/09/25 - Lecture 3: Post-grad planning

MATTHEW SHERIDAN - Oct 02, 2024, 1:23 PM CDT

Title: Lecture 3: Fall Post Graduate Planning

Date: 9/25/2024

Content by: Matt Sheridan

Present: N/A

Goals: To learn about post-grad planning

Content:

- Build a story using undergraduate experience
  - Do your best to gain experience while in school
  - Research is very important for post-degrees and industry
  - Tie everything together to create a big picture
- Connect with alumni to find out what they do, what their title entails.
- Think about letter writers/references early on (3 strong ones)
- Prepare for MCAT or GRE during summer before senior year
- Understand a good way to write your story
  - Start with what you want to do (thesis)
    - How your narrow experiences apply to your broad interest
    - Specific to each position/place that you apply to
  - Personal statement - show these things:
    - What you will achieve at said University
    - What you want to do afterwards
    - Name faculty there who are in your field of interest
  - Defend your plan with your life experiences (Most recent should be first)
- Grad school options
  - Masters, MS
    - Stepping stone/change directions/gain depth/expand credentials for future
      - Reasons
        - Rewrite your story
        - MD: Need time to prep for MCAT/apply to med school
        - PhD: Cannot find funding
        - Opens doors, gives higher starting salary
        - Another summer internship opportunity
      - MS makes you more desirable
        - Fill gaps in resume
        - Increase level of skills (more lab, less class time)
        - More experience (teaching, mentoring, research thesis)
      - Very powerful if you add industry experience
    - Usually industry focused, and generally one year
  - Doctoral, PhD
    - Usually those that want to be independent researchers
    - Write research grants, work in academia, lead projects in industry, startups, and consulting
- 3 MS options
  - Research (1.5-2 years)
    - For those on PhD route
    - Thesis required (Must have lab willing to support before applying)
  - Accelerated Program (1 year)
    - Coursework only
    - Independent study/research is allowed
    - Funding (TA only) stipend only
  - Biomedical Innovation, Design, and Entrepreneurship (1 year)
    - Project based - project required
    - Partnered w/ business school
    - Funding (TA only) stipend only
- Applying for Accelerated MS Programs

    - Application is reviewed separately, special consideration to BME undergrads, need at least 3.0 overall and you get in no matter what.
- Masters elsewhere
    - MEng, MS in Global health or other Eng. dept., MBA (usually paid for by industry)
- NSF - GRFP gives 4 years of funding for a PhD wherever you want to go (Due October 15th, can apply during senior year and then once more during 1st year of grad school)
- PhD application process
    - Apply early, list names
    - Generally >3.5 GPA and 75 percentile Quantitative section of GRE
- Pre-health requirements
    - Premed advising - CHECK REQUIREMENTS EARLY
    - Special requirements for med school
        - Chem 344&345
        - 2 sem of Physics, EMA 201 & 303 (+ BME 315) = Physics 201
        - 2 sem of english - use lib studies
        - I/A & S/H & CommB - use lib studies
        - Psych 202 & Sociology
        - Biochem 501
    - Beyond classroom
        - Research is required
        - Volunteer in a clinical setting
        - Shadow physicians
        - Patient contact time
        - Build relationships (letter writers)
        - Use design experiences
        - Requirements can vary by degree (check pre-health website)

Conclusions/action items:

I need to make sure to fulfill all requirements such as research, internship experience, and leadership in extracurriculars, and balance that with coursework. Need to start doing this stuff now to plan for programs/industry.

2024/10/02 - Lecture 4: Peer Mentoring

MATTHEW SHERIDAN - Oct 09, 2024, 1:42 PM CDT

Title: Lecture 4: Near Peer Mentoring

Date: 10/2/2024

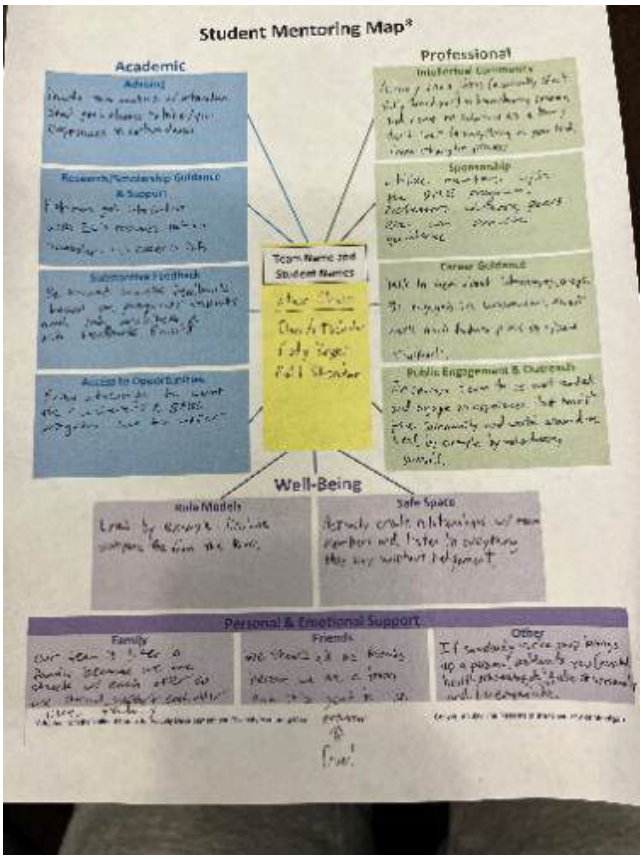
Content by: Matt Sheridan

Present: N/A

Goals: To learn about how to better mentor underclassmen in BME.

Content:

- Why are we mentoring BME 200 students
  - There are aspects of the design process that are brand new to the students that we have experienced once before such as meeting and communicating with clients.
  - Mentoring others can help improve and sharpen our own skills.
  - It is much easier to talk to peer mentors than adults.
  - Transferrable Skills
    - Leadership
    - Communication
    - Active listening
    - Study practices
    - Self-awareness
    - Interpersonal skills
  - General benefits of mentoring
    - Increased self-esteem
    - Increased patience
    - Build positive habits because you want to be a good role model.
    - Foster personal growth
    - Help identify what you don't know
  - How to be a good mentor
    - Be proactive, anticipate what might cause issues down the line, don't just help solve problems when they happen
    - Be emotionally intelligent, create a safe environment to share
    - Show enthusiasm, be reliable and available.
    - Be transparent
  - How to listen effectively
    - Get rid of distractions
    - Act interested
    - Ask follow up questions to make sure you understand
    - React to ideas, not person
- What do you wish you knew in BME 200?
  - It is very important to do things ahead of time, beat deadlines so that when things come up you can solve them without a massive time crunch.
  - Be willing to ask for help when you don't know how to do something (not just in BME but all classes/experiences)
  - How important making relationships with you group members is.

- 

Conclusions/action items:

I will utilize these mentorship skills throughout this semester to help be a better mentor of the 200s in my group.

2024/10/09 - Lecture 5: Sustainable Engineering

MATTHEW SHERIDAN - Oct 09, 2024, 2:00 PM CDT

Title: Lecture 5: Sustainable Engineering

Date: 10/9/2024

Content by: Matt Sheridan

Present: N/A

Goals: To learn about how to apply sustainability to engineering.

Content:

- Health care sector is responsible for ~5% of global emissions, 8.5% in US.
    - In 2018, emissions associated with the health care sector led to loss of ~388,000 life-years.
- Circular economy: Trying to keep everything from the economy (waste) in the economy and out of landfills.
- Carbon footprint: emissions of carbon dioxide.
- Life cycle assessment: Testing how you get a carbon footprint, assessing tradeoffs.
    - Example in medicine: reusable vs disposable (has tradeoffs when it comes to spreading infections vs. environmental impact)
- How does sustainability fit into our project?
    - Using cheap and reusable/recyclable materials in scale modeling.
    - Use long-lasting material in final design so it doesn't wear down quickly.
    - Not using electricity in the mechanism reduces CO2 emissions.
    - A more compact design would require less materials, reducing eventual waste.

Conclusions/action items:

As we make design decisions in this class and in future classes and careers, we must keep sustainability in mind, and do life cycle assessments to weigh pros and cons.

2024/10/16 - Lecture 6: Patenting

MATTHEW SHERIDAN - Oct 16, 2024, 2:09 PM CDT

Title: Lecture 6: Intro to WARF, IP, Disclosing & Licensing

Date: 10/16/2024

Content by: Matt Sheridan

Present: Jeanine Burmania and Justin Anderson

Goals: To learn about process for filing for patents through WARF at UW-Madison and to understand their role at UW-Madison.

Content:

- WARF enables UW-Madison research to solve the world's problems without being misused via licensing and patents.
- WARF is a 501c3 non-profit that is governed by a board of UW-Madison alumni.
- They work at the interface between research results from campus and the market by facilitating the securing of IP rights and commercial licenses.
- Technology Transfer Process
    - Invention --> Invention Disclosure --> Assessment --> Protection --> Marketing --> Licensing --> Financial Return --
      >Invention (In a loop)
- Intellectual Property
    - Patents, Copyrights, Trademarks, Trade Secrets
    - Also biomaterials, technique and know how, and data
- Copyrights
    - Protection for creative works that are expressed in a tangible medium
    - Wide range of subject matter, includes software code
    - Have a term of author's life plus 75 years.
- Trademarks
    - Protection for names, marks, logos, dress, etc.
    - Requires use in commerce
    - Source-identifying function
- Trade secrets
    - Can be used to protect anything of value
    - Protection is good so long as the concept is not generally known.
- Patents
    - Patent is a property right, granted by a government agency.
        - There is no global patent, each country has their own
    - Patent holder has the right to exclude others from making, using, selling, or importing the claimed invention.
    - 3 types of US patents
        - Design (15 year term, limited to ornamental features)
        - Plant (new variety, 20 year term, asexually reproducing, non-tuber)
        - Utility
            - Provisional (1 year placeholder)
            - Non-provisional (20 year term, can claim priority to a provisional)
                - Issued for invention of new and useful process, machine, manufacture, or composition of matter
                - A quid pro quo with USPTO and public, get time limited monopoly on your invention
                - Often takes 2-5 years to issue, costs ~$30k for attorneys
    - Requirements for patenting
        - 101 - eligible (cannot be product of nature, abstract idea, or natural phenomenon
        - 102 - novel (it must be new)
        - 103 - non-obvious (it cannot be simple modification or combination of existing concepts)
        - 104 - enabled and described (must provide enough detail to teach others how to make or use the invention)
- Disclosing an Innovation to WARF
    - Disclosing
        - Describe the innovation
        - Identify its advantages and potential applications
        - Name contributors (inventors and authors)
        - Provide funding and public disclosure details
    - Meeting

        - Discuss the innovation in more detail
        - Ask questions about WARF and patenting processes
        - Discuss next steps
- WARF decision making
    - IP considerations
        - Type of IP protection
        - Potential breadth and strength of IP protection
        - Public disclosure (past and planned)
        - Stage of development
    - Licensing considerations
        - Applications
        - Likelihood of identifying a commercial partner
        - Likely return from licensing
- Marketing and Licensing
    - Market Analysis
        - Market status - established, emerging, new
        - Size and type - e.g., large and growing, medium and contracting, etc.
        - Potential licensees - companies in the market
    - License negotiation
        - Type and terms - e.g., exclusive and field limited, sublicensing, etc.
        - Consideration - e.g., upfront payment, royalties, reimbursement
    - Ongoing
        - Technology development, enforcement, amendment, termination
- Value of licensing
    - Benefits to company
        - Reduced R&D costs
        - Improved time to market
        - Opportunity to enter new markets and expand company quickly
        - New features or products provide additional revenue opportunities
    - Determining value
        - Technology application
        - Key selling points/features/benefits
        - Technology trends
        - Market size, tend, competition
        - Industry standards/historical deals
- AI and IP
    - Patents
        - Can AI invent? (no) An inventor must be a natural person
        - Can AI assist in inventing? Evolving, but likely yes under the Pannu Factors
    - Copyright:
        - Original works of human authorship
        - AI must be incidental to conception and creation
        - Original conception by human mastermind; prompts are not sufficient
        - Combinations of derivative works requires more than de minimis contribution from human
        - Traditional elements of authorship generated by AI? (no)

Conclusions/action items:

If we choose to move forward with attempting to file for a patent for a design, we must keep in mind what we are sharing/making public, but this is very unlikely in the scope of this project. Going through WARF is the best way to do this at this university though.

2024/10/23 - Lecture 7: IRB

MATTHEW SHERIDAN - Oct 23, 2024, 4:10 PM CDT

Title: Lecture 7: Intro to IRBs (Institutional Review Boards)

Date: 10/23/2024

Content by: Matt Sheridan

Present:

Goals: To learn about why we need IRBs and how to go about getting an IRB

Content:

- Origin of IRBs is in response to unethical research being done on humans.
  - WWII: Nazi prisoner experiments --> 1947 Nuremberg Code
  - 1932-1972: Tuskegee Syphilis Study (individuals were not informed what the study was about)--> 1974 National Research Act
  - Belmont principles: Respect for persons, beneficence, and justice
  - Regulations for protection of human subjects by the Department of Health and Human Services(DHHS) "common rule" and the FDA
- Institutional review Boards ...
  - Instituted by Common Rule and FDA regulations
  - Review research studies to ensure that they meet regulatory and ethical standards
  - Must have a scientist and non-scientist on board.
- UW-Madison IRBs
  - Minimal Risk Research IRB
    - Biomedical, Education, and Social/Behavior Sciences research
    - Secondary analysis of data, survey research, behavioral health interventions, evaluations of educational practice.
  - Health Sciences IRB
    - Biomedical, interventional, any risk level
    - All FDA regulated and VA regulated research
  - Serve UW-Madison, UW health affiliates, Madison VA Hospital
  - May cede oversight to other institutions
- Definition of research under Common Rule: Research means a **systematic** investigation, including research development, testing, and evaluation, **designed** to develop or contribute to **generalizable** knowledge.
- Definition of human subjects under Common Rule:
  - Human subject means a living individual about whom an investigator is conducting research:
    - Obtains information or biospecimens through intervention or interaction and analyzes this info; or
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- Definition of human research under Common Rule:
  - Device: intended for use in diagnosis, treatment, or prevention of disease, or that affects structure or function of body.
  - Research/clinical investigation: involves one or more subjects to determine device safety or effectiveness
  - Subject: individual on whom an investigational device is used or as a control in an investigation.
- Preparing for IRB Review
  - Researcher Responsibilities:
    - Complete required training for researchers through CITI
      - Human Subjects Protection Training
      - Conflict of Interest Training
      - Good Clinical Practice Training
      - HIPAA Privacy and Research Training
    - Complete annual Outside Activities Reports
  - Develop your research plan
    - Identify appropriate principal investigator and study team
    - Collect preliminary data & background info
    - Develop a research question and steps to answer it
    - If evaluation device effectiveness or safety, consult UW's FDA RRO Program
    - Consider research participants
  - All applications use UW-Madison's electronic submission system ARROW
  - Basic types are Protocol-based and non-protocol based

        - Protocol document
            - Details study aims, rationale, procedures, analysis plan
            - Details eligibility, recruitment, informed consent process, participant protections
        - Informed consent form
        - Recruitment tools, screening scripts
        - Written assessments
    - Resources on IRB website
- IRB Review process
    - UROC review
    - SRC/PRMS review
    - Pre-review by IRB staff
    - Review at IRB meeting
    - Committee determination: approved, modifications requested, or deferred
- Post-approval responsibilities
    - Obtain all required approvals before beginning research
    - Follow approved protocol precisely
    - Use only IRB-approved materials
    - Submit change of protocol application for IRB approval before implementing any changes
    - Submit annual continuing review progress reports to IRB
      Report unanticipated problems, potential non-compliance, new information
-

Conclusions/action items:

If research is going to be done on human subjects, we must go through IRB and follow FDA protocol.

2024/10/30 - Lecture 8: FDA Device Requirements

MATTHEW SHERIDAN - Oct 30, 2024, 2:11 PM CDT

Title: Lecture 8: Navigating FDA Device Requirements

Date: 10/30/2024

Content by: Matt Sheridan

Present: Jake Rome and BME 300 students

Goals: To learn about the process of navigating FDA device requirements

Content:

- Medical Device: Very broad definition, can entail many things from MRI machine to ankle tape to tongue depressors.
- Non-traditional medical devices include lab devices that are now regulated the same way as medical devices; Apple watches that now do ECG; mouthwash, etc.
- Some software is now considered medical devices
- Applicable FDA Regulations: Labeling, Medical Device Reporting, Investigational Device Exemption, Premarket Approval, Quality Systems Regulations, Protection of Human Subjects, IRB
- Device Classification Overview
    - Device Classes: Class I, Class II, Class III
    - Risk: Low, Moderate, Highest
    - Marketing: Exempt from premarket approval, need 510(k), very strict regulations
- Regulatory Controls Key Elements
    - General Controls
        - Registration and Listing
        - Adverse Event Reporting
        - General Labeling
        - Good Manufacturing Practice
            - Design Controls
            - Document Management
            - Production and Process Controls
            - Management Responsibility
    - Special Controls
        - Performance Standards
        - Special Labeling Requirements
        - Post-market Surveillance
        - Potential Data Requirements
    - Premarket Approval
        - Data to show safety and effectiveness
- Class I Devices
    - Low risk
    - Exempt from premarket notification and Quality System requirements
    - Follow certain general controls
    - Self-registration and listing with FDA
    - Examples: Elastic bandage, Manual toothbrush, Dental x-ray film holder
- Class II Devices
    - Moderate risk
    - Must follow general and special controls, which can include performance standards, specific labeling, post-market surveillance
    - Submission of a 510(k) application to show substantial equivalence; may be exempt
    - Examples: Noninvasive blood pressure measurement system, steerable catheter, integrated continuous glucose monitoring system
- Class III Devices
    - High risk (Sustain or support life, implanted, or potential for unreasonable risk)
    - Must follow general controls and additional stringent requirements, such as clinical trials to demonstrate safety and efficacy
    - PMA submission, which involves comprehensive FDA review of safety and effectiveness data before marketing
    - Examples: Hip joint, implantable pacemaker, replacement heart valve
- Key Points for Classification
    - Depends on intended use and indications for use

- Indications for use: specify the specific conditions, populations, or situations where device is intended to be used

Conclusions/action items:

If our device were to be manufactured and designed for public use, would be a class II medical device, meaning we would need to follow general controls as well as performance, standards, specific labeling, and post-market surveillance.

2024/11/6 - Lecture 9: Regulatory Strategy

MATTHEW SHERIDAN - Nov 06, 2024, 2:06 PM CST

Title: Lecture 9: Regulatory Strategy for Guiding Advanced Therapeutic Product Development

Date: 11/6/2024

Content by: Matt Sheridan

Present: Bill Murphy and BME 300 students

Goals: To learn about the framework that guides product development

Content:

- Advanced Therapeutics refer to Genome Editing, Gene Delivery, Cell Therapy
- FDA Structure
    - Device (CDRH)
        - Premarket approval
        - 510(k)
        - Investigational device exemption
    - Drug (CDER): Drugs are synthetic
        - IND (Investigational New Drug)
        - NDA (New Drug Application)
    - Biologic (CBER): Biologics come from a living thing
        - BLA (Biologics License Application)
        - IND
- FDA Framework
    - US Laws made by Congress
    - Regulations are made by FDA based on laws
    - FDA Guidance documents are made by FDA with help from public to help industry and public interpret regulations
- 351 vs. 361 (for human cells, tissues and cellular and tissue-based products)
    - 351 products regulated as drugs and/or biologics (much slower path to clinical applications)
        - Manipulated, not used for same function, combined with another article AND this brings new safety concerns, systemic effect or dependent on metabolic activity of cells AND no autologous use, or no allogeneic use in first or second degree relative, or no reproductive use.
        - 12 years of marketing exclusivity if 1st in category
    - 361 products are largely unregulated
        - Minimally manipulated, used for same function, not combined with another article (if it is, must not bring new safety concerns), no systemic effect or dependence on metabolic activity of cells (if it is, must be autologous use or allogeneic use in first or second degree relative or reproductive use)
- Difference between studies that are "on the critical path" vs. "good research projects"
- Quality exercise means you do the exact same things every single time; very complex and expensive; every step is evaluated, documented, and perfected.
- Career Options
    - Characterization and Analytics
    - Process Development
    - Manufacturing Development
    - Gene Delivery

Conclusions/action items:

Developing a drug and/or biologic is a very complex process and must be taken into account. When a drug is 351, it must follow quality exercise, which is very expensive and requires lots of perfect attention to detail, and must follow very stringent regulations. However, this results in market exclusivity for 12 years, which can sometimes make back the money spent on this process.

2024/11/13 - Lecture 10: Going from Prototype to Commercial Clinical Use

MATTHEW SHERIDAN - Nov 13, 2024, 2:09 PM CST

Title: Lecture 10: Medical Device Innovation from Prototype to Commercial Clinical Use

Date: 11/13/2024

Content by: Matt Sheridan

Present: Aimee Arnoldussen and BME 300 students

Goals: To learn about the steps to go from a prototype to clinical use.

Content:

- Main steps from Approval to Adoption
  - Clinical Studies -> FDA Approval -> CPT Codes -> CMS National Insurance Decisions -> Standards of Practices -> National/Regional Buying Groups -> Regional/Local IDNs, Hospitals -> Hospital/IDN value Analytics Groups -> Product Evaluations -> Regional/Just in Time Distribution -> Product Implementation
- Stakeholders
  - Administrative: Purchasing, Materials, IT, Billing, Value, Analytics
  - Patient Point of Care: MDs, RNs, RPh, Labs, OR, ER, OT
  - National/Regional Groups: IDNs, Buying groups, Distribution, GPO
  - Standards Organizations: AAMI, ISO, UL, IEC, Clinical Societies
  - National and Regional Payment/Reimbursement: CMS, Insurers
  - National Clinical Oversight: FDA, Clinical Advisory Groups, International Clinical Societies
- Value Drivers
  - Economic: Money, Staff time, resources, waste metrics
  - Clinical: Improve outcomes, reduce risk, reduce complications, etc.
- Potential Reimbursement Path
  - Type of product or solution
  - Stand alone or part of other procedures
  - Established or entirely new?
  - Established CPT codes?
  - CMS vs. Commercial Insurance
  - Formulary or Drug Plans?
  - Research then Confirm/Learn with a Good Consultant
-

Conclusions/action items:

You must provide value with the product in order to get funding and this has to be very clear to the people that will be buying/using the product. There must be a financial or clinical advantage that is worth enough to replace what is being used at the moment at a large scale in order to sell the device.

2024/11/15 - Tong Lecture

MATTHEW SHERIDAN - Nov 15, 2024, 12:53 PM CST

Title: Fall 2024 Tong Lecture

Date: 11/15/2024

Content by: Matt Sheridan

Present: All BME Students

Goals: To learn about the story of Tasso

Content:

- 2 billion blood draws are performed per year in the United States, and it is a very painful/annoying process but incredibly important
- They thought that the future of this could be in the home, and started designing.
- Know when to make changes/fully rethink your product.
- Find your key customer; in the case of Tasso it was USADA; Tasso developed tamper-proof security, now MLB, UFC, and cyclism converted to Tasso.
- When scaling up; quality, culture and HR are of utmost importance.
    - Focus on all of the steps needed to ensure perfect quality.
- Converting something from Class II to Class I can be very advantageous to getting a product out quickly. Tasso decided to sell the lancet separately from tubes; which already had a label, so they only had to clear the lancet, which is a Class I medical device, whereas the two combined would be a Class II device.

Conclusions/action items:

If you do the things that you enjoy and do them with passion, and continue trying new things, you might get lucky and find something that works. Once you find this, go all out for it and don't give up.

2024/11/20 - Lecture 11: How New Product Development Works in the Medical Device Industry

MATTHEW SHERIDAN - Nov 20, 2024, 2:06 PM CST

Title: Lecture 11: How New Product Development Works in the Medical Device Industry

Date: 11/20/2024

Content by: Matt Sheridan

Present: Russ Johnson and BME 300 students

Goals: To learn about another process of new product development

Content:

- Russ' Bio: BSE in BME, MS in Bioengineering, PhD in MS&E and 25 years of experience in the medical device industry.
- Selecting and prioritizing projects
    - Corporate Business Strategy (how the business will sustain itself over next 3-5 yrs)
    - Product Portfolio (Define which product categories to develop, sustain, and eliminate)
    - Project Review (Select and prioritize project to support over next 1-3 yrs)
    - Budgeting and Resource Allocation (Allocate budget and resources based on project prioritization)
- Stage-gate process (Gate Reviews after stage stage of development)
    - Stage 0: Ideation (Brainstorm hundreds of ideas)
    - Stage 1: Exploration (Refine some ideas that will/could work and are good for company)
    - Stage 2: Concept Development (Have 1 leading concept design) (Go/no-go decision is after this stage)
    - Stage 3: Design Development (All about engineering this one design)
    - Stage 4: Design Confirmation (Make sure that the design works through lots of testing/regulation) (Design freeze happens after this stage)
    - Stage 5: Design Transfer & Commercialization (Figuring out how to manufacture the design, market the design, etc.) (Launch is after this stage)
- Case Study
    - Cardinal Health initially had the majority market share on manual suction canisters
    - Stryker developed an automated fluid management system for ORs
    - Cardinal Health then developed ORwell; a simpler version of the Stryker system
    - Stage 0: Ideation
        - Choosing the area of opportunity and reviewing the market via trends, market research, interviewing customers, etc.
        - Creating high-level, napkin drawing ideas
    - Stage 1: Exploration
        - Defining exactly the problem to be solved and what the customer wants (This is the most important step of the design process)
        - Creating concepts for 8-10 ideas based off of your thoughts from stage 0
        - Developing high-level business case about market size and where value can be created
    - Stage 2: Concept Definition
        - Based on customer interviews and use-case assessments, go from 8-10, to 2-3, down to **1** leading concept.
        - Conduct comprehensive IP examination and develop a robust business case that includes market opportunity, an initial forecast and projected expenses.
        - Go/no-go occurs after this stage
    - Stage 3: Design Development
        - Move to a functional prototype, and continue an iterative design process using this prototype. Continually test, evaluate, and update this prototype
        - Confirm the regulatory pathway and begin your formal design control documentation
    - Stage 4: Design confirmation
        - Extensive verification(was the product built well/matches design specs) and validation(was this the right product to build/were the design specs the right ones) testing
        - Finalize product and component drawings/models, and accelerate manufacturing process development/plans for quality control
        - Freeze design at the end of this stage
        - Submit Regulatory documentation, e.g. FDA 510(k)
    - Stage 5: Design Transfer & Commercialization
        - Complete any remaining testing, make final design changes, build molds, assembly/test equipment
        - Create Instructions for Use and user manuals

        - Develop service plan and resources
        - Finalize go-to-market strategy and start limited release
    - Post Market Surveillance
        - Regulatory agencies expect companies to monitor and document customer complaints and field issues post launch
        -

Conclusions/action items:

You must provide value with the product in order to get funding and this has to be very clear to the people that will be buying/using the product. There must be a financial or clinical advantage that is worth enough to replace what is being used at the moment at a large scale in order to sell the device.

10/2/2024 Women Leg Press Strength

Dan Altschuler (daltschuler2@wisc.edu) - Oct 02, 2024, 7:52 PM CDT

Title: Women Leg Press Strength

Date: 10/2/2024

Content by: Dan

Present: n/a

Search Term: old women leg press

Goals: Find the leg press strength of old women so the team knows what to tune the hypothetical stair chair to for mechanical advantage

Content:

- the article examines the leg press and chest press strength for older women and men
    - for the sake of our project, we only need to concern ourselves with the leg press strength of the oldest group of women (80-85)
    - we are doing this because we need to know how much help the weakest user of the stair chair would need from the device
- based on the data, 1.72 is the relative mean strength (load/mass)

Link: **https://www.sciencedirect.com/science/article/pii/S0531556521001832?via%3Dihub**

Citation:

R. L. Parrino, K. L. Strand, A. C. Hockman, and J. F. Signorile, “Leg press and chest press strength normative values by half-decades in older persons,” *Experimental Gerontology*, vol. 150, p. 111401, Jul. 2021, doi: https://doi.org/10.1016/j.exger.2021.111401.

Conclusions/action items:

Based on this data, the team now knows how much we need to tune the device for helping the user. This will be very important for our design considerations and work in the future.

11/15/2024 Electric Stair Chair

Dan Altschuler (daltschuler2@wisc.edu) - Nov 15, 2024, 5:38 PM CST

Title: Electric Stair Chair

Date: 11/15/2024

Content by: Dan

Present: n/a

Goals: Learn about electric stair chairs as a possible competing design for our product so the team can decide how we can better fabricate our device

Search Term: Electric stair chair

Content:

- There is a large market for electric stair chairs
    - this includes the elderly and permanently disabled
    - temporary disability does not seem to be a trait of a typical purchaser of an electric stair chair
- Since our device is mainly targeted at those with temporary disabilities, and is less of a permanent fix, electric stair chairs seem to not be that much of a competing design
    - our design carries a level of novelty that the electric stair chair market is not able to mimic
    - while our design is somewhat novel, it is important to recognize that electric stair chairs do accomplish the same goal
        - these devices are typically not meant for the outdoors, however
- The cheapest stair lift on the source seems to be around $1529
    - The team must be able to fabricate our model at at least halfway cheaper, as to prevent the electric stair chair market from bleeding over into our device's market
    - Our device must also be able to work as efficiently and fast as an electric stair chair
        - these are all things that have been considered as the team has attempted to begin fabrication

Citation:

“Stair Lifts from $1529.00 | Quick Delivery and Nationwide Installation | USM,” Usmedicalsupplies.com, 2024.

Link: https://www.usmedicalsupplies.com/Stair-Lifts.htm

Conclusions/action items:

The team recognizes that electric stair chairs are a device that can do many of the same things that our device is meant to do. We can improve upon the electric stair chair with our design being able to be housed outside, unlike many electric stair lifts, and also by making our device much cheaper to fabricate than a typical electric stair chair.

11/15/2024 Stair Chair Market

Dan Altschuler (daltschuler2@wisc.edu) - Nov 15, 2024, 5:59 PM CST

Title: Stair Chair Market

Date: 11/15/2024

Content by: Dan

Present: n/a

Goals: Learn about the market for stair chairs

Search Term: stair chair market

Content:

- The stair chair market is growing each year
- elderly and disabled make up a wide range of users for these devices
    - they provide alternatives to stair climbing which is integral for the elderly in some cases
- arthritic individuals is a large market for these devices
- user friendliness is key to success in this market
    - small buttons, easy to operate devices, adjustable seats/seatbelts are what make these devices shine more than competitors
- The market is expected to continue to grow as the designs become more and more popular and more advanced
    - wheelchair integration is a major untapped market currently

Citation: “Stair Lifts and Climbing Devices Market,” www.futuremarketinsights.com.

Link: https://www.futuremarketinsights.com/reports/stair-lifts-and-climbing-devices-market

Conclusions/action items:

After considering all the work that needs to be done in the stair chair market, our device is targeting the right customer and makes sense to continue fabrication. While it may not be an electric stair chair, there is enough people that would find our device useful.

10/2/2024 ISO 13485

Dan Altschuler (daltschuler2@wisc.edu) - Oct 02, 2024, 7:59 PM CDT

Title: ISO 13485

Date: 10/2/2024

Content by: Dan

Present: n/a

Search Term: medical device standards

Goals: Learn about ISO 13485, the standard for medical devices

Content:

- this standard outlines the requirements for all medical devices to market in the United States
- devices must be able to prove their quality and have service available for customers
- any organization involved in any part of the lifecycle of a device are to be held to this standard
- can be used by external parties that provide quality system services to organizations

Citation: ISO, “ISO 13485 Medical devices,” ISO, 2016. https://www.iso.org/iso-13485-medical-devices.htm

Link: https://www.iso.org/iso-13485-medical-devices.htm

Conclusions/action items:

Given our device's novelty, there are very limited standards that apply to it. Using this base definition and standard for all medical devices to market is important to consider as we design and eventually fabricate our product.

10/2/2024 Stair Codes in Wisconsin

Dan Altschuler (daltschuler2@wisc.edu) - Oct 02, 2024, 8:06 PM CDT

Title: Stair codes in Wisconsin

Date: 10/2/2024

Content by: Dan

Present: n/a

Search Term: stair code wisconsin

Goals: Learn about the codes on staircases in the state of Wisconsin for application to our stair chair

Content:

- staircases need to be 91.4 cm wide
- for regular staircases (nonspiral) risers can't be any higher than 20.3 cm
- stairs with more than 3 risers must have a handrail associated with it

Citation: “Wisconsin Legislature: SPS 321.04(2)(d),” docs.legis.wisconsin.gov.

Link: https://docs.legis.wisconsin.gov/code/admin_code/sps/safety_and_buildings_and_environment/320_325/321/ii/04/2/d

Conclusions/action items:

These requirements for staircases are for the types of staircases that the medical device we are making. This height and width as well as guardrails on the side are important for designing our product.

9/11/2024 Lecture 1

Dan Altschuler (daltschuler2@wisc.edu) - Sep 11, 2024, 2:09 PM CDT

Title: Lecture 1

Date: 9/11/2024

Content by: Dan

Present: n/a

Goals: Learn about careers and get ready for the career fair

Content:

- Job Search Tips
  - keep track of what you do
  - connect before you become a candidate
  - applying is just step 1, you should always follow-up 2/3 weeks later
  - it takes time!
- ecs.wisc.edu/resources
  - don't wait to be perfect to put yourself out there
  - use quick tailors for the roles you are applying for
- career fair advice for BME
  - identify your purpose - more than just an internship
  - looking beyond the obvious - overlap with other disciplines
  - research the employer - feedback from our partners
    - develop your "value added" statement - why you?

Conclusions/action items:

I must use the upcoming opportunity of the career fair to apply for internships and get one this summer.

9/18/2024 Lecture 2

Dan Altschuler (daltschuler2@wisc.edu) - Sep 25, 2024, 1:17 PM CDT

Title: Lecture 2

Date: 9/18/2024

Content by: Dan

Present: n/a

Goals: Learn about how to be a better leader as an engineer.

Content:

- There are many qualities that make a good leader
  - Including: confidence, organized, understanding, communication, open minded
- Anatomy of a good leader
  - self-awareness
  - vision
  - transparent
  - communication
  - decision making
  - empathy
- Three example styles
  - power model - power = leader
    - someone has to take control and it should be me
  - servant
    - it's not about me, the needs of my followers is most important
  - authentic
    - communication, transparency, genuineness, honesty
- There are many different leadership styles
  - people oriented - glue that holds the team together
  - process oriented - set the pace for the team
  - thought oriented - see the big picture
  - impact oriented - set the bar high and push for performance
- leadership doesn't require a job title
  - can develop these skills regardless of position
- explore and define how you want to lead
  - self-assess - motivations, strengths, values
  - observe and reflect
  - seek out feedback
- team goal - I would like the team to all be friends with each other because I think that makes people more excited to work together. I can do this by talking to my group mates and fostering healthy relationships.
- self goal - I would like to work on my ability to set standards for the team and to make sure that people in my group perform better. I can practice this by asking more of my teammates and expecting them to have their work done for the times that have determined.

Conclusions/action items:

I will do my best to lead my team this semester. Including everyone is a good first step.

9/25/2024 Lecture 3

Dan Altschuler (daltschuler2@wisc.edu) - Sep 25, 2024, 2:06 PM CDT

Title: Fall Post Grad Planning

Date: 9/25/2024

Content by: Dan

Present: n/a

Goals: Get a good idea of the options I have after graduating

Content:

- Use your undergrad experience to "build a story"
  - Find experience while you are in school - it is easier to do it here
- Think about letter writers or references early - 3 strong ones
- Connect with alums - talk to them on Linkedin - find out what you want to do in the future
- Make a clear and concise story about yourself
  - Research/Field Interest: Will do anything! (avoid this)
- Writing your story
  - Start with what you want to do - thesis statement
  - Personal statement: show a reasonable idea of what
    - You will achieve
    - what you want to do afterwards
    - name faculty there who are in your field of interest
  - Defend your plan with life experience (most recent should be first)
- Grad School Options
  - Masters, MS
    - generally one year
    - industry focused
  - PhD
    - desire to be an independent researcher
    - write research grants
    - work in academia
- MS as a stepping stone for further education
  - MS will make you more desirable
  - Higher level of skills - more lab time with less class time
  - Powerful if you add in industry experience
- 3 Masters programs for BMEs in UW
  - Research
    - 1.5 - 2 yrs
    - Can be funded as RA/TA/PA
    - Thesis required
  - Accelerated Program
    - 1 yr
    - Coursework only
    - Independent study/research is allowed
    - Funding (TA only) stipend only
  - Biomedical Innovation, Design, and Entrepreneurship

        - Project based - project required (BME Design project continuity)
        - Partnership with business school
- Do your homework/research
    - Follow your passion, who is working in that area?
- Build your resume/CV
    - REU is a good thing
- PhD programs
    - Generally >3.5 GPA and 75%ile Quantitative GRE

Conclusions/action items:

I must make sure to take on experiences with leadership and research to make myself hireable. Hopefully I can get an internship this summer so that I can get a lot of experience that I would not have previously had the opportunity for.

10/2/2024 Lecture 4

Dan Altschuler (daltschuler2@wisc.edu) - Oct 02, 2024, 2:10 PM CDT

Title: Lecture 4

Date: 10/2/2024

Content by: Dan

Present: n/a

Goals: Learn about how to be a better mentor

Content:

- Why are you mentoring the BME 200 students?
  - Getting them more comfortable with the design process and working with a client
  - Since we are close to them in age and experience it makes sense for us to work with them.
  - Courses are fresh in our mind that they are taking - can also help them with experiences on campus
    - coops, internships, research
  - mutual benefits (transferrable skills)
    - leadership
    - communication
    - active listening
    - study practices
    - self awareness
    - interpersonal skills
- general benefits of mentoring
  - increased confidence
  - increased patience
  - build positive habits
  - foster personal growth
  - help identify gaps in your own knowledge
  - sense of accomplishment
- what does it means to be a "good mentor"?
  - building trust
  - psychological safety (share w/o fear)
  - reliability
  - support and enthusiasm
  - being available
  - transparent
  - humanize their challenges
- listening effectively
  - get rid of distractions
  - stop talking
  - act like you're interested
  - look at the other person
- list of things you wish you knew in BME 200
  - how to use 3D modeling resources
  - how to write a scientific report

- IEEE
- time management
- failing is ok
- put everything in lab archives\

Student Mentoring Map*

Academic

Advising
Provide team members w/ information about good classes to take/your experiences in certain classes.

Research/Scholarship Guidance & Support
Help them get into contact with ECS resources that do scholarships and research info

Substantive Feedback
Be honest. Provide feedback based on progress reports and lab archives, & via feedback fruits

Access to Opportunities
Bring attention to what the university & BME program has to offer

Professional

Intellectual Community
Actively share ideas (especially if not fully formed yet) in brainstorming sessions, and come to solutions as a team; don't just do everything in your head; share thought process.

Sponsorship
utilize mentors w/in the BME program. Professors, advisors, peers etc can provide guidance

Career Guidance
Talk to them about internships/co-ops. Be engaged in conversations about work and future plans to show support.

Public Engagement & Outreach
Encourage team to be well-rounded and engage in experiences that benefit the community and world around us. Lead by example by volunteering yourself

Team Name and Student Names

Stair Chair

Dan Altschuler
Cody Kryzer
Matt Sheridan

Well-Being

Role Models
Lead by example. Include everyone (not from the team.

Safe Space
Actively create relationships w/ team members and listen to everything they say without judgement.

Personal & Emotional Support

Family
Our team is like a family because we are stuck w/ each other so we should support each other like family

Friends
We should all be friends because we are a team and it's good to like each other.

True!

Other
If somebody in the group brings up a personal problem to you (mental health, relationship, etc.), take it seriously and be empathetic.

*Adapted from the National Center for Faculty Development and Diversity Mentoring Map

Conclusions/action items:

We are gonna be great mentors if we follow these steps.

10/9/2024 Lecture 5

Dan Altschuler (daltschuler2@wisc.edu) - Oct 09, 2024, 2:00 PM CDT

Title: Lecture 5

Date: 10/9/2024

Content by: Dan

Present: n/a

Goals: Learn about sustainability in engineering

Content:

- Healthcare sector is responsible for about 5% of global carbon emissions
  - Makes up 8.5% of American emissions
- How do we think about the environmental impact for the medical device industry
- Circular economy: Trying to keep everything in the economy, therefore minimizing waste
- Carbon footprint: upstream and downstream emissions of carbon dioxide and greenhouse emissions
- Trying to fix all these problems is like a game of whack-a-mole
- Life cycle assessment: how you get a carbon footprint and things beyond them
  - Look at the emissions for products during their entire lifecycle (is it circular/landfill/incinerated)
- Coke was the first company to make a life cycle assessment
- The higher the number, the bigger the environmental impact you see
- How does sustainability fit into your project?
  - Can use different materials for our design that are more sustainable
  - Make the whole system reusable so it does not have to continued to be built
  - No CO2 emissions

Conclusions/action items:

I will use everything I learned in this lecture to apply to sustainability on my design project.

10/16/2024 Lecture 6

Dan Altschuler (daltschuler2@wisc.edu) - Oct 23, 2024, 1:21 PM CDT

Title: Intro to WARF, IP, Disclosing and Licensing

Date: 10/16/2024

Content by: Dan

Present: n/a

Goals: Learn about the patent process through WARF

Content:

- WARF exists to help the University of Wisconsin-Madison with licensing and patents
- WARF is important for the technology transfer process
    - WARF tries to add value to and leverage inventions made on campus
    - Also helps to market these products and create some financial return for the inventor
- Technology Transfer
    - intellectual property licenses
    - industry sponsored research
    - consulting arrangements
    - fee for service
- Four common types of IP
    - patents
    - copyrights
    - trademarks
    - trade secrets
- Other, WARF IP
    - biomaterials
    - technique and know how
    - Data
- Non-Patent IP
    - Copyrights
        - protection for creative works that are expressed in a tangible medium
        - a wide range of subject matter, including software code
    - Trademarks
        - protection for names, marks, logos, dress, etc.
        - requires use in commerce
        - source identifying function
    - Trade secrets
        - can be used to protect anything of value
        - protection is good so long as the concept is not generically known
- Patents Generally
    - a patent is a property right, granted by a governmental agency
        - e.g., US Patent and Trademark Office (USPTO)
        - No global patent!
    - to pursue a patent
        - eligible - cannot be a product of nature, abstract idea, or natural phenomenon

        - novel - must be new
        - non-obvious - cannot be a simple modification or combination of existing concepts
        - enabled and described - must provide enough detail to teach others how to make or use the invention
- WARF receives 400 new innovation disclosures each year
- WARF does a market analysis and also negotiates licensing
- Value of Licensing
    - Benefits to the company
        - reduced R&D costs
        - improved time to market
        - opportunity to enter new markets and expand your company quickly
    - determining the value
        - technology application
        - key selling points/features/benefits
        - technology trend
        - market size, trend, competition

Conclusions/action items:

I will use the knowledge I gained from this lecture to make sure I do not make any accidental public disclosures.

10/23/2024 Lecture 7

Dan Altschuler (daltschuler2@wisc.edu) - Oct 30, 2024, 1:22 PM CDT

Title: IRB

Date: 10/23/2024

Content by: Dan

Present: n/a

Goals: Learn about institutional review boards

Content:

- What is an IRB - review board that protects human subjects
- Origin of IRBs
  - In response to recognition of unethical research projects that were occurring - tied into Nazi Germany and Nuremberg code
  - Follow the Belmont principles: respect for persons, beneficence, justice
- Instituted by Common Rule and FDA regulations
- Review research studies to ensure they meet regulatory and ethical standards
- Includes scientists, non-scientists, and members not affiliated with institutions
- Two at UW-Madison
  - minimal risk research IRB
  - health sciences IRB
    - both serve UW-Madison, UW Health
    - can cede oversight to other institutions or independent IRBs
- Research means a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generizable knowledge
- Human subject means a living individual about whom an investigator conducting research
  - obtains information or biospecimens through intervention or interaction, and uses, studies, or analyzes the information or biospecimens
- Device = intended for use in diagnosis, treatment, or prevention of disease, or that affects structure or function of the body
- Research/clinical investigation = involves one or more subjects to determine device safety or effectiveness
- Subject = individual on whom or on whose specimen an investigational device is used or as a control in an investigation
- Preparing for IRB Review
  - Complete required training for researchers through CITI
    - human subjects protection training
    - conflict of interest training
    - good clinical practice training
  - complete annual Outside Activities Report
- Protocol Document
  - details study aims, rationales, procedures, device info, analysis plan
  - details eligibility, recruitment, informed consent, etc.

Conclusions/action items:

If I ever need to involve human subjects in my experiments, I know have a basis of knowledge on IRBs.

10/30/2024 Lecture 8

Dan Altschuler (daltschuler2@wisc.edu) - Oct 30, 2024, 2:05 PM CDT

Title: Lecture 8

Date: 10/30/2024

Content by: Dan

Present: n/a

Goals: Learn about FDA requirements

Content:

- Defining a Medical Device
  - The definition of a medical device is very broad
  - the FDA regulates all these things that are considered medical devices
  - there exist many non-traditional medical devices
    - mouthwash is a crazy example - it is not a drug
  - software can also be considered a medical device
    - the wheelchair tank is considered a medical device
    - since it is a powered wheelchair it fits within the medical device criteria
- Some FDA regulations only apply for certain times
- Device Classification Overview
  - three classes of devices
  - broken down by risk
  - also differences in marketing and regulatory controls
    - three main regulatory controls that apply
      - general (apply to all devices), special (only applies to typically class II devices), and premarket approval
  - Class I Devices
    - Low risk
    - mostly exempt from premarket notifications and quality system requirements
    - self-registration and listing with the FDA
  - Class II Devices
    - moderate risk
    - must follow general and special controls
    - submission of a 510(k) application to show substantial equivalence; may be exempt
  - Class III Devices
    - high risk
    - must follow general controls as well as additional stringent requirements
    - PMA submissions, which involves comprehensive FDA review of safety and effectiveness data before marketing
- Market Submission Types
  - 510(k) exempt
    - registration and listing only
  - PMA-Premarket Approval
    - full safety and effectiveness submission
    - manufacturing details
  - De Novo Classification

        - novel medical devices, no legally marketed predicate
- Classifying a Medical Device
    - many devices can be found in one simple search
    - devices have regulation numbers - can search these to find
    - depends on the intended use and the indications for use
        - intended use - general purpose of the device or its function
        - indications for use - specify the specific conditions populations or situations where device is intended to be used

Conclusions/action items:

While this information may not be entirely useful for the design projects this semester, in the future I am sure this information will be very usable.

11/6/2024 Lecture 9

Dan Altschuler (daltschuler2@wisc.edu) - Nov 06, 2024, 2:07 PM CST

Title: Regulatory Strategy

Date: 11/6/2024

Content by: Dan

Present: n/a

Goals: Learn about the regulatory process

Content:

- When we talk about advanced therapies through the FDA process
  - we are talking about gene delivery, genome editing, cell therapy
- subcomponents of the FDA
  - device (CDRH)
    - apply for an IDE to be able to do clinical studies on a device
    - PMA - premarket approval (approve this device for marketing)
    - 510(k) - clearance related
  - biologic (CBER)
    - BLA - biologics license application
    - IND - investigational new drug
  - drug (CDER)
    - IND - investigational new drug
    - NDA - new drug application
- CARES act allowed the FDA more flexibility and responsibility in the drug approval process
- Companies look at FDA requirements for trials as to not spend money on trials that will eventually get rejected
- 351 products are regulated as drugs or biologics, while 361 are largely unregulated as compared to 351
- 351 needs FDA approval, potency/bioactivity tests, purity tests, etc
- 361 does not really need any of these tests or approval - typically things that have already been accepted as safe and effective prior
  - 361 is a faster path into clinical applications
- Product Development Life Cycle
  - Extremely important to be able to distinguish between studies that are "on critical path" vs "good research projects"
- A Target Product Profile (TPP) is your Product Vision
  - attempts to answer the when to use a product, why to use a product, and how to use a product
  - also includes patient identification, patient benefits, and patient risks
  - is it medically and commercially compelling?
- Considerations for a 351-Regulated CGT
  - nonclinical studies often involve GLP (good laboratory practices)
  - quality controls need CMC development which takes time
    - time = money
- Quality Management System Implementation
  - formalized system to document processes and procedures
- Quality can be defined in many ways in industry
  - must have procedures/protocols for every single thing that you do
- Career options within a regulated environment - Chemistry, Manufacturing, Controls

- characterization and analytics
- manufacturing development
- process development
- gene delivery

Conclusions/action items:

Working on drugs/biologics and developing all these processes/products takes a lot of time and money. There are many quality controls that must be regulated and different types of products and markets to reach.

11/13/2024 Lecture 10

Dan Altschuler (daltschuler2@wisc.edu) - Nov 13, 2024, 2:04 PM CST

Title: Medical Device Innovation

Date: 11/13/2024

Content by: Dan

Present: n/a

Goals: Learn about medical device innovation and how it relates to the commercial market

Content:

- Medical Device Process
  - Innovation Idea and Development
  - Human Testing with IRB Oversight
  - FDA Regulatory Process
  - Reimbursement or Financial Incentive
  - Sales
- Breakthrough Devices Program is a great way to advance your product without having to jump through all the regulatory hoops
  - Still need to do all the regulatory efforts, but this is like a pre approval for the product
- General Steps from Approval to Adoption
  - Clinical Studies -> FDA Approval -> CPT Codes -> CMS National Insurance Decisions -> Standards of Practice -> sales -> product evals -> distribution -> product implementation
- Need to consider the stakeholders of your design
  - Administrative
  - National Clinical Oversight
  - Patient Point of Care
  - National/Regional Groups
  - Standards Organizations
  - National and Regional Payment/Reimbursement
- there is a trickle down effect for new technology
- find a physician that believes in your product
- see what the approval process is for your product - could just be choices on the shelf that are not so bad
  - see how long committee processes take if you have to go before one (multidisciplinary groups normally)
  - this committee will evaluate how valuable your product is before it goes to market and compare it to other products that are currently used
  - data is very important for this time - need to show evidence that your process is better
- Who buys, pays and gets reimbursed
  - Key terms to uncover payment
    - CMS Centers for Medicare and Medicaid Services
    - DRG Diagnostic Related Groups
    - CPT Current Procedural Code
  - existence of codes do not equal financially favorable
  - there are many different reimbursement paths - not a clear answer for each case - need to evaluate case by case
- Discover Through Research and Interviews
  - start with detailed patient flow/care pathway

    - explore pain points and gain creators
- discovery 2 product group is on campus and meant to help students or faculty with the medical device ecosystem

Conclusions/action items:

There a lot of groups on campus that are around to help innovation on campus. The medical device ecosystem is complex, but there are means to evaluate these problems and questions.

11/15/2024 Tong Lecture

Dan Altschuler (daltschuler2@wisc.edu) - Nov 15, 2024, 12:50 PM CST

Title: Tong Lecture

Date: 11/15/2024

Content by: Dan

Present: n/a

Goals: Learn about Tasso

Content:

- 10 billion blood tests in the U.S each year
- the future of healthcare is in the home
    - companies like amazon, netflix, doordash are all based on providing a service to the home
- how do you make a blood test that can be used in the home?
    - must take the leap
        - knocking on doors, lean on the resources that the university provides
    - use the law and entrepreneurship office to help with patents and legal documents
    - getting scrappy with funding opportunities and applying for grants - there is a lot of money out there
- evolution of the technology
    - first, try to make a better product
    - but, kill your product when it is needed
- Finding a key customer - important
    - developed the technology for the customer, early adopter with ownership in technology
    - vocal, outwards facing, champion
    - from that starting point, converted most of the pharma industry
    - Tasso developed a tamper-proof security case to solve the chain-of-custody problem
    - MLB, UFC, cyclism converted to Tasso
- Scaling up
    - quality is the most important part of building a company
    - the culture of a company is also important to build - imprint the mission onto people
    - get your small scale ideas into a larger machine
- in general
    - if you believe in it - gotta go for it
        - take that chance and try it
    - along the way you are gonna hit walls and roadblocks
    - focus on the core tenants
    - innovate

Conclusions/action items:

Apply these design and innovation principles to the projects and designs I create in my life.

11/20/2024 Lecture 11

Dan Altschuler (daltschuler2@wisc.edu) - Nov 20, 2024, 2:07 PM CST

Title: How New Product Development Works

Date: 11/20/2024

Content by: Dan

Present: n/a

Goals: Learn about new product development

Content:

- NPD in the medical device industry is:
  - highly regulated: FDA and other regulatory bodies
  - expensive: requirement for v and v is a cost multiplier
  - resource intensive
  - competitive
- Selecting and prioritizing projects
  - corporate business strategy
  - product portfolio review
  - project review
  - budgeting and resource allocation
- Managing NPD: Stage-Gate Process
  - Ideation -> Exploration -> Concept Development -> Design Development -> Design Confirmation -> Design Transfer and Commercialization
  - After these products are launched, must also do post market surveillance -> typically required by the FDA
- Case Study: fluid management solutions for high volume (>8L) cases existing in 2007 (during surgery)
- Manual: Suction Canisters
- Automatic: Stryker Neptune
- Developed the ORwell Fluid Management System
  - cleaner and easier to use
- Stage 0: Ideation
  - Choose area of opportunity
  - review market trends and/or competitive threats
  - conduct primary and secondary market research
  - identify customer unmet needs
  - create high level, "back of the napkin" ideas
- Stage 1: Exploration
  - Need to define the problem -> talk to the customer and find their needs
- Stage 2: Concept Definition
  - Based on customer interviews and use-case assessments, find 1 leading concept
  - Develop robust business case including market opportunity, initial forecast, and projected expenses
  - conduct comprehensive IP examination
  - Next gate reviews is "go / no go" business decision
- Stage 3: Design Development
  - move to functional prototype
  - continue to iterative design process including initial testing and reviews with customers

        - confirm regulatory pathway
        - begin formal Design Control documentation
            - Mandatory for FDA Class 2 and 3 and almost all EMA devices
            - Includes documentation of customer needs, design requirements, design inputs/outputs, testing, and design reviews
            - tightly aligned with risk management
- Stage 4: Design Confirmation
    - conduct extensive verification and validation testing
    - finalize product and component drawings/models
    - accelerate manufacturing process development along with plans for quality controls
    - "freeze" design at the end of this stage
    - submit regulatory documentation, e.g. FDA 510(k)
- Stage 5: Design Transfer and Commercialization
    - complete any remaining testing
    - make final design changes
    - build molds, assembly/test equipment
    - create instructions for use (IFU) and user manuals
    - develop service plan and resources
    - finalize go-to-market strategy and start limited release (if applicable)
- Post Market Surveillance
    - regulatory agencies expect that companies are monitoring and documenting customer complaints and field issues post launch
    - companies continuously track customer and salesforce feedback via interview and surveys
    - on a 4-6 month cadence project reams report out to stakeholders
- Summary
    - Medical device development is expensive, complex, and highly-collaborative effort

Conclusions/action items:

Medical device development is a long and expensive process. There are a lot of regulatory hoops to jump through before projects can go to market.

Winches

Cody Kryzer - Nov 15, 2024, 9:31 PM CST

Title: Winches

Date: 11/15/24

Content by: Cody Kryzer

Present: just me

Goals: Learn about winches

Content:

Torque is force times distance. There are two torques to consider, the handle on the winch and the arm of the user. A winch can also includes a gear ratio. The intricacies of these mechanical advantages can mostly be ignored. Winches will tell us the final mechanical advantage. For the user, research, or preferably testing, can tell us the force applied.

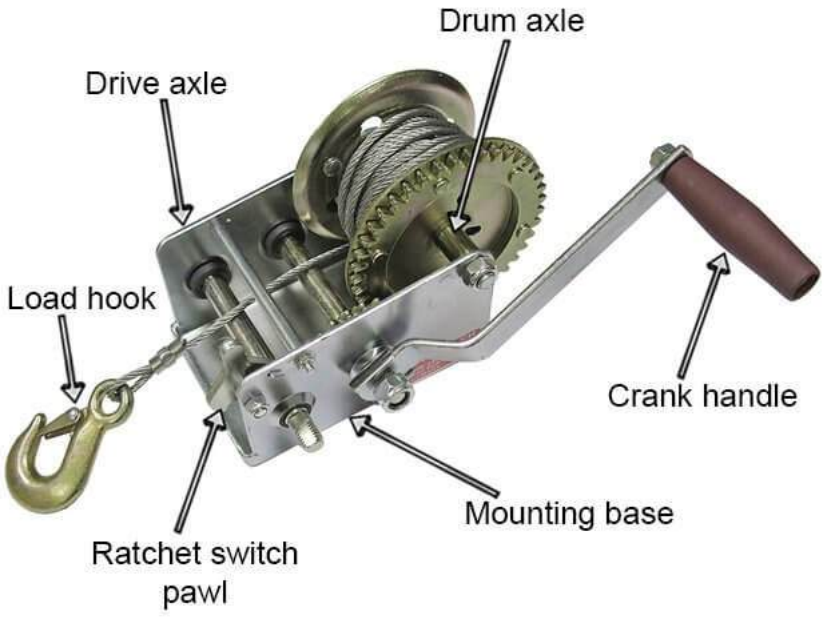
Our goal is to lift 300 pounds not including the moving parts themselves that must be lifted. These parts will likely weigh less than 20 pounds, but the team will measure everything for final numbers.

Even the most simple winches can be bought for less than 30 dollars and lift 600 pounds

https://www.amazon.com/Reese-Towpower-74337-Pound-Capacity/dp/B000WZ4KBS/ref=asc_df_B000WZ4KBS?mcid=34e25f5ee45631a1b542cfe18505606d&tag=hyprod-20&linkCode=df0&hvadid=693670079402&hvpos=&hvnetw=g&hvrand=7985264907819660739&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9018944&hvtargid=pla761869611992&psc=1

^An example being sold on amazon

A winch and is parts can be seen in the photo below.



https://www.siranah.de/html/sail019c.htm#:~:text=A%20normal%20adult%20is%20able,load%20on%20sheets%20and%20halyards.

Conclusions/action items:

Winches are very powerful. For our device, a winch will be purchased, not manufactured. All that our team has to worry about is safety and testing. We will perform tests when the team has a winch. Tests will find the forces required to move a load varying distances.

Other Stair Lifts

Cody Kryzer - Nov

Title: Other stair lifts

Date: 11/15/24

Content by: Cody Kryzer

Present: N/A

Goals: Learn what other stair lifts are on the market and their pros and cons

Content:

Electronic chair lifts are practically permanent. They take hours to install, ours would ideally be less than one hour, either way isn't a huge deal.

Both electric stair lifts and ours would require maintenance but ours could be tuned up between patients.

Many brands of chair lifts exist but all of them are pretty much the exact same. Cheapest ones are about 400 dollars not including installation fees.

https://www.ncoa.org/adviser/mobility/best-stair-lifts/#:~:text=We%20selected%20the%20best%20stair,%2C%20customization%2C%20and%20other%20features.&text=Our%20Reviews%20Team%20recommends%20products,the%20lives%

All marketed stair lifts work the same so companies can only advertise by offering things like free installation or repairs or other warranty perks.

https://www.lifewaymobility.com/resources/product-guides/stair-lift-installation-and-service/#:~:text=On%20average%2C%20the%20installation%20of,time%20lapse%22%20version%20at%20le

Conclusions/action items:

Nothing on the market compares to what we are trying to make. Although we have nothing to infringe on, we have nothing to work off of either. Current chair lifts are too expensive to warrant use temporary injuries, unless they have a lot of money.

Finalized Ratchet Design

Cody Kryzer - Oct 09, 2024, 10:58 PM CDT

Title: Finalized ratchet Design

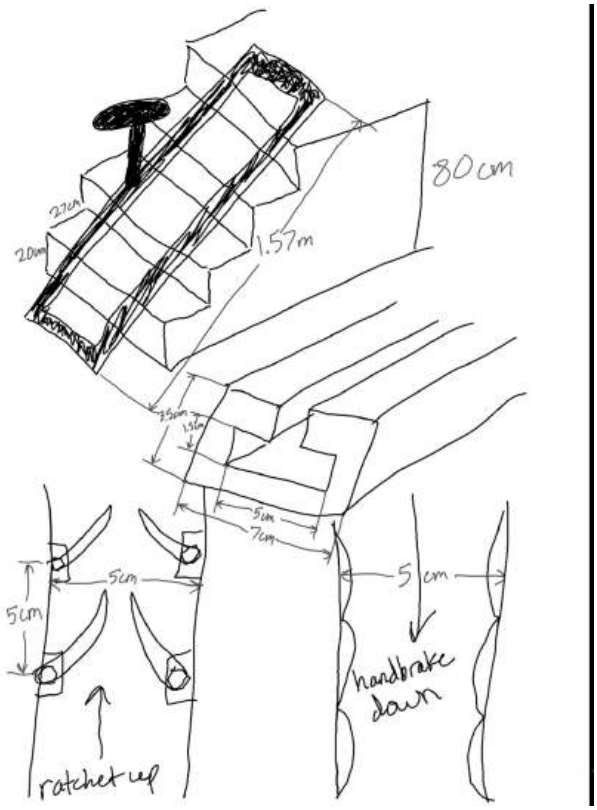
Date: 10/9

Content by: Cody

Present: NA

Goals: Have a presentable design sketch

Content:



Conclusions/action items:

This design likely won't be expanded upon. It is good to have a ratchet design regardless since this is what the clients initial idea and was our jumping off point for all other designs

Chemical Safety and Machining Training

Cody Kryzer - Nov 15, 2024, 8:06 PM CST

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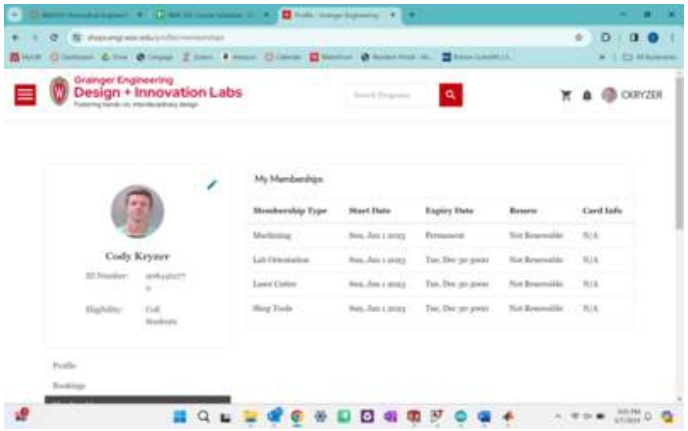
Screenshot_26_.png (299 kB)

Cody Kryzer - Nov 15, 2024, 8:06 PM CST



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Screenshot_32_.png (329 kB)

9/11/24 Career Fair Tips

Cody Kryzer - Sep 11, 2024, 1:53 PM CDT

Title: Lecture 1

Date: 9/11

Content by: Cody Kryzer

Present: All BME 300s

Goals: Get an internship

Content:

- Use the ECS tracking sheet for job applications
- Connect before becoming a candidate
- Follow up after application is required after 2-3 weeks
- Change resume for specific applications
- On resume: design projects, technical skills and coursework, for jobs: organization, location, title, dates
- Use Microsoft word and not google docs
- Make your resume as boring as possible so a computer can run through it easily
- Don't put links on your resume
- No cover letters at the career fair
- Have a purpose beyond just an internship
- Research the employer
- Have a "value added" statement, why I have value

Conclusions/action items:

The fall career fair is September 16-19 11AM to 5PM. Everyday has different employers and they are only there for one day usually. The fair is in engineering hall, engineering centers building, and the mechanical engineering building. Handshake has information under the events tab.

9/18/24 Leadership

Cody Kryzer - Sep 18, 2024, 1:58 PM CDT

Title: Leadership

Date: 9/18

Content by: Cody

Present: BME 300s

Goals: Learn about leadership

Content:

- I am a leader
- Qualities of a leader - confidence, humility, communication, organized
- Anyone can be confident and still be an idiot. Don't blindly follow confidence
- Self awareness, vision, transparent, communication, decision-making, empathy
- Three main styles of leading
    - Power - someone has to take control, I'll do it. Outdated model. Masculinity?
    - Servant - prioritizes needs of the followers. Serves others. Empathetic. Jesus H Christ died for our sins
    - Authentic - Build trust by being genuine. Emotionally intelligent.
- Consider personal strengths when choosing how to lead
- People, process, thought, and impact are other ways to orient leadership
- Ways to improve
    - Self-assess
    - Observe and reflect
    - Seek feedback
- Goal setting

Conclusions/action items:

Our team agrees that a main goal is to create good relationships with everyone. If everyone is friends they will have more fun and be more willing to work hard.

My self goal is of course to foster the team goal. But also to try out new ways of leadership, or maybe not be a leader at all. I want to be less outspoken and do more listening, lead by example, and let others make the decisions while I provide my input. This may seem like being lazy, but I don't think I would contribute any less than I normally would as a leader.

9/25/24 Post-Grad Planning

Cody Kryzer - Sep 25, 2024, 2:06 PM CDT

Title: Post graduate planning

Date: 9/25

Content by: Cody Kryzer

Present: all 300s

Goals: Learn how to plan for after graduation

Content:

- Use my time in undergrad to "build a story"
- Research is helpful for everything
- Have letters of reference
- For cover letter: have a thesis, a personal statement, life experiences, and a CV in paragraph form
- Masters degree can be done in one year, great stepping stone and depth, make you more desirable
- Make about 13k more on average while having a masters
- Being a TA at 14 hours a week can cover tuition
- Program can be simply coursework but a project is recommended, can continue senior capstone
- Application of BME accelerated MS program
    - statement of purpose
    - submit names, not letters of rec.
    - need a 3.0
- Scholarships are mostly available for PHD students and research students, not really for just the masters program

Conclusions/action items:

I need to decide at least a semester before graduation if I want to do the masters program. I need a 3.0 to get admitted automatically. If I don't have a job lined up for after graduation, this is something I would seriously consider doing. I would also have to consider a living situation for 2027.

10/2/24 Near Peer Mentoring

Cody Kryzer - Oct 09, 2024, 10:18 PM CDT

Title: Near peer mentoring

Date: 10/2

Content by: Cody Kryzer

Present: All 300s, Tracy P presenting

Goals: Learn about peer mentoring

Content:

- Consider reaching out to Tracy to mentor highschoolers
- Why are we mentoring BME 200s
    - 200s are not used to working with a client and doing a design course so we show them the ropes
    - Helping others helps us
    - 200s can talk to us about college life in general beyond being a bme
    - We are all learning how to work as a team
    - Helping others builds confidence, patience, communication and leadership skills
    - Identify gaps in own knowledge
- What does it mean to be a good mentor
    - Be proactive
    - Emotionally intelligent
    - Mentees respect you
    - Be reliable, available, supportive, transparent, enthusiastic
- What i wish i knew as a 200
    - solidworks
    - any sort of applicable engineering skills

Conclusions/action items:

Refer back to student mentoring map throughout the semester (Matt has it). Reflect as a mentor, use feedback fruits as a resource. Communicate with 200s about what they'd like to see from the 300s.

10/9/24 Sustainability in Engineering

Cody Kryzer - Oct 09, 2024, 1:57 PM CDT

Title: Sustainable Engineering

Date: 10/9

Content by: Cody Kryzer

Present: All 300s

Goals: Learn about sustainable engineering and how to apply said learning

Content:

- Health care sector is responsible for ~5% of global emissions, 8.5% in US.
    - In 2018, emissions associated with the health care sector led to loss of ~388,000 life-years.
- Circular economy - Trying to keep everything from the economy out of landfills.
- Carbon footprint - CO2 emissions
- Life cycle assessment: Testing how you get a carbon footprint, assessing tradeoffs.
- Reusable vs disposable has tradeoffs when it comes to spreading infections vs. environmental impact
- How can our team be sustainable?
    - Use cheap and recyclable materials for scale models
    - Make final product out of long lasting material
    - No CO2 emissions

Conclusions/action items:

When making decisions for our design project I will keep sustainability in mind. I should do some research on sustainability and learn what good practices are in engineering.

10/16/24 WARF, IP, Disclosing and Licensing

Cody Kryzer - Oct 16, 2024, 2:06 PM CDT

Title: Introduction to WARF, IP, Disclosing, and Licensing

Date: 10/16/24

Content by: Cody Kryzer

Present: all 300s

Goals: Learn about patenting and licensing and WARF

Content:

- WARF helps UW Madison with licenses and patents
- Technology transfer
    - Intellectual property licenses
    - industry sponsored research
    - consulting arrangements
    - service fee
    - A perpetual cycle of inventing, marketing, and licensing
- Four common types of IP are patents, copyrights, trademarks, and trade secrets
- Copyrights are by far the most common for WARF
- Copyrights
    - protect creative works in a tangible medium
    - wide range, includes even software code
    - good for 75 years plus life of the author
- Trademarks
    - Protect names, marks, logos, dress, etc.
    - Required to be used in commerce
- Trade Secrets
    - Can protect anything of value
    - Good so long as the concept is not generally known
    - Example: krabby patty secret formula
- Patents
    - a property right
    - The public must be able to replicate your invention
    - Patent holder can exclude others from making/using/selling their invention
    - Three types: Design, Plant, Utility
    - 30k$
    - Must be eligible, novel, non-obvious, and enabled and described
    -
- WARF gets about 400 innovation disclosures a year
- Application takes about 15 mins but discusses a lot of stuff
- WARF helps with IP considerations
- WARF gives annual gift to campus, this year 100 mil
- Authorship and inventorship are different
- If AI makes the invention it doesn't count but it is allowed to help out

Conclusions/action items:

When I invent something someday, I know now that I can bring it to WARF. They are professionals and can help me safely protect my intellectual property. Especially helps being an alumnus. When this inevitably happens, it is good to be aware that AI laws will be different than they are now.

10/23/24 IRB

Cody Kryzer - Nov 15, 2024, 8:14 PM CST

Title: IRB (Institutional Review Board)

Date: 10/23

Content by: Cody Kryzer

Present: all 300s

Goals: Learn about IRBs

Content:

- Examples of unethical research
  - Nazi prisoner experiments
  - Hepatitis studies at Willowbrook School for Children
  - Shock experiments at Yale
  - Tuskegee syphilis study
- Belmont Principles
  - Respect for persons
  - Beneficence
  - Justice
- Minimal risk IRB
  - Biomedical, education, social sciences
  - Secondary data analysis
- Do I need an IRB?
  - Is it research under common rule?
    - Research is a systematic investigation designed to contribute to generalizable knowledge
  - Does it involve human subjects?
    - Research is about a human or obtains info/specimens from a human.
  - Is it human research under FDA refulations?
    - Device: Used for diagnosis, treatment, or prevention of disease
    - Research: Involves one or more subject to determine safety/effectiveness
    - Subject: Individual whose specimen is used as a control
- Hypothetical project: Designing a ecofriendly band-aid
  - If you ask people wear the band-aid and gather data from their experience, Yes you need an IRB
- Preparing for IRB Review
  - Complete required training through CITI
  - Complete annual outside activities report
  - HIPAA privacy and research training
- Developing research plan
  - Identify principal investigator and study team
  - collect non-human data
  - Have a research question
  - Consider participants: who, how many, why, where, what
- Protocol based and non protocol based IRB
- PBA Components
  - Protocol document
  - informed consent forms
  - recruitment tools
  - written assessments

Conclusions/action items:

Use these notes and do further research before ever testing on humans. Remember the main three requirements for ethical research: Respect for Persons, Beneficence, and Justice. Stair chair will not require human testing, we will be testing materials and mechanisms. UW Madison has a page dedicated to IRB review.

10/30/24 FDA Requirements

Cody Kryzer - Oct 30, 2024, 2:07 PM CDT

Title: Navigating FDA Requirements

Date: 10/30

Content by: Cody Kryzer

Present: All 300s

Goals: Learn about FDA requirements

Content:

- The definition of a medical device is very specific
- Non-traditional medical devices include mouthwash and an apple watch
- Class I Devices are low risk
    - Premarket notification and Quality System requirements not applicable
    - Follow certain general controls
    - Self-registration and listing with FDA
    - Bandage, Toothbrush, Dental x-ray film holder
- Class 2 devices have moderate risk
    - Must follow general and special controls
    - May or may not require submission of 510(k) application
    - Steerable catheter, Noninvasive blood pressure system, Integrated glucose monitoring system
- Class 3 devices have the highest risk
    - About 10% of the market
    - Sustain or support life
    - Anything put in the body and stays there for more than 30 days (implant)
    - Requires PMA submission
    - Hip joint, Pacemaker, Heart valve
- Market submissions
    - Everything should be submitted but some things are exempt
    - 510(k) exempt
        - Registration and listing only
    - 510(k)-premarket notification
        - Substantial equivalence
    - PMA-premarket approval
        - Full safety and effectiveness submission and manufacturing details
    - De Novo Classification
        - Novel medical devices, no legally marketed predicate
- Product Code
    - Device definition and classification
    - Submission type
    - GMP Requirements
    - Recognized consensus standards

Conclusions/action items:

I can use this information while doing research on medical devices. I understand the risk factor of different classes of medical devices and can favor use of class one and two devices in design projects. I understand the definition of a medical device may be more intricate than expected, this is helpful to know when developing a potential medical device.

11/6/24 Regulatory Strategy

Cody Kryzer - Nov 06, 2024, 2:06 PM CST

Title: Regulatory Strategy: The Framework Guiding Advanced Therapeutic Product Development

Date: 11/6

Content by: Cody Kryzer

Present: All 300s

Goals: Understand FDA and how their regulations guide product development. Learn what a quality mindset is.

Content:

- Drugs are made, Biologics come from some cells or living tissue
- 361
    - Minimally manipulated
    - Homologous use
    - Not combined with another article
    - Not dependent on metabolic activity
- 351
    - Manipulated a lot
    - Nonhomologous function
    - Combined with another article
    - Non sterilizing agent
    - No autologous use or reproductive use
- Difference between studies on the critical path vs good research projects
    - Anything that doesn't follow proper techniques is off the critical path
- Target Product Profile
    - Patient identification
    - Patient benefits
    - Patient risks
    - Medically and commercially compelling
- Not practical to always use good laboratory practice because of costs
- A quality exercise clearly defines everything done and it all must be done the same way every time including how you open and close the door

Conclusions/action items:

There are very specific FDA rules for developing a product. They all must be followed to a T in order to be approved. It is important, especially in a lab setting, to have a quality mindset. TO always strive to do quality work that follows regulations, doesn't cut corners, and most importantly is documented and repeatable.

11/13/24 Medical Device Innovation

Cody Kryzer - Nov 13, 2024, 2:11 PM CST

Title: Medical Device Innovation From Prototype to Commercial Clinical Use

Date: 11/13

Content by: Cody Kryzer

Present: all 300s

Goals: Learn about Medical Devices

Content:

- Medical Device Process
  - Innovation Idea and Development
  - Human Testing with IRB Oversight
  - FDA Regulatory Process
  - Reimbursement or Financial Incentive
  - Sales
- General Steps from Approval to Adoption
  - Clinical Studies - FDA Approval - CPT Codes - CMS National Insurance Decisions - Standards of Practice - sales - product evals - distribution - product implementation
- Stakeholder considerations
  - Administrative
  - National clinical oversight
  - patient point of care
  - national/regional groups
  - standards organizations
- Any application for a new product has to undergo much scrutiny
- Economic, clinical, and mission impact are what drive people to discover.
- Codes apply to everything, be aware
- Existence of codes down no imply something is financially favorable
- Medicare is the best insurance
- Key terms to uncover payment
  - CMS Centers for Medicare and Medicaid Services
  - DRG Diagnostic Related Groups
  - CPT Current Procedural Code

Conclusions/action items:

There are many resources on campus to help with device innovation. When pitching a device, there must be clarity in every facet. There also must be incentive for both the creator, investor, and patient in the form of either economics, mission, or clinical impact.

11/15/24 Tong Distinguished Lecture

Cody Kryzer - Nov 15, 2024, 12:54 PM CST

Title: Tasso

Date: 11/15

Content by: Cody

Present: all bmes

Goals: Learn about Tasso and entrepraneurship

Content:

- Nobody likes getting blood drawn
- 2 billion blood draws every year in America
- Get charity from locals
- max out credit cards
- kill your product when necessary
- Fool me once, can't get fooled again
- Found a way to appeal to athletes (rich people)
- Appeal to unions
- quality, culture, and hr matter at large scale

Conclusions/action items:

Important to follow passions as an entrepreneur. Don't give up. There are solutions to every challenge. Consider the product and the goal and the target audience. Let intent drive innovation.

11/20/24 New Product Development

Cody Kryzer - Nov 20, 2024, 2:09 PM CST

Title: How New Prodect Development Works in the Medical Device Industry

Date: 11/20/2024

Content by: Cody Kryzer

Present: all 300s

Goals: Learn about product development in the medical device industry

Content:

- Stage-gate process
  - Stage 0: Ideation-Brainstorm
  - Stage 1: Exploration-Refine the good ideas
  - Stage 2: Concept Development-Have 1 leading concept design
  - Stage 3: Design Development-All focus on one chosen design
  - Stage 4: Design Confirmation-Make sure that the design works through testing
  - Stage 5: Design Transfer & Commercialization-Figuring out how to manufacture and market the design, etc
- Case Study:
  - Fluid management solutions or high volumes in 2007 include
    - manual suction canisters - need to be dumped regularly, not efficient
    - automated Stryker Neptune machine - uses vacuum which is highly variable
  - Stage 0: Observe how current devices are being used and what was wrong with them (the cleaning cycle)
  - Stage 1: Define exactly what the problem is
  - Stage 2: Tubing was the same for all the devices. Ideas involved removable docking station, removable canisters, connecting directly to hospital vacuum. Went with idea 2 to be different from competitors.
  - Stage 3: (real engineering begins) Move on to functional prototype. Piston on the inside was big challenge. Design control is mandatory by now. Tightly aligned with risk management.
  - Stage 4: Design is 85-95% done. The bag deployed to the bottom followed by piston. Collects fluid during procedure and at the end, disconnect everything and bring bag to disposal station. Plunger goes into top and evacuates fluid. Puck is left that can be discarded with regular waste.
  - Stage 5: Somebody is needed to install the device. Client could fully operate the device at this point. Four simple steps to use. Project team sticks together for 4-6 months to monitor the market, the sales, the feedback especially. Stryker released the Neptune 2.0 and dropped prices 50% which was a bummer. The good guys were threatening to take over many hospitals but had to go off market after 8 months.

Conclusions/action items:

Developing and manufacturing is very hard. It requires collaboration and a lot of resources that many people don't have access to. Even with everything at your disposal, market success is far from a guarantee. Case study spent 3-4 years and millions of dollars only to spend 8 months selling the product.

10.3.24 Competing Designs Research

Luke Rosner - Nov 21, 2024, 10:21 PM CST

Title: Competing Design Research

Date: 10.3.24

Content by: Luke R

Present: Luke R

Goals: Document Competing designs for navigating stairs

Content:

https://www.toprostep.com/stair-climber-for-seniors/ - stair climbing aid for seniors - uses a track with a walker to help

https://www.acornstairlifts.com/stairlift/stairlift-outdoor-staircase - outdoor stairlift, expensive

https://www.discovermymobility.com/store/wheelchairlifts/plift52/porch-lift.html?gad_source=1 - wheel chair lift for porch

Conclusions/action items:

There is a lack of affordable solutions that address the problem we are trying to sovle

10.2.24 - Hydraulic Lift Design

Luke Rosner - Oct 16, 2024, 11:21 AM CDT

Title: Hydraulic Lift Design Idea

Date: 10/2/24

Content by: Luke Rosner

Present: Luke Rosner

Goals: To document my hydraulic lift design idea.

Content:

This design involves using a hydraulic pumping system to generate force to push the person up the stairs, similar to the on a barbershop chair. It would use a rail system to guide our mechanism up the stairs.

Conclusion: This design will be included on our design matrix.

9.30.24 Vertical Lift Design

Luke Rosner - Oct 16, 2024, 11:21 AM CDT

Title: Vertical Lift Design Idea

Date: 9/30/24

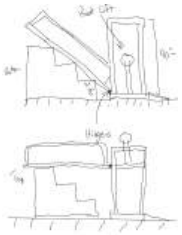
Content by: Luke Rosner

Present: Luke Rosner

Goals: To document my vertical lift design idea.

Content:

This design would use a winch system to pull a platform straight up. This platform would have a straight ramp attached to that would pivot to come flat with the stairs and allow the person to walk straight across at the top of the stairs.



Conclusion: This design will be included on our design matrix

9/20- electric stair chair research

ABI CONNERS - Sep 20, 2024, 4:02 PM CDT

- Uses rail and rack
- pictures helpful for brainstorming- view site for more pictures

Stopher and Individual, “EP0137577A1 - A stair lift - Google Patents.” https://patents.google.com/patent/EP0137577A1/en

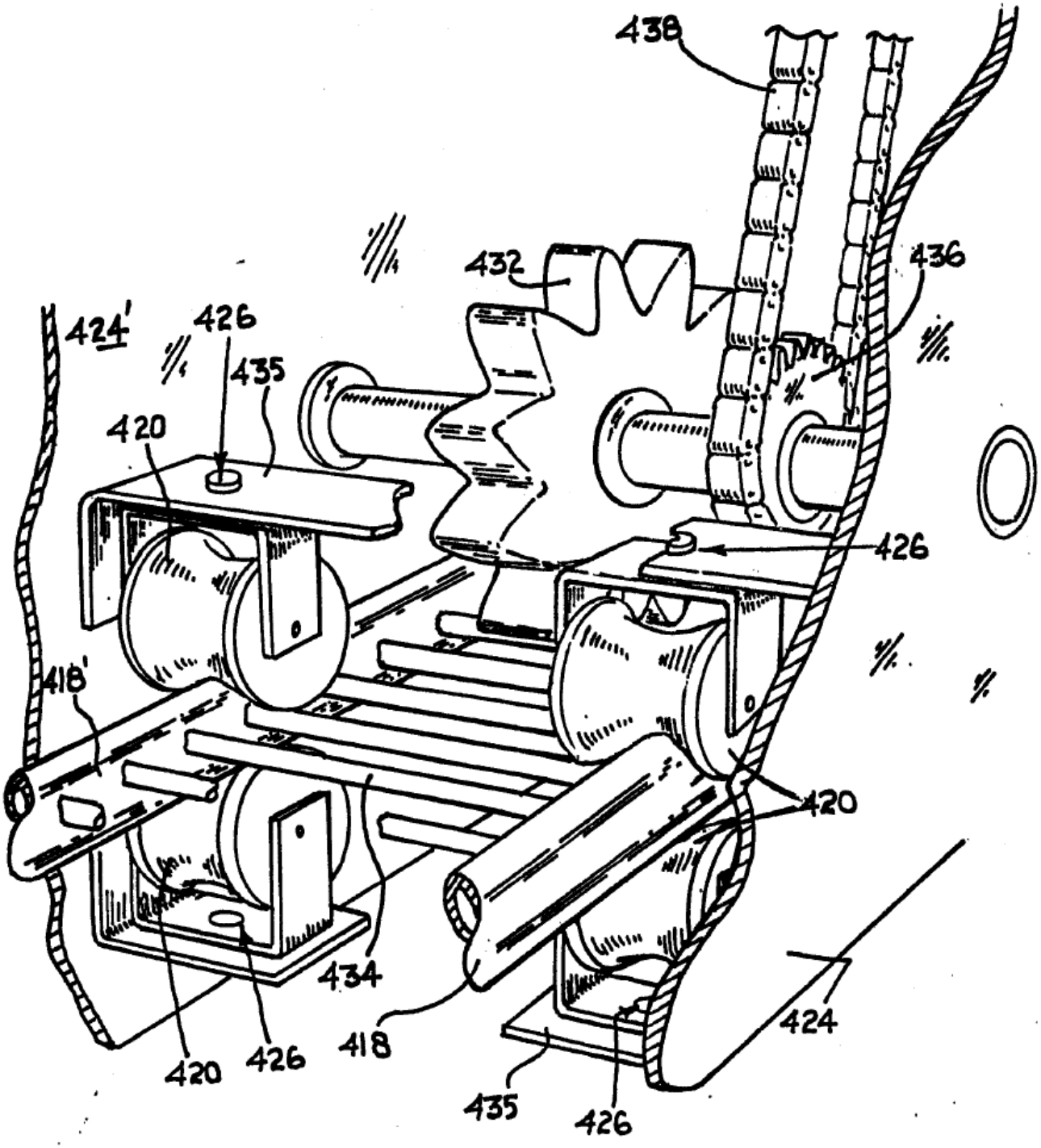

438
432
436
424'
426
435
420
426
418'
420
434
420
426
418
435
426
424

Fig. 21

9/20 Brainstorming

ABI CONNERS - Sep 20, 2024, 4:37 PM CDT

Maybe based off of railroad tracks, car seat, or rolling chair height adjustment

Railroad track/electric stair lift idea

- Initially thinking some kind of pedal (that way patients can use body weight)
- pedal pushes turning conveyor belt type row of bars
- the bars forces the gears to move up/down the track
- Gear exposed which could be a safety hazard. Additionally I don't think it would be able to last 5 years. It would probably be super hinky and unreliable.

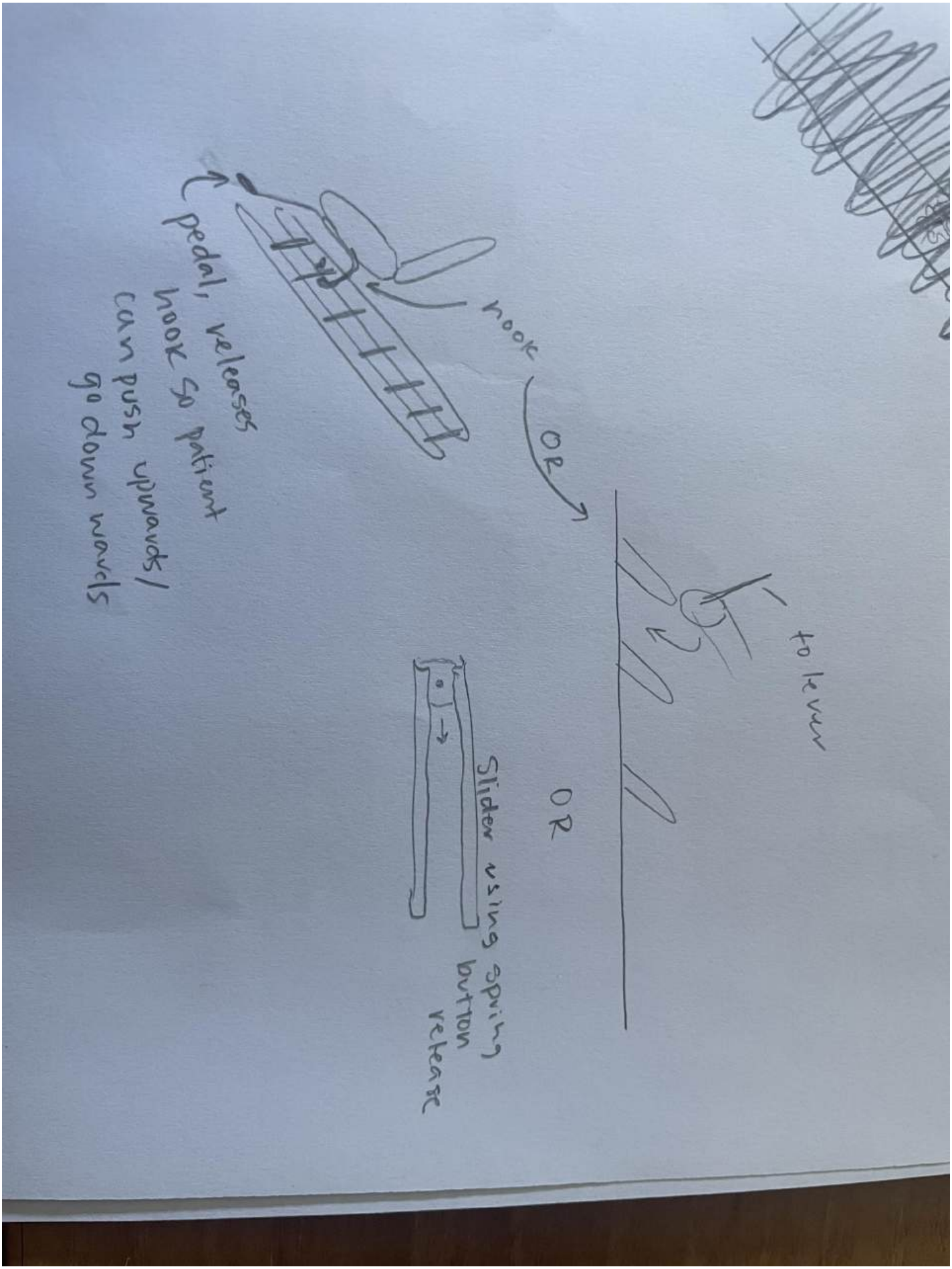
Car seat adjuster

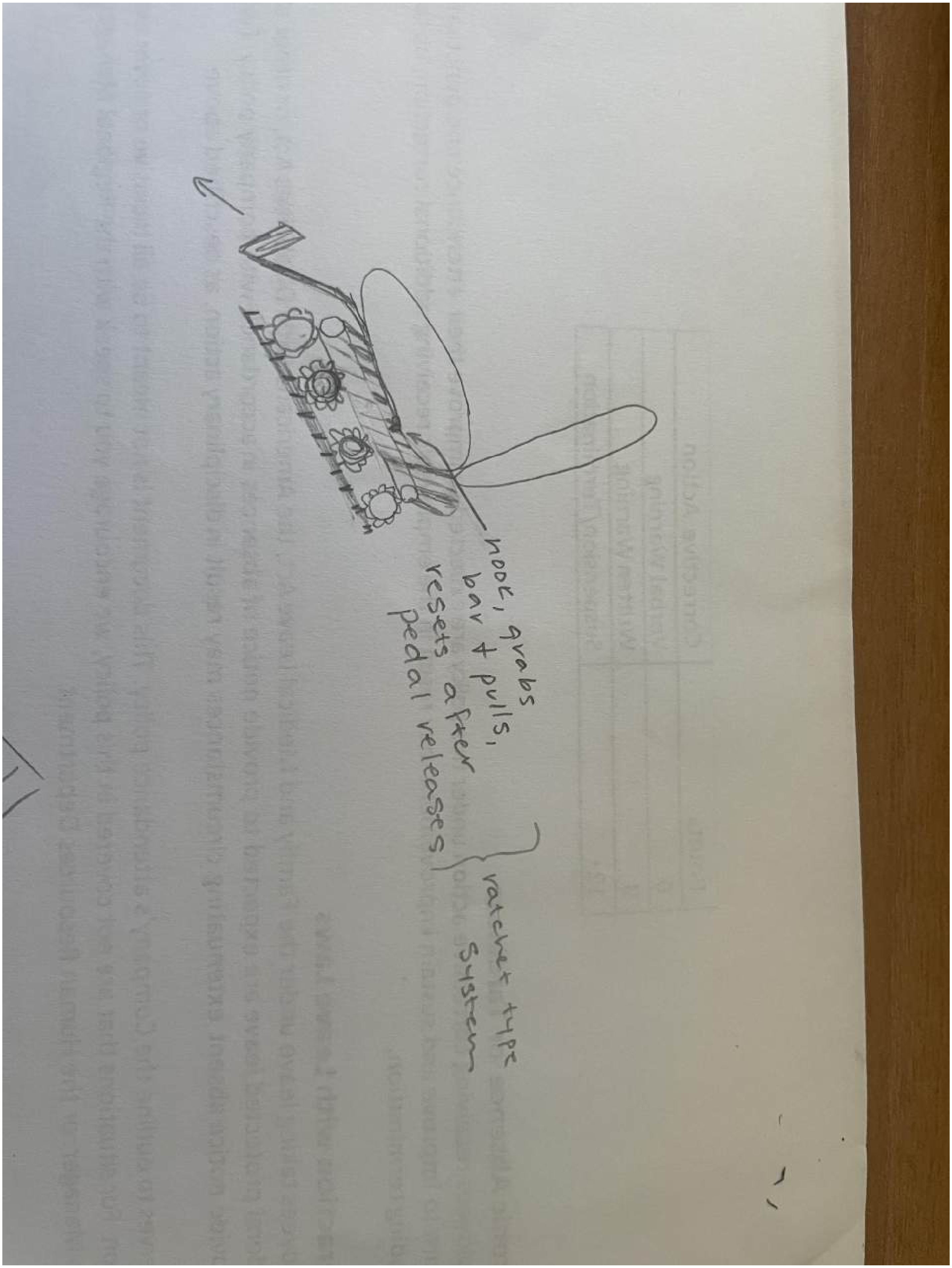
- pedal releases hook and allows for movement
- to prevent sliding maybe we could design the hook so that it can only go down one rung at a time
- I think this design would be safe and more likely to last longer. I also think it's doable and would be more reliable I only worry that it would require too much strength from patients.

Rolling chair adjuster

- This one I think is less doable but could try and use hydraulics
- Downwards would be easy in that case, could use slider for similar motion but without the hydraulics
- Upwards would be more difficult, could try to add it in with one of the other techniques

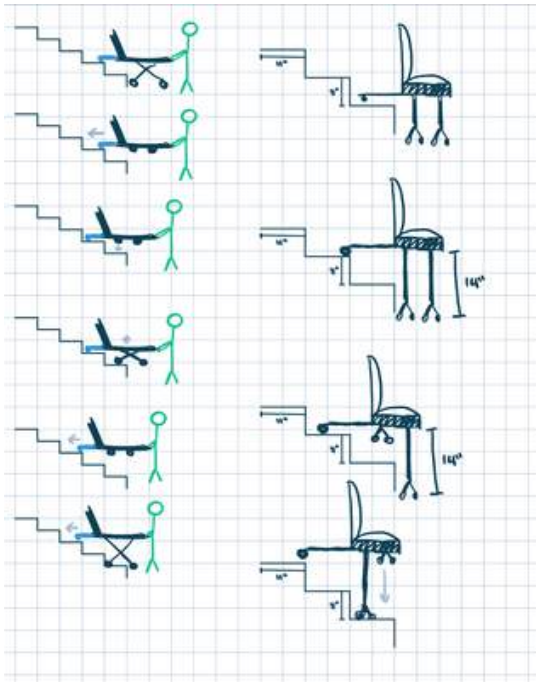
Overall: Prefer car seat method more, will discuss with group and get their thought/other ideas




ratchet type system
hook, grabs bar + pulls, resets after pedal releases

10/2 Stretcher-similar design

ABI CONNERS - Oct 02, 2024, 9:56 PM CDT



Download

Stretcher_similar_idea.JPEG (814 kB)

ABI CONNERS - Oct 02, 2024, 10:00 PM CDT

- As EMT do similar type of movement with a stretcher
- Tried to think of ways that the stretcher method might work for a chair
- Drawing is not to scale, average knee height is 24 in and average stair hight in 7in with 11in run

ISSUES

- Lack of stability
- Wheel would have to only move in one direction
- Not sure how the method would work back down the stairs
- The stair might not be wide enough to fit both wheels so may have to adjust so that the sliders are on 2 separate stairs at a time

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

Cody Kryzer - Nov 15, 2024, 8:06 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: