# BME Design-Spring 2022 - TATUM RUBALD Complete Notebook

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# RACHEL KRUEGER

on

May 02, 2022 @12:03 PM CDT

# **Table of Contents**

Project Information	
Team contact Information	
Project description	
Team activities	
Client Meetings	
2022/02/07: Initial Client Meeting	
2/17: Client Meeting 2	
Advisor Meetings	
2/04: Advisor Meeting 1	
2/11: Advisor Meeting 2	
2/18: Advisor Meeting 3	
3/4: Advisor Meeting 4	
Design Process	
PDS Meeting-2/9/22	
2022/02/16 Design Matrix meeting	
2/23: Team meeting for preliminary presentation	
3/26: Show and Tell Suggestions	
4/5: Team Update	
Materials and Expenses	
2022/05/02 Final Materials and Expenses	
Fabrication	
04/02/2022 New Wheel Designs PVA Supports	
Testing and Results	
Protocols	
Loading/Unloading Initial Testing Protocols-3/24/22	
Experimentation	
3/1: Wheel Testing Spreadsheet Draft	
3/31: Initial Testing Results and Data	
4/29: Final testing Results	
4/29: Learning Curve	
Project Files	
Progress Reports	
Report 2/03	
Report 2/10	
Report 2/17	
Report 2/24	
Report 3/03	
Report 3/10	
Report 3/24	
Report 3/31	
Report 4/7	
Report 4/14	
Report 4/21	
Report 4/28	
PDS	
Design Matrix	

SolidWorks Files for UHold and wheel	
Preliminary Presentation	
Final Poster	
Executive Summary	
Addison Dupies	42
Research Notes	42
Biology and Physiology	42
2022/02/09 General Basics for an endovascular procedure	
Competing Designs	
2022/02/03 Competing Design 1 - Cath Clip	
2022/02/15 Impact on Endovascular Surgeries/Device Market	
2022/2/17 Current Techniques	
2022/02/20 Ethical Implications and Considerations of New Medical Devices	
General	
2022/02/29 No math/chemistry	
•	
Design Ideas 2022/01/31 Client Designs	
0	
2022/04/28 Post Final Presentation Client Design Updated Ideas	
Testing Protocols/Objectives	
2022/02/24 Testing Objectives	
2022/02/24 Testing Analysis Methods	
2022/03/01 Potential Testing Ideas	
2022/03/23 Preliminary Testing Protocol	
Training Documentation	
2022/03/20 WARF Patent Lecture	
Rachel Krueger	
Research Notes	
Biology and Physiology	
Biomedical problem to be solved from 2/3/22	
Engineering Principles and Math	
Biology, Physiology, Chemistry	
Codes and Standards	
Why do we need to solve this problem?	
Competing Designs	
Oliver Catheter and Guidewire Dispenser	
Cath clip design	
Flexible tube	
Design Ideas	
Design Constraints	
Testing Guidewires	
3D printing materials	
Testing Effectiveness of Device	
Dr. Y current design	
Dr Y provided STL files	
Current wheel design	
Training Documentation	
Copy-Green Permit	
Copy - 3/14/2021 Biosafety and Chemical training	
WARF Presentation 3/10	
4/1/2022 Tong Lecture	78
Testing	
Testing Code From 4/6/22	
Testing Code From 4/25/22	
Preliminary Loading Graphs 4/6/22	
Final Loading Graphs From 4/25/22	
ANOVA Test Research From 4/25/22	
Victoria Heiligenthal	
Last Semester	
Last Semester Files-2/8/22	
Last Semester Piles-2/8/22 Last Semester Overview-2/8/22	
Research Notes	90
10000101140100	90

Biology and Physiology	
Overview of Guidewires-2/8/22	
Endovascular Procedure video-2/28/22	
Endovascular Procedure-2/28/22	
Aneurysm Information -2/28/22	
Math and chemistry-2/28/22	
Vascular Procedures for Executive Summary-4/21/22	
Competing Designs	
Guidewire storage devices-2/8/22	
CathClip-2/17/22	
•	
	-
Materials Alternatives-2/17/22	
Team Design Ideas for Stand-2/17/22	
SolidWorks Files for UHold and wheel - 2/28/22	
Alternative 3D printing options-3/24/22	
Executive Summary Video-4/28/22	
All Designs-4/29/22	
Testing	
Testing Alternatives-2/17/22	
Preliminary Unloading Graphs-4/5/22	110
Final Unloading Graphs-4/28/22	
ANOVA Results-4/29/22	
Training Documentation	
WARF Lecture-3/19/2022	
Tatum Rubald	
Research Notes	
Biology and Physiology	
3/1: Final Product Material	
3/1: Operating Room Efficiency	119
Competing Designs	
2/17: Competing Device EU Patent	
4/29: Cath Clip	
General Research	
2/17: Converting Files from Fusion360 to Solidworks	
2/17: Questions for client meeting	
2/28: 3D Printing Outsource	126
3/31: Show and Tell Notes	127
4/29: Market Analysis	128
Design Ideas	129
"UHold" Stand Design - 2/9	129
"UWheel" Wheel design -2/9	123
Dr. Y Design Ideas -2/9 2/18: Design Modification Brainstorm	
2/22: ShortSpout	
3/31: CutChimney	
3/31: Curve Spout	
Training Documentation	137
3/11: WARF Lecture	
Alex Pudzisz	
Alex Old Semester Research	
Alex Pudzisz	
Research Notes	
Biology and Physiology	
2021/09/17 Cardiac Catheterization Biology	139
Competing Designs	
	····· ITI
	1/1
2021/09/21 Cath Clip Competing Design	
2021/09/21 Cath Clip Competing Design 2021/09/21 Japanese Holder Competing Design	
2021/09/21 Cath Clip Competing Design 2021/09/21 Japanese Holder Competing Design Miscellaneous Research	142 144
2021/09/21 Cath Clip Competing Design 2021/09/21 Japanese Holder Competing Design Miscellaneous Research 2021/09/23 Regulations and Standards Research	
2021/09/21 Cath Clip Competing Design 2021/09/21 Japanese Holder Competing Design Miscellaneous Research	142 144

2021/10/07 Chemistry In Project	
2021/10/13 Math In Project + 2021/12/14 Update	
2021/10/19 Engineering Ethics	
2021/12/14 My Activity In Deliverables UPDATED	
2021/10/25 Physics in Project	152
2021/11/10 Impact Research	
Protocols And Procedures	
2021/10/16 Planned Statistics And Testing	155
2021/12/03 Statistics in Project	
2021/12/13 Final Protocol	
2021/12/03 Experiments / Testing Day	
2021/12/11 Analysis (Statistics) and Conclusions of Analysis	
2021/12/14 Conclusion of Project and Semester	
Design Ideas	
2021/09/29 Clamped Wheel Design	
Training Documentation	
2021/10/19 Training + 2021/12/14 Training Update	
Miscellaneous	
2021/11/07 PDS + Constraints	
2021/11/29 Final Design	
Testing Protocols	
2022/02/15 Testing Ideas Based on Advisor Meeting	
2022/02/17 Wheel Testing Protocol	
2022/02/17 Holding Device Possible Test Protocol	
2022/02/24 Holding Device Durability Testing Protocol Ideas (not done in steps)	
2022/03/01 Testing Different Wheels Ideas	
2022/04/14 New Possible Method Of Measurement Or Analysis	
Testing Running Notes	
2022/03/09 Update For This Week and Future Testing	
2022/03/12 - 2022/03/20 Break In Notebook Due To Spring Break	
2022/03/23 Addie Running Test My Notes	
2022/04/07 Testing Wheels And Slight Delays	
2022/04/14 Beginning Testing Notes	
2022/04/21 Updates 1 Week Into Test Running	
2022/04/26 Week 2 Final Testing Notes	
Design Ideas	
2022/02/10 Tube Design	
2022/05/01 Contribution in Group Documents	
2022/02/24 Possible Ideas For Design Changes to UHold Device	
Training Documentation	
2022/02/24 Training Remains The Same As Last Semester	
2022/03/20 WARF Lecture	
BME Design Fall 2021	
Fall 2021 Past Notebook	
2014/11/03-Entry guidelines	
2014/11/03-Template	



# VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:04 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
Witzenburg	Colleen	Advisor	witzenburg@wisc.edu		
Yamanouchi	Dai	Client	yamano@surgery.wisc.edu		
Rubald	Tatum	Leader	trubald@wisc.edu		
Dupies	Addison	Communicator	dupies@wisc.edu		
Pudzisz	Alex	BSAC	pudzisz@wisc.edu		
Krueger	Rachel	BWIG	rjkrueger4@wisc.edu		
Heiligenthal	Victoria	BPAG	vheiligentha@wisc.edu		



VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:08 PM CST

Course Number: BME 301

Project Name: Endovascular Devices for Cath Lab and Operating Room Procedures

Short Name: Endo Cath

**Project description/problem statement:** In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, we will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4-5 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

**About the client:** Dr. Dai Yamanouchi, MD, PhD, is a surgeon at UW-Health. He specializes in vascular and endovascular related procedures, as well as research relating to aneurysm post angioplasty including balloon angioplasty and stent placement. He is passionate about creating a device for his operating room issue of tangled guidewires



ADDISON DUPIES - Feb 07, 2022, 12:16 PM CST

**Title: Initial Client Meeting** 

Date: 02/07/2022

Content by: Addie Dupies

Present: All

Goals: Discuss initial aspects of the design project and itinerary for the semester

#### Content:

#### Testing

- 1. Tech coils wire and puts it in the stand
- 2. Someone threads wire to the tech
- 3. Disk should work for all different types of wires (most stiff and least stiff)

#### Primary goal

- 1. Finalize size of disk (diameter and thickness)
- 2. Currently uses nylon-12
- 3. Stand
- He will give us the .stl for current design to print at the makerspace
- Possible guidewires that we can use (not sure if he can give us any)
- Along with the dimensions
- · Wants the device to work for the stiffest and most flexible wires
- Have two people (one as the tech who is storing wire)

Conclusion/Action Items: Receive the .stl files and begin to print to determine any modifications and design restructuring



TATUM RUBALD - Feb 17, 2022, 5:44 PM CST

#### **Title: Client Meeting In Person**

Date: Feb 17, 2022

Content by: Tatum Rubald

Present: Tatum and Addison

Goals:

We will get guidewires and discuss the project further.

#### Content:

- · current way to organize: coil and put wet towel over it
  - OR Cathclip: wind and clip it
    - Less bulky
    - Less organized
- · Our device has advantage because we can pull out of device directly out of wound position
  - Give wheel to operator with guidewire in it
- Two methods
  - Pull in
    - Wind in with spool method benefit can pull back in
      - Also can pull out inner piece and operate like that
- Place in bucket
- Fusion 360

#### GOALS FOR PROJECT

Product dimensions — EVERYTHING

opening

thickness

diameter

# Conclusions/action items:

I will find what file type is compatible with Fusion 360 and Solidworks.



TATUM RUBALD - Feb 04, 2022, 12:08 PM CST

#### Title: Advisor Meeting 1

Date: 02/04

Content by: Tatum Rubald

Present: Full Team

Goals: Meet with Advisor and discuss course goals.

# Content:

- · We can use his current device and do testing and research for him
- We could use both his current device and make a new storage device
- We can focus on materials for his current design

#### Conclusions/action items:

We need to meet with the client and talk about what he wants. Dr. Witz thinks focusing on testing is a great idea, so we should talk to him about this. Meeting with Dr. Witz is 2:30 next Friday.



ADDISON DUPIES - Feb 11, 2022, 2:53 PM CST

Title: Advisor Meeting 2

Date: 02/11/2022

Content by: Addison Dupies

Present: Addison, Victoria, Rachel, Alex

Goals: Meet with Advisor to discuss last week's accomplishments and future plans

# Content:

- Work with the client to figure out a potential doctor who does not know much about the device to test
- · Maybe use residents to test if our client is too busy to test the prototype
  - Or another BME student would work
  - If not either someone on the team that would not have as much involvement in the fabrication process, so that they would not have as much knowledge about how to use the device
- If the Makerspace is too busy Dr. Witz has other places (more expensive)
- Think about other materials if PLA is not going to work with the new wheel
- Come up with more quantitative testing ideas other than time and entanglement
- Design matrix due next week
- Victoria is able to record her part for the presentation next week
- Get first preliminary printed prototype printed, so that we can begin testing
- · WARF presentation coming up to that we can discuss patent issues with the client

# Conclusions/action items:

Finish design matrix and begin printing the new wheel and stand so that we can begin testing.



Title: Advisor Meeting

Date: 2/18/2022

Content by: Rachel Krueger

Present: Addison, Tatum, Rachel. (Alex and Victoria excused)

Goals: Update advisor on client meeting and discuss design matrix and future work.

# Content:

- 1. Discussed meeting with Dr. Y he gave us his current model, Addie took video, giving us updated solidworks files
- Talked about how we will be making multiple designs with different diameters and test the feel quantify by timing
- 3. Make sure we are able to quantify organization (1 or 0)
- 4. Plan is to 3D print, want to be able to print very thin (do research or consult makerspace) can also use protolabs (not very cheap)
- 5. Make sure we manually measure everything with calipers after printing to confirm dimensions
- 6. Will probably be changing the design we went with on the design matrix because it can get too bulky
- 7. Think about factors such as it gets easier the more that we do it the design isn't getting better. Also think about a lefty versus righty performing this.

# Conclusions/action items:

Begin 3D printing so that the team can begin testing.



RACHEL KRUEGER - Mar 04, 2022, 12:22 PM CST

Title: Advisor Meeting 4

Date: 3/4/2022

Content by: Rachel Krueger

Present: All group members

Goals: Update advisor on progress

Content:

- 1. original testing document has been created
- 2. team is starting testing after spring break
- 3. Preliminary presentation has been graded Prof. Block wants us to make sure we talk with WARF.
- 4. Advisor will send us feedback for PDS
- 5. Warf is presenting next Friday in person some team members are looking to attend via zoom

### Conclusions/action items:

Wait to hear back from Prof. W regarding presentation next Friday. Continue testing after spring break.



Title: PDS Meeting

Date: 2/9/22

Content by: Victoria

Present: All members

Goals: To complete the PDS report

# Content:

- Discussed how the PDS form last semester would be edited and what needed to be added to each section
  - Since the device being tested is from the client and this project is being continued from last semester, the PDS is very similar to last semester's PDS
  - Had to include how the client's prototype would change the course of the project as well as the creation of the stand
- Split up sections among that need to be edited based on new requirements from client and how the design is changing
  - Alex: Ergonomics, size
  - Rachel: Performance, accuracy/reliability
  - Victoria: Cost, life in service
  - Addie: Quantity
  - Tatum: client requirements, function
  - · Everyone contributed equally to completing the whole paper
- Discussed new stand designs we would develop since we need two more stand designs to include in our design matrix apart from the client's
  - Tatum created new stand SolidWorks stand, same dimensions as client's stand design
- · Every section should reference both the stand and the wheel, not crate and hoop for consistency
- · Read through each section to be edited and finalized
- · Talked about what we need to plan for the next coming weeks
  - Design matrix meeting next week, get ready for preliminary presentation, decide on testing and split up into teams within the team to accomplish goals

Conclusions/action items: It was important the team had this meeting to finish the PDS and to talk collectively as a group to address changes that had to be made. The PDS is completed, so the team can look on to the next portion of the project which is the design matrix.



# 2022/02/16 Design Matrix meeting

Alex PUDZISZ - Feb 16, 2022, 12:35 PM CST

#### **Title: Design Matrix Meeting**

Date: Feb 16, 2022

Content by: Alex Pudzisz

Present: Entire Team

Goals: To finish Design Matrix

#### Content:

- Met and created Design Matrix Document
- · Decided that design matrix was only necessary for the holder as last semester matrix was already done for wheel
- Put in the three designs from Tatum, Alex, and the client
- Updated the criteria
  - Compatibility now important as it must fit different sized wheels
  - cost is no longer significant as they will all rate the same due to 3d printing
  - · Learning curve rated very highly along with compatibility as it will only be sold if it requires little work to learn
- Updated definitions in order to match new criteria
- Updated old definitions to clarify better what criteria mean
- Graded the three devices
  - Can be seen in the document under project files.
- Winning Design ended up being Tatum's U hold design

#### Conclusions/action items:

Prep for Preliminary Presentation



TATUM RUBALD - Feb 23, 2022, 4:29 PM CST

#### Title: Prelim presentation meeting

Date: 2/23

Content by: Tatum Rubald

Present: Addison, Victoria, Rachel

Goals: Go over timing and content

#### Content:

- 1. Rachel: 2 min
- 2. Tatum: 1.75 min
- 3. Addie: 2 mins
- 4. Alex: 2.25 mins
- 5. Victoria: 2 mins

Tatum: add demonstration of loading wheel

#### Conclusions/action items:

Submit presentation



#### VICTORIA HEILIGENTHAL - Mar 26, 2022, 1:20 PM CDT

#### **Title: Show and Tell Suggestions**

Date: 3/26/22

Content by: Victoria

Present: Victoria, Alex, Tatum, Addie

Goals: To get suggestions and ideas from other groups for alternative printing materials

#### Content:

After the team's initial prototyping of the design and testing, the team noticed that the PLA material that was used originally to print out the design would not allow the team to remove the supports from inside the rounded ring portion of the design. When we tried to remove the supports, the curved portion cracked. For the show and tell, the team was looking for alterative 3D printing materials or design ideas to avoid this problem. The team still wanted a material that would be somewhat flexible to help with loading and unloading the guidewires, but it needed to be able to remove the supports easily. The two main suggestions the team received was printing the supports in PVA or printing the entire design in Resin at the Makerspace. The PVA material melts when it is placed in hot water. This would be an easy solution to the team's problem because the design wouldn't have to change, and the original material could be persevered. The supports in a Resin material can be easily removed by pushing on them. This would also be a helpful solution to the team's problem. Other suggestions were printing the rounded section in two pieces, so no supports were needed, then attaching hem with a hinge or printing the design upward, requiring less supports and easier removal of them. Although these were good suggestions, they are slightly more difficult than the other two. Moving forward the team will most likely reprint the design using the Resin material or using the PVA material for the supports.

PVA:

Ultimaker PVA material: Water-soluble support for complex prints

Resin:

3D Printing Materials: Engineering Resins (formlabs.com)

Conclusions/action items: The team can apply these suggestions to modeling and continue moving forward with the project.



#### TATUM RUBALD - Apr 29, 2022, 6:11 PM CDT

Title: Team Update April 5th

Date: 4/5

Content by: Tatum Rubald

Goals:

Send information to the team of distribution of activities.

#### Content:

Team,

As we continue to work through this project, I think it may be easier to divide and conquer.

- Alex (ongoing):
  - Test designs (as many trials as possible)
- Victoria and Rachel: (Due Thursday and midnight)
  - Data analysis for loading (from preliminary testing)
    - Bar graph for load ratings\*
    - Box and whisker for loading times
  - Data analysis for unloading (from preliminary testing)
    - Bar graph for unload ratings\*
    - Box and whisker for unload times
- Tatum and Addie (Due Friday at 4pm):
  - Executive summary
  - Pick up print

If you want to switch positions with someone (including myself), or disagree with this, please let me know!!

\*Bar graph format: X axis: rating (0-3); bars: designs (0-2), Y-axis: number of trials with corresponding rank

Chart, bar chart Description automatically generated

# Conclusions/action items:

Send update to team.



ADDISON DUPIES - May 02, 2022, 10:33 AM CDT

#### **Title: Final Materials and Expenses**

Date: 05/02/2022

Content by: Addie Dupies

Present: NONE

Goals: Report the Final Material and Expense Sheet

# Expenses -

Item	Description Manufacturer		Part Number	Date		Cost Each	Total	Link
Component 1								
UHold Stand	Stand for wheels with a back wall for stability	UW MakerSpace	N/A	2/22/22	1	\$22	\$22	<u>UW-</u> <u>MakerSpace</u>
Component 2			•	•				
DYWheel		UW MakerSpace	N/A	2/23/22	1	\$6.00	\$6.00	See above
<b>Component 3</b>								
DYSpool		UW MakerSpace	N/A	2/23/22	1	\$11.28	\$11.28	See above
Component 4								
ShortSpout		UW MakerSpace	N/A	2/23/22	1	\$3.36	\$3.36	See above
Component 5								
	Modification of current							
CutChimney	design	UW MakerSpace	N/A	3/29/22	1	\$15.24	\$15.24	See above
Component 6								
	Modification of current							
CurveSpout	design	UW MakerSpace	N/A	4/6/22	1	\$7.60	\$7.60	See above
TOTAL:			\$65.48					



ADDISON DUPIES - May 02, 2022, 10:59 AM CDT

Title: New Wheel Designs PVA Supports

Date: 04/02/2022

Content by: Addie Dupies

Present: NONE

Goals: Note the PVA supports dissolving process and the properties of the new materials

Content:

- The PVA supports before dissolving are similar to PLA but seem to be more brittle
- Break very easily and can break the PLA because it is still attached
- Must dissolve in warm water cold water does not start the process
- The inner cavity after 24 hours of dissolving still had the PVA supports
  Was a gooey consistency and had to take a sponge to get the rest of it out
- The second wheel was much harder to melt.
  - If the PVA doesn't fully dissolve wait for it to dry so the guidewires do not get stuck in it

Conclusion: Potentially try using BioMed Clear and outsourcing because the Makerspace printers are too small for the design



# Loading/Unloading Initial Testing Protocols-3/24/22

#### VICTORIA HEILIGENTHAL - Mar 24, 2022, 11:49 AM CDT

**Title: Loading/Unloading Initial Protocols** 

Date: 3/24/22

Content by: Victoria (Document created by Tatum)

Present: N/A

Goals: To document the team's testing protocols

Content:

Attached is a link to the team's testing directions/protocols. These may be edited as the semester continues.

https://docs.google.com/document/d/1UWaPm7xDaWNKVvFA4U3wNTdHAk8o6\_3JGUlguBmGikw/edit?usp=sharing

Conclusions/action items: These protocols can used by any test subjects to ensure testing is completed the same across all subjects.



**3/1: Wheel Testing Spreadsheet Draft** 

TATUM RUBALD - Mar 01, 2022, 3:03 PM CST

#### Title: Wheel Testing Spreadsheet Draft

Date: 3/1

Content by: Tatum Rubald

Goals:

I will make a spread sheet to store data for testing different wheel designs. This spreadsheet will include information for:

- 1. number of times member has ran a trial
- 2. left or right handed team member
- 3. what design
- 4. loading time
- 5. unloading time
- 6. which guidewire was used

#### Content:

See attached spread sheet. There are also formulas in the spread sheet that will calculate how many times a member has done a trial, and will calculate how many trials have been done on each design.

#### Conclusions/action items:

We will use this when testing our wheel.

TATUM RUBALD - Mar 01, 2022, 3:03 PM CST

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#### **Download**

Wheel\_Loading.xlsx (16.1 kB)



3/31: Initial Testing Results and Data

TATUM RUBALD - Mar 31, 2022, 9:59 AM CDT

#### **Title: Initial Testing Results and Data**

Date: 3/31

Content by: Tatum Rubald

Goals:

Test wheel and analyze using an AVOVA1

#### Content:

See attached files.

There is no significant difference in means between any of our wheel loading times or loading ratings.

#### Conclusions/action items:

I ran an ANOVA on the loading times/ratings. And here are the results... as you can see there is no significant difference in means between any of the wheels. This is telling me we need to test the new wheels ASAP, so we are able to find a "better wheel". It does tell us that wheels 0 and 1 are pretty similar

	Wheel #	Wheel #	P-Value
	0	1	.973
Loading time	0	2	.534
	1	2	.671
	0	1	.956
Loading rating	0	2	.131
	1	2	.217

23 of 187



<u>Download</u>

Wheel\_Loading.xlsx (22.2 kB)



TATUM RUBALD - Apr 29, 2022, 6:30 PM CDT

Date: 4/29

Content by: Tatum Rubald

Present: Testing by Alex P

Goals:

Record Testing Data

Content:

See attached file.

# Conclusions/action items:

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

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TATUM RUBALD - Apr 29, 2022, 6:30 PM CDT

Download

Final\_Wheel\_Loading\_.xlsx (40.3 kB)



TATUM RUBALD - Apr 29, 2022, 6:34 PM CDT

Title: Learning Curve

Date: 4/29

Content by: Tatum Rubald

Goals:

Determine the learning curve for our wheel.

Content:

See attached file.

### Conclusions/action items:

The graph clearly shows that as number of trials increase, the amount of time to load the wheel decreases. We expect a plateau to occur around 11 seconds.



Download

learning\_curve.xlsx (18 kB)



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:06 PM CST

Title: Report 2/03

Report 2/03

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 2/03

Content:

https://docs.google.com/document/d/1J3GkW8ALmmXCla-GA2Rr3AN8wImGyDHzODw3-utPFBI/edit?usp=sharing



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:06 PM CST

Title: Report 2/10

Report 2/10

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 2/10

Content:

https://docs.google.com/document/d/1sbmHtS1-SZWF3zGrMS0m-\_QZYDLL5CdYIUH3KdcSG4Q/edit?usp=sharing

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:07 PM CST

Title: Report 2/17

Report 2/17

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 2/17

Content:

https://docs.google.com/document/d/1cAyat5zA0OHrKK5KwfoV51eaSXkvjCKr92sVzhZXiRQ/edit?usp=sharing



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:08 PM CST

Title: Report 2/24

Report 2/24

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 2/24

Content:

https://docs.google.com/document/d/18SinySWxV9njxgm-SvU32nBczdm2Uu1DDnSNM8goUpU/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:23 PM CDT

Title: Report 3/03

Report 3/03

Date: 4/28/222

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 3/03

Content:

https://docs.google.com/document/d/1Td8jX7mH1W6iJeupK2JXyN9eXqt0RbvhdWQcGhyh\_\_8/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:24 PM CDT

Title: Report 3/10

Report 3/10

Date:4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 3/10

Content:

https://docs.google.com/document/d/1adGPpu2K5-WNs5Q4PWUUARwCdtCkuQUmSt1C85Mfr3s/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:26 PM CDT

Title: Report 3/24

Report 3/24

Date: 4/28/222

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 3/24

Content:

https://docs.google.com/document/d/1-TkdFeMMxaPkcM9C1NKdiHHlaQvCT-P6Y2Qo4yvA9rl/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:28 PM CDT

Title: Report 3/31

Report 3/31

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 3/31

Content:

https://docs.google.com/document/d/1-TkdFeMMxaPkcM9C1NKdiHHlaQvCT-P6Y2Qo4yvA9rl/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:29 PM CDT

Title: Report 4/7

Report 4/7

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 4/7

Content:

https://docs.google.com/document/d/1dQd31TiUDaH6QQG3J1Eonu5yswtAK-J7y6CHh3ypbxk/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:30 PM CDT

Title: Report 4/14

Report 4/14

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 4/14

Content:

https://docs.google.com/document/d/1jjk5pvzIfSWrMPhOkkMksDKG0tOgFPcm9aKqrtHZOnc/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:31 PM CDT

Title: Report 4/21

Report 4/21

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 4/21

Content:

https://docs.google.com/document/d/1ydmHEQ\_j0LRwW8mMehtPja\_\_\_sqBj1CXIhtgtRhtbVc/edit?usp=sharing


VICTORIA HEILIGENTHAL - Apr 29, 2022, 7:36 PM CDT

Title: Report 4/28

Report 4/28

Date: 4/29/22

Content by: Victoria

Present: N/A

Goals: To include a link to the progress report from 4/28

Content:

https://docs.google.com/document/d/1wYTixcPAGf3p85lcl9BNTCKW0-mHe3skKjajieT\_dME/edit?usp=sharing

PDS



Title: PDS File

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the PDS document

Content:

https://docs.google.com/document/d/15jk1J9i-J-UIO3xErJHEXObTBA\_mIV5UucKeiC7VW9U/edit?usp=sharing



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:05 PM CST

Title: Design Matrix

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the design matrix

Content:

https://docs.google.com/document/d/19DkcDD9upsMeTCP5LWjQcghBkw8Gh2JsAfGANNInX5k/edit?usp=sharing



SolidWorks Files for UHold and wheel

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:09 PM CST

Title: SolidWorks Files for UHold and wheel

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include the SolidWorks Files for UHold and wheel devices

Content:

Files attached below

Conclusions/action items: The team can continue to progress through the project.

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:10 PM CST



**Download** 

#### DYSpool.stl (900 kB)

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:10 PM CST



**Download** 

DYWheel.stl (736 kB)

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:10 PM CST



**Download** 

ShortSpout.STL (359 kB)

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:10 PM CST



**Download** 

UHold.STL (26 kB)



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:03 PM CST

Title: Preliminary Presentation

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the preliminary presentation

Content:

https://docs.google.com/presentation/d/1L35xPlhC-JAYGKd2vvE8JNFUt4ALLVwZf9PM-ePiILc/edit?usp=sharing



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:32 PM CDT

**Title: Final Poster** 

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the final poster

Content:

https://docs.google.com/presentation/d/1BHXr\_D\_Lh-YrawiuN598zkMQMTrMqYXG/edit? usp=sharing&ouid=114507568317266306900&rtpof=true&sd=true



VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:33 PM CDT

Title: Executive Summary

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To include a link to the Executive Summary

Content:

https://docs.google.com/document/d/1bHVi8pNDgPgEaOgubii\_BtWxSG92TAk4/edit? usp=sharing&ouid=114507568317266306900&rtpof=true&sd=true

2022/02/09 General Basics for an endovascular procedure

ADDISON DUPIES - Mar 01, 2022, 11:20 PM CST

Title: General Basics for an endovascular procedure

Date: 02/09/2022

Content by: Addie Dupies

Present: NONE

Goals: Review basics of endovascular procedures to address any misconceptions / unknowns

Content:

- Guidewires are used in many different endovascular procedures up to 4 guidewires can be used in each procedure
- Each guidewire in a procedure can vary in diameter and stiffness because they each have different purposes in the procedure

How it works:

- 1. Guidewire is inserted into the patient and then directed into the area of interest
- 2. The catheter is fed along the guidewire to the correct area
- 3. Once the catheter is in the correct position, the guidewire is removed
- 4. Guidewire must be stored in case it is used again during the procedure

Risk of Endovascular Procedures:

- Endovascular procedures are minimally invasive the guidewire and catheter are inserted through a small incision
  - This lowers the risk of large, invasive surgeries as the only foreign object be inserted into the body is the guidewire and the catheter
- Used to treat problems affecting the blood vessels like in an aneurysm (fixes the swellings of the blood vessels)
- Reduced the need to have open surgeries (positive risk benefit ratio for patients)

https://www.brighamandwomens.org/surgery/vascular-and-endovascular-surgery/procedures https://www.ucsfhealth.org/treatments/endovascular-surgery

Conclusion/Action Items: Reviewed the basics and feel comfortable discussing these topics, especially with the new team members if they have any questions about basics of endovascular procedures.

45 of 187



ADDISON DUPIES - Mar 01, 2022, 11:07 PM CST

Title: Competing Design 1 - Cath Clip

Date: 02/03/2022

Content by: Addie Dupies

Present: NONE

Goals: Assess and evaluate the use of Cath Clip and how they market their product to surgeons and hospitals

Content:

Device:

- Similar to a chip clip the operator winds up the guidewire and clips together at the top
- · Foam pads in the middle to hold the guidewire together

Benefits:

- Decreases risk of stroke from lint that can be left on guidewires when using gauze and cotton towels to hold and wipe devices the foam pads are lint-free
- Reduces sedation time by managing guidewires more efficiently, which is beneficial to the patient and hospital in terms of risk
  - Also allows doctors to focus more on patient care and less on device and guidewire management
- Decreases procedure time by decreasing the time spent on device management (average of 80%)
- Reduces materials costs by more than \$48 per case when used fewer guidewires are contaminated from falling on the ground

Overall: The Cath Clip has benefits for both the hospital and the patient. In terms of the hospital, they are able to reduce time spent in surgery through better device management, which can greatly decrease money wasted in the operating room. Also for the patient, it reduces time spent under sedation, which decreases the risk of each surgery.



https://www.cathclip.com/value-analysis-information.html

Conclusion/Action Items: Cath Clip seems to be very big in the endovascular device market. Designing something that is more efficient and not much harder to learn could potentially take over Cath Clip for the best device in the operating room for endovascular procedures.



# 2022/02/15 Impact on Endovascular Surgeries/Device Market

ADDISON DUPIES - Mar 01, 2022, 11:38 PM CST

Title: Impact on Endovascular Surgeries/Device Market

Date: 02/15/2022

Content by: Addie Dupies

Present: NONE

Goals: Discuss the impact of this device on endovascular procedures and the endovascular device market

## Content:

This device while the concept itself seems quite simple there is nothing on the market that is quite like it. The ability for doctors to store multiple guidewires that are needed for an endovascular procedure could revolutionize endovascular surgeries.

# Why?

- 1. The device (guidewire wheel and stand) would allow for fewer people to be in the operating room, which causes a greater risk because of the possibility of contamination and risk of infection to the patient.
- 2. Allows for them to be stored in one place giving easy access to the operating technician/surgeon that is utilizing the guidewire
- 3. Liability for the hospital also decreases because fewer people are in the operating room
- 4. The patients will benefit because the surgeon will be able to complete the procedure faster with the new device (Cath Clip has proven this)

# Impact on the Device Market

- The endovascular treatment device market is \$2.0 billion and is projected to reach \$2.2 billion by the end of 2022
  - Large room for the device to be implemented and for surgeons to want to use it
- If the device is truly able to save time in the operating room, hospitals will want to buy it
  - Every lost minute in a hospital operating room costs an average of \$60
  - Operating rooms are expensive to run hospitals want to be efficient and save money
  - Gives rise to large room for growth in the endovascular device market.

# https://www.accessefm.com/blog/the-cost-of-a-lost-minute-in-the-or

# https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878988/

**Conclusion/Action Items:** Designing, testing, producing, and then implementing devices can be a quite tedious process. Devices can start in the prototyping phase, but there is not a great enough impact of the device itself to bring it out of that phase and fully implement it into the medical field. So many devices have been prototyped, but then nothing occurs beyond that phase. How can we make sure that this device succeeds in that way and moves beyond the prototyping phase? Research on what makes a project/design successful and how our team can accomplish that. How do ethics play a role?



ADDISON DUPIES - Mar 02, 2022, 12:25 AM CST

Title: Current Techniques

Date: 02/17/2022

Content by: Addie Dupies

Present: Addie, Tatum, Client

Goals: Determine the exact way operating techs work in the OR

Content:

- 3 main ways but it is dependent on the operating technician
  - Feed into the original dispensing tubing slow
  - Cath Clip contamination
  - Wet towel over the guidewire disorganized
- Need a better way to eliminate ALL three of these inconveniences



With the Cath Clip



# With a Towel

Conclusion/Action Items: Show these to the team so they also have a better understanding. This meeting demonstrated why the need for a new device is very large.



ADDISON DUPIES - Mar 01, 2022, 11:55 PM CST

Title: Ethical Implications and Considerations of New Medical Devices

Date: 02/20/2022

Content by: Addie Dupies

Present: NONE

Goals: Further research the ethical implications and considerations of testing new devices in the medical field

Content:

- The guidewire wheel and stand are fairly low risk, along with the surgical setting of endovascular procedures so why is it hard to implement new devices into the medical field?
  - Testing in an engineering setting for quantitative numbers is not the concern in this aspect but the focus is on the safety of the patient
- Testing the device for quantitative data in a non-surgical setting is the step that must be accomplished before testing in the setting of an operating room with a patient
- No patient will consent to a "new device" being used during their surgery because if it is not standard practice for the doctors it could potentially cause a longer time under sedation and other complications

# Why is testing on patients hard?

- When testing medical devices in an operating room with a patient it becomes very difficult
- Testing on patients would be the last step of testing this device
- · Patients must consent to this testing because they are at higher risk of something going wrong
- Clinical research guidelines are in place to ensure that no patient is exploited for the purpose of research and testing
- There are seven main principles in place for clinical research
  - 2 main principles that are crucial to clinical research involving patients are informed consent and a positive risk-benefit ratio
    - The benefit of using the device must outweigh the negatives of using the device (positive risk-benefit)
    - The patient must be aware and understand this is happening and consent to it
- Ethically, it becomes quite hard to conduct continuous clinical studies with devices as the risk-benefit ratio is not always positive.
  - In this device it will be easier there is already little risk ethics must always be considered

# Source: https://clinicalcenter.nih.gov/recruit/ethics.html

Conclusion/Action Items: This was a great follow-up to the impact of the device on the endovascular market and surgeries. There are not many devices because it becomes quite hard to implement testing into an actual operating room. This data is then needed to market the product, which is why there are not many storage devices on the market when the accessible item of the operating room do not need "further testing".



ADDISON DUPIES - Mar 02, 2022, 12:32 AM CST

Title: Math and Chemistry in Project

Date: 02/29/2022

Content by: Addie Dupies

Present: NONE

Goals:

There is no math and chemistry currently in the project.

Conclusion/Action Items: Update as needed.



ADDISON DUPIES - Mar 01, 2022, 10:49 PM CST

Title: Client Designs

Date: 01/31/2022

Content by: Addie Dupies

Present: NONE

Goals: Present designs and specifications given by the client

Content:

- · Consists of three parts wheel, inner spool, and the rack
- · Dimensions are subject to change from testing
- User interface must be easy and should be a large focus of the design





Conclusion/Action Items: Begin printing these designs for testing and be able to edit the dimensions to find the most efficient design. Brainstorm other ideas for stand.



# 2022/04/28 Post Final Presentation Client Design Updated Ideas

ADDISON DUPIES - May 02, 2022, 10:40 AM CDT

Title: Client Designs

Date: 04/28/2022

Content by: Addie Dupies

Present: NONE

Goals: Note possible design modifications for fall 2022 semester

Content:

- 1. Make disposable this will make the device more marketable and easier to sell
- Injection molding (nylon/polyester) a lot cheaper than PLA / 3D printing will also be able to make at a faster rate
- 3. Possibly clear material to see entanglements judges from TONG awards (this will allow the user to see any potential tangles in the guidewires before use)
- 4. Decrease material on the stand and increase the diameter of the stand chimney also will make it cheaper to produce and the wider chimney makes the wheel move less on the stand because it is more secure. This looks a lot cleaner and will also market better
- 5. Investigate business opportunities (marketing the device) Medline Industries (already working with the client) to help bring the device to market

Conclusion/Action Items: If allowed to carry the project forward into next semester, this would be a great way to kick start the fall 2022 semester with strong design modifications, allowing the project to be closed after 2 more semesters.

ADDISON DUPIES - May 02, 2022, 10:43 AM CDT



ADDISON DUPIES - Mar 02, 2022, 12:14 AM CST

Title: Testing Objective

Date: 02/24/2022

Content by: Addie Dupies

Present: NONE

Goals: Discuss the objectives for testing both the guidewire wheel and stand

## Content:

# **Purpose of Testing**

- Determine the final dimensions of the guidewire wheel from the given design from the client
  - Main goal is to be more efficient, but also focus on the user interface and how easy it feels to use the guidewire wheel
- Compare to the competing design of the cath clip and the current method of using the dispensing tubing and feeding the design back through the tubing
- Evaluate the stand and determine any modifications that must be made (dimensions, bulkiness (cut holes in the bottom))
- Evaluate the stand and the guidewire wheel as a unit and how it works with multiple guidewire wheels

# **Testing Objectives**

- Run statistical analysis on the comparison of the guidewire wheels to the current methods mentioned above
   Determine if there is statistical significance
- Determine with binary (0,1) if the guidewire wheel and stand work together well as a unit limits entanglement of the wires/efficient/easy to use with different test subjects
- Determine final dimensions of the stand and wheel
- Present the data to our client and have him compare his use to the data (determine if doctors do better than students)

**Conclusion/Action Items:** Begin testing the week after spring break. Start to write a testing protocol for different tests we can use. Expand from the 300 testing to see if we can gather more quantitative data. Find subject to test the device that have no experience.



ADDISON DUPIES - Mar 02, 2022, 12:38 AM CST

Title: Testing Analysis Methods

Date: 02/24/2022

Content by: Addie Dupies

Present: NONE

Goals: Discuss potential ways to analyze the data we collect

- · T-test is most likely not suitable for our testing
- · ANOVA would give us better results that we will be able to interpret
- Either MATLAB or R-studio can help analyze the data
- Data must be quantitative in order to use either
  - Entanglement/ difficulty can be put into quantitative data either on a scale or with binary

Conclusion/Action Items: Ask the team if anyone wants to perform data analysis, otherwise I am comfortable using MATLAB to analyze the data collected over the next few weeks.



ADDISON DUPIES - Mar 02, 2022, 12:44 AM CST

**Title: Potential Testing Ideas** 

Date: 03/01/2022

Content by: Addie Dupies

Present: NONE

Goals: List potential testing ideas for the guidewire wheel and stand

- 1. Timed test of loading and unloading guidewires with wheel and stand
- 2. Timed test of loading and unloading guidewires with just wheel
- 3. Evaluation of difficultiness (0-10?) (need a scale that stays constant for each test subject)
- 4. Binary evaluation of entanglement (0 = no, 1 = yes)
- 5. Timed test of "loading and unloading" current dispensing tubing
- 6. Timed test of "loading and unloading" Cath Clip
- 7. Number of times user had to start over winding the guidewire for both Cath Clip and the teams wheel

Conclusion/Action Items: Present ideas to the team and potentially brain storm more ideas that can be used for testing



2022/03/23 Preliminary Testing Protocol

ADDISON DUPIES - Mar 23, 2022, 12:10 PM CDT

#### **Title: Preliminary Testing Protocol**

Date: 03/23/2022

Content by: Addie Dupies

Present: NONE

Goals: Test Preliminary wheel design among group members

Loading Protocols:

# Loading

- 1. Start timer
- 2. Wind guidewire by hand
- 3. Pick up wheel from table
- 4. Use one hand to hold wheel, one to hold wire-loop
- 5. Slide wire-loop into wheel
- 6. When guidewire is fully secured within the wheel, place wheel in one hand
- 7. Stop timer

\*If the guidewire is not able to load properly, record load time as MT (mistrial)

# Grade the Load Trial (0-3)

0 - Unable to load guidewire

1 - The wire slid into the wheel, but there were some issues (i.e. the tip of the wire hangs out too far, had to manually maneuver

- the wire to fit into the wheel, e.g.)
- 2 Wire slid into the wheel with ease, but the wheel itself made the sliding motion uncomfortable/less time efficient
- 3 Wire slid into wheel without complications

# Unloading

- 1. Start timer
- 2. Use one hand to hold wheel, and one hand to thread guidewire out of loop
- 3. When wire is fully out of wheel, stop timer

DO NOT STICK FINGERS THROUGH CENTER OF UWHEEL TO AID IN REMOVAL. MUST REMOVE WIRE WITHOUT TOUCHING

\*If the guidewire is not able to unload properly, record load time as MT (mistrial)

# Grade the Unload (Thread trial) (0-3)

- 0 Unable to unload the guidewire
- 1 The guidewire was partially removed from the wheel before tangling and popping out
- 2 The guidewire was removed from the wheel with out tangling but partially falls out of wheel during unloading
- 3 The guidewire was removed without complications



ADDISON DUPIES - Mar 21, 2022, 4:32 PM CDT

Title: Warf Patent Lecture

Date: 03/20/2022

Content by: Addie Dupies

Present: NONE

Goals: Watch the lecture and take notes about the patent process

- Mission: to support scientific research within the UW-Madison community by providing financial support, actively managing assets, and moving innovations to the marketplace for a financial return and global impact
  - Want to enable UW-madison research to solve the world's problems
- The cycle of innovation:
  - UW research and discovery
  - IP protection
  - Licensing and startups
  - Funding to support research and discovery
- What they have done so far:
  - 2000 patential
  - 700 pending patents
  - 50+ licenses annually
  - Over \$1 billion of products sold each year
  - 125 faculty start ups
- Have a lot of grant money -- \$85 million in 2018

Protecting innovation:

- · Patents: machines and devices, compounds, processes and methods, improvements
- Trademarks: words and phrases, color, pictures or logos, sound
- · Copyrights: literary works, webpages, software programs

Requirements for Patentability:

- Eligible
- Useful
- Enabled
- Described
- Novel
- Non-obvious
  - Examination = assessment of the invention -- based on statutory requirements and application of prior art

Licensing Considerations for new disclosures:

- Chance of licensing: potential applications, technology benefits, and impact, state of the market, WARF's
  history in licensing
- Timeline for licensing: stage of the technology, patent status, position in WARF's portfolio
- Licensing strategy: companies (existing or start up), exclusive vs. non, field limitations

Addison Dupies/Training Documentation/2022/03/20 WARF Patent Lecture

- 1. Milestone-based validation funding to speed promising technologies to a commercial license:
- 2. Goal: accelerate commercialization prospects for WARF IP
- 3. Catalysts: expert consultants with significant business experience
- 4. FIVE SECTORS:
  - 1. Computer science and engineering
  - 2. Medical Devices
  - 3. CleanTech
  - 4. Food & Agriculture
  - 5. Research Tools

Start up resources:

- Seed funding
- Innovation roadmap series
- UpStart Program from Minority and Women's Entrepreneurship
- Law and Business entrepreneurship clinics

Relation to our project: our project has intellectual property because the product being created is much different than all products that are on the market right now. We can create something and put a patent on it to introduce to the marketplace.



RACHEL KRUEGER - Feb 28, 2022, 10:04 PM CST

Title: Biomedical problem to be solved

Date: 2/3/22

Content by: Rachel Krueger

Present: N/A

**Goals:** Understand problem/project

Content:

- 1. Surgeons must use multiple guidewires during a single procedure.
- Guidewires are hard to manage they get tangled and disorderly very easily. This increases time in surgery and sterilization procedures
- 3. Client wants us to design a device that serves to increase procedure efficiency and safety do so by decreasing time to load and unload the wires and making the device easy to use.
- 4. Must be easy to remove the wire while in the operating room.
- 5. Device will consist of two parts wheel and stand
- 6. Current wheel design is provided by the client we need to finalize and determine dimensions that maximize efficiency

Conclusions/action items:

Make a plan to solve these problems given our resources and available time



RACHEL KRUEGER - Feb 28, 2022, 10:09 PM CST

Title: Engineering Principles and Math

Date: From 2/7/22

Content by: Rachel Krueger

Present: N/A

Goals: Brainstorm different math techniques and principles to solve the problem

#### Content:

- 1. Using solidworks for designing on a 3D software.
- 2. will be using some sort of statistical analysis to prove effectiveness of device options include p test, t test, etc.
- 3. Calculating time it takes to load and unload the wire while also considering how a person gets better at a procedure the more times they do it possibly be able to quantify that?
- 4. Use problem solving, brainstorming, collaboration to solve the problem.

Conclusions/action items:

Use various techniques to complete the project.



#### RACHEL KRUEGER - Feb 28, 2022, 10:13 PM CST

Title: Biology, physiology, chemistry

Date: 2/4/22

Content by: Rachel Krueger

Present: N/A

Goals: Apply science related ideas to device

#### Content:

Since this project has been continued from last semester, the initial in depth research into guidewires, storage devices, and biocompatibility are stored in the previous lab archives. The team members who were on the project last semester briefed the new members on what they had learned.

#### Conclusions/action items:

Apply the knowledge of previous team members to progress the project.



RACHEL KRUEGER - Mar 01, 2022, 12:59 PM CST

Title: Codes and Standards

Date: 3/1/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline codes and standards to consider

#### Content:

ISO 11070:1998(E) tests help medical device manufacturers to ensure that products such as guidewires are safe for USe (see testing guidewires entry in design ideas for citation).

ISO 25539-2:2020 - Cardiovascular implants, endovascular devices, vascular stents

FDA-16007 - Coronary, peripheral, and neurovascular guidewires

Citation: "Trackability," ViVitro Labs, 09-Aug-2021. [Online]. Available: https://vivitrolabs.com/testing-services/trackability/. [Accessed: 01-Mar-2022].

## Conclusions/action items:

Consider these important standards and codes when we get closer to patent applications.



# Why do we need to solve this problem?

RACHEL KRUEGER - Mar 01, 2022, 3:03 PM CST

Title: Why do we need to solve this problem?

Date: 3/1/22

Content by: Rachel Krueger

Present: N/A

Goals: Understand why we need to solve the problem

## Content:

- 1. surgeons need to keep a sterile field gets broken if wire falls on ground (towel and cath clip)
- 2. surgeons need to use many in a single surgery
  - 1. if they need to reuse the same wire it needs to be easily accessible, organized, and readily available
  - 2. being able to store 3 wires at once decreases disorganization
- 3. current methods are unreliable could be greatly improved
- 4. decreasing time it takes in surgery by increasing efficiency will save the patient money

#### Conclusions/action items:

Aim to incorporate these considerations into the final design



**Oliver Catheter and Guidewire Dispenser** 

RACHEL KRUEGER - Mar 01, 2022, 12:29 PM CST

Title: Oliver Catheter and Guidewire Dispenser

Date: 3/1/22

Content by: Rachel Krueger

Present: N/A

**Goals:** Highlight key aspects of current designs

### Content:

Citation: "Catheter & Guidewire dispensers," *Oliver Healthcare Packaging*. [Online]. Available: https://www.oliverhcp.com/products/catheter-and-guidewire-dispensers. [Accessed: 01-Mar-2022].

- 1. Can be sterilized via EtO and gamma irradiation
- 2. Benefits:
  - 1. clipless
  - 2. dual hoop option for multiple size devices in one system
  - 3. easily contains related procedural components
  - 4. increased convenience for end users
  - 5. reduced end user time and cost
  - 6. reduces puncture risk
- 3. Awarded winner of packaging design of the year by healthcare asia medtech awards 2021
- 4. cons:
  - 1. can bend in device if too much force is applied
  - 2. device is not see-through, can't see what it is getting stuck on
  - 3. walls may increase resistance when loading
  - 4. increased loading and unloading time

# Conclusions/action items:

Consider the benefits of this device when finalizing design



oliver\_dispenser\_.jpg (40.5 kB) Figure: Picture of Oliver device

RACHEL KRUEGER - Mar 01, 2022, 12:30 PM CST



RACHEL KRUEGER - Mar 01, 2022, 12:37 PM CST

Title: Cath clip design

Date: From 2/10/22

Content by: Rachel Krueger

Present: N/A

Goals: Understand the cath clip current competing design

#### Content:

Citation: "The cathclip solution," CathClip. [Online]. Available: https://www.cathclip.com/the-cathclip-solution1.html. [Accessed: 10-Feb-2022].

- 1. securely and gently holds any type of flexible elongated medical device
- 2. small, so many can fit in the sterile field and even in saline-filled bowl
- 3. foam is a lint-free, dimensionally stable polyurethane which does not release lint, thereby eliminating the risk of intra- and post-procedure embolization due to lint.
- 4. Reduced material cost and waste
- CathClip is the only universal, easily adopted, quick to use, and economical solution to holding <u>any</u> guidewire, catheter, or balloon between uses during procedures, safely and securely.
- 6. comes in two colors (white & blue) the different colors are to aid in organization only (there is no functional difference).
- 7. pays for itself in materials cost savings
- 8. efficiency and safety benefits

#### Conclusions/action items:

Consider using less material like the cath clip to minimize waste



Download

cath\_clip\_design.jpg (32 kB) Figure: Cath clip competing design



RACHEL KRUEGER - Mar 01, 2022, 3:15 PM CST

Title: Flexible tube competing device

Date: From 2/17/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline the competing device

#### Content:

See attachments for pdf of article.

- 1. has a very similar purpose
- 2. Is associated with a patent
- 3. the external portion of a guidewire is wound about itself in such a way as to "lock" the wire from springing into its naturally straight configuration
- 4. The wound portion of the guidewire is then placed into a large bowl containing a sterile saline solution so as to keep the wire wet.
- 5. The saline solution also promotes the dissolution of any clots which may have formed on the guidewire after it is removed from the patient and placed in the bowl
- 6. Wound guidewires also have a tendency to straighten once unlocked
- 7. provide a method and apparatus for storing medical guidewires that maintains them submersed in liquid
- 8. provide a method and apparatus for storing medical guidewires that allows for their easy introduction into a patient and removal
- 9. provide a method and apparatus for storing medical guidewires that prevents their contact with non-sterile portions of the procedure room

#### Conclusions/action items:

Possibly use some ideas from here that can increase the effectiveness of our device.

69 of 187



Competing\_Device-\_Flexible\_tube.pdf (345 kB)



Title: Design Constraints

Date: 2/28/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline realistic constraints

#### Content:

- 1. Time. This is obviously a constraint given it is a semester long project. However, the project should not be rushed simply to complete it in the semester. If desired, the client may choose to continue it for another semester.
- 2. Budget. Although the client didn't give us a true budget, it is important to consider any money spent as to not create an overly expensive device. The device needs to be able to be produced for the market, so being able to design and produce a device that is affordable is important.
- 3. Makerspace. We plan to 3D all of the pieces for the protype we will be presenting to our client. Some of the 3D printing is not entirely accurate and can result in incorrect dimensions produced. The team will need to make adjustments after seeing how the variation in dimensions affects the performance of the device.
- 4. 3D printing. Along with number 3, we need to consider how the performance of the prototype will compare to the device that will be presented to the market. The difference in material depending on sterilizability and biocompatibility may alter the performance of the device so our testing and analysis should mention that.
- 5. Quantifying results. We need to be able to quantitatively measure the performance of the device in order to produce statistical results.

## Conclusions/action items:

See how we can work around design constraints to meet the requirements for our client.



Title: Testing Guidewires

Date: From 2/28/22

Content by: Rachel Krueger

Present: N/A

Goals: Understand current guidewire testing method

#### Content:

Citation: [1] S. L. | M. 14, "Putting guidewires to the test," *mddionline.com*, 25-Aug-2017. [Online]. Available: https://www.mddionline.com/testing/putting-guidewires-test. [Accessed: 28-Feb-2022].

- 1. ISO 11070:1998(E) tests help medical device manufacturers to ensure that products such as guidewires are safe for use
- 2. set of relatively quick and uncomplicated methods with which to evaluate different materials, manufacturing means, and engineering configurations in order to optimize the final product
- 3. general requirements for the four devices covered under ISO 11070 include sterilization, biocompatibility, surface, corrosion resistance, and radio detectability, as well as information to be supplied by the manufacturer.
- 4. Corrosion test: subjects the specimen to a five-hour soak in a 0.15 mol/L saline solution at 22°C, followed by 30 minutes of boiling in water, cooling to 37°C, and finally maintaining the 37°C soak for 48 hours. After drying, the guidewire is inspected for signs of corrosion.
- 5. Guidewire fracture test: The guidewire is wrapped around the cylinder in relation to the OD of the wire for eight complete turns, after which the device is unwrapped and inspected for any signs of fracture. In the case of coated guidewires, the coating is also inspected for signs of flaking.
  - 1. This could be useful because we need to finalize the dimensions of wheel to ensure we are not damaging the wire
- 6. Guidewire flexing test: repeated bending and straightening of the device followed by an inspection for any damage and defects

1. performed for 20 cycles

7. tensile test: addresses the union of the coil and core wire of the guidewire or that of the coil and the safety wire

# Conclusions/action items:

Consider the guidewire fracture test and flexing test in testing protocol.

RACHEL KRUEGER - Mar 01, 2022, 12:53 PM CST

Title: 3D Printing Materials

Date: From 2/21/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline possible 3D printing materials

Content:

Link: 3D Printers - UW Makerspace - UW-Madison (wisc.edu)

- 1. Different types of 3D printers we are considering:
  - 1. Ultimaker prosumer printer, efficient and economical
  - 2. Formlabs standard and engineering resins for small and intricate parts
- 2. Possible choice of materials:
  - 1. PLA: high stiffness, high strength, translucent
  - 2. nylon: tough, wear resistant, low friction
  - 3. PETG: tough, chemical resistant, temperature resistant, wear resistant

Conclusions/action items:

Decide on what materials and printer will give us the best quality device


RACHEL KRUEGER - Mar 01, 2022, 2:41 PM CST

Title: Testing effectiveness of device

Date: 3/1/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline how the team can test the device

# Content:

- 1. place 3 guidewire wheels on the stand (currently UHold) with 1 guidewire of a set stiffness in each wheel
- 2. start timer
- 3. operator (someone on team) will unload 1 guidewire from the top wheel
- 4. once fully unloaded, stop timer and record time
- 5. begin timer
- 6. same operator will reload the guidewire back onto the top wheel
- 7. stop timer and record once successfully loaded
- 8. repeat 5 times for each operator, test at least 5 operators
- 9. analyze results using a statistical analysis (not yet decided)

# Conclusions/action items:

Use this general testing plan to write a more professional one

Title: Dr. Y current design

Date: From 2/12/22

Content by: Rachel Krueger

Present: N/A

**Goals:** Watch Dr. Y use his current device.

Content:

See files attached for a video of Dr. Y using his current prototype as well as some competing designs.

#### Conclusions/action items:

Reference when using our device.

RACHEL KRUEGER - Mar 01, 2022, 2:49 PM CST



**Download** 

Dr.\_Y\_performance.mov (277 MB LA S3) Figure: Video of Dr. Y using wheel and stand prototype



RACHEL KRUEGER - Mar 01, 2022, 3:06 PM CST

Title: Dr. Y provided STL files - design idea

Date: 2/9/22

Content by: Rachel Krueger

Present: N/A

Goals: Provide STL files from Dr. Y

Content:

See attachments for designs.

#### Conclusions/action items:

Print and modify these files when considering designs

RACHEL KRUEGER - Mar 01, 2022, 3:07 PM CST



**Download** 

DYSpool.stl (900 kB) Figure: STL files of possible prototypes

RACHEL KRUEGER - Mar 01, 2022, 3:07 PM CST



Download

DYWheel.stl (736 kB) Figure: STL files of possible prototypes

RACHEL KRUEGER - Mar 01, 2022, 3:07 PM CST



**Download** 

ShortSpout.STL (359 kB) Figure: STL files of possible prototypes



RACHEL KRUEGER - Mar 01, 2022, 3:19 PM CST





**Download** 

current\_wheel\_design.jpg (35.7 kB)



### RACHEL KRUEGER - Feb 20, 2021, 12:51 PM CST



# <u>Download</u>

# Green\_Permit.PNG (148 kB)

RACHEL KRUEGER - Mar 25, 2021, 1:01 PM CDT

Image caption: Image showing proof of obtaining a green permit.

RACHEL KRUEGER - Feb 20, 2021, 12:52 PM CST

Title: Green Permit

Date: 2/20/2021

Content by: Rachel Krueger

Present: Rachel Krueger

Goals: Show proof of documentation of green permit.

Content:

Reference attachment

Conclusions/action items:

Obtain any other permits I made need in the future to complete my project.

Copy - 3/14/2021 Biosafety and Chemical training

RACHEL KRUEGER - Mar 24, 2021, 8:42 PM CDT

Title: Biosafety and chemical training

Date: 3/14/2021

Content by: Rachel Krueger

Present: Rachel Krueger

Goals: Show documentation of completed trainings.

Content:

See attachments for proof of training completion.

#### Conclusions/action items:

Continue to be trained in other sections throughout this course and in the BME department to expand my knowledge and abilities.

RACHEL KRUEGER - Mar 24, 2021, 8:43 PM CDT

 University of Wisconsin-Madison

 Counte Kane
 Completed training for the following course(s):

 Counte Kane
 Completion Date
 Expiration Date

 BOOMETY DIS BOOMETY DIS

Data 1964/144 Sat New 14 11/25/00 2020 Report Generated: Fri Mar 12 13:54/14 2021

#### **Download**

Training.JPG (157 kB) Training documentation to show completion of required trainings.

RACHEL KRUEGER - Apr 29, 2021, 1:03 PM CDT

University of Wisconsin-Madison

Course Name	Curriculum or Quiz Name	<b>Completion Date</b>	Expiration Date
BIOSAVETY 105: BIOSAVETY CABINET USE	BIOSAVETY 105: BIOSAVETY CARINET USE QUEZ	11/13/2020	
ROSAFETY SOL: AUTOCLAVE USE	BIOSAFETY 106: AUTOCLAVE USE: SAFETY AND EPIFICACY - VERIFICATION QUIZ	11/13/2020	
ROSAFETY 107. CENTREFUGE SAFETY	BIOSAVETY 107. DENTRIPUGE SAVETY VERIFICATION QUEZ	11/13/2020	
BOSAFETY REQUIRED TRAINING	BOSAFETY REQUIRED TRAINING QUEZ	11/14/2028	
CHEMICAL SAFETY: FUME HOOD SAFETY TRAINING	FUME HOOD FINAL QUIZ	11/13/2020	
DIEMICAL SAFETY: THE OSHA LAB STANDARD	rinal QUI2	4/15/2021	-

#### Download

Capture.JPG (169 kB) Updated chemical safety training



RACHEL KRUEGER - Mar 10, 2022, 11:47 AM CST

Title: Warf Presentation

Date: 3/10/22

Content by: Rachel Krueger

Present: N/A

Goals: Describe how my design might have intellectual property.

#### Content:

My team and I could file a patent for the device design which can then be trademarked under the name of our device along with a logo. We would need to define prior art - competing devices - in order to make a case as to why our invention is worthy of being patented.

#### Conclusions/action items:

Consider the patent process more when our design is finalized.



RACHEL KRUEGER - Apr 01, 2022, 12:48 PM CDT

Title: Tong Lecture

Date: 4/1/22

Content by: Rachel Krueger

Present: N/A

Goals: Listen and gain information from the tong distinguished lecture series.

# Content:

- 1. TITLE: bio entrepreneurship: transforming intent into impact
- 2. Intent: treating complex skin defects. Goal: reduce or eliminate the need for donor site scarring. Impact: StrataGraft skin substitute
- 3. only 14 cell and gene products that are approved by the FDA
- 4. What makes an entrepreneur: innovation, management, opportunity, risk-tolerance (financial, professional, personal).
- 5. find a mentor, be a mentor

# Conclusions/action items:

It will be helpful to use this information in the future.



RACHEL KRUEGER - Apr 30, 2022, 11:52 AM CDT

Title: Testing Code Round 1

Date: 4/30/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline code used in Matlab for testing analysis of first round of testing

#### Content:

figure(1);

subplot(1,2,1);

xD = [0 1 2 3];

yD=[0 0 1; 0 2 2; 5 2 5; 5 6 2];

bar(xD, yD);

xlabel('Rating Number');

ylabel('Number of Occurences for Each Rating');

title('Ratings of Loading Different Wheel Designs');

legend('DY Wheel', 'Short Spout', 'U Wheel');

subplot(1,2,2);

xD = [0 1 2 3];

yD=[10;22;93;310];

bar(xD, yD);

xlabel('Rating Number');

ylabel('Number of Occurences for Each Rating');

title('Ratings of Loading Different Wheel Designs');

legend('Stiff Guidewire', 'Flexible Guidewire');

figure(2);

subplot(1,2,1);

timeD=[12.51 15.56 15.94; 12.00 13.3 17.95; 16.31 13.15 20.76; 18.22 23.16 23.95; 16.55 19.29 19.05; 17.47 17.31 0.00; 25.19 22.02 34.92; 22.9 20.65 21.44; 12.06 15.64 24.12; 14.04 13.2 18.37];

boxplot(timeD);

designs = {'DY Wheel'; 'Short Spout'; 'U Wheel'};

Rachel Krueger/Testing/Testing Code From 4/6/22

set(gca, 'xtick', [1:3], 'xticklabel', designs);

xlabel('Design Type');

ylabel('Time to Load');

title('Time to Load Different Designs');

subplot(1,2,2);

timeG=[12.51 12.00; 15.56 13.3; 16.31 18.22; 17.47 16.55; 25.19 22.9; 12.06 14.04; 15.56 13.3; 13.15 23.16; 17.31 19.29; 22.02 20.65; 15.64 13.20; 15.94 17.95; 20.76 23.95; 0.00 19.05; 34.92 21.44; 24.12 18.37];

boxplot(timeG);

guidewires = {'Stiff'; 'Flexible'};

set(gca, 'xtick', [1:2], 'xticklabel', guidewires);

xlabel('Guidewire Type');

ylabel('Time to Load');

title('Time to Load Different Guidewires')

Conclusions/action items: Use similar code for round 2 testing.



RACHEL KRUEGER - Apr 30, 2022, 11:54 AM CDT

Title: Testing Code From 4/25/22

Date: 4/30/22

Content by: Rachel Krueger

Present: N/A

Goals: Outline code from second round of testing (done in Matlab)

#### Content:

figure(1);

subplot(1,2,1);

xD = [0 1 2 3];

yD=[0 1 1; 8 8 1; 7 7 14; 17 16 14];

bar(xD, yD);

xlabel('Rating Number');

ylabel('Number of Occurences for Each Rating');

title('Ratings of Loading Different Wheel Designs');

legend('DY Wheel', 'Cut Chimney', 'Curve Spout');

subplot(1,2,2);

xD = [0 1 2 3];

yD=[0 2; 5 12; 9 19; 33 14];

bar(xD, yD);

xlabel('Rating Number');

ylabel('Number of Occurences for Each Rating');

title('Ratings of Loading Different Guidewires');

legend('Stiff Guidewire', 'Flexible Guidewire');

figure(2);

subplot(1,2,1);

timeD=[15.3 22.46 24.8; 24.13 32.76 25.99; 21.88 23.59 24.67; 36.73 27.61 24.55; 31.67 21.54 22.29; 25.53 0.00 0.00; 19.84 15.52 17.39; 17.41 14.99 21.56; 26.00 20.76 20.45; 29.76 30.88 21.78; 17.55 19.80 11.66; 18.81 25.06 11.88; 13.13 10.08 13.56; 18.10 15.54 13.28; 21.98 16.99 22.12; 19.80 20.58 16.32; 10.90 23.06 17.16; 14.13 21.66 39.91; 18.48 16.55 14.60; 21.33 20.99 28.95; 9.63 16.35 17.56; 11.46 21.19 15.03; 15.83 15.18 17.73; 20.73 20.01 18.62; 17.31 16.79 20.6; 14.77 18.65 24.32; 17.23 14.73 18.71; 27.12 20.49 22.99; 15.6 15.82 16.09; 19.3 19.29 27.93];

boxplot(timeD);

Rachel Krueger/Testing/Testing Code From 4/25/22

designs = {'DY Wheel'; 'Cut Chimney'; 'Curve Spout'};

set(gca, 'xtick', [1:3], 'xticklabel', designs);

xlabel('Design Type');

ylabel('Time to Load');

title('Time to Load Different Designs');

subplot(1,2,2);

timeG=[26.00 29.76; 17.55 18.81; 13.13 18.10; 21.98 19.8; 10.90 14.13; 18.48 21.33; 9.63 11.46; 15.83 20.73; 17.31 14.77; 17.23 27.12; 15.60 19.30; 18.63 17.41; 22.46 32.76; 23.59 27.61; 21.54 0.00; 15.52 14.99; 20.76 30.88; 19.80 25.06; 10.08 15.54; 16.99 20.58; 23.06 21.66; 16.55 20.99; 16.35 21.19; 15.18 20.01; 16.79 18.65; 14.73 20.49; 15.82 19.29; 14.81 19.35; 24.8 25.99; 24.67 24.55; 22.29 0.00; 17.39 21.56; 20.45 21.78; 11.66 11.88; 13.56 13.28; 22.12 16.32; 17.16 39.91; 14.60 28.95; 17.56 15.03; 17.73 18.62; 20.60 24.32; 18.71 22.99; 16.09 27.93];

boxplot(timeG);

guidewires = {'Stiff'; 'Flexible'};

set(gca, 'xtick', [1:2], 'xticklabel', guidewires);

xlabel('Guidewire Type');

ylabel('Time to Load');

title('Time to Load Different Guidewires')

Conclusions/action items: Use code for testing analysis - plots and graphs.



Title: Preliminary Loading Graphs From 4/6/22

Date: 4/30/22

Content by: Rachel Krueger

Present: N/A

Goals: Provide visual representation of preliminary testing results.

Content:

See attachments.

Conclusions/action items: Do same analysis for final testing round.

Time to Load Different Design Time to Load Different Guide 35 35 30 30 25 to Load Time to Load 20 Stiff Flexible Guidewire Type Design Type

#### **Download**

Box\_and\_Whisker\_Loading.jpg (172 kB) Bar chart for loading ratings. Box and Whisker for loading times.

in these Download

RACHEL KRUEGER - Apr 30, 2022, 11:59 AM CDT

Bar\_Chart\_Loading.jpg (333 kB) Bar chart for loading ratings. Box and Whisker for loading times.

RACHEL KRUEGER - Apr 30, 2022, 11:59 AM CDT





Title: Final Loading Graphs From 4/25/22

Date: 4/30/22

Content by: Rachel Krueger

Present: N/A

Goals: Show results from second round of testing (subjects not from our team)

#### Content:

See attachments.

Conclusions/action items: Perform analysis of these results (ANOVA)



RACHEL KRUEGER - Apr 30, 2022, 12:01 PM CDT

# **Download**

loadinground2testing.jpg (324 kB) Bar chart for loading ratings. Box and Whisker for loading times.

RACHEL KRUEGER - Apr 30, 2022, 12:01 PM CDT



# **Download**

boxandwhiskerround2.jpg (180 kB) Bar chart for loading ratings. Box and Whisker for loading times.



RACHEL KRUEGER - Apr 30, 2022, 12:11 PM CDT

Title: ANOVA Test Research From 4/25/22

Date: 4/30/22

Content by: Rachel Krueger

Present: N/A

Goals: Determine if ANOVA test will be useful for our testing,

# Content:

- 1. ANOVA Analysis of Variance.
- 2. Analyze difference between means of two groups
- 3. One way: Uses one independent variable
- 4. Two way: Uses two independent variables
- 5. Statistical test:

$$F = \frac{\sum n_j (\bar{X}_j - \bar{X})^2 / (k-1)}{\sum \sum (X - \bar{X}_j)^2 / (N-k)}$$

- 6. Critical value is determined.
- 7. If the null hypothesis is true, the F statistic will be small
- 8. If the null hypothesis is false, the F statistic will be large
- 9. Hypothesis Testing Analysis of Variance (ANOVA) (bu.edu)

Conclusions/action items: Would be useful to use to determine if there is a statistical difference between the devices



VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:14 PM CST

Title: Last Semester Files

Date: 2/8/22

Content by: Victoria

Present: N/A

Goals: To document all the presentations and reports created by last semester's team since this project is continuing from last semester

Content:

ATTACHMENTS BELOW

Conclusions/action items: By having all the documents in one spot, it makes it easy to refer back to what was done last semester. As a new team member to this project, it also helps be to better understand the project.

VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:15 PM CST



Download

ı

endo\_cath\_Preliminary\_Report.pdf (1.95 MB)



#### Download

# Preliminary\_Presentation.pdf (1.18 MB)

VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:15 PM CST

Product Design Specifications Date of Last Revision: 08/21/2021

Tale: Guidewire Organizer for Operation Room Client Dr. Dai Yamanouchi

Advisor: Dr. K.ip Ludwig Team: Tatam Rubold, Addison Dupies, Serena Raval, Scottie Waterfield, Alex Padrise, Soriya Patel

#### Function:

From the final sector and the sector of the

Clear replement:
The device runs to user to use and accuse appendix in the opening non.
The device runs to user to use and accuse appendix to base 4.5 galactic wheels
The faul device runs to dimately lave becompatible properties?
The faul device runs to stellarable by another or other abernatives?
\*Clears main goals a successful prototype rul prof of concept

- \*Create name pair a structure in provide period proof of concept Boign requirement: 1. Projectal and Operational Characteristics a Projecta scarse requirements: The denice will consist of two parts: [1] a divided center is status: [2] A 5 shows a provide a structure in galaxies will be placed. The wheel must be able to held pairbareness with denicer states of 0.004 to 0.005 index. Additionally, the galaxies will be a lips of the edge of the center states of 0.004 to 0.005 index. Additionally, the galaxies will be a lips of the edge of the cente for the galaxies to so. It must be any to load and memorithe with the the work of the the operating renear [1]. The wheels matriable be any placed and memorial from the cents. b. Subject The denice work the fails the without have cyclematics and me, glamatidhysis, formalistic placed and memorial from the cents. b. Subject The denice renear [1] shows and the fails with the responsible renear [1]. The wheels must be stated to the state with the denice the couple with the metal test in the operating room [2]. Additionally, then is hould be a renk for the user and all of gestruct be stated to the state with the denice the couple with the resplacement made by the clama, it rends the able with 4.5 carkiver galaxies, when the state hashly for which the 11.1 carkid answer of data with 4.5 carkiver galaxies, which hashly within the 11.1 carkies metal hashes the state and all of gestructures, which hashly within the 11.1 carkies metal hashes and all of the state with a state to the lata to 0.003, 0.011, 0.014 and galaxies (1] is addition in the proteins in which hashly within the 11.1 carkies metal hashes the addies of the carkiver and hashing the the lata the state and the rene addition the addition of the state and hash the fails of data in the operation of a state and the state and hashing the heat and the state addition is the proteins in the proteins of the lata of the state and the state and t

Download

Endo\_Cath\_PDS.pdf (309 kB)



BME 200300 University of Wisconsin - Madison Department of Biomedical Engineering 15 December 2021

Client Dr. Dai Yananovski, MD, PhD University of Wisconsia School of Medicine and Public Health Department of Surgery

> Advisor Dr. Kip Ladwig University of Wisconsin - Madison Department of Biomedical Engineering

Team Members: Tatara Rabala (Team Loader) Addison Dupies (Communicator) Soniya Parel (BPAG) Serena Raval (BWIG) Alex Padzist & Scottie Waterfield (BSACs)

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# EndoCath\_Final\_Report.pdf (2.44 MB)

VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:15 PM CST



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Poster\_BME\_300\_-\_ENDO\_CATH.pdf (547 kB)



VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:16 PM CST

VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:49 PM CST

Title: Last Semester Overview

Date: 2/8/22

Content by: Victoria Heiligenthal

Present: N/A

Goals: To document what the team last semester accomplished with the project

# Content:

- Last semester
  - Design criteria
    - Device should allow for loading and unloading or guidewire during OR procedures
    - Device must keep guidewire organized and untangled while stationed within wheel
    - Device should have 2 parts: guidewire organizer wheels and crate to hold wheels
    - Device must hold guidewire sizes from 0.014 to 0.035 in
    - Should be able to be 3D printed
  - Final design
    - 4 guidewire hoops and cate
    - Inner cavity of hoop is magnetized
    - Team developed a prototype that was testing using loading and unloading time tests as well as an entanglement test
    - Cost \$110
  - Results
    - Significantly different loading times were found for soft vs stiff wires
      - Indicates multiple devices might need to be produced depending on the wire type
    - Design had better unload times vs the original
    - No tangling and there were organization
  - Future
    - Modify crate
    - Make changes to device

Conclusions/action items: Understanding what the team did last semester is extremely important to know so the team can decide what worked well, what needs to be modified and brainstorm new changes to the device to meet the client's needs



#### VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:47 PM CST

## **Title: Overview of Guidewires**

Date: 2/8/22

Content by: Victoria

Present: N/A

Goals: To gain a basic understand and background of guidewires and catheters to know what the device will be used for

# Content:

- Uses
  - placing stents into blood vessels to open blocked arteries
  - Guidewire is used with catheter to guide it for insertions
  - Gives access to blood vessels invasively
  - Catheter has needle that is inserted into veins, guidewire is placed through needle and passed into blood vessel
- Benefits
  - Faster recovery and less surgical trauma
- Navigation of guidewires and catheters in the body during intervention procedures: a review of computer-based models (nih.gov)
- Materials

# • Stainless steel

- Alloy of nickel, titanium, nitinol
- Coated in Teflon or perylene
- Either solid or braided
- Guidewire an overview | ScienceDirect Topics (wisc.edu)
- Problems
  - Kinking, breakage, loss, knotting of guidewire
  - <u>A lost guidewire (nih.gov)</u>

Conclusions/action items: By understanding the general concepts behind the need for the device, it makes it easier to begin the design brainstorming process.





Endovascular Procedure video-2/28/22

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:21 PM CST

Title: Endovascular Procedure Video

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To better understand the procedures our device will be used for

# Content:

- Endovascular: treating blood vessel disorders with balloons, stents and other devices that are placed inside the vessels
  - Increase blood flow
- · Less invasive, avoid anesthesia
- Balloon angioplasty
  - Widens blood vessels due to constriction from plaque from breaking the plaque and extending the blood vessel through a balloon
- Stents
  - Support broken plaque during healing
  - Flexible, small delivery system
  - Not always effective
- · Endographs: treating aneurisms with stents covered in fabric, similar to endovascular procedures
  - Prevent aneurism rupture
  - Relining the weakened blood vessel

# History of Endovascular Surgery - YouTube

Conclusions/action items: By watching this video, I can now better understand the setting and situation that the wheel and stand devices will be used and how they will be beneficial on the market.



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:42 PM CST

## **Title: Endovascular Procedures**

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To better understand the risks and purposes for endovascular procedures

# Content:

# Endovascular Surgery | Conditions & Treatments | UCSF Health

Endovascular surgery: less invasive to treat problems that affect the blood vessels

- What does it treat?
  - Blood vessel disorders like aneurysms
- How does it work?
  - · A small incision is made close to blood vessels to gain access to them
  - A guidewire is inserted into the incision and pushed through the blood vessel to the point of interest
    - Uses an X-Ray to locate the aneurysm
  - An endovascular graft is inserted into the arteries using a catheter
    - Graft: Fabric tube with stainless steel self-expanding stents
      - Catheter: Long and narrow tube that is flexible
  - The graft expands and seals off aneurysms, preventing blood flow into it
    - Graft is permanent
- Benefits
  - · Less invasive than open surgery, which was the old method
  - Shorter recovery period
  - Less discomfort
  - Smaller incisions
  - Low risk
- Risks
  - Blockage of blood flow through graft
  - Infection
  - Leaking of blood around graft
  - Movement of graft away from position
  - Graft breaking

Conclusions/action items: I now understand how the procedures take place as well as the benefits and risks of the procedures.



VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:48 PM CST

#### **Title: Aneurysm Information**

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To understand the problem that our device will be used to help fix

Content:

What is an Aneurysm? | American Heart Association

Aneurysm: artery wall weakens, causing it to widen or balloon

- · Aneurysm types
  - Can occur in any artery
  - Most common in aorta, brain (cerebral), popliteal artery (behind knee), mesenteric artery (blood to intestine) and splenic artery (spleen)
- Symptoms
  - Headache
  - Abdomen or back pain
  - Pulsating abdominal mass
  - Confusion
  - Dizziness
  - Fatigue
  - · Blue coloration of lower extremities
- Causes
  - Family
  - Born with
  - Disease or injury
- Treatment
  - Surgery
- Lowering risk
  - Lowering high blood pressure
  - Eating healthy
  - Exercise
  - Not smoking or using tobacco

Conclusions/action items: Since endovascular procedures typically treat aneurysms, it is important that I understand this condition, so I know how our device relates to it.



#### VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:53 PM CST

Title: Math and chemistry

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals:

Content:

The current standing of this project does not require math, statistics or chemistry research.

Conclusions/action items: Alter this entry as project progresses

Vascular Procedures for Executive Summary-4/21/22

VICTORIA HEILIGENTHAL - Apr 21, 2022, 1:01 PM CDT

Title: Vascular Procedures for Executive Summary-

Date: 4/21/22

Content by: Victoria

Present: N/A

Goals: To understand how many vascular procedures are carried out each year

# Content:

Predicted shortage of Vascular Surgeons in the United States: Population and workload analysis - ScienceDirect (wisc.edu)

- Predicted that 1,020,067 surgeries would be done in 2020
  - · Correct estimation based on other research done by other team members
- Demand for vascular surgeons is increasing

By creating devices to make endovascular surgeries easier, it could allow surgeons from other departments to use them without much additional training.

# Cardiac (Heart) Catheterization Procedures | UPMC

- 23,000 vascular surgeries carried out in a year at this center alone
- · Shows the demand for vascular surgeries
- Making advancements would help with surgery costs

Conclusions/action items: This information can be used in our executive summary to support our point that the endovascular department of surgeries is increasing and that demands are high for better equpiment.



Guidewire storage devices-2/8/22

VICTORIA HEILIGENTHAL - Feb 08, 2022, 12:45 PM CST

Title: Guidewire storage devices

Date: 2/8/22

Content by: Victoria

Present: N/A

Goals: To show competing guidewire storage devices

#### Content:

US5738213A - Guidewire holder with easy guidewire access - Google Patents

- Stores and retrieves coil guidewires
- US5738213A





EP1145730A1 - Medical guidewire storage method and apparatus - Google Patents

- · Flexible pipe that can be turned or coiled to store guidewires
- One end is open to allow for guidewires to be inserted and take out
- EP1145730A1

•



Victoria Heiligenthal/Research Notes/Competing Designs/Guidewire storage devices-2/8/22

- Teirstein Edge<sup>™</sup> Device Organizer
  - Has 6 slits to organize guidewires and catheters
  - Easy identification of guidewires and minimizes loss of guidewires



- Angio Assist<sup>™</sup> Docking Station
  - Holder for single-operator procedures
  - Has catheter loading area and guidewire holding area



Conclusions/action items: By researching these devices already on the market, the team can see what has worked well as well as to gain inspiration from when designing the requested device for the client.



Title: CathClip Competing Design

Date: 2/17/22

Content by: Victoria

Present: N/A

Goals: To document the primary leading competitor on the market

Content:

CathClip - Device Management Tool to Improve Profitability and Safety/Outcomes - Dropped and damaged devices? CathClip can help.







- Functions
  - Simply clips around guidewire loop
  - Dip into saline before use
  - Unclip when ready to use guidewires again
  - · Can be reused during procedures, but should be discarded afterwards
  - Fits into standard bowls
- Structure
  - Foam grip pads that are durable and soft to hold any wire without damage
  - Have absorptive gripping pads that remain moist after dipping in the saline solution
  - 2" x 2.25" x 1.25" (palm of hand)
  - Sterile, biocompatible, latex-free
- Benefits
  - Can hold stiffest and most fragile wires
  - Saves a lot of time compared to standard wire techniques like clipping with kelly forceps, wrapping the wire or returning it to the packaging
  - Avoids damage to wires
  - Multiple wires can be held in one bowl
  - Reduces procedure costs

- Decreases procedure time
- Easier use for doctors
- · Reduces material costs from damaging wires
- Reduces risk of infection
- Instructions for use
  - Remove CathClip from sterile packaging.
  - Wet CathClip's gripping pads with saline solution; CathClip is now ready to hold a guidewire, catheter, balloon, or similar flexible elongated device. One CathClip should hold only one flexible elongated device at a time.
  - Discard CathClip at the conclusion of the procedure.
- Testing to show saves time
  - PDF attached
  - Team could use a similar testing method to show quantitative results
  - Tested different wires and compared other techniques to those of the CathClip to show that CathClip worked faster
- Saves Material costs
  - PDF attached
  - · Shows how money is saved from not wasting or damaging guidewires
- Physician approval
  - PDF attached
  - Shows that physician approve of the product and say the device is efficient
- Cost
  - Cost not posted

Conclusions/action items: By looking into the CathClip, the team can see how the device was designed, what has worked well, how the device was tested quantitatively and qualitatively, and what improvements could be made. Since this device is the team's top competitor currently on the market, it is important to understand the product so the one developed by the team can be even more efficient.

VICTORIA HEILIGENTHAL - Feb 17, 2022, 7:41 PM CST





White Paper – Physician Survey Results Demonstrating User Satisfaction of In-Procedure Use of CathClip

September 2017 Cath Lab Solutions LLC 570 El Camino Real #350-333 Redexoz Oty, CA, 94063 Pitona: (650) 434-3807 Email: (650) 434-3807 Email: (650) 434-3807 Email: (650) 434-3807

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white\_paper\_-\_physician\_survey\_results\_1.pdf (631 kB)

102 of 187





White Paper – Cath Lab Materials Usage at a Major Academic Hospital as Cost Effectiveness Analysis Illustrating CathClip Benefits of Cost Savings (Materials and Time), Improved Clinical Outcomes, & Improved Safety

September 2017 Cath Lab Solutions LLC 5/30 El Camino Roal #139-123 Reducacel Gty, CA, 940 El Phone: [850] #34-3807 Fao:: [850] #34-3807 Ensit: <u>ander Gathage com</u> WebSite: <u>answe cathelie com</u>

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VICTORIA HEILIGENTHAL - Feb 17, 2022, 7:41 PM CST



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white\_paper\_-\_timed\_simulations\_1.pdf (893 kB)



# Title: Materials Alternatives

Date: 2/17/22

Content by: Victoria

Present: N/A

Goals: Both our client and advisor recommended we look into other materials we could use for the stand other than PLA

# Content:

The team originally was planning on using PLA to print the stand, but the client and advisor suggested we look into other options. The first prototype might still be printed with PLA in the case that changes to the design must first be made.

Ultimaker:

- Ultimaker Tough PLA
  - Ultimaker Tough PLA material: Create durable prototypes and tooling
  - Similar strength and higher stiffness than ABS
  - Greater machinability than PLA
  - Creates tough plastic parts, but allows for complex geometries
  - Flexural strength -78 MPA
  - Impact strength (Izod tested to 9 kJ/m<sup>2</sup>)
  - Hardness (79 Shore D)
  - Melting temperature (151 °C)
  - This material could be a good consideration for the team since it is similar to the original PLA, but it is stronger and more durable while allowing for complex printing patterns. This would allow for the stand to be sturdy and to have each component printed properly.
- Ultimaker PC
  - Ultimaker PC material: Strong, tough, and heat-resistant material
  - Strong, tough and maintains shape in high temps
  - Tensile strength (59.7 MPa at break)
  - Impact strength (Charpy tested to 3.41 J/m)
  - Melting temperature (Mass flow rate at 300 °C: 23 26 g/10 min)
  - Glass transition at 112 113 °C
  - This material is another good option, but it might be too strong and stiff for what the team needs.
     The team also does not need a material that will withstand such high temperatures since it will only be in ORs.
- Ultimaker ABS
  - Ultimaker ABS material: 3D print durable and tough prototypes
  - · Good adhesion- might be good when adding weights to bottom of design to prevent tipping
  - Flexural strength (70.5 MPa)
  - Impact strength (Izod tested to 10.5 kJ/m<sup>2</sup>)
  - Hardness (76 Shore D)
  - Melting temperature (from 225 °C)
  - This could be another very good option. It is durable and strong and is similar to PLA. This is also adhesive, which would be good if weights are adding to the design.

# Formlabs:

- Biomed Clear Resin
  - 3D Printing Materials For Healthcare (formlabs.com)
  - Good for medical device and surgical planning tools
  - Good for R&D
  - Biocompatible, short-term skin contact
  - compatible with disinfecting and sterilizing
  - Could be good since the guidewires must also be sterile in the OR
- Rigid Resin
  - Resin Family: Rigid (formlabs.com)
  - Very stiff
  - Very resistant to heat and chemicals
  - Withstand load without bending
  - Another good option for printing
- Tough 1500
  - 3D Printing Materials For Healthcare (formlabs.com)
  - Similar strength and stiffness to polypropylene
  - Good for devices
  - Very resilient and is certified for skin contact
  - Stiff and pliable
  - Could be good since the guidewires must also be sterile in the OR and the stand might need to be a little pliable and flexible

Conclusions/action items: It is important that the team is aware of the material options for 3D printing at the Makerspace that we can consider for the final design.



#### VICTORIA HEILIGENTHAL - Feb 17, 2022, 11:27 AM CST

### Title: Team Design Ideas for Stand

Date: 2/17/22

Content by: Victoria

Present: N/A

Goals: To generate design ideas for the stand to use in the team's design matrix

### Content:

UHold Design- Design by Tatum



- This design has similar dimensions to the standard stand created by our client, Dr. Y. This design differs by including a back wall to hold the wheels in the stand, but still allows for easy access as well as being easy to learn how to use. This design seems to be very durable since it is sturdy, and it will be compatible with storing in different ORs and with the use of wheels that contain varying guidewire types, however the back wall could introduce some limitations of wheel size.
- DYStand-Designed by client, Dr. Y



- This stand was design by our client and is serving as the "standard" design that the team is aiming to develop an alternative stand design from. This stand is very similar to the UHold design, just without a back wall and it also contains slits for the middle projection. This slit helps with ease of insertion and removal of the wheels. This design seems durable, but not as durable as the UHold design since it is thinner and doesn't have the back wall component. It will be compatible with storing in different ORs and with the use of wheels that contain varying guidewire types.
- Door Stand- Designed by Alex



This design includes a door design that allows to remove the guidewire wheels. It would be more difficult to learn how to use this design, it might not be as compatible for varying wheels and ORs, and it overall would be more difficult to design.

Conclusions/action items: The different design generated by the team allow the team to assess what the best device is to be the focus of the project.



SolidWorks Files for UHold and wheel - 2/28/22

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:49 PM CST

Title: SolidWorks Files for UHold and wheel

Date: 2/28/22

Content by: Victoria

Present: N/A

Goals: To include the SolidWorks Files for UHold and wheel devices

Content:

Files attached below

Conclusions/action items: The team can continue to progress through the project.

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:49 PM CST



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# DYSpool.stl (900 kB)

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:49 PM CST



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DYWheel.stl (736 kB)

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ShortSpout.STL (359 kB)

VICTORIA HEILIGENTHAL - Feb 28, 2022, 8:49 PM CST



**Download** 

UHold.STL (26 kB)



Alternative 3D printing options-3/24/22

# Title: Alternative 3D printing options

Date: 3/24/22

Content by: Victoria

Present: N/A

Goals: To find alternative locations and material options for 3D printing

# Content:

After the team conducted loading and unloading testing of the wheel designs, it was clear that the PLA material used at the MakerSpace was too brittle and was easily breakable, especially compared to the client's design. Due to this, the team must find alternative material options or locations to 3D print the wheel design. Alternative materials can be found in my section of "Materials Alternatives" that show different materials from different types of 3D printers at the MakerSpace. Below are some other locations that the team could 3D print from instead for a sturdier material.

- UPS
  - 3D Printing | 3D Print Services | The UPS Store
  - Regent St location
  - Materials used and prices cannot be found on website
- Stratasys printing
  - Local 3D Printing Services New (stratasysdirect.com)
  - Located in Madison
  - Materials used and prices cannot be found on website
- Others found on MakerSpace website
  - All external
    - Midwest Prototyping
    - Engman-Taylor
    - Ponoko
    - Shapeways
    - Xcentric
    - Hubs

Conclusions/action items: If an alternative location needs to be found for 3D printing, these could be options.



**Title: Executive Summary Video** 

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To show the teams Executive Summary Video for the final presentation

Content:

Since I was not going to be able to make it to the final presentations, I recorded the executive summary portion for the team to play at the presentation.

Conclusions/action items: The team can present at final presentations.

VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:39 PM CDT



Download

Executive\_summary.mp4 (7.86 MB)


VICTORIA HEILIGENTHAL - Apr 29, 2022, 8:26 PM CDT

Title: All team designs

Date: 4/29/22

Content by: Victoria

Present: N/A

Goals: To show the teams designs from the semester

Content:

Tatum's folder shows the designs that the team tested or data analysis.

Conclusions/action items: The team can analyze data from testing



#### Title: Testing Alternatives

Date: 2/17/22

Content by: Victoria

Present: N/A

Goals: Our advisor recommended we look into other forms of quantitative testing other than the ones the team has already conducted previously

#### Content:

Last semester, the team conducted testing where they timed how long it took to load and unload the guidewires into the wheel as well as an entanglement test where the device was walked around to see if entanglement occurred. Results from testing last semester can be found in the files in the "Last Semester" folder. Since this semester will mainly surround around testing the client's wheel prototype, our advisor suggested we come up with other quantitative ways of testing. We will also need to find another doctor, resident or student to test the device to replicate the use in the OR and since if the team members tested it, bias could be included.

Ideas:

- · Continue timing-important for design matrix components
- · Compare timing from different guidewire types
- Conduct timing across multiple people
- · Count number of times entanglement occurred during testing?

Conclusions/action items: The team can continue to investigate and brainstorm different testing ideas as that time approaches



Preliminary Unloading Graphs-4/5/22

Title: Preliminary Unloading Graphs

Date: 4/5/22

Content by: Victoria

Present: N/A

Goals: To show the results from preliminary testing in a visual form

#### Content:

Attached to this entry are graphs generated for the unloading portion of preliminary testing. The first plot is a bar graph that shows the number of times a rating number was given for each design and for each guidewire type. The second plot is a box plot that show the time of unloading for each design and for each guidewire type.

Conclusions/action items: The team can continue to analyze this data and use it for future testing.

VICTORIA HEILIGENTHAL - Apr 05, 2022, 9:36 PM CDT



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PreUnload\_box.pdf (74.8 kB)

112 of 187



## Download

PreUnload\_bar.pdf (102 kB)



#### **Title: Final Unloading Graphs**

Date: 4/28/22

Content by: Victoria

Present: N/A

Goals: To show the results from final testing in a visual form

#### Content:

Attached to this entry are graphs generated for the unloading portion of final testing. The first plot is a bar graph that shows the number of times a rating number was given for each design and for each guidewire type. The second plot is a box plot that show the time of unloading for each design and for each guidewire type.

Conclusions/action items: The team can continue to analyze this data for final presentations

VICTORIA HEILIGENTHAL - Apr 28, 2022, 8:37 PM CDT



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## POSTUnload\_Bar.pdf (81 kB)

114 of 187



## Download

POSTUnload\_Box.pdf (54.2 kB)



**Title: ANOVA Results** 

Date: 4/29/22

Content by: Victoria

Present: N/A

Goals: To show the results from ANOVA tests run on the final unloading and loading data.

#### Content:

Attached to this entry are files that show the statistics from an ANOVA test run for the unloading and loading data for each of the designs. One of the most important statistical pieces of data of the p-value. These results show that the difference between the designs were not significant.

Conclusions/action items: The team can continue to analyze this data for final presentations

VICTORIA HEILIGENTHAL - Apr 29, 2022, 8:24 PM CDT

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VICTORIA HEILIGENTHAL - Mar 19, 2022, 8:00 PM CDT

Title: WARF Lecture

Date: 3/19/22

Content by: Victoria Heiligenthal

Present: N/A

Goals: To take notes on the WARF lecture and understand how it relates to our team's project

## Content:

- Beginning
  - Patenting and licensing for UW-Madison
  - Patenting innovations on campus for industry
  - Non-profit and separate from university
- Who they Are
  - Provide financial support, managing assets and move innovations into the marketplace
- Cycle of innovation
  - UW research and discovery
  - IP protection (patenting)
    - In the US
  - Licensing's and startups
  - Funding to support research and discovery
    - Grant to university
    - Royalties to inventors
- Protecting innovation
  - Patents
    - machines and devices, compounds, processes and methods, improvements
  - Trademarks
    - Words and phrases, colors, pictures, sound
  - Copyrights
    - Literary works, webpages, software programs
  - Trade secrets are not available for university because mostly presented at the school
- Prior art
  - "references" created before a specific data
    - By inventor: more than a year before filling date of patent application
    - By another: before filling date of patent application
  - Have a grace period
    - Other countries do not have grace period
- Public disclosure and prior art
  - Examples: journal publication, talk or poster, dissertation, description on internet site
  - Sharing innovation to people
- Requirements of patentability
  - eligible, useful, enabled, described, novel, non-obvious
  - Examine and assess innovation
  - · Based on requirements and prior art to see if done before or not
  - Time intensive
- WARF's IP process
  - · invent and disclose to WARF
  - Disclosure committee meets monthly to review new disclosures

- Patent application drafting, filing and prosecution
- Technology marketing
- Licensing
- Licensing considerations for new disclosures
  - Chance of licensing
  - Timeline for licensing
  - Licensing strategy
  - Plan for next year
  - revenue projections
- Licensing innovation
  - WARF provides exclusive or non-exclusive rights to make, use sell or import
  - Licensee provides development, fees, obligations
  - Timeline varies for licensing
- WARF's accelerator program
  - milestone-based validation funding to speed promising techs to a commercial lease
  - Accelerate prospects for WARF IP
  - Different sectors
  - Results in licenses and money
- Finding a licensee
  - Internal (inventor contacts, meetings, sponsored research) or external (publications, targeting outreach)
- Start-up resources
  - ∘ D2P
    - Campus-wide resource for entrepreneurship
    - Innovation funding
  - Innovation roadmap series
- WARF has accepted BME projects

I think our design definitely has intellectual property. Although there are devices on the market that meet the same goal as ours, our device is unique and is more efficient than other devices currently on the market.

Conclusions/action items: If our device is successful, I believe we could file for a patent.

3/1: Final Product Material

TATUM RUBALD - Mar 01, 2022, 2:43 PM CST

Title: Final Product Material

Date: 3/1/2022

Content by: Tatum Rubald

Goals:

Research a material for our final product that can be autoclaved.

## Content:

Our product must be able to withstand autoclaving environments. All surfaces being sterilized must be able to withstand exposure to pure saturated water vapor at 273.2 degrees F.

- Plastics [1]
  - TECAPEEK MT shows no loss of mechanical properties even after more than 1,500 sterilization
  - TECASON P MT shows no loss of mechanical properties after 800 sterilizations.
  - TECAFORM AH MT shows no loss of mechanical properties after 800 sterilizations, but has discoloration after 200 cycles.
  - TECAPRO MT shows no loss of mechanical properties after 800 sterilizations, but has discoloration after 200 cycles (doesn't apply to the black color)
- Metals
  - stainless steel
    - AISI 316L "surgical steel"- very tough and resistant to corrosion
    - Can withstand temperatures higher than 400 degrees C
  - titanium
  - tantalum
  - platinum
  - palladium

[1] https://www.ensingerplastics.com/en-us/shapes/plastic-material-selection/sterilisable-autoclavable

[2] https://matmatch.com/blog/metals-commonly-used-surgical-instruments/

#### Conclusions/action items:

Both metal and plastic can be a final material to suggest to the client.



TATUM RUBALD - Mar 01, 2022, 2:45 PM CST

Title: Operating Room Efficiency

Date: 3/1/22

Content by: Tatum rubald

Goals: To find out how efficient operating rooms are because our device is targeted at making breast de-epp more efficient.

#### Content:

Each lost minute in a hospital operating room costs an average of \$60 [1]. Operating rooms are expensive to run, and the main goal of almost every hospital is efficiency [2]. All of this additional work does not simply throw away money, but also diverts residents, surgeons, physicians, and nurses from performing other necessary tasks and taking care of patients.

## Conclusions/action items:

Our device will save hospitals money and time, further ensuring efficiency of a hospital.

[1] Strate, C., 2020. *The Cost Of A Lost Minute In The OR*. [online] Accessefm.com. Available at: <a href="https://www.accessefm.com/blog/the-cost-of-a-lost-minute-in-the-or">https://www.accessefm.com/blog/the-cost-of-a-lost-minute-in-the-or</a> [Accessed 1 March 2022].

[2] James G. Wright, A., 2020. *Improving On-Time Surgical Starts In An Operating Room*. [online] PubMed Central (PMC). Available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878988/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878988/</a> [Accessed 1 March 2022].



TATUM RUBALD - Feb 17, 2022, 2:58 PM CST

Title: EP 1 145 730 A1

Date: 2/17

Content by: Tatum Rubald

Goals:

I will look into the EU patent on a design for guide wire organization.

## Content:



- · The device consists of one tube to carry multiple guidewires
  - the tube is completely flexible
  - the tube can be positioned many ways
    - above is just the coiled configuration
- Part 20 is a divider that is attached to the end of the tube
  - this is the only division of guidewires as many are inserted into the single flexible tube
    - I believe this could result in tangling of the guidewires within the tube
- · the flexible tube can be oriented around the patient
- · When many guidewires are used in a procedure, they are often wound and all placed in one bowl of saline
- One open and and one closed end
  - open end elevated
    - allows fluid to be retained within the tube

#### Conclusions/action items:

After looking at this patent, I understand why it never came to market. they guidewires are still wound together. However, it did bring to my attention that we have to think about the saline solution that the guidwires sit in. We may have to slightly modify the storage device to allow it to be placed in a tub of saline

122 of 187



Competing\_Device-\_Flexible\_tube.pdf (345 kB)



TATUM RUBALD - Apr 29, 2022, 6:08 PM CDT

Title: Cath Clip

Date: 4/29

Content by: Tatum Rubald

Goals:

Look into the Cath Clip and see how they presented data.

## Content:

- Inefficiencies include extra costs from replacing materials due to damage and/or contamination: over \$48/case in all cases and over \$217/case in complex cases only, plus wasted procedure time.

(not sure where they got this data from, no source)

-traditional method:



Unorganized OR:

Tatum Rubald/Research Notes/Competing Designs/4/29: Cath Clip



## Conclusions/action items:

We will use this fact for our presentation.



# 2/17: Converting Files from Fusion360 to Solidworks

TATUM RUBALD - Feb 17, 2022, 6:16 PM CST

Title: Converting Files from Fusion360 to Solidworks

Date: 2/17

Content by: Tatum Rubald

Goals:

I will research a method to make Dr. Y's fusion360 file editable in Solidworks.

## Content:

- Must export your Fusion 360 file in STEP format. In the second phase, you can turn to ONSHAPE and it will be your Solidworks read-only conversion feature
- STEP is a neutral format that can be used on Solidworks
- Open your part or asembly in Fusion 360

Under File -> Export

Select " Name" for the part

Select "STEM (\*stp,\*step)" under "Type:" option.

Select "Location:" where you want to save the file

https://www.tutocad.com/fusion-360/how-to-import-fusion-360-to-solidworks/#Can\_you\_convert\_Fusion\_360\_files\_to\_Solidworks

https://forums.autodesk.com/t5/fusion-360-design-validate/export-a-model-from-fusion-360-to-solidworks-2017/td-p/7801550

## Conclusions/action items:

I will send this info to Dr. Y.



TATUM RUBALD - Feb 17, 2022, 2:32 PM CST

## **Title: Questions for Client meeting**

Date: 2/17

Content by: Tatum Rubald

Goals:

Prepare for client meeting.

## Content:

- We can not convert the STL file to a working Solidworks --> change diameter dimensions for us?
  CURRENT 188mm
  - Need: 192, 184, 180, 176
- Are you wanting to use both the inner and outer rim?
  - or test to see which one is better?
- Do you want us to model an alternative wheel that allows for easy removal once wire is taken out?

#### Conclusions/action items:

I will address these questions with Dr. Y today.



TATUM RUBALD - Feb 28, 2022, 10:38 AM CST

Title: 3D printing outsource

Date: 2/28

Content by: Tatum Rubald

Goals:

We need to find a place to 3D print out design that allows for more precise measurements.

## Content:

- Protolabs offers a wide range of materials to print with
- Our client prints using Nylon
- PA 12 white is similar to nylon
  - prints to to 0.3 mm precision
  - known for strength and stiffness
  - Printing would cost 167\$

https://www.protolabs.com/media/jkubinyf/sls-pa-12-white-120821.pdf

#### Conclusions/action items:

We will consider this in the final stages of prototyping

3/31: Show and Tell Notes

TATUM RUBALD - Mar 31, 2022, 9:46 AM CDT

## **Title: Show and Tell Notes**

Date: 3/31

Content by: Tatum Rubald

Goals:

Find a new material for our wheel print.

## Content:

- · Print top and bottom half separately, and then glue together
- Form labs
  - Biomedical clear
- Print supports with PVA on ultimaker

## Conclusions/action items:

The formlabs printer is too small. Thus we will print the wheel in PLA with supports in PVA.



TATUM RUBALD - Apr 29, 2022, 6:04 PM CDT

#### **Title: Market Analysis**

Date: 4/29

Content by: Tatum Rubald

Goals:

Conduct a market analysis for our device

#### Content:

- The global market for endovascular procedures is expected to gain market growth in 2021-2028.
- The market is expected to grow at a CAGR of 6.25% during the time frame mentioned.
- As chronic diseases increase worldwide, the need for minimally invasive procedures becomes more apparent.
- The decreased recovery time that follows these types of procedures in comparison to open surgery helps drive this market.
- Emerging technological advancements in healthcare will create more opportunities to implement endovascular procedures.

#### https://cttc.co/technologies/guide-wire-torque-device-interventional-medical-procedures

- Procedures that use guidewires: angioplasty, stenting, pacemaker insertion, electrophysiology studies, atherectomy, thrombolysis, and endourology and therapeutic endoscopy of the gastrointestinal system.

#### Conclusions/action items:

We will use this for our executive summary



TATUM RUBALD - Feb 09, 2022, 11:09 PM CST

#### Title: "UHold" Stand

Date: 2/09

Content by: Tatum Rubald

## Goals:

Successfully make an alternative stand design with correct dimensions to fit Dr. Y's current wheel dimensions.

## Content:

-Image has all dimensions listed

-This holder allows for a wheel with a U-shaped hole to be held while still being stabilized due to the back wall. (see UWheel for rough sketch of alternative wheel design)

## -STL file of UHold attached



#### Conclusions/action items:

I will present this holder to the team and we will include it in the design matrix.

TATUM RUBALD - Feb 09, 2022, 11:09 PM CST





**Download** 

UHold.STL (0 B)



#### TATUM RUBALD - Feb 09, 2022, 5:51 PM CST

#### Title: "UWheel" Alternative guidewire wheel design

Date: 2/09

Content by: Tatum Rubald

Goals:

I will design an alternative wheel while considering Dr. Y's current design.

#### Content:

(See image attached)

-Flat back surface

-No inner closed off cut out allows for wheels to be take off the stand without having to remove all of the wheels above.

-Can pull wheel right out of stand (See "UStand" design)

DIMENTIONS:

Diameter of semicircle inner cut out: 45mm

Outer diameter: 188mm

Thickness of plate while laying flat on back surface: 26mm

#### Conclusions/action items:

I will contact Dr. Y to see if he would consider using an alternative wheel design, or if he is set on his current design (with us just changing the dimensions)

TATUM RUBALD - Feb 09, 2022, 5:46 PM CST



**Download** 

Screen\_Shot\_2022-02-09\_at\_5.46.50\_PM.png (120 kB)



TATUM RUBALD - Feb 09, 2022, 11:06 PM CST

Title: Dr. Y Design Ideas

Date: 2/9

Content by: Tatum Rubald

Goals:

I will download the STL files Dr. Y provided. These files and designs will be used to recreate on our own, with our own ideas and modifications.

Content:

STL files attached.

## Conclusions/action items:

We will use these files this semester to guide our design process.

TATUM RUBALD - Feb 09, 2022, 11:06 PM CST



**Download** 

stand\_flat\_wire\_holder\_final\_v8.stl (107 kB)

TATUM RUBALD - Feb 09, 2022, 11:06 PM CST



Download

## WIRE\_HOLDER\_OUTER\_RIM.stl (736 kB)

TATUM RUBALD - Feb 09, 2022, 11:06 PM CST



**Download** 

WIRE\_HOLDER\_INNER\_SPOOL.stl (900 kB)



# 2/18: Design Modification Brainstorm

TATUM RUBALD - Feb 22, 2022, 10:23 AM CST

## **Title: Design Modification Brainstorm**

Date: Feb 18

Content by: Tatum Rubald

Goals:

Brainstorm modifications to the wheel design

## Content:

- decrease outer diameter from 19 cm to 16 cm
- make radius of outer rim smaller: currently 2cm radius, make 1.5 cm
- decrease inner spout height from 2.5 cm to 2 cm
- · modify spout to have small opening to pull of stand

## Conclusions/action items:

I will make new STL files with these ideas

Tatum Rubald/Design Ideas/2/22: ShortSpout



TATUM RUBALD - Feb 22, 2022, 10:37 AM CST

## Title: ShortSpout

Date: 2/22

Content by: Tatum Rubald

Goals:

Make short spout wheel modification. Lower the height of the inner chimney of the wheel.

Content:

See STL file

## Conclusions/action items:

We will print this design and test

TATUM RUBALD - Feb 22, 2022, 10:38 AM CST



<u>Download</u>

ShortSpout.STL (359 kB)

TATUM RUBALD - Mar 31, 2022, 9:44 AM CDT

#### **Title: Cut Chimney**

Date: 3/31

Content by: Tatum Rubald

Goals:

Make a design that can be removed from the stand (once guidwirie is removed) without having to take all the above wheels off.

## Content:

- STL file attached

- A cut out in the chimney and base allows for the wheel to be pulled off the stand at any point once the guidewire is taken out.

- The other dimensions are unchanged

## Conclusions/action items:

Print wheel

TATUM RUBALD - Mar 31, 2022, 9:44 AM CDT



Download

CutChimney.STL (471 kB)



TATUM RUBALD - Mar 31, 2022, 9:48 AM CDT

Title: CurveSpout

Date: 3/31

Content by: Tatum Rubald

Goals:

Make design to better support wire removal.

Content:

-STL file attached

-Chimney has curved portion to hold the wire down when being pulled out.

#### Conclusions/action items:

Print using PLA and PVA

TATUM RUBALD - Mar 31, 2022, 9:48 AM CDT



**Download** 

CurveSpout.STL (672 kB)



TATUM RUBALD - Mar 11, 2022, 1:50 PM CST

## Title: WARF Lecture

Date: 3/11

Content by: Tatum Rubald

Goals:

Watch WARF lecture and determine what applies to our device.

## Content:

- 350-400 invention disclosures per year
- 2000 issued US patents
  - WARF focuses on US patents
- 3 classes of intellectual property:
  - patents
    - machines and devices
  - copyrights
    - literary works
  - trademarks
    - words and phrases
- prior art: "references" created before a specific date
  - US gives 12 months before a patent must be filed
- examples of public disclosure and prior art
  - journal publication
  - talk or poster at conference
  - non-confidential department seminar
  - open thesis defense
  - cataloged dissertation
  - some funded grant abstracts
  - Description
- Requirements for patentability
  - eligible
  - useful
  - enables
  - describes
  - novel
  - non-obvious
- examination = assessment of invention
- based on statutory requirements and application of prior art
- US patent costs 30 thousand dollars
- WARFs IP process
  - disclose invention to WARF
  - disclosure committee meets monthly to review new disclosures
  - patent application drafting, filing, and prosecution
  - technology marketing
  - licensing
- WARFs accelerator program
- · factors to consider in starting a company
  - technology
  - market
  - management capital requirements
- start up resources
  - Discovery to product, a campus wide resource for entrepreneurship

## Conclusions/action items:

Our device would require a patent. The device meets the requirements with patentability. Our client is already working on a patent, so we will not be working with WARF.

Tatum Rubald/Training Documentation/3/11: WARF Lecture

# 2021/09/17 Cardiac Catheterization Biology

Alex PUDZISZ - Oct 19, 2021, 3:14 PM CDT

## Title: Cardiac Catheterization Biology

Date: September 17th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To understand more about our project. We will be making the storage device for the wire used in this operation.

Search Term: Google Search: "Cardiac" AND "Catheterization"

**Citation:** "Cardiac catheterization," *Johns Hopkins Medicine*. [Online]. Available: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cardiac-catheterization. [Accessed: 17-Sep-2021].

Link: https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/cardiac-catheterization

#### Content:

What happens during operation:

1. A wire is inserted into the blood vessel. The wire is then pathed up to the heart.

2. Once there it can do pressure measurements, take blood samples, or inject dye

3. While the wire is there other operations are possible such as: angioplasty, stent placement, fractional flow reverse, an intravascular ultrasound, or sample the heart tissue.

Reasons to have one done:

1. Clogged arteries, heart enlargement, congenital heart defects, heart failure, or heart valve disease

2. The symptoms that may lead a doctor towards it: chest pain, short of breath, dizzy, tiredness. (these all seem to suggest poor blood flow)

3. It can also be done after heart procedures and heart complications

Risks of the procedure:

-Bleeding and pain at injection site, infection, blockage or tear in artery, stroke

Picture below is from same source as cited for the contents section

## Coronary angiography



## Conclusions/action items:

Now I know what the wires function is and a common procedure with it. Now I can think more about the access of the wire. It does not seem like they will be changed out very often during the procedure, but the right one must be used. Organization may be more important. For now do more research into competing designs



Alex PUDZISZ - Oct 19, 2021, 3:14 PM CDT

# Title: Cath Clip Competing Design Date: September 21st, 2021 Content by: Alex Pudzisz Present: Alex Pudzisz

Goals: To learn more about Cath Clip and determine what is good or bad about it

Search Term: Google Search "Cath" AND "Clip"

Citation: "Dropped and damaged devices? Cathclip can help.," CathClip. [Online]. Available: https://www.cathclip.com/. [Accessed: 21-Sep-2021].

Link: https://www.cathclip.com/

## Content:



The device is very simple. It is a clip that guarantees that the wire does not move around. The device does not have a cost listed, however it comes in packs of 20. The pros of this device are that the device keeps the surgery area organized, and makes sure that there are not random wires on the floor. It is also small enough to fit into buckets, along with the wire, like shown above. The final pro is that it is incredibly simple to use and already used in over 20 hospitals in the US. The cons are that this is not what our client is looking for. Even in the bucket, it is still messy and wires can become tangled or hard to distinguish. The device the client wishes for must be stackable. The device also does not guarantee the size of the ring, which I am not sure matters. The final con is that it does not look to be sanitizable by easy but harsh means. That could be chemicals or extreme conditions.

## Conclusions/action items:

This design is not what we can base our final project on. However, possibly adding a clip inside of the design can be put into consideration. I will keep looking for more competing designs.

2021/09/21 Japanese Holder Competing Design

Alex PUDZISZ - Oct 19, 2021, 3:25 PM CDT

#### Title: Japanese Holder Competing Design

Date: September 21st 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To learn more about this design and see the pros and cons in comparison to what we need

Search Term: Google Patents "Catheter" AND "Storage" AND "Wire"

Link: https://patents.google.com/patent/JP4280526B2/en?q=catheter+wire+holder&oq=catheter+wire+holder&page=1

#### Patent Number: JP4280526B2

#### Content:



This device is close to the most used storage device out there by Medtronic. I could not find the patent for that, so I found an innovation on their idea. The design is multiple loops that slowly get smaller. The catheter wire gets pushed through by point 8 and will slowly reach the center. The device is an improvement over the Medtronic device. This device coats the inside of the tube and used geometry to lessen the friction. One of the main problems with the Medtronic storage device is the large amount of friction when putting in or taking out the wire. One of the pros of this device, is that the doctor is already used to the original, so the slightly improved version will be very similar. Another pro is that the device does keep the wire organized and the loops of wire will always be the same size. This means that if someone wanted to make a storage device for these holders later it would likely be possible. There are a few cons with this device. This means that although it is easier to put in and take out it is still not easy. Another con is that the device is not symmetrical into and out of the page. This will lead to it being impossible to stack these holders. The final con is that the original method of inserting the wire and then pushing until it gets all the way through it still being used. The idea of our project is to make it faster and easier. This may be slightly easier, but by using the same method it is unlikely to get faster.

Alex Pudzisz/Alex Old Semester Research/Alex Pudzisz/Research Notes/Competing Designs/2021/09/21 Japanese Holder Competing Design 144 of 187 THERE IS A KEY POINT: GEOMETRY AFFECT FRICTION!

#### Conclusions/action items:

Keep in mind that the geometry of the device can have an impact on the friction. Look into the friction of different materials when it becomes relevant. Make my own design.

Alex PUDZISZ - Oct 19, 2021, 3:17 PM CDT




Alex Pudzisz/Alex Old Semester Research/Alex Pudzisz/Research Notes/Miscellaneous Research/2021/09/23 Regulations and Standards Research 145 of 187



Alex PUDZISZ - Oct 19, 2021, 9:00 PM CDT

#### **Title: Regulations and Standards Research**

Date: September 23nd, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To find out what FDA standards we would need to make this a marketable project

#### Content:

There is only one way that I know of to find regulations. This is to go through the FDA and to search for similar products or product groupings. This product would likely be considered as a Class II medical device. This is because it does not cause great danger, but it is also part of the medical equipment in the procedural room. There is no direct FDA regulation for this device, so it will be assumed to follow the same rules as a guide wire kit and guidewire torque device [1, 2]. Both of these are Class II and require premarket approval in the form of a 510k. Normally we would be able to find an exact point of reference, but this item is almost always sold as a set. I tried looking into the regulations of things like Cath Clip, however it did not show and they are not fully patent ready yet. There may be a way to prove that it does not require premarket approval, but the team would need further guidance to determine if it is possible [3].

Sources:

[1] "Product classification," accessdata.fda.gov. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm? id=997. [Accessed: 23-Sep-2021].

[2] "Product classification," accessdata.fda.gov. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm? id=953. [Accessed: 23-Sep-2021].

[3] Center for Devices and Radiological Health, "Convenience Kits Interim Regulatory guidance," U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/convenience-kits-interim-regulatory-guidance. [Accessed: 23-Sep-2021].

#### Conclusions/action items:

Mark these regulations down inside of our PDS

146 of 187

# 2021/09/23 Guide Wire Storage Device Size Research

Alex PUDZISZ - Oct 19, 2021, 9:19 PM C

#### Title: Guide Wire Storage Device Size Research

Date: September 23, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To find out how big the outside of our device should be

Search Term: Google Search "Catheter" AND "WIRE" AND "HOLDER"

Link:https://www.dotmed.com/listing/disposables-general/medtronic/008418/ptfe-guide-wire,-160cm-(x)/2993028? utm\_source=base&utm\_medium=search&utm\_campaign=Base&gclid=Cj0KCQjwqKuKBhCxARIsACf4XuHc3\_0iUeVUkqSUC0EzCzyVIBQcEnz7hJgpC\_qcjNE9VgAhG6uSbnMaAgoeEALw\_v

Citation: "New medtronic 008418 PTFE Guide Wire, 160cm (x) disposables - general for sale - dotmed listing #2993028," DOTmed.com. [Online]. Available:

https://www.dotmed.com/listing/disposables-general/medtronic/008418/ptfe-guide-wire,-160cm-(x)/2993028?

utm\_source=base&utm\_medium=search&utm\_campaign=Base&gclid=Cj0KCQjwqKuKBhCxARlsACf4XuHc3\_0iUeVUkqSUC0EzCzyVlBQcEnz7hJgpC\_qcjNE9VgAhG6uSbnMaAgoeEALw\_v [Accessed: 23-Sep-2021].

#### Content:

I found that Medtronic usually has the wire storage device on the catheter wire prepackaged. I wanted to find out how large something that most surgeons have used was. In the citation above is given that the device is 160 cm long. There appears to be 2.5 loops before the device ends. This gives us a 160/2.5 = 64 cm per loop. Divide by pi to find the diameter and the device ends u being about 20 cm wide. Likely it would be a bit shorter due to my rough loop amount estimation. That means that our device should be about 8 inches wide.

Reference photo is attached.

#### Conclusions/action items:

Find an appropriate size for our own device

Alex PUDZISZ - Oct 19, 2021, 9:19 PM CDT



Download

Screen\_Shot\_2021-10-19\_at\_9.19.09\_PM.png (907 kB)



Alex PUDZISZ - Oct 19, 2021, 10:13 PM CDT

Title: Material Research

Date: September 27th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

**Goals:** To find example materials for the project

#### Content:

This project will first be made out of plastics for the proof of concept, and the idea eventually is to make it out of medical grade steel. Below I will look into what the Makerspace has to offer for our plastic prototype. Afterwards, I will look into a couple of medical grade steels and which one would be most appropriate.

#### Link To MakerSpace Website: https://making.engr.wisc.edu/3d-printers/3dprint-cost/

Given the choices I will first eliminate a few. PLA tends to be brittle, so it will likely not be used as it can break more easily. PVA will also likely not be used as it can dissolve in water. This is not a property we want. Breakaway is meant to break, so again this is out. PP is flexible, which is again not a property we need. This means it give no advantages over the options that will be listed below. CPE is not needed as the prototype will not be under high temperature stress. Nylon will also likely not be used as it has less strength than the other options.

This leaves tough PLA and PC. Both are good options and I will talk to the team to see what preferences they have based on their properties and looks.

Next up is medical grade steel research.

Link:https://bergsen.com/medical-surgical-stainless-steel

Citation: "Medical Grade & amp; Surgical Stainless Steel," Bergsen Metal, 12-Jan-2021. [Online]. Available: https://bergsen.com/medical-surgical-stainless-steel. [Accessed: 27-Sep-2021].

This article talks about two types of medical grade steel 304 and 316. The difference in numbered steel is its composite that makes up the alloy. Regardless, it is the properties that matter. It says that 304 should be enough as it can be sterilized, however I believe 316 with its ability to resist harsh chemicals may be better. I will later have to research the cost of both of these steels. 316 does get used in surgical equipment, and if we wish to classify our device as one it may be best to use this.

#### Conclusions/action items:

Talk with the team about kind of material we want to use to print. Eventually talk with team about which steel to use.



Alex PUDZISZ - Oct 19, 2021, 10:47 PM CDT

#### Title: Chemistry In Project

Date: October 7th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Talk about the chemistry in our project

#### Content:

As of yet, we are not coating the prototype in any sort of chemical. The device in its steel form will not cause any chemical reactions, as it will likely be made of the same steel as surgical equipment. There is also no chemical testing or chemicals involved in the production of the prototype on our part. This leaves only one method using chemicals in this project, which is in cleaning or sterilizing the device. I will talk about how hospitals do so below.

#### Link: https://www.mindflowdesign.com/insights/chemical-resistance-of-plastics-in-hospitals/

**Citation:**A. Moulds, "How to choose plastics that will withstand harsh hospital cleaning processes," Mindflow Design, 28-Apr-2021. [Online]. Available: https://www.mindflowdesign.com/insights/chemical-resistance-of-plastics-in-hospitals/. [Accessed: 07-Oct-2021].

The article talks about choosing plastics that will resist the harsh cleaning chemicals of hospitals. I will put a picture of the chemicals used in medical facilities under attachments. The article mentions that all plastics will crack and deform, but chemicals speed it up. Creep is when the plastic is exposed to constant force below its breaking point causing it to permanently deform. Cracks form in plastics around areas of imperfections. Mindflow (the website) does mention that they have a database of plastics vs chemicals (ranging from low to harsh). This may come in useful if we decide to send our prototype through a sterilization. It does mention that certain plastics should hold for years, even under chemical strain such as nylon 12, and pc+pet. I will have to take a look at the chemicals in the table attached below and see if any of them would affect steel. It is unlikely, however worth a check.

#### Conclusions/action items:

Look into the chemistry of coating the device / look for any more chemistry that could be involved.

Alex PUDZISZ - Oct 19, 2021, 10:47 PM CDT

Categories	Chemical	Use	
Sterilants and high-level disinfectants	Formaldehyde (Formalin)	contact with body fluids	
Sterilants and high-level disinfectants	Glutaraldehyde	High level disinfectant for medic equipment	
Sterilants and high-level disinfectants	Ortho-phthalaldehyde (OPA)	-	
Sterilants and high-level disinfectants			
Sterilants and high-level disinfectants	Peracetic acid		
Sterilants and high-level disinfectants	Hydrogen peroxide/peracetic acid combination	-	
Intermediate-level disinfectants	Sodium Hypochlorite (Bleach)	blood	
Intermediate-level disinfectants	lodophors	antiseptic	
Low-level disinfectants	Phenols	surfaces and non-critical medical devices	
Low-level disinfectants	Quaternary ammonium compounds (Quats)	non-critical surfaces	

#### Download

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Alex Pudzisz/Alex Old Semester Research/Alex Pudzisz/Research Notes/Miscellaneous Research/2021/10/13 Math In Project + 2021/12/14 Update 149 of 187



Alex PUDZISZ - Oct 19, 2021, 10:19 PM CDT

**Title: Math in Project** 

Date: October 13th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To discuss what math can be used in our project.

#### Content:

There is little need for math inside of our project. There is no need to calculate for friction when practical tests will suit it far better. This means that testing it by hand will give much better data than guessing by arbitrary numbers. In the same account, there is not a need for integrals or higher level math in our project. The project is purely a proof of concept. The only math required will be for the statistics, the dimensions of the device, and the cost of the device. There is also the possibility of calculating force that our prototype can take, but for the current stage it is unnecessary. Finally, the last thing I can think of for math is to calculate the tension in the wire when it is inside of the guide wire hoop. This is just to ensure that no matter the weight of the wire it will stick. Overall I do not see a reason to involve higher level math in our project as of yet.

#### Conclusions/action items:

Finish lab notebook for notebook check.

Alex PUDZISZ - Dec 14, 2021, 4:47 PM CST

#### Title: Math in Project Update

Date: December 14th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To discuss what math was used in the project

#### Content:

We did not end up using any higher level math. There was no need to use friction, as the wires radial force (when large enough, already overcame the required force to keep the wire in place. The tricky part is that with softer wires we will need to in the future work on figuring out the tension produced. I still believe it to be better done by hand than be equation, as the wire will become more malleable over time (even a single semester).

#### Conclusions/action items:

Finish Final Notebook



Alex PUDZISZ - Oct 19, 2021, 3:50 PM CDT

#### **Title: Abiding by Engineering Ethics**

Date: October 19th 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: List the engineering ethics from the national society of professional engineers and say I am abiding by them

Search Term: Google Search "Engineering" AND "Ethics"

**Citation:** "Code of ethics," *Code of Ethics* | *National Society of Professional Engineers*. [Online]. Available: https://www.nspe.org/resources/ethics/code-ethics. [Accessed: 19-Oct-2021].

Link: https://www.nspe.org/resources/ethics/code-ethics

#### Content:

The list of ethics on the website are as follows:

"I. Fundamental Canons Engineers, in the fulfillment of their professional duties, shall:

1.Hold paramount the safety, health, and welfare of the public.

2.Perform services only in areas of their competence.

3.Issue public statements only in an objective and truthful manner.

4.Act for each employer or client as faithful agents or trustees.

5.Avoid deceptive acts.

6.Conduct themselves honorably, responsibly, ethically, and lawfully so as to enhance the honor, reputation, and usefulness of the profession."

I have not violated any of these ethics in my research or in my actions for this project this semester.

#### Conclusions/action items:

Continue abiding by the ethical guidelines.

Alex Pudzisz/Alex Old Semester Research/Alex Pudzisz/Research Notes/Miscellaneous Research/2021/12/14 My Activity In Deliverables UPDATED 151 of 187

2021/12/14 My Activity In Deliverables UPDATED

Alex PUDZISZ - Dec 14, 2021, 5:51 PM CST

Title: My Activity In Deliverables				
Date: October 19th 2021				
Content by: Alex Pudzisz				
Present: Alex Pudzisz				
Goals: To write down my participation in the deliverable documents				
Content:				
PDS: Standards and Specifications, Quantity, Life in Service, Size, Materials				
Design Matrix: Made clamped wheel design				
Presentation: Design Matrix				
Preliminary Report: Design Matrix and Evaluation Explanation, Testing				
Testing: Came up with Test protocol and helped with Test 1, did Test 2 by myself				
Poster: Progress Portion				
Poster Presentation: Progress and description of device				
Final Report: Testing and updating other sections.				
Conclusions/action items:				

None



Alex PUDZISZ - Dec 14, 2021, 4:55 PM CST

Title: Physics in Project

Date: October 25th, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain physics in our project

#### Content:

There is not a lot of calculated physics in our project. The force that can be excerted on the casing of the prototype is irrelevent as it is a proof of concept. The medical grade steel that it will eventually be replaced with will be strong enough to support its cause (which is to simply be carried in a hospital). Doing any calculations on a stress test for the prototype in a different material are pointless as it will never reach that point of use and it is not a selling point. Doing physics calculations such as radial force on the wire may give us a better idea of a starting point for the size of the wire holder, I believe it is probably better to allow the team to hold the wire and judge the size of the holder that way. That gives a better approximation for what someone at the hospital might be more comfortable with. We can always size it down later to increase radial force. The wire may also change due to being used and have less radial force later as it becomes used to bending.

#### Conclusions/action items:

None

2021/11/10 Impact Research
•

Alex PUDZISZ - Dec 14, 2021, 6:36 PM CST

Title: Impact Research

Date: 11/10/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Do research to understand more about the impact of our project

Content:

Search Term: Google Search "Hospital" AND "COST" AND "PER" AND "SURGERY"

#### Link:https://www.healthsystemtracker.org/chart-collection/how-do-healthcare-prices-and-use-in-the-u-s-compare-to-other-countries/

**Citation:** R. Kamal, and C. C., "How do healthcare prices and use in the U.S. compare to other countries?," Peterson-KFF Health System Tracker, 25-Oct-2018. [Online]. Available: https://www.healthsystemtracker.org/chart-collection/how-do-healthcare-prices-and-use-in-the-u-s-compare-to-other-countries/. [Accessed: 10-Nov-2021].

The main point of this article is that surgeries in the USA cost more than almost anywhere else in the world. There is a lot of money that is spent every day when talking about this. Every minute that patients are in the hospital rack up more charges, and every minute is another minute a hospital could have another patient. In this case the cost of a coronary bypass in the US is over \$60,000. Lowering this cost per patient would be very helpful if we could significantly reduce the time in the OR. Even if this is not possible, the less time someone spents cut open the better. There is less chance for infection or other complications. Below this rich text I will put a picture of USA costs for the aforementioned price vs other countries.

Search Term: Google Search "Hospital" AND "COST" AND "PER" AND "Minute"

Link:https://www.ajmc.com/view/what-are-the-implications-of-the-costs-of-operating-room-time

**Citation:** K. Ely, "What are the implications of the costs of operating room time?," *AJMC*, 30-Jul-2020. [Online]. Available: https://www.ajmc.com/view/what-are-the-implications-of-the-costs-of-operating-room-time. [Accessed: 10-Dec-2021].

The average cost per minute in a hospital is between \$36-7 in an OR. This is over double the minimum wage in WI per hour. That means that any time we reduce is incredibly beneficial for everyone, but moreso for low income households who will struggle even more substantially from the monetary burdens. The cost per minute is absurd, and it does not seem to vary across race or other factors.

#### Conclusions/action items:

Figure out how to maximize our impact / do more research on other impacts

Alex PUDZISZ - Dec 14, 2021, 6:36 PM CST



Screen\_Shot\_2021-12-14\_at\_6.26.16\_PM.png (102 kB)



Alex PUDZISZ - Oct 19, 2021, 9:04 PM CDT

#### **Title: Planned Statistics and Testing**

Date: October 16th 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain one idea for testing and statistics to be taken from it

#### Content:

The idea would be to test using the protocol below. This would give us a baseline value for times and a time value for our product. This would also bring up any additional complications. The statistical test that can be run off of this is likely just a % difference across the averages. This would be the simplest and most obvious way to show a real change. We can also run tests if we have enough data points to ensure all the data points are valid, such as a t test or ANOVA. The hypothesis is that any device we make will have at least a 10% improvement over the original method.

#### Protocol:

- 1. Give prototype and guidewire to tester
- 2. Instruct participant on method of wire insertion into device
- 3. Start timer when participant is ready
- 4. Stop timer as the participant finishes putting wire into device
  - 1. Record time in notebook entry
- 5. Instruct participant to take wire out of the device
- 6. Start timer when participant is ready
- 7. Stop timer as the participant finishes taking wire out of the device
  - 1. Record time in notebook entry
- 8. Observe wire for any tangles or entwinements
  - 1. If obstructions exist record in notebook entry
- 9. Fill in table below as experiment is ran

#### Conclusions/action items:

Present to my advisor and ask if this seems right

2021/12/03 Statistics in Project

Alex PUDZISZ - Dec 14, 2021, 5:05 PM CST

#### Title: Statistics in Project

Date: 12/03/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To Explain Statistics in our project

#### Content:

Our team met with an alternate advisor, as Dr Ludwig was busy. We talked with him about the testing that we did and then we talked about our proposed statistical tests. The original plan was along the lines of doing a T-test and then doing a % improvement. After the call, however, as we changed from two tested groups to 4 it became that we had to do an ANOVA test. Tatum would do this as she was the best with statistics. We would also not do any statistical tests with the movement tests (as they are a yes or no answer and more qualitative). We will make them quanititative as we will mark the number of times it fails. The final plan is to do an ANOVA test and then add the percentage that it was changed by. The percentage change can be another statistic for the project

#### Conclusions/action items:

None



Alex PUDZISZ - Dec 14, 2021, 5:08 PM CST

#### Title: Final Testing Protocol

Date: 12/13/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put my final protocol below

#### Content:

Instructions

Test 1: Loading and Unloading Instructions:

- 1. Give prototype and stiff guidewire to tester
- 2. Instruct participant on method of wire insertion into device
- 3. Start timer when participant is ready
- 4. Stop timer as the participant finishes putting wire into device
  - 1. Record time in notebook entry
- 5. Instruct participant to take wire out of the device
- 6. Start timer when participant is ready
- 7. Stop timer as the participant finishes taking wire out of the device
  - 1. Record time in notebook entry
- 8. Observe wire for any tangles or entwinements
  - 1. If obstructions exist record in notebook entry
- 9. Repeat Steps 1-8 an additional two times for a total of three trials
- 10. Repeat Steps 1-9 for soft guidewire
- 11. Repeat steps 1-10 with original catheter device

### Test 2: Walking Test Instructions:

- 1. Give prototype with guidewire preloaded to tester
- 2. Look at the wire to make sure that there is no wire entanglement
- 3. Instruct them to walk on the same floor for a minimum of five minutes
- 4. Once they have done so, look at the wire to see if there is any new wire entanglement
  - 1. Record the results in notebook entry
- 5. Repeat steps 1-4 for a total of five trials

- $\ensuremath{\textbf{1}}.$  Give prototype with guidewire preloaded to tester
- $\ensuremath{\text{2.Look}}$  at the wire to make sure that there is no wire entanglement
- 3. Instruct them to walk up and down five flights of stairs
- 4. Once they have done so, look at the wire to see if there is any new wire entanglement
  - 1. Record the results in notebook entry
- 5. Repeat steps 1-4 for a total of five trials

# Conclusions/action items:

None



2021/12/03 Experiments / Testing Day

Alex PUDZISZ - Dec 14, 2021, 6:44 PM CST

#### Title: Experiments / Testing Day

Date: 12/03/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down how we tested and put down the raw data

#### Content:

There were two tests that were done. ALL EXPERIMENTS WERE DONE EXACTLY TO PROTOCOL (METHODICALLY). First a loading and unloading test of our device and the original. We were all at college library so it was easy. We paired into two's and then had one person time while the other followed the protocol. We collected all of the data (which I will paste below). We then tested the other type of wire with loading and unloading. The process was fast and smooth. The analysis will be done later. The second test I did by myself. It involved walking around my apartment building, both inside and outside, and the second half was walked up and down 5 flights of stairs. Doing the testing was very relaxing and the data looks perfect.

**Original** Casing

RAW DATA:

Test 1: Loading And Unloading Results Table:

Einal Dovico

Final Device			Original Casing		
Type Of Wire: Test #	Loading Duration	Unloading Duration	Type Of Wire: Test #	Loading Duration	Unloading Duration
Soft Wire: Test 1	27.26	1.21	Soft Wire: Test 1	25.96	8.44
Soft Wire: Test 2	37.4	0.73	Soft Wire: Test 2	22.32	8.41
Soft Wire: Test 3	26.4	1.26	Soft Wire: Test 3	22.73	9.13
Soft Wire: Test 4	23.12	0.8	Soft Wire: Test 4	25.7	9.54
Soft Wire: Test 5	17.29	0.93	Soft Wire: Test 5	23.43	9.53
Soft Wire: Test 6	21.43	0.78	Soft Wire: Test 6	20.68	10.16
Soft Wire: Test 7	25.62	1.11	Soft Wire: Test 7	21.85	9.11
Soft Wire: Test 8	23.63	1.19	Soft Wire: Test 8	22.71	7.53

Alex Pudzisz/Alex Old Seme	ester Research/Alex F	Pudzisz/Research N	otes/Protoco	Is And Procedures/2021/	/12/03 Experiments	/ Testing Day 160 of 1	87
So	oft Wire: Test 9	19.92	1.04	Soft Wire: Test 9	22.96	5.69	
На	rd Wire: Test 1	28.37	0.35	Hard Wire: Test 1	24.45	7.78	
На	rd Wire: Test 2	13.95	1.15	Hard Wire: Test 2	19.7	7.79	
На	rd Wire: Test 3	25.56	1.35	Hard Wire: Test 3	18.49	11.03	
На	rd Wire: Test 4	13.47	0.98	Hard Wire: Test 4	20.01	10.39	
На	rd Wire: Test 5	18.19	1.23	Hard Wire: Test 5	19.45	10.6	
На	rd Wire: Test 6	15.94	1.24	Hard Wire: Test 6	19.23	7.93	
На	rd Wire: Test 7	14.43	1.74	Hard Wire: Test 7	24.1	11.51	
Ha	rd Wire: Test 8	13.51	1.53	Hard Wire: Test 8	21.48	9.52	
На	rd Wire: Test 9	14.83	0.68	Hard Wire: Test 9	21.75	9.21	

# Test 2: Walking and Stairs Test

Walking Test Trial #	Entanglement at Start?	Entanglement At End?	Stairs Test Trial #	Entanglement at Start?	Entanglement At End?
1	No	No	1	No	No
2	No	No	2	No	No
3	No	No	3	No	No
4	No	No	4	No	No
5	No	No	5	No	No

# 2021/12/11 Analysis (Statistics) and Conclusions of Analysis

Alex PUDZISZ - Dec 14, 2021, 7:30 PM CST

## Title: Analysis and Conclusion of Analysis

Date: 12/11/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain my view of the analysis and conclusions

### Content:

The MATLAB code used to make the ANOVA is available in the team section. The raw data is available in the testing day section. Tatum did the analysis and told our team of two significant results. 1. That there is a significant difference between the loading time of soft and stiff wire. and p = .00617 2. That there is a significant difference between the unloading in our prototype and the original casing p = 3.76e-9. For the movement test the analysis was that it had a 0 percent failure rate.

From here we must draw our conclusions. The first is that it is good that the unloading times are significant different. By looking at the data it is easy to see that ours was better than the original by several fold. The downside is that the loading times between the two devices were nonsignificantly different. This meant that we still have to do more work on the prototype to show results that are truly better in this regard. The team has come up with the future work of adding a back plate so that the wire does not overshoot the case when loading. This should mean a much better result. The other part of the conclusion is that there was no entanglements. That means that our device serves perfectly to hold it in place once it is put there. Overall the project has been a success, but there is still improvements to be made in the loading part of it. We may also consider a slight opening in the ring to allow for a hand to more easily come out from inside.

#### Conclusions/action items:

None, finish Final Notebook

Alex Pudzisz/Alex Old Semester Research/Alex Pudzisz/Research Notes/Protocols And Procedures/2021/12/14 Conclusion of Project and Semester 162 of 187



Alex PUDZISZ - Dec 14, 2021, 7:29 PM CST

#### Title: Conclusion of Project and Semester

Date: 12/14/2001

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Write about my final thoughts

Content:

First off, happy birthday to me :D.

Next up is that I was very happy with this semester. The advice from our instructor has been very practical and actually usuable (much more than previous semesters). The other part is that this project seems about accurate for what the credit requirement suggests it to be. Finally the project itself seems to have gone well and I hope that it will be able to continue on. I would like to work with the same client again as I find his ideas very interesting and he brought up problems in the OR that I didn't know existed.

#### Conclusions/action items:

Say thank you to both the client and the advisor



163 of 187

Alex PUDZISZ - Oct 19, 2021, 1:27 PM CDT

#### **Title: Clamped Wheel Design**

Date: September 29, 2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

**Goals:** Show the design I came up with for our design matrix

#### Content:



This design is a circular ring. The ring can open and close because of the clamps on the side. I have not yet decided on how to stabilized them being open or if how much force will be required to open them. The hole on the bottom is optional. The idea is that it would allow you to put in the wire and then directly take it out from there as a secondary option. The rest of the notes are on the device picture above.

#### Conclusions/action items:

To show this design to my group during our design matrix meeting. Then to grade this design based on the criteria we set.

2021/10/19 Training + 2021/12/14 Training Update

Alex PUDZISZ - Oct 19, 2021, 1:31 PM CDT

Title: No Training Done
Date: October 19, 2021
Content by: Alex Pudzisz
Present: Alex Pudzisz
Goals: To explain the training I have done
Content:
I have training done from prior semesters, however it has not yet been necessary for this project. There is no need for HIPAA or chemical training. So far there is no certifications to report this semester.
Conclusions/action items:
Find out if there is any sort of trainings required for this semester's project.
Alex PUDZISZ - Dec 14, 2021, 4:41 PM CST
Title: Training Update
Date: 12/14/2001
Content by: Alex
Present: Alex
Goals: Explain Training

Content:

Even until the end of this project, no training through the university or otherwise was required.

Conclusions:

None



Alex PUDZISZ - Dec 14, 2021, 5:58 PM CST

#### Title: PDS + Constraints

Date: 11/07/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put an individual section in my notebook that gives breif overview of PDS and constraints

#### Content:

These are the main things from our PDS:

#### **Client requirements:**

- · The device must be easy to use and increase organization in the operating room
- The device must consist of a main storing unit (the crate) to house 4-5 guidewire wheels
- · The final device must ultimately have biocompatible properties\*
- · The final device must be sterilizable by autoclave or other alternatives\*

### \*Clients main goal is a successful prototype and proof of concept

The constraints of this project include several things: not spending too much (amount not specified, but lower is better as it is a proof of concept), the requirement for the device to be storable in groups (must have a fitting design), the need to increase efficiency (no complicated designs). This does not seem to be the most constricting project I have had to do, and the client seems to be very open to ideas. Overall the project is very open and allowing a lot of creativity with little real true boundaries.

#### Conclusions/action items:

None



Alex PUDZISZ - Dec 14, 2021, 7:33 PM CST

**Title: Final Design** 

Date: 11/29/2021

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To put down what our team decided as the final design

#### Content:

I am now marking down our final design as this is the one that the team intends to test. We are already ready to 3d print it, and I am finishing up the final testing protocol. The design is almost the exact same as we had back in the initial presentation. It is a ring, 22 cm in outer diameter, and 20 cm in inner diameter. It has a hollowed inside with a magnetic tape lining it. This design looks like a donut and allows one to put their hand in and release it so that the wire will move to the outer edges and be successfully stored. It successfully meets all of the requires PDS constraints and specifications.

#### Conclusions/action items:

None



Download

Screen\_Shot\_2021-12-14\_at\_6.19.55\_PM.png (72 kB)

Alex PUDZISZ - Dec 14, 2021, 6:16 PM CST



# 2022/02/15 Testing Ideas Based on Advisor Meeting

#### Alex PUDZISZ - Feb 15, 2022, 10:03 AM CST

#### Title: Testing Ideas Based on Advisor Meeting

Date: 02/15/22

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To discuss a possible protocol and things brought up by advisor to fix

#### Content:

My advisor brought up a few concerns for testing. One of them was as to who would be testing. We discussed it as a group and I thought about it. We will try to get the doctor to get his friends to test the devices, however if this does not work then for the sake of time it will likely be us testing. I would like to bring up with my group the possibility of us all finding a friend or two to test for us. This would take out the bias, but has concerns of privacy or a need for a nondisclosure. Again something to discuss with my advisor. Now it is about what to test. In terms of the wheel, when we make adjustments we will have to test speed because that is what the whole procedure is about. The idea is to make it less frustrating, easier, and faster to use that just coiling the wire. The timing testing will follow a similar procedure as last semester where we tested people on the original device vs ours and about 5 tests per person. However, it was brought up by the advisor to use people who know nothing about our device and a video to make sure they do not know exactly how to use it at first. This gives a more accurate learning curve. It will also stop using of specific tricks, like getting a wire in a specific spot to make it easier. I entirely agree with this decision, especially because this is something the client would like to market. During the test by random individuals with a video we can also more accurately rate the ease or learning curve. The frustration is included in this ease test as there will likely be visual cues of giving up. This will be converted to 1's and 0's to be able to numerically record it. That solves what we are testing with the wheel, but we also have to test the holder. In the case of the crate, case, or whatever we decide we will have to test how fast or easy it is to get the wire out, how hard it is to get the wheel out, and making sure that the holder does not move too much. The final criteria is the easiest. By adding some weights to it or a method of stability and then testing with various amounts of force or use to ensure that it does not move it will be solved. This can be done by pushing it with some amount of force or just constant use and making sure that it does not move. The first two criteria, getting wire and wheel out speed, has to be tested in a similar way to the wheel. That all solves the testing aspect. The issues with modeling the data or ways to demonstrate it will have to come after.

#### Conclusions/action items:

Print the device, and write up specific test protocol.



Alex PUDZISZ - Feb 17, 2022, 9:57 AM CST

#### **Title: Wheel Testing Protocol**

Date: Feb 17 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down one of the wheel testing protocols

#### Content:

Disclaimer: This protocol is for the wheel by itself, it does not include unloading while inside of the holding device.

Protocol:

- 1. Show participant video of doctor loading and unloading device, but do not give any other hints
- 2. Start Timer as participant says they are ready to load
- 3. Stop Timer as they finish loading wire into wheel
- 4. Record data inside of google spreadsheet
- 5. Inspect wheel for any tangles
- 6. Start Timer as participant says they are ready to unload
- 7. Stop Timer as they finish unloading wire from wheel
- 8. Record data inside of google spreadsheet
- 9. Record any issues with tangling when unloading
- 10. Repeat steps 2-9 3 times per participant
- 11. Repeat steps 1-10 for original device as well

#### Conclusions/action items:

Write a test protocol with the holding device (must be done after device is chosen, but before print)



2022/02/17 Holding Device Possible Test Protocol

#### Alex PUDZISZ - Feb 17, 2022, 9:56 AM CST

#### **Title: Holding Device Possible Test Protocol**

Date: Feb 17 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Write down a possible test protocol for the holding device (specifically testing loading and unloading of wheel times)

#### Content:

DISCLAIMER: The device is not yet printed, so this is just a possible protocol. Adding steps to measure new variables, taking out steps, or adding another protocol may be needed.

- 1. Demonstrate to participant how to use holder (both loading and unloading)
- 2. Ask participant to load the three wheels
- 3. Start Timer as participant is ready
- 4. Stop Timer as participant finishes
- 5. Record data in spreadsheet
- 6. Tell participant to unload the devices from top to bottom
- 7. Start Timer as participant is ready
- 8. Stop Timer as participant finishes
- 9. Record data in spreadsheet

10. Repeat steps 2-9, but in step 6 each times require them to take it out in a different order (do this for a total of 3 times)

#### Conclusions/action items:

Write 2 more test protocols, one for attempting to knock over the test device and the force required, and the other of attempting to unload the wire from the device inside of the holder. Also need to add comparison to some sort of original device.



Alex PUDZISZ - Feb 24, 2022, 10:20 AM CST

### Title: Holding Device Durability Testing Protocol Ideas (not done in steps)

Date: Feb 24, 20222

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To talk about how we might test whether or not it can take damage, or if it tips over easily

#### Content:

For durability an idea may be to drop it from various heights, from 1-3.5 feet. This should give the average height of a table, of course if we decide to go with this I will have to research how tall the average table it. Another idea is various items hitting it, whether that be a person or an object this would test how easily it chips. On the other hand, when the actual device is made it will be made out of steel and much stronger, but this could possibly represent dents (which would also be bad). Other tests would be to see whether or not it slides on tables (non-desirable outcome). This should be the same as the final version, and we may need to add abrasive or heavy things to the bottom. Or we could add magnets. Here you would test by pushing it with various amounts of force and make sure that it does not fly around like it is made of paper. Optimally it would be able to take small hits while moving only a few inches.

#### Conclusions/action items:

Talk to advisor to see if any of them are viable



Alex PUDZISZ - Mar 01, 2022, 9:26 AM CST

#### **Title: Testing Different Wheels Ideas**

Date: March 1, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To give ideas for testing different wheels.

#### Content:

I just wanted to write down ideas for testing wheels that were not straight efficiency tests. Of course we are able to test unloading the wire from the device in or out of the stand (and we will), but they should all have similar times unless there is structural issues. I am more concerned with how the wheel stays put or is able to be unloaded from the stand. We can test and see if we throw the wheel on randomly what are the chances that the wall in the UHold device blocks the wire from coming out. We can also test the wheels to see what kind of openings allow it to slip out past the stand easier. We could also see if putting a different material on top allows two wheels to act independently easier. While they should act independent in general it is always good to test and minimize the interactions.

#### Conclusions/action items:

Test different wheels



# 2022/04/14 New Possible Method Of Measurement Or Analysis

Alex PUDZISZ - Apr 19, 2022, 10:39 AM CDT

Title: New Possible Method Of Measurement Or Analysis

Date: 2022/04/14

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain the possible method of using percentage improvement as a method of measurement or analysis.

# Content:

Originally we were/ are using the outright times across each participant to conclude which one would be best. I believe (but do not yet have significant data to show) that this will cause very high p values. This is for obvious reasons. First off, as I must test people who have never used the device before the spread of data will be massive. Is is possible for me to do something in 15 seconds, but someone who is new and figuring it out might take up to 30 seconds. Does this mean the device is the issue? No it means they are inexperienced, and as we cannot fix this we need another method of improvement. That is why I would like to use percentage improvement (i.e. 50% faster or 50% slower than what we determine is the basis for times (would need to choose a model)). This should work fine as the extremes should work out in our favor in this case. Having a time of 30 seconds is now comparable to my 15 second time if they have the same percentage improvement. A possible issue with this method is that you must keep track of which participants data is which, but I have set up the data sheet in such a way that this is achievable. I will explain this to my team and we may possibly use this for the final presentation of data.

### Conclusions/action items:

To explain to my team and my advisor the possible use of this method



Alex PUDZISZ - Apr 19, 2022, 10:39 AM CDT

#### Title: Update For This Week And Future Testing

Date: March 09. 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain what has happened over past week and what we will do after spring break

#### Content:

Over the past week we presented the preliminary presentation. The presentation went amazingly. I think I have approved upon my public presenting skills. The professors did not have any major concerns for our project, but one of them was very excited for how truly applicable our project was. I do not think they brought up any major data for us to improve upon, but we will see after we get back our grades. From now On we must consider testing, and we will hopefully start next week or right after spring break. I have already written up lots of testing ideas, and we might use some of them, but again I have to talk to the team. I have looked them over and drawn a few good ideas from them, but I wont explain them here as in the future it should be possible to look at my ideas and the ones implemented to see which ones got through. There is no new data for this week and we will update our advisor to talk about more future steps.

#### Conclusions/action items:

Wait till after spring break and then talk with team about future plans



# 2022/03/12 - 2022/03/20 Break In Notebook Due To Spring Break

Alex PUDZISZ - Apr 19, 2022, 10:28 AM CDT

#### Title: Break In Notebook Due To Spring Break

Date: March 12th to March 20th 2022

**Content by:** Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain gap in notebook

#### Content:

Between these two dates none of us will have access to print the wheels that we need and because of this it is impossible for us to test or do anything during this time. We will pick up the week after, however this gap will exist.

Conclusions/action items:

Relax and plan for future steps



Alex PUDZISZ - Apr 19, 2022, 10:26 AM CDT

#### Title: Addie Running Test My Notes

Date: 2022/03/23

Content by: Alex Pudzisz

Present: Addie, Tatum, Alex

Goals: To explain to myself and future readers what I saw with the testing, and as I will be testing in the future, what I need to do.

#### Content:

I walked into Engineering Hall and I was prepared to take the test as I had taken it before. There were a few new rules from last time. One of which is that the participant must be standing when doing the test (this makes it easier for the participant, and makes it easier to standardize data as there is one less variable). Addie and Tatum ran the test on me the same as last semester. The scale of difficulty will be explained when I do my testing or Addie may have it under her section. The test ran fine, but I know that we will be replacing one of the wheels so my data will start as a completely new set. The other reason to start anew is that I will be the one testing in the future and having the test runner standardized will eliminate differences in testing methods. Overall the test ran fine and went about as well as it could. I did have trouble with the thin wire (as it is getting worn and even more thin and malleable) which made me mistrial on one of the devices. This may affect the data set in the future, but I am not sure. It may also be beneficial to have multiple wires on hand to run more tests at once (and eliminate the problem of wires getting worn). I am curious what kinds of data we will draw from this.

#### Conclusions/action items:

Prepare to test rest of data set, and find people to do so



Alex PUDZISZ - Apr 19, 2022, 10:17 AM CDT

Title: Testing Wheels And Slight Delays

Date: 2022/04/07

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain the delay in testing

#### Content:

I would like to update the notebook to explain the slight gap in testing updates or method ideas. So far I have received two of the wheels and started to ask people when they will have time to test. This is beneficial to me as I can block out portions of their time so guarantee that I have test subjects. The downside is that I only have two of the three wheels I will be testing. I still have to ask my group if I will have to get all of the data for these individuals or if we can grab randomized data (but I suspect I will need all of it from one group). This means that I will have to be able to retrack down all of the participants which may be hard. On the other hand I am excited to finally start testing. The idea is going to be to put in order which of the wheels and wires we tested first to ensure that they are equally distributed (i.e. that wheel 1 wire 1 should be tested 1st, 2nd, 3rd, etc as often as wheel 2 wire 1 or any other wheel) as this makes sure that we are not getting results better on the final wheel because people are learning tricks or easier methods as they go. We will move forwards with testing the time to load and unload (done by me consistently (as in error should be same every time) on my phone). We will also continue to measure the difficulty with which it was to load or unload. A 0 means a mistrial or it is completely messed up. A 1 means very poor performance (it might have temporarily gone in but then it exploded out or it tangled completely). A 2 ensures that the device works fine (this is not the best result as maybe it took extra effort to get the wire in or maybe it took too much effort to take out). A 3 (the best) would ensure that the device works flawlessly with the minimum amount of effort to put in the wire or take it out with no tangles or complications. The system is not exact, but as I am the one doing it each time it should represent a consistent feeling (not exactly quantitative) of how frustrated I feel people are combined with device performance. It does not need to be e

Conclusions/action items:

Get last wheel and start testing



Alex PUDZISZ - Apr 19, 2022, 9:59 AM CDT

#### **Title: Beginning Testing Notes**

Date: 2022/04/14

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain how testing has gone so far

#### Content:

The testing so far has been average. People tested who are not of science majors, or more specifically engineering majors, have lots of questions and tend to have many more struggles testing devices. I believe they lack the prior knowledge to understand what our device could be used for. and this overthinking leads to them performing slower on the tests. That is why I have come up with another way of measuring performance that I will describe more inside of the research notes (by percentage improvement). Other than this the testing has been slow. Doing one practice run and then 6 or more real runs tends to take more time than people expect and it is possible for them to leave in the middle of testing, which leads me to needing to retest them next week. That is fine but there are several possible solutions. One of which is to use the new percentage improvement testing method and then you are only required to run three tests at a time (division based on wire thickness) as we will not be comparing across data sets. This is not to say that we will not correlate the two, but the direct times are not comparable. (i.e. we might use a rank system for which device is best for each type of wire, but we will not compare percentage improvement to determine if there is something fundamentally different between stiff vs soft wire on device 3). I will continue to test next week. I hope to have 17-18 data points per wheel and type!

#### Conclusions/action items:

Complete testing on test subjects who have done less than 6 wheels, and get more test takers.



Alex PUDZISZ - Apr 21, 2022, 9:37 AM CDT

Title: Updates 1 Week Into Test Running

Date: 2022/04/21

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To explain any notes I have found about running the test on nonmember participants this past week

#### Content:

It was actually easier to find people than I thought it would be, however there was some down sides. Some of the people got competitive or had much better times after they learned how to use it, so I had to remind them to try for consistency and not speed. It is more important for us to measure over time the change due to the device not the individual (but this is what the changing order of testing is for). I will have to drop one person from the data, as they did not have time to complete the full data collection. That is fine, and now I only need 2 more non-team member responses (which I should be able to get today). Then tomorrow I should be able to test the team members to get the final data set, and it should get me 18 participants total if I get 2 more random individuals. I will attach the final spreadsheet tomorrow to a notebook page for future reference on formatting and what exactly it looked like.

#### Conclusions/action items:

Finish testing tomorrow



Alex PUDZISZ - May 01, 2022, 2:42 PM CDT

#### Title: Week 2 Final Testing Notes

Date: April 26th 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Explain my final bit of testing

#### Content:

Final Notes about testing: I was able to get 16 people as two of my group members were not available. By the end the wires were almost completely kinked and would need to be replaced. Overall I think it went well. The data collection went much faster since the last time when I reorganized how the data was laid out. If I were to do this testing again I think that splitting the project into two sections (soft vs stiff wire) and running three tests per individual would have been optimal. I could definitely see learning occurring in between trials (but the randomized order should have been good enough to sort out this issue).

#### I WILL ATTACH SPREADSHEET TO THIS DOCUMENT

#### Conclusions/action items:

Have team do analysis of the data. Also record video because I will be gone for presentation

Alex PUDZISZ - May 01, 2022, 2:44 PM CDT

Embedded private docs from Google Drive cannot be displayed in PDF



Alex PUDZISZ - Feb 10, 2022, 9:33 AM CST

#### Title: Tube Design Idea

Date: Feb 10, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down an idea of mine so that we can possibly use in design matrix later

#### Content:



The design above is tubular. The top will come off to allow devices to be put inside many at a time. The side door is only on one side and will extend far enough for it to allow devices to be pulled out. It will have three hinges to make sure that it does not wobble. The bottom will not be detachable. The idea is that it is possible to stack three devices and then drop them in from the top. After that it should be possible to pull out the wire from the gap between the door and other side of the wall. When you are done using the device it is possible to open the door and selectively take out one or many devices. The reason for the wall is to make sure that the devices do not just fall out after all of the wire is taken out. The flaw in the design is that I still have not come up with a way to ensure that the device stays orientated correctly in the holder.

#### Conclusions/action items:

Decide if we will use this in the design matrix.



2022/05/01 Contribution in Group Documents

Alex PUDZISZ - May 01, 2022, 2:47 PM CDT

#### **Title: Contribution in Group Documents**

Date: Last Updated May 1st, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: To write down my individual contributions

#### Content:

I will not be including verbal contributions in conversation, simply what I did in documentation or presentation.

PDS: Updated basics at top of document, looked over with team entire document, personally edited / rewrote : Ergonomics, Size, Weight,

Design Matrix: Made a design "Door", Helped create criteria and rate the devices

Prelim Presentation: Criteria + Design Matrix

Tested New Three Devices Completed

Final presentation - Missed due to MCAT, but put in video of me using device

Final Documents: This will be turned in before that occurs so I will do my part in the documents (likely testing plus a couple more sections)

#### Conclusions/action items:

Update This



# 2022/02/24 Possible Ideas For Design Changes to UHold Device

Alex PUDZISZ - Feb 24, 2022, 10:24 AM CST

Title: Possible Ideas For Design Changes to UHold Device

Date: Feb 24, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Talk about what I might suggest to change in our current design

#### Content:

One Idea could be to open up the back wall design slightly, so that you are still able to grab a wire if the wheel is pointed that direction. This would allow the device to point any direction, while still keeping the wheels from randomly falling out. Another change could be to add things to the bottom of the device to make it more sticky or a way to adhere to a surface. Like I mentioned in the durability test, this would be important to make sure it does not slide off of a table and ruin all of the guide wires by contamination. Another design change could be making the middle pole hollow, this could reduce weight and material cost. We could also add a way to wall mount the device. That would be cool as it would eliminate the need for table space.

#### Conclusions/action items:

Test design and see if any of these changes need to be made.



# 2022/02/24 Training Remains The Same As Last Semester

Alex PUDZISZ - Feb 24, 2022, 10:13 AM CST

Title: Training Remains The Same As Last Semester

Date: Feb 24, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Update Training

Content:

Training Remains The Same As Last Semester. Look under Alex Old Semester Research for old document,.

Conclusions/action items:

None



Alex PUDZISZ - Mar 20, 2022, 12:35 PM CDT

#### Title: WARF Lecture Notes

Date: March 20, 2022

Content by: Alex Pudzisz

Present: Alex Pudzisz

Goals: Write Notes

#### Content:

- 6th in Research funding
- \$1 billion products sold per year
- 50 average license per year
- · Deals with copy rights, patents, and trademarks
- To patent need absolute novelty
- Many ways to disclose an invention
- Requirements for patent:
  - Eligible
  - Useful
  - Enabled
  - Described
  - Novel
  - Non-Obvious
- WARF takes royalties
- · Licensing takes months to years
- · WARF can help catalyze with expert consults
- Need to make sure there is a market

#### Conclusions/action items:

Our product is in the process of being patented. The entire ring design is intellectual property.



# TATUM RUBALD - Jan 31, 2022, 10:34 AM CST

BME Design-Fall 2021 - TATUM RUBALD Complete Notebook	
FCF Vender presented to	
TATUM RUBALD	
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Table of Contents	
hoad Internation	
Teamcontact Internation	2
Project description	0
em chiles	
Oler: Wedings	
917 - Olient Meeting 1	
918.9021 - Cilert Interview	6
Tearshielings	7
9/04/01: Team Meeting PDS	7
1018 1.2.1: Team Meeting Proliminary Presentation Overview	
10/08/2021 Tasket Maeting Prefer Presentation	9
10111/20211 Taken Meeting Preferinary Presentation Review	10
10(182021) Teore Maning Preferinary Report	
10/292021 Team Meeting Brow and Tell	12
11 (E10021) Teore Meeting (Room and Tell	13
11 ISS2C011 Team Meeting Probinging	н
111152021 Tasm Maring Preliminary Principle Testing	17
11 (220)(21 Taken Meeting Testing	18
11 (2)(2)(2)1 Tasen Meeting Final Presentation Pester	21
128 T0C01 Team Meeting First Detrevoldes and Preserbation Produce 1211/20201 Team Meeting Completing First Detrevoldes	2
	20
Advisor Needings	
917 - Advisor Newling 1 924 - Advisor Newling 2	34 25
9/04 -Advisor Newling 2 10/1 -Advisor Newling 0	2
1011 - Activate Needing 0 11112: Activate Meeting 4	
Design Process	
Property Report	
Property Report	
Property Reports	
Property Report	2
Property Reports	40
Promis Republic	
Praymon Report 7	i i i i i i i i i i i i i i i i i i i
Promis Result	
Propes Reports	50
Progress Report 10	55
Property Report 11	87
Propess Report 12	
Male Kats and Dopertone	61
Material Cool	61
FalenceRie	
The Guideuterhage	
00 Printing	64
Final Design	
Testing and Results	60

## **Download**

Fall\_2021\_Lab\_Notebook.pdf (18.8 MB)



### 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.

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: