Bioengineering Devices Lab Compact Vessel Cleaner and In-Vitro Flow Model Development

Preliminary Proposal

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Spring 2022 - Fall 2022

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DISCLAIMER

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1 BACKGROUND

1.1 Introduction

The overall objective of this project is to enhance an In-Vitro Flow Model developed by the NAU Bioengineering Devices Lab (BDL). The In-Vitro (within the lab environment) flow model is a Circle of Willis model meant to simulate the physiological conditions of human brain vasculature subjected to aneurysms, which makes it suitable for device deployment prior to In-Vivo (within the body) testing and treatment. Due to similarities in material properties, the vasculature model is created from 3D-printed materials. This objective is divided into two main goals: 1) to develop a pump-system capable of cleaning 3D support material and 2) to improve the physiological and operational conditions of the existing model by adding various devices to the existing system. Such devices include temperature modifiers and programmable “kill-switches” for emergency shutdown.

The BDL specializes in biomaterials research and aneurysm treatment/prevention [1], which makes the flow model an important cornerstone of their research. Therefore, Goal #1 is needed for the effective replacement of any damaged or expired Circle of Willis models, and Goal #2 is necessary for comprehensive evaluation of various medical devices such as Balloon Stents, Liquid Embolics, and various guide catheters. The sponsor of our project is Dr. Tim Becker, the BDL’s Principal Investigator (PI), who is the primary stakeholder of this project. However, the stakeholders with the greatest risk are victims of stroke. According to the Brain Aneurysm Foundation, 500,000 people die from brain aneurysms each year, and roughly 66% suffer from long-term neurological deficit [2].

1.2 Project Description

At the beginning of the semester, both goals of the project were separate capstone proposals. However, both goals could be completed within the allotted time frame, which resulted in a merger.

The following is Goal #1 as provided by the sponsor:

> The scope of this project is to design, build, and test a compact cleaning system for 3D models. This system will provide an efficient way of cleaning 3D models. The goal is to develop a simple design, easy to use, and portable.

The following is Goal #2: as provided by the sponsor:

> The scope of this project is to upgrade a neurovascular in-vitro flow model that simulates physiological conditions. A preliminary model has already been developed but needs further testing before it can effectively test aneurysm treatment methods and devices. Furthermore, the system must be user friendly and capable of long-term testing for any practicing bioengineer or neurosurgeon.

1.3 Original System

1.3.1 Original System Structure

The preliminary vessel cleaner design involved a Stenner© pulsatile pump, a fluid reservoir, a pressure clamp, and a sphygmometer. A one-liter plastic bucket acted as the reservoir.

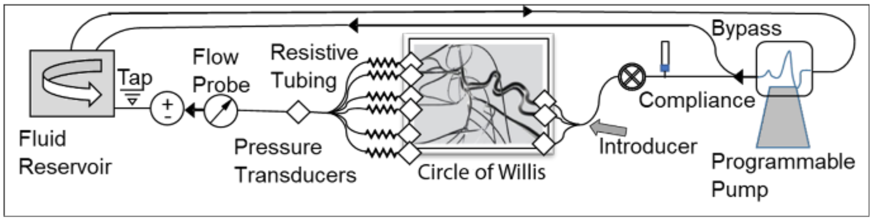


Figure 1. In-Vitro Flow Model Flowchart

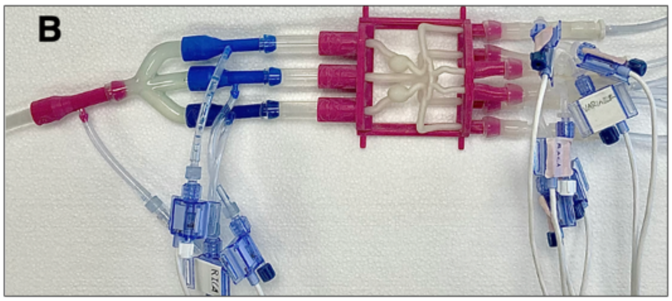


Figure 2. 3D Circle of Willis Model

[Insert Figure]

Figure 3. Preliminary Vessel Cleaner

1.3.2 Original System Operation

Prior to the preliminary design's cleaning process, each model undergoes a pre-cleaning process. The entrance(s) of each model would be cleared using an electric screwdriver or an expired catheter. After clearing the entrance, the model is injected with 0.5 molarity NaOH (Sodium Hydroxide) to break down the … This region of the model is occupied by the synthetic vasculature material, which is vulnerable in comparison to the entrance material.

1.3.3 Original System Performance

While there is no empirical data collected from the model, the performance is based on observations from Steven Schwartz, the team lead, and Mana Alyami, the project mentor.

The system had optimum performance, as the vessels would

1.3.4 Original System Deficiencies

While the system performed its main objective - to clear support material - the preliminary design had a few deficiencies and left much to be desired, which is reflected in the customer requirements of Chapter 2.2. One flaw of a sphygmomanometer was their vulnerability to fluids and particles that do not consist of air. If the model was placed incorrectly or tampered with, water could easily enter the sphygmomanometer's gauge entrance. As mentioned before, the fluid reservoir did not have a proper insulation system for keeping the water at

Furthermore, the temperature of the system was neither adjustable, nor measurable.

2 REQUIREMENTS

2.1 Customer Requirements (CRs) - Milo

- Cost within budget
  - The budget prived is $1,500
- Durable and Robust design
  - Product is expected to be transported and still functioning within size parameters
    - 24 to 30 inches long
    - 10 to 16 inches wide
    - 8 to 10 inches tall
- Reliable design
  - Usable for many years
- Safe to operate
  - High-temperature and pressure water, and complex circuitry should now harm users or surrounding equipment/lab space
- Pressure gauge
  - Must measure in millimeters of mercury
- Temperature gauge
  - Must be highly responsive and read in degrees Celsius
- Switch On/Off
  - One for heat and one for entire system to maintain safety
- Mesh filtration
  - Remove support material and be easily removable for cleaning
- Universal plugs
  - Allow for use on multiple models
- Water reservoir
  - Primary water source for easy refilling
- Timer
  - Track cleaning time
- Water Pump
  - Pulsate or constant flow for different cleaning methods
- Adjustable setup
  - Leveling or system balance

2.2 Engineering Requirements (ERs) - Mason

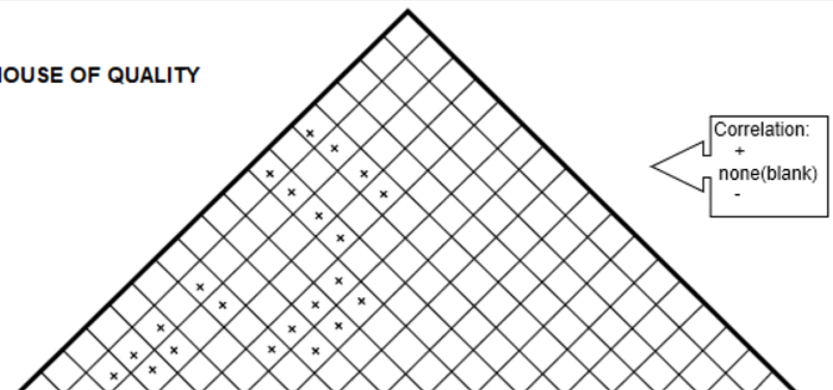
- Water Temperature: Max water temperature, 80^{o}C.
- Flow Rate: Max flow rate, needs testing, general value (100mL/s).
- Water pressure: Max water Pressure, 220 mmHg.
- Reservoir Volume: Max Volume, General value (10in by 10in by 10in).
- Water heater Volume: Max Volume, General value (10in by 10in by 10in).
- Frame Length: max value, 3ft.
- Frame Width: max value, 2ft
- Frame Height: max value, 0.83ft.
- Frame Durability: Total Load Capacity, 50lbs-100lbs.
- Filtration Size: Design Goal; Must separate support material from fluid. Size requirement; Must fit in frame and system, testing required for final max size (Predicted size: 5in by 5in, Mesh Size:

2 - 3 mm/0.07 - 0.11 in.)

2.3 House of Quality (HoQ) - Mason

The house of quality is used to relate the customer requirements and the engineering requirements. The customer requirements are each given a weight/importance score, this score will help the team balance the final score to ensure the clients most desired or attainable requirements are sure to be met. When comparing the customer requirements and engineering requirements the values 1, 3, 9 are used to quantify the relationships, a blank space means that there is no relationship between the two requirements. A 1 represents a weak relationship between the requirements, a 3 represents a medium relationship between the requirements, and a 9 represents a strong relationship. One strong relationship in our HoQ is the customer need for fast cleaning and the flow rate has a strong relationship. The HoQ also compares the project to other companies designs for cleaning 3D printed vessels. The HoQ also compares the effects of each engineering requirement on the others. For example, as flow rate increases it will cause water pressure to increase.

HOUSE OF QUALITY



Customer Requirements \ Design Requirements	Importance	Water Temperature °C	Flow Rate (L/s)	Water Pressure (mmHg)	Pressure (mmHg)	Resevior Capacity (L)	Filtration Size (in^3)	Angular Velocity (rpm)	Width (in)	Length (in)	Height (in)	On/Off Controls*	Level*	Pipe Durability*					They Have	We Have	Both Have	N/A	
Improvement Direction						+	-		-	-	-	+		+									
Water Pump	5	3	9	9	9	1		3	3	3	3	9	1	9							X		
Water Heater	5	9							3	3	3	9	1	9							X		
Heat On/Off	5	9										9		3						X			
System On/Off	5	3	3	3	3	3		9				9		3						X			
Fast Cleaning	3		9	9	9	3		3				3								X			
Leveling System	3												9							X			
Mesh Filtration	4		3	3			9		3	3	3											X	
Universal Plugs	3													3								X	
Timer	3		3									9											
Pulsation	5		3	9	9			3						9							X		
Size	4						3		9	9	9		3										
Sodium Chemical(NaOH)	2		3		3									3							X		
Technical Importance: Absolute		120	129	144	138	29	48	84	78	78	78	216	49	180	0	0	0	0					
Technical Importance: Relative		9%	9%	11%	10%	2%	4%	6%	6%	6%	6%	16%	4%	13%									

Figure 4: House of Quality

3 DESIGN SPACE RESEARCH

3.1 Literature Review – Mason, Milo, and Muath

[Use this section to describe what sources were used for benchmarking and design research. This could have been done by examining similar systems, literature review, or web searches. Each student should have at least five relevant sources (academic and professional journals, books, websites, catalogs, interviews with sponsor, advisor, design tools etc.), given in the following subsections. For each source, include a summary and discuss how it specifically applies to your project design space.

3.1.1 Student 1 (Milo Gubler)

One of the primary components to this cleaning system is reliable water heating. Using prebuilt water heating systems reduces the chance of overcharging electrical circuits, they either don't fit the size requirements or increase the chances of burning oneself on un-insulated metals. By pre-heating the water into the water heater, less electricity is used [Expert]. By instead allowing the water in the closed system only to interact with the water reservoir a majority of the temperature can be saved and increase the efficiency of the system. This effectively creates a tankless water heating system, which is considered the most efficient and responsive system in electric water heating [Energy]. With this method an electrical circuit that does not overload the system from the connected power outlet must be designed. A primary concern is not short circuiting the power supply harming the transformers [Harm]. A primary protection is ensuring the designed circuit stays under 15 to 20 amps (1800 to 2400 Watts) [family]. As this is an electrical system interacting with water, reducing human contact to the water is a high priority. Even though the water will be filtered, have a reduced mineral concentration, electricity can still travel and cause physical harm or fatal injury. The necessary steps that should be taken if water is leaking from the water heating unit is to turn off all power to the system [CPR]. This will ensure no more electricity is introduced to the fluid. Then any water leaked should be given time to discharge before being cleaned. The water heater will then need to be emptied, inspected and properly serviced, including additional leaks or areas where a new leak can start.

3.1.2 Student 2 (Muath)

3.2 Benchmarking - Mason

To benchmark for the entire system of this project we looked at companies that currently have vessel models and tried to find the ways that they cleaned them. The other benchmarking that took place was for the three subsystems; pumping, heating, and mesh designs. At the system level we looked at the companies BioModex and United Biologics. These companies currently have vessel models that they have procedures to clean the support material out of and procedures to clean/sanitize the vessel model. Research on these companies were performed on-line through articles that the companies have published. For the subsystem level benchmarking we looked online at companies and products to compare and draw ideas from in order to develop concepts for our subsystem designs. The benchmarked subsystems were also used as help to determine which of our concepts would be used based on the ability of each concept compared to the benchmarked versions.

3.2.1 System Level Benchmarking

3.2.1.1 Existing Design #1: BioModex Cleaning Procedure

The company BioModex uses a hand cleaning method for the majority of their cleaning processes. This research was on the company 3 years ago. The company only briefly described their cleaning of support material out of the vessel models by describing a method of mostly hand cleaning with wire brushes and hot water, or using an undisclosed chemical to dissolve the support material. BioModex most likely uses a more developed system currently but the company does not disclose the method. This method is similar to the current BDL method because the BDL lab currently uses a pulsating pump along with a hand cleaning method.

3.2.1.2 Existing Design #2: United Biologics Silicon Cleaning Procedure

This company uses a different method for cleaning because the vessel models are not 3D printed. The company uses a chemical and a hand cleaning method to clean the silicon models. Methods from this company are applicable because after the support material is removed from our system the vessels can still be cleaned using our system. This company does not disclose the chemicals they use and they do not disclose whether or not they use an automated system.

3.2.2 Subsystem Level Benchmarking – Meshes, Pumping, Heating

3.2.2.1 Subsystem #1: Mesh types - Steven

3.2.2.1.1 Existing Design #1: Descriptive Title

3.2.2.1.2 Existing Design #2: Descriptive Title

3.2.2.1.3 Existing Design #3: Descriptive Title

3.2.2.2 Subsystem #2: Pumping

This subsystem will control the flow of fluid through the system. The pump that is desired by the customer requirements should be pulsatile. The pump will control the flow rate and have a strong correlation to the max water pressure engineering target and requirement.

3.2.2.2.1 Existing Design #1: General Pump (basic model from Amazon)

A general pump will fulfill the requirements of being able to control the pressure and flow rate. This will not be a pulsatile pump therefore will not meet the customer requirement. This pump will be purchased from a third party.

3.2.2.2.2 Existing Design #2: BDL Current Pulsatile Pump

This pump is the current method of pumping in the BDL lab. The pump is connected to a wall near the water outlet in the lab. The pump is then connected to the vessel model after the vessel has been cleaned by hand. The pulsatile pump then pumps uncontrolled hot water through the vessel to remove the final support materials. This method is not autonomous and cannot be turned off if the pressure gets too high it must be personally monitored. This pump matches the customer requirements of being pulsatile. The controls of the flow rate have not been tested to see if they will match to our project design. This pump may be used in our project if we need/desire. This pump in our project will be improved by adding control systems to make the system autonomous.

3.2.2.2.3 Existing Design #3: Sink Spout pump

This design is a method of using the flow out of general buildings as the pump. This method is not good for pressure control because the water coming out of the sink can not be controlled well. This also will not lend itself to the customer requirement of being temperature controlled. This method also can not be controlled to be a pulsatile pumping method. This is not a conventional pump but it was good to benchmark this as a method because it is a possible method in powder to keep the cost down by not having to purchase a pump.

3.2.2.3 Subsystem #3: Heating

This subsystem controls the temperature of the fluid. As desired by the customer in engineering requirements, the maximum temperature should be 80°C.

3.2.2.3.1 Hot Plate

This design is a simple water tank that sits on a hot plate. The primary advantages of this design are the pre-designed circuit and temperature setting with on/off switch. The disadvantages of this design are the price, limitations on insulation and safety precautions, and size of the system. With a very small height limitation, placing a small container on a hot plate while surrounding the system with insulation and a protective layer is no longer feasible.

3.2.2.3.2 Heating Element

This design utilizes a small heating element that can be found in a household water heater. It allows for more consistent heating, and connecting a voltage transducer to the circuit can regulate the temperature output. Another advantage is the ability to fully insulate the heating tank and cover it in a protective layer without exceeding the height requirements. The disadvantage to this design is the need to design a circuit that meets the general requirements for any circuit to be connected to a standard 120V wall outlet.

3.2.2.3.3 Heat Exchanger

3.3 Functional Decomposition - Steven

3.3.1 Black Box Model

Based on the Customer Requirements, discussed in Chapter 2.1, the inflows and outflows were simplified using a black box model in Figure #. The bold arrows represent the materials, the light-weight arrows represent the system's energy, and the dashed arrows represent the signals throughout the system. The arrows pointing toward the black box are the inflows (materials, signals, energy) going into the system. The arrows pointing away from the box are the outflows. The overall objective of the black box is contained within the box itself. The black box model aided the team in developing a more advanced breakdown, known as the Functional Decomposition model in Section 3.3.2.

Figure 5. CVC Black Box Model

3.3.2 Functional Model/Work-Process Diagram/Hierarchical Task Analysis

Due to the array of moving parts throughout the system, a simple flowchart would not suffice. Using the black box model in Chapter 3.3.1, a Functional Decomposition model was developed (see Appendix A). The functional decomposition model uses the same notation as a black box model, but creates a breakdown of each step throughout the device's process. Each step was conceived from the customer requirements and the preliminary vessel cleaner design. Using the functional decomposition, the team created several preliminary designs for their concept generation phase in Chapter 4.

4 CONCEPT GENERATION

4.1 *Full System Concepts-*

4.1.1 Full System Design #1: Compact Vessel Cleaner Alpha

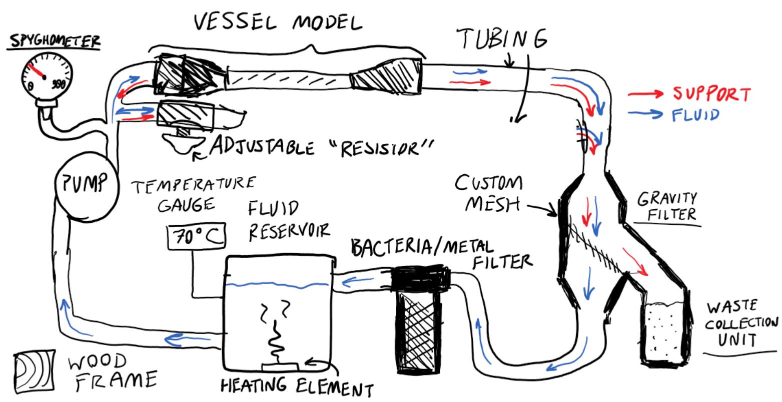


Figure 6. Compact Vessel Cleaner Alpha Design

4.1.2 Full System Design #2: Compact Vessel Cleaner Beta

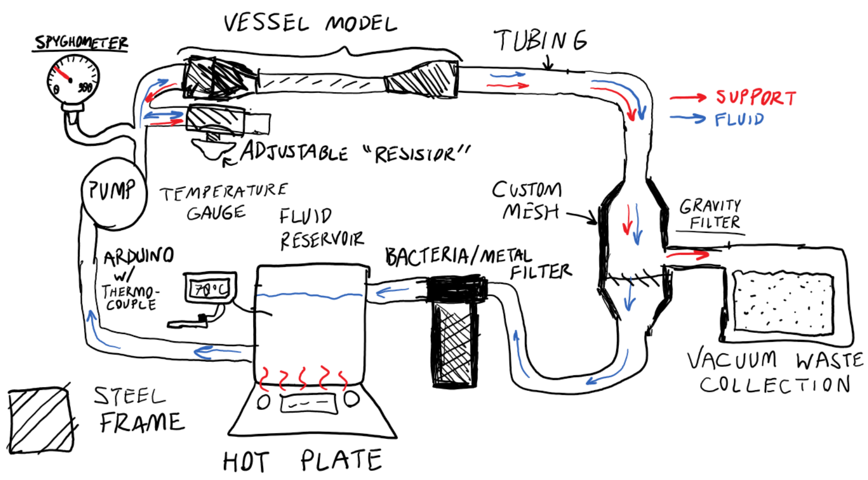


Figure 7. Compact Vessel Cleaner Beta Design

4.1.3 Full System Design #3: Compact Vessel Cleaner Gamma

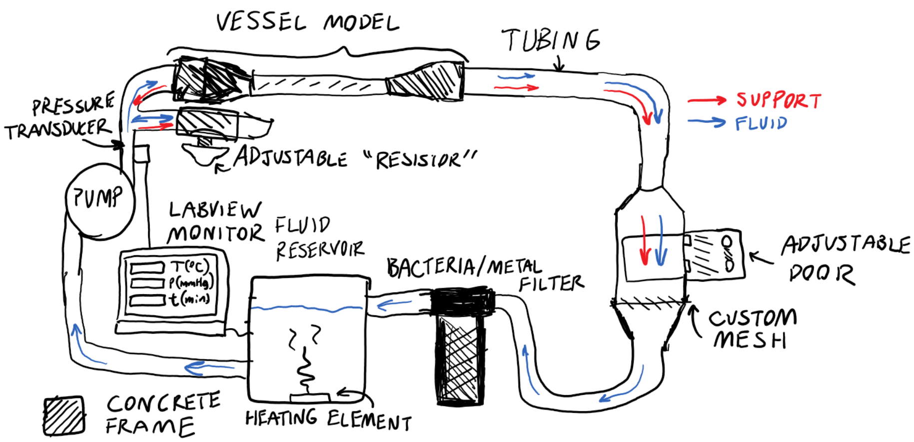


Figure 8. Compact Vessel Cleaner Gamma Design

4.2 Subsystem Concepts

The subsystems that we developed concepts for are heating, filtration, and transportation. Mason developed the transportation concepts, Milo developed the heating concepts, and Steven developed the filtration concepts. These concepts were used to create the full system designs. These concepts were also judged in a decision matrix to see which of each was the best concept. The concepts were developed with the ER, CR, and benchmarking to develop the best most usable concepts.

4.2.1 Subsystem #1: Heating Elements

4.2.1.1 Design #1: Descriptive Title

4.2.1.2 Design #2: Descriptive Title

4.2.1.3 Design #3: Descriptive Title

4.2.2 Subsystem #2: Filtration Methods

4.2.2.1 Design #1: Descriptive Title

4.2.2.2 Design #2: Descriptive Title

4.2.2.3 Design #3: Descriptive Title

4.2.3 Subsystem #3: Transportation

This subsystem is a method of transportation for the entire system. This concept needed to be generated because the total system will be around 50lbs-100lbs and will be hard to move.

4.2.3.1 Design #1: Handles

Handles can be applied to any frame for the cleaning device, making it easy to manufacture. However, one to two people may be required to transport the device depending on the final mass and weight of the device.

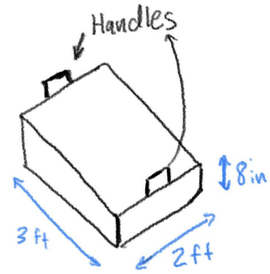


Figure 9. Transportation Design 1: Handles

4.2.3.2 Design #2: Wheels

Transporting the device will be easy on the user with the use of fixed wheels. However, wheels will give the device extra volume with the additional height it creates. Furthermore, the wheels may be difficult to add depending on the material of the frame.

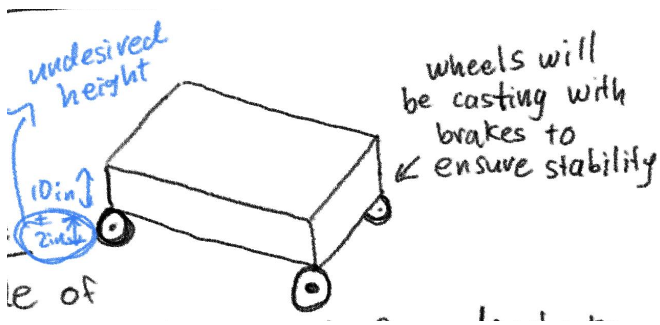


Figure 10. Transportation Design 2: Wheels

4.2.3.3 Design #3: Moving Straps

Transporting the device with straps reduces the likelihood of dropping the device in comparison to the handles. However, this will induce more strain on the user with increased machinery and heavier frames. Just like the handles, this method can be applied to any type of shape.

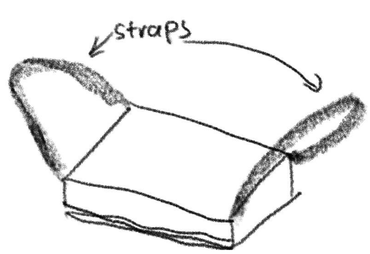


Figure 11. Transportation Design 3: Moving Straps

4.2.3.4 Design #4: Cart

Using a cart simplifies the manufacturing requirements needed with the pump design. However, an oversized model may be difficult to transport with the average cart size. Regardless, the BDL has several carts available for use if transportation is necessary, which makes this the cheapest option.

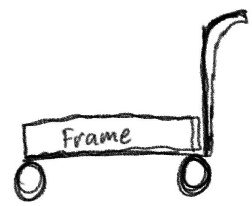


Figure 12. Transportation Design 4: Cart

5 DESIGNS SELECTED – First Semester

5.1 Technical Selection Criteria

5.2 Rationale for Design Selection

6 REFERENCES

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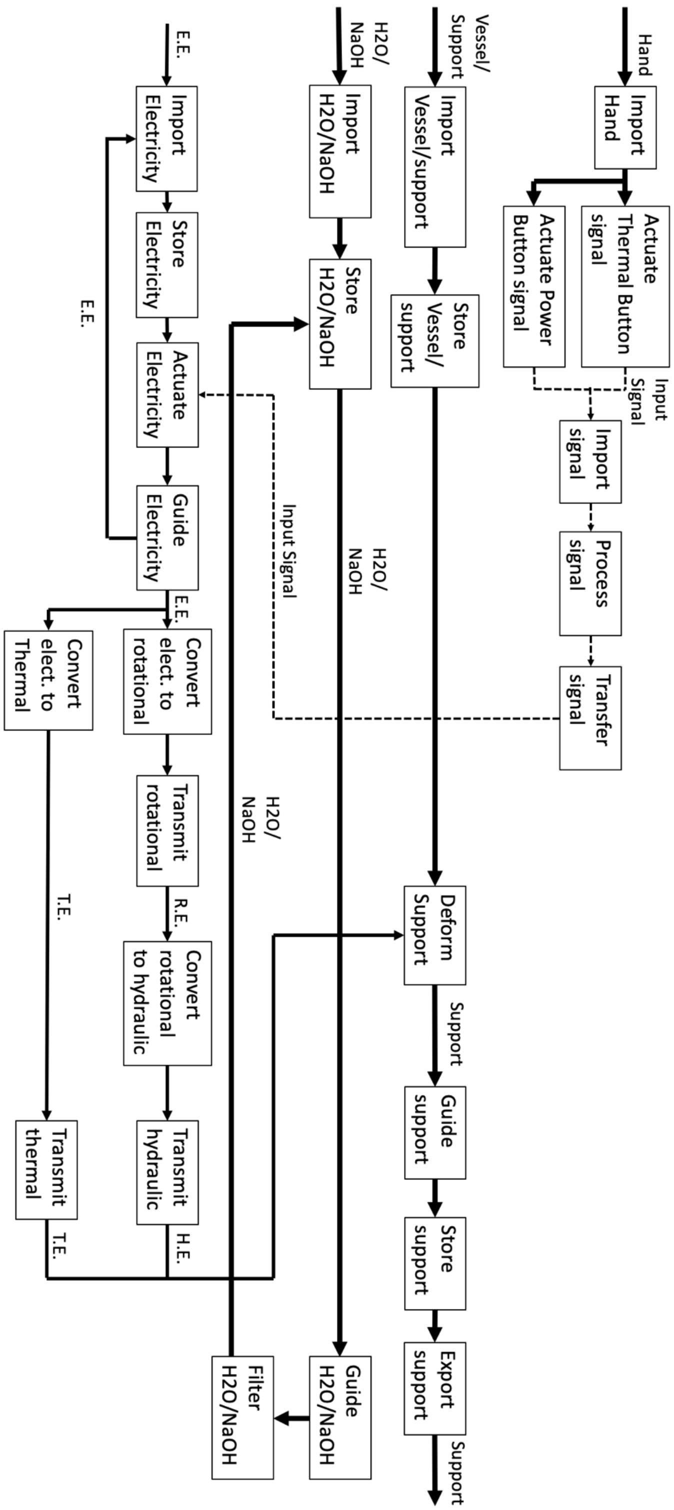
7 APPENDICES

7.1 Appendix A - Functional Decomposition Model



7.2 Appendix C: Bill of Materials