CT Circulation Phantom - BME 200/300

Final Report

BME 200/300 Design

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Abstract

Thousands of people require some form of life support every year [1][2]. The use of one form, Veno-Arterial Extracorporeal Membrane Oxygenation (VA-ECMO) has increased significantly in recent years, especially with the COVID-19 pandemic [1]. Many patients on VA-ECMO require CT diagnostic imaging with the use of iodine contrast. The ECMO machine, however, affects how the contrast media is distributed throughout the body, and there is currently no medical standard for administering contrast to patients on VA-ECMO. While there are several designs of similar CT circulation phantoms used to understand the circulatory system and imaging, nothing exists to mimic VA-ECMO. Therefore, a CT Circulation Phantom is necessary to assist researchers in assessing the best procedure when it comes to patients on VA-ECMO. The design consists of a small acrylic water-filled tank with the top half of the heart situated inside. The heart is connected to a pump that mimics ECMO capabilities, with an iodine contrast injector site. The goal of this project is to allow researchers to identify the best practices regarding VA-ECMO patient imaging, which will in turn improve patient care and outcomes.

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Introduction

Motivation

With the COVID-19 pandemic, cases of heart failure requiring VA-ECMO life-saving machines have been on the rise [1], [2]. These machines allow for a patient to survive without heart function for a short period of time by utilizing an exterior pump and blood oxygenator to take the place of the heart and lungs [2]. Oftentimes, radiologists need to be able to see what is happening inside the patient that is causing the heart failure. This is done using a Computed Tomography (CT) scan [3], and it is often done with an iodinated contrast agent that assists the radiologists in diagnosis. The manner in which the contrast medium mixes with blood is well understood in patients with normal heart function, but there is no medical standard for contrast administration to patients who are on VA-ECMO life support. Additionally, because the iodine contrast administered is radioactive, radiologists seek to limit the amount of contrast used [4]. A dynamic flow phantom is needed to determine the best practices for these patients.

Current Methods and Existing Devices

There are existing studies using similar cardiovascular system models and studying the use of contrast media. Examples of these studies include *Reduced Iodinated Contrast Administration in Coronary CT Angiography on a Clinical Photon-Counting Detector CT System: A Phantom Study Using a Dynamic Circulation Model* [5], which had the goal of determining the least amount of contrast for the best quality of CT image, *Intravascular Enhancement with Iodine Delivery Rate Using Different Iodine Contrast Media in a Circulation Phantom* [6], which studied how iodine delivery rates are dependent of iodine concentration, and *Contrast Media Injection Protocol Optimization for Dual-Energy Coronary CT Angiography: Results from a Circulation Phantom* [7], which investigated the minimum iodine delivery rate to achieve diagnostic coronary attenuation. These models all focused on iodine delivery rates and concentrations in individuals not on VA-ECMO. This design will specifically allow researchers to determine how VA-ECMO affects iodine delivery.

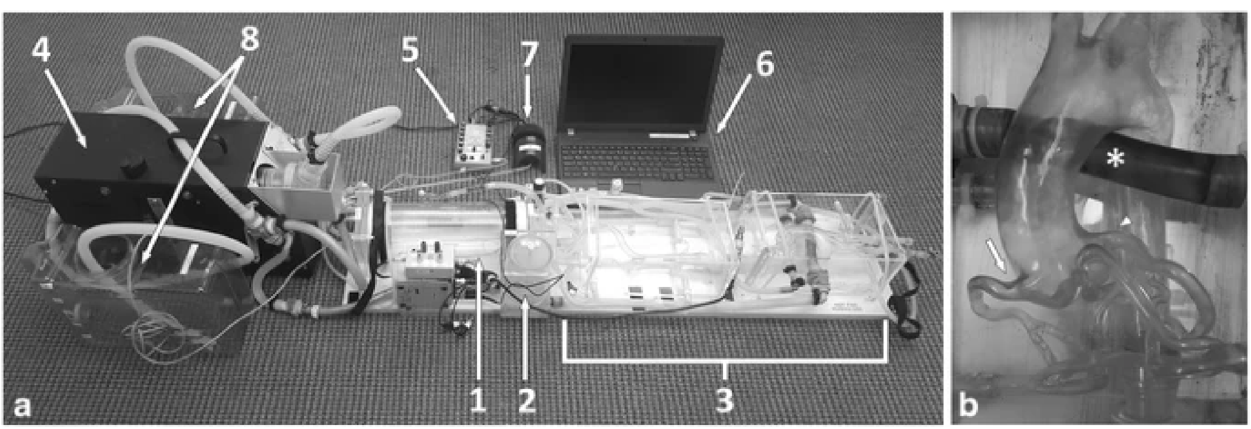


Figure 1: *An example of a circulation phantom used to determine minimum IDR for diagnostic coronary attenuation [7]*

Problem Statement

No medical standards currently exist to guide radiologists in the administration of iodinated contrast for CT imaging of patients on VA-ECMO. Researchers need a safe way to study and determine the best practices regarding these procedures. Therefore, the team was tasked with creating a computed tomography phantom to assess hyperdynamic flow rates in VA-ECMO patients. The phantom will include pertinent, anatomically accurate sections of the heart, an iodinated contrast injector site, and a fluid flow circuit meant to replicate the flow of blood in a VA-ECMO device. The goal of this device is to assist researchers in determining the correct procedure when imaging VA-ECMO patients, which in turn will improve patient outcomes.

Background

Client Information

The client, Dr. Giuseppe Toia, is a part of the Department of Radiology at University of Wisconsin School of Medicine and Public Health and is also an Assistant Professor in Abdominal Imaging and Intervention. Dr. Toia's academic focus includes radiology physics, specifically CT imaging, and optimization [8].

Biological Background

For the design, knowledge of human anatomy is key because the goal of the phantom is to mimic the behavior of the circulatory system in order to get physiologically accurate results to study. This phantom will simulate a patient connected to a VA-ECMO machine, which relieves the heart and lungs while the machine oxygenates and pumps blood throughout their body on their behalf [9]. The phantom was modeled off the dimensions of a healthy adult's heart. The human heart is approximately the size of a fist, with the length, width, and thickness being 12 cm, 8 cm, and 6 cm respectively [10].

Materials Background

While the phantom design does not need to follow FDA guidelines regarding CT phantom dimensions and materials [11], the items used should be compatible with the CT machine and safe for human use. While there are no materials that pose a safety hazard when imaged in a CT scanner, metals can interfere with image quality [4]. Specific materials must be used to be as compatible as possible with CT scanners, allow proper flow through the circuit, and effectively mimic a human heart.

Engineering Principles and Relevant Equations Background

The design addresses the need for a dynamic flow phantom that models blood interaction with iodinated contrast agent. To make predictions about the behavior of these fluids, fluid dynamics principles can be applied. The blood pumped from the ECMO machine is around 3-4 L/min [1], and the contrast agent is injected into the bloodstream at 9 mL/s [12]. In order to study the mixing mechanics of these two liquids, it is necessary to classify the flow. For this purpose, the Reynolds number should be determined for each of the liquids [13]:

$$Re = \frac{\rho v L}{\eta}$$

where:

- Re is the Reynolds number (dimensionless)
- ρ is the density of the fluid (kg/m^3)
- ν is the velocity of the fluid (m/s)
- L is a characteristic length (m), often the diameter of the tube
- η the dynamic viscosity of the fluid ($N \cdot s/m^2$)

If the Reynolds number is less than 2000, the flow is characterized as laminar. If the Reynolds number is greater than 4000, the flow is characterized as turbulent. If it lies between these two benchmarks, it is characterized as being in the transitional region. The mixing behavior can be predicted by characterizing blood and the contrast agent in the context of the design's system. The nature of the use of the design can contribute to very high-pressure buildup in various areas of the circuit. It is of critical importance to recognize where the pressures might be most significant. One way to study the pressure of dynamic fluid is by utilizing the Hagen-Poiseuille Equation[14]:

$$\Delta P = \frac{\pi r^4 Q}{8 \eta L}$$

where:

- ΔP is the pressure drop across the length of the pipe (Pa)
- Q is volumetric flow rate (m^3/s)
- r is the radius of the pipe (m)
- L is the length of the pipe (m)
- η the dynamic viscosity of the fluid ($N \cdot s/m^2$)

Ensuring that materials used can withstand the pressure differences in the various components of the phantom will be crucial in avoiding material failure.

In order to develop an imaging procedure for patients on VA-ECMO, the client would like to investigate the characteristics of imaging on the phantom. The metric that will be used is the Hounsfield Unit. This is a relative quantitative measurement for CT images that is indicative of the attenuation coefficient of radiation within materials [15].

Product Design Specifications

The client requests the following specifications:

- A CT phantom with the main components of the heart and circulatory system pertaining to VA-ECMO
    - The right atrium and ascending aorta [2]
- A pump and fluid flow system that models an ECMO device, complete with adjustable flow rates up to 3.0-4.0 L/min and phantom connectability [1]
- An iodinated contrast injector access point
- A reservoir or other method to fill and empty the fluid
- Easily cleaned
- HU enhancement values between 300 and 800 [16]

See Appendix B for the complete Product Design Specifications.

Preliminary Designs

Phantom Designs

Design I. Acrylic Box with 3D Printed Heart with an Open Circuit

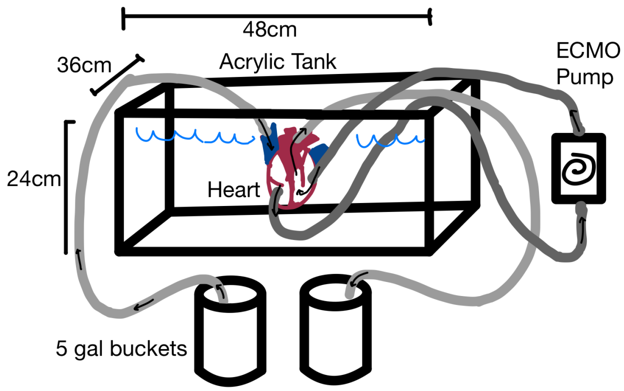


Figure 2*: Schematic showing the open circuit system of the thin-walled 3D print design*

The first phantom design featured an acrylic box filled with water, in which is placed a thin-walled 3D print of the heart. The system starts with the pump pulling water from the reservoir into the heart, through the pump, and finally dumped into the waste container. As with all the phantom designs to be mentioned, the dimensions are such that the phantom can fit into the CT scanner. The typical dimension for a CT gantry is 78 cm, and this and the following designs fit well within the diameter of the opening [17].

Design II. Acrylic Box with 3D Printed Heart with a Closed Circuit

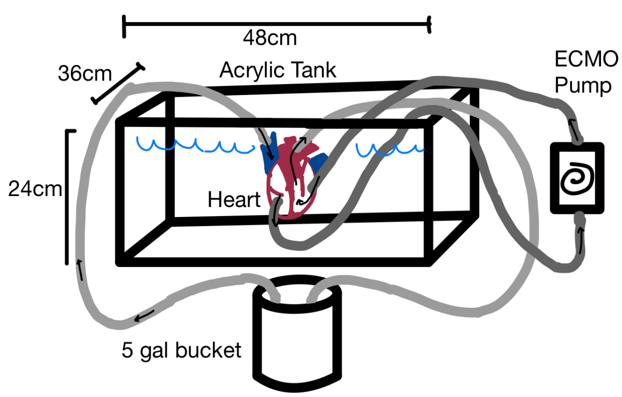


Figure 3*: Schematic showing the closed circuit system of the thin-walled 3D print design*

The second phantom design was very similar to the first phantom design in that it has the same acrylic box and thin-walled 3D print components. The difference comes from the system design. This system is a closed loop meaning that the water moves continuously through the tubing, heart, and pump without any external reservoir or waste components.

Design III. Negative Space Phantom with an Open Circuit

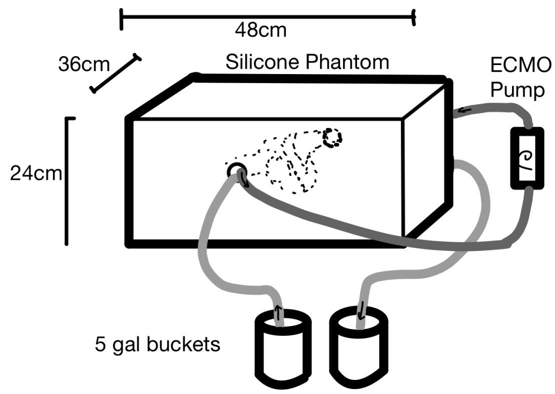


Figure 4: *Schematic showing the open circuit system of the negative space silicon mold design*

The third phantom design featured a solid silicone rectangular prism with the heart 3D print and necessary space for tubing removed from the silicone. The system starts with the pump pulling water from the reservoir into the heart, through the pump, and dumping into the waste container.

Design IV. Negative Space Phantom with a Closed Circuit

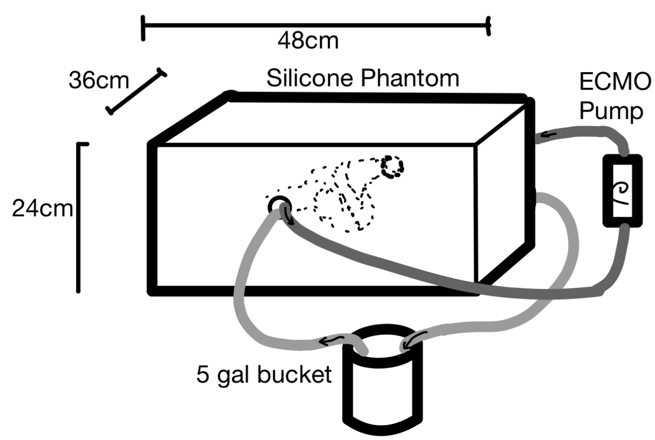


Figure 5: *Schematic showing the closed circuit system of the negative space silicon mold design*

The fourth phantom design was very similar to the third phantom design in that it had the same negative space heart model component. The difference comes from the system design. This system is a closed loop, meaning that the water moves continuously through the tubing, heart, and pump without any external reservoir or waste components.

ECMO Circuit Designs

Design I. ECMO Device

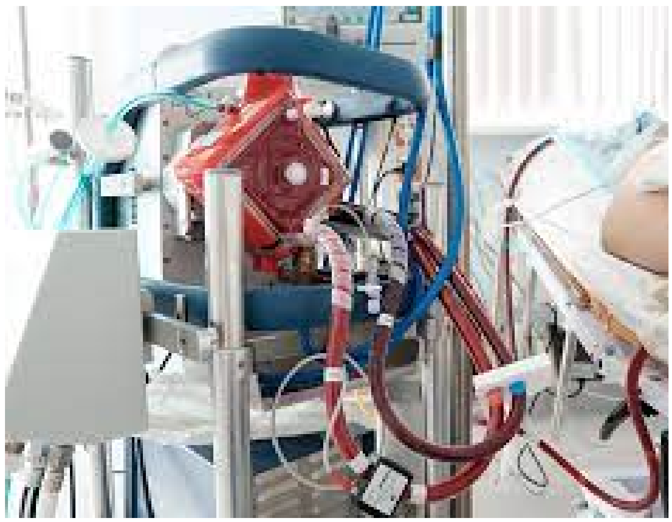


Figure 6: *Patient on an Extracorporeal Membrane Oxygenation Device [18]*

The most accurate way to achieve a phantom that mimics ECMO capabilities would be to use an ECMO machine. This would ensure the correct flow rates and the ability to modulate them. However, ECMO machines are expensive, bulky, and have functions that the phantom does not need, such as oxygenation.

Design II. Centrifugal Pump

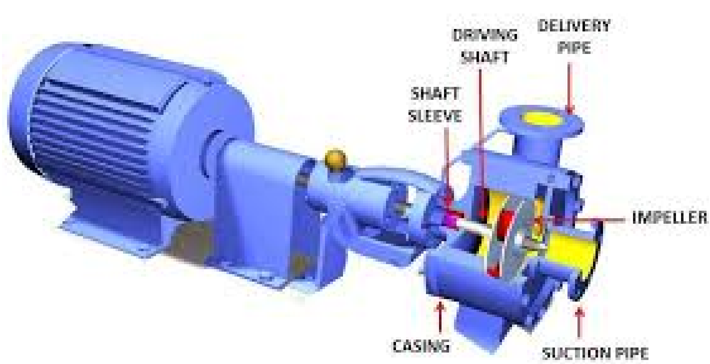


Figure 7: *Schematic of a Centrifugal Pump [19]*

The second pump idea was a centrifugal pump. This design works well because a centrifugal pump is the main pump currently used in ECMO devices [20]. Therefore, it will work well as it can mimic the flow rates of the ECMO machine while avoiding unnecessary functions and costs. The main component of a centrifugal pump is the impeller. This impeller, or rotor, rotates quickly and casts fluid out of the delivery pipe via centrifugal force. This creates a suction pressure that brings more fluid in through the suction pipe, which is stationed at the 'eye' of the impeller [21]. Centrifugal pumps are well suited to low-viscosity, high-velocity applications [21]. A centrifugal pump works well because the circulation phantom needs to pump fluid (water) out quickly (around 3-6L/min). These pumps can sometimes be costly, but not nearly as expensive as an ECMO device.

Design III. Pulsatile Pump

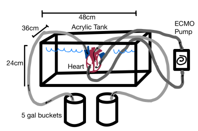
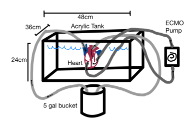
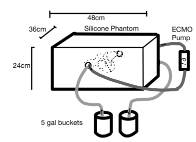
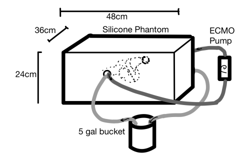
Figure 8: *Harvard Apparatus Pulsatile Pump [22]*

The third pump considered was a Pulsatile Pump, which works by imitating the beating action of a heart. Many studies have used a pulsatile pump in their applications successfully, for example determining whether pulsatile flow or constant flow is best in a cardiopulmonary bypass [23]. It is a similar cost to the centrifugal pump, if not slightly more affordable. However, this phantom design mimics patients with little to no cardiac output, so a pulsatile feature is not necessary.

Preliminary Design Evaluation

Design Matrix

Table 1: Phantom Design Matrix: *Weighted Score = Weight*(Score/5)*

<table>
<tr><th>Phantom</th><th></th><th colspan="2">Acrylic Box with 3D Printed Heart with an Open Circuit</th><th colspan="2">Acrylic Box with 3D Printed Heart with a Closed Circuit</th><th colspan="2">Negative Space Phantom with an Open Circuit</th><th colspan="2">Negative Space Phantom with a Closed Circuit</th></tr>
<tr><td>Pictures</td><td></td><td colspan="2">
</td><td colspan="2">
</td><td colspan="2">
</td><td colspan="2">
</td></tr>
<tr><td>Criteria</td><td>Weight</td><td>Score (max 5)</td><td>Weighted Score</td><td>Score (max 5)</td><td>Weighted Score</td><td>Score (max 5)</td><td>Weighted Score</td><td>Score (max 5)</td><td>Weighted Score</td></tr>
<tr><td>Anatomical Accuracy</td><td>30</td><td>3</td><td>18</td><td>4</td><td>24</td><td>2</td><td>12</td><td>3</td><td>18</td></tr>
<tr><td>Ease of Fabrication</td><td>25</td><td>5</td><td>25</td><td>5</td><td>25</td><td>2</td><td>10</td><td>1</td><td>5</td></tr>
<tr><td>Maintenance</td><td>20</td><td>5</td><td>20</td><td>4</td><td>16</td><td>4</td><td>16</td><td>3</td><td>12</td></tr>
<tr><td>Duration of single-use</td><td>15</td><td>3</td><td>9</td><td>5</td><td>15</td><td>3</td><td>9</td><td>5</td><td>15</td></tr>
<tr><td>Cost</td><td>10</td><td>4</td><td>8</td><td>4</td><td>8</td><td>2</td><td>4</td><td>2</td><td>4</td></tr>
<tr><td>Sum</td><td>100</td><td></td><td>80</td><td></td><td>88</td><td></td><td>51</td><td></td><td>54</td></tr>
</table>

Anatomical Accuracy: Anatomical accuracy describes how closely the phantom mimics actual circulatory function. This category was weighted highest because this criterion is crucial to the design being able to solve the client's problem. They need a device that simulates conditions well enough that it can be used to calibrate CT settings and other variables for clinical use. Without achieving anatomical accuracy, the design does not accomplish its main function. Each design loses a point from the maximum due to none of the designs replicating the size and shape of an entire human torso. Between the Acrylic Box with 3D Printed Heart designs and the Negative Space Phantom designs, the former scored higher due to the water being more physiologically accurate than the silicon in the negative space phantom. In comparing the open circuit designs with the closed circuit designs, the closed circuit designs were deemed more anatomically accurate due to the closed circuit better representing the human circulatory system.

Ease of Fabrication: Ease of fabrication refers to how difficult it would be to make a functioning phantom with the tools and skills within the team's capabilities. This criterion includes a consideration of the time of fabrication and prototyping, the cost of fabrication and prototyping, and how easy it would be to work with the materials. It is the second highest weighted criterion because the production of a functional prototype is an integral step towards meeting the requirements of the design specifications. In general, both acrylic box designs score much higher than the negative space designs for these criteria. Creating an acrylic box is, generally speaking, pretty easy, and it wouldn't take many iterations to produce, and adjusting the internal circuitry wouldn't be difficult. The most complicated piece would be the heart, but that is also a piece that can be 3D printed. Between the open and closed variations of this design, the open design would be easier to fabricate because there would be more considerations to make the closed circuit anatomically accurate. The negative space design would be very difficult to fabricate for two main reasons. First, designing a heart in negative space that is both sturdy and moves the solution correctly would be very difficult to design. Secondly, if anything isn't correct with the design, the entire design of the mold would have to change and be reproduced—a time and cost-intensive process. For these reasons, the Acrylic box design with an open design scored the best for ease of fabrication.

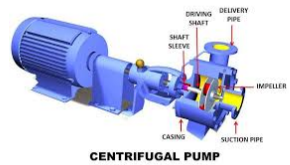
Maintenance: Maintenance of the design describes the capability of the design to be cleaned after each trial. The contrast agents that are to be used tend to dry and get sticky if not thoroughly cleaned after use. This was determined to be of middle importance in the weighting process because the quality of the design after multiple uses will be better with a design that is easier to clean. However, this aspect of the design is not absolutely crucial to its function. Between the open and closed circuit designs, the closed circuit designs automatically scored lower. In the closed circuit, it would be very difficult to flush new water through the tubing while having a way for the old water with the contrast agent moved out. In comparing the Acrylic Box designs with the Negative Phantom designs, the Negative Phantom scored worse due to the material around the "heart" being harder to clean. In the Acrylic Box design, the water around the heart can just be removed and replaced in the case of a leak or other mishap. In the case of the negative phantom, if the solution were to leak, it could get trapped in the silicone and cause issues with future scans.

Duration of Single Use: This design criteria specifies how long the product can be used continuously. It is important that the product be able to last through at least one CT scan. However, because CT scans are very quick (less than a minute), this criterion was given less weight than the other criteria (save for cost). The closed circuit designs scored better in this category because they have no constraint for the amount of time they can run. The time constraint for the open circuit designs is based on the amount of water in the system.

Cost: The cost refers to how much money each design would require for all of its components. This includes both the market value of a new item and takes into consideration the portions that can be fabricated from already obtained parts. While it is important to be cognizant of the client's resources, this criterion was rated lowest because each of the phantom designs is similar in cost and because client funding prioritizes a functioning prototype. The two acrylic box designs were rated well because acrylic sheets are cheap and accessible, as well as water. The open and closed circuits' components are also expected to cost the same. The negative space phantom was rated lower because the price and volume of silicone needed are more expensive than the acrylic box phantom.

Table 2: ECMO Circuit Design Matrix: *Weighted Score = Weight*(Score/5)*

VA - ECMO		ECMO Machine	Centrifugal Pump	Pulsatile Pump

Circuit							
Pictures							
Criteria	**Weight**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**
Adjustable Flow Rates	25	5	25	4	20	3	15
Compatibility	20	3	12	4	16	4	16
Usability	20	2	8	5	20	5	20
Maintenance	15	2	6	4	12	4	12
Safety	10	5	10	3	6	3	6
Cost	10	1	2	3	6	5	10
Sum	**100**	**Sum**	63	**Sum**	80	**Sum**	79

Design Criteria:

Adjustable Flow Rates: The adjustable flow rates category describes the ability of a design to adjust the flow rate of the fluid through the ECMO/phantom circuit. This category was ranked as the most important for the VA-ECMO design because the main goal of the design/project is to address the current lack of knowledge on CT scanning phantoms with dynamic flow rates. The ECMO machine scored a perfect five out of five because it has complex components, such as a pump and a flowmeter, already built into it, which allow the operator to easily monitor and measure the flow rate as well as adjust it in real-time. The second device, the centrifugal pump, had the second highest score of four out of five compared to the pulsatile pump, which scored the lowest with a three out of five. The centrifugal pump scored higher than the pulsatile pump in this category because the centrifugal design has a constant flow rate that can be more easily adjusted versus the more difficult-to-adjust pulsing flow of a pulsatile pump.

Compatibility: The compatibility category describes how easily the VA-ECMO design/substitute can be incorporated into the entire design/circuit as a whole. The circuit consists of various parts, such as the phantom, which must be connected to mimic a patient's anatomy on a VA-ECMO machine. The compatibility category was tied for the second most important category because it is vital to the design that the VA-ECMO design works with the phantom and the rest of the circuit. For the flow of the iodinated contrast to properly mimic a patient's blood flow in a CT scanner, the device needs to connect properly without leaks and provide a means to measure the flow rate correctly. Both the centrifugal and pulsatile pumps scored the best with a four out of five, while the ECMO machine scored last with a three. This is because the two pumps are independent components and can more easily be connected to the circuit via tubing. The ECMO machine is more complicated than the two pumps and would, therefore, be less compatible with the design of the circuit, which requires just one input and one output for the pump.

While the ECMO has more functionality than the two pumps, the requirements of the project are better suited by either the centrifugal pump or the pulsatile pump.

Usability: The usability category describes how easily and how effectively the device can be used by the person operating it. It was tied for the second most important category because a key aspect of the design is that it can be used by the clients to effectively address any clinical or research questions they may have in regard to ECMO and CT scans. The centrifugal and pulsatile pumps scored the highest with five out of five because they are straightforward, independent devices requiring little training. The ECMO machine, on the other hand, is far more complicated as it has more uses. This caused it to score the lowest with a two out of five, because it takes more knowledge and training to operate properly. In order to optimize the efficiency and effectiveness of the device, the circuit needs to be, technically speaking, as straightforward as possible to remove any operating difficulties.

Maintenance: Maintenance was ranked fourth at a weight of 15 because, in an ideal this device would be able to be used for years to further knowledge and understanding of the blood flow rates and patterns of patients on VA-ECMO machines. In order to guarantee the longest possible lifespan for this device, it may need occasional maintenance upkeep. The ECMO machine was ranked the lowest as it is the most complex of the three pumps. Unless the operator had prior experience with ECMO machines, fixing any possible issues would likely be difficult. The centrifugal pump and pulsatile pump were both ranked at a 4. This is because both pumps are relatively simple machines, so even if the operator had no prior experience with the equipment, they should be relatively simple to work with.

Safety: The safety category depicts the risk of injury for the technician who performs a scan on the phantom. This was rated relatively low in the weighting of the matrix because the project itself does not pose a very big risk of injury. The phantom does not directly impact patient care, making it less important in the design. The ECMO machine received a perfect rating because there are numerous federal regulations and other medical standards that ensure that the ECMO is safe to use in a clinical setting. Another reason why the ECMO scored higher than the other two pumps is that the ECMO is designed specifically to pump fluid through the human circulatory system, which the design aims to mimic. The other two pumps lost a point in their respective scores due to the fact that they were not designed to pump through the human circulatory system. However, the two other designs still score highly because the risk of injury would not be high in the case of some type of mechanical failure in the design.

Cost: Cost is determined based on either the market value for the pre-existing devices or the estimated cost to fabricate the pump. The client did not provide an explicit budget and believed that they would be able to source components for the team to borrow for the duration of the project. Because of this, cost was weighted as least important. The ECMO machine was ranked at a 1 for cost. An ECMO machine can cost upwards of $100,000 and, therefore, is not a realistic option for the design. The centrifugal pump was ranked the next highest at a 3. ECMO circuits on the market that utilize centrifugal pumps cost around $10,000, which is still out of the budget range. The pulsatile pump was given a 5 as they can be purchased online for just a few hundred dollars.

Final Design

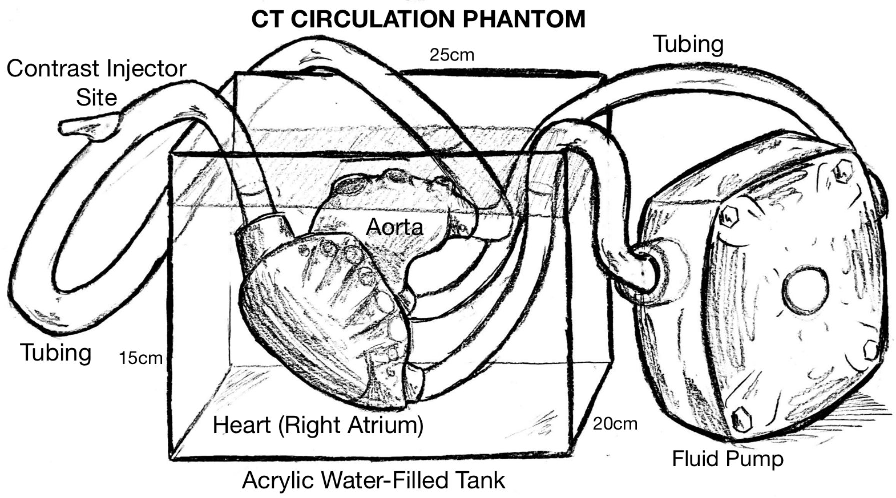


Figure 9: *Final design sketch. See below for an image of the completed fabricated prototype.*

Fabrication and Development

Materials

The materials of the device can be broken down into two separate categories: the pump and the phantom. The pump was borrowed from the UW Cardiovascular Fluid Dynamics Laboratory in the Departments of Mechanical Engineering and Radiology. The lab only had one pump available, which was the roller pump featured in figure 10 below. This type of pump was not examined in the preliminary design stage. However, it performed adequately for the final prototype.

Figure 10: *Roller pump borrowed from the UW Cardiovascular Fluid Dynamics Laboratory. The left image shows a top-down view with the motor information, and the right shows the roller pump information.*

The phantom was modeled using a heart stereolithography file, which was imported into Meshlab, Meshmixer, and Blender, where it was modified to fit this design's needs. The model was then printed on the Stratasys out of ABS M30 resin. ⅜" diameter vinyl tubing connected the heart, injection site, and pump. The tubing produces the same pressure gradient that a typical VA-ECMO produces. VA-ECMO tubing pressure gradients vary widely, from 13 up to 60 mmHg, which is easily handled by the rugged vinyl [24]. Standard ⅜" tubing connectors joined the components. Epoxy resin was used to seal any cracks, which ensured a tight seal with no leaks. A contrast is also needed when testing a phantom and is injected intravenously via computer-controlled contrast injectors. To accommodate for this, an injection site was added on the tubing so that a built-in contrast injector is not needed. The injection site was modeled in Solidworks and utilized a pre-existing Butterfly luer-lock stereolithography file. It was printed with PLA on the Ultimaker printers at the UW Makerspace.

See Appendix A for the detailed budget.

Methods

To make the acrylic box, ⅛" clear acrylic sheets from the UW Makerspace were measured, marked, and cut into 5 pieces. This created a box with final dimensions of 25 cm x 20 cm x 15 cm. The pieces were glued together by two-part Epoxy, also sourced from the Makerspace. Additional Epoxy was spread on the inside of the box to ensure the design is water tight.

The phantom heart was created with 3D modeling, as seen in figure 11 below. The right atrium was modeled from a stereolithography file of both atria found on Printables [25]. In Meshlab, the atria model was cut and remeshed to get only the right atrium. The aorta file from Cgtrader was imported into Meshmixer, hollowed, and then cut to size [26]. After completion of the individual parts, both files were loaded into Blender and combined into one object and remaining holes were filled. The final model can be seen in figure 12.

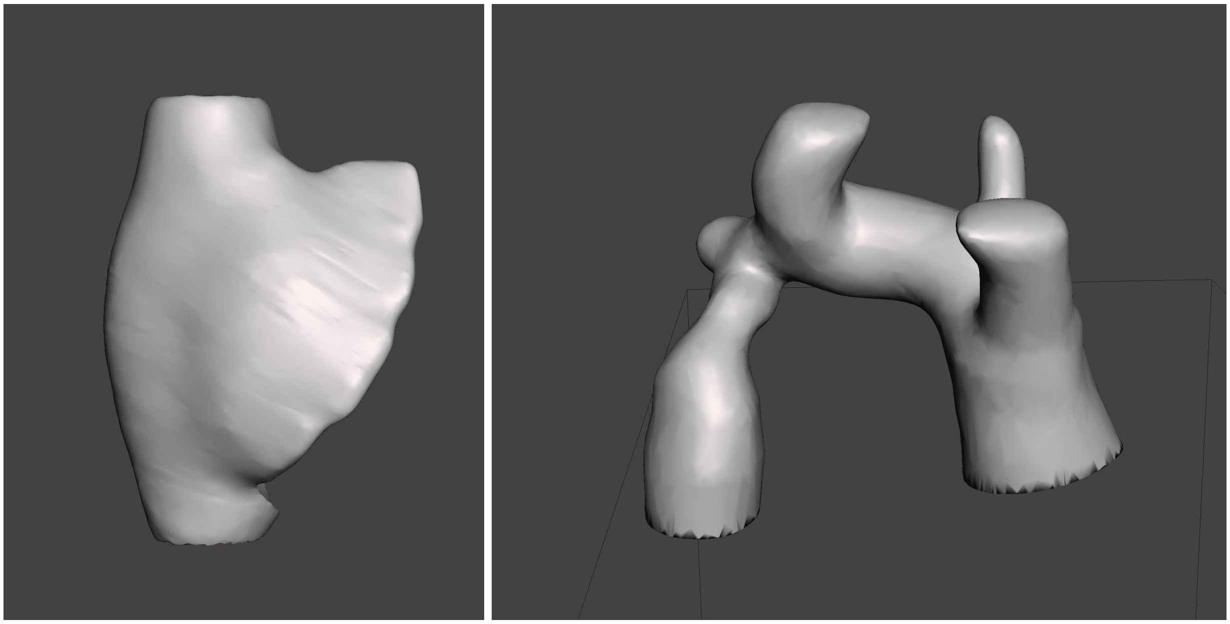


Figure 11: *3D model of the right atrium (left) and 3D model of the aortic arch (right). The arch is hollow, but the top portions are closed off so as to have only one flow output.*

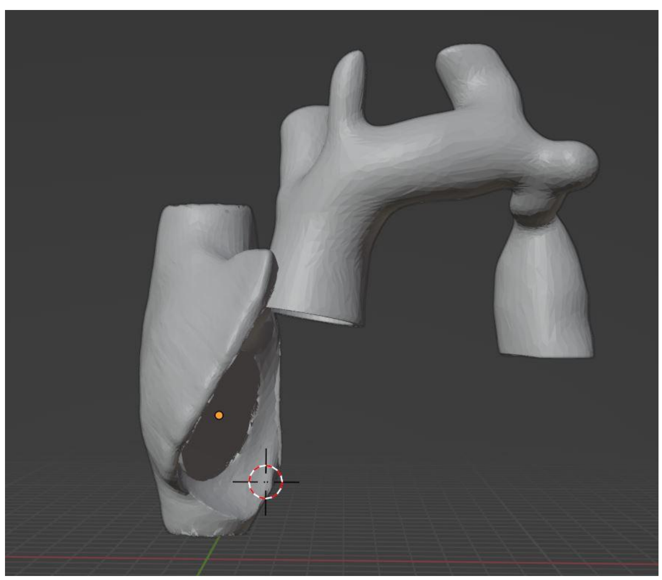


Figure 12: *3D model of the combined right atrium and aortic arch.*

This combined file was exported as a stereolithography file and printed on the Stratasys printer out of ABS resin with dissolvable supports. After printing, standard tubing connectors were glued onto the ends of the atrium and aorta using Epoxy and additional clear acrylic to fill gaps. See figure 13 below for the complete heart phantom.

Figure 13: *Printed heart phantom with connectors secured with Epoxy and clear acrylic to fill any gaps. The right atrium is on the left in the above image, and the ascending aorta is on the right.*

The injection site was modeled using Solidworks and a pre-existing luer-lock file from GRABCAD [27]. An Ultimaker in the Makerspace printed the piece shown in figure 14 out of PLA. Standard connectors were fitted into the piece at each end using a mallet. The iodinated contrast injector fit snugly into the piece, which prevents backflow and leakage.

Figure 14: *Printed injection site with connectors on both ends and the luer-lock extruding from the top.*

Final Prototype

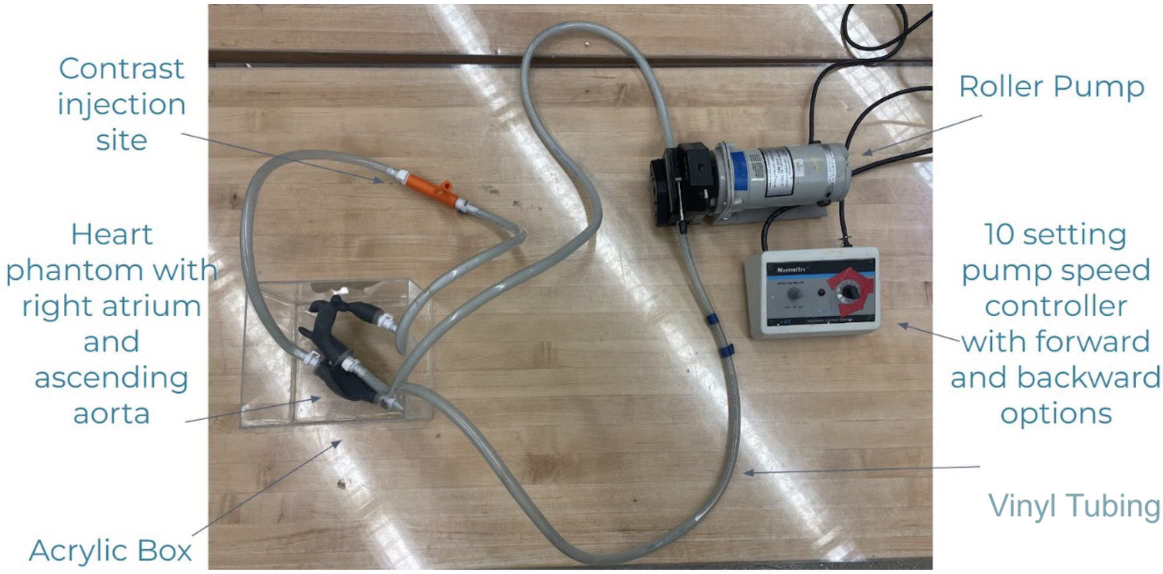


Figure 15: *Final fabricated circulation phantom prototype with acrylic box, heart phantom, injection site, roller pump, speed controller, tubing, and connectors*

Testing

Flow Rate Testing

Flow rate testing was performed to gain initial insight into the speeds of the dial settings of the circuit pump. The test was done by filling the tubing with water, setting the dial to an unknown setting, running the pump for 15 seconds, and finally measuring the collected water. The water was then weighed and converted into volume units. The process was repeated 3 times for each of the 10 dial settings on the pump.

Flow Rate Verification

In order to ensure the accuracy of flow rates, a flow rate verification was performed. A flow meter was utilized to measure the exact flow rates of the dial settings. The process involved filling the system with water and attaching the flow meter to the circuit. A dial setting was chosen, and the flow rate was measured for 15 seconds. These experimental values were then compared to the initial flow rate testing values.

CT Scan Testing

The CT scan testing aimed to verify that the attenuation of contrast in the flow phantom is similar to that of a real patient and the values provided by the client. It also served to determine the amount of time it takes for the CT contrast to mix fully with the water. The test was performed by first setting up the water-filled device circuit on the CT machine. The device incorporates a connector that allows the client to use a proprietary CT contrast injection machine. Once the injector is connected, the pump flow rate is set to 3.5 L/min, similar to that of a VA-ECMO device. The pump is run for 30 seconds prior to the CT scan. This is done to simulate a patient on ECMO life support receiving a scan. The CT scan was run in 24 series with 86 pictures per series. Multiple series were incorporated to scan the same location of the phantom at different points in time. Once scanned, a region of interest identified by the client was evaluated to derive Hounsfield Units (HU). Hounsfield Units of the region of interest were plotted and analyzed at different points in time. See figure 16 below for an image of the testing setup.

Figure 16: *Complete flow phantom set up on the CT machine in the Wisconsin Institute for Medical Research Building for testing*

See Appendix C for the complete testing protocol.

Results

The initial flow rate testing produced data that were analyzed to determine a linear regression model to predict the flow rate output based on the categorial dial number. It was determined that the flow rate can be predicted using the line of best fit displayed in the bottom right corner of figure 17. Further testing was performed to determine the accuracy of the linear regression model.

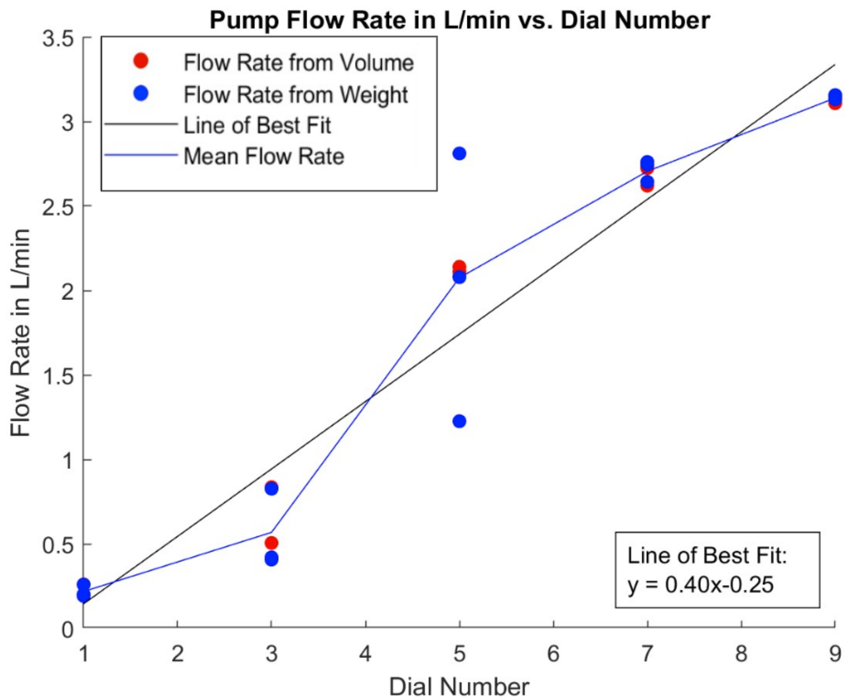


Figure 17: *Flow rates measured from three calculated flow rate tests which recorded both volume and weight*

The data collected from the flow rate verification test was also imported into MATLAB to perform statistical analysis. Figure 18 below shows the calculated measurement from the linear regression model versus the flowmeter measurement for each pump flow rate that was tested. A paired-sample T-Test was performed on the two datasets to determine the accuracy of the linear regression model. This test determined that the samples fail to reject the null hypothesis. It was concluded that there was no statistically significant difference between the samples and the model is an accurate method to determine the flow rate produced by the pump. Both the flow rate testing and the flow rate verification tests concluded that the design specification of creating a phantom with adjustable flow rates (3.0-4.0 L/min) has been met.

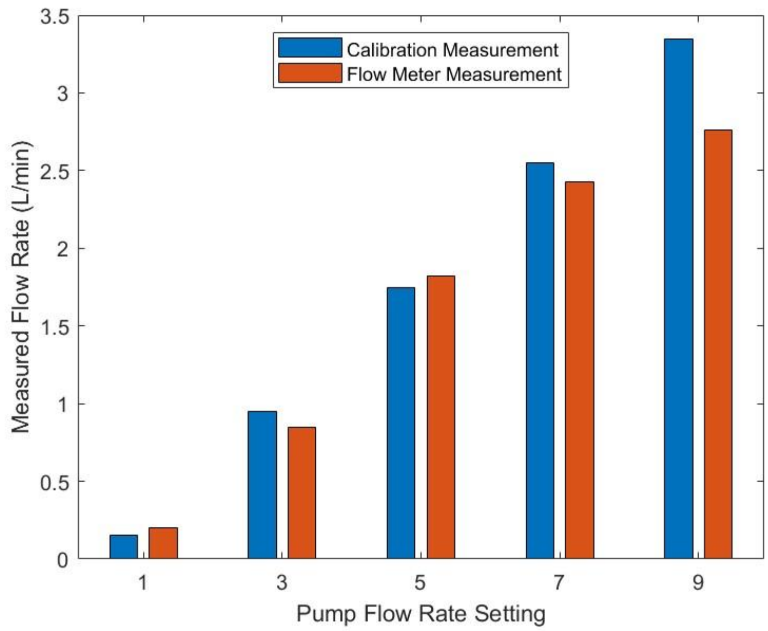


Figure 18: *Flow rates measured in calculated testing versus with a flow meter for the odd-numbered categorical dial settings.*

The CT test of the phantom was the final and most insightful test for the design. It first demonstrated the inclusion of an iodinated contrast injector access point as per the design specifications. Although the injector piece needed last-minute taping and sealing support to withstand the pressure from the injector, it successfully moved the contrast agent into the fluid circuit as required. One slice of the phantom at various times in the CT scan is shown in figure 19. Prior to the contrast agent, the average HU in the region of interest was 15.50, after the addition of the contrast agent, the average HU was 1272.91. The difference in the values before and after shows that the contrast agent did successfully mix into the fluid circuit. However, this attenuation value is outside of the range specified by the design specifications.

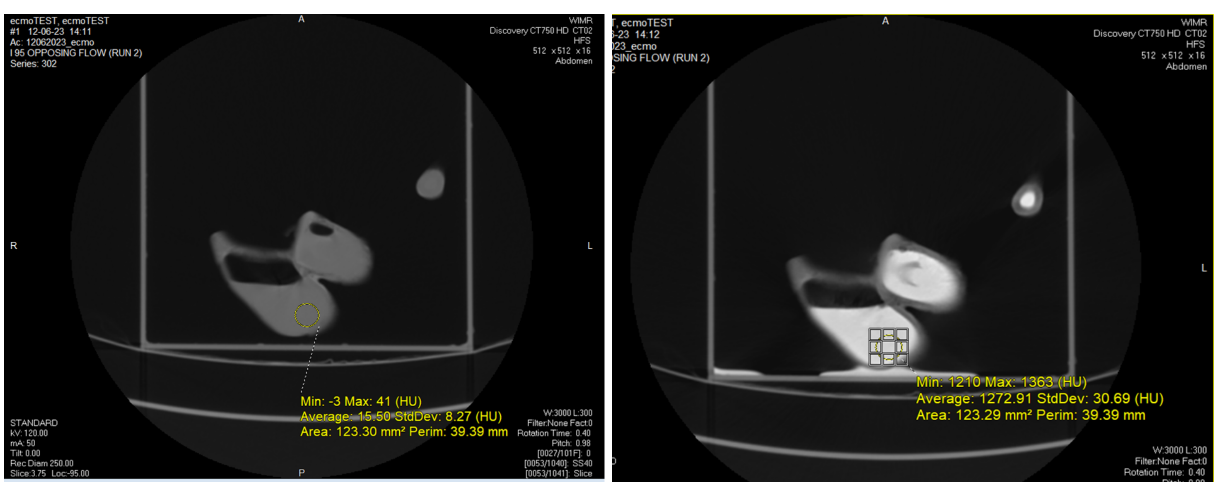


Figure 19: *Side-by-side CT images of the phantom (3 L/sec) at different times during the scan. Left image is prior to the addition of the contrast agent, the right image after.*

Finally, the CT testing demonstrated the amount of time that it takes for the contrast agent to fully mix with the fluid in the circuit could be ascertained with the phantom. As shown in figure 20 below, it could be determined the amount of time that it takes for the contrast agent to fully mix with the fluid circuit, and the relative HU to become constant over time in the region of interest. From the plot it was estimated that the contrast agent fully mixes in the phantom after about 25 seconds.

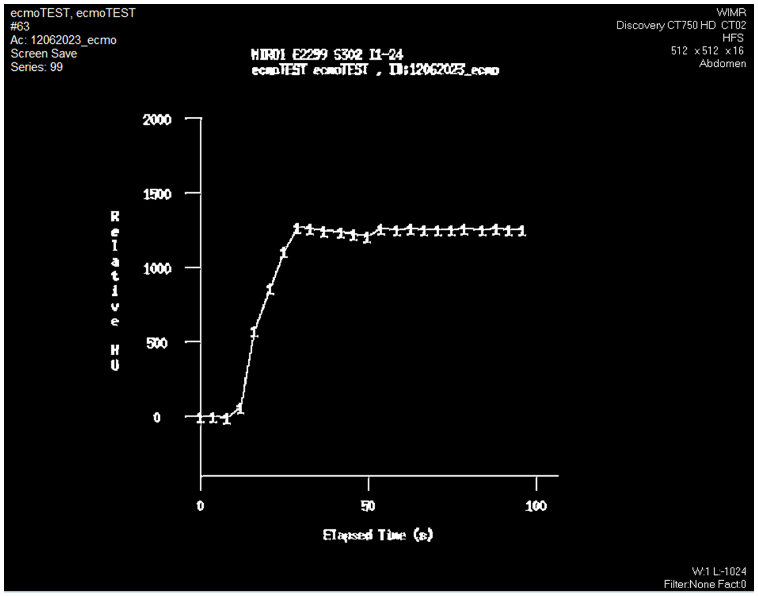


Figure 20: *This plot features the temporal variation in relative Hounsfield Units for the region of interest in the scans from figure 19.*

Discussion

It is important to discuss and acknowledge the ethical considerations of this product. Those who need to be put on VA-ECMO are in a vulnerable and delicate state, and thus, adequate precautions must be taken in administering care to them. If the device is unable to produce accurate and reliable results, it can not be used to determine appropriate injection rates for the patients. Along with this, it is also important to recognize that this device is designed and fabricated to mimic the flow rates of patients on Veno-Arterial ECMO (VA-ECMO). If it is desired to calculate the injection rates for patients on Veno-Venous ECMO machines (VV-ECMO), further research should be done, and the necessary adjustments should be made to the device.

According to relevant research, inaccurate contrast injections or imaging techniques can result in an incorrect analysis of a VA-ECMO patient's current condition [28]. Because of this risk, accurate and quick images must be taken under dynamic blood and contrast flow conditions. The results of the device's testing establish that the device can be tested to provide accurate measurements of relevant parameters such as Hounsfield Units per second. As a result of testing and evaluation, the device could be altered to facilitate for VV-ECMO flow by altering the 3D model of the heart to include the right atrium and the vena cava. For this version of the device, the flow would enter the inferior vena cava and exit through the superior vena cava. By having a 3D model for both types of ECMO devices, the client and other researchers would be able to apply the device to more patients and make a greater impact.

One possible source of error in the determination of the linear regression model used to determine the flow rate was that only the odd dial numbers were measured in the trials. The procurement of more data for the even dial numbers would contribute to a more accurate flow rate prediction. The flowmeter could have collected the even dial number data to optimize the process. A possible error in the flow rate verification test is that the verification data was collected with the completed circuit with the phantom, whereas the initial flow rate test was performed with only the pump and tubing. While this most likely did not make a significant error, recalibrating the curve with the flowmeter and the completed circuit would eliminate this source of error. One of the possible errors from the CT testing could be that there was too much contrast agent added relative to the amount of water that was initially in the circuit. This error could be the reason the relative HU measured in the right image of figure 19 was much higher than the value range outlined by the design specification. Another possible error from the CT testing could be that the small volume of fluid in the phantom leads to an inaccurate measurement of the time it takes for the contrast agent to fully mix. More research in the physiology of patients using VA-ECMO is required to determine how much more tubing and heart modeling is needed to get a satisfactory measurement of the time it takes to fully mix. Other errors in the testing of the device could come from device and human error, such as losing water during the measurement of the pump's output in the flow rate testing (see Flow Testing Protocol). The dimensions (diameter, length, shape) of the vinyl tubing used in the circuit could cause errors in the CT testing due to not being the exact size, shape, and orientation of the veins/arteries involved in a real patient on VA-ECMO support. Overall, the device allows the client to perform significant and relevant research to further understand hyperdynamic flow in patients on VA-ECMO. Any updates to the device's anatomical accuracy will only improve the device's ability to further the understanding of the heart's physiology and how iodinated contrast mixes with blood.

Conclusions

Future Work

Given the resources, budget, and time frame, the product was satisfactory to the client's needs. However, future work would need to be done to improve the precision and accuracy of the device. Either a VA-ECMO device or a higher power pump would be obtained and incorporated into the circuit. This would allow the circuit to produce flow rates higher than what the roller pump in the original design was able to produce. A new pump system should be designed to simulate partial heart function with flow against the VA-ECMO circuit. A more anatomically accurate fluid circuit would be designed to better represent the flow patterns seen in patients. This could be done by making changes to the material of the phantom to make it less static and rigid, the diameter of the tubing, the length of the tubing, and the location of the injector site, and by incorporating fresh fluid input instead of having a closed loop circuit. Lastly, for fabrication, the injector piece would be redesigned and created out of rubber instead of PLA to ensure a tight seal without any leakage.

Changes also need to be made to the testing protocol of the device. First, more trials through the CT scan would need to be performed in order to get more normalized and accurate results. Also, a fluid more similar in composition to human blood would be utilized in the circuit. This would allow for a better understanding of how the iodinated contrast is mixed and distributed in a patient. Possible fluids that could be incorporated include an aqueous-glycerol solution or pig blood [29].

Summary

VA-ECMO is a life support machine for patients who have experienced heart failure. It is important that radiologists are able to see what is happening inside the patient in order to determine the cause of the problem and how to proceed with treatment. One way to do this is to perform a CT scan. It is not well understood how to properly administer iodinated contrast for patients on ECMO life support as there is no medical standard. The team was assigned the task of creating a heart phantom and flow circuit in order to model the flow rates and patterns of individuals on VA-ECMO and calculate the proper injection rate and volume.

After conducting thorough research and brainstorming possible solutions, the team came up with four possible phantom designs and three possible pumps. The phantom designs include “Acrylic Box with 3D Printed Heart with an Open Circuit”, “Acrylic Box with 3D Printed Heart with a Closed Circuit”, “Negative Space Phantom with an Open Circuit,” and “Negative Space Phantom with a Closed Circuit.” The pump options were “ECMO Machine”, and “Centrifugal Pump.” “Pulsatile Pump”. Due to its anatomical accuracy, ease of fabrication, and low cost, the “Acrylic Box with 3D Printed Heart with a Closed Circuit” phantom design was chosen. Although the “Centrifugal Pump” scored the highest on the design matrix, the team decided to implement a roller pump for the pump component of the design. This was due to budget constraints and the resources available. Fabrication of the circuit mainly involved SolidWorks modeling and 3D printing, as the heart phantom and injector piece were both 3D printed. Other components of the circuit, such as the tubing and pump, did not require fabrication and only needed to be pieced together with the rest of the circuit.

Once the prototype was completely assembled, the team began their testing procedure. Flow rate testing, flow rate verification, and CT scan testing were all performed. The results from all three tests were satisfactory to both the team's and the client’s expectations. Future work will need to be done on the product to improve the device's precision and anatomical accuracy. Several changes in fabrication are needed, including a new pump system, a more anatomically accurate circuit, and an injector piece made out of rubber. Changes in testing include running more trials through the CT scanner and switching out the fluid in the circuit for something more similar in composition to human blood.

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Appendix

A. Materials List

Table 3: Cost for fabrication.

Item	Description	Manufacturer	QTY	Cost Each	Total	Link
Component 1						
Ultimaker tough PLA	High flex and durability plastic. Used to create the injector piece.	Ultimaker	65.75 g	$0.08 / gram	$5.26	Ultimaker tough PLA
Component 2						
Roller Pump	Roller pump for ECMO circuit. Borrowed from WIMR.	NA	1	NA	$0.00	NA
Component 3						
Plastic Tubing and connector pieces	Tubing and connectors for the circuit. Gifted from WIMR.	NA	2 m	NA	$0.00	NA
Component 4						
Acrylic Sheets	36x24” clear acrylic sheets	NA	1	NA	$0.00	NA

	used to create the acrylic box.					
Component 5						
Epoxy	Epoxy used to create the acrylic box and seal holes in the phantom	Hardman	10	$1.50	$15.00	Epoxy
Component 6						
Stratasys ABS M30 resin / Stratasys QSR Support	Used to create the 3D printed heart phantom.	Stratasys	76.02 cm^3 resin, 46.55 cm^3 support	$0.17 /$cm^3$ for resin $0.24/$cm^3$ for support	$25.15	Stratasys Printing
TOTAL:						**$45.41**

B. Preliminary Product Design Specifications

Function:

A CT phantom is a device used to calibrate Computed Tomography machines by acting as a "stand in" for human tissues [1]. Most phantoms currently in use are static; they do not allow for dynamic flow. Some patients obtaining a CT scan may need a circulatory support device, such as a VA-ECMO (veno-arterial extracorporeal membrane oxygenation) device [2]. There is a clinical need for a CT phantom with dynamic flow capabilities to study the correct ways to conduct CT vascular imaging for patients on ECMO devices. This phantom should model the inflow and outflow of an ECMO patient and have capabilities to simulate the addition of contrast media into the vascular system. Ultimately, this device will help medical personnel to better understand the flow of CT contrast through a patient on an ECMO machine, as the circulation pathways of an ECMO patient differs from a patient not on ECMO.

Client requirements:

- A CT Phantom with the main components of the heart and circulatory system accessed during VA-ECMO, capable of dynamic flow. The inflow and outflow cannulas are typically placed in the right atrium and ascending aorta, respectively [3]
- A ECMO pump and tubing with adjustable flow rates, and connectability to the phantom
- An access point in the phantom for an iodine contrast injector
- A reservoir to draw fluid from and a disposal chamber
- Easily cleaned

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The CT Circulation Phantom will be tested and used in a CT machine. CT, or computed tomography, scans take less than a minute to complete. The phantom would be used up to thirty times a day, for up to many years. The phantom must therefore be constructed in a durable manner to withstand loading and unloading from the CT gantry, as well as in a way that can withstand the effective dose, which is the energy deposited by ionizing radiation x-rays. This dose can range between 7 mSv (millisievert) and 20 mSv for a torso scan, depending on the use of a contrast agent [4]. Because this device will not be used to calibrate a CT machine, the phantom does not have to adhere to specific FDA CT phantom dimension and material regulations [5]. See *Standards and Regulations* for more information regarding FDA requirements for CT equipment.

b. *Safety*: There are no explicit safety standards regarding static CT phantoms. There are, however, extensive criteria for ECLS (Extracorporeal Life Support) machines. These measures primarily refer to patient safety and are not required for our client and user safety, but they are important parameters for the machine to achieve. The circuit should support fluid flow of 3-6 L/m^2/min. The inlet and outlet pressure should not exceed -300 mmHG and 400mmHg respectively [6]. The Circulation Phantom does not need to be sterilized, but should be cleaned thoroughly after each use to prevent staining and mold/bacteria growth. All components should be water tight to prevent leakage and therefore damage. In general, all materials should be non-toxic, secure, and non-sharp.

c. *Accuracy and Reliability*: The design is intended to create a better understanding of the injection rates and volume of contrast needed to properly conduct CT scans on VA-ECMO patients. In performing a scan it is essential that the phantom produces data to exemplify flow rates and associated Hounsfield Unit (HU). The Hounsfield unit must be between 10 and 600 HU for a readable image [7]. It is important that our phantom can produce precise results across multiple scans of the same settings, most notably at the flow rate generated by VA-ECMO (500mL/s) [3]. The standard deviation of the trials at each flow rate tested should be no more than 100 HU.

d. *Life in Service*: The device is designed to be used to test and assess dynamic flow rates through a fabricated phantom. The consumer, likely a medical team, would buy the product to calibrate a CT machine with dynamic flow rates for patients that have dynamic blood flow rates.

e. *Shelf Life*: Because the product's purpose is the specialized usage of phantoms, the device will remain out of use during many periods of its life cycle. Due to this fact, the device is designed to resist normal shelf life conditions for many years. Pre-existing, medical-grade static phantoms are typically in use for many years if not decades. Our design utilizes inexpensive off-the-shelf materials which will lower its shelf life when compared to manufactured products. Due to all of the moving components, the shelf life of the dynamic phantom is believed to be several years, or until one of the components loses accuracy or functionality.

f. *Operating Environment*: The device will operate in a standard CT scanning room. A CT scanning room is very close to 22°C, never to exceed 24°C or fall below 18°C [8]. The standard humidity for operating rooms is between 30% and 70% which the device will be subject to. The procedure is done meticulously, ensuring cleanliness of the area for maximum accuracy of the scan.

g. *Ergonomics*: The phantom should not be excessively difficult to move around. The efficiency of testing procedures should not be affected by a device that is physically demanding to handle. Technicians should not experience ergonomic strain and discomfort when performing testing with the phantom. Research shows that technician fatigue can be a source of excessive radiation administration [9]. Fatigue should not be a byproduct of operating with the phantom.

h. *Size*: The final design will be run through a Computed Tomography scanner for testing. Therefore the size limitation will be determined by the size of the gantry aperture. Typical CT scanner openings range in diameter from 75-85 cm, with some older models being as small as 70 cm [10]. The design should be kept under 70 cm to ensure that testing will be able to take place.

i. *Weight*: The design will have to adhere to the weight limitations of the CT scanner. These limitations state that the device that is put onto the couch that will go into the scanner must be less than 500 pounds, or 228 kg. This is a very obtainable limitation. The device should probably be easy to carry and maneuver, so less than 100 pounds, or 45 kg would be preferable for the purposes of testing and fabrication.

j. *Materials*: The CT Scanner doesn’t have a limitation for the materials that we can or can’t use while scanning, however, for imaging purposes the prototype should be built without any metals or plexiglass. This primarily rules out using metals and avoiding plexiglass. In addition, the prototype is going to go through many many tests, which means that the construction needs to be robust. Strong plastics, such as PVC [11], should be used for tubing, and other pieces of the construction should be strong enough to hold the key components of the mock-ECMO circuit. The addition of an off the shelf pump is dependent on the availability of an unused ECMO machine/pump to be used with the prototype. If there is not an ECMO pump available, the pump must be able to pump fluid up to the levels of an ECMO pump (500ml/s) [3]. A contrast pump will be provided in the form of a clinical injector.

k. *Aesthetics, Appearance, and Finish*: The preferred shaping of this phantom would be that of something reminiscent of a torso on the exterior, with a tubing circuitry system within to simulate the body of a patient on a VA-ECMO machine. This device should also be adjustable in terms of catheter placement on the body. However, this doesn't need to be a perfect replica as the main goal of the phantom is to show the effects of the varying flow rates within the circuitry. Therefore there is room for appearance adjustments in favor of functionality. Aesthetics and Finish are both non-priority as the point of the device is to be scanned, and neither of those two pieces change the functionality of the device.

2. Production Characteristics

a. *Quantity*: For the duration of this project the goal is to produce one final working prototype. However, the design will be made and documented in detail so that the product could be duplicated in the future.

b. *Target Product Cost*: As of (10/11/2023) the team intends to borrow phantom components from various departments of UW Health. For anything that cannot be procured from our contacts, the intention is to keep products costs under 200 dollars.

3. Miscellaneous

a. *Standards and Specifications*: Standards and specifications have been established to optimize performance of CT equipment. These guidelines help to ensure that our design will assist in providing accurate diagnoses while minimizing unnecessary radiation exposure to patients and technicians. The FDA's CFR title 21, subchapter J, section 1020.33 establishes standards that feature the importance of employing phantoms to test CT equipment. It requires specific data to be reported from phantom calibration that can be used as evidence of compliance with regulations: contrast scale, noise, nominal tomographic section thickness, and spatial resolution capability of the system for low and high contrast objects [5]. ASTM E1695-20e1 is a standard test method for CT system performance measurement. Section 5 outlines physical specifications for the phantom testing apparatus including shape, size, material, and finish [12]. Other relevant standards include IEC 61223-3-5, AAPM Report No. 111, NEMA XR 21, and IPEM Report 87.

The FDA classifies our device as a Class I medical device with general controls. The FDA recognizes that this device is exempt from premarket notification 510(k) procedures, and exempt from current good manufacturing practice requirements of the quality system regulation except for general requirements concerning records and complaint files [13].

b. *Customer*: Our customers/clients in the department of Medical Physics at UW Madison are in need of a phantom to be used for the testing and calibrating of a Computed Tomography machine. The phantom must be able to mimic the dynamic blood and contrast flow that occurs in a patient when they are using a VA-ECMO machine. By using an off the shelf pump, the phantom must be built with a structure similar to a VA-ECMO machine as well as the heart and major systemic arteries. Current phantoms with static flow rates are well understood and allow for proper imaging to take place on real patients. Meanwhile, vascular imaging with dynamic flow rates is not as well understood which is why the clients need the phantom device to allow for alterable flow rates.

c. *Patient-related concerns*: While the device is important for the care of many patients, it will not be in contact with any as its main purpose is to calibrate and be used for testing in CT machines. That being said, the device must still follow strict guidelines in its creation in order to eliminate any risk when running tests on it.

d. *Competition:* There are currently phantoms designed with dynamic flow rates for CT testing. One such device is a two-compartment, 3D printed phantom which allows for testing on various CT, MRI, and PET machines. Testing on the device allows for the creation of TACs (Typical Clinical Time-Attenuation Curves) which can be analyzed for DCE-CT (Dynamic Contrast Enhanced Computed Tomography) validation and to create more realistic imaging models of patients [14]. Another device was created because photoacoustic (PA) spectroscopy, while useful, was found to be too slow. Dynamic PA flow cytometry (PAFC) platforms have fast-moving cells that can have velocities from 20-50 cm/s which does not work with most blood phantoms that involve static flow. The team created a device that resembles the properties of whole flowing blood and CTCs (circulating tumor cells). Their device used silicone and "Layer-by-Layer" assembled capsules that had hemoglobin and "natural melanin micro- and nanoparticles." They found it challenging to make these objects seem similar to the real things and to "simulate their optical properties". Finally, their device represented different cell types and used "scattering-absorbing medium" and plastic tubing. It was successfully used to test "high speed signal processing in PAFC." Hollow polymer and silica capsules correctly simulated blood cells and melanoma markers which allowed the device to resemble blood in its optical and dynamic properties [15].

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C. Fabrication Protocols

Acrylic Box Protocol

Materials

- ⅛” clear acrylic
- Two Part Epoxy
- Bandsaw
- Sandpaper or Sanding Belt
- Deburring tool

Methods

1. Measure and mark one 25cm x 20 cm, two 25 cm x 15 cm, and two 20 cm x 15 cm pieces of acrylic
2. Using the bandsaw, carefully cut out the clear acrylic pieces
3. Using sandpaper or the sanding belt, smooth down the sides to a flat edge
4. Use a deburring tool to scrape off excess shrapnel
5. Assemble pieces to form a rectangular prism with open top
6. Glue and seal with epoxy

Heart Model Protocol

Materials

- PLA
- Acrylic
- Epoxy
- Standard Connectors
- Modeling Software:
    - Meshlab
    - Meshmixer
    - Blender

Methods

1. Acquire .stl files either from online sources or from a DICOM
2. Import the file into either Meshlab or Meshmixer
3. If in Meshlab (works well for cutting irregular shapes)
    a. Select the “Select faces in a rectangular region” in the options menu at the top
    b. Holding down the control key, select the faces that need to be cut. They should be highlighted in red
    c. Press delete
    d. Repeat steps a-c until left with the needed parts
    e. Re-mesh and smooth using the drop-down menus at the top
    f. Once the part is complete, export as a .stl file
4. If in Meshmixer (works well for plane cuts)
    a. Select the “Edit” option on the left side of the screen
    b. In the dropdown, select “Plane Cut”
    c. Use the sliders that appear on screen to adjust where the model is cut
    d. If needed, use the “Make Solid” and/or “Close Cracks” options (also under “Edit”) to smooth the model and close holes.
    e. Once the part is complete, export as a .stl file
5. Import both pieces into Blender. Ensure the program is in “Object Mode”
6. Using the toolbar on the right side, scale, translate, and rotate the two models into the correct position
7. Holding down the shift key, select both objects
8. Select the “Object” dropdown at the top of the screen
9. Select “Join” to make the objects into one. Make sure there is ample overlap between the two parts so that it can print correctly.
10. Export the final 3D object as a .stl file
11. Upload the .stl file to the Stratasys 3D printer (or another 3D printer) and print
12. Once printed, dissolve supports
13. Attach 4 tubing connectors (two female and two male, one each for the atrium and aorta) to the heart phantom. Use clear acrylic and epoxy to fill any gaps and secure the attachments.
14. Test to ensure the device is water tight. Fill holes with Epoxy as needed

Injection Site Protocol

Materials

- Ultimaker tough PLA
- Standard connectors
- Modeling Software:
    - Meshlab
    - Meshmixer
    - Blender

Methods

1. Open Solidworks
    a. Extrude a circular region into a cylinder at least 3 in tall and with a diameter of at least 2 in
    b. Make an extruded cylindrical cut through the cylinder of ⅜", which is the same dimension as the outside of the tubing connectors
    c. Extrude another cylinder, this time at an angle of 45° to the center of the object, and only extrude halfway through the object
    d. Export as an STL
2. Open Blender
    a. Import the Solidworks tube and a luer-lock file acquired from online into Blender
    b. Using the same methods as the Heart Model, combine the two into one and export the combined object
3. Print the injection site on an Ultimaker printer out of Tough PLA
4. Once supports are removed, insert the connectors into each end (one female and one male). If the connectors do not fit, use a file to widen the injector site opening
5. Tap connectors into place with a mallet if need be

D. Testing Protocols

Flow Testing Protocol

Materials

- Roller Pump
- 3 ft. ⅜ in tubing
- Graduated cylinder
- Weigh scale
- Water collecting vessel
- Reservoir

Methods

1. First, ensure that the roller pump and tubing are connected properly. See figure 15 for an image of the correct setup.
2. Using either gravity or running the pump, fill the entirety of the tube with water.
3. Set a timer for 1 minute. Position the pump and tubing so that water is drawn from a reservoir and deposited into a dry, empty vessel.
4. Turn the speed dial to 1. See figure 15. Start the timer.
5. Once the timer ends, stop collecting water. Turn off the pump.
6. Measure the resulting volume of water using a graduated cylinder for the volume and the scale for the weight. Make sure to zero the scale with the weight of the empty collecting vessel beforehand.

7. Repeat steps 3-6 twice more, and report the average and standard deviation of each trial for each method of measurement.
8. Repeat steps 3-7 for each speed on the pump.
9. Analyzing the data, determine which speeds correspond to the different rates of volume output, and, therefore, which ones most accurately mimic the flow rates of an ECMO circuit (4-6 L/min).

Flow Verification Using Flow Meter Protocol

Materials

- Flow Phantom
  - Roller pump
  - Tubing circuitry
  - Heart model
  - Acrylic box
- Flow Meter
- Water collecting vessel
- Water source

Methods

1. Ensure all tubing circuitry is able to connect properly.
2. Take two open ends and place both in the water source. Run the pump at medium setting (4-5) and run until the water is fully through the circuitry with no air bubbles.
   a. May require inverting the heart model to let air escape from the heart.
   b. Once the pump is turned off, make sure all holes are closed to avoid leakages.
3. Reconnect open circuitry. Attach the flow meter along the circuitry.
4. Set the timer for 15 seconds.
5. Set the pump dial to 1 and allow it to run for 15 seconds.
6. Record the average flow rate captured by the flow meter.
7. Repeat steps 4-6 two more times to ensure accurate data.
8. Repeat steps 4-7 with every odd-numbered setting on the dial.
9. Compare data with brute force testing data, and determine the appropriate dial setting for usage.

CT Scanner Testing Protocol

Materials

- Flow Phantom
  - Roller pump
  - Tubing circuitry
  - Heart model
  - Acrylic box
  - Iodinated contrast injector site
- Water source
- Sink
- Iodinated contrast injector
- Spill protection pads
- CT Scanner

Pre-Work

1. Connect together all of the tubing.
   a. Right atrium and aorta should be connected via short tubing with the injector site in the middle.
   b. Long tubing should connect the other ends of the right atrium and aorta.
2. Place the middle of the long tubing into the pump.
3. Disconnect the tubing from the injector piece.

4. Place one or both ends of the free tubing into a water source.
5. Turn on the pump at medium setting (4-5) and turn up to ten once the direction is determined.
6. Run the pump until water is present through the tubing without air bubbles.
    a. Inversion of the heart model is necessary to get air bubbles out of the heart.
    b. When the pump is turned off, make sure all holes are covered to prevent leakage.
7. Re-connect the injector site, attempting to keep all water in the system.
8. Make sure the injector site remains pointing upwards.
9. Cover the CT Scanner and bench with spill-protection padding.
10. Place the Acrylic box onto a bench on spill protection padding.

Calibration

1. Once the acrylic box is set, remove everyone from the room and make sure only the acrylic box will be scanned.
2. Scan the acrylic box to calibrate the scanner to that specific location.
3. Make sure that the acrylic box stays in that location throughout the scanning process.

Testing

1. Place the heart model inside the acrylic box.
2. Put the iodinated contrast injector into the injector site.
    a. To ensure a secure connection, an extra connector piece and tape will be required to reduce backflow.
3. Wrap the injector and injector site in towels in case of a spill.
4. Perform a final check to make sure everything is connected.
5. Turn on the pump at setting 10.
6. Make sure the room is cleared.
7. Scan phantom.
    a. 70+ seconds at cycles just over 2 seconds
8. Turn off the pump.

Post Work

1. Dispose of liquid left in the phantom.
    a. Go to sink (or other disposal location)
    b. Disconnect tubing around the injector site
    c. Place one end into the water source, and the other into the sink
    d. Run pump at medium setting (4-5) until pure water has cycled through the system
    e. Take water source end out of water
    f. Run the pump until water is no longer in the circuitry
2. Clean up spillages and spill pads.

E. Matlab Code

Flow Rate Testing

```
flow_data = table2array(FlowTestingData);
test_1_vol = flow_data(:,1);
test_1_w = flow_data(:,2);
test_2_vol = flow_data(:,3);
test_2_w = flow_data(:,4);
test_3_vol = flow_data(:,5);
test_3_w = flow_data(:,6);
```

```
dial_number = flow_data(:,7);
mean_tests = mean(flow_data(:,1:6)');
std_tests = std(flow_data(:,1:6)')
x = [1,3,5,7,9];
meanies = [0.2186, 0.5685, 2.0754, 2.7050, 3.1390];
[p, S] = polyfit(x, meanies, 1)
err = [0.0325, 0.2068, 0.5035, 0.0587, 0.0175]
hold("on")
scatter(dial_number, [test_1_vol test_2_vol test_3_vol], "r", "filled")
scatter(dial_number, [test_1_w test_2_w test_3_w], "b", "filled")
%scatter(dial_number, test_2_vol, "r")
%scatter(dial_number, test_2_w, "b")
%scatter(dial_number, test_3_vol, "r")
%scatter(dial_number, test_3_w, "b")
plot(x, 0.3989.*x-0.2530, "black")
plot(x, mean_tests, "blue")
title("Flow Rate in L/min for the Roller Pump according to Dial Number")
xlabel("Dial Number")
ylabel("Flow Rate in L/min")
hold("off")\
```

Flow Rate Verification Testing

```
setting = [1,3,5,7,9]'
FlowMeter = [0.2,0.85,1.82,2.43,2.76]';
calibration = (setting .* 0.40) - 0.25;
data = [calibration,FlowMeter];
figure(1);
bar(setting,data,'BarWidth', 0.7)
xlabel("Pump Flow Rate Setting")
ylabel("Measured Flow Rate (L/min)")
legend("Calibration Measurement","Flow Meter Measurement","location","north")
[h, p, ci, stats] = ttest2(FlowMeter,calibration)
if h
   fprintf('Reject the null hypothesis. There is a significant difference
between the groups.\n');
else
   fprintf('Fail to reject the null hypothesis. There is no significant
difference between the groups.\n');
end
```