CT Circulation Phantom - BME 200/300

Preliminary Report

BME 200/300 Design

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Abstract

Thousands of people need some form of life support every year. The use of one form, Veno-Arterial Extracorporeal Membrane Oxygenation (VA-ECMO) has increased significantly in recent years, especially with the COVID-19 pandemic. 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]. These machines allow for a patient to survive without a functioning heart for a short period of time, utilizing an exterior pump and blood oxygenator to take the place of the heart and lungs [1]. Oftentimes, radiologists need to be able to see what is exactly happening inside the patient that is causing the heart failure. This is done using a Computed Tomography (CT) scan [2]. These scans require iodinated contrast in the bloodstream to be able to clearly see the blood in imaging. Iodinated contrast is injected directly into the vena cava in the opposite direction of the blood flow, which can potentially be problematic if there is too much disruption in the blood flow. On the other hand, if there is not enough iodinated contrast in the bloodstream, then CT imaging will not be effective. There is no safe way to test the amount of iodinated contrast that can be injected into the bloodstream without disrupting blood flow, so a phantom must be made to determine what the limits are for the iodinated contrast injection. Additionally, because the iodine contrast administered is radioactive, radiologists seek to limit the amount of contrast used to strictly the amount necessary [3].

Current Methods and Existing Devices

While there are no CT circulation phantom devices tackling this problem on the market, circulatory phantoms are not a new concept, and there have been several studies using similar models of the cardiovascular system and even 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* [4], 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* [5], 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* [6], 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: either healthy hearts or a different disease. This design will specifically allow researchers to determine how VA-ECMO affects iodine delivery.

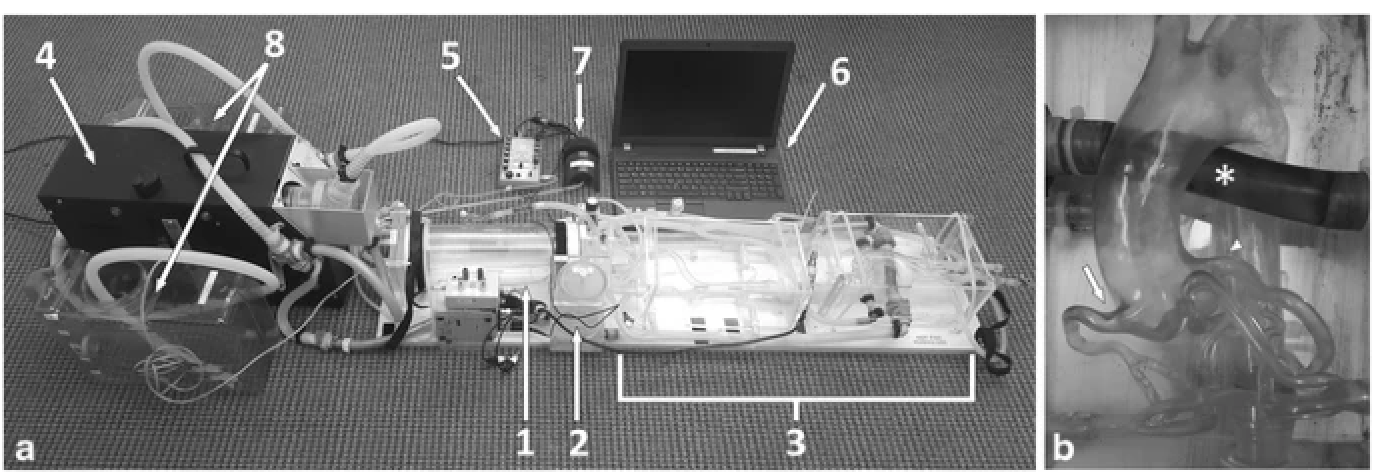


Figure 1: *An example of a circulation phantom used to determine minimum IDR for diagnostic coronary attenuation [6]*

Problem Statement

No medical standards currently exist to guide radiologists in the use of iodinated contrast CT imaging for 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, 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 for this project, Dr. Giuseppe Toia, is a part of the Department of Radiology at UW Madison and is also an Assistant Professor in Abdominal Imaging and Intervention. Dr. Toia's academic focus includes radiology physics, specifically CT imaging and optimization [7].

Biological Background

For this project, strict knowledge of human anatomy is key because the goal of any CT phantom is to mimic how a real human body would appear with x-ray imaging. The important parts for this project primarily include the heart as the phantom will mimic a person connected to a VA-ECMO machine which allows their heart and lungs to rest while the machine oxygenates and pumps blood throughout their body for them [8]. The phantom will include a 3D-printed Aorta and Right Atrium which will need to be modeled with dimensions and properties of a healthy adult's heart.

Materials Background

While the phantom design does not need to follow FDA guidelines regarding CT phantom dimensions and materials [9], 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 scan, metals can interfere with image quality [3]. This includes the plastic tubing that will be used to connect the pump to the phantom and the rest of the circuit. Specific materials will need to be used in order to be as compatible as possible with CT scanners, as well as allow proper flow through the circuit and effectively mimic a true human heart. For the 3D printing of the top half of the heart, Ultimaker tough PLA will be used because it has greater machinability than normal PLA and is highly resistant to heat and impacts [10].

Product Design Specifications

The client requests the following specifications:

- A CT phantom with the main components of the heart and circulatory system accessed during VA-ECMO
    - Typically the right atrium and ascending aorta [1]
- A pump and fluid flow system that models an ECMO device, complete with adjustable flow rates and phantom connectability
- An iodinated contrast injector access point
- A reservoir or other method to fill and empty the fluid
- Easily cleaned

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

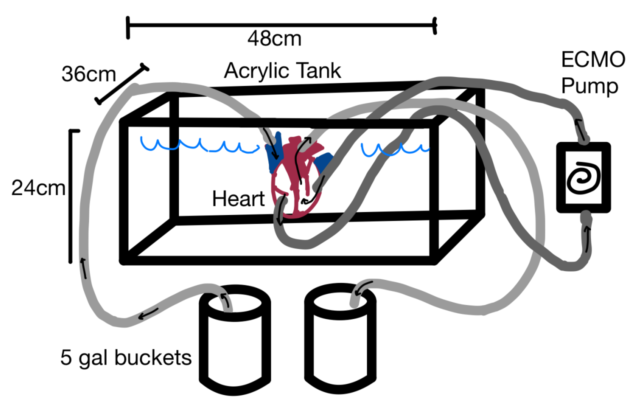


Figure 2: *Schematic showing the open circuit system of the thin walled 3D print design*

The first phantom design features 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 dumps 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.

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

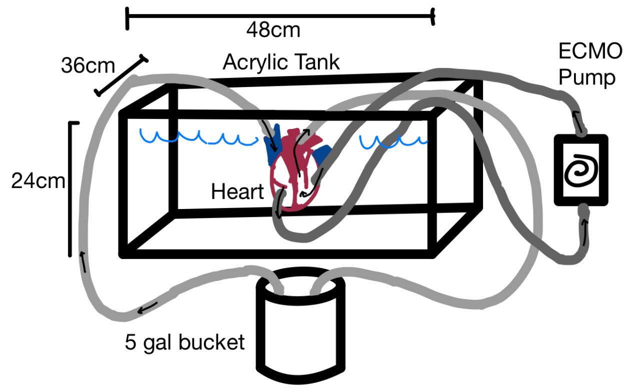


Figure 3*: Schematic showing the closed circuit system of the thin walled 3D print design*

The second phantom design is 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

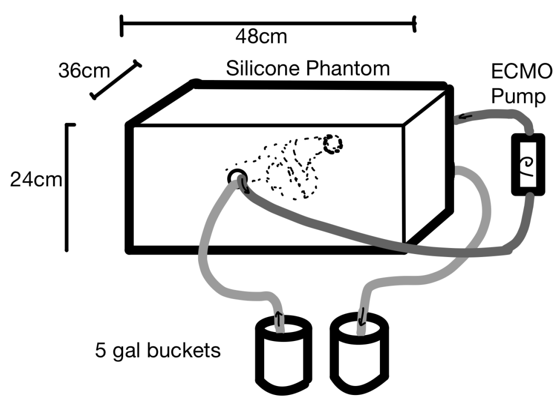


Figure 4: *Schematic showing the open circuit system of the negative space silicon mold design*

The third phantom design features 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 finally dumps into the waste container.

Design VI. Negative Space Phantom with a Closed Circuit

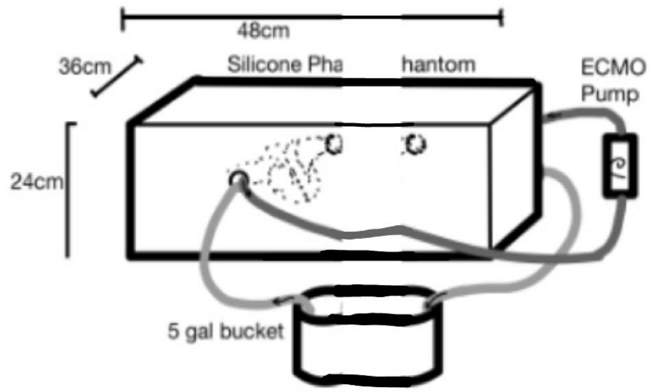


Figure 5: *Schematic showing the closed circuit system of the negative space silicon mold design*

The fourth phantom design is very similar to the third phantom design in that it has 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

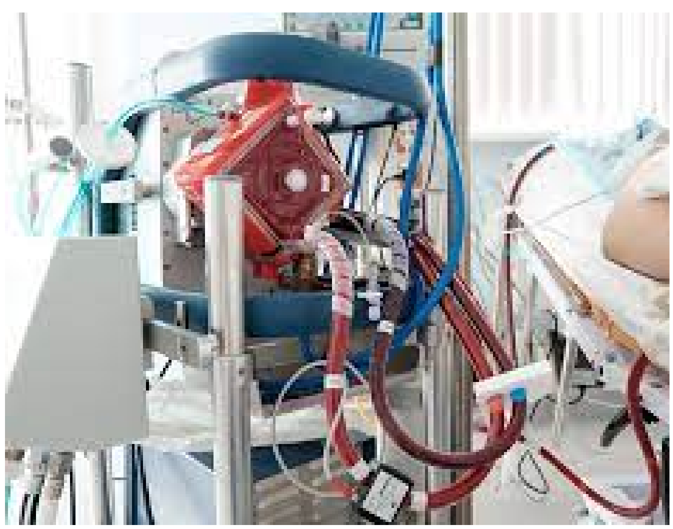


Figure 6: *Patient on an Extracorporeal Membrane Oxygenation Device [11]*

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

Design II. Centrifugal Pump

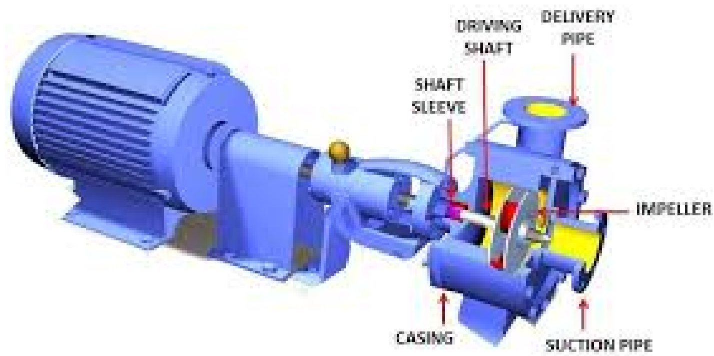


Figure 7: *Schematic of a Centrifugal Pump [12]*

The second pump idea is a centrifugal pump. This design works well because a centrifugal pump is the main pump currently used in ECMO devices [13]. The pump, therefore, will work well, because it can mimic the flow rates of the ECMO machine while avoiding unnecessary functions and cost. The main component of a centrifugal pump is the impeller. This impeller, or rotor, rotates quickly and casts fluid out 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 [14]. Centrifugal pumps are well suited to low viscosity, high velocity applications [14]. Because the circulation phantom needs to pump fluid (water) out quickly (around 4-6L/min), a centrifugal pump works well. These pumps can sometimes be costly, but not nearly as expensive as an ECMO device.

Design III. Pulsatile Pump

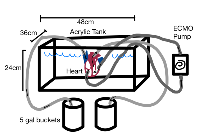
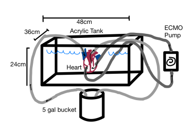
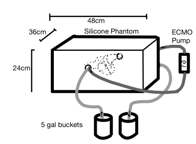
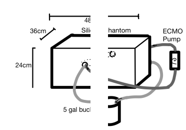
Figure 8: *Harvard Apparatus Pulsatile Pump [15]*

The third pump considered is a Pulsatile Pump. A Pulsatile Pump works by imitating the beating action of a heart. Many studies have used a pulsatile pump in their applications successfully, such as determining whether pulsatile flow or constant flow is best in a cardiopulmonary bypass [16]. 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)*

Phantom		**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**		**Negative Space Phantom with a Closed Circuit**	
Pictures									
Criteria	**Weight**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**
Anatomical Accuracy	30	3	18	4	24	2	12	3	18
Ease of Fabrication	25	5	25	5	25	2	10	1	5
Maintenance	20	5	20	4	16	4	16	3	12
Duration of single use	15	3	9	5	15	3	9	5	15
Cost	10	4	8	4	8	2	4	2	4
Sum	**100**		80		88		51		54

Anatomical Accuracy: Anatomical accuracy describes how closely the phantom mimics actual circulatory function. This category was the highest rated criteria because that criteria is crucial to our design being able to solve our 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, our 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 foam to be used 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.

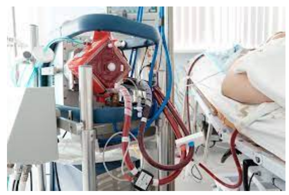
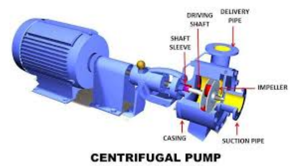
Ease of Fabrication: Ease of Fabrication refers to how difficult it would be to make a functioning phantom with the tools and skills we have. This criteria includes a consideration of time of fabrication and prototyping, cost of fabrication and prototyping, and how easy it would be to work with the materials. It is the second highest weighted criteria because if we can't feasibly produce a functional phantom, then that design doesn't really work for the design process. In general, both Acrylic box designs score a lot higher than the negative space designs for this 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. One, designing a heart in negative space that is both sturdy and moves our solution correctly would be very difficult to design. Two, if anything isn't correct with our design, the entire design of the mold would have to change and be produced, a both time and cost intensive process. For these reasons our 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 we will use tend to dry and get sticky if not thoroughly cleaned after use. We determined this 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 comparison of the Acrylic Box designs versus 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. For the open circuit designs, the time constraint 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 are similar in cost and because a 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 components for the open and closed circuit are also expected to be the same cost. The negative space phantom was rated lower because the price and volume of silicone needed is more expensive than the acrylic box phantom.

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

VA - ECMO Circuit		ECMO Machine		Centrifugal Pump		Pulsatile Pump	
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	10	4	12	4	12
Safety	10	5	10	3	6	3	6
Cost	10	1	2	3	6	5	10
Sum	**100**	**Sum**	67	**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 iodinated contrast 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 need to be connected to mimic the anatomy of a patient on a VA-ECMO machine. The compatibility category was tied for the second most important category because it is vital to our design that the VA-ECMO design works with the phantom and the rest of the circuit. In order for the flow of the iodinated contrast to properly mimic blood flow of a patient in a CT scanner the device needs to connect properly without leaks and provide a means to correctly measure the flow rate. 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 regards to ECMO and CT scans. The centrifugal and pulsatile pumps both scored the highest with five out of five because they are straightforward, independent devices that can take little training to use. 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. It is likely that this device would be used in an environment with professionals who have experience working with ECMO devices. Due to this experience they would likely have an understanding on the protocols for upkeep of the device. Because of this, the ECMO machine was ranked the highest. Centrifugal pumps were ranked the next highest as they are often utilized in ECMO circuits. Therefore, the operator would likely have an understanding of the pump and its components. A pulsatile pump was also ranked at a 4 as they are not as often seen in ECMO machines so the operator may not have as much experience working with them than the other two pump options. However they are known to be simple machines and are used to mimic cardiac flows in other medical settings.

Safety: The safety category depicts the risk of injury for the technician that performs a scan on the phantom. This was rated relatively low in our 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, which makes it less of an important factor in our 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 our 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 due to 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. 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.

Proposed Final Design

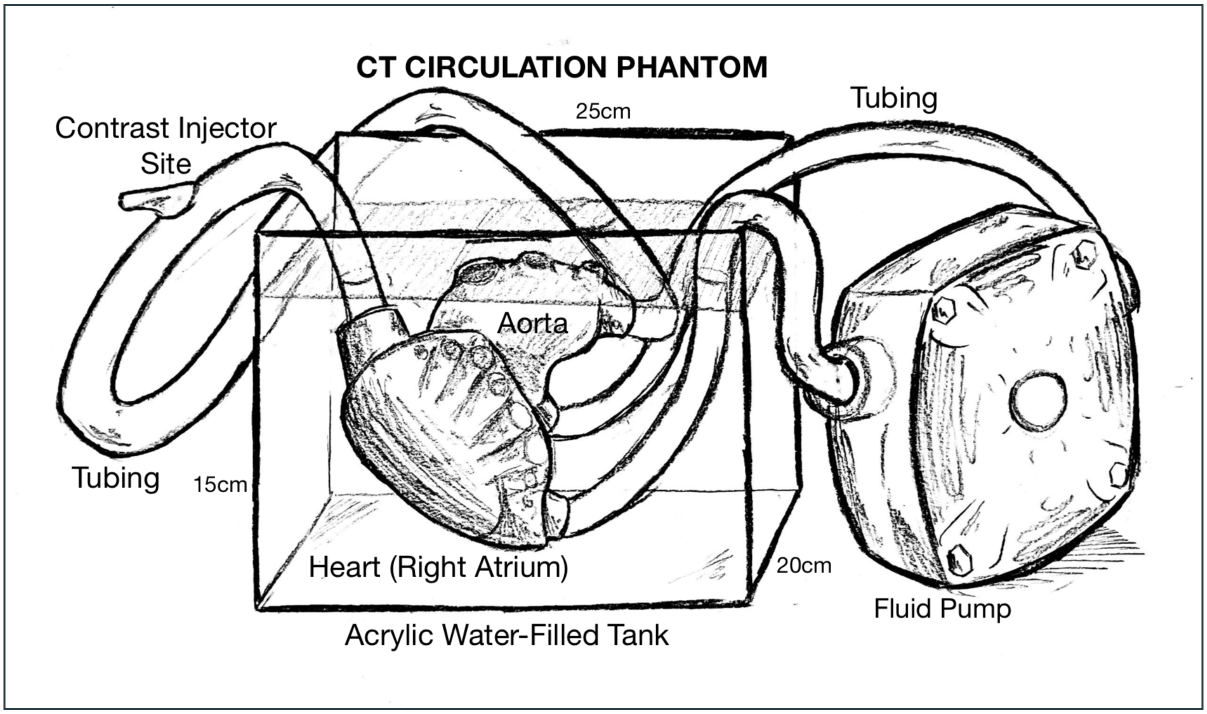


Figure 9: *Full schematic of the proposed final design: an acrylic box with 3D printed heart with a closed circuit and centrifugal pump*

Through the use of the two design matrices, it was determined that the team would move forward with the Acrylic Box with 3D Printed Heart with a Closed Circuit design with a centrifugal pump. The centrifugal pump proved itself to be a suitable alternative to an actual ECMO pump machine, and it even scored much higher than the ECMO machine in the teams evaluation. The acrylic box with 3D printed heart was chosen as it also scored the highest in our evaluation. The thin walled design of the heart contributed to its high scores in anatomical accuracy, ease of fabrication, maintenance and cost. The closed circuit aspect of the system supported its high scores in anatomical accuracy and ease of a single use.

Fabrication/Development Process

Materials

The materials of the device can be broken down into two separate categories: one for the pump and another for the phantom. The pump pump will be a roller pump, although it is yet to be acquired, borrowed from the UW Cardiovascular Fluid Dynamics Laboratory at the Wisconsin Institute for Medical Research (WIMR). The phantom will be made out of Ultimaker PLA, which will be printed, modified, and finalized through 3D modeling. To connect the two pieces of the device, robust PVC tubing will be used to transfer flow from the pump to the phantom. The PVC will produce 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 PVC [17]. Connection adapters for the tubing at the site of the pump and phantom will be 3D printed using the aforementioned PLA. A contrast is also needed when testing a phantom and is injected intravenously via computer-controlled contrast injectors. To accommodate for this, there is an added injection site on the tubing so that a built-in contrast injector will not be needed. Instead, the user will use a proprietary contrast injector in tandem with the dynamic-flow phantom. Along the tubing will be a flow meter so that we can accurately measure and calibrate the flow from the pump. A turbine flow meter can measure flow up to 7.5 liters/minute which is more than enough for this application. An Arduino microcontroller will be added in the future to simplify flow rate controls and view current flow.

See Appendix A for the detailed budget.

Methods

The method for creating an initial prototype involves truncating an existing 3D model for a phantom heart. Because VA-ECMO bypasses the lungs and many circulatory systems, the phantom only needs to include anatomically accurate models of the right atrium and aorta. The 3D phantom model was provided by the UW Cardiovascular Fluid Dynamics Laboratory and modified by comparison to datasets from real CT scans to ensure anatomical accuracy while focusing on the main components of the heart. Once finalized, HU values can be determined through testing during CT scans and final modifications can be made.

Testing

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. 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 (3-6 L/min). Once the device is assembled, it will undergo initial testing to verify that the flow rate generated by the dynamic-flow phantom system is comparable to that of a VA-ECMO device. The device first be tested outside of a CT environment so that we can modify the design to garner accurate and precise results. Then, it will be tested during a CT scan so that HU united can be derived and compared to known data.

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. This needs to be acknowledged and the 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. If it is desired to calculate the injection rates for patients on Veno-Venous ECMO machines further research should be done and the necessary adjustments should be made to the device.

Conclusions

In conclusion, researchers are in need of a CT Circulation phantom to assess hyperdynamic flow rates for patients on VA-ECMO. While circulation phantoms do exist and have been used for other studies, nothing exists tackling this exact problem: the behavior of iodine contrast in the body of a patient on VA-ECMO. The final phantom design includes an acrylic-water filled box that houses an anatomically accurate heart, complete with tubing and a pump capable of ECMO flow rates and modulation. An iodine contrast injector site is also included. While fabrication and further testing are required to determine the efficacy of the design, the goal is to have a functioning prototype by the end of the semester to assist researchers in determining proper imaging procedure for patients on VA-ECMO. The ultimate goal of this project is to improve patient care and outcomes.

References

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Appendix

A. Materials List

Table 3: Proposed 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 3D print of the phantom.	Ultimaker	20 g	$0.08 / gram	$1.60	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	Tubing for phantom. Gifted from WIMR.	NA	2 m	NA	$0.00	NA
Component 4						
Acrylic Box	Acrylic box for phantom to sit in.	Amazon	1	$24.99	$24.99	Acrylic Box
PROPOSED TOTAL:						**$26.59**

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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