CT Circulation Phantom - BME 301

Preliminary Report

BME 301 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]. Even before 2020, radiologists have seen an increase of 458% between 1990 and 2019 [1]. Veno-Arterial Membrane Oxygenation machines allow for a patient to survive with minimal to no heart function for a short period of time, utilizing an exterior pump and blood oxygenator to take the place of the heart and lungs [1]. Patients on VA-ECMO often require diagnostic imaging, which is done using a Computed Tomography (CT) scan [2]. These scans require iodinated contrast in the bloodstream to be able to acquire clear images and assist in diagnosis. Iodine contrast administered is radioactive, radiologists seek to limit the amount of contrast used to strictly the amount necessary [3]. The amount of contrast, as well as the rate of injection, varies from patient to patient, and there is no medical standard for contrast injection for patients on VA-ECMO [1]. VA-ECMO complicates hemodynamics in that the oxygenated blood returning from the machine is pumped retrograde to typical blood flow [4]. Therefore, researchers need a phantom with flow capabilities to test on in order to determine the best practices for imaging patients on VA-ECMO. This will ultimately improve patient care and outcomes.

Current Methods and Existing Devices

While there do not seem to be any dynamic flow circulation phantoms on the market, there are several that have been fabricated and utilized in research and clinical settings. 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 [5]. In a 2008 study by Behredt et al., researchers fabricated a Dedicated Circulation Phantom in order to devise a standard for contrast material application [6]. This phantom replicated the lung, body, aortic and coronary artery circulation using a pulsatile pump. Other researchers such as Emrich et al. [7], who investigated how iodinated contrast should be administered for Coronary CT Angiography, and Mihl et al. [8], who compared different iodinated contrast media, used Behredt's circulatory phantom as inspiration (figure 1 below). These studies added elements such as a 3-way stopcock extension at the injection port which had a cutoff pressure of 325 psi , and this acted as a safety measure to protect the device and surrounding expensive equipment. A more recent 2023 study with further similarity to the client's problem statement was done by Yambe et al. [4], and it used ultrasound vector flow imaging during VA-ECMO to determine what occurs in the "mixing zone" (figure 2 below). The mixing zone is where the cardiac outflow meets retrograde VA-ECMO flow. The study used a PVA anatomically accurate thoracic aorta phantom with four outputs. The phantom was connected to both a pulsatile pump and a centrifugal pump, one to represent heart function and the other to simulate ECMO function. The team also used a blood-like fluid comprised of water, glycerin, and silica particles [4].

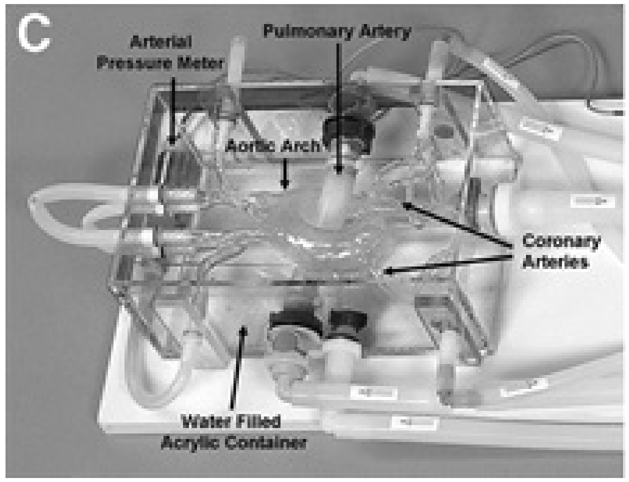

Figure 1: *Dynamic flow phantom used to determine iodinated contrast injection protocol for patients receiving CT scans [6]*

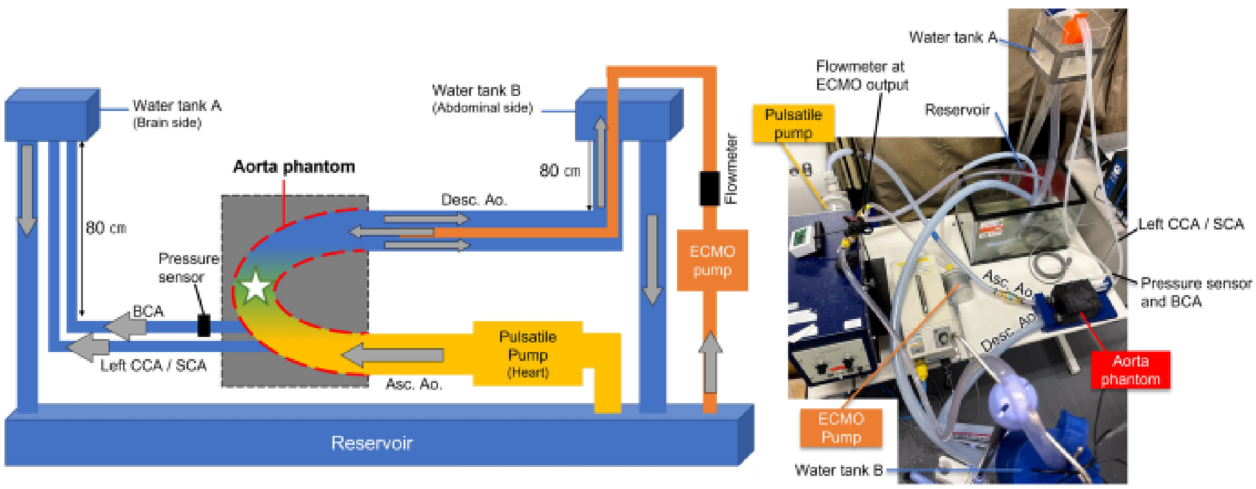

Figure 2: *Dynamic flow phantom with both pulsatile and retrograde ECMO flow. Includes the flow schematic (left) and image of setup (right) [4]*

Problem Statement

There is a lack of standards that exist to guide radiologists in imaging patients on VA-ECMO in CT scanners. Researchers and radiologists need a safe way to study flow rates and mixing patterns seen in these patients and determine the best procedures. The team was tasked with creating a CT phantom to assess hyperdynamic contrast flow rates in order to model individuals on VA-ECMO. The phantom and circuit will be created with anatomically accurate values in mind. The fluid circuit will replicate the flow rates and patterns that are seen in patients on VA-ECMO. The device is aimed to assist researchers and radiologists 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 an abdominal radiologist and an assistant professor of Abdominal Imaging and Intervention. He is also a part of the Department of Radiology at UW Madison. Dr. Toia's academic focus includes radiology physics, specifically CT workflow and optimization [9]. This interest includes limiting the amount of materials used in a single CT scan as well as limiting patient exposure to radiation and iodinated contrast.

Biological Background

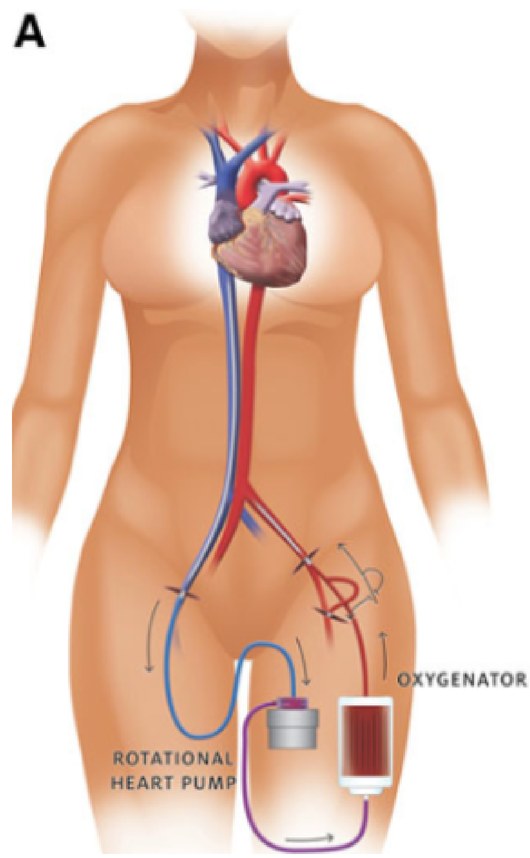

Figure 3: *Schematic for peripheral placement of a VA-ECMO device [10]*

In order to produce a phantom that accurately reproduces the haemodynamic qualities of a patient on VA-ECMO, it is crucial to understand how the device is incorporated into the circulatory system. As previously mentioned, VA-ECMO (Veno-Arterial Extracorporeal Membrane Oxygenation) devices are employed to replace the function of the heart and lungs during cardiac surgery or other instances of heart failure [11]. There are various locations where the device can be incorporated into the circulatory system, but the most common method involves cannulation of the femoral artery and femoral venous return [10]. This technique, referred to as peripheral placement, is schematized in figure 3 above. The arrows of figure one exemplify that the machine moves blood in retrograde with respect to the normal circulation of blood.

In order to replicate blood flow produced by a peripherally placed VA-ECMO device, it is important to note the anatomical size of the circulatory system that is involved. It was determined by a recent study that the standard approximate length between the cannulation site and the aortic arch (the region of interest for this project) is 60 cm (± 4.1 cm) [12]. Figure 4 below further illustrates the location of the region of interest by indicating the site where blood is deposited into the heart in the aortic arch and where it is drained via the vena cava.

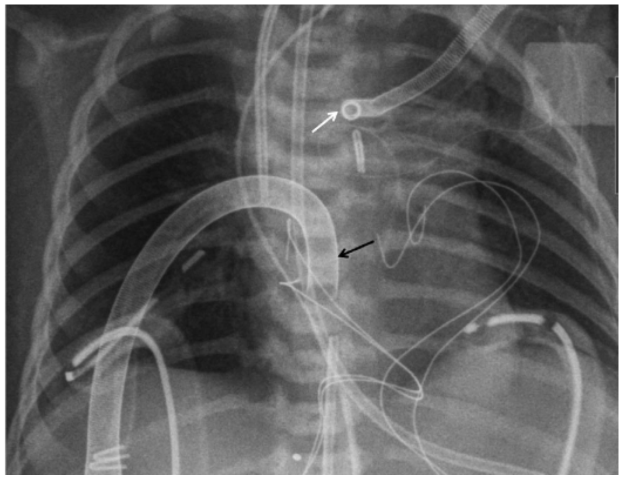

Figure 4: *Chest radiograph of a pediatric patient on VA-ECMO utilizing central placement. The white arrow points to the blood return location through the subclavian artery and the black arrow points to the blood disposal location through the superior vena cava [13].*

CT (computed tomography) imaging of the circulatory system requires injection of iodinated contrast into the bloodstream. VA-ECMO complicates the fluid dynamics of blood mixing with the contrast agent due to the previously mentioned retrograde flow, along with competition between the mechanical support of the VA-ECMO pump and the potential native ejection fraction of the patient's heart. These complications lead to complicated mixing and subsequent image artifacts appearing in the aortic arch. For radiologists, this can cause diagnostic confusion in determining whether the image artifact is truly a flow related issue from VA-ECMO, or if there was thoracic trauma prior to VA-ECMO [13]. It is crucial that this phenomena can be recreated for further research into combating this diagnostic challenge.

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 4-5 L/min, and the contrast agent is injected into the bloodstream at 9 mL/s [14]. 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[15]:

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

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 [16]:

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

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 ($N \cdot s/m^2$)

In terms of anatomical accuracy, this project is focused on studying mixing qualities in the aortic arch, which features a 3D bend which twists more than 180 degrees. Flow in a curved tube can be analyzed by utilizing a parameter which relates the centrifugal forces to viscous forces[17]:

$$Dean\,number = (2\delta)^{1/2} \cdot 4Re$$

where:

- δ is the ratio of the radius of the tube cross section to the radius of curvature of the centerline (dimensionless)
- Re is the Reynolds number (dimensionless)

The dean number works to describe the two flow conditions of the aortic arch. First, if flow into the entrance of the arch is not developed, then the core of the fluid in the curve may act like a vortex, with velocity skewing toward the inner wall. Second, a fully developed flow upstream of, or through curved tubes will exhibit velocity that skews toward the outer wall. Classification of the flow that we expect to observe will help to determine the quality of the mixing between the blood and the contrast agent in this specific region.

Materials Background

Materials for this project include the material for the phantom, the plastic tubing that will be used to connect the pump to the phantom, and the pump. While the phantom design does not need to follow FDA guidelines regarding CT phantom dimensions and materials [18], 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]. For the phantom, specific materials will need to be used in order to be as accurate as possible on the CT scans, so the material should match the HU (Hounsfield Units) similar to that of the human heart which is 50+/-10HU [19]. Additionally, all materials should be waterproof to ensure it can contain the fluid flowing through. It is important that the team selects a material that will be anatomically accurate to mimic a human aortic arch on VA-ECMO.

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
    - Focusing on the aortic arch
- A pump and fluid flow system that models an ECMO device, complete with adjustable flow rates and phantom connectability
    - Pump should be able to support flow rate of 5 L/min
- CT phantom and entire circuit must have no leakage of fluid
- Eliminate bubble build up in the phantom
- An iodinated contrast injector access point
- A 6L reservoir or other method to fill and empty the fluid
- Easily cleaned

See Appendix B for the complete Product Design Specifications.

Preliminary Designs

Pump Designs

Design I. Roller Pump

Figure 5: *Cole-Parmer MasterFlex I/P Peristaltic Pump 77410-10 w Easy-Load Head 77602-1 [20]*

The Cole-Parmer MasterFlex I/P Peristaltic Pump, also referred to as a roller pump, is a type of displacement pump for moving fluids. It utilizes two or more rollers that are attached to a rotor which compresses flexible tubing as they rotate. This motion continuously forces fluid through the tubing. The Cole-Parmer MasterFlex pump produces a flow rate of up to maximum 19 L/min and to a minimum of 0.2 L/min (operation speed of 33-650 rpm). The speed can be controlled with a resolution of 0.047 L/min [20]. This is the type of pump that was used successfully for the design of the previous semester. The drawback of this pump from previous experience is that the friction between the roller and the tubing was enough such that the tubing melted and caused leakage.

Design II. Piston Pump

Figure 6: *IVEK Megaspense Piston Pump [21]*

Piston pumps function through mechanical displacement of the piston that will push the fluid. This allows for function in high pressure situations. This may allow for variable or fixed displacement, so the team could set the pump to output the same amount of fluid through every oscillation or different fluids through each. The IVEK Megaspense piston pump is a pump generally used for industrial purposes however could be compatible with our system. The pump is compatible with a variety of tubing including 3/8in tubing, which is required for the phantom [21]. Piston pumps are generally more expensive than centrifugal and roller pumps and also are generally more powerful with higher output. This one specifically was chosen as the output is 5L/min, which is the desired value for ECMO.

Design III. Centrifugal Pump

Figure 7: *Terumo Capiox iCP Centrifugal Pump [22]*

The Terumo Cardiovascular Capiox iCP pump has a flow rate of 8L/min and has rotation speed of 3600 rpm [22]. Testing of the pump showed that it did not produce adverse heat generation when circulating the fluid. Furthermore, this pump utilizes magnetic coupling in order to produce the torque that generates the flow rate of the fluid. The testing shows that the magnets did not decouple in various extreme conditions, which provides evidence that this pump reduces the amount of leakage and likelihood of disconnect [22]. Generally, centrifugal pumps are around $300, which is a more cost effective option than other pumps. This pump is easy to set up for the user as it has only a few components that need to be assembled, and is energy efficient as it doesn't require any more power than from a regular outlet.

Phantom Material Designs

Design I. Stratasys ABS M30i Resin

Figure 8: *Human skull fragment printed from Stratasys ABS M30i Resin (i indicates the biocompatible version of the material) [23]*

Stratasys ABS M30 Resin is an ideal 3D printing plastic for general purpose concept models, early prototyping and functional prototypes. This material was utilized in the final prototype last semester. While the material is very strong, tough, and lightweight, the mechanical properties are very far from that of human cardiac tissue. It has a yield strength of 30.8 MPa and elongates 8.1% at break [23]. This material is available at the makerspace and can be printed for under $30.

Design II. Formlabs Elastic 50A Resin

Figure 9: *An artery model printed from Formlabs Elastic 50A Resin [24], [25]*

Formlabs' Elastic 50A Resin filament is 3D printing material that is good for silicone-like parts. It is a soft material that can bend, stretch, and compress while holding up under repeated cycles of load. As such, it works well for soft tissue anatomy models. It has an ultimate tensile strength of 3.4 Mpa, 160% elongation before breaking, and a tear strength of 12.3 kN/m. While the phantom will not experience significant loading, this material guarantees that the phantom will not undergo deformation over several experiments, which could impact the results [24]. Elastic 50A is available off of the Formlabs website for $199 per liter, or at the UW Makerspace for $290 per liter. The final phantom volume is estimated to be in the range of mL, so the price should not exceed $60.

Design III. Stratasys TangoPlus

Figure 10: *Stratasys TangoPlus Heart Model [26]*

Stratasys TangoPlus is a 3D printing material created by Stratasys. It is a flexible and soft material often used to create parts with rubber-like qualities. It has a tensile tear strength of 0.8-1.5 MPa and has 170-220% elongation at break. It has a shore hardness of 26-28 on scale A which is between a rubber band and pencil eraser [26]. TangoPlus has been used to create heart models and was selected due to its tendency to stretch similar to a human heart. Stratasys TangoPlus is not available in the Makerspace so the print would have to be outsourced, likely through Stratasys itself. TangoPlus costs $1,778 for a spool weighing 3.6 kg, which is equivalent to $0.49 per gram [27]. The model weighted is expected to be on the scale of grams so printing cost should be minimal.

Preliminary Design Evaluation

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

Pump		**MasterFlex I/P Peristaltic Pump**		**IVEK Megaspense Piston Pump**		**Capiox iCP Centrifugal Pump**	
Pictures							
Criteria	**Weight**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**
Compatibility	35	5	35	2	14	3	21
Flow Rate	35	5	35	2	14	5	35
Cost	15	3	9	1	3	5	15
Ease of Operation	10	2	4	5	10	5	10
Energy Efficiency	5	4	4	3	3	4	4
Sum	**100**	**Sum**	87	**Sum**	44	**Sum**	86

Compatibility: Compatibility describes the ability of the pump to be incorporated into the circuit. It is crucial that the design is entirely leak proof to obtain the cleanest images possible. Because this is a critical objective of the design, compatibility was given the highest possible weighting in the matrix. The MasterFlex I/P Peristaltic pump scored the highest in this category because it does not require a break in the circuit for its incorporation. The tubing is placed into the head of the pump which simply clamps on around the tubing. The Capiox iCP Centrifugal Pump scored the next highest with a score of 3. It lost two points due to the necessity to add a break in the tubing to incorporate it into the circuit. The IVEK Megaspense Piston Pump scored the worst in this category with a score of 2. It had the same ceiling as the centrifugal pump due to the same reasoning of having to break the circuit to add it in, and it loses an additional point due to the irregular sizing of the connections.

Flow Rate: Flow Rate describes the pump's ability to both reach the flow rate necessary and to adjust the flow rate within the available range. This was the next highest priority category because an essential component of our design is to simulate the flow that is produced by an ECMO machine (4-5 L/min). The MasterFlex I/P Peristaltic pump scored the highest in this category because it can achieve flow rates from 0.2 to 19 L/m. Further, this pump has the ability to adjust the levels with an accuracy of 0.047 L/min. The next highest scoring pump was the Capiox iCP Centrifugal Pump. This pump does a good job of mimicking the flow produced by ECMO because it is the type of pump that is featured in actual ECMO machines. However, this option lost some points because its flow rate is outside of the desired range (8

L/min) and the flow rate is not adjustable. Finally, the IVEK Megaspense Piston Pump scored the lowest due to having a non-adjustable flow rate (30 L/min).

Cost: Cost refers to the sum of total expected expenses for the pump The team was not given an explicit budget for this design project. It was mentioned that if necessary, a pump could be purchased. Cost is not a top priority for the team as it is possible that the team may borrow a pump for the duration of the project. However, it is a possibility that a pump will be purchased and therefore cost is still an important factor to consider. The centrifugal pump was ranked the highest at a 5/5 because it was the cheapest of the three pump options. It costs $270 which is relatively low when compared to other pumps on the market. The peristaltic pump was ranked next at 3/5. It costs $1,200 which is significantly more than the centrifugal pump. The piston pump was ranked next at 1/5. The piston pump cost $2,360 which is likely out of the budget for this project.

Ease of Operation: Ease of operation refers to the difficulty level expected to run the circuit during imaging. Simple operation is ideal in order to create a smooth experience for the user. It is important to limit any unnecessary complications over the short duration of the scan. Despite this importance, ease of operation was ranked second to last as it is expected that all three pumps should be relatively simple to use. The piston pump and centrifugal pump were both ranked that same at a 5. Once calibrated both pumps should be very easy to use and will simply require the user to flip a switch or press a button. The pumps will be connected into the flow circuit at a fixed spot so the operator will never have to worry about moving it. The peristaltic pump was ranked last. This is due to prior experience using a similar roller pump. After a few minutes of use, the roller pump began to melt the tubing forcing the circuit to be turned off and the pump to be relocated to a new spot on the tubing that was not deformed. Although the pump was easy to use otherwise, the melting of the tubing was a big issue that would need to be solved if used again.

Energy Efficiency: Energy Efficiency is important in this matrix because multiple options of pumps are being compared, and all of them must be plugged in and using electricity. Ideally, the team does not want to use a pump that requires a very large amount of power, for both ease of plugging in and environmental concerns. This pump will be working for up to a few hours at a time, and so large amounts of energy usage should be avoided as much as possible. Additionally, previous pumps have been using too much power and this caused the machine to heat up significantly. This poses a risk to melt tubing, which could ruin the circuit. The roller pump and centrifugal both scored a 4/5, as they can be plugged into a regular outlet, easily turned on and off, and are not using any excess power. These pumps were meant to pump around 5L/min and are capable of slightly more so will not overheat and waste energy. The piston pumps, generally, are designed for higher power needs, generally with a minimum of 5L/min. As a result, these are heavier duty and will use more energy than the other pump options. As a result, the roller pump scored a 2/5.

Table 2: Phantom Material Design Matrix: *Weighted Score = Weight*(Score/5)*

Phantom Material		**Stratasys ABS M30 Resin**		**Elastic 50A Resin**		**Stratasys TangoPlus**	
Pictures							
Criteria	**Weight**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**	**Score (max 5)**	**Weighted Score**
Compatibility	30	2	12	4	24	5	30
Low Permeability	30	3	18	5	30	4	24
Anatomical Accuracy	20	1	4	5	20	5	20
Accessibility	15	5	15	5	15	2	6
Sustainability	5	3	3	1	1	3	3
Sum	**100**	**Sum**	52	**Sum**	90	**Sum**	83

Compatibility: Compatibility refers to the ability that the tubing will connect to the heart phantom and for the fluid to flow through the heart. It is important that the team selects a material that will be compatible with the tubing and fluid attached to the phantom. Ideally, the material must be soft enough for the fluid to flow through the tubing connected to the printed phantom. The material chosen must be flexible enough to mimic cardiac tissue, and should be durable enough to not break. The material must be compatible with the fluid as well, to mimic the pulsatile motion of the heart. Stratasys TangoPlus scored the highest, as it has the most flexibility of the materials and it had the highest elongation at break percentage of 170-220% [26]. This indicates that TangoPlus can be stretched more before failure. TangoPlus also had the lowest shore hardness value indicating that it was the softest material of the three. FormLabs Elastic 50A Resin scored a 4/5 as it was also a flexible and soft material, but it had slightly lower elongation of break percentages of 160% and was slightly less flexible and soft than TangoPlus [24]. Finally, the Stratasys ABS M30 Resin scored the lowest at a 2/5, because it is a very strong and durable material. The tensile strength was very high at 26-31 MPa and the elongation of break was low at 8.1%, indicating it was a very tough thermoplastic material that may not be as compatible and flexible for the heart phantom [23].

Low Permeability: Low Permeability refers to the ability of the circuit to not leak. Previous designs struggled with maintaining a sealed circuit with no fluid leaking in and out. This is very important because the phantom must have a certain amount of fluid pumping through it to properly model ECMO. We also don’t want any excess liquid leaking from our circuit as we will be using it in very expensive CT equipment. The Stratasys ABS M30A resin scored a 3/5 because it is a strong material that mimics rubber and is waterproof. This material is 3D printed in a layered pattern however, which may cause points where leaking may occur. The Elastic 50A resin scored a 5/5 in low permeability because not only is it listed as watertight and airtight, but the Formlabs website states that it can deform to fill the shape of a gap and still maintain that airtight seal. Therefore this would be beneficial for adapting into our system and working to reduce bubbles [28]. Additionally, Elastic 50A is meant to mimic the mechanical properties of soft tissue, so is more likely to deform and move rather than leak. The Stratasys TangoPlus resin scored a 4/5 because the plastic is deformable and mimics rubber, so will be waterproof. However, this is manufactured layer by layer, with curing steps in between, which may cause locations for leaking to occur between those layers. However, the deformability of this material may assist in moving bubbles or air pockets.

Anatomical Accuracy: Anatomical accuracy refers to how close to the shape, size, and material properties of an anatomical human heart the material allows for. The most important factor is the size and shape, so the materials were evaluated according to how precisely the phantom can be printed from the material. Material properties, such as tensile modulus, elasticity, and stiffness, are of secondary importance. Cardiac anatomical material properties do impact the hemodynamics, but the client has stated that the shape is of primary importance for research purposes with the dynamic flow phantom. Material attenuation, while often important in clinical CT contexts, is being evaluated as least important for anatomical accuracy at this time, because the attenuation of the fluid, and not the phantom membrane, is the research subject. Elastic 50A Resin scored 5/5 because it best mimics both physical properties, but also attenuation properties. TangoPlus also closely mimics soft tissue physical properties, but was ranked slightly lower, a 4/5, simply because its attenuation properties were not as close as Elastic 50A. ABS Resin ranked 3/5 because it does do a great job keeping its shape, but does not mimic physical properties nearly as closely of the more flexible materials.

Accessibility: Accessibility refers to how easily it is to obtain the material. It includes the cost of the material and the time it takes to retrieve it. Cost refers to the amount of money required to purchase the materials as well as any costs included in the fabrication process, such as 3D printing or machining. Time refers to the amount of time acquiring the material would take (such as shipping) and the amount of time the material requires to fabricate with it. Mindfulness of the client's resources is important, therefore accessibility must be taken into consideration when choosing the material. However, because a functional, leak-free, and accurate product is the priority, accessibility was rated the second lowest of the 5 categories for the phantom material. Elastic 50A Resin and ABS Resin both ranked 5/5 because they are similar in cost and both easily accessible from the UW Makerspace. TangoPlus ranks 2/5 because it is more expensive and would have to be outsourced.

Sustainability: Sustainability refers to how the material affects the environment. It is important that the team utilizes a material that promotes sustainability and is environmentally friendly. The team does not want to contribute to harming the environment and planet with fabricating this project and that is why this criteria was included in the design matrix. The Stratasys ABS M30 received a score of 3/5 and the Stratasys TangoPlus also received a 3/5. Stratasys makes it clear that their company prioritizes sustainability and ensures that their materials are composed of ingredients that can be reused and limit the amount of harm to the environment. These materials are made of thermoplastic polymers and elastomers which can be recycled and molded to be reused. Both materials are made of non-toxic materials that can be recycled. According to their safety data sheets, ABS M30 and TangoPlus are classified as non-hazardous materials that don't emit greenhouse gasses following production [29]. TangoPlus was also classified as not hazardous to the ozone layer [29]. Finally, the Formlabs Elastic 50A Resin received a low score of 1/5 because it is not environmentally friendly. Elastic 50A contains two main ingredients that are harmful. Acrylate monomers are a "water hazard class 1: slightly hazardous to water" and Isobornyl acrylates are a "Water hazard class 2: obviously hazardous to water". According to the Formlabs safety data sheet, Elastic 50A is regarded as a marine pollutant as chronic exposure is very toxic to aquatic life [30]. Therefore, the most sustainable material is either Stratasys ABS M30 or Stratasys TangoPlus.

Proposed Final Design

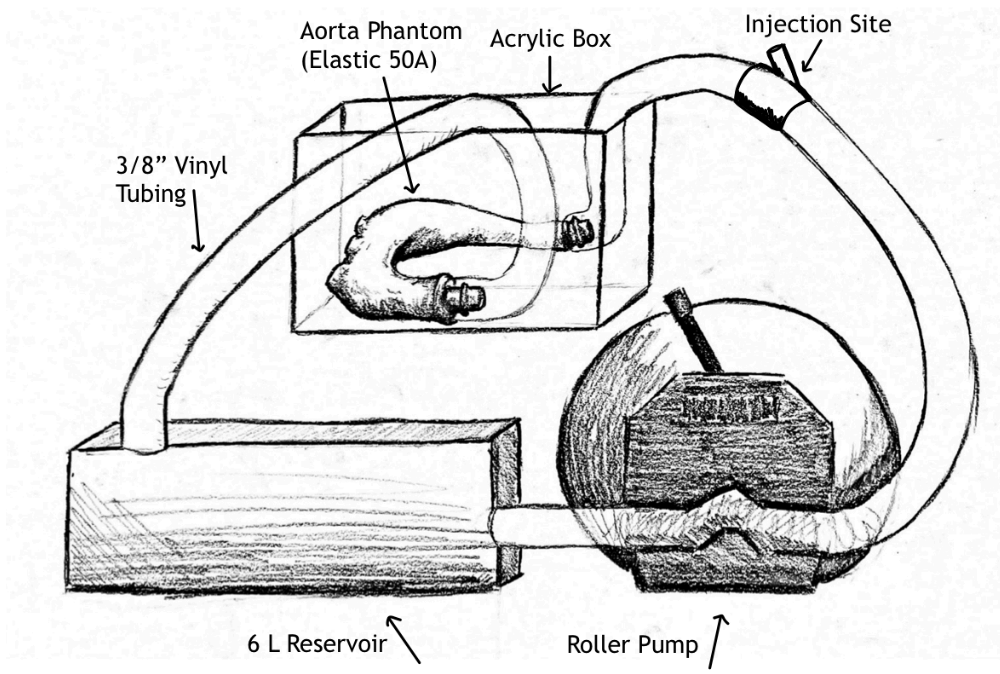

Figure 11: *Full schematic of the proposed final design: an acrylic box with 3D printed heart with a closed circuit and peristaltic (roller) pump*

After evaluating the design matrices for pump selection and material selection, the team will move forward with the Peristaltic Pump and the Elastic 50A Resin to 3D print the aortic arch. The Peristaltic Pump was selected as it received the highest score since the range of flow rate is large and can accommodate the flow rate of 4-5 L/min. Additionally, the peristaltic pump would be the most leak-proof, as it does not require a break in the circuit to incorporate the pump with the tubing. Elastic 50A Resin was the highest scoring material because it proved to be a flexible but also durable material that would ensure that the material's connectivity to the circuit would be leak proof.

Fabrication/Development Process

Materials

The exact pump model that will be implemented in the circuit is not yet determined as it will likely be borrowed for the duration of the project in order to save on costs. The phantom will be modeled after a human aorta in order to best represent mixing of contrast in the heart as a simplified model. This will be printed out of Formlabs Elastic 50A Resin. An injector site must be added to the circuit in order to be able to inject the iodinated contrast directly into the flow circuit without having to break it. This injector piece will be created out of an STL file in order to guarantee that the piece is compatible with the proprietary contrast injector. The model will then be 3D printed out of Ultimaker PLA. Both Ultimaker PLA and Formlabs Elastic 50A Resin are available in the UW Makerspace. The tubing that will be used to connect the circuit together will be clear vinyl ½ inch tubing. This tubing is very common and accessible. It will likely be borrowed from the BME teaching lab or purchased online. The connector pieces to join the tubing to the phantom will be purchased online and are made out of plastic. They are very cheap and easy to find as the ½ inch tubing size is a very common universal tubing size. Lastly, The ends of the circuit will be placed in a reservoir of water so the pump has a source to pull water from and dump water into. This reservoir will be a plastic tub that can hold at least 7 liters of water and will be purchased online.

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, and the new pump is connected, 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 will 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. To verify the accuracy of the device to an actual CT scan, a CT scan from a patient on ECMO will be given to the group from the client. This verification will involve matching size, CT attenuation (HU) and qualitative shape of the phantom to an actual scan.

As the team is planning to acquire a pump for the project, pump testing will be performed to determine which pump will be the best option for the methods of this project. Two different pumps will be tested, a roller pump and centrifugal pump, as these pumps scored very similarly in the design matrix. A MasterFlex roller pump and a Graco Husky 515 centrifugal pump will be evaluated on a few different criteria. The pumps will be tested on their ability to output 5L/min accurately and consistently. The compatibility of the pumps will be tested by connecting them to the circuit tubing and phantom to ensure that a good fit can be achieved. They will also be tested on their ability to not generate heat that melts the tubing, as this was a struggle last semester. This will be tested by running the pump for 20 minutes and then checking the pump, fluid and tubing for change in temperature.

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 and volumes 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 the exact issue of how iodinated contrast mixes in the body of a patient on VA-ECMO. The final phantom design includes an acrylic box that houses an anatomically accurate aorta, complete with tubing and a pump capable of ECMO flow rates and modulation, and a large reservoir of water for the pump to pull from and dump into. An iodine contrast injector site is also included along the circuit at a location representative of the actual contrast injection site in humans. The device will be fabricated, tested, refined, and fabricated again until it is a functioning prototype able to assist in the determination of proper imaging procedures for patients on VA-ECMO. In the end, the ultimate goal of this project is to improve patient care and outcomes.

References

[1] J. Shen, MD, J. Ruey Tse, MD, F. Chan, MD, PhD, and D. Fleischmann, MD, “CT Angiography of Venoarterial Extracorporeal Membrane Oxygenation,” *Stanford Univ. Sch. Med. Dep. Radiol.*, p. 16, Feb. 2022.

[2] “Failure to Adjust CT Scanners to Pediatric Settings is a Major Cause of Unnecessary Radiation Exposure to Children.” Accessed: Sep. 22, 2023. [Online]. Available: https://www.researchsquare.com

[3] “CT scan - Mayo Clinic.” Accessed: Oct. 11, 2023. [Online]. Available: https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675

[4] K. Yambe, T. Ishii, B. Y. S. Yiu, A. C. H. Yu, T. Endo, and Y. Saijo, “Ultrasound vector flow imaging during veno-arterial extracorporeal membrane oxygenation in a thoracic aorta model,” *J. Artif. Organs*, Jul. 2023, doi: 10.1007/s10047-023-01413-z.

[5] B. Driscoll, H. Keller, and C. Coolens, “Development of a dynamic flow imaging phantom for dynamic contrast-enhanced CT,” *Med. Phys.*, vol. 38, no. 8, pp. 4866–4880, Aug. 2011, doi: 10.1118/1.3615058.

[6] F. F. Behrendt *et al.*, “Introduction of a Dedicated Circulation Phantom for Comprehensive In Vitro Analysis of Intravascular Contrast Material Application,” *Invest. Radiol.*, vol. 43, no. 10, p. 729, Oct. 2008, doi: 10.1097/RLI.0b013e318182267e.

[7] T. Emrich *et al.*, “Reduced Iodinated Contrast Media Administration in Coronary CT Angiography on a Clinical Photon-Counting Detector CT System: A Phantom Study Using a Dynamic Circulation Model,” *Invest. Radiol.*, vol. 58, no. 2, p. 148, Feb. 2023, doi: 10.1097/RLI.0000000000000911.

[8] C. Mihl *et al.*, “Intravascular Enhancement With Identical Iodine Delivery Rate Using Different Iodine Contrast Media in a Circulation Phantom,” *Invest. Radiol.*, vol. 48, no. 11, p. 813, Nov. 2013, doi: 10.1097/RLI.0b013e31829979e8.

[9] “Profile,” Department of Radiology. Accessed: Oct. 11, 2023. [Online]. Available: https://radiology.wisc.edu/profile/

[10] P. Rao, Z. Khalpey, R. Smith, D. Burkhoff, and R. D. Kociol, “Venoarterial Extracorporeal Membrane Oxygenation for Cardiogenic Shock and Cardiac Arrest,” *Circ. Heart Fail.*, vol. 11, no. 9, p. e004905, Sep. 2018, doi: 10.1161/CIRCHEARTFAILURE.118.004905.

[11] A. Le Gall, A. Follin, B. Cholley, J. Mantz, N. Aissaoui, and R. Pirracchio, “Veno-arterial-ECMO in the intensive care unit: From technical aspects to clinical practice,” *Anaesth. Crit. Care Pain Med.*, vol. 37, no. 3, pp. 259–268, Jun. 2018, doi: 10.1016/j.accpm.2017.08.007.

[12] M. H. Olsen, T. Thonghong, L. Søndergaard, and K. Møller, “Standardized distances for placement of REBOA in patients with aortic stenosis,” *Sci. Rep.*, vol. 10, no. 1, p. 13410, Aug. 2020, doi: 10.1038/s41598-020-70364-9.

[13] D. Douraghi-Zadeh *et al.*, “Extracorporeal membrane oxygenation (ECMO): Radiographic appearances, complications and imaging artefacts for radiologists,” *J. Med. Imaging Radiat. Oncol.*, vol. 65, no. 7, pp. 888–895, 2021, doi: 10.1111/1754-9485.13280.

[14] M. Friebe, “Computed tomography and magnetic resonance imaging contrast media injectors: technical feature review – what is really needed?,” *Med. Devices Auckl. NZ*, vol. 9, pp. 231–239, Jul. 2016, doi: 10.2147/MDER.S106338.

[15] V. Streeter, *Fluid Mechanics*, vol. 3rd ed. McGraw-Hill, 1962.

[16] “Poiseuille’s Law.” Accessed: Dec. 07, 2023. [Online]. Available: https://sciencedemonstrations.fas.harvard.edu/presentations/poiseuilles-law

[17] D. N. Ku, “Blood Flow in Arteries,” *Annu. Rev. Fluid Mech.*, vol. 29, no. 1, pp. 399–434, 1997, doi: 10.1146/annurev.fluid.29.1.399.

[18] “CFR - Code of Federal Regulations Title 21.” Accessed: Sep. 21, 2023. [Online]. Available:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.33
[19] A. G. Gheorghe *et al.*, "Cardiac left ventricular myocardial tissue density, evaluated by computed tomography and autopsy," *BMC Med. Imaging*, vol. 19, p. 29, Apr. 2019, doi: 10.1186/s12880-019-0326-4.
[20] "Used & Refurbished Lab Equipment," New Life Scientific. Accessed: Mar. 08, 2024. [Online]. Available: https://newlifescientific.com/
[21] "Megaspense™ Liquid Pump Head Module | IVEK." Accessed: Feb. 29, 2024. [Online]. Available: https://www.ivek.com/megaspense.html
[22] "Capiox® iCP Centrifugal Pump : Perfusion Circuits : Products : Terumo Cardiovascular Systems." Accessed: Feb. 29, 2024. [Online]. Available: https://www.terumocv.com/products/ProductDetail.aspx?groupId=1103&familyID=943&country=1
[23] "ABS-M30i: A Biocompatible Thermoplastic Material." Accessed: Feb. 29, 2024. [Online]. Available: https://www.stratasys.com/en/materials/materials-catalog/fdm-materials/abs-m30i/
[24] "Elastic 50A Resin V2," Formlabs. Accessed: Feb. 29, 2024. [Online]. Available: https://formlabs.com/store/materials/elastic-50a-resin-v2/
[25] "Can You 3D Print Silicone? Best Silicone 3D Printers and Alternatives," Formlabs. Accessed: Feb. 15, 2024. [Online]. Available: https://formlabs.com/blog/silicone-3d-printing/
[26] "Tango: A Soft Flexible 3D Printing Material." Accessed: Feb. 29, 2024. [Online]. Available: https://www.stratasys.com/en/materials/materials-catalog/polyjet-materials/tango/
[27] "TANGOPLUS / FLX930 / 3.6KG," GoEngineer Store. Accessed: Mar. 08, 2024. [Online]. Available: https://store.goengineer.com/products/tangoplus-flx930-3-6kg
[28] "Formlabs Elastic 50A Resin | Solid Print3D." Accessed: Mar. 08, 2024. [Online]. Available: https://www.solidprint3d.co.uk/shop/consumables/resin/elastic-50a-resin/
[29] "Material Safety Data Sheets | Stratasys™ Support Center," Stratasys. Accessed: Mar. 08, 2024. [Online]. Available: https://support.stratasys.com/en/materials/sds?pageNumber=1&phrase=ABS%20M30
[30] "formlabs Safety Data Sheet Elastic 50A Resin." [Online]. Available: https://formlabs-media.formlabs.com/datasheets/2001417-SDS-ENUS-0.pdf

Appendix

A. Materials List

Table 3: Proposed cost for fabrication.

Component 1						
Formlabs Elastic 50A Resin	Flexible and durable material. Used to create the 3D print of the phantom.	Formlabs	100 mL	$0.29/mL	$29.00	UW Makerspace
Acrylic Box	Acrylic box to house phantom in. Fabricated in previous semester	NA	1	NA	NA	NA
Component 2						
Pump	Pump for ECMO circuit. Borrowed from the BME teaching lab.	NA	1	NA	$0.00	NA
Component 3						
Plastic Tubing	Tubing for phantom. Borrowed from	NA	2 m	NA	$0.00	NA

	the BME teaching lab.					
Connector Pieces	Connector pieces to connect tubing to the phantom	Drip Depot	4	$0.25	$1.00	Drip Depot
Component 4						
Plastic tub	Plastic tub for water reservoir	Walmart	1	$4.93	$4.93	Walmart
PROPOSED TOTAL:						**$34.93**

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 or perform tests in research settings [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], [3]. When obtaining a CT scan, most often patients are administered an iodinated contrast to enhance the quality of the images and assist in diagnostics [4]. However, iodinated contrast is radioactive and medical professionals should seek to limit the amount administered to prevent harm.There is a clinical need for a CT phantom with dynamic flow capabilities to study CT vascular imaging techniques for patients on VA-ECMO devices because currently there is no medical standard for administering iodinated contrast to patients on VA-ECMO, and the hemodynamics at the mixing of cardiac output and VA-ECMO backflow is not well understood. This phantom should model the inflow and outflow of a VA- 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 a VA-ECMO machine, as the circulation pathways of a VA-ECMO patient differs from a patient not on VA-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 [5]
- 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 is intended to calculate the appropriate iodinated contrast volumes and injection rates. It will be tested and used in a CT machine. A CT scan only takes a few seconds to complete. However, the phantom is intended to be able to be used for many trials. Because of this the phantom should be composed of materials that are able to withstand the effective dose, which is the energy deposited by ionizing radiation X-rays, without any degradation. This dose can range from 7-20 mSv for a single torso scan [6]. This device will not be used to calibrate a CT machine, and therefore does not have to adhere to FDA CT phantom dimension and material regulations [7].

b. *Safety*: There are no explicit safety standards regarding static CT phantoms. There are, however, extensive criteria for Extracorporeal Life Support machines. These criteria primarily regard patient safety and are not applicable to this device as it will not be in direct contact with the patient, but they are important parameters to take note of. The circuit should support fluid flow of up to 5 L/m^2/min with the inlet and outlet pressures not exceeding -300 mmHG and 400mmHg respectively [8]. The injector piece needs to be able to support an injection rate of up to 9 mL/sec [9] .The Circulation Phantom does not need to be sterilized as it will not come in contact with the patient, but should be cleaned thoroughly after each use to prevent staining or bacterial growth. All components should be water tight to prevent leakage leading to damage.

c. *Accuracy and Reliability*: The design is intended to create a better understanding of the injection rates and volume of contrast required to properly conduct CT scans on VA-ECMO patients. It is expected that a scan of the device will demonstrate the relative Hounsfield Unit in a region of interest (ROI) with respect to time. For the purpose of testing the accuracy of the device, a patient case will be chosen to create a model patient and eventually compare the device test data. The circuit of the design should be able to model the chosen patient's total blood volume. The device should be capable of circulating up to 5L of blood, however the Nadler Equation or Lemmens-Bernstein-Brodsky Equation may be utilized for the estimation of the chosen patient case [10]. The design should include a pulsatile pump that can be turned on to simulate partial heart function of the patient. This pulsatile pump should be able to remain in the circuit without being turned on in the case that the patient has total heart failure. The pump should be able to handle flow rates of VA-ECMO devices or up to 5 L/min [3]. The device should model the chosen patient's ECMO settings through control of the pump and should be within 0.1 L/min of the patient's flow rate. The time for the HU in the ROI to normalize should be within 3 seconds of the time in the given patient case. The HU of this normalized value should be within 100 HU of that of the patient case.

d. *Life in Service*: The consumer, likely a radiologist, will use the product to calibrate iodinated contrast injection rates and volumes for patients with dynamic flow rates. The device would be used multiple times for each patient so it needs to maintain effectiveness after over many uses.

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 the shelf life of 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, and then must be replaced by newer parts.

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 . The standard humidity for operating rooms is between 30% and 70% [11]. The phantom should operate successfully within these temperature and humidity conditions. Since the procedure is completed in a meticulous manner, it is imperative that the operating environment is clean and free of factors that may affect the accuracy of the scan, in order for the phantom to produce viable and accurate results.

g. *Ergonomics*: Since the phantom will be used during procedures by many individuals, 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 or heavy to handle. Technicians should not experience ergonomic strain or discomfort when performing testing with the phantom. Research shows that technician fatigue can be a source of excessive radiation administration [12]. It is important to our client to reduce the amount of excessive radiation with the phantom being in use, therefore opportunities for technician fatigue must be limited. 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 [13]. The size of 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. The device should be easy to carry and maneuver, so less than 50 pounds, or 22.5 kg would be ideal for the purposes of testing and fabrication.

j. ***Materials*****:** The phantom will be CT scanned and metal artifacts can appear as streaks or shadows [14]. To preserve the quality of our scans, 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 [15] or vinyl, should be used for tubing, so that there is no deformation when fluid flows through and causes pressure. All other pieces of the construction should be strong enough to hold the key components of the mock-ECMO circuit. Additionally, a pump will be included for this phantom that must be purchased. This pump must be able to pump fluid up to the levels of an ECMO pump. (500ml/s) [5] Additionally, a contrast pump will be purchased and connected to the system with a catheter, which must be compatible with the pump and system.

k. ***Aesthetics, Appearance, and Finish*****:** The preferred shaping of this phantom must include the aortic arch, as this is the location where the mixing is most likely to have an issue. To further simulate the heart, the right atrium should also be included. Additionally, there should be an additional 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. While the aesthetics of this phantom can provide some additional understanding of anatomical accuracy, the main goal of the phantom is to demonstrate varying flow rates within the circuitry. As a result, the phantom does not need to be a perfect visual replica. The 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*****:** One final working prototype should be created, however the process should be well documented for the purpose of replication by other interested researchers.

b. ***Target Product Cost*****:** The major costs associated with the design are the pseudo ECMO pump, pseudo heart pump, printed model, the injection pump connection, and tubing. It is the intention to keep the total cost under $400.

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 [7]. 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 [16]. 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 [17].

b. *Customer*: Our client in the department of Medical Physics at the Wisconsin School of Medicine and Public Health is in need of a phantom to be used for the testing and calibrating of Computed Tomography machines for use with patients on VA-ECMO. The purpose of this device is to research factors that impact imaging of these patients. Our client aims to learn more about imaging these patients to make the process more effective and efficient. The nature of this device is not conducive to widespread market production. However, it is the goal to create a reproducible phantom that will encourage research into sustainable CT practices[18].

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.

d. *Competition:* While there do not seem to be any dynamic flow circulation phantoms on the market, there are several that have been fabricated and utilized in research and clinical settings. 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 [19]. In a 2008 study by Behredt et al., researchers fabricated a Dedicated Circulation Phantom in order to devise a standard for contrast material application [20]. This phantom replicated the lung, body, aortic and coronary artery circulation using a pulsatile pump. Other researchers such as Emrich et al. [21], who investigated how iodinated contrast should be administered for Coronary CT Angiography, and Mihl et al. [22], who compared different iodinated contrast media, used Behredt's circulatory phantom as inspiration. These studies added elements such as a 3-way stopcock extension at the injection port which had a cutoff pressure of 325 psi [22], and this acted as a safety measure to protect the device and surrounding expensive equipment. A more recent 2023 study with further similarity to the client's problem statement was done by Yambe et al. [23], and it used ultrasound vector flow imaging during VA-ECMO to determine what occurs in the "mixing zone." The mixing zone is where the cardiac outflow meets retrograde VA-ECMO flow. The study used a PVA anatomically accurate thoracic aorta phantom with four outputs. The phantom was connected to both a pulsatile pump and a centrifugal pump, one to represent heart function and the other to simulate ECMO function. The team also used a blood-like fluid comprised of water, glycerin, and silica particles [23].

References

[1] "What Are Imaging Phantoms?," *NIST*, Apr. 2018, Accessed: Sep. 13, 2023. [Online]. Available: https://www.nist.gov/physics/what-are-imaging-phantoms

[2] M. S. Choi, K. Sung, and Y. H. Cho, "Clinical Pearls of Venoarterial Extracorporeal Membrane Oxygenation for Cardiogenic Shock," *Korean Circ. J.*, vol. 49, no. 8, pp. 657–677, Jul. 2019, doi: 10.4070/kcj.2019.0188.

[3] A. Le Gall, A. Follin, B. Cholley, J. Mantz, N. Aissaoui, and R. Pirracchio, "Veno-arterial-ECMO in the intensive care unit: From technical aspects to clinical practice," *Anaesth. Crit. Care Pain Med.*, vol. 37, no. 3, pp. 259–268, Jun. 2018, doi: 10.1016/j.accpm.2017.08.007.

[4] "CT scan - Mayo Clinic." Accessed: Oct. 11, 2023. [Online]. Available: https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675

[5] J. Shen, MD, J. Ruey Tse, MD, F. Chan, MD, PhD, and D. Fleischmann, MD, "CT Angiography of Venoarterial Extracorporeal Membrane Oxygenation," *Standford Univ. Sch. Med. Dep. Radiol.*, p. 16, Feb. 2022.

[6] S. Seed, "How Much Radiation Do You Get From CT Scans?," WebMD. Accessed: Sep. 22, 2023. [Online]. Available: https://www.webmd.com/cancer/radiation-doses-ct-scans

[7] "CFR - Code of Federal Regulations Title 21." Accessed: Sep. 21, 2023. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=1020.33

[8] "ELSO Guidelines | Extracorporeal Membrane Oxygenation (ECMO)." Accessed: Sep. 22, 2023. [Online]. Available: https://www.elso.org/ecmo-resources/elso-ecmo-guidelines.aspx

[9] H. J. Park *et al.*, "Relationship between Lower Dose and Injection Speed of Iodinated Contrast Material for CT and Acute Hypersensitivity Reactions: An Observational Study," *Radiology*, vol. 293, no. 3, pp. 565–572, Dec. 2019, doi: 10.1148/radiol.2019190829.

[10] R. Sharma and S. Sharma, "Physiology, Blood Volume," in *StatPearls*, Treasure Island (FL): StatPearls Publishing, 2024. Accessed: Feb. 08, 2024. [Online]. Available: http://www.ncbi.nlm.nih.gov/books/NBK526077/

[11] "The Best CT Scan Room Temperature and Humidity for Maximum Uptime." Accessed: Sep. 22, 2023. [Online]. Available: https://info.blockimaging.com/bid/99019/the-best-ct-scan-room-temperature-and-humidity-for-maximum-uptime

[12] "Failure to Adjust CT Scanners to Pediatric Settings is a Major Cause of Unnecessary Radiation Exposure to Children." Accessed: Sep. 22, 2023. [Online]. Available: https://www.researchsquare.com

[13] D. M. Fursevich, G. M. LiMarzi, M. C. O'Dell, M. A. Hernandez, and W. F. Sensakovic, "Bariatric CT Imaging: Challenges and Solutions," *RadioGraphics*, vol. 36, no. 4, pp. 1076–1086, Jul. 2016, doi: 10.1148/rg.2016150198.

[14] "Computed Tomography (CT)," National Institute of Biomedical Imaging and Bioengineering. Accessed: Feb. 08, 2024. [Online]. Available: https://www.nibib.nih.gov/science-education/science-topics/computed-tomography-ct

[15] L. Lequier, D. Horton, and R. Bartlett, "Extracorporeal Membrane Oxygenation Circuitry," *Pediatr Crit Care Med*, vol. 14, pp. S7-12, Jun. 2013, doi: 10.1097/PCC.0b013e318292dd10.

[16] "Standard Test Method for Measurement of Computed Tomography (CT) System Performance." Accessed: Sep. 22, 2023. [Online]. Available: https://www.astm.org/e1695-20e01.html

[17] "CFR - Code of Federal Regulations Title 21." Accessed: Sep. 22, 2023. [Online]. Available:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=892.1940
[18] "UW Saves Waste – and Time – With Sustainable CT Practices," Department of Radiology. Accessed: Feb. 08, 2024. [Online]. Available: https://radiology.wisc.edu/news/uw-saves-waste-and-time-with-sustainable-ct-practices/
[19] B. Driscoll, H. Keller, and C. Coolens, "Development of a dynamic flow imaging phantom for dynamic contrast-enhanced CT," *Med. Phys.*, vol. 38, no. 8, pp. 4866–4880, Aug. 2011, doi: 10.1118/1.3615058.
[20] F. F. Behrendt *et al.*, "Introduction of a Dedicated Circulation Phantom for Comprehensive In Vitro Analysis of Intravascular Contrast Material Application," *Invest. Radiol.*, vol. 43, no. 10, p. 729, Oct. 2008, doi: 10.1097/RLI.0b013e318182267e.
[21] T. Emrich *et al.*, "Reduced Iodinated Contrast Media Administration in Coronary CT Angiography on a Clinical Photon-Counting Detector CT System: A Phantom Study Using a Dynamic Circulation Model," *Invest. Radiol.*, vol. 58, no. 2, p. 148, Feb. 2023, doi: 10.1097/RLI.0000000000000911.
[22] C. Mihl *et al.*, "Intravascular Enhancement With Identical Iodine Delivery Rate Using Different Iodine Contrast Media in a Circulation Phantom," *Invest. Radiol.*, vol. 48, no. 11, p. 813, Nov. 2013, doi: 10.1097/RLI.0b013e31829979e8.
[23] K. Yambe, T. Ishii, B. Y. S. Yiu, A. C. H. Yu, T. Endo, and Y. Saijo, "Ultrasound vector flow imaging during veno-arterial extracorporeal membrane oxygenation in a thoracic aorta model," *J. Artif. Organs*, Jul. 2023, doi: 10.1007/s10047-023-01413-z.