Computed Tomography (CT) Circulation Phantom to Assess Hyperdynamic Contrast Flow Rates

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Team Members:
Sawyer Bussey (Team Leader)
Alec Schabowsky (Communicator)
Shashandra Suresh (BWIG)
Shreya Venkatesh (BPAG)
Charlotte Thomas (BSAC)

Client: Dr. Giuseppe Toia
Advisor: Dr. Chris Brace

ABSTRACT

Patients undergoing extracorporeal membrane oxygenation (ECMO) face unique challenges in computed tomography (CT) imaging, as current CT standards do not account for the altered circulatory dynamics introduced by ECMO. This limitation hampers physicians' ability to accurately diagnose and assess ECMO patients. Current solutions, such as adjusting ECMO settings or increasing iodinated contrast agent dosages, pose significant risks, including heightened mortality or unnecessary radiation exposure. To address this, a phantom circuit was designed to mimic human circulatory conditions under ECMO, providing a controlled environment for testing and calibrating CT machines. The circuit incorporates two pumps that simulate antegrade and retrograde blood flow, a phantom aorta made from TPU 95A, a water reservoir, and an injection site for contrast agents. This system allows for experimentation with contrast injection rates and flow conditions, helping to optimize imaging for ECMO patients. After initial fabrication of the design, flow and leak tests will be conducted, culminating with a test under the CT machine.

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1 INTRODUCTION

1.1 Motivation

Cardiovascular and respiratory complications due heart disease is the leading cause of death in the United States [1], and has been further amplified by the COVID-19 pandemic. As these conditions become more frequent, the use of extracorporeal membrane oxygenation (ECMO) procedures has also increased to address them. ECMO is a life support system that has an approximate 50% rate of mortality depending on the patient's condition [2]. Patients who are on ECMO often require a computed tomography (CT) scan to make diagnoses and plan treatment. ECMO can impact CT scan image quality, affecting diagnostic accuracy. Therefore, a device is needed to simulate ECMO treatment conditions, allowing a CT machine to be tested and calibrated for optimal performance under varying patient conditions.

1.2 Existing Devices & Current Methods

The main competitors in the market are dynamic CT phantoms, which are critical for evaluating and maintaining CT scanner performance.

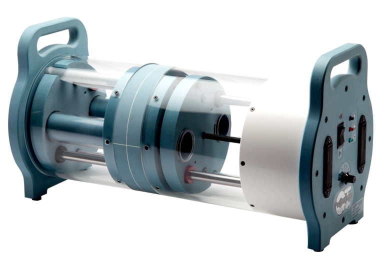


Figure 2: CT Perfusion Phantom (GammexTM Technology) [3]

Dynamic phantoms are used in advanced imaging studies, such as simulating the flow of contrast fluid in tissues. The Gammex Perfusion Phantom mimics tissue density and porosity in structures like arteries, veins, and brain matter, offering controlled settings for studying perfusion. However, it doesn't replicate the detailed anatomical structures of the heart.

Figure 3: Cardiac perfusion phantom inside the anthropomorphic thorax along with the pulsatile pump [4]

Another option is the Dynamic CT Perfusion Cardiac Phantom, which simulates cardiac perfusion with an anthropomorphic thorax, providing valuable data on real-patient CT scans. Yet, it lacks an anatomically accurate aortic valve and isn't tailored for specific contexts like VA-ECMO, where pulsatile flow and accurate aortic valve simulation are essential.

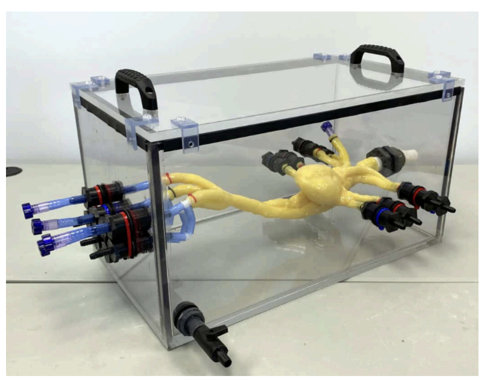


Figure 4: Adult Heart for X-Ray CT, US, MRI from True Phantom Solutions [5].

The True Phantom Solutions Adult Heart Phantom is the most similar to the design the team has in mind for the VA-ECMO phantom. It supports a beating functionality and lifelike motion for multiple medical imaging applications. The phantom is also made from synthetic material with properties similar to biological tissue, allowing a variety of contrast solutions to be tested, and its shape is anatomically accurate. However, the one downside to keep in mind is the size of the tank and complications on mounting in the CT scanning setup.

After analyzing the current competition, it is clear that the target is to prioritize both representations of a VA-ECMO patient through a dynamic yet anatomically accurate phantom.

1.3 Problem Statement

Currently, there is not a definitive way to test and calibrate CT machines for use on patients who are undergoing an ECMO procedure. Because of this, there is an increased difficulty in treating patients on ECMO, as physicians are not able to effectively assess and diagnose patients using CT imaging. One alternative solution involves changing the settings of the ECMO machine, which can increase the risk of mortality for an already critical individual [6]. Another alternative solution is to inject the patient with a higher amount of iodinated contrast solution, however, given the radioactivity of this solution, the amount of solution that is injected into a patient should be kept at a minimum. Thus, a need emerges for a device that mimics the human circulatory system and simulates the conditions produced by ECMO. This system will consist of a two pump anatomical circuit with variable flow rate and a CT phantom to simulate a CT target area. This would allow for a consistent, controllable environment where physicians can determine the rate at which iodinated contrast solution can be injected into an ECMO patient, as well as learning more about how the rate of the ECMO machine will affect CT results.

2 BACKGROUND

2.1 ECMO, CT, and Anatomical Flow Background

CT is an imaging technique that uses X-rays to produce images of the inside of the body. CT scans can occasionally make use of iodinated contrast solution when conducting scans that involve the circulatory system [7]. This solution makes it easier to see the flow dynamics of blood. ECMO can make it difficult for physicians to read and analyze the results of an ECMO CT scan. This is because of the retrograde flow that ECMO generates. ECMO pumps the patient's blood for them, oxygenates the blood, warms the blood and removes CO2. However, the blood is not reintroduced to the body's circuit directly at the heart where it could flow along with the normal anatomical direction of the body. Instead, it is returned to an artery, typically the femoral artery. From this point, the blood flows in two directions from the ECMO machine. One direction, the antegrade direction, is away from the heart, which is where the blood should be flowing in an artery, and the other is towards the heart, which causes the blood to flow in the retrograde direction, or the opposite direction of where blood normally pumps. This creates what is known as a watershed area, where the flow from the ECMO meets the flow from the heart. This causes the iodinated contrast solution to pool in one area which can obstruct the scan results [8].

2.2 Phantom Background

A phantom is a device that is used to mimic physiological conditions. In the scope of this project, the targeted area of CT scans is the aortic arch, so the phantom will be modeled after a 3D modeled aorta created by a CT scan.

2.3 Materials Background

The phantom itself does not pose any safety concerns for the patient, so it does not need to follow FDA regulations for medicinal use. It should however be compatible with the CT machine with regards to producing eligible and realistic imaging results. It should not contain any metal in the target area which in this case is the phantom aorta. This includes any metal fastenings or attachments that could possibly be used for securing the circuit.

2.4 Relevant Equations

The device will be used to replicate conditions produced by the contrasting flow rates of the heart and ECMO machine. Because of this, it is essential to record where high pressure areas may occur to plan accordingly during fabrication. The Hagen-Poiseuille equation can be used to determine this pressure along a length of tubing [9].

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

ΔP is the change in pressure along the length of the tube (Pa)

r = radius of the tube(m)

Q = volumetric flow rate (m^3/s)

η = dynamic viscosity of the fluid (N*s/m^2)

L = length of the pipe (m)

This equation will be useful in determining the approximate pressure in an area at any specified distance from a pump. Additionally, when calculating contrast flow rates, the flow rate used will be the difference between the two flow rates moving in opposite directions.

Another useful relationship to understand relates to the imaging aspect of this project. CT is based off of a scale known as the Hounsfield Scale [10]. This is a scale that represents the radiodensity of a material, which quantifies how a material shows up on a CT scan. Materials of different densities deflect X-rays differently, the image that the CT machine produces is based off of the variation of Hounsfield units across different materials. For example, fatty tissue (-70 HU) will appear differently on CT compared to bone (around 400 HU) because bone is more dense and has a higher HU value [11].

$$HU = \left(\frac{\mu_{material} - \mu_{water}}{\mu_{water}} \right) \times k$$

HU = Hounsfield unit

$\mu_{material}$ = the attenuation coefficient of a specific material

μ_{water} = the attenuation coefficient of water

k = a constant (typically 1000)

This formula helps to determine the Hounsfield unit of a chosen material. This could be used during testing to assess the anatomical accuracy of the chosen material with respect to how it shows up on a CT scan. The material chosen to be used in the CT phantom should be similar to that of cardiovascular tissue as the target area is the aortic arch [12]. For the aortic arch, the typical HU value is around 150.

2.5 Client Information

The client, Dr. Giuseppe Toia, is in the Department of Radiology at the University of Wisconsin School of Medicine and Public Health, and he is also an Assistant Professor in

Abdominal Imaging and Intervention. His clinical research involves genitourinary radiology, novel abdominal CT applications such as dual-energy/spectral CT, oncologic imaging biomarkers, and non-invasive characterization of abdominal tumors.

2.6 Product Design Specification

In terms of performance, the heart pump must produce a pulsatile flow and be capable of a variable flow rate ranging from 0 L/min to 6 L/min [13]. The lower end of the range replicates patients who have a lower heart rate or none, and the higher end of the range at 6 L/min replicates a healthy heart flow. All patients on ECMO have different heart rates and it is crucial that the heart pump has an adjustable flow rate so the phantom can be customized to each patient. Another vital aspect is fluid pressure. The phantom must be able to endure a fluid pressure of up to 300 mm/Hg. This accounts for fluid pumping from the heart pump as well as the retrograde flow from the ECMO pump [14]. Valves and connections should be water-tight to avoid leakage, as that would cause inaccurate data and the patient would not be diagnosed correctly. The circuit should be made anatomically accurate. The distance between the ECMO pump arterial insertion and the heart phantom from the femoral artery should be anatomically accurate to simulate real conditions. Along with accuracy, the 3D-printed aorta should be of similar size to one in the human body to simulate what the pressure and flow would look like in a patient. The circuit should include a reservoir to mimic the dilution of iodine contrast solution in the body as a patient goes through a CT machine.

The circuit does not need to be sterilized, but to ensure effective simulation results, it should be flushed between each cycle [15]. The materials that are used should not break or wear, they need to withstand many cleanings and uses while maintaining effectiveness. If materials start to degrade and break, the phantom will no longer work. The circuit must be contained within a reasonable space for ease of transportation and maneuverability onto and off of the machine. It must be reasonably lightweight. A single adult person should be able to lift it without extreme effort, therefore, it should be at most 50 pounds.

The client requested one final working prototype that was made within a $200 to $300 budget, and the Department of Radiology and medical physics will reimburse the money spent.

The phantom will be produced in accordance with the FDA 21 CFR, section 1020.33 [13]. It will also aim to stay within the size specified by 21 CFR 1020.33. A detailed procedure will be formulated for the phantom's use, along with a place to document the tests performed, and the methods used.

3 PRELIMINARY DESIGNS

3.1.1 Design 1 - Elastic 50A

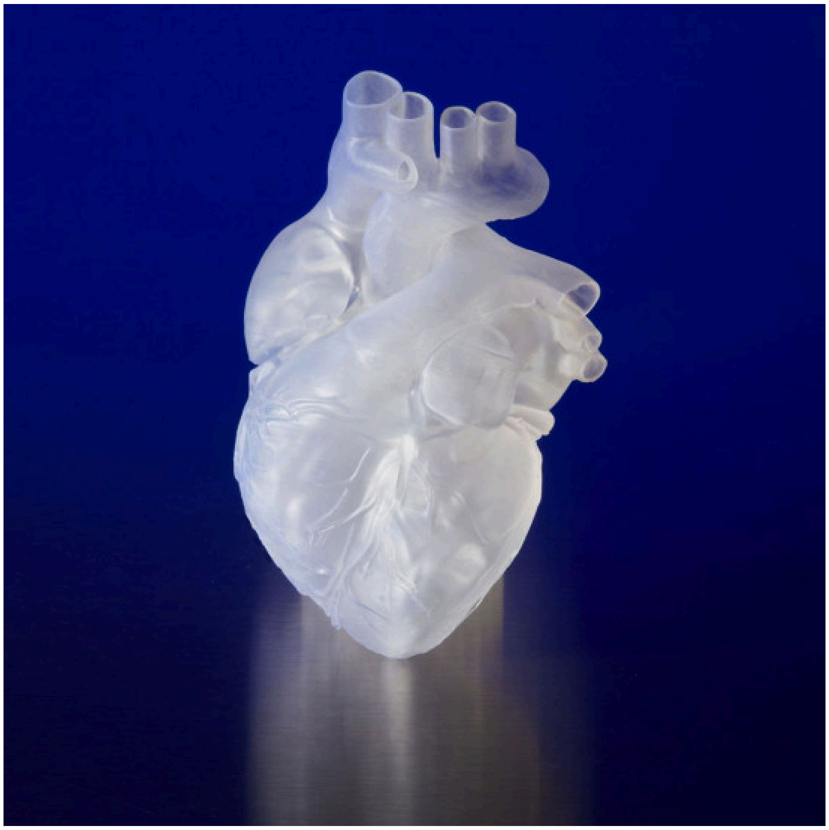


Figure 1: Model of heart made from Elastic 50A

Elastic 50A is a material that is commonly used for printing silicone prototypes. Even though it has a shore hardness of 80A, its softness and flexibility can be compared to the likes of soft tissue and other organic materials, which could prove useful in making an anatomically accurate aortic arch for more efficient calibration. It also has a strong capability to carry large amounts of water without breaking, as its 24 hour weight gain percentage comes at only 0.7% [17]. However, these properties can change with exposure to ultraviolet radiation, as Elastic 50A can degrade over time, making the material more brittle and more likely to fracture. Additionally, the process of removing the supports after 3D printing the aortic arch can be difficult and time-consuming, and could form holes that may cause leaks in the phantom.

3.1.2 Design 2 - TPU 92A

Figure 2: Piping made from TPU 92A

TPU 92A is a thermoplastic that is used to 3D print elastomer parts. With dissolvable support structures, the printing process is quick and efficient, and there is a lower likelihood of causing leaks during the post-processing of the material due to its absence of support structures and high tear strength of 84.6N/mm. It has a shore hardness of 92A so it is quite durable, but it also has some degree of flexibility [18].

3.1.3 Design 3 - Stratasys TangoPlus

Figure 3: Model of Organ using Stratasys TangoPlus

Stratasys TangoPlus is a rubber-like material that has often been used to manufacture models of organs. It is significantly softer than the other choices for material, at a shore hardness of 26-28A. The method of 3D-printing leads to the addition of more complex shapes, even with a higher speed of printing and post-processing. This material would allow for a more professional print with a lower risk of any mistakes or causing leaks, as this would have to be outsourced. However, this would also create an intermediate of communication, which can be time-consuming, and the outsourcing process would raise the costs of manufacturing the aortic arch. Additionally, this material would also degrade with exposure to ultraviolet radiation, which decreases its durability.

3.2.1 Pump 1 - LKB Microperpex Peristaltic Pump

Figure 4: LKB Microperex Pump in ECB Teaching Lab

The LKB Microperpex Peristaltic Pump is a small-form factor pump that uses a series of rollers to push water through a flexible tubing. The pump is available at no cost to the team through the BME Teaching Lab. The pump offers a relatively easy setup with a simple 120V power connection and no other materials, and the closed nature of the design with no connectors for tubing decreases the chance of leakage. A glaring downside of the pump is its maximum flow rate, which, although variable and reversible, only reaches an output of 500mL/hr, which is much lower than specified in the PDS [19].

3.2.2 Pump 2 - Graco Husky 515 Diaphragm Pump

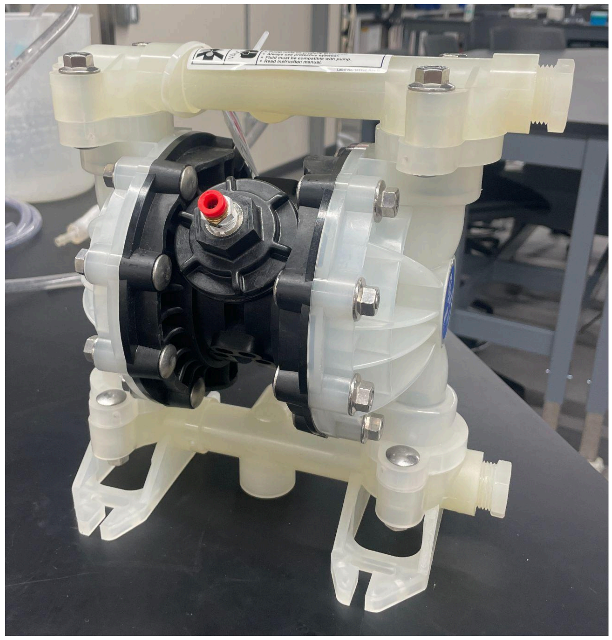


Figure 5:The Husky 515 Pump in ECB Teaching Lab

The Graco Husky 515 Diaphragm Pump uses an air powered diagram to produce a vacuum that sends water through the system via input and output barb fittings. The pump is capable of an extremely high flow rate of 57 L/min and can be varied based on the output of the air compressor [16]. The pump offers a relatively cumbersome design, but still manages to be viable within the CT scanner environment. The pump has a higher chance of leakage due to its high, variable output and the lack of a controlled user interface or “STOP” button. Finally, the pump is available to the team through the BME Teaching Lab.

3.2.3 Pump 3 - BDC Labs PD-1100 Pulsatile Pump

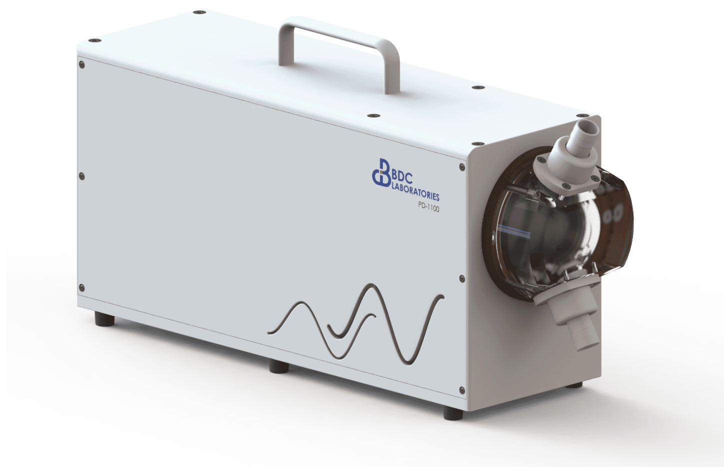


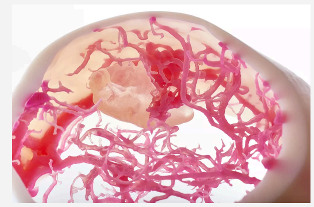
Figure 6: BDC Labs PD-1100 Pulsatile Pump

The PDC Labs PD-1100 pulsatile pump offers a flow rate of up to 10 L/min using a piston design that gives a pulsatile output between 10-240 beats per minute [17]. Along with its high flow rate, the pump offers a digital user interface and the ability for real-time data collection to view testing parameters. The pump, or pumps similar to it, are not available through the BME Teaching Lab and would require an outright purchase, which is not an option given the team's budget.

4 PRELIMINARY DESIGN EVALUATION

4.1 Phantom Material Design Matrix

Table 1: Design matrix for the evaluation of 3 proposed materials

Design Categories (Weight)	**Design 1:** Elastic 50A 		**Design 2:** TPU 92A 		**Design 3:** Stratasys TangoPlus 	
Durability(30)	4/5	24	4/5	24	3/5	18
Reproducibility (20)	4/5	16	5/5	20	3/5	12
Supports(20)	2/5	8	5/5	20	3/5	12
Anatomical Accuracy(15)	4/5	12	3/5	9	5/5	15
Cost(15)	4/5	12	4/5	12	2/5	6
Total Points:	**72**		**85**		**63**	

<u>Reasonings for Scores:</u>

Durability

TPU 92A has scored highest on durability and general flexural strength. TPU 92A can endure CT scan environments and is known for its high tear strength and abrasive qualities out of a variety of 3D printing materials. [22]

Reproducibility

TPU 92A scored the highest on reproducibility due to the most efficient process of fabrication. The TPU 92A would be easiest to fabricate out of the three materials due to the TPU supports, making it easy to remove rigid aspects of the design and cutting time with post-processing compared to Elastic 50A. TangoPlus on the other hand may be efficiently effective to fabricate quickly, but can experience downsides due to the fact that the printing process will be outsourced, so there are many intermediates of communication and delivery.

Supports

TPU 92A has dissolvable support structures, earning it the highest score in this category, since support structures are almost not a factor within the build itself. The previous group's experience with removing support structures in the Elastic 50A compromised the structural integrity of the aorta, causing leaks. Meanwhile, the TangoPlus material would be outsourced, which would allow for a more professional print that the team feels would mitigate leaks as opposed to methods done by the current design team.

Anatomical Accuracy

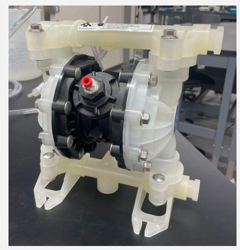
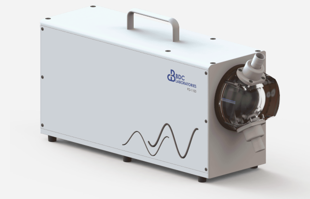
The Stratasys TangoPlus scored the highest for anatomical accuracy. This is because TangoPlus has been used to accurately mimic cardiovascular tissue [23]. It scored higher than the Elastic 50A because Elastic 50A showcases a degree of brittleness; this was easy to spot during inspection by the team and during initial testing of the previous group's device. It also scores higher than TPU 92A because products that are made of this material are more rigid than the other two filaments [24].

Cost

TPU 92A ranked highest in cost efficiency, with an estimated printing cost of around $40. The Spring 2024 design team printed the same artificial aorta file using Elastic 50A filament, which cost $46.82. TangoPlus scored the lowest because it requires outsourcing, as neither the material nor the necessary printer is available in the MakerSpace, making it more expensive and time-consuming.

4.2 Pump Design Matrix

Table 2: Design matrix for the 3 pump designs

Design Categories (Weight)	**Pump 1:** LKB Microperpex Peristaltic Pump 		**Pump 2:** Husky 515 Air Diaphragm Pump 		**Pump 3:** PD-1100 Pulsatile Pump System 	
Flow Dynamics(30)	2/5	12	4/5	24	5/5	30
Cost/ Availability(25)	5/5	25	5/5	25	1/5	5
Ease of Use(15)	3/5	9	2/5	9	4/5	12
Weight(15)	5/5	15	4/5	12	2/5	6
Size(10)	5/5	10	4/5	8	2/5	4
Safety(5)	4/5	4	3/5	3	5/5	5
Total Points:	**75**		**82**		**61**	

<u>Reasonings for Scores</u>

Flow Dynamics

The PDC Labs PD-11000 scored the highest in flow dynamics due to its specialized, laboratory focused design that has very precise adjustability and measurement capabilities, as well as having sufficient output [17]. The Husky pump offers a more robust industry option that is able to provide sufficient output and flow variability, but at the cost of precision. Finally, the LKB Microperpex pump does not offer a sufficient flow, which also causes it to compromise on flow variability.

Cost/Availability

The LKB and Husky pumps both achieved the highest score as they were available to the team for use from the university, whereas the PDC Labs pump was not available immediately without outreach to additional resources.

Ease of Use

Due to the PDC Labs pump containing specific controls for laboratory use and a modern design, it scored the highest in this category [17]. This was followed by the LKB Microperpex pump that had a control panel user interface that controlled flow, as opposed to the lowest scorer in this category, the Husky pump, whose only user interface is the pressure gauge on the air compressor being used.

Weight

All the pumps are within the 50 lb. weight limit and maintain a robust design within this weight, so higher scoring pumps were simply the ones that were the lightest, and most easy to transport.

Size

The pumps with the largest size were given a lower score, as they are more difficult to transport and move in a cramped CT room. As long as the pump maintains functionality, a larger size device does not contribute any benefit for testing purposes.

Safety

The PDC Labs pump was concluded to be the safest as it is the newest from industry and also specializes in the testing environment of a laboratory. This was followed by the LKB Microperpex pump, whose low flow output and small size makes it not suitable for simulating physiological conditions. The LKB pump is archaic, however, much like the Husky 515, scoring it slightly lower than the LKB. Due to the Husky pump's powerful nature and less laboratory-specific design, it was given the lowest safety score.

4.3 Final Proposed Heart Pump for Circuit

Figure 9: Final Proposed Heart Pump

Due to changes in availability, the team has deviated from the originally proposed Graco Husky 515 Pump from the design matrix. Instead, they have selected the Cole Parmer Masterflex L/S Economy Drive Peristaltic Pump. This pump operates using a peristaltic roller system to move fluid through flexible tubing. The absence of input and output ports reduces the risk of leakage during testing. Additionally, the user-friendly interface and ON/OFF buttons provide an easy-to-use experience and allow for quick shut-off in case of failure. The pump can achieve a maximum output rate of 2.9 L/min with the thickest gauge tubing, which falls within the lower range of the proposed specifications in the PDS.

4.4 Proposed Final Circuit Design

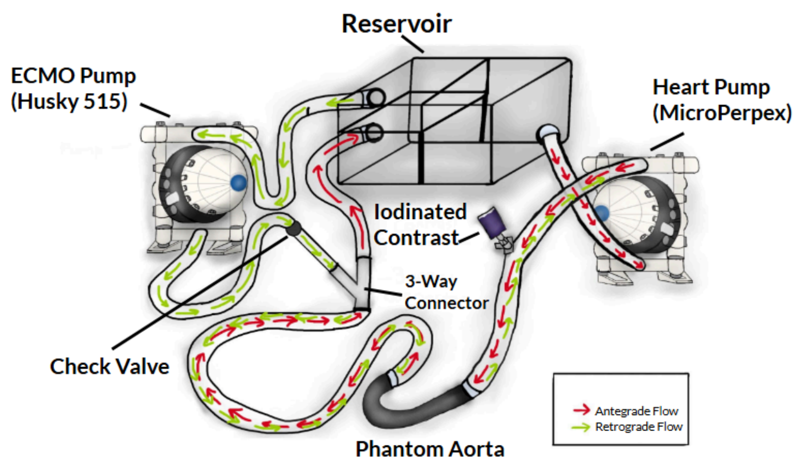


Figure 9: Sketch of final circuit design

The final design circuit consists of a two-pump system, a phantom aorta, a water reservoir, and an injection site for the iodinated contrast solution. The circuit is intended to mimic the anatomical flow of a patient on VA-ECMO. The MicroFlex L/S pump will act as the heart, generating antegrade flow throughout the system, while the Husky 515 pump will act as the ECMO, introducing a retrograde flow into the system. A 3-way barbed connector will be used to secure the pump tubing at the point of highest pressure, where the antegrade and retrograde flows converge. A check valve ensures unidirectional flow from the ECMO pump. Additionally, an air hose will connect the air compressor to the Husky 515 Pump, while the Masterflex L/S pump will require an electrical power source. The reservoir will store the recycled water for both the Husky 515 and Microflex L/S pumps.

5 DEVELOPMENT PROCESS

5.1 Materials

The pump that will replicate the antegrade flow of the heart and the retrograde flow of the ECMO machine will be the Cole Parmer Masterflex L/S Economy Drive Peristaltic Pump and the Graco Husky 515, respectively. The tubing that will be used for the roller pump is the L/S 36 tubing that is capable of pumping 2900 ml/min. If this tubing cannot be found within reasonable availability, then the L/S 24 tubing provided by Dr. Brace will also work. This will feed into the rest of the circuit that will be made up of 0.25 in diameter tubing, this tubing will be borrowed from the BME teaching lab. The aortic arch phantom will be printed from TPU 92A filament material in the makerspace. A site for injection of the iodinated contrast solution will also need to be included, this will likely be a plastic piece that creates a T intersection with the circuit that can be opened and closed at the appropriate time. Connecting pieces between tubes with different diameters will be done with a combination of hose barb fittings and zip ties in order to ensure a secure connection. A dilution reservoir that holds 7 liters of water to act as a simulated contrast solution sink will also be borrowed from the BME teaching lab.

5.2 Methods

The .stl file for the phantom aorta will be retrieved from the previous project's LabArchives and modified to fit the design's tubing dimensions. Then, the MakerSpace will be consulted for guidance on printing before finally printing the phantom aorta on their Stratasys F370 3D-printer. The circuit will be constructed by sourcing the necessary connectors, fittings, and plumbing equipment from Ace Hardware, where physically testing the components will ensure a proper fit on the first purchase. The circuit, along with the pumps, will then be assembled in the BME Teaching Lab. Once fabrication is complete, the team will begin testing.

5.3 Testing

Flow rate accuracy guarantees consistency of the flow rate within the phantom. The system is filled with water, and the flow meter is attached to the circuit. A dial setting is chosen, and the flow rate is measured over a 15-second interval. The experimental values obtained from the flow meter are then compared to the initial values from the flow rate.

A Leak Test ensures that the fastenings and piping are sealed between multiple parts of the phantom. The system is filled with water and pressurized with a pressure pump. The pressure is monitored using a gauge. Significant discrepancies between the final and initial pressure indicate leaks.

CT scan test confirms whether the phantom successfully mimics the situation of VA-ECMO patients and is an overall test of the phantom. The phantom will be placed on the patient's bed, the iodinated contrast solution will be injected into the injector site, and the settings on the pumps will be turned on. From this, attenuation (HU) of the phantom will be acquired, as well as qualitative CT images, to determine the proper contrast injection rate.

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7 APPENDIX

7.1 Product Design Specification

Function:

Computed tomography (CT) is an imaging technique that uses rotating X-rays to obtain images of the human body. These images are used by medical specialists to diagnose issues within the body. Since the COVID-19 pandemic, respiratory and heart conditions have been more common, resulting in increased use of treatments such as ECMO (Extracorporeal Membrane Oxygenation). This device assists the heart and lungs by pumping blood outside of the body and oxygenating it before returning it to the bloodstream. CT machines are often calibrated by a CT phantom. These phantoms are meant to replicate normal bodily blood flow. Therefore, in the case of using CT scanners on an individual who is undergoing ECMO treatment, the rate at which the Iodinated Contrast medium should be injected into the bloodstream is unclear due to the variability of blood flow during ECMO. Previous groups have been successful in creating a prototype for simulating blood flow through a 3D-printed artery using a dynamic flow pumping system. The client, Dr. Giuseppe Toia, has requested that this semester's team focus on creating a pulsatile pump to mimic the antegrade flow of the heart. He has also requested that a method of diluting the iodinated contrast solution be put in place. Specifically, one that can simulate how the rest of the body dilutes the contrast solution away from the physiological target area.

Client Requirements:

1. The device must ensure stable operation during CT scanning, with a robust, leak-free circuit that maintains proper flow and functionality.
2. The heart pump must produce pulsatile flow and be capable of a variable flow rate ranging from 0 L/min to 6 L/min [1].
3. The heart pump and circuit must be able to sustain operation in retrograde flow conditions.
4. The device must be compatible and integrated with previous versions of the project.
5. The device should allow for hassle-free maintenance and easy cleaning for repeated testing.
6. The system must provide measurable data to derive a mathematical formula for determining the optimal IV contrast fluid and injection rate for accurate cardiovascular imaging in ECMO patients.

Design Requirements:

1. **Physical and Operational Characteristics:**

   a. *Performance Requirements:*

i. A durable model, able to withstand loading and unloading for up to many years
ii. The device should have modular components for ease of repair and replacement for testing.
iii. The heart pump should output at a rate of 60-100 strokes/minute to mimic typical ECMO patient heart rates, as well as patients experiencing acute myocardial infarction [2]. The total output of the pump should have a variable range from 0 L/min to 6 L/min. The low limit accounts for patients undergoing cardiogenic shock (the leading among ECMO patients) at flow rates < 2.2 L/min., as well as accounting for the higher range of cardiac output in normal adults of 6 L/min [3][1].
iv. The heart phantom should be composed of a material that:
    1. Attenuates within the range of normal tissue (20-40 Hounsfield) [4]
    2. Allows Iodinated Contrast attenuates to 100 - 600 Hounsfield [same as above].
v. The heart phantom material should mimic the material properties of myocardial tissue
    1. Myocardial heart tissue has a Young's Modulus of 0.012 to 0.198 MPa [5].
vi. The heart phantom must endure a fluid pressure of up to 300 mm/Hg [6].

b. *Safety:*
i. No specific safety standards regarding CT phantoms
ii. Does not need to be sterilized, but to ensure effective simulation results, the circuit should be flushed between each cycle [7].
iii. Valves and connections should be water-tight to avoid leakage
iv. Radiation [8]:
    1. The team must understand the common side effects of radiation
    2. Use of the CT machine must be kept to a minimum, following ALARA protocols
    3. Proper shielding must be used
    4. Users must stay away from X-ray beam trajectories
    5. The CT machine must only be operated by users certified in Radiation 106: X-Ray Devices through the UW-Madison EH&S Department.

c. *Accuracy and Reliability:*
i. This design intends to provide a better understanding of CT scans of patients on VA-ECMO, and the volume of contrast required to create a legible image of the arteries.
ii. A three-pump system will be used so that the volume of each fluid can be controlled to provide an accurate simulation.
iii. The phantom will be able to provide a flow rate from 0 L/min to 6 L/min while maintaining the strength of the materials used [1].
iv. The arteries of the phantom will withstand the flow of the iodinated contrast fluid.

v. The system must withstand repeated testing without leakage, degradation, or total failure of the pump circuit. The system must be able to be easily transported without becoming disconnected or losing parts.

d. *Life in Service:*
   i. Withstand many uses over time, will be used to calibrate CT machine for each patient
   ii. Should not break or wear, materials need to withstand many cleanings and uses while maintaining effectiveness
   iii. Able to be assembled and disassembled without loss of use or effectiveness

e. *Shelf Life:*
   i. When stored under normal operating conditions, the device will remain functional and its materials will not degrade over extended periods of time without use.

f. *Operating Environment:*
   i. The operating environment will be the same as that of the usual operating environment of a CT machine.
   ii. The product must be able to function between temperatures of 64 and 75 degrees Fahrenheit and the humidity of the room of operations should be between 30% and 50% [9]. This is to ensure that the plastic tubing does not dry out in low humidity, and that moisture does not collect in the mechanical and electrical components of the pumps.

g. *Ergonomics:*
   i. The device must be easy to operate with a clean user interface and instructions regarding the pumps and flow rate variability, various tubes, liquid reservoirs, and pumps kept orderly and organized.

h. *Size:*
   i. The device must be small enough to fit inside the CT machine, which is typically between 75 and 85 inches [10].
   ii. The device must be contained within a reasonable space for ease of transportation and maneuverability onto and off of the machine.

i. *Weight:*
   i. The device must be reasonably lightweight so as not be strenuous to place into the CT machine.
   ii. A single adult person should be able to lift it without extreme effort, therefore it should be at most 50 pounds.

j. Materials:

i. While a CT machine is not as strict as an MRI machine regarding materials, certain materials could result in decreased quality of images.

ii. Metal should not be included in any area of the circuit that will act as a mock target area. Metal can distort the image by transmitting X-rays differently than tissue or bone. This would result in distortions [11].

k. Aesthetics, Appearance, and Finish:

i. The phantom must include a model of the aortic arch.

ii. Certain blood vessels, such as the coronary arteries, arteries traveling to the head, and the femoral artery, should be included.

iii. Pumps must be added to simulate blood flow, which should be visible to any observers.

l. Spatial Configuration / Pump compatibility:

i. The design will feature a pump that allows for a stroke volume of 50-100 mL, at up to 6 Liters per minute [8, 9]. This pump will simulate blood flow in a direction opposite to that of the ECMO pump. The distance between the ECMO pump arterial insertion, and the heart phantom will be anatomically accurate from the femoral artery to better simulate real conditions.

2. Product Characteristics

a. Quantity:

i. One final working prototype should be created

ii. Must be well documented for future research and replication

b. Target Product Cost:

i. The major costs associated with this design are the heart pump, renewed pump connectors, and tubing.

ii. The device should be within a $200 to $300 budget, and the department of radiology and medical physics will reimburse it.

3. Miscellaneous

a. Standards and Specifications:

i. The phantom will be produced in accordance with the FDA 21 CFR, section 1020.33 [14]. Through testing, the phantom shall be able to provide data on contrast scale, noise, nominal tomographic section thickness, the spatial resolution capability of the system for low and high contrast objects, and measuring the mean CT number of water or reference material. The phantom will also aim to stay within the size specified by 21 CFR 1020.33. A detailed procedure will be formulated for the phantom's use, along with a place to document the tests performed with the phantom and the methods used to calculate the mean CT number and standard deviation.

b. *Customer*

i. The client, Dr. Giuseppe Toia, is in the Department of Radiology and Medical Physics and needs a phantom to be used for testing the use of Computed Tomography (CT) machines on patients using VA-ECMO. The device must be easily configurable, provide accurate testing, and be low maintenance.

ii. This product will simulate the flow of blood in a patient using VA-ECMO, resulting in easier monitoring of CT scans of the patient.

iii. The phantom will include a three-pump system to study how the flow of blood pumped from the heart, VA-ECMO blood, and contrast fluid affect CT scans and aid in further research.

c. *Patient-Related Concerns*

i. The phantom will aim to mimic with precision and accuracy the dynamic fluidic environment of a patient on VA-ECMO so as to provide accurate guidelines for medical professionals on how much contrast fluid to inject into a patient. Higher accuracy ensures better efficacy of the CT-machines, while reducing a patient's exposure to radiation.

d. *Competition*

i. Phantom's for use in CT can be either static phantoms or dynamic, and may be used either to test a CT scanner's functionality or aid in examining the perfusion of contrast fluid through a particular part of the body.

1. Gammex CTDI Phantom - This phantom follows the regulations specified in the 21 CFR 1020.33 document and is used to measure the Dose Index of a CT machine, as well as measure other parameters such as noise, spatial resolution, and measuring the CT number of a given material [14].
2. Gammex Perfusion Phantom - Allows researchers to view the perfusion of a contrast fluid through simulated arteries, veins, and brain tissue. The device mimics the density and porosity properties of these various tissues so that their perfusion may be studied in a controlled environment. The device lacks any reference to the shape and anatomical structure of these tissues [15].
3. Dynamic CT Perfusion Cardiac Phantom - A study done by the University of California - Irvine, this cardiac phantom was used to study the perfusion within the heart. The phantom uses an anthropomorphic thorax to simulate a real-patient CT-scan. The device does not use an anatomically accurate aorta valve and does not account for VA-ECMO situations [13].

7.2 Expense Spreadsheet

Item	Description	Manufacturer	Part Number	Date	#	Cost Each	Total	Link
Masterflex L/S Economy Drive Peristaltic Pump	Peristaltic pump for heart function	Cole-Parmer	**77200-62**	10/03/2024	1	$565	$565	Link
Husky 515 Diaphragm Pump	Diaphragm pump for ECMO function	Graco	**2**46484	9/13/2024	1`	$1515	$1515	Link