Product Design Specifications: Computed Tomography (CT) circulation phantom to assess hyperdynamic contrast flow rates

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BME 300/200

Client: Dr. Giuseppe Toia

Advisor: Dr. Chris Brace

Team Members:

Team Leader: Sawyer Bussey

Communicator: Alec Schabowsky

BWIG: Shashandra Suresh

BPAG: Shreya Venkatesh

BSAC: Charlotte Thomas

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 stability during CT scanning while being durable, mobile, and easily transportable on and off the scanner to minimize user stress.
2. The heart pump must produce pulsatile flow and be capable of varying the flow rate between 0 L/min and 6 L/min [1].
3. The heart pump must be able to sustain operation in retrograde flow conditions.
4. Must be compatible and integrated with previous versions of the project.
5. The device must be able to mimic the body in the sense that Iodinated contrast fluid should get diluted as the fluid continues to flow around the circuit as it does when observed within the human body on a regular CT Scan.
6. Key parts of the device should be detachable to allow for hassle-free maintenance.

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 be customizable to reflect the heart rate of a patient on VA-ECMO. Typical heart rates are between 60 and 100 beats per minute, however, this could vary widely depending on the patient's condition [2].

b. Safety:

i. No specific safety standards regarding CT phantoms

ii. Does not need to be sterilized, however, to ensure effective simulation results, the circuit should be flushed between each cycle [3].

iii. Valves and connections should be water-tight to avoid leakage

iv. Radiation [4]:

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 and
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 humidity between 30% and 50% [5].

g. Ergonomics:

i. The device must be user-friendly and clean, with its 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. This is typically between 75 and 85 bpm [6].
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 when it comes to materials, there are certain materials that 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 as it transmits X-rays differently than tissue or bone. This would result in distortions [7].

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 for the simulation of 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 stay within a 400-dollar budget and will be reimbursed by the department of radiology and medical physics.

3. Miscellaneous

a. Standards and Specifications:

i. The phantom will be produced in accordance with the FDA 21 CFR, section 1020.33 [10]. 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 a 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. Our 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 to 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 [10].
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 [11].
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, however, use an anatomically accurate aorta valve, and does not account for VA-ECMO situations [9].

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