CT Circulation Phantom - BME 301

Product Design Specifications

BME 301 Design

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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].

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