CT Circulation Phantom - BME 200/300

Product Design Specifications

BME 200/300 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 [1]. Most phantoms currently in use are static; they do not allow for dynamic flow. Some patients obtaining a CT scan may need a circulatory support device, such as a VA-ECMO (veno-arterial extracorporeal membrane oxygenation) device [2]. There is a clinical need for a CT phantom with dynamic flow capabilities to study the correct ways to conduct CT vascular imaging for patients on ECMO devices. This phantom should model the inflow and outflow of an ECMO patient and have capabilities to simulate the addition of contrast media into the vascular system. Ultimately, this device will help medical personnel to better understand the flow of CT contrast through a patient on an ECMO machine, as the circulation pathways of an ECMO patient differs from a patient not on ECMO.

Client requirements:

- A CT Phantom with the main components of the heart and circulatory system accessed during VA-ECMO, capable of dynamic flow. The inflow and outflow cannulas are typically placed in the right atrium and ascending aorta, respectively [3]
- A ECMO pump and tubing with adjustable flow rates, and connectability to the phantom
- An access point in the phantom for an iodine contrast injector
- A reservoir to draw fluid from and a disposal chamber
- Easily cleaned

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The CT Circulation Phantom will be tested and used in a CT machine. CT, or computed tomography, scans take less than a minute to complete. The phantom would be used up to thirty times a day, for up to many years. The phantom must therefore be constructed in a durable manner to withstand loading and unloading from the CT gantry, as well as in a way that can withstand the effective dose, which is the energy deposited by ionizing radiation x-rays. This dose can range between 7 mSv (millisievert) and 20 mSv for a torso scan, depending on the use of a contrast agent [4]. Because this device will not be used to calibrate a CT machine, the phantom does not have to adhere to specific FDA CT phantom dimension and material regulations [5]. See *Standards and Regulations* for more information regarding FDA requirements for CT equipment.

b. *Safety*: There are no explicit safety standards regarding static CT phantoms. There are, however, extensive criteria for ECLS (Extracorporeal Life Support) machines. These measures primarily refer to patient safety and are not required for our client and user safety, but they are important parameters for the machine to achieve. The circuit should support fluid flow of 3 $L/m^2/min$. The inlet and outlet pressure should not exceed -300 mmHG and 400mmHg respectively [6]. The Circulation Phantom does not need to be sterilized, but should be cleaned thoroughly after each use to prevent staining and mold/bacteria growth. All components should be water tight to prevent leakage and therefore damage. In general, all materials should be non-toxic, secure, and non-sharp.

c. *Accuracy and Reliability*: The design is intended to create a better understanding of the injection rates and volume of contrast needed to properly conduct CT scans on VA-ECMO patients. In performing a scan it is essential that the phantom produces data to exemplify flow rates and associated Hounsfield Unit (HU). The Hounsfield unit must be between 10 and 600 HU for a readable image [7]. It is important that our phantom can produce precise results across multiple scans of the same settings, most notably at the flow rate generated by VA-ECMO (500mL/s) [3]. The standard deviation of the trials at each flow rate tested should be no more than 100 HU.

d. *Life in Service*: The device is designed to be used to test and assess dynamic flow rates through a fabricated phantom. The consumer, likely a medical team, would buy the product to calibrate a CT machine with dynamic flow rates for patients that have dynamic blood flow rates.

e. *Shelf Life*: Because the product's purpose is the specialized usage of phantoms, the device will remain out of use during many periods of its life cycle. Due to this fact, the device is designed to resist normal shelf life conditions for many years. Pre-existing, medical-grade static phantoms are typically in use for many years if not decades. Our design utilizes inexpensive off-the-shelf materials which will lower its shelf life when compared to manufactured products. Due to all of the moving components, the shelf life of the dynamic phantom is believed to be several years, or until one of the components loses accuracy or functionality.

f. *Operating Environment*: The device will operate in a standard CT scanning room. A CT scanning room is very close to 22°C, never to exceed 24°C or fall below 18°C [8]. The standard humidity for operating rooms is between 30% and 70% which the device will be subject to. The procedure is done meticulously, ensuring cleanliness of the area for maximum accuracy of the scan.

g. *Ergonomics*: The phantom should not be excessively difficult to move around. The efficiency of testing procedures should not be affected by a device that is physically demanding to handle. Technicians should not experience ergonomic strain and discomfort when performing testing with the phantom. Research shows that technician fatigue can be a source of excessive radiation administration [9]. Fatigue should not be a byproduct of operating with the phantom.

h. *Size*: The final design will be run through a Computed Tomography scanner for testing. Therefore the size limitation will be determined by the size of the gantry aperture. Typical CT scanner openings range in diameter from 75-85 cm, with some older models being as small as 70 cm [10]. The design should be kept under 70 cm to ensure that testing will be able to take place.

i. *Weight*: The design will have to adhere to the weight limitations of the CT scanner. These limitations state that the device that is put onto the couch that will go into the scanner must be less than 500 pounds, or 228 kg. This is a very obtainable limitation. The device should probably be easy to carry and maneuver, so less than 100 pounds, or 45 kg would be preferable for the purposes of testing and fabrication.

j. *Materials*: The CT Scanner doesn't have a limitation for the materials that we can or can't use while scanning, however, for imaging purposes the prototype should be built without any metals or plexiglass. This primarily rules out using metals and avoiding plexiglass. In addition, the prototype is going to go through many many tests, which means that the construction needs to be robust. Strong plastics, such as PVC [11], should be used for tubing, and other pieces of the construction should be strong enough to hold the key components of the mock-ECMO circuit. The addition of an off the shelf pump is dependent on the availability of an unused ECMO machine/pump to be used with the prototype. If there is not an ECMO pump available, the pump must be able to pump fluid up to the levels of an ECMO pump (500ml/s) [3]. A contrast pump will be provided in the form of a clinical injector.

k. *Aesthetics, Appearance, and Finish*: The preferred shaping of this phantom would be that of something reminiscent of a torso on the exterior, with a tubing circuitry system within to simulate the body of a patient on a VA-ECMO machine. This device should also be adjustable in terms of catheter placement on the body. However, this doesn't need to be a perfect replica as the main goal of the phantom is to show the effects of the varying flow rates within the circuitry. Therefore there is room for appearance adjustments in favor of functionality. Aesthetics and Finish are both non-priority as the point of the device is to be scanned, and neither of those two pieces change the functionality of the device.

2. Production Characteristics

a. *Quantity*: For the duration of this project the goal is to produce one final working prototype. However, the design will be made and documented in detail so that the product could be duplicated in the future.

b. *Target Product Cost*: As of (9/21/2023) the team is intending to borrow phantom components from various departments of UW Health. For anything that cannot be procured from our contacts, the intention is to keep products costs under 200 dollars.

3. Miscellaneous

a. *Standards and Specifications*: Standards and specifications have been established to optimize performance of CT equipment. These guidelines help to ensure that our design will assist in providing accurate diagnoses while minimizing unnecessary radiation exposure to patients and technicians. The FDA's CFR title 21, subchapter J, section

1020.33 establishes standards that feature the importance of employing phantoms to test CT equipment. It requires specific data to be reported from phantom calibration that can be used as evidence of compliance with regulations: contrast scale, noise, nominal tomographic section thickness, and spatial resolution capability of the system for low and high contrast objects [5]. ASTM E1695-20e1 is a standard test method for CT system performance measurement. Section 5 outlines physical specifications for the phantom testing apparatus including shape, size, material, and finish [12]. Other relevant standards include IEC 61223-3-5, AAPM Report No. 111, NEMA XR 21, and IPEM Report 87. The FDA classifies our device as a Class I medical device with general controls. The FDA recognizes that this device is exempt from premarket notification 510(k) procedures, and exempt from current good manufacturing practice requirements of the quality system regulation except for general requirements concerning records and complaint files [13].

b. ***Customer*****:** Our customers/clients in the department of Medical Physics at UW Madison are in need of a phantom to be used for the testing and calibrating of a Computed Tomography machine. The phantom must be able to mimic the dynamic blood and contrast flow that occurs in a patient when they are using a VA-ECMO machine. By using an off the shelf pump, the phantom must be built with a structure similar to a VA-ECMO machine as well as the heart and major systemic arteries. Current phantoms with static flow rates are well understood and allow for proper imaging to take place on real patients. Meanwhile, vascular imaging with dynamic flow rates is not as well understood which is why the clients need the phantom device to allow for alterable flow rates.

c. ***Patient-related concerns***: While the device is important for the care of many patients, it will not be in contact with any as its main purpose is to calibrate and be used for testing in CT machines. That being said, the device must still follow strict guidelines in its creation in order to eliminate any risk when running tests on it.

d. ***Competition:*** There are currently phantoms designed with dynamic flow rates for CT testing. One such device is a two-compartment, 3D printed phantom which allows for testing on various CT, MRI, and PET machines. Testing on the device allows for the creation of TACs (Typical Clinical Time-Attenuation Curves) which can be analyzed for DCE-CT (Dynamic Contrast Enhanced Computed Tomography) validation and to create more realistic imaging models of patients [14]. Another device was created because photoacoustic (PA) spectroscopy, while useful, was found to be too slow. Dynamic PA flow cytometry (PAFC) platforms have fast-moving cells that can have velocities from 20-50 cm/s which does not work with most blood phantoms that involve static flow. The team created a device that resembles the properties of whole flowing blood and CTCs (circulating tumor cells). Their device used silicone and "Layer-by-Layer" assembled capsules that had hemoglobin and "natural melanin micro- and nanoparticles." They found it challenging to make these objects seem similar to the real things and to "simulate their optical properties". Finally, their device represented different cell types and used "scattering-absorbing medium" and plastic tubing. It was successfully used to test "high speed signal processing in PAFC." Hollow polymer and silica capsules correctly simulated blood cells and melanoma markers which allowed the device to resemble blood in its optical and dynamic properties [15].

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] 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.

[4] S. Seed, "How Much Radiation Do You Get From CT Scans?," *WebMD*. https://www.webmd.com/cancer/radiation-doses-ct-scans (accessed Sep. 22, 2023).

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

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

[7] "Relationship between Hounsfield Unit in CT Scan and Gray Scale in CBCT" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4120902/ (accessed Sep. 22, 2023).

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

[9] "Failure to Adjust CT Scanners to Pediatric Settings is a Major Cause of Unnecessary Radiation Exposure to Children," Aug. 24, 2023. https://www.researchsquare.com (accessed Sep. 22, 2023).

[10] 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.

[11] 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.

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

[13] "CFR - Code of Federal Regulations Title 21." https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=892.1940 (accessed Sep. 22, 2023).

[14] 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.

[15] A. Kozlova *et al.*, "Dynamic blood flow phantom for in vivo liquid biopsy standardization," *Sci. Rep.*, vol. 11, no. 1, Art. no. 1, Jan. 2021, doi: 10.1038/s41598-020-80487-8.