

The Product Design Specification (PDS)

Title: Heart Phantom

Function: This project consists of designing a heart phantom to be used for the initial testing of a new, solenoid-tipped catheter in order to gain future FDA approval for the device. This catheter will ultimately be used to treat atrial fibrillation under MRI guidance. The transparent phantom will reduce the need for animals to be used in testing the catheter, and will consist of clear tubing of various sizes representing tortuous vasculature leading to a single heart chamber. All “veins” must terminate at one end of the phantom and be sealed so they may be filled with a saline solution in either a static or dynamic state without risk of leaking. The phantom will ultimately be used to test the maneuverability of the catheter under MRI guidance as well as the high resolution imaging capabilities in the vicinity of the solenoid tip.

Client Requirements:

- Must fit inside a cylinder with height and radius both equaling 13 inches.
- No ferrous materials are allowed.
- The heart can be simply defined by two chambers separated by a thin, replaceable membrane (disposable septum).
- The catheter must be able to puncture through the membrane separating the two heart chambers.
- Tortuous vasculature
- All inlet vessels must converge into one single large “vein” that goes into the heart.
- The outlet vessel connects the heart to the outlet pump must be on the same side of the cylinder as the inlet pump.
- Vessels should vary in diameter from 0.25 inches to 0.5 inches.
- The entire circuit of vessels should be filled with saline solutions.
- The entire circuit of vessels is submerged in agarose gel inside the cylinder.
- The entire circuit of vessels should be transparent.
- Absolutely leak proof.
- Under \$1000

1. Physical and Operational Characteristics

a. *Performance requirements:* All parts should be capable of being removed and replaced as necessary. The device will be surrounded in a casing that is completely leak proof and able to withstand movement in all directions. The vasculature and heart should also be completely leak proof and able to withstand the poking, sliding and turning movements of the catheter while inside the phantom.

b. *Safety*: The heart phantom must be completely leak proof and lack ferrous materials so as to avoid a negative interaction with the MRI machine.

c. *Accuracy and Reliability*: The vasculature of the heart phantom should be a close approximation to that of a normal human. The phantom's vasculature will be changed as necessary to allow for testing the maneuverability of the catheter. The heart itself can be as simple as a plastic sphere with potential to be opened, improved, or completely replaced in the future. The vasculature and heart will be somewhat free to move within the casing (similar to that of normal human vasculature) so each time the catheter is inserted, the path it follows may be slightly different. The pressure waveform created by the pumping of saline through the heart phantom should closely resemble that of a pressure waveform created by blood in a human body.

d. *Life in Service*: Our device should have a life of at least five years. The device will be used approximately five times daily with and without the pump. It should incorporate materials that can easily be removed and replaced when needed.

e. *Shelf Life*: The heart phantom will be stored primarily at room temperature and at an altitude of approximately 300 meters. All batteries associated with the pumping mechanism will need to be replaced as needed.

f. *Operating Environment*: The device will operate inside an MRI scanner during which a saline solution will be pumped through the vessels. The remainder of the container will be filled with an agarose gel. All materials will need to be corrosive free.

g. *Ergonomics*: The tubing will need to handle the pressure exerted upon it from the fluid pump.

h. *Size*: The product will need to fit into a cylindrical MRI scanner that has a diameter of 13 inches and a length of 13 inches. The interior of the product will need to be accessed for cleaning and replacement of the disposable septum. The device will also need to be portable/able to be carried by an individual.

i. *Weight*: The product should weigh no more than 20 lbs. when completely filled with saline and agarose gel.

j. *Materials*: No corrosive material. No ferrous material as this device needs to be used in MRI scanners.

k. *Aesthetics, Appearance, and Finish*: The device should be completely transparent and should be cylindrical in shape to mirror the shape of the MRI scanner. The shape of the tubing should be cylindrical. The heart should be spherical or more closely mimic the shape of the human heart.

2. Production Characteristics

a. *Quantity*: 1

b. *Target Product Cost*: under \$1,000.

3. Miscellaneous

a. *Standards and Specifications*: N/A

b. *Customer*: N/A

c. *Patient-related concerns*: N/A

d. *Competition*: N/A