PDS – Heart Phantom

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Function: A heart phantom will need to be designed to be used for the initial testing of a solenoid tipped catheter in order to gain FDA approval. The catheter will ultimately be used to treat atrial fibrillation under MRI guidance. The transparent phantom will have vasculature mimicking the superior vena cava, the inferior vena cava and the four pulmonary veins. The heart will consist solely of the two atrial chambers separated by a disposable septum. The vasculature and heart will need to be filled with a saline solution in both a static and dynamic state without the risk of leaking. The phantom will ultimately be used to test the maneuverability of the catheter under MRI guidance as well as high resolution imaging capabilities in the vicinity of the solenoid tip.

Client Requirements:

- Casing
  - Fit inside a cylinder with a length and diameter of 13''
  - Drain attachment to empty fluid in casing
- Vasculature
  - Superior and inferior vena cava with diameter between 20 – 30 mm (0.75 - 1.25 inches)
  - Pulmonary veins with diameter between 10 – 20 mm (0.4 – 0.75 inches)
  - Superior vena cava functions as the outlet for the system
  - Inferior vena cava functions as catheter entry point and will be statically filled with fluid
  - Pulmonary veins function as the inlets to the system
- Heart chamber
  - Left and right atrium separated by a thin disposable septum
  - Superior and inferior vena cava terminate in right atrium
  - Pulmonary veins terminate in left atrium
- General
  - Leak proof
  - No ferrous material
  - Transparent

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device will be used on a weekly basis under MRI. All parts should be capable of being removed and replaced as necessary. The heart should be able to be taken apart for insertion or removal of the disposable septum.

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 and prevent damage.

c. *Life in Service*: Our device should have a minimum lifespan of five years with internal vasculature and septum being replaced as necessary.

d. *Shelf Life*: The heart phantom will be stored at room temperature when not in use.

e. *Operating Environment*: The device will operate inside an MRI scanner while a saline solution or water is pumped through the vasculature. The casing will either be filled with water or an agarose gel for weighting purposes. The internal vasculature will be under pressure while fluid is being pumped though the circuit.

f. *Size*: The product will need to fit into a cylinder that has a length and diameter both equal to 13 inches. The internal vasculature will need to have diameter between 20 and 30 mm for the superior and inferior vena cava and between 10 and 20 mm for the pulmonary veins. The heart chamber will need to be approximately 3 inches in diameter. The device will also need to have an access area on the top so that tubing and the disposable septum can be changed on a regular basis.

g. *Weight*: The product should weigh no more than 20 lbs. when completely filled with saline or water so that one individual can easily move the phantom on and off the MRI table.

h. *Materials*: No corrosive or ferrous materials as this device will come in contact with fluids on a regular basis and be used in MRI scanners.

i. *Aesthetics, Appearance, and Finish*: The device should be completely transparent. The casing should be cylindrical in shape to mirror the shape of the cylindrical MRI coil and to maximize the internal space available for vasculature. The heart chamber should resemble the actual human heart as much as possible. The location of the pulmonary veins in the left atrium should be accurate, since this is the portion of the heart where the ablation procedure is performed.

2. Production Characteristics

a. *Quantity*: 1

b. *Target Product Cost*: Under $1,000.