BME 400: Final Report

Heart Phantom Team

Co-Team Leader: Peter Strohm
Co-Team Leader: Lacey Halfen
Communicator: Jessica Hause
BSAC: Erin Main
BWIG: Fan Wu

Advisor: Willis Tompkins
Client: Orhan Unal

Table of Contents

Abstract

Atrial fibrillation is a disease that affects over 2 million Americans, with possible complications ranging from fatigue to stroke. In order to treat this disease, a catheter may be used to scar the tissue of the atria in order to disrupt the electrical signals that cause the irregular beating of the atria. Dr. Unal created a solenoid-tipped catheter that may be used to perform this procedure under MRI guidance, but FDA approval must be obtained before its use. The heart phantom designed this semester will be used to mimic the procedure in order to test the new catheter developed by Dr. Unal. The phantom was designed following the client's constraints, and includes a square acrylic casing with 12”diameter end caps. This casing encloses several tygon tubes of varying sizes, as well as y-fittings and reducers, representing tortuous vasculature. It also includes a spherical heart chamber and a high-resolution testing block made of acrylic. The testing block will be used to ensure the vasculature surrounding the catheter can be visualized. The device was tested by connecting the tubing to a pump that was used to move water through the vasculature, simulating blood flow. This testing demonstrated a need for improved fluid flow. Also, MRI testing was performed and a solution of Gadolinium was able to be visualized moving through the vasculature. In the future, a phantom that incorporates an improved heart chamber with smaller vasculature will be developed that provides more consistent fluid flow.

Motivation

Atrial fibrillation is characterized by irregular beating of the atria. This erratic beating is caused by chaotic electrical signals within the atria of the heart and may lead to heart palpitations and chest pain. Disorganization of the pumping of the heart causes poor blood flow throughout the body. This may lead to shortness of breath, fatigue, and lightheadedness.[1]

Other, more serious, complications arise from the increased risk of blood clots in the atria. This results from the possibility of blood pooling in the atria when the heart beats out of sync. The blood clots increase the possibility of the patient experiencing a stroke. Another highly serious complication is the possibility of heart failure due to the wear this disease causes on the heart.[1]

Background Information

Treatments for atrial fibrillation generally involve attempting to either reset the heart rhythm or to disrupt the

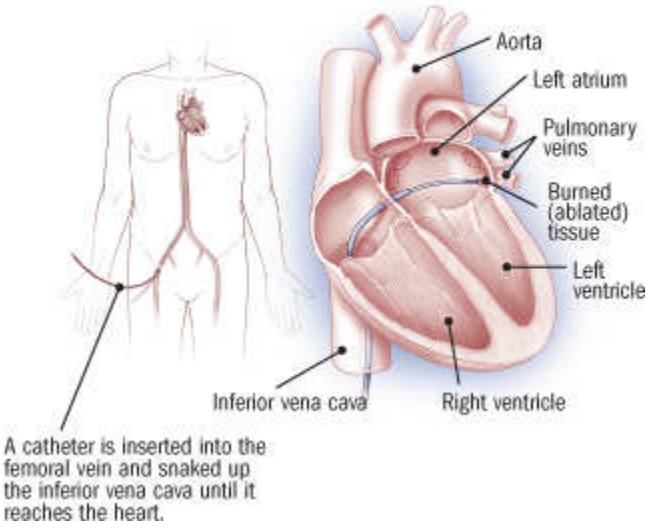

Figure 1: Image of a catheter being used for atrial ablation[2]

erratic electrical signals.[1] Dr. Unal is interested in treatments involving catheter intervention. This may be necessary when rhythm-controlling or resetting drugs fail to work. The catheter would be inserted into the femoral vein at the groin and moved through the vasculature until reaching the left atrium of the heart. Once there, it would be used to scar the heart tissue in a pattern meant to interrupt the electrical signals that cause atrial fibrillation.[1] This burning process is referred to as ablation, and can be seen in Figure 1.

Dr. Unal is interested in performing this procedure under MRI guidance. Unfortunately, catheters are not visible under MRI. In order to solve this problem, Dr. Unal has developed a solenoid-tipped catheter that could be imaged under MRI. In order to use this device with humans, however, FDA approval is required. This means a protocol must be developed, followed by animal (or phantom) testing before human testing may be conducted. Instead of animal testing, a phantom that mimics the surroundings for the procedure may be used.

Current Products

One heart phantom currently on the market is the Ultrasound Heart Phantom for cardiac image training that was developed by Computerized Imaging Reference Systems, Inc. Although this phantom includes the left and right atriums, it is ultrasound, not MRI, compatible. It also does not include any pathways for the insertion of a catheter, and is unnecessarily complex for Dr. Unal's purposes.[3]

The heart phantoms currently available are generally not MRI compatible, and do not include an opening for a catheter to enter the phantom. This is necessary to mimic the procedure and ultimately gain FDA approval. Commercially available phantoms are also often unnecessarily complex, and therefore expensive.[3] Other current phantoms are less complex, but have been developed for specific procedures. These phantoms are either not compatible with the desired procedure or not available for purchase. This semester's project involves developing a heart phantom specific for Dr. Unal's needs.

Figure 2: Heart phantom available from CIRS, Inc. for use with ultrasound[3]

Problem Statement

The heart phantom developed will be used for the initial testing of a new, solenoid-tipped catheter awaiting FDA approval. This catheter will ultimately be used to treat atrial fibrillation under MRI guidance. The transparent phantom will 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. It 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.

Design Constraints

Figure 3 is a basic representation of the components of our design. The device, including the acrylic casing, must be able to fit inside a cylindrical of height and diameter both equaling 13". An external pump (not to be included in our device) should carry a saline solution through an inlet and outlet vessel (both with diameters less than 1"). Several (one to four) smaller vessels (diameters 0.25 to 1") must twist inside the casing and eventually connect somewhere along the inlet vessel. The inlet and outlet vessel should connect to a spherical casing (diameter 3") representing the heart. A thin membrane, representing the heart septum, should be mounted inside the heart casing and should be able to be punctured by the catheter. Agarose gel should surround parts inside the casing not only to provide support, but also to simulate loading of the MRI machine in a similar way to that seen with a human. All parts should be MRI compatible (no metals), leak proof, and transparent.

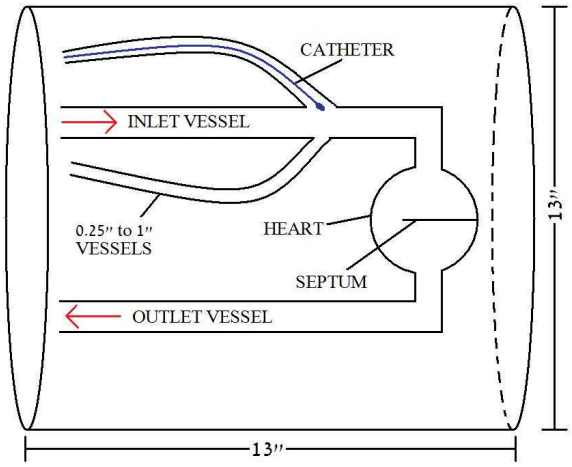

Figure 3: The basic components of the phantom

Preliminary Designs

Tubing Design

The Tubing design includes clear flexible tubes to represent various vessel sizes, an acrylic spherical casing for the heart, and an outer casing made of acrylic. The vasculature would be connected together through y-connectors and reducers (to allow connecting tubes of different diameters). Holes would be drilled on one side of the acrylic casing to allow the tubes to pass through. Plugs, clamps, and cable ties around tubes and connections, as well as glue and caulk securing the casing, would prevent leakage. The vessels and heart chamber would be supported by the agarose gel (Figure 4).

The Tubing design has several advantages. The geometry of the tubes can be easily modified by the addition or removal of tubing, y-connectors, and reducers. This ability to change tube lengths, diameters, and positions will be helpful during pumping

tests; decreasing the length of tubes will decrease their resistance and thus increase fluid flow. The external tubes can also be easily attached to the client's pump via quick disconnects. The y-connectors will serve as an easy inlet port for the catheter. Disadvantages include varying diameters due to y-connections and reducers, as well as tube flexibility being limited to tube material and wall thickness.

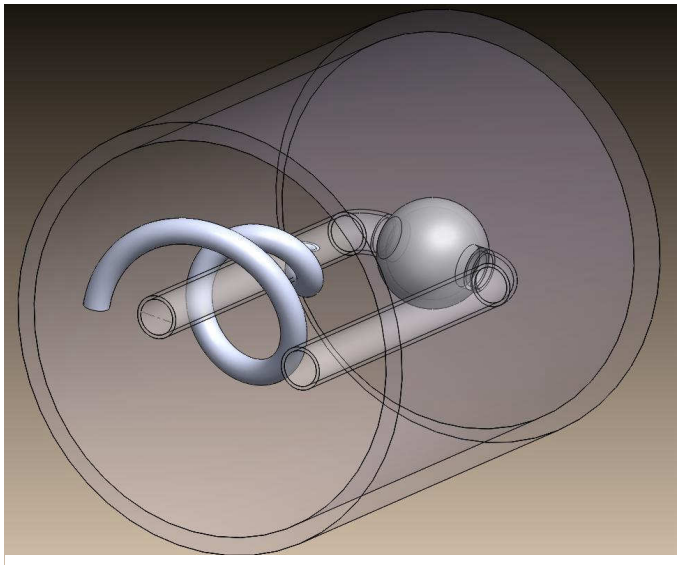

Figure 4: Tubing design with tortuous vasculature and test heart

Polymer Block Design

As an alternative to the Tubing design, the Polymer Block design consists of a cylindrical polymer block with tunnels inside that represent the vasculature and the heart chamber. The first step of the construction procedure requires the creation of a "dummy" vasculature. The "dummy" vasculature will then be set and temporarily fixed inside an open-top cylindrical container with dimensions specified by the client (less than 13" diameter). Liquid polymer will be poured into the cylindrical container with the "dummy" vasculature inside until completely full. Once the polymer solidifies, the "dummy" vasculature will be removed, leaving behind hollow tunnels within the polymer block. Finally, the solid polymer can be removed from the cylindrical container.

The rationale behind the Polymer Block design is that it avoids some of the intrinsic problems and inconveniences involved with the Tubing design. First, the Tubing design requires leak proof tubing connections between different branches of the vasculature. Because the client desires the phantom to contain as much convoluted vasculature as possible, there will be a large number of tubing segments that require flawless connections. Construction of such a complex system with absolutely no leakage would be difficult. In contrast, the vasculature within the Polymer Block design would be completely engulfed in the thick, hydrophobic polymer, eliminating the risk of water leakage. In the Tubing design, the entire vasculature complex, including the heart chamber, would need to be suspended inside the cylindrical casing. This raises the issue of whether the vasculature system could be firmly supported to resist movement and the stress caused by the tubing's own weight. Considering the possibly copious amounts of

tubing, the stress felt by the tubing at the bottom of the complex could cause mechanical failure, especially at the junctions of the tubing segments. On the other hand, the tunnels inside the Polymer Block design would have orientations and dimensions strictly defined by the solid polymer. Because the volume of tunnels should greatly exceed the polymer volume, the weight would be much less than with the Tubing design. The mechanical stress throughout the system would also be approximately uniform.

Final Design Selection

Although the Polymer Block design has certain advantages over the Tubing design, it has doubtful aspects that cause uncertainty with regards to a successful completion within the time given. The most difficult part of the Polymer Block design is the construction of the "dummy" vasculature. As mentioned above, the "dummy" vasculature must be stable and fixed inside the container when it makes contact with the liquid polymer. However, after the polymer solidifies, the "dummy" vasculature must not adhere onto the polymer and must be easily removed. Some ideas include using compressible materials such as Styrofoam or dissolvable materials such as clay or dough. It may seem reasonable to assume that these materials can be pulled or washed out of the solidified polymer, but it is unsure how much they will adhere onto the polymer or how they be formed into the shape of the vasculature. Much preliminary testing is needed and it would require a significant amount of time. Because the Tubing design has a proven concept and was envisioned by the client at the beginning of semester, it was decided that the Tubing design should be pursued. See Appendix A: Design Matrix.

Tubing

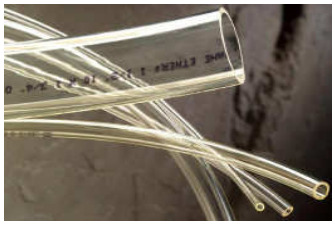

Figure 5: Polyurethane tubing

For the tubing aspect of the phantom, the two most feasible choices were polyurethane and tygon. Polyurethane (Figure 5) is a stronger, but more rigid, form of tubing. The thicker, rigid tubes would move less within the casing, but would be not be able to bend or curl in different directions.

Tygon (Figure 6) is more flexible and could easily be bent and curled within the casing in order to better simulate the human vasculature. The tygon is also thinner and clear, making it easy to see through for maneuvering the catheter within the phantom. As a result, it was decided that tygon tubing would be used in the final design.

Figure 6: Tygon tubing

Connectors

Figure 7: Twist connector

In order to connect the tubes to each other and to the heart, a number of different connectors were explored. The first was a twist connection design (Figure 7) that includes a male and a female part that are simply twisted together to form a water-tight connection. However, these connectors only came in solid colors and limited angles and have a very small inner diameter that would prevent the catheter from passing through smoothly. A quick connector design was also explored (Figure 8). For this connector, the tubes are easily pushed into the connector but in order for them to be removed, one must push on the connector and pull on the tubing at the same time. These connectors also only came in solid colors, limited angles, and employing metal springs which were prohibited in the design. The last connector that was considered was a barbed tubing connector (Figure 9). It is extremely simple with an inner diameter only slightly larger than the diameter of the tubing it is used with so one simply pushes in and pulls out the tubing as needed. They are clear, come in a variety of different angles, and leave a large diameter for the catheter to pass through. As a result, these were the connectors chosen for the phantom.

Figure 8: Quick connector

Figure 9: Barbed connector

Heart Chamber

The heart chamber will be made to mimic the two atrial chambers of the human heart. To construct the heart chamber, two 3" diameter acrylic hemispheres, each having a small flange around the outside, will be connected using plastic screws and bolts (Figure 10). The two hemispheres represent the two atrial chambers of the heart. Between the flanges of the two hemispheres, an O-ring will be used to ensure that the seal between the two hemispheres was fluid tight. A thin septum will be placed between the two hemispheres to correspond to the division between the right and left atrium. The septum will be used by the client in the future to simulate puncturing a catheter through the tissue between the right and left atrium. The septum only separates approximately half of the hemispheres, to allow for continual and uninterrupted fluid flow through the heart chamber. The septum will be made from a sheet of paraffin film that cut to fit the correct size of the heart chamber.

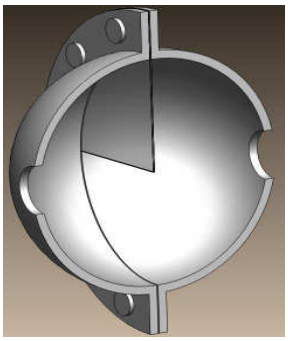

Figure 10: Two acrylic hemispheres are bolted together to form the phantom heart.

The heart chamber will allow the client access to the septum to replace it following each practice procedure. For access, the client will simply need to remove each of the screws to separate the two hemispheres.

High Resolution Block

A high resolution area of the heart phantom will be created to allow the client to insure that the catheter placed in a larger vessel doesn't inhibit the visualization on MRI of the surrounding vasculature. An acrylic block (3" in height and length and ½" in width) will be used for the high resolution area. A large hole will drilled into the block to allow for the threading of the tubing that will represent the larger vasculature where the catheter will pass through. Several small holes (1/16" in diameter and 1/32" in diameter) are to be drilled as shown below to mimic the surrounding vasculature (Figure 11).

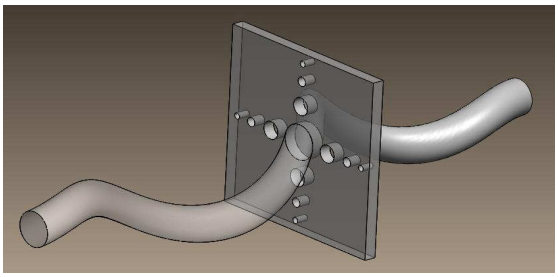

Figure 11: Acrylic block to be used for high resolution testing

Final Design

The phantom has a square acrylic casing 12" long and ½" thick with circular acrylic end caps 12" in diameter and ¼" thick. The top of the casing was attached with plastic screws for easy removal so that the case could be opened and the parts cleaned or replaced. The rest of the casing is held together with acrylic glue and sealed with silicon calk to make it completely leak proof.

All tubing begins and terminates on one side of the phantom so that it can be connected to a fluid pump for quick, even filling and flowing. There is one large inlet (1/2'' diameter), three small inlets (3/8'' diameter) and a single large outlet. Stiff polycarbonate tubing goes through the acrylic wall to connect the flexible tubing on both sides and is sealed with silicon calk in the acrylic wall. The flexible tubing is sealed onto the polycarbonate tubing with snap grip tubing clamps to ensure that they fit together snugly. The four flexible inlet tubes on the outside of the phantom are connected to four barbed tube fittings that screw into a manifold. The manifold then connects to two branches of flexible tubing with quick-disconnects to be attached to the fluid pump. All external tubes are connected to barbed y-fittings with one end connected to a sheath for catheter entrance and the other end going on to the pump.

The flexible tubing is tygon tubing with a 3/8" outer diameter and ½" inner diameter that branches into smaller tygon tubing with a 5/8" outer diameter and 3/8" inner diameter. The tubing branches via barbed y-fittings and reducing couplings.

As a result of complications with our original heart parts, the heart is represented by two 3" diameter plastic hemispheres that fit together and are sealed with acrylic glue and silicone caulk. Stiff polycarbonate tubing goes through both sides of the heart to connect the flexible tubing to the hemispheres.

The high resolution testing block was also incorporated into the prototype. The block has four sets of two different sized holes that will test the resolution of the catheter in the MRI. The holes in the acrylic block will represent small vasculature and the resolution of the catheter will be determined based on which of the holes can be seen in

the MRI image and how well. The total cost of our phantom was under $600, well under our budget. See Appendix B: Materials and Cost for details.

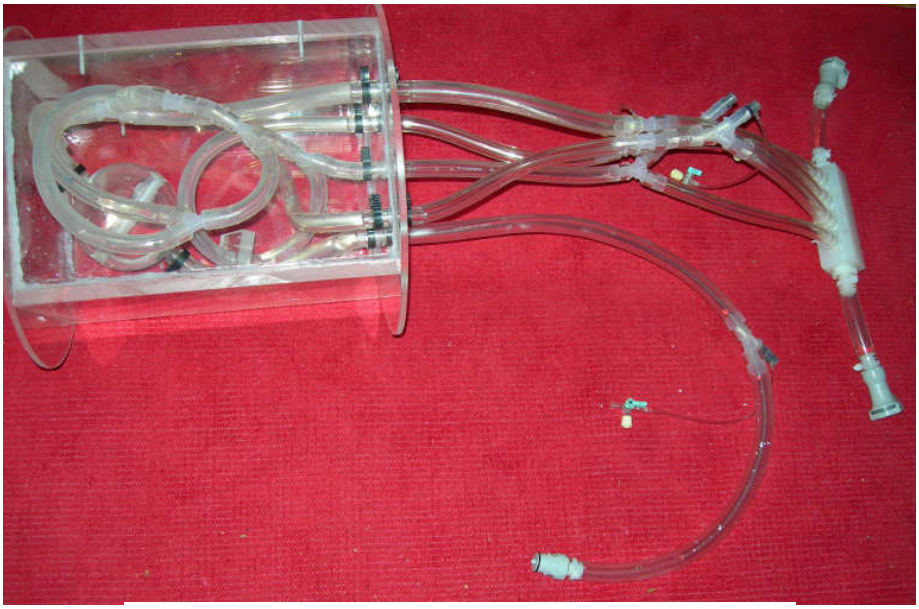

Figure 12: Completed heart phantom with pump connection, heart, vasculature and casing.

Testing

In order to test the device, three types of testing were performed: fluid containment, flow consistency, and MRI. For the fluid containment, the heart phantom was tested in both the static state and the dynamic state with pressure from the pump. For the static testing, the entire casing as well as the tubing was filled with water. This allowed testing for any leaking in the joints of the casing or tubing connections. The dynamic state testing with pressure was performed by attaching the phantom to the pump. This allowed the determination of how the device responded under pressure. With the dynamic test, there was some leaking around the connections between the tygon and polycarbonate tubing when only the zip-ties were used. To remedy this, snap grip tubing clamps were used to provide a tighter seal between the tubing connections. Also, during this testing the heart chamber had some slight leaking at the junction between the two halves. Additional acrylic glue and silicone caulk was applied around the junction between the two halves to provide an improved seal for testing.

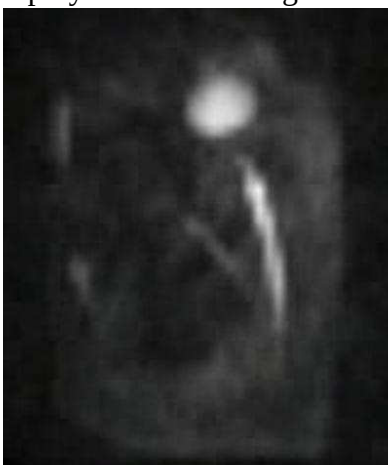

Figure 13: 2D MRI image of phantom.

The flow consistency testing was also performed when the heart phantom was attached to the pump. Flow was observed in all the branches of the tubing, as well as through the heart cavity. The flow through the reducers, y-fittings and connections was interrupted due to the decrease in diameter associated with the connections. Also, flow through the heart and smaller tubing was not consistent due to the build-up of air pressure and the pump capacity.

A solution such as a venting hole will need to be implemented in the future to fix this issue.

The final testing performed on the device was MRI testing. For this testing, the cavity of the heart phantom was filled with water for loading purposes. Typically, when this device is being used on a regular basis, it would be filled with agarose to provide the necessary loading. Once filled with water, the pump was turned on to fill the vasculature. Unfortunately, the sealing between the two hemispheres of the heart was unable to take the pressure exerted on it by the pump and the seal failed. Despite this failure, testing continued and 2D and 3D images of the heart phantom were taken. Following this, a solution of 10% gadolinium was injected into the heart chamber over a period of approximately 5 seconds. MRI images were then taken over a period of 30 seconds to observe the flow through the heart phantom. Looking at the MRI images over the period, flow is visible through the vasculature. As a result of the seal on the heart chambers breaking earlier in testing, small traces of the gadolinium solution can be seen leaving the heart on the MRI images. The heart chamber, as well as the other issues that were discovered will need to be resolved in the future.

Figure 14: 3D MRI image of heart phantom.

Conclusions and Future Work

This semester's prototype was an excellent start to this project, although several improvements must be made. The plastic hemispheres currently representing the heart are inadequate, as they are weak and incapable of being sealed properly. The acrylic hemispheres already ordered will be durable and sealable with the help of O-rings. These hemispheres will also allow a disposable septum to be added or removed. Additionally, fluid flow through tubes needs to be improved, as all tubes cannot contain any air and must maintain a sufficient flow rate. This could be done by decreasing tube lengths, tube height (vertical position in the casing), and tube diameter, all of which will decrease the resistance to flow. The client mentioned it may be acceptable for all tubes to be of equal diameter, which would eliminate the need for reducers and improve flow and flexibility. It would also be appropriate to experiment with tubing of different materials and thicknesses to optimize flexibility without causing kinking. The y-connectors also must be modified so the catheter does not get stuck when entering. This could be solved by tapering the entrance with a file. Additionally, the geometry of the tubing must be modified to more closely resemble human vasculature, with the degree of resemblance determined by the client's requirements.

Appendix A: Design Matrix

Design	Cost (0.05)	Usable (0.25)	Feasible (0.1)	Resemblance to human (0.2)	Reproducible (0.15)	Replaceable (0.25)	Total
Polymer Block	9 (0.45)	7 (1.75)	9 (0.9)	5 (1.0)	8 (1.2)	3 (0.75)	4.25
Tube	7 (0.35)	10 (2.5)	8 (0.8)	9 (1.8)	8 (1.2)	8 (2.0)	8.65

Appendix B: Materials and Cost

Project Component	**Part**	**Cost**
Casing	Acrylic Sheets, 1/2" thick	$98.40
	Acrylic Circles, 1/4" thick	$37.76
Tubing	Tygon 1/2" ID, 3/4" OD	$38.71
	Tygon 3/8" ID, 5/8" OD	$72.60
	Polycarbonate 1/4" ID, 3/8" OD	$2.61
	Polycarbonate 3/8" ID, 1/2" OD	$2.80
Tube Fittings	1/2" OD Y-fittings	$17.90
	3/8" OD Y-fittings	$8.55
	Reducers, 1/2" to 3/8"	$5.00
	Other	$28.38
Pump Connections	Quick-Disconnects, 3/8" size	$44.24
	Manifold, 4 outlets	$42.75
	Barbed Tube Fittings	$14.42
TOTAL		**$414.12**

Appendix C: Product Design Specifications (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 awaiting FDA approval. This catheter will ultimately be used to treat atrial fibrillation under MRI guidance. The transparent phantom will 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. It 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.

Client Requirements:

- Must fit inside a cylinder with height and diameter 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.
- Must include tortuous vasculature.
- All inlet vessels must converge into one single large vessel that goes into the heart.
- Must include an inlet and outlet tube, through which saline can be pumped. The inlet and outlet tubes must be on the same side of the cylinder.
- Vessels should vary from ¾ to ½ inch inner diameter, and at no point be smaller than ¼ inch.
- The entire circuit of vessels should be capable of being filled with a saline solution and submerged in agarose gel without leaking.
- All parts inside cylinder should be transparent.
- 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. Tubing must be able to fill completely to attain continuous fluid flow within vasculature.

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 an approximation to that of a normal human. The heart itself may be a simple plastic sphere with the potential to be opened, allowing for a disposable septum or piece of meat to be placed within. 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*: The phantom should have a life of at least five years. The device will be used frequently 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. All batteries associated with the pumping mechanism will need to be replaced as necessary.

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

g. *Ergonomics*: N/A

h. *Size*: The casing is a rectangle 12 inches long, with circular end caps of 12 inch diameter to fit the phantom into a cylindrical MRI scanner of diameter 13 inches and length 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 or 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. It should have circular caps on each end slightly smaller than 13 inches in diameter so the phantom can easily slide into the outer-most cylindrical casing provided by the

client. The shape of the vasculature is cylindrical, and the heart is spherical.

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

Appendix D: References

I) Mayo Clinic Staff (2007) *Heart Disease: Atrial Fibrillation.* Retrieved October, 2008, from http://www.mayoclinic.com/health/atrial-fibrillation/DS00291

II) Harvard Medical School Faculty (2006) *Atrial Fibrillation: Beyond Drug Therapies.* Retrieved December, 2008, from http://www.aolhealth.com/conditions/atrial-fibrillation-beyond-drug-therapies

III) CIRS (2008) *Ultrasound Heart Phantom.* Retrieved October, 2008, from http://www.cirsinc.com/067_ultra.html