Esophageal Simulator

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Abstract

Eso-technologies is in need of an simulator that will allow them to test and develop their cardiac monitoring device without the need for patient interaction. After weeks of brainstorming and researching, we have decided upon a single tube pressure design that will express the pressure waves within the esophagus by pumping gas into a flexible tube. Fabrication of our design was completed with ease, however finding the right machinery to drive air into the tube turned out to be our biggest challenge to overcome.

Problem Statement

Eso technologies is currently developing a new, less invasive device to replace the pulmonary artery catheter (PAC). The PAC measures cardiac pressures and heart conditions during surgery. The PAC, despite its benefits, caused ~40000 heart related complications in patients last year. Eso technologies' new device will monitor the heart and respiratory function via the esophagus. The device is still in the research and development phase and is being tested on patients. However, because the device is limited to 40 patient trials by the FDA, our goal is to design an esophageal simulator that minimizes patient interaction while allowing quicker testing and refinement of the device. Our device needs to be able to replicate the dynamic pressure from the heart and lungs as well as the static pressure of the esophagus.

Introduction to Eso-technologies

Eso-technologies is a small, growing biomedical engineering company from Middleton, Wisconsin. Currently Eso-technologies has patents on several designs, including an esophageal cardiac monitoring system, that is designed to replace the PAC. The new design will be less invasive which should limit complications, cost less, and be easier to handle.

The device will monitor the cardiac pressure, specifically the left atrium, lung pressure, esophageal static pressure, and the dynamic pressure from peristalsis. The new device uses human anatomy to read required pressures. The wall of the left atrium of the heart is in direct contact with the wall of the esophagus, so any pressure developed in the atrium will be translated through the tissues into the esophagus, where any push onto the probe will equate to a specific pressure. In Figure 1, the esophagus is the small opening toward the center of the photo, and the left atrium is the dark cavity that contains the teal color. The esophagus resides within the chest cavity and therefore the static pressure in the esophagus will be manipulated to oscillate with the positive and negative pressure waves of the lungs. The lungs can be seen on either side of the heart in Figure 1, taking up the majority of the chest cavity. This allows the Eso-technologies' device to be less invasive while monitoring similar areas as the PAC because their device does not need to be inserted into the heart, causing additional stress.

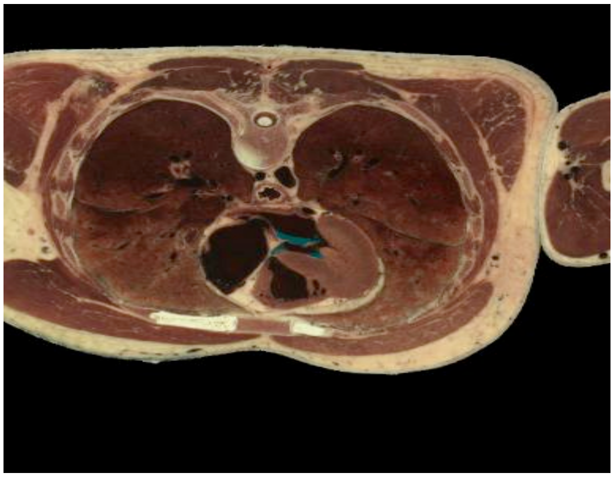

Figure 1: Anatomical slice including the esophagus, heart, and lungs (1).

Current Testing Methods

The Eso-technologies device is still in the refinement process. To determine areas where the device requires improvement, the device needs to be tested in the environment. The best way to do this is in patients during clinical trials. However, the problem with this method is that the FDA has limited each probe to just 40 clinical trials, requiring more probes to be fabricated, which delays the refinement process and is a lag on costs for the new company. Therefore, if a device can be designed to replicate the testing environment, more tests can be run per probe which increases refinement turnaround and decreases the need to fabricate a large number of probes.

Client Requirements

The most important aspect of this design is the simulation of cardiac pressure (Figure 2). In order to do this, a programmable pump will be used. With the data provided by the client, the pump will be used to recreate the pressure waveforms of the heart, specifically the left atrium. In addition to this, it is important that other pressures of the thoracic cavity are produced, one of which is the static pressure of the esophagus. Because the esophagus is essentially a deflated tube when resting, it will exert pressure on anything that is it, including Eso-technologies' probe.

Eso-technologies' provided sample waveforms to guide our design (Figure 2). The top trace is of an ECG and the bottom trace shows the esophageal waveforms. Another pressure generating component of the thoracic cavity is respiration. During respiration, a negative pressure process causes air to enter and leave the lungs. The air, or lack thereof, causes pressure changes in the chest that can be measured in the esophagus. The final pressure that needs to be accounted for is the esophageal pressure during peristalsis. When swallowing occurs, a wave of contraction occurs down the esophagus, resulting in pressure exertion on the probe. Although this is an important pressure wave to generate, it may be out of the scope of the first semester of the design.

Figure 2: ECG and pressure waveforms provided by Eso-Technologies (2)

Before choosing materials to use, ranges and frequencies of the previously mentioned pressures must be known. With the help of Dr. Reikersdorfer, we were able to gain quantitative values for these pressures (Table 1).

Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	0-30 mmHg	40-140 per min
Chest Cavity	-10-30 cmH2O	0-20 per min
Esophagus (static)	0-50 mmHg	Constant
Esophagus (dynamic)	0-100 mmHg	0-10 per min

Table 1: Required Pressure Ranges

In order to generate these pressures, several different mechanical and software components must be used. Although the clients do not require any specific components or programs, it is required that the pressures may be independently varied and also changed in frequency in order to simulate different situations. In addition, a system must be put in place to measure the generated pressure, to verify that the pressure output as calculated by the program actually matches what the probe is sensing. This system will also provide a feedback loop to make any necessary corrections.

Design Alternatives

Pressure Tube

The first possible design is a rigid tube with an inflatable inside that replicates the pressure waveforms from the chest cavity. The inside tubing would be flexible and mimic the properties of an esophagus. The inflexible outside tube could be made of inexpensive PVC tubing. The inside flexible tubing would wrap around each end of the rigid outside tubing and be sealed off by o-rings to prevent air loss with a clamp. A pressure generator or pump would be attached to the rigid tubing pumping air between the outside and inside tubing (Figure 3).

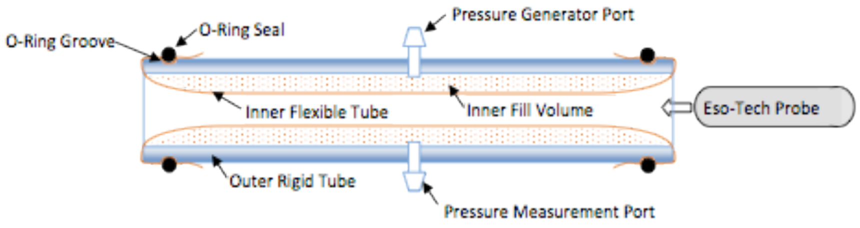

Figure 3: Pressure Tube Design

Also, a pressure measurement device would be attached to the tubing system to read what pressure is being delivered to the esophageal probe. The measurement of the delivered pressure can be used to make a closed loop system (Figure 4). The input and output pressures could be used to calculate the error and adjust automatically. Two simulators could be placed in line so each pressure bulb on the probe is reading a different pressure. One simulator would generate the respiratory and static pressures while other would generate the same pressures as well as the cardiac pressure waveforms. This would allow both bulbs on the probe to be tested separately. One positive aspect of this design is the simplicity of construction and maintainability while still delivering the correct pressure waves to the esophageal probe. A negative aspect of this design is the programming of the motor driving the air into the system, since all three pressure waveforms are delivered from one source.

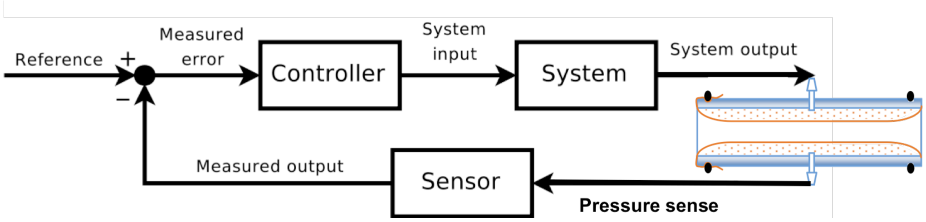

Figure 4: Closed Loop

Thoracic Cavity

The second design idea tries to replicate the anatomy of heart in relation to the esophagus (Figure 5). The design consists of a rigid box containing a flexible tube, replicating the esophagus. A fluid filled sac would be placed next to the esophagus and impinge on it, acting like the heart in a human. The "heart" would have its own pump allowing it to have a separate waveform than the respiratory pressure. To hold the esophagus in place, a rigid "back bone" could be placed behind it, like in the human body. Pressurizing the rigid box and regulating the flow of air with a pump would generate the pressure from the lungs. The static pressure is also provided by the pressurization of the rigid box. A positive aspect of this design is the low

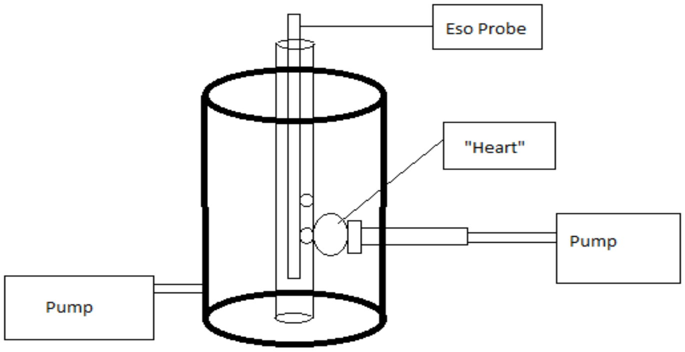

Figure 5: Thoracic Cavity Design

complexity in programming the pumps. Also, the anatomy is closer to what is seen in a human body. Our client may in the future want to test the device with real organs, allowing this design to be modified later. The heart provides a contact pressure on the esophagus, just like in the chest.

A negative aspect to this design is the complex construction and maintenance. The rigid container must be sealed, which may be difficult with the esophagus tubing exiting from each end. In addition, keeping the heart in a specific position may be difficult. Possibly making a rigid tube that extends from the inside wall to the esophagus may be a solution to the problem. The probe also must face a specific direction and be placed a specific distance down the tube. This may cause inconsistent results from testing, causing the simulator to be less accurate if all that needs to be tested is the pressure sensors on the probe.

<u>Double Bladder Apparatus</u>

The third design alternative is the double bladder apparatus (Shown in Figure 6). In this design, the pressure sources are the two liquid filled bladders, shown in black in Figure 6. These sacs are made of a strong, elastic material, capable of frequent expansion and contraction while undergoing contact pressure from the surrounding apparatus. The bladders are connected to a separate glass syringes, each filled with enough fluid to simulate the required pressures. The upper bladder impinges on the reference balloon and will be used to generate the static pressure of the esophagus and respiratory pressure simultaneously. The lower bladder will simulate cardiac, respiratory, and

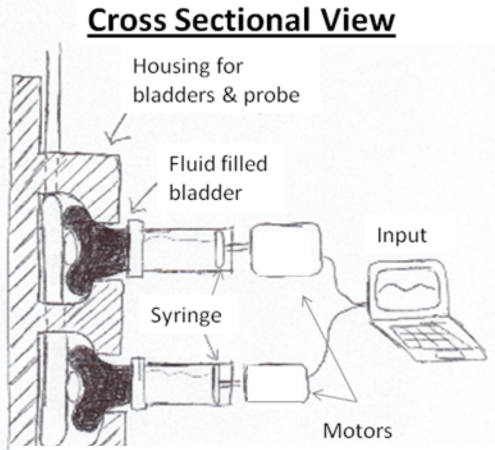

Figure 6: Cross-Sectional View of the Double Bladder

esophageal pressures simultaneously. The two bladders and the probe are held firmly in place by the rigid support apparatus (cross-hatched structure in Figure 6). The glass syringes are each driven by their own motor, which will in turn create the respective pressures of the two fluid filled sacs. These two motors will receive input from data programmed into LabView.

The advantages of this design are its two fluid filled bladders permits simultaneous data collection of the reference and left atrial pressure sensors. This allows the program to subtract the pressures applied to the reference sensor from the pressures on the left atrial sensor and in theory, leave only the cardiac pressures. Also the implementation of the liquid filled balloons versus air filled allows for a more accurate representation of the contact pressure of the left atrium in a human because the heart is a liquid filled organ. This design also incorporates the rigid housing that will hold the probe and bladders in place. This housing will prevent the bladders and probe from moving relative to each other during testing, allowing for more reproducible results.

However, this design has some drawbacks as well. One issue with this design is that the bladders create a unidirectional pressure on the probe's sensors; therefore, if the bladders are not positioned so they are uniformly distributed over the sensor, the pressure readings will be skewed. This design is also anatomically inaccurate because it lacks an esophageal analog and each bladder generates multiple pressure waves, instead of having a separate system for each waveform. Straying from an anatomically correct design disallows for future expansion of the design through the incorporation of real organs and tissues. This design uses two motors to generate the pressure waveforms, which create the possibility of synchronization issues. This includes lag between the two motors due to a programming error or a mechanical malfunction of one of the motors; this would cause inaccurate readings of the pressure waves.

In addition, the overall fabrication of this design would be difficult because the rigid support apparatus (cross-hatched structure in Figure 6) is complicated to construct.

Design Matrix

To evaluate which design would best fulfill the client's requirements, a design matrix (Figure 7) was created. This matrix evaluates each design on five categories: the accuracy of the pressures produced, the reproducibility of the pressure measurements, the cost of each design, the simplicity or ease of construction of the designs and lastly how anatomically correct each design is. Each category was allotted a certain number of points for a total of 100 points between the five categories. The accuracy of the generated pressures was given the highest point allowance at 40 because it is most important for the design to create pressure waveforms of the correct magnitude and frequency so that the data collected by the probe is representative of the pressures found in a human body.

The reproducibility of the measurements was allotted the next highest point total at 25 because it is imperative that the probe experiences the same pressures from trial to trial so that malfunctions or design flaws of the probe can be detected by obtaining results that deviate from the norm. The simplicity or ease of construction was given a point total of 20 because the design should be feasible to build in a timely manner so that testing with the probe can get underway. The anatomical accuracy of each design accounted for 10 points out of the 100 because an anatomically correct design allows for future expansion by incorporating real organs and tissues. Also an anatomically accurate design may account for pressure losses or other phenomenon that occur in the human body as the waveforms are translated through the various tissues before they reach the esophagus. Lastly the cost of the design was weighted at 5 points out of 100. Cost was least important out of all the categories because many of the materials and devices required to build the designs can be donated by Eso-technologies and their affiliates. These point allowances are based off the clients design specifications point allowances are based off the clients design specifications.

	Design Matrix					
	accuracy 40	**reproducibility 25**	**Cost 5**	**Simplicity (ease of construction) 20**	**Anatomy 10**	**Totals**
Pressure Tube	35	23	5	18	5	86
Thoracic Cavity	30	15	2	10	10	67
Frame w/two balloons	30	20	4	13	5	72

Figure 7: Design Matrix based on our clients design specifications.

After evaluating each design against all five categories, it became apparent that the pressure tube design would best fulfill Eso-technologies design specifications. The thoracic cavity, even though it is anatomically correct and produces fairly accurate pressure waveforms, would have major issues producing consistent results due to the interaction of so many dynamic systems. In addition, the design would be costly and difficult to build and therefore scored the lowest out of all three designs. The double bladder apparatus scored moderately across all categories with the exception of anatomical accuracy due to its simpler design. However, the pressure tube was found to produce the most accurate and reproducible waveforms as well as being the cheapest and easiest to fabricate. Therefore, the best design for Eso-technologies esophageal simulator is the pressure tube.

Final Design

The pressure tube was to be built to incorporate a tube-in-tube design that would accomplish our goals in a simple straightforward manner. Our tube-in-tube consists of a rigid outer shell with an inner flexible membrane that will translate changes in pressure. The outer shell is a simple PVC pipe roughly an inch inner diameter. The flexible membrane, a penrose drain, is simply stretched across the inside of the PVC pipe. To ensure no air leakage, we used a combination of o-rings and pipe clamps to ensure a tight seal (Figure 8).

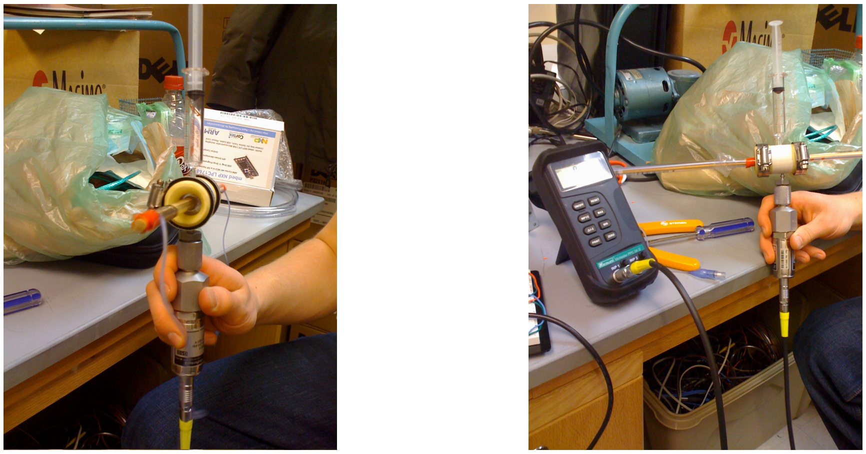

Figure 8: Pressure Tube and Measurement System

To generate our pressure fluctuations we needed a way to "pump" air into our flexible membrane to manipulate the pressures of the heart, lungs, and peristalsis. We decided to use a glass syringe. Glass was chosen because it has less resistance than a similar plastic syringe. We drilled a small hole into the PVC pipe and inserted the syringe, and with a complete seal any movement of the syringe plunger would increase or decrease the pressure within the "esophagus." In order to move our syringe plunger in the necessary patterns, we used a stepper motor connected to a gear shaft connected to the plunger head (Figure 9). The gear shaft proved to be an important component, as it translated the motor's rotational movement into the linear movement of the syringe.

Figure 9: Rack and pinion to convert rotational motion to transverse motion.

To control the movement of our stepper motor we used a 5V microprocessor that used C++ computer code connected to a 5V micro-controller that translated the microprocessor information into an output sent to control the 30V motor (Figure 10). During the semester, a computer program that only mimicked the waveforms of the lungs was generated. The lungs require the motor acceleration to resemble a cosine wave, which when integrated represents a velocity sine wave. The velocity graph correlates to a gradual pressure waveform that resembles a smooth respiratory cycle.

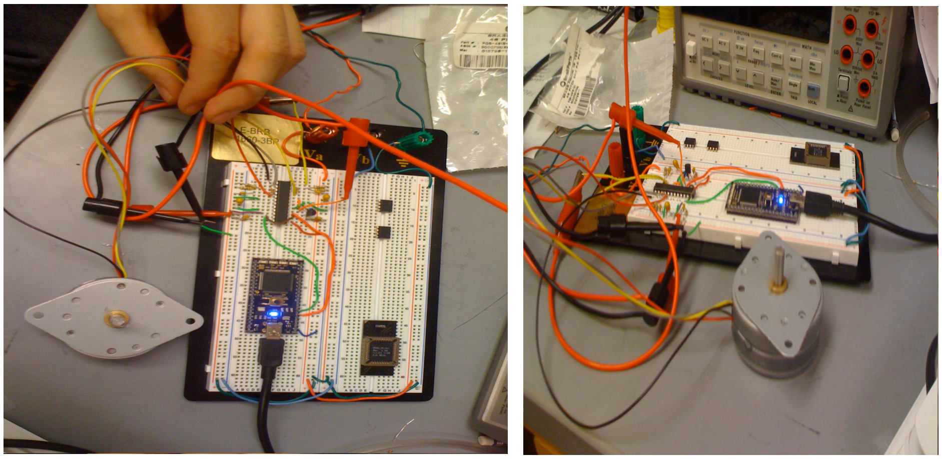

Figure 10: Circuit and stepper motor design.

Our final design also incorporated a pressure transducer which reads the pressures we were able to create within the flexible membrane environment. To add the transducer to the esophagus system we used the same technique that we used when we connected the syringe.

We drilled a small hole and with a tight seal inserted the transducer head into the hole. The transducer was not as exact as we had hoped, recording at minimum of .1 psi, which is equivalent to 5.17 torr (mmHg).

Testing

Due to time constraints, only preliminary testing was preformed on the physical components of the design. The pressure, as mentioned above, was one of the parameters measured. On the transducer, the measured pressure maximum was .7 psi for a 5 ml syringe, which is equal to 36.19 mmHg. Before the transducer was available for use, a sphygmomanometer was used to make rough estimates, which approximated to 30-40 mmHg. With the 5 mL syringe as the mechanical component causing pressure changes, it was discovered that the volume of air was not sufficient to produce the wanted pressure. In order to resolve this, the tube size was reduced. This decreased the volume, and therefore increased the pressure.

Testing also occurred in developing the stepper motor program. This testing was conducted on several different computer programs. Our first motor was controlled by serial terminal and a program provided with the controller board. We discovered after turning on the motor that it was not fast enough and did not have enough torque to push a lead screw. To fix these problems, a new motor was chosen and a gear and rack was chosen as the means for motion transmission.

After acquiring a more powerful stepper motor, a new controller was needed. This controller stored and ran developed programs, which were in C++. In order to generate sine waves, much testing was done to critique and change the control system to generate the angular velocities and accelerations desired.

Cost Analysis

This semester we did not nearly exceed our budget of $500 (Table 2). However, more costs are likely to turn up as more improvements are made. The Jameco motors were purchased with the serial converters. When this method did not succeed, a new motor, gears, and a rack were necessary for purchase.

Cost Analysis			
Part (including shipping)	Quantity	Description	Cost
Stepper motor	2	Jameco 224022	$43.90
Stepper motor	2	Jameco 155433	$49.40
Plumbing (PVC), Clamps, O-rings			$7.00
Serial to USB Converter	2		$9.88
Gears and Rack			$53.29
Stepper motor	1	Bipolar	$67.00
Total			$230.47

Table 2: Cost Analysis

Future work

After successfully simulating a respiratory wave, we will continue to add complexity to the design. This will include pressure waves replicating the atrial pressure in real time (motor speed permitting). If the speed and/or torque of the motor does not allow for a real time simulation, there is an option to slow down the entire cycle to ensure that all the pressure waves can be generated and recorded. In addition to this, options can be added that can increase or decrease frequency of the pressure waves to model different situations and different patient conditions.

Another aspect for improvement is the pressure monitoring and feedback system. Currently, we are able to determine the pressure inside the tube, but not able to provide feedback to make any necessary corrections. This is due to a lack of a transducer and connection to the stepper motor controller. However, we have recently acquired a transducer that would perform this function, and plan to use it in the future (Figure 11). We must also consider the changes in pressure due to the volume of the probe's measuring probe. It was reasonable to assume that an increase in size of the object would produce more pressure if the same volume of air was pushed into the tube. This was the case after basic testing.

Figure 11: Pressure sensor that can interface with computer to provide feedback.

Conclusion

Due to many different delays in progress due to insufficient or incompatible parts, only the sinusoidal component of the thoracic cavity could be simulated. However, recently acquired parts and extended work with the computer program have shown a proof of concept. Therefore, we think it is possible to recreate the pressures of the thoracic cavity in real time, and are excited to do so.

References

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- John Webster-Advisor
- Dennis Bahr

Appendix A- Product Design Specifications

Project Title: Esophageal Simulator

Team members: Joel Schmocker, Luke Juckett, Ian Linsmeier, Tyler Klann

Function: Eso-Technologies is currently in the process of developing a pressure sensing device that will measure the cardiac pressure from the left atrium. Because they have limited testing sessions on patients, they have requested that a pressure simulator be constructed. The device needs to have a programmable pump that can reproduce and vary the frequency and size of the pressures generated by the heart, lungs, and esophagus.

Client requirements: Shown below are the required pressure ranges.

Left Atrium	0-30 mmHg	40-140 per min
Chest Cavity	-10-30 cmH20	0-20 per min
Esophagus (static)	0-50 mmHg	Constant
Esophagus (dynamic)	0-100 mmHg	0-10 per min

In addition to this, the device must be able to independently read the pressures to provide feedback to the pump.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device needs to be able to produce pressure waves from the esophagus, heart, and lungs. The pressure waves must also be able to be varied in both magnitude and frequency.

b. *Accuracy and Reliability*: It is very important that the pressures exerted on the probe are correct. In order to do this, real measurement provided by Eso-Technologies will be programmed into the system. In addition there will need to be an external pressure sensor to ensure the correct pressure and to provide feedback when necessary.

c. *Life in Service*: The device will be used as new developments of the probe occur and need to be tested.

d. *Shelf Life*: During normal use, the device will last very long. However, different materials will likely be placed into the tube to simulate the esophagus.

e. *Operating Environment*: The system will be used in a lab. It will not need any special materials to prevent wear and tear from the environment.

f. *Size*: The pressure tube will likely be a small size, because a small contact point is needed for the probe. In order to be portable, a laptop computer could be used as the source of the pump information

g. *Materials*: The material in the tube should mimic the esophagus, as the probe will be placed in the esophagus. Currently a penrose drain is a suitable option for this.

2. Production Characteristics

a. *Quantity*: There is a need for one system, with an option to replace the material inside the tube.

b. *Target Product Cost*: The budget is allowed up to $500

3. Miscellaneous

a. *Competition*: Currently there is no device that reproduces pressures in order to test an esophageal probe