Esophageal Simulator

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Abstract

Eso-technologies needs a simulator that will allow them to test and develop their cardiac monitoring device without the need for patient interaction. After a semester of considering design alternatives, a single tube pressure design that will express the pressure waves within the esophagus by pumping gas into a flexible tube was decided upon. The goal of this semester is to further develop and improve this design by integrating and testing necessary components, such as pressure transducers and a computer/microcontroller interface.

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.

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 incorporate into biological environments.

The device will monitor cardiac pressure, specifically of 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 is in direct contact with the wall of the esophagus, so any pressure developed in the atrium will be translated

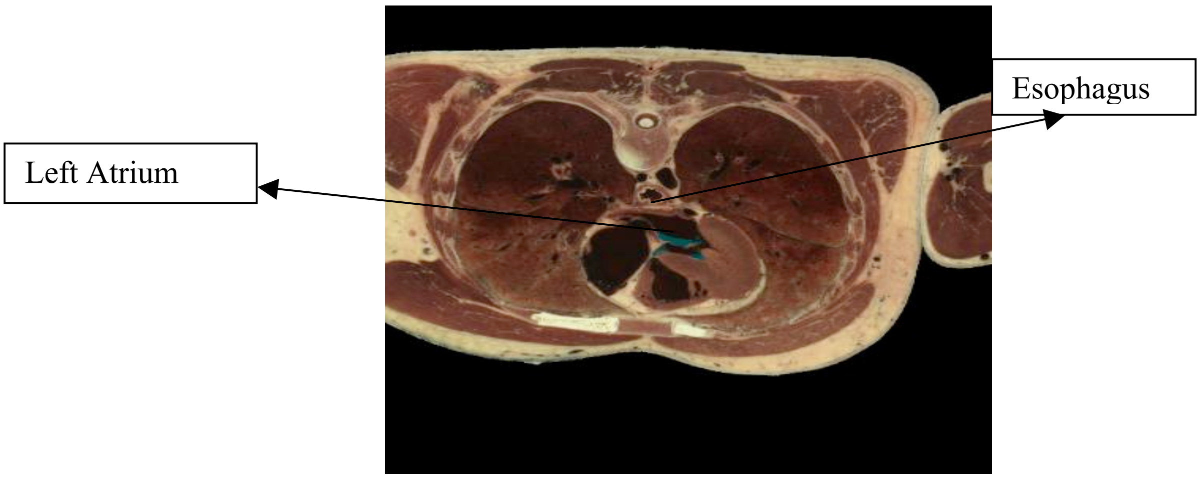


Figure 1: Anatomical slice including the esophagus, heart, and lungs (1).

through the tissues into the esophagus, where any push onto the probe will equate to a specific pressure. In Figure 1, the lateral anatomical cut shows the esophagus and the heart. The esophagus resides within the chest cavity and therefore the static pressure in the esophagus will 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. This is because their device does not need to be inserted into the heart, which will reduce the risk of potential unwanted physiologic reactions.

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 surgical 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 adds additional costs for the 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 respiratory pressures felt by the esophagus. Because the esophagus is essentially a deflated tube when resting, it will pass pressure to anything that is inside 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 inspiration, the ribs move outward to create negative pressure. Then air enters the lungs. The air 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 travels down the esophagus, resulting in pressure exertion on the probe. Although this is an important pressure wave to generate, it is not the waveform that will be focused on.

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).

Design Requirements		
Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	**.8 – 2.93 kPa**	**40 – 140 per min**
Chest Cavity	**0 – 2.93 kPa**	**3 – 8 per min**
Esophagus (static)	**0 – 6.67 kPa**	**Constant**

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.

Previous Work

Pressure Tube

The design that was decided on last semester is a rigid tube with an inflatable inside that replicates the pressure waveforms from the chest cavity. The inside tubing is a flexible material, called penrose, that has properties similar to that of the esophagus. The inflexible outside tube is made of inexpensive PVC tubing. The penrose wraps around each end of the rigid outside tubing and is sealed off by O-rings to prevent air loss with a clamp. A syringe is attached to the rigid tubing pumping air between the outside and inside tubing (Figures 3, 5).

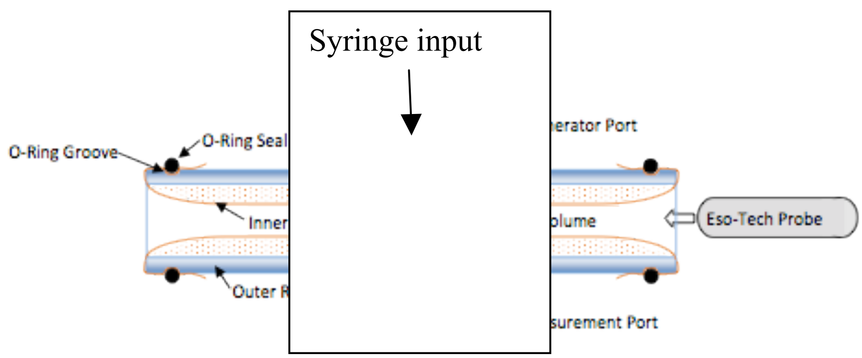


Figure 3: Pressure Tube Design (3)

Also, a pressure measurement device was intended to be attached to the tubing system to read what pressure is being delivered to the esophageal probe. This was not completed as of last semester, but is in the process of incorporation. 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 (Figure 5). 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 the pressure waveforms are delivered from one source.

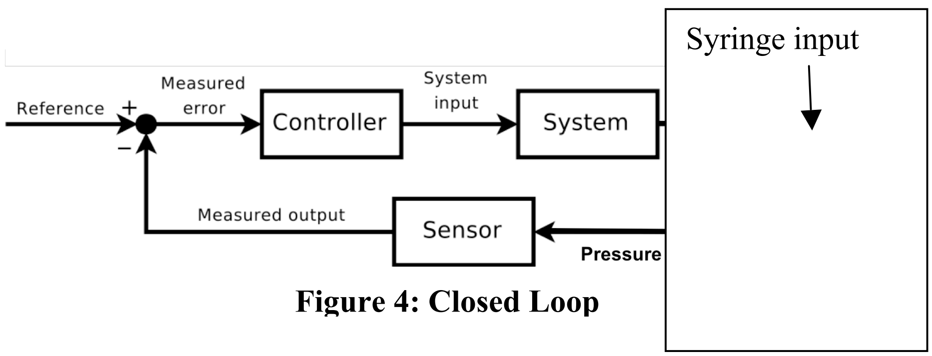


Figure 4: Closed Loop

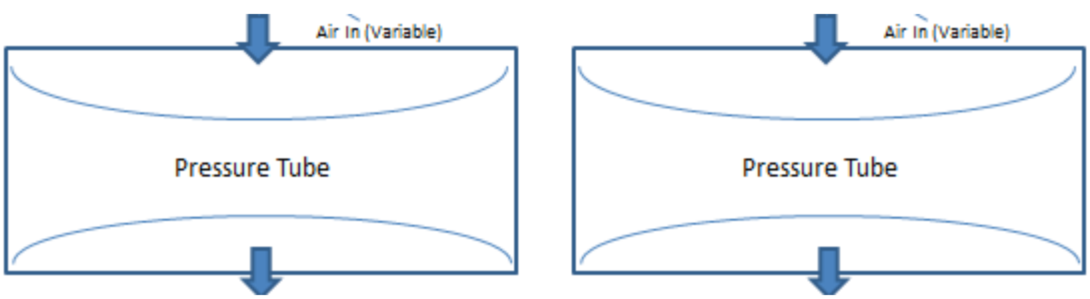


Figure 5: Duplicated Pressure Tubes for Testing Both Balloons

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."

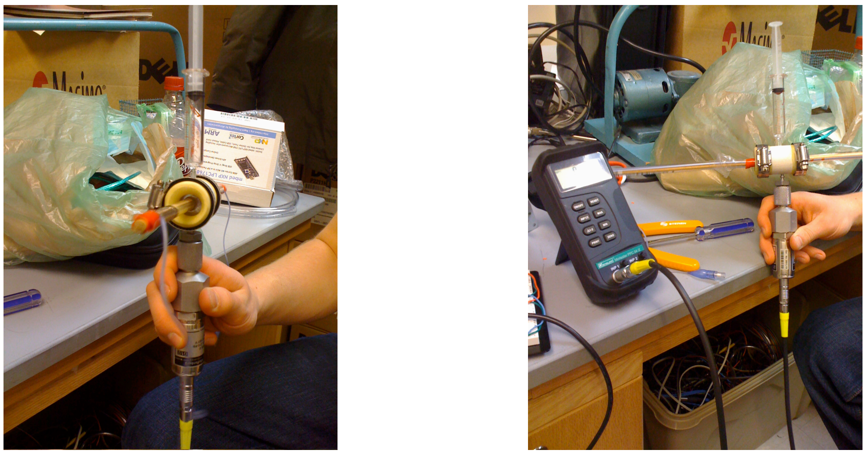


Figure 6: Pressure Tube and Measurement System

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 7). The gear shaft proved to be an important component, as it translated the motor's rotational movement into the linear movement of the syringe. This was chosen over a lead screw because of foreseen difficulty of attaching the syringe to the lead screw.

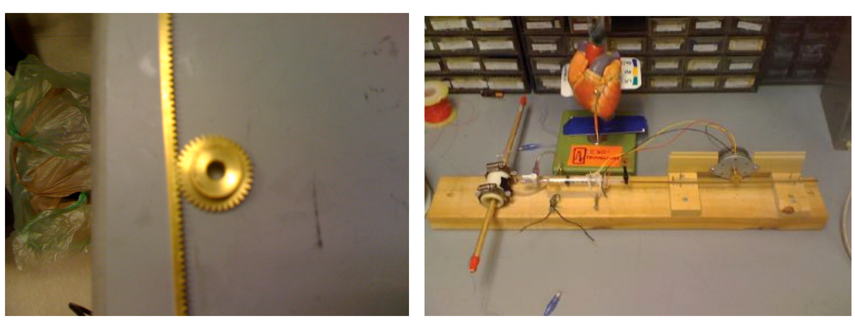


Figure 7: Rack and pinion and mechanical system of design.

To control the movement of our stepper motor we used a 5 V microprocessor that used C++ computer code connected to a 5 V microcontroller that translated the microprocessor information into an output sent to control the 30 V motor (Figure 8). 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.

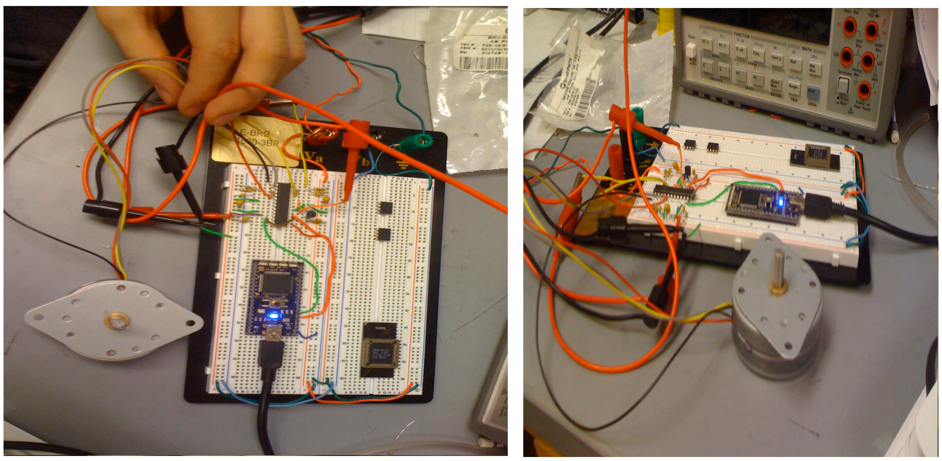


Figure 8: Circuit and stepper motor design.

Our final design also incorporated a pressure sensor which reads the pressures we were able to create within the flexible membrane environment. To add the sensor 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 sensor was not as exact as we had hoped, recording at minimum of 0.1 psi, which is equivalent to 689 Pa.

Testing

Due to time constraints, only preliminary testing was performed on the physical components of the design. The pressure, as mentioned above, was one of the parameters measured. On the sensor, the measured pressure maximum was 4826 Pa for a 5 ml syringe, which is equal to 36.19 mmHg. Before the sensor was available for use, a sphygmomanometer was used to make rough estimates, which approximated to 4000-5332 Pa (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 outer rigid 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.

Current Semester

To create the desired cardiac and respiratory waveforms, we rely on the accuracy of the programmed stepper motor to compress and decompress the syringe at the proper rate. Our current design uses a rack and pinion system to convert the rotational motion of the stepper motor into linear motion of the syringe. However, the current system requires that we run our stepper motor at very slow speeds because the gear translates one step angle progression of the stepper motor into a large linear movement and we quickly run out of available linear space of the syringe. Running the stepper motor at slow speeds causes jerky movements of the syringe and a lack of waveform resolution. To improve both the motor control and resolution of our motor, we proposed three design alternatives to better convert the rotational motion of the motor into linear movement of the syringe.

Gear Reduction Design

In our design from last semester, one of the problems we encountered was the conversion of the rotational motion from the stepper motor into the linear motion, which moved the plunger of the syringe. When we ran the motor, it ran so slowly that the movement of the syringe was not smooth and the desired sine pressure waveform was not achieved. In order to improve this conversion from rotational to linear motion, a gear reduction system for the motor could convert faster rotational speeds of the motor into slower linear speeds of the syringe. Using gear ratios we can calculate the size of the gears needed. If we wanted to double the speed of the motor while keeping the output linear motion the same speed, we would need two gears, giving the larger rack gear double the teeth of the smaller gear. We would have to reverse the output of the motor since having a two-gear system reverse the output direction.

There are two ways we could implement this idea into our current design. One implementation is to build our own gear system. This would involve buying individual gears and attaching one to the motor and another to the rack. Another implementation would to buy a pre-made gear system. We could either buy a system that would attach to our current motor or a new motor with the gear system built in. There wouldn't need to be much modification to our current system with this option. Building our own gear system would allow us to select the gear ratios we want and have the ability to change the gears later if we wanted. The difficult part about building or own system is getting the gears to mount and align properly, meaning the implementation of a self-built gear system would be difficult in our current design. Buying a pre-made system would be easier to implement, but the availability of motors with gear reduction built in is small, so finding the correct motor would be difficult.

Constrained Motion/Piston Design

The second option for improvement includes a piston-like design that can attach to both the stepper motor and syringe. This will allow for relatively smooth movements of the piston and therefore the syringe. This will cause the pressure output wave to also be relatively smooth, but not as much as the other design alternatives.

Some of the negatives of this design include incorporation into the current simulator, and the programming changes that must be made. The program will need to be modified in order to compensate for the fact that a full rotation of the motor will result in both an increase and decrease of pressure, as the syringe will be pushed and pulled during this cycle.

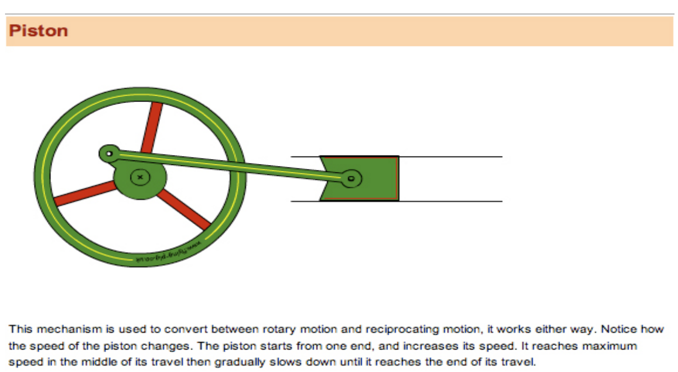


Figure 9: Piston Design [4]

Micro-Step Design

Another solution to improve our rotation to linear conversion is to continue to use our current motor and change the phase current waveform to enable microstepping. Microstepping enables the motor to run at slower speed more smoothly due to decreased size of microsteps. A single rotation of a stepper motor's spindle can be divided into a certain number of steps depending on the step angle of the specific motor. Our motor has a step angle of 7.5˚, which results in 48 steps per revolution. These steps can be further divided into microsteps if the correct phase current waveform is fed to the motor. In full step mode, what we used in our previous design, the motor is fed two phases, each a square wave. In microstepping mode, the phases are sine waves, allowing one step of the motor to be divided into micro steps based on the amplitude of the sine wave. These micro steps enable motor operation to become smoother. Resolution is limited to mechanical static friction, backlash, and other sources of error between the motor and the syringe plunger.

Implementing this idea would involve a change to the C++ code on the microcontroller and a change in circuitry. The current code outputs two square wave phases to the stepper motor driver, which runs the stepper motor in full step mode. Instead of having a digital output from the microcontroller, we would need to enable analog output to output a sinusoidal AC waveform. Also, we also would need to change the stepper motor driver since the driver used in the previous design could only handle half step mode or full step mode. The advantage to this design is the ability to keep the same mechanical components with only a change to the coding and circuitry. However, the coding of the sine wave phase output would become more complicated than the square wave output.

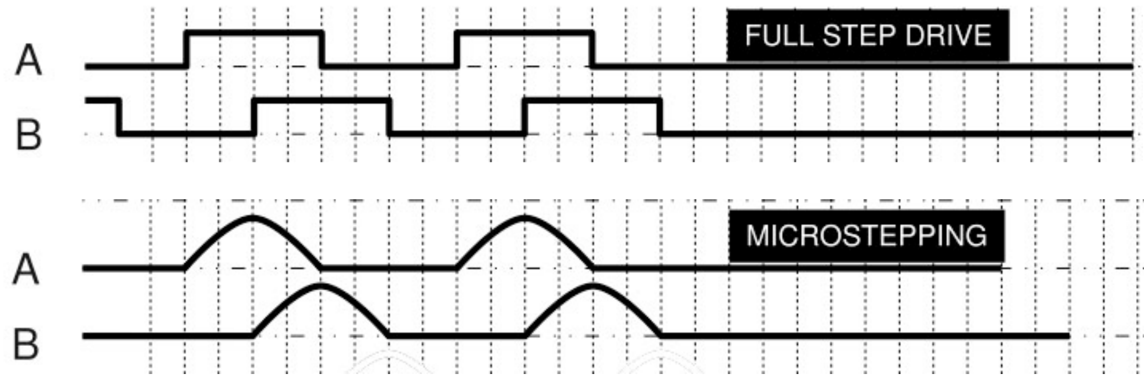


Figure 10: Microstep Mode

Design Matrix

To determine which design alternative would best improve the waveform resolution, we created a design matrix, shown in Figure 11. This matrix evaluates each of the designs based on four categories: the resolution of the produced pressure waveforms, the simplicity of incorporation into the preexisting design, cost and ease of programming. Each category was allotted a certain number of points for a total maximum score of 100 points.

	Resolution (40)	Design Incorporation (25)	Cost (10)	Programming (25)	Total (100)
Micro-Step Mode	33	23	10	13	79
Gear Reduction	32	15	7	17	71
Piston-like System	27	20	4	15	66

Figure 11: Design Matrix

The resolution category of the design matrix was given the highest point allowance at 40 because the overall objective of each design was to improve the resolution of the current design. It is important to maximize the resolution of our design so that it can produce accurate and fluid waveforms that are representative of the pressures produced within the body. Design implementation and ease of programming were both given the next highest point allowance at 25. It was important that each of the three designs were easy to incorporate into the preexisting design, both on the hardware and software side, to avoid having to completely redesign the esophageal simulator. Lastly, cost was given the lowest point allotment at 10 because all three designs were relatively inexpensive or could have been fabricated in the shop.

After evaluating the three designs based on each of the four categories, it became apparent that micro-step mode would most improve the resolution of the produced waveforms and it would be the easiest to incorporate into our design. The piston-like system would not improve the waveform resolution by much, if at all, and it would have been the hardest to integrate into the design; therefore, it scored the lowest out of all three designs. The gear reduction system would have improved the resolution to an acceptable amount, but it would have been very difficult to manually fabricate this system, causing this design to receive the second highest overall screw. Micro step mode was the best choice to improve the waveform resolution because it has the highest degree of accuracy out of all three designs. Additionally, it was the easiest to incorporate into the preexisting design because only the programming needed to be changed; there was no mechanical change to the design and no money was spent because the existing design used the correct motor.

Final Design

Our final design changed significantly during the course of the semester as we found new and more efficient ways to build our project. Below is the block diagram and picture of our final design.

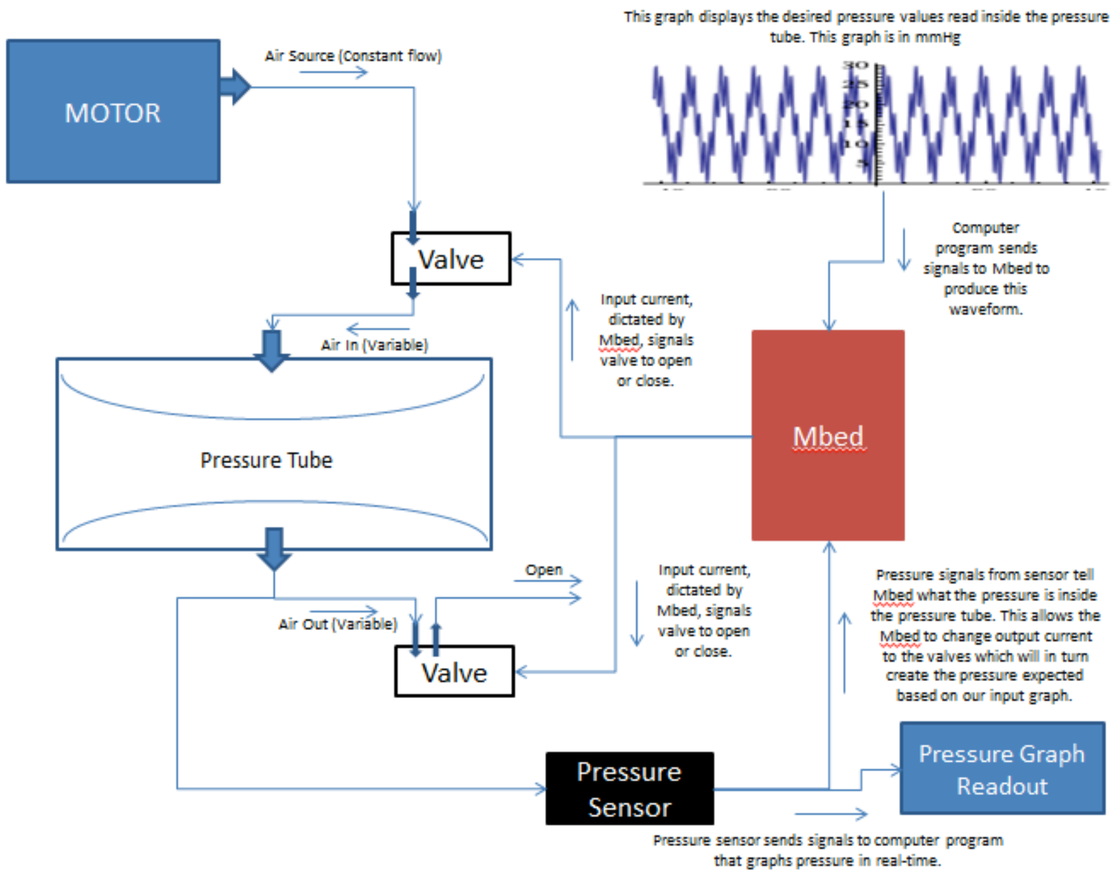


Figure 12: Block Diagram of Final Design

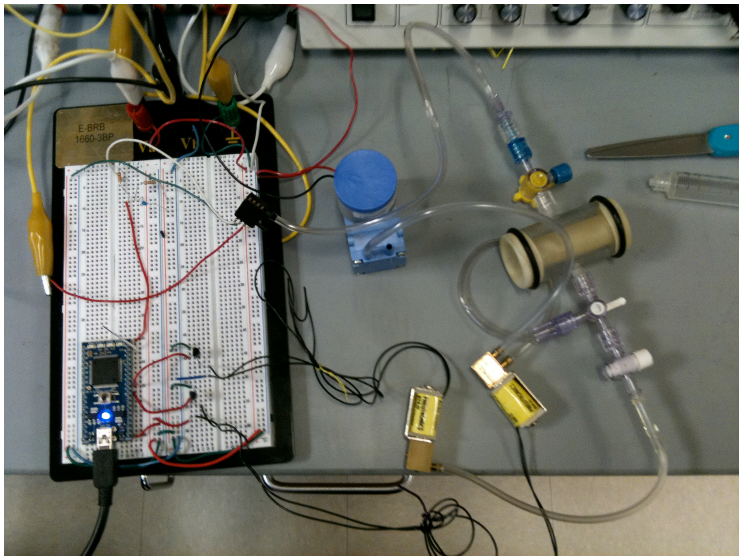


Figure 13: Final Design

Our design used a pressure tube, of which we have kept throughout our design changes. We did however improve it; we used the 3D printer to customize it to fit the needs of our design. In the fall we had trouble creating tight seals around air input tubes we connected to the PVC pipe tube; we were unsuccessful using glue and tape. Our client, Dr. Reikersdorfer, supplied us with stopcocks and plastic tubing to help create a closed system, (Figure 14). We used SolidWorks to add "male" stopcock ends to our custom tube; this allowed us to screw a stopcock system directly onto our pressure tube creating a tight seal and a closed system.

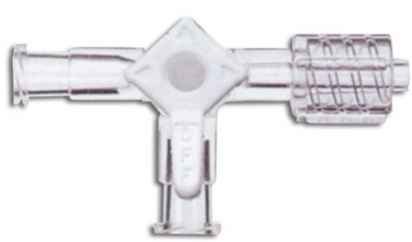


Figure 14: Luer lock [5]

We continued to use pen-rose drain as our flexible membrane or “esophagus” material. The membrane is used to translate changes in pressure onto the Eso-Technologies' device when they begin testing. The pressure tube is discussed greater in detail in the later sections.

Our methods for inputting pressure saw the most significant changes in design from fall to spring final design. At the beginning of the spring semester we discovered the progress of our project was slowed due to limitations discovered in our fall semester design. Our stepper motor-to-syringe air supply system, rotational motion translated into linear motion, was extremely limited as we tried to program more complex and faster pressure waveforms into the motor. So we decided on a design where we could manipulate a constant air flow using valves to create our desired pressure waveforms.

Our first goal was to find a steady air pressure source. Professor Bahr supplied us with a 12 VDC piston motor that outputted a steady stream of air. To manipulate the air supply we used two current controlled, solenoid valves: one for controlling air-in and one for controlling air-out. We were able to write a program and build a circuit, so each valve was either entirely open or closed for a given time, based on signals sent from the Mbed chip. The graph program allowed the Mbed to understand when current was needed to manipulate the valves so that the tube would reach the designed pressure. For example, as our desired pressure builds the Mbed would cue the input valve to open for a longer time, allowing more air to enter the tube, while also cueing the output valve to close allowing for pressure to build. We selected two valves that were designed exactly opposite, so sending the current to both valves required one valve to close and one valve to open.

We also installed a pressure sensor. We designed the pressure sensor to send its signals to a computer program that took these signals, translated them back into pressure readings, and graphed the values in real-time. The pressure sensor also sent signals back to the Mbed. These signals allowed the Mbed to take the desired pressure given by our input graph and compare it to the actual pressure in the tube. If the recorded pressure was too high, the Mbed open the release valve, allowing more air out, and closed the input valve. If the recorded pressure was too low, the Mbed opened the input valve, allowing more air in, and closed the release valve. In the end, we had a feedback loop program that would ensure our tube reached the pressures that we and our client desired.

Due to time constraints we were unable to add the reference tube to the entire project. The reference balloon would house just the respiratory sine function. With that pressure tube, Eso-Tech could subtract out the respiratory wave function from the recording tube (our finished product) and single out the cardiac function.

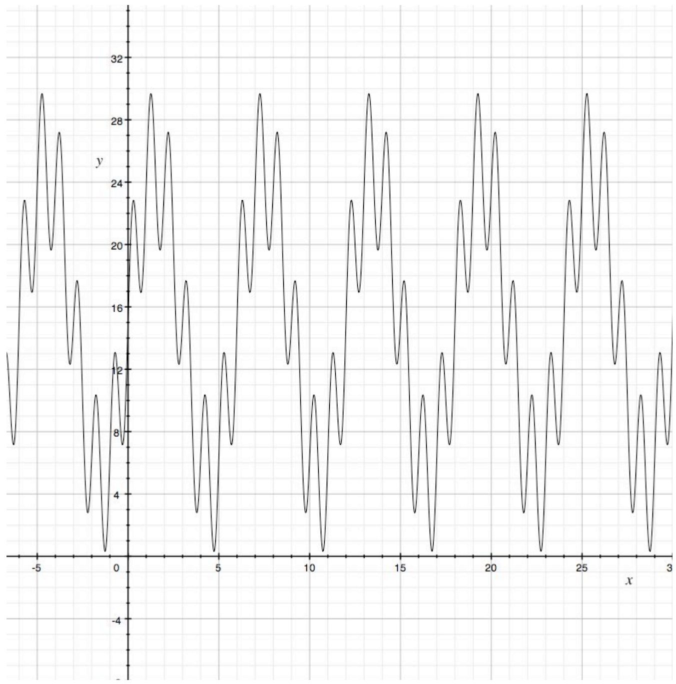
Components

Circuit Design

Our final design for the circuit of the system is much simplified than that from previous designs. We use our mBed microcontroller to provide two digital outputs, one for each valve. The digital connections go to an N-Type MOSFET transistor, which controls the current to the solenoid valve. Each valve is a current controlled, normally open, solenoid valve; one valve is 68 ohms impedance, which we use to control the input pressure, while the other is 274 ohms impedance, which is used for the release of pressure. Since each valve has different impedance, a different current is required to fully close either one. The input valve uses a +6 volt supply voltage to provide the current. The output valve uses a +18 volt supply to provide its current. For both valves, the power supply is connected in series with the valve and then in series with the MOSFET. The valve is connected to the drain side of the MOSFET and the mBed digital out pin is connected to the gate of the MOSFET. The source side of the MOSFET is connected to ground.

We used a pressure transducer to read the pressure in our "esophageal" tube. This is part of our negative feedback system, in which the actual pressure is read and compared to what the pressure is supposed to be. The pressure sensor is connected to the analog-in pin on our mBed microcontroller. The MPXV7025 pressure sensor outputs a voltage from 2.5 V to 5.0 V corresponding to a pressure range of 0 kPa to 25 kPa. Since the mBed microcontroller can only read a maximum voltage of 3.3 volts, the pressure sensor output needs to put through through a voltage divider. The resistor values used in the divider are 3.3 ohms and 2.2 ohms, modifying the voltage output by 3/5. So instead of a 2.5 V to 5.0 V, the output is from 1.5 V to 3.0 V.

We used a negative feedback system to output a desired pressure waveform in the pressure tube. The code on the microcontroller reads the output from the pressure sensor and compares it to the desired pressure. If the pressure is correct, the mBed closes both valves. If the pressure is too high, the mBed opens only the release valve. If the pressure is too low, only the input valve is opened. Our mBed calculates the desired pressure every loop of the code by using an equation we created (Figure 15).



Input:

$$10\sin\left(\frac{\pi}{3}t\right)+5\sin(2\pi t)+15$$

Figure 15: Function sent from mBed.

The desired output has a maximum pressure of 4 kPa and a minimum pressure of 0 kPa. The output has two sine waves, one with a frequency of 10 periods per minute, and the other with a frequency of 60 periods per minute. This corresponds to a breathing rate of 10 breaths per minute and a heartbeat of 60 beats per minute.

Since the mBed reads the voltages on a range from 0 to 1, 0 being 0 volts and 1 being 3.3 volts, along with the voltage divider, some modifications to the desired pressure waveform must occur. We first we used our calibration equation obtained from the calibration of our pressure sensor to convert the pressure equation into a voltage equation. Next, we used a voltage divider on the pressure sensor so we needed to modify our equation by multiplying by 3/5. Finally, the mBed converts voltages to a floating point number on a scale from 0 to 1 so we needed to divide our equation by 3.3 volts to get its floating point number. This number is what we compared to the analog-in pin readout.

Pressure Tube

In the beginning of the semester, our pressure tube was a 2.5 inch long PVC pipe, with an inner diameter of 1 inch and two bored holes for pressure input and release. The penrose drain was attached to this tube by threading the membrane through the center of the PVC pipe and stretching the ends over the outside of the tube thereby creating an expandable pressure chamber between the inside of the rigid PVC pipe and the penrose drain. O-rings and adjustable metal clamps were used to ensure a tight seal of the penrose drain over the ends of the tube. This PVC pressure tube frequently leaked due to the poor seals formed between the bored holes and the tubing that provided the input and output air. We created air tight seals between the PVC pipe and the pneumatic tubing by super gluing the ends of the tubes into the bored holes of the pipe. This greatly diminished the interchangeability of our design because once we glued in the tubing, it was extremely difficult to remove. Additionally, the cut PVC pipe had sharp edges that tore holes in our penrose drain during testing.

After switching designs to a pneumatic valve system, we began interfacing many of our components with Luer lock fittings, common leak-free fluid fittings used in the medical field. The Luer lock fittings allow for simple interchangeability between our pneumatic components, while ensuring that the entire system was air tight. Our team soon saw the merits of redesigning our entire pressure

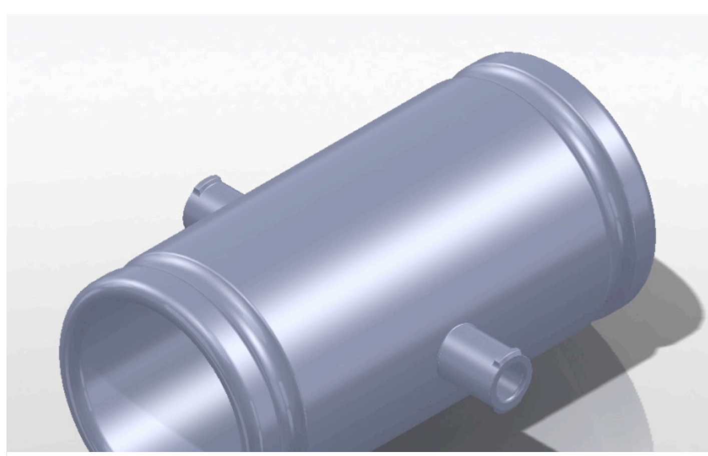


Figure 16. CAD rendering of 3D printed esophageal tube. Shown here are the two luer lock fittings as well as the o-ring grooves at the ends of the tube. All edges are rounded on this

tube to allow for a more ergonomic design with two built in Luer lock fittings that would allow us to easily interface our existing valve system with our esophageal tube. We enhanced our esophageal tube design further by adding shallow recessions to the outside of the tube to create tighter, more reliable seals of the penrose drain around the outside of the tube by positioning the rubber O-rings into these grooves. Also, we chose to round all the edges of the tube to prevent tearing of the penrose drain and an overall more aesthetically pleasing design. The dimensions of the new tube were kept the same as the previous tube, as the initial dimensions were chosen to make a physiologic analog of the esophagus. To create the Luer lock fittings, our team used the data sheet found in Appendix B. We constructed the new esophageal tube in SolidWorks (Shown in Figure 16) and used the FDM – The Dimension Elite printer, which uses fused deposition of a strong thermoplastic called acrylonitrile butadiene styrene to print 3D models. This machine can print parts up to 8 x 8 x 12 inches in size and builds in layers of either 0.007 or 0.010 inches with the smallest standalone feature of 0.014 inches. We chose this printer to build our design because it ensured that our part was strong enough to endure the pressures provided by our valve system as well as reduced the chance of mechanical failure of the Luer lock fitting.

Testing

Throughout the semester, our team was constantly testing our project so that we could improve upon our design and ultimately achieve our client's specifications. This testing subsequently became the driving force behind the progression of our design. Our design at the beginning of the semester consisted of a syringe driven by a stepper motor to produce the desired waveforms. Initially, this system was unable to achieve proper waveform resolution because the progression of one step angle of the motor caused too large of a linear compression or decompression of the syringe that generated the pressure. We attempted to use the motor's micro-step mode, which breaks each single step of the motor into 64 micro steps, to increase its accuracy. After subsequent testing with this feature, we saw no observable improvement because it either did not improve the resolution or we were unable to properly implement this mode. We were also concerned that this design would be unable to produce the rapid and frequent left atrial waveform due to a lack of speed.

We began by testing the max speed of the motor and found that it was able to spin faster than any observably quantifiable speed. However, the real issue was the motors slow response to directional changes as the left atrial pressure wave requires multiple changes in direction within one second (period of the left atrial pressure wave) or less. After extensive testing of this system, we found that it was incapable of achieving our client's specifications and we decided to pursue another design.

We then changed directions and decided to use valves to regulate the air flow into or out of our system provided by a constant source of air. Specifically, our new design used a current controlled solenoid valve to regulate the input pressure from a pump and used a constant bleed off to allow air out of the system. The current controlled valve operates by remaining open when it receives no input current and proportionally closing its orifice with increases in current until the maximum current required to fully close the valve is achieved. We looked up the current required to close the valve on its data sheet, but after testing the valve for closure at the maximum current, we found that it remained open. We proceeded by incrementally increasing the current to the valve until it closed After testing multiple different source voltages and resistors in series with the valve, we discovered that the valve was not closing because the operational amplifier in the circuit was unable to output enough current to close the valve.

After obtaining a 10 psi pump, our team began further testing of this design and found that our previous assumption that the op-amp could not provide an adequate amount of current was wrong. While using the pump, we found that the valves did not respond correctly unless they were under constant input pressure and the op amp was actually able to provide the necessary current to close the valve. Once we were able to get this system working, we programmed the mbed microcontroller to control the valve to follow a sinusoidal wave, which in theory should produce a sinusoidal pressure response within the tube. Using our calibrated pressure transducer (see later discussion) we measured the voltage output of the pressures in the esophageal tube. The pressure response resembled an asymmetric sine wave that plateaued for a period of time upon reaching its max amplitude. Many rounds of testing ensued to attempt to achieve symmetric sinusoidal pressure response; however, nothing mediated the plateau phenomenon. Although this design was able to produce more representative waveforms than its predecessor, the lack of control over the air release most likely rendered this system incapable of producing the actually desired waveforms.

To resolve the issue of unregulated air release, we introduced a second current controlled valve into our system. With the introduction of a new valve, we had to completely redesign our circuit once again This also brought about successive tests to ensure that the separate source voltages provided to each of the valves generated a large enough current to completely close them. Later, we introduced the 3D printed pressure tube into this design and input a constant amount of pressure to confirm that it was air tight. This design underwent many more rounds of testing; however, these tests pertained to the software on the mbed microcontroller and not to the hardware of the system.

Most of our testing was quantified through the use of our pressure transducer, which outputs a voltage that is proportional to a given input pressure. In order quantify this relationship between output voltage and input pressure, the pressure transducer had to be calibrated. To calibrate this device we used a pressure generation machine to input known pressures and record the corresponding output voltages. We took data for pressures in the range of 0-180 mmHg, recording the output voltage at 5 mmHg intervals (the raw data is displayed in Table 1 in the Appendix B). This data was then plotted on a graph of voltage (V) vs. pressure (mmHg), shown in Figure 3 of Appendix B, and a trend line equation was derived; this equation was found to be y=0.0121x + 2.5035 with an R^2=1, indicating accurate results. Y is the output voltage at a given input pressure x. This equation can be solved for x, allowing the calculation of input pressure given a certain output voltage. After calibrating the pressure transducer, we were able to use a java-based data acquisition program that would read the voltages sent to the mbed from the transducer and subsequently convert them into their corresponding pressures and graph the result in real time. This graphical output program provided all of our future tests with more concrete data because we were able to directly read the pressures in the tube. A sample pressure reading using this program is shown in Figure 17.

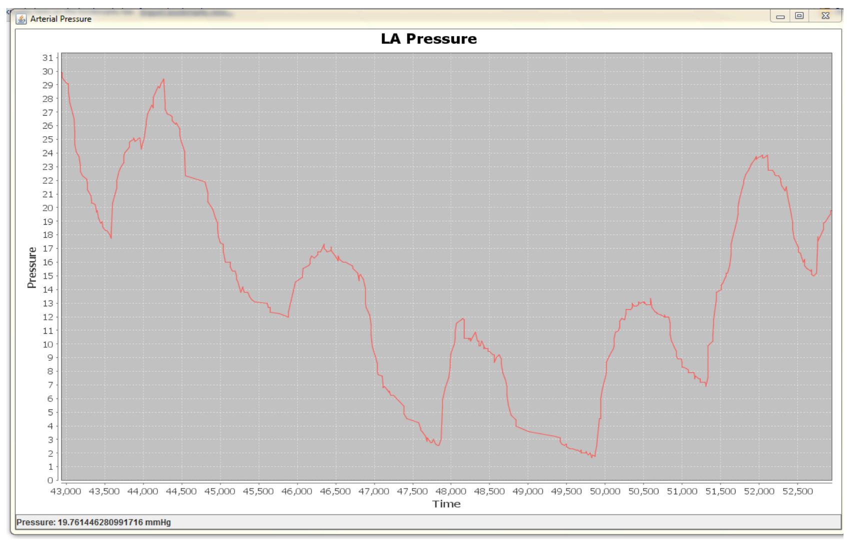


Figure 17. Pressure response displayed via the graphical java program.

Not only did the calibrated pressure sensor allow us graphically interpret the pressures within our tube, but it also allowed us to establish a software feedback loop. Initially, all of our designs were programmed with an open loop; open loop style programs are intended to drive a system according to a specific waveform. However, if the response of the system does not match the input waveform, it does not correct itself and continues to run according to the inputted function. After testing open loop programming across all of our different designs, we found that in each design there were unaccounted variables that prevented the open loop from achieving the proper response. To account for these variables, a close loop software feedback system was implemented. Feedback systems constantly work to match the desired waveform by assessing the current pressure within the tube, comparing it to the desired pressure, as given by the waveform at that instant in time. Implementation of the feedback system required the generation of multiple different code structures as well as variation of both the sampling frequency and the magnitude of the feedback correction factor before we were able to finally get it to work.

Future Work

Our design has been completed and works as specified, but it is not entirely complete. The reference balloon pressure tube must be added by completely recreating the system we have. Additional modifications can also be made to make the simulator more user friendly. These include making a graphical user interface that allows pressure ranges and frequencies to be changed and condensing the circuit to a circuit board. Although the pressure values can be changed, the code must be changed to a set of sampling data points to form the desired output. The circuit board would make the system smaller and more portable.

References

[1] *Visible Human Server*. Web. 13 Oct. 2010. <http://visiblehuman.epfl.ch/>.

[2] Eso-Technologies Inc. *An Esophageal Simulator with Cardiothoracic Pressure Signals*. Sept 9, 20210.

[3] Gorski, Steve. Company Memorandum. Eso-Technologies Inc. Oct 4, 2010.

[4] http://www.makingthingsmove.org/blog/wp-content/uploads/2008/10/piston.jpg

[5] http://www.sai-infusion.com/Infusion-Accessories/Stopcocks/3-Way-w/Swivel-Nut/3-Way-Stopcock-with-Swivel-Nut.html

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- Peter Klomberg

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.

Design Requirements		
Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	**.8 – 2.93 kPa**	**40 – 140 per min**
Chest Cavity	**0 – 2.93 kPa**	**3 – 8 per min**
Esophagus (static)	**0 – 6.67 kPa**	**Constant**

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

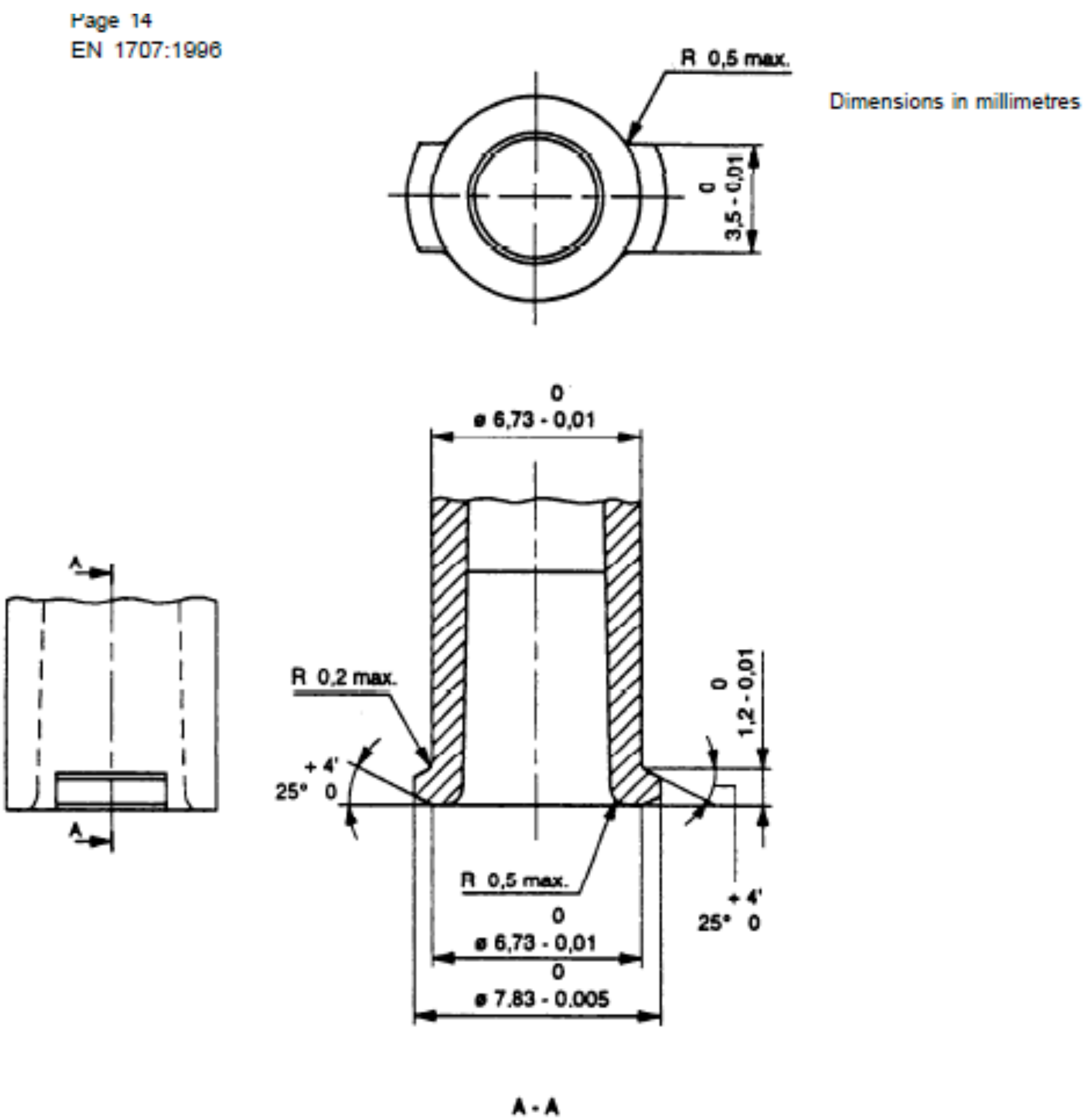
a. *Quantity*: There is a need for one system, with an option to replace the material inside the tube.

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

Appendix B Testing and Dimensions



NOTE. All outside edges of lug or thread form shall have a radius between 0,15 mm and 0,2 mm (unless otherwise specified).

Figure 2. Dimensional data sheet for a male 6% luer lock fitting. All dimensions are in millimeters. **http://www.pro-ficientllc.com/PDF_files/luer_specs.pdf.**

Pressure (mmHg) ± .1	Voltage (V) ± .001
0	2.505
5	2.565
10	2.625
15	2.685
20	2.745
25	2.806
30	2.866
35	2.926
40	2.987
45	3.047
50	3.108
55	3.168
60	3.229
65	3.289
70	3.350
75	3.410
80	3.470
85	3.531
90	3.591
95	3.651
100	3.712
105	3.772
110	3.833
115	3.893
120	3.953
125	4.014
130	4.075
135	4.135
140	4.195
145	4.255
150	4.316
155	4.376
160	4.437
165	4.497
170	4.568
175	4.618
180	4.678

Table 1. Raw data from the calibration of the pressure transducer (MPXV7025)

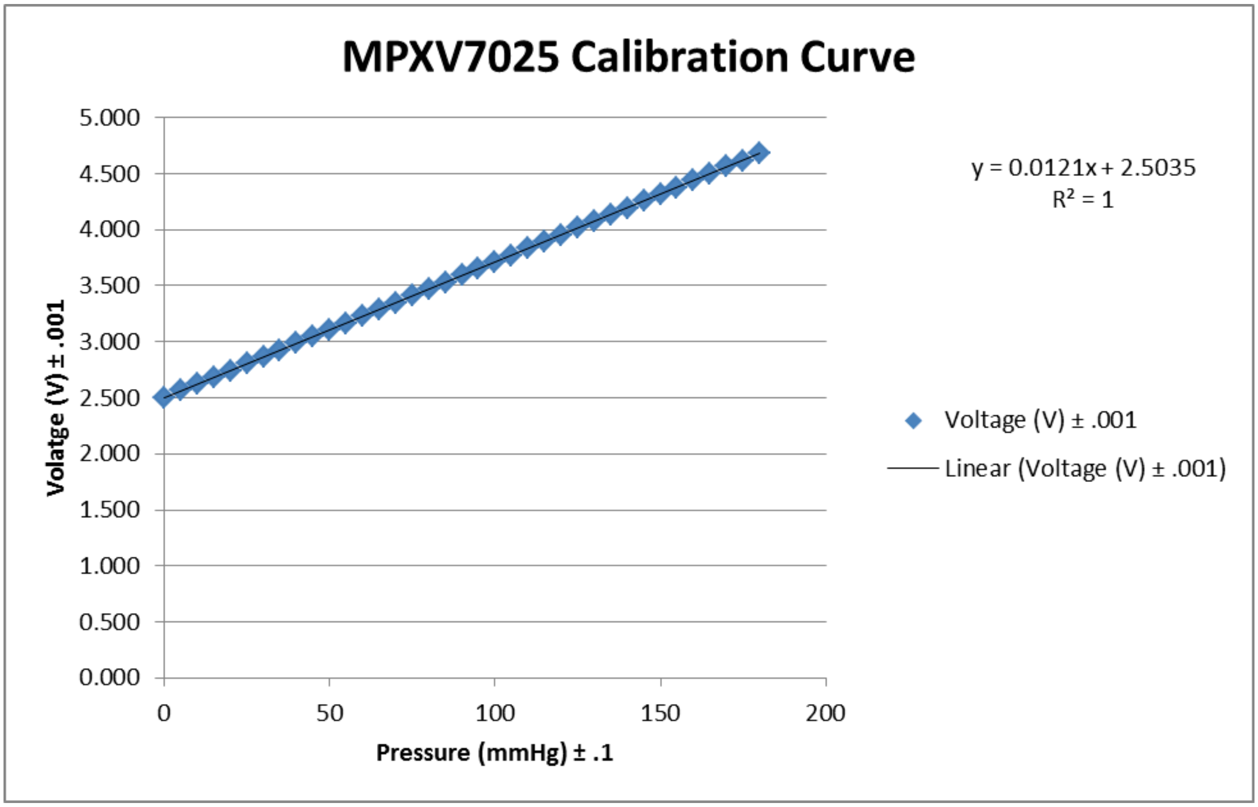


Figure 3. Voltage vs. Pressure calibration curve for MPXV7025 pressure transducer. The calibration equation is shown in the upper right corner of the graph.

Appendix C User Instructions

Setting Up the System

1. Connect the blue pump to the solenoid valve labeled 68 ohms to the "in" port.
2. Connect the "out" port of the 68 ohm valve to one of the "luer lock" ports on the "esophageal pressure tube".
3. Connect the "in" port of the 274 ohm valve to one of the "luer lock" ports on the "esophageal pressure tube".
4. Connect the MPXV7025 pressure transducer to one of the "luer lock" ports on the "esophageal pressure tube".
5. Connect the red wire of the pressure transducer to the 5 volt voltage regulator, the white wire to the voltage divider and the green wire to ground.
6. Connect the mBed microcontroller to the computer via USB, and start up the graphing program.
7. Start the graphing program and turn on the power supply to begin pressure generation, and graphing of the pressure in the tube.

Appendix D: Semester Cost Analysis

DESCRIPTION	AMOUNT
Development Board LPC1768 MBED – Microcontroller	$79.85
IC Stepper Motor Driver 24 Powerdip + IC Voltage Reference	$11.42
3 MPXV7002DP-ND Pressure Sensors	$40.58
2 MPXV7025 Pressure Sensors	$27.78
Design Poster	$36.00
TOTAL	$195.63