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 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 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

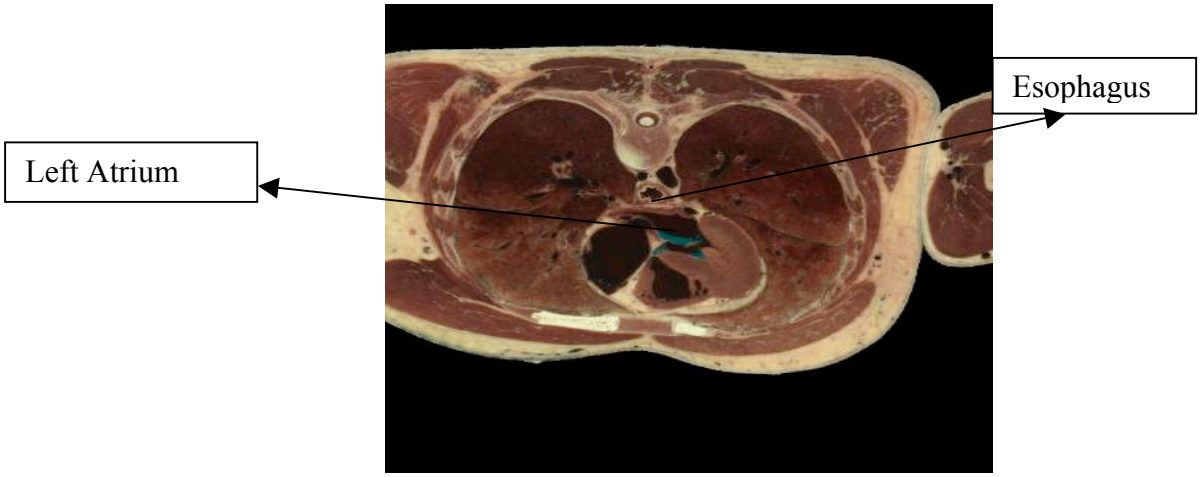

Figure 1: Anatomical slice including the esophagus, heart, and lungs (1).

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 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. 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 on 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 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 is not the waveform that will be focused on.

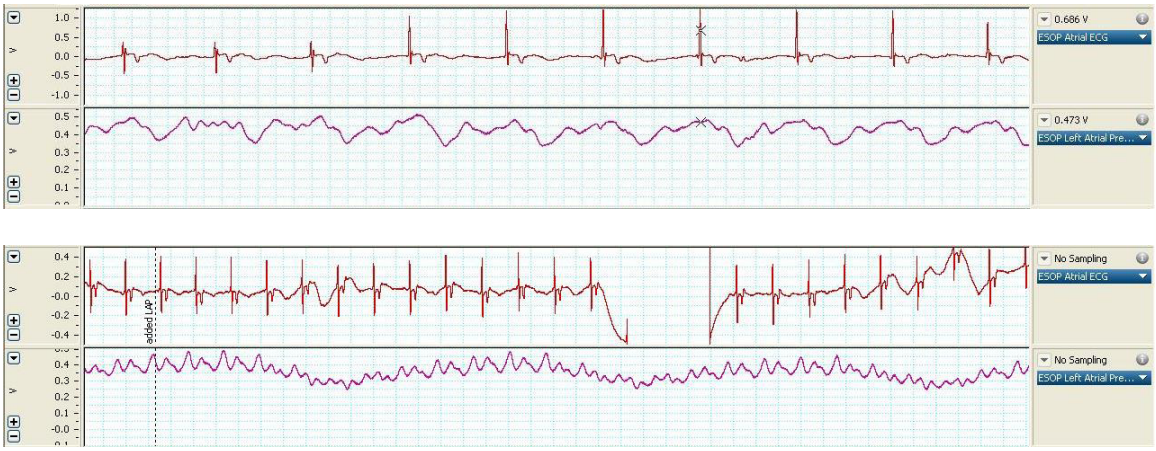

Figure 2: ECG and pressure waveforms provided by Eso-Technologies (2)

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).

Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	.8-2.93 KPa	40-140 per min
Chest Cavity	0-2.93 cmH2O	0-20 per min
Esophagus (static)	0-6.67 mmHg	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 be 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).

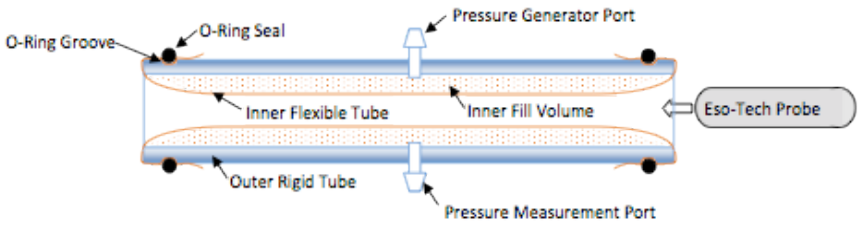

Figure 3: Pressure Tube Design (3)

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. 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.

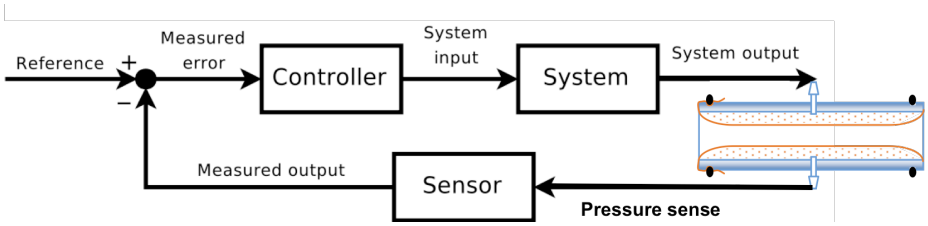

Figure 4: Closed Loop

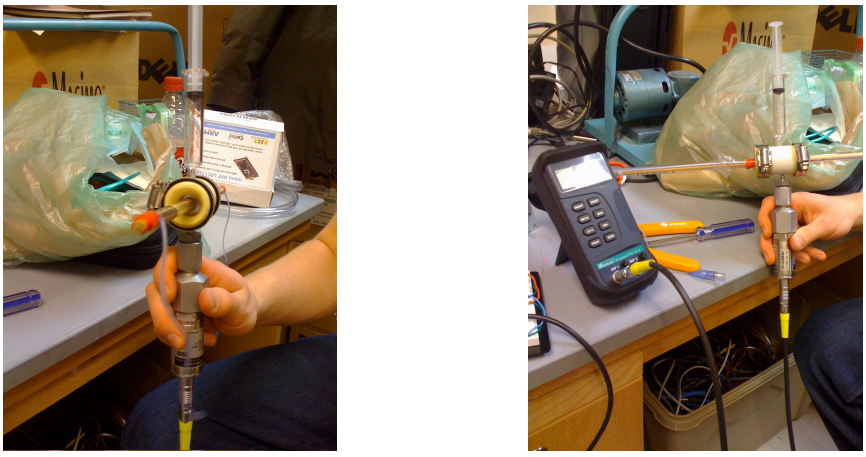

Figure 5: Pressure Tube and Measurement System

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 6). 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 6: 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 7). 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.

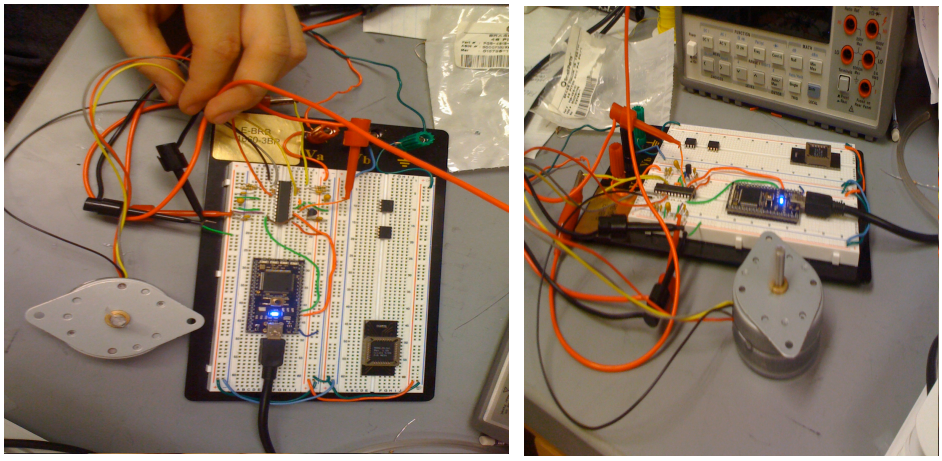

Figure 7: Circuit and stepper motor design.

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 performed 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.

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 a 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 gear double the teeth of the smaller gear. The smaller gear would be attached to the motor and the second larger gear would be connected to the rack. The gear ratio of a system with the larger gear having double the teeth as the smaller gear would be 2:1, meaning the smaller gear needs to make 2 revolutions for the larger gear to make one revolution. 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.

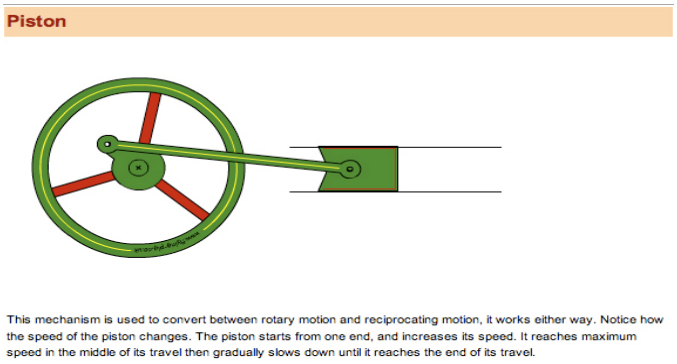

Figure 8: Piston Design [4]

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 more 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.

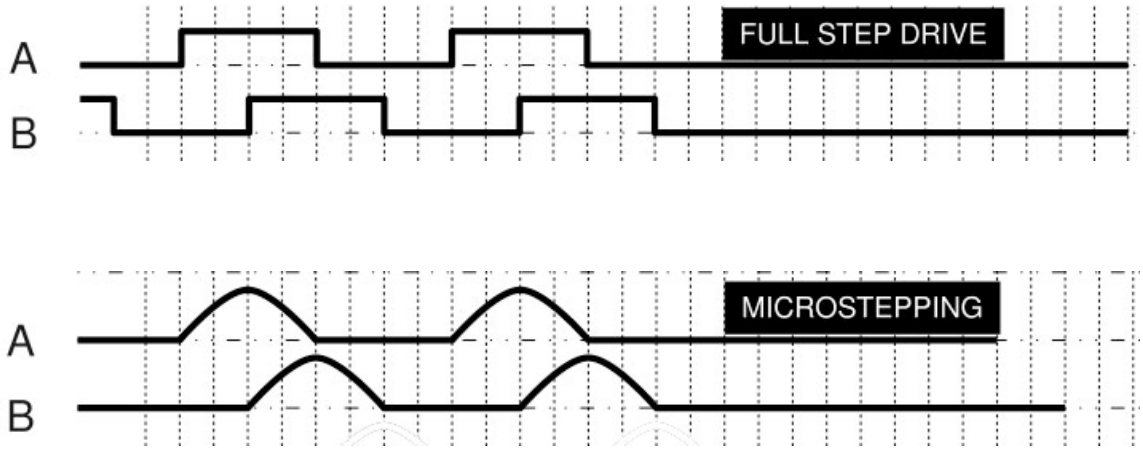

Figure 9: Microstep Mode

Design Matrix

To determine which design alternative would best improve the waveform resolution, we created a design matrix, shown in Figure 10. 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.

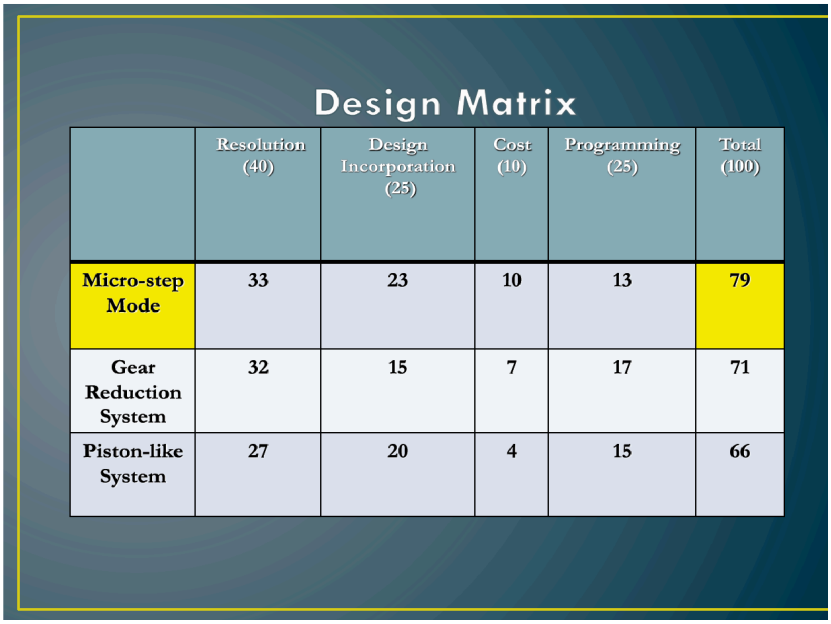

Figure 10: Design Matrix

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

Eso-Technologies' cardiac monitor makes use of two balloons, reference and recording. Thus our final design will incorporate two individual pressure tubes, each designed to relate to the specific balloons on the monitor. Our goal is to finish the recording pressure tube (tube that will house the recording balloon) before we add the reference pressure tube because the recording balloon is significantly more difficult to program and construct.

Our final design will be complete with two pressure tubes, stepper motors, micro-

controllers, stepper motor drivers, rack and pinion systems, pressure sensors and three syringes. The recording balloon will house the combined pressures of the lungs and left atrium. Currently, there has been trouble adding the cardiac waveform to the preexisting respiratory waveform code, a completely separate stepper motor and syringe system will be used to add the cardiac waveform. The combination of the two stepper motor systems should create, via readings from the pressure sensor, the lung/cardiac pressure waveform desired.

The addition of the reference balloon will be relatively simple. The respiratory pressure is measured by both balloons and is very similar between the two. Therefore, we need to connect the respiratory waveform system to both tubes at the same time. We can accomplish this by adding a "connector" between the two syringes which will be attached to the rack. In theory, this should promote the same syringe displacement in both syringes and create similar respiratory pressure outputs.

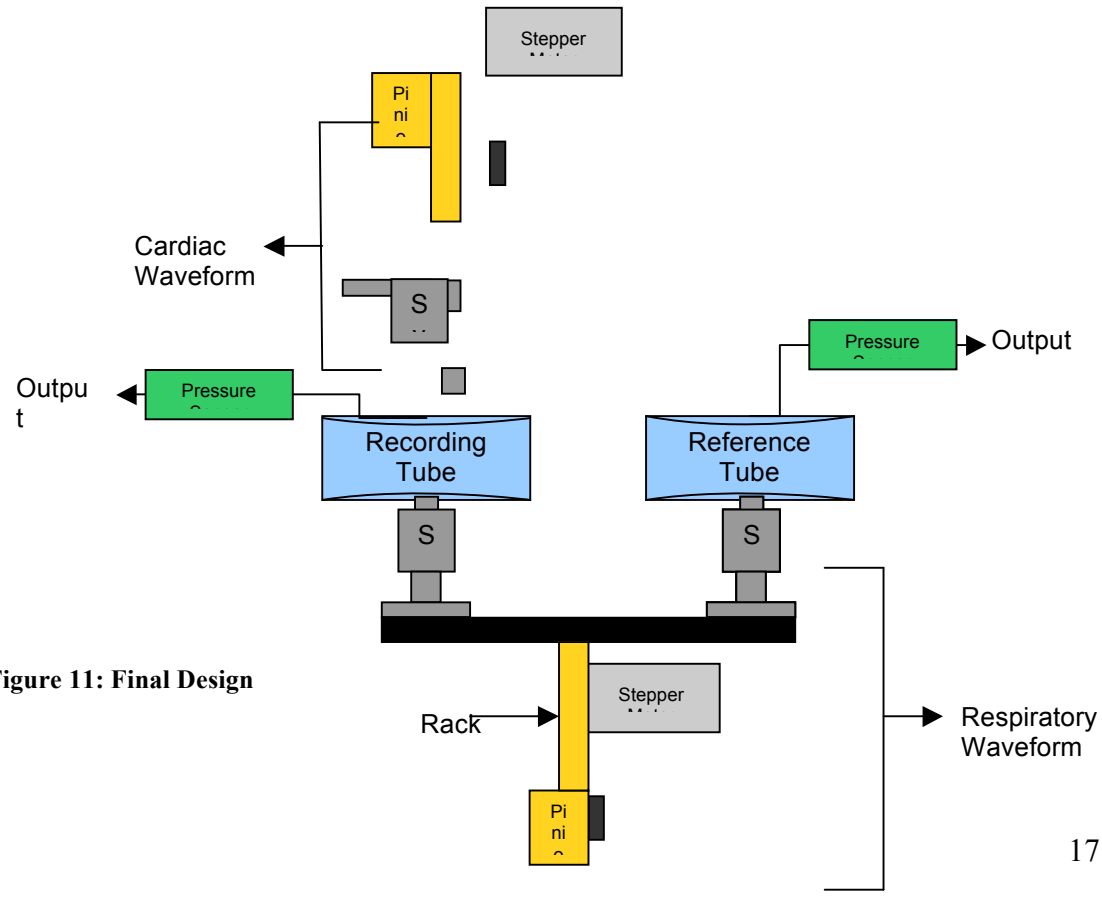

Figure 11: Final Design

Testing

Before testing begins, integration of the pressure sensors into the system must be finished. We have the computer reading voltage changes (how the sensor transmits changes in pressure), however, we need to translate these voltages into pressure readings, by establishing a pressure reference, and we need the computer to plot these values. This will allow us to view what the pressure is inside our pressure tubes in real time. We can use the pressure sensor to determine if our system is closed and all our connections are sealed. This will be an important step because if we do not have a closed system we will constantly be losing pressure and after a time our pressure readings will be significantly lower than our desired values.

For testing, we will install a mock Eso-Technologies probe into our system which will establish a similar environment to that inside the esophagus. We will then test each pressure waveform for accuracy of output values and overall consistency. For each waveform we were given “ideal” values measured during previous examinations, and we will test to make sure our syringes insert enough air into our tubes to reach these desired measures. We will also test to make sure that the each desired waveform is achieved. After making sure that individually each waveform is working properly, we will test the success of the cardiac/lung waveform. We should see our programmed cardiac waveform superimposed on top of our respiratory waveform. Again, we will test for consistency and accuracy of values. The success of our pressure sensors to output pressure data in real-time will be crucial to identifying how successful our system is operating.

Once we finish testing with the mock probe, and our waveforms are generating a consistent, accurate pressure waves, we will use Eso-Technologies' actual probe for further

testing. For this testing we will compare the pressure output from our pressure sensor to the monitor readings from inside the tube. From this testing we will identify if the pressures are being translated efficiently from the tube to the monitoring probe. If the monitor's readings are low, we might need to increase the pressure we are inputting to the pressure tube, and if the readings are high, we might need to decrease to pressure inputted. Consistency and accuracy of the waveform graphs and values are our most important goals.

Future Work

At this point, we are optimistic that we will be able to successfully incorporate the pressure transducer into the system. In addition to this, a computer program will be integrated/modified in order to print the pressures in the tube versus time. The final modification will be in the mechanical system, which will include possible updates to valves, syringes, etc.

References

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

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- Dr. Chris Reikersdorfer
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- Dennis Bahr
- Amit Nimunkar
- 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.

Anatomical Structure	**Pressure Range**	**Frequency**
Left Atrium	.8-2.93 KPa	40-140 per min
Chest Cavity	0-2.93 cmH2O	0-20 per min
Esophagus (static)	0-6.67 mmHg	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