

HEART & BREATH SOUNDS AMPLIFIER

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Abstract

The standard acoustic stethoscope has become the hallmark of the medical profession. In wide use for over a hundred years, it is not a device that is easily replaced by new technology. In recent years electronic stethoscopes have entered the market for prices roughly two times as much as standard stethoscopes. Our client is requesting that we design an electronic stethoscope that increases the functionality of the standard stethoscope three fold while maintaining the fidelity of standard acoustic stethoscope. The three areas of increased functionality are: converting the acoustic sound waves from the stethoscope to a filterable, amplifiable electronic signal, increasing the length of the stethoscope so the heartbeat can be heard from further away, and creating both headphone and speaker listening capabilities. In order to do this we ran conducted some data collection to determine the ideal amplification and frequencies. After the data collection we created a plan for a current design consisting of three main components: initial sound pick-up, conversion of acoustic sound to an electric signal, and amplification, filtration and audio sound of the signal. With all of these in mind we considered different design alternatives through design matrices and determined that the ideal microphone type is a condenser microphone, the ideal microphone location is inside the tubing, and the ideal power source is battery powered. From this we have a future work plans that involve testing the designed circuits, building a prototype, and testing the prototype.

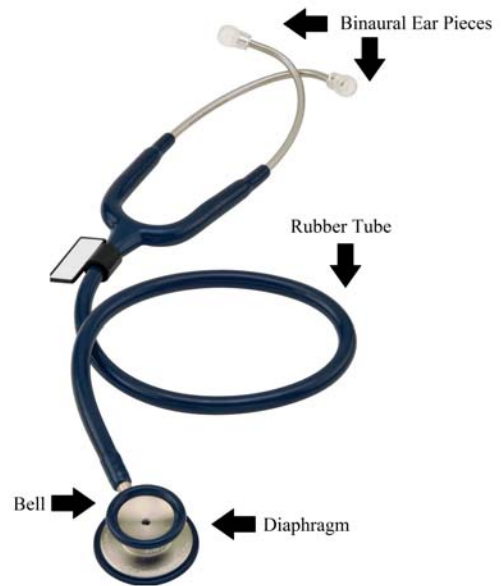
Problem Statement

The goal of this project is to increase the functionality of the standard medical stethoscope in three ways without diminishing the diagnostic ability of the device in any way. The three functionalities to be increased: converting the acoustic sound waves from the stethoscope to a filterable, amplifiable electronic signal, increasing the length of the stethoscope so the heartbeat can be heard from further away, and creating dual listening capabilities so the sounds from the stethoscope can be heard both in standard headphones as well as a speaker.

Background & Other Methods

The medical stethoscope was first invented in 1816 by French physician René Théophile Hyacinthe Laënnec in order to hear the sounds of the heart and other organs in the chest (Bause 2010). As the process of listening to the sounds of the organs in the chest became widely practiced, it became known as auscultation (Sterne 2010). But, the use of the stethoscope was not widely practiced initially; however, it provided many advantages over direct ear to chest auscultation including no interference from the rest of the face and the ability to listen to areas where face to body contact was not appropriate or possible (Sterne 2010).

The basic acoustic stethoscope has evolved over time, but is still based on a fairly simple design. The stethoscope operates using a diaphragm that is placed on the chest which vibrates in and out with the vibrations of the body (Rappaport and Sprague 1941). The sounds created by the diaphragm then travel into the bell of the stethoscope and pass through a long rubber tube (Rappaport and Sprague 1941). The tube serves as a filter to guarantee that only sounds from the body are transmitted to the ears (Rappaport and Sprague 1941). The final step is the passage of the sound through binaural ear pieces for the listener to hear (Rappaport and Sprague 1941) (figure 1).



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figure 1: Diagram of a standard acoustic stethoscope including labels for different stethoscope elements. (Alibaba.com 2011)



Figure 2: 3M Littman 3100 Electronic Stethoscope (Medisave 2011).

The standard acoustic stethoscope is still the most widely used type of stethoscope, but as technology has increased, different variations of stethoscope have entered the market including electronic stethoscopes. One of the more popular electronic stethoscopes on the market is the 3M Littman 3100 Electronic Stethoscope (3M Corporation 2011) (figure 2). The Littman 3100 Electronic Stethoscope maintains all of the functionality of a standard stethoscope but is also able to amplify heart sounds 24x and reduce the effects of ambient noise on the sounds by up to 85% (3M Corporation 2011). The largest downfall of the Littman 3100 Electronic Stethoscope is the cost, its listed MSRP is \$342.47 while that of a standard medical grade stethoscope ranges from \$75.00 to \$95.00 (Welch-Allyn Medical Supply Store 2011). For this design project we are looking to emulate the functionality of the Littman 3200 Electronic Stethoscope in its ability to amplify sounds, but we want to extend beyond its functionality in the length of the stethoscope and its ability to be heard on multiple audio components. To do this we plan on using the components of the standard acoustic stethoscope and using a microphone to create an electric signal.

Client Requirements

The client has specified three components of the stethoscope's functionality that he would like to see increased as well as a few design specifications that must be met.

The first aspect of the functionality is the conversion of the acoustic sound signal into an electronic signal that is both filterable and amplifiable. This is a critical improvement in the operating room setting that our client normally works in because operating rooms often have a large amount of background noise. The ability to increase the volume of the stethoscope will thus guarantee that the client is always hearing the heartbeat and breath sounds clearly.

The second aspect of functionality the client has asked us to address is the stethoscope length. This design aspect comes from the fact that the client is an anesthesiologist and often has to adjust medication dosages during surgery. The stethoscope cannot reach the machine where dosages are adjusted. This requires the client to stop listening to the heart and breath sounds of the patient while adjusting medication. Increasing the length of the stethoscope should easily alleviate this problem.

The final aspect the client has asked us to address is the audio output of the device. The client would like to see the stethoscope be able to transmit sounds to both headphones and a speaker. This would increase the functionality because heart and breath sounds could be heard individually in the operating room, and could be heard by a group in an educational setting such as a medical educator is training medical students.

Along with these three aspects of functionality the client has a few design constraints including that the device must incorporate the existing stethoscope design and preserve its diagnostic capabilities, it must be transportable from operating room to operating room, it cannot create an electrical interference on the head of the stethoscope which might interrupt the function of an electrical device implanted into a patient, and the budget must be within \$100 to \$300.

Data Collection & Interpretation

The primary goal of the design is to create an electronic version of the stethoscope with added functionality over the current standard. With this goal in mind, there are several important considerations to be made in creating a working prototype. Primarily, the design must be created to deal with the excess noise levels associated with recording a very faint noise and amplifying it to ranges easy audible to the human ear. These high frequency background noises can pollute the recorded signal rendering it useless to the client. Signal filtering will therefore be necessary. Additionally, excess amplification can cause clipping or distortion of the recorded signal rendering it equally useless to the client. Thus, to create an electronic stethoscope that matches the fidelity of a current acoustic stethoscope the prototype will need to utilize appropriate signal filtering schemes as well as an overall amplification gain that balances the need for an audible signal with the need to preserve the subtle diagnostic aspects embedded into a patient's heart and breath sounds.

Data Collection

With the goal of determining which parts of the frequency spectrum are active in heart and breath sounds, our team deemed it necessary to collect several samples of heart and breath sounds for analysis. An existing stethoscope was modified as shown (figure 3) to digitally capture sample recordings of heart and breath sounds. The rubber tube was cut from the ear buds and a small actively powered condenser microphone was attached to the top of the tube, protected in foam, and fastened with duct tape. The heart was measured at variable gain levels from different loci on the chest and breath sounds were recorded from a location above the sternum and also below the right shoulder blade on a subject's back. Each location was recorded at a total of four different gain levels (25%, 50%, 75%, 100%) This was done to determine how much amplification would be required in our prototype as well as to determine how much gain was harmful to the signal.

Signal Processing

In order to determine which frequencies made up the sound of a heartbeat, a sample recording of the heart was imported into MATLAB for digital signal processing. Through the use of the Discrete Fast-Fourier-Transform (FFT), we were able to obtain a plot of the frequency spectrum vs. amplitude for our sample recording. Figure 4 shows the FFT plot. Initial research indicated that the sound of the heart beating resided around 300Hz and below (Jin et al. 2009), and this information is confirmed by our data.



Figure 3: Recording Apparatus used to obtain heart and breath sounds samples.

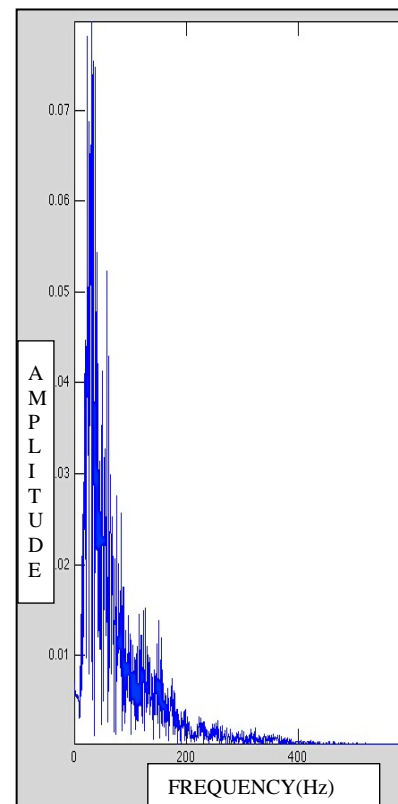


Figure 4: Single-sided amplitude spectrum of sample recording

Filter Modeling

While listening to the given sample (recorded at 100% gain), the heartbeat can be easily discerned. However, the high gain in recording resulted in excess noise dominating the signal. A low-pass filter is necessary to remove the unwanted hiss from the recording. Our team has decided to construct an active filter circuit to filter the signal instead of providing our prototype with DSP capabilities. Using the data we collected from the FFT on our signal, we modeled a low-pass filter appropriate for our design. Figure 5 shows the low-pass filter model that we created. It is an active, low-pass, third order, Butterworth filter with a cutoff frequency of 400Hz.

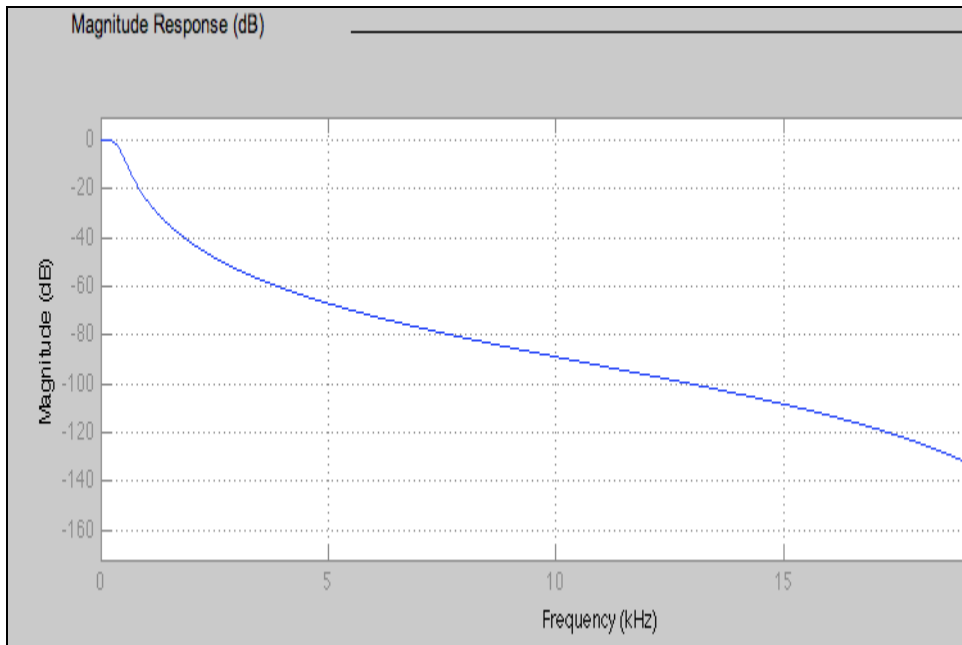


Figure 5: Low-Pass digital filter model (MATLAB)

Current Design

Using the data collected on heart and breath sounds, we have laid out plans to create a device that will maintain the initial design concepts of an acoustic stethoscope and convert the acoustic signal to an electronic signal which will allow us to increase functionality as planned.

The major design components of the current design can be divided into three main components: the initial sound pick-up, the conversion of acoustic sound to an electric signal, and the amplification, filtration and audio sound of the signal (figure 6).

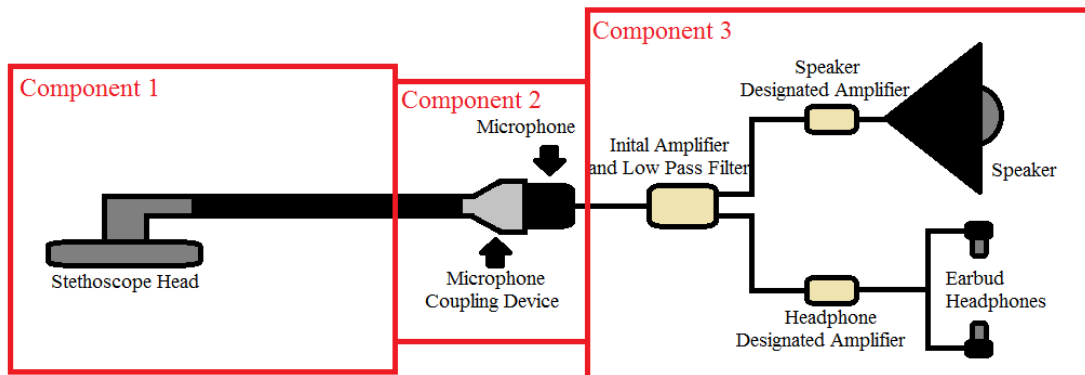


Figure 6: General block setup for current design showing three major design components: initial sound pick-up, conversion of acoustic sound to electrical signal, and amplification, filtration, and audio sound of the signal

The first component of the design focuses on maintaining as much of the standard stethoscope design as possible. In the design the head of the stethoscope and the rubber tubing are kept because they will help to maintain the fidelity of the original acoustic stethoscope design and keep the design simple as possible. The head of our stethoscope is crucial because it has the unsurpassed noninvasive ability to retrieve heartbeat and breath signals. These signals then lead into the rubber tubing, another important design, due to its ability to filter out excess noise not wanted by the user (Rappaport and Sprague 1941). The tubing will then lead off the chest away from the body to component two.

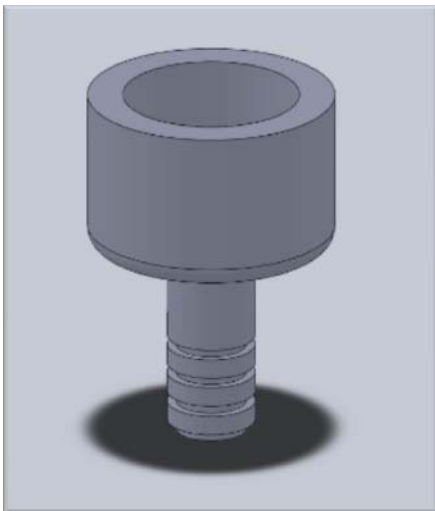


Figure 7: Drawing of microphone tube coupling in SolidWorks. Ridged edges are inserted into rubber tubing and microphone sits in the large cup on top.

Component two is the conversion of the acoustic sound to an electronic signal. It is located away from the body to avoid any interference between the microphone and any electronic device inside a patient, such as a pacemaker. The design will require a small microphone with high quality pick-ups so even a quiet heartbeat can be clearly picked up and sent into the amplifier. In order to connect the microphone to the tubing, a coupling device was designed that would pressure fit into the tubing and couple with the microphone without allowing it to slip or allowing sound to escape pickup by the microphone. The microphone

tube-coupling device was created in SolidWorks and in the near future will be printed on a 3-D printer (figure 7).

Although the tubing is able to filter out excess noise to a degree, there is still a need for additional filtering and amplification which is the purpose of the third component of the design. In order to create this filtering and amplification, the signal will travel from the microphone into a box containing an analogue filtering circuit as well as an amplifier. The decision to use analogue as opposed to digital was made for ease of design, and cost effectiveness. The filter design to be used is a low-pass Butterworth filter which is based on the digital filter applied using MATLAB. The Butterworth filter (figure 8) is an active filter meaning it has gain, is able to filter out signals, and can create a clear filtered signal due to rapid decay of unwanted frequencies and a longer pass-band (figure 5). With a higher order Butterworth filter, the decay of unwanted frequencies and the length of the pass-band increase (Storr 2011). We chose to use a third order low-pass filter, in order to make the signal of the heartbeat as clear as possible. The equations for both gain and corner frequency of the Butterworth filter are found in figure 9. In addition to the filter the second part of the third component is amplifying the signal so that the heartbeat and breath can be heard in both speakers and ear phones. The gain value of the amplifier and the amplifier model itself have been researched but have yet to be selected.

The final step in the third component is conversion of the electronic signal to actual audio. Because there will be two audio options, headphones and speakers, a switch can be selected for either the earphones or the external speaker. Both will have independent amplifiers contained in the circuit box which will have controls used to adjust volumes for the listener to hear.

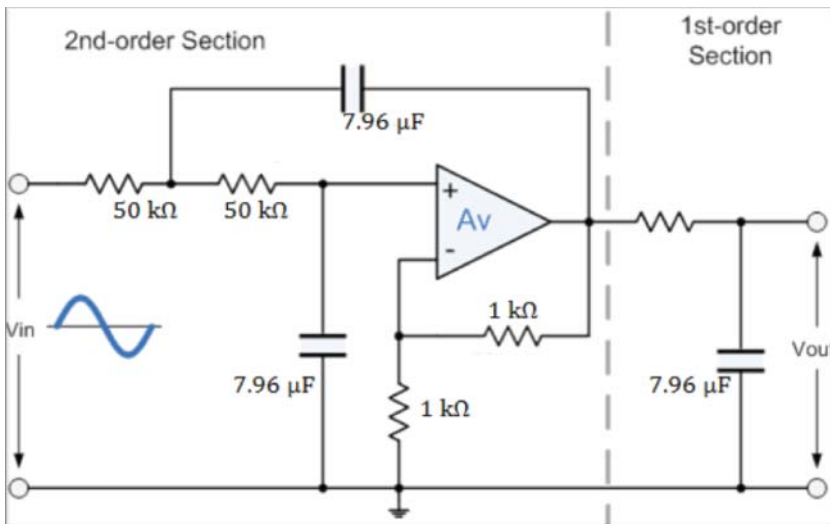


Figure 8: 3rd Order Butterworth filter circuit. Order is additive, second order section combines with first order second to create a third order filter (Storr 2011).

$$A_v = 1 + \frac{R_2}{R_1}$$

$$f_c = \frac{1}{2\pi \sqrt{R_3 R_4 C_1 C_2}}$$

Figure 9: Circuit equations for cutoff frequency and open loop gain used to calculate resistance in Butterworth circuit

Design Options

Despite having a general outline of the overall design, there are three main components of the device that need to be considered. These design options are broken down into three different categories, microphone type, power source, and microphone location in the device. The general set up for the device will consist of parts taken from a basic acoustic stethoscope, a microphone that may be housed in two different places in the device, a circuit enclosed in a circuit box that is expected to be no larger than a 15cm cube, an external speaker, and a pair of headphones.

Microphone Type

Advantages and disadvantages of three different types of microphones were analyzed and compared. The three types of microphones that were considered were: a condenser microphone, a dynamic microphone, and a piezo microphone. Condenser

microphones (figure 11), otherwise known as capacitor microphones, work by means of a capacitor, which converts acoustical energy into electrical energy (MediaCollege 2011). They require an external power source, which is reason for their higher output than that of dynamic microphones, which do not require external power. Condenser microphones are very sensitive to sound, which is why they are not

commonly used for high-volume recording. In order to function, condenser microphones rely on a capacitor, which has two plates with a voltage between them. The front plate, otherwise known as the diaphragm, is made of a very light material so that when sound waves come into contact with it, the distance between the plates change and a current is produced. The closer the plates are, the greater the current produced, corresponding to the intensity of sound waves.

The second microphone considered is the dynamic microphone (figure 12). They are very common in settings that require a microphone that can handle a high input volume. They do not contain

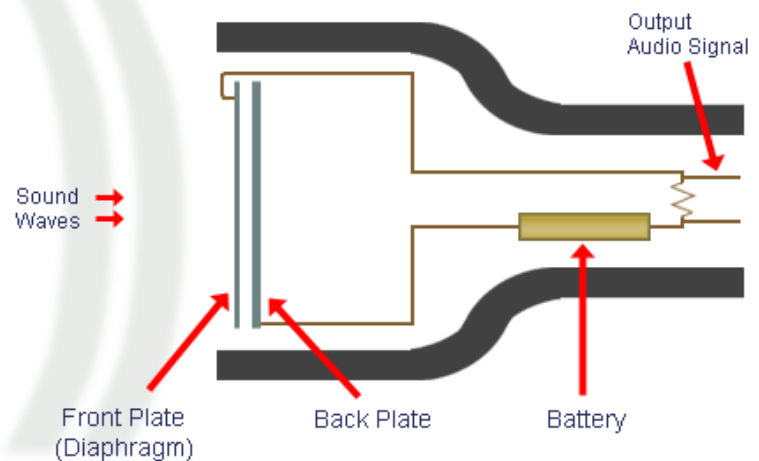


Figure 11: Cross-Sectional view of condenser microphone

Cross-Section of Dynamic Microphone

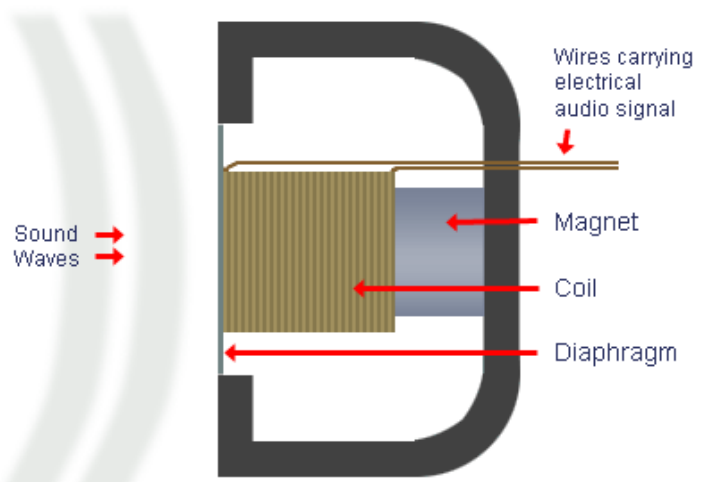


Figure 12: Cross-sectional view of dynamic microphone element

an internal amplifier, and also are able to operate without a power source, unlike the condenser microphone. Instead of a capacitor plate, dynamic microphones rely on a magnet and coil to create a current. The coil is attached to a diaphragm, which will vibrate as it is impacted by sound waves. The vibrations cause the coil to move in relation to the magnet, which creates a current. This phenomenon is known as the electromagnet principle.

The final microphone consideration is the piezo microphone. The piezo microphone functions by means of piezoelectricity, which is the ability of a material to produce a voltage when pressure is applied to it. These microphones are often used to amplify sound from acoustic instruments, such as a guitar. Rather than using a diaphragm as illustrated by the condenser and dynamic microphones, the piezo microphone utilizes materials such as crystal or certain ceramics to produce an electric current.

Microphone Location

Within the device, two possible locations for the microphone were considered. The first design would place the microphone inside the tubing, some distance away from the diaphragm of the stethoscope (Figure 6). Acoustic stethoscopes sound the way they do, because of the mechanical filtering done by the tube, prior to the sound reaching the doctor's ears. This low-pass filter is responsible for the sound that doctors have become accustomed to. Placing the microphone in this location would require a coupling of some sort to act as the medium between the tubing and circuit box, which could be made on a rapid prototyping machine. This design allows for preservation of the mechanical filtering, yielding a sound consistent with that of a standard mechanical stethoscope.

The second location considered involved placing the microphone directly inside the diaphragm at the end of the tube. This could improve the aesthetics and stability of the stethoscope, but as a compromise, the mechanical filtering done by the tube would be lost. It would require some creative manipulation of the stethoscope head in order to fit the microphone inside.

Power Source

Because this is an electronic device, some external power will be required to power it. The two power sources considered were battery operated and an external power cord, which would be plugged into a standard wall outlet. It is estimated that a 9-volt battery will be sufficient enough to power the device for an extended period of time. 9-volt batteries are used to power devices that show moderate drain levels, such as a clock radio or baby monitor. The battery would be housed within the circuit box, and would supply power to both the circuit and condenser microphone, should that be the type selected.

The other option is to use an external power source that plugs into a wall outlet. This would definitely limit range of motion with the device, as it would be constrained to the length of the cord. On the positive side though, there would never be the need to replace the power source. The cord would extend out of the circuit box, and have some type of Velcro strap to secure it when it is not in use to increase ease of transportation.

Design Matrices

Based on our assessment of the problem, we determined three key areas in which design decisions needed to be made: microphone type, power source, and microphone location.

Microphone Type				
Factors	Weight	Rating (1-10)		
		Condenser Mic	Dynamic Mic	Piezo Mic
Cost	0.10	4	5	2
Sensitivity/Fidelity	0.40	9	4	3
Size	0.25	7	6	4
Simplicity/Circuit Requirements	0.25	4	8	8
TOTAL	1.00	6.75	5.60	4.40

Figure 13: microphone type matrix

Figure 13 contains the design matrix for the microphone type to be used in the device. Sensitivity/Fidelity was rated highest for this matrix, because in order to have a usable stethoscope, the sound that it produces must be as accurate as possible in terms of replicating a mechanical stethoscope. The sensitivity of the condenser microphone ranked highest out of the three, because of its excellent transient response, coverage of a wide frequency band, and high output volume. The condenser microphone is commonly used with quieter sounds, because the external power allows for the signal to be amplified upon recognition. Size and simplicity were both rated second. Should the microphone be too large, portability of the device would be compromised, which our client defined as a necessity. The condenser microphone that is currently being implemented is 10.0mm in diameter, by 5.0mm in depth, plenty small to maintain portability of the device. The simplicity of circuit requirements was given the same weighting as size, because in order to have a functioning electronic stethoscope, the microphone must be correctly integrated into the device. The condenser microphone received a lower score than the other two microphones, because of the external power source requirement that's associated with that type of microphone. Finally, cost was weighted the lowest in this design matrix. The specified budget of \$100-\$300 makes cost less of a factor, and without the proper fitting microphone for the device, diagnostic information may be compromised. Piezo microphones are the most expensive of the three. The numbers show that the condenser microphone is the best option for the device.

Power Source			
Factors	Weight	Rating (1-10)	
		Batteries	External Power
Life	0.30	2	9
Life-Cycle Cost	0.15	3	4
Portability	0.35	9	2
Client Preference	0.20	7	5
TOTAL	1.00	5.60	5.00

Figure 14: Power source design matrix

Figure 14 contains the design matrix for how the device will be powered. The client emphasized portability of the device, so that it can be carried from operating room to operating room with ease. Given that, portability was ranked highest to ensure the best power source option was chosen. Batteries were rated highly in this factor, because a battery-powered device can be transported much easier than one that requires a wall outlet. External power would limit range of motion, and would also introduce another cord in the operating room, creating a potential tripping hazard. The life of the power sources was weighted second highest, because a constant need to replace batteries would not only cause an annoyance to the user, but could also be problematic should the device lose power during a critical situation. Batteries were rated very low, due to the fact that they do run out of power over time, and will have to be replaced. External power is of course incredibly reliable, and will only need to be replaced should the cord fail. Client preference was weighted third highest, as the client explicitly noted that he would prefer batteries to an external power. Finally, life-cycle cost was weighted lowest, because pricing for either option is not all that expensive. As for the batteries, rechargeable batteries have been considered, which could greatly reduce life-cycle cost. After taking all factors into consideration, it was determined that batteries would be the best power source to fit the design specifications.

Microphone Location			
Factors	Weight	Rating (1-10)	
		Inside Tubing	Inside Diaphragm
Fidelity	0.35	7	4
Stability/Portability	0.10	4	7
Aesthetics	0.05	5	8
Multifunctionality	0.10	8	2
Safety	0.40	8	2
TOTAL	1.00	7.10	3.50

Figure 15: Microphone location design matrix

Figure 15 contains the design matrix for microphone location in the device. The two designs being considered were a device that housed the microphone inside the diaphragm of the stethoscope, or at the end of the tube connected to the diaphragm (Figure 7). Safety of the device was most heavily weighted, because it is ultimately counterproductive to introduce a new hazardous variable into the operating room that may harm the patient. It was noted by our client that a design in which the microphone would come in direct, or very close contact with the patient, could potentially be harmful to patients who have electronic devices such as a pacemaker. Given that, it was decided that the microphone should be housed in the tubing to minimize that risk. The second most important factor in this design matrix involves maintaining the fidelity of the acquired signal. The design for this device is not intended to re-invent the traditional stethoscope sound, but to preserve the sound that doctors have become accustomed to, and increase its volume. The tube attached to the diaphragm acts as a low-pass filter, which is reason for why stethoscopes sound the way they do. Placing the microphone inside the diaphragm would result in a loss of the mechanical filter, and potentially a completely different sound in comparison to traditional stethoscopes. Ratings defined in safety and fidelity alone made it evident that the microphone should be housed in the tubing for the best possible design.

Future Work

More work is needed to be done in the frames of testing and revising our circuits. The specific amplifier to be used and a suitable gain is still to be determined using different resistor and capacitors, for listening purposes. A low-profile speaker needs to be selected and applied to our circuit to create audible sound. Once complete, we will need to test our apparatus on a patient with irregular heart function, such as murmurs and stuck valve to guarantee that the fidelity is maintained and these sounds can still be heard. From this, we will find out if our chosen gains and filters were correct and if not we will rework the design of our filter to accommodate these changes.

Our future work also extends beyond the time frame of this design project to another increase in functionality that our client would like to see in the future, wireless capabilities. This is currently well beyond the scope of the current design project and budget, but is rather future work to be considered after a wired prototype is successfully created.

References

- 3M. 2011. "3M Littman Electronic Stethoscope Model 3200." http://www.shop3m.com/3m-littmann-electronic-stethoscope-model-3200.html?WT.mc_ev=clickthrough&WT.mc_id=shop3m-AtoZ-Littmann-Stethoscopes (accessed March 2, 2011).
- Alibaba.com. 2011. "MDF 77704 Stainless Steel Dual Head Stethoscope." http://www.alibaba.com/product-gs/346985222/MDF_77704_STAINLESS_STEEL_DUAL_HEAD.html. (accessed March 8, 2011).
- Bause, G. 2010. Laennec's 1819 Stethoscope. *Anesthesiology* 1(112): 18.
- Dynamic microphones.
<http://www.mediacollege.com/audio/microphones/dynamic.html> (Retrieved March 8, 2011).
- Condenser microphones.
<http://www.mediacollege.com/audio/microphones/dynamic.html> (Retrieved March 8, 2011).
- Jin, F., Satter, F., Goh, D.Y.T. 2009. A filter bank-based source extraction algorithm for heart sound removal in respiratory sounds. *Computers in Biology and Medicine* 39: 768-777.
- Medisave. 2011. "3M Littman Model 3100." <http://www.medisave.net/3m-littmann-model-3100-electronic-3100-stethoscope-black-3100bk.html> (accessed March 8, 2011).
- Rappaport, M., Sprague, H., 1941. Physiologic and physical laws that govern auscultation and their clinical application: the acoustic stethoscope and the electrical amplifying stethoscope and stethograph. *American Heart Journal* 3(21): 257-318.
- Repas, R. Sensor sense: Piezoelectric force sensors, February 7, 2008.
<http://machinedesign.com/article/sensor-sense-piezoelectric-force-sensors-0207> (Retrieved March 8, 2011).
- Sterne, J. 1990. Early Chapters in the Stethoscope's Evolution. *Journal of the American Medical Association* 21(264): 2817-2820.
- Welch Allyn Medical Supply Store. "Welch Allyn, Medical Supply Store and Medical Equipment." (accessed on March 8, 2011).

Appendix A: Product Design Specifications

Heart and Breath Sound Amplifier Preliminary Product Design Specifications Drew Birrenkott, Caleb Durante, Brad Wendorff, Jared Ness

Function: The function of the device being designed is to increase the functionality of the standard medical acoustic stethoscope in three ways while maintaining the diagnostic capabilities of the original stethoscope design. The three areas of functionality are to be increased are: converting the acoustic sound waves from the stethoscope to a filterable electronic signal, increase the length of the stethoscope so the heartbeat can be heard from further away, and create dual listening capabilities so the sounds from the stethoscope can be heard both in standard headphones as well as a speaker.

Client Requirements:

1. Ability to hear sounds clearly with both headphones and speakers.
2. Device must be able to be transported from one operating room to another.
3. Device cannot introduce harmful electrical interference onto the body of the patient.
4. Amplification process must preserve all diagnostic information that a normal stethoscope can provide.
5. Device needs to stay within a budget of \$100-\$300.

Design Requirements:

1. Physical and Operational Characteristics

- a. *Performance Requirements:* The device can be expected to be used multiple times daily and must perform to medical standards each time. Amplification must be to a minimum of 60 dB and the frequency must not exceed 300 Hz.
- b. *Safety:* The device cannot introduce any harmful electrical interference to the patient or anyone operating the device. This is especially important for electrical devices that have been implanted such as pacemakers. Furthermore, the device must be approved for use by the proper committees and hospital staff members.
- c. *Accuracy and Reliability:* The device needs to provide heart and sound amplification of the same or better diagnostic quality as a medical stethoscope.
- d. *Life in Service:* There is no specific life in service characteristic for this device, but it likely needs to be reliably used for multiple years.
- e. *Shelf Life:* The device will likely be battery operated and the only shelf life concern is battery replacement every three to four months.
- f. *Operating Environment:* The heart and breath sound amplifier will be used in a standard hospital operating room as well as in an educational setting.
- g. *Ergonomics:* The device must allow the anesthesiologist to easily listen to on headphones to the heart and breath sound amplifier and alter medication dosages up to three meters away.
- h. *Size:* The main operating box cannot exceed a cube size of 15cm x 15 cm x 15cm.
- i. *Weight:* Overall weight of the system cannot exceed 3.0 kg.

- j. *Materials*: Device will be made out of various circuit components including a condenser microphone and a polymer outer housing. The device will utilize a standard stethoscope head and esophageal tube to initially receive sound vibrations. Materials cannot create electrical interference that would jeopardize patient or operator safety.
 - k. *Aesthetics, Appearance, and Finish*: Device needs to be visually appealing. Device should not be exotically colored and follow standard operating room style.
- 2. Production Characteristics:**
- a. *Quantity*: One
 - b. *Target Product Cost*: \$100-\$300
- 3. Miscellaneous:**
- a. *Standard and Specification*: Built to United States legal standards. Must be approved by proper hospital committees and staff to comply with HIPPA and patient disclosure or release. Needs to receive FDA approval.
 - b. *Customer*: Dr. Scott Springman and the anesthesiology staff of the University of Wisconsin-Madison Hospital
 - c. *Patient-Related Concerns*: The device will need to receive proper sterilization between uses as laid out in operating room protocol. If necessary use of device during surgery may need to receive patient approval.
 - d. *Competition*: Multiple similar devices are on the market including products by 3M Littmann Stethoscope, Thinklab Digital Stethoscope, and Cardionics EScope. Prices for competition are not within the price range of the client.