UNIVERSITY OF WISCONSIN – MADISON: DEPARTMENT OF BIOMEDICAL ENGINEERING

Electronic Stethoscope

Fall 2011

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October 26, 2011

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ABSTRACT

The traditional acoustic stethoscope has been in use for nearly 200 years, changing very little over that time. As one of the most important diagnostic tools in a doctor's repertoire, and comparatively low-tech by today's standards, many recent attempts have been made to upgrade the design of the stethoscope. However, as they are at least twice the cost of traditional stethoscopes and produce a sound different from a traditional stethoscope, these electronic stethoscopes have had a hard time catching on. As such, our client requests a redesigned electronic stethoscope consisting of a main receiver box, with both speakers and a headphone jack for listening, along with two wireless microphones that attach to the patient and detect the heart and lung sounds. In order to effectively develop the prototype, a schematic of the design layout was developed, digital and analog amplifiers were compared, and two design matrices for microphone types and wireless technology were created. Based on research done into two different types of amplifiers, class – AB and class – D, class – AB was selected for its ease of implementation into our circuitry. After comparing three different types of microphones – condenser, fiber optic, and MEMS – it was determined that MEMS microphones were the best choice moving forward. For wireless technology, an FM transmitter, Bluetooth technology, and a PurePath wireless kit were researched. Based on our limited knowledge in dealing with the complexities of Bluetooth technology, the PurePath kit was chosen to implement the wireless capability of the prototype. Future work includes finalizing the design, ordering materials, assembling and testing the prototype, and performing final modifications based on client input and the tests results.

BACKGROUND

PROBLEM STATEMENT

Anesthesiologists need to listen to patients' heart and breath sounds during anesthesia care. Manual stethoscopes are commonly used but only allow for one listener and are uncomfortable for extended wear. An electronic stethoscope was developed which utilizes a speaker and microphone system, but it is too large for practical purposes. In order to improve upon the existing device, a more suitable power supply must be found. Ideally, changes should also be made to allow for a dual microphone system with wireless capabilities, as well as a main receiver with a speaker and a headphone jack for private listening.

Stethoscope Background

Although it is a very simple device, the stethoscope is one of the most important diagnostic tools in the medical world. Over almost two centuries, the stethoscope has been changed and refined often, but it has never strayed too far from the original design. Rene Theophile, a French physician, is attributed with the invention of the first stethoscope in 1816 when he was examining an obese patient [1]. His first model of the stethoscope was simply a wooden tube resembling a candlestick [2]. Over the years, this model has evolved into the device that we now recognize as the stethoscope through many small changes, such as adding earpieces for each ear and developing the combined bell and diaphragm chest piece [2]. Very few changes have been made to the model of the stethoscope since 1961, when Dr. David Littman patented a new, lighter model with a single binaural tube that drastically improved the acoustic technology. The stethoscopes that are now commonly used are called "Littman stethoscopes" for this reason.

A stethoscope is a very straightforward device. The chest piece consists of a shallow, bell-shaped piece and a clear, stiff diaphragm, which is then connected to the metal earpieces by a flexible tube. The bell is used to pick up lower frequency sounds, and the diaphragm is used for higher frequency sounds. When the chest piece is placed on the skin, vibrations within in the body are amplified by either the bell or diaphragm. These acoustic pressure waves then travel up through the tubing to the earpieces and into the listener's ears [3].

Very few changes have been made to the overall design of the stethoscope over the years because it does its job so well. However, there are a few problems with current models. For example, with the standard acoustic stethoscope, the listener is not able to amplify the sounds. This is sometimes a problem if he or she is only getting very quiet sounds through the stethoscope. Also, the earpieces of stethoscopes can be quite uncomfortable [4]. Although these are not enormous problems, current technology has introduced alternatives to the acoustic stethoscope.

Current Methods

In 1961, right around the same time that Littman patented his new model, a company named Amplivox produced the first electronic stethoscope. It was only meant to be an academic tool due to its large size and weight, and it also produced distinctly different sounds than what doctors were used to hearing [5]. Because of this, the idea was largely abandoned, and users returned to the conventional stethoscope [2]. However, some companies have returned to this idea and have introduced new devices to the market. Some enhancements that modern electronic stethoscopes have are sound transducers, adjustable gain amplifiers, and frequency filters [4].

Although these improvements have been made, the electronic stethoscope still has not been embraced by the medical community. This is because the sounds that the listener receives through the earpieces are mixed in with electronic noise, causing the sounds to be different than the non-electronic, acoustic stethoscope [4]. Also, electronic stethoscopes are very sensitive to surrounding noises, and these will distort the sound that the listener hears [4]. Many electronic stethoscopes on the market do not have the original bell and diaphragm or tubing, which help filter background noise and produce a sound that the listener is more familiar with [4]. Electronic stethoscopes, like standard acoustic stethoscopes, only allow one listener, which is not preferable for a teaching environment. They are also much more expensive than an acoustic model. Current models on the market only have one input microphone, so sounds from different parts of the body cannot be heard at the same time. This project will fix many of the problems of currently marketed electronic stethoscopes tailor the stethoscope to our client's specific needs.

Previous Prototype

The current prototype follows the general block setup featured in Figure 1. The target sounds originate from the vibrations of the stethoscope's thin diaphragm, and the sound waves reverberate through the rubber tube. This tubing acts as a mechanical low pass filter, assisting in imitating the original sound of a non-electronic stethoscope. Located at the end of the tube is a condenser microphone housed in a plastic coupling device designed in SolidWorks and printed on a 3D printer.

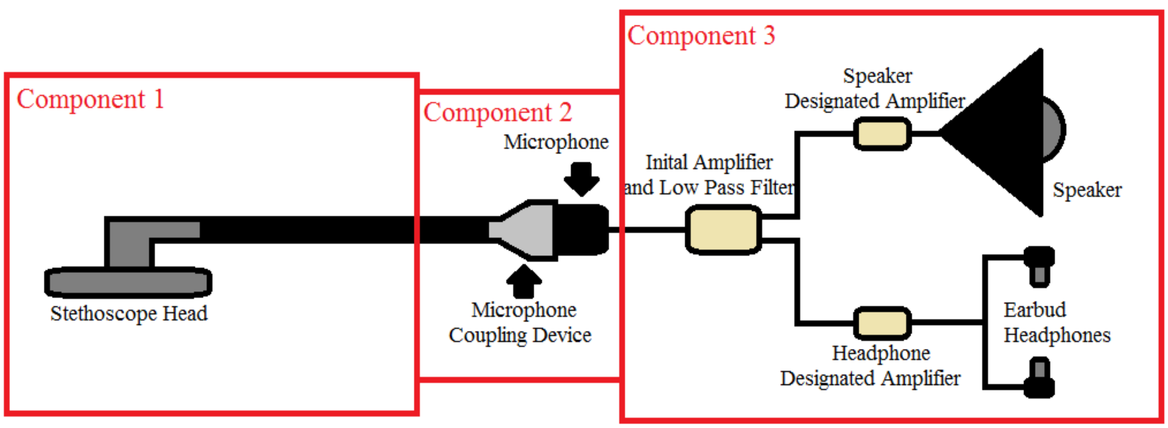

Figure 1: General block setup for current design showing three major design components: initial sound pick-up, conversion of acoustic sound to electrical signal, and amplification, filtration, and audio sound of the signal
Image Courtesy of: Spring 2011 Stethoscope Team

The signal is then sent through a DC blocking capacitor followed by a non-inverting voltage follower, a second-order low pass filter, and finally an active gain stage providing a gain of 10. The corner frequency for the filter is 800 Hz. Before the signal is routed to the desired audio outputs, it is subjected to voltage dampening by a potentiometer that acts as a volume control. The speakers currently being utilized are rated for 5 watts at 4 ohms. For headphone amplification, the LM386 was chosen and offers a nominal gain of 20. In order to drive the speakers, a high-powered TDA2003 was chosen to provide a gain of 100, which can be altered by varying the resistors and capacitor values within the circuit. Currently the device draws 12V DC and pulls approximately 100mA at peak speaker output from a variable power supply. The collection of single supply operational amplifiers utilizes a virtual ground of 6 volts, created by a series of buffered voltage dividers (Figure 2).

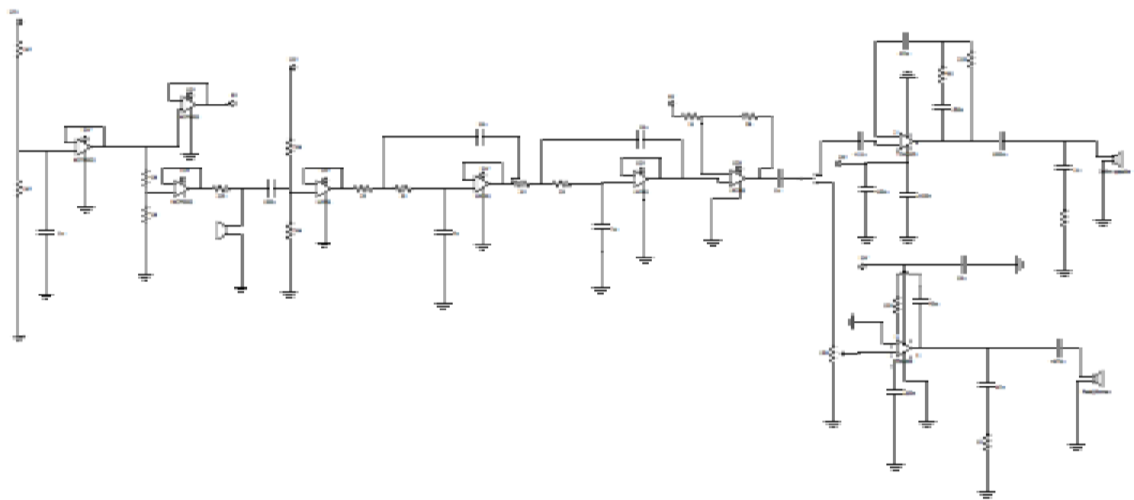

Figure 2: Current electronic circuit diagram with microphone input located on the left and audio outputs on the right
Image Courtesy of: Spring 2011 Stethoscope Team

The housing for the main receiver box is a clear polycarbonate box, which contains the speakers and all the user controls including power switches and volume controls for both headphones and speakers. On the side of the box is a small hole for the input wires from the condenser microphone, with the lid to the housing being secured by six screws [6].

Considerations for improvement this semester include shrinking the overall dimensions of the housing to make the device more practical for clinical use. The target size is no greater than a 5” cube. The loose wires will also need to be secured and protected in accordance with improving aesthetics and safety. An additional input microphone will be added to allow for the user to compare and contrast two separate lung sounds, which will be especially useful in determining which bronchi the endotracheal tube enters during pediatric procedures. A final consideration would be to ideally make both input microphones wireless.

Design Criteria and Considerations

Despite having a general schematic (see Figure 3) for how the final prototype will look, there are three main components of the design that need to be evaluated. Therefore, the design options are broken up into three different categories: microphone type, wireless technology, and amplifiers. As can be seen in Figure 3, the final prototype will consist of a main receiver box holding the speaker and headphone jack, all the internal circuitry components, and the wireless receivers for the two microphones. Attached to each stethoscope head will be a microphone, a lithium coin battery for power supply, and a wireless transmitter.

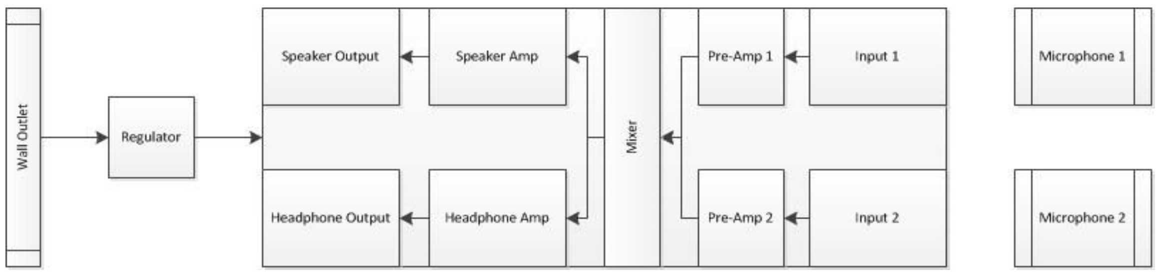

Figure 3: A preliminary schematic of the main components of the design. Inputs from microphones are located on the right, with power from a standard AC wall outlet on the left. Arrows inside main receiver box designate the direction of signal processing.

Funding

Funding for the prototype will be supplied by the client, Dr. Scott Springman. Dr. Springman suggested a budget of $200-$300, with the team contacting Dr. Springman when the money is needed. If the team expects to go over this budget, Dr. Springman must be notified in order to work out an alternative funding source or request a larger budget.

Microphones

In order to determine the best microphone to use in our final design, three different types were analyzed and compared. The three types of microphones that were considered for use were a condenser microphone, a fiber optic microphone, and a MicroElectrical-Mechanical System (MEMS) microphone.

The first option, a condenser microphone, works by means of a capacitor, which converts acoustical energy into electrical energy (Figure 4).The front plate, diaphragm, is made of

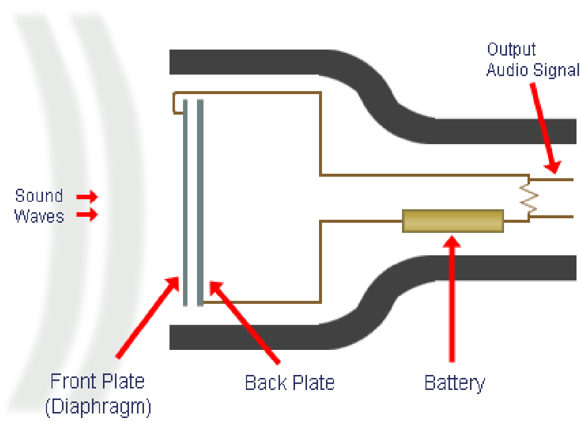

Figure 4: A cross-section look at a condenser microphone. *Image Courtesy of: http://www.mediacollege.com/audio/microphones/condenser.html*

lightweight material and vibrates when hit by sound waves. This causes the distance between the diaphragm and the back plate to change; resulting in a change of capacitance as given by the formula $C = \frac{\varepsilon A}{d}$. In order for the change in capacitance to take place, a voltage must be supplied across the two capacitor plates. This voltage is supplied by some type of external power source, usually a small battery within the microphone. The external power source also allows for the condenser microphone to have a higher output when compared to types of self-powered microphones, such as the dynamic microphone. Due to their sensitivity to sound and good frequency response, condenser microphones are a popular choice in laboratory and sound recording studios [7].

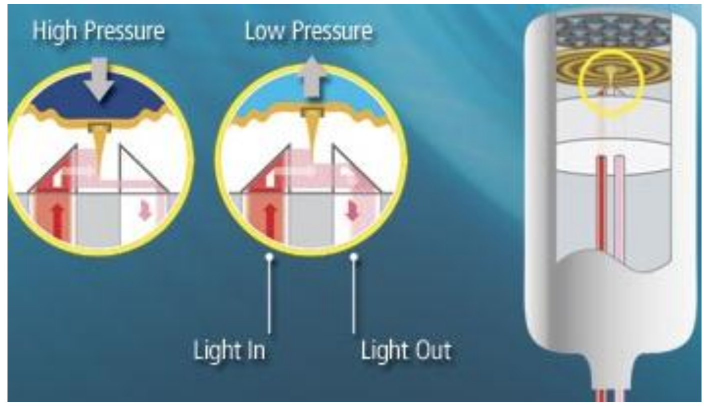

Figure 5: The inner workings of a fiber optic microphone.
Image Courtesy of:
http://www.optoacoustics.com/technology/core-sensor-platform

The second microphone option was a fiber optic microphone (Figure 5). Fiber optic microphones work by sensing changes in light intensity, rather than changes in capacitance or magnetic fields like traditional microphones. Light from a laser source travels through an optical fiber, where it illuminates the surface of a reflective diaphragm at the tip of the microphone. When the diaphragm vibrates due to sound waves, the light intensity being reflected off the diaphragm is changed. This change of light intensity, transmitted by a second optical fiber, is detected by a photo detector. The photo detector then transforms the light intensity into an analog or digital audio signal for transmission. Because fiber optic microphones do not react to electrical or magnetic fields (EMI/RFI immunity), and because they possess a large frequency response range, fiber optic microphones are ideal for use inside industrial turbines or in MRI suites, places where traditional microphones are ineffective [8].

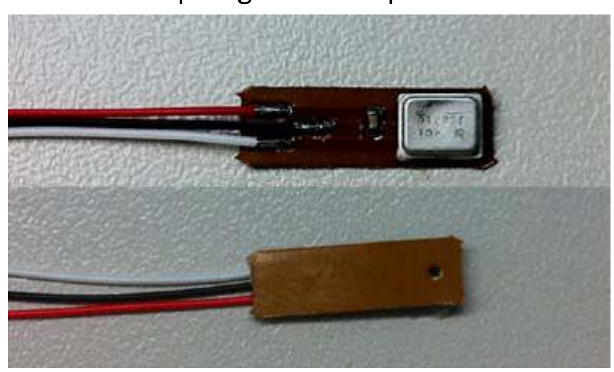

Figure 6: An MEMS microphone attached to the evaluation board.
Image Courtesy of:
http://www.analog.com/en/audiovideoproducts/imems-microphone/admp401/products/product.html

The final microphone considered was a MEMS microphone (Figure 6). MEMS, or MicroElectrical-Mechanical System, is the name given to very small mechanical devices driven by electricity. The microphone's mechanics are similar to a condenser microphone, the main difference being that the MEMS microphone is mounted on a circuit board of approximately 15 mm^2. The microphone element consists of an impedance converter and an output amplifier, transmitting a digital audio output signal recorded from the microphone head. The microphone head faces through a hole in the bottom of the circuit board, while the body of the microphone element is located on the top. Due to their extremely small size, MEMS microphones are used in smartphones and Bluetooth headsets, as well as other similar applications [9].

Wireless

For audio transfer, three wireless signals were considered: Bluetooth chipsets, an FM transmitter, and PurePath wireless. Bluetooth chipsets utilize low-power radio frequency transmission [10]. They are extremely small and relatively inexpensive. However, they are more difficult to integrate into a circuit, as they are inflexible in their implementation. A circuit must be built around the Bluetooth chip, increasing its complexity.

The second wireless option analyzed was an FM transmitter. This method would be similar to sending the audio from an iPod to the radio of a car. An FM transmitter system would be easy to implement, but would use significantly more power. The transmitter is larger than desired, and the high power necessary to run it would require additional bulky batteries attached to the stethoscope. The problem of ensuring the FM signal was not in use would also have to be considered.

The final wireless option was TI's PurePath Wireless system. PurePath Wireless sends an uncompressed digital audio signal over a strong radio frequency link [11]. PurePath was designed solely for audio transmissions, so the sound quality is excellent. This system is available in development kits, making it easy to implement. The kits also come with rechargeable batteries with a 22-hour battery life.

Amplifiers

Two main classes of amplifiers were considered for signal amplification, AB and D. Both act in similar fashions, taking power from a source and using it to increase the amplitude of a signal while maintaining the input signal's shape. The main advantage of a class-D amplifier is power efficiency. Usually metal–oxide–semiconductor field-effect transistors are used and operate with extremely low resistance and thus have minimal power dissipation and can reach peak efficiencies of over 90% [12]. However, using a class-D amplifier which converts the analog input signal into a digital value introduces distortion called quantization error [13]. This error can be hard to compensate for, especially if implemented incorrectly.

For this reason, class-AB will be used in our design in order to greatly improve feasibility. Class-AB amplifiers sacrifice some efficiency in favor of linearity. Peak efficiencies will be lower than 78.5%, and thus would require a heat sink [14]. Since our design calls for a relatively large speaker, the receiver box housing will be spacious enough to accommodate several of these heat sinks. Utilizing class-AB amplifiers will also allow for the circuit to remain analog, simplifying the detailed schematic and allowing for easier alterations to be made after testing.

DESIGN EVALUATION

MICROPHONE

The condenser, fiber optic, and MEMS microphones were evaluated on a weighted scale ranging from zero to ten over a variety of design criteria (Table 1). The most important design criteria were given the highest weight and include size and sensitivity/frequency response. These two aspects were determined to be the most important design aspects since they are critical if the microphones were to fit on the back of a stethoscope head and give a quality sound back to the user.

Table 1: The design matrix for the three microphone options

Weight	Desgin Aspects	**MEMS**	Fiber Optic	Condenser
0.3	Size	**10**	9	7
0.3	Sensitivity/Frequency Response	**9**	10	10
0.15	Cost	**8**	3	7
0.1	Power	**9**	7	6
0.1	Feasibility	**8**	5	7
0.05	Interference from Medical Devices	**7**	10	7
	Total	**8.95**	7.85	7.8

Since a priority in this design was to use two wireless microphones, the size of the microphones was very important and therefore given a weight of 0.3. The microphone must be small enough to attach to the back of an existing stethoscope, so as not to be overly large and uncomfortable for the patient. The microphone's sensitivity and frequency response were equally important, also receiving a weight of 0.3. The frequency response of the microphone must allow for the user to hear the heart and lung sounds as much as possible; the microphone must be able to detect sounds as low as 100 Hz. All three microphone choices scored well in these two categories, with the exception of condenser microphone size. Condenser microphones, while small and able to fit on the back of a stethoscope head, were not available as small as MEMS microphones. All three microphone choices could detect sounds as low as 100 Hz, with the fiber optic and condenser microphones able to detect sounds as low as 20 Hz.

Cost was the next most important aspect, given a weight of 0.15 due to the budget set forth by our client. Both the MEMS and condenser microphones are relatively inexpensive, while the fiber optic microphones cost upwards of $400.00, resulting in a low score in the cost category.

Power and design feasibility were the next two aspects, both receiving a weight of 0.1. The microphones must be able to be powered using a small power source, such as a lithium coin battery, and the circuitry for the microphones must be straightforward enough to allow us to build the prototype. MEMS scored high in this category as it takes the lowest power of the three at 1.5 Volts. MEMS also received the highest score in feasibility, with many companies offering MEMS microphones on prebuilt "evaluation boards", ready to be incorporated directly into a prototype.

Finally, interference from medical devices was the sixth design aspect rated. At a weight of 0.05, it was the least important of the six. The fiber optic microphone scored the highest in this category due to its EMI/RFI immunity, while the other two types scored lower due to their components being susceptible to magnetic interference

Overall, the MEMS microphone received the highest total score of 8.95, followed by the fiber optic microphone at 7.85 and the condenser microphone at 7.8. Because of this, the MEMS microphone is the microphone of choice for the final design. However, if the MEMS microphone proves unsatisfactory, a small condenser microphone will be used instead.

Wireless

The Bluetooth chipset, FM transmitter, and PurePath wireless system were also evaluated on a weighted scale ranging from zero to ten over five design criteria (Table 2). Transmission quality was given the highest weight because accurate transmission of heart and lung sounds is imperative in an emergency room setting. PurePath, with its lossless CD-quality, was rated the highest in this category. Bluetooth and an FM transmitter had lower quality than desired. Feasibility was given the next highest weight. A workable circuit design is necessary in order for the semester deadline to be met. In this respect, an FM transmitter would be the easiest, with PurePath having similar feasibility. A Bluetooth chipset, on the other hand, would be extremely difficult to integrate into the stethoscope system. Because the budget is specified as $300, cost was rated third most important. While the chipset and transmitter were both fairly inexpensive, the PurePath option is significantly more expensive. However, this does not remove PurePath from consideration.

Table 2: The design matrix for the three wireless options

Weight	Design Aspects	Bluetooth Chipset	**Purepath**	FM Transmitter
0.3	Transmission Quality	8	**10**	7
0.25	Feasibility	4	**7**	8
0.2	Cost	8	**6**	9
0.15	Power	8	**9**	7
0.1	Size	10	**6**	5
	Total	7.2	**7.9**	7.45

Power needed to run the wireless was the fourth design aspect rated. An FM transmitter takes up the most power and would need AAA batteries that would be replaced often. A Bluetooth chip takes up very little power and could run on a lithium coin cell for long periods of time. The PurePath system was rated the best because it has a rechargeable battery that can simply be plugged in to a USB port or wall outlet. Size was considered the least important because the different wireless options are all fairly close in size, and any difference would be minor. Because the stethoscope bell will be attached to the patient, the wireless system must be small enough that it is not bulky, even on a child. The Bluetooth chip is only about the size of a fingernail, so it was given the best size rating. PurePath and an FM transmitter are similar in size, with the PurePath being slightly smaller. With all factors considered, it was determined that PurePath wireless is the best wireless option for the electronic stethoscope design.

FINAL DESIGN

The receiver box will house the main circuit, comprising of multiple components synergistically working to successfully produce the desired audio output. Signal processing begins with input from two microphones located on the right side of the schematic diagram (Figure 3 pg. 7). These raw signals are sent through a series of specifically chosen operational amplifiers in order to filter out unwanted frequencies. The corner frequency will initially be set at 800 Hz; consistent with the previous prototype. This value, however, will need to be tested on patients to ensure it allows for sufficient high frequency response while still minimizing noise. Due to our custom pre-amps, we will be able to alter this corner frequency and improve the quality of the final audio output. This stage will also include the required buffering and impedance matching.

Figure 7: Example of a mono power amplifier
Image Courtesy of:
http://store.qkits.com/moreinfo.cfm/FA604

Once the signals are successfully filtered to the desired frequencies, each signal is joined via a mixer, to allow for crossfading between signals. This stage will permit the user to hear differences between lung sounds when each microphone is place on a respective lung. A multiple input mono mixer with independent level control for each input will be purchased to fulfill this. It will be purchased through an online vendor in the form of a kit which requires assembly, but includes all necessary components to mix the signals successfully.

The signal, now joined to one, will pass by a switch determining which output the user is interested in: speaker or headphones. Each output needs its own amplifier to increase the power of the signal. This will be attained by a high fidelity audio amplifier for each, again in the form of a kit to successfully amplify the audio signals (Figure 7). The speaker amp will call for roughly 15 VDC and a maximum current consumption of 800 mA at peak usage in order to obtain a peak output of 8W into an 8 ohm load, or 12W into a 4 ohm. This demand in power requires the device to utilize a wall outlet, which in turns requires an FDA approved isolation regulator to ensure no leakage current develops.

The final design will contain two wireless MEMS microphones attached to the bell of the stethoscope, each powered by a lithium coin cell battery (Figure 8). The noise picked up by these microphones will be sent via PurePath wireless signal to the PurePath wireless receiver in the main box. The main receiver box will be powered by a wall outlet, after going through a power regulator.

Figure 8: A depiction of the final design, featuring a main receiver box with a speaker, a headphone jack, and volume controls and one of the wireless microphones.

The digital signal will then be sent out one 100W 4-inch speaker that permits the client-specified 100Hz sound to be heard. Inserting headphones into the headphone jack will reroute the audio to the headphones, where one person can listen individually. A volume control will be available for the speaker and headphones.

FUTURE WORK

The next step of this project will be to design the internal circuitry. A large portion of this step will be to decide on the amplifiers necessary for sufficient volume and quality sound. Supplies, including amplifiers and other circuit elements, the PurePath wireless system, the speakers, and two microphones, will then need to be ordered. Next, the initial prototype will be assembled. This prototype must be tested in an operating room setting, including the ambient noise that would be present during surgery. The stethoscope must be determined to be audible over this ambient noise. If it is not, or does not meet with client approval, the prototype will be reworked.

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Appendix A: Product Design Specifications

Product Design Specifications—Refinement of Electronic Stethoscope

September 16, 2011

Team: Kyle Jamar, Michael Scherer, Meghan Anderson, Taylor Weis
Client: Dr. Scott Springman
Advisor: John Webster

Problem Statement:

Anesthesiologists need to listen to patients' heart and breath sounds during anesthesia care. Manual stethoscopes are commonly used but only allow for one listener and are uncomfortable for extended wear. An electronic stethoscope was developed which utilizes a speaker and microphone system, but it is too large for practical purposes. In order to improve upon the existing device, a more suitable power supply must be found. Ideally, changes should also be made to allow for a dual microphone system with Wi-Fi capabilities, as well as a main receiver with a speaker and a headphone jack for private listening.

Client Requirements:

- One high-quality microphone; ideally two wireless microphones
- Microphones should be attachable using standard medical adhesive
- Option for headphone or speaker listening
- Universal headphone jack
- Main receiver should fit in someone's hand
- Cleanable with disinfectant wipes
- Cost efficient
    - ~ $300.00
- Must be able to withstand long term storage at room temperature

Design Requirements:

1) Design Requirements
    a. *Performance Requirements:* Must accurately convey heart and lung sounds at correct frequencies and appropriate amplification. Must be able to easily and quickly switch between headphone and speaker listening functions.
    b. *Safety:* The device must not endanger or contaminate the patient on which it is being used in any way or cause danger to the person who is operating it.
    c. *Accuracy and Reliability:* See Performance Requirements. The frequency and amplification must be accurate enough to detect problems in the patients' cardiovascular system.

d. *Life in Service:* The device must not degrade or become unreliable for up to 10 years of usage, assuming correct precautions in cleaning and protection of electronics are taken by the owner. Battery life should be at least 12 hours.
e. *Shelf Life:* The prototype should not degrade over time in storage for at least 10 years.
f. *Operating Environment:* The device must be able to operate reliably in a hospital operating room. The device may be exposed to blood or other bodily fluids throughout the course of a procedure, but should not be exposed to large amounts of liquid for an extended period of time.
g. *Ergonomics:* The receiving station with speakers should not have rough edges or any loose components, and the volume adjustment for the speakers should be easy to use. Microphones should comfortably, yet securely, attach to the patients' chest. The device interface and its connection should not obstruct or obscure the use of the stethoscope.
h. *Size:* The receiver with the speaker should be no larger than the size of a hand and the microphones should be of comparable size to a stethoscope head.
i. *Weight:* No quantitative limit, but must be easily portable by one person.
j. *Materials:* The materials used should be safe for use around humans. They should meet standards for surgical use, such as being non-abrasive, non- toxic, non-radioactive, non-flammable, and non-corrosive. The materials should be easily disinfected by use of cleaning wipes.
k. *Aesthetics, Appearance, and Finish:* The device should be aesthetically pleasing, with a smooth, clean finish. All wires should be properly concealed within the receiver housing.

2) User Specifications
   a. *Intended Use*: The client will not be using the device for diagnostic purposes. It will be used to monitor a patient's heartbeat during surgical procedures and as a result only needs to be able to detect a heartbeat and not determine abnormalities.
   b. *Frequency Range*: Because the device will not be used to diagnose heart abnormalities, the prototype does not need to detect frequencies below 100 Hz. In order to limit interference from other devices in the operating room, the high frequency cut off should be close to 2,000 Hz.
   c. *Sound Quality*: The sound quality should be sufficient enough to determine that the heart is beating and the respiratory system is functioning normally. This means filtering out interference from other operating room machinery. The client would prefer if the sound reproduced is similar to what is heard from a traditional stethoscope but also commented that it would be interesting to hear new sounds generated by our device. The client also noted that since it was not being used for diagnostic purposes, sound quality as good as that found in a traditional stethoscope is not necessary.
   d. *Volume*: Since the device will be used in a standard operating room, the biggest concern with volume level is whether it can be heard over the ambient sounds of the other operating equipment present. As the operating room is not a very large

room, sound projection is not an issue; if the device can be heard over other operating room equipment, it will be loud enough for the room size.

e. *Power*: The main receiver and speaker box portion of the prototype can be powered via a wall outlet. The individual microphones should be battery powered.
f. *Additional*: The client requested that the main box of the prototype should have a way to be attached to the instrument cart currently used in the operating room. He suggested attaching brackets to the side of the device and securing it to the instrument cart.

3) Product Characteristics
   a. *Quantity:* One fully functional prototype is required at this time.
   b. *Target Product Cost:* The target manufacturing cost for the product is no more than $300.00, which includes microphones, receiver, speakers, and headphones.

4) Miscellaneous
   a. *Standards and Specifications:* The device as a whole will need FDA approval because it is a medical device that has the possibility to be used on humans. The device will adhere to client specifications.
   b. *Customer:* The product should follow the client's requirements for the headphone and speaker interface, while ideally having two wireless microphones.
   c. *Patient Related Concerns:* The device will come in direct contact with the patient. Therefore, the device must be sure not to: cause damage to the patient's skin, infect or poison the patient in any way, or leave debris after use. The device should not endanger the operator.
   d. *Competition:* There are currently a handful of similar devices on the market. However, none are optimal for our client's needs due to their excessive cost.