Final Report - Continuous Monitoring of Asthma Control

BME 301 - Spring 2017

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This project entails creating an efficient and accurate method of continuously monitoring asthma symptoms in severe asthmatic patients. Currently, the symptoms of an asthma exacerbation are not sensed by the patient until days after the exacerbation has begun. Delayed diagnosis of an exacerbation results in a delayed start to the patient's asthma action plan (AAP). This can mean extra trips to the clinic or hospital for something that was treatable at home only a few days prior. The implementation of a continuous asthma monitoring shirt will alert patients to begin their AAP before needing to make unnecessary trips to the hospital, thus saving a large portion of hospital resources that are being used on asthma related visits. Last semester, the team was able to create a working microphone that was able to distinguish between normal speaking and coughing. Now, the team has focused on expanding the system to two redesigned microphones incorporated into a chest band that are able to accurately distinguish between normal speaking and coughing using frequency ranges. This diagnostic technique can further be used to find each patient's unique range, and can also be expanded for different asthma symptoms, such as wheezing.

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Introduction

In the United States alone, approximately 26 million people suffer from asthma with related costs estimated to be $60 billion annually [1]. There is no cure for the disease, so patients must treat their symptoms continuously in order to keep them under control. In recent years, there has been an increase in the number of asthma diagnoses, and with that, an increase in severe asthma patients [2]. These severe asthma patients, while only 5-10% of total asthmatics, have symptoms that are more intense and more frequent compared to a patient with well controlled asthma. Consequently, this small population accounts for a disproportionate amount of health-care costs, hospital admissions, doctor visits (both scheduled and unscheduled), and emergency services [2]. Asthma patients have asthma action plans (AAP), which are procedures for a patient to follow in the event of an asthma exacerbation. The purpose of an AAP is to try and treat the asthma exacerbations before they become too severe, but many times the symptoms are not felt for two days (AAP protocol is listed in Appendix 2). Our device will allow the symptoms of these asthma exacerbations to be detected earlier, letting the patient begin their AAP sooner, saving both time and resources for the patient as well as cutting down on hospital costs.

Currently, there are no devices that can continuously monitor asthma symptoms and alert patients when an asthma exacerbation has started. The most common way for analyzing asthma symptoms is with a stethoscope [3]. For a couple hundred years, stethoscopes have been used to listen to biological sounds, especially the lungs. The limitations are that most individuals do not have access to a stethoscope at home and they often are not experienced enough for self-diagnosis. In addition, a spirometer test is used to assess an individual's asthma severity and lung function. An example of a spirometer is given by patent US6238353 [4]. One measurement commonly used from spirometry is FEV1, or forced expiratory volume in 1 second [5]. It uses the maximum amount of air an individual can forcefully exhale in 1 second in order to gauge lung function [6]. This is often done in a clinic during annual check-ups or when a patient starts to feel an exacerbation. In home spirometer tests do exist, but these are less common. The main limitations of these two techniques are that they are not easily accessible in the home, they do not measure continuously, and they are typically used after symptoms are felt as well.

The main asthma symptoms, wheezing, coughing, and increased respiratory rate, are often not experienced by the asthma patients for a couple of days after they start. This is due to the fact that the initial changes can sometimes be very minor and indistinguishable to the patient from their normal breathing habits. A device that could detect these symptoms sooner would lead to faster implementations of AAPs. While the target patient for a device such as this would be a small percentage of asthmatics (those with severe asthma), they use a large portion of the medical resources. If a device could be made to alert the severe asthma patients to the signs of an asthma exacerbation earlier than current methods, it poses the potential to save significant amounts of time, money, resources, as well as potentially decreasing the severity of the asthma attack.

Last semester, our team was able to develop a device that collected lung sounds using a stethoscope head with a microphone. A shielded cable transfered the data from the microphone to the Data Acquisition Device. The signals were then fed into LabVIEW for real time processing. While the device was alright for collecting some initial data, there were some key limitations. Firstly, the design was large, heavy and bulky. This is not ideal for a wearable device. In addition, last semester's design only featured one microphone. This semester we will start by refining the microphone system. We will make the device slimmer and more ergonomic so that it can be integrated into a wearable chest band. It will feature two microphones to collect data from both of the lungs simultaneously.

Background

Asthma is a chronic condition characterized by inflammation and narrowing of the bronchial tubes in the lungs [2]. The air travels from there to the bronchioles, which are the smaller tubes that branch off from the larger bronchi. All of the bronchi and bronchioles have mucus lining them, which, along with cilia, help keep the lungs clean of debris. At the end of the smallest bronchioles, the air enters the alveoli. Alveoli are small, hollow spheres of thin tissue with capillaries surrounding them. The alveoli are epithelial cells which facilitate and expedite the process of gas exchange. An individual with severe asthma has bronchi and bronchioles which are continuously inflamed. This limits the amount of air that can enter the alveoli per breath to provide the body with oxygenated blood.

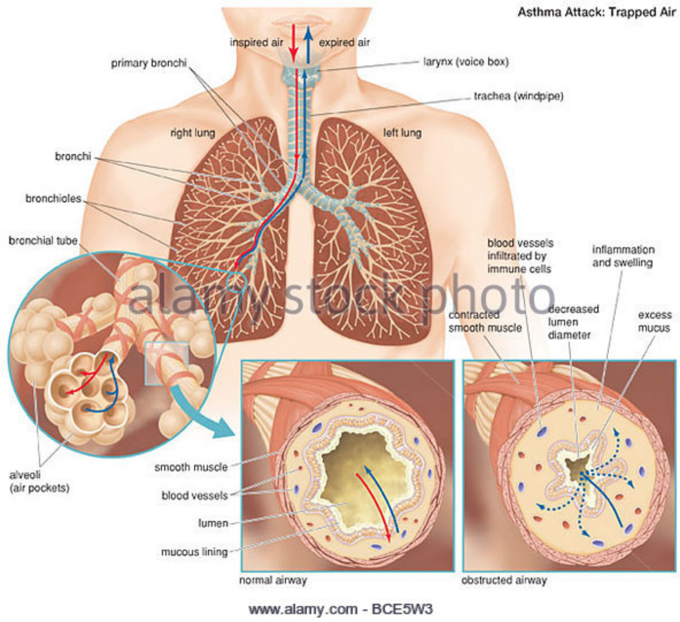

Figure 1: Anatomy and physiology of an asthma attack

When a person's asthma is triggered, the bronchi and bronchioles constrict and can become even more inflamed [7]. This constriction can have a variety of adverse effects, which are commonly termed asthma symptoms. In addition, their body sends out an immune response due to the allergen/irritant that triggered their asthma exacerbation. Their bodies T helper cell type 2 (Th2) cells release cytokines, which in turn produce and release histamines and cysteinyl leukotrienes that contract the smooth muscles in the airways and promote mucus production. This cell response leads to bronchospasms, edema, and increased mucus secretion, all of which are the characteristic symptoms of asthma [8]. The excess mucus builds up in the lungs making it even harder for the patient to breathe and sometimes lead to a phlegm-sounding cough [7]. As the exacerbation progresses, breathing becomes increasingly difficult and the performance of the respiratory system suffers drastically. The respiratory system is responsible for supplying oxygen to red blood cells while simultaneously removing carbon dioxide from the body. When the respiratory system does not work correctly, the lack of oxygen can cause major issues [9]. A complete lack of oxygen (anoxia), or even a decrease in oxygen (hypoxia), can be fatal. Asthma is responsible for 3,300 deaths annually in the United States alone [1]. Even just four minutes without sufficient oxygen to the brain can cause brain cell death, and the results can be permanent.

There are four main symptoms of asthma: coughing, wheezing, chest tightness, and shortness of breath [1]. Nevertheless, the specific symptoms felt and their severity can vary widely from one individual to the next. Unfortunately, this can cause the disease to go unrecognized, under diagnosed, and undertreated [10]. Asthma severity can greatly increase due to poor or inconsistent treatment, which makes the asthma much more difficult to control and treat [2]. An asthma exacerbation is an acute worsening of the disease. Often, asthma triggers are responsible for the attack. These triggers can be airborne such as pollen, pet dander, mold, smoke, and chemical fumes [1]. Other triggers include sickness (often the cold or flu), exercise and stress. When asthma exacerbations occur, their symptoms may not be felt by the patient for a few days. This causes the symptoms to worsen and makes treatment more difficult.

Coughing and wheezing symptoms are both categorized as lung sounds, meaning that they are audible symptoms. These lung sounds are created by turbulence of the constricted airways [11]. Upon inhalation, the air rushing in creates a turbulent flow as the air creates pressure against the respiratory walls. These sounds can be transmitted to the chest wall via airways or the lung parenchyma. Some lung sounds are audible by the human ear (such as coughing), but often times a stethoscope placed on the chest wall is used. Wheezing, which is a high pitched sound with a frequency of 400 Hz or higher, is a symptom of particular interest where a stethoscope in normally used. Wheezing occurs when air passing through a narrowed airway at a high velocity produces a decrease in the gas pressure in the constricted airway. These audible sounds are the symptoms targeted by our microphones in order to diagnose the onset of an asthma exacerbation.

For severe asthma patients, approximately the top 10% of the total asthma population, asthma exacerbations tend to be more common and their symptoms more extreme [2]. Even after the asthma is under control, it can take up to a month for the patient's lung function to return to normal. This heightened airway inflammation and extended recovery time can take a toll on the bronchi. The continuous tissue destruction and airway remodeling in severe asthma patients creates a “chronic wound” with ongoing epithelial injury and repair [2]. Over time, these conditions can lead to thickened and stiffer airways, which are more resistant to anti-inflammatory drugs. This demonstrates that the damage from asthma exacerbations can last long after the asthma is under control.

The best way to solve this problem is to reduce the number of recurring, prolonged asthma exacerbations. Dr. Sameer Mathur is an allergist working at the UW-Madison School of Medicine and Public Health. He believes that if the symptoms of an asthma exacerbation can be detected even before the patient feels them, the exacerbation can be treated more quickly and easily which could ultimately reduce the number emergency room visits, hospital admissions, and even deaths. The goal is to create a wearable “asthma shirt” that will be able to detect various lung sounds that are characteristic of asthma-- specifically coughing and wheezing. With the guidance of Dr. Mathur, the team was able to come up with specific produce design specifications. The full PDS can be found in Appendix 1, but a few important features are noted below.

The device created must be able to accurately and reliably detect the different asthma sounds of the lungs. This is crucial to ensuring the results are precise and consistent. The device needs to be wearable, such as a shirt, for patient testing. The goal for the microphone system is to weigh no more than one pound with the thickness of the casing being less than ¾ of an inch. The device must be slim and ergonomic to maximize patient comfort. Any material that comes into contact with the skin will need to be comfortable and not have any adverse reactions with the skin. In addition, the device should have a battery life of at least 12 hours for testing. Eventually, the device will need to run 24/7.The group has a pre-approved IRB protocol that allows the shirt to be tested on asthma patients undergoing methacholine tests. These tests last approximately four hours and hence, the device should run for at least that amount of time. Dr. Mathur's long-term goal is to develop a shirt with multiple components that will be able to be worn 24/7, however, he expects us to design a simplified device that will work in testing situations. More protocol specifics will be discussed in the Testing section of this report.

Preliminary Designs

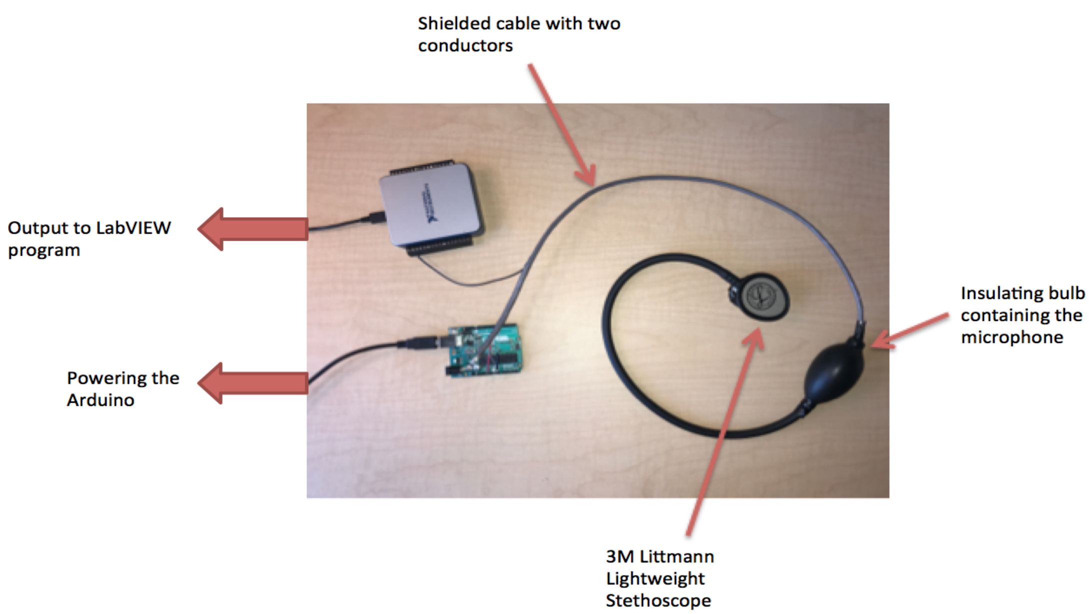

Figure 2: Design from the previous semester features a stethoscope head attached to a data acquisition assistant. The stethoscope amplifies lung sounds for the microphone to pick up.

The first design that was considered is called the stethoscope design. This was a spin off on the previous semester's final design. It would incorporate several of the same components such as the stethoscope, microphone, shielded cable, and data acquisition device (DAQ). Originally, the microphone was placed at the end of the stethoscope in place of the earpiece. Although the microphone was encased in a rubber bulb, it still picked up ambient noise. In the new design, the microphone and the rubber bulb would be moved to the base of the stethoscope head. This removes the need for the signal to travel long distances through the stethoscope tube and keeps the signal from being altered. It also moves the microphone closer to the body and farther away from other possible sources of noise.

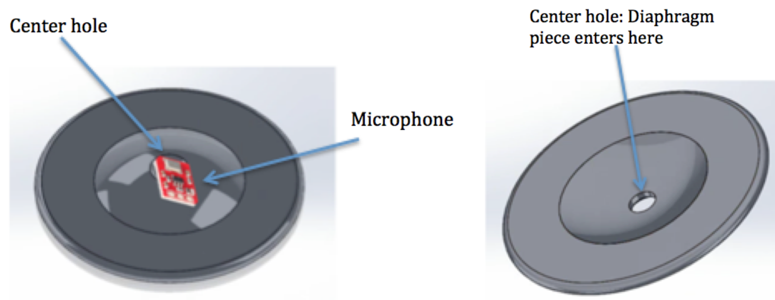

Figure 3: The diaphragm microphone would have the microphone on the outside of the casing, with the diaphragm piece sticking through the center hole.

The next design, called the diaphragm microphone design, incorporates a circular disc instead of a stethoscope. The disc mimics the design of a speaker with its concave shape and center hole. This shape directs sounds to the center of the dome and out through the center hole. A microphone which vibrates with sound using a small circular piece (diaphragm piece) would extend off the microphone. In order to capture the sound waves at their highest concentration, the diaphragm piece would lay directly outside of the center hole. Since this microphone cannot lay flush with the design, it would be attached to the back of the disc. Lastly, the shielded cable wires soldered to the microphone would be attached to the DAQ.

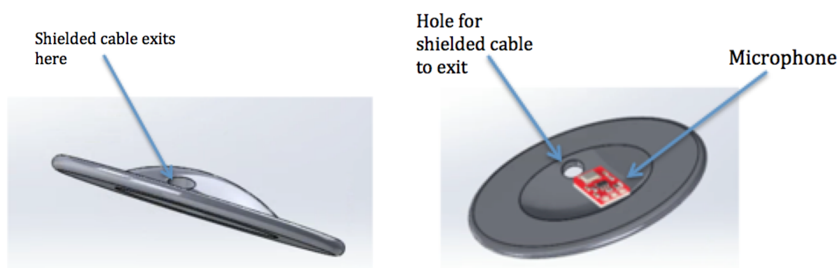

Figure 4: The encased microphone design would have the microphone inside the dome. The cable attached to the microphone would then be threaded through the hole.

The last design, called the encased microphone design, uses the same circular disc as the previous design. However, there would be no center hole and a different microphone would be used. This design removes the need for the center hole by utilizing the idea that sound can be concentrated to a focal point. Instead, the microphone can lay flat inside the dome at this calculated focal point. In order for the microphone to lay flat, a different microphone must be used. This microphone is the same one used in the previous semester and does not utilize a diaphragm piece to detect signals. The shielded cable wires from this microphone would then be threaded through a small hole in the disc and attached to the DAQ.

After choosing and fabricating one of the three designs listed above, it would be integrated into a t-shirt. This would be done by placing the microphone casings or stethoscope heads inside two pockets on the back of the t-shirt. Since the client wanted the team to solely focus on the microphone system and data acquisition this semester, the t-shirt design would not change. Instead, we would use the t-shirts that the client already owns.

Preliminary Design Evaluation

Design / Criteria (weight)	Stethoscope		Diaphragm Microphone		Encased Microphone	
Patient comfort (25)	2/5	10	4/5	20	5/5	25
Effectiveness (20)	5/5	20	4/5	16	4/5	16
Ease of Use (20)	3/5	12	4/5	16	4/5	16
Cost (15)	3/5	9	5/5	15	5/5	15
Adjustability (10)	3/5	6	4/5	8	4/5	8
Safety (10)	4/5	8	3/5	6	4/5	8
Total	**65**		**81**		**88**	

Table 1: Preliminary Design Matrix

Patient Comfort is defined as the level of comfort in the overall experience of using the device. We chose this as criteria because the device is being created for use in the patient's everyday life. In order to obtain useful data, the device must be worn for roughly four hours per day. Due to its frequency of use, the patient's overall comfort level is extremely important, thus justifying our highest overall weight. We gave the encased microphone design the highest grade of 5. This design earned the highest grade because of the flush design of the microphone casing due to microphone being contained within the casing. This design will offer the highest level of while the patient is leaning against something during their everyday life. The Diaphragm microphone earned the next highest grade of 4 due to microphone protruding from the casing. This would cause mild discomfort for the patient if they are sitting and leaning. Finally, we gave the stethoscope design the lowest grade of 2. This was due to the bulky design that would cause a large level of discomfort.

Effectiveness is defined as the accuracy with which the design will be able to capture information related to asthma symptoms. We gave effectiveness a weight of 20, which is tied for our second highest weight. This category was included because accurate and effective data collection is extremely important in the diagnosis of these asthma symptoms. The stethoscope design received the highest score of 5 because it is very similar to our design from last semester. Since our design from last semester was able to accurately detect and isolate the lung sounds last semester, the stethoscope design should be able to do the same. The other two designs received a 4. These designs feature similar (if not the same) microphones, which should allow the devices to accurately capture the lung sound. Nevertheless, their effectiveness has not been proven yet, so these two designs did not receive the full 5.

Ease of Use is defined as the ability of the design to be implemented effectively and efficiently. It is crucial that a wide number of patients and doctors are able to use the device. This also includes how easy the device will be in implement into a shirt. Due to it's importance in the success of the product, this category also received a weight of 20. The two highest score were the diaphragm microphone and the encased microphone with scores of 4. These two designs are rather compact and will be easy to integrate with the shirt. With that being said, the device will still need to be hooked up to the computer by wires, making it someone less easy to use. The stethoscope design received the lowest score of a 3. The design is bigger and bulkier in addition to need to be wired to the computer, making it slightly harder to use.

Cost is defined as total expenses needed to create the device. This category received a weight of 15, which is one of the lower scores. Due to the limited funds available for this project, cost is a constraint on our design, but nevertheless we felt other categories were more important to the design. The diaphragm microphone and encased microphone both received perfect scores of 5. These designs would be the cheapest to make since they consist of various inexpensive pieces. 3D printing is fairly inexpensive, especially when printing parts as small as the ones needed for these two designs. Lastly, the stethoscope received a score of 3, since it is by far the most expensive. The cost of a stethoscope instrument is much greater than the other designs, and therefore it was assigned the lowest score.

Adjustability is defined as the amount of change we can make in our design to fit our patients needs. This includes where we can put the device on the patient and our ability to move it or adjust is for better comfort or usefulness. We gave it a weight of 10 because it once you have it on, it shouldn't need to move. We chose this category because it is important for the device to be adjustable because the better the fit, the better data we can record. Since all three of our designs require that the device is physically attached to the DAQ, the patient will have limited range of movement. This led us to give both the diaphragm microphone and encased microphone scores of 4. While they both restrict movement of the patient, their designs don't restrict the patient in any other way. These two also allow the team to customize the design as needed. Lastly, we gave the stethoscope a score of 3. Along with movement restriction, this design is bulky and heavy, which may weigh down the patient and make it harder to attach to the shirt. The stethoscope is also pre-designed, so the design may not be customized.

Safety is defined as how likely the patient would be able to perform the diagnosis without being harmed. We gave safety a weight of 10 because we believe that none of these designs would put the patient in danger. We want to consider the patient's safety because this will be a medical device that the patient will use extensively and we want to minimize the potential for the patient to be injured. We gave the stethoscope and encased microphone a score of 4. These designs earned their grade because they both are free of exposed components, but did not earn a perfect 5 due to the fact that the patient is still tethered to the administrator's computer. We gave the diaphragm microphone a grade of 3 due to its exposed components. If there is exposed circuitry, there is a possibility for complications that could harm the patient.

Fabrication/ Development Process

Materials

The materials for this project consist of two microphones, shielded cable with two conductors and a drain wire, an Arduino microcontroller, cotton elastic bandage, a National Instruments USB-6002 Data Acquisition Device and LabVIEW software. The microphones chosen were the Sparkfun MEMS Microphone Breakout-INMP401, which features a built in amplifier with a peak to peak output of 200mV. They require a 3.3V DC power supply, which was provided by the Arduino. We picked this microphone because of its ability to detect low frequency physiological signals and its built in amplifier. In addition, this is the microphone used in last semester's design, so it will work well with the existing code. The microphones are encased in a custom, 3D printed ABS plastic casing. Using ABS plastic as the material allowed the casing to be lightweight and inexpensive, satisfying the needs of our budget and our design specifications. This casing was concave in shape in order to direct the sound waves directly to the microphone which was located at the focal point. The exact design/dimensions of the casing are listed below in Figure 5.

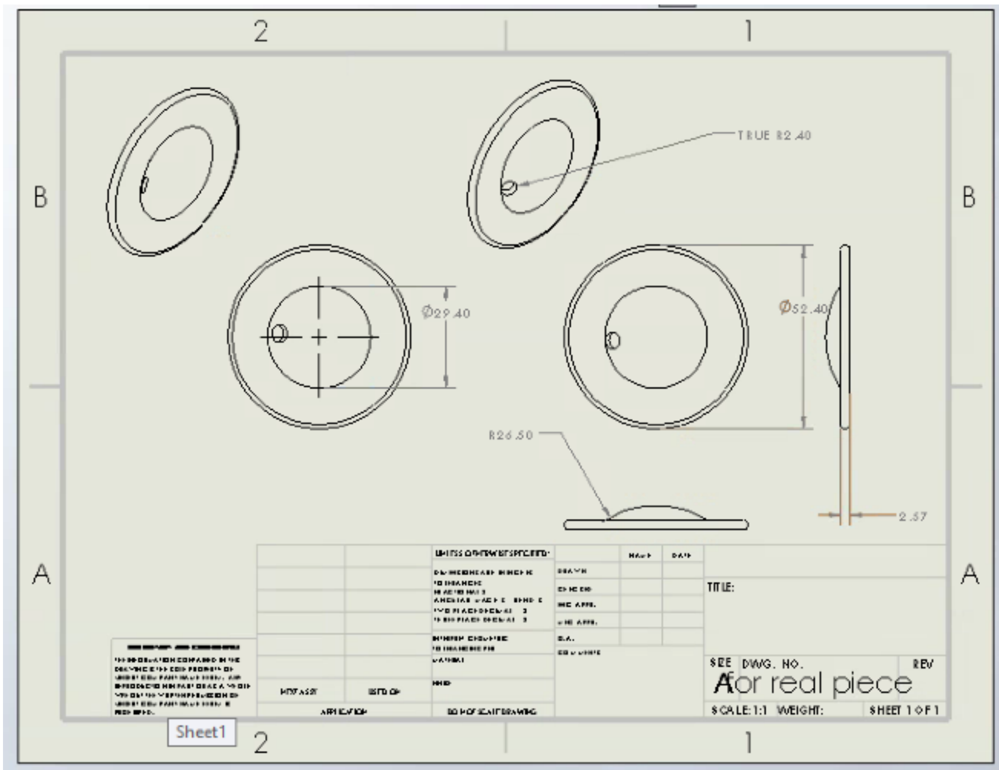

Figure 5: Engineering drawing and dimensions of the microphone casing

A two conductor shielded cable was used due to its ability to limit the effects of electromagnetic interference (EMI). When dealing with such small signals, any amount of interference could greatly affect the accuracy of the device. In addition, this specific cable was chosen because it had two conductors for the 3.3 voltage input and the audio output as well as a drain wire for the ground. These cables then connect the microphones to the Data Acquisition Device. The DAQ allowed us to collect multiple inputs, perform ADC conversions, and transfer the data to the computer. This reduced the complexity of the data collection process especially for multiple inputs. We used the 2015 LabVIEW program to process the data once on the computer. We chose this version over the previously installed 2010 version because the IRB laptop used for patient testing will also run LabVIEW 2015. Since the new design lab computers are CAE, which do not allow for the downloading of new software, we set up an older computer from the instrumentation lab. We utilized band pass filters and waveform charts in order to analyze the data collected. In order to link the DAQ to the LabVIEW program, we downloaded and ran the NI-DAQmx 16.0 software. Lastly, we utilized the Matlab for frequency analysis. It was chosen because of its compatibility with .wav files and its ability to easily perform Free Fourier Transforms and plot the frequency data. This code is listed in Appendix 3**.**

Methods

To begin the fabrication, we created a 3 dimensional image of our microphone casing in SolidWorks. Then, a member of our team submitted the image to Dr. Puccinelli to be constructed in the shop using Dimension Elite 3D printing. Next, we cut two, ten-foot sections of the shielded cable and stripped two inches worth of shielding from each end of both of the wires. From there we stripped a one-centimeter section of insulation from each of the conductors inside of the cables. The wires were then fed through the hole in the microphone casing and soldered to the microphones. The white conductor was carefully soldered to the Vcc, the black wire to the audio output, and the drain wire to the ground port. We soldered these connections in order to ensure that the wires would not cross, which would create an inaccurate output from the microphones. The flush bottom of the microphone was then fixated inside of the casing as close to the focal point as possible using a bonding agent on the cable on the outside of the casing. The equation used to calculate the focal point is listed below as equation 1. Our values for x and a were 14.7 mm and 8.9 mm respectively, yielding a focal point of 6.07 mm from the top of the microphone.

$$f = x^2/4a.$$

Equation 1: Calculation of the focal point for the microphone casing

The insulated cables then extended ten feet to the DAQ to allow for separation of the patient and the testing computer. The exposed conducting wires were then connected to Arduino 3.3 V output, DAQ a0 and a1 analog inputs, and DAQ ground. Next, one velcro end of the cotton elastic bandage was removed. Two inches of this end was then fed through a metal ring, similar to what is used for a blood pressure cuff, and glued to the close end of the fabric creating a tightening mechanism. Then, the first and second microphones were glued to the bandage six and 12 inches from the metal ring. Using an exacto knife, the circular sections of cloth covering the microphones were removed. Finally, the NI DAQ device was connected via USB cable to the computer which ran the LabVIEW program.

Final Prototype

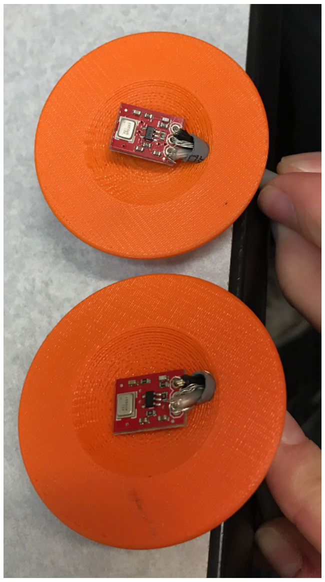

Figure 6:
Inside view of microphone casing

Figure 7:
Fully fabricated device

The final prototype features the two microphones inside the 3D printed casing. These casings are then hot glued to an adjustable band made from a cotton elastic bandage. We decided to go with a band because it can easily be adjusted to fit any patient. Otherwise, we would have had to use multiple shirts of different sizes to ensure that the microphone is tight against the skin while not being uncomfortable for the patient. This material was chosen because it was made to be used on the human body. In addition, its flexible, stretchy material allows for a tight interface with the subjects back. The band sits just under the armpits of the patient, and the location of the microphones were determined based on measurements take from male test subject, since the IRB protocol is written for males only. We tried to research the optimal location but could not find anything in literature, and so we used the measurement of six inches between the microphones. Since the bandage is flexible and stretchy, the exact location of the microphones on the test subject will depend on their size and the tightness of the band. In addition, any slight variances in the microphone location will not affect the nature of the sound. It could slightly affect the intensity of the signal, but that would not greatly alter our results.

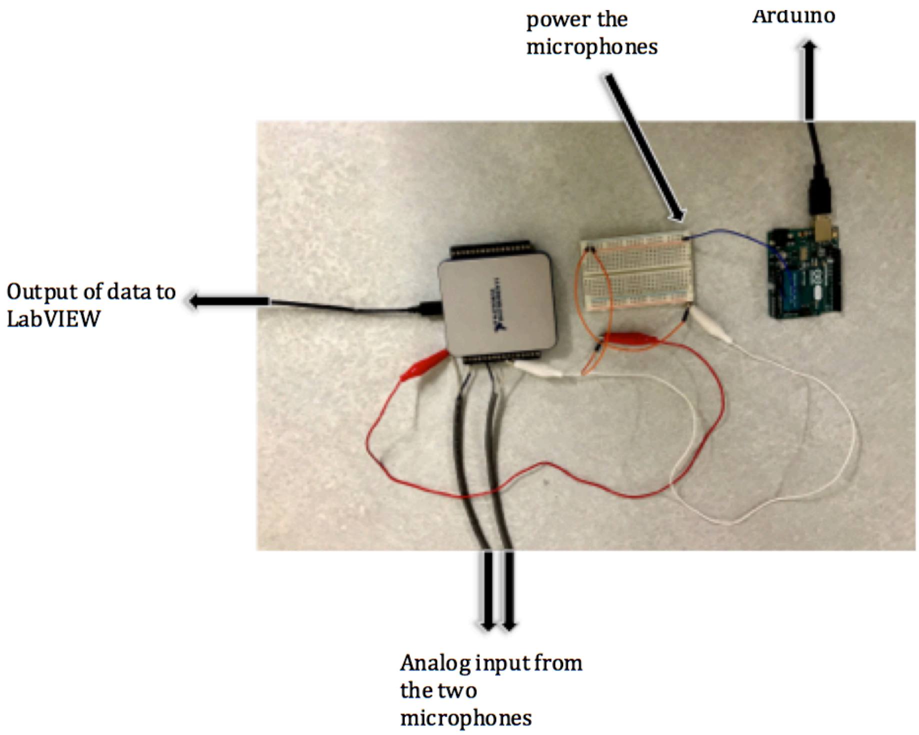

Figure 8: Arduino and DAQ circuitry

The microphones are then connect to the shielded cable. The white wire is attached to the 3.3V output of the Arduino, which is powered by a USB cable plugged into the computer. This output voltage is first fed into a breadboard, allowing it flow into two parallel wires and power both of the microphones simultaneously. The black wire with the audio output from the microphone and the drain wire are connected to the DAQ. The black wire from the right microphone is fed into the a0 analog input and the one from the left microphone is fed into the a1 port. The drain wires from both microphones are connected to ground. The DAQ then transfers the signal to the computer via a USB cable.

The next part of the final prototype are programs written in LabVIEW and Matlab. The first LabVIEW program we have is used to import the data from the DAQ using the DAQ Assistant function and convert the signal to a .wav file (shown in Figure 9 below). This feature was included because it allows the data to be stored and processed later on. Previously, all the data analysis was done in real time which limits its capabilities, especially when looking at frequency. We then wrote Matlab code that performs a Free Fourier Transform to convert the data from the time domain to the frequency domain (Full code provided in Appendix 3). We then were able to plot the amplitude versus the frequency for the entire .wav file at the same time. This provides increased insight into the frequencies behind different lung sounds. These graphs were then compared to determine thresholds for the filters in our final LabVIEW program (shown in Figure 10 below). This program collects the input from both microphones simultaneously using the DAQ Assistant. Then, the split function was used to separate the signal into two distinct data paths. Both unfiltered inputs were plotted using a waveform graph. Both signals were also fed through 130-150 Hz bandpass filtered and graphed again. This allows the filtered and unfiltered data from both microphones to be analyzed side by side at the same time.

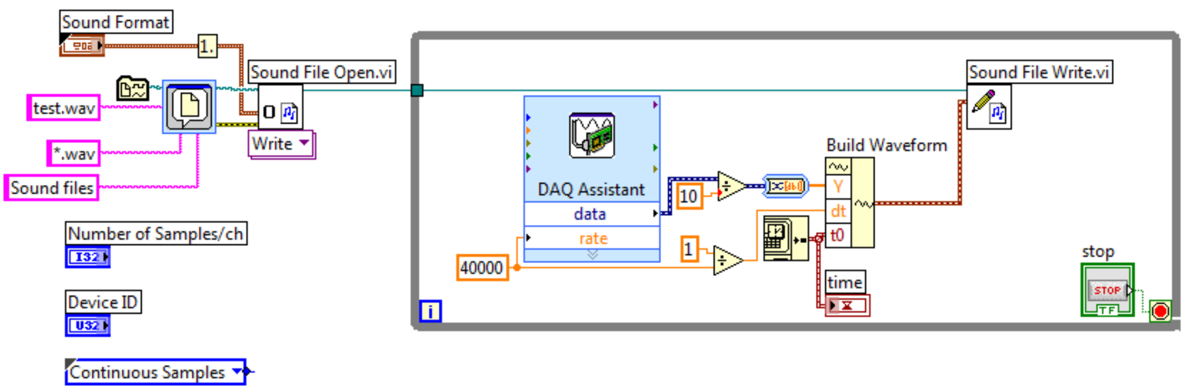

Figure 9:Block Diagram for writing a .wav file with output from the microphone system

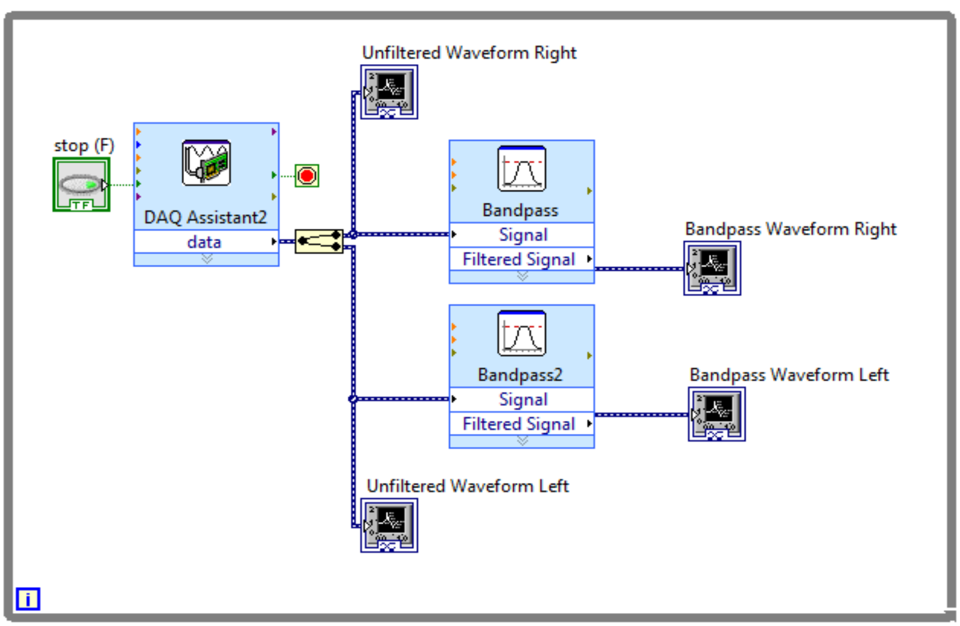

Figure 10: Block Diagram for displaying the real time output of the filtered and unfiltered from both the left and right microphones

Testing

First, the functionality of the microphones was tested. This was done by comparing the live output signals of the microphones using the same sound input. Examples of sounds tested included snapping fingers and clapping hands. If the microphones outputted the same signals, they were functioning correctly. This means the signal shape and amplitude remained the same between microphones.

Next, the wear ability of the device was tested. Since the microphones are incorporated into a stretchy material, we wanted to ensure that sufficient data could still be collected from different sized people despite slightly different locations of the microphones on the back. All three team members wore the chest band and attempted to collect sufficient lung sound data despite different chest circumferences. If each member collected lung sound data with similar signal strength and appearance, then the team could confidently conclude that the different microphone placements due to stretch of the chest band did not significantly influence the data collected. Therefore, any potential change in signal intensity from slight variability in microphone location could be considered negligible.

Finally, the signal processing testing was completed. The main source of testing for this analysis came from group members. The team had a pre-approved IRB protocol, but was not able to utilize it because there were no patients scheduled for testing after we completed fabrication of the device.

The first step for testing our signal processing included diagnosing a certain frequency range for the individual subject's cough. Each individual has a different range of frequencies that are detected during coughing and other noises, say talking. Therefore, the first step was to find these ranges that that the coughs could be isolated. We were able to do this by recording a subject in three different sessions. The first had the patient sit and breath normally for 30 seconds. The second had the patient say "testing" every 10 seconds for 30 seconds (starting at 5 seconds, then at 15 seconds and lastly at 25 seconds). The third, and final, session followed the same procedure as the second session, but had the patient cough during the corresponding time intervals. All of these signals were recorded using the LabVIEW code in Figure 9, which turned them into .wav files. These files were then converted into frequency domains using the Matlab code in Appendix 3. Next the amplitude versus frequency was plotted, and they were compared to find the specific frequency ranges that were unique to coughing. This frequency domain was then used as the range for the band pass filters in Figure 10. Now that we obtained the correct frequency range for diagnosing a cough, we tested the LabVIEW code for Figure 10 by having the subject talk for three seconds then cough immediately after. Doing this allowed us to see if the code was able to detect the both signals in the unfiltered data, but only detect the cough while attenuating the talking in the filtered signal. Finally, this process of coughing and talking was repeated multiple times to ensure that the output was correct.

Results

Testing the microphone functionality immediately led us to realize that the right microphone was broken. The right microphone was outputting an almost identical signal to the left except for the intensity was much lower. This led the team to believe the issue was with the amplification aspect of the microphone. The team first checked to ensure that the microphone was receiving the 3.3V power supply from the Arduino. When we confirmed that the issue was not with the power supply, the team had no choice but to replace the microphone entirely. The microphone was cut off and replacement one was soldered onto the same cable. After replacement, both microphones outputted signals of the same strength. However, two days before presenting our data, the left microphone began malfunctioning in the same way. Similar to before, the left microphone lacked amplification compared to the right microphone. There was not enough time to order a replacement, but it could be fixed easily in the same way.

While testing the device wear ability, we measured each team member's chest circumferences and how far apart the microphones were on their back. Each team member has a different chest circumference (98 cm, 107 cm, 111 cm), which led the microphones to be placed in different locations on the back. While these locations could not be tracked quantitatively, we measured the distance between the microphones instead. This served as a way to see how much stretch caused the microphones to displace. However, the distance only increased by 0.63 centimeters between the smallest and largest chest circumference. In addition, there are more factor that can affect the exact location of the microphones including the tightness of the band. Furthermore, each were able to detect coughing and talking without a significant difference in signal strength. From our preliminary testing, it was concluded that these small variations in microphone placements caused by chest circumference, stretch of the chest band, etc. does not significantly affect the data acquired.

To begin testing our signal processing we compared the frequency domains for the three different testing sessions. The domains are listed below in Figure 11**.** The goal of comparing these frequency domains was to find a frequency range that was specific to only coughing; this is called the diagnostic region. Upon comparison, we determined diagnostic region for this subject was 130-150 Hz. We selected this region even though it was not the strongest signal in the coughing domain because the other, higher amplitude, regions were also present in the talking domain. Choosing a diagnostic region that was present during talking would result in the filter failing to isolate only coughing.

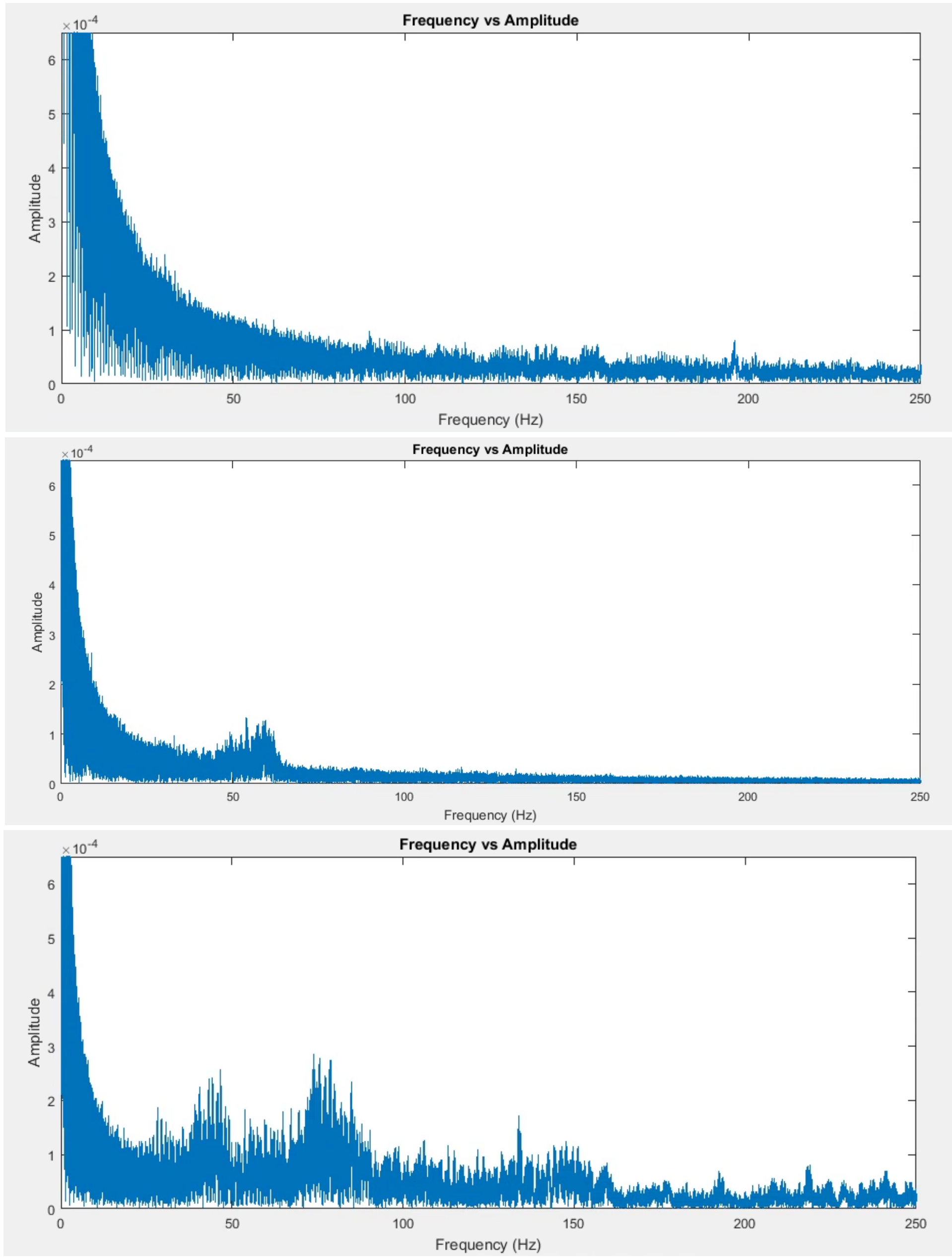

Figure 11: These graphs display frequency results of the .wav files after running them in Matlab. The results were collected from the subject during normal breathing (top), talking (middle), and coughing (bottom).

Next, the values 130 and 150 Hz were added to the band pass filter from the LabVIEW code in Figure 10. The output of this block diagram is shown below in Figure 12. The top two waveform charts are the unfiltered data from the right and left lungs when the subject is talking then coughing. The talking can be seen as a low amplitude, while the coughing can be seen as the higher amplitude signal. The bottom two charts show the output of the signal once it is filtered through the band pass filter. We are able to see that the filter successfully attenuates the talking signal while still sensing, and displaying, the coughing signal. As can be seen in the left waveform, the output has a much lower overall amplitude. This reduction in the signal intensity stemmed from a malfunction in the amplification of the microphone, similar to the problem we encountered in functionality testing. Unfortunately, we did not have sufficient time to order a new microphone and replace it, but this is a simple fix with extra time. Nevertheless, the same signal appears as the right microphone, just not as distinct.

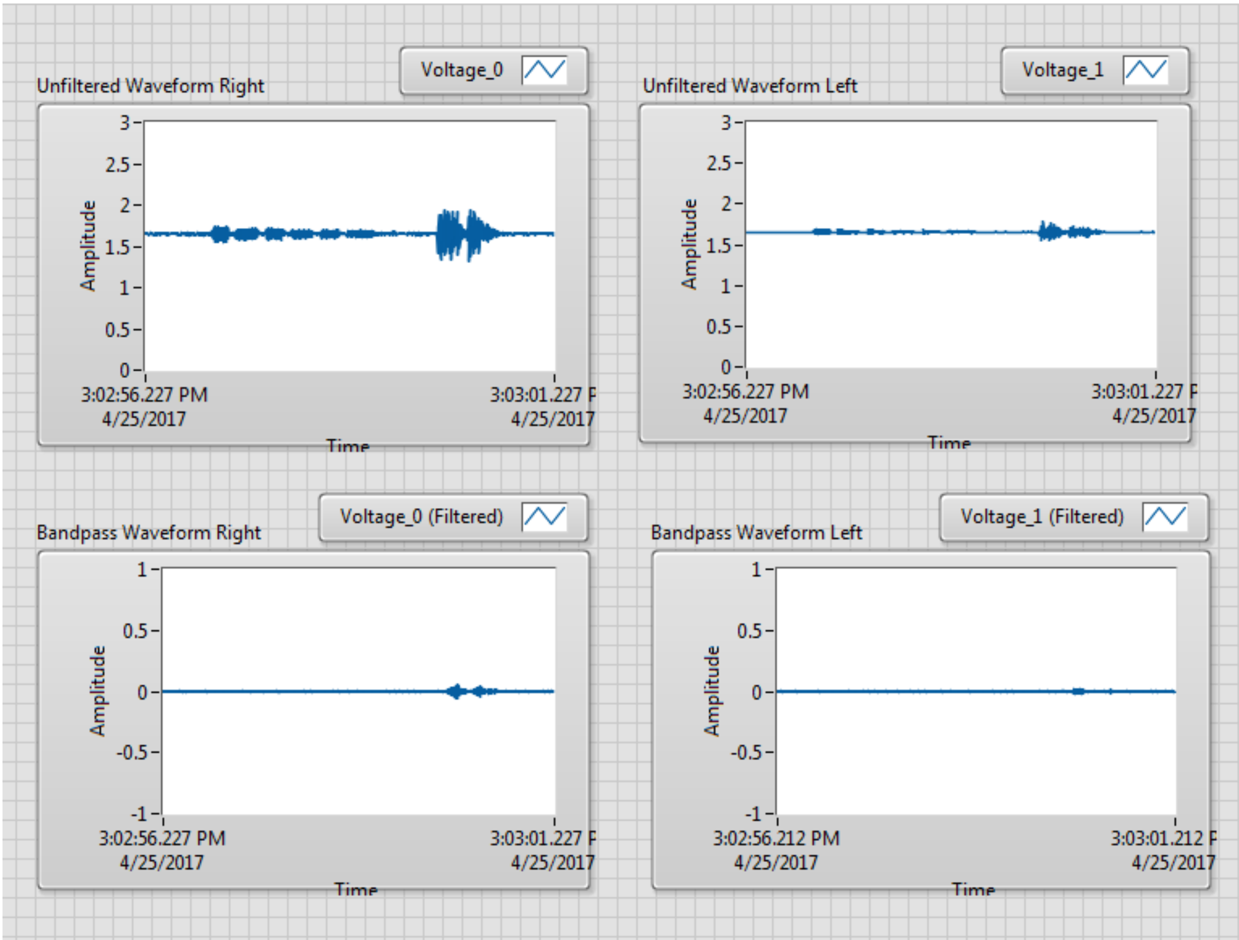

Figure 12: Front Panel from the block diagram in Figure 10. Shows the filtered and unfiltered outputs from both microphones while the test subject is talking and coughing.

Discussion

Overall, our testing proved that we successfully created a wearable, functional asthma detection device. Although we were not able to test this device on actual asthma patients, our signal processing tests proved that we can isolate coughing frequency ranges, and use these ranges to filter out talking noises. Most design project teams are able to evaluate the success of their design by comparing their results to data found in literature and research. Unfortunately, there is no current data or research that can be directly related to our project. Much of this is due to the lack of standardization in the field of lung sound research with no widely available commercial equipment for measuring these lung sound signals [3]. Consequently, few researchers use the same or even similar instruments making it very difficult to compare results even from similar experiments. Our group experienced this issue when trying to relate our results from last semester to this one. Initially, we thought that the thresholds determined would be the same, but even after using the same microphones, the device collected very different data. Another reason our group had trouble comparing our data to that in literature is the numerous ways that lung sound data can be processed and displayed. The team decided to look at amplitude vs frequency and voltage vs time as the two main comparisons. However, in literature, many studies choose to compare other data points such as power vs frequency [3], intensity vs flow [12], and % of spectra vs flow [13]. While all these data comparisons provide insight into the nature of lung sounds, they are not directly comparable to our results.

Consequently, the team had to evaluate the success of the design signal processing on its ability to find these ranges and use them to create our band pass filter. Since different people have different voice tones and different coughing pitches, these frequency ranges for talking and coughing differ from person to person. However, the ability to graph and compare frequency versus amplitude graphs for these different sounds will allow us to identify and isolate appropriate frequency ranges for any patient. This leads to a customized band pass filter with corner frequencies correlating to the patient's specific frequency range data. In addition, this technique can be used for other asthma symptoms that we were not able to test on ourselves, such as wheezing. In addition, as we collect data from more and more subjects, we can start comparing these frequencies ranges. While individuals have their own ranges, we may be able to draw some correlations between various factors such as sex, age or asthma severity. The process created this semester can easily be repeated and extended to a wide variety of subjects.

While the team has the programs and protocols in place, the left microphone should be replaced and its functionality retested before any further use of our device. Additionally, we want to utilize Dr. Mathur’s IRB protocol to test the device on actual asthmatics. On big reason is that the data collected from non-asthmatic test subjects may not be very comparable to the asthma patient data. In one study, even asthma patients with mild, stable asthma and “normal lung function” had lung sounds that were lower in intensity and higher pitch than the non-asthmatic subjects [12]. Our target population is those with the most severe asthma, and so their lung sounds are most likely very different from normal test subjects. Therefore, it is important that we perform the same testing on asthma patients undergoing methacholine test, especially since the device is designed for asthmatics. Collecting data from non-asthmatic subjects can help provide a proof of concept, but only patient testing will determine the true functionality of the device.

Conclusion

The creation of an asthma shirt holds the potential to decrease the number of emergency services, hospital admissions, and doctor visits for those with severe asthma. Since asthma symptoms cannot be sensed by a patient for up to two days after the exacerbation has started, these patients fail to enact their AAP in time. By reducing the time between the start of the asthma attack and the start of the AAP, the level of inflammation and amount of lung function lost can also be reduced, keeping them from making unnecessary hospital visits. This is especially important for severe asthma patients whose asthma exacerbations are more intense and harder to fight. Our team has created the first working prototype for the future asthma shirt. This prototype will be used to test on actual asthma patients and collect large amounts of lung sound data that can be used to prove the validity of this design idea. From our testing, we can conclude that band pass filters must be customized from patient to patient, but with our data processing technique, this can easily be done. If we were to redo our semester of work, we would consult Dr. Amit Nimunkar earlier in our testing process, since he gave us the advice we needed to finish our LabVIEW and MATLAB setup. Consulting him earlier would have allowed us to run more trials of our testing. In the future, the team hopes to apply this same testing method on asthma patients, as well as add other functions to the shirt for monitoring asthma like thermistor bands that measure lung volume changes. Additionally, we would like to make the device wireless using Bluetooth technology. Nevertheless, the device created holds great potential to provide insight into the lung sounds of asthmatics and is a huge step in creating the first device for continuously monitoring asthma.

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Appendix 1

Product Design Specifications

Function:

The function of our product will be to continuously monitor asthma patients. In severe asthma patients (the top 10%), the asthma symptoms are often more frequent and more extreme. This small group accounts for a large portion of health-care costs, hospital admissions, doctor visits (both scheduled and unscheduled), and emergency services. In addition, the frequent symptoms and long recovery times can lead to a “chronic wound” with the ongoing epithelial tissue damage and repair. Oftentimes, patients who undergo asthma exacerbations do not notice the symptoms for up to two days after they have started. The goal of our project is to detect the onset of an asthma exacerbation earlier in order to try and prevent the asthma attack rather than just treat it. Our product will be able to detect changes in lung sounds and alert the patient to start their asthma action plan (AAP). We will make a device to detect asthma lung sounds using a microphones and 3D printed casings. The three main symptoms we will try to detect are coughing, wheezing, and respiratory rate.

Client requirements:

- Refine lung monitor device to better detect wheezing and coughing by perfecting the thresholds
- Incorporate thermistor bands to monitor the respiratory rate
- Design a less bulky version of the microphone casing
- Integrate design into shirts used in previous semesters
- Get the DAQ software to work with the version of labVIEW used for testing
- Continue to figure out “thresholds” or previously determined measurements for this type of data since they are not known
- Test the product on actual asthma patients

Physical and Operational Characteristics

a. *Performance requirements:* The device must be able to collect data for a minimum of 4 hours to start. Eventually, the device should be able to run 24/7. It should be able to continuously monitor asthma, although it might not necessarily be worn all the time. At this point, it will be powered by a physical 3.3 V hookup, but in the end, the device will be run wirelessly and be powered with batteries with a target battery life of 12 hours. When integrated into a shirt, the microphones must be able to be removed in order to wash the shirt.

b. *Safety:* Safety is not huge concern with this device because there is very low potential for danger. However, any part of the device that comes into contact with the patient’s skin must be made of a material that will not cause adverse reactions. The connections between the microphone, the cable and the DAQ must be properly encased/ tapped to prevent any electrocution/ short circuiting. Since the patient will be attached to the device, it may restrict their movement. While not ideal, this situation is not extremely harmful. The only other safety concern is making sure the device does not falsely detect an asthma exacerbation, but determining thresholds for this will come later in the project.

c. Accuracy and Reliability: The microphone must accurately and precisely detect sound differences in asthma symptoms such as wheezing and coughing. The device must be able to distinguish these from talking, movement, ambient noise, etc. This will mostly be done using various filters. We will use frequency plots to help determine the thresholds for these filters, which will increase their reliability. The group would also like to detect changes in respiratory rate. This will require looking at the changes in the signals rather than just values at an instant in time. Exact specifications and thresholds will be determined during testing.

d. Life in Service: Due to the fact that this is continuous monitoring of asthma symptoms, there will be no limit on the microphones life in service. It will only end if there is another technology that is more effective than this microphone. The batteries will be the only part of the device that will need regular replacement. The target goal is 12 hours of battery life during use so the patient can go all day without needing to replace the batteries.

e. Shelf Life: This is not a major concern for this project. The only aspect of the device that would be affected by shelf like are the batteries, but they will be able to be replaced easily. The product should be able to work no matter how old it is, but the older it gets, the more technology advances. If the product is too old, its technology will probably become outdated.

f. Operating Environment: One operating environment concern is that the electrical components will need to stay dry. The microphone will be encased in plastic so any moisture, from perspiration for example, will not damage the device. The device ideally will not be used at extremely hot or extremely cold temperatures because it could affect the electrical components. The ideal temperature for use is 20-30C. In addition, if the operating environment is very noisy, it will be difficult to gather consistent, reliable data.

G. Ergonomics: The device should be able to fit into many different shirt sizes so it can be adaptable to individuals of all sizes. The device will go against the skin of the patient on the lower back, so it should be as comfortable as possible. In order to fit as many patients as possible during initial testing, the device will be integrated into an adjustable band made from medical bandage wraps. This will ensure that the device has a snug fit while also maintaining patient comfort.

H. Size: Ideally, the device will be as small as possible so that the patient hardly notices they are wearing it. The diameter of the casing hear is not a huge concern but we have a target of 5 cm. , The thickness on the other hand will greatly affect patient comfort, so we have a target thickness is less than 2 cm. The microphone casing must be small enough to be integrated into the shirt worn by the patient.

I. Weight: The main concern is that the patient will be able to wear the shirt. This means that the product will need to be light enough to wear without much discomfort/ without causing the shirt to sag down. Our target weight for the device is one pound. The weight becomes an even larger concern when making the device wireless and adding batteries/bluetooth capabilities.

J. Materials: The ABS plastic surrounding the microphone will not be affected by contact with the skin. However, we have to make sure the plastic does not cause discomfort or irritation to the skin. All the other materials do not come into contact with the patient, so they are not of major concern. Since we have the bandage wrap between the casing and the patient, this is not a major concern. In addition, the band is intended to be worn over the patient's shirt, thus further reducing that concern.

K. Aesthetics, Appearance, and Finish: The primary goal for this semester is functionality. When the device is integrated into a shirt, we want the shirt to appear as normal as possible. This is another reason why we want the device to be as small/ lightweight as possible. The color, texture, design, shape etc of the shirt will be variable parameters that can be determined by each individual.

Production Characteristics

a. Quantity: We are developing two microphones this semester that will both be used in a single asthma shirt. Each patient should only need one of these devices, but they may have various shirts to use with it.

b. Target Product Cost: Currently, there are no similar products like the one we are working on in which to compare the expected cost. There was a group who worked on this project last year and were able to develop a similar shirt for just under $300. Our budget is $300 for this semester. Many of the components for the device are rather inexpensive except for the DAQ. Ideally, this product would be inexpensive enough so that as many asthma patients that need it can afford to buy one.

Miscellaneous

a. Standards and Specifications: In order to test this on asthma patients, we need an IRB protocol. Dr. Mathur has a protocol pre-approved that we can use. The group can be added to the protocol once the necessary online training has been complete. The HIPAA regulations regarding patient data will need to be followed as well.

b. Customer: Since there is no such product on the market, there really is not any customer likes, dislikes, preferences, etc. The customer will have to wear this shirt, so they probably want the shirt to be as comfortable as possible. A good target for this is trying to make this shirt feel as close to wearing a normal shirt as possible.

c. Patient-related concerns: If the microphone in the shirt cannot filter out outside noises, the patient may worry about the reliability of the product. The device should only notify the patient when they are actually having an asthma exacerbation. False alerts could be a major issue, especially if the individuals AAP include taking medications. Also, another patient related concern is that the patient's information must remain safe and confidential. That way they won't be worried about invasion of personal privacy.

d. Competition: As of now there are no similar items that exist. The devices that are used to detect asthma are not at for at home use and they are not continuous. There are various wearable technologies on the market, like fitbits and hexoskin shirts, but those have nothing to do with asthma.

Appendix 2

Specifications for an Asthma Action Plan

Asthma Action Plan

For: ______ Doctor: ______ Date: ______

Doctor's Phone Number ______ Hospital/Emergency Department Phone Number ______

GREEN ZONE

Doing Well

- No cough, wheeze, chest tightness, or shortness of breath during the day or night
- Can do usual activities

And, if a peak flow meter is used,

Peak flow: more than ______
(80 percent or more of my best peak flow)

My best peak flow is: ______

Take these long-term control medicines each day (include an anti-inflammatory).

Medicine	How much to take	When to take it

Before exercise ☐ ______ ☐ 2 or ☐ 4 puffs ______ 5 minutes before exercise

YELLOW ZONE

Asthma Is Getting Worse

- Cough, wheeze, chest tightness, or shortness of breath, or
- Waking at night due to asthma, or
- Can do some, but not all, usual activities

-Or-

Peak flow: ______ to ______
(50 to 79 percent of my best peak flow)

First

Add: quick-relief medicine—and keep taking your GREEN ZONE medicine.

______ (short-acting $beta_2$-agonist) ☐ 2 or ☐ 4 puffs, every 20 minutes for up to 1 hour ☐ Nebulizer, once

Second

If your symptoms (and peak flow, if used) return to GREEN ZONE after 1 hour of above treatment:

☐ Continue monitoring to be sure you stay in the green zone.

-Or-

If your symptoms (and peak flow, if used) do not return to GREEN ZONE after 1 hour of above treatment:

☐ Take: ______ (short-acting $beta_2$-agonist) ☐ 2 or ☐ 4 puffs or ☐ Nebulizer

☐ Add: ______ (oral steroid) mg per day For ______ (3–10) days

☐ Call the doctor ☐ before/ ☐ within ______ hours after taking the oral steroid.

RED ZONE

Medical Alert!

- Very short of breath, or
- Quick-relief medicines have not helped, or
- Cannot do usual activities, or
- Symptoms are same or get worse after 24 hours in Yellow Zone

-Or-

Peak flow: less than ______
(50 percent of my best peak flow)

Take this medicine:

☐ ______ (short-acting $beta_2$-agonist) ☐ 4 or ☐ 6 puffs or ☐ Nebulizer

☐ ______ (oral steroid) mg

Then call your doctor NOW. Go to the hospital or call an ambulance if:

- You are still in the red zone after 15 minutes AND
- You have not reached your doctor.

DANGER SIGNS

- **Trouble walking and talking due to shortness of breath**
- **Lips or fingernails are blue**

- **Take ☐ 4 or ☐ 6 puffs of your quick-relief medicine AND**
- **Go to the hospital or call for an ambulance ______ (phone) NOW!**

See the reverse side for things you can do to avoid your asthma triggers.

Appendix 3

Full code used in Matlab

```
[y,fs] = audioread('test1.wav');
t = linspace(0,length(y)/fs,length(y));
plot(t,y)
Nfft = 1024;
F = linspace(0,fs,Nfft);
G = abs(fft(y,Nfft));
figure ; plot(F(1:Nfft/2),G(1:Nfft/2))

NFFT = 2^nextpow2(length(y)); % Next power of 2 from length of y
Y = fft(y,NFFT)/length(y);
f = fs/2*linspace(0,1,NFFT/2+1);

% Plot single-sided amplitude spectrum.
plot(f,2*abs(Y(1:NFFT/2+1)))
title('Frequency vs Amplitude')
xlabel('Frequency (Hz)')
ylabel('Amplitude')
ylim([0 6.5e-4])
```