

Preliminary 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 shirt that will be able to accurately distinguish between normal speaking, wheezing and coughing. As the project continues, this report will expand to include testing, results and implications from data analysis.

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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 an average asthma patient. 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) in place to treat 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). An AAP is a procedure for a patient to follow in the event of an asthma exacerbation. 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 hospital costs.

Currently, there are no devices that can continuously monitor asthma symptoms and alert patients when an asthma exacerbation has started. Often, 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 [3]. One measurement commonly used from spirometry is FEV1, or forced expiratory volume in 1 second [4]. It uses the maximum amount of air an individual can forcefully exhale in 1 second in order to gauge lung function [5]. 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, do not measure continuously, and are typically used after symptoms are felt as well.

The previous team's approach to measure asthma symptoms included two microphones to listen to the lungs and two resistor bands to measure breathing rate. This was built into a shirt with an arduino collecting the data and sending it to LabVIEW. We were unable to build off of their current device because it could not collect usable data. Their device had too many inputs which caused interference to occur across multiple elements. This, along with trying to measure too many signals at once, led to them getting no useable data from any of their tests. As a result, last semester we decided to focus on creating an operating microphone before moving on to other aspects of the shirt. Now that we have a functional microphone, we will focus on refining the microphone system, which will include creating a more streamlined microphone casing and adding another microphone. Finally, these microphones will be fixed into a shirt.

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.

Background

Asthma is a chronic condition characterized by inflammation and narrowing of the bronchial tubes in the lungs [2]. The air travels from here 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. When a person's asthma is triggered, the bronchi and bronchioles constrict and can become even more inflamed [6]. This constriction leads to, in some cases, panting; increased breathing rate due a decrease in the allowed air intake. 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 [7]. The excess mucus builds up in the lungs making it even harder for the patient to breathe and sometimes includes a phlegm-sounding cough [6]. This combination of symptoms leads to the patient initiating their AAP. 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 [8]. 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, underdiagnosed, and undertreated [9]. 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.

For severe asthma patients, approximately the top 10% of the total asthma population; asthma exacerbations can 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 will be integrated into a shirt. The goal for this shirt is to have it weigh one pound with the thickness of the casing being less than $\frac{3}{4}$ of an inch. The shirt should appear as similar to a normal shirt as possible so the patient is comfortable wearing the device. The shirt will be in direct contact with the patient, so the material of the shirt and the device should be safe and

comfortable on 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

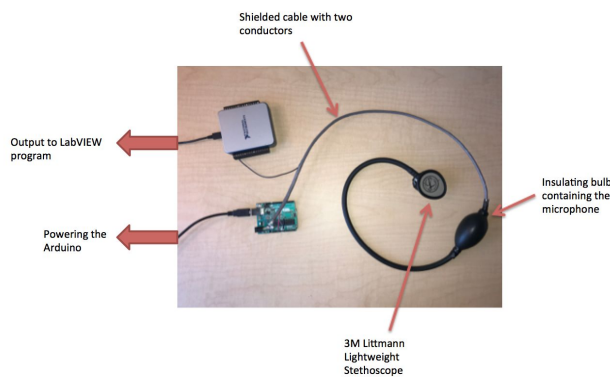


Figure 1: Stethoscope design from the previous semester.

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.

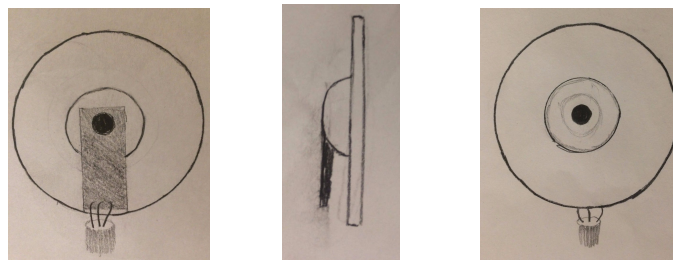


Figure 2: Top view, side view, and inside view of the diaphragm microphone design.

The next design, called the diaphragm microphone design, incorporates a circular disc instead of a stethoscope. The disc acts as the stethoscope head, but is more tailored to integrate into a t-shirt. This design also uses a microphone which vibrates with sound. A small circular piece (diaphragm piece) extends off the microphone and is responsible for sensing the vibrations. Since this microphone cannot lay flush with the design, it would be attached to the back of the disc with the diaphragm piece entering a small hole in the center of the disc. Lastly, the wires from the microphone would be threaded through a shielded cable and attached to the DAQ and arduino.

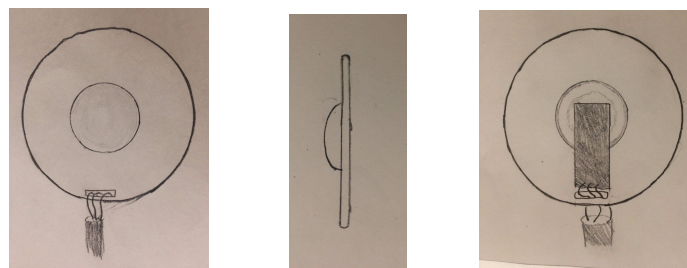


Figure 3: Top view, side view, and inside view of the encased microphone design.

The last design, called the encased microphone design, uses the same circular disc as the previous design. However, a different microphone would be used. This microphone is the same one used in the previous semester and does not utilize a diaphragm piece to detect signals. Since this microphone lays flat, it would be placed inside of the circular disc and would pick up signals immediately. The wires from this microphone would be threaded through a small slit in the disc and then threaded through a shielded cable.

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 a 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 design received a 4. This 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 microphones, shielded cable with two conductors, Arduino microcontroller, National Instruments USB-6002 Data Acquisition Device and LabVIEW software. The microphones chosen are the Sparkfun MEMS Microphone Breakout-INMP401 which features a built in amplifier with a peak to peak output of 200mV. They require a 3.3VDC power supply which will be 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 should work well with the existing code. The microphone will be encased in a custom, 3D printed ABS plastic casing. The exact design/dimensions of the casing are still being decided. A two conductor shielded cable will be 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. These cables will connect the microphones to the Data Acquisition Device. The DAQ will allow us to collect multiple inputs, perform ADC conversions, and transfer the data to the computer. This reduces the complexity of the data collection process especially for multiple inputs. We will use the 2015 LabVIEW program to process the data once on the computer. We will utilize various filters, waveform graphs, and waveform charts in order

to analyze the data collected. In order to link the DAQ to the LabVIEW program, we will need to download and run the NI-DAQmx 9.9 software.

Methods

To begin the fabrication, we will create a 3 dimensional image of our microphone casing in SolidWorks. Then, a member of our team with green pass credentials will fabricate the casing using a 3D printer. Next, we will strip roughly two inches from each side of the insulated cable and .5 inches off the ends of the conducting wires. The wires will then be soldered to the connections of the microphones. Doing this will ensure that there is no crossing of the wires, which will create an inaccurate output from the microphones. The flush bottom of the microphone will be fixated to the inside of the microphone casing. The insulated cable will then extend roughly six feet to allow for separation of the patient and the testing computer. The exposed conducting wires will be connected from Arduino ground to microphone ground, Arduino 3.3 V output to the microphone power, and analog input of the DAQ device to the output of the microphone. Finally the NI DAQ device will be connected via USB cable to the computer which will be running the LabVIEW program.

Final Prototype

The final prototype will consist of two microphones connected to an arduino. When in use, the two microphones will be fixed to the back of the asthma shirt in a predetermined position to maximize data collection of the asthma sounds.

Testing

The main source of testing will come from human trials. The team has a pre-approved IRB protocol and will begin testing the previous semester's design on actual asthma patients sometime this semester. The new design will not be used until the end of the semester once it is fabricated. With these tests, more accurate thresholds will be determined. Previous thresholds were determined by testing the device on the team members. Since the team members do not suffer from asthma, there was no way to detect wheezing. The coughing thresholds may not be as accurate as predicted for this reason as well.

The team will begin testing the new design by wearing the device ourselves and comparing the results to those from the previous semester's design. If the design reduces ambient noise and is more easily integrated into the asthma shirt, it is a more effective option.

Results

Last semester, we were able to isolate coughing using the previous design. We anticipate similar results for the isolation of coughing, but we hope to see a successful isolation of wheezing for our new device because we will be using the same DAQ device and LabVIEW code. At this time we have not conducted any tests with our anticipated prototype. Results will be reported as soon as data is obtained.

Discussion

After we have determined the thresholds for diagnosis and performed testing on asthma patients through Dr. Mathur's IRB protocol, we will have the proof of concept that Dr. Mathur needs to continue developing the shirt. If our results indicate that the asthma shirt is able to successfully and accurately alert the patient of an asthma exacerbation it will deem the shirt as a useful method in preventing dangerous asthma attacks. This would mean that the shirt can further be developed to reach its potential as a continuous monitor for asthma controlling. In the future, the team hopes to be able to add other functions to the shirt for monitoring asthma, such as thermistor bands that measure lung volume changes. As mentioned earlier, this application of continuous asthma control will help reduce the high usage of hospital resources on asthma related incidents, and will help severe asthmatics live with a higher sense of security.

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 the asthma symptoms felt by patients can be delayed for up to two days after the exacerbation has started, the patients are already experiencing decreased lung functions. 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. This is especially important for severe asthma patients whose asthma exacerbations are more intense and harder to fight. In addition, it takes these patients longer to return to full lung function as well. Any time saved can greatly improve the quality of life for severe asthma patients. There is no cure for asthma, and so the only solution is treatment. The asthma shirt poses great potential not only to change the way asthma is treated but also to prevent asthma exacerbation before they become severe.

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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 our own electronic stethoscope using a stethoscope head along with an audio microphone to listen to the lung sounds. 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. The part of the device that is in contact with the patient is the

stethoscope head, which does not pose any danger. The connections between the microphone, the cable and the DAQ must be properly encased/ taped 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. 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 good, 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.

H. Size: Ideally, the device will be as small as possible so that the patient hardly notices they are wearing it. The stethoscope head diameter is not a huge concern, but the thickness will greatly affect patient comfort. The target thickness is less than $\frac{3}{4}$ an inch. 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.

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, the patient 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

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 _____
(50 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.

_____ 2 or 4 puffs, every 20 minutes for up to 1 hour
(short-acting beta₂-agonist) 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: _____ 2 or 4 puffs or Nebulizer
(short-acting beta₂-agonist)

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

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:

_____ 4 or 6 puffs or Nebulizer
(short-acting beta₂-agonist)

_____ mg
(oral steroid)

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** ➡ ■ **Take 4 or 6 puffs of your quick-relief medicine AND**

■ **Lips or fingernails are blue** ➡ ■ **Go to the hospital or call for an ambulance _____ NOW!**
(phone)

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