

## **Continuous Monitoring of Asthma Control Product Design Specifications**

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### **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:**

- The client does not want use to try and tackle the entire “asthma shirt” but rather start on just part of it
- The first focus of the project is to design a device to monitor lung sounds (breathing, coughing, wheezing, etc.)
- The client suggested using a stethoscope inspired microphone system to capture the sounds, but the team will explore other options as well.
- A data acquisition device will be used along with the device in order to get the data into the labview program
- There are not any “thresholds” or previously determined measurements for this type of data, so we will have to try and figure those out on our own
- The primary focus for this semester is not to necessarily have a complete, finished product by the end, but rather get preliminary data that can be built upon

### **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. 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. 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.

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 life 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 stethoscope head is not affected by moisture, so any perspiration 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. 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:* The size of the device does not matter a lot for this semester. 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.

*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. This becomes a larger concern when making the device wireless and adding batteries.

*J. Materials:* The stethoscope is made for contact with the skin, so the material of that is not an issue. If in the future we create our own stethoscope head/ microphone casing, then the material must be one that does not irritate the skin (most likely a plastic).

*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:* Right now, we are only developing one microphone. Eventually, the shirt will incorporate 2 microphones, one for each lung. 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:* As of now this product will not need FDA approval but if it is implemented in the future for diagnosis it will. 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 members must follow all the HIPAA regulations regarding patient data.

*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.