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 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.