Continuous monitoring of asthma control

February 5, 2016

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Function: The asthma shirt will allow continuous monitoring of tidal volume in lungs, respiratory rate, and detection of coughing or wheezing sounds from patients and send the analyzed data in real time to the patient. The asthma shirt would allow the patient to notice their symptoms of an asthma exacerbation sooner, allowing them to contact their physician for treatment.

Client requirements

- Measure lung volume
  - collect data from chest and lower abdomen
- Detect cough and lower airway wheeze from audio files
  - collect data from 4 regions of back (Right/Left mid-scapular ; Right/Left bottom of rib cage)
- Allow shirt to washable/detachable electronics
- Non-restrictive wires
- Size-adjustable; comfortable; burn-proof
- Battery life is at max 6 hours (for clinical testing)
  - Rechargeable for night-use testing
- Allow for continuous monitoring/transfer information quickly

Design requirements: This device description should be followed by list of all relevant constraints, with the following list serving as a guideline. (Note: include only those relevant to your project):

1. *Physical and Operational Characteristics*
   a. *Performance requirements:* The shirt must detect the severity and the combination of the main indicators of the onset of an asthma exacerbation: cough, shortness of breath, and wheeze over a 6-hr period with a maximum of 3 uses per day.
   b. *Safety:* The electrical wiring should be safe for the user. No electrical components should have direct exposure to the skin.
   c. *Accuracy and Reliability:* The detected signal will be within the 0.167–0.50 Hz range for respiratory rate and within the 100 Hz - 1600 Hz range for cough detection. The device should capture these signals with 95% CI. The signal-to-noise ratio should be no less than 40 dB [1].
   d. *Life in Service:* The product should last 1000 uses over 6-hr trials.

e. *Shelf Life*: Battery life should last 5 years with the ability to be recharged through a USB port. The product should be stored a dry area at room-temperature (25℃) to prevent cold damage to the electrical components.
f. *Operating Environment:* The product will be used in the clinical setting at room-temperature (25℃) handled by trained providers.
g. *Ergonomics:* The electrical storage container should provide an easy access point to the battery and encapsulate the circuit board so there are no loose wires. The user will be provided with a user manual if any electrical components need to be replaced (microcontroller, operational amplifiers, and other wires will be soldered on a PCB).
h. *Size:* The electrical storage container should not exceed 8.4 cm × 5.3 cm x 5 cm [1]. The shirt design should be modified for each adult shirt size: small, medium, large, extra large.
i. *Weight:* The electrical storage container should not weigh more than 5 lbs.
j. *Materials:* Velcro or any similar material should not be used for the shirt as it may produce additional background noise.
k. *Aesthetics, Appearance, and Finish:* The electrical storage container will have a rectangular shape with a smooth texture so it is comfortable for the user. The shirt should have no visual wires and be tight-fitting to the patient's' upper body.

2. Production Characteristics

a. *Quantity:* 1 shirt, 1 electrical storage container
b. *Target Product Cost:* Under $300 for all materials

3. Miscellaneous

a. *Standards and Specifications:* FDA approval may be required if this becomes a diagnostic tool in the future.
b. *Customer:* The main focus is to record tidal volumes and to audio data. Aesthetics should be considered later in the design process.
c. *Patient-related concerns:* The shirt must be washed between uses, thus the electrical storage container must be detachable. Data will be recorded and must be kept confidential. No identifiers will be used to store data, only the lung volume measurements and deconstructed audio files will be stored on a secure, log-in computer.
d. *Competition:* HEXOSKIN uses a similar setup, but they only focus on breathing patterns of athletes in different conditions.

[1] K. Chun, J. Webster, I. Santos and S. Mathur, "Real-time measurement of ventilation and respiratory sound for continuous monitoring of asthma control", Physiological Measurement, 2015.