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Executive Summary

The goal of this project is to demonstrate the feasibility of a demand oxygen cannula using mechanomyography (MMG) to sense inhalations and exhalations. This MMG signal controls a valve enabling oxygen to flow only during inhalation. The motivation for this project stems from the needs of young children who require oxygen therapy, in particular children with interstitial lung disease. The prototype developed over the course of this year demonstrates a great potential for this new type of demand oxygen system to improve the quality of life of these children.

Clinical Need

Currently available oxygen therapy systems for children waste oxygen because the oxygen flows continuously regardless of breathing state.

This reduces the amount of time the oxygen tank lasts, constricting their mobility. Therefore, demand oxygen systems are in need to efficiently supply oxygen and enable patients to live better lifestyles. Current demand oxygen systems work based on pressure gradients and are targeted towards adults and the elderly. Children with interstitial lung disease cannot generate a large enough pressure difference for these systems.

Description of Market

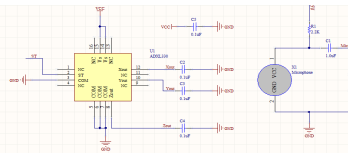
The primary targeted market group for this oxygen demand system is children (0-3 years old) with interstitial lung disease. However, the concept of this product can be used in oxygen systems for all ages to help conserving oxygen and improve their lifestyles.

After a refined proof of concept is generated, more segments in the respiratory lung illness category can be targeted as potential users of the product. Portable delivery systems are becoming an increasingly popular choice for people with a variety of conditions.

Currently, there are no direct competitors to the proposed product since oxygen demand systems do not use MMG signals.

The cost of the device will approximately be \$150, which is much cheaper than the price of currently available oxygen demand systems.

Description of Design



Mechanomyography (MMG) sensor

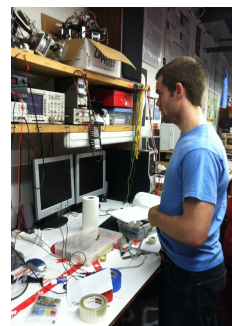
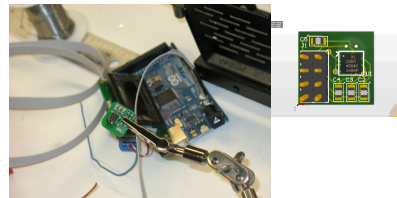
- Detects the noise and movement that a muscle makes
- Consists of an omni-directional microphone (Panasonic WM-63PRT) and an accelerometer (Analog Devices ADXL330KCPZ-RL)

Sensor's PCB Board

- Contains surface mount components (SMD components)
- SMD components pass analog outputs from sensors to the micro-controller
- Obtains power from the micro-controller to power the sensor

Micro-controller

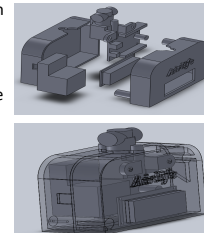
- Obtains the input from the microphone and accelerometer
- Performs signal processing on the data to obtain information on breathing state



Connected directly to the oxygen tank is an oxygen regulator. Oxygen will flow from this regulator through quarter inch tubing to a fitting on a solenoid valve, which will be housed in a case worn by the patient. The nasal cannula will attach directly to the other side of the solenoid valve and lead to the patient's nostrils.

Oxygen regulator

- Reduces pressure of oxygen from 3000 psi to 50 psi in the tubing
- Limits the flow of oxygen escaping the cylinder (8 liters per minute)



Novelty of Concept

This innovative demand oxygen system incorporates the use of mechanomyography to sense breathing patterns of a patient. The MMG sensor uses a microphone to detect the low frequency sound of diaphragm contraction. This leads the valve to open during inhalation and close during exhalation, thus conserving oxygen. This concept has never been built in an actual product before, and uses a different sensing technique from what is currently available in the market.

Anticipated Regulatory Pathway

The most appropriate regulatory pathway for this device is the 510k. There are similar demand oxygen systems which have already been approved. However, the breath sensing mechanism is different for these currently approved systems.

The sensor for this device rests on skin, similar to electromyography sensors; the sensor is attached to skin using medical adhesive and is easily removable.

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References

- [1] Silva, Jorge. *Mechanomyography Sensor Design and Multisensor Fusion for Upper-Limb Prosthesis Control*. University of Toronto (2004).