PowerNap: Electrically Stimulating Mouthpiece for Patients with Mild to Moderate Obstructive Sleep Apnea

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Purpose

To add a more comfortable and more effective means of managing mild to moderate obstructive sleep apnea

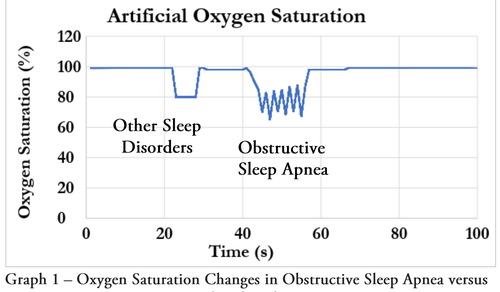
Background Research

- Obstructive sleep apnea is a condition where the airway becomes obstructed during sleep
- Blocked airway causes the oxygen level in the blood to drop, causing abrupt arousal from sleep
- Most common treatment is a CPAP machine
- Other treatment options include oral appliances and surgical intervention

Project Goals

Create a sleep apnea treatment that is less invasive, more comfortable, and more effective than traditional treatment options available on the market. It must:

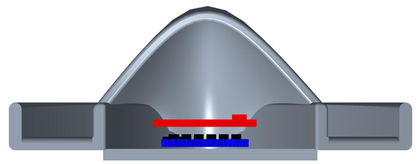
- Output a stimulation directly to the soft palate musculature at 3 mA to cause contraction in response to an apnea
- Electrically stimulate only the muscle while protecting the rest of the oral cavity from unnecessary electrical stimulation
- Use pulse oximetry to continuously monitor oxygen saturation when in use with built in fail-safe mechanism to prevent shocking in the event that the pulse oximeter-human interface is disrupted
- Oxygen saturation oscillates during the event of an apnea. The sensor must be able to interpret that variability to actuate an electrical response



Graph 1 – Oxygen Saturation Changes in Obstructive Sleep Apnea versus other disorders

Conceptual Design

Goal: design and build a biomedical device that utilizes pulse oximetry to sense the onset of an apnea, and respond with an electrical stimulus to the soft palate to clear the airway without disrupting the sleep cycle



Microcontroller

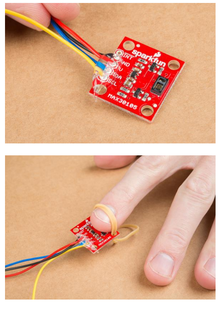
Figure 2.0 - Actual printed mouthpiece casing. Casing size based on MRI Scan of oral cavity. Used as a light blocking shield for the sensor-controller unit for testing purposes

Physical Specifications

Casing: Hard Acrylics
- ✓ Supportive
- ✓ Nonconductive
- ✓ Easily altered
- ✓ Biocompatible

Microcontroller: Arduino Pro-Mini

Sensor: MAX30105 Particle Board



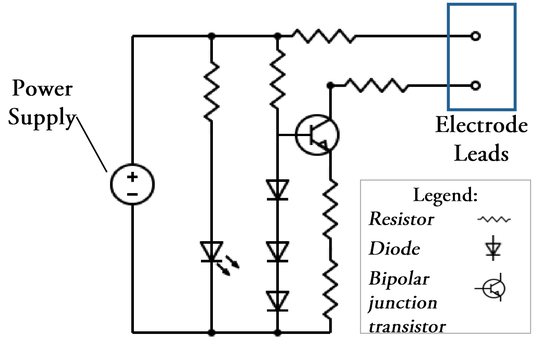
Figures 2.1 and 2.2 – MAX30105 Particle Sensor (1) without test subject with jumper cables and (2) with test subject stabilized with a rubber band for support and constant pressure application.

Muscle Stimulation Specifications

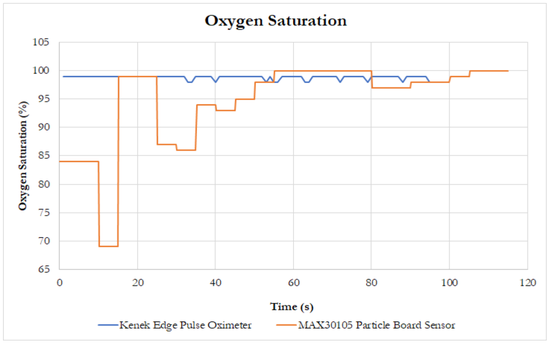
Stimulation Output: 3 mA

Electrode Test Material: Copper
- ✓ Commonly used for electrode leads
- ✓ Biocompatible
- ✓ Conductive

Housing Material:
- Hard Acrylics for locations not on soft palate
- Thin, flexible, non-conductive material for soft palate



Data



Graph 2 - Comparison of sensor reading to consumer grade pulse oximeters. Deviations from consumer grade measurements may be due to inconsistent finger placement or insufficient light shielding.

Future Work

- Validate electrode output (Target = 3 mA)
- Thermal testing of materials to ensure safe range of temperatures on electrode stimulation point and supporting materials
- Identify battery/power source component
- Finalize characterization of oxygen variability in oxygen saturation during an apnea and determine final actuation point
- Conduct initial pilot studies on a small population to determine preliminary safety and performance
- Conduct study on long-term usage of electrical stimulation on the soft palate
- Incorporate data acquisition capabilities into mouthpiece to track compliance data using thermally sensitive materials

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