FABRICATION OF A VARIABLE DEAD SPACE SLEEP APNEA THERAPY DEVICE

Team Members: William Guns, Calvin Hedberg, Tanya Iskandar, Aman Nihal, and John Riley
Biomedical Engineering Department, University of Wisconsin – Madison
Client: Dr. John Webster, Advisor: Dr. Jeremy Rogers, Biomedical Engineering, University of Wisconsin - Madison

Abstract

- 20 million Americans affected by Sleep Apnea [1].
- Increased risk of heart issues, high blood pressure, stroke, and other diseases [2].
- Current Sleep Apnea treatments, such as Continuous Positive Airway Pressure (CPAP) devices, are rejected by 46% of those who try them [3].
- Our device uses the "Smart CO_2" system developed at UW-Madison that has been proven to reduce the occurrence of apneas in Central Sleep Apnea (CSA) patients [4].
- Smart CO_2 elevates CO_2 in the lungs by increasing the dead space, inducing mild hypercapnia and alleviating symptoms of sleep apnea [4].

Problem Definition

Motivation:

- Need for an alternate to CPAP due to high rejection rate
- Three types of sleep apnea:
  - Obstructive Sleep Apnea (OSA) - caused by physical obstructions in the airway [5]
  - Central Sleep Apnea (CSA) - caused by lack of neurological drive to continue breathing [5]
  - Complex/Mixed Sleep Apnea - combination of both OSA and CSA symptoms [5]
- Our Smart CO_2 device has the ability to benefit those with CSA, approximately 4.2 million in the U.S. alone [6].

Background:

- Dead space = Volume of air remaining in the respiratory tract following exhalation (approximately 150 mL on average and is CO_2 rich) [7]
- Increasing dead space increases CO_2 intake which increases PCO_2, augmenting breathing rates, reducing symptoms of CSA [4].

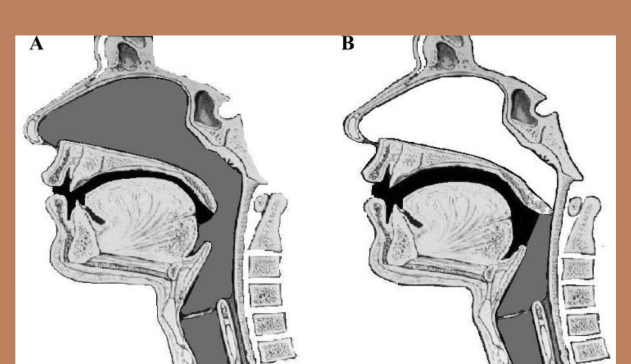

Figure 1: Illustration of CO_2 levels in respiratory tract after exhalation (A) and inhalation (B).
White = Oxygen rich, CO_2 depleted air
Shaded = Oxygen depleted, CO_2 rich air

Design Criteria

- Product Design Specifications:
  - Weight: less than 1 kg
  - Length: less than 200 mm
  - Diameter: less than 80 mm
  - Loose-fitting, comfortable mask that will allow the user to sleep on his/her back or side
  - Volume: 1 L (not including the mask and connected tubing)
  - Battery operated and able to withstand 8-10 h of use per night
  - Lifespan: 3-4 months
  - Vary the dead space in response to presence/absence of apneas
  - Control variation in dead space with an airflow sensor and an Arduino microcontroller
- Based on these criteria we created the following preliminary designs:

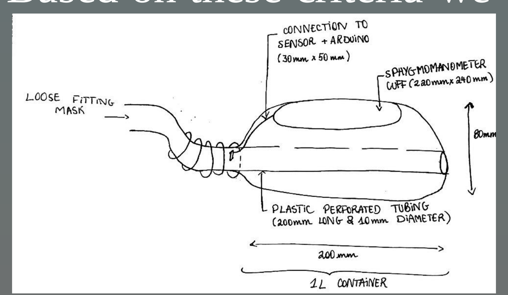

Figure 2: Bladder Design.
This design uses the inflatable cuff of a blood pressure measuring device (sphygmomanometer) as the means to vary the dead space. This is the easiest to fabricate and most durable.

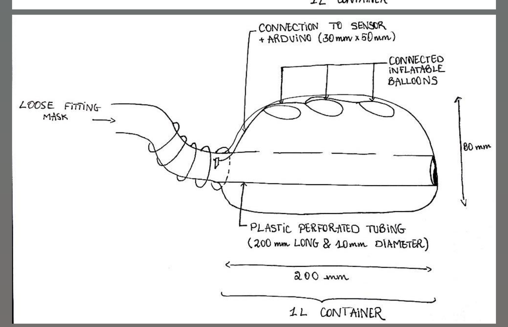

Figure 3: Triple Balloon Design
This design uses three separate balloons powered by three separate motors to vary the dead space. This offers the most dead space variability.

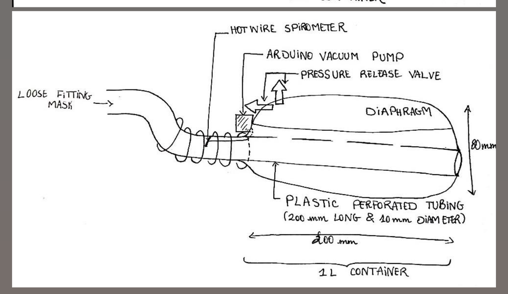

Figure 4: Diaphragm Design
This design uses a diaphragm sealed to the inside of our bottle to vary the dead space. This would be the most cost effective.

- Based on our client's preferences and the following design matrix we concluded that the Bladder Design would be most effective at fulfilling the requirements in an efficient and cost-effective manner

Criterion	*Bladder Design*	*Triple Balloon Modification*	*Diaphragm Modification*
Dead Space Variability (15)	(3/5) 9	(5/5) 15	(4/5) 12
Ease of Fabrication (15)	(5/5) 15	(2/5) 6	(3/5) 9
Safety (10)	(5/5) 10	(5/5) 10	(5/5) 10
Weight (10)	(5/5) 10	(4/5) 8	(5/5) 10
Power Consumption (5)	(4/5) 4	(5/5) 5	(3/5) 3
Durability (15)	(5/5) 15	(3/5) 9	(3/5) 9
Comfort (15)	(5/5) 15	(5/5) 15	(5/5) 15
Cost (15)	(5/5) 15	(2/5) 6	(3/5) 9
Total Value (100)	**93**	**74**	**77**

Table 1: Design Matrix. Through ranking our three preliminary designs on different criteria we found the bladder design to be the best of the three.

Proposed Final Design

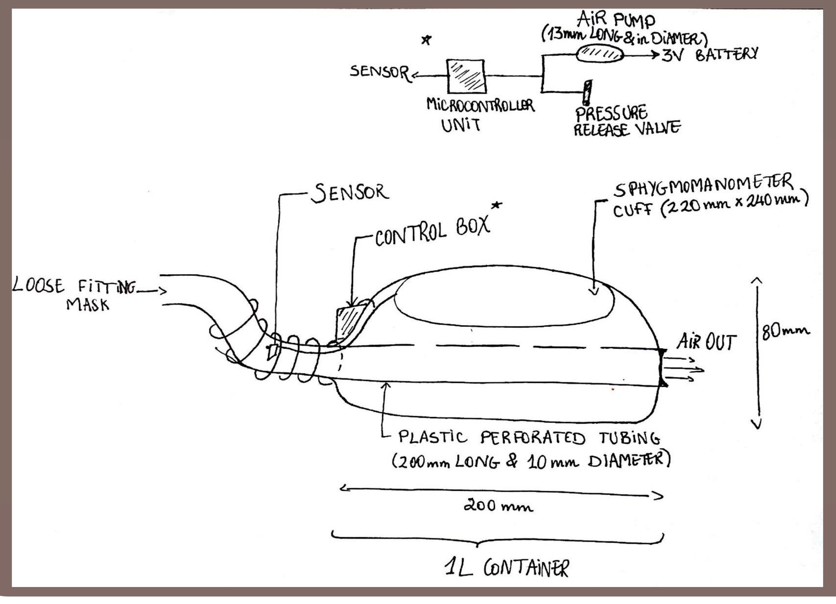

Figure 5: Heavily based on the bladder design, with some modifications from the other two designs such as the inclusion of a pressure release valve

Progress and Results

- After settling on our design and ordering materials, the first order of business was to develop our algorithm through which the Arduino Microcontroller would interpret the breathing data from the airflow sensor and adjust the volume of the bladder accordingly.

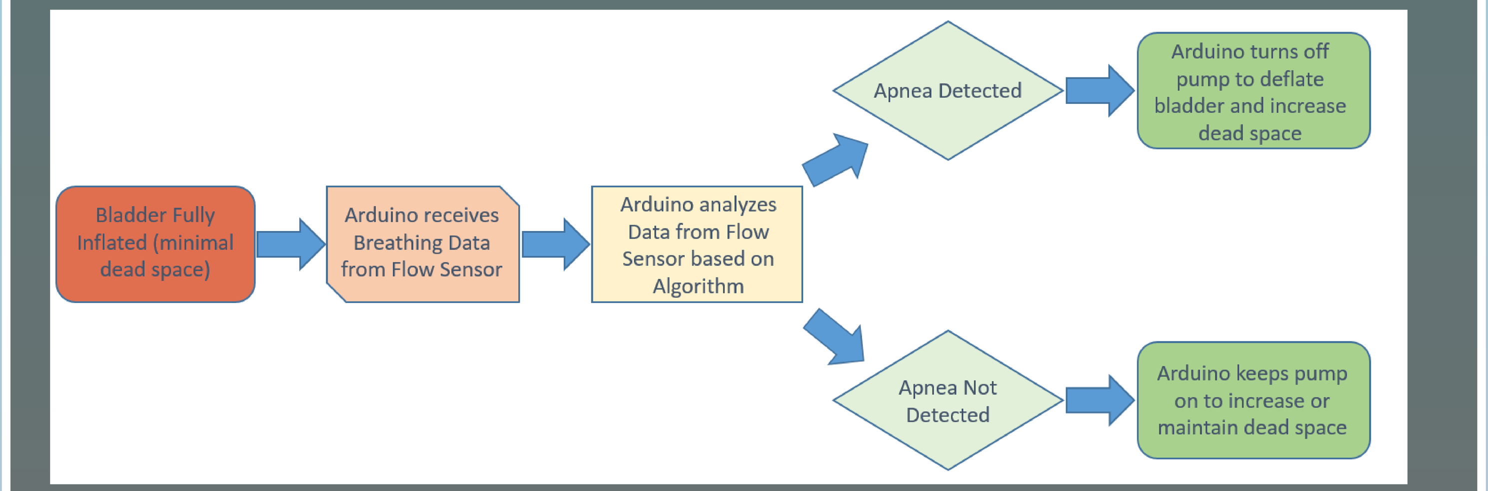

Figure 6: General Outline of Algorithm embedded in Arduino Microcontroller

- After creating the algorithm we set up the following circuit that would later be installed within our device.

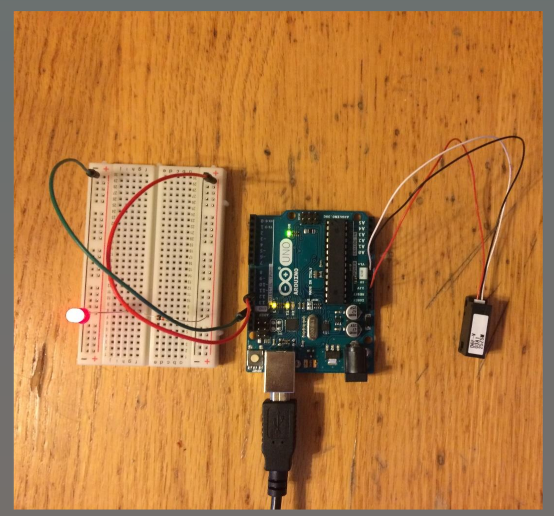

Figure 7: Apnea detection circuit including flow sensor (right), microcontroller and resistor LED combo (left). The LED lights up when apnea is detected by the algorithm

- We tested our algorithm by measuring the breathing of one group member. In one trial he breathed normally to serve as a basis of comparison, in the next he simulated an apnea by ceasing breathing

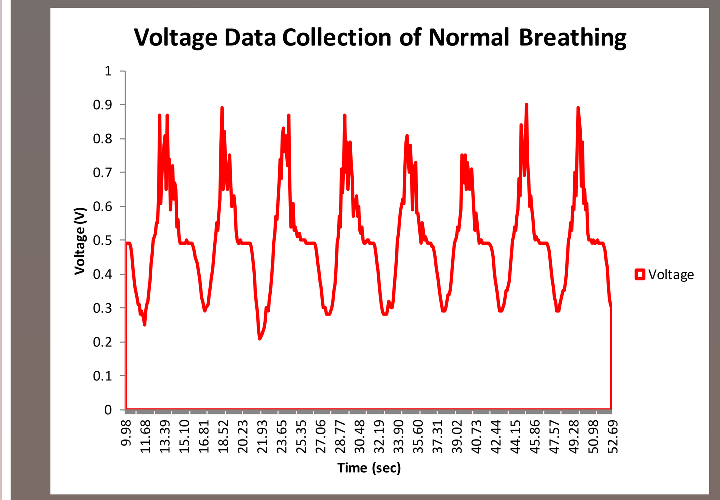

Figure 8: Normal breathing data. This serves as a basis of comparison for the data in Figure 9.

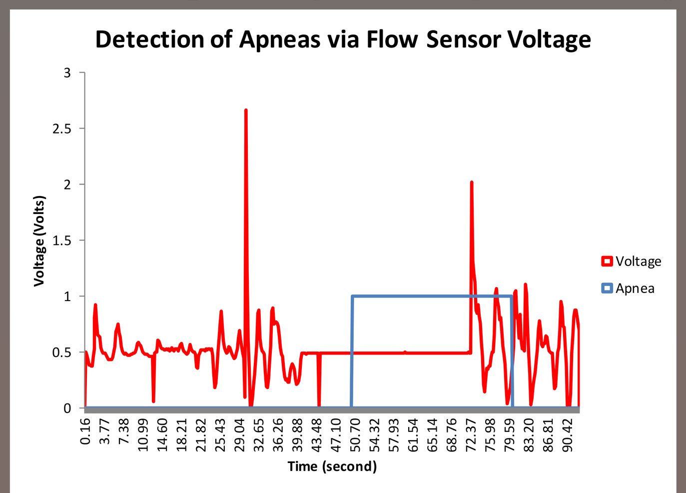

Figure 9: Detection of Apneas via Flow Sensor Voltage. Upon the ceasing of breathing our algorithm determined an apnea was present which indicates that it works correctly.

Fabrication

- All materials are purchased and ready for assembly
- Circuitry is assembled and ready to be implemented
  - Will be placed into an electronics box
- Work remaining as of December 5:
  - Volume container must be drilled to accommodate breathing and pump tubing
  - Breathing tube and air bladder will be attached to container using adhesive tape
  - All seals will be coated with waterproof adhesive prior to assembly

Future Works

- Variety of tests left to perform
  - Perform Human testing to determine limitations and efficacy
  - Develop relationship between PCO_2 and dead space
  - Analyze durability, battery lifetime, stress-cycle testing
- Additions to the device:
  - Condensation drain valve, higher quality flow sensor, vacuum pump for bladder
- Moving forward
  - Appears worth advancing beyond proof of concept

References

[1] Sleepdex, "Sleep Apnea - 18 million Americans have it," in Sleepdex. [Online]. Available: http://www.sleepdex.org/apnea.htm. Accessed: Nov. 30, 2016.

[2] Gottlieb DJ, Yenokyan G, Newman AB, O'Connor GT, Punjabi NM, Quan SF, Redline S, Resnick HE, Tong EK, Diener-West M (2010) Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure the sleep heart health study. Circulation 122:352-360

[3] Catcheside, P. G. (2010). Predictors of continuous positive airway pressure adherence., 2, Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2954420

[4] Dempsey JA, Xie A, Patz DS, and Wang D. Physiology in medicine: obstructive sleep apnea pathogenesis and treatment--considerations beyond airway anatomy. J Appl Physiol (1985) 116: 3-12, 2014.

[5] White,D.P (1985). Central Sleep Apnea., The medical clinics of North America - 69(6):1205-1219

[6] Roth, Erica. "Central Sleep Apnea." Healthline. Ed. Debra Sullivan. N.p., 7 Dec. 2015. Web. 27 Nov. 2016.

[7] "Interactive Respiratory Physiology." Johns Hopkins School of Medicine. Johns Hopkins University, 1995. Web. 10 Oct. 2016. http://oac.med.jhmi.edu/res_phys/Encyclopedia/dead space/dead space.HTML

Acknowledgements

- Thank you to our client, Dr. John Webster, for offering this project and his unyielding support.
- Thank you to our advisor, Dr. Jeremy Rogers, for guiding us through this project.
- Thank you to Mehdi Shokoueinejad and Fa Wang for providing their expertise and aiding us in the fabrication of our device.
- Thank you to the BME Department for funding this project.