Sleep Apnea Therapy Device

BME Design 301

2/22/2017

Client: Professor John Webster - Biomedical Engineering

Advisor: Dr. Megan McClean - Biomedical Engineering

Team members: Calvin Hedberg (Team Leader), Jen Rich (BWIG), Taylor Karns (Team Communicator/BPAG), Ben Mihelich (BSAC)

Abstract:

Sleep Apnea is a sleep disorder affecting more than 20 million Americans that prevents people from reaching deep sleep due to cessation of breathing throughout the night. Sleep apnea is known to increase the risk of heart issues, high blood pressure, stroke, and other diseases. Current Sleep Apnea treatments, such as Continuous Positive Airway Pressure (CPAP) devices, focus primarily on obstructive sleep apnea and are rejected by nearly 50% of individuals due to loudness, lack of comfort and side effects such as nasal congestion and mouth dryness. This drives the need for an alternative treatment for central sleep apnea and eliminate the problems in current treatments. After completing an initial prototype during the fall semester, the team was planning to rework the circuitry however it was decided to redesign the device. The new proposed final design incorporates a variable dead space technique as well as a rotational pump to effectively treat sleep apnea. Increasing re-breathed CO_2 levels through dead space variation has been shown to reduce the occurrence of apneas and stabilize breathing. By inducing mild hypercapnia, ventilatory stimulation is increased and the symptoms Central Sleep Apnea (CSA) may cause are reduced.

Table of Contents: **Page**

I. Introduction

A) Motivation

Sleep Apnea is a disorder characterized by interruptions in a person's natural breathing cycle which causes frequent waking throughout the course of the night [1]. This prevents those with this disorder from reaching REM sleep. This lack of proper rest has been correlated with many issues, including decreased heart health, reduced cognitive function, and a reduction in overall wellness [2]. There are three primary types of sleep apnea: Obstructive Sleep Apnea (OSA), which is caused by physiological obstructions in the airway; Central Sleep Apnea (CSA), which is characterized by intermittent disruptions in the brain's ability to signal the muscles to continue breathing; and Complex/Mixed Sleep Apnea which is a combination of both OSA and CSA [3]. Approximately 1 in 15 people, or 21.3 million individuals, in the United States suffer from some form of sleep apnea [4]. The American Sleep Apnea Association (ASAA) estimates that 84% of these individuals suffer from OSA and 20% suffer from CSA [5]. This comes with an overlap of roughly 15% of sufferers exhibiting both forms [6]. If our team is successful in creating a working a sleep apnea therapy device, approximately 4.2 million individuals suffering from CSA in the U.S. alone could have the quality of their lives improved.

B) Existing Devices / Current Methods

The gold standard for treatment of sleep apnea is Constant Positive Air Pressure (CPAP) machines. CPAP machines work by increasing the air pressure on the walls of the user's airway which forces it to remain open preventing the throat from closing due to obstruction. CPAP is extremely effective in preventing OSA but falls short of being able to completely prevent CSA. Furthermore, many CPAP users may ultimately end up rejecting it. CPAP requires a mask that is sealed tightly to the face in order to preserve positive pressure, but users have complained about the discomfort it has caused. CPAP has also been known to cause nasal congestion, nose and throat dryness, and other minor irritations. In addition, CPAP devices are bulky and loud which can further disturb the sleep of a user and/or their partner. All of these factors contribute to a treatment rejection rate of nearly 50% [7]. As a result, there is a sizable market for anyone who can create a satisfactory alternative that reduces or eliminates the negative side-effects of CPAP.

C) Problem Statement

Sleep Apnea is a sleep disorder in which natural breathing is interrupted during sleep. The frequent waking caused by apneas often prevents those affected from reaching deep sleep, leaving them tired throughout the day. Current treatments for sleep

apnea, such as CPAP machines, are bulky, loud, uncomfortable, and primarily designed for those with OSA. In addition, they face an extremely high rate of rejection by users. Our client, Dr. John Webster, has tasked us with creating a lightweight, quiet, and comfortable alternative sleep apnea therapy device using a newly tested technique that varies dead space volume to combat CSA.

II. Background

A) Background Research Including Relevant Biology and Physiology

Dead space is defined as the area in the respiratory tract that does not participate in gas exchange. This includes the volume in the nose, mouth, trachea and large portions of the bronchi; approximately 150 mL in the standard human body [8]. After a breath is exhaled, residual air must remain in this space and this air is CO_2 rich because it just left the lungs [8]. By increasing the dead space in the respiratory tract, it is possible to increase an individual's CO_2 intake for the next breath. Increasing the Partial Pressure of CO_2 (PCO_2) in the bloodstream creates mild respiratory acidosis. The body responds to this by increasing an individual's rate and depth of breathing, effectively reducing the symptoms of CSA [9].

B) Research Required to Design and Build Prototype

After evaluating the design from last semester, new research was done to create unique design concepts and improve upon the old one. The Arduino Uno will still be the main programming platform because it is flexible, offering a variety of digital inputs, inexpensive, around $30 per board, and easy to use, connecting to computer via USB and communicating using standard serial protocol [10]. Despite its relatively large current draw and power consumption it is still the best choice for our design. Our client and his associates, Fa Wang and Mehdi Shokoueinejad, have offered suggestions to help lower power consumption through use of printed circuit boards (PCB) that can transform power and by altering the code to run less frequently to avoid taking unnecessary data.

Research was also conducted to find a new source of dead space variability. The team has shifted from a pump and bladder approach to using a mechanical element. Through suggestions offered by our client, we were directed towards the possibility of using either a mechanical stepper motor or a worm gear motor to mechanically vary dead space levels. Our research dictates that while both types of motors are highly controllable and accurate, the stepper motor requires fewer pieces and less bulk to operate. This makes it ideal for use in our apnea therapy device.

In order to further the efficacy of the device, the algorithm could be improved to be able to detect apnea and shallow breathing more accurately. Research was conducted into the breathing patterns of humans during sleep cycles. According to Douglas et al

(1982), the average minute ventilation for humans is approximately 7.66 L/min when resting, 7.18 L/min while asleep and 6.46 L/min during REM sleep [11]. Also shown is that REM sleep can have huge variability in tidal volume (up to 73% reduction) which gives the team a notion of how to improve the apnea detection algorithm. Additionally, the standard breathing flow rate was found to be 1.3-1.4 m/s in humans which is data that can help relate the minute ventilation to the voltages we may receive from our flow sensor [12]. We believed this data to be necessary to improve our Arduino script.

C) Client Information

Our client is Dr. John Webster, a researcher of the Biomedical Engineering Department at the University of Wisconsin - Madison. Dr. Webster received his PhD in 1967 from the University of Rochester. He is currently working with graduate students to research a variety of topics including an implantable intracranial pressure monitor and a miniature sternal hot flash monitor. He has also been greatly interested in sleep apnea therapy and has contributed heavily to the research concerning the dead space variation technique.

D) Design Specifications Summary

The device that the client has requested must treat the effects of CSA while avoiding the complications and side-effects individual's experience using CPAP devices. While CPAP is large, bulky, and uncomfortable, this device will weigh under 1 kg, be a maximum of 200 mm in length and 80 mm in diameter, and utilize a loose-fitted, comfortable mask that will allow the user to sleep on his/her back or side. The volume of the device will be approximately 1 L, not including the mask. Further, the device must be battery operated and able to withstand heavy use. The device must have a lifespan of 3 to 4 months with an intended use of 8-10 hours per night. More design specifics can be found in Appendix A.

III. Preliminary Designs

A) Design 1: Hard Body with Pump (HBwP)

Our first design (Figure 1), is a continuation of the last semester design teams work (Hard bodied with pump design- HBwP). It is a "Smart CO_2" therapy device that varies the amount of dead space by means of an inflatable bladder. As exhibited in the diagram below, the device consists of a loose-fitted, comfortable mask, a 1 L hard plastic container, perforated and corrugated tubing, a hotwire breathing sensor, an Arduino microcontroller, an air pump, and a bladder (removed from a sphygmomanometer). The tubing, measuring 10 mm in diameter, will run entirely through the 1 L plastic container, measuring 200 mm in length. At one end of the container, the tubing will connect to the

flexible corrugated plastic tubing of the mask worn by the patient. The tubing at the opposite end of the container will be connected to an outlet which is open to allow for gas exchange with atmospheric air.

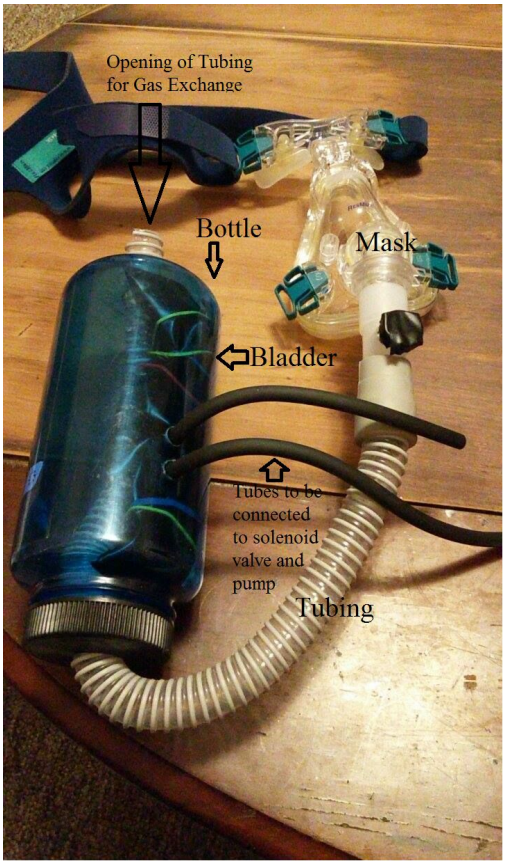

Figure 1: An image the final design built by last semester's design team. It features an inflatable bladder as the mechanism for varying dead space volume.

As the patient breathes out, the exhaled air travels through the flexible corrugated plastic tubing of the mask and into the tubing and the connected volume of the 1 L plastic cylindrical container. It should be noted that the tubing running across the inside of the container would be open to a volume of air which can be varied in order to control the amount of dead space. A hotwire built into the mask will send an analog signal to the Arduino allowing us to record the quantity of apnea events occurring over a period of time based on an algorithm we would create. Based on the presence of apneas, the Arduino would adjust the dead space of the patient as necessary in order to control the CO_2 intake and the occurrence of apneas. The battery-powered motor, by default, would drive air through the air pump to inflate the bladder; however, if an apnea were detected, the air pump would switch off and the bladder volume would decrease via diffusion, increasing the dead space. Note that all design ideas utilize the same airflow sensor, an

arduino microcontroller as the processor, and air flow tubing with perforations in the section overlapping with deadspace. The different design ideas only alter the techniques for effectively altering dead space.

B) Design 2: Soft Body with Pump

A second design proposed utilizes the same conceptual mechanisms as HBwP with a few key alterations. This design replaces the hard body with a soft, lightweight, and flexible alternative (Soft body with pump design-SBwP). The tubing would run directly through the soft body, with the available dead space being monitored by the same pump/valve technique displayed in HBwP. The channels connecting the pump and valve would then be connected directly into the the soft bodied dead space chamber, as opposed to an internal bladder. Thus, the CO_2 levels would be altered by inflating and deflating around the tubing to vary dead space directly, and the bladder component would be eliminated altogether. Many components of HBwP would be able to be scrapped, and used on SBwP, thus being cost effective. One alteration that would be necessary to change would be the coding behind when to activate the pump/valves. In HBwP, the pump is activated during normal breathing to minimize the dead space, while the valve is activated during detected apnea to increase the dead space. In SBwP, the valve is activated during normal breathing (thus minimizing the volume of the soft body dead space), while the pump is activated when apnea is detected (thus maximizing the dead space volume). View Figure 2 as a visual aid for this design.

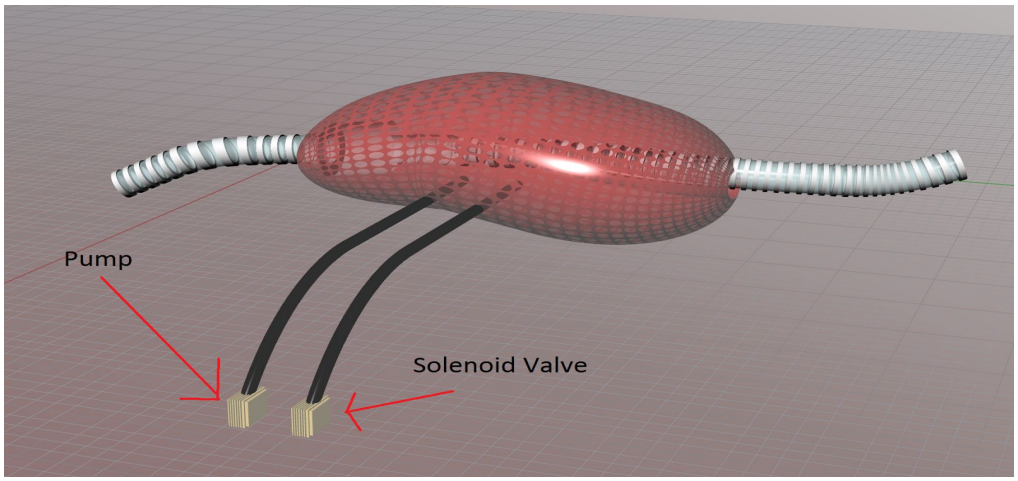

Figure 2: A CAD design of SBwP while apnea is detected (the body is inflated thus maximizing dead space). During normal breathing the body would be deflated and snug to the air tubes, thus minimizing dead space.

C) Design 3- Soft Body with Rotation (SBwR)

A final proposed design utilizes a soft body, however takes an alternate route to controlling the CO_2 levels. This design is very similar to SBwP, however it eliminates the use of pumps and valves. Instead of changing the size of the dead space, it will change the accessibility to the dead space to monitor CO_2 intake. The technique behind this will be to have an internal cover that blocks the slits that allow gas exchange between the dead space and the air tube. For this reason, it will be referred to as Soft Body with Rotation (SBwR). During normal breathing, the cover will be aligned with the tube slits, thus blocking the addition CO_2 to the airway. When apnea is detected, the cover will be rotated by a stepper motor, revealing the slits, and allowing gas exchange with the deadspace. To accomplish this, the cover will be attached directly to the stepper motor, as seen in Figure 3. One additional aspect to this design is that the air tube diameter must be enlarged at some location to fit the stepper motor. This is so the airway remains open to facilitate easy breathing.

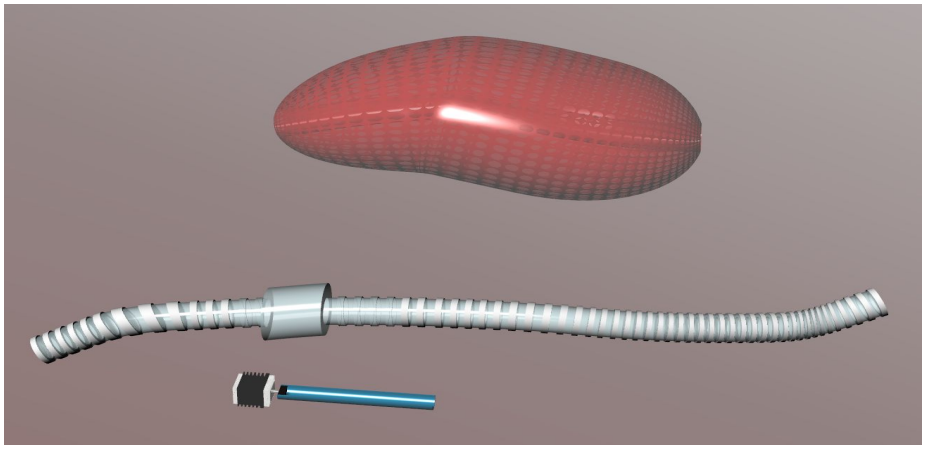

Figure 3: An image of SBwR with the parts separated for aid in visibility. When the design is fully assembled, the stepper motor/cover will be located in the air tube, and the air tube will be located in the soft body.

IV. Preliminary Design Evaluation

A. Design Matrix

	Hard bodied with pump (HBwP)	**Soft body with pump (SBwP)**	**Soft body with rotation (SBwR)**
Brief Description	Professor Webster's original design	Original design modified to have a soft body container	Uses a mechanical motor vary dead space levels
Dead Space Variability (15)	(4/5) 12	(4/5) 12	(5/5) 15
Durability (15)	(5/5) 15	(5/5) 15	(5/5) 15
Ease of Fabrication (15)	(5/5) 15	(3/5) 9	(3/5) 9
Comfort (15)	(3/5) 9	(5/5) 15	(5/5) 15
Weight (15)	(4/5) 12	(5/5) 15	(5/5) 15
Safety(10)	(5/5) 10	(5/5) 10	(5/5) 10
Cost (10)	(5/5) 10	(5/5) 10	(5/5) 10
Power Consumption (5)	(5/5) 5	(4/5) 4	(4/5) 4
Total (100)	88	90	**93**

Table 1: Design matrix to determine which preliminary design is most suitable for our client

B. Summary of Design Matrix

Our design matrix (Table 1), includes the categories dead space variability, durability, ease of fabrication, comfort, weight, safety, cost, and power consumption. Dead space variability was deemed one of the most important categories with a weight of 15 because our client, John Webster, has done a lot of research in the area and found the ability to control dead space was the most effective way to combat sleep apnea. The variation of dead space should range from the fixed dead space of the mask and central tube (minimum), to as close to the full volume of the body (approx. 1 liter) as possible. This is vital to allow the user to stay asleep.

The categories of durability, ease of fabrication, comfort, and weight were tied at 15 with dead space variability a top our design matrix as they are also very important in our design. Durability is significant because the device needs to last and must not rupture if the user were to roll over onto it. Overall, all of our designs are highly durable. Ease of fabrication was also highly considered because we need to be able build the product in a semester and have a working prototype by our final presentation. We already have a prototype of the hard body design from last semester and all that needs to be completed on this design is the circuitry and housing for the electrical components. The pump and rotational component of the soft body designs complicate the fabrication process which is why they were scored lowered. Comfort and weight are intertwined because they are both for the comfort of the user. The user needs to be able to sleep comfortably with device. It needs to be lightweight so it is able to sit on the chest, back, or on the bed without a huge hassle, therefore it needs to be less than 1kg. Additionally, because we want the device to be the most appealing to all users, it must be comfortable which is why the soft bodied designs scored higher in this aspect. The soft body is highly effective due to the fact it can form fit to the user's body and is very light weight.

Safety and cost were tied as the next two most important categories at 10 a piece. We are not very concerned with the safety of many of these designs. The algorithm is designed to prevent the wearer of this device from ever experiencing difficulties breathing making safety a lower weighted criteria. The cost of the device is also a lower weighted category because many of the parts for our designs are the same so they are all similarly priced. Funding is available for prototyping which allows the team more freedom in the design than last semester when there was a $100 budget.

The lowest weighted category was power consumption with a weight of 5. The power consumption would be the most efficient in Professor Webster's design because it only requires a 9V battery and only one component would be operated at a time. The soft body with rotation potentially needs two motors and has a higher power consumption than the hard body design. The soft body with pump also exhibits higher

power consumption than Professor Webster's design as it must run the pump more frequently. This makes the initial design the best in regards to power consumption. .

C. Proposed Final Design

Upon analyzing the results of the design matrix and further considering the benefits and pitfalls of each alternative, our team concluded that the soft body with rotation design is the most effective. While the hard body design is highly durable, cost effective and power efficient, while we were testing it at the beginning of the semester, it had too many issues and it was decided to completely re-design. The soft body with pump design was also highly rated but it's pitfall was that it didn't have as high an ability to vary dead space as the soft body with rotation. We plan to fabricate the prototype in the coming weeks.

V. Fabrication/Development Process

A) Materials

The final design of our "Smart CO_2" therapy device (SBwR) consists primarily of a loose-fitting, comfortable mask, a 1 L soft plastic container, perforated corrugated tubing, an air flow sensor, an Arduino microcontroller, and a stepper motor.
The mask attaches the device to the nose and mouth of the patient in order extend their respiratory tract. Elastic straps are used to secure the mask to an individual in a snug manner. The cylindrical 1 L container, measuring roughly 11.25"H x 5.75"W (when flat), rests on the sternum of a sleeping patient or next to them. The container is made of a thin plastic for durability and allows sufficient flexibility without losing integrity. The tubing used is a flexible plastic with perforations located within the plastic container to open up access to the increased volume of dead space. The tubing extends from the mask, through the container and opens at the distal end of the bottle for gas exchange. The flow sensor is pre-manufactured and converts air flow to voltages from which we can detect apneas using the simple algorithm we developed (detailed later in the Methods section). The processing of data from the sensor is handled by an Arduino Uno microcontroller. The algorithm is programmed to operate a 12V bipolar stepper motor which turns a plastic cover to reveal holes in the breathing tube for dead space variation. The motor has four individual leads that allow it to be activated to turn both clockwise and counterclockwise with an accuracy of 1.8º per step.

B) Methods

The fabrication process last semester consisted of three parts:

Algorithm Development

We first developed an algorithm to detect apneas based on voltage data received from the flow sensor. This algorithm transduces air flow rate into electrical signals. Through testing and calibrating the flow sensor under conditions of normal, reduced and no breathing, we programmed our Arduino microcontroller to count apneas and take the proper countermeasures regarding dead space within the device (Figure 4). A copy of our algorithm with annotations can be found in Appendix D.

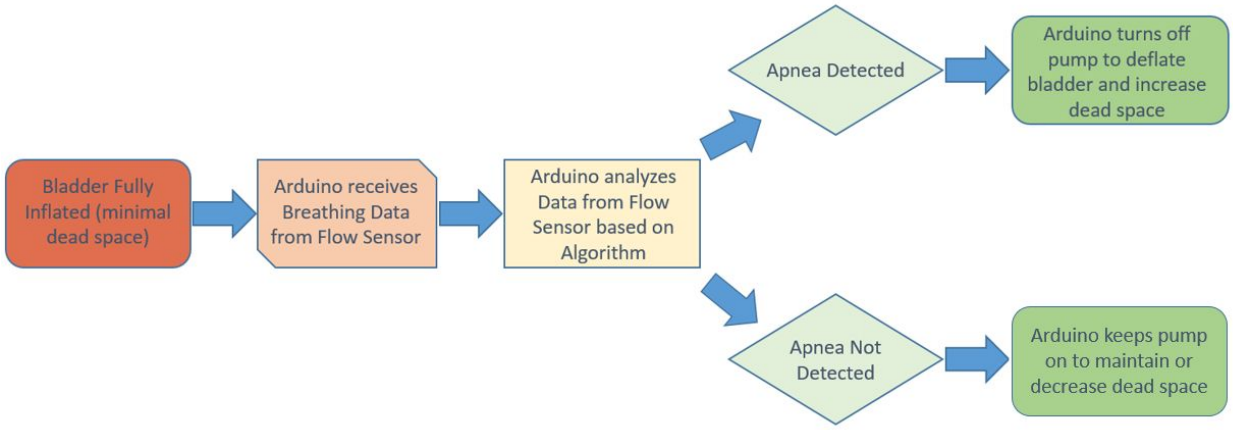

Figure 4: Flow Diagram of the function of the varying dead space system. The algorithm for detecting apnea will be utilized in the analysis of the voltage data from the flow sensor.

Electrical Components

After our algorithm, we set up the circuit that will later be installed within our device (Figure 5). This circuit connects the flow sensor (right) to the Arduino microcontroller containing our algorithm (middle). When an apnea is detected by the flow sensor and Arduino microcontroller, the algorithm will make the rotate the stepper motor to uncover slits in the plastic tubing to increase the dead space. Prior to fabrication, extensive testing was done on this circuit to assure it functions as desired and would not fail once installed.

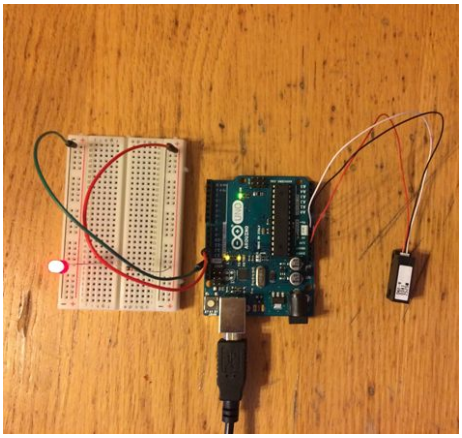

Figure 5: Apnea detection circuit including a flow sensor (right), microcontroller, and resistor LED combo (left). The LED lights up when an apnea is detected by the algorithm to show the circuit is working.

Physical Components

Two 9 mm diameter holes will be drilled into the top of the plastic container to allow for the stepper motor to be connected to the electronic components of the device outside of the container. A 17 mm diameter hole will be drilled into the cap and bottom of the container, in order to accommodate the plastic tubing running through the container. At both ends, the hole will be sealed off by rubber grommets around the tubing to provide an airtight seal. Adhesive will be used to ensure the tightness of the seal, in the event that the seal provided by the grommet is not sufficient. This tube will run along the underside of the container and be secured by double-sided adhesive tape. Perforations, spaced one inch apart, are cut along the tube so as to have a variable volume of air within the container.

VI. Testing/Results

After fabrication of our SBwR prototype, we plan to spend the remainder of the semester on testing. We need to test the circuitry and device to ensure it properly regulates dead space and, in turn, breathing. Also, we want to ensure comfort for the user by running tests with the user wearing the device for both short time periods (a few minutes) and overnight.

VII. Conclusion

The current treatments for sleep apnea, such as CPAP devices, are often bulky, uncomfortable, and rejected by many users. Our client, Dr. Webster, asked us to design and develop a lighter device that uses a “Smart CO2” dead space varying technique developed in his research. A suitable alternative has been designed and will be fabricated during the semester. The goal of this device is to build and test an

autonomous prototype to show the viability of the “Smart CO2” technique. We plan to show that it is possible to detect and respond to apneas using this technique. Once the soft bodied design has been completed, the rest of the semester will be testing the effectiveness of the new design. We would like to determine the durability of this product and battery lifetime of this device, and to conduct stress-cycle testing. Between this semester and last semester, it has been shown that this concept appears worth advancing beyond this proof-of-concept stage and may, in the long run, prove to be a viable alternative to CPAP.

VIII. References

[1] Young T, Peppard PE, Gottlieb DJ (2002) Epidemiology of obstructive sleep apnea: a population health perspective. Am J Respir Crit Care Med 165:1217-1239

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

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

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

[6] Morgenthaler TI, Kagramanov V, Hanak V, Decker PA (2006) Complex sleep apnea syndrome: is it a unique clinical syndrome? SLEEP-NEW YORK THEN WESTCHESTER-29:1203

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

[8] “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

[9] 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.

[10] Varesano, Fabio. "What Is Arduino, Why We Choose It, What Can We Do with It?" What Is Arduino, Why We Choose It, What Can We Do with It? | Varesano.net. N.p., 4 June 2010. Web. 27 Nov. 2016.

[11] Douglas, N J et al. "Respiration during Sleep in Normal Man." *Thorax* 37.11 (1982): 840–844. Print.

[12] Tang, Julian W., Andre D. Nicolle, Christian A. Klettner, Jovan Pantelic, Liangde Wang, Amin Bin Suhaimi, Ashlynn Y. L. Tan, Garrett W. X. Ong, Ruikun Su, Chandra Sekhar, David D. W. Cheong, and Kwok Wai Tham. "Airflow Dynamics of Human Jets: Sneezing and Breathing - Potential Sources of Infectious Aerosols." PLoS ONE. Public Library of Science, 2013. Web. 27 Nov. 2016.

IX. Appendix

A) PDS

Problem Statement/Function:

Clinically significant sleep apnea is a sleep disorder that takes place when person's breathing is obstructed or ceases during sleep. Those who suffer from sleep apnea develop increased risk of heart attack, high-blood pressure, arrhythmia, stroke, and diabetes. Continuous Positive Airway Pressure (CPAP) is the current standard for therapy. However, approximately half of all patients suffering from sleep apnea tend to reject it due to complications that include discomfort, nasal congestion, headaches, and continued tiredness. Continuous dead space rebreathing has been researched and been observed to stabilize respiratory output in patients with central sleep apnea and also mild to severe obstructive sleep apnea without the complications of CPAP.

Our team has thus been assigned the task of designing and fabricating a "Variable Dead Space Rebreathe Device" based on guidelines and research conducted by our client Dr. John Webster et al. When a breath exits from your body there is always a residual volume that remains in the non-gas exchanging section of the airway. This region,

known as dead space, retains CO_2 rich air that will precede fresh air on the next breath. The amount of dead space depends on the distance the air has to travel to escape the respiratory system and can in effect be increased using an external extension (i.e. plastic tubing). The longer the extension used in the variable dead space rebreathe device causes there to be a greater volume of CO_2 in a person's airway. This increased CO_2 generates stronger stimuli in the brain for inhalation.

Dr. Webster wants a device that will vary the amount of dead space in response to the presence or lack of an apnea. The therapy device our team is currently designing consists of a mask connected to a one liter plastic container by way of flexible plastic tubing. The container's inlet will be connected to the plastic tubing and the outlet will be open for fresh airflow. The container will also accommodate an inflatable bladder and the tubing within the container will have a series of slits that will serve to vary the dead space. Specifically, dead space is increased when the bladder is deflated (apnea present) and decreased when inflated (no apnea present). A battery-powered motor positioned directly below the inlet will direct the bladder to either expand or deflate depending on the presence of apneas. A flow sensor measuring the presence or absence of a patient's breathing will also be placed within the container in order to control the amount of dead-space volume available for rebreathing.

Client requirements:

- A functional prototype of the device described to us, available in time for preliminary testing
- Use of inflating/deflating bladder design to increase and decrease dead-space while breathing
- Comfortable application of device to the chest during sleep
- Active control of breathing dead-space throughout 8-10 h of sleep

Design requirements:

- Lightweight/Compact
- Durable
- Battery Operated (independent of outlets)
- Comfortable application of mask to the face and device to the chest

1. Physical and Operational Characteristics

a. *Performance requirements*: The product must be able to function for a period of 8-10 hrs, the average length of sleep for a human, in a single battery charge. Ideally, the batteries will be rechargeable to minimize cost of use. The product must be able to endure numerous strain cycles on the body of the device, as well as on the breathing tube from inflating and deflating the internal bladder. Furthermore, the product should be able to support the weight of an average human body lying on it, as some users may roll in their sleep.

b. *Safety*: The nose/face mask of the design might lead to skin irritation, nasal congestion, and/or dryness. The increase in dead-space during respiration could potentially lead to difficulty in breathing or shortness of breath. The mask should be easy to take on and off to prevent causing a potentially dangerous situation. A small rigid breathing tube should prevent the inflating bladder in the device from blocking the airway.

c. *Accuracy and Reliability:* The product should be able to function each night for 8-10 hrs. The air pump and release valve should be able to inflate and deflate the air bladder at controlled intervals of approximately 10ml.

d. Life in Service: As the product will be used every night of its service life, it will likely experience wear and tear and will need to be serviced. The most likely need of service will be battery replacements, which will occur at a period of time dictated by the lifespan of the chosen rechargeable batteries. The flow sensor in the tubing may also corrode from moisture during breathing and need replacing as well. The object should be functional for 1 year, or more, with regular daily use.

e. Shelf Life: As the product lacks any biological components, it will not need stringent storage conditions. The product should be stored in a humidity controlled room at room temperature to minimize strain on the materials and electronic components in the device. The shelf life will likely be limited primarily by the lifespan of the batteries. These parts may, in some capacity, be able to be replaced without need for an entirely new product.

f. Operating Environment: Overall, the environmental conditions will be fairly moderate, and the product will likely not operate in any extreme conditions. The device will be attached to the users as they sleep on any given night and will contain breath directly from them. The high humidity of their breath may affect the lifespan of the internal components. Users may roll in their sleep, and therefore the device will need to

be able to withstand the weight of an average human body. Further, if we pursue a design in which the device is not harnessed to the user, it is possible that it may fall off of the user's bed. Therefore, it should be able to withstand such a force.

g. Ergonomics: The product will feature a comfortable breathing mask attached to the face of the user. No positive pressure environment is created eliminating the need for the mask to be forcefully fastened onto the user's face. The device will ideally rest on the chest of a back-sleeping user, and to the side of side- and front- sleeping users. For the former option, the product will need to be light enough to rest on a user's chest comfortably, and will need to not roll off. The product should also not cause heat or excessive noise. Comfort is an important criterion.

h. Size: The product casing should have no sharp corners; not exceeding 15 cm in diameter and 30 cm in length. This will help to ensure that the device is not too large or bulky when being fitted on those with smaller body types. This size limitation is also to prevent having unnecessary amounts of dead-space in the breathing tube.

i. Weight: The product will need to be light enough to rest on a user's chest comfortably. Ideally, it would weigh under 1 kg which should not be a problem as the designs we are considering should weigh less than 0.5 kg.

j. Materials: As previously stated, users may roll onto the product during the night, so the main body should be made out of a durable material. The external tubing should be flexible so that it is comfortable for the user.

k. Aesthetics, Appearance, and Finish: There are no requirements for color but the casing should be transparent in order to observe whether or not the internal bladder is inflating/deflating properly in response to breathing patterns. The electronics should be covered with opaque material to prevent ambient light that may irritate the user and physical damage to the electronics.

2. Production Characteristics

a. Quantity: Only one prototype is currently needed.

b. Target Product Cost: Our client has given a target cost of approximately $100 for the device but additional funds may be used to create the prototype

3. Miscellaneous

a. Standards and Specifications: There are currently no federal standards we must meet for this product.

b. Customer: Our client would like the sleep apnea therapy device to be compact and portable. The design is already in place and just needs fabrication and testing

c. Patient-related concerns: The comfort level of the patient must be high or else it may be rejected. If the product is rejected by the subject it will be of no use. The patient should consider sterilizing the mask and connective tubing after prolonged use to prevent infection and build-up of bacteria.

d. Competition: In previous years, Dr. Webster has offered this project to other BME Design groups, so there are similar items which exist. However, Dr. Webster has modified his criteria and requirements, so none of these products are very similar to what we are attempting to create. In our research, we have not come across any third party designs that are similar to ours.

B) Algorithm

The applied algorithm uses voltage values obtained from the flow sensor. The 10-bit resolution Arduino microcontroller converts ADC values from the sensor into voltage values. A 10 (sec) sample of 50 voltage values are taken and put into an array. The maximum and minimum values in this array are calculated and subtracted to produce a voltage tidal volume. The tidal volume is matched with a 0.01V threshold. If the tidal volume falls below the threshold, the solenoid valve is activated for 2 (sec) to increase dead space by deflating the bladder. If the threshold is not reached, it is not considered an apnea and a place holding integer is incremented. After 1 (hr) or 360 cycles of no apnea being detected, the pump is activated for 2 (sec) to inflate the bladder and decrease dead space. The code with comments are detailed below.

```
// Initiate integers for electronic components
// Initiate float array to sample voltages from flow sensor
// Initiate Apnea toggle and max and min voltage floats
int pump = 8;
int valve = 9;
int adc;
float Voltage;
float Volts[50];
```

```
float maxvolt;
float minvolt;
int Apnea = 0;
// int to time when bladder should reinflate due to extended normal breathing
int normal = 0;

void setup() {
 // Designate Analog 0 as input from flow sensor
 // Designate pump and valve as inputs set to LOW
 Serial.begin(9600)
 pinMode(A0, INPUT);
 pinMode(pump, OUTPUT);
 pinMode(valve, OUTPUT);
 digitalWrite(pump, LOW);
 digitalWrite(valve, LOW);
}

void loop() {
  // Capture 50 voltage points over 10 seconds
  for(int i = 0; i < 50; i++){
  // Convert analog to digital values to voltage values
  adc = analogRead(A0);
  Voltage = adc * (5.0 / 1023.0);
  Volts[i] = Voltage;
  delay(200);
  }

  for(int i = 0; i < 49; i++){
  // Find maximum and minimum voltages from the sample
  maxvolt = max(Volts[i],Volts[i+1]);
  minvolt = min(Volts[i],Volts[i+1]);
  }

  // Subtract max and min to find voltage tidal volume
  // Detect apnea if TV is below 0.01V
  if(maxvolt-minvolt <= 0.01){
    digitalWrite(LED, HIGH);
    Apnea = 1;
  }
```

```
 if(maxvolt-minvolt > 0.01){
  digitalWrite(LED, LOW);
  Apnea = 0;
 }

 // Activate solenoid valve for 2 seconds if Apnea is detected
 if(Apnea == 1){
  digitalWrite(valve, HIGH);
  delay(2000);
  digitalWrite(valve, LOW);
 }

 // Count up int normal in response to no apnea
 if(Apnea == 0){
  normal++;
 }

 // Activate pump to decrease dead space after 1 hr of normal breathing
 // Activates pump for 2 seconds and resets int normal
 if{normal == 360){
  digitalWrite(pump, HIGH);
  delay(2000);
  digitalWrite(pump, LOW);
  normal = 0;
 }
}
```