

Sleep Apnea “Smart CO₂” Therapy Device

BME 200/300

10/19/2016

Client: Professor John Webster

Advisor: Professor Jeremy Rogers

Team members: William Guns (Team Leader), Calvin Hedberg (BWIG), Tanya Iskandar (Team Communicator), Aman Nihal (BPAG) and John Riley (BSAC)

Table of Contents:

- Abstract
- I. Introduction
 - A. Motivation / Global / Societal Impact
 - B. Existing Devices / Current Methods
 - C. Problem Statement
- II. Background
 - A. Background Research including Relevant Biology and Physiology
 - B. Research Required to Design and Build Prototype
 - C. Client Information
 - D. Design Specification Summary
- III. Preliminary Designs
- IV. Preliminary Design Evaluation
- V. Fabrication / Development Process
 - A. Materials
 - B. Methods
 - C. Final Prototype
 - D. Testing
- VI. Results
- VII. Discussion
- VIII. Conclusions
- IX. References
- X. Appendix
 - A. PDS
 - B. Design Matrix
 - C. Materials

Abstract:

Sleep Apnea is a sleep disorder which currently prevents more than 30 million Americans from reaching “deep” sleep. In many cases, sleep apnea has been known to increase risk of heart issues, high blood pressure, stroke, and other diseases. Current Sleep Apnea treatments, such as the Continuous Positive Airway Pressure (CPAP) device are rejected by nearly 50% of those who try them as they are vastly uncomfortable and loud, and can cause nasal congestion and dryness. As an alternative, we propose a device using the “Smart CO₂” system developed in the lab of our client, Dr. John Webster. Smart CO₂ elevates the amount of CO₂ in the lungs by increasing dead space, effectively preventing the levels of CO₂ from falling below the apnea threshold of P_ACO₂ (partial pressure of CO₂ in arterial blood) and stimulating the body to breathe normally, but not to the point that it wakes the user. This concept has been proven to reduce the occurrence of apneas, and shows great potential as a long-term alternative to CPAP.

I. Introduction

A) Motivation / Global and/or Societal Impact

Sleep Apnea is a disorder characterized by interruptions in the natural breathing cycle throughout the course of the night (Young et al, 2002), causing frequent waking. This prevents those afflicted by this disorder from reaching REM sleep, the portion of sleep that “recharges” the brain. This lack of proper rest has been correlated with many issues, including decreased heart health, reduced cognitive function, and a reduction in overall wellness (Gottlieb et al, 2010). There are 3 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 a lack of neurological drive to continue breathing, and a combination of the two different apneas (White, 1985). In total, approximately 10% of the population of the U.S. suffers from some form of sleep apnea (Peppard et al, 2013). Of these, a large majority suffer from OSA, but a smaller portion, approximately 15%, exhibit both forms (Morgenthaler et al, 2006).

B) Existing Devices / Current Methods

The current popular treatment for sleep apnea is CPAP (Constant Positive Air Pressure). CPAP works by increasing the air pressure to the mouth and nose of the user which forces the airways to remain open, thus preventing the airway from closing when the user breathes in. CPAP is extremely effective in preventing OSA. However, many of those who use CPAP may ultimately end up rejecting it. CPAP requires that the mask be sealed tightly to a user’s face in order to prevent air leakage, and this has been suggested to be uncomfortable for users. CPAP has also been known to cause nasal congestion, nose and throat dryness, and other minor irritations. Furthermore, CPAP devices are large and loud which is not ideal for sleep. All of these factors contribute to a treatment rejection rate of up to 50% (Catcheside, 2010). As a result, there is a sizable market for anyone who can create a satisfactory alternative that reduces or eliminates the negative effects caused by 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 afflicted 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 sleep alternative apnea treatment device using the variable dead space technique developed in his lab.

II. Background

A) Background research including relevant biology and physiology

The volume of air remaining in the respiratory tract following expiration is called dead space, which is approximately 150 mL in a standard human body. The air in the dead space is CO₂ rich, having just left the lungs, but not having been able to equilibrate with atmospheric air (Guyton et al, 2010, Johns Hopkins University, 1995). By increasing the dead space in the respiratory tract, it would theoretically be possible to increase an individual's CO₂ intake. It has been found that by increasing the PCO₂ in the bloodstream of an individual, the user's breathing patterns can be increased without causing the same level of wakefulness caused by an apnea. This, then, has been shown to be effective in reducing the symptoms of central sleep apnea (Dempsey et al, 1985, Eckert et al, 2013).

B) Research required to design and build prototype

First and foremost, our client wants this design to use a bladder as a means to vary dead space. Our team, then, will have to decide what type of bladder will be used to accomplish this. We are currently considering using the inflatable part of a blood pressure cuff, known as a sphygmomanometer. However, to understand the efficacy of this, further research will be required. Moreover, we will have to research the most efficient flow sensor available on the market within our limited price range of \$100. Ideally, we would choose one that detects apneas with a high degree of accuracy, however this is unlikely as the high-accuracy sensors are typically priced in the \$100-200 range.

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 Smart CO₂ idea. Dr. Webster would like to see this research come to fruition by creating a working prototype that uses the Smart CO₂ concept.

D) Design specifications summary

Ideally, this product would be everything that CPAP fails to be. Whereas 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-fitting, comfortable mask that will allow the user to sleep on his/her back or side. The volume of the device should be approximately 1 L, not including the mask. Further, the device must be battery operated and able to withstand heavy use. The device should also have a lifespan of 3 to 4 months with an intended 8-10 h of use per night. More design specifics can be found in the Appendix.

III. Preliminary Designs

Our first design (Figure 1), is a “Smart CO₂” device that varies the amount of dead space by means of an inflatable bladder. As exhibited in the diagram below, the device will consist of a loose-fitted, comfortable mask, a 1 L plastic container, perforated and corrugated tubing, a hotwire breathing sensor, an Arduino microcontroller, an air pump, a pressure release valve, 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.

As the patient breathes out, the exhaled breath 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 the number of apneas per period of time, the Arduino will then either increase or decrease the dead space of the patient, as necessary, in order to both minimize the CO₂ intake and the occurrence of apneas. A battery-powered motor drives air through the air pump to inflate the bladder and the valve is used to prevent bladder deflation.

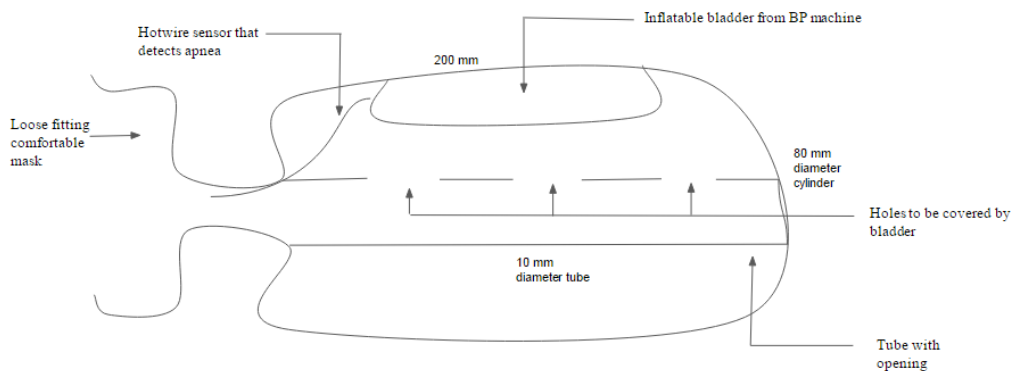


Figure 1). A diagram illustrating the initial design considered for the Smart CO₂ device, which featured an inflatable bladder as the mechanism for varying dead space volume.

The previous design works well for maximizing volume control (thus resulting in more variation in our dead space) but may not be optimal for control of the volume of the container, as it has to fill a uniquely shaped volume. In response, our team created the design shown below in Figure 2 in an attempt to correct this. It divides the container into three subunits. Each small section will be equipped with an inflatable balloon. This design has an identical programming system regarding the measurement of apneas as the previous design, the key difference being that by using three separate, more ductile balloons to fill the volume, a more complete control could be achieved, and with smaller motors and pumps as well.

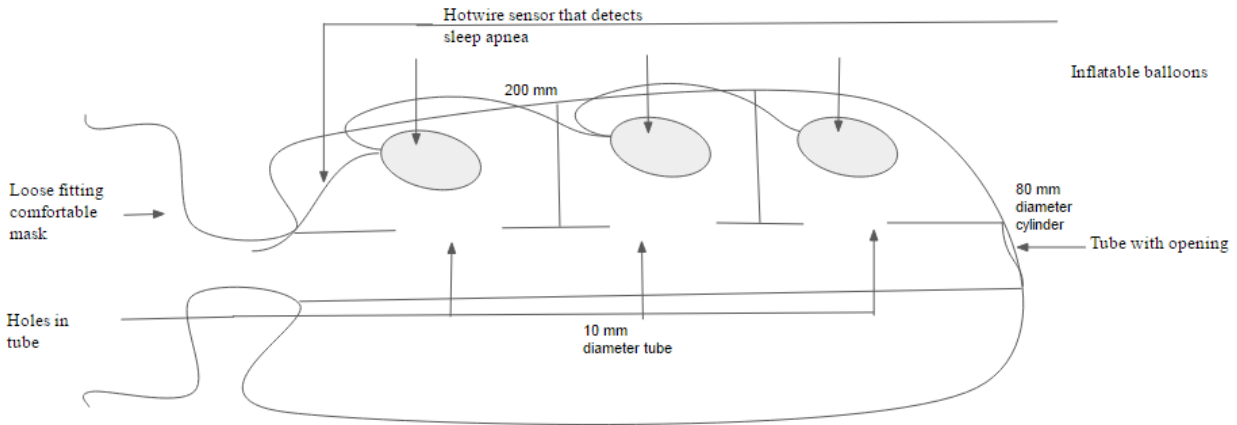


Figure 2). A diagram illustrating the second design considered for the Smart CO₂ device. This design is unique in that it uses 3 separate balloons to vary 3 separate containers for air.

The final design concept, shown below in figure 3, uses an air-sealed diaphragm as the mechanism for dead space variation. The benefit from this particular design is that the minimum volume of dead space would be defined during the creation of the apparatus, alleviating the possibility in the other two designs of incomplete volume filling. This design would feature a pump removing pressure from the area designated by the diaphragm, instead of a pump increasing pressure. It is believed this would be a negligible difference. This device features the same mechanism as the previous designs for measuring and responding to the prevalence of apneas over a period of time. An extra design feature of this design that was not included in the diagram is the possibility of a smaller tube attached to the mask to allow for this device to be positioned farther away from the patient. The volume would remain the same due to the decrease in diameter being correlated with an increase in length, and the change in air pressure during a breath would be negligible, due to the low viscosity of air. This feature would allow the device to be placed on a bedside table or at the patient's side to allow for side and front sleeping positions.

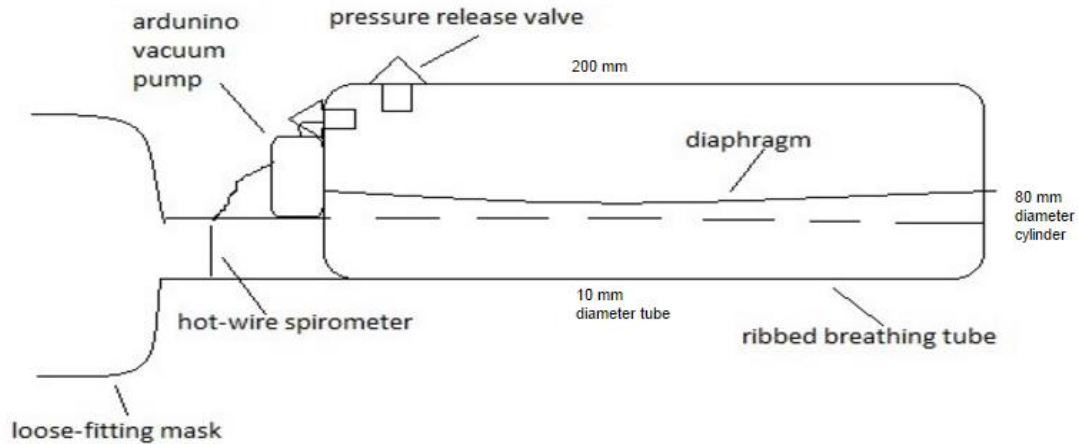


Figure 3). A diagram illustrating the third design considered for the Smart CO₂ device. This design features a deflatable diaphragm in order to vary dead space.

IV. Preliminary design evaluation

Based on the design matrix (see Appendix) as well as our client's preferences, our team concluded that Professor Webster's original design, as detailed above (Figure 1), would be the most effective for fulfilling our project design specifications in an efficient and cost-effective manner. Below are the criteria that we considered for our design matrix:

a) Dead Space Variability: The means to vary dead space is one of the most important criterion for our design. It is important to have the largest range of variation in dead space as possible. The balloon-based design guarantees the optimal range of volume. The diaphragm-based design has the potential to span the full range of volume, however, it may be difficult for it to achieve the maximal volume as a large vacuum would need to be produced. The design team has doubts about whether or not the original design, using the blood pressure cuff, would have the proper elasticity required to fully occupy the entire volume of the container when fully inflated. However, these concerns will be resolved upon the testing of the inflation of the blood pressure cuff.

b) Ease of Fabrication: In this criterion, our client's initial design is far superior to the others. Among the three designs, both the coding for the hotwire sensor and the manufacturing of the outer regions of the device will be fairly constant. However, the three designs differ slightly upon evaluation of the devices used to vary the dead space. The balloon design would require three separate internal compartments and three separate motors to be intricately hooked up to these balloons. The diaphragm design, on the other hand, would require careful gluing of the diaphragm and a positive pressure valve. Finally, our client's design would only require us to insert and secure the bladder from a sphygmomanometer and have it hooked up to a small air pump.

c) *Safety*: All three designs would be fairly safe. The ease of use, and the coding (which is where we will deal with any potential safety issues) required for them to work properly will be constant among them, making safety essentially a non-factor.

d) *Weight*: Our client would prefer the lightest possible design without inhibiting function. Professor Webster's design and the diaphragm modification are very lightweight. Aside from the mask, tubing, and bladder modification, there is not much weight to either of these. On the other hand, the triple balloon design would weigh the most because it requires three motors in its design instead of just one. The additional weight, although not completely insurmountable, handicaps this design.

e) *Power Consumption*: Here, the balloon design would be the best as the smaller balloons would be more efficient and require less energy than both the bulky bladder of Prof. Webster's design and the diaphragm used in the third design.

f) *Durability*: The blood pressure cuff is designed to be used in repeated stress cycles, and due to the low elasticity of the cuff, it would likely withstand wear and tear. In contrast, the balloon and diaphragm based designs feature highly ductile rubber undergoing frequent stress cycles with large degrees of strain at their maximal inflation and deflation levels. This would increase the chances of the rubber pieces failing prematurely compared to the blood pressure cuff design.

g) *Comfort*: All of these design alternatives will be equally comfortable as they all will have the same loose-fitting mask, and a relatively low mass.

h) *Cost*: Our client's initial design outweighs the others in this criterion too. Since the other two designs are more complicated, they would necessarily cost more.

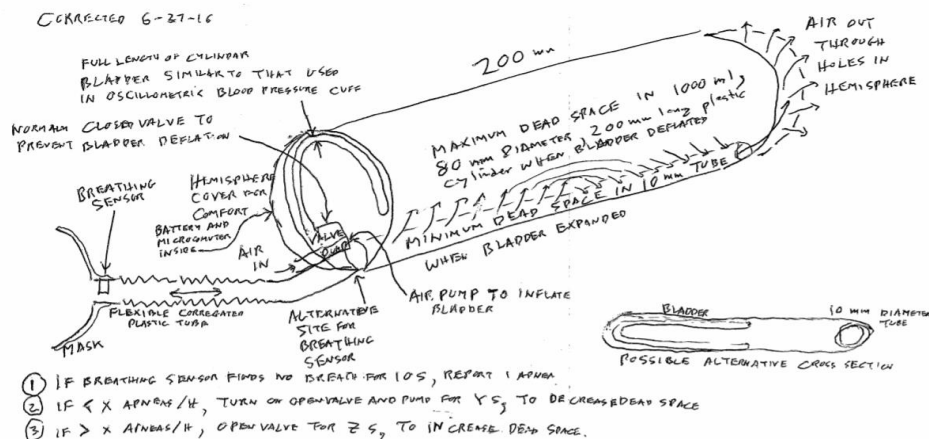


Figure 4). Proposed Final Design

Though we have determined our client's initial design to be the best one, and the one we will pursue, there are many aspects of the other designs that we may incorporate into our final design. For example, the pressure release valve present in the Diaphragm design would benefit the initial design greatly as it would allow easier deflation of the air bladder.

V. Fabrication/Development Process

A) Materials

Our Smart CO₂ device will consist of a loose-fitting, comfortable mask, a 1 L plastic cylindrical container, perforated and corrugated tubing, a hotwire breathing sensor or other form of flow sensor, an Arduino microcontroller, a battery powered air pump, a pressure release valve, and a bladder (removed from a sphygmomanometer). A list of all parts, quantity, and estimated cost can be found in the Appendix.

The mask will function to attach the device to the nose and mouth of the patient to extend their respiratory tract. Straps will be used to secure the mask to a snug but not tight fit. The 1 L container, measuring 200 mm in length and 80 mm in diameter, will be cylindrical in shape to be able to rest on the sternum of a sleeping patient or next to them as they sleep on their side. The container will be made of a thick plastic for durability and to allow expansion of the air bladder against it without losing integrity. The tubing used in the design will be a flexible plastic with perforations located within the plastic container to open up access to the increased volume of dead space. The tubing will extend from the mask, through the container and be open to the air for gas exchange on the other side. The flow sensor will either be a temperature probe that sends electrical signals based on cooling rates or another manufactured flow sensor that converts air flow to electrical signals for use in apnea detection. The processing of data from the sensor will be handled by an Arduino Uno micro controller. The air pump is a small pump, approximately 13 mm in diameter and 13 mm in length that is battery-powered and is used to inflate the air bladder. A pressure release valve will be included with pump to allow air out of the bladder. The air bladder itself will be the plastic cuff included in a sphygmomanometer and will have an approximate volume of 1 L. This bladder will inflate and deflate to vary dead space.

B) Methods

The fabrication process will consist of three parts:

First, we need to develop an algorithm to detect apnea based on data received from the flow sensor. This algorithm would need to transduce variables such as the hot wire cooling rate or air flow rate into electrical signals that represent normal breathing and apnea/shallow breathing. Testing and calibrating the chosen flow meter under

conditions of normal, reduced and ceasing of breath will result in an apnea threshold. Using this threshold, apneas can be counted and proper countermeasures can be taken in the form of varying the levels of dead space within the device (Figure 5).

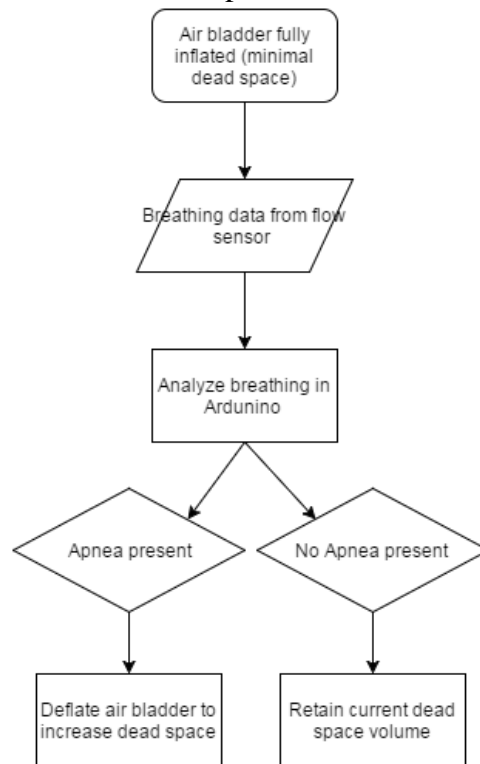


Figure 5). Flow Diagram of the function of the varying dead space system. The algorithm for detecting apnea will be utilized in the analysis of the breathing data from the flow sensor.

Second, we need to insert and secure the sphygmomanometer air bladder to the top of the inside of the 1 L container and connect it to a miniature air pump. The air pump will be connected to and controlled by an Arduino micro controller that is programmed with the apnea detection algorithm. The Arduino will be connected to the hot-wire sensor/flow meter which will serve as an input. All the electronics will ideally be concealed in a circuit box or similar container.

Third, we need to insert a ribbed plastic tube into the container along the bottom/ventral side and safely secure it. This tube will be ribbed inside the container and closed where it comes out of the device to connect to the mask. An opening will be cut in the distal end of the container to allow the tube to extend out into fresh air for gas exchange. At the end of these steps we should have a fully functioning Variable Dead Space CO₂ device.

C) Final prototype

The final prototype will be modeled after the design in Figure 4. Changes and alterations will be made as seen fit during the fabrication process.

D) Testing

As we have just finished determining our proposed design, we have not yet conducted any testing. Once testing does begin, it is essential that our team first tests whether or not the elasticity of the bladder will allow it to fully occupy the entire volume of the container when fully inflated. Further, we need to determine the threshold for apnea and figure out the standard breathing range of an individual not affected by apnea. This data will be analyzed by the Arduino to detect whether or not an apnea is present. A final test our team anticipates involves the inner tubing contained within the 1 L container. The dimensions for the inner tube we anticipate (see Figure 4) might not be the ones needed. To test the ideal tube diameter, Dr. Webster suggested that we use different-sized soda straws and find the diameter that is easiest to breathe through.

VI. Results

At this point of our design process, no results are available.

VII. Discussion

Though we have not conducted any testing yet, and though we have no data to analyze, our client is confident that if we are able to successfully construct this device, it will be the only one of its kind. He hopes that, in time, this device will reach human testing. However, reaching this point may prove to be difficult. Human testing is strictly controlled by law given the ethical implications associated with it. Given the time constraints and scope of this class, it is highly unlikely that we will be able to do anything of this magnitude. As an alternative, a colleague of our client has access to machines that can simulate breathing. Using these machines would allow us to test our device without having to go through an Institutional Review Board.

VIII. Conclusions

The current treatments for sleep apnea, such as CPAP devices, are often bulky, uncomfortable, and ineffective/rejected by most users. Our client, Dr. Webster, has asked us to design and develop a lighter device that uses a Smart CO₂ dead space varying technique developed in his research. This technique uses an air bladder and is mechanically different than the one used in previous designs. At this stage, we have not yet created a prototype of the device and therefore have not conducted any significant testing. The goal is to build and test a prototype to show the viability of the Smart CO₂ technique. Future work to achieve this begins with deciding on materials to be used in the fabrication of the device. An exact budget must be formed and parts that are not readily available from the BME labs will be ordered. Following this process will be the development of the sleep apnea detection algorithm and programming of a micro controller. Testing will be done on each part of the device, including the inflation of the air bladder and the accuracy of the flow meter, as well as on the device as a whole. The end goal is testing the device for effectiveness, as a proof-of-concept.

IX. References

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

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.

Eckert DJ, White DP, Jordan AS, Malhotra A, and Wellman A. Defining phenotypic causes of obstructive sleep apnea. Identification of novel therapeutic targets. *Am J Respir Crit Care Med* 188: 996-1004, 2013.

EZ, S. (2016, September 10). Privacy policy. Retrieved October 14, 2016, from <http://snoozeez.com/category/sleep-apnea/cpap/>

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

Guyton, A. C., Hall, J. E., & Guyton, J. W. (2010). *Guyton and hall textbook of medical physiology: With student consult online access*, 12th edition. New Delhi, India: Saunders (2010)

"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

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

Peppard PE, Young T, Barnet JH, Palta M, Hagen EW, Hla KM (2013) Increased prevalence of sleep-disordered breathing in adults. *Am J Epidemiol*:kws342

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

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

X. Appendix

A) PDS

Problem Statement/Function:

Clinically significant sleep apnea is a sleep disorder that takes place when person's breathing is interrupted during sleep. Those who suffer from sleep apnea and experience interrupted sleep develop increased risks to maladies like heart attacks, high-blood pressure, arrhythmias, strokes, and diabetes. Currently, Continuous Positive Airway Pressure (CPAP) is the standard therapy despite the fact that approximately half of all patients suffering from sleep apnea cannot adhere to it well due to complications that include discomfort, nasal congestion, headaches, and continued tiredness. Continuous dead space rebreathing has also been researched and has been seen 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 Rebreath Device" (also called "Smart CO₂") based on guidelines and research conducted by our client Dr. John Webster (et al.). Dr. Webster explained that when we inhale or exhale not all of the CO₂ exits our lungs. There is an area known as dead space where CO₂ rich air remains in the conducting airways. 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 tubing used in the variable dead space rebreath device causes there to be a greater volume of CO₂ in a person's airway. Moreover, the increased CO₂ generates stronger brain signals telling the body to inhale.

Dr. Webster wants a device that will vary the amount of dead space in response to the presence or lack of an apnea. The Smart CO₂ device our team is currently designing will consist 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 apneas or no apneas. Airstream sensors 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: 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):

- 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 h, 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 laying 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 h. Pumps and valves should cause 20 mL increases and decreases in bladder/dead-space volume at intervals of 10 min or more.

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 hot-wire sensor in the tubing may also corrode from moisture during breathing and need replacing as well. The object should be functional for 3-4 months, 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 and the hot-wire sensor. 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, such as the hot-wire sensor. 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 noise. Comfort is an important criteria.

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 some 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 is providing us with a budget of \$100 in order to build the one prototype he has asked us for.

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. He already has a design idea which is detailed in the Problem Statement/Function section. Previous designs have been disregarded at this point, but new novel designs are always open for consideration.

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) Design Matrix

	Design A	Design B	Design C
Brief Description	Prof. Webster's Design	Balloon Modification	Diaphragm Modification
Dead Space Variability (15)	(3/5) 9 (or 15, testing required)	(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	93	71	77

C) Materials List

Material	Quantity	Size (Approximate, requires further research)	Estimated Cost (From our client)
Mask	1	N/A	Available from Client
1-L Container	1	1L	Available from Client
Sphygmomanometer cuff	1	Fits arm of about (220 mm) x (240 mm)	\$30
Hotwire sensor/flow meter	1	Negligible	\$50

Tubing	1	10 mm diameter and 200 mm long	*Free
Arduino Microcontroller	1	30 mm x 50 mm	Already Possess
Air pump	1	42 mm x 12 mm	\$15
Pressure Release Valve	1	3 mm x 10 mm	\$10
Total	N/A	80 mm diameter x 200 mm length	\$105