

# *Sleep Apnea “Smart CO<sub>2</sub>” Therapy Device*

BME 200/300

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## **Abstract:**

Sleep Apnea is a sleep disorder which currently prevents more than 20 million Americans from reaching “deep” sleep. Sleep apnea has been 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, are rejected by nearly 50% of individuals who have used them because they are loud, uncomfortable, and may cause nasal congestion and dryness. Our team firmly believes that these side effects should not be ignored and therefore proposes a device which may reduce them. This alternative device incorporates “Smart CO<sub>2</sub>” which was developed in the lab of our client, Dr. John Webster. The “Smart CO<sub>2</sub>” system has been proven to reduce the occurrence of apneas and shows great potential as a long-term alternative to CPAP. “Smart CO<sub>2</sub>” elevates the amount of CO<sub>2</sub> in the lungs by increasing dead space, effectively inducing mild hypercapnia which has been proven to improve ventilatory stimulation and the symptoms Central Sleep Apnea (CSA) may cause.

## **I. Introduction**

### **A) Motivation / Global and/or Societal Impact**

Sleep Apnea is a disorder characterized by interruptions in the natural breathing cycle which causes frequent waking throughout the course of the night [1]. 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 [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]. In the United States, 1 in 15 people or approximately 21.3 million Americans suffer from some form of sleep apnea [4]. It is estimated that 84% of these individuals suffer from OSA, and the American Sleep Apnea Association (ASAA) estimates that CSA accounts for approximately 20% of all sleep apnea cases [5], with roughly 15% exhibiting both forms [6]. If our team is successful in creating a working “Smart CO<sub>2</sub>” 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 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 airways from closing when the user breathes. 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 preserve positive pressure, 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. 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 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, alternative sleep apnea therapy 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 the standard human body [8]. The air in the dead space is CO<sub>2</sub> rich, having just left the lungs [8]. By increasing the dead space in the respiratory tract, it is possible to increase an individual's CO<sub>2</sub> intake. Increasing the Partial Pressure of CO<sub>2</sub> (PCO<sub>2</sub>) in the bloodstream increases an individual's rate of breathing, effectively reducing the symptoms of CSA [9].

### B) Research Required to Design and Build Prototype

In order to fabricate the "Smart CO<sub>2</sub>" therapy device that our client requested, our team conducted research on different bladders to vary dead space. We also studied voltage regulation and airflow dynamics in order to determine what components would need to be purchased to create a working prototype. The system our team originally proposed would use a flow meter to measure a patient's breathing during sleep in order to detect the presence of apneas. Initially, our team looked at using a hot-wire anemometer to measure the rate of airflow, but after consulting with Mehdi Shokouejad and Fa Wang, two post-graduate researchers who have spent time working with our client on the "Smart CO<sub>2</sub>" project, our team decided against this option (fabrication difficulty purposes) and instead pursued alternatives. They recommended using a flow sensor created by Sensirion because it would be accurate, programmable to an Arduino microcontroller, and work using digital (rather than analog) outputs for our prototype. It should be noted that the Arduino will 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].

The initially proposed system also requires an air bladder that can be inflated or deflated based on apnea detection from the flow meter. Originally, our team planned to purchase an automatic sphygmomanometer and disassemble it for its air bladder and pump. Mehdi and Fa advised against this option, explaining that disassembly and programming would pose a major problem. Instead, they suggested using a programmable, miniature air pump and a manual blood pressure cuff. The bladder can easily be taken from a manual sphygmomanometer and can be inflated or deflated by the pump just as easily.

A final key piece of research our team conducted prior to fabrication was gathering standard flow of breathing in humans. The standard breathing flow rate is 1.3-1.4 m/s [11]. We believed this data to be necessary to create an Arduino script that can recognize when an apnea is occurring.

### 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 “Smart CO<sub>2</sub>”. Dr. Webster would like to see this research come to fruition by creating a working prototype that uses the “Smart CO<sub>2</sub>” concept.

### D) Design Specifications Summary

Our client tasked us with creating a “Smart CO<sub>2</sub>” therapy device that will reduce the complications and side-effects individual’s experience using CPAP devices. 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-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

Our first design (Figure 1), is a “Smart CO<sub>2</sub>” 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 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.

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<sub>2</sub> 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 be shut off and the bladder volume would decrease via diffusion, increasing the dead space.

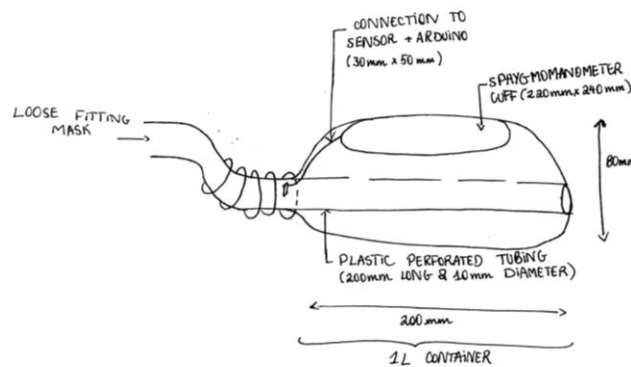


Figure 1). A diagram illustrating the initial design considered for the Smart CO<sub>2</sub> device, which featured an inflatable bladder as the mechanism for varying dead space volume.

Our initial design would be the easiest to fabricate and likely the most durable, but would not offer the greatest range of dead space variability. In response, our team created the design shown below in Figure 2. This design divides the container into three subunits. Each small section would be equipped with an inflatable balloon. It 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.

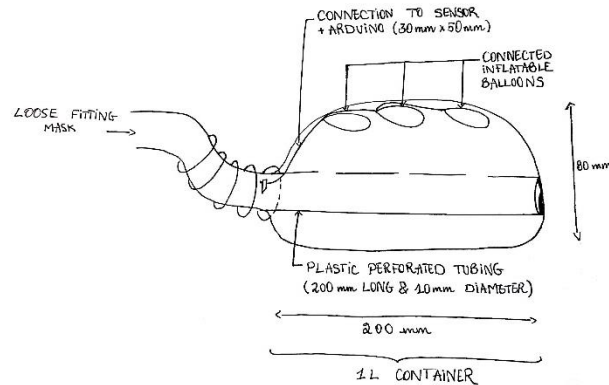


Figure 2). A diagram illustrating the second design considered for the Smart CO<sub>2</sub> device. This design is unique in that it uses 3 separate balloons to control the dead space.

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. Though the mechanism of varying the dead space is slightly different, the effects should be identical. This device features the same manner as the previous designs for measuring and responding to the presence of apneas over a period of time.

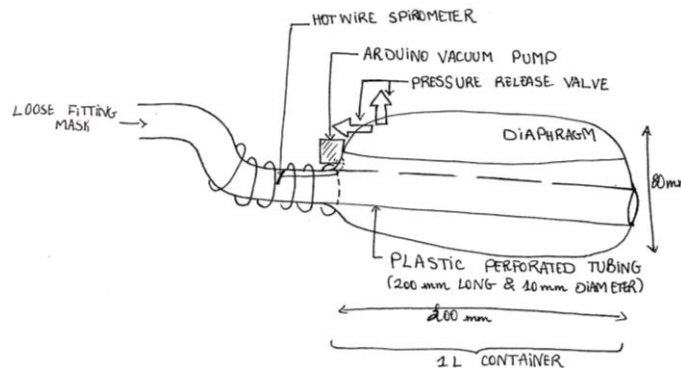


Figure 3). A diagram illustrating the third design considered for the Smart CO<sub>2</sub> device. This design features a deflatable diaphragm in order to vary dead space.

#### IV. Preliminary Design Evaluation

Based on the design matrix (see Appendix B) as well as our client's preferences, our team concluded that our original design, as detailed above (Figure 1), would be the most effective for fulfilling our product 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 a large range of variation in dead space. 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 to achieve maximal volume as a large vacuum would need to be produced. The design team questioned 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 testing of the inflation of the blood pressure cuff.

*b) Ease of Fabrication:* For this criterion, our client's initial design appeared 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 requires three separate internal compartments and three separate motors to be intricately hooked up to inflatable balloons. The diaphragm design requires careful gluing of the diaphragm and a positive pressure valve. Our client's design only requires insertion and securing of the bladder to the container and connecting a small air pump.

*c) Safety:* All three designs are considered safe. Each uses the same mask and respective tubing to connect to the "Smart CO<sub>2</sub>" therapy device. Moreover, coding required for each design to work properly will remain constant, making safety essentially a non-factor.

*d) Weight:* Our client prefers the lightest possible design without inhibiting function. Our initial design and the diaphragm modification are very lightweight. Apart from the mask, tubing, and bladder modification, there is not much weight to either of these. On the other hand, the balloon design weighs 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:* The designs that utilize the bladder and diaphragm run on a single motor while the balloon design necessitates three, consuming additional power.

*f) Durability:* The bladder is designed to be used in repeated stress cycles, and due to its low elasticity, it would likely withstand significant 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 increases the chances of the rubber pieces failing prematurely compared to the bladder design.

*g) Comfort:* All of these design alternatives will be equally comfortable as they all will have the same loose-fitted mask.



*h) Cost:* Our initial design is more cost-effective than the other two designs. Per unit component costs as well as the cost to fabricate are lower.

In reviewing our design matrix and receiving feedback from our advisor following a preliminary presentation, our team concluded that our client's bladder design is the most effective. It is the design choice that advanced onto testing, fabrication, and further development. However, modifications were made and additional components, such as a pressure release valve, were added to the original bladder design to improve it. This final design can be seen below in Figure 4.

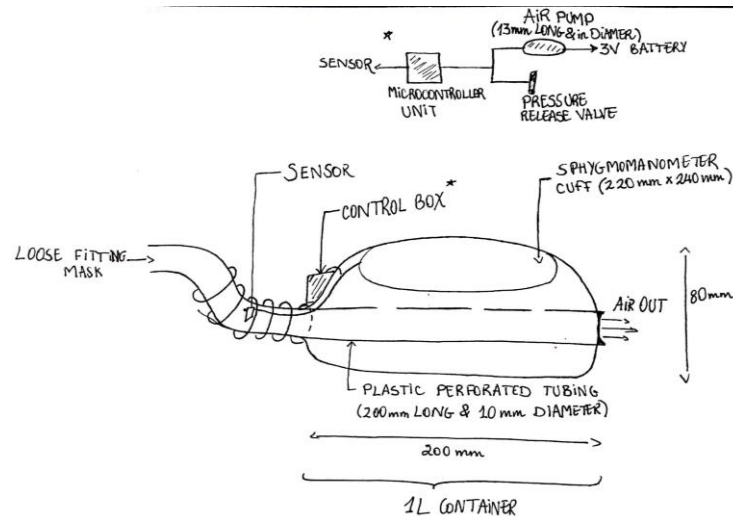


Figure 4). A diagram illustrating our team's proposed final design. This design features an Arduino Uno microcontroller programmed to inflate or deflate a bladder as the means to vary dead space.

## V. Fabrication/Development Process

### A) Materials

The final design of our "Smart CO<sub>2</sub>" therapy device consists primarily of a loose-fitting, comfortable mask, a 1 L plastic cylindrical container, perforated corrugated tubing, an air flow sensor, an Arduino microcontroller, a battery powered air pump, a pressure release valve, a bladder (removed from a sphygmomanometer), and rubber bands. A list of all parts ordered, quantity, and cost can be found in the Appendix C.

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 200 mm in length and 80 mm in diameter, rests on the sternum of a sleeping patient or next to them. The container is made of a thick plastic for durability and allows sufficient expansion of the air bladder 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 in the Methods section). The processing of data from the sensor is handled by an Arduino Uno microcontroller. The air pump is a small pump, approximately 24 mm in diameter and 59 mm in length that is battery-powered and is used to inflate the air bladder. A pressure release valve is included with the pump to allow air out of the bladder. The air bladder inflates and deflates to vary dead space, as necessary, and rubber bands around the bladder aid in diffusion once the pump is turned off.

## B) Methods

The fabrication process 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 detect apneas and take the proper countermeasures regarding dead space within the device (Figure 5). The code for our algorithm with annotations can be found in Appendix D.

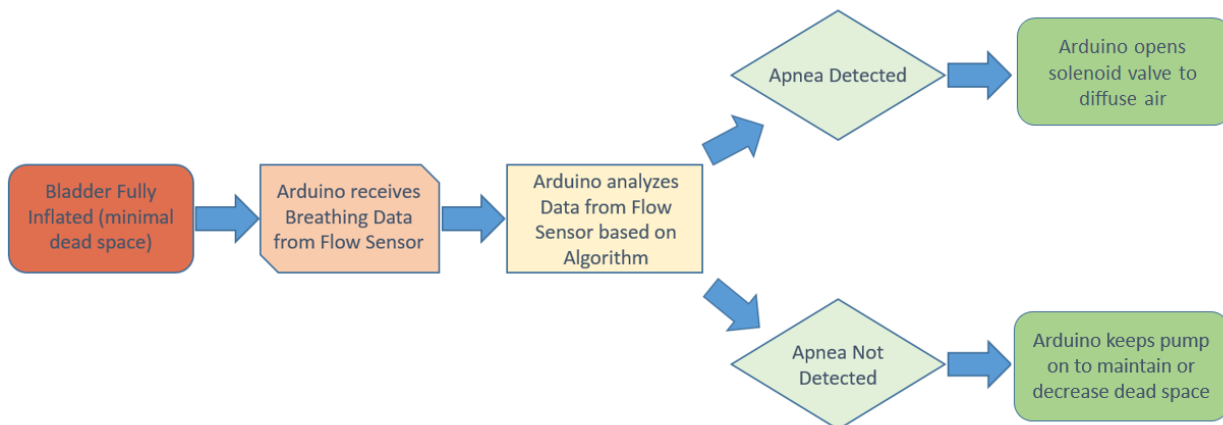


Figure 5). Flow Diagram of the function of the varying dead space system. The algorithm for detecting apnea will be utilized in the analysis of the voltage data from the flow sensor.

### *Electrical Components*

After our algorithm, we set up a test circuit containing an LED that would later be replaced by a solenoid valve and pump to use as countermeasures (Figure 6). 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, power is given to open a solenoid valve to deflate the bladder and increase the dead space. If no apnea is detected in an hour, a pump is activated to maintain or decrease dead space. Prior to fabrication,

extensive testing was done on this circuit to assure it functions as desired and would not fail once installed.

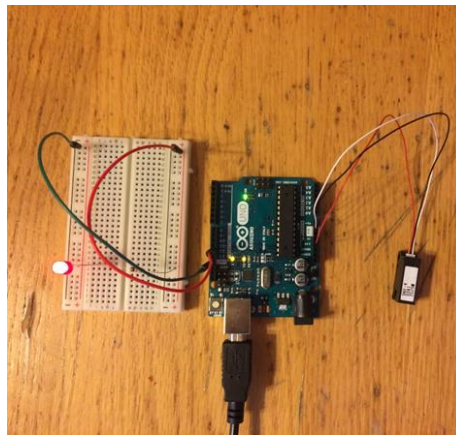


Figure 6). Apnea detection circuit including a flow sensor (right), microcontroller, and resistor LED combo (left). The LED lights up when an apnea is detected by the algorithm.

### *Physical Components*

We inserted and secured the air bladder to the top of the inside of the 1 L container. This attachment was done using double-sided adhesive tape to allow easy assembly and disassembly, as were most of the attachments in this prototype. Two 9 mm diameter holes were drilled into the top of the container adjacent to the air bladder, to allow for the tubing of the bladder to be connected to the electronic components of the device outside of the container. The intake tube of the air bladder was run through one of the two holes, and attached to the air pump. The outflow tube was run through the other hole, through a solenoid valve attached to the Arduino, to allow for evacuation of air. The air pump is powered by a 9 V battery, and controlled by the Arduino microcontroller that is programmed with the algorithm. The Arduino connected to the flow meter serves as an input.

Third, a 17 mm diameter hole was 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 was sealed off by rubber grommets around the tubing to provide an airtight seal. Adhesive was used to ensure the tightness of the seal, in the event that the seal provided by the grommet is not sufficient. This tube runs along the underside of the container and is secured by double-sided adhesive tape. Perforations, spaced one inch apart, were cut along the tube so as to have a variable volume of air within the container.

### C) Final prototype

After fabrication, our final product looked as follows:



Figure 7 (left): This image shows our device prior to insertion of the circuitry. The bladder is visible inside of the bottle. Rubber bands around the bladder aid in diffusion once the pump is turned off.

Figure 8 (right): This image shows bladder inside of bottle in greater detail. The cap is removed from bottle to show where main tubing is run.



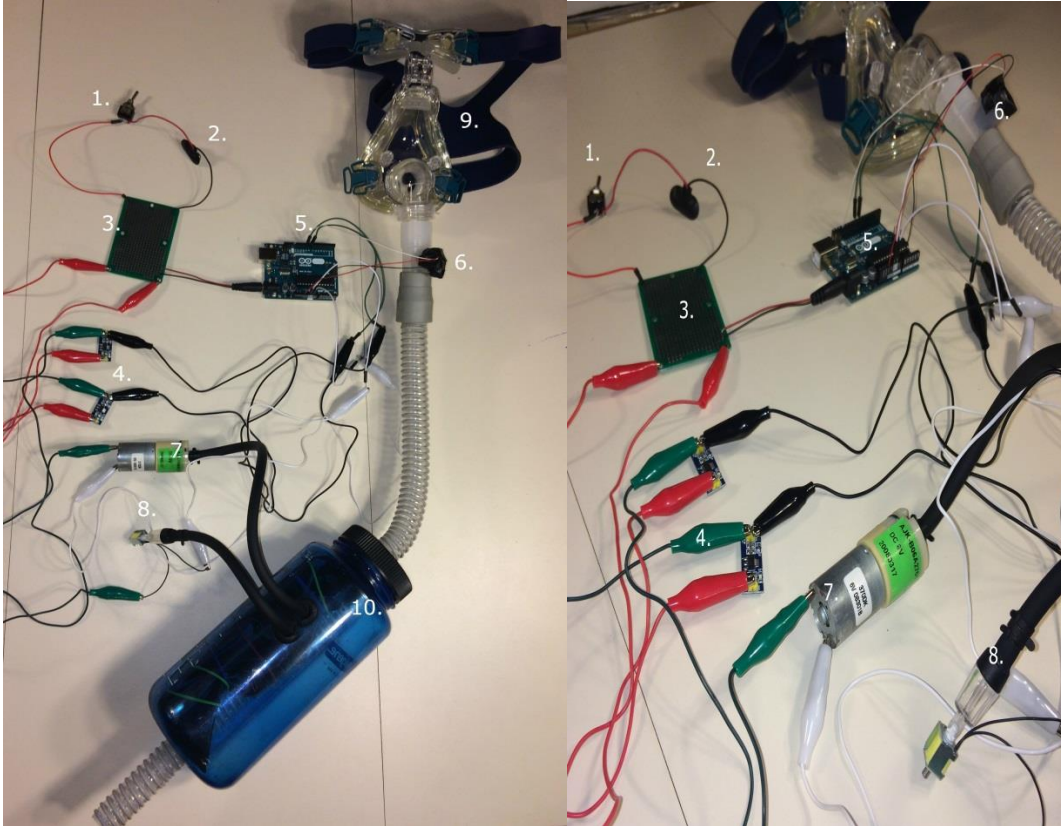


Figure 9 (left): This image shows our finally constructed device. All circuitry is attached and the bladder is deflated (maximum dead space). See components list below.

Figure 10 (right): This image highlights the electronic components used with the device from an alternate angle. See components list below.

Components list: 1. On/Off Switch; 2. 9V Battery Connection; 3. Circuitry Board; 4. 9V to 3.3V Buck Converters; 5. Arduino Microcontroller; 6. Flow Sensor; 7. Micro Air Pump; 8. Solenoid Valve; 9. Face Mask; 10. Variable Volume Container

The device toggled on and off by a switch and powered by a 9V battery. The power from the battery is split between the solenoid valve, pump and microcontroller. A flow sensor sends data to the microcontroller which uses the described algorithm to make apnea detection decisions. The microcontroller then enables/disables 9V to 3.3V buck converters to toggle on and off the pump and solenoid valve based on required apnea countermeasures.

## **VI. Testing/Results**

Our first round of testing was conducted on the circuitry shown in the Methods section to determine if our algorithm was working as intended and would allow us to actually vary the dead space as required. The way our algorithm works is by determining the difference in voltages received by the flow sensor over a period of time. In normal breathing the flow sensor measures

approximately 0.2 V for an inhale and 0.9 V for an exhale. Over a range of time the high and low voltages would differ by approximately 0.7 V. However, if breathing ceases the flow sensor measures 0.5 V (set as a default by the makers of the device). Our algorithm determines the high and low voltages over 10 seconds and takes the difference to find a voltage tidal volume. If the tidal volume is greater than 0.01 V then the algorithm does not detect apnea and keeps the bladder fully inflated. However, if the tidal volume is less than that threshold then an apnea is detected and the solenoid valve is opened which will slowly deflate the bladder and increase the dead space.

To verify that this is actually what is happening we had one of our group members simulate normal and apnea breathing patterns to see how the circuit responds. First, we had him simulate normal breathing through the mask and tube with the flow sensor sitting at the end of the tubing, connected to the Arduino which in turn was connected to the pump and bladder. As he proceeded breathing normally, the bladder remained fully inflated, and the LED remained off indicating that no apneas were detected. The Arduino gave us the following Voltage-time graph (Figure 11) that supported this observation.

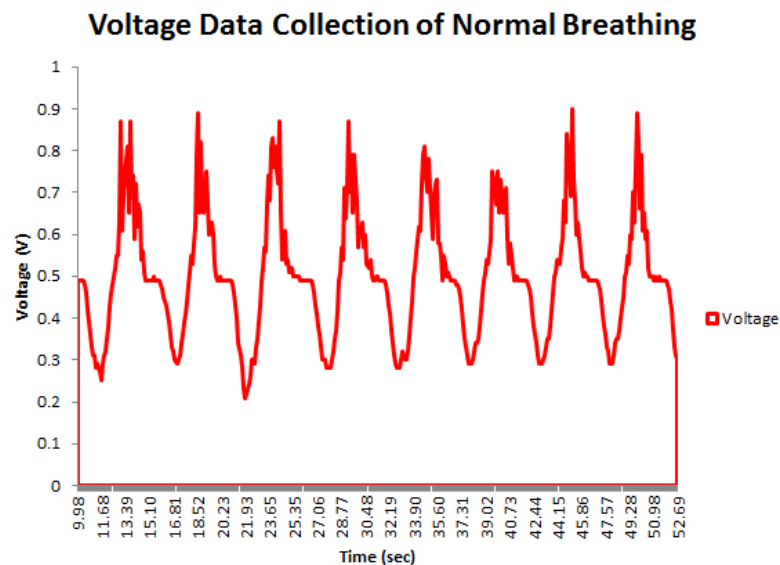


Figure 11). Normal Breathing Data. Supports observation that no apneas detected by algorithm in normal breathing. This serves as a basis of comparison for the data in Figure 12.

After this, we had our group member simulate apnea breathing patterns by proceeding to breath normally, then stopping all of a sudden for as long as possible, and finally inhaling and resuming normal breathing. As the group member breathed normally the bladder remained fully inflated, as expected. Ten seconds after our member ceased breathing, the bladder began to deflate and the LED lit up, indicating an apnea was detected. The Arduino gave us the following Voltage-time graph (Figure 12) that supported this observation.

### Detection of Apneas via Flow Sensor Voltage

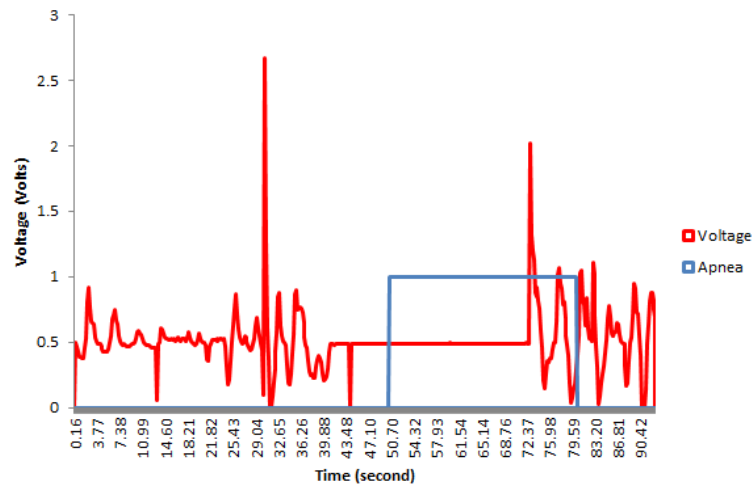


Figure 12). Detection of Apneas via Flow Sensor Voltage. Nearly 10 seconds after ceasing breathing, the Arduino detected an apnea (blue box) which indicated the algorithm works as expected.

We conducted these tests numerous times to attempt to find any irregularities and to replicate our results. We found no such irregularities, which indicates that our algorithm works as designed and was ready to be implemented within our design.

Before fabrication, we also tested the elasticity of our bladder which would give us the range of variable dead space for our device. We found that the bladder itself had a volume that could range from approximately 0.1, to 1.8 L. This number was determined and confirmed by two separate methods. First, we used equations known to us to calculate theoretical values of volumes. When the bladder is completely inflated it is roughly ellipsoidal. The volume of an ellipsoid is  $\frac{4}{3} \pi a*b*c$  where a, b, and c are the radii in the x, y, and z directions of the ellipsoid. Through simple measurement we found these values to be 6.0 cm, 4.9 cm, and 16.1 cm, respectively in our inflated bladder which means that the maximum volume is 1.982 L. When the bladder was completely deflated it assumes a roughly prismatic shape with side lengths 5.1 cm, 0.1 cm, and 16.1 cm. This gives us the deflated volume as 0.0082 L. The next method we used to calculate volumes of the inflated and deflated bladder was to submerge the bladder in water and note the volume change. Through this we found that the deflated bladder has a volume of 0.1 L, and the inflated bladder has one of 1.8 L. The theoretical volume and actual volumes of both are quite close which gives us a high degree of confidence in our calculations. For our future calculations we used the 0.1 and 1.8 L values as these were the experimentally calculated ones.

From here, we determined the dead space range by noting that the volume of our bottle was 1 L. The tube is cylindrical in shape with radius 1.1 cm and length of 47 cm, which gives a volume of 0.178 L. The maximum dead space volume will be when the bladder is fully deflated and will be equal to the volume of the tube and bottle subtracted by the volume of the deflated bladder. This turns out to be about 1.08 L. The minimum dead space will be when the bladder is

inflated to its maximum capacity. Since this is limited by the volume of the container itself, the maximum volume that the bladder can assume is 1 L. Thus the minimum dead space of our device is the dead space in the tube itself, which is just 0.178 L. This gives us a total dead space range of 0.902 L, which is quite respectable.

One final test we did was to determine if the mass of our device remained under the preferred 1 kg, which it was well under at 481 grams.

## **VII. Discussion**

In short, we have created a device that can actively combat apneas. The “Smart CO<sub>2</sub>” therapy prototype we have created detects apneas occurring and takes the proper countermeasures, increasing and decreasing dead space when appropriate. However, there is much room for improvement. For example, given our time and budget constraints it remains unknown how accurate and successful this device is in reducing apneas for an entire night since we have not done testing over any extended period of time, but rather just tested if the algorithm works and could theoretically reduce apneas. If time and money were not issues and if we received the approval of an Institutional Review Board (IRB), we could have truly tested the efficacy of this design.

Another area in which this product is less than ideal is in the quality of the parts used to construct it. The parts we used were often cheaper and lower quality than the ones that we ideally would have used, and this may have altered the overall quality of our product. For example, during the fabrication process our postgraduate advisors recommended using a flow sensor created by Sensirion to measure airflow. Our team would have liked to purchase the SFM3000 Sensirion flow meter which measures the flow of air and other non-aggressive gases at rates of up to 200 standard liters per minute (slm) with excellent accuracy and extremely high speed [12]. It also features a 2-wire interface, making it easy to connect directly to a microcontroller [12]. Unfortunately, this option was priced above our budget and could not be implemented within the design of our prototype. Although the flow meter used in our design suffices for the product specifications of our client, the added precision, accuracy, and speed offered from the SFM3000 would have vastly improved the manner in which our device measures flow. Given the proper resources and an increased budget, a product with higher quality parts could be created.

Before this device could ever be able to be put into use, extensive research on the effects of inducing mild hypercapnia for significant periods of time would need to be researched. Moreover, the device would need to be fine-tuned to account for the amount of re-breathable CO<sub>2</sub> available based on dead space. We would need to provide enough dead space so that apneas are reduced, but not to the extent that the user experiences any physiological or psychological damage.

Despite the issues detailed above and the work that remains to be done, the product we created satisfies our client’s original product design specifications. Our device is under 1 kg, fits the space limitations of 200 mm in length and 80 mm in diameter, is fairly comfortable, operates via battery, has a wide range of dead space, and can respond to apneas as they occur. In all, we



have created a device that, given the proper resources, testing, and modifications, is a promising, viable alternative to CPAP.

### **VIII. Conclusions**

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 CO<sub>2</sub>” dead space varying technique developed in his research. Through extensive testing we have created a device that is able to vary the dead space automatically in response to presence or absence of apneas. The goal of this device was to build and test a prototype to show the viability of the “Smart CO<sub>2</sub>” technique, which it has achieved. Though we have shown that it is possible to detect and respond to apneas using this technique, our device is not very fine tuned. If more time and resources were available to us we would have liked to carry out more testing to further understand the efficacy and limitations of this design. We would also like to determine how much the bladder should be deflated to optimally respond to apneas instead of fully deflating upon presence of apneas and then fully re-inflating when the apneas cease. This would likely be done by establishing a relationship between PCO<sub>2</sub> and dead space. Further, we would like to determine the durability of this product and battery lifetime of this device, and to conduct stress-cycle testing. That said, thus far we have 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.

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## **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 Rebreather Device” (also called “Smart CO<sub>2</sub>”) 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 CO<sub>2</sub> exits our lungs. There is an area known as dead space where CO<sub>2</sub> 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 rebreather device causes there to be a greater volume of CO<sub>2</sub> in a person’s airway. Moreover, the increased CO<sub>2</sub> 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 CO<sub>2</sub> 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 the presence of 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, 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 20ml 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 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 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

<b>Criterion</b>	<b>Bladder Design</b>	<b>Triple Balloon Modification</b>	<b>Diaphragm Modification</b>
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
<b>Total Value (100)</b>	<b>93</b>	<b>74</b>	<b>77</b>

## C) Materials List

<b>Item Name</b>	<b>Quantity</b>	<b>Cost (Dollars)</b>	<b>Provider</b>	<b>Code/Part Number</b>
Blood Pressure Cuff / Bladder	1	12.90	Amazon	B0126MS6Z0
1 L Plastic Container	1	0.00	Dr. Webster	Provided to us beforehand
Tubing	1	6.59	Amazon	B00GNGZ7AI
Mask (just the headgear)	1	0.00	Mehdi and Fa	Had to begin with
Airflow Sensor	1	23.32	Digikey	D6F-V03A1
Airflow Sensor wiring	1	11.63	Digikey	D6F-CABLE2
Arduino Microcontroller	1	0.00	Calvin	Had to begin with
Mini Air Pump	1	6.99	Amazon	B01CB0ROSW
9 V Battery connector	1	0.00	Mehdi and Fa	Had to begin with
9V barrel connector	5	5.99	Amazon	B00NIP0P9U
Toggle Switch	1	2.99	Amazon	B016Q9X8AW
Rubber Grommet	10	4.88	Amazon	B00880SC4A
9v to 3.3v converter module	1	1.23	Amazon	B01IR7N3KQ
Solenoid Valve	1	7.79	Amazon	B00JR3ZQSC
Rubber Bands	10	0.00	Aman	Had to begin with
Check Valves	1	4.99	Amazon	B00H4YDY0S
<b>Cost of Parts</b>	<b>89.30</b>			
<b>Shipping for DigiKey Products</b>	<b>11.43</b>			
<b>TOTAL</b>	<b>100.73</b>			

## D) 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.

#### Arduino Code:

```
// 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;
}
}
```