Sleep Apnea Therapy Device

BME Design 301

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Abstract:

Sleep Apnea is a sleep disorder in which natural breathing is interrupted causing frequent waking. This frequent waking caused by apnea prevents a person from reaching deep sleep leaving them tired throughout the day. It affects more than 20 million Americans and is a contributing cause of high blood pressure, weight gain, and stroke. Our design focuses on the treatment of Central Sleep Apnea (CSA), which is characterized by intermittent disruptions in the autonomic nervous system that controls breathing. There are few treatment methods that only treat CSA, many of which are rejected by users, which drives the need for an effective and comfortable treatment. Our design incorporates a variable dead space method via a rotational motor to effectively treat sleep apnea. Increasing CO_2 levels for future inhalation by varying dead space volume reduces the occurrence of apneas and stabilizes breathing. By inducing mild hypercapnia, ventilatory stimulation is increased and the symptoms of CSA are reduced.

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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% 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 Airway 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 the device. 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 [8]. 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 on the next breath, increasing the partial pressure of CO_2 (PCO_2) in the alveoli and bloodstream. This elicits a response from the pons and medulla oblongata in the brainstem (autonomic nervous system) which has been shown to stabilize breathing patterns, effectively reducing the symptoms of CSA [9]. A 5% increase in re-breathed CO_2 has been shown to be effective for this method.

B) Fall 2016 Final Design

This project is a continuation of a project that began in the Fall of 2016. Last semester's final design is shown in Figure 1.

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.

It is a "Smart CO_2" therapy device that varies the amount of dead space by means of an inflatable bladder. As exhibited in Figure 1, 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, a solenoid 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 air travels through the flexible corrugated plastic tubing of the mask, and into the connected volume of the 1 L plastic cylindrical container. It should be noted that the tubing running across the inside of the container is 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 sends an analog signal to the Arduino allowing us to record the quantity of apnea events occurring over a period of time based on the algorithm which can be seen in Figure 2. Based on the presence of apneas, the Arduino adjusts the dead space of the patient as necessary, in order to control the CO_2 intake and treat the occurrence of apneas. Normal breathing would cause the air pump to inflate the bladder, in turn decreasing the dead space; however, if an apnea were detected, the air pump would switch off, a solenoid valve would open and the bladder volume would decrease via diffusion, thus increasing the dead space.

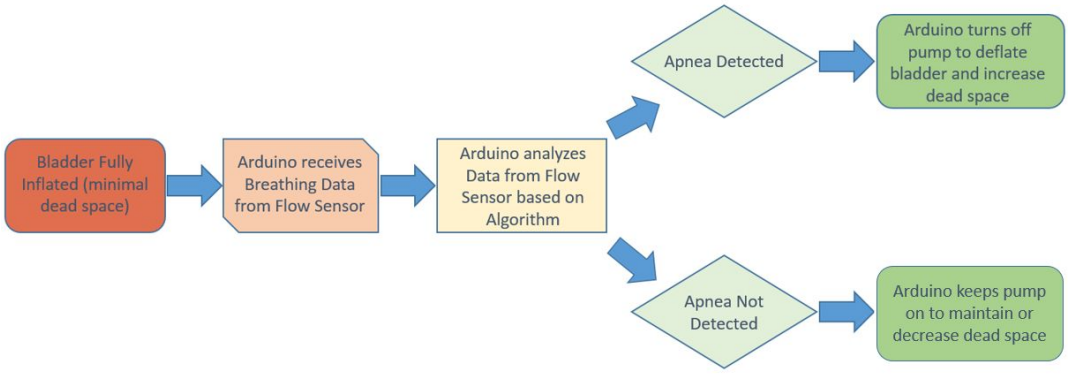

Figure 2: Flow Diagram of the function of the varying dead space system. The algorithm for detecting apnea will be utilized in the analysis of the voltage data from the flow sensor.

C) Research Required to Design and Build New Prototype

After evaluating the design from last semester, new research was compiled to

create a unique design concept, and improve upon the old one. The Arduino Uno will still be the main programming platform because it is: flexible in offering a variety of digital inputs; inexpensive at 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 a printed circuit board (PCB) that can efficiently transform power and a smaller microcontroller that uses less power to operate.

Research was also conducted to find a new source of dead space variability. The team has shifted from a pump and bladder to vary dead space volume to using a mechanical element that controlled air flow through an expanded dead space. The mechanical element was narrowed to using a stepper motor or a worm gear motor. We opted to use a stepper motor over a worm gear motor for a variety of reasons, with the main one being the direction of resultant displacement to motor operation. Our research dictates that while both types of motors are highly controllable and accurate, the stepper motor required fewer pieces and was more compact. Additionally, the stepper motor we used runs on 5V DC making it good to use with an Arduino as it has a 5V rail. The motor driver that was included fit on a breadboard and only required a 600 mV current to operate. This makes it ideal for use in our apnea therapy device.

In order to further the efficacy of the device, the algorithm would 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) with an approximate 15 breaths per minute 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.

D) 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 heavily interested in sleep apnea

therapy and has contributed greatly to the research concerning the dead space variation technique.

E) 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. The goals of continuing the previous design are to order new parts for the circuit, make sure the circuit is integrated properly with the flow sensor to effectively inflate or deflate the bladder. Another goal of continuing the previous design is to complete testing on multiple people. Even though we will not have Institutional Review Board (IRB) approval, we plan to have at least one person, most likely a team member, try to sleep a night with the device.

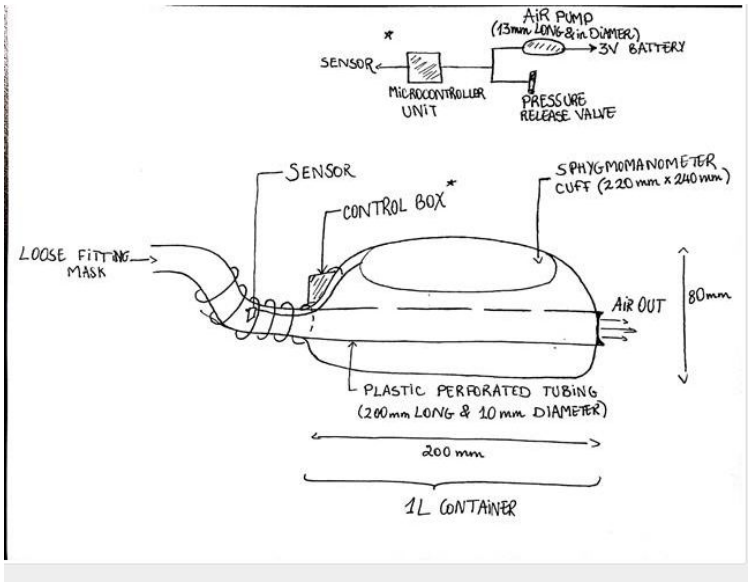

Figure 3. An illustration of how the final prototype from the Fall of 2016 should function.

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 the container 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 4 as a visual aid for this design.

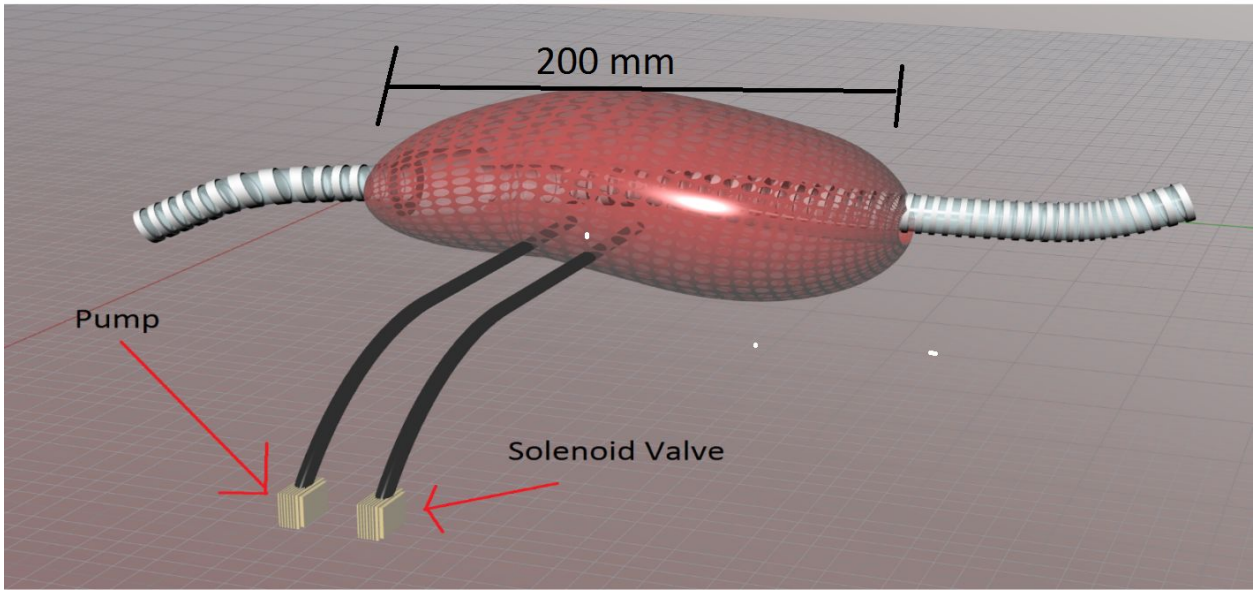

Figure 4: A CAD design of SBwP while apnea is detected (the body is inflated thus maximizing dead space). During normal breathing the body would be deflated and snug to the air tubes, thus minimizing dead space.

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 of 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 5. 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.

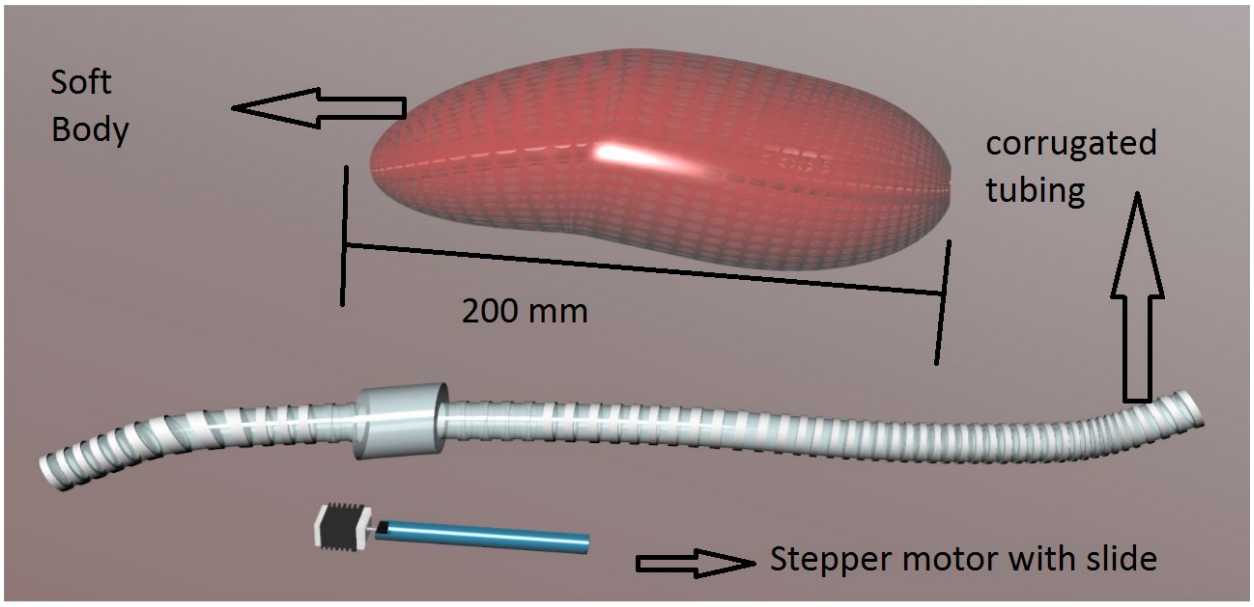

Figure 5: An image of SBwR with the parts separated for aid in visibility. When the design is fully assembled, the stepper motor/cover will be located in the air tube, and the air tube will be located in the soft body

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 achieve satisfactory sleep.

The categories of durability, ease of fabrication, comfort, and weight were tied at 15 with dead space variability at the top of 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. We want the device to be appealing to all users so 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 each. There were limited safety risk, and little to no variations in safety exists between the designs. The algorithm is designed to prevent the wearer of this device from ever experiencing difficulties breathing, ensuring all the designs to be be safe. The purpose is to expand anatomical dead space which may cause a small change in air resistance but should not cause asphyxiation. 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 the hard body with pump 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 the hard body with pump 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. Even though the hard body design is highly durable, cost effective and power efficient while conducting testing at the beginning of the semester, the previous design had too many existing bugs, so the team 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. Even though we were planning to move forward with the SBwR design, after a client meeting, Dr. Webster expressed his dislike of a soft body design. All other aspects of the design were kept the same, except the body of the device was switched back to a hard body. The proposed final design then became Hard Body with Rotation.

V. Fabrication/Development Process

A) Materials

The final design of our Sleep Apnea therapy device consists primarily of a loose-fitting, comfortable mask, a 1 L hard plastic container, flexible corrugated tubing, perforated PVC tubing, a delrin slide, an Omron D6F-V03A1 air flow sensor, an Arduino Uno microcontroller, and a 5V DC (32-step by 1/16 gearing) stepper motor with a L293D Dual H-Bridge stepper driver.

The mask attaches the device to the nose and mouth of the patient in order to 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 3.4" X 3.4" X 11", rests on the sternum of a sleeping patient or next to them. The container is made of a thin plastic for durability and to minimize weight while maintaining structural integrity. The flexible corrugated tubing connects the mask to the plastic body. This allows for easy movement of the patient's head without displacing the device as a result. The tubing extends from the mask, and plugs into PVC tubing. The PVC tubing system runs through the container with perforations to allow access to additional dead space as well as an opening at the distal end of the bottle for gas exchange. The flow sensor was pre-manufactured and converts air flow to voltages from which we can detect apnea through an 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 stepper motor which turns a plastic slide to reveal slits 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. A list of materials and their costs are located in Appendix C.

B) Methods

The fabrication process consisted of three parts:

1) Fabrication Development

Multiple PVC tubes were machined to different diameters, such that they fit together in a secure fashion within the 1 litre body. These individual pieces can be seen in Appendix D with letter assignments, and fully assembled in Appendix E. Piece A was an adaptor that allows a secure connection between the corrugated tubing to the PVC tubing. Part B is specialized tubing designed to hold the air flow sensor, while creating a secure

connection between the rigid PVC tubing system and the 1 liter body. Part C opens to the external environment which allows gas exchange (more clearly displayed in appendix E), and was machined to be as thin as possible for weight concerns. Part D was a specially machined adaptor that allows the stepper motor to securely sit within, while not restricting airflow. Part E attaches to the motor and rotates internally to open or close the slits on part F. Part F has perforations that allow gas exchange between the subject and the additional dead space contained by the 1 litre body. For further detail on the fabrication protocol, see Appendix F.

2) Algorithm Development

An algorithm to detect apneas was designed around taking voltage data received from a flow sensor. This algorithm converts air flow rate signals, in the form of analog-digital-conversion (ADC) values, into voltage values from 0-2V. These voltage values can be collected and plotted over time to represent a pseudo tidal volume (Figure 6). The algorithm takes advantage of this tidal volume to detect apnea based on the amplitude of the waves produced compared to a threshold that signifies the cessation of breathing. After the algorithm was able to detect apnea, coding was included to run a stepper motor using a L293D Dual H-Bridge stepper driver (600mA). This included using the included stepper motor library included in the Arduino software. Finally, the algorithm includes the program PLX-DAQ by Parallax Inc to write data to Microsoft Excel files. A flow-chart found in Figure 7 outlines the algorithm operation and a copy of our algorithm code with annotations can be found in Appendix B.

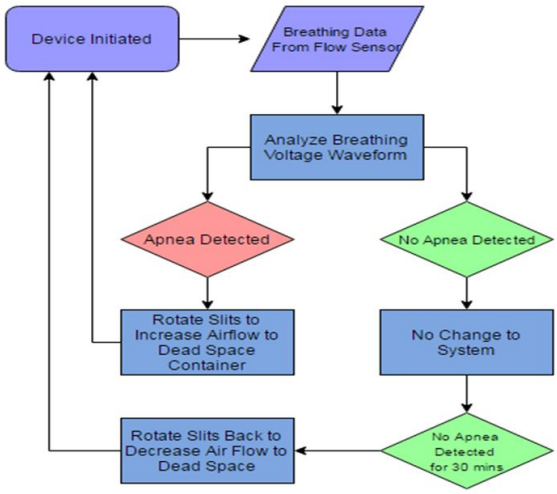

Figure 6. Flow sensor voltage and apnea detection data. The red line represents when apnea was detected and the blue line represents the breathing pattern of the test subject. Testing verified the functionality of the algorithm.

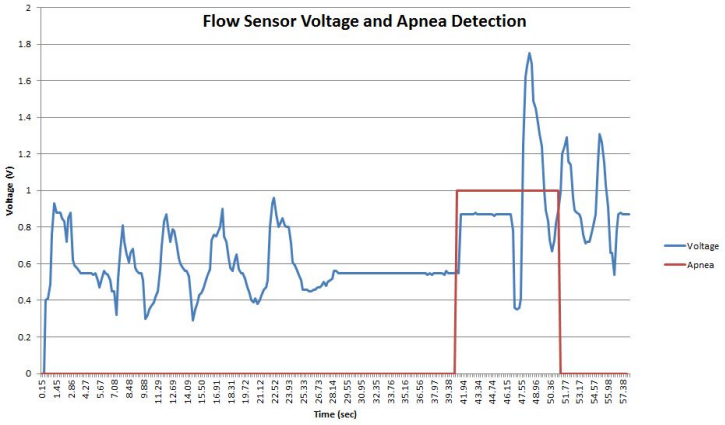

Figure 7. Apnea detection algorithm flow chart that drives the device as an dynamic and active apnea therapy system.

3) Circuit Design

An experimental circuit was created on a breadboard to operate the device using the developed algorithm (Figure 8). Powering to the circuit is provided through the USB port adaptor on the Arduino Uno. From this the microcontroller functions and all other components are powered from voltage rails. The motor driver is powered by the 5V rail which connects to each quadrant for powering each individual inductor on the motor. The current from this 5V rail is controlled by a TIP41C (NPN type) transistor which is operated by a 20 mA digital pin. The use of the transistor is for power saving as the motor will only need to be powered to move in the case of apnea. Digital pins 12-9 connect to the stepper driver which transfer signals from the microcontroller to the connected motor. The flow sensor is powered by the 3.3V rail and the current is controlled by another TIP41C transistor for power saving. The flow sensor sends analog signals to the Analog 0 pin on the microcontroller. Two LED's are also connected to the circuit: one is connected to a digital pin to be lit when apnea is detected; the other is connected in parallel with the 5V rail power to be lit when the motor current is activated.

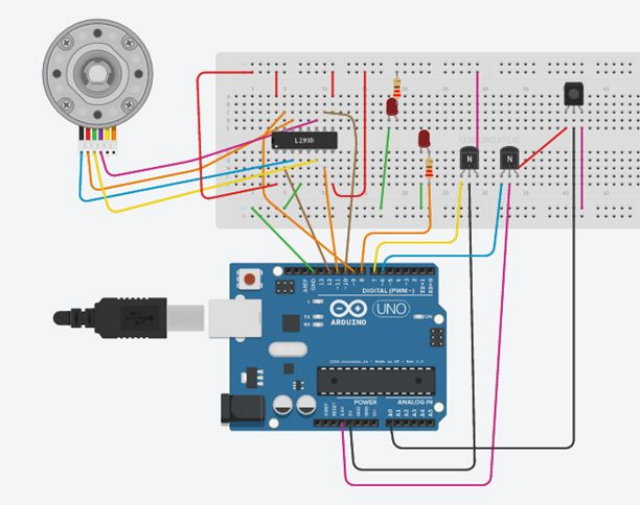

Figure 8. A schematic of the circuit that controls the stepper motor based on the readings from the flow sensor.

C) Final Prototype

The device consists of a loose-fitted, comfortable mask, a 1 L hard plastic container, perforated PVC tubing, corrugated tubing, a flow sensor, an Arduino microcontroller with attached circuit, and a stepper motor with a rotating cover slide. The tubing, measuring 10 mm in diameter and 200 mm in length, will run entirely through the 1 L plastic container. At one end of the container, the PVC tubing will connect to the flexible corrugated plastic tubing of the mask worn by the patient. The PVC 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 inner tubing found within 1 L container acting as extra dead space. The inner tubing has perforated slits, covered by a motor controlled slide piece, that open into the expanded dead space container. A flow sensor built into the tubing will send an analog signal to the Arduino allowing us to record apnea events using our developed algorithm. Based on the presence of apneas, the Arduino will adjust the slide to vary access to extra dead space as necessary in order to control patient CO_2 levels to stabilize breathing.

The technique behind this will be in controlling the opening of the slits in the inner tube. During normal breathing, the cover is aligned with the tube slits to block addition CO_2 from entering the airway. When apnea is detected, the cover will be rotated by a stepper motor, revealing the slits, and allowing gas exchange with the additional dead space. To accomplish this, the cover will be attached directly to the stepper motor, as seen in Figure 9. One additional aspect to this design is diameter varying adaptor pieces. This allows the stepper motor and flow sensor to fit into the device without obstructing the airways for breathing. The final prototype is pictured in Figure 10.

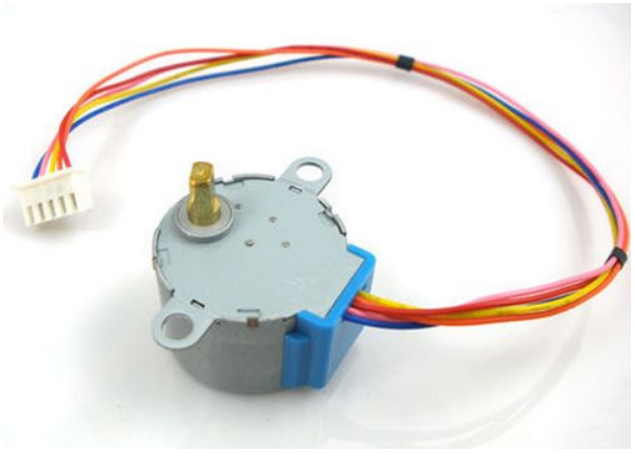

Figure 9. A stepper motor is secured at the end of the PVC pipe. It is connected to a cover slide that rotates to cover or uncover slits cut in the PVC pipe.

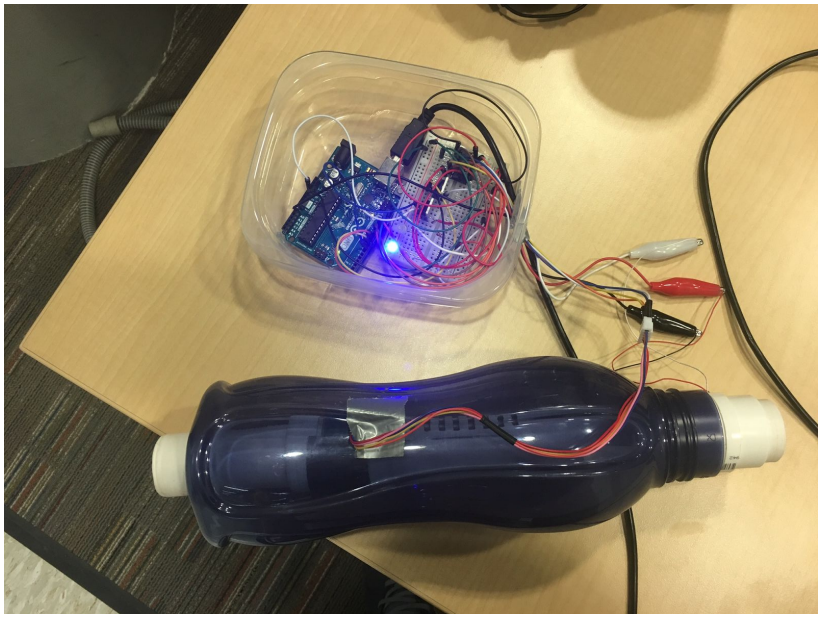

Figure 10. The final assembled prototype.

VI. Testing/Results

Testing was an important part of our design process because the current device has such a high rejection rate. Comfort testing was conducted to ensure the device would not be rejected by the user. A convenience sample of 30 was taken. Each test subject was asked to wear the device for a duration of ten minutes and were then asked to fill out a survey shown in Appendix G. The test subjects were asked four personal questions for demographic data and then four questions about their experience with the device.

The first three questions were answered on a scale of (1) to (5) with (1) being unbearable and (5) being unnoticeable. These three questions inquired about the ability of the person to breathe through the device, the comfort of the device, and if they thought they would be able to sleep while wearing the mask. The final question was a yes or no question regarding if the subject thought they would be able to sleep with the body of the device on their chest or near them while they were sleeping. The results of the survey are illustrated in Figure 11 and 12.

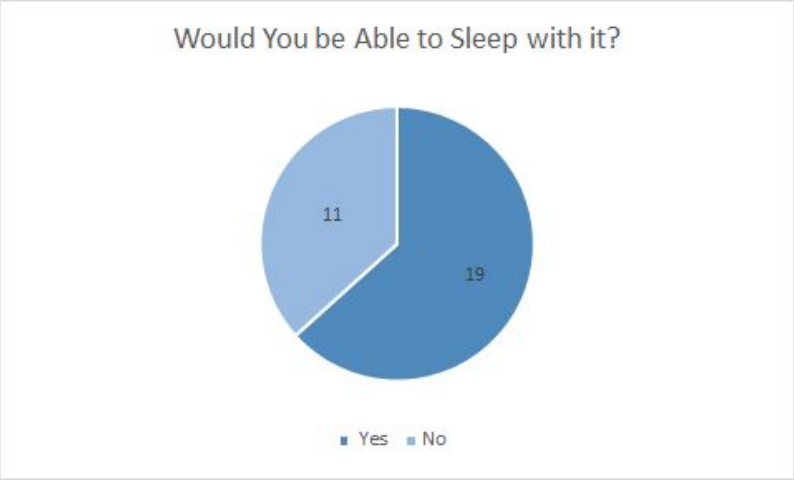

Figure 11. 19 out of the 30 people surveyed said they could sleep at night with the 1 L container either on their chest, next to them, or above them.

Figure 12: This graph shows the amount of surveyed people who responded with each rating (1-5) for each of the three categories.

VII. Discussion

The results of testing and data show the device to be promising in the improvement of sleep apnea therapy device comfort. For the comfort testing, the majority of people surveyed ranked the device 3 (satisfactory) or higher in all categories (comfort, ability to breath, and ability to sleep). Since the average rejection rate of CPAP machines is greater than 50% due to comfort [7], it is believed that the sleep apnea device has superior comfort. This data however is slightly skewed due to the testing population demographic. Sleep apnea is most prominent in individuals 40+ in age and overweight [4]. During testing, 100% of the testing subjects were between the ages of 20-24, 6.66% were overweight, and 0% have ever worn a CPAP mask, so they had nothing to compare it to. Additionally, the test was for a duration of 10 minutes which does not accurately represent a full night of attempted sleep. Further in depth testing must be performed to prove the hypothesis that the sleep apnea device is superior in comfort to the CPAP machine.

Due to the design being a medical therapy device, there are many ethical issues associated with testing it. In order to test on sleep apnea patients, IRB approval would need to be obtained and enough patients willing to do overnight sleep studies while wearing the new device would need to be found. Further testing would also need to occur to ensure the safety of our machine before it is tested on humans. This would include chemoreceptor testing for CO_2 levels introduced for each variation of the opening of the slits. This would ensure that there isn't more than the desired 5% increase of CO_2 that has been shown to be beneficial for sleep apnea treatment. Harmful effects such as hypoventilation or respiratory acidosis may occur if the levels are too high. Another consideration is the amount of airway resistance that is included with the device. If it is too high it could cause difficulty in breathing which is not proactive for improving comfort and deep sleep. Additional testing and expert opinion from physiologists should be sought out for this device before seeking IRB approval. One safety feature that could be included is an alarm that will sound after one minute of the patient not activating the flow sensor by breathing. This could ensure that a patient is roused or a partner is roused in the unlikely event that the device or the patient's condition causes any prolonged cessation of breathing.

VIII. 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 variable dead space technique he developed in his research. The final design registers when apnea occurs and activates the stepper motor to rotate the cover slide to open slits in the PVC tube increasing the amount of dead space, triggering the user to

breath.

In the future, we would like to improve on the machine's physiological accuracy and continue with testing. To improve the machine's accuracy, further research needs to be done to ensure 10 second intervals between apnea checks is optimal. Additionally, more testing needs to occur, specifically testing how much CO_2 comes out of each open slit to ensure the device has the correct rate of slit opening to stop apnea once it occurs. After that, IRB approval will need to be obtained to test the device on patients with apnea to ensure the machine works properly and allows them to sleep through the night. Additionally, to make the device more compact, a printed circuit board would be purchased and placed inside the body of the device to eliminate the exposed wires from the body and decrease the weight of the device.

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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 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 analog-digital-conversion (ADC) values from the sensor into voltage values. Fifty voltage values are taken into an array over a ten second period. The maximum and minimum values in this array are calculated and the difference is taken of them to produce a voltage tidal volume. The tidal volume is matched with a 0.10V threshold. If the tidal volume falls below the threshold, apnea is detected and the motor rotates the inner cover slide 100 steps to open the slits to the extended dead space. If the threshold is not reached, it is not considered apnea and a place holding integer is incremented. After 0.5 hrs or 180 cycles of no apnea being detected, the motor is rotated back 100 steps to decrease access to the extended dead space. The code also features the use of a program called PLX-DAQ by Parallax Inc to write collected data to an Excel file for analysis. The code with comments are detailed below:

// Sleep Apnea Device Algorithm

// Include Arduino Stepper library

```
#include <Stepper.h>

// Initiate integers for electronic components
// Initiate float array to sample voltages from flow sensor
// Initiate Apnea toggle, Apnea threshold and max and min voltage floats
// Initiate I/O pins for stepper, transistors and LEDs
// Initiate number of steps for motor to move for each activation and max movement
range
int in1Pin = 12;
int in2Pin = 11;
int in3Pin = 10;
int in4Pin = 9;
int LED = 8;
int motortrans = 7;
int sensortrans = 6;
int steps = 100;
float thresh = 0.1;
int adc;
float Voltage;
float Volts[50];
float maxvolt;
float minvolt;
int Apnea = 0;
int steplimit = 600;
int stepct = 0;
// int to time when cover should be rotated back due to extended normal breathing
int normal = 0;

// Set up stepper motor according to pin connections and specs
Stepper motor(513, in1Pin, in2Pin, in3Pin, in4Pin);

void setup() {

 // Begin serial monitor and baud rate
 // Set up Serial Monitor to write to Excel file using PLX-DAQ
 Serial.begin(9600);
 Serial.println("CLEARDATA"); //clears up any data left from previous projects
Serial.println("LABEL,Time,Timer,Voltage,Apnea"); //names of the columns
Serial.println("RESETTIMER"); //resets timer to 0
```

```
// Designate Analog 0 as input from flow sensor and begin Serial monitor
// Set up indicator LED ports, transistor modes and set stepper motor rotation speed
 motor.setSpeed(10);
 pinMode(motortrans, OUTPUT);
 pinMode(sensortrans, OUTPUT);
 pinMode(A0, INPUT);
 pinMode(LED, OUTPUT);
 digitalWrite(LED, LOW);
}

void loop() {

  // Start motor as unpowered
  digitalWrite(motortrans, LOW);

  // Reset max and min volt
  maxvolt = 0;
  minvolt = 100;

  // Capture 50 voltage points over 10 seconds
  for(int i = 0; i < 50; i++){
  // Code used to write data points into Excel file
  Serial.println();
  Serial.print("DATA,TIME,TIMER,");
  Serial.print(Voltage);
  Serial.print(",");
  Serial.print(Apnea);
  // Activate flow sensor for data collection in Voltage array
  // Convert analog to digital values (adc) to voltage values
  digitalWrite(sensortrans, HIGH);
  delay(100);
  adc = analogRead(A0);
  Voltage = adc * (5.0 / 1023.0);
  Volts[i] = Voltage;
  digitalWrite(sensortrans, LOW);
  delay(100);
  }
```

```
for(int i = 0; i < 49; i++){
// Find maximum and minimum voltages from the sample array
// Compares each voltage value with previous max and min
float temp = Volts[i];
if(temp > maxvolt){maxvolt = temp;}
if(temp < minvolt){minvolt = temp;}
}

// Subtract max and min to find voltage tidal volume
// Detect apnea if TV is below threshold - activate LED for Apnea
if(maxvolt-minvolt <= thresh){
  digitalWrite(LED, HIGH);
  Apnea = 1;
}
if(maxvolt-minvolt > thresh){
  digitalWrite(LED, LOW);
  Apnea = 0;
}

// Activate motor transistor if motor is not at rotation limit
// Rotate cover one step degree after apnea is detected
// Reset normal breathing counter
if(Apnea == 1){
  if(stepct < steplimit){
    digitalWrite(motortrans, HIGH);
    motor.step(steps);
    stepct = stepct + steps;
    digitalWrite(motortrans, LOW);
  }
    normal = 0;
}

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

// Activate motor if not at rotation limit
// Rotate cover back one step degree after 1/2 hr of normal breathing
```

```
  // Resets int normal
  if(normal == 90){
    if(stepct > 0){
      digitalWrite(motortrans, HIGH);
      motor.step(-steps);
      stepct = stepct - steps;
      digitalWrite(motortrans, LOW);
    }
    normal = 0;
  }
}
```

C) Material Costs

Part	Cost	Supplier
Body – Tupperware water bottle	$17.51	tupperware.com
5V Stepper Motor and Driver	$13.04	Amazon.com
1” PVC and 2 x 1” PVC Adaptor	$2.91	Home Depot
Poster	$41.00	College Library
Total	$74.46	

D) Image of unassembled machined parts

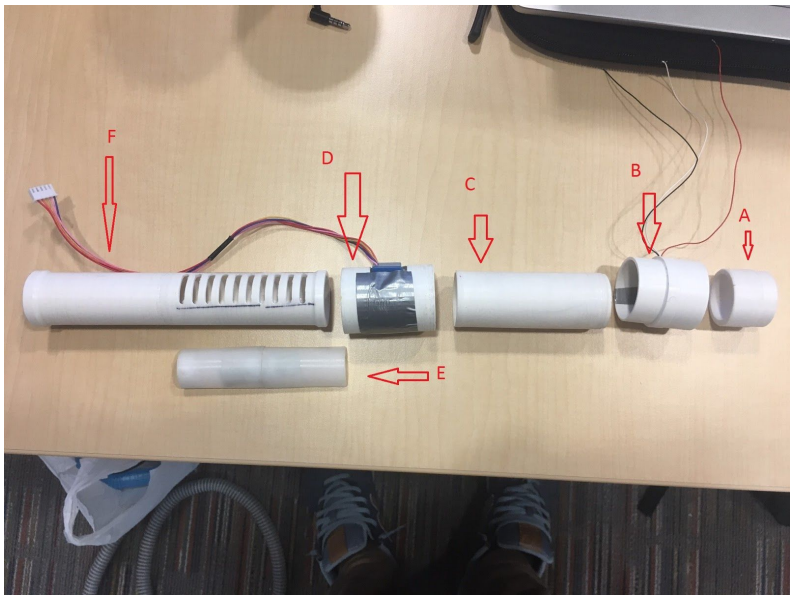

Figure 13. This figure is an aid to be used while reading the fabrication protocol.

E) Image of assembled machined parts

Figure 14. This figure displays what the machined parts look like when assembled. This configuration runs through the interior of the 1 liter body.

F) Machining Protocol

Starting material:

1) 1 - 1 liter water bottle
2) 1 - 2 foot long PVC tubing of 1” diameter

3) 2 - 3” long, 1” PVC adaptor
4) 1 – 6” long, 1” diameter delrin cylinder

Protocol:

On a bandsaw:

1) Saw a 2.5” ,5.5”, and a 9.5” piece from the 1” diameter PVC tubing. These will be used for parts A, C and F respectively.

On a lathe:

2) Turn the outside diameter of one of the PVC 1” adaptors down to 1.3” for half of its length (1.5”). This will be part B.
3) Face the sawed ends of parts A, C, and F so they have a smooth finish.
4) Bore the inside of part C such that the thickness is reduced to .1”.
5) Turn down the outside diameter of the delrin to .9”
6) Drill a hole in the hollow delrin to the wall thickness is .1”. This will be used to make part E.

On a mill:

7) Take part F and mill 10 slits with a .2” end mill. Each slit should be .2” separated from the next.
8) With the unused PVC 1” adaptor, mill a centered square window with the dimensions of 1” by 1.5”. This will be used for part D.

Back to Bandsaw:

9) Saw the hollow delrin tube in half. One of these halves will be used as the as part E.

G) Comfort Test Survey

SLEEP APNEA MACHINE COMFORTABILITY TESTING

1. Age:
2. Gender:
3. Approximate Weight:
4. Approximate Height:
5. How comfortable was this to wear? (5 being the mask was barely noticeable 1 being the mask was unbearable)

   1 2 3 4 5

   Comments:

6. How much did wearing this mask impair your breathing? (5 being the mask barely 1 being unbearable)

1 2 3 4 5

Comments:

7. How well do you think you would be able to sleep while wearing this machine? (5 being it would not affect your sleep at all 1 being you would not be able to sleep at all wearing it)

1 2 3 4 5

Comments:

9. While sleeping, do you believe the bottle would be comfortable on your chest?

YES or NO

Comments:

10. Do you have any comments on the overall design to improve wearability?

H) Survey Responses

Age-Gender-Weight-Height-Comfort-Impaired breathing-Able to Sleep-Bottle comfort
22 Male 171 6'1.5 4 4 3 yes
22 Male 185 5'8" 3 4 1 no
22 Male 210 6'6" 4 4 5 yes
22 Male 170 5'8" 4 3 4 no
22 Male 155 5'11" 3 5 3 yes
22 Male 140 5'10" 3 5 3 yes
21 Female 180 5'11" 3 4 2 yes
20 Female 240 6'2" 2 3 1 no
21 Female 120 5'4" 2 3 2 yes
20 Female 125 4'11" 2 3 1 no
21 Male 195 6'0" 5 4 3 no
23 Male 180 5'8" 1 2 1 no
21 Female 155 5'10" 2 2 3 yes test subject noted she has asthma
21 Female 125 5'8" 4 3 1 no
21 Female 125 5'4" 3 4 2 yes
21 Female 125 5'0" 4 4 4 no
21 Female 130 5'5" 2 2 3 yes
20 Female 130 5'9" 3 4 yes
22 Male 145 5'10 2 4 1 yes
22 female 135 5'5" 3 5 1 yes
23 male 170 5"11' 3 4 3 yes

22 female 105 5'4 4 4 2 yes
21 female 105 5'0 3 3 2 no
22 male 155 5'5 3 5 4 no
20 male 190 6'0 4 5 3 no
20 female 130 5'6 4 4 4 yes
20 female 160 5'6 4 4 3 yes
21 female 130 5'6 3 4 4 yes
21 male 140 5'7 4 5 3 no
20 male 210 6'0 4 4 3 yes