Product Design Specifications - Sleep Apnea Therapy Device – 2/2/2017

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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.