Product Design Specifications
CO2 Prevents Sleep Apnea
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Problem Statement: Sleep apnea is a common sleeping disorder in which an obstruction of the throat or absence of respiratory response prevents air from entering the lungs. Halted breathing results in increased concentrations of carbon dioxide in the blood stream, leading to an unconscious, regulatory respiratory response. A device must be designed and fabricated to monitor and maintain carbon dioxide concentration levels during sleep, accordingly adjusting levels to prevent apnea, while also being easy to use, minimally invasive, and universally marketable.

Client Requirements

- The device must induce hypocapnic conditions in the bloodstream.
- The device must increase the effective amount of dead space present in the breathing system.
- The device must be comfortable, small, and quiet since it is worn during sleep.
- The device will be used in a home setting; therefore, it must be easy to use and safe for those of all ages.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:* The device should be able to withstand repeated nightly use and maintain extended functionality. The facial mask should cover the nose and mouth while also generating an effective airtight seal through the use of straps, sealants, or individually molded face masks. The device should also increase the amount of dead space available during respiration to maximize an effective treatment
    b. *Safety:* The device's ability to function effectively should continue throughout the duration of the night. In addition to this, if the device should fail, further breathing difficulty should not arise and the patient should be able to maintain a stable and safe respiratory rate. The device should not contain small pieces that pose possible choking hazards for patients of all ages.
    c. *Accuracy and Reliability:* The device must be more effective than the current methods of preventing obstructive sleep apnea. Given the chronic nature of sleep apnea, the device must be able to function accurately and reliably on a daily basis to ensure an effective treatment.
    d. *Life in Service:* The device should remain operational indefinitely over its lifetime. If a carbon dioxide reservoir is used, the reservoir must function for over twelve hours.
    e. *Shelf Life:* The device must be safe to store at room temperature. The device should not contain any biological or perishable items that would suggest that the

device has a maximum shelf life. If a carbon dioxide reservoir is required, the carbon dioxide must remain usable for the entirety of its life.

f. *Operating Environment:* The device will mainly be operated in an individual's home, with many diverse individual users. The device must accommodate individuals of all "shapes and sizes". The use of individual facial molds is most effective in creating an effective seal for individuals with different physical builds. The targeted users are elderly adults and those who are at more risk to suffer from obstructive or central sleep apnea (overweight adults, those exhibiting particular facial features, etc.).

g. *Ergonomics:* The device must be user friendly (easy to understood and simple to operate for individuals without a medical or technical background) and comfortable (generates an effective seal while not disturbing the user during sleep)

h. *Size:* The device must be small enough to not be cumbersome or uncomfortable during sleep and all attachments should be portable.

i. *Weight:* The device should be light enough so as not to disturb the user during sleep. The device and its corresponding parts should be easily transferable from location to location to ensure ease of use.

j. *Materials:* The device and the entirety of its parts should not be carbon dioxide permeable, and must not react with relatively high concentrations of carbon dioxide. Materials must be light weight, malleable, and soft as to eliminate any sharp edges that may cause harm to an individual.

k. *Aesthetics, Appearance, and Finish:* The device should look professionally crafted. The device should be comfortable and contain a finish that is hypoallergenic.

2. Production Characteristics:

a. *Quantity:* One product will be needed.

b. *Target Product Cost:* A budget has not yet been proposed. Costs associated with device's construction should try to be minimized.

3. Miscellaneous:

a. *Standards and Specifications:* The device will need to be FDA approved before implementation.

b. *Customer:* the customers will be those (or the caretakers of those) with central sleep apnea, obstructive sleep apnea, or complex sleep apnea.

c. *Patient-Related Concerns:* The device must be safe and effective while also maximizing patient comfort. The device must be capable of being sterilized without physical damage; the materials should be non-carcinogenic and not cause allergic reactions or irritation upon contact or association with an individual. The materials should be antimicrobial and antifungal to reduce possible health concerns that may arise from use.

d. *Competition:* Multiple commercial devices are available, they are as follows:

i. *Continuous Positive Airway Pressure (CPAP):* A machine that delivers air pressure through a facial mask placed over the nose and mouth during sleep. The air pressure provided is slightly greater than the surrounding air

pressure, causing the upper airway passage of the patient to remain open, allowing for the movement of air. This is the most common and reliable treatment method, but can be uncomfortable and cumbersome to patients.

ii. *Adjustable airway pressure device:* A device that automatically adjusts air pressure during sleep.

iii. *Automatic Positive Airway Pressure (APAP):* A device that decreases air pressure when the upper airway is stable, and increases air pressure when the upper airway is blocked.

iv. *Bilevel Positive Airway Pressure (BPAP):* A device that provides more air pressure during inhalation and decreases air pressure during exhalation.

v. *Expiratory Positive Airway Pressure (EPAP):* A small, single use device that is placed over each nostril before sleep; device allows unrestricted air flow in, but restricts airflow out, thus increasing air pressure in the dead space.

vi. *Oral Device:* A device that keeps the airway open by 1.) Pushing the lower jaw forward using a mandibular advancement device, 2.) Preventing the tongue from falling back over the airway using a tongue retaining device, or 3.) A combination of the previous devices.