Project Design Specifications
Sleep Lab Monitor
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Function:

Currently there are two devices in a child's nostrils during polysomnography (sleep studies): a thermistor to detect temperature difference between inhaled and exhaled air, and a cannula with measuring both pressure during upper airway narrowing and end tidal carbon dioxide ($ETCO_2$). This can cause obstruction of the patient's nostrils which can increase nasal resistance, thus skewing the results of the study. Also, if one nostril is obstructed, then the measurements coming from that nostril may be unavailable. Moreover, the current apparatus may be uncomfortable for the child. The goal is to design and develop a prototype that combines these three measurements into one apparatus that samples from both nostrils of the nose as well as the mouth, and attaches to the child in both a durable and comfortable fashion.

Client Requirements:

- The device will combine a way of measuring air flow, pressure, and $ETCO_2$ during a polysomnogram.
- The device will measure from both nostrils and the mouth.
- The device should fit pediatric patients.
- It should stay on the patient throughout the night.
- The device should be entirely diposable
- It needs to be comfortable, durable, and limit sleep disruption.
- Complete a working prototype by the end of the semester.

Design Requirements:

1. Physical and operational characteristics

a. Performance requirements

- This device should be able to take continuous measurements of temperature, $ETCO_2$ %, and nasal pressure during an overnight sleep study.
- The entire device should sterilized prior to packaging and be disposed of after each use.
- It should be able to send the information directly to currently used devices where it will be monitored and recorded. These devices are the Respironics Alice 5 Diagnositc Sleep System and the Respironics Capnogard Capnograph.

b. Safety

- The device should not obstruct the breathing pathway of the patient in any way.
- The device should not irritate the patient's face, preventing them from sleeping.

- The packaging of the device should have a warning label attached to it listing any materials contained in the device.
- The tubing should be secured to the patient to prevent the cord from tangling around the patient during sleep.

c. Accuracy and Reliability:

- The thermistor should be able to measure temperatures between 20 and 45 degrees Celsius.
- The nasal pressure cannula should be able to measure pressure values between 0 and 20 cmH_20.
- The $ETCO_2$ cannula should be able to measure CO_2 values between 0 and 80 mmHg.

d. Life in Service:

- The temperature sensor one time before being disposed of.
- The pressure and CO2 sensors should be combined in a cannula that can be discarded after each use.
- The device should be able to be constantly used for up to 12 hours at a time.

e. Shelf Life

- The thermistors should last through an entire night study before being discarded.
- The cannulas should last through an entire night study before being discarded.

f. Operating Environment

- The thermistor and cannula should be able to operate in 20-50% ambient humidity and 100% humidity in exhaled air.
- The wires and tubes should be durable and long enough to resist periodic head movement and tugging from the hands during sleep.

g. Ergonomics

- The interface should utilize the existing adhesives.
- The thermistor wires and cannula tubes should be durable and wide enough to be secured on the face by the existing adhesives used.
- The wires and tubes should be long enough not to restrict movement during sleep.

h. Size

- The device must be able to fit comfortably between the mouth and nose across the upper lip.
- Since the device's intended use is for children, it must be small enough to fit between the child's nose and mouth.
- The device must not restrict movement or impair breathing.

- The tubing/cords for the device must be at least 8 feet long
- The diameter of the tubing must be large enough to be adequately secured by tape.
- The device must be portable.

i. *Weight*

- The device must be lightweight, resting comfortably on the nose and mouth.
- It must not cause any discomfort to the patient
- The staff must be able to easily carry and transport it.

j. Materials

- All materials used in this device should be biocompatible.
- Should not induce possible allergic reactions.
- Latex free.
- The materials should be lightweight and easily sanitized.
- The device must be durable and easily stored.

k. Aesthetic, Appearance, and Finish

- The design should accommodate children, but have a professional appearance.
- Adhesive must not leave large amounts of residue and should not be painful to remove.

2. Production Characteristics

a. *Quantity*: The device should be able to be produced in mass quantities.

b. *Target Product Cost*: A thermistor costs around $8 and a cannula between $2 and $3. The end product will contain these two items and thus should be under $15 total.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval of a class I device would be required to use the device in a clinical setting.

b. *Customer*: Device needs to be comfortable, durable, and limit sleep disruption. The wearer of the device will be a sleeping infant or child, thus comfort is a big issue.

c. *Patient-related concerns*: Device should not cause discomfort or sleep disruption. The thermistor part of the device will need to be reusable and thus sterilized. The cannula portion of the device can be disposable.

d. *Competition*: There are cannulas which allow for measurement of CO_2 and delivery of O_2 simultaneously made by Oridion. There are also split cannulas which measure pressure and CO_2. However, no devices which measure all three items could be found.