Sleep Lab Monitor

BME 400
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Team:
Jack Page, Team Leader
Nicole Daehn, Communicator
Lindsey Carlson, BSAC
Robyn Hrobsky, BWIG

Client:
Christopher G. Green, MD
Department of Pediatrics
School of Medicine and Public Health

Advisor:
Willis Tompkins
Department of Biomedical Engineering
University of Wisconsin - Madison

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Abstract

Sleep disordered breathing (SDB) is a very common disorder among all ages which can be detrimental to behavioral, emotional, social, and physical health. These disorders are diagnosed by polysomnography, or more simply, sleep studies. Most of the people who suffer from SDB are undiagnosed, and thus these sleep studies become very important for diagnosing these disorders. For pediatric patients, there are many weaknesses to the current method of studies. Currently, a unit containing thermistors and a cannula are stacked on top of each other under the patient's nose. Because of the small size of a child's nose, this method can obstruct the nostrils and make it difficult to breathe. Also, because of the small size of a pediatric patient's head and face, the method used to secure the devices is not sufficient and the devices may not stay in place throughout the night. These problems can lead to inaccurate measurements, discomfort, and sleep disruption, especially in pediatric patients. To help solve these problems, many different design options were explored and evaluated. A prototype of the design that best solves the current issues has been built. The prototype combines temperature change during exhalation, pressure, and end tidal carbon dioxide ($ETCO_2$) measurements into one device, samples from both nostrils and the mouth, and attaches to a pediatric patient in both a durable and comfortable fashion.

Background

Sleep Disordered Breathing

Sleep disordered breathing (SDB) refers to a class of breathing disorders which occur when a person is sleeping. SDB includes sleep apnea, hypopnea, heavy snoring, or even increased airway resistance during sleep. Three types of sleep apnea are included in this group,

which affect more than 18 million Americans [1]. These are obstructive, central, and mixed apnea. Obstructive apnea is characterized by a blocked airway, which ceases breathing. However, with obstructive apnea, the patient is still attempting to breathe [2]. Central apnea means that the patient is not breathing, but there is no effort to breathe [2]. Mixed apnea is a combination of obstructive and central. Hypopnea is different than apnea because there is actually airflow occurring. However, the patient is experiencing very shallow breaths or a very low respiration rate [3].

These disorders can be very detrimental to the health of the individual experiencing them. These individuals can wake up hundreds of times each night without even knowing it [1]. This can lead to behavioral, social, emotional, and physical problems. Behavioral problems include the inability to pay attention which can lead to misdiagnoses of Attention Deficit Hyperactivity Disorder (ADHD), poor academic performance, or poor on the job performance caused by fatigue and being tired throughout the day. Social and emotional problems include irritability, being easily agitated, and depression [1] [2]. More serious physical health problems include delayed mental and physical growth, memory problems, weight gain, and hypertension which can lead to a heart attack or stroke [3] [2].

Since these disorders occur at night, most of the people who suffer from them do not even know that there is a problem. For example, it is estimated that more than 50 percent of the people who suffer from sleep apnea are undiagnosed [1]. This is an immense problem which needs to be resolved. The diagnosing of SDB is very important.

Polysomnography

Polysomnography is the technical name for a sleep study. Physiological parameters related to sleep and breathing are measured and recorded continuously throughout the night

during polysomnography. These measurements include an electroencephalogram (EEG) to measure brain electrical activity, an electrooccuIogram (EOG) to measure eye movement, an electromyogram (EMG) to measure muscle movement, an electrocardiogram (ECG) to measure heart rate and rhythm, piezo crystal effort sensors to measure respiratory effort, and a pulse oximeter to measure oxygen saturation. These measurements are made by electrodes, effort belts, and other sensors places on the head, eyes, chin, chest, abdomen, and legs (see Figure 1). There is also a thermistor unit to measure flow and a cannula to measure nasal pressure and end-tidal carbon dioxide ($ETCO_2$) which are placed on top of each other between the nose and upper lip (see Figures 2 and 3). All of the sensors which are hooked up to the patient during the studies are shown in Figure 4.

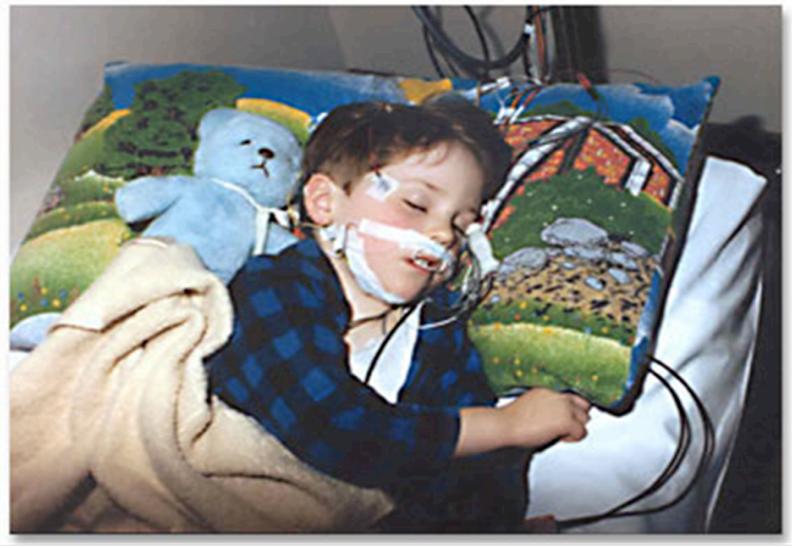

Figure 1. Pediatric Sleep Study [4]

Figure 2. Thermistors measuring flow [5]

Figure 3. Cannula for Pressure & $ETCO_2$ [6]

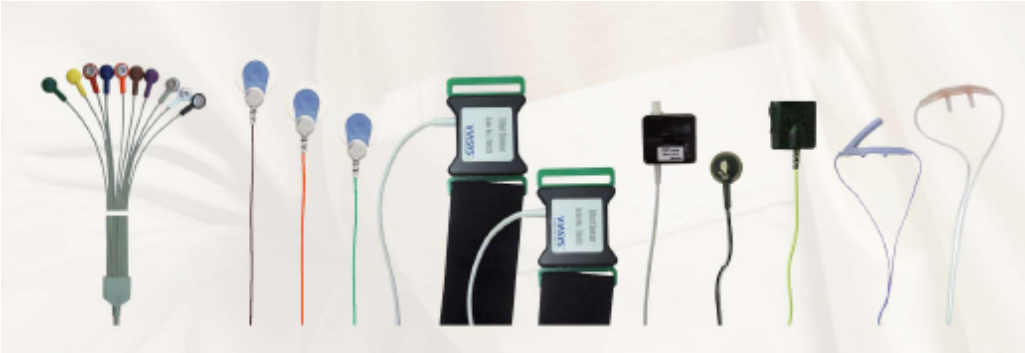

Figure 4. Sensors left to right: EEG, EOG, EMG electrodes, ECG electrodes, 2 effort belts CPAP sensor, Snoring Mic, Finger Sensor, Thermistor, Nasal prong [7]

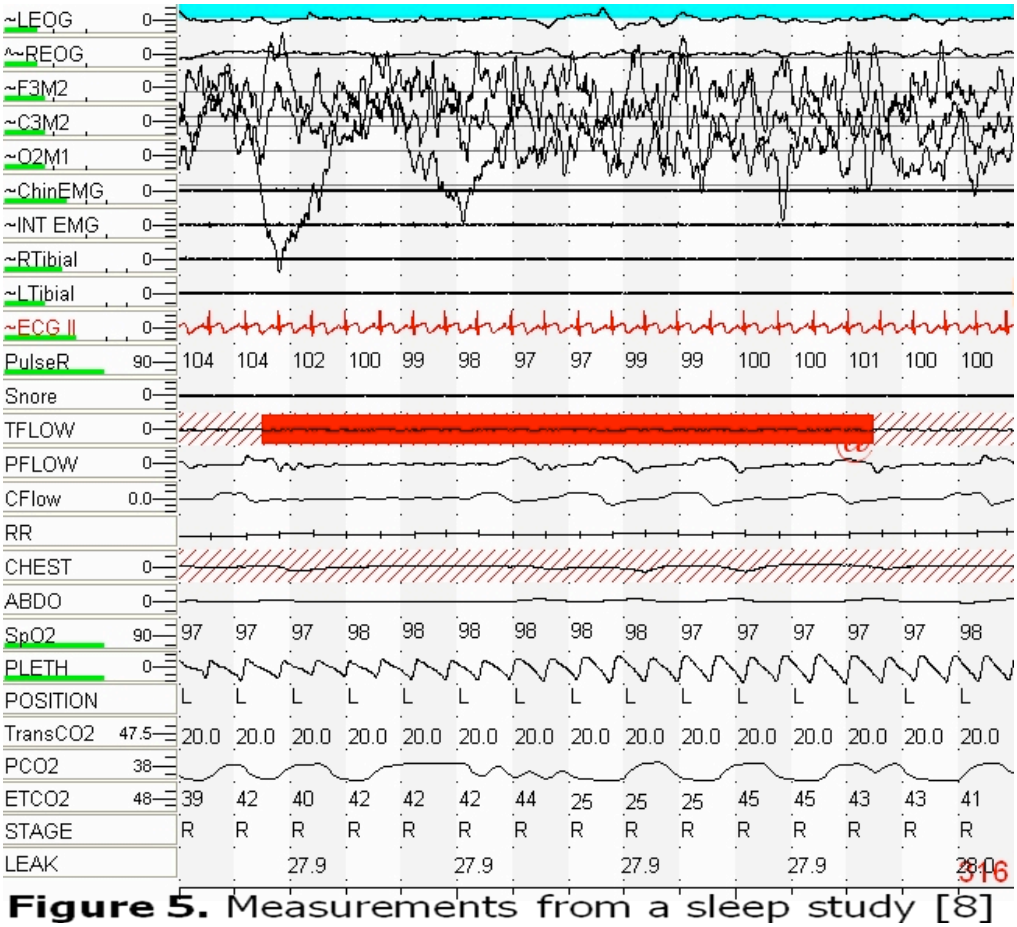

Figure 5. Measurements from a sleep study [8]

Each of the measurements taken throughout the night is displayed on computers using software where technicians and doctors can monitor them. Figure 5 shows a screenshot of this information. The doctors use this information to determine if the patient is suffering from many different conditions. For example, if the TFlow channel does not show breathing, then the doctor knows the patient is experiencing an apnea episode. Then the doctor looks at movement in the chest and the abdomen to determine if the apnea is obstructive or central. If there is no effort in the chest and abdomen channels, then it is central apnea, which is shown highlighted in Figure 5.

Problem Overview and Problem Statement

The three measurements this design focuses on are the measurements taken directly from each breath by devices placed under the nose. The following devices are used: a thermistor to detect temperature difference between inhaled and exhaled air, pressure sensors that show a flattening pressure profile during upper airway narrowing, and CO_2 sampling tubes to sense $ETCO_2$. These three measurements are taken from two different devices placed under the child's nose, with two prongs going into each nostril. For the pediatric patient, there are many different problems with the way these measurements are taken. The thermistor unit shown in Figure 3 is stacked on top of a cannula similar to the one shown in Figure 4. Since the nostrils of a pediatric patient are so small, this method can obstruct the child's breathing, which can lead to discomfort and sleep disruption. This method can also be inaccurate if a nostril was to become obstructed, and each device may not sample from both nostrils as well as the mouth. Moreover, the current apparatus may be uncomfortable for the child as well as insecure on the child's face since the wires from the thermistor unit and the tubes from the cannula are both secured with tape. To solve these problems, the goal is to design and develop a prototype that combines these three

measuring devices into one apparatus that samples from both of the nostrils as well as the mouth, and attaches to the child in both a durable and comfortable fashion.

Product Design Specifications Summary

The design needs to combine devices to measure flow, $ETCO_2$, and airway pressure into one apparatus. This includes using three thermistors in series which are able to measure temperatures between 20 and 45 degrees Celsius. These thermistors need to have a resistance at room temperature of 10 kΩ and be able to operate accurately in high humidity environments. The thermistors need to be connected to a cannula with openings to both nostrils as well as the mouth. The device needs to fit pediatric patients and be compatible with existing measuring devices used in the sleep lab. It should be able to send the information collected during the night directly to the currently used devices where it will be monitored and recorded. An attachment system needs to be designed which secures the device on a pediatric patient's face for the entire duration of the night. This system needs to attach in a way that does not use irritating adhesives or disrupt sleep. The system should also be able to stay secured to the face if the patient were to move or roll over while sleeping. Finally, the entire apparatus should be inexpensive since it needs to be disposable.

Alternate Designs

Cuff Design

This design consists of three cuffs which slide over the top of each nasal/oral prong. Each plastic cuff will have one surface mount, negative temperature coefficient thermistor attached to the outside. The three thermistors will be attached to one another in series. The thermistors are in

essence, resistors. Thus, with a negative temperature coefficient thermistor (NTC), when the patient inhales, the resistance of the thermistor increases and when the patient exhales, the resistance decreases, due to the increasing temperature. The thermistor wires will run along each side of the cannula and plug into the existing equipment.

The advantages of this design are numerous. First, the cuffs slide over the nasal/oral prongs, allowing them to be reusable (see figure 6). When the patient is finished using the

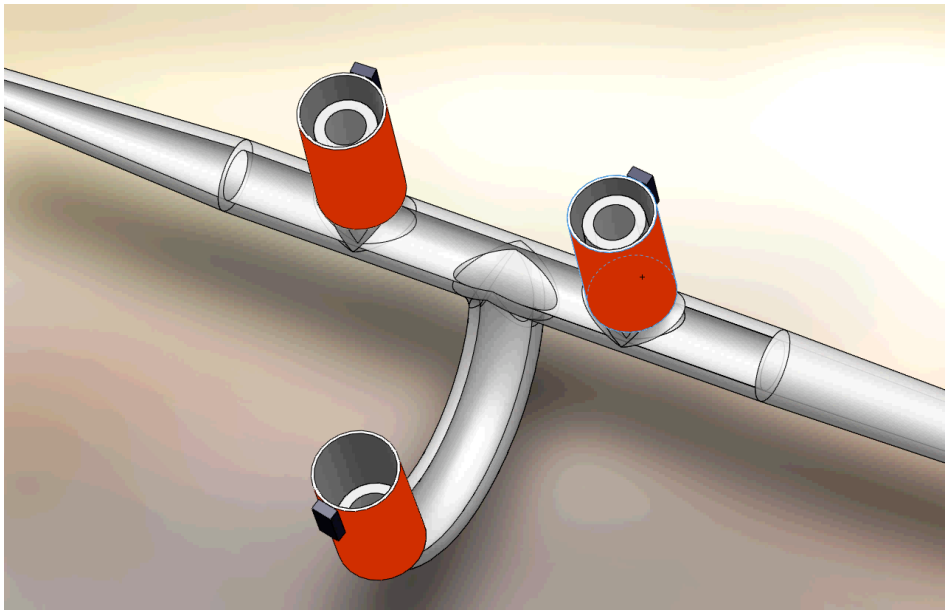

Figure 6. Cuff Design

thermistors, the cuffs can be removed for disinfection and use on another patient. Also, the cannula allows for nasal and oral sampling of both $ETCO_2$ and nasal pressure, while the thermistors allow for sampling of breath. In this design, all three measurements are combined into one device.

However, disadvantages also exist with this device. Often throughout the night patients, especially children, move during sleep. In order to prevent the cannula and thermistor from sliding off the face, technicians tape the wires to the cheekbones. Unfortunately, the wires do not have a large radius and often tape is not sufficient to keep the cannula and thermistor in place all night. The cuff design does not contain any extra attachments to further prevent the device from

falling off the patient during sleep. Furthermore, the client would prefer a device that is disposable, which is not a feature of this design. Finally, another disadvantage of this device is that since the cuffs are removable, the wires of the thermistors cannot be connected to the cannula in any way and must remain separate. If they were to be imbedded in the plastic of the cannula for example, then the cuffs would not be able to be removed.

Clip Design

The clip design utilizes only one surface mount, NTC thermistor. This thermistor is attached to a clip, which can be clipped to the cannula in between the two nasal prongs (see figures 7 and 8). The cannula in this design only samples from the nasal cavities and not the mouth. Therefore, in order to eliminate error due to nasal occlusion, the nasal prongs on the cannula are modified in this design. Each nasal prong is split in two so that it can sample both $ETCO_2$ and nasal pressure. The top half of each nasal prong goes to the capnograph, which measures $ETCO_2$ and the air entering the bottom half flows in the opposite direction to measure nasal pressure. The thermistor wires in this design will run along both sides of the cannula and plug into the existing equipment.

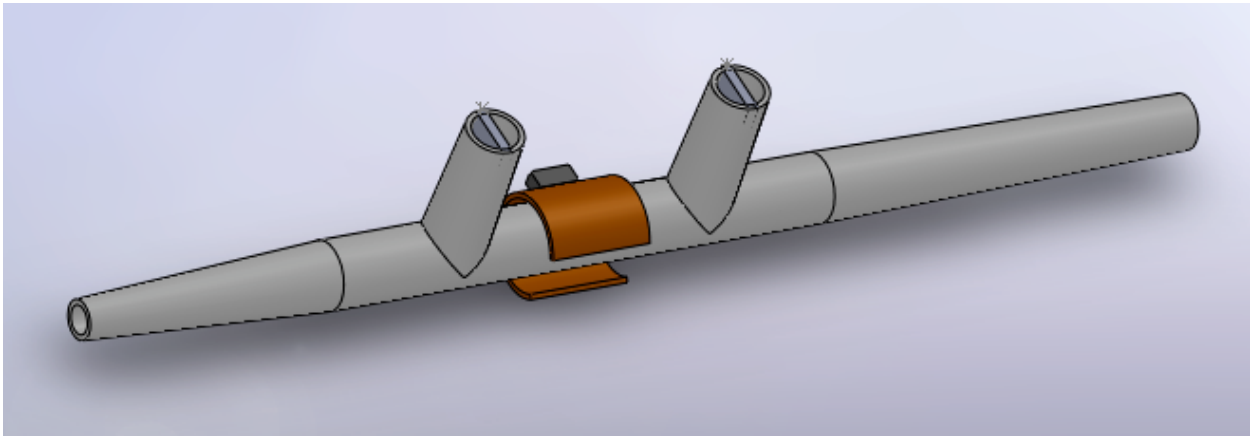

Figure 7. Back view of clip design

This design has several advantages. First, it eliminates discrepancies in the data due to occlusion of a nostril by allowing sampling of $ETCO_2$ and nasal pressure from both nostrils. In addition, it incorporates all three monitoring methods into one device.

However, this design has more disadvantages. First, only one thermistor is used, which makes the device less accurate. The use of three thermistors is currently the standard in the Wisconsin Sleep Lab. In addition, although the thermistor is reusable because the clip can be removed and disinfected, the client prefers that the thermistor be disposable. Furthermore, there is no attachment system for the face so children can easily remove the device when moving during sleep. Finally, the thermistor wires are separate from the cannula, which allows for an increased chance of it snagging on something during sleep.

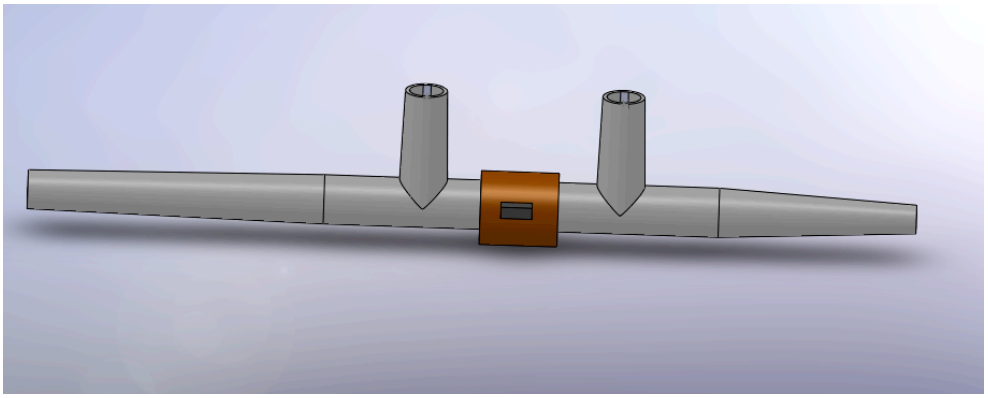

Figure 8. Front view of clip design

Final Design

Imbedded Wire Design

The final design is an imbedded wire design. This design consists of three thermistors that are attached to the cannula body; one on each nasal extension and a third on the oral extension. These three thermistors are connected in series, with the wires injection molded onto

the cannula body. Because three thermistors would be used instead of one, the device would be much more accurate, collecting data from both the oral and nasal airways (see Figure 9). Additional wires are imbedded in the plastic of the oral and nasal extensions to allow for flexibility. This would allow the sleep lab technician to adjust the position of the cannula to fit all mouth and nose sizes. Due to the low cost of thermistors and wires that would be added to the cannula, this entire interface is disposable. This eliminates the need for disinfection between each use as is needed now with the reusable thermistor that is used for several sleep studies before being disposed of.

This imbedded wire design scored the highest on the design matrix and as a result was chosen for the final design (see Table 1). The main reason for this high score is client interest. The client wanted a disposable product that did not need to be disinfected between each use. Because of the low cost of the imbedded wire design, this is possible.

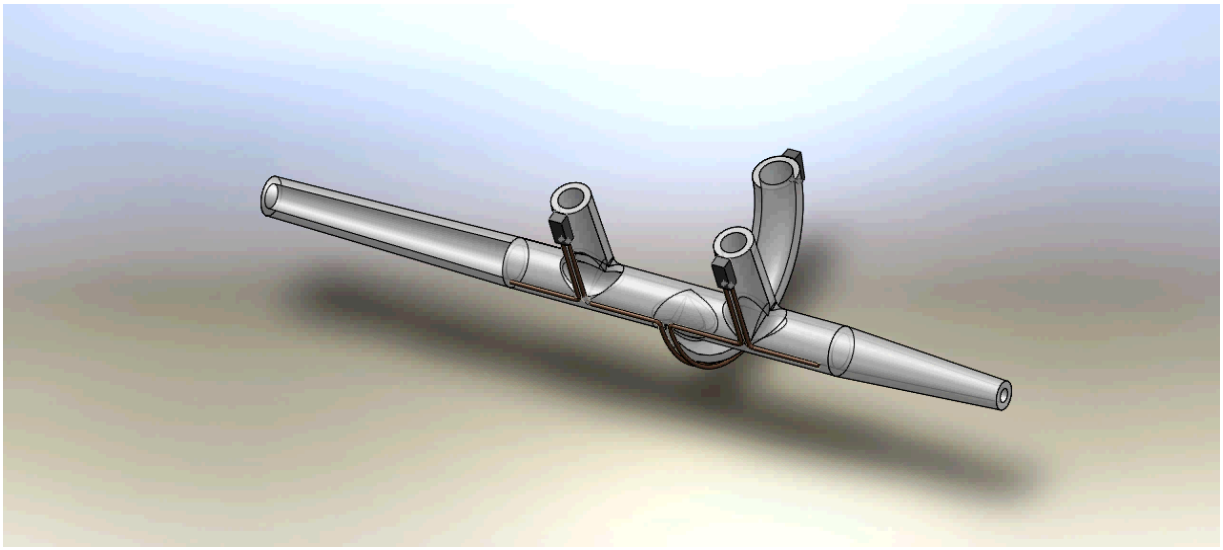

Figure 9. Embedded wire design

	Weight	Clip Design	Cuff Design	Imbedded Wire
Accuracy	0.25	1	3	3
Disposable	0.2	2	2	3
Cost	0.2	1	1	2
Client Interest	0.2	1	2	3
Feasibility	0.15	1	2	2
TOTAL	**1.0**	**1.20**	**2.05**	**2.65**

Table 1: The design matrix

Attachment Alternative Designs

To ensure that data is collected accurately and continuously through the duration of a sleep study, the apparatus must not move away from the nasal and oral airways during testing. Two attachment options were considered to make this possible: a Velcro strap and a wide tube. The Velcro strap design includes a strap that is secured to each side of the cannula near the upper lip and nostrils and secured tightly behind the head and neck (see Figure 10). The strap would be made out of a comfortable breathable fabric to decrease irritation on skin and include a broad area of Velcro lining to allow for adjustability for different sizes. This would also allow the technician to control how tightly the strap is secured to the face. The wide tube design includes extra pieces of flexible plastic that are added to either side of the cannula. The alternative attachment design, the tube design, is a wide piece of plastic that is attached to either side of the cannula body. This plastic piece would have a wide, flat base and broad sloped edges which would allow for more surface area for attachment to the face (see Figure 10). Latex-free

materials would be used to build the piece to avoid skin irritation. The tube would be attached using existing adhesives currently used by the Wisconsin Sleep Laboratory.

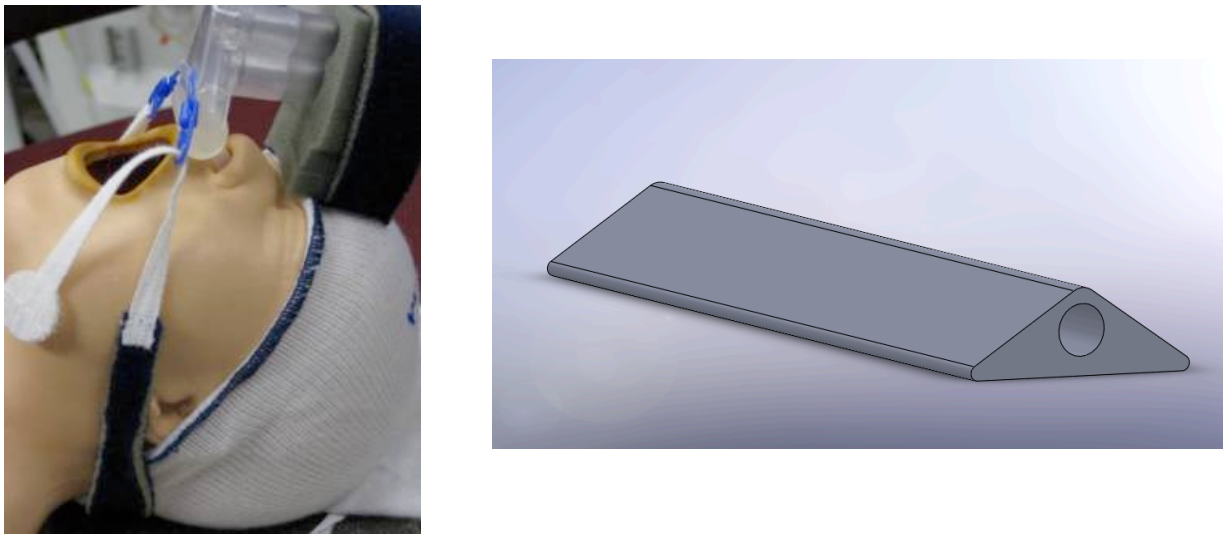

Figure 10. Velcro attachment (left), Wide Tube Attachment (right)

Attachment Design Matrix

	Weight	Velco Strap	Wide Tube
Comfort	0.35	1	2
Durability	0.65	2	3
TOTAL	**1.0**	**1.65**	**2.65**

Table 2: The design matrix for the attachment design alternatives.

Two major designs were considered for attachment of the device to the face: the Velcro strap and the wide tube (see Figure 10). The durability of the attachment system is important because the cannula must stay attached to the face in the airways to allow for accurate data to be

continuously acquired. A sleep study lasts for 8 hours so the attachment of the device must be able to withstand the tossing and turning of subjects during sleep. The Velcro strap only scored a two out of three for durability because the strap is only secured to the back of the head. This keeps the device held down on the face, but does not prevent the cannula from sliding up and down, out of the airways. The free strap is also available for child to tug on and damaging the cannula during a study. The wide tube is a better solution to prevent the cannula from moving in all directions, and as a result it scored a three out of three for durability.

Comfort was less important but was still considered because the child would be less susceptible to try and pull on the device if it were less irritating. Both of the designs are not considerably comfortable but the Velcro strap would be more irritating since the strap can slide around on the child's face during the study, irritating the skin. The wide tube would be a slightly better solution because it cannot cause facial abrasion after being taped to the face.

Attachment Final Design

The wide tube final design includes two attachment pieces 2" x 0.6" x 0.23" (see Figure 11). The diameters of each of the tube attachments are 0.9" to fit around the pressure tubing and 0.135" to fit around the CO_2 tubing of the cannula. The attachments were molded out of a white, flexible silicone rubber.

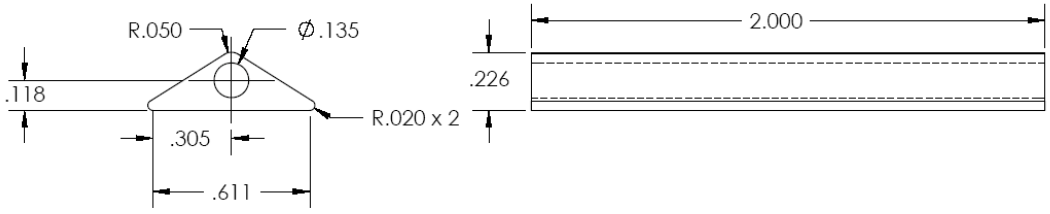

Figure 11. Attachment Design

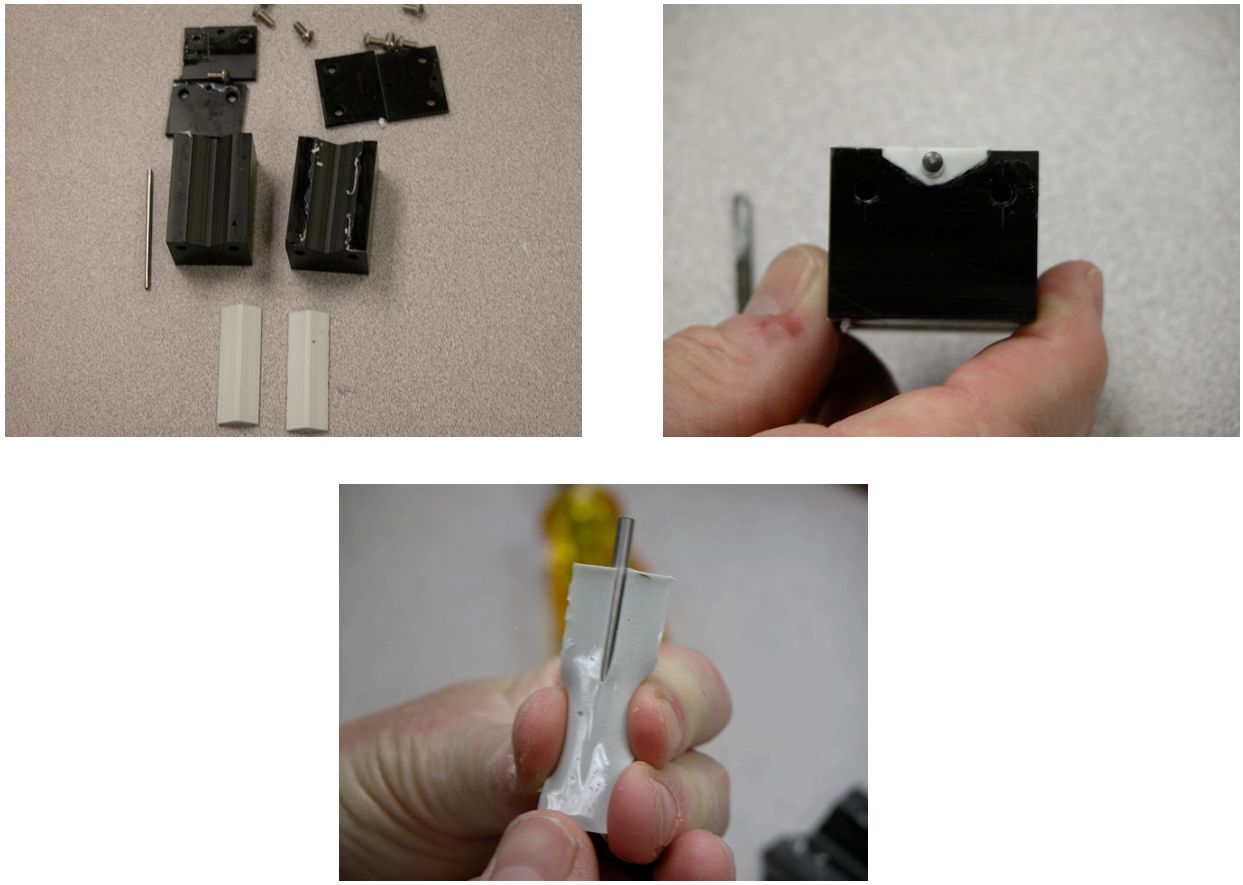

Figure 12. The removed attachment pieces and molds (upper left), the mold with one side removed (upper right) and the removal of the metal rod (lower middle)

The wide tube attachment pieces were constructed by using two molds (see Figure 12). The molds were made out of delrin and consist of grooves 0.611" x 2" and 0.23" deep with a 115-degree angle which was built using a mill. Two end pieces were screwed onto the ends of each block with holes drilled with diameters of 0.09" and 0.135. Two rods with the specified diameters were inserted through the drilled holes through the entire length of the mold as shown in Figure 12. The molds were rubbed with oil to prevent sticking of the liquid silicone. Ten parts liquid silicone was thoroughly mixed with one part blue curing liquid and poured into the molds. The excess silicone was wiped off of the top of the mold and was cured for 24 hours in a warm, dry area. The attachment pieces were taken out of the molds by removing the ends of the

molds and lifting the attachment pieces out. The metal rods were removed by making a length-wise incision down the center of the attachment as show in Figure 12.

The attachment pieces will be glued to either side of the cannula body so that the flat side of the attachment is in contact with the cheeks of a pediatric patient on either side of the upper lip. The attachment piece can be placed around the cannula tubing by opening the vertical incision. The pieces will then be taped down on the patient's cheeks securing the tubes and cannula to the face.

Testing

Several different types of tests were performed on two different types of thermistors prior to choosing the materials and building the final prototype. The two types of thermistors used were a surface mount thermistor and a wire lead thermistor that also had a protective coating. The first of these tests was done to compare the ability of different types of thermistors and wires to withstand the high temperatures of the injection molding process. In the future, the client is interested in taking this design to a manufacturer to have several cannulas built for use in the sleep lab. A manufacturer would need to attach the thermistors to the cannula when it was still hot, so the ability for the device to withstand these high temperatures was a very important aspect of the design. To do this test, the injection molding machines in the UW Polymer Lab were used to pour plastic molds of silicone. Silicone is a flexible plastic, very similar to that used to make the cannulas. Thermistors and wires were placed in the mold prior to pouring the plastic, to ensure that they were exposed to the extreme temperatures of the injection molding process. When the silicone plastic was melted and poured on the thermistors, it reached a temperature of 150 degrees Celsius or about 300 degrees Fahrenheit. The silicone molds, with

the thermistors imbedded in them, were then removed and used in the remaining of the tests along with new thermistors.

The second test that was performed with the thermistors was done to see their performance while being exposed to rapid changes in temperature, similar to that experienced when breathing. This was done by hooking different types of thermistors up in a circuit to obtain voltage readings as the resistance changed with temperature. The voltage across the thermistors was amplified using an op-amp and was then displayed using a LabView program. This LabView program continuously plotted the voltage values across the thermistors throughout time. The graphs for each of these thermistors are displayed in Figures 13 and 14 below.

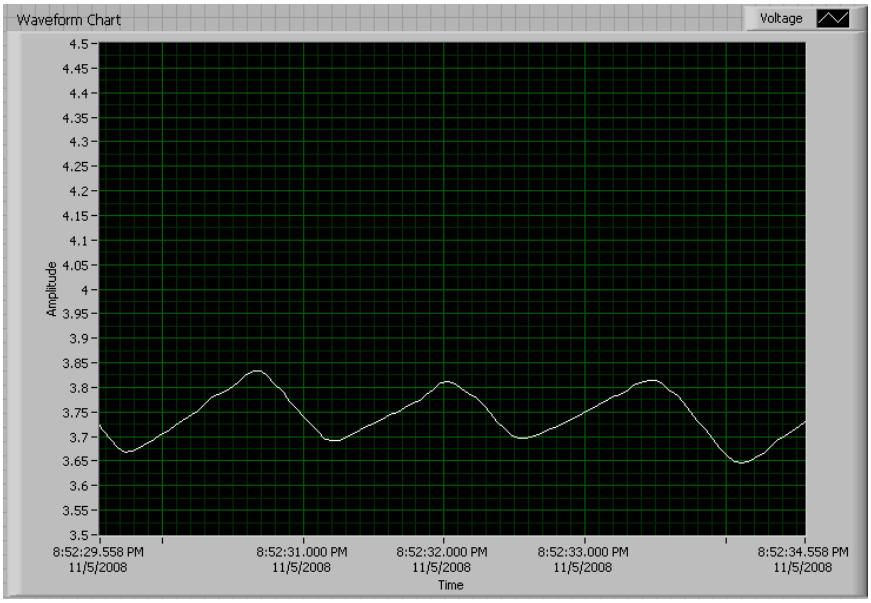

Figure 13. Voltage vs. Time graph for wire lead thermistor.

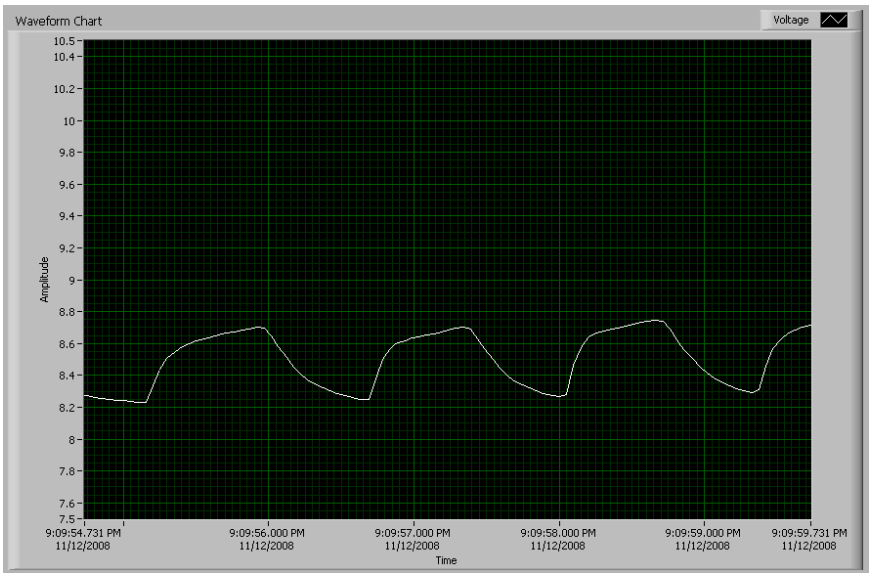

Figure 14. Voltage vs. Time graph for surface mount thermistor.

The thermistors that were earlier imbedded in plastic were also tested this way. Their graphs were almost identical to those displayed above. This ensures that the thermistors could withstand the injection molding process when the device would be manufactured. The thermistors used were negative temperature coefficient thermistors. This means that as the temperature increases, the resistance across the thermistors decreases. This can be seen on the two graphs shown above. The higher portion of the graphs corresponds to inhalation, when room temperature air is running past the thermistors. The lower portions of the graph are during exhalation when body temperature air is being pushed past the thermistors. This higher temperature, compared to room temperature, creates a lower resistance across the thermistors, which results in the lower voltage reading during exhalation.

Initially, surface mount thermistors were going to be used for the final design. This is because the shape of the voltage waveform for the surface mount thermistors was more square-like, making it easier to determine when inspiration and expiration was occurring. However, the

wire-lead thermistors are much more durable than the surface mount thermistors. Because children often pull on the device while they are sleeping, durability is a very important part of the final design. As a result, the wire-lead thermistors were chosen for the final prototype.

For the final prototype, the Salter Labs 5055 pediatric oral/nasal cannula was used. This cannula is the one that is currently being used at the UW Sleep Lab. This cannula was chosen because it takes $ETCO_2$ and nasal pressure measurements from both the nasal and oral airways. One end of the cannula connects to a capnograph, which measures $ETCO_2$, while the other end, which measures nasal pressure, attaches to the Alice device. The Alice is a sleep diagnostic device that takes several different types of measurements during a sleep study, such as ECG readings, leg, chest, and abdominal strap measurements and values from nasal pressure and flow. Three wire-lead, protective coated thermistors are soldered to wires in series. Because the thermistors are attached in series, the voltage seen across them is an average of each of their individual voltages. This is important because some people breathe through their nose, while others only breathe through their mouth while they are sleeping. Also, if one nasal prong becomes clogged with mucus, the other two extensions will still allow for accurate breath detection. The three thermistors are attached to the cannula via heat shrink. The melted heat shrink holds the thermistors and wires tight to the cannula tubing, so that they will not be pulled on during the sleep study.

In addition, the thermistors were tested in the temperature ranges that a sleep study is run under, room temperature (25 degrees C) to body temperature (37 degrees C). The voltage through the thermistors was amplified and displayed over time using a LabView program. A heat gun and thermometer were used to change the temperature across the thermistor. A 10 kΩ surface mount, 10 kΩ coated wire lead, and a 1 kΩ disk thermistor were tested. The heat gun

was directed toward the thermistor at different distances and the temperature and voltage were recorded each time. The graph below, in Figure 15, shows the data for each thermistor. Each thermistor exhibited a linear relationship between temperature and voltage in this range. This testing did not show any appreciable difference between the three thermistors and was therefore not used to choose a thermistor for the final prototype.

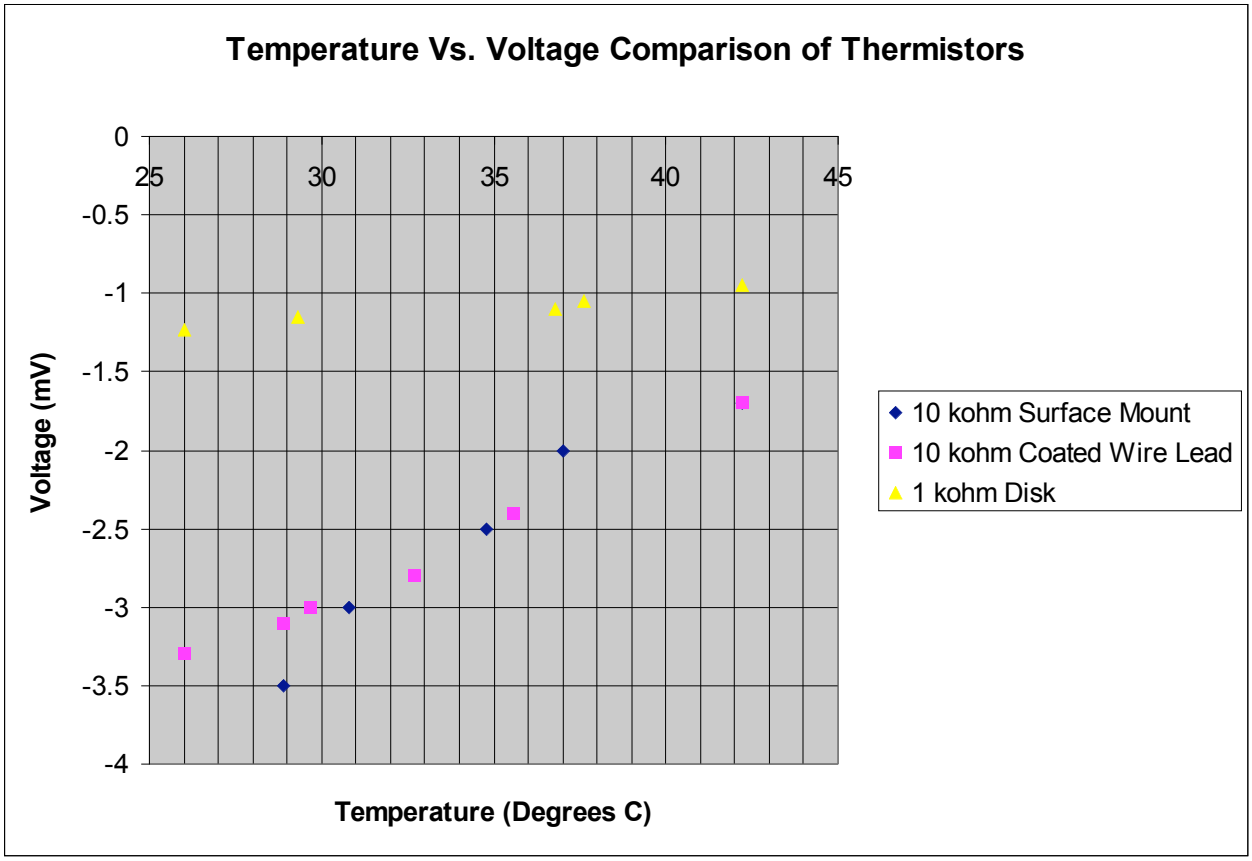

Figure 15: Temperature vs. Voltage comparison for three different types of thermistors.

Future Work and Ethical Considerations

Our current plan for next semester is to continue testing and improving our prototype. We have already built the prototype and tested the thermistors to make sure that they function in

series. We have also performed some preliminary testing on each of the thermistors we purchased to confirm that they function in the temperature range we need. Therefore, we would like to continue testing our prototype, in the Sleep Lab on ourselves to make sure that it functions with the existing equipment and software and is reliable. Before testing on ourselves, we will need to get permission from the Sleep Lab to do so. We also need to design a better way to attach the surface mount thermistors to the device. Furthermore, we would also like to begin working with companies to manufacture this device on a commercial scale. In working with these companies, we would like to develop a way to have the attachment pieces and thermistor wires injection molded with the cannula so that it is all one piece. If we want to work with a company to produce this device, we will most likely have to work with the FDA as well to get this device cleared for commercial sale. We will have to make sure that the device is safe and reliable by performing various durability and accuracy tests. Finally, we would also like to redesign the attachment pieces so that the edges are more rounded so they do not irritate the patient.

APPENDICES

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Project Design Specifications
Sleep Lab Monitor
October 1, 2008
Jack Page, Nicole Daehn, Lindsey Carlson, Robyn Hrobsky

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.
- At least a portion of the device should be reusable.
- It needs to be comfortable, durable, and limit sleep disruption.
- Complete a 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.
- It should be possible for this device to be used several times with a disinfection procedure performed between each use. The cannula portion 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.

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 warnings about sterilization and reuse.
- 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 will be reused several hundreds of times before being disposed of (replaced once a year).
- 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 be able to last for a year before replacement. The thermistors should be able to endure hanging from a stand while not in use.
- 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 $180 and a cannula between $2 and $3. The end product will contain these two items and thus should be under $200 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.