

A Device to Monitor Flow, End Tidal Carbon Dioxide, and Nasal Pressure During Pediatric Sleep Studies

Nicole S. Daehn, Lindsey C. Carlson, Robyn J. Hrobsky, and Jason Tham

Abstract—

Pediatric polysomnography studies require cumbersome facial instrumentation that can impede patient comfort and testing results. Current procedures require a nasal cannula with a separate thermistor circuit rigged on top, typically with adhesive tape. This study created a hybrid cannula with fixed thermistors in order to concurrently measure pneumatic flow, end tidal carbon dioxide (CO₂), temperature and nasal pressure. A study of efficacy of the proposed system versus current methods, thermistor sensitivity with distance from the nose and a validation of thermistor function comprised the three testing phases in this study. It was shown that the system was able to detect breaths with 100% selectivity during relaxed respiration and deep slow respiration, and 97.5% selectivity in shallow, fast respiration. Signal detection strength was reduced 61.1% when the cannula moved from 3 mm to 7 mm from the nasal cavity, yet breaths were still accurately detected. The thermistors indicated temperature changes linearly with a regression of 0.9988. It was shown through the suite of tests that the device is a viable polysomnographic instrument for clinical use.

INTRODUCTION

A sleep disorder is characterized by pausing in breathing during sleep. Each event lasts long enough that one or more breaths are missed. Clinically important levels of sleep apnea are defined as five or more episodes per hour of any type of apnea. Some examples of sleep apnea include obstructive apnea and central apnea. [5] Obstructive sleep apnea is caused by a blockage of the airway, usually when the soft tissue in the rear of the throat collapses and closes during sleep. Therefore, when the patient attempts to inhale, the throat closes completely and air cannot pass to the lungs. [1] Central apnea is a condition in which a person stops breathing during sleep because the brain temporarily stops sending signals to the muscles that control breathing. [2] Individuals with sleep disordered breathing are disrupted hundreds of times each night, yet these individuals are rarely aware of having difficulty breathing, even upon awakening. [5]

Sleep disordered breathing affects approximately 18 million Americans every year, of which 10 million cases remain undiagnosed [3]. It is especially important that children with these conditions are diagnosed as behavioral, emotional, and social problems can develop if left untreated. Undiagnosed sleep disordered breathing can lead to delayed mental and physical growth in children as well. [3]

In order to diagnose sleep disordered breathing, an overnight polysomnography study is performed. This study measures various functions including EEG, airflow, oxygen saturation, nasal pressure, end-tidal carbon dioxide, and chest wall and upper abdominal movement to diagnose these conditions [4]. Current methods of polysomnography can lead to inaccurate measurements, discomfort, and sleep disruption. Specifically, air flow, nasal pressure, and end-tidal carbon dioxide measurements are made using a separate thermistor and cannula respectively. The thermistors are not only expensive, but non-disposable as well. Inaccuracies can occur when children have occluded nostrils or disrupt the cannula by pulling at it or moving during sleep. Thermistors exist that overlay a cannula so that all three measurements can be combined, but these devices do not measure from both the nasal and oral passages and are reusable, making them more expensive. The objective of this project is to design and develop a cost effective, disposable prototype that combines air flow, nasal pressure, and end-tidal carbon dioxide measurements into one device. This device should sample from both nostrils and the mouth, and attach to the face in both a durable and comfortable fashion.

I. DEVICE DESIGN, FABRICATION, AND COST

A. General Design Description

The device was designed to satisfy the following design criteria:

- 1) Continuous measurements of air flow, nasal pressure, and ET/CO₂ % during a polysomnography test
- 2) Measurements collected from both nostrils and the mouth
- 3) Information sent directly to the currently used devices where it will be monitored and recorded. These devices are the Respironics Alice 5 Diagnostic Sleep System and the Respironics Capnogard Capnograph.
- 4) Device should fit on pediatric patients and remain on them throughout an eight hour study.
- 5) Device should be entirely disposable
- 6) Device needs to be comfortable, durable, and limit sleep disruption.

The design (Figure 1) consists of a Salter Labs 5055 cannula and a thermistor array. The cannula collects data to measure nasal pressure and end tidal carbon dioxide (ET/CO₂) and has sampling capabilities from the face piece nasal prongs and the oral extension. The face piece divides into two tubes, one small clear gas sampling tube and one large nasal

pressure tube. The airflow pressure tube contains a filter on the end of it. The nasal pressure and carbon dioxide measurements are continuously taken from the cannula as the pediatric patient inhales and exhales. The nasal pressure measurement is taken by the Respironics Alice 5 Diagnostic Sleep System while the end tidal carbon dioxide measurement is taken from the Respironics Capnograph.

The three 10 kΩ thermistors (Honeywell 112-103FAJ-B01 Discrete Thermistors) are soldered together in series. The leads of these thermistors are platinum iridium and therefore a platinum iridium solder was used to connect them. This thermistor array was then attached to the cannula. One thermistor was located on each nasal prong with a third thermistor fixed to the oral extension. These thermistors are negative temperature coefficient thermistors. The thermistors have an operating range of -60 degrees Celsius to 300 degrees Celsius and a time constant of four seconds.

The thermistor wires are securely attached to the cannula tubing via clear heat shrink. This is done to reduce the number of wires and tubes that are individually attached to the patient's face. This is beneficial because children often pull on the device during the night so this allows for more accurate data collection. The wires and tubing are also durable and long enough to resist periodic head and body movement. Two 1.5 mm safety lead connectors are attached to the end of the thermistor wires. The air flow measurement is taken by the Respironics Alice 5 Diagnostic Sleep System. The thermistors measure air flow by measuring the change in temperature that occurs as the patient inhales and exhales air as they breathe. Because the thermistors are negative temperature coefficient, the resistance across them decreases with increasing temperature.

The nasal pressure and end tidal carbon dioxide measurement values are quantitative measurements while the air flow measurement is only qualitative. The capnograph measures the EtCO₂ values between 0 and 80 % and the Alice 5 Sleep System measures nasal pressure values between 0 and 20 mmHg. These values give the clinician valuable information on the type of sleep disordered breathing that the patient may have. The thermistor measures temperature changes between the inhaled room temperature (about 20 °C) and exhaled body temperature air (about 45°C). This measurement is only used to determine whether or not the patient is breathing to conclude if they are having episodes of sleep apnea.

This device is attached to the patient's face using existing adhesives. Two attachment pieces (Figure 2) are connected to the cannula tubes on either side of the facial piece. These pieces are made of white silicon plastic. The purpose of these two pieces is to increase the surface area that the adhesive can attach to, to help keep the device on the child's face for the entire duration of the sleep study. One of the attachment pieces has a slightly larger hole through it to fit over the larger nasal pressure tubing.

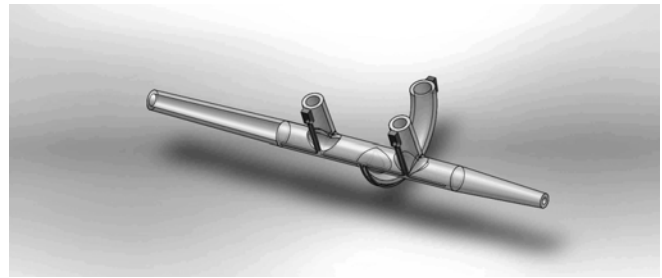


Fig. 1. A 3D SolidWorks drawing of final design. This does not include the additional six feet of tubing extending to the capnograph and pressure sensor. The right end extends to the pressure sensor and the left end extends to the capnograph.

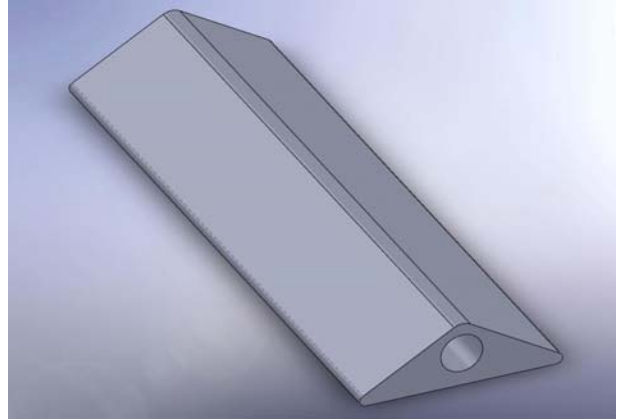


Fig. 2. A 3D SolidWorks drawing of an adapter piece created previously to aid in the fixation of the cannula to the face. Two attachment pieces are used on either periphery of the cannula and are made of white silicon plastic.

B. Electronics and Software

In a clinical setting, the device is used to collect air to be measured by the existing equipment. Therefore, it does not include any electronics. The voltage source used to read the resistance changes across the thermistors is supplied directly from the Respironics Alice 5 Diagnostic Sleep System.

In a lab setting, a simple voltage divider circuit is used to power the resistors and read the resistance changes across them as someone inhales and exhales. The wires of the cannula device were connected in series with a 30 kΩ resistor, to form the voltage divider circuit. The circuit was powered by a 5 V DC source and the output was sampled using a LabJack U12 DAQ device. The data is then processed and displayed using LabVIEW software (National Instruments; Austin, TX; LabVIEW) which converts the voltage changes (V) across the thermistor to a resistance change by equation (1).

$$R_T = \frac{(5V - V) \cdot 30 \text{ k}\Omega}{V} \quad (1)$$

LabVIEW continuously displays a graph of Voltage vs. Time which shows the waveform corresponding to the breath cycle of the patient. A flow diagram of the Labview Program is shown below in Figure 3.

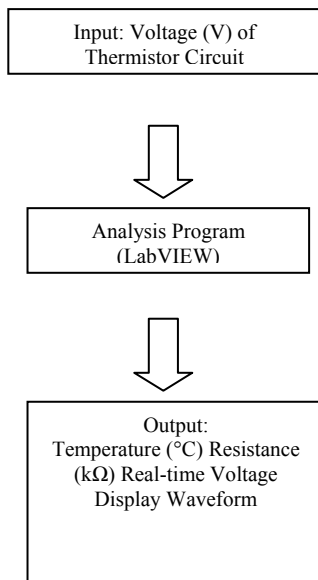


Fig. 3. Flow diagram of LabVIEW program. There is one input, the voltage across the 30 k Ω resistor in series with the thermistor circuit. There are 3 outputs, temperature ($^{\circ}$ C), resistance of thermistor circuit, and real-time voltage waveform.

C. Cost

The total cost of the device is about \$35. The majority of this cost is from purchasing the three 10k Ω thermistors individually. If the thermistors were bought in larger quantities, the cost would drop significantly.

II. EXPERIMENTAL TESTING

A series of tests were performed to determine the functionality of the thermistor portion of the device. These tests include a thermistor comparison test, a thermistor distance test, and a thermistor temperature test.

A. Thermistor Comparison Test

The purpose of the thermistor comparison test was to qualitatively compare the breath detection waveforms for the thermistor currently used in the sleep lab and the new prototype. Currently in the sleep lab, the Respironics Pro-tech pediatric thermistor is used to capture when breaths are occurring throughout the sleep study.

The data for this test was obtained by taping the two devices together, one on top of the other. The nasal and oral extensions were aligned so that both devices were reading the same inhaled and exhaled air. The devices were then placed on the subject using the adhesive that the sleep lab technicians currently use on their patients. The nasal prongs were placed in the nostrils and the oral extension was placed directly in front of the mouth. A reference electrode was attached to the skin on the side of the subject at the lower left rib. This was used to free the signal of any unwanted noise. The Respironics Pro-tech thermistor was connected to the TFLOW channel of the Alice 5 Sleep System and the prototype was connected to the LEOG channel so that both signals could be read simultaneously. An adaptor was used to connect the prototype because pediatric devices use smaller safety lead connectors than the adult devices.

The subject was asked to use several types of breathing throughout the test. These breathing styles include relaxed, shallow and fast, deep and slow, and deep and fast breathing. The signals for each of the thermistors were read using the Alice 5 software in the technician's computer room at a frequency of 100 Hz. A 0.7 Hz low pass filter was applied to the LEOG channel in order to minimize any noise. The TFLOW channel is designed with a 0.02 Hz low pass filter and a 47 Hz high pass filter.

B. Thermistor Distance Test

The purpose of the thermistor distance test was to determine the response of the prototype's thermistors from different distances from the nasal and oral airways. Pediatric patients who take part in the sleep study tend to tug on the cannula, pulling the nasal and oral extensions out of the direct airway. It needs to be proven that when this occurs, that the thermistors will still be able to detect the patient's breathing. The thermistor reading is a very important part of the sleep study evaluation because it determines whether or not the patient is breathing. This helps diagnose people with apnea, who stop breathing for several seconds many times throughout the night.

The data for this test was again obtained by taping the two devices together, one on top of the other. The nasal and oral extensions were aligned so that both devices were reading the same inhaled and exhaled air. Initially the devices were mounted on the subject's face with the nasal prongs directly in the nostrils and the oral extension in front of the mouth. A reference electrode was placed on the left side of the body at the location of the lower rib. This was used to minimize any noise. The thermistors were connected to the same channels as in the comparison test, with the same sampling rate and filters.

The subject was asked to breathe using a resting breathing rate. After data was collected for approximately one minute, the two devices were moved about three mm lower than the original position. The subject was again asked to breathe normally. The same measurements were taken with the device seven mm lower and then ten mm lower than the original location. The Alice 5 software recorded the output waveforms in order to be analyzed. A maximum distance of ten millimeters was used, because if the device were to move farther than this out of the direct airway, a lab technician would go into the patient's room and replace the device.

C. Thermistor Temperature Test

The purpose of this test is to quantitatively compare the functionality of the thermistor in comparison with theoretical calibrations. Currently, in the sleep lab the thermistor output is used qualitatively to detect breaths. This test assesses the temperature vs. resistance curve and can be used to develop an algorithm to calculate temperature vs. voltage.

The thermistor/cannula device was suspended into a glass container with a thermometer. The glass container was submerged in water in a heated bath as depicted in Figure 4. Using the LabVIEW program, the resistance change calculated was used to determine the temperature change of

the thermistor circuit using equation (2). The B-value for the thermistors was 3974, R_0 was 10 k Ω , and T_0 was 299 K.

$$T = \frac{B}{\ln\left(\frac{R_T}{3R_0 e^{-B/T_0}}\right)} \quad (2)$$

The temperature was increased from 25 °C to 45 °C by heating the water bath. For each degree increase in temperature from the thermometer, the voltage, resistance, and temperature of the thermistor circuit was recorded.



Fig. 4. The experimental set-up of the temperature test. The glass container was taped to the to the waterbath to keep it from floating.

III. RESULTS

A. Thermistor Comparison Test

Waveforms were obtained for each of the four breathing style trials. The number of peaks (number of breaths) for the prototype device and the Pro-tech thermistor were counted to determine how many breaths occurred in a one minute period for each type of breathing. The percentage of breaths detected by the prototype was then calculated. These numbers are recorded below in Table 1.

One hundred percent of the breaths were detected when the breathing was resting and deep and slow. 97.5 percent of the breaths were detected when the breathing was shallow and fast. The percentage of breaths detected while the breathing was deep and fast was unable to be determined. This is because the waveform for the prototype device was very noisy; therefore it was difficult to determine when the individual breaths were occurring.

TABLE 1: Percent of Breaths Detected by Prototype

Type of Breathing	# of breaths (prototype)	# of breaths (Pro-tech thermistor)	Percent of breaths detected by prototype (%)
Resting	11	11	100
Shallow and fast	39	40	97.5
Deep and slow	8	8	100
Deep and fast	Unable to determine	26	Unable to determine

B. Thermistor Distance Test

Waveforms were obtained through the tests from each of the thermistor positions. This distance was measured from the top of the lip to the bottom of the thermistor devices. These distances were 0 mm, 3 mm, 7 mm, and 10 mm. The data was collected by the Alice system at 100 Hz. It was passed through a low pass filter at 0.7 Hz before being plotted in the waveforms. Each of the waveforms was analyzed to determine the average amplitude. These values were measured as peak-to-peak voltages. The average amplitude signal for the prototype design and the Pro-tech thermistor are listed in Table 2 below for each trial.

TABLE 2: Average Signal Amplitudes for Prototype and Pro-Tech Thermistor at all distances

Distance (mm)	Average Amplitude of Prototype (mV peak-to-peak)	Average Amplitude of Pro-tech thermistor (mV peak-to-peak)
0	44	2000
3	36	800
7	14	350
10	11	90

The amplitudes for the prototype design were on a much smaller scale than those for the Pro-tech thermistor that is currently used at the sleep lab. The amplitudes for the prototype varied from 44 to 11, while the Pro-tech thermistor varied from 2000 to 90. One reason this occurs is because the TFLOW channel, used for the Pro-tech thermistor, is designed to amplify the signal. The LEOG channel used for the prototype did not have this capability. Although the amplitude was much smaller for the prototype design, breaths were still accurately detected at all distances.

C. Thermistor Temperature Test

The thermometer temperature vs. the calculated temperature was plotted as shown in Figure 5. The average resistance change for each degree temperature change was 0.9947 k Ω . The correlation coefficient was 0.99879. This has a very strong linear relationship in this range of temperatures. Calculated temperature changes from resistance were in good agreement with measured temperatures. The measurements of thermometer temperature, thermistor resistance, temperature, and voltage are shown below in Table 3.

TABLE 3: Temperature Test Results for Small Glass Bead Thermistor Circuit

Thermometer Temperature (°C)	Thermistor Temperature (°C)	Resistance (k Ω)	Voltage (V)
23	22.7	34.4	2.32

25	24.6	31.56	2.44
26	25.7	30.35	2.49
27	26.57	29.076	2.54
28	28.1	27.31	2.62
29	29.47	25.65	2.7
30	30.45	24.6	2.74
31	31.84	23.148	2.83
32	33.3	22.244	2.87
33	34.29	21.4	2.92
34	35.1	20.77	2.96
35	36.7	19.548	3.02
36	37.3	18.91	3.08
37	38.5	18.15	3.12
38	39.8	17.33	3.16
39	40.55	16.758	3.21
40	41	16.19	3.28
41	43.1	15.376	3.32
42	44.18	14.781	3.35
43	45.03	14.265	3.39
44	46.02	13.88	3.42
45	46.6	13.51	3.45

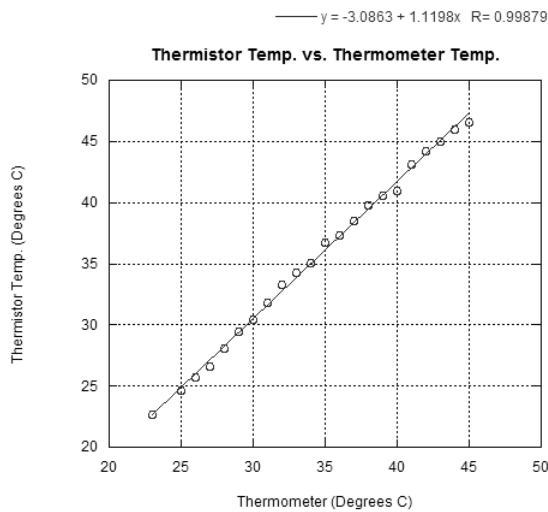


Fig. 5 The thermometer vs. thermistor temperature graph. The linear fit equation is shown in the upper right corner.

IV. DISCUSSION

A device was successfully created to monitor flow, end tidal carbon dioxide, and nasal pressure during pediatric sleep studies. The device consisted of a three pronged nasal cannula capable of sampling from all three respiratory orifices. Each prong was outfitted with an affixed thermistor to measure temperature from each orifice during respiration. Research was conducted on the device, relating to detection accuracy, ability to measure at varying distances from the nasal openings and corroboration of thermistor characteristics.

Results from validation studies suggest a promising technology, most notably in the enhancement of patient comfort and study accuracy. The device was able to aid in the measurement of continuous air flow measurements including temperature, nasal pressure, and ETCO₂ % during a polysomnogram. The device was able to detect respiration with 97.5% accuracy in a worst case scenario test, wherein the patient was breathing shallow with a fast respiratory rate.

This result suggests that an embedded thermistor is a viable candidate for consistent breath detection.

Testing on breath detection with varying distance from the nasal openings and mouth suggest that the device is effective even with movement during sleep. It was shown that breathing was detectable up to 1 cm from the nasal openings, but optimal readings were found within 3 mm of the nostrils. These results imply functionality of the device even if the cannula shifts during sleep.

Thermistor validation studies showed a linear trend between ambient temperature changes and measured thermistor temperature. This verified that the thermistors used in the study were up to specification. The thermistors used were the Honeywell 112-103FAJ-B01 Discrete Thermistors. It is recommended that further reliability tests and precision studies be conducted on the thermistors before a finalized decision.

There were several potential sources of systematic and random error in the conduct of this study. The largest concern was the sample size used in the respiration studies; granted only one patient was monitored. Future studies conducted must monitor a larger population, including pediatric patients. There was also concern raised in the thermometer used to measure ambient temperature in the thermistor temperature test, as its time constant is slower than the thermistor tested. In future studies, the baseline temperature reading should be better suited for the application.

Results of the testing suite are promising. There is demonstrated efficacy in the integration of temperature measurements in cannulas for polysomnography. The device was able to satisfy the client's needs, and showed efficacy in potential clinical use. Further studies should be conducted. It is recommended that an extensive study be conducted on pediatric subjects. Such a study would ensure that the device is functional on a demographic of interest. The study should include a focus on patient comfort, accuracy of breath detection, thermistor distance test and evaluation from a clinician perspective. Another test that should be conducted is an optimal thermistor test, wherein multiple thermistors are tested as candidates for a finalized device. A focus should be made on time constant, sensitivity in the desired temperature range and cost. The test would be used from a product development standpoint. After completion of these studies, it is paramount that a cost-analysis be conducted as well as further market research to ensure the idea is feasible.

V. CONCLUSION

A nasal cannula with affixed thermistors would be a useful instrument in pediatric polysomnography. We have developed a device combining air flow, nasal pressure, and end-tidal carbon dioxide measurements into one disposable device. Making this device disposable makes it more cost-effective. The device has undergone initial testing, which verified that it measures air flow, nasal pressure, and end-tidal carbon dioxide. However, the thermistor used for the device is not as accurate as the thermistor currently used in sleep labs. Although the device is functional, further testing

and development of the thermistor component is needed to ensure accuracy. In addition, testing needs to be completed on pediatric patients who are participating in a polysomnography study, to ensure that the device is reliable throughout a study. Although further development is needed, this device has the potential to be very valuable in a clinical setting.

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APPENDIX

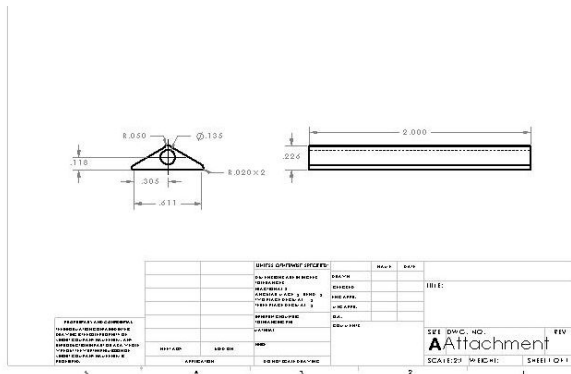


Fig. 6. A flattened image of an adapter piece created previously to aid in the fixation of the cannula to the face..

PDS

Project Design Specifications

Sleep Lab Monitor

April 19, 2009

Nicole Daehn, Lindsey Carlson, Robyn Hrobsky, Jason Tham

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 (ETCO₂). 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 ETCO₂ 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 disposable
- 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, ETCO₂ %, and nasal pressure during an overnight sleep study.
- The entire device should be 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 Diagnostic Sleep System and the Respironics 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 cmH₂O.
- The ETCO₂ cannula should be able to measure CO₂ 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 CO₂ and delivery of O₂ simultaneously made by Oridion. There are also split cannulas which measure pressure and CO₂. However, no devices which measure all three items could be found.