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Automated Home Apnea System


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Howser, Collin G. and Grieco, Trevor, "Automated Home Apnea System" (2013). *Chancellor's Honors Program Projects*.

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May 2, 2013

Dear Dr. Reinbolt, Dr. Hamel, and Mr. Wheelock,

First and foremost, Volunteer Medical Technologies would like to thank you for serving as our stakeholders for the duration of the project. Your guidance and advice regarding team management was instrumental in the success of our final design.

This report outlines all of the steps that were taken in order to complete the design process for our infant sleep apnea device and produce a functional prototype. As you'll see, all phases of the design process will be discussed in depth. The report also contains an objective evaluation of our design.

Upon looking over the report, we ask that you give your feedback on our final product as well as the individual components of our design process. Any feedback, whether positive or negative, would be greatly appreciated. Also, if you have any questions regarding our design, please feel free to contact our team leader, Trevor Grieco and he will be happy to assist you.

Best regards,

Volunteer Medical Technologies

**FINAL DESIGN REPORT FOR THE AUTOMATED HOME APNEA SYSTEM
DR. JEFF REINBOLT, ASSISTANT PROFESSOR
DR. WILLIAM HAMEL, MABE DEPARTMENT HEAD
MR. TIMOTHY WHELOCK, SIEMENS HEALTHCARE DIRECTOR**

May 2, 2013

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Executive Summary

Volunteer Medical Technologies (VMT) designed a device that can be used in the treatment of central sleep apnea in infants. The assessed needs of the stakeholders stated that the device must be able to accurately detect an episode of apnea, provide a stimulus that will correct the apnea, and sound an alarm if the stimulus does not restore a normal breathing pattern.

The final design consists of a pulse oximeter, RIPmate thorax inductance kit, a solid-state relay, and a belt with vibrating motors. During concept development, however, several alternatives were considered. Some of the alternatives that were considered included thermistors as a monitoring mechanism, a servo controller to be used to transfer the signal from the computer to the stimulus hardware, and a motion bed or audio as our stimulus. Upon evaluation of all of the considerations, VMT settled on the components that were used for the final design for a number of reasons. The monitoring devices, the pulse oximeter and the RIPmate belt were chosen because they are the best indicators of an apnea episode. Two different biosignals were monitored in order to be in compliance with the American Society of Sleep Medicine (ASSM). The solid-state relay was chosen because of the simplicity of the design. The vibrating motors were chosen as the stimulus because they are effective and can be easily manipulated to avoid the patient becoming immune to them.

After construction, the device was tested multiple times. First, each individual component was tested to ensure proper functioning. Next, the integrated system was tested. The tests consisted of members of VMT wearing the device and holding their breath for a period of 10 seconds or until there was a 3% drop in oxygen saturation. In the properly functioning device, these events would trigger the vibrating motors to turn on and if the normal breathing pattern was not restored within 5 seconds, the alarm sounded.

This device is currently the only product that incorporates both detection and stimulation into one device. This notion is very innovative and can prove to be very lucrative in the future. It can also lead to more groundbreaking devices and research that will further impact central sleep apnea in infants.

Background

There are three types of sleep apnea – central sleep apnea, obstructive sleep apnea, and mixed sleep apnea. Central sleep apnea involves a brain deficiency that leads to successions of breathing. Obstructive apnea is a result of physical airway blockage and mixed sleep apnea is a combination of central and obstructive apnea [3]. An apnea episode is defined by 10-20 seconds without breathing [6]. Apnea home monitoring systems are prescribed to infants who have prolonged episodes of apnea and/or bradycardia resulting from prematurity [2,8]. Home monitors are also prescribed to infants who are direct siblings of SIDS victims [2,8].

Contemporary monitors record respiratory and cardiac data using leads on the heart held in place by a Velcro belt or adhesive strip [8]. The monitors have adjustable sensitivity and they sound an alarm for the caregiver when intervention is necessary [8]. Intervention involves simple physical stimulation via a sternum rub. In extreme cases cardio-pulmonary resuscitation may be required [8].

The need for a device that accurately detects apnea episodes, and provides an automated stimulus to restore natural breathing patterns has been proposed by the University of Tennessee Graduate School of Medicine. It is believed that such a device will aid infants and caregivers in a positive manner with respect to improved sleep architecture and soundness of mind. Furthermore, a device of this nature will reduce the amount of parental intervention during sleep cycles. This device has a large market, and the opportunities of this device are multifaceted. A successful design can lead to both improved infant sleep patterns as well financial gains.

Upon analyzing the competitive technologies, VMT found that there are no devices that seek to aid central sleep apnea in infants by automated stimulation. As previously stated the only technology for infants is a monitor system that incorporates an alarm for notification of necessary parental intervention. One notable claim was found while researching Adaptive Servo-Ventilation systems. This system claims to correct apnea episodes of multiple natures. The system accurately detects and corrects both obstructive and central sleep apnea in adults by detecting the patient's need to breathe and administering pressure when necessary via a respiratory mask [12,13]. Many technologies, including continuous positive airway pressure (CPAP) and expository positive airway pressure (EPAP), seek to correct obstructive apnea because of its growing appearance in the adult population. Obstructive apnea is especially prevalent in obese adults. VMT researched the methods of correcting obstructive apnea to see if any useful information could be applied to the proposed device. Unfortunately, these technologies focus primarily on opening the airway via multiple methods. This is not applicable to central sleep apnea in infants, because the issue does not involve a blockage of airway, but rather a brain deficiency with respect to breathing.

A notable technology that has been tested on infants in the past is the use of rhythmic waterbeds. *Reduction of Sleep Apnea and Bradycardia in Preterm Infants on Oscillating Water Beds: A Controlled Polygraphic Study* by Korner et al. investigated the effects of vestibular-proprioceptive stimulation on early development. The setup involved infants sleeping on a waterbed that involved periodic wave movement. One of the most striking developments of this study was that infants in the experimental group experienced a marked reduction in sleep apnea occurring during sleep. Instances of apnea of prolonged length (10 seconds or longer) were reduced more when on the waterbed, suggesting that regular periodic movement plays a critical role in patients who suffer from central sleep apnea [7]. Although this method was successful in reducing the quantity of apnea episodes experienced, it does not seek to correct the apnea episodes that do occur. Furthermore, this rhythmic method can lull the infant into deeper sleep making it less likely for them to be aroused out of an apnea episode without intervention.

Problem Definition

The overall purpose in designing this device is to allow a patient suffering from sleep apnea to have the condition accurately detected, and once detected, disrupt the apnea episode in order to assist the patient in returning to a normal pattern of sleep. The nature of this project has consisted of gaining a basic understanding of what is required to successfully follow through with the project, notably by determining the required specifications and assessing the costs associated with them.

After meeting with stakeholders and reviewing the needs for sleep apnea, VMT planned a new home device to aid in sleep apnea. This device should accurately detect and monitor sleep apnea in a patient at home. Once an apnea episode is detected, the device should issue a stimulus to disrupt the patient's irregular sleeping pattern. The device should be capable of producing a random stimulation when certain criteria are met in order to disrupt the apnea episode. The device should also be capable of gradually increasing the intensity of stimulation if there is no response from the patient. In the event that a patient's breathing is not restored by the random stimulus, this device should be able to alert a caregiver. The device will need an adjustable sensitivity. The device should be comfortable, portable, and easily put on and taken off.

The ultimate function of this product is to monitor the breathing of infant patients who suffer from central sleep apnea. It needs to perform the following tasks to accurately detect and stimulate any patient suffering from sleep apnea: accurately monitor apnea, issue a stimulus once an apnea episode is detected, and alert any caregivers if stimulus is ineffective. This device should be able to calibrate accordingly to each patient's sensitivity to the stimulus, as well as, be comfortable, portable, and easily applied. This device should accurately detect life threatening sleep apnea episodes with a respiratory inductance plethysmography (RIP) belt and pulse oximeter in order to comply with the AASM. The device should be able perform the previous stated tasks with minimal error and in real time. Detection and stimulation via the RIP belt, pulse oximeter, and stimulation mechanism will be the most vital requirements for this device.

The primary data elements of this system will be real-time, analyzed physiological signals from the patient. These monitored biosignals consist of oxygen saturation of hemoglobin, and the respiratory pattern. The data for each of these signals will be obtained via a pulse oximeter and a RIP belt respectively. The control system algorithm will analyze the real time biosignals from the monitors and deduce the appropriate measures to take going forward. If the data signals suggest an apnea episode is occurring ($>3\%$ drop O_2 and cessation of breathing for >15 sec) the controller will then signal the vibration mechanisms to start vibrating [3]. If the stimulation is unsuccessful the control system will activate an alert mechanism. The thresholds for the alert can be modified by the user, as some caregivers would like to know when every apnea episode is occurring and not just the prolonged episodes.

The functions and requirements for this prototype are again stated below:

- RIP belt should fit securely, but comfortably around patient
- Pulse oximeter should connect to patient directly via finger
- Biosignals should be gathered and processed with a computer algorithm
- Stimulants will consist of small vibrators that are incorporated into the RIP belt and automatically triggered based on biosignals.
- An alarm should be attached to the device for patients in need of immediate attention from a caregiver if stimulation is not adequate.

The primary constraints of this device will be FDA regulations. The FDA is particularly stringent on devices that come into direct contact with patients, especially infants. As the design process proceeds particular attention will be paid to FDA regulations to ensure a functional, producible, profitable device can be manufactured for wide scale use. Another constraint will be adherence to the AASM's diagnostic factors of central apnea episodes in infant patients. Societal expectations will also be considered heavily in the proposed design because of the patient demographic and the setting in which the device will be used. Parents will expect the device to have minimal to no safety hazards because the device will be used on infants.

Concept Development

The eventual objective of this design project was to create a prototype that monitors the sleeping patterns of infants, specifically, at risk infants suffering from sleep apnea. The device originally focused on infants within a hospital setting; however, the group felt the device could also be suited for home use as well. Before reaching the final product of the device, the VMT had to perform extensive research and consider concepts to eventually reach a design that felt suitable to create.

In particular, the team felt it was important to investigate two aspects that would make the device perform to its maximum potential. First, would be components that would promote a high level of efficiency for the device, and secondly, making sure proper safety precautions are accounted for, given the target group of the device.

In terms of efficient components, since the primary function of the device was to monitor apnea, the team needed to consider a proper monitor that would best fit the device as well as the resources provided. Examples of common monitoring instruments include thermistors, pressure transducers, electroencephalogram (EEG), audio, RIP belts and pulse oximeters. Out of these six types of monitoring instruments the team decided to incorporate two: a RIP belt, and a pulse oximeters.

The team felt that thermistors and pressure transducers would not tailor to their needs because these instruments collect data in the facial region. VMT decided that the device needed to be as comfortable as possible and thus sought to avoid any instruments gathering data at or near the face. EEGs were ruled out for the same reason. VMT felt that monitoring audio would be subject to noise and thus inaccuracies in detection of apnea.

Next, is accounting for safety. Since the team decided to use a stimulating method to alarm the patient and caregiver in case of emergency, the team had to account for the intensity of an alarm. A method the team agreed absolutely not to use by any means was electrical shock. Electrical shock could place the patient in unnecessary harm, interfering with the monitoring of data. Additionally, since the target group for this design was infants, it would be extremely unethical to apply electrical shock on a fragile infant, which may result in possible lawsuits for damages. In summary, these concepts are taken into account, so that the team would approach a suitable method to create its intended device.

To further elaborate on the concept of the design, the team needed to investigate approaches that would help its quality and allow it to stand out as an apnea device. Specifically, the team investigated obtaining bio-signals of blood oxygen saturation. Given that a pulse oximeter represents a device that monitors blood oxygen saturation, the team investigated the type of pulse oximeter that would be efficient, but also adhered to a non-invasive method. Ultimately, these considerations lead to the decision to use a transmission based pulse oximetry method. This method would simply involve the patient to have his or her blood measured by a monitoring device that goes on the finger. Because the team definition of non- invasive meant anywhere below the neck, using the transmission based pulse oximetry felt like the best choice in terms of reliability as well as compliance with a non-invasive approach.

Another method acknowledged was a motion bed. This option would serve as a stimulant mechanism for patients in the middle of an apnea episode. Although a seemingly dependable resource, the team felt it was not ideal for this project for two main reasons. First, if an infant were to use this bed, he or she may adapt to the comfort of the bed and may not respond to the stimulus applied. Secondly, since motion beds could be used by infants, the cost of these beds could be much higher than the price of a crib, which may discourage parents and caregivers from purchasing it for the infant. This is why the team felt it would not be the best method to use for the design project.

With the extensive amount of information Volunteer Medical Technologies researched from the deliverable assignments, the team had to use the information it learned in order to create guidelines concerning the design process. An important concept the team deduced from its research was creating a device that was silent, portable and easy to use. In particular, after researching about EPAP (Expository Positive Airway Pressure) devices produced by a company known as Provent, the team was able to gain that concept and attempt to apply it to the design project. In contrast, one of the major concepts considered out of the entire project was to make the design approach non-invasive.

A further step, which was determined, based on the decision of the group was to define non-invasive as any contact between the device and patient that is below the neck. This was a foundation for the project because much of the research and considerations made toward constructing the design primarily depended on whether the design was non-invasive or not.

One way that team members could understand the concepts considered and design approach simultaneously was by figures. Shown below as Figure 1, is the Traceability Matrix which inspected function requirements for the design. Shown in Figure 2, is the Quad Chart which details the design approach of the team.

Requirements Traceability Matrix

Functional Requirements	Validation		
	Inspection	Measurement	Testing
1 Monitor	X	X	X
1.1 RIPmate Belt	X		
1.1.1 Accurately Measure Respiratory Patterns		X	X
1.1.2 Housing for Entire Device	X		
1.1.2.1 House Vibrating Motors	X		
1.1.2.2 House Battery	X		
1.1.2.3 House Pulse Oximeter	X		
1.1.3 Convenience Factors	X		
1.1.3.1 Comfortable	X		
1.1.3.2 Easily put on and taken off	X		
1.1.3.3 Portable	X		
1.2 Reflectance Pulse Oximeter	X	X	X
1.2.1 Accurately Measure O ₂ Saturation		X	X
1.2.1.1 Measure at Chest		X	X
1.3 Algorithm	X	X	X
1.3.1 Adjustable Sensitivity	X	X	
1.3.2 Detect Apneic Episodes	X	X	X
1.3.2.1 Determine Severity of Apneic Episode		X	
2 Stimulate	X	X	X
2.1 Deliver Signal to Vibrating Motors	X		X
2.1.1 Stimulate in Random Pattern	X		X
2.1.2 Increase Signal if No Response		X	X
3 Alert Caregiver if Necessary	X		X
3.1 Audible From All Parts of House	X		

Fig 1. Traceability Matrix A functional requirements outline and guide on how the project would proceed and validate processes.

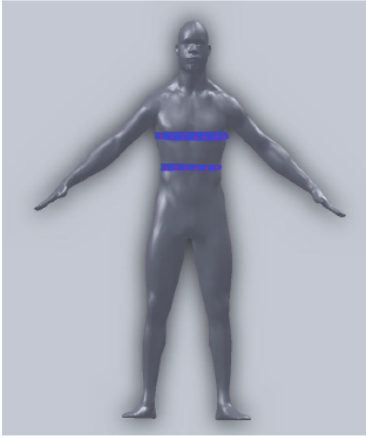
<p>Technology and Objective</p> <ul style="list-style-type: none"> • Our proposed design to stimulate patients who suffer from episodes of sleep apnea will automate an action of the patient caregiver. This automation will improve patient quality of life and satisfy a market need with regards to sleep aid. • System specifications are as follows: <ul style="list-style-type: none"> -Monitor biosignals -Provide responsive stimulation to the patient when required -Sound an alarm if the stimulation does is ineffective in restoring biosignals to normal 	<p>Graphic</p> 
<p>Proposed Technical Approach</p> <ul style="list-style-type: none"> • In order to successfully complete this project and produce a solution to the problem, we must first understand the requirement specifications and market needs. Then we will choose a concept design that we feel will provide the best and most feasible solution. The technology involved includes respiratory belts, a pulse oximeter, vibration motors, and a signals analysis software (Labview). The signals and stimulus will be controlled by a C based algorithm. 	<p>Costs</p> <ul style="list-style-type: none"> • Sensors- \$830 • Stimulants- \$50 • Software- \$3,000 • Hardware- \$120 <p>Schedule and Deliverables</p> <p>See Gantt Chart (Appendix)</p> <p>Participants</p> <ul style="list-style-type: none"> • Trevor Grieco – Team Leader tgrieco@utk.edu • Collin Howser- Team Member chowser@utk.edu • Sharae Cockrill- Team Member scockril@utk.edu • Mia Mitchell- Team Member mmitch@utk.edu • Chandler Wallace- Team Member cwalla18@utk.edu

Fig. 2 Quad Chart Preliminary design approach that would be taken in order to plan and develop the prototype.

Product Description

This prototype consists of four main components. The prototype first collects the necessary biosignals, and then processes the biosignals using specific thresholds for each signal respectively. The threshold comparison is used to trigger the stimulus, and the amount of time that the stimulus is active is monitored. If the stimulus is unsuccessful in restoring natural breathing patterns, then an audible alert mechanism is activated. The majority of this was accomplished through the integration of multiple algorithms in LabVIEW (National Instruments). The control diagram for this prototype can be found below in Figure 3.

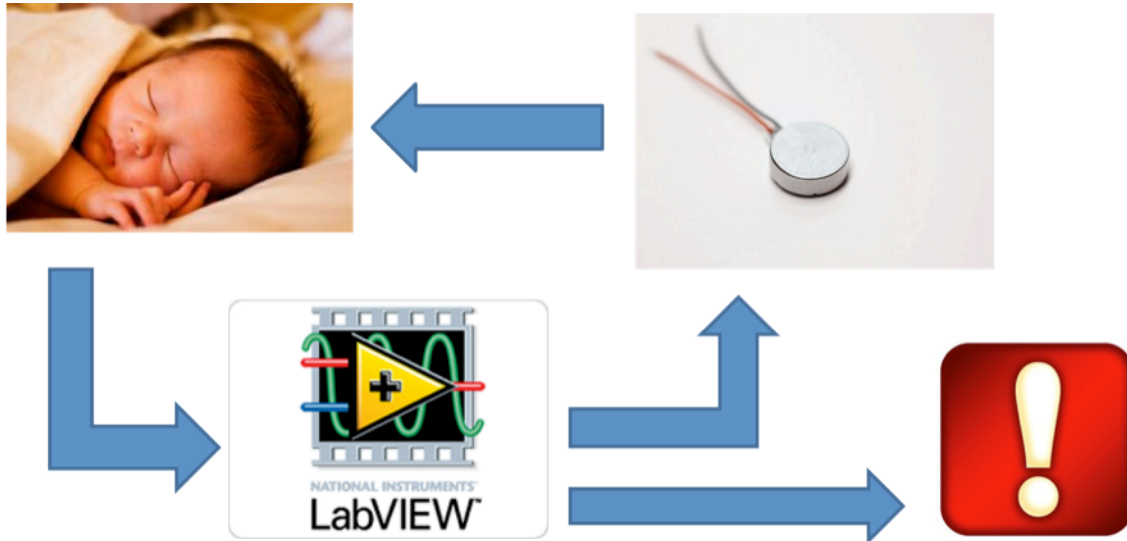


Fig. 3 Control System This system consists of four main parts: gathering biosignals, processing biosignals, a stimulus mechanism, and an audible alert mechanism.

The first algorithm consisted of gathering the data from the Ambu RIPmate belt. The RIPmate belt outputs a voltage signal in the mV range. Using LabVIEW in conjunction with the Measurement Computing 1208FS A/D converter, the voltage signal was continuously streamed into the system. The raw data signal was filtered in LabVIEW using a low pass filter with a cutoff frequency of 0.16 Hz. A sample of the raw signal and the respective filtered signal can be found below in Figure 4. This specific cutoff frequency was recommended by Ambu in the technical specifications for the belt. The filtered signal was analyzed with respect to its amplitude. The amplitude of the respiratory signal was constantly monitored for “flat-line” characteristics. Based on the ASSM guidelines, a period of 15 seconds without breathing is considered an apnea episode. When the respiratory signal started to flat-line, a clock was started. For this program, the signal was considered flat-line when the amplitude was less than or equal to 1nV. The clock reset to zero when acceptable amplitude was measured. If the signal remained at flat-line for more than 15 seconds, the stimulus was triggered.

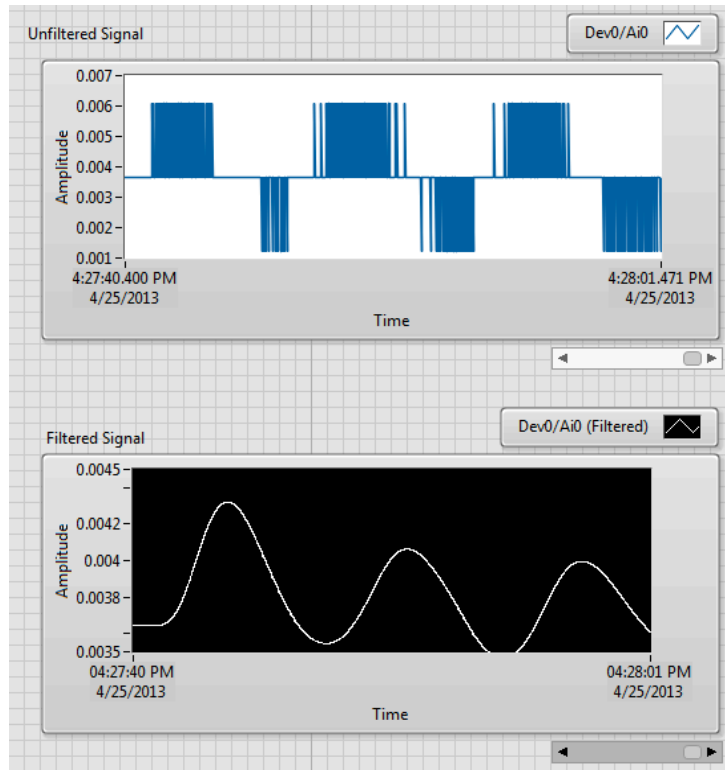


Fig. 4 Respiratory Signal The raw respiratory signal shown on top was filtered using a low pass filter with a cutoff frequency of 0.16 Hz to produce the smooth signal shown on the bottom.

The second algorithm involved processing pulse oximeter data. The NONIN 8500m pulse oximeter was used in conjunction with the NONIN 1000 USB adapter to stream serial data into the computer. LabVIEW read the serial packet in COM6, which consisted of the logical data. This data included both oxygen saturation and heart rate data. An open source LabVIEW code was used to continuously stream the logical data into a display window on the computer. VMT continued with the programming by separating the O_2 data from the heart rate data. Once separated the data was converted from string to numerical format so that it could be used in numerical threshold comparisons. Once the program was streaming meaningful data, the program would collect data for the calculation of the reference saturation. This was accomplished by building an array of saturation data. Once the array was filled with the desired number of data points, the array was. The size of the array was programmed as a control; for demonstration purposes it was set to 10. The average of this saturation array was stored as the reference saturation and could be recalculated during any time while the program was running. Once the reference saturation was in hand, the program proceeded by comparing each new data point to the reference. Based on the ASSM guidelines, a 3% drop in oxygen saturation is considered an apnea episode. The algorithm was programmed such that if the difference between the current saturation and the reference was greater than 3 the stimulus was triggered.

The third component of this prototype is the stimulus algorithm along with its manufacturing. VMT decided to use VPM2 Vibrating Disk Motors for the stimulus. These particular disks operate at a voltage of 3V. The vibrating disks' leads are soldered together in series and three 9V batteries are connected in series. These batteries supply a total of 27V to the 9 vibrating disks, which effectively distributes 3V to each disk. The disks are attached with an adhesive to the stimulus belt. This belt is simply an elastic band with Velcro that wraps around the patient torso. The battery pack is connected to a solid-state relay (NTE Electronics) that acts as a switch. When supplied with the proper voltage the switch closes the circuit, otherwise the circuit remains open. The solid-state relay is connected to the Measurement Computing 1208FS A/D converter output voltage channels. Channel 12 serves as the ground and channel 13 distributes the voltage. A LabVIEW algorithm streams continuous voltage out of the A/D converter. While the program is running the voltage can be controlled. If no stimulus is needed, 0V is sent out of the A/D converter and the solid-state relay remains open and no stimulus is activated as seen below in Figure 5. If the stimulus needs to be activated, 4V is sent to the solid-state relay, the circuit closes, and the batteries power the vibrating disks. This is shown below in Figure 6.

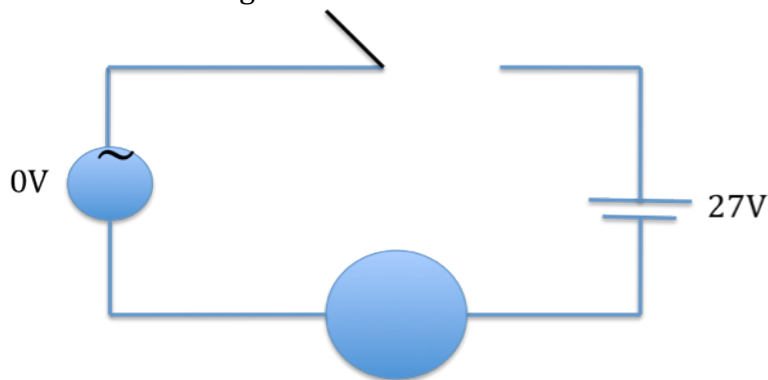


Fig 5. Open Stimulus Circuit When no stimulus is necessary zero volts are supplied to the solid-state relay and the circuit remains open.

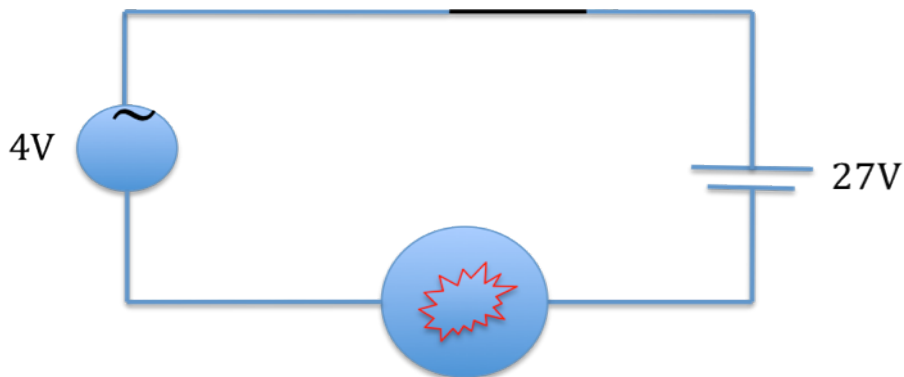


Fig 6. Closed Stimulus Circuit When a stimulus is necessary four volts are supplied to the solid-state relay and the circuit closes.

The final component of this prototype is the audible alert mechanism. This is built in to the system as a safety net. If the stimulus is unsuccessful in restoring natural biosignals, then the audible alert will awake the caregiver to intervene. For this prototype the audible alert is the Microsoft Windows “beep”. This alert is based on the amount of time that the stimulus is continuously activated. As soon as the stimulus is triggered a clock starts. If the stimulus goes off before the safety time, then the clock resets to zero. If the stimulus was active for a period greater than or equal to the safety time, then the LabVIEW algorithm continuously calls the Windows “beep” until the program is stopped. The safety time is a control; for demonstration purposes it was set to 10 seconds.

Integration of the four components was fairly simple. The final system worked effectively. Both signals successfully streamed together without interference. The threshold analysis was based on an “or” comparison such that if the respiratory “or” oxygen saturation thresholds were met, the voltage was sent out the A/D converter. The stimulus activated only when necessary and turned off if normal biosignals were restored. If the stimulus was active for a period greater than or equal to the safety time the alert mechanism was coded to activate. The alert mechanism successfully triggered in the separate applications but for an unknown reason, when the two biosignals were integrated, the alert mechanism failed to sound.

The integrated system has a graphic user interface (GUI) that is easy to navigate. For the respiratory aspects, the GUI consists of two waveform generators depicting the unfiltered and filtered respiratory signal. The cutoff frequency is a control on the GUI. The pulse oximeter aspects consist of a window that streams both oxygen saturation and heart rate data. Also the array that is built to obtain the reference saturation is visible, and the user can watch as the array fills to the desired size. In the GUI the user can control all necessary variables, and observe all changing parameters. The clocks are all displayed in the GUI as well, so that anyone can easily understand when and what is being triggered. The separate components of the GUI are displayed below.

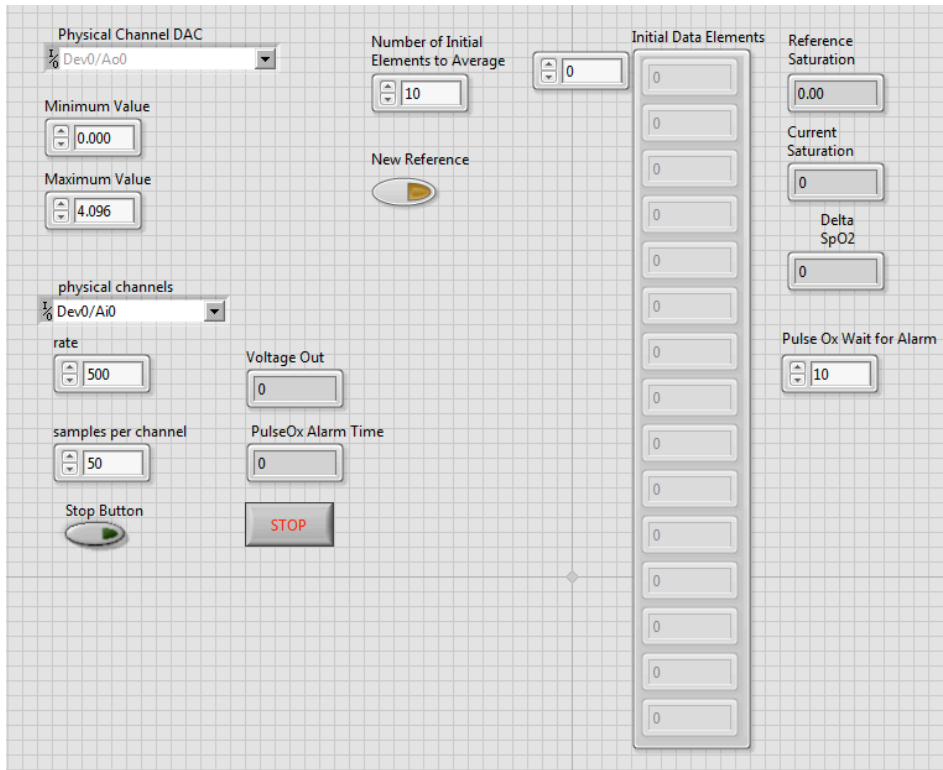


Fig. 7 Channels and Pulse Oximeter The channels for sending voltage in and out of the A/D converter can be controlled on the left, and the array for determining the reference saturation is displayed on the right.

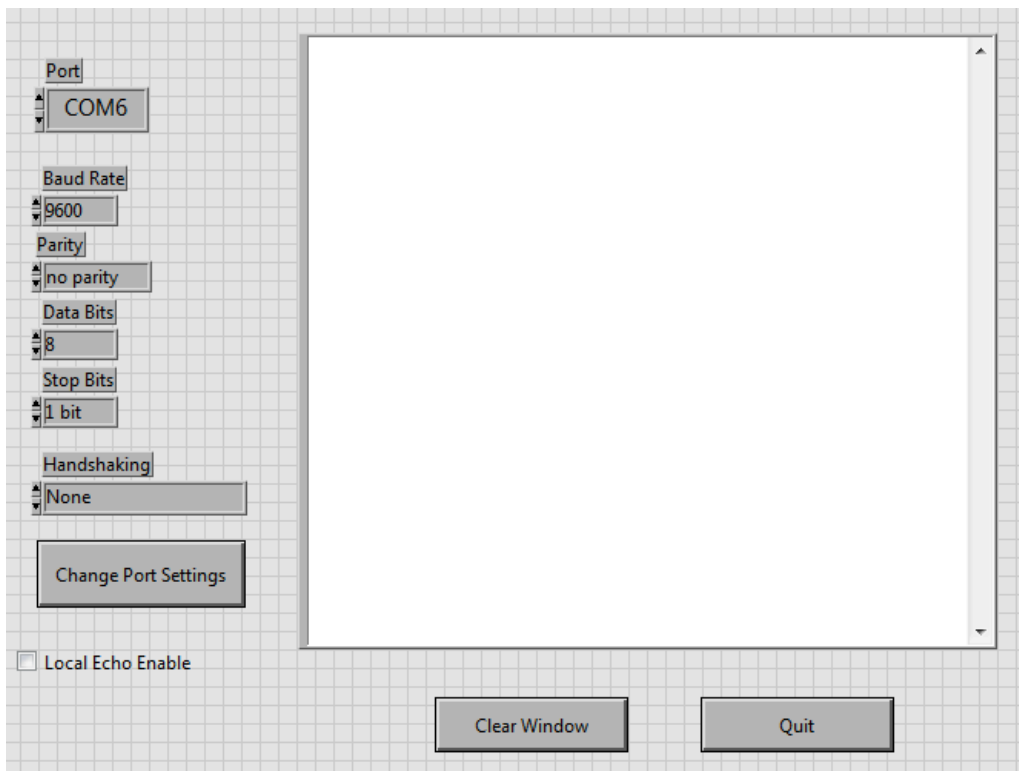


Fig. 8 Pulse Oximeter Display Window Both the oxygen saturation and the heart rate are continuously displayed in this window. The settings for the serial data streaming from the pulse oximeter are displayed here as well.

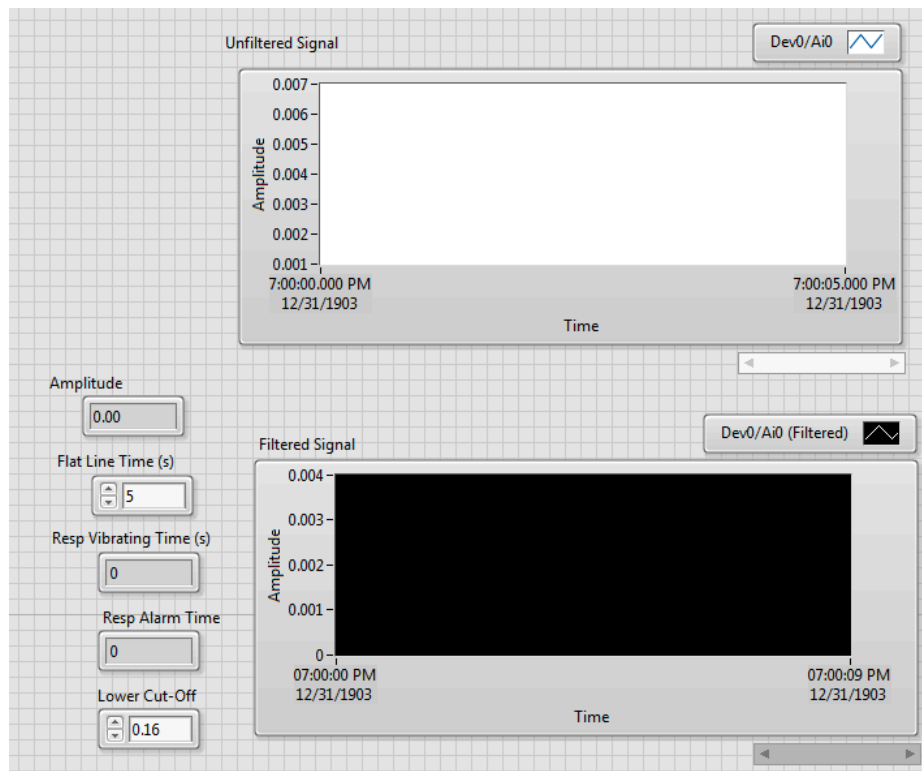


Fig. 9 Respiratory Waveform Generators and Controls The raw respiratory signal is continuously displayed on top while the respective filtered respiratory signal is displayed below. The controls for the filter and timer are to the left of the waveform generators.

Design Evaluation

As described in the previous sections, a functional prototype has been constructed that monitors breathing rate and can generate a stimulus to return breathing to normal patterns. In regards to actually constructing the prototype, there were various tests that were performed. Two of the tests involved making sure the voltage relay was being triggered correctly. There were two methods for triggering the relay: pulse oximeter trigger and RIP belt trigger. A LabVIEW code was constructed that monitored the blood oxygen saturation levels continuously. Once the oxygen dropped to a preset level, the relay was triggered. In order to test that the relay was triggered a voltmeter was connected to the A/D converter to ensure that the minimum voltage (4V) was being produced. The same method was employed for the RIP belt trigger. Once a cessation in breathing was recognized by the code, the A/D converter was triggered to release a voltage to trigger the connected relay. Again, a voltmeter was used to ensure that the requisite voltage was being produced. There were also two other tests that were performed involving

the pulse oximeter and RIP belt: triggering the alarm with these two devices. This was tested by simply making sure that the alarm went off after a specified time. Again, this alarm was controlled by a Labview code. Once all the individual components were tested to ensure that they triggered the vibration stimulus and alarm, the components were combined into one device. As previously mentioned, when fully integrated the vibrating stimulus acted as expected but the audible alert mechanism did not sound. It is still unknown why the alarm did not function properly with the two biosignals acting together.

It should be noted that there were other tests that need to be performed to further validate the efficacy of the proposed prototype to effectively monitor apnea episodes and provide stimuli to interrupt such episodes. The most obvious test would be to have someone, without apnea, sleep with the device on and see if they could be woken by the vibrating motors. This was not able to be accomplished for a variety of reasons. One reason was that, the current prototype is not easily portable and is located in a research lab on campus. This would involve someone sleeping in a lab for a prolonged period of time, which is simply not realistic in the current location of the device. Another reason that this test was not performed is centered around legal issues concerning human testing. It is very hard to test any medical device on humans without proper paper work and prior approval from the FDA. Since legal considerations should always be taken into account with any development of a novel device, we believed it was in our and the university's best interest to not conduct such testing. In addition to stimulus response testing, apnea monitoring testing would also be a test that needs to happen to ensure the viability of the proposed device. Again, such human testing would require extensive paperwork and actually someone with apnea, both of which were not able to be obtained.

As with any new device, one of the principle limiting factors to continuing production to a marketable, complete product is the price to produce each device. After careful review of invoices and receipts, it was determined that some of the expenditures would not need to be included in the final expected cost of prototype reproduction. Excluding a LabVIEW software license, reproducing this prototype of an automated home apnea system would cost approximately \$1150.00. The breakdown of these expected costs can be found in *Appendix A*. It should be noted, that actual production costs would be considerably less due to buying the necessary components in bulk and at a wholesale price.

In evaluation of the final constructed prototype, it can be confidently stated that a minimally viable product has been constructed to participate in the first stages of beta testing. This concept of a minimally viable product is the new normal in terms of product development. The thought process behind this is a development group quickly builds a functional prototype that is far from complete, in order to adapt to the markets wants and needs in an efficient manner. Once this prototype is being tested, consumer surveys can be given routinely in order to constantly improve the product while still building traction in the market (see *The Lean Startup* by Eric Reis). The automated home apnea system is on the precipice of beta testing and can be considered a minimally viable product.

Recommendations and Future Work

As with any prototype development, there is a multitude of things to be done in the future to ensure that this product makes it to market and can be considered financially viable. However, there are certain aspects of this device that already give it competitive advantages over existing products. This prototype is the only device available that is marketed explicitly for home use. Other existing monitoring devices for infants are specifically designed for clinical use and cannot be incorporated for home use. Devices that currently exist for home use do not possess the accurate measurement capabilities of the one that is proposed in this report. In addition to this, the proposed device is the only known device that incorporates monitoring and stimulation into one combined device. Although the functionalities of this device do not currently exist in a home market, the price of reproduction would be a significant limiting factor to wide spread adoption and sustained revenue generation. Any devices that cost more than a thousand dollars severely limits the accessible markets; significant reduction in price would have to be achieved to bring this product to market and generate significant revenue.

The future development of this device consists of a variety of actions. The main aspect that needs to be addressed is testing on subjects who actually suffer from apnea, and then progressing to infants that suffer from apnea. As mentioned earlier, there is extensive documentation and FDA approval required for such testing. In addition to testing there are some hardware related components of the device that need to be addressed in the future development of the product. The major area that needs addressing is to consolidate the device down into an extremely portable, compact system. At its current status, a computer is needed for the device to function. Theoretically everything that the computer does can be hard coded onto a chip and be contained on the device itself. Ideally the final, market ready design would consist of just a belt that is placed on the patient that simultaneously monitors breathing, blood oxygen (via reflective pulse oximetry on the chest), emits a stimulus (via vibrating disks embedded in the belt), and alerts the caretaker of any prolonged apnea episodes (via an alarm that is sent to a phone or other device). Complete development of a market ready device would most likely take at least two years of continuous work. Also increasing the size of the development team would be required to ensure that this product can be fully completed.

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Appendix A

Manufacturing Bill of Materials

Item	Description	Vendor	Quantity	Price per product*
1.	RIPmate Adult Thorax Inductance Kit	Ambu Incorporated	1	\$437.75
2.	Banana Plugs	Univ. of Tennessee MABE Department	2	\$1.89
3.	Plastic Safety Shrouds	Univ. of Tennessee MABE Department	2	\$0.88
4.	Wires	Univ. of Tennessee MABE Department	4	Depends on manufacturer
5.	Measurement Computing 1208FS A/D Converter	Univ. of Tennessee MABE Department	1	Free**
6.	National Instruments LabVIEW	Univ. of Tennessee	1	Free**
8.	NONIN 8500 Hand Held Pulse Oximeter	Turner Medical	1	\$325.00
9.	NONIN 1000 USB Download Cable	Turner Medical	1	\$90.00
13.	Vibrating Disk Motor	RobotShop	10	\$3.40
14.	9 Volt Battery	Walgreens	1	\$3.00

	NTE Electronics Solid-State Relay	Shield's Electronics	1	\$75.00
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