Infant Cardiorespiratory

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Abstract
Sudden Infant Death Syndrome (SIDS) is the sudden, unexplained death of an infant under the age of one, usually while sleeping. There are over four million neonatal deaths annually, with over 99% of these deaths occurring in low to mid income nations. Infant respiratory monitors have been shown to decrease the number of infant deaths while sleeping, but the current models on the market are cost prohibitive and too energy dependent to be an effective means of decreasing these tragic events in resource-scarce areas. To help reduce the incidence of SIDS in developing countries, a prototype infant respiratory monitor has been developed in semesters past utilizing impedance pneumography as its means of detection. The monitor has been designed to significantly reduce power consumption in addition to being less expensive than comparable devices, so it can feasibly be implemented in developing countries. A PIC18F14K22 has previously been selected as a low-power microcontroller, running off one rechargeable lithium ion battery power source to allow for recharging. The ethical considerations concerning device reliability as well as patient and user safety were integral to the development of this device. This semester, heart rate detection was implemented, as well as data logging capabilities.

Motivation
- United Nations Millenium Development Goal #4 – *Reduce by two thirds, between 1990 and 2015, the under-five mortality rate*

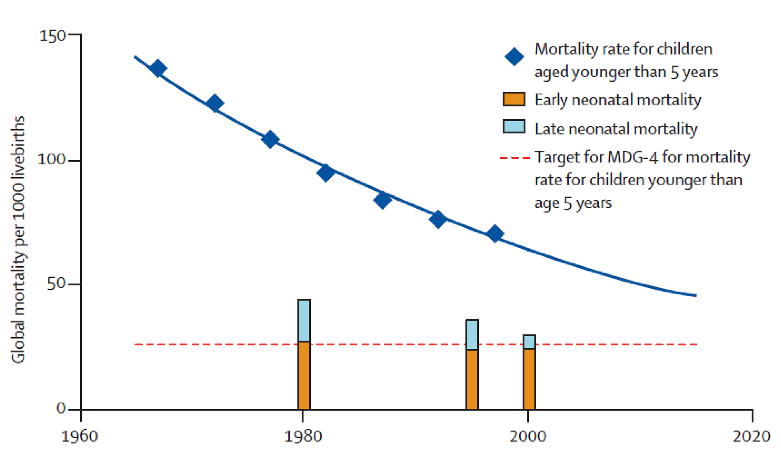


Figure 1: Actual and projected global mortality rate per 1000 live births in children under 5, early neonates, and late neonates, 1965-2015 (Lawn et al. 2005) .

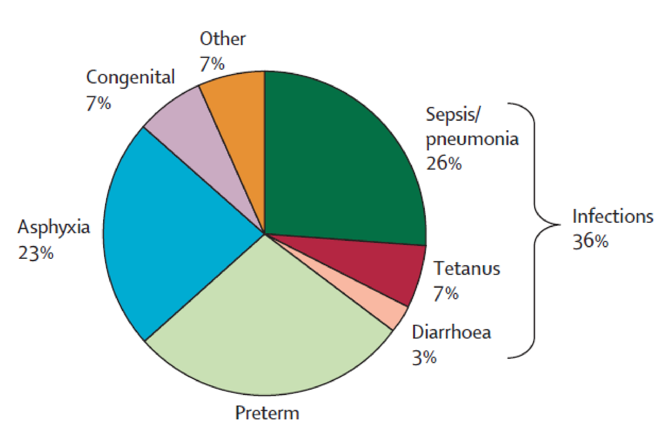


Figure 2: Estimated distribution of causes of neonatal deaths in 2000 (Lawn et al. 2005) .

- Asphyxia 3rd highest cause of neonatal death (behind infections and preterm birth (Lawn et al. 2000)
- Resuscitation can reduce morbidity due to perinatal asphyxia (Duran et al. 2012)
- Haiti and Ethiopia are the primary areas of focus
- Despite drops in under-five infant mortality, neonatal mortality rates remain high in Haiti and Ethiopia (UNICEF 2012, Lawn et al 2005) (Figure 3)

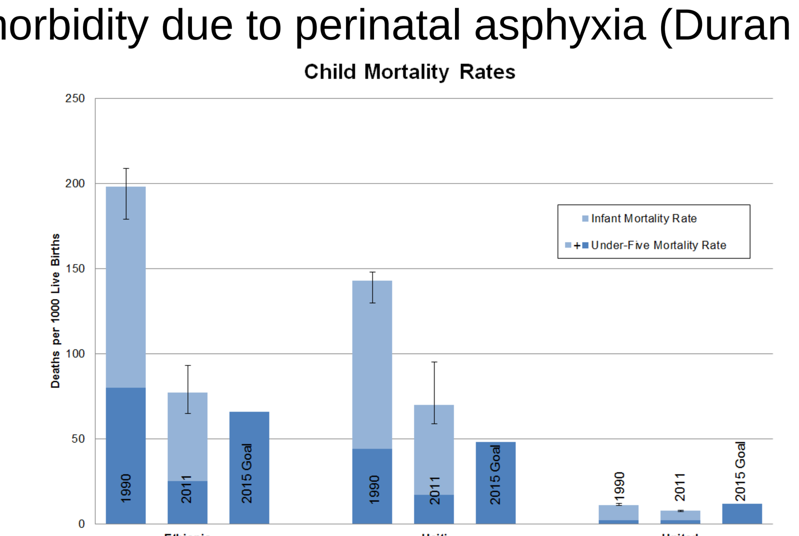


Figure 4: 1990, 2011, and 2015 MDG4 Goal for under five mortality rate and infant mortality rate in Ethiopia, Haiti, and the United States (UNICEF 2012) .

Background
- Apnea is defined as cessation of respiratory airflow for > 20s (Rocker et al 2012)
- Three types of apnea – Central, Obstructive, and Mixed
- The monitor relies on the principles of Impedance Pneumography (Figure 5)
- *Class II* medical device according to the FDA

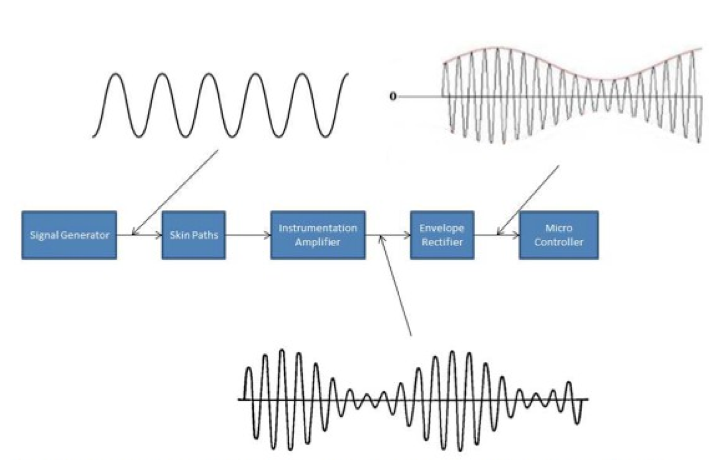


Figure 5: Impedance pneumography uses a carrier wave, differential amplification, and demodulation as shown here. The resulting waveform can be read by a microcontroller and algorithms can be applied that will determine if breathing has taken place.

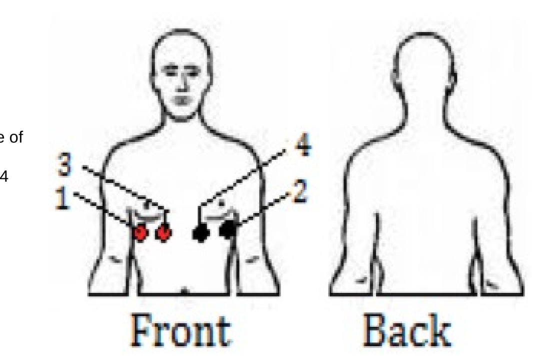
Design Criteria
- Monitor must sound an audible alarm if breathing seizes for greater than 20 seconds
- External wiring must not present a strangulation risk
- Should contain no small, loose parts that pose a choking hazard
- Multilingual user interface
- Operate continuously for 24 hours on a single fully charged battery
- Universal, one size fits all electrode band
- Guidelines and requirements presented in *Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA*
- Final product cost of $30

Device Design
- Powered by single Lithium-polymer rechargeable battery boosted to supply 5 V
- 1 mA carrier signal oscillating at 30 kHz is generated by the quadrature oscillator
- Four lead electrode system interfacing with the patient connecting via a four pin DIN termination (Figure 7)

Signal of Interest	Frequency Spectra (Hz)
Respiration	0.5-1
Heartbeat (QRS components)	17

Table 6: Signals of Interest and their component frequencies

Figure 7: Diagram of lead placement on ventral side of chest cavity as proposed by Gupta (2011). Leads 1 and 2 pass carrier wave through body, leads 3 and 4 pick-up wave after it has been modulated by chest cavity.



User Interface
- Device is active when switch is in the **On** positon, and **Engage Monitor Button** is depressed (Figure 8)
- Monitor Status LED indicates battery level
- Apnea LED turns red if apneic event is detected
- Cardiac Event LED blinks when QRS is detected, turns solid red during extreme brachycardia
- Electrode Connector is the DIN input for the lead system

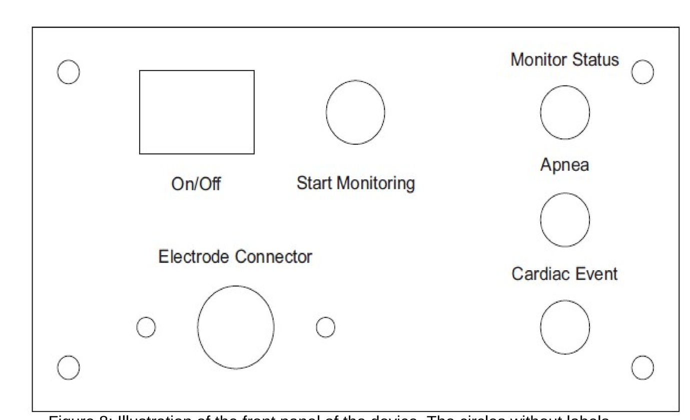


Figure 8: Illustration of the front panel of the device. The circles without labels represent holes to fasten components to the housing or panel.

Software Design
- Calibration on startup adapts specifically to the patient's anatomy (Figure 9)
- Wave walking detection algorithm and drift effect reduction make for reliable detection of apnea
- Interrupt based processing lets the microcontroller default to an idle state, conserving power
- 10-bit analog to digital converter allows for signal resolution to 5 mV

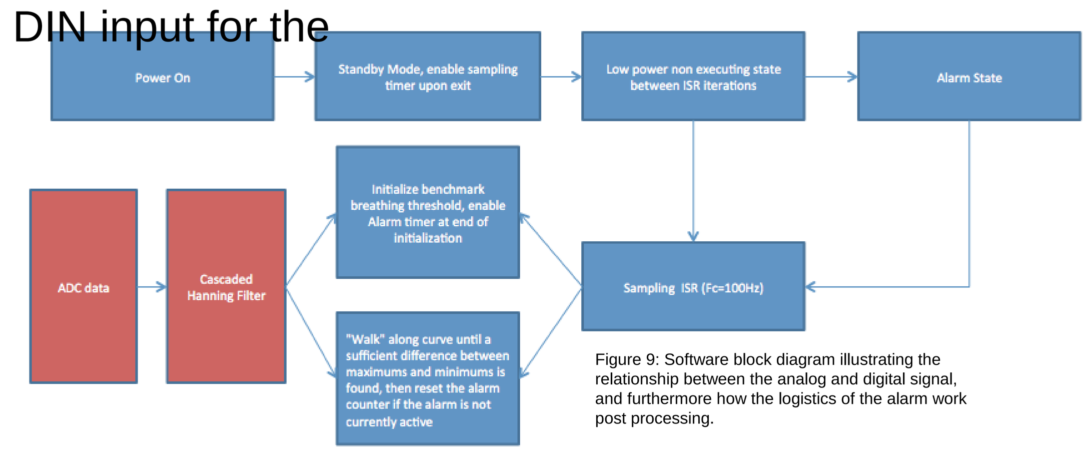


Figure 9: Software block diagram illustrating the relationship between the analog and digital signal, and furthermore how the logistics of the alarm work post processing.

Digital Signal Filtering Algorithm
- Analog In → Sum of ECG and Respiration Signals
- Detector pre-processing: 2 separate routes
- Respiration
  - "pseudo"-sinusoid Isolated with 3rd-order Hanning Filter (low-pass filtering)
- Heartbeat
  - R-wave peaks isolated with custom integer filter

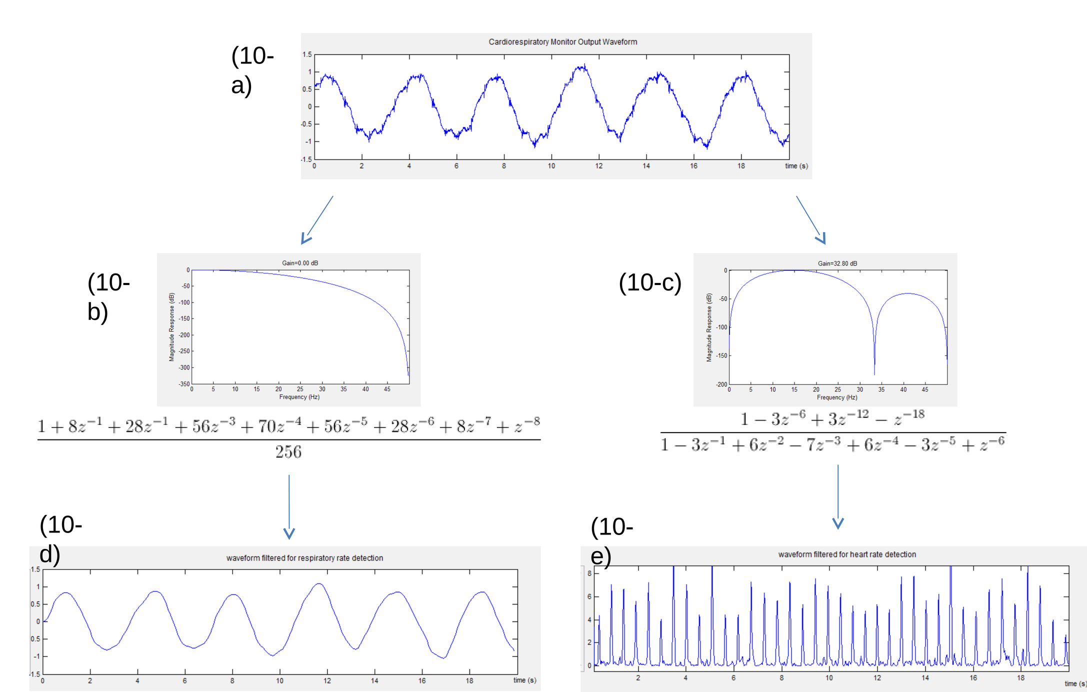
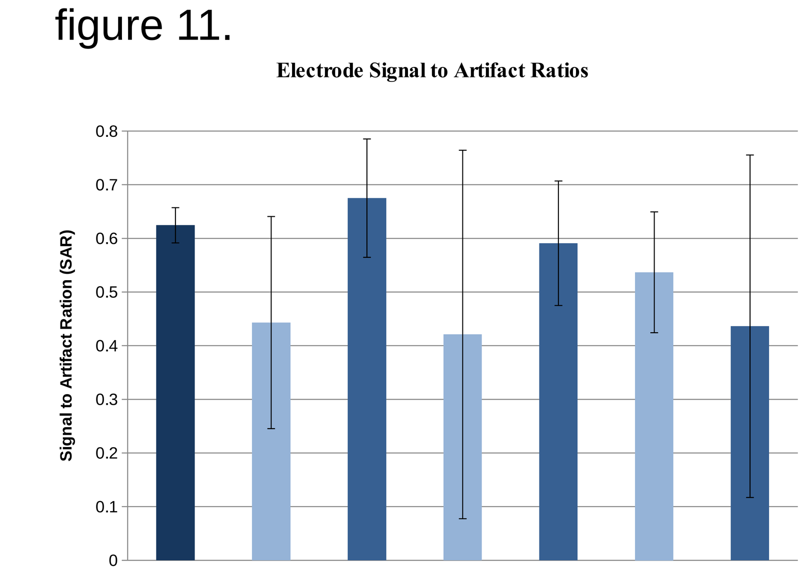


Figure 10: Cardiorespiratory detector preprocessing. (10-a) Analog waveform input to the analog-to-digital converter (ADC). (10-b) Frequency response and transfer function of the 3rd order Hanning filter. (10-c) Frequency response and transfer function of the integer filter used to isolate the r-wave peaks in the ECG. Pole located at ~16.5 Hz. (10-d) Resultant respiration signal after smoothing. (10-e) Resultant heartbeat signal after R-wave isolation.

Testing
Electrode Study
- Motion artifact can be caused by acquiring of EMG signals, or the electrode physically translating on the body (Kearny, 2007)
- Respiration data was captured and analyzed in Matlab
- Three subjects were tested with each electrode configuration listed below figure 11.



Electrode Type	Ultra II CardioSense	Rubber	Rubber	Rubber	Rubber	Metal Disc	Metal Disc
Adhesion	N/A	Tape	Band	Tape	Band	Tape	Band
Conductive Solution	N/A	No	No	Yes	Yes	No	No

Figure 11: Comparison of the signal to artifact ratio in clinical Ultra II CardioSense, Carbon/Rubber electrodes with and without conductive solution, and metal discs. The table corresponds with the graph above.

- Ultra II CardioSense were used as the clinical standard
  - Avg. SAR: **0.624**
  - Standard dev: **0.033**
- Dry, rubber electrodes were found to be the most viable option for electrodes after conducting a signal to artifact test (Figure X)
  - Avg. SAR: **0.674**
  - Standard dev: **0.110**

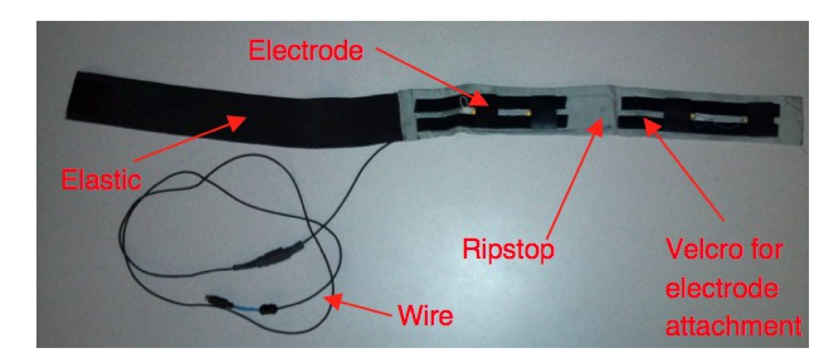


Figure 12: A picture of the electrode band that was used for testing. The lead wire is fed through the ripstop and out from the patient's back to limit the risk of strangulation.

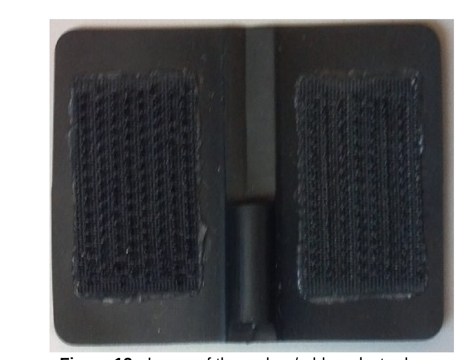


Figure 13: Image of the carbon/rubber electrodes with velcro that will be implemented in conjunction with the electrode band in figure 12.

Proof of Concept Testing
- A group of 10 subjects were tested using the electrode band with carbon/rubber electrodes.
- Subjects held their breath, while being timed to examine the consistency of the device to sound the alarm during simulated apnea

Future Work
- Design the circuit in EAGLE for implementation on a printed circuit board
- Completion of more rigorous bench testing to be eligible for a 510(k) premarket notification
- Implementation of telemedicine capabilities
- Develop algorithms to highlight periods of apnea, brachycardia, and tachycardia
- Develop mobile application that can read the waveform, and provide diagnostic information on location

Acknowledgements
- Special thanks to Dr. Amit Nimunkar, Dr. Laura Houser, Tim Balgemann, Dennis Bahr, Professor John Webster, and Eric Oberstar

- Kearney, K., et al. (2007, August). Quantification of Motion Artifact in ECG Electrode Design. Sensor Technology & Devices Ltd., 4 Heron Road, Belfast, UK. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/18002260
- Lawn, J.E., Cousens, S., Zupan, J. 2005. 4 million neonatal deaths: When? Where?Why? Lancet 365:891-900.
- UNICEF. 2012. Levels & Trends in Child Mortality, Report 2012. The United Nations Children's Fund.
- Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA [Online]. (2002). Available FTP: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDoc uments/ucm072846.htm