GLOBAL HEALTH PROJECT:
INFANT CARDIORESPIRATORY MONITOR

BME 400
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Table of Contents

Abstract

Sudden Infant Death Syndrome (SIDS) is the sudden, unexplained death of an infant under the age of one, usually while sleeping. While the national SIDS rates indicates a higher prevalence in developed countries, the lack of documentation and autopsies in third world countries has skewed this data. A more accurate portrayal of the situation worldwide is the number of neonatal deaths, or the deaths in the first four weeks of an infant's life. 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 to 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, specifically Ethiopia, a prototype infant respiratory monitor has been developed in semesters past utilizing impedance pneumography as its means of detection. The monitor has significantly reduced 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, and two rechargeable lithium ion batteries are integrated as the power source to allow for easy recharging. The ethical considerations concerning device reliability as well as patient and user safety were integral to the development of this device. This semester additional features are to be added, including heart rate detection and data logging capabilities. The powering system will be reduced from a dual supply to a single supply system for safety reasons. Furthermore, the low power PIC microcontroller will be replaced with a more computationally powerful Arm microcontroller to allow for more advance algorithms to be executed.

Background & Motivation

In 2000 the United Nations came up with a list of eight Millennium Development Goals (MDGs) and set the goal of achieving them all by 2015. The fourth of those goals was, “to reduce by two thirds, between 1990 and 2015, the under-five mortality rate,” (UNICEF 2012).

While there is still a lot of progress to be made in reaching this goal, the risk of a child dying within the first five years of life has been halved between 1960 and 1990 and continues to drop (Lawn et al 2005) (Figure 1). This pace however has not been similar across all under-five age groups, in particular, there has been very slow progress in reducing global neonatal mortality (Lawn et al 2005) (Figure 1). Estimates have shown that child mortality between the ages of two and five have fallen by about a third while the neonatal mortality rate (NMR) has dropped only by about a quarter (Lawn et al 2005). This means that a higher proportion of the under-five mortality rate is now due to neonatal mortality, and if the Millennium Development Goals are to be met, a successful means to lower the neonatal mortality rate must be implemented.

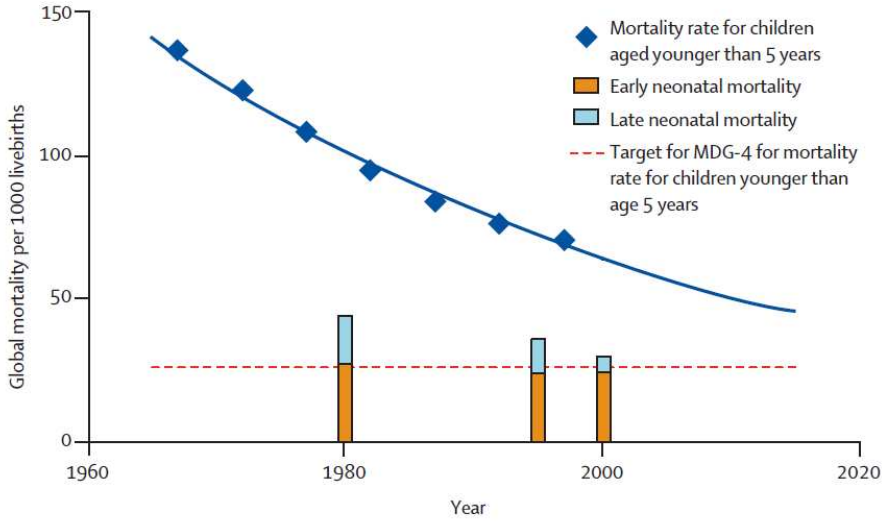


Figure 1: Actual and projected global mortality rate per 1000 live births in children under 5, early neonates, and late neonates, 1965-2015. Graphs indicate a drop in the mortality rate for children younger than five, but a much slower decrease for early and late neonatal mortality rates (Lawn et al. 2005).

The most effective way to devise a strategy of reducing NMR is to understand what is causing the NMR to be so high. Current research suggests that the problem is two-fold. The first problem is that of the inverse care law which states, “the availability of good medical care tends to vary inversely with the need for it in the population served,” (Lawn et al 2005). It has been observed that 99% of neonatal deaths arise in low-income and middle-income countries, but that the 1% of neonatal deaths that occur in high-income countries are the ones that receive the most attention and study (Lawn et al 2005). The second problem is that neonates are dying from conditions that are treatable and preventable. Studies have shown the three major causes of neonatal mortality to be

from three major causes: 36% from infections, 27% from preterm birth, and 23% from asphyxia (Lawn et al 2005) (Figure 2).

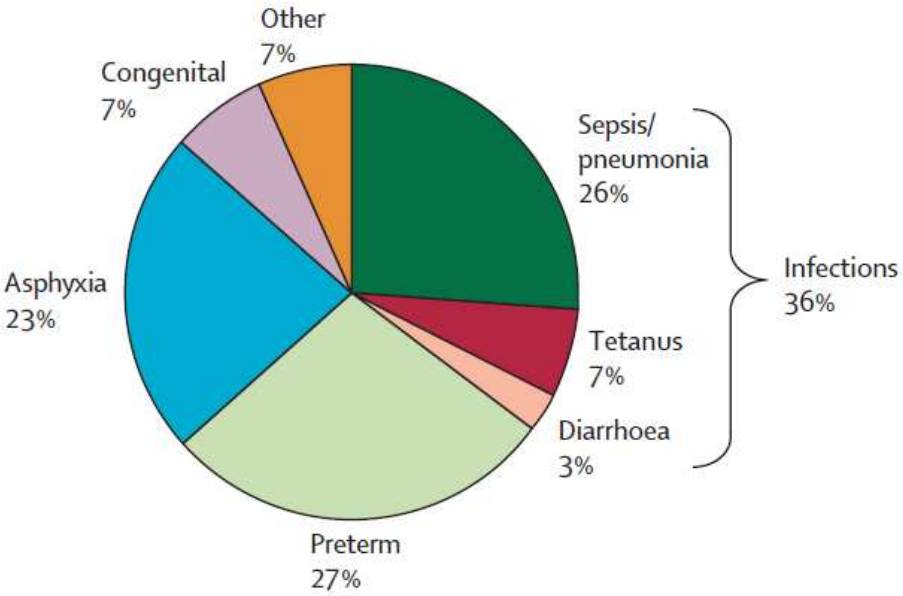


Figure 2: Estimated distribution of causes of neonatal deaths worldwide in 2000 (Lawn et al. 2005).

It is by looking at these two major problems in addressing neonatal mortality that our team draws our motivation. We are seeking to address these problems by developing a reliable, low-cost cardiorespiratory monitor to issue early warning alarms in the case of neonatal and infant apnea, asphyxia, or bradycardia that could easily be implemented in the countries where 99% of the neonatal deaths occur.

We believe that by doing this we will begin to address the problem of neonatal mortality. Our monitor will provide an adequate modality for monitoring neonates, and thus will address the inverse care law. In addition, our device will provide a warning system for neonates at risk for symptoms associated with asphyxia and preterm birth.

Pathophysiology

Two of the major causes of death of neonates that we seek to address with this monitor are asphyxia and preterm birth. While the two causes of death may seem to be quite different, the designations of these two groups can be misleading as both encompass a large number of pathologies, many of which are related to respiration. For example, one study in the United Kingdom found approximately 49% of preterm births between 2002 and 2008 were due to respiratory ailments (Berrington et al 2012). Additionally, asphyxia has been associated with a number of pathologies including apnea and bradycardia in full term infants.

In discussing the pathology and physiology that results in a respiratory emergency in a neonate, we will focus on apnea. While there are a number of different reasons for a respiratory emergency, apnea is a common cause of death in both preterm and full-term neonates.

Apnea in its strict clinical sense is defined as the cessation of respiratory airflow for a length of time greater than 20 seconds (Rocker et al 2012). It is important to note that it is not uncommon for infants to undergo apneic events with duration less than 20 seconds during normal sleep, however, once the event exceeds 20 seconds it becomes a health concern (Marcus 2001). There are three types of apnea: central apnea, obstructive apnea, and mixed apnea (Rocker et al 2012).

Central apnea is associated with the nervous system and can result from a lack of stimulus by the central respiratory centers or the failure of the respiratory muscles or efferent peripheral nerves to process the nervous signals from the brain (Rocker et al 2012). Often this is seen in premature infants as these systems have yet to fully develop (Rocker et al 2012). Infants suffering from central apnea have no respiratory effort and thus will have no chest wall movement or breathing sounds (Rocker et al 2012). Obstructive apnea is caused by a blocked airway and is not signified by a lack respiratory effort (Rocker et al 2012). Obstructive apnea is associated with a number of other conditions including small airways or decreased strength in the pharyngeal dilator muscles (Rocker et al 2012). Mixed apnea is simply a combination of conditions from both central and obstructive apnea that together create a health risk (Rocker et al 2012).

Apnea can be used to explain many of the respiratory emergencies found in infants, but certainly not all of them. Unfortunately, the pathophysiology of each possible respiratory ailment cannot be covered here, but what is clear is that regardless of respiratory ailment, early resuscitation using a bag valve mask is of critical importance. One study found that a delay in the time of initiation in bag valve mask resuscitation resulted in more neonatal deaths. Infants that survived had a delay of 82+/-58 seconds while infants that died had a delay of 100+/-78 seconds (Ersdal et al 2011). Ultimately, this means that our monitor has a critical role to play because it can alert caregivers when an infant has stopped breathing and allow them to provide care more quickly and reduce respiratory related neonatal mortality, regardless of specific cause.

Our Area of Focus

The ultimate goal of our infant cardiorespiratory monitor is to be available at low cost for countries with the highest rates of under-five mortality and neonatal mortality. We currently have targeted two distinct countries to focus our efforts: Ethiopia and Haiti. These choices were made because both countries have demonstrated a great need for devices such as ours and we have contacts there who are working with doctors, nurses, and midwives who can ensure that our device is properly used. This will allow us to test its effectiveness for implementation on the broader scale.

Currently, both Ethiopia and Haiti have seen a drop comparable to the global average in under-five infant mortality rate, but suffer from neonatal mortality rates that are still very high. (UNICEF 2012, Lawn et al 2005) (Figure 3). Currently, neither one has reached the 2015 Millennium Development Goal, but with a strong effort to reduce the neonatal mortality rate, the goal is within reach for both nations.

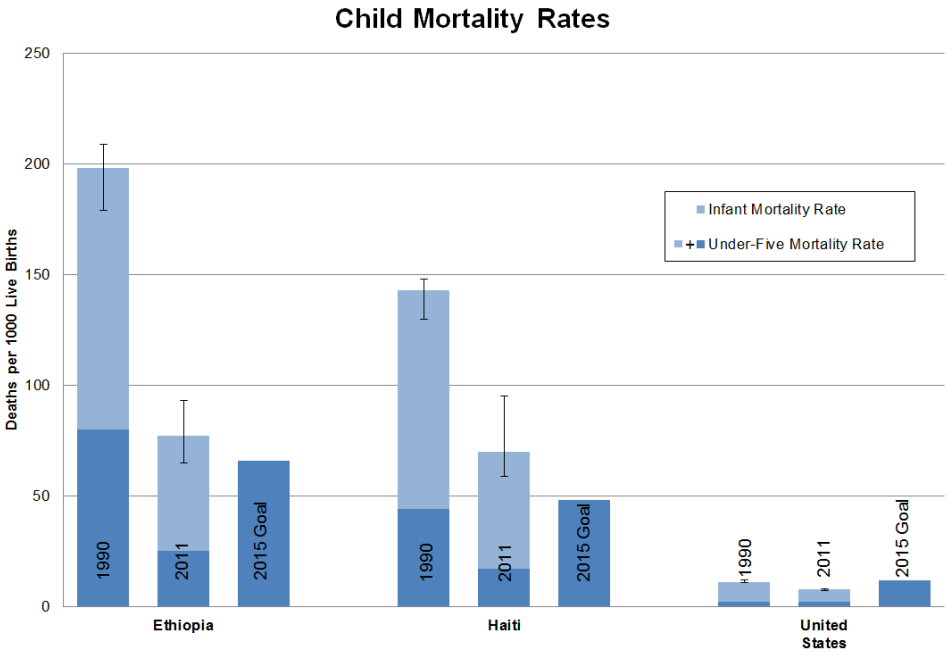


Figure 3: 1990, 2011, and 2015 MDG-4 for under-five mortality rate and infant mortality rate in Ethiopia, Haiti, and the United States (UNICEF 2012).

Current Methods

There are many devices that are currently on the market that provide monitoring systems for infants while they sleep in an in-home setting. Typically, these monitors ensure that infant respiration rates maintain steady levels on a per minute basis, and that cessation of breathing does not occur. There are many ways to monitor respiration including impedance pneumography, which measures changes in chest cavity resistance during breathing (Grenvik, 1972). Pulse oximetry can also be used to monitor respiration rates by measuring oxygen levels in the bloodstream; force plates are another form of respiration monitoring, and they monitor infant motion artifacts and sound an alarm in motion absence of more than twenty seconds (SUDC.org, 2012). A fourth way of monitoring infant respiration is using temperature sensitive thermistors to measure temperature fluctuations consistent with inhalation and exhalation and the heat content of the surrounding air (Norman, 2012).

The first competitive respiratory monitor currently on the market is the Babysense II (Figure 4), which utilizes two large force pads placed under the crib mattress to sense if the infant is breathing properly. The Babysense depicts a green, 'all-clear', light when the infant is breathing normally, but emits an audible alarm if the infant's respiration rate decreases to less than ten breaths per minute or breathing ceases for more than twenty seconds. The monitor is powered by standard AA batteries and costs $279.00 per unit (Hisense Ltd. 2012).

Figure 4: The Babysense II Monitor detects breathing motion through the use of a force mat (Hisense Ltd., 2012).

Another respiratory monitor available for home use is the Angelcare 201 model (Figure 5). This monitor also uses a force mat that is placed under the crib mattress to monitor the infant during the night. The Anglecare model sounds an alarm when the infant stops breathing for more than twenty seconds. The power source for this monitor is an AC adaptor as well as a battery backup for use in the case of a power outage that requires eight AA batteries. The cost of the unit is $129.99 (Angelcare Monitors Inc., 2012).

Figure 5: The Angelcare 201 monitor, like the Babysense II Monitor, uses a force mat to detect forces that indicate breathing (Angelcare Monitors Inc., 2012)

The Respisense baby monitor differs from the previous two monitors mentioned in that it uses a motion detection method of monitoring respiration rates (Figure 6). The device clips onto the infant's diaper, which allows for supervision away from the crib, which a permanent force mat does not allow. After twenty seconds of inactivity, the sensor alerts the caregivers with a built-in alarm system. The system also tickles the infant's stomach if movement ceases for fifteen seconds. The price for the Respisense monitor is $100 (Infantrust, 2012).

Figure 6: The Respisense monitor attains mobility by clipping directly to an infant's diaper, and senses breaths by measuring pressure between a baby's belly and the waistband of the diaper (Infantrust, 2012).

While these systems are compatible for use in developed countries, all three models present obstacles for use in a mobile clinic setting, where resources are scarce and a consistent source of batteries is limited. The recurring cost and difficulty of obtaining batteries in the Babysense and Respisense monitors is too high, and the lack of consistent electric power in mobile clinics eliminates the Angelcare (AC adapter) from consideration (Infantrust, 2012). In addition, the devices described have an overhead cost that can be prohibitively expensive for use in a mobile clinic.

Impedance Pneumography

Impedance Pneumography uses the changing resistance through the thoracic region to track respiration. By passing a carrier wave through the trunk of a patient, and comparing it to the output wave on the opposite side of the trunk, an amplitude modulated sine wave is produced, where sections of higher amplitude correspond to inhalations and vice versa. By passing the wave through a demodulating envelope rectifier, a sine wave that corresponds to breathing can be produced. A block diagram of the method can be seen in Figure 7.

The resistance that is encountered at the skin path stage of the method is a summation of skin resistance, which is “fixed” on short time scales, but can be susceptible to drift overtime based on skin moisture as well as other factors. Impedance below the skin is increased during inhalations because the path length is increased, and because air is more resistant than tissue. Since the variation in thoracic impedance is small when compared to skin resistance, a high gain needs to be applied to the differential amplification stage for a useful wave to be produced.

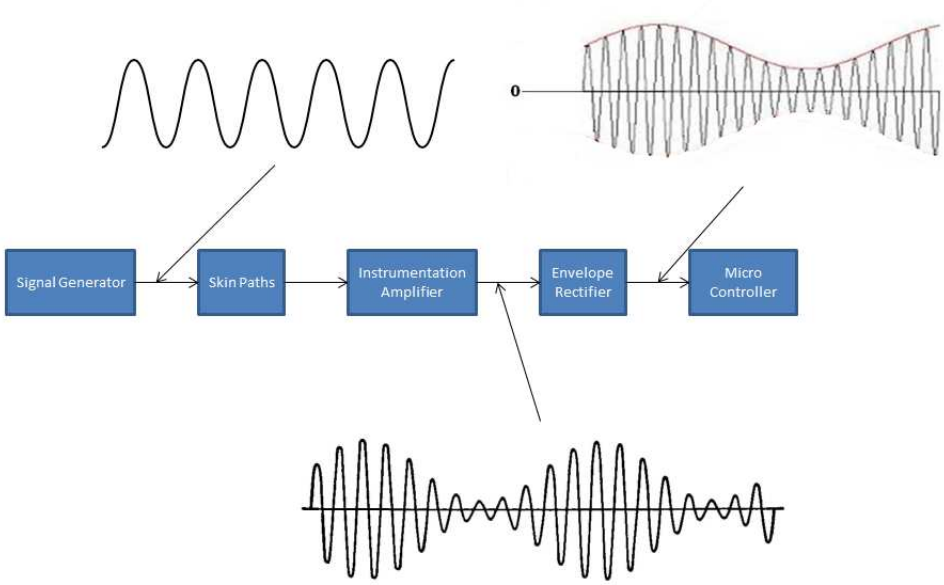


Figure 7: Impedance pneumography uses a carrier wave, differential amplification, and demodulation as shown here. The resulting waveform can be read by a microcontroller and algorithms can be applied that will determine if breathing has taken place.

Problem Statement

The goal of this project is to produce an infant apnea monitor that will detect and alert a caregiver after an infant between 0 and 12 months has stopped breathing for more than 20 seconds. The device's intended environment will be in disaster stricken or developing regions of the world. Thus, the unit must be very inexpensive and its ease-of-use is of the utmost importance. Additionally, the device must still maintain high levels of durability, reliability, and safety in accordance with governing regulatory agencies.

Client Requirements & Design Constraints

The primary function of the device must be to effectively alert nearby caretakers in the event that the infant ceases breathing for more than 20 seconds. Therefore, the device must be capable of monitoring an infant's breathing pattern and alert nearby caretakers via audio and/or visual alarm if breathing is not detected for 20 seconds. The device must be highly reliable and consistent, since a failure of the device could result in the death of an infant. Because a failure to detect breathing cessation could have fatal consequences, the device should be designed to tend to be more oversensitive than under sensitive, as false negatives pose a greater threat than false positives. However, if the device sounds too many false alarms, caretakers may begin to dismiss it, therefore device accuracy is important. The device must be safe to use both for the infant and operators. It cannot interfere with healthy electrical signals in the infant, nor pose the risk of shock to the infant or caretakers. Any external wiring used must not present a risk of strangulation or entanglement to the infant, and there should be no small, easily breakable parts that could present a choking hazard. The device should allow for comfortable, normal sleep for the infant. Any device components that come in contact with the infant must receive sterilization between uses. In designing the device with the operator in mind, it must be simple to use and easy to operate with minimal training. As a medical device, the device must meet all regulatory demands outlined by the government and other agencies. Therefore, it must comply with HIPPA and patient disclosure standards, as well as receive FDA approval.

A portable device must be small with a maximum size of 10 cm x 10 cm x 10 cm and a maximum weight of 1.0 kg. The device should weigh at least 200g to prevent it from being easily knocked off a table, stand, etc. The device must be robust and able to withstand reasonable wear due to use. Since acquiring replacement devices or pieces and performing repairs on the device may not be an option for organizations using the device in the field, the risk of broken parts must be minimized. The device should have a long shelf life, with the only regular maintenance needed being replenishing the power supply from time to time. This power will be provided by a battery, since power grids in many of the intended environments of operation are often either unreliable or non-existent. Ideally the power source will require minimal replacement and/or recharging, and so in addition to having a long lasting reliable power source implemented into the device, the device itself must be as power efficient as possible. Therefore, the device should operate on 70 mA or less.

The aim of this project is to produce two functional prototype units to prove manufacturability. The cost of the device must be kept low, due to the nature of the project. Therefore, the target cost per unit is a maximum of $30 per unit. Device components will include basic circuitry such as resistors, capacitors, and amplifiers, wiring, a microprocessor, instrumentation amplifiers and standard op-amps, a battery, a speaker, electrodes, and housing. A more detailed product Design specification can be seen in appendix A.

Design Options & Selection Matrices

Microcontrollers

While many powerful microcontrollers are available for device development, including the Hitachi SuperH, Analog Devices ADuC, and Intel 8051, we have narrowed our selection process down to the PIC family from Microchip and the AVR family from Atmel. We made this decision based on the fact that we already have development boards available for these microcontroller families; development boards can cost up to $200, so this decision reduced the cost of development (Atmel, 2012). The quality of our design did not suffer from this decision, as both microcontroller families contain a wide range of models with hardware that meets our basic needs for this project and both have a large online support community.

Our basic hardware requirements for the project are: analog-to-digital converter (ADC) with sample rate of at least 100ksps, pulse-width modulation (PWM) with output speed of at least 30 KHz, serial communication interface capability, timer interrupt capability, and flash memory expansion capability. As stated previously, the AVR and PIC families both offer microcontroller models fulfilling these minimum hardware requirements (Atmel, 2012) (Microchip, 2012). The AVR and PIC families differ in some aspects such as the complexity of the instruction set and the size of instructions, but for the requirements of this project, they are nearly functionally identical.

Two areas in which the microchip families do differ that are relevant to the performance of this device are the working memory and sleep modes. The AVR family has 32 working registers while the PIC family has one working register. Working registers store intermediate values created during calculations; values that do not fit in the working register are backed up to memory. The advantage of having a larger number of working registers is that a larger number of variables can exist simultaneously without having to be backed up to memory; this increases the speed of calculations. Since we are planning to increase the complexity of our detection algorithm by adding volume and slope variables, we will need to keep track of a larger number of variables. It would therefore be advantageous to use the AVR family since this will allow a greater computation speed. Sleep states are used to turn off the system clock when the device does not need to be active to conserve power. The PIC family offers a slightly more power efficient sleep mode than the AVR family. Power consumption is a concern in this project because the device will run on battery power.

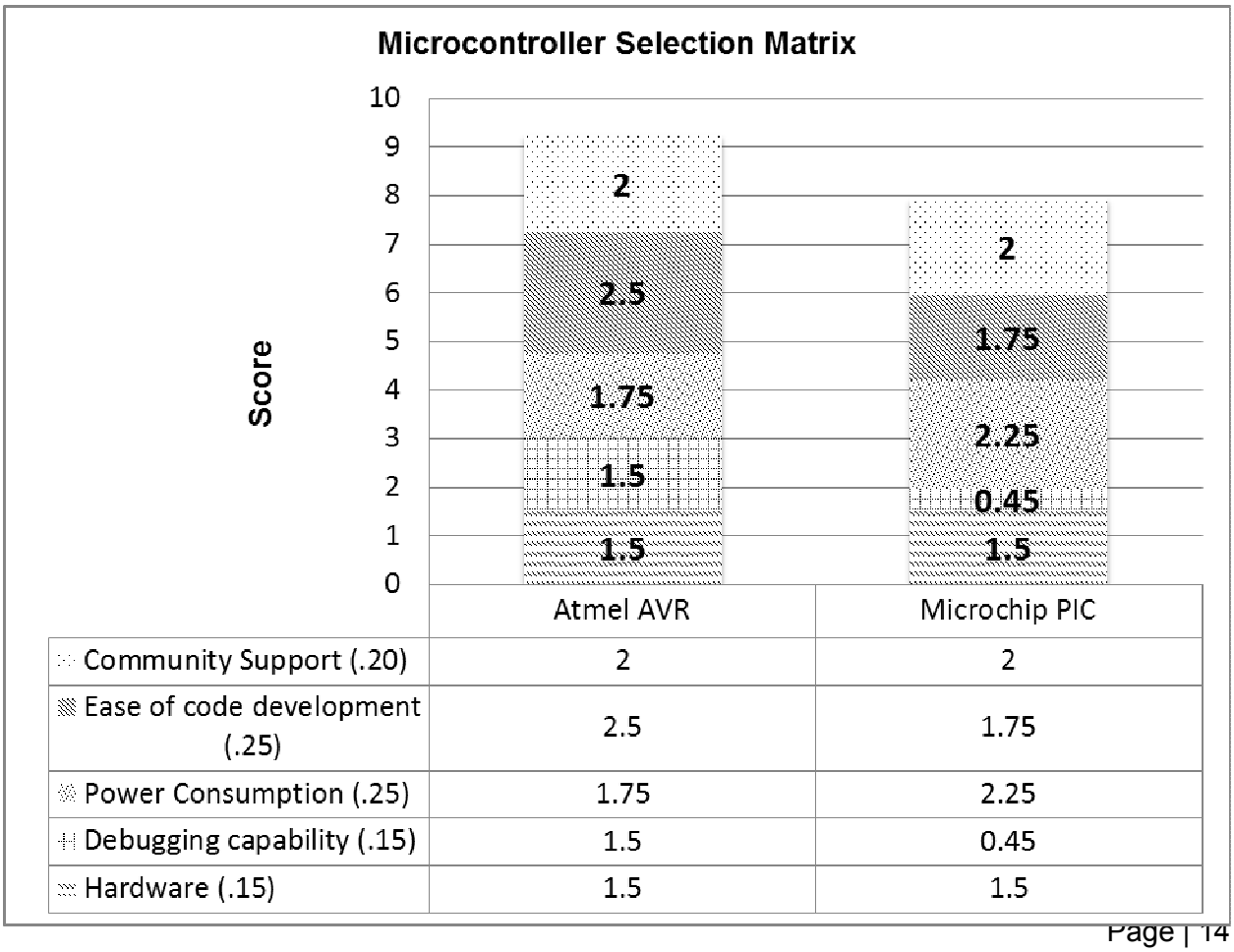
When developing a device with and embedded microcontroller, a development board is an essential tool. Development boards allow the user to program the microcontroller program memory, and check that the microcontroller performs properly before integrating it into the device. We have received the permission of the mechatronics lab to use their STK600 development boards, which are designed to be used with Atmel microcontroller families. The BME department also has custom development boards available for the PIC microcontroller family. Another resource that can be useful when developing an embedded system is an on-the-chip debugging tool. These tools allow the user to step through program code one line at a time while observing changes in variable value and I/O values; this can allow the user to find problems that might otherwise be hidden due to the high speed of code execution. The

mechatronics lab has given us permission to use the JTAG-ICE mkII debugging tools for the Atmel microcontroller family. While the PIC family has on-the-chip debugging tools available for purchase, we do not have access to any of these tools.

Integrated development environment (IDE) software is a useful tool for programming a microcontroller. Atmel Studio 6 and MPLAB 8 are two free IDEs for Atmel and Microchip microcontrollers, respectively. Both IDEs offer an integrated C-compiler. Atmel Studio 6 offers over 1,000 pre-written code examples to help developers get started on their project. An additional software resource we have for the AVR family is CodeVisionAVR. This software program is available through CAE and features a CodeWizard tool that automatically generates code for Timers, ISRs, I/O setup, and many other peripheral settings. The use of such a tool would greatly reduce the time needed to develop and edit code, and thus would greatly reduce the length of the design cycle.

While our current device prototype uses a PIC microcontroller and the PIC family offers a more power efficient sleep mode, we have chosen to use the Atmel AVR family for our final device. As can be seen in the microchip selection matrix, PIC and AVR families are matched in hardware and community support. Ultimately, we felt that the ease of code development and code debugging capabilities of the AVR family outweighed the slight reduction in power efficiency.

Table 1: Design matrix quantifying the weighting of each category considered in choosing a microcontroller, and how the Atmel AVR chip and PIC microcontroller scored in each category.



	Atmel AVR	Microchip PIC
Community Support (.20)	2	2
Ease of code development (.25)	2.5	1.75
Power Consumption (.25)	1.75	2.25
Debugging capability (.15)	1.5	0.45
Hardware (.15)	1.5	1.5

Electrode Selection

Design Constraints

As the only part of the monitor that will actually be in contact with the patient, the selection of the electrodes for the monitor is of critical importance. In the current design, the lead system we are incorporating will include four separate electrodes. One will serve as the carrier electrode, which will be connected to the output of the carrier generation circuit. This signal flows into the body and through an adjacent electrode that is connected to ground. The other two electrodes will be used to measure the signal amplitude at different points along the thoracic cavity. Based on this system, two commercially available electrodes types were considered and evaluated when deciding which electrode would be most suitable for this monitor—carbon/rubber electrodes and Ag/AgCl electrodes. To determine which electrodes are best for this application, four factors are considered for effectiveness and also the conditions under which the electrodes will be used. Each factor was given a weight out of a total weight of 1.0. These four factors (and their weight) are: reusability (0.5), cost (0.3), sensitivity (0.15), and allergen risk (0.05). An explanation of each factor and the rating that each electrode type received, and why, follows below.

Reusability

The most critical factor for our selection of electrodes was the reusability of the electrodes we chose. All available evidence suggests that if the electrodes the monitor is designed to use are one time use, the monitor will be used until the electrodes run out, and then will not be used again. This does not suggest a sustainable system to us or one that really works to address our ultimate goal of reducing the neonatal infant mortality rate. Of the two electrode systems considered, only one really fit this requirement—the carbon/rubber electrodes.

The vast majority of Ag/AgCl electrodes are one-time use. In our case they would be used for one night and then disposed of. There are a few examples of Ag/AgCl electrodes on the market that are termed “reuseable” however this often means they can be used reused upwards of seven to ten times before being replaced. Ultimately though, they suffer from the same problem as single use electrodes (Luo et al 1992). The Ag/AgCl electrodes were given a final rating of one out of ten because they don’t meet the criteria, but they were not given a zero because there are a small number of available electrodes that could perhaps be considered semi-reusable.

Conversely, the carbon/rubber electrodes are truly reusable. In testing they are held in place using elastic bands or tape, can be removed and sterilized, and reapplied to the same or a different patient (Luo et al 1992). These leads, if properly cared for, are truly reusable, and received a rating of eight out of ten. They however did not score perfectly because over a long period of time they will wear out and need to be replaced. For all intents and purposes, they are the most reusable electrodes available on the market.

Cost

Another very critical factor in the design of the electrodes that was considered was the cost which received a weight of 0.3 out of 1.0. This factor was weighted so

heavily because the goal of this monitor is to be implemented in developing regions where often the daily wage is below $10.00 per day (Chen and Ravallion, 2008). Therefore, the more cost effective every element of the monitor, the more realistic its mass implementation will be.

The most commonly used Ag/AgCl electrode is the 3M Red Dot®. The average cost of one 3M Red Dot® electrode is approximately $0.50 per electrode for the average consumer (www.amazon.com). If four of these electrodes were required per day and the monitor was used every day, this would correlate to a total cost of $730.00 per year. In comparison, the carbon/rubber electrodes have an average cost of $10.00 per electrode (www.amazon.com). Reusable electrodes thus incur to a total cost of $40.00 per year.

Both of these costs were obtained off of a commercial site and it can be expected that the cost of both of these electrode types would be significantly reduced when they were purchased in large quantities. The comparison however is obvious, simply because so many of the Ag/AgCl electrodes would be required per year; therefore the price will easily outpace the cost of the reusable electrodes. The Ag/AgCl electrodes were given a score of two out of ten and the rubber electrodes were given a score of eight out of ten.

Sensitivity

The third design factor considered was sensitivity. This factor was given a weight of 0.15 out of 1.0; much smaller than the previous two factors. Electrode sensitivity does not constrain our design to the degree that reusability and cost do. This is because signals acquired by insensitive electrodes can be filtered, amplified, and ultimately "designed around". This factor is still very important and must not be taken lightly or overlooked, as picking sensitive electrodes will only make the design process easier.

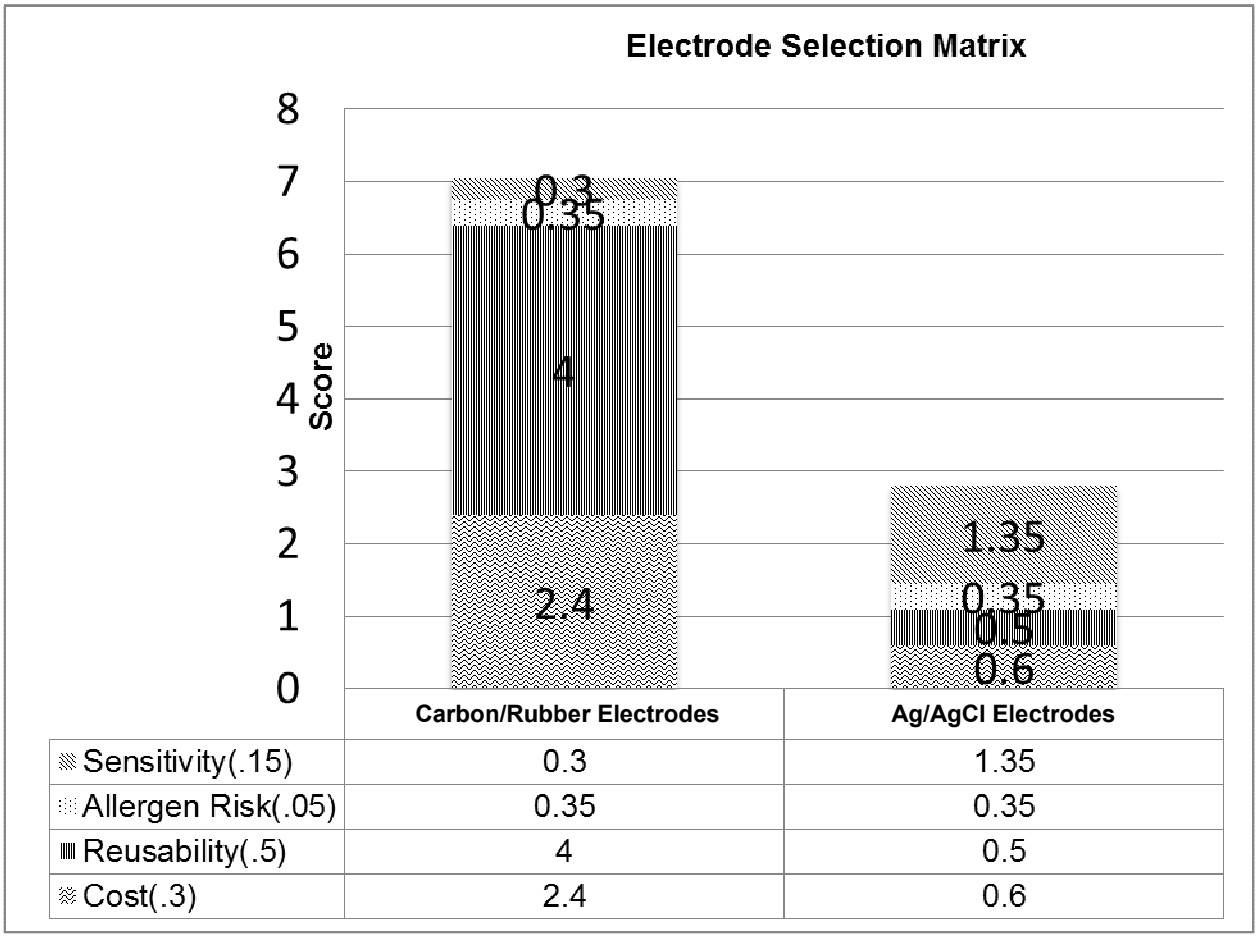
Again in this category, there was a clear electrode type that performed best, but it was not the carbon/rubber electrode. The sensitivity of electrodes is often measured as the signal-to-artifact ratio (SAR). The SAR is amount of noise in the signal that in our case would be returned to the monitor to be evaluated (Luo et al 1992). A study looking at a number of different electrode types ultimately concluded that adhesive-gel electrodes were preferred to rubber electrodes, because even using tape and tight elastic bands, the SAR was far from ideal for the rubber electrodes (Luo et al 1992). The SAR for rubber electrodes was so great that they were not even considered in a follow-up study looking at pediatric electrodes (Mayotte et al 1994). Due to these reports the Ag/AgCl electrodes were given a rating of nine out of ten and the carbon/rubber electrodes were given a rating of two out of ten.

Allergen Risk

The final design factor for the electrodes that was considered was the allergen risk of both types of leads. This was given a weight of 0.05 out of 1.0. This factor is important to consider, but was not given a large weight. This is because both electrodes are commercially available, indicating that for the most part they are clinically used and thus the allergen risk is low. The two electrode types considered were both given a score of seven out of ten.

Design Matrix

Table 2: Design matrix quantifying the weighting of each category considered in choosing electrodes, and how the carbon/rubber electrodes and the Ag/AgCl electrodes scored in each category



	Carbon/Rubber Electrodes	Ag/AgCl Electrodes
Sensitivity(.15)	0.3	1.35
Allergen Risk(.05)	0.35	0.35
Reusability(.5)	4	0.5
Cost(.3)	2.4	0.6

Based on these scores and the weights assigned to each factor a design matrix was created by multiplying the score out of ten each electrode got for each factor by the factor weight and adding all of the factors together (Table 2). Due to the heavy weighting of reusability and cost, the carbon/rubber electrodes scored much more highly (7.05) than the Ag/AgCl electrodes (2.8).

The results of this matrix however are a little unsettling especially since the use of carbon/rubber electrodes poses a risk for very high SAR in the final design. In order to combat this, a number of modifications will be considered in order to use the carbon/rubber electrodes but ensure that their sensitivity is of a high enough quality to meet clinical standards. Four different electrode-specific factors will be extensively tested and assessed in order to create the highest SAR for the carbon/rubber electrodes. These factors are: electrode size, electrode placement, conductivity solution, and electrode to body attachment.

In at least two reports in which electrode size was considered, it has been found that the larger the size of the electrode, the larger the SAR is (Mayotte et al 1994, Luo et al 1992). In testing this factor the size of an infant and the risk of the electrodes

touching will be balanced with electrode size to yield the largest electrodes possible. Electrode placement has also been considered in previous studies in adults where it was found that the most effective electrode placement was directly over the sternum on the upper back approximately on the T5 vertebrate (Luo et al 1992). This however will need to be tested and confirmed in infants as well as altered to account for the use of four leads as opposed to the two lead system used by Luo et al (1994). The third factor will be the use of a conductivity solution for use with the carbon/rubber electrodes. It was found that the SAR was greater in carbon/rubber electrodes when a saline solution was used (Luo et al 1992). Based on this finding, a conductive solution will be designed that is both adhesive and conductive to better adhere the electrodes. Additionally, the conductive solution will be fabricated out of items that are commonly available in developing countries such that it can be re-made when it runs out. Finally, the attachment of the electrodes to the body will be studied. It is expected that the electrodes will be placed within an elastic band that has both a strap around the chest cavity as well as two straps over the shoulder to hold the electrodes in place. It is the hope that by securing the electrodes to the body in all three planes, the artifact due to electrode slippage on the body can be reduced.

Ultimately, the best choice in electrodes for this monitor was the carbon/rubber electrodes because of their reusability and cost. However, in further consideration of the required sensitivity, it is the goal to modify the conditions in which these electrodes will be used to create the most sensitive and effective electrode system.

Current Design

Hardware Specifications

Power Supply

A single Lithium-polymer rechargeable battery will be used to power the device. These batteries are similar to those found in cell-phones and other portable electronic devices available today. A typical 3.7 Volt LiPo battery can hold approximately 2200 mAH of current, which makes them ideal for a continuous monitoring device. The majority of the components in the subsequent analog instrumentation circuit require a supply voltage of 5 Volts, and thus a 5 V boost regulator will also be implemented in the power supply functional block.

To facilitate controlled recharging of the LiPo battery, without the need to physically remove the battery from the device, an onboard recharge circuit will be included capable of recharging at a rate of 500mA/H. The power circuit will also include an under-voltage protection block that functions to interrupt the connection between battery and circuit in the event that the available voltage from the battery falls below 2.6 Volts. This feature is critical to ensure the long-term quality of the device by removing the possibility for component damage caused by an insufficient voltage source.

With the aforementioned design requirements in mind, the device will implement power supply circuitry of the Power Cell – LiPo Charger/Booster (PRT-11231) from Sparkfun electronics. (Figure 8)

Figure 8: Power Cell – Lithium Polymer rechargeable battery charger and boost regulator. Capable of sourcing up to 600mA @ 5V. (sparkfun.com)

Analog Instrumentation

Carrier Generation

Impedance pneumography operates by extracting the amplitude modulation signal of a known high-frequency carrier wave that is injected across the chest. This carrier signal will be generated by a connection of operational amplifiers with positive feedback causing unstable oscillation between the power rails. The circuit depicted in figure 9 produces a true analog sine (as opposed to cosine) wave when V_{out} is attached to the second output of the quadrature oscillator.

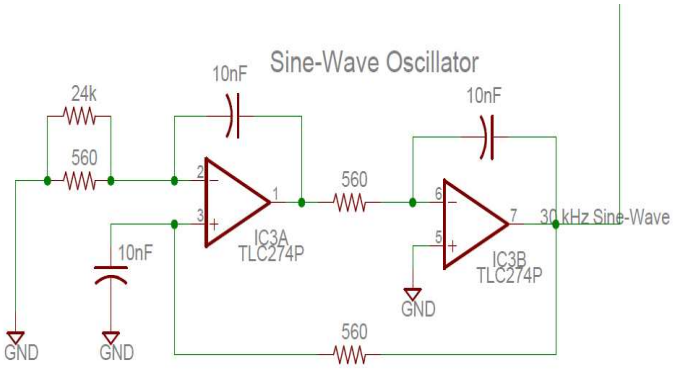


Figure 9: Quadrature Oscillator – An unstable connection of operational amplifiers causes periodic switching between the two power rails. In this case, the frequency of oscillation is determined by $f = 1/(2\pi RC)$, and amplitude is controlled by the parallel combination of 24 kΩ & 560 Ω

Patient Isolation

Proper patient isolation is commonly accomplished by integrating transformers or optocouplers between the patient and device. Though both transformers and optocouplers provide effective isolation, optocouplers will be used in the design, as they rely on LED light to transmit an electrical signal, and therefore emit no electromagnetic interference (and can't be interfered with by other EMI emitting devices nearby), as is characteristic of a transformer. A simple block diagram illustrating the location of the optocouplers with reference to the patient can be seen in figure 10.
Optocouplers surround the patient at input, and output, as well as between the analog and digital components of the device, which ensures that the microcontroller will also remain functional in the event of an electrostatic discharge or power surge.

Figure 10: Functional block diagram illustrating the position of optoisolators in the circuit.

In choosing an optocoupler, the working voltage of the device must be considered, as it dictates the necessary creepage and clearance distances of the component. Creepage distance is defined as the shortest surface path over a solid dielectric between two galvanically isolated conductors; likewise, clearance is shortest distance through the air. At or below a working voltage of 17 V_{DC}, or 12 V_{rms}, optocouplers providing reinforced insulation have a creepage distance of 3.4 mm and a clearance of 1.6 mm (Been, 2007).The IL300 Linear Optocoupler by Vishay Semiconductors meets the requirements for reinforced isolation, and is currently the component of choice to ensure patient isolation. Three IL300's will be integrated in the circuit in accordance with the block diagram in figure 10**.**

Instrumentation

An instrumentation amplifier subtracts the voltage present at the ground side of the chest from the voltage present at the carrier side of the chest synchronously. The difference is then amplified by a gain factor, which is controlled by a single resistor '*Rg'*. The resultant waveform is an amplitude-modulated version of the original carrier signal as shown in figure 11. By Ohm's law, the peaks of the AM signal correspond to points of full inhalation and the valleys correspond to the moments of complete exhalation. The amplitude values at these points of inflection are of significant importance to the apnea detection algorithm, and will be discussed in subsequent sections. In addition to modulation due to respiration, the electrical activity of the heart also modulates the carrier signal. The result is a respiratory sinusoid with a superimposed ECG.

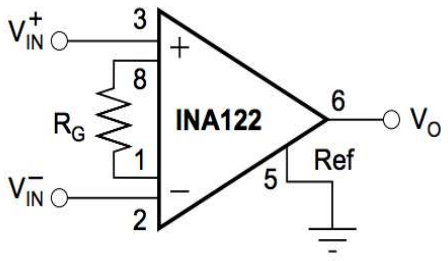


Figure 11: Instrumentation Amplifier – Texas Instruments INA122. Vo = G[(Vin+)-(Vin-)] where:

$$G = 5 + \frac{200k\Omega}{R_G}$$

(Taken from www.ti.com)

Amplitude Demodulation

Demodulation is accomplished by a precision full-wave rectification block that takes the absolute value of the AM signal by passing it through an operational amplifier configured as a superdiode. The resulting positive signal is then passed through an envelope detector, which extracts the modulation signal from the waveform. This smooth, periodic, signal corresponds to the change in chest impedance as a function of respiration, and is the signal of interest. In figure 12 the parallel combination of R1 and C1 is selected such that $1/(2\pi R_1 C_1) << f_{carrier}$. This allows capacitor C2 to store the peak charge of the envelope without fully discharging before the next voltage peak of the envelope.

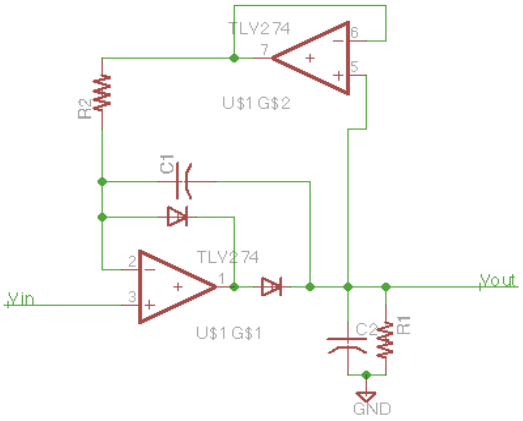


Figure 12: Amplitude demodulation block. A precision full-wave rectifier followed by an envelope detector accomplishes AM demodulation. The envelope detector will extract the positive envelope of the signal provided that $1/(2\pi R_1 C_1) << f_{carrier}$

AC Coupling and Analog Filtering

The envelope of the AM signal contains a DC-offset that is equal to the voltage drop caused by the patient's baseline chest impedance at full-exhalation. To prevent ADC saturation, and to improve the resolution of the signal at the input to the microcontroller, it is imperative that the signal be AC-coupled to remove this DC-offset.

A high-pass filter configured to have f_c = .05 Hz removes the DC-offset of the signal and also prevents the signal from drifting away from a provided analog reference value in the event of motion artifacts of changes in patient orientation. A low-pass filter configured to have f_c = 17 Hz will sufficiently attenuate high frequencies (including noise contributed by 60 Hz power line interference) without attenuating the respiratory rate signal or the QRS complexes of the ECG (Tompkins, 1993). The combination of these two filters is a band-pass filter with bandwidth .05 Hz – 17 Hz and some gain value determined by resistive combination R_f/R_i. At this point the signal is conditioned enough to be fed into the ADC of the microcontroller for sampling and processing.

QRS Detection

Figure 13 shows schematic for the QRS detector consisting of the following five subunits:

1. Band-pass filter. The power spectrum of a normal ECG signal has the greatest signal-to-noise ratio at about 17 Hz. Therefore to detect the QRS complex, the ECG is passed through a band-pass filter with a center frequency of 17 Hz and a band-

width of 17 Hz. This filter has a large amount of ringing in its output (Tompkins, 1993).

2. Half-wave rectifier. The filtered QRS is half-wave rectified, and subsequently compared with a threshold voltage generated by the detector circuit.
3. Threshold circuit. The peak voltage of the rectified and filtered ECG is stored on a capacitor. A fraction of this voltage (threshold voltage) is compared with the filtered and rectified ECG output.
4. Comparator. The QRS pulse is detected when the threshold voltage is exceeded. The capacitor recharges to a new threshold voltage after every pulse. Hence a new threshold determined from the past history of the signal is generated after every pulse.
5. Monostable. A 200-ms pulse is generated for every QRS complex detected. This pulse drives an indicator LED.

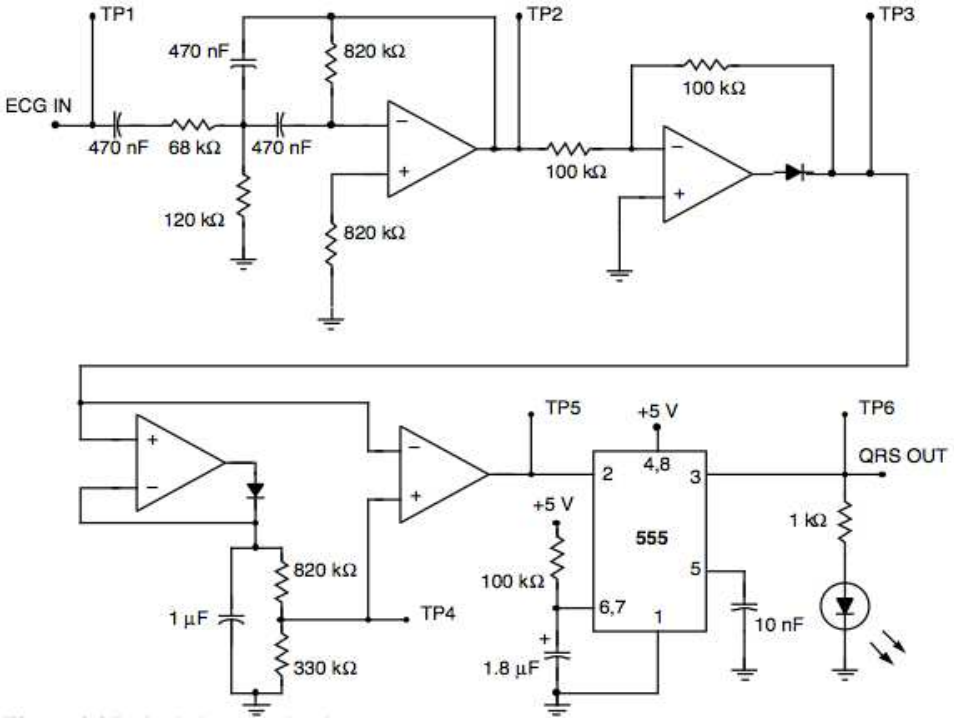


Figure 13: QRS Detection Circuit – Optional QRS filter (TP1-TP2), Half-wave rectifier (TP2-TP3), Threshold Circuit (TP3-TP4), Comparator (TP4-TP5), Monostable (TP5-TP6). (Tompkins, 1993)

The monostable pulse is connected to an input pin on the microcontroller which counts the pulses and can thereby calculate a real-time value for average heart rate to serve as a backup metric for alarm in the event the apnea detection algorithm fails to signal the presence of an adverse event.

Software Specifications

The PIC18F14K22 microcontroller previously chosen for implementation in this device is a low-cost, low-power alternative to a typical prototyping microcontroller. The code can be seen in Appendix A. The logic tree that the microcontroller utilizes can be seen in figure 14**.** The incoming signal from the envelope detector resembles a low frequency sine wave, with maximums corresponding to the peak lung volume of the patient, while the minimum values correspond to exhalation. The microcontroller is programmed to recognize the incoming wave from a patient after it is turned on, and to use this initial data to operate until it is turned off.

The microcontroller first initializes and determines the comparison value that it will use during the course of its operation. When the microcontroller is started, it

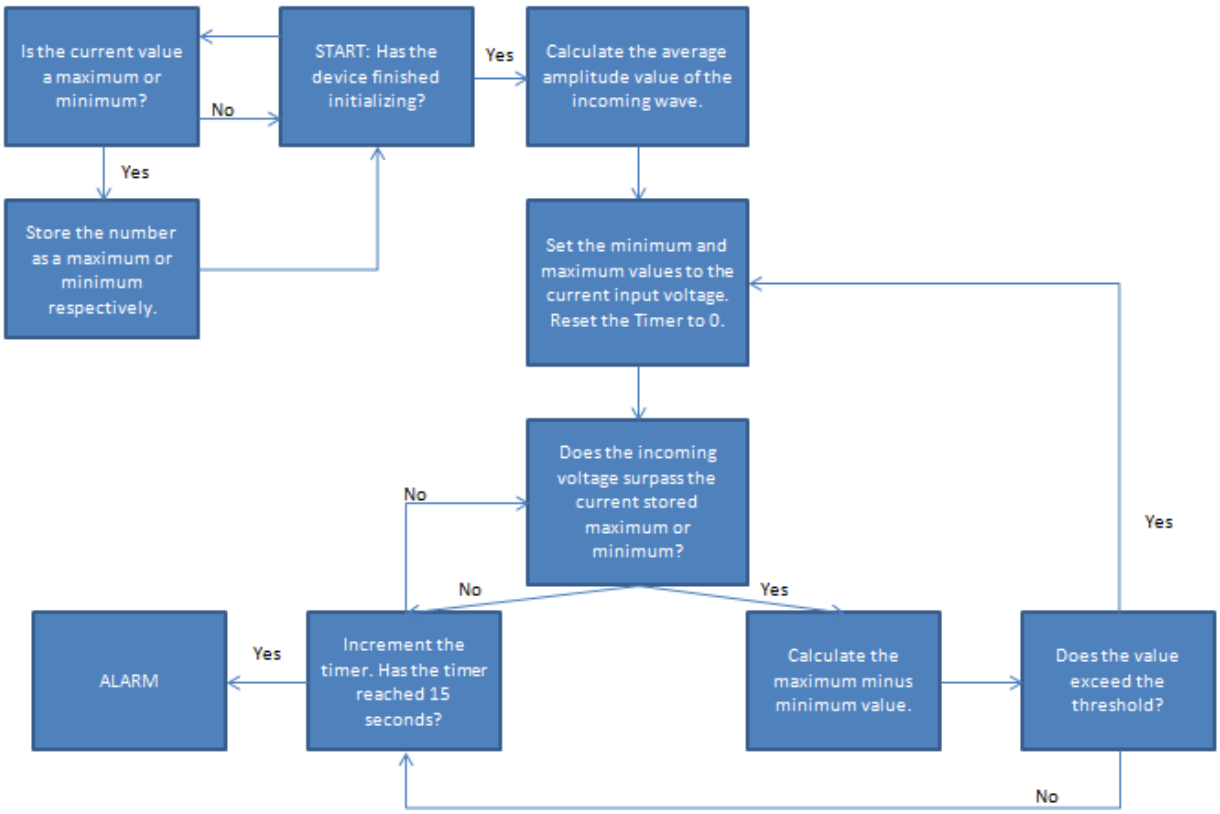


Figure 14: This is the decision tree that the PIC18F14K22 follows to determine if the alarm should be sounded. To see this decision tree as a state transition diagram, **see appendix C**.

undergoes a 30 second initialization that stores the five maximum points, as well as the five most minimum points during these 30 seconds. At the completion of this time, an average difference is calculated between the peak values.

Once an average difference has been stored, the program continually checks the incoming voltage then compares it to the currently stored maximum and minimum values. When the point is checked (and stored if appropriate) the microcontroller calculates the difference between the stored maximum and minimum. If this value satisfies the necessary threshold (40 percent of the initialized value in the previous

prototype) then the timer is reset, the maximum and minimum values both set to the current value being read, and the process is repeated. In the event that the threshold is not met for a full fifteen seconds, then the alarm is sounded to alert caretakers that a satisfactory breath has not been taken in fifteen seconds.

New Specifications

The new prototype that is building on the old model will add on to the current algorithm. The code will filter the incoming data through two sets of digital filters, one that is low pass and one that is high-pass, to separate the cardiogenic artifact from the impedance generated sine wave. The data will be stored as two separate digitally modified data sets that can then be used to indicate breathing and heart rate. The average of these numbers will be calculated every 10 seconds during periods of inactivity and stored on the external memory.

The algorithm must also be able to detect periods of anomalous behavior, and in these cases will take a constant read of data to be analyzed at a later time. Due to memory space limitations, an ideal design will be able to store these data sets as an image rather than as an array of points. This method will allow for more data to be stored, as well as produce a more readable data set for physicians and researchers to use.

To watch for cardiogram signals the sampling rate must be increased from 10 Hz, which was sufficient for breath detection according to the Shannon-Nyquist sampling theorem, to a significantly larger value. 125 Hz is necessary to detect a heartbeat for simple heart rate calculation, but a sampling rate of 250 Hz is the minimum necessary sampling rate to get a clean ECG wave (Pizzuti, 1985).

The power required to reach these two minimum clock cycles will ultimately be the determining factor in which benchmark is used.

Safety and Compliance

In order for this infant respiratory monitor to be effective from an Engineering World Health standpoint, it must harbor the necessary approvals from regulatory agencies, deeming it safe for patient use. After assessing the rate of infant mortality in developing countries throughout the world, and taking into account current partnerships, it was decided that this device will first be implemented in Ethiopia.

The Ministry of Health is responsible for the accessibility of quality health service to all citizens throughout Ethiopia, and more specifically, the *Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA)* provides the checks and balances between different directorates. *FMHACA* references many of the same international standards as the *US Food and Drug Administration (FDA)*, and the *Medical Device Directive (MDD)*, but is still not as acutely regulated as the aforementioned. Documentation for device design and testing is more explicitly defined by the *FDA* and *MDD*, so in order to ensure that the device is designed with patient safety as the highest priority, the device will be designed according to the guidelines laid out by the *FDA*.

The *FDA* identifies an apnea monitor as:

"An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection such as monitoring of heart rate and other physiological parameters linked to the presence of absence of adequate respiration."

(FDA Code of Federal Regulations, 2002)

Apnea monitors are *Class II* medical devices according the *FDA*, and *Class IIb* medical devices by the *MDD's* standards, meaning that they pose "medium risk" to patient safety. *Class II* devices encapsulate a wide variety of devices, ranging from apnea monitors to surgical lasers, and because of this, all devices of this classification are accompanied by a special control document. For apnea monitors, this document highlights the risks associated with using the device, which can then be decomposed into design requirements that must be included to minimize the risk and therefore comply with standards set by the *FDA*. It also includes relevant material for testing and validation to be submitted with a 510(k) premarket notification. 510(k) premarket notifications are required of medical devices that have already been approved for market; therefore in order to gain approval, thorough testing will be required to prove that the device is substantially equivalent to those already on the market. Figure 15 below outlines a general overview of the possible routes that can be taken in pursuit of device approval.

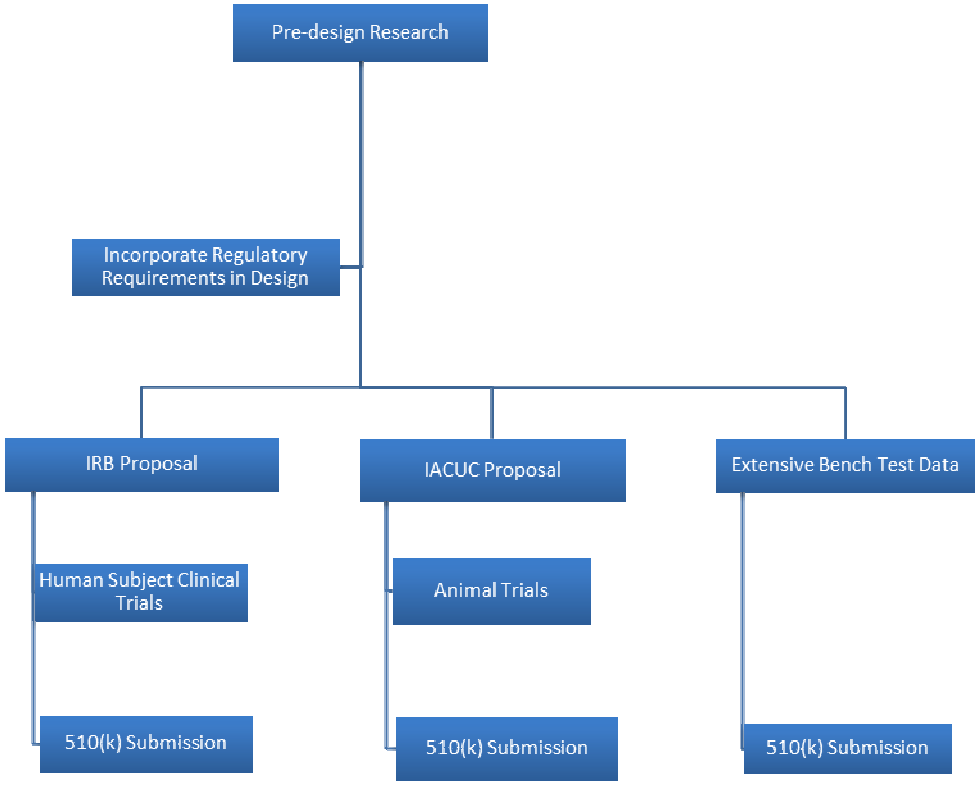


Figure 15: Flowchart illustrating possible routes to 510(k) premarket submission.

The special control document for apnea monitors identifies the following risks to health associated with apnea monitors: Inadequate alarms, electrical shock, electromagnetic interference, inaccurate detection, and tissue reactivity. These risks can be managed with the integration of necessary electrical components, proper software validation through scenario based bench testing, and the design of an electrode system using biocompatible materials where patient contact occurs over long durations of time. In reference to figure 15, the pre-design research includes risk assessment included in *FDA's* control document.

As the semester progresses, the team will continue to break down the risks highlighted by the *FDA*, and minimize them through testing of leakage currents, proper electrode selection, and scenario based bench testing to validate the software algorithms. When sufficient proof of concept data has been collected, it will be decided whether clinical trials, animal trials, or thorough bench testing will be required for submission of a 510(k) premarket notification.

Future Work

The ultimate purpose of this device is to be implemented in developing countries. In order to reach this point there is still work to be done. Throughout the semester, the team will maintain communication with contacts in the industry to ensure that the finished product may be implemented quickly when the time comes. The team will also need to complete rigorous bench testing on the final product to be eligible for a 510(k) premarket notification. The major development work to be accomplished for the product consists of two categories: software and hardware.

Software

Preliminary code will be written to determine the necessary memory requirements for our microcontroller, so that a specific model can be chosen. The specific transfer functions for the filters to be implemented will be determined. New software must be written that can analyze the cardiac and respiratory information in parallel. In an effort to begin telemedicine implementation, preliminary code that can recognize markers associated with anomalous data and can compress data into an image will be constructed separately from the prototype in development.

Hardware

Rubber electrodes will be obtained so testing can begin on their associated impedance and noise levels. The testing will allow appropriate analog components to be added to the circuit to attenuate undesirable signals and noise, and apply gain to the desirable components of the signal.

The implementation of telemedicine capabilities will begin in early stages this semester, but the bulk of the work on this is planned to be accomplished in the following semester. This process includes determining how much memory will be required, and choosing the appropriate parts; the team has decided to use EEPROM for storage of data. In the next semester, once the circuit is finalized, an EAGLE schematic needs to be developed so that several printed circuit boards can be produced. The board size will be taken into account so that a professional housing can be dimensioned appropriately.

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Appendix A: Product Design Specifications

Engineering World Health: Infant Respiratory Monitor
Preliminary Product Design Specifications
Caleb Durante, Drew Birrenkott, Don Weier, Michael Nonte, Bradley Wendorff

Function:
The monitor shall function as an early warning and detection system of infant central apnea in developing countries by providing a reliable detection mechanism that alerts nearby caretakers of an adverse event. Using captured respiratory and ECG data, the monitor will trigger its alarm after breathing ceases for more than 20 seconds, or if the average heart rate falls below 60 beats per minute. This will allow the caretaker a greater amount of time to determine the proper course of action to resuscitate the infant.

Client Requirements:
1) The monitor must cost under $30.
2) The monitor must be reliable and consistently alert caretakers when breathing has stopped for more than 20 seconds or if the average heart rate ever falls below 60 beats per minute.
3) The monitor must be easy to operate with minimal training.
4) The monitor must be tamper-proof with no user serviceable parts (excluding battery)
5) The monitor should be suitable for use in newly industrialized and developing nations.

Physical and Operational Characteristics:

a. *Performance Requirements:*

- The monitor must be capable of monitoring an infant's breathing pattern and alerting nearby caretakers if there is a 20 second or more cessation in breathing.
- The monitor must be capable of monitoring an infant’s heart rate and alert nearby caretakers if there is a drop in heart rate below 60 beats per minute.

b. *Safety:*

- The monitor cannot interfere with healthy bioelectrical electrical signals in the infant or present a shock risk to an operator.
- Any external wiring must not present a strangulation risk.
- There should be no small, easily breakable parts that can present a choking hazard.
- The alarm shall not be above levels which damage the infant’s hearing ability
- The monitor must meet all regulatory demands outlined by government or other agencies.

c. *Accuracy and Reliability:*

- The monitor must have reliable accuracy, and cannot allow for a false negative in the monitor.
- The design must minimize the occurrence of false positives to maintain user confidence in the monitor

d. *Life in Service:*

- Excluding the monitor's battery and lead system, the monitor shall function for at least 5-10 years.
- The monitor must be able to withstand reasonable wear due to use.
- The monitor must be designed to minimize the risk of broken parts.

e. *Shelf Life:*

- Excluding the monitor's battery and lead system, the monitor shall function for at least 5-10 years regardless of usage frequency.
- The monitor will require batteries that should be easily replaced.

f. *Operating Environment:*

- The monitor should be designed to function in a mobile hospital setting
- The monitor shall be able to tolerate temperature ranges of 0-41 degrees C
- The monitor enclosure shall prevent the buildup of ambient particulate on the inner electronic components
- The monitor enclosure shall prevent the encroachment of moisture within its housing

g. *Ergonomics:*

- The monitor should not interfere with comfortable sleep.
- The monitor electrode system shall be designed to ensure consistent placement location on the infant's body

h. *Size:*

- The monitor should have a maximum size of 10x10x5 cm.
- The monitor's electrode band shall be designed according to anthropometric data from infants under 1 year of age

i. *Power Source:*

- The monitor will be battery-powered and should maximize power efficiency
- The monitor shall operate continuously for 24 hours on a single fully-charged battery
- The batteries shall be rechargeable, allowing for pairs of batteries to be cycled for use in the same monitor without disruption of daily monitor usage

j. *Weight:*

- The monitor must be lightweight, not exceeding 1.0 kg but weigh more than 200g

k. *Materials:*

- The monitor shall consist of a printed-circuit board including both passive elements and active integrated circuits, as well as a microprocessor.
- The electronic components will reside within a plastic enclosure with holes machined for external connections to electrodes
- The monitor housing will contain one buzzer/speaker
- The housing must be sterilizable

l. *Aesthetics, Appearance, and Finish:*

- The monitor appearance should align with other devices found in a hospital setting
- The monitor's controls shall be easily understood and operated by individuals from all cultures, races, and dialects

m. *Product Characteristics:*

- Quantity: Two
- Target Product Cost: $10 - $30

n. Miscellaneous:

Standard and Specification:

- The monitor must comply with HIPPA, AAMI , and patient disclosure standards

Patient-Related Concerns:

- Device components in contact with the infant must receive sterilization between uses.
- Must not pose risk of shock or infant entanglement.

Competition:

- Devices on the market include the products made by Babysense, Respisense, CloudMonitor, AngleCare, and Snuza

Customer: **Engineering World Health or Similar NGO**

Appendix B: C Code for PIC18

```
/* EWH Respiratory Monitor Operating Code
 Ben Smith, Don Weier, Matthew Bollom
 3/24/12
 BME 301 Design class*/
#include <p18f14k22.h>
#include <usart.h>

#define TRISA_MASK 0x09
#define TRISB_MASK 0xA0
#define TRISC_MASK 0x00

#define ALARM LATCbits.LATC0
#define LED LATCbits.LATC1
#define LED2 LATCbits.LATC2

 /*set timer start value*/
#define timer0_highbyte 0x3C
#define timer0_lowbyte 0xB0
#define timer0_overflow INTCONbits.TMR0IF

void transmitASCII(int result);
int hanning (int result1, int result2, int result3);
int initialize(void);
void alarm(void);
void high_isr(void);
void boss(void);

int wait = 0;
int result3; //these integers will store raw data to be filtered
int result2;
int result1;
int filtered;

int lightwait = 0;
int lighton = 1;

int max; //these will store the current min and max values
int min;

int delta; //these will store the current delta

int deltaave; //this will store the initialized average gathered from 5 waves

int count = 0; //this will keep track of the time to determine if breathing has ceased for to long

int first = 1;



#pragma code high_vector = 0x08
void high_ISR(void) {
   _asm
   goto high_isr
```

```
    _endasm
}
#pragma code
#pragma interrupt high_isr
void high_isr(void) {
    if(timer0_overflow) { /* check to make sure it was the timer that interrupted */
        TMR0H = timer0_highbyte; /* reset timer */
        TMR0L = timer0_lowbyte;
        timer0_overflow = 0; /* clear the overflow flag */
        boss();
    }
}

void main() {
    OSCCON = 0x76;
    OSCCON2 = 0x00;
    OSCTUNE = 0x00;

    INTCON = 0x20;
    INTCON2 = 0x84;
    INTCON3 = 0x00;

    PIR1 = 0x00;
    PIR2 = 0x00;

    PIE1 = 0x00;
    PIE2 = 0x00;

    IPR1 = 0x00;
    IPR2 = 0x00;

    RCONbits.IPEN = 1;

    TRISA = TRISA_MASK;
    TRISB = TRISB_MASK;
    TRISC = TRISC_MASK;

    ADCON0 = 0x00;
    ADCON1 = 0x00;
    ADCON2 = 0xA5;
    ADCON0bits.ADON = 1;

    OpenUSART( USART_TX_INT_OFF &
            USART_RX_INT_OFF &
            USART_ASYNCH_MODE &
            USART_EIGHT_BIT &
            USART_CONT_RX &
            USART_BRGH_HIGH,
            34
            );
       baudUSART(BAUD_IDLE_CLK_LOW &
            BAUD_16_BIT_RATE &
            BAUD_WAKEUP_OFF &
            BAUD_AUTO_OFF       );
/* Timer code*/
```

```
      T0CON = 0x02;
      timer0_overflow = 0;
      TMR0H = timer0_highbyte;
      TMR0L = timer0_lowbyte;
      T0CONbits.TMR0ON = 1;     /* turns timer on*/

      ALARM = 0;
      LED = 0;
      LED2 = 0;

  deltaave = initialize();

INTCON = 0xA0;
   while(1){
      OSCCONbits.IDLEN = 1;
      OSCCONbits.SCS1 = 0b1;
      OSCCONbits.SCS0 = 0b0;
      Sleep();
   }
}

void boss(){
      /*start conversion*/
      ADCON0bits.GO = 1;
      while(ADCON0bits.GO == 1){/*wait for conversion to complete*/}

    ADCON0bits.GO = 0;

      result3 = result2;
      result2 = result1;
      result1 = (((unsigned int)ADRESH) << 8|ADRESL);

      //filtered = hanning(result1, result2, result3);
      filtered = result1;

    if(first){
      max = filtered;
      min = filtered;
      first = 0;
   }
   if(filtered > max){      //these will store the min and maxes
      max = filtered;
      }
   if(filtered < min){
      min = filtered;
   }
   delta = max - min; //recalculate delta

   if(delta >= (deltaave * .3)){
      max = filtered;
      min = filtered;
      count = 0;
   }
   else{
      count++;
   }
```

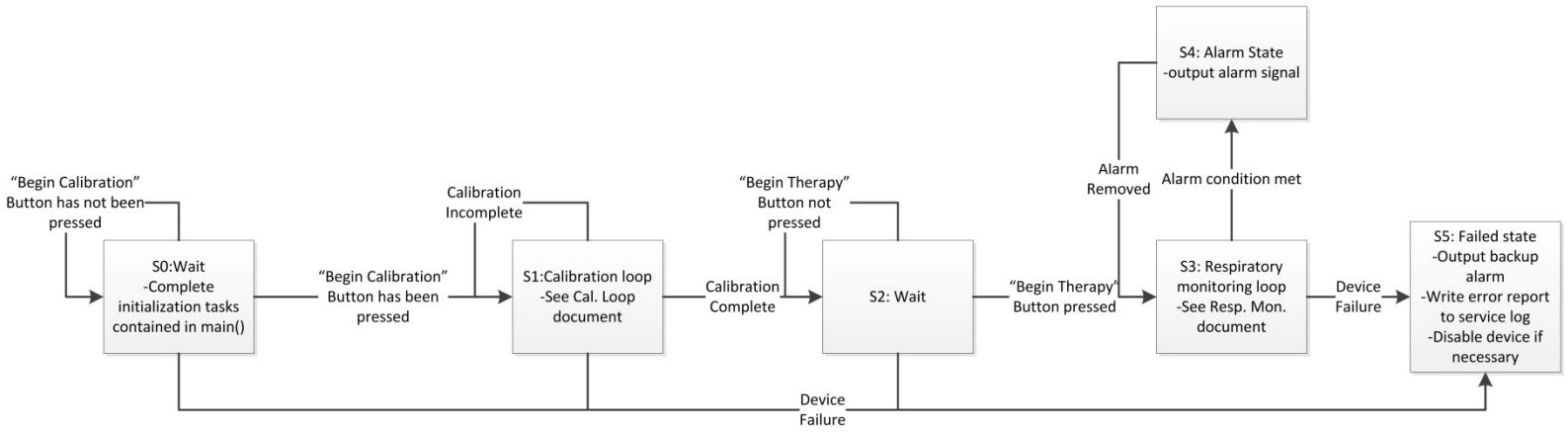
```
            transmitASCII(count);

    if(count >= 150){ //at count = 150, there has not been an acceptable delta in 15 seconds
        INTCONbits.GIE = 0;
        alarm();
        INTCONbits.GIE = 1;
    }
}



int hanning(int result1, int result2, int result3){
    int filtered;

    filtered = (result1 + 2*result2 + result3)/4;

    return filtered;
}

int initialize(void){
    int first = 1;
    int stored = 0; //this will tell the program if the value is already stored
    int max1; // these will store our max and min values over the fifteen second period
    int max2;
    int max3;
    int max4;
    int max5;
    int min1;
    int min2;
    int min3;
    int min4;
    int min5;

    int avedelta; //this is the value the function should return

    int time = 0; //this will count to 15 seconds

    LED = 1;

    while(1){
        while(!timer0_overflow) {/*wait for timer overflow*/}

        TMR0H = timer0_highbyte;
        TMR0L = timer0_lowbyte;
        timer0_overflow = 0;
        time++;

        ADCON0bits.GO = 1;
        while(ADCON0bits.GO == 1){/*wait for conversion to complete*/}
        /*store result*/

        while(wait <= 3){

        /*start conversion*/
        ADCON0bits.GO = 1;
```

```
    while(ADCON0bits.GO == 1){/*wait for conversion to complete*/}
    ADCON0bits.GO = 0;
    /*store result*/

    result3 = result2;
    result2 = result1;
    result1 = (((unsigned int)ADRESH) << 8|ADRESL);

    filtered = hanning(result1, result2, result3);

    wait++;
}
    result3 = result2;
    result2 = result1;
    result1 = (((unsigned int)ADRESH) << 8|ADRESL);

    //filtered = hanning(result1, result2, result3);
    filtered = result1;

    if(first){
       first = 0;
       max1 = filtered;
       max2 = filtered;
       max3 = filtered;
       max4 = filtered;
       max5 = filtered;
       min1 = filtered;
       min2 = filtered;
       min3 = filtered;
       min4 = filtered;
       min5 = filtered;
    }
    if(filtered >= max1 && !stored){
       max1 = filtered;
       stored = 1;
    }
    else if( filtered >= max2 && !stored){
       max2 = filtered;
       stored = 1;
    }
    else if(filtered >= max3 && !stored){
       max3 = filtered;
       stored = 1;
    }
    else if( filtered >= max4 && !stored){
       max4 = filtered;
       stored = 1;
    }
    else if( filtered >= max5 && !stored){
       max5 = filtered;
       stored = 1;
    }
    else if( filtered <= min1 && !stored){
       min1 = filtered;
       stored = 1;
    }
```

```
        else if(filtered <= min2 && !stored){
            min2 = filtered;
            stored = 1;
        }
        else if(filtered <= min3 && !stored){
            min3 = filtered;
            stored = 1;
        }
        else if(filtered <= min4 && !stored){
            min4 = filtered;
            stored = 1;
        }
        else if(filtered <= min5 && !stored){
            min5 = filtered;
            stored = 1;
        }
        stored = 0;

        if(time >= 297){
            avedelta = (max1+max2+max3+max4+max5-min1-min2-min3-min4-min5)/5;
            LED = 0;

            return avedelta;
        }
    }
}
void alarm(){
    int time = 0;

    int odd = 0;

    while(1){
    while(!timer0_overflow) {/*wait for timer overflow*/}

        TMR0H = timer0_highbyte;
        TMR0L = timer0_lowbyte;
        timer0_overflow = 0;
        time++;
        ALARM = 1;
        if(time == 10){ // this will pulse the alarm in one second intervals
            time = 0;
            if(odd){
                LED = 1;
                odd = 0;
            }
            else{
                time = 0;
                LED = 0;
                odd = 1;
            }
        }
    }
}
```

Appendix C: State Transition Diagrams

Condensed Full State Transition Diagram



Vdif Detection Method/Resp. Monitor Loop