

Project Proposal and Feasibility Study

Team 6: [Rhythm Reloaded]

ENGR 339

Team Members:

Nathan Brinks

Andy Gabler

Ben Moes

David van Geest

Team Advisor:

Dr. Steven H. VanderLeest

December 10, 2007

Revision 3.1

Revision History:

Date	Comment	Author	Revision
10-04-2007	Outline	Ben Moes, David van Geest	Rev 1.0
10-14-2007	Revised as per VL's comments	Ben Moes	Rev 1.1
11-14-2007	First addition of content / format	Ben Moes	Rev 1.2
11-20-2007	Addition of Sections 7.1.2 and 7.2.1	David van Geest	Rev 1.3
11-21-2007	Format revised, added Section 2	Nathan Brinks	Rev 1.4
11-24-2007	Addition of Sections 4 and 7.2.2	David van Geest	Rev 1.5
11-26-2007	Added list of references, revision for Draft 1	Andy Gabler	Rev 1.6
12-01-2007	Revised content from comments, revised section orders	Ben Moes	Rev 2.0
12-05-2007	Revised OS and microprocessor sections, added missing headings, fixed pagination and headings in Appendices, moved Abstract	David van Geest	Rev 2.1
12-07-2007	Added content to various sections, revised revision history format, added Appendix D	Nathan Brinks	Rev 2.2
12-06-2007	Added 5.2.1, glossary, acknowledgements	David van Geest	Rev 2.3
12-09-2007	Added remaining sections, revised as needed	Team	Rev 3.0
12-10-2007	Final grammar and style revision	David van Geest	Rev 3.1

Abstract

[Rhythm Reloaded] is a team of electrical and computer engineering students at Calvin College participating in a year-long senior design project. The team aims to design an electronic stethoscope that records, filters, stores, and transmits to a computer audio data from a medical patient. Some electronic stethoscopes currently on the market have a few of these features, but none of them combine all of the features into one coherent package. A survey of the medical community has indicated that medical personnel would respond favorably to the proposed device. The team has decided to design a microprocessor-controlled prototype that runs μ Clinux as its operating system. The device shall make use of a an LCD module, button interfaces, hardware CODEC, electret microphone, flash storage, and USB interface. A budget has been created that the team will meet. The many project tasks have been assigned to different team members and scheduled throughout the year. Based on the planning and design work completed in the first semester, the team concludes that this project is feasible.

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Glossary of Terms and Abbreviations

Term or Abbreviation	Definition
ADC	Analog to Digital Converter
ASIC	Application Specific Integrated Circuit
Auscultation	The technique of listening to specific characteristics of body sounds
BDM	Background Debug Module
BGA	Ball Grid Array
BOM	Bill of Materials
Chest Piece	The part of the stethoscope placed on the patient during auscultation
CODEC	Encoder/Decoder
COTS	Commercial Off the Shelf
DAC	Digital to Analog Converter
DDR	Double Data Rate
DMA	Direct Memory Access
DSP	Digital Signal Processor / Digital Signal Processing
DSPI	Master/Slave Serial Peripheral Interface
DW	DornerWorks
eMAC	Enhanced Multiply and Accumulate
EMC	Electromagnetic Compliance
EMI	Electromagnetic Interference
FDA	Food and Drug Administration
FET	Field Effect Transistor
FIR	Finite Impulse Response
FPGA	Field Programmable Gate Array
GNU	GNU's Not Unix
GPIO	General Purpose Input Output
GPL	GNU General Public License
HIPAA	Health Insurance Portability and Accountability Act
HMI	Human Machine Interface
IDE	Integrated Development Environment
IIR	Infinite Impulse Response
JTAG	Joint Test Action Group
LCD	Liquid Crystal Display
LED	Light Emitting Diode
Li-Ion	Lithium Ion
NiCD	Nickel Cadmium
NiMH	Nickel Metal Hydride
OEM	Original Equipment Manufacturer
OS	Operating System
PBGA	Plastic Ball-Grid-Array
PCB	Printed Circuit Board
QSPI	Queued Serial Peripheral Interface
RAM	Random Access Memory
RFID	Radio Frequency Identification
RoHS	Reduction of Hazardous Substances
RTOS	Real Time Operating System

SDRAM	Synchronous Dynamic Random Access Memory
SNR	Signal to Noise Ratio
Spectrogram	A visual display of frequency versus time with the intensity of the sound indicated by a color gradient
SPI	Serial Peripheral Interface
SREC	Motorola S-Record
Tap	Coefficient and delay pair used to implement digital filters
TFTP	Trivial File Transfer Protocol
UART	Universal Asynchronous Receiver-Transmitter
USB	Universal Serial Bus

1 Introduction

1.1 Engineering Senior Design

The engineering program at Calvin College culminates in a senior design project sequence. A series of courses, Engineering 339 and 340, serves as a transition from the academic to the professional world. In Engineering 339, students form teams of three to five students and select a project within their field of study to complete over the duration of their senior year. The first semester focuses on defining the scope of the students' project and its feasibility. The class lectures focus on the design process, teamwork, design norms, communication, management, conflict resolution, research, and ethics, and the integration of these themes with the Christian worldview. Engineering 340 focuses primarily on the design and prototyping of the team's chosen project. The lectures continue to teach the integration of faith and design. The course culminates with a final public presentation of the project on senior design night at the end of the spring semester.

1.2 Team [Rhythm Reloaded]

[Rhythm Reloaded] is an engineering senior design team consisting of four electrical and computer engineering seniors: Nathan Brinks, Andy Gabler, Ben Moes, and David van Geest. Nathan grew up in Grand Rapids, Michigan and is interested in audio power amplifiers, automotive electronics, and robotics. He also enjoys working on automobiles and flying radio controlled aircraft. Andy is a son of missionaries and has lived in Bolivia, Colombia, the Philippines, and the US. He is intrigued by electromagnetic propagation and audio signal processing. His hobbies include running live sound, fixing things, and working with kids at his church. Ben is a native of Sioux Center, Iowa and enjoys studying embedded systems, medical devices, and renewable energy. Aside from his academic work, Ben spends his time playing lacrosse, snowboarding, ministering with his Church, and being a wonderful husband. David hails from London, Ontario, Canada. He is passionate about digital hardware and software design as well as the French language. In his spare time, David enjoys playing guitar, travelling, and downhill skiing. The team is pictured in Figure 1.1.

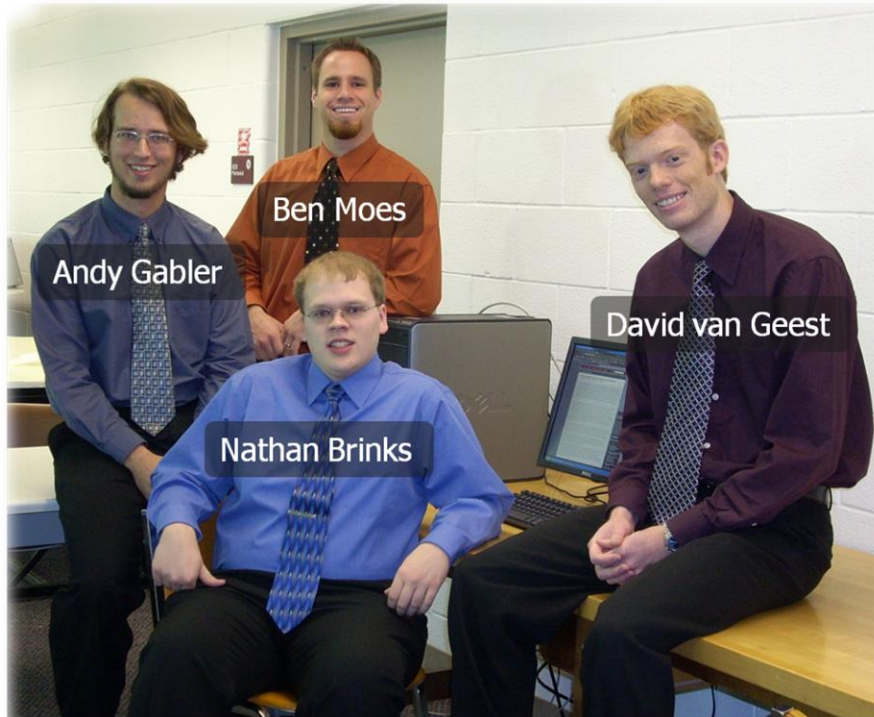


Figure 1.1: Team [Rhythm Reloaded]

1.3 Introduction to the Problem

Nearly all medical personnel actively involved in the treatment and diagnosis of patients use stethoscopes on a daily basis. Stethoscopes are used for pulse measuring, blood pressure monitoring, and diagnosis of cardiovascular, respiratory, and digestive diseases.

The majority of stethoscopes currently on the market are acoustic devices that use purely passive mechanical parts to isolate and focus sound generated by the body. Though these methods have been used for years, the simplicity of such devices is overshadowed by poor sound quality, discomfort, and high cost. These devices are also difficult to interface with modern technologies such as computers to record and analyze body sounds.

The goal of this project is to design and prototype an electronic stethoscope that is comparable in cost, has better acoustic response, and can interface with modern technologies better than the current acoustic stethoscope.

2 Objectives

A detailed requirement outline can be seen in Appendix A. This section contains a breakdown and explanation of the various objectives associated with the team's electronic stethoscope project.

2.1 Definition of Project Success

The team defines success as completing a project that meets the requirements outlined in Section 2.2, 2.3, and 2.4. The project shall produce a prototype that demonstrates these requirements. The prototype shall be, at minimum, implemented on a development board; however, the team shall strive to implement the design on a custom PCB.

2.2 Main Requirements

The project consists of three main objectives. All successive requirements and design decisions must take into account the following core requirements.

1. The team must present the client with a demonstrable electronics stethoscope that meets or exceeds the succeeding requirements.
2. The team must assemble a project which includes the stethoscope design, prototyping, and business aspect of a full scale production.
3. The device must conform to the following three design norms: **Transparency, Integrity, and Stewardship.**

Although other design norms such as Cultural Appropriateness, Justice, Mercy, Caring, and Trust will play important roles in the overall design of the device, the team has decided that the three selected design norms will govern the majority of the work performed by the team.

The device must be transparent for it to be accepted by the market. A device that is used on a daily basis must be intuitive for even a non-technical user. A doctor or nurse must be able to pick up the device and use it, without instruction, within a few minutes. Without this characteristic, the device will not be accepted in a market dominated by an acoustic solution recognized for its simplicity.

The device must have integrity to comply with health regulations, electronics regulations, and to accurately reproduce body sounds. A poor representation of the sounds produced by the body will make the device an unviable option for those working in the medical field, and may cause a medical professional to misdiagnose a disease.

The device must also use resources in a stewardly manner. If the device costs more than an acoustic stethoscope without providing improved features, it is a poor use of financial resources. The device must also minimize environmental impact. If the device is not energy efficient, it will use up too much energy to be useful for long shifts and high-stress environments.

2.3 Course Requirements

Several course requirements must be met by the team. The team shall strive to cooperate in a civil and professional manner. The team members are required to give a weekly status report of their progress and present any issues they have discovered for the team to discuss. All members must seek the approval of the team before making any final design choices. As well, the team as a whole must meet all course deadlines and submit all course required documents.

2.4 Product Requirements

2.4.1 Functional

The device must provide the user with a way to listen to the internal body sounds of a patient and should operate in a similar fashion to a traditional acoustic stethoscope. The device will require an instrument to hear the body sounds, the ability to electronically process these sounds, and the capability to output these sounds to the user. Furthermore, the device must provide a way to emphasize and separate the sounds of the heart, lung, and bowels. Also, it must allow the user to record these sounds and play them back at a later time.

2.4.2 Power

The device must be provided with its own portable power source. The power source must enable the device to function continuously for a minimum of 8 hours. The power source and circuitry must provide adequate voltage for the electronic components to function properly. The selected power source must be simple to recharge and replace.

2.4.3 Interface

2.4.3.1 *Human-Machine Interface*

The human interface shall be intuitive and simple to use. It provides the user with a first impression of the device and often is a deciding factor in its acceptance by the market. The essential HMI that the device must provide are visual and tactile.

2.4.3.1.1 Visual

The visual interface must provide the user with information about operating modes, recording information, and audio file names. The interface must give timely feedback to the user when the user provides tactile input.

2.4.3.1.2 Tactile

The tactile interface must be able to pass user commands to the device to control its operation. This interface must be intuitive and simple, but with enough functionality to fulfill the device operating requirements.

2.4.3.2 *Data*

The data interface must provide the user with a method of transferring audio files from the device to a computer. This interface must be readily available, easy to understand, and have a high data transfer rate.

2.4.3.3 *Audio*

The audio interface must provide the user with an accurate representation of body sounds. This means that there must be no noticeable time delay or distortion between analog audio input and output.

2.4.4 Audio Storage

The device shall be able to store audio recordings in non-volatile memory.

2.4.5 File Protection

The stored audio files must be protected to abide by HIPAA regulations. A third party must not be able to access the stored data without authorization.

2.4.6 Environmental

The materials and components selected for the device, as well as any proposed manufacturing processes, must have minimal impact on the environment relative to alternative solutions.

2.4.7 Economic

The final market device must be constructed so that the price falls within or below the price of similar electronic stethoscope products. The prototype must be constructed within the team's budget.

2.4.8 Safety

The device must not harm the patient or the user. The component and materials selection should not cause discomfort or pain.

3 Market Research

3.1 Medical Community Surveys

To determine whether the medical market would respond favorably to the team's proposed product, surveys were distributed to any accessible member of the medical community. Receivers of the survey included hospice nurses at Hospice of Michigan, nurses and doctors at Hospice of Union County, students in Calvin's nursing program, and various other contacts. Thirty respondents participated in the survey, including 21 nurses (70%), 2 doctors (7%), 6 students (20%), and 1 nurse practitioner (3%). A compilation of the survey questions and results can be seen in Appendix E. Overall, the response to the product was favorable. Seventy-eight percent of respondents indicated that they would use the stethoscope if it was provided by their employer. This is a relevant statistic because in some hospitals and clinics, stethoscopes are purchased by the organization for use by their employees, especially when these stethoscopes are specialty diagnostic devices. Twenty-five percent of survey respondents indicated that they had not purchased their stethoscope with their own funds.

When asked whether they would purchase the stethoscope if they had to use their own funds, 18 percent indicated that they would, 46 percent indicated that they would not, and 36 percent indicated that they were unsure. While the team would have liked more people to be favorable towards purchasing the device with their own funds, there were a number of factors that influenced the responses. Firstly, the question did not actually have an 'Unsure' response, so respondents were forced either to choose between 'Yes' and 'No', or had to write in their own answer. In retrospect, the survey should have used a scale from 1 to 10 to indicate willingness to purchase the device. Furthermore, most of the survey respondents (89 %) were in the nursing field. While the stethoscope would also be used by nurses, the team had envisioned doctors being the primary market because of their larger disposable income and their need for more specialized tools.

Other valuable information was also obtained from the survey. Respondents indicated that they would prefer to put the stethoscope casing in their pocket, they would like a rechargeable battery, and that they would pay, on average, \$150 for the device. Many respondents also indicated that they were unsatisfied with their current stethoscope, citing problems such as uncomfortable earpieces, skin irritation caused by rubber, difficulty in blocking out exterior noise, and lack of amplification ability. All of these problems are addressed by the team's proposed device.

In addition to distributing surveys, the team met with Dr. Srinivas Janardan of Grand River Gastroenterology to discuss the proposed product. Dr. Janardan responded favorably to the idea, although he was not sure of the product's usefulness in his particular area of specialization (gastroenterology – the study of the digestive system). However, he did think that the product would be helpful to cardiologists, and he was able to put the team in contact with two of these specialists. The team is currently attempting to setup meeting times with these doctors.

3.2 Existing Products

3.2.1 Acoustic Solutions

Acoustic stethoscopes are comprised of a chest piece connected by hollow tubing to two earpieces, as shown in Figure 3.1. The chest piece typically has two different sides, a bell and a diaphragm. The bell side is in the shape of a hollow cup. When placed on the patient, the vibration of the skin is transmitted as sound waves through the tubing to the earpieces. The bell is used to listen to low-frequency sounds such as those produced by the heart. The diaphragm side of the chest piece is usually a plastic disc stretched over a hollow cup. Sound waves from the body vibrate the diaphragm, sending acoustic pressure waves through the tubing to the earpieces. The diaphragm is used to listen to high-frequency sounds, such as those produced by the lungs.

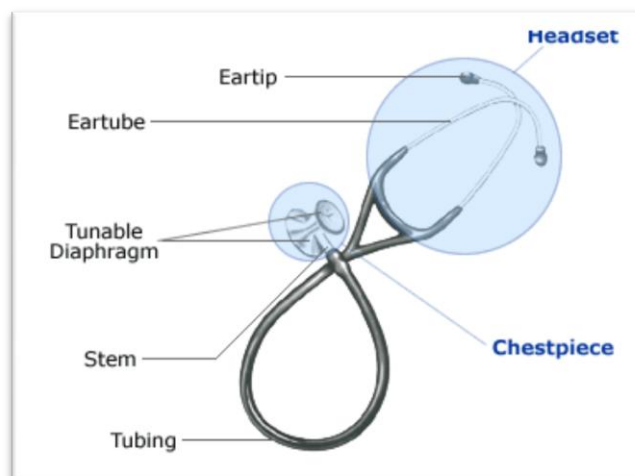


Figure 3.1: 3M® acoustic stethoscope

The biggest problem with existing acoustic stethoscopes is that they lack any kind of amplification, sometimes making body sounds difficult to hear. In the survey conducted by the team, 14 of 30 respondents, all of whom use acoustic stethoscopes, cited difficulty in hearing body sounds in answering the question “What do you dislike about your current stethoscope?” Seven of these 14 respondents specifically cited ambient noise as a cause of this difficulty. Other difficulties given by survey respondents included uncomfortable earpieces (6 of 30), and a dislike for having to carry it around the neck (3 of 30). However, the acoustic solution does have some advantages. Acoustic stethoscopes are typically less expensive than electronic stethoscopes, although some high-end models, such as the 3M Littman Master Cardiology, can cost as much as \$250. When asked what they liked about their current stethoscope, survey respondents primarily listed simplicity, durability, convenience, and clarity.

3.2.2 Historical Electronic Solutions

Electronic stethoscopes have been used for the last couple decades, although it is only recently that they have gained any acceptance in everyday medical practice. This is because historical electronic stethoscopes were typically bulky and non-portable, requiring large separate cases to house the electronics. Because of this, electronic stethoscopes were only used in research and advanced diagnostic settings. Recent advances in microelectronics have led to smaller, more portable devices, and a subsequent rise in electronic stethoscope usage in everyday medicine.

3.2.3 Existing Electronic Solutions

The existing electronic solutions to this problem are summarized in Table 3.1.

Table 3.1: Existing Market Electronic Stethoscopes

Company	Product	List Price	Features (As Given By Product Documentation)
3M	Littmann® Model 4100WS	\$510.88	75% ambient noise reduction
			Includes PC or Pocket PC software to see heartbeat
			Infrared transmission to other stethoscope or PC (115 Kbps data rate)
			3 frequency modes: bell (20 - 200 Hz), diaphragm (100 - 500 Hz), extended (20 - 1000 Hz)
			Recording/playback of 6 tracks of 8 seconds in uncompressed WAV format
			Heart rate display on LCD
			20 hour use from 2 AAA batteries
			7.2 ounces, 27 inch length, normal form factor
3M	Littmann® Model 3000	\$375.00	75% ambient noise reduction
			Single AAA battery gives 200 hours use
			Auto shut-off after 3 minutes
			Available in 5 colours
			5.6 ounce, 29 inch length, traditional form factor
			Low friction chest piece
			Different frequency modes
Thinklabs	ds32a	\$279.00	Acoustic/electronic mode, tunable diaphragm
			2 AAA batteries, 6.4 ounces
			Ambient noise reduction
			Power, bell-diaphragm, amplify buttons, volume control
			Auto shut-off (customizable)
			Analog audio input/output
			15 Hz - 20000 Hz frequency response
Cardionics	E-Scope II	\$335.00	Optional PDA interface, PDA display software
			Frequency switch: heart (20 - 1000 Hz), lungs (70 - 2000 Hz)
			2 minute auto-off
			AAA battery with 6 month life
		Volume control, frequency switch	
		\$430.00	Headphone model

		\$575.00	EMS model (high-quality studio-style headphones)
Welch Allyn	Master Elite	\$281.38	Rotating earpieces
			Bell/diaphragm modes, 20 - 20000 Hz
			1 year battery life
			170 grams
			PC software
ADSCOPE	657	\$249.98	Bell (15-200 Hz), Diaphragm (100 - 500 Hz), Extended (15 - 4000 Hz)
			16 level volume control
			3 V lithium battery (150 hours)
			3 minute auto shut-off

While some of these existing electronic stethoscopes have some features in common with the team’s proposed device, only one, the 3M Littman 4100, has recording capability. However, this recording ability is limited to six tracks of eight seconds each. The team recognizes that storage capacity is typically easy to increase, but because the 4100 maintains the form factor of a traditional acoustic stethoscope, adding enough flash memory to this device to compete with the memory offered by the team’s device may be a more difficult operation than usual. In a busy hospital environment where numerous recordings may be taken during a shift, the data on the 4100 stethoscope would need to be downloaded to a PC at regular intervals, a task that busy medical personnel do not have time for. Furthermore, the audio data must be transferred by infrared; downloading all six tracks of uncompressed wave audio at the data rate provided by the 4100 (115 kbps) takes 9.5 minutes. Further exacerbating the problem is the fact that each track must be downloaded individually, meaning that user input is required at least every 1.6 minutes. The 4100 also keeps the same form factor as existing acoustic stethoscopes. The team feels that although it may require some adjustment, medical personnel will be open to the form factor proposed by our device, and will actually like it better because they will no longer have to deal with uncomfortable ear pieces and having to carry it around their neck. Lastly, this stethoscope has a list price of \$511, although it may be bought online for approximately \$420. Even the lower online price is twice the projected cost of the team’s device. In light of these disadvantages, the team feels that it can present a product that is superior to the 4100.

4 Intellectual Property Concerns

4.1 Previous work

An electronic stethoscope is not a new idea. The German patent website www.depatistnet.de, an excellent international patent website, finds 179 different patents when “electronic stethoscope” is entered as the search term. The team briefly reviewed several of the international patents and did not find any that its product would be violating. The team did a more in depth review of all the US patents listed newer than 1974, and the results of this review can be seen in Appendix C. Again, the team’s idea seems to be fairly unique. However it does use ideas found in some of the patents, for example, the use of different listening modes, placement of the microphone within the chest piece, recording, transfer to computer, and LCD display. One or more of these are parts of different patents; however, the team’s

design combines them in a new way. A few of the patents summarized in Appendix C that were fairly close to one aspect of the team’s design were marked accordingly and are summarized in Table 4.1. The team, acknowledging its lack of experience in this area, does not feel that Table 4.1 is an exhaustive list of the different patents that its design may build on. Therefore, it is suggested that before the team’s final electronic stethoscope design goes to market, or before any patent application is made, a patent lawyer or someone more skilled in understanding patents be engaged to help in the patent reviews.

Table 4.1: Intellectual Property Concerns

Publication number	Title	Comments/Description	Year
US020030002685A1	[] Electronic stethoscope	An auscultation aid that couples with an acoustic stethoscope, but also could transmit wirelessly to a base station which transfers real time data to a computer.	2003
US000006396931B1	[] ELECTRONIC STETHOSCOPE WITH DIAGNOSTIC CAPABILITY	Describes a self-contained device with a screen and built-in speaker that stores typical sounds to compare with what is heard. Chest piece is built into device.	2002
US000005825895A	[] Electronic stethoscope	Describes a stethoscope with several "modes" of operation: heart, lungs, abnormal heart and normal heart boost. Same package as a traditional stethoscope. Digital but no recording.	1998
US000005774563A	[] COMBINED ELECTRONIC ACOUSTICAL STETHOSCOPE	Describes a dual electronic/acoustic stethoscope. Rotatable chest piece. Mic placement in the chest piece is the only concern.	1998
US000005932849	Stethoscope having microphone therein	Describes a chest piece with a microphone within the acoustic pathway.	1999

4.2 Current IP issues

On October 23, 2007, the team gave a presentation to DornerWorks, an embedded systems design firm that maintains ties to Calvin. Currently, DornerWorks has offered \$1000 of funding to the team, however, due to questions regarding ownership of intellectual property, the team has not yet agreed to terms of the relationship with DornerWorks. The situation is further complicated by the fact that Dr. Steven VanderLeest, the team adviser, is the Director of Engineering at DornerWorks. Meeting with the team, Dr. VanderLeest divulged his conflict of interest and recommended that the team speak to Dr. Sykes or Prof. Nielson regarding patent issues. The team will continue to report to Dr. VanderLeest through the year; however, it will meet with either Dr. Sykes or Prof. Nielson on all matters relating to patentable ideas and issues over sponsorship.

5 Alternative Solutions

5.1 Form Factor

There were three main form factors considered for the electronic stethoscope. The traditional form factor, which is based on a standard acoustic stethoscope, was first considered. It follows an in-line approach that is demonstrated by Littman's 4100WS seen in Figure 5.1. This format is very popular with electronic stethoscopes found in market research.



Figure 5.1: Littman 4100WS -Traditional Form Factor

The second form factor considered was a compact design. This form factor removes the cord between the headset and the chest piece by placing everything in a single unit. The user is provided with a headphone jack on the device and a small selection of buttons. This form has the benefit of removing weight from the headset and placing it in the user's hand.

A third option involves a complete departure from the traditional design. A central unit contains the electronics, and a chest piece and headphones are connected to this unit by cables. The Cardionics E-Scope II Headphone Model demonstrates this form factor in Figure 5.2.



Figure 5.2: Cardionics E-Scope II – Non Traditional Form Factor

All of these solutions are viable, as they each have certain advantages and disadvantages. The traditional design is widely accepted with medical personnel and may be considered as a status symbol. However, traditional designs can be bulky and often cause the user discomfort when worn around the neck, as discussed in the survey results.

The compact design is beneficial because it has fewer cords. This would provide greater convenience to the user who does not have to spend time untangling cords. The major disadvantage of the compact design is that it requires a significant amount of mechanical design, which the team is not capable of doing in a limited time frame. It also limits the functionality of the HMI on the device because of its size.

The non-traditional design also has distinct advantages and disadvantages. The device can be conveniently clipped to a belt or waist band, or simply placed in a pocket. Also, since the weight of the electronics are not being supported by the user's ears, the casing can contain features not suitable for a traditional stethoscope, such as an LCD screen, larger battery, and more storage capacity. The non-traditional design may also be favorable to the young user because it is reminiscent of a portable media player. Therefore, the team has chosen the traditional design because it feels that this form factor has the most potential.

5.2 Functional

5.2.1 Controller

5.2.1.1 Criteria

One of the main architectural decisions made by the team was the choice of a controller type. There were a number of different criteria considered during this decision. Ease of design and development time are very important factors because of the limited time available and the inexperience of the team. Power consumption is an important factor because the device must have a long battery life. Versatility, also an important aspect, describes the potential of the architecture to implement different functions, while included functionality describes the functions that are already present without any design work. Because this device shall be low-cost compared to other products, the price of the controller is

important. Size also figures prominently because of the portable nature of the device. Other factors considered included durability, speed, availability, and hardware abstraction.

5.2.1.1.1 Controller Options

5.2.1.1.1.1 FPGA

FPGAs are extremely versatile because they can be used to implement a wide range of functionality. They are priced comparably to microprocessors, and can be designed to process data very quickly. However, FPGAs require long development time and have very weak hardware abstraction. Much of the FPGA design work for this project would be redesigning components that have already been designed and implemented in different forms; therefore the team felt that FPGA design was not a favorable choice.

5.2.1.1.1.2 FPGA with Soft-Core Microprocessor

This option is more attractive than the FPGA option because it combines the versatility of the FPGA with the included functionality and hardware abstraction of the microprocessor. It retains many strengths of the FPGA, such as speed and power consumption. However, the number of available soft-core processors is much smaller than the number of available microprocessors. The team does have extensive experience with one FPGA/Soft-Core Processor system, namely the Altera Nios, but this experience has shown that while trivial designs can be implemented very easily and quickly, more complicated designs frequently require exponentially increasing amounts of time and effort.

5.2.1.1.1.3 Microprocessor

Microprocessors are widely used in similar designs because of their many strengths in comparison to other options. They are inexpensive, low-power, and small sized. The wide range of available parts allows the designer almost the same degree of versatility as an FPGA, but without the added design effort. Hardware abstraction is very strong; the designer can use complex software algorithms instead of relying on hard-wired logical design. While software design can be as complex as hardware design, there are many resources available to the developer, and software is readily available in many different forms. Development time for microprocessor software is slightly better than development time for an FPGA.

5.2.1.1.1.4 ASIC

An ASIC is a similar solution to an FPGA, except that it refines the design process one step further. This refinement results in lower power consumption and faster speeds. The many disadvantages include the fact that the team has never designed an ASIC, the extreme difficulty the team would have in finding a manufacturer willing to produce a custom ASIC, and the additional design elements that must be considered in comparison to an FPGA. The team considered this option to be prohibitively difficult, and thus it was not seriously considered.

5.2.1.1.1.5 Analog Control

Analog control does not present any advantages except for speed. Analog controllers must be assembled from many different parts, causing the cost, size, and power consumption to be very unfavorable. They do not interface easily with other modern components, and the team has no experience in their design. While it is theoretically possible for an analog controller to direct all the

functionality of the proposed device, it is extremely impractical. These disadvantages are evidenced by the lack of any similar modern devices using this control method. Because of these extreme disadvantages, the team did not seriously consider this option.

5.2.1.1.2 Controller Decision

The preceding criteria and how they affected the team’s decision are summarized in the decision matrix shown in Table 5.1. The microprocessor option was clearly the most advantageous, therefore it was chosen.

Table 5.1: Controller Decision Matrix

Criterion	Weight	FPGA	FPGA w/ Soft-Core	Microprocessor	ASIC	Analog Control
Cost	7	7	5	7	1	3
Versatility	8	9	10	8	9	2
Ease of Design	10	4	5	6	0	0
Included Functionality	8	3	9	9	3	3
Durability	5	5	5	6	7	1
Power Consumption	9	5	5	5	8	1
Speed	6	7	7	5	8	10
Availability	2	5	4	9	1	2
Hardware Abstraction	5	3	7	10	0	0
Development Time	10	3	2	5	0	1
Size	7	5	5	8	8	1
	Total:	387	447	524	316	156

5.2.2 Power

There are two options for the portable power source. The first option is to use a standard alkaline battery. This is not a favorable option. It promotes wasted resources because the user is forced to continuously buy and dispose of batteries. Since the device would be used daily, this option is very inappropriate.

The second option, which the team chose, is to use a rechargeable battery pack. Specific rechargeable technologies, such as Li-Ion, are more versatile because they come in a convenient, flat form factor. This option is also favorable because it promotes stewardship by the reuse of a battery pack. The general response from the surveys also gave favor to this option.

5.2.3 Interface

5.2.3.1 Human-Machine Interface

5.2.3.1.1 Visual

The visual interface provides the user with information about the status of the device. The visual interface should assist the user in operating the device. There are two primary options to provide this functionality: LEDs or an LCD module.

LEDs are a popular method of informing a user of the condition of an electronic device. In many electronic devices they are the primary source of visual feedback to the user. The team has decided, however, that in this situation they are not adequate. LEDs would limit the functionality of the device because they cannot practically display enough information.

A LCD module is the team's chosen option to provide visual feedback to the user. An LCD can present a wide variety of information. LCDs, by nature, are very flexible devices. They allow the designer to easily add or remove functionality. They also benefit the user by providing graphical or textual feedback that is easily understandable instead of relying on the simple logical state of an LED being off or on. An added advantage of LCD display is the ability to break the language barrier. The LCD display language can be translated to make the device usable in a variety of demographic settings.

LCD modules come as graphical displays or character displays. While the team feels that a graphical display would be beneficial in the final market product, a character display is suitable for the prototype. This choice was made to minimize the development time for the LCD display. A character display requires minimal design time and generally is less expensive than a graphical alternative. This allows the team to focus its time on other crucial elements of the project while still maintaining a functional visual interface.

5.2.3.1.2 Tactile

The tactile interface is used in conjunction with the visual interface. Based on feedback from the visual interface, the user can decide the appropriate tactile input. Possible solutions for the tactile interface include: scroll wheel, buttons and a joystick.

Scroll wheels are an option suitable for navigating through long menus and large amounts of data. Since the device contains neither of those the team has decided that a scroll wheel would be inappropriate.

A joystick is another option. However, joysticks are obtrusive, and would not add any additional functionality to the device. They are also generally regarded as unprofessional and better suited for devices such as video games requiring motion control and directional input.

The team has decided to use buttons for the tactile interface. Buttons provide a simple way for the user to interact with the device. Since buttons are separate entities, the button layout can be custom-tailored to provide maximum efficiency. Buttons are also very simple and intuitive to implement in an electronic device. This allows the team to better balance the tactile interface development with other elements of the project.

5.2.3.2 Data Interface

The data interface of the device shall provide communication to a computer in order to transfer audio files to or from the device. Several options include USB, RS-232, Infrared, Bluetooth™, Wireless USB™, or an electromagnetic induction loop.

The slow speed of RS-232, electromagnetic induction, and infrared interfaces render these options cumbersome and inconvenient for the user. Lack of these interfaces on most modern PCs also prevents them from being used easily. These interfaces will not be implemented on the device.

Wireless technologies such as Bluetooth™ and Wireless USB™ may be seen as convenient for the consumer; however, these interfaces require additional expense to be added to most COTS PCs, and demand that the user have a certain degree of technical expertise to configure the connection. These interfaces may also have additional hurdles to overcome in a hospital setting given the number of restrictions on wireless devices. Furthermore, wireless transmission of patient data raises serious issues with data privacy, unless the transmission is encrypted. Encryption requires another level of technical expertise and configuration effort. The team has concluded that wireless data transmission makes the device more complicated while not making it any more convenient.

Currently, a USB™ (Version 2.0) interface presents the most advantages to today's consumers. Most modern PCs are equipped with USB ports supporting Version 2.0 and 1.1. The low cost of standard USB™ cables are also ideal. The high speed data transmission rates of USB™ also help make this the best option to be implemented on the device.

5.2.4 Media Storage

5.2.4.1 Media Type

Many options are available for media storage including, flash, removable flash media (SD or thumb drive), mini hard drive, and optical media such as CDs or DVDs.

Size and weight requirements of the device prevent optical media from being used. Optical media, typically 12 cm in diameter, would increase the overall size and weight of the device beyond the constraints envisioned for a final market product.

While removable flash media provide the possibility of expandable memory capabilities (memory cards may be replaced as larger capacity cards becomes less expensive), these devices also pose potential problems for physical size constraints. These media require additional connectors, increasing the overall size of the device. Such devices may also become obsolete as time goes on. Though current removable flash media have large market shares, these may eventually be phased out by another technology. Another disadvantage of using removable flash media is the issue of data security. If patient data is stored on media that is easily stolen or lost, the device will not comply with HIPAA regulations for patient privacy.

On board memory presents the best option given its low cost, small size, and large memory density. Flash memory can be easily incorporated internally to the device. Given its cost, size, and density advantages, the storage media for the device will be internal flash.

5.2.4.2 Audio Recordings

Once an audio file has been recorded, the file must be identified for later playback or transfer. Options for file naming include automated numbering by sequential order, by date, by patient number (assigned by health center), or by prompting the user to specify a file name.

Automated number schemes based on sequential order (file1, file2, etc.) would be the simplest to implement in the device. However, if several recordings are taken in a single shift and accessed at the end of that shift, it may prove difficult for the user to remember which recordings are for which patient.

File names specified by date and time would be more intuitive for the user than sequential numbering, however, identification of these files may also prove difficult during busy shifts if multiple recordings are taken in rapid succession. This method would also require a real-time clock running on the device to keep accurate measure of the date and time. A real-time clock could require extra hardware on the prototype, and would require a continuous power source even while the device was turned off.

File names automatically specified by patient number would allow for a more intuitive and faster naming method for the user. However, in order to automatically upload the patient number, the device would need an interface capable of reading the patient number. A barcode scanner, RFID receiver, or plug-in data reader would need to be added to the device in order to access the patient number. These interfaces would add cost not only to the device but also to the health care center.

Prompting the user for a filename is the most intuitive method for the naming of audio files. The user would be able to specify the necessary file information at the time of recording. A user accessing files several days after recording would find it easier to identify files they had named than if they were accessing files specified by a date and time.

Prompting for a filename does have some drawbacks. Because the device will have a limited number of buttons, the user will be required to scroll through each character choice one by one, drastically increasing the amount of time it will take to complete a recording. Using a patient name as the filename also poses possible conflicts with HIPAA regulations, but the team defers to the user to comply with these rules. To mitigate the time-consuming process of entering filenames manually, the device will also allow the user to use an auto-generated sequential filename as discussed previously.

5.2.5 Audio

5.2.5.1 Input

There are multiple microphone types that can be used in the chest piece of an electronic stethoscope for converting body sounds into an electronic signal. There are four standard types of microphones that may be considered for application in an electronic stethoscope: electro dynamic, carbon granule, electret condenser, and piezo electric microphones. The other two standard microphone types, ribbon and condenser, would not be applicable for the electronic stethoscope for several reasons. The ribbon microphone has a very good frequency response but it is very fragile and large. The standard condenser microphone requires a large polarization voltage to operate, generally on the order of +48V.

5.2.5.1.1 Electro Dynamic

A microphone, in general, works on the principle of a circuit that generates a voltage in proportion to the displacement of a diaphragm. The electro dynamic microphone, frequently abbreviated as dynamic microphone, is the simplest type. It consists of a permanent magnet surrounded by a coil of wire that moves within the magnetic field as the diaphragm of the microphone moves, thus generating a current in the coil. This current varies in proportion to the displacement of the diaphragm and gives the output of the microphone (Microphone 2007). The challenge of a dynamic microphone is that it tends to have limited sensitivity (White 1998), a measure of the amount of electrical input compared to the sound pressure level applied to the diaphragm (Bohn 2007).

5.2.5.1.2 Carbon Granule

The carbon granule microphone is inexpensive and durable, though it is an older technology. The carbon microphone consists of carbon granules compressed between two metal plates. A voltage is applied across the two plates and the sound pressure on the one plate, acting as the diaphragm, compresses the carbon granules, changing their resistance, and varying the output current (Microphone 2007). The sensitivity of the carbon granule microphone tends to be fairly high. However, the frequency response is poor (Gentex Corporation 2007).

5.2.5.1.3 Electret Condenser

Electret condensers use the sound pressure incident on the diaphragm to vary a capacitance attached to the gate of a Field Effect Transistor (FET) and corresponding source resistors (Gentex Corporation 2007). One disadvantage of this type is that the electret requires a bias current to operate; however, its benefits outweigh this disadvantage. Electret microphones have good frequency response and high sensitivity.

5.2.5.1.4 Piezo Transducer

The piezo transducer differs from the previous three types because it is not air coupled, but rather directly coupled to the surface to measure the vibrations. These microphones work due to the physical properties of piezo crystals which generate a voltage when stressed (Microphone 2007).

From this basic introduction one should be able to better understand the decision matrix seen in Table 5.2.

Table 5.2: Microphone Type Decision Matrix

Criterion	Weight	Electret	Carbon Granule	Electro Dynamic	Piezo
Integrity	5	7	4	5	4
Cost	5	6	9	6	5
Availability	5	9	5	5	6
Familiarity	1	10	5	10	7
Frequency Response	9	9	5	9	5
Sensitivity	5	8	4	5	3
Shock Resistance	3	9	9	5	7
Element Size	5	9	6	6	7
EMI Immunity	1	9	9	9	8
Weight	1	9	7	5	7
	Total:	331	233	255	213

5.2.5.1.5 Major Microphone Criteria

Table 5.2 compares the four types of microphones discussed above and assigns various weights to each criterion. Helpful in this decision were Jon S. Wilson's *Sensor Technology Handbook* and "Apply electret microphones to voice-input designs," a white paper published by Gentex Corporation. The major criteria warrant a brief description. The first of these criteria is integrity. This is a design norm that the team feels is important to this project. The electronic stethoscope that is designed must accurately represent any signal it receives, and a high quality microphone is crucial to fulfill this requirement. The next criteria is cost; inexpensive microphones are rated more highly. Availability requires that many

different models of the microphone type are available for purchase, and easy to order from an OEM. Frequency response is the most significant factor, because if the microphone type does not respond well to the frequency range needed, 10Hz to 2kHz (Andries Acoustic, 1999), it cannot be used. Sensitivity is another important consideration. If the sensitivity level is too low, the signal to noise ratio becomes intolerable. The last major criterion is the size of the element itself. In the team's application the microphone needs to be fairly small to fit well within the chest piece without major modification.

5.2.5.1.6 Minor Microphone Criteria

The other four minor criteria that can be seen in Table 5.2 are familiarity, shock resistance, electromagnetic interference (EMI) immunity, and weight. Familiarity was chosen as a criterion because using a technology familiar to the team and widely used in many applications makes the design process go more smoothly. Another minor criterion is the microphone's ability to resist shock. This is important because the electronic stethoscope must be able to withstand a fall. EMI immunity is important for a microphone that will be used in medical settings which have many electronic devices. Finally, the weight of the microphone is considered because the chest piece should not be too heavy.

5.2.5.1.7 Microphone Decision

It can be seen in Table 5.2 that the electret condenser is an excellent choice. It should be noted that this is one of the most common microphones used in electronic stethoscope designs and was recommended to the team by David Josephson, owner of Josephson Engineering and designer of multiple extremely high quality measurement microphones.

5.2.5.2 Conversion

In order to store audio files in flash, the analog audio stream must be converted into a digital stream. This conversion also allows the device to digitally filter the audio stream. The digital audio stream must be converted back into an analog audio stream for real-time listening, as well as audio file playback. These conversions may be done in several different ways, including analog to digital converters (ADCs) and digital to analog converters (DACs) on-board the microprocessor, separate ADC and DAC components, or by using a hardware CODEC.

ADCs and DACs on-board the microprocessor require few extra components, thus reducing cost. However, most on-board ADCs and DACs offer lower resolution than their discrete counterparts. These devices also require additional software implemented inside the microprocessor to control the input and output volume.

External ADCs and DACs are often low cost and simple to implement, but also require additional software to control input and output volume levels as well as software to control each individual component.

Hardware CODECs, though more expensive than either previous option, do not add significant costs to the device (\$3.00 or less, typically). CODECs have the advantage of internal gain adjusters for the input and output, internal headphone drivers, and audio stream mixing. These devices do require software to control the device as well as the interface with the audio stream; however, these interfaces are often simple to implement.

The difference between a hardware and software codec should be specified. A hardware CODEC, which stands for encoder and decoder, is a device that uses both ADCs and DACs, along with additional hardware, to convert audio streams to digital and analog, whereas a software codec is an algorithm used to compress digital audio or digital video into a smaller file size. For the remainder of this document, the word “CODEC” will be used to specify a hardware CODEC.

For this device, the team has decided to use a CODEC for conversion of audio to digital and analog streams. The specific CODEC chosen will be presented in the preliminary design (Section 6.1.2).

5.2.5.3 Filtering

5.2.5.3.1 Auscultation

The purpose of a stethoscope is to aid in auscultation which defined as “the art of listening to specific characteristics of body sounds.” To do this, the stethoscope must accurately reproduce the five major characteristics of body sounds: timing, frequency, duration, intensity, and shape (Andries Acoustics, 12 1990). It is essential that a stethoscope not interfere with these characteristics. This is especially critical for an electronic stethoscope when it filters the sounds it receives. The microphones used in electronic stethoscopes often pick up background noise, which, if transmitted to the user, will distort the intensity and shape of the body sound; therefore, it is important to filter that signal and only reproduce the sounds of interest.

The major three organs listened to by an auscultator are the heart, lungs, and bowels (Andries Acoustics, 12 1990). The frequencies of the sounds produced by each of these organs primarily range from 20Hz to 2kHz (Durand, 9 1997). The experimental study performed by Andries Acoustic while designing the electronic stethoscope for the Space Station Freedom Health Maintenance Facility indicates a similar range of 20Hz to 600Hz; with a range of 20Hz to 220Hz for the heart, 50 to 600Hz for the lungs, and 20Hz to 600Hz for the bowels. This data explains the primary reason the majority of modern acoustic and electronic stethoscope offer different listening modes.

5.2.5.3.2 Mechanical Filtering

Most acoustic stethoscopes offer two operating modes to the user using mechanical filtering. The chest piece of a traditional acoustic stethoscope is often designed with two sides: a bell and a diaphragm. The bell is used to listen to the heart, and the diaphragm to the lungs (Dicken, 5 2000). Some of the newer stethoscopes use a pressure sensitive diaphragm to simulate similar mechanical filtering. The mechanical filtering utilizes the shape of the chest piece itself to pass only the frequencies desired.

5.2.5.3.3 Analog Electronic Filtering

There are two kinds of electronic filtering, analog and digital, that can be used in an electronic stethoscope to reduce the ambient noise and increase the intensity of the desired signal. Analog filtering uses combinations of active and passive components to implement different filters such as the Butterworth, Bessel, and Chebyshev. The biggest disadvantage of the analog filter is the large number of components needed to implement a filter that has sufficient roll-off at the desired cutoff frequency. Another disadvantage is the nonlinear group delay that characterizes many of these analog implementations. Also, the multiple analog components required can add noise to the signal.

5.2.5.3.4 Digital Electronic Filtering

Digital filters, however, can be implemented without this added noise and nonlinear group delay. The two primary digital filter types, finite impulse response (FIR) and infinite impulse response (IIR), can both be implemented on a microprocessor in software. The FIR filter has the advantages of easy design for linear group delay, simple implementation, and coefficients requiring fewer bits of precision than the IIR. The IIR filter differs from the FIR in that it utilizes feedback. The result is that the IIR suffers from compounding calculation errors. The major benefit of the IIR is that it can be implemented using less memory and fewer taps (Iowegian, 2006). The IIR filter, however, was derived from analog filters and generally has a nonlinear group delay (Lecture 8 2006). This delay is undesirable in an electronic stethoscope because it can cause delay in body sounds of different frequencies and may lead to a misdiagnosis. Therefore, the FIR is a good choice for filtering the body sounds.

[Rhythm Reloaded] has chosen to use filtering to model the functionality provided by a traditional stethoscope, and the team has chosen to implement a digital FIR filter because it will give the greatest fidelity to the sampled body sound. This does not mean, however, that mechanical and analog filtering will not also be used in the stethoscope. Mechanical filtering in the chest piece will be used to pass the body sound into the microphone and reject ambient noise. Analog filters will be used for anti-aliasing before the ADC, and for reconstruction after the DAC.

5.2.5.4 Output

It is necessary for [Rhythm Reloaded]'s electronic stethoscope to accurately reproduce the body sounds to the user. The output of the electronic stethoscope must be capable of reliably reproducing sounds from 20Hz to 5kHz. Because an audio codec is being used for the analog to digital and digital to analog conversion, a headphone (line level) driver with volume control is already provided.

The alternatives are then a choice of how the user will listen to the reproduced analog signal. There is a choice of headphones, commercial or proprietary; an external speaker; or an internal speaker. The internal speaker, necessarily small to fit inside the stethoscope's desired form factor, would be difficult for the user to hear in loud noise situations. The external speaker option can easily be interfaced to the most common commercial headphone interfaces. A proprietary pair of headphones could also easily be made to interface with that same interface; thus the choice is between an eighth inch or quarter inch standard headphone jack. The quarter inch jack is physically too large for the desired form factor; therefore, the team chose a standard eighth inch headphone jack.

The team also had to decide between designing a proprietary pair of headphones or using a commercially available pair. The latter is the most reasonable approach because this team does not feel confident designing a pair of headphones that would be of high enough fidelity for the stethoscope. Thus, for the prototype, high quality commercial headphones will be used for the output of the electronic stethoscope.

5.3 Block Diagram

The block diagram shown in Figure 5.3 gives a system-level overview of the device as described in the previous sections. The components selected to fulfill these functional blocks will be outlined in Section 6.

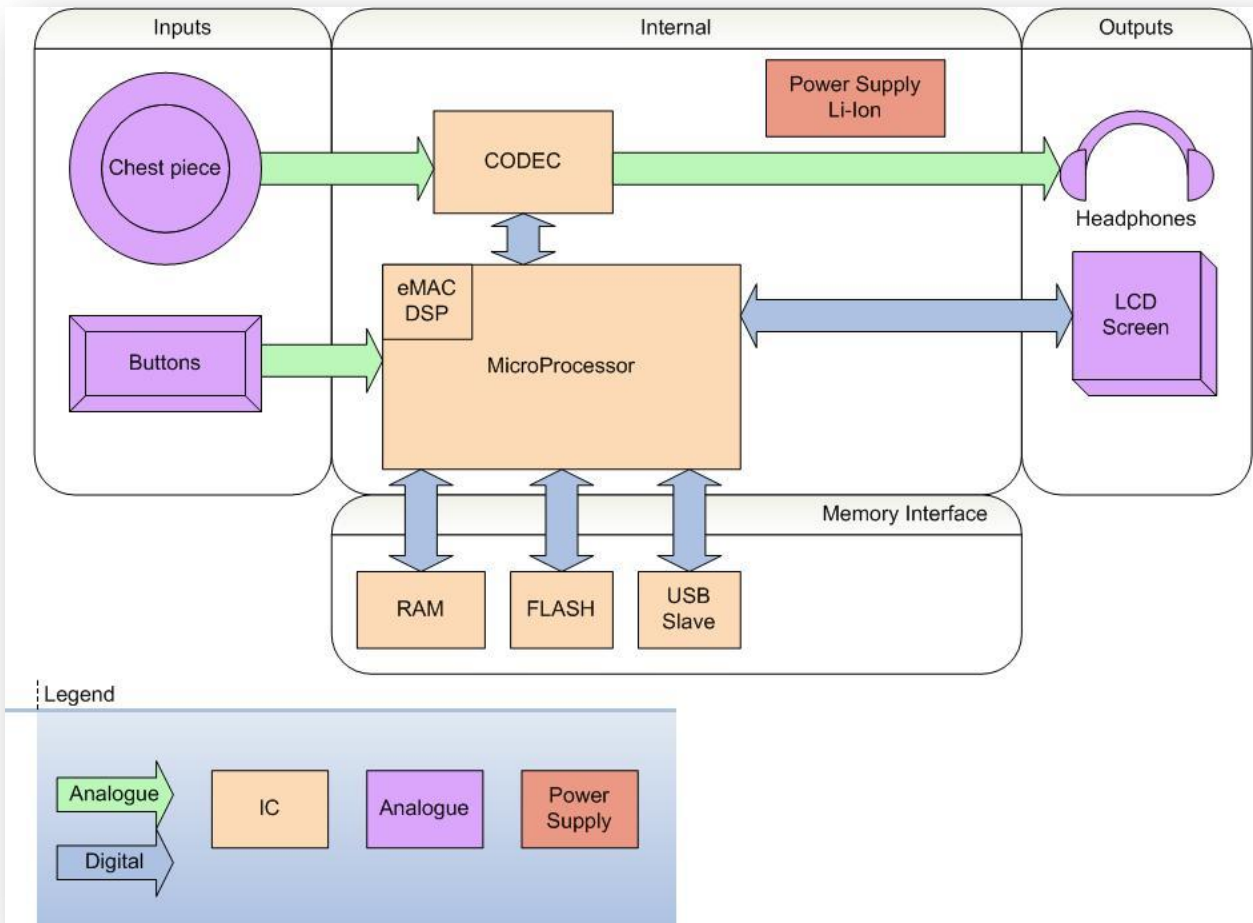


Figure 5.3: Overall Block Diagram

6 Preliminary Design

6.1 Hardware

6.1.1 Power

A rechargeable battery will power the device. Many different rechargeable battery types are available, including NiMH, NiCD, and Li-ion. The team has chosen to use the Li-ion technology. Li-ion cells possess almost double the energy density of a typical NiMH or NiCD cell, and the 3.6 V nominal voltage makes them very practical for portable electronic use. Currently, the team is planning to use a single Li-ion cell. The circuitry required to charge Li-ion cells safely can be challenging and the team has decided it cannot be included in the scope of the project. A COTS Li-ion battery charger will be used to meet the charging needs of the prototype. A set of linear voltage regulators will be used to provide the various voltages used by the components.

6.1.2 CODEC

Analog Devices, NXP, and Wolfson were all researched as possible suppliers for the CODEC. The decision matrix in Table 6.1 shows the criteria with which the possible options were evaluated. The decision matrix shows that the Wolfson WM8731 appears to be the best option for this component. Its high degree of accuracy (low distortion, 24-bit encoding / decoding), and the availability of a development board makes this device the best choice for the team. The development board was loaned to the team by Johnson Controls Inc., where Ben is currently employed.

The Analog Devices CODECs (SSM602 and AD1981BL) along with the NXP CODEC (UDA1380) performed better than the Wolfson CODEC (WM8731) in a few areas (power, volume step size); however, these devices seem to be poorly supported in their datasheets and their available documentation found online.

Table 6.1: CODEC Decision Matrix

Criterion	Weight	SSM602		AD 1981 BL		WM 8731		UDA 1380	
Transparency	7	5		5		8		6	
Integrity	9	9		6		9		9	
Stewardship	8	10	RoHS	10	RoHS	10	RoHS	10	RoHS
Format	8				AC '97				
Cost	2	6	\$2.80	5	\$3.00	6	\$2.80	7	\$2.40
Inputs	1	7	3	7	9	4	3	4	3
Interface	8	8	4 wire	6	5 wire	6	5 wire	4	6 wire
Headphone Driver	1	10	Yes	10	Yes	10	Yes	10	Yes
Size	3	7	28 L QFP	3	48 L QFP	7	28 L QFP	5	32 L QFP
DAC Resolution	8	9	24	7	20	8	24	9	24
ADC Resolution	9	9	24	6	16	8	24	9	24
Internal Filtering	2	0	No	0	No	0	No	0	No
Digital Equalizer	6	0	No	4	3 Channel	0	No	0	No
Dynamic Range In	4	5	unkown	9	90 dB	9	90 dB	10	135 dB
Dynamic Range Out	4	5	unkown	7	45 dB	7	90 dB	10	135 dB
Volume Step Size	3	9	1.5 dB	8	1.5 dB	6	3 dB	10	.5 dB
SNR ADC	10	8	90 dB	8	85 dB	8	90 dB	9	97 dB
SNR DAC	8	9	100 dB	9	100 dB	9	100 dB	9	100 dB
Analog Supply	5	8	3.3 V	8	3.3 V	7	3.6 V	6	3.6 V
Digital Supply	4	8	3.3 V	8	3.3 V	7	3.6 V	6	3.6 V
Power (Full Power)	7	7	22 mW	9	2.87 mW	7	22 mW	5	70 mW
Power (Passthrough)	1	7	7 mW	9	2.87 mW	8	12 mW	5	70 mW
Dev Board	5	0	No	0	No	10	Yes	0	No
Sample Parts?	4	10	Yes	10	Yes	10	Yes	10	Yes
Total:		850		811		892		837	

6.1.3 Human-Machine Interface

The user interface consists of a character LCD and a variety of buttons. These interfaces combine to form the HMI. The user interacts with these interfaces to control the device. The LCD provides feedback to the user so tha she can select the desired function by pressing the appropriate button.

6.1.3.1 Character LCD

The LCD interface displays the status of the device to the user and aids in using the device effectively. The LCD must be easy to read and the interface must be simple to understand. It is important that the interface be intuitive to meet the transparency project requirement.

A character LCD was selected to provide visual feedback to the user and several component options were researched. The device does not require a large amount of information to be presented to the user; therefore, a large, multi-line LCD would be impractical and would occupy more space, forcing the device to be larger. A two-line LCD is suitable to provide the user with all the necessary functionality. The number of characters per line was also an important factor in selecting an LCD. Since it is a requirement that the device be small, a modest 16x2 character display was selected by the team. This will allow the device to display all necessary information, to serve as a debugging aid, and to provide the user with the appropriate visual feedback.

Aesthetics were also a consideration in selecting the LCD. Given the options, the team felt that a blue backlit display with white text was the easiest to read and the most aesthetically pleasing. An example, available from Crystalfontz, is shown in Figure 6.1.



Figure 6.1: Crystalfontz 16x2 STN Negative Blue Transmissive White Edge LED Backlit LCD Module

The specific LCD that the team will be using in the prototype has not been selected at this time. However, the team already has experience interfacing with the industry-standard HD44780 LCD controller. This experience will allow the team to quickly develop any LCD that uses the HD44780 controller. The team has a selection of LCDs with this controller at its disposal, so development can begin immediately while the team waits for delivery of the selected component.

6.1.3.2 Buttons & Layout

The buttons allow the user to control the device by providing a way for the user to switch between functional and filtering modes, as well as naming audio recordings, changing the volume, and turning the device on and off. The button layout must be intuitive to the user and provide satisfying tactile feedback. Much of the button design and function depends on the corresponding mechanical case design. Because of this fact, the team has decided that the button layout is more crucial than the button type. Standard board-mountable normally closed buttons will be used in the prototype to keep the design simple.

Appendix D demonstrates how the HMI will function and Figure 6.2 displays the basic layout.



Figure 6.2: HMI Simulation and Layout

The LCD will show the user which current functional mode the device is in, display the current filtering selection, and prompt the user for input. The Mode button is used to change the filtering option. It is necessary to make this a separate button because the user will be changing the filtering selection frequently during use. The arrow keys are used to navigate the menus and enter file names, as well as control the rate of audio playback. The oval key in the middle of the arrow keys is an action key. It is pressed to confirm a selection when the user is prompted for input and to control audio playback and recording.

Other buttons that the device will have, but are not pictured above in Figure 6.2, are a power button and volume controls. At this time there has been no selection mode for these buttons, but it must be clear to the user what their function is.

6.1.4 Chest Piece

The quality of an acoustic stethoscope is greatly affected by the quality of its chest piece. [Rhythm Reloaded] has considered this and has concluded that the team does not have the technical expertise necessary to design the mechanical aspects of a high quality chest piece. The team has chosen to modify an existing COTS chest piece and place the microphone within it to maximize the benefits of mechanical filtering that are already present. The decision has not been made as to which specific chest piece to use; however, there are two major categories under consideration. The first is a standard two-sided chest piece and the other is a pressure sensitive diaphragm chest piece. The first option is the most common. It has one side that uses a diaphragm and is used to listen to the lungs and for general auscultation. The other side is bell-shaped and is designed to specifically transmit heart sounds. The second chest piece option uses a single diaphragm that changes its sound characteristics when pressure is applied, and is designed to offer similar functionality to the two-sided option.

6.1.4.1 Microphone

The team has chosen to use an electret condenser microphone. The next step is to choose which specific microphone to use. In this decision there are several criteria that must be examined. The first criterion is the microphone's frequency response. It must be able to pick up sounds in the range of 20Hz to 2kHz. Another option to consider is the directionality of the electret microphone. Omni-directional microphones pick up signals equally well from all directions, while noise-cancelling microphones allow the sound pressure to approach the diaphragm from both sides. The disadvantage of using a noise

canceling microphone is that it will be sealed inside the chest piece and its noise canceling abilities will probably not function properly. Also, it is a concern that many of the noise canceling microphones do not operate in the required frequency range. A final consideration in the choice of a microphone is its sensitivity; the microphone must be able to reproduce the correct intensity of body sounds that it receives. The microphone that meets these requirements at the lowest cost will be the one chosen for the design. Currently, specific microphones are being tested to determine their suitability

6.1.4.2 Analog Circuitry

The chosen electret microphone will require a biasing circuit to operate and a pre amplifier to maintain a good signal to noise ratio (SNR) between the chest piece and the audio CODEC. There are several viable methods for biasing the electret. One method is to use a simple RC circuit and small battery to apply the required voltage (Elliott 2007). Although this is suitable for testing the microphone, it is not the best option for the prototype. The more preferable option for biasing the microphone is to have a separate preamplifier circuit provide the biasing (Elliot 2002, Electret Mic Apps 2007, Collinson 2007). Another option is to use the built-in microphone preamplifier and biasing circuit in the audio codec. The decision between using a commercially available preamplifier or a custom designed circuit is a simple one. The commercial pre-amp is a proven technology that is readily available, simple, and inexpensive to implement. [Rhythm Reloaded] has chosen to use the microphone preamplifier and microphone bias circuits offered on their CODEC.

6.1.5 Storage Media

Given the limited amount of audio storage required for the prototype, the flash media will not have strict constraints on size. The decision for audio storage file format has yet to be made because this decision has a large effect on the fidelity of the stored audio. Sample parts were obtained from Spansion with capacity of 512 Mb of storage. Most audio files in raw .wav format are approximately 80kB per second, making the device capable of storing more than 13 minutes of raw audio. The team has decided that this is more than enough storage space to showcase a working prototype.

The Spansion parts obtained are from the component family S29GL-P. These components are all pin-compatible, meaning that the prototype can be modified to add or remove available capacity. Though it is not necessarily practical to remove a BGA from a prototype, additional prototypes will not require layout changes in order to change the storage capacity. This reduces PCB redesign time and cost.

6.1.6 Microprocessor

6.1.6.1 Main Requirements

There are a number of different criteria that the device microprocessor must meet.

6.1.6.1.1 USB Device Functionality

Although the USB Device functionality could be implemented with a separate ASIC, or on an FPGA, the team decided that integration of this part into the processor would simplify the project and make it more power-efficient.

6.1.6.1.2 DSP Functionality

Likewise, the DSP functionality could be implemented on a DSP chip separate from the microprocessor. However, the DSP functions needed, namely FIR filtering and lossless audio file compression, are not extremely complex or processor-intensive. For example, an FIR filter can be implemented with only the addition of hardware multiplication and division to process real-time data. Because hardware multiplication and division is present in many microprocessors with integrated DSP functionality, the team chose this option. Because of the relative simplicity of the DSP functions, a processor without specific DSP hardware could potentially have been a viable option. However, microprocessors with additional hardware to perform DSP functions are commonplace and are usually priced similarly to non-DSP devices. For example, the Coldfire MCF5206, a processor without dedicated DSP hardware, is priced at \$10.10 for orders of more than 1000. The Coldfire MCF5208, a processor very similar to the MCF5206, but with dedicated DSP hardware and a faster core, is priced at \$7.22 for orders of more than 1000. In fact, all Coldfire processors based on the latest three cores (V2, V3, and V4) have integrated DSP hardware. Given this price similarity and the wide availability of microprocessors with DSP hardware, the choice of a combined microprocessor and DSP is obvious.

6.1.6.1.3 RoHS Compliance

To gain FDA approval as a device safe for use in medical environments, the stethoscope must be free of hazardous substances such as lead. Therefore the microprocessor must be RoHS (Reduction of Hazardous Substances) compliant.

6.1.6.1.4 Power Consumption

For the device to have a sufficiently long battery life, the microprocessor must have low power consumption. There is not a defined maximum power consumption for the purposes of this decision, but microprocessors with lower power consumption were rated more highly than others.

6.1.6.1.5 Clock Frequency

The microprocessor must be able to handle the calculations required of it in near real-time, therefore, higher clock frequencies were rated better than lower clock frequencies.

6.1.6.1.6 General-Purpose Input/Output Pins

To interface to off-chip peripherals, such as an LCD, the microprocessor must have general-purpose input-output (GPIO) pins. A microprocessor with a higher number of GPIO pins gives greater flexibility and was rated higher.

6.1.6.1.7 Other Considerations

Other factors, such as the size of on-chip memory, number and types of communication buses, presence of flash media interfaces, presence of an analog-digital converter (ADC), and hardware encryption capability were also considered, although not deemed to be crucial criteria. The features and availability of a suitable development kit for the microprocessor were also considered. The design criteria are outlined in the decision matrix in Table 6.1.

6.1.6.1.8 Donation from Freescale Semiconductor

Many different processors from many different companies fit these criteria, so a deciding factor in the team's decision was availability. Ben, one of the team's members, was able to secure a donation

through his contact at Freescale Semiconductor for a microprocessor development board. Development boards of this type typically cost between five hundred and one thousand dollars, so for a team with an initial budget of about five hundred dollars, the availability of a free development board was not an insignificant factor. Freescale has a wide range of processors available, many of which fit the project requirements, so the decision was made to select a microprocessor from that company.

Table 6.2: Microprocessor Decision Matrix

Criterion	Weight	MCF5251		MCF5485		MCF5473		i.XML (ARM)		MCF5275	
Transparency	9	4		6		7		9		8	
Integrity	10	10	RoHS	10	RoHS	10	RoHS	10	RoHS	10	RoHS
Stewardship	8	8		8		8		8		7	
Cost	5	8	\$9.50	4	\$27	6	\$20	8	\$9.50	7	\$13.12
Development Kit	10	6	Yes	7	Yes	8	Yes	6	Yes	9	Yes
Speed	8	5	140 MHz	7	200 MHz	7	200 MHz	7	200 MHz	6	166 MHz
Power Rating	8	7	500 mW	5	600 mW	5	600 mW	3	1.3 W	7	500 mW
Cache	5	3	8 KB I	7	32 KB I/D	7	32 KB I/D	5	16 KB I/D	5	16 KB
Internal RAM	6	7	128 KB	3	32 KB	3	32 KB	5	32 KB	5	64 KB
RAM Controller	6	5	SDRAM	8	DDR	8	DDR	5	SDRAM	8	DDR
Address Bus Width	4	8	24	5	16	5	16	8	24	8	24
Data Bus Width	4	5	16	10	32	10	32	10	32	5	16
Removable Media Interface	1	10	Yes	0	No	0	No	10	Yes	0	No
DMA Channels	5	5	4	8	16	8	16	7	11	5	4
Audio Interface	6	7	QSPI	5	DSPI	7	QSPI	8	2x SPI	7	QSPI
Ethernet	4	0	No	10	2x 10 / 100	10	2x 10 / 100	0	No	10	10 / 100
UART	3	3	3	4	4	4	4	2	2	3	4
Floating Point Unit	10	8	eMAC	8	eMAC	8	eMac	3	No	8	eMAC
USB	7	10	2.0 OTG	9	2.0 Slave	9	2.0	10	2.0 OTG	9	Slave 2.0
LCD	2	0	No	0	No	0	No	10	Yes	0	No
ADC	2	7	6x12 bit	0	No	0	No		No	0	No
Temp Range (C)	1	6	-20 to 70	8	-40 to 85	4	0 to 70	7	-30 to 70	7	0 to 85
Encryption	1	10	No	10	Yes	10	Yes	0	No	10	Yes
Size	3	7	225 PBGA	5	388 PBGA	5	388 PBGA	7	225 PBGA	7	256 PBGA
Sample Parts	1	10	Yes	10	Yes	10	Yes	10	Yes	10	Yes
Total:		832		755		743		839		919	

6.1.6.2 Initial Decision: The MCF5251

Initially, the team chose the Freescale Coldfire MCF5251 processor. At the time the MCF5275 had not been considered, and the MCF5251 processor fit the specifications well. It has a USB On-the-Go interface, meaning that it can act as either a USB host or device, and a 32-bit hardware multiply and divide unit (eMAC), which provides the necessary DSP functionality. The MCF5251 is available in an RoHS-compliant package, it has low power consumption, and is relatively inexpensive at \$9.23 per part

in lots of over \$1000. In addition, the processor has a Secure Digital (SD) and flash memory interface, a Real-Time Clock, and an integrated ADC.

6.1.6.3 Hardware Progress

6.1.6.3.1 Problems with the MCF5251

The team received the M5251C3 development board from Freescale, and attempted to load the operating system (discussed in more detail in Section 6.2.1). It soon became apparent that the team had not researched the development board as thoroughly as it should have. The processor does not have integrated Ethernet, so the board lacks this functionality. This lack of Ethernet functionality forced the team to transfer the OS memory image over serial RS-232, which is a very slow process. The factory-installed board firmware, dBug, can only transfer files in the Motorola S-record format (SREC) if they are to be transferred over serial RS-232. Ceding to this limitation, the team converted the binary OS image to an SREC file. It was soon discovered that the generated 17 MB SREC file was too large to fit in the board's 8 MB of flash memory. It was later discovered that the team used the wrong version of GNU's objcopy utility to convert the binary file; *m68k-elf-objcopy*, meant for Coldfire/68k architectures, should have been used instead of *objcopy*, which is meant for x86 architectures. This mistake, and the team's general unfamiliarity with converting binary files to SREC format, caused the team to conclude that it would be very difficult, if not impossible, to load the OS image on to the board. The team decided to research other processor options and to see if the M5251C3 could be traded for a more suitable development kit. Other options, such as programming the chip via the Background Debug Module (BDM) or JTAG interface were pursued, but only as a last resort because of their perceived difficulty and the lack of applicable documentation.

6.1.6.3.2 Second Microprocessor: the MCF5275

After learning that the development board could be traded for another, the team began researching other microprocessor options. At this stage in the development, the decision had already been made to use μ CLinux as the device operating system. This OS decision had not been finalized at the time of the initial microprocessor decision, so it did not impact the first choice. However, it did become an important factor in the choosing of the replacement microprocessor. μ CLinux did not fully support the MCF5251, although it did support the MCF5249, a very similar part. The team anticipated having to write some device drivers to make the MCF5249 fully functional. When making the second microprocessor decision, the team found a processor that both fit the requirements and was supported by a fully-functional μ CLinux port: the MCF5275. This processor also includes integrated Ethernet hardware, allowing the team to transfer memory images using this interface. In addition, the processor includes hardware encryption, which the team thought might be useful in complying with the Health Insurance Portability and Accountability Act (HIPAA) and other government regulations regarding medical patient privacy. The MCF5275 does not include integrated support for removable flash media, but by this time the team had decided not to use any removable media because of patient data privacy concerns. For these reasons, the team elected to use the MCF5275 and its associated development board, the M5275EVB.

6.2 Software

6.2.1 Operating System

6.2.1.1 *Different Types of Embedded Operating Systems*

There is a multitude of different operating systems available to the embedded designer. Some are commercially developed and have licensing fees associated with them, while others are developed by the open-source community and are freely available to anyone. Open-source operating systems are usually based on Linux. Some embedded systems require an operating system with excellent real-time characteristics, meaning that the OS must be able to schedule tasks such that they are guaranteed to be completed by a certain deadline. These are known as real-time operating systems (RTOS). The Linux kernel, however, is not designed to provide this real-time functionality. Developers have modified Linux to improve its real-time capabilities, and some have even run Linux as another process on top of a true RTOS, as is the case with RTLinux. The following section outlines the main choices facing the team and their comparative advantages and disadvantages. For a full decision matrix, see Section 6.2.1.5.

6.2.1.2 *Operating System Criteria*

6.2.1.2.1 Cost

Cost can be separated into the initial cost for one license, ensuing royalties necessary to use the OS in a manufactured product, and costs associated with supporting the OS once the product is in the market. The cost of an initial development license, although it is not relevant to the final product, is important because the team is on a limited budget. The device software will be well-tested regardless of the chosen OS, therefore, post-market release support costs are assumed to be equal.

6.2.1.2.2 Hardware Support

Hardware support was a very important factor in choosing the OS; if a particular OS did not support the team's chosen processor, then it could not be considered as an option. When the team made the final decision on which OS to use, the first microprocessor had already been chosen. However, a different microprocessor was subsequently chosen, *after* the final OS decision, as detailed in Section 6.1.6.3. Thus, support for the MCF5249 played a role in the OS decision, and support for the chosen operating system played a large role in the second microprocessor decision.

There are different levels of hardware support. In this particular case, there are a number of operating systems that have a generic port to the 68k/Coldfire architecture, but that do not necessarily have all the necessary drivers and code to make a specific processor fully-functional. For the most part, these operating systems are open-source, and thus part-specific drivers can be added or written as needed, but at additional effort.

6.2.1.2.3 Code Availability

This criterion is dependent on whether the OS is open- or closed-source. Open-source has many advantages compared to commercial options. Because the source code is available to the team, modifications and fixes can be made as needed without any reverse-engineering or infringement of intellectual property. The code can be changed to perfectly suit the device; unnecessary code can be removed and code to support additional features can be added. If commercial operating systems

require modification or patching, this work must be done by the vendor, which can result in delays and extra cost.

6.2.1.2.4 Familiarity

Although the team is not averse to learning to develop with a new operating system, familiarity is preferable. The learning curve of a new OS environment can result in long delays. Because software development is typically one of the most unfamiliar processes among electrical engineering teams, this team included, the team would like to minimize the potential for software problems by choosing a familiar environment.

6.2.1.2.5 Code Footprint

The OS code must be small enough to fit on flash memory resources available on the microprocessor development kit, leaving adequate storage space for custom software and data generated by the team. For the M5249C3, the initial development board, there is a total of 8 MB available. There is 2 MB available on the M5275EVB, the second development board, although this number did not play a part in the OS decision because it was chosen later.

6.2.1.2.6 User Community and Documentation

When learning a new skill, such as embedded software development, it is very important to have resources available to solve problems as they arise. This category can include sources such as mailing lists, forums, printed documentation, wikis, white papers, etc.

6.2.1.2.7 Security

The OS should not be susceptible to viruses or malicious programs. Because the final product will be an embedded device with no accessible network capability, the risk of compromise by other software is extremely low. The only route of entry for malicious software is through the USB connection, unless the user purposefully modifies the system software using the JTAG interface.

6.2.1.2.8 Real-time Capability

The team has determined by studying similar systems that an RTOS is not necessary. There are numerous examples of similar systems, such as MP3 audio players, running on Coldfire processors with non-real-time operating systems. However, the OS should have a small overhead so as not to overwhelm the processor.

6.2.1.2.9 Development Tool Availability

Some operating systems have development tools or Integrated Development Environments written especially for them. These tools can ease development and reduce time spent troubleshooting and debugging.

6.2.1.2.10 Multi-tasking

The OS must be capable of robustly managing and scheduling multiple processes.

6.2.1.3 FDA Software Validation

6.2.1.3.1 Feasibility of Validation

Because this project is a medical device, there was some speculation that there might be specific operating system requirements. Particularly, for security, safety, and privacy reasons, it was postulated that an open-source OS might not be allowed by various governmental regulations. However, reading through all of these regulations, particularly the *General Principles of Software Validation: Final Guidance for Industry and FDA Staff*, does not reveal any prohibition of open-source software. Rather, the emphasis of the document is on the documentation and review process. Because embedded Linux in medical devices is a relatively new concept, there are not any readily available examples of any medical devices running open-source software that have been approved by the FDA. However, there is speculation that open-source software may actually have an advantage over closed-source software in the validation process because the regulatory bodies have access to all of the source code without any issues of unavailable proprietary information. Therefore, the team believes that, given a well-documented development and review process that follows the rules dictated by the FDA, there is no reason why an open-source software system cannot be validated by the FDA.

6.2.1.3.2 GPL Compliance

Because many components of an open-source operating system are licensed under the GNU General Public License (GPL), any derived work, such as a customized embedded OS based on the Linux kernel, must also be licensed under the GPL. The GPL requires that source code for any derived project be available on request if the software is distributed in any way. This would also apply in the case of software distribution in embedded devices. However, the GPL does not apply to application-level software running on the GPL-derived code, meaning that this software may be kept under a proprietary license. Because much of a device's functionality is contained in this application-level software, a company need not divulge the results of its expensive research and development (Epplin, "Using GPL software in embedded applications").

6.2.1.3.3 GPL and the FDA

With regard to FDA validation, there remains the issue of a competitor using the FDA validated open-source OS code which was validated at great expense by the original company. This allows one company to let a competitor absorb all the cost of validation while reaping the same benefits. However, according to the *General Principles of Software Validation: Final Guidance for Industry and FDA Staff*, "Whenever software is changed, a validation analysis should be conducted not just for validation of the individual change, but also to determine the extent and impact of that change on the entire software system." (12) Therefore, unless one company were to use exactly the same software, an extremely unlikely case because it would also require the use of exactly the same hardware, the code obtained through the GPL would need to be at least partially revalidated. Furthermore, it is legal to release code under two licenses. For example, MySQL AB bases their software on GPL code, and releases the source as required. However, it also sells the same code under a proprietary license to third parties who wish to use it on closed-source projects. The company's entire business model is based on this dual-licensing concept. If this device were to be mass-produced, a similar method could be used to recoup losses due to high FDA validation costs.

6.2.1.4 *Operating System Choices*

6.2.1.4.1 μ Clinux

μ Clinux is a widely used embedded open-source OS based on the Linux kernel. It has a wide, active user base and strong community support, including a number of mailing lists (uClinux-dev, uClinux-coldfire), and websites (www.uclinux.org and www.ucdot.org) with links to a range of documentation. Because it is open-source, it is free, and it requires no future royalties or licensing for use on any commercial products. μ Clinux is used as the factory-installed OS in a number of commercially available products, including media players, such as the Mattel Juicebox, and network hardware from Arcturus and SnapGear. It has also been ported by open-source developers to many other commercial products, such as the iPod, the Nintendo DS, the Playstation, and the Playstation Portable. There is a specific port for the MCF5275 and the M5275EVB, including all necessary drivers to run Ethernet and USB hardware. Because it is based on the Linux kernels, the OS provides a familiar environment that can easily be modified and customized. The Linux kernel is known to be secure, and it robustly handles multiple processes. Furthermore, because of its wide adoption in the embedded market, several different third-party software vendors provide Eclipse-based IDEs specifically for μ Clinux, and one of those vendors has donated a software license to the team.

6.2.1.4.2 *The Custom-Built OS*

The team did consider building its own OS, that is, writing its own processor initialization code and device drivers. This option, however, presents a significant number of disadvantages. Firstly, the team has no experience writing either processor initialization code or any complex device drivers, such as those required by USB. Secondly, the processor will have to run multiple processes, the audio filtering, compression, and storage process, and the user interface process. While the team could write the code needed for such multi-tasking capability, the learning curve is potentially steep. When combined with the learning curve for writing device drivers and processor initialization code, the team felt that it would be better served by an operating system which addressed these issues in a robust manner. With the team freed from writing low-level hardware code, time can be used to address the core features of the project, namely audio filtering, compression, storage, and transmission.

6.2.1.4.3 FreeRTOS

FreeRTOS is an open-source RTOS that has been ported to a number of processors. It has a very small code footprint (4 kB), and good task scheduling. Community support is well developed, with several mailing lists and websites. However, it is not familiar to the team, and more importantly, the Coldfire port is unsupported, meaning that users from the community have submitted a port, but it is not verified and the documentation is not very well developed. This lack of official hardware support was seen as a large problem by the team.

6.2.1.4.4 eCos

eCos is an open-source RTOS with qualities similar to FreeRTOS. It is highly configurable, so the code footprint can be changed to a certain extent. This OS has a large developer community. There is a port for the Coldfire MCF5272, but it is currently marked as non-functional. While the team felt that it would be possible to restore the port to full functionality, this work could potentially take a prohibitive amount of time. This aspect largely disqualified eCos as a serious contender.

6.2.1.4.5 Custom GNU/Linux Based OS

The team also considered modifying the Linux kernel to create a custom OS. This option, however, has a long list of disadvantages. The team does not have any experience with this sort of modification, and even if successful, it would likely yield an OS similar to other readily available systems such as μ Clinux. The time involved in this process would likely be prohibitive, and the robustness of the code would likely be questionable. Community support is very general for this sort of endeavor. Like the non-Linux Custom OS option, the team felt that its time could be better used on other aspects of the project.

6.2.1.4.6 Nucleus RTOS

Nucleus RTOS is a commercial OS produced by Mentor Graphics. It officially supports all functionality of the Coldfire architecture. While the OS is not open-source, the code can be downloaded and viewed at no charge to aid in debugging. The OS is royalty free, but does have associated licensing costs. It is very secure, with different encryption options built-in to overcome the risk of data theft. Because it is a commercial OS, Nucleus RTOS comes with a wide variety of development tools, including an IDE and JTAG debugging tools. Although numerous inquiries have been made to Mentor Graphics regarding licensing fees, no response had been received at the time of this writing.

6.2.1.4.7 μ C/OS-II

μ C/OS-II is an RTOS developed by Micrium that is free for non-commercial use and supports the MCF5275, with the exception of hardware encryption. It is open-source, but still requires a licensing agreement on a per-product basis if the host devices are to be sold. For a single product with license to sell unlimited devices, the fee is \$4,995 for the kernel. Other modules have extra fees associated with them; the additional modules required by the team are the USB Device module, priced at \$6,700, and the FAT file system module, priced at \$3,750. Again, these module licenses provide for a single product with the ability to sell unlimited devices. For a product line consisting of multiple devices and unlimited sales, these costs increase to \$29,970, \$28,200, and \$22,500 respectively. The OS has a large user base and good documentation, but it does not come with development tools. It does present the large advantage of being pre-certified for FDA 510(k), which is the FDA certification for medical devices. This OS does present many advantages, therefore if the team finds an RTOS to be absolutely necessary, μ C/OS-II would become a viable option.

6.2.1.4.8 Other Operating Systems Considered

Other popular embedded operating systems such as QNX, VxWorks, LynxOS, and various BSD variants were researched but ultimately disqualified from consideration because of their lack of Coldfire hardware support.

6.2.1.5 *Operating System Decision*

The team created a decision matrix incorporating these criteria, shown in Table 6.3. Based on this matrix, the team decided to use μ Clinux as the device operating system.

Table 6.3: Operating System Decision Matrix

Criterion	Weight	uClinux	No OS	FreeRTOS	eCos	GNU/Linux	Nucleus RTOS	uC/OS-II
Initial Cost	5	10	10	10	10	10	5	7
Open Source	8	10	10	10	10	10	4	10
Familiarity	8	7	5	3	3	5	3	3
OS Size	7	6	10	9	9	7	10	9
Royalties	9	10	10	10	10	10	10	10
Hardware Support	10	10	9	3	2	2	10	7
User Community	7	9	1	5	3	2	5	6
Documentation	10	9	3	6	8	5	7	7
Security	4	7	10	7	7	5	10	10
Real-Time	3	2	10	10	10	1	10	10
IDE Availability	5	10	3	5	5	6	10	5
Multi-tasking	6	9	3	10	10	7	8	10
	Total:	709	560	575	571	488	614	629

6.2.1.6 Operating System Progress

The team has compiled the μ Clinux kernel using the GNU 68K/Coldfire C/C++ Toolchain. This compilation produces a binary memory image approximately 1 MB in size, depending on the different options specified. The binary memory image has been transferred to the M5275EVB development board, and the OS has been booted successfully using the factory-installed dBug firmware.

6.2.2 Application Software

6.2.2.1 Software Flow Diagram

A software flow diagram is presented in Figure 6.1. This diagram presents the flow for the primary audio processing application, as well as how user input will be handled by an Interrupt Service Routine (ISR). The ISR will of course handle interrupts other than user input, such as USB connection detection, but the details of these interrupts have not yet been planned.

6.2.2.2 Application Software Progress

A sample “Hello World” program has been written in C and compiled using Sourcery G++. The binary file produced is 16 kB in size. This binary file has been run in μ Clinux by transferring the file over Trivial File Transfer Protocol (TFTP) to the development board from a host computer, as well as by including the binary in the pre-compiled OS memory image. When run, both binaries produced the expected “Hello World” output in the μ Clinux terminal, which was captured by a serial connection between the development board and the host computer.

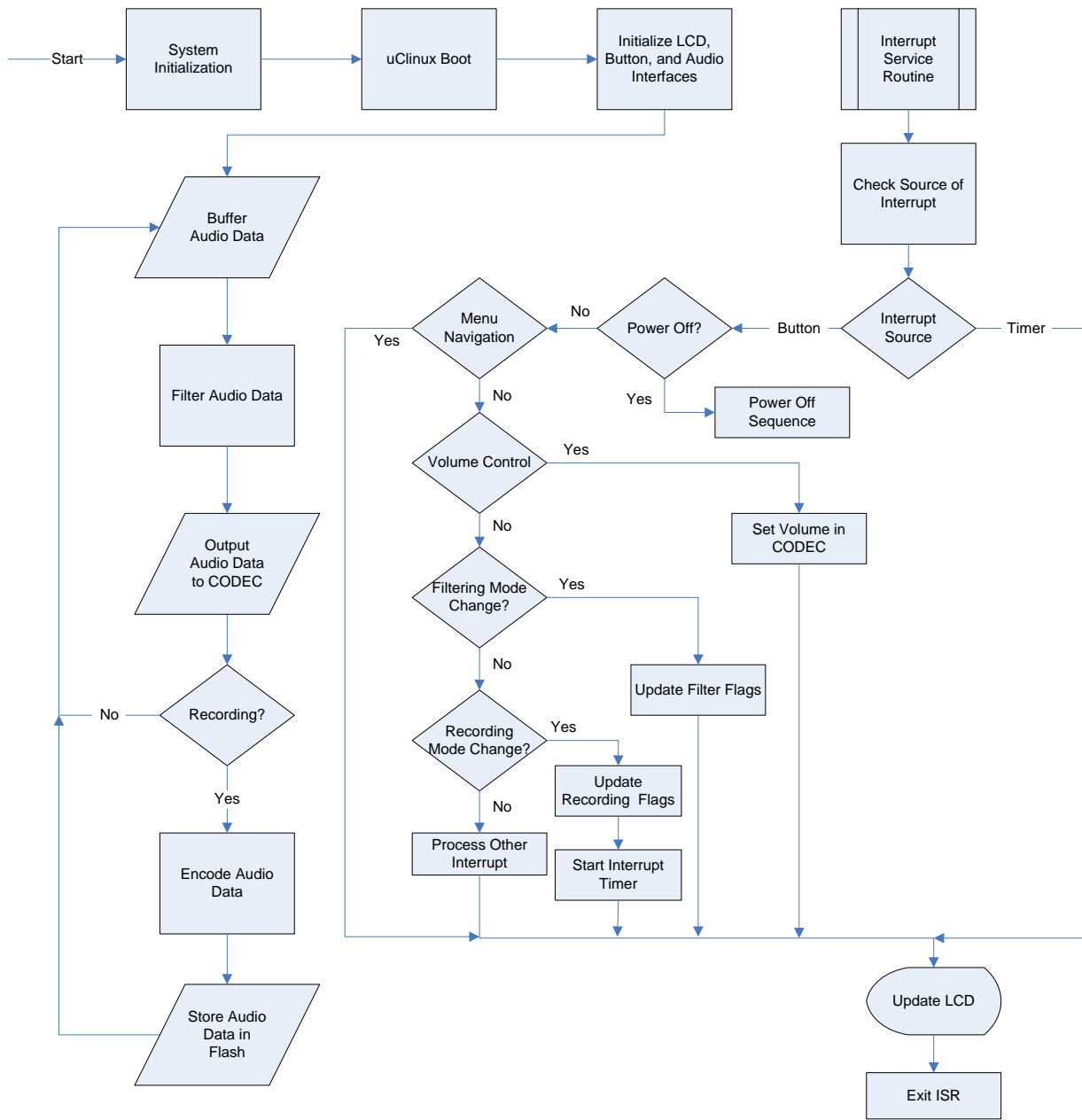


Figure 6.1: Software flowchart

7 Testing Plan

[Rhythm Reloaded] has defined a Test Plan (Gabler, Testing Plan) that defines the purpose, scope, and procedures for testing the functional requirements of the electronic stethoscope. The plan defines two major areas in the design process which utilize testing: decision making processes and the final verification of the prototype. The purpose of the tests is to document and support the various decisions and to validate that the electronic stethoscope prototype meets the requirements. The majority of the tests performed will be documented using the form seen in Appendix B. On this form, the tester will record the item under test (hardware or software), the functional block (as seen in Figure 5.3), member

name, date, a description of the test, the results, and the test's implications. This form will be used primarily to record the procedure and results of tests performed while the team is in the process of making decisions about certain components of the design. It will also be used while developing the formal procedures to be used in the final prototype verification tests, which will demonstrate compliance with the electronic stethoscope requirements included in Appendix A. Each test in this verification will have a formal procedure and the results will be recorded as pass or fail. The team's goal is to have the prototype pass every test by May 3, 2008.

7.1 Decision Making Testing

There are several parts of the design which warrant the use of experimental testing to determine the most suitable component. The first of these parts is the microphone; several different options for an electret condenser microphone will be chosen according to their specifications and will be tested to determine their adequacy for the design. Other tests that will be defined and implemented as this design process continues are tests of different linear power supplies, button interfaces, oscillator circuits, and various software blocks. The tests on the linear power supplies will be comparing the noise, load capacity, and fidelity of the signal. The buttons will be compared according to their style and functionality that is needed. For the oscillators, different configurations compatible with the microprocessor will be compared. Various different software components, such as drivers and filtering algorithms, will be tested and compared against each other in terms of performance, complexity, and accuracy.

7.2 Requirement Testing

The final stethoscope prototype will need to be tested to verify that it complies with the requirements found in Appendix A. All these tests will be fully defined in the Test Plan document by the end of next semester.

7.2.1 Interface

The first aspect of the design to test is the HMI. The functionality of each button will be verified. The mode button shall cycle through modes, the arrow keys shall navigate as expected, and the enter button shall function correctly. The feedback from these tests shall be seen on the LCD. This will test the proper functionality of both the LCD and buttons.

7.2.2 Functionality

The formal tests will also verify that the electronic stethoscope prototype can be used for auscultation, can record the body sounds, playback the recorded sounds, and transfer the recorded sounds to a computer. These will be tested by simply performing the required actions. A user will listen to a patient's heart; the sounds will be recorded, played back, transferred to a computer, and played back from the computer. The test subjects will be volunteers from the team and previously recorded heart sounds played through Andries Auscultations' "The Patient."

7.2.3 Audio Performance

The stethoscope will also be tested for its audio performance. This test will be performed using "The Patient" which will play back a three minute logarithmic frequency sweep from 20Hz to 2000Hz. The stethoscope shall record this audio input. The sound captured by the stethoscope will then be plotted

on a spectrogram using Cool Edit Pro 2, and MATLAB will be used to plot a Bode diagram of the same data. This data will be compared with the spectrogram and Bode plot of the original sound. Ideally the two plots will be similar. The magnitude Bode plot will also be compared to the Bode plots presented by Watrous, Grove, and Bowen in their article on characterizing electronic stethoscopes (655 2002). Ideally, an experimental setup similar to the one described by Watrous would be built; however, such a setup maybe difficult to arrange. This same test will be run several times with the electronic stethoscope running in its three filtering modes. The result should show that the undesired frequencies are highly attenuated.

7.2.4 Power Usage

The power consumption of the electronic stethoscope will also be tested. The current draw of the device running in its different modes will be measured and battery life will be computed from this measurement.

7.2.5 Audio Storage

Also to be tested is the storage of the audio files in non-volatile memory. The stethoscope will record a number of different tracks. The device will be power cycled and the stored memory will be played back to the user. Those tests will also verify that the transfer of files from the stethoscope to a computer prompts for authorization to comply with HIPAA regulations.

7.2.6 Environmental

The formal tests will specify a verification of the BOM to insure that the device is ROHS compliant.

8 Budget

8.1 Prototype Cost Estimates

The prototype, as defined by the team in the objectives (see Section 2), will have costs associated with purchase of individual components, board layout design, PCB fabrication and population, and shipping and handling. The team aims to have a working prototype that can be shown in the final presentation.

8.1.1 BOM

Costs associated with the individual components will consist mostly of shipping and handling, since the circuit elements themselves have such a small individual cost. Many of the more expensive parts—the microprocessor, flash, RAM, and CODEC—have been given to the team as sample parts for prototype models. The most expensive individual component for the prototype will be the LCD screen.

Table 8.1 lists the estimated number of components, their types, costs, amounts, and whether they may be obtained as samples.

Table 8.1: Component Costs

Part Type	# of parts	Decided	Sample Parts	Supplier	Part Cost	Cost to team:
MicroProcessor	1	Yes	Yes	Freescle	\$ 12.00	\$ 00.00
Flash (512 Mb)	1	Yes	Yes	Spansion	\$ 5.00	\$ 00.00
RAM	1	Yes	Yes	Micron	\$ 4.00	\$ 0.00
CODEC	1	Yes	Yes	Wolfson	\$ 3.00	\$ 0.00
LCD Screen	1	No	No	-----	\$ 20.00	\$ 20.00
Microphone	1	No	No	-----	\$ 2.00	\$ 2.00
Battery	1	No	No	-----	\$ 15.00	\$ 15.00
Analog Parts	161	No	No	-----	\$ 38.00	\$ 38.00
Connectors	8	No	No	-----	\$ 11.00	\$ 11.00
Total:	176				\$ 110.00	\$ 86.00

8.1.2 PCB

Currently, the estimate for PCB fabrication and population is \$300 per board. This price was given as an estimate by Petra Electronic Manufacturing Inc. They are currently the supplier selected for fabrication and population; however, this is subject to change because the design will not be out for fabrication until March. The team will continue to pursue all options until the layout deadline.

The current disadvantage with using Petra is that its population process requires a high quality stencil for the solder paste. The team is researching different possibilities for obtaining either off-the-shelf stencils provided by chip manufacturers, or having stencils made by a third party. It may be necessary to have the PCBs fabricated by one company and populated by another company; however, this may add complexity in managing the delivery of boards and parts to different companies.

The design of the PCB will be done by the team, which does have access to current software packages supported by most PCB shops, including Eagle PCB and Pspice. The team is hoping to receive PCB footprint drawings that it can insert into these layout editors to ensure accuracy of footprint and to reduce the design time.

Table 8.2 lists the fabrication and population quotes of several different companies.

Table 8.2: Current Quotes

Company	Price Per Board	Advantages	Disadvantages
Petra	\$300	Less expensive, closer to Michigan, no minimum order, have given student discounts before	Smaller company, requires costs for stencils for BGA's
Nexlogic	\$200	Can help with design, large company	10 board minimum
PCB express	\$300	More cost effective for fabrication	No population capabilities

8.1.3 Software

8.1.3.1 Embedded Software

All software embedded in the prototype will be either open source or written by the team. Currently, the only third-party software being used on the prototype is μ Clinux, the chosen operating system. Because it is open source, the team will not have to pay for use of μ Clinux.

8.1.3.2 Development Software

Software used to design the prototype (schematic, PCB layout) and develop the prototype software will be provided by supporting companies, open-source projects, and Calvin. Software programs used will include (but not be limited to): background debug modules, schematic editors and simulators, and PCB layout software. CodeSourcery has donated a license for their Sourcery G++ for μ Clinux IDE. This software, in conjunction with open-source GNU tools, will be used for software development. Therefore, the team does not expect to incur any software costs during prototyping.

8.1.4 Total

The total cost for components, PCB fabrication, population, stencils, and shipping and handling is estimated at \$586. Table 8.3 shows the total estimated costs per board for prototyping. The cost of stencils will be a factor if the team chooses to use Petra to populate the prototype. This prototype estimation is within the team budget.

Table 8.3: Prototype Costs

Component	Cost
Components	\$ 86.00
Software	\$ 00.00
PCB Fabrication	\$ 150.00
PCB Population	\$ 150.00
Stencils	\$ 200.00
Total:	\$ 586.00

8.2 Team Budget

The team budget is presented in Table 8.4. This budget represents monthly totals throughout the semester for hard costs (purchased components, 3rd party expenses), soft costs (team labor, donated parts), and income. Currently, the budget includes the donation from the team's sponsor DornerWorks, but does not include monetary support from Calvin. It is assumed that if the team does not use the entire donation from DornerWorks, Calvin will not give the team any additional funding.

Table 8.4: Budget

Hard Costs	September	October	November	December	January	February	March	April	May	Total
BOM	\$0.00	\$0.00	\$0.00	\$0.00	\$110.00	\$0.00	\$0.00	\$0.00	\$0.00	\$110.00
Services	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$600.00	\$0.00	\$0.00	\$600.00
Hard Costs Total:	\$0.00	\$0.00	\$0.00	\$0.00	\$110.00	\$0.00	\$600.00	\$0.00	\$0.00	\$710.00
To Date:	\$0.00	\$0.00	\$0.00	\$0.00	\$110.00	\$110.00	\$710.00	\$710.00	\$710.00	\$710.00

Soft Costs	September	October	November	December	January	February	March	April	May	Total
Hours	\$8,000.00	\$16,000.00	\$20,000.00	\$8,000.00	\$16,000.00	\$24,000.00	\$32,000.00	\$32,000.00	\$12,000.00	\$168,000.00
"Free" parts	\$0.00	\$0.00	\$20.50	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$20.50
"Free" tools	\$0.00	\$0.00	\$2,320.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$2,320.00
"Free" Services	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Soft Costs Total:	\$8,000.00	\$16,000.00	\$20,020.50	\$8,000.00	\$16,000.00	\$24,000.00	\$32,000.00	\$32,000.00	\$12,000.00	\$168,020.50
To Date:	\$8,000.00	\$24,000.00	\$44,020.50	\$52,020.50	\$68,020.50	\$92,020.50	\$124,020.50	\$156,020.50	\$168,020.50	\$168,020.50

Month:	September	October	November	December	January	February	March	April	May	Total
Total Costs	\$8,000.00	\$16,000.00	\$20,020.50	\$8,000.00	\$16,110.00	\$24,000.00	\$32,600.00	\$32,000.00	\$12,000.00	\$168,730.50
Income	\$0.00	\$0.00	\$0.00	\$0.00	\$1,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$1,000.00
Cost to Date:	\$8,000.00	\$24,000.00	\$44,020.50	\$52,020.50	\$68,130.50	\$92,130.50	\$124,730.50	\$156,730.50	\$168,730.50	\$168,730.50
Income To Date:	\$0.00	\$0.00	\$0.00	\$0.00	\$1,000.00	\$1,000.00	\$1,000.00	\$1,000.00	\$1,000.00	\$1,000.00

Net Soft Balance:	-\$167,730.50
Net Hard Balance:	\$290.00

Currently, the estimated cost for parts and services is \$710. Given that these are the only hard costs for the team, the team is within budget by \$290 assuming a \$1,000 donation. Cost of labor by the team is calculated at \$100 an hour.

9 Work Structure

9.1 Team Organization

Each team member has different interests, strengths, and experiences, and these are reflected in the tasks that the member is assigned. The team does not have a specific leader, rather each member is assigned an area of responsibility by team consensus. A team member in charge of a certain area may delegate certain tasks to other members as needed. Members formally report their progress to the rest of the team at weekly meetings, or informally during the week as needed. Email is used extensively as another method of communication.

9.2 Task Specification

9.2.1 Administration

There are a number of tasks that must be completed on an ongoing basis for the team to function coherently.

9.2.1.1 Status Reports

A summary of the team's hours, goals, accomplishments, and encountered issues is emailed to Dr. VanderLeest on Wednesday every week. Each team member is responsible for entering their hours in a time spreadsheet and for emailing a summary of their work to David, who compiles the status report and sends it to Dr. VanderLeest.

9.2.1.2 Meeting Agendas

Andy and Ben share the responsibility of writing agendas for the weekly team meetings. Team members suggest agenda items to Andy or Ben as needed.

9.2.1.3 Meeting Minutes

Andy is responsible for taking notes during team meetings, compiling these notes into meeting minutes, and for emailing the list of action items to the team.

9.2.1.4 Scheduling

Ben and David share responsibility for maintenance of the Microsoft Project file that tracks the progress of the team throughout the year.

9.2.1.5 Information Technology

David is responsible for information technology support matters. This includes project folder organization, installation and maintenance of workstation software and operating systems, and administration of the team's local area network.

9.2.1.6 Website Design and Maintenance

David is responsible for the design of the team website and for updating it on a regular basis.

9.2.1.7 *Finances*

Ben is responsible for maintaining the team's finance spreadsheet. Each team member is responsible for adding expenses that they have incurred.

9.2.1.8 *Marketing and Graphics*

Nate is responsible for producing marketing materials and graphics for use in team documents. This includes working with David on the design of website graphics.

9.2.2 *Documentation*

Each team member is responsible for generating documentation of their particular area of design. In some cases, one team member is assigned to write a document that is reviewed by the entire team. For larger documents such as this PPFS, sections are assigned to team members by area of specialty and then reviewed by other members of the team. The documentation that must be submitted throughout the year includes the Project Definition, Project Objectives, PPFS Table of Contents, Industrial Consultant Brief, PPFS Draft, PPFS Final, and Final Report. In addition, each team member maintains a Design Notebook containing class notes, job search notes, and design notes.

9.2.3 *Presentations*

The team must make six presentations throughout the year: four to the class, one to the Calvin Engineering Advisory Council (CEAC), and one to the larger Calvin community on senior design night. The team also presented a project overview to DornerWorks for funding consideration. Each team member shall present at least once during the year. All presentations are reviewed by the team, even if they are given by only one or two team members. The team shall prepare collectively for major reviews with engineering faculty and industrial consultants.

9.2.4 *Research*

9.2.4.1 *Intellectual Property Research*

Andy has the responsibility for conducting patent research and determining if the team's device will infringe or derive from any other entity's intellectual property rights.

9.2.4.2 *FDA Validation Research*

David has the responsibility for researching pertinent FDA regulations that the team must comply with for the device to be accepted in the medical market.

9.2.4.3 *Market Research*

David is responsible for market research, including conducting surveys of the medical community and researching existing products similar to the team's device.

9.2.4.4 *Design Research*

Each team member is responsible for conducting design research in their particular area of specialty.

9.2.5 *Hardware Selection*

Decisions on hardware selection are made by the team as a whole. However, certain members are responsible for presenting different options, along with their advantages and disadvantages, to the rest

of the team. Ben and David are responsible for researching microprocessor options, David is responsible for researching software options, Ben is responsible for researching CODECs, RAM, and flash, Andy is responsible for researching microphones and chest piece hardware, and Nate is responsible for researching human interface and power system options.

9.2.6 Chest Piece Design and Testing

Andy has responsibility for the design and testing of the chest piece and the associated analog electronics. This category includes microphone testing, microphone selection, COTS chest piece selection, chest piece prototyping, and chest piece audio testing.

9.2.7 Power System Design

Nate has responsibility for designing the device power system. This includes tasks such as battery selection and voltage regulation design.

9.2.8 Software Design

David is leading the software design process. There are many subtasks under this category, and they will be assigned by area of specialty so that each team member is responsible for writing software for their area of design. David is responsible for OS, bootloader, flash interface, and USB interface development. Nate is responsible for LCD and button interfaces, audio compression and storage, and the RAM interface. Andy is responsible for DSP development. Ben is responsible for audio streaming and playback and the CODEC interface. Each member shall be responsible for testing their own software.

9.2.9 PCB Design

Ben shall be responsible for leading the PCB design effort. Each team member shall generate circuit schematics for their area of specialty and Ben shall integrate these circuits as specified. Ben is also responsible for researching different population and fabrication companies.

9.2.10 Requirement Testing

Each team member shall be responsible for testing the functionality of his particular area of design.

9.3 Schedule

9.3.1 Milestones

The team has defined a variety of milestones to accomplish over the course of the next semester. These are defined in Table 9.3. If these milestones are not completed by the indicated date, contingency time will be used to finish them.

Table 9.3: Project Milestones

Milestone	Definition	Status
1	Boot μ Clinux and run "Hello World" program	Done
2	Finish PPFS	Done
3	Interface LCD with development board.	By February 15
4	Interface CODEC control to enable pass through audio	By February 15
5	PCB layout complete	By February 28

6	Stream audio from CODEC through microprocessor. Filter the streaming audio.	By February 29
7	Chest piece completed and tested	By March 9
8	Transfer a file to the development board over Ethernet and transfer it back to computer over USB. Have the development board show up to the computer as a mass storage device using generic drivers.	By March 15
9	Receive PCB.	By March 20
10	Record audio input from chest piece.	By March 21
11	Boot μ Clinux from FLASH using custom boot loader	By March 23
12	Playback recorded audio through headphones.	By March 28
13	Requirement Testing Complete	By April 3
14	Finish Final Report	TBD

9.3.2 Overview

The Microsoft Project schedule was generated by setting the final deadline for the project and then working backwards. Figure 9.1 shows the schedule for the year with the subtasks hidden. A contingency time of 20 days has been included at the end of the semester.

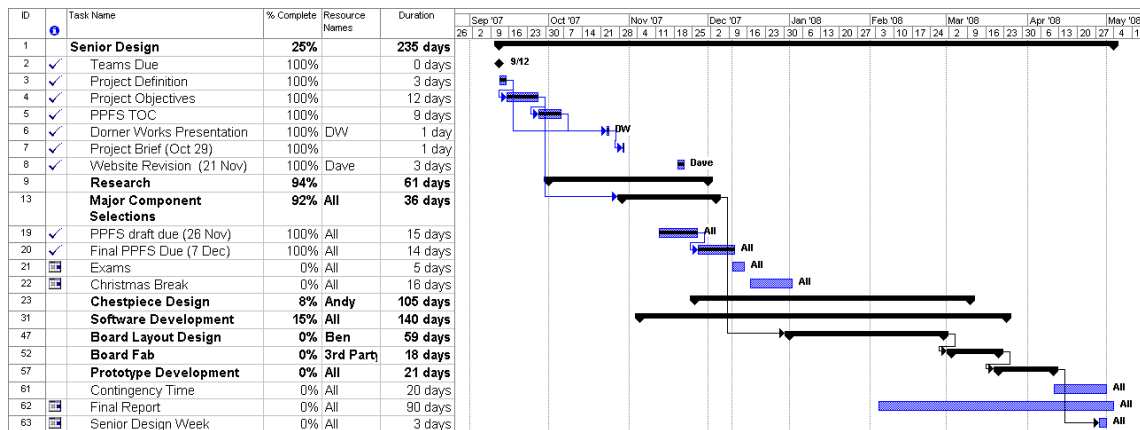


Figure 9.1: Overall Schedule

9.3.3 Software Design

Because of the capabilities of the development board, the majority of software development can be done in parallel with the hardware design. This gives the team an advantage because the time spent on software development will not depend on hardware design. OS development on the development kit has already begun. Figure 9.2 shows the schedule for the software design subtasks.

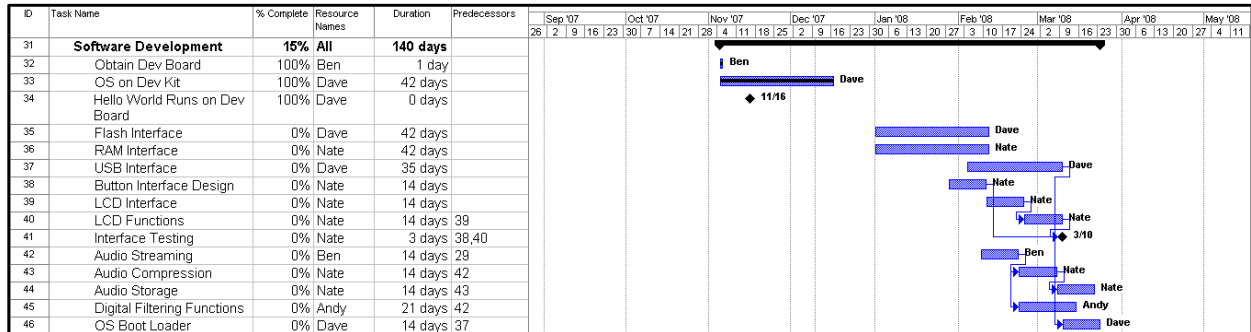


Figure 9.2: Software Development Subtasks

9.3.4 PCB Design

Schematic generation will begin in January. PCB layout design will begin once schematic generation is complete. Figure 9.3 shows the PCB design, fabrication, and population schedule.

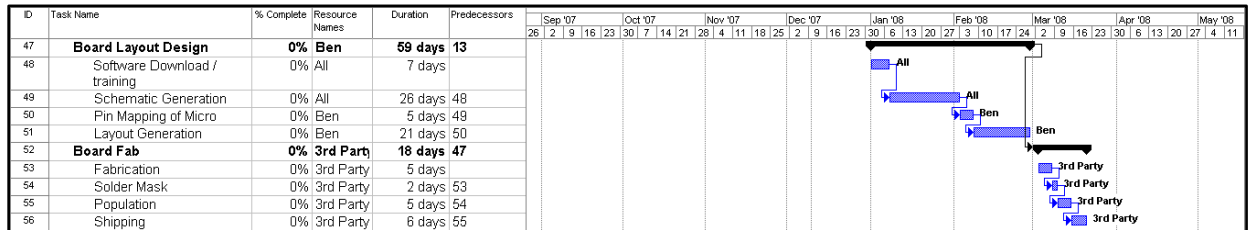


Figure 9.3: PCB Subtasks

9.3.5 Chest Piece Design

The chest piece design process includes the microphone testing and selection, the prototyping of the chest piece, and the analog audio interface design. Microphone testing has already begun, and this process will continue through January of 2008.

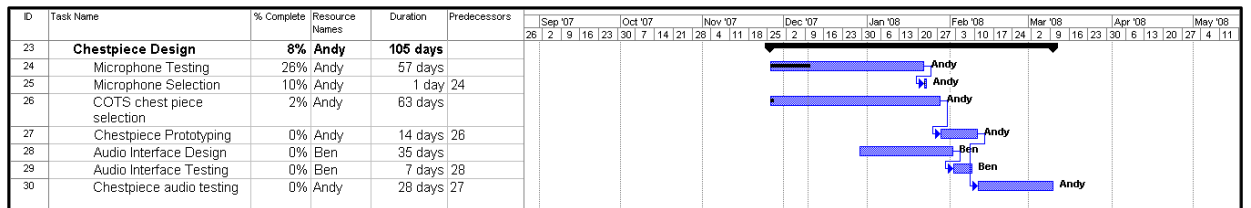


Figure 9.4: Chest Piece Subtasks

10 Final Market Product Design

The team has decided that the final market product should differ from the prototype in several significant ways. For the device to stand out in the market, a wireless chest piece design should be pursued. Several patents exist for wireless stethoscopes and are listed in Appendix C; however, there are no wireless stethoscopes on the market. Another major difference is the mechanical design. The prototype will have minimal mechanical design due to time constraints, but the final product will require significant case packaging design to make it durable, ergonomic, and aesthetically pleasing. Also, a wireless chest piece will require a redesign of the prototype chest piece to make room for the transceiver and battery. The prototype will use a character LCD, but the final market product should use a graphical LCD to increase the aesthetic appeal. The final product could also come in several different models, such as a budget model targeted toward nurses and an executive model targeted toward doctors. The final product could also come with a diagnostic software package for analyzing the recorded body sounds on a computer. These are aspects of the design that the team would like to pursue; however, they are beyond the scope of this project.

11 Conclusion

Feasibility can be evaluated on three different levels: budget, schedule, and scope.

11.1 Budget

Because of the donations of material received by the team, many of the major project costs have been mitigated. With the financial support provided by DornerWorks or Calvin, the team will be able to meet all expenses incurred over the year. In the unlikely event that the team finds itself underfunded, some plans, such as multiple prototype boards, may need to be abandoned, but this will not affect the overall success of the project.

11.2 Schedule

All project tasks have been scheduled using Microsoft Project. The team is currently on schedule, and there are no indications that this will change in the near future. The team has included twenty days of contingency time to deal with any problems that arise.

11.3 Scope

The team has precisely outlined the scope of the project such that it presents a challenge while remaining feasible. The focus of the project shall be on the crucial aspects of the project such as audio performance, recording, and file transfer, while aspects such as mechanical design and aesthetics will only be addressed only if time permits. All technical aspects of the project have been previously proven in other applications; the originality of this project lies in its combination of these aspects. The team feels that it has the expertise and experience in the areas required to bring these elements together into a coherent and functional package.

11.4 Feasibility Verdict

Based on the planning and design work done throughout the first semester, the team concludes that the project is feasible.

Acknowledgments

The team would like to thank the following people and organizations for their assistance:

Dick Almay, Spansion, for providing sample flash components.

Francis Andries, Andries Auscultation, for helpful advice on the design of electronic stethoscopes and a generous donation of his book on auscultation, his heart sound CD, and “The Patient”

Dr. Rob Bossemeyer, for meeting with the team to give advice on Digital Signal Processing.

Todd Burghgraef, David Dorner, Tim Walker, and Andy Wallner of **DornerWorks Embedded Systems Engineering** for meeting with the team and expressing their corporate desire to support the project.

Dr. Randall Brouwer, for sharing his knowledge of the SREC format and information about LCD modules.

CodeSourcery, for donating a license for its *Sourcery G++ for μ Linux* IDE to the team.

Bob DeKraker, for helping the team with parts ordering and IT support.

David Dunayczan, Freescale Semiconductor, for providing invaluable support with the donation of two microprocessor development boards.

Dr. Srinivas Janardan, Grand River Gastroenterology, for meeting with the team and providing valuable feedback on the proposed stethoscope, and for giving the team contact information for two cardiologists.

David Josephson, Josephson Engineering, for providing helpful advice on microphone selection.

Tim Theriault, GE Aviation, for meeting with the team to give advice and discuss the feasibility of the project.

Dr. Steven VanderLeest, for advising the team and evaluating coursework.

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Appendix A: Requirements

1. Main Objectives
 - 1.1. Have a demonstrable electronic stethoscope that meets or exceeds the project requirements
 - 1.2. Have a Project Plan that includes the design, prototyping, and business aspects of full-scale production
 - 1.3. Have a device that meets design norms of Transparency, Integrity, Stewardship
2. Course Requirements
 - 2.1. The team shall exhibit excellent team cooperation
 - 2.1.1. Team members shall give a full report in team meetings of progress or, if absent, an email of a full report
 - 2.1.2. Team members shall seek approval for final design choices from the entire team
 - 2.2. The team shall meet all deadlines in a timely fashion
 - 2.3. The team shall submit all required documents
3. Product Requirements
 - 3.1. Functional
 - 3.1.1. Normal Operation
 - 3.1.1.1. The Device shall stream audio data from the patient to the user
 - 3.1.1.2. The Device shall minimize ambient noise
 - 3.1.1.3. The Device shall have a method for controlling the volume
 - 3.1.1.4. The Device shall have a method for muting the audio output
 - 3.1.1.5. The Device shall provide a method to emphasize sounds from the heart, lungs, and bowels
 - 3.1.2. Recording
 - 3.1.2.1. The Device shall record audio from a patient's body
 - 3.1.2.2. The Device shall playback previously recorded audio
 - 3.1.2.3. The Device shall have a method for navigating menus
 - 3.1.2.4. The Device shall have a method for controlling the recording and playback process
 - 3.1.2.5. The Device shall have a method for naming files
 - 3.1.3. The Device shall transfer audio files to a computer
 - 3.2. Power
 - 3.2.1. Power Source
 - 3.2.1.1. The Power source shall be readily available for the user ("standard" batteries, normal power jacks)
 - 3.2.2. Power Consumption
 - 3.2.2.1. The device shall be operable for an eight hours (length of a nurse's working shift)
 - 3.3. Physical
 - 3.4. Audio Performance
 - 3.4.1. The Device shall accurately reproduce body sounds
 - 3.5. Interface
 - 3.5.1. Human
 - 3.5.1.1. The device shall have a tactile interface to control operation
 - 3.5.1.2. The device shall have a visual interface for the user to see information about the devices operation

- 3.5.1.3. The device shall have an audio interface for the user to hear sounds produced by the body
- 3.5.2.Data
 - 3.5.2.1. The Device shall interface to a PC for audio file transfer
- 3.6. Media Storage
 - 3.6.1.1. The Device shall store audio files in non volatile memory
 - 3.6.1.2. The Device shall comply with HIPAA regulations
- 3.7. Environmental
 - 3.7.1.Materials
 - 3.7.1.1. The Device shall be latex free
 - 3.7.1.2. The Device shall be RoHS compliant
 - 3.7.2.ESD
 - 3.7.2.1. The Device shall be able to withstand static discharge
 - 3.7.3.Operating Temperature
 - 3.7.3.1. The Device shall be able to operate in standard operating conditions
 - 3.7.4.Sterilization
 - 3.7.4.1. The Device shall be able to be sterilized with mild chemical cleaners
- 3.8. Economic
 - 3.8.1.The final market device shall cost the same or less then competitive products
- 3.9. Safety
 - 3.9.1. The Device shall not emit sounds harmful to the user

Appendix B: Test Report Form

[Rhythm Reloaded]		
Team 6: Nate Brinks, Andy Gabler, Ben Moes, David van Geest		
Informal Test Procedure		
Item Under Test:	Name:	
Functional Block:	Date:	
<u>Test Description:</u>		
<u>Results:</u>		
<u>Application to Project:</u>		

Appendix C: Patent Research Summary

Search "electronic stethoscope"				
Publication number	Title	Conflict	Comments/Description	Year
US020070154024A1	[EN] Electronic stethoscope	no	Identical to AG_OD -- US000005825895A	2007
US020060245597A1	[EN] Detection of coronary artery disease using an electronic stethoscope	no	A system using recorded data from an electronic stethoscope to detect a certain disease using signal processing.	2006
US020060227979A1	[EN] Contact type electronic stethoscope with a noise interference resisting ...	no	Specially formed chest piece using a piezeo transducer and special way to offset from body to reduce noise.	2006
US020060098825A1	[EN] Electronic adaption of acoustical stethoscope	no	Application: places an adapter into a stethoscope that transmits data via IR to a PDA type device for further use.	2006
US020050157888A1	[EN] Electronic stethoscope with piezo-electrical film contact microphone	no	Describes a traditional look but using a piezeo transducer and wireless transmit to a computer. Neat	2005
US020050107715A1	[EN] Electronic stethoscope system	no	A reciever listening device to listen while in auscultation and a remote device over RS232 for the listening.	2005
US020040105556A1	[] Electronic stethoscope measurement system and method	no	Application: Describes a method for measuring Electronic Stethoscopes	2004
US020040096069A1	[EN] Electronic stethoscope	no	Application: Describes an electronic stethoscope that looks traditional with inline devices that connects to a computer	2004
US020030072457A1	[] ELECTRONIC STETHOSCOPE	no	Patent Application for US020070154024A1	2003
US020030002685A1	[] Electronic stethoscope	no/pos	Application: an auscultation aid that couples with an acoustic but also it possibly could transmit wirelessly to base station which transfers real time to computer.	2003

Publication number	Title	Conflict	Comments/Description	Year
US020020186851A1	[] International battery holder for use with a electronic stethoscope	no	Application: Describes a battery placement/holder in chest piece	2002
US020020186850A1	[] Rotating control barb for use with an electronic stethoscope	no	Application: Describes a control feature by twisting the head it is a switch.	2002
US020010014162A1	[] PICK-UP HEAD FOR AN ELECTRONIC STETHOSCOPE	no	Application: Combines a piezo transducer with a little peg and a bell shaped head.	2001
US000007115102B2	[EN] Electronic stethoscope system	no	Patent for US020050107715A1 application	2006
US000007006638B1	[EN] Electronic stethoscope	no	Describes a stethoscope using a vibration sensor and digital filtering and in ear headphones for those hard of hearing. Very vague.	2006
US000006757392B1	[] Electronic stethoscope	no	Describes a traditional looking electronic stethoscope but it has three electrodes for taking an ECG and an LCD to display it on the chest piece has ear pieces as well.	2004
US000006396931B1	[] ELECTRONIC STETHOSCOPE WITH DIAGNOSTIC CAPABILITY	no/build	Describes a self contained device with a screen but has built in speaker and stores typical sounds to compare with what is heard. Chest piece built into device.	2002
US000006324289B2	[] PICK-UP HEAD FOR AN ELECTRONIC STETHOSCOPE	no	Patent for US020010014162A1 application	2001
US000006134331A	[] ELECTRONIC STETHOSCOPE	no	Identical to US000007006638B1	
US000006026170A	[] ELECTRONIC STETHOSCOPE WITH IDEALIZED BELL AND IDEALIZED DIAPHRAGM ...	no	Describes a stethoscope with ideal 'diaphragm' and 'bell' modes to model acoustic styles. Same package as a traditional stethoscope. All analog no digital it seems. Battery low.	2000
US000006005951A	[] ELECTRONIC STETHOSCOPE	no	Same as US000005825895A	1999

Publication number	Title	Conflict	Comments/Description	Year
US000006002777A	[] ELECTRONIC STETHOSCOPE	no	Same as US000005825895A	1999
US000005825895A	[] Electronic stethoscope	build	Describes a stethoscope with several "modes" of operation: heart, lungs, abnormal heart and normal heart boost. Same package as a traditional stethoscope. Digital but no recording.	1998
US000005774563A	[] COMBINED ELECTRONIC ACOUSTICAL STETHOSCOPE	no/build	Describes a dual electronic/acoustic stethoscope. Rotatable head. Mic placement in head is only concern. Placed in line with air going up tube.	1998
US000005561275A	[] Headset for electronic stethoscope	no	Describes a Headset to use with an Electronic Stethoscope.	1996
US000005557681A	[] Electronic stethoscope	no	Describes mic in a handheld box with an adjustable analog active filter. Amplifies what it hears through headphones.	1996
US000005367575A	[] Electronic stethoscope having battery carriage	no	Describes a traditional looking device which uses a mic and reproduces that for the ear pieces. Has a removable pattery cartridge.	1994
US000005347583A	[] Electronic stethoscope having binaural earpiece	no	Describes a traditional looking device. Analog electronics and mics mixed with accoustical tubing.	1994
US000004792145A	[] Electronic stethoscope system and method	no	Descirbes a frequency shifting system for hearing the inaudible.	1988
US000004783813A	[] Electronic sound amplifier stethoscope with visual heart beat and ...	no	Describes a traditional looking stethoscope with a small box with LEDs showing the pulse rate and indicating blood flow.	1988
US000004618986A	[] Electronic stethoscope	no	Described a traditional looking stethoscope with chest piece assoustically coupled with mic in a box at joint going to ear pieces that amplifes the sound.	1986

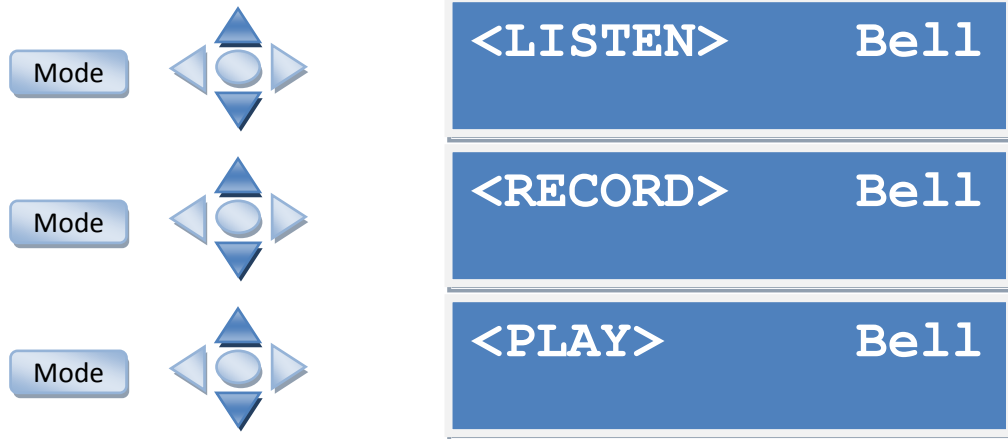
Publication number	Title	Conflict	Comments/Description	Year
US000004598417A	[] Electronic stethoscope	no	Describes a traditional style but with mics that run a variable gain amplifier.	1986
US000004594731A	[] Electronic stethoscope	no	Describes and electronic stethoscope that frequency shifts the signal to a more audible range	1986
US000004534058A	[] Electronic stethoscope with automatic power shut-off	no	Describes a traditional looking device. Turns off automatically. Uses analog components.	1985
US000004498188A	[] Electronic stethoscope for monitoring the operation of a prosthetic ...	no	Describes a electronic stethoscope for monitoring prosthetic heart valves.	1985
US000004254302A	[] Electronic stethoscope	no	Describes a traditional looking scope that has an mic - amplifier - then speakers in line.	1981
US000004170717A	[] Electronic stethoscope	no	Describes a stethoscope with detachable ear pieces and optional hook up to analog recording device.	1979
US000003790712A	[] ELECTRONIC STETHOSCOPE SYSTEM	no	Describes head containing mic with a Class A amplifier outputting to anything one wants (multiple headphones, tape, etc...)	1974
US000003539724A	[] COMBINATION ELECTRONIC AND AIR-COLUMN ACTUATED STETHOSCOPE	no	Old: acoustic electric box with volume and tone nob.	1970
Search "wireless stethoscope"				
US020010050992A1	[EN] Two-piece wireless electromechanical corpometer/stethoscope	no	This is an application. Sends signal wirelessly from chest piece to headphones but by analog means.	2001
US000006533736B1	[] Wireless medical stethoscope	possibly	Devices has a J shaped clip to the ear which connects with the detachable chest piece and all slides into a carrying case. Transmits wireless sounds not a digital kind of unspecific in format. But no body pack.	2003

Others found out of Google Patent Search				
Publication number	Title	Conflict	Comments/Description	Year
US000005602924	Electronic Stethoscope	no	Describes an electronic stethoscope designed to reduce noise handling and ambient as much as possible.	1997
US000005932849	Stethoscope having microphone therein	possibly	Describes a chest piece with a microphone with in the acoustic pathway.	1999
US000000361840	Stethoscope Head	no	Ornamental design for a electronic stethoscope head.	1995
US000003525810	Microphone assembly for use in a stethoscope	no	Describes a microphone assembly with fluid cushion to minimize handling noise.	1966
US000006498854	Transducer for sensing body sounds	no	Describes a transducer that is essentially an electret mic probably bigger.	2002
US000005610987	Active noise control stethoscope	no	Describes a stethoscope with three audio transducers all piezo. The stethoscope is designed to minimize noise.	1997
US000006340350	Transmitter/Receiver stethoscope and holder therefor	no	Describes a stethoscope with removable wireless chest piece and the housing device with wireless ear pieces.	2002
Legend (Conflict Column):		no/pos	Probably will not conflict with the team's design but it might	
		no/build	Probably will not conflict but might be a building block	
		build	Project may possibly build on this patent.	
		possibly	May conflict with the design but probably not	

Appendix D: HMI Operation

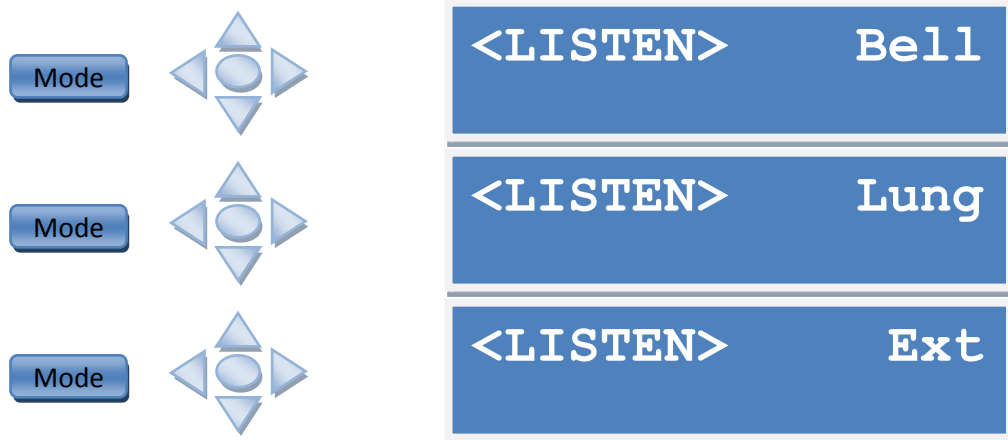
OPERATIONAL MODES:

Pressing the Up or Down keys cycle through the available operational modes.



LISTEN:

Pressing the Mode button cycles through available filtering modes.



RECORD:

Pressing the Mode button cycles through available filtering modes.





Start a Recording:

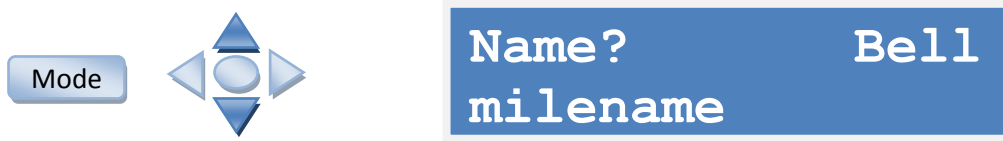
Pressing the action button in the record menu prompts the user to enter a file name.



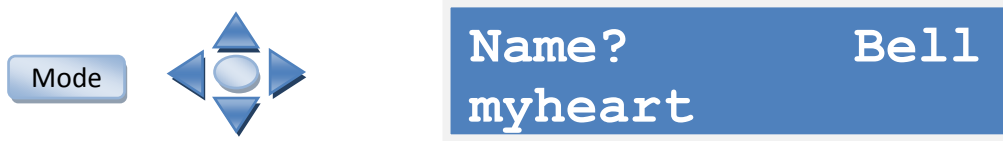
Pressing the Left/Right keys moves the cursor left and right



Pressing the Up/Down keys cycles through the available ASCII characters.



Combine the functions of the Up/Down/Left/Right Keys to enter the filename



Pressing the action button will start the recording process. The filename and record time are displayed.



Pressing the action button again will stop the recording process.



PLAYBACK:

Pressing the Left/Right keys cycles through the available recordings.



Pressing the action key plays the selected recording.



Pressing the Left/Right keys rewinds and fast forwards through the recording.



Pressing the action key stops the playback.



Appendix E: Survey Results

Question 1: What is your position in the medical community?		
	Number of Responses	Percentage of Responses
EMS	0	0
Nurse	21	70
Doctor	2	6.7
Student	6	20
Professor	0	0
Other	1	3.3
No Response	0	0
Other Responses: Nurse Practitioner		

Question 2: In what setting do you work, volunteer, or study?		
	Number of Responses	Percentage of Responses
Hospital	8	26.7
Clinic	5	16.7
Private Practice	1	3.3
University/College	1	3.3
Hospice/Home Care	14	46.7
Other	1	3.3
No Response	0	0
Other Responses: Correctional Institution		

Question 3: Please state your gender and age		
	Number of Responses	Percentage of Responses
Male	6	25
Female	17	70.8
No Response	1	4.2
18-29	7	25
30-39	2	7.1
40-49	3	10.7
50-60	11	39.3
60+	5	17.9

Question 4: Do you use a stethoscope regularly?		
	Number of Responses	Percentage of Responses
Yes	30	100
No	0	0

Question 5: What do you like about your current stethoscope?
Responses:
It amplifies 10x normal
Lightweight (3)
"heavy to hear"
Great sound quality
Convenient
Quality
Clarity
Portable (2)
Size
Good sensitivity, easy to work with
Simple to use and operate
It works well
Durable
Trust, replaced every 3 years
It does the job
It works well
Good length, can reach patient easily
I'm not as happy with it as I thought I would be. Of course, a stethoscope is necessary to my job and I couldn't do without it.
It's light weight. It has both a bell and a diaphragm easily accessible. It's very clear. It's easy to warm up the diaphragm.
It's blue and fits my face well
I use a Littmann Select which I like mostly because it doesn't have a bell side – if I press down lightly I can hear the high frequency sounds and if I press down more firmly I hear low frequency sounds.
Dual heads, dual tubes, sound acuity
Comfortable, long time use
Can be used for both children and adults
Strong amplification

Question 6: What do you dislike about your current stethoscope?

Responses:

Company says it can only be cleaned with soap and water, not alcohol wipes. Used something stronger, discolored it.

Earpieces turn and hurt ears

Earpieces hurt

Uncomfortable earpieces. Had to replace them.

Hard to hear sometimes, esp. w/ obese patients

Can't always get rid of external noises

Size of earpiece

Can't always pick up sounds in good quality

Heavy

Hard to hear

Hard to hear

nothing

heavy

It picks up sounds of my joint movements in my fingers making it harder for me to hear.

Can't block out outside noise

Rubber irritates skin on neck

Actually, I was just discussing our concern about hearing acuity with some physician colleagues and we were expressing concern about our own hearing capacity (we are all middle aged or older). Given the widespread use of telemedicine, this could have patient applications as well. Pulmonary changes occur even more frequently than cardiac. Homebound patients with CHF could be taught correct placement and they or a caregiver could send to a clinician.

Sometimes the ear inserts are uncomfortable or unscrew. My hearing is good (just had it checked!) and sometimes I wish I could hear better...sometimes the ambient noise interferes ...baby crying, spouse talking through the exam, etc..

I hate having it hang around my neck – it's always in the way

Bulky when worn around neck

It doesn't keep out outside noises like it's advertised to do. I'm not sure I hear any better with it than with my 30 year old stethoscope from nursing school days.

Outside noises are barely diminished causing difficulty listening to lung sounds when outside noises are present.

Pretty satisfied

The ear pieces are not the best – the softer/foamier they are the better they fit in your ear, and the better the sounds that you hear. I'd really like a cardiac stethoscope!

Length, ear pieces

Sometimes difficult to hear heart sounds, e.g. with congested lungs, sometimes difficult to hear bowel sounds

Can't increase volume

Plastic gets hard

Sounds are muffled because of background noise, doesn't quite fit into lab coat

There can be a lot of background noise

**Question 7: Have you ever used an electronic stethoscope before?
What did you like or dislike about it?**

	Number of Responses	Percentage of Responses
Yes	4	13.8
No	25	86.2
Likes/Dislike:		
	I prefer to hear things for myself	
	Expensive	
	Was able to pick up distant sounds	
	Not as clear as I would like	
	Very large and clumsy	

Question 8: Did you purchase your stethoscope with your own funds?

	Number of Responses	Percentage of Responses
Yes	21	75
No	7	25

Question 9: Would you use the electronic stethoscope described if you did not have to pay for it?

	Number of Responses	Percentage of Responses
Yes	21	77.8
No	2	7.4
Unsure	4	14.8
If you had to pay for the stethoscope yourself, would you still purchase it?		
Yes	5	17.9
No	13	46.4
Unsure	10	35.7

Question 10: Estimate how many times in 8 hours you would record audio from a patient's body, and how long these audio tracks would be

Average Number of Recordings	5
Average Length Per Recording	2 minutes
Average Recording Time Per Shift	10 minutes

Question 11: Would you want to clip the casing of the device to you belt? If not, where else?

	Number of Responses
Yes	7
No	7
Other Places:	On uniform or on top of pants
	Pocket (9)
	Scrubs
	In care bag
	On should strap
	Carrying case
	Bag
	Waistband
	Around neck

Question 12: What is the maximum amount you would pay for the electronic stethoscope described?

	Number of Responses
\$30	1
\$50	1
\$60	1
\$75	1
\$100	5
\$125	2
\$150	2
\$200	5
\$275	1
\$350	1

Question 13: What different listening modes would you like to use? Can you separate these modes by frequency?

Number of Responses	
Unsure/No Response:	5
Response:	Heart/Lung/Bowel
	Heart/Pulse
	Heart/Lung/Bowel/Carotid
	Heart rate and regularity, S1, S2, and other sounds; apical pulse

Question 14: What kind of batteries would you prefer?

	Number of Responses	Percentage of Responses
AAA	5	9.7
AA	10	32.3
Built-In Rechargeable	18	58.1
Other:	Plug into wall	
	9 volt	

Question 15: What kind of measured data would you want the stethoscope to display?

Number of Responses	
Unsure	1
Response:	Heart rate, rhythm, lung sounds (2)
	Heart rate, respirations
	Heart rate
	Heart, lung, bowel
	Heart rate, blood pressure, temperature
	Loudness of beat
	Heart rate, respiration rate, SpiO2
	Watch or stopwatch
	Rhythm, rate, murmurs
	Respiration rate

Question 16: What features of the stethoscope would you use most frequently?

Number of Responses	
Unsure	1
Response:	Heart rate/sounds
	Heart rate (2)
	Heart rate/respirations
	Audio
	Record anomalies for teaching purposes
	Turn up the audio
	To record and be able to go back and listen to what you heard earlier in the shift would be excellent to listen for small changes in breath sounds/heart tones.

Question 17: If the casing were approximately the size of an iPod video player (4" x 2" x 0.5"), would that be acceptable?

Number of Responses	
Yes	21
No	2
Unsure	4
Comments:	A little bigger

Question 18: What is your color preference for such a device?

Number of Responses	
Black	3
Silver	4
Yellow	2
Blue	1
Red	1
Purple	1
Green	1
Pink	2
Multiple	1
No Preference	9

Question 19: If recordings were named in sequence (e.g. 001, 002, 003), would that be acceptable?	
	Number of Responses
Yes	13
No	2
Unsure	1
Comments:	Patient initials (4)
	Simpler the better, remember, we're old
	Location, patient
	Most outpatient practices use patient names or initials with DOB, inpatient people get number.
	Room number
	Some link to patient info
	Select what kind of data it is (heart, lungs, apical pulse)
	Patient ID or room number
	What would be nice is if you could choose letters A-G and then have the time in hrs:min behind the letter to distinguish between patients (A-G) and assessment time.

Question 20: Other thoughts
Have built-in amplifier
One you don't have to place in ears
Need password to access data (HIPPA/confidentiality regulations)
Portable
Simple
Respectful of HIPAA
Most of the time, I use stethoscope for blood pressure. I think an item like this would be more useful doing examinations and physicals, perhaps screenings for heart issues. It would be great if ambient noise could be filtered, and if names could easily be assigned to audio files immediately, like just before recording the sounds without too much hassle.
I use my stethoscope multiple times every shift that I work. I use it to listen to heart sounds, breath sounds, and bowels sounds, and sometimes I use the small bell of my stethoscope to listen for bruits over vascular areas. I have had my stethoscope for almost 12 years, and it hasn't broken yet, so I like the durability of it.
You need to think about BBP-blood born pathogens. Providers often spread bacteria or viruses through devices. How would you prevent this? Ease of downloading data, Providers are in a hurry, support staff would have to do this. Who would support any software, hardware (including the stethoscope itself) problems. Would software be needed at both the end where data is downloaded and uploaded? Cost of this? Etc?
Sounds like a good idea overall. Best wishes!
Although the device looks nice, I would not use it. It just is not practical. Why would I want to record

<p>the data unless it is something very unusual? I am a Family Medicine physician and for routine use, there is little benefit to me to use a device like this...sounds great but I would prefer to (I must really sound old now) use my simple stethoscope. How about designing a much simpler device (please send royalties) that just augments the sound on a stethoscope?</p>
<p>Concern about storage of patient data in an instrument that would move in and out of the acute care setting – confidentiality and security of both information the device.</p>
<p>In my job at Hospice I listen to all kinds of sounds...heart...lungs...bowel sounds. **Will your stethoscope listen to/record sounds other than heart sounds? I think it would be a helpful feature as there are times when I'd love to have another health care professional listen to what I'm listening to, but because I work out of homes I'm the only professional there. Would be nice to bring it back to our office and have another RN listen to it. A case in point, I have a patient right now that suffered a bowel obstruction and was put in the hospital. She's back to the assisted living facility now and there's a question about whether she may be heading towards another obstruction. I would have loved to have had a recording of her bowel sounds to take back to my colleagues to see what they thought and compare with my findings.</p>
<p>(A question...what is "other data" that you mention in the features at the top after "calculated heartbeat"?)</p>
<p>Some people are allergic to latex. Could it be made out of a different material?</p>
<p>All in all, I think it sounds like an interesting and helpful tool! I'll be interested in seeing how your project turns out! :)</p>
<p>Some people might not want to rely on technology to do something as easy as listening to patient's heart sounds.</p>
<p>I wouldn't buy it unless the place I was working wanted us to use them because I already have a stethoscope and I just wouldn't see the need to get a new one. Some stethoscopes have a nice neck before the head of the stethoscope where you can hold it without it flopping around and therefore you don't have the sounds from where you are hold the stethoscope interfering with what you are listening too.</p>
<p>Under-chin headphones instead of overhead</p>
<p>Simple to use, easy to clean</p>
<p></p>