Cardiovascular Instrumentation

8888 University Drive, Burnaby, BC V5A 1S6
Phone: (778) 899-9351 Email: kam32@sfu.ca

March 11, 2013

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
8888 University Drive
Burnaby, British Columbia
V5A 1S6

Re: Design Specifications for Wireless Auscultation with Decision Support

Dear Dr. Rawicz:

The following enclosed document presents the design specifications for the Cardiovascular Instrumentation (CVI) wireless auscultation system with decision support. The purpose of this product is to implement an electronic stethoscope that supports automated qualitative auscultation analysis and real-time remote diagnosis via wireless communication.

This document outlines the design specifications for describing a proof of concept system. The architecture and development implemented for the prototype system aims to mediate the current issue with subjective auscultation analysis using stethoscopes in clinical practice. Further design iterations will be discussed but not implemented at this stage of development.

Please also find appended to this submission CVI's official test plan documentation for use in testing procedures. These are attached as a procedural reference to the relevant section of the document.

Please feel free to forward any questions or concerns about our proposal to (778) 899-9351 or kam32@sfu.ca. We hope that this proposal will meet your approval.

Sincerely,

Scott Greene

Scott Greene
Chief Executive Officer
Cardiovascular Instrumentation

DESIGN SPECIFICATION FOR WIRELESS AUSCULTATION WITH DECISION SUPPORT

CARDIOVASCULAR INSTRUMENTATION, LTD.

Document Revision History		
Revision	**Description**	**Date**
1.0	Submission to Dr. Andrew Rawicz and Steve Whitmore	March 11, 2013

DESIGN SPECIFICATIONS FOR WIRELESS AUSCULTATION WITH DECISION SUPPORT

EXECUTIVE SUMMARY

This document details the design specifications of Cardiovascular Instrumentation's prototype electronic wireless stethoscope with decision support software. The goal of this document is to give the reader a detailed look at each portion of the product from hardware to software and including safety and sustainability.

The hardware prototype includes three basic sections. The first is the electronic amplification and filtering circuit. This circuit is designed to read in the voltage from the microphone, amplify the signal, filter out noise and out of band frequencies, and finally convert the signal to a voltage required for the next portion of the design. This next portion is the microcontroller unit and wireless transmission system. The signal voltage passes through a analog to digital converter to create a digital value for the voltage coming from the microphone. This is then sent through the microcontroller to the wireless transmitter to be sent to the mobile device. The last hardware portion is the case and stethoscope head. The case will be designed to be light and easy to use while hanging from a cord around the neck. The microphone will be embedded near the head of the stethoscope to ensure all the sound is recorded. The distance form device to head will be optimised for comfort and user safety.

Once the signal has passed through the hardware to the mobile device it enters the software designed by CVI's expert programmers. This software will convert the signal to a visual graph as well as do minimal signal processing to assist the reader. The programming team has made sure to keep the software easy to use so that even users with minimal training will easily be able to take readings.

Safety and reliability have also been designed into every aspect of the product as well. The case will be dust and water resistance as well as being able to withstand small drops. The device will be build using many off the shelf components, thus reducing the chance of failure and allowing for a cheaper product. The actually manufacturing will be done in North America to ensure that there are no issues with build quality. Having onshore workers assemble the device will allow for greater training and quality assurance. These extra steps will ensure that customers will be happy with their products and spread news of it to their coworkers.

The final section of the report outlines some basic test plans to ensure that the prototype will meet required medical regulations before production planning begins. This section outlines specific goals that will be achieved and how they will come about. If more information is required please refer to the specific section for detailed information.

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GLOSSARY OF TERMS

AC	Alternating Current
ADC	Analog to Digital Converter
API	Application Programming Interface
CVI	Cardiovascular Instrumentation, Ltd.
DC	Direct Current
DFT	Discrete Fourier Transform
DPST	Double Pole Single Throw
ER	Emergency Room
FDA	Food and Drug Administration
FFT	Fast Fourier Transform
GUI	Graphical User Interface
IC	Integrated Circuit
iOS	Apple's Mobile Operating System
IP	Internet Protocol
JFET	Junction Gate Field-Effect Transistor
LED	Light Emitting Diode
LSB	Least Significant Bit
MCU	Microcontroller Unit
MSB	Most Significant Bit
PCB	Printed Circuit Board
RAM	Random Access Memory
SD Card	Secure Digital Card
SIT	System Integration Test
SPST	Single Pole Single Throw
TCP	Transmission Control Protocol
UDP	User Datagram Protocol
UPS	Uninterruptible Power Supply
Wi-Fi	Wireless Fidelity

1 INTRODUCTION

The CVI Analytical Wireless Stethoscope is a system that allows for wireless transmission of auscultation sounds from a stethoscope to a mobile device. Observations of heart rate, heart beat patterns and detection of abnormalities can be supported with digital signal processing of the stream of auscultation sounds. Reviewing and forwarding past records is supported via electronic storage and wireless transmission. Additionally, the live visual tracking feature of this electronic stethoscope benefits physicians who suffer from hearing disabilities and the provided visual representation of the auscultation sounds and spectral analysis will aid in honing auscultation skills for inexperienced nurses and medical students. Implications of this technology also lead to applications in telemedicine where physicians can remotely attend patients and provide quality health care to rural areas.

1.1 Scope

This document presents the design requirements of the CVI Analytical Wireless Stethoscope. The set of requirements presented will fully describe the design specifications for the proof of concept system and partially describe the specification for the production device. Requirements that are implemented are applicable to the proof of concept system and are categorized with a priority of [**Rn-p**], where **p** is A or B. Further work for future design iterations are also provided but not implemented.

1.2 Intended Audience

The intended users of this document include CVI members and potential stakeholders of this project including health care professionals and clients. Project managers can use this document as a guide to measure their progress in implementation while developers and testers can refer to this to guide their designs to reflect the required needs of this product. Stakeholders can use this guide to verify what required functions this system entitles.

2 SYSTEM SPECIFICATIONS

A high-level block diagram for CVI Analytical Wireless Stethoscope is shown below in Figure 1.

Figure 1: System Overview

The design consists of three major subcomponents: an auscultation device integrated with wireless trans-receiving circuitry, an iOS application on an Apple iPad for data interpretation and display, and a wireless communication interface – a router in our case – to link both the auscultation device and iPad. The auscultation device is a standard stethoscope modified to incorporate an electronically controlled amplification circuit consisting of high-quality components for perfect sound reconstruction. The auscultation device is connected to a microelectronic circuit where the amplified signal is converted to a wireless signal that complies with industry standards for reliability and security. The wireless signal is sent to an Apple iPadwhere it undergoes analysis specific to the cardiovascular system[1]. The application records the stethoscope data and displays the information in real-time based on incoming information representative of voltage fluctuation. Upon completion of the examination, the application analyzes the signal to discover the location of heart pulses and displays the results on screen. The four primary heart pulses during atrioventricular action are the S1, S2, S3, and S4 signals. S1 and S2 represent the lower frequency components, while S3 and S4 result from

higher frequencies emanated by the human heart [7].Upon detection of abnormalities, specifically heart murmurs, appropriate data will accompany an automatically generated alert.

The electronic auscultation circuit consists of a number of amplifiers and filter sub-components that prepare the signal for wireless transmittal as well as condition the signal for further processing in the iOS application. A small electret microphone will generate an electric signal based on the sound that it receives. Initially, this signal will pass through a low-noise preamplifier to prepare it for further processing. In the next stage, the signal is passed through a low-pass filter circuit, which will act to reduce unwanted noise in the signal. The final stage consists of a power amplifier that boosts the signal strength for analog-to-digital conversion in the Arduino later transmitted wirelessly across the network.

As briefly mentioned above, the heart generates four specific sounds referred to as S1, S2, S3, and S4.Each of these sounds is associated with a specific frequency range detectable by applying a Fast Fourier Transform (FFT) to the incoming signal. Upon separation of the respective frequency spectrums, further analysis is applied for abnormality detection purposes. If, for example, the S1 heart sound is found to contain a pattern deviating from the expected pulse, an alert is displayed on screen. The user can make an educated decision of the signal in question to determine the validity of said detection. This method provides users with a backup to traditional manual auscultation techniques in the event important murmurs go unnoticed. The generated waveforms are then saved into the central repository where authorized users may investigate the patient's data in depth.

Operation of the application requires minimal training and basic knowledge of the Apple platform. Additionally, the application is limited to preauthorized accounts as determined by the system administrator. The combination of security and minimalism minimizes any overhead that may accumulate from complicated implementations. Furthermore, automatic alerts assist the user in making informed decisions without undermining their medical knowledge. A user has the option to dismiss any information deemed fallacious by further examination. As with the example given in the previous paragraph, all alerts are stored into a database accessible by a specific set of individuals.

The proof of concept for the CVI Analytical Wireless Stethoscope encompasses all the basic functionality listed above excluding a complex database of varying heart murmurs. The addition of advanced security and database storage as defined by industry and medical standards are a result of an iterative design process ensuring a high quality product prior to market release.

3 OVERALL SYSTEM DESIGN

3.1 High Level System Design

The Wireless Auscultation device, from the end user's point of view, will consist of a handheld device and an iOS interface running on an iPad. The monitoring device will be designed in a manner that is intuitive and comfortable to use: the operation of this device will be similar to that of a standard stethoscope, and its physical footprint will not be so large as to make handheld use ungainly. The final dimensions of the device's enclosure will be determined upon the finalization of PCB layout design for the hardware described herein.

The device itself will have an intuitive appearance consisting of a standard stethoscope bell that is used for observation, a headphone port for observing a signal in real-time, and a single button for recording a period of patient cardiac activity. When the user presses the "record" button when a patient session is activated, an LED indicator will light up, and data will be transferred to and stored in the database through the iOS application.

The application will allow the user to view the information of relevant patients, view patients' previous sessions, and share information all through a user-friendly, secure interface. The software will provide data analytics on the signal in question: and anomalies the software detects will produce user alerts and direct the user to the source of the problem. For a detailed look at the user interface and analysis provided, please refer to Section 6.

Because of the fast-paced work environment of medical professionals, the device must be durable: the device shall be capable of withstanding a shock of 1000 G's, and shall be water-resistant to a NEMA-3 equivalent degree.

For a detailed description of the hardware and software components that comprise the wireless auscultation device, please refer to their respective sections of this design specification.

3.2 Software Overview

The interface for the CVI Analytical Wireless Stethoscope is implemented for iOS applications. The iOS application is the primary interface between the stethoscope and the user administering the test. Various stethoscope analytics displayed in the application include audio waveforms, sound reproduction, and automated pre-analysis of S heart pulses. Loading and saving patient data functions are displayed on the main auscultation analysis screen. The application connects to a central cloud-based data storage device capable of providing secure access and storage to patient information. Upon initial start-up of the application, the user is prompted for login credentials and encryption services are used to provide security to the system. Reliability in wireless transmission is considered in this system to minimize data loss. In Section 6, a detailed outline of these different components of the software solution is provided. Figure 2 describes the overall functionalities of the software system.

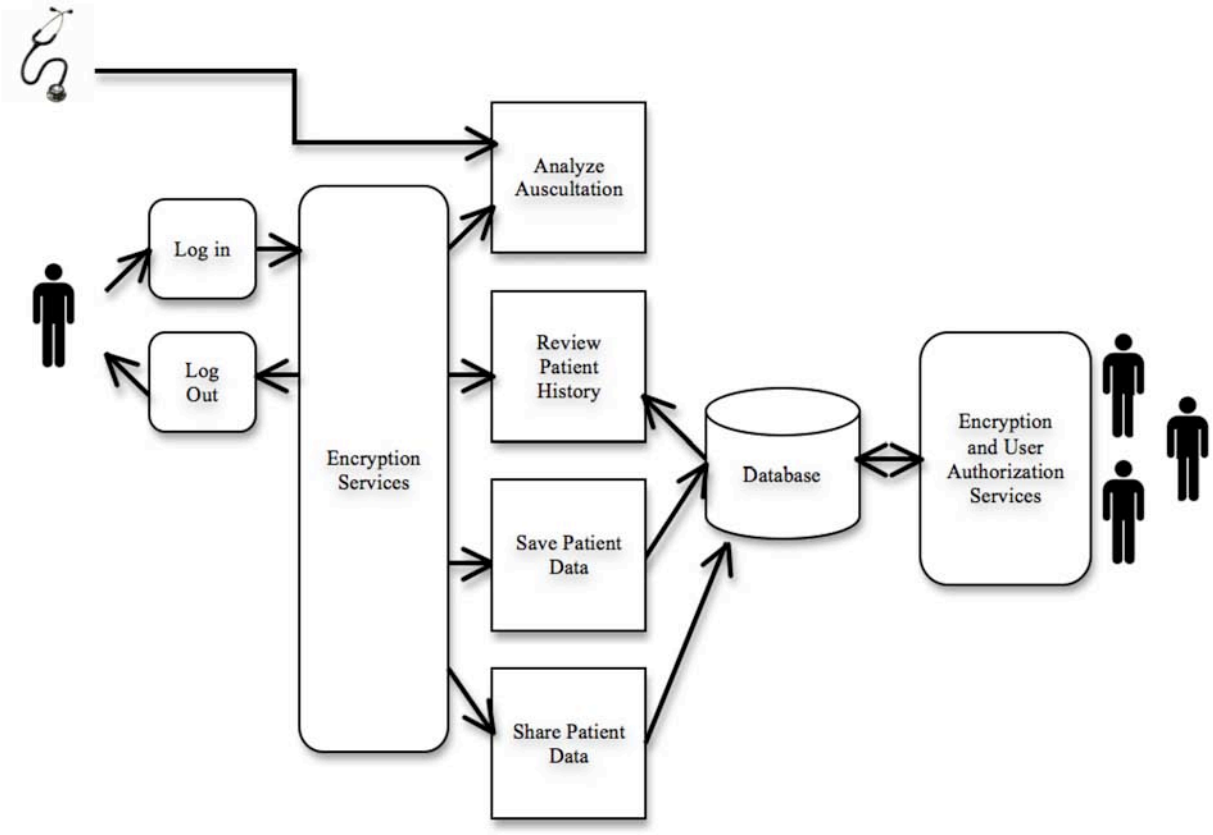


Figure 2: Overall Software System Functionalities

4 AUSCULTATION HARDWARE

This section will present the detailed design of the stethoscope amplification and filtering circuitry. The purpose of this circuit is to receive an electrical signal from an electret microphone, filter, amplify, and process the signal, and then pass it to the Arduino microcontroller board as well as an integrated headphone jack for user listening purposes. This stethoscope circuit schematic as well as a brief description of its function was procured and subsequently modified and adapted from a project on the website www.electronics-lab.com by an active contributor who goes by the pseudonym Audioguru [2]. The ultimate realization of this circuit will be constructed on a PCB using mostly surface mount components with a few necessary through-hole components. At this time, the prototype of the described circuit has been constructed using all through-hole components on a breadboard. Moving to the PCB design will allow the circuit to be miniaturized such that it will fit into a reasonably sized case as well as resulting in lower noise in the audio electronic signals.

At the time of writing this document, the schematic diagram of this circuit has been created using the Altium Designer PCB creation software [14] and the majority of figures in this section have been taken from this schematic diagram. A copy of this schematic as well as a photocopied version outlining the major sub-components can be found in Appendix A and B. The next steps for the hardware design team include:

- Transferring of Altium Design schematic diagram into PCB layout design
- Purchase of circuit components from Digikey
- Ordering PCB from AP Circuits

The stethoscope circuit consists of 6 main sub-components that each serves a separate necessary function. These sub-components are as follows:

1. Microphone and microphone pre-amplifier circuit
2. Microphone recording switch and LED recording indicator
3. Sallen-Key low pass filter
4. 2.5 V DC offset circuit (required for input into Arduino microcontroller which is described in Section 5)
5. Volume control and headphone power amplifier circuit
6. Power and power LED indicator circuit

The remaining sub-sections of this section will provide a detailed description of the function of each of the sub-components of the stethoscope circuit. For a more detailed view of the sub-component interconnections refer to the schematic in Appendix B.

4.1 Microphone Pre-Amplification Circuit

The microphone pre-amplification sub-component of the stethoscope circuit can be seen inFigure 3. It consists of an electret microphone, an operational amplifier (one of the amplifiers inside the TL072 IC package), and various resistors and capacitors.

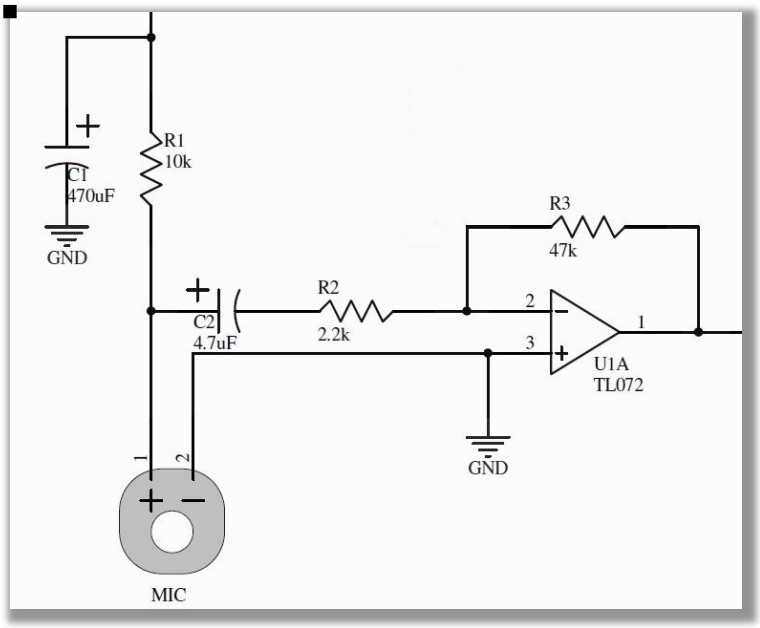


Figure 3: Microphone Pre-Amplification Circuit

The operational amplifier topology is that of an inverting amplifier and as such we would expect the closed-loop gain of the circuit to be,

$$A = \frac{v_o}{v_i} = -\frac{R_3}{R_2} = 21.4\,\frac{V}{V} \qquad (1)$$

However, this equation does not accurately describe the gain of this sub-component. The reason for this is that the electret microphone contains a large output impedance, and when combined with R2 the op-amp sees an effective input resistance of about 12.2 kΩ. Modifying the equation above yields the correct gain,

$$A = \frac{v_o}{v_i} = -\frac{R_3}{R_2} = 3.9\,\frac{V}{V} \qquad (2)$$

The internal structure of the electret microphone can be seen inFigure 4. The microphone consists of a parallel plate capacitor made of an electret material connected to the gate of a JFET transistor.

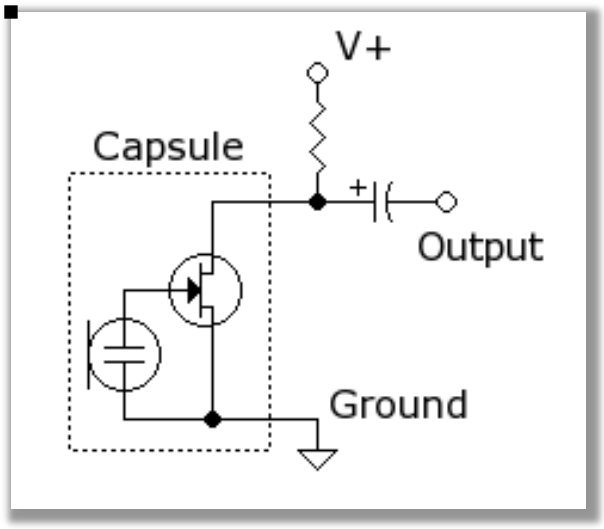


Figure 4: Elecret Microphone Internal Circuit Schematic[12]

The electret microphone operates due to changes in sound pressure that move the electret material of the capacitor. This movement in turn creates a voltage difference at the gate of the transistor. This voltage difference allows a varying amount of current to flow through the drain of the transistor. When a resistor is used and a supply voltage provided, this varying current is converted to a varying voltage, which is taken as the output of the electret microphone. The capacitor in Figure 3acts as a coupling capacitor to pass through the AC signal while blocking any DC components.

4.2 Microphone Recording Switch and LED Recording Indicator Circuit

This circuit can be seen in Figure 5and serves two purposes. Its first purpose is to provide a way of stopping the microphone from constantly receiving audio signals. This is a useful feature for the user of the stethoscope because without it the device would be constantly receiving audio signals even when the stethoscope head is not placed on a patient's chest. In this case, the stethoscope would just be picking up ambient noise from the environment. Adding the capability of turning off the microphone will also be useful because it allows the user to only transmit the wireless signal to the iPad device when they wish to and when the stethoscope head is properly placed on the patient. This will eliminate unwanted wireless data transmission as well as unwanted audio output to headphones. The switch used will be of the SPST type.

The second purpose of this sub-component is to provide a visual indicator via the use of an LED (red) to the user of the electronic stethoscope to inform them when the microphone is powered and thus when the circuit is recording and wirelessly sending data to the iPad device. This is accomplished with the use of an LED and resistor connected between the +9 V supply and

ground. Assuming a forward biased LED voltage drop of +2 V, the resistor limits the current through the LED to,

$$i = \frac{(9-2)\,V}{680\,\Omega} = 10.3\,mA \tag{3}$$

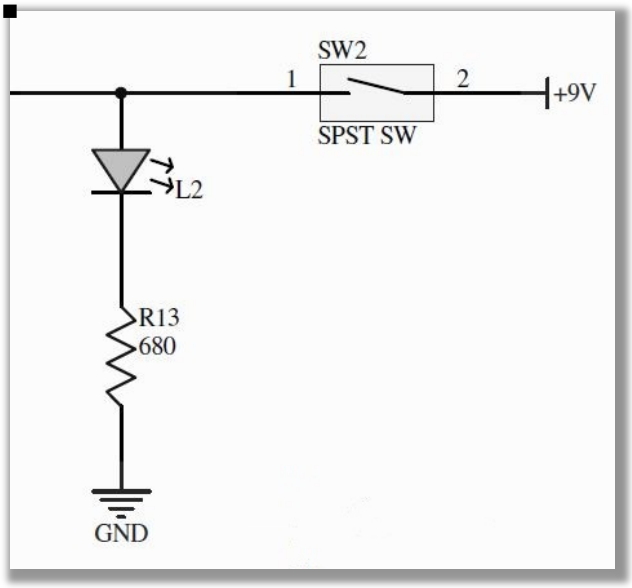


Figure 5: Microphone Recording Switch and LED Recording Indicator Circuit

4.3 Sallen-Key Low Pass Filter

After the signal has been pre-amplified, the next sub-component of the stethoscope circuit consists of a Sallen-Key, or KRC, low-pass filter topology and can be seen in Figure 6. This is a second order filter circuit that has a number of desirable properties. The inclusion of an operational amplifier (the other amplifier inside the TL072 IC package) in the circuit allows for a DC gain greater than 1 when a negative feedback loop is incorporated. This means that in addition to filtering the electronic signal, the circuit can also boost its amplitude in the pass band. Another advantage of the Sallen-Key low pass filter is its ability to specify a value for Q. Q determines the behaviour of the filter around its cut-off frequency.

The circuit we have utilized for this project is a special type of Sallen-Key filter that uses equal components for resistors and capacitors (R4 = R5 = R and C3 = C4 = C). This design greatly simplifies the analysis of the circuit and it can be shown that the three parameters that describe the characteristics of the circuit are,

$$H_{OLP} = K = 1 + \frac{R_6}{R_7} = 1.59 \frac{V}{V} = 4.02\ dB \tag{4}$$

$$\omega_o = \frac{1}{RC} = 102.6\ Hz \tag{5}$$

and,

$$Q = \frac{1}{3-K} = 0.709 \approx \frac{1}{\sqrt{2}} \tag{6}$$

The above three equations specify that the filter has a DC gain of 4.02 dB, a cut-off frequency of 102.6 Hz and a quality factor Q, of 0.709. Note that the largest value of Q before peaking occurs is 0.707, which is very close to the value of Q in this circuit.

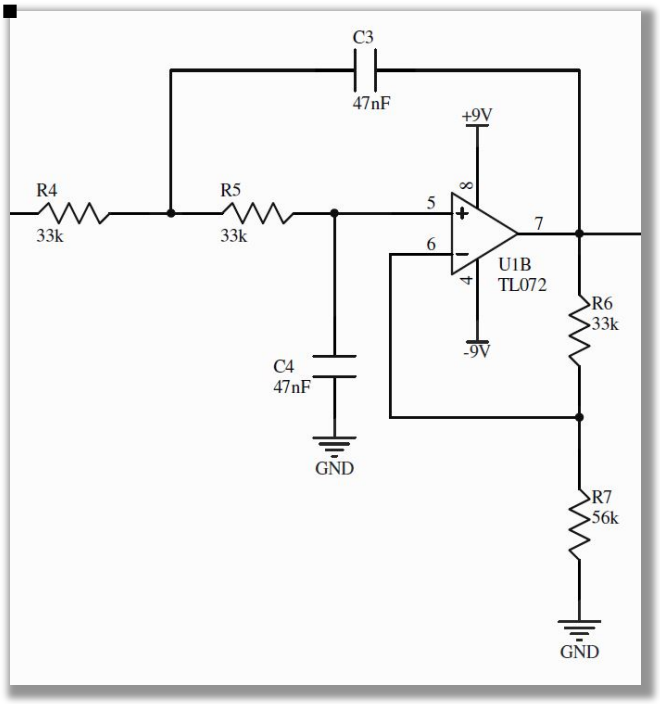


Figure 6: Equal-Component Sallen-Key Low Pass Filter

Using the parameters noted above, the transfer function of the low-pass filter can be written as,

$$H(s) = \frac{1.589}{(2.41 \cdot 10^{-6})s^2 + (2.19 \cdot 10^{-3})s + 1} \quad (7)$$

In order to verify the parameters found above, the filter was constructed in LTSpice IV and a bode plot simulated. This simulation can be seen in Figure 7. It is clear from this plot that the simulation matches the expected parameters very closely.

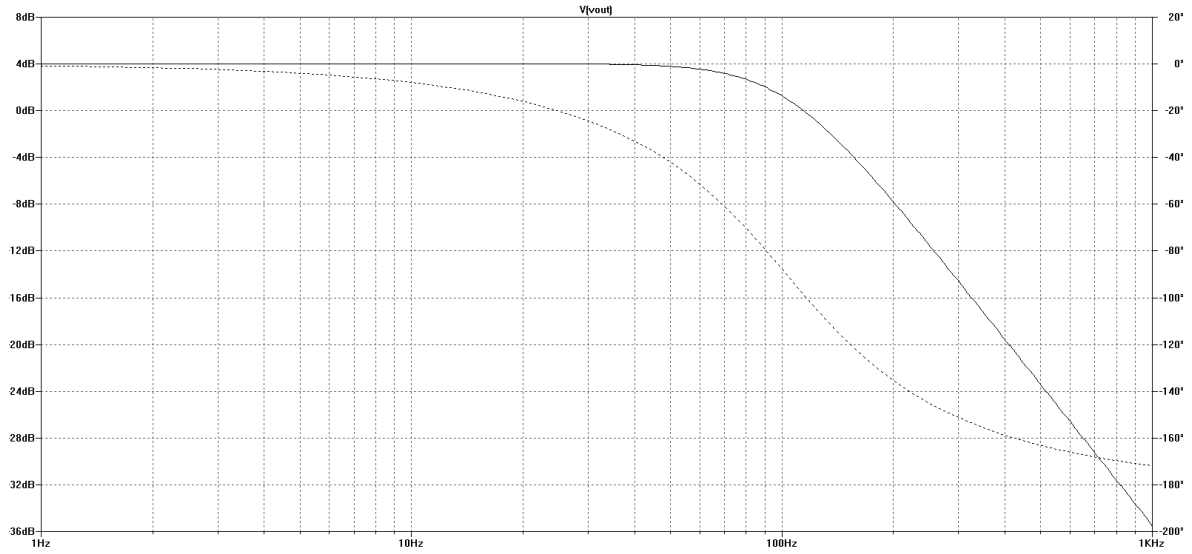


Figure 7: Sallen-Key Low-Pass Filter Bode Plot

4.4 2.5 V DC Offset Circuit (Signal Conditioning for Arduino)

After the signal has passed through the low-pass filter it branches to two different circuits, the first of these circuits is used to condition the output signal such that it can be passed into the Arduino microcontroller for subsequent wireless transmittal. This circuit can be seen in Figure 8and its purpose is to provide a DC offset of approximately 2.5 V.

The Arduino is capable of reading an analog input from 0 – 5 V. At the output of the low-pass filter, the signal exists as a sinusoid that varies from -2.5 V to +2.5 V. Thus, a simple voltage divider has been utilized to shift this sinusoid up by 2.5 V such that it can be passed into the Arduino microcontroller as an analog input signal.

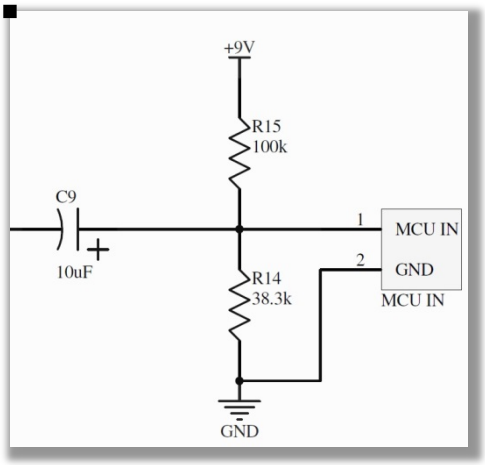


Figure 8: DC Offset Circuit

A simple voltage divider equation can be used to show that the DC voltage offset at the input to the microcontroller is,

$$V_{MCU\ IN} = V_{+}\frac{R_{14}}{R_{14}+R_{15}} = 9\frac{38.3}{38.3+100} = 2.49\,V \qquad (8)$$

4.5 Volume Control and Headphone Power Amplifier

After the signal has passed through the low-pass filter, it also branches off to the volume control and power amplification circuit. It is this circuit that prepares the signal for listening to the audio signal through headphones (provided separately by user of electronic stethoscope). This circuit can be seen in Figure 9and consists of a 10-kΩ logarithmic potentiometer as well as an LM386 ¼ W power amplifier. The potentiometer will be externally accessible to the user of the device and will allow them to manually set the volume of the audio signal passed to the headphones. It should be noted that different headphones provide different impedances, which will result in different volumes. It is left up to the user of the device to manually adjust the potentiometer to obtain a volume that is adequate for them.

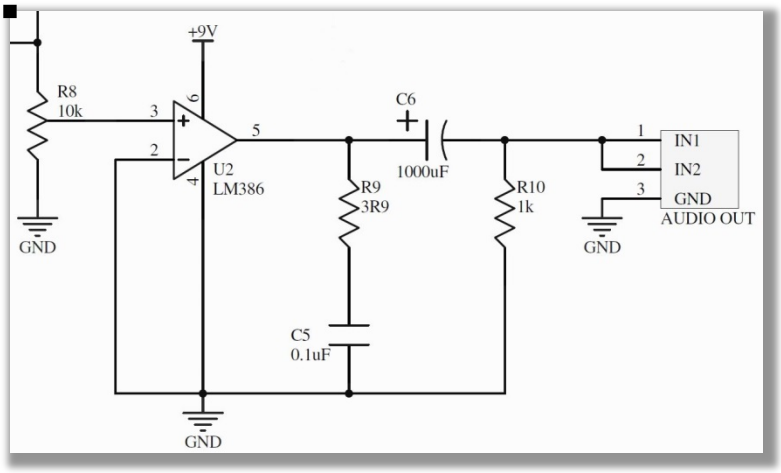


Figure 9: Volume Control and Power Amplification Circuit

The power amplifier in this circuit has an internally set gain of 20 V/V or 26 dB. This gain boosts the small AC signal output from the low-pass filter to a larger signal suitable for listening with headphones. The audio out component will be a 3.5 mm stereo headphone jack and will be easily accessible to the user of the device.

4.6 Power Circuit and LED Power Indicator

The final component of the stethoscope circuitry is the power and LED power indicator circuit. It is this circuit that provides power to all the components in the circuit, including the active operational amplifiers. Two 9 V batteries will be used in series and grounded in the middle to provide ±9 V as well as a ground node (0 V). These batteries will be internal to the circuitry case but will be accessible to the user for replacement when they run out of charge. The batteries will be connected to a DPST switch that will be accessible to the user for turning on/off the device. After the switch, a pair of decoupling capacitors is used on the power supply rails. This circuit also contains an LED (green) that will be visible to the user of the device and will inform them that the device is powered on. The same equation derived for the current through the LED in the recording indicator circuit section applies here as well.

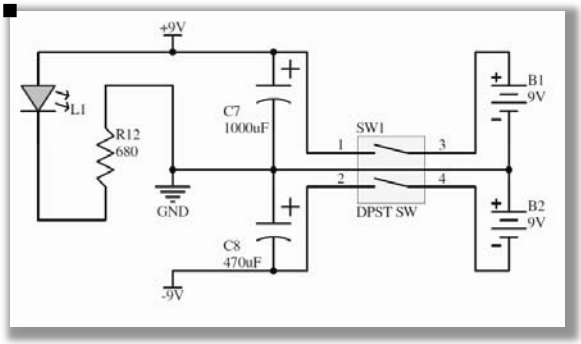


Figure 10: Power and LED Indicator Circuit

5 MICROCONTROLLER IMPLEMENTATION

The second half of the stethoscope hardware begins from the voltage divider circuit shown in Figure 8. From here the signal is passed into the Arduino single-board Microcontroller Unit (MCU). This unit is designed to be an easy to use 8-bit Atmel AVR microcontroller with a large amount of open source libraries available to make it easy to quickly prototype electronic designs [12]. The MCU will be used to convert the analog signal to a digital word and then transfer this word through the MCU to a Secure Digital card (SD card) before finally transferring the data through a Wi-Fi shield to the application on the mobile device. A block diagram of this process can be found in Figure 11.

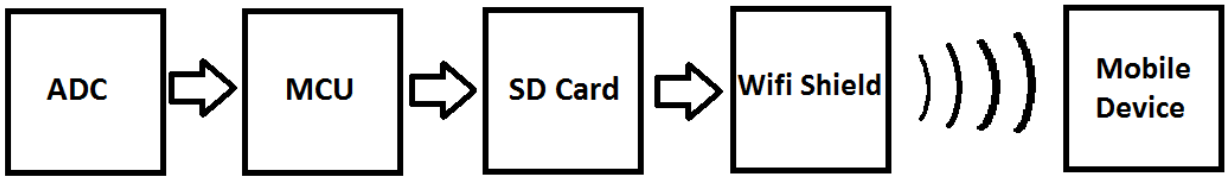


Figure 11: Arduino Block Diagram

As discussed in the previous section the Arduino microcontroller unit requires that the input analog signal be a voltage between 0 and 5 volts. The Arduino also requires as common ground between the filter and amplifying circuit and itself as shown in Figure 8.

5.1 Analog to Digital Converter

The Atmel AVR MCU features a 10-bit successive approximation ADC that has four different input channels, a minimum conversion time of 13us, and a ±2 Least Significant Bit (LSB) absolute accuracy [13]. The ADC requires 13 clock cycles to completely convert the analog signal to a 10-bit word between 0 and 1023. Unfortunately this conversion takes too long (125us) to finish to accurately record an audio signal and can only sample at a rate of 8kHz. The average sampling rate suggested for audio signals is 44.1 kHz, but the Arduino's ADC can only reach a maximum of 38.5 kHz. This is achieved by bypassing the commands provided in the Arduino library and setting the ADC registers manually. The ADC clock is set to 500 kHz by selecting a prescaler value of 32 such that

$$\frac{16\ MHzMCUClock}{32\ prescaler} = 500\ kHz$$

With this new clock speed and the 13 clock cycles that it takes to fully complete a analog to digital conversion we can now achieve a sampling rate of 38.5 kHz

$$\frac{500\ kHz}{13\ ClockCylces} = 38.5\ kHz$$

It can now be seen that the time it takes to calculate one sample has been reduced from 125us to 26us [14]. Unfortunately the downside to increasing the sampling rate of the ADC is that there is a resolution loss from 10-bits down to 8-bits. The reason for this lies in that to be able to properly convert each number the program only looks at the 8 Most Significant Bits to save time. This is deemed acceptable for proof of concept and can be improved by using a higher quality ADC at a higher cost. Once the conversion has been completed it is placed in the ADC Register named ADCH.

5.2 Microcontroller Unit and Secure Digital Card

For this application the microcontroller has a rather simple job and is used to monitor the digital values coming out of the ADC at a constant rate of 26us. This is the exact time it takes to create a new digital word and thus the MCU will only read a new value right after it has been changed in the ADC register. Once a new digital word has been read, the MCU temporarily saves the value in its onboard Random Access Memory (RAM) before transferring it to the SD card located as part of the Wi-Fi Shield. This step is necessary because the wireless transfer of data is much slower than the ADC and the SD card is used to store the backlog of data that will occur with each recording.

5.3 Wi-Fi Shield and Wireless transfer

The Wi-Fi shield hardware component connects to the Arduino board through the Arduino's serial ports. This shield is based on the HDG104 wireless LAN 802.11b/g system and provides a network stack capable of both TCP and UDP [15]. This application will use the SD card combined with the onboard wireless processor to pull data off of the SD card in a chronological order and create TCP packets that will be sent over a Wi-Fi network to be received by the application installed on the mobile device paired to the hardware. More detail on this will be provided in the software sections.

6 SOFTWARE SYSTEMS

The software systems of the CVI Wireless Auscultation device provide the physician/medical professional with all the data collected from the hardware aspect of the design. As stated, information is transmitted from the auscultation device through a wireless network to the iOS device, in our case an iPad. The specific method of communication is listed in section 6.1. Once usable data is acquired, a refinement algorithm responsible for displaying information in a user-friendly version analyzes it. One of the primary features of CVI's design is the ability to real-time track information as it is received from the stethoscope. Upon completion of data transmittal, the central repository stores a secure record of the patient tests readily accessible by other pre-approved medical professionals. Cloud based technology ensures guaranteed 24/7 uptime to maintain reliability in a medical setting.

6.1 Communication Channels

The primary function of the CVI Wireless Auscultation device is the transmittal of data from the auscultation device, administered by a health care professional, to the iOS device via wireless communication. To ensure the signal representation of specific heart sounds is accurate, a reliable and efficient method of synchronization is essential. Additionally, the data must arrive with minimal delay to ensure the real-time tracking information displayed on screen correlates with the patient's heartbeat.

6.1.1 User Datagram Protocol Utilization ThroughWi-Fi

Rather than developing a brand new protocol for sending and receiving information between the mobile platform and auscultation device, we opted for UDP. Before divulging detailed information about the protocol, let's establish a basic understanding of the connection methods.

Both the Arduino board and iOS device connect wirelessly to a router where they are assigned a unique Internet Protocol address as determined by the network. This unique address distinguishes each device thus simplifying the data routing procedure. Below, in Figure 12, is a diagram outlining how each device communicates with one another over the wireless network.

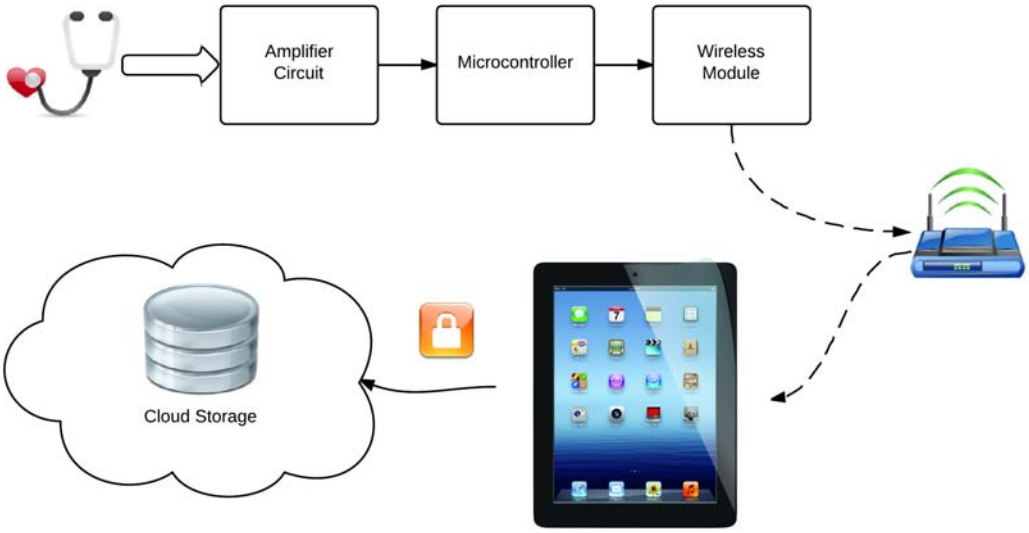


Figure 12: Device Communication Flow Diagram

Since IP addresses are pre-determined in our design, both the mobile application and hardware are hardcoded with their respective counterpart's unique identifiers. This minimalistic approach circumvents the need for an overly complicated device-searching algorithm. Prior to establishing Wi-Fi as our primary wireless protocol, alternatives such as Bluetooth were proposed. The limitations of the Bluetooth protocol are quite prevalent when the large bandwidth of the transmitted signal requires live and reliable streaming. Wi-Fi not only meets our bandwidth requirements, but also exceeds them noticeably. The IEEE 802.11N capabilities used in our test environment require no modification and minimal understanding on a low-level [8]. The most important aspect of this communication channel is the ability to handle UDP connections effectively.

UDP, as opposed to the Transmission Control Protocol (TCP), is a simple non-handshaking algorithm well suited for real-time systems [9].The absence of handshaking unfortunately may contribute to potential network errors resulting in the corruption of transmitted data. The use of a TCP based system avoids this problem by guaranteeing your data packets arrive to the receiver as intended, but with a latency cost. Since UDP doesn't require sophisticated verification algorithms, there is no unwanted delay. Additionally, the performance limited Arduino board doesn't suffer from the potential overhead associated with handshaking algorithms.

Streaming media is fundamental to the operation of our device and it cannot suffer any compromises. The high sampling rate of our intended signal nullifies lost packets through network transmission essentially removing the possibility of dropping vital packets. Our graphing algorithm will detect any abnormalities in the incoming signal, such as random,

unexpected spikes, and perform necessary corrections guaranteeing accurate audio to visual reconstruction.

6.1.2 Arduino Implementation of UDP

The Arduino Uno features built-in UDP capabilities through the use of specific Application Programming Interface's (API). Coupling the ArduinoWi-Fi shield and the microcontroller grant us the ability to transmit UDP packets wirelessly to the mobile application through the intermediate router. Below, in Figure 13, is a basic flowchart describing the packaging and processing of data packets transmitted over the air.

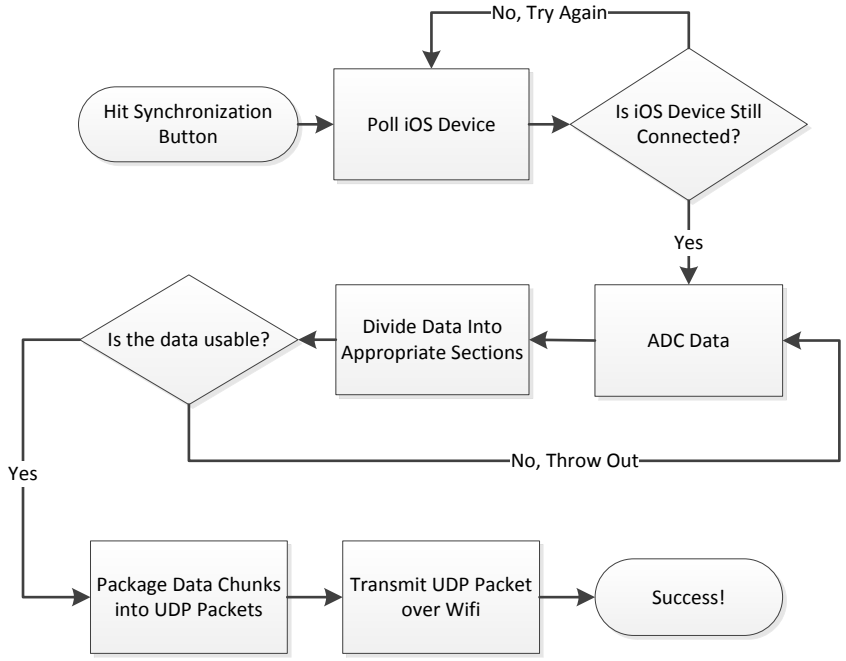


Figure 13: Wireless Data Packaging and Processing

Assuming a reliable connection, the implemented algorithm and pre-programmed APIs should provide a relatively glitch free transmission.

6.1.3 iOS Implementation of UDP

Unfortunately, unlike the Arduino board, the iOS development platform does not feature any built-in functionality for UDP broadcasting. A beautifully designed library called GCDAsyncSocketUDPis readily available online and maintained regularly[10]. The library offers a reliable set of straightforward UDP specific methods without the need for any further manipulation. Figure 14, shown below, specifies a basic algorithm for UDP data transmittal utilizing the GCDAsyncSocketUDP library.

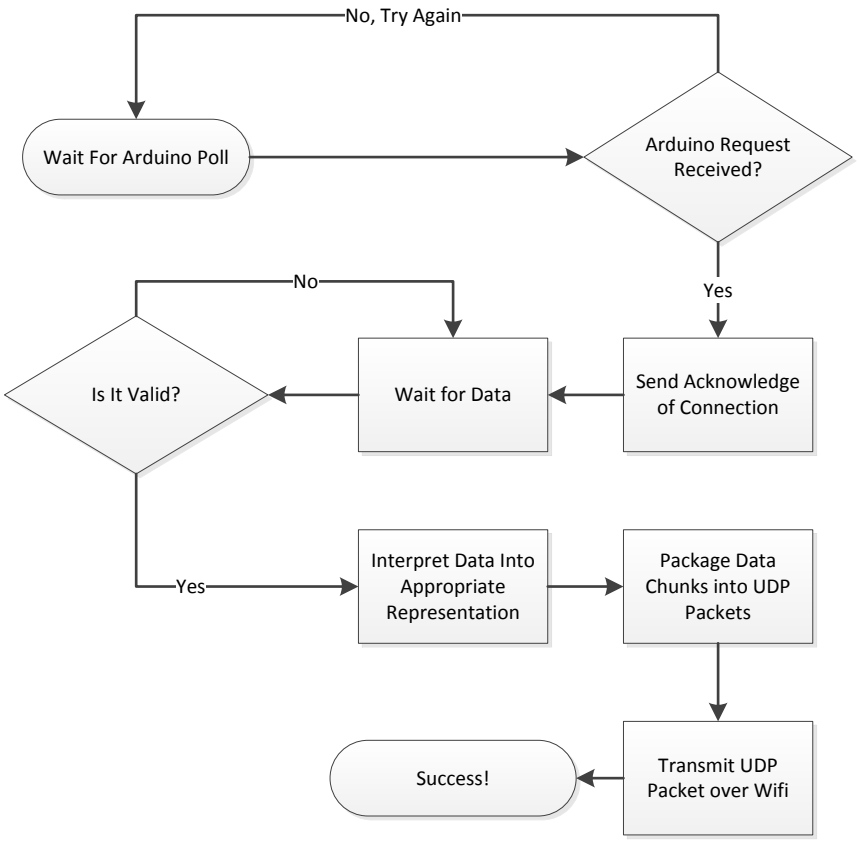


Figure 14: UDP Transmission Algorithm

The exact implementation of the Arduino and iOS implementation of UDP transmission may vary as time progresses.

6.1.4 Synchronization

The CVI Wireless Auscultation device features a minimalistic approach to synchronization between the auscultation device and the mobile platform. Once the user logs in to the application, they can issue a synchronization command that sends an appropriate UDP packet across the network to the desired location containing basic setup parameters. If the device responds to the incoming packet within a ten second-time period, the mobile platform displays a somewhat discrete message indicating synchronization was successful. On the contrary, if no acknowledgement is sent back to the mobile platform, the user receives a detail-specific error message about the issue. Since establishing a communication channel is a high-priority item of the design, a basic handshaking algorithm verifies device connectivity before issuing an auscultation test.

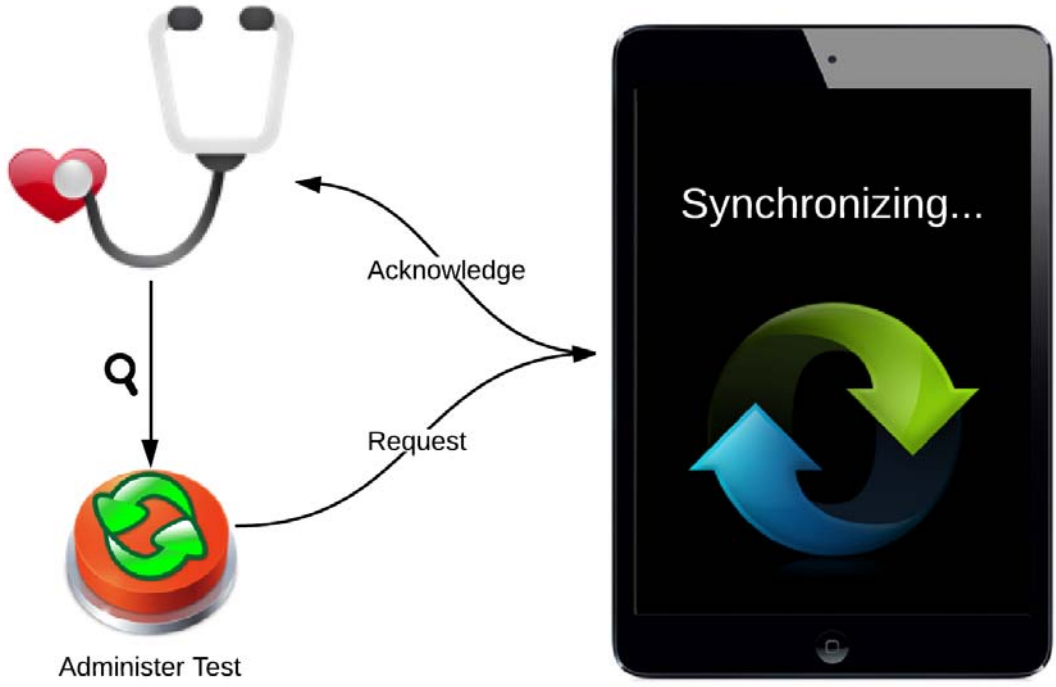


Figure 15: Device Synchronization

The physical design of the stethoscope encapsulates basic LED indicators for power and sound recognition, and a button to signal the start of a test. The diagram above, Figure 15, outlines the basic data synchronization abilities of the physical device. As mentioned in the previous paragraph, both the sender and receiver issue verification notifications discretely ensuring the communication channel is still active. The user is prompted with an alert message if at any point there is a substantial loss in crucial data, which is indicative of a communication glitch. It is essential to develop sophisticated error handling algorithms since wireless communication lacks the reliability of a hard-wired connection. Further explanation of general product reliability is mentioned in the succeeding section.

6.1.5 Reliability of Communicated Data

Creating a reliable device with a minimal failure rate is CVI's primary goal in bringing its medical innovations to market. A corollary of our rigorous design and testing procedures is the reliability of data sent across the communication channel. The two potential pitfalls to instituting a wireless communication protocol are router-based network connections and the transmission of UDP packets.

The wireless abilities of current standards far surpass technology utilized many years ago, but unfortunately at a cost. Without a physical connection present between two communicating

devices, the added complexity contributes to potential total network disconnections. Unfortunately, this kind of error is unavoidable as its dependent on the devices and algorithms developed by other corporations. The best CVI can do is ensure the user is notified of potential problems swiftly and non-ambiguously. If in the case of a network disconnection, the user receives a message alert concerning network problems. Due to constraints set by networking protocols and Apple's development platform, the user must deal with these issues independently. Any incomplete or corrupt data available to the mobile application will automatically be removed to prevent misinterpretations and further corruption in the database. Below, in Figure 16 and Figure 17, is a set of sample alert messages.

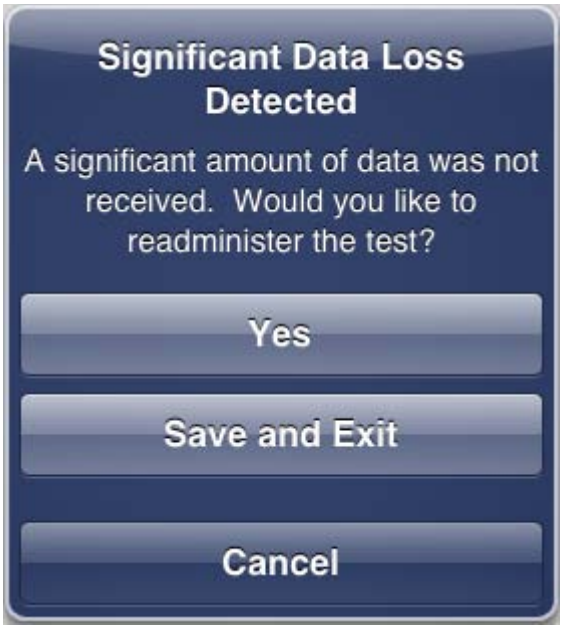


Figure 16: Data Loss Error

Figure 17: Network Error

As mentioned in Section 6.1.1, UDP does not offer any handshaking algorithms to deal with data corruption and loss along its pathway. It is imperative for the receiving application to handle these potential errors in a sophisticated and discrete manner. The first case deals with

undesired packets present in the data collection algorithm. Since the sample rate of the auscultated signal is sufficiently high, we can make basic data a comparison against neighbouring packets to ensure the variance is within a reasonable tolerance. If for some reason a strange packet possesses a completely irrational value, it is dropped. The second issue concerning UDP packets concerns dropped packets. A typical auscultated signal, as mentioned in the first case, is sampled at a sufficient rate. If the algorithm detects a certain jump in data not expected through normal operation, the user receives a message alert containing data issues during a certain interval. The health care professional may re-administer the test or choose to save the corrupted signal. Keep in mind the preceding situation is high unlikely during normal operation.

TCP communication would offer a much more reliable method for data transfer, but the addition of real-time auscultation tracking adds overhead to the current implementation. A future development will offer improved communication hardware so it is possible to reap the benefits of TCP.

6.2 Data Processing

The data processing methodology for CVI's Wireless Auscultation device follows two streams; upon reading a stream of data from the database, the data stream is broken into two components: graphical representation of the signal and anomaly detection, as shown inFigure 18.

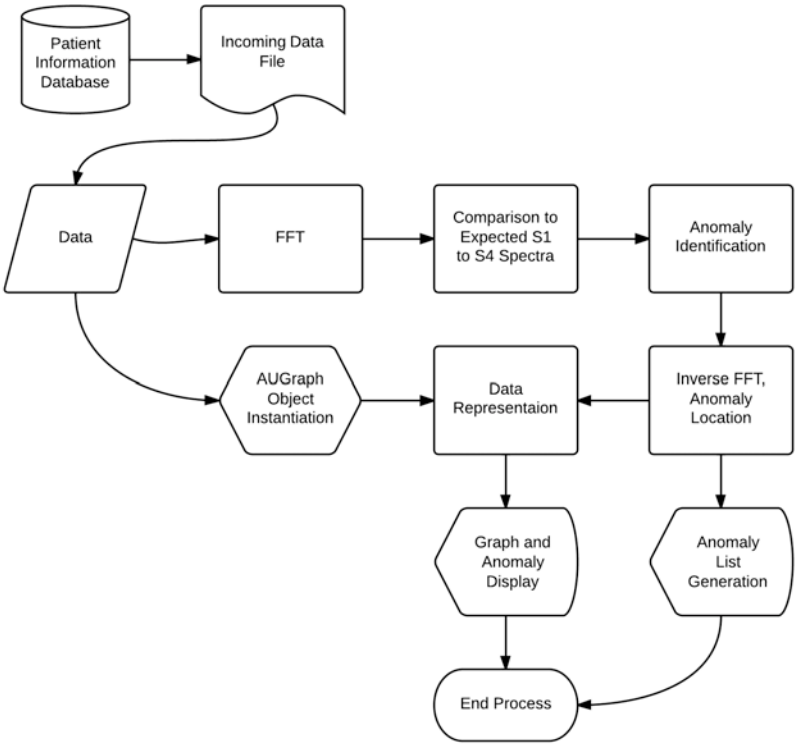


Figure 18: Data Processing Flow Chart

Data representation takes advantage of the third-party AUGraph object library. Using this library, the application developer is able to instantiate an AUGraph object using a data set of dynamic length and easily output a visual representation of the data. In this graph, the initial data will be collected at 40 000 samples per second; however, should the instantiation of the graph prove too noisy for easy interpretation, a software filter will be applied by calculating statistical averages of neighbouring points in order to "smooth out" the graph.

For anomaly detection, a frequency spectrum analysis will be used on the S1, S2, S3, and S4 pulses. The measured frequency spectra will be compared to the expected spectra shown inFigure 19. Should significant discrepancies arise, an alert will be generated in the user interface.

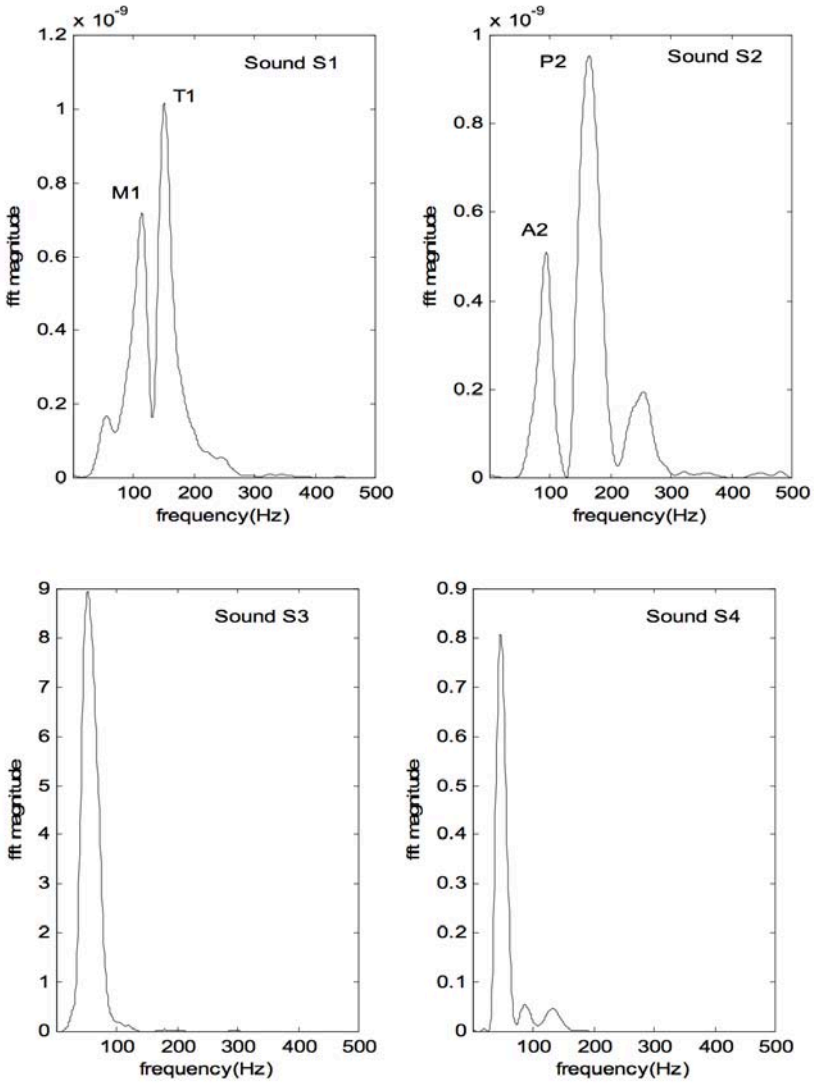


Figure 19: S1, S2, S3, and S4 Frequency Spectra [5]

User alerts will contain the pulse that is showing an abnormality and identify the location of the abnormality. This will be translated into the AUGraph object as an alert, and identified on the graphical output.

The Cooley-Tukey Fast-Fourier Transform (FFT) algorithm shall be used for frequency spectrum analysis. This is a recursive algorithm that breaks a composite Discrete Fourier Transform (DFT) of size $N=N_1N_2$ into sizes N_1 and N_2 recursively. This algorithm was chosen for its relatively simple recursive code and its fast computation speed. Due to its recursive nature, calculation time is on order O(NlnN) for highly composite, or "smooth" discrete signals. It is beyond the scope of this documentation to provide the details of this well-documented calculation; please refer to Reference [6] for a detailed discussion of the algorithm, or Reference [5] for a general overview of Fourier Transforms as they apply to auscultation.

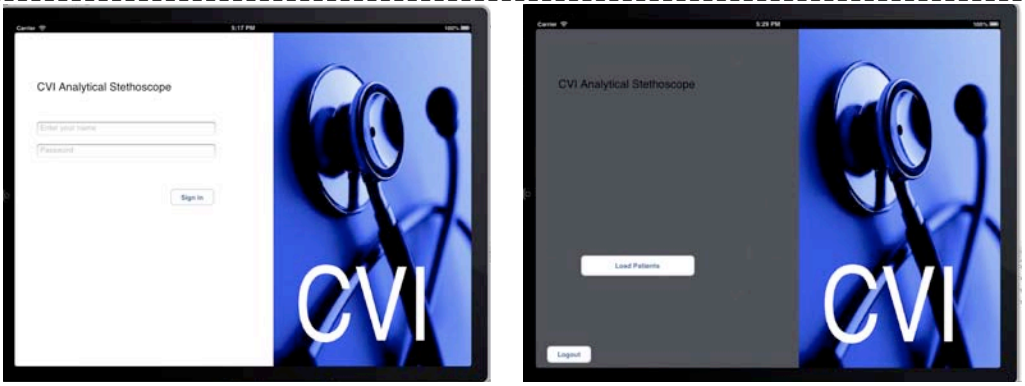
The end result of these calculations will be a visual representation of the audio signal that marks anomalous heart activity, as well as a list of anomalies as they occur in different pulses.

6.3 User Interface

The graphical user interface primarily provides as a mean for reviewing the auscultation sounds with visual metrics. The reviewed data can be from previous auscultation sessions or streamed from a stethoscope. The following sections outline the different components of the user interface for implementing such requirements.

6.3.1 Account Access Protocol

To ensure patient confidentiality, only authorized users, typically health care professionals, are allowed to use this software. The welcome screen prompts the user to enter their username and password and upon ending a session, a log out button is provided to ensure that data during this session is logged and not accessible for others. These views are seen in the following images.



In order to ensure that the patient's information is only viewed by their designated health care professional, a list is provided in the user interface so the user can only view the patients that are assigned to them. As seen in Figure 20, the user can choose which patient to view and is also given an option to edit or add a new patient.

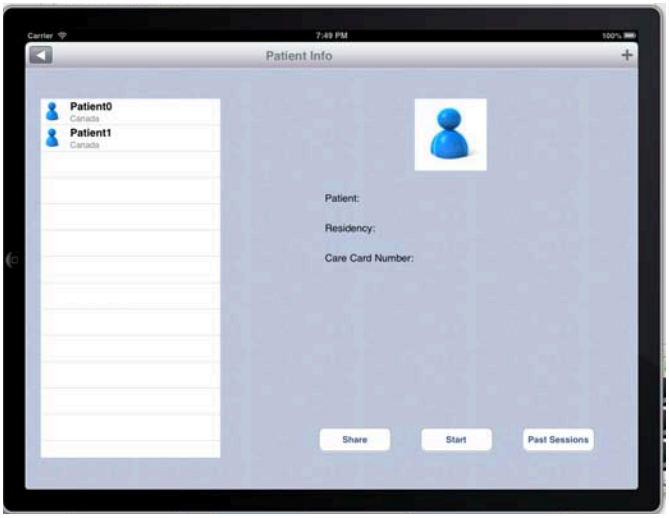


Figure 20: Patient Database

After choosing the correct patient, the user can choose one of three options: sharing the patient with other health care professionals, starting an auscultation session or reviewing past recording sessions. In the following section, the design specifications for a basic patient session are provided.

6.3.2 Basic Patient Session Profile

During a session, the user can share patient data, analyze auscultation sounds and review past patient history. The following presents the design specifications for a basic patient session.

6.3.2.1 Sharing Data

One of the functions of this system is being able to share patient information between health care professionals for assisted diagnostic support. In addition this feature provides for a foundation for supporting telemedicine. Upon pressing the 'share' button of the previous menu seen in Figure 20, the user is given a list of professionals that they can choose to share from. This list of professionals is part of a global database, limiting the access for others to view personal patient data.

Figure 21: Sharing Patient Design

6.3.2.2 Signal Analysis

When analyzing auscultation sounds, the view of the audio signal is presented with adjustable volume inputs via a volume slider bar. When running the analysis on a live signal, the interface provides three options: recording the audio signal, running analysis on the signal and saving the session. When reviewing a previous signal, the interface is read-only to prevent data corruption. Figure 22shows a potential design for this interface.

Figure 22: Signal Analysis Session Design

In clinical practise, multiple locations are auscultated for a better assessment of the patient. In reflecting such needs, the user can manually save the recorded signal and its analysis and recorded multiple signals in one session.

6.3.2.3 Patient History Review

The patient's health history provides useful information during diagnosis and is favourable if it can be conveniently retrieved. Aiming to support this need, a review of past sessions with a brief summary of the session is provided and seen in Figure 24. In addition, selecting a particular session can allow the user to view the recorded signals of that session in the form of a list presented in Figure 23.

Figure 24: Past Patient History Database

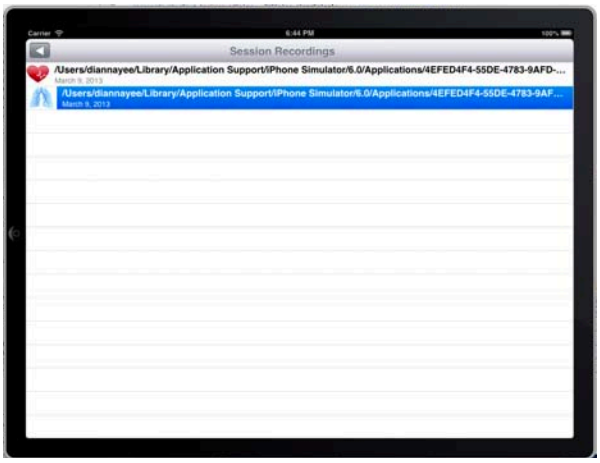


Figure 23: Menu of Signals Recorded

In order to support reviewing data and maintenance of patient and health care professional profiles, a database is required for this application. In the following Section 6.4, the design specifications for the database are provided.

6.4 Database Management

One of the primary functions of this system is being able to stream data between health care professionals to provide a supporting foundation for telemedicine. In addition, electronic logging and reviewing data are preferable features for better bookkeeping of patient data. In supporting such needs, a third party software library, TICoreDataSync, is used to share data between iOS devices using Dropbox for providing cloud-based synchronization.

TICoreDataSync is an open source framework that allows for cloud-based synchronization between Mac OS X and iOS applications. This framework allows for uploading and downloading local SQLite database files that are used by the iOS application. Local changes can then be saved to the cloud for others to download with the option of encrypting the data for security purposes. This framework also provides synchronization mechanisms for various events outlined in Section 6.3.1.

6.4.1 Data Access

During an auscultation session, the user may choose to review past sessions or upload current session recordings and updated patient information. In addition, multiple users may concurrently view the same content. The design flow of these processes is outlined in the following subsections.

6.4.1.1 Concurrency Issues

The CVI Analytical Wireless Stethoscope supports consultation and sharing auscultation data among healthcare professionals such that multiple users have access to the same data. In order to avoid data corruption, only one user may change a patient profile at one time. For example, a live auscultation session will upload the updated patient profile to the cloud and the other authorized users may view this content but cannot change the data until the session is complete. The diagram below shows the design flow of limiting writing access to a single user.

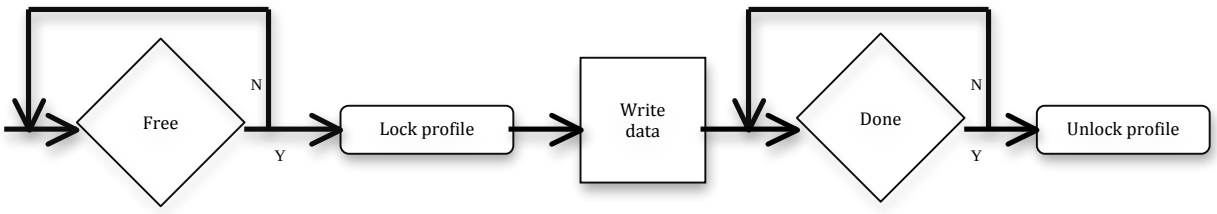


Figure 25: Workflow for limiting conflicting concurrency

TICoreDataSync also provides syncing mechanisms whenever a change has been uploaded so that other users will view the most recent content. Any changes to the file system are also logged. In addition, prior to viewing and writing to the cloud, the local copy of content to be uploaded is sync first to resolve conflict in data between users. In limiting the writing access to one user at a time, the frequency of conflict is minimized and only arises when a user wishes to add or delete data. If conflicts are found, these are either fixed automatically, or by asking the user or application for input. The following diagram describes this workflow.

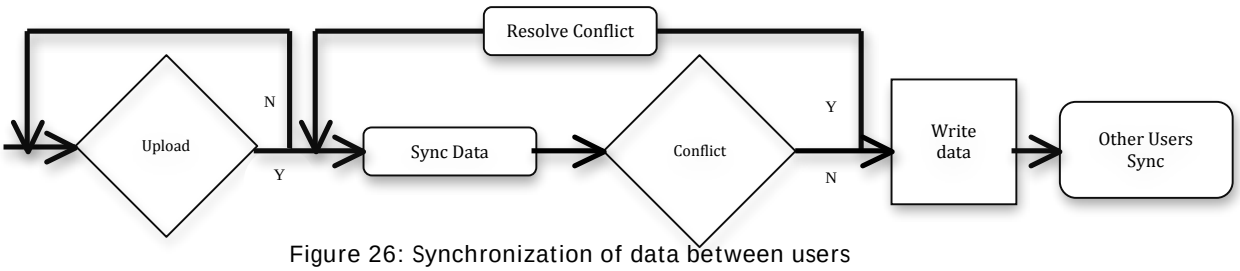


Figure 26: Synchronization of data between users

6.4.1.2 Reading Data

When reading data, users simply sync to the most recent data in the cloud. Changes made by other users are automatically synced to their local copy. This workflow is described in Figure 27.

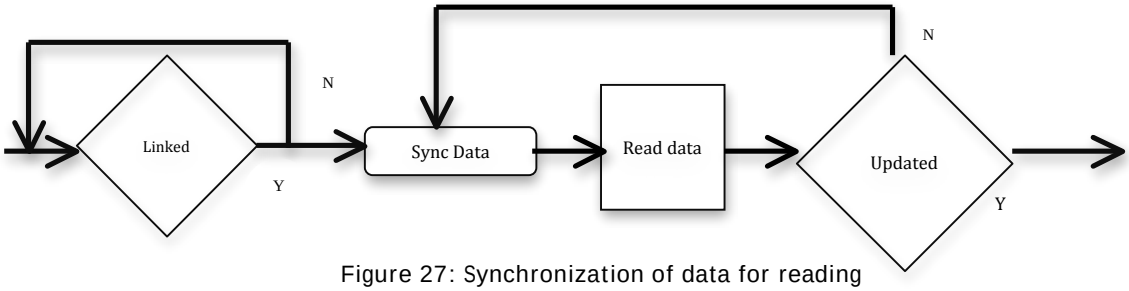


Figure 27: Synchronization of data for reading

6.4.1.3 Writing Data

When writing information to the cloud, the user first reads the data, checks that writing privileges are available and then proceeds to edit the patient profile. After he or she has finished editing, the information is then uploaded. Prior to uploading, changes are sync first to check for conflicts. The entire workflow for the writing process can be viewed as the concatenation of the workflows shown in Figure 27, Figure 25 and Figure 26.

6.4.2 Security and Encryption

To ensure security of the database, encryption services are used. TICoreSync offers access to encryption services such that the content is only viewable within the application. In order to verify that a user has access to this file space in the cloud, they must have the correct key and

value pair corresponding to that file space. Only if the correct key and value pair is given can the application be granted access to that file space. Figure 28 shows the sign in prompt when the correct key and value pair is given.

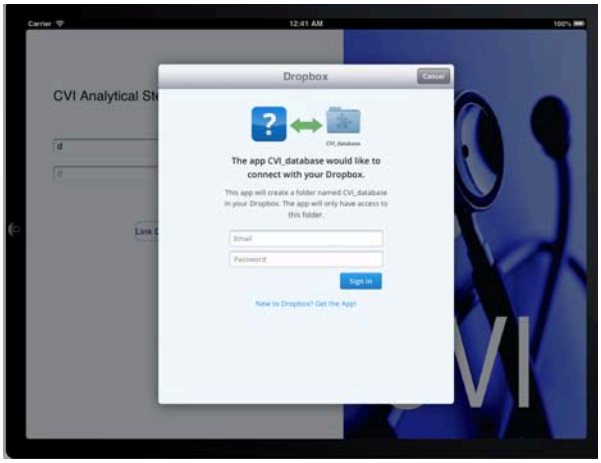


Figure 28: Sign in Window for Accessing Dropbox

Using the key and value pair for each cloud space limits users to seeing only patients within their relevant file space. Although Dropbox is not the ideal choice for a medical device application, it is more convenient to work with an established cloud service for proving the proof of concept for this system.

7 HARDWARE PACKAGING

All electronic parts will be housed in a case designed for both durability and comfort of use. The case will be suspended on a cord that can be hung around the neck to support the case and allow for easy reading of the patients auscultation. Durability and protection are the key elements of the case and for this reason a hard polymer plastic will be used to decrease weight and provide high impact resistance. The side that opens to allow electronic components to be placed in the case and for battery maintenance will be sealed with a soft rubber seal to resist dust and water for outdoor use. The size of the case will be determined exactly once the dimensions for the complete stack of Amp PCB, Arduino, wireless hardware, and battery. The case will have several LEDs placed to represent ON/OFF, recording ON, and activity. There will also be a 3.5mm headphone jack, volume control potentiometer, and gain adjustment precision potentiometer. A rubber hose will cover the shielded cable that reaches to the microphone and stethoscope head. The length of this cable from case to stethoscope head will be a similar length to that of a standard stethoscope but will allow the user to stand at a further distance from sick patients while still receiving high quality body sounds. This is an improvement over standard stethoscopes where distance from source to the ear effects sound quality but also endangers the user by placing them in close proximity to the patient.

This prototype will be larger than the final product but will allow for use and testing. Once verification on the product has been completed future efforts will be made to miniaturize the system to increase usability.

8 SYSTEM TEST PLAN

Cardiovascular Instrumentation, Ltd. has produced a series of test procedures to ensure proper device functionality. The majority content described herein has been related to the client previously; however, test procedures have been created to specify testing processes and ensure proper quality control measures are taken in the testing process. A reference document number precedes each section below: please refer to the corresponding document (appended to the submission of this document) for a detailed test procedure and the official CVI System Integration Test Report (to be filled in by tester at time of testing).

8.1 Database Functionality

REF: 003TS-001-001

The database access test procedure shall focus on two primary deliverables: access speed and reliability. A tester will perform a series of database queries on a variety of data types, and an average access speed will be calculated. A passing score shall be an average access time of less than two seconds, with a maximum time of ten seconds. Zero corrupted data streams are acceptable.

Reliability will be tested through endurance testing: a device will be connected to the database and scripted to periodically poll the service over the course of one week, or seven days. This shall be done during a business-as-usual environment, when regular server traffic is present. No outages are acceptable.

Reliability testing will be performed on both primary and backup servers independently to ensure equal reliability and to minimize risk of lost data in the event of an outage.

8.2 User Interface

REF: 003TS-002-001

An employee of CVI shall be provided the user interface map described in Section 6.3 herein. Navigating through the user interface, the tester shall ensure that all interface windows behave as intended, and all restricted-access areas of the software act as expected. The tester will attempt to “break” the software, using whatever inputs he or she can in a manner not intended so as to expose any outstanding bugs and software deficiencies.

8.3 Access Permissions

REF: 003TS-002-001

Due to the sensitive nature of patient medical information, it is essential that adequate security measures be taken to restrict access to registered medical professionals only. However, the information must be shareable between registered medical professionals if deemed necessary. The test procedure for access permissions is as follows:

- A doctor logging in to the system shall be able to access the information patients under his or her jurisdiction.
- A doctor, unless consented by an administrating medical professional and/or the patient in question (patient consent required where legally mandated), may not access the information of patients not in his or her care.
- A doctor, with patient consent where legally necessary, may grant access rights to another medical professional through the software interface.
- Transfer of patient information access rights shall provide only access to the information of the patient in question, and no other patients.

The testing personnel shall log in using several test accounts, each with its own set of patient information. The tester shall confirm that each account has only access to the information in that account's jurisdiction. The tester will then begin sharing the information between the test accounts, confirming on both accounts in each transaction that only the patient being shared is indeed shared.

8.4 Analytics

REF: 003TS-002-001

The device shall be for tested for analytical quality by a staff member experienced with medical procedures. This will ensure that the signals processed by the software will provide a reliable and accurate analysis that adheres to medical practice standards. The designated tester will verify three key components of analytics:

- Accurate anomaly detection
- Clean signal reproduction
- Fit on screen

The tester will use a set of sample data and collected data to ensure cleanliness of the reproduced signal and accuracy of the analytical recommendations. The pass/fail criteria will be subjective under the purview of the staff member familiar with medical practice.

8.5 Hardware Functionality

REF: 003TS-003-001

Significant testing is to be performed on the hardware component of the project to ensure reliable signal quality. Testing staff will conduct unit tests on the following functional blocks, with the pass criteria specified below:

- Audio quality: the tester shall ensure that audio is available and clear in real-time through the device's headphones. This is a subjective test that will be performed by an employee with medical experience. The audio must be clear and free from electrical or mechanical interference.
- Audio Amplifier: The audio amplifier must produce a clean, accurate audio signal for the A-D converter. This is a subjective measurement to be performed by an employee with relevant medical experience to judge sufficient audibility.
- Analog-Digital Converter: The A-D converter shall convert the amplified signal to a digital representation in a manner that provides sufficient resolution and accuracy for medical analysis. Conversion to a digital audio signal through the intermediary device will be judged fit by a medically experienced employee.
- Wireless Communications: The wireless communications between the stethoscope and the intermediary device shall be established through the sending of test packages. Two-way communication shall be established, and zero data loss will be accepted in the transmission, in either direction.

9 SYSTEM RELIABILITY AND SUSTAINABILITY

9.1 Safety and Reliability

Any company that produces medical devices must have safety as paramount to every design. At CVI we strive to produce devices that exceed the highest standards for medical technology. Each design uses components of the highest quality from the most trusted brands available. CVI's electronic stethoscope has been designed with safety and reliability in mind for both the hardware as well as the software components. The device will be sealed in a robust case and will be both dust and water resistant. The stethoscope has been designed to operate in a wide range of temperatures and environments. This will allow users such field nurses or aid workers who may operate in very different environments the peace of mind that the device will operate properly. Additionally the device will be easy to use and weigh as little as possible so that no physical harm can come from its use.

The electronic components will be surface mounted on a specially designed PCB allowing for less noise and a smaller chance of component failure due to being dropped. The battery has been designed to last for a long period of continues use and electronic switches have been implemented such that idle power loss will be limited. The microphone is placed in a sturdy rubber tube connected to the stethoscope head; it is also connected to the PCB through a shielded cable to reduce signal noise during transmission. Lastly the Arduino and Wireless components are all third party assured and tested to a high quality by their manufactures. The software created for the stethoscope has been written by programmers of the highest quality and stringent bug testing has and will continue to take place. CVI will stand above its competition by working with its customers to improve and identify any bugs or issues that may arise over the products lifetime.

Production of this product will be done onshore to allow for the highest quality of construction and also give easy access for quality assurance. As these are high quality medical devices each one will be hand tested by a trained technician before being packaged. Having these extra steps may increase overhead costs but the return from the reputation gained by having low manufacturing problems will outweigh to cost. All of these reasons lead to the CVI Electronic Stethoscope being the leading device for high quality auscultation recording.

9.2 Sustainability

As a medical device producing company CVI strongly believes that not only will its products help to improve the quality of life for society, but the way the products are made will as well. CVI plans to use manufactures that meet our high standards of sustainable production by limiting waste and reducing toxic materials. Electronic devices sometimes need to be produced using certain materials, but CVI plans to introduce a device buyback system with incentives to allow CVI to sustainably recycle the electronic components used in our products. This system

will allow users to request, free of charge, their new CVI Electronic Stethoscope to be sent in a reusable box allowing them to simply take out their new device and send us back the old one. This system will allow CVI to not only reuse any components that may be easily recycled for internal use, but will also oversee the disposal and recommitment of all other components that may not be able to be used in our product. The goal of these objectives is to make it easy for customers to dispose of their device in a sustainable manner with little to no additional cost.

10 CONCLUSION

This document has outlined all of the key design specifications that CVI plans to follow through to production of its electronic stethoscope. The overall theme of each specification will be adhered to in order to meet the functional specifications detailed in the previous document. Some portions of both the hardware and software remain to be completed and may be adjusted or changed in order to complete the prototype. Although a large portion of hardware testing has been completed, system integration with both software and hardware remains to be completed. This integration will require further testing and may include changes to the originally planned design specifications if needed to ensure that the product meets our demand for a safe and quality product.

11 SOURCES AND REFERENCES

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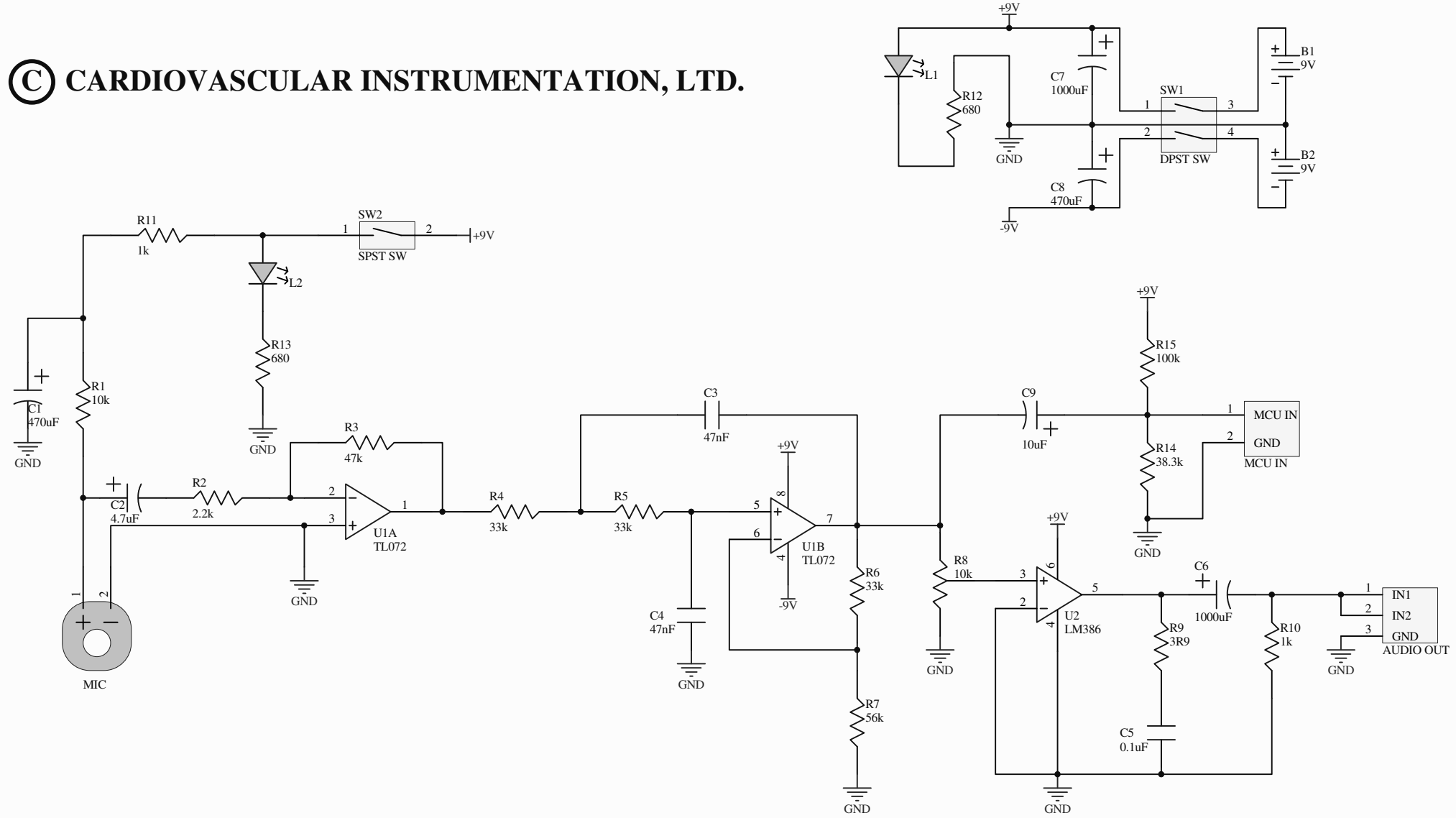
APPENDIX A – ELECTRONIC STETHOSCOPE CIRCUIT SCHEMATIC DIAGRAM

Please refer to the attached drawing for a stethoscope circuit diagram.

APPENDIX A – ELECTRONIC STETHOSCOPE CIRCUIT SCHEMATIC DIAGRAM

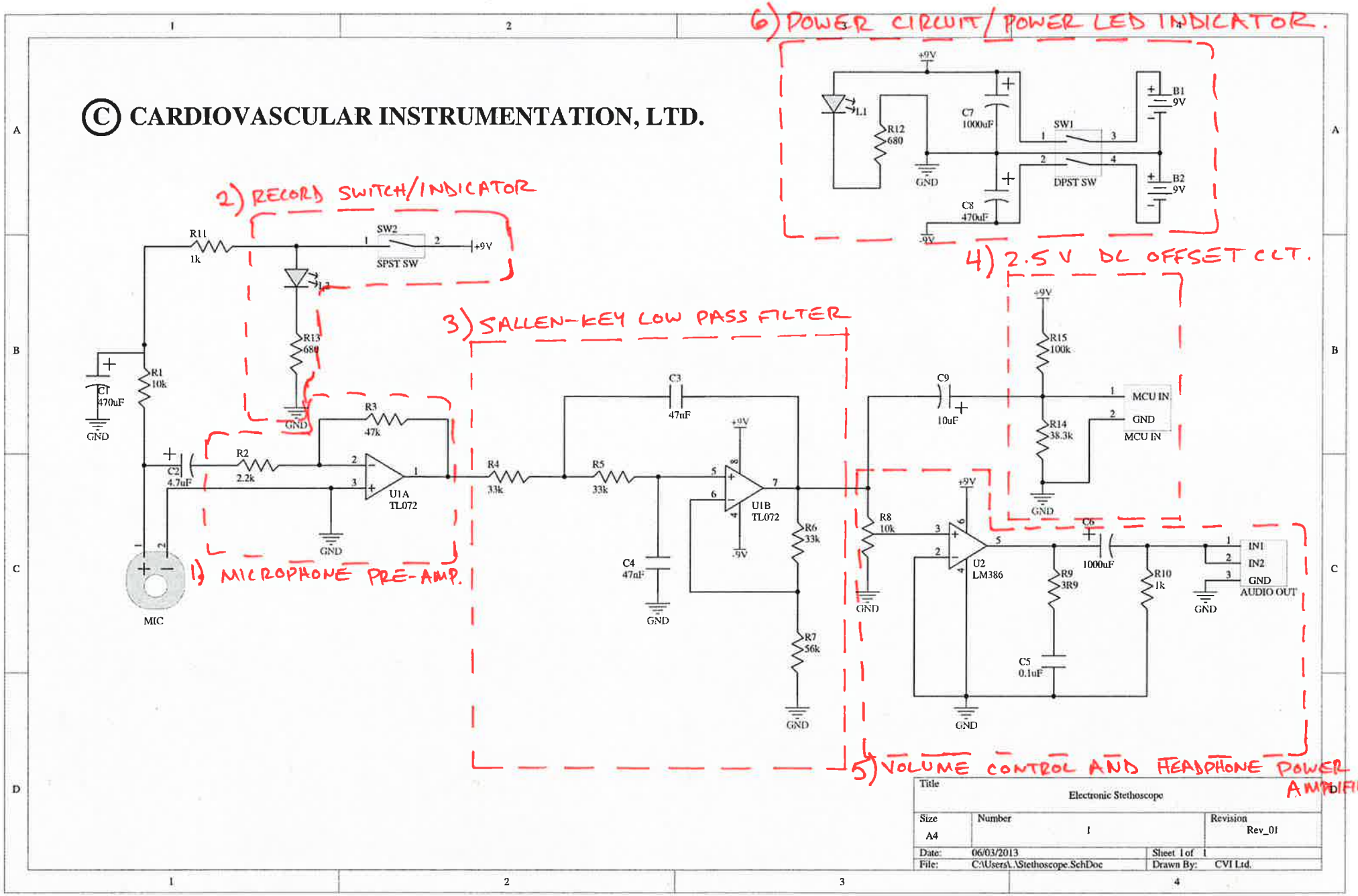
© CARDIOVASCULAR INSTRUMENTATION, LTD.



Title	Electronic Stethoscope	
Size: A4	Number: 1	Revision: Rev_01
Date: 06/03/2013		Sheet 1 of 1
File: C:\Users\..\Stethoscope.SchDoc		Drawn By: CVI Ltd.

APPENDIX B – ELECTRONIC STETHOSCOPE CIRCUIT SUB-COMPONENTS

Please refer to the attached drawing for a stethoscope circuit sub-component segregation.


© CARDIOVASCULAR INSTRUMENTATION, LTD.
6) POWER CIRCUIT / POWER LED INDICATOR.
2) RECORD SWITCH/INDICATOR
3) SALLEN-KEY LOW PASS FILTER
4) 2.5 V DC OFFSET CCT.
1) MICROPHONE PRE-AMP.
5) VOLUME CONTROL AND HEADPHONE POWER AMPLIFIER.
+9V
GND
-9V
L1
R12 680
C7 1000uF
SW1
B1 9V
B2 9V
DPST SW
C8 470uF
R11 1k
SW2
SPST SW
L2
R13 680
R1 10k
C1 470uF
MIC
R3 47k
R2 2.2k
C2 4.7uF
U1A TL072
C3 47nF
R4 33k
R5 33k
U1B TL072
C4 47nF
R6 33k
R7 56k
R15 100k
C9 10uF
MCU IN
R14 38.3k
R8 10k
U2 LM386
C6 1000uF
R9 3R9
R10 1k
C5 0.1uF
IN1
IN2
AUDIO OUT
Title
Electronic Stethoscope
Size
A4
Number
1
Revision
Rev_01
Date:
06/03/2013
Sheet 1 of 1
File:
C:\Users\..\Stethoscope.SchDoc
Drawn By:
CVI Ltd.

APPENDIX C – BILL OF MATERIALS

Please see the attached bill of materials.

Callout	Quantity	Description	Product Number	Unit Price	Extended Price
Electronic Stethoscope Circuit					
R1	1	10K 1/4W Resistor	ERJ-8ENF1002V	$0.12	$0.12
R2	1	2.2K 1/4W Resistor	ERJ-8ENF2201V	$0.12	$0.12
R3	1	47K 1/4W Resistor	ERJ-8ENF4702V	$0.12	$0.12
R4, R5, R6	3	33K 1/4W Resistor	ERJ-8ENF3302V	$0.12	$0.36
R7	1	56K 1/4W Resistor	ERJ-8ENF5602V	$0.12	$0.12
R8	1	2.2K to 10K audio-taper (logarithmic) volume control	270X232A103B2B1	$5.02	$5.02
R10, R11	2	1K 1/4W Resistor	ERJ-8ENF1001V	$0.12	$0.24
R9	1	3.9 Ohm 1/4W Resistor	ERJ-8RQF3R9V	$0.64	$0.64
R12, R13	2	680 Ohm 1/4W Resistor	ERJ-8ENF6800V	$0.12	$0.24
R14	1	38.3K 1/4W Resistor	ERJ-8ENF3832V	$0.12	$0.12
R15	1	100K 1/4W Resistor	ERJ-8ENF1003V	$0.12	$0.12
C1, C8	2	470uF/16V Electrolytic Capacitor	EEE-1CA471UP	$0.90	$1.80
C2	1	4.7uF/16V Electrolytic Capacitor	EEE-1CA4R7NR	$0.57	$0.57
C3, C4	2	0.047uF/50V Metalized plastic-film Capacitor	ECQ-V1H473JL	$0.30	$0.60
C5	1	0.1uF/50V Ceramic disc Capacitor	C1206C104J5RACTU	$0.31	$0.31
C6, C7	2	1000uF/16V Electrolytic Capacitor	EEV-TG1C102UQ	$2.43	$4.86
C9	1	10uF/35V Electrolytic Capacitor	EEE-1VA100WR	$0.54	$0.54
U1 a/b	1	TL072 Low noise, dual op amp	TL072CN	$0.50	$0.50
U2	1	LM386 1/4W power amp	LM386N-1/NOPB	$1.03	$1.03
MIC	1	Two-wire Electret Microphone	CMB-6544PF	$1.24	$1.24
AUDIO OUT	1	1/8" Stereo Headphones Jack	SJ1-3515	$1.65	$1.65
N/A	2	IC 8 Pin Through Hole Socket	1-390261-2	$0.21	$0.42
SW1	1	DPST Toggle Switch	ST242D00	$4.68	$4.68
SW2	1	SPST Toggle Switch	M2011SS1W01/UC	$3.67	$3.67
L1	1	Green LED	SLR-343MCT32	$0.53	$0.53
L2	1	Red LED	SLR-343VRT32	$0.53	$0.53
Microcontroller					
Arduino Uno	1	Arduino Uno R4 Board	N/A	$38.70	$38.70
Arduino Ethernet Shield	1	Arduino Ethernet Shield	N/A	$61.40	$61.40
TL-WR702N	1	Wireless Nano Router	TL-WR702N	$18.19	$18.19
Battery Pack	1	9 Volt Battery Pack 1000 mAh min	N/A	$70.00	$70.00
				Total Price	$218.44

Wireless Auscultation with Decision Support

DATABASE ACCESS AND RELIABILITY SYSTEM INTEGRATION TEST

Prepared By	K. McNiece		
Reviewed By	A. Siddiqui		
Reviewed By	D. Yee		
Approved By	S. Greene		

Document No.	003TS-001-001	Rev: 0

DATE
March 2013

PASS ☐	**PASS** ☐ with deviations listed on p. 3	**FAIL** ☐	**RETEST** ☐

Test ID: DB A&R SIT

Title: Verify Database Access and Reliability SIT

Commencement Date and Time:	Completion Date and Time:
Estimated Duration: 1 Day	Actual Duration:

Project Area: Database

Prerequisites: This test may take place once a preliminary database has been established and the iOS application has developed database interface capability.

I certify that this procedure has been performed according to the procedures detailed herein except as noted, and that the results recorded are accurate and complete.

Tester:	_____	_____	_____
	Name	Signature	Date and Time
Witness:	_____	_____	_____
	Name	Signature	Date and Time

I certify that I have validated the results recorded against the test procedure and the deviations are noted below.

Reviewer:	_____	_____	_____
	Name	Signature	Date and Time

Supporting Documentation:
N/A

Requirements List:
Refer to Prerequisites above.

Scope:
This procedure includes database response time and reliability testing.

Observations

Procedure Overview:
The purpose of this testing procedure is to ensure timely and reliable database access. Prior to the commencement of the test, CVI personnel are to write a testing script for the iOS device interface that will repeatedly push and pull data to and from the database, and record the response times. Data packet sizes are to vary from 50 kB to 10 MB. Response times are to fall within the pass criteria specified below. Speed tests shall be completed manually; endurance reliability testing shall be done by means of the pre-designed script over a set period of time.

Notes:
- One person will be required to complete the testing.
- Use this document to mark the test results. Once the test is complete, remove the test report cover page provided as the last page of this document and staple it to the front of the document.
- Scripting shall be provided at the tester's discretion. Script must be demonstrated to produce reliable results and be included in product documentation.
- Data should be recorded in a recoverable file and attached to test report.
- In this Proof of Concept stage, database reliability is granted some leniency: any failure to adhere to industry standards will be corrected in commercial product.

Deviations / Modifications

Test Case 1 SPEED TESTING

Method: The iOS interface will be configured to transmit and receive data from the database before testing begins. In this test, the tester will manually send and receive packages of varying sizes, ranging from 50 kB to 10 MB, and recording response times and confirm complete and accurate transmission.

Expected Results: Each data package is sent swiftly without error at an average speed of 50 kB/s or greater.

Pass Criteria: No errors are found in transmission of data packages. Each data packet shall transfer with an average speed of 40 kB/s or greater.

Checklist: Data Transfer Speed

Package Number	Package Size (kB)	Transmission Times (s)	Accurate Data Transfer (Tx)?	Accurate Data Transfer (Rx)?	Pass/Fail
1	10		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
2	25		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
3	50		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
4	75		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
5	100		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
6	500		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
7	1000		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
8	5000		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
9	10000		Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )

Test Case 2 RELIABILITY TESTING

Method: The iOS interface will be configured to transmit and receive data to and from the database by means of a tester-written script. The script shall record package size, transmission time, and record successful transmissions. This test will run for seven days; else for as long as time permits. To prevent a buildup of unnecessary data on the servers, the script shall remove data after testing use.

Expected Results: Each data package is sent and received swiftly without error at an average speed of 50 kB/s or greater. All packets are received.

Pass Criteria: 95% of all packets are received. Average transmission speed shall be 40 kB/s or greater.

Checklist: Data Transfer Speed

Package Number	Package Size (kB)	Average Transmission Times (s)	Data Transfer Success Rate (Tx)?	Data Transfer Success Rate (Rx)?	Pass/Fail
1	10				P ( ) / F ( )
2	25				P ( ) / F ( )
3	50				P ( ) / F ( )
4	75				P ( ) / F ( )
5	100				P ( ) / F ( )
6	500				P ( ) / F ( )
7	1000				P ( ) / F ( )
8	5000				P ( ) / F ( )
9	10000				P ( ) / F ( )

Wireless Auscultation with Decision Support

DATABASE ACCESS AND RELIABILITY SYSTEM INTEGRATION TEST

Reference SIT Procedure #: 003TS-00X

Prepared by: _____ _____

Approved by: _____ _____

Name Signature

Document No.	003TS-001	Rev: 0

_____
dd/mm/yy
DATE

Distribution:

☐ CVI Development Team ☐ ENSC Supervisory Committee ☐

☐ CVI Project Management ☐ ☐

Wireless Auscultation with Decision Support

SOFTWARE FUNCTIONALITY SYSTEM INTEGRATION TEST

Prepared By	K. McNiece		
Reviewed By	D. Yee		
Reviewed By	A. Siddiqui		
Approved By	S. Greene		

Document No.	003TS-002-001	Rev: 0

DATE
March 2013

PASS ☐	**PASS** ☐ with deviations listed on p. 3	**FAIL** ☐	**RETEST** ☐

Test ID: SOFTWARE SIT

Title: Verify Software Functionality

Commencement Date and Time:	Completion Date and Time:
Estimated Duration: 1 Day	Actual Duration:

Project Area: Software GUI and Functionality

Prerequisites: This test may take place once visualization, analytic, and user/patient sharing functionality has been added to the iOS software interface.

I certify that this procedure has been performed according to the procedures detailed herein except as noted, and that the results recorded are accurate and complete.

Tester:	_____	_____	_____
	Name	Signature	Date and Time
Witness:	_____	_____	_____
	Name	Signature	Date and Time

I certify that I have validated the results recorded against the test procedure and the deviations are noted below.

Reviewer:	_____	_____	_____
	Name	Signature	Date and Time

Supporting Documentation:
N/A

Requirements List:
Refer to Prerequisites above.

Scope:
This procedure includes software functionality testing, including basic UI, signal representation, analysis, and sharing capabilities.

Observations

Procedure Overview:
In this test, the tester will test the sharing functionality as well as the signal display and analysis capabilities of the software. For sharing test, the tester will ensure that doctors and medical professionals have access to the records of only their patients, and that when a patient is shared, *only* that patient is shared, and only to the intended recipient.

When testing the signal display and analysis, the tester will be provided with a series of sample signals to display. Certain signals will have anomalies in their heartbeats; the data analytics should pick up this anomaly and point out the location.

Notes:
- One person will be required to complete the testing.
- Use this document to mark the test results. Once the test is complete, remove the test report cover page provided as the last page of this document and staple it to the front of the document.
- Sample signals shall be procured from online medical libraries for the purposes of this test.
- In this Proof of Concept stage, fault detection accuracy is granted some leniency: any failure to adhere to industry standards will be corrected in commercial product.

Deviations / Modifications

Test Case 1 USER INTERFACE

Method: The tester will be provided with the User Interface (UI) map included in the design specification. Navigating the software application, the tester will ensure the UI functionality meets that specified. The tester will then attempt to “break” the software by attempting unconventional user operations.

Expected Results: The user interface behaves as expected and does not perform erratically in extreme cases.

Pass Criteria: The user interface behaves as expected and does not perform erratically in extreme cases.

Checklist: User Interface

Test Number	Test Name	Expected Behaviour?	Notes	Pass/Fail
1	User Interface Behaves Normally	Y ( ) / N ( )		P ( ) / F ( )
2	User Interface is Robust	Y ( ) / N ( )		P ( ) / F ( )

Test Case 2 PATIENT SHARING

Method: The tester will create four sample accounts. Two of these, User A and UserB, shall be configured to have unique patient records; the other two, User C and User D, will have access to no patients. The tester will begin by logging into each of the four accounts and ensuring that each is only able to view the patients they have access to initially.

Next, the tester will log in as User A. The tester will share a patient from User A to both User B and User C. The tester will then sign out of User A and check that User B and User C each have access to the shared patient profile, but no other patient profiles, and that User D still has no patients on record. The tester will then repeat this procedure, sharing from User B to Users A and B.

The tester will then attempt to share a patient from User D. No patients should be shareable, and the appropriate error message should result.

Expected Results: In each sharing transaction, the intended recipients will receive the patient information of *only* the patient shared, and no other users aside from the intended recipients should receive this information. When no patients are available to share, the appropriate error message is returned.

Pass Criteria: The system performs as described above, with no exceptions.

Test A: Sharing Functionality

Test Number	Sender	Recipient	Only Desired Information Sent?	Accessible to Unintended Recipients?	Pass/Fail
1	User A	User B	Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
2	User A	User C	Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
3	User B	User A	Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )
4	User B	User C	Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )

Test B: Sharing From Empty User

Test Number	Sender	Recipient	Information Sent?	Error Message Generated?	Pass/Fail
1	User D	All Users	Y ( ) / N ( )	Y ( ) / N ( )	P ( ) / F ( )

Test Case 3 ANALYTIC TESTING

Method: The tester will be provided with several audio files procured from online medical record databases. These files will be loaded into a patient session and visualised for testing. Prior to the test, each audio file will be analysed by trained personnel to identify any irregularities. The software will run an analysis on these files, and attempt to identify the anomalies. The tester will ensure that all anomalies are caught and all signals are clearly and accurately represented on-screen. In this Proof of Concept device, CVI does not expect to attain an ideal algorithm; therefore not all anomalies must be detected to meet the passing criteria. This shortcoming, if it occurs, will be resolved in the commercial product.

Expected Results: Signals are represented on the screen clearly, and all anomalies are detected.

Pass Criteria: 80% of anomalies are detected. Signal is clear and relatively free of noise.

Checklist: Data Transfer Speed

Signal Number	Signal Displayed Clearly?	Anomalies Detected?	Notes	Pass/Fail
1	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
2	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
3	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
4	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
5	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
6	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
7	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
8	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )
9	Y ( ) / N ( )	Y ( ) / N ( )		P ( ) / F ( )

Wireless Auscultation with Decision Support

SOFTWARE FUNCTIONALITY SYSTEM INTEGRATION TEST

Reference SIT Procedure #: 003TS-002-001

Prepared by: _____ _____

Approved by: _____ _____

Name Signature

Document No.	003TS-002-001	Rev: 0

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dd/mm/yy
DATE

Distribution:

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☐ CVI Project Management ☐ ☐

Wireless Auscultation with Decision Support

HARDWARE FUNCTIONALITY SYSTEM INTEGRATION TEST

Prepared By	K. McNiece		
Reviewed By	A. Oudijn		
Reviewed By	A. Siddiqui		
Approved By	S. Greene		

Document No.	003TS-003-001	Rev: 0

DATE
March 2013

PASS ☐	PASS ☐ with deviations listed on p. 3	FAIL ☐	RETEST ☐

Test ID: HARDWARE SIT

Title: Verify Hardware Functionality

Commencement Date and Time:	Completion Date and Time:
Estimated Duration: 2 Days	Actual Duration:

Project Area: Hardware Functionality

Prerequisites: This test has several components. Once an individual hardware system is fabricated for the end product, testing on that sub-system may begin immediately. The final test requires a working database and iOS interface capable of establishing a connection between the Arduino device and the database.

I certify that this procedure has been performed according to the procedures detailed herein except as noted, and that the results recorded are accurate and complete.

Tester: _____ _____ _____
Name Signature Date and Time

Witness: _____ _____ _____
Name Signature Date and Time

I certify that I have validated the results recorded against the test procedure and the deviations are noted below.

Reviewer: _____ _____ _____
Name Signature Date and Time

Supporting Documentation:
N/A

Requirements List:
Refer to Prerequisites above.

Scope:
This procedure describes hardware testing procedures, including analog signal amplification, analog/digital conversion, Signal-to-Noise Ratios (SNRs), and wireless communications.

Observations

Procedure Overview:
In this test, the tester will test the functionality of the analog signal processing circuitry, the analog/digital converter, and the proper storage and transmission of data

Notes:
- One person will be required to complete the testing.
- The tester may use a second person as a test subject for collecting audio data.
- Use this document to mark the test results. Once the test is complete, remove the test report cover page provided as the last page of this document and staple it to the front of the document.
- The functioning Arduino board must be configured before the wireless test takes place, and data must be sent from the registers used to store incoming signal data in the wireless network test.
- In this Proof of Concept stage, database reliability is granted some leniency: any failure to adhere to industry standards will be corrected in commercial product.

Deviations / Modifications

Test Case 1 ANALOG SIGNAL PROCESSING

Method: The tester shall use a test subject or his or her own body to collect an audio signal. The electrical audio signal output shall be collected over a brief time span of several heartbeats using a high-sample rate data collection device. While collecting this data, the tester will simultaneously listen to the audio transmitted through the audio port on high-quality headphones and verify whether the signal is clean and understandable. The Signal-to-Noise Ratio will be estimated based on the data collected. Due to the nature of the device, an accurate calculation may prove difficult, as stethoscopes are prone to picking up environmental noise prior to the signal conversion.

Expected Results: The analog circuitry will produce a clean signal for transmission to the A/D converter, as well as to the headphone jack on the device.

Pass Criteria: The audio signal to the headphones is clear and valuable, and the Signal-to-Noise Ratio estimated from the collected data output shall be greater than 5.

Testing Checklist: Analog Signal Testing

Test Number	Test Name	Notes	Pass/Fail
1	Audio Signal Clarity		P ( ) / F ( )
2	SNR		P ( ) / F ( )

Test Case 2 ANALOG/DIGITAL CONVERSION

Method: The tester will configure the Arduino board to take an analog input to the A/D converter and record the output in a file. The file will then be read by the tester and graphed by the desired means. The tester will compare this digital representation to a direct conversion of an analog signal as generated in Test Case 1.

Expected Results: The digital representation of the signal will match with reasonable accuracy the direct conversion of the analog signal created using the procedure of Test Case 1.

Pass Criteria: The digital conversion of the audio signal from the Arduino board closely matches the analog output from the amplifier circuit. The analog signal is recoverable from the digital signal.

Testing Checklist: Analog-to-Digital Conversion

Test Number	Test Name	Notes	Pass/Fail
1	Digital matches Analog		P ( ) / F ( )
2	Analog recoverable from digital		P ( ) / F ( )

Test Case 3WIRELESS COMMUNICATIONS

Method: The tester will configure the Arduino board to transfer a set of recorded data files from the on-board data storage location to the working database across the wireless network. First the connection must be established through the iOS interface, then the data must be transferred securely to the specified database location and be recoverable in the iOS interface. This is essentially an end-to-end test of product information management capabilities.

Expected Results: The given audio files are recoverable in the iOS interface with no corruption or data loss.

Pass Criteria: All files are transferred correctly with no loss or corruption.

Testing Checklist: Wireless Data Transfer

Test Number	Test Name	Notes	Pass/Fail
1	Data Transfer Completed, Data Recovered		P ( ) / F ( )
2	No Data Loss or Corruption		P ( ) / F ( )

Wireless Auscultation with Decision Support

HARDWARE FUNCTIONALITY SYSTEM INTEGRATION TEST

Reference SIT Procedure #: 003TS-002-001

Prepared by: _____ _____

Approved by: _____ _____

Name Signature

Document No.	003TS-003-001	Rev: 0

_____
dd/mm/yy
DATE

Distribution:

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