Cardiovascular
Instrumentation

8888 University Drive, Burnaby, BC V5A 1S6
Phone: 604-555-5555 Email: CVI_team@cvi.ca

February 11, 2013

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

Re: Function Specifications for Wireless Auscultation with Decision Support

Dear Dr. Rawicz:

Cardiovascular Instrumentation, Ltd., (CVI) is pleased to present the enclosed document, which outlines the functional specifications for their wireless auscultation system with decision support. The goal of our project is to implement an electronic stethoscope that supports automated qualitative auscultation analysis and real-time remote diagnosis via wireless communication.

This document serves as a guide for the system architecture and development needed for mediating the current issue with subjective auscultation analysis using stethoscopes in clinical practice. The proposal gives an overview of the hardware and software components of our system, including a breakdown of functionalities and standards of performance expected.

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

Sincerely,

Scott Greene

Scott Greene
Chief Executive Officer
Cardiovascular Instrumentation

FUNCTIONAL 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	February 11, 2013

FUNCTIONAL SPECIFICATIONS FOR WIRELESS AUSCULTATION WITH DECISION SUPPORT

EXECUTIVE SUMMARY

CVI is founded on the idea that every person in the world deserves the best medical treatment possible. With this idea we strive to expand and simplify wireless medical technology that will allow people in remote areas access to a doctor. Our first product, an electronic stethoscope, is designed to allow a nurse or other trained medical personnel to take samples in the same way a regular stethoscope would be used. These samples will be saved and wirelessly transmitted to a mobile device. This device will be able to do basic analysis and display the samples in a clear visual form. The samples will also be saved on a secure server and may be accessed by and authorized doctor.

Having the ability to save samples on a server will allow a doctor that may not be able to make it to the location or is on route from a different area to view the graphs by downloading them to their own mobile device. This technology will also allow the doctor to track their patient's conditions over an extended time. CVI believes that producing these instruments at a low cost will expand the area of care that a doctor can provide to people in both remote and developing areas.

The main goal in the design of the stethoscope is to create a device that needs very little additional training and is very easy to use. This will be achieved by designing the device to be used just like a regular manual stethoscope. The electronic parts will all be contained within a tough rugged case, extending from this case the microphone will be housed in a head exactly like that of a manual stethoscope. With no differences in shape of feel, a nurse will not have to learn anything new beyond the simple software user interface.

The basic system will have electronic amplifiers and filters designed specifically to capture the sounds needed for medical diagnosis. From here the signal will be transmitted to a microcontroller to be then transmitted via Bluetooth to the mobile device. The case will also contain a battery that will have enough charge to last long enough to appease any medical need.

CVI is lucky to employ one of the strongest software development teams possible. With the wealth of knowledge and ideas flowing into the software design it will be assured to be both easy to use and very effective. The doctor will be able to download and view all the patients data as well as have specific anomalies flagged for easier diagnosis.

This document will outline both the software and hardware functional specifications with their respective sub categories. Several other topics will be covered as well including an outline of the proposed test plan. Please refer to individual sections for more detailed descriptions of the functional specifications of CVI's electronic stethoscope.

TABLE OF CONTENTS

LIST OF FIGURES

GLOSSARY OF TERMS

CVI	Acronym; Cardiovascular Instrumentation
ER	Acronym; Emergency Room
FDA	Acronym; Food and Drug Administration
FFT	Acronym; Fast Fourier Transform
GUI	Acronym; Graphical User Interface
iOS	Apple's Mobile Operating System
UPS	Acronym; Uninterruptible Power Supply

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. The live stream of auscultation sounds can be used for observing heart rate, heart beat patterns and detection of abnormalities. Electronic storage and transmission of data is also supported such that reviewing and forwarding past records is possible. Additionally, the live visual tracking feature of this electronic stethoscope benefits physicians who suffer from hearing disabilities and aid in honing auscultation skills for inexperienced nurses and medical students. The wireless communication of data can also lead to applications in telemedicine where physicians can remotely attend patients. This has a heavy social impact as quality health care can be delivered to rural areas.

1.1 Scope

This document outlines the necessary functional requirements of the CVI Analytical Wireless Stethoscope. Providing a basis for high-level requirements for the proof of concept prototype, future design documents will refer to this document for design revisions. The set of requirements presented will fully describe the functional specifications for the proof of concept system and partially describe the specification for the production device.

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.

1.3 Classification

The following convention is used to describe a functional requirement:

[**Rn-p**]	A functional requirement.

where **n** is the functional requirement number and **p** refers to its priority. The priority is assigned one of three values:

- A Requirement is only applicable to the proof of concept system.
- B Requirement is applicable to the proof of concept and final production system.
- C Requirement is only applicable to the final production system

2 SYSTEM OVERVIEW

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

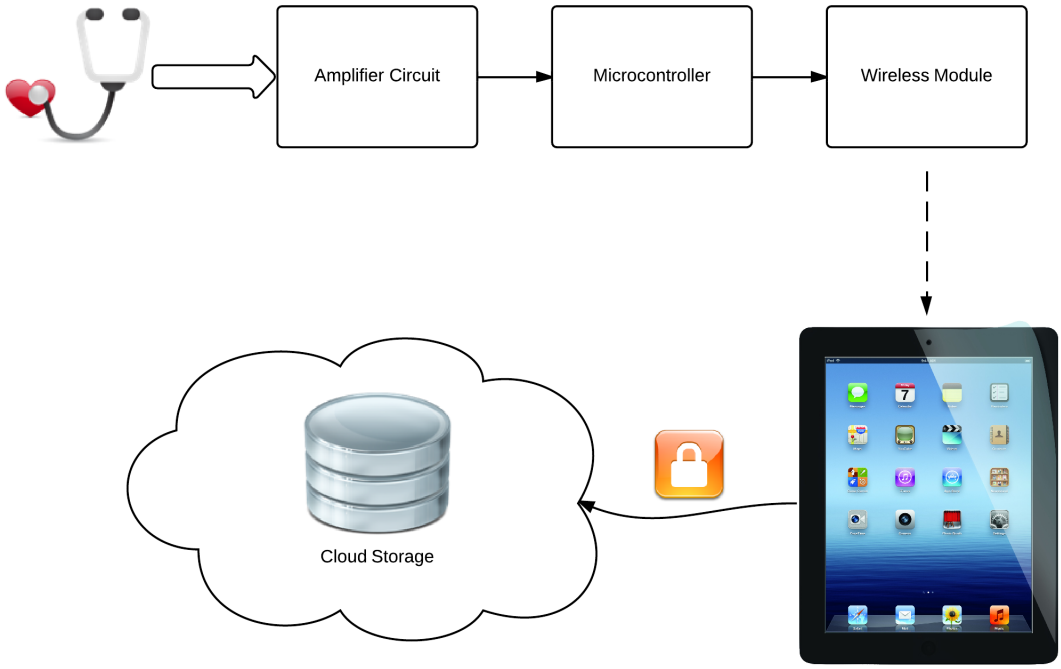

Figure 1: System Overview

The design consists of four major subcomponents: an auscultation device coupled with high-quality digital amplifiers, a wireless transmitter, an iOS application to interpret data, and a central database for storage. 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 iPad where it undergoes analysis specific to the cardiovascular system [1]. The application records the stethoscope data for a total of one minute and displays the information in real-time based on incoming voltage fluctuation relative to time. Upon completion of the examination, the application analyzes the signal to discover the location of S1, S2, S3, and S4 heart pulses and displays the results on screen. Upon detection of abnormalities, specifically heart murmurs, appropriate data will accompany an automatically generated alert.

The electronic auscultation circuit will consist of a number of amplifiers and filter sub-components that will 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 which boosts the signal strength for wireless transmittal.

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 an 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 the detection. This method provides users with a backup to traditional manual auscultation techniques in the event an important murmur goes 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 without major refinement generally associated with a complete product. 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.

2.1 General Requirements

[R1-A] The stethoscope shall be capable of both manual acoustic and electrical digital functionality.

[R2-A] The stethoscope product cost shall not exceed $800.

[R3-A] The stethoscope shall be capable of both manual acoustic and electrical digital functionality.

[R4-A] The system as a whole shall satisfy the requirements of all applicable medical standards, as specified individually herein.

[R5-A] The system shall adhere to all applicable privacy, reliability, and encryption standards necessary to protect patient information.

[R6-B] The stethoscope, amplifier, and transmission hardware must be enclosed in a tamper-resistant structure to prevent unintentional damage or wilful vandalism.

2.2 Physical Requirements

[R7-A] The amplifier and stethoscope apparatus shall be comfortable for a user to hold in his or her hand.

[R8-B] The stethoscope shall be water- and shock-resistant.

[R9-B] The intermediary processing and interface device shall be a reliable, consumer-grade handheld product readily available on the market.

2.3 Electrical Requirements

[R10-A] Stethoscope data collection and transmission shall be battery-powered.

[R11-A] The stethoscope shall have a power switch that enables and disables data transmission. Manual functionality must be maintained regardless of power state or battery charge.

[R12-B] The intermediary device shall be an existing consumer-grade product and have a minimum six-hour battery life.

[R13-B] The servers used for data storage and retrieval shall be hosted remotely by a third party. Servers must back up data and be supported by one or more UPS to ensure continued functionality in a power outage.

2.4 Environmental Requirements

[R14-A] The stethoscope, amplifier, and all communications equipment shall junction normally between the temperatures of 0°C and 40°C.

[R15-A] All equipment shall be fully operational from 0% to 90% relative humidity, noncondensing.

3 HARDWARE REQUIREMENTS

This section will detail the hardware requirements for the wireless electronic stethoscope device. The hardware will consist of three main components. The first component consists of the circuit board that amplifies and filters the signal received from the microphone transducer including the power supply for the circuit. This signal will then be converted to a digital signal and sent to a single board computer with a separate power supply which will prepare the digital signal for wireless transmission. The final component of the hardware for this device consists of the stethoscope case which will house the above mentioned components.

3.1 Microphone, Amplification, and Filtering Circuit Requirements

The amplifier circuit will be entirely contained within the case, with the exception of the microphone transducer which will be external to the case and tethered to the circuit through a shielded cable. The circuit will be used to receive the analog signal generated by the microphone. This signal will then be passed through a preamplifier and then to a low-pass filter. In the last stage of the circuit, the signal will be passed through an amplifier that will prepare the signal for conversion to a digital signal [2]. This signal will then pass through an analog to digital converter (ADC) and then into the single board computer.

[R16-B]	Must not have loose or cold-soldered wires or components
[R17-B]	Dimensions of the circuit board must not exceed 10 cm by 7 cm by 3 cm
[R18-B]	Power supply must be easily accessible for replacement
[R19-B]	Power supply must last at least 10 hours (continuous) without needing replacement
[R20-C]	Must remain operational at temperatures between -20 C and 90 C
[R21-B]	Circuit must be able to detect heartbeat of a human patient and convert to an electrical signal
[R22-C]	Must be easy and intuitive to operate
[R23-B]	On/off switch must be provided for turning on device
[R24-C]	Separate switch must be included to initiate data collection from microphone

3.2 Single Board Computer and Wireless Transmission Requirements

The Raspberry Pi [3] single board computer will be used to receive the digital signal from the amplifying circuit and transmit this signal through a wireless application to the mobile hardware. To achieve this it will need to be able to accept the digital signal without losing accuracy. It will also need to be able to mate with a wireless technology. The single board computer will need to be easy to use and robust as this is a medical application. It should also have a low power draw to increase battery life.

[R25-B] Must have a battery life of at least 4 hours (continuous operation)
[R26-B] Must be able to convert electrical digital signal to wireless signal for transmission
[R27-C] Must be able to transmit wireless signal in real-time
[R28-B] Must be able to accept signal in digital form
[R29-C] Must conform to IEEE 802.15 standards relating to wireless communications [4]
[R30-C] Must not introduce significant error into the signal that is received

3.3 Stethoscope Housing Requirements

The hardware case will house the single board computer, amplifying/filtering circuit board, as well as the power supplies for both components. It must be made light enough for extended use and be resistant to the ingress of water and dust. The case should be able to withstand daily medical use in harsh environments with no loss in accuracy and it should be closed and not easily accessible without the necessary tools to remove the fasteners and access the internal components. The microphone will be housed inside the rubber tubing of a conventional acoustic stethoscope. This will isolate the microphone from picking up unwanted sounds as well as producing a signal that is comparable to the sound produced from an acoustic stethoscope.

[R31-B] Must weigh less than 1 kg
[R32-B] Must be able to withstand a two-foot drop test
[R33-B] Must house all stethoscope electrical components (except microphone transducer which is external to case)
[R34-B] All electrical components inside case must be secured to case so that they cannot shift or move
[R35-B] Microphone transducer must be located in a separate housing for protection as well as sound isolation
[R36-B] Microphone transducer housing must be connected to circuit board housing via a tubing that is comparable in length to a standard acoustic stethoscope
[R37-C] Must be water and dust resistant
[R38-B] Must be able to be closed securely using fasteners
[R39-B] Must be able to be opened easily by removing fasteners to allow for maintenance and battery replacement
[R40-B] Dimensions of the stethoscope case must not exceed 13 cm by 10 cm by 7 cm
[R41-B] Distribution of weight inside case must be uniform such that it is easy to hold
[R42-B] Must include a means of wearing the case around users neck for ease of use
[R43-B] Must be made of a robust and rigid material that will not bend or crack under normal usage
[R44-B] On/off switch must be mounted on the outside of the case

4 SOFTWARE REQUIREMENTS

The iOS application is the primary interface between the stethoscope and the user administering the test. Various information regarding stethoscope analytics including but not limited to waveforms, sound reproduction, automated pre-analysis of S heart pulses, and load/save functions are displayed on the main auscultation testing screen. The application connects to a central cloud-based data storage device capable of providing secure access and storage to patient information. Below are general requirements for the proposed software application.

4.1 GUI Requirements

[R45-A] Upon initial start-up of app, user should be prompted to enter login credentials including unique username and secure password

[R46-A] All content fit within iPad (both non-retina and retina) display

[R47-A] Main screen should incorporate a plotting diagram for stethoscope data, patient information, load/store options, email functionality, and a logout button

[R48-B] Patient access screen will prompt for a care card number corresponding to a specific patient

[R49-A] Plotting diagram for stethoscope data must show real-time tracked information for specific time intervals

[R50-A] Load, share, and store options will display and save to the database, respectively, collected stethoscope information

[R51-C] Email functionality will send alerts with updated stethoscope data to appropriate caregivers

4.2 Analytical Requirements

[R52-A] The signal must transfer appropriate time-converted frequency spectrums to the plotting diagram

[R53-C] The signal must stream from a remotely located physician if additional assessment is needed

[R54-A] The quality of signal must be interpretable by the human ear

[R55-B] Detected S1, S2, S3, and S4 heart pulses will automatically be shown corresponding to their appropriate figures

[R56-C] The deduced labelled components must have less than 2% error compared to current auscultation software analysis programs

[R57-B] A visual alert will be displayed on the screen if any heart murmurs are detected

[R58-A] The system must record the patient's heart rate for one minute

4.3 Database Requirements

[R59-B] The storage of patient information will be organized in a central database
[R60-C] Patient information will be securely backed up using cloud technology
[R61-C] The mobile app will be able to access information pertaining to a specific patient
[R62-B] Data may not be deleted without the primary user's permission

4.4 Security Requirements

[R63-C] Encryption of patient information must meet or exceed current industry standards
[R64-B] Patient information cannot be accessed by any unauthorized users regardless of circumstances
[R65-B] The application will automatically logout after 15 minutes of non-activity
[R66-C] Shared information must be preauthorized by the administrator

4.5 Reliability and Durability Requirements

[R67-C] The database will have 100% uptime 24 hours a day, 7 days a week
[R68-C] Cloud-based data redundancy will store all relevant patient information and analytical data
[R69-B] The app will be able to access the database in a time period no more than 10 seconds
[R70-B] The live stream signal must be transmitted with reliable measures such that the signal is not lost or distorted

5 USER DOCUMENTATION

This section details the functional requirements for the user documentation that will accompany the wireless electronic stethoscope and will assist users in the proper operation of both the hardware and software components of the device.

[R71-B] User documentation must be included in the software application that will inform users of the functionality as well as directions on how to use the application. This documentation will also include a separate section that will aid the user in interpreting the data displayed by the application

[R72-B] A user manual detailing the step-by-step operation of the stethoscope hardware will be printed and included with the product. This manual will also include a troubleshooting section describing common issues and their solutions

6 TEST PROCEDURES

Cardiovascular Instrumentation, Ltd. has produced a series of preliminary testing procedures to ensure proper device functionality. Due to the non-technical nature of this specification, CVI cannot ensure the finality of these documents: under technical review, the details of testing procedures may change to adapt to the chosen integration technologies.

6.1 Database Functionality

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.

6.2 Access Permissions

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.

6.3 Analytics

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.

6.4 Hardware Functionality

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 bot through analog and digital operation of the device. 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 acceptable in the transmission, in either direction.

Test reports will be updated with all unspecified test tolerances upon technical review and specification.

7 CONCLUSION

This document has clearly and succinctly laid out the functional specifications for the Wireless Auscultation with Decision Support electronic stethoscope product and will act as a key guiding document as we move forward into the detailed design phase of this project. The functional requirements have been divided into three categories based on their priority. An 'A' requirement is classified as a high priority requirement that is essential for the operation of the electronic stethoscope and completion of a proof of concept. The 'B' category represents a medium priority requirement that will be required for the product to move from proof of concept to a marketable product. Lastly, 'C' is a low priority requirement that will be implemented in the final consumer product. This three tier system will allow us to focus our time and efforts during the prototyping phase to produce a functioning wireless electronic stethoscope. Once we are satisfied that all high priority requirements have been met, and time permitting, we will move onto the implementation of lower priority requirements.

8 SOURCES AND REFERENCES

[1] Apple Inc. "iPad" (2013) in Apple Inc (Canada) [Online]. Available: http://www.apple.com/ca/ipad/ [Jan. 19, 2013]

[2] Audioguru. (2004, October 20). "Electronic Stethoscope" [Online]. Available: http://electronics-lab.com/projects/science/003 [Feb 4, 2013]

[3] Raspberry Pi. (2013) "FAQs" [Online]. Available: http://www.raspberrypi.org/faqs [Feb 5, 2013]

[4] IEEE Standard for Information Technology – Telecommunications and information exchange between systems – Local and metropolitan area networks – Specific Requirements, IEEE Standard 802.15, June 14, 2005