

Cardiovascular Instrumentation

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

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

Dear Dr. Rawicz:

In compliance to the course requirements for ENSC 305/440, Cardiovascular Instrumentation, Ltd., (CVI) would like to present the following project proposal, "*Proposal for Wireless Auscultation 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 presents the current issue with subjective auscultation analysis using stethoscopes in clinical practice and our proposed solution to mediate such problems. The proposal gives an overview of our project, including a breakdown of our tasks, approaches, sources of information, estimated budget and project scheduling. This proposal also presents some existing solutions and how our proposed solution encompasses areas that can be improved, thus highlighting its market potential.

CVI consists of five motivated senior engineering students: Scott Greene, Kevin McNiece, Andrew Oudjin, Amir Siddiqui, and Dianna Yee. The company profile is also included in this proposal for your reference. 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

PROPOSAL FOR WIRELESS AUSCULTATION WITH DECISION SUPPORT

CARDIOVASCULAR INSTRUMENTATION, LTD.

Document Revision History				
Revision	Description	Date		
1.0	Submission to Dr. Andrew Rawicz and Steve Whitemore	January 21, 2013		

EXECUTIVE SUMMARY

There are currently 7.06 billion people in the world as of the July 2012, roughly 15% of these people live in developed countries that have access to a level of medical treatment [1]. This leaves 85% of the world's population living in countries with varying levels of development. Medical aid is more readily accessible in developed countries with a higher concentration of physicians practicing in densely populated areas. On the other hand many countries have very little access to doctors and the minimal access that they have causes the level of care provided by doctors to be stretched very thin.

The idea of tele-health is a proposed solution to some of the issues related to the many issues associated with the high demand on a low supply of doctors. Tele-health allows doctors to treat patients without even being in the room, or maybe even the same town. This can be very powerful when it may cost a lot of money or time to have a doctor travel to the patient. This idea involves having a nurse use medical instruments to retrieve the vital signals of a patient then using telecommunication technology to the transfer the retrieved signals to a doctor for analysis [2]. Having this information stored and transferred electronically has other added benefits including patient tracking, second doctor opinions, and easy patient information forwarding.

We propose to create a system that will focus on one specific medical instrument, the stethoscope, to prove the concept of a tele-health patient profile. A trained nurse will administer the electronic stethoscope to the patient; the information will then be transferred through a micro controller to an intermediate device such as a tablet or mobile phone. This device will then do basic analysis using software to make the signal into a readable or audible form. From this point the device will upload the information to a database that the doctor has access to. The doctor would then have the ability to download the information to his own device and make opinions from whatever current location he or she is at.

Not only will this increase the amount of people that have access to a doctor, but it will also reduce the cost of healthcare for rural communities if the doctor can remotely administer basic care. Often it is still a good idea to have the doctor see the patient in person, but this technology would allow the doctor to make better use of their time in the area by assessing the patient before they meet. Also allowing the doctor to check up on a patient that could be a very large distance away can reduce the need for the doctor to travel back to the same area.

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GLOSSARY OF TERMS

CVI Cardiovascular Instrumentation

ER **Emergency Room**

FDA Food and Drug Administration

1 INTRODUCTION

The stethoscope is often accredited to an iconic symbol of physicians. The term stethoscope literally translates to "chest-seeing device" and is used for a quick and non-invasive means of diagnosis by relating biological sounds heard to patient physiology. Invented in 1816 by R.T.H. Laennec, the stethoscope has grown in sophistication substantially [3]. Evolving from its early models made out of wood, then later rubbers and metals, the modern stethoscope has gone through several design iterations for improved performance.

The typical modern stethoscope is basic and useful, however, it still is particularly sensitive to subjectivity of the physician or nurse using it. It is predicted that the upcoming generation of stethoscopes will incorporate digitalization in order to improve diagnostic accuracy with amplifying and noise filtering systems [4].

Auscultation is the term used to describe listening to the internal sounds produced by a body for diagnostic purposes. Experience in accurately interpreting auscultation sounds requires regular practice and can take years to hone [5]. With the digitalization of auscultation sounds, decision support systems can aid in providing suggestions based on knowledge-based model created from cumulated medical expertise of experienced physicians. In clinical practice, nurses often use the stethoscope as a quick diagnostic test and only when problems, or suspicion of potential problems arise does the patient gets attended by a physician [5]. Increasing accuracy in this simple process will aid in providing better patient care and can help in educating medical staff members.

With digital stethoscopes, patient signals can be stored, analyzed, and shared amongst professions to help spread medical expertise. Applying digital signal processing can aid in quantifying anomalies when comparing frequencies between healthy and abnormal sounds. In addition, allowing for objective auscultation in real-time is particularly useful in telemedicine applications where a remotely located physician can view the spectral analysis of the biological sounds while listening to the sounds. This is most beneficial for populations living in rural regions where there may be a lack of medical expertise. Remote medical assessment can be a relatively cheaper solution for patient diagnosis and routine checkups in managing diseases since travel costs and time are reduced.

Currently, the support for tele-auscultation, which refers to remote monitoring of auscultation, emphasizes the store-and-forward principle where data is recorded and later reviewed. In this document, we propose a method for wirelessly transmitting auscultation sounds for real-time analysis. Our proposed solution addresses the subjectivity of auscultation with basic anomaly detection while allowing support for real-time tele-auscultation diagnosis. The proposed solution also supports possible extension in assessing other patient vitals. In the following sections, we present an overview of our proposed solution, design considerations and choices, sources of information consulted, budgeting funds and project scheduling.

2 EXISTING SOLUTIONS

In this section, a brief overview of existing technologies used for auscultation, namely the stethoscope, will be presented. The stethoscope is a medical device capable of listening to the sounds produced by the circulatory, respiratory, and gastrointestinal system. Stethoscope can either be acoustic or electronic in nature.

2.1 Acoustic Stethoscope

The acoustic stethoscope is the traditional and most commonly used technology for auscultation and is based on the principle of a changing air pressure that produces sound waves. An acoustic stethoscope can be seen in Figure 1 and consists of three main components:

- Chest Piece: consists of a diaphragm and bell. On one side is the diaphragm which consists of a
 plastic disc that is used to listen to high frequency sounds such as sounds produced by the lungs
 and the heart during normal function. On the other side of the chest piece is the bell which is
 used to listen to low frequency sounds such as potential heart problems such as heart murmurs
 and bowel sounds.
- Tube: consists of a hollow air filled tube which facilitates the transmittal of sound waves from the chest piece to the ear piece for listening.
- Ear Piece: inserted into the ear for listening to the sounds produced by the body.



Figure 1: Acoustic Stethoscope

Despite their longstanding use in the medical field and while still being the most commonly used technology for auscultation, the traditional acoustic stethoscope suffers from a number of drawbacks when compared to newer more advanced electronic stethoscopes. By nature, the acoustic stethoscope is only able to transmit the sound generated by the bell or diaphragm and unable to provide significant amplification of sound. As a result, doctors or nurses who are hearing impaired or working in a loud

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environment such as a busy hospital or the back of an ambulance may have difficulty getting an accurate reading from a patient. Another inherent problem with acoustic stethoscopes relates to the subjective nature of readings and the skill required in order to correctly interpret the sounds heard. The skill of administering a stethoscope test to a patient and interpreting the results heard is a difficult process to become proficient in. Two doctors listening to the same sounds from a patient could potentially come to two different diagnostic conclusions based off of their expertise or past experiences. This can also hinder the learning process for medical students as there is no way to record or listen to the same sound multiple times. This can make it difficult to learn to recognize the more subtle sounds that could suggest a medical issue such as a heart murmur.

2.2 Electronic Stethoscope

In recent years, companies have begun developing electronic stethoscopes that are able to overcome many of the disadvantages of the traditional acoustic stethoscopes as well as providing additional functionality facilitated by the generation of an electronic signal as opposed to the air pressure change produced by acoustic stethoscopes.

Electronic stethoscopes utilize a variety of transducers such as microphones, piezo-electric sensors, or capacitive sensors that are capable of converting sound waves to electronic signals. This electronic signal can then be amplified, filtered, or processed to produce a much louder and clearer sound than is capable of achieving with an acoustic stethoscope. Additionally, having an electronic signal allows the sounds captured by the device to be recorded and stored for playback at a later time. This can make it easier for medical students to learn how to correctly use and diagnose patient illnesses with a stethoscope as well as eliminating the subjectivity of readings as multiple doctors can listen to the same patient and come to a more solid conclusion. The ability to record the sounds produced by a human body using an electronic stethoscope also has applications for telemedicine as patients in remote rural locations can be served by doctors more easily through remote medical assessment.

Digital signal processing can also be performed on the electronic signal generated by the stethoscope and algorithms can be utilized to detect potential abnormalities automatically. This also allows for the electronic signal to be displayed as a graphical output as well as an audio output increasing the diagnostic capability of a doctor as small abnormalities difficult to hear could easily be seen in the signals graphical waveform.

3 SYSTEM OVERVIEW

The Cardiovascular Instrumentation (CVI) Analytical Wireless Stethoscope is to be constructed from high quality, precise audio amplifiers for accurate sound reproduction. The generated signal from the instrument wirelessly synchronizes with a pre-authorized mobile device for signal capture and analysis. The mobile device narrows in on a specific frequency range, as specified by the user, to detect abnormalities in various bodily functions the same way a physician uses auscultation techniques. Figure 2, shown below, outlines the visual display of data collected from the stethoscope.



Figure 2: Visual Display of Stethoscope Data

After the finalization of information analysis on the mobile device, the information is transmitted securely to a patient's medical record stored in a central database. This allows a physician to pull up archived information from the database to view a patient's past examination for further investigation. By depositing crucial patient information in a secure, single location, the physician can make direct comparisons between recent and past diagnostic information to detect any potentially new ailments in a patient.



Figure 3: System Overview

The diagram, shown above, in Figure 3 represents a very high-level overview of the proposed system. Ideally, the intuitive interface and removal of complicated wires creates an easy to use system operable by anyone. Trained professionals will no longer suffer from countless distractions resulting from colleague's misdiagnoses.

As mentioned earlier, the CVI Analytical Wireless Stethoscope interfaces with tele-health type systems via wireless persistent storage in a central database. The database stores vital patient measurements easily accessible by another mobile device via a secure connection. This eliminates the need for a physician to be present in the examination room while another individual administers basic cardiac tests. The physician will have access to a digital replication of the measured heartbeat through the audio jack on their mobile device. With this robust system, wait times and misdiagnosis are a thing of the past.

4 PROPOSED DESIGN SOLUTION

In this section, our proposed design solution for an electronic wireless stethoscope and software application will be presented and discussed along with a high-level overview of functionality and operation of the device.

The proposed design consists of three main components, the audio to electric transducer, the electronic stethoscope, and the software application.

4.1 Audio to Electric Transducer

This component will be responsible for converting the sound waves produced by the patient's internal organs to an electrical signal. It will be located in a housing such that it is isolated from outside unwanted noises yet sensitive enough to pick up internal body sounds. The part of the housing that is placed on the patient's body will be similar in construction to the diaphragm of an acoustic stethoscope but with the transducer spaced slightly away from the diaphragm. A number of technology options including electret and electric microphones, piezo-electric sensors, and capacitive sensors will be investigated during the detailed design phase of this project to determine the appropriate technology which will be best suited for this application.

4.2 Electronic Stethoscope

This component will consist of all circuitry required for the pre-amplification, filtering, and amplification of the electronic signal generated by the microphone. This signal will then be passed to a wireless transceiver for transmittal to a remote mobile device. Since this device is intended to be used in the healthcare industry, high quality components must be utilized to comply with the health and safety standards for medical systems as well as using precise audio amplifiers for accurate and precise sound reproduction. We must also strive to ensure reliability and security in the system as we cannot afford to lose data or incur significant losses in the transfer of data from the stethoscope to the mobile device.

4.3 Software Application

The software application will run on a mobile device such as an iPad/iPhone and provide real-time access to the signal transmitted from the electronic stethoscope. The application will be capable of playing not only the audio, but will also display a graphical representation of the signal on the screen of the mobile device. The user of the application will also be able to select a specific frequency to listen to in the hopes that potential abnormalities will be easier to detect and interpret. This is similar to the process in which physicians use their formal training to listen to particular components of a patient's heartbeat. In addition to real-time viewing of the stethoscope signal on the mobile device, the software application will be capable of saving the signal so that it can be viewed at a later date or transferred to a central database for storage and archival.

A high-level block diagram showing the three components of the proposed design can be seen in Figure 4.

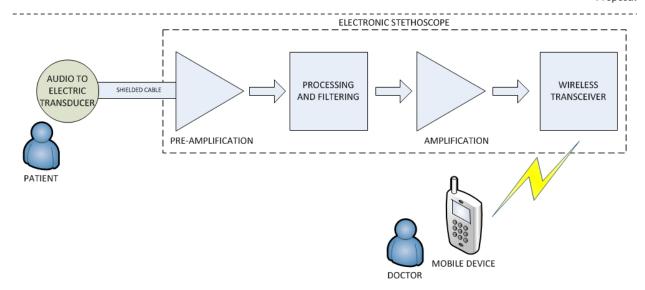


Figure 4: Proposed System Block Diagram

As electronic stethoscopes already exist in the market as well as software applications that can run on mobile devices, the two main features that set our proposed design apart from existing technology is our ability to transmit the stethoscope data wirelessly and in real-time to a mobile device.

5 SOURCES OF INFORMATION

This project was inspired through an interview with a registered nurse in ER who voiced her frustration in the subjectivity that exists in analyzing auscultation sounds. Her experience as a nurse manager has been a very useful in understanding general workflow in hospitals and how this device can be smoothly integrated in current procedures. In refining our proposed project, we have also interview other nurses for a better understanding of the problem at hand and plan to continue seeking their opinions, in addition consulting other health care staff, medical students for their feedback in verifying signals retrieved, anomaly detection and usability.

In addition, we also are referring to the health care regulations outlined by the FDA and coupled with the Canadian standards outlined by Health Canada for compliance with medical device regulations.

For implementing the hardware component of our project, we will be resorting to textbooks, published wireless transceiver protocol implementations, and manufacturer's component specification sheets for the amplifying, signal retrieval and broadcasting circuitry. In addition we will continue to consult several faculty members of the SFU Engineering Science department for their expertise in medical devices, digital signal processing and analog and digital circuit design.

For implementing the software component of our project, we will be resorting to online tutorials for mobile application development and consulting the previously mentioned peoples for their feedback to ensure usability.

6 BUDGET AND FUNDING

Cardiovascular Instrumentation has produced a cost estimate for the research and development of a prototype Analytical Wireless Stethoscope, which is broken down below.

6.1 Budget

Below is the budget breakdown, complete with a 20% contingency.

Table 1: Project Budget

Number	Equipment	Projected Cost
1	Microcontroller (Raspberry Pi - Model B)	\$ 35.00
2	USB Bluetooth Audio Transmitter	\$ 39.99
3	Stethoscope	\$ 141.95
4	USB Mini Microphone	\$ 199.00
5	Wireless Router	\$ 20.00
6	Amplification, transmission and filtering circuitry	\$ 160.00
7	Noise Cancelling Headphones (borrowed)	\$ 20.00
8	Contingency	\$ 100.00
	Total Cost	\$715

6.2 Funding

Funding for this project has been granted by the ESSEF. The team presented a short power point presentation followed by a question period. The team received \$800 in funds with the obligation to return any components used that may be recyclable for future generations of students. The amount granted meets the requirements of this project and no further funding will be sought at this point.

7 SCHEDULE

Cardiovascular Instrumentation has proposed a five-stage project implementation schedule. This schedule consists of the Proposal, Functional Specification, Technical Specification, Implementation, and Testing and Commissioning. Because of the exacting deadlines of the project, Cardiovascular Instrumentation has taken proactive measures in ensuring the preparedness of all staff members: although functional and technical specifications have yet to be completed at the time of this proposal, anticipatory training based on the proposed solution contained herein has already begun for all employees and executives. Training, Design, Implementation, and Construction activities will run in a limited capacity parallel to the specification process, as afforded by the requirements that have been specified to date.

For a detailed project task outline, including a Gantt chart and project flow chart, please refer to Appendix A.

7.1 Proposal

The project proposal stage shall determine the initial scope of the project and include the Project Charter, the Project Scope, Project Plan, and the formal Proposal. The former three documents shall remain internal, with their results summarized in the latter. This Proposal shall also include the proposed design solution.

All team members shall be responsible for the completion of their respective components of the Proposal as outlined in Appendix A. The completed Proposal shall be submitted to the review committee no later than January 21, 2013.

7.2 Functional Specification

The Functional Specification document shall describe, in detail, all functional requirements of the project proposed herein. Kevin McNiece, Amir Siddiqui, and Dianna Yee shall be responsible for specifying all software elements: user interface, data management, signal analysis, and data processing. Scott Greene and Andrew Oudijn shall specify the mechanical and signalling components: the stethoscope and communications device hardware.

Parallel to this specification being written, the software team will educate themselves on relevant software protocols for the determined designed platforms, signal processing algorithms, and application development. The hardware team will research specific requirements for signal processing.

The functional specification shall be completed no later than February 11, 2013.

7.3 Technical Specification

The Technical Specification shall describe, in detail, all requirements of the hardware and software required to meet the functional specifications of the February 11 submission. The hardware and software teams outlined above will specify their respective components. The teams shall simultaneously begin construction and programming of the system. This document shall be submitted no later than 11 of March, 2013.

7.4 Implementation

Hardware and Software streams shall be allotted three weeks of dedicated construction and commissioning time. During this time, all group members will construct the portions of software and/or hardware assigned to them in Appendix A. Commissioning shall be completed no later than April 1, 2013.

7.5 Testing and Commissioning

In order to meet project deadlines, testing and commissioning will begin one week after Implementation begins. Implementation will be modularized so that testing of specific device functions may be completed without interfering with the development process. This testing procedure will continue throughout the implementation stage and be completed no later than April 1, 2013.

8 TEAM ORGANIZATION

8.1 Scott Greene

Scott is finishing his final year at Simon Fraser University. He is majoring in Systems Engineering, while also completing a minor in Computer Science. Some of his recent work includes Project Management with the District of North Vancouver as well as research and development with Ballard Power Systems, a hydrogen fuel cell company. Working on leading edge research at Ballard will give him the necessary skills to develop the hardware systems needed to complete this project.

8.2 Kevin McNiece

Kevin McNiece is a fourth year Engineering Physics student at Simon Fraser University. He brings to the team a cumulative twenty months of co-op work experience: one year working as a Systems Engineer at Pulse Energy, an energy-management software company; and eight months at SNC-Lavalin as a Systems Engineering co-op in Rail and Mass Transit. At Pulse Energy, he coordinated several Energy Management Information System (EMIS) design and installation projects, including the initial stage of BC Hydro's Remote Community Electrification initiative; and spearheaded EMIS hardware R&D. At SNC-Lavalin, he was in charge of technical procurement specifications for the Edmonton North LRT expansion, and acted as Installation Coordinator and a Testing and Commissioning agent on the Calgary West LRT. His project management experience and practical field experience with communications systems will enable him to participate in and coordinate design efforts on this project.

8.3 Andrew Oudijn

Andrew Oudijn is a fourth year Systems Engineering student at Simon Fraser University who has past co-op experience at PBA Engineering Ltd., a consulting engineering firm which focuses on transportation, security, and industrial projects. While working at PBA for three co-op terms as a Junior Design Engineer, Andrew developed skills which include the writing of specification documents, creation of rough order and detailed cost estimates, and design of electrical security and infrastructure projects.

8.4 Amir Siddiqui

Amir is a fourth year Computer Engineering student at Simon Fraser University with cooperative work experience at both Sierra Wireless and Intel of Canada Ltd. Throughout his months at Intel, Amir developed an advanced understanding of the digital design/verification process used in Application Specific Integrated Circuits (ASICs). SystemVerilog, C, and assembly on the ARM A9 processor are three of Amir's most proficient coding languages as a result of his work on the ASICs found on Intel Solid State Drives (SSDs). His exposure to various coding environments makes him an efficient and respectable software developer.

8.5 Dianna Yee

Dianna is a fourth year Biomedical Engineering student with a minor in Computer Science. She has finished three co-op terms working at Macdonald Dettwiler (MDA), Robotics Algorithm & Motion Planning Lab (RAMP), and Electronic Arts (EA) as an associate software engineer. Through her work experience, she was able to hone her programming skills for UI development in flight-trajectory planning, simulation of collision detection in robotics and animation software, low-level memory management and ensuring tool usability.

9 COMPANY PROFILE

The CVI team is comprised of five senior Simon Fraser University engineering students, each an expert in their field. Each individual brings a unique skillset to CVI creating a level of ingenuity apparent in the proposed innovative design plan. Through rigorous design/testing specifications, CVI instrumentation will meet the highest standards in reliability and usability.

CVI follows a standard organization scheme to maximize efficiency and reduce unnecessary overhead. The president and Chief Executive Officer (CEO), Scott Greene, founded this company with one goal – provide cutting-edge biomedical instrumentation at a fraction of the cost of the competitor. His supporting staff includes Kevin McNiece, Chief Operating Officer (COO), Amir Siddiqui, Chief Financial Officer (CFO), Dianna Yee, Chief Software Developer, and Andrew Oudijn, Chief Hardware Developer. The delegation of roles aids in maintaining a rigid structure imperative to the success of CVI.

As with most companies, CVI's weekly team meetings provide an opportunity to synchronize progress between team members and ensure accurate time-management. To prevent squabbling and distractions, a predetermined chair conducts the weekly meetings by outlining specific action and discussion items. Although open discussion seems appealing, especially in a small-group setting, the potential for entropic conversations may prolong the brief sync-up meetings.

Each member of CVI possesses different skillsets, as mentioned above. To maximize each individual's strengths, the project is broken into different sections each emphasizing on particular engineering disciplines. For example, delegating the software aspect of our design to computing science proficient members ensures a more complete/reliable product. Additionally, to prevent potential loss of information and to veer away from biased design choices, each section of the project requires a minimum of two working members. In the event that all five team members are capable of carrying out a certain task, the team lead may pick a maximum of two additional individuals. The corporate staff at CVI foresees disagreements if too many members involve themselves in a single task.

CVI strives to create the most robust and reliable solutions to pave a path for prosperity and integration for the ever-growing medical industry. Mobile devices continue to play an important role in the advancement of medical instrumentation around the world. The ability to communicate information concisely between patients and physicians will help to facilitate routine diagnostics and to prevent lifethreatening emergencies. "CVI offers a better tomorrow through the advancement of technology."

10 CONCLUSION

Cardiovascular Instrumentation is a forward-thinking organization that strives to enable premium health care services to all people both at home and abroad. Our Analytical Wireless Stethoscope will not only afford doctors and nurses quick, detailed access to a patient's medical record at home; but it will also enable tele-health for doctors and nurses in under-staffed remote communities or developing countries.

The Analytical Wireless Stethoscope's preliminary data analysis and fault detection algorithms will assist doctors and nurses in identifying problematic heart signals, and store them on a secure database for medical professionals to access. This not only ensures that fewer improper diagnoses are made, but it also enables doctors and nurses to get a quick second opinion by transmitting the patient's data to another doctor for review.

Cardiovascular Instrumentation sees this device's development as the first step in a new era of tele-health and medical record-keeping: as more devices are interfaced with our secure patient database, and more patients are treated using our devices, patient medical profiles will become more detailed and more accessible to certified professionals, enabling better care for both those living far away and those living next door.

11 **SOURCES AND REFERENCES**

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APPENDIX A - PROJECT WORK FLOW CHART

Please refer to the attached document, "Cardiovascular Instrumentation Project Flow Chart", for Appendix A information.



APPENDIX B - PROJECT GANTT CHART

Please refer to the attached document, "Cardiovascular Instrumentation Gantt Chart", for Appendix B information.

