Cardiowave Technologies
8888 University Drive, Burnaby, BC, V5A 1S6
cardio-wave@sfu.ca

March 19th, 2015

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

RE: ENSC305W/440W Design Specification for a Carotid Artery Ultrasound System

Dear Dr. Rawicz,

The following document, 'Design Specification for a Carotid Artery Diagnosis Tool,' is submitted as a requirement for ENSC305W/440W. The main goal of the project is to develop a less expensive alternative to a full ultrasound system, making it widely available in every doctor's office. As a result, patients who are at risk of a stroke will be able to get faster diagnosis.

The purpose of the specification is to outline the methods that will be used to implement the requirements listed in the functional specification, as well as an accompanying test plan for the software and hardware. Our product, Carotid Artery Real-time Echo's (CARE), is our proposed solution.

Cardiowave Technologies is comprised of four senior engineering students, all from different disciplines: Nick Pizzacalla, Bonnie Ha, Scott Beaupré, and Alexandra Hauser. If you have any questions or concerns, please feel free to contact us through email, at cardio-wave@sfu.ca.

Sincerely,

Alex Hauser

Alexandra Hauser
Chief Technology Officer
Cardiowave Technologies

Enclosed: Design Specification for CARE: A Carotid Artery Diagnosis Tool

Design Specification

for CARE, A Carotid Artery Diagnosis Tool

Revision:	1.10
Submitted To:	Andrew Rawicz
	Steve Whitmore
University:	Simon Fraser University
Contact	cardio-wave@sfu.ca
Written By:	***Cardiowave Technologies***
	Scott Beaupré
	Bonnie Ha,
	Alexandra Hauser
	Nick Pizzacalla
Date:	March 19, 2015

Executive Summary

Cardiowave Technologies is a new company based out of Burnaby, BC and is currently operated by four members. We are aiming to put a new ultrasound based concept on the market that is both effective and affordable. Affordability will be our main focus to establish a competitive edge on the market.

Our design will consist of a pair of ultrasonic transducers: one will produce the emitting waves and will be driven by an oscillator circuit, and the other will receive the reflected waves. These reflected waves will be modified through a few stages of circuitry. First will be amplification, followed by filtering to reduce the overall noise, and finally be converted to a digital signal. Accompanying application software, which can be run on a smartphone or tablet, will process the digital signal. The device will initially be powered and connected through USB, while the final production design will have Bluetooth compatibilities as well as an internal rechargeable battery integrated into it.

Our initial goal is to get our first working prototype done by late-March, 2015. By completing our initial goal, we will be able to produce more advanced systems. By the end of the first year, we hope to have established a credible place on the market with multiple ideas in the making that demonstrate viable competition to the leading technologies. We will also maintain the highest standards of professionalism and integrity to ensure a friendly, creative, and diverse workplace that prides new ideas and hard work.

This document will give an overview of the system along with detailed descriptions of both the hardware and software components. It will also outline specific requirements we must meet in our design that will apply to the proof of concept version, prototype version, and the production version. In conjunction with these requirements, implementations will also be specified to explain how these requirements will be met and will be categorized by a numerical scheme for simplicity.

Table of Contents

List of Figures

List of Tables

Glossary

Word	Definition
ADC	Abbreviation for analog-to-digital converter; outputs a digital signal by sampling an analog signal
AIUM	Abbreviation for American Institute for Ultrasound in Medicine
ALARA	Abbreviation for As low as Reasonably Attainable
CARE	Abbreviation for Carotid Artery Real-time Echoes
CSA	Abbreviation for Canadian Standards Association
DAQ	Abbreviation for data acquisition
GUI	Abbreviation for graphical user interface
IEC	Abbreviation for International Electrotechnical Commission
IEEE	Abbreviation for Institute of Electrical and Electronics Engineers
NEMA	Abbreviation for National Electrical Manufacturers Association
USB	Abbreviation for universal serial bus; an industry standard to transfer data and supply power

1. Introduction

The purpose of the CARE product is to produce a portable, cost-effective, ultrasound system. Designed specifically for detecting carotid artery disease, the product aims to aid in the efforts of providing early diagnosis to patients. The current market cost of ultrasound machines has hindered patients' desires to get tested on a regular basis. As well, due to the current market cost, not all medical professionals have the availability of an ultrasound machine for diagnosis purposes. CARE aims to be a practical solution for all medical professionals and patients, to be proactive about carotid artery disease. The following details the product's system overview, design specifications and how they will be implemented, for all product stages. The testing plan for the current stage of the product is also outlined.

1.1. Background

Ultrasound, or "medical ultrasonography", is a non-invasive, low-risk method of detecting and visualizing biological structures within the body. As shown in Figure 1, a transducer does this by sending a high-frequency sound wave through the tissues and measuring the wave that is reflected back off of structural interfaces.

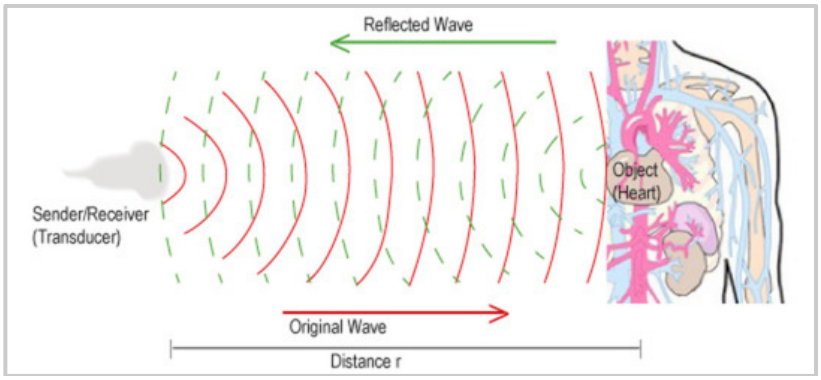

Figure 1: Principle of an Ultrasound [1].

There are three different modes of sonography: A-mode, B-mode, and M-mode. A-mode (Amplitude mode) imaging displays 1D data, which is at one location. B-mode (Brightness mode) imaging displays a 2D image of the internal structures of the body. This uses the entire transducer array and is also the most common type of ultrasound. M-Mode (Motion mode) imaging displays the A-mode scan over time. Using a single transducer, the M-Mode scan enables the user to measure the diameter of the artery, or thickness of plaque, at that location. During the scan time, the artery contracts and relaxes according to systole and diastole blood pressure, and is clearly visible in the M-Mode scan. Our product will utilize the M-Mode scan, to measure the diameter of the artery and to detect plaque.

1.2. Classification of Requirements

In the following sections, the functional requirements will be labelled as follows:

$< Section\ Number >.< Subsection\ Number >.< Requirement\ Number > - < Product\ Stage >$

where Table 1 lists the definitions of each part of the label.

Table 1: Definition of Functional Requirement's Label

Label	Refers To
Section Number	The section or subsection of the functional requirement
Requirement Number	The place of the functional requirement in the current section/subsection
Product Stage	The product stage in which the functional requirement applies must be one of the following: 1. Proof of Concept Version 2. Prototype Version 3. Production Version 4. All versions

2. System Overview

CARE consists of a probe and corresponding software. As shown in Figure 2, the probe uses ultrasound technology against the carotid artery while the software displays the information captured by the probe. The software can be installed on any portable devices, such as a smartphone or tablet. Both components significantly reduce the cost of the product from current ultrasound systems due to its ease of use and portability. Featuring a handheld design and compatible software, CARE is an alternative to traditional ultrasound systems for providing early diagnosis of carotid artery disease.

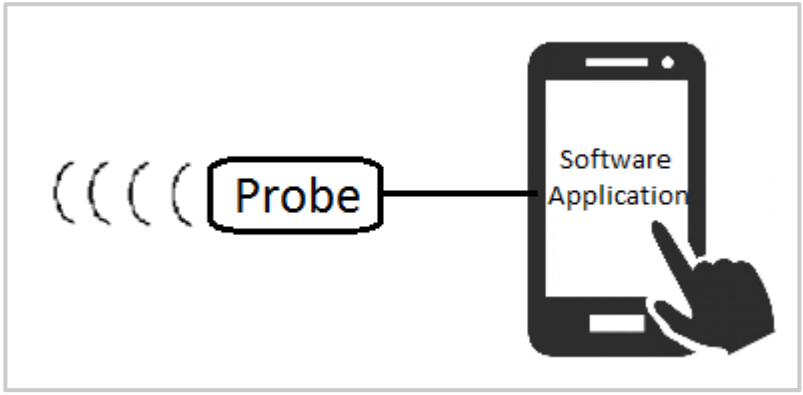

Figure 2: System Overview of CARE

2.1. General Requirements

Table 2 lists the general requirements of the overall system. The justifications of the system stem from maintaining a cost-effective device. In order to make the device simple to use, and incur minimal training, there will be limited hardware and software user inputs. The system will be designed to be as simple as turning it on and acquiring data. The idea behind this is similar to 'point-and-shoot' cameras. A user manual will also be supplied outlining the hardware components, and software interface to create a fast learning curve for users.

Table 2: General Requirements and Implementation

	Requirement	Implementation
2.1.1-3	The system must be simple to operate	Create a user manual, and design a minimal user interface
2.1.2-3	The system must require minimal training	Create a user manual, and design a minimal user interface
2.1.3-3	The system must resale for under $1500 CAD	Cost of parts, including: Olympus Sonopen Transducer, Analog devices board and various circuitry

Regarding requirement 2.1.3-3, the greatest hurdle is the cost of the transducer. In this system, an Olympus Sonopen Transducer will be utilized, costing $611. The remaining circuitry and software is negligible compared to this expense. The reasons for selecting such an expensive transducer will be explained in 3.

2.2. Physical Requirements

Table 3 lists the physical requirements of the system. These requirements are put in place to ensure the user can carry the system and transport it easily, but will not need to hold the system while it is in use. The enclosure will have a handle for ease of carrying and all circuitry will be firmly secured inside. For the proof of concept and prototype versions, a plywood box will be built, due to the wide availability and low expense of the material, and for the production version a plastic box will be designed in SolidWorks and built, as it will be more durable over time and be of better quality.

Table 3: Physical Requirements and Implementation

	Requirements	Implementation
2.2.1-2	The cable connecting the probe to the system shall be long enough to maneuver and easily reach patient	Using a 4-6ft microdot to BNC cable, gives enough length for mobility of user
2.2.2-3	The system must be portable	Build an enclosure with easy grip on it, such as a handle
2.2.3-3	The system must take up less space than a typical ultrasound system	Circuitry will be in a compact enclosure

2.3. Electrical Requirements

Table 4 lists the electrical requirements of the system. The power supply used for each stage will range from the lab bench power supply for the proof of concept version, to having the phone supply the power to the system in all subsequent versions. A battery pack will also be necessary in case of a power interruption from the phone. To protect the hardware, the power driving the transducers will be measured using a DMM, and oscilloscope. For the production version, an automatic shut off of the system will occur after 30 minutes of continuous use. Ultrasound examinations are typically 10 minutes long, for safety reasons, so extra time before and after an examination is given here. The duty cycle will be limited with this feature, and reduce heating and possible damage to the transducer, requiring a system shut down in between patient examinations.

Table 4: Electrical Requirements and Implementation

	Requirements	Implementation
2.3.1-3	The smartphone is used as a power supply for the system.	USB cable is standard and most common among portable devices
2.3.2-3	There must be a back-up power supply.	Battery pack
2.3.3-4	The power at the transducer must be limited to 0.125 watts [2].	Oscillator circuit (driver of transducer) will be tested at output for current and voltage
2.3.4-4	The voltage and duty cycle must be limited [3].	Automatic shut off of power to the transducers, after 30 minutes of continuous use
2.3.5-3	There must be an on/off power switch.	Build in switch to circuit to control hardware and software

2.4. Environmental Requirements

Table 5 lists the environmental requirements for the system. Both requirements are put in place to advise users to not use the product in extreme conditions. The system will be built, tested, and used only indoors under typical conditions.

Table 5: Environmental Requirements and Implementation

	Requirements	Implementation
2.4.1-3	The system must be operated indoors.	Only build, test, and use indoors
2.4.2-3	The system must operate normally at room temperature (25 °C ± 10°C).	Only build, test, and use indoors

2.5. Reliability Requirements

Table 6 lists the reliability requirements for the system. In order to compete with current ultrasound systems, Requirement 2.5.1-3 ensures the life span of the product is comparable to current ultrasound systems.

Table 6: Reliability Requirements and Implementation

	Requirements	Implementation
2.5.1-3	The system must remain reliable for a minimum of 10 years.	Use hardware parts that are rated for extended use

2.6. Safety Requirements

Table 7 lists the safety requirements for the overall system. Requirement 2.6.1-4 is a general safety precaution for handling electronic devices. For all stages, the electronics need to be enclosed in a protective casing. Besides safety precautions with electronic components, the product is a safe device for users and patients, even with ultrasound technology.

Table 7: Safety Requirements and Implementation

	Requirements	Implementation
2.6.1-4	All cables and electronics must be in protective enclosures.	Build a plywood or plastic box, see physical requirements

2.7. Usability Requirements

Table 8 lists the usability requirements of the system. Both requirements are listed for diagnosis purposes. Diagnosis purposes refer to providing accurate and timely diagnosis. Hence, it is necessary for the system to provide real time information about the patient's internal tissue structure.

Table 8: Usability Requirements and Implementation

	Requirements	Implementation
2.7.1-4	The system must display the measured signal in real time	Send receive signal to computer, see software requirements
2.7.2-3	The system must display pulse Doppler in real time	Obsolete

Requirement 2.7.2-3 will not be implemented because to produce a pulse Doppler display, the transducer must be a 2D array of elements. Since we are using two single element transducers, we do not have the data to produce a pulse Doppler image.

2.8. Security Requirements

Table 9 lists the security requirements of the system. Requirement 2.9.1-3 is listed in case the data transmission is intercepted. By encoding the data prior to transmission, regardless of a fault in the transmission protocol, the patient's data will not be exposed to unauthorized personnel.

Table 9: Security Requirements and Implementation

	Requirements	Implementation
2.8.1-3	The system must anonymize/encode patient data over wireless transmission	Create a password protected interface

3. Probe Specifications

The probe will be used to collect information about patients' internal body structures, using ultrasound technology. Figure 3 illustrates the components of the probe. The probe consists of four distinct areas: transducer, oscillator circuit, data acquisition (DAQ), and the USB.

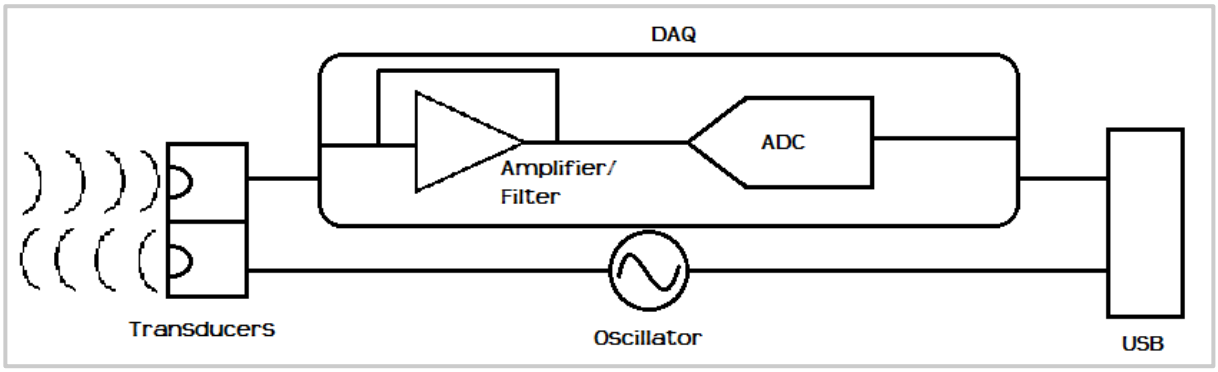

Figure 3: Block Diagram of Probe

The applied alternating voltage will be provided by the oscillator circuit, which we will design to output the appropriate frequency and amplitude. A crystal resonator that vibrates at a certain frequency when coupled to a voltage will provide the oscillations. As the crystal vibrates, an alternating voltage is produced which is then amplified and fed back into the resonator where the output will stabilize at a highly specific frequency. This follows the same behaviour as in the transducer.

3.1. Transducer Design

The transducer sends and receives ultrasound waves. It is possible to use a single transducer to send out a signal and receive the reflected signal. However, this product will utilize two transducers: one for sending out the signal (actuator) and one for receiving the reflected signal (sensor). Using two transducers will reduce the complexity of the circuit by having separate circuits for each transducer.

A single transducer consists of a small piezoelectric membrane, which oscillates when an alternating voltage is applied. As shown in Figure 4: Simple diagram of the piezoelectric effect, this voltage establishes an electric field, which interferes with the polarization (aligned dipole moments) of the molecules within the crystal lattice of the material. Depending on the direction of the electric field, the molecules are either pulled towards or pushed away from the direction of the field causing the membrane to move one way and then the other (i.e. concave,

convex, concave, convex, etc.). Likewise, when mechanically compressed or stretched, a measurable voltage is produced due to the deformation of the dipole moments. We will be using the first of the two conditions.

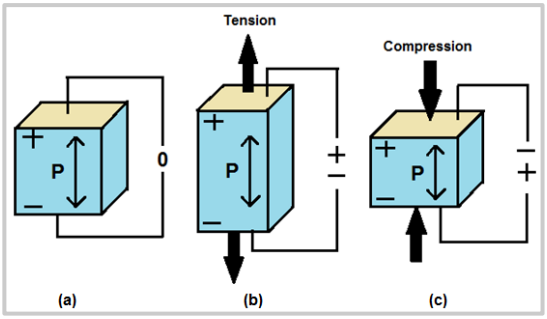

Figure 4: Simple diagram of the piezoelectric effect

Table 10 lists the functional requirements for the transducer. The listed requirements are needed to operate the transducers at a safe and functional manner.

Table 10: Transducer Requirements and Implementation

	Requirements	Implementation
3.1.1-1	The transducer must send signals timed by a function generator	Transducer will driven by the output of the function generator
3.1.2-2	The transducer must send signals timed by an oscillator circuit	Transducer will be driven by the output of the oscillator circuit
3.1.3-3	The transducer must send signals timed by a microcontroller	Transducer will be driven by the output of the microcontroller
3.1.4-4	While in use the transducer must not measure the same tissue for more than 10 minutes at a time	Operating session will be limited to 10 minutes
3.1.5-3	The transducer must be easy to hold and maneuver	Characteristic of Olympus Sonopen
3.1.6-4	The temperature of measured tissue must not increase more than 1 degree centigrade	Operating session will be limited to 10 minutes; hence, measured tissue will not heat up to more than 1 degree centigrade
3.1.7-4	The transducer must be at a frequency higher than 10MHz	A frequency of 15MHz will be used
3.1.8-4	The frequency must be lower than 40MHz	A frequency of 15MHz will be used
3.1.9-3	Must be easily disinfected/sterilized after every use	After each use, the transducer will be disinfected/sterilized
3.1.10-4	Must be water/gel resistant	Characteristic of Olympus Sonopen

Since Ultrasound Systems for medical use typically range from 1-10MHz, this gave us an idea of where to begin. Regarding Requirement 3.1.7-4, we want a higher frequency to obtain a higher resolution signal, so anything higher than 10Mhz was desired. We were also limited by what is

available to purchase; most single element transducers in this range are 10MHz, 15MHz, or 20MHz.

Doing a quick calculation (assuming speed of sound in tissue c = 1540m/s, max attenuation L = 80dB, and attenuation coefficient a = 1dB/cm*MHz), gives a nice approximation of how deep the ultrasound signal will travel into the tissue. The assumption for these variables is that tissue acts very similarly to water, and these values are used commonly as approximations [4].

Using the following equation [4]

$$d_p = \frac{-L}{2af}$$

to calculate the depth of penetration of the signal transmitted by the transducer, we produce Table 11 to determine the specifications of our transducer.

Table 11: Relation between Transducer Frequency and Depth of Penetration

Transducer Frequency (MHz)	Depth of Penetration (cm)
10	4
15	2.6
20	2

Typical carotid artery diameter for women is 5.11 ± 0.87mm, and for men is 6.52 ± 0.98mm [5]. The artery is not very deep into the neck, so these values tell us that a 15MHz transducer will be acceptable for our purpose, balancing image resolution with image depth. The Sonopen from Olympus was a recommended transducer to use for this application. Since we are only using a single element, we avoid many of the complicated calculations involved in transducer probe design and implementation, such as beam-forming and phase delay.

To send and receive signals properly, it can only send a signal once the previous signals echo has attenuated. The pulse repetition interval is calculated using the max depth of penetration, calculated above.

$$T_R \geq \frac{2d_p}{c}$$

The pulse repetition rate, the following equation, gives the number of pulses per second.

$$f_R = \frac{1}{T_R}$$

Using the above values for a 15MHz transducer, the repetition interval is 0.0337 ms, and the repetition rate is 29,000 pulses/second, or frames/second. For medical systems, typically 10-100 frames/second are processed [4]. To reduce processing power for our simple system, we will pulse every half second.

3.2. Data Transmission Design

Data will need to be transferred from the hardware components to the software components to display. Data can be transferred via USB cable. The USB connection is an industry standard for communication and power supply between computers and devices. Both communication and power supply features will be used in our prototype design. The pins of a standard USB consist of 2 for power and 2 for differential data transfer for a total of 4 pins.

Table 12 lists the functional requirements for the data transmission portion of the probe. The method of data transmission depends on the product stage. Requirement 3.2.1 would be an ideal requirement for the production version to improve the system's ease of use. However, for the proof of concept version, requirement 3.2.2 is needed, as it is the required cable for the transducer. In the prototype version, requirement 3.2.3 is the simplest and most common method to physically connect to smartphones. To implement any of the described requirements, the output signal from the ADC would be directed to the specified port.

Table 12: Data Transmission Requirements and Implementation

Requirements		Implementation
3.2.1-3	The data must transmit wirelessly using Bluetooth	From the ADC, direct the signal to a Bluetooth port. Then, program the software to collect data from the receiving Bluetooth port.
3.2.2-1	The data must transmit via BNC cable to oscilloscope	Connect the transducer to the oscilloscope via BNC cable.
3.2.3-2	The data must transmit using USB connection	From the ADC, direct the signal to a USB port. Then, connect the USB port to the smartphone via a USB cable.
3.2.4-3	The software must store patient data securely	Create a password protected software program

To implement requirement 3.2.4, two options were considered to keep medical data confidential: encrypt the data or create a password-protected program. Data encryption involves encoding messages in such a way that it is unreadable for the user unless the user can decrypt the message with the specific encryption code. Although this method protects the data, this method does not deny access to the data. Therefore, the better option would be to make the data password-protected to securely store the data. Password-protection can be implemented by authenticating the user upon launching the program. The user would be required to enter a valid password before viewing any patient data.

3.3. Signal Conditioning Design

Signal Conditioning is required to manipulate the incoming signal to a form that is suitable for the ADC. This will include amplification and filtering. Amplification is done by an inverting circuit as shown in Figure 5. The amplifier takes the input voltage and multiplies it by a controllable

factor depending on the values of the components (resistors, capacitors, inductors, etc.). The filtering is done with similar components as in the amplification; however, the circuit will only allow a certain range of frequencies through, thus reducing the overall noise. Due to their similarities, merging the two will be employed to minimize the overall size and complexity of the circuit.

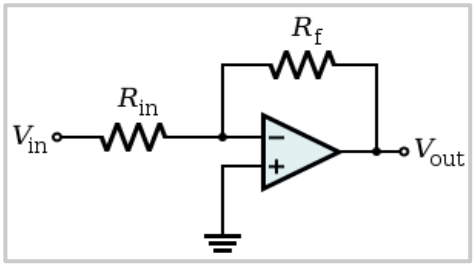

Figure 5: Basic diagram of an amplifying circuit. Output gain = R_f/R_{in}

The ADC is needed to take the analog signal of the sensor and convert it to a digital signal, which can then be used by a digital system such as a computer. This is done by essentially taking measurements of the incoming voltage at distinct time intervals and sending the measured value to the system (computer) in binary where it can then be interpreted and used. Figure 6 illustrates the conversion of an analog signal to a digital signal.

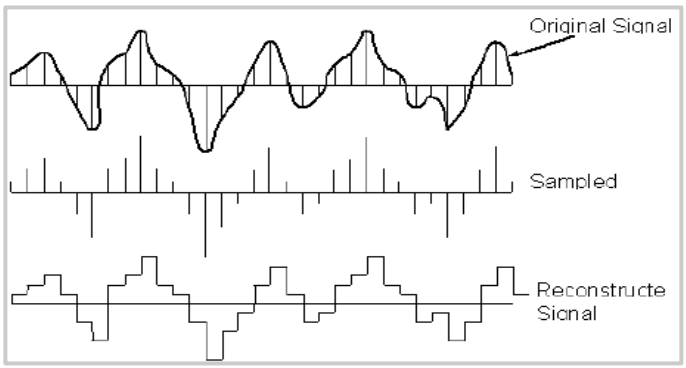

Figure 6: Converting an Analog Signal to a Digital Signal

Table 13 lists the functional requirement for signal conditioning of the probe. The requirement is needed to minimize data loss during the conversion of the signal from analog to digital form. The requirement can be implemented by setting the sampling rate of the ADC to at least 60Mz, since the incoming signal has a frequency of 15MHz.

Table 13: Signal Conditioning Requirements and Implementation

	Requirements	Implementation
3.3.1-4	The analog to digital converter and data acquisition device must operate at 4 times higher frequency than the transducer	Set sampling rate to at least 60MHz

4. Software Specifications

The role of the software is to display the data from the probe. The data will be displayed in two forms: A-mode and M-mode scan. The A-mode scan is simply the amplitude modulation of the radio frequency signal, and the M-mode scan can be acquired from the A-mode. The image is determined by finding the envelope of the A-mode signal. To do this the magnitude of the imaginary part of the signal is calculated, using the Hilbert Transform. The M-mode scan displays the envelope of the signal over time at a specific location. The following describes the implementation details of software to display the two scans. Each implementation detail originated from one of the functional requirements.

4.1. User Interface Design

Table 14 lists the user interface requirements for the software portion of the system. The requirements aim to provide additional information regarding sending and receiving ultrasound waves. The first two requirements provide the execution constraints for the data being displayed. The remaining requirements are needed for diagnosis purposes.

Table 14: User Interface Requirements and Implementation

	Requirements	Implementation
4.1.1-3	The software must indicate on screen the testing parameters	Testing parameters will include the transducer frequency and sampling frequency. This information will be collected from the transducer and ADC.
4.1.2-3	The software must indicate on screen duration of testing	The duration of testing can be determined by starting an on-screen timer when data starts being received and stopping the timer when data is no longer being detected.
4.1.3-4	The software must indicate on screen if plaque is present in artery	Using the incoming raw data, the walls of the artery can be determined.
4.1.4-4	The data must be displayed in real time	The program will handle a constant stream of incoming data by sampling the data in intervals.

To implement requirement 4.1.2, an on-screen timer will be displayed. Since requirement 4.1.4 specifies a constant stream of incoming data, the timer should start when there is incoming data. The timer should stop when a data is no longer being detected after a certain time interval.

5. Product Stages

There are three distinct stages in the product's development: proof of concept, prototype, and production. The design specifications of the first two stages will be detailed below. However, a general outline of the Production stage will be described, as specific details will change as we move through the product stages. Hence, a detailed design of the Production stage would not be accurate at this point.

5.1. Proof of Concept

Our proof of concept is to confirm that our transducers receive appropriate signals. Figure 7 illustrates the setup to test our proof of concept. The setup has two parts: the function generator and the oscilloscope. First, we verify that the function generating circuit outputs a 15MHz signal to the 'sending' transducer. Secondly, we ensure the 'receiving' transducer is receiving is an appropriate signal.

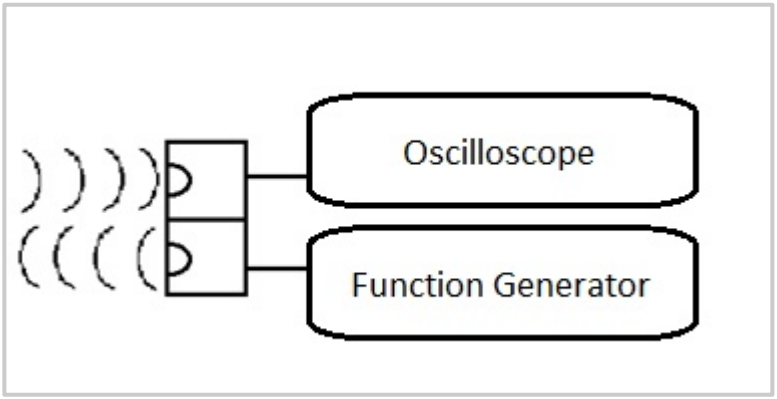

Figure 7: Block Diagram of Proof of Concept

The 15MHz signal is generated via a full can crystal oscillator. It is a simple component that once voltage is applied, produces a steady 15MHz signal in pulses. The signal is not completely sinusoidal and flattens at the bottom regions.

To implement this stage, the transducers will be placed up to a carotid artery of a volunteer. The sending transducer will send a signal and the receiving transducer will pick up the reflected signal. The reflected signal will be displayed onto an oscilloscope via a microdot to BNC cable connection between the transducer and the oscilloscope. Figure 8 displays a representation of the desired signal we want, which shows us the walls of the artery circled in red. In addition, the volunteer will also be tested with the Ultrasonix machine. If the signal on the oscilloscope is similar to what is viewed on the Ultrasonix machine [6] our proof of concept will be completed.

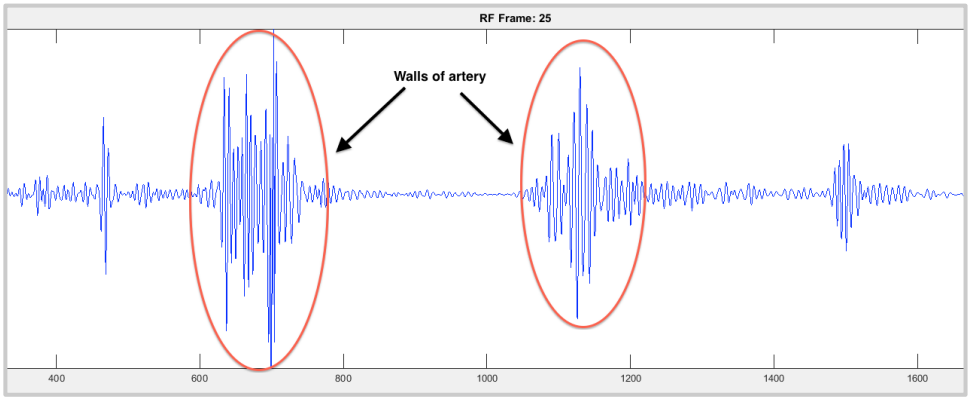

Figure 8: Transducer Signal of Carotid Artery

5.2. Prototype

Once the proof of concept stage is complete, the next step will be to create a working prototype as illustrated in Figure 3. This stage builds on top of the proof of concept by adding an analog to digital converter and a data acquisition circuit, as well as integrating with an application. The prototype will consist of an ultrasound probe, a development board, and a software application. The probe will have the oscillating circuit and two transducers from the proof of concept.

The reflected signal from the receiving transducer will then be sent to the development board. The development board consists of a DAQ circuit, which consists of two parts: signal conditioning section and an ADC. The ADC will sample the signal at four times the rate it is inputted in to reduce data loss. That is, the DAQ circuit will sample the data at a rate of 60MHz since the receiving signal will be 15MHz. In speaking with engineers in the ultrasound field, a sampling rate of four times the generated rate of 15MHz is ideal for imaging purposes, which is common practice. The DAQ circuit will then send the digital data to the software application for processing.

The sampled data will then be sent to the software application. The application will interpret the data and display an M-Mode scan of the carotid artery. It will also display analytics such as minimum and maximum thicknesses of carotid artery, thickness of any obstructions inside the carotid artery, and display systolic and diastolic blood pressure. These analytics are all done via the digital data sent to the application.

The focus for this stage is to ensure the system is completely functional and the data can be computed into viable information for the end user. As signal accuracy is very important in our application, confirmation of accuracy of raw data will come from comparing the data sent to the computer to data gathered from the Ultrasonix machine. We will need to place the transducers very precisely over the same area or object for this comparison.

5.3. Production

After demonstration of the prototype, the production stage focuses on creating an ergonomic enclosed probe and an attractive GUI. The enclosed probe will feature placing the DAQ onto a small chip that fit inside the enclosure. The production version is scheduled to include a B-Mode image of the area that the probe is scanning. In addition, the production version will have Bluetooth capabilities as shown in Figure 9. The Bluetooth transmitter will require allocation for rechargeable batteries within the probe. Using rechargeable batteries, the product will be more useful and intuitive to doctors and patients to detect carotid artery disease. Plaque is usually centered on the area where the common carotid splits into the internal carotid and external carotid, and with a 2D image displayed on the application, this area would be very simple to find.

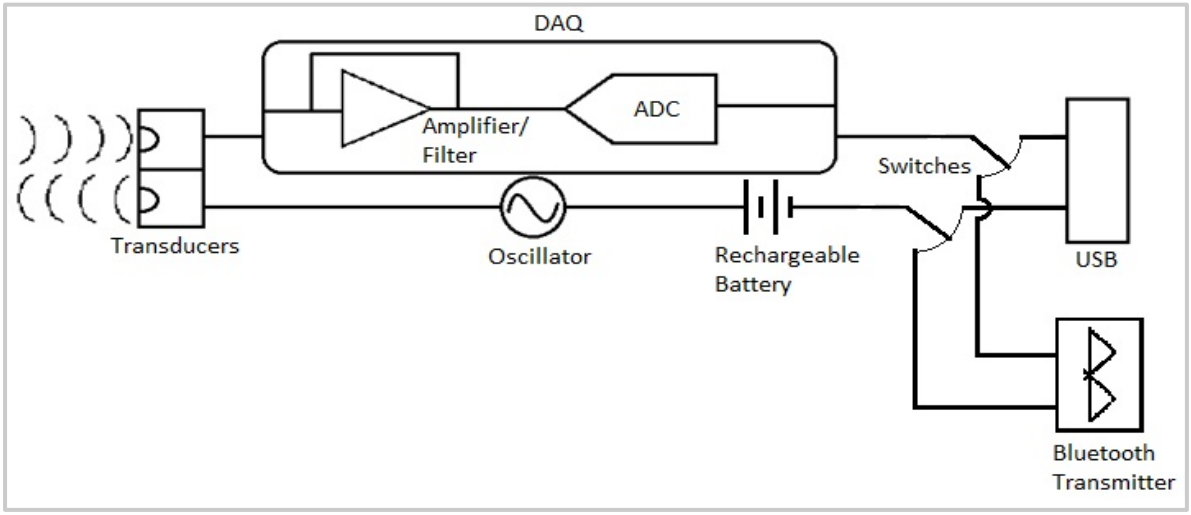

Figure 9: Block Diagram of Production Version

6. Engineering Standards

The regulation of diagnostic Ultrasound Devices is controlled by many groups, specifically in North America; the main standards have been outlined in this document. Following are the major standards produced by IEC (International Electrotechnical Commission), CSA (Canadian Standards Association), NEMA (National Electrical Manufacturers Association), Health Canada, and AIUM (American Institute for Ultrasound in Medicine). For the proof of concept, we will complete a test to measure the temperature increase produced by our system, in tissue. To comply with these standards, we will do a test similar to that used in industry. Ultrasonix leaves a transducer on for thirty minutes, using a piece of rubber to simulate skin, and measures the temperature of the rubber using a thermocouple. The temperature must not increase more than 1°C.

Table 15 lists the engineering standards that the product must comply with. For the proof of concept, we will complete a test to measure the temperature increase produced by our system, in tissue. To comply with these standards, we will do a test similar to that used in industry. Ultrasonix leaves a transducer on for thirty minutes, using a piece of rubber to simulate skin, and measures the temperature of the rubber using a thermocouple. The temperature must not increase more than 1°C.

Table 15: Engineering Standards and Justification

	Requirements	Justification
6.1-3	The system must comply with CSA/ IEC 60601-2	General safety of medical electrical equipment
6.2-3	The system must comply with CSA/IEC 60602-2-37	Safety specific for diagnostic ultrasonic device
6.3-3	The system must comply with CSA/IEC 62359	Cradle-to-cradle lifecycle of product
6.4-3	The system must comply with Health Canada H46-2/01-255E	Safe operation of diagnostic ultrasound devices
6.5-3	The system must comply with NEMA UD 2-2004	Measurement of system parameters
6.6-3	The system must comply with NEMA UD 3-2004	Calculating thermal and mechanical indices

The most important standard is the IEC standards for medical devices, which are separated into two parts. The first part is a general medical device standard, entitled IEC 60601-1 [7], which gives the general safety guidelines for all electrical medical devices. The second part is entitled IEC 60602-2-37 [8], which is the standard specifically for medical ultrasound devices to be used in conjunction with the first part. This particular standard outlines the safety requirements for only diagnostic and not therapeutic ultrasound devices. Also included, is a standard on sustainability, for the cradle-to-cradle discussion, the IEC collateral standard 60601-1-9 outlines environmentally conscious design of medical electrical equipment throughout all stages of the product life cycle [9].

The IEC also has collateral standards pertaining to this project, which include IEC 60529 (Degrees of Protection Provided by Enclosures) [9], IEC 62127-1 (Measurement and Characterization of medical ultrasonic fields up to 40 MHz) [9], IEC 61157 (Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment) [9], and IEC 62359 (Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields) [10]. Many national standards, including the CSA, have adapted the IEC standards, which for medical devices are identical [11], so it is unnecessary to re-list them here under the CSA title.

The NEMA UD 2-2004 (R2009) Revision 3 standard (Acoustic Output measurement and labelling standard for diagnostic ultrasound equipment) [12], outlines the output measurement,

calibration and labelling of the necessary data. This only applies to medical diagnostics, including echo ranging devices.

The following NEMA UD 3-2004 (R2009) rev 2 standard (Standard for real time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment) [13], is specifically for diagnostic ultrasound for human use, and which are also capable of exceeding a thermal or mechanical index of 1.0. This standard is for determining resolution, thermal and mechanical indices, center frequency, and acoustic power. The thermal index can be computed from directly measured properties of ultrasonic field as determined in water (under standard conditions) [14], since it is not feasible to monitor actual temperature. This is split into three main categories: Soft Tissue Thermal Index (TIS), Bone Thermal Index (TIB), and Cranial Bone Thermal Index (TIC) [14]. The AIUM standards have been harmonised with the NEMA standards, and appear as AIUM/NEMA standards [13].

The main difference between these two standards is that the first is focused on the methods of measurement, and the second is focused on methods of computation of the thermal index, which is the acoustic power necessary to achieve a temperature increase of 1 degree Celsius [13].

Health Canada H46-2/01-255E [14] also outlines parameters for thermal and mechanical indices, heavily referencing the above AIUM/NEMA standards. Thermal and mechanical indices should be kept ALARA (as low as reasonably attainable) [14]. Thermal indices must be displayed during testing to assess ultrasonic heating. It has been proven that this is higher during m-mode, pulsed Doppler, and colour Doppler [14]. High mechanical indices typically occur in b-mode and can induce capillary hemorrhaging from the ultrasonic waves, with a higher risk of this occurring in lung and intestine tissue. Due to these risks, the mechanical index must be displayed during any B-mode scanning. To reduce these risks, the best technique is to reduce dwell time of the testing [14]. If undergoing any type of ultrasound, all patients should be informed of exposure and potential risks associated with it. There is very low risk for patients during ultrasound imaging; however, it should only be used for medical reasons [14].

For this project, there are not only safety standards to look at, but Bluetooth as well. For this particular project, Bluetooth data transmission will be implemented. The IEEE Standard 802.15.1-2002 was the standard defining Bluetooth, until 2005 when it was superseded by 802.15.1-2005 for MAC specifications [15]. Bluetooth is now managed by the Special Interest Group (SIG), which oversees development, manages qualification program and protects trademarks.

7. Test Plan

The test plan lists the functional requirements that can be tested. The requirements were selected to verify the major functionalities of our prototype version. The test plan can be found in the Appendix.

8. Conclusion

The design specification includes all pertinent information on our approach to designing our product, CARE. Our design focuses on completing the prototype stage and all software and hardware explanations in this specification are discussed as to reach that stage.

We have taken the time to carefully research the proper equipment and components to borrow and purchase as to both save money and frustration. We purchased multiple items where possible to save waiting/stand-by times in the future if something does go wrong. The design specification lays out how we are building our prototype and clearly describes what is involved in each section of the prototype.

We have all the necessary parts and have completed assembly on various sections of the design. These sections are being tested for consistency. Some key sections still need to be completed. Then, all parts will be integrated together and tested as one. We are on track to have a working prototype by our demo in mid-April.

References

[1] "What is Diagnostic Medical Ultrasound?," Ultrasound Imaging Solutions, [Online]. Available: http://ultrasoundsolutions.net/. [Accessed 22 January 2015].

[2] "Frequently Asked Transducer Questions," Olympus, [Online]. Available: http://www.olympus-ims.com/en/knowledge/ultrasound/applications/transducer-faq/. [Accessed 12 February 2015].

[3] "Ultrasonic Transducer," Olympus, [Online]. Available: http://www.olympus-ims.com/data/File/panametrics/panametrics-UT.en.pdf. [Accessed 12 February 2015].

[4] J. L. Prince and J. M. Links, "Medical Imaging Signals and Systems," 2nd ed., Upper Saddle River, NJ: Pearson Education, Inc., 2015.

[5] Y. Limbu et al., "Assessment of carotid artery dimensions by ultrasound in non-smoker healthy adults of both sexes," 8 Sept 2006. [Online]. Available: http://www.ncbi.nlm.nih.gov/pubmed/17203830. [Accessed 17 March 2015].

[6] L.-K. Merhi, G. Wu and D. C.Y. Cheng, "Biomedical Instrumentation Sonix CEP User Manual," SFU, Burnaby.

[7] International Electrotechnical Commission IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety," 2004. [Online]. Available: http://webstore.iec.ch/webstore/webstore.nsf/ArtNum_PK/46826. [Accessed 11 February 2015].

[8] International Electrotechnical Commission IEC 60601-2-37, "Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment," 2007. [Online]. Available: http://webstore.iec.ch/webstore/webstore.nsf/artnum/038208!opendocument . [Accessed 11 February 2015].

[9] International Electrotechnical Commission IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety - Withdrawn," 2001. [Online]. Available: http://webstore.iec.ch/p-preview/info_iec60601-2-37%7Bed1.0%7Den.pdf. [Accessed 15 February 2015].

[10] International Electrotechnical Commission IEC 62359, "Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields," 2005. [Online]. Available: http://webstore.iec.ch/webstore/webstore.nsf/artnum/044596!opendocument . [Accessed 15 February 2015].

[11] "CAN/CSA-C22.2 NO. 60601-2-37-08 (R2014)," CSA, 2008.

[12] NEMA Standards Publication AIUM/NEMA UD 2-2004, "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3," National Electrical Manufacturers Association, Rosslyn, VA; American Institute of Ultrasound in Medicine, Laurel, MD, 2004b.

[13] NEMA Standards Publication AIUM/NEMA UD 3-2004, "Standard For Real-Time Display of Thermal and Mechanical Acoustic Output Indices On Diagnostic Ultrasound Equipment, Revision 2," National Electrical Manufacturers Association, Rosslyn, VA; American Institute of Ultrasound in Medicine, Laurel, MD, 2004.

[14] Ministry of Public Works and Government Services Canada, "Guidelines for the safe use of diagnostic ultrasound," 2001. [Online]. Available: http://publications.gc.ca/site/eng/104000/publication.html. [Accessed 11 February 2015].

[15] "802.15.1-2005 - IEEE Standard for Information Technology," IEEE Standards Associations, 2010. [Online]. Available: http://standards.ieee.org/findstds/standard/802.15.1-2005.html . [Accessed 11 February 2015].

Appendix

Test Plan	
Group 13 - Cardiowave Tech	Date:
Hardware Components	
1. Transducer • Send a 15MHz signal ☐ Yes ☐ No	Comments:
2. Signal Conditioning • Sample the signal at 4 times the transducer frequency ☐ Yes ☐ No	Comments:
3. Data Transmission • Send data via USB connection to external device ☐ Yes ☐ No	Comments:
Software Components	
4. Display radio frequency signal ☐ Yes ☐ No	Comments:
5. Display M-mode image ☐ Yes ☐ No	Comments:
6. Display operating conditions: • Transducer frequency • Sampling frequency ☐ Yes ☐ No	Comments:
7. Display duration of testing ☐ Yes ☐ No	Comments:
8. Indicate the walls of artery ☐ Yes ☐ No	Comments:
9. Display data in real-time ☐ Yes ☐ No	Comments: