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February 16th, 2015

Dr. Andrew Rawicz
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RE: ENSC305/440 Functional Specification for Carotid Artery Ultrasound System

Dear Dr. Rawicz,

The following document, 'Functional Specification for CARE: A Carotid Artery Diagnosis Tool', is our functional specification document for ENSC305/440. The main goal of this project is to develop an inexpensive alternative to a full ultrasound system, making it widely available in every doctor's office. This would result in faster diagnosis for patients at risk of stroke.

This document's purpose is to outline the product we wish to develop. Carotid Artery Real-time Echo's (CARE) functional requirements are listed, as well as justifications for each one. Also included is the cradle-to-cradle sustainability for each development cycle, and the main standards associated with diagnostic ultrasound medical devices.

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: Functional Specification for CARE: A Carotid Artery Diagnosis Tool

Functional Specification

for CARE, A Carotid Artery Diagnosis Tool

Written by:

Cardiowave Technologies – Scott Beaupré, Bonnie Ha,

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February 16, 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. The digital signal will be processed by accompanying application software which can be run on a smartphone or tablet. 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. This will lead to improving and producing more 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 as well as all the requirements and standards we will be following throughout the project. These requirements will apply to the proof of concept version, prototype version, and the production version and will be categorized by a numerical scheme for simplicity.

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1. Introduction

The purpose of the CARE product is to produce a portable cost-effective ultrasound system. Designed especially for detecting carotid artery disease, the product aims to aid 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, functional specifications, product stages, engineering standards, and sustainability considerations.

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.

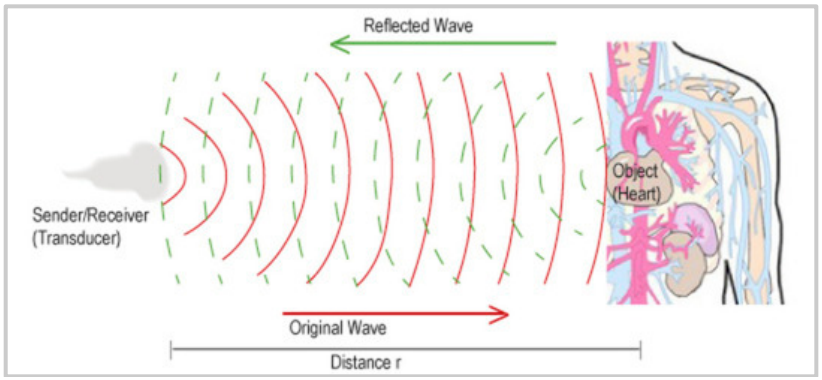

Figure 1: Principle of an Ultrasound. [1]

There are five different modes of sonography: A-mode, B-mode, M-mode. A-mode (Amplitude mode) imaging displays 1D data, at one location of an artery over time. 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. [2] M-Mode (Motion mode) imaging displays the same A-mode scan over time. Using a single transducer, this enables the user to measure the diameter of the artery, or thickness of plaque, at that location. During this scan time, the artery contracts and relaxes (systole and diastole), and is clearly visible. [2] Doppler mode is used to measure the blood flow through the arteries, [2] and in some cases color codes the B-mode scan it is overlaid on to visually describe the flow velocity and direction. [2] Our product will utilize, at least initially, the Colour Doppler mode. As the name implies, it uses the Doppler Effect to provide information about velocity of blood flow. Figure 2 depicts a 2D plane of the coloured blood in a carotid artery. The reflected wave's frequency is altered

due to the velocity of the blood flowing either towards or away from the source. This change is directly related to how fast the blood is flowing.

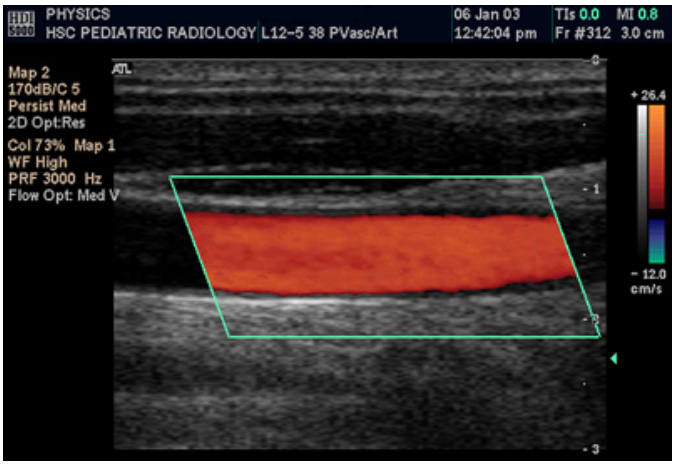

Figure 2: Colour Doppler Scan of the Common Carotid Artery. [3]

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 3, the probe uses ultrasound technology against the carotid artery while the software displays the information captured by the probe. 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.

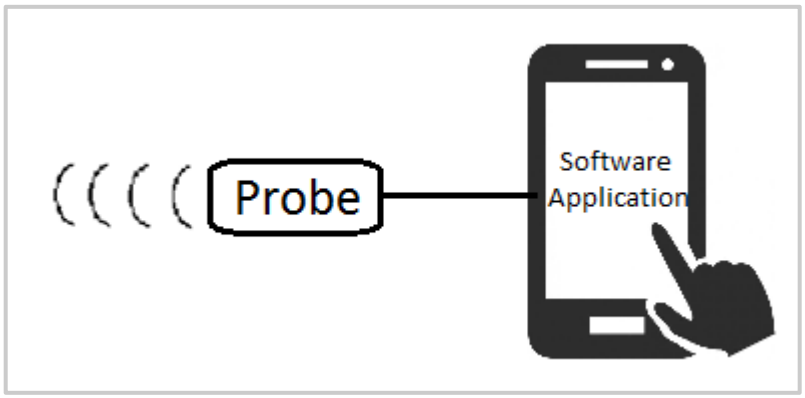

Figure 3: System Overview of CARE

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.

Table 2: General Requirements & Justification

	Requirement	Justification
2.1.1-3	The system must be simple to operate	To minimize the cost of additional training
2.1.2-3	The system must require minimal training	To minimize the overall cost of product
2.1.3-3	The system must resale for under $1500 CAD	To compete competitively with existing ultrasound systems

2.2. Physical Requirements

Table 3 lists the physical requirements of the system.

Table 3: Physical Requirements and Justification

	Requirements	Justification
2.2.1-2	The cable connecting the probe to the system shall be long enough to maneuver and easily reach patient	For product to be usable
2.2.2-3	The system must be portable	For versatility, such that product may be used in a non-hospital settings
2.2.3-3	The system must take up less space than a typical ultrasound system	For portability and to compete competitively with existing ultrasound systems

2.3. Electrical Requirements

Table 4 lists the electrical requirements of the system.

Table 4: Electrical Requirements and Justification

	Requirements	Justification
2.3.1-3	The phone is used as a power supply for the system	To power the system without need for outside sources
2.3.2-3	There must be a back up power supply	In case of power interruption during testing of patient
2.3.3-4	The power at the transducer must be limited to 0.125 watts [4]	To prevent damage to transducer
2.3.4-4	The voltage and duty cycle must be limited.	To prevent transducer overheating [5]
2.3.5-3	There must be an on/off power switch	For usability purposes

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.

Table 5: Environmental Requirements and Justification

	Requirements	Justification
2.4.1-3	The system must be operated indoors	To ensure electronic components function in ideal conditions
2.4.2-3	The system must operate normally at room temperature (25 °C ± 10°C)	To ensure electronic components function in ideal conditions

2.5. Reliability Requirements

Table 6 lists the reliability requirements for the system. In order to compete competitively 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 Justification

	Requirements	Justification
2.5.1-3	The system must remain reliable for a minimum of 10 years	To justify the cost of the product to potential buyers

2.6. Safety Requirements

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

Table 7: Safety Requirements and Justification

	Requirements	Justification
2.6.1-4	All cables and electronics must be in protective enclosures	To protect electronics from liquids and wet environments

Ultrasound technology is generally viewed as a safe technology. Through numerous studies, two major bio-effects of ultrasound waves were considered: thermal effects and mechanical effects. The thermal effects of absorbed ultrasound waves by body tissues were examined. [6] The mechanical effects were examined based on the intensity and frequency of the ultrasound waves, as well as the duration of exposure. [7] However, there has not been any conclusive evidence to suggest ultrasound technology is harmful. Nonetheless, the cautionary use of ultrasound technology should be restricted for medical purposes.

2.7. Usability Requirements

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

Table 8: Usability Requirements and Justification

	Requirements	Justification
2.7.1-4	The system must display the measured signal in real time	For diagnosis purposes
2.7.2-3	The system must display pulse Doppler in real time	For diagnosis purposes

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 Justification

	Requirements	Justification
2.8.1-3	The system must anonymize/encode patient data over wireless transmission	To prevent patient confidential violation

3. Probe Specifications

The probe will be used to collect information about patient's internal body structures, using ultrasound technology. Figure 4 illustrates the components of the probe. The probe consists of four distinct areas: transducer, oscillator circuit, data acquisition (DAQ), and the USB.

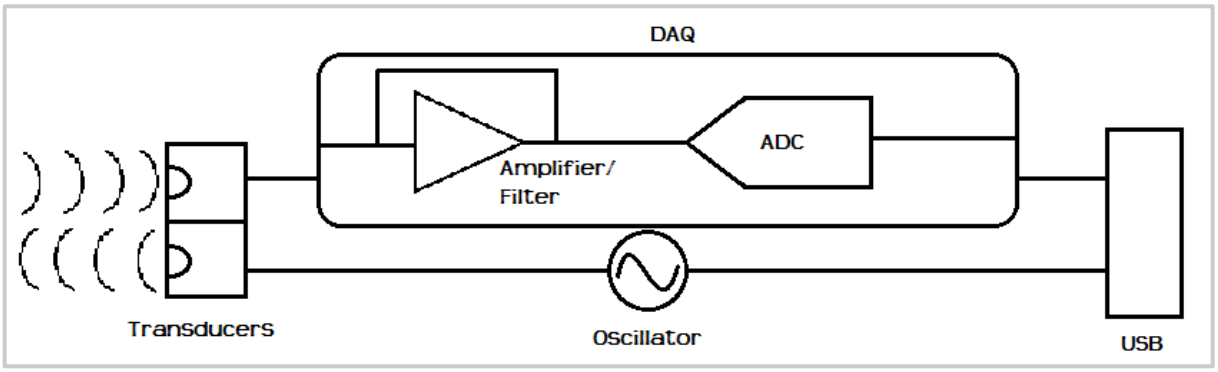

Figure 4: Block Diagram of Probe

The transducer sends and received 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 to specifically send the signal (actuator) and one to receive the reflected signal (sensor). The reason for using two transducers is to reduce the complexity of the circuit by having separate circuits for each transducer.

The oscillator circuit applies an alternating voltage. The output will be designed to produce the appropriate frequency and amplitude to acquire adequate information about the patient's health status.

The DAQ consists of Signal Conditioning and an Analog-to-Digital Converter (ADC). Signal Conditioning is required to manipulate the incoming signal to a form that is suitable for the ADC. The ADC is needed to take the analog signal of the sensor and convert it to a digital signal that can then be used by a digital system such as a smartphone. To ensure the system has enough data points to reconstruct the analog signal without error, it is necessary for the ADC to

have a sample rate which is at least 4x the frequency of the incoming signal. Figure 5 illustrates the conversion of an analog signal to a digital signal.

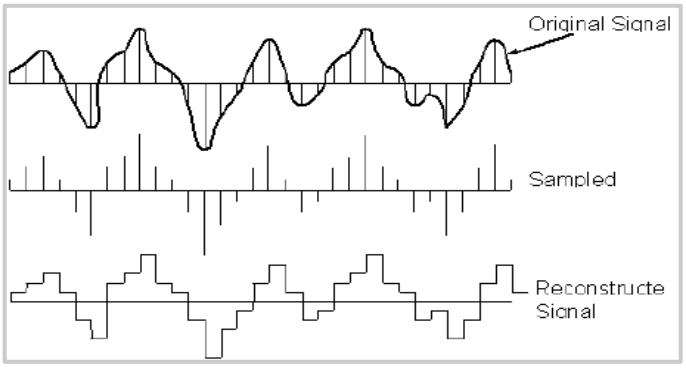

Figure 5: Converting an Analog Signal to a Digital Signal

The USB is an industry standard for communication and power supply between computers and devices. Both features will be used in our prototype design.

4.1. Transducer Requirements

Table 10 lists the functional requirements for the transducer.

Table 10: Transducer Requirements and Justification

	Requirements	Justification
3.1.1-1	The transducer must send signals timed by a function generator	Simplest way to operate system
3.1.2-2	The transducer must send signals timed by an oscillator circuit	Component to integrate into system
3.1.3-3	The transducer must send signals timed by a microcontroller	More compact and reliable
3.1.4-4	While in use the transducer must not measure the same tissue for more than 10 minutes at a time	Safety requirement to reduce thermal and mechanical effects, see standards
3.1.5-3	The transducer must be easy to hold and maneuver	For ease of use by system operator
3.1.6-4	The temperature of measured tissue must not increase more than 1 degree centigrade	Safety requirement
3.1.7-4	The transducer must be at a frequency higher than 10MHz	Need enough resolution to diagnose plaque
3.1.8-4	The frequency must be lower than 40MHz	Signal can't attenuate before the end of the artery
3.1.9-3	Must be easily disinfected/sterilized after every use	To reduce infection transmission between patients
3.1.10-4	Must be water/gel resistant	To not damage transducer, or create electrical hazard

4.2. Data Transmission Requirements

Table 11 lists the functional requirements for the data transmission portion of the probe.

Table 11: Data Transmission Requirements and Justification

	Requirements	Justification
3.2.1-3	The data must transmit wirelessly using Bluetooth	This removes need for wires, and makes the system easier to use
3.2.2-1	The data must transmit via BNC cable to oscilloscope	Required cable for transducer
3.2.3-2	The data must transmit using USB connection	Main way to connect system to phone
3.2.4-3	The software must store patient data securely	Medical data is confidential

4.3. Signal Conditioning Requirements

Table 12 lists the functional requirements for signal conditioning of the probe.

Table 12: Signal Conditioning Requirements and Justification

	Requirements	Justification
3.3.1-4	The analog to digital converter and data acquisition device must operate at 4 times higher frequency than the transducer	This ensures minimal data loss when sampling

4. Software Specifications

The role of the software is to display the data from the probe. The following lists the functional requirements of the software.

4.1. User Interface Requirements

Table 13 lists the user interface requirements for the software portion of the system.

Table 13: User Interface Requirements and Justification

	Requirements	Justification
4.1.1-3	The software must indicate on screen the testing parameters	For operator knowledge to adhere to safety standards
4.1.2-3	The software must indicate on screen duration of testing	For operators knowledge of testing duration to adhere to safety standards
4.1.3-4	The software must indicate on screen if plaque is present in artery	To aid in the diagnosis of carotid artery disease
4.1.4-4	The data must be displayed in real time	To aid in diagnosis

5. Product Stages

There are three distinct stages in the product's development. The following outlines the characteristics of each stage.

5.1. Proof of Concept

The proof of concept is to confirm the transducer and circuit sends appropriate raw data to the computer. Figure 6 illustrates how components of the probe in this stage. To verify this functionality, the raw data collected by the transducer will be compared with the raw data collected from the Ultrasonix ultrasound machine. Although the proof of concept stage seems quite rudimentary, it is a necessary stage to prove that the transducer is functioning as expected.

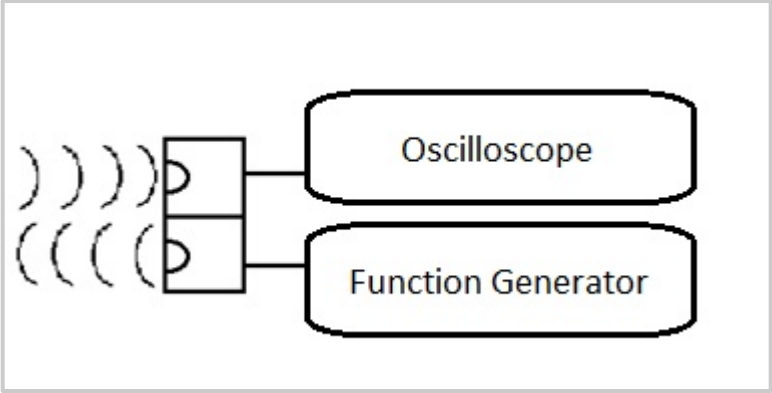

Figure 6: Block Diagram of Proof of Concept

5.2. Prototype

Once the proof of concept phase is complete, the next stage will be to create a working prototype as illustrated in Figure 4. The prototype will consist of an ultrasound probe and a smartphone application. The probe will detect the carotid artery and send data, which includes artery thickness and material thickness inside the artery, via USB to the connected smartphone. The application on the phone will then interpret the data and display an M-Mode scan of the carotid artery. It will also display the minimum and maximum thicknesses of carotid artery, thickness of any obstructions inside the carotid artery, and display systolic and diastolic blood pressure. The focus for this stage is to ensure the system is functional.

5.3. Production

After demonstration of the prototype, the production stage focuses on creating an ergonomic probe and an attractive GUI. 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 7. This will make the product more useful and intuitive to the

doctor and patient as it would make detecting carotid artery disease more efficient. Plaque is usually centered on the area where the common carotid splits into the internal carotid and external carotid, and with a 2-D image displayed on the smartphone, this area would be very simple to find.

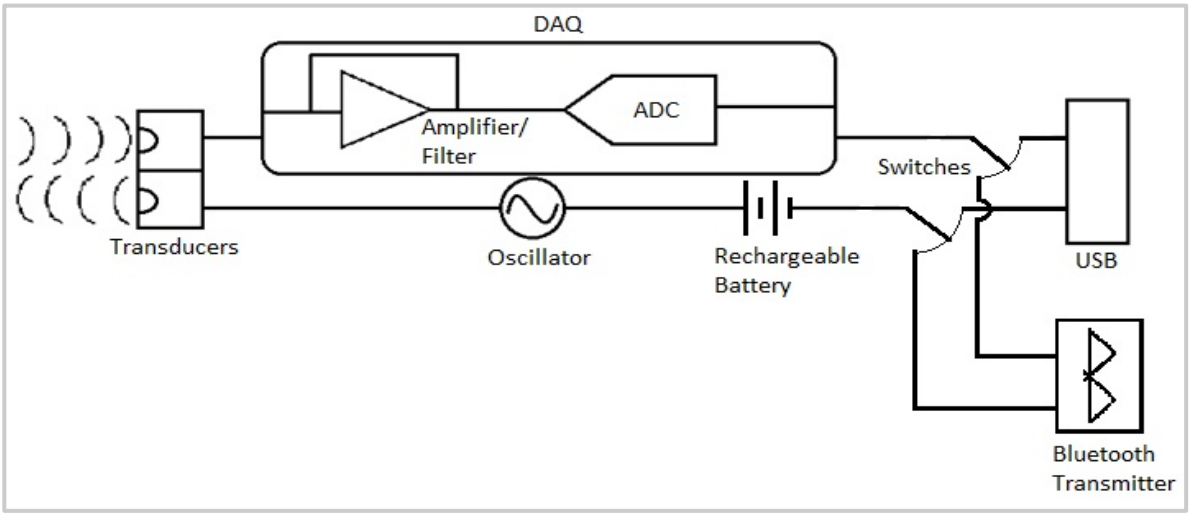

Figure 7: Block Diagram of Production Version

6. Engineering Standards

The regulation of diagnostic Ultrasound Devices is controlled by many groups, and 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). Table 14 lists the engineering standards that the product must comply with.

Table 14: 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 [8], which gives the general safety guidelines for all electrical medical devices. The second part is entitled IEC 60602-2-37 [9], 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 standards 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. [10]

The IEC also has collateral standards pertaining to this project, which include IEC 60529 (Degrees of Protection Provided by Enclosures) [10], IEC 62127-1 (Measurement and Characterization of medical ultrasonic fields up to 40 MHz) [10], IEC 61157 (Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment) [10], and IEC 62359 (Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields). [11] Many national standards, including the CSA, have adapted the IEC standards, which for medical devices are identical [12], 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) [13], 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) [14], 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) [15], 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). [15] The AIUM standards have been harmonised with the NEMA standards, and appear as AIUM/NEMA standards. [14]

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. [14]

Health Canada H46-2/01-255E [15] 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 possible). [15] 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. [15] 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. [15] 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. [15]

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. [16] Bluetooth is now managed by the Special Interest Group (SIG), which oversees development, manages qualification program and protects trademarks.

7. Sustainability Considerations

Today, environmental concerns are an important consideration in product designs. For the CARE product, the cradle-to-cradle model was examined. In a cradle-to-cradle process, "all material inputs and outputs are seen either as technical or biological nutrient. Technical nutrients can be recycled or reused with no loss of quality and biological nutrients composted or consumed." [17] By definition, technical nutrients consist of man-made materials whereas biological nutrients are organic materials. The following details the strategies to produce a cradle-to-cradle CARE product.

7.1. Prototype Version

As described earlier, the prototype version of CARE consists mainly of electronic components. In the cradle-to-cradle model, electronic components are considered technical nutrients. Hence, the design and disposal of the prototype version will include using used electronic parts and proper recycling of used electronics parts respectively.

During the design stage, the cost of new and used electronics parts will be evaluated prior to acquiring parts. For new parts, sustainable manufactures will be preferred, especially those with an established recycling or buy-back program. For used parts, cost and proper functionality will be compared to favour an inexpensive high-quality piece. To conclusion, we will obtain used parts over new parts when the part is more economical.

Upon completion, the prototype version will either be donated or recycled. The prototype may be donated to facilities that would like to continue to expand the prototype version, such as local research centres. As an alternative, the prototype version can be disassembled and the functionality of the electronic parts can be verified. If the parts are still functional as originally designed, the parts can be donated for re-use. An example would be donating the part to the ESSS Parts Library for students' use in their personal projects. Otherwise, the part can be recycled at local electronic waste recycling facilities. As part of British Columbia's Recycling

Regulation, there will be a cost of $1.20 for recycling medical devices, weighing between 2-10kg. [18] From the beginning to the end of the prototype version, electronic components will be reused and recycled.

7.2. Production Stage

In the production stage, CARE will include a power source and product casing. The addition of these two components must meet cradle-to-cradle standards. In addition to the prototype's sustainability factors, several more sustainability factors will need to be considered for the production stage; such as a renewable power source, recyclable product casing, product packaging, and recycling tag.

A cradle-to-cradle certified product only uses renewable power sources. [19] When selecting a power source, sustainability, portability, and costs are factors that need to be considered. A rechargeable long-lasting power source, such as a rechargeable battery, may be a sufficient option.

The product casing will need to be a technical or biological nutrient to follow the criteria of cradle-to-cradle certification. In addition, the material of the casing needs to be waterproof and lightweight. The material needs to protect the internal electronics from water damage. For portability and ease of use, a lightweight material should be considered. An option would be to make the product casing out of recyclable plastics.

For product packaging, a biological nutrient will be heavily considered in support of the cradle-to-cradle certification. Recycled or compostable materials will need to be tested to ensure the product is delivered safely and without damage from transportation. With its wide availability, biodegradable materials are a capable alternative to plastic packaging options.

A recycling tag will need to be considered to support increasing the efficiency of electronic recycling efforts. An initiative of using RFID tags on electronics tracked the product's life cycle. The tags provide information about the product's condition and composition. [20] At a few cents, the tags help recyclers identify which components can be reused in an effective manner. [20] Although the RFID tags are not eco-friendly, the idea of the recycling tags on electronic products needs to be considered to ensure proper disposal of the product's technical nutrients.

8. Conclusion

This functional specifications defined in this document include all the necessary information about the current design of our product; CARE. It has listed all the product stages, necessary standards, and requirements.

Here at Cardiowave, we have chosen to use only the best possible parts for our product that fall into our creative cradle-to-cradle design process. While some aspects of making sure our product can be fully recycled means a smaller profit margin, we are here for a better future. Starting in Vancouver, Cardiowave understands how important reusable materials are and how accessible these materials really are.

We are striving, and are on pace, to complete the prototype stage by early April 2015. As each stage progresses, we will focus on their requirements in order to have the best possible product.

9. 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 Possible
CARE	Abbreviation for Carotid Artery Real-time Echoes
CSA	Abbreviation for Canadian Standards Association
DAQ	Abbreviation for data acquisition
ESSS	Abbreviation for Engineering Science Student Society; a student union for the School of Engineering Science
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
RFID	Abbreviation for radio frequency identification; a wireless method for transferring data
SFU	Abbreviation for Simon Fraser University
USB	Abbreviation for universal serial bus; an industry standard to transfer data and supply power

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