

February 20, 2017



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

Re: ENSC 440 Functional Specification for CF (Cystic Fibrosis) Scanner

Dear Dr. Rawicz,

Enclosed is our *Functional Specification for a Cystic Fibrosis Scanner*, proposed by CFTR Solutions. CFTR Solutions' goal is to design a cystic fibrosis scanner that will detect the chloride level through conductivity measurements analyzed from sweat of potential victims. It reduces cost and simplifies instructions to increase the availability in developing countries.

The purpose of this Functional Specification is to outline the functionality of the CF Scanner. Furthermore, it will provide an in depth analysis of the system overview, overall device requirements, engineering standards, and the sustainability and safety issues of our product.

CFTR Solutions is an innovative medical technology company that will always focus on improving individual's life quality with passionate and detail-oriented members of Bradley Dalrymple, Johnny Chou, Christopher Le, Ted Lee, Jae Min Song, and Winston Ye. Please feel free to contact us for further questions or concerns regarding the proposal.

Sincerely,

A handwritten signature in blue ink, which appears to read 'Bradley Dalrymple', is positioned below the 'Sincerely,' text. The signature is fluid and cursive.

Bradley Dalrymple
CEO
CFTR Solutions



Advancing cystic fibrosis detection

Functional Specification

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Executive Summary

Cystic Fibrosis is a terrible disease that is affecting the lives individuals around the world. This hereditary disease is a mutation of the CFTR gene which can cause fill the lungs with mucous [1] [2]. In addition, this disease also targets the “pancreas, liver, intestines, sinuses, and sex organs”. Currently there is no cure for this disease and a mortality rate of about 2% [3]. While treatments exist to improve the quality of care, detection is the priority. Since genetic testing is expensive, pre-screening tests are done to reduce the amount of applicants that need to be genetically tested.

This document will outline CFTR Solutions’ approach, the CF Scanner, an accurate, cost-efficient solution for pre-screening cystic fibrosis. We will account for the necessary medical device regulations and safety requirements. In addition, we will analyze the prototyping and production of a sustainable product.

In our project, we are going to engineer the CF scanner. This product will replace the sweat test in developing countries that are unable to afford the infrastructure or proximity to medical professionals. We will be implementing many of the sweat test features such as the induced sweating and small electric current to control the sweating environment. The CF scanner results in real time by testing the properties of the sweat, such as resistance and pH. Therefore, the CF Scanner eliminates the need to build the infrastructure; no laboratory or medical technicians are needed due to the design simplicity of our device.

CFTR Solution is a company composed of six engineers who strive to help advance cystic fibrosis detection. With the cost of the CF Scanner being cheaper than the traditional screening test and real time, we can bring the technology to developing countries. We aim to not only improve the lives around us, but around the world.

1. Introduction

1.1 Background

Cystic fibrosis (CF) is the most common fatal genetic disease affecting children and young adults. It is a multi-system disease that affects mainly the lungs and the digestive system. CF is caused by the presence of mutations in both copies of the gene for the cystic fibrosis transmembrane conductance regulator (CFTR) protein. [1] The protein is involved in production of sweat, digestive fluids, and mucus. The malfunction of the CFTR protein causes the secretion of mucus become thicker than normal which can lead to severe lung conditions such as coughing and shortness of breath. [3]

There is no cure for CF at the moment. The outlook for patients with the disease has improved steadily over many years, largely as a result of earlier diagnosis. Therefore, early detection is extremely important in order to keep the disease under control. CF is diagnosed by a sweat test and genetic testing. The sweat test is considered the gold standard for screening CF due to its distinct symptom of five times the normal amount of sodium and chloride in patient's sweat. [1]

Unfortunately, research has shown that the current sweat test has several disadvantages such as inconsistent results due to human error during the test and high cost. The average cost of performing sweat test is around \$400 in Canada [19]. These drawbacks of the current sweat test lead to the development of Sweat Scanner. Sweat Scanner is a reliable, cost effective, and fast screening technology for CF. Sweat Scanner modifies the existing sweat test technology to increase the accessibility of the test by removing the necessity of medical professionals to perform CF screening.

The Sweat Scanner developing by CFTR Solutions has two major objectives. One is to create an user friendly and real time medical device that can be used to detect the amount of sodium and chloride that exists within a patient's sweat in a non-invasive manner. The other goal is to provide an affordable and reliable screening test for CF in third countries. The product will be carefully designed in such a way that it is easy to use by any individual, and will be able to provide consistent and accurate measurements of sodium and chloride content to provide reliable testing result. With the technology, CFTR solutions believes that we can help to fight cystic fibrosis.

According to the Cystic Fibrosis Foundation Patient Registry, in the United States, there are currently about 30,000 people living with cystic fibrosis CF in the United States and more than 80,000 worldwide. [4] In addition, statistics reveal that approximately 1,000 new cases of CF are diagnosed in the country each year. However, the diagnosis of the disease is still often delayed or mistakenly conducted. Based on the statistics, the rate of misdiagnosis of CF is about four percent. [4]

CF was first identified by Dr. Dorothy Anderson in 1938. It is the most common lethal genetic disease. In the 1950s, median life expectancy for patients with CF was a few months. The median age of survival has increased progressively over the past 60 years and it is now more than 40 years in developed countries. [3]

The overall quality of life and life expectancy of CF patients have improved significantly over the past two decades, largely as a result of earlier diagnosis, more advanced therapy, and provision of care in

specialized CF centers. [5] Research has shown that newborn screening reduces the disease severity, burden of care, and costs of care. The diagnosis of CF is usually done by a screening sweat test followed by a genetic testing if the screening result is positive. The sweat test remains the most common and readily available way of screening of CF provided as CF has a distinct symptom of five times the normal amount of sodium and chloride in patient’s sweat. [4] The sweat test is done by applying pilocarpine onto the person being tested to induced sweating and sweat is collected for 30 minutes. Several laboratory methods are then used to determine the sodium and chloride concentrations in the sweat quantitatively. [5]

1.2 Scope

This document outlines all the important functional requirements for CF Scanner, and the relevant health and safety standards. All the listed requirements are ordered from highest to lowest priority, and they fully describe the specification for our device prototype.

1.3 Audience

This document is to be used by CFTR Solutions members to help them with the design process, and development of both electronics and software components of CF Scanner. Test plans will not be discussed in this document; however, subsequent plans will be made to ensure that the development/QA team at CFTR Solutions meets all requirements.

1.4 Classification

Classification for the requirement specification is as follows [Req#-P-Version]. For more information, see Table1.

Req-#	This is the requirement number for the section that the requirement is in. e.g. 3.1.2
P	Priority P3: High priority P2: Medium priority P1: Low priority
Version	I: This requirement is critical to the system and must be met for the proof-of-concept stage II: This requirement should be met for both the proof-of-concept stage and the final product III: This requirement is not critical to the functionality of the system; it should be met for the final stage of production

Table 1: Requirements Specification Notation

2. System Overview

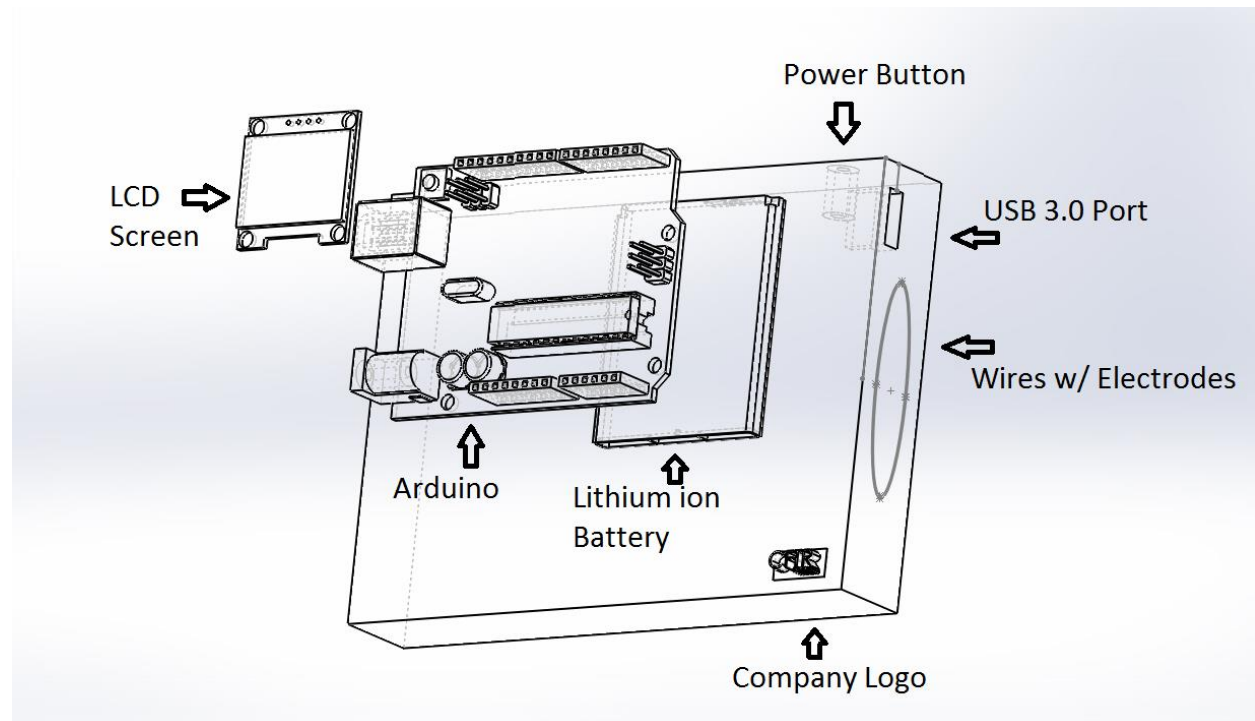


Figure 1: Illustration of the Prototype of CF Scanner [6]

In order for us to create a cost effective yet user friendly product, our team went through several stages of design models. The prototype can be seen in Figure 1. Before we finalize and produce our very own unique personalized circuit boards with the assistance of Dr. Michael Adachi at SFU, we will be conducting our testing using an Arduino board. The primary aim for this product is to help third world countries gain easy access to sweat tests, a standard way of screening CF, under reasonable cost. In order to do so, we have designed our product in such a way that every component is crucial to the system, features such as Bluetooth and Wi-fi may be added in the future depends on the market. Currently, the CF Scanner is assembled so that it can be used in an area where technologies are limited.

Current sweat test in the market is too costly and time consuming. Although early diagnosis can help improve the patient's life quality, rural areas and third world countries are almost always neglected of this luxury. Our team saw an opportunity to tackle this problem, hence we came up with a compact and easy to carry sweat testing device. From our prototype, which can be seen Figure 1, you may notice that there is an Arduino board in the center of the system, this will be the microprocessor that every component will feed into. The LCD screen will display result as well as the fitness of the patient. Since we want to make this device travel friendly, we have included a rechargeable lithium ion battery within, where you can charge it using the USB port on the side. Wires with sensors are attached to the box which help assist in the process of the testing. The system block diagram layout is presented in Figure 2.

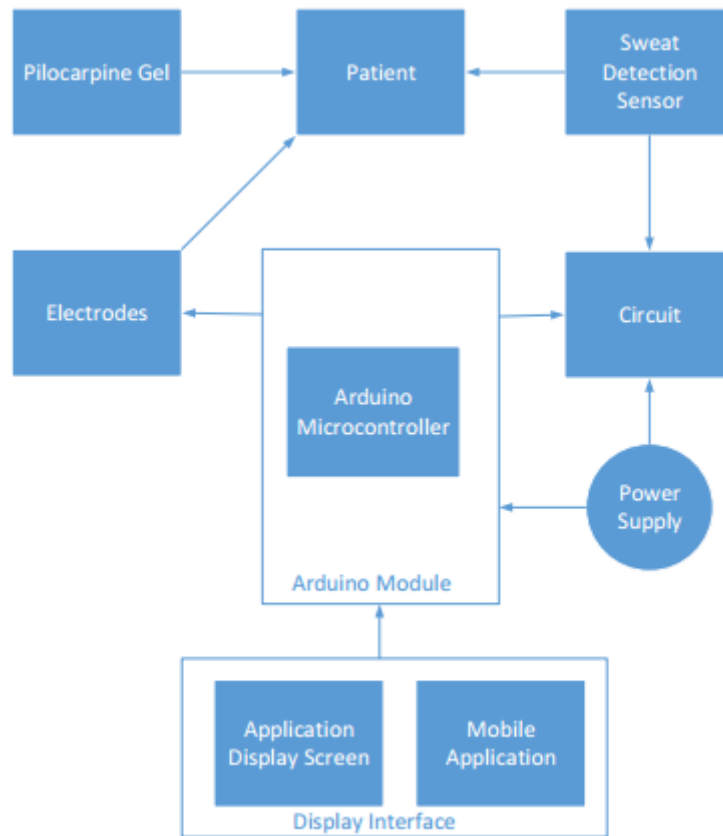


Figure 2: System Block Diagram of CF Scanner

The block diagram shows the process of conducting our sweat test. This is largely similar to the current sweat test but differs at the final stage of analysis. Instead of the sweat result being sent to the lab for further analysis we will test the sweats properties in real time. First the patient must apply the chemical and electrodes to their skin as seen in state 2, and wait 5 minutes. A small current will be induced which will indicate the controlled sweating. Next, a second set of sensors are applied to determine the amount of salt content in the sweat through a combination. We will analyse the conductivity properties as well as the PH and run the output through our algorithm to determine if there salt content in mL/moles is within an acceptable range.

Through the second four months of this course we will fabricate our own PCB board but initially we have designed our system using an Arduino board. We selected this as our option because of the versatility that this board allows, with options for Wi-Fi and Bluetooth for testing too many different GPIOs. This will help our R&D, to not be limited by hardware components in our design phase. Our power supply will initially be used as a wall outlet, but once we have fabricated our board, we will use a rechargeable USB lithium ion battery. For more information on battery requirements, see the requirements section. Finally, the sweat detection sensors will relay the information back to the Arduino board where they are finally displayed on the screen the LCD screen as seen by Figure 1.

3. System Requirements

3.1 General Design Specification

In this section, we will cover the core requirements that the CF scanner will uphold to. These requirements have been broken down into sections and further categorized by notation. For more information on notation, see section 1.4. The following system requirements have been broken down by general, hardware, and software. This matches the breakdown of our group tasks and is our goal to complete all requirements based on priority. This will ensure that our product will adhere to our product and industry standard.

3.1.1 Device Safety Requirements

[3.1.1-P3-II] The device shall have sufficient insulation to prevent user from direct contact with electronic components.

[3.1.1-P3-II] The device shall not cause an electrical shock, maintaining no more than 2mA.

[3.1.1-P2-III] The device shall be able to detect improper use such as faulty contact point.

[3.1.1-P2-III] The electronic components, as well as power connections shall be enclosed.

3.1.2 Environmental Requirements

[3.1.2-P1-III] The device shall work and results shall not be affected over a range of temperatures

[3.1.2-P1-III] The device shall work over a range of humidity levels

3.1.3 User Documentation Requirements

In the developing countries, access to professional health care workers are more difficult to come by. We hope to create a user friendly device that will guide any user without prior knowledge to operate the device safely and successfully.

[3.1.3-P3-I] User documentation shall include a user manual, written in English.

[3.1.3-P2-I] User manual shall be written for people with minimum knowledge of sensor, ergonomics and application usage.

[3.1.3-P2-I] User documentation shall be provided in other languages in order to satisfy the requirements for international markets

[3.1.3-P3-II] User manual shall provide the installation guide for technicians and vendors.

[3.1.3-P1-III] User documentation shall provide the information for warranty

[3.1.3-P2-III] User manual shall provide guide for troubleshooting and contact information

3.1.4 Testing Requirements

The specifications for testing can be broken down into three standardized forms of testing: unit, system and regression testing. For more information on the timeline of our testing procedure please see the Gantt chart submitted in our project proposal. Testing will encompass both HW and SW components and system test will test how these components integrate and work together. Because of the scope of this system, as for most systems, all possible test cases cannot be accounted for, but randomized testing will be implemented to ensure that all corner and use cases are covered.

[3.1.4-P2-I] Unit testing shall be implemented on each milestone (see Gantt chart)

[3.1.4-P2-II] System testing shall implement randomized testing to ensure that as many use cases are tested within the specified time frame schedule.

[3.1.4-P2-III] Regression testing must be implemented when a new hardware piece has been implemented into the design

[3.1.4-P2-III] Regression testing must be implemented when over 100 LOC have been modified to an existing program

3.1.5 Power Requirements

The power consumption specifications are listed as seen below. The CF Scanner will contain a compact lithium ion battery that will be rechargeable of approximately 10000 mA. This may vary to ensure that the specifications below are met.

[3.1.5-P1-II] The charging time of the CF Scanner battery pack must be charged to 100% in less than 8 hours at an input voltage of 120 volts and frequency of 60 Hz.

[3.1.5-P2-II] The CF Scanner must allow for over 30 test on a single battery charge with a range of plus or minus 5.

[3.1.5-P1-III] The CF Scanner shall not be run at a power level less than 10% and the user will be notified with an error in less than five seconds after this occurs.

3.2 Hardware Design Specification

3.2.1 Galvanic Skin Sensor Requirements

The Galvanic Skin Sensor (GSR) detects the sweat levels by measuring skin conductance. Patients with CF will have much higher salt content therefore directly affecting the results. Proper placement of the sensors is necessary to obtain the best results. Results will be picked up by a microcontroller with an ADC pin.

[3.2.1-P3-II] The working voltage of the galvanic skin sensor shall be in range of 3.0 V to 5 V DC.

[3.2.1-P3-II] Current flow in Galvanic Skin Sensor shall be under 200 μ A

[3.2.1-P1-III] The Galvanic Skin Sensor should be waterproof.

[3.2.1-P2-III] The Galvanic Skin Sensor shall be attached to the forearms firmly.

- [3.2.1-P1-III] The device must be one size to fit all users
- [3.2.1-P2-II] Data readings should be accurate and not affected by motion
- [3.2.1-P1-III] The device shall be comfortable to wear
- [3.2.1-P1-I] The product shall not show quick signs of wear and shall be durable for prolonged usage
- [3.2.1-P2-I] The product shall not dissipate excessive amounts of heat during wear

3.2.2 I/O Components Requirements

The section of requirements is dedicated to input and output specifications that interact with the software of the CF scanner. These components will be connected to the Arduino board through GPIO ports.

- [3.2.2-P1-II] Push buttons shall be debounced with a 10 ms signal to reduce noise of the signal being sent to the processor.
- [3.2.2-P2-II] LCD display screen shall be viewable in direct sunlight.
- [3.2.2-P3-II] The audio speaker must output predefined messages with an audio frequency between 300 to 3400 Hz.

3.3 Software Design Specification

The below specifications are outlined for the software element of the CF scanner. This code will be written and loaded onto an Arduino board in an executable format. This code will analyze the results of the sweat content and determine a pre-screening result for CF. The below requirements are guidelines for the executable code.

- [3.3-P1-II] The CF Scanner shall boot in less than 5 seconds after the power button is pressed.
- [3.3-P2-I] Software code will be documented with a one line of documentation code for every three LOC (Lines of Code).
- [3.3-P3-II] The LCD screen UI will have an usability score higher than 8/10 for completing basic tasks after 10 minutes of user training.
- [3.3-P2-II] The synthesized algorithm to detect sweat content will run in less than 5 seconds.
- [3.3-P2-II] The accuracy of the software compared to predetermined test results will allow for no more than a 15% false positive result.
- [3.3-P3-II] Executable Arduino source code must be no larger than 350KB.

4. Sustainability and Safety Requirements

4.1 Sustainability Requirements

CFTR Solutions strives not only to improve the quality of patients with cystic fibrosis lives', but also to build a better future for the environment. This justifies our reason to, as much as possible, abide by the cradle-to-cradle (C2C) methodology for our material selection [7].

An important component is the power supply of the CF Scanner. CFTR Solutions has designed the product to be battery powered and will use rechargeable lithium ion batteries. Being rechargeable, this will reduce the number of batteries being disposed into landfills and lithium ion batteries can also be recycled once their life span is depleted. These lithium ion batteries can be charged and discharged 300 to 500 cycles [8]. It is noticed that lithium ion batteries are not fully certified by the cradle-to-cradle methodology, but a majority of the components can be recycled and no other alternative is feasible due to unavailability such as organic carbon batteries [9]. Therefore, the CF Scanner will satisfy the following sustainability requirements for both the prototyping and production stage:

[4.1-P1-III] For all casing and enclosures CFTR Solutions shall use polylactide (PLA) plastic; a biodegradable thermoplastic that can be 3D printed. PLA is derived from renewable resources such as cornstarch and can be both recycled and composted [9].

[4.1-P2-III] The medical electrodes shall be sent to metal recycling facilities once their life span is complete [10].

[4.1-P3-III] The micro controller shall be repurposed and reused for future projects.

[4.1-P2-III] The power supply shall be lithium ion battery powered and shall be rechargeable.

For the current prototyping stage, we will use all of the aforementioned materials, but create the circuit on a breadboard for testing purposes. All circuit components such as resistors and wires can be recycled, therefore abiding by the C2C methodology. During production, CFTR Solutions will instead use a custom PCB and all of the aforementioned components to maintain the sustainability and C2C methodology.

[4.1-P2-I] For the prototype stage, CF Scanner shall use a breadboard combined with lead free active and passive electrical components. All of which can be repurposed.

[4.1-P3-III] For the production stage, CF Scanner shall use a custom printed circuit board (PCB). This component can be recycled once the project is complete [11].

4.2 Safety Requirements

CF Scanner's goal is to advance cystic fibrosis detection; therefore, safety is a crucial aspect of our company. That being said, we aim to abide by the regulations provided by the Medical Device Regulations of Canada [12]. CFTR Solutions endeavors for patient safety, therefore prototyping and production stage have equivalent safety requirements. The CF Scanner will satisfy the following safety requirements:

[4.2-P3-II] The device shall include a safety cut-out that limits the current of 5mA or lower [13].

[4.2-P2-II] The pilocarpine gel shall be acquired from a recognized manufacturer.

[4.2-P2-III] During the sweat inducing stage, the current shall start at a minimum of 1.5mA and gradually increase to a maximum of 4mA and be maintained at maximum for a minimum of 3 minutes to a maximum of 5 minutes [14].

[4.2-P3-III] The system shall allow sweat to accumulate for a minimum of 20 minutes and to a maximum of 30 minutes to provide accurate results by implementing a timer.

[4.2-P1-III] The CF Scanner shall be designed with and only use electrical components that abide by the CAN/CSA Standard C22.2 No. 61010-1-12 [15].

[4.2-P1-II] The CF Scanner shall use batteries that abide by IEEE Standard 1625 for rechargeable batteries [16].

[4.2-P2-II] All electrical circuits and systems abide by the IEC standard 60950-1 and amendments A1 and A2 for the safety of information technology equipment [17].

[4.2-P2-III] The device enclosure shall have no sharp edges or burrs to prevent risk of injury and shall be made from insulated PLA plastics to prevent electric shock.

[4.2-P3-III] The manufacturers of the CF Scanner shall abide by the Medical Device Regulations of Canada pertaining to the Manufacturer's Obligations [18].

[4.2-P3-III] The CFTR Solutions team shall wear insulated gloves and be attached to an antistatic wristband to prevent electrical shock.

5. Engineering Standards

As mentioned in the previous section, the CF Scanner is intended to be sold to both developing countries and developed countries. Therefore, the design of the product, testing of the product, and the product itself have to abide the regulations set forth by the authorities depends on the region. CF Scanner is designed to be a screening medical device; hence, it has to follow medical device regulation. At the current stage, the team is planning to set the first market to be India.

Prior to 2005, no medical device regulations existed in India. Currently, there are registration procedures for certain types and classes of medical devices regulated under the provisions of the Drugs and Cosmetics Rules. [19]

In order to register medical devices in India, the company must supply evidence of prior regulatory authorization in the US, Canada, Europe, or Australia. Therefore, the team decides to abide the regulations set by the Canadian government first then submit the technical documentation to the Central Drugs Standard Control Organization (CDSCO), an agency of the Ministry of Health and Family Welfare in India. [19]

In this section, several voluntary standards are listed that are related to the CF Scanner. Majority of them are from IEC, ISO, and CSA. At the time of production, CF Scanner is expected to be in compliance with all the standards listed in Table 1.

IEC 60601 is a series of technical standards for the safety and effectiveness of medical electrical equipment, published by the International Electrotechnical Commission. The IEC 60601-1 standard is widely accepted benchmark for medical electrical equipment. It has become a requirement for the commercialization of electrical medical equipment in many countries. [20]

Standards	Justifications
IEC 60601-1 [20] <ul style="list-style-type: none"> IEC 60601-1-6 Collateral standard: Usability IEC 60601-1-9 Collateral Standard: Requirements for environmentally conscious design 	General requirements for basic safety and essential performance
CAN/CSA-ISO 10993 [21] <ul style="list-style-type: none"> ISO 10993-1 Evaluation and testing in the risk management process ISO 10993-10 Tests for irritation and skin sensitization ISO 10993-11 Tests for systemic toxicity 	Evaluation of the biocompatibility of medical devices and the safe use evaluation of medical devices
CAN/CSA-ISO 11737 [22]	Sterilization of medical devices
CAN/CSA-ISO 13485 [23] <ul style="list-style-type: none"> ISO 9001 Requirements of a quality management system 	Design quality control management for medical device manufacturing
CAN/CSA-ISO 14971 [24]	Risk management framework for medical devices

Table 2: Engineering Standards for CF Scanner

6. Conclusion

The outlined functional requirements will be used to design and produce a CF Scanner. The requirements have been divided into major sections which are software, hardware and experiment to manage and achieve the milestones of the overall project in a more efficient manner.

Due to the nature of the device, finding the right amount of current required to induce sweat during experimentation must be done prior to anything to guarantee the safety of the patients. A built-in platform, such as Arduino, will be used for the poster presentation to ensure the feasibility of the CF Scanner's main functionality. A simple user interface will be developed for bettering the user experience. Gathering individual components which will be done in the second period of the project will allow our group to customize our own PCB (Printed Circuit Board). Finalizing and producing the device following the requirements will greatly increase the accessibility of testing CF without any professional help in developing countries, and ideally reduce the cost of each treatment for individuals by keeping the required components to an absolute minimum and removing unnecessary functionalities.

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