March 30, 2017

Dr. Andrew Rawicz
School of Engineering Science
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Re: ENSC 440 Design Specification for CF (Cystic Fibrosis) Scanner

Dear Dr. Rawicz,

Enclosed is our *Design 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 Design Specification is to outline the design concept 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,

Bradley Dalrymple
CEO
CFTR Solutions

Advancing cystic fibrosis detection

Design Specification

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Submission Date:
Mar 30th, 2017
Version 1.0

Abstract

Cystic Fibrosis is a terrible disease that is affecting the lives of many individuals around the world. According to the Cystic Fibrosis Foundation website, it is stated that there are more than 70,000 people worldwide that are currently being affected by this disease [1]. The numbers can vary since testing in rural areas is limited. This hereditary disease is a mutation of the CFTR gene, which can cause the lungs to fill with mucous [2]. In addition, this disease also targets the "pancreas, liver, intestines, sinuses, and sex organs"[3]. With a mortality rate of about 2% [4], we should treat CF patients with the maximum amount of care, as there is currently no cure for this disease. 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. This product will replace the sweat test in developing countries that are unable to afford the infrastructure or proximity to medical professionals and provide better support to remote communities in more developed countries. The CF scanner gives results in real time by testing the properties of the sweat, such as the NA content. Therefore, the CF Scanner eliminates the need to build the infrastructure; such as laboratories or medical technicians. 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 results in real time, we can bring this technology to developing countries to improve the quality of care. We aim to not only improve the lives around us, but around the world.

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1.0 Introduction

1.1 Background

Cystic fibrosis (CF) is a fatal genetic disease affecting children and young adults mainly in the lungs and the digestive system. CF is caused by the presence of mutations in both copies of the gene for the cystic fibrosis trans membrane conductance regulator (CFTR) protein, which is involved in the production of sweat, digestive fluids, and mucus [2]. The malfunction of the CFTR protein causes the secretion of mucus to become thicker than normal which can lead to severe lung conditions, such as coughing and shortness of breath. [4]

At the moment, there is no cure for Cystic Fibrosis. 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. A sweat test and genetic testing diagnose Cystic Fibrosis. 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 the patient's sweat. [2]

Unfortunately, research has shown that the current sweat test has several disadvantages, such as its high cost and inconsistent results due to human error. The average cost of performing a sweat test is around $400 in Canada [5]. The drawbacks of the current sweat test led to the development of the Sweat Scanner that we are designing for this project. The Sweat Scanner is a reliable, cost effective, and fast screening technology for CF which 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, developed by CFTR Solutions, has two major objectives. Firstly, to create a user-friendly medical device which operates in real time 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 world countries. The product will be carefully designed in such a way that it will be easy to use by any individual, and will be able to provide consistent and accurate measurements of sodium and chloride content to provide a reliable testing result. With the technology, CFTR solutions believe that we can help to fight cystic fibrosis.

According to the Cystic Fibrosis Foundation Patient Registry, there are currently approximately 30,000 people living with CF in the United States and more than 80,000 worldwide. [6] Statistics also 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 when pre-screening with the existing sweat test. [6]

CF is the most common lethal genetic disease and was first identified by Dr. Dorothy Anderson in 1938. In the 1950s, the median life expectancy for patients with CF was just a few months. The median age of survival has increased steadily over the past 60 years and is now more than 40 years old in developed countries. [4]

The overall quality of life and life expectancy of CF patients has improved significantly over the past two decades, largely as a result of earlier diagnosis, more advanced therapy, and provision of care [7]. Research has shown that newborn screening reduces the disease severity as well as the burden and financial hardships of care. The diagnosis of CF is usually done by a screening sweat test followed by genetic testing if the screening result is positive. The sweat test remains the most common and accessible way of screening for CF offered, as CF has a distinct characteristic of five times the normal amount of sodium and chloride in the patient's sweat. [6] The sweat test is done by applying pilocarpine onto the person being tested to induce 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. [7]

1.2 Scope

This document outlines all the important design specifications for the CF Scanner, and the relevant health, safety, and UI specification of our product. The following sections will detail how we have and will continue to design and develop our hardware sensors, software, and firmware over the next four months.

1.3 Intended Audience

This document is to be used by CFTR Solutions members to aid them in design process, as well as the development of both electronic and software components of the CF Scanner. Test plans are included in this document as the prototype transitions between stages, and a regression test will be run. A system test as well as a user test is also included to allow for a detailed quality assurance process to be completed on our product.

2.0 System Overview

The CF scanner tests the salt content on the patient's skin, which can increase in salt content by two to five times if the CFTR gene is mutated. Below is the state diagram for our CF Scanner. We have chosen the method below to closely match the existing test but allow for real time results to improve the quality of life for CF patients globally.

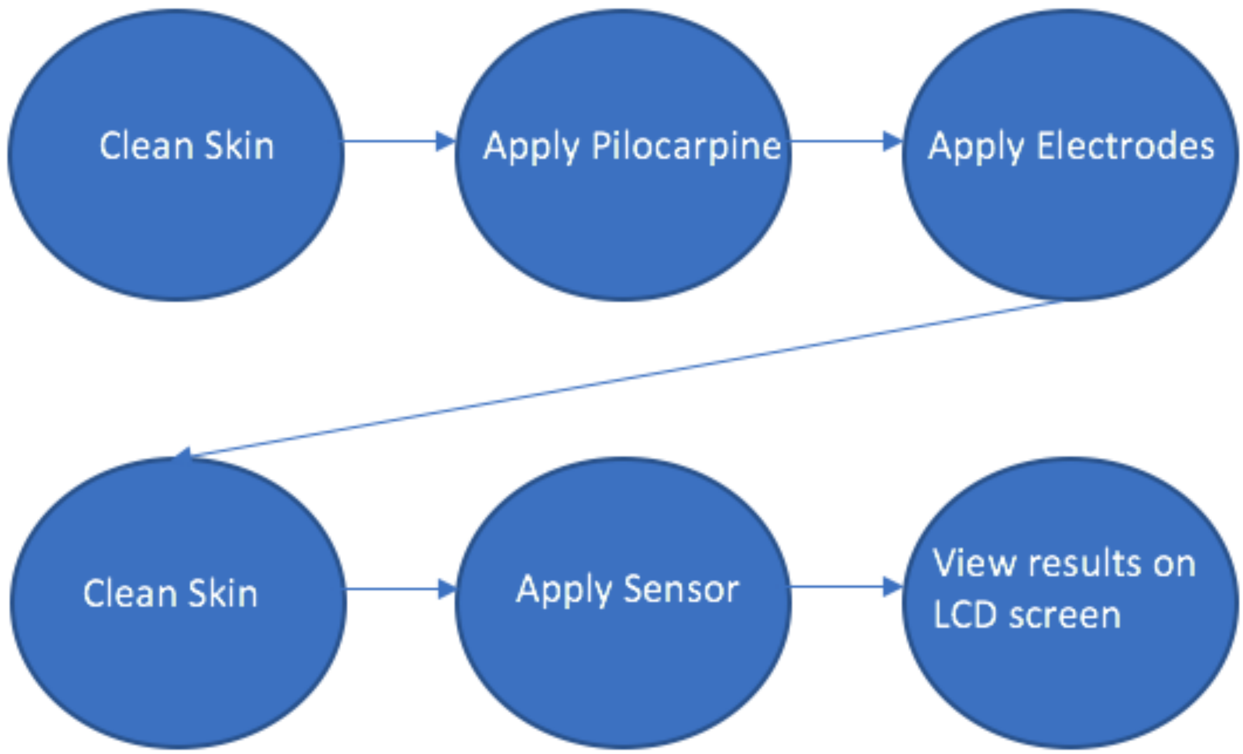

Figure 1 State Diagram of our current CF Scanner

Table 1. Action and Result of the State Diagram in Figure 1

Phase	Action	Result
Clean Skin	Clean the skin with with water to remove any chemicals that may be on the skin	This will ensure that there is no contaminant in the sweat
Apply Pilocarpine	Apply this chemical to the skin	This chemical is designed to induce a controlled sweat in the existing sweat test
Apply Electrodes	Add a 0.4 mA current to the patient through the Pilocarpine applied above	Sweating will be induced at this step and wait five minutes
Clean skin	Clean the skin with with water to remove any chemicals that may be on the skin such as the chemical applied above	Controlled sweating will leave a thin layer of ionized NA ions from the sweat that we will measure
Apply Sensor	Measure the salt content in the sweat	Determine if the amount of salt is within

		the range of CF patients
View results	In real time see the results of the test	Improve on the quality of life for patients who don't have access to labs

In Table 1, we have used a combination of hardware and software designs that you can see below in section 3 and 4. Additionally, we have added a testing tool that allows us to test our product, a skin phantom. A skin phantom is a chemical recreation of real skin that will mimic the chemical properties of different sweat contents on the skin. We chose to use this technology to test a baseline to ensure that our readings account for the exact chemical makeup before accounting for different impurities. Below, we will detail the technologies we will create and use to design the CF Scanner.

3.0 Hardware Design

The CF Scanner uses a combination of hardware and software components in its implementation. The hardware breakdown of our design can be found below in Figure 2. There are two users outside of the design, the user and the patient, but we hope to improve our design to make it easy enough to use so that the patients will have the ability to self-diagnose by running the test on themselves.

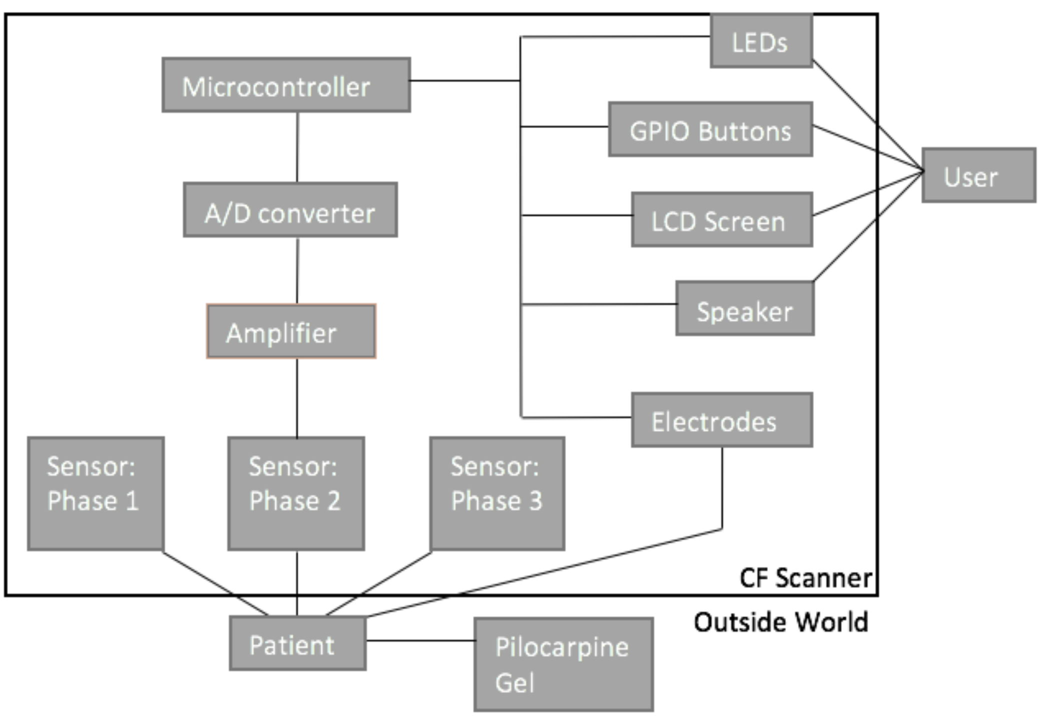

Figure 2 Component Breakdowns for the CF Scanner

3.1 Arduino

Prior to deciding the use of Arduino Uno for our project, we compared other competitors such as Raspberry Pi and Intel Edison. The following table lists some of the key features to help us determine the suitability of each option.

Table 2. Specification Comparison for Arduino Uno, Raspberry Pi and Intel Edison

Categories	Arduino Uno	Raspberry Pi	Intel Edison
Price	$25	$35	$75
Size	7.5x1.9x6.4cm	8.5x5.6x1.7cm	3.5x2.5x0.39cm
Memory	0.002MB	512MB	1GB
Onboard Network	None	10/100 Ethernet socket	Dual-band (2.4&5 GHz) Wifi, BT 4.0
Input voltage	5, 7-12V	5V	3.3-4.5V
Flash Memory	32KB	Micro SD Card	4GB eMMC
Operating System	None	Linux	Yocto Linux v1.6
Integrated Development Enviornment (IDE)	Arduino IDE	Scratch, IDLE, anything with Linux	Arduino IDE, Eclipse, Intel XDK
SoC	ATmega328P	BCM2836	Intel Atom Z34xx
Cost of SoC	$2.50	N/A	N/A

Table 2 most noticeable feature is the price difference, where Arduino is substantially cheaper than Intel Edison, and slightly more expensive than Raspberry Pi. Additionally, Pi and Edison both have an onboard network, while Uno does not. The most important aspect to note is the absence of an OS in Uno. The input voltage should be noted as well, as it affects the battery life.

Ultimately, we decided to go with Arduino Uno for several reasons. Firstly, we do not need a full OS as our product has very specific tasks and will not need additional processing. Secondly, purchasing the SoC for Uno is possible at only $2.50, whereas the other SoC options cannot be purchased in a bulk amount. Since we are only at our prototype phase where we are using off-the-shelf products, it is also important to keep in mind for our future production where we will be creating custom PCB. This will allow us to have a unique product specific to our usage, and help cut down the costs of removing components not being used. Also, the programming in Arduino IDE in the prototype allows our software to easily transfer over in the same environment using ATmega328P.

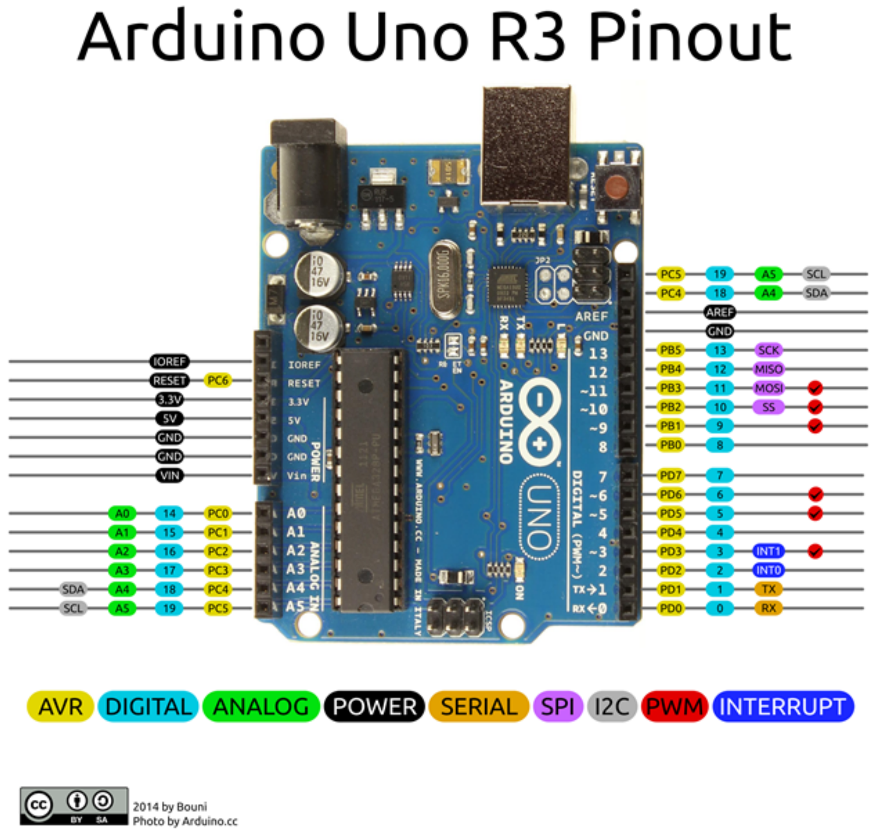

Figure 3 Arduino Peripherals [8]

3.2 Sweat Sensor

We will be going through several sweat sensor prototypes to establish what will provide the best values to be used for our medical device. We will be going through purchasing off-the-shelf to creating a custom GSR sensor, and potentially creating a sensor that only detects sodium chloride (NaCl).

3.2.1 Sensor (Phase One) Grove Galvanic Skin Response

An increase in salt will increase the current flow. The GSR, also known as Skin Conductance Response (SCR) or more commonly Electro-dermal Activity (EDA), passes a weak current through the skin and measures changes in electricity flow.

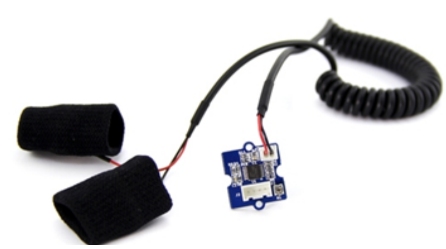

Figure 4 Grove GSR with Electrodes

For our first prototype, we purchased an off-the-shelf Grove GSR Sensor (Figure 4), which is a simple circuit that can be broken down into four separate parts.

1. Two electrodes connected to Vcc with 200K ohms and ground (to be placed on the forearm)
2. Two unity gain amplifier, one for the power signal, and the other from the electrode
3. Differential amplifier with a low pass filter (RC)
4. Output Signal

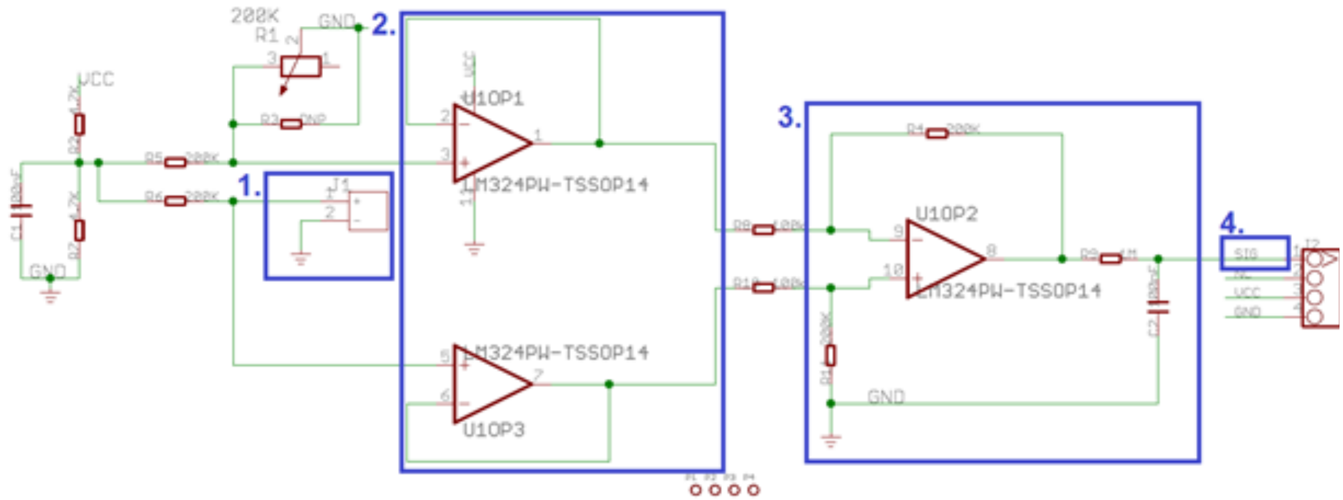

Figure 5 Schematic of the GSR Grove [9]

Using a universal 4-pin connector, we connect SIG, VCC and GND to Arduino Uno. The SIG must be connected to any Analog In pins that goes through an ADC. Using the analogRead() command, it will then map the input voltages ranging from 0 to 5V [3.2.1-P3-II] into integer values 0 to 1023 (max 5V).

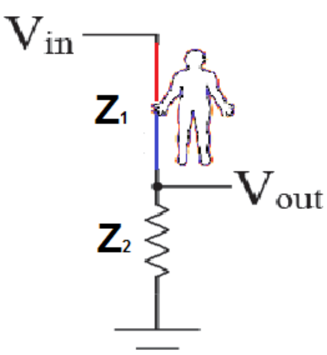

Figure 6 Voltage Divider with Human as Z_1

3.2.2 Sensor (Phase Two): Custom Circuit

After testing a GSR and obtaining several values, we concluded it would be beneficial to create our own custom circuit. As you can see in Figure 5, the differential amplifier from the off-the-shelf sensor currently compares the change in voltage to a constant value. Instead, we would like to measure the conductance directly and a simpler method can be used. By using the voltage divider in Figure 6, we can set V_{in} and R_2, and by measuring V_{out},, R_1 can be found through the following Formulas,

$$Vout = Vin\frac{R_2}{R_1 + R_2} \quad (1)$$

$$R_1 = R_2(\frac{Vin}{Vout} - 1) \quad (2)$$

We came up with this method after having inconsistent value readings from our phantom skin, even though we were able to obtain readings on human skin. Since this is a research-based project, further testing will be done to determine which sensor to use, or an integration of both.

3.3 LCD Screen

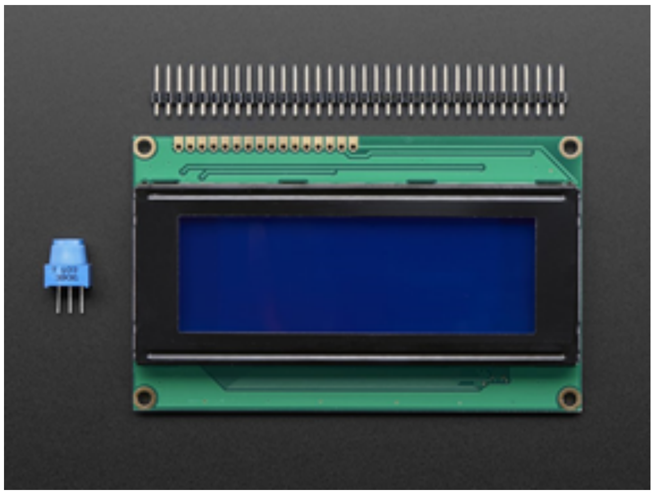

Figure 7 HD44780U LCD, Arduino Compatible Monitor

The LCD screen will display the results from our sensor indicating whether the patient is clear of CF or will require additional testing. Also, when there is poor contact point, our LCD will notify the user by displaying text “BETTER CONNECTION REQUIRED” [3.1.1-P2-III]. From the datasheet of our LCD module, the block diagram is included in Figure 8.

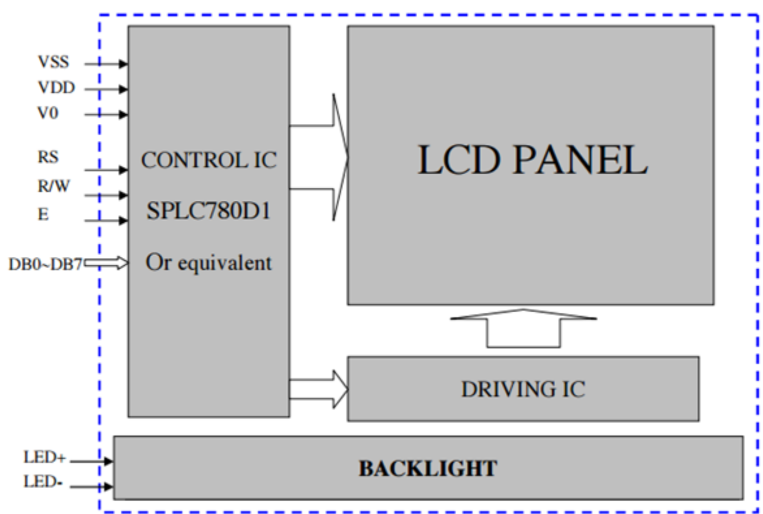

Figure 8 Block Diagram of LCD for the Arduino Board

We chose this LCD because it includes the common Hitachi's HD44780U liquid crystal display controller, which Arduino provides a standard Library for (Liquid Crystal). There will be a total of 16 pins, but we only need a total of 6 to communicate with LCD for our current prototype; RS, EN, and D4-D7 highlighted in red font in the table. We can connect D0-D3 as well, but the only benefit we will receive is the speed, which we do not require. Additionally, a potentiometer can be added to adjust the contrast of the screen [3.2.2-P2-II].

Table 3. Pin No and Function for the Hd44780 LCD Screen

Pin No.	Function	Pin No.	Function	Pin No.	Function	Pin No.	Function
1	VSS GND	5	R/W	9	DB2	13	DB6
2	VDD 5V	6	EN	10	DB3	14	DB7
3	Contrast	7	DB0	11	DB4	15	LED 5V
4	RS	8	DB1	12	DB5	16	LED GND

3.4 Speaker

As per [3.2.2-P3-II], the speaker must output audio frequency between 300-3400 Hz in order for us to play pre-recorded messages such as instructions or warnings.

Figure 9 Mini 8-Ohm Speaker for the Arduino Board

3.5 Future Implications

3.5.1 Microcontroller

As mentioned in 3.1, we picked Arduino Uno with the future product in mind. With the easily accessible ATmega328P, we can customize our board design to our specific needs. All the components such as MCU, LCD, sensors and speakers can be on one physical board, rather than having wires going across several different pins. This is also beneficial when we are designing a case that can synergize with, that can easily be accessible for debugging of hardware.

3.5.2 Sensor (Phase Three): NaCl Sensor

For our final sensor iteration, we will create a sensor that detects the NA ion in sweat. Our past sensors have been able to detect and therefore determine concentrations based on the conductivity of the ion. With the increase in salt content, there is a decrease in resistance, but this is however not the only factor in conductivity. We will be developing this sensor over the next four months in addition to the microcontroller and UI mentioned above and below in section 4. There are current sensors that have this ability and as our design changes we will update this living document to reflect our most current circuit. At this point this is a concept design and we will continue to use our existing circuit and sensors. This new sensor will add to our existing sensors in improving upon our detection algorithm and reduce the risk of misdiagnosis with the CF scanner.

4.0 Software Design

4.1 Arduino

To build our proof of concept for our poster presentation, Arduino has been chosen due to its ability to allow users to do low-level programming. Arduino Integrated Development Environment primarily supports C/C++ functions that can be used without any libraries. Since we needed detailed manipulation and control of our GSR sensor, Arduino was more suitable for our project. Moreover, due to the nature of the learning process in SFU Engineering, our group members were more comfortable working with a programming language they are familiar with.

By connecting the GSR sensor to an Arduino board, we were able to use a built function "analogRead()" which is a 10-bit analog to digital converter (ADC). The function reads integer values directly from the sensor that is within the range of 0 to 1023. For the further calculation of finding electrical conductance, this raw data must be converted into voltage within the range of 0 to 5, which can be done by multiplying and dividing the obtained raw data by 5 and 1023 respectively. From this point, it is possible to test and determine which sweat solution has more sodium chloride content in it. The more sodium chloride the sweat solution contains, the more conductive it will get. Consequently, solutions with higher density of sodium chloride will produce a smaller integer value of raw GSR data that indicates a decrease in voltage and resistance and increase in conductance. The calculated conductance will continuously be obtained and stored to keep track of the test progress. The displayed values will then be compared to a threshold value, and if the values match, the system will inform the user on the serial monitor with a warning or signal [10].

4.2 User Interface

Before we start with the UI testing, we would first need to establish a system within our prototype where a LCD can display simple letters and numbers. To do so, we can implement the Arduino LCD library within our code. For our prototype, we only require simple characters from the ASCII table to be able to display onto the LCD screen. A Tutorial can be found in the following link [https://www.arduino.cc/en/Reference/LiquidCrystal]. For convenience, this information can also be displayed on a CLI if the hardware components are attached to a CPU, but for our PoC, we want to display a working prototype. The implementation of the UI for the CF Scanner will begin in the final stage of the second prototype. We will be programing the above mentioned LCD screen and allow the user to move through different states of the process with different buttons to allow them to notify the CF scanner if each process has been completed or not. Pre-loading several created images to help the user understand the process that they will need to undertake to complete one test will create this.

5.0 Sustainability and Safety

The goal here at CFTR solutions is to not only help create a product that can help improve the lives of patients affected by CF, but also construct a product that is sustainable and safe for the user. In order for us to achieve our goal, we included the cradle-to-cradle methodology in every single step when selecting our material [11]. Although, not all components within our product are recyclable, we tried to minimize the negative impact that it will have on the environment.

With the rising popularity of 3D Printing, our CF Scanner's enclosure is made entirely of polylactide (PLA) material. This is a biodegradable thermoplastic that is derived from renewable resources such as cornstarch, and it can be recycled and composted. The power supply for our product uses a Lithium Ion Rechargeable Battery that can be charged and discharged for 500 cycles [12]. Although these batteries are not fully certified by the C-2-C methodology, a majority of the components can be recycled. Due to the absence of organic carbon batteries [13] we have chosen this route, as there are no other feasible alternatives. The micro-controller and medical electrodes can be sent to metal recycling facilities once their life span is complete [14], they can also be repurposed and reused for future projects.

CF Scanner's goal is to advance cystic fibrosis detection; therefore, safety is a crucial aspect within our company. All testing and assemblies are performed under the regulations provided by the Medical Device Regulations of Canada [15]. Since our product induces a small current into the skin, our device consists of a safety cut-off that limits the current, thus never exceeding 5mA [16]. To do so, we have implemented a program that turns the device off once it detects a current of 5mA or greater. All acquired chemicals are from well-known manufacturers and reviews of the product are thoroughly examined before purchasing. The enclosure of the device will contain no sharp edges, and all CFTR solutions team members shall wear insulated gloves and be attached to an antistatic wristband when testing to prevent electrical shock. This is to help ensure the safety of each and every CFTR employee. The CF Scanner is designed with components that abide by the CAN/CSA Standard C22.2 No.61010-1-12 [17]. It also contains Lithium Ion Batteries that abide by IEEE Standard 1625 for rechargeable batteries [18]. All electrical circuits follow the IEC standard 60950-1 and amendments A1 and A2 for the safety of information technology equipment [19]. We hope that by following these standards, will help promote a hazard free working environment as well as to help prolong the lifespan of the final product.

6.0 Test Plan

6.1 Unit Test

To ensure the quality of our final product, the team at CFTR has developed a series of testing techniques to help verify its functionalities. The test plan is separated into two main components: hardware and software. The following section will detail the procedures necessary for each part.

6.1.1 Hardware

The main focus of our hardware test plan is to confirm that the output of each of our major component is to be working as designed. Since our product relies heavily on the correct measurement of salt (NaCl) content, emphasis will be put into the testing of the GSR sensors, as it is the only method within our product that will be measuring electrical conductance of the skin. Verification of other sensors will also be conducted throughout a series of unit testing. A white-box testing technique can be applied to the following test cases [20].

Testing procedures for individual components:

1. GSR sensor successfully measures conductivity and can be displayed onto the LCD screen
2. Customized DMM can successfully measure resistance on phantom skin
3. LCD screen is able to display letters, future implementation will include pictures
4. Specific actions activates upon successful push of button
5. Speaker should produce clear sounds with minimal noise
6. LED should light up when the machine is on
7. Battery can be successfully charged through an outlet/power source

6.1.2 Software

A custom made PCB board will be implemented in our final product, but as of now, we will be programming mainly in C/C++ due to the prototype being an Arduino UNO R3 board. The concept for the CF Scanner is to be used anywhere in the world, hence the simplicity and straightforwardness of our GUI. Each feature will be tested individually prior to being assembled as a whole.

Testing Procedures for Individual Components:

1. The Arduino can detect the GSR sensor successfully, and the program we create in C can run and display results on the computer
2. The Arduino can successfully detect the LCD Screen. Text and number can be viewed on the screen.
3. The Arduino can successfully detect the speaker. The speaker should be able to play a series of sounds.
4. Testing of our algorithm, so that once the conductivity measured from the sensors exceeds a certain value, immediate instructions will be displayed on the LCD screen

Please refer to Appendix A for our Test Case Evaluation Sheets.

6.2 Regression Testing

As we move forward from Prototype-I to Prototype-II, new components will be implemented, including a customized PCB board as well as a customized GSR sensor. Our Hardware group will be working closely with Prof. Parameswaran from Simon Fraser University as he specializes in the field of electronics. Within each new build, a regression test will be ran to ensure that old bugs do not reoccur, and that the new components are working in the new iteration.

6.3 System Testing

Before we finalize on our product, a complete system test will be ran. This crucial process helps determine to ensure our fully integrated software product meets the end-user requirements. Unlike the white-box testing technique we used in the hardware section above, this is a black-box testing technique, where testers do not need to know the internal structure of the product [20]. As a result, they must base their testing solely on the user's point of view.

7.0 Conclusion

The design specification will be used to produce the CF Scanner. This document has been divided into three major sections: system overview, software, and hardware to achieve the milestones of the project in a more efficient manner. A user interface will continue to be developed to improve the user experience and allow a non-technical people to operate this device, as the sweat test has no potential risk. Finalizing and producing the device by following our testing guidelines for the user, remission and system testing will increase our product development as we continue to build our prototype over the next four months. We will improve our risk management by developing the different phases of our sensors and improve our solution. We hope to create a product that has the potential to be developed as we improve upon the foundations of CFTR Solutions.

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Appendix A: Test Plans

A.1 Hardware Test Plans

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Evaluation Sheet

<table>
<tr><td>Tester ID:</td><td>Department:</td><td>Phone Number:</td><td>Test Date:</td></tr>
<tr><td>Prepared By:</td><td>Date:</td><td>Verified By:</td><td>Date:</td></tr>
<tr><td colspan="4">Results (Please Select one of the following Boxes)</td></tr>
<tr><td>Approved</td><td>Conditionally Approved</td><td>Disapproved</td><td>Not Applicable</td></tr>
<tr><td colspan="4">Observations and Additional Comments:</td></tr>
</table>

<table>
<tr><td>Tester Name:
(Please Print)</td><td>Signature:</td><td>Date:</td></tr>
</table>

Hardware Test Case 1: GSR Sensor successfully measures conductivity and can be displayed onto the LCD Screen.

Method of Testing:

The Tester will attach the Electrodes on some form of skin, whether it be human skin, pig skin, or phantom skin. Prior to the attachment of the electrodes, the surface of the skin must contain sweat content. Turn the machine on.

Criteria for Passing:

In order for this test to pass, the LCD screen must display the Conductivity Level of the skin that is being tested on.

<table>
<tr><td colspan="6">Test Summary</td></tr>
<tr><td colspan="3">Measures Conductivity</td><td colspan="3">Displays on LCD Screen</td></tr>
<tr><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td colspan="2">Results:</td><td colspan="2">Approve</td><td colspan="2">Disapprove</td></tr>
<tr><td colspan="6">Observations and Additional Comments:</td></tr>
</table>

Hardware Test Case 2: LCD Screen is able to display letters. Future implementation will include pictures.

Method of Testing:

The Tester will send a command onto the Arduino where Texts and Numbers should be displayed onto the attached LCD Screen. A Tutorial of how this works can be found in the following link: https://www.arduino.cc/en/Tutorial/TFTDisplayText

Criteria for Passing:

In order for this test case to pass, the LCD screen must display both Texts and Numbers.

<table>
<tr><td colspan="6">Test Summary</td></tr>
<tr><td colspan="3">LCD displays Texts & Numbers</td><td colspan="3">LCD displays Pictures</td></tr>
<tr><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td colspan="2">Results:</td><td colspan="2">Approve</td><td colspan="2">Disapprove</td></tr>
<tr><td colspan="6">Observations and Additional Comments:</td></tr>
</table>

Hardware Test Case 3: Specific actions activates upon successful push of a Button

Method of Testing:

Press the Button and check to see if it goes to the next set of instructions as well as giving a notification sound to confirm that the button has been pressed.

Criteria for Passing:

In order for this test to pass, the LCD screen must iterate through the instruction steps whenever the button is pressed and a Beeping sound should be heard.

Test Summary			
Noise Produced		Instructions Being Displayed on LCD Screen	
Results:	Approve		Disapprove
Observations and Additional Comments:			

Hardware Test Case 4: Speaker should produce clear sounds with minimal noise.

Method of Testing:

Send a command to the Speaker through the computer and examine the noise that it produces

Criteria for Passing:

In order for this test to pass, the Speaker must be able to produce audible sounds in English and in notification noises such as a Beep

<table>
<tr><td colspan="6">Test Summary</td></tr>
<tr><td colspan="3">Speaker can produce a Beeping Sound</td><td colspan="3">Speaker can produce a English speaking narrator</td></tr>
<tr><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td colspan="2">Results:</td><td colspan="2">Approve</td><td colspan="2">Disapprove</td></tr>
<tr><td colspan="6">Observations and Additional Comments:</td></tr>
</table>

Hardware Test Case 5: LED should light up when the machine is on, and turns off when the machine is off

Method of Testing:

Turn the machine on, and then turn the machine off.

Criteria for Passing:

In order for this test case to pass, the LED light should be turned on when the machine is on and off when it is off.

<table>
<tr><td colspan="6">Test Summary</td></tr>
<tr><td colspan="3">LED ON</td><td colspan="3">LED OFF</td></tr>
<tr><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td colspan="2">Results:</td><td colspan="2">Approve</td><td colspan="2">Disapprove</td></tr>
<tr><td colspan="6">Observations and Additional Comments:</td></tr>
</table>

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Hardware Test Case 6: Battery can be successfully charged through an outlet/power source

Method of Testing:

Plug the battery to a wall plug and observe the battery icon. Do the same thing to a external power source.

Criteria for Passing:

In order for this test case to pass, the battery icon must show signs of charging.

Test Summary		
Plug device to a wall outlet	Plug device to a external power source	
Results:	Approve	Disapprove
Observations and Additional Comments:		

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A.2 Software Test Plans

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Evaluation Sheet

Tester ID:	Department:	Phone Number:	Test Date:
Prepared By:	Date:	Verified By:	Date:
Results (Please Select one of the following Boxes)			
Approved	Conditionally Approved	Disapproved	Not Applicable
Observations and Additional Comments:			

Tester Name: (Please Print)	Signature:	Date:

Software Test Case 1: The Arduino can detect the GSR sensor successfully, and the program we create in C++ can run and display results on the computer

Method of Testing:

The tester will run the demo code that will check and ensure the USB connection between the Arduino board and the computer. If the connection is successfully established, the system will start to display conductivity values on the computer monitor

Criteria for Passing:

In order for this test to pass, the demo code needs to be successfully run and displays test values.

Test Summary		
Demo code successfully compiled and run	Displays test values on the computer	
Results:	Approve	Disapprove
Observations and Additional Comments:		

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Software Test Case 2: The Arduino can successfully detect the LCD Screen. Text and number can be viewed on the screen.

Method of Testing:

The tester will run the demo code that will check and ensure the availability to establish a connection between the Arduino board and the LCD screen. If the connection is successful and they can communicate with each other, the system will notify the tester.

Criteria for Passing:

In order for this test to pass, the demo code needs to be successfully run and the tester needs to be notified by the system.

Test Summary		
Demo code successfully run		Tester notified
Results:	Approve	Disapprove
Observations and Additional Comments:		

Software Test Case 3: The Arduino can successfully detect the speaker. The speaker should be able to ply a series of sounds.

Method of Testing:

The tester will run the demo code that will check and ensure the availability to establish a connection between the Arduino board and the speaker. If the connection is successful and they can communicate with each other, the system will notify the tester and play sound samples.

Criteria for Passing:

In order for this test to pass, the demo code needs to be successfully run and the tester needs to be notified by the system and hear the sound samples.

Test Summary		
Demo code successfully run	Tester notified and samples played	
Results:	Approve	Disapprove
Observations and Additional Comments:		

Software Test Case 4: Testing of our algorithm, so that once the conductivity measured from the sensors exceeds a certain value, immediate instructions will be displayed on the LCD screen

Method of Testing:

The tester will run the demo code that will check and ensure if the algorithm is passed successfully. If it is successful, the system will immediately stop the current process and notify user.

Criteria for Passing:

In order for this test to pass, the demo code needs to be successfully run and the tester needs to be notified by the system and must be able to see system instructions displayed on the LCD screen.

<table>
<tr><td colspan="6">Test Summary</td></tr>
<tr><td colspan="3">Demo code successfully run</td><td colspan="3">Tester notified and instructions displayed</td></tr>
<tr><td colspan="3"></td><td colspan="3"></td></tr>
<tr><td colspan="2">Results:</td><td colspan="2">Approve</td><td colspan="2">Disapprove</td></tr>
<tr><td colspan="6">Observations and Additional Comments:</td></tr>
</table>

Appendix B: UI Design

1.0 Introduction

Medical devices can be complicated equipment to operate, many of which are handled by trained medical professionals such as doctors or lab technicians. This motivates CFTR Solutions to design the usability of the CF Scanner to a point where a non-medical professional can operate the device and observe results easily. Since many developing countries do not have access to advance medical labs or technicians, designing an easy and intuitive device removes that infrastructure that was once necessary. This document will outline why CFTR Solutions aims to achieve such a level of usability, as well as our approach. It will cover various mechanisms such as a step-by-step voice-over feature and others that will make the device usable for an untrained person.

2.0 User Analysis

CF Scanner is designed in a way that both trained medical professionals and regular users can operate the device easily. Therefore, having an intuitive and clean user interface is crucial. For medical professionals, there is almost no extra knowledge and no restrictions with respect to their prior experience with similar systems, as the set up and the procedure to use CF Scanner are pretty much identical to the current "gold standard" sweat test that medical professionals are familiar with.

In terms of non-medical regular users, there will be simple audio and visual commands, similar to AED, for the users to follow such as "Apply the Pilocarpine on the forearm", "Wait for 5 minutes", and "Wait for 30 minutes". Table 4 compares the current sweat test procedure with the procedure to prepare and operate CF Scanner. The only difference between CF Scanner and current sweat test is after the sweat being induced. The procedure to induce the sweat for both methods is identical. (the steps above the red line)

Apart from that, there is almost no restriction on the users' physical abilities as CF Scanner is a compact device that is light and small. The device provides both visual instructions and audio instructions simultaneously which will ensure people with disabilities can still operate the device correctly. CF Scanner is also designed to provide as much user support as possible. For instance, once the wait time has elapsed, the next step button will become green to inform the users. The audio and video instructions within a step will also repeat themselves after a short period of time.

Table 4. Procedure Difference Between Sweat Test and CF Scanner

Sweat Test	CF Scanner
Visually check condition of power pack, connections, and electrodes.	Visually check condition of power pack, connections, and electrodes and CF Scanner.
Select sites for iontophoresis, mostly inner	Select sites for iontophoresis, mostly inner

surface of the forearm with hairless area.	surface of the forearm with hairless area.
Wipe clean the patient's forearm with Mediswab (Skin Cleansing Swab with 70% IPA)	Wipe clean the patient's forearm with Mediswab (Skin Cleansing Swab with 70% IPA)
Dry forearm with tissue then moisten the selected area with deionized water and wool ball	Dry forearm with tissue then moisten the selected area with deionized water and wool ball
Apply pilocarpine gel onto the selected area to induce sweating and cover the area with gauze pad	Apply pilocarpine gel onto the selected area to induce sweating and cover the area with gauze pad
Electrodes are placed over the gauze pad and a mild current will be applied for 5 minutes	Electrodes are placed over the gauze pad and a mild current will be applied for 5 minutes
After 5 minutes, remove the electrodes and the pads then wipe clean the forearm again	After 5 minutes, remove the electrodes and the pads then wipe clean the forearm again
Place gauze pad onto the selected area tightly and wait for 30 minutes to collect the sweat	Place gauze pad onto the selected area tightly and wait for 30 minutes to collect the sweat
Put the gauze in a container and send to a medical lab for analysis	Apply CF Scanner onto the sweating area to run analysis

3.0 Technical Analysis: [1]

3.1 Discoverability

The ability of finding controls, switches and content of a medical device of crucial to designing a simple and intuitive design. The following discoverability features will be implemented to achieve such a feat:

- A power on/off button visibly available on the corner of the device dictates the on/off mode and the battery percentage will be displayed on the LCD
- Since the medical procedure of obtaining sweat from patients is sequential, the majority of the possible actions are restricted. An LCD screen combined with a speaker will guide the user to the next step in the process.
- An asynchronous reset button with confirmation will be available at all times.

3.2 Feedback

Given the linearity of the medical procedure, the user must know about their current state while using the device. This gives rise to the LCD display and voice-over speaker that will guide the user through the operation.

- A greeting to the operation procedure will be emitted when the device is powered on.
- A confirmation will be requested when the device is being powered off.
- The LCD will output the current state along with a timer of how long they should be in that state for.
- A speaker guides the user through exactly what to do in the state.

3.3 Affordances

In order to execute the desired design, the device must be intuitive to the user. In order for the user to perceive our device naturally, we implemented the following features:

- A power button will be placed on the corner of the device and in a red color.
- As previously stated, the user will be guided through the entire medical procedure with a LCD and a voice-over.
- The pilocarpine gel will be stored within a storage compartment that can be easily accessed with a latch locking mechanism. The latch locking mechanism will be adjacent to the compartment itself.

3.4 Signifiers

To guide the user through our intended design actions, we will use subtle yet informative labels. The following signifiers can be found throughout our design:

- The power button is labeled with a power symbol to indicate the functionality of the button.
- A confirmation will be requested by the device prior to turning off the device, which is done by the LCD and the speaker.
- Each step in the medical procedure will result in the LCD to change its output, as well as a different instruction emitted by the speaker.
- A symbol will be embedded on the latch locking the compartment holding the pilocarpine gel.

3.5 Mappings

The controls for the device must intuitively correspond to their actions; this can be explained in greater detail below:

- Controls, such as power button, are mounted into the device that is to be controlled.
- The latch controlling the lock of the compartment holding the pilocarpine gel shall be adjacent to the compartment, making it intuitive that it in fact encapsulates the gel.

3.6 Constraints

By adding constraints into the design, it clarifies how to use our device and what each module is meant for. Therefore, the following constraints on our device shall be implemented:

- The device shall be physically constrained and it is to be held with a single hand, by restricting the physical dimensions and the weight of the device.
- Each step in the medical procedure will be temporally constrained by a software timer and a speaker that will dictate when to proceed to the next step.
- Semantically, the voice-over guide will be using no medical jargon, as to simplify the instructions and emphasize the use of this device to non-medical professionals.

3.7 Conceptual Model

Using the six above design elements, we can create a clear conceptual model for the CF Scanner.

- A medical device that allows non-medical professionals to conduct a sweat test and observe the results.
- A combination of an LCD and a voice-over tutorial that will guide the user through the procedure, and therefore eliminate the once necessary medical infrastructure for traditional sweat tests.

4.0 Engineering Standards: [2]

CF Scanner's UI is designed to be comply with ISO 9241 which is a multi-part standard from the International Organization for Standardization covering ergonomics of human-computer interaction. The following standards will be used as guidance for CF Scanner UI design.

- ISO 9241-11 deals with the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.
- ISO 9241-12 contains specific recommendations for presenting and representing information on visual displays. It includes guidance on ways of representing complex information using alphanumeric and graphical/symbolic codes, screen layout, and design as well as the use of windows.
- ISO 9241-13 provides recommendations for the design and evaluation of user guidance attributes of software user interfaces including Prompts, Feedback, Status, On-line Help and Error Management.
- ISO 9241-14 provides recommendations for the ergonomic design of menus used in user-computer dialogues. The recommendations cover menu structure, navigation, option selection and execution, and menu presentation.
- ISO 9241-15 includes recommendations for the ergonomic design of command languages used in user-computer dialogues. The recommendations cover command language structure and syntax, command representations, input and output considerations, and feedback and help.
- ISO 9241-16 contains recommendations for the ergonomic design of direct manipulation dialogues, and includes the manipulation of objects, and the design of metaphors, objects and attributes. It covers those aspects of Graphical User Interfaces that are directly manipulated, and not covered by other parts of ISO 9241.
- ISO 9241 - 210 provides guidance on human-system interaction throughout the life cycle of interactive systems

4.1 Analytical Usability Testing

The intension of this medical device is to be used by users who could be untrained in the medical field; our design must be minimalistic in complexity. The device is guided via an LCD and a voice-over; the geographical region of the device must correspond to the semantics of the instructions. The instructions must be emitted in layman's terms and unambiguous. The power supply must be protected from external harm, and adjacent to the battery holder will be a sticker instructing compatible batteries only. Since the device induces a minimal 0.4mA current during one phase of the medical, as a safety precaution there will be a a current safety cut-out and an automatic timer that will both instruct the user to proceed to the next step and automatically shut off the current if it has been induced for too long or has gone over a limit. The compartment encapsulating the pilocarpine gel will display a sticker that will instruct the user to only use gels from a recognized manufacturer, and using a latch mechanism will lock the compartment.

4.2 Empirical Usability Testing

Different users will test the CF Scanner at different stages of the product development to ensure great usability. Whenever there is an iteration done on the device, the CF Scanner will be modified based on the feedback from the users at the different stages.

For the first stage, trained medical professionals who have had experience with Cystic Fibrosis patients and sweat test will be testing the CF Scanner. They will be asked to perform the traditional sweat test on one of the forearm's of a patient, and then use CF Scanner on the other forearm. By doing direct comparison like this, the medical professionals can experience the workflow difference between the sweat test and CF Scanner. They will have good idea how CF Scanner works compares to their prior experience. The medical professionals can also give constructive feedback on whether the audio and visual instructions are accurate and easy to follow. The design team can obtain these first-hand user experience from the medical professionals to further improve the UI, audio and visual instructions.

In terms of the second stage, the CF Scanner will be tested by a group of medical professionals that lacks experience when it comes to executing sweat tests. They will be asked to use CF Scanner on patients. They will be learning how to perform a standard CF screening test using CF Scanner. The steps and procedure that they have difficulty with will be recorded and examined. This stage of testing can help the design team to determine whether there is any learning difficulty. Then the next implementation will improve on making CF Scanner more intuitive and user friendly.

In third stage, regular users who do not have any knowledge regarding medical equipment will test the CF Scanner. At this stage, CF Scanner should have fairly straightforward user interface and clear instructions on how to operate the device. However, the previous test users are medical professionals, they have more experience using medical device on others and some related medical knowledge that regular people don't have. Therefore, having regular users to test CF Scanner can make sure our user interface does not have jargons that other uses might be confused about and our audio and visual instructions are informative, clear and easy to follow. The design team can receive the feedback and use it to fine tune CF Scanner before the final stage.

For the last stage, all users listed above will be testing CF Scanner again to ensure regression testing is done properly. At this stage, the design team will need to consider the feedbacks from each group and come up with a best user interface for CF Scanner.

4.3 Graphical Presentation

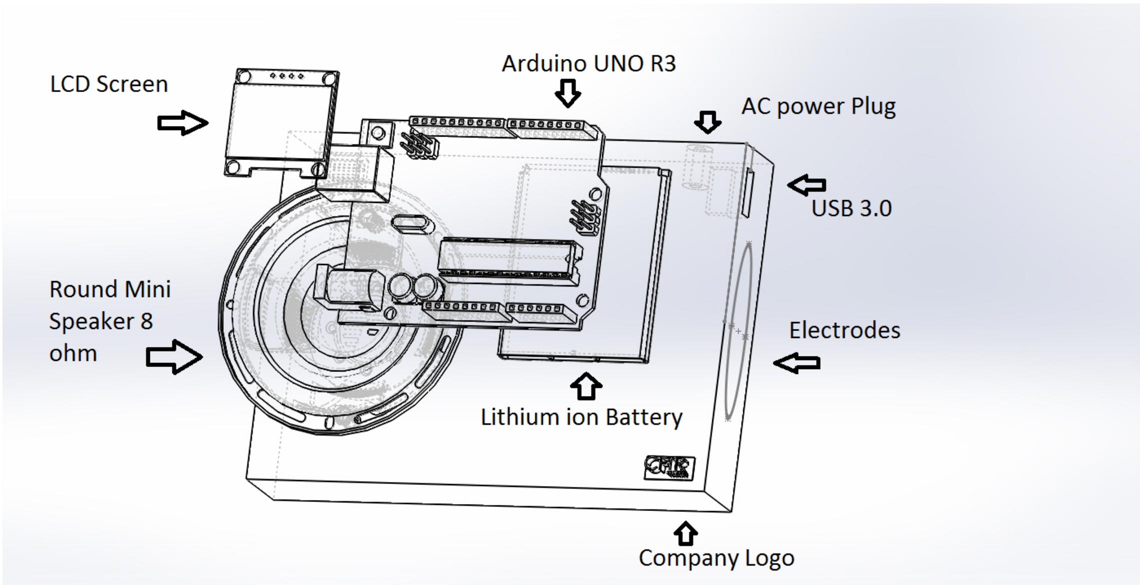

Figure 10 Solidworks schematic for the CF Scanner [3], [4]

Figure 10 shows a Solidworks schematic of the CF Scanner. As previously stated, it is equipped with a LCD screen to display results and to guide the user through the medical procedure. A speaker will emit a voice tutorial to assist. A red power button with the power symbol is available at the top corner, following a conventional design to ease usability.

5.0 Conclusion

The user interface design of a medical device is crucial to the usability and the execution of the medical procedure. Currently the CF Scanner has a strong conceptual foundation. Using a combination of the LCD and voice-over speaker, it will guide the user through the entire medical procedure. The mechanical buttons such as latches and switches will use signifying markers to indicate their functionality, as well as instructions for replacing batteries and pilocarpine gel. The major concern with respect to user interface is the uncertainty with regards to practically testing a prototype. Without a demo we do not know for certain if all users can semantically interpret correctly. This can be verified by creating a live prototype and display a demo for users to test. Therefore, once the prototype is constructed, the empirical usability testing must be done properly at each stage of the development to ensure great usability of CF Scanner.

References for Appendix B: UI Design

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