Department of Computer Science and Engineering

Seattle Pacific University

U-Catalyst: Senior Design Project

Functional Specifications

Project – The Second Wind

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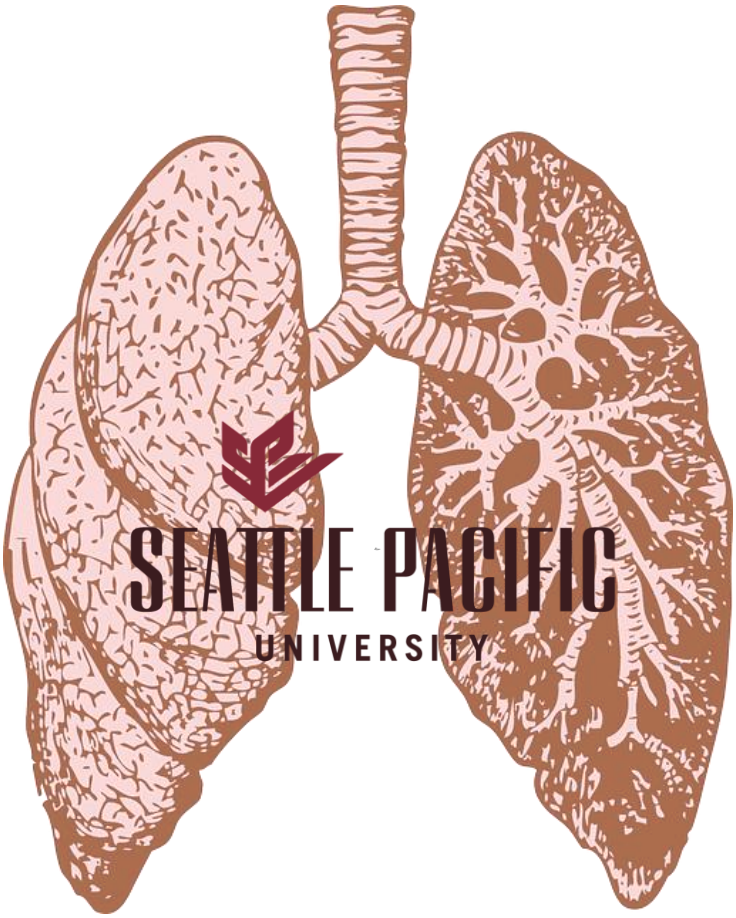

April 6, 2022

Design Goals for Incentive Spirometer 2.0

Project Definition

The Incentive Spirometer 2.0 is a re-imagination of the current line of incentive spirometers, with the ability to record and display whether the user/patient is successfully following their prescribed therapy.

- The device will accurately inform pulmonologists of successful inhalation therapies performed by the patient.
- The electronic components of the device will be detachable and be able to be reconnected to other spirometers.
- Spirometer 2.0 will have an adapter for an OPEP (Oscillating Positive Expiratory Pressure) device if prescribed by doctor.
- The device will have an audible reminder to alert patients to perform inhalation therapy.

Functional Specifications

1. EFFECTIVENESS (E)

Incentive Spirometer 2.0 functions similarly to the existing spirometers currently on the market. Incentive Spirometer 2.0 needs to be designed such that exhalations therapies performed by patient per doctor's prescription are digitally recorded and displayed for the doctor and patient. Our device will also be designed to be able to accommodate exhalation therapy if necessary. And this is what sets Incentive Spirometer 2.0 apart from other spirometers. These expectations are realistic, and we feel confident about a prototype built.

E001: Record Patient Inhalation: **The Incentive Spirometer 2.0 shall accurately measure, alert, and display the number of successful prescribed SMI (Sustained Maximal Inspiration) in less than a second, and should accurately measure, alert, and display the number of successful SMI in less than 0.5 seconds.** The time in which it takes for the microcontroller to display the result from the laser sensor will tell us how consistent and accurate our electrical system is. We will measure the time with a stop watch, to verify this specification.

E002: Overlap elimination: **The Incentive Spirometer 2.0 shall not double count an inhalation therapy at an accuracy of 90% and should not double count at an accuracy 95%**. To successfully record inhalations without overlap, the electrical system will quickly interpret the sensor's output and display it to the user while pausing the program. This will be manipulated through the code for the microcontroller and shall be manually measured with a timer.

2. DESIGN (D)

Incentive Spirometer 2.0 will be designed to accommodate an OPEP device, if prescribed by a Pulmonologist. Not all spirometer users require an OPEP, but Incentive Spirometer 2.0 provides inhalation and/or exhalation therapies. The device must be designed to alert patients so that they remember when to perform an exhalation therapy within a prescribed interval.

D001: OPEP Resistance Amplitude: **Using the Aerobika as a reference, the OPEP shall be within 10% of the maximum pressure of the Aerobika and should be within 5% of maximum pressure of the Aerobika.** Resistance will be measured using a manometer and we will seek to replicate the performance of the Aerobika. Based on preliminary testing the Aerobika's pressures range from 2.14kpa to 3.36kpa at lowest and highest resistance levels.

D002: Level of OPEP Resistances: **The OPEP shall have 3 increasing levels of resistance to exhalation and should have 5 increasing levels of resistance to exhalation.** Resistance will be measured using a manometer. Just as the Aerobika has 5 levels of resistance that increase gradually in accordance with the difficulty scaling, we will have at least 3 gradual levels of resistance that will lie within the range of resistance levels of the Aerobika. Once we have our own OPEP device printed, we will be able to measure and compare the pressure data to the Aerobika device. This specification will be verified by recording data with a manometer.

D003: Multi-Functional: **The Incentive Spirometer 2.0 will be able to function without the electrical components and the OPEP device module attachment.** The spirometer needs to be able function without the electrical component attached because the patient will take home the spirometer, while the electrical component will remain in the hospital. We will verify this specification by testing the spirometer with and without the electrical component attached.

D004: Patient Reminder: **The Incentive Spirometer 2.0 will remind the user for an inhalation exercise 10 times over the course of an hour.** To receive proper rehabilitation, a user should use the spirometer 10 times an hour, so the alerting time is used to keep the user on one track. It will be manipulated by code and shall be manually reset by a timer throughout test inhalations. This specification will be tested by using a stopwatch to time the interval between the reminders.

3. EFFICIENCY (EF)

EF001: Battery Life: **The Incentive Spirometer 2.0 shall have a battery life of 25 hours and should have a battery life of 30 hours.** Given the battery size we calculate the approximate battery life the system is rated for. We will verify this specification by observing how long it takes for the battery to drain.

4. DATA RETENTION (DR)

The incentive spirometer will only retain data for a single patient at a time and delete it after the patient has completed their breathing exercises. Information will be displayed on a screen for the patient and attending physician to verify the patient's performance.

DR001: Data Retention: **The incentive spirometer will only retain data for a single patient at a time and delete it after the patient has completed their breathing exercises.** The patient's attendant will be checking in on the patient every cycle (10 repetitions) and data for that cycle will need to be retained. When a new cycle is begun for that patient or a new patient, the information from the previous cycle will not be available. This specification will be verified by visually inspecting the code output.

DR002: Information Display: **Information will be displayed on a screen for the patient and attending physician to verify the patient's performance.** The patient's performance over the period of an hour will be displayed on a screen that is connected to the microcontroller. The screen will be used for any other encouraging message or confirmation of a successful repetition of the exercise. This specification will be verified through visual inspection of the LCD screen.

5. PHYSICAL CHARACTERISTICS (PC)

This device is likely to be handle by a large variety of people and therefore needs to be simple to use and aesthetically pleasing. The design of the spirometer also needs to be as compact as possible as it will be in a hospital setting where space is a limited resource.

PC001: Spirometer Dimensions: **The Incentive Spirometer 2.0's dimensions shall remain within 11 inches in height, 7 inches in width, and 4 inches in depth, and should remain within 10 inches in height, 6 inches in width, and 3 inches in depth when all components, like the electronics and OPEP, are attached to the spirometer.** Dimensions of the device can affect user interaction both in storing and when performing breathing exercises. This can be verified physically and in CAD models.

PC002: ON/OFF Switch: **The electronics on the spirometer will have a ON/OFF switch.** An ON/OFF switch is necessary to save on battery usage and will be used to reset memory. We will verify this specification by testing the on/off switch and verifying that it powers off the system, as well as resets the inhalation count.

6. COST (C)

Given that our product incorporates multiple devices the cost will be greater than other spirometers on the market. We aim to be competitive by increasing the functionality and lifetime of each subsystem on our device.

C001: System Cost: **The cost of the Incentive Spirometer 2.0's electrical house and its components shall be less than $75 after the initial production cost. The cost of the Incentive Spirometer 2.0's electrical house and its components should be less than $50 when producing 50 or more.** This refers to the production costs of building the device and does not include research. This specification will be verified by examining the bill of materials and final cost, as well as discussing actual manufacturing cost with Mr. Curran

7. SAFETY(S)

Since the device will be used for rehabilitation, it is essential for the electrical parts to stay hidden to account for overall safety. The device must not harm the user at all, be that from electrical shock or from other events.

S001: Wire Exposure: **The electrical device will not show any exposed wires, nor will the user be able to access any exposed wires.** Hiding wires will not allow the user to be able to tamper with hot wires that may cause electric shock. We will verify this specification through visual inspection.

S002: Electrical Component Access: **The user will not be able to access the internal electrical components including the wires, microcontroller, and sensor.** When using the device, the user will simply connect it to the spirometer. They will not have access to internal components that could cause them harm. This specification will be verified through visual inspection of the electrical housing.

ID	Spec	Threshold	Objective	Verification	Notes
E001	Record Patient Inhalation	Attained Inhalation level recorded in less than 1 second	Attained Inhalation level recorded in less than 0.5 seconds	Timing inhalation level (50 trails)	Minimize time delay from reaching inhalation goal and recording result.
E002	Overlap Elimination	The sensor shall accurately count the number of repetitions with 90% accuracy.	The sensor should accurately count the number of repetitions with 95% accuracy.	Observe Timer (100 Trials). One count for every successful inhalation.	Conduct 100 trails to have a 95% confidence level. There will be no double counting if diaphragm rises above the sensor and interrupts the sensor again as it descends.
D001	Amplitude of OPEP resistance	±10% maximum resistance pressure of the Aerobika OPEP device	±5% maximum resistance pressure of the Aerobika OPEP device	Recorded experimentation via a manometer (100 trails)	Flow and exhalation resistance must be strong enough for effective therapy and respiratory rehabilitation. 100 trails will yield a confidence interval of 90%

D002	Levels of OPEP resistances that can be selected by the user	3 optional levels of exhalation resistance	5 optional levels of exhalation resistance	measured by experimentation via a manometer	Each interval will increase the resistance linearly.
D003	Multi-Functional	Spirometer can function w/o electrical component	N/A	Testing and observation	The patient will take home the spirometer but not the electrical component
D004	Patient Reminder	Audible reminder for patients every 6 min.	N/A	Timed reminder with stopwatch (50 trials)	Forgetful or tired users will be periodic. Measured with +/- 10 seconds accuracy. 50 trails will have a 90% confidence level
EF 001	Battery Life	The battery life shall last 25 hours	The battery life should last 30 hours	Calculations and observation. (2 Trails)	We will conduct 2 trials, as well as verifying through calculations
DR 001	Data Retention	The number of successful inhalation repetitions over the period of 1 hour will be recorded	To ensure that the patient's performance can be verified by an attending medical worker	Visually inspect and verify that the lcd display shows accurate count each time the laser gets interrupted.	The microcontroller stores and displays the current number of successes.
DR002	Information Display	Display different messages input from the microcontroller	Display information on patient's inhalation performance.	Screen dynamically outputs messages from microcontroller	The medical provider reads from the LCD display the number of successful inhalation therapies

PC001	Spirometer Dimension	Height: 11 in Width: 7 in Depth: 4 in	Height: 10 in Width: 6 in Depth: 3 in	Measured with calipers and CAD model	Our customer Kerry Curran requested that the new spirometer design remain similar in size to the original design.
PC002	ON/OFF switch	Preserve battery life while not in use	N/A	Simulation and code	
C001	Cost	Cost of the electrical components shall not exceed $75 and	Cost of the electrical components should not exceed $40	Analysis of the bill of materials and the final cost	Since the electrical unit will be reused across multiple cheaper spirometer units, their cost is spread out over a massive volume of consumer-type product, the cost can remain competitive against forgoing our product.
S001	Wire Exposure	No exposed wires	N/A	Visual Inspection	Keeping the wiring within the electrical housing will prevent damage to both user and the device
S002	Electrical Component Access	No user access to electrical components	N/A	Visual Inspection	Prevent access to all the electrical components besides the ON/OFF switch

Signatures

Authors:

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Supervisors:

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