Department of Computer Science & Engineering
The University of Texas at Arlington

System Requirements Specification
CSE 4316: Senior Design I
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Sim Breathe Repeat
Breathe Easy Sim

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1 Product Concept

This section describes the purpose, use, and intended user audience for the Breathe Easy Sim. The Breathe Easy Sim is a system that performs simulated functionality of the AVEA Ventilator systems currently used by the University of Texas at Arlington's (UTA) SMART Hospital. Users of the Breathe Easy Sim will be able to touch the screen and turn the knobs to simulate the functionality of the AVEA Ventilator, while providing reduced airflow to the mannequins to ensure the bladders within the mannequins do not burst.

1.1 Purpose and Use

The Breathe Easy Sim is expected to be used in simulation scenarios in the UTA SMART Hospital. It will emulate a ventilator in physical appearance, software functionality, and airflow capability.

1.2 Intended Audience

The Breathe Easy Sim is intended to be used by UTA nursing students and faculty. It is specifically designed to be used in the UTA SMART Hospital with the SimMan mannequins currently in the SMART Hospital for simulation scenarios designed to prepare nursing students for real-world situations they may encounter in the nursing field after graduation.

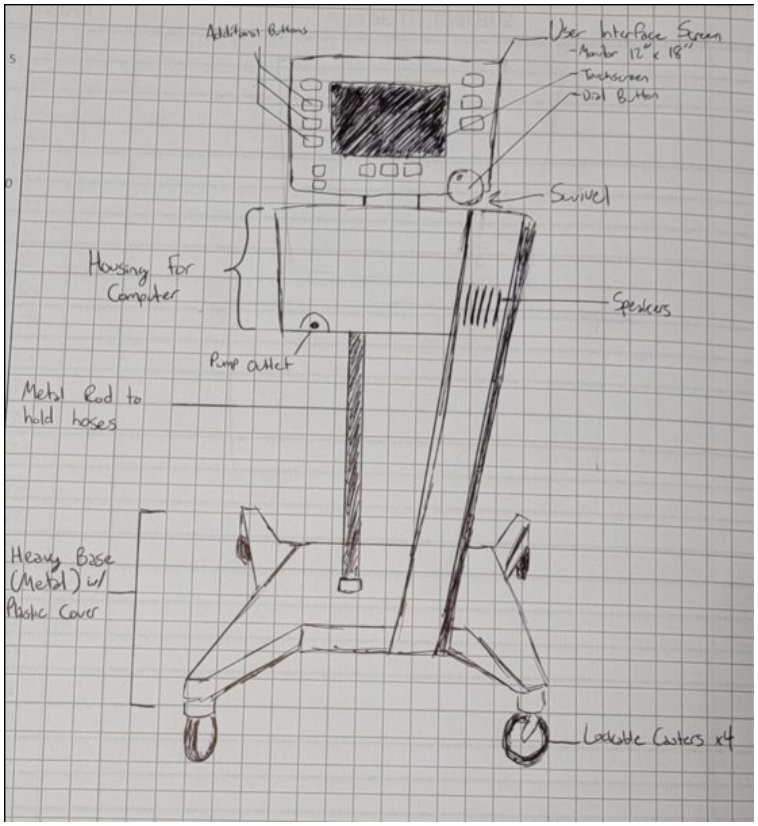

Figure 1: Breathe Easy Sim conceptual drawing

2 Product Description

This section provides an in-depth description of the Breathe Easy Sim product, as well as, its applications in practice. The main components of the system such as: Features and Functions, System Communications, and Interfaces will be defined in detail. Images and Diagrams will be utilized to simplify the characteristics of the design.

2.1 Features & Functions

The Breathe Easy Sim is designed to look similar to an authentic medical ventilator to provide students with a realistic training experience. However, its main focus lies in providing students with an advanced educational experience, with safer functionality and protection for the mannequin patient (SimMan).

The main features included are the Touch Screen, Processing Units, Air Pump System, Oxygenation Tubing, and AC Power Connector. Refer to figure 2.

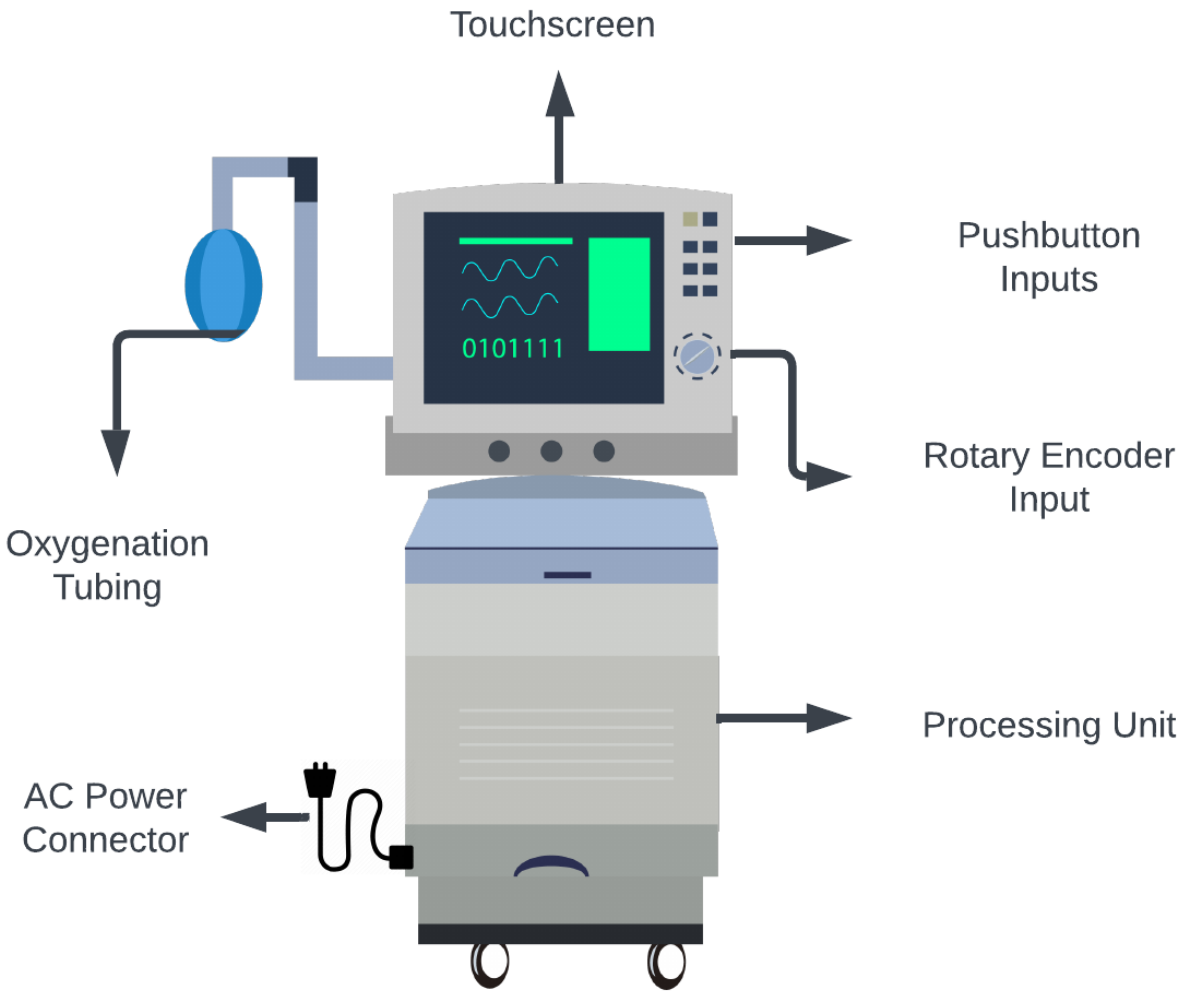

Figure 2: Ventilator Features

2.1.1 Touch Screen

The system contains a Touch Screen that will be utilized as the main interface for the user. This screen will allow the user to control any parameter with ease through the user interface. The screen will be attached and powered by the main processing unit.

2.1.2 Processing Unit

The processing unit consists of two components: a Raspberry Pi 4, and a TM4C123G Microcontroller. The Rpi will be considered the main processing unit of the system. It will be in charge of the Graphical User Interface as well as the Touch Screen. A microcontroller is used to facilitate motor control and communicate with the Raspberry Pi. Once these signals are received and processed, they will be sent to the Rpi and implemented into the GUI. The two main types of user inputs will be Push-buttons and Rotary Encoder Knobs. The Processing Unit will also interface with the Air Pump System.

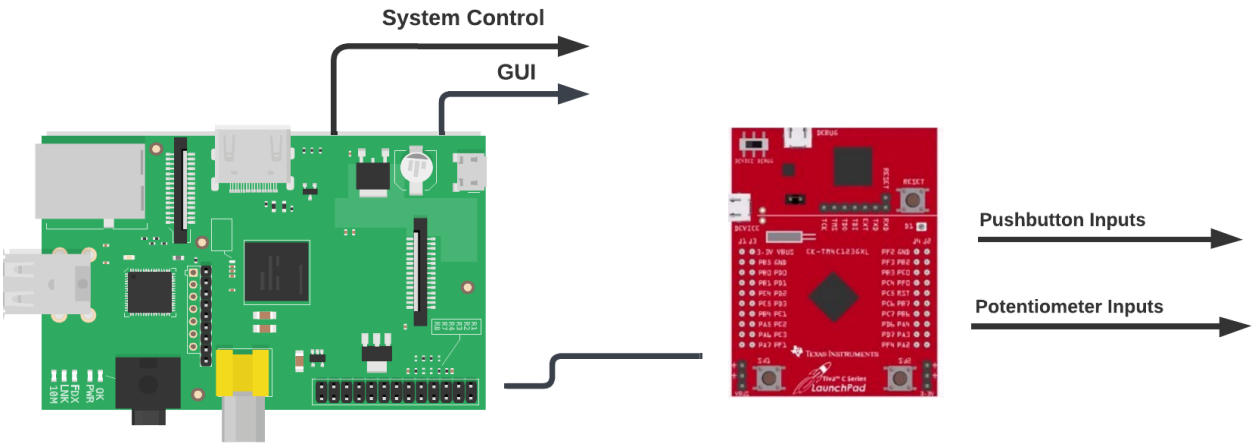

Figure 3: Processing Unit Design

2.1.3 Air Pump System

The air pump system will provide controlled positive and negative air pressure to the smart mannequins without rupturing the internal bladders. The pump will be powered and controlled by two synchronized stepper motors in the junction with limit switches for operation and calibration.

2.1.4 Oxygenation Tubing

The oxygen connector will be attached to the patient simulator mannequin. Once successfully attached, this tubing will direct the airflow straight to the mannequin lung bladders and continue the cycle until it is detached. Similarly, the tubing of the system will mirror that of a common medical ventilator.

2.1.5 AC Power Connector

The entire system will be powered by an alternating current connector straight from a 120V outlet source. This current will be converted into DC using a power supply unit to then power the whole system.

2.2 External Inputs & Outputs

The Breathe Easy Sim will have one external input and two external outputs. The one external input to the system is the user. A user is expected to provide all parameters to the system including rate, pressure and flow cycle of the airflow. The first output of the ventilator will be the user itself. The GUI

inside the system will display the necessary information for the user to comprehend the status of the procedure and apply its expertise to continue the process. The second external output of the system will be the mannequin patient. As said previously, this product is intended to be used as an educational tool, and safety is a top priority. For that reason, all input parameters provided by the user will have a limited impact on the output to the mannequin, this way we can ensure the safety of the user and the protection of all tools.

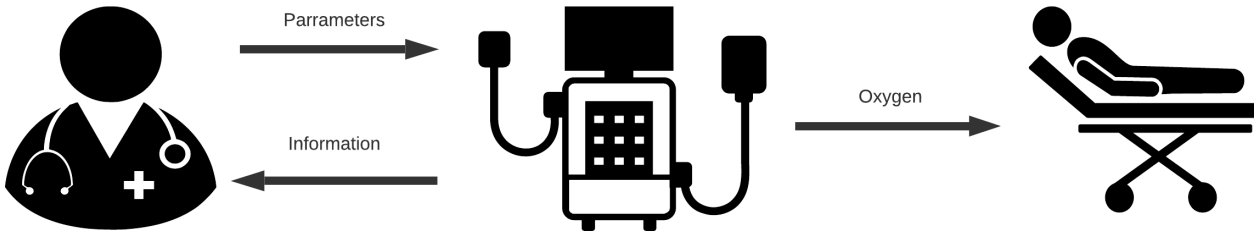

Figure 4: System Input and Output Design

2.3 Product Interfaces

The main feature of the system is a Graphical User Interface (GUI). This interface will be purposely designed to look similar to already existing ventilator interfaces. A mock-up picture is provided below. It will display multiple parameters that can be modified as needed, along with simulated patient diagnostic information.

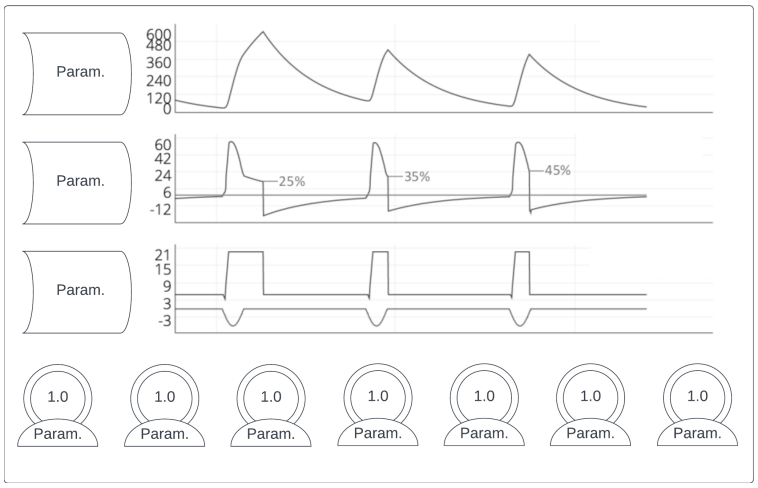

Figure 5: GUI Sample Design

3 Customer Requirements

In this section, we outline the specific customer requirements for the Breathe Easy Sim product. These requirements define the "look and feel" of the product, ensuring that it aligns with the expectations and needs of the intended end-users. Each requirement corresponds to a distinct customer need and contributes to the product's usability and functionality.

3.1 Power Source

3.1.1 Description

The Breathe Easy Sim shall be designed to operate when plugged into an AC power source. The ability to use the Breathe Easy Sim while connected to a power supply is a key customer requirement to ensure continuous operation.

3.1.2 Source

Customer

3.1.3 Constraints

The Breathe Easy Sim must be equipped with the necessary power input and circuitry to function when plugged in. The constraints include the need for a stable power source and compatible power connectors.

3.1.4 Standards

IEC 60335 - Household and similar electrical appliances - Safety
IEC/BS EN 62305-3:2011 - Good earthing (grounding) standards
ISO 12100 - Safety of machinery - General principles for design - Risk assessment and risk reduction

3.1.5 Priority

Critical

3.2 Battery Mode

3.2.1 Description

While the primary operation relies on being plugged in, the Breathe Easy Sim should be designed with the capability for future enhancements. Specifically, it should allow for the integration of a battery power option in addition to the standard plugged-in mode, providing flexibility for different use cases.

3.2.2 Source

Future

3.2.3 Constraints

Constraints include the need for a modular power design to accommodate a battery option in the future, and the battery integration should adhere to safety and regulatory requirements.

3.2.4 Standards

EC 62133 - Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
ISO 14971 - Medical devices - Application of risk management to medical devices

3.2.5 Priority

Future

3.3 Visual Resemblance to AVEA Ventilator

3.3.1 Description

The Breathe Easy Sim should closely resemble a real ventilator, with an aesthetic design inspired by the AVEA Ventilator. This visual resemblance is vital to provide students with an immersive and authentic educational experience.

3.3.2 Source

Customer

3.3.3 Constraints

Constraints include adhering to design copyright or trademark regulations related to the AVEA Ventilator's appearance, and the product's materials and design should comply with safety and usability standards.

3.3.4 Standards

None

3.3.5 Priority

High

3.4 Software Similarity to AVEA Ventilator

3.4.1 Description

The software inside the Breathe Easy Sim shall be designed to be as similar as possible to the interface and functionality of the AVEA Ventilator. This approach aims to ensure that students can comfortably use the Sim Vent, given its resemblance to the actual ventilator.

3.4.2 Source

Customer

3.4.3 Constraints

Constraints include operating within the same response time of a real ventilator.

3.4.4 Standards

None

3.4.5 Priority

Critical

3.5 Constant Air Flow

3.5.1 Description

The Breathe Easy Sim shall provide a constant rate of positive and negative airflow, replicating the behavior of a real ventilator. This constant airflow is essential for creating an accurate and effective simulation for educational purposes.

3.5.2 Source

Customer

3.5.3 Constraints

Constraints include the need for airflow control mechanisms and sensors and the product must meet safety standards to ensure consistent airflow without fluctuations.

3.5.4 Standards

None

3.5.5 Priority

Critical

3.6 Mannequin Readings Simulated by Ventilator

3.6.1 Description

The Breathe Easy Sim shall be capable of simulating read outs from a mannequin patient. The readings should be generated by the ventilator, replicating the data and measurements that would be observed in a real clinical setting.

3.6.2 Source

Customer

3.6.3 Constraints

Constraints include the live readings being similar to the live readings of a patient.

3.6.4 Standards

None

3.6.5 Priority

Critical

3.7 Sounds Like AVEA Ventilator

3.7.1 Description

The audio produced by the Breathe Easy Sim shall closely resemble the sounds of the AVEA Ventilator. This auditory simulation is crucial to immerse students in a lifelike environment, enhancing the educational experience.

3.7.2 Source

Customer

3.7.3 Constraints

Constraints include being able to gather the sounds from the machine and the sounds produced must adhere to any applicable noise level regulations. Additionally, many of the alarms present on a real ventilator are not able to be replicated on the Breathe Easy Sim due to a lack on additional sensors.

3.7.4 Standards

None

3.7.5 Priority

High

3.8 Mute Button/Switch

3.8.1 Description

An optional mute button/switch should be included in the Breathe Easy Sim. This feature allows users to temporarily silence the ventilator's sounds if necessary.

3.8.2 Source

Customer

3.8.3 Constraints

Constraints include the need for the mute button to be easily accessible and user-friendly and the optional mute feature should not interfere with the overall operation of the Sim Vent.

3.8.4 Standards

ISO 15223 - Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied.

3.8.5 Priority

Low

3.9 Rolling Capability

3.9.1 Description

While not mandatory, it is desirable for the Breathe Easy Sim to have rolling capability. This feature would enhance the product's mobility and ease of transport, allowing users to move it conveniently within a laboratory or educational setting.

3.9.2 Source

Customer

3.9.3 Constraints

Constraints include the need for a durable and reliable rolling mechanism.

3.9.4 Standards

None

3.9.5 Priority

Moderate

4 Packaging Requirements

In this section, we outline the packaging requirements for the Breathe Easy Sim product. These requirements define how the final product will be delivered to the end-users, emphasizing ease of use and mobility. The Sim Vent is designed to be a user-friendly, preassembled add-on, and the packaging should reflect these principles, ensuring safe delivery and convenient handling.

4.1 Delivery as Preassembled Add-On

4.1.1 Description

The Breathe Easy Sim shall be delivered to customers in a preassembled state, requiring no professional installation or assembly. The product should be ready for immediate use upon delivery.

4.1.2 Source

Customer

4.1.3 Constraints

The Breathe Easy Sim design and packaging must ensure that all components are securely assembled before delivery to prevent damage or misalignment during transportation. User-friendly instructions for setup and operation should be included to assist customers in using the product effectively. Packaging materials must be selected to protect the Sim Vent during transit and storage to prevent any damage to delicate components or sensors.

4.1.4 Standards

None

4.1.5 Priority

Low

4.2 Handling and Mobility

4.2.1 Description

The packaging should facilitate ease of handling and mobility. Users should be able to transport the Breathe Easy Sim with minimal effort.

4.2.2 Source

Customer

4.2.3 Constraints

The packaging design should consider the weight and size of the Breathe Easy Sim to ensure that it can be maneuvered conveniently by end-users. The packaging should be designed with suitable handles, grips, or wheels to enhance mobility. It should be compact enough to fit through standard doorways and corridors without excessive effort.

4.2.4 Standards

None

4.2.5 Priority

Low

5 Performance Requirements

In this section, we outline the performance requirements for the Breathe Easy Sim. These requirements define the operational characteristics of the product. The Breathe Easy Sim is designed to emulate the AVEA Ventilator and to be used by nursing students in the UTA SMART Hospital for simulation scenarios mimicking real-world scenarios, thus these requirements should ensure that the product is similar to the AVEA Ventilator as well as being able to withstand it being used by all the students.

5.1 Response Time

5.1.1 Description

The Breathe Easy Sim shall perform all tasks with a delay of less than two seconds. This requirement is to ensure the product performance emulates that of the AVEA Ventilator.

5.1.2 Source

Kyle Henry

5.1.3 Constraints

Constraints include being able to observe the response time of the AVEA Ventilator for every task and being able to implement that in the Breathe Easy Sim.

5.1.4 Standards

None

5.1.5 Priority

Critical

5.2 Product Lifespan

5.2.1 Description

The Breathe Easy Sim shall be able to withstand the use of students like the AVEA Ventilator by lasting for at least two years to match the time guaranteed for the AVEA Ventilator to be without defect.

5.2.2 Source

Kyle Henry

5.2.3 Constraints

Constraints include durable materials to withstand the use of students, the need for access to a proper power source for the processing unit in the Breathe Easy Sim, and the processing unit being secured in the Breathe Easy Sim.

5.2.4 Standards

AVEA Ventilator Requirements

5.2.5 Priority

High

6 Safety Requirements

The Breathe Easy Sim is designed to be used for learning purposes ONLY, and is not to be used on any living being under any circumstance. Do not remove any of the covers or panels unless performing maintenance on the ventilator. Maintenance should only be performed by competent personnel in order to prevent risk of electrical shock or damage to the ventilator.

6.1 National Electric Code (NEC) wiring compliance

6.1.1 Description

Any electrical wiring will be completed in compliance with all requirements specified in the National Electric Code. This includes wire runs, insulation, grounding, enclosures, over-current protection, and all other specifications.

6.1.2 Source

CSE Senior Design laboratory policy

6.1.3 Constraints

High voltage power sources, as defined in NFPA 70, will be avoided as much as possible in order to minimize potential hazards.

6.1.4 Standards

NFPA 70
IEC/BS EN 62305-3:2011 - Good earthing (grounding) standards

6.1.5 Priority

Critical

7 Security Requirements

The Breath Easy Sim will not need any security requirements. This is because there is no aspect to this project that needs securing. A ventilator does not store personal information and doesn't connect to the internet. In the same way, the Breath Easy Sim will not need to do those actions, so no security is needed since there is nothing to secure.

8 Maintenance & Support Requirements

Maintenance of this product will be limited considering it is mostly a hardware device. Most of the problems that may surge will be How-To-Use questions, for which the user manual is created. Any mechanical maintenance corresponding to malfunctioning hardware will be subject to the availability and budget of the project team. Software support and updates will be unavailable considering the system is a local environment and has no connection to any network. The main resources for maintenance and support for the product will an all-encompassing Service Manual as well as documented source code.

8.1 User Manual

8.1.1 Description

The Service Manual will include step-by-step instructions on how to use all the components of the system. These components include the following sections: Set-Up and Installation, Software User Guide, Wiring Diagram, Troubleshooting, Parts List, and Recommendations for Future Projects. The purpose of this document is to offer the user an easier learning period without the need for contacting the product developers. The document will be limited to the high-level basics on how to set up and use the system and provide high level troubleshooting information for common repairs and replacements. This means that the person using this product should have previous knowledge on what the system is, and how to adapt it to every situation.

8.1.2 Source

CSE Senior Design project specifications

8.1.3 Constraints

The contents of the document will be based on information gathered by the team during the design process. Due to the nature and timeline of the project, user feedback of the prototype system will be severely limited and can not be completely accounted for in the documentation.

8.1.4 Standards

List of applicable standards:

- FCC Manual Statement: Â§15.21 Information to user.
- FCC Manual Statement: Â§15.105 Digital Devices Statement

8.1.5 Priority

High

9 Other Requirements

In this section, we outline the specific requirements that are necessary to consider the Breathe Easy Sim product complete. These requirements encompass elements related to the product's architecture, design, programming language, user setup, and the development environment. By adhering to these completeness requirements, we aim to ensure that the Breathe Easy Sim is a fully functional, user-friendly, and adaptable simulation system that can be seamlessly integrated into various laboratory environments.

9.1 Programming Language

9.1.1 Description

The Breathe Easy Sim shall be developed using the Java programming language. This choice of programming language is essential to ensure efficient and robust code that can handle the computational demands of the simulation while providing compatibility with the chosen development framework.

9.1.2 Source

Kyle Henry

9.1.3 Constraints

The use of the Java programming language imposes constraints on the development team to have proficiency in Java for coding, debugging, and maintaining the software. Constraints related to Java compatibility across various platforms must be considered to ensure cross-platform functionality. The development process should adhere to best practices and coding standards for Java to maintain code readability and maintainability.

9.1.4 Standards

None

9.1.5 Priority

Moderate

9.2 Software Framework

9.2.1 Description

The Breathe Easy Sim software shall be built using the Java Swing library. Java Swing provides a platform-independent development environment that offers tools and libraries for creating graphical user interfaces (GUIs) and ensures cross-platform compatibility.

9.2.2 Source

Kyle Henry

9.2.3 Constraints

Development and design constraints associated with the Java Swing library include familiarity with Java Swing libraries, adherence to Java Swing's coding conventions, and utilization of Java Swing's GUI design principles. Compatibility constraints regarding the chosen version of the Java Swing library should be addressed to ensure consistent behavior across various platforms.

9.2.4 Standards

None

9.2.5 Priority

Moderate

9.3 Laboratory-Based Development

9.3.1 Description

The Breathe Easy Sim product shall be developed and tested within a laboratory environment, such as the senior design lab at the University of Texas at Arlington (UTA). This controlled setting will ensure rigorous testing, calibration, and validation of the product before deployment.

9.3.2 Source

Team

9.3.3 Constraints

Constraints include the need for access to a suitable laboratory space and equipment for development and testing. Compliance with safety and ethical guidelines within the laboratory setting is essential to safeguard against risks and potential hazards.

9.3.4 Standards

None

9.3.5 Priority

Low

10 Future Items

The following are features/functions that were considered/discussed and documented herein, but will NOT be addressed in the prototype version of the product due to constraints of budget, time, skills, technology, feasibility analysis, etc.

10.1 Rechargeable Battery Power/UPS

10.1.1 Description

Product to run off of backup battery power in the event of a power outage, similar to ventilators used by Customer.

10.1.2 Source

Customer

10.1.3 Constraints

Time and Skill

10.1.4 Standards

IEC 62040-1:2017 EXV

10.1.5 Priority

Future

REFERENCES