PRELIMINARY REQUIREMENTS DOCUMENT
SMART INHALER

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Table of Contents

1 Introduction

This document contains the system requirements for Smart Inhaler.

1.1 Purpose of This Document

This document is intended to guide development of Smart Inhaler. It may go through several stages during the course of the project. The first version is compiled after the Statement of Work has been formally approved, and is then proposed as a potential requirements specification for the project. The proposed document should be reviewed by several parties, who may comment on any requirements and any priorities, either to agree, to disagree, or to identify missing requirements/information. Readers include consumers, developers, project managers, and any other stakeholders. The document may be amended several times before moving to the next stage. Once the various stakeholders have agreed to the requirements in the document, it is to be signed by all parties as an appropriate statement of requirements for the project. The developers then use this approved requirement document as a guide to implementation of the Functional Specification.

1.2 How to Use This Document

We expect that this document will be used by people with different skill sets. This section explains which parts of this document should be reviewed by various types of readers in order assist with the readers objectives.

1.2.1 Types of Reader

- Project managers
- Engineering team
- Health officials (pharmacists, physicians, Doctors…)
- Programmers
- Design managers
- Consumers

1.2.2 Technical Background Required

An elementary background in computer programming, PCB manufacturing, and product design in addition to prior knowledge pertaining to asthma related issues and or common medical practices. These practices include but are not limited to, how consumers receive medication from health officials, how a proper dose of medicine is inhaled from an inhaler, and how a consumer goes about being diagnosed for asthma.

1.2.3 Overview Sections

1.3 Scope of the Product

Traditionally, the inhaler has been misused and consumers found it difficult to properly receive medication due to common consuming mistakes. Mistakes such as improper inhalation timing, coating the mouth with medicine rather than the lungs, and incorrect angle at which the inhaler is held. These are just some of the many common misuses of the traditional inhaler. This project is aimed to develop a smart medical device, using a traditional inhaler and spacer setup. The smart device is to be integrated with smart phones collecting data on when, where, and how well the patient use the device. Measuring spirometer -a type of test that shows how much air can be inhaled and exhaled by a person- allowing a more complete picture of a person's pulmonary health. Thuvia Systems will be upgrading the prototype inhaler with a more efficient microprocessor, debugging systems, and sensors. In the pursuit of a funding the team will continue in their pursuit in a grant from the National Heart, Lung, and Blood Institute at the National Institutes of Health.

1.4 Business Case for the Product

There is a large market for those with asthma and a large number of individuals improperly taking their medicine. Since the goal of the institution, it to drive innovation in the asthma market, creating a device focused on the need of the user is necessary. Although asthma designs are available, none stand out like the Thuvia Systems design. With the smart phone compatibilities and its ability to inform your pharmacy about your current supply, Thuvia Systems is redesigning what was formally known as the smart inhaler and making is even smarter.

1.5 Overview of the Requirements Document

- ThunderBoard Capabilities and Functionality
- Integration of Digital Sensors
- Integration of User Interface
- Prototype Design

2 General Description

Focusing on the patient, the inhalers design is intended to not only incentivize the consumer but gamify the product, thus keeping the individual engaged and actively participating. Since the creation of the inhaler people have misused it. In order to counteract the negative consequences of both forgetting and misusing, the Smart Inhaler team is working to make a more efficient inhaler device/attachment that can integrate with a cellphone application via Bluetooth. The application will combine inhaler data such as contacting a pharmacist, letting them know you're do for a refill or timing your inhalation so that you receive the maximum dose of medication in your lungs rather than in your mouth, along with much more. The generation of graphs and trend analyses will not only create an engaging user interface but can also notify a health official and the patient of disease progression. In turn, doctors can easily analyze the seriousness of their patients' conditions and gauge if their medication prescribed to the patient is helping. In addition, the Smart Inhaler team adding more features on the device like tracking the inhaler using GPS embedded into the device board, measuring the inspiratory flow rate using digital pressure sensors, visual/audio feedback to allow for a pleasurable response. The device will consume in minimum power, in turn optimizing the battery life to minimize charging. Lastly, the device will have easily replaceable components in case the device is faulty or in operatable. This ensures that consumers don't have to buy a new device when something goes wrong.

2.1 Product Perspective

Asthma is a health and economic problem that manifests as a chronic inflammatory disorder of the airways. It affects 235 million people worldwide and is projected to increase by another 100 million cases by 2025[1-3]. Asthma costs the US an estimated $82 billion annually. In New Mexico, asthma is one of the most common chronic diseases with an estimated 150,000 adults and 47,000 children currently having asthma (*Source*- New Mexico Department of Health; New Mexico Council on Asthma, 2019). Individuals with asthma are intended to benefit from this product.

2.2 Product Functions

The Smart Inhaler utilizes a 32bit microcontroller to handle all the functions of the system. The Smart Inhaler must have Bluetooth capabilities for connection between the device and a smartphone application. To improve the adherence of the medication and usage technique, the Smart Inhaler should be integrated with several digital sensors. A Flow sensor that can measure the rate and force of inhalation. A 6-axis IMU sensor for proper device orientation and angle. Dispense of the asthma medication should be time-released and in sync with other functions on the device. The Smart Inhaler needs to incorporate interactive gamification, so adherence is engaging and fun. The device must be equipped with LEDs for visual user feedback, and a speaker for audio queues, that help improve usage of the product. The Smart Inhaler needs to have an easy-to-use smartphone application. The phone app will need to track data on when and how the asthma medication was administered. It will need to remind the consumer to take their medication with notifications. The app will create reports about inhaler usage and provide information to improve techniques.

2.3 User Characteristics

Individuals diagnosed with asthma related issues are the intended consumers for this device. With the smart inhaler, little to no prior knowledge is assumed.

2.4 General Constraints

Size and weight of the unit is to be minimized as much as possible in order to increase ease of portability. With the application, the developer is expecting to use the .kivy library for python. Here is where the UI will be developed. The benefit of using .kivy is to increase the applications use-ability. The .kivy library has cross platform capabilities such as Android, IOS, Raspberry Pi, Linux, and more. In addition, special awareness of power consumption is expected as to not require the user to charge the device frequently or too often need batteries. In addition to software, an additional constraint is an adapting piece used toto connect the devise to that of a standard inhaler.

2.5 Assumptions and Dependencies

This project was assumed to need both electrical, mechanical, and computer engineers in order to have a finalized product with the intended features mentioned above in section 2.2. As prototype version two is proceeding, future expectations are to be assumed – a smaller and lighter device with further data collection features as well as compatibility to a smart phone devise. Additionally, to the most recent prototype the Thunderboard integration is necessary because the engineering team's ability to acquire training.

3 Specific Requirements

This section of the document lists specific requirements for Smart Inhaler. Requirements are divided into the following sections:

1. User requirements
2. Reporting requirements
3. System and Integration requirements
4. Security Requirements
5. User Interface requirements.

3.1 User Requirements

With the smart inhaler, little to no prior knowledge is assumed.

3.2 Reporting Requirements

Thuvia Systems oversees all documents pertaining to the product.

3.3 System and Integration Requirements

Asthma is a serious inflammatory disorder affecting millions of people worldwide. Thuvia Systems has recently been researching the way patients consume their inhaler medication. The goal is to develop a -smart medical inhaler that enhances asthma medication adherence. Creating a smart device will help patients properly use the inhaler and allow integration with a smart phone application. This device will collect data on when, where, and how well the patient uses the device. This design is user friendly, utilizing audio queues and visual feedback. The smart inhaler will be created with a computer development board, equipped with multiple sensors and a debugging system. This product will re-imagine and re-design a crude prototype of the inhaler that was previously developed. This product will supply state-of-the-art embedded computer development boards, debugging systems, sensors, and 3D printing materials. The device will incorporate NOx sensors and digital pressure sensors to capture patient data that interfaces with Bluetooth Low Energy. The smart inhaler will be integrated with functions that allow for varied device operation through an inhalation and exhalation. There will be specific action functions, which will protect the flow sensing device, reducing the possibility of damaging the flow sensing device components. In the case that the flow sensor becomes fouled from regular and/or incorrect usage, the flow sensing device should be easily replaceable. In addition, the device should give positive visual/audio feedback to the user for proper device operation. Finally, the students will develop a power management system. Overall, the device should collect inspiratory flow and NOx data, store it, then transfer it to a collection system through wireless interfacing. In the end, students will have learned how to make real products “smart”.

3.4 Security Requirements

The phone application would require a password to access.

3.5 User Interface Requirements

The Smart Inhaler will require a button to turn on and off the device. There will be several LEDs to indicated how the device is used. LEDs will emit a green color for correct usage and a red color for improper usage. The Smart Inhaler will also have a speaker that can output audio to alert the consumer if the device is either in a correct or incorrect position and angle.

4 High-Level Technology Architecture

The large components of the project consist of the housing, microcontroller, and additional basic level electronic components. In further detail, the microcontroller, being the Silicon Labs Thunderboard will be the main component utilized in the production of the Smart Inhaler. The controller will be responsible for retrieving, analyzing, and sending data tom which an application will quantify and interpret. Additionally,

the board will be responsible for distributing power to multiple sensors in the order that it is needed. Meaning, if a sensor is unneeded the microcontroller will distribute power only to the active components. Assisting the board will be elementary electronic component such as LED's, amplifiers, audio speakers, a battery (Li-Po), and voltage sensor modules. To wrap all the functions together will be a 3D printed housing. The housing will be created with the user in mind. For example, some water resistance is preferred along with its ability to reduce damage to the device when jostled or dropped.

5 Appendices

6 Glossary

UI: User Interface
Cross Platform:
LED: Light emitting Diode

7 Approvals

Approver Name	Title	Signature	Date
Amelia Bierle	Sponsor		
Michael McDonald	Technical Mentor		
Bishwanath Bastola	Project Manager		
Ramiro Jordan Ganesh Balikrishna	Instructor(s)		12/13/2021