FUNCTIONAL SPECIFICATION
SMART INHALER

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SPONSOR BUILD WITH ROBOTS
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REVISION HISTORY			
Name	**Date**	**Changes**	**Version**

Table of Contents

1 Introduction

This document will specify the design, improvement and uses of Smart Inhaler Device. Build with Robots already have a pre-made prototype, but it is lacking some important features. The goal of our team to design a SI that is capable of measuring asthma medication adherence and to develop a digital intervention program that nudges and rewards patients for medication adherence.

1.1 Summary

A smart inhaler is an inhaler that integrates connectivity with a mobile app, via Bluetooth, for instance. These devices are built with sensor technology that helps record data about the time and date of use, and the location of the patient at each use. Our team propose to develop a SI that is capable of measuring PIF during inhaler use. PIF will indicate whether the dose was delivered to the lungs to achieve optimal clinical benefit. The Asthama patient will be rewarded with audio and visual feedback from the device once the device registers that a dose of medication has been taken. This positive feedback will further reinforce the medication adherent behaviour.

1.2 Requirements

Our team is trying to accomplish the following deliverables by the end of May 2022 by leveraging several resources at UNM.

Deliverable 1– Improved prototype that accurately measures PIF and stores the relative data by integration of digital pressure sensors with I2S or SPI buses.

Deliverable 2– Prototype that gives the user positive visual, audio, and/or sensory feedback because of correct device usage and medication adherence by Integration of user interface sensors and output devices such as lights (LEDs), Displays (OLED displays), and Sound

Deliverable 3– The last two months of the project will involve writing a final report that will include the goals that we achieved and any challenges that we faced during this proposal period.

1.3 Numbers

The SI is a fast-growing market – the total addressable market for asthma therapeutics today is $17.6 billion[17]. Within this market is the serviceable available market, the niche SI market is currently valued at $34 million[18] However, by 2027 the total addressable market is expected to grow to $19.13 billion due to increased population and a decline in air quality[17]. The serviceable available market is growing even more rapidly. It is expected to reach $1.4 Billion by 2027[18]

1.4 Existing System

The Smart Inhaler prototype was successfully able to measure the PIF (breath intake during inhaler use) during patients' inhalation manoeuvres and in integrating the inhaler device with a smart mobile device (iPhone) via Bluetooth Low Energy (BLE) that allowed the patients' inhalation data transmission to the mobile device.

Our current SI device includes the following components

- A 3D printed plastic enclosure that
  - channels the intake air through a Venturi-type air restrictor and
  - holds an analog pressure sensor, electronics, and battery
- An analog differential pressure sensor that measures the pressure drop across the Venturi (+/- 2000 Pa, five VDC; volts of direct current)
- An ESP32, which is a low-cost, low-power system on a chip (SoC) microcontroller with integrated Wi-Fi and dual-mode Bluetooth to communicate with other devices, analog to digital converters to read pressure sensor data. The electronics package included power management to allow it to be run from a battery and a USB interface to support software development
- LiPo batteries a battery power supply (3.3 & 5V taps).
- Associated electronics

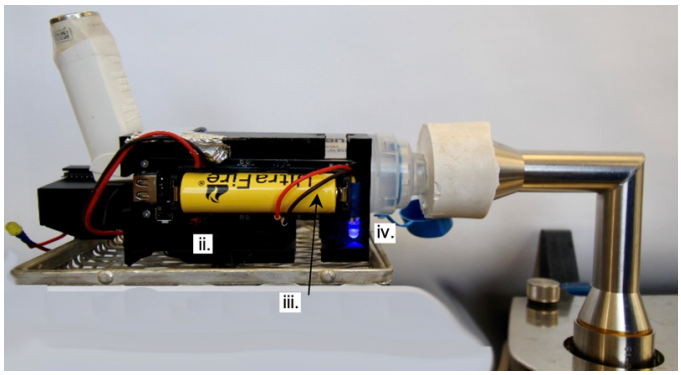

Fig: Current Prototype

The SI prototype still lacks several features needed for a usable SI system. Further, the electronics, sensor, and battery are bulky and lack user interface components necessary for practical patient use. Also, the iPhone App is basic and lacks the features needed for actual patient use. During our interviews with various asthma stakeholders as part of the I-Corp program, we discovered that the device should include a patient-centered design that lends itself to gamification to develop a reward system that reinforces medication adherence habits. With this critical information, we have developed a preliminary design concept.

Our design concept includes:

- Designing a new electronics package to include:
  - Extremely low power BLE-Focused SoC (System on a Chip)
  - Digital pressure sensor
  - User interface elements (e.g., displays, lights, buttons, or motion sensors)

Because our project is in the initial stages of development, we have prioritized our sequence of development. For example, we plan to do the electronics design and implementation first because we have current access to UNM's Electrical and Computer Engineering students who will implement the electronics as a learning opportunity in the classroom.

1.5 Terminology

- SI – Smart Inhaler
- BLE – Bluetooth Low Energy
- SoC – System on a Chip
- PIF –
- Pa – Pascal

1.6 References

- *COPD and Asthma Drug Devices Market Size, Trends, Opportunities & Forecast*. (2019, August 12). Verified Market Research. https://www.verifiedmarketresearch.com/product/copd-and-asthma-drug-devices-market/
- Thomas, L., MD. (2021, May 4). *What are Smart Inhalers?* News-Medical.Net. https://www.news-medical.net/health/What-are-Smart-Inhalers.aspx

2 Functional Description

The later part will discuss the functional description of the Smart Inhaler Device.

2.1 Use Cases

We hope to build an improved version of our SI prototype where our digital pressure sensors are integrated with I^2S or SPI buses. These interfaces are being used to communicate PCM audio data between integrated circuits in electronic devices. Thus, we expect to develop a SI with synchronous serial communication interfaces that allow for short-distance communication, between a device (smartphone) and the embedded systems within the SI.

Users own the data, but can share them with anyone, such as health care provides or caregivers which can be easily analyzed by the doctors which will made the doctors realize the seriousness of the condition of the patient. Then it will be a lot easier for doctors to provide and consult the correct medication. Researchers and clinicians, with permission from the users, may also use another dashboard component to track usage among entire populations of patients anonymously.

We will also allow users to adjust their own preferences on the app. The app will remind the patients either by autogenerated messages or by activating automatic alarms for taking their medication on time. And after each medication the SI will provide positive audio-visual feedback if it's the correct technique used or not. SI will also be combined with external devices that assess inhaler-use techniques by providing audio prompts based on the patient's inhalation flow pattern

The sensor can also track overuse of rescue inhalers, which is sometimes overlooked, Engelhard says: A patient using a rescue inhaler, say, five times during a run when they've previously only used it a couple times, for instance, can signal an underlying issue. "There could be something wrong. Your airways are getting inflamed narrowed, and we make it more transparent to you," he says.

We believe it is critical to guide patient's choices in directions that will improve their medication adherence and make their lives better.

2.2 User Community

The Smart Inhaler Device is targeting all those Asthma Patients around the Globe. According to Verified Market Research, the Global COPD and Asthma Drug Devices Market was valued at USD 32.03 Billion in 2018 and is projected to reach USD 43.99 Billion by 2026, growing at a CAGR of 4.3% from 2019 to 2026.
So, this is a very serious problem and challenging problem to solve.

2.3 Administration Functions

Every feature will be available to the patients using their Mobile Phone App. The App will be password protected for sake of protecting the Users Health Data. Users will be able to change their preferences related to SMS/ Alarms, time period of their medication, their Inhalation rate, and their overall condition. All the data collected from device will be analysed and the suggestion will be shown in the device if the condition worsen.

2.4 Error Handling

The SI device will send a notification and prompt the user via display that there is an error in the device. Additionally, we will add some alarms or LEDS indicating that maintenance is required for the device. In this way, Users will have an idea that they need the repairment of their device.

2.5 Security

The app will be password protected for sake of preserving and avoiding the manipulation of data by any other persons.

2.6 Help

After installing the mobile app for the SI device, the prompt window will open which will describe the working mechanism for the device.

2.7 Printing

Manual will be delivered along with the product.

2.8 Interfaces

2.8.1 User

Any normal user with no basic knowledge will also be able to download the app and connect their Smart Inhaler Device.

2.8.2 Software

Software is yet to be designed, but our team have pretty much the idea of how the app should be and all the features to be included. After the product is launched, we may even provide update to the app. The app offers several features: a diary that tracks potential triggers, peak flow, and symptoms; notifications for upcoming or missed doses; a percentage of prescription adherence; and a “badge” system for users, which rewards them for certain “good” behaviours.

2.8.3 Hardware

All the hardware parts chosen will be assembled into a final product, so users won't have to assemble anything. However, if any parts are damaged then ESP 32 micro-controller will be able to send out notification to the user's phone and they will be able to order the individual parts for the device. Our team is working on building the sensor for continuous data storage, along with blinking LED reminders, while allowing for long battery life. The sensor's onboard memory holds about 400 data points and lasts six to 12 months. So, the app grabs data from the sensor and sends it to the cloud, even if the app isn't opened and even if the phone device is off.

2.8.4 Mechanical

The SI will be equipped with sensors and onboard memory that fits over the canister of most metered-dose inhalers. When a user presses down to deliver a dose, the onboard memory stores that data. Then, when the user is near a mobile device, the cap automatically connects and syncs to the cloud and to the product's app. Lights around the cap also illuminate when it's time for a dose.

2.9 Boundary Conditions

The SI will run on LiPo batteries a battery power supply (3.3 & 5V taps). We have not really tested if this will perfectly work at any temperature in the world. We assume that the battery life will last for at least a year.

Since our product consider all the Asthma patients around the world, it may be necessary for the patients to calibrate the digital pressure sensors in the device before using.

The location tracer sensors, pressure sensors may not be able to connect to the user's phone in case the signal ain't transmitting from the SI, then the users will lose all the smart features and they won't be reminded of their medication through our automated messages or from alarms.

2.10 Constraints

No constraints to consider at this moment.

2.11 Platforms

Mobile app will be required to get all the Smart Features from the device.

2.12 Internationalization

The Smart Inhaler device target all those humans suffering from Asthma. So, our product is made to be internationalized.

2.13 Performance

Before designing the product, we assume to consider the following parts:

2.13.1 LiPo batteries a battery power supply (3.3 & 5V

2.13.2 ESP 32 Micro-controller

2.14 Portability

The size of our SI will be like a regular inhaler device. However, the SI device will be compact with smart features. Patients will have no problem keeping it in their pocket.

2.15 Expandability

No plan for expandability.

2.16 Customization

Not working on it in the project.

2.17 Support & Maintenance

There are no specific support and maintenance. If we made the product, then we will be including all the replaceable parts used in the design of SI.

2.18 Configuration Management

It doesn't relate to our project.

2.19 Documentation

No idea.

3 Approvals

The signatures of the people below indicate an understanding in the purpose and content of this document by those signing it. By signing this document you indicate that you approve of the proposed project outlined in this Functional Specification and that the next steps may be taken to proceed with the project.

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