

**PROJECT STATEMENT OF WORK**  
**SMART INHALER**

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## **1. EXECUTIVE SUMMARY**

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 applications. 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 NO<sub>x</sub> 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 NO<sub>x</sub> 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”.

## **2. BUSINESS NEED**

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 uses the device. 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.

## **3. PRODUCT SCOPE 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 inoperatable. This ensures that consumers don't have to buy a new device when something goes wrong.

#### 4. PROJECT SCOPE DESCRIPTION


Project Schedule			
Task	Duration, Days	Start	End
<b>Thunder Board Capabilities and Functionality</b>	30	11/1/21	12/10/21
Integration of Digital Sensors	33	12/13/21	1/27/22
<b>Integration of User Interface</b>	23	1/31/22	3/2/22
<b>Prototype Design</b>	32	1/31/22	<b>3/16/22</b>
Testing	61	1/10/22	4/5/22

#### 5. SPONSOR SUPPORT ELEMENTS

Sponsor Support Elements		
Element	First Needed	Needed Until
Sponsor's Technical Advisor, at least 1 hr/wk	9/20/21	4/29/22
Sponsor's Internal Research Reports on Smart Inhaler	9/20/21	10/31/21
Funding to order Sensors and PCB	12/13/21	4/5/22
Access to 3D printing	1/31/22	3/16/22
Assistance with Testing the Prototype	1/31/22	3/16/22

#### 6. 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 Statement of Work and that the next steps may be taken to create a Requirements Document and 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