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SmartInhaler: A Platform for Measurement of Inhaler Usage in Asthma Patients

by

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Abstract

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Asthma is a widespread chronic pulmonary disease. Poor management of Asthma results in over 450,000 hospitalizations each year, the majority of which are preventable by strict adherence to asthma control medication. In this thesis, we propose, design and benchmark SmartInhaler, a system which performs automated and unobtrusive measurement of inhaler usage behavior and tracking of outdoor air quality parameters.

SmartInhaler consists of an attachment to Metered Dose Inhalers (MDI) developed as a configurable platform with an aim to measure patient adherence to asthma control medication. The attachment is designed to track the parameters associated with asthma medication dosage: number of dosages, time stamp of dosage, location of use and verify the patient taking the medication. Furthermore, based on the location of use, SmartInhaler can also track outdoor air quality parameters (concentration of pollutants) using readily available online pollution data. Tracking air quality is useful for the asthma patients since their lung airways can be sensitive to air pollutants.

The SmartInhaler attachment communicates with smart phones or tablets through a custom Android application developed for delay-tolerant data collection for both adherence and air quality. In this thesis, we also
demonstrate a proof of concept training module for correcting MDI dosage administration technique through air-flow modeling.
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Asthma is a chronic inflammatory lung disease which causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. The lung airways of asthmatics are more constricted than normal healthy individuals and become inflamed when exposed to allergens or pollutants in the air. The inflammation in the lungs result in the patients not being able to breathe. Figure 1.1 shows the difference in lung airways for a normal healthy individual, an asthmatic and an asthmatic when exposed to allergens (during the onset of an asthma attack). Asthma exacerbation (asthma attacks) generally occur due to exposure to pollutants, particulate matter, ozone and allergens in the air that react with lung airways and cause swelling. According to Centers for Disease Control and Prevention (CDC), about 26 million people in the U.S. suffer from asthma out of which 7.1 million are children below the age of 18 years [1]. The costs incurred due to it is $56 billion per year and the mortality rate due to this disease is increasing every year [2, 3, 4].

There is no cure for asthma yet. The current treatment options for managing Asthma include two types of medication viz. controller medication and quick relief (rescue) medication. Both the medication are generally available in the form of an aerosol and administered using Metered Dose Inhalers (MDI) fitted with a spacer
Figure 1.1: Figure shows the difference in lung airways for a normal individual, an asthmatic and an asthmatic during an asthma exacerbation.

as shown in the Figure 1.2. A MDI dispenses a fixed amount of medication every time the inhaler is pressed. A spacer is a breathing chamber used with an MDI that increases the ease and efficiency in administering medication through MDI. Although the spacer is required to be used by both children and adults, due to its size being larger than the MDI, patients find it inconvenient to carry it around. Thus, doctors have made the use of spacer mandatory for children below the age of 18 and highly recommend it for adults.

The regular use of controller medication ensures that the lung airways are less likely to react to potential triggers. The quick-relief (rescue) medication is taken only during an asthma exacerbation for temporary relief and is not a preventive medication. The rescue medication is to be used rarely, only during an emergency situation, since the effect of these strong steroids last only for a few hours. Over-use of the rescue inhalers can in the long-run decrease the patient’s natural capacity to fight against triggers. Also, rescue medication is most effective when the patient is compli-
ant with controller medication. Thus, patients can prevent an asthma exacerbation by regularly taking daily long-term controller medicines and avoiding exposure to asthma triggers by monitoring air quality [5, 6]. However, the rising expenditure for this disease, increasing number of ER visits, hospital admissions and rising mortality rate suggest that this disease is still poorly controlled, mainly because most patients are not adherent, with their long-term controller medication [7, 5] and rely excessively on their rescue medication.

![Image of a Metered dose inhaler and a spacer](image)

Figure 1.2: Figure shows a Metered dose inhaler and a spacer to be used for administering medication to patients.

### 1.1 Non-Adherence in Asthma

The adherence level for Asthma controller medication reported by a number of studies carried out using electronic MDI-usage trackers for adult and pediatric patients was less than 50% [8, 9, 10, 11]. The most common current methods of measuring adherence relies on patient reported MDI usage information which are generally very inaccurate and cumbersome to maintain. A study carried out to compare patient...
reported MDI usage with an automatic electronic time-stamped MDI usage log revealed a large discrepancy between the two logs [12]. In short, manual diary logs maintained by the patients are highly unreliable. The study also suggests that on many occasions, the patients dispense the medication elsewhere instead of inhaling it, especially just before a visit to the physician in order to maintain a perfect-looking MDI record. Such cases of medication dumping result in misdiagnosis of the patient’s condition since the physician cannot identify non-adherence as the cause of deteriorating asthma condition.

Poor control of asthma can also occur with patients who take their controller medication regularly but their medication delivery technique is incorrect, resulting in majority of the medication getting deposited in the mouth rather than reaching the lungs. One study found that 40% of compliant patients perform incorrect MDI usage technique, which results in their medication being ineffective to control their condition [13]. Such cases of incorrect inhaler maneuvers need to be identified so that the patients can be trained by their physicians for performing proper technique during MDI usage.

Lastly, since change in asthma condition is highly associated with the concentration of pollutants in the air, tracking related variables such as outdoor air quality over time may help prevent potential asthma exacerbation [14, 6, 15]. Currently, asthma patients do not regularly track air quality and are, therefore, not well-informed or prepared for possible asthma exacerbation in the near future.

In summary, an accurate adherence measurement system could provide much needed data for improved care of asthmatic patients. The adherence measurement should ideally log the amount of medication taken, the time stamp of the dosage, who took the medication and air quality in and around the location of the patient.
1.2 SmartInhaler System

In this thesis, we study the design, development and preliminary benchmarking of an inhaler attachment to measure patient adherence. The overall system is labeled SmartInhaler and consists of a stand-alone electronic attachment for MDI, designed to reliably measure MDI usage behavior for asthma patients. SmartInhaler measures the amount and time stamp of the dosage along with who actually took the medication for verification purposes and the accurateness of the dosage maneuver to address the key challenges in adherence.

The attachment accurately records the time stamp of inhaler usage to maintain an automatic and accurate MDI usage diary. In order to identify medication dumping by the patients, a camera system is available on the attachment which captures a picture of the scene in front of the inhaler, verifying medication delivery to the patient. SmartInhaler connects to smart phones or tablets through Bluetooth for synchronizing the collected data and passively maintaining an accurate electronic diary for MDI usage. SmartInhaler collects data for the personalized location-based air quality information using WiFi Positioning System (WPS) for determining location of use and a public website [16] for collecting air quality information. The system enables patients to quantitatively understand current and predicted air quality indices in the geographical regions of the user.

The inhaler usage data and location of usage for air quality information is imported to a smart phone/tablet using a custom Android application and stored for sharing with caregivers and physicians. By ensuring that the system is unobtrusive and automatic, SmartInhaler system can be used during medication delivery without having to learn any new maneuvers. The system is low power, the current prototype has a battery life of 2.96 years. SmartInhaler directly communicates to a smart phone or tablet via Bluetooth. For the first prototype, an Android device is used as
a proof of concept. A full Android application was developed, to collect all forms of data (medication adherence, location and public air quality data from the government website [16]) in one application, opening the door to personalized analytics on the spatio-temporal user data.

Currently, a training module is also being developed for the SmartInhaler that can be used to identify errors in MDI usage technique and provide real-time feedback for correcting erroneous maneuvers.

Chapter 2 of the thesis describes the challenges encountered in tackling non adherence in patients and their proposed solution using the SmartInhaler system. In Chapter 3 we explain the features of SmartInhaler and the design criteria set for the developed prototype. Chapter 4 provides an overview of the system architecture for the design of SmartInhaler, including hardware and software design, features and implementation.

Chapter 5 provides the results for the experiments carried out to test the features of SmartInhaler. The current and battery consumption are covered in the chapter along with results of two small-scale studies, conducted at Rice University, to demonstrate the accuracy of key features of a working prototype of the SmartInhaler system. The results from a user trial demonstrated 100% accuracy of the sensor used in the SmartInhaler attachment in detecting actuations and the WPS tested at 88 locations in Houston could correctly identify 85 out of 88 locations within a 200m radius giving the accuracy of 96.59%. The results of a feasibility study carried out with 20 asthma patients to gauge their interest in using SmartInhaler is also reported. 95% of the patients feel that SmartInhaler will help them take medication more consistently. Finally in Chapter 6, further innovations for the inhaler attachment are discussed. The ultrasonic sensor based architecture of a new flow-meter attachment for the spacer is discussed. The ultrasonic attachment can be used as a potential training device for
the patients. Results for a preliminary experiment carried out to identify erroneous inhaler maneuvers are also discussed. Chapter 7 provides the future direction and conclusion to the project.
Challenges for Non Adherence and Proposed Solutions using SmartInhaler

The most common reasons cited for non-adherence among patients are forgetfulness, lack of faith in the effectiveness of medication and difficulty or inconvenience in using an inhaler[17, 5, 18]. Figure 2.1 shows the reasons cited by adolescent patients after being interviewed to provide the major reasons towards non-adherence to asthma control medication [17].

A number of small scale studies [19, 20, 21, 22, 12, 23] have been conducted to address one or a subset of the reasons given in Figure 2.1 through monitoring patient adherence to medication and education about asthma. Monitoring medication usage requires keeping a log of the time, date and number of dosages taken by the patients and sharing them with caregivers while education about asthma is provided through intervention groups and telephonic calls. For monitoring medication usage, most of the studies rely on hand written logs which are obtrusive and prone to manipulation. In some cases, the estimation of MDI usage is obtained through automated pharmaceutical claims data and electronic monitors [23, 12] but these methods are unreliable since there is no way of knowing whether the patients actually inhaled the medication.
or dumped it elsewhere. Hence, although the studies have shown improved adherence and, in some cases, better asthma control, they are ineffective for large scale and permanent improvement in adherence due to obtrusive data acquisition systems [5], lack of verification of both medication inhalation and proper inhaler usage technique, and lack of preventive methods for asthma exacerbation by reducing exposure to pollution.

In order to avoid the above sources of error in adherence measurement, the most effective way to collect accurate inhaler usage data is automatic, passive and verified electronic monitoring of inhaler usage in patients [5, 24, 12, 25, 26]. In the next few sections, three major challenges associated with non-adherence to control medication have been identified based on the above discussion and a solution to the challenges using SmartInhaler system is proposed.
2.1 Challenge I: Voluntary Non-Adherence to Medication

The first challenge is voluntary non-adherence to asthma control medication. Voluntary non-adherence is termed for those patients who deliberately avoid taking control medication. From Figure 2.1, we can observe that the reasons such as embarrassment about having asthma, laziness, fear of side effects, denial about having asthma and inconvenience may be classified as reasons for voluntary non-adherence towards asthma control medication. Patients also tend to fabricate adherence data in order to have a clean record for their physicians to look at and in turn place their asthma condition at high risk. Thus, the patient maintained manual diary log of MDI dosage becomes highly unreliable and inaccurate. In addition, there does not exist any mechanism of finding out whether the medication was dumped outside or actually inhaled by the patients.

Proposed Solution

In order to solve the challenge of voluntary non-adherence, SmartInhaler was developed with a reliable and automated electronic medication time-stamp logging system. SmartInhaler also takes a picture of the scenario in front of the MDI whenever a dosage has been taken to keep track of where the medication is dispensed. The electronic logs can be shared directly with the physician ensuring that the physician has complete information about the patient’s condition and adherence to control medication. Figure 2.2 shows the SmartInhaler device attached with a an inhaler and a spacer.

The on-board camera may also have an effect on the patient’s behavior. A number of studies have shown that even displaying an image of a pair of eyes can cause people
to behave more cooperatively because the image of eyes may induce the notion of being watched by a third party [27, 28, 29]. The studies claim that the incentives in the form of punishment avoidance and maintaining good reputation through compliance are only obtained where someone else comes to know about one’s behavior. Asthma patients are aware that a strong compliance with control medication results in a direct positive impact on her own health. However, the patient’s reputation in terms of compliance in front of her physician has a higher perceived importance to the patient than her health condition. The above effect of observation on reputation has been shown in an experiment conducted [12] where the time stamp of the patient’s medication intake was being recorded without the patient’s knowledge. The results
showed that the majority of the patients had very poor compliance throughout the month but dumped their medication on the day before their visit to the doctor. Thus, the patient is more concerned about the reputation in front of a third party, the doctor. Using the SmartInhaler device for measuring MDI usage, the physician or guardian of the patient will not only have access to the accurate inhaler usage information but also a picture verifying the inhaler usage. The camera will essentially act as a pair of eyes observing the patient that may increase patient compliance with medication.

2.2 Challenge II: Involuntary Non-Adherence to Medication

The second major challenge is involuntary non-adherence to asthma control medication which addresses the problem of forgetfulness, ineffective medication and difficulty using inhaler as mentioned in Figure 2.1. Patients in this category understand the importance of regularly taking control medication but are unable to effectively do so. In order for the daily MDI usage to become a habit, the patient should get a cue that actively or passively reminds her to take the medication [30]. The cue for general habit formation techniques is a result or the effect of successfully completing the task, in this case a cue may be obtained from taking the daily dosage. However, improvement in lung function due to regular usage of the control medication is very difficult to obtain since the primary objective of the medication is to control the condition and not cure it. Thus, there are no cues to be obtained from just taking the medication which leads to forgetfulness in patients to use the control medication.

Involuntary non-adherence also arises due to the fact the maneuver of taking an MDI dosage is fairly complicated and difficult to perform correctly. Incorrect maneuvers are very common, over 40% of compliant patients perform erroneous techniques
which arise due to the coordination required between pressing the MDI and inhaling the medicine. Thus the medication becomes ineffective even for patients who are compliant with inhaler usage. Physicians provide regular training for the patients who have been identified as having very poor technique of medication delivery. However, there does not exist a method to automatically detect erroneous maneuvers, provide real-time feedback and record the maneuvers to be shared with physicians for further training.

Proposed Solution

SmartInhaler is designed as an automated system such that there are no new maneuvers to learn for taking, logging and maintaining medication adherence data. The method of taking medication with the SmartInhaler is convenient due to its small form factor. The SmartInhaler has in-built timers for reminder systems which can potentially solve the problem of forgetfulness in taking medication and encourages regularity. The reminder acts as an external cue for the patient to take an MDI dosage. SmartInhaler automatically updates the data to a software application running on the mobile device whenever in the vicinity. This form of maintaining an unobtrusive electronic diary requiring minimal input from the patients increases the chance of permanent adherence.

In order to solve the problem of poor technique in medication administration, a training module is being developed for the SmartInhaler based on measurement of the flow of air or medication inside the spacer. Whenever medication is dispensed there is a steep rise in flow inside the spacer tubing due to the forced release of the aerosolized medication. Then, as soon as the patient starts inhaling the medication, it causes another change in the flow of air inside the spacer. By measuring the air flow, the timing of actuation and inhalation as well as the magnitude of flow rate (or
inhalation rate) one can identify erroneous maneuvers in real time. The flow meter uses ultrasonic sensors and transmitters. The developed prototype is being improved such that the maneuver can also be video recorded using the camera on board and the data pertaining to the flow and maneuver video can be shared with the doctor for further analysis. Proper training and identification of erroneous maneuvers can help in increasing the effectiveness of medication by improving medication delivery. The training module along with the reminder system solves the second challenge on involuntary non-adherence.

2.3 Challenge III : Lack of Preventive Measures

The main risk factors associated with asthma exacerbation are inhaler usage and location based Air Quality Index (AQI) for identification of pollutants responsible for triggering asthma exacerbation. A number of studies have determined strong correlations between the occurrences of exacerbation and outdoor air quality information such as the concentration of ozone, PM2.5 and PM10 [15, 14]. These air pollutants may irritate the lung airways of asthmatics. However, the body has a buffer mechanism such that the irritation may manifest after a time delay of a few hours to 3 days. Hence, tracking the concentration of these pollutants over time can help in preparing for a possible onset of exacerbation and reduce its severity through administration of appropriate rescue medication. AQI is tracked at various locations in the US based on the area zip-code by environmental government agencies [31] and are available to the public on a website known as AIRNow [16]. However, tracking the variables manually poses an additional overhead to the patient and is never practically implemented. These variables are, therefore, not monitored regularly by the patient and places the patient’s condition at higher risk.
Proposed Solution

The SmartInhaler system monitors location based AQI values for the patient and maintains a record on the smart phone application. The SmartInhaler attachment can record the location of inhaler use. An indoor location tracking system in the stand alone SmartInhaler system is implemented using WiFi Positioning System (WPS) through geolocation APIs. Indoor tracking is useful since long-term control MDIs are generally used in an indoor environment where GPS may not be very efficient. WPS can also be used for outdoor location tracking, however, it is limited to areas with sufficient WiFi connectivity available outdoors. The location-based concentration levels for each of the dangerous pollutants and the combined AQI are obtained from the AIRNow website over regular intervals of time and displayed to the patient on the smart phone. The patient can now keep track of air quality in and around her locality without having to manually check the concentrations on a website. The

Figure 2.3: Screenshot of SmartInhaler Android Application.
Android application developed for SmartInhaler wirelessly communicates with the hardware attachment to collect data regarding the time stamp of MDI usage, the picture of the patient and location of use. Figure 2.3 shows screen-shots from the SmartInhaler application.

Future versions of SmartInhaler will utilize the air quality data for predicting onset of future exacerbation based on adherence and AQI which can improve management of this disease [23]. Table 2.1 shows the various features of SmartInhaler and how it compares with alternate electronic monitors.

<table>
<thead>
<tr>
<th>Features</th>
<th>SmartTrackLive</th>
<th>Nexus6Tracker</th>
<th>Asthmapolis</th>
<th>SmartInhaler</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time-stamp</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Reminder System</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Indoor Location</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>✔</td>
</tr>
<tr>
<td>Outdoor Location</td>
<td>×</td>
<td>×</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Air Quality</td>
<td>×</td>
<td>×</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Sync with Smart Phone</td>
<td>×</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Identity Capture</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>✔</td>
</tr>
<tr>
<td>Usage Technique</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>✔</td>
</tr>
<tr>
<td>Storage (number of logs)</td>
<td>1400</td>
<td>3200</td>
<td>no data</td>
<td>1.60 million</td>
</tr>
<tr>
<td>Battery Life</td>
<td>2-4 weeks</td>
<td>1 year, non-rechargeable</td>
<td>30-40 day</td>
<td>2.96 years</td>
</tr>
</tbody>
</table>

Table 2.1: Features of SmartInhaler Platform in comparison with alternate electronic inhaler usage monitors
Chapter 3

Features and Design Requirements of SmartInhaler Platform

The SmartInhaler system is designed to solve the three challenges with measurement of non-adherence to asthma medication as elaborated in Chapter 2, viz., voluntary non-adherence, involuntary non-adherence and lack of preventive measures. It is a well known theory in psychology that habit formation at an early age has a lasting impact in adult life [32]. Therefore, the targeted end user for the SmartInhaler platform are patients under the age of 18 since the higher goal of SmartInhaler system is to induce a permanent improvement in adherence through habit formation.

SmartInhaler has a number of features on the hardware attachment as well as the Android Application that aid in the accurate and reliable measurement of MDI usage behavior and risk factor such as AQI. Since pediatric patients are the target group, smart phones may not be easily available to them at all times of the day (especially in a school environment) and a separate inhaler dosage tracker is necessary. SmartInhaler attachment consists of two parts, a stand-alone hardware attachment for inhalers and a software application for data sharing using smart phones. None of the current electronic MDI usage tracking devices have the capability to take a picture or video for
identification of the patient during administration of dosage, track the indoor location
of usage or perform error checking for the maneuver in real time. The features have
been tabulated in Table 3.1.

<table>
<thead>
<tr>
<th>Features</th>
<th>Voluntary</th>
<th>Involuntary</th>
<th>Lack of Preventive Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>Time and date of dosage</td>
<td>Reminder System</td>
<td>Indoor Location using WPS</td>
</tr>
<tr>
<td></td>
<td>Camera to capture picture or video</td>
<td>Training module using flow measurement and video capture</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>Bluetooth for easy and automatic data transfer</td>
<td>Bluetooth for easy and automatic data transfer</td>
<td>-</td>
</tr>
<tr>
<td>Software</td>
<td>Sharing of picture-verified data with physician</td>
<td>Sharing of picture-verified data with physician</td>
<td>Air Quality Index based on location</td>
</tr>
</tbody>
</table>

Table 3.1: Features of SmartInhaler Platform

The features have been implemented on a hardware platform with an aim that it
can be easily attached onto or detached from a spacer. The data from the hardware
is quickly and easily transferred to a smart phone or tablet for further analysis,
storage, display and sharing with physicians. However, implementation of the above
hardware and software platform must meet certain design criteria such that they can
be seamlessly integrated into the existing maneuver of MDI dosage administration.
The design criteria have been tabulated in Table 3.2.

First and foremost, the hardware attachment must be low power and have a small
form factor. The prototype built for the SmartInhaler hardware attachment is 4in x
1.8in x 1in in dimension and weighs 93g including the 23g rechargeable battery. The
battery is rated 1100mAh and the typical battery life for the prototype is 2.96 years.
<table>
<thead>
<tr>
<th>Hardware</th>
<th>Design Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Power</td>
<td></td>
</tr>
<tr>
<td>Small Form Factor</td>
<td></td>
</tr>
<tr>
<td>On board storage of data</td>
<td></td>
</tr>
<tr>
<td>Passive measurement of</td>
<td></td>
</tr>
<tr>
<td>Inhaler Usage</td>
<td></td>
</tr>
<tr>
<td>Inhaler usage maneuver remains the same</td>
<td></td>
</tr>
<tr>
<td>Software</td>
<td></td>
</tr>
<tr>
<td>Reliable data transfer from</td>
<td></td>
</tr>
<tr>
<td>the platform</td>
<td></td>
</tr>
<tr>
<td>Easy access to data about</td>
<td></td>
</tr>
<tr>
<td>asthma predictors (AQI)</td>
<td></td>
</tr>
<tr>
<td>Simple user interface that</td>
<td></td>
</tr>
<tr>
<td>is easy to use</td>
<td></td>
</tr>
<tr>
<td>Data sharing with</td>
<td></td>
</tr>
<tr>
<td>physician</td>
<td></td>
</tr>
</tbody>
</table>

Table 3.2: Design requirements for the development of SmartInhaler system.

Therefore, the battery can be replaced with one that has a lower rating and weight as needed for specific use cases. A possible replacement battery option is one that is rated 150mAh and weighs 3.5g, the battery will then last about six months without having to recharge.

Secondly, there should be a provision to store the data on the hardware itself in case there is no access to a smart phone or tablet. This has been implemented in the SmartInhaler attachment with a micro SD card slot. The patient is, therefore, not limited by the amount of data that can be stored on board since each dosage reading occupies a space of a few KBs and SD cards of sizes upto 64GB are available off-the-shelf.

The next criteria takes into consideration the ease of use of SmartInhaler platform in combination with an inhaler and a spacer. The system should be as passive and
automated as possible. SmartInhaler ensures that there are no new maneuvers to be performed other than pressing the inhaler. The sensor that detects a MDI actuation is an Interlink Force Sensing Resistor (FSR). The FSR sits on top of the inhaler canister and automatically sends a signal to the hardware to take the necessary data parameters associated with the dosage administration (i.e. time, date, picture and location). The FSR sensor is also mechanically very stable and robust, rated for 1 million actuations.

Lastly, the Android application for the SmartInhaler system should be simple, the user interface very easy to use and reliably sync all the data from the hardware platform automatically. The application should also be able to change the settings of the hardware remotely if required. The application developed performs reliable two-way communication through Bluetooth with the hardware platform for the transfer of MDI usage parameters and hardware settings. The application also tracks location based AQI values and displays them on a map. The simplified view of the dosage and AQI information makes it easier for the patient to access all of the data. The data can be shared with the physician from the smart phone or stored in cloud servers for further analysis.

Implementation of all the features of SmartInhaler reliably tracks the patient’s inhaler usage behavior. Since, the SmartInhaler prototype has been built such that all the design criteria are met, the challenges to non-adherence may be solved using the SmartInhaler system. The attachment does not interfere with the dosage delivery in the front of the inhaler, the amount of medication dispensed remains the same and therefore, reaches the benchmarks set for a standard inhaler.
The architecture of SmartInhaler system is designed as a tightly knit interconnection of hardware and software components as shown in Figure 4.1. The hardware segment consists of a stand-alone, portable electronic attachment for the spacer as shown in Figure 2.2. The attachment monitors the parameters associated with inhaler usage and location of use for obtaining air quality predictors. The data stored in the hardware platform are communicated to an Android device via the software platform consisting of the Android application on a smart phone or tablet. The software application wraps a repository of the time varying data from the hardware platform and the location based AQI and shares this information with patients and physicians.

4.1 Hardware Design

The SmartInhaler attachment consists of a programmable, low power hardware board developed at Rice University based on some of the requirements of SmartInhaler. The SmartInhaler attachment also consists of a camera sensor module from Aptina with a fisheye lens (interfaced with the board) and the Interlink FSR 402 for sensing actua-
tion of MDI. The hardware components have been used to build portable spirometers and previous versions of the SmartInhaler [33]. The hardware board has a number components for the measurement and wireless transfer of data. The microprocessor on the board is Texas Instruments MSP430F6726. The SmartInhaler is powered by a rechargeable Li-ion Polymer battery and the attachment can be recharged using a standard micro-USB cable. The Figure 4.2 shows the core hardware board with an image sensor.

The MSP430 microprocessor in the SmartInhaler has a Real Time Clock (RTC) which runs on an external 32kHz crystal. The RTC implements the time stamp and reminder system. The RTC can be updated from the Android device to allow customization of time-zones. The MSP is connected to a WiFi module for obtaining the SSID (Service Set Identification) of nearby WiFi Access Points (APs) for the
determination of location. Bluetooth is available on the hardware board for data transfer to a smart phone or tablet.

The hardware attachment measures the time, date, SSIDs and takes a picture of the scenario in front of the MDI when the inhaler is pressed. The following subsections elaborate on the features and the implementation of the FSR, interfacing of the various board components and a camera module. The hardware features enable the above functions to be performed such that the design criteria mentioned in Chapter 3 are met.

4.1.1 Determination of Actuation using FSR

The SmartInhaler attachment contains a Force Sensing Resistor (FSR) which detects dosage dispensed by the inhaler. It is a polymer thick film sensor and its resistance decreases non-linearly with an increase in the force applied to its surface. The minimum actuation force required is 0.1N and its sensitivity range is 20N. It is small with a diameter of 5mm, very robust and supports up to 1 million actuations. When the inhaler is pressed, the force applied causes a decrease in the resistance of the FSR. The FSR is connected to the 24-bit Sigma Delta (SD24) converter and the power pin present in the microprocessor. The SD24 converts the resistance of the FSR to
a digital value. A threshold operation on the digital value takes place, with respect to the force applied for the actuation, to differentiate it from a random press. The simple process of pressing the FSR during actuation ensures that the patient doesn’t have to learn any new maneuvers to use SmartInhaler with their inhaler. The Figure 4.3 shows an FSR and its characteristics.

![FSR Image](image.png)

Figure 4.3: The figure shows an FSR in comparison to a quarter and its characteristics of change in resistance(kΩ) with force(g) applied.

4.1.2 Scene capture using on-board Camera

To enable verification of patient inhaling the medication versus medication dumping, a small camera is connected to the hardware board to capture the scene in front of the inhaler when it is pressed. As the hardware board is based on a low-power microprocessor that lacks processing power needed to support high bandwidth imaging, a dedicated hardware exists separately on the board for the camera that interfaces to the microprocessor. The image sensor MT9D131 outputs jpeg compressed images. This approach is different from the conventional methods where the image sensor sends raw images to be compressed later by a processor.
As there is no local storage on the image sensor and board, the jpeg images need to be saved to an external storage in real time. To achieve this, an SD host control chipset SDIO101 on the board is utilized. In conventional hardware, this chipset talks directly to a high speed processor but due the difference in the data bus requirements of the image sensor and SD control, a CPLD (Complex Programmable Logic Device) on the board by Altera is employed instead. It is a low-power programmable fabric that translates the 8 bit bus of the image sensor to the 16 bit bus of the SD control. It also acts as a Direct Memory Access (DMA) control between the two. Upon receiving a trigger from the microprocessor, the camera hardware takes a snapshot and saves it in the micro-SD card without interrupting the microprocessor in the process.

The architecture offers minimum control overhead for the host microprocessor. Thus, the images can be captured while the microprocessor is busy recording other medical input, i.e., the SmartInhaler can take a picture while the patient is performing a maneuver and the microprocessor is recording the time stamp and location of use. The images saved on the micro-SD card can later be synced to a smart-phone/tablet device via Bluetooth. The process of taking a picture takes an average of 1.04s.

4.1.3 Determination of Location using WPS

The hardware board in the SmartInhaler attachment has a CC3000 WiFi chip on board which can be used to establish indoor location through WiFi Positioning System (WPS). The WiFi chip talks to the MSP through Serial Peripheral Interface (SPI). The WiFi chip scans the local access points and records their SSIDs. The hardware platform uploads the SSIDs corresponding to the location of use to the software application which uses Google Geolocation APIs to determine accurate indoor location using the SSIDs sent. A minimum of two SSIDs are required by the geolocation API to obtain the indoor location. The WiFi module takes an average of
1.66s to scan and record two SSIDs in the SD card. In case, the module is not able to find at least two SSIDs, it keeps scanning until either 30s are up or it finds two SSIDs. The board then switches off to save power.

Location tracking can also be performed using GPS systems as implemented in Asthmapolis monitoring system (not yet commercially available) [34]. GPS based location determination is very accurate in an outdoor environment. However, in most of the cases, the control medication is taken in indoor environments at regular, fairly predictable, intervals of time daily. GPS also requires a longer time to lock on the location if it is not kept continuously running but switched on only during every inhaler use. This presents a trade-off between power consumption and coverage. GPS chips are generally slower and more power hungry than their WiFi counterparts for geolocation application in urban areas. Another method of location estimation is the use cell towers for tracking location using GSM. GSM tracking is consumes lower power than GPS for locking on a location but it may not be as accurate as GPS. WPS can also be used for outdoor location tracking although it is limited to areas with sufficient WiFi connectivity available outdoors. Nevertheless, if the user travels to areas with limited or no WiFi coverage, then alternate methods of location determination are essential.

4.1.4 Data Transfer

The size of the data packet associated with one actuation, i.e. time, data, two SSIDs and a camera picture is on average 40KB. If a micro SD card with a size of 64GB is used, approximately 1.6 million readings can be stored. However, storing all the data on-board is not advised as accurate predictions of asthma control can be possible only through frequent updates of data points.

The data is transferred using Bluetooth communication which is reliable and rea-
sonably low power. As shown in Table 5.1, it consumes 60.0mA on average to send the data packet for one reading which takes 1.8s (in addition to the connection time of 5-10s).

4.1.5 Modes of operation

The FSR sensor acts as a switch for the hardware board. As soon as the FSR is pressed beyond a fixed threshold, i.e. when the resistance of the FSR reduces from 10MΩ to the first threshold of 1kΩ and powers the MSP430 into active mode. In order to validate the actuation from a random press, the SD24 polls the resistance value for a short period of time. In the case of an actual inhaler actuation, the resistance reduces further below a second threshold and starts the process of recording the parameters time, date, SSID and picture. This data is stored on the micro SD card available on board. The RTC on the MSP430 can be powered with an auxiliary source such that the MSP can be switched off to save power after the actuation, without disturbing the RTC. The RTC consumes only 15µA of current and therefore gives SmartInhaler an impressive minimum battery life of 2.96 years (with a 1100mAhr Li-ion Polymer battery).

The LCD screen and an LED on the hardware board act as a feedback system to let the user know about the different modes of operation. During actuation of the inhaler, the LCD displays a message, “Dosage Taken,” reports the time and date recorded along with the percentage of battery charge remaining. The on-board LED indicates the operation of the camera. Thus when the inhaler is pressed, the camera takes a picture and the LED turns on as an indication. The LED turns off after the camera finishes writing the picture on the SD card, i.e. after 1.6s. When the Bluetooth mode is switched on by pressing a push button on the SmartInhaler attachment, the LCD displays “Bluetooth Mode” and the percentage of battery charge left. The LCD
is interfaced with the MSP430 using SPI. The LED also indicates the data transfer by blinking until all the data has been synced. This way the patient gets a feedback about the data transfer operation.

Thus the SmartInhaler hardware performs all the features meeting the design criteria as given in Table 3.2.

4.2 Software Design

The SmartInhaler attachment talks to a smart phone or tablet in order to transfer data, analyze it further and share the records with the patient and physician. The Titanium cross-platform mobile application development environment from Appcelerator is used for implementing the above features on a smart phone or a tablet [35]. The software application has been currently built for use on an Android device but can be easily expanded to other platforms since the Titanium is cross-platform and the only native module used is a Bluetooth module for Android. Titanium utilizes Javascript API making the implementation very straightforward. The application has a layered architecture as shown in Figure 4.1.

4.2.1 Software Architecture

The first layer of the architecture is the hardware interface API layer which implements low-level drivers to communicate with the SmartInhaler attachment. The raw data for inhalation maneuvers received in this layer through Bluetooth communication undergo post processing in this layer. The Android application can also control the settings of the SmartInhaler hardware (e.g. set the time) by sending the necessary data back to the hardware. Thus a two-way communication is established.

The next layer aggregates the data and performs further analysis. The post pro-
cessing involves determining the location using Google geolocation APIs with the received SSIDs and Air Quality Index (AQI) information from websites [16]. The AQI is based on zip code of the area of interest. The geolocation API provides the location information in the form of latitude and longitude coordinates and is converted into zip code using available web-services. The data obtained from all the web services and APIs are in JSON format. The application parses the JSON data and stores it as inhaler usage logs with corresponding AQI for the locations of use.

The third layer displays the logs as a serial entry with each log consisting of the inhaler usage data. The logs can also be viewed as points on a map that show the distribution of locations of use. A touch-tap on the points on the screen show the corresponding AQI values for the day. In future versions, the data will be analyzed to view trends in inhaler usage and AQI values over time and location. Figure 4.4 shows screen-shots of the data visualization layer showing the logs and map views.

Figure 4.4: The figure shows the data visualization on the app. After the logs are synced, the user can view them by selecting the respective option on the application.
**Location-Based Air Quality Index** There are air quality monitors at more than a thousand locations across the U.S. recording concentrations of the major pollutants. The U.S. Environmental Protection Agency converts these raw measurements into Air Quality Index (AQI) values ranging from 0 to 500 (where the larger value corresponds to an increased level of pollution). They provide separate AQI values for each pollutant (ground-level ozone, particle pollution, carbon monoxide, and sulfur dioxide). The highest of these AQI values is reported as the AQI value for that day. When the location based AQI is requested by the user from the SmartInhaler application, the data aggregation layer of SmartInhaler API extracts the AQI information from the Environmental Protection Agency website [16]. The data consisting of AQI for each pollutant and overall index is displayed to the user.

### 4.3 Case Design for Prototype

The hardware components consisting of the hardware board, FSR, camera module and battery pack are housed in a 3D printed plastic case for prototyping purposes. The 3D CAD and rendering for the case was developed using AutoDesk Inventor. The design was printed using an Afinia H-series 3D printer which performs Fused deposition modeling using ABS filament (thermoplastic) for printing the model. The resolution of the printer is 0.15mm and is used for the prototype built. Figure 4.5 shows various views of the 3D rendered case design for the SmartInhaler attachment.
Figure 4.5: The figure shows the 3D rendering of the different parts of the plastic casing for the hardware components of SmartInhaler attachment.
The SmartInhaler attachment has been designed using a low power hardware board to ensure a very small battery charge consumption. The current consumed for each of the operations, keeping the RTC running, taking a picture and writing to SD card, performing a scan for SSIDs of APs and connecting as well as transferring one data reading through Bluetooth to the smart phone are shown in the Table 5.1.

<table>
<thead>
<tr>
<th>Mode of operation</th>
<th>Average current consumed (mA)</th>
<th>Maximum charge consumed in one day (mAh)</th>
<th>Minimum charge consumed in one day (mAh)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RTC, CPU off</td>
<td>0.015</td>
<td>0.3598</td>
<td>0.3600</td>
</tr>
<tr>
<td>SD card</td>
<td>69.1</td>
<td>0.0051</td>
<td>0.0051</td>
</tr>
<tr>
<td>Camera</td>
<td>162.4</td>
<td>0.0938</td>
<td>0.0938</td>
</tr>
<tr>
<td>WiFi scan</td>
<td>133.6</td>
<td>2.3499</td>
<td>0.1232</td>
</tr>
<tr>
<td>Bluetooth</td>
<td>60.0</td>
<td>0.3933</td>
<td>0.1933</td>
</tr>
</tbody>
</table>

Table 5.1: Current and charge consumption by SmartInhaler platform. The difference in the two columns for charge consumption occurs due to how long WiFi takes to find two SSIDs (1.66s to 31.66s) and Bluetooth takes to connect with the smart phone (5s-10s).
The asthma control medication is generally taken twice everyday. Thus, the minimum and maximum charge consumed during a typical 24-hour operation of the MDI (two dosages and corresponding two Bluetooth transfers) is reported in the table. The difference in the charge consumption occurs due to the time taken by WiFi in finding two SSIDs (1.66 - 31.66s) and connection time through Bluetooth to a smartphone (5-10s).

The battery pack being used currently is a 1100mAh Li-ion Polymer battery. The self discharge rate of the battery is at most 15% per year. The self discharge contributes to a significant amount of the battery charge loss and is comparable to the typical per year battery discharge due to the user operation, which is 27%. Based on the discharge due to user operation and self discharge, the battery will typically last 2.96 years, which may reduce to a minimum of 10.6 months in case of poor WiFi and Bluetooth connectivity. Thus, a replacement battery pack with a much smaller rating and weight can be utilized in future versions. Based on the twice-a-day dosage regimen, the current and charge consumption characteristics for a typical 24-hour period are given in Figure 5.2(a) and (b). The worst case usage refers to the case when for every actuation, the WiFi takes 31.66s to find the SSIDs and the SmartInhaler takes 10s to connect with the Android device via Bluetooth.

The camera and WiFi consume the highest amount of current among all the modes of operation as shown in Table 5.1. However, the camera operates only for 1.04s per dosage as compared to 1.66-31.66s of WiFi. Hence, the total battery discharge due to WiFi is much greater than camera. We test and verify the contribution of the two features WiFi and camera on battery discharge by disabling the features alternately during the operation of SmartInhaler and analyzing the charge consumed. Figure 5.2(c) shows the simulated discharge characteristics of the typical and worst case usage of the SmartInhaler with a 1100mAh battery for the three experimentation
cases, i.e., all the features enabled, camera disabled and WiFi disabled. The graph shows that for two of the cases, worst-case usage with all features and worst-case usage without camera, the battery discharge is at a much higher rate and goes to zero before one year. But the worst-case usage with WiFi disabled, is almost the same as the typical usage curves with or without WiFi. Therefore, the biggest determinant of battery life is the time taken by WiFi to scan and obtain two SSIDs.

In the next two sections, we discuss the small-scale studies carried out to test the accuracy of key features of SmartInhaler. First, to test the SmartInhaler hardware, a user trial was carried out to evaluate the actuation and time-stamp feature. Second, the geolocation feature of SmartInhaler system was tested at 88 indoor locations in Houston. Both trials demonstrated high accuracy, the SmartInhaler attachment was able to detect the actuations with 100% accuracy and the geolocation APIs showed 96.59% accuracy (upto 200m).

The last section reports the results of a feasibility survey carried out with 20 asthma patients. The survey gauges patient’s reaction to having SmartInhaler for the measurement of their adherence to asthma control medication. According to the survey results, 19 of the 20 patients reported that SmartInhaler would help them take their medication more regularly.

5.1 Accuracy of actuation : User Trial

For the purpose of testing the accuracy of the actuation mechanism of the SmartInhaler hardware, a user trial was conducted with 17 healthy students (14 male and 3 female) from Rice university, aged 18-34. This enabled persons in different age groups and genders with varied physical strengths to operate the SmartInhaler. They were asked to operate three different types of MDIs having varying length, canister diameter, weight and required force applied for actuation. To ensure the safety of
the individuals, two of the inhalers used were empty, hence, did not contain any medication and the third was a placebo to provide a closer emulation of using an actual inhaler. The participants pressed the inhaler while the SmartInhaler attachment recorded the actuation through the FSR. The readings were transferred to an Android tablet and analyzed to check how many actuations were correctly recognized along with their time-stamp and updated to the application.

5.1.1 Actuation Results and Discussion

The SmartInhaler was able to detect 100% of the total 250 actuations by all the users. The distribution of usage for the three inhalers is shown in Figure 5.1.

![Figure 5.1](https://via.placeholder.com/150)

Figure 5.1: Results of the user-trial shows the actuations performed on each of the three inhalers [36] and the detected actuations. There were a total of 250 actuations performed with 100% accuracy.

The data logged in the application with the time stamp matched correctly with the actual usage. Thus, the SmartInhaler hardware is reliable and accurate in detecting MDI actuations.

The protocol followed for the testing of the mechanical system required the Smart-
Inhaler to detect a complete actuation which is an important feature and should be completely error free since it is the sole source of adherence data. This is verified for the system built for SmartInhaler.

5.2 Indoor Location through WPS

The testing of the accuracy of the indoor location feature using WPS requires collection of SSIDs of nearby Access Points using the WiFi chip on board and calculating the location with the help of available geolocation APIs. A small scale experiment was carried out in which an android phone that collects the SSIDs and stores them in the phone memory was taken to various locations in Houston. The SSIDs for access points in 88 indoor locations in Houston were collected through this process and the location was determined using Google Geolocation API.

5.2.1 WPS Results and Discussion

The default accuracy provided by Google geolocation API when the exact location has been determined is 150m radius. In the experiment, 82/88 locations were accurately determined with 150m accuracy. Out of the 88, 3 of the locations had an accuracy between 150-200m and the rest had an accuracy larger than 200m. Therefore, the reported accuracy for indoor location in the Houston city through the small-scale experiment is 96.59% for 200m radius.

The radius for determining the accuracy has been chosen as 200m since the AQI data is based on zip-code information which doesn’t require a very high accuracy. Zip code area spans a range of 2-100mi² and, therefore, a 200m radius is 2.5% of the minimum zip code area of 2mi² which gives a reasonably accurate estimation. There are certain limitations with this method to be discussed. The first limitation
is that this application works well only if one is able to obtain more than one SSID at a particular place as required by the geolocation services. If only one SSID is available, the API just yields a pre-determined point in the city as an approximation for the location (accuracy $>200m$). Due to the widespread usage of wireless devices in cities, most indoor locations can provide more than one SSIDs, but there may still be uncertainty in some locations. The second limitation arises due to the third-party nature of the database of locations, built by Google. There can be cases in which the SSIDs are not present in the database and therefore, it is unable to provide the location. For both these cases, the user needs to manually provide information about the location of use when prompted.

5.3 Feasibility Study for SmartInhaler

SmartInhaler device from an engineering perspective is a platform that can accurately measure inhaler usage. However, the features on the device, especially the location tracker and camera, may not be welcomed by a number of patients or their parents due to privacy concerns. In order to understand patient reaction to the SmartInhaler system and the individual features, 20 asthma patients from the Texas Children’s Hospital in Houston under the age of 18 and their parents were asked to watch a video demonstration of the SmartInhaler and answer questions based on the video.

The survey answers revealed that only 20% of the patients were fully adherent to asthma control medication. In addition, 95% of the 20 patients and their guardians answered that SmartInhaler would help them take their medication more consistently. For the questions gauging patient interest in the features, time-stamp, location and picture, two of the patients and their parents thought that having a camera on board may breach their privacy and one of them would not be interested in tracking their location. The survey results show that asthma patients and their guardians are aware
and concerned about improving their asthma control in order to avoid exacerbation
and would like to use SmartInhaler to achieve this.
Figure 5.2: The figure(a) shows the average current in a typical 24 hour usage, (b) shows the average charge consumed in a typical 24-hour period compared with the worst case usage due to delay in WiFi and Bluetooth connectivity, (c) shows the typical and worst-case discharge characteristics for three cases: all the features enabled, camera disabled and WiFi disabled.
On-going Work: Ultrasonic Flow-meter based Training Module

One of the most difficult problems in asthma control is effective administration of medication to the lungs. Aerosolized metered dose inhalers are designed to deliver medication all the way to the lung airways through the high force at which the medication is dispensed. Nevertheless, a fair amount of coordination is still required, with respect to the time of actuation, the time at which inhalation starts and the speed of inhalation. Thus, even if the patient is compliant with the control MDI regime, the medication may be ineffective and result in poor control of asthma. As mentioned before, over 40% of compliant patients don’t use an inhaler correctly [13]. The SmartInhaler attachment is being modified currently such that it can identify the potential sources of error while performing the maneuvers and provide real-time feedback to the patients. The maneuvers will also be video recorded such that even the physicians can view them for identification of erroneous maneuvers for high-risk patients.
6.1 Inhaler Dosage Administration Technique and Potential Errors

Figure 1.2 shows an inhaler with a spacer attachment. The use of a spacer is strongly advocated, and in most cases mandated, by doctors for children under the age of 18 years of age. The purpose of the spacer is to make MDI dosage administration easier and more effective. It is essentially a breathing chamber in which the medication is first dispensed and then very slowly inhaled at a constant rate. Thus, the patient is not impacted directly with the full force of the aerosolized medicine. However, children and adolescents still find it difficult to learn the correct technique while using a spacer and thus, reduce the effectiveness of control medicine. Most of the current spacers have a whistle that allows air to enter. The whistle starts blowing if the inhalation rate is too high resulting in more air than medication traveling to the lungs. However, that is just one of the sources of errors as explained in Table 6.1.

There exist a number of training inhalers but only work without medication in them for the purpose of teaching the correct technique. These training inhalers work with a desktop computer based software for analysis of the maneuver limiting the use to in-home environments only. However, none of the training modules work with off the shelf control MDIs or provide real time feedback or capture a video to be shared with the physicians.

The potential sources of errors while operating the MDI with a spacer are presented in Table 6.1. If the patient starts inhaling too early, she may not inhale all of the medicine by completing the inhalation sooner. If she starts too late some of the medication may get deposited on the spacer before inhalation. The inhalation rate shouldn’t be too low due to deposition of the medication on the spacer and neither should it be too high since the patient would inhale more air coming from the
vent and/or whistle lowering the concentration of medicine in the inhaled air. Lastly the inhalation duration should be optimal such that all of the medication is inhaled without getting deposited on the spacer.

<table>
<thead>
<tr>
<th>Maneuver</th>
<th>Errors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation Starting Time</td>
<td>Early</td>
</tr>
<tr>
<td>Inhalation Rate</td>
<td>Low</td>
</tr>
<tr>
<td>Inhalation Duration</td>
<td>Short</td>
</tr>
</tbody>
</table>

Table 6.1: Sources of errors while performing an inhalation with an MDI and a spacer.

### 6.2 Ultrasonic Spacer: Principle and operation

For the purpose of characterizing and detecting the errors with inhalation technique, explained in the previous section, in real time, the spacer can be modified to measure the flow of air inside the tubing. Ultrasound based flow-meters are very accurate, reliable and have been used in validated simple air flow-meters (e.g. in spirometry). The principle of operation can be understood from the Figure 6.1. The transmitter sends ultrasonic waves at 40kHz and under no airflow are received at the same time by both the receivers due to their symmetric placement on the spacer. However, due to airflow, the receiver R2 receives the waves before R1. Thus, the air flow causes a proportional phase shift in the waveforms received by R1 and R2. Quantification of this phase shift gives the air flow rate in the spacer tube. The quality of the received signal improves with higher frequency ultrasonic waves.
6.3 Experiment: Identification of Erroneous Maneuvers using Ultrasonic Flowmeter

An experiment was carried out to gauge whether the sources of errors mentioned in Table 6.1 could be detected using an ultrasonic flow meter. Figure 6.3 shows the flow versus time curve obtained in the experiment for a good maneuver and some of the erroneous maneuvers. The curves are negative valued due to the direction of flow, positive shows exhalation and negative inhalation. The red curve shows the flow versus time which is the parameter of interest. From the figures, we can very well distinguish the high flow rate (sharp trough) at the beginning as the medication being dispensed. Then the flow rate dips and rises a little again as soon as the inhalation starts. The flow rate remains steady and reasonably low in a correct maneuver as shown in Figure 6.3(a). In case of early inhalation, the flow rate dips only slightly after the medication is dispensed and the flow goes to zero early indicating end of inhalation as shown in Figure 6.3(b). In the case of a very high inhalation rate resulting in a short duration of inhalation, the flow rate rises sharply again and goes
quickly back to zero as shown in Figure 6.3(c).

However, the waveform can’t always distinguish between no inhalation and early inhalation since in both cases there is no second rise in the flow rate. For the case of early inhalation, the flow rate is already quite high when the inhalation starts and doesn’t indicate a sudden second rise. In the case of no inhalation, the flow rate doesn’t dip below a certain value and remains constant throughout giving rise to a similar waveform as shown in Figure 6.3(d). The constant flow rate is due to the fact that aerosolized particles dispensed in the spacer, if not inhaled, may change the medium of ultrasonic wave transmission as shown in Figure 6.2. Therefore,

![Figure 6.2: Change in medium due to aerosolized particles in the spacer. The difference in medium of transmission between T-R1 and T-R2 results in a constant phase-shift pertaining to the erroneous flow measurement in Figure 6.3 (d).](image)

a constant phase difference still remains without airflow due to the difference in medium between receivers R1 and R2. This source of error for no inhalation is being characterized currently and being researched on for a modification to the principle that can differentiate between all the sources of errors.
(a) A good inhalation maneuver

(b) Early Inhalation

(c) Short Inhalation with high flow rate

(d) No Inhalation

Figure 6.3: Flow versus time curves for the Ultrasonic Spacer.
Reliable and accurate measurement of patient adherence to asthma control medication is the first step towards solving the grand challenge of improvement of adherence. Our solution, SmartInhaler, can accurately measure the three important parameters of inhaler usage, viz., time stamp, location of usage and verification of the patient by a picture, as well as location based outdoor air quality parameters. The communication between the stand-alone hardware attachment and software application allows easy synchronization of the data and provides a ground for further analytics.

Future work using the SmartInhaler platform would be to test the robustness and accuracy of the attachment as well as the effect of using the platform on adherence to control medication for actual asthma patients. We are collaborating with the Texas Children’s Hospital in Houston for carrying out the clinical trial with patients below the age of 18 years.

Implementation of the ultrasonic flow meter based spacer will provide a solution to the final hurdle in the measurement of medication adherence by quantifying the efficacy of dosage administration. In addition, the combined measurement of air flow and video capture may eliminate the possibility of fabrication of adherence data by the patient. The video footage along with air-flow curves can be analyzed offline by
the physician as a diagnostic tool to figure out the cause of incorrect maneuvers.

Future versions of the SmartInhaler system will also address the development of the personalized metrics for the assessment and prediction of asthma control, exacerbation and gamification of inhaler usage for habit formation.
References


