# Networked GPS-enabled metered-dose inhaler to support real-time mapping of asthma exacerbations


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## Abstract:

Asthma is a disease of growing public health importance, and is unique in that inhalers and the medications they supply are often used at the exact time and location of exposure to environments that trigger attacks. By monitoring these factors in real-time instead of relying on the proper documentation and collection of data, patterns in symptoms could be deciphered and could help to identify common risk factors in populations. The goal of this project is to create a device that can store and transmit the time, date, and location of medication use by utilizing Global Positioning System (GPS) technology.



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## Problem Statement

The aim of our team over the next three semesters is to create a prototype of an asthma inhaler (or a device that can be attached to an inhaler) capable of communicating the time, date, and location where the inhaler was used, as well as to design the software to accompany the data. This project is important in the tracking of allergy and asthma symptoms, outbreak control, and general health observations with respect to populations in certain areas of the United States and, ultimately, the entire globe. Surveillance to this point has been limited to the delayed analysis of emergency department visits and hospitalizations for relatively severe episodes, or diaries of patients that may or may not be accurate.

Overall Goals:

1. The creation of a prototype of an inhaler or an add-on device for existing inhalers that communicates the time and location when used to a remote data collection system. This could be accomplished by equipping an inhaler with telematics to communicate wirelessly on the Internet and a GPS device for tracking where it has been used.

2. The development of a database, web-based mapping, and analytic system (future semesters).

## Background Information

*Asthma and inhalers*

Asthma is a chronic respiratory disease in which the airways are blocked or narrowed due to allergy or inflammation. Asthma is commonly classified into allergic asthma and non-allergic asthma. Patients suffering from asthma will have difficulty in breathing. Currently, there are about twenty million Americans affected by this disease.

Figure 1: Inhaler
Courtesy of
www.nlm.nih.gov

The asthma inhaler is a medical device that ejects steroids in a vapor form to ease the symptoms of asthma in patients. There are several different kinds of inhalers available to help relieve or control asthma symptoms, including the common metered-dose inhalers (MDI) and dry powder inhalers. The main difference between these two types of inhalers is that the MDI requires a chemical propellant that pushes the vaporized drug out of the inhaler, which can sometimes cause throat irritation if not properly deployed. The severity of each asthma case can determine what kind of medicine is right for that patient. Both types rely on some sort of pressure at the top of the inhaler to eject the medication.

*Global Positioning Systems (GPS)*

At any given moment, the coordinates of a particular point of interest on earth can be pinpointed by a system of satellites and antennae. This navigation system was first used by the U.S. Department of Defense for military purposes (twenty-seven total satellites orbit the earth; twenty-four in operation and three backups). A GPS receiver's job is to locate four or more satellites, figure out the distance to each, and use this information to deduce its own position. Gradually, it has been introduced into the automotive industry, marine and outdoor sporting use, surveying, and even recreational jogging. Any certain cell phone can be located with the push of a button. Using this technology along with the advances of modern medicine, it is hoped that the tracking of disease symptom outbreaks across the globe can be accomplished by "following" the users of asthma inhalers.

Figure 2: GPS Satellites courtesy of www.denisduboisag.com

## Current Devices

On the market, there are not currently any inhalers capable of tracking their users' movements through GPS, although there are some that have been introduced to the marvels of technology. The most similar devices are inhalers with electronic monitoring systems for the date, time, and dosage of medication taken. Three main competitors exist in this realm of inhaler technology: the MDILog™, SmartMist™ and Doser CT™. These devices are necessary both for the welfare of the patients (so that they know when they last took their medication or when they are running low) and for doctors, who can ensure that their instructions are being followed in the case that the inhaler doesn't work properly.

*MDILog™*

The MDILog™ has several useful features, and is the most expensive of the three competitors. This device records the date and time of medicine use, has a separate "docking station" to download data into a computer, and uses software to show medication usage and make suggestions for more effective deployment. The drawbacks to this device are that it is expensive (around $700 with the docking station and software) and that it comes permanently attached to the inhaler it is meant to be used with. Due to budgetary constraints of the hospitals and clinics that will use our device, the cost should not exceed about $300 at the most.

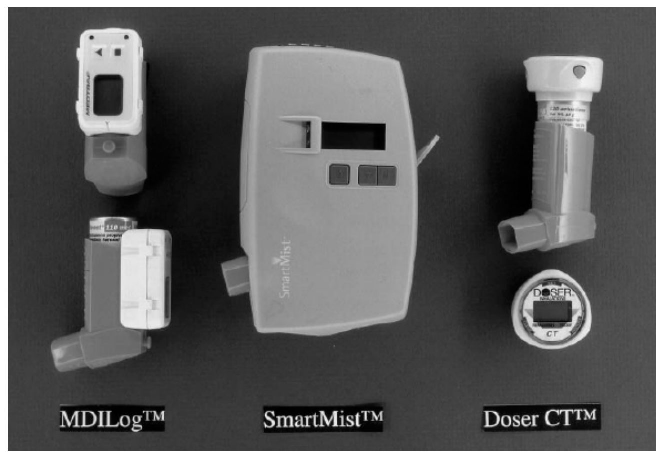

Figure 3: Existing Devices courtesy of www.chestjournal.org

*The SmartMist™*

The SmartMist™ device is not as aesthetically pleasing as the other two in that its size more than overpowers the small form factor of the inhaler itself. While it measures the flow rate of the medication and helps to minimize technique error, it is too bulky to be carried around during daily use and therefore is only practical in closed-study applications. It, like the MDILog™, also can download its data to the computer but its software is fairly outdated at this time. It is also costly, and because the SmartMist™ isn't universal for different kinds of medication, it never really got the support of doctors in the United States and is therefore difficult to purchase.

*Doser CT™*

The Doser CT™ is the most portable of the three devices, and also happens to be the cheapest. Unfortunately, its abilities match its price range. The Doser attaches to the top of the inhaler and is automatically activated when it senses the pressure of a deployment. Then, it starts to count. With each deployment, a pre-programmed dose counter will add one to the doses "given" and subtract one from the doses "remaining." While this is beneficial to the patient, it does not assure the doctor that the patient actually *inhaled* the medication (the Smartmist and MDILog can tell if inhalation occurred). The Doser will be beneficial to take apart and analyze the pressure sensor and battery (which can last up to twelve months), but doesn't take the time or date, much less the location, of medication use.

## Design Guidelines and Constraints

In order to achieve a successful design, the prototype must be able to perform three tasks:

- Detect user's administration of asthma medicine.
- On detection, receive and record GPS coordinates as well as date and time.
- Transfer user information to centralized database for analysis.

Towards these ends, there are several design possibilities that were considered.

This semester's design must adhere to several requirements that have been specified by the client. Singularly most important among the design specification is that any modification cannot negatively impact the performance of the existing drug delivery method within the inhaler, including changing pressure and loading capability. Food and Drug Administration (FDA) approval for use in humans is required in order to successfully market and produce the product. Because asthmatics of all ages will be using this inhaler, any addition to the device must be securely attached to avoid extra pieces; also, it must be able to withstand normal wear such as being dropped or stored in pockets, and withstand small amounts of water. The GPS location and time/date, which is communicated from satellites, should be as accurate as possible without compromising safety in any way. A wireless system including a small rechargeable battery made with hypoallergenic plastics would be ideal. The semester goal is to produce a working prototype to display proof of concept. (A full product design specification is available in **Appendix A**.)

## Design 1: Pressure Detection with GPS Separate

The detection component of the first design consists of a pressure sensor mounted on the asthma medicine container. During normal use of the inhaler, a pressurized medicine container is inserted upside down into the top port of the inhaler. When the user wishes to administer a dose of medicine he/she presses down on the medicine container, which then releases a metered dose into the mouth port. The user simply puts their mouth to the mouth port and inhales subsequent to an administration. The pressure sensor should be activated at the time that a threshold force to be determined in advance, (the force required for a successful release of the medicine) is exceeded.

From there, a microcontroller would detect the administration and communicate via wireless transmission to a cell phone that the users would be required to carry with them. New models of cell phones all have built in GPS systems, so keeping these separate would cut costs without limiting reliability. On successful communication between the cell phone and the microcontroller in the asthma inhaler, a program written for the cell phone would download the users GPS coordinates and format a data message that contains that user's id number, time of administration, and location. The message would then be transmitted to a centralized database where the data would be stored and parsed to obtain the relevant statistical information.

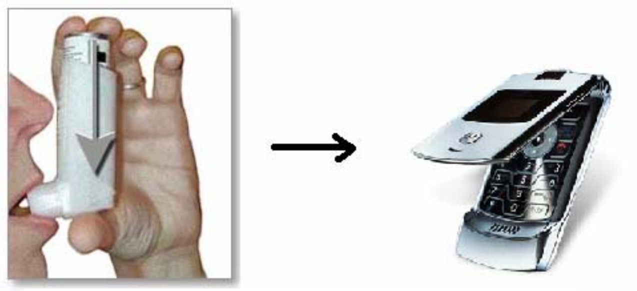

Figure 4: Inhaler courtesy of www.nlm.nih.gov
Cell phone courtesy of images.businessweek.com

*Advantages*

The strength of this design is in its portability. The main working of the detection system has only four components (microcontroller, wireless transmitter, pressure sensor, and battery), making its package size comparatively smaller than a package that also includes a GPS receiver (see Designs 2 and 3). This design also in no way alters or impedes the workings of the stock asthma inhaler, which is extremely important for drug delivery and patient safety.

*Disadvantages*

The pressure detection system has some inherent flaws. If the threshold pressure is set at too high of a value, then the system runs the risk of missing the application, even after the user successfully administers the medicine. Conversely, if the threshold pressure is set too low, then the system runs the risk of mistaking small bumps and jostles as successful administrations.

With the GPS receiver separate from the inhaler, this design runs the possibility of the user administering, the microcontroller detecting the administration, but the system not recording GPS coordinates post-application. If the user forgets to bring the phone with him/her or if the phone is out of communication range with the inhaler, location would not be recorded for a detected administration. Since location is the key measure, this possibility proves to be the major shortcoming of this design iteration.

## Design 2: Contact Detection with GPS Separate

The detection component of the second design consists of two leads; one mounted on the inner-wall of the inhaler, the other on the medication canister. When the canister is depressed, as during medication administration, the two leads will meet, completing a circuit which is attached to the microcontroller. The microcontroller will detect when the circuit is active and in response, will run the wireless communication program. The program will transmit again to a cell phone, where a program written for the cell phone will be initiated. GPS coordinates can then be taken, and a data message with the user's id number, location of administration and time of administration can be created and sent to a central database. There the data will be analyzed.

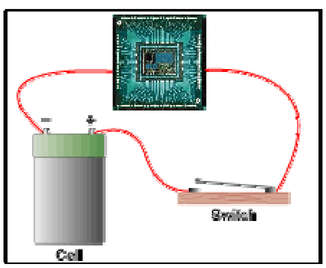


Figure 5: Typical detection circuit

*Advantages*

The contact detection system in the second design is much more resistant to detection of false positives than a pressure detector would be since there is no range of detectable pressures; the application detection is binary in nature. Either the leads meet and the circuit provides five volts to the input pins on the microcontroller, or the circuit is broken and there is no input. Again, since the GPS receiver is not on the inhaler itself, the form factor is greatly reduced.

*Disadvantages*

The contact system requires an invasive alteration of the inhaler, which if executed improperly, could change the workings of the inhaler. Additionally, as the GPS receiver is not directly attached to the inhaler, there is the risk that a user could forget his/her cell phone and no location data would be recorded for an administration. Again, this is a major shortcoming of the design.

## Design 3: Contact Detection with GPS Attached

Figure 6: GPS Satellite image of UW Engineering, courtesy of Google Maps

The detection component on the third design iteration is identical to that of the second, but the microprocessor is more intelligent. When the medication canister is depressed, two leads will meet and complete a circuit. The microcontroller will register the completed circuit as a signal that the inhaler has been used and will run an algorithm with pre-programmed steps to follow. The microcontroller first talks to the onboard GPS components and receives the current coordinates and time, which it stores in its memory.

The microcontroller then attempts to connect to the user's cell phone via a Bluetooth wireless connection. If the user's cell phone is detected, the microcontroller sends the information, which is then formatted by a program on the cell phone into a data message and sent to a central database for processing. If the cell phone is not detected, the inhaler goes into a sleep cycle and attempts to connect again after a certain time interval. It repeats this until it successfully completes transmission with the cell phone.

*Advantages*

The major advantage to this design is that the GPS receiver is now directly attached to the inhaler, making it possible to record coordinates even if the cell phone is turned off or out of range. It relies less heavily on all of the different components being in the same place at the same time, and also makes the creation of an appropriate cell phone program much more feasible as the coding for creating a message is less complicated than that for retrieving coordinates, date, and time.

*Disadvantages*

Inside use of a separate GPS device, which probably will not be as sophisticated as the one in a given cell phone to keep costs low, can be limited in its connectivity and result in a failure to record coordinates when a dose is deployed. Upgrading the GPS will increase the cost, which will already have gone up due to the need to buy a separate one instead of using the one in a phone. Also, additional power may be required for the microcontroller to run all of the different processes at once, so we may need to research rechargeable batteries.

## Design Solution

| Criterion (Weight) | Design 1 | Design 2 | Design 3 |
|---|---|---|---|
| **Patient Safety (3)** | **5** | **4** | **4** |
| **Accuracy (3)** | **3** | **4** | **5** |
| **Low Cost (3)** | **4** | **5** | **3** |
| **Data Backup (2)** | **3** | **3** | **5** |
| **Feasibility (2)** | **3** | **3** | **5** |
| **Ease of use (2)** | **3** | **3** | **5** |
| **Connectivity (2)** | **3** | **3** | **4** |
| **Portability (1)** | **5** | **5** | **3** |
| **Battery Life (1)** | **5** | **5** | **3** |
| **Aesthetics (1)** | **5** | **5** | **4** |
| **TOTAL** | **75** | **78** | **84** |

The most important considerations made while choosing a design are Patient Safety, Accuracy and Low Cost. Subsequently, these criteria carried the most weight in our decision. As patients rely on their inhalers, the design cannot reduce its efficacy. Design 1 was the winner in this category, as the pressure system requires no alteration of the workings of the existing inhaler.

The entire purpose of the study is to obtain location data after use, so accuracy is of the utmost importance. In this category, Design 3 was the clear winner as it is the design that would obtain GPS coordinates whenever they could be obtained. Finally, this inhaler would be part of a study that would require many participants, so the price of the inhaler cannot be constrictive. In this category, Design two is the winner for the simplicity of the detection system. In the end, Design 3 won out among the three as it is the most accurate and reliable of the designs, yet requires very little on the part of the user to operate. To this point we have ordered the necessary supplies and taken a mini-course on microcontrollers that we hope will help us to build and program our device.

## Conclusion

The device that we have chosen will need to be built to fit the aims of our team over the next three semesters. It will need to communicate the time, date, and location where the inhaler was used wirelessly, so that software can be designed in future semesters to analyze data and detect irregularities. This project has major applications in the lives of the twenty million people affected by asthma symptoms, as well as to the researchers who can help prevent the spread of disease. By collecting data at the exact time and location that symptoms occur, doctors can get a head start in identifying causes keeping others away from the same sources of irritation or infection. In the end, a mother may not have to worry every morning that her son will have an asthma attack on his way to school – authorities may be notified immediately in the case of an emergency and be able to respond accordingly. Security protocols will need to be in place to protect the identity and location of individuals from public perusal, but overall the implications of this project make dealing with shortcomings worth the trouble.

## Future Development

There is a copious amount of future work needed to validate and develop the new design for an addition to the asthma inhaler. Our remaining work for the semester can be divided into three key goals:

- Creation of an inhaler or add-on device
- The physical sending of data to collection location, and
- The use of mapping based on location so that outbreaks can be tracked.

David Van Sickle has supplied many specifications and design constraints. One task will be to finalize the proposed design, which must meet the client's requirements found in the Project Design Specifications (**Appendix A**). Also, a broader knowledge base of microcontrollers, GPS systems, and wireless information transmitting will aid in the designing process. As of now, there is a general idea of how the prototype will look and how it should operate, however, exact dimensions and how it will fit onto the existing inhalers must still be specified.

More extensive research will need to be conducted to locate and obtain information on manufacturing companies. There are a few companies that work with small GPS systems, and contact needs to be made to possibly estimate large-scale manufacturing for economic production. Given budget constraints of roughly $300 per device, the total cost must be investigated and minimized to facilitate a viable design that will gain the support of healthcare professionals. Once these goals are accomplished we can look to various companies or physicians for help manufacturing or marketing our design. As always, research, acquisition of new skills, and recording all of our findings and results will go along with all aforementioned work. We will also need to consider patenting our project to protect Dr. Van Sickle's intellectual property.

In order to accomplish the desired outcome, clinical testing will need to be done. While David Van Sickle donated current versions of the inhalers, research in how to test the design is also necessary. Testing with LabVIEW will be a way of testing transmission accuracy, and error testing will also be necessary in order to articulate types of misuse and their effects on the inhaler recording system. This information could also be helpful in creating the training tools and cautionary section of the user's manual.

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## Function

The aim of our team over the next three semesters is to create a prototype of an asthma inhaler (or a device attachable to an asthma inhaler) capable of communicating the time, date, and location where the inhaler was used, as well as to design the software to accompany the data. This project is important in the tracking of allergy and asthma symptoms, outbreak control, and general health observations with respect to populations in certain areas of the United States and, ultimately, the entire globe.

## Client Requirements

- **Stage 1:** The creation of a prototype of an inhaler or an add-on device for existing inhalers that records the time and location when the inhaler is used.
- **Stage 2:** The physical sending of data (as often as possible) to a remote collection location.
- **Stage 3:** The mapping of use based on location so that instances can be tracked and associations made with symptoms and therefore inhaler usage. Outbreaks can be tracked to their sources based on this technology.

## Design Requirements

### 1. Physical and Operational Characteristics

a. *Performance requirements*: Must be able to attach to a common inhaler to minimize the extra hassle of carrying something else along with it. It must function as many times daily as the inhaler is used, which can vary from never to several dozen times depending on symptoms.

b. *Safety*: Cannot compromise the deployment of medication (i.e. can't change pressure, loading capability, or otherwise interefere).

c. *Accuracy and Reliability*: Must be repeatable until study is over or until inhaler is no longer needed. GPS location and time/date should be as accurate as possible without compromising safety. Small error can be tolerated as long as recording is successful when symptoms occur.

d. *Life in Service*: Should be usable across the entire globe, with GPS communicated via satellite, and should last at least as long as the inhaler. Depending on the final cost of the device, it may be necessary to use it on several different types of inhalers if it is not easily replaceable.

e. *Shelf Life*: Will need some sort of power supply that can either be replaced or recharged. Shelf life of device will be entirely dependent on battery life.

f. *Operating Environment*: Should be usable at temperatures conducive to inhaler use (generally 0-100 degrees Fahrenheit) and at all locations and elevations. Must be able to withstand normal wear and tear such as being dropped, stored in pockets, and (ideally) exposed to small amounts of water as well.

g. *Ergonomics*: Must not carry enough electricity to cause damage in the event of malfunction. Wireless usage is ideal.

h. *Size*: Must be portable and have a replaceable or rechargeable power supply within the unit. Smaller is better.

i. *Weight*: Should be easily portable and not weigh too much (must not make use of inhaler difficult for children). Definitely under 2-3 lbs.

j. *Materials*: Nothing should be used that could trigger allergies in users (plastic or metal that can be easily cleaned is ideal).

k. *Aesthetics*, *Appearance, and Finish*: Preferably should not look bulky or out of place when attached to inhaler.

**2. Production Characteristics**

a. *Quantity*: Eventually enough for thorough testing in up to 10,000 trial patients. Licensing may be considered if product is successful (mass production will make device more cost effective).

b. *Target Product Cost*: Prototype can cost a fair amount of money if the ability exists to lower cost by mass production in the long run.

**3. Miscellaneous**

a. *Standards and Specifications*: FDA approval may be required to make sure that device does not alter the correct amount of medication deployed by inhaler.

b. *Customer*: Since some customers may be children, issues such as portability and discreetness must be high priorities.

c. *Patient-related concerns*: Confidentiality should be considered, although memory will not likely hold personal information (just general usage data).

d. *Competition*: There are some devices which can take the time and date, but not location, of inhaler usage. Current products cannot transmit wirelessly or within a decent time span of when the device was actually used.

## Appendix B: Patent Search 02/02/2007

**US Patent Number 9958691**

This is an idea for a system for the delivery of medicament comprising of a medicament container, dispensing mechanism, electronic data management system, and communicator for wireless communication with network computer. The electronic data management system comprises of memory storage of data, a microprocessor for analyzing data, and transmitter from device to computer. While this patent does not specify how it is to be built, there is evidence of intellectual property disclosures. This device is neither feasible nor idealized. The inventor apparently had an idea for a "Swiss-army-knife" inhaler.