Final Report

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 this team 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 of the inhaler's use to a central database, 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. Research to this point has been limited to the delayed analysis of emergency department visits and hospitalizations for relatively severe episodes. Clinic visits rely on accurate accounts of where patients were and what they were doing when symptoms occurred, which can often be forgotten in the stress of the moment or fabricated to make it seem as though physician instructions are being exactly followed. By tracking exacerbations in real-time, it is possible to eliminate speculation and receive more accurate information in attempting to control asthma in large populations. Overall goals of this project include:

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, and is commonly classified into allergic and non-allergic asthma. Patients suffering from asthma have difficulty in breathing, either on a daily basis or after long periods of exertion. Currently, there are about twenty-million Americans affected by this disease.

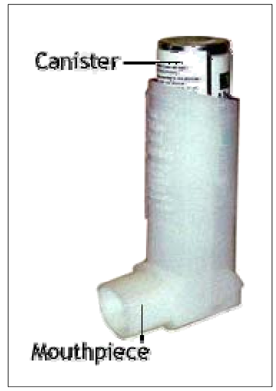


Figure 1. Asthma Inhaler [www.nlm.nih.gov]

The asthma inhaler (see Figure 1) 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. Since the size and shape of asthma medication canisters is fairly uniform, it is hoped that this project will produce a device that can be easily moved from one inhaler to another.

Global Positioning Systems (GPS)

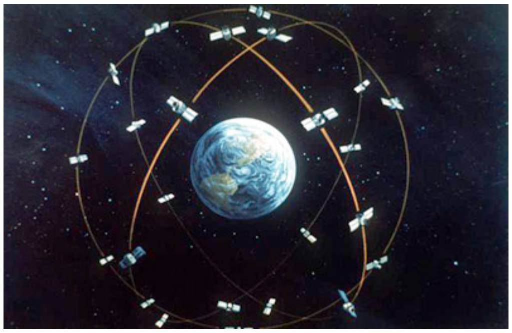


Figure 2. View of GPS Satellites triangulating to gather a longitude and latitude [www.denisduboisag.com]

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, exhibited in Figure 2). The function of a GPS receiver is to locate four or more satellites, calculate the distance to each, and use this information to deduce its own position. Gradually, this technology has been introduced into the automotive industry, marine and outdoor sporting use, surveying, and even recreational jogging. Using GPS 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.

Current Devices

There are not currently any inhalers on the market capable of tracking patient movements through GPS. 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 (who can stay informed on how much medication remains in an inhaler) and for doctors, who can ensure that their instructions are being followed in the case that the inhaler doesn't work properly or unexplained symptoms occur.

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.

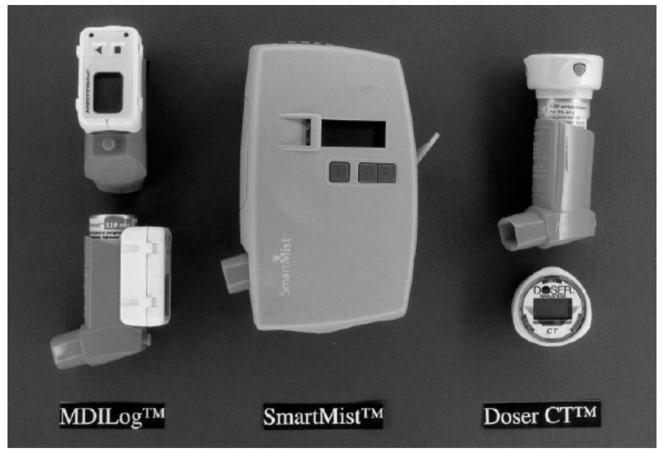


Figure 3. Existing devices on the market; possible competition for our design [www.chestjournal.com]

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. The purpose of the SmartMist™ is to measure the flow rate of the medication and help to minimize technique error, but the device itself 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. The SmartMist™ is also difficult to purchase, as it never really got the support of doctors in the United States due to its size and inability to do anything unique.

Doser CT™

The Doser CT™ is the most portable of the three devices, but has limited abilities that also contribute to it being the cheapest. The Doser attaches to the top of the inhaler and is automatically activated when it senses the pressure of a deployment, at which time it begins 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™ is easily transferable between inhalers.

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 medication.
- 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.

Singularly most important among the design specifications is that any modification cannot impact the performance of the existing drug delivery method within the inhaler, including changing pressure or loading capability. Approval by the United States Food and Drug Administration (FDA) for use in humans will be required in order to successfully market and produce the product. Also, physicians so far have been hesitant to invest in devices as expensive as the MDI Log, implying that success within the market depends on the cost of this product not exceeding an upper bound of $300. Because asthmatics of all ages will be using this inhaler, any addition to the device must be securely attached to avoid extra pieces, and must be able to withstand normal wear such as being dropped or stored in pockets or subjected to 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. (A full product design specification is available in **Appendix A**.)

Design 1: Pressure Detection with GPS Separate

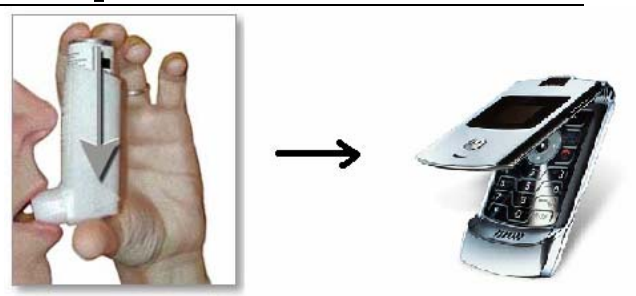


Figure 4. Asthma inhaler and cellular phone pictorial [www.nlm.nih.gov and www.images.businessweek.com,

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 they press down on the medicine container, which then releases a metered dose into the mouth port and is directly inhaled. 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 user would be required to carry. New models of cell phones have built in GPS systems, so keeping the inhaler and GPS module 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 user's GPS coordinates and format a data message that contains a personalized 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.

Advantages

The strength of this design is in its portability, as the detection system has only four components: microcontroller, wireless transmitter, pressure sensor, and battery. The package size would be comparatively smaller than a package that also includes a GPS receiver (see Designs 2, 3, and 4). 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 carry their phone 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.

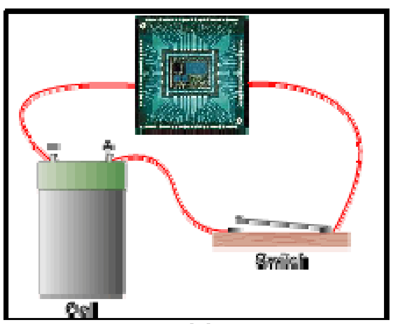


Figure 5. Typical detection circuit
[schematic by Mollie Lange]

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: an integrated GPS device [http://news.bbc.co.uk/2/low/uk_news/magazine/3307471.stm]

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, first communicating with the onboard GPS components and receiving the current coordinates and time, which it stores in its memory (see Figure 6 for an example of a device with both built in). 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 specified time interval, repeating until it successfully completes transmission.

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 unit instead of using the GPS in a phone. Also, additional power may be required for the microcontroller to run all of the different processes at once, requiring common replaceable or rechargeable batteries.

Design 4: Contact Detection with GPS Attached Utilizing GM-862

A fourth design, which is a modified version of Design 3, was created due to the discovery of a new microchip that utilizes the GSM network as well as GPS to triangulate the inhaler's location. This technology assures the user that latitude and longitude can be acquired even while indoors. The GM-862 GPS microchip by SparkFun Technology™ (see Figure 7) not only includes GPS, but also eliminates the need for Bluetooth and an external cell phone by incorporating a SIM card in the microchip itself. This results in a device that can find its location, connect to cell phone towers, and send data without relying on a network of separate devices.

Figure 7: Sparkfun GM-862 microchip courtesy of *http://www.sparkfun.com/datasheets/Cellular%20 Modules/GM862-USB-Eval.pdf*

Advantages

The major advantage to this design is the ability to easily miniaturize the whole device and incorporate it onto an inhaler, with a minimal risk of various parts not staying securely attached. By utilizing this chip, the device is not only simplified and more aesthetically pleasing, but it also functions without the use of a cellular phone to relay data. This design has the capability to send data using GSM technology, which allows for exact locations to be found while indoors. Another advantage is that the microchip includes built-in memory, which can be used to store programs and information as well as to hold coordinates to be sent later if a connection cannot be made immediately.

Disadvantages

Depending on the final manufacturing of this design, it is possible that it might not be as portable from unit to unit as the others due to its need to house many connections in one small area. It also requires a very specific power supply that can generate voltage without allowing the microchip to pull too much power at once.

Design Solution

In order to compare the designs, a design matrix (Table 1) was created to grade each design on its merits in five categories that are relevant to the project: *Patient Safety*, *Accuracy*, *Price*, *Data Backup*, *Feasibility*, *Ease of Use*, *Connectivity*, and *Portability*. The most important considerations made while choosing a design were *Patient Safety*, *Accuracy*, and *Price*; subsequently, these criterion are weighted more heavily. *Patient Safety* takes into account the likelihood of failure or reduction of efficacy; Design 1 was the best design in this category, as the pressure system requires no alteration of the working of the existing inhaler. *Accuracy* is important in this device for data analysis and to create a viable option for our client's precise location research. Designs 3 and 4 were ranked the highest in this category because of the use of more than one back-up function, such as the ability to store data for short periods when the cellular phone is absent. Design 4 utilizes a chip module that uses GPS and GSM triangulation to gather data utilizing radiofrequency and GPS satellites, greatly increasing accuracy. Finally, *Price* is important for the success of future marketing continuation. Research has concluded that the target price needs to be less than three hundred dollars to ensure market success.

Table 1: Design Matrix

Criterion* (Weight)	Design 1	Design 2	Design 3	Design 4
Patient Safety (3)	5	4	4	4
Accuracy (3)	3	4	5	5
Low Cost (3)	4	5	3	3
Data Backup (2)	3	3	5	5
Feasibility (2)	3	3	5	5
Ease of use (2)	3	3	5	5
Connectivity (2)	3	3	4	5
Portability (1)	5	5	3	5
Battery Life (1)	5	5	3	3
Aesthetics (1)	5	5	4	5
TOTAL	75	78	84	89

Each criterion is ranked out of five possible points.

Since the main goal of this project is to obtain accurate information as quickly as possible, Design 4 is the best option because of its ability to triangulate positions while indoors and to store and transmit the data at the earliest convenience. *Price*, while important, is not enormously different than the other designs is therefore not a deciding factor. Also, when considering the reliability and user interaction required, having as few components as possible is the ideal solution – both of which are encompassed by Design 4's ability to minimize complications. In the end, this design was chosen for its simplicity in the final theoretical design even though it was harder to implement in a short period of time (it requires working knowledge of several different programming languages).

Final Design

The final design for this semester centered on the benefits of Design 4, which seemed to be the most convenient method despite the fact that it required a lot of detailed computer work to accomplish. A flowchart detailing the general flow of data is shown below (see Figure 8):

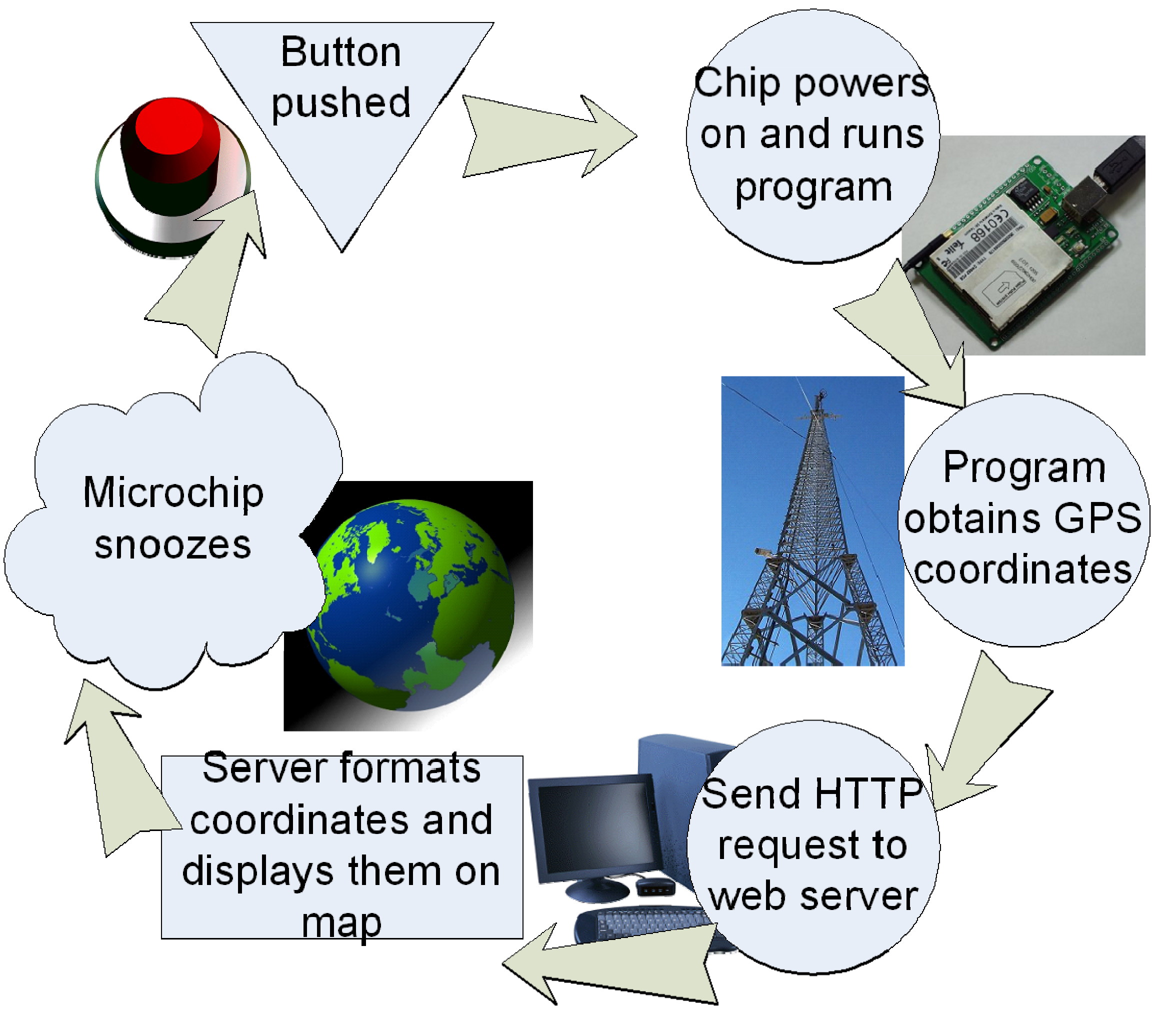


Figure 8: General flow of information through device network

The technical aspects of our design include the following components:

1) Momentary push button which completes a circuit upon depression, causing power to flow briefly to the microchip so that it knows to wake from sleep and run the program.
2) GM 862-GPS microchip and SIM card reader which can store data as ROM so that it is maintained even when the microchip is powered off. This gives it the ability to wait until it acquires a signal before trying to submit the data to the web server.
3) 3.7V lithium-ion power supply that can be recharged similarly to a cell phone battery and maintains a current of less than 1000mA at any given time.
4) Web space on the college of engineering server, which includes a website that can plot coordinates sent from the phone onto mapping software provided by Google Maps (see Figure 9).
5) GPS and GSM antennae which triangulate coordinates for use with the program.
6) Laptop for programming that will not be needed once the Python script will run properly.

Figure 9: Final display of mapped coordinates
on [http://asthmahq.engr.wisc.edu]

Prototype

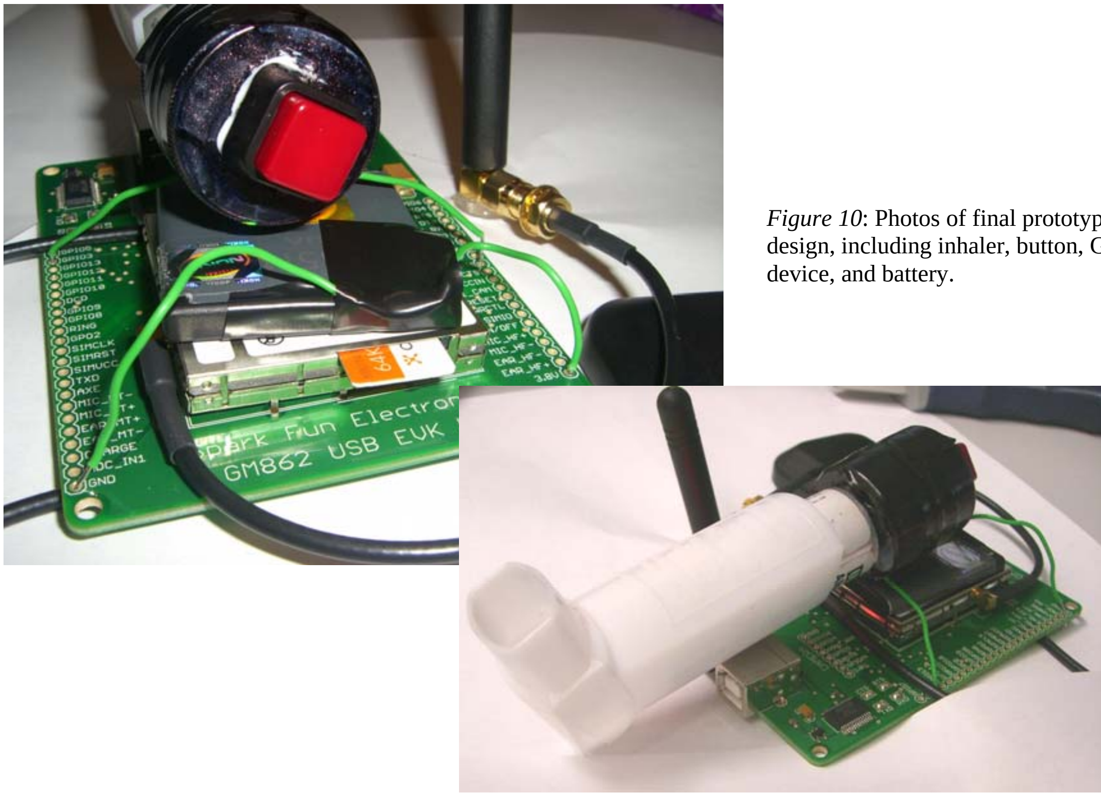


Figure 10: Photos of final prototype design, including inhaler, button, GPS device, and battery.

The final prototype demonstrated a proof of concept of the overall design, and included the ability to retrieve GPS coordinates and use an HTTP request to contact the website. The output of all of the components is a map with the location of the device when the button was pushed (see the Testing section for accuracy information). Each depression triggers an additional mark to be displayed along with the previous ones, so that patterns can be detected by analyzing more than one dosage. Eventually a filtering algorithm will need to be added to the online database to help sort the medication usages and predict symptom outbreaks (see Future Development). The html and php code for several web files can be found in Appendix E, along with the HTTP request sent by the device to the server.

Discussion

The GPS model used for the prototype was powered by a multimeter, until an ideal battery source can be found. The ideal battery will need to be one that was made for a cell phone or other wireless device that can handle rapid changes in current without powering off - a lithium-polymer battery from a regular cell phone did not work for this purpose. This source is also ideal because batteries for mobile devices also tend to have small form factors.

The current prototype has a button secured by hot glue on the top of the inhaler, which was used to prove that the canister will be properly depressed by using a momentary push button. This will need to be modified into a more permanent solution that can be transferred easily from inhaler to inhaler without being pushed unexpectedly in transit.

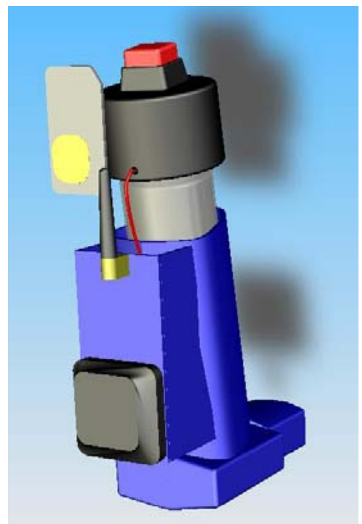


Figure 10: Future vision of prototype

The current design centered on the idea of signal processing by sending signals through the built-in GSM antenna and receiving positioning data from the satellites. Integrating the circuit board and other electronic components together into an attachment of the appropriate size will be the goal in future, including getting a board manufactured that can help to minimize size. Eventually the goal is to come up with a device that is about the same size as the MDILog™ (see Current Devices) but as portable as the Doser™. Figure 10 illustrates this vision.

Cost Analysis

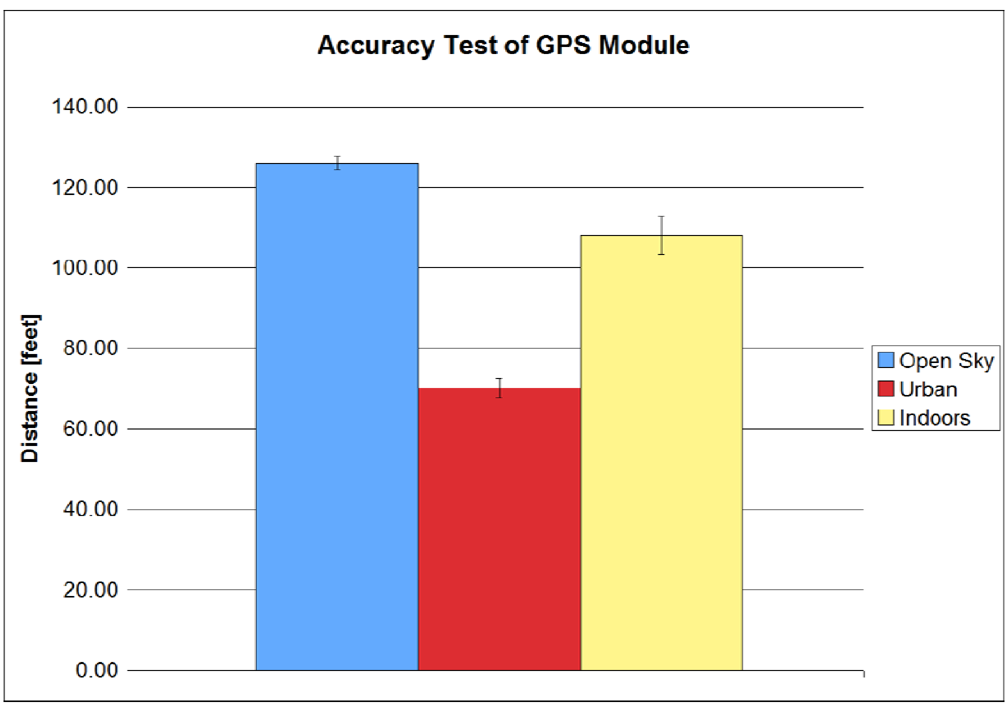
This device had a target mass production cost of about three hundred dollars, which will eventually be dependent on the manufacturing company chosen. A full budget for the prototype can be found below in Table 2. The final design comprised of a prepaid SIM card, used to transmit data, and the GM862 chip module (some earlier purchases were not used in the building of the prototype). The total spent on the device was $315.91, which leads the inventors to be confident that through mass production and buying in high quantities that the final cost will be below the target cost.

Table 2. Cost analysis of how money was allocated throughout the semester

Item Purchased	Function	Quantity	Total Cost
Doser Inhaler	Analyze inhaler with existing timestamp	1	$35.00
Microcontroller Kit	Education of microcontrollers as well as spare parts	1	$149.95
GPS Addition		1	$79.95
Bluetooth Addition		1	$69.95
DC Adapter		1	$8.95
GM862-PCS Kit USB	Uses cellular technology to combine GSM and GPS, and is programmable to send and receive text messages. This device removes the need for a separate cell phone or a Bluetooth adapter.	1	$279.00
Prepaid SIM card		1	$36.91
		Total	**$659.71**

Testing

The prototype was tested for GPS accuracy in order to ensure that coordinates obtained from the GPS unit were precise enough for further statistical analysis. Testing began with the selection of locations that were representative of settings in which the GPS unit would be functioning out in the field. Three locations were chosen to include one in which the GPS antenna had a clear view of the open sky, one in a urban environment with surrounding buildings and sources of interference, and one that was indoors. In each location, a landmark was chosen, and the GPS coordinates for that landmark were found and recorded on a map using Google Earth. Next, ten sample GPS coordinates were obtained at the site of the landmarks using the GPS unit on the module for each location. Distances between the landmark GPS coordinate and that obtained by the module where measured and statistical analysis was performed (see Graph 1).



Graph 1: Test results

In the open sky setting, the average triangulated distance from the landmark was found to be 126 ft with a standard deviation of 1.62 ft. In the urban setting, the average distance was found to be 70.1 ft with a standard deviation of 2.36 ft. In the indoor setting, the average distance was found to be 108.18 ft with a standard deviation of 4.8 ft. All three are within the client-specified accuracy of 200 ft.

The urban setting data produced the lowest error from the actual coordinate, followed by the indoor setting and finally the open sky setting. This result was surprising in that the open sky setting was expected to be the most accurate. One possible explanation for this trend is the amount of time the module is powered up before taking GPS measurements. The open sky data was taken first, so the module had acquired less satellite signals than when the urban and indoor measurements were taken. The amount of time the unit must be warmed up before taking GPS coordinates is an important consideration in the final design; if the coordinates are taken too soon then the measurement won't be as accurate, but too late and the subject could have moved from the position of medication. Further testing must be done in order to determine the appropriate warm up time required. As was expected, the standard deviation of the open sky measurements was the smallest, followed by the urban and indoor settings. The open sky measurements were subject to less interference than the other two, and were subsequently more precise in their repeatability,.

Future Development

The design and prototype created this semester serves as a proof of concept, however, there is considerable room for future work to be done. The work accomplished this semester effectively shows that a GPS module and Bluetooth chipset can be controlled using a microcontroller; this demonstrates that the final design attaching to an asthma inhaler can be used as a device for studying asthma through real patients. There is a copious amount of future work needed to validate and replicate our final design for an addition to the asthma inhaler. The remaining work can be divided into three key goals:

- Miniaturization of current design
- Utilizing mapmakers to help generate real-time images on the website, including web filtering of data to derive patterns
- Clinical testing, in which devices will be given to patients and the accuracy of the tracking will be tested

The next step in the design process would be to improve the current design by finding a circuit board company to miniaturize and refine the current layout. David Van Sickle, the project's client, would like to continue this work by contacting Design Solutions in Madison to create ten small, working prototypes. The immediate goal of this project would be to have a device that looks similar to the one depicted in Figure 11.

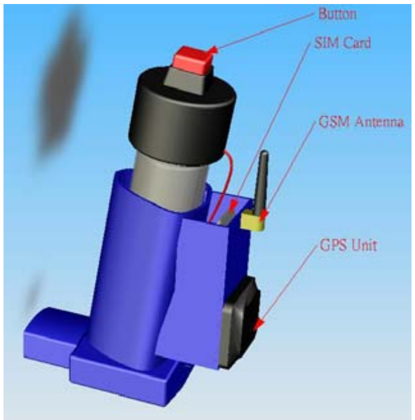


Figure 11: Depiction of ideal aesthetics [Created with SolidWorks].

The device would be constructed using a smaller chipset and only the ports needed to operate. Since the resources to do this are not readily available, this goal can be accomplished with the help of PCB Express. Once ten circuitry boards are printed and available, the chips will be inserted to a hard plastic, sealed casing. This encasing will attach to any medicament canister on the market by means of a flexible plastic tube. There is still a need for extensive research to be conducted regarding which non-allergenic plastics would work best for this application.

In order to accomplish the desired outcome, field tests will need to be carried out. Error testing will be necessary in conjunction with safety/accuracy testing 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.

More research will need to be conducted to obtain a contract with a manufacturing company. There are a few companies that work with small GPS systems and miniaturizing circuitry boards; estimations of large-scale manufacturing for economic production are underway. Given budget constraints, 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. An invention disclosure has been submitted to WARF (see Appendix D) for the protection of intellectual property.

Conclusion

The following goals have been accomplished to this point:

1. The creation of a prototype of an inhaler or an add-on device for existing inhalers that communicates the location where used to a remote data collection system, although this process has not yet been automated to work without human commands.

2. The development of a web-based mapping software and contact with the cartography department to translate that software into real-time tracking equipment.

Overall, the goal of this project so far has been to gain support of local and national institutions and to illustrate that the concept for its design is feasible both regarding cost and technical aspects. With much future work to be done, it is the goal of this team to keep in contact with the client and to concentrate on miniaturization over the summer months.

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[12] *SmartMist™ Product Specifications.* Retrieved February 9, 2007 from http://www.aradigm.com

Appendix A: Product Design Specification

Team Members:

Mollie Lange………………Team Leader
Sammy Bergh……………..Communicator
Mike Alexander……………BSAC
Peter Ma………………….. BWIG

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, but up to 200ft of error is acceptable 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.

US Patent Number 6,958,691

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.

US Patent Number 7,191,777

This is a very similar patent to the one cited above, and remains dissimilar to the design discussed in this paper. A medicament dispenser for use in the storage, presentation and/or dispensing of medicament comprising a body shaped for receipt of a medicament container. In association with the body, there is a first transceiver for transmitting and receiving data. A medicament container is receivable by the body. In association with the medicament container, there is a second transceiver for transmitting and receiving data. Data is transferable in two-way fashion from the first transceiver to the second transceiver. The medicament dispenser may be supplied in kit of parts form.

	Open Sky	Urban	Indoors
	125.95	65.62	104.34
	124.70	68.07	113.31
	125.31	68.73	111.75
	124.85	69.20	112.30
	125.65	70.55	110.57
	123.68	69.46	110.09
	126.38	72.09	108.00
	126.44	73.04	109.94
	127.76	72.82	103.34
	129.34	71.69	98.13
	126.01	70.13	108.18
Std Dev	**1.62**	**2.36**	**4.80**
Std Error	**0.51**	**0.75**	**1.52**

Appendix D: Patent Disclosure as Submitted to WARF 04/24/2007

UW-Madison Invention Disclosure Report Date: April 24, 2007
WARF Case No.

Invention Summary

Title of invention: *GPS-Enabled Asthma Inhaler*

Technical abstract of the invention (or attach a publication or draft).
This will be provided, when required, to sponsoring agencies.

We have created a prototype of an integrated device to be attached to a metered-dose inhaler, that communicates the time, date and location of its use to a centralized server without the use of an external device (i.e cellular phone or pager). The device detects activation of the inhaler using a pushbutton switch, captures the time and location of the inhaler at that point using GPS (Global Positioning System) and GSM (Global System for Mobile Communications) localization, stores that information in memory, and then transmits that information over mobile cellular networks to a centralized database as a text message (SMS).

What makes this invention superior to existing technology?
There are currently no devices available that perform the functions outlined by this invention.
However, US Patent Numbers 7,191,777 & 6,958,691 describe a device similar to our own. Our device differs in several ways, including:
1) *Our device is not a two-way device that can both send and receive data; our primary interest is in sending data*
2) *Our device transmits data using BlueTooth technology rather than infrared*
3) *Our device does not require two separate devices to process and send the data - one chip does both.*
4) *Our goals are to map the location of medication usage, describe patterns of medication use, and reveal statistical anomalies in the time and location of use; the patent cited has the goal of monitoring whether people are taking their medication as directed. Their device, also, in essence, includes a "breathalyzer".*
5) *The cited patent does not mention using a layering map; they give vague comments about a "host computer"*

The invention was conceived of at least as early as:
By David Van Sickle on October 15, 2006

When was the invention shown to work?
The invention is expected to be functional by May 3, 2007.

Inventor Information

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Is any inventor employed by or affiliated with:

	Yes	No
USDA		√
USDA/Forest Products Lab		√
Veterans Administration		√
UW Hospitals and Clinics		√
Howard Hughes Medical Institute		√
Any organization or company other than the UW Madison		√

Funding and Materials

Which federal funds (144-accounts) contributed to making this invention?

	Sponsoring Agency	Grant, Contract or Agreement Number	UW Account Number
Primary			144-
Secondary			144-

(expand as needed for more sources)

Which non-federal funds contributed to making this invention?

Sponsoring Agency	Grant, Contract or Agreement Number	UW Account Number
Robert Wood Johnson Foundation	UW grant proposal #90009; RWJF award #045825	133-FD14

(expand as needed for more sources)

Check if any other agreements are relevant to this invention (list):

Check Here	Agreement Type	Other parties to agreement, and description of agreement
	Material transfer agreement	
	Confidentiality agreement	
	Collaboration agreement	
	Research agreement	
	Consortia agreement or funding	
	Consulting agreement	
	Other	

If none, check here__X__

Have you disclosed this invention to anyone in a non-confidential manner? If so, when and to whom? If not, do you anticipate such a disclosure in the next six months (when and to whom)? *A presentation on the general concept was made to the UW First Look Investor Forum on April 10, 2007. In addition, a mid-semester presentation was made on March 9, 2007, during which the invention was shared in a confidential manner with Biomedical Engineering students and faculty. On May 4, 2007 a presentation of the invention will be made that will be open to the public.* *David Van Sickle submitted a proposal requesting funding for the project, which outlined the invention, to the Robert Wood Johnson Foundation Health and Society Scholars program at the University of Wisconsin, on December 8, 2006. Funds were allocated for the project, and these funds have been used to purchase materials for the prototypes and to cover project expenses. In addition, a presentation will be made on the device at the Robert Wood Johnson Foundation annual meeting on May 3, 2007.*

Name of person completing this form:	Samantha Bergh
Phone:	651.210.6815
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Appendix E: Web Coding

Test.html
This is the file to which coordinates are sent from our device, or input on the website for testing purposes.

```
<!DOCTYPE HTML PUBLIC "-//W3C//DTD HTML 4.01 Transitional//EN">
<html>
<head>
<meta http-equiv="Content-Type" content="text/html; charset=iso-8859-1">
<title>test</title>
</head>
<body>

<table width="890" border="1">
  <tr><td width="420" height="107">
   <form method="GET" action="coordinate.php">
       <input type="hidden" name="create" value="true">
        <table width="257" height="67" border="1">
          <tr>
            <td width="70">Latitude?</td>
            <td width="171"><input name="lat" type="text"></td>
          </tr>
          <tr>
            <td>Longitude?</td>
            <td><input name="lng" type="text"></td>
          </tr>
        </table>
        <p><input type="submit" name="Submit" value="Submit"></p>
   </form>
</body>
</html>
```

Device HTTP request:

http://asthmahq.engr.wisc.edu/coordinate.php?create=true&lat=123456&lng=987654&Submit=Submit

Coordinate.php
Takes the resulting variables from test.html and sends them to the XML file for input into the mapping documents.

```
<?php
if(isset($_GET['create'])){
        echo "Coordinate Created";
        $lat = $_GET['lat'];
        $lng = $_GET['lng'];
$rootELementStart = "<marker ";
    $xml_doc .=  $rootELementStart;
        $xml_doc .=  "lat=\"";
        $xml_doc .=  $lat;
        $xml_doc .=  "\" lng=\"";
        $xml_doc .=  $lng;
        $xml_doc .=  "\"/></markers>";
  $fname="data.xml";
  $f = fopen($fname,'r+');
            $pos=-10;
  fseek($f, $pos, SEEK_END);
                        fwrite($f,$xml_doc);
        fclose($f);
}
?>
```

Data.xml
Acts as the file with web markers for Google Maps to read.

```
<markers>
<marker lat="43.0725944" lng="-89.4134777"/>
<marker lat="43.5186" lng="-89.1234"/>
</markers>
```