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 can be deciphered and help to identify common risk factors in populations. The goal of this project was to create a device that could obtain 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 project was to create a device that could be attached to an inhaler that was capable of communicating the time, date, and location of the inhaler's use to a central online database. 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 patient accounts of 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 included:

1. The creation of an add-on device for asthma inhalers that communicates the time and location when the inhaler was used to a remote data collection system.

2. The development of a database, web-based mapping, and analytic system that can recognize abnormalities and trends in inhaler use.

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.

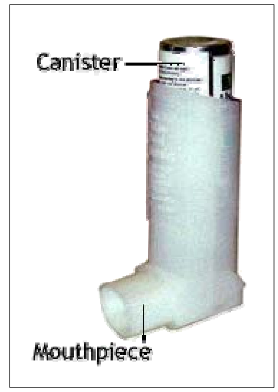

Figure 1. Asthma Inhaler [www.nlm.nih.gov]

The asthma inhaler (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, and the severity of each asthma case is what determines which 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 inhalers and medication canisters is fairly uniform, it was a goal of this project to create a device that could be easily transferred from one inhaler to another, and also allow for medication canisters to be changed easily when they run out.

Global Positioning Systems (GPS)

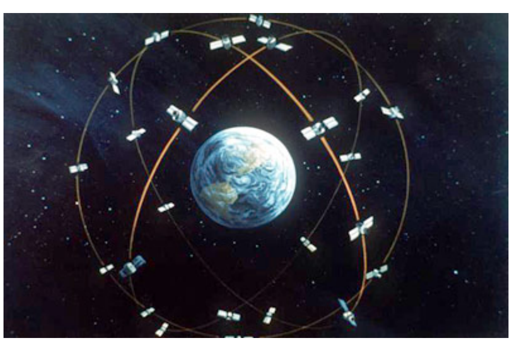

Figure 2. View of GPS Satellites triangulating to gather a longitude and latitude [www.denisduboisag.com]

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

A quick patent search (**Appendix A**) revealed that 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™ (Figure 3). 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.

The SmartMist™

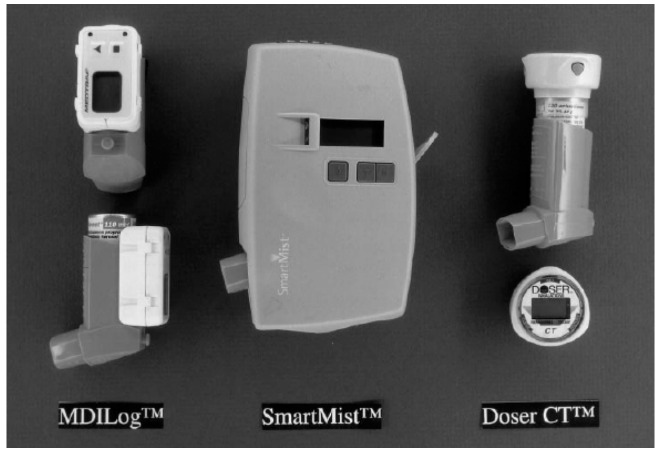

Figure 3. Existing devices on the market; possible competition for our design [www.chestjournal.com]

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:

1. Detect user's administration of asthma medication.
2. On detection, receive and record GPS coordinates as well as date and time.
3. 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 was that any modification could not 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 B**.)

Several different combinations of parts were considered in order to create a prototype including pressure vs. contact detection buttons, utilizing the patient's cell phone to transmit data via Bluetooth technology, and the advantages and disadvantages of different types of microchips. The final design exhibited below took all of these considerations into account and proved to be the most plausible, portable, and reliable system possible, while still meeting the client specifications as laid out in the PDS.

Final Design

The final design specifications revolve around the discovery of a microchip that utilizes the GSM (cell phone) network as well as GPS to triangulate the inhaler's location. This technology will eventually ensure that latitude and longitude can be acquired even while indoors. The GM-862 GPS microchip by SparkFun Technology™ (see Figure 4) not only includes GPS, but also eliminates the need for Bluetooth communication between the device and an external cell phone by incorporating a SIM card in the microchip itself. This ability 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. A flowchart detailing the general movement of data is shown below (see Figure 5):

Figure 4: Sparkfun GM-862 microchip courtesy of http://www.sparkfun.com/datasheets/Cellular%20 Modules/GM862-USB-Eval.pdf

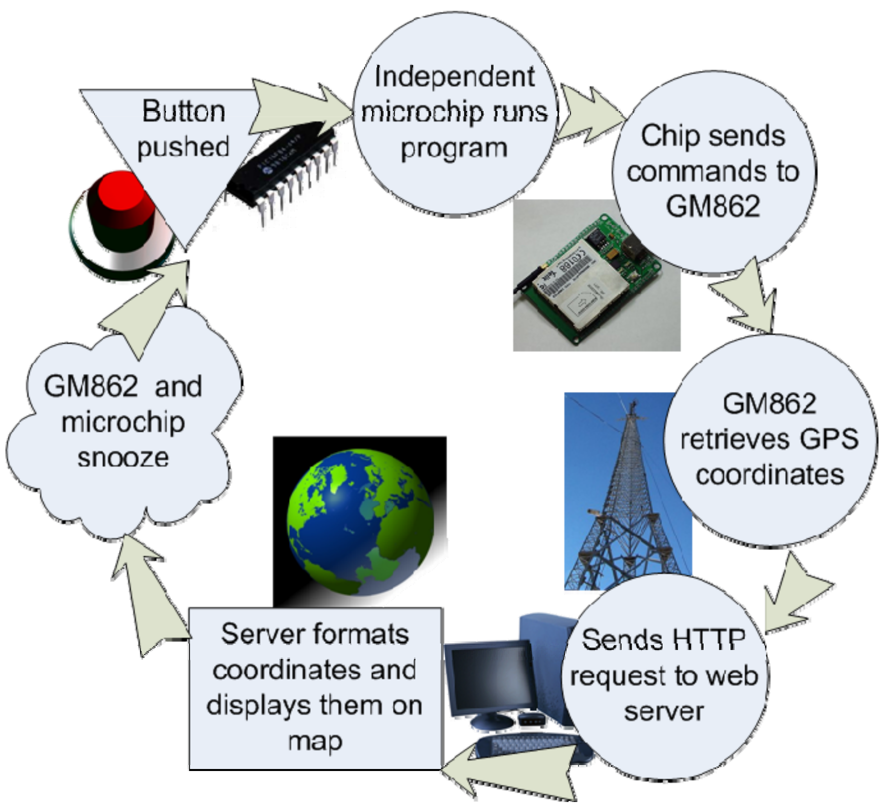

Figure 5: General flow of information through device network

Upon purchasing the GM-862 and testing it with the software program designed to transmit the data, it was found that the microcontroller function was not robust enough to perform its task reliably every time. This was due partly to an error in the native Python scripts as well as to an issue of powering the device, which draws up to two amperes of current when connecting to the cell network and often causes the whole controller to shut down at that time. To remedy these shortcomings, an independent microcontroller was used to control the functions of the GM-862, and all of the components were integrated together by a printed circuit board that also included capacitors, resistors, and diodes to help control power.

The technical aspects of the 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) Microchip 16-F88 PIC microcontroller with 256 bytes of EEPROM data memory as well as the built in 7kb program memory size. This will eventually allow the microchip to store data briefly if the coordinates and other information cannot be immediately transmitted when they are received (bad signal, etc).
3) GM 862-GPS microchip and SIM card reader which can retrieve coordinates via GPS and then transmit them via GSM to the online host.
4) 3.7V lithium-ion power supply that can be recharged similarly to a cell phone.
5) Recharge circuit for the battery.
6) Capacitors, resistors, and diodes to control power flow to the device.
7) Online database system (MySQL) that formats data from the GM-862 and displays them on a map, as well as performing statistical analysis to watch for anomalies in inhaler usage (a screen shot of mapping software with test data is shown in Figure 6.).
8) GPS and GSM antennae which triangulate coordinates for use with the program.

Prototype

Figure 6: Photos of final prototype design, relative to size of average inhaler.

The final prototype (Figure 6) is one of several that will be made in order to collect data over the next semester, and addresses most of the issues that were problematic in the past. Accomplishments this semester included the following, with a detailed description of each point in the following pages:

- Learned Eagle CAD Program
- Created Pinouts andSchematics
- Programmed microcontroller
- Created battery holder and recharge circuit
- Integrated with mapping software

Learned Eagle CAD Program

The EAGLE (Easily Applicable Graphical Layout Editor), from CadSoft Computer, Inc., was used to design the circuit boards. Light Edition is the Freeware version of the EAGLE but has 3 limitations:

- Designable board area is limited to 100 x 80 mm (4 x 3.2 inches),
- Only two signal layers (Top and Bottom) can be edited,
- Only create one sheet can be created by the schematic editor.

These limitations provided more than enough capability for this project.

The Telit Wireless Solutions provided a circuit layout of the GM 862 modules for download into the EAGLE software. Pin locations have been clearly shown in Fig 7.

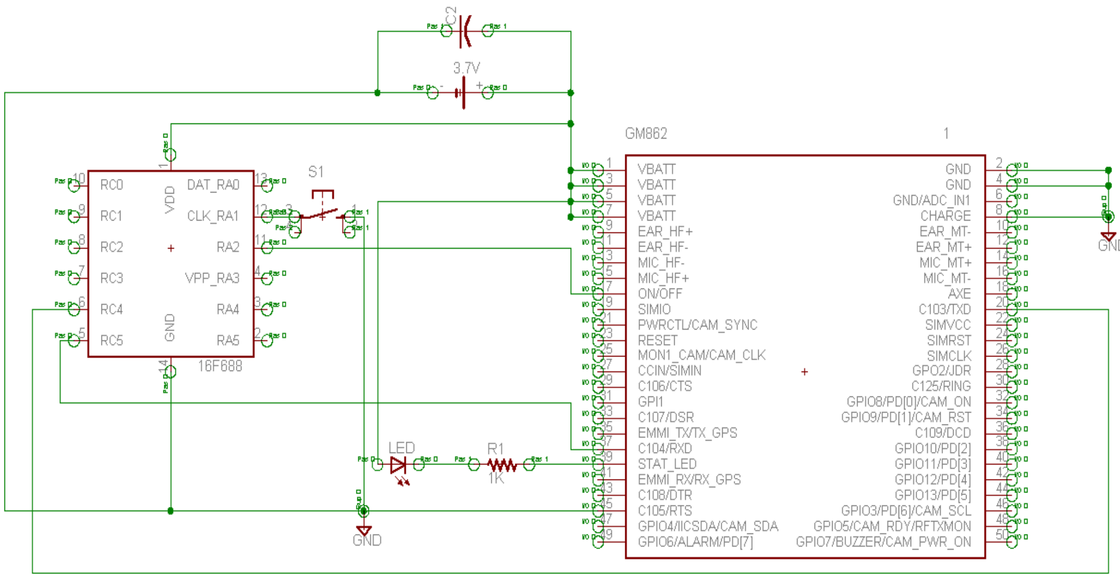

Figure 7: Schematic layout of GM862 and PIC 16f-688 with all pins labeled and other components included.

Not all 50 pins are used in this application, only a few connections were required to allow the GM862 to communicate with all of our devices:

- RX, a communication pin, to RC5 in PIC 16F688
- TX, a communication pin, to RC4 in PIC 16F688
- RTS to ground
- Status LED connects to a LED and a 1K resistor
- On/off to power on the PIC
- VBATT to power source (3.7V Li-ion battery)
- GND and CHARGE are grounded

Created Pinouts and Schematics

The layout editor helps placing the electronic component on a 1.9 X 2.3 inches board. The "Autorouter" function automatically changes all airwires (unrouted electrical connections between pads, Figure 8) into routed tracks. The red and blue lines on the board are the routed tracks on the top and bottom layer of the board respectively. White circles represent through-holes for supporting pins and mounting the board. Green circles refer to solder pads that provide a larger surface area for electronic components to be soldered on. Green squares are via pads which connect the tracks in top layer and bottom layer together.

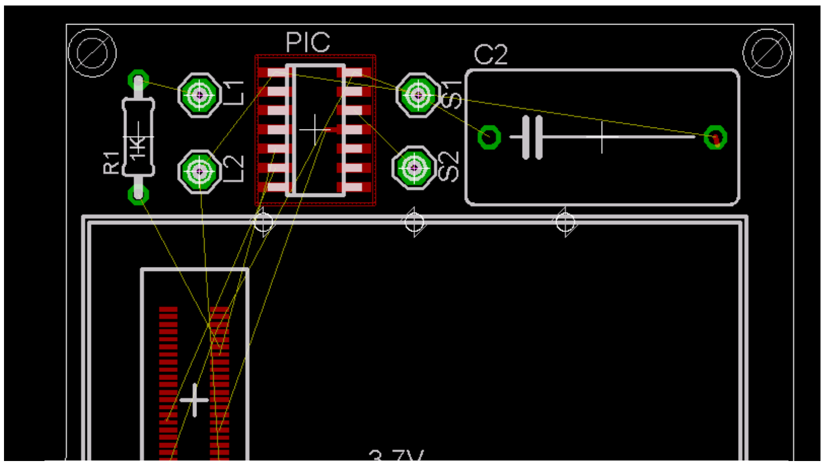

Figure 8: Yellow lines show where airwires occur.

The completed schematic drawing (below) was sent to PCB Express for printing.

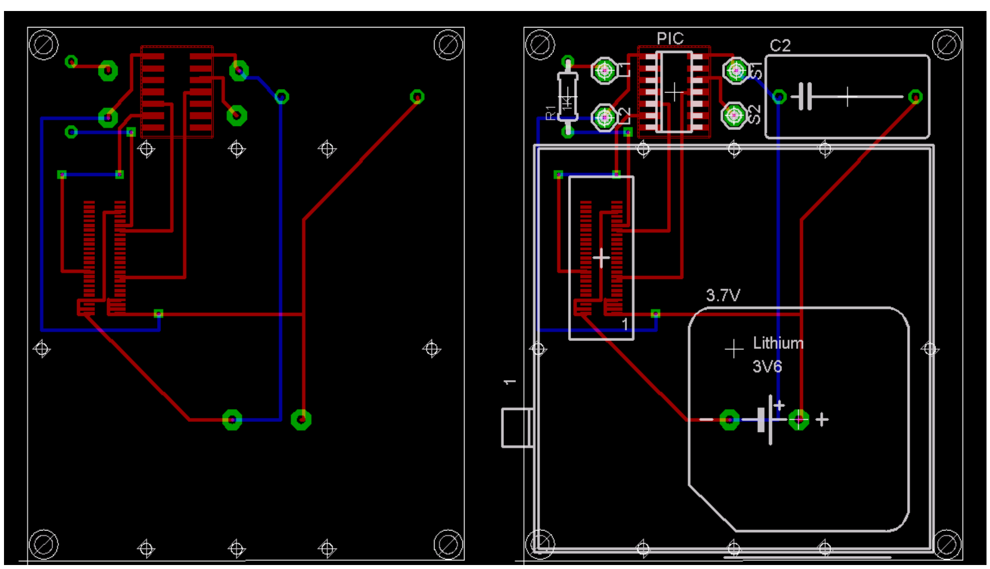

Figure 9: Board layout with circuit (L) and all components (R).

Programmed Microcontroller

The final prototype utilizes a Microchip brand PIC 16F688 microcontroller to detect state changes corresponding to use of the asthma inhaler and to communicate and control the GM862-GPS. The PIC 16F688 (Figure 10) comes with several features that make it an ideal component for the prototype. The 16F688 comes with native serial communication, which is necessary to control the GM862. Furthermore, the microcontroller comes with 4Kbs of onboard memory so it can store the long strings that it acquires from polling for GPS coordinates and the strings it uses to send those coordinates to the database.

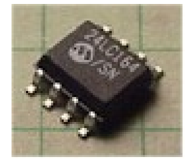

Figure 10:
PIC 16f-688

For debugging purposes, a plastic duel in-line (PDIP) package version of the 16F688 was used that can be easily taken off a breadboard, reprogrammed and put back onto the board. When the program was finalized, a small outline integrated circuit (SOIC) package version of the 16F688, which is significantly smaller, was programmed and soldered directly onto the PCB.

Programming for the microcontroller was performed in BASIC language and converted to machine code with the free-ware compiler, mikroBASIC (http://www.mikroe.com/). The version of the code used to program the prototype can be seen in **Appendix C**. The program can be divided into six primary sections: Declarations, Startup/Interrupt instructions, instructions to receive a GPS location, instructions to check the validity of the revived location, a function to send the location to the database, and Error Checking/debugging directives.

The Declaration portion of the code defines the set-up of the microcontroller; physical pins that control the communication and the various inputs and outputs are reserved so they can be easily invoked in the body of the code. Next, the main function of the code polls the pin connected to the button, looking for the state change that corresponds to inhaler usage. If no change is found, the microcontroller goes to sleep in order to conserve power until it senses a usage.

The microcontroller then runs the “get_location” function, which starts up the GM862 and requests a location fix. The string that gets returned is sent to the “check_location” function that parses the string searching for on of the parameters that indicates a successful fix. If the correct indicator is found, the string is sent to the “send_location” function. Otherwise, the GM862 is continuously polled until a good location is obtained, or the function times out.

The “send_location” instructions first checks if the GM862 is properly registered on the network and then opens up a general packet radio service (GPRS) connection, obtains an IP address, and then connects to a web/database server that was set up to collect the patient data. If all connections are successful, the function then sends an HTTP request that contains coordinates, timestamp, and user ID to a server script that enters the information in to the MySQL database.

The program also contains checkpoints along the progression of the script to check the status of the various connections that have to be made. If an error is found, the script outputs those errors to the debug functions that have been set up so that one can follow the progression of the script and figure out why a connection is failing. Currently not all error checkpoints have been initialized successfully, so the program isn’t fully autonomous. Some work must be done to discern the appropriate timeouts and course of action should a step fail.

Battery Holder

One of the features that was important this semester was the ability for the patient or user to replace the battery without disrupting the circuitry, similar to a cell phone. However, battery holders for 3.7V lithium ion batteries are not available even though they are widely used in portable electronics. Several methods were researched including extracting components from cell phones and utilizing them, but with further research, ShapeLock® was discovered. ShapeLock® is a moldable plastic that becomes putty-like at 160°F. Once molded and cooled, this plastic is heat resistant, waterproof, and virtually indestructible. Additionally, three-prong brass connectors were used to create a reliable contact surface for the battery to power the circuitry. Figure 11 illustrates the resulting prototype.

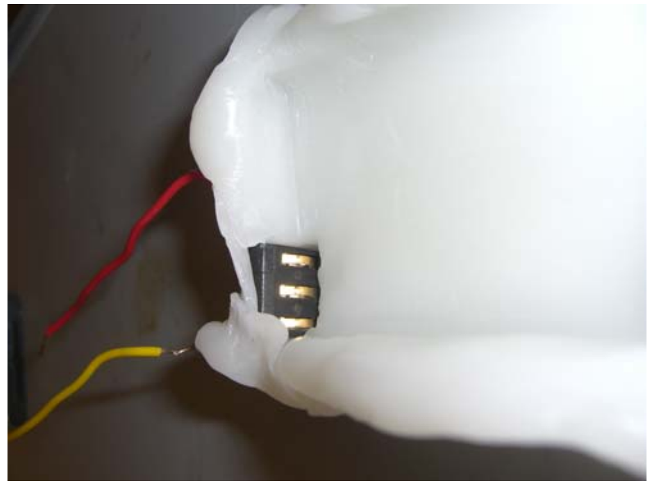

Figure 11: Photo of three-prong brass connector and battery holder molded from ShapeLock®.

Rechargeable Circuit

Another feature that was important was the ability to recharge the battery. In order to prove that this concept was possible, much research was conducted. The research concluded the following:

1. Lithium ion batteries do not have intelligence built into them;
2. Portable electronics are very complex to reverse engineer to gain understanding;
3. This was not within the scope of the project for this semester.

Figure 12:: Photo of Nokia Desk Stand DT-14 from www.nokia.com.

Finally, it was decided that a desktop charger, or battery charger that requires the battery to be removed from the device in powers, would be utilized and incorporated into the design in one prototype. This involved taking apart a Nokia Desk Stand model DT-14 (Figure 12) to remove the internal PCB, which was removed and tested in order to gain understanding of the device. After thorough research, it was concluded that the device regulated battery charging with a series of transistors to ensure that regardless of the duration that the charger was attached, the battery would not be damaged or get hot. Additionally, an LED was used to inform the user of the batteries status; yellow when a battery is charging, and green when the battery is fully charged. Finally, the DC connector jack, LED, and leads were soldered onto the PCB board.

Discussion

The programming this semester was quite exhaustive. Halfway through the semester, it was discovered that the GM-862's microcontroller was not robust enough to handle the code that was required. Using a PIC microcontroller and re-establishing the proper code in a new language successfully ran the GM-862, making the device functional. Additionally, the program was loaded onto the microcontroller and the device became completely wireless for the first time.

A battery powered the GPS model used for the prototype. This power source is ideal because batteries for mobile devices tend to have small form factors. Previously, a lithium-polymer battery did not work due to the transient current spikes that occur while the device retrieves GPS coordinates. However, a combination of capacitors and resistors were found to aid in the regulation of these transient currents and successfully power the device. Now, not only can the device be reliably power with a rechargeable battery, but it has also been ensured that the user can replace batteries as necessary. Additionally, the transient current spikes can be fully regulated.

The current prototype has a button secured by ShapeLock® on the top of the inhaler, which is not only transferable from inhaler to inhaler, but also proves that the canister will be properly depressed by using a momentary push button. This will need to be studied and modified if necessary in order to reduce the number of false positives and accidental activation while in transit.

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 was accomplished this semester. After receiving a manufactured board, which helped to minimize size, it was noted that the GM-862 is too large to decrease the size of the device much further. 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™.

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 1. The final design comprised the listed components, not including one-time purchases that would not be necessary for each device (such as an adapter to transfer the program onto the microchips). The total spent on the device was $254.37, 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 1. Cost analysis of how money was allocated throughout the semester

Item	Cost for four	Cost per prototype
GM862	$ 735.80	$ 183.95
PIC	$ 25.14	$ 6.29
PCB	$ 75.00	$ 18.75
Capacitors	$ 5.20	$ 1.30
Battery	$ 3.96	$ 0.99
Casing	$ 18.86	$ 4.72
Button	$ 4.75	$ 1.19
Molex connector	$ 23.80	$ 5.95
ShapeLock ®	$ 24.95	$ 6.24
SIM cards /service	$ 100.00	$ 25.00
TOTAL PER PROTOTYPE:		**$ 254.37**

Testing

One of the aspects of this project that has not yet been tackled is the testing of prototypes in many different areas, in order to ensure that the safety of the patient and dispensement of medication will not become risk factors during clinical testing. Table 2 shows the testing order that will be followed when one or more working prototypes are ready for distribution.

Table 2: Testing Order

1.	Basic Function Analysis
2.	Accuracy of Coordinate Retrieval
3.	Accuracy of Dosage Detection
4.	Program Execution
5.	Power Regulation Over Time
6.	Durability
7.	Ease of Use
8.	Multiple Coordinate Acceptance of Website
9.	Patient Safety Analysis

I. Basic Function Analysis

This will include repeated tests of function as well as the potential for false-positives that may be sent by the GPS application.

II. Accuracy of Coordinate Retrieval

This test was performed in May but at that time did not meet the specifications of the client or the theoretical accuracy according to the GM-862's documentation. This will be repeated with new components being taken into account, such as the addition of capacitors which may help boost power and increase accuracy. Data from the first accuracy trials can be found in **Appendix D.**

III. Accuracy of Dosage Detection

An analysis of the function of the button and detection of the number of false positives per thousand uses will be performed.

IV. Program Execution

Number of times the device fails to execute the program, based on button inaccuracy, power issues, or loose cords that may cause the device not to recognize an exacerbation or fail to run the program properly.

V. Power Regulation Over Time / Battery Life

A document from Round Solutions suggests the use of a Battery Monitor BM 1000, which includes the functions to estimate remaining capacity, safety monitoring, and battery specific data storage. This monitor is a probe that connects between the battery and the application unit so as to monitor the battery usage. A PC is connected with this probe through a USB connector to achieve information of battery usage (see Figure 13). There is a 25m Ohm internal resistance which is relatively minimal compared to the GM862 application.

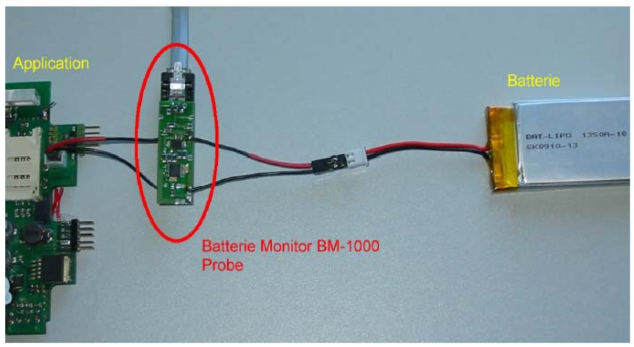

Figure 13: Battery Monitor connects between circuit and battery and enables measurement by connected PC (www.roundolutions.com)

This monitor also works with Li-ion rechargeable batteries. This device consumes very low power (Active: 60µA typically, 90µA maximum; Sleep: 1µA typically, 2µA maximum) and can accurately measure temperature, voltage, and current. Figure 14 shows a screenshot of the accompanying software.

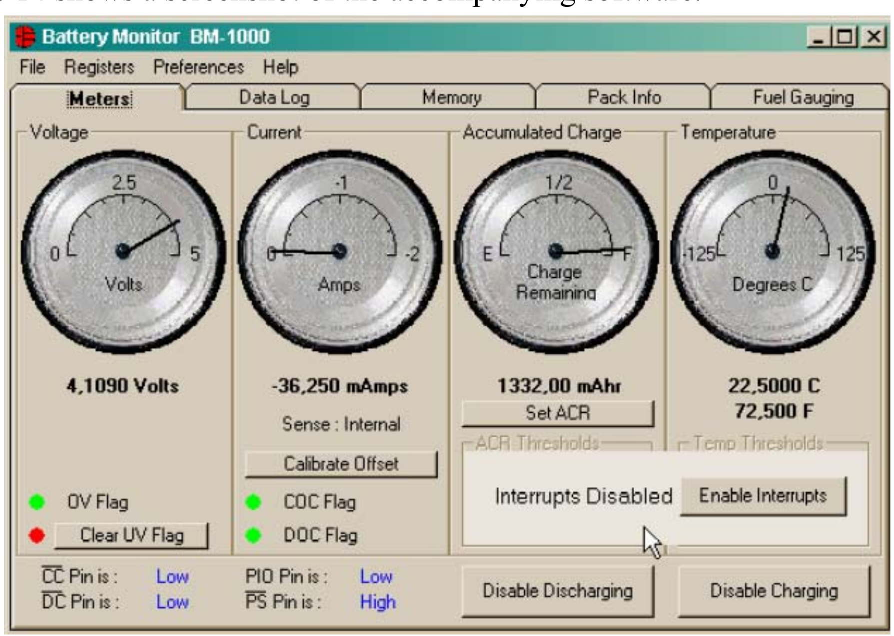

Figure 14: Battery monitoring software from Round Solutions (www.roundolutions.com)

VI. Durability

Waterproof

In order to test the ability of waterproof, all holes should be tightly sealed by proxy. Any liquid entering the case will affect the circuit and fail the device. We have to visually check that the case has no leakage and then immerse the case in water for 5 minutes. Any liquid found inside the case after the immersion is considered as a failure.

Impact

There is a possibility that the patients will drop this device before or after each usage. To ensure the device will not crash or fail to function, a dropping test will be performed. The designed testing method is to have the device dropped from a shoulder (acromion) height at standing posture, which is about 152.4cm (95th percentile of Male Civilian Body). Operate the device after each impact and record the result to see if it still functions well.

VII. Ease of Use

The easiest way to perform this test will be to give the device to a randomly selected population and document any difficulties in operation.

VIII. Multiple Coordinate Acceptance of Website

This issue includes two parts: having more than one coordinate at all, as well as having more than one sent at the exact same time. Both of these have already been successfully tested by adding a second entry to the database via the program, as well as by ensuring that the method of data entry is an HTTP request. This can accommodate far greater numbers of simultaneous hits than will ever be necessary for these studies, similarly to a website being accessed simultaneously in two locations.

IX. Patient Safety

Patient Safety will be tested in conjunction with IRB and FDA approval and will be followed by use of the device in a clinical study.

Future Development

Currently, the most pressing design issue to be worked out is the occurrence of brown-outs during the network connect sequence. When the GM862-GPS attempts to connect to the cell phone network, it searches for a suitable cell tower with a stable signal. Once that cell tower is found, the module boosts the current supplied to the GSM antenna. While only transitory in nature, the current spike can reach upwards of two amps, and can put a tremendous load on the power circuitry. If the module senses it is not receiving the necessary power, it simply shuts-down. Efforts to fortify the power system with additional capacitance have resulted in a moderate success rate, but before the prototype can be handed out to research subjects we must be certain that the prototype can perform autonomously.

Additionally, reliability concerns motivate a modification of the microcontroller's programming. Currently, the prototype will perform all necessary functions if strong GPS and GSM signals are present. Future versions of the prototype must account for the various signal conditions that exist in a real world environment. The program must be able to recognize low-signal, no-connect conditions and take the appropriate course of action to rectify those problems. This could include time delays before retrying a connection, storing good coordinates for later transmission, or simply ignoring an inhalation should the module fail to get the users coordinates in a timely manner.

Once reliability issues have been worked out, additional prototypes will need to be assembled and handed out for testing. This will include the purchase of additional parts and the printing of more PCBs. When enough prototypes have been assembled, and the experimental procedure has been approved by IRB, the GPS enabled asthma inhaler can go out for clinical testing. The last thing to accomplish is a plan for how to deal with intellectual property issues (patent disclosure to WARF can be found in **Appendix E**).

Conclusion

The focus of this project was the creation of a device that could be attached to an inhaler and communicate the time, date, and location of the inhaler's use to a central database, and this was accomplished to the client's specifications this semester. Minor details such as power regulation issues are minimal problems when considering the challenge that this concept presented as well as the broad impact it may have on patient care.

The final prototype (Figure 15) is one of several that will be made in order to collect data over the next semester, and addresses most of the issues that were problematic in the past. To create this prototype the team had to acquire extensive expertise in formerly unknown areas and tackle problems with resolve and timeliness. It was also important to maintain healthy relations with many resources who offered guidance and support throughout the length of the project.

It is with a great feeling of accomplishment for this semester's efforts and confidence in next semester's success that the device below has been presented to the client.

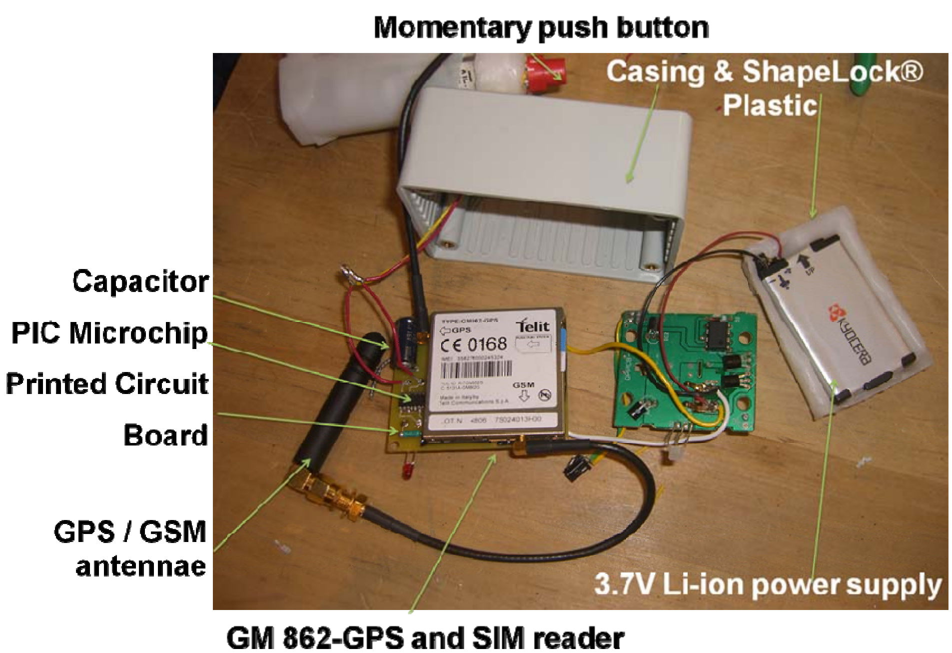

Figure 15: Final prototype with case open and labeled components

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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.

Appendix B: Product Design Specification

Team Members:

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

Function

The aim of our team over the next two 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 interfere).

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 200 ft 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 be either 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. Device 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 more than 3 lbs (must not make use of inhaler difficult for children).

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 that can record the time and date, but not location, of inhaler usage. Current products cannot transmit wirelessly or within a reasonable time span of when the device was actually used.

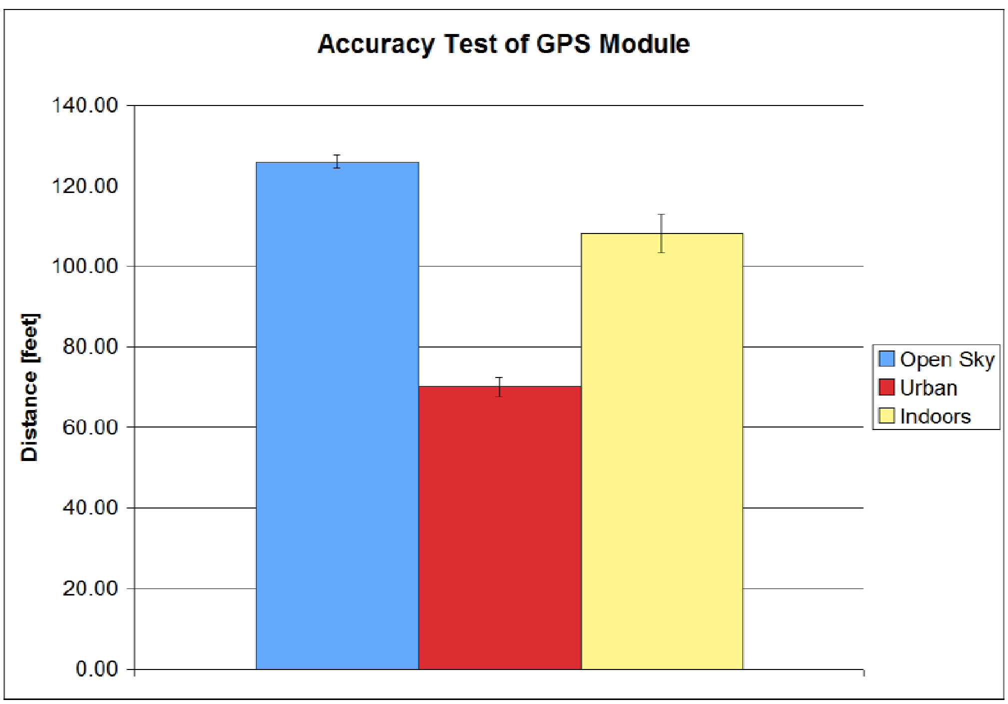
Appendix C: Code Sample

```
program gpsprj

symbol  t_dbg_pin = TRISA.5
symbol  dbg_pin = PORTA.5
symbol  app_pin = PORTA.1
symbol t_app_pin = TRISA.1
symbol  on_off_pin = PORTA.2
symbol  t_on_off_pin = TRISA.2
symbol delaybit = 400

symbol userID = "1"

dim latitude as string[11]
dim longitude as string [12]
dim timeStamp as string[10]

dim resp as string[60]
dim b,got_loc as byte
dim dummy as string[7]

sub procedure dbg_ch(dim ch as char)
dim j,mask as byte

  mask = 1
  dbg_pin = 0
  Delay_us(delaybit)
  for j = 0 to 7
    if ((mask and ch) <> 0) then
      dbg_pin = 1
    else
      dbg_pin = 0
    end if
    mask = mask << 1
    Delay_us(delaybit)
  next j
  dbg_pin = 1
  Delay_us(delaybit)
end sub

sub procedure dbg_str(dim byref st as string[80])
dim j,k as byte

  if strlen(st) > 0 then
    k = strlen(st) - 1
    for j = 0 to k
      dbg_ch(st[j])
    next j
  end if
end sub

sub procedure dbg_ln(dim byref st as string[80])
  dbg_str(st)
  dbg_ch(10)            'line feed
  dbg_ch(13)            'return
end sub

sub procedure dbg_ln_in(dim byref st as string[80])
'  dbg_str("<I>")
  dbg_ch("<")
  dbg_ch("I")
  dbg_ch(">")
  dbg_ln(st)
end sub

sub procedure dbg_ln_out(dim byref st as string[80])
'  dbg_str("<O>")
  dbg_ch("<")
  dbg_ch("O")
  dbg_ch(">")
  dbg_ln(st)
end sub

sub procedure get_resp(dim tout as byte)
dim ch as char
dim cnt as integer
dim tlimit,slen as byte

  cnt = 0
  tlimit = 0
  slen = 0
  resp = ""
  while TRUE
    if Usart_Data_Ready = 1 then
      ch = Usart_Read
      if (ch = chr(13)) or (slen = 48) then    'limit string
to 48 chars
        exit
      else
        strAppendSuf(resp,ch)
        slen = slen + 1
      end if
    else
      delay_ms(1)
      cnt = cnt + 1
      if cnt = 1000 then
        cnt  = 0
        tlimit = tlimit + 1
        if tlimit = tout then
          resp = ""
          exit
        end if
      end if
    end if
  wend
end sub

sub procedure power
    on_off_pin = 0
    t_on_off_pin = 0
    Delay_ms(1200)
    t_on_off_pin = 1
end sub

sub function checklocation as byte
    if (strlen(resp)> 42) then
    result = 1
    else
    result = 0
    end if
end sub
```

```
sub procedure send_command(dim byref st as
string[100])
  dim ch as char

  while Usart_Data_Ready = 1          'clear receive
buffer
    ch = Usart_Read
    Delay_ms(10)
  wend
  Usart_Write_Text(st)              'send command
end sub

sub procedure getlocation
dim cnt as word
    resp = "AT"
    dbg_ln_in(resp)
    resp = "AT"+Chr(13)
    send_command(resp)
    get_resp(5)
   dbg_ln_out(resp)
    if (resp[0] <> "0") Then
       exit
    end if
    Delay_ms(20)
    resp = "AT$GPSACP"
    dbg_ln_in(resp)
    resp = "AT$GPSACP"+Chr(13)
    send_command(resp)
    get_resp(5)
  dbg_ln_out(resp)
  resp="GPSACP:
080220.479,4542.82691N,01344.26820E,259.07"
    got_loc = checklocation
    if got_loc = 1 then
    longitude = "good loc"
  dbg_ln_out(longitude)
       timeStamp = ""
       for cnt=8 to 17
         strAppendSuf(timeStamp,resp[cnt])
       next cnt
   dbg_ln_out(timeStamp)
       latitude = ""
       for cnt=19 to 29
          strAppendSuf(latitude,resp[cnt])
       next cnt
    dbg_ln_out(latitude)
       longitude = ""
       for cnt=31 to 42
          strAppendSuf(longitude,resp[cnt])
       next cnt
    dbg_ln_out(longitude)
    end if
end sub

sub procedure sendlocation
dim conn,cnt as byte

'    dim gprs_con=0,skt_con=0, send_con=0, i=0 as
byte

    conn = 0
    cnt = 0
    Delay_ms(100)
    while (conn = 0) and (cnt < 10)
      resp = "AT+CREG?"+Chr(13)
      dbg_ln_out(resp)
      send_command(resp)
      get_resp(5)
      dbg_ln_in(resp)
      dummy = "0,1"
      if (Strstr(resp,dummy) <> $FF) and (Strlen(resp)
<> 0) then
        conn = 1
      else
        Delay_ms(5000)
        cnt = cnt + 1
      end if
    wend
    if conn = 0 then
      resp = "No network"
      dbg_ln_out(resp)
'      exit
********************************
    end if
    cnt = 0
    conn = 0
    Delay_ms(100)
    while (conn = 0) and (cnt < 5)
      resp = "AT#GPRS=1"+Chr(13)
      dbg_ln_out(resp)
      send_command(resp)
      get_resp(30)
      dbg_ln_in(resp)
      dummy = "+IP"
      if (Strstr(resp,dummy) <> $FF) and (Strlen(resp)
<> 0) then
        conn = 1
      else
        Delay_ms(5000)
        cnt = cnt + 1
      end if
    wend
    if conn = 0 then
      resp = "GPRS failed"
      dbg_ln_out(resp)
'      exit
***************************************
    end if
    Delay_ms(100)
    resp =
"AT#SKTD=0,80,"+Chr(34)+"asthmahq.engr.wisc.ed
u"+Chr(34)+",255"+Chr(13)
    dbg_ln_in(resp)
    send_command(resp)
    get_resp(30)
    dbg_ln_out(resp)
    dummy = "1"
    if Strstr(resp,dummy) = $FF then
      resp = "No socket"
      dbg_ln_out(resp)
'      exit
*****************************************8
    end if
```

```
   Delay_ms(100)
   resp = "GET /add.php?Timestamp="
   Usart_Write_Text(resp)
   Usart_Write_Text(timeStamp)
   dbg_str(resp)
   dbg_str(timeStamp)
   resp = "&Lat="
   Usart_Write_Text(resp)
   Usart_Write_Text(latitude)
   dbg_str(resp)
   dbg_str(latitude)
   resp = "&Long="
   Usart_Write_Text(resp)
   Usart_Write_Text(longitude)
   dbg_str(resp)
   dbg_str(longitude)
   resp = "&SubjectID="
   Usart_Write_Text(resp)
   dbg_str(resp)
   resp = userID
   Usart_Write_Text(resp)
   dbg_str(resp)
   resp = "&Submit=Submit
HTTP/1.1"+Chr(13)+Chr(10)
   Usart_Write_Text(resp)
   dbg_str(resp)
   Delay_ms(100)
   resp = "Host:
asthmahq.engr.wisc.edu"+Chr(13)+Chr(10)+Chr(13)+
Chr(10)
   send_command(resp)
   dbg_str(resp)
   get_resp(30)
   dbg_ln_in(resp)
end sub

'sub procedure sendlocation()


main:
  OSCCON = 0x60          '4MHz clock
  CMCON0 = 0x07          'compaator off - PORTA
digital
  OPTION_REG = 0x0B
  ANSEL = 0              'PORTA all digital
  WPUA.1 = 1             'weak pull up on PORTA.1 -
switch
  b = PORTA              'clear port change flag
  INTCON.RAIF = 0
  INTCON.RAIE = 1        'enable port change
interrupt
  IOCA.1 = 1             'enable RA1 change interrupt
  t_app_pin = 1          'switch input
  t_dbg_pin = 0          'debug output
  dbg_pin = 0            'debug off
  Usart_Init(2400)
  while TRUE
      sleep
      power              'module on
      dbg_pin = 1
      Delay_ms(1000)
      got_loc = 0        'no gps location
      getlocation
      if got_loc <> 0 then
        sendlocation
        Delay_ms(1000)
      end if
      power              'module off
      dbg_pin = 0        'debug off
      b = PORTA          'clear change flag
      INTCON.RAIF = 0
  wend
end.
```

	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**



Graph 1: Test results

Appendix E: 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.

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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.

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