Ophthalmic Dose Compliance Monitor

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Abstract

It has been proposed to design and miniaturize an ophthalmic dose compliance monitor. The monitor will measure patient compliance by recording each time an ophthalmic dose is administered. The device will do this by sensing when the cap of the bottle has been removed and when the bottle has been rotated past 180 degrees. The current device must be miniaturized and discretely placed on the outside of a medication bottle. A data transfer system must also be incorporated into the device so that each recording of the date and time of administration will be displayed on a computer for study.

Problem Statement

Our objective is to develop and miniaturize a dose compliance monitor that would record (unknown to the client) when (date and time) a topical ophthalmic medication was delivered. There are currently older designs of compliance monitors designed for ophthalmic medications, but our design should be a cost effective, improved model (16,17,18). Ideally we would be able to manufacture approximately 10 of these devices for use in studies. It could be as simple as some of the older models that recorded when the top of the bottle was removed and the bottle was inverted. Maintenance of sterility of the medication is imperative.

Motivation

The purpose of building a dose compliance monitor is to determine how accurately patients follow prescription orders given by their physician. Ophthalmic medication is often prescribed for a duration of 4-6 weeks. Our client, Dr. Murphy, would like to know how compliant pet owners are in order to determine the most effective treatment plans possible. For instance, if compliance is found to be low our client may elect to perform surgery on the animal's eye rather than waiting 4-6 weeks to discover that the medication was not administered properly and the animal's health has decreased. Many diseases of the eye need to be cured as soon as possible before irreversible damage occurs. Our client is trying to determine how he can best treat his patient's.

Client Requirements

The ophthalmic dose compliance monitor's most important client requirement is that it be able to record the date and time of each administered dose. The device, which will be located on bottle, must be discrete so that the user does not know it is located on the bottle or alter their dose administrations. In order for this to happen, the monitor needs to be less than 25.4 mm in diameter to fit on the bottom of the medication bottle. The device must maintain the sterility of the medication. In order to do this, no part of the device can touch the inside of the cap or bottle. This client requirement is important because of the legal action that could be taken against him if harm was caused after the administration of medicine from a bottle with our device on it. Also, in order for the client to use the information, the administered dosage data must have the ability to be transferred and displayed in a logical format on a computer. Finally, our client would like the price of each bottle to be one hundred dollars or less.

Background Information

This project was initiated in the fall of 2005 by a previous group of biomedical engineering students. As our group began to move forward from their progress we had to do much research. We were given a breadboard containing a circuit which would record the date and time of a dose if the circuit registered that the bottle cap had been displaced and the bottle had been rotated past 180 degrees. The circuit contains many elements which needed to be thoroughly researched so that our group could understand what work had already been completed. A schematic of the circuit can be seen in Figure 1.

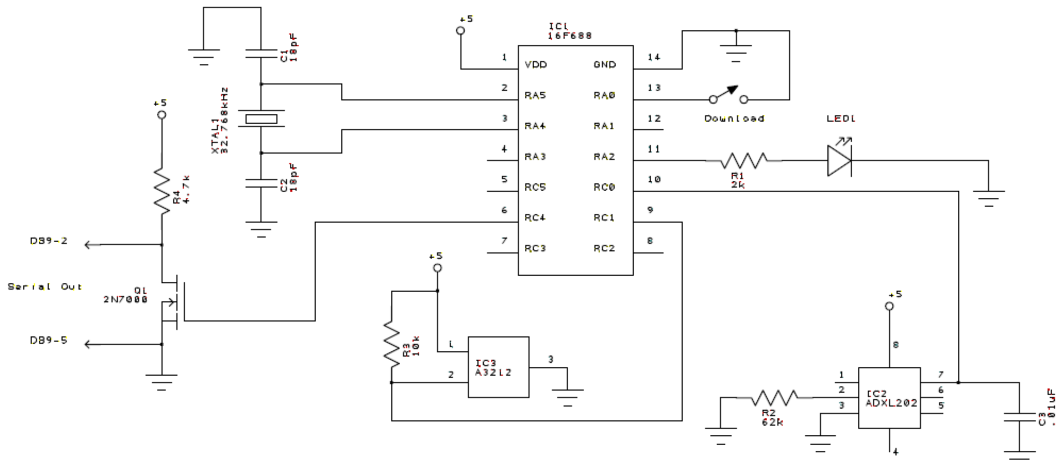

Figure 1. Schematic of dose compliance circuit (1).

Microprocessor

The element in the circuit that records and stores the data for each administered dose is the PIC 16F688 I/P microprocessor. A microprocessor is essential to the project as it is the part that integrates the signals from the sensors located on the eye drop bottle and decides when a dose has been administered. The microprocessor is programmed to store information if and only if it receives both an input for cap displacement and bottle tilt. This specific processor has a memory which is able to store 256 bytes. This low power microprocessor has 14 pins which connect to the power supply, ground and various other circuit inputs, including the sensors which indicate that the cap has been displaced or that the bottle has been rotated. A visual of the microchip is shown in Figure 2. (2)

Figure 2. Photograph of a PIC microchip (2).

Magnetic Sensor

The ophthalmic dose compliance device needs to monitor the times that the cap has been removed from the bottle to accurately determine when the medication is applied. The magnetic sensor accomplishes this goal by utilizing the Hall Effect. This principle explains that when current is placed into a magnetic field, voltages are produced at right angles to both the current and magnetic field vectors. The "Hall" sensor that has been chosen is the A3211 Magnetic Field Sensor produced by Alegro. The sensor is shown in the figure below (Figure 3) and is only two by two millimeters, a size small enough to be discretely hidden on the medication bottle (3).

Figure 3: Magnetic sensor appearance (3).

The actual sensor will be placed slightly below the cap of the bottle, on the exterior surface of the bottle. The magnet that will provide the magnetic field will be located directly above the sensor on the cap. The sensor monitors the cap being on and off by providing an output voltage of approximately five volts when the sensor is not in the presence of a magnetic field. When in the presence of a magnetic field, the sensor does not produce an output voltage. The magnetic field that needs to exist to register a "cap on" reading is approximately 37 Gauss (3). The magnet used in last year's testing had to be about 1 cm away from the sensor in order to register a "cap off" reading. Once the PCB prototype is constructed, tests will have to be conducted to explore how far away the magnet must be from the sensor in order to induce a signal.

Power Source

The current circuit has been tested using a standard electrical outlet. The previously mentioned battery was not chosen as the final battery for our design because it was determined to be too large. The PCB final prototype will have to be independently powered as the bottle will not be attached to anything. For the battery to power the dose compliance monitor we will use a 3V Lithium Coin Cell from Panasonic with capacity 120mAh as seen in figure 4. We have both 12 mm and 16 mm coin cell batteries to test as well as 12 mm and 16 mm, as seen in figure 5, surface mount coin cell holders to be mounted underneath the bottle that has diameter 25.4 mm. The BR Series Lithium battery provides stable voltage discharge for low drain devices and can operate at temperatures between -30 and 80 degrees Celsius.

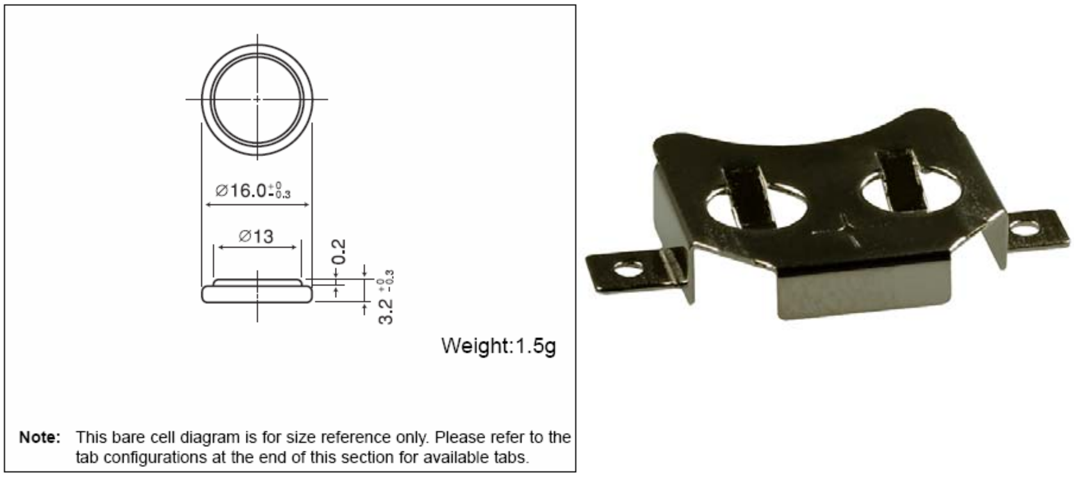

Figure 4: The coin cell battery on the left, and the coin cell battery holder on right. (20,21)

Data Transfer Options

An important component to our design is the data transfer from the device to a computer. The current method of receiving data from the device is to use a serial cable. This was ideal for the large circuit from last semester since two leads could be placed easily into the breadboard and then the serial cord could be placed into the serial port on the computer. However, for our miniaturized design, this may not be ideal. For this reason, we have come up with two other options of data transfer. These two options are RFID and Free-Space optics, both of which are wireless. All three of these options will be discussed in greater detail in the following sections.

Data Transfer Option #1: Serial Cable

The serial cable has already been implemented in the design. It is a serial cable that will fit into a 9-pin serial port on a computer. This port is pictured below in figure 5. If the computer or laptop being used does not have a serial port (as some of the newer laptops do not) it is not a problem. A USB connection piece would need to be purchased to connect the serial cable to the computer. The serial cable/port way of transferring data has been around for decades. The older serial cables send data at about 1,920 bytes/sec and the newer cables send data at about 11,520 bytes/sec. Since our microprocessor only holds 256 bytes of data, this cable will transfer the data very fast (in approximately .13 seconds). (5)

Figure 5. This figure above shows the serial port (we will be using the 2 smaller 9-bit ports on the bottom) (5).

There are a few pros and one large con that this particular design option presents. The major pro is that it has been previously implemented in the design, and so the computer program on the microprocessor and the computer will not need to be altered. It also has a very fast transfer time and is very inexpensive, only about $10 and this would be a one time cost (6). The major drawback to this design is that placing two leads from the serial cable to the miniaturized circuit will be very difficult. Dr. Murphy will be acquiring the data from the device, and this process should be relatively simple and easy. We feel that this option, which is being used currently, could be improved on.

Data Transfer Option #2: RFID Data Transmission System

For our second design option we decided to set up a Radio Frequency Identification (RFID) transmission system. RFID is a simple technology that allows for the transfer of information wirelessly. There are two basic components to the RFID system: the RFID tag and the RFID reader. The tag stores information while the reader scans and retrieves the information from the tag. By placing a tag onto our bottle we should be able to simply and wirelessly transfer the information from the bottle to the reader which will be connected to a computer for data viewing.

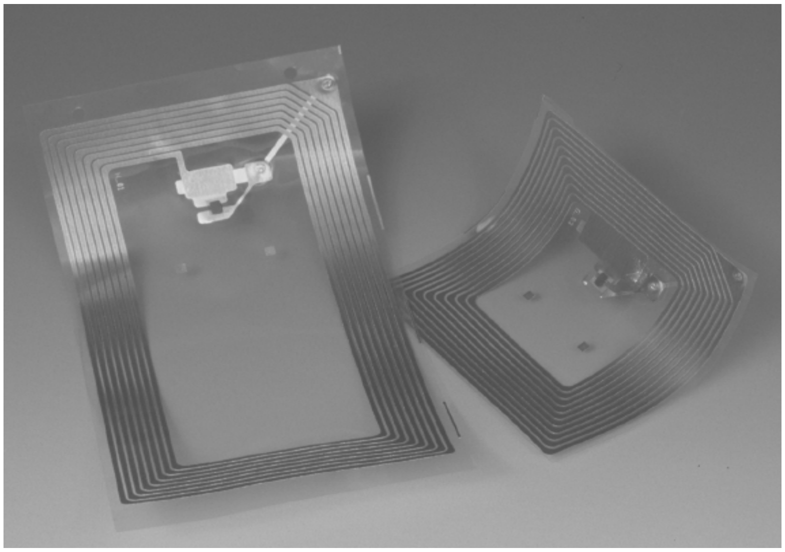

Figure 6. Shows a paper-thin version of an RFID tag. Generally one side of the tag is sticky so it can be adhered to a surface (7).

RFID tags come in a variety of shapes and sizes, some tags can be as large as a small cell phone, while the smallest can be made into .25 mm^2 (I). This would allow us a variety of options and styles so we could find a tag that best fits our needs, although a small tag will most likely be easier to hide than a large tag. In addition to the size of RFID tags, tags have the option of being passive or active. Active tags are generally slightly larger, but can carry more information and can transmit data further distances. Our target distance is approximately three feet. Passive tags do not store as much information, and have limited transmission distances, but do not require the use of battery power like an active tag does. Hence, by using a passive tag we can increase the longevity of our battery and thus record information for longer periods. Our target longevity of the powered circuit is approximately three weeks. Passive tags also allow information storage up to 256 kb, more than 1000 times the storage capacity of the PIC 16F688 I/P microprocessor used in our circuit (7).

A large appeal to the RFID data transmission system is not just its size and data storage, but the overall cost of the RFID tags. RFID tags are remarkably cheap, with companies offering tags for as little at $0.07 per tag when purchased in large quantities (generally 1000 or more). The cost of a reader for a RFID system has a broad range. Readers can be found for as little as $40 or as much as $3000 dollars, depending upon the data transfer speed, distance, power and ease of use. The cost of a reader would be a one time purchase, as only our client would need to have one (8).

Although RFID data transmission sounds simple enough, it will involve some complications to our circuit. One of the largest complications it will bring will be its compatibility with the microprocessor. Completely relying upon the RFID memory to store the data from the sensors could go along with this option

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Data Transfer Option #3: Free-Space Optical Transmission

For our third design option we proposed a Free-Space Optical Transmission (FSOT) system. FSOT is currently used by NASA and the military to transmit information over long distances quickly and efficiently, generally using laser and UV light. FSOT operates by representing digital information (a sequence of 1’s and 0’s) as a sequence of flashing light. By turning the light on, it represents a 1, by turning it off it represents a 0. By doing this extremely quickly (as quickly as 10 MHz) one can achieve information transfer as quickly as 10 Mbytes per second. This light display is received and translated back into basic digital information by an optical receiver. The optical receiver (Figure 7) can then be plugged into a computer to create a virtual wire between the light source and computer (9).

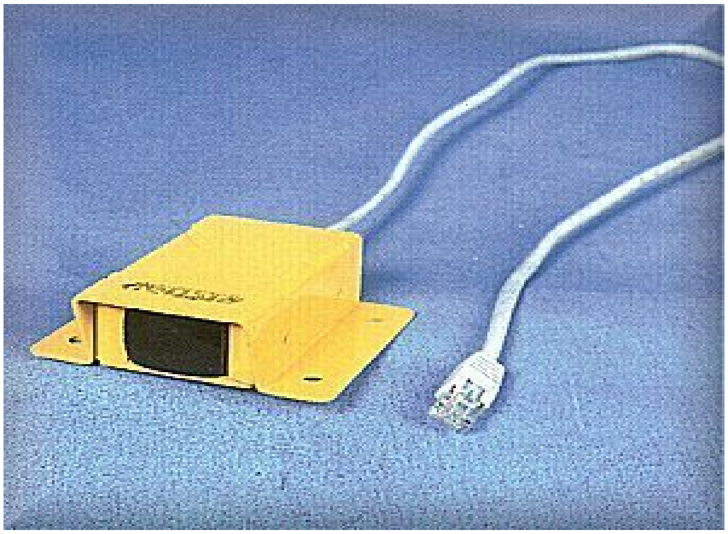

Figure 7. An optical transmitter with Ethernet connection for a computer link (10).

For our design, a simple LED light will be utilized as the light source. This will allow for relatively fast transfer of information (remember only 256 bytes has to be transferred) while keeping power use down. Although using LED light will not allow for long distance transfer of information, by placing a LED on the bottle we will be able to transfer the information up to 100 cm from the optical receiver or by placing the bottle in a dark enclosure containing the optical receiver. This will minimize interference by room lights or other light sources that may interfere with the data transfer (10).

The cost of this design is inexpensive, with LED lights costing $0.20 per light and $90 for the optical receiver (10). Although many LED lights will have to be purchased; only one receiver will need to be purchased.

A large disadvantage to this design is in its integration into the bottle and circuit. Not only would the LED light need to be integrated into our circuit, but the LED would have to be cleverly disguised on the bottle so that the client's subjects would not be aware of the change in the bottle. This would be difficult to do because a LED light is not a common object to neither find nor hide on an ophthalmic bottle.

Mid-Semester Design Decision

Our group analyzed each of the three design decisions by ranking each one on the same categories. The categories were chosen based upon the client requirement and each designs ease of use by the client as well as ease of implication. Rankings were given on a scale of 1-5 with 5 being good and 1 being poor. Table 1 shows a decision matrix of each category followed by the design rankings. Each category was decided to be of equal importance and therefore was weighed equally. This was done because no one parameter was stressed by our client and no one parameter would make the design unusable.

Our group decided to move forward with the RFID design. We chose this design as it received the most points in the decision matrix. Some characteristics that set this design apart were its size and ease of use by our client. The transmission of this data is wireless and does not require our client to hook up any leads to the circuit itself. The small size of the RFID tags will be important as the entire device must be hidden on the bottle. Our group will now move forward with our project with continued work on the circuit and integration of an RFID transmission system into it.

	RFID	**Optics**	**Serial Cable**
Cost	5	5	5
Ease of Use	5	4	1
Transfer Speed	5	5	5
Difficulty	4	3	5
Size	5	3	5
Total	**24**	20	21

Table 1. Decision matrix with design rankings based on a scale of 1-5, with 5 being the best ranking.

Mid-Semester Decision Revision

Initially we intended our project to posses Radio Frequency Identification (RFID) information transfer capabilities. This would allow the client to transfer the information wirelessly in a very simple manner, making the design useful and efficient. Due to the brevity of the project time and the desire to create a prototype, we determined that it would not be feasible to build a working prototype using the RFID technology. After some research into the RFID technology system, it was determined that we would have to integrate an entirely different circuit into our already existing circuit. This would have taken an extraordinary amount of time; especially because the RFID technology is not a field any of us have any experience in.

We feel that RFID is still an extremely great alternative to the current transfer of data. In the future, with more time and resources, we feel that it would be a beneficial information transfer system for our prototype, and that it should be pursued if possible. The benefits of having a wireless transfer system are not only contained in its simplicity of transfer, but also within its ability to be disguised yet still functional. With an RFID tag on the bottle, and a proper reader, the client would be able to transmit the information from the patient without ever having to plug any wires in, and thus would be able to transmit the data without patient knowledge right in front of the patient.

If RFID transfer were to be pursued, a proper tag and transponder would have to be acquired. Tags are simple and cheap to find, but proper readers can cost considerably more. Any person wishing to add this to our design would have to design a pathway for the RFID tag to be integrated into the circuit, and also determine a way to store the information properly so that a successful transfer of the information would be possible. After a transponder was purchased and proper software installed, transfer should be relatively easy.

Current Data Transfer

Serial Port and Excel

After data has been collected over a period of time by the microcontroller, it has to be transferred to an easily understood format that is user friendly. Because we are in the process of finishing fabrication of the PCB board and we have yet to record data with the miniaturized design, the following is a step by step procedure of how the data is transferred from the larger circuit prototype.

The cable that connects from the circuit to a personal computer contains two open conductors on one end and a 9 pin female D-sub connector on the other end. The D-sub connects to a data serial port located on the user's personal computer. If the user does not have a data serial port, various converting cables can be purchased in order to fit the computer's connective ports, such as a serial to USB converter. Conductor 1 is soldered into pin 5 of the D-sub connector and conductor 2 is soldered into pin two of the D-sub. Both conductors are physically inserted into the circuit at the locations specified in the schematic of the dose compliance circuit.

Once the serial data port is attached and the conductors are in the correct locations, the user should open Excel on their computer. An Excel program was created specifically for the task of displaying data points and times of dose administrations for this project. When the program opens, a box is displayed requesting the time that the user would like to use as their starting point for observation. Figure 8 illustrates this.

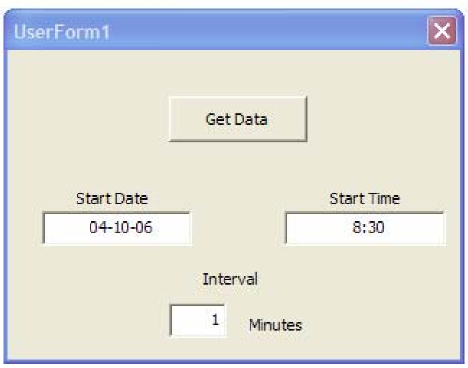

Figure 8: User input entry box that displays in Excel when the administration display program is opened.

The user inputs the observation start date in the mm-dd-yy format and the specific time that the medication was given to the patient formatted as shown in figure 8. The user can also specify the time interval between observations that is displayed in the Excel data. It is important to note that the current prototype does not contain an internal clock. The result of this is that whatever time is entered into the “Start Date” and “Start Time” becomes the reference time that the microcontroller started receiving power. For example, say the microcontroller was turned on at 12:30 pm, medication was delivered at 12:35 pm, and data was transferred at 12:40 pm. If the user entered in 9:00 pm as the start time, the microcontroller would report that one dose was administered at 9:05 pm on whatever date that the user entered. This could be a potential problem and future prototypes should definitely try to incorporate an internal clock to ensure the data is always accurate. Currently, if the program user just records the time that the medication was given to a patient (the person that will be administering the medication), and enters this time and date into the initial inputs, the accurate times will be recorded and displayed. This solution is reliable and achieves the goal of finding out when medicine was taken, but could be improved upon.

After the user enters the desired starting date, time, and time interval, they will click on the “Get Data” button and a “Waiting…” message is displayed in the previous box. Figure 9 shows what the user will see while using the program.

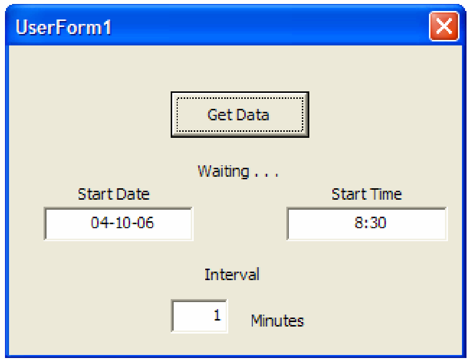

Figure 9: The box that is displayed after the user has input the desired information and clicked the "Get Data" button.

While the computer is waiting to receive the data, the user must inform the microcontroller to send its stored information via the conductors to the serial port. To do this, the user connects a switch by inserting a wire at a specific location in the circuit for approximately 1 or 2 seconds, completing a loop and telling the microcontroller to send its stored data once. The location of where this wire is located and inserted is shown in the circuit schematic and is labeled with a switch that says "Download" beneath it. For the PCB prototype and future work, the method for inserting the wire will be done by a switch and all the user will have to do is press a button and the data will be sent.

The data is transferred in approximately one or two seconds and upon completion of transfer a box is displayed with the message "Data has been received". The user will click the "OK" button and a chart is displayed as shown in Figure 10.

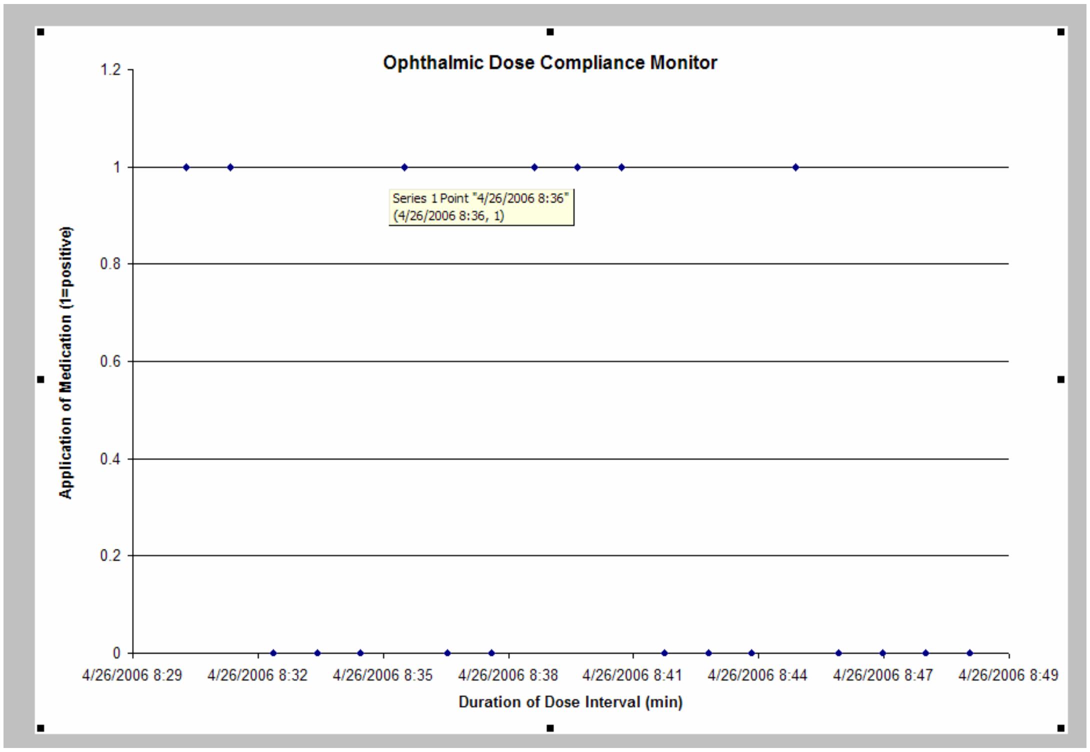

Figure 10: The Ophthalmic Dose Compliance Monitor chart that displays when each does was administered. Each data point with a y-value of 1 is showing that a dose was given. Each data point with a y-value of zero is showing an interval where no medicine was administered.

The chart displays a y-value (Application of Medicine) of 1 when medicine was administered. Each data point with a y-value of zero represents an interval in which no medicine was administered. The box located in the middle of the chart was displayed after putting the mouse over the third data point with a y-value of 1. The user can also view an excel spreadsheet with the all of the data points by clicking off of the chart tab in Excel and onto the sheet tab, which contains the data that the chart is made from.

MatLab

When the data is transferred to Excel the output is displayed as a graph. In order to offer our client a second option for the data output, in tabular form, we have created a program in Matlab. This offers the client an alternative way to visualize the information, to quickly skim the results, and to determine how compliant the pet owner was.

The Matlab program loads the data stored in Excel for each bottle tested into its own files. The data is then filtered so that all data entries not corresponding with the administration of the medication, or the entries with a zero, are removed. The remaining data entries are then displayed in a new window to tell the client the date and time of administration. An example of the output is displayed below using data obtained from the testing of our circuit. The program script can be found in the Appendix.

The dose was given on 11/30 at 3:20
The dose was given on 11/30 at 3:10
The dose was given on 11/30 at 3:18
The dose was given on 11/30 at 3:34
The dose was given on 11/30 at 3:42
The dose was given on 11/30 at 3:58

In order for our client to be able to execute this program he does not need to have any background knowledge of Matlab. He must download the program on his computer which is available to him at no cost. The program can then be saved to his personal files and be used by our client by clicking on the 'run' option in Matlab. We feel that the client will be pleased to have both data outputs available to him as visual guides. The Matlab program also displays the data in a format that could easily be used for research.

In Progress

Currently the larger breadboard circuit has been tested and is working properly as can be seen by figure 10 displaying the output. The process of miniaturizing the circuit has been underway since before the mid-semester marker and is currently in the construction phase. Many components of the final PCB prototype have been ordered and will be compiled once we have received them. These parts include a miniature magnetic hall affect sensor as mentioned above from Allegro. Black heat shrink with a 1.5 inch diameter and a 4:1 shrinking ratio (how small the tubing can shrink compared to its original diameter). Heat shrink is made of polyolefin and is often used in the production of cables. The heat shrink will be placed around the bottle, circuit, and sensors and after heating, will shrink to fit tightly around the bottle. This will hold the components tight to the bottle and disguise them from the medicine user. The coin cell battery previously mentioned and its holder were also ordered along with other PCB and surface mount related parts discussed in the following section.

Express PCB

In order to miniaturize the circuit given to us this semester we had to learn how to use a program that would allow us to draw out a schematic using surface mount components. There is a company called ExpressPCB in which you can layout your circuit and get proto boards made. We were able to make boards the size of the bottom of the bottle by using surface mount parts of size 0603 and 0805. These numbers are related to the sizes 1.6 x 0.8 mm and 2 x 1.25 x 0.8 mm, respectively. Using parts this size will allow us to fit all of the components (except for the Hall sensor, which will be on the top of the bottle near the cap) onto the bottom of a 25.4 mm diameter bottle. The final layout of our circuit in ExpressPCB can be seen below in Figure 11.

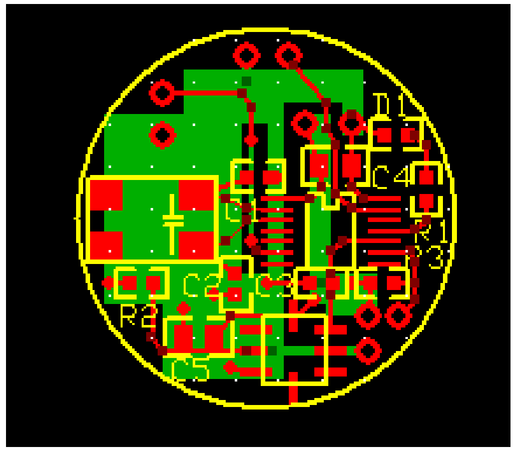

Figure 11: Drawing of the circuit layout in ExpressPCB.

While we were able to layout the resistors and capacitors in the schematic of the circuit board, the more specific parts such as the crystal and the accelerometer needed a footprint. A footprint is the surface mount layout for parts that are not found in ExpressPCB's component catalog. The reason for this is because these specific parts do not just come as a standard, but rather we did research on the web to find these specific parts on the size scale that we needed. We were able to find a crystal that is about 6.2 x 2.1 mm and an accelerometer that is 5 x 4.5 mm. The prices of the crystal and the accelerometer are $1.08 and $9.70, respectively. (15, 19) The ExpressPCB board costs $101, but since the minimum amount of boards that can be ordered is two and each board contains seven miniaturized circuits, each circuit layout only costs $7.21. When the printed circuit boards arrive we will have to complete the tedious process of soldering the circuit elements onto the boards.

Testing and Future Work

In order to test to see if our product is working properly, we must test it using conditions that mimic its actual use as close as possible. By creating a proper test we can determine whether or not the circuit we have constructed, the sensors that have been added, the memory storage, and the power source are all working properly during the usage it will experience in clinical trials. One of our large concerns, and thus a primary reason for preliminary testing of the prototype, is if the power source will be able to power the circuit. In previous testing of the breadboard a 5 V power source was used and found to be sufficient. However, due to size constraints of the bottle we will be using a 3 V coin cell battery to power the miniaturized circuit. This must be tested but is believed to be sufficient based on a brief meeting with Prof. John G. Webster. One of the disadvantages to our circuit is that if the processor looses power, all the information stored in memory is erased. Thus, by ensuring we have a proper power source to last the significant amount of time (4-6 weeks) needed we can be more confident that our prototype would work under clinical trials.

When we run the tests of the prototype, we want to be able to ensure that each component is working properly. Although this is difficult for the hall sensor and gravity sensor, we can easily test if the circuit is transferring information properly by inputting a few data entries (simply by removing the cap and flipping the bottle), waiting ten minutes for the data to store properly, and then transferring the information to a computer. After this simple test, we should be ready to move onto a test trial. This will involve having a subject, who is minimally aware of the bottles capabilities, use the bottle for an extended time while inputting the data points at random times a few times a day (by the same method as before). Ideally, we would like this to be for as long as a time as the client requested the bottles to be able to run for (approximately 4-6 weeks), but due to the time constraints of this class we may only be able to run a test trial for a few days. Unfortunately, this will not be able to test if our power source is sufficient for use in clinical trials, but if everything runs smoothly in the test trials we will have the confidence of a working system.

To ensure that the power source is adequate, the client may want to continue to use the bottle under the test trial conditions for a week or two longer. By continuing on the original test trial bottle he will be able to know if the power source is adequate as soon as possible. After the prototype passes these test trials, we feel it will be ready to undergo production for use in clinical trials by our client. At this time ten more circuits must be constructed and given to the client.

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Appendix

I. Product Design Specification

Ophthalmic Dose Compliance Monitor
February 15, 2006

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Function: Our objective is to develop and miniaturize a dose compliance monitor that would record (unknown to the client) when (date and time) a topical ophthalmic medication was delivered. There are currently older designs of compliance monitors designed for ophthalmic medications, but our design should be a cost effective improved model. Ideally we would be able to manufacture approximately 10 of these devices for use in studies. It could be as simple as some of the older models that recorded when the top of the bottle was removed and the bottle inverted. Maintenance of sterility of the medication is imperative.

Client requirements: Our client's requirements are as follows -

- Minimize the size of the circuit in order to discretely place on eye dropper bottle
- Device must be placed on the outside of the bottle
- Device must record date and time of each application

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The device will be used daily based on prescription. It must be able to store each application's information for up to six weeks.

b. *Safety*: In order to prevent contamination of the medication, the device must be applied to the outside of the bottle without opening the cap.

c. *Accuracy and Reliability*: The device must record information only when the medication is used and not when it is simply moved from one place to another.

d. *Life in Service*: Our device should be sustainable with every day use for a duration of up to six weeks.

e. *Ergonomics*: The device cannot interfere with the patient's application of eye drops. It must be small enough to fit on the side or bottom of a 2cm diameter bottle. The device must also be unbeknownst to the patient.

f. *Size*: The device must be miniaturized in order to discretely fit on an eye drop bottles of 5-15 mL volumes.

g. *Weight*: Weight will be restricted due to the size.

h. *Materials*: We will be using a circuit or sensor and an insulating sleeve.

2. Production Characteristics

a. *Quantity*: 10

b. *Target Product Cost*: $100/bottle

3. Miscellaneous

a. *Customer*: Any parent or pet owner that will be applying ophthalmic doses to their child or pet.

b. *Patient-related concerns*: There should be no concerns because the patient should not be aware of the device.

II. Matlab Program

```
D= load('dosecomp3.txt');
for n = 1: length(D)
if D(n, 1)==1
    disp(['The dose was given on ', num2str(D(n,2)), '/',
num2str(D(n,3)), ' at ', num2str(D(n,4)), ':', num2str(D(n,5))])
end
end
```