Glaucoma Medicine Reminder

Department of Biomedical Engineering
BME 200/300

Final Report

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Client: Leo Wang
Advisor: John Webster

Chris Webster – Team Leader
Ksenija Bujanovic – Communications
Jessica Hause – BSAC
Mike Oldenburg – BWIG

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Abstract

Glaucoma treatment involves taking various types of eye drops at different times during the day. This kind of disease management requires following strict regiment that numerous patients do not adhere to. In a study done by Stewart *et al.* it was found that 34% of patients admit to noncompliance. This study also revealed that 94% of physicians believe that noncompliance may lead to loss of vision (1). Furthermore, 38% of patients stated that memory is the reason for noncompliance. This is not surprising since the average age of onset of the disease is in patients who are in their late sixties. Since noncompliance is one of the most important causes of aggravating glaucoma, it is critical to find a way to successfully remind patients of when their next medication is to be taken (2). This would greatly improve their chances of stabilizing and retaining their sight. Our goal is to develop a portable electronic device which can indicate glaucoma patient when it is time to take their next dose of medication. An audio will be necessary because many of the patients are severely sight-impaired. The device needs to be programmable for up to six different medications that can be used in different dose regimens. A reset mechanism, types of reminder signals, durability/portability, power options, and power level indicators all must be taken into consideration.

Background

Glaucoma is the leading cause of blindness in the United States. Often called the "silent killer," this disease shows few obvious symptoms until the patient's vision is already compromised. Glaucoma comes in two different forms, open angle glaucoma and acute closure glaucoma. Loss of vision due to intraocular pressure build up in the eye is common in both. In open angle glaucoma, gradual build up of pressure in the eye causes damage to the optic nerve, and can result in blindness in a few years if left untreated. Peripheral vision is usually the first to deteriorate and patients often develop tunnel vision in the advanced stages of the disease. Acute closure glaucoma occurs suddenly due to a rapid rise in ocular pressure. This condition requires immediate medical attention or blindness can occur within a few hours.

The main cause of increasing intraocular pressure in the eye can be traced back to the eye's drainage system. In order to keep pressure constant in the eye, the body constantly regulates a fluid called aqueous humor. Its purpose is to flow in and out of the eye cavity, providing nourishment and keeping the eye free of debris (see Appendix A, Figure 1). In a healthy eye, the body produces aqueous humor at the same rate at which it is drained out of the eye cavity, keeping a constant pressure. In open angle glaucoma, the drainage channel remains open but aqueous humor drains too slowly, resulting in a build up of pressure in the eye. This type of glaucoma occurs in approximately 2% of adults over the age of 40 and approximately 8% of adults over 70.

The goal of treatment is to reduce pressure in the eye and to control the flow of aqueous humor. This can be accomplished in many ways including surgery, laser treatment, systemic medications, but most often through eye drops. Because the treatment often consists of several medications per day and the patients are often elderly, noncompliance is a major issue for physicians. Also, in terms of our medication reminder device, it is important to realize that patients may have other medical conditions that limit movement or mental capacity. These additional problems must be taken into consideration. Glaucoma is a condition that affects millions of people in the United States, and although it cannot be cured, early detection and proper treatment can go a long way in retaining a patient's vision.

Specifications

Most importantly, the device needs to remind patient which medication needs to be taken and when. The device must be programmable for up to six different medications in order to ensure that it will provide service to the patient with the most severe cases of glaucoma. In order to minimize confusion as to which medication is to be taken with each alarm, the device should have six different colored stickers that correspond to matching colored stickers on eye-drop bottles. Since these patients may be severely visually impaired, the stickers must be large and correspond with colors that are easy for the patient to distinguish. Also, the device must have an audio alert option along with a flashing light reminder to indicate that the medication should be taken. The alarm should last for about 1min. It should have no offensive sounds and be equipped with a volume control button. Volume control must not be changed easily, however, in order to prevent from accidental muting. There also needs to be a large reset button that can turn the alarm off once the patient h medication.

Next, the device needs to have a digital clock displaying the current time to allow for programming. Numbers on the clock must be big, bold and black since the patient may have difficulties reading letters that are too small or colored. Along with the main clock, the device may also have additional count-down timers for each medication. These timers would let the patient know how long until the next medication is to be taken, but in order to keep with a reasonable size of the device, these timers may be too small for the patient to see. The device needs to be portable. The ideal size, given by the patient, is 5½ inches by 2¾ inches by ½ to ¼ inches. Even though the majority of glaucoma patients are older than 45 years, the disease may occur at any point in life (2). With this in mind, the device needs to be durable and sturdy enough to accommodate the lifestyles of children, teenagers, and adults. To contribute to this, there should be a plastic, lightweight, durable, washable plastic case that would protect it from bumping and breaking in various situations.

Additionally, in order to prevent patient from tampering with the device and turning it off, the device must be programmable and lockable by the physician. The patient must not be able to change the schedule of the medications. In addition, the device needs to be battery operated. Ideally it would be run on a lithium, rechargeable battery allowing the device to remain on at all times. This is important due to the fact that we don't want the memory of the device to be erased while the battery is charging. Also, being powered by a lithium battery would permit physicians to schedule medications for any time of the day, accommodating to the patient, since it would remain on at all times. An alternative to the lithium battery is a AA powered device. This would not be as convenient because even if the AA batteries were rechargeable they must be removed from the device in order to recharge, risking losing all of the saved information. To ensure that the patient knows when to replace/recharge the battery, there must be a low battery indicator on the device. Furthermore, the device must not be easily turned OFF. This would prevent the patient from turning it off if they become irritated by the frequency that the medications need to be taken. Lastly, the device should be accompanied by an easel that allows it to stand upright. This easel should be able to recess for travel.

Previous Work

Because it is so common for patients to forget their medications, several pharmaceutical companies have marketed devices or services to help remind them. Some of devices come in the form of pagers or wrist watches, some also include automatic an pill dispenser, there are even telephone services that will call households when its time for a medication.

A common pager-sized device called the “12 Alarm Pager” (Displayed in Appendix A, Figure 2) is marketed by e-pill Medication Reminders and Time Now, Inc. Its key features include support for twelve alarms, vibrating alert, and small size, all for an average price of around $30. This device has bright, easy to press buttons, though the display is dim and the letters are small. These are important characteristics and prevent the “12 Alarm Pager” from being an adequate solution to our client’s problem.

Timex and several other companies have created reminders in the form of a wrist watch. The major draw to these devices is their inherent portability. They typically have bright displays and audio alarms, some are even marketed specifically for children. They range in price from $30 for single reminders to upwards of $100 for more advanced styles. Most lack a vibrating alert, however, and all have small, hard to press buttons.

B. Independent, Inc. markets several variations of automatic pill dispensing medication reminders (see Appendix, figure 3). The dispensers can be programmed for

31 days of the month or 24h in the day. However, they too have small, illegible buttons for the elderly eyes. They also run fairly expensive, ranging between $150 and $250.

Rx Notify and Prescription Reminder are two leaders in a group of companies who provide a telephone reminder service. Customers can receive calls or text messages to either their home or mobile phone. These companies also abide by HIPAA standards. Some companies charge per call or some use a subscription. The downside to this method is that it requires the patient to own a mobile phone in order to be reminded when away from home and the overall cost is usually more than the aforementioned methods.

Each device or method on its own has desirable features, but none fit all of the essential requirements of our client. It is, therefore, necessary to make modifications to existing devices or create an entirely new one.

Design Ideas

LCD system

The first design idea attempts to integrate a wide variety of visual capabilities with an easily programmable and operable user interface. It involves an LCD touch screen and windows based software.

Several LCD screens have been considered. The first screen investigated is a 6" analog TFT, which supports 262K colors at a resolution of 640x480. The upside to this screen is that it provides plenty of room for large, colorful buttons for the patient to read and press. The display is also visible in the sunlight. Unfortunately, it requires direct connection to a PC in order to be programmed and is ultimately too large to be a viable part of the design. It also exceeds the price range set by the client, costing $900 for only the screen and graphics controller.

The next screen is a much smaller touch LCD. This 2.7 inch unit has a wide variety of functions, including a resolution of 240x160 and 64Kb flash ROM to support TTF fonts and bitmap images. It is fully compatible with USB 1.1 and Serial ports, and can be programmed remotely. The screen's form is much more compatible for a hand held device; however, the screen itself lacks a protective coating, and is designed to be powered by a stationary source. Also, a separate controller is necessary, raising the total cost of the screen and controller to $250.

The final screen investigated has been selected for the first prototype and can be seen in Figure 4 in Appendix A. It is very similar to the previously mentioned 2.7 inch screen, with a resolution of 240x160, 256 colors for a wide variety of unique button options, and USB 2.0 (faster than the previous) and serial ports for remote programming and data transfer. Its square form is even more compliant with a handheld design. The feature that sets this screen apart from the others is its built in battery compatibility. The battery pack is an additional cost, but eliminates the need for a bulky power source adaptation that is required for the first two screens. A controller and all drivers are provided. Even with a protected coating on the screen, a case of some sort will be required for protection.

Once the system is constructed, the software needs to be programmed. Because the system is windows based, there are many options for languages. Java is the language most familiar to the design team so it will be used. There is a wide variety of programming tools, but because UW has licenses to many, the software will not be factored into the total cost.

Once the components were chosen the prices were analyzed. The best option came from EarthLCD.com. The required components are the LCD kit, which includes the 2.7 inch screen and graphics, the USB drivers, the evolution board to integrate the display and controller, the battery attachment, and a case. Table 1 in Appendix B contains a full price list.

Upon viewing this price list, an overall disadvantage comes to mind. The cost of this system is rather high compared to the technology that is already available. Also, this design requires a fair amount of manufacturing on the group's part, and will therefore have an increased risk of malfunctioning. These factors will be taken into account when deciding the final idea to produce.

PDA System

The second design consists of modifying a Personal Digital Assistant (PDA) by writing a computer program that meets the client's needs. This design is similar in nature to the LCD system but will utilize a PDA as a base system for programming.

One advantage of this system is that it would be very easy to mass distribute because it would only require a PDA and the suitable program. From a potential marketing perspective this is a large advantage over a product that requires a considerable amount of manufacturing. Another advantage is that it is easy to program a locking mechanism. This prevents the patient from changing the medication regimen directly because the physician is the only one able to unlock it with a username and password.

Also, compared to the LCD, the system is relatively cost effective. This is especially true in terms of mass distribution because the programming software is only a one-time purchase. The PDA would also be the smallest design idea, enabling the patients to carry it from place to place in a purse or a pocket.

On the other hand, a major shortcoming of this design is that it would be more difficult to program than the LCD because it is Palm based. Because most PDAs are non windows based systems, the programming difficulty automatically increases and the cost of the programming software can increase as well. Along with the increased cost of programming comes the high cost of the PDA itself, depending on the purchased model. Some patients can barely afford the medications themselves so cost is definitely a factor. A major hurdle that would have to be overcome to implement this design is the short battery life of a PDA. The average battery life of a PDA is around 4h. To account for this shortcoming, we must either write a program that extends this time to an entire day, or create a program that only turns the PDA on when an alarm is going off. Unless this is accomplished, the PDA design will not work.

The total cost of this design is estimated to be between $100-$550 (see cost analysis in Appendix B, Table 2), depending on the model of the PDA chosen and the programming software needed. Another important consideration is the interaction that the user will have with the device. Since most of the patients are elderly, some of them might not be familiar with using a PDA. This could create frustration and potentially lead to noncompliance. Also, patients that have other health problems might not be able to control the stylus of the PDA well enough to interact with the user interface provided.

Modified Egg Timer

The third, and final design, will be called the “modified egg timer”. This design is much more mechanical than the LCD or the PDA and is one of the most basic solutions available for this particular project. The modified egg timer is equipped with six different countdown timers, sets of stop and go lights, and colored lights coordinated with the each medication. It also has a main screen that reads the current time and the battery level. Each screen will be an LCD screen with bold, black numbers against a gray background to allow for easy legibility in sight-impaired patients. Ideally, this device will also have an audio and vibration alert system, volume control, and a USB interface to allow for scheduling (see appendix, Figures 5 and 6)

The idea behind this design is that the patient’s doctor will use the device’s USB port and scheduling program to import the scheduling for up to six different types of medication. The device will then be set for the following weeks/months to go off at the time the patient is supposed to be taking their different medications. When the timer goes off the device will give an audio, visual and vibration alert and the patient will simply hit the “stop” button to turn off the alarm. Patients will then match the illuminated colored light with its corresponding medication, take their medication, and continue with their everyday activities. Upon hitting the “stop” button, the device will reset itself to go off at the next time that particular medication is to be administered.

The major advantages of this design include its cost, alert system, and “locking” mechanism. The modified egg timer is by far the most cost effective of the three designs, it involves the simplest technology and as a result, all of its parts are relatively cheap (cost is further evaluated in the following paragraphs). In addition, this device is equipped with an audio, visual and vibration alert. These three alternatives allow for even very sight-impaired patients to be notified when the device is going off and reduces the chance that a patient will miss a dosage. Lastly, the USB port and doctor scheduling system prevent patient tampering by completely eliminating patient access to the scheduling system. This allows for a very simple “set it and forget it” design.

In addition to the various advantages of the modified egg timer our team also chose to pursue this design because we felt it fit the closest with out client’s needs. Due to the fact that most glaucoma patients are fairly elderly, we felt a simple design made the most sense. A simple design encourages patient compliance by allowing for easy access to the device’s features and allows for use by patients from a spectrum of technological intelligence levels. The modified egg timer is also equipped with bold, black letters and numbers and only colors that are visible by sight-impaired patients common to glaucoma. Lastly, the glaucoma patient we are working with initially favored this design over the other two, indicating that it may also be the most user-friendly.

Despite its many advantages, this device also has a number of disadvantages, including limited capabilities, the requirement of an outside casing system, a high degree of manufacturing and heightened risk of malfunction. Because this device is much simpler than the LCD or the PDA, it is not equipped with any of the “extra” features that the other two devices have. This device still has all of the capabilities it needs to perform the desired functions, they are simply more basic. In addition, this device requires an outside casing system to prevent accidental malfunction due to everyday bumping while patients are carrying it around. On the manufacturing level, this device requires the most physical labor on the part of the team members. All of the parts will have to be bought separately and put together by hand. As a result of this high degree of manufacturing on the group's part, this device also has a higher degree of malfunction.

The "modified egg timer" is the most cost effective of the three designs. All of the parts have to be bought separately and put together by hand thus, reducing costs at the expense of our labor. Most of the modified egg timer's parts; the LED screens with bold black numbers and letters, colored LED lights, plastic casing, speakers and control knobs are under $20.00 per part. The only parts of this design that are slightly costly are the timers and programming circuit which are still only around $50. Altogether, this design will probably cost $85-100 (see Appendix B, Table 3)

Design Matrix

After narrowing the ideas to three main designs, the LCD system, modified PDA and modified egg timer, a design matrix was used to determine which design to pursue. Each idea was evaluated based on ease of unit interface, size, cost, ease of implementation, ease of use, durability, production time, and client requirements. An emphasis was placed on cost, ease of use and client requirements by ranking each of these categories on a scale from 1-10 (10 being best, 1 being worst) while ranking all of the others on a scale from 1-5 (5 being best, 1 being worst). Table 4 in Appendix B shows the scores each design received in each category. Each score was tallied and, although all were close, the "modified egg timer design" fit the client's design requirements the closest.

Final Design

In order to ensure client satisfaction, two final designs were produced.

The first is an interface intended for a PDA. It was programmed using Visual Studios 5. It contains a main screen and a scheduling screen. The main screen can be seen in figure 7. It displays the count down times for six different medications as well as one large box which changes to the color of the corresponding timer that has elapsed. When a timer has run out, it continues counting in the negative direction, indicating how much time has passed since the patient should have taken their medicine. A reset button allows the patient to start the timer over once they have taken the indicated medicine.

On the main screen is a link to the scheduling screen. This screen is intended for the physician. The user must first input a username and password in order to reach this screen. This is meant to prevent patients from accidentally or intentionally changing their dose regiments. After inputting an accepted name and password, the user is prompted with the scheduling screen, as seen in figure 8. Clockwise and starting from the top, the three fields are the countdown start time, the duration of each medicines countdown time, and the current time. The physician first inputs the length of time between each dose regiment, then the time that he wishes for the timer to begin in relation to the current time. When all of these values are adequate, the physician presses accept and the timers prepare to start counting.

The most important part of this design is that it is capable of meeting the largest number of the client's requirements. It has the desired visual accommodations, as well as a variable auditory alarm. It's even smaller than the client's size limit. It is also capable of storing more than six medications and counting for many hours, far beyond the twenty-four that the client initially required.

Because the client's patient was slightly intimidated by the idea of having to use a PDA, an analog design was also constructed. It was made up of four cooking timers which were altered to set of an LED in conjunction with the alarm. They were mounted longitudinally to a casing made of PVC using epoxy, as can be seen in figures 9 and 10. The screen and reset button are adequately large for the client to use, but the time setting buttons are too small. This issue was accepted, however, because the only person intended to use these buttons is the physician.

These timers were unique in that they had automatic time reset capability, but were limited to a maximum of a nineteen hour countdown. Overall, this design accomplished fewer requirements set by the client, but was built as a second option for the patient. The team hoped that our clients would accept the PDA idea.

Testing

In order to test our prototypes, we asked 10 volunteers with visual impairments to attempt to use our designed products. Our volunteers ranged in age from 19-45 and all attempted to use our prototypes without their visual aids (i.e. glasses, contacts, etc.).

For the PDA program, we asked our volunteers to attempt to work our designed program off of a laptop. This gave us a basic idea of the changes that needed to be made. However, since the program wasn't actually on a PDA, the size of the numbers and letters was not what it would be in our final product. As a result, further testing will be required to evaluate this aspect of the final design. After the volunteers had attempted to use the program for a short time, we asked them to fill out a survey that evaluated the various aspects of our design (see Form 1, Appendix C). Overall, we found that our volunteers thought the background color of the green, blue, and red screens was too dark and therefore, needed to altered in order to increase visibility. In addition, most felt the text needed to be enlarged and an audio alert put it. However, they liked the fact that the device was simple and that they only had to tamper with the main screen.

Testing for the executive design was very similar to that of the PDA. Once again volunteers were asked to attempt to use our prototype and fill out a survey regarding their thoughts on the device (see Form 2, Appendix C). The survey questions were very similar to those for the PDA. However, the executive design was an actual working prototype and therefore, the survey questions were more specific allowing for more concrete volunteer feedback. For this design, volunteers felt that the colors of the LED lights needed to be differentiated better (they thought it was hard to tell the difference between the red, yellow, and orange lights) and that the various buttons and screens were a bit confusing to try and use. However, the felt the size of the numbers on the screens was very visible and they liked the fact that the device had an audio as well as a visual alert.

After using both of the designs and taking their respective surveys, volunteers were lastly asked to choose which of the two designs they felt best fit our requirements (see Form 3, Appendix C). Our findings showed that 8/10 people preferred the PDA design over the executive design due to its simplicity, usability, and appearance. We than took our design's criticisms and used them during evaluation and when making our final changes.

Cost Analysis

The PDA design was programmed on previously owned software for no charge. A finished product requires the purchasing of a color PDA. A Palm Z22 is sufficient and may be purchased for less than $60.00.

The kitchen timer design required the purchasing of several components. These are listed in table 5 in appendix b. The most expensive component was the four timers, each costing $7.99. In a more mass produced scenario, this price would decrease greatly. The total cost was still less than the cost of just a PDA, however.

Future Work

In the future, the modified PDA design will undergo some revisions to make it a marketable product. After talking to a patient, it was discovered that the current shades of blue, green and red need to be substituted for lighter shades because glaucoma patients have a difficult time seeing letters if there is no significant contrast between the background and letter color. Also, it would be helpful for the patients if the letters were bold. Some of the colors do not flash once their particular timer goes off; this feature needs to be revised so that each color flashes at the appropriate time. Another problem is that once the timer is reset, the color that had been flashing remains on the main screen. This could potentially confuse the patients into thinking that they have not taken their medication yet. Thus, the device needs to be modified so that after pressing the reset button, the main screen returns to white.

In order for this program to successfully work on a PDA, some revisions need to be made in the size of the screens. All screens that contain writing should be enlarged in order to make it as easy as possible for patients to use. Once the program is finalized on the computer, it will be translated into a current version of Visual Basic so it is able to be compiled and used on a PDA. Also, it will be necessary to ensure that the PDA can "sleep" while not in use, but "wake up" when the timer runs out. This feature will extend the PDA battery life allowing the patient not to recharge it as often while fulfilling its original function. Also, an audio and vibrating alert should be present with each alarm. The second design, the egg timer, would only be helpful if microprogramming was used. Since this would exceed the desired budget and would require help of hired specialists, both the team and the client agree that this design is to be eliminated.

Appendix A (Figures)

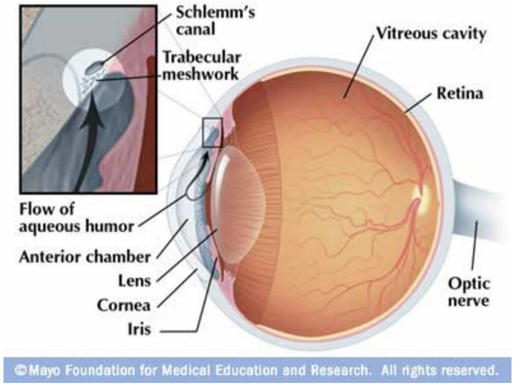

Figure 1: *Depiction of the drainage system in the eye as it applies to glaucoma.*

Figure 2: *"12 Alarm Pager" marketed by e-pill Medication Reminders and Time Now, Inc.*

Figure 3: *Pill dispensing medication reminder marketed by B. Independent.*

Figure 4: *Screen chosen for LCD design, with a 2.7" diagonal.*

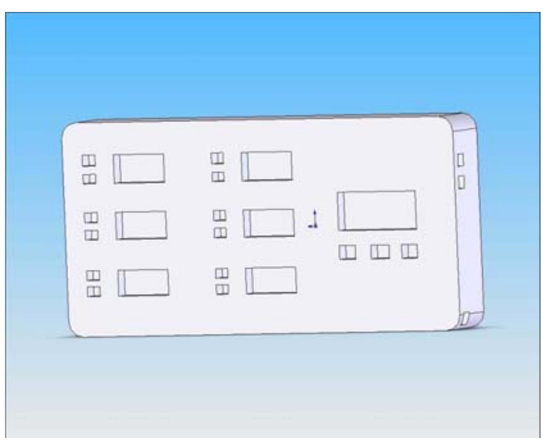

Figure 5: *Solidworks drawing of Modified Egg Timer design*

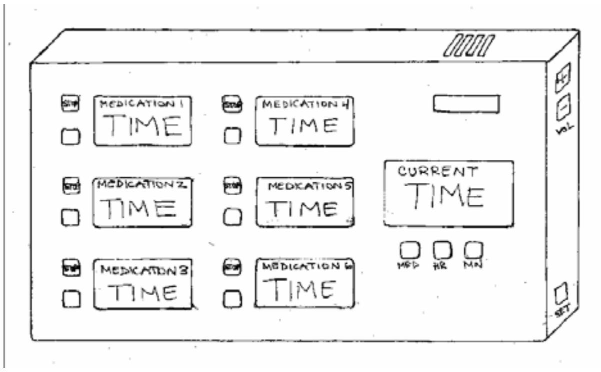

Figure 6: *Sketch of Modified Egg Timer design. It has six different count-down timers for each medication and a main screen reading the current time.*

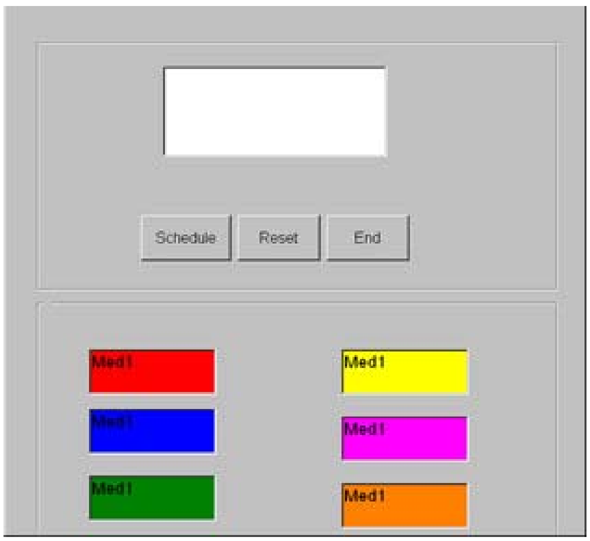

Figure 7*: Screenshot of Main Program Screen.*

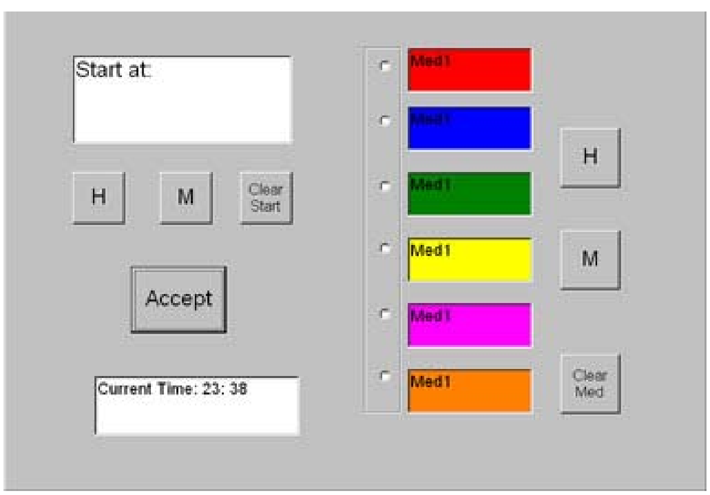

Figure 8*: Screenshot of Scheduling Screen.*

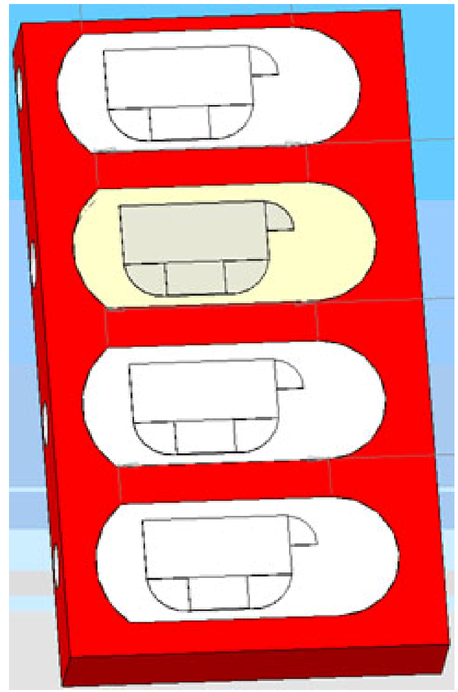

Figure 9*: Diagram of finished Modified Egg Timer design*

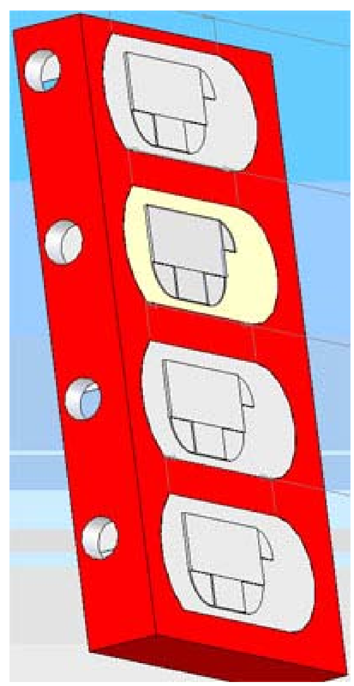

Figure 10*: Side view of finished Modified Egg Timer design*

Appendix B (Tables)

Materials	*Cost*
LCD Kit (includes screen and graphics/USB drivers)	$199
Display Controller	$69
Protective Casing	$10
Battery	$25
Total	**$303**

Table 1: *(Projected) Cost analysis for LCD system*

Materials	*Cost*
PDA	$50-250
Programming Software	$50-300
Total	**$100-550**

Table 2: *(Projected) Cost analysis for modified PDA*

Materials	*Cost*
Grey LED screens with bold black numbers and letters	$10-20
Colored LED lights	$5-10
Plastic casing	$10
Timers and programming circuit	$50
Speakers	$10
Control knobs	$2
Total	**$87-102**

Table 3: *(Projected) Cost analysis for modified egg timer.*

Design	*Modified Egg Timer*	*Modified PDA*	*LCD System*
Ease of Unit Interface	3	5	5
Size	4	5	4
Cost	10	8	6
Ease of Implementation	3	4	4
Ease of Use	8	6	10
Durability	4	4	4
Production Time	5	3	2
Met Client Requirements	10	8	8
Total	47	43	43

Table 4: Design Matrix. *Cost, ease of use, and satisfaction of client requirements were all ranked on a 1-10 scale (10 being best, 1 being worst) while all other components were ranked on a 1-5 scale (5 being best, 1 being worst).*

Item	Cost	From
4 Timers	$31.96	Sears
4 LEDs	$1.10	ECE Shop
PVC Casing	$0	Scrap
Paint	$9.98	Dorn Hardware
Padding	$4.98	Dorn Hardware
Glue	$4.49	Dorn Hardware
Sub Total	$52.51	
Tax (5.5%)	$2.89	
Total	**$55.40**	

Table 5: *(Final) Cost analysis for modified egg timer.*

Appendix C (References)

Mayo Clinic Staff. "Glaucoma overview." Mayo Health. 2006 <http://www.mayoclinic.com/health/glaucoma/DS00283/DSECTION=5>.

Stewart, William C. "Patient and Ophthalmologist Attitudes Concerning Complaince and Dosing in Glaucoma Treatment." Journal of Ocular Pharmacology and Therapeutics. 20 (2004): 461-469

Unknown. "All You Need To Know About Complaince." The Glaucoma Foundation. 2006. April 2003. http://www.glaucomafoundation.org/news_story.php?i=17

Appendix D (PDS)

Problem Statement

Develop a portable electronic device which can indicate glaucoma patient when it is time to take their next dose of medication. An audio will be necessary because many of the patients are severely sight-impaired. The device needs to be programmable for up to six different medications that can be used in different dose regimens. A reset mechanism, types of reminder signals, durability/portability, power options, and power level indicators all must be taken into consideration.

1. Physical and Operational Characteristics

a. *Performance requirements*: The device must alert the user for up to six different medications. The alert must be through sound or vibrations. The device must be turned on all the time. It must be programmable by the doctor, not the patient, with a lock or a password. There must be a button to reset the alarm as well.

b. *Safety*: The device cannot contain any bare wires that may electrocute the user. It should have rounded edges.

c. *Accuracy and Reliability*: The time should be accurate to the second, but needs to only display the minute. It must alert for every dose.

d. *Life in Service*: The device will be used as long as the patient's medication is prescribed.

e. *Shelf Life*: The device may be used for one patient or for several. It should function for many years. The device must either be rechargeable or contain batteries that are easily disposable. There must be an indicator when the batter is going low.

f. *Operating Environment*: The device will be with the patient wherever they go. It may be kept in a pocket, purse, bag, etc.

g. *Ergonomics:* Function and reliability are most important. Look and feel are secondary considerations.

h. *Size*: It must be small enough to be transportable. It must be easy to hold. It would preferably be operable with one hand.

i. *Weight*: The weight must correspond with the mobility requirement.

j. *Materials*: Plastic would be optimal.

k. *Aesthetics*, *Appearance, and Finish*: The device must be easy to use by elderly and someone with poor sight. Preferably a digital screen.

2. Production Characteristics

a. *Quantity*: Only one unit is needed for the time being. Multiple is a possibility for the future.

b. *Target Product Cost*: We have potentially $1000 available, but product should be as inexpensive as possible.

3. Miscellaneous

a. *Standards and Specifications*:

b. *Customer*: Paul Kaufman, M.D., Dept. of Ophthalmology and Visual Science, UW Medical School; and Liane Seyk

c. *Patient-related concerns*: Easy to use, accurate, and durable.

d. *Competition*: There are several similar products on the market. Our goal is to make an equally functional, more cost effective, and more visually sensitive alternative.