Colorimetric Time Indicator

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Abstract

Intravenous (IV) therapy is frequently used to deliver medicine or other fluids directly into the vascular system. This technique breaks the skin barrier, creating a constantly open wound. To prevent infection, the catheter is moved to a different part of the body every 72 to 96 hours (Soifer, 1998). In order to ensure the catheter gets replaced, the date and time of catheter insertion is printed on a label, which is attached to the IV tubing. However, this is easily overlooked, creating the need for a more noticeable design. The new notification design is an electric timer, which illuminates LEDs and activates an alarm at certain programmable time periods (with default at 72 and 96 hours) while the IV is inserted. The final prototype was constructed and programmed with an Arduino Duemilanove USB board and various circuit elements. It was then placed in an acrylonitrile butadiene stryene (ABS) case with a Velcro strap to connect it to IV tubing. Initial testing was completed, confirming the benefits of the LED design compared to the current method. Future work will consider minimizing size and power consumption, along with incorporating wireless technologies to integrate the device with monitoring systems and electronic medical records.

Background

Intravenous Therapy

Intravenous therapy (IV therapy) is a common medical procedure used to introduce medications, blood components or nutritional support directly into a vein (Medical Disability Adviser, 2009). When compared to other drug delivery methods, IV therapy is considered the fastest and most efficient way to deliver fluid to the body.

Peripheral IV lines (Figure 1) consist of IV fluid, a drip set, connector tubing and a catheter (Weinstein, 2001). The IV fluid is attached to the IV catheter via a drip set and connector tubing. The drip set includes a spike, which can be inserted into the IV fluid bag, and a drip chamber, which collects fluid as it drains from the bag. It also can be used to

Figure 1 – Peripheral IV lines consist of IV fluid, a drip set, connector tubing and a catheter

Image courtesy of dvm360:
http://marketplace.dvm360.com/community/UserFiles/abbott.jpg

regulate the rate of flow or to stop the flow via pinch clamps. The connector tubing provides various access ports, which are used to administer intravenous medications. At the end of the connector tubing, there is a Luer lock adapter, which is attached to the IV catheter.

The catheter is injected with a needle through the skin into a peripheral vein in the arm or hand. The needle is removed while the small catheter tube remains in the skin. The catheter is then fixed to the patient's skin with adhesive tape (Medical Disability Adviser, 2009).

Problem Statement

IV therapy is used in numerous medical situations to deliver medicine or other fluids directly into a vein. This method, however, breaks the skin barrier and prevents the wound from closing, creating an easy site for infection. To decrease this chance of infection, the U.S. Center for Disease Control and Prevention states that the IV system is to be changed every 72 to 96 hours (Soifer, 1998). If ignored, the IV insertion site can become infected, causing localized rash, fever and swelling. This infection can then potentially spread to the patient's blood stream, causing phlebitis, cellulitis (O'Grady, 2002) or systemic inflammatory response syndrome (SIRS), a disease with a death rate of 40% in adults. This mortality rate can be as great as 80% for elderly (Stoppler, 2008). It is therefore necessary to have a reliable indicator that ensures the IV system is changed regularly.

Current Solution and Competition

Currently, medical personnel write the time and date of catheter insertion on a strip of paper that attaches to the IV tubing (Figure 2). At a later date, this information can be referenced, indicating to medical personnel when the catheter needs to be changed; this solution has drawbacks. First, the handwriting on the label could be difficult to read or even illegible, resulting in an ambiguous insertion date and time. Furthermore, since hospitals can be busy and fast-paced environments, medical personnel may not have time or may forget to glance at the insertion information. Although making daily patient observations should theoretically solve this problem, reading stickers to obtain the date and time of insertion is inefficient and time-consuming when not done properly. These factors combined create a situation that could endanger the patient.

Figure 2 – The current solution involves writing the date and time of catheter insertion and attaching it to the IV tubing
Image courtesy of MarketLab:
http://www.marketlabinc.com/files/products/images/medium/ml5786a.jpg

Color-changing chemical reactions and migrating dyes are two technologies used in existing competitive products. An acid base reaction with a color changing pH indicator is the simplest way to create a gradually changing color. The reaction rate varies, depending on temperature, humidity and concentrations and pH values of the acid or base used. More sophisticated methods are used in existing commercial product to achieve a constant reacting speed. One example is the OnVu indicator, which is a sticker used for monitoring perishable foods and beverages. After the goods are packaged, an OnVu sticker is placed and activated by an ultra violet (UV) light source. The sticker then gradually change color from dark blue to white over a period of several hours to several weeks. This sticker, however, still depends on temperature (Figure 3) (BASF, 2009). A similar product, as described in U.S. patent No 5,053,339, consists of an activator tape and an

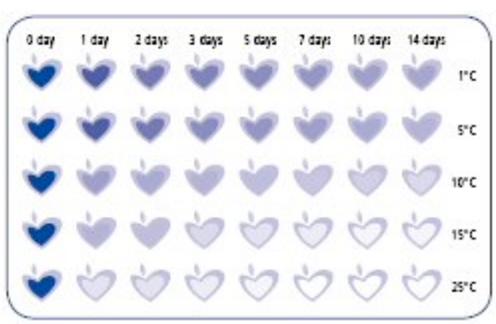

Figure 3 – The OnVu sticker is time and temperature dependant
Image courtesy of OnVu:
http://www.onvu.com

indicating tape. The assembled device requires radiation, such as the UV light in order to activate the chemicals contained in the activator tape. For example, a commonly used chemical is diphenyliodonium chloride, which produces HCl when irradiated with UV light. In a similar mechanism, triphenylsulfonium hexafluoroantimonate produces superacids such as HF and $HAsF_6$ (Patel, 2001). The problem associated with this type of design is that the chemical reaction rate depends on temperature. These temperature-dependent designs are advantageous when used to indicate the freshness and shelf life of food since the spoilage process also depends on temperature. However, when faced with the design criteria for this project, this is a disadvantage. The notifications of the device must be accurate without any interference caused by environmental factors.

The second color-changing technology involves migrating dyes. Two methods are used in this approach; one uses an opaque film to gradually absorb and display ink from back layer, while the other uses a dot pattern of pigment dyes, which enlarges and displays a visible color change. One such product, "Visually Changing Paper," is a two-part paper-like product, which uses opaque film technology. By placing the pressure-sensitive front layer in contact with the back image layer, the product is activated. Upon contact, dye contained in the image layer will begin to bleed through the front layer. After a predesigned time –from several minutes up to several days – the front layer will change color to reveal images such as "VOID" on an ID badge. Many unavoidable problems exist with the gradual color change. There is no instantaneous color change to accurately indicate time intervals, and the time intervals can not be adjusted to longer time periods, such as months or years (Haas, 1990).

Ergonomics and Ethics

An issue of utmost importance was the usability and accessibility of the design. Since the product was going be used in a hospital setting where the exchanges between patients and medical staff were numerous, ergonomics were crucial. Furthermore, the device needed to be accessible to medical personnel but hard to access for the patient. It was important to restrict patient access to the device since patients have the tendency to tamper with instruments in the hospital room. Therefore, "patient-proofing" the device was one of the top considerations of the design. Patient and medical personnel safety were also crucial for this product. As seen in the design matrix (Table 1), safety, dependability, and accuracy were the highest-rated categories; this is due to the vital importance of the device. While it is not used directly in life-and-death situations, it has the potential to prevent infections that could lead to serious complications.

The device epitomized the second guiding principle of ethics: beneficence. That is, the design needed to protect the patient, while maximizing the benefits and minimizing the risks that may occur through use of the product. Its proper function would ensure that the patient would receive prompt medical attention, thus preventing him or her from harm. That said, when considering the prototype, there are some risks involved in using this device. For example, it may slip off of the IV and strike the patient’s body. However, this is very unlikely to occur, considering the strap and minimal mass of the device. The colorimetric time indicator prototype directly follows the established ethical guidelines, minimizing the risks to the patient while greatly increasing the medical benefits.

Design Criteria

Due to the chance of error involved with the current design, a new device needed to be created. The device needed to alert medical personnel to an IV that required attention by changing color based on an indicated passage of time. Included with this general description of the device was a set of design criteria (see Appendix A for Product Design Specifications):

Color change at 72 and 96 hours

The safety of an IV system is dependent upon how long it is left within the body; the U.S. Center for Disease Control and Prevention states that 96 hours (4 days) is the maximum amount of time an IV system can be inserted before it requires attention (Soifer, 1998). For this design, an indication at 72 hours is also desired, as some IVs need to come out after this time period. The 72-hour indication can also serve as a warning of later action required by medical personnel.

Attachment to IV tubing

The device needs to connect directly to the IV tubing. This allows for the association of the device with the patient's IV and prevents it from needing to be removed until the IV needs to be changed. Additionally, attachment to the tubing makes the device less accessible to the patient, which, as mentioned in the above ergonomics and human factors section, is incredibly important to patient safety.

"Patient-Proofing"

The issue of patient-proofing the prototype was also mentioned extensively in the ergonomics section. The patient should not be able to interact with the device in any way, while medical personnel should have easy access. This should be accomplished by creating a simple mechanism that allows medical staff to easily operate the device; this interaction requires simple technical knowledge held by medical personnel but not the patient. The device should not be dangerous upon activation or termination and must not be a choking hazard.

Cost Effective

Finally, the device should be inexpensive at the mass-production level, with an upper limit of $5. Given that IV setups usually cost around $15, an indicator which has the sole purpose of assisting the changing of IVs should be much less expensive than this. This $5 cost assumes a one-time use device. However, a reusable indicator with a larger mass-production cost would be considered. Moreover, this cost only refers to the device as a unit of mass-production. The prototype cost is higher due to research and lack of time and technology, so this will not be factored into the cost effectiveness of the final device.

Preliminary Designs

Environmental Exposure

The first design incorporated an inert membrane that would be peeled back to reveal a chemical strip underneath (Figure 4). This strip would respond to the environment by reacting with either oxygen or carbon dioxide and would create a color gradient that would change slowly with time. This had the simplest activation mechanism of the three design options. It was also relatively safe since the chemical strip would not be harmful if touched and would be quite easy to manufacture cheaply. Furthermore, its low mass would create little strain on the IV tubing.

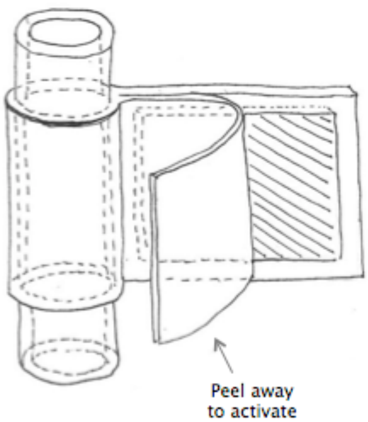

Figure 4 – Environmental Exposure design: an activation layer is peeled away, exposing a chemical strip. This allows it to react with oxygen or carbon dioxide, changing the color of the strip

Unfortunately, there were several flaws with this design. First, since the time indication mechanism is based on environmental exposure, the indication could vary slightly depending on the environment of the hospital room the device would be in. Secondly, even though it would be cheap to manufacture, it was designed for one-time use; this would lead to extra waste, and the benefits of the low manufacturing costs would be outweighed in the long run by a more costly, reusable model. This device also couldn't be visibly seen in dark rooms. Additionally, this design option would require a long development stage in order to perfect the time interval over which it would operate. After this was accomplished, however, it would still be met with competition from existing patents (Haas, 1998) used for similar purposes.

Migration Layers

The migration layers design (Figure 5) utilized a transparent, migration, and dye layer. A pull-tab that would be impermeable to the dye would initially separate the latter two layers. When the tab would be removed, the dye from the dye layer would begin to bleed through the migration layer. After 72 to 96 hours, the dye would become visible through the transparent layer, providing an indication to medical personnel that the IV

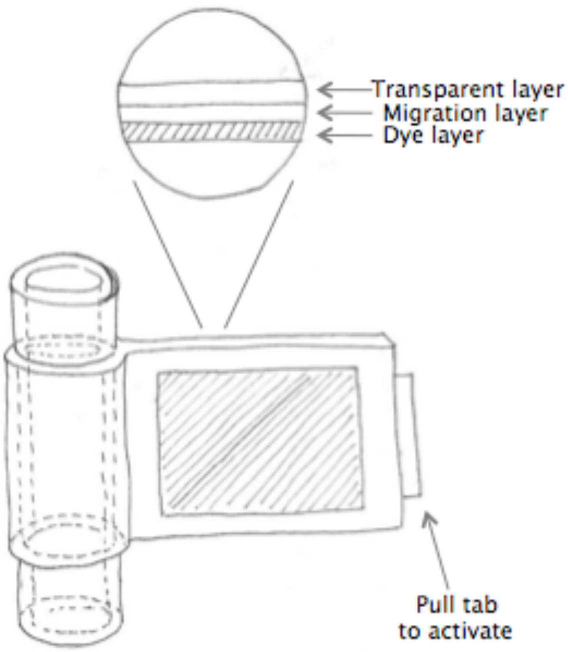

Figure 5 – Migration layers design: utilizes a transparent, migration and dye layer. An activation pull-tab separates the latter two layers. When removed, it initiates the migration of dye through the migration layer. This migration clocks a 72 to 96-hour time period

tubing needed to be changed. The exact time it takes the dye to reach the transparent layer would be determined by the thickness of the migration layer.

This design provided a clear time indication, eliminating the issue of having to decipher a color gradient. The materials would be inexpensive and the size could be easily varied to meet the needs of the user. However, many of the issues that existed in the previous environmental exposure design subsisted in this one as well. Environmental factors, such as humidity and temperature, could affect the amount of time it takes the dye to travel through the migration layer. This product only allowed for one-time use and would be unreadable in the dark. Furthermore, if this device were to break or tear, chemicals could potentially leak onto the patient or surrounding medical equipment.

Electric LED Timer

The main components of the electric time indicator (Figure 6 and Figure 7) are the microprocessor, circuit board, light-emitting diodes (LEDs), and casing. The microprocessor is programmed to give commands to the attached circuit board. This program tells the circuit board to activate a green LED from 0 to 72 hours. A yellow, warning LED then turns on at 72 hours, and a red LED switches on at 96 hours. The LED arrangement provides a clear visual indication to medical personnel of the status of the time period that the catheter has been in place.

Figure 6 – The electric LED time indicator consists of three LEDs (green, yellow and red – top to bottom) that turn on at different time intervals, a recessed reset button and a speaker

The microprocessor and circuit board are enclosed in a durable, plastic ABS casing, while the LEDs are visible to the user. There is a recessed reset button on the front, which can easily be pressed with a pen or other pointed object. There is also a small speaker on the front of a device that gives an audible indication at set intervals when the red LED illuminates. The plastic casing is attached to the IV tubing using a Velcro and rubber strap (Figure 8) that prevents the device from sliding along the length of the tube. This strap firmly grasps the IV tubing without deterring the flow of IV fluids.

Figure 7 – CAD of the electric LED time indicator

This design addresses many of the issues that the other two designs had. The LEDs provide a clear and precise time indication, even in dark settings. This device can be used multiple times and will not expose the patient to harmful chemicals. The recessed reset button cannot be pressed using fingers, making it difficult for the patient to tamper with. Furthermore, the design contains a microprocessor, which allows timing intervals to be reprogrammed. This feature allows the device to adapt to the needs of different patients. Most importantly, the audio and visual indications guarantee that this design is precise and accurate, ensuring that the IV tubing will be changed in a timely manner.

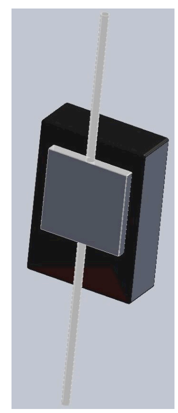

Figure 8 – Back view of the electric LED time indicator design CAD drawing. Velcro firmly grasps the IV tubing, with rubber preventing the device from sliding along the tube

The flaws in this design are minor. It is the largest and most costly of the three designs, but this is due to the limited technology and time allowed for the project. In a mass-production setting, the size of the product would be smaller and the cost would be lower. Since it is electrical, this device would need to be removed for some medical procedures, such as MRI's. However, the strap allows for easy detachment and reattachment.

Design Evaluation

The environmental exposure, migration layers and electric LED timer designs were all evaluated on a scale of one to ten and weighted for a variety of design criteria [Table 1].

Table 1 – The design matrix displays the design evaluation on a scale of one to ten (one = poor, ten = excellent) and is weighted on a variety of design criteria for all three design concepts.

Weight	Design Aspects	Environmental Exposure	Migration Layers	Electric LED Timer
0.03	Prototype Cost	6	6	5
0.1	Mass Production Cost	8	7	7
0.1	Ergonomic	10	7	7
0.19	Safety	8	6	10
0.19	Dependability	7	7	10
0.19	Accuracy	6	6	10
0.15	Mass	10	10	5
0.05	Reusable	0	0	10
1	**TOTAL**	**7.47**	**6.88**	**8.69**

The most important criteria, which include safety, dependability and accuracy, were given more weight in the matrix. These aspects were determined to be the most important design characteristics since they are the most important in terms of patient safety and effective functionality of the final product. The mass of the product was also highly weighted. If the indicator were too heavy, it would pull on the IV tubing causing annoyance and possibly removing the catheter from the patient. Mass production cost and ergonomics where weighted the next highest. The mass production cost was important because there is a current solution already being used; if the product is too expensive, it is unlikely it will be purchased. Ergonomics were somewhat complicated for these designs. The product has to be easily activated by medical personnel while simultaneously preventing the patient from interfering with any aspect of the device. Prototype cost and reusability were determined to be less important, for they do not inhibit the effective use of the product in medical communities. After evaluating each of the designs, it was determined that the electric LED timer scored the highest and therefore was selected as the design to pursue.

Prototype

Programming

The prototype was programmed using an Arduino USB Board. Arduino is an open-source computing platform based on an input/output board. It functions using an ATMega168 microcontroller that implements the wiring programming language. Wiring is an open source form of java specifically used for electronics with input/output boards. By downloading the Arduino-0017 and Wiring-0022 programs, code could then be uploaded to the Arduino Board via an USB cord. The code for the final prototype controlled the timing intervals of the LEDs, the reset button and the speaker. The code is written so that a person with minimal knowledge of the Wiring language can change the LED timing intervals, turn the speaker on or off and vary the intervals at which the speaker beeps. This along with the complete code can be seen in Appendix B.

Circuitry

The constructed circuit contained five elements: three LEDs, a reset button and a Piezo speaker. Much of the circuitry was determined by looking at example projects. Figure 9 demonstrates the circuitry used for the LEDs. The only variation between this figure and the actual circuitry is that three LEDs were used instead of six, and 270 Ω resisters were used instead of 220 Ω. Figure 10 is an exact representation of how the reset button was wired, with a resistor value of 100 Ω. The final component of the circuit was the Piezo speaker, as seen in the circuit diagram in Figure 11, and did not require any resistors.

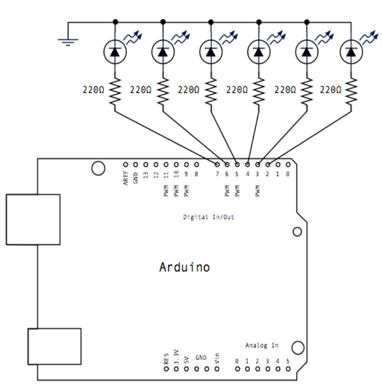

Figure 9– Circuitry for LEDs

Image courtesy of Arduino: http://arduino.cc/en/uploads/Tutorial/forLoop_schem.png

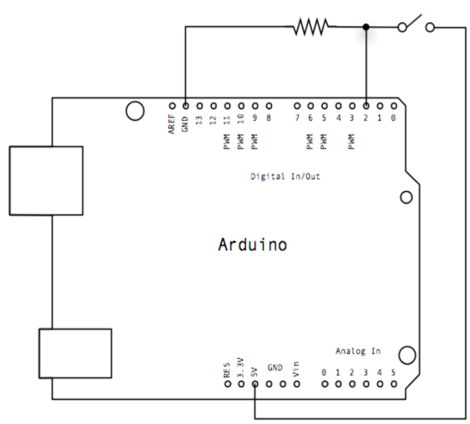

Figure 10– Circuitry for reset button

Image courtesy of Arduino: http://arduino.cc/en/uploads/Tutorial/butto

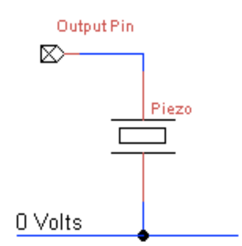

Figure 11– Circuitry for Piezo speaker

Image courtesy of Servdotnet: http://www.servdotnet.com/Tutorials/Wiring/Pie

Protoshield

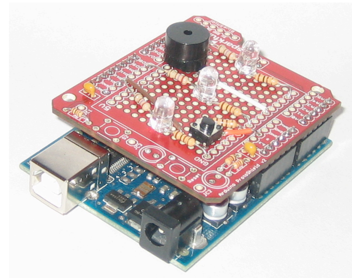

Figure 12 – The protoshield with all of its circuitry elements connected to the Arduino board

The protoshield (Figure 12) used was a soldering board built specifically for the Arduino board. By soldering stackable female connectors onto the protoshield, the pins on the Arduino board were brought to the top of the protoshield. The three LEDs, reset button, and speaker were then soldered to the protoshield using the wiring described in the Circuitry section.

Casing

Figure 13 – The two-part ABS casing with various holes drilled for design components

The protoshield and Arduino Board were connected via the stackable female connectors. This component was then enclosed in a two-piece ABS casing. In order for the LEDs to be seen, the speaker to be heard and the reset button to be pressed, five holes had to be drilled into the face of this casing. Two further holes were drilled into the bottom of the casing to allow room for the USB cord and other external power sources to plug-in to the Arduino Board. The two separate pieces of the casing are held together by screws (Figure 13). Appendix C includes additional prototype images.

Strapping

Figure 14 – The Velcro and rubber strap attached to the back of the ABS casing

The casing attaches to the IV tubing via a Velcro strap. This strap was created by cutting the hook and loop layers of the Velcro into two 5 by 5 cm pieces. These pieces were then sewn together using black button thread along one side as seen in Figure 14. The back of the hook side was then attached to the casing using Velcro adhesive. Using more Velcro adhesive, black strapping was secured to the back of the loop side to create an aesthetically pleasing surface. Gorilla Glue was then used to attach two 3.5 by 3 cm rubber strips to the hook and loop sides of the Velcro. The rubber was added to increase the friction between the strap and tubing, preventing the device from sliding down the IV tubing.

Testing and Results

An online survey was created and distributed to medical personnel with IV experience (see Appendix D for the non-online version of the survey). This survey rated various aspects of both the current method of handwritten labels (Appendix D: questions 3-6) and the electric time indicator (Appendix D: questions 7-12) on a scale from 1 to 5. Once data was obtained, the results were standardized and averaged to find that the current method (n=13) had a rating of 2.3 while the electric time indicator design (n=13) received a rating of 4.05 (Figure 15). The standard deviation was calculated to be 0.88 for the current method and 0.75 for the electric time indicator while the standard error was 0.24 for the current method and 0.21 for the electric time indicator.

The set up time for the current method was collected in the survey (Appendix D: question 13) and tested for the electric time indicator. The results show the current method (n=9) had an average set-up time of 34.4 seconds with a standard deviation of 22.83 seconds and a standard error of 7.61 seconds, while the electric time Indicator (n=10) had a average set up time of 4.45 seconds, a standard deviation of 0.43 seconds and a standard error of 0.14 seconds (Figure 16).

Not only did the electric time indicator receive almost double the rating of the current solution, but it also had a significantly decreased set-up time. While the set up time for the current method ranged from 10 to 60 seconds for different people, the electric time indicator could be consistently set-up in 4 to 5 seconds for all individuals. These results demonstrate that the electric time indicator is an improvement to the current handwritten label method.

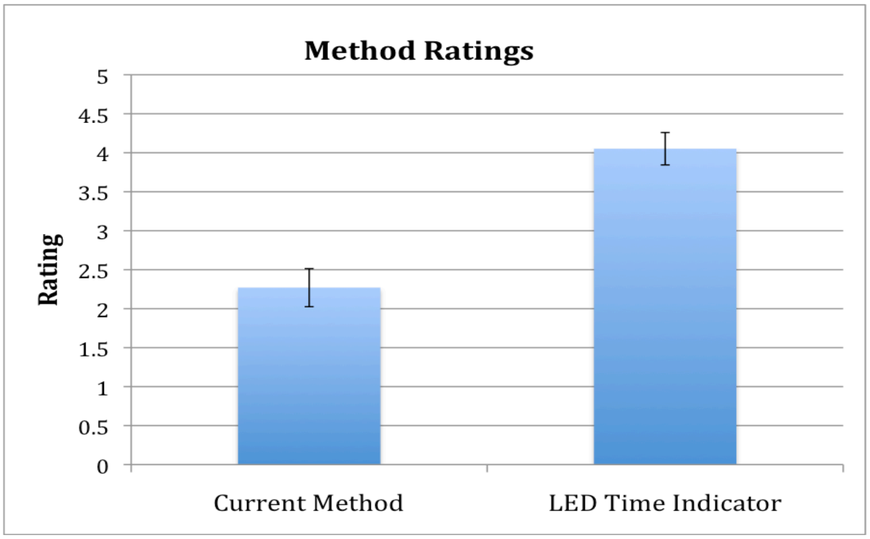

Figure 15 – A survey was distributed to medical personnel with IV experience who rated certain aspects of each design on a scale from 1 to 5. The current solution results (n=13) gave a mean of 2.3, a standard deviation of 0.88 and a standard error of 0.24, while the LED Time Indicator (n=13) had a mean of 4.05, a standard deviation of 0.75 and a standard error of 0.21.

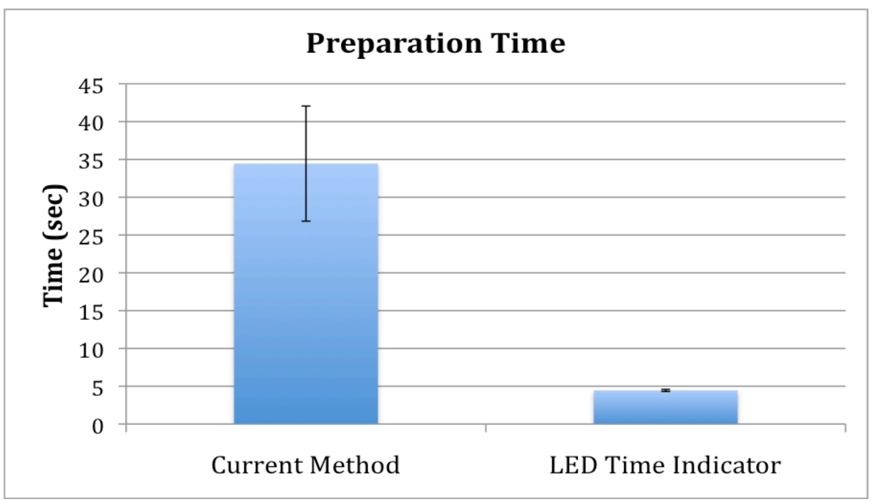

Figure 16 – The average time of set-up was acquired via a survey for the current solution and via testing for the LED Time Indicator. Results showed that the current solution (n=9) has a mean of 34.4 seconds, standard deviation of 22.83 seconds and a standard error of 7.612 seconds, while the LED Time Indicator (n=10) had a mean of 4.45 seconds, a standard deviation of 0.43 seconds and a standard error of 0.14 seconds.

Management Planning

At the beginning of the semester, the Gantt chart seen in Figure 17 was created as a work and time management tool. It was roughly followed throughout the semester to ensure that the project was on track and deliverables were finished on time.

Task	September				October					November				December	
	4	11	18	25	2	9	16	23	30	6	13	20	27	4	11
Project Research and Development															
Researching	■	■	■	■	■	■					■	■			
Brainstorming			■	■	■										
Design Matrix/ Cost Estimation					■										
Design Selection					■	■									
Ordering Materials						■	■	■			■	■			
Prototyping									■	■	■	■			
Testing											■	■			
Final Prototype													■	■	
Deliverables															
Progress Reports	■	■	■	■	■	■	■	■	■	■	■	■		■	
PDS	■	■	■	■	■	■	■	■	■	■	■	■			
Mid-semester Presentation						■	■								
Mid-semester paper						■	■								
Final Presentation												■	■	■	
Final Paper														■	
Meetings															
Client		■		■				■			■				

Figure 17 – Gantt chart created for time management of the project throughout the semester

Cost estimates were made and all expenses were recorded throughout the semester in order to stay under the project's budget of $100 (see Appendix E for finalized list of expenses), which was accomplished with a final total $95.56.

Future Work

The colorimetric time indicator prototype succeeds in that it shows added functionality, such as programmability and additional audible signals, which is a marked improvement over the current solution. Although the design serves as a functional proofof-concept, there are improvements that can be implemented and further testing that can be done to refine the design.

First, the current prototype should be tested in a clinical setting. This will assess medical personnel and customer satisfaction of using the device. If feedback is positive, mass-production of the device can be considered. The ideal mass-produced prototype would retain all of its current functionality, while reducing size, mass, and dependence on power cords. These changes allow for a more inexpensive, energy efficient and smaller device that would be easier to attach to IV tubing, while not causing any strain.

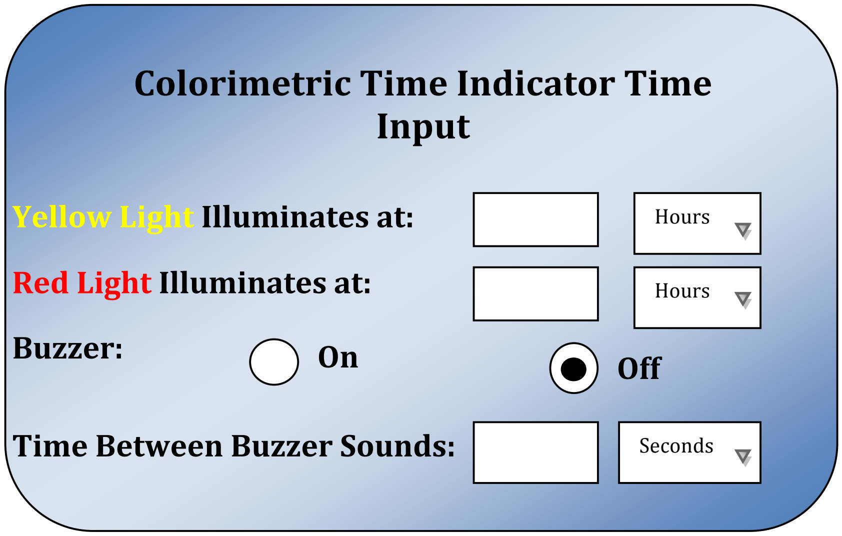

Figure 18 – A proposed time input user interface for the electric time indicator

Finally, an improvement to the time-input interface would ease medical personnel interaction with the device. The current interface provides a simple way to change time intervals between lights, but some limited programming knowledge is required. An example of a possible improved interface is shown in Figure 17. This allows for simple input, while also being able to control aspects of the LEDs and buzzer. Specifics for each patient's IV time are entered into the blank spots. The magnitudes of time (seconds, minutes, hours) can be changed via a drop-down menu according to patient needs.

In the more distant future, assuming the device has great success in clinical settings, an additional upgrade could be made. Instead of each device functioning individually, the indicators could all be synched simultaneously to a computer, integrated into an electronic medical records database. To do this, the indicator would have to send a signal to the computer, notifying the time elapsed since the IV was changed. This provides an extra measure of safety, as the status of the patient could not only be checked by going into the room but also monitored wirelessly. If this device could be integrated seamlessly in a hospital setting to a point where nurses are comfortable and familiar with the technology, the rates of infection from unchanged IVs would undoubtedly be reduced.

Conclusion

A successful colorimetric time indicator prototype for IV notification was created with an electric LED design. The final design fits well with the design specifications and testing proved that it was a notable improvement compared to the current handwritten label method. Despite the success of the prototype, there are several changes that can be made in the future to simplify the design and minimize size, cost and power consumption. Implementing these modifications and commercializing the design has the potential to significantly improve the safety of patients using IV therapies. Ultimately, this design eradicates the potential for IV tubing to be overlooked, thus eliminating any possibility for infection.

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Appendix A: Product Design Specifications

Project Design Specifications—Colorimetric Time Indicator

September 15, 2009

Team: Ali Johnson, John Cheadle, Ella Li, Nick Anderson
Client: Scott Springman, M.D. UW Department of Anesthesiology
Advisor: Wan-Ju Li, Ph.D.

Function:

The purpose of the colorimetric time indicator is to notify medical personal when an IV needs to be changed. The indicator should be easily read, smaller than 30 cm^2, cost-effective and change color at appropriate time intervals. It should also securely attach to IV tubing or dressing but also be removed with out difficulty.

Client Requirements:

- Cost Efficient
- Small (< 30 cm^2)
- Attach to IV tubing or dressing

Design Requirements:

1) Physical and Operational Characteristics
    a) *Performance requirements* – Must change color at appropriate time intervals. Ideally in a color gradient form. Attach to IV tubing or dressing.
    b) *Safety* – Must contain any chemicals or substances used securely to prevent contact with skin. Uses chemicals that are safely disposed.
    c) *Accuracy and Reliability* – Must have clear and drastic color changes
    d) *Life in Service* – One-time use, 3-5 days
    e) *Shelf Life* – Able to withstand a basic medical storage environment and remain inactive until use.
    f) *Operating Environment* – Must work properly at room temperature.
    g) *Ergonomics* – Should not interfere provide discomfort to the patient or introduce any harmful substances.
    h) *Size* – Must be smaller than 30 cm^2.
    i) *Weight* – Should be as light as possible.
    j) *Materials* – Cost-efficient, no latex
    k) *Aesthetics* – Simple and clean
2) Production Characteristics
    a) *Quantity* – One, but should be designed with the intent of mass production in the future.
    b) *Target Product Cost* – Under $5
3) Miscellaneous
    a) *Standards and Specifications* – Must change color at appropriate time intervals
    b) *Customer* – Medical Community
    c) *Patient-related concerns* – Do not include latex due to allergies. Make sure substances used are securely contained and would not harm patient if broken.
    d) *Competition* – There are other types of colorimeters, most which change with temperature.

Appendix B: Prototype JAVA Code

```
//time at which yellow LED will turn on
int hours = 72;
int minutes = 0;
int seconds = 0;

//time at which red LED will turn on

int hours2 = 96;
int minutes2 = 0;
int seconds2 = 0;

//turn speaker on or off (true = on; false = off)

boolean speakerOn = true;

//time between beeps

int hours3 = 0;
int minutes3 = 10;
int seconds3 = 0;

 const int  yellowSwitch = 10 * ((hours * 3600) + (minutes * 60) + (seconds)) ;    // defines when yellow LED
will turn on
 const int  redSwitch = 10 * ((hours2 * 3600) + (minutes2 * 60) + (seconds2)) ;    // defines when red LED will
turn on
 const int timeBetweenBeeps = 10 * ((hours3 * 3600) + (minutes3 * 60) + (seconds3)) ; //defines time
between speaker beeps// defines when red LED will turn on
 const int  buttonPin = 12;    // the pin that the pushbutton is attached to
 const int greenPin = 2;       // the pin that the green LED is attached to
 const int yellowPin = 8;       // the pin that the yellow LED is attached to
 const int redPin = 13;       // the pin that the red LED is attached to
 #define SPKR 5 //this is the digital pin that you plugged the red wire into
 int timer;
 // Variables will change:
 int buttonPushCounter = 0;   // counter for the number of button presses
 int buttonState = 0;         // current state of the button
 int lastButtonState = 0;     // previous state of the button
 void setup() {
         // initialize the button pin as a input:
         pinMode(buttonPin, INPUT);
         // initialize serial communication:
           Serial.begin(9600);
           pinMode(greenPin, OUTPUT);
           pinMode(yellowPin, OUTPUT);
           pinMode(redPin, OUTPUT);
 }
 void loop() {
         timer = 0;
         seconds = 0;
         // read the pushbutton input pin:
```

```
buttonState = digitalRead(buttonPin);
// compare the buttonState to its previous state
if (buttonState != lastButtonState) {
        // if the state has changed, increment the counter
         if (buttonState == HIGH) {
                  // if the current state is HIGH then the button
                  // wend from off to on:
                 buttonPushCounter++;
                Serial.println("on");
                  Serial.print("number of button pushes:  ");
                  Serial.println(buttonPushCounter, DEC);
         }
        else {
                 // if the current state is LOW then the button
                 // wend from on to off:
                 Serial.println("off");
         }
        // save the current state as the last state,
        //for next time through the loop
        lastButtonState = buttonState;
  }
  // turns on the LED every four button pushes by
  // checking the modulo of the button push counter.
  // the modulo function gives you the remainder of
  // the division of two numbers:
  while (buttonPushCounter % 2 == 1 && timer < yellowSwitch ) {
                 digitalWrite(greenPin, HIGH);
                 buttonState = digitalRead(buttonPin);
                  // compare the buttonState to its previous state
                  if (buttonState != lastButtonState) {
                                // if the state has changed, increment the counter
                                 if (buttonState == HIGH) {
                                // if the current state is HIGH then the button
                               // wend from off to on:
                               buttonPushCounter++;
                               Serial.println("on");
                               Serial.print("number of button pushes:  ");
                               Serial.println(buttonPushCounter, DEC);
                               }
                              else {
                            // if the current state is LOW then the button
                             // wend from on to off:
                            Serial.println("off");
                             }
                            // save the current state as the last state,
                           //for next time through the loop
                           lastButtonState = buttonState;
                  }
                 delay (100);
                  timer ++;
}
 while (buttonPushCounter % 2 == 1 && timer < redSwitch) {
        digitalWrite(greenPin, LOW);
        digitalWrite(yellowPin, HIGH);
        delay (100);
```

```
            buttonState = digitalRead(buttonPin);
            // compare the buttonState to its previous state
        if (buttonState != lastButtonState) {
            // if the state has changed, increment the counter
            if (buttonState == HIGH) {
                    // if the current state is HIGH then the button
                    // wend from off to on:
                    buttonPushCounter++;
                    Serial.println("on");
                    Serial.print("number of button pushes:  ");
                    Serial.println(buttonPushCounter, DEC);
            }
            else {
                    // if the current state is LOW then the button
                    // wend from on to off:
                    Serial.println("off");
            }
            // save the current state as the last state,
            //for next time through the loop
            lastButtonState = buttonState;
        }
        timer ++;
}
  pinMode(SPKR, OUTPUT); //set the speaker as output
  seconds = 0;
  while (buttonPushCounter % 2 == 1) {
          digitalWrite(yellowPin, LOW);
          digitalWrite(redPin, HIGH);
          if (speakerOn && seconds % timeBetweenBeeps == 0){
                  for (int j=0; j<5; j++){
                          for (int i=0; i<100; i++) {  // generate a 1KHz tone
                                  digitalWrite(SPKR, HIGH);
                                  delayMicroseconds(500);
                                  digitalWrite(SPKR, LOW);
                                  delayMicroseconds(200);
                          }
                          for (int i=0; i<100; i++) {  // generate a 1KHz tone
                                  digitalWrite(SPKR, HIGH);
                                  delayMicroseconds(500);
                                  digitalWrite(SPKR, LOW);
                                  delayMicroseconds(100);
                          }
                          for (int i=0; i<100; i++) {  // generate a 1KHz tone
                                  digitalWrite(SPKR, HIGH);
                                  delayMicroseconds(500);
                                  digitalWrite(SPKR, LOW);
                                  delayMicroseconds(300);
                          }
                          buttonState = digitalRead(buttonPin);
                          // compare the buttonState to its previous state
                          if (buttonState != lastButtonState) {
                                  // if the state has changed, increment
                                  if (buttonState == HIGH) {
                                          // wend from off to on:
```

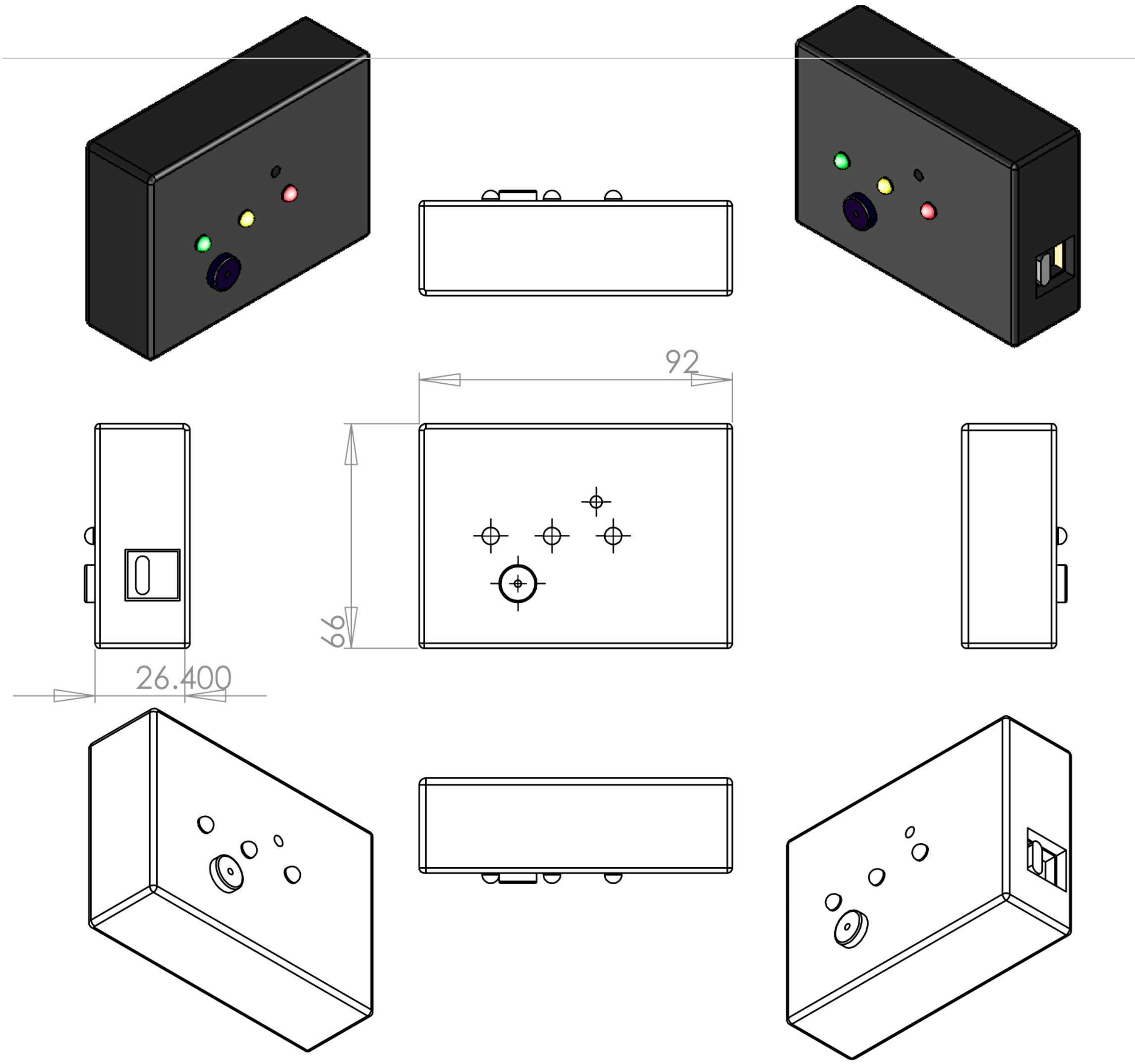
```
                        buttonPushCounter++;
                        Serial.println("on");
                        Serial.print("number of button pushes:
                        Serial.println(buttonPushCounter, DEC);
                    }
                    else {
                        // wend from on to off:
                        Serial.println("off");
                    }
                    // save the current state as the last state,
                    //for next time through the loop
                    lastButtonState = buttonState;
                    j = 10;
                }
                 seconds++;

            }
        }

        delay (100);
        buttonState = digitalRead(buttonPin);
        // compare the buttonState to its previous state
        if (buttonState != lastButtonState) {
            // if the state has changed, increment the counter
            if (buttonState == HIGH) {
                // if the current state is HIGH then the button
                // wend from off to on:
                buttonPushCounter++;
                Serial.println("on");
                Serial.print("number of button pushes:  ");
                Serial.println(buttonPushCounter, DEC);

            }
            else {
                // if the current state is LOW then the button
                // wend from on to off:
                Serial.println("off");
            }
            // save the current state as the last state,
            //for next time through the loop
            lastButtonState = buttonState;
        }
        seconds++;
    }
    digitalWrite(greenPin, LOW);
    digitalWrite(yellowPin, LOW);
     digitalWrite(redPin, LOW);
}
```

Appendix C: Additional Prototype Images



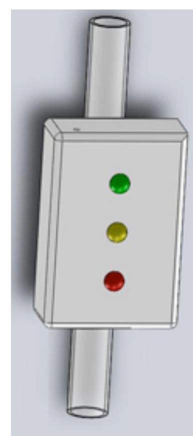
Appendix D – Survey

Colorimetric Time Indicator for IV Notification – Survey

The purpose of this survey is to test the effectiveness and necessity of a design create by an UW-Madison Biomedical Engineering design team for their semester design project. Please read the following problem statement and design description and then fill out the following questions. Thank you!

Problem Statement: IV therapy is used in numerous medical situations to deliver medicine or other fluids directly into a vein. This method of introducing fluids to the vascular system, however, breaks the skin barrier and prevents the wound from closing, creating an easy site for infection. To decrease this chance of infection, the U.S. Center for Disease Control and Prevention states that the IV system is to be changed every 72 to 96 hours. If ignored, the IV insertion site can become infected, causing localized rash, fever and swelling. It is therefore necessary to have an indicator to ensure that the IV system is changed regularly.

Design Description: To replace the current method of notification – handwritten information on a strip connected to the IV system – an electrical device has been designed. The device will attach to the IV tubing and have a recessed power/reset button that can be pressed by the insertion of a pen [to prevent patients from resetting]. On the front of device there are three LEDs – Green, Yellow and Red – to indicate how long the IV has been in place. The green LED would be on for 0-72 hours, yellow from 72-96 hours. These time intervals, however, are free for manipulation by the user via a computer. At 96 hours the red LED will turn on, clearly indicating that the IV needs to be changed. The device will also beep every 5 minutes thereafter (also programmable) to further notify medical personnel.



Please answer the questions on the following page

	Strong Disagree	Disagree	Neutral	Agree	Strongly Agree
General Questions					
1. I frequently am in charge or monitor those in charge of changing IVs	1	2	3	4	5
2. I think it is important that IVs are changed in a timely fashion to prevent infection	1	2	3	4	5
Current Method Questions					
3. I find it a hassle to have to write out the date and time of IV insertion	1	2	3	4	5
4. The current method of handwriting information can be easily overlooked or forgotten	1	2	3	4	5
5. The current method of handwriting information can sometimes be hard to read	1	2	3	4	5
6. An improved method would be beneficial for the patients safety	1	2	3	4	5
New Design Method Question					
7. It would be quicker/easier to press a button to start an electronic device than to write down the date/time of IV insertion	1	2	3	4	5
8. A three LED system would be much more noticeable than handwritten information	1	2	3	4	5
9. A three LED system would be easier to read than handwritten information	1	2	3	4	5
10. Having a buzzer to alert personnel that the IV has been in too long would be beneficial to preventing IVs from being in more than 96 hours	1	2	3	4	5
11. Being able to program the LED time intervals would help fit different patient situations and needs	1	2	3	4	5
12. This method is an improvement to the current method	1	2	3	4	5

13. How long would you say it takes you to fill out the information for the current method?
____

Any comments, suggestions or concerns? ____
____
____
____
____
____
____

Thank you for your time!

Appendix E – Expenses

Order Date	Item	Cost
18-Oct-09	Adruino USB Board	$29.95
20-Oct-09	Basic LED – Yellow (x3)	$1.50
20-Oct-09	Super Bright LED - Yellow - 10,000mcd (x3)	$2.85
20-Oct-09	Super Bright LED - Red - 10,000mcd (x3)	$2.85
20-Oct-09	Basic LED- Red (x3)	$1.50
20-Oct-09	Basic LED – Green (x3)	$1.05
20-Oct-09	Basic LED – Green (x3)	$0.75
20-Oct-09	Super Bright LED - Green - 10,000mcd - (x3)	$2.85
20-Oct-09	Super Bright LED - Green 10mm	$1.50
20-Oct-09	Mini Push Button Switch - SMD	$0.95
20-Oct-09	Momentary Push Button Switch - 12 mm Square	$0.50
20-Oct-09	Project Box, 2.6" x 3.6" x 1.1"	$4.15
20-Oct-09	Project Box, 2.6" x 3.6" x 0.83'	$3.50
12-Nov-09	Adruino ProtoShield Kit	$16.95
13-Nov-09	Adruino ProtoShield Kit	$1.95
20-Nov-09	Rubber Gasket, 6x6x1, (x2)	$2.49
20-Nov-09	Velcro [Industrial Strength]	$13.99
20-Nov-09	Black Nylon Strapping	$3.29
20-Nov-09	Velcro adhesive	$2.99
	TOTAL	**$95.56**