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. In order to ensure the catheter gets replaced, the date and time of catheter insertion is printed and attached to the IV tubing. However, this date and time is often overlooked, to combat this issue, three preliminary new indicator devices have been designed. The first involves exposing a chemical strip to the surrounding environment. This device slowly changes color due to reactions with oxygen or carbon dioxide; the second design utilizes the migration of dye through layers until the dye is exposed on the outer layer, indicating a given time interval. The final design is an electric timer, which illuminates LEDs (green, yellow and red) depending on the 72 to 96 hour time interval. Although all of these options have potential, upon evaluation, it was determined that the best design is the electric time indicator. Future work includes finalizing the specifications for circuitry and hardware, constructing the prototype, extensively testing the prototype, and modifying the prototype based on the testing results.

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 whole 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 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 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).

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

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 (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%. This mortality rate increases to 80% for elderly (Stoppler, 2008). It is therefore necessary to have an indicator to ensure that the IV system is changed regularly.

Current Solutions

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. In theory this solution should work well, but realistically it has drawbacks. First, the handwriting on the strip of paper could be difficult to read or even illegible, resulting in an ambiguous insertion date and time. Furthermore, since hospitals can be fast-paced environments, a nurse or doctor may not have time or may forget to glance at the insertion specifics. These two factors combined create a situation that could endanger the patient.

Figure 2 – The current solution to prevent infection 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

Ergonomics and Human Factors

When considering the multiple aspects of a product over the course of the brainstorm and development period, an issue of utmost importance is the usability and accessibility of the design. Since the product will be used in a hospital setting where the exchanges between patients and medical staff will be numerous, ergonomics will be a key factor in its success. In this case, the ergonomics of the product is a catch-22; the device needs to be easily accessible to medical personnel but hard to access for the patient. It is important to restrict patient access to the device since patients tend to tamper with instruments in the hospital room. Therefore, "patient-proofing" the device will be one of the top considerations in the design. Ideally, initial activation of the device would be the only action needed by medical personnel. After this, no further human input would be required or allowed for the device; it would solely run its color change sequence over the indicated interval of time. In this setting there would be minimal means for the patient to alter the activity of the product, short of physically breaking it. The patient-proofing idea is already encompassed by one of the most important aspects of ergonomics: patient and medical personnel safety. As seen in the design matrix (Table 1), safety, dependability, and accuracy were the highest-rated categories. The reasoning behind this is due to the vital importance of the device: while not used directly in life-and-death situations, it has the ability to prevent infections that could lead to serious complications.

Design Criteria and Preliminary Designs

Due to the elevated chance of error involved with the written insertion dates on IVs, a new device needs to be designed. The device needs to alert medical personnel to an IV that needs 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:

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). 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 preferred mode of attaching the device is connecting it 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 potentially keeps the device out of reach, which is incredibly important to patient safety, as mentioned in the above ergonomics and human factors section.

"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 is accomplished by creating a simple mechanism that allows medical staff to easily operate the device; this interaction is less intuitive, and 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 the cost of 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.

Environmental Exposure

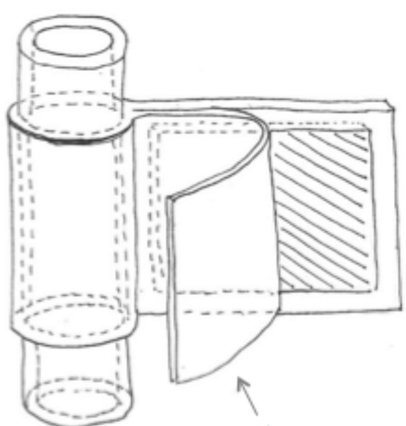

Figure 3 – Environmental Exposure design: An activation layer is peeled away, exposing a chemical strip. This allows it to react with oxygen or carbon dioxide, changing the color of the strip.

The first design incorporates an inert membrane that is peeled back to reveal a chemical strip underneath (Figure 3). This strip responds to the environment by reacting with either oxygen or carbon dioxide and creates a color gradient that changes slowly with time. This has the simplest activation mechanism of the three design options. It is also relatively safe since the chemical strip is not harmful if touched and is quite easy to manufacture cheaply. Furthermore, its low mass creates little strain on the IV tubing.

Unfortunately, there are several flaws with this design. First, since the time indication mechanism is based on environmental exposure, the indication may vary slightly depending on the environment of the hospital room the device is in. Secondly, even though it would be cheap to manufacture, it is designed for one-time use; this leads to extra waste, and the benefits of the low manufacturing costs may be outweighed in the long run by a more costly, reusable model. This device also can't be viewed when the room is dark. Additionally, this design option requires a long development stage in order to perfect the time interval over which it would operate. After this is 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 4) utilizes a transparent, migration, and dye layer. A pull-tab that is impermeable to the dye initially separates the latter two layers. When the tab is removed, the dye from the dye layer begins to bleed through the migration layer. After 72 to 96 hours, the dye becomes visible through the transparent layer, providing an indication to medical personnel that the IV tubing needs to be changed. The exact time it takes the dye to reach the transparent layer is determined by the thickness of the migration layer.

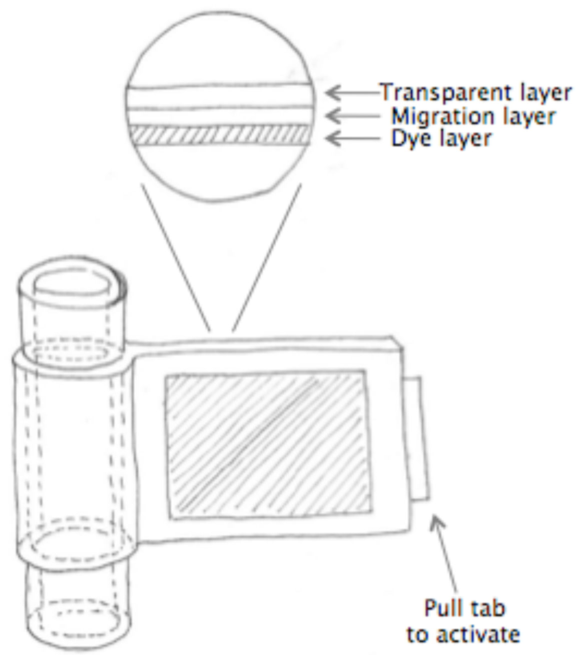

Figure 4 – Migration layers design: utilizes a transparent, migration and dye layer. An activation pull-tab separates the latter two layers. When removed, it initiates the migration of dye through the migration layer. This migration clocks a 72 to 96 time period.

This design provides a clear time indication, eliminating the issue of having to decipher a color gradient. The materials are inexpensive and the size can be easily varied to meet the needs of the user. However, many of the issues that exist in the previous environmental exposure design, subsist in this one as well. Environmental factors, such as humidity and temperature, can affect the amount of time it takes the dye to travel through the migration layer. This product also allows for one-time use only and is 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 5) 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.

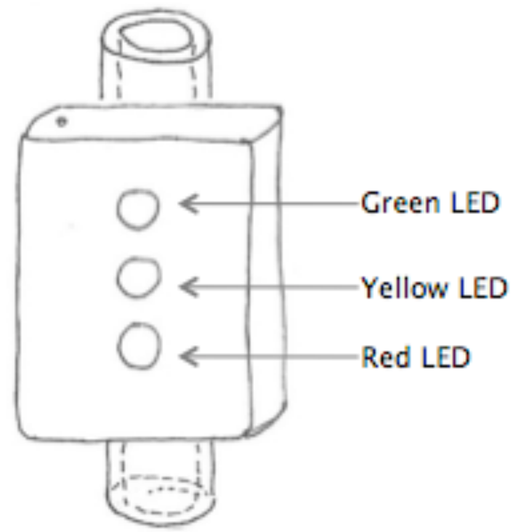

Figure 5 – Front view of the electric LED timer. The device consists of three LEDs (green, yellow and red) that turn on at different time intervals and a recessed reset button on the top.

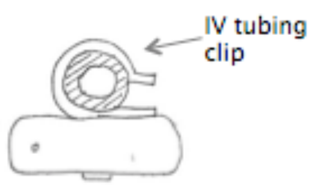

Figure 6 – Top view of the electric LED timer design showing the clipping mechanism.

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 upper face, which can easily be pressed with a pen or other pointed object. The plastic casing is attached to the IV tubing using a basic clipping mechanism (Figure 6) that prevents the device from sliding along the length of the tube (Figure 7). This clip firmly grasps the IV tubing without deterring the flow of IV fluids.

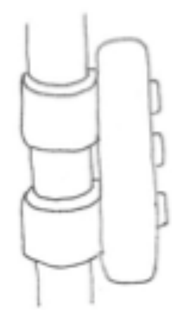

Figure 7 – Side view of the electric LED timer design. Clips firmly grasp the IV tubing, preventing the device from sliding along the tube.

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. Most importantly, this design is precise and accurate, ensuring that the IV tubing will be changed in a timely manner.

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 clipping mechanism 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]. The most important criteria were given more weight in the matrix, which include safety, dependability and accuracy. 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 because 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 is important because there is a current solution already being used; if the product is too expensive, it is unlikely it will be purchased. Ergonomics is always an important factor in any product, however it becomes somewhat complicated for these designs. The product has to be easily activated by medical personnel, yet at the same time prevent 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.

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**

Future Work

Materials and manufacturing specifications need to be established for both the hardware and software design. Currently, two-piece acroylonitrile-butadiene-styrene (ABS) cases are being researched for the exterior of the design. For the interior circuitry, an Arduino USB Board will be used. This bored includes an ATmega168 microcontroller, has a recommended input voltage of 7-12 V and has the ability to be powered via USB connection or an external source (Arduino, 2009). After ordering the board and other materials, such as resistors and LEDs, experimentation will have to be done with Arduino's open-source software in order to determine how to communicate with the board. Once this is established, code will be written for the specific timer and time intervals. A push-button will also be connected to the device and be programmed to reset the timer program and to turn the device on and off. After the initial prototype is completed, testing will be done to establish the effectiveness and limitations of the device, and a survey will be done to determine if it will be valuable to the medical community. The design will then be modified to fit the results.

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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.