Project Proposal

Accessible Infusion Pump User-Interface

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Executive Summary

Home infusion pumps are vital to the health and independence of many patients. These pumps are used to deliver materials in the body fluids of patients. However, due to interfacing problems misuse leads to dosing errors risking the health of the patient. In reviewing works on the market, many research groups have actively studied the inherent problems with pump interfaces. Through usability testing and human factor studies new designs that minimized errors were created. Patents already on the market include many design changes to infusion pumps as complete units but few augment pumps currently in use. The design will incorporate a highly visible display, auditory output, and tactility distinguishable input buttons. The device will be lightweight, easily portable, and battery operated increasing patient independence. Considering our limited budget, purchasing a medical infusion pump would be detrimental to our project and limit our freedom of choosing other major components for the final design. As a result, we hope to receive a donated infusion pump from a local hospital or medical business. Our current estimated price values for our design components are subject to change with the progression of our project and will be finalized upon determining the final components needed.
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1 Introduction

1.1 Background

For patients with physical limitations, infusion pumps can be difficult to operate correctly. Whether it is a vision problem, a hearing impairment or an ailment that restricts motor function, disabilities increase the risk of patient error in device operation. Our visually disabled clients, Mat and Akiko, require tactile cues to be added to the interface for proper use, along with auditory confirmation of the input. To cater for patients with hearing loss like Dolores there must be a large easily viewable display. Jorge, Lakisha, Sani, and Dolores all suffer from some form of limited dexterity due to carpal tunnel syndrome, Parkinson’s disease, arthritis, or partial paralysis. The buttons must be large enough to accommodate an unsteady hand while also being easily triggered with slight pressure. Warnings from the interface will need to be communicated through both auditory and visual cues in order to encompass the wide variety of the patients’ disabilities.

1.2 Purpose of the Project

With current infusion pumps there is not appropriate feedback to the input controls of the unit. This gives an opportunity for erroneous entries without any warning. Due to these errors, over- or under-dosing may occur leading to serious health risks for the patient. Patients in need of an infusion pump may also have learning disabilities or apprehension about technology. To encourage widespread use for all patients, a simple method of operation and short learning curve should be implemented. This would allow a patient to become more independent, especially if there are warnings included in the interface to limit dosing errors. Further promoting independence is a small interface that would ensure portability and patient privacy.

Infusion pumps are instrumental for patients’ very survival with errors in material delivery, both over- and under-dosages, carry the risk of detrimental effects for the patients. Often these errors are due to misuse by patients or their caregivers, such as miscalculation of dosage levels, data entry error or titration error. Users are often physically limited by age or illness, leading to the above mentioned problem. As preliminary requirements, precautions must be administered by the device to ensure accurate operation. Audio output from the device would assist users with visual impairment on confirming the correct dosages. In turn, the confirmation buttons, as well as operational buttons should be easily distinguishable, both visually and tactically, in order to prevent over- and under-dosage accidents by the visually and physically limited users. Additionally, visual displays should be considered to allow the hearing impaired
to correctly operate the device. The design alone should be easy to learn and operate by the patient and/or caregiver, while being aesthetically pleasing and non-threatening to technology-impaired users. As the infusion pump should be easily accessible, designing a portable interface is a necessity.

1.3 Previous Work Done by Others

Juliana Brixey, J. Frenzel, M. Chalambaga, and Todd R. Johnson all of The University of Texas Health Science Center at Houston studied and prototyped an interface for an infusion pump. They focused on the implementing the usability Engineering Lifecycle in which the basic requirements for an infusion pump were gathered and field testing was completed to develop the prototype. Their work was presented during a poster session at AMIA 2002.

A similar study was completed by Karin Garmer, Erik Liljegren, Anna-Lisa Osvalder and Sven Dahlman from Chalmers University of Technology Department of Human Factors Engineering in Göteborg, Sweden. This group used a human factors approach alongside usability tests in order to design a new interface. Tests were performed with nurses from two Intensive Care Units with daily infusion use and a dialysis ward where infusions were rare. To create a baseline the facilities current infusion pumps were used and problems were recorded via video-recording, think-aloud protocols, and surveys. From these usability tests, the interface was designed and evaluated by the original test subjects in a clinical setting. The research group found that the human factors approach gave them the feedback needed to make the new interface less problematic while the usability tests provided more specific solutions to problems that were identified. Their work was published in the *Journal of Clinical Monitoring and Computing* in 2002.

Mark J. Graham, Tate K. Kubose, and Vimla L. Patel from Columbia University’s College of Physicians and Surgeons, Department of Biomedical Informatics along with Desmond Jordan from Columbia University’s College of Physicians and Surgeons, Department of Biomedical Informatics and Department of Anesthesiology and both Jiajie Zhang and Todd R. Johnson from the University of Texas Health Science Center’s School of Health Information Sciences at Houston did research in evaluating infusion pumps in order to progress patient safety in Intensive Care Units. Since the pumps weren’t being redesigned the researcher’s goal was to identify errors, mark their respective severity, and pass this information onto the users to avoid future errors. This was accomplished through a heuristic evaluation using four raters, three with cognitive science and heuristic methodology background and one nurse in surgical intensive care. Upon completion, the researchers found a few catastrophic problems including: no override function for air in tube failures, pressure too high to activate buttons with a low confirmation beep that is hard to hear in working environment, and
the pump will start even if programmed with a high volume. All of the problems were listed and categorized in order to pass the information to the clinical environment and the designers of the product. This work was published in the *International Journal of Medical Informatics* in 2004.

### 1.3.1 Products

There is an extensive market for infusion pumps which is filled by many of the medical device manufactures from around the world. However, the infusion pumps are sold as stand alone units with an interface designed into the main body of the product. These means there aren’t any separate interfaces that are sold that plug into the units. The products below highlight the majority of the current infusion pumps in the this niche of the market.

Abbott – Aim Plus, Lifecare 5000 Plum and Plum XL - [www.abbott.com](http://www.abbott.com)

![Abbott - Aim Plus, Lifecare 5000 Plum and Plum XL](image1.png)

Baxter – Colleague and FLO-GARD - [www.baxter.com](http://www.baxter.com)

![Baxter - Colleague and FLO-GARD](image2.png)

B Braun - Outlook™ Safety Infusion Systems, Vista ® Basic - [www.bbraunusa.com](http://www.bbraunusa.com)

![B Braun - Outlook™ Safety Infusion Systems, Vista ® Basic](image3.png)
Cardinal Health – Alaris®, Alaris® SE pump, MedSystem III® -
www.cardinalhealth.com/alaris/

Curlin Medical – PainSmart, 4000 CMS, 4000 Plus, and 2000 Plus -
www.curlinmedical.com

Sigma International – 8000 and 6000 series pumps -
www.sigmapumps.com

Smiths Medical - Deltec ® 3000 and 3100 series pumps – No pictures available -
www.smiths-medical.com
1.3.2 Patent Search Results

Patent research when designing a new product for market is necessary because of the restrictions that are placed on existing patented products. When a new patent is issued there is a generally 20 year term that begins from the date the application was filed. This term gives the rights to the patentee to prohibit others from “making, using, offering for sale, selling or importing the invention.”¹ This must be implemented by the patentee in order to have a case of patent infringement.

A search using the site http://www.uspto.gov/patft/index.html and the term ‘medical infusion pump’ in the title and ‘interface’ in all fields only resulted in three patents being found. The most relevant patent found was 5,782,805 Medical infusion pump - July 21, 1998 - Meinzer, et al. This patent describes the infusion pump as a complete unit including the main body with interface, at least one removable pump module with IV attachment area, an auxiliary display for supplemental information, and a microprocessor which provides the calculations for the interface and pumping mechanism. Another patent in this search was 6,999,854 - Medical infusion pump capable of learning bolus time patterns and providing bolus alerts - February 14, 2006 - Roth which described a pump that can actively learn bolus time patterns for patients who must undergo medication injections regularly around the same time. This device is specifically geared towards patients such as diabetics undergoing insulin injections around their eating patterns. By broadening the search term to only ‘medical infusion pump’ in the title the results jumped to seven patents which included D430,288 - Medical infusion pump - August 29, 2000 - Mason, et al. This is a design patent which only had ornamental pictures of the pump but it was a manually operated syringe type pump that isn’t in the scope of our project as we are designing an electronic interface. Another result was D268,206 - Medical infusion pump - March 8, 1983 - Kosako which is also a design patent which had only ornamental pictures including the one shown below in Figure 1.

![Figure 1: D268,206 - Medical infusion pump](image)

Browsing the referenced patents I came upon the term peristaltic pump which is the common delivery method for infusion pumps due to its sanitary and mechanical benefits. Another search using the term ‘medical peristaltic pump’ provided 4 patents with 4,544,336 - Medical peristaltic pump - October 1, 1985 -

¹ United States Patent and Trademark Office
http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent
Faeser, et al. being the most relevant. This patent describes how the pump squeezes the contents through the tube via rollers mounted on a wheel. Unfortunately there was only one patent found that specifically dealt with medical pump interfaces. This was D507832 - User interface for a medical device - July 26, 2005 - Yanniello, et al. and was found using the terms ‘infusion pump’ and ‘interface’ together in all field searches. This is another design patent but unfortunately the pictures weren’t available due to an internet plug in error. There were 783 results found with this search and the other most relevant patents include:

This patent describes the need for a more-readily usable interface for electronics devices but it could be implemented for a medical device.

This patent explains how a programmable system can actually predict a user’s desired inputs based on past data. This would allow the interface to slowly learn the desired functions the user chooses most often via a closed loop feedback system. This technology can also be incorporated into a medical device.

This patent allows the infusion pump to be loaded with a library of drugs which could be selected from or added to by the user. This would allow the product to check for errors in entries from patients or caregivers who aren’t familiar with the infusion pump.

5,664,270 - Patient interface system - September 9, 1997 - Bell, et al.
This patent deals with interfacing a multitude of medical devices into one remote controller for ease of use. Even though the device isn’t specifically for an infusion pump the technology for creating an easily usable interface for a patient still exists in this patent.

2 Project Description

2.1 Objective

The objective of the project is to design a portable, steadfast, low-cost user interface to allow easy operation of a medical infusion pump for the patient and/or caregiver, to provide accurate delivery of necessary materials (fluids, medications or nutrients) to the patient’s body. One of the major problems
found from many medical infusion pump users is the lack of accessibility of the user interface. In turn, this project will reduce the occurrence of over- or under-dosages, data entry errors, titration errors, and greatly reduce the detrimental health risks for the patient, while increasing user ease and patient independence.

The intended project design will connect to a medical infusion pump via an external port (i.e. serial, USB), creating a secondary user interface. This project will not only reduce input errors, but also allow easy navigation for patients and/or users with physical, visual, and auditory disabilities. In response to inputs provided by patients and/or caregivers with visual impairment, the interface will provide an auditory output to confirm the selected options (dosage, rate, volume, etc.) to help reduce the risk of miscalculation. On top, the auditory output will provide instructions to the patient and/or caregiver in pressing the correct buttons in response to their input selection. Confirmation buttons (ON/OFF, START, STOP, YES, NO, etc.) will be greatly distinguishable and distal in proximity relative to each other to prevent accidental problems, such as over- and under-dosage for the visually and physically impaired. In addition, a visual display (i.e. LCD screen) will allow the hearing impaired to correctly operate the device by providing the correct values as entered on the user interface, in addition to providing visual warnings of possible calculation errors to prevent the accidental confirmation of inaccurate input values.

Nonetheless, the device in general will be aesthetic to the eye and allow ease of operation for technology-impaired users. Patients in need of a medical infusion pump may also have learning disabilities. To encourage widespread use for all patients, a simple method of operation and short learning curve will be implemented. This would allow a patient to become more independent, especially if there are warnings included in the interface to limit dosing errors. The user interface will be small and portable with the medical infusion pump to further promote independence and privacy for the patient. Since most medical infusion pumps are positioned on a rolling stand (Figure 2), the user interface will be placed in close proximity to prevent lose and/or damage.

2.2 Methods

An accessible interface between and infusion pump and the user is intended to enhance the function of the infusion pump in two main areas. First, the
interface is intended to increase the accessibility of the infusion pump. By providing augmented visual, auditory and tactile control and confirmation options, the market of customers is expanded while making the self-operation of an infusion pump and alternative to a home assistant for many patients. Second, the interface is to provide a level of safety against over- or under-dosing.

The first point of accessibility will be the visual display. In order to make the pump accessible to those with poor vision, a large, high contrast display is necessary. The characters must be large and bright enough that those with low eyesight can read them, but the size and brightness will also be limited by other factors. To remain accessible, the unit must be battery powered as many infusion pumps are. Therefore the intensity of the screen must be limited so as to give the device a reasonable lifetime per battery charge. In the same light, the device must be of a reasonable size to be easily transported around the home. This will limit the size of the display. Considering that there must be enough characters to convey information accurately, the size limitation on the entire display translates into a size limitation on the characters themselves. The display must also be simple and inviting to those who do not feel comfortable operating high tech equipment.

To supplement the visual display for those who have low eyesight, the interface must also have auditory confirmations. Ideally these auditory cues will take advantage of speech software to convey information. For those who cannot read the screen of the device, directions for what is to be entered as well as repetition of what has been entered will help patients with low eyesight maintain correct dosage levels. The control of the auditory component must be considered. Patients who do not need the auditory cues could become annoyed by their constant presence. Therefore, auditory component must be optional. Volume control should also be an option. If the auditory settings were built into the menu structure of the device, people who need the auditory cues intermittently would have a hard time navigating the device to turn them on when needed. For this reason, auditory cues and the volume thereof should be physically controlled by buttons on the outside of the unit. A single on/off toggle button with a volume wheel would be easy and familiar to users.

It is likely that some patients using this interface will be suffering from arthritis or other conditions which decrease their dexterity. For these people, as well as patients with low eyesight, a simple and clearly distinguishable set of input buttons is required. These buttons must be large and distinguishable by touch. This can be accomplished either through spacing on the device or tactile signals such as bumps in different patterns and the shape of the buttons. The buttons must be easy to press while at the same time offering enough resistance to being pressed that the accidental triggering of a button is minimized.
The layout and function of buttons should be as intuitive as possible. Much can be learned from the plethora of handheld electronics with which people work daily. The iPod digital music player, for instance, has only five buttons in addition to a scroll wheel. The use of these buttons to navigate the device is easily learnable. Along these lines, the number of buttons on the infusion pump interface should be kept to a minimum. Well designed function architecture can reduce the number of needed input buttons to as few as three.

Two buttons, an up and a down button for instance, would be designated for navigation within the menus of the device as well as selecting digits for dosing levels. A third button would be used to select a highlighted function or confirm and entry into the system. A fourth button with the function of 'cancel' or 'back' could also be implemented in lieu of a 'back' option at the bottom of every menu. This decision must be made based on menu length and the number of menus needed. A back button, bringing the total to four input buttons, would not over complicated things and may make the device easier to use.

The necessity of accessibility puts several constraints on the design. Physically, the device must be relatively small and light. Patients using infusions pumps are often elderly or weakened by their illnesses. A device that they can maneuver around their home is needed. In addition to being light and small enough to be moved, the interface must also be mounted in a useful location. Many infusion pumps are mounted to the poles of IV stands. This should therefore, be an option for the interface. One
possible problem with this is that the many tubes running to and from the infusion pump itself may interfere with access to a pole-mounted interface. To work around this, a pole mounting arm of some sort may be considered in the design (Figure 4).

As most infusion pumps are battery operated, the interface should also be. Having a battery operated device places several limitations on design. The visual display is likely to be the main power draw, especially considering that it must be very bright to increase visual accessibility. The screen should therefore be efficient. An LCD would be the most power conservative. A dimming option will also be considered to allow for longer life if the full brightness is not required by the patient. A screen saver function could also be employed if a display such a color LCD panel is used.

For the interface to be accessible, it must be easily maintained. The battery itself should be easily accessible and require only moderate force and dexterity to remove. The simpler the battery removable, the more easily the patient can use the device. Ideally the device would not need to be dismounted to remove the battery.

As mentioned above, the second major function of the infusion pump interface is to ensure the patients’ safety by preventing incorrect dosing. This can be accomplished in a variety of ways. The most basic safety feature is making sure that a dosage was not entered incorrectly. This can be done by simply reviewing the entered data for the patient. Using both visual and auditory interfaces, the device should recount the selected dose and schedule in order to allow the user to catch and correct any mistake that he or she may have made. Confirmation of the dosing should be failsafe. The user should be asked a question along the lines of “Is this correct?” with the ‘No’ answer highlighted. The patient must then select yes and confirm. This way, the patient is made aware of what the device has received for data.

A method that is even more error-free may be available. There exist barcode systems which identify the drug name and concentration. If this system is nonproprietary, it may be possible to include a laser scanner on the interface. The patient would simply have to scan the barcode and the dose and dosing schedule would be entered into the device automatically. At the very least, the drug name and concentration would be reported to the user so as to ensure that the infusion pump is being loaded with the proper medication.

Another way to reduce patient error is to allow dosing protocols to be saved. If a patient is on a standard drug regimen, there is no need to reenter the same dosing requirements every time a new vial is inserted. Allowing a protocol to be saved and reloaded will decrease the chance of high- or low-dosing.
As the device is to be battery operated, a low battery warning is essential. The warning must be both visual and auditory. The warning should begin on a regular basis an adequate period of time before operation ceases. The length of this warning will be determined based on the battery life of the interface.

The interface is designed to make the infusion pump more accessible. Therefore, all warning and messages sent by the infusion pump must be presented through the interface in order to ensure that the patient can perceive the information. This includes all warnings, such as open doors, occlusion, check injector, check syringe, and so on. If possible, further instructions for dealing with the errors can be given, but this is unlikely as there are many different infusion pumps available and they all operate differently.

The connection with the infusion pump itself may prove to be haphazard. It is unlikely that infusion pumps come with serial bus ports. If this is found to be the case, interfacing between the devices will be done along these lines. However, there is a possibility that the interface will need to be wired into the pump. If this is found to be the case, releasable connectors will be used to allow the devices to be separate in the event of failure or transport.

3 Budget

The budget for this design project is currently under revision and precise amounts will be determined near the beginning of next year when the final design is set and the ordering of the device components are planned. Nonetheless, preliminary components have been established for the consideration of the infusion pump user interface, shown in Table 1.

The retail market values and estimated price for the device components are of rough estimate and are subject to change during the progression of establishing the final outline for the infusion pump user interface.

The purchase of a new medical infusion pump would greatly deplete our budget of $2000, which in turn will limit our freedom of purchasing other device components. As a result, we hope to receive a medical infusion pump donated from a local hospital or medical business to help us assist in designing a communication pathway between the pump and the secondary user interface to initiate our design outline for the project.
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<th>Item</th>
<th>Retail Value in Market</th>
<th>Estimated Buying Price for Project</th>
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<td>LCD Display Interface</td>
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<td><strong>Estimated Total</strong></td>
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*Table 1: Estimated Budget for Accessible Infusion Pump User-Interface*

The various components (LCD display interface, Voice hardware, software, electronics) for the interface range greatly in price; buying the cheapest component may be helpful in reducing costs and expenditures for the budget; nonetheless, high quality for the end product is greatly desired. As price correlates proportionally with quality, finalizing the components upon ordering will be greatly considered.

4 Conclusion

For patients with physical limitations, medical infusion pumps can be difficult to operate correctly. Whether it is a vision problem or an ailment that restricts motor function, there is always a risk of delivering the wrong dosages. With current medical infusion pumps there is no appropriate feedback to the input controls of the unit. This gives an opportunity for errors to be entered into the system without any warning. Once this phase of the patients’ interaction with the pump has passed, over- or under-dosing may occur leading to serious health risks for the patient.

This project’s intended design approach will greatly reduce the patients’ health risk. By designing tactile cues, users with motor disabilities will not have great of a problem using the interface compared to using a regular infusion pump.
interface. Vocal commands will be incorporated into the design to allow easy navigation for users with visual impairment. In addition, a visual display will be placed on the design to assist users with auditory impairment, and provide as a safeguard in displaying accurate input values the user requires. Learning ease will be another feature provided by the design to allow easy navigation by numerous users, especially the technology impaired. The design of the device will be aesthetic to the eye allowing comfort to all users. None of the aforementioned characteristics are found in modern medical infusion pumps, making this design project quite unique and worth the venture.

Introducing the final accessible infusion pump user interface device into the industrial market will greatly increase its desire from biomedical corporations. Considering majority of infusion pump users find difficulty using the pump interface, in addition to the device’s low budget cost, biomedical corporations would be steadfast in implementing this device with their medical infusion pumps. Consecutively, the companies will gain great credibility in achieving a more reliable, cost-effective medical infusion pump for their patients and/or caregivers. Considering the importance of the home infusion pumps to patient health, the need for an accessible interface is paramount.
References


1.)
http://www.amia.org/meetings/f02/2002online/S64.HTM

**Title** Redesign and Prototype for the Interface of a Volumetric Infusion Pump Following the Usability Engineering Lifecycle

**Participants** Ms. Juliana Brixey, MSN, MPH, RN University of Texas Health Science Center at Houston University of Texas Health Science Center at Houston J. Frenzel, MD, University of Texas Health Science Center at Houston, Houston, TX M. Chalambaga, MCP, University of Texas Health Science Center at Houston, Houston, TX T.R. Johnson, PhD, University of Texas Health Science Center at Houston, Houston, TX

**Abstract** The object of this project was to redesign and prototype an interface for a volumetric infusion pump following the usability engineering life cycle. Healthcare has been slow to follow the lead of other high-risk industries in applying usability engineering and human factors principles to error reduction. The U. S. Food and Drug Administration-Center for Device and Radiological Health (CDRH) acknowledges that a lack of attention to human factors during product design may result in a biomedical device ill suited to use in a critical environment. This study utilized several usability techniques to develop a prototype interface for field-testing. Findings from the field tests led to refinements in the infusion pump interface.

**Keywords** Human factors and user interfaces Technology assessment Quality assessment and improvement Outcomes assessment


2.)
http://www.springerlink.com/content/edk88ghwuhunfuvu/
http://www.springerlink.com/content/edk88ghwuhunfuvu/fulltext.pdf

**Arguing for the Need of Triangulation and Iteration when Designing Medical Equipment**

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Arguing for the Need of Triangulation and Iteration when Designing Medical Equipment
Abstract  **Objective.** There is a need to develop adequate methods for use by the manufacturers of medical equipment when specifying requirements for their development and in order for hospitals to critically assess their usability qualities before purchase. A Human Factors approach was used to determine requirements for the redesign of an existing volumetric infusion pump. With these requirements as a starting point, a new user interface for an infusion pump was designed. Usability tests were carried out to verify whether the new interface had better usability than the existing interface or whether further improvements were needed. This paper has two aims: 1) to compare the nature of the requirements derived from a Human Factors approach and from usability tests and 2) to evaluate the use of usability tests on existing medical equipment as a basis for redesign and for evaluating the redesign. **Method.** The user requirements derived from the Human Factors approach were compared with the user requirements derived from the usability tests. **Results.** The results show that the requirements derived from the Human Factors approach adequately covered contextual aspects of use. However, to derive requirements for a specific and operational level, usability tests must be conducted on existing equipment and prototypes. This study indicates that usability tests on existing medical equipment as a basis for redesign give a better understanding of problems with existing equipment. Moreover, it is important to carry out usability tests to evaluate a redesign and find a satisfying solution. Expert users of the equipment had the experience, competence and confidence to be critical and suggest improvements based on their practical knowledge. The novice users on the other hand were important test users as they uncovered most of the serious handling problems and also committed most errors. **Conclusion.** The requirements derived from the Human Factors approach and the usability tests are important for the development of a new and improved user interface. The requirements derived from the Human Factors approach can be attributed to contextual requirements. The requirements derived from the usability tests have a higher degree of concreteness, are more specific and focus more on design solutions compared to the requirements derived from the Human Factors approach. It is important to consider intended user groups when carrying out usability tests, as the nature of the information from the different groups can be different.
Similar problems have occurred related to FDA’s recall of eight Colleague models of the medical infusion pump manufactured by Baxter Healthcare Corporation issued in July 2005. The devices have been known to have flaws in their user interface. As a result, the device would allow the user to accidentally turn off the medical infusion pump when planning to begin infusion. As shown in figure 1, the ON/OFF button of the medical infusion pump is in close proximity to the START button, thus allowing the accidental powering-off of the device. Such defects can be life-threatening to patients and/or users with visual and/or physical disabilities. About nine people have been seriously injured or killed due to the medical infusion pump defects.

Current commercial infusion pumps from companies such as Alaris Medical Systems, Baxter, Baxa Corporation, and B. Braun, such improvements (mentioned above) for the acoustically, visually, and physically impaired would greatly enhance the marketing of their products for home infusion pumps and greatly decrease errors in drug/nutrient delivery.