Optimal Design Report

Accessible Infusion Pump User-Interface

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1 Optimal Design

1.1 Introduction

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. The Accessible Infusion Pump Interface will attempt to alleviate these concerns by providing a highly visible, easy-to-use system with which the infusion pump can be set. The system will also allow inputs and outputs to be transmitted audibly and it will use controls that are easy to manipulate and that can be identified by touch. 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.

Figure 1.1.1: Pole-mounted Interface

Figure 1.1.2: Basic Circuit Design (in section 1.2.8)
The subunits section of this report details the major components of this Design. A text-to-voice unit are used to interface with the user. Buttons and a joystick allow for easy user input. A Blackfin chip will serve as the microcontroller and coordinate between the elements of the interface and the pump itself. The connection to the pump will be made using Bluetooth wireless protocols. A mounting arm will secure the interface to the IV stand when not in use, but due to the wireless capability, the interface will be detachable to increase accessibility.

In this iteration of design, the Blackfin chip has been explored as an option for the microcontroller. The mounting arm will allow the patient to easily position the interface to his/her liking. Packaging was added and a pair of buttons has been replaced with a joystick. The Bluetooth technology was removed due to the difficulty of writing the drivers for operation. The software architecture was redesigned to enhance the ease of use of the interface for the patient. The LCD display was changed from a graphical to a colored display with a power and video input.

It was discovered that the RS-232 output on the back of the infusion pump could not be used to interface with the unit. Instead, the infusion pump must be accessed directly through the stepper motor. An analysis of these motors for interfacing accompanies the report. Power plugs were also included to power the stepper motor, as well as the entire device through a 120VAC outlet. A new 12V rechargeable battery was selected to operate the user-interface.

1.2 Subunits

1.2.1 7” Widescreen Open Frame TFT Active Matrix Color LCD Monitor (Part #: ALCD7X)
The colored LCD display module from AEI components will be used as the display for the accessible infusion pump user-interface. This subunit's main function is to display a visual display to allow the hearing impaired to correctly operate the device. The display will provide 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.

Initially, the colored LCD display will be connected to a PC to test the functionality via video and power input. A standard yellow video input will be used in connecting the LCD to the PC’s LABVIEW program (for testing purposes), while a 12V power adapter will power the display (which is supplied by the 12V battery. The colored LCD display will easily display the LABVIEW program’s output. In turn, once the program is burned onto the Black Fin processor, we hope to also program the chip to display the appropriate screen for the colored LCD display.
Figure 1.2.1.2: LCD Dimensions
Table 1.2.1.1: Color LCD Specifications in [1]
1.2.2 Toggle Switch / Joystick

Replacing the scrolling arrow buttons with a single axis joystick will provide patients with an easier means to choosing the correct menu or number from the LCD. This particular joystick comes with a restrictor plate to make it one axis from its normal two. Reducing the joystick to one axis of motion allows only up or down inputs from the patient. The J1 low profile joystick as seen in Fig. 1.2.2.1 on the next page has a plus or minus twelve degree movement from center which is enough to avoid inadvertent inputs. This degree of movement also isn’t large enough to make the motion strenuous to the user when scrolling through menus or numbers for selection.

<table>
<thead>
<tr>
<th>SPECIFICATIONS</th>
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</thead>
<tbody>
<tr>
<td>DISPLAY: 7” Color TFT-LCD Active Matrix Monitor</td>
</tr>
<tr>
<td>INPUT SIGNAL: NTSC/PAL/Auto switching</td>
</tr>
<tr>
<td>DOT FORMAT: 1440 x 234</td>
</tr>
<tr>
<td>BACK LIGHT: CCFT</td>
</tr>
<tr>
<td>LAMP LIFE: 15,000 Hrs.</td>
</tr>
<tr>
<td>BRIGHTNESS RATING: 350 NITS</td>
</tr>
<tr>
<td>CONTRAST RATIO: 150:1</td>
</tr>
<tr>
<td>VIEWING ANGLE (L/R/T/B): 55°/55°/15°/35°</td>
</tr>
<tr>
<td>POWER REQUIREMENTS: 12VDC @ 700 mA</td>
</tr>
<tr>
<td>VIDEO INPUT LEVEL: 1.0 V p-p (Positive) 75 Ohm</td>
</tr>
<tr>
<td>MODULE (HxWxD): 3 15/16” x 6 1/2” x 1/4”</td>
</tr>
<tr>
<td>DRIVER BOARD: 2 11/16” x 4” x 3/8”</td>
</tr>
<tr>
<td>CONTROL BOARD: 1 3/4” x 2” x 1/2”</td>
</tr>
<tr>
<td>MONITOR MOUNTING: None</td>
</tr>
<tr>
<td>OPERATING TEMPERATURE: 0° ~ 60°C</td>
</tr>
<tr>
<td>STORAGE TEMPERATURE: -20 ~ 80°C</td>
</tr>
<tr>
<td>WEIGHT: 12 oz.</td>
</tr>
</tbody>
</table>
Figure 1.2.2.1: Picture of J1 Low Profile "Switch Stick" Joystick from etisystems.com

Figure 1.2.2.2: Engineering drawing of J1 Low Profile "Switch Stick" Joystick showing dimensions from etisystems.com
The joystick will be integrated into left side of the interface as seen in Fig. 1.2.3.2 on the next page to allow the user to select the confirm or cancel buttons with their right hand much like a gaming controller.

**1.2.3 Buttons**

A tactility distinct intuitive button interface is essential to accessible operation of the infusion pump interface. Using different shapes and raised patterns on the buttons, they can be easily identified by touch. The spring constant of the buttons must also be carefully determined so as to offer enough resistance to deter accidental button pushes but not be so arduous that a disabled user cannot use the system.

![Possible confirmation and cancel button layout](image)

**1.2.3.1:** Possible confirmation and cancel button layout

As seen in Fig. 6, a two button construction is being considered for this interface. The up and down functions from the joystick will facilitate navigation through the graphic user interface as well as selection of digits (0-9) when inputting rates and volumes to be infused. The OK button is the general select button serving to select the highlighted portions of the graphic user interface as well as confirm inputs once they are correct. The BACK button will step back one step with every push. It will move incrementally back through the various menus until it reaches the main menu. For this reason, it may be wise to include a main menu button as well so as to provide an easy way back to a recognizable reference point for someone who feels lost in the device.

When placing the buttons on the interface, layout will be important. If the buttons are too cluttered than the user may mistakenly hit the wrong input. Separating the joystick from the confirmation and back buttons will provide two distinct areas with very different functions. These isolated areas of function will reduce problems when inputting information to the interface for disabled patients. Ideally the buttons and joystick will be mounted on the sides of the LCD display which would force the patient to scan across the front of the interface before making a confirmation or change to flow rates. An example of this layout is shown in Fig. 1.2.3.2 on the next page.
1.2.4 Rhino 12 Volt 3.4Ah Sealed Lead Acid Battery (Code: SLA-3-12)

A lead acid battery will be used in powering the accessible infusion pump user-interface. Figure 1.2.4.1 displays the battery that will be used in connection to our interface circuit. Since the terminals of this battery are hooks, connection to the circuit will require simple wiring. Considering the use of this battery within an interface, which is connected to a continuous infusion pump; continuous use and ability to recharge is paramount (Figure 1.2.4.2-next page). A 12V lead acid battery (3.4 Ah) has the ability to recharge, and considering these batteries are used in most infusion pumps, the battery will be very reliable. Since the LCD requires a 5V, a 12V battery would be well enough to power all the electronic subunits. Nonetheless, the battery will be used as a backup power supply when the 120V AC outlet power is not connected, lasting for 5 hour use. Upon completing the circuit board required for the user interface, a simulation protoboard circuit will be used in testing the subunit within the subsystems.
**Figure 1.2.4.2:** Recharging Circuit Schematic from www.electronicpeasant.com

**Figure 1.2.5.1:** Power Cable Connection from alibaba.com

**1.2.5 Power Cable and Connection (Model #: DYST7/DYSZ7)**

Approximate switching points:
- Green/Yellow: 12.9 Volts
- Yellow/Orange: 11.8 Volts
- Orange/Red: 10.7 Volts

For 3 L.E.D. indicator, omit all components indicated with *.
Specifications:
1) ST7:
   a) NISPT-1 18AWGX2C
   b) NISPT-2 18AWGX2C

2) SZ7:
   a) 7A 125V

Figure 1.2.5.1 will be the plug used in operating our infusion pump from the 120V outlet. This will be connected to our stepper motor and microprocessor. Once disconnected our 12V battery will be able to supply the required power. In addition, the plug-outlet frame will be connected to the back of the casing.

1.2.6 Mounting Arm:

Mounting the interface separate from the pumping mechanism via a mounting arm separates the two functioning entities. This gives the patient the ability to focus strictly on inputting the infusion rates and information before needing to load the IV tubing and medications. These isolated functioning areas will decrease the risk of inadvertent use because the patient will be undergoing one distinct task at a time.

The arm itself will be some form of Moffatt Product’s flexible arms. Since our clients suffer from many different forms of motor impairment, an arm with only a few hinge points could be difficult to operate and adjust properly. The flexible arm means there will be no specific hinged areas but rather a completely adjustable design. Another beneficial design feature for the Moffatt flexible arms are the hollow interiors.
These examples show a variety of connectors and bases that can be applied to the flexible arm. The bracket at the top left of the examples with the square base will be the template that will be used in the design of our bracket. This bracket will be mounted to both the interface and the battery and pumping casing and contains a center hole to allow the wiring to run directly into each casing. By allowing the wires to run directly into the interface they won’t be exposed and will pose less of a risk to patients. The following diagrams were drawn in Microsoft Visio and include the dimensions for the top, side, and two three dimensional views.

Figure 1.2.6.1: Examples of Moffatt Product’s flexible arms for a variety of applications
Figure 1.2.6.2: Bracket top view with dimensions in inches

Figure 1.2.6.3: Bracket side view with dimensions in inches
**Figure 1.2.6.4:** Bracket three dimensional view one

**Figure 1.2.6.5:** Bracket three dimensional view two
On the casing that will contain the battery and the pumping mechanism there will be a mounting block. This mounting block will be machined out of 6061 aluminum 1.5" by 1.5" aluminum stock as shown by Fig. 1.2.6.10 on the following page. Aluminum is easily machined while also being lightweight and corrosion resistant. These features make aluminum the idea metal for our design. Using an aluminum mounting block with a nut and bolt will allow the metal to bend slightly when the fastener is tightened. This bending causes pressure to be applied to the IV pole to prevent the arm from slipping. The following diagrams were drawn in Microsoft Visio and include the dimensions for the top, side, two three dimensional views and 1.2.6.10 represents the square stock from Metalsdepot.com.

![Diagram](image)

**Figure 1.2.6.6:** Casing mounting block top view with dimensions in inches
Figure 1.2.6.7: Casing mounting block side view with dimensions in inches

Figure 1.2.6.8: Casing mounting block three dimensional view one
The arm must be able to withstand the force generated by the weight of the interface without losing shape. In order to find the appropriate strength for the flexible arm the worst possible orientation should be used.
Table 1.2.6.1: Maximum load for flex arms when mounted horizontally from Moffatt Products.

This is the horizontally mounted position because it maximizes the distance from connection point causing the moment to be the greatest. The preceding table comes directly from Moffatt Product's customizable flex arm design guide.

With an approximate weight of five pounds for the interface and an arm length of twelve inches, it’s apparent that the design will need a stronger flex arm that can support the weight of the unit. The best option will be to get internal stiffeners by Moffatt Products. The hollow interior of the arm can be modified with these stiffening bars in order to increase the maximum weight that can be added to the end of the arm. Also the hollow interior of the arm will provide a sealed space to run the wiring from the interface to the pumping and battery case.

**1.2.7 Text to Voice Unit**

The interface’s text to voice unit is the crucial link to the project for our clients that suffer from visual disabilities. Without proper auditory cues, patients run the risk of delivering wrong dosing amounts which can cause serious harm or even death. This makes the auditory output from our interface a vital portion of the correct drug delivery interface system.
Winbond currently produces the WTS701 which is a single chip, integrated circuit that can convert text to speech. For our interface, we will be incorporating the Parallax Emic Text-To-Speech Module that contains the Winbond WTS701. By using the module rather than design the circuit from the chip alone, our group has the complete hardware module that can convert the lines of text on the LCD into English. This design is also very small and includes the speaker needed for the converted output which will allow for our design to meet its size and portability objectives.

**Emic Platform SIP**

![Emic Platform SIP Diagram]

**Emic Platform OEM**

![Emic Platform OEM Diagram]

**Figure 1.2.7.1:** Emic modules in both SIP and OEM configurations from Parallax Inc.
Table 1.2.7.1: Pin descriptions for Parallax Emic Text-To-Speech Modules.

<table>
<thead>
<tr>
<th>Pin (OEM)</th>
<th>Pin (SIP)</th>
<th>Pin Name</th>
<th>Type</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>7</td>
<td>VCC</td>
<td>P</td>
<td>System power, +5V DC input.</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>BUSY</td>
<td>O</td>
<td>Busy notification line. Digital logic HIGH when Emic Platform is in-use (e.g., receiving characters, converting text-to-speech, etc.) or when a system error has occurred. Logic LOW when the Emic Platform is idle and ready to receive new commands or text. The visible LED on the Emic Platform is red when BUSY is HIGH and green when BUSY is LOW.</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>SIN</td>
<td>I</td>
<td>Serial In. TTL-level interface, 2400bps, 8 data bits, no parity, 1 stop bit.</td>
</tr>
<tr>
<td>4</td>
<td>2</td>
<td>SOUT</td>
<td>O</td>
<td>Serial Out. TTL-level interface, 2400bps, 8 data bits, no parity, 1 stop bit.</td>
</tr>
<tr>
<td>5</td>
<td>8, 11</td>
<td>GND</td>
<td>G</td>
<td>System ground. Connect to power supply's ground (GND) terminal.</td>
</tr>
<tr>
<td>6</td>
<td>14</td>
<td>/RESET</td>
<td>I</td>
<td>External system reset pin. Active LOW digital input. Bring this pin LOW to reset the Emic Platform. Recommended use is after the host controller power-up or an Emic Platform system error. This pin should be left floating if it is not used.</td>
</tr>
<tr>
<td>7</td>
<td>10</td>
<td>AOUT (ANA)</td>
<td>O</td>
<td>Audio output buffer pin provides a single-ended analog output of the synthesized speech for external amplification. Drives a minimum load of 5k Ω up to a maximum of 1Vp-p. The AC signal is superimposed on approximately 1.2VDC bias and must be capacitively coupled to the load.</td>
</tr>
<tr>
<td>8</td>
<td>15</td>
<td>SP-</td>
<td>O</td>
<td>Differential negative speaker driver output. Designed to drive an 8 Ω speaker up to a maximum of 23.5mW for the OEM version and 300mW for the SIP version. Do NOT connect this pin if using SP+ as single-ended output (OEM version only).</td>
</tr>
<tr>
<td>9</td>
<td>16</td>
<td>SP+</td>
<td>O</td>
<td>Differential positive speaker driver output. Designed to drive an 8 Ω speaker up to a maximum of 23.5mW for the OEM version and 300mW for the SIP version. On the OEM version, this pin is biased to approximately 1.2VDC and can be used as a single-ended output if capacitively coupled to the load.</td>
</tr>
<tr>
<td>---</td>
<td>9</td>
<td>AIN</td>
<td>I</td>
<td>Analog input pin for SIP version only. Allows an audio signal to be fed through the Emic Platform to either the AOUT or SP+/SP- pins. The input has a nominal 654mVp-p level. There is no gain control on this signal. The audio signal must be AC coupled to the AIN pin. No signal should be active on the AIN pin when it is not in use, or else the signal may bleed through to the Emic Platform's audio output at undesirable times. This pin should be left floating if it is not implemented.</td>
</tr>
</tbody>
</table>

Note: Type: I = Input, O = Output, I/O = Bidirectional, P = Power, G = Ground

The above pin descriptions show that the module only requires +5V DC for power which will be supplied by the batteries, contains both a serial in and out for information transfers, and has pins for both positive and negative speaker driver output to provide the speaking voice. These pins will be used in coordination with our microprocessor to supply the relevant information from our LCD for the overall voice output.

1.2.8 Circuit Elements

The physical link between the infusion pump and the interface will ideally be done via a serial bus. RS 232 seems like a likely candidate due to its pervasiveness and relative simplicity. The procured infusion pump is a Baxter Flo Gard® 6200 which has no serial bus outputs. If another pump with a serial port cannot be found, the Baxter Flo Gard® 6200 must be dissected in order to install a port through which interfacing can be accomplished. Signals must be
received from and sent to the infusion pump in a way that they are discernable by both devices. Figure 1.2.8.1 is a basic circuit element schematic. A more complex schematic cannot be generated until more is known about the data protocols of the infusion pump, as well as those of the visual display, buttons and text-to-voice module. Essentially input signals will be generated by input buttons and will be relative to what is on the display. This data will be processed by a microprocessor into signals which the infusion pump can comprehend. The signals will then be transmitted via a serial bus to the infusion pump itself where they will result in action being taken, such as a flow rate being set or infusion beginning. The system must also work in reverse. Warnings and status information from the infusion pump must be transmitted along the serial bus and displayed visually and audibly.

Figure 1.2.8.1: Basic Circuit Design

One disadvantage to the use of a microprocessor is that any graphics interface must be generated from scratch in assembly code. This can prove to be tedious and unnecessary given the many operating systems available with graphics interfaces already present. As more is learned about the protocols of the infusion pump, it may become apparent that a single board computer is a better choice. This is limited by several factors including price and the ability of the single board operating system to interface with the infusion pump’s protocols. An optimization study will be run when enough information has been gathered.
Table 1.2.8.1: Input and Output Signals of Baxter Flo Gard® 6200 Infusion Pump

<table>
<thead>
<tr>
<th>Input (to Infusion Pump)</th>
<th>Output (from Infusion Pump; Alarms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Infusion Rate Select</td>
<td>Air</td>
</tr>
<tr>
<td>Primary VTBI (Volume to be Infused) Select</td>
<td>Door Open</td>
</tr>
<tr>
<td>Start Primary Infusion</td>
<td>Failure</td>
</tr>
<tr>
<td>Secondary Rate Select</td>
<td>Stopped</td>
</tr>
<tr>
<td>Secondary VTBI Select</td>
<td>Battery Low</td>
</tr>
<tr>
<td>Start Secondary Infusion</td>
<td>Occlusion Upstream</td>
</tr>
<tr>
<td>View Total Volume Infused</td>
<td>Occlusion Downstream</td>
</tr>
<tr>
<td>Clear Total Volume Infused</td>
<td>KVO (Keep Vein Open)</td>
</tr>
<tr>
<td>Stop Infusion</td>
<td>Primary Rate = 0</td>
</tr>
<tr>
<td></td>
<td>Primary VTBI = 0</td>
</tr>
<tr>
<td></td>
<td>Secondary Rate = 0</td>
</tr>
<tr>
<td></td>
<td>Secondary VTBI = 0</td>
</tr>
<tr>
<td></td>
<td>Titrate</td>
</tr>
<tr>
<td></td>
<td>Secondary Program</td>
</tr>
</tbody>
</table>

1.2.9 Software Architecture

One essential requirement of the infusion pump interface is that it be easy to operate and not intimidating. Because of this, simple and intuitive software architecture is needed. The inputs will be split into three groups. The primary infusion, the secondary infusion and the total volume infused will each be represented by a different ‘window’ on the colored LCD user interface. Using the “OK” and “BACK” buttons and joystick, the user will be able to easily operate the device. For the primary and secondary infusion windows, this selection will bring about a protocol through which to program rates and volumes to be infused, as seen in Fig. 15. The rate will first be set digit by digit using the toggle joystick to select a digit 0-9 and the OK button to move the cursor to the next digit. After all digits are entered, a final OK will bring about a confirmation. The user will be asked visually and audibly if the entered information is correct. (Fig. 1.2.91 shows operational procedure) The user will basically press “OK” to confirm the input values. If “BACK” is selected, the user will be returned to the rate select screen and will be able to modify the information. Following the entry of the rate, the volume to be infused will be entered in a similar fashion. Once a rate and a volume to be infused has been entered, the user will be returned to the top level of the color user interface where “OK” will start infusion and “BACK” will stop infusion are now available options.
Figure 1.2.9.1: Display Screen Flow-Diagram

α—corresponding to the screen display where the error originates
Accessible Infusion Pump User-Interface

Created by: Michael Cahill, Kevin Golebieski, Hassam Sultan
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Department of Biomedical Engineering

Primary Infusion

Flow Rate: _ _ _ mL/hour
Volume to be infused: _ _ _ _ mL

Scroll flow rate and volume values with joystick, press “OK” when correct for each value.

Primary Infusion Confirmation

Flow Rate: xyz mL/hour
Volume to be infused: abcd mL

Is the flow rate and volume for primary infusion correct?
If YES, press “OK” , If NO, press “BACK”
Secondary Infusion?

If YES, press “OK”
If NO, press “BACK”

Primary Infusion

Flow Rate:     xyz mL/hour
Volume to be Infused:   abcd mL
Total Volume Currently Infused: qrs mL
Time Left:      h:ij hours

To START INFUSION, press “OK”
To go BACK, press “BACK”

Primary Infusion in Operation

Flow Rate:     xyz mL/hour
Volume to be Infused:   abcd mL
Total Volume Currently Infused: qrs mL
Time Left:      h:ij hours

To STOP , press “BACK”
Auditory Output
- “Infusion complete”
- “To power down, press circular button”
- “To infuse, press square button”

ENTIRE INFUSION COMPLETE
To Power Down, Press “OK”
To INFUSE, Press “BACK”

Secondary Infusion
Flow Rate: _ _ _ mL/hour
Volume to be infused: _ _ _ _ mL

Scroll flow rate and volume values with joystick, press “OK” when correct for each value.

Secondary Infusion Confirmation
Flow Rate: xyz mL/hour
Volume to be infused: abcd mL

Is the flow rate and volume for primary infusion correct?
If YES, press “OK”, If NO, press “BACK”
Secondary Infusion
Flow Rate: xyz mL/hour
Volume to be Infused: abcd mL
Total Volume Currently Infused: qrs mL
Time Left: h:ij hours

To START INFUSION, press “OK”
To go BACK, press “BACK”

PRIMARy INFUSION COMPLETE
SECONDARY INFUSION STARTING

Secondary Infusion in Operation
Flow Rate: xyz mL/hour
Volume to be Infused: abcd mL
Total Volume Currently Infused: qrs mL
Time Left: h:ij hours

To STOP, press “BACK”

Auditory Output
-“To start, press circular button”
-“To go back, press square button”
-“Primary Infusion complete”
-“Secondary Infusion starting”
-(Every 5 minutes) “Total Volume currently infused is qrs milliliters, h hours and ij minutes left for infusion.”
It is not yet clear whether there must always be a secondary rate and volume to be infused set. If this turns out to be the case, then the interface will direct the user through entering both a primary rate and volume to be infused as well as a secondary rate and volume to be infused before they will be allowed to start the infusion. A similar software limitation can be used to ensure that the user does not run a secondary infusion without a primary infusion set, if this is determined to be a problem.

Displays F & L will display a running tally of the total volume infused. This can be done by continuously probing the total volume infused function on the infusion pump. The running tally may need to be modified if it becomes apparent that constant probing of the function adversely affects infusion pump operation. At this point it will be changed to an on demand information source that the user
can select and view. In either case, selecting the window will give the user the option to clear the total volume infused, via confirmation similar to that used with other inputs.

The current button layout provides for a back button. This button will step sequentially back through all possible selectable domains. For example, when entering the volume to be infused, the back button will step back through each digit and then back to the infusion rate entry point before returning to the top level of the graphic user interface. This may prove to be tedious for some patients, to the addition of a ‘return to main menu’ button may be considered.

As seen in table 1.2.8.1, there are many alarms that are generated by the infusion pump. These alarms must be conveyed through the interface in order to assure accessibility. Most of the alarms, such as ‘Air in Line’ or ‘Door Open’ can simply be presented with the interface’s enhanced visual and auditory outputs. Other alarms, such as ‘Primary Rate = 0’ or ‘Secondary VTBI = 0’ can be eliminated all together through software. By not allowing the patient to begin infusion until all necessary data is entered, the infusion pump will never need to generate these alarms.

1.2.10 Blackfin Processor (Part Number: ADZS-BF537-EZLITE)

An ADSP-BF537 Blackfin Processor will be used to integrate majority of our subunits within our medical infusion pump user-interface. The processor will be with an “EZ-KIT Lite®” (Fig. 1.2.10.1) from National Instrument.

![BF537 EZ-KIT Lite from [3]](image)

**Figure 1.2.10.1:** BF537 EZ-KIT Lite from [3]
As described from [3], the ADSP-BF537 EZ-KIT Lite® provides developers with a cost-effective method for evaluation of the ADSP-BF537 Blackfin® Processor and its rich set of system peripherals, including the IEEE 802.3 10/100 Ethernet MAC and CAN 2.0B controller. A TCP/IP stack with integrated device driver and example code is provided in VisualDSP++ release 4.0. This evaluation system was designed with an emphasis on modularity and expandability. Additionally, the ADSP-BF537 EZ-KIT Lite contains the National Instruments Educational Laboratory Virtual Instrumentation Suite (ELVIS) interface. This interface will allow using the DC voltage and current measurement modules, oscilloscope and bode analyzer modules, function generator, arbitrary waveform generator and digital I/O. NI ELVIS is a LabVIEW-based design (Fig. 1.2.10.2) and prototype environment for university science and engineering laboratories curriculum.

The EZ-KIT Lite includes an ADSP-BF537 Processor desktop evaluation board along with an evaluation suite of the VisualDSP++® development and debugging environment with the C/C++ compiler, assembler, and linker. It also includes sample processor application programs, CE-approved power supply, a USB cable, both straight through and cross-over Ethernet cables, a 3.5mm stereo cable, and a pair of stereo headphones.

The features this analog device entails include as follows:

- ADSP-BF537 Blackfin Processor
- Max Core Clock Rate of 600MHz
- 64 MB (32M x 16) SDRAM, 4 MB (2 M x 16) FLASH memory
- SMSC LAN83C185 10/100 PHY with RJ 45 Connector

Figure 1.2.10.2: Labview-based Blackfin processor from [3]
- CAN TJ A1041 Transceiver with 2 RJ 10 Connector
- AD1871 96 KHz stereo DAC with 1/8” Jack Connector
- AD1854 96 KHz stereo ADC with 1/8” Jack Connector
- RS-232 UART line driver/receiver
- National Instruments Educational Laboratory Virtual Instrumentation Suite (NI ELVIS) interface

Minimum Requirements

- Pentium® 166 MHz or higher, Minimum of 32 megabytes of RAM
- Windows® 2000, Windows XP
- One available USB connector

By designing an appropriate algorithm within LABview in our design laboratory, we will be able to install the program into the Blackfin chip and allow it to receive input data (i.e. infusion rate, volume flow rate, time, etc) from the infusion pump, and graphically display the appropriate values onto our color LCD.

1.2.11 Case / Packaging

Since the interface must be small enough to not be intrusive, yet still retain all the accessible features, packaging becomes an important aspect of design. There will be two casing: LCD – interface casing, and motor-pump – battery casing. The LCD is 6.5” x 3.9375” and will be the center entity for our interface because it will be communicating the information to the patient. Placing the LCD in the center of the casing means the rest of the features should be designed around its placement. The button layout places the confirmation and cancel button on one side with the toggle joystick for number and menu selection on the other. The buttons are roughly one and a half inches across for both the confirmation circle and square cancel. The toggle joystick needs to be mounted in an area that is roughly 1.5” by 1.5”. Simple addition of these dimensions gives an absolute minimum length of 9.5” and a minimum width of 4”. Since the components on the interface can’t be touching or overlapping on the interface, the minimum dimensions should be increased to 11” x 5.5”. With dimensions that are fairly uncommon it’s most effective to create our own box out of ABS and industrial glue. We will accomplish this by using a sheet of ABS that’s .25” thick cut to 11” x 5.5” and beveling the edge at 45 degrees.
each piece except the back panel being beveled at 45 degrees, the surface area for the glue increases to create a sturdier enclosure. On the backside of the plastic enclosures we will use screws to allow for the back to be removable. An example of the ABS sheet in both white and black, glue and applicator is shown below in Fig. 1.2.11.

![ABS sheet](image)

**Figure 1.2.11.1:** ABS plastic sheet model from rplastics.com

![ABS Weld-On glue](image)

**Figure 1.2.11.2:** ABS Weld-On glue from rplastics.com

![ABS Weld-On glue possible applicators](image)

**Figure 1.2.11.3:** ABS Weld-On glue possible applicators from rplastics.com

Examples of the pieces that will be used for making the enclosure are included below. The left side is pictured with dimensions but is a mirror image of the right side. The same is true for the top and bottom. The back portion of the enclosure will be connected with screws through the extra ABS added to each side portion. By using screws through the back panel it will be removable for service and changes.
Figure 1.2.11.4: Enclosure front panel front view

Figure 1.2.11.5: Enclosure front panel top view

Figure 1.2.11.6: Enclosure front panel three dimensional view
Figure 1.2.11.7: Enclosure side front view

Figure 1.2.11.8: Enclosure side top view
Figure 1.2.11.9: Enclosure side three dimensional view

Figure 1.2.11.10: Enclosure top top view

Figure 1.2.11.11: Enclosure top side view
Figure 1.2.11.12: Enclosure top three dimensional view

Figure 1.2.11.13: Enclosure back front view

Figure 1.2.11.14: Enclosure back top view
Figure 1.2.11.15: Enclosure back three dimensional view

Figure 1.2.11.16: Enclosure exploded three dimensional view
Considering the casing for the battery and the stepper motor pump, an ABS plastic sheet similar to the LCD-interface casing will be used, but of 12”x9”x6” dimensions. This casing will house the rechargeable battery, the Baxter motor assembly from the Baxter Flo-gard 6201, and any related circuitry.

1.2.12 Baxter Pump Head Assembly

The heart of our pumping and errors will be provided via the Baxter pump head assembly (mfg. part number F049120022) that follows in Fig. 1.2.12.1

![Pump head assembly](image)

Within the assembly there is a stepper motor that controls the rate of pumping via cams and pumping fingers, an optical encoder that converts the rotational movement of the motor into an analyzable signal for the CPU (both Fig. 1.2.12.2), and multiple detectors for errors.
Figure 1.2.12.2: Motor with cams and pumping fingers and encoder with associated parts from pumping assembly

The stepper motor's function in relation to the optical encoder will be the key to the LABview program. The rate of infusion directly relates to the rotation of the motor which can be measured through the signals collected by the encoder. As the motor spins the shaft (12 in Fig. 1.2.12.2), the slotted disk (4 in Fig. 1.2.12.2) also spins at the same speed. The light is either detected by the encoder or
blocked by the slotted disk which creates a digital square wave function of either 1 or 0 as seen in Fig. 1.2.12.3. From this function, the rate is determined.

*Figure 1.2.12.3: Square wave function created by encoder*

By manipulating the outputs and inputs of the stepper motor and encoder from the pumping assembly, the PCB's functionality can be transferred to LABview and controlled remotely.

The same type of overrides can be performed with the sensors that detect the errors within the system. The following information on the sensors was obtained from the Baxter 6201 service manual.

The occlusion sensors (Fig. 1.2.12.4) are made up of a sliding ferrite core that is positioned within a mechanically fixed oscillator coil. The core is placed on a spring that moves according to the collapse or expansion of the IV tubing. When an occlusion occurs, the tube changes diameter. This is sensed by the system because the frequency within the oscillator coil changes according to the movement in the ferrite core.

The air sensor (Fig. 1.2.12.4) functions via an ultrasonic transmitter, receiver and transducers that measure the efficiency of energy transmission through either the fluid being infused or the air bubble in the IV line. When an air bubble is sent through the line it is detected because it transmits the energy worse than any corresponding fluid. Using this knowledge and referring to the circuitry listed in the service manual will allow a LABview circuit to be created to detect the same warning as the regular pump.
The tube misleading detectors (Fig. 1.2.12.5) are actually force sensing resistors that have corresponding output voltages. When the IV tube is loaded incorrectly, these output voltages change due to the change in resistance. These voltages are sensed by the CPU and a tube mislead alarm is displayed on the infusion pump.
The front door assembly (Fig. 1.2.12.6) is the plastic enclosure that protects the mechanical pumping mechanism. It encloses and puts pressure on the IV tube so that the sensors and pumping action can work accordingly.
1.2.13 Implementation

The Blackfin chip, if used, would be the nerve center of the design. The signals from the infusion pump motor alone would be transmitted and received by the Blackfin chip. This microcontroller would then send the signals to the text-to-voice unit and the colored LCD display. Input from the user in response to this information would be entered via the buttons and joystick and processed by the microcontroller. This will either result in a change in the GUI which will be sent back to the display (as shown in display flow diagram) and text-to-voice unit, or a signal sent to the infusion pump itself to generate a desired operation.

The Blackfin chip will make operation intuitive and easy. It will allow for a LabVIEW panel to serve as the GUI, which will make the device intuitive and
welcoming. The chip itself will allow signals to be routed efficiently, ensuring the accurate operation of the device.

1.2.14 Test

To test the viability of design, the performance of the interface-enhanced infusion pump must be compared against that of a regular infusion pump. To do this, the infusion rate with and without the interface must be measured to ensure that the device is communicating the desired performance accurately to the pump.

The interface must also be evaluated for accessibility. This can be accomplished by having users unfamiliar with the design, attempt to use it while having their capabilities (visual, auditory, tactile) reduced. For example, an arthritic patient could be simulated by immobilizing portions of the test subject hands.

2 Realistic Constraints

Human factors are the key to design constraints for any medical device. The final device itself, must be limited and designed with the patients and/or user in mind. Constraints in engineering, economics, environmental, sustainability, manufacturability, ethical, health and safety, social, and political limitations must all be considered in the final development of the medical device; such as an infusion pump user-interface, before implementation on the market.

Health and safety constraints implemented on the user-interface are well designed by the Food and Drug Administration (FDA). Listed below are the “Rule of Thumb” for health and safety constraints on controls/displays on user-interfaces designed by the FDA in [1], which will be considered for our final project design.

- Make all facets of design as consistent with user expectations as possible. Both the user’s prior experience with medical devices and well-established conventions are important considerations.
- Design workstations, controls, and displays around the basic capabilities of the user, such as strength, dexterity, memory, reach, vision, and hearing.
- Design well-organized and uncluttered control and display arrangements. Ensure that the association between controls and displays is obvious. This facilitates proper identification and reduces the user’s memory load.
- Ensure that the intensity and pitch of auditory signals allow them to be heard easily by device users. Consider the effects of ambient noise.
• Ensure that the brightness of visual signals is sufficient to be perceived by users working under various conditions of ambient illumination. Also, brightness contrast and color contrast can help to optimize legibility.
• Make labels and displays so that they can be easily read from typical viewing angles and distances. Symbol size, contrast, color, and display depth are important considerations.
• Ensure that the abbreviations, symbols, text, and acronyms placed on, or displayed by, the device are also used consistently in the instructional manual. They also should correspond to standard nomenclature, if possible.
• Design control knobs and switches so that they correspond to the conventions of the user population (as determined by user studies and existing medical device standards).
• Arrange and design knobs, switches, and keys in a way that reduces the likelihood of inadvertent activation.
• Space keys, switches, and control knobs sufficiently apart for easy manipulation. This will also reduce the likelihood of inadvertent activation.
• Make sure that controls provide tactile feedback.

As for software design, users can become frustrated by cumbersome data entry steps and make errors not directly related to those steps, thus leading to detrimental health and safety risks. Listed below are the “Rule of Thumb” for health and safety constraints on software design on user-interfaces designed by the FDA in [1], which will be considered for our final project design.

• Be consistent and unambiguous in the use and design of headings, abbreviations, symbols, and formats.
• Always keep users informed about current device status.
• Provide immediate and clear feedback following user entries.
• Design procedures that entail easy-to-remember steps.
• Use prompts, menus, etc. to cue the user regarding important steps; do not "strand" the user.
• Give users recourse in the case of an error. Provide conspicuous mechanisms for correction and troubleshooting guides.
• Do not overload or confuse users with information that is unformatted, densely packed, or presented too briefly.
• Consider the use of accepted symbols, icons, colors, and abbreviations to convey information reliably, economically, and quickly.
• Do not over use software when a simple hardware solution is available, e.g., a stand-alone push button for a high priority, time-driven function.
• Consider using dedicated displays or display sectors for highly critical information. In such cases, do not display other data in these locations.

Alarms provided by the user-interface should be greatly considered in warning patients and/or users from health and safety risks. Listed below are the “Rule of Thumb” for health and safety constraints on alarms on user-interfaces designed by the FDA in [1], which will be considered for our final project design.
• Be sure that visual and auditory alerts and critical alarms are included in the design requirements for the device.
• Carefully consider the effects of over-sensitivity, electromagnetic interference, and static electricity on alarm functioning.
• Design alarms so they meet or exceed normal hearing and visual limits of the typical user.
• Make sure that both brightness contrast and color contrast are sufficient for legibility under a variety of lighting conditions.
• Use codes, such as color, that correspond to established conventions.
• Design alarms to be distinguishable from one another and, to the extent possible, from alarms on other devices used in the same setting.
• Design alarms to activate immediately following the onset of a critical problem. It is important that alarms identify the source of the problem.
• Consider giving a priority status to critical alarms. Critical alarms should provide redundant auditory and visual signals.
• Design alarms so that when they are silenced, they remain silent temporarily. They ideally will have visual indicators to indicate status and a mechanism for querying the reason for the alarm.

Economic constraints should also be considered with the patient and/or user in mind. The device is a supplemental design that adheres to a standard volumetric infusion pump which some health insurance may or may not cover. The purchase of an infusion pump is substantial and range between at least $1,000 to $6,000. Nonetheless, the final infusion pump user-interface should not further hinder the patient from purchasing the device. The final design will be relatively inexpensive compared to a standard infusion pump and the purchase of a user-interface should be supplementary with the infusion pump with an additional price for supporting the device. However, insurance coverage should not be limited to the user-interface, but only for the infusion pump as appropriate for the patient.

Since home infusions occur inside the house within modest conditions, the pump’s operating temperature will be between thirty two degrees Fahrenheit and one hundred and five degrees Fahrenheit. The dust within the house should be lower than ten parts per million in order to not effect the interfaces functionality.

Further environmental restraints are focused more towards disposal and environmentally friendly materials than the interface’s functioning environment. These types of regulations include the Restriction of Hazardous Substances Directive (RoHS), which limits the levels of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ether in products for sale in countries within the European Union and the Waste Electrical and Electronic Equipment Directive (WEEE) which attempts to limit waste.
created by the expanding field of technology and electrical components by placing the responsibility of discarding products on the manufacturer. Since our interface won’t be mass produced, the directives don’t play an important role in creating the circuitry but the parts market has definitely been altered since the induction of these directives.

3 Safety Issues

The interface that is being designed is for the majority, an electrical product. This means the design with respect to safety will go into protecting the user from the electrical components and the current that will be traveling through them.

The complete interface will be encapsulated inside plastic which will be glued and screwed together. Without removing the screws, the main body of the interface will protect the average user from the majority of the electrical risk while the interface is in use. To avoid bare wires, the bracket that will be mounted to the back of the interface will sit flush and also be screwed into the main body. This will eliminate another area where electrical components could be exposed. Another area of risk will be the actual connection to the infusion pumping mechanism.

Along with keeping bare wires to a minimum, our group will need to design around spark risks that can lead to explosions. This risk is high because when medical equipment is in an oxygen or another flammable medical gas environment a simple spark can be a disaster. This will be accomplished by using preprinted circuit boards to keep sparks at contact points eliminated. Also, hot surfaces and electric static discharge will be eliminated by choosing the appropriate circuit components.

As the device will be operating in a home environment, dust becomes a concern. Human beings shed cells at rapid rates, filling the air will particles that, when accumulated, can interfere with the proper operation of the interface. To take measures against this, all cracks in the unit must be sealed with gaskets. The seals need not be air tight, but simply barriers to particulate matter entering the confines of the device. Simple filters on any fan unit will also aid in minimizing dust interaction with the device.

Since infusions are associated with a liquid, the interface must be able to be safe for patients with damp or slightly moist hands. Electrically safe buttons can be designed that have tight tolerances to the gap in the interface will minimize the chance that liquid can enter the interface. A better design solution that will be implements will be to have a plastic or laminate sheet over the entire
interface. By placing a non-porous plastic over the interface the liquid won’t be able to penetrate into the body that houses the electronics.

The mechanical risks for our interface aren’t quite as important as the electrical but still will play a factor into the completed design. To provide a stable interface for the clients with dexterity problems, the flexible arm will need to be strong enough to hold its own weight along with the force from pressing buttons. If the flexible arm is too ‘soft’ when the buttons are pressed the interface will move backwards which will allow the possibility for an incorrect input. In case the patient is mobile with their infusion system, the interface has the chance of inadvertently moving which poses an impact risk. This means the flexible arm will need to be stiff enough to be able to withstand vibration when the IV pole is being transported to a new area without swinging. Also associated with an impact risk would be the clamp to the IV pole loosening throughout use and eventually falling. To reduce this risk, the clamp will be given rubber backing to allow for a better contact to be made with the metal IV pole. When the interface and pumping mechanism is added to the IV pole the center of gravity of the overall system could possibly be raised. By raising the center of gravity the IV pole will be more likely to fall over. However, this can be alleviated by including instructions with the interface that it should have it’s mounting point lower rather than higher on the IV pole. Lastly, the buttons on the interface could stick while in use leading to improper dosages or worse, not being able to use the system completely. By using an appropriate spring rate to return the buttons back to their resting points the buttons have less of a chance to get stuck. This can also be fixed by using buttons that are dome switches. These would have less friction because they aren’t sliding directly on into the plastic cutouts in the main body.

There is also a risk of the infusion pump not stopping after the designated time or volume to be infused. This means that an emergency stop will need to be programmed into the interface to send an extra stop signal to the infusion pump just in case the normal stop signal doesn’t register.

4 Impact of Engineering Solutions

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. Our designed user-interface will succeed and impact the biomedical world where majority of many current infusion pump user-interfaces have failed. Consecutively, the companies will gain great credibility in achieving a more
reliable, cost-effective medical infusion pump for their patients and/or caregivers. The impact the final device will implement to humanity will be due to the problems it will solve caused from most medical infusion pumps.

Infusion pump problems have occurred related to FDA’s recall of eight Colleague models of the medical infusion pump (Fig. 4.1) manufactured by Baxter Healthcare Corporation issued in July 19 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 [1]. As shown in Fig. 4.1, 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. As a result, the final design will eliminate accidental turn off due to its distinguishable tactile cues. If implemented by Baxter Healthcare Corporations, the final device will eliminate the company’s aforementioned problems and greatly increase the reliability of their medical infusion pump for patients, thus allow them to increase in market shares in an economic perspective.

Another problem found with medical infusion pumps, which our final design will solve is found in [2]. Human error is one problem found with most infusion pumps leading to wrong dosage, incorrectly programming the pumps, and improperly using the equipment. The final design project will provide safeguards in verifying the accuracy of the input values through a graphical LCD visual display. In addition, the user-interface will be greatly easy to use due to the implementation of a short learning curve and simple design. In
tum, the impact the patient society in the field of healthcare by greatly reducing human error and risk of patient death.

Alaris® Products have gone through detrimental drawbacks due to their faulty infusion pumps and lack of following the FDA’s medical device manufacturing regulations in [3]. The FDA seized Alaris Signature Edition Gold infusion pumps, model numbers 7130, 7131, 7230, and 7231 (in August 25, 2006), manufactured by Cardinal Health Care 303, Inc (see Fig. 4.2). The design defect found in these models were called key bouncing causing over-infusion since the buttons pressed on the pump are registered twice although the user pressed the key once. Since Alaris distributed their products globally, the seizure of the devices valued Alaris more than an estimated $1.8 million. If produced and implemented earlier, the final design would have saved Alaris from their 1.8 million dollar loss and preventing their loss of credibility within the media and economic market. If implemented, the devices impact on Alaris can redeem their credibility in the future since the user-interface does not experience such key bouncing flaws. Nonetheless, before initiating the infusion, the interface will verify the values through the LCD display. As a temporary solution, Alaris recommended steps in minimizing key entry errors by requesting an independent double check of pump settings by another practitioner before starting infusion. By observing these steps, the patients independence and privacy is greatly hindered, whereas the final infusion pump user-interface will counteract this feature and increase the patient’s independence.

The success of some medical infusion pump companies, such as B. Braun Medical and Curlin Medical, in [4], is the expected impact of our final user-interface device after implementation in biomedical infusion pump companies. The partnership between the companies has provided “the most dependable infusion pumps featuring breakthrough safety technology and industry-leading expertise”, leading to their “strong growth in market shares and units”. As a result, the market conditions “created an environment for significant market growth and adoption in hospital and outpatient settings”, providing the “medical community with the highest level of supply and service support, training and technical support”. As a result, the impact of our final user-interface will have similar to those found between B. Braun Medical and Curlin Medical. The impact of our device on biomedical companies with faulty pumps will provide dependable infusion pumps with great safety and accuracy in input values. In turn, the growth of the company will be substantial, leading to further excellence in product service and support, increase in job opportunities of field staff service representatives, and production capacity expansion.

Baxter Healthcare Corporation, and Alaris® Products are one of many companies, which the final user-interface can greatly impact. Any biomedical company experiencing flaws within their engineering design are inevitably to
experience financial and integral setbacks. Implementation of the final design is bound to bring any solution to the pump’s problems. Nonetheless, successes found by B. Braun Medical and Curlin Medical, are sure to be the consequences of the impact of our final user-interface device upon applying to biomedical companies with infusion pump problems, such as, Baxter and Alaris. Thus, the impact of this device will be paramount.

5 Life Long Learning

Even in its early stages, it is clear that this project will foster new learning out of necessity. In engineering, classroom learning is essentially a survey. One must take in many different concepts and theories so that one understands what is available and understood in the world at large. This knowledge is then drawn upon specifically when one takes on a design project. Things that were not clear before must be further researched and learned as there is no partial credit in design: the design operates, or it does not.

One thing that has already been discovered is the immense wealth of human experience students have at their disposal on campus. When staring at the looming façade of what seems an insurmountable challenge, simply discussing the basics with a faculty member can bring about new enthusiasm. A few ideas tossed off the top of a much more experienced person’s head can serve as starting grains upon which the young engineer can begin to build the design concept.

This project is intensely electrical. Interfacing with a commercial device, possibly without the aid of a preexisting serial port, presents many challenges. In this group, no one is particularly strong in bioinstrumentation, but it is clear that this strength will be developed. Foreseen challenges include programming a microprocessor and designing and writing a graphic user interface in assembly code. There will surely be more as the circuit gains complexity. The protocols of the infusion pump must be analyzed in order to ensure proper interfacing is accomplished.

Adding new components has brought with it more material to learn. Blackfin chips can be programmed with LabVIEW programs. This simplifies the once tedious act of programming a microcontroller, but difficulties persist. The microcontroller is the heart of the design, and it must be properly programmed for the various elements of the interface to function with each other.

When using an existing technology such as the Baxter pumping mechanism, much of the difficulty comes from having to reverse engineer to use its features. By communicating directly with the technicians from Baxter, the complicated
functions are easier to understand and integrate into a new system. Also, by obtaining and analyzing the information provided within the service manual, the exact function of every part can be broken down into its simplest components. This method allows the product to be broken down into exactly what our group will need. From this point a new device can be created with much better results for patients with disabilities.
6 References

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Realistic constraints:


Impact of engineering solutions:
