

Alternative Design 2 Report

Accessible Infusion Pump User-Interface

By:

Michael Cahill, Kevin Golebieski, Hassam Sultan

Team 2

Rehabilitation Education Research Center on Accessible Medical Instrumentation

Dr. John D. Enderle, Ph.D.

University of Connecticut

Biomedical Engineering Department

Program Director & Professor for Biomedical Engineering

Bronwell Building, Room 217C

260 Glenbrook Road

Storrs, Connecticut 06269-2247

Voice: (860) 486-5521

FAX: (860) 486-2500

Email: jenderle@bme.uconn.edu

Website: www.eng2.uconn.edu/~jenderle

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1 Alternative Design Project 1

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. 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.

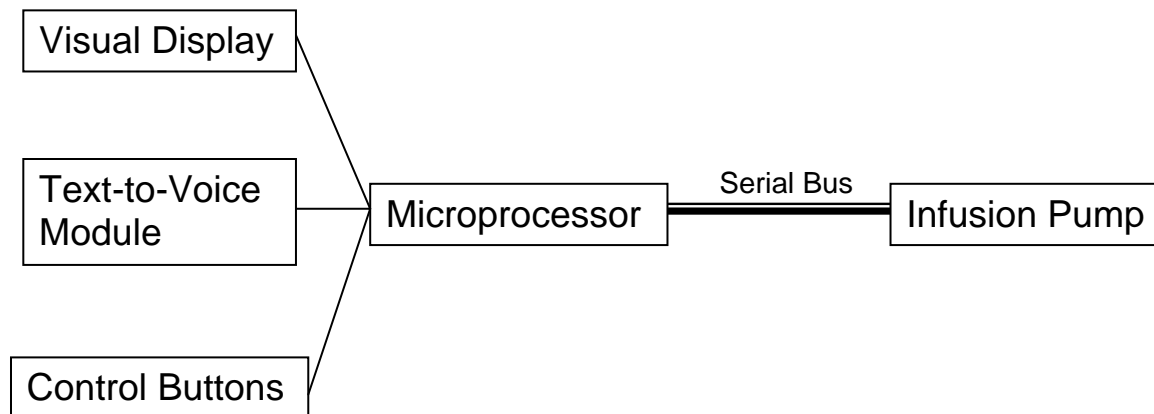


Figure 1: Basic Circuit Design (in section 1.2.6)

Various components within the medical infusion pump-user interface include a graphical LCD display, battery, text to voice module, mounting arm and brackets, accessible buttons, software architecture, and serial port connections.

From our first design we have included a portion on buttons and a possible layout. The c-clamp that attached to the IV pole in design one has been changed to a mounting block for better and more uniform compression on the pole. In addition, a theoretical graphical user-interface (GUI) was design.

1.2 Subunits

1.2.1 Graphical LCD Display (Model: *GLK240128-25-GW*)



Figure 3a: Graphic LCD Display – Front in [1]

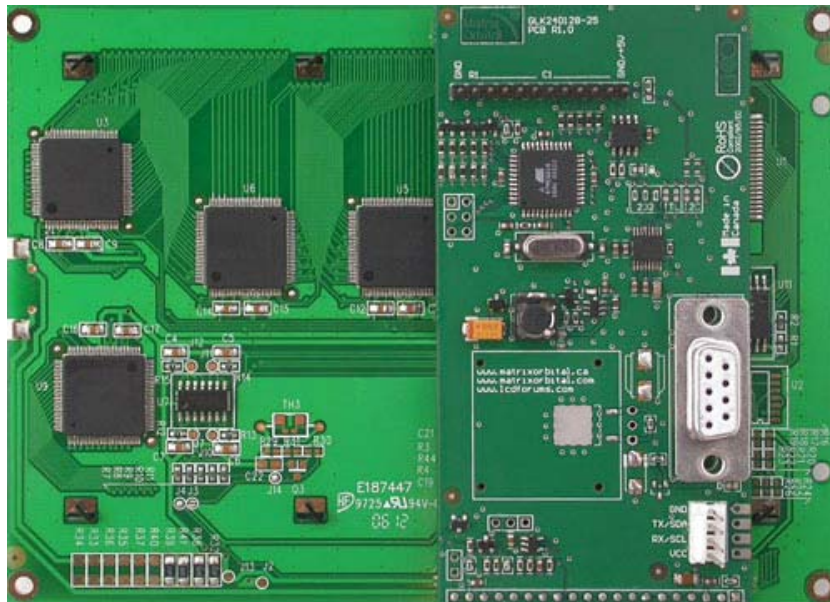


Figure 3b: Graphic LCD Display - Back in [1]

The GLK240128-25 graphical LCD display module from Matrix Orbital 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.

Table 1: Power Requirements in [1]

	Standard	-V	-VPT
Supply Voltage	+5Vdc \pm 0.25V	+9V to +15V	+9V to +35V
Supply Current	31 mA typical		
Supply Backlight Current	160 mA typical		

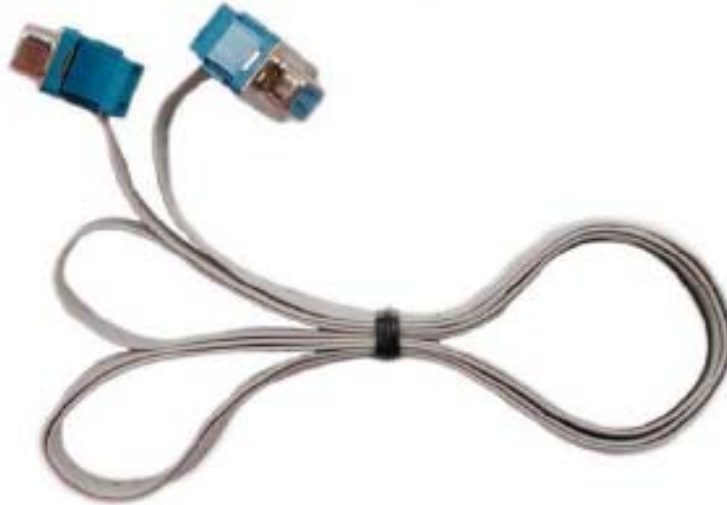


Figure 4: Serial Cable 4FT in [1]

Initially, the graphical LCD display will be connected to a PC to test the functionality and uploading of new fonts and bitmaps. A standard RS-232 9-pin serial cable (Fig. 4) will be used in connecting the LCD to the PC, while a 5V power adapter will power the display. Upon connecting to the computer, the MOGD# software (graphic display tool kit) will be downloaded to manage font and graphical downloads as well as exercise all the features of the graphical display. The GLK240128-25 graphical LCD display module comes with a DB-9 connector to readily interface with serial devices (Baud Rate: 19,200 bps) which use the EIA232 standard signals levels of \pm 12V [1]. In turn, this connector will allow the PC to display an image on to the graphical LCD. In terms with the overall interface device, the display screen will be connected to the microprocessor receiving the digital output from the infusion pump.

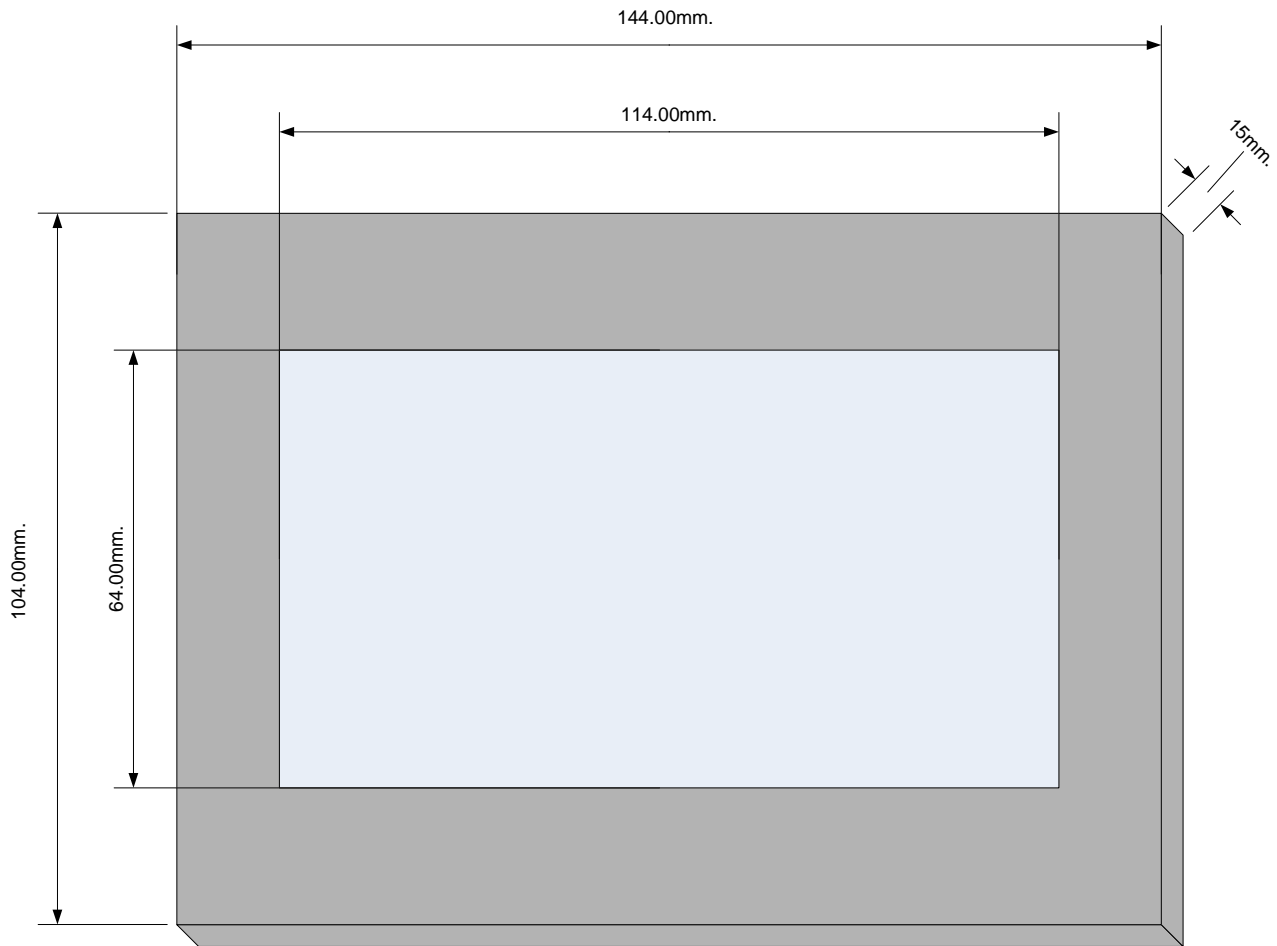


Figure 5: LCD Dimensions

Table 2: LCD Specifications in [1]

Features					
<u>Keypad</u>		<u>One Wire</u>		<u>GPO</u>	<u>Advanced GPO</u>
25		N/A		N/A	N/A
Interface					
<u>RS232</u>		<u>RS232TTL</u>		<u>Buffer</u>	<u>Other</u>
9600		9600		120	I2C
19200		19200			
33600		33600			
56700		56700			
115000		115000			
Environmental Conditions					
<u>Standard Temp.</u>			<u>Extended Temp.</u>		<u>Max Humidity</u>
Min		Max	Min	Max	90.00%
0.00°C	to	50.00°C	-20.00°C	to	

1.2.2 Buttons

A tactilely distinct intuitive button interface is an 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.



Figure 6: Possible Button Layout

As seen in Fig. 6, a four button construction is being considered for this interface. The up and down buttons 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 arrows 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 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 below in Fig. 7.

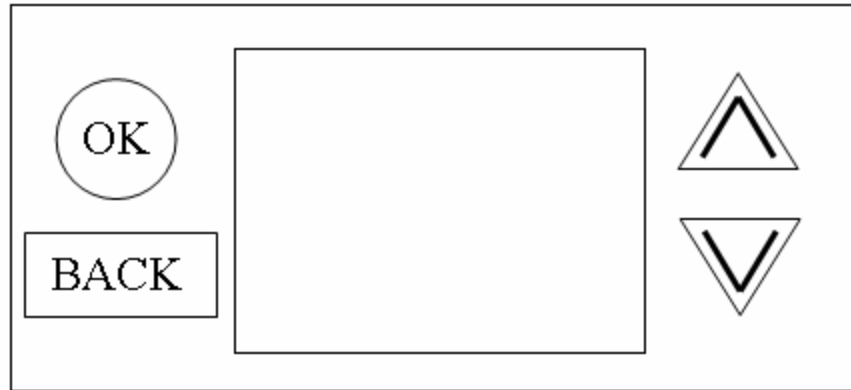


Figure 7: Possible button layout with separate areas for information input

1.2.3 Interstate Batteries AMED2911 (Model: *MED2911*)



Figure 8: Rechargeable NiMH 6V battery in [2]

A nickel-metal hydride (NiMH) battery will be used in powering the accessible infusion pump user-interface. NiMH battery cells provide more power (in equivalently sized packages) than nickel-cadmium (NiCd) cells while also eliminating some of the concerns over use of heavy metals in the cells [2]. Figure 7 displays the battery that will be used in connection to our interface circuit. Since the terminal of this battery is a plug, connection to the circuit will be quite simple and efficient. 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. A 6V NiMH battery(1700 mAh) 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 6V battery would be well enough to power. 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.

1.2.4 Mounting Arm:

Mounting the interface to the IV pole that holds the infusion pump body will allow the interface to stay close without being a burden to the pumps normal functioning. If the interface was mounted directly to the infusion pump, there would be a risk of inadvertently pressing the normal interfacing buttons. By moving the interface off the pump and into a separate area for inputs the risk is minimized. The differentiation of the input and outputs will also give the infusion pump the ability to function without the accessible interface for professionals who are trained to use the pumps normal features.

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. The hollow interior is covered with vinyl leaving an enclosed area that the wiring can run from the interface to the IV pole.



Figure 9: Examples of Moffatt Product’s flexible arms for a variety of applications

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 directly to the interface and will include a center hole that the wiring will be able to run through. 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 bottom, top, and side views.

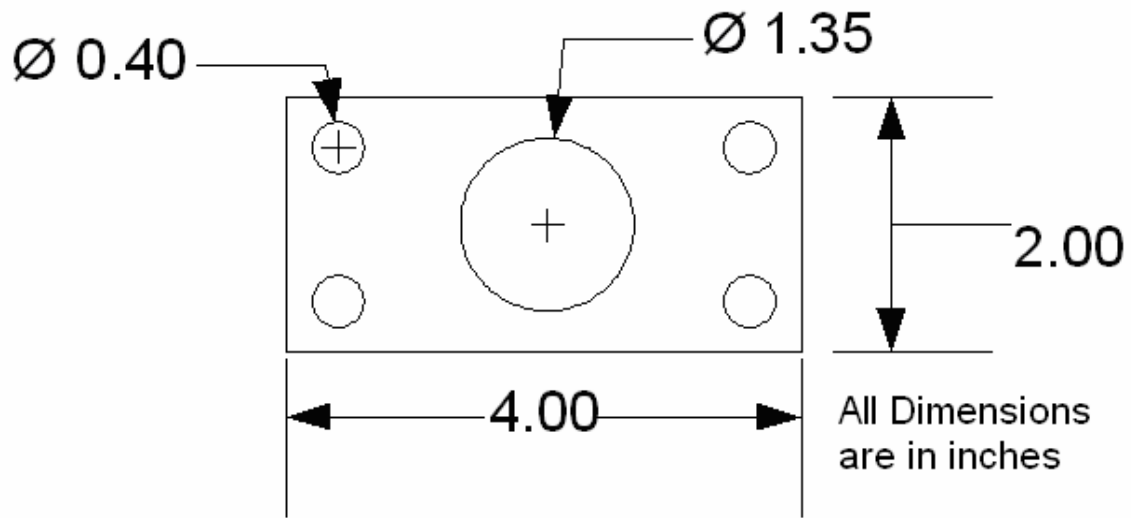


Figure 10a: Flexible arm mount interface bracket bottom view

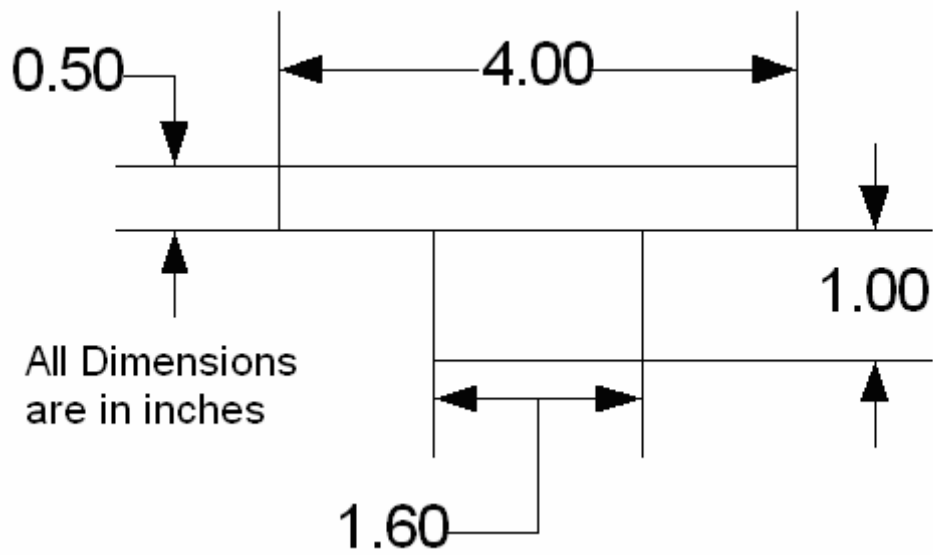


Figure 10b: Flexible arm mount interface bracket top view

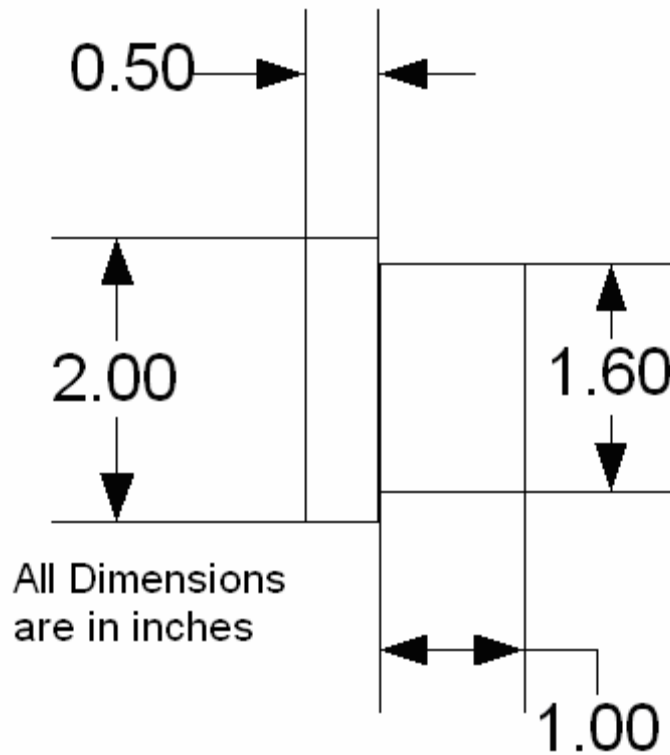


Figure 10c: Flexible arm mount interface bracket side view

On the opposite end of the flexible arm will be the bracket that mounts to the IV pole. This mounting block will be machined out of UltrAlloy® 6020 1.5" by 1.5" aluminum stock as shown by Fig. 11d on the following page. UltrAlloy® 6020 by Alcoa Global Cold Finished Aluminum Products is a lead free, easily machinable aluminum that is also very corrosion resistant. These features make this aluminum the idea variety for our design. Using an aluminum mounting block with a wing nut will allow the metal to bend slightly when the screw 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, two side views, and the Fig.9.d from IndustrialMetalsales.com.

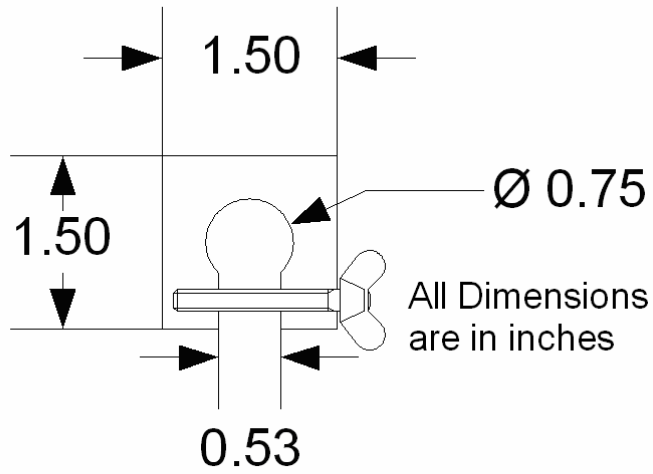


Figure 11a: Flexible arm mounting block top view

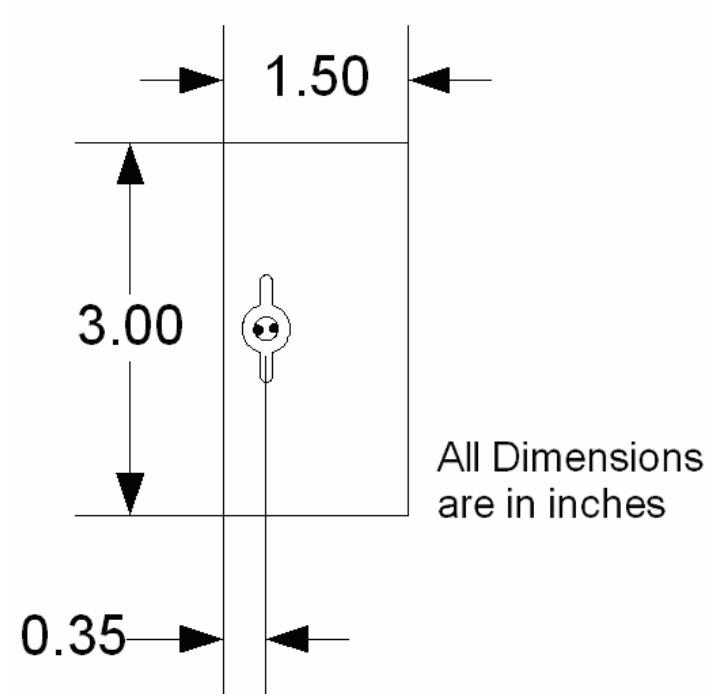


Figure 11b: Flexible arm mounting block side view one

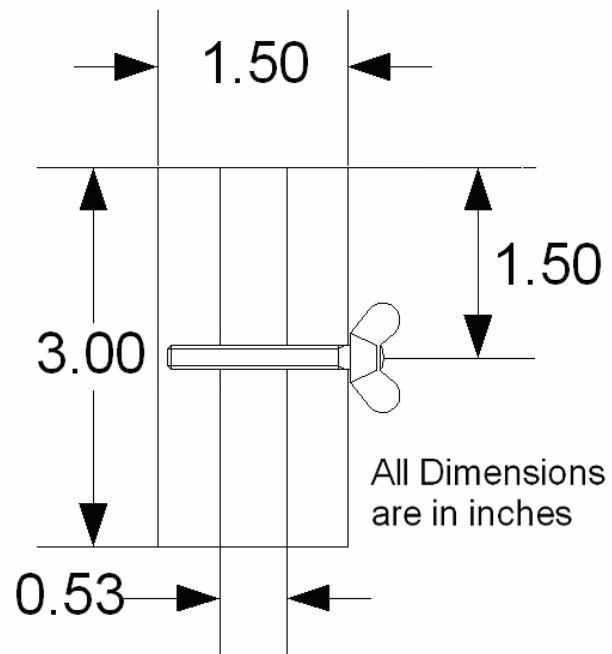


Figure 11c: Flexible arm mounting block side view two

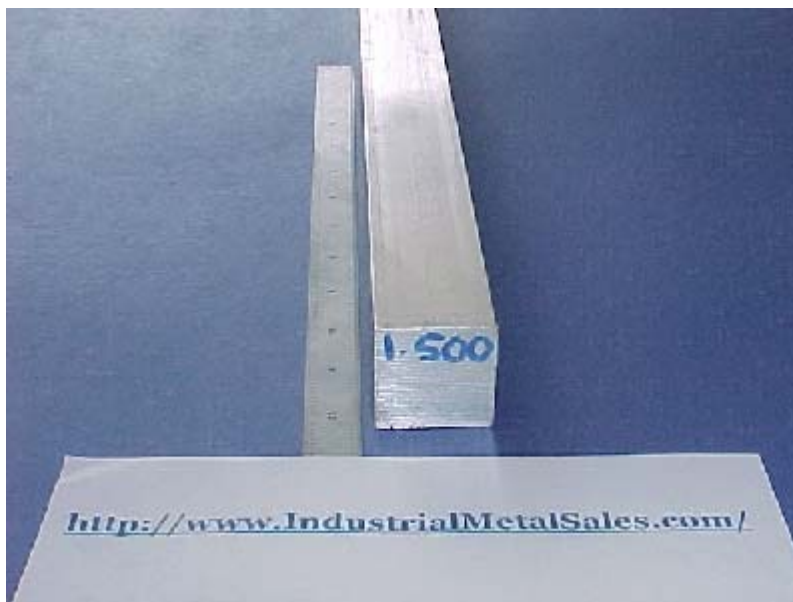


Figure 11d: Aluminum stock for machining mounting block from IndustrialMetalSales.com

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 3: Maximum load for flex arms when mounted horizontally from Moffatt Products.

OD = Outside Diameter in Inches
 ID = Inside Diameter in Inches
 Spring Wire Size is in Inches



Arm Length	Type A .675 OD .325 ID .155 wire	Type B .640 OD .325 ID .135 wire	Type C .580 OD .320 ID .118 wire	Type D .460 OD .263 ID .090 wire	Type E .360 OD .204 ID .070 wire
3"	9.6 lb	9.1 lb	8.0 lb	3.9 lb	3.1 lb
6"	7.2 lb	6.5 lb	5.5 lb	1.8 lb	1.4 lb
9"	4.4 lb	3.6 lb	3.4 lb	0.9 lb	0.7 lb
12"	2.8 lb	2.4 lb	2.2 lb	0.6 lb	0.5 lb
15"	2.0 lb	1.8 lb	1.6 lb	0.3 lb	0.2 lb
18"	1.6 lb	1.4 lb	1.2 lb	0.2 lb	-
21"	1.4 lb	1.0 lb	0.7 lb	-	-
24"	1.3 lb	0.9 lb	0.3 lb	-	-
27"	0.8 lb	0.5 lb	-	-	-

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.

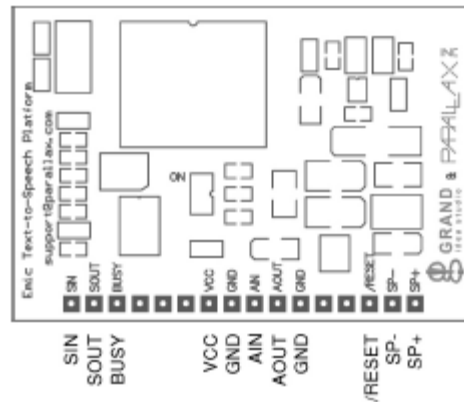
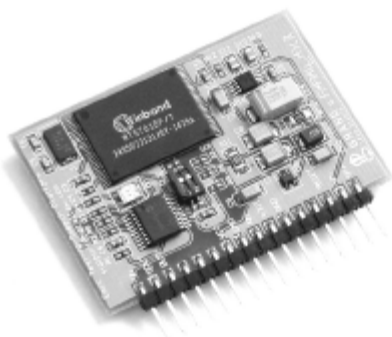
With an approximate weight of five pounds for the interface and an arm length of twelve inches, it’s apparent that the design will need a second flex arm that can support the weight of the unit. Another option will be specially ordering a larger tube diameter that has a thicker wire resulting in greater strength. The last option will be to get internal stiffeners that can be added by Moffatt Products. This increase in strength however causes a loss of inner diameter which could restrict the wiring that will be running through the arm.

1.2.5 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 OEM

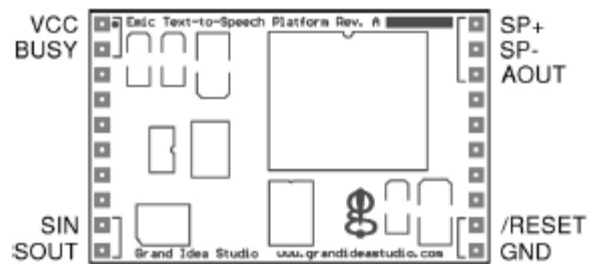


Figure 12: Emic modules in both SIP and OEM configurations from Parallax Inc.

Table 4: Pin descriptions for Parallax Emic Text-To-Speech Modules.

Pin (OEM)	Pin (SIP)	Pin Name	Type	Function
1	7	VCC	P	System power, +5V DC input.
2	3	BUSY	O	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.
3	1	SIN	I	Serial In. TTL-level interface, 2400bps, 8 data bits, no parity, 1 stop bit.
4	2	SOUT	O	Serial Out. TTL-level interface, 2400bps, 8 data bits, no parity, 1 stop bit.
5	8, 11	GND	G	System ground. Connect to power supply's ground (GND) terminal.
6	14	/RESET	I	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.
7	10	AOUT (ANA)	O	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.
8	15	SP-	O	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).
9	16	SP+	O	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.
---	9	AIN	I	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 694mVp-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.

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.

1.2.6 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 13 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.

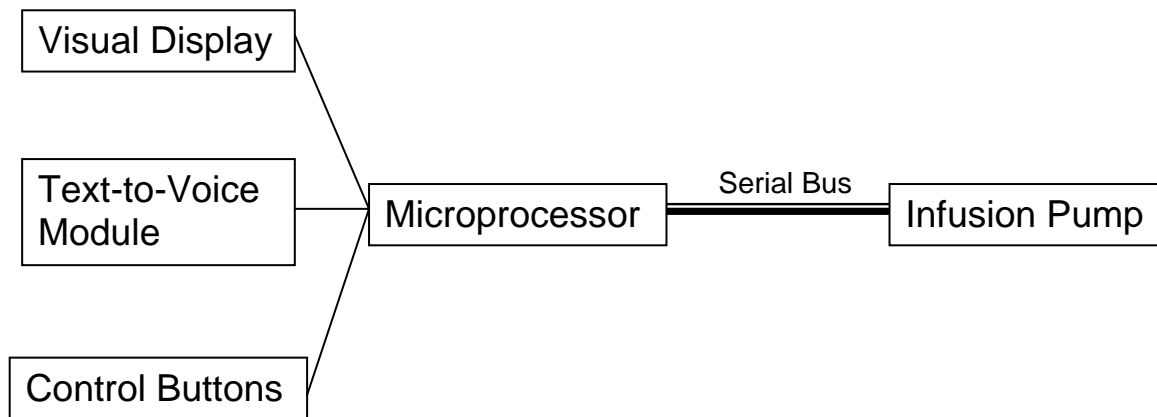


Figure 13: Basic Circuit Design

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 5: Input and Output Signals of Baxter Flo Gard® 6200 Infusion Pump

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

1.2.7 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 graphic user interface. Using the arrow buttons a highlighting frame will be moved clockwise or anti-clockwise around the graphic interface, depending on which arrow button is used. When a window is highlighted by this frame, the OK button will select it. 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 arrow buttons 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. The user will then have to actively select [YES] to confirm this by using one of the arrow buttons to move a cursor off of [NO] and onto [YES] and then pressing the OK button. If [NO] 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 graphic user interface where [START INFUSION] and [STOP INFUSION] are now available options.

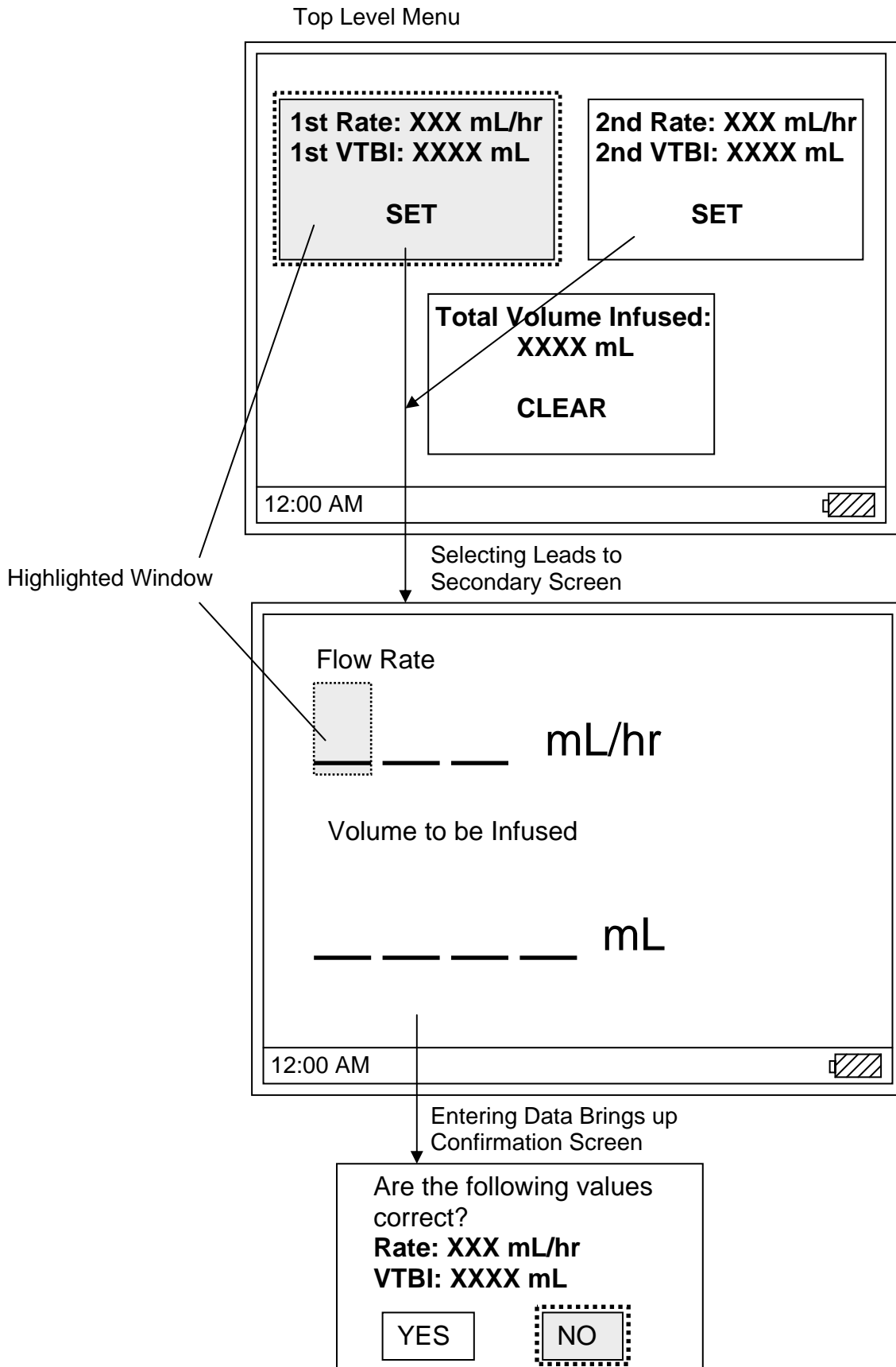


Figure 14: Graphic User Interface Samples

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.

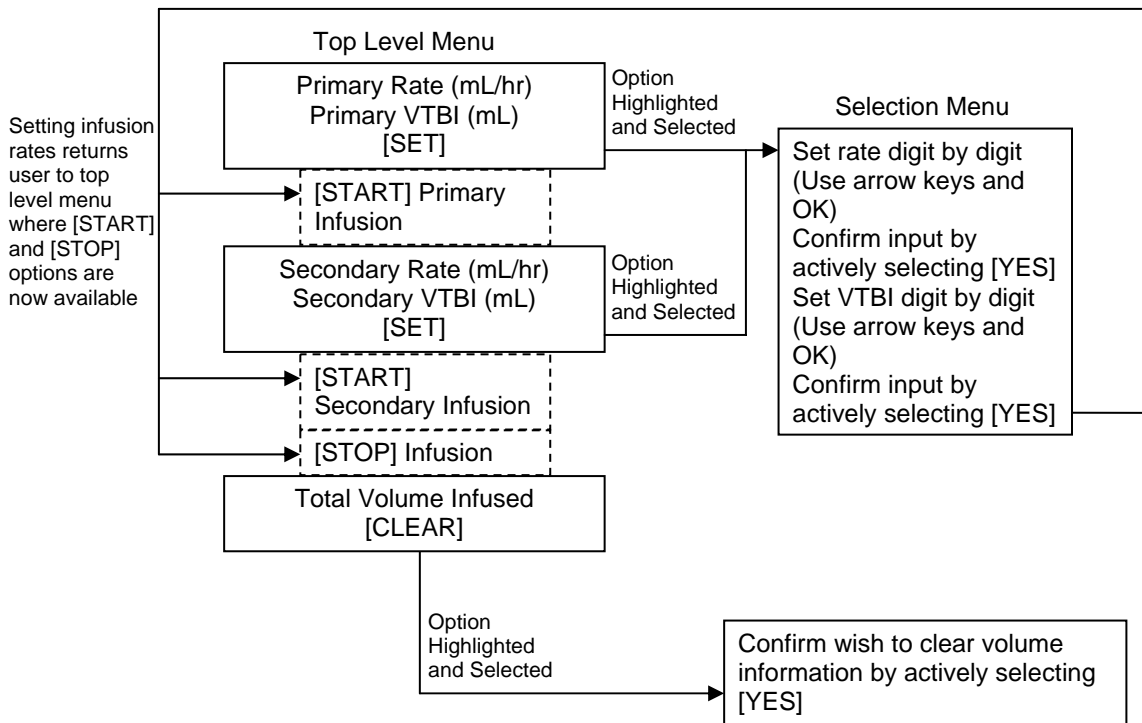


Figure 15: Software Architecture

The third window available on the graphic user interface will be the total volume infused window. This window 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 5, 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.

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 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 pump. As stated before, the infusion pump which our group obtained doesn't have a built in serial port. With a lack of a serial port we run the risk of needing to hardwire into the circuitry of the infusion pump. If this is the case then the wires will need to be properly connected and shrink wrapped to avoid exposed metal. Ideally, the infusion pump will be able to be mocked up with a serial port that has the wiring contained within the unit. This would provide a simple RS 232 connection between the interface and infusion pump which would minimize electrical risks similar to the serial ports on more current pumps.

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 with 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 implemented 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 house 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 is added to the IV pole the center of gravity of the overall system will 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 its mounting point below the infusion pump or slightly above it. 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.

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. 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. 16) 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. 16, 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.



Figure 16: Baxter Colleague 3 in [1]



Figure 17: Alaris 7230 Signature Gold Medical in [3]

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 turn, 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. 17). 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 counter act 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.

A unique problem is presented by the fact that the procured infusion pump has no serial port. If no other option is found, a substantial part of the project will be backwards engineering the infusion pump so as to be able to install a serial port. Schematics for the pump must be located and the protocols determined in order to ensure an accurate interface. In the process, much about the infusion pump's design will be learned.

It has also become very apparent how much budget controls the project. For this project an infusion pump was needed. Infusion pumps, however, cost more

than the entire budget allocated for this project. As a result, other resources had to be employed to secure an infusion pump. Human networking saved the day as an old infusion pump was donated to the project. The pump is not ideal, but as the adage goes, beggars cannot be choosers. A design is truly done when there is no more money.

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