Accessible Insulin Pump

Michigan State University

Senior Design - ECE 480 - Team 3

Sponsors

Recourse Center for Persons with Disabilities

Asante Solutions

Facilitator

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Team Members

Miriel Garcia

Anthony Iafrate

Marshall Williams

Hoyoung Jung

Executive Summary

The majority of insulin pumps currently available on the market pose a great concern for the visually impaired, lacking communication between the device and the user. Many of the diabetics with sight disabilities rely on memory and or assistance to navigate throughout the pumps many menus and options. Due to this unresolved problem that affects nearly 5 million diabetics, the team must design an insulin pump's user interface that communicates the necessary information to the user through audio commands. Thus, allowing the visually disabled the convenience to operate their pump independently and accurately.

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Introduction

As diabetes poses a threat to the lives of millions worldwide, it is up to the current generation of engineers to develop a solution to the problematic insulin pumps currently

available to the public. Due to fact that diabetes is the leading cause of blindness in adults, it is astounding that none of the current insulin pumps on the market have the functionality tailored to the visually impaired. An insulin pump performs many calculations and actions that are critical to the regulation of blood sugar levels of the user, and require a precise level of data to be entered into the pumps controller. The pump is also responsible for relaying crucial information to the user, pertaining to the systems diagnostics and insulin levels. For the visually disabled, these pump functions lack the ability to communicate the data from the pump to the user.

In order to tailor to the needs of the visually impaired, the insulin pump must include an audio feature that relays the current information on the screen to the user. The pump's software must allow the user to navigate throughout the options with ease, along with performing a voice over action. The pump must have the ability to log date and insulin delivery settings via device RAM.

The team's goal is to ultimately create a necessary solution to the lack of communication from the insulin pump to the blind user. The pump that the team will create, will not only perform the necessary functions of any standard insulin pump, but will also include the audio applications needed for an individual without sight.

Customer Requirements

The insulin pump is required to meet a certain variety of standards, developed by Asante Solutions and the Michigan State Resource Center for the Persons with Disabilities. Below are the design constraints applicable to our mission:

- Design must enable independent use by blind users
- The device must look, feel, and operate like a real insulin pump
- The device must house a small speaker and audio jack for discrete use
- The user interface and all operating characteristics must be programmable

Background

The American Foundation for the Blind has released the statement that the lack of speech output on an insulin pump currently prevents 5.3 million people with diabetic retinopathy from reaching the next stage in managing diabetes. The Journal of Diabetes Science and Technology states, "For Insulin Pumps to be used safely and independently by blind and visually impaired patients, they must include voice output to communicate all the information presented on their display screens. Enhancing display contrast and the size of the displayed information would also improve accessibility for visually impaired users." These facts are the main influence behind so many companies, such as Asante Solutions, to develop the next generation of insulin pumps that cater to the needs of the visually impaired.

Objectives

Mission Statement

With an alarmingly high number of diabetes patients affected by retinopathy, the need to supply new technologies to suffice this group of the diabetes population has grown. New developments towards providing a solution to the visually impaired insulin pump users have surfaced, but not enough attention have been given to this issue. That is why the team is aiming to create an insulin pump that will not only provide the much needed help for the visually impaired users but also to the rest of the diabetic population.

The final product must be lightweight and of reasonable size. This is due to the fact that insulin pump user must carry the device with them at all times. In addition, it must have a user friendly interface. In conclusion, the final product must be a small-lightweight device with a good battery life that can be operated for any diabetic user regardless of their sight condition.

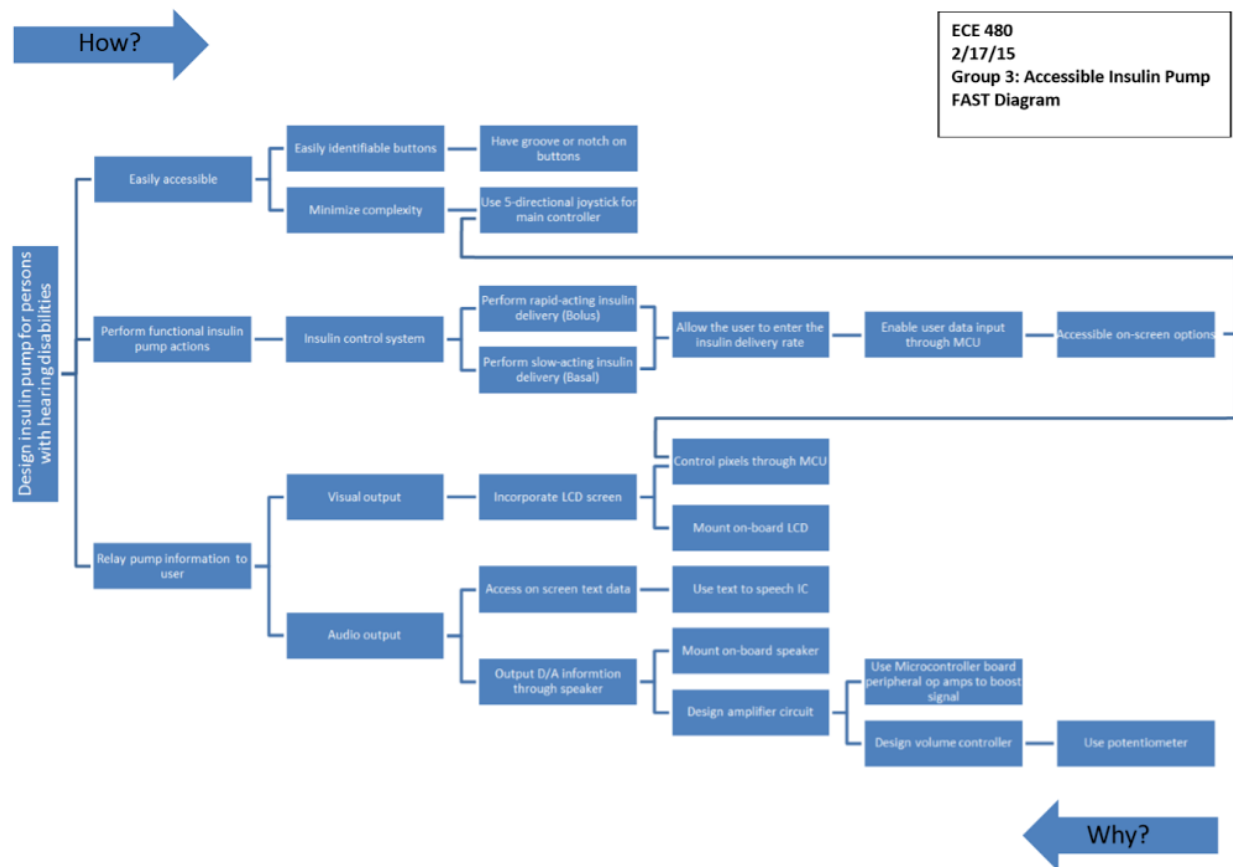## FAST Diagram

Figure 1
Conceptual Design Descriptions

The designs our team has come up with to assess the tasks at hand vary quite a bit. As we meet with our customers, we gain a better understanding of what exactly we need to create to

satisfy each of their needs. The main focus of our project is to make an insulin pump that will be accessible to individuals with visual imparities. To make the pump useful to them, we must make a device that will read menus within the pump and make them audible. We, however, must keep in mind the general public that does not have visual imparities. They must be able to utilize the pump in such a fashion that doesn't hinder them in any way. To tackle such a task, we have come up with a few different ideas.

Method 1: Add-on module

This design utilizes the pump that we were supplied by our sponsors, Asante. This approach leaves us with a platform to work from. We would already have the LCD screen, pre-programmed menus, and pre-programmed buttons. From this point, we will have to add a small speaker and attach a text-to-speech module. This will be an easy integration with the help of Asante to access the programming. We will build a housing around the existing Asante pump and enclose each of the elements within. This will include a power source that will run our text to speech module, which will likely be an alkaline battery.

This method was also used by the previous team working on this project. They used an umbilicus cord to obtain the data from the sponsored pump. Once the data was obtained, the program would send the data through the text-to-speech chip and convert the information into audio via the speakers. This method proved effective in some ways, but they encountered a few problems. Although they were able to do a general audible pump, they were unable to successfully obtain the full functionality from the sponsored pump. Also, the device they created was too large for users who carry these devices around daily.

Method 2: The Next Gen Insulin Pump

This design we have is actually an entirely new design in which we will not be using any actual pump at all. This allows the design team to have free range of production to create the perfect insulin pump. Within a general design framework, there are a couple different methods that the design team has provided and those can be seen in the list below.

> General concepts
> > ○ Analog / Button vs. Touch screen
> > ○ App via smartphone vs. Text-to-speech
> > ○ Bluetooth vs. Wireless
> > ○ Separated pump vs. Full body

The separated pump concept will be using an entirely new LCD screen, programming our own menus, and programming the navigation of the buttons. Using 3D modeling, we will create a housing that will actually only contain the LCD, the touch contacts, and the speaker. A bus will serve as the transportation of information to an external chip. This chip will serve as the central

station for the text-to-speech module, and the microcontroller that will read the selections of the functions and navigate through the menus. This idea utilizes the idea that upon actual production, the components will be on-board and will be a great deal smaller than what we can create in such a time constraint. If time permits, the full pump production would create a better model for prototyping.

The first design via the buttons system will only consist of two navigational arrows as well as one "selection" button and one "back" button. Each of these buttons will have it's own texture that will allow the user to know which button they are pressing. The 3-D printer will allow us to do this generally easily. Although this is the general concept for most pump designs, this method is the simplest form. The general issue with most pumps with such a simple design is the functionality of the pump, which is due to the software. The code for this next gen pump will be seamlessly integrated into this intuitive design, creating the perfect balance between simplicity and functionality for the users.

Similarly, the analog system would function the same but increase functionality by having one essential figure capable of five directional buttons, "up", "down", "right", "left", "center". This is in contrast to the design via touch screen, which was inspired by the Voiceover program via Apple. Although unconventional, Voiceover was able to create a touch sensitive language system using the fingers to navigate through the software. It is an operation that could be formatted easily with time via an app. An obvious constraint with this design is the purchasing of an external device. Being visually impaired, many may not have access to a smartphone. The idea's pros and cons could be for a time after completion of the software for the pump. But initially, the design would require more board spacing and could pose a problem in simplicity. Due to the fact that many diabetics can be affected by neuropathy, the analog and button system have been deemed to be the appropriate method for this design.

The app design would create a simplistic body since the method would allow the user to essentially only carry the pump. This can be integrated in a small and simple design. Communication between the phone could be done with either bluetooth or wireless connections. This idea was created with the increasing smartphone market in mind. Many phone companies have been striving for the total smartphone push. Since most would have a smartphone in the future, our design was to integrate the smartphone technology to the pump. This design would utilize all of the necessary features on the phone, leaving only the bluetooth controller, a small microcontroller, and the physical pump body. This could very well be done in a later time, but this raised a few concerns as well. The phone could run out of power, leaving the diabetic unable to access the pump. Also, Roberta McCall, a member of this team with diabetes, stated that she is comfortable with the manual access of the pump. This would only leave this feature as an add-on design that could be incorporated into a typical pump.

Ranking Designs

Design Criteria	Importance (0-5)	Design Methods	
		Method 1	Method 2
Size	4	3	3
Safety	5	5	5
Cost	3	4	5
Weight	4	3	5
Durability	3	4	4
Intuitiveness	5	4	5
Simplicity	5	5	5
Run-Time	5	5	5
Functionality	5	4	5
Production Time	2	4	3
	Total	41	45

House of Quality

In order to determine the best possible solution, our designs were put through a House of Quality assessment. The team analyzed consumer needs with technical requirements to determine the qualities that would produce the best design. Analysis of the House of Quality shows that the key requirements include safety, size, and functionality. These consumer needs have a general effect to the audio output functions of the pump and also the program software. This analysis does not conclude that the other requirements should be neglected, but rather the order of which the team should allot their time.
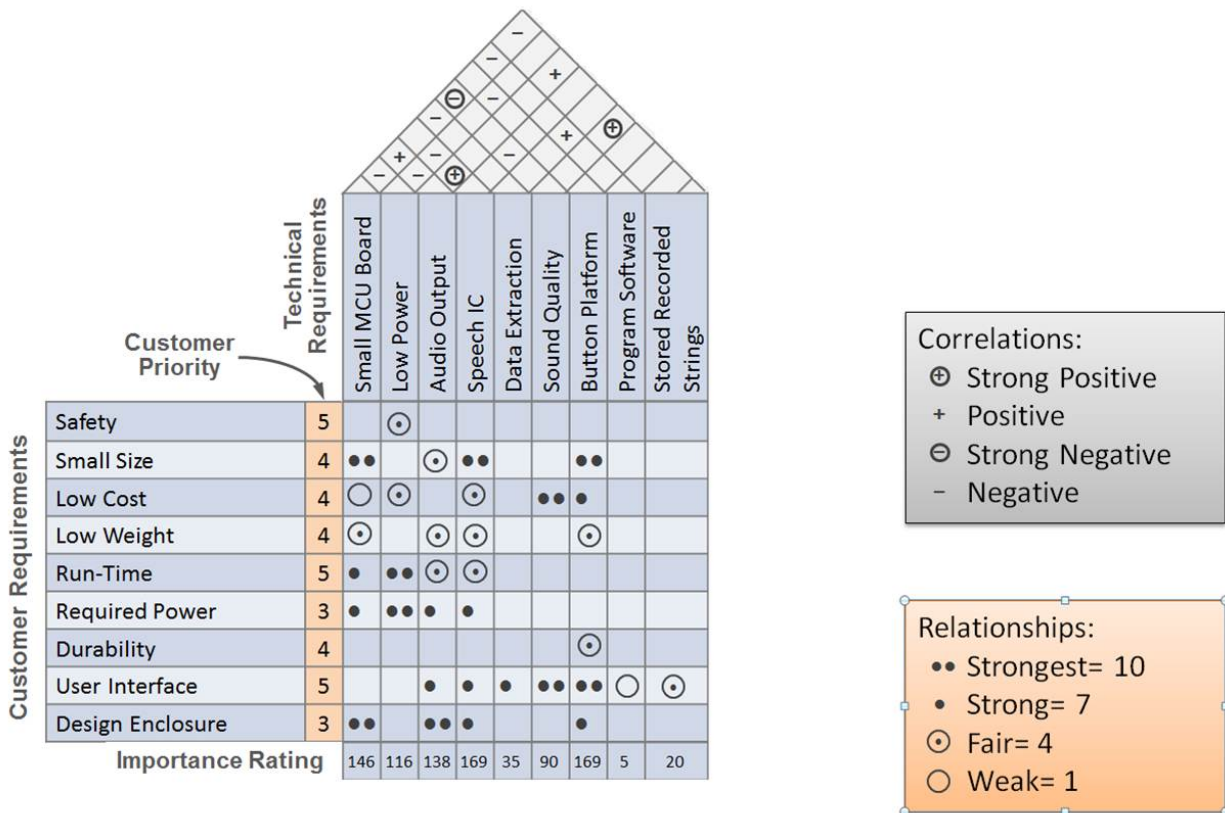
Correlations:
- ⊕ Strong Positive
- + Positive
- ⊖ Strong Negative
- – Negative

Relationships:
- •• Strongest= 10
- • Strong= 7
- ⊙ Fair= 4
- ○ Weak= 1

Customer Requirements	Customer Priority	Small MCU Board	Low Power	Audio Output	Speech IC	Data Extraction	Sound Quality	Button Platform	Program Software	Stored Recorded Strings
Safety	5			⊙						
Small Size	4	••		⊙	••			••		
Low Cost	4	○	⊙		⊙		•••	•		
Low Weight	4	⊙		⊙	⊙			⊙		
Run-Time	5	•	••	⊙	⊙					
Required Power	3	•	•••	•	•					
Durability	4							⊙		
User Interface	5			•	•	•	••	••	○	⊙
Design Enclosure	3	••		•••	•			•		
Importance Rating		146	116	138	169	35	90	169	5	20

Figure - 2

Proposed Design Solutions

Methodology

The design to model will be the foundation of the next generation of insulin pumps, as it will set a standard to which all insulin pumps should abide by. Although the initial model will be a slight variation of what we intend physically, we will be creating an insulin pump that has a fully functional and intuitive software while maintaining a simplistic and safe design. The design to be selected will be based on the ranking system above and by proving the design will meet the evaluation criteria below through a series of testing.

Evaluation Criteria

The design must prove that all conditions are consistently met for the safety of users and complete functionality of the product. First, the design must not create interference with neighboring electronics and or the pump body itself. Secondly, the design must be completely intuitive for all users of the insulin pump without creating any errors in the functionality of a typical insulin pump. The next condition requires that the pump speech is clearly audible via the speakers and headphones. Lastly, the design must pass a usability test provided by RCPD.

The Design

The model design will make use of a microcontroller, a text-to-speech chip, a battery source, an LCD-screen, and a speaker. The microcontroller will be controlled via a USB, connecting the microcontroller to a computer for coding. The program will contain all functionalities of an insulin pump. But unlike a typical insulin pump, our code will output audibly the menus, options, and the current display to the user, based on the input triggers from the user. This will be done via the coding and the connection between the microcontroller and the text-to-speech chip. This will allow the input functions to be audible through a speaker or headphone. Similarly to the current generation of insulin pumps, the pump will maintain a strong emphasis on the general diabetic population as well by keeping a memory unit for data storage and simple button recognition. We will keep a simplistic design with legible fonts.

Based on time, we will be creating a full insulin pump with all elements inside of the physical pump. This will give a true idea on what we envision for the final product, minus the pump body and infusion set. But for the initial design, we have the microcontroller and text-to-speech chip in a separate compartment, while providing a design and model for a smaller scaled version of the product. The body will contain a space for the reservoir in the pump body, with an LCD-display, buttons, and a speaker. The parts list that we have selected is listed below in the budget section. The team selected a microcontroller that meant the most requirements and purchased additional components based on the microcontroller. The MSP-430F5438 Experimental Board contained the desired features such as an LCD, analog and button configuration, and audio output. The schematic can be seen in the figure below.
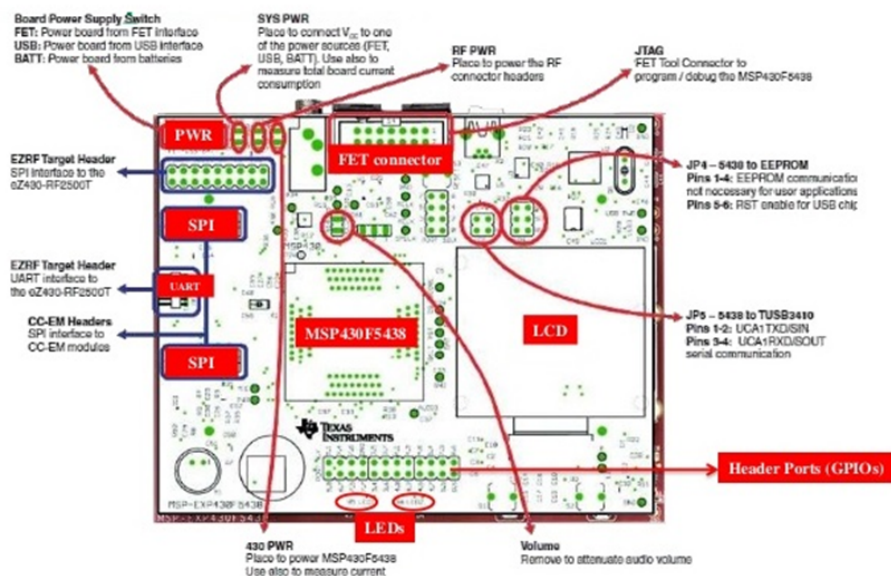

Figure - 3

The Text-to-Speech chips that were chosen come in a set, where the TTS256 contains a built-in 600 rule phoneme codes and the SpeakJet contains the voice synthesizer. Those can be visualized in the two chips below.
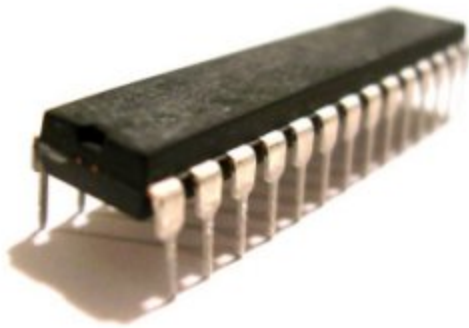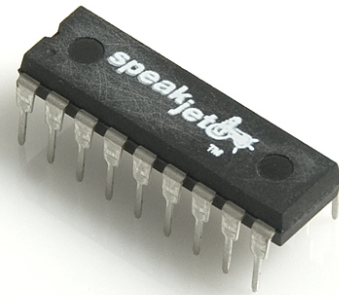

Figure - 4   **Figure - 5**

Risk Analysis

Miscommunication

Designing such a commonly used medical device requires attention and precision. Our device will be the intermediate between the user and their medicine. Any misunderstanding between the user and pump could cause serious implications. Today's standard insulin pumps already have a problem with communication as blind users cannot access the information on the device. Our pump must be taken into extra consideration in the testing process to confirm the integrity of the physical and audible functions of the pump.
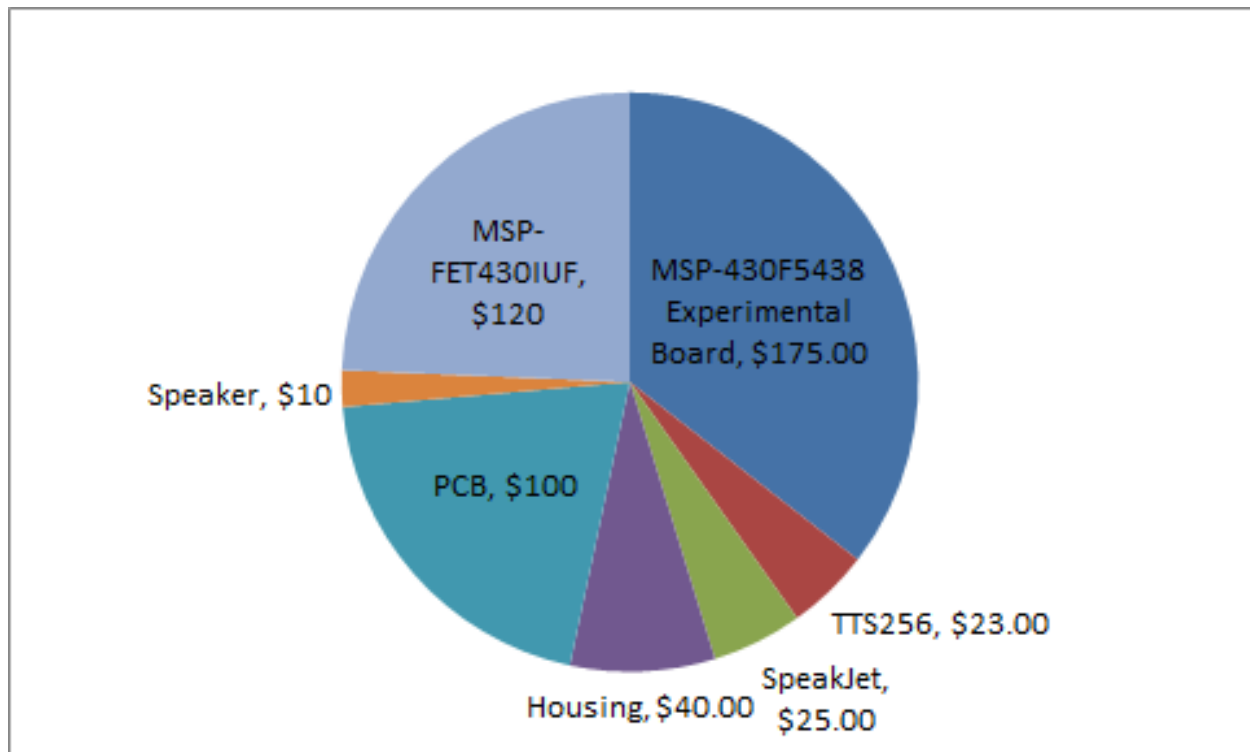
Functionality

Many pumps in the current market do have a simplistic concept and design, but this does not apply for every user. The designed pump must not complicate the functionality compared to that of a standard pump. The audible interface must be clearly recognizable, leaving no room for misinterpretation. If the integrity of the standard pump is compromised, testing procedure should further continue.

Electrical Integrity

Electrical devices require detailed analysis and testing prior to professional performance. The slightest interference between electrical components can lead to detrimental results, especially in the medical field. Thorough testing should be implemented to prove that the pump is functioning properly without any internal issues and without any interferences between outside elements, such as other medical devices. There must be a fully integrated system between the software and the hardware in the pump, creating a seamless interaction.

Budget

Project Management Plan

Team Roles

Hoyoung Jung - Management

Hoyoung will maintain and improve the quality of the team's engineering design process and, in cooperation with the instructors, the quality of the course tasks. He will be responsible for scheduling meetings and project management. This includes project task list and timeline management, group processing, reporting to the facilitator the progress and problems on the project, and completing the course assignments. Also, being short a member for the role of document coordinator, he is responsible for proper distribution of written documents and editing.

Anthony Iafrate - Lab Coordinator

Anthony will provide support for a smooth functioning and appearance of the ECE480 Capstone lab. He will coordinate ordering of parts for the team and report problems with any lab equipment.

Marshall Williams - Presentation Coordinator

Marshall will provide support for professional, high-quality oral communication in the team's engineering design process. He will coordinate the oral reports and peer evaluation of presentations. He will coordinate the preparation of posters showing the designed project at Design Day.

Miriel Garcia - Webmaster

Miriel will support the team's shared information workspace to effectively use web technology in the team's design process, creating the image of the team. She will coordinate the design process of the web page design and upload the necessary documents to the team's web page.

Having four members, we determined it was best to tackle goals in pairs with communication and collaboration. Anthony and Marshall will be focusing on much of the hardware accessibility, while Miriel and Hoyoung will be focusing on the software of the pump. As this project is stressing the functionality of the software, the team will primarily allot their focus and time to the program of the pump.
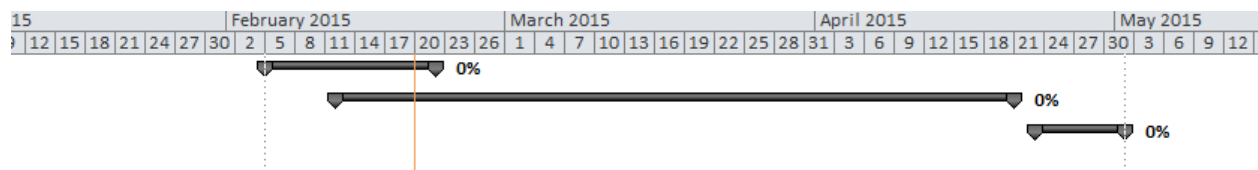
Sponsors and Resources

This project would require much more time without the assistance provided by our sponsors. Asante Solutions provided us the necessary pump equipment for experimenting and testing. The RCPD provided us connections to resources that directed us in our design process. The RCPD has also connected us to the Usability Test Center, which would later give the team access to thorough product testing. The ECE department has provided the team a lab that would give the team access to equipment for design production.

GANTT Chart

Task Name	Duration	Start	Finish	Predecessors
⊟ **Project Definition**	**12 days**	**Thu 2/5/15**	**Sat 2/21/15**	
Meet with project's creator	1 day			
Meet with industrial sponsor	1 day			
Meet with customers	1 day	Thu 2/5/15	Thu 2/5/15	
Brainstorm design ideas	3 days	Fri 2/6/15	Tue 2/10/15	4
Research for parts/Coding Language	3 days	Wed 2/11/15	Fri 2/13/15	5
Homework Assignment (Voice of Customer)	0 days	Fri 2/6/15	Fri 2/6/15	
Select preferred design	1 day	Wed 2/11/15	Wed 2/11/15	5
Determine Budget	1 day	Fri 2/13/15	Fri 2/13/15	16
Submit FAST Diagram	0 days			
Submit Pre-Proposal	0 days	Fri 2/6/15	Fri 2/6/15	
Oral Pre-Proposal Practice	0 days	Fri 2/13/15	Fri 2/13/15	
Proposal Presentation	0 days	Mon 2/16/15	Mon 2/16/15	
Submit Final Proposal to facilitator, sponsor & Profs. Grotjohn and Udpa,	0 days	Sat 2/21/15	Sat 2/21/15	

Initial Design	48 days?	Thu 2/12/15	Mon 4/20/15	
Create parts List	1 day	Thu 2/12/15	Thu 2/12/15	8
Order Parts	8 days	Fri 2/13/15	Tue 2/24/15	16
Determine Budget	1 day?	Fri 2/13/15	Fri 2/13/15	16
Start Coding	4 days	Wed 2/25/15	Mon 3/2/15	17
Run tests	4 days	Wed 2/25/15	Mon 3/2/15	
Modify Design/Source Code	4 days	Wed 2/25/15	Mon 3/2/15	
Demo #1	0 days	Mon 3/2/15	Mon 3/2/15	20
Progress Report Due	0 days	Fri 3/20/15	Fri 3/20/15	
Technical Lectures due	0 days	Mon 3/30/15	Mon 3/30/15	
Design Issues paper due	0 days	Sat 4/11/15	Sat 4/11/15	
Modify Design/Source Code	35 days	Tue 3/3/15	Mon 4/20/15	22
Design/Create Pump body	35 days	Tue 3/3/15	Mon 4/20/15	
Individual Application Notes due to facilitators			Fri 4/3/15	
Demo #2	0 days	Mon 4/20/15	Mon 4/20/15	
Professional self-assessment papers due	0 days	Thu 4/16/15	Thu 4/16/15	

Final Design	7 days	Thu 4/23/15	Fri 5/1/15	
Customer testing of final design	3 days	Thu 4/23/15	Sat 4/25/15	
Modify Design/Source Code, If needed	4 days	Mon 4/27/15	Thu 4/30/15	32
Final Report due	0 days	Wed 4/29/15	Wed 4/29/15	
Final Presentation (Design Day)	0 days	Fri 5/1/15	Fri 5/1/15	

Resources

http://www.afb.org/info/programs-and-services/technology-evaluation/published-results/insulin-pumps/1245

http://www.magnevation.com/pdfs/speakjetusermanual.pdf

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2769864/

https://www.sparkfun.com/datasheets/LCD/HD44780.pdf

https://www.sparkfun.com/products/9578

https://www.sparkfun.com/products/9811

http://www.ti.com/tool/msp-exp430f5438

http://www.webmd.com/eye-health/eye-problems