

ECE 480 Proposal
Team 4 – Accessible Insulin Pump Design
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Executive Summary

Due to a growing demand for an insulin pump that can be controlled by a blind user, more companies are trying to find new ways to provide this service to their customers. Due to this demand, the team must create an add-on module to a current insulin pump design that forms a path of auditory communication between pump and user. Without changing any of the pump's functionality, the add-on should report all necessary information from the viewing screen to the user allowing a blind user to control it independently.

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Introduction:

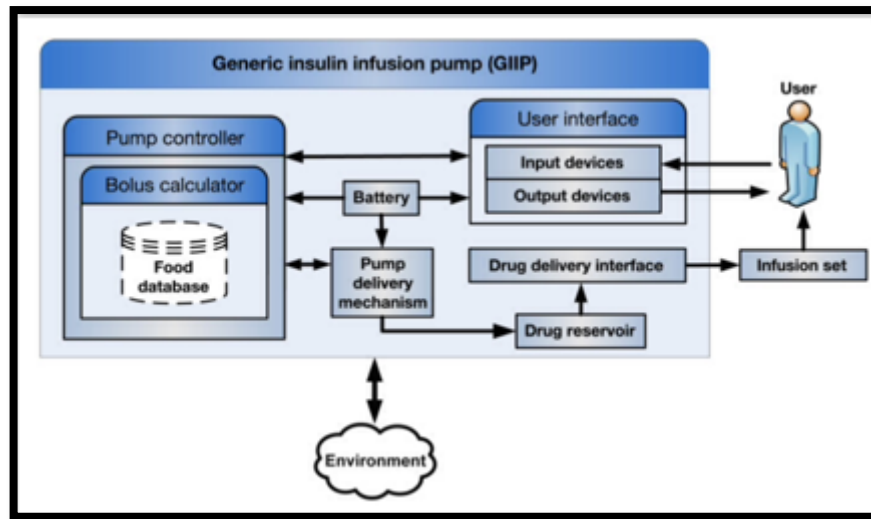


Figure 1
Generic Insulin Infusion Pump Model

According to the Generic Insulin Infusion Pump model (GIIP), seen in Figure 1 above, the main functional component in an insulin pump is the pump controller. It manages the pump delivery mechanism to provide the patient with insulin at a prescribed rate and duration. The pump controller is responsible for the user interface, recommending appropriate dosage, alerting the patient, and logging important data. All these features are extremely important to a diabetic patient, but the flexibility of the insulin pump's user interface remains to be seen. Nurses and doctors agree that current insulin pumps on the market need to better address patients of various age groups and disabilities.

In the United States, approximately 40% of diagnosed diabetics have a form of diabetic retinopathy, which leads to decreased vision and blindness. This represents a significant portion of diabetics, resulting in an increasing need for an insulin pump that can communicate its data to someone who cannot readily read a screen. Currently, Asante Pump Solutions and the Resource Center for Persons with Disabilities are working with our team to create possible solutions to this ongoing problem.

In order to create a path of communication between a blind user and their insulin pump, an auditory pathway must be created. To do so, there are multiple options. In order to organize the options available to create this pathway, two pathways must be addressed. The first is from the insulin pump to the add-on and the second is the connection from the add-on to the user. For example, the add-on could transfer its data to the user by a speaker already contained inside the insulin pump. Though this would be a good use of resources, it may not completely satisfy the customer.

The goal of this project is to create an easy way for a blind user to access the information they need from the insulin pump and should take into consideration size, cost, and the users themselves. In

order to do so, the pathway to reach the end goal must be created. The team will create at competing models that will focus on different design criteria. For example, though cost might be more important than size to the customer, another model that weighs more importance to cost will still be made.

Customer's Needs and Requirements

As with most medical equipment, insulin pumps have to meet a variety of standards and requirements. At Pennsylvania State University, a team is working on a generic infusion pump, which the Food and Drug Administration references on its website. Below are the safety standards the Pennsylvania State University team has proposed that are applicable to our mission:

- The insulin pump user interface should prevent risking patient safety or causing a dangerous flow error.
- It should have at least two steps to change the settings and should not require buttons to be pressed simultaneously.
- If the patient decides to reset the pump, the patient will receive some form of audible confirmation.
- If a button is pressed for less than 't' seconds, it will not register as a button press.

At the 2010 AAMI/FDA Infusion Device Summit, nurses and doctors voiced their opinions on how infusion pumps could be made easier to use. A few of those concerns which may relate to our project include:

- Offering a magnifying glass that fits over screens, larger print or brighter screens.
- Offer pumps screen text in more languages.
- Explore the effectiveness of alarm tones on different age groups.
- The inclusion of a strong vibrating alarm to help alert sleeping or inattentive patients.

Background:

The Food and Drug Administration is currently mandating a change in the design of infusion pumps, which include insulin pumps. This mandate has opened the doors for many new companies, like Asante Solutions, to come up with better, easier to use insulin pumps. Figure 2 below shows Asante's Snap Pump, which provides a user friendly, low cost, insulin pump option for diabetics. By going through the new regulations set by the FDA, our team is working on following these new guidelines. Another source of information is the doctors and nurses who take care of these diabetic patients. Seeing as they have to interact with both the patients and the insulin pump itself, they have a vital insight into an easier to use insulin pump. Lastly, Asante Solutions has a great wealth of resources found in their engineering employees.

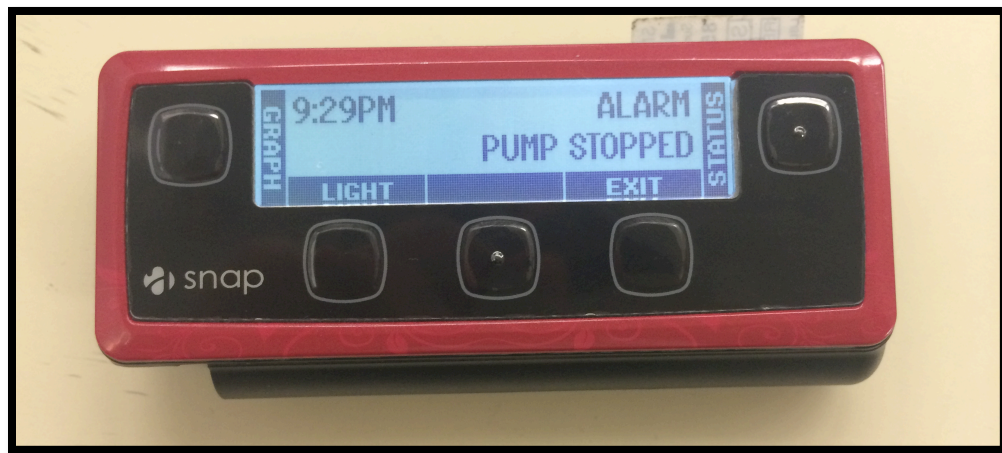


Figure 2
Asante Snap Pump

Design Specifications:

Mission Statement:

Using the multiple facilities available, models will be created that focus on various design criteria to produce an auditory channel between user and an insulin pump with little or no effect on the current design of the insulin pump.

Design Criteria:

Type A: **Vital**

- Size – Rank: 4
Diabetic patients wear insulin pumps on their hips, thighs, arms, etc. It is required they have their insulin pump with them at all times. For this reason, it is important to our team that our add-on will not make the insulin pump any more cumbersome than it already is. Ideally, it should be as light weight and compact as possible.

- **Material – Rank: 3**
Though not meant to be highly durable, it is understood insulin pumps are at risk for damage during their lifetime. This could include dropping on a hard surface, being submerged in water, or general wear and tear from the elements. So, another criterion is the material used to keep the add-on durable, while at the same time avoiding encroaching on the size and weight criteria.
- **Cost – Rank: 3.5**
Asante Solutions has come up with an insulin pump that rivals current insulin pump providers with its low cost. In order to give Asante Solutions an add-on that is reasonable for their customers, cost must be taken into consideration. This goal can be reached in multiple ways. For example, an easy to manufacture case and hardware would make for a less costly product.
- **Safety – Rank: 5**
Seeing as insulin pumps provide a vital service to their users, it is extremely important that the add-on does not adversely affect the functionality of the pump itself. On top of this, the add-on requires a design that enables it to come into contact with the user consistently. For example, it is important that the add-on does not overheat since the insulin pump is always directly in contact with the user.

Type B: **Esthetics**

- **Product Design – Rank: 3**
Though it may be put on the back burner, how a product looks is important in the design. A consumer does not want a design that is cluttered and unorganized. On that note, our customer, Asante Solutions, is known for sleek and visually appealing designs, and so that standard must be upheld.
- **Intuitive – Rank: 3**
It is important to consumers and project designers that the product created should not require extensive background on the subject. It should be quickly responsive with understandable commands and functions.

FAST Diagram:

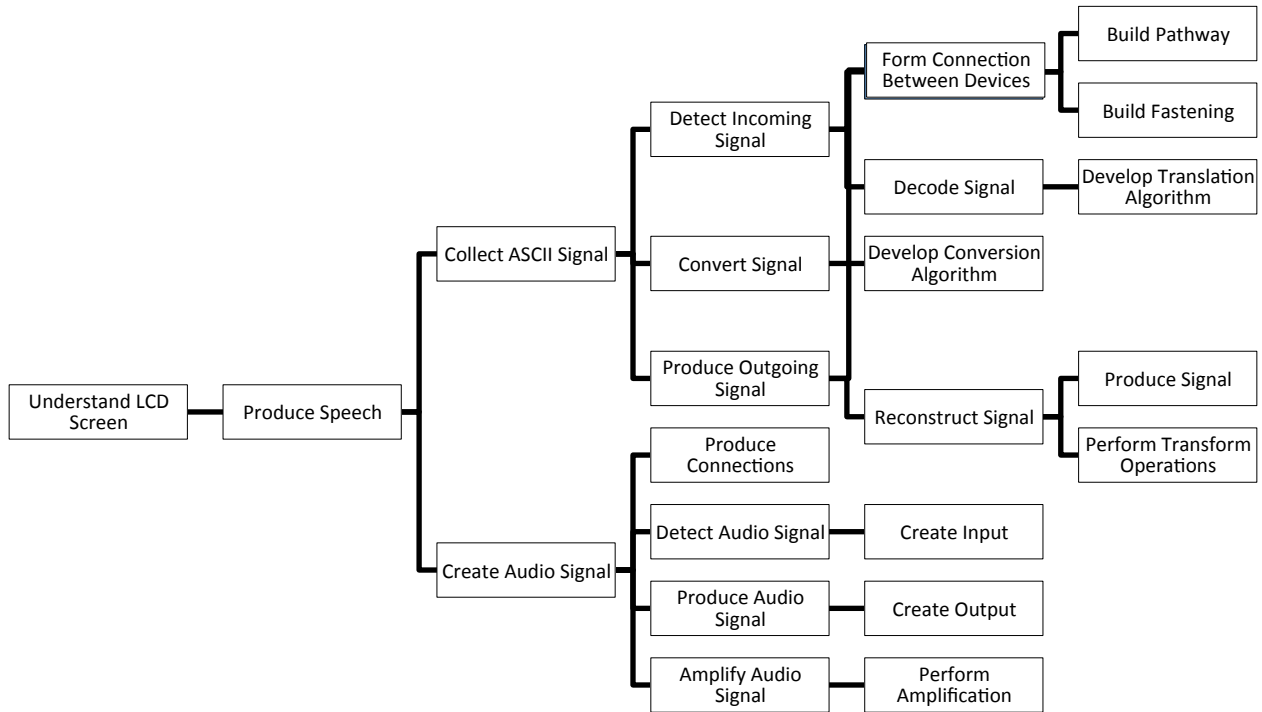


Figure 3
FAST Diagram

Ranking of Conceptual Designs:

As seen in Figure 4 below, desirability criteria will be broken down into nine components: safety, size, weight, cost, intuitiveness, simplicity, reliability, programming, and power. The most important of the design criteria will be durability. The design should be able to withstand as much as possible to ensure the health of the patient. Compared to durability, cost is next in line of importance. The consumer and our customer, Asante Solutions, will not choose a design, no matter how durable, if it is out of their price range. Lastly is size. Though it is important to attempt to keep within the size parameters of the insulin pump, it must be understood that an add-on will inherently require more space.

Design Criteria	Importance	Possible Solutions		
		Text-to-Speech	Digital Speech	Bluetooth
Safety	5	4	3	1
Size	4	2	4	5
Weight	4	3	4	5
Cost	3	5	4	2
Intuitiveness	3	4	4	5
Simplicity	3	3	5	4
Reliability/Durability	5	4	4	3
Programming	4	2	3	1
Power	4	2	3	4
Totals		112	130	113

Figure 4
Feasibility Matrix

Model I: Text-to-Speech

The first design will include a text to speech 8-bit microprocessor, which will read the contents of the viewing screen using a built-in algorithm. The microprocessor produces a translation of English ASCII characters into allophone addresses. The text to speech microprocessor will be combined with the SpeakJet, a single-chip voice and complex sound synthesizer. The SpeakJet allows for unlimited vocabulary speech synthesis and complex sounds. The limitations of this configuration are its size. As seen in Figure 5, the circuit will require an additional microcontroller to manage the microprocessor input. These microprocessors are quite large relative to the insulin pump and, with the additional microcontroller, the entire circuit will require more space than the team allows. Also, the voice produced by the SpeakJet has proved indecipherable by the user due to its inability to produce phonetic enunciation for certain letter combinations. Another limitation, voiced by the nurses and doctors, is its inability to accommodate non-English speakers. For our purposes now, this concern would be better addressed once a working English prototype is produced.

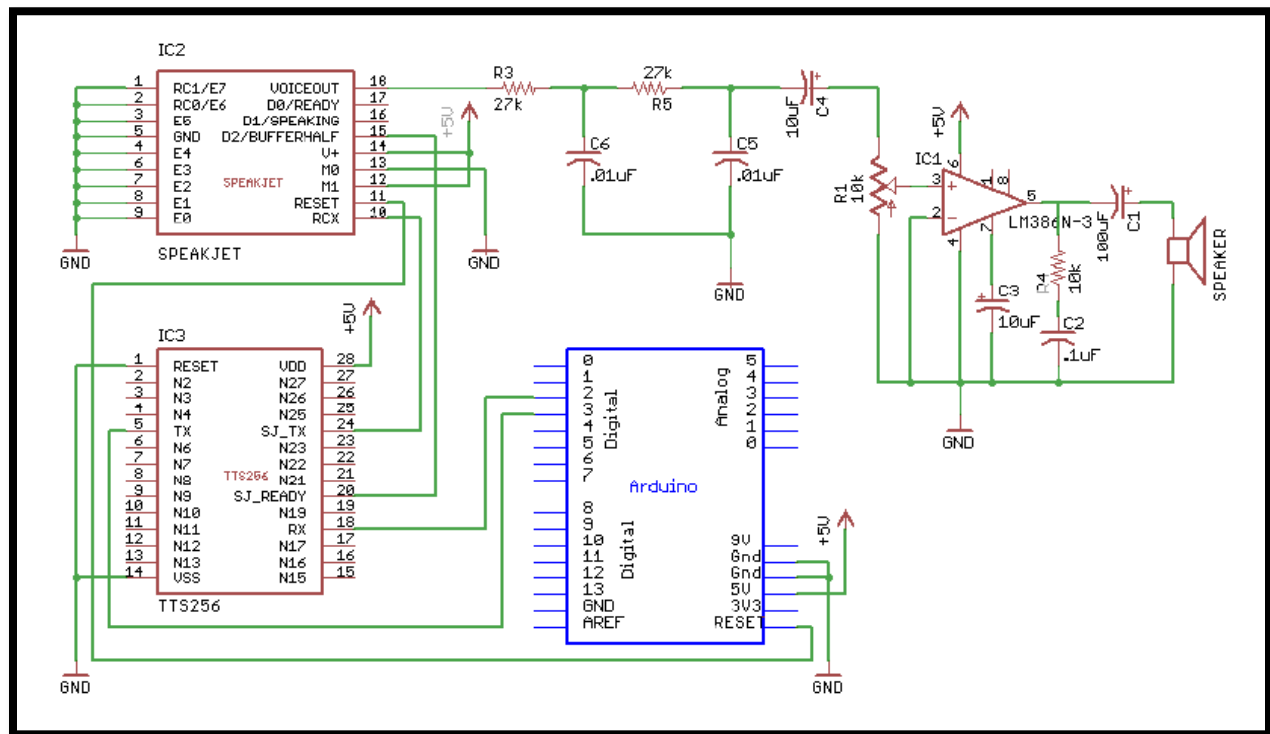


Figure 5
Text-To-Speech Schematic

Model II: Digital Speech

The second design will use digital speech to communicate the pump screen to the user. Digital speech uses a Voice Record and Playback integrated chip to play previous recordings depending on the input. One team member will record his or her voice reading the screen and button text, and the team will program the integrated chip to relate the recordings to the ASCII characters sent from the insulin pump. As seen in Figure 6 below, the integrated circuit has the ability to output a signal to a speaker and auxiliary jack. A limitation of the digital speech system is the amount of time it will require to record and program each recording into the microchip. Also, there is a larger chance, compared to the text-to-speech, of the add-on not communicating the insulin pump information because the team simply forgot to record a command. The better sound quality is a large benefit of the digital speech compared to the text-to-speech. Digital speech allows indecipherable words to be rerecorded. Also, digital speech gives the team a greater ability to explain the button options through the add-on. Lastly, digital speech allows for multiple language options because the team can record different languages along with the primary language.

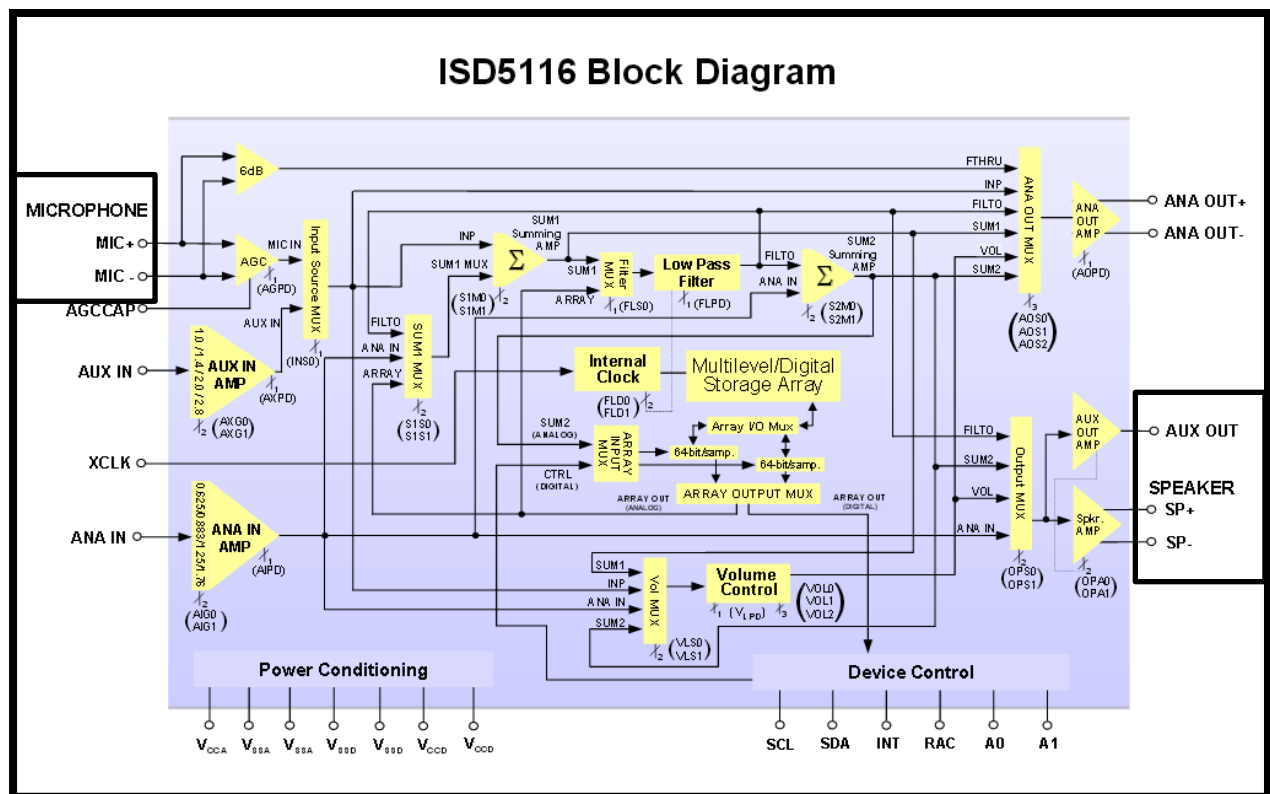


Figure 6
Voice Record/Playback ISD5116 IC
Block Diagram

Model III: Bluetooth Connection

Approximately 90% of blind individuals choose iPhones as their preferred smart phoned device. This is due to the user-friendliness of the voiceover option, which uses verbal commands to help them navigate through their phone. Therefore, the third proposed model is to incorporate a Bluetooth connection as a means of establishing communication between the add-on unit and a programed smart phone application. This would be achieved by transmitting the information seen on the screen to a RF antenna, which would then communicate the data to an awaiting Bluetooth enabled device (such as an iPhone) through a low powered radio wave. A block diagram depicting this is shown in Figure 7 below. The first benefit for this model is that it would incredibly small and compact, requiring a just small antenna and a simple microcontroller, which would make it relatively comfortable for the user to wear. The second benefit is that it would use the voice capabilities already incorporated in the smartphone (i.e. Siri), which has already been established as a highly effective speech device. However, the main concern with this model is that the FDA is understandably uneasy about the use of Bluetooth when it comes to medical devices. Since the Bluetooth signal is wireless, it has a much higher chance of being lost or intercepted; and because the information being sent through this signal directly relates to the patients health, any miscommunication could be potentially detrimental to the patients well being. Therefore, while this model is feasible and effective, it is an impracticable and time-consuming choice until the Bluetooth technology advances and becomes more reliable.

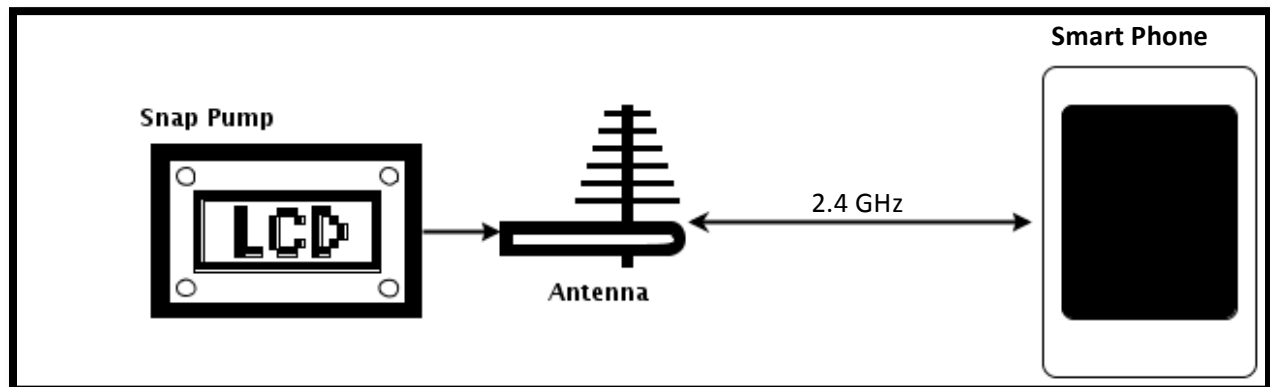


Figure 7
Bluetooth Connection

Proposed Design Solution:

Design Methodology

The plan for reaching a prototype that will both satisfy the customer and consumer will require more than one design to be considered. The proposed plan will focus on two-three designs, chosen from the Ranking of Design Solutions section, which will be tested by the criteria listed below in the Evaluation Criteria section. After testing, one design will be chosen that fills all requirements and passes all tests, which the team, as a whole, will refine and perfect to be presented at Design Day.

Evaluation Criteria

Four failure modes have been selected that will constitute the overall success or failure of a prototype. The first failure mode is undistinguishable audio signals or no audio is produced. The next failure mode is any effect on the performance of the insulin pump. A third failure mode is the production of interference that negatively affects the performance of electronics in close proximity. A fourth failure mode is if the user does not find it effective in facilitating and improving their use of the insulin pump.

Risk Analysis:

Concerns and Challenges

Affect functionality– Rank: 5

Though the project does not require the design to interact with the administration of insulin, there is still a large possibility that it may. This must be avoided for the safety of the customer. Our design is solely made for the auditory communication of the screen information, which has nothing to do with the insulin flow rate. There are strict health regulations for insulin pumps that our team is not qualified to work under.

Miscommunication – Rank: 4

Our potential customers will be almost completely dependent on our auditory communication pathway, which means that if there is any miscommunication, be it with the pump to add-on or add-on to customer, this also must be avoided as much as possible. Any miscommunication could be potentially harmful to the customer.

Interference – Rank: 4

Being an electronic device, the add-on unit has the potential to emit waves that may cause interference on surrounding devices. These surrounding devices could be other medical components and any interference could cause unintentional functionality errors. Since they are medical devices, any error has the potential to cause detrimental effects on the user. The same can be said in the reverse sense. Outside products must not produce any interference on the add-on unit either.

Project Management Plan:

Personnel Tasks

Due to the resources available roles are subject to change depending on the situation.

August Garrett – Management

August will work on the programming for the microcontroller and microchip. He and Caitlin will focus on the microcontroller's response to the signal from the insulin pump. He will work individually on the microchip's response to the microcontroller's commands concerning text on the screen, not the button functions (for clarification see *Jianwen Lu* tasks).

Matt Clary – Lab Coordinator

Matt will focus on circuit and case design for the team. Using Eagle software, Matt will create the schematics required to print the circuit boards. He will also use software to create a case that will be printed at DEC's for the team.

Jianwen Lu – Webmaster

One of Jianwen's responsibilities will be creation of hardware that will connect the microcontroller to the microchip. He will also work with Caitlin to program the microchip with her voice. He will focus on the button programming, in other words, how the add-on will explain to the user the options the buttons provide.

Caitlin Ramsey – Document Preparer

Caitlin will work with Jianwen to program her voice into the microchip. She will help Jianwen with programming the buttons' functions into the add-on and help August program the microcontroller's response to the ASCII 8-bit signal from the insulin pump.

Michael Greene – Presentation Preparer

Michael has taken on the role of monitoring power intake of the add-on. By working with the team to create a design that will intake as little power necessary from the pump and designing a power supply for the add-on that will not interfere with the pump, he will help the team reach a sustainable solution.

Facilities and Resources

Facilities and resources include the ECE shop, the Resource Center for Persons with Disabilities, and the 480 lab. The ECE shop has the ability to create integrated circuits and supply various materials. The Resource Center for Persons with Disabilities will provide the opportunity for potential consumers to give their input on the model. The ECE 480 lab will provide an adequate working space that contains a variety of tools, such as oscilloscopes and soldering irons, which will be valuable with the construction and testing of all possible designs. Our sponsor, Asante Solutions, will provide guidance and pertinent insight that will allow for designs to adhere to the proper health regulations and standards

Schedule

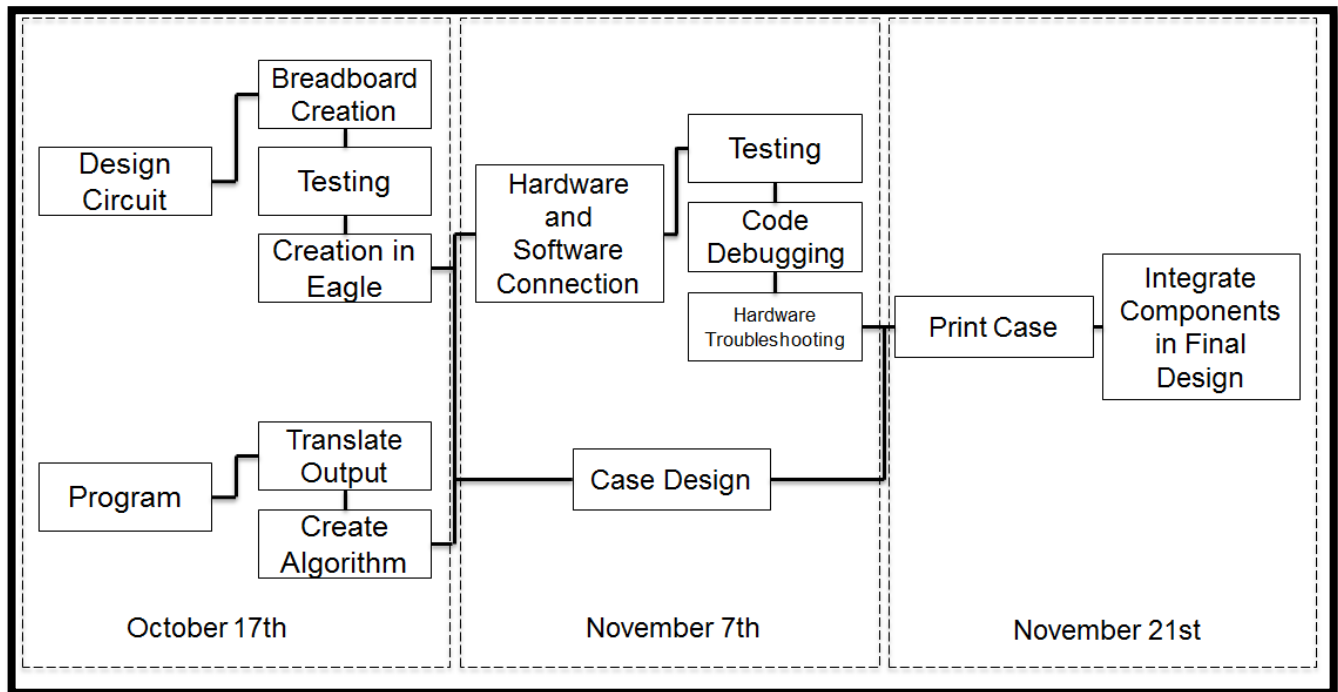


Figure 7
Important Events and Dates

All team meetings with Professor McGough will occur every Friday at 5pm in 2203A and will be adjusted based off of any varying schedules of either involved party. Team members will meet Monday evenings at 6pm to discuss weekly goals and will meet at various times throughout the week to achieve project objectives. Meetings with both of the project sponsors will occur when appropriate throughout the semester. Important dates and events have been outlined in Figure 7. Furthermore, the team has outlined a project timeline in a Gantt chart, which can be seen in Figures 8, 9, 10, and 11.

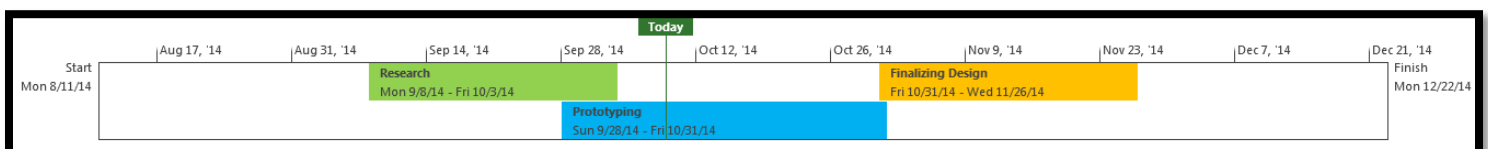


Figure 8
Main Components of Gantt Chart:
Research, Prototyping, Finalizing
Design

		Task Mode ▾	Task Name ▾	Durat ▾	Start ▾	Finish ▾	Predecessors ▾
1			 Research	22 days	Mon 9/8/14	Fri 10/3/14	
2			Research Various Options (Microcontrolle Text-to-Speech	8 days	Thu 9/18/14	Sat 9/27/14	
3			Receive and Reverse Engineer Pump	36 days	Mon 8/11/14	Sat 9/27/14	
4			Meet with Customer	3 days	Fri 9/19/14	Tue 9/23/14	
5			Meet with Sponsor	3 days	Fri 9/19/14	Tue 9/23/14	
6			Voice of Customer Paper Due	0 days	Fri 9/26/14	Fri 9/26/14	
7			Select 1-2 Models to Prototype	2 days	Sun 9/28/14	Mon 9/29/14	2
8			Determine Technical Roles	2 days	Tue 9/30/14	Wed 10/1/14	7
9			FAST Diagram Due	0 days	Fri 10/3/14	Fri 10/3/14	
10			Determine Budget	2 days	Thu 10/2/14	Fri 10/3/14	8

Figure 9
Research Component of Gantt
Chart

		Task Mode ▾	Task Name ▾	Durat ▾	Start ▾	Finish ▾	Predecessors ▾
11			▾ Prototyping	28 days	Sun 9/28/14	<u>Fri 10/31/14</u>	
12			Create Schematics	4 days	Sat 10/4/14	Wed 10/8/14	10
13			Proposal Presentation and Proposal Due	0 days	Mon 10/6/14	Mon 10/6/14	
14			Order Parts	2 days	Thu 10/9/14	Fri 10/10/14	12
15			Make First Connection	11 days	Sat 10/11/14	Fri 10/24/14	
16			Engineering Project Notebook Due and Progress Report	0 days	Fri 10/24/14	Fri 10/24/14	
17			Demo Project, Individual Application Notes	0 days	Mon 10/27/14	Mon 10/27/14	
18			Begin Programming	28 days	Sat 10/11/14	Fri 12/12/14	14
19			Begin Testing	11 days	Sat 10/11/14	Fri 10/24/14	
20			Modify Design	11 days	Sat 10/11/14	Fri 10/24/14	
21			Complete Connections	0 days	Fri 12/12/14	Fri 12/12/14	18

Figure 10
Prototyping Component of Gantt
Chart

22	★	Finalizing Design	21 days	Fri 10/31/14	Wed 11/26/14	
23	★	Technical Presentation	0 days	Mon 11/3/14	Mon 11/3/14	
24	📅 ➡	Field Testing With Nurses and Sponser	6 days	Mon 12/15/14	Mon 12/22/14	21
25	★	Further Revisions	7 days	Sat 11/8/14	Sat 11/15/14	24
26	★	Finalize Prototype	4 days	Mon 11/17/14	Thu 11/20/14	25
27	★	Design Issues Paper	0 days	Fri 11/21/14	Fri 11/21/14	
28	★	Demo Project, Self Assesment Paper	0 days	Mon 11/24/14	Mon 11/24/14	
29	★	Create Case and Finish Assembly	4 days	Fri 11/21/14	Wed 11/26/14	26

Figure 11
Finalization Component of Gantt Chart

Budget

Digital Speech with Voice Record/Playback Device

Materials

DigiKey – Demo Board – Amount: 1 – Price per unit: \$70.18

DigiKey – Voice Record/Playback IC – Amount: 2 – Price per unit: \$18.04

ECE Shop – Various Circuit Components – Amount: N/A – Price per unit: \$0.00

Texas Instruments – Microcontroller – Amount: 3 – Price per unit: \$5.00

Services

ECE Shop – Printed Circuit Board – Amount: 2 – Price per unit: N/A

DECS – 3D printed Case – Amount: 2 – Price per unit: \$10.00

Total

\$500 will be allotted to Digital Speech

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