Affordable Insulin Pump

ME EN 4010 – Final Report

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1.0: Front Matter
1.1: Executive Summary
1.1.1: Introduction
Individuals that have been diagnosed with Type I diabetes do not produce enough insulin naturally to sustain their bodies. [1] They have to inject insulin into themselves on a regular basis to maintain their blood sugar levels. One method of doing this is with an insulin pump. However, the high cost of insulin pumps makes it difficult for an individual to purchase an insulin pump. Much of the time, individuals have no choice but to purchase one, if they want to maintain their lifestyle in a somewhat normal fashion.

We designed and manufactured an infusion pump that functions tantamount to existing commercial insulin pumps, but is also more affordable. This goal was achieved by building a user-constructed infusion pump. The user will purchase an infusion pump kit with all the necessary parts to assemble a functional infusion pump. This removes manufacturing costs, allows customizability, and gives the option for simple part replacement.

1.1.2: Key Project Focus Areas
The primary focus of this project is to create a convenient, functional and reliable insulin pump that is safe and easily accessed by the average individual. The primary functions of the insulin pump can be categorized into three categories:

- Motor propulsion system
- User interface
- Sensor system

The **motor propulsion** system will translate the motor's rotational motion into linear motion. This forces insulin from the cartridge, through the tube, and to the user.

The **user interface** will allow the ability to inject controlled doses of insulin as well as control the insulin injection rates. A LCD screen and button configuration is provided for the user to track the status of their system for maintenance.

The **sensor system** includes both a strain gauge pressure sensor and an optical position sensor on the cartridge system. These sensors work together to monitor the insulin injection rate. Speaker and display notifications will inform the users of any errors or actions that need to be performed. This provides both safety within the system and comfort for the user, as well as prevent any large changes in insulin dosage.

1.1.3: Conclusion
Through thorough testing, it was determined that the primary functions of motor propulsion, user interface, and sensor system worked to the desired specifications, with the entire system costing under $250. Of the design goals of convenient, functional, reliable, safe, and accessible; the team built an insulin pump meeting each goal except convenience. The battery life of the infusion pump lasts 6 hours with a set of rechargeable batteries, where ideally the batteries would last through the day and charge at night. This provides direction for the next iteration: replacing components which consume too much power with

more efficient parts. Upgrades done to improve the battery life of the device will also improve the safety, accuracy, and size of the system.

1.2: Acknowledgements

1.2.1: Student Design Team Members

The Affordable Insulin Pump team is composed of four undergraduate mechanical engineering students. Each student brings their own set of unique skills to the table. Individual and group tasks are assigned to members based on their skill sets, and interests. This allows the team to work together in a timely and efficient manner.

McKayla Whitehead – Team Captain/Coder
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McKayla pushes the team to meet their deadlines, and leads in project assignments. She keeps the team at task during meetings, and makes sure that all members are informed of upcoming deadlines, and assignments. As the main coder, McKayla codes and debugs programs for each aspect of the insulin pump.

Joshua Stubbs – SolidWorks/Manufacturing Design
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Joshua leads manufacturing decisions regarding the pump design. This includes component purchase decisions, and designing component configurations. Solidworks parts are similarly created by Joshua. This includes all simulations and model prototypes in a 2D and 3D form.

Young Jun Jeon – Electrical/Research
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Young brings a resourcefulness that is necessary for the design process. Young has good knowledge in SolidWorks as well as soldering and wiring electrical components. He researches for what is necessary in choosing possible components. He assists Joshua with CFP and design.

Cherry Gregory – Treasurer/Design Testing
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Cherry Gregory is interested in project management, design testing, and mechanical design. She brings excellent written communication skills and testing experience to the team. She is currently working on a research fellowship and is interested in the power management of the system. Her primary responsibilities are keeping meeting notes for record, and budgeting for the project.

1.2.2: Teaching Team

Dr. Bruce Gale – Team Advisor
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Dr. Gale has provided support and guidance in key design decisions throughout the project. His knowledge and experience in biomedical engineering has provided a great resource for the team. Often-times, he has helped the team move past design problems and allowing access to lab devices, which is critical to manufacturing of the final device.

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1.2.1: Additional Acknowledgements

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Deb Williams – Presentation Assistance

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2.0: Design Requirements

2.1: Introduction

The design requirements for the Affordable Insulin Pump have been determined by the customer, senior design team, and team advisor. [3] The primary needs for the device include:

- Delivery of the insulin to be accurate and reliable, for both basal and bolus rates
- Casing be durable
- Easy to maintain and repair
- Easy and comfortable to wear/carry
- Affordable when compared to other on the market brands
- Easy to control

The primary needs are shown in a customer needs hierarchy in Table 2.1 and are also described in further detail in section 2.2 to 2.5.

Table 2.1. Customer Needs Hierarchy

No.	Ranking	Primary Need	Secondary Need
1	5	Reliable	
			Accurate/Consistent Basal/Bolus Rate
2	4	Durable	
			Water Resistant
			Shock Resistant
3	4	Affordable	
			Kit Setup
	3	Easy to Wear	
4			Portable
			Discreet
5	2	Interactive Display	
			Easy to View
			Intuitive Buttons
6	1	Easy Maintenance	
			Easy to Replace Battery
			Easy to Replace Cartridge
			Easily Replaceable Parts

2.2: Reliability

The primary customer requirement of the Affordable Insulin Pump design is that it must be reliable and safely deliver insulin to the customer. The concern of many people who change insulin pumps is the quality of the medical administration provided by their new pump. As the pump is placing a medical fluid directly into their body, the accuracy of those injections largely impacts the user's comfort, health, and safety.

2.2.1: Accurate and Consistent Basal and Bolus Rate

Infusion pump users solely rely on small consistent dosages throughout the day (basal), and larger doses right before mealtime (bolus). Each user requires a different amount based on their weight and the progression of their Type I diabetes, as recommended by their doctor. [15] Basal and bolus rates must be consistent and accurate to help them maintain their blood sugar levels, thus reducing the impact on their health and safety.

2.3: Durable

The purpose of an insulin/infusion pump is to allow people with Type I diabetes to live their lives with minimal disturbance. By creating a product that is robust in nature, we allow users to participate in daily activities and exercises with little worry in the integrity of their device. A durable design eliminates the worry of damage to internal parts.

2.3.1: Water Resistant

To prevent damage when the device is accidently placed in an aquatic environment, it must be water resistant. To ensure water resistance, the casing will not have air gaps and the buttons will have a covering. This will prevent water getting into electronic components and causing damage to the system.

2.3.2: Shock Resistance

Most handheld devices require some degree of shock resistance, as they are often dropped or mishandled during their regular life cycle. Limiting the movements of the components to their function will create a shock resistant device. Precise manufacturing methods will be used to create the casing that holds the components of the insulin pump, in a way that limits the movement, and provides space for dampening material.

2.4: Affordable

The problem many customer with Type I diabetes face when considering using an insulin pump is the initial cost of a new insulin pump. Often, people are unable to obtain an insulin pump without going into a large amount of debt. In order to make insulin pumps available to more people, this pump is manufactured in a kit setup, with easily replaceable parts.

2.4.1: Kit Setup

One large cost of manufacturing products is the part assembly. In order to avoid as much cost as possible in production, the pump will be user assembled. Several safety checks will be preprogrammed into the system to check on the system quality before the pump can be used to deliver insulin to ensure the health and safety of the customer.

2.4.2: Easily Replaceable Parts

Often times with medical devices, when one component of the device is damaged and breaks, the user is forced to replace the entire device. In making a user assembled product, the potential for user part replacement and maintenance is created. The team designed a kit setup with individual parts available for purchase, minimizing the cost of replacement by allowing the user to only replace the damaged component.

2.5: Easy to Wear

The purpose of an insulin pump is to allow the user to live a life with minimal hassle. The device needs to be convenient and not bother them during their day-to-day life. This includes a portable, and discreet system.

2.5.1: Portable
A quality insulin pump allows the user to move freely in their daily lives. This is best accomplished when the device is both small and lightweight, as it can be ignored during day to day use.

2.5.2: Discreet
Many users find it most convenient to attach their pump to their clothing. However, the device may protrude, and become a distraction. An ideal device is discreet and does not take away from a user's ensemble.

2.6: Interactive Display
In any new electronic device, user confusion needs to be minimized. Most importantly, the device will have all the necessary features to ensure the customer can control the insulin dosage. To ensure a user-friendly device, there will be sound notifications, a display screen panel, and button controls.

2.6.1: Easy to View
The display needs to be easy to view, and easily navigated in order to examine each feature of the device. For best results, clear and concise messages should be displayed on for each insulin pump function.

2.6.2: Intuitive Buttons
An intuitive and easily understood user interface is required for user convenience and safety. The generic 5-button input setup, with 4 directional buttons and a select button; a 3-button input setup, with up, down, and select buttons, are examples of easily recognized interfaces. Familiar button layouts provide intuitive and easily understood user interface.

2.7: Easy Maintenance
Another common customer complaint of any insulin pump is the hassle of maintaining the device. In order to appeal to users, a system with easily maintained components is necessary. For an insulin pump, the system needs a daily change in insulin cartridges and a monthly replacement of batteries.

2.7.1: Easy to Replace Battery
Batteries need to be easily replaceable so the user can keep their device in functioning order without need of help from a professional. Current commercially available insulin pumps use readily available batteries with common battery holders, such as a cover held in with a single screw holding in a AA battery. This provides a maintenance system easily understood by most users.

2.7.2: Easy to Replace Cartridge
The use of an insulin pump requires a daily replacement of insulin. Since the replacement of the cartridge is done on a regular basis, access to the cartridge needs to be easy for the user. Following the models of other insulin pumps, we created a familiar back-end-first screw in top loading system for the user.

3.0: Design Specifications

3.1: Overview of Design Specifications

A list of customer needs was developed through consultation with insulin pump users. [3] Using the list of customer needs, the design team has formulated specifications to meet the customer's needs and desired improvements. The list considers the insulin pump, but many items may apply to a single or multiple subsystem. All of the design specifications are represented below in Table 3.1

Many of specification metrics were decided by reviewing current insulin pump models and by interviewing customers who use an insulin pump to manage their diabetes. The current insulin pump models provide insights on what the Insulin Pump Kit needs to make it comparable with other insulin pumps on the market, as well as many benchmarking metrics to which our design can be compared.

Table 3.1. Specifications/Metrics List

Metric #	Metric	Units	Imp.	Ideal Value	Margin	Performance	Metric Met
1	Safely and Accurately Delivers Medical Fluid	Units	5	± .5	± 1	± 0.87	Margin
2	Accuracy of Force Sensor	Grams	5	± 2	± 5	± 2.54	Margin
3	Reflective Sensor Able to Compute Error	Yes/No	5	Yes	-	Yes	Ideal
4	Accuracy of Motor	Degree	5	± 1	± 5	± 1	Ideal
5	Length of Battery Life	Hours	2	24	>12	6.2	Failed
6	Design creates a Feeling of Control and Confidence	-	4	8<x>10	>6	8	Ideal
7	Easy to Travel with and Non Obtrusive to Everyday Life	mm^3	3	185,000	<230,000	226,302	Margin
8	Price to Purchase Assembly Kit	$	4	$400	<$550	$250	Ideal

3.2: Safely and Accurately Delivers Medical Fluid

The total error of the system should not exceed ± 1 unit of insulin in regards to the prescribed function, as greater error risks harming the patient. The Insulin Pump Kit must be carefully designed and programed to include multiple safety features to prevent a large dose of insulin from being accidently delivered, or not delivered. The insulin pump requires several sensors that will monitor the amount of insulin injected into the patient. The programming needs to monitor the inputs from the sensors and notify the patient if there is any error or action that needs to take place to ensure the patient's health. Our goal is to supply an accurate basal and bolus rate, as programmed by the user. The total error of the system is ± 0.87 units of inulin.

3.2.1: Accuracy of Force Sensor

The force sensor is able to measure the force being applied to the cartridge by the motor. By determining the true value that should be applied to the cartridge when the motor is running, the value measured by the force sensor can be compared to find the error. The acceptable error for the force sensor is ± 2 grams. The error of the force sensor used is ±2.54 grams.

3.2.2: Reflective Sensor Able to Compute Error

The reflective sensor is able to notice differences in transparency. As the sensor is set level with the teeth of the gear, it is able to reflect the changes between the teeth of the rotational gear and the spaces between them. It is measured with a Yes/No parameter, indicating that the gear is rotating when it is supposed to when injecting insulin. The reflective sensor was successful and was able to reflect the changes in teeth.

3.2.3: Accuracy of Motor

The motor selected for the insulin pump kit is a servo motor that has gear inside of it. It is able to move in controlled degree increments. This metric was found by programming the motor to a specific position and then measuring the angle traveled. The acceptable accuracy of the motor is ±1 degree. The accuracy of the motor used for the insulin pump kit is ± 1 degree.

3.3: Battery Life

The battery life of the insulin pump is important to the customer as the frequency of replacing the battery can interfere with the delivery of the insulin from the pump. Surveying users of insulin pumps to find the average time between battery replacements determined the battery life metric. The average battery life of current insulin pumps was found to be about 750 hours, which is approximately one replacement per month, for current insulin pumps on the market. The current battery life of the insulin pump is 6.2 hours with a rechargeable, 9-volt battery. As the system efficiency in energy use and storage are further optimized, this goal should be reached. Other battery options will also be considered.

3.4: Confident Control of Device

Insulin pumps need to inspire confidence in the customer that they are in control of their diabetes. Most insulin pumps have key features, such as an interactive display that is easy to understand and intuitive buttons that give the customer control over their insulin delivery. This metric is found by using a survey on a 1 to 10 scale with 10 marking highest customer satisfaction. The acceptable customer confidence value is an average rating of 8-10, as it marks acceptability in 80% of the user market. The rating of user interface used by our design team is an 8.

3.5: Easy to Travel with and Non-Obtrusive to Every Day Life

The customer would be easily able to wear the entire product case. The edges of the casing will have fillets to prevent having the sharp edges that dig into the customer, so that the customer will be able to wear the insulin pump for a long period of time. The case material itself will be made of a 3D printed case coated in soft material so that the customer won't feel the rough texture against their skin and clothing. The material such as plastic will be the top candidate to satisfy the customer needs. This material would be soft enough to prevent damage to the customer's skin and would be sturdy enough to prevent the case from breaking if dropped, yet be lightweight enough that the customer will be able to carry it all day. For the object to be able to easy to travel with, it must be small in size. The acceptable value for the casing volume is anything less than 230,000 mm^3. The volume of the designed insulin pump is 226,302 mm^3.

3.6: Price to Purchase Assembly Kit

Many customers have mentioned how prohibitive the cost of an insulin pump can be. They often are forced to choose between their health and other necessities. By creating a kit that will be assembled by the customer, a large amount of money can be saved. Additionally, by using products and parts that are readily available on the market, even more money can be saved by the consumer.

3.6.1: Assembly

A self-assembled infusion pump must be designed so that it can be easily assembled by the consumer. It must be fully customizable by the user, as mentioned in Section 4.2.5. This requires a concise instruction manual, that will give a description of the parts and how they are to be assembled. It should include the coding on the provided microcontroller, as well as, the initial casing. The kit should have everything necessary to create a fully functioning infusion pump. The only thing the user will need to supply will be a soldering iron, as well as the medical cartridge and tubing that have been hermetically sealed during manufacture.

3.6.2: Cost

Many of the customers outlined the high price of conventional insulin pumps as one of the major considerations when determining whether to purchase an insulin pump or do multiple daily injections of insulin to maintain their blood sugar at a healthy rate. If the customer has health insurance, that will cover the majority of the cost, a typical insulin pump can still cost them $800.00 or more. Without health insurance, the price of a typical insulin pump ranges between $4,000.00 to $11,500.00, depending on the features, brand and size of the insulin pump. Additionally, if any part of that pump were to fail, the entire insulin pump would need to be replaced. An acceptable cost for the kit design will be around $400.00, making it cost about half as much as a conventional insulin pump that has been purchased with health insurance. The actual cost of the insulin kit is $250.00.

4.0: Conceptual Design

During brainstorming sessions, initial design ideas were presented. These ideas were discussed and looked into further. The most valuable four ideas were compared using a selection matrix. The selection matrix was used to compare the proposed designs with the metrics it would be used to accomplish. From the selection matrix, a final design was selected and was used in the project.

4.1: Conceptual Designs for Rotational to Linear Motion Mechanism

The final four valuable ideas for transferring the rotational motion of the motor to linear motion for the syringe and cartridge are listed and described below. Sketches of design ideas are found in Appendix 10.1.

4.1.1: Rack and Pinion Gear Model

The rack and pinion gear model involves having a small gear, called a pinion, that moves a linear gear, called the rack. The pinion would be attached to the motor and move in a rotational motion. It would then move the rack in a linear motion. The rack would be attached to the syringe pusher.

4.1.2: Crank Gear Model

The crank gear model involves having two rods connected to the motor and the syringe pusher. The first arm would be connected to the motor and bring a rotational motion. The second arm would be connected to the syringe pusher and be limited to only linear motion.

4.1.3: Gear Screw Model

The gear screw model involves having two gears. One would be attached to the motor and would be connected to a screw. The rotational motion of the gear would cause the screw to move linearly and push the syringe into the cartridge.

4.1.4: Threaded Gear Model

The threaded gear is very similar to that of a gear screw model. However, a threaded shaft would be threaded through the threaded gear and linearly displaced as the gear rotates. This would push the syringe with a linear motion during the rotational motion of the motor.

4.2: Rotational to Linear Motion Mechanism Design Selection

A selection matrix, as shown in Table 4.1, was created by the design team. It was created to help the design team narrow down design ideas and compare them to the metrics of the project. The metrics used were the ones that pertained to the design of rotational to linear motion mechanism. Before starting this process, the design team had believed the threaded gear model would be the best option, and used it as a reference point for the other models. This design seemed to be the most straightforward and accurate at the time. Once the selection matrix process was complete, the threaded gear model did have the highest score. However, one of the constraints for this project as size. All of the design selections, except for the rack and pinion, did not receive a positive scoring on the size metric. Because of this constraint, and that the rack and pinion only scored lower than threaded gear by one point, the rack and pinion was selected for the rotational to linear motion mechanism.

Table 4.1. Selection Matrix for Rotational to Linear Motion Mechanism

Selection Criteria	A Rack and Pinion Gear Model	B Crank Gear Model	C Gear Screw Model	D Threaded Gear Model
Small	+	-	-	-
Durable	+	+	0	+
Reliable/Accurate	-	-	+	+
Precision	0	-	+	+
Easily Manufactured	+	+	-	+
Continuous Movement	-	+	+	-
Maintain Structure	+	+	+	+
Sum of +'s	4	4	4	5
Sum of 0's	1	0	1	0
Sum of –'s	2	3	2	2
Net Score	2	1	2	3
Rank	3	1	2	4
Continue?	Yes	No	No	Yes

4.3: Initial Concepts to Final Design

The initial design of the prototype included a DC motor [4] attached to the small gear to drive the larger gear that would then drive a threaded rod into the plunger to deliver insulin to the user. However, one downside of this design is how the rod is required to be in the same orientation, as the shaft motor. This requirement causes dimensional issues, as it would force the system to be elongated in one direction, which negatively impacts the discrete and portable feature of the system. The design is shown and demonstrated below in Figure 10.1 in the Appendix 10.1. The threaded gear model was then replaced by the rack and pinion model as shown in Figure 10.2 in Appendix 10.1. This design prevents dimensional issues. The rack will be connected to the plunger for continued stabilization during the pushing and pulling motions. Additionally, a servo motor [5] was chosen to replace the DC motor that was originally designed. The servo motor is being used to increase the accuracy of the system. Since the servo motor has a gear system within it, it can also be used as a safety check and confirm the accuracy of the fluid being injected into insulin users. The initial design can be seen on Figure 10.6 in Appendix 10.3. The updated, final design is seen on Figure 10.7 in Appendix 10.3.

5.0: Final Design

The final design of the Affordable Insulin pump integrates the three primary design requirements that were determined from the customer needs. This was done by incorporating the accuracy of the system, the component selection, and the assembly itself. Figures 5.1 and 5.2 show the individual components used, as well as the assembly of them. A CAD model as well as photo of the final product are shown.

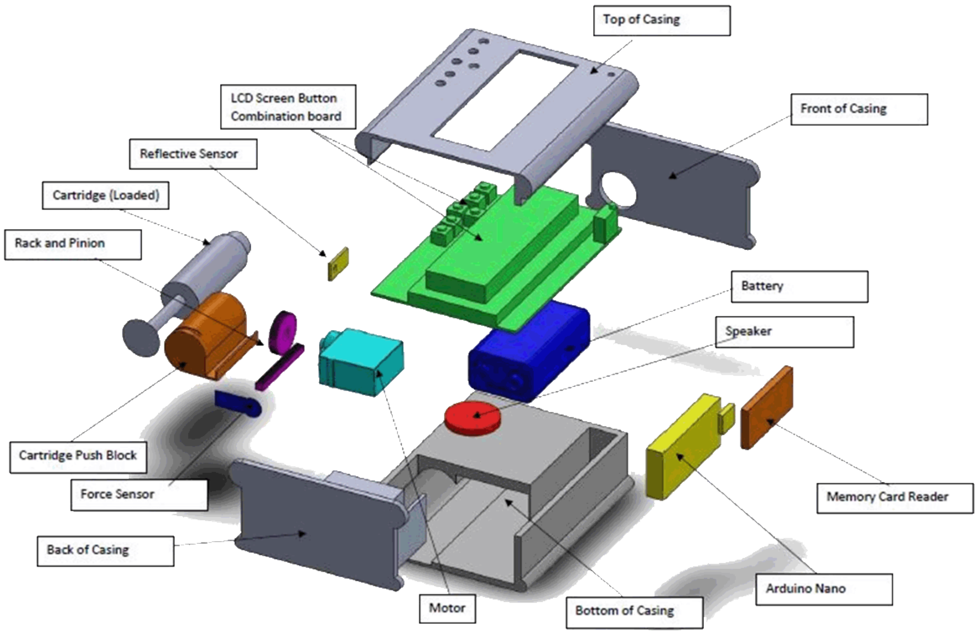

Figure 5.1. Exploded Insulin Pump

Figure 5.2. Assembled Device

This design achieves the following results:

- Reliably, accurately, and consistently deliver the medical fluid
- Durable
- Affordable

The overall design was created to achieve the design requirements and to do so in the safest and most effect means possible, while still being affordable. The conceptual design can be summarized as a device that accomplishes the following ideas:

- Accurately and safely deliver medical fluid
- Easy to use/Creates a feeling of control
- Customizable/Easy to replace parts

The accurate and safe delivery of medical fluid is accomplished through the use of a servo motor with a rack and pinion set up. As shown in Figure 5.3, the servo motor has the pinion gear attached to the end and will move a certain number of degrees when prompted by the user (for the bolus rate) or at set time intervals (for the basal rate). This moves the rack, which is attached to the syringe pusher, that then moves the plunger into the cartridge, moving the medical fluid into the tube which delivers it directly into the user.

The design team added a memory card shield to the Arduino Nano to record the basal and bolus rates that were delivered. It was also used to record any errors that occurred, to help debug the system and improve the safety of the device. The customer mentioned that they would like this record during a follow up, as they would need to review the delivery of the medical fluid with their physician to improve their treatment.

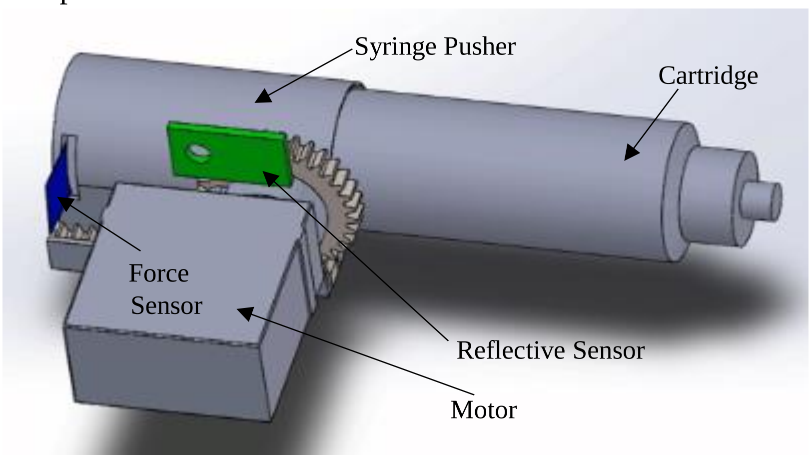

Figure 5.3. Insulin Delivery System

The device is easy to use by the implementation of an easy to read LCD screen, an interactive menu and intuitive buttons. The user can read the prompts from the LCD screen, update the amount of insulin they need with the menu, and input commands using the buttons. The user interface menu follows the flow chart shown in Figure 5.4.

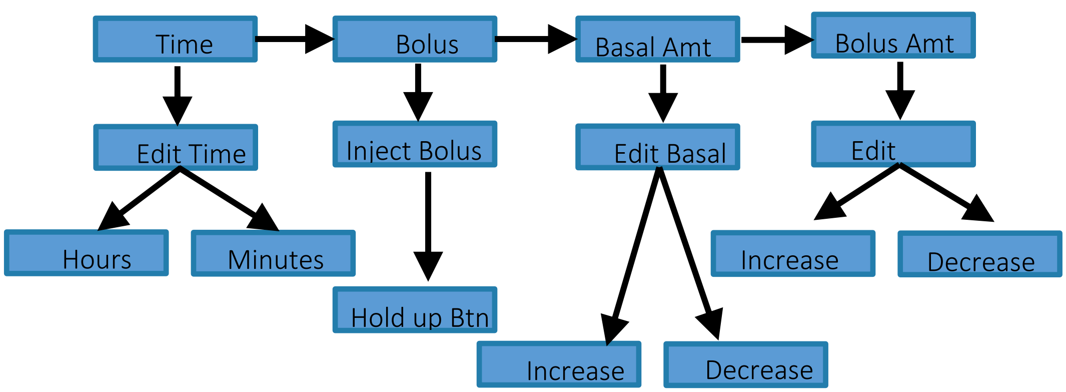

Figure 5.4. User Interface Flow Chart

The device is fully customizable as the casing can be 3D printed in different colors and the individual components can be replaced when they break. This is important as other insulin pumps on the market need to be fully replaced if an single component fails, while with our kit design, the user can replace the part that is broken.

Table 5.1 shows the bill of materials used to create the device, along with the manufacturer specific part number if applicable.

Table 5.1. Affordable Insulin Pump Bill of Materials

Part Name	# Required	Part #/Dwg #	Vender
LCD Screen	1ea	B006OVYI1G	Amazon
Servo Motor	1ea	B01608II3Q	Amazon
Arduino Nano	1ea	LYSB019SXND4O	Amazon
Memory Card Reader	1ea	B06XRD9LH5	Amazon
Battery	3ea	9SIA27C25S7466	Newegg
Battery Charger	1ea	9SIABFB52F7234	Newegg
Force Sensor	1ea	1696	Amazon
Reflective Sensor	1ea	2458	Pololu
Casing	1ea	AIP-001	NA
Rack and Pinion Gear	1ea	AIP-002	NA

6.0: Performance Verification

6.1: Delivery of Insulin

The critical feature of the insulin pump is to accurately and reliably deliver insulin to the customer, to protect their health and safety. Therefore, two tests were done to determine the accuracy of the insulin delivery.

6.1.1: Accuracy of the Motor

For testing the motor, the microcontroller was programmed to move the servo motor a certain number of degrees and was verified by using protractor as shown in Figure 6.1. The test consisted of the motor being told to move a certain number of degrees and seeing how many degrees off from the desired degree it was. The error was then calculated and is shown in Table 6.1.

The results show that the motor is accurate within 0.61 degrees of the desired movement. This is within the margin of 2 degrees for the motor specification, so our conclusion is that the motor is accurate.

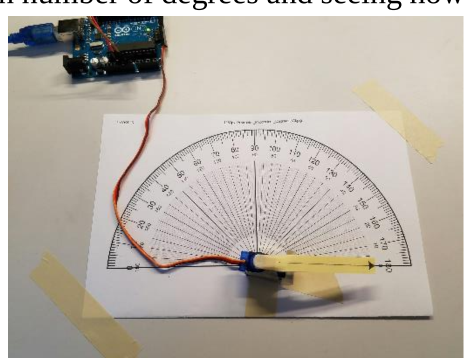

Figure 6.1. Motor Accuracy Test

Table 6.1. Motor Accuracy Test

Theoretical Angle	Test 1		Test 2		Test 3		Average % Error	Deviation	Standard Deviation
	Angle	% Error	Angle	% Error	Angle	% Error			
10	12	20%	11	10%	10	0%	10%	1.00	0.82
20	21	5%	20	0%	21	5%	3%	0.67	0.47
30	30	0%	30	0%	30	0%	0%	0.00	0.00
40	40	0%	40	0%	41	3%	1%	0.33	0.47
50	51	2%	49	2%	50	0%	1%	0.00	0.82
60	60	0%	58	3%	59	2%	2%	1.00	0.82
70	71	1%	70	0%	70	0%	0%	0.33	0.47
80	79	1%	81	1%	80	0%	1%	0.00	0.82
90	89	1%	89	1%	91	1%	1%	0.33	0.94
100	99	1%	101	1%	99	1%	1%	0.33	0.94
110	110	0%	111	1%	111	1%	1%	0.67	0.47
120	121	1%	120	0%	119	1%	1%	0.00	0.82
130	131	1%	130	0%	131	1%	1%	0.67	0.47
140	140	0%	141	1%	140	0%	0%	0.33	0.47
150	150	0%	150	0%	149	1%	0%	0.33	0.47
160	159	1%	159	1%	160	0%	0%	0.67	0.47
170	168	1%	170	0%	169	1%	1%	1.00	0.82
180	177	2%	178	1%	178	1%	1%	2.33	0.47
Average							**1.4%**	**0.56**	**0.61**

6.1.2 Change in Volume

Testing the change in volume was done by placing a measured volume in the cartridge and then measuring the displaced fluid as the motor moved the linear gear into the plunger. The displacement was measured with a small syringe which would normally be used for manual injection of inulin. The test setup is in Figure 6.2.

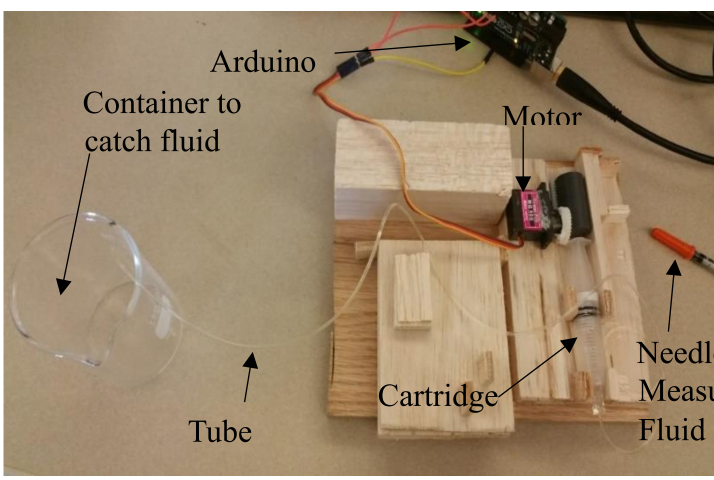

Figure 6.2. Change of Volume Test

In order to relate the number of degrees the motor rotates to the amount of insulin released, the distance traveled needed to be numerically related to the rotational and linear gear. For every 6.75 degrees the rotational gear rotated, the linear gear moved 1 millimeter, which equals to half of a milliliter of insulin. For our cartridge, there are 100 units of insulin in 1 milliliter, and 1 milliliter is equal to 9 millimeters on the cartridge used for testing. Therefore,

$$\frac{6.75°}{1\ mm}\left|\frac{9\ mm}{1\ mL}\right|\frac{1\ mL}{100\ units} = 0.675°/unit$$

Where a unit is the unit of insulin. As the results show, the change in volume is within the specification margin, but not the ideal value.

Table 6.2. Change of Volume Test

Desired Units	Angle Input	Angle Output	Theoretical	Test 1	Test 2	Test 3	Average	Error	% error
1	1	1	1.67	1.8	2.1	1.2	1.7	0.7	70
2	1	1	1.67	1.8	2.1	1.2	1.7	0.3	15
3	2	2	3.33	3.1	3.2	3.2	3.17	0.17	5.56
4	2	2	3.33	3.1	3.2	3.2	3.17	0.83	20.83
5	3	3	5	5.2	4.9	5.4	5.17	0.17	3.33
6	4	4	6.67	6.8	6.5	6	6.43	0.43	7.22
7	4	4	6.67	6.8	6.5	6	6.43	0.57	8.1
8	5	5	8.33	7.8	8.4	8.2	8.13	0.13	1.67
9	5	5	8.33	7.8	8.4	8.2	8.13	0.87	9.63
10	6	6	10	10	9.8	10	9.93	0.07	0.67

6.2 Safety Features
The insulin pump has several sensors to help prevent an over or under dosage of insulin. These sensors are also critical to helping determine that the device was set up correctly by the user.

6.2.1 Force Sensor
The force sensor sits between syringe pusher and the plunger of the cartridge, as shown in Figure 6.2. It records the force that is being used to move the syringe and will sent an alert if the force is too high, such as during a blockage in the tube that delivers insulin to the customer. The average force measured from the tests was 2.54 grams, which is with the specification margin for the force sensor.

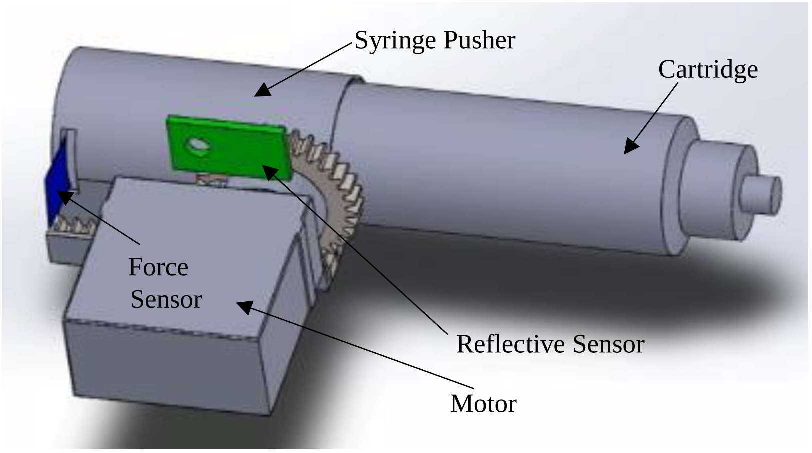

Figure 6.3. Location of Sensors

6.2.2 Reflective Sensor
The reflective sensor, shown in Figure 6.3, was originally intended to record how far the cartridge moved, but the resolution for the reflective sensor was too low to be used for this function. Therefore, the reflective sensor will be used as another safety feature and will alert the customer if the motor is moving too far when delivering insulin. This is a yes/no metric on the specifications and meets the specification for the reflective sensor.

6.3 Battery Life
Battery life was determined to find how long the battery would last with all the components attached. The Arduino requires at least 5 volts to operate, while the other components require about 2400 milliamp-hours to last 24 hours and meet the specifications. Thus, a 9 Volt battery was chosen to meet the voltage requirement. However, the 9 Volt battery was not able to last for more than 9 hours, which did not meet the specification for the battery life. The design team went with several rechargeable 9 volt batteries instead, each that lasted 6 hours. This still did not meet the design specification, but the customer indicated that specification was a low priority to the safety of the device. The next iteration would include a different microcontroller and LCD screen which would be smaller and allow for more space within the casing to hold a battery that had the right amount of voltage and current for the device, to meet the battery life specification.

7.0: Project Planning

7.1: Schedule

In order to successfully complete this project, our team created and followed a schedule. Our team utilized the methods of a Design Structure matrix and a Milestone Calendar to keep our team organized and on track. The Milestone Calendar allowed us to see proposed completion dates, actual completion dates as well as our progress. The Design Structure matrix shown on Figure 10.5 in Appendix 10.2 allowed us to see properties and dependence of tasks.

7.1.1: Fall Semester

The table below shows important milestones and key dates for the fall semester. During the fall semester, the objective was to gain an understanding of the needs of a customer, being designing, and complete a Critical Function Prototype (CFP). These dates and milestones were needed and adjusted to ensure the completion of the CFP.

Table 7.1. Fall 2016 Milestone Schedule

Milestone	Date	Rev. Date	Status
Determine and Order Microcontroller, LCD Screen and Speaker to be used	9/29/2016	-	Complete
Design CAD model of keypad, Determine Sensors to be used and if Microchip is necessary.	10/1/2016	-	Complete
Complete Coding for LCD Screen and Speaker, Start CAD Model for Motor/Pump Configuration.	10/7/2016	-	Complete
FEA analysis of Motor/Pump assembly	10/21/2016	-	Complete
Order and Test Sensors, and Coding for Keypad	11/1/2016	-	Complete
CAD Design for Insulin Pump Casing, and Start Coding the Motor/Pump Assembly	11/7/2016	-	Complete
CFP assembly	11/14/2016	-	Complete
Results evaluated for improvements needed on final design	11/18/2016	-	Complete
CFP results assembled for CFP presentations	11/23/2016	-	Complete
CFP presentation	12/1/2016	-	Complete

7.1.2: Spring Semester

The table below shows important milestones and key dates for the Spring semester. Spring semester was used to redesign, problem solve, and evaluate. Verification and tests were done to validate the functions of the insulin pump. These dates and milestones were needed and adjusted to ensure the completion of our project for Design Day.

Table 7.2. Spring 2017 Milestone Schedule

Milestone	Date	Rev. Date	Status
Code the keypad with screen for pump	1/14/2017	-	Complete
Update Solidworks Casing	1/14/2017		Complete
Design Review 1	1/18/2017	-	Complete
Power Management	1/23/2017	1/25/2017	Complete
Incorporate speaker into code	1/23/2017	1/15/2017	Complete
Testing Sensors	1/23/2017	2/12/2017	Complete
Configure Memory Card	1/28/2017	2/10/2017	Complete
Code Menu of LCD Screen	2/11/2017	2/5/2017	Complete
Design Review 2	2/16/2017	-	Complete
Control Motor using keypad-Basil and Bolus	3/5/2017	2/27/2017	Complete
Apply batteries instead of computer	3/5/2017	3/5/2017	Complete
Incorporate Sensors into Design	3/19/2017	3/26/2017	Complete
Design Review 3	3/22/2017	-	Complete
Update Code of Speaker	3/25/2017		Complete
Update Code of LCD Screen	3/25/2017	-	Complete
Test pump	3/25/2017	-	Complete
Final Update Solidworks Casing	3/31/2017	-	Complete
Test Pump w/ cartridge	4/7/2017	4/9/2017	Complete
3D print the casing	4/7/2017	4/13/2017	Complete
Assemble System Together	4/15/2017	4/16/2017	Complete
Design Day	4/20/2017		Complete

8.0: Budget

The project development budget came from the contribution of each team member's class fees. The class fees provided $50 per person, per semester, totally $400 between Fall and Spring semester. As a key objective of the project was to make the insulin pump affordable, the budget of $400 was the target for all iterations of the project.

The following tables outline the team budget and what was spent on the project.

Table 8.1. Team Budget Sources

Income	Amount
Mechanical Department	$400
Total	$400

Table 8.2. Project Expenses

Expenses	Development	Production
Testing	$47	-
Assembly	$25	-
Pump	$160	$250.00
Iterations	$165	-
Total	$397	250.00

Table 8.3. Total Budget Remaining

Budget	Totals
Income	400
Expense	397
Budget Remaining	3

8.1 Sustainability Planning

The team did not focus on sustainability due to the nature of the product. Medical devices should not be reused unless it is by the same individual. However, the fact that the parts can be replaced instead of need the entire system to be replaced if a single component fails mean that the material usage and waste will not be very high. Future plans include making a custom LCD screen and microcontroller that will reduce the size and environmental impact of the insulin pump.

9.0: Conclusion

Overall, the design of the Affordable Insulin Pump was a success. The insulin pump designed was able to be constructed for $250.00. This is well below the average of existing insulin pumps. The accuracy of the fluid delivery was verified through several calculations and experimentations. They accuracy of the motor was also verified to confirm the accuracy of the fluid delivered. The safety of the insulin pump was verified by applying the force and reflective sensors, and testing them accordingly. The length of battery life was lower than anticipated, however by optimizing individual components, the life can be elongated. The user interface system was successful in creating a feeling of control and confidence for the user.

9.1 Future tasks

Future tasks for the Affordable Insulin Pump include reducing the size, increasing the battery life, and developing the kit instructions and assembly procedures into a condensed but easy to understand form. All three are necessary to meet all of the design requirements that the customer desired. If this project was continued by future design teams, they would also need to review the requirements of the FDA.

Both the reduction in size and increasing the battery life can be achieved if a new LCD screen shield is used that is not as large and a custom microcontroller is used. The length and width of the insulin pump casing is currently constrained by the size of the LCD/Button shield that is being used. A smaller LCD screen without attached buttons can reduce the size and we can attach the buttons separately to reduce the size. Additionally, a custom microcontroller would get rid of the excess electronics that are on the Arduino Nano would not take as much battery life.

The Affordable Insulin Pump Kit would need to have a set of clear and concise instruction manual written to help the customer build the insulin pump and test that all of the components are working together properly. This increases the safety of the device and reduces the cost of the pump to about $160 for all the components. Adding in a margin for profit and overhead costs, the total cost of the Affordable Insulin Pump kit would come to around $250, which is a bit more than a quarter of the price of a current on the market insulin pump with health insurance.

10.0: Appendix
10.1 Design Concepts

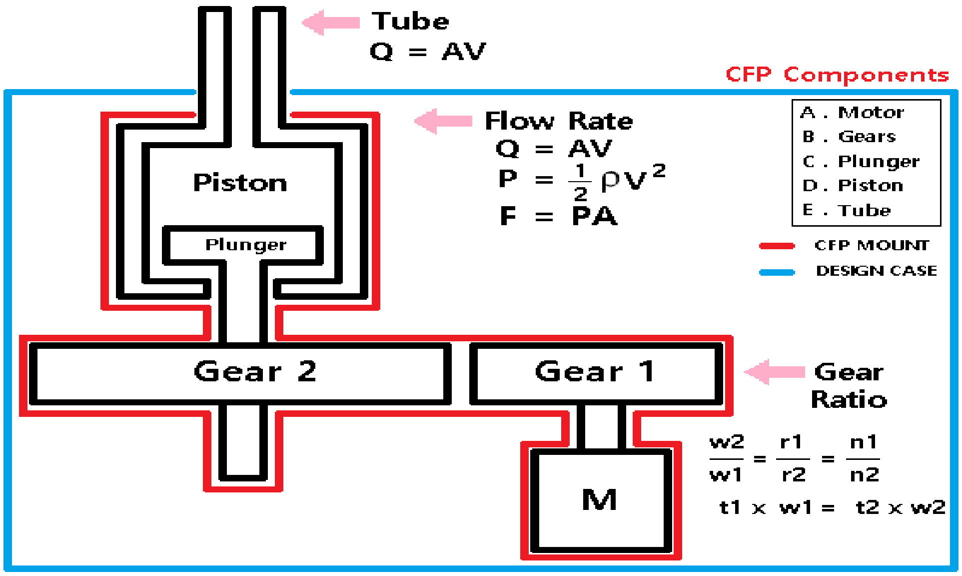

Figure 10.1. Threaded Gear Model

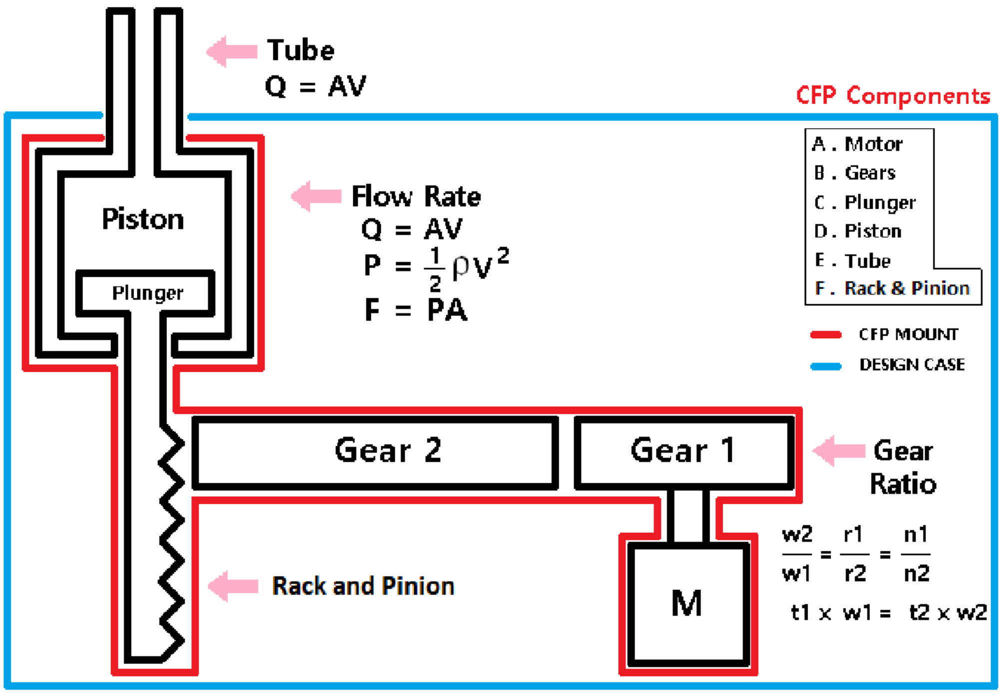

Figure 10.2. Rack and Pinion Model

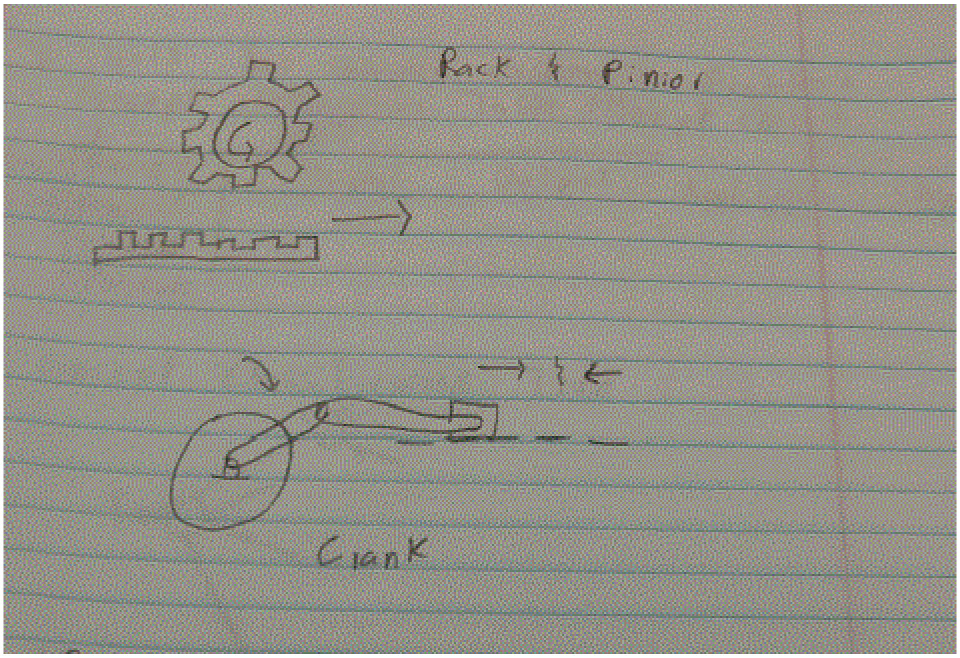

Figure 10.3. Conceptual Designs

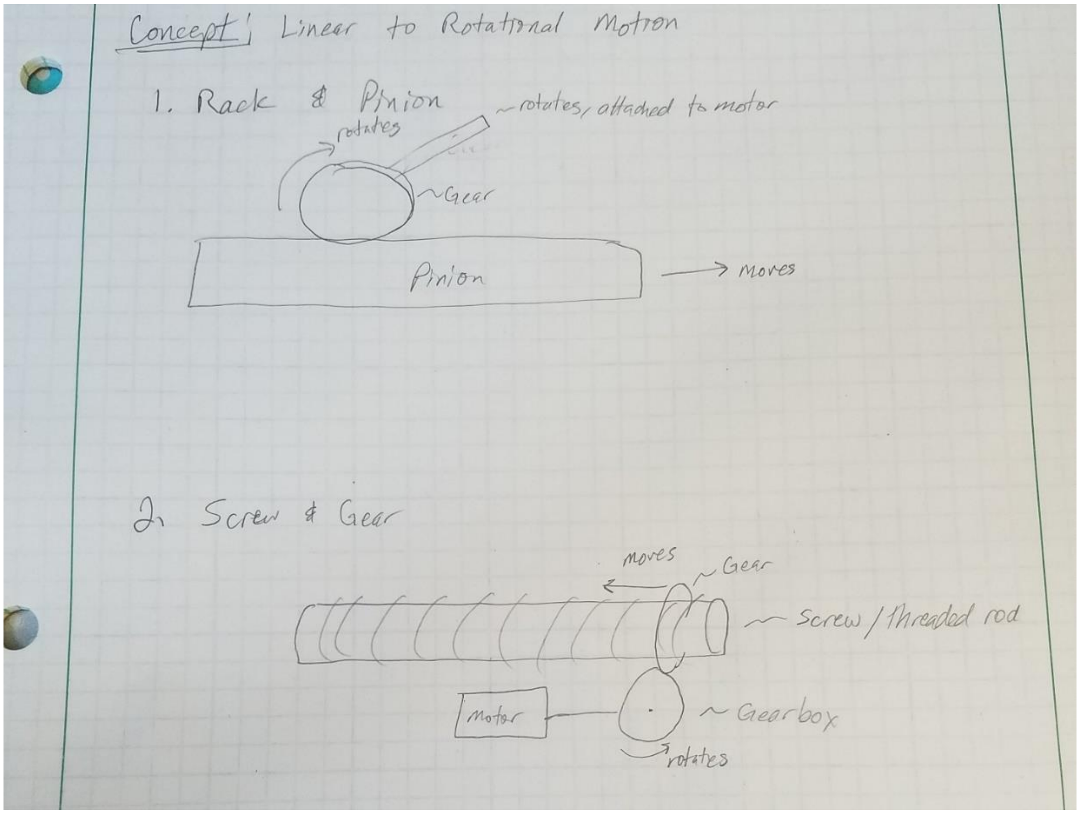

Figure 10.4 Conceptual **Designs**

10.2 Design Matrix

Task		A	B	C	D	E	F	G	H	I	J	K	L	M	N
a. Research Type I Diabetes	A	A													
b. Pump – Research and Configure	B	x	B												
c. Microcontroller – Research and Obtain	C	x	x	C											
d. Coding 1 – Learn and code the motor and pump	D	x	x	x	D										
e. LED Screen – Set up and test	E				x	E									
f. Coding 2 – Code for the Screen	F				x	x	F								
g. Speaker – Set up and test	G							G							
h. Coding 3 – Code for speaker	H				x			x	H						
i. Design Keypad – 5 buttons total, power switch	I				x	x			x	I					
j. Power Management	J	x	x			x		x	x		J				
k. Configure memory card	K		x								x	K			
l. Microchip/electronics configuration	L	x	x			x		x		x	x		L		
m. Sensors – Set up and test	M	x	x											M	
n. Test Pump	N	x				x									N
o. Reset System	O		x												
p. Test pump w/ cartridge	P	x				x									
q. Solidworks design	Q														
r. 3D Print Case	R														
s. Assembling Systems	S	x	x			x		x		x	x			x	

Figure 10.3. Design Matrix [13]

10.3 CAD Designs

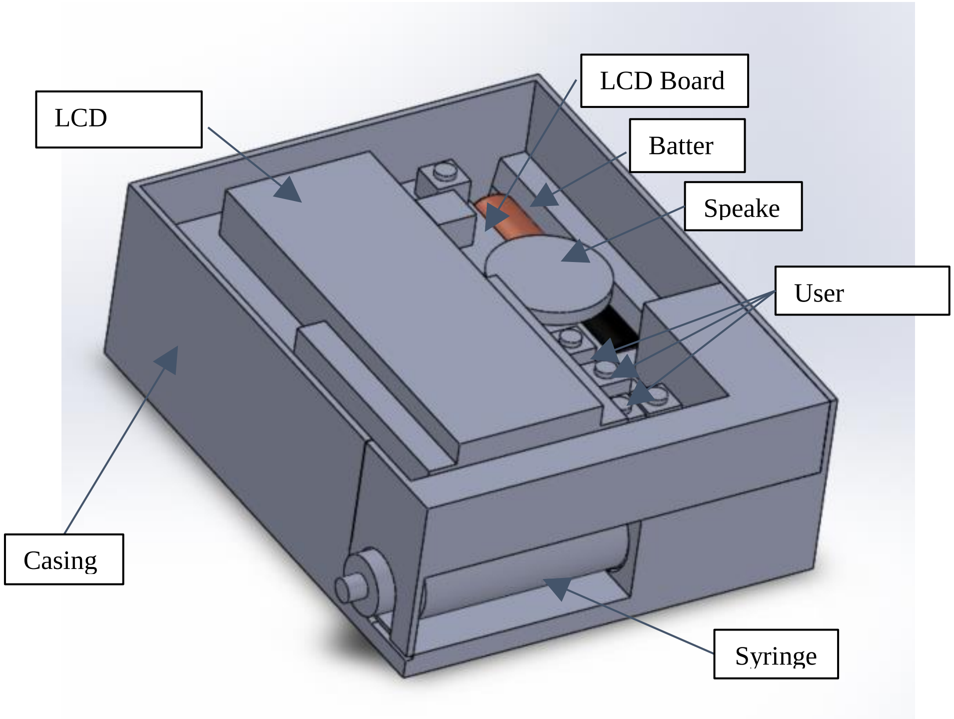

Figure 10.4. Assembled Infusion Pump Iteration 1 [14]

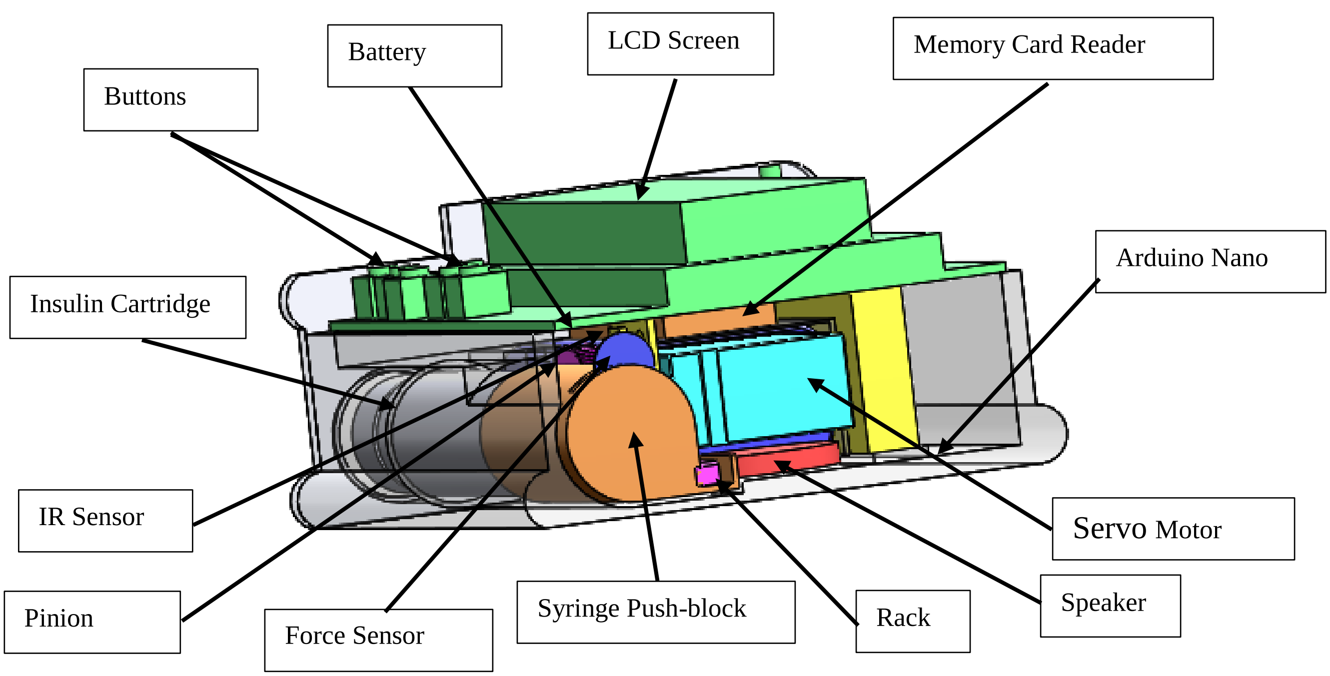

Figure 10.5. Assembled Infusion Pump Final Iteration [14]

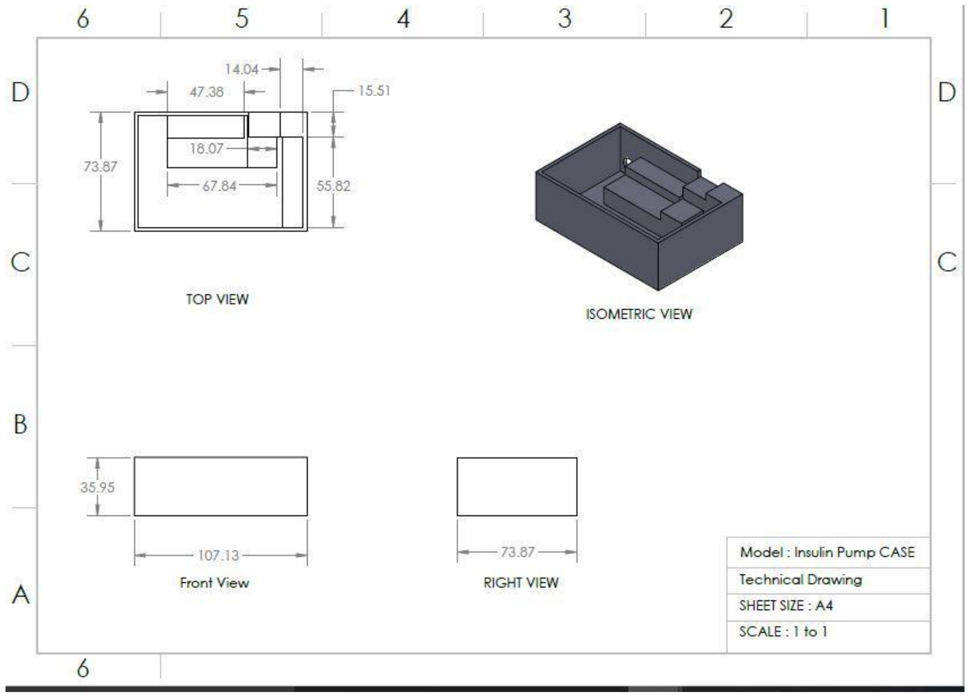

Figure 10.5. Casing Drawing

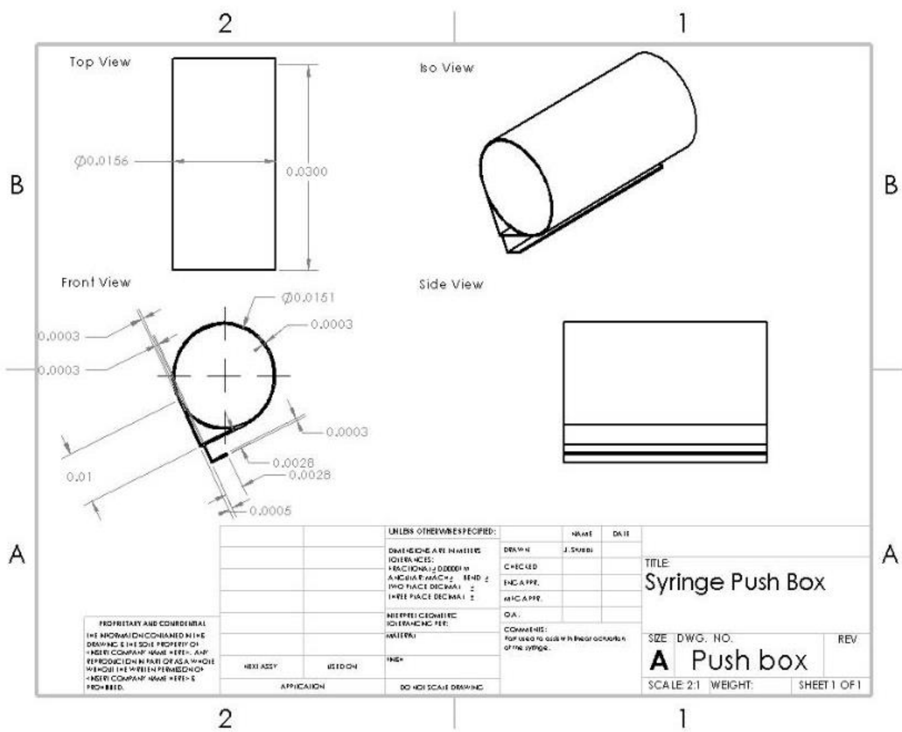

Figure 10.8. Syringe Push Box Drawing

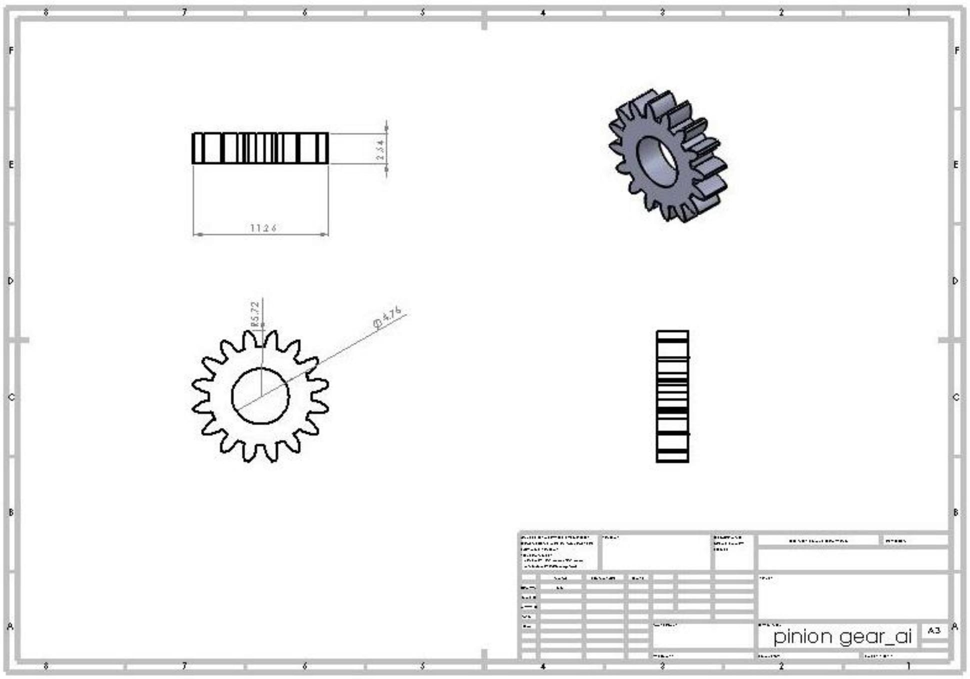

Figure 10.9. Pinion Gear Drawing

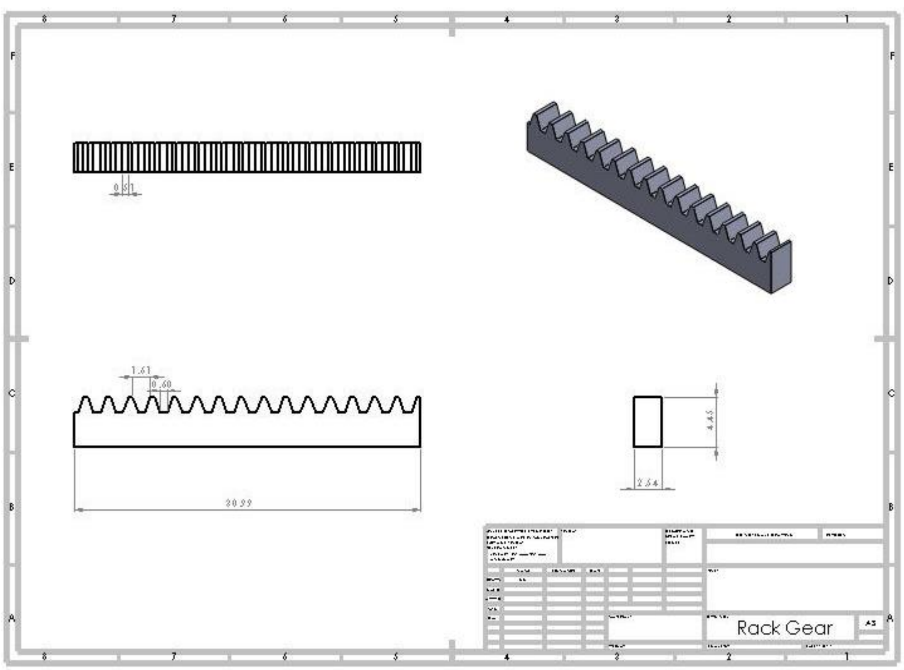

Figure 10.10. Linear Rack Gear Drawing

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