Affordable Insulin Pump

ME EN 4000 – Final Report

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1.0: Executive Summary

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. One method of doing this is with the usage of an insulin pump. When looking at insulin pumps, one of the first things noticed is how expensive they are. This high cost makes it difficult for an individual or family to purchase an insulin pump. This cost hits the individual hard and usually means having to choose between their health or to sacrifice something else in their lives. The majority of the time, the individual doesn't have a choice but to purchase one, if they want to be able to continue the life in a somewhat normal fashion.

Our goal is to design and manufacture an infusion pump that has the same functions as an existing insulin pump, but is also more affordable. This goal can be 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 pump. This removes manufacturing costs, allows customizability, and gives the option for simple part replacement.

1.2: Key Project Focus Areas

The primary focus of this project is to create a usable and reliable insulin pump that is safe and easily accessible to the average individual. The primary function of the insulin pump can be categorized into three basic functions:

- Motor propulsion system
- User interface
- Sensor systems

The motor propulsion system will translate the motor's rotational motion into linear motion. This forces insulin from the cartridge to the user. As a safety factor, the rotational velocity will be reduced using a gear set. This allows any error regarding the number of turns a motor takes to be negligible when translated to linear motion.

The user interface will allow the user to control the insulin injection rates and spikes. A LCD screen and button configuration is provided for the user to track the status of their system for maintenance. Speaker and display notifications will inform the users of any errors or actions that need to be performed, such as replacing the battery or cartridge.

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. This will provide both safety within the system and comfort for the user, as well as preventing any large changes in insulin dosage.

1.3: Challenges

The largest challenge regarding the infusion pump project is manufacturing. The pump requires small dimensions of individual parts, as well as the pump itself. This criterion can result in part selection issues, and small parts manufacturing problems. Similarly, the entire system needs to be durable, which requires a small margin of error regarding part placement within the system. As the pump becomes an accessory, the casing and other externally visible components need to be aesthetically pleasing. All of these restraints combined into a very small infusion system create a very difficult manufacturing and design process.

Other challenges originate from the medical nature of the device. The purpose of the infusion pump is to use a small motor to displace fluid out of a syringe into the user. This directly illuminates the issue of translating rotational motor motion into linear motion of the syringe, while requiring precision of injecting the medical fluid.

In order to appeal to the general user, the infusion pump must be easy to use with a simple user input system. This requires an LCD screen user interface following the norm of other pumps, as well as having an intuitive button system. Generating a LCD integrated user interface with multiple options, user utility computations, and configuration controls requires intricate coding within the infusion electrical system. This is compounded by the necessary safety, sensor checks, constant battery level readings, and accurate motor control system.

1.4: Conclusion

The goal of the design team is to provide an affordable insulin pump that is safe for the user. To meet this goal, the pump must perform the functions of a current insulin pump, while also being available to type I diabetics at a reduced cost with simple part replacement. The success of this device will be reliant on the motor propulsion system, the user interface, and the sensor system.

2.0: Context

2.1: Need Statement

Type I diabetes is a growing medical issue, not only in the United States, but throughout the world. People are often diagnosed with diabetes in childhood or early adulthood. It is a chronic disease where the immune system attacks the insulin-producing beta cells in the pancreas. There is no known cure or prevention system to stop the progression of Type I diabetes and is usually passed down by parents. [2]

The lack of insulin caused by Type I diabetes causes symptoms such as: frequent urination, increased thirst, increased hunger, weight loss, blurry vision, feeling tired, and poor healing or wound recover. This not only affects their health, but their social and mental welfare. People with diabetes are constantly having their daily routine interrupted with the need for insulin injections. Failure to do so could lead to impaired of mental function, seizures, coma, or even death. This leads to not being able to participate in activities or being excluded from social events. If diagnosed as a kid, these problems could have a greater effect as an adult and have a lasting impact.

Current treatment for Type I diabetes is done by injecting insulin into the body via the lymphatic system. When first diagnosed, patients are prescribed dosages of insulin that are taken periodically throughout the day in the form of a shot. While many insulin users continue with this form of treatment, others are able to use the more convenient method of having insulin injected continuously with a pump. An automated insulin pump provides two types of injection flow rates: a basal and a bolus injection flow. A basal injection is known as a frequent small injection of insulin that is provided throughout the day to maintain blood sugar levels at a constant rate, while a bolus is a larger dose scheduled by the user to be injected around meal times. The pump allows the user to move through their day with less stress regarding the injection of the insulin.

2.2: Problem Statement

While there are many advantages to the use of the insulin pump, many patients can't afford to buy one due to the high cost. Other complaints from consumer surveys include the lack of customization, the ability to repair individual parts, and USB accessibility of device usage information. Our goal as a design team is to find solutions for these problems, and create a product that provides a safe, secure, low-cost, customizable, and reliable treatment for Type I diabetes. Bearing in mind the needs of our customers, our team has decided to focus on the low-cost, safety, and performance of the insulin pump, in regards to the reliability of the insulin flow. While this is our main goal, our team will also incorporate other wants/needs of consumers in the product design.

In order to meet our goals, our group has designed a self-assembled infusion pump kit. This kit will provide the user with all the parts and instructions needed to assemble an insulin pump. The pump will be safe, easy to assemble, customizable, and have a USB plug-in. Individual parts from the kit will also be available for purchase, rather than having only a full set available. Having the infusion pump kit be user-assembled greatly reduces the price placed on the consumer.

2.3: Design Team

2.3.1: 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 skill sets 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.

2.3.2: Team Advisor

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 both CFP's and the final device.

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3.0: Design Requirements

3.1: Customer Overview

People with type I diabetes require an insulin pumps that is durable, accurate, autonomous, user-friendly, safe, and reliable. [3] The user-friendly setup should initiate an autonomous and accurate flow throughout the rest of the day. The reliability, safety, and accuracy will provide peace of mind for the user as the autonomous system won't require their input for most of the day. The durability will keep all other requirements safe for the lifetime of the pump. Autonomy, durability, and the user-friendly use of the insulin pump should be easily set up. The safety, reliability and accuracy are the parts most worried about as continued use and reproducibility between devices is hardest to test for. For user affordability, the pump is professionally manufactured and user assembled. This also provides easy part replacement, and full customizability for the user.

Table 1. Customer Needs Hierarchy

Primary Need	Secondary Need
Durable	
	Water Resistant
	Shock Resistant
Reliable	
	Accurate/Consistent Basil/Bolus Rate
Easy Maintenance	
	Easy to Replace Battery
	Easy to Replace Cartridge
Interactive Display	
	Easy to View
	Intuitive Buttons
Easy to Wear	
	Portable
	Discreet
Affordable	
	Kit Setup
	Easily Replaceable Parts

Table 2. Ranking of Customer Needs in Order of Importance

Primary Need	**Secondary Need**	**Scores**
Reliable	Accurate/consistent Basil/Bolus rate	5
Durable	Water resistant	**4**
	Shock resistance	
Affordable	Kit setup	**4**
	Easily replaceable parts	
Easy to wear	Portable	**3**
	Discreet	
Interactive display	Easy to view	**2**
	Intuitive buttons	
Easy Maintenance	Easy to replace battery	**1**
	Easy to replace cartridge	

3.2: 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 breakage.

3.2.1: Water Resistant

To prevent damage when the device is 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.

3.2.2: Shock Resistance

Precise manufacturing methods will be used to create the casing that holds the components of the insulin pump. This allows the movements of the components to be limited to their function. By doing this, it decreases the worry of elements being damaged by a fall or drop.

3.3: Reliable

The worry 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, and safety. The constant, and reliable administration of the insulin allows the user peace of mind.

3.3.1: Accurate/Consistent Basal/Bolus Rate

Infusion pump users solely rely on a constant supply so small doses (basal), and meal time focused larger doses (bolus). Each user requires a different amount based on the degree of their type I diabetes. User rely on the accuracy of the basal and bolus rates as it effects their health and stability.

3.4: Easy Maintenance

One very common customer complaint of any product, 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.

3.4.1: Easy to Replace Battery

Batteries need to be easily replaceable so the lay man can keep their device in functioning order without need of help from a professional. For our device, we will be using AAA batteries. A single screw holding system will be used in order to accomplish this, while not affect the water resistance of the device.

3.4.2: 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 of 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.

3.5: 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.

3.5.1: Easy to View

Incorporated into the system is a standard 2-line LCD display. The display we be easy to view, and easily navigated, to examine each feature of the device. Clear and concise messages will be displayed on the LCD screen for each insulin pump function.

3.5.2: Intuitive Buttons

The button system consists of a 5-button input setup. There are 4 directional buttons and a select button. This button layout provides an intuitive and easily understood user interface.

3.6: 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.

3.6.1: 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. Creating a portable device generates the most comfort for the user.

3.6.2: 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 person's ensemble.

3.7: Affordable

The problem many people, with type I diabetes, face when considering using an insulin pump is the cost of a new insulin pump. Often case 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.

3.7.1: Kit Setup

One large cost of manufacturing products is the part assembly. In order to avoid as much cost as possible in production the affordable insulin pump, 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.

3.7.2: Easily Replaceable Parts

In making a user assembled product you also create the direct potential for user part replacement and maintenance. Often times with medical devices, when one component of the device is damaged and breaks, the user is forced to replace the entire device. By manufacturing individual parts, the cost of replacement is minimized by allowing the user to only replace the damaged component.

4.0: Design Specifications

The Insulin Pump needs to be safe for the customer to use. The insulin pump will need to deliver a constant tiny dose of insulin to the customer throughout the day, which is called the Basal rate. These constant tiny dosage of insulin helps the diabetic patient's blood sugar stay constant throughout the day. When the patient eats, they will input the number of carbs they are to eat into the insulin pump. The insulin pump will then calculate the amount of insulin the patient needs and deliver a large dose of insulin, called the Bolus rate. The accuracy of the insulin pump to deliver the insulin correctly is vital to the health of the patient. If the insulin pump were to deliver too much or too little insulin, the patient would be at risk of a great many health issues, which include, but are not limited to, seizures, coma, and/or death.

4.1: Overview of Design Specifications

After through consultation with users of insulin pumps [3], a list of customer needs was developed and included below in Table 3. The list considers the insulin pump as a whole, but many items may apply to a single or multiple subsystems. The customer needs provide insight to the requirements expected by insulin using diabetics that depend on insulin pumps to survive. Using the list of customer needs, the design team has formulated specifications to meet the customers' needs and desired improvements.

Table 3. Customer Needs List

Customer Needs
1. Durable
2. Accurate Basal Rate
3. Accurate Bolus Rate
4. Long Battery Life
5. Interactive Display
6. Easy to Understand
7. Intuitive Buttons
8. Portable
9. Discreet
10. Affordable
11. Easily Replaceable Parts

All of the design specifications are represented below in Table 4. Each of the metrics listed represents a specific customer need, and column 2 of the table references the need is influenced by that metric. The level of importance of a metric for the customer can be found in column 5. Safety and accuracy are of the highest priority to both the customer and the design team. The ideal metric value is represented in column 6, with the acceptable margin of error to be found in column 7. Many of specification metrics were decided by reviewing current insulin pump models and by interviewing customers that were currently using an insulin pump to manage their diabetes on what improvements they desired for their insulin pump. The current insulin pump models provided insights on what the Insulin Pump Kit would need to make it comparable with other insulin pumps on the market, as well as providing many benchmarking metrics to which our design can be compared to.

Table 4. Specifications/Metrics List with Customer Needs Comparison

Metric #	Need #	Metric	Units	Imp.	Ideal Value	Margin of Error
1	1,9	Can Withstand Large Forces	N	4	1500	<500
2	2,3	Safely and Accurately Delivers Medical Fluid	% error	5	± 1%	<0.5%
3	4	Length of Battery Life	Hours	2	750	<200
4	5,6,7,11	Design creates a Feeling of Control and Confidence	-	4	8-10	<6
5	8,9	Easy to Travel with and Nonobtrusive to Everyday Life	mm^3	3	70000	<20000
6	10	Price to Purchase Assembly Kit	$	4	$400	<$150

4.2: General Specifications

Table 4 represents the entire system. Since some of the metrics pertain to subsystems, only the metrics that apply to the overall system (metrics numbered 1, 2, 3, and 4) will be explained in this section. The remaining metrics will be described and supported in more detail with in respective subsystems below.

4.2.1: Durability

The casing of the insulin pump needs to be strong enough to endure the day-to-day activities of the customer, as it is constantly attached to the customer to provide a steady dosage of insulin. The case needs to be able to withstand any accidental drops or bumps, while being able to continuously deliver the medication that the customer needs. The case should be able to withstand a force of 1500 N with a margin of error of less than 500 N. This metric was determined using the average person's force if the person were to stand on the casing, with a safety factor of 3.

4.2.2: Safety of Product Use

The Insulin Pump Kit has been carefully designed and programed to include multiple safety features to prevent a large dose of insulin from being accidently delivered. The Insulin Pump uses the transition from rotational motion of the motor to the linear motion of the rack and pinion gear set as an additional factor of safety. As the motor rotates, the gear ratio for the motor gear (called a rack) that connects a straight rod with gear teeth (called the pinion) will prevent the plunger from delivering too much insulin if the motor's rotation is offset. The Insulin Pump Kit will come with several sensors that will monitor the amount of insulin that is being injected into the patient. A force sensor will monitor how much force the plunger is experiencing in the cartridge. This will be used to determine the pressure within the cartridge. An encoder will monitor the speed and rotation of the motor to ensure that it isn't moving too far. Lastly, a distance sensor will measure the distance that the plunger moves, to ensure that enough insulin has been delivered depending on the consumer's needs. The programming will 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. The total error of the sensor system should not exceed 1% of the overall performance.

4.2.3: Battery Life

The battery life of the insulin pump is important to the customer as the frequency of replacing the battery can interfere the delivery of the insulin from the pump. This metric was determined by determining the average life of a standard AA battery for current insulin pumps on the market, by surveying users of insulin pumps to determine the average time between battery replacements. The average battery life was found to be about 750 hours, which is approximately once per month, for current insulin pumps on the market.

4.2.4: Confident Control of Device

The assembled Insulin Pump Kit will need to inspire confidence in the customer that they are in control of their diabetes. The Insulin Pump Kit will have key features such as an interactive display that is easy to understand and intuitive buttons that give the customer control over their insulin deliver. This metric will be evaluated by people that use an insulin pump by having them fill out a survey. This survey will be rating scale between 1 and 10. The highest average rate, between 8 and 10, is desired to achieve our design team goal.

4.2.5: Customizable/Replaceable Parts

One of the chief complaints by the customer was that the entire insulin pump needs to be replaced if there is any malfunction in the device. Additionally, the customer wants to be able to customize the outer case to match their lifestyle. Therefore, the Insulin Pump Kit will include a list of all the parts, so that the customer can order a new motor or speaker should it fail. The programming will be able to send warnings to the customer so that they can debug the system and determine which part needs to be replaced or repaired. The customer can pick the color and outer design of the casing to match their personality when they are getting the case 3D printed. This is also rated by a survey on a 1 to 10 scale, with a goal between 8 and 10.

4.3: Casing Ergonomics

The core components will be orientated strictly vertically and horizontally to prevent the components from wobbling within the case from minor vibration or contact for the customers. Having the components in these orientations will clearly indicate how the wires will be organizing from each of the components. This will ensure the wires will not come into contact each other that will prevent the wires of each components from crossing and causing shortages within the case. Each one of the components will be mounted into a compartment within the casing for the safe installation. In case a malfunction in one of the components, most of the components will be easy to replace. The main casing will be divided into two, half for bottom and another half for the top, so it can be easily opened to replace any components that have malfunctioned. The separate slot within the casing will be made for the battery, to allow for easy replacement when the battery is depleted.

4.3.1: Product Comfort Wearing

The customer would be easily able to wear the cased product. Each edges of the casing will have fillet 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 the customers' skin from damages and would be sturdy enough, yet light enough in weight, when it is compared to heavy materials such as metals.

4.3.2: Leaking

The cartridge will be designed in such a way that the plunger would be press fitted to the cartridge. This will prevent any fluid from leaking to the components inside of the device. The more fluid that leaks within the case, the danger of more electrical components would be shorted out by the fluid. As a consequence, having a leak means the customer would not get the amount of fluid that they need, which would likely cause health problems and lead to potentially deadly health issues. Minimizing the fluid wasted means the customer would get precise amount of fluids that he/she needs, without wasting the expensive but lifesaving medical fluid. Thus, preventing the fluid from leaking is very crucial. As long as the plunger is tightly fitted with the cartridge, the chance of having a leakage would least likely to occur. To ensure that our design team meets this standard, it was decided to use cartridges that are already available on the market. These cartridges meet the FDA requirements for insulin pump, and are perfect for our purpose.

4.3.3: Cracks

Considering the amount of force and pressure the plunger is applied in the cartridge, the possibility of a crack occurring in the cartridge is very unlikely. If the crack occurs, it will likely occur in the outer casing itself, do to it being dropped by the user. Since the case will be divided in to two parts, that will be used as an assembly. The strain that will occur would likely occur on the parts that is frequently replaced. One common parts that will be replaced often by the customer will be the battery. After replacing the battery and while placing the battery cover back in, the slot piece that is in contact with the casing would get most friction and the stress applied at the same time. Although this slot piece will be used every couple of days when the battery life is low, the customers would have higher chance of pushing the battery cover harder than it is necessary due to the tendency of making sure the cover is closed and tightly fitted to the case. Thus, applying the human factor would increase the higher chance of one of the assembling parts such as the battery cover developing a crack in the case.

The non-human factor that the crack will occur would be the teeth of the gear pushing the pinion/plunger into the cartridge to deliver the insulin. Since the design itself is quite small in dimension, the gears are going to be quite small as well. Having tiny gears would increase the high chance of the gear teeth breaking overtime. The short length of the teeth with multiple number of teeth highly increase friction due to constant contact each other and would most likely cause the crack compared to other components with in the insulin pump. This is another main reason why the casing will be designed in a way of customers having easy access to the components to be able to replace parts that break overtime.

4.3.4: Volume of Cartridge

The length of the cartridge and the circular diameter of the cartridge will be measured to calculate the exact maximum volume of the cartridge. The customers would be able to fill the cartridge with fluid until the maximum limit is reached. Also, the customers would be able to fill the cartridge only to the amount that they desire, should the maximum volume be too much. The increment mark on how much volume is drawn on the cartridge surface side so that the customers would know how much fluid they are putting inside the cartridge. The customers will be using the fluid volume rate to deliver an accurate bolus and/or basil rate. The amount of insulin is very minimal, so the insulin pump kit will need to be able to accurately deliver the exact amount.

4.4: Assembly and Cost

Many customers have mentioned how prohibitive the cost of an insulin pump can be. They often are forced to choose between their medical 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.

4.4.1: Assembly

The Insulin Pump Kit has been easily designed so that it can assembled by the consumer. This means that the Insulin Pump Kit is also fully customizable by the user, as mentioned in Section 4.2.5. The Kit contains a concise instruction manual that will give a description of the parts and how they are to be assembled. It includes the coding on the provided microcontroller, as well as, the 3D model for the casing that will be printed by the consumer. The kit will have everything necessary to create a fully functioning infusion pump. The only thing the user supply will be a soldering iron, access to a 3D printer, and a computer, as well as the medical cartridge and tubing that have been hermetically sealed during manufacture.

4.4.2: Cost

Many of the customers outlined the high price of conventional insulin pumps as one of the major consideration 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 cost around $800.00. Without health insurance, a typical insulin pump can cost between $4,000.00 to $6,500.00, 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. Our plan is to build a kit that can be assembled into a working insulin pump. The Insulin Pump Kit will cost only around $400.00, making it cost about half as much as a conventional insulin pump that has been purchased with health insurance.

5.0: Design Development

5.1: Brainstorming

Out of approximately 29 million diabetic patients in United States, more than 300,000 people use insulin pumps today. Despite the fact that insulin pump is very useful on helping to achieve a flexible lifestyle and is accurate and precise in the delivery of insulin, many insulin dependent diabetes ends up choosing to not use an insulin pump. The main reason is that the cost of this critical device is often very expensive, even with the health insurance coverage. Thus, our goal is to create the affordable design that is low cost yet include most of the critical functions, so that our customers still maintains their daily lifestyle with minimal interruption. In taking consideration the possibility of malfunction of the device, the sub goal is to set up the insulin pump in such a way that the customers would be able to remove and replace non-working component and replace it with a new one. Creating the design in such way as to be easy to assemble would satisfy our customers, so that they won’t have to worry about purchasing the whole insulin pump device.

5.2: Initial Design

The DC motor [4] is attached to the gear to drive another gear that will be driven along a threaded rod which would move the threaded rod into the end of the plunger to deliver insulin to the user. The nut is installed center of the driven gear to control the threaded rod inside when it rotates so that the threaded rod will push and pull the plunger within the insulin case so that it can easily be refilled. The design is shown and demonstrated below in Figure 1.

5.3: Final Design

The previous design was suitable to use since it clearly shows the transition from rotational motion to linear motion. However, considering the size of the threaded rod design, it will be very difficult to make the insulin case small enough for the user to comfortably carry. The nut and threaded rod are most likely to be made out of hard material, such as metals. Our goal of the design is not only to create an affordable design, but to also minimize the ergonomic problems that conflict or cause delays with the customers’ daily routines. Thus, it is necessary to come up with the materials that is lightweight, which would also cause less torque and friction that will be applied into the motor, gears and the syringe that moves the insulin. In addition, the threaded rod will be likely to wobble during the linear motion unless there was an additional nut that holds the screw on the other end. If this is done in that way, then there will be more friction between the nuts and the threaded rod which will require more power from the motor which eventually makes less efficient on the battery life of the insulin pump device. Keeping the concept of rotating motion to linear motion mechanism, it is required to have lightweight materials, as well as be sturdy enough to handle the forces required to move the syringe.

Therefore, instead of a threaded rod, a rack and pinion model, found on Figure 2, was chosen as it would have more stable to have a rack move linearly using the rotating pinion gear. This design concept will prevent any side motion of the rack during the linear motion. The rack is a long rectangular shaped gear with teeth on one side which will be easily fit and installed into the case of the design. The rack will be connected to the plunger for continued stabilization with the pushing and pulling motion of the plunger so that the amount of insulin dosage will be exact. Delivering exact amounts of insulin is critical to our customers’ health, because when given an insufficient or excessive dosage will increase the risk of adverse health conditions. Considering the soft material such as plastic for the rack and gears, the rack and pinion model will most likely to fit better within the case than the previous model of the threaded rod and nuts were. Additionally, a servo motor [5] was chosen to replace the DC motor that was previously used for better accuracy. A model of this design that was used for our critical function prototype is found on Figure 3

5.3.1: Material Selection

Even though the final design of the rack and pinion model will work frequent amount of times without malfunction, there are always the possibility of a failure of a component after a long run. Considering the amount of possible failures and number of testing and iterations trails, it is safer to use materials such as plastic for building the prototype. Although plastic is not the strongest material, if the mechanical components such as gears and rack made out of plastic then they are unlikely to crack or break apart during the many iterations of the testing process. Using such materials would save on the cost of budget which allows the adequate amount of cost that is necessary to build the finalized design.

The plunger and the cartridge will be made of medical grade plastics, on both the prototype model and the finalized model. To be fair, these components will be purchased from other providers. It is not a major concern so long as the fluids, such as water or insulin, do not leak between the plunger and the cartridge. To prevent any leakage, the rubber O-ring on the medical plunger will be the best candidate in material selection. Having the two O-rings around front end of the plunger will completely seal the fluid inside of the syringe, preventing leaks and wastage of the medical fluid

5.4: Test Plan, Calculations, and Experimental Results

5.4.1: Test Plan

For testing the motor, we will need to program the microcontroller to move the stepper motor a certain number of degrees and verify that the motor has moved exactly that much. This test will be conducted with a protractor, a marked paper to indicate the direction of the servo motor, and a servo motor. The test consists of the motor being told to move a certain number of degrees and seeing how many degrees that the motor has moved. This test will be repeated 3 times for accuracy.

Testing the change in volume will be simply done by placing a set volume in the cartridge and measuring the change in volume and the displacement of the plunger. This will be done by measuring the volume that left the cartridge after a set amount of time. The displacement will be measured by making small marks on the cartridge at equal distances and seeing how far the plunger has moved after a set amount of time. We will need a timing device, a graduated beaker to measure the fluid into the cartridge and a second beaker to catch the fluid as it leaves.

Battery life will be tested by finding out the total amps that the various components actually draw from the battery and determining the true amount of time that they will be used in a day. This will then be used to determine the true draw of energy from the battery to determine the battery life of the total system. We will use a voltmeter to measure the resistance of each component and is that to find the amount of current that will flow through that component.

5.4.2: Calculations

The main part of the CFP is to move the fluid out of the pump. The initial step is to change the rotational movement of the motor into a linear movement. The best way to do this has been determined to be a rack and pinion gear system [6] that is attached to the motor and the plunger of the cartridge to move the plunger up. The plunger is attached to the linear gear, known as a rack, and is installed in micro scaled cylinder piston, known as the cartridge. The cartridge is the medical device that holds the insulin to be delivered the diabetic patient. The amount of fluid volume pumped out inside of the cartridge depends on the surface area of the plunger and the displacement of the plunger that has been pushed. Assuming the diameter of the plunger is diameter plunger is 16 mm and the length of the cylinder is 25 mm, then circular area and the cylinder volume would be:

$$A = \pi r^2$$

$$A_c = \pi(8\,mm)^2 = \mathbf{201.062\,mm^2}$$

$$Vol_{cartridge} = A_c * L_{cartridge}$$

$$Vol_{cartridge} = 201.062\,mm^2 * 25\,mm = \mathbf{5026.548\,mm^3}$$

With the equations listed above, it is clear to know how much fluid will be left in the cartridge, depending on how far the plunger has moved inside the cylinder piston at any distance from 0 to 25 mm. Since the customer must be injected with a continuous and minimal amount of medication into their body, the fluids inside the cartridge have to be transferred to the smaller sized tube, which delivers the medication into their body. Assuming that the diameter of the tube is 1 mm and length of the cartridge is 30 mm, then the area and volume of the tube can be determined to be:

$$A = \pi r^2$$

$$A_t = \pi(0.5\,mm)^2 = \mathbf{0.78539\,mm^2}$$

$$Vol_{tube} = A_t * L_{tube}$$

$$Vol_{tube} = 0.78539\,mm^2 * 30\,mm = \mathbf{23.5619\,mm^3}$$

Once again from above, it is clear to find out how much fluid will be remained depending on how much the fluid is injected to the customers' body at any distance from 0 to 30 mm. The flow rate Q of fluid in relation from cylinder to cartridge while plunger pushing is found to be:

$$Q = A_c * \text{Vel}_{\text{cartridge}} = A_t * \text{Vel}_{\text{tube}}$$

Suppose the amount of fluid rate that customer need is 0.5 mm/s, which is the velocity of the cartridge going out. Using the flow rate equation, Q, listed above, we could figure out how fast the plunger should be pushed through the cylinder piston at certain time to achieve the exact amount that the customer needs. Solving backwards would result:

$$Q = A_c * \text{Vel}_{\text{cartridge}} = A_t * \text{Vel}_{\text{tube}}$$

$$\text{Vel}_{\text{cartridge}} = \frac{(A_t * \text{Vel}_{\text{tube}})}{A_c}$$

$$= \frac{(0.78539\,mm^2 * 0.5\,m/s}{201.062\,mm^2}$$

$$\mathrm{Vel}_{\mathrm{cartridge}} = \mathbf{0.02}\ \boldsymbol{mm/s}$$

Therefore, the velocity of the plunger should be 0.02 mm/s to push to acquire the desired amount of fluid at a rate of 0.5 mm/s that has been set as the consumer.

Lastly the battery life [7] is another significant factor to consider how long it will be used before the battery needs to be replaced by the customer. The battery life can be determined by using the following equation:

$$BL = \frac{(BC * DP)}{\left[CL + \left(AL * \left(\frac{AT}{24}\right) * AU\right)\right]}$$

Where BL is the expected battery life, BC is the battery capacity, DP is the Percentage until the battery is counted as dead, CL is the circuit load which occurs when the component is not in use, AL is the active load which occurs when the component is in use, AT is the average time that the component is being used, and AU is the average use of the product.

A sample calculation would be for the DC motor, where the AL is set to 250 mA, CL is set to 10mA and the duration of use, AT is 12 hours. Assuming the battery is an AA battery with a DP set to 95%, plug it into the formula for battery life:

$$\mathrm{BL_m} = \frac{(2900 * 0.95)}{\left[10 + \left(250 * \left(\frac{12}{24}\right) * 0.7\right)\right]}$$

$$\mathrm{BL_m} = 63.576\ \text{hrs.}$$

This shows that the motor will take most of the battery life, but it can be improved by using a MOSFIT transistor. However, the other electrical component would take power as well, but individually, they would not take much power when compared to the motor. But, using the equation above, the average battery life for all the components combined would be around 43.8 hours. This is far less than the average insulin pump on the market, but that can be corrected once the components arrive and tested. A figure of the circuitry used for calculations can be found on Figure 4.

5.4.3: Experimental Results

Much was learned from the testing results. The motor was found to be moving too far for each degree that was inputted into the system. The motor was found to move 1° as the code was loaded into the microcontroller and then it would move the desired degrees from its location. So, if the motor was told to go to 20°, it would move 1°, then add 20 to that and go to 21°. For each new change in location, the error would increase as the extra degree would be added before the change in motion. If the move was larger than a 20° increment, then the error would be greater as the motor would move more than 1° before changing location. The test results can be found in Table 5.

Table 5: Motor Degrees

Input Degree	Test 1	Test 2	Test 3
20°	21°	21°	21°
40°	42°	42°	42°
70°	74°	75°	75°
90°	96°	97°	97°
110°	117°	118°	118°
140°	148°	149°	149°
160°	169°	169°	169°

The change in volume test was done using two methods. The first was to fill the syringe, place it above a graduated cylinder, have the motor move from 0° to 180°, then stop the motor, and measure the fluid. The second test was to fill the syringe, place it above a graduated cylinder, have the motor move from 0° to 20°, then stop the motor, and measure the fluid. From observation of the displacement of the plunger, the motor was expected to move the plunger a distance of 1.6 mL. However, due to the error in the number of degrees that the motor moved, the volume that was measured was closer to 1.68 mL. When the motor was programed to go from 0° to 30° and back to 0°, the cartridge was expected to dispense 0.20 mL of fluid, but when tested the fluid measured was found to be an average of 0.204 mL.

Table 6: Change in Volume with Motor Moving Set Number of Degrees

Test	0-180°	0-30°
1	1.78	0.21
2	1.73	0.22
3	1.66	0.21
4	1.72	0.19
5	1.79	0.19
Average	1.736	0.204

Battery life was tested by using a Multimeter to find the milliamperes that the motor was consuming. The test found that the amperes were higher than the spec sheets estimate of 250 mA, with the average from the test found to be 265 mA. Table 7 shows the exact values found during the testing.

Table 7: Microamperes Test

Measurement	Micro Amps
1	265
2	263
3	267
4	265
5	265
Avg.	**265**

6.0: Preliminary Recommendations

6.1: Lessons learned During CFP

Much was learned from reviewing the testing results that were found. The gear that was first used was found to be too small and prone to breaking. The second gear that was made might be too large and is causing the plunger to travel too far and potentially delivering too much fluid. Another error is that the motion of the motor has a slight error in it that accumulates over time. As the gear turns and moves the plunger, the distance traveled by the plunger is greater each time the gear is turned. This will be corrected by the programing, which will take into account the accumulated error and move the motor a few degrees less each time it is moved until it reaches the end.

The motor that was used during the prototype was a 180° servo motor, which will be replaced with another servo motor that will rotate a full 360°. This will allow the motor to move the pinion the full distance of the plunger allowing the customer to use the full 3 mL of available space. This will also increase the accuracy of the delivery of insulin to the user, without the user needed to refill the cartridge more than once a day.

6.2: Future Recommendations

To improve on stabilize our final model, it will be highly recommended that the rack be connected to the plunger in the center. Currently the rack is placed at the lower end of the circular face of the plunger. This would not affect the rack or the plunger for now, but it might cause break as it is used over time. Thus, having a rack in a centered position with the center of the plunger face will give less chance of material damage. Thus, there has been a part created called the Syringe Pusher, with is on Figure 5. This will allow the plunger to move without causing any excess pressure on the plunger that could cause damage.

Additionally, one of the challenge in the next semester would be how to place and install the sensors among the components into the outer casing. For example, the sensor that measures the force to calculate pressure will be place in between the rack and the plunger. The current CFP is set having the rack and the plunger glued together. Due to the sensor positioning, measurement would not work if glued together. This will be done with the Syringe Pusher mentioned above. The sensor will be placed onto the end of the Syringe Pusher, so that it can measure the force when the plunger is moved by the Syringe Pusher.

Since we are heading towards the single gear method, the precision in terms of measuring the increments of distance and the volume would be more challenging. In the future, if there is a chance of gear being brake or crack, we should take consideration of the gear model. For example, the drill hole size of the center gear for the motor shaft to fit in would affect highly on those circumstances depending on if the drill hole will be press fit or not. If we have to increase the number of gear teeth for the higher precision, the increase of gear diameter should be considered very carefully depending on how many teeth will be added, or vice versa if decrease of gear diameter. Having the same number of teeth while changing the length of gear diameter could lead to failure in the accuracy and precision of the insulin which would give customers the possibility of a life-threatening experience.

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 Gantt chart and Design Structure matrix to keep our team organized and on track. The Gantt chart shown on Figure 6 allowed us to see start dates, proposed completion dates, as well as our progress. The Design Structure matrix shown on Figure 7 allowed us to see proprieties and dependence of tasks.

7.1.1: Fall Semester

The table below shows important milestones and key dates for the fall semester. These dates and milestones were needed and adjusted to ensure the completion of the Critical Function Prototype (CFP).

Table 8. Fall 2016 Milestone Schedule

Date	Task/Milestone	Status	Comments
29-Sep	Determine and Order Microcontroller, LCD Screen and Speaker [10]	Complete	
1-Oct	Design CAD model of keypad, Determine Sensors to be used and if Microchip is necessary.	Complete	
7-Oct	Coding for LCD Screen and Speaker, Start CAD for Motor/Pump	In Progress	Speaker and LCD Coding to be updated to incorporate Keypad
17-Oct	Begin to Electronic Configuration of Microchip	Eliminated	
21-Oct	FEA analysis of Motor/Pump assembly	Complete	
1-Nov	Order and Test Sensors, and Coding for Keypad [11]	In Progress	Sensors need to be tested still. Keypad Delayed for CFP
7-Nov	CAD Design for Pump Casing, and Start Coding the Motor/Pump	In Progress	Coding motor needs to incorporate keypad

14-Nov	CFP assembly	Complete	
18-Nov	Results evaluated for improvements needed on final design	Complete	
23-Nov	CFP results assembled for CFP presentations	Complete	
1-Dec	CFP presentation	Today	

7.1.2: Spring Semester

The table below shows important milestones and key dates for the Spring semester. These dates and milestones are needed and will be adjusted as necessary to ensure the completion of our project for Design Day.

Table 9. Spring 2017 Milestone Schedule

Date	Task/Milestone	Status	Comments
19-Dec	Update Code for Speaker [10]		
19-Dec	Update Code for LCD [12]		
11-Jan	Configure Memory Card and Determine Power Management of System [9]		
18-Jan	Testing of Pump Delivery System		
10-Feb	Make adjustments to the Insulin Pump Casing		
24-Feb	Test the Motor/Pump configuration with Cartridge		
6-Mar	3D Print Casing		
17-Mar	Assemble Entire System Together		

27-Mar	Testing Entire Insulin Pump Assembly (in Casing)		
28-Mar	Design revisions and recommendations		
13-Apr	Design Day		

7.2: Budget

7.2.1: Fall Semester

All money contributing to this budget was from lab costs from tuition costs. Each member contributes $50.00 a semester, which gave the team $200.00 to spend over Fall 2016 semester. Table 10 shows the breakdown of how the money was spent over the semester as well as what money remains. Many items the team had on hand, were donated to the team or were manufactured by the team.

Table 10: Fall 2016 Budget

Item	**Price**	**Quantity**	**Cost**
Motor	32.99	1	32.99
Cartridge	0	1	0
LCD Screen	19.13	1	19.13
Microcontroller	8.99	1	8.99
Speaker	9	1	9

Total Budget	200
Total Cost	70.11
Remaining Budget	129.89

7.2.2: Spring Semester

All money contributing to this budget was from lab costs from tuition costs. Each member contributes $50.00 a semester, which gave the team $200.00 to spend over spring semester. With the remaining budget from fall semester included, the team has a grand total of $329.89 available for the Spring 2017 semester. Table 10 below shows the expected costs of the parts necessary to finish building the generator.

Table 11: Spring 2017 Budget

Item	**Price**	**Quantity**	**Cost**
Sensor	57.99	3	173.97
Case	19.99	1	19.99
Circuitboard	2.99	1	2.99
Breadboard	2.99	1	2.99
Jumper Cables	6.99	1	6.99

Total Budget	329.89
Additional Cost	206.93
Future Budget	122.96

8.0: References

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9.0: Appendix

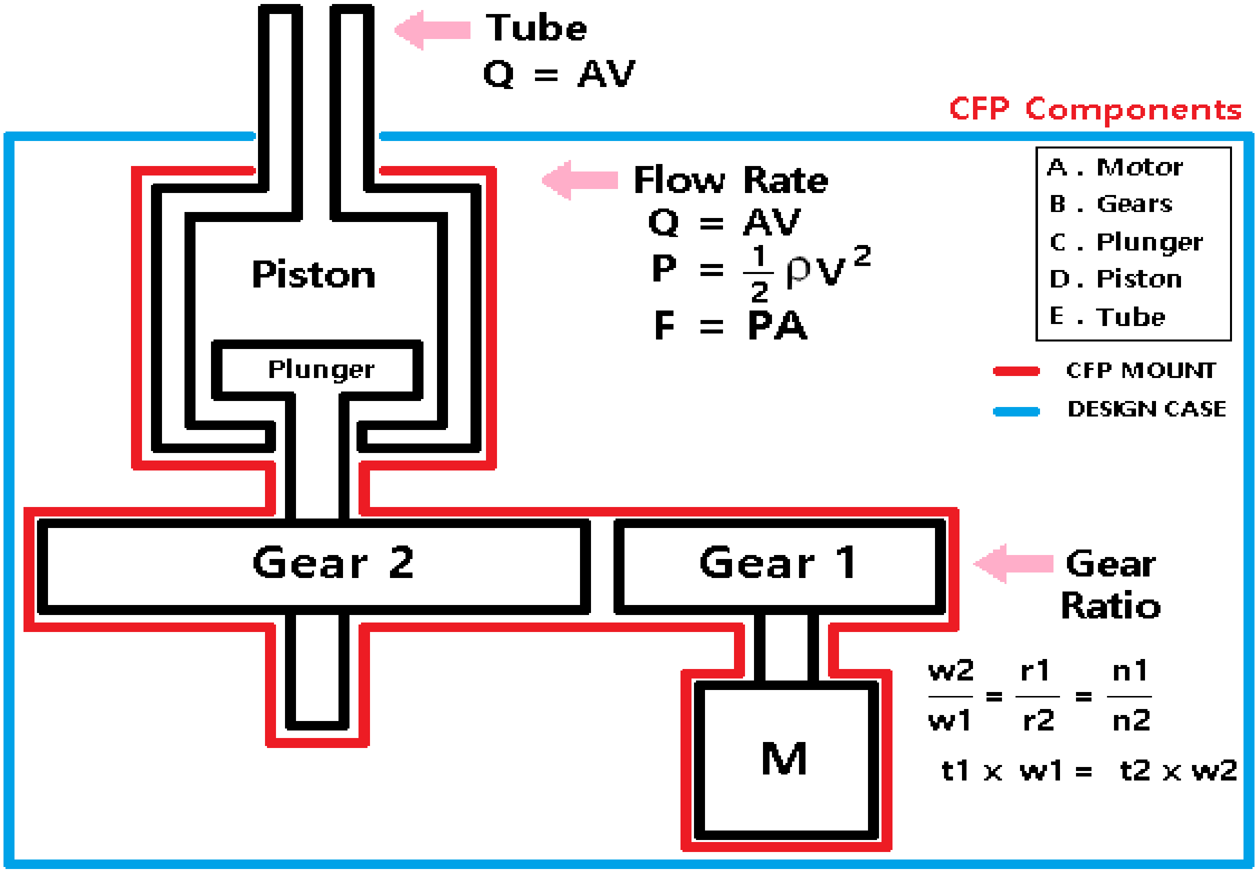


Figure 1. Threaded Gear Model

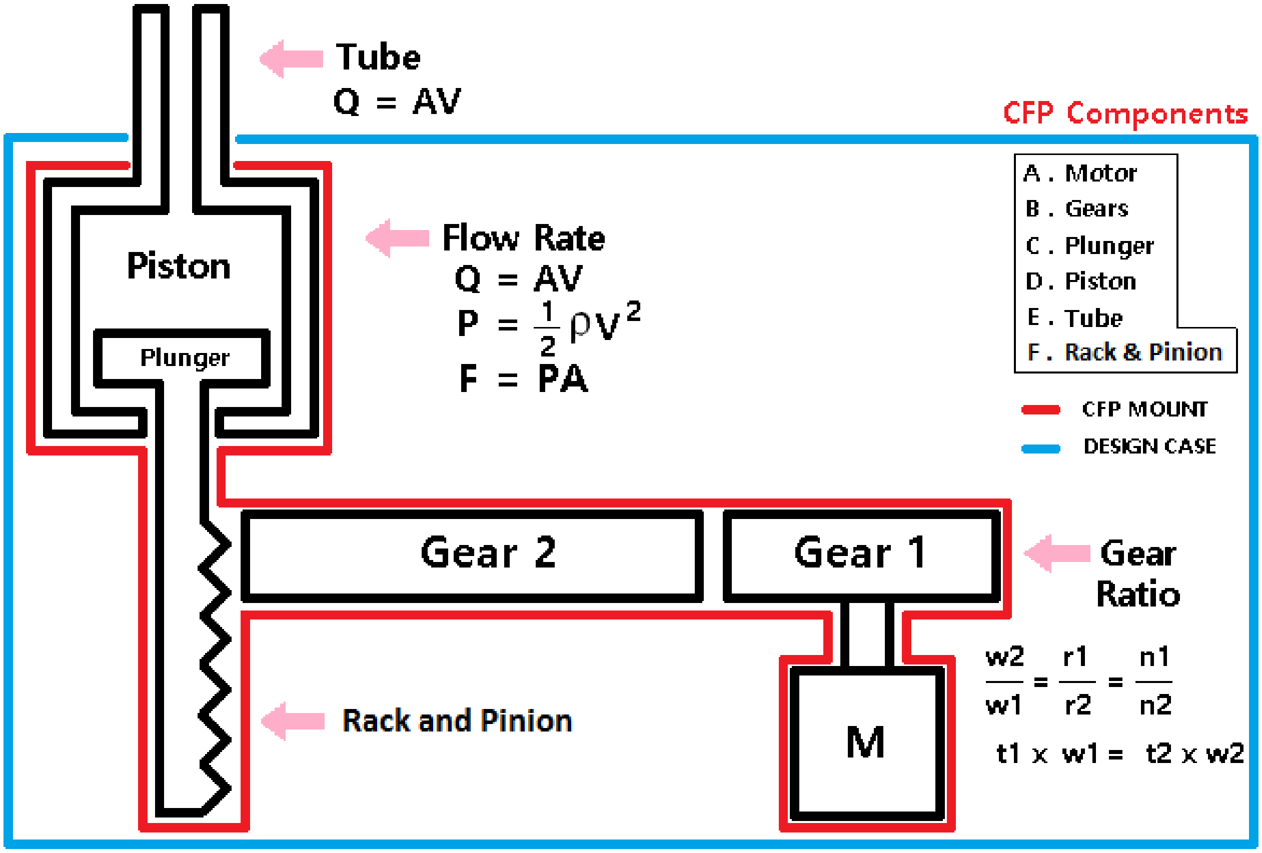


Figure 2. Rack and Pinion Model

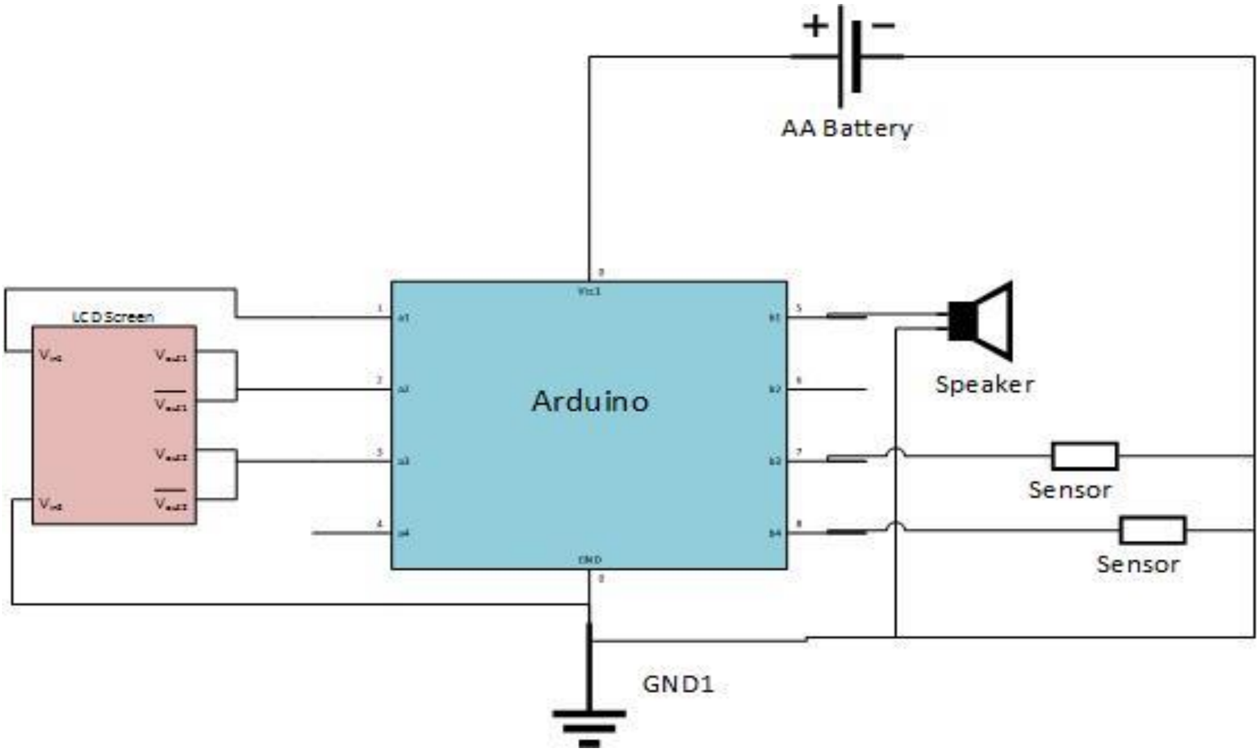


Figure 3. Critical Function Prototype Setup

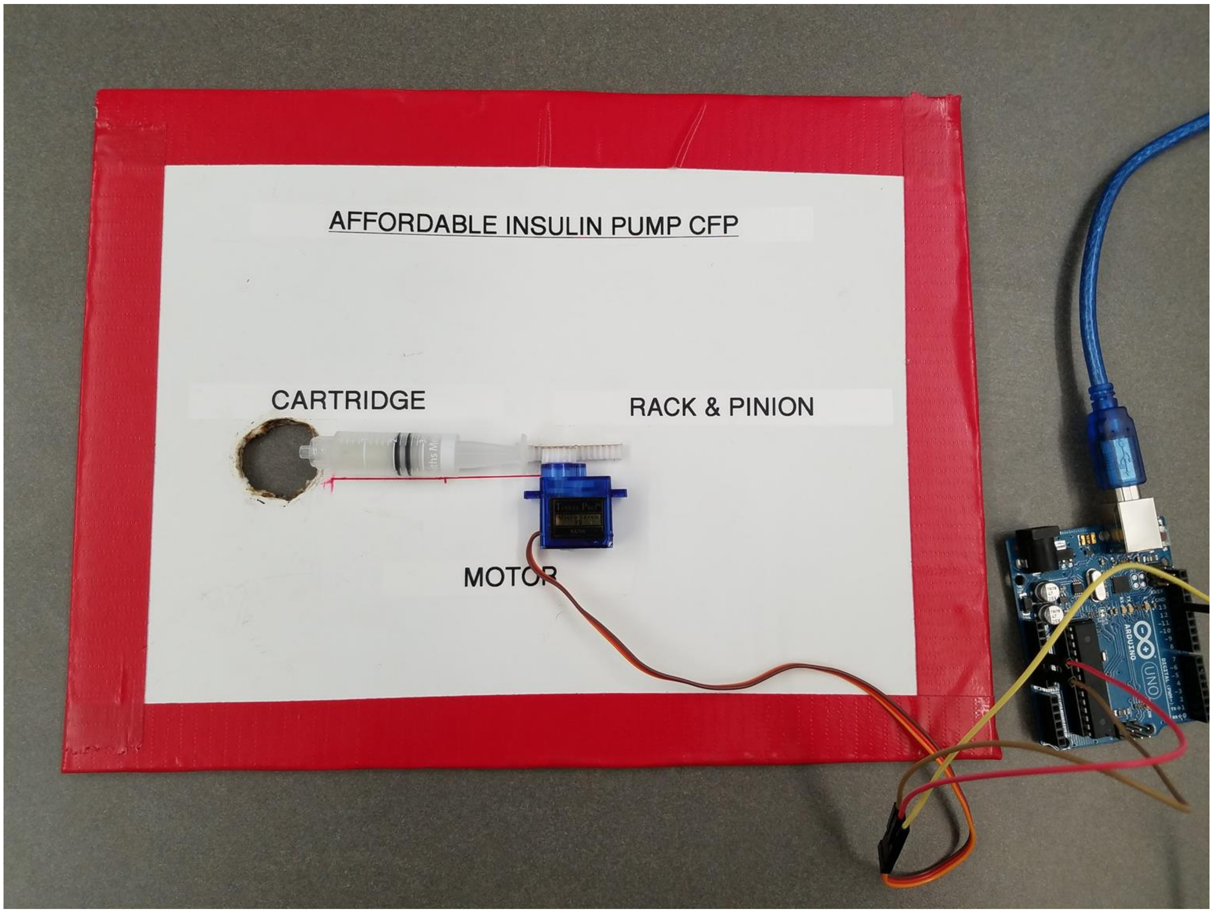


Figure 4. Arduino Circuitry

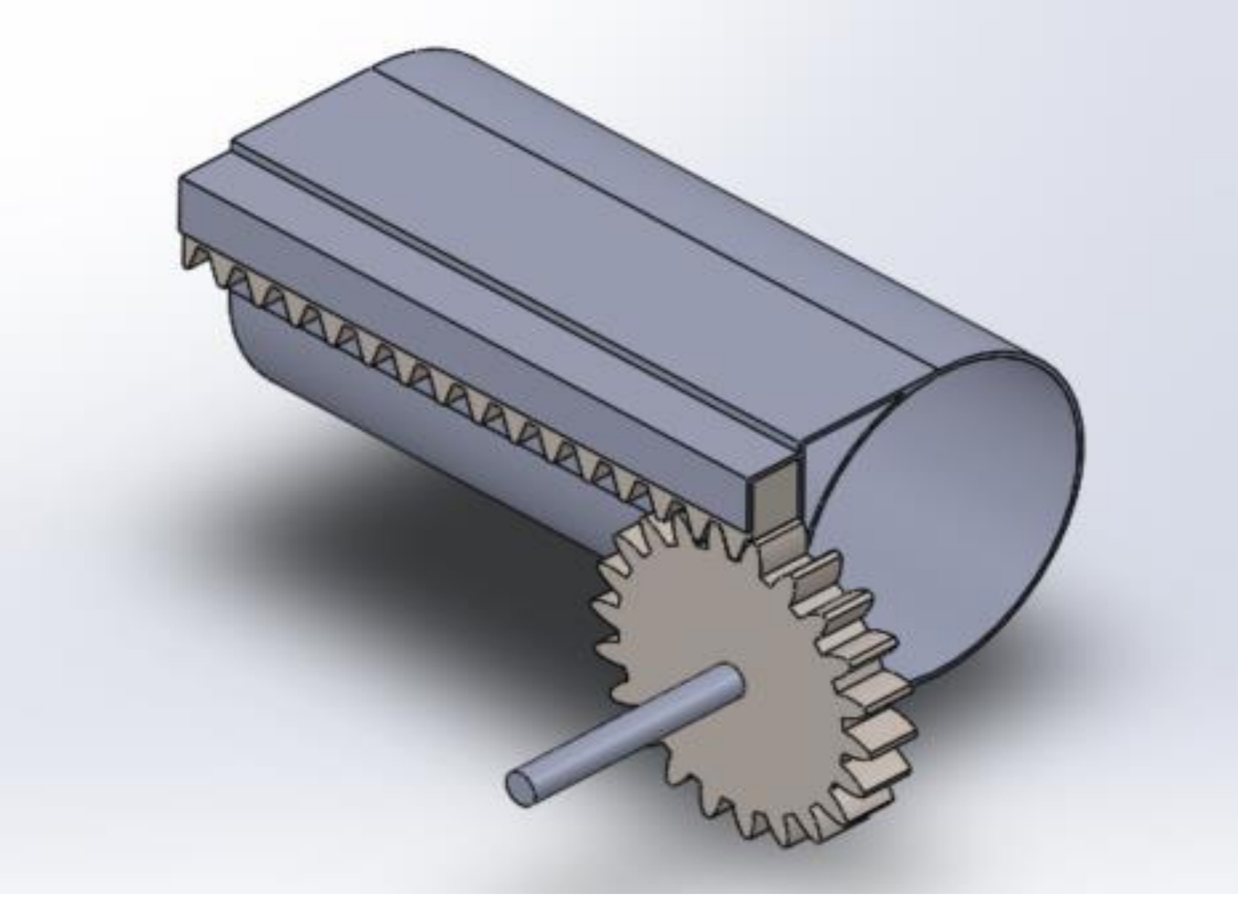
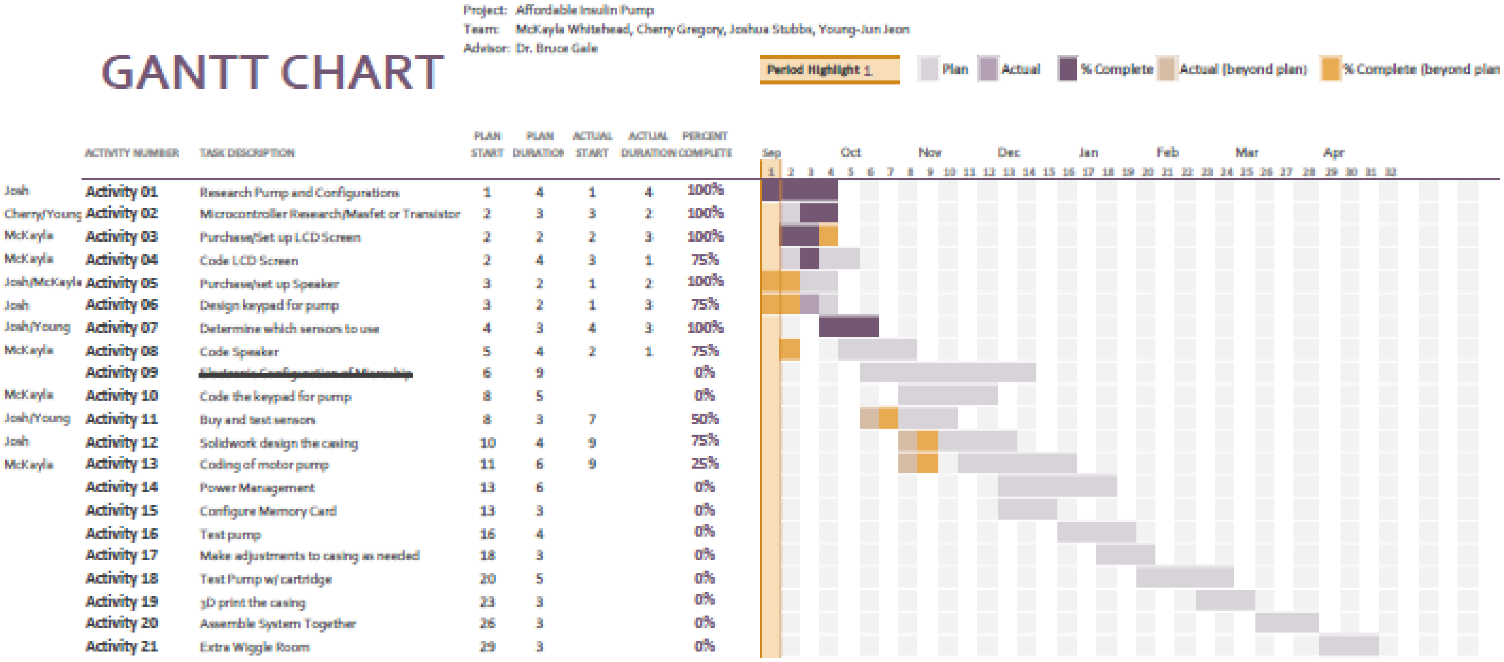


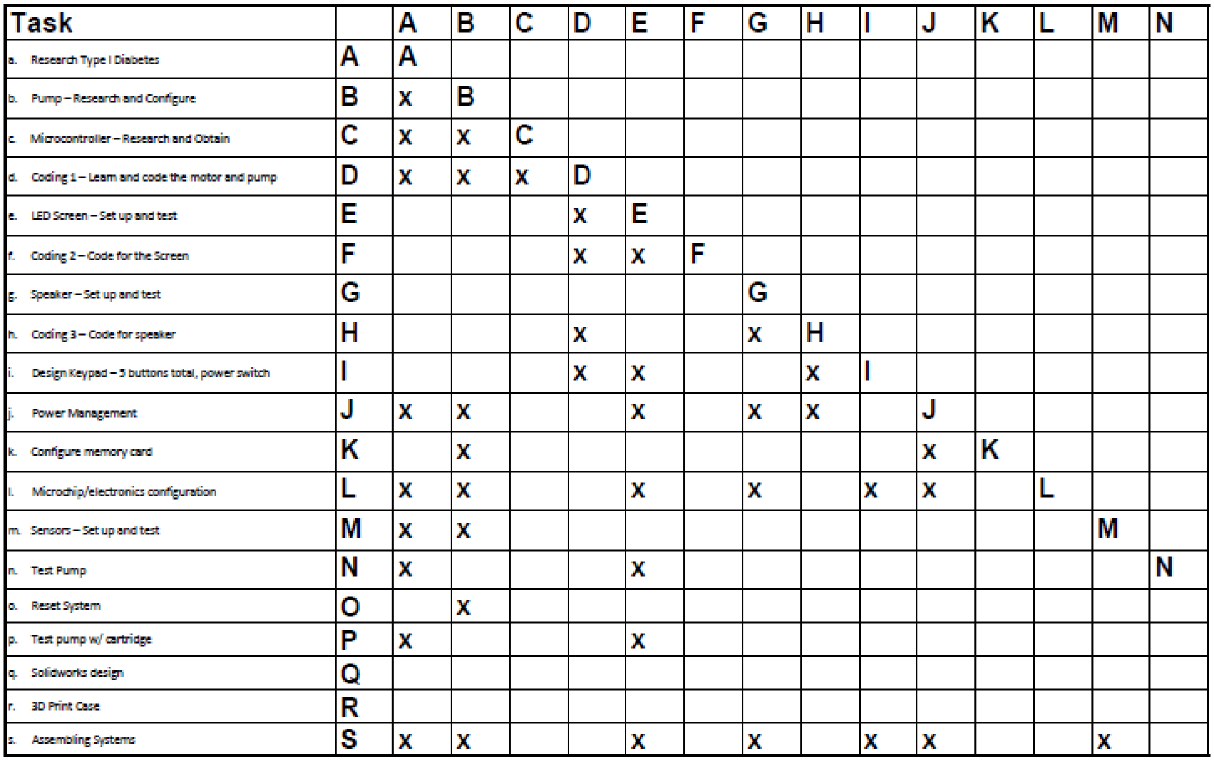
Figure 5. Syringe Pusher



Project: Affordable Insulin Pump
Team: McKayla Whitehead, Cherry Gregory, Joshua Stubbs, Young-Jun Jeon
Advisor: Dr. Bruce Gale

	ACTIVITY NUMBER	TASK DESCRIPTION	PLAN START	PLAN DURATION	ACTUAL START	ACTUAL DURATION	PERCENT COMPLETE
Josh	**Activity 01**	Research Pump and Configurations	1	4	1	4	100%
Cherry/Young	**Activity 02**	Microcontroller Research/Masfet or Transistor	2	3	3	2	100%
McKayla	**Activity 03**	Purchase/Set up LCD Screen	2	2	2	3	100%
McKayla	**Activity 04**	Code LCD Screen	2	4	3	1	75%
Josh/McKayla	**Activity 05**	Purchase/set up Speaker	3	2	1	2	100%
Josh	**Activity 06**	Design keypad for pump	3	2	1	3	75%
Josh/Young	**Activity 07**	Determine which sensors to use	4	3	4	3	100%
McKayla	**Activity 08**	Code Speaker	5	4	2	1	75%
	Activity 09	~~Electronic Configuration of Microchip~~	6	9			0%
McKayla	**Activity 10**	Code the keypad for pump	8	5			0%
Josh/Young	**Activity 11**	Buy and test sensors	8	3	7		50%
Josh	**Activity 12**	Solidwork design the casing	10	4	9		75%
McKayla	**Activity 13**	Coding of motor pump	11	6	9		25%
	Activity 14	Power Management	13	6			0%
	Activity 15	Configure Memory Card	13	3			0%
	Activity 16	Test pump	16	4			0%
	Activity 17	Make adjustments to casing as needed	18	3			0%
	Activity 18	Test Pump w/ cartridge	20	5			0%
	Activity 19	3D print the casing	23	3			0%
	Activity 20	Assemble System Together	26	3			0%
	Activity 21	Extra Wiggle Room	29	3			0%

Figure 6. Gantt Chart [13]



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 7. Design Matrix [13]

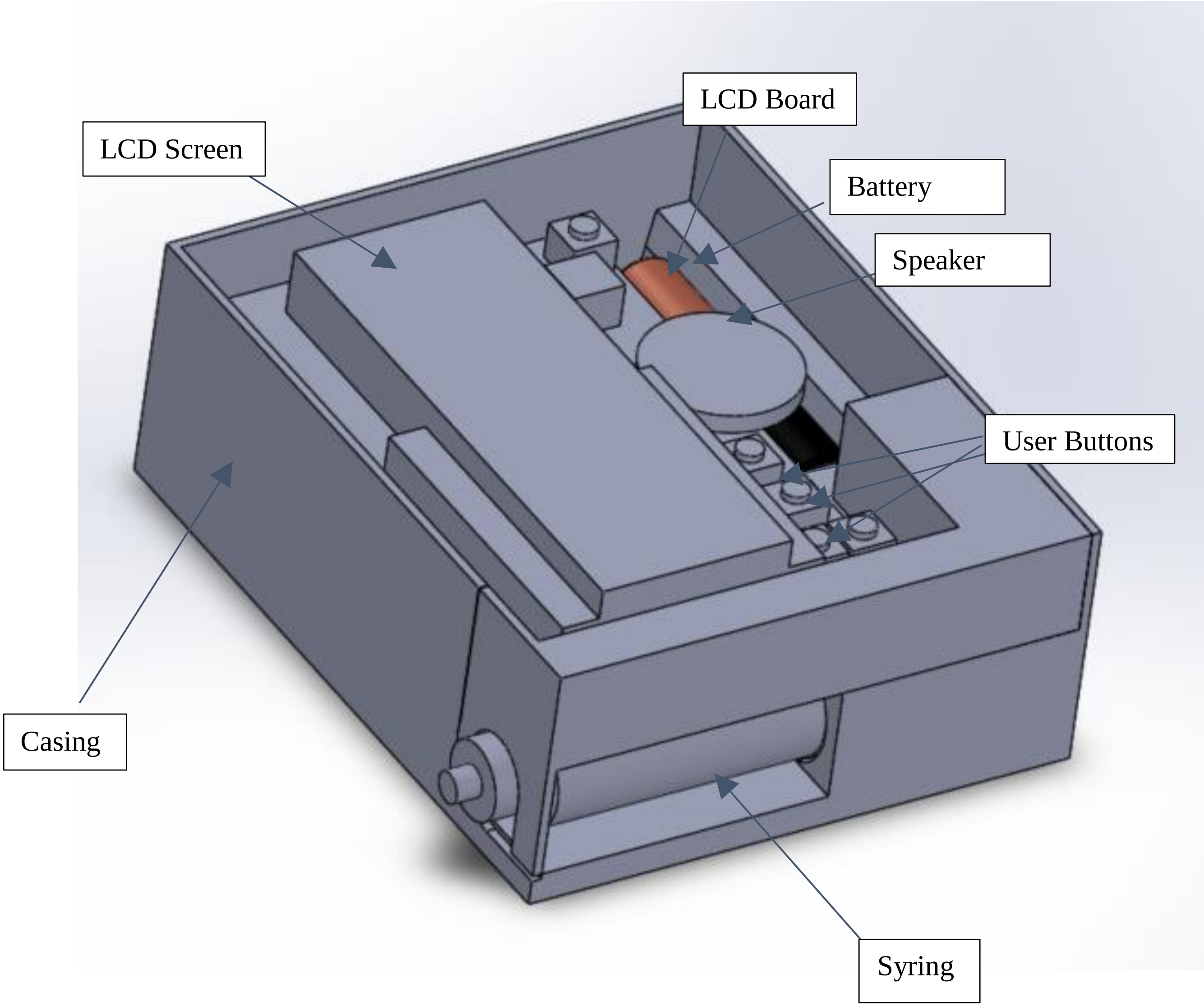


Figure 8. Assembled Infusion Pump Iteration 1 [14]

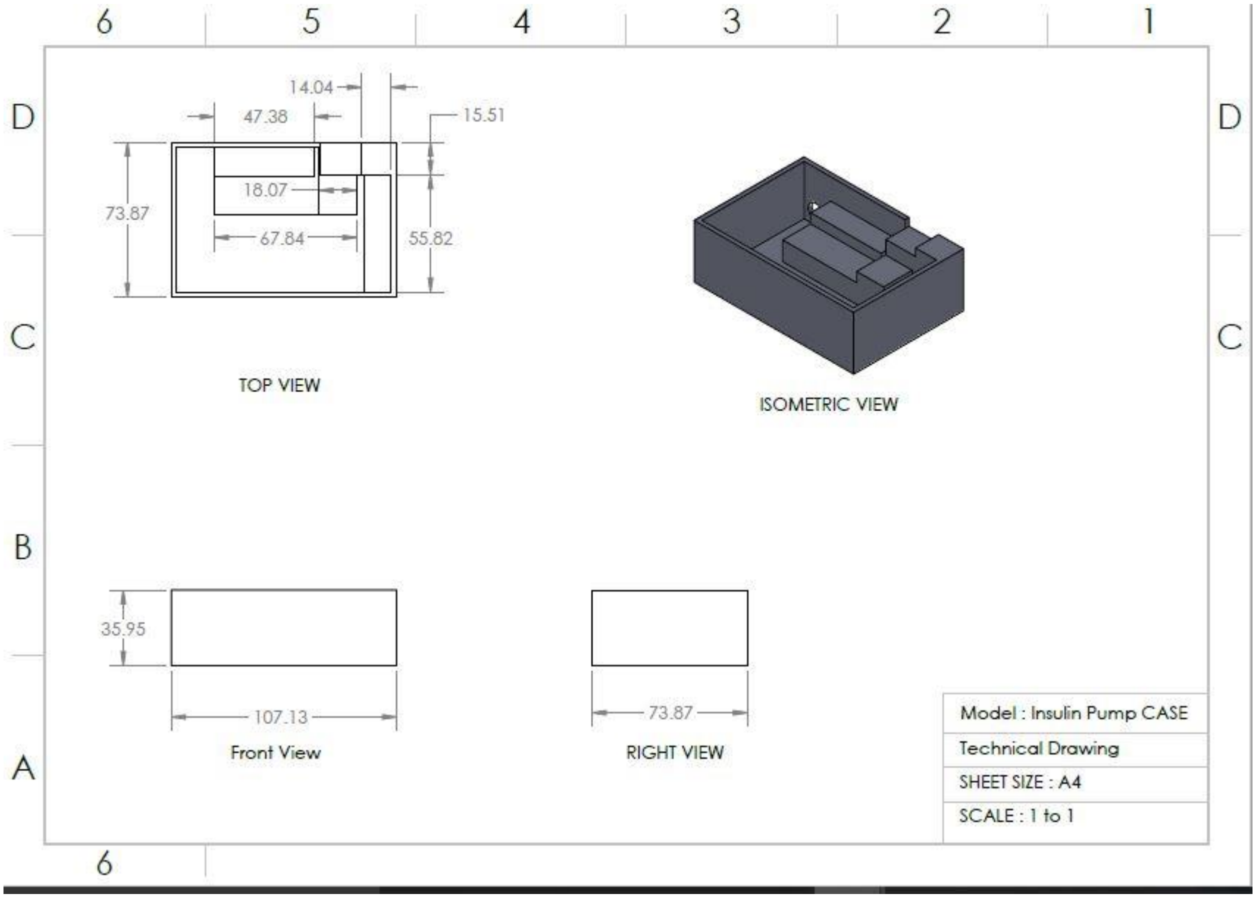


Figure 9. Casing Drawing

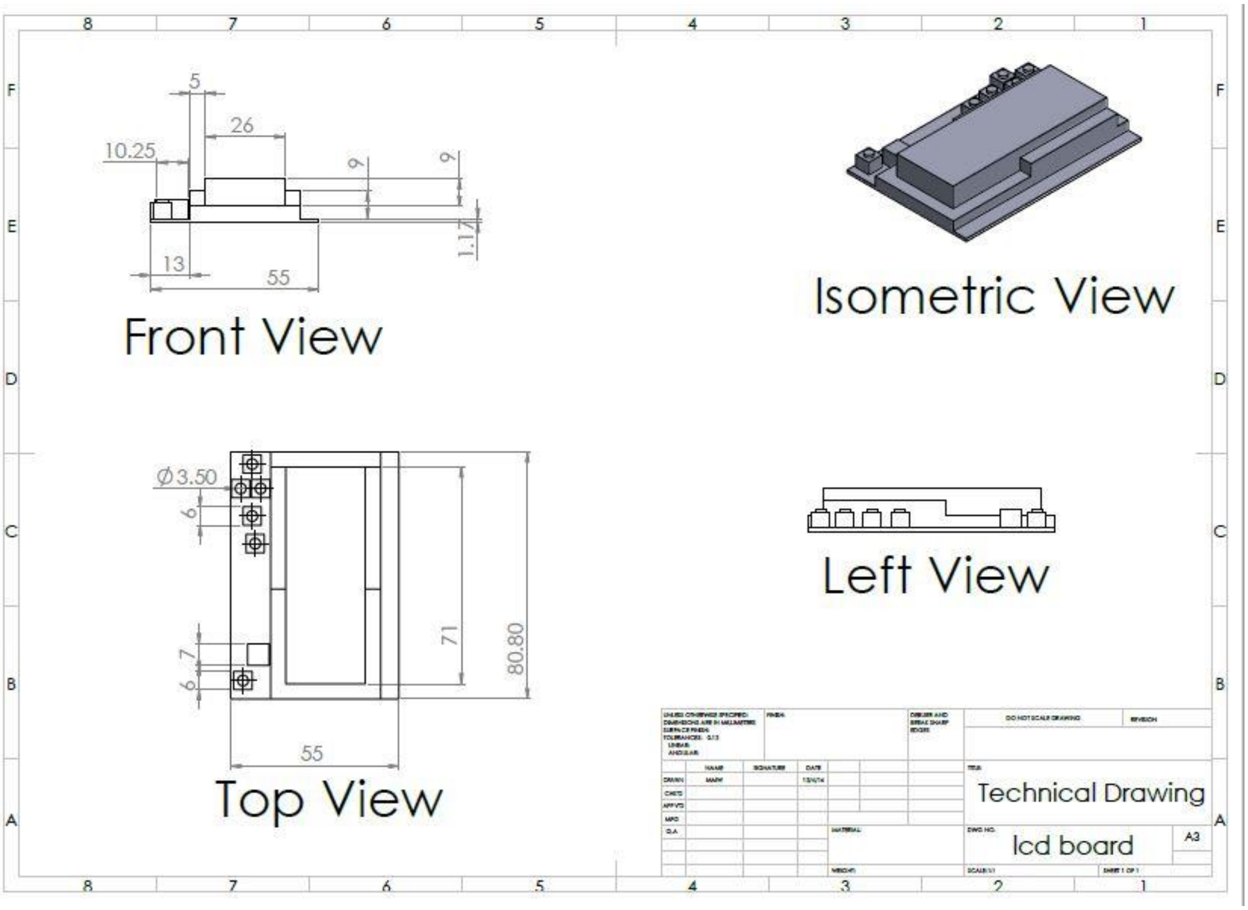


Figure 10. LCD Screen Drawing

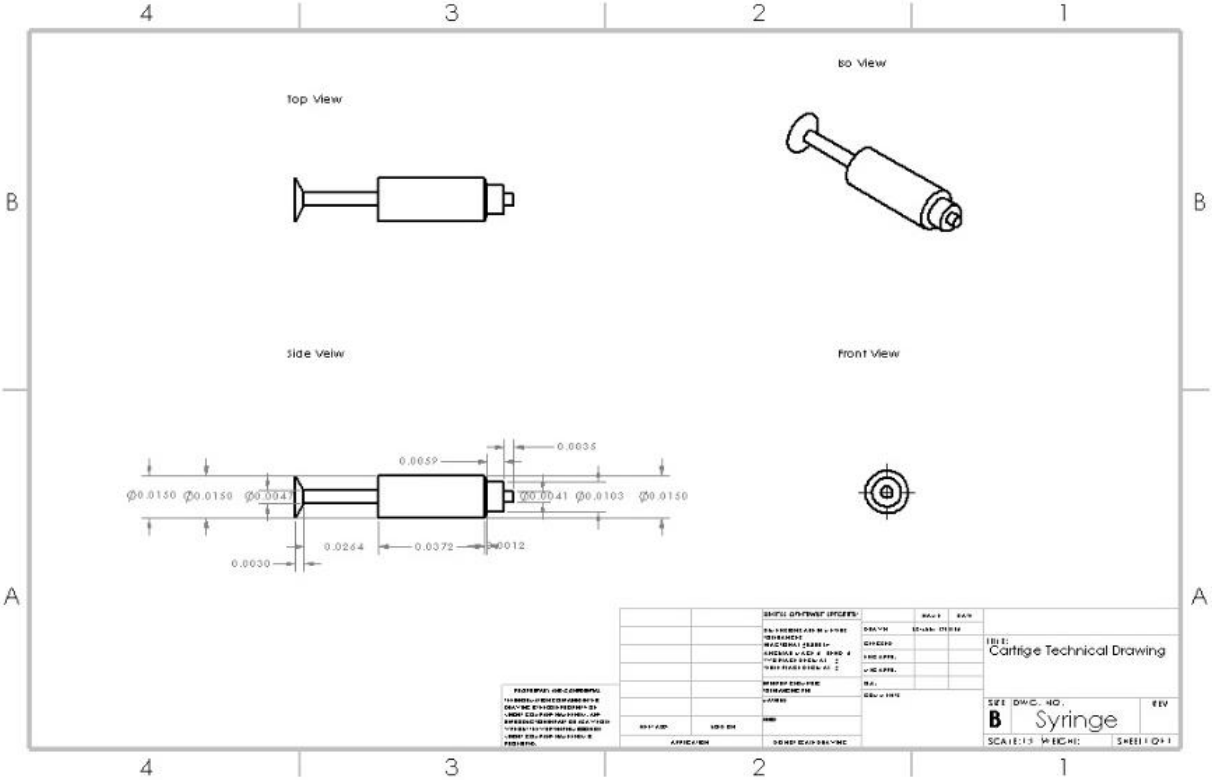


Figure 11. Syringe Drawing

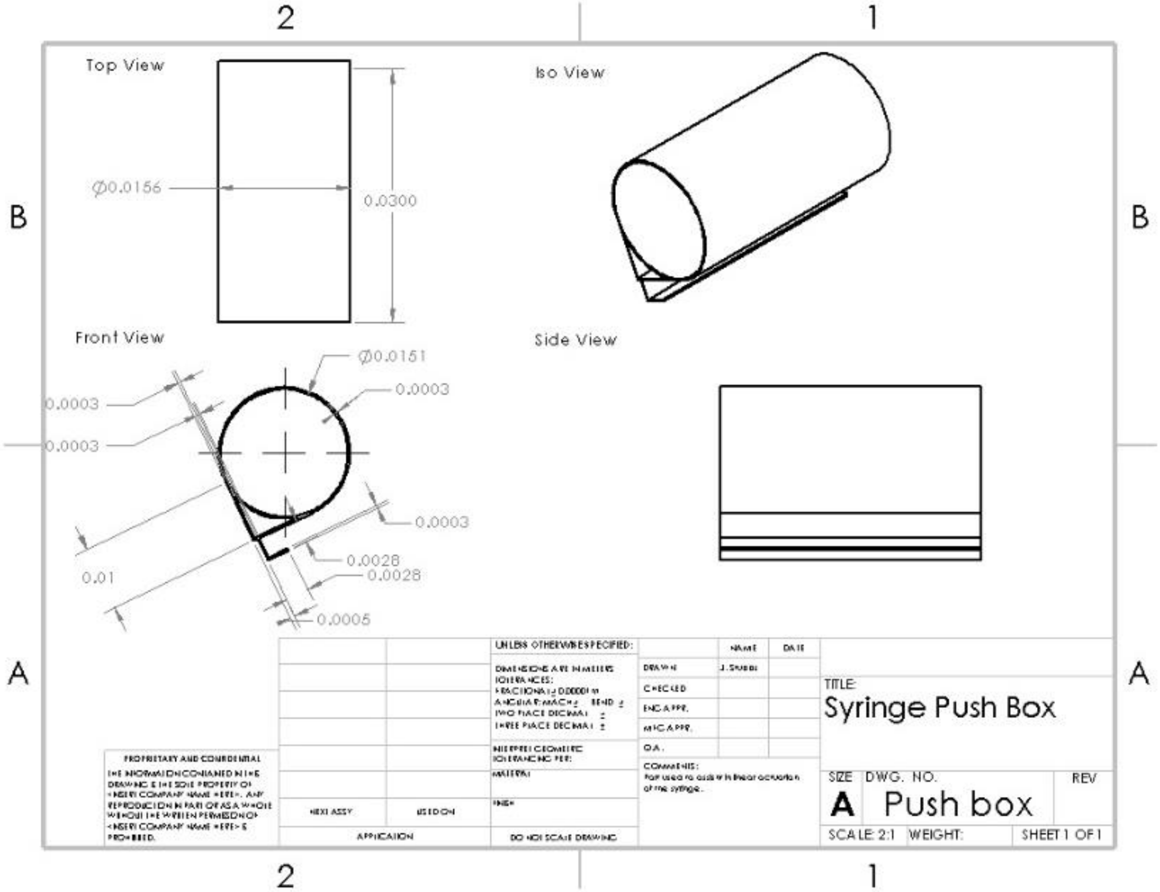


Figure 12. Syringe Push Box Drawing

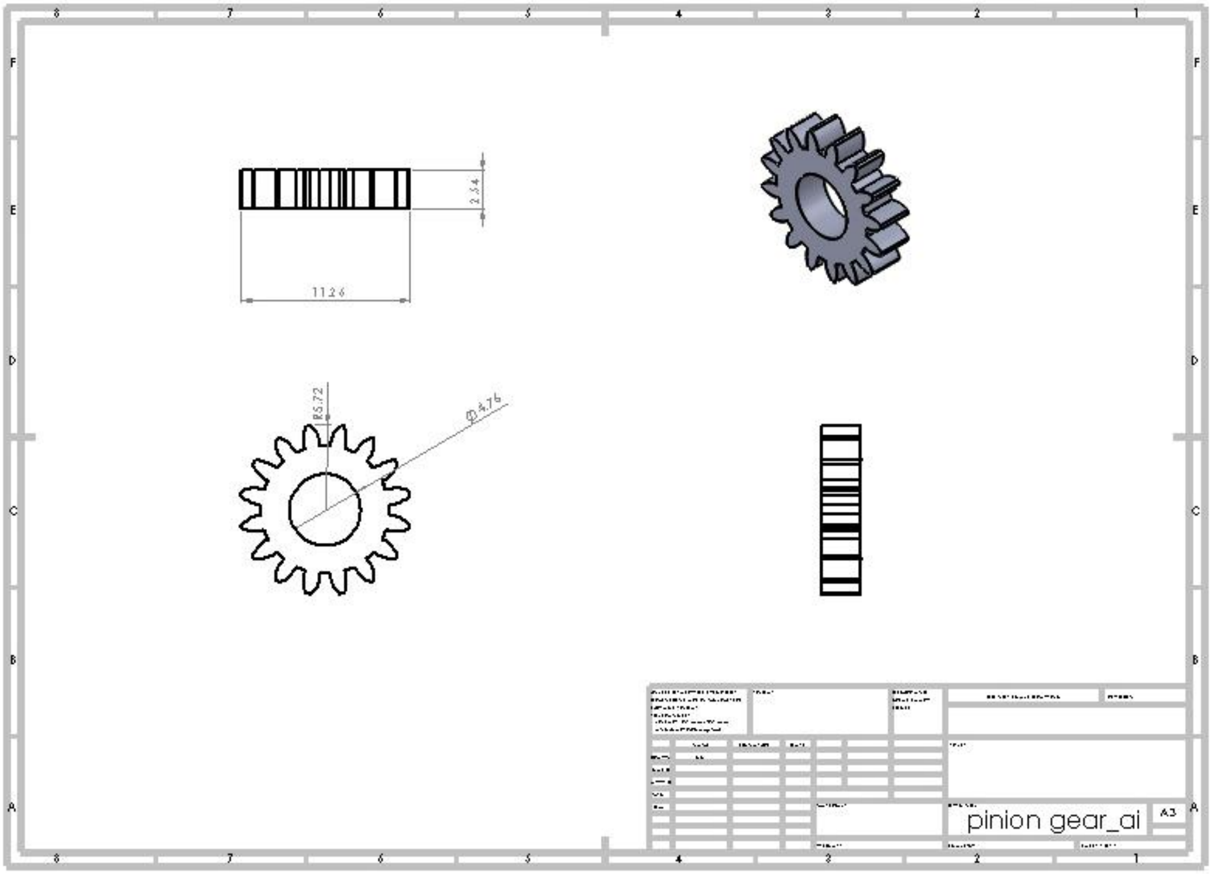


Figure 13. Pinion Gear Drawing

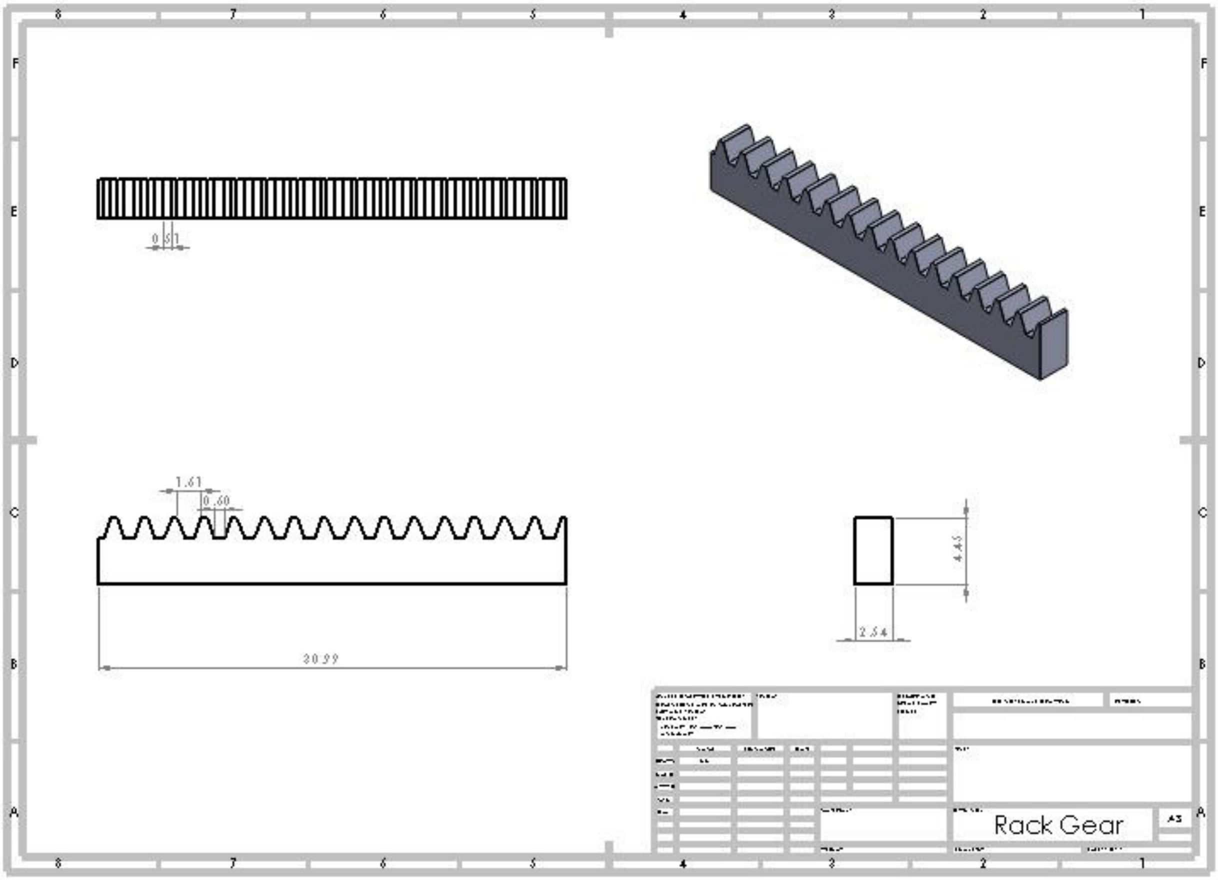


Figure 14. Linear Rack Gear Drawing

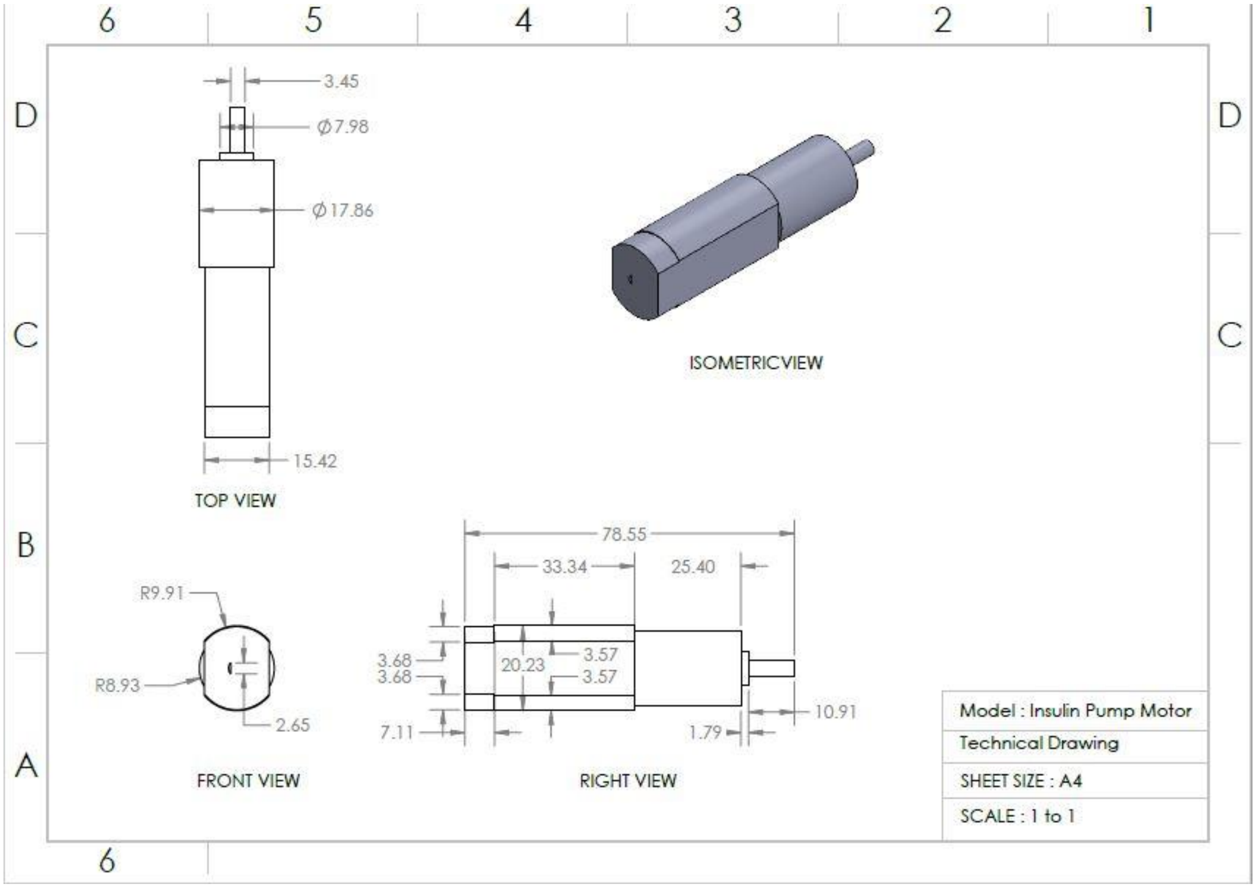


Figure 15. Motor Drawing

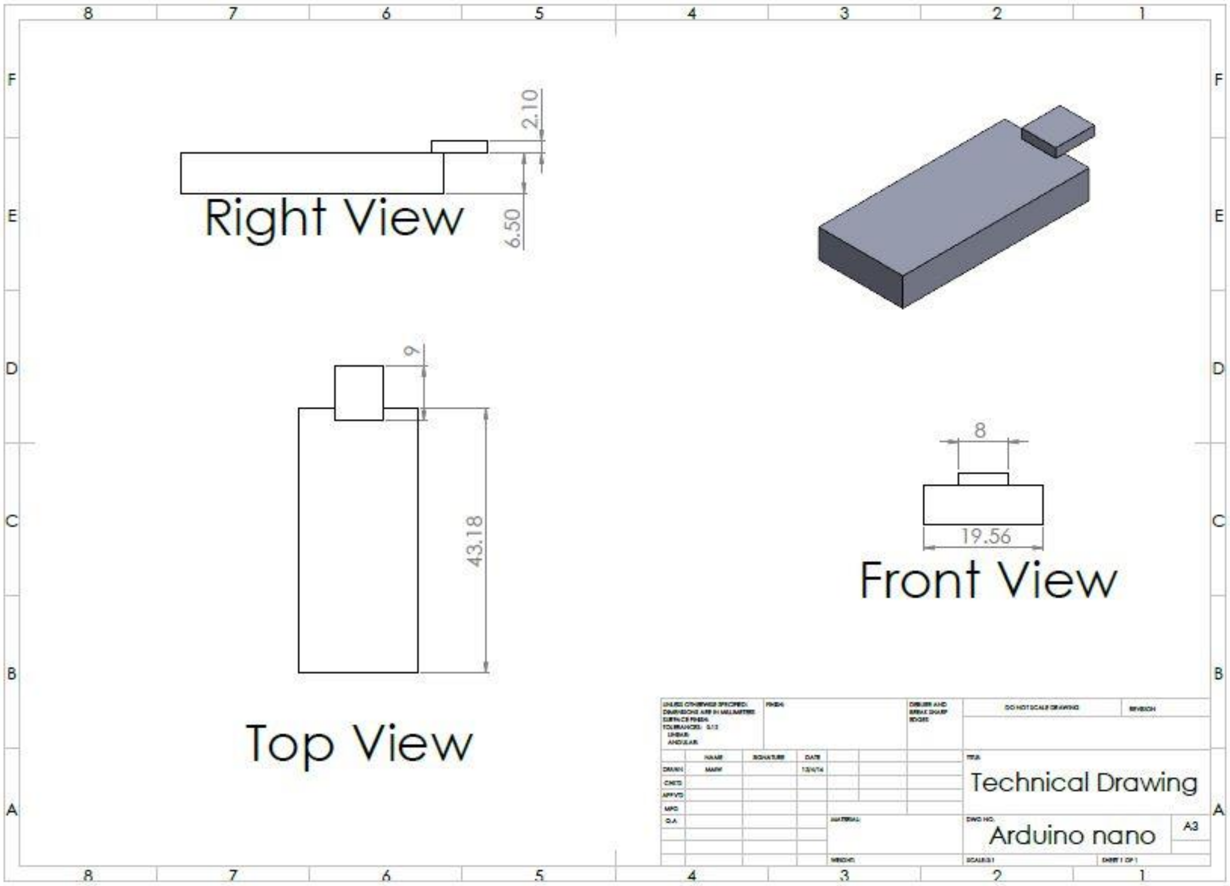


Figure 16. Arduino Nano Drawing