Nimble Needles: Insulin Filling Station

Biomedical Engineering Design Fall 2019 | December 11, 2019

Abby Drake - Team Leader
Jessica Wang - BPAG
Noah Ambroz - BWIG
Aaron Patterson - Communicator
Elizabeth Liu - BPAG

Advisor: Dr. John Puccinelli
Department of Biomedical Engineering
University of Wisconsin - Madison

Client: Michelle Somes-Booher
Wisconsin Small Business Development Center
University of Wisconsin - Madison: School of Business

Table of Contents

Abstract

Self-administering insulin injections can be challenging for elderly individuals with diabetes and lower dexterity. When lining the needle up with the insulin vial, patients with lower dexterity often poke themselves or bend, contaminate, or break the needle, increasing the risk of injury or infection. This risk can be avoided through the creation of a syringe-filling aid, which decreases risk of contamination or needle poke while also increasing the ease of use for patients. Three cost-effective preliminary models of a syringe-filling device were explored to decrease needle-anxiety, financial burden, and safety risk to patients. These models included the Sliding, Corkscrew, and Layered models. Through evaluation via design matrix, the Sliding Model was chosen as the final preliminary design. Building off of this preliminary model, two proposed final prototypes were designed, both incorporating a sliding and locking mechanism. The first proposed final prototype was the Binder Design, which incorporated a rod and clips to create a smooth and secure sliding mechanism. The second proposed final prototype was the Drawer Design, which incorporated a track with grooves to form a sliding and locking mechanism. After conducting MTS testing on both proposed final prototypes and consulting with Proto-Labs for assessment of feasibility of injection molding, the Binder design was designated the final design because it possesses more steady usage and is more feasible for injection molding.

1. Introduction

1.1. Motivation

Diabetes affects one in ten Americans, with type I diabetes affecting only 5% of this diabetic population and type II affecting roughly 95% [1, 2]. In the elderly community these rates are even greater, with 25.2% of people above age 65 living with diabetes [2]. While diabetes is mainly managed through behavioral changes, individuals with diabetes can receive supplemental insulin to maintain blood glucose levels if they have insulin-dependent type I or type II diabetes. One form of insulin supplementation is insulin injections, which is the most affordable option and the option provided through Medicare.

Filling the syringes with insulin is both technically difficult and requires fine motor control. Syringes are filled through three steps: priming the syringe, inserting the needle into the vial, and filling the syringe with insulin. Priming involves first filling the syringe with the same volume of air as the recommended insulin dosage, placing the syringe needle into the insulin vial, and ejecting the air into the insulin vial. This permits insulin to be pulled into the syringe and for the individual to administer the insulin.

Complications of diabetes, such as neuropathy and retinopathy, further inhibit successful completion this life-saving procedure (see Sec. 2.1). In addition, low income and elderly populations are disproportionately impacted by diabetes, and most often use insulin injections, due to this method being the cheapest form of supplemental insulin and Medicare only offering insulin injections [3]. These populations are impacted by additional factors that can further hinder the syringe-filling process, such as lack of access and resources. Thus, accidental needle pokes, needle contamination, bent needles, and insulin wastage, especially while attempting to insert the needle into the vial opening, have a greater impact on these populations [4]. These risks are not only painful and contribute to needle anxiety, but also can be life-threatening, especially when considering the financial burden of insulin and the increased likelihood of infection for an individual with diabetes.

1.2. Existing Devices and Current Methods

Currently, there are three alternatives for insulin injections with a syringe and vial. Insulin pens contain a cartridge, dial to measure dosage, and a disposable needle. The pens can be disposable or reusable, with a replaceable insulin cartridge. This method is growing in popularity due to its ease of use and convenience [4]. Individuals with diabetes can also receive an insulin pump [5], which is a device that mimics pancreatic function by delivering small doses of insulin continuously to the fatty tissue. It is worn on the outside of the body and delivers

insulin via an infusion set and catheter. These two options are both extremely expensive and require extensive training, thus less accessible for lower socioeconomic populations.

Inhaled insulin is also an option, but much less popular than the other three alternatives due to risk of complications if the user has lung problems [6, 7]. An inhaler allows the insulin to be administered via the blood vessels in the lungs. However, it is difficult to ensure an accurate dosage of insulin and is thus used as a back-up plan.

Figure 1: Pictured above is the Prodigy Count-A-Dose with a syringe and two insulin vials in place [8].

In addition, there are devices on the market that aim to ease syringe-filling for individuals with diabetes [9]. For example, the Prodigy Count-A-Dose allows blind individuals with poor motor control to accurately measure out their insulin dosage [8]. However, it is extremely expensive at $69.95 per unit; this would still be unaffordable and inaccessible for the target population. The device also lacks large and consistent surface area upon which to hold, inadequately accommodating the need for easier grip and aided alignment; this would pose a challenge for individuals with lower motor dexterity. There are also devices for visually impaired individuals that magnify the dosage markings on the syringe such as the Insul-eze (Fig. 2), but they also do not address or ease the fine motor techniques required [10].

Figure 2: Pictured above is the Insul-exe with a syringe and vial loaded. The syringe fits into the channel, which aligns the vial and needle. The vial clips into the device as well. It features a two times magnifying tool over the syringe readings to accommodate users with lower visual ability [10].

1.3. Client Information

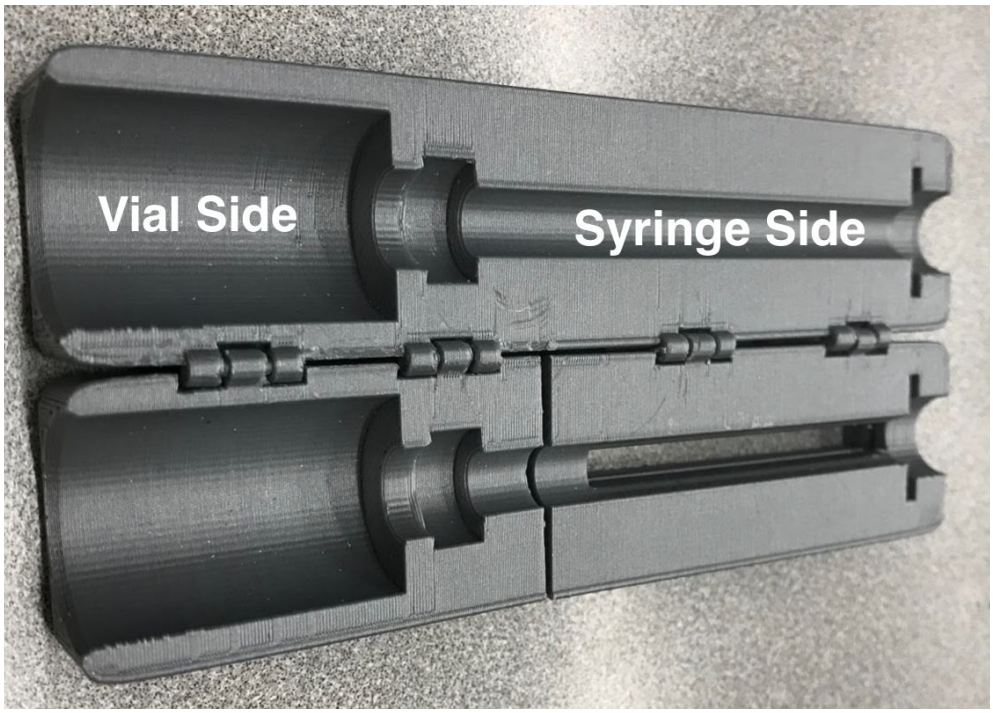


Figure 3: Depicted above is the client's original prototype. It features a well-fit vial cut out, syringe cut out, and cap to cover them during use. It also features a window over one side of the syringe.

Ms. Somes-Booher is the Director of the Wisconsin Small Business Development Center at the University of Wisconsin - Madison and has done thorough research on the viability of putting a syringe-filling aid to market. Her father, an elderly man with insulin-dependent type II diabetes, relies on daily insulin injections and has low motor and visual dexterity. To address his challenges involving insulin injections, he created a prototype and received feedback from peers who also use insulin injections. Based on their feedback, it was evident that a low-cost device that would address the dexterity challenges of insulin injections would be applicable and affect the lives of many diabetic individuals, not just elderly and low-cost populations.

1.4. Problem Statement

Diabetes is one of the most prevalent chronic conditions in the United States [11]. A current treatment option for diabetes is using a syringe to inject insulin; this option is often used by lower income and elderly diabetic patients. Due to complications with diabetes, old age, and financial instability, it is difficult to align the syringe needles and insulin vial opening without risk of insulin waste and syringe needle poke, bending, or breaking. Thus, the team aims to design a device that eases filling syringes with insulin for elderly patients while remaining cost effective, affordable, and accessible.

2. Background

2.1. Diabetes Disease State

Diabetes is a disease that results in excess blood glucose levels. The three types are type I, type II, and gestational. Type I diabetes is caused by an autoimmune reaction that attacks insulin-producing cells, which results in insulin dependence. Thus, individuals with type I diabetes must take supplementary insulin to regulate blood glucose. Type II diabetes is caused by a combination of lifestyle and genetic factors and develops gradually into insulin resistance over a long period of time. Individuals with type II diabetes can often manage the disease through behavioral changes, but may also use supplemental insulin. Gestational diabetes develops during pregnancy but often disappears post-partum [12].

There is no cure to diabetes, so individuals have to manage the disease and blood glucose levels through behavior and lifestyle changes, such as: maintaining a healthy diet and exercising regularly. As previously mentioned, individuals with diabetes can also receive supplemental insulin in a variety of forms (see Sec. 1.2).

The most relevant complications for the project are neuropathy, or numbness and tingling in the limbs, and retinopathy, or blurry vision. Both of these arise due to high blood pressure in diabetic patients and are chronic conditions [13]. In addition, having diabetes can increase the risk of infections and conditions that often result in poor motor control, such as stroke [14].

The epidemiology of diabetes is also important to acknowledge because it disproportionately impacts low socioeconomic and lower educational levels, as well as certain racial groups [3]. These populations also tend to be impacted by additional barriers to diabetes management, such as limited resources due to geographic location or financial constraints. Thus, the public health implications of this device are significant, as reducing barriers and increasing accessibility to self-administration of insulin injections is vital to addressing disparities in diabetes treatment and management.

2.2. Design Specifications

This product will primarily be aimed at making administering insulin injections easier, safer, and more affordable for individuals with low dexterity and economic status. However, it could be applied to at-home injection treatment. Therefore, the main three criteria that the design must meet include cost-effectiveness, safety, and ease of use for the user.

The cost of manufacturing per product must be under three dollars per device. In addition, the device must increase ease of use in filling a syringe with insulin, so the user must be able to grip it more easily and visually measure how much insulin is entering the syringe. Because the client wishes to take this product to market, the exterior must also be customizable

for advertising purposes. Thus the material must be able to dye or print on, and there must be a surface to place advertisements on.

The device must also increase the safety of filling syringes by decreasing the risk of broken or bent needles. Therefore the device must align the syringe needle and vial opening while stabilizing both during syringe filling. The most significant safety requirement is ensuring the sterility of the needle, inhibiting bacteria growth, and preventing secondary infections in the patient. The device must be made of sanitary non toxic materials and contain minimal crevices where bacteria could colonate. In addition, it must be easy to sanitize the device, likely through hand-washing in the sink. The device must also allow for visual measurement of the amount of insulin entering the syringe; therefore there must be a window or a read-out for the units of insulin in the syringe. In addition, the device must be able to withstand the daily axial loading of 5.29N involved with loading a syringe with insulin. This daily wear and tear should be able to be withstood on a regular basis, and the device must maintain its performance while being used two to four times per day. The user needs to be able to strongly grip the vial and syringe to prevent slippage or insulin waste.

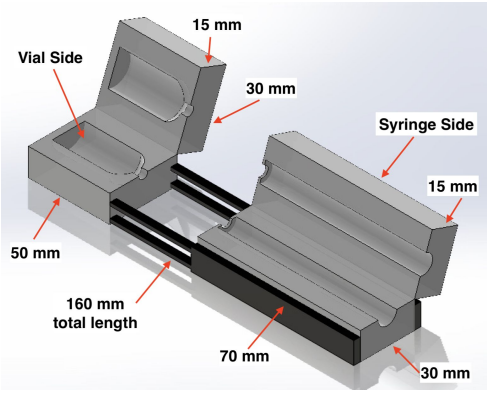
The device must be able to durably withstand a certain set of environmental conditions related to the insulin storage and insulin injection. Since it will likely be used in nonclinical settings, the device must be able to withstand a wide variety of temperatures. Insulin is generally kept in the patient's refrigerators, so if the device is also stored in these locations for convenience, it will have to sustain in long term conditions between 4°C-23°C [15]. The product will have to sustain in 15%-50% humidity levels [16], and an average outdoor temperature range of the United States climate, 4°C-32°C [15], as this product is being marketed for sale in the U.S. It must survive under these diverse environments for at least five years. In addition, the device must also be able to withstand drops from up to two meters, such as from household surfaces such as bathroom countertops or from a standing height [17]. Since the average male height is greater than the average female height at 1.71 meters and most surfaces are lower than human height, a threshold drop height of two meters is sufficient. The device should be easy to grip, even when in contact with water, since patients often perform insulin injects in bathrooms or kitchens, which often have wet countertops.

To further increase ergonomics, the device should not weigh more than 0.227 kg with the syringe and vial included [18], therefore means that the device alone can weigh no more than 0.214kg due to syringe weight with insulin [19]. This is to ease the effort for a low motor dexterity user. The device must have a flat base, such that it inhibits rolling when placed on a flat surface during use. In addition, the device must accommodate all syringe and vial sizes to make the device as accessible and applicable for as many populations as possible (see App. 13.2).

3. Preliminary Designs

3.1. Preliminary Design 1: Sliding Model

The Sliding Model has the vial and syringe in separate compartments. The compartments are connected by a sliding mechanism, so that the distance between them is adjustable. This design ensures that the needle is inserted into the vial in a straight line and without being bent. The sliding mechanism will be designed so that specific lengths can be locked in place by the user using either notches or friction. Being able to adjust the lengths between the two components is advantageous because it can accommodate various needle lengths especially since needle sizes vary drastically (See Fig. 6). This design also adjusts accordingly to the volume of insulin left in the vial by being able to customize the depth of the needle inserted in the insulin vial. Since insulin is extremely expensive, being able to use all of it is beneficial to target consumers. One of the biggest cons to the sliding design is that devising a way to both lock and slide the device without adding multiple components would be challenging. The fact that the device slides also adds one more adjustment step for the user. If the mechanism does not slide smoothly, it could cause trouble for low dexterity users that the device is intended to fix.



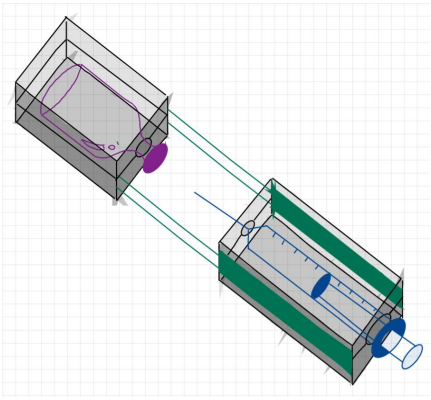


Figure 4: Depicted above is the sliding model in Solidworks. **Figure 5:** Drawn above is the sliding model.

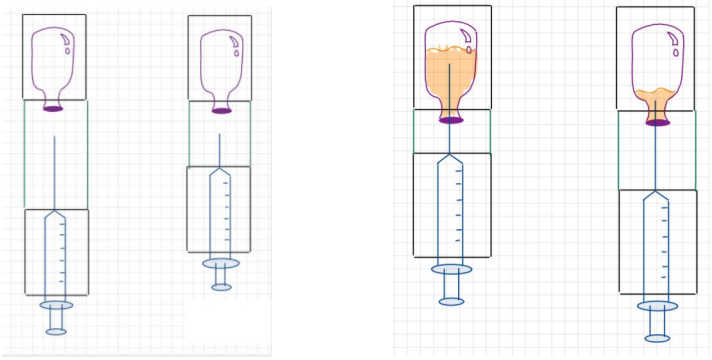


Figure 6: This design is able to accommodate for the greatest range of length, which is optimal due because levels of insulin within the vial are not consistent. The image on the left is displaying different needle lengths, and the image on the right is displaying different needle penetration depths.

3.2. Preliminary Design 2: Corkscrew Model

The Corkscrew Model uses a cone-shaped insert to fit various sized syringes and uses a threaded cone insert to fit various sized vial heads. The vial end would be a threaded cone so that any radius of vial head could be twisted snuggly into the device. The design is simple and easy to fabricate as it only requires drilling and threading. The syringe is pushed into the tapered cone and snuggled in based on its radius (see Fig. 8). Both the threaded and tapered cones accommodates for varying vial and syringe. Although the mechanics of the design would help guide the needle into the vial, the motion to tighten and screw the syringe in would be difficult to accomplish for an individual with low motor dexterity. Because the design does not fully guide the user's motion when inserting the syringe, the needle may get caught on the threading or edges and thus break more frequently than normally. After filling the syringe, the user would also have to unscrew a loaded syringe, which could prove cumbersome. This also introduces risk of contamination should the needle come into contact with the inside of the device.

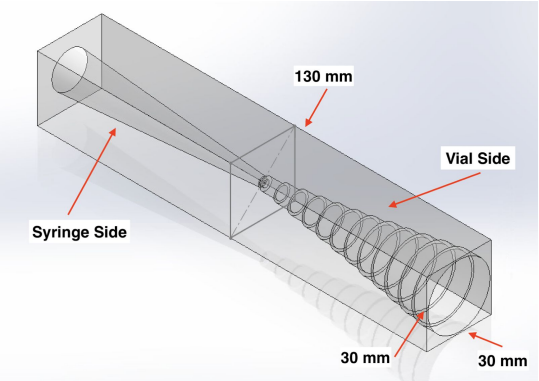


Figure 7: Depicted above is the corkscrew model in Solidworks.

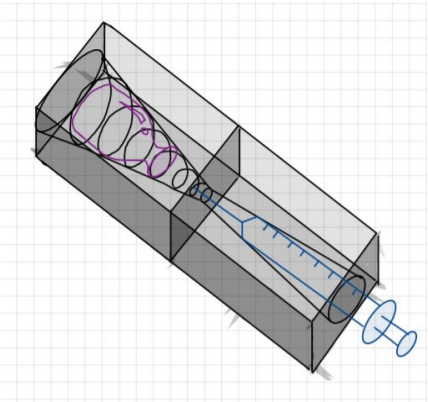


Figure 8: Drawn above is the corkscrew model.

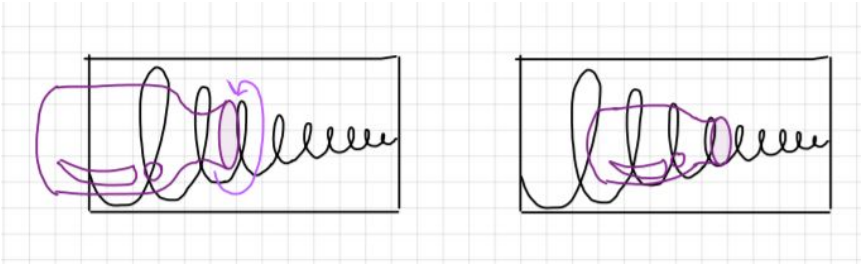


Figure 9: As the vial, shown in purple, is twisted into the device, the lip of the vial itself will be screwed in tightly.

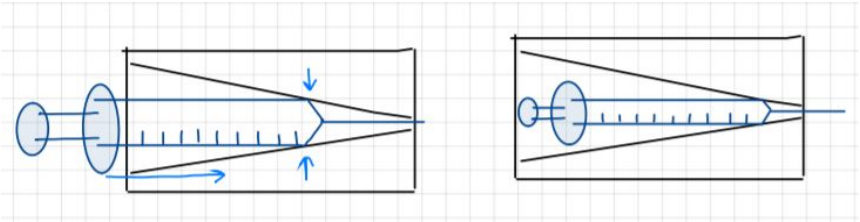


Figure 10: As the syringe, shown in blue, is pushed into the device, the threaded cone will eventually inhibit forward motion, but ensure that the syringe is snug within the device.

3.3. Preliminary Design 3: Layered Model

The Layered Model design consists of three separate layers, a velcro component, and a clip in function. It also possesses a surface for advertising purposes. The innermost layer would be made of a material with a grip to prevent sliding. This would interact with the syringe and vials directly, prevent vial and syringe translation in the device, thus ensuring a snug fit. The middle layer is made of malleable silicone to accommodate different radii of vial or syringe. The outermost layer would be a hard external silicone shell. This layer enhances the devices durability, and gives the user a hard component that is easy to grip firmly. There would also be an open window so the user can easily see how much insulin is being drawn.

On the syringe side, there would be an opening for the syringe plunger, and on the vial side, there will be an opening for the vial end. Velcro will wrap around the exterior of the device to secure the vial end and plunger. The transverse pressure from the malleable middle layer and innermost layer with grip would help minimize vial and syringe movement during syringe loading. Due to the use of multiple materials, cost of production may be the greatest with this preliminary design. Additionally, manufacturing would be more complicated due to the variable materials and need for assembly. This would likely decrease the durability and longevity of this design because the added components are likely to break or rip off with long-term use. Crevices in the velcro would also foster bacteria colony growth and would be difficult to sanitize.

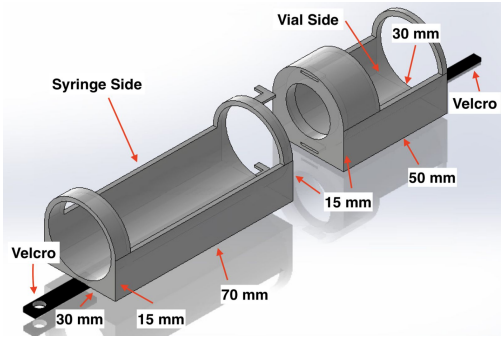


Figure 11: Depicted above is the layered model in Solidworks.

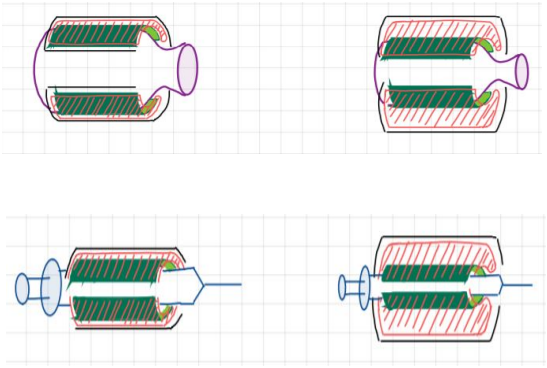
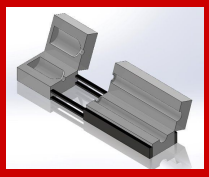
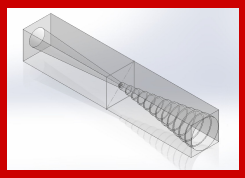
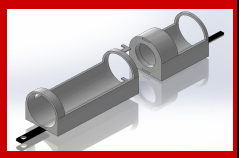


Figure 12: Drawn above is the layered model.

4. Preliminary Design Evaluations

4.1. Preliminary Matrix and Criteria

Design Criteria	Weight	 Sliding Model		 Corkscrew Model		 Layered Model	
Safety	20	5/5	**20**	2/5	**8**	3/5	**12**
Ease of Use	15	3/5	**9**	5/5	**15**	2/5	**6**
Manufacturing	15	5/5	**15**	4/5	**12**	3/5	**9**
Adaptability	15	3/5	**9**	4/5	**12**	5/5	**15**
Durability	10	4/5	**8**	5/5	**10**	4/5	**8**
Feasibility	10	5/5	**10**	4/5	**8**	3/5	**6**
Marketability	5	5/5	**5**	5/5	**5**	4/5	**4**
Total	100		**76**		**70**		**60**

Safety: The goal of this insulin filling aid is to reduce the number of unnecessary needle pricks and bends, ensure a sterile environment, and improve dose accuracy. Thus, this category was given a weight of 20/100. It is the highest ranked criteria because these specifications all improve safety of user. There should also be a reduced number of crevices that foster bacteria growth, be easy to sterilize, and be made of non-toxic materials.

Ease of Use: The insulin filling aid should be easy to use; meaning, the device should limit the amount of steps and movements necessary to operate effectively. The viewing window of the syringe should be large, the device should be easy to grip, and the cleaning technique should be quick and simple. This category was given a weight of 15/100 because the device is intended to ease filling a syringe with insulin, meaning the process of using the device should take less time, steps, and energy than filling a syringe without the device.

Manufacturing: The device is meant to be a lower-income alternative to other syringe-filling aids; meaning, the device's manufacturing must be three dollars per device or less to be

cost-effective enough for the lower socioeconomic market. This criteria should also include cost of manufacturing equipment. This category was given a weight of 15/100, equal to ease of use, because the manufacturing method, and therefore price, could determine the product's success.

Adaptability: The aid must be able to accommodate various sizes and lengths of insulin vial, needle, and syringe because they are not standardized. Any size should fit snugly within the device while also allowing for easy removal. This was given a weight of 15/100, equal to manufacturing and ease of use, because it has the ability to greatly increase the potential market population and determine the applicability of the device.

Durability: The device must be able to withstand drops, forces involved with syringe loading, and extreme temperatures. This was given a weight of 10/100 because the use of this device does not warrant large distance drops or the use of large force upon the device.

Feasibility: The aid should be able to be fabricated with ease due to the time constraints of the project and limited experience of the fabricators. This category was given a weight of 10/100 because none of the proposed designs were above the team's ability to fabricate. Ensuring university access to manufacturing equipment and tools is a component of feasibility.

Marketability: The outer surface of the device must have the ability to be personalized, and market cost must be affordable for the lower-socioeconomic class. This was given a weight of 5/100 because as long as the device is within the manufacturing guidelines, it will be within an affordable market price range. Also, each of the designs has the ability to be customized.

4.2. Preliminary Design Matrix Evaluation

The Sliding Model ranked the highest in safety because the design greatly reduces the risk of contamination, needle pokes, or needle bends. With safety being the highest weighted design criteria, it was important that the design chosen addressed this specification. The Corkscrew and Layered Model scored lower in safety because of the increased risk of contamination in each design. In the Corkscrew Model, there is an increased risk of needle contamination within the tapered-cone syringe side; this tapered cone also introduced increased risk of needle bending, as they are extremely fragile and cannot withstand great force. In the Layered model, the velcro straps and crevices of this design introduce breeding grounds for bacteria, which increase the risk of infection to the user.

The Corkscrew Model scored highest in ease of use because of its intuitive design. The user would easily the device in two steps: put the syringe in one side and twist the vial into the other. There are many steps necessary to effectively use the Sliding model, so it was scored just a

three out of five. The intricate design caused the Layered model to score very low in ease of use with a three out of five. The design has many steps in use which drives ease of use down.

In manufacturing, the Binder Model has another top score because the design incorporates halves, which would be very easy and cost effective to injection mold. The Corkscrew Model did not receive perfect notes in manufacturing due to the closed design, making it difficult to injection mold. Lastly, the Layered Model scored the lowest in manufacturing due to the variability in material necessary to produce.

Scoring only three out of five in adaptability, this Sliding Model accommodates different lengths very well, but does not have the best mechanism set in place to accommodate for different vial and syringe radii. With four out of five in adaptability, the Corkscrew Model is able to accommodate different lengths and radii well, but there was concern of how stable those tight fits would be, so it did not have a perfect adaptability score. The Layered Model, the lowest scoring model, received highest marks only in adaptability. The model has great adaptability, as it accommodates for any length or radius of needles, vials, and syringes.

Because there are fragile sliding tracks incorporated into the Sliding Model, it is more likely to break and thus scored just four out of five on durability. The heft of the design, with no small pieces, awarded the Corkscrew model a perfect score in durability. The Layered model also relatively low scores for durability because of the intricacies of this design. Small components mean the design is more fragile, harder to fabricate within the desired time frame, and creates less surface area upon which to market. The mechanical mismatch between layers also introduces points of strain.

The Sliding Model ranked highest in feasibility because the design incorporates many design concepts from the client's original prototype, so guidance would be available. The Corkscrew Model received a four out of five in feasibility due to the challenge of creating a thread that is both tapered and big enough to accomodate all vials. Lastly, the Layered Model is ranked lowest in feasibility due to the intricacies of the design.

The Sliding Model and Corkscrew Model were ranked highest in the last criteria, marketability, because they each feature a large surface upon which to market or personalize. The Layered Model does not have as great of a surface, so it was ranked below these two.

Overall, the Sliding design was also the most intuitive design to the client due to it's easy to use and familiar sliding nature. Although the Corkscrew Model is scored just six points beneath the Sliding Model, the risk of contamination is of great importance in the design of this product and thus takes the Corkscrew model in the current state out of consideration. Last, although the Layered Model does an impeccable job of adapting to different sized needles, syringes, and vials, it forfeits many other qualities in the effort to adapt. For this reason, it was awarded the least amount of points.

4.3. Final Preliminary Design

After evaluating the three proposed design ideas (see Sec. 3), the Sliding Model will be used as a preliminary prototype. This model was chosen because of multiple aspects that will benefit the client and the diabetes community in general. Most importantly, it reduces the risk of contamination during insulin syringe filling. It is vital to keep insulin injection process sterile to avoid any risks of infection from the needle. Also, the device is easy to manufacture. The proposed method of manufacturing is injection molding. Using this process, the sliding device will be efficient to manufacture. The two halves could be injected at the same time and then could be easily attached to create the whole device with a few steps for full manufacturing. Similarly, the sliding mechanism of the device is simple to fabricate. The sliding portion requires a small amount of material, which can also be injected molded similar to the other aspects of the device. This lowers cost and time of fabrication, making the manufacturing process more affordable and time-effective. The sliding aspect also provides easy sliding ability. Specifically, the user can easily slide the syringe half towards the vial with little trouble. This also removes visual and motor obstacles of aligning the syringe needle and vial, which is important for lower dexterity users. Finally, the device, if needed, can be customizable for the user. As mentioned previously, the client requires a device that is marketable. The large surface area of the device can accommodate for various levels of marketing (personal sleeves, stickers, etc.). Because the sliding model provides necessary safety, mobility, customizability for the user, while also being easy to fabricate, the sliding model will be the design used to create a preliminary prototype.

5. Proposed Final Designs

5.1. Design 1: Binder Model

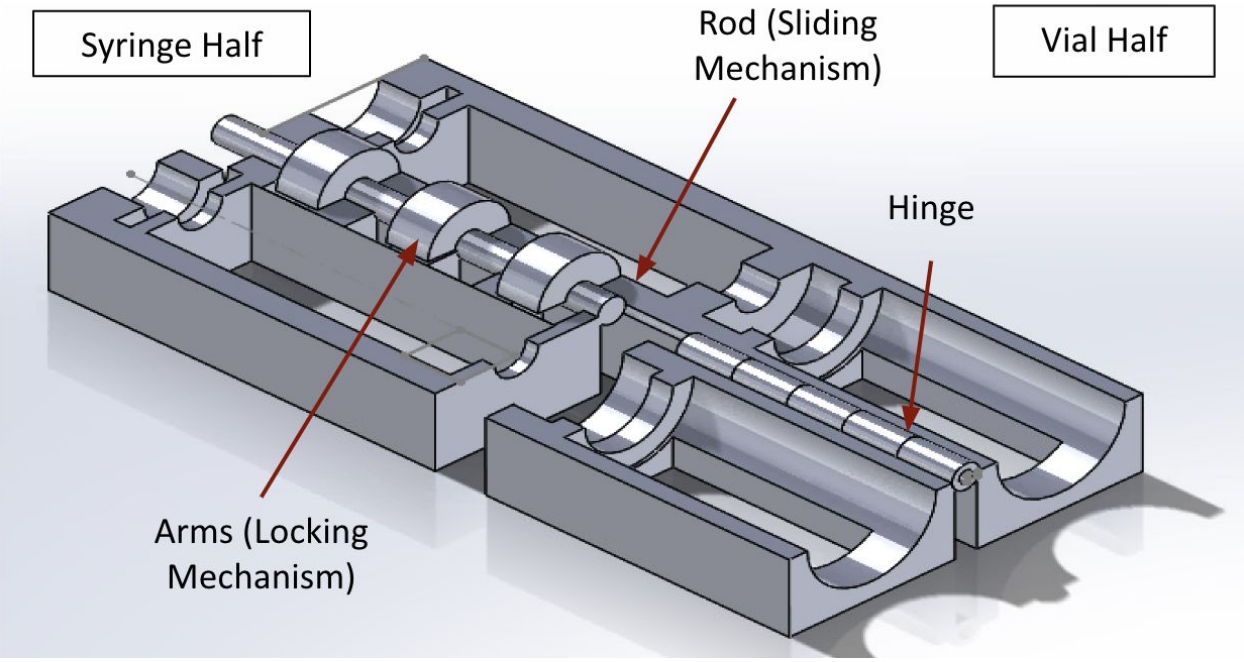


Figure 13: Depicted above is the Binder Model design in Solidworks.

The Binder Model features dual viewing windows, a vial cutout with hinges on one side, and a syringe cut out with a rod-like sliding mechanism on the other side. This sliding mechanism incorporates a rod and arms that glide the needle into the vial opening. Once in alignment, the device can be closed and locked in the axial direction, allowing the user to steadily withdraw insulin. The arms slide into holes along the opposite half to function as a locking mechanism, and the spacing of the holes allows for different needle penetration depths. A downfall is that the binder design lacks the degrees of freedom in the unlocked position that the drawer design possesses. In addition, the design lacks stability when opened, as the sliding syringe half has the ability to completely slide off of the device.

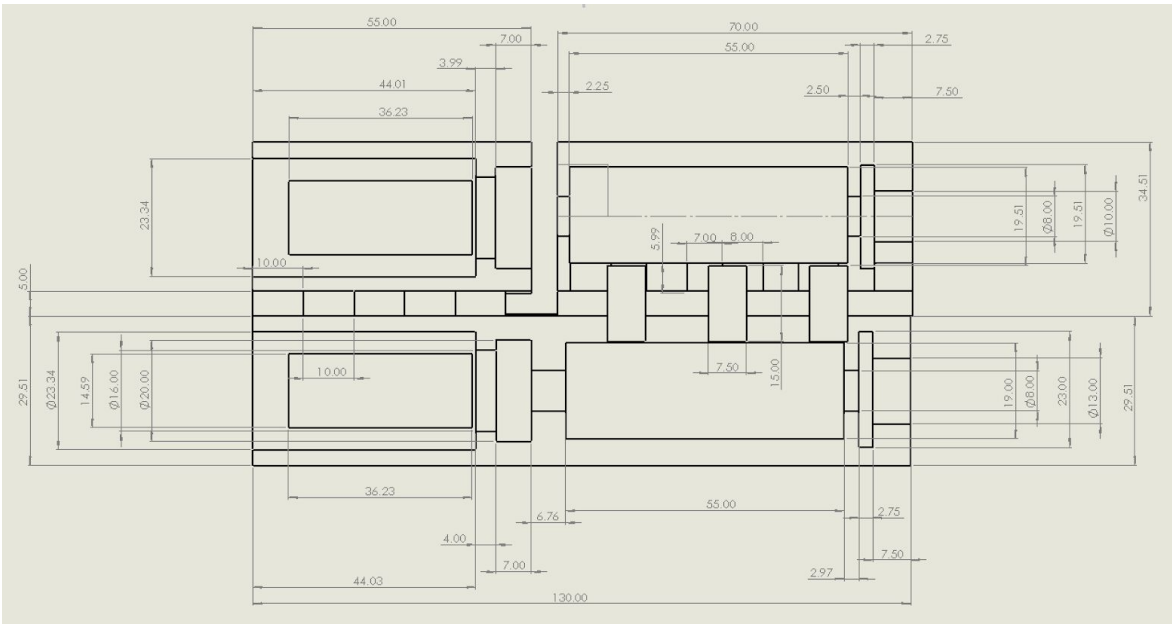


Figure 14: Depicted above is an aerial drawing of the Binder design. All dimensions are in millimeters, and a circle with a backslash denotes a diameter.

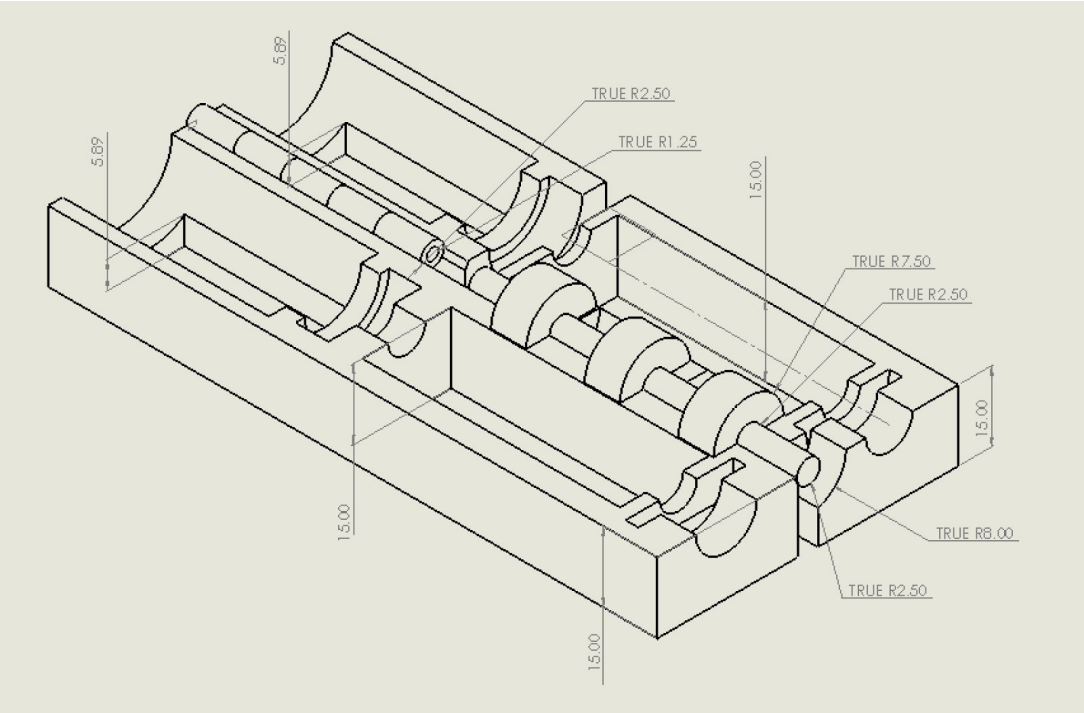


Figure 15: Depicted above is another drawing of the Binder design. Again, all dimensions are in millimeters, and a circle with a backslash denotes a diameter.

5.2. Design 2: Drawer Model

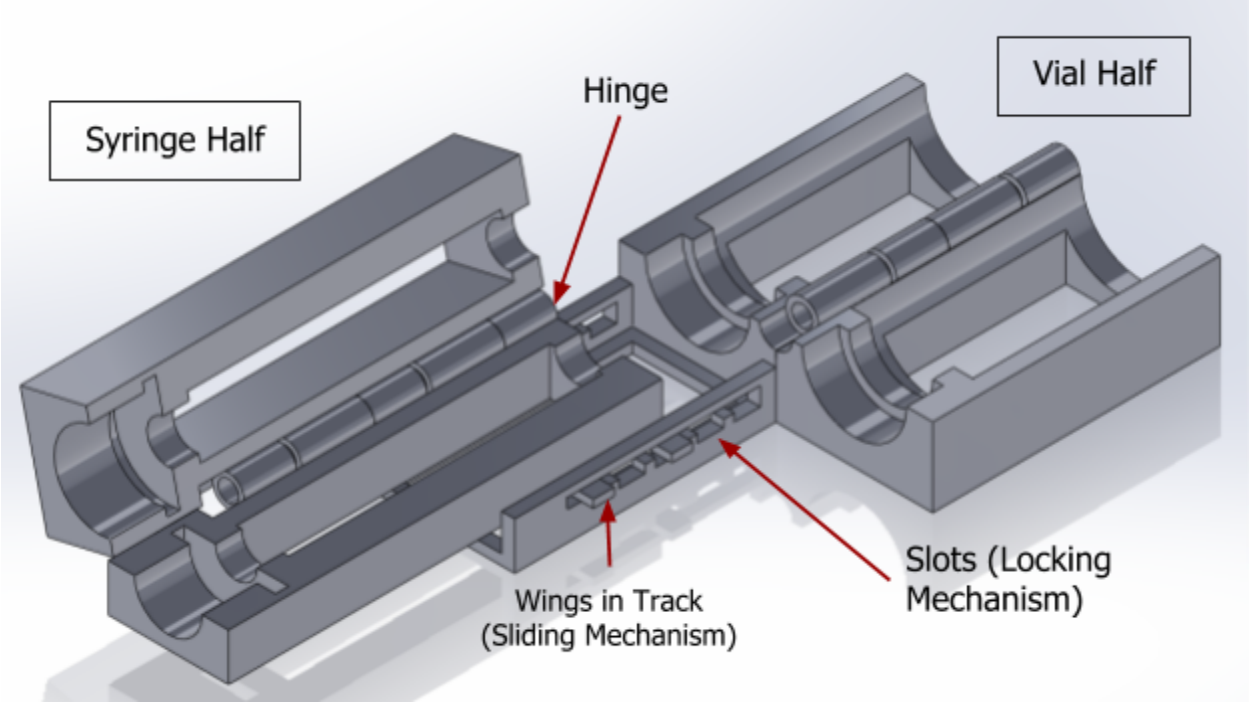


Figure 16: Depicted above is the Drawer Model design in Solidworks.

The Drawer Design also features dual viewing windows, a vial cutout with hinges on one side, and a syringe cut out with a drawer-like sliding mechanism on the other side. The syringe side slides on a track built into the side of the device. Wings hold the syringe side in place as it glides, and grooves serve as a locking mechanism. The grooves also inhibit axial motion during syringe loading and maximize needle angle flexibility. Like the Binder Design, the grooves sit at different spacing to allow for different needle penetration depths. The Drawer Design when locked when locked into place, however, is less secure than the Binder Design. Additionally, the drop in syringe height when the device goes from the unlocked to locked position increases risk of needle bends.

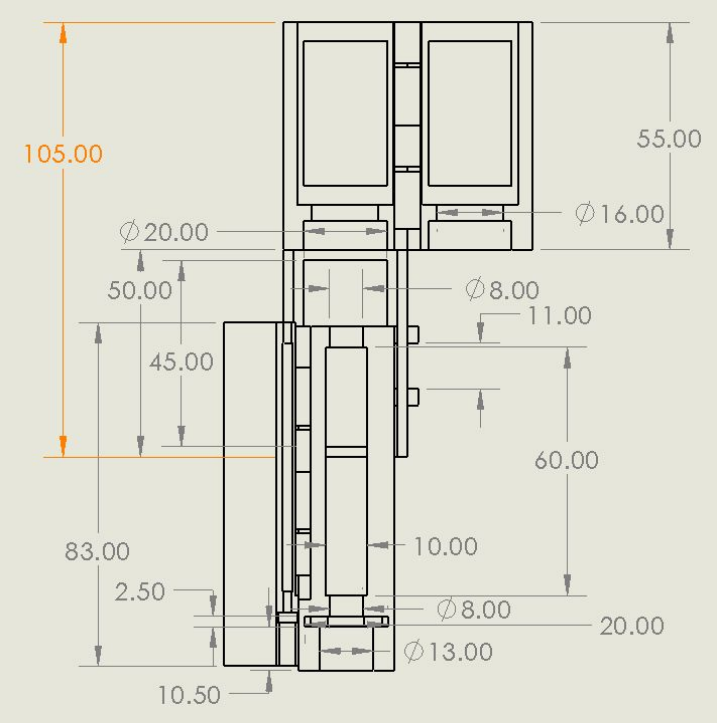


Figure 17: Depicted above is an aerial drawing of the Drawer design. All dimensions are in millimeters, and a circle with a backslash denotes a diameter.

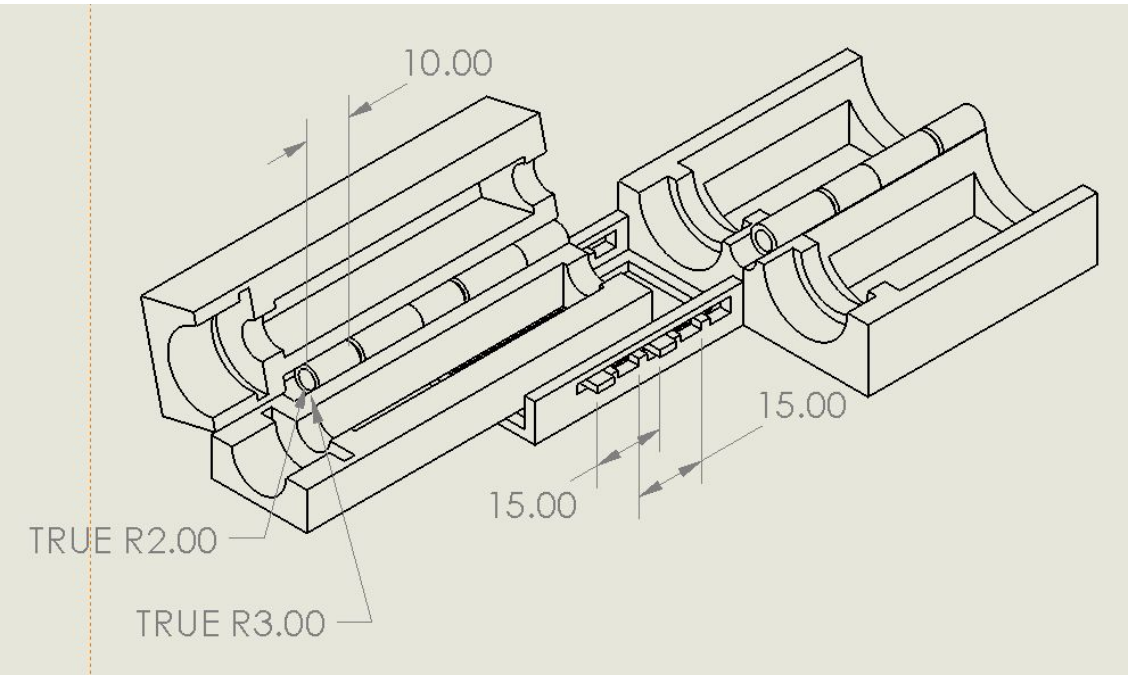


Figure 18: Depicted above is another drawing of the Drawer design. Again, all dimensions are in millimeters.

6. Final Design Evaluations

6.1. Final Criteria

Design Criteria	Weight	Original Prototype		Binder Model		Drawer Model	
Safety	25	3/5	**15**	5/5	**25**	4/5	**20**
Ease of Use	25	2/5	**10**	4/5	**20**	5/5	**25**
Manufacturing	20	5/5	**20**	4/5	**16**	3/5	**12**
Component Stability	20	5/5	**20**	4/5	**16**	3/5	**12**
Durability	10	5/5	**10**	4/5	**8**	4/5	**8**
Total	100		**75**		**85**		**77**

Safety: The goal of this insulin filling aid is to reduce the number of unnecessary needle pricks and bends, ensure a sterile environment, and improve dose accuracy, thus this category was given a weight of 25/100. It is the highest ranked criteria because these specifications all improve safety of user. There should also be a reduced number of crevices where bacteria could gather, and the material must be non-toxic.

Ease of Use: The insulin filling aid should be easy to use, meaning the device should limit the amount of steps and movements necessary to operate effectively. The viewing window of the syringe should be large, it should be easy to grip, and the cleaning technique should be quick and simple. This category was given a weight of 25/100 because the device is meant to make filling a syringe with insulin easier, meaning the process of using the device should take less time, steps, and energy than filling a syringe without the device. Additionally, the sliding and locking mechanism of the device should be intuitive for the user.

Manufacturing: The device is meant to be a lower-income alternative to other syringe-filling aids, meaning the device's manufacturing must be three dollars per device or less to be cost-effective enough for the lower socioeconomic market. This criteria should also include cost of manufacturing equipment. This category was given a weight of 20/100, equal to ease of use, because the manufacturing method, and therefore price, could determine the product's success.

Component Stability: The vial, syringe, and needle should be secure in the sliding and locking portions of the device to reinforce safety and prevent slipping of the needle. Also, the syringe

and vial halves should lock securely and withstand the forces involved in filling the syringe with insulin, i.e. hand tensile and compressive forces. Thus, the category was given a weight of 20 out of 100.

Durability: The device must be able to withstand drops, bumps, and extreme temperatures. This was given a weight of 10/100 because the use of this device does not warrant large distance drops or the use of large force upon the device.

*Many of these criteria are similar to the preliminary design criteria set in Sec. 4.1. They are repeated here with alterations based on the final design criteria for reference and new weights.

6.2. Final Design Matrix Evaluation

Each model was evaluated using the criteria above. The Binder Model ranked highest in the most important criteria, safety. The Binder Model is the most stable upon closure. The stability decreases the chance of adverse events by driving down the occurrence of needle bends, breaks, and pokes. The original prototype also had great stability, but it has no mechanism to avoid needle bends, thus the user must still manually line up the needle and vial head. This design also features less pinchability than the Drawer Model, whose sliding track may catch skin or fingers.

Equal weight to safety, ease of use is next on the list of final design criteria. The Drawer Model scored the highest in this category because it is the most user friendly. By simply dropping in the syringe, vial, and then shutting the caps, the user has a larger, more ergonomic device to hold when sliding. The Binder Model, on the other hand, must be slid together while open, allowing for less gripping surface area. Lastly, the original design was given a low score for ease of use due to no alignment aid in alignment of the needle and vial head.

As for the manufacturing rankings, ProtoLabs was consulted regarding the feasibility of injection molding. Due to the lack of mechanical or chemical connections between the sliding components in the Drawer design, it would be impossible to manufacture via injection molding because the parts cannot be molded together and cannot be assembled after.

Once closed, the original prototype has the greatest component stability. This makes sense, as the window on this prototype was the smallest, so there was more surface area of the device to make contact with the syringe and vial within the device. The Binder Model achieved the next best component stability due to the secure nature of the device in the locked position. When locked axially, there is virtually no axial movement possible, keeping the components in place. Lastly, the Drawer Model kept the components the least stable as the syringe side was able to move independently of the vial side even when locked.

Lastly, the original model ranked highest in durability. With no small pieces, it is least likely to be broken during drops or usage. The Binder Model ranked below the original because

of the clips used in the locking mechanism; they could break easier because they are smaller features, which are inevitably more fragile. The Drawer Model tied the Binder because it, too, has small features like the wings on the track that have the potential to break easily during use or drops.

7. Fabrication Methods

7.1. Materials

7.1.1. Tough PLA

The preliminary prototypes were printed in Tough PLA (Polylactic acid) due to its affordability. Prototyping locking and sliding mechanisms using Tough PLA allowed multiple iterations to be printed for a low cost to determine specific dimensions and tolerances. In addition, Tough PLA has similar material properties to ABS, which is what the injection molded device will be made of [20]. For example, the tensile strength of Tough PLA is approximately 1.82 GPa, and the tensile strength of 2.5 GPa. However, it is still easier to print with and work with than ABS, which resulted in quicker prints and a faster prototyping process [21].

7.1.2. ABS

ABS (Acrylonitrile butadiene styrene) is a widely used material for injection molding due to its high strength, low cost, and versatility [22, 23]. In addition, it is customizable since it is easy to color the exterior. The two final prototypes and testing pieces, the Binder Design and the Drawer Design, were both printed in ABS. This not only allowed the testing results to be more applicable to injection molded versions of the device, but also produced final prototypes that are more similar to an injection molded version of the device.

7.2. Methods

7.2.1. Computer Aided Design

Prior to printing prototypes, the design was first created in Solidworks. This process not only allowed for 3D printing in the future, but also allowed for visualization and initial testing of the designs in Solidworks, especially regarding the hinge connections, sliding mechanisms, and locking mechanisms.

7.2.2. 3D Printing

The initial prototypes, such as the prototype iterations of the locking and sliding mechanisms, were printed using the Ultimaker 3D Printer with Tough PLA. This resulted in a lower cost and faster print, but it also had lower a lower accuracy [24]; this worked well for the prototyping process because it allowed for multiple iterations to be printed cost-effectively and for the dimensions and tolerances to be determined quickly. Preliminary design prototypes were also printed on this 3D printer, which aided with preliminary design matrix decisions.

The two most feasible final designs were then printed using the Stratasys F370 using ABS [25]. This was a more expensive print but it did allow for more accurate print and a smoother exterior. However, the greater accuracy and print quality was necessary to print certain aspects of the final designs, such as the closed cylinders needed for the hinge connections.

While the final designs were printed to mimic injection molded products, there were crucial differences between the products from injection molding and 3D printing. For example, in 3D printing, layers of thermoplastic material are deposited on a build platform via pushing filament through a heated nozzle. The material then quickly solidifies. While it is affordable and easy to work with, a key weakness of the process is the anisotropic material properties of the resulting parts. The filament is strong, but the bonds between layers is weak, resulting in a more brittle product overall [26].

7.2.3. Vapor Smoothing

Vapor smoothing was used on the final designs to create a smooth and shiny surface. By suspending the 3D printed part in a closed system over heated acetone, gaseous acetone is formed. The gaseous acetone chemically reacts with the ABS printed parts, weakening the surface bonds in the polymer chain to allow the molecules slide past each other into a more stable position: the glass transition state [26]. The acetone diffuses from the surface plastic when the part is removed from the system, and the part rehardens with a glassy, smooth surface, the result from the glass transition. This process is aided by the fact that the boiling point of acetone at 56 degrees Celsius is lower than the glass transition temperature of ABS at 105 degrees Celsius [27, 28].

7.2.4. Prototype Assembly

First, the final designs were created in Solidworks in 3 separate parts. For the Binder Design, the syringe container, vial container, and the combined syringe and vial lid were all printed and designed in Solidworks separately. For the binder design, the syringe cap, the vial cap, and the combined syringe and vial container were all designed in Solidworks and printed separately.

Both final designs were printed on the Stratasys using ABS. After printing, there was assembly required for both final designs. For the Binder Design, the vial hinge halves had to be assembled and connected using a metal pin. For the Drawer Design, both the syringe and vial hinge halves had to be assembled and connected using a metal pin.

8. Prototype Testing

8.1. Visibility Testing

As low visual dexterity is a result of diabetes complications and old age, three options were considered to improve the visibility of the syringe measurement marks in the device. The first was a window on the front and reflective silver paint on the back, which may help reflect incoming light to assist with visibility. The second was a double window, one on the front and back, which may allow for backlight to enter the device. The third was a window on the front and a solid, white ABS on the back. The team qualitatively analyzed the syringe in the three options to determine which improved visibility of the syringe measurement marks.

These three options were tested with a syringe both on a table and held up to direct light in low and high light conditions because this device will likely be used in a variety of nonclinical settings, such as at the patient's home or workplace.

8.2. Force Testing

Testing was performed to characterize the forces involved with filling a syringe with insulin. These results would then allow certainty that the devices can withstand the forces, especially in the locked position, as this would be the position of the device when the patient is actually filling the syringe and thus applying the most force to the device.

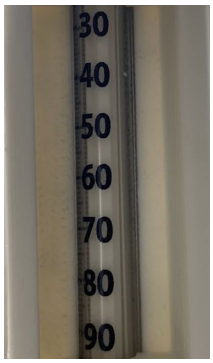
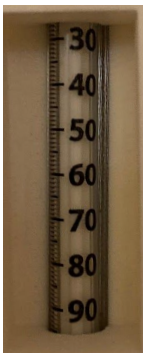
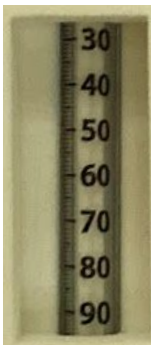
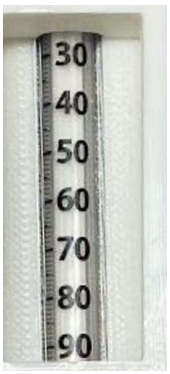
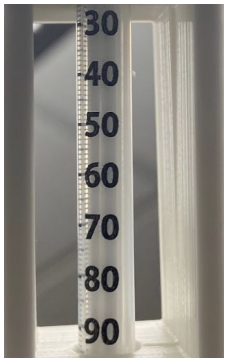
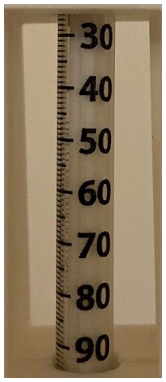
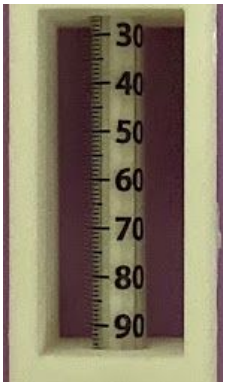
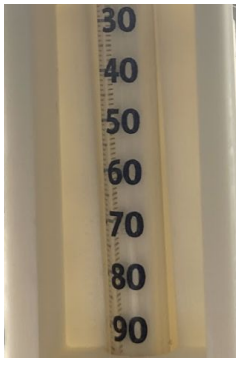
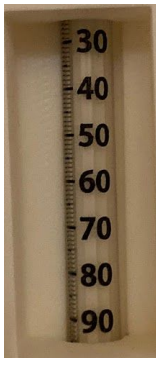
To characterize the force needed to pull the plunger of the syringe, the syringe was inserted into MTS machine clamps. Then, while recording the force experienced, the plunger was pulled back. This test was performed five times and averaged the maximum forces from each trial (see App. 13). A factor of safety of two was then applied to the average maximum force to determine a threshold force for testing the two final designs.

Using this threshold force, the two final designs were placed in their locked positions in separate MTS machine clamps. A strain was then applied at a constant rate of 1 mm/s until the threshold force was achieved. This test was repeated five times, recording the maximum force achieved, stopping the test either if when the design broke or if the threshold force was achieved.

9. Testing Results

9.1. Visibility Testing Results

Table 1: The three testing conditions, a reflective background, a double window, and a single window, were evaluated in a light room, in a dark room on a table, in a dark room, and in a light room on a table.

	Environment			
Background	Held Up in Light Room	Held Up in Dark Room	Table in Dark Room	Table in Lightroom
Reflective Background				
Double Window				
Single Window				

After visibility testing, the double window was determined to be the best because it had the largest amount of brightness and subtle magnification of the syringe readings. This was especially apparent in the light room condition. The magnification of the syringe readings from the double window significantly benefit the user while holding up the device to a simple LED room light. The reflective background and single window were not as effective at visualizing the syringe readings when held up to a room light and in the darker room settings. Additionally, the double window design was most advantageous for injection molding because the design uses less material, which lowers cost and weight of the design. The reflective background and single window both require additional material for manufacturing, and the reflective background requires the addition of spray paint and assembly, which would increase manufacturing costs.

9.2. Force Testing Results

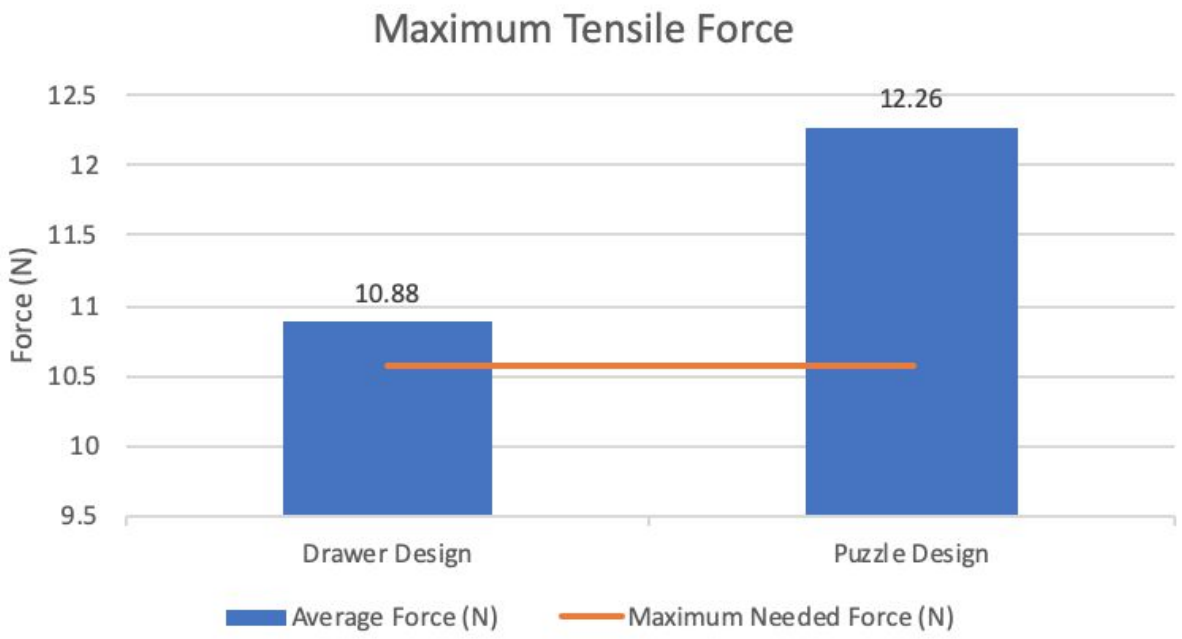


Figure 19: Maximum Tensile Forces found via testing of the two proposed final prototypes. Force testing data is in Appendix 13.

MTS testing was used to characterize the axial forces involved in syringe filling for both designs. The test showed that both devices are strong enough to withstand the threshold axial forces (maximum needed force) while in the locked position for everyday syringe filling. Neither of the devices were tested to fracture because the final device would not need to undergo that amount of stress during everyday use.

10. Discussion

10.1. Final Design

The Binder Design was chosen to be the final design for the semester. First, the design was chosen because of its stability in multiple areas. This design has a greater stability of syringe and vial halves once the device is locked into place. The stability ensures that no slippage will occur when the needle head is punctured into the vial; maximizing the safety to the user. The Binder Design also has a smaller amount of fragile pieces that could break during use. The arms that serve multiple purposes for the device are strong and can resist daily wear and tear, unlike the wings in the drawer design which are fragile. The stability of the sliding mechanism itself for the Binder Design is superior as well. The Drawer Design is unstable in the unlocked position which could be a safety hazard for the user because of potential needle slippage from the vial head. Finally, after receiving feedback from Proto-Labs, the Binder Design is the only design that can be injection molded with some modifications. The Drawer Design is not feasible to manufacturing via injection molding due to its sliding mechanism, and would thus require significant design changes.

11. Conclusion

11.1. Future Work

Should the project timeline be expanded, further collaboration with Proto-Labs would be beneficial. Proto-Labs has already been useful to determine which designs have the possibility of being injection molded for manufacturing. However, more in-depth feedback from injection molding professionals is necessary to make design changes and improve injection molding feasibility of the device. After collaborating to make the most cost-effective and strong device, further evaluation of injection molding materials would be beneficial to make the most educated choice of which material to injection mold with. It is important to find a material that is both cost-effective for manufacturing and strong enough so the device can withstand daily wear and tear during use.

The injection molded final design would then be tested for usability. There are multiple brands of vials and syringes in the diabetes community, so it is important to accommodate every user in the United States and potentially beyond. Along with usability testing, additional force testing will also be used to confirm the stability of the final design and to determine if more modifications to the design need to be made.

12. References

[1] “Type 2 Diabetes | Basics | Diabetes | CDC,” https://www.cdc.gov/diabetes/basics/type2.html.

[2] Diabetesresearch.org. (2019). Diabetes Statistics. [online] Available at: https://www.diabetesresearch.org/diabetes-statistics [Accessed 11 Dec. 2019].

[3] dc.gov. (2019). Addressing Health Disparities in Diabetes | Diabetes | CDC. [online] Available at: https://www.cdc.gov/diabetes/disparities.html [Accessed 9 Oct. 2019].

[4] Felman, A. and Alan Carter, P. (2019). Insulin pens: Types, benefits, and how to use them. [online] Medical News Today. Available at: https://www.medicalnewstoday.com/articles/316607.php [Accessed 9 Oct. 2019].

[5] Grazia Aleppo MD, F. (2019). Insulin Pump Overview. [online] EndocrineWeb. Available at: https://www.endocrineweb.com/guides/insulin/insulin-pump-overview [Accessed 9 Oct. 2019].

[6] Afrezza.com. (2019). Afrezza | Rapid Acting Inhaled Insulin for Type 1 and Type 2 Diabetes. [online] Available at: https://www.afrezza.com/ [Accessed 9 Oct. 2019].

[7] Webmd.com. (2019). [online] Available at: https://www.webmd.com/diabetes/inhaled-insulin [Accessed 9 Oct. 2019].

[8]Prodigy Diabetes Care. (2019). Prodigy Count-a-Dose® Insulin Syringes | Prodigy Diabetes Care. [online] Available at: http://www.prodigymeter.com/consumers/diabetic-supplies/prodigy-count-a-dose-insulin-syringe/ [Accessed 7 Dec. 2019].

[9] Main.diabetes.org. (2019). [online] Available at: http://main.diabetes.org/dforg/pdfs/2015/2015-cg-injection-aids.pdf [Accessed 9 Oct. 2019].

[10] Ambi Med Inc. (2019). Insul-eze Syringe Magnifier magnifies 2x for easy viewing. [online] Available at: https://www.ambimedinc.com/insul-eze/ [Accessed 9 Dec. 2019].

[11] NCOA. (2019). 10 Most Common Chronic Diseases [Infographic] - Healthy Aging Blog | NCOA. [online] Available at: https://www.ncoa.org/blog/10-common-chronic-diseases-prevention-tips/ [Accessed 11 Dec. 2019].

[12] Centers for Disease Control and Prevention. (2019). Gestational Diabetes and Pregnancy | CDC. [online] Available at: https://www.cdc.gov/pregnancy/diabetes-gestational.html [Accessed 11 Dec. 2019].

[13] Mayo Clinic. (2019). Diabetic neuropathy - Symptoms and causes. [online] Available at: https://www.mayoclinic.org/diseases-conditions/diabetic-neuropathy/symptoms-causes/syc-20371580 [Accessed 11 Dec. 2019].

[14] Healthline. (2019). Diabetes and Stroke: Is There a Connection?. [online] Available at: https://www.healthline.com/health/diabetes/diabetes-and-stroke [Accessed 9 Oct. 2019].

[15] “Residential Indoor Temperature Study - nrel.gov.” [Online]. Available: https://www.nrel.gov/docs/fy17osti/68019.pdf. [Accessed: 05-Oct-2019].
[16] “What is the Recommended Humidity Level for my Home?,” HVAC.com. [Online]. Available: https://www.hvac.com/faq/recommended-humidity-level-home/. [Accessed: 05-Oct-2019].
[17] Roser, M., Appel, C. and Ritchie, H. (2019). Human Height. [online] Our World in Data. Available at: https://ourworldindata.org/human-height [Accessed 11 Dec. 2019].
[18] “TUFTS ENVIRONMENTAL HEALTH AND SAFETY IN CASE YOU HAVEN T ...” [Online]. Available: https://publicsafety.tufts.edu/ehs/files/October2014.VI2-Backpacks.pdf. [Accessed: 05-Oct-2019].
[19] [Barb, S. F, Reid, Harold, Susan, Roger, and L. G, “BD Ultra Fine U-100 Insulin Syringes 31G 8mm 90 Count: ADW Diabetes,” ADW Diabetes - Your Diabetic Supplies Superstore!, 09-Aug-2019. [Online]. Available: https://www.adwdiabetes.com/product/1279/bd-ultra-fine-u100-syringes-31g-3-10cc-5-16in-90ct. [Accessed: 05-Oct-2019].
[20] “Ultimaker Tough PLA material: Create durable prototypes and tooling,” ultimaker.com. [Online]. Available: https://ultimaker.com/materials/tough-pla. [Accessed: 10-Dec-2019].
[21] “Ultimaker NFC Tough PLA Filament 2.85mm (750g),” 3D Universe. [Online]. Available: https://shop3duniverse.com/products/ultimaker-nfc-tough-pla-filament-2-85mm-750g. [Accessed: 10-Dec-2019].
[22] “Acrylonitrile Butadiene Styrene (ABS) and its Features,” Acrylonitrile Butadiene Styrene (ABS Plastic): Uses, Properties & Structure. [Online]. Available: https://omnexus.specialchem.com/selection-guide/acrylonitrile-butadiene-styrene-abs-plastic. [Accessed: 10-Dec-2019].
[23] “ABS Injection Molding Plastic: Excellent Strength and Versatility,” ProtoLabs, 05-Sep-2017. [Online]. Available: https://proto-cast.com/abs-injection-molding-plastic/. [Accessed: 10-Dec-2019].
[24] “3D Printers,” UW Makerspace. [Online]. Available: https://making.engr.wisc.edu/equipment/3d-printers/. [Accessed: 10-Dec-2019].
[25] “Stratasys F123 Series Printers,” Stratasys 3D Printing. [Online]. Available: https://www.stratasys.com/3d-printers/f123. [Accessed: 10-Dec-2019].
[26] H. Gao, D. V. Kaweesa, J. Moore, and N. A. Meisel, “Investigating the Impact of Acetone Vapor Smoothing on the Strength and Elongation of Printed ABS Parts,” Jom, vol. 69, no. 3, pp. 580–585, Dec. 2016.
[27] “Acetone,” National Center for Biotechnology Information. PubChem Compound Database. [Online]. Available: https://pubchem.ncbi.nlm.nih.gov/compound/Acetone. [Accessed: 10-Dec-2019].
[28] A. Łagoda and R. Gabor, “Strength parameters of the ABS materials used in 3D printing,” 2018.

[29] “Insulin Routines,” ADA. [Online]. Available: https://www.diabetes.org/diabetes/medication-management/insulin-other-injectables/insulin-routines. [Accessed: 05-Oct-2019].
[30] “Giving Safe Injections,” WHO. The International Council of Nurses, Department of Blood Safety and Clinical Technology. [Online]. Available: https://www.who.int/occupational_health/activities/1bestprac.pdf
[31] “DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for ...” [Online]. Available: https://www.cdc.gov/niosh/docs/2011-199/pdfs/2011-199.pdf. [Accessed: 05-Oct-2019].
[32]“Syringe Dimensions,” Syringe Dimensions | Laboratory | Hamilton Company. [Online]. Available: https://www.hamiltoncompany.com/laboratory-products/syringe-knowledge-base/syringe-dimensions. [Accessed: 05-Oct-2019].
[33]“Diabetes: How to Use Insulin,” American Family Physician, 01-Aug-1999. [Online]. Available: https://www.aafp.org/afp/1999/0801/p649.html. [Accessed: 05-Oct-2019].
[34]“What's the average room temperature and thermostat setting in the UK?,” Average room temperatures and thermostat settings | OVO Energy. [Online]. Available: https://www.ovoenergy.com/guides/energy-guides/average-room-temperature.html. [Accessed: 05-Oct-2019].
[35]O. of the Commissioner, “Are You Storing Food Safely?,” U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/consumers/consumer-updates/are-you-storing-food-safely. [Accessed: 05-Oct-2019].
[36]INSULIN BASICS: THE REASONS BEHIND THE RECOMMENDATIONS. [Online]. Available: https://nfb.org/images/nfb/publications/vod/vodsum0401.htm. [Accessed: 05-Oct-2019].
[37]National Research Council (US) Committee on the Role of Human Factors in Home Health Care, “Medical Devices in Home Health Care,” The Role of Human Factors in Home Health Care: Workshop Summary., 01-Jan-1970. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK210047/. [Accessed: 05-Oct-2019].
[38] “Information on Dishwasher Cycle Time,” Whirlpool Home Appliances, 13-Jun-2019. [Online]. Available: https://producthelp.whirlpool.com/Dishwashers/Dishwasher_Product_Assistance/Information_on_Dishwasher_Cycle_Time. [Accessed: 05-Oct-2019].
[39]“What is the best water temperature for dishwasher.” [Online]. Available: https://removeandreplace.com/2016/03/24/what-is-the-best-water-temperature-for-dishwasher/. [Accessed: 05-Oct-2019].

[40] “Robert Wadlow: Tallest man ever,” Guinness World Records. [Online]. Available: https://www.guinnessworldrecords.com/records/hall-of-fame/robert-wadlow-tallest-man-ever. [Accessed: 05-Oct-2019].
[41] “Humalog 100 units/ml, solution for injection in vial,” Humalog 100 units/ml, solution for injection in vial - Summary of Product Characteristics (SmPC) - (emc). [Online]. Available: https://www.medicines.org.uk/emc/product/1640/smpc. [Accessed: 05-Oct-2019].
[42] “Insulin Administration,” Diabetes Care, 01-Jan-2003. [Online]. Available: https://care.diabetesjournals.org/content/26/suppl_1/s121. [Accessed: 05-Oct-2019].
[43]“What size insulin syringe should I buy?: Insulin,” Sharecare. [Online]. Available: https://www.sharecare.com/health/insulin/what-size-insulin-syringe-buy. [Accessed: 05-Oct-2019].
[44]“The Role of FDA in regulating Diabetes Devices and ...” [Online]. Available: https://carbdm.org/wordpress/wp-content/uploads/2015/03/beck-presentation_bay-area-diabetes-summit_march-15-2014-2.pdf. [Accessed: 05-Oct-2019].
[45] Center for Devices and Radiological Health, “Overview of Medical Device Classification and Reclassification,” U.S. Food and Drug Administration. [Online]. Available: https://www.fda.gov/about-fda/cdrh-transparency/overview-medical-device-classification-and-reclassification. [Accessed: 05-Oct-2019].
[46] BMP Medical, “What's the Difference between a Class I Medical Device and a Class II?,” BMP Medical, 25-Sep-2018. [Online]. Available: https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-2/. [Accessed: 05-Oct-2019].
[47] “What diabetic supplies are covered by Medicare? - Medicare FAQs,” eHealthMedicare. [Online]. Available: https://www.ehealthmedicare.com/faq/what-diabetic-supplies-are-covered-by-original-medicare/. [Accessed: 05-Oct-2019].
[48] R. D. Seidler, J. A. Bernard, T. B. Burutolu, B. W. Fling, M. T. Gordon, J. T. Gwin, Y. Kwak, and D. B. Lipps, “Motor control and aging: links to age-related brain structural, functional, and biochemical effects,” Neuroscience and biobehavioral reviews, Apr-2010. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2838968/. [Accessed: 05-Oct-2019].
[49] R. D. Seidler, J. A. Bernard, T. B. Burutolu, B. W. Fling, M. T. Gordon, J. T. Gwin, Y. Kwak, and D. B. Lipps, “Motor control and aging: links to age-related brain structural, functional, and biochemical effects,” Neuroscience and biobehavioral reviews, Apr-2010. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2838968/. [Accessed: 05-Oct-2019].
[50] A. Pietrangelo, “Diabetes and Stroke: Is There a Connection?,” Healthline, 19-Apr-2019. [Online]. Available: https://www.healthline.com/health/diabetes/diabetes-and-stroke. [Accessed: 05-Oct-2019].

[51] “Infection in Patients With Diabetes Mellitus,” Practice Essentials, Overview, Ear, Nose, and Throat Infections, 01-Feb-2019. [Online]. Available: https://emedicine.medscape.com/article/2122072-overview. [Accessed: 05-Oct-2019].
[52] A. Felman, “Insulin pens: Types, benefits, and how to use them,” Medical News Today, 27-Mar-2019. [Online]. Available: https://www.medicalnewstoday.com/articles/316607.php. [Accessed: 05-Oct-2019].
[53] Sanofi, “New Sanofi insulin savings program aims to lower out-of-pocket costs for people living with diabetes,” PR Newswire: press release distribution, targeting, monitoring and marketing, 27-Jun-2018. [Online]. Available: https://www.prnewswire.com/news-releases/new-sanofi-insulin-savings-program-aims-to-lower-out-of-pocket-costs-for-people-living-with-diabetes-300624743.html. [Accessed: 05-Oct-2019].
[54] J. Cafasso, “Insulin Prices: Pumps, Pens, Syringes, and More,” Healthline, 10-Jan-2019. [Online]. Available: https://www.healthline.com/health/type-2-diabetes/insulin-prices-pumps-pens-syringes. [Accessed: 05-Oct-2019].
[55] B. Mcadams and A. Rizvi, “An Overview of Insulin Pumps and Glucose Sensors for the Generalist,” Journal of Clinical Medicine, vol. 5, no. 1, p. 5, Apr. 2016.
[56] A. Pietrangelo, “Diabetes Pills vs. Insulin: What You Should Know?,” Healthline, 15-May-2019. [Online]. Available: https://www.healthline.com/health/diabetes/diabetes-pills-vs-insulin. [Accessed: 05-Oct-2019].
[57] “Metformin Prices, Coupons & Patient Assistance Programs,” Drugs.com. [Online]. Available: https://www.drugs.com/price-guide/metformin. [Accessed: 05-Oct-2019].
[58] Sharecare. (2019). What size insulin syringe should I buy? | Insulin. [online] Available at: https://www.sharecare.com/health/insulin/what-size-insulin-syringe-buy [Accessed 28 Sep. 2019].
[59] Bd.com. (2019). Insulin syringes. [online] Available at: https://www.bd.com/en-us/offerings/capabilities/diabetes-care/insulin-syringes [Accessed 28 Sep. 2019].
[60] Easytouchstore.com. (2019). Easy Touch Store. Easy Touch Insulin Syringes. [online] Available at: https://www.easytouchstore.com/easy-touch-insulin-syringes [Accessed 28 Sep. 2019].
[61] Totaldiabetessupply.com. (2019). Most Popular Insulin Syringes | Total Diabetes Supply. [online] Available at: https://www.totaldiabetessupply.com/collections/most-popular-insulin-syringes [Accessed 28 Sep. 2019].
[62] 100, T. (2019). Buy TRUEplus Lancets 33 Gauge 100 per Box at ADW Diabetes!. [online] Adwdiabetes.com. Available at: https://www.adwdiabetes.com/product/17927/trueplus-lancets-33-gauge [Accessed 28 Sep. 2019].

[63] All, S. and 100/box, A. (2019). Advocate U-100 Insulin Syringes 31G 1cc 5/16" 100/box. [online] Advocate Meters. Available at: https://advocatemeters.com/syringes-31g-1cc/ [Accessed 28 Sep. 2019].
[64] Anon, (2019). [online] Available at: https://www.sigmaaldrich.com/analytical-chromatography/analytical-products.html?TablePage=17558144 [Accessed 28 Sep. 2019].

13. Appendices

13.1. PDS

Insulin Filling Station

Preliminary Product Design Specifications

Team Members:
Abigail Drake, Team Leader
Aaron Patterson, Communicator
Jessica Wang, BSAC
Noah Ambroz, BWIG
Elizabeth Liu, BPAG

Date: September 16, 2019

Biomedical Engineering 200/300:
Biomedical Engineering Fundamentals & Design
Fall 2019

Client: Michelle Somes-Booher

Advisor: Dr. John Puccinelli

Function:
Diabetes is one of the most prevalent chronic conditions in the United States [11]. A current treatment option for diabetes is using a syringe to inject insulin; this option is often used by lower income and elderly diabetic patients. Due to complications with diabetes, old age, and financial instability, it is difficult to align the syringe needles and insulin vial opening without risk of insulin waste and syringe needle poke, bending, or breaking. Thus, the team aims to design a device that eases filling syringes with insulin for elderly patients while remaining cost effective, affordable, and accessible.

Client requirements:

- This device's production must be cost effective enough to produce a profit, but it also must be affordable. Thus, the cost of manufacturing per product must be under $3 per device (see Cost section under Production Characteristics for more details).
- The device must increase ease of use in filling a syringe with insulin, so the user must be able to grip it more easily and visually measure how much insulin is entering the syringe.
- The external material has to be customizable (ex. silk screen, engraved, etc.) for advertising and marketing purposes.

Design Requirements:

Physical and Operational Characteristics

1. *Performance Requirements:* The device will align the insulin syringe with the vial to decrease the occurrence of broken or bent needles during attempts to fill syringes from insulin vials. The device must also allow for visual measurement of the amount of insulin entering the syringe, so there must be a window or a read-out for the units of insulin in the syringe. In addition, the device must be strong enough to not break under axial forces while filling the syringe. The device also must be able to strongly grip the vial and syringe to prevent slippage or insulin waste. To be used with every insulin injection, this device must maintain adequate performance while being used two to four times each day, every day [29].

2. *Safety:* The device must maintain a sterile environment to minimize chances of infection upon insulin injection, so washing protocol must be outlined for user to follow [30]. As this device is intended for at-home use, maintenance of the device will require manual

cleaning. In addition, the device design must reduce crevices or pinch points where bacteria communities could form and lead to secondary infections. Also, the device cannot be made out of any material that is toxic or dangerous to humans, specifically avoiding materials that include skin contact toxins [31].

3. *Accuracy and Reliability:* The device must allow the user to view and quantify how much insulin is entering or exiting the syringe because the insulin doses must be precise. This will require a window of 7.8 mm to ensure full visibility of measurement marks on the syringe, since this is the outer diameter of the largest size of insulin syringe [32].

4. *Life in Service:* The device will be used two to four times [33] per day for regular injections. The device should also be portable so it can be used for injections outside of the home. The device should last for at least five years of use.

5. *Shelf Life:* The device should be comfortable staying at normal room temperature, 23 °C [34], when not in use by the client. The device should be able to endure refrigerator temperature, 4 °C [35], since insulin normally is stored in colder temperatures to prevent bacteria from breaking down the insulin [36].

6. *Operating Environment:* The operating environment for this device will be nonclinical, namely the patient's home [37]. The device must be operable in temperatures from 4 °C to 32°C, but must withstand temperatures of up to 75°C for sterilization purposes [15, 38, 39]. The relative humidity in this environment is between 15% and 50% [16]. As the user may drop the device, it should also expect and be able to withstand drops from up to three meters [40]. During storage or idle time, the device may be stored within the household in these same conditions, or within the refrigerator at around 4°C where it must remain intact and a viable solution.

7. *Ergonomics:* The product must be able to be easily gripped by the user post hand-washing, since the device will likely be used in the bathroom or kitchen. Specifically, the exterior of the device must induce sufficient friction to withstand resulting shear forces and torques caused when filling the syringe with insulin and potential turning of the device during filling, respectively. This will be a feature that will be tested after fabricating the prototype.

8. *Size:* The device must be able to accomodate the standard sized syringe, needle, and insulin vial. That noted, the standard insulin vial is 10 mL [41], the standard syringe is up to 2 mL [42], and the standard short needle length is 8 mm [43]. The maximum length of the device should only be slightly longer than the lengths of the vial, needle, and syringe combined when the syringe is not extended. The width of the device should be easy and comfortable to hold in an average size human hand per client’s request; average hand

width ranges between 38 and 50 mm. The device size should be portable so, if needed, the user can take their device and administer injections in various locations. The device shape must inhibit rolling, thus cannot be a cylinder or spherical. See section 13.2 “Standards Tables” for more information on syringe, needle, and vial size variations.

9. *Weight:* Keeping the weight of the syringe, needle, insulin vial in mind, the weight of the device should be no greater than 2.225 N. Any greater weight could hinder the process of filling due to strength restrictions for elderly patients [18]. That noted, the syringe, needle, and insulin vial weigh an estimate of 0.01246 N [19], leaving 2.1004 N for the device weight.

10. *Materials:* The client requests that the material be economical and easy to fabricate, resistant to slipping, as well as easily sterilized in a household setting. As sterilization processes may include using a dishwasher, the material must be dishwasher-safe and thus, withstand temperatures of at least 75 °C for four hours [38, 39]. Furthermore, the material must be safe for human skin contact.

11. *Aesthetics, appearance, and finish:*. The shape and form of the device will form around the needle and vial of the user. The texture of the exterior should allow the user to firmly grip the device while filling the syringe, even when the device is wet. The device will also be designed so that the exterior is customizable for advertising and marketing purposes. Thus, it should allow for personalization through methods such as using dyes, silk screening, or other customization methods.

Production Characteristics:

1. *Quantity:* The quantity per user of the device is intended to be two as the client intends to sell the device in packs of two. This is so the customer can keep one device at home and keep the other portable. However, for this semester, the client only requests one prototype.

2. *Target Product Cost:* To provide access lower income and underrepresented communities in the diabetes population, cost should not be a barrier for consumers. The client advised that the product could be sold for $19.99 in a two pack, thus manufacturing costs per product should not surpass $3.00. This limit is to ensure that the product is affordable for all diabetes patients, regardless of socioeconomic standing, yet still makes a profit. Comparing this cost with the competition listed in the next section, it is obvious that this device will be the most cost effective alternative to more high-tech solutions.

Miscellaneous:

1. *Standard and Specification:* This device would be categorized as a Class II medical device according FDA regulations [44, 45, 46]. This is due to the risks involved with using the device, such as accidental needle pokes, or contamination of the syringe needle. Because of these factors, there is a moderate to high risk to the user. Thus, FDA standards for Class II medical devices must be fulfilled prior to releasing this product on the market.

2. *Customer:* The targeted customer population are elderly diabetics (over the age of 65). Not only is this population rapidly growing (by 2030, an estimated one in five U.S. residents will be over the age of 65), but all will qualify for Medicare, which only provides materials for insulin injections [47, 48]. Thus, these individuals will be using needles for injections. In addition, motor deficits occur more frequently with age, and concurrent conditions, such as diabetes, can lead to higher risk of disease states, such as stroke [49, 50]. While there are alternative products currently on the market, there is a need for a lower cost alternative.

3. *Patient-Related Concerns:* The product must be able to be sterilized, since it will be used to assist insulin injections. As diabetes patients are already more susceptible to secondary infections, maintaining sterility of the syringe needle is vital [51]. Thus, the prototype must be able to withstand repeated wash in a household setting and therefore temperatures of at least 75 °C for four hours. The product must be able to provide proper dosage for every use, as dosage amount can vary for patients daily.

4. *Competition:*

    Prefilled insulin pens [52]: This product is a combination of vial and syringe that has a specific amount of pre-filled insulin. It is accurate, easy to use, and convenient to carry around. However, it is very expensive, as it is not usually covered by insurance and always wastes insulin. A box of five pens costs around $500 [53].

    Insulin Pumps [54]: This product is an automated continuous delivery system for insulin using a catheter. It closely monitors insulin levels in the body and delivers insulin accordingly. It is more accurate and eliminates the use of needles. However, it is extremely expensive, at a cost of around $6,000 out of pocket [55].

    Diabetes Pills [56]: This product entails a variety of pills that push the pancreas to release insulin or regulate glucose levels. It is a very cheap option, as one of the medications, Metformin, costs $11 for 14 tablets [57]. It helps with fear of needles, but it is not as effective as insulin because it may not reach targeted sites

and has varying side effects. This type of treatment is also not effective for people with type I diabetes.

13.2. Standards Tables

Syringe Standards Table

Table 1: The table below provides information on the different standard insulin syringe volumes [58, 59, 60].

Volume (cc)
0.3
0.5
1

Needle Standards Table

Table 2: The table below provides information on the different standard insulin needle gauges and lengths [61, 62, 63].

Gauge (Thickness)	Length (Inches)
28	5/16
29	3/8
30	1/2
31	

Vial Standards Table

Table 3: The table below provides information on the different standard insulin vial volumes, heights, and diameters [64].

Volume	Height (mm)	Outside Diameter (mm)	Inside Diameter (mm)
10 ml	46	22.6	12.5
	54.5	23	12.7
		22.5	
		20	

13.3. MTS Testing

13.3.1. Data

Syringe Force Characterization Results

Test Number	Maximum Tensile (N)	Maximum Compressive (N)
1	5.4576	8.0254
2	5.2800	11.5322
3	4.3124	10.6781
4	5.6659	10.0259
5	5.7387	11.3330
Average	5.29	10.32
Threshold Force:	**10.58**	20.64

Binder Design Results

Test Number	Maximum Force
1	13.2435
2	11.8745
3	11.6959
Average	12.26

Drawer Design Results

Test Number	Maximum Force
1	10.5915

2	11.0651
3	10.9949
Average	10.88

13.3.2. MATLAB Code

Syringe Axial Force Analysis Code: extracts maximum force from MTS file

```
close all;
clear all;
file=uigetfile;
data=load(file);
disp=data(:,1);
force=data(:,2);
time=data(:,3);
force_calibrated=force-force(1);
disp_m=(disp-disp(1))/1000;
minforce=min(force_calibrated)
cutoff=2*minforce
```

Failure Analysis Code: can find the maximum force experienced by device prior to reaching threshold force

```
close all;
clear all;
file=uigetfile;
data=load(file);
disp=data(:,1);
force=data(:,2);
time=data(:,3);
force_calibrated=abs(force-force(1));
maxforce=max(force_calibrated)
```