Insulin Filling Station

Preliminary Product Design Specifications

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Function:

Ms. Somes-Booher's father, an elderly man with insulin-dependent type II diabetes, relies on daily insulin injections. These injections are difficult to patients, such as the client's father, who has reduced dexterity due to age. Currently, a treatment option is to use a syringe to inject insulin from a vial; this option is often used by lower income and Medicare insulin-dependent type II and type I diabetic patients because it is less costly. However, the elderly patients often experience difficulties lining up the syringe with the insulin vial and inserting the syringe into the vial. These difficulties frequently result in accidental pricks or bending of the needle, which renders the needle useless. For lower income and Medicare patients, this is particularly impactful, as it results in wasting syringe and insulin, and therefore financial loss. Thus, we are aiming 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 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 shear and compressive forces, and torques 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 [1].

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 [2]. As this device is intended for at-home use, maintenance of the device will require manual cleaning, whether that involves sterilization via dishwasher or by hand. 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 [3].

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 a 2 mL syringe [4].

4. *Life in Service:* The device will be used two to four times [5] per day for regular injections. The device should also be portable so the client can use it for injections outside of the home. The device should last for at least five years of use, as the daily forces and torques imparted on the device are not significant.

5. *Shelf Life:* The device should be comfortable staying at normal room temperature, 23 °C [6], when not in use by the client. The device should be able to endure refrigerator temperature, 4 °C [7], since insulin normally is stored in colder temperatures to prevent bacteria from breaking down the insulin [8].

6. *Operating Environment:* The operating environment for this device will be nonclinical, namely the patient's home [9]. The device must be operable in temperatures from 4 °C to 32°C [10]. The relative humidity in this environment is between 15% and 50% [11]. As the user may drop the device, it should also expect and be able to withstand drops from up to three meters [12]. 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, especially when wet, 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. 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 [13], the standard syringe is up to 2 mL [14], and the standard short needle length is 8 mm [15]. 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 Appendix A 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 0.5 lbs. Any greater weight could hinder the process of filling due to strength restrictions for elderly patients [16]. That noted, the syringe, needle, and insulin vial weigh an estimate of 0.0028 lbs [17], leaving 0.472 lbs 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 degrees Celsius for four hours [18, 19]. 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 [20, 21, 22]. 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 [23, 24]. 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 [24, 25]. While there are alternative products currently on the market, these products are expensive. As diabetes already disproportionately affects underrepresented groups, such as Hispanics and Blacks, it is vital to reduce these health disparities by providing a product that improves accessibility to receiving life-saving insulin injections and prevents wasting needles and insulin [26]. Thus, this will also help reduce health disparities in diabetes management. In addition, this aging population will respond well to easily understandable language, familiar components, and the ability to personalize the device [27].

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 [28]. Thus, the prototype must be able to withstand repeated use in a household dishwasher, and therefore temperatures of at least 75 degrees Celsius for four hours.

4. *Competition:*

    <u>Prefilled insulin pens [29]:</u> 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 [30].

Insulin Pumps [31]: 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 [32].

Diabetes Pills [33]: 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 [34]. 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.

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Appendix A

Syringe Standards Table

Table 1: The table below provides information on the different standard insulin syringe volumes [35, 36, 37].

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 [38, 39, 40].

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 [41].

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