Project #2 for NREC-AMI
Student Design Competition, 2007/2008

Proposal
Automated Syringe Loading Device

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Executive Summary

Here we look at a proposed device to assist diabetes patients in obtaining their medicine. Diabetes is a metabolic disorder affecting millions of adults and children in America today. It is the result of the body’s failure to regulate blood sugar, though the use of its own insulin, either because the body cannot produce or properly use it. It is therefore the responsibility of a patient afflicted with diabetes to regulate insulin levels by monitoring their blood sugar, and manually injecting insulin from artificial resources. While modern technology has made it relatively easy to monitor one’s own blood sugar with electronic devices, certain conditions that result from diabetes are still making the manual regulation difficult. It is not uncommon for someone with diabetes to develop low vision or blindness, low strength, poor hearing, and reduced motor control. These disabilities, among others, make filling a syringe with insulin to accurate levels very difficult.

The proposed device is a syringe loading machine that fills a syringe with insulin for the patient. All the user has to do is tell the device how much insulin is desired. This can be done using a keypad on the device. And along the way, a display with large letters tells the patient what they can expect, while accompanied by an audio output that tells them what the display says in the event they cannot see it. The device will be accurate to 1/1000th of a cc (or milliliter). And it will also come with several safety features.

The proposed device will meet the following criteria
- fill the syringe accurately (to within 1/1000th cc),
- inform the user how much insulin remains in the device reserves,
- keep a time stamped record of doses drawn,
- be digital with a voice output,
- accept any size insulin bottle,
- accept standard size disposable syringes (0.5cc’s or 1.00cc’s),
- be accessible to users who are hard of hearing,
- be accessible to users who are blind or have poor vision,
- be easy to use by those with limited movement capabilities,
- be portable.

While there are some devices already on the market that assist diabetes patients in similar ways, they fall short of providing the level of accuracy, variability, and ease of use. The patient will be able to rely on the device more than almost any other product.
1. Introduction

1.1 Background

Diabetes is a disorder in which the body does not efficiently produce, or properly use insulin. Insulin is a hormone that is required to convert, mainly sugars and starches, into energy needed for daily life. Although the cause of diabetes is unknown, much is known about assisting the body with external sources of insulin [1].

The amount of insulin required is dependent upon a variety of factors that the person has just done or intends on doing through the day, such as the level of physical activity they have engaged in and food they are planning to eat. Therefore, the dosages of insulin that a diabetic injects can greatly vary, in addition to the frequency of the dosages. It is extremely important that the required amount of insulin be measured precisely. This measurement can be difficult for those with low vision or trembling hands.

Diabetes affects 20.8 million children and adults in the United States alone. Therefore, it is necessary to explore a variety of injection methods. Among the inherent disorder of diabetes, many are affected by disabilities. One disability that diabetes can cause is blindness and low vision. Such a side effect is especially limiting to the patient. An intended client list has been provided to ensure that the device can be accessible for diabetes patients with a variety of disabilities. The client list for the syringe-loading device is:

- Phyllis, 77 years old, suffers from rheumatoid arthritis. Due to her arthritis, she has diminished hand strength, joint stiffness, and pain. She tends to stay away from the current, high-tech, devices and therefore prefers those with simple interfaces.
- Aaron, 23 years old, is a returning Iraq war veteran who has an arm amputation above the elbow, and suffers from chronic neck pain, and reoccurring headaches. He most often uses one hand instead of wearing a prosthetic device.
- Keisha, 84 years old, recently had a stroke, which caused hemiplegia on her right side and has affected the function of her dominant hand. Due to the hemiplegia, the side affected by it can become paralyzed or weakened [2]. Since the stroke, she has experienced some memory loss so she depends on her family’s care. Independent of the stroke, Keisha also suffers from hearing loss, which has progressively worsened with age and although she has a hearing aid, she rarely uses it.
- Jerry, 82 years old, has Parkinson’s disease. The disease causes him to tremor and his range of motion is rigid and decreased. Jerry is also experiencing the early symptoms
relating to Dementia, but with the help of his family, he would like to remain at home as long as possible.

- Jamie, 42 years old, has a T11 spinal cord injury, which causes her to use a wheelchair and despite her condition, she stays active playing basketball.
- Betty, 65 years old, has a bad hip that caused limited and asymmetrical lower extremity range of motion. In addition, she has limited strength in her right leg due to the decreased use of her hip, associated with the pain.
- Violet, 32 years old, is a very active mother of three that is on blood pressure medication.
- Paul, 43 years old, has diabetes, which caused neuropathy in his hands and feet, which also caused two below-the-knee amputations and some loss of vision. Neuropathy can be controlled, but if left untreated can lead to numbness, pain, weakness, and incoordination [3].

1.2 Purpose of the Project

The purpose of the syringe-loading device is to help those with diabetes and other disabilities that may inhibit their dependence on insulin. By creating such a device, people who are required to take one or more doses of insulin per day, with amounts that vary, can easily utilize it. The device will be able to fill a syringe with a specific and accurate amount of insulin.

In accordance with the purpose of the syringe-loading device, it will be designed so that the user will have limited responsibilities when it comes to operating it. The extent of interaction between the user and the syringe-loading device will include loading the insulin bottle, and syringe into the device, entering the dosage amount, and confirming the entries. The overall design of the syringe-loading device will have safety and user friendly compatibility in mind.

1.3 Previous Work Done by Others

In implementing a justified design for the project, it is important that research is done on similar devices that have already been completed. Products that are on the market and patents that are submitted are two of the resources available. In addition, previous senior design groups have already completed the syringe-loading device project in 2005. The results from those projects are expected to positively contribute to the current design.
1.3.1 Products

There are many syringe-loading products that are on the market, available for consumers. They vary depending on the potential user and their disabilities, but are based on the same concept of delivering a safe and efficient dosage of insulin. The National Federation of the Blind (NFB) provides many products, ideas, and reviews for insulin measurement devices [4].

Count-A-Dose\textsuperscript{®}: An insulin-measuring device by Jordan Medical Enterprises. The device comes with cassette instructions and it accepts only one specific syringe type, B-D U100 50 unit (½ cc). The Count-A-Dose\textsuperscript{®} works by using a distinct click that can be heard and felt with each unit of insulin. The device allows two kinds of insulin to be used. It is considered, by NFB, to be easy, reliable, and accurate for non-sighted insulin measurement. Despite NFB reviews, downfalls of this device are that the controls may be hard to see, even for those without visual impairments, the clicking may not be heard by all users, and the adjustment knob can require too much strength. The suggested retail price is $59.95 but it can be purchased for $40 from the NFB.

The Syringe Support: A second insulin-measuring device is available from Cleveland Sight Center’s Eye-Dea Shop. Instructions are provided in standard print only and come bilingual (English and French). It also only uses one type of syringe, B-D 1 cc/100-unit disposable syringes. The device can measure insulin by 1- or 2-unit increments in doses from 1 to a maximum of 100 units. In order to use two different types of insulin with the device, it is necessary to remove the vials and switch. The Syringe Support works by using a set screw with a raised flange at 12 o’clock. One full turn of the dial draws two units and one-half turn draws a single unit of insulin. In most cases the error from the dial is minimal, even though it lacks definite tactile or audio indicators. The device is best for those who draw greater than ten units at a time. The price of the Syringe Support is $26.

The Load-Matic: The third insulin-measuring device shown on the NFB website is available from Palco Labs, Inc. It comes with cassette and printed instructions. However, the cassette instructions tell the blind user to draw 700 units out of an insulin vial with the device to assure that air isn’t drawn into the syringe, and the printed instructions fail to mention such information. Like the previous two devices, it too accepts only one type of syringe, the B-D 1 cc/100-unit disposable. The device allows two different measurement increments. It works by using a level that the user depresses to measure a 10-unit increment of insulin. By turning the dial on the device, for one click, a single-unit is measured. Similar to the Syringe Support, insulin vials must be removed and switched to change types. Due to the complexity of the operating drill, there are many opportunities for user error. One such error is that if the user fails to completely depress the lever, measurement error is extremely likely. The failure of including complete
instructions for the device contributes to the user errors. The Load-Matic device can be purchased for $49.95.

**Insul-Cap®**: The device is made by Palco Labs and comes with instructions. It also comes with two different colored insulin vial caps for distinction between two different vials. The device allows loading of syringes with one hand. It is a one-piece syringe-loading device with a built-in magnifier that magnifies increments by two times. The device is intended for diabetics with impaired vision and unsteady hands. The advantage to the device, unlike the others, is that it can fit most standard syringes. It claims to increase the independence of those who are dependent on friends, relatives, or visiting nurses to prepare insulin-loaded syringes. Insul-Cap® sells for $6.95 [5].

In addition to the insulin measurement systems, the National Federation of the Blind website [4] conveniently includes ideas for homemade insulin measurement gauges. It points out that the simplest devices are ones that allow the plunger, of the syringe, to move a set distance and no more. In doing so, accurate and easy-to-duplicate amounts of insulin can be dispensed. Unfortunately, this technique requires a various set of syringes set at different amounts, which is not practical for an active patient with diabetes. The website includes, in further detail, how gauges can be made for syringes, and the different materials they can and cannot be made from. It also recommends purchasing commercially made gauges, called Insulgages, from Meditec, Inc. The gauges are made for specific syringe types, B-D or Monoject syringes. The prices of the commercial gauges are $9.75. Meditec, Inc. also sells a device, Holdease needle guide, which guides the syringe into the insulin vial for a price of $15.75.

A new-age system to insulin delivery for diabetic patients is an insulin pump. Although manufactured by different companies, all have the same design. They work by delivering rapid-or short-acting insulin 24 hours a day. The delivery of the insulin is through a catheter placed under the skin. The doses are separated into three types, basal rates, bolus doses that cover carbohydrate in meals, and correction or supplemental doses. The basal insulin is delivered continuously over 24 hours and keeps the blood glucose levels in the correct range between meals and over night. The doctor determines this range frequently, and therefore increased amounts of visits are required with the pump. The amount is programmable and is usually changed over various periods of the day. When eating, the bolus amount of insulin is injected. Depending on the carbohydrates in a particular meal, different amount of bolus doses are required. For instance, if there are more carbohydrates in the meal than planned for, the buttons on the pump can be selected to give a larger bolus of insulin. For the third type of dosages by the insulin pump, a bolus dosage can also be used to treat high blood glucose levels. If a person has high levels before eating, a correction or supplemental bolus of insulin can be injected to bring it back to the target range [6].
The insulin pump itself can be worn as a cell phone. It can be attached to a belt or placed in a pocket, among other places. When showering the pump is disconnected and the tube that runs external to internal of the body and it can be left untouched. For many diabetics, the insulin pump is most favorable because of its convenience and practicality. However, the price of the pump can be over $5,000 with the supplies ranging from $60 to $80 a month [7, 8].

Since this year’s syringe-loading device project is a repeat, there is additional information online on past senior design projects. Information was found on the project through the University of Connecticut, Marquette University, University of Wyoming, and the University of Wisconsin-Madison. The designs used previously will be of careful consideration since there is much to be learned by those with experience.

1.3.2 Patent Search Results

The following patents were found on http://www.freepatentsonline.com:

**Patent 4357971** - Syringe gauging, loading and injection apparatus: The apparatus is intended to enable a person with low vision and/or the loss of fine motor control to accurately fill a syringe with the predetermined amount that is followed by self-injection. The device can be adjusted for various dosages and verification of the dosage is accomplished through tactile stimulus and/or audible sound. It included a dial, which measures dosage by rotation, which then results in a signal to the sense of touch and hearing.

**Patent 4778454** – Syringe loading fixture: The device is designed to load a syringe from a vial of liquid for those with poor or no vision. The fixture uses a gauge for measuring quantities of air to be injected into the vial prior to loading and the quantity of liquid to be loaded into the syringe.

**Patent 7025757** – Syringe loading devices for use with syringes and medical injectors: The device includes a syringe mounting mechanism adapted for use with an attachment mechanism. The syringe is attached to the syringe loader and a drive member is adapted to impart motion to the syringe plunger.
2. Project Description

2.1 Objective

To make obtaining medicine for diabetes patients easier, a device is to be built that can fill a syringe with the required dose of medicine. This dosage needs to be accurate, easily changeable, and reproducible. The device must also be easy to use for patients with diabetes, who may be afflicted with some of the other effects present in most diabetes cases. It will also accept either 0.50cc or 1.00cc disposable syringes, and fill them according to specifications as detailed a 1/8\textsuperscript{th} of a unit (each unit is 1/100\textsuperscript{th} of a cc) with accuracy to 0.1 units.

For simplicity and accuracy, the device will load the syringe on its own. In most devices on the market today, the syringe is still loaded using manual power, and the device merely assists them. The syringe loading device under development by Team 2, however, will use an electrically powered motor to move the plunger to a desired dosage. The amount of insulin loaded into the syringe will be calculated by an on-board microprocessor using a reading from a high-grade potentiometer.

To ensure the health of the patient, the syringe will not fill if the device is not oriented properly. For safety reasons, air bubbles cannot be allowed to collect in the syringe, and to prevent them, the insulin bottle must be inverted. If the device is in a position in which the insulin bottle is not properly oriented, the device will not allow the loading of the syringe. Also, the device will eject a small portion of the insulin to make sure any air bubbles that may have formed do not enter the patient.

The electrical power for the device will come from rechargeable batteries. These batteries should not need to be removed from the device for recharging, and the device will announce when the batteries are getting low in charge.

To ensure a sterile process for loading the syringe, the device will only accept the syringe to be loaded. This way, opened syringes are not present and vulnerable to contamination. The insulin bottle, however, will be able to remain in the device. So long as necessary precautions are taken to ensure proper insertion of the insulin bottle, there should be no risk of contamination.

For the patient’s interaction with the device, a liquid crystal display (LCD) will be present. This display will produce letters approximately 1cm across and 1cm high for easy reading. The display will also be accompanied by a voice output and speakers for those patients
who have low vision abilities. As important information appears on the display, a voice recording will play through the speakers, repeating the information displayed. The device will also have a volume control and the ability to be muted for patients who do not require it. A headphone jack will also be included for times when it is convenient for the patient.

In order for the patient to make use of the syringe loader, he or she must be able to communicate through it. This will be made possible through the use of a keyboard. The keyboard will have only numbers, volume controls, and a few other necessary options, and it will also be in Braille.

Lastly, for the patient’s convenience, the device will record the doses the patient has taken. This information can be used in doctor visits, but it will also be used by the syringe loader to keep the expected volume of insulin remaining in the bottle current. When the levels in the bottle get low, the device will warn the patient that a replacement will be needed, and it will also warn the patient when an inadequate supply of insulin exists to fulfill the requested dosage.

2.2 Methods

For this device to work, the syringe must be held stationary while the electric motor pulls the plunger. This will be accomplished by the implementation of the syringe tray shown in Figure 1. This tray will hold the syringe though the use of a spring loaded locking grip (not shown). The grip will be strong enough to ensure the syringe cannot fall out of place, while being easy for the patient to use, and able to accept different sized syringes. The tray will also have crevices in it for the plunger and grip. The plunger and grip will be able to fit into these crevices, allowing the cylinder of the syringe to lie flat in the tray.

**Figure 1: Syringe Tray.** The drawing shows the tray that will hold the syringe during loading. Note the grooves that provide space for the plunger and handle, allowing the syringe to lie flat.
To access the syringe tray, a hatch made of clear plastic will be added to the outside of the device. This hatch will allow easy access to the syringe tray for adding or removing syringes, and allow the user to see the operation of the device to ensure nothing is wrong. It will also lock in a closed position when the syringe is being loaded, so no moving parts, or potential energy that could launch the sharp point of the syringe, can harm the patient. Blue and red LED’s near the hatch will indicate if the hatch can (blue light) or cannot (red light) be opened. These colors were chosen for their contrast. An audio direction will also state whether or not the syringe can be removed.

The device will fill the syringe using a sliding gear mechanism. This sliding gear will consist of one bidirectional motor with a circular gear controlled by the microprocessor, one linear gear, a grip between the linear gear and the syringe plunger, and one potentiometer with a circular gear. As the motor turns, the gear on it will move the line of gear teeth in a straight line. This motion will pull the plunger back along a straight path. As this happens, the teeth of the linear gear will turn the gear of the potentiometer. The varied resistance value produced by this will be used in a calculation by the microprocessor to determine the distance the plunger has traveled. The entire operation is displayed in Figure 2. The microprocessor will pull on the plunger until the calculated dosage matches the dosage indicated by the patient. Then the process of overfilling will occur.

**Figure 2: Sliding Gear Mechanism.** The drawing below shows the manner in which the gears, grips, motor and potentiometer work together to fill the syringe to a specified volume.

The added safety measure of overfilling is an attempt to remove any air bubbles that could have made their way in. This action is produced by overfilling the syringe by a measured amount, and then pushing that measured amount back out. When the patient tells the device to fill a syringe with a specific dosage, the device will automatically add a small amount to that
dosage. Once the syringe has been filled to the specified level, the motor will continue pulling the plunger. The motor will then stop pulling once the measured overfill is reached, then push the plunger until the overfill is gone, and the original dosage remains. Hence the need for a bidirectional motor.

When the syringe is about to be loaded, the computer will determine whether or not the device is properly oriented. This will be accomplished by a simple device in which a ball bearing, or similarly small weight, is allowed to move freely in a chamber. If the device is in an adequate position, the ball bearing will fall on a switch. This switch will “close” the circuit for the computer, and tell it whether or not the syringe loading can take place. A simplified diagram of this machine can be seen in Figure 3.

**Figure 3: Orientation Switch.** The drawing demonstrates the simple method of determining whether the loading device is properly set up.

In the picture, the left a cone is oriented properly, and the bearing is able to depress the sensor at the bottom. The loading device will recognize this as a properly oriented situation, and the loading will be allowed to commence. The right cone is slanted, however, and the sensor is not depressed. Loading will not commence.

The interaction between the user and the device will be made possible by an interface comprising of a liquid crystal display (LCD), a keypad, and an audio output. The display will be controlled by the microprocessor. The characters produced on the screen will be at least 1cm high and wide. For the patients input, the keyboard will be an off the shelf product. The keys on it are number 0 through 9, Clear, Enter, Help, and up/down arrows. These number keys will be used for inputting the desired dosage. Since a decimal point “.” is not available, the prompt for inputting the insulin volume will start the characters at the end. For example, the desired dosage
may be 0.57cc’s. To request this amount, the user will punch in the numbers 5, 7, and 0. The display will change thusly:

1) Start: 0.000cc’s (value is adjustable to 1/8th of a 1/100th cc unit),
2) User pushes the “5” button, and the resulting display is 0.005cc’s,
3) User pushes the “7” button, and the resulting display is 0.057cc’s,
4) User pushes the “0” button and the resulting display is 0.570cc’s.

The other functions of the device will be accessed using the “Help” button. Pressing this button will bring up a main menu for the dosage history, volume controls, etc. Selecting functions will be done by using the up/down arrows to highlight the desired function, and pushing “Enter”. The volume of the audio output will be controlled by the up/down arrows.

While it may cost more, programming the interface will be much easier if the development kits that are supplied by the manufacturers are utilized. They do not cost an extreme amount, and they come with all of the necessary information for fast data manipulation.

The voice output will be accomplished by utilizing the Double-Talk® system. This system allows users to use text to speech outputs. This will allow the programming to “speak” directly to the user. As the text data is sent to the display, it will also be spoken. Also, should the text to speech capabilities prove to be too impersonal for the device, or not clear enough for a user to understand, audio recordings can be made into the programming by the same product. This change would not require the purchase of new software or hardware. It will also be the memory for the device, since it can store information along with the recorded outputs. This memory will hold the dosage information, which will be used by the processor in determining when the insulin bottle is running low. The audio output will tell the user when the insulin bottle and the batteries are low.

The microprocessor will be programmed to take the requested doses from the interface, and translate them into a distance for the motor to pull the plunger. The programming will hold the distance in memory, and pull the plunger until the distance the plunger has moved matches that in memory. This plunger distance will be calculated by the microprocessor as a function of resistance. The potentiometer will increase its given resistance as the plunger moves, and a simple calculation can convert this value into millimeters.

The power will come from rechargeable batteries. These batteries can be any size or shape to fit the final device design. Lithium ion batteries are preferred for their longevity and resilience. As the batteries get low on charge, an LED will glow on the outside of the device with an appropriate label. The device will also have an audio output to tell the user the batteries are low when the device is turned on. This will be done before the batteries get too close to dead so the user has time to charge the batteries without worry of the device failing to fill a syringe without warning.
After the syringe has finished being loaded, and has been removed, the device will not reset the location the plunger grip. The grip will be replaced by the user each time a syringe is placed in the tray. This way, the device can determine the position of the plunger and be able to tell the size of the syringe. This will also zero the device each time it is used, so accuracy can be preserved.

The program imbedded in the microprocessor will follow the directions in the flow chart in Figure 4 when filling the syringe.

**Figure 4**: Device Operation Flow Chart. Follow the icons and arrows through parts 1, 2 and 3 to see the path of information and commands within the device.
3. Budget

In accordance with the Rehabilitation Engineering Research Center’s design competition guidelines, an upper limit of $2000 has been placed on the budget for this project. The approach towards the development of a syringe auto-loading device, (that was outlined in the Methods section), was analyzed to determine which components would be needed in assembling an initial prototype. The following is a list of the materials that will be required, accompanied with manufacturer and pricing information.

To aid in the implementation and configuration of the microprocessor and sound synthesizer aspects of this project, it was decided that the purchase of development kits would be a wise investment. They will greatly aid in configuring and testing the hardware and software components, without requiring that work on the 2 line LCD display, the speaker, and the keypad be completed first.

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</tr>
</tbody>
</table>

Materials Total: **$421.32**

Prototype Total (Minus Development Kit Expenses): **$183.32**
4. Conclusion

While being accurate to $1/1000^{th}$ of a milliliter, the proposed syringe loading device still manages to be user friendly. With an audio assisted interface, and easy to see and use controls, the device is perfect for those who live with the effects of diabetes. This, along with the straightforward design, and solid construction make this an obvious choice over most, if not all, other product on the market. The proposed syringe loading device could be a relatively low priced alternative to current medication assistants. The cost does fall above many devices, but well below that of an insulin pump. The benefits to the patient fall in a likewise manner. The syringe loading device provides many advantages over cheaper tools, like an electric motor, large display, automatic dosage recording, and compatibility with different syringes. It also is comparable to the ease of use and low maintenance of an insulin pump.
Resources