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UNIVERSITY OF MORATUWA**



BM 1190 - Engineering Design Project

Project Report

Simple Low-Cost Insulin Pump

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1 Introduction

The simplified Insulin Pump is a device that injects insulin to Type 1 and certain Type 2 diabetic patients in need. It consists of a needle and a patch that should be kept injected into the body at all times. It injects insulin automatically into the body at prescribed times.

1.1 Problem Description

Patients with Type-1 and some patients with Type-2 diabetes require the administration of insulin at certain times of the day to control their blood glucose levels. Using conventional methods requires self-injection by the use of a pen and most elderly patients need another person to do it on their behalf. However, elderly people with difficulty injecting needles by themselves and also younger patients with issues due to being afraid of needles are facing problems with this.

When addressing this problem, we found out that there are existing electronic insulin pumps which address this solution in other countries. An insulin pump is a product consisting of a needle attached to the body alongside a portable electronic device which can be refilled with insulin cartridges, designed to administer insulin periodically. Existing insulin pumps are highly advanced with real-time monitoring of blood glucose levels. And therefore, a very high price, ((over 1000 USD for a simple pump) is unaffordable for Sri Lankans. Therefore our target is to build a simpler insulin pump, which suits the needs and economy of Sri Lankan patients.

1.2 Product Idea Validation

When researching what kind of problems exist in the healthcare industry, we contacted doctors to get their opinions. A diabetic clinic doctor mentioned that their elderly patients, and certain other patients with type 1 diabetes in the clinic have a difficulty in administering insulin by themselves through the conventional insulin pen. Our project addresses this difficulty faced.

According to the diabetic clinic doctors we consulted, the device will be of use to the above mentioned categories. This device will especially be of use to type 1 diabetic patients and type 2 elderly diabetic patients who become drug intolerant due to age. This will be of help for those patients having disabilities and difficulties due to age. It was also mentioned that the unavailability of insulin pumps causing issues was observed in clinics.

Due to aforementioned reasons, we decided to build a device that helps Sri Lankan patients.

2 Our Device

The simplified insulin pump has a needle attached to a small patch that needs to be attached to the body at all times. At prescribed times, the device will inject insulin into the body automatically. It has an emergency button, to inject a certain amount of insulin in an emergency. It also provides audio feedback (a beep) to indicate when insulin is injected. The device also contains a reset button, so that the device starts timing when the button is pressed, an ON/OFF button and also an indicator to show that the device is switched on and working. However, the needle attached to the body needs to be changed at least once every three weeks to avoid infection and to change the place of injection. (This time differs from patient to patient and advice of a physician is recommended). Also, the attached patch should be watertight such that the injected place will be free from contact with water and other infections.

3 Technical specifications

3.1 Performance in quantitative terms

Dosage

This is the main measurement of the device. When it comes to the dose, patients in Sri Lanka are prescribed to get a specific no. of units of insulin by the doctors. Here, $1\text{Unit} = 0.01\text{ml}$.

Our product injects this dose of insulin with 1unit accuracy.

Time Duration

This is the other measurement taken by this device. 8 Hrs duration is used by Sri Lankan patients typically to get 3 doses per day. The time alongside dosage might vary from patient to patient. But for this prototype we have only considered this fixed time alongside 12 unit dosage. With use of the microcontroller (Atmega328p), we can give this dose with an accuracy of 1ms .

Power

Power is provided by 3 LiPo batteries of 3.7V each in series.

Product Dimensions

Without packaging: 16 cm x 10.7cm x 2.75 cm, 200g approximately With packaging - 20 cm x 14 cm x 6 cm , 250g approximately

Warranty terms

A 6 month warranty for the motor and 1 year warranty for the other components will be provided.

4 Product Architecture

4.1 Block Diagram Abstraction of the Device

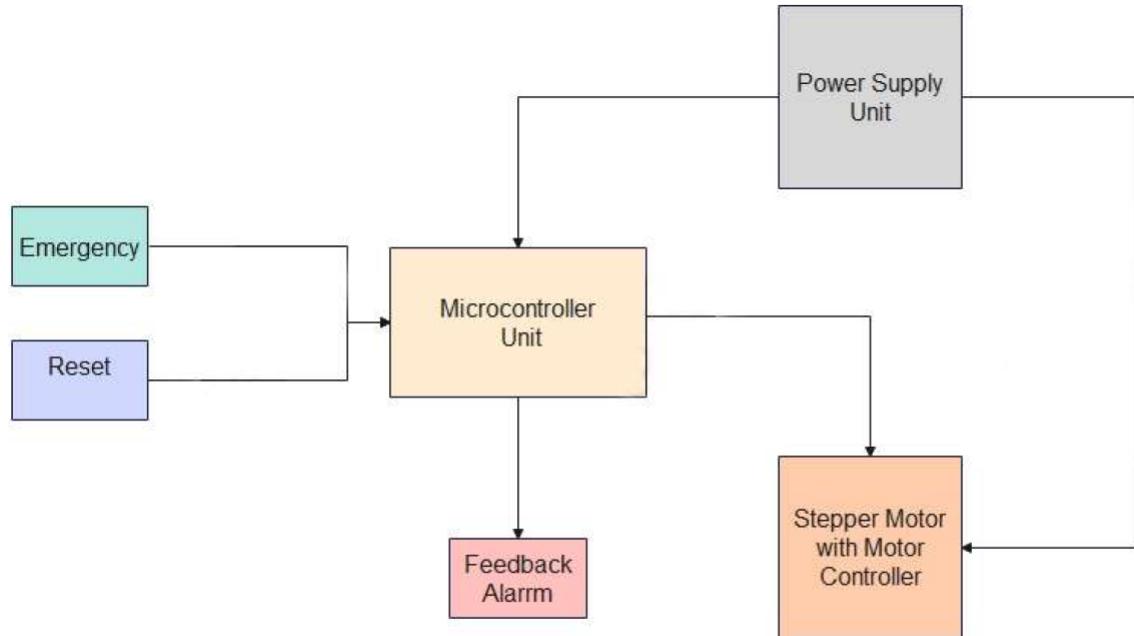


Figure 1: Block Diagram of the Device

4.2 Functionality of the Blocks

Micro-controller unit

This is an ATmega328p microcontroller programmed such that it produces required signals with an 8 hr time interval as an output. These signals manage the direction as well as the no. of steps of motor driver. This is also programmed and connected in such a way it sends the signals even when the emergency button is pressed.

Stepper motor

A D8-MOTOR80 stepper motor with a slider is connected to, and is controlled by an A4988 stepper motor driver. This motor driver is used to drive the motor so that the slider moves in either of the directions back or forth as specified. The motor driver also specifies the step size that the slider of the stepper motor will move. These specifications are controlled base on the signals of the microcontroller.

The injection consisting of insulin is connected to this slider such that insulin is injected with the notion of the slider of the stepper motor.

Feedback alarm

A buzzer provides a beep when insulin is injected to the body, providing confirmation to the user that insulin was injected. This is connected to the microcontroller, with the same connection connected with the motor driver, so that the buzzer works every time the signal is sent to the motor driver.

Power supply

Three 3.7V rechargeable batteries are used to power the device. A 5V voltage regulator is connected to power up the Microcontroller unit and the buzzer. The 11.1V power supply is directly connected to the motor driver.

A power switch and an indicator that the device is switched on will also be available.

Emergency switch

During an emergency, when this switch is pressed, a fixed amount of insulin will be injected into the body instantly. Once this button is pressed, the next dose will automatically be injected after the fixed time duration specified.

This is connected to the motor driver.

Reset Switch

When this reset switch is pressed, the microcontroller resets the timer to zero. After pressing this button the first dose will be injected after the fixed specified time duration between doses (i.e. After 8 hours in our prototype)

However, the above mentioned time may differ if the person used the emergency button before that.

5 The Circuit

5.1 Voltage Controller Circuit

This circuit consists of a LM7805 CV Voltage Controller, and two capacitors.

This outputs 5V when a higher input voltage is supplied. The maximum input Voltage that can be supplied is 35 V.

The three pins are for input Voltage, Ground and Output Voltage respectively.

The output voltage is used to power the microcontroller and the logic circuit of the motor controller.

The two $47\mu F$ capacitors are connected to the input and output voltages to filter ac voltages. For functionality of the voltage controller, the capacitor values should be above $47\mu F$, therefore we have used $47\mu F$ capacitors for this.

5.2 16 MHz Crystal Oscillator

This will supply a clock signal to the microcontroller so that it refreshes in a frequency of 16 MHz. The capacitors are connected to the two terminals and grounded. These are essential for the functionality of the oscillator.

The capacitor values selected is $22pF$. These are selected based on the datasheet of the Crystal oscillator.

5.3 Motor driver

This has two supply Voltages. 5V is supplied as the Logic circuit and 12 V is supplied as the power supply. This power supply is connected through a capacitor so that Alternating current is filtered. The maximum rated voltage that can be supplied as the power, is 35 V.

The motor driver is also supplied with two voltage signals from the microcontroller. These two signals controls the no. of steps and direction that the motor should move. We need to inject 12 units of insulin per dose. Therefore, per each dose, the motor should move 7mm, in order to achieve this.

In the motor, for each cycle, it has 200 steps. For each cycle the motor slider moves 5mm across. Therefore, per dose,

$$\begin{aligned} \text{No.of steps} &= \frac{200}{5} \times 7 \\ &= 280 \text{steps} \end{aligned} \tag{1}$$

The microcontroller sends 280 pulses per dose to the motor driver. This is used to move the slider of the motor. The 4 outputs of the motor driver is sent to the motor. These are the ground, Supply voltage, Step and Direction.

5.4 D8-Motor 80

This motor moves and pushes the syringe 7mm per dose. When the syringe volume is over, and after the syringe is refilled, the user has to press the reset button. Then, this slider of the motor moves back to the initial position.

The four outputs of the motor driver is connected as the inputs for this.

5.5 ATmega328p microcontroller

Inputs from the crystal oscillator, reset button and emergency button are connected to this. Power is supplied to this through the voltage controller. Outputs signals of step size and direction of the motor is sent to the motor driver as the outputs.

6 Testing

Current control to the motor

Even though the motor needs 9 - 12 V for functionality, when 11.1 V is supplied to the motor through the driver, due to the high current drawn motor gets damaged. To avoid this, we need to control the current to the motor.

This is adjusted by turning the screw in the motor driver. When the reference Voltage between the ground and the screw when the motor driver is powered should be,

$$\begin{aligned} V &= \text{MaximumMotorCurrent} \times 0.8 \times \text{CurrentSensingResistanceoftheMotorDriver} \\ &= 0.8 \text{ A} \times 0.8 \times 0.068 \\ &= 0.435 \text{ V} \end{aligned} \tag{2}$$

When we adjust it to this value, the current to the motor is controlled. The level can be increased or decreased by turning the screw.

Continuity of components in the PCB

This was tested by using a multimeter.

Further testing will be done when going beyond prototype in order to adhere NMRA regulations.

7 PCB Design

The following images are of the PCB design.

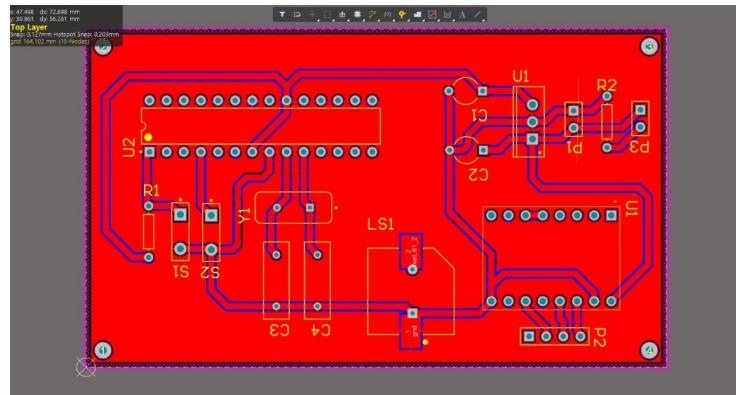


Figure 2: Top Layer Design

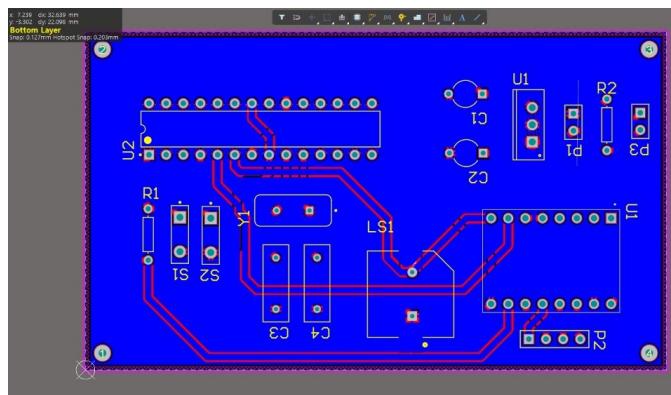


Figure 3: Bottom Layer Design

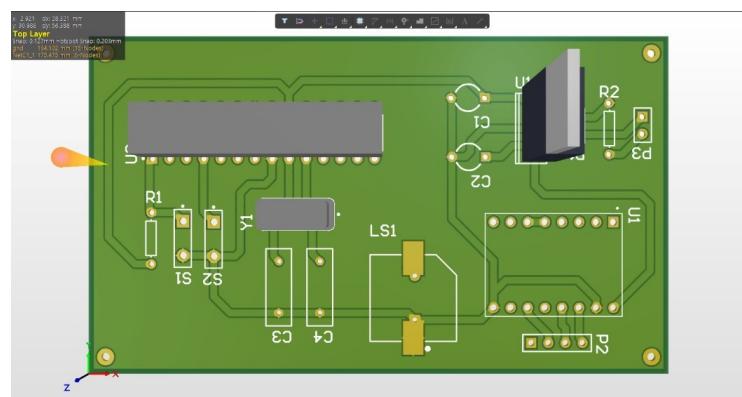


Figure 4: 3D View

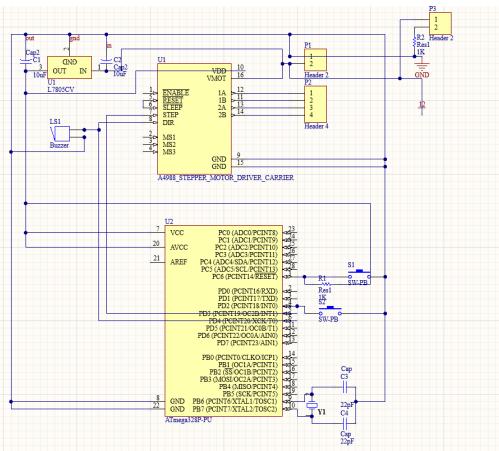


Figure 5: Schematic Diagram

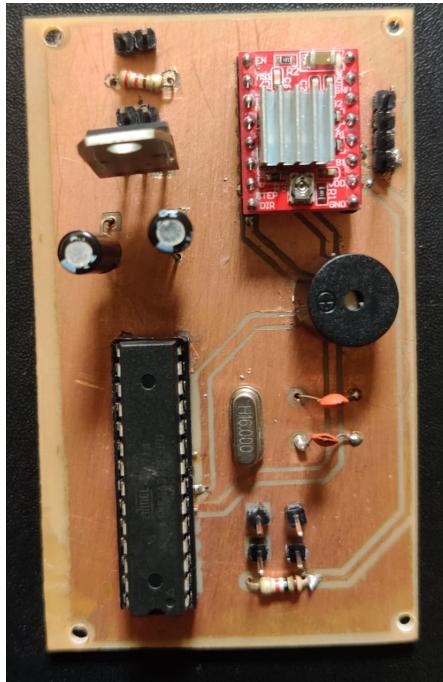
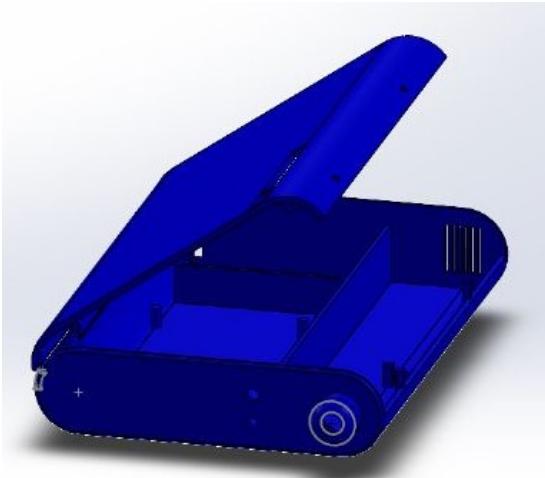


Figure 6: Printed View

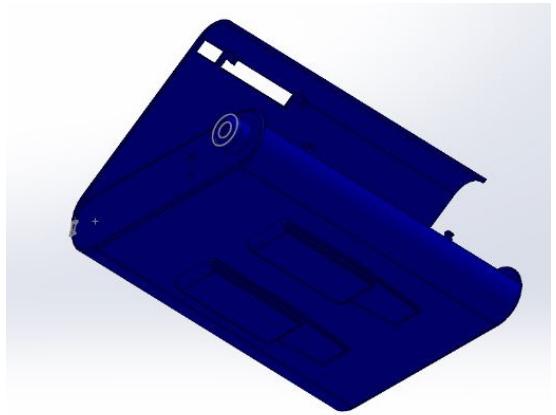
8 Enclosure Design

The product is a wearable device that is connected to the patient by a cannula and is worn throughout the day. Therefore it is lightweight so as to not affect the daily essential tasks of elderly patients. The device should be worn on a belt or a similar article of clothing. The user controls are minimal as the dosage and the times are preprogrammed. There is a button to administer a dose at any given time at a time of emergency. Additionally, a button to reset the device once insulin is refilled is also available. The user will be notified of any administration with audio feedback, it will also provide a long beep, to indicate that the syringe needs to be refilled. It will also have an indicator light to show that the device is turned on. The patient has no involvement in the administration of the doses, but only in changing the insulin cartridge after the refill. The side with the insulin cartridge has an exposed area on the top face so that the patient can monitor and have an idea of how much is left. When insulin refilling is required, the user has to open the enclosure, take the syringe out, refill it and press the reset button after placing it back again.

Considering the safety, manufacturability and user experience, the final enclosure design is as follows.



(a) Solidworks Design - Top Appearance



(b) Solidworks Design - Bottom Appearance

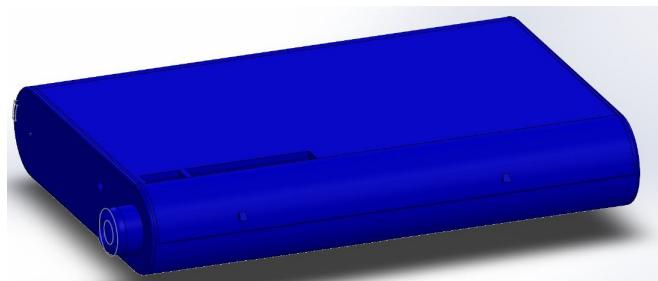
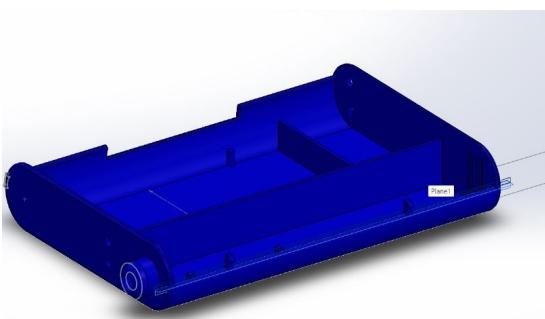


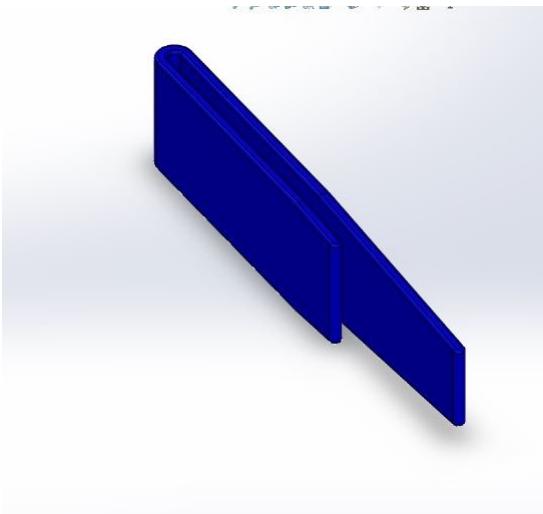
Figure 8: Solidworks Design - Outer Appearance



(a) Solidworks Design - Inside View of Bottom Half



(b) 3D Print - Inside View of Bottom Half



(a) Solidworks Design - Holder Clip



(b) 3D print - Holder clip

9 Delivery Method

First, the needle should be injected into the body by a medical professional. This needle should be kept watertight to stop infections. The needle should be changed in a maximum time of two weeks by medical professionals. Within two weeks, refilling the insulin syringe is sufficient. The insulin pump can be worn on the body by a belt, or on any other clothing item. The reset button should be pressed after refilling the syringe and keeping it back inside.

10 Business Model

10.1 Small Scale Production

Our target is to manufacture 200 - 500 units. However, for the initial stage, we would manufacture 50 units. We target to bulk print the PCB through a foreign company, and bulk produce the 3D print the enclosures through local companies. We hope to assemble these by ourselves.

10.2 Marketing

After the product is tested and the functionality and durability are ensured, we aim to get the NMRA approval for our device. Thereafter, we aim to send our product to the market. Our target is to market through specialists in the diabetic field. By ensuring the advantages and functionality of our device to them, we aim to introduce our product to our target patients through hospitals, clinics, pharmacies, etc.

Product packaging

The device will be packed in a rigid foam casing, and that will be enclosed by a box.

Maintenance

Other than providing a detailed trilingual handbook on how to use the device, we will also be providing details on using the device to the hospital staff of diabetic clinics. During an issue with a user, they can contact the hospital staff. If a problem arises within them we will be providing a hotline to contact us.

Repair

6-month warranty will be provided for the moving parts of the device and a 1-year warranty will be provided for the other components. Minor breakdowns and disruptions will be fixed by our team if sent to our manufacturing sites within the warranty periods. Thereafter, the users will be charged for components and the service of repairs.

Reuse/Recycle

The batteries should be recycled at battery recyclers. Other parts can be recycled at local electronics recyclers.

Disposal

The device should be disposed of at e-waste recycling stations

11 Project Budget

11.1 Cost of Modules and Components

Component	Unit Price (Rs.)	No.of units	Price (Rs.)
Atmega 328p	2000	1	2000
16 MHz Clock Crystal	50	1	50
22 pF Ceramic Capacitor	30	2	60
100pF Ceramic Capacitor	30	1	30
10F Capacitor	10	1	10
L7805 Voltage Regulator	70	1	70
220 Ohm Resistor	5	2	10
17 F Capacitor	10	1	10
A4 988 Motor Controller	450	1	450
Stepper Motor	3200	1	3200
Push Button	25	2	50
Switch	50	1	50
3.7V battery	780	3	2340
Buzzer	60	1	60
Syringe and butterfly cannula	60	1	60
Total			8450

11.2 Product Price of the Prototype

Price of components	Rs. 8450
PCB printing	Rs. 550
3D printing	Rs. 4500
Other expenses	Rs. 1,200
Profit (15%)	Rs. 3,675
Total Product Price	Rs. 18,375

12 Areas of possible improvement

- The device can be made so that the time and dosage can be selected and adjusted as necessary.
- This improvement would allow the device to be used by patients of all ages rather than the targeted elderly patients.
- With the development of smart insulin patches (still in research stage), they can be implemented to the device, so that the patients can experience a painless insulin delivery.
- With use of smaller batteries, the enclosure can be further miniaturized.
- The size and weight of the device could be reduced to make the ability to wear and engage in daily tasks easier. This would also be only required when going to the broader group of patients.

13 Installation Guide



- When u first buy the product.**
- 1** Fill the syringe and the cannula part with insulin.
 - 2** Open the device and place the syringe in the position shown.
 - 3** Connect the cannula to the needle of the syringe.
 - 4** Connect the butterfly cannula to the patient. (Obtain medical professionals assistance if necessary)
 - 5** Make sure the end of the syringe is in contact with the slider. (Shown in diagram)
 - 6** Close the device
 - 7** Power on the device.
 - 8** Confirm the device is switched on by the power light.
 - 9** Wear the device on the body as required.

When u first buy the product.

Open the device and take the
syringe out.

1

2 Refill the syringe.

Place the syringe so that the end
is in contact with the slider as
shown in image.

3

4 Close the device.

Press the reset button.

5

The device starts timing once you press the reset
button. (Ex: First dose will be injected after 8
hours)

In an Emergency

Press the emergency button.

12 units will be injected once you press
the button. The 8 hours start from the
beginning once you press this button.

This can be pressed if you want a dose as
soon as you refill the syringe.