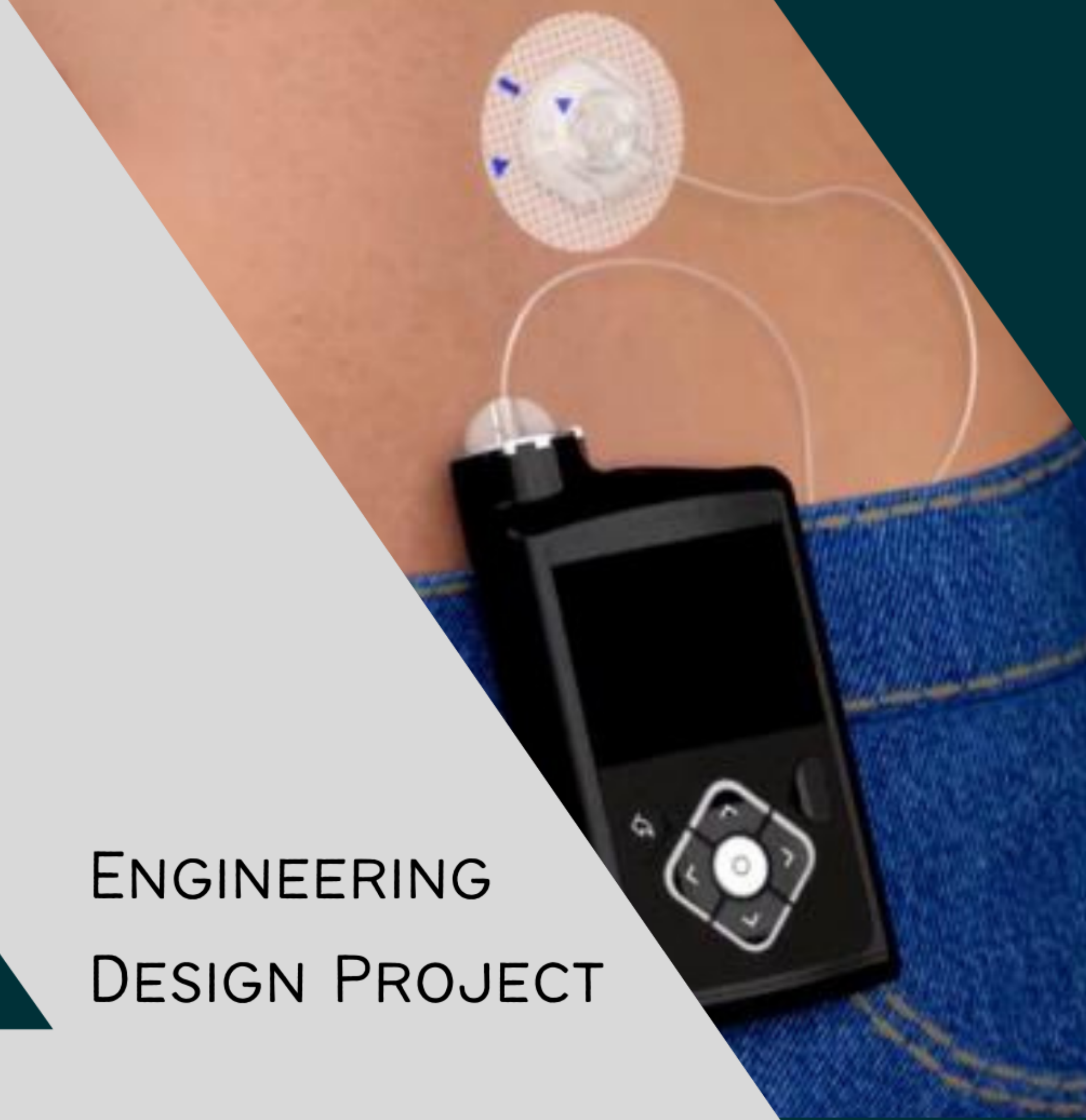

BM1190

Engineering

Design Project

SIMPLE LOW COST INSULIN PUMP

Detailed design Project Proposal

Group BM-04

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Problem Description

Starting point

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.

Motivation

Elderly people have difficulty injecting needles by themselves. Also, even younger patients have issues due to being afraid of needles. 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, is of very high price, being unaffordable for Sri Lankans. Therefore our target is to build a simpler insulin pump, which suits the needs and economy of Sri Lankan patients.

Our solution

The simplified insulin pump will have 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 to the body automatically. It will have an emergency button, to inject a certain amount of insulin in an emergency. It will also provide 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 infections, and to change the place of injection. (This time differs from patient to patient). Also, the attached patch should be watertight such that the injected place will be free form contact of water and other infections.

Who benefits from this solution?

–The users are type -1 and a certain number of type 2 diabetic patients. This is about 2000 - 3000 people in our country.

Product Idea Validation

Difficulties are faced by elderly type 1 and certain type 2 diabteic patients in injecting insulin by themselves. Also other than that, there are patients who have fears in injecting needles to themselves. Also, parental supervision is needed for children with type 1 diabetes, so that doses won't be missed. Other than this, the product can also be used by any other patient who finds it inconvenient to inject insulin every time by themselves.

How the problem affect the end users

Due to the above mentioned problem, they need a caregiver (their children etc.) to take care of that. But due to the economic crisis, there are problems with constant availability of such a person.

Elderly people miss doses due to the aforementioned issue, and due to considering it an inconvenience to bother someone to inject insulin to them everyday.

Perspective of medical professionals associated in this field

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.

Technical Specifications

Performance in quantitative terms

In our design we have to concern about two measurements

- Time duration between two doses

- Dosage

When it comes to the dose, patients in Sri Lanka are prescribed to get a specific unit of insulin by the doctors.

1 Unit= 0.01ml

So our product can inject insulin with 1 unit accuracy.

Regarding the Duration between two doses, 8 Hrs duration is used by Sri Lankan patients typically to get 3 doses per day. And since we use a microcontroller (Atmega328p), we can give this dose with an accuracy of 1ms.

Power will be provided by a 9V battery

Product dimensions

Without packaging - 14 cm x 7 cm x 2.5 cm, 200g approximately

With packaging - 20 cm x 10 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.

Technical feasibility

Hardware Requirements

- Atmega 328p Microcontroller - can provide the time accurate to 1ms.
- 9-12V Stepper Motor - one step linear displacement of 0.025 mm can provide the accuracy of 0.01 ml dosage.
- 9V battery

Software Requirements

- Altium(PCB Designing)
- Solidworks((Enclosure Designing)

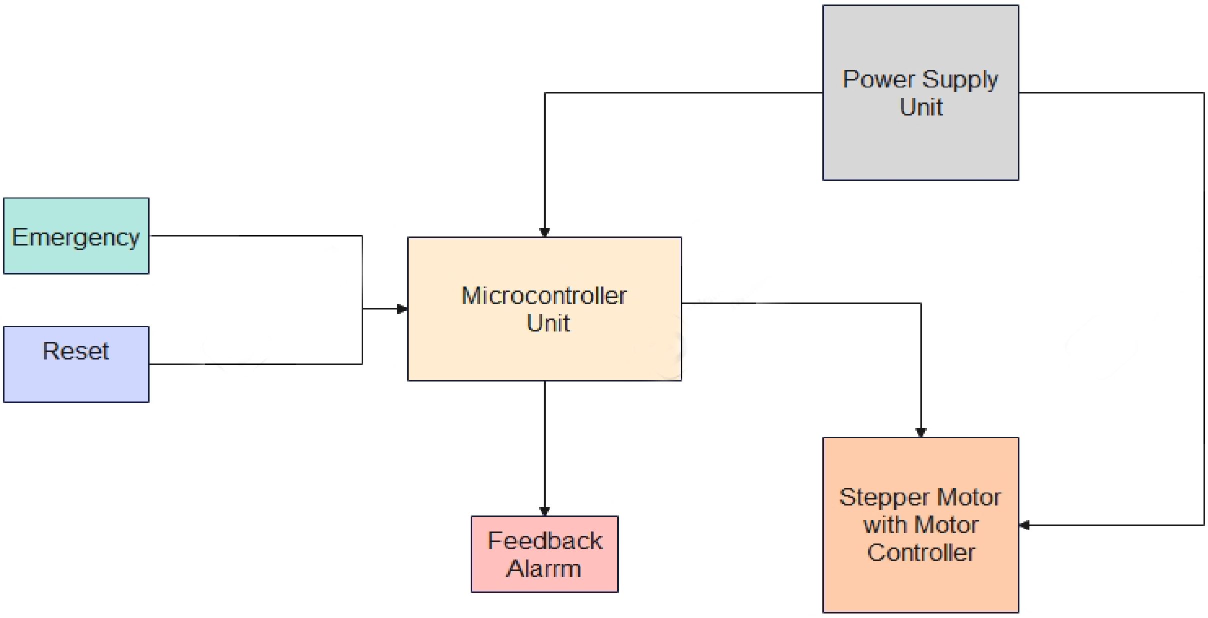
Programming Languages

- C/C++

Therefore, we can come to the conclusion that the performance requirements of the device are reachable.

Product Architecture

Block diagram of our device



Functionality of the blocks

Microcontroller unit

- An Atmega 328p microcontroller is programmed so that it can produce a signal with an 8 hr time interval as an output.

Stepper motor

- A D8-MOTOR80 stepper motor with a slider connected controlled by an A4988 stepper motor driver is used to drive the motor with the slider in both directions .

Feedback alarm

- A buzzer provides a beep when insulin is injected to the body, providing confirmation to the user that insulin was injected.

Power supply

- A 9V replaceable battery is used to power the device, 5V voltage regulator is connected to power up the MCU and a power switch and an indicator will be available.

Emergency switch

- During an emergency, when this switch is pressed, a fixed amount of insulin will be injected to the body instantly.

Reset switch

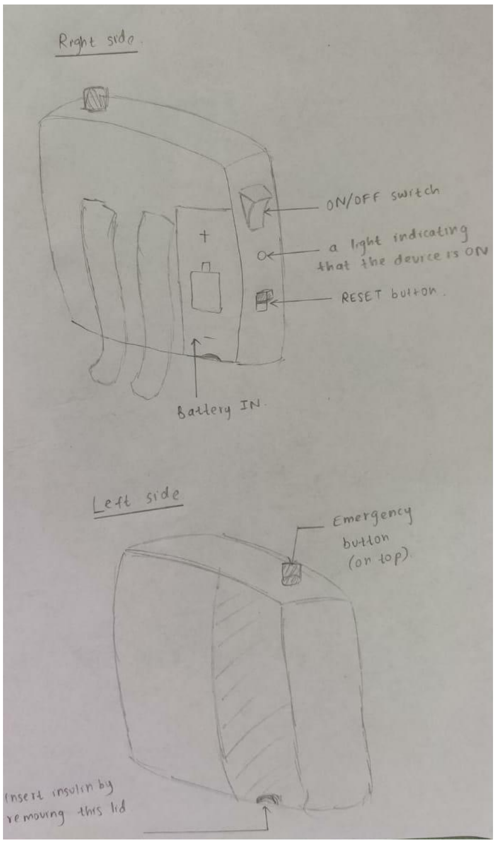
- When this reset switch is pressed, the microcontroller resets the timer to zero.

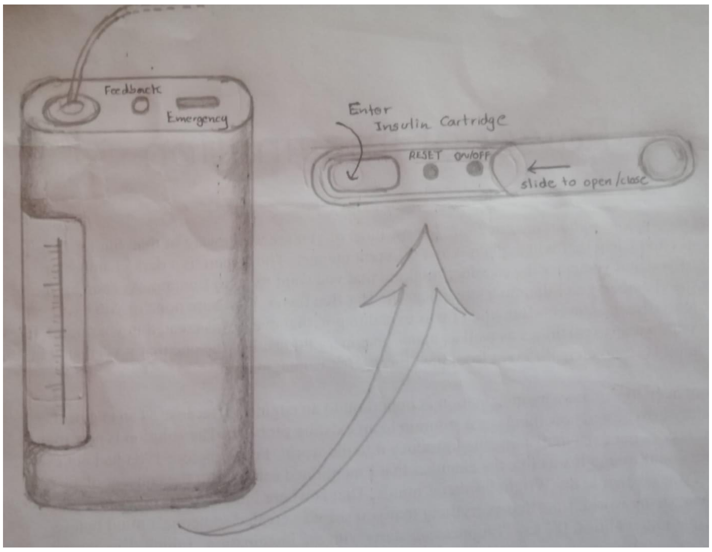
Alternatively a 12V rechargeable battery pack can be used as the power source instead of the replaceable 9V battery.

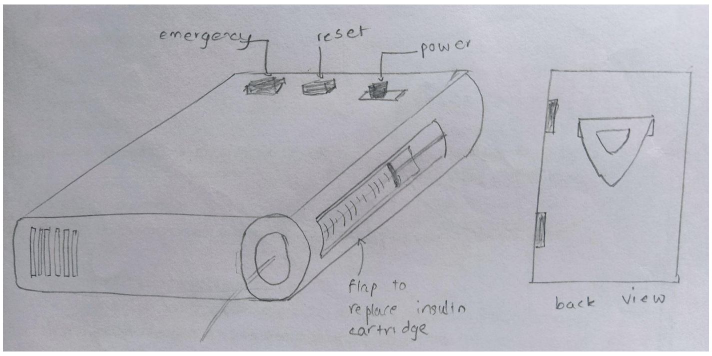
Enclosure Design

- The product is a wearable device that is connected to the patient by a cannula and is worn throughout the day. Therefore it has to be lightweight and not affect the daily essential tasks of the elderly patients.
- The user controls have to be simplified as the patient is not expected to make any adjustments but in any emergency they must be able to administer a dose.
- The device should be worn on a belt or a similar article of clothing so the size has to be manageable.
- The user controls are minimal as the dosage and the times are preprogrammed. There will be 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.
- The side with the insulin cartridge will have an exposed area so that the patient can monitor and have an idea of how much is left.
- The expected way is for the patient to have no involvement in the administration of the doses, only changing the insulin cartridge after refill is necessary to be done.

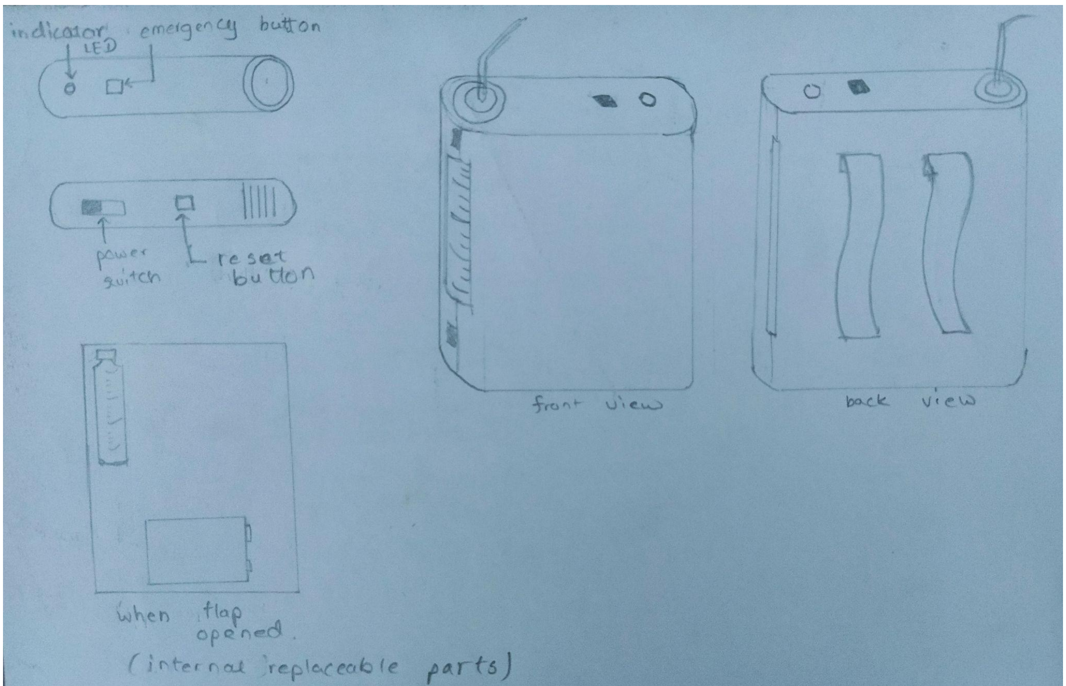
Initial sketches







Final sketch



Considering the safety, manufacturability and the user experience, the final sketch was done as above.

- The product will have a simple enclosure and it will involve as few removable or moving parts as possible, hence it will be possible to be 3D printed.
- The colour would be white, grey or light blue generally used in medical devices.
- The enclosure will not require handling except for instances of refilling insulin or changing the cannula. Therefore ergonomics are only considered for the wearability of the device on a belt.

Marketing and Sales and Beyond

After the product is tested and the functionality and durability is ensured, we aim to get the NMRA approval for our device. Thereafter, we aim to send our product to the market.

•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 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 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.

Project Budget

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
10µF 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	1500	1	1500
Stepper Motor	4000	1	4000
Push Button	25	2	50
Switch	50	1	50
9V Battery	2000	1	500
Buzzer	60	1	60
Cartridge	800	1	800
Total			9200

Product Price for the prototype (Approximately)

Price of components	Rs. 9,200
PCB printing	Rs. 1,000
3D printing	Rs. 4,000
Other expenses	Rs. 1,000
Total Product Price	Rs. 15,200

•Manufacturing:

- Our target is to produce around 200 - 500 units.

•Marketing

- Our target is to market through specialists in 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.

Task Allocation

PCB Design and Circuit Building	Pahansith Tharuka (200641T) Umesha Tilakarathna (200664P)
Enclosure Design	Senul Samarasekera (200558U)
Delivery System	Umesha Tilakarathna (200664P)