# Reliable and Affordable Embedded System Solution for Continuous Blood Glucose Maintaining System with Wireless Connectivity to Blood Glucose Measuring System

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## ABSTRACT
Even though diabetes has been a rapidly increasing health problem, adequate quality treatment continues to be an economic burden to common man. Nowadays patients rely on treatments like oral medication and manual injection of insulin because of the high cost of insulin pumps. So to help the common man, especially patients at the acute stage of Diabetes, a reliable and affordable embedded system solution including complete hardware and software development for continuous blood glucose maintaining system with wireless connectivity to blood glucose measuring system is proposed.

## Keywords
Diabetes, Embedded system solution, Insulin pump, Glucometer, MEMS pump, Continuous maintaining system, Basal dose, Bolus dose.

## 1 INTRODUCTION
Diabetes is a condition in which human body lost its ability to control the Blood Glucose level to its adequate amount. Glucose is the main source of energy to our body. Carbohydrates, proteins, fats that our body receives through food intake is digested and converted into glucose. This glucose is used by body cells for energy and excessive glucose should be converted into fat which will be stored in cells. The hormone that helps for conversion of excessive energy into fat is called insulin, produced by Beta cells of the Pancreas.

The patient with diabetes fails to produce adequate amount of insulin to maintain the blood glucose level. There are two main types of diabetes: Type 1 diabetes occurs more frequently in children and young adults. Here, pancreas fails to produce sufficient amount of insulin. Type 2 diabetes is much more common and nearly 90-95% of adults fall under this category. Here insulin produced is defective and cannot move glucose to cells. The most common complication of Type 2 diabetes is heart disease, also known as macro-vascular disease, leading to heart attack. It may also increase risk of developing micro-vascular disease of eyes, kidneys and nerves which can result in blindness, kidney failure, foot ulcers requiring amputation, and impotence in men. These complications usually occur after many years of diabetes due to delay of medication. As of now there is no cure for either type of diabetes and the only solution is to keep diabetes under control.

At the initial stage, usually treatment is done with combination of diet, exercise and oral medication which helps the body to produce more insulin. In advanced stages, the patient needs to take insulin along with oral medication. Usually one injection of long-acting insulin or two injections of intermediate-acting insulin is required per day. In the acute stage of diabetes if the pancreas is not functioning properly, we need some mechanism for continuous maintenance of glucose level like an artificial pancreas. There comes the need of insulin pump.

According to the survey, by 2030 in India alone, 87 million people are expected to suffer from Diabetes [1]. For the treatment of Diabetes, Glucose meter and Insulin pumps are available in the market. However available pumps from mainstream companies are expensive - about $6000 approximately. Cost of running the pump for a month is around $300. Thus it is estimated that an average Indian family has to spend 25% of their income, for proper Diabetes Care. Hence, this research aims at designing and developing a low cost embedded system solution for continuous blood glucose maintaining system with blood glucose measuring system.

There have been many attempts towards Insulin Infusion therapy. But many have stopped with simulations. The few attempts for developing Insulin delivering system prototype were based on syringe pump and used stepper motor controls [2]. There have been some attempts to develop a solution for integrated intelligent MEMS based Insulin Pump [3].

The general architectural feature and design of insulin pump is given in the website of Texas Instruments [4] and design and solution for development of general infusion pump is given in the website of MAXIM-IC [5]. Glucometers are already well established in the market. But Bluetooth enabled models and control using Android mobile phones is very few [6]. The general architecture of Glucometer is given in the website of MAXIM-IC [7]. Android application development is done in Eclipse IDE with ADT [8]. Secured Connectivity is made using Bluetooth wireless technology. Analysis and testing of secured communication was done based on the methods suggested by Nathanel Paul and et al.,[9]. Proposed embedded system solution for the low cost insulin pump and glucose meter along with Bluetooth communication and Andriod based user interface will play major role in providing medical care for diabetic patients with low initial investment and running cost for maintenance.

# 2 SYSTEM FEATURES

The system consists of mainly two parts: Insulin Pump and Glucometer. Insulin pump is the main part of the system which will inject accurate amount of insulin to the patient's body and maintains the blood glucose level. Insulin is injected in two ways. For continuously maintaining the blood glucose level, a small dose of insulin is injected every 3 minutes. This is called Basal dose. After food, the blood glucose level shoots up, so to avoid the sudden raise, a heavy dose of insulin injection is given before break-fast, lunch and dinner. This is called Bolus dose. Based on the doctor's prescription, the adequate dosage is stored inside the insulin pump. Once dosage is stored, the pump will automatically inject based on the glucose level. Patient can manually take the bolus injection before food. But the body can receive only a limited amount of insulin per day. This is called the total delivery limit of the day (TDD). This will be already programmed inside insulin pump, so pump will not inject insulin once TDD is reached.

MEMS pump is capable of pumping 0.02unit per cycle called 1 dose. 1unit is equal to 10µ litre. The pumping is achieved by giving a pulse of 500ms ON and 500ms OFF cycle. Thus number of pulse is decided by checking how much dosage needs to be pumped.

The basal doses are set in different profiles, according to the activities a person may perform in different days such as working days, holidays, party days and fasting days. Alarms are provided in Insulin Pump to inform the patient about the events happening. Visible LED alarms, audible buzzer alarms and vibrating alarms using vibrator motor is provided here. Red LED for critical and yellow LED for warning alarm. Separate tones are produced for warning and critical buzzer alarms. Vibrator is provided only for critical alarms and vibrates once after every bolus dose. Every alarm events and bolus dose are saved in the memory with time stamp from integrated RTC. The history of events can be sent to doctor's device through Bluetooth and saved in excel sheet for future reference. One of the unique feature of this Insulin pump is the protection of the device from accidental shutdown without the knowledge of the patient and the unit can be put out only through software modules with the help of power module and microcontroller.

Insulin Pump is designed to work in two different modes. Mode-1: As an independent Profile based insulin pumping unit. Here the profile is set by doctor in consulting with patient. Mode-2: Insulin Pump work together with Glucometer to provide suggestion regarding the bolus dose in comparison with the saved glucose reading for the corresponding profiles.

The patient can measure his current blood glucose level using the Glucometer. Glucometer is an independent system. It is developed in a manner to work together with insulin pump. Glucometer operates in two modes. Mode-1: It works as an independent glucose monitoring device, with the help of an Android application. The Android application in the mobile phone controls Glucometer, display glucose concentration and alarms associated with it. Mode-2: Glucometer's operation is connected to insulin pump through Bluetooth. This mode provides the current blood glucose concentration to insulin pump and suggests diet and medication.

The MEMS pumping module used for this work is designed and developed by AMBE Research Centre, Amrita Vishwa Vidyapeetham, Coimbatore, India.

# 3 ARCHITECTURE

System architecture of Insulin Pump includes MSP430 controlling unit that generate control signals for the proper functioning of Graphic LCD and keypad for user interface, RTC for real time functionalities, EEPROM for permanent storage of events, power module for achieving independent functioning unit that will provide constant power supply by boosting single cell battery voltage, Bluetooth for communication with Glucometer and doctor's device. It also consists of alarm modules such as LEDs, Buzzer and Vibrator. One of the challenging units of insulin pump is the MEMS pump module, consisting of driver circuit and occlusion pressure feedback signal sensing circuit. Figure 1 shows the architecture of insulin pump.

System architecture of Glucometer includes MSP430 control unit, power module, Bluetooth communication module and alarm LEDs. The major unit of Glucometer is the circuit comprising glucose sensor together with sensor interface circuit, consisting of potentiostat and current to voltage converter.

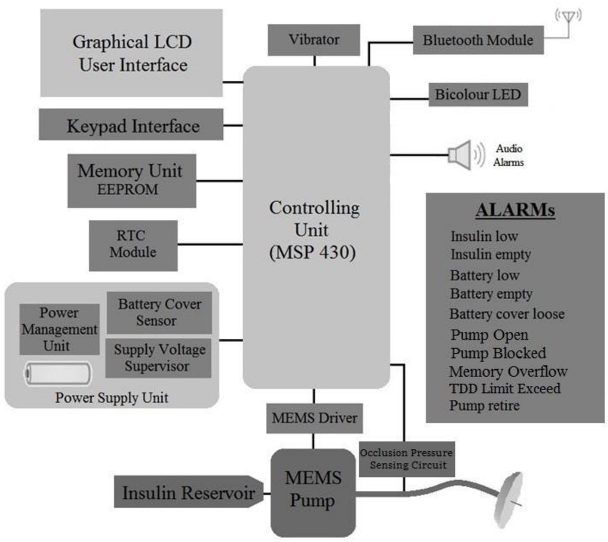



**Fig 1: Architecture of Insulin pump**

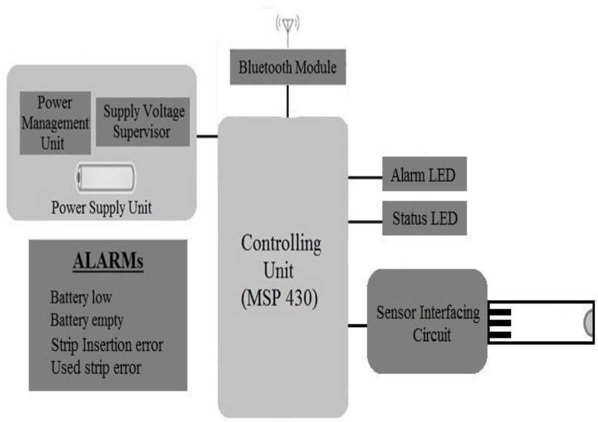



**Fig 2: Architecture of Bluetooth enabled Glucometer**

# 4 DESIGN AND DEVELOPMENT

We had designed and developed two independent systems (i.e) Insulin Pump and Glucose Meter with secured Bluetooth Communication between the two systems for exchange of critical data from Glucose meter to Insulin Pump.

## 4.1 Insulin Pump

For an acute Diabetes patient where pancreas is not functioning properly, the blood glucose level will be beyond his/her control. So the blood glucose level should be continuously monitored and should be maintained to its normal level. Insulin Pump pumps Basal dose and Bolus dose of Insulin for maintaining glucose level in blood. Pumping is done with the help of MEMS pump. Insulin Pump also contains User interface, Keypad, Bluetooth, Memory, Real Time Clock, LED, Audio and Vibrator Alarms.

Insulin Pump is having an insulin reservoir and syringe for injecting insulin into the body, through canula. Air present in the canula at the time of inserting needle to the body should be removed. So a function called Prime is added to the program. User can select the function with the help of LCD and switch. Insulin Pump has the provision for adjusting the amount of Basal dose and Bolus dose by the doctor. There are several profiles such as Working Day, Holiday, Party Day, Fasting Day, etc. For each profile, the dosage will be different. Also there are provision for Extended Bolus dose and Correction Bolus dose for extra bolus amount as desired by the patient. Each and every event of bolus dose will be stored in the memory with time stamp with the help of RTC.

Alarms for any malfunctions are provided to add high reliability to the system. Alarms such as Low Battery alarm, Battery empty, Battery cover loose, Insulin low, Insulin empty, Pump blocked, Pump open, Battery over heat and other few. Battery alarms are provided with the help of Power module while the battery cover alarm is provided with the help of small push button switch, Insulin alarms with the help of counter set inside the program, Pump open and closed with the help of Occlusion pressure sensing with the help of feedback signal from the MEMS piezo-disc. Alarms are also classified into warning and critical alarms. Warning alarms include Low battery, Insulin low. Critical alarms include Battery empty, Insulin empty, Battery cover loose, Pump blocked, Pump open, Battery over heat. For warning alarms Yellow LED will glow and a warning tone will be given. For critical alarms Red LED will glow, Vibrator will be on and critical tone will be given.

Each and every alarms and all bolus dose are stored in the memory with time stamp. This history of events can be seen from the LCD menu options in the Insulin pump. Insulin Pump will also send this information to the doctor's device through Bluetooth and will be stored as in a spread sheet form in the computer.

## 4.2 Glucose Monitoring System

Glucometer uses amperemetric sensor strip for measuring glucose concentration from human blood. Amperometric sensors give current output corresponding to the concentration of glucose in the blood, at constant potential applied to the strip terminals. Strip used here consist of three terminals, working electrode (WE), counter electrode (CE) and reference electrode (RE). Current generated from working electrode of test strip is converted to corresponding voltage and fed to microcontroller's ADC. This section is implemented with potentiostat and current to voltage converter circuits. This ADC reading is mapped to glucose concentrations through predefine look up table method. This glucose concentration is used for Glucometer Mode 1 and Mode 2 operation.

In Mode-1: Glucometer communicates with android application in the mobile phone. Here the mobile phone acts as the controlling device of Glucometer. The glucose values received from Glucometer is displayed and stored in the android application. Warnings such as improper test strip insertion, low battery voltage, error in glucose reading associated with Glucometer will be displayed on the android application for user information. The stored glucose concentrations can be further forwarded to the doctor for further analysis. This enables Glucometer to be a part of remote patient monitoring system [10].

In Mode-2: When Glucometer and Insulin Pump are in Mode-2 they work together. Glucometer sends the current glucose readings to the Insulin Pump and Insulin Pump will give suggestion regarding the diet and medication by comparing with the stored blood glucose level for the corresponding profile that is currently in action and will also inject appropriate dose of insulin.

# 5 SCREEN FLOW AND ALGORITHM

## 5.1 Screen Flow of Insulin Pump

Complete working of Insulin Pump can be controlled by the patient using the Graphic LCD and keypad interface. The some of the screen shots are as shown in figure 3

## 5.2 Algorithm of Glucometer

The logical operations of Glucometer is described using the algorithm

**Procedure for making use of Glucometer:**

Step 1: Start glucometer
Step2: Connect glucometer to Android application/Insulin pump via wireless
Step 3: Start testing commands
Step 4: Insert test strip

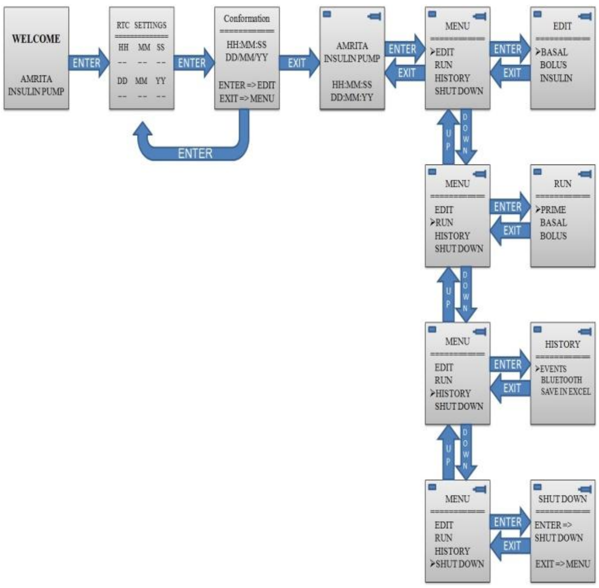



**Fig 3: Screen flow of Insulin Pump**

Step 5:Check: if test strip inserted properly
Goto step 6
else
Goto step 4
Step 6: Apply blood on strip for testing
Step 7: Perform glucose concentration testing
Step 8: Send glucose concentration to android phone/Insulin pump
Step 9: Stop glucometer

## 6 HARDWARE AND SOFTWARE IMPLEMENTATION

Hardware unit of Insulin Pump includes interfacing of graphic LCD using SPI, RTC using I2C, EEPROM using I2C, Power module with power-up and shutdown action, Bluetooth using UART and MEMS pump with its driver circuit interfaced to MSP430 microcontroller. The alarms modules LEDs are interfaced directly with a resistor, buzzer is driven directly and vibrator motor is driven with the help of SSR module. The feedback signal from piezo disc is given to ADC through signal conditioning circuit consisting of current to voltage converter and non-inverting amplifier. The hardware setup of Insulin Pump is illustrated in figure 4.
Hardware unit of Glucometer consists of MSP430 interface with glucose sensing circuit through ADC, power module, Bluetooth through UART and LEDs with current limiting resistor. The hardware setup of Glucometer is illustrated in figure 5. For the development purpose LCD is also included in Glucometer. This design can also be used as an independent device with user interface LCD and keypad.

Software control logic for Insulin Pump and Glucometer is programmed in to MSP430 using IAR embedded Workbench and debugged using MSP-FET430UIF. For the PCB layout design Proteus-ARES is used.

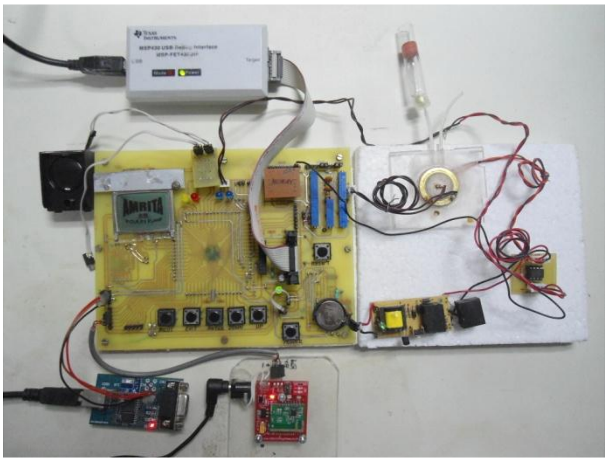



**Fig 4: Insulin Pump hardware implementation**

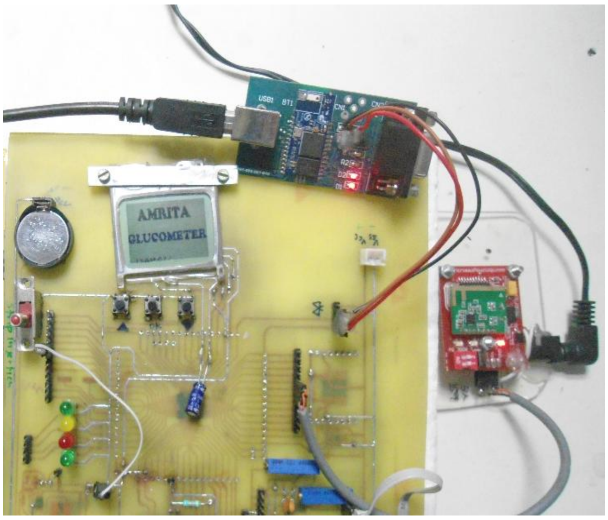



**Fig 5: Glucometer hardware implementation**

## 7. COMMUNICATION

Communication is utilized in three situations. They are: Between Insulin Pump and doctor's device, Insulin Pump and Glucometer, Glucometer and Android application in the mobile phone.
Communication between Insulin Pump and Doctor's device is achieved with Bluetooth V2.0. Controlling of Glucometer with the help of Android mobile phone is also achieved with the help of Bluetooth V2.0. Secured communication between Insulin Pump and Glucometer is done with the help of secret PIN.

## 8 ANDROID APPLICATION DEVELOPMENT

Glucometer is controlled with Android phone with the help of application installed in it. Eclipse IDE with ADT is used for application development. The Android application used for controlling Glucometer is as shown in figure 6. On starting the application it will ask the user for enabling the Bluetooth module of mobile phone. Here after the user needs to pair mobile phone with Glucometer with user set pin code of Glucometer, after successful pairing android application will be connected to Glucometer. The android application includes provision for testing glucose concentration, view history, setting

Glucometer in low power mode and to wake Glucometer from low power mode. After successful measuring of glucose concentration the application will display the concentration in mg/dl. If there is any error in glucose reading and malfunctioning with Glucometer it will be indicated in the android application as error and warning


**Fig 6: Android application**

# 9. SYSTEM ANALYSIS

The developed system was tested under various conditions and exhaustive output analysis was done and is tabulated as below

**Analysis of Power module**

Power module boosts the voltage from single cell battery to constant supply of 3.3V. Output voltage is supervised continuously and digital logic is developed for various alarms related with power module. Outcome of Power module analysis is tabulated as in Table 1 below.

**Table 1: Power Analysis**

| **Battery Input**<br><br>**Voltage in volts** | **Power Module Supervisor logic** | **Battery Condition /Alarm** | **Battery**<br><br>**icon**<br><br>**(No. Of**<br><br>**Blocks**<br><br>**(x/4** |
|---|---|---|---|
| Less than 0.8 | 00 | Battery empty | 1 block |
| 0.8-1.0 | 01 | Battery low | 2 block |
| 1.0-1.2 | 10 | Battery average | 3 block |
| 1.2-1.5 | 11 | Battery good | 4 block |

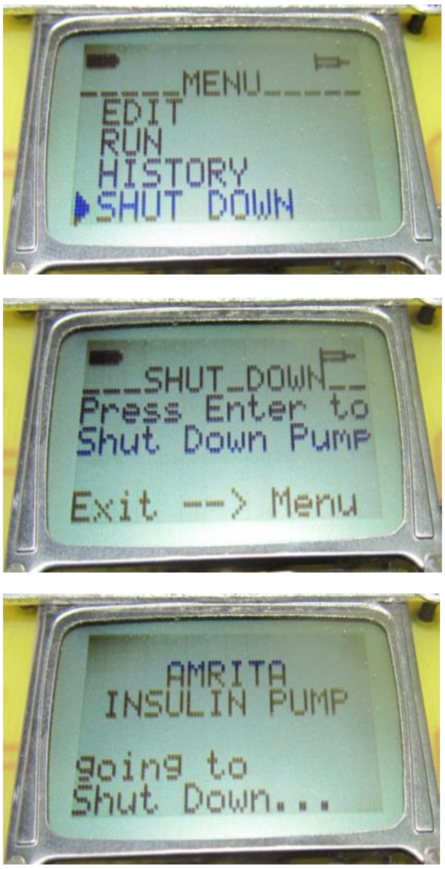



**Fig 7: Options in Power Module**

**Table 2**: **Analysis of alarm events of insulin Pump**

| Situations | Alarms | LED | Buzzer tone | Vibrator |
|---|---|---|---|---|
| Battery Low | Low Battery alarm | Yellow | Warning | No |
| Battery is empty | Battery empty, Shutdown | Red | Critical | Yes |
| Battery Cover is Loose | Battery cover loose, Shutdown | Red | Critical | Yes |
| Insulin level Low | Insulin low | Yellow | Warning | No |
| Insulin level Empty | Insulin Empty | Red | Critical | Yes |
| TDD Limit is reached | TDD Limit Exceeded | Red | Critical | Yes |
| Occlusion pressure low | Pump Open | Red | Critical | Yes |
| Occlusion pressure high | Pump Blocked | Red | Critical | Yes |
| Memory Overflow | Memory overflow | Yellow | Warning | No |
| Situations | Actions | Red | Critical | Yes |

**Table 3**: **Analysis of communication between Insulin pump and Glucometer**

| **Properties** | **Settings** | **Actions** |
|---|---|---|
| Availability | Visibility settings | Bluetooth of glucometer and insulin pump was made visible only to the intended users |
| Confidentiality | PIN code settings | Patient can set the PIN code for secure Bluetooth communication |

**Table 4** : **Conditions of shutdown of insulin pump**

| **Situations** | **Actions** |
|---|---|
| Software Shutdown | Shut down action with the help of option in the MENU |
| Battery Empty | Battery Alarm will occur. Pump automatically go to shutdown mode by time-stamping the event shutdown due to battery empty |
| Battery Cover Loose | Battery Cover Loose alarm will occur. Pump automatically gets shutdown after 2minutes if battery cover is not properly inserted. |
| Pump Retire | Upon 2years from the deployment of pump, Pump Retire alarm will occur and Insulin pump will automatically goes to shutdown. Tested on virtual mode. |

## 10 RESULTS AND CONCLUSION

User interface using graphic LCD and push button switch was developed for this unit to provide easy access. Sensor circuit in Glucometer is calibrated using standard glucose solutions and tested with human blood. Hardware is able to inject Basal and Bolus doses in a pre planned manner with high accuracy. Various Alarms and Bolus events are successfully time stamped using RTC and stored in the EEPROM. Bluetooth communication between Glucometer and Insulin Pump are successfully achieved and suggestions / medication details are displayed on graphic LCD. Secure Bluetooth communication is tested by hacking the connection between Glucometer and Insulin Pump and it is proved that the wireless connection is hard to break without knowing the secret 4 digit PIN. History of the units can be transferred to the customized computer application in the doctor's device. Sample screens of a single event are shown in the figure 8. Figure 9a and 9b shows the excel sheet created as a part of storing the History information of Insulin Pump and Glucometer respectively.

## 11 FURTHER WORKS AND FUTURE SCOPE

This system only gives the suggestions on diet and medications based on the predefined parameters set by the doctor. By incorporating additional patient information regarding glucose level that may naturally develop in his body based on the food intake, body characteristics and activities performed, the required insulin dosage can be calculated using intelligent computational algorithms. This intelligent unit can be integrated into the Insulin Pump to make it as a complete artificial pancreas for the diabetic patients.

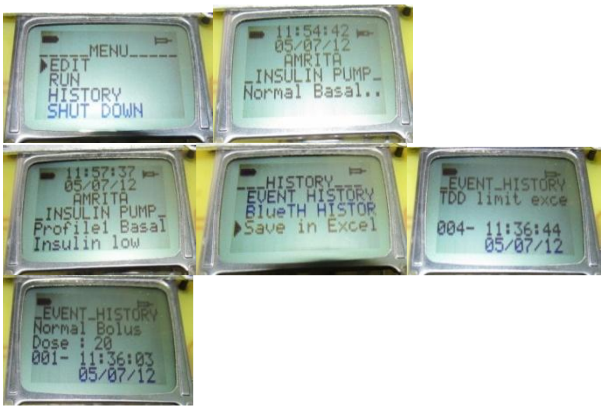
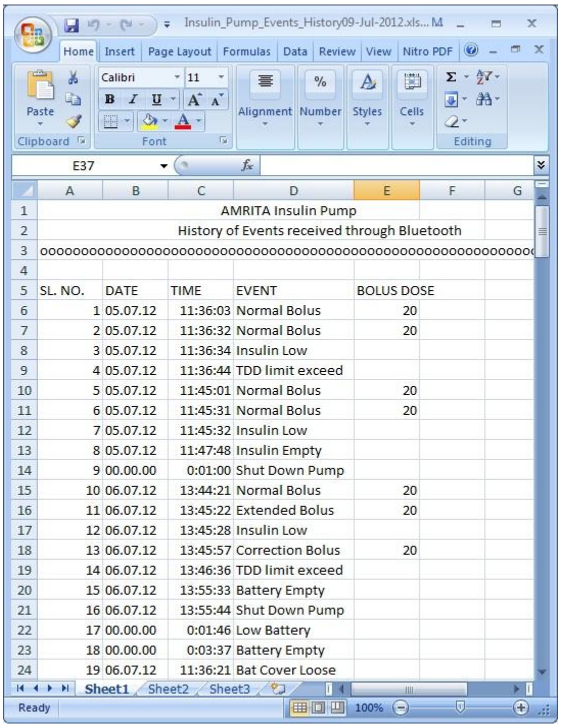



**Fig 8: Screen shots of Insulin Pump**.

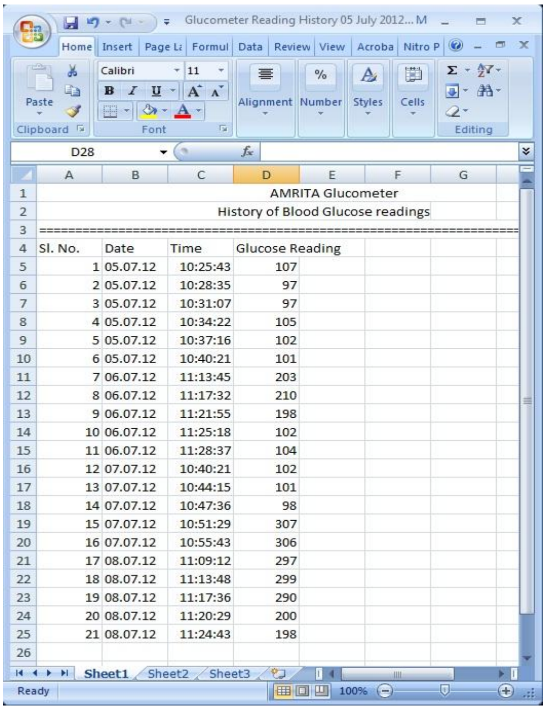
Insulin Pump can be also be programmed to communicate with doctor's device and can send message to mobile phone or send email to the doctor regularly and as and when any abnormal events happens, like abnormal glucose levels high/low read by Glucometer or alarms associated with insulin pump. It is planned to conduct various test on the Glucose Meter to validate the data integrity and confidentiality. Currently, the default security mechanism of Bluetooth communication by securing through PIN is deployed and in future it is planned to incorporate a simple and reliable crypto mechanism for the wireless communication between the Insulin Pump and the Glucose Meter. It is also planned to do interference study of communication between the two units in home environment as well as Hospital and other public environments.



AMRITA Insulin Pump
History of Events received through Bluetooth

| SL. NO. | DATE | TIME | EVENT | BOLUS DOSE |
|---|---|---|---|---|
| 1 | 05.07.12 | 11:36:03 | Normal Bolus | 20 |
| 2 | 05.07.12 | 11:36:32 | Normal Bolus | 20 |
| 3 | 05.07.12 | 11:36:34 | Insulin Low | |
| 4 | 05.07.12 | 11:36:44 | TDD limit exceed | |
| 5 | 05.07.12 | 11:45:01 | Normal Bolus | 20 |
| 6 | 05.07.12 | 11:45:31 | Normal Bolus | 20 |
| 7 | 05.07.12 | 11:45:32 | Insulin Low | |
| 8 | 05.07.12 | 11:47:48 | Insulin Empty | |
| 9 | 00.00.00 | 0:01:00 | Shut Down Pump | |
| 10 | 06.07.12 | 13:44:21 | Normal Bolus | 20 |
| 11 | 06.07.12 | 13:45:22 | Extended Bolus | 20 |
| 12 | 06.07.12 | 13:45:28 | Insulin Low | |
| 13 | 06.07.12 | 13:45:57 | Correction Bolus | 20 |
| 14 | 06.07.12 | 13:46:36 | TDD limit exceed | |
| 15 | 06.07.12 | 13:55:33 | Battery Empty | |
| 16 | 06.07.12 | 13:55:44 | Shut Down Pump | |
| 17 | 00.00.00 | 0:01:46 | Low Battery | |
| 18 | 00.00.00 | 0:03:37 | Battery Empty | |
| 19 | 06.07.12 | 11:36:21 | Bat Cover Loose | |

**Fig 9a: Insulin Pump History of events saved in excel format**.



AMRITA Glucometer
History of Blood Glucose readings

| Sl. No. | Date | Time | Glucose Reading |
|---|---|---|---|
| 1 | 05.07.12 | 10:25:43 | 107 |
| 2 | 05.07.12 | 10:28:35 | 97 |
| 3 | 05.07.12 | 10:31:07 | 97 |
| 4 | 05.07.12 | 10:34:22 | 105 |
| 5 | 05.07.12 | 10:37:16 | 102 |
| 6 | 05.07.12 | 10:40:21 | 101 |
| 7 | 06.07.12 | 11:13:45 | 203 |
| 8 | 06.07.12 | 11:17:32 | 210 |
| 9 | 06.07.12 | 11:21:55 | 198 |
| 10 | 06.07.12 | 11:25:18 | 102 |
| 11 | 06.07.12 | 11:28:37 | 104 |
| 12 | 07.07.12 | 10:40:21 | 102 |
| 13 | 07.07.12 | 10:44:15 | 101 |
| 14 | 07.07.12 | 10:47:36 | 98 |
| 15 | 07.07.12 | 10:51:29 | 307 |
| 16 | 07.07.12 | 10:55:43 | 306 |
| 17 | 08.07.12 | 11:09:12 | 297 |
| 18 | 08.07.12 | 11:13:48 | 299 |
| 19 | 08.07.12 | 11:17:36 | 290 |
| 20 | 08.07.12 | 11:20:29 | 200 |
| 21 | 08.07.12 | 11:24:43 | 198 |

**Fig 9b: Glucometer History of Blood Glucose readings saved in Excel format**

## 12. ACKNOWLEDGEMENTS

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