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Design and Development of a Simulating Prototype Cost Effective Insulin Management System

KEYWORDS: Diabetes Mellitus, Blood Glucose, Hyperglycemia, Hypoglycemia, Insulin Infusion System

Mohsen Ahmadi
Department of Biomedical Engineering, Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

Neda Hajizadeh
Department of Biomedical Engineering, Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Tehran, Iran

ABSTRACT *Diabetes is a major worldwide health concern. Insulin pump is used to mimic the human pancreas by delivering short-acting insulin at varying rates as a Basal dose to control glucose levels continuously. It can also deliver Bolus doses to control glucose levels around meal times or to correct high blood glucose level. Current insulin pumps are still expensive and not available to most diabetes patients in many countries. The aim of this work is to design, develop and construct a robust and inexpensive simulating prototype insulin management system. The technologies used in the construction of insulin pumps are sophisticated and include delicate electromechanical components as well as artificial intelligence. The device will have full capability to maintain various functions at all times including that of insulin delivery program and a whole host of other features that will make the management of diabetes a lot easier. The knowhow can be used in the manufacture of systems with great dosing accuracy, ease of use and lifestyle flexibility for diabetes patients at a very low cost.*

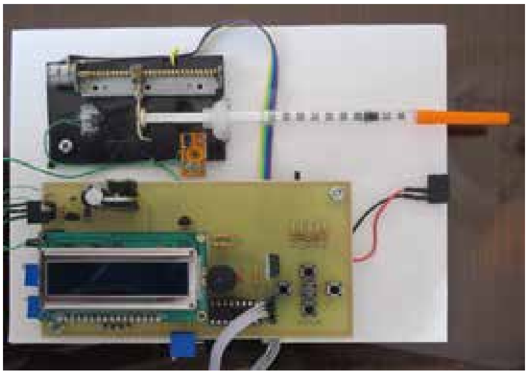
I: INTRODUCTION

Diabetes is a disease that affects millions of people every year worldwide. Many need to take injections of insulin to normalize the level of sugar in their bodies to prevent complications such as kidney failure, loss of circulations and blindness. Although there is no known cure for diabetes, there are several treatments which can control this disease.

Intensive diabetes management can be achieved in two ways: 1) Multiple Daily Injections (MDI), 2) Continuous Subcutaneous Insulin Infusion (CSII). [1,4]. MDI method can be a great inconvenience and imposes restrictions on diabetic's activities and life style. Also, it can be difficult to maintain a consistent level of blood glucose because of limitation to the number of injections that most patients can receive [2, 3].

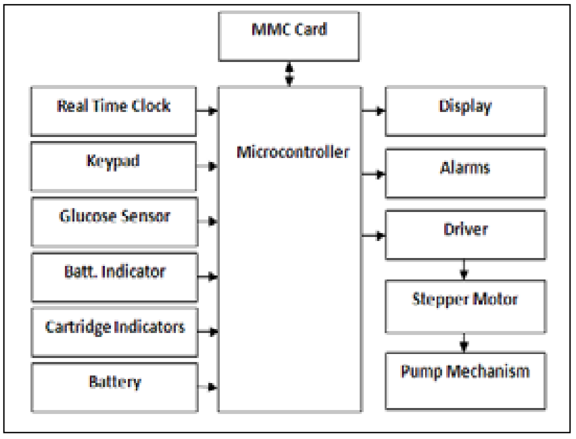
Continuous Subcutaneous Insulin Infusion is a method for insulin delivery that mimics the human pancreas by delivering short-acting insulin at varying rates as a Basal dose to control glucose level continuously. It can also deliver Bolus doses to control glucose level around meal time or to correct high blood glucose level [5]. Currently, insulin pumps provide insulin to a diabetic at constant rates, but they are so expensive [6]. In this work, we design, develop and construct a simulating prototype insulin management system. It compares very well with available commercial systems, although it is user friendly, low cost and offers extended functionalities.

Figure 1: Insulin Management System Prototype



II: MATERIALS AND METHODS:
SYSTEM DESIGN
A. Hardware: Electronic control board

Figure 2: An overview of the micro and the relevant signals



System's hardware consists of a control board and an electro-mechanical unit that delivers insulin to patient (Figure 1). At the heart of the board there is a Microcontroller, ATmega32, from Atmel Corporation. Figure 2, shows the block diagram of the microcontroller with all relevant signals. The system is powered by an Alkaline 9 volts DC battery which is regulated to 5 volts where needed. The two signals that enter the inbuilt analog digital converter (ADC) of the Micro, measure blood glucose and battery's voltage level respectively. Information is displayed on a text liquid crystal display (LCD), LM016L from Hitachi (Figure 3). A keypad provides input communication with microcontroller and consists of five push-buttons that satisfy all necessary user interaction with the system (Figure 1). Signals that are transmitted from the Micro, shown in Figure 2, are those for the LCD control, audible alarms, reminders and other functions. The beginning and end of insulin supply cartridge is sensed by two micro switches whose outputs are fed into the Micro. Finally, data trends such as insulin delivery size, time and date are stored on a Multi media card (MMC) card.

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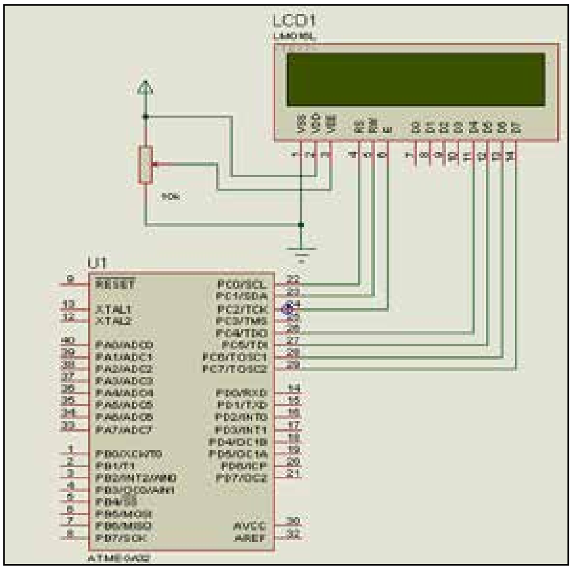
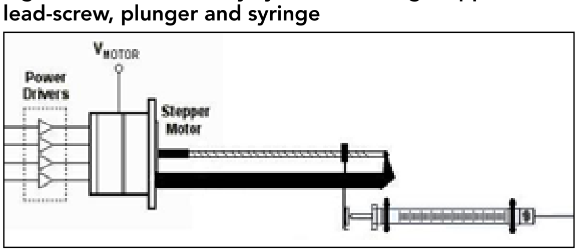
Figure 3: Signal connections between micro and the LCD



Micro's real time clock (RTC) provides the application program with real-time so that the functions executed by the micro can track and control the actual time that insulin delivery and other events occur. Furthermore, it provides precise time durations used for alerts, alarms, reminders and other functions.

Figure 4: Insulin delivery system including stepper motor, lead-screw, plunger and syringe



ELECTROMECHANICS

The actual insulin delivery system consists of a stepper motor whose rotating shaft drives a lead-screw that moves a plunger inside a syringe linearly (Figure 4). In this prototype system, the motor comes from a broken DVD writer/reader device found on any computer and has sufficient torque and step resolution for this application. The stepper motor is controlled by the microcontroller in full-step mode. This is because pulling and pushing the plunger needs high torque. Since the system does not need to work in high speed, in this mode, stepper has maximum torque rate because of active 2 phase contemporaneous which improves torque-speed curve and yields more holding torque. This allows the motor to hold its position when it is not in motion; this is essential because steady position of the stepper motor will not cause any back flow of the insulin [7].

SYSTEM DESIGN
B: SOFTWARE

The system is controlled by a menu-driven application program written in C language. The design objectives were ease of use and robustness. The compiler used to develop the code was CodeVisionAVR from HP Infotech. On system power on, the program initializes some parameters and sets the input output pins (I/O) of the microcontroller to their initial states. Program main menu is then illustrated on the LCD and the keys are scanned (Figure 5). The key pads are used to select menu items.

Figure 5: An overview of the system application interface

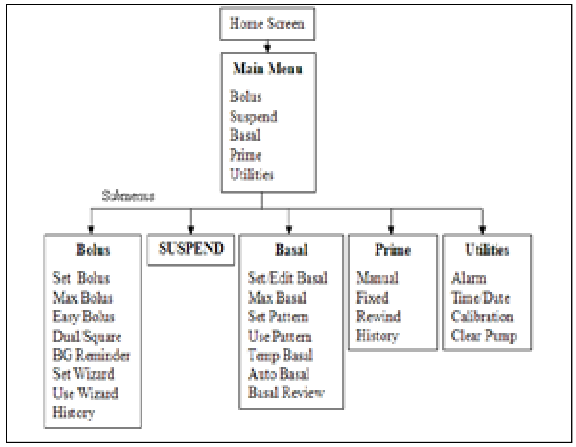


Figure 5 shows an overview of the software package designed for the system. This package can perform various tasks. Insulin delivery formats, speed, step size and delays between steps can be easily tuned that helps the user to meet up any circumstances. Various utilities make system management a simple task. The program can also show insulin delivery trends over certain time period.

III: EVALUATION OF SYSTEM PERFORMANCE

To evaluate the performance of the system comprehensively, some test protocols were devised that would principally verify insulin deliveries in all possible modes. Consequently, software's integrity, stability and correct interaction with system's hardware were tested. Precision, accuracy, resolution and repeatability in delivery of insulin were indices of interest. However, prior to evaluation tests the pump is calibrated. It delivers 50 units of insulin for 313 motor steps corresponding to 0.159 units in each step (pump resolution). The system delivers 1 unit of normal Bolus in 3 seconds.

BASAL DELIVERY MODE

To evaluate Basal routine, we tested the pump at five different delivery rates. For each rate the number of motor steps were counted and multiplied by 0.159 to obtain actual delivery rate. Table 1 shows the differences between the set and delivered rates. As can be seen, they are minimal and within the norms.

Table 1: Evaluation of the basal delivery test results

Test no.	Setting Rate (U/H)	Number of Steps	Delivered Rate (U/H)
1	10	62	9.858
2	5	31	4.929
3	3	18	2.862
4	2	12	1.908
5	1	6	0.954

In a further test, the pump was set specific Basal deliveries in standard and patterned formats for specific time durations. The deliveries were quite accurate both for timing and volume settings. In auto basal mode, the system reverts to deliveries for this mode, correctly, every time, according to the input Basal rate.

In temporary Basal mode, the pump is made to deliver a different set rate temporarily, for a specific time, before returning to its standard Basal routine and whatever delivery rate it was set at. The system performed this manoeveure correctly every time.

To evaluate the system's stability over time in Basal delivery mode, the system was tested for 10 continuous hours. First, 2 hours with the rate of 1U/H, then 3 hours with the rate of 0.8U/H and finally 5 hours with the rate of 1.2U/H. No change in delivery accuracy was observed and the pump performed robustly at all times.

BOLUS DELIVERY

To assess System's performance for Bolus delivery, some 9 different doses were tested. However, Bolus doses delivered in square wave or dual wave shapes were also tested.

Table 2, shows the results for 9 different set doses. The differences between delivered and set doses are negligible and quite acceptable.

Table 2: Evaluation of the bolus delivery test results

Test no.	Setting Dose(U)	Delivered Dose(U)
1	1	0.94
2	2	1.88
3	3.2	3.13
4	4	3.91
5	5.4	5.31
6	6	5.94
7	7	6.88
8	8.6	8.59
9	9	8.91

In further evaluation of other features of the system when blood glucose reminder is set to on, after a set period, a reminder alarm is activated to warn the user to test blood sugar. As well, when user information is fed to the bolus wizard, all calculations are performed correctly and an estimate of insulin needed for correction Bolus or food Bolus is indicated.

To evaluate the system's stability over time in Bolus delivery mode, 3 different doses of 4, 3.2 and 5.4 unit were set within 10 continuous hours and actual delivered doses were measured. There were no changes observed in system's accuracy and the pump remained robust throughout the test. The actual results were identical with those obtained in Table 2.

DISCUSSIONS

The evaluation tests of the prototype system have shown the correct interaction of system's hardware and software. The functions that control insulin delivery worked flawlessly. The overall resolution and accuracy of the system meets the design criteria and compares quite well with similar commercial systems currently on the market. The functionalities built within this insulin management system are quite adequate for effective management of insulin for diabetic patients. The system user interface has been designed to be extremely simple and user friendly. The Bolus wizard built within the system takes simple inputs from user and calculates estimated insulin needed for a whole range of food intakes. Data trending capabilities of the system saves useful information regarding insulin deliveries over time and dates.

CONCLUSIONS

Current insulin pumps are still expensive and not available to most diabetes patients in many countries. In this work, we designed and built a prototype intelligent insulin management system that offers a wide range of functionality and features that enable a diabetic patient to manage his or her insulin needs very effectively. The user interface on the system has been designed to be very easy and simple to use. This prototype system can be the basis of a very low cost industrially built insulin management system comparable to most expensive present devices on the market.

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