Insulin pump testing platform for robust control framework

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***Abstract* — This paper presents the concept of an insulin pump hardware used for testing and analyzing the results of research tasks in the field of physiological modeling and diseases controlling in real environment. It summarizes the available insulin pumps from the market and presents an insulin pump testing platform hardware developed at the recently created Physiological Controls Group of the John von Neumann Faculty of the Óbuda University.**

Keywords: Diabetes, T1DM, robust controller, insulin pump

I. Introduction

Due to the continuous development in control engineering and measurement theories, the possibilities of biomedical engineering are extending. The aim of physiological control—a sub-discipline of biomedical engineering [1]—is to study, model and apply identification and control strategies in order to understand and help automated treatment of various diseases or injuries of the human body.

In many biomedical systems, external controllers provide biosignal input or inject given specific dosage substituting the internal physiological procedure because the patient's body cannot ensure or produce it. The external control can be partially or fully automated. The regulation has several strict requirements, but once designed it permits not only to facilitate the patient's life, but also to optimize (if necessary) the amount of the used dosage. The research team of the recently created Physiological Controls Group of the John von Neumann Faculty of the Óbuda University has gained solid knowledge in the field of physiological control, modeling and identification [2], [3], [4].

Diabetes is predicted by the World Health Organization (WHO) to be the "disease of the future" especially in the developing countries [5]. If for some reasons the human body is unable to control the normal glucose-insulin interaction (e.g. glucose concentration level is constantly out of the above mentioned range), diabetes is diagnosed. The consequences of diabetes are mostly long-term [6], demonstrating that the disease is a serious metabolic problem, and investigating new and potentially more effective methodologies should be welcomed.

Type I (also known as insulin dependent diabetes mellitus) is one of the four classified types of this disease (type II, gestational diabetes and other types, like genetic deflections are the other three categories of diabetes), and is characterized by complete pancreatic cell insufficiency [6]. As a result, the only treatment of patients is insulin injection (subcutaneous or intravenous), usually administered in an open-loop manner.

From an engineering point of view, the treatment of diabetes mellitus can be represented by an outer control loop, to replace the partially or totally deficient blood glucose control system of the human body. This is known in the literature as the "artificial pancreas" problem, an intensively researched topic what requires two additional components beside the "closing-the-loop" algorithms which are [7], [8]: continuous glucose sensor for measurements and insulin pump for infusion.

Our research group has been working on the realization of such controlling environments from a long time. The developed tools are capable of handling and describing the human body's glucose-insulin establishment model, and through this formulates a controlling environment, it becomes realizable, which could make possible the constant, real time glucose level metering and adjustment on both real and virtual patients (CGM – Continues Glucose Monitoring). Until now, we have analyzed the most important and used metabolism models both on absorption and glucose-insulin establishment areas respectively and by applying these we have built an own controlling environment with the use of multiple controller designing and identification methods [10], [11].

The development has reached a state, where it became necessary for our systems not to being only used in simulated environments, but to try them out in a realized hardware environment. To achieve this, it requires a certain hardware which is able to emulate our system. The tools available on the market do not have this feature, because the manufacturers- obviously- are producing a closed developing environment, in order to maintain authority over their product and software; hence, creating a constant development and product cycle this way. Because of this, the devices are not suitable to run our own software or firmware, not only because their closed state, but also for their task specific feature. An ideal hardware environment for our research represented a developing environment built out from general modules, meanwhile being fully capable of running our own systems. Creation of such a hardware has become really important to enable us achieving the goals mentioned above.

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II. PRELIMINARIES

A. Insulin pump based on Microchip PIC32 USB starter kit

At the beginning, the developer panels (manufactured by Microchip) were selected [12]. The main component of the hardware is a PIC32MX460F512L microcontroller, which is located on the Microchip PIC32 USB Starter Kit evaluation board. The architecture of PIC32MX460F512L microcontroller is a 32-bit one, able to operate on low supply voltage, and high speed clock frequency, e.g. 80 MHz. Internal memories consists of 512k Byte program memory, with 12 kByte Boot Flash memory area, and 32 kBytes data memory. The PIC32MX460F512L includes a USB module, which has a dedicated DMA channel. This microcontroller has UART and Timer peripherals as well, these two peripherals are especially important because of the simple communication interface and machine control design.

The PIC32 USB Starter kit contains 3 LED (Light Emitting Diode) and 3 buttons. PICtail Plus connector allows expanding the card, making it well suited to other hardware components, and extended set has to stick together in a complex system suitable for performing an insulin pump control unit.

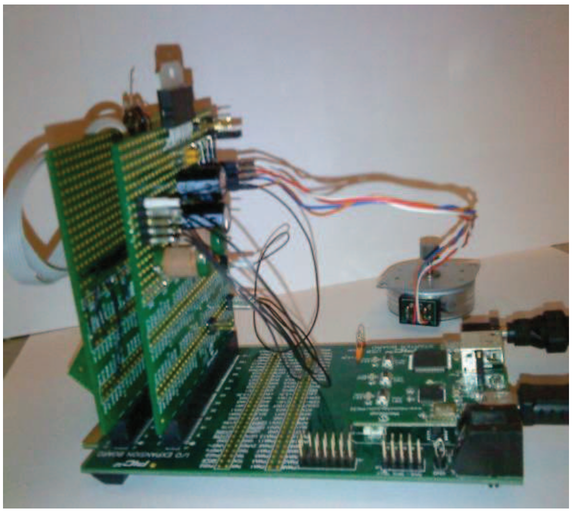

Figure 1. The insulin pump prototype based on Microchip evaluation boards (PIC32 USB starter kit, PIC32 I/O extension board and Pictail boards) and bipolar stepper motor)

The PIC32 I/O Expansion Board for PIC32 starter module development for a panel is presented on Fig. 1. The PIC32 USB Starter Kit for PIC32 connected module is available for all the input and output signals. Terminals on the Expansion Board are further enhanced by the application of Microchip specific cards, such as Graphics PICtail Plus Daughter Board for PICtail Plus board Ethernet PICtail board for SD and MMC. Connectors on the card allow connecting to development tools via the JTAG and ICSP interface, so that the device is programmed easily and it can be tested easily during operation. Due to the PIC32 I/O Expansion Board card is possible to extend PIC32 USB starter kit with communication to the stepper motor driver modules and bipolar stepper motor. The last two units are responsible for the pump moving.

The bipolar stepper motor driver circuit was created on an empty PICtail board, which can be connected to bipolar stepper motor. The engine control panel can be easily connected to the PIC32 I/O Expansion Board; hence, the system is very flexible.

We chose serial communication between the PC and microcontroller components. The reason for this choice was that PIC32 microcontroller has UART peripheral, which is easy to use and is a reliable interface, and the side of the computer is easy to use in case of serial port communication. To let the microcontroller UART periphery connected to a computer, it is necessary for the UART peripheral to a level matching to be aligned to the RS-232 line. In many cases, especially for portable computers (laptop, notebook, etc.) there is no serial port on the computer, but the device needs to be connected to the computers. Therefore, we need to use a RS-232 to USB converter cable that can connect to a computer's USB port, and emulate serial port for the computer. The RS-232 to USB converter cable is available in many computer or electronics store. The developed system is presented in Fig. 1. The software of the microcontroller handles the communication between the computer and the microcontroller, and manages the motor driver circuits.

The designed hardware is very flexible, but there are many risks. The connector damage may cause instability in the connection between each unit. Therefore, we decided to develop an own insulin pump hardware.

B. The commonly used insulin pump architecure on the market

An insulin pump is an electrical device which helps the patient with appropriate indications to manage their diabetes comfortably. The patient’s adequate health and resistance state is an important indication parameter, since the insulin pumps subcutaneous glucose level sensor and insulin injection catheter is embedded under the skins adipose tissues; therefore, it poses a constant threat, because it disrupts the integrity of the skin surface.

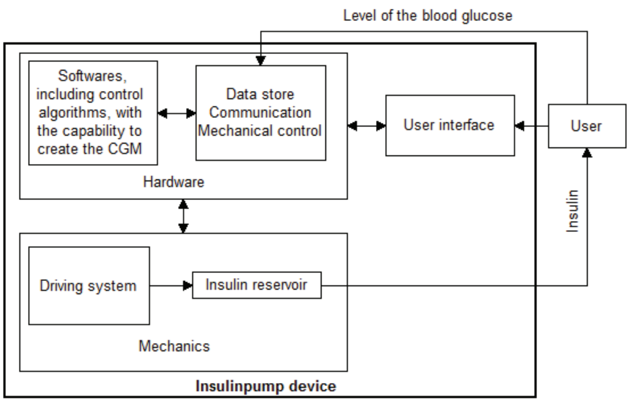

Figure 2. The concepts of the insulin pump device, which measure and send to blood glucose level and dosage the adequate unit of insulin

In most cases, insulin pumps are suggested for patients with Type 1 Diabetes Mellitus (T1DM. In these cases the patients do not have their own insulin production, therefore it should be externally supplied. The device is capable of continuous glucose monitoring, and interruption. Most of the pumps are made up similar way to conception which can be seen on Fig. 2.

There are a lot of available devices on the market, each with different structure. Manufacturers prefer the compact, closed device designs, where only the accumulator and insulin reservoirs are replaceable.

Before the beginning of our development, we have analyzed the available devices on the market, to get an idea of which way we should turn our development. We have found three possible ways two of them being available on the market. [13], [14], [15], [16], [17], [18], [19].

C. The available structure solution on the market

One of the most common approaches is that all functionalities are integrated in one device (for example Medtronic Paradigm Revel).

Advantages:

- Whole product cycle is realizable.
- Safer than other structures, harder to hack.
- Can be sold with higher profit.

Disadvantages

- Collection of user data is more difficult.
- Use of device requires more learning.
- In case of any damage, the whole device must be repaired or replaced.

The other solution divides the system into two separate units. One part measures the glucose level and control the system. The other part contains the insulin pump and the mechanical unit which is controlled by other part (for example Insulet Omnipod).

Advantages:

- The PDA can be custom or commercial.
- Product cycle is realizable.
- Modular, the whole unit.

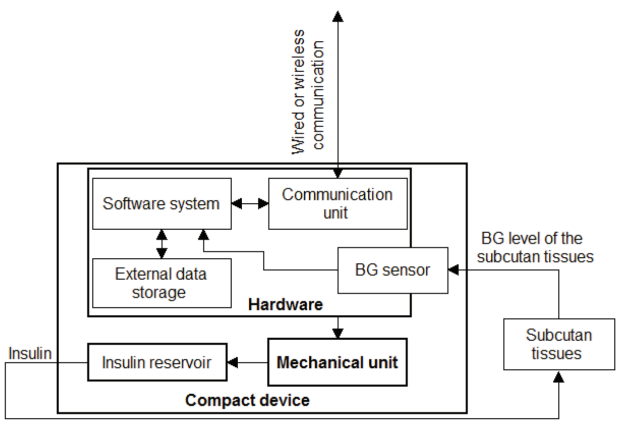

Figure 3. The concept of first type of insulin pump which is available on the market (all functionalities are in one device)

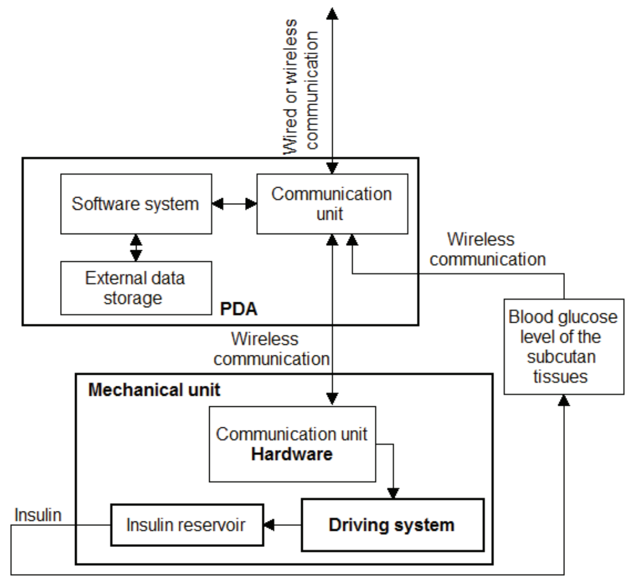

Figure 4. The concept of second type of insulin pump which is available on the market (mechanical unit and the software control unit are separated

Disadvantages:

- Unauthorized persons access to private data typically on communication channel between PDA and mechanical unit
- Data collecting is more difficult
- It can be a more expensive solution

There is a third realization when the controller unit is a smartphone. Such configuration has been unavailable on the market yet, but due to the spread of smartphones and tablets, it will also appear on the future in the future.

Advantages:

- Cheaper solution.
- Custom firmware is not been necessary; software runs on platform of smartphone (e.g. Android).
- Smartphones have Wi-Fi and Bluetooth modules for wireless communication to collect data.

Disadvantages:

- It is vulnerable in terms of security; it is difficult to solve this question in case of open systems.
- Solution of data handling can be problematic.
- Glucose level sensing requires the feed unit or a separate unit also, which is not a good solution, because the glucose level sensing and insulin injection has to be made on separate spots. (Possibly on opposite body parts).

After analyzing the market we have decided, that the first solution would be the best for us, which is the development towards a compact device, but we opened the opportunity for all of the available settlings. So our expansion is capable to run in any given way, it will be depending from the software what we will be created in the near future. Presently by all viewpoints, the product design and the technology are the most mature in the first case.

III. Insulin Pump Development

We began to design our own hardware device along with the chosen development path. We declared the specifications as follows:

- Hardware structure is for general use, easily programmable, possibly built from the best price/value ratio units.
- Make the emulation of our own control environments possible, and give a universal interface, where different controllers, models and patient data (virtual or real) are usable for the full testing of our systems.
- Got to have a user interface, which means that it has such units built in which make the user-system communication possible.
- Possible wired and wireless communication.
- Generated data saving.
- Accessible manufacturers interface, which are universal, but usable for our own custom preferences. (E.g. graphic user interfaces with predefined execution methods; transmitting software to burn C or C++ codes etc.)

We wanted to create a prototype, with no single task oriented units, so we decided to use the products of Microchip Technology Inc. We selected the 32 bit general and 16 bit general/graphics specific chips. We used these in order to control and execute motor control, and graphic display, etc. tasks. Because we are talking about greater data quantities and complex operations, we used flash and SRAM (Static Random Access Memory) memories in our designs. For data storage a MicroSD (Secure Digital) card socket has been built in, which can handle various microSD memory cards. Various sockets have been installed to burn up the chips (as a prototype this was acceptable, but in case of market product, special software and socket is – which can switch between the devices – used. We wanted our device to mean a starting foundation for further development; hence, we designed it, to make multiple communication methods available. In order to do this a FFC/FPC socket has been built in, which has an attachable commercially available LCD/TFT screen (with 240x320 resolution), with touchscreen and seven pushbuttons (5 with not predefined functions) and this is attachable with a separate socket in a similar way, as with the commercial device.

Among most of the available insulin pump devices, the insulin injection, electric motors are used with the following driving system: electric rotary motor with a mechanical converter system which transforms the rotary movement to linear movement.

We decided that the use of a bipolar stepping motor would be the best for insulin injection, as it is simple, but allows accurate controlling. Among the available mini motors, the 1° turning is most typical, which means, that if we use a soft-mechanical thread to convert the rotating motion with 0.5 mm thread rising, the 6 μl will be achievable, that is exactly the 0.6 U injection accuracy. Commercial devices are more accurate than this (e.g. Medtronic Paradigm Revel 0.025 U), but this value for a prototype is acceptable.

The designed hardware structure is presented in Fig. 5 and Fig. 6.

First, the manufactured hardware was checked optically. This means checking the PCB and the individual components soldering with the naked eye and magnifier or microscope. The X-ray examination is carried out in case of complex hardware. This is especially advantageous in the case of surface-mount components (for example BGA package). Our hardware does not contain any special surface mount components, which would require X-ray examination, so this test was not performed.

Thereafter, we measured the accessible power supply and ground wires, and plans to find short circuits by multi-meter, in order to avoid damaging the hardware. Next, the hardware was turned on with a current limit. After everything was set up to work correspondingly, some functionalities of hardware were tested by embedded software of PIC32 microcontroller. The software initializes the microcontroller after turning on the device (e.g. clock configuration, interrupt settings, ports, and communication interfaces initialization) and run in an infinite loop which is called the main loop. The software is able to detect the button press. If Button1 is pressed, one of the LEDs (Light Emitting Diode) is turned on and the bipolar stepper motor turns for a few seconds. If the Button2 is pressed, the other LED is turned on and bipolar stepper motor rotates other direction for few seconds.

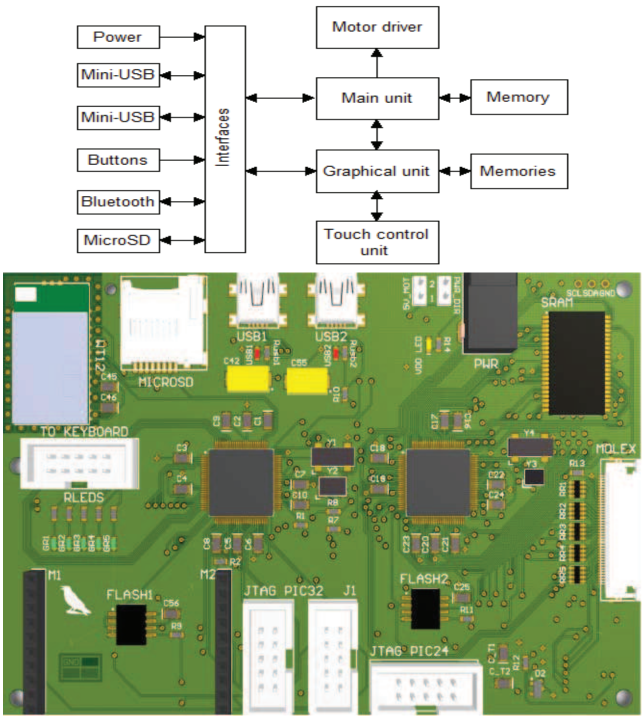

Figure 5. The block diagram of the device (above) and the 3D model of the device in CAD designer software

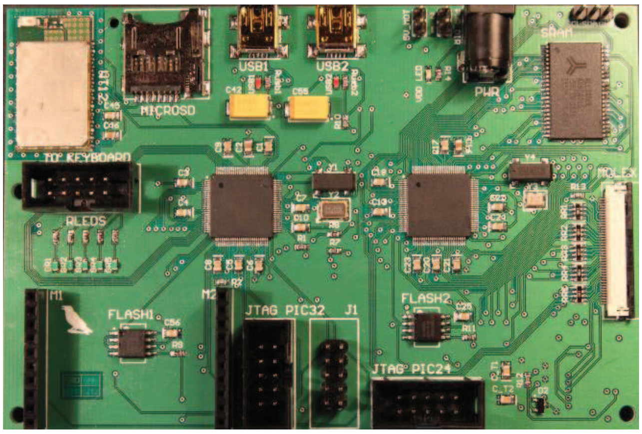

Figure 6. The hardware system

IV. SOFTWARE

During our recent work in the topic, we concentrated on hardware development. Therefore, we will begin firmware development in the near future. The achievable goal was to build in the recent virtual environment controls and models into the software with a graphic interface which utilizes every hardware feature; through, we could test our results. Due to the lack of such open-source software, we were not able to compare our hardware performance with the commercially available hardware. Further developments will make up for this issue.

V. CONCLUSIONS

With this device we reached our first and most important goal: to create a hardware from where on we can try out our simulations and model-based control environments. The second step in our development will be to convert the codes and simulations from MATLAB® system to C++ or any computer languages what we can use directly to "burn up" into this device what we created like main firmware.

VI. FUTURE WORK

The paper summarized the current research tasks in the field of insulin pump hardware development to verify physiological models and controls of diseases with high public health impact carried out by our research group in a real environment. In the future we will focus on the embedded software solution for the insulin pump. In the beginning the software ensures wired and wireless communication between the computer and the insulin pump device, insulin dosage control, and it provides graphical user interface for the patients. The long term plan is that we implement various control algorithms on the device and it will be able to control blood glucose level on an autonomous way.

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