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The design of an insulin pump – preliminary requirements (a technical note)

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The material presented in this paper is an attempt to lay down requirements for the planned design of an insulin pump. An insulin pump is a device for continuous dosage of insulin at a selected rate, which facilitates treatment and improves the lives of diabetic patients. This paper is a compilation of medical requirements and user suggestions of presently offered insulin pumps.

It seems important to establish proper requirements for a device before starting developing any design for an insulin pump.

Key words: Insulin pump, insulin administration, diabetes.

Introduction

An insulin pump is a device for continuous dosage of insulin at a selected rate, which facilitates treatment and improves the lives of diabetic patients.

Basic information along with an example of an insulin pump with an infusion set attached to its user may be seen in [4]. Pictures and parameters of the most popular insulin pumps may be found in [3].

This small mechatronics device makes the life of patients more normal. It is especially important in the case of children. The youngest patients need to educate and socialize with their peers and to grow up in better conditions, which is decisive in their future life.

Unfortunately, insulin pumps are not easily affordable because of their price, as high as several monthly incomes of an average family in Poland. There is no manufacturer of such pumps in Poland, which is one of the reasons of their high price. Starting production in Poland would lower the price and make the device more affordable, which is one of the reasons why we started our design.

Our work is the result of the analysis of the insulin pump market [1, 6, 7, 9, 10], various publications [5, 11] and user suggestions. The Internet diabetes forums were used as a source of insulin pump user opinions (see [12, 2]). The preliminary requirements are the compilation of a medical and user requirements along with existing product parameters.

There were two (as far as we know) attempts to design an insulin pump in Poland, but so far there is no working model or prototype available.

Insulin pumps

An insulin pump is a small mechatronic device that may be split into blocks as shown in Figure 1. Each of the blocks or modules must be well defined to meet medical, technical and user requirements.

The requirements may be divided into three groups:

- Clinical / medical requirements, i.e. treatment parameters, biocompatibility, etc.
- Technical requirements, i.e. accuracy, power consumption, reliability, lifetime, etc.
- User requirements, i.e. usage, shape, colour, etc.

From a scientific point of view we want to propose an original and intelligent system of insulin administration, built on the basis of a predictable neural network system.

As mentioned before, the key feature of the device is to deliver insulin constantly, at varying rates determined by the patient. In conventional therapy [11], two types of insulin administration are needed: long term demand for a daily insulin and short-term demand of insulin, whose dose depends on meals. An insulin pump uses only short-term insulin which is distributed evenly during the day, so it works on a long-term (called *basal*) basis, and a dose to counteract food (called *bolus*) that works on a short-term basis.

Treatment requires that the person be connected to an insulin pump for nearly 24 hours a day. Thus he carries the pump with himself (or herself) all the time and the

Figure 1. Block diagram of the insulin pump

pump becomes almost a part of his body. This indicates the importance of a well-thought out design.

In addition to these functional requirements, two other requirements are reliability and miniaturization.

- Reliability – health or even human life depends on the proper functioning of the device, so durability and reliability of an insulin pump is of the greatest importance. The device must have a monitoring system that ensures safe operation in case of hardware failure or improper usage. It is obvious that it must comply with various legal standards for a group of similar medical devices. It is also important that the pump can undergo in-depth tests under various usage conditions.
- Miniaturization – an insulin pump must be a small compact device that may be carried all the time with the patient, so its size and weight are limited. Miniaturization also implies energy-efficient design that is dictated on one hand by light weight and on the other hand by a long battery and/or recharge life.

Main requirements

All of the requirements need to be established in consultation with medical specialists and users of insulin pumps.

Each functional block must be described with its technical, medical and user requirements; some of them are mandatory type but some may be treated as optional.

The user interface

The user interface must be easy to operate and must allow for both ways of communication with the user. The insulin pump is to be provided with a screen and keyboard, but also a sound and a vibration signalisation are desirable. A wide range of user's age requires different pictogram menus for children and big symbols for elder persons. The keyboard itself should have a small number (about 4) of large keys. Keys have to be easily accessible and recognizable by touch even through clothing layers. Another requirement is that the screen must be readable in full sunlight as well as in night light.

The user interface must also communicate with a computer provided with necessary programming. Requirements:

- Keyboard with big touch recognizable keys, function to lock keyboard,
- Display: big, contrastable, backlighted and graphical,
- Menu: multileveled, version simplified, advanced and graphical,
- Alarms: sound, visual, vibrational,
- Signalised events: previous \ current \ next dose, total units, alarms, battery and cartridge level, time to replace the infusion set, reminder to measure blood glucose level, etc.

Cartridge

Cartridge, i.e. a reservoir for insulin. Insulin from the cartridge goes into the blood system and that is why it is important that it is aseptic and sterile. The best option is that cartridges come preloaded with the required type and amount of insulin from pharmacist companies. However, most pumps require refilling by users. There is no standard for insulin reservoirs used in the pumps so it may be good idea to establish such a standard.

If refilling a cartridge is for some reason unavoidable, we need to supply the user with an easy to use and sterile disposable set. Requirements:

- Capacity: 3 ml / 300 units
- Prefilled and disposable or sterile self-filling.

The Processing Module

The Processing Module is a 'brain' of the whole unit and is a master device for all other functional blocks. It is responsible for insulin pump options, dosage and communication with the user, programming or storing data. It may also accomplish some extra functions of an alarm clock or note taking. The stored data and configuration must remain undeleted when power is disconnected (when replacing the battery).

The Power Supply Module

The Power Supply Module with batteries has to provide power to the unit for at least several (4-6) weeks without replacing or recharging the battery. It also needs to be able to deliver information about the battery charge level. If a rechargeable (storage) battery is used, it has to be recharged by a external unit because of the heat emitted during this process. The size and weight of the battery is also important. Requirements:

- Battery or accumulator (one or two AAA size or one Lithium CR123 battery),
- Lifetime of at least 4 weeks.

The Infusion Set

The Infusion Set – It is a link between the human body and the insulin pump. It consists of a thin tubing and a needle or cannula. The material from which it is made must be soft and not react with medication and blood or cause any allergies. The infusion set must have an option of disconnecting the tubing from the pump and from the cannula. The cannula or needle has to be secured to the body by glue or tape. There should be a possibility of using an automatic insertion device that helps to place a needle in position and reducing the stress for some people who do not like to do it by hand.

The design and materials used for the insertion set should allow for the tubing and the cannula to last as long as possible, because of the discomfort when connecting it and limited number of places on the body to insert it. A longlife infusion set eliminates the need to install a new set and/or filling tubing and needle with insulin, etc. Requirements:

- Soft and elastic tubing
- Different lengths of tubing available

Requirements

The Pump – has to dose out medication from the cartridge with a preselected accuracy. It also has to work silently. The actuator used in the pump module must be energy efficient. Requirements:

- Accuracy of 0.05 unit
- Efficiency of at least 35 units/hour

The Monitoring Module

The Monitoring Module may play the role of the Processing Module instead of being a device by itself. It has to monitor proper work of all blocks of the pump. It must detect any malfunction of the whole unit and also has to inform the user about it, e.g. about a disconnected infusion set. Another function of the Monitoring Module is to respond to circumstances that may impair the pump or affect the proper operation such as dropping the pump, overheating or exposing to radiation, etc.

The Case

The Case, which, due to the need for miniaturization, has to be esthetical, functional, ergonomic, waterproof and easy to clean and fasten. Requirements:

- Protection Class IP67 or IP68 (dust and waterproof – immersion of up to or more than 1 m)
- Mass of about 150 g
- Size about $90 \times 60 \times 20$ mm
- Different colours available
- Different ways of mounting

The Blood Glucose Monitoring Module

The Blood Glucose Monitoring Module with a Sensor – Our plan is that the Glucose Sensor would allow creating a closed loop control of insulin dosage making the insulin pump work almost as an artificial pancreas. However, this may reduce the function only to glucose monitoring. The problems to overcome are, for example, long organism

response to insulin or low accuracy of the presently available glucose sensors. On the other hand, the information we have should be sufficient for us to predict an insulin dose using the artificial neural network system that we plan to implement.

There are also many other requirements such as basal range, duration, frequency, or types of bolus. All the requirements will be discussed with medical specialists to select a proper range.

Patient wish list

Some users would like to have some extra features in their pumps [13] among which the feature often mentioned is the remote control. Most users prefer to have their pumps concealed on them. Pumps are quite often hidden under clothing and secured to underwear or taped to the body, so using a remote control would help to take a bolus or check an alarm when in public or when in haste. Remote control in the form of a hand watch is a solution suggested by some users.

Another feature that users of the insulin pumps would like to have is the possibility of scanning meal for contents of carbohydrates leading to automatic insulin dosage. Unfortunately, this feature will not be implemented in the first model because it still looks sci-fi. However, we can create a user-edited library with meals and their contents of carbohydrates rather than determine body response to insulin and carbohydrates and thus calculate the insulin bolus.

Conclusion

All the above specified requirements will make it possible to design an insulin pump with all the necessary functions. This pump will be also easy to use and to maintain and most importantly safe to use. We hope that this work will result in a working model of an insulin pump. This model will be functionally and medically tested, so in the future we can build a final working device which will be commercially available alternatively to existing pumps. Our insulin pump will fill a hole in the market. The Polish market, not to mention the international market, is ready to absorb some 20 000 devices enough to start a large-scale production.

We have already started consultation with medical specialists to meet medical requirements of an insulin pump. From the scientific point of view, our design will enable us to inter-compare typical insulin treatments to meet individual requirements using a closed loop insulin control based on a glucose sensor and a neural network system.

References

- [1] Accu-Chek Polska, www.accu-chek.pl
- [2] Cukrzyca i pompa insulinowa, www.pompiarze.pl/
- [3] Diabetes Mall – Comparison of Current Pumps, www.diabetesnet.com/diabetes_technology/insulin_pump_models.php.
- [4] Insulin pump, en.wikipedia.org/wiki/Insulin_pump
- [5] Krzysztof Lewenstein, Maciej Grabowski, Maciej Chojnacki: A family of computer controlled infusion pumps – technology transfer from university to the small industry. *Eng Mechanics*. 2005; 12(3): 179-185.
- [6] Krzysztof Lewenstein, Maciej Chojnacki: Cooperation of the university and the small firm – a family of computer controlled infusion pumps. 4th Int. Conf. Inter-academia 2005, Wuppertal, sept. 2005, vol.1, p.49-56.
- [7] Medtronic, www.medtronic.pl
- [8] Roche Diagnostics, www.rochediagnostics.pl/
- [9] Smith Medical, www.smiths-medical.com/
- [10] Soil, www.sooilusa.com
- [11] Taton J. [Cukrzyca wymagająca wstrzyknieć insuliny – Poradnik dla pacjentów]. 1st ed. Warszawa: Wydawnictwo Lekarskie PZWL; 1998. 424 p. Polish.
- [12] The Diabetes Mall Forums, www.diabetesnet.com/forum/
- [13] Your Insulin Pump Proposals, www.diabeteshealth.com/read/2007/12/13/5586.html