Mobile Cyber-Physical System for Diabetic Patients' Health Status Monitoring

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Abstract

Continuous monitoring of the health status of diabetic patients using a mobile cyber-physical system (continuous glucose monitor) is currently an urgent task. The aim of this study is to develop a method and design the architecture of an invasive mobile cyber-physical system for diabetic patients' health status monitoring. The developed method and mobile cyber-physical system for diabetic patients' health status monitoring provide: measuring the patient's blood sugar level, analyzing the sugar level, issuing a notification to the patient about the onset of a hypo- or hyperglycemic state, as well as the threat of hypo- or hyperglycemic coma, as well as sending messages about the existing threat of hypo- or hyperglycemic coma to the patient's relatives. In addition, the developed method and system provide the formation of a set of ten-minute indicators of the patient's blood sugar level per day, the formation of a set of average daily indicators of the patient's blood sugar level per month and the formation of a set of indicators of the patient's average monthly blood sugar level per year in order to demonstrate the dynamics of changes in the patient's blood sugar level to the patient and his doctor. The developed mobile cyber-physical system for diabetic patients' health status monitoring is convenient and easy to use and wear, has a compact size, and is cheaper than known analogs.

Keywords

Mobile cyber-physical system, health monitoring, diabetes mellitus, blood sugar measurement, subcutaneous sensor for measuring blood sugar.

1. Introduction

Diabetes mellitus is an endocrine disease characterized by a malfunction of the pancreas and, as a result, a complete or partial cessation of the production of the hormone insulin or a decrease in the sensitivity of insulin-dependent tissues to insulin. It is a chronic metabolic disease characterized by high blood sugar (glucose) levels. It is a chronic hyperglycemia syndrome that leads to disorders of all types of metabolism, primarily carbohydrate metabolism, vascular damage (angiopathy), nervous system (neuropathy), and other organs and systems. It is a condition in which the body does not produce enough insulin or does not use it effectively [1-3].

According to the World Health Organization, the number of people with diabetes was more than 537 million in 2021, which is 10% of the world's population. This number is expected to rise to 643 million by 2030 and 783 million by 2045 [4]. Diabetes mellitus leads to other diseases, such as complete or partial vision loss, liver failure, heart attack, stroke, vascular disease, and lower limb amputation. This disease ranks seventh among the diseases that most often lead to disability and mortality in the world. The terrible fact is that the trend of the disease is growing and "getting younger". Until the early

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2000s, diabetes was most often found in people over 25 years old, but now 15% of people with the disease are children and adolescents under the age of 20 [4].

The following types of diabetes are distinguished:

1. type 1 diabetes is a complete or partial cessation of insulin secretion by the pancreas. This type of diabetes develops when the body's immune system attacks and destroys the pancreatic cells that produce insulin. It causes the body to be unable to produce enough insulin to control blood glucose levels. This type of disease manifests itself immediately after birth, in childhood or adolescence. It is usually caused by heredity. The prevalence of the first type of diabetes is 10-15% of all cases of diabetes. In this type, the main method of regulating blood glucose is insulin therapy, which is carried out in the form of injecting artificial insulin into human adipose tissue by injection, which allows you to balance the body's metabolism. People with type 1 diabetes need to inject insulin as needed to control blood sugar levels [1]
2. type 2 diabetes mellitus is a decrease in the sensitivity of the cell membrane to incoming insulin, in some cases accompanied by impaired insulin secretion by the pancreas. This type of diabetes occurs when the body does not produce enough insulin or does not use it effectively. Type 2 diabetes occurs when the body becomes less sensitive to insulin, or the pancreas does not produce enough insulin. This type of diabetes usually develops slowly. It is the most common type of diabetes and is often associated with poor lifestyle choices, including poor diet, lack of physical activity, and being overweight. It is considered acquired and is usually detected in people at an older age who have diseases associated with metabolic disorders, overweight. The disease develops slowly, which is often the reason for late detection. The blood glucose level is maintained through the use of hypoglycemic drugs, insulin injections, diet and regular exercise. Treatment of type 2 diabetes may include dietary changes, physical activity, oral medications, insulin injections, or a combination of these methods [2, 3, 5, 6]
3. gestational diabetes occurs in pregnant women who did not previously have diabetes. It usually disappears after childbirth, but women who have had gestational diabetes are at increased risk of developing type 2 diabetes in the future [7, 8].

It is vital for people with diabetes to maintain normal blood glucose levels. The blood glucose level in a healthy person should reach from 4.0 to 6.0 mmol/l (in general, the reference values are 3.5-6.7 mmol/l). Determination of this indicator is a mandatory procedure when taking a complete blood count of every patient admitted to a clinic or hospital. Glucose control is an important component of the life of every person with diabetes, so it is most important that this process is as quick, painless and accurate as possible. Collecting blood sugar readings plays an important role in the timely, proper treatment and control of diabetes. Insulin therapy and medication administration (dose calculation, frequency, and specifics of use) are prescribed by a doctor, but are performed by patients themselves on a daily basis at home. Since blood glucose levels can change after physical activity, depending on the emotional state of a person and other factors, it is advisable to measure glucose levels before each medication administration. This manipulation has become possible thanks to glucose meters that can be used at home without medical supervision and assistance [9-11].

At the moment, the most common method is to pierce a person's skin and extract a drop of blood onto a test strip, which is a component of a glucometer, which is currently most often used to measure blood sugar levels. The test strip contains chemicals that are sensitive to glucose in the blood sample. This method is the most affordable, but not always convenient.

A blood glucose monitoring system is a very important tool for people with diabetes. Such systems provide the ability to monitor blood glucose levels and take the necessary measures to maintain them in the normal range. A glucose monitor is a medical device used to measure blood glucose levels. It works by using test strips that interact with a drop of blood obtained with a lancet. After the drop of blood hits, the test strip, the glucose monitor measures the glucose level and displays the result on the screen. This can help people with diabetes manage their disease and reduce the risk of complications [12-14].

Given the current trend toward the introduction of information technology [15-17] and cyber-physical systems [18, 19] in all areas of medicine, and given the importance of continuous monitoring of the health of patients with diabetes, it is necessary to make such monitoring permanent and automate it as much as possible using a cyber-physical system that combines the complex physiological dynamics of patients in the modern medical field with built-in programmable control devices. Glucose control using modern continuous monitoring technology is more accurate and efficient today. In this case, a mobile cyber-physical system for diabetic patients' health status monitoring in the form of a subcutaneous sensor and mobile app will be useful for continuous automatic blood glucose measurements, which will continuously monitor the blood glucose level of a patient with diabetes (continuous measurement and transmission of readings to a mobile application) and will promptly notify the patient and his or her family of excessively high or excessively low glucose levels, allowing them to take timely measures to normalize sugar levels. So, continuous monitoring of the health status of diabetic patients using a mobile cyber-physical system (continuous glucose monitor) is *currently an urgent task*.

2. Case Study

There are two types of blood glucose monitoring systems – invasive and non-invasive (Figure 1).

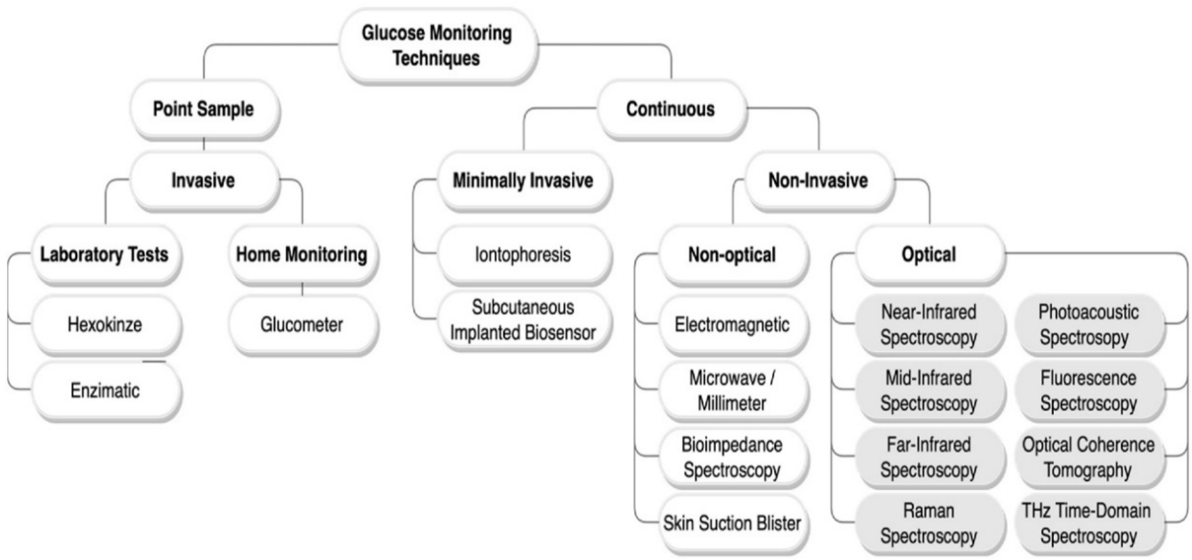

Figure 1: Blood glucose monitoring systems [10]

Invasive blood glucose monitoring is used to accurately and continuously monitor glucose levels in people with diabetes. This method requires the insertion of a sensor directly into the body to measure glucose levels. The data from the sensor can be transmitted directly to an external device or read only by a reader that is placed on the skin over the sensor. Continuous glucose monitors measure blood sugar every few minutes using a sensor inserted under the skin [20-22].

The advantages of invasive blood glucose monitoring include [20-22]:

1. constant availability of information about glucose levels, which allows you to see the dynamics of changes and respond appropriately
2. assistance in decision-making – with the help of information provided by invasive monitoring tools, it is possible to better understand the impact of nutrition, physical activity and treatment on blood glucose levels, which helps to make more effective decisions about diabetes treatment and behavior of diabetic patient.

However, invasive monitoring also has its limitations and disadvantages [20-22]:

1. high cost of commercial invasive monitoring systems
2. measurement error that needs to be taken into account (but invasive monitoring provides more accurate data than traditional glucose measurement methods)
3. the need for proper care and maintenance (regular replacement of sensors, proper calibration of the system, etc.)
4. the risk of infections and complications when the sensor is inserted under the skin (it is important to follow proper hygiene and care procedures)
5. the impact of external factors on the monitoring system (high humidity, temperature, magnetic fields, etc.).

Non-invasive blood glucose monitoring is used to continuously monitor glucose levels without the need to insert a sensor under the skin. These methods are based on measuring glucose using external devices that do not require penetration into the body. However, it is worth noting that to date, non-invasive blood glucose monitoring has not yet reached the same accuracy and reliability as invasive methods [23-26].

Here are some modern types of non-invasive blood glucose monitoring [23-26]:

1. near-infrared spectroscopy – measures the reflection or absorption of infrared light from tissues to determine glucose levels and is based on the fact that glucose levels affect the light characteristics of tissues
2. electrochemical sensors – use electrodes that react with glucose in the blood and create an electrical signal that can be measured, but for accurate measurement, the problem of the influence of other substances on the results must be solved
3. optical sensors – use optical methods, such as photoplethysmography (measuring pulse with light), to determine changes in blood glucose; based on the observation of the dependence of the optical properties of blood on glucose levels
4. non-contact technologies – include the use of technologies, such as radio wave or microwave devices to measure glucose levels in the body, which do not require physical contact with the body
5. breathing equipment – assesses the relationship between blood glucose and exhaled glucose; this method may require special breathing equipment and exhaled air analysis.

Non-invasive glucose monitoring systems have the following advantages that make them attractive to users: painlessness (no need for a skin puncture to measure glucose levels) and reduced risk of infection (due to no skin puncture and no contact with blood).

Although non-invasive blood glucose monitoring has potential in the future, some of these technologies are still under research and development. The accuracy and reliability of their measurements still need to be further improved.

The aim of our study is to develop a method and design the architecture of an invasive mobile cyber-physical system for diabetic patients' health status monitoring, which will consist of a subcutaneous sensor and a mobile application, will be cheaper than known analogues, convenient and easy to use and wear, have a compact size; will perform continuous monitoring of blood glucose levels in a patient with diabetes; Analyzing the results of such monitoring, it will promptly notify the patient and his or her family of excessively high or excessively low glucose levels; as well as accumulate and display (in the form of numbers and charts) the dynamics of changes in the patient's blood sugar level during the day, month, year, etc.

3. Mobile cyber-physical system for diabetic patients' health status monitoring

Method for diabetic patients' health status monitoring consists of the followings stages:

1. measurement of the patient's blood sugar level (variable *bsl*) every 10 minutes
2. analysis of the patient's blood sugar level (of variable *bsl*):
   - if $bsl \geq 3.5$ *mmol/l* and $bsl \leq 6.7$ *mmol/l,* then patient's blood sugar level is normal and no action is required
   - if $bsl < 3.5$ *mmol/l* and $bsl \geq 2$ *mmol/l*, then patient is notified: "Hypoglycemia"
   - if $bsl > 6.7$ *mmol/l* and $bsl \leq 16.5$ *mmol/l*, then patient is given a message: "Hyperglycemia"
   - if $bsl < 2$ *mmol/l*, then message "Threat of hypoglycemic coma" is issued not only to the patient, but also sent to his relatives (the patient's geolocation and name and surname are also added to the message)
   - if $bsl > 16.5$ *mmol/l*, then message "Threat of hyperglycemic coma" is issued not only to the patient, but also sent to his/her relatives (the patient's geolocation and name and surname are also added to the message)
3. generating a set of ten-minute blood sugar levels per day (set *DBSL*): $DBSL = \{bsl_1, bsl_2, bsl_3, ..., bsl_{144}\}$ – this set is available in the patient's mobile application (in the form of numbers and/or diagrams) so that the patient and his/her doctor can see the dynamics of changes in blood

sugar levels during the day (there are 24 hours in a day, 1440 minutes, i.e. 144 10-minute intervals)

4. calculation of the average daily (144 10-minute intervals) blood sugar level of the patient by the formula (1):
$$adbsl = (\sum_{i=1}^{144} bsl_i)/144 \quad (1)$$
5. generating a set of average daily blood glucose levels for a patient for a month (set *MBSL*): *MBSL = {*$adbsl_1$*,* $asbsl_2$*,* $adbsl_m$*}* – this set is also available in the patient's mobile application (in the form of numbers and/or diagrams) so that the patient and his/her doctor can see the dynamics of changes in the average daily blood sugar level during the month; we assume there are m days in a month
6. calculation of the patient's average monthly (m days in a month) blood sugar level by the formula (2):
$$ambsl = (\sum_{j=1}^{m} adbsl_j)/m \quad (2)$$
7. generating a set of average monthly blood sugar levels for the patient for the year (set *YBSL*): *YBSL = {*$ambsl_1$*,* $ambsl_2$*,* $ambsl_{12}$*}* – this set is also available in the patient's mobile application (in the form of numbers and/or diagrams) so that the patient and his/her doctor can see the dynamics of changes in the average monthly blood sugar level during the year.

The developed method for diabetes patients' health status monitoring provides: measuring the patient's blood sugar level, analyzing the sugar level, issuing a notification to the patient about the onset of a hypo- or hyperglycemic state, as well as the threat of hypo- or hyperglycemic coma, as well as sending messages about the existing threat of hypo- or hyperglycemic coma to the patient's relatives. It is possible case, that information about the level of sugar that characterizes a hyperglycemic state or warns of the threat of hyperglycemic coma is transmitted to the insulin pump to ensure the calculation of the insulin dose and the performance of an insulin injection, if necessary. In addition, the developed method provides the formation of a set of ten-minute indicators of the patient's blood sugar level per day, the formation of a set of average daily indicators of the patient's blood sugar level per month and the formation of a set of indicators of the patient's average monthly blood sugar level per year in order to demonstrate the dynamics of changes in the patient's blood sugar level to the patient and his doctor.

Mobile cyber-physical system for diabetic patients' health status monitoring is based on the developed method for diabetic patients' health status monitoring.

The mobile cyber-physical system for diabetic patients' health status monitoring includes a subcutaneous sensor for measuring blood sugar levels (such sensors are usually worn for several weeks to several months, and then need to be replaced; such sensor is the physical component of the system), as well as a web server (receiver) and a specially developed mobile application that is installed on the patient's and his relatives' phone.

The mobile application has two possible roles: "patient" or "patient's relative". When registering in the mobile application, the patient indicates his or her name and surname, mandatory provides access to geolocation data, and specifies the mobile phone numbers of relatives to whom notifications about the existing threat of hypo- or hyperglycemic coma should be sent. When registering in the mobile application, the patient's relatives select from the database by name, surname and/or phone number of patient, whose critical health condition they authorize to send them notifications.

The subcutaneous sensor measures the patient's blood sugar level every 10 minutes, the sensor transmits the received value to the receiver (web server), which organizes online data recording to the database and online transmitting the measurement results to the patient's mobile application, where the sugar level is analyzed. The blood sugar level is measured and analyzed automatically, and the information is recorded in the database every 10 minutes. If the blood glucose level does not fall within the range of reference values, the patient receives a notification in the mobile application about the hypo- or hyperglycemic state. If the blood sugar level is critically low or critically high, the mobile application sends a notification about the existing threat of hypoglycemic or hyperglycemic coma to both the patient and his or her relatives (the patient's geolocation and name and surname are also included in the notification to the relatives).

In addition, the mobile application provides accumulation (in the database) and display (in the form of numbers and charts) of the dynamics of changes in the patient's blood sugar level during the day, month, year, etc., which can be useful both for the patient in the selection of physical activities, nutrition, etc., and for his or her doctor in the selection of medications and their dosage to avoid hypoglycemia or hyperglycemia in the future.

Architecture of mobile cyber-physical system for diabetic patients' health status monitoring is represented on Figure 2.

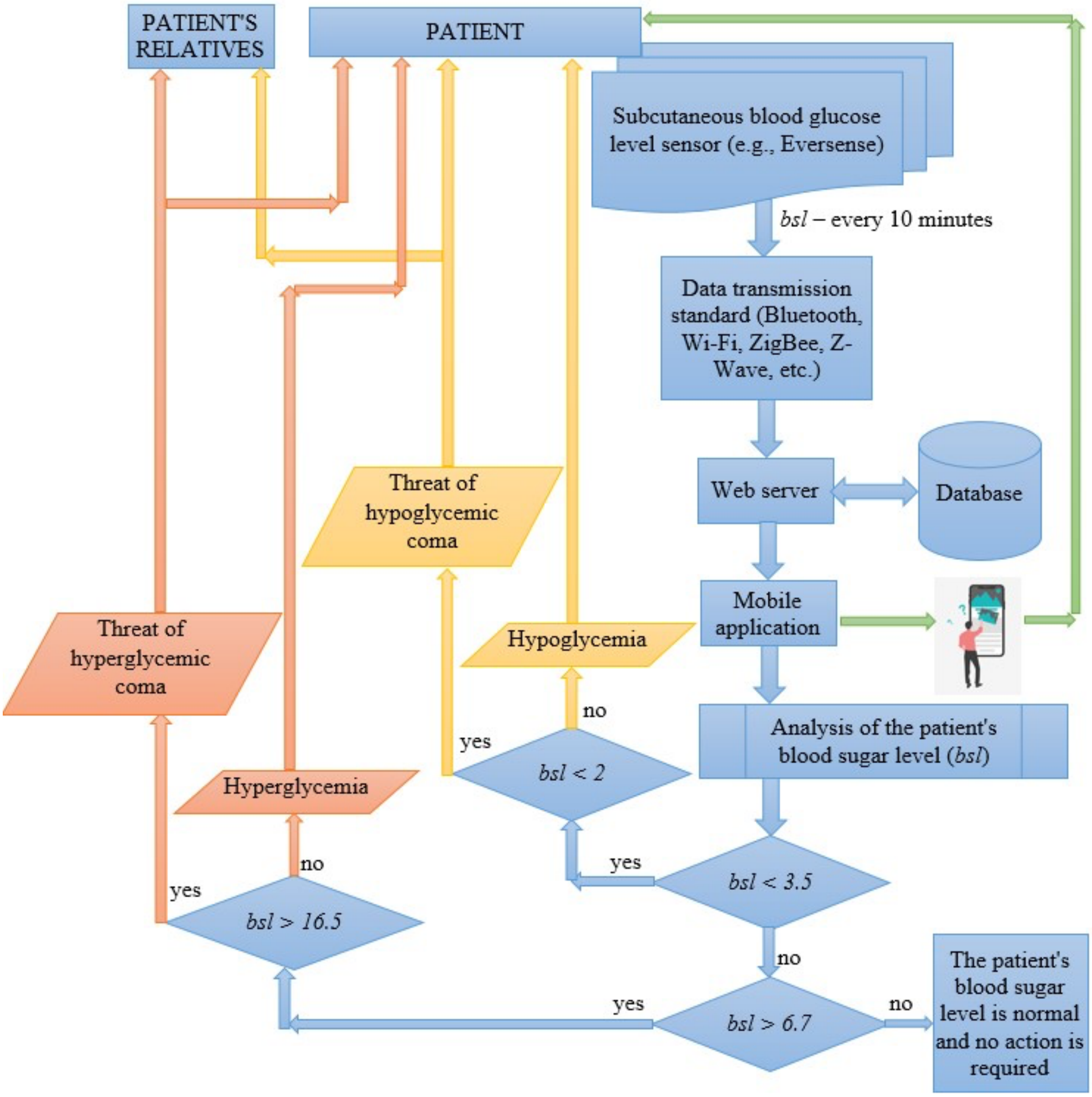

Figure 2: Architecture of mobile cyber-physical system for diabetes patients' health status monitoring

4. Results & Discussion

Let's consider the case of using the developed method and cyber-physical system for diabetic patients' health status monitoring.

The patient decided to use the developed cyber-physical system. To do so, he purchased an Eversense sensor to measure his blood sugar level, and his doctor implanted the sensor under the skin on his forearm. The patient installed the developed mobile application on his phone and on the phone of his relatives. When registering in the mobile application, the patient chose the role of "patient", indicated his first and last name, provided access to geolocation data, and indicated the mobile phone numbers of relatives to whom notifications about the existing threat of hypoglycemic or hyperglycemic coma should be sent. When registering in the mobile application, the patient's relatives chose the role of "patient's relative" and selected from the database by name, surname and/or phone number the patient whose critical health condition was allowed to be notified. After that, the mobile cyber-physical system began to function.

The results of the mobile cyber-physical system functioning on 20 measurements, starting from time *i* and then every 10 minutes, during which the patient developed a threat of hyperglycemic coma, are presented in Table 1.

Table 1
Results of the mobile cyber-physical system functioning on 20 measurements

Variable	Blood sugar level	Actions of the cyber-physical system
bsl_i	5.8	The patient's blood sugar level is normal and no action is required
bsl_{i+10}	5.75	The patient's blood sugar level is normal and no action is required
bsl_{i+20}	5.9	The patient's blood sugar level is normal and no action is required
bsl_{i+30}	6.3	The patient's blood sugar level is normal and no action is required
bsl_{i+40}	6.7	The patient's blood sugar level is normal and no action is required
bsl_{i+50}	7	The patient was given a message: "Hyperglycemia"
bsl_{i+60}	7.2	The patient was given a message: "Hyperglycemia"
bsl_{i+70}	8	The patient was given a message: "Hyperglycemia"
bsl_{i+80}	8.9	The patient was given a message: "Hyperglycemia"
bsl_{i+90}	9.7	The patient was given a message: "Hyperglycemia"
bsl_{i+100}	11.1	The patient was given a message: "Hyperglycemia"
bsl_{i+110}	14	The patient was given a message: "Hyperglycemia"
bsl_{i+120}	15.8	The patient was given a message: "Hyperglycemia"
bsl_{i+130}	17.9	Message "Threat of hyperglycemic coma" was sent to the patient and his relatives (the patient's geolocation and name and surname were also added to the message to the relatives)
bsl_{i+140}	16.5	The patient was given a message: "Hyperglycemia"
bsl_{i+150}	13.4	The patient was given a message: "Hyperglycemia"
bsl_{i+160}	10.8	The patient was given a message: "Hyperglycemia"
bsl_{i+170}	8.7	The patient was given a message: "Hyperglycemia"
bsl_{i+180}	7.75	The patient was given a message: "Hyperglycemia"
bsl_{i+190}	6.5	The patient's blood sugar level is normal and no action is required

This example demonstrates how rapidly a patient's blood sugar can change. Obviously, most probably the patient missed the notifications of the hyperglycemic state and did not take an insulin injection on time, so the blood sugar level began to rise rapidly and reached a level that threatens to cause a hyperglycemic coma. After the system sent a message about the threat of hyperglycemic coma to the patient and his relatives, the patient apparently took an insulin injection, because his blood sugar level began to drop rapidly, until it returned to normal.

Figure 3 shows a chart of the patient's ten-minute blood sugar levels for the day (from time 0, which is the start of the day, to time 1440 minutes, which is 24 hours), from which the 20 measurements for Table 1 were taken. Figure 4 shows a chart of the patient's average daily blood sugar levels for August 2023, during which he used the proposed mobile cyber-physical system.

In the above case, the developed mobile cyber-physical system for diabetic patients' health status monitoring helped save the patient and prevent the onset of hyperglycemic coma. The developed system also helps the patient to monitor his health status, in particular, blood sugar levels, and to take the necessary medications in time in case of hypo- or hyperglycemic conditions. In addition, the proposed system provides accumulation and display of the dynamics of changes in the patient's blood sugar level during the day, month, and year, which can be useful for self-diagnosis by the patient and for research by the doctor to avoid hypoglycemia or hyperglycemia in the future.

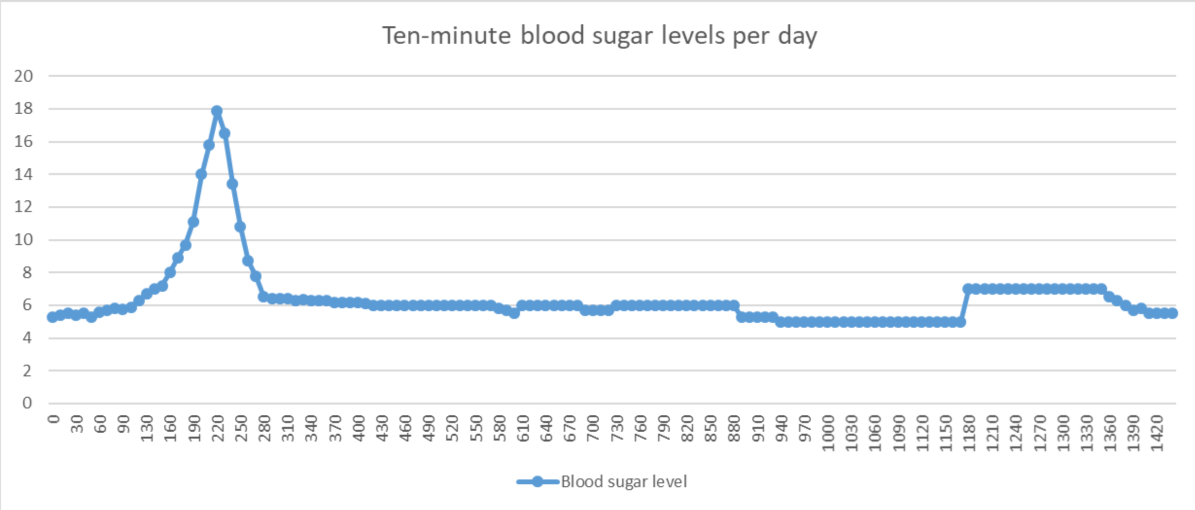

Figure 3: Chart of ten-minute blood sugar levels for a patient per day

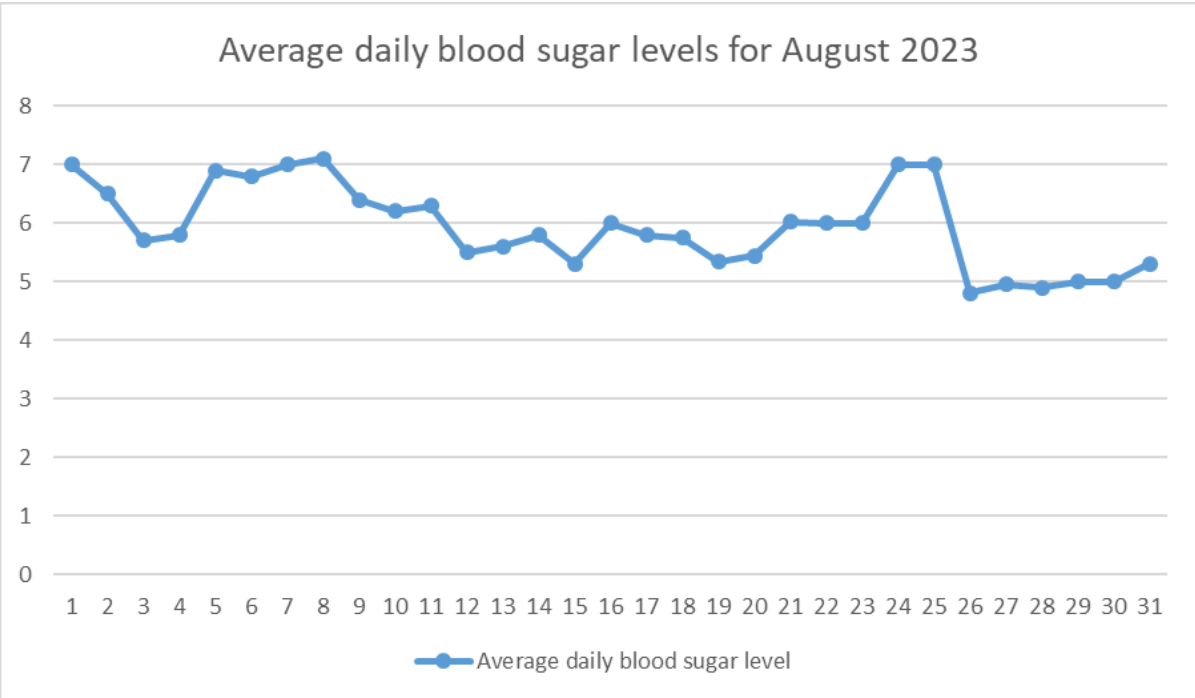

Figure 4: Chart of average daily blood sugar levels for a patient for August 2023

The developed mobile cyber-physical system for diabetic patients' health status monitoring is convenient and easy to use and wear, has a compact size (subcutaneous sensor and smartphone app), and is cheaper than known analogues, as the patient currently only has to purchase the sensor, the mobile application is currently developed as a pilot sample and is free of charge. In the future, it is planned to set a small fee for the patient's use of the mobile application to cover the costs of hosting and cloud storage.

In summary, the proposed mobile cyber-physical system for diabetic patients' health status monitoring helps patients with diabetes monitor their blood sugar levels and receive emergency assistance in case of a threat of hypoglycemic or hyperglycemic coma.

5. Conclusions

The aim of this study is to develop a method and design of the architecture of an invasive mobile cyber-physical system for diabetic patients' health status monitoring, which will consist of a subcutaneous sensor and a mobile application, will be cheaper than known analogues, convenient and easy to use and carry, and will have a compact size; it will continuously monitor the blood glucose level of a patient with diabetes; will promptly notify the patient and his/her relatives of excessively high or excessively low glucose levels, as well as accumulate and display (in the form of numbers and charts) the dynamics of changes in the patient's blood sugar level during the day, month, year, etc.

The developed method for diabetic patients' health status monitoring provides: measuring the patient's blood sugar level, analyzing the sugar level, issuing a notification to the patient about the onset of a hypo- or hyperglycemic state, as well as the threat of hypo- or hyperglycemic coma, as well as sending messages about the existing threat of hypo- or hyperglycemic coma to the patient's relatives. In addition, the developed method provides the formation of a set of ten-minute indicators of the patient's blood sugar level per day, the formation of a set of average daily indicators of the patient's blood sugar level per month and the formation of a set of indicators of the patient's average monthly blood sugar level per year in order to demonstrate the dynamics of changes in the patient's blood sugar level to the patient and his doctor.

The proposed mobile cyber-physical system for diabetic patients' health status monitoring helps the patient to monitor their health status, in particular, blood sugar levels, and to take the necessary medications in time in case of hypo- or hyperglycemic conditions. In addition, the proposed system provides accumulation and display of the dynamics of changes in the patient's blood sugar level during the day, month, and year, which can be useful for self-diagnosis by the patient and for research by the doctor to avoid hypoglycemia or hyperglycemia in the future.

The developed mobile cyber-physical system for diabetic patients' health status monitoring is convenient and easy to use and wear, has a compact size, and is cheaper than known analogues, as the patient currently only needs to purchase a sensor, the mobile application is currently developed as a pilot sample and is free of charge. In the future, it is planned to charge a small fee for the patient's use of the mobile application to cover hosting and cloud storage costs. Directions for further research: standardization of the developed mobile cyber-physical system, certification of the developed mobile application, ensuring cybersecurity of the developed mobile cyber-physical system.

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