(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
03 March 2022 (03.03.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/040947 A1

(51) International Patent Classification:
A61M 5/172 (2006.01) *G16H 20/17* (2018.01)
A61B 5/145 (2006.01)

(21) International Application Number:
PCT/CN2020/111169

(22) International Filing Date:
26 August 2020 (26.08.2020)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant: MEDTRUM TECHNOLOGIES INC. [CN/CN]; 7F, Building 8, No. 200 Niudun Road, Zhangjiang Hi-Tech Park, Pudong New Area, Shanghai 201203 (CN).

(72) Inventor: YANG, Cuijun; 7F, Building 8, No. 200 Niudun Road, Zhangjiang Hi-Tech Park, Pudong New Area, Shanghai 201203 (CN).

(74) Agent: J.Z.M.C. PATENT AND TRADEMARK LAW OFFICE (GENERAL PARTNERSHIP); YU, Mingwei, Room 5022, No.335, Guo Ding Road, Yang Pu District, Shanghai 200433 (CN).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,

(54) Title: CLOSED-LOOP ARTIFICIAL PANCREAS INSULIN INFUSION CONTROL SYSTEM

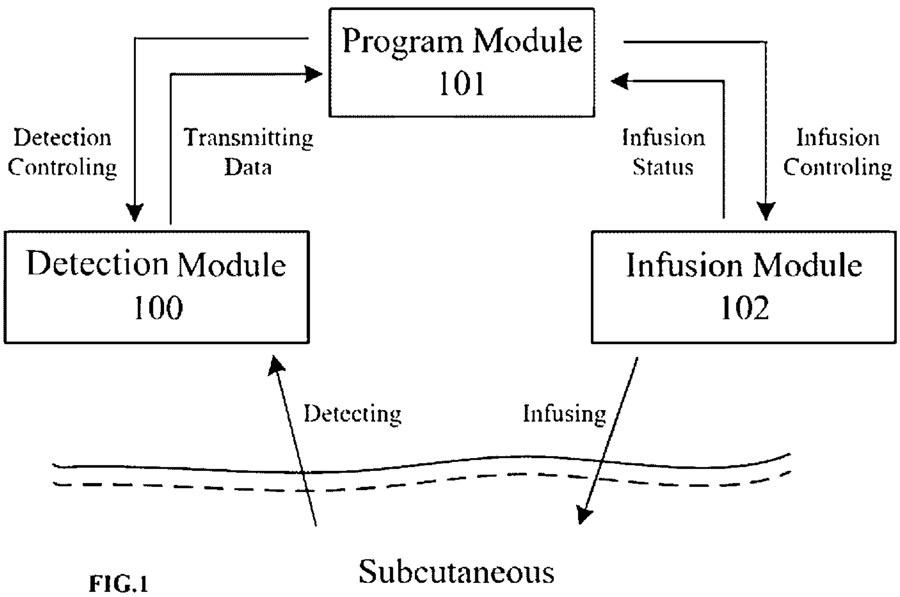

FIG.1

(57) Abstract: A closed-loop artificial pancreas insulin infusion control system, includes: a detection module (100); a program module (101) is configured to obtain the insulin dose infused per day by users; an infusion module (102), connected to and controlled by the program module (101), is configured to infuse insulin required according to the data of the current insulin infusion dose; and a motion sensor configured to sense the user's physical activity status which can be sent to the program module (101) and is one of the variable factors of the total daily dose algorithm or the current insulin infusion algorithm. This system can automatically detect the physical condition of the user and accurately calculate the TDD value and the current insulin infusion dose, enhancing user experience.

WO 2022/040947 A1

[Continued on next page]

TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

CLOSED-LOOP ARTIFICIAL PANCREAS INSULIN INFUSION CONTROL SYSTEM

TECHNICAL FIELD

The present invention mainly relates to the field of medical device, and in particular, to a closed-loop artificial pancreas insulin infusion control system.

BACKGROUND

The pancreas in a normal person can automatically monitor the amount of glucose in the blood and automatically secrete the required dosage of insulin/glucagon. However, for diabetic patients, the function of the pancreas is abnormal, and the pancreas cannot normally secrete required dosage of insulin. Therefore, diabetes is a metabolic disease caused by abnormal pancreatic function and also a lifelong disease. At present, medical technology cannot cure diabetes, but can only control the onset and development of diabetes and its complications by stabilizing blood glucose.

Patients with diabetes need to check their blood glucose before injecting insulin into the body. At present, most of the detection methods can continuously detect blood glucose, and send the blood glucose data to the remote device in real time for the user to view. This detection method is called Continuous Glucose Monitoring (CGM), which requires the detection device to be attached to the surface of the patients' skin, and the sensor carried by the device is inserted into the subcutaneous tissue fluid for testing. According to the blood glucose (BG) level, the infusion device, as a closed-loop or semi-closed-loop artificial pancreas, injects the currently required insulin dose.

At present, the detection device and the infusion device are connected to each other to form a closed-loop artificial pancreas with the processing of the program module. While the program module is calculating the insulin infusion dose, total daily dose (TDD) is an important parameter with many determinants, such as physical conditions, physiological conditions, etc.

However, the closed-loop artificial pancreas in prior art needs to be manually input the physical conditions instead of automatically detecting, and the TDD value cannot be accurately obtained, resulting in inaccurate current insulin infusion dose and worsening user experience.

Therefore, in the prior art, there is an urgent need for a closed-loop artificial pancreas insulin infusion control system that can automatically detect the physical condition and accurately calculate the current infusion dose.

BRIEF SUMMARY OF THE INVENTION

The embodiment of the present invention discloses a closed-loop artificial pancreas insulin infusion control system which can automatically detect the physical condition of the user and accurately calculate the TDD value and the current insulin infusion dose, enhancing user experience.

The invention discloses a closed-loop artificial pancreas insulin infusion control system, including: a detection module configured to detect blood glucose; a program module, connected to the detection module, is configured to obtain the insulin dose infused per day by users, and is also imported into the total daily dose algorithm and the current insulin infusion algorithm, wherein, according to the insulin dose infused per day by users, the total daily dose algorithm is used to calculate the total daily dose; according to the blood glucose detected, the insulin dose infused per day by users or total daily dose, the current insulin infusion algorithm is used to calculate the current insulin infusion dose; an infusion module, connected to and controlled by the program module, is configured to infuse insulin required according to the data of the current insulin infusion dose; and a motion sensor configured to automatically sense the user's physical activity status which can be sent to the program module and is one of the variable factors of the total daily dose algorithm or the current insulin infusion algorithm.

According to one aspect of the present invention, the program module includes a manual input interface or an automatic detection sub-module, and the method for the program module to obtain the insulin dose infused per day by users includes: the insulin dose infused per day by users is manually input into the program module through the manual input interface; or the insulin dose infused per day by users is automatically detected, stored and calculated by the automatic detection sub-module.

According to one aspect of the present invention, the insulin dose infused per day by users includes the total amount of daily infusion dose data, or the bolus and basal data infused in different time periods, or the temporary basal data and the correction bolus data, or the infusion data after different events.

According to one aspect of the present invention, the total daily dose is obtained by calculating the total amount of daily infusion dose data in the previous two or more days according to the total daily dose algorithm, and the total daily dose is the average or median of the insulin dose infused per day by users, and the total daily dose is one variable factor of the current insulin infusion algorithm.

According to one aspect of the present invention, the average includes an arithmetic average or a weighted average.

According to one aspect of the present invention, the variable factors of the total daily dose algorithm include one or more of the user's physical activity status, physiological status, psychological status, and meal status.

According to one aspect of the present invention, the physiological status includes one or more factors of weight, gender, age, disease, and menstrual period.

According to one aspect of the present invention, the physical activity status includes general body stretching, exercise, or sleep.

According to one aspect of the present invention, the meal information, exercise information, sleep information, or physical condition information can be manually input into the program module through the manual input interface.

According to one aspect of the present invention, the motion sensor is provided in the detection module, the program module or the infusion module.

According to one aspect of the present invention, the motion sensor includes a three-axis acceleration sensor or a gyroscope.

According to one aspect of the present invention, any two of the detection module, the program module and the infusion module are connected to each other configured to form a single structure whose attached position on the shin is different from the third module.

According to one aspect of the present invention, the detection module, the program module and the infusion module are connected together configured to form a single structure which is attached on only one position on the skin.

Compared with the prior art, the technical solution of the present invention has the following advantages:

In the closed-loop artificial pancreas insulin infusion control system disclosed in the present invention, the detection module is used to detect blood glucose; a program module, connected to the detection module, is configured to obtain the insulin dose infused per day by users, and is also imported into the total daily dose algorithm and the current insulin infusion algorithm, wherein, according to the insulin dose infused per day by users, the total daily dose algorithm is used to calculate the total daily dose; according to the blood glucose detected, insulin dose infused per day by users or total daily dose, the current insulin infusion algorithm is used to calculate the current insulin infusion dose. The program module is imported into the total daily dose algorithm and the current insulin infusion algorithm. Using the detection data, the insulin dose infused per day by users and the total daily dose alone or in combination makes the current insulin infusion dose more accurate. Secondly, the control system also includes a motion sensor configured to automatically sense the user's physical activity which can be sent to the program module and is one of the variable factors of the total daily dose algorithm or the current insulin infusion algorithm. Compared with manually inputting, the motion sensor can automatically and accurately sense the user's physical activity status which can be sent to the program module, improving the accuracy of the calculation of the total daily dose or the current insulin infusion dose, and enhancing the user experience.

Furthermore, the program module includes a manual input interface or an automatic detection sub-module, and the method for the program module to obtain the insulin dose infused per day by users includes: the insulin dose infused per day by users is manually input into the program module through the manual input interface; or the insulin dose infused per day by users is automatically detected, stored and calculated by the automatic detection sub-module. The manual input interface or the automatic detection sub-module can be used alone or a combined, which enhances the flexibility using the device. Secondly, with the manual input interface and the automatic detection sub-module used in combination, the data automatically detected and manually input can be combined and compared to make the program module adjust the algorithm in real time, helping to make the calculation result more accurate.

Furthermore, the physical activity status includes general body stretching, exercise or sleep. The control system can distinguish normal activities, exercise and sleep, making the control system more refined to control blood glucose level.

Furthermore, the motion sensor is provided in the detection module, the program module or the infusion module. The motion sensor provided in the control system, not disposed in other structure, can improve the integration of the control system as much as possible, reduce the size of the device, and enhance the user experience.

Furthermore, the motion sensor includes a three-axis acceleration sensor or a gyroscope. The three-axis acceleration sensor or gyroscope can sense the body's activity intensity, activity mode or body posture accurately, ultimately improving the accuracy of the calculation result of the infusion dose.

Furthermore, the detection module, the program module and the infusion module are connected together configured to form a single structure which is attached on only one position on the skin. If the three modules are connected as a whole and attached in the only one position, the number of the device on the user skin will be reduced, thereby reducing the interference of more attached devices on user activities. At the same time, it also effectively solves the problem of the poor wireless communication between separating devices, further enhancing the user experience.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG.1 is a schematic diagram of the module relationship of the closed-loop artificial pancreas insulin infusion control system according to one embodiment of the present invention.

DETAILED DESCRIPTION

As mentioned above, the artificial pancreas in the prior art cannot accurately sense the physical condition of the user and obtain total daily dose.

Studies have found that the reasons for the above problems are that the artificial pancreas in the prior art has insufficient algorithms, with single calculation method, for calculating the total daily dose, and has no structural components that can accurately sense user’s physical activity.

In order to solve this problem, the present invention provides a closed-loop artificial pancreas insulin infusion control system which can automatically detect the physical condition of the user and accurately calculate the TDD value and the current insulin infusion dose, enhancing user experience.

Various exemplary embodiments of the present invention will now be described in detail with reference to the drawings. The relative arrangement of the components and the steps, numerical expressions and numerical values set forth in the embodiments are not to be construed as limiting the scope of the invention.

In addition, it should be understood that, for ease of description, the dimensions of the various components shown in the figures are not necessarily drawn in the actual scale relationship, for example, the thickness, width, length or distance of certain units may be exaggerated relative to other structures.

The following description of the exemplary embodiments is merely illustrative, and is not intended to be in any way limiting the invention and its application or use. The techniques, methods, and devices that are known to those of ordinary skill in the art may not be discussed in detail, but such techniques, methods, and devices should be considered as part of the specification.

It should be noted that similar reference numerals and letters indicate similar items in the following figures. Therefore, once an item is defined or illustrated in a drawing, it will not be discussed further in the following description of the drawings.

FIG.1 is a schematic diagram of the module relationship of the closed-loop artificial pancreas insulin infusion control system according to the embodiment of the present invention.

The closed-loop artificial pancreas insulin infusion control system disclosed in the embodiment of the present invention mainly includes a detection module 100, a program module 101, and an infusion module 102.

The detection module 100 is used to continuously detect the user's real-time blood glucose (BG) level. Generally, the detection module 100 is a Continuous Glucose Monitoring (CGM) for detecting real-time BG, monitoring BG changes, and also sending them to the program module 101.

The program module 101 is used to control the detection module 100 and the infusion module 102. Therefore, the program module 101 is connected to the detection module 100 and the infusion module 102, respectively.

Here, the connection refers to a conventional electrical connection or a wireless connection.

The infusion module 102 includes the essential mechanical structures used to infuse insulin and controlled by the program module 101. According to the current insulin infusion dose calculated by the program module 101, the infusion module 102 injects the currently insulin dose required into the user's body. At the same time, the real-time infusion status of the infusion module 102 can also be fed back to the program module 101.

The embodiment of the present invention does not limit the specific positions and connection relationships of the detection module 100, the program module 101 and the infusion module 102, as long as the aforementioned functional conditions can be satisfied.

As in an embodiment of the present invention, the three are electrically connected to form a single structure. Therefore, the three modules can be attached together on only one position of the user's skin. If the three modules are connected as a whole and attached in the only one position, the number of the device on the user skin will be reduced, thereby reducing the interference of more attached devices on user activities. At the same time, it also effectively solves the problem of the poor wireless communication between separating devices, further enhancing the user experience.

As in another embodiment of the present invention, the program module 101 and the infusion module 102 are electrically connected to each other to form a single structure while the detection module 100 is separately provided in another structure. At this time, the detection module 100 and the program module 101 transmit wireless signals to each other to realize mutual connection. Therefore, the program module 101 and the infusion module 102 can be attached on the same position of the user's skin while the detection module 100 is attached on the other position.

As in another embodiment of the present invention, the program module 101 and the detection module 100 are electrically connected to each other forming a single structure while the infusion module 102 is separately provided in another structure. The infusion module 102 and the program module 101 transmit wireless signals to each other to realize mutual connection. Therefore, the program module 101 and the detection module 100 can be attached on the same position of the user's skin while the infusion module 102 is attached on the other position.

As in another embodiment of the present invention, the three are respectively provided in different structures, thus being attached on different position. At this time, the program module 101, the detection module 100 and the infusion module 102 respectively transmit wireless signals to each other to realize mutual connection.

It should be noted that the program module 101 of the embodiment of the present invention also has functions such as storage, recording, and access to the database, thus, the program module 101 can be reused. In this way, not only can the user's physical condition data be stored, but also the production cost and the user's consumption cost can be saved. As described above, when the service life of the detection module 100 or the infusion module 102 expires, the program module 101 can be separated from the detection module 100, the infusion module 102, or both the detection module 100 and the infusion module 102.

Generally, the service lives of the detection module 100, the program module 101 and the infusion module 102 are different. Therefore, when the three are electrically connected to each other to form a single device, the three can also be separated from each other in pairs. For example, if one module expires firstly, the user can only replace this module and keep the other two modules continuous using.

Here, it should be noted that the program module 101 of the embodiment of the present invention may also include multiple sub-modules. According to the functions of the sub-modules, different sub-modules can be respectively assembled in different structure, which is not specific limitation herein, as long as the control conditions of the program module 101 can be satisfied.

In the embodiment of the present invention, the program module 101 is also used to obtain data including the insulin dose infused per day by users. Generally, for artificial pancreas, the current insulin dose required is closely related to the insulin dose infused per day by users in history. Preferably, in the embodiment of the present invention, the insulin dose infused per day by users includes the total amount of daily infusion dose data (*d*), or the bolus and basal data infused in different time periods, or the temporary basal data and the correction bolus data, or the infusion data after different events.

The program module 101 includes a manual input interface (not shown) or an automatic detection sub-module (not shown). By using the manual input interface or the automatic detection sub-module alone, or using the two combination, the program module 101 can obtain the user's physical condition data. This alone or combination using of these two modules enhances the flexibility in using the device.

For example, in an embodiment of the present invention, with the manual input interface, users can manually input the insulin dose infused per day by users into the program module 101 according to the clinical guidance. In another embodiment of the present invention, the program module 101 has already stored and recorded the user's previous insulin infusion data. With the automatic detection sub-module, the program module 101 can automatically obtain and calculate the insulin dose infused per day by users. Preferably, in the embodiment of the present invention, the user uses the manual input interface in combination with the automatic detection sub-module. At this time, the data automatically detected and the manually input can be combined and compared, making the program module 101 adjust the algorithm in real time for obtaining more accurate calculation outcome.

In other embodiments of the present invention, through the manual input interface, users can also input other information, such as meal information, exercise information, sleep information, and physical condition information into the program module 101, which is not specifically limited herein.

Generally, the purpose of using an artificial pancreas is to stabilize the BG level, that is, an appropriate dose of insulin needs to be infused into the user's body. However, the current insulin infusion dose is closely related to the total daily dose (TDD) which is an important factor influencing the current insulin infusion dose. Therefore, the program module 101 is imported into the total daily dose algorithm and the current insulin infusion algorithm, which are used to calculate the TDD and the current insulin infusion dose, respectively.

The current insulin infusion algorithm is used to calculate the current insulin infusion dose required. In the embodiment of the present invention, there are also many factors affecting the current insulin infusion dose, such as physical activity status, TDD, etc.. Preferably, in the embodiment of the present invention, the TDD is one of the variable factors. Therefore, the more accurate the TDD or the more accurate the artificial pancreas sensing the user's activity status, the more accurate the current insulin infusion dose will be. And TDD can be obtained from calculating the aforementioned insulin dose infused per day by users according to the total daily dose algorithm. At the same time, the program module 101 can alone or in combination uses the detection data, the insulin dose infused per day by users and TDD data to calculate the current insulin infusion dose.

There are many factors that affect TDD, and some of them are related to the user's physical condition. Therefore, in the embodiment of the present invention, the variable factors of the total daily dose algorithm include one or more of the user's physical activity status, physiological status, psychological status, and meal status.

Here, the physiological status of the user includes one or more factors of weight, gender, age, disease condition, and menstrual period.

The user's psychological status includes emotional conditions such as anger, fear, depression, hyperactivity, and excitement.

The user's physical activity status includes general body stretching, exercise, or sleep. The control system can distinguish normal activities, exercise and sleep, making the control system more refined to control BG levels.

As mentioned above, TDD is obtained by the program module 101 by calculating the total amount of daily infusion dose data (d) in the previous two days or more according to the total daily dose algorithm. Preferably, in the embodiment of the present invention, TDD is obtained by the program module 101 by calculating the total amount of daily infusion dose data (d) in the previous seven days. Preferably, TDD is the average value of the total amount of daily infusion dose data (d).

In an embodiment of the present invention, if d_7, d_6, ... , d_2, d_1 respectively represent the total amount of daily infusion dose data in the previous seventh day, the previous sixth day, ... , the day before yesterday, and yesterday, then:

$$\mathrm{TDD} = (d_7 + d_6 + ... + d_2 + d_1) / 7$$

that is, TDD is the arithmetic average of the total amount of daily infusion dose data (d).

If the time is much closer to the today, the total amount of daily infusion dose data (d) is much closer to the actual TDD. Therefore, in another embodiment of the present invention, different d_n has different weights γ_n, such as the corresponding weights γ_7, γ_6, ... , γ_2, γ_1, then:

$$\mathrm{TDD} = \gamma_7 d_7 + \gamma_6 d_6 + ... + \gamma_2 d_2 + \gamma_1 d_1$$

that is, TDD is the weighted average of the total amount of insulin infused per day (d).

It should be noted that the embodiment of the present invention does not limit the statistical method of d_n. In yet another embodiment of the present invention, the TDD value can be determined by the median of the total amount of daily infusion dose data (d) in the previous seven days. In another embodiment of the present invention, the maximum value and minimum value of d_n may be eliminated firstly, and then the averaging process is performed. Another embodiment of the present invention introduces variance or standard deviation method with discarding points with larger errors firstly and then performing averaging processing. In other embodiments of the present invention, a method of combining weighted average with a sliding data frame may also be used to make the calculation result of TDD more accurate.

Here, it should be noted that the sliding data frame refers to select the data, like from previous five consecutive days, as a data frame for statistics. And according to the passage of time, the data frame as a whole moves backward for several days, but still keeps including data of another previous five consecutive days. For the specific statistical method of the data in the sliding data frame, please refer to the foresaid, which will not be repeated herein.

As mentioned above, both TDD and the current insulin infusion dose are affected by physical activities. Therefore, the closed-loop artificial pancreas insulin infusion control system also includes a motion sensor (not shown) which is used to sense the user's physical activity. And the program module 101 can receive physical activity status information. The motion sensor can automatically and accurately sense the physical activity status of the user which will be sent to the program module 101, making the calculation result of the TDD or the current insulin infusion dose much more accurate, and enhancing the user experience. At the same time, providing the motion sensor in the module of the control system can improve the integration of the control system as much as possible, reduce the device size, and enhance the user experience.

The motion sensor is provided in the detection module 100, the program module 101 or the infusion module 102. Preferably, in the embodiment of the present invention, the motion sensor is provided in the program module 101.

It should be noted that the embodiment of the present invention does not limit the number of motion sensors and the installation positions of these multiple motion sensors, as long as the conditions for the motion sensor to sense the user's activity status can be satisfied.

The motion sensor includes a three-axis acceleration sensor or a gyroscope. The three-axis acceleration sensor or gyroscope can more accurately sense the body's activity intensity, activity mode or body posture, which ultimately makes the calculation result of the infusion more accurate. Preferably, in the embodiment of the present invention, the motion sensor is the combination of a three-axis acceleration sensor and a gyroscope.

In summary, the present invention discloses a closed-loop artificial pancreas insulin infusion control system which can automatically detect the physical condition of the user and accurately calculate the TDD value and the current insulin infusion dose, enhancing user experience.

While the invention has been described in detail with reference to the specific embodiments of the present invention, it should be understood that it will be appreciated by those skilled in the art that the above embodiments may be modified without departing from the scope and spirit of the invention. The scope of the invention is defined by the appended claims.

CLAIMS

1. A closed-loop artificial pancreas insulin infusion control system, characterized in that, including,

a detection module configured to continuously detect the real-time blood glucose level;

a program module, connected to the detection module, is configured to obtain the insulin dose infused per day by users, and is also imported into the total daily dose algorithm and the current insulin infusion algorithm, wherein,

according to the insulin dose infused per day by users, the total daily dose algorithm is used to calculate the total daily dose;

according to the blood glucose detected, the insulin dose infused per day by users or total daily dose, the current insulin infusion algorithm is used to calculate the current insulin infusion dose;

an infusion module, connected to and controlled by the program module, is configured to infuse insulin required according to the data of the current insulin infusion dose; and

a motion sensor configured to sense the user’s physical activity status which can be sent to the program module and is one of the variable factors of the total daily dose algorithm or the current insulin infusion algorithm.

2. A closed-loop artificial pancreas insulin infusion control system of claim 1, characterized in that,

the program module includes a manual input interface or an automatic detection sub-module, and the method for the program module to obtain the insulin dose infused per day by users includes:

the insulin dose infused per day by users is manually input into the program module through the manual input interface; or

the insulin dose infused per day by users is automatically detected, stored and calculated by the automatic detection sub-module.

3. A closed-loop artificial pancreas insulin infusion control system of claim 2, characterized in that,

the insulin dose infused per day by users includes the total amount of daily infusion dose data, or the bolus and basal data infused in different time periods, or the temporary basal data and the correction bolus data, or the infusion data after different events.

4. A closed-loop artificial pancreas insulin infusion control system of claim 3, characterized in that,

the total daily dose is obtained by calculating the total amount of daily infusion dose data in the previous two or more days according to the total daily dose algorithm, and the total daily dose is the average or median of the insulin dose infused per day by users, and the total daily dose is one variable factor of the current insulin infusion algorithm.

5. A closed-loop artificial pancreas insulin infusion control system of claim 4, characterized in that,

the average includes an arithmetic average or a weighted average.

6. A closed-loop artificial pancreas insulin infusion control system of claim 3, characterized in that,

the variable factors of the total daily dose algorithm include one or more of the user's physical activity status, physiological status, psychological status, and meal status.

7. A closed-loop artificial pancreas insulin infusion control system of claim 6, characterized in that,

   the physiological status includes one or more factors of weight, gender, age, disease, and menstrual period.

8. A closed-loop artificial pancreas insulin infusion control system of claim 6, characterized in that,

   the physical activity status includes general body stretching, exercise, or sleep.

9. A closed-loop artificial pancreas insulin infusion control system of claim 6, characterized in that,

   the meal information, exercise information, sleep information, or physical condition information can be manually input into the program module through the manual input interface.

10. A closed-loop artificial pancreas insulin infusion control system of claim 1, characterized in that,

    the motion sensor is provided in the detection module, the program module or the infusion module.

11. A closed-loop artificial pancreas insulin infusion control system of claim 10, characterized in that,

    the motion sensor includes a three-axis acceleration sensor or a gyroscope.

12. A closed-loop artificial pancreas insulin infusion control system of claim 1, characterized in that,

    any two of the detection module, the program module and the infusion module are connected to each other configured to form a single structure whose attached position on the shin is different from the third module.

13. A closed-loop artificial pancreas insulin infusion control system of claim 1, characterized in that,

    the detection module, the program module and the infusion module are connected together configured to form a single structure which is attached on only one position on the skin.

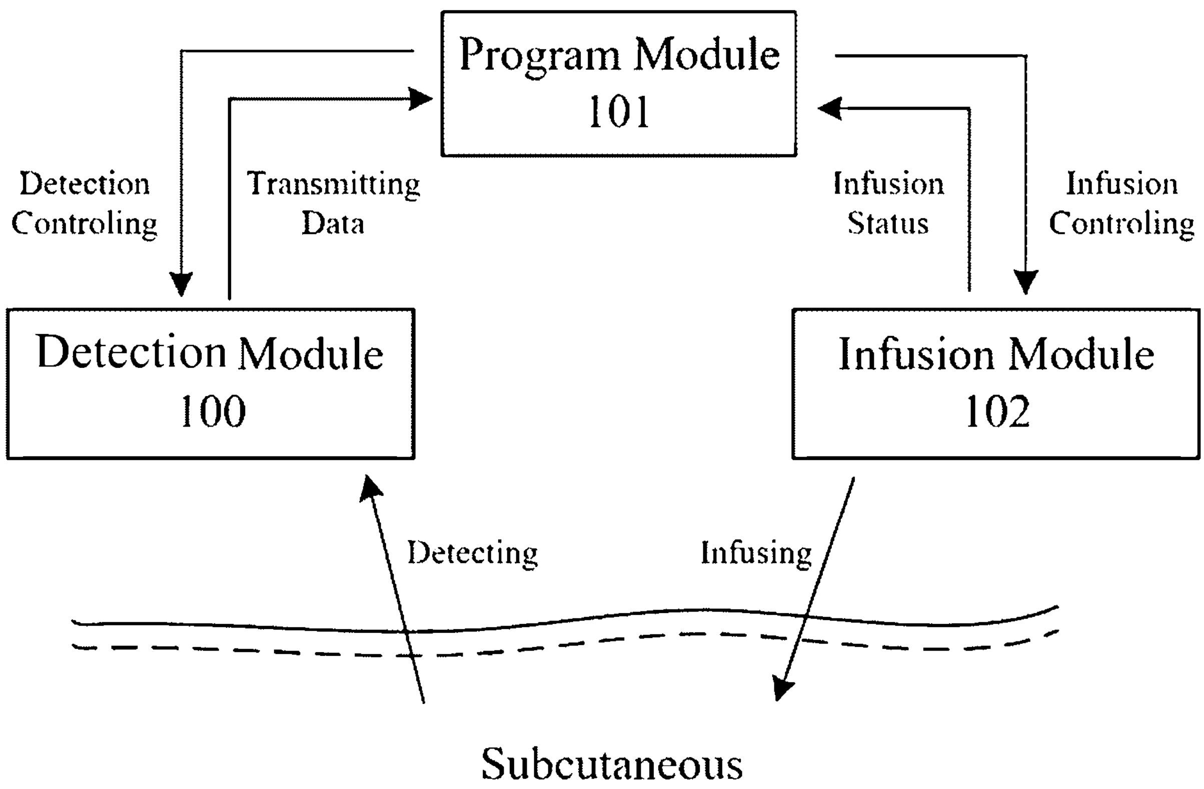
Program Module
101
Detection
Controling
Transmitting
Data
Infusion
Status
Infusion
Controling
Detection Module
100
Infusion Module
102
Detecting
Infusing
Subcutaneous

FIG.1

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2020/111169

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/172(2006.01)i；A61B 5/145(2006.01)i；G16H 20/17(2018.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M5/-；A61B5/-；G16H20/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI,EPODOC,CNKI,CNPAT:closed-loop,artificial,pancerea,insulin,infus+,detect+,glucose,algorithm,total,daily,dose,TDD, current,motion,sensor,physical,status,activity,accelerat+,gyroscope

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 108261591 A (SHANGHAI MEDTRUM TECHNOLOGIES INC.) 10 July 2018 (2018-07-10) paragraphs [0038]-[0121] in the description, figures 1-4	1-13
Y	US 2019321553 A1 (MEDTRONIC MINIMED INC.) 24 October 2019 (2019-10-24) paragraphs [0025]-[0093] in the description, figures 1-5	1-13
Y	CN 108261585 A (SHANGHAI MEDTRUM TECHNOLOGIES INC.) 10 July 2018 (2018-07-10) paragraphs [0032]-[0055] in the description, figures 1-5	1-13
A	CN 110582231 A (ELI LILLY AND COMPANY) 17 December 2019 (2019-12-17) the whole document	1-13
A	CN 109804434 A (MEDTRONIC MINIMED INC.) 24 May 2019 (2019-05-24) the whole document	1-13
A	CN 110913930 A (LIFESCAN IP HOLDINGS L.L.C.) 24 March 2020 (2020-03-24) the whole document	1-13
A	WO 2018120096 A1 (MEDTRUM TECHNOLOGIES INC.) 05 July 2018 (2018-07-05) the whole document	1-13

☐ Further documents are listed in the continuation of Box C. ☑ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 April 2021	**26 May 2021**

Name and mailing address of the ISA/CN	Authorized officer
National Intellectual Property Administration, PRC **6, Xitucheng Rd., Jimen Bridge, Haidian District, Beijing 100088** **China**	**ZHANG,Meng**
Facsimile No. **(86-10)62019451**	Telephone No. **86-(10)-53962402**

Patent document cited in search report			Publication date (day/month/year)	Patent family member(s)			Publication date (day/month/year)
CN	108261591	A	10 July 2018	None			
US	2019321553	A1	24 October 2019	CN	112005310	A	27 November 2020
				KR	20210004993	A	13 January 2021
				WO	2019209602	A1	31 October 2019
				EP	3785276	A1	03 March 2021
CN	108261585	A	10 July 2018	None			
CN	110582231	A	17 December 2019	JP	2020518340	A	25 June 2020
				US	2020197605	A1	25 June 2020
				WO	2018204568	A1	08 November 2018
				EP	3618713	A1	11 March 2020
CN	109804434	A	24 May 2019	US	2018099092	A1	12 April 2018
				EP	3523808	A1	14 August 2019
				KR	20190062492	A	05 June 2019
				US	10561788	B2	18 February 2020
				WO	2018067748	A1	12 April 2018
				JP	2019528996	A	17 October 2019
CN	110913930	A	24 March 2020	US	2018296757	A1	18 October 2018
				WO	2018194838	A1	25 October 2018
				EP	3612255	A1	26 February 2020
				KR	20190141704	A	24 December 2019
				JP	2020518327	A	25 June 2020
WO	2018120096	A1	05 July 2018	EP	3562380	A1	06 November 2019
				US	2019328340	A1	31 October 2019