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Intelligently controlled miniature fully closed-loop artificial pancreas

Abstract

The invention discloses an intelligently controlled miniature fully closed-loop artificial pancreas, comprising: infusion unit configured to deliver drugs; program unit comprising input end and output end, and the input end comprises a plurality of electrically connective regions for receiving signals of analyte data in the body fluid, after the output end is electrically connected to the infusion unit, according to the received signals of analyte data in the body fluid, the program unit controls whether the infusion unit delivers drugs; an infusion cannula with conductive area, the infusion cannula is the drug infusion channel; and a plurality of electrodes for detecting analyte data in body fluid, the electrode comprising conductive-area electrode and cannula-wall electrode, and one or more cannula-wall electrodes being located on/in the wall of the infusion cannula. It takes only one insertion to perform both analyte detection and drug infusion.

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Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION

(1) This application is a 371 of international application of PCT application serial no. PCT/CN2019/130435, filed on Dec. 31, 2019, which claims the priority benefits of PCT application serial no. PCT/CN2019/096673, filed on Jul. 19, 2019. The entirety of each of the above-mentioned patent applications is hereby incorporated by reference herein and made a part of this specification.

TECHNICAL FIELD

(2) The present invention mainly relates to the field of medical instruments, in particular to an intelligently controlled miniature fully closed-loop artificial pancreas.

BACKGROUND

(3) Diabetes is mainly a metabolic disease caused by abnormal human pancreatic function. Diabetes is a lifelong disease. At present, medical technology cannot cure diabetes. It can only control the occurrence and development of diabetes and its complications by stabilizing blood glucose. The normal human pancreas automatically monitors changes in the body's blood glucose levels and automatically secretes the required insulin. At present, the medical device for stabilizing blood glucose works by dynamically monitoring the blood glucose changes of the human body by a glucose sensor implanted in the subcutaneous tissue of the human body; and continuously accurately infusing insulin into the subcutaneous tissue of the human body through a medical

cannula implanted in the subcutaneous tissue of the human body.
(4) This method requires separately inserting glucose sensor and infusion cannula under the human skin. Even though there are some devices that can integrate the sensor probe and the infusion cannula into one device, the sensor and cannula still need to be separately inserted at different positions, increasing the risk of infection.
(5) Therefore, there is a need in the prior art for an intelligently controlled miniature fully closed-loop artificial pancreas that can perform both detection and infusion at the same time.

BRIEF SUMMARY OF THE INVENTION

(6) Embodiments of the present invention disclose an intelligently controlled miniature fully closed-loop artificial pancreas in which a plurality of electrodes are disposed on an infusion cannula comprising conductive area(s), and the infusion cannula itself acts as an electrode and infusion channel. It takes only one insertion to perform both analyte detection and drug infusion, thus reducing the risk of infection.
(7) The invention discloses an intelligently controlled miniature fully closed-loop artificial pancreas, comprising: an infusion unit; the infusion unit comprises drug storage unit(s), piston(s) and rigid screw(s), the piston is arranged in the drug storage unit, metal piece, fixedly connected to a rigid screw, is arranged on the piston; rotating shaft, driving unit(s) and driving wheel(s) provided with wheel teeth, the driving unit includes at least two driving portions, the driving unit can rotate around the rotating shaft in the driving direction and the returning direction, when rotating in the driving direction, one driving portion of the driving unit pushes the wheel teeth to rotate the driving wheel which engages the rigid screw to move forward in a non-rotating way, when rotating in the returning direction, all driving portions of the driving unit slide synchronously on the surface of the wheel teeth; and power unit(s) and rebound unit(s), the power unit and the rebound unit cooperate with each other to apply force to the driving unit to rotate the driving unit; position detector(s), the metal piece and the position detector interact to generate signal(s); a program unit, the program unit comprises input end and output end, and the input end comprises a plurality of electrically connective regions for receiving signals of analyte data in the body fluid, after the output end is electrically connected to the infusion unit, according to the received signals of analyte data in the body fluid, the program unit controls whether the infusion unit delivers drugs, and convert received signal(s) into the piston position information and can select a specific driving portion to push the driving wheel according to requirements to adjust infusion rate; an infusion cannula with conductive area(s), the infusion cannula is the drug infusion channel; and a plurality of electrodes for detecting analyte data in body fluid, the electrode comprising conductive-area electrode(s) and cannula-wall electrode(s), the conductive area of the infusion cannula being at least as a conductive-area electrode, and one or more cannula-wall electrodes being located on/in the wall of the infusion cannula, when the infusion cannula is installed to the working position, the infusion cannula is connected with the infusion unit, the drug can then be injected into the body through the infusion cannula, and the different electrodes are electrically connected to different electrically connective regions respectively, inputting signal of analyte data in the body fluid to the program unit.
(8) According to one aspect of this invention, cannula-wall electrode is located on the outer surface of the infusion cannula wall or in the infusion cannula wall.
(9) According to one aspect of this invention, cannula-wall electrode is located on the outer surface of the infusion cannula wall, and when the infusion cannula is installed to the working position, the conductive-area electrode and the cannula-wall electrode are directly electrically connected to different electrically connective regions, respectively.
(10) According to one aspect of this invention, cannula-wall electrode is located on the subcutaneous part of the outer surface of the infusion cannula wall, and the outer surface of the infusion cannula wall is further provided with electrode lead electrically connected to the cannula-wall electrode, and when the infusion cannula is installed to the working position, the electrode

lead and the conductive-area electrode are electrically connected to different electrically connective regions, respectively.
(11) According to one aspect of this invention, the infusion cannula includes an infusion steel needle and a hose which is placed on the outer wall surface of the infusion steel needle, and the needle cavity of the infusion steel needle is used for infusion of drugs.
(12) According to one aspect of this invention, when the infusion cannula is installed to the working position, the depth of the hose into the skin is d.sub.1, while the depth of the infusion steel needle into the skin is d.sub.2, d.sub.1≤d.sub.2.
(13) According to one aspect of this invention, the infusion steel needle is conductive-area electrode, and the cannula-wall electrode is located on the outer/inner surface of the hose wall, or is located on the outer wall surface of the infusion steel needle.
(14) According to one aspect of this invention, when the infusion cannula is installed to the working position, the cannula-wall electrode located on the outer wall surface of the infusion steel needle is exposed in the subcutaneous tissue fluid or covered in whole or in part by the hose.
(15) According to one aspect of this invention, when the cannula-wall electrode located on the outer wall surface of the infusion steel needle is covered in whole or in part by the hose, or when the cannula-wall electrode is located on the inner surface of the hose wall, the material of hose wall is permeable membrane or a semi-permeable membrane.
(16) According to one aspect of this invention, the infusion cannula comprises a plurality of electrically conductive areas isolated from each other, the infusion cannula comprising a plurality of electrically conductive-area electrodes, different conductive-area electrodes being different conductive areas of the infusion cannula.
(17) According to one aspect of this invention, the electrodes include working electrode and auxiliary electrode, and the number of the working electrode(s) and the auxiliary electrode(s) is one or more, respectively.
(18) According to one aspect of this invention, conductive-area electrode is working electrode or auxiliary electrode.
(19) According to one aspect of this invention, the auxiliary electrode is counter electrode, or the auxiliary electrode includes counter electrode and reference electrode.
(20) According to one aspect of this invention, a plurality of electrodes form one or more electrode combinations, each electrode combination comprising working electrode and auxiliary electrode, the program unit choosing one or more electrode combinations to detect analyte data in body fluid.
(21) According to one aspect of this invention, also comprises a remote device, the remote device and the program unit transmitting wireless signals to each other, the program unit transmitting the data of analyte in body fluid or the drug infusion information to the remote device, and the remote device sending the manually selected electrode combinations for detection or drug infusion instruction to the program unit.
(22) According to one aspect of this invention, the input end is an elastic member, and the elastic member comprises one of or a combination of conductive strip, oriented conductive silica gel, conductive ring and conductive ball.
(23) According to one aspect of this invention, the infusion unit includes a plurality of infusion subunits, the plurality of infusion subunits being electrically connected to the output ends, respectively, and the program unit controlling whether each infusion subunit delivers drugs.
(24) According to one aspect of this invention, the intelligently controlled miniature fully closed-loop artificial pancreas is composed of a plurality of parts, the infusion unit and the program unit are arranged in different parts, and the different parts are connected by waterproof plugs.
(25) According to one aspect of the present invention, the rigid screw is a metal screw, and the metal piece is electrically connected with the metal screw, so that the metal piece and the corresponding position detector constitute a capacitor, and the linear movement of the metal piece causes a change in capacitance making the corresponding position detector generate an electrical

signal.
(26) According to one aspect of the present invention, the metal piece is a magnetic metal piece, and the position detectors are magnetic induction detectors, the linear movement of the magnetic metal piece causes a change in the magnetic field around each position detector making each position detector generate a magnetic signal.
(27) According to one aspect of the present invention, the infusion unit further includes a clutch structure movably disposed on the driving wheel, the rigid screw passes through the clutch structure, and the clutch structure is provided with an internal thread that cooperates with the rigid screw, the driving wheel drives the clutch structure to rotate which, with the internal thread, pushes the rigid screw to move forward in a non-rotating way.
(28) According to one aspect of the present invention, the infusion unit further includes blocking wall(s), and the driving unit stops rotating upon contacting the blocking wall.
(29) According to one aspect of the present invention, the vertical projections of the front ends of any two driving portions on the driving unit do not coincide.
(30) According to one aspect of the present invention, the number of driving portions provided on one driving unit is n ($n \geq 2$), if the distance, in pushing direction, between the vertical projections of the front ends of any two adjacent driving portions which cooperate with the same driving wheel is t, and the wheel tooth pitch is T, then $t=T/n$.
(31) According to one aspect of the present invention, one driving unit provided with two driving portions and two driving wheels are provided in the infusion unit, the two driving wheels are fixedly connected to realize synchronous rotation, the two driving portions are respectively matched with the two driving wheels, the wheels are arranged on the same side of the rotating shaft, and the teeth of the two driving wheels are staggered.
(32) According to one aspect of the present invention, one driving unit is provided with two driving portions, and the two driving portions are matched with the same driving wheel, if the distance, in pushing direction, between the vertical projections of the front ends of the two adjacent driving portions is t.sub.1, and the tooth pitch is T, then t.sub.1=3 T/2.
(33) Compared with the prior arts, the technical solution of the present invention has the following advantages:
(34) In the intelligently controlled miniature fully closed-loop artificial pancreas disclosed herein, firstly, one driving unit includes at least two driving portions, and the driving unit can rotate in the driving direction and the returning direction around the rotating shaft, when rotating in the driving direction, one driving portion of the driving unit pushes the wheel teeth to rotate the driving wheel which engages the rigid screw to move forward in a non-rotating way, when rotating in the returning direction, all the driving portions of the driving unit slide synchronously on the surface of the wheel teeth. When the driving unit is provided with two or more driving portions, after rotating in the returning direction by less than one tooth pitch, the driving unit will be ready for the next driving. The intelligently controlled miniature fully closed-loop artificial pancreas reduces the unit amount (or the infusion increment) of drug infused per single driving. In addition, the program unit can intelligently select a specific driving portion to push the wheel according to requirements to adjust infusion rate. The unit amount of drug infused per driving changes with the selection of driving portion to push the wheel teeth, resulting in different infusion rates. Therefore, patients also have more infusion rate options, which increases the flexibility of controlling drug infusion. Secondly, the infusion cannula includes conductive area. The conductive area is directly used as the detecting electrode, so that the infusion cannula performs analyte detection and drug infusion at the same time. Once the puncture is performed at one position, the analyte detection and the drug infusion can be completed simultaneously, reducing the risk of the user's infection. Thirdly, the intelligently controlled miniature fully closed-loop artificial pancreas is provided with a plurality of electrodes for detecting data of the body fluid analyte. The conductive area of the infusion cannula makes up at least one conductive-area electrode, and one or more cannula-wall electrodes are

located in/on the wall of the infusion cannula. The conductive area of the infusion cannula acts as an electrode, so that the infusion cannula itself is an electrode, which reduces the difficulty of the electrode design process. At the same time, the plurality of electrodes located in/on the infusion cannula can also form specific electrode combinations while completing the detection of the analyte data, so that the program unit or the user can select one or part of them according to actual needs. In addition, when the infusion cannula is installed to the working position, the infusion cannula connects with the infusion unit to allow the drugs to flow through the infusion cannula into the body, and the different electrodes are electrically connected to different electrically connective regions inputting the analyte data signal to the program unit. With this design method, after the user attaches the intelligently controlled miniature fully closed-loop artificial pancreas to the skin surface, the mounting unit for installing the infusion cannula is pressed. When the infusion cannula is installed to the working position, the intelligently controlled miniature fully closed-loop artificial pancreas can begin to work. This approach reduces the user's pre-using steps and improves the user experience.

(35) Furthermore, the infusion cannula comprises an infusion steel needle and a hose placed on the outer wall surface of the infusion steel needle, and the needle cavity of the infusion steel needle is used for drug infusion. The process of designing the electrodes on the surface of the hose is relatively simple, so that this design reduces the difficulty of the electrode manufacturing process and improves the preparation efficiency. Secondly, the wall material of the hose can be selected according to needs, and the wall of the cannula can only allow specific analytes to pass through, weaken the interference of other substances, and improve the accuracy of analyte data detection.

(36) Furthermore, when the cannula-wall electrode located on the outer wall surface of the infusion steel needle is covered in whole or in part by the hose, or when the cannula-wall electrode is located on the inner surface of the hose wall, the hose wall is a permeable membrane or a semi-permeable membrane. The hose wall material is selected from a permeable membrane or a semi-permeable membrane to ensure the required analyte passes through the hose wall to the electrode surface. It can improve the flexibility of electrode position design without affecting the detection.

(37) Furthermore, the infusion cannula comprises a plurality of electrically insulated conductive areas, the infusion cannula comprises a plurality of conductive-area electrodes, and the different conductive-area electrodes are different conductive areas of the infusion cannula. The different conductive areas of the infusion cannula itself serve as electrodes, which can further reduce the number of electrodes on the surface of the cannula wall and simplify the manufacturing process of the infusion cannula.

(38) Furthermore, a plurality of electrodes constitute one or more electrode combinations, each electrode combination includes working electrode and auxiliary electrode, and the program unit selects one or more electrode combinations to detect the body fluid analyte data. On the one hand, when a combination of electrodes fails to detect, the program unit can select other electrode combinations for detection according to the situation to ensure the detection process of the body fluid signal is uninterrupted. On the other hand, the program unit can select multiple electrode combinations to work at the same time, performing statistical analysis on multiple sets of data of the same parameter at the same time, improving the detection accuracy of the analyte data, and then issue a more accurate infusion signal.

(39) Furthermore, the infusion unit comprises a plurality of infusion subunits, the plurality of infusion subunits being electrically connected to the output end respectively, and the program unit controlling whether each infusion subunit delivers drugs. Different drugs are reserved in different infusion subunits, and the program unit sends different drug infusion instructions to different infusion subunits to achieve precise control of the analyte level in body fluid.

(40) Furthermore, the rigid screw of the intelligently controlled miniature fully closed-loop artificial pancreas moves linearly in a non-rotating way. After the rigid screw is fixedly connected to the metal piece, the metal piece also moves linearly in a non-rotating way, so that position

signal(s) only need to be detected in the one-dimensional axial direction or the two-dimensional plane (determined by the moving direction of the screw and a detector), simplifying the detection method and reducing the design and production cost.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) FIG. **1** is a flow chart of the operation of an intelligently controlled miniature fully closed-loop artificial pancreas according to an embodiment of the present invention;

(2) FIG. **2***a* is a schematic cross-sectional view of an infusion cannula of an intelligently controlled miniature fully closed-loop artificial pancreas in a pre-installation position according to one embodiment of the present invention;

(3) FIG. **2***b* is a schematic cross-sectional view showing the infusion cannula of the intelligently controlled miniature fully closed-loop artificial pancreas in a working position according to an embodiment of the present invention;

(4) FIG. **3***a*-FIG. **3***b* are top views of an intelligently controlled miniature fully closed-loop artificial pancreas in accordance with another embodiment of the present invention;

(5) FIG. **4** is a schematic diagram of an infusion unit according to an embodiment of the present invention;

(6) FIG. **5***a*-FIG. **5***b* are schematic structural diagrams of a driving portion pushing a wheel tooth under different perspectives according to an embodiment of the present invention;

(7) FIG. **6***a*-FIG. **6***b* are schematic diagrams of the clutch structure under different perspectives according to an embodiment of the present invention;

(8) FIG. **7** is a schematic structural diagram of a metal piece and a position detector according to an embodiment of the present invention;

(9) FIG. **8** is a schematic structural diagram of a driving portion pushing a wheel tooth according to another embodiment of the present invention;

(10) FIG. **9** is a schematic structural diagram of a metal piece and a position detector according to another embodiment of the present invention;

(11) FIG. **10***a* is a schematic structural diagram of a driving unit pushing a wheel tooth according to another embodiment of the present invention;

(12) FIG. **10***b* is a schematic structural diagram of staggered teeth of two driving wheels according to still another embodiment of the present invention;

(13) FIG. **11** is a schematic structural diagram of three driving portions pushing wheel teeth according to still another embodiment of the present invention;

(14) FIG. **12***a*-FIG. **12***b* are partial longitudinal cross-sectional views of an infusion cannula and an electrode according to one embodiment of the present invention;

(15) FIG. **13***a*-FIG. **13***b* are partial longitudinal cross-sectional views of an infusion cannula and an electrode in accordance with another embodiment of the present invention;

(16) FIG. **14** is a partial longitudinal cross-sectional view of an infusion cannula and three electrodes in accordance with still another embodiment of the present invention;

(17) FIG. **15** is a partial longitudinal cross-sectional view showing an infusion steel needle casing hose according to still another embodiment of the present invention;

(18) FIG. **16***a* is a partial longitudinal cross-sectional view of an infusion cannula having a plurality of electrically conductive areas in accordance with yet another embodiment of the present invention;

(19) FIG. **16***b*-FIG. **16***c* are partial transverse cross-sectional views of an infusion cannula having a plurality of electrically conductive areas in accordance with yet another embodiment of the present invention;

(20) FIG. **17** is a schematic structural view of an intelligently controlled miniature fully closed-loop artificial pancreas and a remote device according to still another embodiment of the present invention.

DETAILED DESCRIPTION

(21) As described above, in the prior art device, the detection and the infusion are performed separately to control the analyte level in the body fluid, and it is necessary to puncture at multiple positions on the skin, thereby increasing the pain of the user and increasing the risk of infection.

(22) The study found that the cause of the above problems is that the sensor detection device and the drug infusion device are two independent units. Or even if the two are designed into a single structure, a plurality of puncture positions are still required on the body surface.

(23) In order to solve this problem, the present invention provides an intelligently controlled miniature fully closed-loop artificial pancreas, the infusion cannula contains conductive area, which makes the infusion cannula itself as an electrode for detecting analyte data and a drug infusion channel. And it can perform detection and infusion with only one puncture.

(24) 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.

(25) 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.

(26) 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.

(27) 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.

(28) FIG. **1** is a flow chart showing the operation of an intelligently controlled miniature fully closed-loop artificial pancreas according to an embodiment of the present invention.

(29) The intelligently controlled miniature fully closed-loop artificial pancreas of the embodiment of the invention comprises three basic parts: electrodes, a program unit and an infusion unit. The body fluid analyte data is obtained by the electrodes and converted into an electrical signal. Electrical signals are passed to the program unit via electrodes and/or electrode leads. After analyzing the body fluid analyte data signal, the program unit sends a signal to the infusion unit controlling whether to perform a drug infusion, thereby stabilizing the body fluid parameters. The body fluid analyte data are detected by the electrodes in real time, and the cycle of detection and infusion is without interruption. This process does not require human intervention and is done directly through program analysis to control the stability of body fluid parameters.

(30) FIG. **2***a*-**2***b* are cross-sectional views of an intelligently controlled miniature fully closed-loop artificial pancreas **100** according to an embodiment of the present invention, and the intelligently controlled miniature fully closed-loop artificial pancreas **100** is an integral structure. FIG. **2***a* shows the infusion cannula **130** in the pre-installation position while FIG. **2***b* shows the infusion cannula **130** in the working position.

(31) Program unit **120** includes an input end **121** and an output end **122**. The input end **121** is used for receiving a body fluid analyte data signal. In the embodiment of the invention, the input end **121** includes electrically connective regions **121***a* and **121***b*. When in operation, the electrically connective region is electrically connected to the electrode or electrode lead to receive the analyte signal. In other embodiments of the invention, the input end **121** may also include more electrically

connective regions depending on the number of electrodes. The output end **122** is electrically coupled to the infusion unit **110**, allowing the program unit **120** to effectively control the infusion unit **110**. In the embodiment of the present invention, the program unit **120** is used for controlling drug infusion, controlling power output of the power unit, receiving signals from position detector(s), establishing wireless communication with remote devices, and the like. The program unit **120** can also select different driving portions to push the wheel teeth to achieve different infusion rates, which will be described in detail below.

(32) During the use of the intelligently controlled miniature fully closed-loop artificial pancreas of the embodiment of the present invention, the infusion cannula **130** can slid relative to the input end **121**, while the input end **121** is provided as an elastic member. The elastic member is to ensure an interference fit between the infusion cannula **130** and the input end **121** to avoid poor electrical contact. The elastic member includes: conductive rubber strip, oriented conductive silica gel, conductive ring, conductive ball, etc. When the number of electrodes is relatively large, the electrically connective regions are relatively dense. In this case, according to different structural designs, the elastic members may be one or more combinations of the above.

(33) In an embodiment of the invention, the infusion cannula **130** is mounted on the mounting unit **150**. When the infusion cannula **130** is in the pre-installation position, the mounting unit **150** protrudes from the outer surface of the intelligently controlled miniature fully closed-loop artificial pancreas **100**, as shown in FIG. **2***a*. When the infusion cannula **130** is installed to the working position, the mounting unit **150** is pressed into the intelligently controlled miniature fully closed-loop artificial pancreas **100** with the top portion integral with the intelligently controlled miniature fully closed-loop artificial pancreas **100** housing, as shown in FIG. **2***b*. Prior to use by users, the mounting unit **150** holds the infusion cannula **130** in the pre-installation position. After the intelligently controlled miniature fully closed-loop artificial pancreas **100** is attached on the surface of the human body, the mounting unit **150** is pressed to insert the infusion cannula under skin, and the intelligently controlled miniature fully closed-loop artificial pancreas can start operation. Compared with other infusion cannula installation methods, the installation method of the embodiment of the invention reduces the steps required for installation, makes the installation more convenient and flexible and improves the user experience.

(34) The manner of setting the infusion cannula **130** in the mounting unit **150** can be various, and is not specifically limited herein. Specifically, in the embodiment of the present invention, the other side of the mounting unit **150** also protrudes from the partial infusion cannula **130** (shown by a dotted line in FIG. **2***a* and FIG. **2***b*) for subsequent connection with the outlet of the infusion unit **110** to achieve drug circulation.

(35) In an embodiment of the invention, the infusion cannula **130** includes one or more electrically conductive areas. Here, the conductive area refers to different areas in/on the wall of infusion cannula **130**, and the cannula wall itself is electrically conductive. The material of the conductive area includes stainless steel, metal alloy or other conductive materials, and is not specifically limited herein. Specifically, in the embodiment of the present invention, the whole material of the infusion cannula **130** is stainless steel. At this time, the infusion cannula **130** as a whole has one conductive area. The infusion cannula **130** itself acts as an electrode and can reduce the number of electrodes and simplify the electrode design process.

(36) In other embodiments of the invention, the infusion cannula **130** further includes an electrical contact region **140** coupled to the input end **121**. As shown in FIG. **2***a*, the electrical contact region **140** is not electrically coupled to the input end **121** when the infusion cannula **130** is in the pre-installation position. And the other end of the infusion cannula **130** is also not connected with the infusion unit **110** outlet. As shown in FIG. **2***b*, when the infusion cannula **130** is mounted to the working position, one end of the infusion cannula **130** is inserted subcutaneously (indicated by the solid line portion of the infusion cannula in FIG. **2***b*) and the other end (illustrated by the dotted portion of the infusion cannula in FIG. **2***b*) is connected with the outlet of the infusion unit **110**,

thereby establishing a flow path for the drug from the infusion unit **110** to the body tissue fluid. At the same time, the electrical contact region **140** reaches the electrically connective region of the input end **121**, enabling electrical connection between the program unit **120** and the electrical contact region **140**.

(37) It should be noted that even if the infusion cannula **130** and the infusion unit **110** are connected, and the input end **121** and the electrical contact region **140** of the infusion cannula **130** are electrically connected, as long as the infusion cannula **130** does not penetrate the skin, the program unit **120** will not enter working mode, so that the intelligently controlled miniature fully closed-loop artificial pancreas does not generate any analyte data signal, nor does it issue an instruction to inject drug. Therefore, in other embodiments of the present invention, when the infusion cannula **130** is in the pre-installation position, the electrical contact region **140** may also be electrically connected to the electrically connective region of the input end **121** or the infusion cannula **130** may be coupled to the outlet of the infusion unit **110**. And there are no specific restrictions herein.

(38) In an embodiment of the invention, a medical tape **160** for attaching the intelligently controlled miniature fully closed-loop artificial pancreas **100** to the skin surface is used to paste the program unit **120**, the infusion unit **110**, the electrode and the infusion cannula **130** as a whole on the skin. When the infusion cannula **130** is installed to the working position, the portion of the infusion cannula **130** that is inserted into the skin is **13**.

(39) FIG. **3***a* is a top view of an intelligently controlled miniature fully closed-loop artificial pancreas **100** in accordance with another embodiment of the present invention.

(40) In one embodiment of the invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** comprises two parts. The program unit **120** is disposed in one part, the infusion unit **110** is disposed in another part, and the two parts are electrically connected by the waterproof electrical plug **123**. The part of the infusion unit **110** can be discarded after being used once, and the part of the program unit **120** can be reused, saving the users cost.

(41) In other embodiments of the present invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** may also be composed of more parts, and parts that do not require electrical connection may be connected using a common waterproof plug.

(42) FIG. **3***b* is a top view of an intelligently controlled miniature fully closed-loop artificial pancreas **100** in accordance with another embodiment of the present invention.

(43) In an embodiment of the invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** comprises two parts, and the infusion unit **110** comprises two infusion subunits **110***a* and **110***b*. The infusion subunits **110***a* and **110***b* can be used to reserve different drugs such as insulin, glucagon, antibiotics, nutrient solution, analgesics, morphine, anticoagulants, gene therapy drugs, cardiovascular drugs or chemotherapeutic drugs, etc. Infusion subunits **110***a* and **110***b* are electrically coupled to outputs **122***a* and **122***b*, respectively, allowing the program unit **120** to effectively control the infusion unit **110**. The outlets of infusion subunits **110***a* and **110***b* can be connected with the **130***a* portion and **130***b* portion of infusion cannula respectively. **130***a* and **130***b* are connected with the **130***c* portion of infusion cannula, respectively. The **130***c* portion of the infusion cannula is used to penetrate the skin, thereby establishing a path for the two drugs to flow from the infusion unit **110** into the body fluid. That is, the intelligently controlled miniature fully closed-loop artificial pancreas still penetrates the skin only in one position. In the embodiment of the present invention, after the body fluid analyte data signal is transmitted to the program unit **120**, program unit **120** can output different infusion signals to different infusion subunits to control whether infusion of drug is required. This method realizes accurate detection and control of body fluid analyte level to stabilize the physiological state of the user.

(44) In other embodiments of the present invention, there may be more infusion subunits according to actual needs, and multiple infusion subunits may be disposed in different parts of the intelligently controlled miniature fully closed-loop artificial pancreas **100**. There are no specific

restrictions herein.
(45) Please refer to FIG. **4**, FIG. **5***a* and FIG. **5***b*. FIG. **4** is a schematic main structural diagram of an infusion unit of an intelligently controlled miniature fully closed-loop artificial pancreas according to an embodiment of the present invention. FIG. **5***a* to FIG. **5***b* are schematic structural diagrams of the driving portions **1510***a* and **1510***b* pushing the wheel teeth **1410** in FIG. **4**. And FIG. **5***b* is a left side view of the structure of FIG. **5***a*.
(46) The internal structure of the infusion unit mainly includes the drug storage unit **1000**, the piston **1200**, the rigid screw **1300**, the driving wheel **1400**, the driving unit **1500**, the rotating shaft **1600**, the rebound unit **1700** and the power unit **1800**.
(47) The drug storage unit **1000** is used for storing liquid drug.
(48) The piston **1200** is used to infuse liquid drug into the body.
(49) The rigid screw **1300** is connected to the piston **1200** and the driving wheel **1400**, respectively. In the embodiment of the present invention, the driving wheel **1400** advances the rigid screw **1300** forward by screwing, the rigid screw **1300** then forces the piston **1200**, arranged in the drug storage unit **1000**, to move forward, so as to achieve the purpose of drug infusion.
(50) The peripheral surface of the driving wheel **1400** is provided with wheel teeth **1410**. The wheel teeth **1410** are gear teeth or ratchet teeth. Specifically, in the embodiment of the present invention, for improving driving efficiency, the wheel teeth **1410** are ratchet teeth which can be pushed more easily.
(51) The driving unit **1500** is movably connected to the rotating shaft **1600**, and is also connected to the power unit **1800** and the rebound unit **1700**, respectively. The power unit **1800** and the rebound unit **1700** cooperate with each other to cause the driving unit **1500** to rotate reciprocally in a driving direction and a returning direction around the rotating shaft **1600**. Here, the driving direction refers to the counter-clockwise direction in FIG. **5***a*, and the returning direction refers to the clockwise direction in FIG. **5***a*. The driving direction and returning direction of the driving unit hereinafter are the same as here. When the driving unit **1500** performs one reciprocal rotation, the driving wheel **1400** drives the rigid screw **1300** forward by one step, and pushes the piston **1200** to complete one unit of drug infusion.
(52) One end of the driving unit **1500** is provided with at least two driving portions for pushing the wheel teeth **1410**, thereby rotating the driving wheels **1400**. Specifically, in the embodiment of the present invention, the driving unit **1500** includes two driving portions **1510***a* and **1510***b*. In the perspective of FIG. **5***a*, the driving portion **1510***b* (shown as a dotted line) is covered by the driving portion **1510***a*. In the perspective of FIG. **5***b*, according to the structure and position characteristics, the projections of different driving portions may not be parallel.
(53) In the embodiment of the present invention, the rebound unit **1700** is a spring. In other embodiments of the present invention, the rebound unit **1700** can also be an elastic piece, an elastic plate, an elastic rod, etc. The type and material selection of the rebound unit **1700** are not specifically limited herein, as long as it can satisfy the condition of making the driving unit **1500** rotate in the return direction.
(54) The power unit **1800** is a linear actuator. In the embodiment of the present invention, the power unit **1800** is an electrically driven linear actuator or an electrically heated linear actuator. By alternately turning on and off, the power unit **1800** outputs power in pulses. In other embodiments of the present invention, the power unit **1800** may be other types, eg. mini-airbag.
(55) As shown in FIG. **5***a*, in the embodiment of the present invention, two driving portions **1510***a* and **1510***b* cooperate with the same driving wheel **1400**. Here, the cooperation means that the driving portions can push the wheel teeth **1410** to rotate the driving wheel **1400** or that all the driving portions slide synchronously on the surface of the wheel teeth **1410** to stop the driving wheel **1400** from rotating. When the power unit **1800** pulls the driving unit **1500** with force F.sub.P, the driving unit **1500** rotates in the driving direction around the rotating shaft **1600**, driving the driving portion **1510***a* to push the wheel teeth **1410** and rotate the driving wheel **1400** which then

engages the rigid screw **1300** in the D.sub.A direction. At this time, the rebound unit **1700** generates a gradually increasing elastic force F.sub.R. When the power unit **1800** stops providing power and under the action of the elastic force F.sub.R, the driving unit **1500** rotates around the rotating shaft **1600** in the returning direction. At this time, the driving portion **1510***a* stops pushing the wheel teeth **1410** and the driving wheel **1400** stops rotating. The driving portions **1510***a* and **1510***b* slide on the surface of the wheel teeth **1410** synchronously until sliding to the next driving position, in which way the driving unit **1500** completes one reciprocal rotation.

(56) It should be noted here that in order to minimize the impact of manufacturing tolerances and ensure that the wheel teeth **1410** can be pushed during each reciprocal rotation for infusion safety, after the driving portion **1510** slides to the next driving position, the driving unit **1500** can be further rotated clockwise by an appropriate distance to move the driving portion **1510** slightly away from the driving position.

(57) In the embodiment of the present invention, when two or more driving portions are matched with the same driving wheel, the vertical projections of the front ends of any two adjacent ones of these driving portions do not coincide. Here, the vertical projection misalignment means that the front ends (as shown in FIG. **5***b*) of any two adjacent driving portions have a certain distance tin the pushing direction, as shown in the FIGURES. When the number of the driving portions provided on the driving unit is n, if the tooth pitch of the wheel teeth is T, then t=T/n. In this case, after the completion of one pushing, the driving unit rotates in the returning direction, and all the drive portions need only slide 1/n distance of one tooth pitch to reach the next drive position and push again. Compared with a driving unit equipped with only one driving portion, the intelligently controlled miniature fully closed-loop artificial pancreas, according to the embodiment of the present invention, reduces the unit amount of drug infused per single driving and improves the infusion accuracy of the drug infusion. Patients or the program unit can control the drug infusion more accurately and precisely to stabilize body fluid levels. At the same time, patients will be able to adjust the infusion rate by changing the unit amount of drug infused per single driving, which is made possible by choosing different driving portions to drive the wheel teeth according to the infusion requirements

(58) Specifically, in the embodiment of the present invention, the distance between the vertical projections of the front ends of the two driving portions **1510***a* and **1510***b* in the pushing direction is t.sub.1, the tooth pitch of the wheel teeth **1410** is T, and t.sub.1=T/2. After the driving portion **1510***a* pushes the wheel teeth **1410** once and slides only ½ the distance of the tooth pitch in the returning direction, the driving portion **1510***b* can slide to the driving position of the next wheel tooth **1410** and can start next pushing. Therefore, compared with a driving unit equipped with only one driving portion, the unit amount of drug infused per single driving is halved with the improvement of infusion accuracy, and the patient can control the drug infusion rate more precisely. At the same time, the program unit can control the infusion device to use only the driving portion **1510***a* to drive, or only the driving portion **1510***b* to drive, or both the driving portions **1510***a* and **1510***b* to alternately push the wheel teeth **1410**. Since the unit amount of drug infused per single driving in different driving modes is different, the infusion device can offer different drug infusion rates.

(59) For example, in the beginning of drug infusion, the patient can choose to drive the wheel teeth **1410** using only one driving portion—either the driving portion **1510***a* or **1510***b*—to set a higher infusion rate and save infusion time. When the infusion is nearly complete, the patient can choose to use both driving portions **1510***a* and **1510***b* to alternately push the wheel teeth **1410**, which would halve the infusion rate. This infusion method can make the terminal infusion rate more stable and reduce the fluctuation of the patient's body fluid levels. Obviously, patients can also switch between high-rate and low-rate infusion during one infusion process.

(60) In another embodiment of the present invention, t.sub.1=3 T/2, which can also satisfy the infusion conditions described above. In other embodiments of the present invention, it is not

limited to t=T/n, as long as the vertical projections of the front ends of any two adjacent driving portions do not coincide, the purpose of improving the infusion accuracy can be achieved. And at the same time, the infusion device can offer multiple infusion rates.

(61) In the embodiment of the present invention, blocking walls **1710** and **1720** that can stop the driving unit **1500** from rotating are also provided. And an electrical signal may be triggered when the driving unit **1500** contacts the blocking wall **1710** or **1720**, allowing the program unit to control the power output of the power unit **1800**. In another embodiment of the present invention, only the blocking wall **1710** or only the blocking wall **1720** may be provided, so that the driving unit **1500** can stop rotating in either direction. Blocking wall(s) in combination with a time controller allow the program unit to control the power output of the power unit **1800**. In another embodiment of the present invention, no blocking wall is provided, and the rotation of the driving unit **1500** is completely controlled by a time controller in the program unit.

(62) It should be noted that, the position of the blocking wall **1710** or **1720** is not specifically limited in the embodiment of the present invention, as long as the condition that the driving unit **1500** stops rotating can be satisfied.

(63) FIG. **6***a*-FIG. **6***b* are schematic structural diagrams of a clutch structure **1310** according to an embodiment of the present invention. FIG. **6***b* is a schematic cross-sectional view of the clutch structure **1310** taken along the line A-A′ in FIG. **6***a*.

(64) The embodiment of the present invention further includes a clutch structure **1310**. The clutch structure **1310** is disposed at the central position of the driving wheel **1400**, and the rigid screw **1300** passes through the clutch structure **1310**. The clutch structure **1310** is provided with an internal thread matching the external thread of the rigid screw **1300**, as shown in FIG. **6***b*. During drug infusion, the driving wheel **1400** drives the clutch structure to rotate synchronously, and the clutch structure advances the rigid screw **1300** forward through the internal thread. Obviously, in the embodiment of the present invention, the rigid screw **1300** only advances in its own axial direction without rotating. In another embodiment of the present invention, the driving wheel **1400** has an internal thread, which can directly cooperate with the external thread of the rigid screw **1300**.

(65) FIG. **7** is a schematic structural diagram of a metal piece **1100** and a position detector **1900** according to an embodiment of the present invention.

(66) The intelligently controlled miniature fully closed-loop artificial pancreas according to the embodiment of the present invention further includes one or more position detectors **1900**. The position detector **1900** interacts with the metal piece **1100** to detect the position of the metal piece **1100**, and thereby determine the position of the piston **1200** to calculate the remaining amount of drug in the drug storage unit **1000**. Specifically, in the embodiment of the present invention, the metal piece **1100** is a magnetic metal piece, and the position detector **1900** is magnetic position detector. When the metal piece **1100** is located at a certain position, the location of every position detector **1900** has a certain magnetic field size and direction, allowing the position of the piston **1200** to be accurately detected. When the piston **1200** is moving, the magnitude and direction of the magnetic field at the location of every position detector **1900** changes accordingly, in which way the position of the piston **1200** is detected in real time. The position detector **1900** sends magnetic signal(s) or magnetic signal change to the program unit. After processed, the signal is converted into position information of the piston **1200**, which is then used to calculate the remaining drug amount.

(67) According to the specifications of the drug storage unit **1000**, the number of the position detectors **1900** can be one, two or more. Specifically, in the embodiment of the present invention, the number of the position detectors **1900** is seven. In another embodiment of the present invention, the number of the position detectors **1900** is two. In still another embodiment of the present invention, only one position detector **1900** is provided.

(68) It should be noted that when there are more than two position detectors **1900**, preferably, the

position detectors **1900** are linearly and equally spaced. The position detector **1900** can be disposed in the infusion unit, or at a position, corresponding to the changing position of the piston **1200**, in the program unit, or embedded in the side wall of the drug storage unit **1000**, or located on the inner surface of the drug storage unit **1000**. The position detectors **1900** may also be arranged in other ways, which are not specifically limited herein, as long as the conditions for detecting the position of the piston **1200** can be satisfied.

(69) As previously mentioned, the rigid screw **1300** only moves along its own axial direction without rotating. Therefore, the metal piece **1100**, embedded in the piston **1200** and fixedly connected to the rigid screw **1300**, can also be advanced non-rotating only along the axial direction of the rigid screw **1300**. Compared with detecting position with a rotating screw, the embodiment of the present invention only detects magnetic field signal(s) in one-dimensional axial direction or two-dimensional plane (determined by the moving direction of the screw and a detector). The detecting principle, the operation and structural design are much simpler, and the position information is more accurate, reducing the cost of design and production.

(70) FIG. **8** is a schematic structural diagram of the driving portions **2510***a* and **2510***b* pushing the wheel teeth **2410** according to another embodiment of the present invention. The difference between this embodiment and the foresaid embodiment is that the two driving portions **2510***a* and **2510***b* of the driving unit **2500** are staggered. In the vertical direction, the driving portion **2510***b* is not completely covered by the driving portion **2510***a* (compared to the foresaid embodiment). The driving wheel **2500** is appropriately widened to ensure that both driving portions **2510***a* and **2510***b* can complete the pushing. In the embodiment of the present invention, t.sub.2=T/2. The other structural relationships and driving principles are consistent with the foresaid embodiment, and are not repeated herein.

(71) FIG. **9** is a schematic structural diagram of metal piece **2100** and position detector **2900** according to an embodiment of the present invention.

(72) In the embodiment of the present invention, the rigid screw **2300** is made of metallic material. The metal piece **2100** is fixedly and electrically connected to the rigid screw **2300**. At a certain position, the metal piece **2100** and a corresponding position detector **2900** will form a capacitor to generate electrical signal(s). When the piston **2200** moves, the capacitance changes with the area of the electrode plate, and the corresponding position detector **2900** generates a changed electrical signal to accurately detect the position of the piston **2200**. The corresponding position detector **2900** transmits the electrical signal to the program unit to be converted to the position information of the piston **2200**. And then the program unit outputs the remaining drug amount. Specifically, in the embodiment of the present invention, for accurate position detection, a plurality of position detectors **2900** are provided, and the setting manner thereof is as described above.

(73) FIG. **10***a* to FIG. **10***b* are schematic structural diagrams of the driving portions **3510***a* and **3510***b* pushing the wheel teeth **3410** according to another one embodiment of the present invention. FIG. **10***b* is a left side view of the two driving wheels **3400***a* and **3400***b* in FIG. **10***a*. The embodiment of the present invention is different from the foresaid embodiments in that the two driving portions **3510***a* and **3510***b* on one driving unit **3500** are respectively matched with different driving wheels **3400***a* and **3400***b*. And the driving wheels **3400***a* and **3400***b* are fixedly connected and can move synchronously.

(74) As shown in FIG. **10***a*, in the embodiment of the present invention, two driving wheels **3400***a* and **3400***b* are provided. And the driving wheel **3400***a* and the driving wheel **3400***b* are both located on the same side of the rotating shaft **3600**. The projections of the front ends of the two driving portions **3510***a* and **3510***b* in the vertical direction do not coincide. Similarly, when the driving unit **3500** rotates in the driving direction, the driving portion **3510***a* pushes the wheel teeth **3410***a* or the driving portion **3510***b* pushes the wheel teeth **3410***b*, so that the two driving wheels are synchronously rotated, and the rigid screw **3300** is advanced forward.

(75) In the embodiment of the present invention, in order to enable the two driving portions to push

alternately, the wheel teeth **3410***a* and **3410***b* of the two driving wheels **3400***a* and **3400***b* are staggered, and the distance between two staggered wheel teeth is h. The distance h can be set according to the rotation amplitude of the driving unit **3500** and the width or pitch of the driving wheels **3400***a* and **3400***b*, which is not specifically limited herein. Preferably, h=T/2.

(76) Similarly, as described above, in the embodiment of the present invention, the driving portions **3510***a* and **3510***b* are used to alternately push the wheel teeth, after the driving unit **3500** completes one rotation in the driving direction, driving portions slide on the teeth surface by a distance smaller than one wheel tooth pitch in the returning direction before they can reach the next drive position and start the next push. Compared with only one driving portion, the intelligently controlled miniature fully closed-loop artificial pancreas of the embodiment of the present invention improves the infusion accuracy. The program unit or patients may select only the driving portion **3510***a* to drive, or only the driving portion **3510***b* to drive, or use both the driving portions **3510***a* and **3510***b* to alternately push the wheel teeth, so that the infusion device has different infusion rates.

(77) It should be noted that, in other embodiments of the present invention, three or more driving portions may be provided to cooperate with corresponding driving wheels, respectively, and the working principle is similar to that described above. In addition, the front ends of the two driving portions may coincide or not according to the rotation amplitude of the driving unit **3500**, the width or pitch of the driving wheels **3400***a* and **3400***b*, and the distance h, which is not specifically limited herein.

(78) FIG. **11** is a schematic structural diagram of a driving unit **4500** according to still another embodiment of the present invention. The difference from the foregoing embodiments is that the driving unit **4500** is provided with three driving portions **4510***a*, **4510***b*, and **4510***c*. The three driving portions cooperate with the same driving wheel. The positional relationship of the three driving portions is similar to that described above.

(79) In the embodiment of the present invention, if the wheel tooth pitch is T, then t.sub.3=t.sub.4=T/3. Compared with only one driving portion, when the three driving portions are used to push the wheel teeth in turn, the unit amount of drug infused per single driving is reduced by ⅔, that is, the infusion accuracy is tripled, which makes the drug infusion volume more accurate. The driving principle and other structural relationships are as described above, and are not repeated here.

(80) Similarly, the program unit can intelligently select only one driving portion to push the wheel teeth, or select any two driving portions to alternately push the wheel teeth, or the three driving portions to push the wheel teeth in a sequential manner, and the infusion device will have more different infusion rates. For example, in the beginning of drug infusion, the patient or the program unit selects only one driving portion, e.g. the driving portion **4510***a*, to push the wheel teeth, resulting in the highest infusion rate and shorter infusion time. After the infusion has been performed for a period of time, the driving portion **4510***b* and the driving portion **4510***c* are selected to drive the wheel teeth in an alternating mode to perform a medium-rate infusion. Near the end of infusion, the three driving portions **4510***a*, **4510***b*, and **4510***c* are all used to sequentially push the wheel teeth in order to set the lowest infusion rate to achieve smoother drug infusion. Similarly, according to actual needs, patients or the program unit can switch freely among the above-mentioned different rates.

(81) The driving unit according to other embodiments of the present invention may further include more than two driving portions. Or the infusion device includes more driving units. Different driving units are coaxially designed, or are arranged on both sides of one driving wheel to alternately drive the driving wheel to rotate, which is not specifically limited herein. Therefore, the infusion accuracy of the infusion device is further improved, and the patient's choice of the infusion rate is more flexible.

(82) FIG. **12***a*-FIG. **12***b* are partial longitudinal cross-sectional views of the infusion cannula **130**.

(83) In an embodiment of the invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** includes a plurality of electrodes that detect analyte data. When the electrodes are conductive areas of the infusion cannula, the electrodes act as conductive-area electrodes. Or when the electrodes are disposed on the wall of the infusion cannula **130**, the electrodes are cannula-wall electrodes.
(84) In one embodiment of the invention, the cannula-wall electrode **172** is plated on the outer surface of the cannula wall of the infusion cannula **130**. The cannula wall **132** of the infusion cannula **130** itself serves as a conductive-area electrode **171** also used for infusion of the drug. Generally, an insulating layer (not shown) is disposed between the conductive-area electrode **171** and the cannula-wall electrode **172** to isolate them. It will be apparent that in the embodiment of the invention, the infusion cannula **130** itself acts as both an electrode and an infusion conduit. This design reduces the number of skin punctures required to use the intelligently controlled miniature fully closed-loop artificial pancreas. With only one puncture at one place, analyte detection and drug infusion can both be completed, which reduces the risk of infection. At the same time, the method of integrally plating the electrode layer on the cannula wall **132** of the infusion cannula **130** can simplify the preparation process of the infusion cannula **130** and facilitate the process implementation.
(85) In order to facilitate electrical connection of the electrodes and electrically connective regions **121***a* and **121***b*, the electrical contact region **140** (the position of the dotted line in FIG. **12***a*) needs to expose the stainless steel cannula wall **132**, while the other locations of the infusion cannula **130** are plated with electrode layers. As shown in FIG. **12***b*, when the infusion cannula **130** is mounted to the working position, the conductive-area electrode **171** and the cannula-wall electrode **172** are directly electrically connected to the electrically connective regions **121***a* and **121***b* of the input end, respectively, which allows electrical signals of the body fluid analyte data to be transmitted to program unit **120**.
(86) It should be noted that, in the embodiment of the present invention, when the infusion cannula **130** is mounted to the working position, a part of the cannula-wall electrode **172** is located in the subcutaneous tissue fluid, while another part is located above the skin, so that electrical signals can be transmitted on the cannula-wall electrode **172**. The corresponding electrode arrangements in the other embodiments below have the same function and will not be described in detail later.
(87) In the embodiment of the present invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** has only two electrodes, the conductive-area electrode **171** is a working electrode, and the cannula-wall electrode **172** is an auxiliary electrode. In another embodiment of the invention, the conductive-area electrode **171** is an auxiliary electrode while the cannula-wall electrode **172** is a working electrode. The auxiliary electrode is a counter electrode.
(88) FIG. **13***a*-FIG. **13***b* are partial longitudinal cross-sectional views of an infusion cannula **130** in accordance with another embodiment of the present invention. For ease of marking and narration, the electrode lead and the infusion cannula are shown separately in FIG. **13***a*, and the related structural illustrations below are the same as those herein, which will not be described again.
(89) In this embodiment, the cannula wall **132** itself is a conductive-area electrode **271**, the cannula-wall electrode **272** is disposed on a portion of the surface of the cannula wall **132**, and the surface of the cannula wall **132** is further provided with an electrode lead **2720** electrically connected to the cannula-wall electrode **272**. A layer of insulating material (not shown) is formed between the electrode lead **2720** and the cannula wall **132**. When the infusion cannula **130** is mounted to the working position, the electrically connective regions **121***a*, **121***b* at the input end are electrically connected to the conductive-area electrode **271** and the electrode lead **2720**, respectively. At this time, the cannula-wall electrode **272** is indirectly electrically connected to the input end, and the body fluid data signal can be transmitted to the program unit.
(90) The cannula-wall electrode **272** in FIG. **13***b* is arranged in a ring shape, and the annular cannula-wall electrode **272** surrounds a part of the outer surface of the cannula wall **132**. The

cannula-wall electrode **272** may have other shapes, and is not specifically limited herein.
(91) FIG. **14** is a partial longitudinal cross-sectional view of an infusion cannula **130** in accordance with yet another embodiment of the present invention.
(92) In the embodiment of the present invention, three electrodes are disposed on the infusion cannula **130**: a conductive-area electrode **371**, a cannula-wall electrode **372**, and another cannula-wall electrode **373**. The cannula wall **132** of the infusion cannula **130** itself serves as a conductive-area electrode **371**, and the cannula-wall electrode **372** and **373** are respectively disposed on a portion of the outer surface of the cannula wall **132**. At the same time, the surface of the cannula wall **132** is further provided with electrode leads **3720** and **3730** which are electrically connected to the cannula-wall electrodes **372** and **373**, respectively. When the infusion cannula **130** is mounted to the working position, the conductive-area electrode **371**, the electrode lead **3720**, and the electrode lead **3730** are electrically connected to the input end's electrically connective regions **121***a*, **121***b*, and **121***c*, respectively, thereby realizing electrical connection between the input end and each electrode. The shape of the cannula-wall electrode **372** and **373** may be various, and is not specifically limited herein.
(93) In the embodiment of the present invention, in order to simplify the design of the electrically connective region, the elastic member at the input end is an oriented conductive silica gel or a conductive ring. By doping different elements in the silica gel, it is possible to achieve directional conduction, such as horizontal conduction or vertical conductivity. Thus, even if **121***a* and **121***c* are adjacent to each other, the two can still be electrically insulated from each other. The electrically connective region **121***b* may be a conductive rubber strip or a conductive ball or the like, and is not specifically limited herein.
(94) In the embodiment of the present invention, the conductive-area electrode **371** is a working electrode, and the cannula-wall electrode **372** and the wall electrode **373** are both auxiliary electrodes. At this time, the conductive-area electrode **371** and the cannula-wall electrode **372** or the cannula-wall electrode **373** may constitute a different electrode combination, that is, the two electrode combinations share the conductive-area electrode **371**. Program unit **120** can select different electrode combinations to detect body fluid analyte data. After the electrode combination is formed, on the one hand, when a working electrode combination fails to detect, the program unit **120** can select other electrode combinations for detection according to the situation to ensure that the detection process of the body fluid signal is uninterrupted. On the other hand, the program unit **120** can select a plurality of electrode combinations to work simultaneously, perform statistical analysis on multiple sets of data of the same parameter at the same time, improve the accuracy of the analyte data, and thereby output a more accurate drug infusion signal.
(95) Similarly, the conductive-area electrode **371** and the cannula-wall electrode **372** and **373** form one working electrode and two auxiliary electrodes, and can be arbitrarily selected according to actual needs. In another embodiment of the present invention, the conductive-area electrode **371** and the cannula-wall electrode **372** and **373** form an auxiliary electrode and two working electrodes, which can also be arbitrarily selected according to actual needs, and is not specifically limited herein.
(96) As an embodiment of the present invention, the conductive-area electrode **371** is a working electrode, the cannula-wall electrodes **372** and **373** are auxiliary electrodes, and the cannula-wall electrodes **372** and **373** are used as a counter electrode and a reference electrode, respectively, thereby forming a three-electrode system. Similarly, the three electrodes can be arbitrarily selected according to actual needs, and are not specifically limited herein.
(97) Also, in other embodiments of the invention, more electrodes may be provided. The system includes a plurality of working electrodes and a plurality of auxiliary electrodes, but it should be ensured that the conductive area of the infusion cannula **130** serves as at least one electrode. At this time, each electrode combination includes at least a working electrode and an auxiliary electrode, and thus a plurality of electrodes may constitute a plurality of electrode combinations. Program unit

120 may select one or more electrode combinations to detect body fluid analyte data, as desired.
(98) FIG. **15** is a partial longitudinal cross-sectional view of an infusion cannula **130** in accordance with yet another embodiment of the present invention. For ease of marking and description, the wall of the hose **180** of FIG. **15** is shown separated from the outer wall of the infusion steel needle **170**.
(99) In an embodiment of the invention, the infusion cannula **130** includes an infusion steel needle **170** and a hose **180** that is placed on the outer wall of the infusion steel needle **170**. Setting electrodes on the surface of the hose **180** simplifies the electrode manufacture and improves the preparation efficiency. In addition, the wall material of the hose **180** can be selected according to requirements, such as the wall of the hose **180** can only allow specific analytes to pass through, weakening the interference of other substances, and improving the detection accuracy of the analyte.
(100) The needle cavity **131** of the infusion steel needle serves as a drug infusion channel, and the wall of the infusion cannula **130** includes a steel needle wall and a hose wall. The infusion steel needle **170** itself serves as a conductive-area electrode **471**, the cannula-wall electrode **472** is disposed on the outer surface of the infusion steel needle **170**, and the cannula-wall electrode **473** is disposed on the outer surface of the hose **180**. At this time, the cannula-wall electrode **472** is disposed in the wall of the infusion cannula **130**.
(101) In the above embodiment, the cannula-wall electrode **472** may be partially covered by the hose **180**, or completely covered or the cannula-wall electrode **472** may be exposed in the tissue fluid. The cannula-wall electrode **473** may also be disposed on the inner surface of the hose **180**, that is, between the steel needle wall and the hose wall, and the cannula-wall electrode **473** is electrically connected to the electrically connective region **121***c* through the electrode lead **4730**. When the cannula-wall electrode **472** (the electrode lead of the cannula-wall electrode **472** is not shown) is partially covered or completely covered by the hose **180**, or the cannula-wall electrode **473** is disposed on the inner surface of the hose **180**, the wall material of the hose **180** is permeable membrane or semi-permeable membrane. Such a selection can facilitate the passage of the body fluid analyte through the wall of the hose **180**, allowing the analyte to be detected by the electrode, thereby improving the flexibility of the electrode position design without affecting the detection.
(102) In an embodiment of the invention, when the infusion cannula **130** is installed to the working position, the hose **180** and the infusion steel needle **170** have a certain relationship to the depth of penetration into the skin. Here, the depth refers to the distance from the distal end of the hose **180** or the infusion steel needle **170** which is inserted into the skin, respectively, to the surface of the skin, as shown in FIG. **15**. Generally, the infusion steel needle **170** has a greater hardness than the hose **180**. As shown in FIG. **15**, in the range of the subcutaneous portion **13**, the depth of the hose **180** into the skin is d.sub.1, and the depth of the infusion steel needle **170** into the skin is d.sub.2, d.sub.1≤d.sub.2. This design enables the infusion cannula **130** to penetrate the skin smoothly.
(103) FIG. **16***a*-**8***c* are partial longitudinal cross-sectional views of an infusion cannula **130** in accordance with yet another embodiment of the present invention. FIG. **16***a* is a longitudinal cross-sectional view of the infusion cannula **130**, and FIGS. **16***b* and **8***c* are transverse cross-sectional views of the infusion cannula **130**.
(104) Please refer to FIG. **16***a* and FIG. **16***b*. FIG. **16***b* is a schematic cross-sectional view of the infusion cannula **130** of FIG. **16***a*.
(105) In an embodiment of the invention, the cannula wall **132** of the infusion cannula **130** includes a plurality of electrically conductive areas, one or more of which are used as electrodes. For example, when the cannula wall **132** includes two conductive areas, they function as the conductive-area electrode **571** and the conductive-area electrode **572**, respectively. The conductive-area electrode **571** and **572** may be a working electrode and an auxiliary electrode, respectively, and are electrically connected to the electrically connective regions **121***a* and **121***b*, respectively, for electrical signal transmission. The different conductive areas of the infusion cannula itself serve

as electrodes, which can further simplify the electrode design on the surface of the cannula wall and reduce the production process of the infusion cannula. The insulating portion **190** achieves electrical insulation between the two conductive areas of the infusion cannula **130**.
(106) Referring to FIG. **16***c*, the infusion cannula **130** is integrally formed of three conductive areas, and the adjacent conductive areas are separated by the insulating portion **190**. The infusion cannula **130** itself serves as three electrodes: conductive-area electrodes **671**, **672** and **673**, respectively. The conductive-area electrode **671** is a working electrode, and the conductive-area electrodes **672** and **673** are auxiliary electrodes, or are selected according to actual needs as described above.
(107) Referring to FIG. **17**, signals are transmitted between the remote device **200** and the intelligently controlled miniature fully closed-loop artificial pancreas **100**.
(108) The embodiment of the invention also includes a remote device **200**. The remote device **200** includes but is not limited to a handset, a mobile terminal, or the like. The remote device **200** and the program unit **120** transmit wireless signals to each other. Program unit **120** may send body fluid analyte data or drug infusion information (including infusion or no infusion) to remote device **200**. The remote device **200** can receive, record, store, display body fluid information or infusion information, as well as other functional options. The user can view historical or real-time information at any time from the remote device **200**. Through the remote device **200**, the user can also manually set the infusion instructions and transmit the information wirelessly to the program unit **120**. Under the premise that the program unit **120** guarantees the communication security and infusion security, the infusion unit is controlled to perform the drug infusion, thereby realizing remote manual control.
(109) In some embodiments of the invention, the intelligently controlled miniature fully closed-loop artificial pancreas **100** further includes a plurality of electrodes to form a plurality of electrode combinations as previously described. The user can manually select different electrode combinations to detect body fluid data according to the situation.
(110) In summary, the present invention discloses an intelligently controlled miniature fully closed-loop artificial pancreas that has both infusion and detection functions to reduce the number of punctures on the skin. With only one puncture at one position, analyte detection and drug infusion can be completed, reducing the risk of infection.
(111) 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. An intelligently controlled miniature fully closed-loop artificial pancreas, comprising: an infusion unit, the infusion unit includes: a drug storage unit, a metal piece, a piston and a rigid screw, the piston is arranged in the drug storage unit, the metal piece, fixedly connected to the rigid screw, is arranged on the piston; a rotating shaft, a driving unit and a driving wheel provided with a wheel teeth, the driving unit includes at least two driving portions, the driving unit is capable of rotating around the rotating shaft in a driving direction and a returning direction, when rotating in the driving direction, one driving portion of the driving unit pushes the wheel teeth to rotate the driving wheel which engages the rigid screw to move forward in a non-rotating way, wherein a moving direction of the rigid screw is parallel to a rotation axis of a rotation of the driving wheel, when rotating in the returning direction, all driving portions of the driving unit slide synchronously on a surface of the wheel teeth; and a power unit and a rebound unit, the power unit and the rebound unit cooperate with each other to apply force to the driving unit to rotate the driving unit; a position detector, the metal piece and the position detector interact to generate a signal; a program

unit, the program unit comprises an input end and an output end, and the input end comprising a plurality of electrically connective regions for receiving signal of an analyte data in a body fluid, after the output end is electrically connected to the infusion unit, according to a received signal of the analyte data in the body fluid, the program unit controls whether the infusion unit delivers drugs, and the program unit is capable of converting the received signal into the a piston position information and is capable of selecting a specific driving portion to push the driving wheel according to requirements to adjust an infusion rate; an infusion cannula with a conductive area, the infusion cannula is a drug infusion channel; and a plurality of electrodes for detecting the analyte data in the body fluid, each of the electrodes comprising a conductive-area electrode and a cannula-wall electrode, the conductive area of the infusion cannula being at least as one conductive-area electrode, and one or more cannula-wall electrodes being located on/in a wall of the infusion cannula, when the infusion cannula is installed to a working position, the infusion cannula is connected with the infusion unit, the drugs are capable of being injected into a body through the infusion cannula, and the different electrodes are electrically connected to the different electrically connective regions respectively, inputting signal of the analyte data in the body fluid to the program unit.

2. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the cannula-wall electrode is located on an outer surface of the infusion cannula wall or in the wall of the infusion cannula.

3. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 2, wherein: the cannula-wall electrode is located on the outer surface of the infusion cannula wall, and when the infusion cannula is installed to the working position, the conductive-area electrode and the cannula-wall electrode are directly electrically connected to the different electrically connective regions, respectively.

4. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 3, wherein: the cannula-wall electrode is located on a subcutaneous part of the outer surface of the infusion cannula wall, and the outer surface of the infusion cannula wall is further provided with an electrode lead electrically connected to the cannula-wall electrode, and when the infusion cannula is installed to the working position, the electrode lead and the conductive-area electrode are electrically connected to the different electrically connective regions, respectively.

5. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 2, wherein: the infusion cannula includes an infusion steel needle and a hose which is placed on an outer wall surface of the infusion steel needle, and a needle cavity of the infusion steel needle is used for infusion of the drugs.

6. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 5, wherein: when the infusion cannula is installed to the working position, a depth of the hose into a skin is d.sub.1, while a depth of the infusion steel needle into the skin is d.sub.2, d.sub.1≤d.sub.2.

7. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 6, wherein: the infusion steel needle is the conductive-area electrode, and the cannula-wall electrode is located on an outer/inner surface of the hose wall, or is located on the outer wall surface of the infusion steel needle.

8. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 7, wherein: when the infusion cannula is installed to the working position, the cannula-wall electrode located on the outer wall surface of the infusion steel needle is exposed in a subcutaneous tissue fluid or covered in whole or in part by the hose.

9. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 8, wherein: when the cannula-wall electrode located on the outer wall surface of the infusion steel needle is covered in whole or in part by the hose, or when the cannula-wall electrode is located on the inner surface of the hose wall, the hose wall is a permeable membrane or a semi-permeable membrane.

10. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 2, wherein:

the infusion cannula comprises a plurality of electrically conductive areas isolated from each other, the infusion cannula comprising a plurality of electrically conductive-area electrodes, the different electrically conductive-area electrodes being the different electrically conductive areas of the infusion cannula.

11. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 7, wherein: the electrodes include a working electrode and an auxiliary electrode, and the number of the working electrode and the auxiliary electrode is one or more, respectively.

12. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 11, wherein: the conductive-area electrode is the working electrode or the auxiliary electrode.

13. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 11, wherein: the auxiliary electrode is a counter electrode, or the auxiliary electrode includes the counter electrode and a reference electrode.

14. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 12, wherein: the plurality of electrodes form one or more electrode combinations, each electrode combination comprising the working electrode and the auxiliary electrode, the program unit choosing the one or more electrode combinations to detect the analyte data in the body fluid.

15. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 14, wherein: also comprises a remote device, the remote device and the program unit transmitting wireless signals to each other, the program unit transmitting the analyte data in the body fluid or a drug infusion information to the remote device, and the remote device sending a manually selected electrode combination for detection or the drug infusion information to the program unit.

16. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the input end is an elastic member, and the elastic member comprises one of or a combination of a conductive strip, an oriented conductive silica gel, a conductive ring and a conductive ball.

17. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the infusion unit includes a plurality of infusion subunits, the plurality of infusion subunits being electrically connected to the output ends, respectively, and the program unit controlling whether each infusion subunit delivers the drugs.

18. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the intelligently controlled miniature fully closed-loop artificial pancreas is composed of a plurality of parts, the infusion unit and the program unit are arranged in different parts, and the different parts are connected by a waterproof plug.

19. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the rigid screw is a metal screw, and the metal piece is electrically connected with the metal screw, so that the metal piece and the corresponding position detector constitute a capacitor, and a linear movement of the metal piece causes a change in capacitance making the corresponding position detector generate an electrical signal.

20. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the metal piece is a magnetic metal piece, and the position detector is magnetic induction detector, a linear movement of the magnetic metal piece causes a change in a magnetic field around each position detector making each position detector generate a magnetic signal.

21. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the infusion unit further includes a clutch structure movably disposed on the driving wheel, the rigid screw passes through the clutch structure, and the clutch structure is provided with an internal thread that cooperates with the rigid screw, the driving wheel drives the clutch structure to rotate which, with the internal thread, pushes the rigid screw to move forward in a non-rotating way.

22. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein: the infusion unit further includes a blocking wall, and the driving unit stops rotating upon contacting the blocking wall.

23. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 1, wherein:

vertical projections of front ends of any two driving portions on the driving unit do not coincide.

24. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 23, wherein: the number of driving portions provided on one driving unit is n (n≥2), if a distance, in a pushing direction, between the vertical projections of the front ends of any two adjacent driving portions which cooperate with the same driving wheel is t, and a wheel tooth pitch is T, then t=T/n.

25. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 23, wherein: one driving unit provided with two driving portions and two driving wheels are provided in the infusion unit, the two driving wheels are fixedly connected to realize a synchronous rotation, the two driving portions are respectively matched with the two driving wheels, the two driving wheels are arranged on a same side of the rotating shaft, and the wheel teeth of the two driving wheels are staggered.

26. The intelligently controlled miniature fully closed-loop artificial pancreas of claim 23, wherein: one driving unit is provided with two driving portions, and the two driving portions are matched with the same driving wheel, if a distance, in a pushing direction, between the vertical projections of the front ends of the two adjacent driving portions is t.sub.1, and a tooth pitch is T, then t.sub.1=3 T/2.