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(54) SINGLE NEEDLE INTEGRATED ARTIFICIAL PANCREAS

(57) Disclosed is a single needle integrated artificial pancreas, wherein the single needle integrated artificial pancreas comprises a drug reservoir unit (1); a dosing drive unit (2) connected to the drug reservoir unit (1); an indwelling unit (3) connected to the drug reservoir unit (1) and comprising a glucose sensor (31), an insulin-indwelling hose (32), a puncture needle (33) and an mounting means (34); wherein the glucose sensor (31) and the insulin-indwelling hose (32) are simultaneously implanted in the same subcutaneous tissue in a patient via the mounting means (34) under the aid of the puncture needle (33); and the puncture needle (33) is a steel puncture needle or groove puncture needle; and a blood glucose monitoring and insulin administration controlling unit (4) is respectively connected to the drug reservoir unit (1), the dosing drive unit (2) and the indwelling unit (3). The single needle integrated artificial pancreas is able to simultaneously implant the insulin-indwelling hose (32) and the glucose sensor (31) of the artificial pancreas into the same site of a subcutaneous tissues in a patient, thus reducing the chance of a diabetic patient being infected; and is simple in installation and convenient to use.

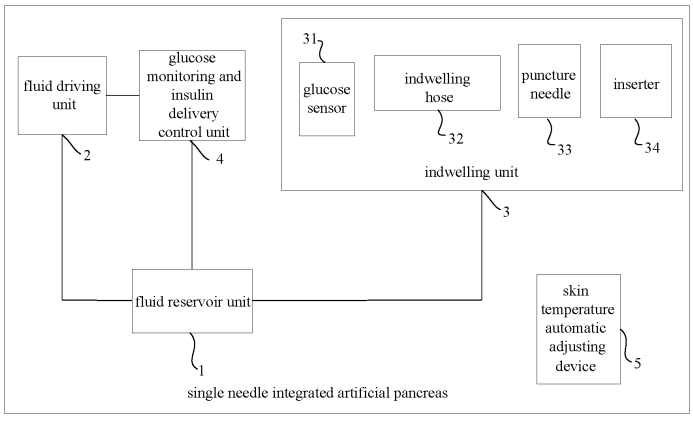

Figure 1

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Description

TECHNICAL FIELD

[0001] The present disclosure generally relates to the field of medical appliance, specifically to an artificial pancreas, and more particularly, to a single needle integrated artificial pancreas.

BACKGROUND

[0002] As is known to all, diabetes is a metabolic disease caused by pancreatic dysfunction. Diabetes is a lifelong disease which can't be cured by current medical technology. The only way to control the initiation and development of diabetes and its complications is stabilizing glucose. A normal pancreas may automatically monitor the changes of glucose, and may automatically secrete insulin required. "Real time dynamic glucose monitoring system" indicates a device that can real-timely and dynamically monitor the changes of glucose by using a glucose sensor implanted in the subcutaneous tissue of a patient. "Insulin pump" indicates a device that can continuously and accurately deliver insulin to the subcutaneous tissue of the patient for 24 hours by using an indwelling cannula implanted in the subcutaneous tissue of the patient. "Artificial pancreas" indicates a device that can real-timely and dynamically monitor the change of glucose, and can continuously and accurately deliver insulin to the subcutaneous tissue of the patient for 24 hours. A conventional artificial pancreas usually consists of two sets of devices, a real time dynamic glucose monitoring system and an insulin pump system. Therefore, the patient is required to wear at least two sets of discrete components, a glucose sensor and an indwelling cannula, at the same time, when the diabetes is being treated by the conventional artificial pancreas. Considering the comfort level of patients when they are wearing these components, the two discrete components are both made of slender and soft medical polymer material. Because of the special nature of the material and the shape of the two discrete components, they both need to be put into the subcutaneous tissue of a patient with a help of a puncture needle with a certain rigidity to puncture the skin of patients. Thereafter, the needle is pulled out, leaving the two components in the subcutaneous tissue. For using the above two components, the patient must have subcutaneous tissue punctures in two positions of his/her body. Obviously, the more the places to be punctured are required, the more complex the installation is, and the greater the chance of infection may be. The patient must also use large volume auxiliary installation device such as install catapults of glucose sensor and indwelling cannula, etc. The glucose sensor and the indwelling cannula have similar processes of puncture and indwelling, and similar mechanical structures for realizing these processes. Moreover, the glucose sensor and the indwelling cannula are also the same in the aspects such as area of action on body, disposable using, aseptic production, etc.

[0003] Moreover, the temperature of human skin surface can greatly affect the insulin peak action time. The longer the insulin peak action time is, the worse the function of insulin in real-time glucose regulation is. The temperature of human skin surface usually ranges from 32° to 37°. In this temperature range, the insulin peak action time is relatively long. The lower the temperature is, the longer the insulin peak action time is. Currently, conventional artificial pancreas systems cannot solve the delay between the desired glucose concentration and the insulin peak action time. Therefore, currently conventional artificial pancreas systems cannot real-timely and rapidly adjust the glucose concentration.

SUMMARY

[0004] Regarding the above-mentioned shortcomings of the prior art, an object of the present disclosure is to provide a single needle integrated artificial pancreas for solving the problems that when a patient uses the current conventional artificial pancreas, as a glucose sensor and an indwelling cannula are required to be respectively placed in the subcutaneous tissue, multiple punctures are required. As a result, the installation of the device is complex and the chance of infection is high.

[0005] In order to achieve the above-mentioned purposes and other related purposes, the present disclosure provides a single needle integrated artificial pancreas, including: a fluid reservoir unit configured to store insulin; a fluid driving unit connected to the fluid reservoir unit and configured to deliver the insulin stored in the fluid reservoir unit to the subcutaneous tissue of a patient; an indwelling unit connected to the fluid reservoir unit, including a glucose sensor, an indwelling cannula, a puncture needle and an inserter; and a glucose monitoring and insulin delivery control unit, which are connected to the fluid reservoir unit, the drug delivery system and the indwelling unit, and configured to process effective glucose signals output by the glucose sensor, and to control the fluid reservoir unit, the fluid driving unit and the indwelling unit; wherein the glucose sensor and the indwelling cannula are simultaneously implanted in the same subcutaneous tissue in the patient via the inserter with the aid of the puncture needle; wherein the puncture needle is a steel puncture needle or a groove puncture needle.

[0006] Optionally, the glucose sensor includes an electrode sensor, a fibre optic sensor, or a combination thereof

[0007] Optionally, the electrode sensor is integrated in an outer surface of the indwelling cannula, and the steel puncture needle is located inside the indwelling cannula.

[0008] Optionally, the electrode sensor is integrated in the outer surface of the indwelling cannula, and the electrode sensor together with the indwelling cannula are located in a groove of the groove puncture needle.

[0009] Optionally, the electrode of the electrode sensor is ring-shaped or fan-shaped, and an electrode contact point of the electrode sensor is ring-shaped or fan-shaped.

[0010] Optionally, the electrode sensor has an electrode coating structure including an anti-interference layer, an enzyme layer, a regulation layer and a protective layer.

[0011] Optionally, the electrode sensor has an electrode coating structure including an enzyme layer, a regulation layer and a protective layer.

[0012] Optionally, the electrode sensor has an electrode coating structure including an anti-interference layer, a bonding layer, an enzyme layer, a bonding layer, a regulation layer and a protective layer.

[0013] Optionally, the indwelling cannula and the glucose sensor are arranged in parallel and located in the groove of the groove puncture needle.

[0014] Optionally, a distance between an end of the indwelling cannula and an end of the glucose sensor ranges from 1mm to 8mm.

[0015] Optionally, the end of the indwelling cannula and the end of the glucose sensor are both tip shaped.

[0016] Optionally, the single needle integrated artificial pancreas further includes a skin temperature automatic adjusting device configured to heat the skin tissue where the glucose sensor and the indwelling cannula are implanted.

[0017] Optionally, the skin temperature automatic adjusting device includes a skin heating film, a heating module, a temperature control module, a heat preservation module and a temperature detection module.

[0018] Optionally, the inserter is an automatic ejecting inserter or a manual inserter.

[0019] Optionally, the single needle integrated artificial pancreas further includes a pump base and a controller which is connected to the pump base, wherein the pump base includes the fluid reservoir unit, the fluid driving unit and the indwelling unit, wherein the controller includes the glucose monitoring and insulin delivery control unit.

[0020] In comparison with prior art, technique solutions provided by the present disclosure have following advantages.

[0021] In the present disclosure, the indwelling cannula and the glucose sensor of the artificial pancreas are implanted in the same place of the subcutaneous tissue, so the chance of patient infection decreases.

[0022] Moreover, the single needle integrated artificial pancreas is easy to install and use.

[0023] Moreover, the single needle integrated artificial pancreas solves the delay between the desired glucose concentration and the insulin peak action time, real-timely and rapidly adjusts the glucose concentration, and reduces the effect of temperature change on glucose monitoring.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024]

Figure 1 illustrates a schematic diagram of a single needle integrated artificial pancreas in this disclosure;

Figure 2 illustrates a schematic diagram of the glucose sensor with an electrode sensor in a single needle integrated artificial pancreas in this disclosure;

Figure 3 illustrates a schematic diagram of the glucose sensor with a fiber optic sensor in a single needle integrated artificial pancreas in a single needle integrated artificial pancreas in this disclosure;

Figure 4 illustrates a schematic diagram of a puncture needle in the indwelling cannula integrated with an electrode sensor in a single needle integrated artificial pancreas in this disclosure;

Figure 5 illustrates a schematic diagram of the electrode's structure of a electrode sensor integrated in the outside surface of the indwelling cannula in a single needle integrated artificial pancreas in this disclosure;

Figure 6 illustrates a schematic diagram of the electrode's structure of a electrode sensor integrated in an outside surface of the indwelling cannula in a single needle integrated artificial pancreas in this disclosure;

Figure 7 illustrates a schematic diagram of the electrode contact point's structure of a electrode sensor integrated in an outside surface of the indwelling cannula in a single needle integrated artificial pancreas in this disclosure;

Figure 8 illustrates a schematic diagram of the electrode contact point's structure of a electrode sensor integrated in an outside surface of the indwelling cannula in a single needle integrated artificial pancreas in this disclosure;

Figure 9 illustrates another schematic diagram of an indwelling cannula and an electrode sensor integrated in an outside surface of the indwelling cannula in puncture needle of a single needle integrated artificial pancreas in this disclosure;

Figure 10 illustrates a schematic diagram of an indwelling cannula and an electrode sensor in puncture needle of a single needle integrated artificial pancreas in this disclosure;

Figure 11 illustrates a schematic diagram of a fiber

optic sensor and an indwelling cannula arranged in parallel in puncture needle of a single needle integrated artificial pancreas in this disclosure;

Figure 12 illustrates a schematic diagram of an electrode sensor and an indwelling cannula arranged in parallel in puncture needle of a single needle integrated artificial pancreas in this disclosure;

Figure 13 illustrates a schematic diagram of an electrode sensor, a fiber optic sensor and an indwelling cannula arranged in parallel in puncture needle of a single needle integrated artificial pancreas in this disclosure;

Figure 14A illustrates a schematic structure diagram of a skin temperature automatic adjusting device of a single needle integrated artificial pancreas in this disclosure; and

Figure 14B illustrates a schematic structure diagram of a skin temperature automatic adjusting device of a single needle integrated artificial pancreas in this disclosure.

Brief description of reference signs

[0025]

1 fluid reservoir unit
2 fluid driving unit
3 indwelling unit
4 glucose monitoring and insulin delivery control unit
5 skin temperature automatic adjusting device
31 glucose sensor
32 indwelling cannula
33 puncture needle
34 inserter
35 electrode sensor
36 fiber optic sensor
51 skin heating film
52 heating module
53 temperature control module
54 heat preservation module
55 temperature detection module
331 steel puncture needle
332 groove puncture needle
351 counter electrode
352 working electrode
353 reference electrode
354 electrode contact point
361 acquisition area of fiber signal
362 transmission area of fiber signal

DETAILED DESCRIPTION OF THE DISCLOSURE

[0026] The embodiments of the present disclosure are described in the following through specific examples, and those skilled in the art can easily understand other advantages and effects of the present disclosure according to the content disclosed in the specification. The present disclosure may also be implemented or applied through other different specific examples, and various modifications and variations may be made to the details in the specification on the basis of different opinions and applications without departing from the spirit of the present disclosure.

[0027] Referring to the figures, it should be noted that, the drawing provided in this embodiment exemplary shows the basic concept of the present disclosure, so that components related to the present disclosure are merely shown in the drawings and are not drawn based on the actual number, shape or size in implementation. The actual shape, number and proportion of each component in implementation may vary arbitrarily, and the layout of the components may also be more complex.

[0028] The embodiments of the present disclosure will be described in detail in conjunction with the accompanying drawings.

[0029] The present disclosure provides a single needle integrated artificial pancreas, referring to FIG. 1, a schematic diagram of a single needle integrated artificial pancreas is illustrated, the single needle integrated artificial pancreas includes: a fluid reservoir unit 1, a fluid driving unit 2, an indwelling unit 3, a glucose monitoring and insulin delivery control unit 4, and a skin temperature automatic adjusting device 5. The indwelling unit 3 includes a glucose sensor 31, an indwelling cannula 32, a puncture needle 33, and an inserter 34. The puncture needle 33 is a steel puncture needle 331 or a groove puncture needle 332. The inserter is an automatic ejecting inserter or a manual inserter. The single needle integrated artificial pancreas further includes a pump base and a controller connected to the pump base, wherein the pump base includes the fluid reservoir unit, the fluid driving unit, and the indwelling unit, the controller includes the glucose monitoring and insulin delivery control unit.

[0030] The fluid reservoir unit 1 is configured to store an insulin;

[0031] The fluid driving unit 2 is connected to the fluid reservoir unit 1 and configured to deliver the insulin stored in the fluid reservoir unit 1 to the subcutaneous tissue of a patient;

[0032] The indwelling unit 3 is connected to the fluid reservoir unit 1, and the indwelling unit 3 includes the glucose sensor 31, the indwelling cannula 32, the puncture needle 33 and the inserter 34.

[0033] The glucose sensor 31 is configured to real-timely monitor a change of the glucose, produce effective glucose signals based on the change of the glucose, and output the effective glucose signals. In some embodiments, the glucose sensor may be an electrode sensor 35, a fiber optic sensor 36, or a combination thereof. The glucose sensor is implanted in the subcutaneous tissue, when it is used to monitor the glucose.

[0034] The glucose sensor 31 may be an electrode sensor which monitors the glucose by current signal. The glucose electrode sensor mainly includes an enzyme layer, and a Clark electrode or a hydrogen peroxide electrode. The glucose may occur an oxidation reaction under the catalysis of glucose oxidase, consume oxygen, and produce glucolactone and hydrogen peroxide. The glucose oxidase is fixed on the surface of the platinum electrode by using physical adsorption method by semipermeable membrane, whose activity depends on the oxygen concentration around it. The reaction between the glucose and the glucose oxidase produces two electrons and two protons. The glucose oxidase reduced reacts with oxygen, electron and proton which are enclosing the glucose oxidase, and produces hydrogen peroxide and the glucose oxidase which may react with glucose. The higher the glucose concentration is, the more oxygen is consumed, and the more hydrogen peroxide is produced; the lower the glucose concentration is, it is opposite. Therefore, the consumption of oxygen and the production of hydrogen peroxide may both be detected by the platinum electrode, and which are used as a method to detect the glucose. The glucose sensor may be a three electrode system or a two electrode system, wherein the three electrode system includes a counter electrode, a reference electrode, and at least one working electrode. The present disclosure has two cases based on the number of the working electrode:

1) Single working electrode, there is only one working electrode;

2) Double working electrode, there is two working electrodes, one is called "working electrode", which is configured to occur electro oxidation reaction or electro reduction reaction with the materials detected, and produce electrical signal; the other is called "auxiliary electrode", which is configured to detect the response signal of the interferent and the background solution.

[0035] The reference electrode in three electrode system is configured to effectively control detection electric potential, and prevent electric potential drifting. For the two electrode system, its structure is simpler, and its production cost is lower. Referring to FIG. 2, a schematic diagram of the glucose sensor with an electrode sensor is illustrated. In some embodiments, the glucose sensor uses the electrode sensor 35, wherein the electrode sensor 35 is a three electrode system, which includes a counter electrode 351, a working electrode 352, a reference electrode 353 and an electrode contact point (PAD) 354.

[0036] An electrode coating structure of the electrode sensor in the glucose sensor includes: (1) the electrode sensor has an electrode coating structure including an anti-interference layer, an enzyme layer, a regulation layer and a protective layer; (2) the electrode sensor has an electrode coating structure including an enzyme layer, a regulation layer, and a protective layer; (3) the electrode sensor has an electrode coating structure including an anti-interference layer, a bonding layer, an enzyme layer, a bonding layer, a regulation layer, and a protective layer. Using such electrode coating structure of the electrode sensor may improve the accuracy and specificity of the glucose monitoring, and such electrode coating structure of the electrode sensor has good stability in vivo or in vitro.

[0037] The glucose sensor 31 may be a fiber optic sensor 36 which monitors the glucose by optical signal, wherein the fiber optic sensor includes the fiber optic biosensor based on fluorescence. The glucose fiber optic sensor produces fluorescence when the semiconductor quantum dots are irradiated by light of specific wavelengths transmitted by micro optical fiber. Reaction between the glucose and the glucose oxidase produces the hydrogen peroxide which may reduce the intensity of fluorescence, and even quench the fluorescence. The degree of light intensity decreasing has a certain linear relation with the glucose concentration. By the linear relation, the glucose concentration is monitored. Referring to FIG. 3, a schematic diagram of the glucose sensor with a fiber optic sensor is illustrated. In the embodiment, the glucose sensor uses the fiber optic sensor 36, wherein the fiber optic sensor 36 includes an acquisition area of fiber signal 361 and a transmission area of fiber signal 362. The indwelling cannula 32 is configured to deliver the insulin in the fluid reservoir unit 1, wherein the indwelling cannula 32 is connected to the fluid reservoir unit 1.

[0038] The puncture needle 33 is configured to puncture the skin of the patient. In some embodiments, the puncture needle 33 is the steel puncture needle 331 or the groove puncture needle 332.

[0039] The inserter 34 is configured to simultaneously implant the glucose sensor 31 and the indwelling cannula 32 in the same subcutaneous tissue in the patient with the aid of the puncture needle 33. The inserter 34 may simultaneously implant the glucose sensor 31 and the indwelling cannula 32 in the same subcutaneous tissue in the patient, so the installation is easy, and the chance of patient infection decreases. When the glucose sensor 31 and the indwelling cannula 32 are integrated, and the puncture needle 33 is the steel puncture needle 331 or the groove puncture needle 332. That is, the indwelling cannula 32 and the glucose sensor 31 which is integrated in the outer surface of the indwelling cannula 32 are implanted in the subcutaneous tissue in the patient by using the steel puncture needle 331 or the groove puncture needle 332 located inside the indwelling cannula 32. When the glucose sensor 31 and the indwelling cannula 32 are arranged in parallel, the puncture needle 33 is the groove puncture needle 332.

[0040] In some embodiments, simultaneously implanting the glucose sensor 31 and the indwelling cannula 32 in the same subcutaneous tissue in the patient may be implemented in the following embodiments:

[0041] The first embodiment, referring to FIG. 4, a

schematic diagram of a puncture needle in the indwelling cannula integrated with an electrode sensor is illustrated. In the first embodiment, the glucose sensor 31 uses the electrode sensor 35; the puncture needle 33 is the steel puncture needle 331. At the moment, the steel puncture needle 331 is located inside the indwelling cannula 32. The electrode sensor 35 is integrated in the outer surface of the indwelling cannula 32, the electrode of the electrode sensor 35 is ring-shaped or fan-shaped, and the PAD 354 of the electrode sensor 35 is ring-shaped or fan-shaped. The electrode of the electrode sensor 35 is ring-shaped or fan-shaped, referring to FIG. 5, a schematic diagram of a ring-shaped electrode's structure of a electrode sensor integrated in an outside surface of the indwelling cannula is illustrated; referring to FIG. 6, a schematic diagram of a fan-shaped electrode's structure of a electrode sensor integrated in the outer surface of the indwelling cannula, and the PAD 354 of the electrode sensor is ring-shaped or fan-shaped is illustrated; referring to FIG. 7, a schematic diagram of a fan-shaped PAD's structure of a electrode sensor integrated in the outer surface of the indwelling cannula is illustrated; referring to FIG. 8, a schematic diagram of a ring-shaped PAD's structure of a electrode sensor integrated in the outer surface of the indwelling cannula is illustrated. The glucose sensor 31 and the indwelling cannula 32 integrated are implanted in the subcutaneous tissue in the patient by the steel puncture needle 331 in the indwelling cannula. In order to reduce the puncture resistance in the process of implantation, the end of the indwelling cannula is tip shape.

[0042] The second embodiment, referring to FIG. 9, a schematic diagram of an indwelling cannula and an electrode sensor integrated in the outer surface of the indwelling cannula in puncture needle is illustrated. In the second embodiment, the glucose sensor 31 uses the electrode sensor 35; the puncture needle 33 is the groove puncture needle 332. At the moment, the glucose sensor 31 and the indwelling cannula 32 are located in the groove of the groove puncture needle 332, and they are implanted in the subcutaneous tissue in the patient by using the groove puncture needle 332. The electrode of the electrode sensor 35 is ring-shaped or fan-shaped; the PAD 354 of the electrode sensor 35 is ring-shaped or fan-shaped. In order to eliminate the effect of insulin injection on glucose monitoring, the distance between the end of the indwelling cannula 32 and the end of the glucose sensor 31 ranges from 1mm to 8mm. In first embodiment and second embodiment, the distance between the end of the indwelling cannula 32 and the end of the glucose sensor 31 ranges from 2mm to 4mm.

[0043] The third embodiment, referring to FIG. 10, a schematic diagram of an indwelling cannula and an electrode sensor arranged in parallel in puncture needle is illustrated. In the third embodiment, the glucose sensor 31 uses the electrode sensor 35, wherein the electrode sensor 35 is a three electrode system, which includes the counter electrode 351, the working electrode 352, the reference electrode 353 and the electrode contact point (PAD) 354; the puncture needle 33 is the groove puncture needle 332. At the moment, the glucose sensor 31 and the indwelling cannula 32 are arranged in parallel in the groove of the groove puncture needle 332, and they are implanted in the subcutaneous tissue in the patient by using the groove puncture needle 332. When the glucose sensor 31 and the indwelling cannula 32 are arranged in parallel, in order to reduce the puncture resistance in the process of implantation, the end of the indwelling cannula 32 and the glucose sensor 31 are both tip shape. Moreover, in order to eliminate the effect of insulin injection on glucose monitoring, the distance between the end of the indwelling cannula 32 and the end of the glucose sensor 31 ranges from 1mm to 8mm. In some embodiments, the distance between the end of the indwelling cannula 32 and the end of the electrode sensor 35 ranges from 2mm to 4mm.

[0044] The fourth embodiment, referring to FIG. 11, a schematic diagram of an indwelling cannula 32 and a fiber optic sensor 36 arranged in parallel in puncture needle 33 is illustrated. In the fourth embodiment, the glucose sensor uses the fiber optic sensor 36, wherein the fiber optic sensor 36 includes the acquisition area of fiber signal 361 and the transmission area of fiber signal 362; the puncture needle 33 is the groove puncture needle 332. At the moment, the fiber optic sensor 36 and the indwelling cannula 32 are arranged in parallel in the groove of the groove puncture needle 332. In some embodiments, the distance between the end of the indwelling cannula 32 and the end of the fiber optic sensor 36 ranges from 2mm to 4mm.

[0045] The fifth embodiment, referring to FIG. 12 and FIG. 13, a schematic diagram of an indwelling cannula 32 and a glucose sensor 31 arranged in parallel in puncture needle 33 are illustrated. In the fifth embodiment, the glucose sensor 31 uses the electrode sensor 35 and the fiber optic sensor 36; the puncture needle 33 is the groove puncture needle 332. At the moment, the electrode sensor 35, the fiber optic sensor 36 and the indwelling cannula 32 are arranged in parallel in the groove of the groove puncture needle 332. Simultaneously using the electrode sensor 35 and the fiber optic sensor 36 to monitor glucose, and using special algorithm may improve the reliability and accuracy of glucose monitoring.

[0046] In some embodiments, the inserter of the single needle integrated artificial pancreas may be an automatic ejecting inserter or a manual inserter. There are two installation method in some embodiments, one is that installing the automatic ejecting inserter in artificial pancreas, the glucose sensor 31 and the indwelling cannula 32 are simultaneously implanted in the same subcutaneous tissue in the patient via the automatic ejecting inserter under the aid of the puncture needle 33; the other is that the glucose sensor 31 and the indwelling cannula 32 are simultaneously implanted in the same subcutaneous tissue in the patient via the manual inserter under the aid of the puncture needle 33. After the inserter completes

the installing of the glucose sensor 31 and the indwelling cannula 32, the puncture needle 33 is pulled out.

[0047] The glucose monitoring and insulin delivery control unit 4 is configured to process a useful blood sugar signal output by the glucose sensor 31, and to control the fluid reservoir unit 1, the drug delivery system 2 and the indwelling unit 3, wherein the glucose monitoring and insulin delivery control unit 4 is connected to the fluid reservoir unit 1, the drug delivery system 2 and the indwelling unit 3. The glucose monitoring and insulin delivery control unit 4 may real-timely monitor and detect the glucose concentration, so the patient and the paramedic may real-timely know the change of the glucose concentration, and make a response.

[0048] The skin temperature automatic adjusting device 5 is configured to heat the skin tissue at which the glucose sensor 31 and the indwelling cannula 32 are implanted. The skin temperature automatic adjusting device 5 is stuck on surface of the skin tissue at which the glucose sensor 31 and the indwelling cannula 32 are implanted. After the skin temperature automatic adjusting device 5 is electrified, it may produce a desired temperature which may reduce the effect of temperature change on glucose monitoring, and reduce the delay of the insulin peak action time. Referring to FIG. 14a and FIG. 14b, a schematic diagram of a skin temperature automatic adjusting device 5 are illustrated. The skin temperature automatic adjusting device 5 includes a skin heating film 51, a heating module 52, a temperature control module 53, a heat preservation module 54 and a temperature detection module 55.

The skin heating film 51

[0049] The heating module 52 is configured to heat the skin tissue at which the glucose sensor 31 and the indwelling cannula 32 are implanted to 32°C~45°C, wherein the heating module 52 is located in the skin heating film 51. In some embodiments, the heating module 52 may be a fast heating integrated circuit which includes a heating element, a power, a temperature sampling element and a switching element.

[0050] The temperature control module 53 is configured to regulate heating parameter and control the temperature range, wherein the temperature control module 53 is located in the skin heating film 51 and connected to the heating module 52. In some embodiments, the temperature control module 53 may be a temperature control circuit which includes a temperature sensor, a relay and a temperature regulation circuit, and control the temperature of skin tissue at 32°C~45°C.

[0051] The heat preservation module 54 is configured to preserve the skin tissue at which the glucose sensor 31 and the indwelling cannula 32 are implanted at 32°C~45°C, wherein the heat preservation module 54 is located in the skin heating film 51 and connected to the temperature control module 53. In some embodiments, the heat preservation module 54 may be a heat preservation circuit, the temperature is set at 32°C~45°C, wherein the heat preservation circuit includes a temperature sensor, an operational amplifier, a comparator and a heating unit.

[0052] The temperature detection module 55 is configured to detect the skin tissue at which the glucose sensor 31 and the indwelling cannula 32 are implanted. In some embodiments, the temperature detection module 55 may be a temperature detection circuit which includes a temperature sensor, a singlechip and a temperature detection circuit unit.

[0053] In some embodiments, the heating module 52, the temperature control module 53, the heat preservation module 54 and the temperature detection module 55 may be located in the skin heating film 51, and constitute the skin temperature automatic adjusting device 5, wherein the temperature detection module 55 is connected to the temperature control module 53. In some embodiments, the heating module 52, the temperature control module 53 and the heat preservation module 54 may be located in the skin heating film 51, connecting the temperature detection module 55 and the skin heating film 51, which constitutes the skin temperature automatic adjusting device 5.

[0054] The skin temperature automatic adjusting device 5, the fluid reservoir unit 1, the fluid driving unit 2, the indwelling unit 3, and the glucose monitoring and insulin delivery control unit 4 complete the glucose monitoring and insulin injection together. In the process, the skin is heated by the skin temperature automatic adjusting device 5, which may solve the delay between the desired glucose concentration and the insulin peak action time, and reduce the effect of temperature change on glucose monitoring.

[0055] The single needle integrated artificial pancreas according to the present disclosure provides the inserter which is configured to simultaneously implant the glucose sensor and the indwelling cannula in the same subcutaneous tissue in the patient under the aid of the puncture needle, so the chance of patient infection decreases, and the installation of the single needle integrated artificial pancreas is easy; while the single needle integrated artificial pancreas according to the present disclosure provides the skin temperature automatic adjusting device which may heat the skin, so which may solve the delay between the desired glucose concentration and the insulin peak action time, and reduce the effect of temperature change on glucose monitoring.

[0056] In summary, the present disclosure overcomes the various shortcomings of the current technology and has high industrial utilization value.

[0057] Although the present disclosure has been disclosed as above with reference to preferred embodiments thereof but will not be limited thereto. Those skilled in the art can modify and vary the embodiments without departing from the spirit and scope of the present disclosure. Accordingly, without departing from the scope of the present invented technology scheme, whatever sim-

ple modification and equivalent variation belong to the protection range of the present invented technology scheme.

Claims

1. A single needle integrated artificial pancreas, comprising:

   a fluid reservoir unit configured to store insulin;
   a fluid driving unit connected to the fluid reservoir unit and configured to deliver the insulin stored in the fluid reservoir unit to the subcutaneous tissue of a patient;
   an indwelling unit connected to the fluid reservoir unit, comprising a glucose sensor, an indwelling cannula, a puncture needle and an inserter; and
   a glucose monitoring and insulin delivery control unit, which are connected to the fluid reservoir unit, the fluid driving unit and the indwelling unit, and configured to process effective glucose signals output by the glucose sensor, and to control the fluid reservoir unit, the fluid driving unit and the indwelling unit;
   wherein the glucose sensor and the indwelling cannula are simultaneously implanted in the same subcutaneous tissue in the patient via the inserter with the aid of the puncture needle;
   wherein the puncture needle is a steel puncture needle or a groove puncture needle.

2. The single needle integrated artificial pancreas according to claim 1, wherein the glucose sensor comprises an electrode sensor, a fibre optic sensor, or a combination thereof

3. The single needle integrated artificial pancreas according to claim 2, wherein the electrode sensor is integrated in an outer surface of the indwelling cannula, and the steel puncture needle is located inside the indwelling cannula.

4. The single needle integrated artificial pancreas according to claim 2, wherein the electrode sensor is integrated in the outer surface of the indwelling cannula, and the electrode sensor together with the indwelling cannula are located in the groove of the groove puncture needle.

5. The single needle integrated artificial pancreas according to claim 3 or 4, wherein the electrode of the electrode sensor is ring-shaped or fan-shaped, and an electrode contact point of the electrode sensor is ring-shaped or fan-shaped.

6. The single needle integrated artificial pancreas according to claim 2, wherein the electrode sensor has an electrode coating structure comprising an anti-interference layer, an enzyme layer, a regulation layer and a protective layer.

7. The single needle integrated artificial pancreas according to claim 2, wherein the electrode sensor has an electrode coating structure comprising an enzyme layer, a regulation layer and a protective layer.

8. The single needle integrated artificial pancreas according to claim 2, wherein the electrode sensor has an electrode coating structure comprising an anti-interference layer, a bonding layer, an enzyme layer, a bonding layer, a regulation layer and a protective layer.

9. The single needle integrated artificial pancreas according to claim 1, wherein the indwelling cannula and the glucose sensor are arranged in parallel, and located in a groove of the groove puncture needle.

10. The single needle integrated artificial pancreas according to claim 1, wherein a distance between an end of the indwelling cannula and an end of the glucose sensor ranges from 1mm to 8mm.

11. The single needle integrated artificial pancreas according to claim 1, wherein the end of the indwelling cannula and the end of the glucose sensor are both tip shaped.

12. The single needle integrated artificial pancreas according to claim 1, further comprising a skin temperature automatic adjusting device configured to heat the skin tissue where the glucose sensor and the indwelling cannula are implanted.

13. The single needle integrated artificial pancreas according to claim 12, wherein the skin temperature automatic adjusting device comprises a skin heating film, a heating module, a temperature control module, a heat preservation module and a temperature detection module.

14. The single needle integrated artificial pancreas according to claim 1, wherein the inserter is an automatic ejecting inserter or a manual inserter.

15. The single needle integrated artificial pancreas according to claim 1, further comprising a pump base and a controller connected to the pump base, wherein the pump base comprises the fluid reservoir unit, the fluid driving unit and the indwelling unit, wherein the controller comprises the glucose monitoring and insulin delivery control unit.

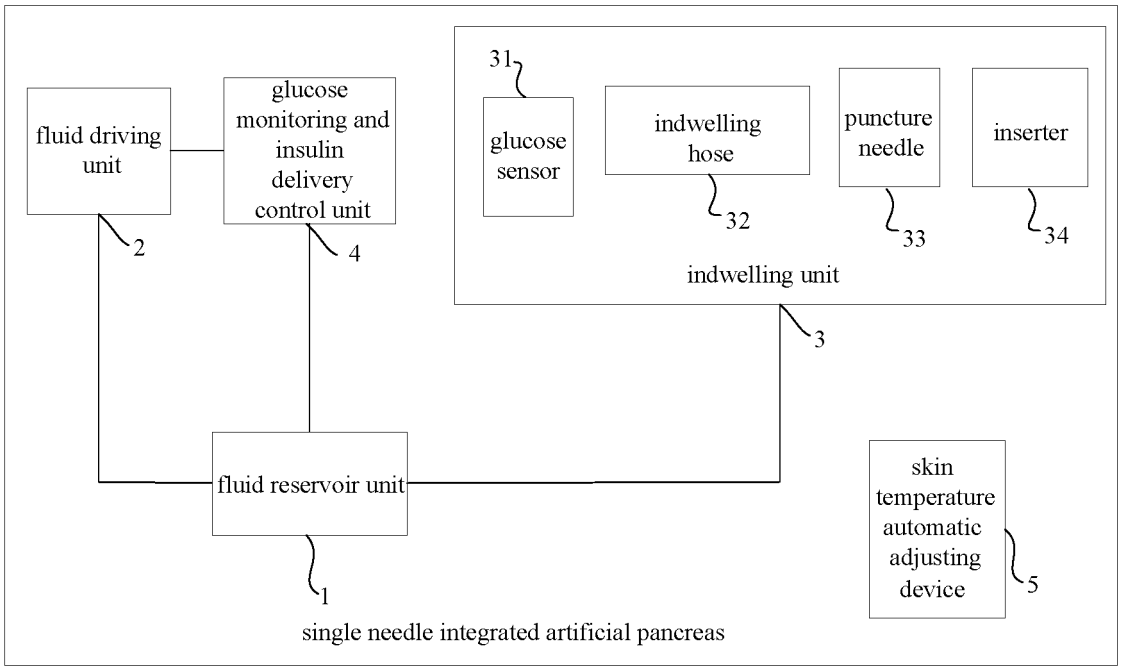

Figure 1

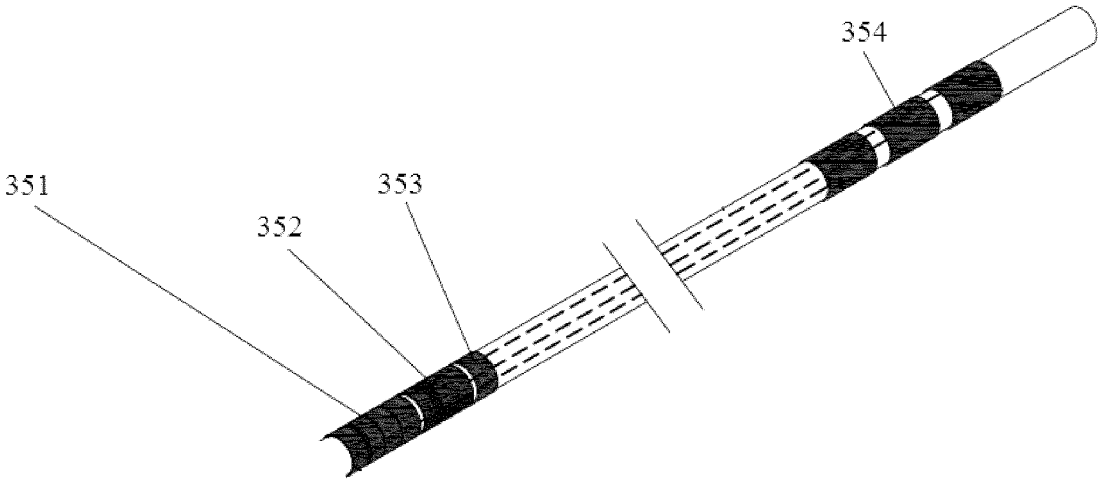

Figure 2

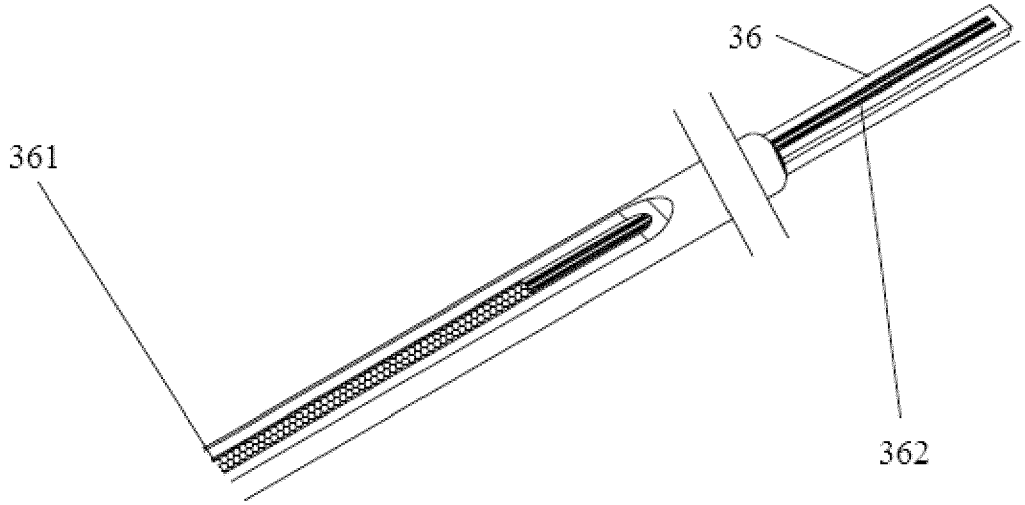

Figure 3

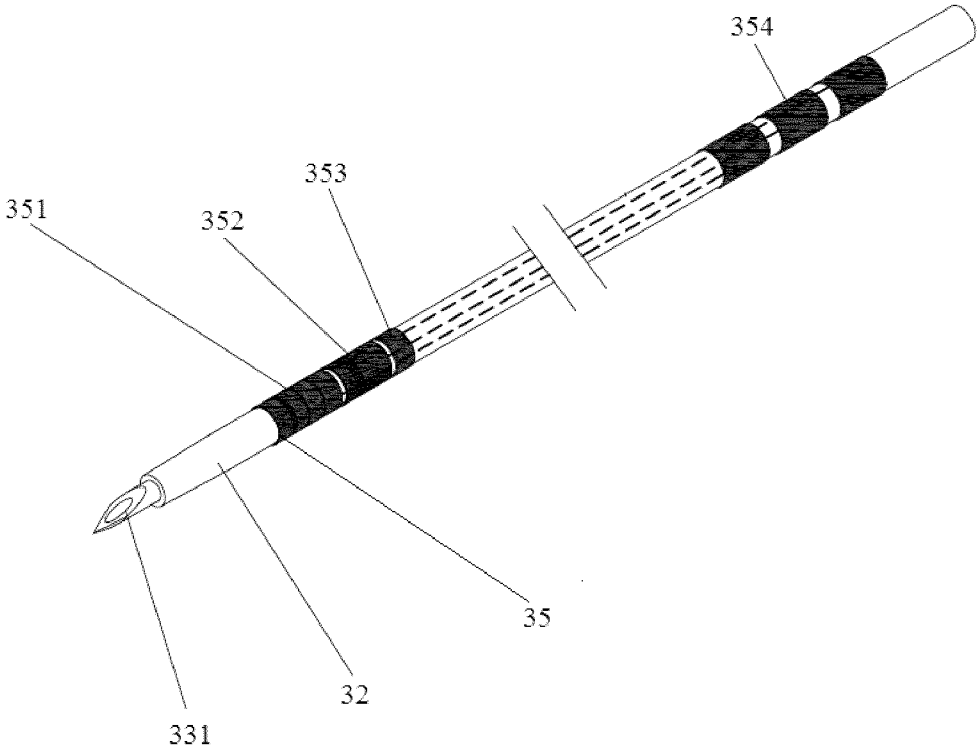

Figure 4

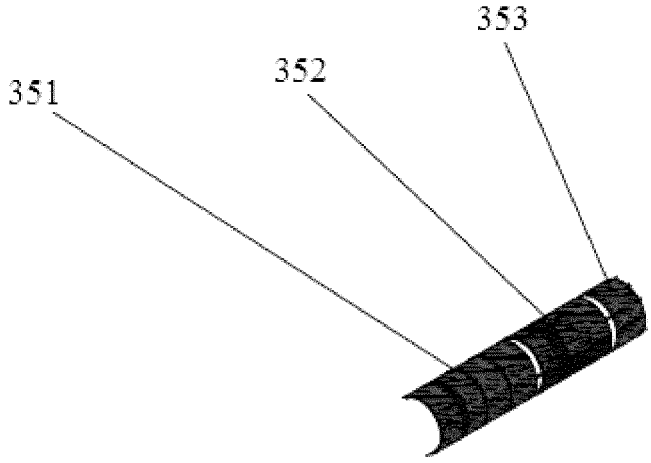

Figure 5

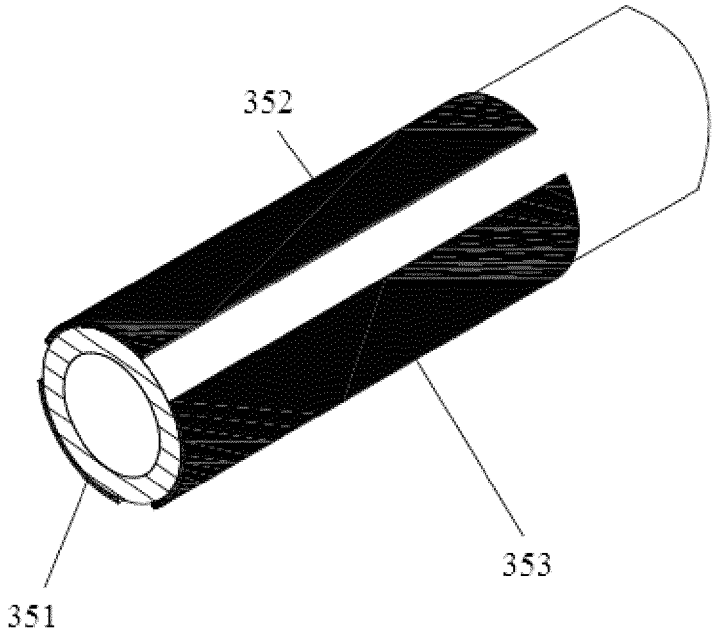

Figure 6

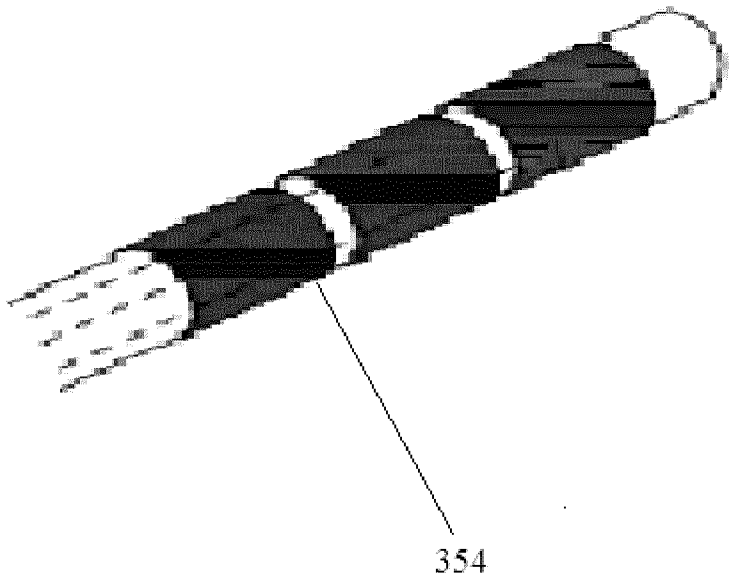

Figure 7

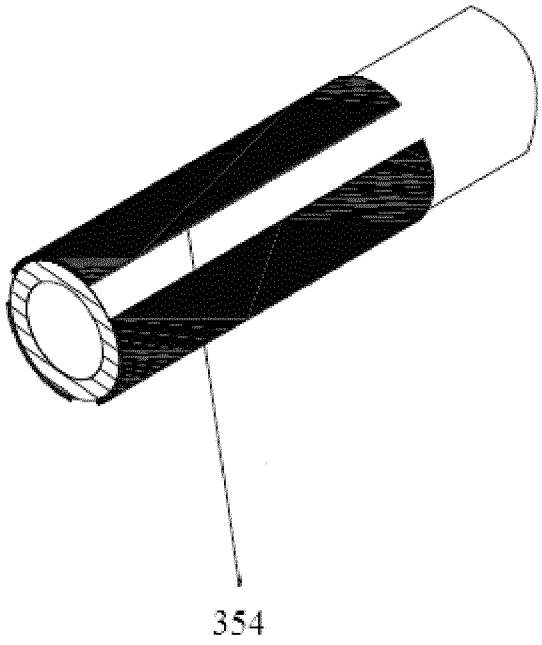

Figure 8

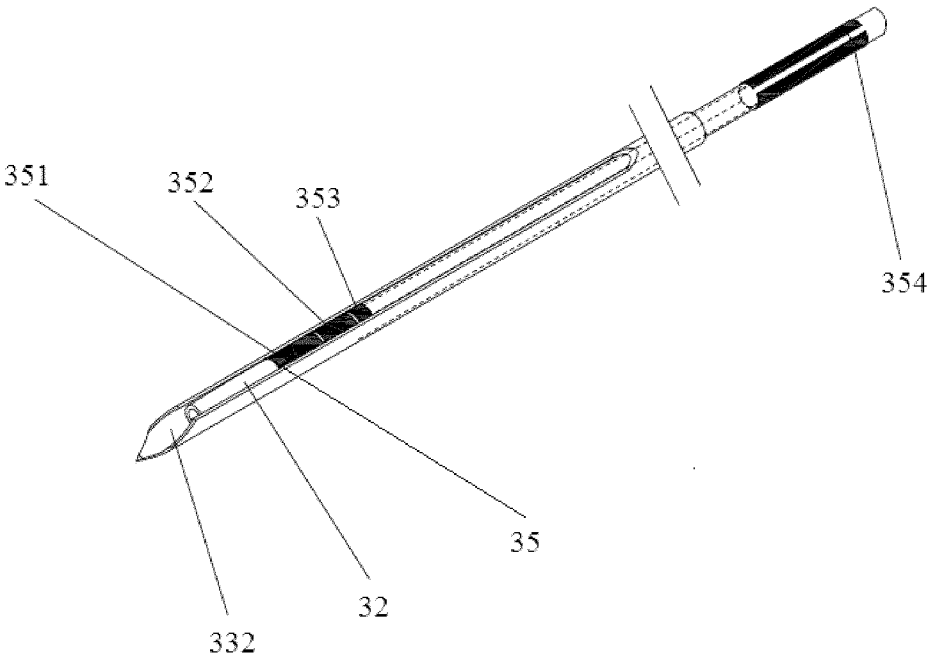

Figure 9

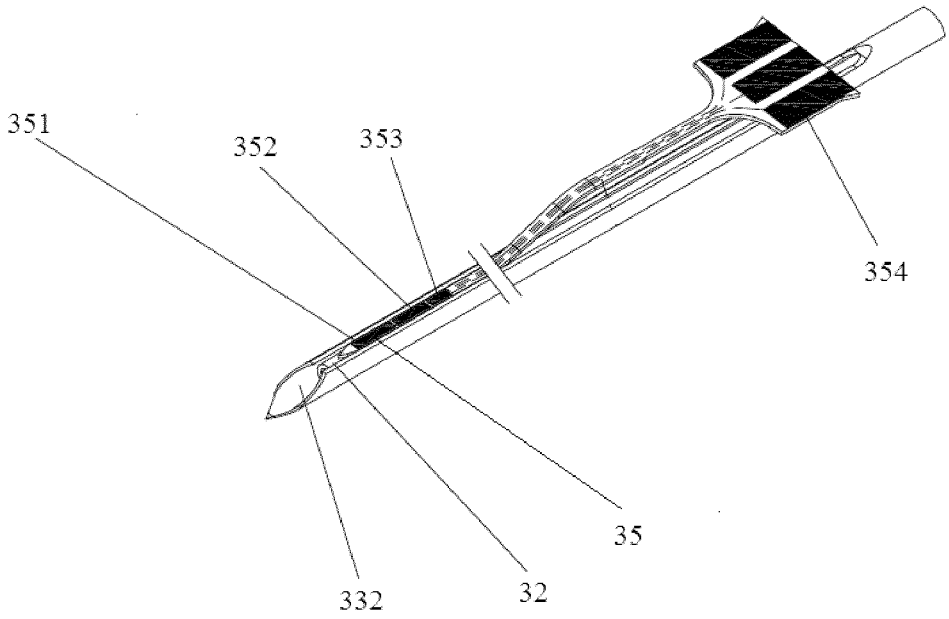

Figure 10

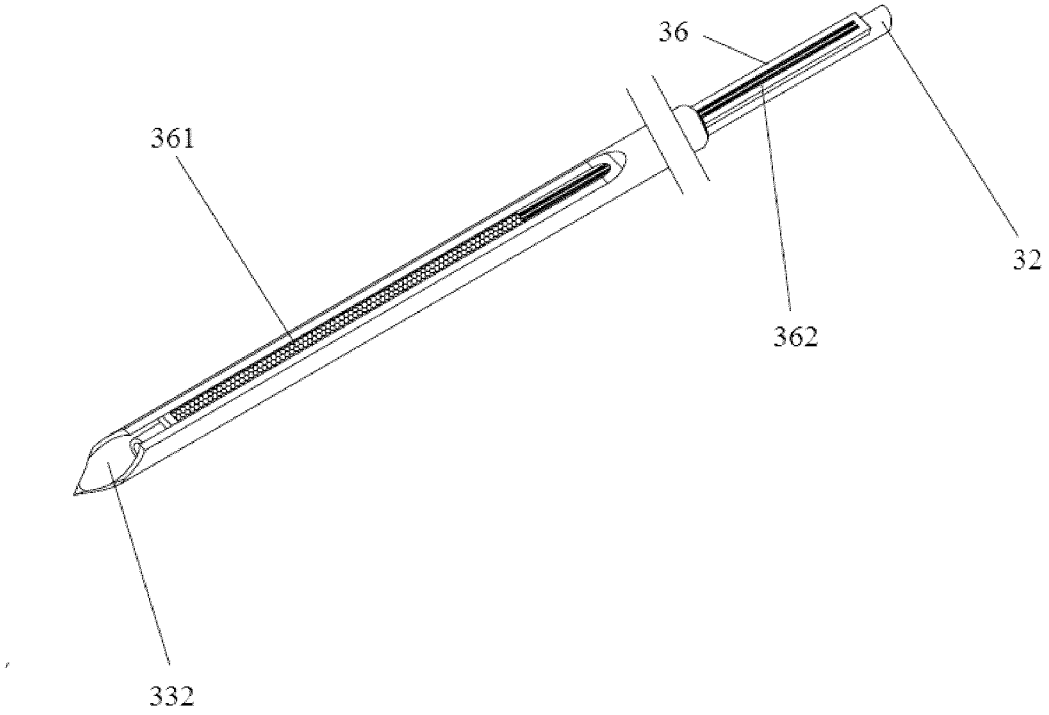

Figure 11

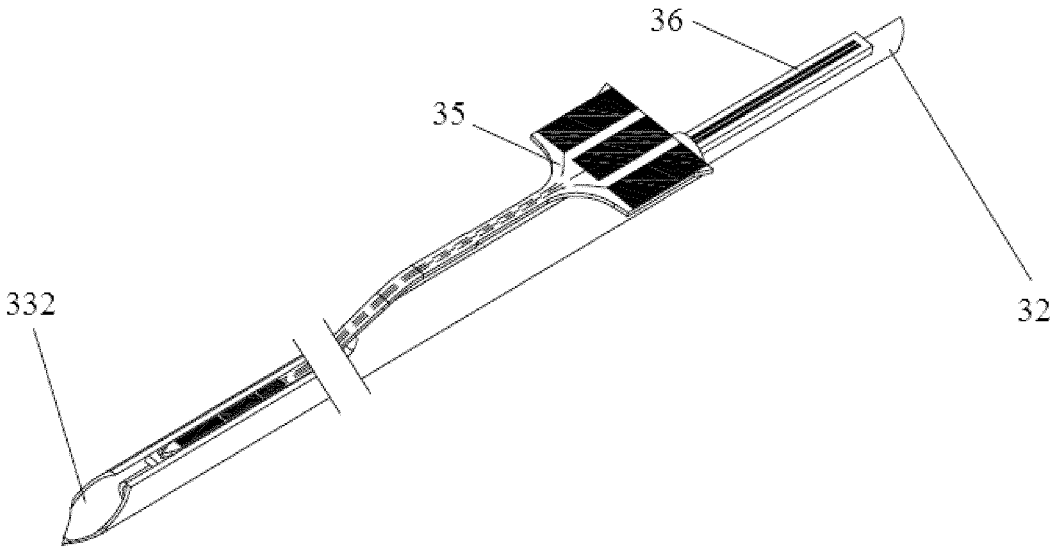

Figure 12

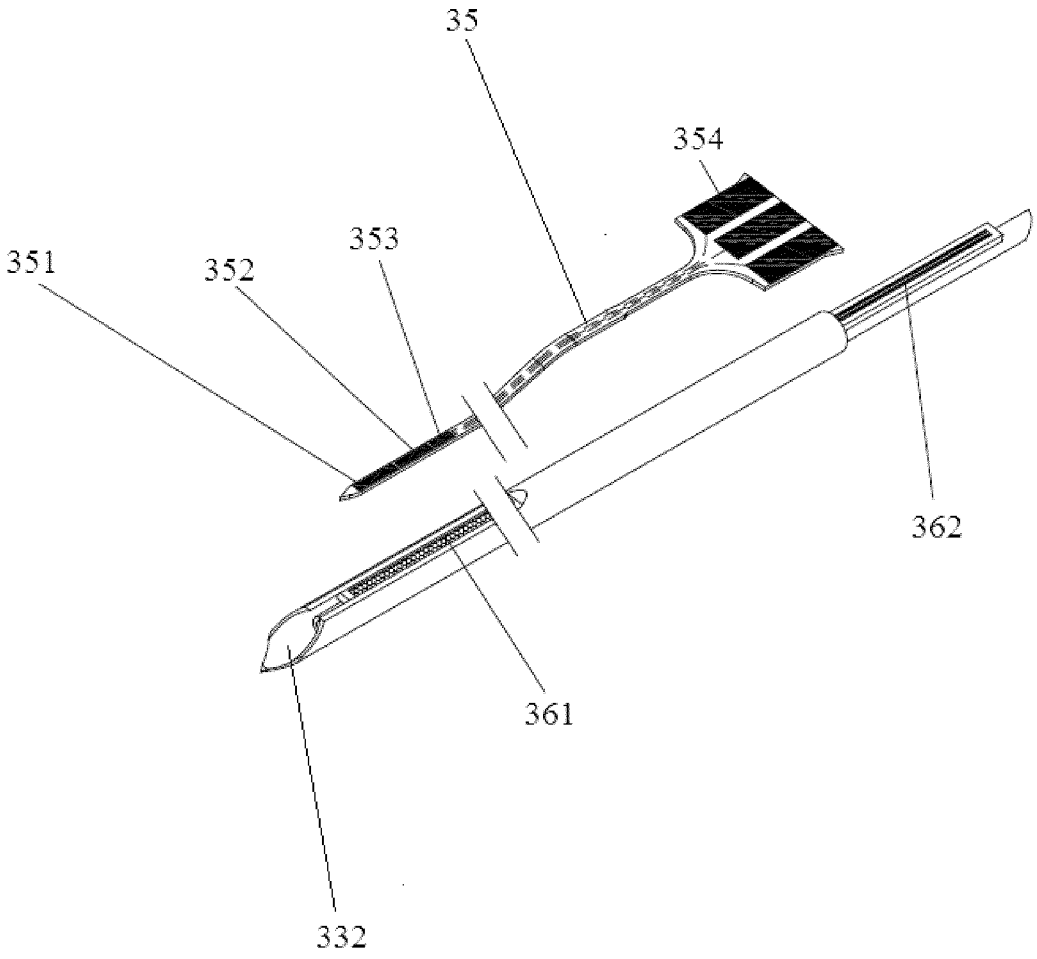

Figure 13

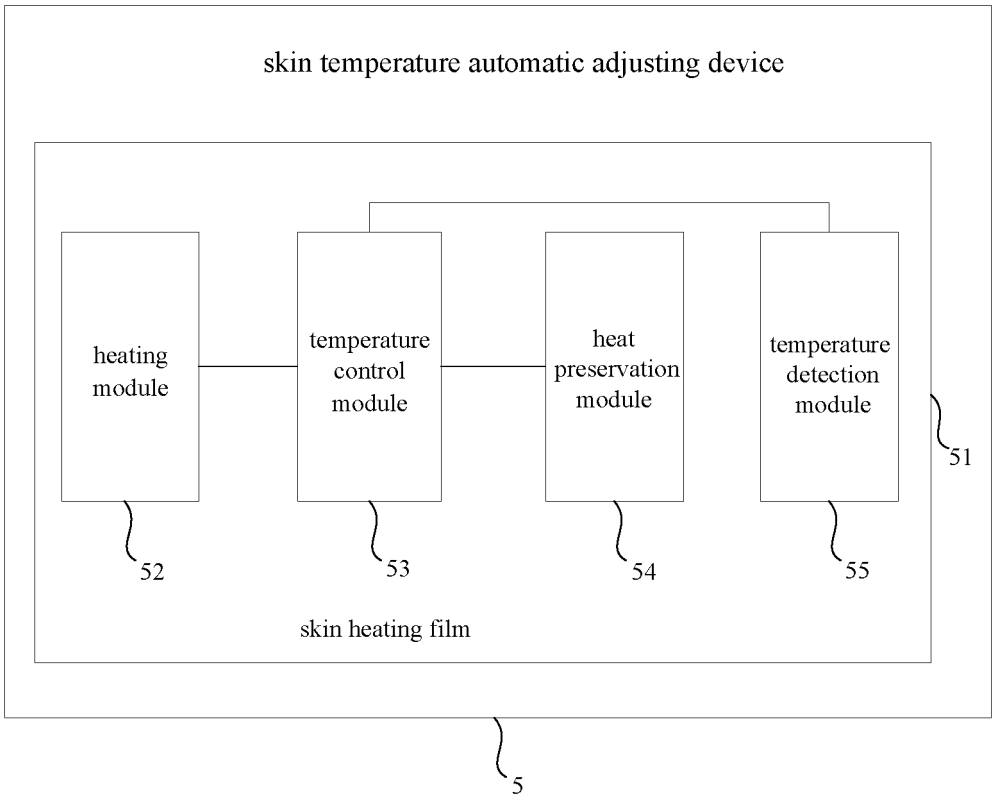
skin temperature automatic adjusting device
heating module
temperature control module
heat preservation module
temperature detection module
51
52
53
54
55
skin heating film
5

Figure 14a

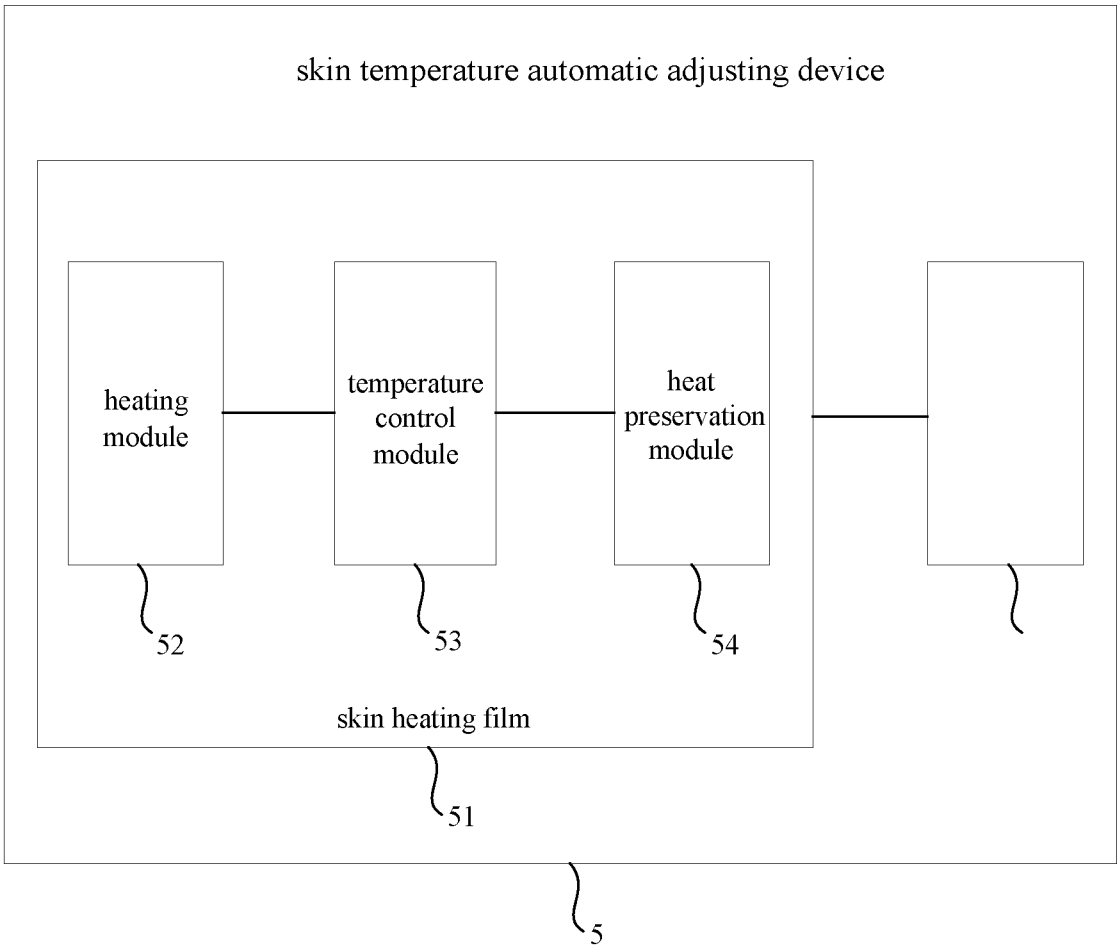
skin temperature automatic adjusting device
heating module
temperature control module
heat preservation module
52
53
54
skin heating film
51
5

Figure 14b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2014/071526

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/145 (2006.01) i; A61M 5/142 (2006.01) i; A61M 5/00 (2006.01) 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)

IPC: A61M

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)

CJFD; CNABS; VEN: yang cuijun, needle, sensor, integration, pancreas, glucose, indwelling needle, single needle, insulin, artificial pancreas, pump, blood glucose, monitor, diabetes, medtrum tech. co., ltd, artificial pancreas, holter, tube, glucose, single-needle, insulin

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 102946923 A (MEDTRONIC MINIMED INC.) 27 February 2013 (27 February 2013) description, paragraphs [0043]-[0061] and figures 1-6	1, 2, 11, 15
Y	US 2008221509 A1 (MEDTRONIC MINIMED INC.) 11 September 2008(11 September 2008) description, pages 3-6 and figures 1, 7 and 8B	1, 2, 11, 15
Y	CN 1859943 A (BECTON DICKINSON & CO) 08 November 2006 (08 November 2006) description, pages 8-16 and figures 1-6	1, 2, 11, 15
Y	US 2008275384 A1 (MASTROTOTARO JOHN J) 06 November 2008(06 November 2008) description, paragraphs [0046]-[0111] and figures 1-14	1, 2, 11, 15

☒ 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
06 August 2014	19 August 2014
Name and mailing address of the ISA State Intellectual Property Office of the P. R. China No. 6, Xitucheng Road, Jimenqiao Haidian District, Beijing 100088, China Facsimile No. (86-10) 62019451	Authorized officer TIAN, Yunqing Telephone No. (86-10) 62085631

Form PCT/ISA /210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2014/071526

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	CN 102970927 A (MEDTRONIC MINIMED INC.) 13 March 2013(13 March 2013) description, paragraphs [0043]-[0061] and figures 1-6	1, 2, 11, 15
A	CN 202682463 U (LIU, Chunying) 23 January 2013 (23 January 2013) the whole document	1-15
A	CN 101925372 A (MEDINGO LTD) 22 December 2010(22 December 2010) the whole document	1-15
A	CN 1973768 A (CHINA SCI ACAD ELECTRONICS RES INST) 06 June 2007(06 June 2007) the whole document	1-15

Form PCT/ISA /210 (continuation of second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CN2014/071526

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA /210 (continuation of first sheet (2)) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2014/071526

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
CN 102946923 A	27 February 2013	CA 2800828 A1	29 December 2011
		WO 2011162970 A1	29 December 2011
		JP 2013529500 A	22 July 2013
		US 2011313390 A1	22 December 2011
		EP 2585133 A1	01 May 2013
US 2008221509 A1	11 September 2008	JP 4711627 B2	29 June 2011
		WO 03074107 A2	12 September 2003
		US 2004064086 A1	01 April 2004
		JP 2005536239 A	02 December 2005
		AU 2003213613 A8	16 September 2003
		WO 03074107 A3	17 June 2004
		EP 1487529 A4	24 January 2007
		CA 2476650 A1	12 September 2003
		US 7833157 B2	16 November 2010
		EP 1487529 A2	22 December 2004
		US 2011046457 A1	24 February 2011
		AU 2003213613 A1	16 September 2003
		US 7500949 B2	10 March 2009
		CA 2747852 A1	12 September 2003
		CA 2476650 C	01 May 2012
US 2008275384 A1	06 November 2008	US 7785313 B2	31 August 2010
		WO 2009023407 A1	19 February 2009
		WO 2009023406 A1	19 February 2009
		US 2008269714 A1	30 October 2008
		US 2012136336 A1	31 May 2012
		US 8454576 B2	04 June 2013
CN 102970927 A	13 March 2013	WO 2012006208 A2	12 January 2012
		WO 2012006208 A3	24 May 2012

Form PCT/ISA /210 (patent family annex) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CN2014/071526

		CA 2802271 A1	12 January 2012
		EP 2590559 A2	15 May 2013
		US 2012006100 A1	12 January 2012
CN 202682463 U	23 January 2013	None	
CN 101925372 A	22 December 2010	AU 2008327483 A1	28 May 2009
		CN 101925372 B	11 September 2013
		US 2010256593 A1	07 October 2010
		EP 2224977 A1	08 September 2010
		JP 2011504129 A	03 February 2011
		WO 2009066288 A1	28 May 2009
CN 1973768 A	06 June 2007	CN 100446724 C	31 December 2008

Form PCT/ISA /210 (patent family annex) (July 2009)

专利名称(译)	单针一体化人工胰腺		
公开(公告)号	EP2997988A1	公开(公告)日	2016-03-23
申请号	EP2014861997	申请日	2014-01-27
[标]申请(专利权)人(译)	上海移宇科技有限公司		
申请(专利权)人(译)	MEDTRUM科技股份有限公司.		
当前申请(专利权)人(译)	MEDTRUM科技股份有限公司.		
[标]发明人	YANG CUIJUN		
发明人	YANG, CUIJUN		
IPC分类号	A61M5/145 A61M5/142 A61M5/00 A61B5/00		
CPC分类号	A61M5/1723 A61B5/14503 A61B5/14532 A61M5/14276 A61M2005/1726 A61M2205/36		
优先权	201310560946.9 2013-11-12 CN		
其他公开文献	EP2997988B1 EP2997988A4		
外部链接	Espacenet		

摘要(译)

本发明公开了一种单针一体化人工胰腺，其中单针一体化人工胰腺包括药物贮存器单元（1）;计量驱动单元（2）连接到药物储存器单元（1）;留置单元（3），连接到药物储存器单元（1）并包括葡萄糖传感器（31），胰岛素留置软管（32），穿刺针（33）和安装装置（34）;其中葡萄糖传感器（31）和胰岛素留置软管（32）在穿刺针（33）的帮助下通过安装装置（34）同时植入患者的同一皮下组织中;穿刺针（33）是钢穿刺针或穿刺针;血糖监测和胰岛素给药控制单元（4）分别连接到药物储存器单元（1），剂量驱动单元（2）和留置单元（3）。单针集成人工胰腺能够将胰岛素留置软管（32）和人造胰腺的葡萄糖传感器（31）同时植入患者皮下组织的相同部位，从而减少糖尿病患者的机会被感染;安装简单，使用方便。

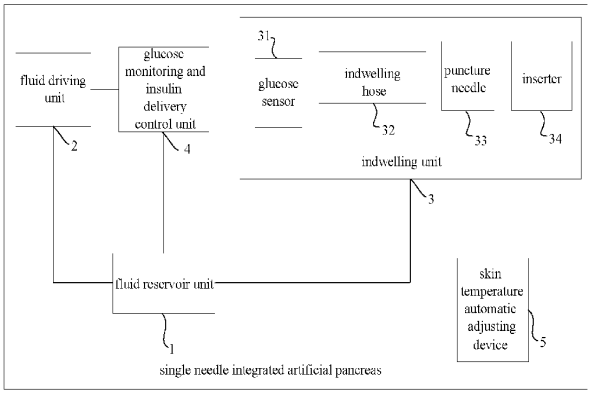

Figure 1