



US012390588B2

(12) **United States Patent**  
**Yang**

(10) **Patent No.:** **US 12,390,588 B2**

(45) **Date of Patent:** **Aug. 19, 2025**

(54) **BILATERALLY DRIVEN INTEGRATED MEDICAL DEVICE**

(71) Applicant: **MEDTRUM TECHNOLOGIES INC.**,  
Shanghai (CN)

(72) Inventor: **Cuijun Yang**, Shanghai (CN)

(73) Assignee: **MEDTRUM TECHNOLOGIES INC.**,  
Shanghai (CN)

(\*) Notice: Subject to any disclaimer, the term of this  
patent is extended or adjusted under 35  
U.S.C. 154(b) by 947 days.

(21) Appl. No.: **17/611,574**

(22) PCT Filed: **Jun. 1, 2020**

(86) PCT No.: **PCT/CN2020/093706**

§ 371 (c)(1),

(2) Date: **Nov. 16, 2021**

(87) PCT Pub. No.: **WO2021/012797**

PCT Pub. Date: **Jan. 28, 2021**

(65) **Prior Publication Data**

US 2022/0226574 A1 Jul. 21, 2022

(30) **Foreign Application Priority Data**

Jul. 19, 2019 (WO) ..... PCT/CN2019/096673

(51) **Int. Cl.**

**A61M 5/172** (2006.01)

**A61B 5/00** (2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ..... **A61M 5/1723** (2013.01); **A61B 5/14532**  
(2013.01); **A61B 5/1473** (2013.01);

(Continued)

(58) **Field of Classification Search**

None

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2003/0199824 A1 10/2003 Mahoney et al.

2003/0236498 A1 12/2003 Gross et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CN 103347551 10/2013

CN 104168935 11/2014

(Continued)

OTHER PUBLICATIONS

“International Search Report (Form PCT/ISA/210) of PCT/CN2020/093706,” mailed on Sep. 7, 2020, with English translation thereof, pp. 1-4.

(Continued)

*Primary Examiner* — Jay B Shah

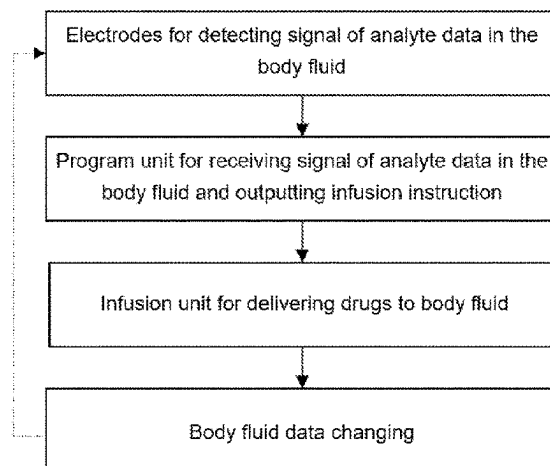
(74) *Attorney, Agent, or Firm* — JCIP GLOBAL INC.

(57)

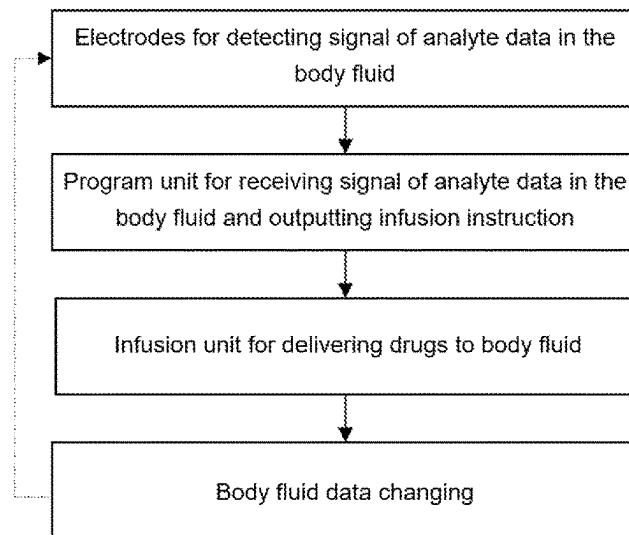
**ABSTRACT**

The invention discloses a bilaterally driven integrated medical device, comprising: infusion unit; 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 power unit, the program unit controls whether the infusion unit delivers drugs; an infusion cannula with conductive area(s); 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. It takes only one insertion to perform both analyte detection and drug infusion.

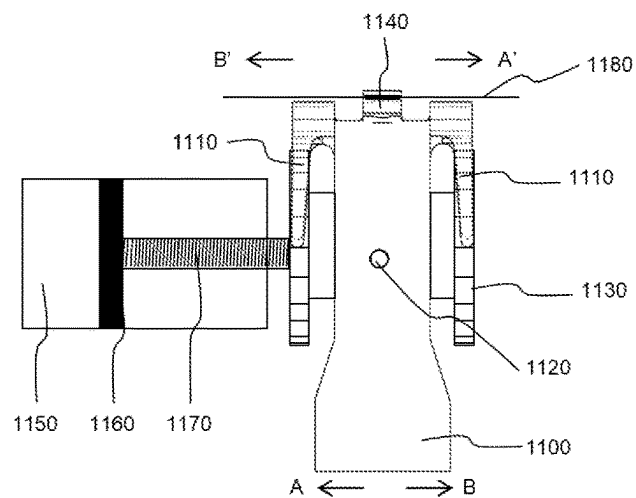
**19 Claims, 10 Drawing Sheets**



- (51) **Int. Cl.**  
*A61B 5/145* (2006.01)  
*A61B 5/1473* (2006.01)  
*A61F 2/02* (2006.01)  
*A61M 5/14* (2006.01)  
*A61M 5/142* (2006.01)  
*A61M 5/145* (2006.01)  
*A61M 5/158* (2006.01)  
*A61M 5/20* (2006.01)  
*G16H 20/17* (2018.01)  
*G16H 40/63* (2018.01)
- (52) **U.S. Cl.**  
 CPC ..... *A61B 5/4839* (2013.01); *A61F 2/022*  
 (2013.01); *A61M 5/14236* (2013.01); *A61M*  
*5/14244* (2013.01); *A61M 5/14248* (2013.01);  
*A61M 5/1452* (2013.01); *A61M 5/1454*  
 (2013.01); *A61M 5/158* (2013.01); *A61M*  
*5/172* (2013.01); *G16H 20/17* (2018.01);  
*G16H 40/63* (2018.01); *A61B 2560/0209*  
 (2013.01); *A61B 2562/043* (2013.01); *A61M*  
*5/1413* (2013.01); *A61M 2005/14208*  
 (2013.01); *A61M 2005/14252* (2013.01);  
*A61M 2005/14268* (2013.01); *A61M*  
*2005/14506* (2013.01); *A61M 2005/1585*  
 (2013.01); *A61M 2005/1726* (2013.01); *A61M*  
*2005/2006* (2013.01); *A61M 2205/0216*  
 (2013.01); *A61M 2205/0233* (2013.01); *A61M*  
*2205/0266* (2013.01); *A61M 2205/33*  
 (2013.01); *A61M 2205/3317* (2013.01); *A61M*  
*2205/3327* (2013.01); *A61M 2205/3553*  
 (2013.01); *A61M 2205/3576* (2013.01); *A61M*  
*2205/3592* (2013.01); *A61M 2205/50*  
 (2013.01); *A61M 2205/502* (2013.01); *A61M*  
*2209/088* (2013.01); *A61M 2230/005*  
 (2013.01); *A61M 2230/20* (2013.01); *A61M*  
*2230/201* (2013.01)
- (56) **References Cited**  
 U.S. PATENT DOCUMENTS  
 2005/0059871 A1 3/2005 Gough et al.  
 2005/0238507 A1 10/2005 Dilanni et al.  
 2012/0277667 A1 11/2012 Yodat et al.  
 2014/0350460 A1\* 11/2014 Moore ..... A61M 5/19  
 604/89
- FOREIGN PATENT DOCUMENTS  
 CN 108331731 7/2018  
 WO 2008078319 7/2008  
 WO 2011064780 6/2011
- OTHER PUBLICATIONS  
 "Search Report of Europe Counterpart Application", issued on Jul.  
 27, 2023, p. 1-p. 8.  
 \* cited by examiner



**FIG.1**



**FIG.2a**

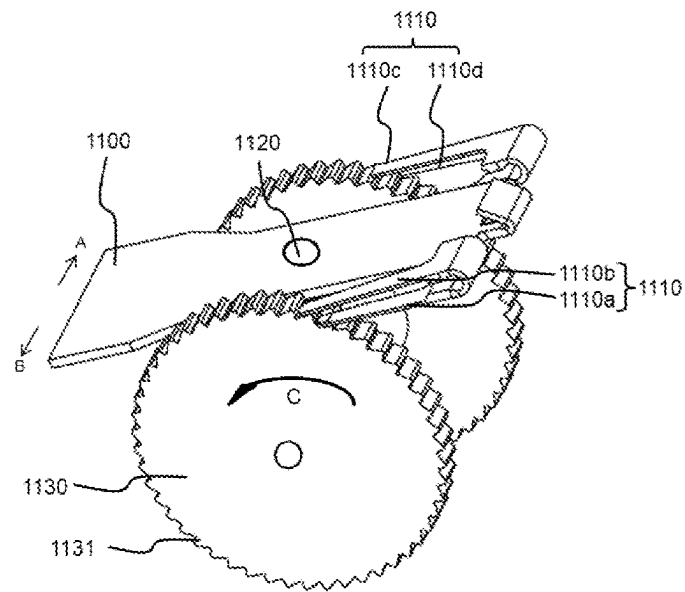


FIG. 2b

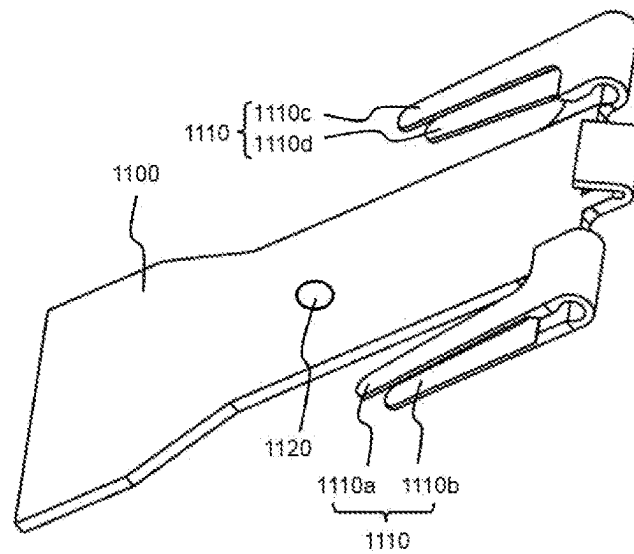


FIG. 3a

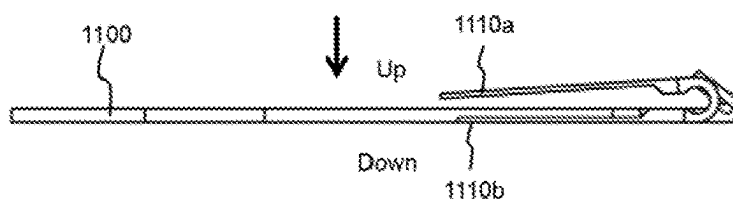


FIG. 3b

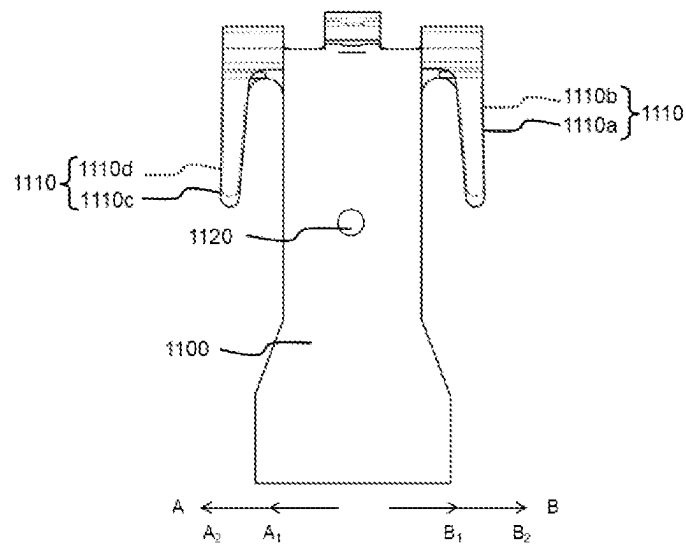


FIG. 4

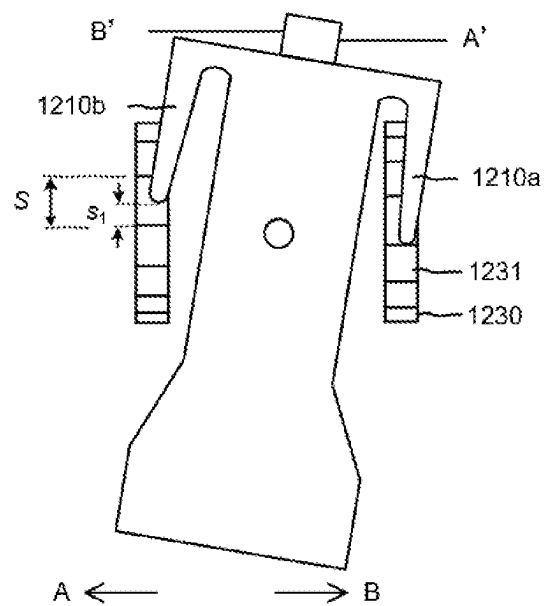


FIG. 5a

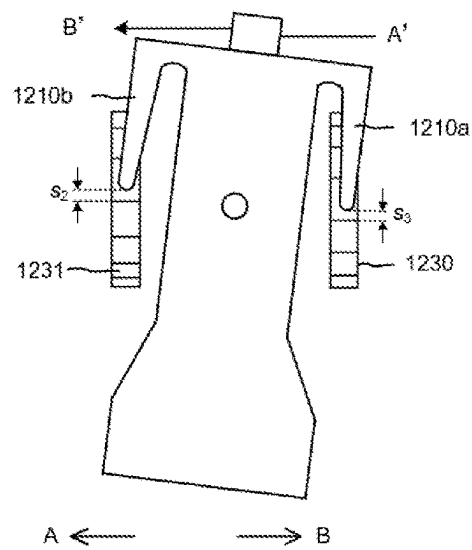


FIG. 5b

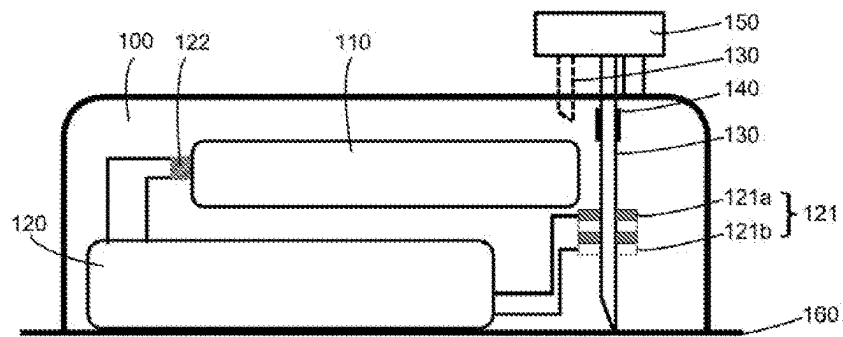


FIG. 6a

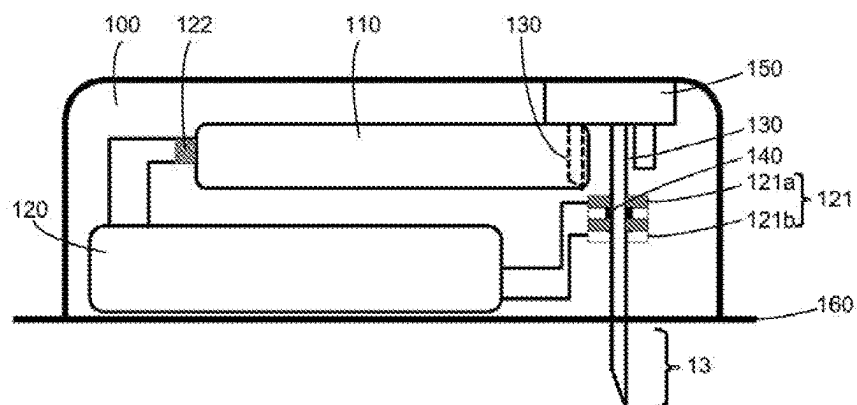


FIG. 6b

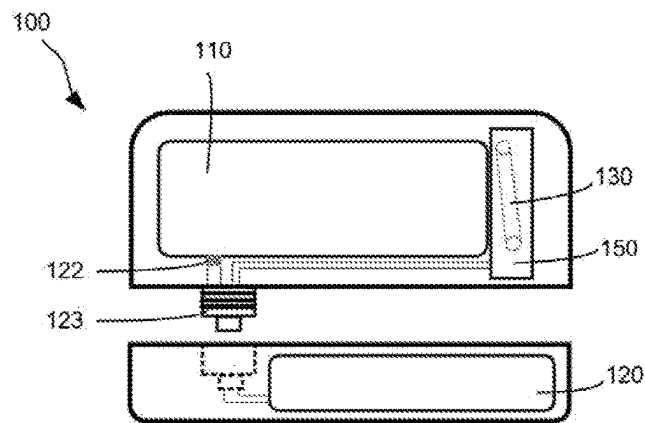


FIG. 7a

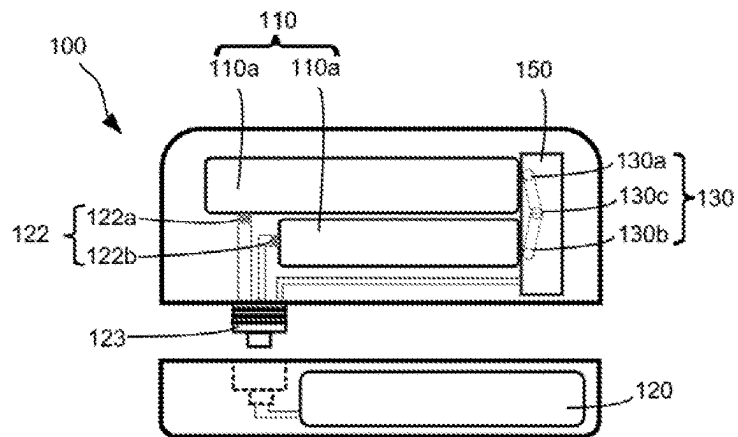


FIG. 7b

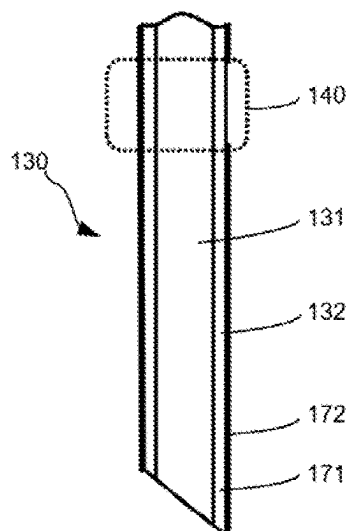


FIG. 8a

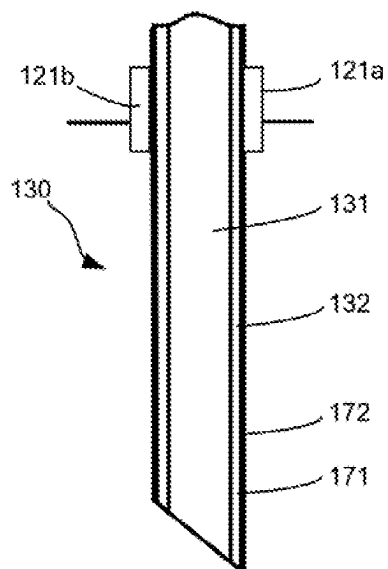


FIG. 8b

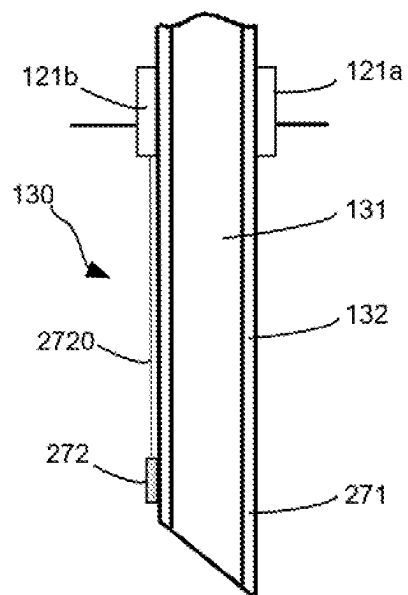


FIG. 9a



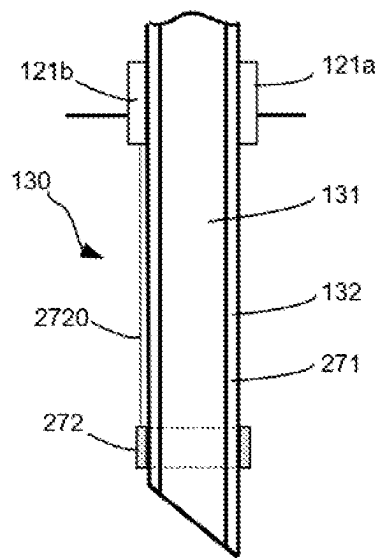


FIG. 9b

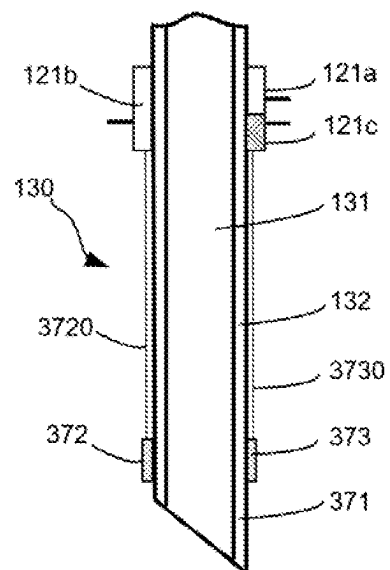


FIG. 10

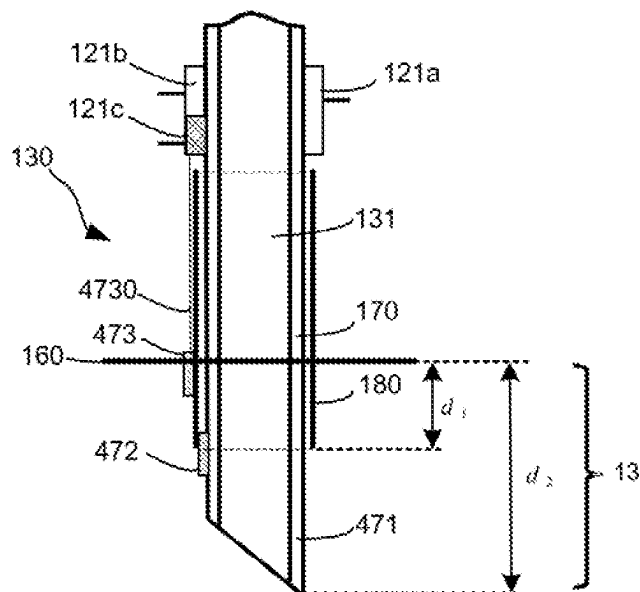


FIG. 11

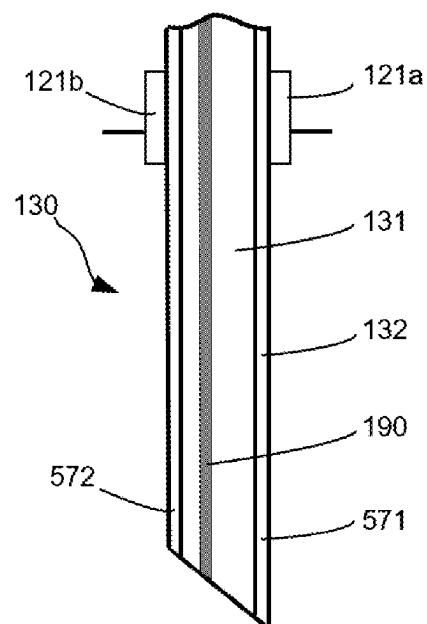


FIG. 12a

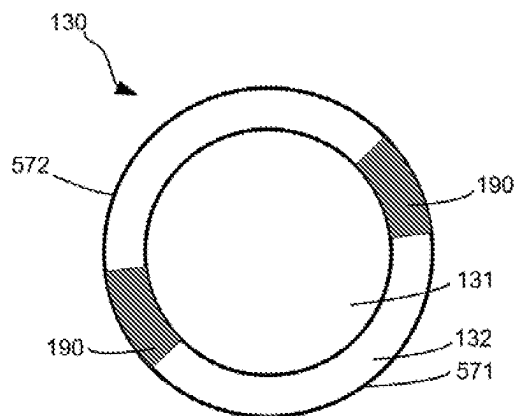


FIG. 12b

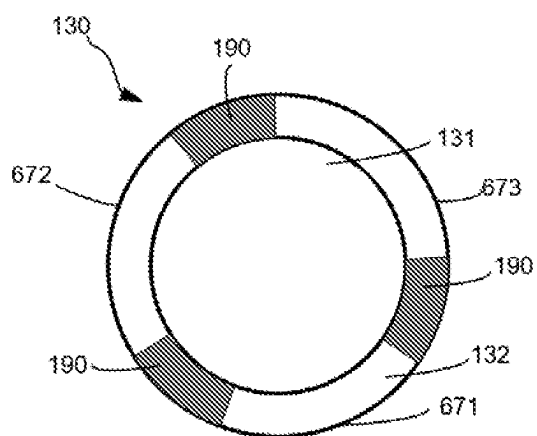


FIG. 12c

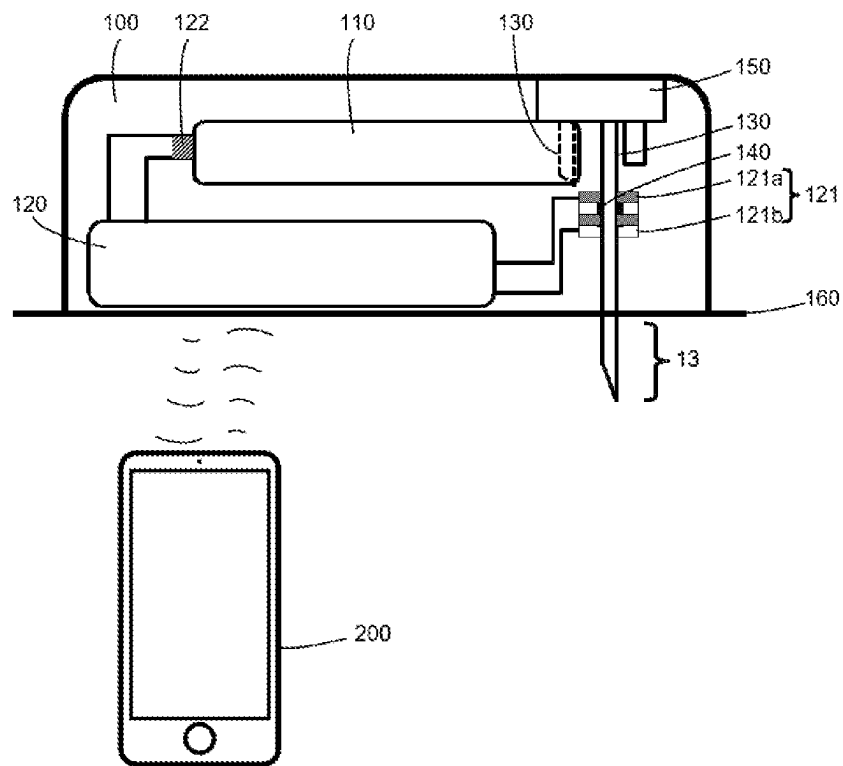


FIG.13

1

## BILATERALLY DRIVEN INTEGRATED MEDICAL DEVICE

### CROSS-REFERENCE TO RELATED APPLICATION

This application is a 371 of international application of PCT application serial no. PCT/CN2020/093706, filed on Jun. 1, 2020, 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

The present invention mainly relates to the field of medical instruments, in particular to a bilaterally driven integrated medical device.

### BACKGROUND

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.

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.

Therefore, there is a need in the prior art for a bilaterally driven integrated medical device that can perform both detection and infusion at the same time.

### BRIEF SUMMARY OF THE INVENTION

Embodiments of the present invention disclose a bilaterally driven integrated medical device 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.

The invention discloses a bilaterally driven integrated medical device, comprising: infusion unit, including: at least one drug storage unit; a screw connected to a piston and a driving wheel provided with wheel teeth, respectively, the driving wheel drives the screw to move by rotation, pushing the piston, provided in the drug storage unit, forward; a driving unit cooperating with the driving wheel, the driving unit includes at least two driving portions, the driving unit pivots, around a pivot shaft, in different pivot modes, thus driving the driving portions, in different directions, to push the wheel teeth to rotate the driving wheel; a power unit

2

connected to the driving unit, the power unit outputs two forces in different directions on the driving unit, making the driving unit have multiple pivot modes; a 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 power unit, according to the received signals of analyte data in the body fluid, the program unit controls the pivot modes of the driving unit to implement whether the infusion unit delivers the drug; 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.

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.

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.

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.

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.

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  $d_1$ , while the depth of the infusion steel needle into the skin is  $d_2$ ,  $d_1 \leq d_2$ .

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.

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.

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.

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.

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.

According to one aspect of this invention, conductive-area electrode is working electrode or auxiliary electrode.

According to one aspect of this invention, the auxiliary electrode is counter electrode, or the auxiliary electrode includes counter electrode and reference electrode.

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.

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.

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.

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.

According to one aspect of this invention, the bilaterally driven integrated medical device 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.

According to one aspect of this invention, the pivot mode of the driving unit includes pivot amplitude or pivot rate, and multiple different pivot modes include multiple different pivot amplitudes or pivot rates.

According to one aspect of this invention, the driving wheel includes at least two sub-wheels, the pivot shaft is disposed between the two sub-wheels, one or more of the driving portions are provided on both sides of the driving unit, and each sub-wheel is cooperated with each driving portion.

According to one aspect of this invention, two driving portions are respectively provided on both sides of the driving unit, and the two driving portions on one side of the driving unit are disposed up and down or left and right.

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

In the bilaterally driven integrated medical device disclosed herein, 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. Secondly, the bilaterally driven

integrated medical device 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 bilaterally driven integrated medical device 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 bilaterally driven integrated medical device can begin to work. This approach reduces the user's pre-using steps and improves the user experience. In addition, the power unit exerts two different forces on the driving unit in different directions, making the driving unit have multiple pivot modes. The user or the closed-loop system can flexibly select the infusion mode according to the actual needs, thus making the infusion process controlled accurately.

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.

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.

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.

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

5

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.

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.

Furthermore, the pivot mode of the driving unit includes pivot amplitude or pivot rate, and multiple pivot modes include a plurality of different pivot amplitudes or pivot rates. The user or closed-loop system can flexibly select the appropriate pivot amplitude or pivot rate of the driving unit according to the actual needs of the body, thereby selecting the appropriate infusion mode.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a flow chart of the operation of a bilaterally driven integrated medical device according to an embodiment of the present invention;

FIG. 2a-FIG. 2b are schematic views showing the structure of the infusion unit according to an embodiment of the present invention;

FIG. 3a is a schematic view of the driving unit according to an embodiment of the present invention;

FIG. 3b is a side view of the driving unit in FIG. 3a;

FIG. 4 is a schematic view of a position structure of multiple pivot amplitudes of the driving unit according to an embodiment of the present invention;

FIG. 5a-FIG. 5b are schematic views of the driving unit including two driving portions according to another embodiment of the present invention;

FIG. 6a is a schematic view of an infusion cannula of a bilaterally driven integrated medical device in a pre-installation position according to one embodiment of the present invention;

FIG. 6b is a schematic view showing the infusion cannula of the bilaterally driven integrated medical device in a working position according to an embodiment of the present invention;

FIG. 7a-FIG. 7b are top views of a bilaterally driven integrated medical device in accordance with another embodiment of the present invention;

FIG. 8a-FIG. 8b are partial longitudinal views of an infusion cannula and an electrode according to one embodiment of the present invention;

FIG. 9a-FIG. 9b are partial longitudinal views of an infusion cannula and an electrode in accordance with another embodiment of the present invention;

FIG. 10 is a partial longitudinal view of an infusion cannula and three electrodes in accordance with still another embodiment of the present invention;

FIG. 11 is a partial longitudinal view showing an infusion steel needle casing hose according to still another embodiment of the present invention;

6

FIG. 12a is a partial longitudinal view of an infusion cannula having a plurality of electrically conductive areas in accordance with yet another embodiment of the present invention;

FIG. 12b-FIG. 12c are partial transverse views of an infusion cannula having a plurality of electrically conductive areas in accordance with yet another embodiment of the present invention;

FIG. 13 is a schematic structural view of a bilaterally driven integrated medical device and a remote device according to still another embodiment of the present invention.

#### DETAILED DESCRIPTION

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.

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

In order to solve this problem, the present invention provides a bilaterally driven integrated medical device, 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.

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

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

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

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

FIG. 1 is a flow chart showing the operation of a bilaterally driven integrated medical device according to an embodiment of the present invention.

The bilaterally driven integrated medical device 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, through the power 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.

FIG. 2a is a schematic view showing the structure of the infusion unit according to an embodiment of the present invention. The infusion unit includes a driving unit 1100, a driving wheel 1130, a drug storage unit 1150, a piston 1160, a screw 1170, and a power unit 1180. FIG. 2b is a schematic view of the cooperation between the driving unit 1100 and the driving wheel 1130 according to an embodiment of the present invention.

The screw 1170 is connected to the piston 1160 and the driving wheel 1130, respectively. In the embodiment of the present invention, the driving wheel 1130 is movably mounted on the device base (not shown), and the driving wheel 1130 moves the driving screw 1170 through rotation to advance the piston 1160 disposed in the drug storage unit 1150 to move forward for the purpose of injecting drugs.

The driving unit 1100 is used to drive the driving wheel 1130 to rotate. The driving unit 1100 is movably connected to the device base through the pivot shaft 1120. The power unit 1180 is used to apply a force to the driving unit 1100 leading the driving unit 1100 to pivot. In the embodiment of the present invention, the power unit 1180 is fixedly connected at the top position 1140 of the driving unit 1100, thereby dividing the power unit 1180 into two left and right portions, such as the A' direction portion and the B' direction portion in FIG. 2a. The driving unit 1100 is alternately led to pivot in the A' direction or the B' direction through the pivot shaft 1120. Specifically, in the embodiment of the present invention, when the power unit 1180 leads the driving unit 1100 to A' direction, the driving unit 1100 pivots in the A direction through the pivot shaft 1120, while the power unit 1180 leads the driving unit 1100 to the B' direction, the driving unit 1100 pivots in the B direction through the pivot shaft 1120. By alternately leading the driving unit 1100 to the A' direction and the B' direction, the driving unit 1100 can be alternately pivoted through the pivot shaft 1120 in two different directions, like the A direction and the B direction.

Specifically, in the embodiment of the present invention, the power unit 1180 is made of shape memory alloy. The A' direction portion and the B' direction portion of the shape memory alloy are alternately powered on and off, and a leading force is applied to the driving unit 1100 by a change in the length of the power unit 1180 thereof. The power unit 1180 may be composed of one piece of shape memory alloy, or may be composed of left and right segments (such as the A' direction segment and the B' direction segment) of shape memory alloy, and is not specifically limited herein, as long as the force can be applied to lead the driving unit 1100 to pivot.

Here, it should be noted that the power unit 1180 includes, but is not limited to, a shape memory alloy. In other embodiments of the present invention, the power unit 1180 may also be other structures, and the location where the power unit 1180 applies force to the driving unit 1100 is also not limited to the top position 1140, as long as the action of applying a force to the driving unit 1100 can be satisfied to cause the driving unit 1100 to alternately pivot left and right.

As shown in FIG. 2a and FIG. 2b, the driving wheel 1130 includes a plurality of sub-wheels, and the circumferential

surface of the sub-wheels is provided with wheel teeth 1131. Driving unit 1100, through the wheel teeth 1131, cooperates with the driving wheel 1130.

In the embodiment of the present invention, a plurality of driving portions 1110 are installed on each side of the driving unit 1100. Therefore, a plurality of sub-wheels are also installed on both sides of the driving unit 1100 to cooperate with the driving portions 1110. Specifically, in the embodiment of the present invention, the driving unit 1100 includes four driving portions 1110, which are 1110a, 1110b, 1110c, and 1110d, respectively. 1110a, 1110b are installed on one side of the driving unit 1100, while 1110c, 1110d are installed on the other side of the driving unit 1100. The driving wheel 1130 includes two sub-wheels, one of which cooperates with 1110a, 1110b and the other of which cooperates with 1110c, 1110d.

FIG. 3a and FIG. 3b are respectively schematic view, a side view of the driving unit 1100.

In the embodiment of the present invention, the two driving portions 1110 on one side of the driving unit 1100 are installed up and down. Here, the up and down settings refer to the up and down positional relationship representations shown in FIG. 3b. Specifically, the two driving portions 1110 (such as 1110a and 1110b) on the side of the driving unit 1100 can be seen in the side view FIG. 3b, and 1110b and 1110d are blocked by 1110a and 1110c, respectively.

It should be noted that, in other embodiments of the present invention, these four driving portions may be disposed by other means, such as the two driving portions on one side of the driving unit are disposed left and right, as long as the arms are able to drive the driving wheel to rotate, and is not specifically limited herein.

FIG. 4 is a schematic view of a position structure of a plurality of pivot amplitudes of the driving unit 1100, and is also a top view in the direction of the arrow in FIG. 3b.

In a single pivot in the direction A, driving portion 1110a and/or 1110b engage the wheel teeth 1131 to rotate the driving wheel 1130, while 1110c and 1110d can slide on the wheel teeth 1131, but not exert a force for driving the driving wheel 1130 to rotate. And obviously, 1110c slides to the next adjacent driving position firstly. At this time, the driving unit 1100 stops pivoting and the driving portions 1110a and/or 1110b stop engaging the wheel teeth 1131, therefore, the driving wheel 1130 stops rotating. Thus, the driving unit 1100 completes one kind of pivot amplitude. At this time, the driving unit 1100 pivots in the A direction to reach A<sub>1</sub> position. The next moment the driving unit 1100 continues to pivot in the A direction, 1110d will slide to the next adjacent driving position. Similarly, the driving unit 1100 completes another kind of pivot amplitude. At this time, the driving unit 1100 still pivots in the A direction to reach A<sub>2</sub> position. And the driving unit 1100 completes the whole process of single pivot in the A direction, performing A<sub>1</sub> and A<sub>2</sub> two pivot amplitudes, respectively, thereby driving the driving wheel 1130 to rotate by two steps, realizing two kinds of infusion modes of the medical device.

It should be noted that, in the above pivoting process, the driving portion 1110d may firstly slide to the next gear tooth 1131, and then 1110c slides to the next gear tooth 1131, which is not specifically limited herein. Similarly, when the driving unit 1100 pivots in the B direction, it can perform B<sub>1</sub> and B<sub>2</sub> two pivot amplitudes, respectively.

Obviously, in the whole process of the above-mentioned single pivot in the A direction, the driving unit 1100 undergoes an alternate action of pivot and stop, and the driving portions 1110 alternately engage and stop engaging wheel teeth 1131 to drive the driving wheel 1130 to rotate and stop



rotating, realizing two-step rotation of the driving wheel, and finally achieving two infusion modes of the medical device.

Referring to FIG. 4 again, in another embodiment of the present invention, the driving unit 1100 pivots to the  $A_1$  position, and then pivots one or two amplitudes in the B direction, that is, reaching the  $B_1$  or  $B_2$  position until the pivot in the B direction stops. This process completes the alternate pivot of the driving unit 1100 in two directions, so that the driving wheel 1130 can be rotated in multiple steps. Therefore, in the embodiment of the present invention, the driving unit 1100 can alternately switch amplitudes among  $A_1$ - $B_1$ , or  $A_1$ - $B_1$ - $B_2$ , or  $B_1$ - $A_1$ - $A_2$ , so as to achieve the purpose of switching among different infusion modes.

Referring to FIG. 4 again, in another embodiment of the present invention, the driving unit 1100 can also be pivoted directly to the  $A_2$  position without passing through the  $A_1$  position, then directly pivoted to the  $B_2$  position without passing through the  $B_1$  position, that is, the driving unit 1100 alternately pivots between the  $A_2$ - $B_2$  positions. As described above, the driving unit 1100 can also alternately pivot between the  $A_1$ - $B_1$  positions.

As with the medical device of the embodiment of the present invention, when the infusion is started, the amount of drug required is relatively large, and the patient or the closed-loop system can select the large  $A_2$ - $B_2$  pivot amplitude for infusion. After a period of time, the intermediate  $A_1$ - $B_1$ - $B_2$  pivot amplitude or  $B_1$ - $A_1$ - $A_2$  pivot amplitude can be used to reduce the rate of drug infusion. When the drug infusion is about to be completed, the patient or the closed-loop system can switch to the small  $A_1$ - $B_1$  pivot amplitude to further reduce the infusion rate and achieve precise control of the drug infusion. Of course, the patient or the system can also choose one or several of the modes for infusion, and there are no specific restrictions.

It should be noted that in another embodiment of the present invention, further more driving portions, like three, four, etc., can be disposed on one side of the driving unit. And the total number of driving portions may also be an odd number, such as three, five or more, that is, the numbers of driving portions on both sides of the driving unit are not equal. Moreover, the structural relationship between the different driving portions can be similar to that described above, and no specific restrictions are imposed herein.

FIG. 5a-FIG. 5b are schematic views of the driving unit 1200 including two driving portions.

When the driving portion 1210a or 1210b reaches a different position, the driving unit 1200 can still continue to rotate in the direction A or B to move the driving portion away from the driving position. If the distance of the driving portion 1210a away from the driving position is  $s_1$ , if the tooth pitch is S, then  $s_1 = \frac{1}{3}S$ ,  $\frac{1}{2}S$ ,  $\frac{3}{4}S$ , or S. Therefore, during the pivot of the driving unit 1200, at a certain moment, neither of the driving portions 1210a and 1210b push the gear teeth 1231, for example, the front end of the driving portion and the driving position are separated by  $s_2$  and  $s_3$ , respectively. At this time, the driving wheel 1230 does not rotate, nor does the medical device perform drug infusion. According to this working principle, the driving unit 1200 will pivot at any different amplitude, and the medical device has a variety of different infusion modes.

In the embodiments of the present invention, the frequency of the force output by the power unit can be changed to further change the pivot frequency of the driving unit, so that the medical device has a variety of different infusion rates. The user or the closed-loop system can flexibly select

the appropriate infusion rate as needed, making the infusion process flexible and controllable.

FIG. 6a-FIG. 6b are views of a bilaterally driven integrated medical device 100 according to an embodiment of the present invention, and the bilaterally driven integrated medical device 100 is an integral structure. FIG. 6a shows the infusion cannula 130 in the pre-installation position while FIG. 6b shows the infusion cannula 130 in the working position.

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 121a and 121b. 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 power unit 1180, allowing the program unit 120 to effectively control the infusion unit 110.

During the use of the bilaterally driven integrated medical device 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.

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 bilaterally driven integrated medical device 100, as shown in FIG. 6a. When the infusion cannula 130 is installed to the working position, the mounting unit 150 is pressed into the bilaterally driven integrated medical device 100 with the top portion integral with the bilaterally driven integrated medical device 100 housing, as shown in FIG. 6b. Prior to use by users, the mounting unit 150 holds the infusion cannula 130 in the pre-installation position. After the bilaterally driven integrated medical device 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 bilaterally driven integrated medical device 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.

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. 6a and FIG. 6b) for subsequent connection with the outlet of the infusion unit 110 to achieve drug circulation.

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

## 11

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.

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. **6a**, 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. **6b**, 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. **6b**) and the other end (illustrated by the dotted portion of the infusion cannula in FIG. **6b**) 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**.

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 bilaterally driven integrated medical device 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.

In an embodiment of the invention, a medical tape **160** for attaching the bilaterally driven integrated medical device **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**.

FIG. **7a** is a top view of a bilaterally driven integrated medical device **100** in accordance with another embodiment of the present invention.

In one embodiment of the invention, the bilaterally driven integrated medical device **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.

In other embodiments of the present invention, the bilaterally driven integrated medical device **100** may also be composed of more parts, and parts that do not require electrical connection may be connected using a common waterproof plug.

## 12

FIG. **7b** is a top view of a bilaterally driven integrated medical device **100** in accordance with another embodiment of the present invention.

In an embodiment of the invention, the bilaterally driven integrated medical device **100** comprises two parts, and the infusion unit **110** comprises two infusion subunits **110a** and **110b**. The infusion subunits **110a** and **110b** 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 **110a** and **110b** are electrically coupled to outputs **122a** and **122b**, respectively, allowing the program unit **120** to effectively control the infusion unit **110**. The outlets of infusion subunits **110a** and **110b** can be connected with the **130a** portion and **130b** portion of infusion cannula respectively. **130a** and **130b** are connected with the **130c** portion of infusion cannula, respectively. The **130c** 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 bilaterally driven integrated medical device 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.

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 bilaterally driven integrated medical device **100**. There are no specific restrictions herein.

FIG. **8a**-FIG. **8b** are partial longitudinal views of the infusion cannula **130**.

In an embodiment of the invention, the bilaterally driven integrated medical device **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.

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 bilaterally driven integrated medical device. With only one puncture at one place, analyte detection and drug infusion can be both 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.

In order to facilitate electrical connection of the electrodes and electrically connective regions **121a** and **121b**, the electrical contact region **140** (the position of the dotted line in FIG. **8a**) 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. **8b**, when

13

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 **121a** and **121b** of the input end, respectively, which allows electrical signals of the body fluid analyte data to be transmitted to program unit **120**.

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.

In the embodiment of the present invention, the bilaterally driven integrated medical device **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.

FIG. **9a**-FIG. **9b** are partial longitudinal 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. **9a**, and the related structural illustrations below are the same as those herein, which will not be described again.

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 **121a**, **121b** 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.

The cannula-wall electrode **272** in FIG. **9b** 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.

FIG. **10** is a partial longitudinal view of an infusion cannula **130** in accordance with yet another embodiment of the present invention.

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

14

input end's electrically connective regions **121a**, **121b**, and **121c**, 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.

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 **121a** and **121c** are adjacent to each other, the two can still be electrically insulated from each other. The electrically connective region **121b** may be a conductive rubber strip or a conductive ball or the like, and is not specifically limited herein.

In the embodiment of the present invention, the conductive-area electrode **371** is a working electrode, and the cannula-wall electrode **372** and the cannula-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.

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.

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.

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.

FIG. **11** is a partial longitudinal view of an infusion cannula **130** in accordance with yet another embodiment of the present invention. For ease of marking and description,

15

the wall of the hose **180** in FIG. **11** is shown separated from the outer wall of the infusion steel needle **170**.

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.

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**.

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 **121c** 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.

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. **11**. Generally, the infusion steel needle **170** has a greater hardness than the hose **180**. As shown in FIG. **11**, in the range of the subcutaneous portion **13**, the depth of the hose **180** into the skin is  $d_1$ , and the depth of the infusion steel needle **170** into the skin is  $d_2$ ,  $d_1 \leq d_2$ . This design enables the infusion cannula **130** to penetrate the skin smoothly.

FIG. **12a**-FIG. **12c** are partial longitudinal views of an infusion cannula **130** in accordance with yet another embodiment of the present invention. FIG. **12a** is a longitudinal view of the infusion cannula **130**, and FIG. **12b** and FIG. **12c** are transverse views of the infusion cannula **130**.

Please refer to FIG. **12a** and FIG. **12b**. FIG. **12b** is a schematic view of the infusion cannula **130** of FIG. **12a**.

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**, respec-

16

tively. 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 **121a** and **121b**, 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**.

Referring to FIG. **12c**, 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.

Referring to FIG. **13**, signals are transmitted between the remote device **200** and the bilaterally driven integrated medical device **100**.

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.

In some embodiments of the invention, the bilaterally driven integrated medical device **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.

In summary, the present invention discloses a bilaterally driven integrated medical device 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.

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.

The invention claimed is:

1. A bilaterally driven integrated medical device, comprising:

an infusion unit, including:

at least one drug storage unit;

a screw connected to a piston and a driving wheel provided with wheel teeth, respectively, the driving wheel drives the screw to move by rotation,

17

- pushing the piston, provided in the at least one drug storage unit, forward;
- a driving unit cooperating with the driving wheel, the driving unit includes at least two driving portions, driving unit pivots, around a pivot shaft, in different multiple pivot modes, thus driving the at least two driving portions, in different directions, to push the wheel teeth to rotate the driving wheel;
  - a power unit connected to the driving unit, the power unit outputs two forces in different directions on the driving unit, making the driving unit have the multiple pivot modes;
  - a program unit comprising 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 power unit, according to a received signal of the analyte data in the body fluid, the program unit controls the pivot modes of the driving unit to implement whether the infusion unit delivers a drug;
  - 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 drug is 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,
- wherein the cannula-wall electrode is located on an outer surface of the infusion cannula wall or in the wall of the infusion cannula,
- 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.
2. The bilaterally driven integrated medical device of claim 1, 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.
  3. The bilaterally driven integrated medical device of claim 2, 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.
  4. The bilaterally driven integrated medical device of claim 1, wherein:

18

- 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 drug.
5. The bilaterally driven integrated medical device of claim 4, wherein:
    - when the infusion cannula is installed to the working position, a depth of the hose into the skin is  $d_1$ , while a depth of the infusion steel needle into a skin is  $d_2$ ,  $d_1 \leq d_2$ .
  6. The bilaterally driven integrated medical device of claim 5, 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.
  7. The bilaterally driven integrated medical device of claim 6, 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.
  8. The bilaterally driven integrated medical device of claim 7, 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.
  9. The bilaterally driven integrated medical device of claim 6, 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.
  10. The bilaterally driven integrated medical device of claim 9, wherein:
    - the conductive-area electrode is the working electrode or the auxiliary electrode.
  11. The bilaterally driven integrated medical device of claim 10, 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.
  12. The bilaterally driven integrated medical device of claim 11, 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.
  13. The bilaterally driven integrated medical device of claim 9, wherein:
    - the auxiliary electrode is a counter electrode, or the auxiliary electrode includes the counter electrode and a reference electrode.
  14. The bilaterally driven integrated medical device 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.

15. The bilaterally driven integrated medical device 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 drug. 5

16. The bilaterally driven integrated medical device of claim 1, wherein:

the bilaterally driven integrated medical device 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. 10

17. The bilaterally driven integrated medical device of claim 1, wherein: 15

the pivot modes of the driving unit include multiple pivot amplitudes or multiple pivot rates, and the multiple different pivot modes include the multiple different pivot amplitudes or pivot rates.

18. The bilaterally driven integrated medical device of claim 1, wherein: 20

the driving wheel includes at least two sub-wheels, the pivot shaft is disposed between the at least two sub-wheels, one or more of the at least two driving portions are provided on both sides of the driving unit, and each sub-wheel is cooperated with each driving portion. 25

19. The bilaterally driven integrated medical device of claim 18, wherein:

the at least two driving portions are respectively provided on the both sides of the driving unit, and the at least two driving portions on one side of the driving unit are disposed up and down or left and right. 30

\* \* \* \* \*