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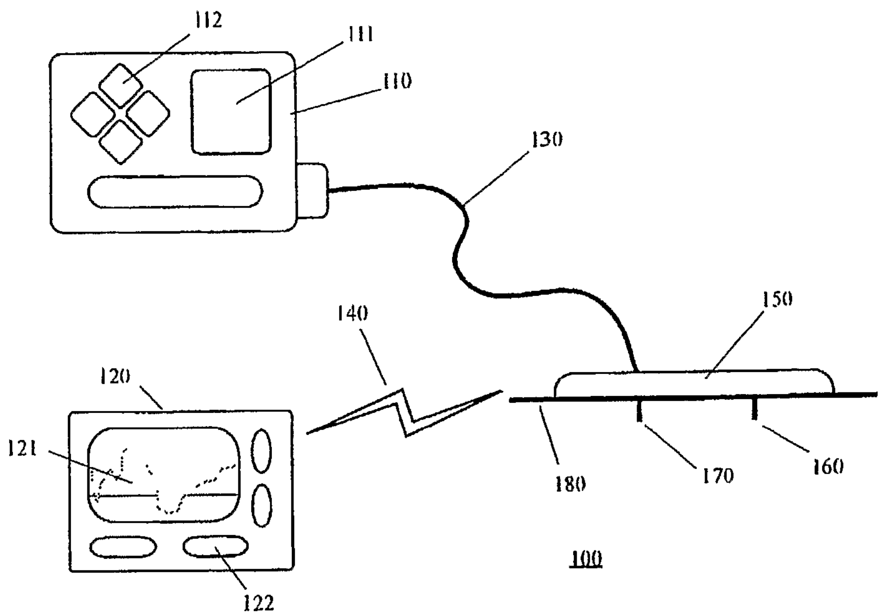
(54) Title: METHOD AND SYSTEM FOR PROVIDING INTEGRATED MEDICATION INFUSION AND ANALYTE MONITORING SYSTEM



(57) Abstract: Method and system for integrating infusion device and analyte monitoring system including medication infusion device such as an insulin pump and an analyte monitoring system such as a glucose monitoring system are provided.

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METHOD AND SYSTEM FOR PROVIDING INTEGRATED MEDICATION INFUSION AND ANALYTE MONITORING SYSTEM

FIELD OF THE INVENTION

The present invention relates to methods and systems for integrating infusion systems and analyte monitoring systems. More specifically, the present invention relates to methods and systems for integrating insulin infusion devices with continuous analyte monitoring systems.

BACKGROUND OF THE INVENTION

Type 1 diabetics must periodically be administered with insulin to sustain their physiological conditions. Typically, these patients administer doses of either fast acting or slow acting insulin using needle type syringes, for example, prior to meals, and/or at a suitable time during the course of each day contemporaneously with the blood glucose level testing using fingerstick testing, for example. If insulin is not suitably administered, the diabetic patients risk serious if not fatal damage to the body.

Continued development and improvement in the external infusion pump therapy in recent years have drawn much appeal to the diabetic patients for, among others, improved management of diabetes by better regulating and controlling the intake of insulin. Typically, the patient inserts a cannula which is connected to as infusion tubing attached to an external pump, and insulin is administered based on a preprogrammed basal profiles. Moreover, the external infusion devices presently available include computational capability to determined suitable bolus doses such as carbohydrate bolus and correction bolus, for example, to be administered in conjunction with the infusion device executing the patient's basal profile.

The basal profiles are generally determined by the patients' physician or caretaker and are based on a number of factors including the patient's insulin sensitivity and physiological condition which are diagnosed by the patient's physician, for example, and are typically intended to as accurately estimate the patient's glucose levels over a predetermined time period during which the patient is infusing insulin. The glucose levels may be estimated based on the patient's periodic discrete testing using a test strip and a blood glucose meter such as Freestyle® Glucose Meter available from Abbott

Diabetes Care, Inc., of Alameda, California. Such estimations are, however, prone to error, and do not accurately mirror the patient's actual physiological condition.

SUMMARY OF THE INVENTION

In view of the foregoing, it would be desirable to have an integrated system combining the functionalities of an infusion device such as insulin infusion pumps, and analyte monitoring systems such as continuous glucose monitoring systems.

These and other objects, features and advantages of the present invention will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 illustrates an integrated infusion device and analyte monitoring system in accordance with one embodiment of the present invention;

FIG. 2 illustrates an integrated infusion device and analyte monitoring system in accordance with another embodiment of the present invention;

FIG. 3 illustrates an integrated infusion device and analyte monitoring system in accordance with yet another embodiment of the present invention;

FIG. 4 illustrates an integrated infusion device and analyte monitoring system in accordance with still another embodiment of the present invention;

FIG. 5 illustrates an integrated infusion device and analyte monitoring system in accordance with still a further embodiment of the present invention;

FIG. 6 illustrates an integrated infusion device and monitoring system in accordance with yet still a further embodiment embodiment of the present invention;

FIG. 7A illustrates the integrated infusion device and monitoring system shown in FIGS. 6 in further detail in one embodiment of the present invention, while FIGS. 7A-7B illustrate the analog front end circuitry located at the patient interface and the pump assembly, respectively, of the integrated infusion device and monitoring system shown in FIG. 7A in accordance with one embodiment of the present invention;

FIGS. 8A-8C illustrate a passive sensor configuration for use in a continuous analyte monitoring system, and two embodiments of an active sensor configuration for use at the patient interface in the integrated infusion device and monitoring system, respectively, in accordance with one embodiment of the present invention;

FIG. 9 illustrates an integrated infusion device and analyte monitoring system with the infusion device and the monitoring system transmitter integrated into a single patch worn by the patient in accordance with one embodiment of the present invention;

FIG. 10 is a detailed view of the infusion device cannula integrated with analyte monitoring system sensor electrodes in accordance with one embodiment of the present invention;

FIG. 11A illustrates a component perspective view of the infusion device cannula integrated with analyte monitoring system sensor electrodes in accordance with another embodiment of the present invention, while FIG. 11B illustrates a top planar view of the analyte monitoring system transmitter unit integrated with infusion device in accordance with one embodiment of the present invention;

FIG. 12A-12C each illustrate a cross sectional view of the infusion device cannula integrated with continuous analyte monitoring system sensor electrodes of FIG. 10 in accordance with the various embodiments respectively, of the present invention; and

FIG. 13 is a timing chart for illustrating the temporal spacing of blood glucose measurement and insulin delivery by the integrated infusion device and monitoring system in one embodiment.

DETAILED DESCRIPTION

FIG. 1 illustrates an integrated infusion device and analyte monitoring system in accordance with one embodiment of the present invention. Referring to FIG. 1, the integrated infusion device and analyte monitoring system 100 in one embodiment of the present invention includes an infusion device 110 connected to an infusion tubing 130 for liquid transport or infusion, and which is further coupled to a cannula 170. As can be seen from FIG. 1, the cannula 170 is configured to be mountably coupled to a transmitter unit 150, where the transmitter unit 150 is also mountably coupled to an analyte sensor 160. Also provided is an analyte monitor unit 120 which is configured to wirelessly communicate with the transmitter unit over a communication path 140.

Referring to FIG. 1, in one embodiment of the present invention, the transmitter unit 150 is configured for unidirectional wireless communication over the communication path 140 to the analyte monitor unit 120. In one embodiment, the analyte monitor unit 120 may be configured to include a transceiver unit (not shown) for bidirectional communication over the communication path 140. The transmitter unit 150 in one embodiment may be configured to periodically and/or intermittently transmit signals associated with analyte levels detected by the analyte sensor 160 to the analyte monitor unit 120. The analyte monitor unit 120 may be configured to receive the signals from the transmitter unit 150 and in one embodiment, is configured to perform data storage and processing based on one or more preprogrammed or predetermined processes.

For example, in one embodiment, the analyte monitor unit 120 is configured to store the received signals associated with analyte levels in a data storage unit (not shown). Alternatively, or in addition, the analyte monitor unit 120 may be configured to process the signals associated with the analyte levels to generate trend indication by, for example, visual display of a line chart or an angular icon based display for output display on its display unit 121. Additional information may be output displayed on the display unit 121 of the analyte monitor unit 120 including, but not limited to, the substantially contemporaneous and real time analyte level of the patient received from the transmitter unit 150 as detected by the sensor 160. The real time analyte level may be displayed in a numeric format or in any other suitable format which provides the patient with the accurate measurement of the substantially real time analyte level detected by the sensor 160.

Additional analytes that may be monitored or determined by the sensor 160 include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be determined.

Referring back to FIG. 1, the sensor 160 may include a short term (for example, 3 day, 5 day or 7 day use) analyte sensor which is replaced after its intended useful life. Moreover, in one embodiment, the sensor 160 is configured to be positioned subcutaneous to the skin of the patient such that at least a portion of the analyte sensor is maintained in fluid contact with the patient's analyte such as, for example, interstitial fluid or blood. In addition, the cannula 170 which is configured to similarly be positioned under the patient's skin is connected to the infusion tubing 130 of the infusion device 110 so as to deliver medication such as insulin to the patient. Moreover, in one embodiment, the cannula 170 is configured to be replaced with the replacement of the sensor 160.

In one aspect of the present invention, the cannula 170 and the sensor 160 may be configured to be subcutaneously positioned under the skin of the patient using an insertion mechanism (not shown) such as an insertion gun which may include, for example, a spring biased or loaded insertion mechanism to substantially accurately position the cannula 170 and the sensor 160 under the patient's skin. In this manner, the cannula 170 and the sensor 160 maybe subcutaneously positioned with substantially little or no perceived pain by the patient. Alternatively, the cannula 170 and/or the sensor 160 may be configured to be manually inserted by the patient through the patient's skin. After positioning the cannula 170 and the sensor 160, they maybe substantially firmly retained in position by an adhesive layer 180 which is configured to adhere to the skin of the patient for the duration of the time period during which the sensor 160 and the cannula 170 are subcutaneously positioned.

Moreover, in one embodiment, the transmitter unit 150 may be mounted after the subcutaneous positioning of the sensor 160 and the cannula 150 so as to be in electrical contact with the sensor electrodes. Similarly, the infusion tubing 130 may be configured to operatively couple to the housing of the transmitter unit 150 so as to be in accurately positioned for alignment with the cannula 170 and to provide a substantially water tight seal. Additional detailed description of the analyte monitoring system including the sensor 160, transmitter unit 150 and the analyte monitor unit 120 is provided in U.S. Patent No. 6,175,752, assigned to the assignee of the present invention, Abbott Diabetes Care, Inc.

Referring back to FIG. 1, the infusion device 110 may include capabilities to program basal profiles, calculation of bolus doses including, but not limited to correction bolus, carbohydrate bolus, extended bolus, and dual bolus, which maybe performed by the patient using the infusion device 110, and maybe based on one or more factors including the patient's insulin sensitivity, insulin on board, intended carbohydrate intake (for example, for the carbohydrate bolus calculation prior to a meal), the patient's measured or detected glucose level, and the patient's glucose trend information. In a further embodiment, the bolus calculation capabilities may also be provided in the analyte monitor unit 120.

In one embodiment, the analyte monitor unit 120 is configured with a substantially compact housing that can be easily carried by the patient. In addition, the infusion device 110 similarly may be configured as a substantially compact device which can be easily and conveniently worn on the patient's clothing (for example, housed in a holster or a carrying device worn or clipped to the patient's belt or other parts of the clothing). Referring yet again to FIG. 1, the analyte monitor unit 120 and/or the infusion device 110 may include a user interface such as information input mechanism by the patient as well as data output including, for example, the display unit 121 on the analyte monitor unit 120, or similarly a display unit 111 on the infusion device 110.

One or more audio output devices such as, for example, speakers or buzzers may be integrated with the housing of the infusion device 110 and/or the analyte monitor unit

120 so as to output audible alerts or alarms based on the occurrence of one or more predetermined conditions associated with the infusion device 110 or the analyte monitor unit 120. For example, the infusion device 110 may be configured to output an audible alarm or alert to the patient upon detection of an occlusion in the infusion tubing 130 or the occurrence of a timed event such as a reminder to prime the infusion tubing upon replacement of the cannula 170, and the like. The analyte monitor unit 120 may be similarly be configured to output an audible alarm or alert when a predetermined condition or a pre-programmed event occurs, such as, for example, a reminder to replace the sensor 160 after its useful life (of 3 days, 5 days or 7 days), or one or more alerts associated with the data received from the transmitter unit 150 corresponding to the patient's monitored analyte levels. Such alerts or alarms may include a warning alert to the patient that the detected analyte level is beyond a predetermined threshold level, or the trend of the detected analyte levels within a given time period is indicative of a significant condition such as potential hyperglycemia or hypoglycemia, which require attention or corrective action. It is to be noted that the examples of audible alarms and/or alerts are described above for illustrative purposes only, that within the scope of the present invention, other events or conditions may be programmed into the infusion device 110 or the analyte monitor unit 120 or both, so as to alert or notify the patient of the occurrence or the potential occurrence of such events or conditions.

In addition, within the scope of the present invention, audible alarms may be output alone, or in combination with one or more of a visual alert such as an output display on the display unit 111, 121 of the infusion device 110 or the analyte monitor unit 120, respectively, or vibratory alert which would provide a tactile indication to the patient of the associated alarm and/or alert.

Moreover, referring yet again to FIG. 1, while one analyte monitor unit 120 and one transmitter unit 150 are shown, within the scope of the present invention, additional analyte monitor units or transmitter units may be provided such that, for example, the transmitter unit 150 may be configured to transmit to multiple analyte monitor units substantially simultaneously. Alternatively, multiple transmitter units coupled to multiple sensors concurrently in fluid contact with the patient's analyte may be configured to transmit to the analyte monitor unit 120, or to multiple analyte monitor units. For example, an additional transmitter unit coupled to an additional sensor may be provided in the integrated infusion device and analyte monitoring system 100 which does not include the cannula 170, and which may be used to perform functions associated with the sensor 160 such as sensor calibration, sensor data verification, and the like.

In one embodiment, the transmitter unit 150 is configured to transmit the sampled data signals received from the sensor 160 without acknowledgement from the analyte monitor unit 120 that the transmitted sampled data signals have been received. For example, the transmitter unit 150 may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the analyte monitor unit 120 may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the transmitter unit 150 and the analyte monitor unit 120 may be configured for bi-directional communication over the communication path 140.

Additionally, in one aspect, the analyte monitor unit 120 may include two sections. The first section of the analyte monitor unit 120 may include an analog interface section that is configured to communicate with the transmitter unit 150 via the communication path 140. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the transmitter unit 150, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the analyte monitor unit 120 may include a data processing section which is configured to process the data signals received from the transmitter unit 150 such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery, for example.

In operation, upon completing the power-on procedure, the analyte monitor unit 120 is configured to detect the presence of the transmitter unit 150 within its range based on, for example, the strength of the detected data signals received from the transmitter unit 150 or a predetermined transmitter identification information. Upon successful synchronization with the transmitter unit 150, the analyte monitor unit 120 is configured to begin receiving from the transmitter unit 150 data signals corresponding to the patient's detected analyte, for example glucose, levels.

Referring again to FIG. 1, the analyte monitor unit 120 or the infusion device 110, or both may be configured to further communicate with a data processing terminal (not shown) which may include a desktop computer terminal, a data communication enabled kiosk, a laptop computer, a handheld computing device such as a personal digital assistant (PDAs), or a data communication enabled mobile telephone, and the like, each of which may be configured for data communication via a wired or a wireless connection. The data processing terminal for example may include physician's terminal and/or a bedside terminal in a hospital environment, for example.

The communication path 140 for data communication between the transmitter unit 150 and the analyte monitor unit 120 of FIG. 1 may include an RF communication link, Bluetooth communication link, infrared communication link, or any other type of suitable wireless communication connection between two or more electronic devices. The data communication link may also include a wired cable connection such as, for example, but not limited to an RS232 connection, USB connection, or serial cable connection.

Referring yet again to FIG. 1, in a further aspect of the present invention, the analyte monitor unit 120 or the infusion device 110 (or both) may also include a test strip port configured to receive a blood glucose test strip for discrete sampling of the patient's blood for glucose level determination. An example of the functionality of blood glucose test strip meter unit may be found in Freestyle® Blood Glucose Meter available from the assignee of the present invention, Abbott Diabetes Care, Inc.

In the manner described above, in one embodiment of the present invention, the cannula 170 for infusing insulin or other suitable medication is integrated with the adhesive patch 180 for the sensor 160 and the transmitter unit 150 of the analyte monitoring system. Accordingly, only one on-skin patch can be worn by the patient (for example, on the skin of the abdomen) rather than two separate patches for the infusion device cannula 170, and the analyte monitoring system sensor 160 (with the transmitter unit 150). Thus, the Type-1 diabetic patient may conveniently implement infusion therapy in conjunction with real time glucose monitoring while minimizing potential skin irritation on the adhesive patch 180 site on the patient's skin, and thus provide more insertion sites with less irritation.

In addition, the integrated infusion device and analyte monitoring system 100 as shown in FIG. 1 maybe configured such that the infusion tubing 130 may be disconnected from the infusion device 110 as well as from the housing of the transmitter 150 (or the adhesive patch 180) such that, optionally, the patient may configure the system as continuous analyte monitoring system while disabling the infusion device 110 functionality.

Moreover, in accordance with one embodiment of the present invention, the patient may better manage the physiological conditions associated with diabetes by having substantially continuous real time glucose data, trend information based on the substantially continuous real time glucose data, and accordingly, modify or adjust the infusion levels delivered by the infusion device 110 from the pre-programmed basal profiles that the infusion device 110 is configured to implement.

FIG. 2 illustrates an integrated infusion device and analyte monitoring system in accordance with another embodiment of the present invention. Referring to FIG. 2, the integrated infusion device and analyte monitoring system 200 in one embodiment of the present invention includes an integrated infusion device and analyte monitor unit 210 which is coupled to an infusion tubing 220 connected to the cannula 260. Also shown in FIG. 2 is a transmitter unit 240 which is in electrical contact with an analyte sensor 250, where the cannula 260 and the analyte sensor 250 are subcutaneously positioned under the skin of the patient, and retained in position by an adhesive layer or patch 270.

Referring to FIG. 2, the integrated infusion device and analyte monitor unit 210 is configured to wirelessly communicate with the transmitter unit 240 over a communication path 230 such as an RF communication link. Compared with the embodiment shown in FIG. 1, it can be seen that in the embodiment shown in FIG. 2, the infusion device and the analyte monitor are integrated into a single housing 210. In this manner, the transmitter unit 240 may be configured to transmit signals corresponding to the detected analyte levels received from the analyte sensor 250 to the integrated infusion device and analyte monitor unit 210 for data analysis and processing.

Accordingly, the patient may conveniently receive real time glucose levels from the transmitter unit 240 and accordingly, determine whether to modify the existing basal profile(s) in accordance with which insulin is delivered to the patient. In this manner, the functionalities of the analyte monitor unit may be integrated within the compact housing of the infusion device to provide additional convenience to the patient by, for example, by providing the real time glucose data as well as other relevant information such as glucose trend data to the user interface of the infusion device, so that the patient may readily and easily determine any suitable modification to the infusion rate of the insulin pump.

In one embodiment, the configurations of each component shown in FIG. 2 including the cannula 260, the analyte sensor 250, the transmitter unit 240, the adhesive layer 270, the communication path 230, as well as the infusion tubing 220 and the functionalities of the infusion device and the analyte monitor are substantially similar to the corresponding respective component as described above in conjunction with FIG. 1.

Accordingly, in one embodiment of the present invention, the additional convenience may be provided to the patient in maintaining and enhancing diabetes management by, for example, having a single integrated device such as the integrated infusion device and analyte monitor unit 210 which would allow the patient to easily manipulate and manage insulin therapy using a single user interface system of the integrated infusion device and analyte monitor unit 210. Indeed, by providing many of the information associated with the glucose levels and insulin infusion information in one device, the patient may be provided with the additional convenience in managing diabetes and improving insulin therapy.

FIG. 3 illustrates an integrated infusion device and analyte monitoring system in accordance with yet another embodiment of the present invention. Referring to FIG. 3, the integrated infusion device and analyte monitoring system 300 in one embodiment of the present invention includes an infusion device 310 connected to an infusion tubing 340 coupled to a cannula 370. The cannula 380 is configured to be positioned subcutaneously under the patient's skin and substantially retained in position by and adhesive layer 380. Also retained in position, as discussed above and similar to the embodiments described in conjunction with FIGS. 1-2, is an analyte sensor 360 also positioned subcutaneously under the patient's skin and maintained in fluid contact with the patient's analyte. A transmitter unit 350 is provided so as to be electrically coupled to the analyte sensor 360 electrodes. Also, as can be seen from FIG. 3, in one embodiment, the infusion tubing 340 is connected to the housing of the transmitter unit 350 so as to connect to the cannula 370 disposed under the patient's skin.

Referring to FIG. 3, also provided is an analyte monitor unit 320 configured to wirelessly communicate with the transmitter unit 350 to receive data therefrom associated with the analyte levels of the patient detected by the analyte sensor 360. Referring to FIG. 3, in one embodiment, the infusion device 310 does not include a user interface such as a display unit and/or an input unit such as buttons or a jog dial. Instead, the user interface and control mechanism is provided on the analyte monitoring unit 320 such that the analyte monitoring unit 320 is configured to wirelessly control the operation of the infusion device 310 and further, to suitably program the infusion device 310 to execute pre-programmed basal profile(s), and to otherwise control the functionality of the infusion device 310.

More specifically, all of the programming and control mechanism for the infusion device 310 is provided in the analyte monitoring unit 320 such that when the patient is wearing the infusion device 310, it may be worn discreetly under clothing near the infusion site on the patient's skin (such as abdomen), while still providing convenient access to the patient for controlling the infusion device 310 through the analyte monitoring unit 320.

In addition, in one embodiment, the configurations of each component shown in FIG. 3 including the cannula 380, the analyte sensor 360, the transmitter unit 350, the adhesive layer 380, the communication path 320, as well as the infusion tubing 340 and the functionalities of the infusion device and the analyte monitoring unit 320 are substantially similar to the corresponding respective component as described above in conjunction with FIG. 1. However, the infusion device 310 in the embodiment shown in FIG. 3 is configured with a transceiver or an equivalent communication mechanism to communicate with the analyte monitoring unit 320.

In this manner, in one embodiment of the present invention, configuration of the infusion device 310 without a user interface provides a smaller and lighter housing and configuration for the infusion device 310 which would enhance the comfort in wearing and/or carrying the infusion device 310 with the patient. Moreover, since the control and programming functions of the infusion device 310 is provided on the analyte monitoring unit 320, the patient may conveniently program and/or control the functions and operations of the infusion device 310 without being tethered to the infusion tubing 340 attached to the cannula 370 which is positioned under the patient's skin. In addition, since the programming and control of the infusion device 310 is remotely performed on the analyte monitoring unit 320, the infusion tubing 304 may be shorter and thus less cumbersome.

FIG. 4 illustrates an integrated infusion device and analyte monitoring system in accordance with still another embodiment of the present invention. Referring to FIG. 4, the integrated infusion device and analyte monitoring system 400 in one embodiment of the present invention includes an infusion device 410 configured to wirelessly communicate with an analyte monitoring unit 420 over a communication path 430 such as an RF (radio frequency) link. In addition, as can be further seen from FIG. 4, the infusion device 410 is connected to an infusion tubing 440 which has provided therein integral wires connected to the analyte sensor electrodes. As discussed in further detail below, the measured analyte levels of the patient is received by the infusion device 410 via the infusion tubing 440 and transmitted to the analyte monitoring unit 420 for further processing and analysis.

More specifically, referring to FIG. 4, the integrated infusion device and analyte monitoring system 400 includes a patch 450 provided with a cannula 470 and an analyte sensor 460. The cannula 470 is configured to deliver or infuse medication such as insulin from the infusion device 410 to the patient. That is, in one embodiment, the cannula 470 and the analyte sensor 460 are configured to be positioned subcutaneous to the patient's skin. The analyte sensor 460 is configured to be positioned to be in fluid contact with the patient's analyte.

In this manner, the analyte sensor 460 is electrically coupled to integral wires provided within the infusion tubing 440 so as to provide signals corresponding to the measured or detected analyte levels of the patient to the infusion device 410. In one embodiment, the infusion device 410 is configured to perform data analysis and storage, such that the infusion device 410 may be configured to display the real time measured glucose levels to the patient on it display unit 411. In addition to or alternatively, the infusion device 410 is configured to wirelessly transmit the received signals from the analyte sensor 460 to the analyte monitoring unit 420 for data analysis, display, and/or storage and the analyte monitoring unit 420 may be configured to remotely control the functions and features of the infusion device 410 providing additional user convenience and discreteness.

Referring back to FIG. 4, in one embodiment, the patch 450 may be configured to be substantially small without a transmitter unit mounted thereon, and provided with a relatively small surface area to be attached to the patient's skin. In this manner, the patient may be provided with added comfort in having a substantially compact housing mounted on the skin (attached with an adhesive layer, for example), to infuse medication such as insulin, and for continuous analyte monitoring with the analyte sensor 460.

FIG. 5 illustrates an integrated infusion device and analyte monitoring system in accordance with still a further embodiment of the present invention. As compared with the embodiment shown in FIG. 4, the integrated infusion device and analyte monitoring system 500 of FIG. 5 includes an integrated infusion device and analyte monitoring unit 510. Accordingly, one user interface is provided to the user including the display unit 511 and input buttons 512 provided on the housing of the integrated infusion device and analyte monitoring unit 510. Also shown in FIG. 5 are infusion tubing 520 with integral wires disposed therein and connected to an analyte sensor 540 electrodes in fluid contact with the patient's analyte. Moreover, as can be seen from FIG. 5, an adhesive patch 530 is provided to retain the subcutaneous position of a cannula 550 and the analyte sensor 540 in the desired positions under the patient's skin.

Optionally, the integrated infusion device and analyte monitoring unit 510 may be provided with wireless or wired communication capability so to communicate with a remote terminal such as a physician's computer terminal over a wireless communication path such as RF communication link, or over a cable connection such as a USB connection, for example. Referring back to FIG. 5, in one embodiment of the present invention, the diabetic patient using an infusion therapy is provided with less components to handle or manipulate further simplifying insulin therapy and glucose level monitoring and management.

FIG. 6 illustrates an integrated infusion device and monitoring system in accordance with yet still a further embodiment embodiment of the present invention.

Referring to FIG. 6, the integrated infusion device and analyte monitoring system 600 is provided with an infusion device without a user interface, and configured to wirelessly communicate with an analyte monitoring unit 620 over a communication path 630 such as an RF link. The infusion device 610 which may be provided in a compact housing since it does not incorporate the components associated with a user interface, is connected to an infusion tubing 640 having disposed therein integral wires correspondingly connected to the electrodes of analyte sensor 660 in fluid contact with the patient's analyte. In addition, the compact adhesive patch 650 in one embodiment is configured to retain cannula 670 and the analyte sensor 660 in the desired position under the skin of the patient.

Similar to the embodiment shown in FIG. 3, the analyte monitoring unit 620 is configured to control and program the infusion device 610 over the communication link 630. In this manner, the control and programming functions of the infusion device 610 may be remotely performed by the analyte monitoring unit 620, providing convenience to the patient.

FIG. 7A illustrates the integrated infusion device and monitoring system shown in FIGS. 6 in further detail in one embodiment of the present invention, while FIGS. 7A-7B illustrate the analog front end circuitry located at the patient interface and the pump assembly, respectively, of the integrated infusion device and monitoring system shown in FIG. 7A in accordance with one embodiment of the present invention. Referring to FIG. 7A, an infusion device 710 connected to an infusion tubing 720 with integral wires provided therein for connection to the electrodes of the analyte sensor is shown. The infusion tubing 720 is further connected to an adhesive patch 730 which is configured to retain cannula 750 and analyte sensor 740 in the desired subcutaneous position under the skin of the patient.

Referring to FIG. 7A, in one embodiment of the present invention, the infusion device 710 may be provided with a first analog front end circuitry unit 711, while the adhesive patch may be provided with a second analog front end circuitry unit 731. The integral wires from the analyte sensor 740 is configured to extend from the infusion device 710 to the adhesive layer 730 via the infusion tubing 720. Since the analyte sensor 740 in one embodiment is a passive component, the signals on the working electrode and the reference electrodes of the analyte sensors are subject to noise given the high impendence of the electrodes and the length of the integral wires (in excess of a few centimeters). The noise in turn may potentially adversely affect the signals on the working and reference electrodes which may distort the measured analyte levels detected by the analyte sensor 740.

Given the length of the integral wire which corresponds to the length of the infusion tubing 720, in one embodiment, the signals from the working and reference electrodes may be converted to low impedance signals to minimize adverse impact from the noise. Accordingly, the infusion device 710 may be provided with a first analog front end circuitry unit 711, while the adhesive patch 730 may be provided with a second analog front end circuitry unit 731 as discussed in further detail below in conjunction with FIGS. 7B and 7C.

Referring now to FIG. 7B, the second analog front end circuitry unit 731 disposed on the adhesive patch 730 on the patient's skin, in one embodiment includes an a trans-impedance amplifier (current to voltage converter or "I-to-V") 731A configured to convert the working electrode (W) current to a voltage (Vw), and to provide a guard signal (G), and a servo segment 731B to drive the counter electrode (C) voltage (Vc) based on the reference electrode (R) voltage. Also shown in FIG. 7B is a Low-Pass Filter (LPF) and gain stage 711A that follow each of the I-to-V and servo stages, and which is configured in one embodiment to drive an A/D (Analog-to-Digital) converter unit 711C whose results are read by a controller such as a central processing unit (CPU) 711D. The A/D converter unit 711C and the CPU 711D and other peripherals are maybe combined into a single integrated circuit (IC) known as a microcontroller (μC) such as the MSP430 product line.

Referring now to FIG. 7C, in one embodiment, the second analog front end circuitry unit 731 may be implemented by a pair of operational amplifiers (731A and 731B), four resistors (R1, R2, R3, Rf), and a bypass capacitor (Cb). The I-to-F stage using operational amplifier 731A is generated by the action of the input current from the working electrode (W) flowing through the feedback resistor (Rf) and creating a voltage differential that is driven by the operational amplifier 731A as the low impedance signal Vw. The offset for the Vw signal is established by the resistor divider comprised of R1, R2 and R3 which also creates the voltage of the guard signal (G) – a signal that is at the same potential or voltage as the working electrode (W).

The servo, using operational amplifier 731B, in one embodiment, drives the counter electrode (C) voltage to the sensor so that the reference electrode (R) is at the second value set by the resistor divider comprised of resistors R1, R2 and R3. This maintains the working electrode (W) voltage above the reference electrode (R) by a set amount known as the "Poise Voltage" (i.e 40mV). The bypass capacitor (Cb) may be a small, low equivalent series resistance (ESR) capacitor, such as a 0.1uF (100nF) multi-layer ceramic (MLC) capacitor, that acts to provide local energy and reduce noise on the circuit. The voltage source for this circuit may be provided by the potential difference between V+ and V- where, for example, V+ may be 5V and V- may be ground (GND) or V+ may be +3V and V- may be -3V.

In one embodiment, the operational amplifiers 731A, 731B may be acquired as a dual operational amplifier integrated circuit (IC) in a single, small 8-pin, surface mount technology (SMT) package such as the OPA2349 in a SOT23-8 package (3mm by 3mm). Similar dual operational amplifier products maybe available in even smaller ball-grid array (BGA) packages and as bare die that may be mounted directly to the circuit substrate, such as a printed circuit board (PCB) or flex circuit, using techniques such as "flip-chip" and wire-bond.

FIGS. 8A-8C illustrate a passive sensor configuration for use in a continuous analyte monitoring system, and two embodiments of an active sensor configuration for use at the patient interface in the integrated infusion device and monitoring system, respectively, in accordance with one embodiment of the present invention. Referring to FIG. 8A, analyte sensor 810 includes working electrode 811, a guard trace 812, a reference electrode 813, and a counter electrode 814. In one embodiment, the "tail" segment 815 of the analyte sensor 810 is configured to be positioned subcutaneously under the patient's skin so as to be in fluid contact with the patient.

Referring now to FIG. 8B, analyte sensor 820 is provided with the analog front end portion 821 where the four contacts shown are V+, V-, Vw, and Vc signals in accordance with one embodiment in place of the working electrode 811, a guard trace 812, a reference electrode 813, and a counter electrode 814, respectively. In this manner, in one embodiment of the present invention, these signals of the active analyte sensor 820 are low impedance and thus less subject to noise than the passive sensor signals. Moreover, in one embodiment, the analyte sensor 820 configuration may include a flex circuit.

Referring now to FIG. 8C, in a further embodiment, an active sensor of similar construction to the active sensor 820 of FIG. 11B but with much smaller dimensions is shown. More specifically, analyte sensor 830 is provided with four contacts configured for direct wire bonding rather than a mechanical contact system as indicated by the large contact areas on the previous two sensor configurations shown in FIGS. 8A-8B. Since the shape of the analyte sensor 830 is reduced, the sensor 830 may be wrapped around the cannula (for example, cannula 470 of FIG. 4) and thus only a single entry site may be required for the patient analyte monitoring and insulin infusion. Moreover, within the scope of the present invention, additional sensor/cannula configurations may be provided where the sensor circuitry and cannula are created as a single assembly such as a cannula with the circuit 831 fabricated on the surface.

FIG. 9 illustrates an integrated infusion device and analyte monitoring system with the infusion device and the monitoring system transmitter integrated into a single patch worn by the patient in accordance with one embodiment of the present invention. Referring to FIG. 9, the integrated infusion device and analyte monitoring system 900 includes an integrated patch pump and transmitter unit 910 provided on an adhesive layer 960, and which is configured to be placed on the skin of the patient, so as to securely position cannula 950 and analyte sensor 940 subcutaneously under the skin of the patient. The housing of the integrated infusion pump and transmitter unit 910 is configured in one embodiment to include the infusion mechanism to deliver medication such as insulin to the patient via the cannula 950.

In addition, the integrated patch pump and transmitter unit 910 is configured transmit signals associated with the detected analyte levels measured by the analyte sensor 940, over a wireless communication path 930 such as an RF link. The signals are transmitted from the on body integrated patch pump and transmitter unit 910 to a controller unit 920 which is configured to control the operation of the integrated patch pump and transmitter unit 910, as well as to receive the transmitted signals from the integrated patch pump and transmitter unit 910 which correspond to the detected analyte levels of the patient.

Referring back to FIG. 9, in one embodiment, the infusion mechanism of the integrated patch pump and transmitter unit 910 may includes the infusion device of the type described in US Patent No. 6,916,159 assigned to the assignee of the present invention Abbott Diabetes Care, Inc. In addition, while a wireless communication over the communication path 930 is shown in FIG. 9, the wireless communication path 930 may be replaced by a set of wires to provide a wired connection to the controller unit 920.

In this manner, in one embodiment of the present invention, the integrated infusion device and analyte monitoring system 900 does not use an infusion tubing which may provide additional comfort and convenience to the patient by providing additional freedom from having to wear a cumbersome tubing.

FIG. 10 is a detailed view of the infusion device cannula integrated with analyte monitoring system sensor electrodes in accordance with one embodiment of the present invention. Referring to FIG. 10, there is shown in infusion device cannula with analyte sensor electrodes 1020 disposed therein, and mounted to an adhesive patch 1010 so as to retain its position securely in the patient. More specifically, as can be seen from FIG. 10, the cannula with analyte sensor electrodes 1020 include sensor electrodes 1021, 1022, 1023 (which may correspond to working, reference and counter electrodes, respectively) each of which are provided within the cannula tip 1020, and further, positioned so as to maintain fluid contact with the patient's analyte.

FIG. 12A-12C each illustrate a cross sectional view of the infusion device cannula integrated with continuous analyte monitoring system sensor electrodes of FIG. 10 in accordance with the various embodiments respectively, of the present invention. Referring to FIG. 12A, in one embodiment, the wire and tubing are provided in parallel such that the tubing wall 1020, the tube bore for insulin flow 1024, the wire outer casing 1020 and the individual insulated wires 1021, 1022, 1023 are substantially provided as shown in FIG. 12A. More specifically, it can be seen from the Figure that each of the three insulated wires are provided with an insulation layer 1020 of tubing wall individually surrounding each insulated wires 1021, 1022, 1023, and further, where the three insulated wires 1021, 1022, 1023 are in turn surrounded by the tubing wall 1020.

Referring now to FIG. 12B in one embodiment of the present invention, the insulated wires 1021, 1022, 1023 respectively connected to the sensor electrodes are co-extruded into tubing wall 1020, with the tube bore 1024 for insulin delivery and the insulated wires 1021, 1022, 1023 configured substantially as shown in the FIG 12B. Referring now to FIG. 12C, in still a further embodiment of the present invention, each of the insulated wires 1021, 1022, 1023 are wrapped around the tubing 1020 and covered with a sheath 1210, thus providing the tubing wall 1020, the tubing bore 1024 for insulin delivery, the individual insulated wires 1021, 1022, 1023, and the outer protective sheath 1210, which may also serve as an electromagnetic shield to eliminate electronic noise as substantially shown in the Figure.

Referring again to the Figures, the embodiments shown in FIGS. 12A and 12C may have larger cross-sectional area (thus a larger hole needed to be punctured on the skin of the patient), but are likely easier to manufacture, more reliable and easier to make connection to the analyte sensor electronics). Additionally, within the scope of the present invention, an optical data transmission (i.e. fiber optics) along insulin delivery tubing between sensor and pump may be provided instead of integral wires as discussed above.

FIG. 11A illustrates a component perspective view of the infusion device cannula integrated with analyte monitoring system sensor electrodes in accordance with another embodiment of the present invention, while FIG. 11B illustrates a top planar view of the analyte monitoring system transmitter unit integrated with infusion device in accordance with one embodiment of the present invention. Referring to FIGS. 11A-11B, in one embodiment of the present invention, integrated analyte sensor and infusion device cannula 1100 comprises five laminated layers including a top insulation layer 1101, a conductive layer 1102 with electrode traces disposed thereon, followed by three layer substrate with integrated infusion cannula 1103.

In one embodiment, the three layer substrate with integrated infusion cannula 1103 includes a separation/insulation layer 1103A to insulate the sensor electrodes from the infusion cannula, a channel layer 1103B configured to guide the flow of the insulin or any other suitable medication, and an inlet/outlet layer 1103C. Also shown in FIG. 11A is an assembled view of the integrated analyte sensor and infusion device cannula 1100.

Referring now to FIG. 11B, it can be seen that a patch pump as shown in one embodiment is provided with a transmitter unit 1110 and an insulin pump 1130 coupled to insulin reservoir 1120, and operatively coupled or mounted to the transmitter unit 1110. Also shown in FIG. 11B is the analyte sensor contacts 1140 which are configured to establish electrical contact with the respective electrodes of the integrated infusion cannula and analyte sensor 1100. Also shown in FIG. 11B is insulin port 1150 which is connected to the channel layer 1103B of the integrated infusion device cannula and analyte sensor 1100.

In this manner, in one embodiment of the present invention, the patch pump may be worn by the patient on skin and which includes the insulin infusion mechanism as well as the analyte sensor and transmitter unit.

FIG. 13 is a timing chart for illustrating the temporal spacing of blood glucose measurement and insulin delivery by the integrated infusion device and monitoring system in one embodiment. More specifically, insulin pumps typically deliver insulin in a periodic manner with the period of delivery in the range of 2 to 3 minutes and the duration of delivery at each period being on the order of a few seconds or less. The amount of insulin that is delivered each period may be varied depending on the overall insulin delivery rate that is desired. The analyte data is collected continuously (as, for example, a continuous current of glucose oxidation) but is typically reported to the user periodically. The analyte reporting period is typically 1 to 10 minutes and glucose oxidation current needs to be collected for 10 to 30 seconds in order to generate a reportable glucose value (to allow for filtering etc.).

Indeed, the integration of analyte monitoring and insulin delivery may necessitate placement of a analyte sensor in close proximity to an insulin infusion cannula on the body. Such close proximity engenders the possibility of insulin delivery interfering with the analyte measurements. For example, if insulin infusion should result in a localized decrease in the glucose concentration in the area of the body near the infusion site, then glucose measurement in this area would not be representative of the glucose concentration in the body as a whole. Accordingly, in one embodiment of the present invention, there is provided a method for temporal spacing of blood glucose measurements and insulin delivery to mitigate the possible interference between insulin infusion and glucose measurements.

In accordance with one embodiment, the temporal spacing of analyte measurement and insulin delivery may include providing as large a temporal gap from after insulin delivery and before taking a analyte measurement. Since both analyte measurement and insulin delivery are performed periodically, a maximum spacing in time may be achieved if analyte measurement substantially immediately precedes insulin delivery. During the time between insulin delivery and the subsequent glucose measurement, infused insulin has time to diffuse and be transported away from the infusion site due to normal circulation of interstitial fluid. An example timeline of temporally spaced analyte measurement and insulin delivery is shown in FIG. 13. If multiple analyte measurements are taken between insulin delivery points, there should always be a reading just prior to insulin delivery and as well just after insulin delivery to minimize the affect of injected insulin on the glucose measurement readings.

Although readings are typically taken periodically for simplicity in processing, a reading may be taken out of time with other readings and scaled appropriately for the overall reading average. Similarly, the insulin delivery point may be delayed slightly until after the reading with little or no affect as the readings typically occur much more frequently than the infusions, which are intended to act over longer periods of time. In addition, other timing considerations may be considered depending on the environment in which the integrated infusion device and analyte monitoring system is used by the patient, within the scope of the present invention to minimize potential error on measured analyte levels and/or introduce noise or potential adverse effects to the infusion rates of the infusion device.

More specifically, fluctuation in the power supplies of the infusion device and/or the analyte monitoring system including, for example, batteries or related power distribution circuitry may introduce electrical noise effects which may adversely affect the measured readings associated with the analyte monitoring system. For example, when the analyte monitoring system is configured to be in an active state so as to be transmitting or receiving data, or when the pump cycle of the infusion device is active, the power supply may be affected by the load from the data transmission/reception, or the pumping cycle. The adverse effect of the power supply in addition to noise from other components of the electronic circuitry may introduce undesirable noise and adversely affect the accuracy of the analyte sensor measurements.

Accordingly, the transmitter unit 150 (FIG. 1) for example, may be configured to monitor the timing or occurrence of the measured analyte level received from the analyte sensor 160 and the data transmission timing of the transmitter unit 150 such that the two events do not substantially overlap or occur at the substantially the same time. Alternatively, the analyte monitor unit 120 (FIG. 1) may be configured to compare the timing of the analyte sensor 160 measurement and the timing of the data transmission from the transmitter unit 150, and to discard data analyte related data received from the transmitter unit 150 which coincide with the timing of the analyte measurements by the analyte sensor 160.

Moreover in one embodiment, air bubble detection in the insulin tubing may be provided, by monitoring fluid motion that would also detect the absence of fluid such as that due to an air bubble in the line. In one embodiment, the flow sensor may be configured to generate zero current when an air bubble was present.

In addition, colorization of insulin may be provided for air bubble detection in the tubing. Since pharmaceutical insulin is a clear colorless liquid, it is difficult to visually discriminate between insulin and air in tubing that carries insulin from the insulin pump to the cannula. By providing a color tint to the insulin it would be much easier to visually identify air bubbles in the tubing and be able to remove them before they cause problems. An insulin tint in one embodiment is biocompatible and insulin compatible.

Accordingly, a system including an infusion device and an analyte monitoring unit in one embodiment of the present invention includes an infusion device, an on-body unit including a data transmission section, the on-body unit further coupled to the infusion device, the on-body unit configured to receive one or more signals corresponding to a respective one or more analyte levels, and further, the on-body unit configured to infuse a fluid received from the infusion device, and a receiver unit operatively coupled to the on-body unit, the receiver unit configured to receive data from the on-body unit, wherein the received data is associated with the analyte level.

The system may further include an analyte sensor at least a first portion of which is in fluid contact with an analyte of a patient, and further, where at a second portion of the analyte sensor is in signal communication with the data transmission section.

The data transmission section may in one embodiment be configured to transmit the one or more signals corresponding to a respective one or more analyte levels substantially periodically at one or more predetermined time intervals, where the one or more predetermined time intervals may include one or more of 30 seconds, one minute, or 90 seconds.

In one aspect, the on-body unit may include a cannula at least a portion of which is subcutaneously positioned under a skin layer, and further, may also include an infusion tubing connected to the infusion device to deliver the fluid to the on-body unit. The infusion tubing and the on-body unit in a further aspect may be connected in a substantially water tight seal.

In yet another embodiment, the infusion tubing may be configured to operatively couple to the cannula to deliver the fluid.

The on-body unit may be configured to wirelessly transmit the one or more signals corresponding to the respective one or more analyte levels to the receiver unit, where the on-body unit and the receiver maybe configured to wirelessly communicate over one or more of an RF communication link, a Bluetooth communication link, or an infrared communication link.

In addition, the infusion device in a further embodiment may be configured to control the delivery rate of the fluid based on the one or more signals corresponding to the respective one or more analyte levels received by the receiver unit, and further, where the infusion device may be configured to determine a modified delivery protocol for delivering fluid such as insulin based on information associated with the one or more signals corresponding to the respective one or more analyte levels.

In yet another aspect, the modified delivery protocol may include one or more of a correction bolus, a modified basal profile, a carbohydrate bolus, an extended bolus, or combinations thereof.

The receiver unit in one embodiment may be configured to wirelessly communicate with the infusion device.

In a further embodiment, the receiver unit maybe integrated into a housing of the infusion device.

A method of integrating analyte monitoring and fluid infusion in another embodiment of the present invention includes infusing a fluid at a predetermined delivery rate, detecting one or more analyte levels, transmitting one or more signals associated with the respective detected one or more analyte levels, and determining a modified delivery rate based on the transmitted one or more signals.

In one aspect, the one or more signals maybe transmitted substantially immediately after the associated respective one or more analyte levels are detected.

Moreover, the transmitting step in one embodiment may include wirelessly transmitting the one or more signals which wirelessly transmitted over one or more of an RF communication link, a Bluetooth communication link, an infrared communication link, or combinations thereof.

The method in a further aspect may also include the steps of receiving the transmitted one or more signals, and displaying the received one or more signals.

Moreover, the method may also include the step of displaying the modified delivery rate. In addition, the method may also include the step of implementing the modified delivery rate, where the predetermined delivery rate may include one or more basal delivery rates.

The modified delivery rate in a further embodiment may include one or more of a correction bolus, a modified basal profile, a carbohydrate bolus, an extended bolus, or combinations thereof.

An apparatus including an analyte sensor and a fluid delivery channel in yet another embodiment of the present invention includes a fluid delivery unit having an inner wall and an outer wall, and a plurality of electrodes disposed between the inner wall and the outer wall of the fluid delivery unit, where a portion of the of the fluid delivery unit and a portion of the plurality of electrodes are subcutaneously positioned under a skin layer.

In one aspect, the plurality of electrodes may comprise an analyte sensor, including, for example, one or more of a working electrode, a counter electrode, a reference electrode, or combinations thereof.

The fluid delivery unit may include a channel for delivering a fluid such as insulin, the channel substantially formed by the inner wall.

An apparatus including an analyte sensor and a fluid delivery channel in accordance with still another embodiment of the present invention includes a first tubing having a first tubing channel, and a second tubing having a second tubing channel including a plurality of electrodes disposed within the second tubing channel, where at least a portion of the first tubing and at least a portion of the second tubing are subcutaneously positioned under a skin layer.

In one embodiment, the plurality of the electrodes may be substantially and entirely insulated from each other.

In another embodiment, the first tubing and the second tubing may be integrally formed such that an outer surface of the first tubing is substantially in contact with an outer surface of the second tubing.

A system including an infusion device and an analyte monitoring unit in accordance with still another embodiment of the present invention includes an infusion and monitoring device, an on-body unit including a data transmission section, the on-body unit further coupled to the infusion and monitoring device, the on-body unit configured to receive one or more signals corresponding to a respective one or more analyte levels, and further, the on-body unit configured to infuse a fluid received from the infusion and monitoring device, and a connector coupled at a first end to the infusion device, and further, coupled at a second end to the on-body unit, the connector configured to channel the fluid from the infusion device to the on-body unit, and further, configured to provide the one or more signals corresponding to the respective one or more analyte levels to the infusion and monitoring device.

In one aspect, the infusion and monitoring device may be configured to execute fluid delivery to a patient, and further, to detect analyte levels of the patient over a predetermined time period.

In a further aspect, the infusion and monitoring device may include a continuous glucose monitoring system.

In still another aspect, the infusion and monitoring device may include an insulin pump.

A method of fluid delivery and analyte monitoring in accordance with still another embodiment of the present invention includes determining a delivery profile for fluid infusion, wherein the delivery profile including a plurality of predetermined discrete fluid infusion each temporally separated by a predetermined time period, and sampling an analyte level substantially immediately prior to each predetermined discrete fluid infusion.

The method may further include the step of sampling an analyte level substantially immediately after each predetermined discrete fluid infusion.

Various other modifications and alternations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments.

WHAT IS CLAIMED IS:

1. A system including an infusion device and an analyte monitoring unit, comprising:

an infusion device;

an on-body unit including a data transmission section, the on-body unit further coupled to the infusion device, the on-body unit configured to receive one or more signals corresponding to a respective one or more analyte levels, and further, the on-body unit configured to infuse a fluid received from the infusion device; and

a receiver unit operatively coupled to the on-body unit, the receiver unit configured to receive data from the on-body unit, wherein the received data is associated with the analyte level.

2. The system of claim1 further including an analyte sensor at least a first portion of which is in fluid contact with an analyte of a patient, and further, wherein at a second portion of the analyte sensor is in signal communication with the data transmission section.

3. The system of claim 1 wherein the data transmission section is configured to transmit the one or more signals corresponding to a respective one or more analyte levels substantially periodically at one or more predetermined time intervals.

4. The system of claim 3 wherein the one or more predetermined time intervals includes one or more of 30 seconds, one minute, or 90 seconds.

5. The system of claim 1 wherein the on-body unit includes a cannula at least a portion of which is subcutaneously positioned under a skin layer.

6. The system of claim 5 further including an infusion tubing connected to the infusion device to deliver the fluid to the on-body unit.

7. The system of claim 6 wherein the infusion tubing and the on-body unit are connected in a substantially water tight seal.

8. The system of claim 6 wherein the infusion tubing is configured to operatively couple to the cannula to deliver the fluid.

9. The system of claim 1 wherein the on-body unit is configured to wirelessly transmit the one or more signals corresponding to the respective one or more analyte levels to the receiver unit.

10. The system of claim 9 wherein the on-body unit and the receiver are configured to wirelessly communicate over one or more of an RF communication link, a Bluetooth communication link, or an infrared communication link.

11. The system of claim 1 wherein the infusion device is configured to control the delivery rate of the fluid based on the one or more signals corresponding to the respective one or more analyte levels received by the receiver unit.

12. The system of claim 11 wherein the infusion device is configured to determine a modified delivery protocol for delivering fluid based on information associated with the one or more signals corresponding to the respective one or more analyte levels.

13. The system of claim 12 wherein the fluid is insulin.

14. The system of claim 13 wherein the modified delivery protocol includes one or more of a correction bolus, a modified basal profile, a carbohydrate bolus, an extended bolus, or combinations thereof.

15. The system of claim 1 wherein the receiver unit is configured to wirelessly communicate with the infusion device.

16. The system of claim 1 wherein the receiver unit is integrated into a housing of the infusion device.

17. A method of integrating analyte monitoring and fluid infusion, comprising:

infusing a fluid at a predetermined delivery rate;

detecting one or more analyte levels;

transmitting one or more signals associated with the respective detected one or more analyte levels; and

determining a modified delivery rate based on the transmitted one or more signals.

18. The method of claim 17 wherein the fluid is insulin.

19. The method of claim 17 wherein the one or more signals are transmitted substantially immediately after the associated respective one or more analyte levels are detected.

20. The method of claim 17 wherein the transmitting step includes wirelessly transmitting the one or more signals.

21. The method of claim 20 wherein the one or more signals are wirelessly transmitted over one or more of an RF communication link, a Bluetooth communication link, an infrared communication link, or combinations thereof.

22. The method of claim 17 further including the steps of:

receiving the transmitted one or more signals; and

displaying the received one or more signals.

23. The method of claim 17 further including the step of displaying the modified delivery rate.

24. The method of claim 17 further including the step of implementing the modified delivery rate.

25. The method of claim 17 wherein the predetermined delivery rate includes one or more basal delivery rates.

26. The method of claim 17 wherein the modified delivery rate includes one or more of a correction bolus, a modified basal profile, a carbohydrate bolus, an extended bolus, or combinations thereof.

27. An apparatus including an analyte sensor and a fluid delivery channel, comprising:

a fluid delivery unit having an inner wall and an outer wall; and

a plurality of electrodes disposed between the inner wall and the outer wall of the fluid delivery unit;

wherein a portion of the of the fluid delivery unit and a portion of the plurality of electrodes are subcutaneously positioned under a skin layer.

28. The apparatus of claim 27 wherein the plurality of electrodes comprise an analyte sensor.

29. The apparatus of claim 27 wherein the plurality of electrodes include one or more of a working electrode, a counter electrode, a reference electrode, or combinations thereof.

30. The apparatus of claim 27 wherein the fluid delivery unit is including a channel for delivering a fluid, the channel substantially formed by the inner wall.

31. The apparatus of claim 30 wherein the fluid is insulin.

32. The apparatus of claim 27 wherein at least a portion of the plurality of electrodes is in fluid contact with an analyte.

33. An apparatus including an analyte sensor and a fluid delivery channel, comprising:

a first tubing having a first tubing channel; and

a second tubing having a second tubing channel including a plurality of electrodes disposed within the second tubing channel;

wherein at least a portion of the first tubing and at least a portion of the second tubing are subcutaneously positioned under a skin layer.

34. The apparatus of claim 33 wherein each of the plurality of the electrodes are substantially and entirely insulated from each other.

35. The apparatus of claim 33 wherein the first tubing and the second tubing are integrally formed such that an outer surface of the first tubing is substantially in contact with an outer surface of the second tubing.

36. The apparatus of claim 33 wherein the plurality of electrodes comprise an analyte sensor.

37. A system including an infusion device and an analyte monitoring unit, comprising:

an infusion and monitoring device;

an on-body unit including a data transmission section, the on-body unit further coupled to the infusion and monitoring device, the on-body unit configured to receive one or more signals corresponding to a respective one or more analyte levels, and further, the on-body unit configured to infuse a fluid received from the infusion and monitoring device; and

a connector coupled at a first end to the infusion device, and further, coupled at a second end to the on-body unit, the connector configured to channel the fluid from the infusion device to the on-body unit, and further, configured to provide the one or more signals corresponding to the respective one or more analyte levels to the infusion and monitoring device.

38. The system of claim 37 wherein the infusion and monitoring device is configured to execute fluid delivery to a patient, and further, to detect analyte levels of the patient over a predetermined time period.

39. The system of claim 37 wherein the infusion and monitoring device includes a continuous glucose monitoring system.

40. The system of claim 37 wherein the infusion and monitoring device includes an insulin pump.

41. A method of fluid delivery and analyte monitoring, comprising:

determining a delivery profile for fluid infusion, wherein the delivery profile including a plurality of predetermined discrete fluid infusion each temporally separated by a predetermined time period; and

sampling an analyte level substantially immediately prior to each predetermined discrete fluid infusion.

42. The method of claim 41 further including the step of sampling an analyte level substantially immediately after each predetermined discrete fluid infusion.

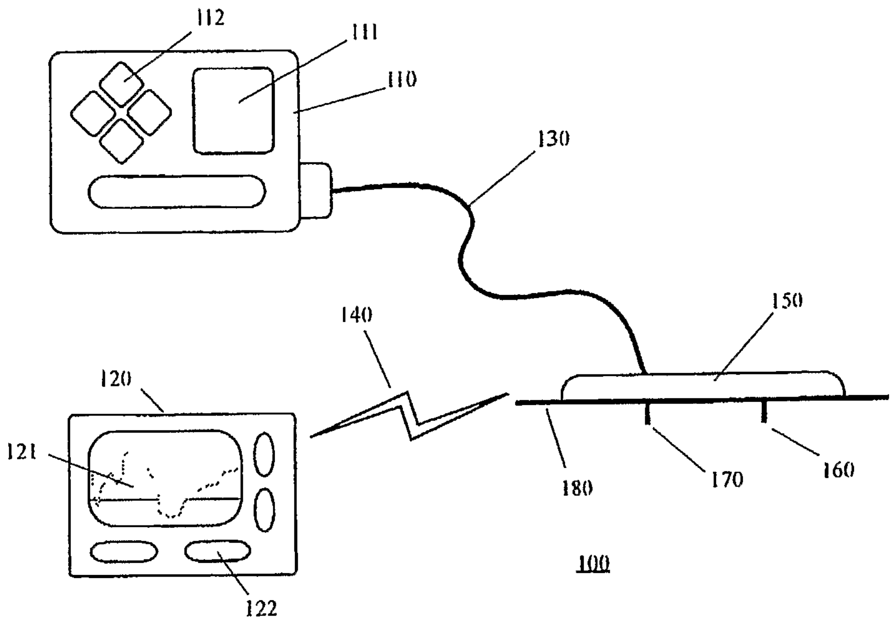


FIGURE 1

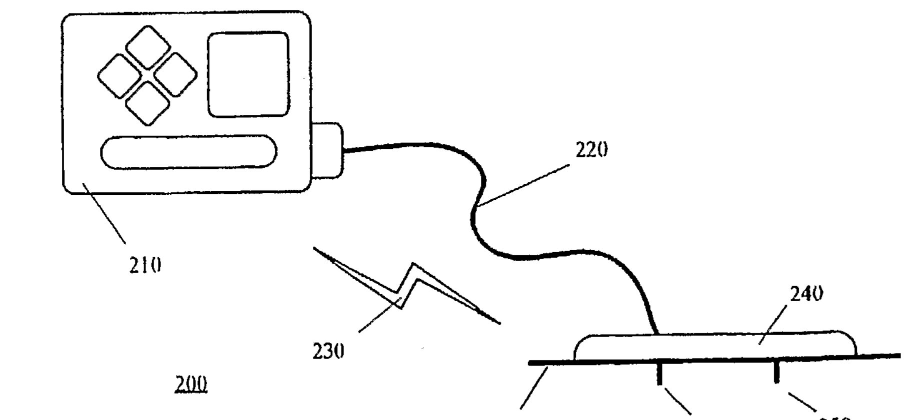


FIGURE 2

FIGURE 3

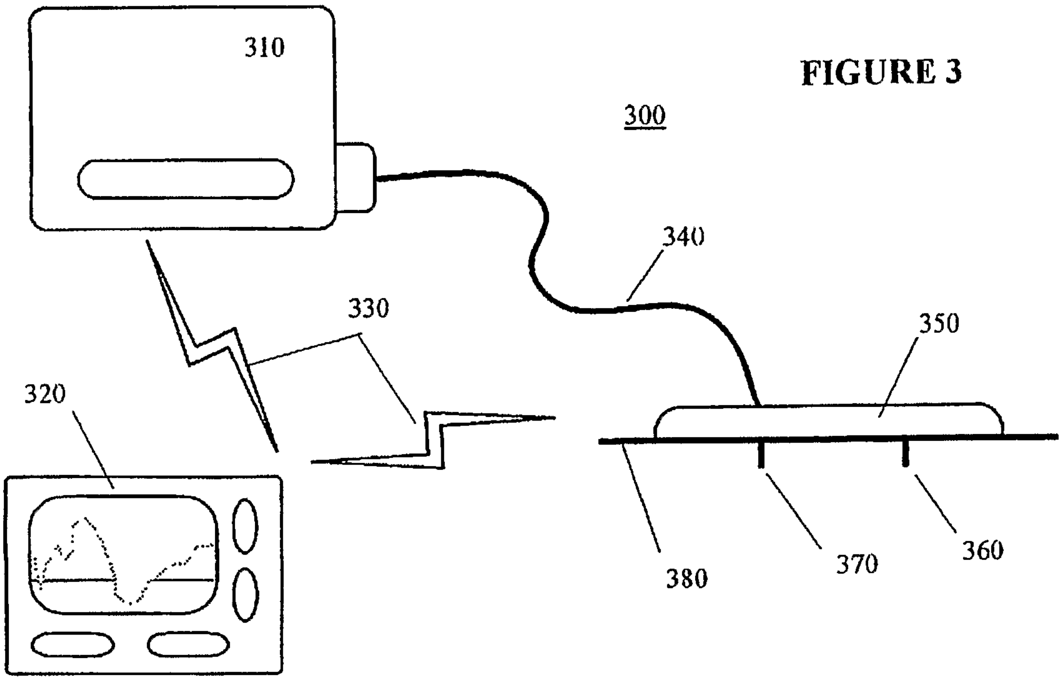
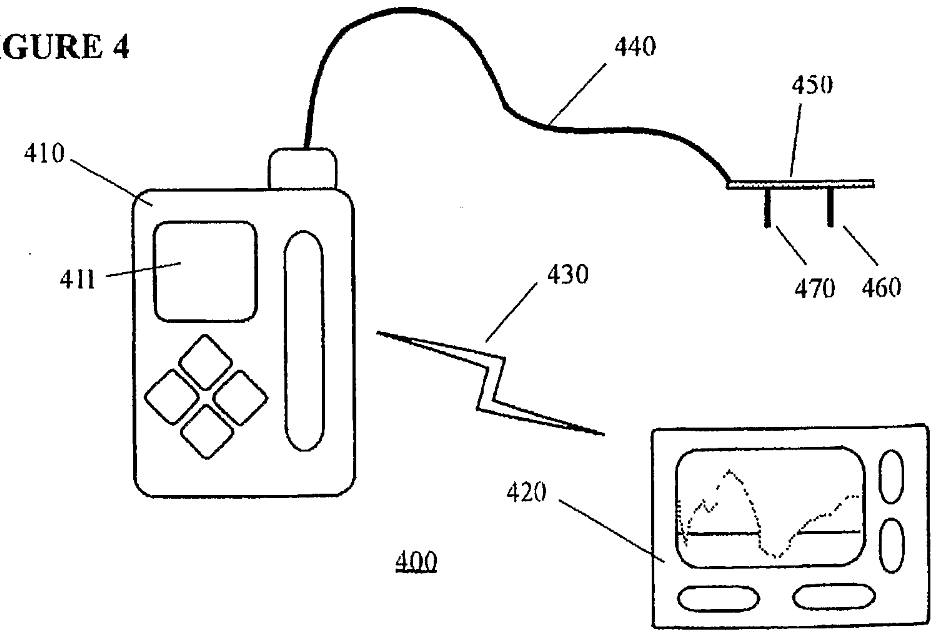


FIGURE 4



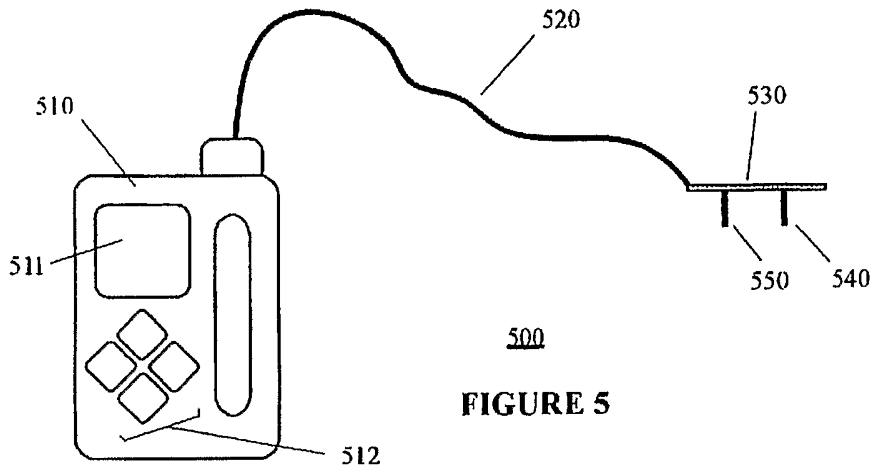


FIGURE 5

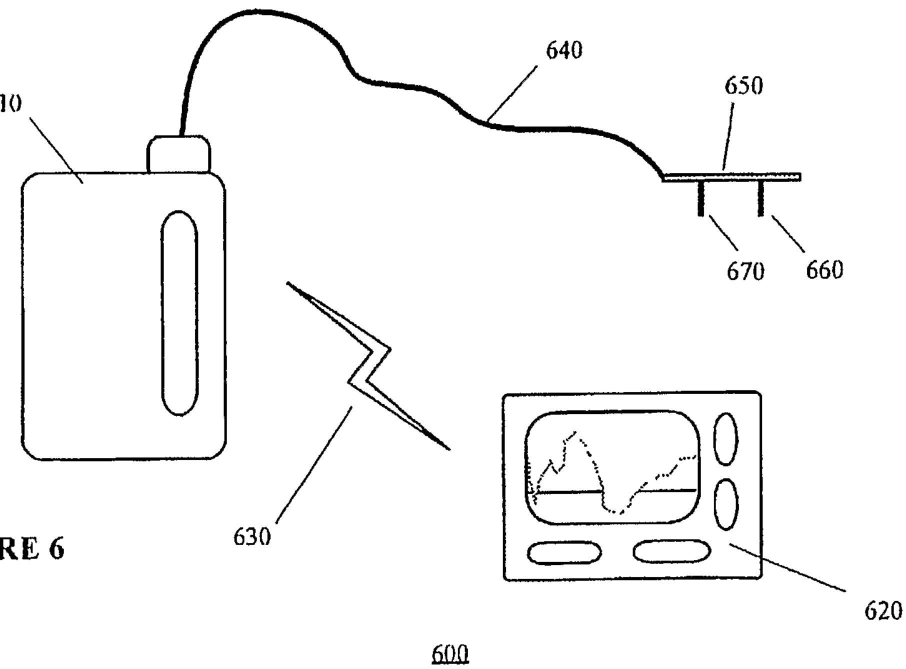


FIGURE 6

FIGURE 7A

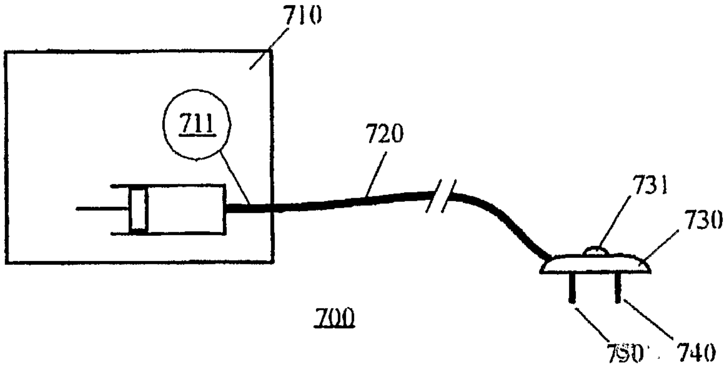


FIGURE 7B

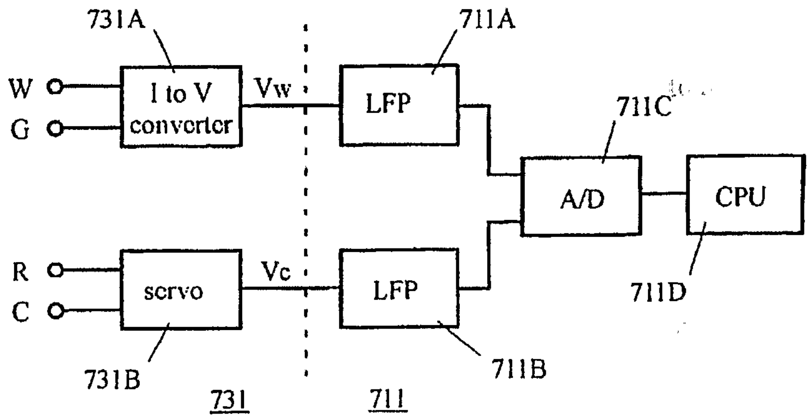
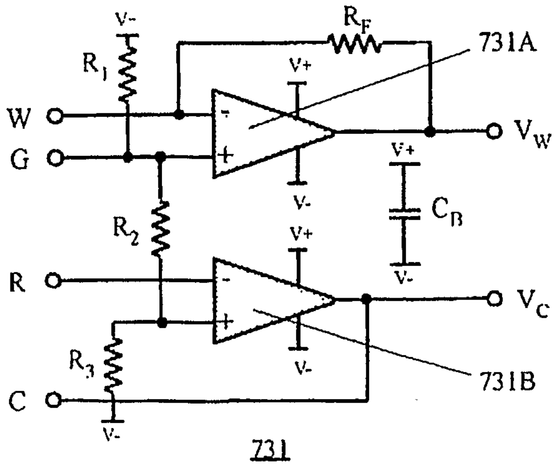


FIGURE 7C



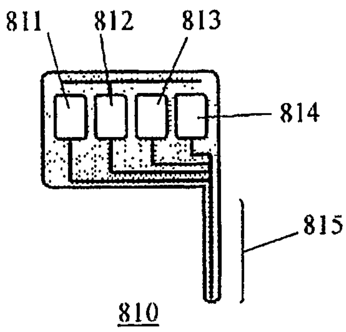


FIGURE 8A

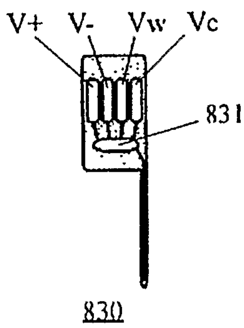


FIGURE 8C

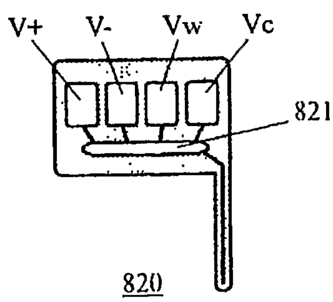


FIGURE 8B

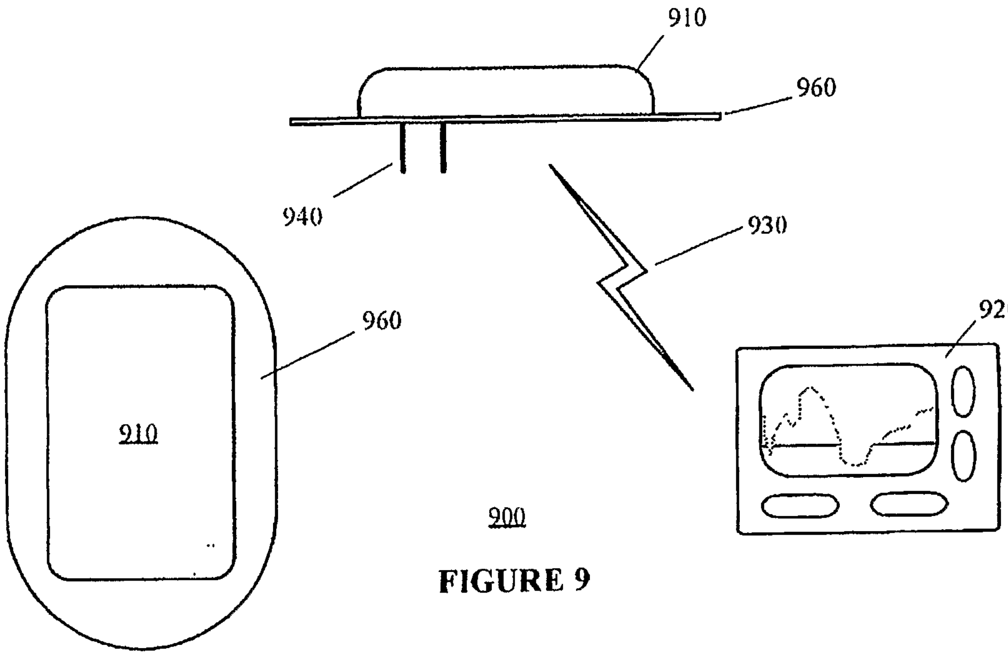


FIGURE 9

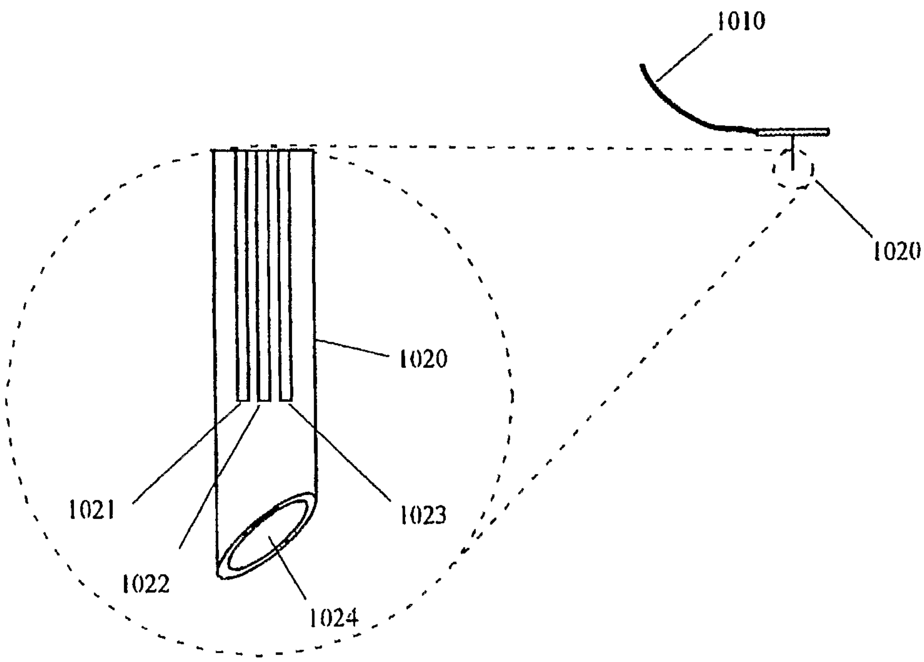


FIGURE 10

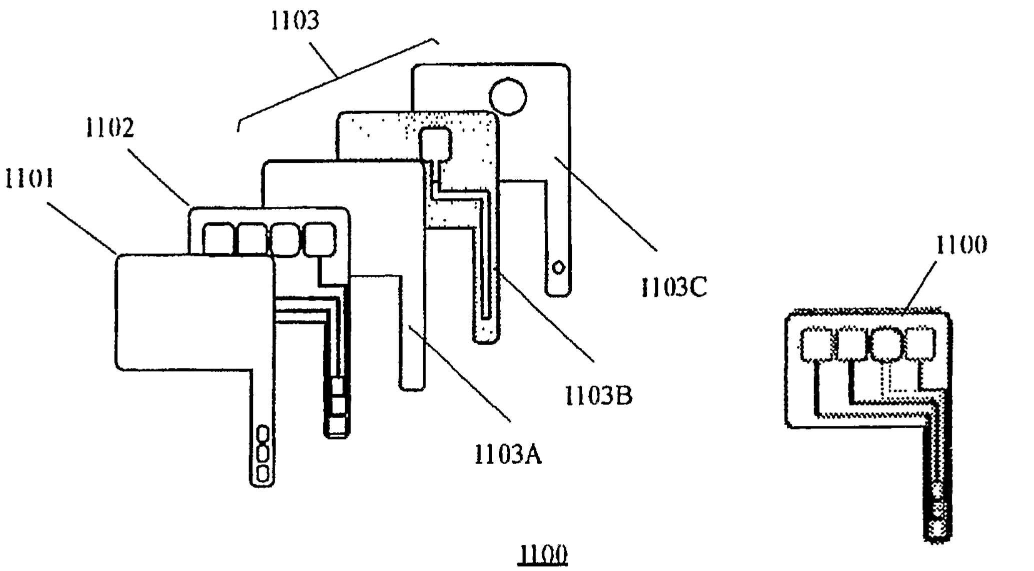


FIGURE 11A

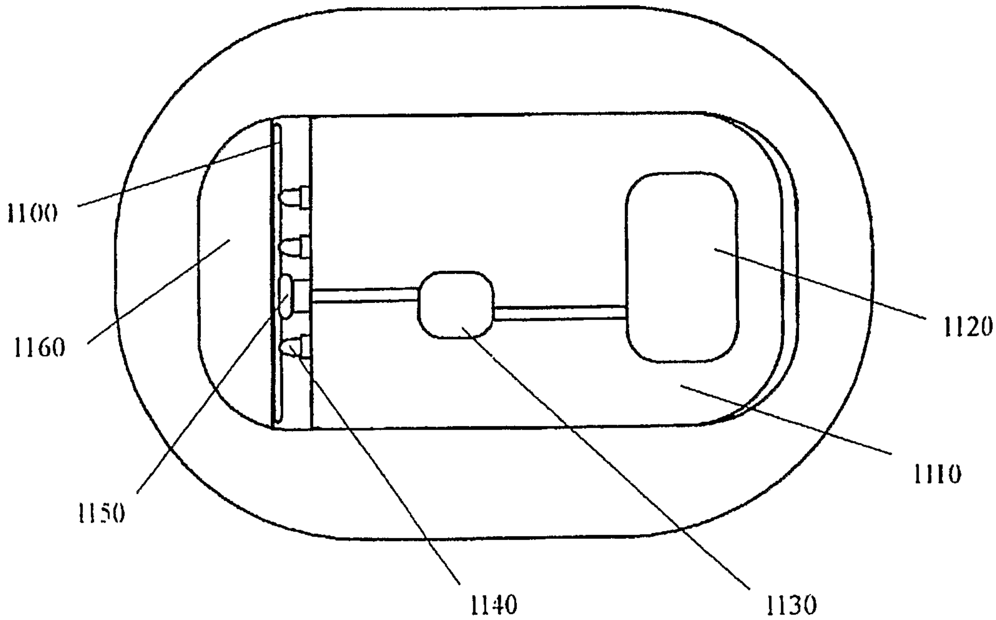


FIGURE 11B

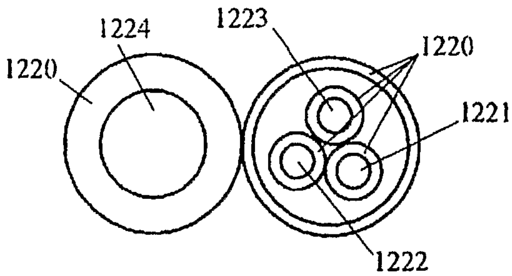


FIGURE 12A

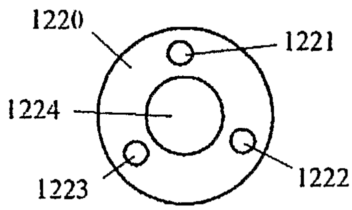


FIGURE 12B

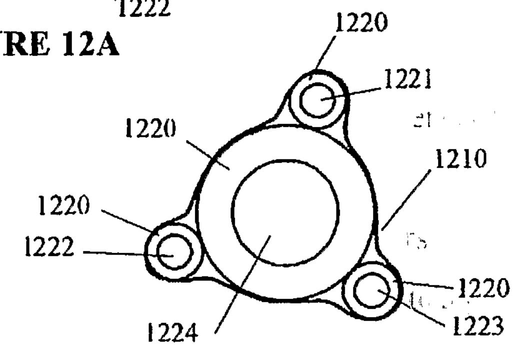


FIGURE 12C

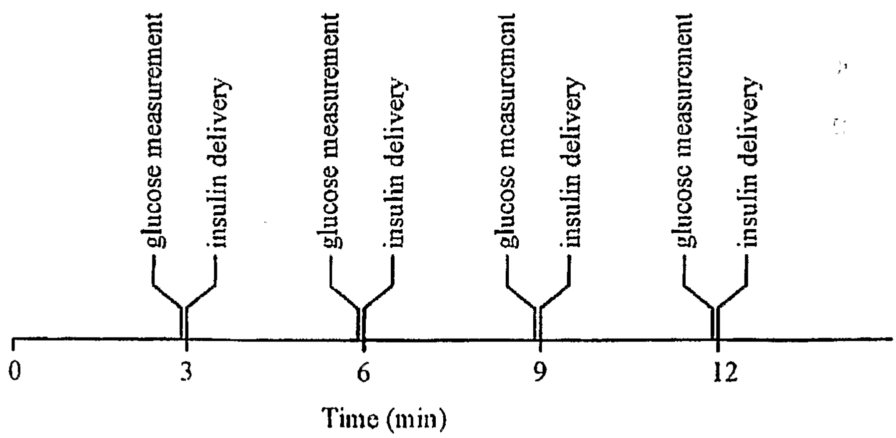


FIGURE 13