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(54) **CLOSED LOOP CONTROL SYSTEM INTERFACE AND METHODS**

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(58) **Field of Classification Search**
USPC 604/48, 65–67, 93.01, 503, 504, 890.1
See application file for complete search history.

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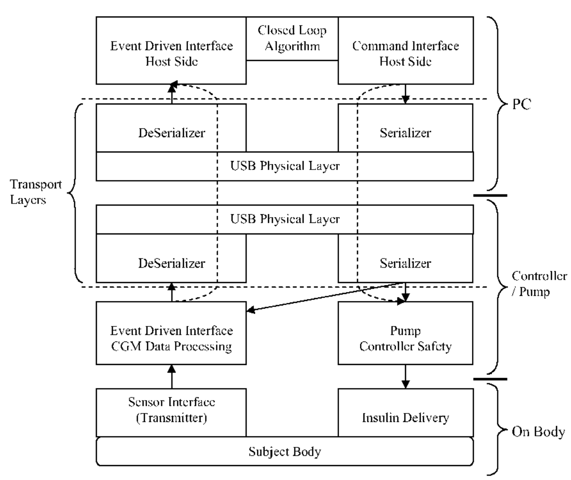
(57) **ABSTRACT**

Method and apparatus including calling, retrieving and/or initiating a programmed function in conjunction with execution of one or more commands related to a closed loop control algorithm, receiving one or more data in response to the one or more commands over a data interface, and executing the one or more commands related to the closed loop control algorithm based on the received one or more data are provided.

7 Claims, 7 Drawing Sheets



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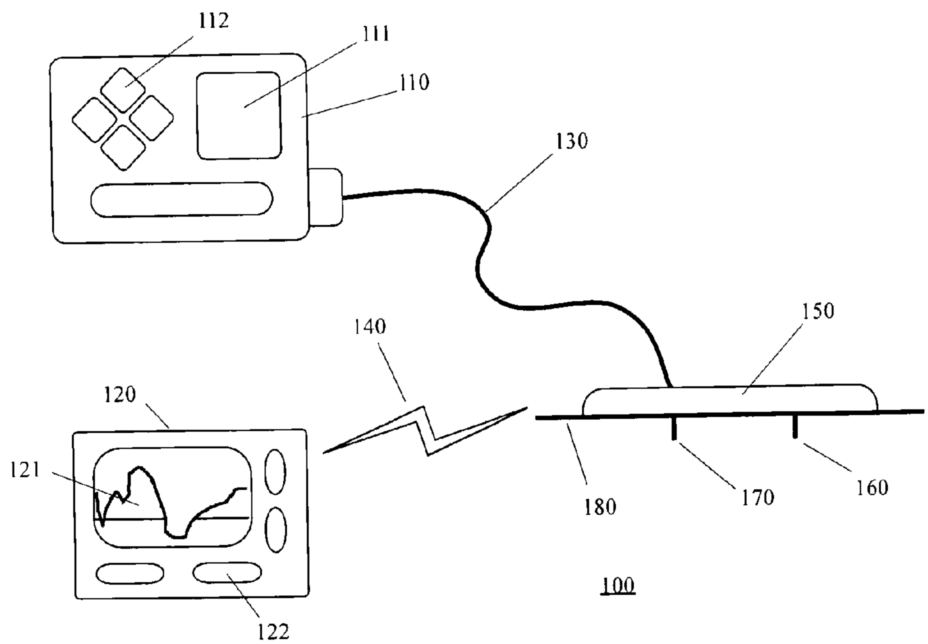


FIGURE 1

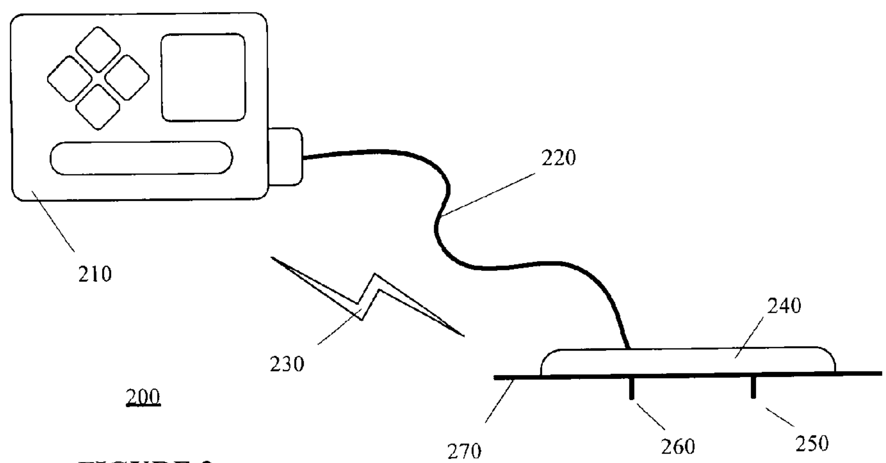


FIGURE 2

FIGURE 3

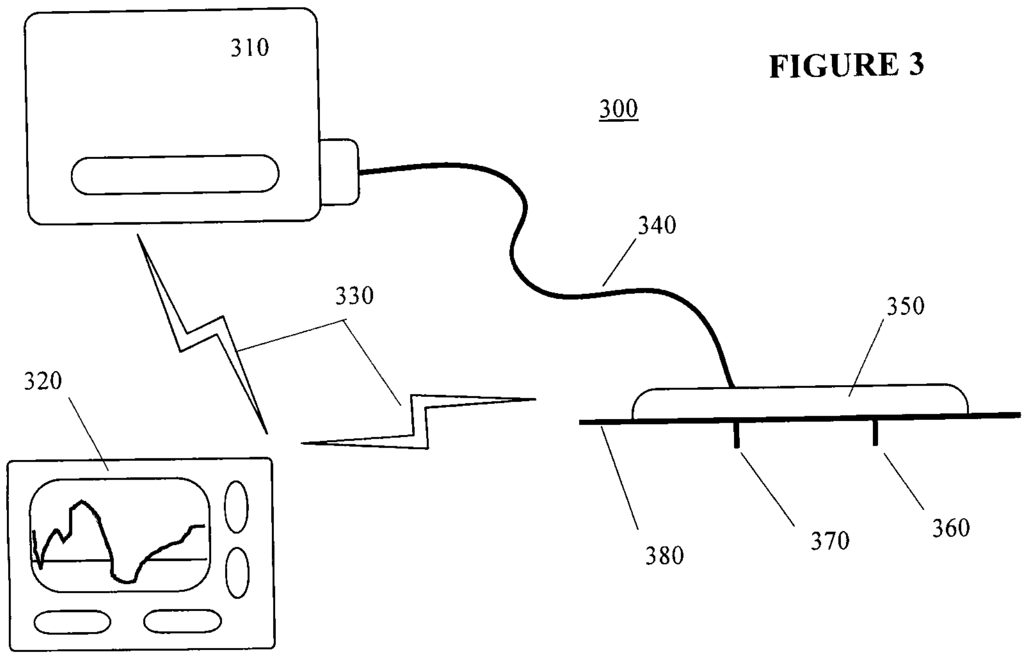
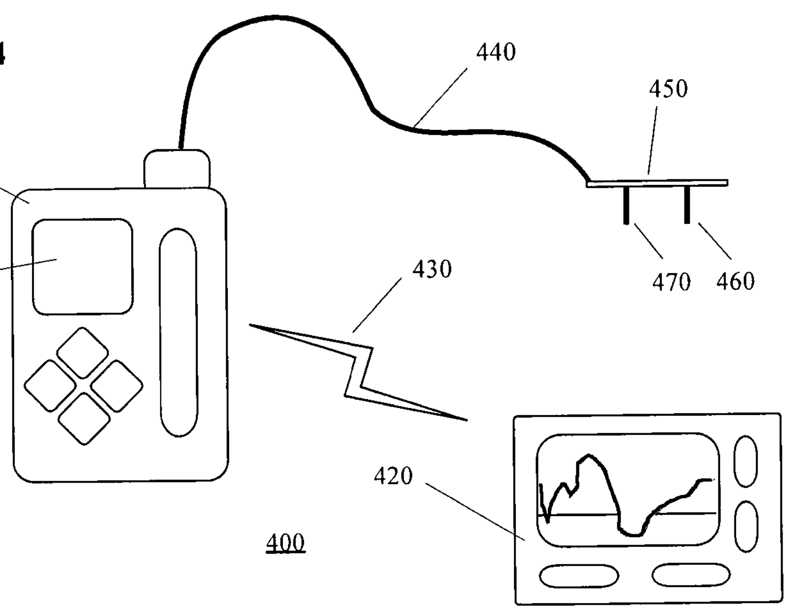


FIGURE 4



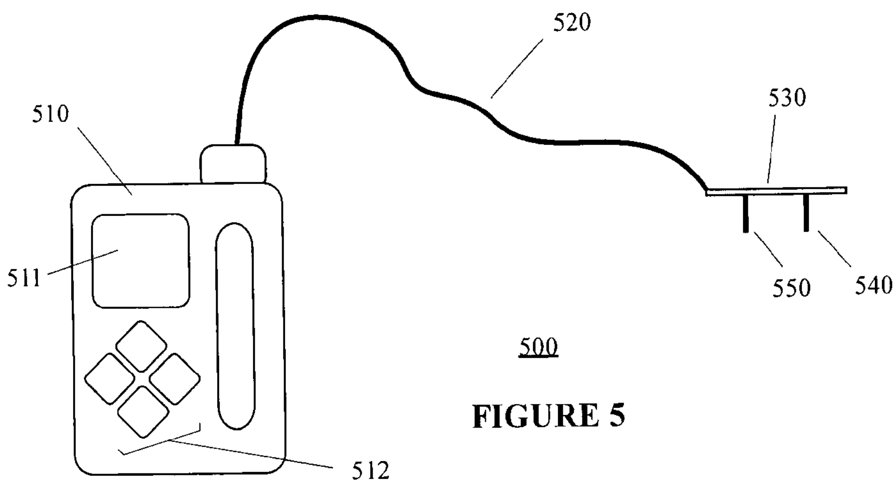


FIGURE 5

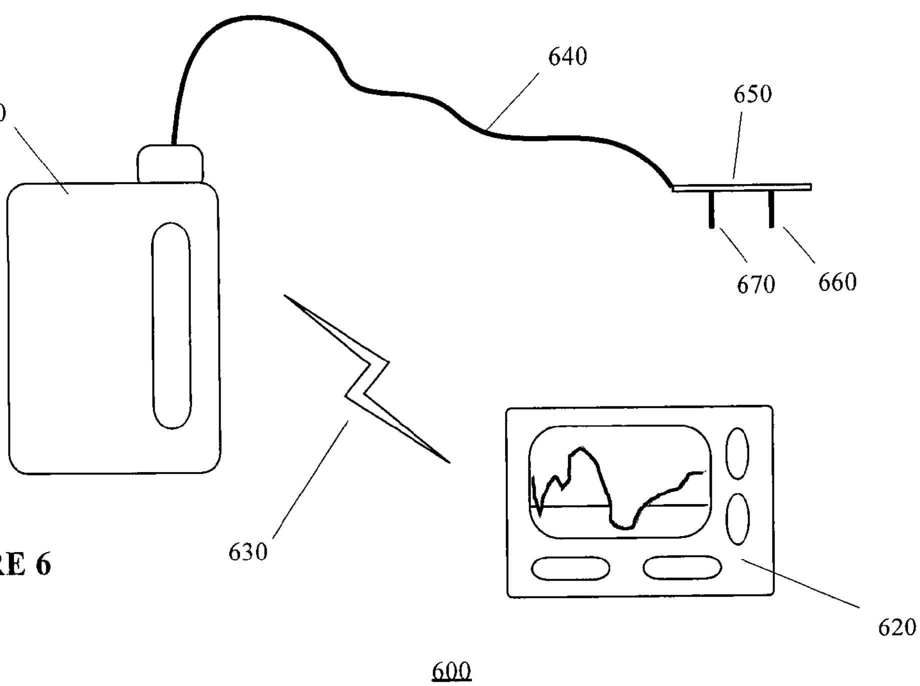


FIGURE 6

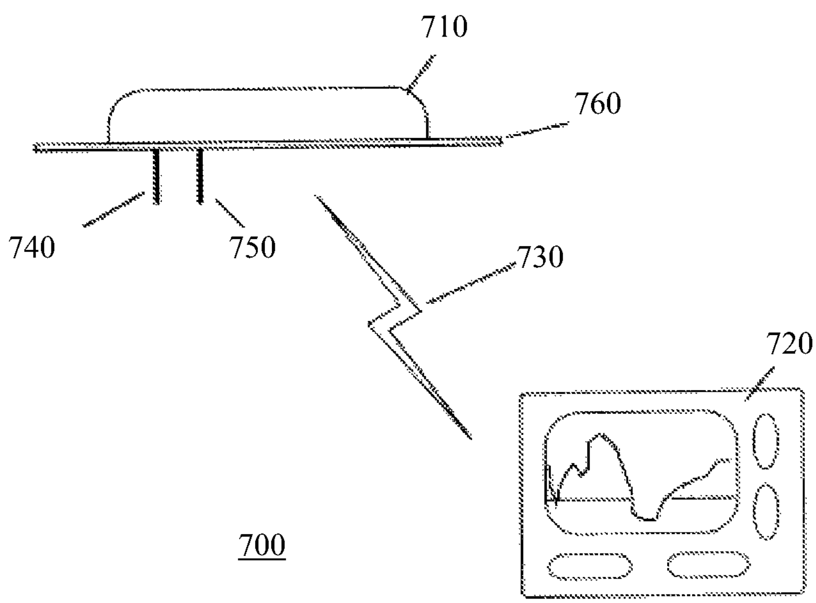


FIGURE 7A

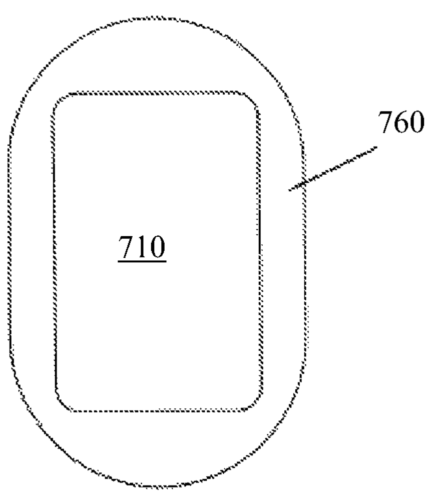


FIGURE 7B

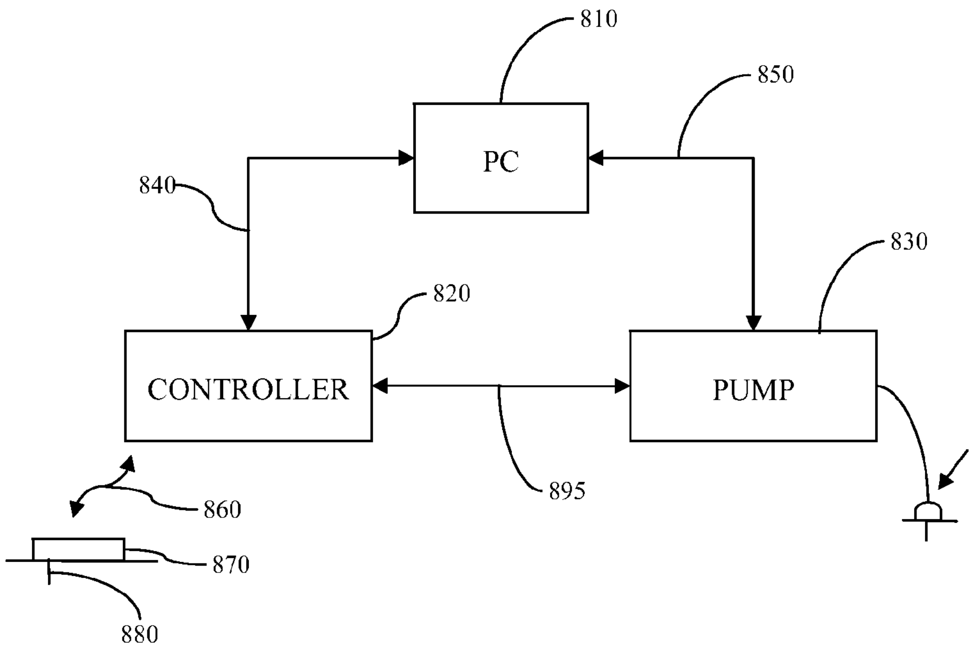


FIGURE 8

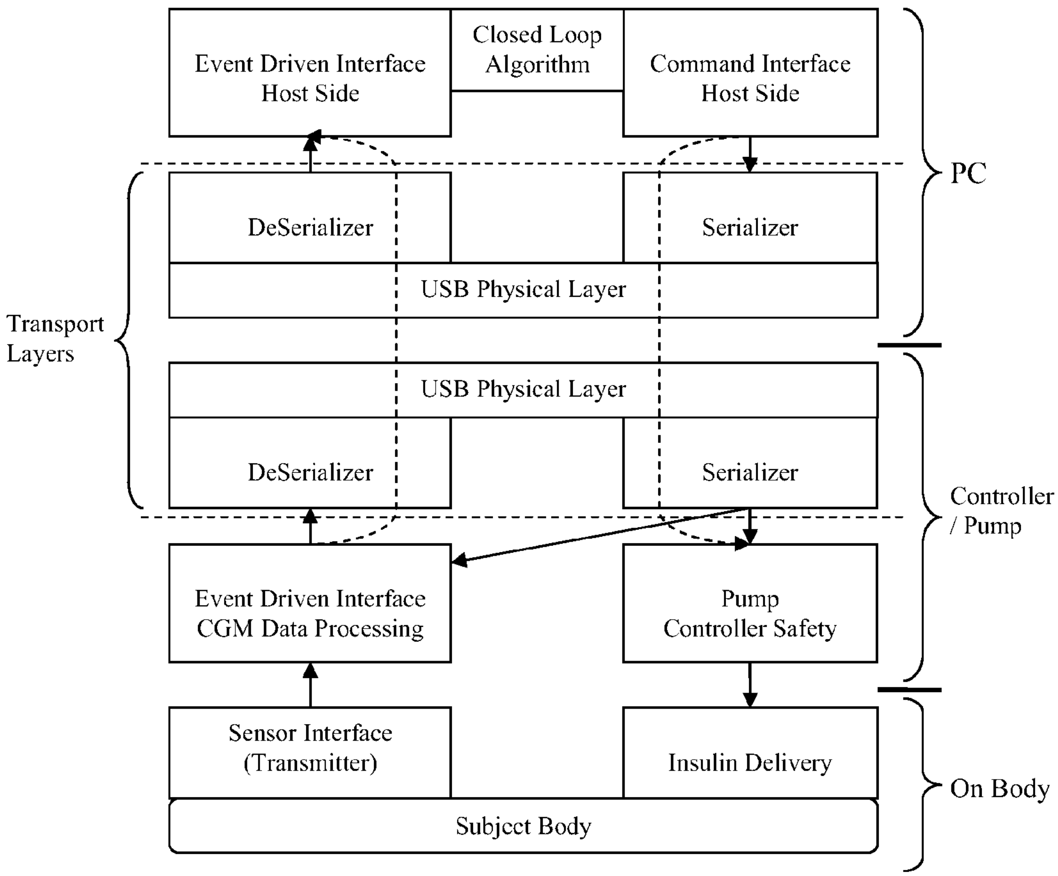

Event Driven Interface Host Side
Closed Loop Algorithm
Command Interface Host Side
PC
DeSerializer
Serializer
USB Physical Layer
Transport Layers
USB Physical Layer
DeSerializer
Serializer
Controller / Pump
Event Driven Interface CGM Data Processing
Pump Controller Safety
Sensor Interface (Transmitter)
Insulin Delivery
On Body
Subject Body

FIGURE 9

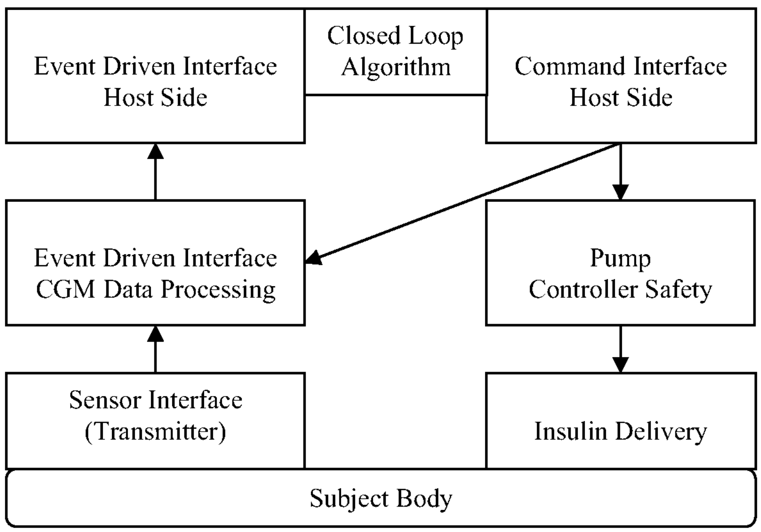

Event Driven Interface
Host Side
Closed Loop
Algorithm
Command Interface
Host Side
Event Driven Interface
CGM Data Processing
Pump
Controller Safety
Sensor Interface
(Transmitter)
Insulin Delivery
Subject Body

FIGURE 10

CLOSED LOOP CONTROL SYSTEM INTERFACE AND METHODS

RELATED APPLICATIONS

The present application claims priority under §35 U.S.C. 119(e) to U.S. provisional application No. 61/080,677 filed Jul. 14, 2008 entitled "Closed Loop Control System Interface and Methods", the disclosure of which is incorporated by reference for all purposes.

BACKGROUND

Commercial devices and systems for monitoring glucose levels in a patient are currently available. For example, FreeStyle Navigator® Continuous Glucose Monitoring System available from Abbott Diabetes Care Inc., provides diabetes management tools for monitoring glucose levels of a patient over an extended time period using a subcutaneous analyte sensor, for example, in contact with interstitial fluid of the patient. Such devices and systems provide real time glucose information to the patient to assist in improving glycemic control. Also available are infusion devices such as external insulin pumps which are programmable to deliver insulin based on a programmed delivery profile to diabetic patients, for example. Typically, such pumps are programmed to deliver a predetermined basal delivery profile, and periodically administer user specified bolus dosage or temporary basal delivery.

In recent years, developments have been on going in closed loop therapy systems which automate the control of the insulin delivery based on real time feedback of the patient's glucose levels. There are known closed loop control algorithms that are intended to model artificial pancreas to provide a fully automated and integrated system of glucose monitoring and insulin delivery.

With the development of different algorithms for closed loop control as well as glucose monitoring systems and infusion devices, integration of such components to provide compatibility has become a challenge.

SUMMARY

In view of the foregoing, a closed loop system interface device and methods are provided in accordance with various embodiments of the present disclosure which provide compatibility with any developing closed loop algorithm, and integration with the analyte monitoring system.

In one aspect, method and apparatus for calling a programmed function in conjunction with execution of one or more commands related to a closed loop control algorithm, receiving one or more data in response to the one or more commands over a data interface, and executing the one or more commands related to the closed loop control algorithm based on the received one or more data are provided.

These and other objects, features and advantages of the present disclosure 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 disclosure;

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

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

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

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

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

FIG. **7**A 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 disclosure and FIG. **7**B illustrates a top view of the patch of FIG. **7**A;

FIG. **8** illustrates a closed loop system interface for practicing one or more embodiments of the present disclosure;

FIG. **9** illustrates an architecture for providing interface to integrate the components of the closed loop system in one aspect; and

FIG. **10** illustrates an architecture for providing interface to integrate the components of the closed loop system in another aspect.

DETAILED DESCRIPTION

FIG. **1** illustrates an integrated infusion device and analyte monitoring system in accordance with one embodiment of the present disclosure. Referring to FIG. **1**, the integrated infusion device and analyte monitoring system **100** in one embodiment of the present disclosure 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 **150** over a communication path **140**.

Referring to FIG. **1**, in one embodiment of the present disclosure, 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 disclosure, 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** may be 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 may be 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. Pat. No. 6,175,752, assigned to the assignee of the present disclosure, Abbott Diabetes Care Inc., the disclosure of which is incorporated by reference for all purposes.

Referring back to FIG. **1**, the infusion device **110** may include capabilities to program basal profiles, calculation of bolus doses including, but is not limited to, correction bolus, carbohydrate bolus, extended bolus, and dual bolus, which may be performed by the patient using the infusion device **110**, and may be 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 **112**, **122** 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 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 disclosure, 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 disclosure, 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 disclosure, 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 disclosure, 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 disclosure, Abbott Diabetes Care Inc.

In the manner described above, in one embodiment of the present disclosure, 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** may be configured such that the infusion tubing **130** may be disconnected from the infusion device **110** as well as from the housing of the transmitter unit **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 disclosure, 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 disclosure. Referring to FIG. **2**, the integrated infusion device and analyte monitoring system **200** in one embodiment of the present disclosure 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, 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 disclosure, 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 disclosure. Referring to FIG. **3**, the integrated infusion device and analyte monitoring system **300** in one embodiment of the present disclosure includes an infusion device **310** connected to an infusion tubing **340** coupled to a cannula **370**. The cannula **370** is configured to be positioned subcutaneously under the patient's skin and substantially retained in position by an 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 monitoring 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 **370**, the analyte sensor **360**, the transmitter unit **350**, the adhesive layer **380**, the communication path **330**, 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 disclosure, 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 **340** 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 disclosure. Referring to FIG. **4**, the integrated infusion device and analyte monitoring system **400** in one embodiment of the present disclosure 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 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 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 disclosure. 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** with 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 disclosure, 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 of the present disclosure. 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. **7**A 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 disclosure and FIG. **7**B illustrates a top view of the patch of FIG. **7**A. Referring to FIGS. **7**A and **7**B, the integrated infusion device and analyte monitoring system **700** includes an integrated patch pump and transmitter unit **710** provided on an adhesive layer **760**, and which is configured to be placed on the skin of the patient, so as to securely position cannula **750** and analyte sensor **740** subcutaneously under the skin of the patient. The housing of the integrated infusion pump and transmitter unit **710** is configured in one embodiment to include the infusion mechanism to deliver medication such as insulin to the patient via the cannula **750**.

In addition, the integrated patch pump and transmitter unit **710** is configured to transmit signals associated with the detected analyte levels measured by the analyte sensor **740**, over a wireless communication path **730** such as an RF link. The signals are transmitted from the on body integrated patch pump and transmitter unit **710** to a controller unit **720** which is configured to control the operation of the integrated patch pump and transmitter unit **710**, as well as to receive the transmitted signals from the integrated patch pump and transmitter unit **710** which correspond to the detected analyte levels of the patient.

Referring back to FIGS. **7**A and **7**B, in one embodiment, the infusion mechanism of the integrated patch pump and transmitter unit **710** may include the infusion device of the type described in U.S. Pat. No. 6,916,159 assigned to the assignee of the present disclosure, Abbott Diabetes Care Inc., the disclosure of which is incorporated by reference for all purposes. In addition, while a wireless communication over the communication path **730** is shown in FIG. **7**A, the wireless communication path **730** may be replaced by a set of wires to provide a wired connection to the controller unit **720**.

In this manner, in one embodiment of the present disclosure, the integrated infusion device and analyte monitoring system **700** 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. **8** illustrates a closed loop system interface for practicing one or more embodiments of the present disclosure. Referring to the Figure, in one aspect, the closed loop architecture includes a PC terminal **810**, such as a computer terminal which includes the predefined closed loop algorithm, in communication with a controller **820** and a pump **830**. The controller **820** in one aspect is configured to receive analyte data over a data connection **860** such as an RF link, from a data transmitter **870** which is connected to an analyte sensor **880**. In one aspect, the controller **820** in combination with the transmitter **870** and the analyte sensor **880** comprise the analyte monitoring system described above.

Referring again to FIG. **8**, the pump **830** is connected to an infusion set/tubing **890** for delivering medication such as insulin to a user. While not shown, the analyte sensor **880** and the cannula of the infusion set/tubing is transcutaneously positioned under the skin layer of the patient to monitor analyte levels and deliver medication, respectively. As can be seen, there are provided data interface **840**, **850** between the controller **820** and PC terminal **810**, and the pump **830** and the PC terminal **810**. In one aspect, the data interfaces **840**, **850** include USB data connection for data transfer between the various components described. In a further aspect, the closed loop algorithm may be provided in the controller **820** in which case, the PC terminal **810** shown in FIG. **8** may be an optional device, and the data interface **840**, **850** may be similarly optional. In such configuration, the controller **820** in one aspect may be configured to communicate with the pump **830** via data interface **895** which may include, for example, one or more of an RF (radio frequency) communication interface/link, a wired data interface such as a USB (universal serial bus) or serial data communication interface or any other suitable data interface for bi-directional data communication between the controller **820** and the pump **830**.

As discussed in further detail below, in accordance with embodiments of the present disclosure, architecture to support integration of closed loop control algorithm (whether developed and resident in the PC terminal **810**), or integrated into controller **820** are provided. That is, by providing application programming interface (API) to the components of the closed loop system, integration with different control algorithm for implementation as well as testing may be easily achieved with data compatibility and little or no modification to the closed loop control algorithm.

FIG. **9** illustrates an architecture for providing data/control interface to integrate the components of the closed loop control system in one aspect. Referring to FIG. **9**, as can be seen, there is provided transport layers between the controller/pump and the PC terminal. That is, in one embodiment, using the existing USB data ports, data communication may be achieved by serial communication with the PC terminal such that between the devices, an interface layer such as a serializer is provided which encapsulates, for example, the serial commands from the continuous glucose monitoring (CGM) controller to the closed loop algorithm resident in the PC terminal. In one aspect, the serializer may be configured to provide API to execute the necessary and/or desired commands for monitoring and updating the status of the commands.

Referring to FIG. **9**, the closed loop algorithm resident in the PC terminal as shown may be configured to call or retrieve for execution/implementation one or more desired functions based, for example, on its internal clock or timer (or programmed or pre-programmed), and in response, triggers or initiates the CGM (continuous glucose monitoring) data processing to serialize the responsive (based on the function call) data which is then provided to corresponding deserializer on the PC terminal via the USB connection. For example, the function call may include a serial command requesting glucose data for the past 10 minutes. The closed loop algorithm may execute this function call to the controller, and in response thereto, the controller may be configured to retrieve the stored glucose data received from the CGM transmitter and provide that information to the deserializer in the PC terminal as a data table, for example.

That is, in one aspect, the application programming interface (API) provided on the controller and the PC terminal are configured to communicate over the data connection (for example, the USB connection) based on serial commands, and thereafter, provided to the closed loop control algorithm for appropriate processing related to control of one or more of the pump parameters or the controller (continuous glucose monitoring) parameters. More specifically, as shown in FIG. **9**, the command interface resident in the PC terminal may be configured to generate the appropriate or suitable serial command to implement the desired closed loop control based on the data received from the controller, and thereafter, via the serializer provide the command to the pump and/or the controller over the data connection, which, in one aspect, are configured to deserialize the command for execution and/or implementation.

In this manner, in one aspect, there is provided an interface module which is configured to integrate the closed loop control algorithm with the continuous glucose monitoring system and infusion device that do not require modification to the closed loop control algorithm to provide compatibility and functional integration. For example, in one aspect, serial commands in conjunction with application programming interface (API) are provided to integrate the closed loop system components without changing the closed loop control algorithm. In one aspect, without modifying the interface communication or control, the patient may alter or replace the existing closed loop control algorithm to another algorithm that may be more suited to the patient.

Referring to FIG. **9**, while the closed loop control algorithm is shown to reside in the PC terminal, within the scope of the present disclosure, the closed loop control algorithm may be provided in the controller, which, in turn, may be configured for data communication with the pump as well as the sensor interface (transmitter) coupled to an analyte sensor for analyte monitoring. That is, in a further aspect, the PC terminal may be provided as an optional data processing terminal and the closed loop control algorithm may be implemented using the controller device in conjunction with the analyte sensor interface and the pump. This embodiment is further described in detail below in conjunction with FIG. **10**.

FIG. **10** illustrates an architecture for providing interface to integrate the components of the closed loop control system in another aspect. As shown, in one aspect, the closed loop control algorithm is integrated in the controller such that the use of the PC terminal with closed loop algorithm may be optional, and the serial commands used may not be necessary. For example, with the application programming interface (API) provided to the controller and the pump, in one aspect, the closed loop control algorithm may be executed based on the data received from the controller related to the real time monitored glucose levels, and in response thereto, provide or issue one or more function calls to command or control the pump and/or the controller to implement the determined command or control based on the executed closed loop control algorithm. As discussed, in accordance with the embodiments of the present disclosure, the defined APIs may be implemented with any closed loop control algorithm and integrated with compatibility.

Within the scope of the present disclosure, other compatible configurations are contemplated in conjunction with a closed loop control system for insulin therapy and diagnosis which are compatible with a variety of closed loop control algorithms without specific modifications to the control algorithms for implementation. In aspects of the present disclosure, the function calls or commands executed or implemented by the one or more APIs include data integrity verification, for example, by including a CRC (cyclic redundancy check) verification such that it may be necessary to verify the checksum of the API command before calling the associated function.

In a further aspect, the defined or programmable APIs may be associated with one or more functions related to the medication delivery profile (e.g., one or more basal delivery profiles, temporary basal profile, delivery rates, delivery duration), delivery profile modification (including, for example, conditions for start/stop of one or more predetermined delivery profiles, conditions defining switching between multiple delivery profiles), safety shut off routine, device (pump and/or controller) operational status monitoring, data processing modes including, for example, batch mode, backup, upload, retrieval, time stamping, logging and the like. Moreover, other compatible APIs are contemplated within the scope of the present disclosure to provide compatibility with multiple closed loop control algorithms and which does not require modification to the algorithms in order to execute or call associated functions or parameters.

In still a further aspect, the defined or programmable APIs may be associated with one or more functions related to the analyte monitoring such as, but not limited to, frequency of analyte data logging, analyte sensor based events such as sensor calibration schedule, modification to the calibration schedule, diagnosis of sensor operation, failure modes related to the analyte sensor, or analyte sensor replacement schedules. In further aspects of the present disclosure, the defined or programmable APIs may be associated with one or more data processing functions from the analyte sensor interface and/or the pump, including, for example, time corresponding the medication delivery profile with the monitored analyte levels, determination or processing of the rate of change information of the monitored analyte levels in conjunction with the medication delivery profile such as the basal profile, monitoring of the temperature (on-skin, body temperature, and the like), for example. In addition, alarm or alert conditions associated with the closed loop control algorithm may be implemented using one or more of the defined or programmable APIs including, for example, but not limited to, occlusion detection in the medication delivery path, rapid rise or decline in the monitored analyte levels, for example.

Accordingly, a method in one aspect includes initiating a programmed function in conjunction with execution of one or more commands related to a closed loop control algorithm, receiving one or more data in response to the one or more commands over a data interface, and executing the one or more commands related to the closed loop control algorithm based on the received one or more data.

The programmed function may be initiated based on an application programming interface function.

The closed loop control algorithm may include closed loop diabetes management algorithm.

In one aspect, the closed loop control algorithm may be configured to modify a delivery profile of a medication.

The closed loop control algorithm may be configured to request a blood glucose value.

The one or more commands in one aspect may include one or more serial commands, where the received one or more data over the interface may be serialized or formatted for serial communication.

The one or more commands may include a command to retrieve one or more of the current or prior monitored analyte level, where the analyte level may include glucose level.

An apparatus in accordance with another embodiment includes a storage unit, and one or more processors coupled to the storage unit, the one or more processors configured to initiate a programmed function in conjunction with execution of one or more commands related to a closed loop control algorithm, to receive one or more data in response to the one or more commands over a data interface; and to execute the one or more commands related to the closed loop control algorithm based on the received one or more data.

A system in accordance with yet another embodiment includes a control unit including a memory unit having stored therein a closed loop control algorithm for execution, and an insulin delivery device in signal communication with the control unit for executing one or more medication delivery functions based on one or more signals received from the control unit, wherein the control unit may include a user interface for initiating one or more application programming interface function associated with one or more of the operation of the insulin delivery device, and further wherein the insulin delivery device may be configured to execute the one or more functions associated with the one or more of the initiated application programming interface functions.

The closed loop control algorithm stored in the memory device of the control unit may include a plurality of closed loop control algorithms.

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, comprising:

a control unit including a memory unit having stored therein a closed loop control algorithm for execution; and

an insulin delivery device in signal communication with the control unit for executing one or more medication delivery functions based on one or more signals received from the control unit;

wherein the control unit includes a user interface for initiating one or more application programming interface functions associated with one or more of the operations of the insulin delivery device;

wherein the one or more application programming interface functions are initialized at a serializer, and the closed loop control algorithm is integrated with the insulin delivery device and is compatible with both the control unit and the insulin delivery device without the closed loop control algorithm being modified; and

wherein the insulin delivery device is configured to execute the one or more medication delivery functions associated with the one or more of the initiated application programming interface functions.

2. The system of claim **1**, wherein the closed loop control algorithm stored in the memory unit of the control unit includes a plurality of closed loop control algorithms.

3. The system of claim **1**, wherein the control unit includes a deserializer.

4. The system of claim **1**, wherein the one or more application programming interface functions are related to one or more of analyte monitoring, a frequency of analyte data logging, a diagnosis of an analyte sensor operation, at least one failure mode related to an analyte sensor, and an analyte sensor replacement schedule.

5. The system of claim **1**, wherein the one or more application programming interface functions are related to one or more of a medication delivery profile, a medication delivery modification, a safety shut off routine, operational status monitoring, and a data processing mode.

6. The system of claim **1**, further comprising an analyte monitoring device in signal communication with the control unit.

7. The system of claim **1**, wherein the serializer is configured such that the closed loop control algorithm can be replaced or modified without modifying the control unit or the insulin delivery device.

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