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(54) **ANALYTE MONITORING AND MANAGEMENT SYSTEM AND METHODS THEREFOR**

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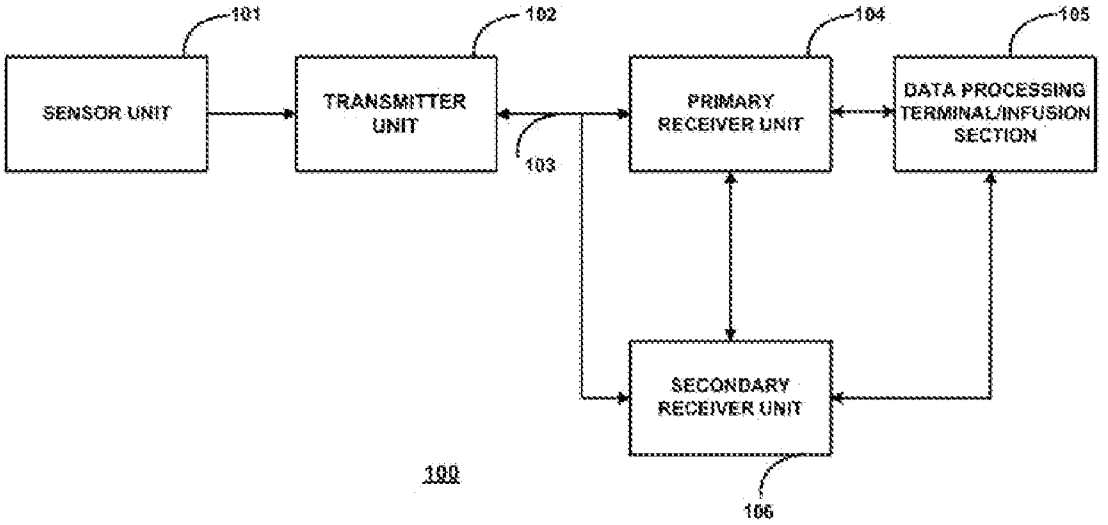
(57) **ABSTRACT**

Method and apparatus for providing multiple data receiver units in a data monitoring and management system such as analyte monitoring system where a first data receiver includes all of the functionalities for the data monitoring and management system receiver unit, and a second data receiver unit is configured with a limited functions to provide application specific convenience to the user or patient is disclosed.



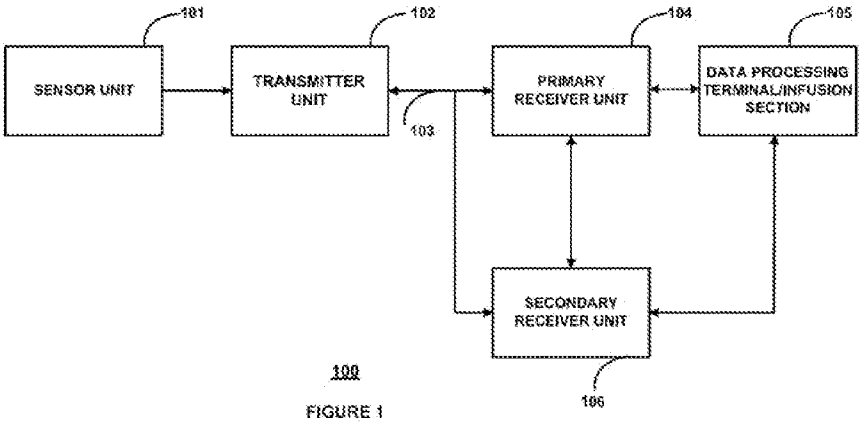


FIGURE 1

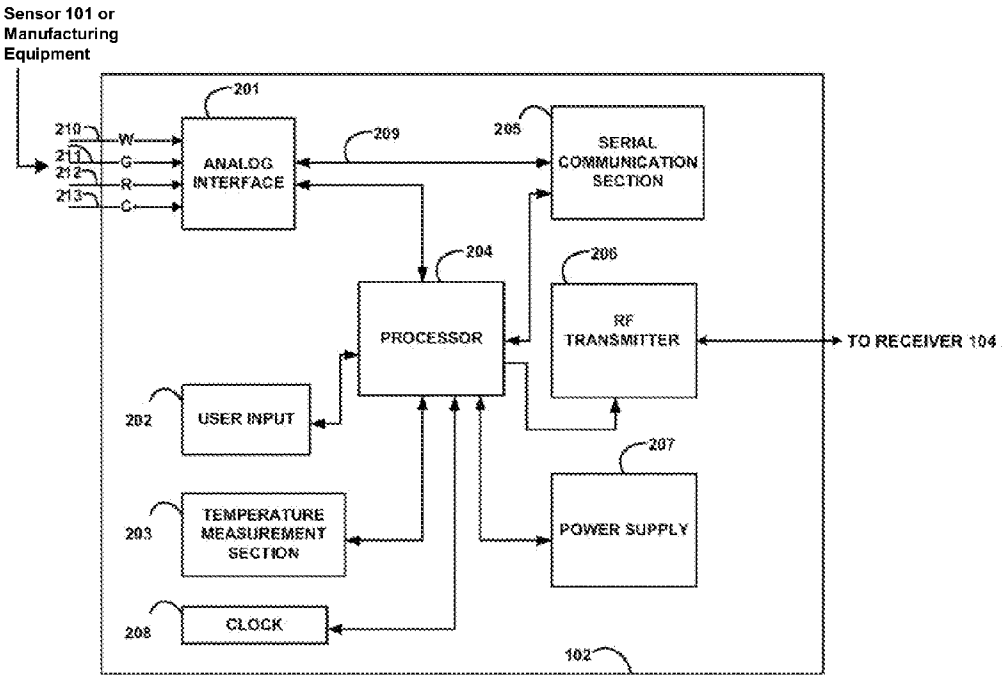


FIGURE 2

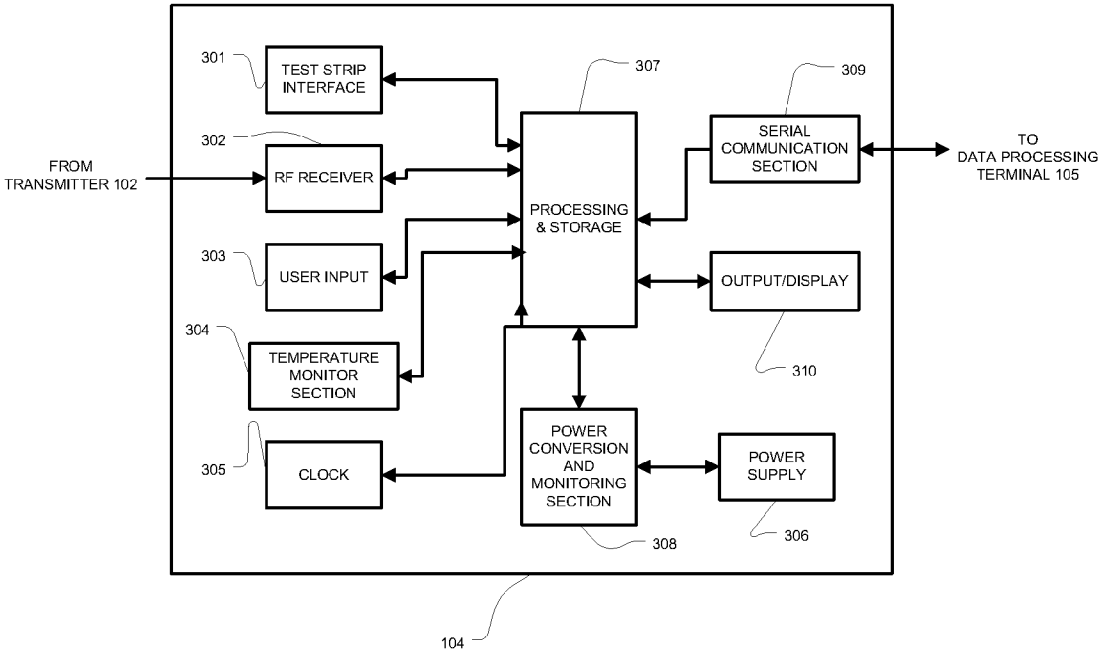

301
TEST STRIP INTERFACE
307
309
302
FROM TRANSMITTER 102
RF RECEIVER
PROCESSING & STORAGE
SERIAL COMMUNICATION SECTION
TO DATA PROCESSING TERMINAL 105
303
USER INPUT
OUTPUT/DISPLAY
304
TEMPERATURE MONITOR SECTION
310
305
CLOCK
POWER CONVERSION AND MONITORING SECTION
POWER SUPPLY
308
306
104

FIGURE 3

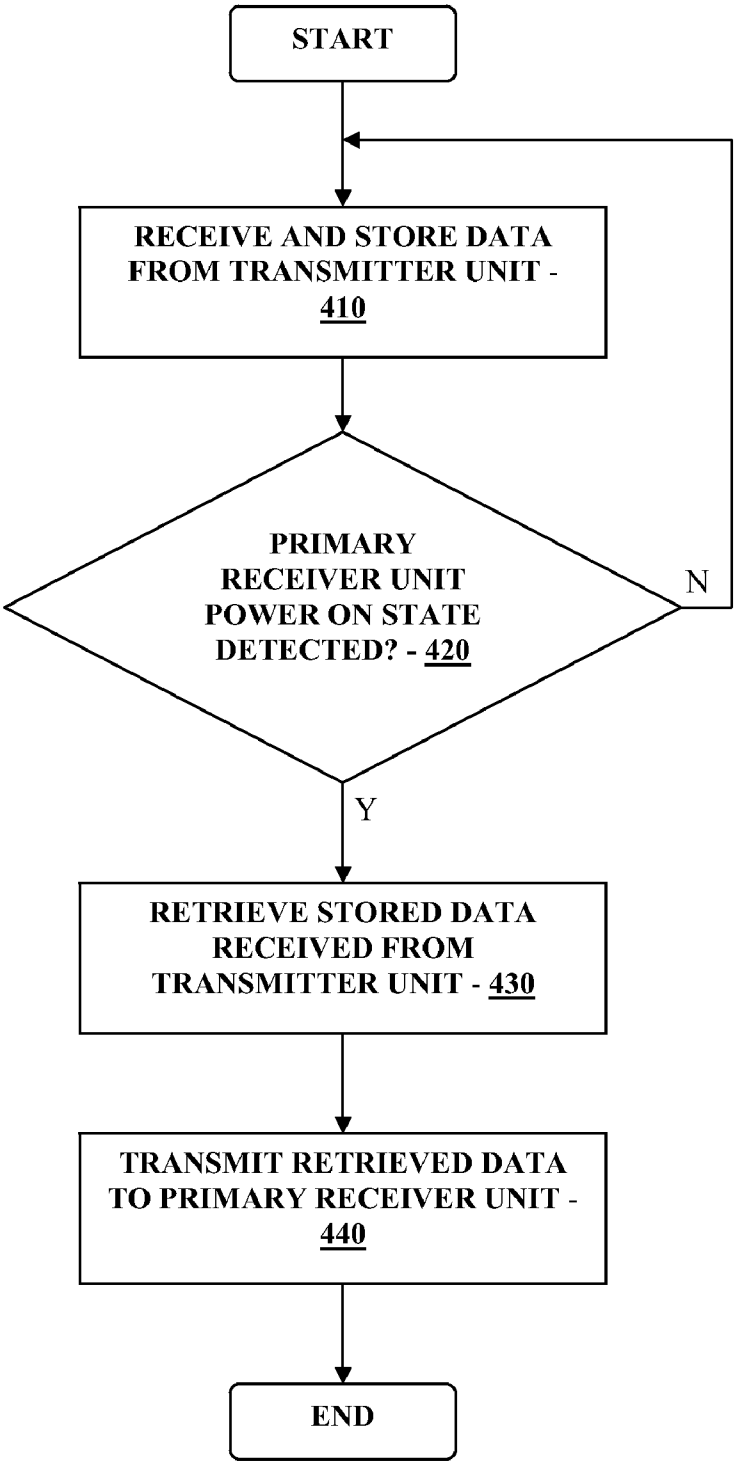

START
RECEIVE AND STORE DATA FROM TRANSMITTER UNIT - 410
PRIMARY RECEIVER UNIT POWER ON STATE DETECTED? - 420
N
Y
RETRIEVE STORED DATA RECEIVED FROM TRANSMITTER UNIT - 430
TRANSMIT RETRIEVED DATA TO PRIMARY RECEIVER UNIT - 440
END

FIGURE 4

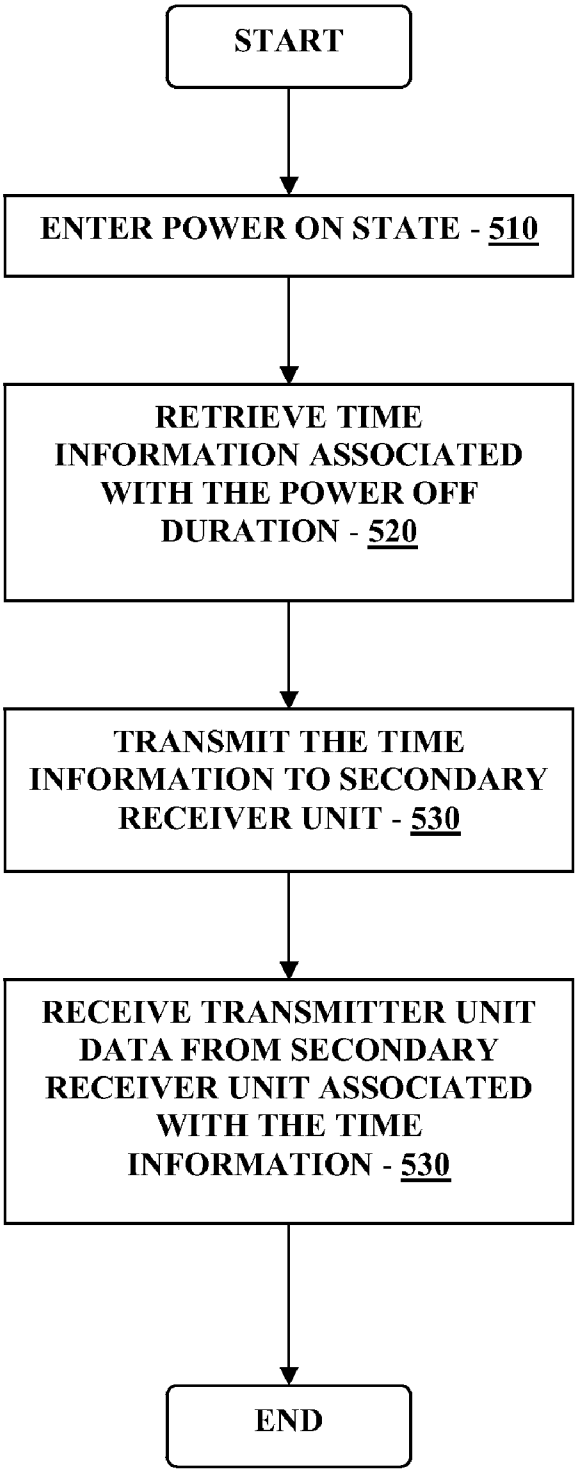

START
ENTER POWER ON STATE - 510
RETRIEVE TIME INFORMATION ASSOCIATED WITH THE POWER OFF DURATION - 520
TRANSMIT THE TIME INFORMATION TO SECONDARY RECEIVER UNIT - 530
RECEIVE TRANSMITTER UNIT DATA FROM SECONDARY RECEIVER UNIT ASSOCIATED WITH THE TIME INFORMATION - 530
END

FIGURE 5

ANALYTE MONITORING AND MANAGEMENT SYSTEM AND METHODS THEREFOR

RELATED APPLICATIONS

[0001] The present application is a continuation of pending U.S. patent application Ser. No. 12/606,890 filed Oct. 27, 2009, which is a continuation of U.S. patent application Ser. No. 11/396,181 filed Mar. 31, 2006, now U.S. Pat. No. 7,801,582, the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

[0002] Analyte, e.g., glucose monitoring systems including continuous and discrete monitoring systems generally include a small, lightweight battery powered and microprocessor controlled system which is configured to detect signals proportional to the corresponding measured glucose levels using an electrometer, and RF signals to transmit the collected data. One aspect of certain analyte monitoring systems include a transcutaneous or subcutaneous analyte sensor configuration which is, for example, partially mounted on the skin of a subject whose analyte level is to be monitored. The sensor cell may use a two or three-electrode (work, reference and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit connected through a contact system.

[0003] The analyte sensor may be configured so that a portion thereof is placed under the skin of the patient so as to detect the analyte levels of the patient, and another portion of segment of the analyte sensor that is in communication with the transmitter unit. The transmitter unit is configured to transmit the analyte levels detected by the sensor over a wireless communication link such as an RF (radio frequency) communication link to a receiver/monitor unit. The receiver/monitor unit performs data analysis, among others on the received analyte levels to generate information pertaining to the monitored analyte levels.

[0004] The receiver/monitor units generally include sophisticated functionalities and features, while providing robust data management system, also provide a steep learning curve and challenge to the initial users of such devices. In addition, due to its sophistication and robust functionality, the reduction in the size of the receiver/monitor unit can be limited. For diabetic children that use the analyte monitoring system, for example, having a complex device such as the receiver/monitor unit may pose a health risk in addition to its intended benefit. Indeed, the receiver/monitor unit may be misprogrammed, or otherwise, its settings and/or features modified by the user and thus not operate properly.

[0005] In addition, due to its size, it is cumbersome to engage in physical activities such as exercise while carrying the receiver/monitor unit so as to be in signal range with the on-body transmitter unit.

[0006] In view of the foregoing, it would be desirable to have a system which includes a receiver/monitor unit for use with the data monitoring and management system which is compact in size and that has limited set of primary features that is less cumbersome to transport and which is easy to manipulate and use by children, for example.

SUMMARY OF THE INVENTION

[0007] In view of the foregoing, in accordance with the various embodiments of the present invention, there is provided a method and system for providing a secondary receiver/monitor unit in a data monitoring and management system which is configured for data communication with the primary receiver/monitor unit, and further, where the secondary receiver/monitor unit can replace the functionalities of the primary receiver/monitor unit during a predetermined time periods such as exercise periods, sleeping periods, travel periods, or any other periods during which access to the full functionality of the primary receiver/monitor unit is not needed.

[0008] 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 DRAWINGS

[0009] FIG. **1** illustrates a block diagram of a data monitoring and management system for practicing one embodiment of the present invention;

[0010] FIG. **2** is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

[0011] FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention;

[0012] FIG. **4** is a flowchart illustrating data synchronization procedure between the primary receiver unit and the secondary receiver unit of the analyte monitoring system in accordance with one embodiment of the present invention; and

[0013] FIG. **5** is a flowchart illustrating data synchronization procedure between the primary receiver unit and the secondary receiver unit of the analyte monitoring system in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION

[0014] FIG. **1** illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system **100** in accordance with one embodiment of the present invention. The subject invention is further described primarily with respect to a glucose monitoring system for convenience and such description is in no way intended to limit the scope of the invention. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes, e.g., lactate, and the like.

[0015] Analytes that may be monitored 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 monitored.

[0016] The analyte monitoring system **100** includes a sensor **101**, a transmitter unit **102** coupled to the sensor **101**, and a primary receiver unit **104** which is configured to communicate with the transmitter unit **102** via a communication link **103**. The primary receiver unit **104** may be further configured to transmit data to a data processing terminal **105** for evalu-

ating the data received by the primary receiver unit **104**. Moreover, the data processing terminal in one embodiment may be configured to receive data directly from the transmitter unit **102** via a communication link **103** which may optionally be configured for bi-directional communication.

[0017] Also shown in FIG. **1** is a secondary receiver unit **106** which is operatively coupled to the communication link and configured to receive data transmitted from the transmitter unit **102**. Moreover, as shown in the Figure, the secondary receiver unit **106** is configured to communicate with the primary receiver unit **104** as well as the data processing terminal **105**. Indeed, the secondary receiver unit **106** may be configured for bi-directional wireless communication with each of the primary receiver unit **104** and the data processing terminal **105**. As discussed in further detail below, in one embodiment of the present invention, the secondary receiver unit **106** may be configured to include a limited number of functions and features as compared with the primary receiver unit **104**. As such, the secondary receiver unit **106** may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, for example. Alternatively, the secondary receiver unit **106** may be configured with the same or substantially similar functionality as the primary receiver unit **104**, and may be configured to be used in conjunction with a docking cradle unit for placement by bedside, for night time monitoring, and/or bi-directional communication device.

[0018] Only one sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105** are shown in the embodiment of the analyte monitoring system **100** illustrated in FIG. **1**. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system **100** may include one or more sensor **101**, transmitter unit **102**, communication link **103**, and data processing terminal **105**. Moreover, within the scope of the present invention, the analyte monitoring system **100** may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system **100**.

[0019] In one embodiment of the present invention, the sensor **101** is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor **101** may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the transmitter unit **102**. In one embodiment, the transmitter unit **102** is mounted on the sensor **101** so that both devices are positioned on the user's body. The transmitter unit **102** performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit **104** via the communication link **103**.

[0020] In one embodiment, the analyte monitoring system **100** is configured as a one-way RF communication path from the transmitter unit **102** to the primary receiver unit **104**. In such embodiment, the transmitter unit **102** transmits the sampled data signals received from the sensor **101** without acknowledgement from the primary receiver unit **104** that the transmitted sampled data signals have been received. For example, the transmitter unit **102** 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 primary receiver unit **104** may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the analyte monitoring system **100** may be configured with a bi-directional RF (or otherwise) communication between the transmitter unit **102** and the primary receiver unit **104**.

[0021] Additionally, in one aspect, the primary receiver unit **104** may include two sections. The first section is an analog interface section that is configured to communicate with the transmitter unit **102** via the communication link **103**. 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 **102**, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the primary receiver unit **104** is a data processing section which is configured to process the data signals received from the transmitter unit **102** such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

[0022] In operation, upon completing the power-on procedure, the primary receiver unit **104** is configured to detect the presence of the transmitter unit **102** within its range based on, for example, the strength of the detected data signals received from the transmitter unit **102** or a predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter unit **102**, the primary receiver unit **104** is configured to begin receiving from the transmitter unit **102** data signals corresponding to the user's detected analyte level. More specifically, the primary receiver unit **104** in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter unit **102** via the communication link **103** to obtain the user's detected analyte level.

[0023] Referring again to FIG. **1**, the data processing terminal **105** may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital assistants (PDAs)), and the like, each of which may be configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal **105** may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected analyte level of the user.

[0024] Within the scope of the present invention, the data processing terminal **105** may include an infusion device such as an insulin infusion pump or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit **104** for receiving, among others, the measured analyte level. Alternatively, the receiver unit **104** may be configured to integrate an infusion device therein so that the receiver unit **104** is configured to administer insulin therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the transmitter unit **102**.

[0025] Additionally, the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may each be configured for bi-directional wireless communication such that each of the transmitter unit **102**, the primary receiver unit **104** and the data processing terminal **105** may be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication

link **103**. More specifically, the data processing terminal **105** may in one embodiment be configured to receive data directly from the transmitter unit **102** via the communication link **103**, where the communication link **103**, as described above, may be configured for bi-directional communication.

[0026] In this embodiment, the data processing terminal **105** which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit **102**, and thus, incorporate the functions of the receiver **103** including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link **103** may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth enabled communication protocol, an 802.1 1x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements) while avoiding potential data collision and interference.

[0027] FIG. **2** is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to the Figure, the transmitter unit **102** in one embodiment includes an analog interface **201** configured to communicate with the sensor **101** (FIG. **1**), a user input **202**, and a temperature detection section **203**, each of which is operatively coupled to a transmitter processor **204** such as a central processing unit (CPU). As can be seen from FIG. **2**, there are provided four contacts, three of which are electrodes—work electrode (W) **210**, guard contact (G) **211**, reference electrode (R) **212**, and counter electrode (C) **213**, each operatively coupled to the analog interface **201** of the transmitter unit **102** for connection to the sensor unit **201** (FIG. **1**). In one embodiment, each of the work electrode (W) **210**, guard contact (G) **211**, reference electrode (R) **212**, and counter electrode (C) **213** may be made using a conductive material that is either printed or etched, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched.

[0028] Further shown in FIG. **2** are a transmitter serial communication section **205** and an RF transmitter **206**, each of which is also operatively coupled to the transmitter processor **204**. Moreover, a power supply **207** such as a battery is also provided in the transmitter unit **102** to provide the necessary power for the transmitter unit **102**. Additionally, as can be seen from the Figure, clock **208** is provided to, among others, supply real time information to the transmitter processor **204**.

[0029] In one embodiment, a unidirectional input path is established from the sensor **101** (FIG. **1**) and/or manufacturing and testing equipment to the analog interface **201** of the transmitter unit **102**, while a unidirectional output is established from the output of the RF transmitter **206** of the transmitter unit **102** for transmission to the primary receiver unit **104**. In this manner, a data path is shown in FIG. **2** between the aforementioned unidirectional input and output via a dedicated link **209** from the analog interface **201** to serial communication section **205**, thereafter to the processor **204**, and then to the RF transmitter **206**. As such, in one embodiment, via the data path described above, the transmitter unit **102** is configured to transmit to the primary receiver unit **104** (FIG. **1**), via the communication link **103** (FIG. **1**), processed and encoded data signals received from the sensor **101** (FIG. **1**). Additionally, the unidirectional communication data path between the analog interface **201** and the RF transmitter **206** discussed above allows for the configuration of the transmitter unit **102** for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

[0030] As discussed above, the transmitter processor **204** is configured to transmit control signals to the various sections of the transmitter unit **102** during the operation of the transmitter unit **102**. In one embodiment, the transmitter processor **204** also includes a memory (not shown) for storing data such as the identification information for the transmitter unit **102**, as well as the data signals received from the sensor **101**. The stored information may be retrieved and processed for transmission to the primary receiver unit **104** under the control of the transmitter processor **204**. Furthermore, the power supply **207** may include a commercially available battery.

[0031] The transmitter unit **102** is also configured such that the power supply section **207** is capable of providing power to the transmitter for a minimum of about three months of continuous operation after having been stored for about eighteen months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor **204** operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter unit **102** may place the transmitter unit **102** in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit **102** may be significantly improved. Moreover, as shown in FIG. **2**, while the power supply unit **207** is shown as coupled to the processor **204**, and as such, the processor **204** is configured to provide control of the power supply unit **207**, it should be noted that within the scope of the present invention, the power supply unit **207** is configured to provide the necessary power to each of the components of the transmitter unit **102** shown in FIG. **2**.

[0032] Referring back to FIG. **2**, the power supply section **207** of the transmitter unit **102** in one embodiment may include a rechargeable battery unit that may be recharged by a separate power supply recharging unit (for example, provided in the receiver unit **104**) so that the transmitter unit **102** may be powered for a longer period of usage time. Moreover, in one embodiment, the transmitter unit **102** may be configured without a battery in the power supply section **207**, in which case the transmitter unit **102** may be configured to receive power from an external power supply source (for example, a battery) as discussed in further detail below.

[0033] Referring yet again to FIG. **2**, the temperature detection section **203** of the transmitter unit **102** is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface **201**. The RF transmitter **206** of the transmitter unit **102** may be configured for operation in the frequency band of 315 MHz to 322 MHz, for example, in the United States. Further, in one embodiment, the RF transmitter **206** is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit **104**.

[0034] Referring yet again to FIG. **2**, also shown is a leak detection circuit **214** coupled to the guard electrode (G) **211**

and the processor **204** in the transmitter unit **102** of the data monitoring and management system **100**. The leak detection circuit **214** in accordance with one embodiment of the present invention may be configured to detect leakage current in the sensor **101** to determine whether the measured sensor data are corrupt or whether the measured data from the sensor **101** is accurate.

[0035] Additional detailed description of the continuous analyte monitoring system, its various components including the functional descriptions of the transmitter are provided in U.S. Pat. No. 6,175,752 issued Jan. 16, 2001 entitled "Analyte Monitoring Device and Methods of Use", and in application Ser. No. 10/745,878 filed Dec. 26, 2003 entitled "Continuous Glucose Monitoring System and Methods of Use", each assigned to the Assignee of the present application, and the disclosures of each of which are incorporated herein by reference for all purposes.

[0036] FIG. **3** is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. **1** in accordance with one embodiment of the present invention. Referring to FIG. **3**, the primary receiver unit **104** includes a blood glucose test strip interface **301**, an RF receiver **302**, an input **303**, a temperature detection section **304**, and a clock **305**, each of which is operatively coupled to a receiver processor **307**. As can be further seen from the Figure, the primary receiver unit **104** also includes a power supply **306** operatively coupled to a power conversion and monitoring section **308**. Further, the power conversion and monitoring section **308** is also coupled to the receiver processor **307**. Moreover, also shown are a receiver serial communication section **309**, and an output **310**, each operatively coupled to the receiver processor **307**.

[0037] In one embodiment, the test strip interface **301** includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output **310** of the primary receiver unit **104**. This manual testing of glucose can be used to calibrate sensor **101**. The RF receiver **302** is configured to communicate, via the communication link **103** (FIG. **1**) with the RF transmitter **206** of the transmitter unit **102**, to receive encoded data signals from the transmitter unit **102** for, among others, signal mixing, demodulation, and other data processing. The input **303** of the primary receiver unit **104** is configured to allow the user to enter information into the primary receiver unit **104** as needed. In one aspect, the input **303** may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section **304** is configured to provide temperature information of the primary receiver unit **104** to the receiver processor **307**, while the clock **305** provides, among others, real time information to the receiver processor **307**.

[0038] Each of the various components of the primary receiver unit **104** shown in FIG. **3** is powered by the power supply **306** which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section **308** is configured to monitor the power usage by the various components in the primary receiver unit **104** for effective power management and to alert the user, for example, in the event of power usage which renders the primary receiver unit **104** in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply **306** while the processor **307** (thus, the primary receiver unit **104**) is turned on. Moreover, the power conversion and monitoring section **308** may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

[0039] The serial communication section **309** in the primary receiver unit **104** is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit **104**. Serial communication section **104** can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output **310** of the primary receiver unit **104** is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output **310** may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit **104** also includes an electro-luminescent lamp configured to provide backlighting to the output **310** for output visual display in dark ambient surroundings.

[0040] Referring back to FIG. **3**, the primary receiver unit **104** in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor **307**, or provided separately in the primary receiver unit **104**, operatively coupled to the processor **307**. The processor **307** is further configured to perform Manchester decoding as well as error detection and correction upon the encoded data signals received from the transmitter unit **102** via the communication link **103**.

[0041] Referring back to FIGS. **1** and **3**, in one embodiment of the present invention, the secondary receiver unit **106** may be configured substantially in the manner described in conjunction with FIG. **3**. Alternatively, in another embodiment of the present invention, the secondary receiver unit **106** may be configured to include a limited number of functionalities as compared with the primary receiver unit **104** described in detail in conjunction with FIG. **3**.

[0042] For example, in one embodiment of the present invention, the secondary receiver unit **106** maybe substantially incorporated into a wrist watch worn by the user of the analyte monitoring system. Accordingly, in addition to keeping accurate time, the secondary receiver unit **106** is configured to receive the transmitted signals from the transmitter unit **102** worn by the user. In one embodiment, the wrist watch/secondary receiver unit **106** configuration includes a display section that, in addition to displaying the time and date information, displays the monitored analyte levels substantially in real time received from the transmitter unit **102**. This configuration is also programmable to store the received analyte data from the transmitter unit **102** which can later be transferred to the primary receiver unit **102**. Other features of the receiver unit display such as trend information or graphical representation of the trend data, may not be displayed in this configuration given the limited display area size on the wrist watch.

[0043] In one embodiment, the communication link between the primary receiver unit **104** and the secondary receiver unit **106** may be established using Bluetooth communication protocol, and each device is configured to peri-

odically transmit data such that the information stored in the primary receiver unit **104** and the secondary receiver unit **106** are maintained substantially up to date and in synchronization with each other. In addition, each of the primary receiver unit **104** and the secondary receiver unit **106** maybe configured to uniquely identify the transmitter unit **102** such that both primary receiver unit **104** and the secondary receiver unit **106** are configured to receive data transmission from the transmitter unit **102** without interruption, and to store the same in the respective storage sections of the receiver units.

[0044] In this manner, in one embodiment of the present invention, the user or patient may conveniently interchange the use between the primary receiver unit **104** and the secondary receiver unit **106** without any interruption in the analyte monitoring system **100**, and importantly, without losing data transmitted from the transmitter unit **102**. For example, a diabetic child using the analyte monitoring system **100** may carry the primary receiver unit **104** in her backpack during the course of the day, and wear the secondary receiver unit **106** which is configured as a wrist watch. During the time period when the backpack containing the primary receiver unit **104** is in close proximity to the transmitter unit **102** attached to the body of the diabetic child, the primary receiver unit **104** is configured to receive the transmitted data from the transmitter unit **102** corresponding to the monitored analyte levels of the diabetic child. During recess at school or any other time period during which the backpack containing the primary receiver unit **104** is not in signal range of the transmitter unit **102**, the secondary receiver unit **106** is configured to receive the signals from the transmitter unit **104**. Periodically during the day or at a preprogrammed time during a **24** hour period, the primary receiver unit **104** may be configured to synchronize with the secondary receiver unit **106** such that all of the transmitted signals from the transmitter unit **102** is stored in the primary receiver unit **104**.

[0045] Such multiple receiver unit implementation of the analyte monitoring system may be additionally beneficial in other circumstances. For example, the secondary receiver unit **106** may be used during the time period that the user or patient is engaged in physical activities such as sports or other types of activities where carrying an electronic device such as the primary receiver unit **104** may be cumbersome.

[0046] In addition, the secondary receiver unit **106** may be configured to operate in a low power transmission state such as that complying with Class B transmission regulated by the Federal Aviation Authority (FAA) which mandate electronic transmission devices to be turned off during airplane take off and landing procedures. In such cases, the primary receiver unit **104** may be powered down completely while the Class-B compliant secondary receiver unit **106** maybe configured to continue receiving the signals from the transmitter unit **102**. Thereafter, at a later time period when the primary receiver unit **104** may be turned on, the primary receiver unit **104** is configured to synchronize data with the secondary receiver unit **106** so that the transmitted signals from the transmitter unit **102** during the time that the primary receiver unit **104** was turned off can be captured and stored in the primary receiver unit **104**.

[0047] FIG. **4** is a flowchart illustrating data synchronization procedure between the primary receiver unit and the secondary receiver unit of the analyte monitoring system in accordance with one embodiment of the present invention. Referring to FIG. **4**, at step **410** in one embodiment of the present invention, the secondary receiver unit **106** (FIG. **1**) is configured to receive and store the signals received from the transmitter unit **102** that are associated with the monitored analyte levels. Thereafter at step **420**, the secondary receiver unit **106** determined whether the primary receiver unit **104** is back in the power on state. In one embodiment, the primary receiver unit **104** may be configured to broadcast a power on state signal as soon as it is powered on. Alternatively, in another embodiment, the secondary receiver unit **106** is configured to periodically transmit a signal to the primary receiver unit **104**, and when a return acknowledgement signal is received by the secondary receiver unit **106** as originating from the primary receiver unit **104**, it is determined that the primary receiver unit **104** is in the powered on state.

[0048] Referring back to FIG. **4**, if it is determined at step **420** that the primary receiver unit **104** is not in the power on state, then the secondary receiver unit **106** returns to step **410** where the transmitter unit **102** signals are continuously received and stored. If however it is determined at step **420** that the primary receiver unit **104** is in the power on state, then at step **430**, the secondary receiver unit **106** is configured to retrieve the stored data received from the transmitter unit **102**, and at step **440**, the secondary receiver unit **106** is configured to transmit the retrieved data corresponding to data received from the transmitter unit **102** to the primary receiver unit **104**. Thereafter, optionally, the secondary receiver unit **106** may be configured to enter a powered down or hibernate mode to conserve its power supply. In the hibernate mode, the secondary receiver unit **106** may be configured to not accept data transmitted from the transmitter unit **102**.

[0049] In an alternate embodiment, the secondary receiver unit **106** may be configured to continue to receive the transmitted data from the transmitter unit **102** even when the primary receiver unit **104** is in the power on state and receiving data from the transmitter unit **102**. In this manner, transmitter unit **102** data redundancy may be achieved.

[0050] FIG. **5** is a flowchart illustrating data synchronization procedure between the primary receiver unit and the secondary receiver unit of the analyte monitoring system in accordance with another embodiment of the present invention. Referring to FIG. **5**, at step **510**, the primary receiver unit **104** (FIG. **1**) entered the power on state by, for example, the user or patient powering on the primary receiver unit **104**. Thereafter at step **520**, the primary receiver unit **520** is configured to retrieve the time information associated with the power off state duration. For example, in one embodiment, the primary receiver unit **104** is configured to retrieve the time stamp information (as maybe provided by its internal clock **305** (FIG. **3**) of the beginning of the power off state, and the time stamp information of the beginning of the power on state.

[0051] Referring to FIG. **5**, the retrieved time information associated with the power off duration is transmitted to the secondary receiver unit **106** at step **530**. Thereafter, at step **540**, the primary receiver unit **104** is configured to receive transmitter unit **102** data from the secondary receiver unit **104** that correspond to the time information associated with the power off duration. That is, since during the power off state the primary receiver unit **104** did not receive any data from the transmitter unit **102** which are associated with the monitored analyte level, the primary receiver unit **104** may be configured in one embodiment to receive this data from the secondary receiver unit **106**.

[0052] In addition, within the scope of the present invention, the primary receiver unit **104** and the secondary receiver

unit **106** may be configured as a bedside monitor system where, the secondary receiver unit **106** (or interchangeably the primary receiver unit **104**) may be placed at or near the bedside of the child or patient wearing the transmitter unit **102**. The primary receiver unit **104** (or interchangeably the secondary receiver unit **106**) may be placed at another location within the house (or hospital or any other location within communication range with the secondary receiver unit **106**. In this manner, even though the RF communication link **103** between the transmitter unit **102** and the remotely located primary receiver unit **104** may not be enabled due to distance, the secondary receiver unit **106** which is in signal communication with the transmitter unit **102** may be configured as a relay device to retransmit the received transmitter unit **102** signals to the primary receiver unit **104**. In this manner, parents of diabetic children wearing a transmitter unit **102** to monitor the children's glucose levels, or patients in hospitals may conveniently and remotely monitor the analyte levels substantially in real time.

[0053] Accordingly, a system for providing analyte monitoring in one embodiment of the present invention includes a sensor configured for subcutaneous placement for detecting a plurality of analyte levels, a transmitter unit configured for electrical communication with the sensor; the transmitter unit configured to transmit a plurality of signals each associated with a respective one or more of the detected plurality of analyte levels, a first receiver unit configured to receive a first portion of the transmitted plurality of signals from the transmitter unit, a second receiver unit configured to receive a second portion of the transmitted signals from the transmitter unit.

[0054] In one embodiment, each of the plurality of signals transmitted by the transmitter unit maybe associated with a corresponding detection time information, where each detection time information may substantially correspond to the detection time of the corresponding associated analyte level by the sensor.

[0055] The second receiver unit maybe configured to transmit the received second portion of the signals to the first receiver unit, where the first portion of the plurality of signals and the second portion of the plurality of signals may be substantially non-overlapping.

[0056] Further, the first receiver unit may include a storage unit for storing the first and second portions of the plurality of the signals.

[0057] In addition, the first receiver unit may include an output unit for outputting one or more of a visual indication, an audible indication or a vibratory indication associated with the received one or more of the plurality of signals.

[0058] In a further aspect, the second receiver unit may include a housing substantially configured as one of a wrist watch, a bed side monitor unit, a two way radio communication unit, a mobile telephone, a pager, or a personal digital assistant.

[0059] The first receiver unit and the second receiver unit in yet another aspect may be configured to communicate over a communication link which may include one or more of an infrared communication link, an RF communication link, a Bluetooth communication link, or a cable connection.

[0060] In yet another aspect, each of the first and second receiver units may be configured for bi-directional communication.

[0061] A method of analyte monitoring in accordance with another embodiment of the present invention includes transmitting a plurality of signals associated with detected analyte levels, receiving a first portion of the plurality of signals at a first remote location, receiving a second portion of the plurality of signals at a second remote location, wherein the first and second portions of the plurality of signals are substantially non-overlapping.

[0062] The method may further include the step of transmitting the second portion of the plurality of signals from the second remote location to the first remote location.

[0063] In another aspect, the method may also include one or more steps of storing the plurality of signals, or displaying at least a portion of the plurality of signals.

[0064] A method of analyte monitoring in accordance with still another embodiment of the present invention includes receiving one or more signals associated with a respective one or more analyte levels being monitored, storing the received one or more signals, detecting an active state of a receiver unit, and transmitting the stored one or more signals to the receiver unit.

[0065] In another aspect, the method may also include the steps of detecting the one or more analyte levels, and transmitting the one or more signals each corresponding to the detected one or more analyte levels substantially in real time.

[0066] A method of analyte monitoring in still yet another embodiment of the present invention includes retrieving a time information associated with an inactive state, transmitting the retrieved time information, and receiving one or more signals each associated with a monitored analyte level corresponding to the time information.

[0067] The time information may include a beginning time and an end time of the inactive state.

[0068] In a further aspect, the method may also include the step of storing the received one or more signals.

[0069] Various other modifications and alterations 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. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

1. (canceled)

2. A system for continuous measurement of a blood glucose level of a host, the system comprising:

a continuous analyte sensor configured to determine a blood glucose level of a host;

a storage device for storing a plurality of blood glucose levels of the host at each of the plurality of sample times;

a sensor electronics module physically connected to the continuous analyte sensor during operation of the continuous analyte sensor, wherein the sensor electronics module is configured to determine whether at least some of the blood glucose levels match one or more requirements associated with a hypoglycemia or near hypoglycemia condition; and

in response to determining that the one or more requirements associated with the hypoglycemia or near hypoglycemic condition are matched by the at least some of the blood glucose levels of the host, generate a first data package for transmission to a first device associated with the host, wherein the first data package

includes displayable data indicating that the one or more requirements associated with the hypoglycemia condition or near hypoglycemic condition are matched; and substantially concurrently generate a second data package for transmission to a second device associated with a caretaker of the host, wherein the second data package includes displayable data indicating that the one or more requirements associated with the hypoglycemia condition are matched, wherein the first data package comprises data content customized for display on the first device and the second data package comprises data content customized for display on the second device.

3. The system of claim **2**, wherein the caretaker of the host comprises one of a parent, a relative, a guardian, a doctor, and a nurse.

4. The system of claim **2**, wherein the data indicating that the one or more requirements associated with the hypoglycemia condition are matched comprises an arrow, a numeric value and/or a graphical illustration.

5. The system of claim **2**, further comprising: a telemetry module configured to wirelessly transmit the first data package to the first device and to wirelessly transmit the second data package to the second device.

6. The system of claim **5**, wherein the telemetry module is configured to transmit data packages using one or more of: radio frequency (RF), infrared (IR), Bluetooth, frequency hopping, IEEE 802.11, paging network, and inductive coupling communication protocols.

7. The system of claim **6**, wherein the first data package is transmitted via a first communication protocol and the second data package is transmitted via a second communication protocol that is different than the first communication protocol.

8. The system of claim **7**, wherein the first communication protocol comprises Bluetooth and the second communication protocol comprises wireless local area network.

9. The system of claim **2**, wherein the requirements include at least a threshold blood glucose level.

10. The system of claim **2**, wherein the one or more requirements include at least a required trend in the blood glucose levels over a predetermined time period.

11. The system of claim **10**, wherein the trend is associated with one or more of an amplitude, a rate of change, an acceleration, or a direction of the blood glucose levels over a predetermined time period.

12. A method for continuous measurement of a blood glucose level of a host, the method comprising:

determining a plurality of blood glucose levels of the host at each of a plurality of sample times based on at least a measured concentration of an analyte at respective of the sample times;

determining whether at least some of the blood glucose levels match one or more requirement associated with a hypoglycemia or near hypoglycemia condition; and

in response to determining that the one or more requirements associated with the hypoglycemia or near hypoglycemia condition are matched by the at least some of the blood glucose levels of the host, generating a first data package for transmission to a first device associated with the host, wherein the first data package includes displayable data indicating that the one or more requirements associated with the hypoglycemia or near hypoglycemia condition are matched, and substantially concurrently generating a second data package for transmission to a second device associated with a caretaker of the host, wherein the second data package includes displayable data indicating that the one or more requirements associated with the hypoglycemia or near hypoglycemia condition are matched.

13. The method of claim **12**, wherein the second data package further comprises displayable data indicating one or more trends associated with blood glucose levels of the host over a predetermined time period.

14. The method of claim **12**, further comprising receiving at least some of the requirements from the caretaker.

15. The method of claim **12**, wherein the second device comprises a mobile telephone of the caretaker.

16. The method of claim **12**, wherein the second data package comprises a message

17. The method of claim **12**, wherein the one or more requirements are modified in response to a current status of the host.

18. The method of claim **12**, wherein the second data packages comprises data from another sensor associated with the host.

19. The method of claim **18**, wherein the another sensor is a temperature sensor.

20. The method of claim **12**, further comprising transforming at least some of the blood glucose levels into transformed sensor data indicating at least one trend in the sensor data.

21. The method of claim **12**, wherein the displayable data of the first data package is configured for display on the first display device without further analysis of the blood glucose levels by the first display device and the displayable data of the second data package is configured for display on the second display device without further analysis of the blood glucose levels by the second display device.

22. A computer readable medium storing software code thereon, the software code configured for execution by one or more processors of a computing device configured for coupling to a biological sensor that is attached to a host, wherein the software code, if executed by the computing device, causes the computing device to perform a method of transmitting sensor data to each of a plurality of display devices, wherein the method comprises:

determining a plurality of blood glucose levels of the host at each of a plurality of respective sample times based on data from a biological sensor at respective sample times;

determining whether at least some of the blood glucose levels match one or more requirement associated with a hypoglycemia or near hypoglycemia condition; and

in response to determining that the one or more requirements associated with the hypoglycemia condition are matched by the blood glucose levels of the host, generating a first data package for transmission to a first device associated with the host, wherein the first data package is configured for display on the first display device and includes displayable data indicating that the one or more requirements associated with the hypoglycemia or near hypoglycemia condition are matched, and substantially concurrently generating a second data package for transmission to a second device associated with a caretaker of the host, wherein the second data package is configured for display on the second display device and includes displayable data indicating that the one or more requirements associated with the hypoglycemia or near hypoglycemia condition are matched.

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