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(54) **METHOD AND APPARATUS FOR PROVIDING ROLLING DATA IN COMMUNICATION SYSTEMS**

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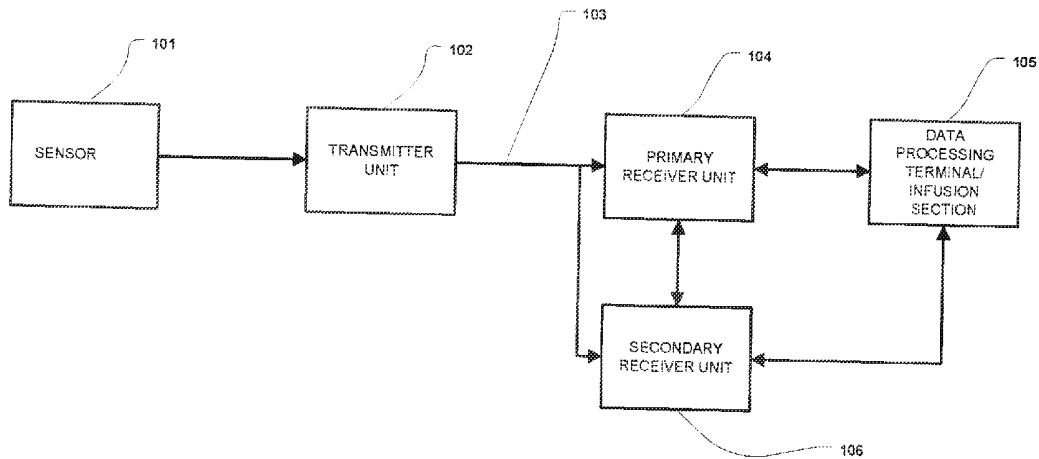
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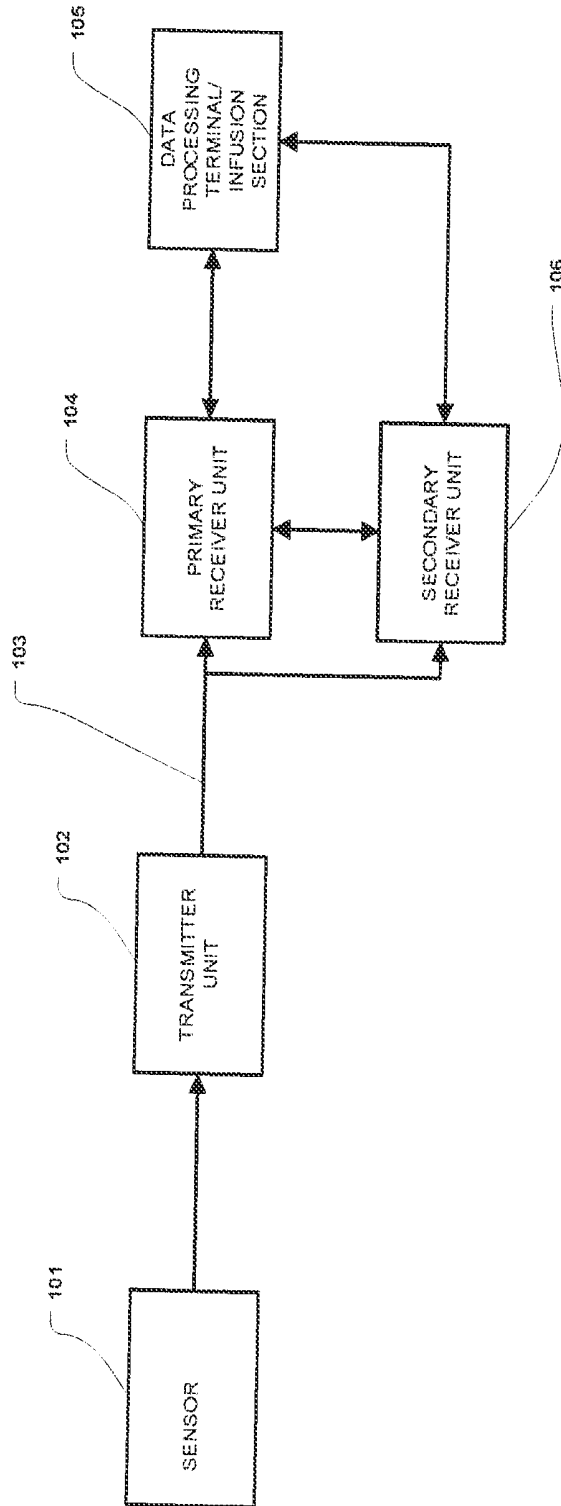
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(57) **ABSTRACT**

Methods and systems for providing data communication in medical systems are disclosed.





100

FIGURE 1

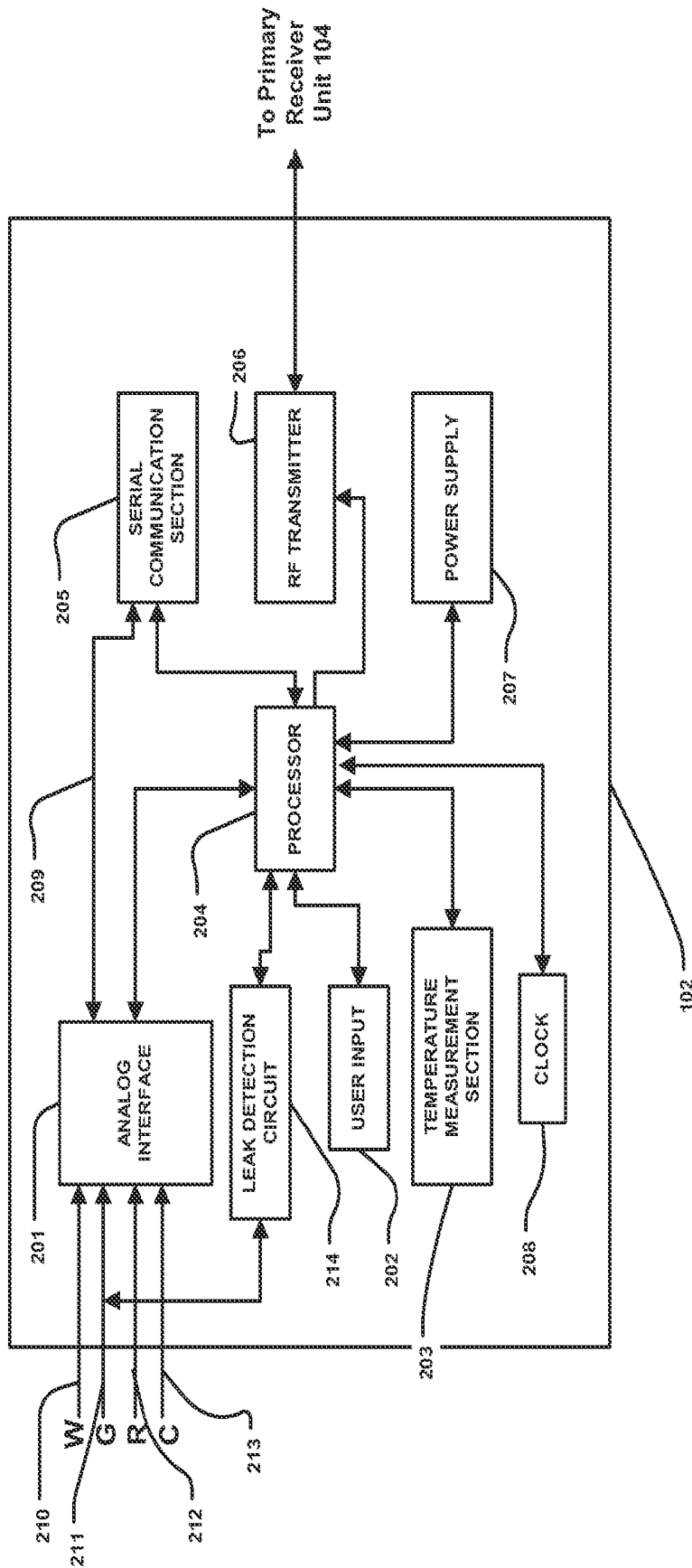


FIGURE 2

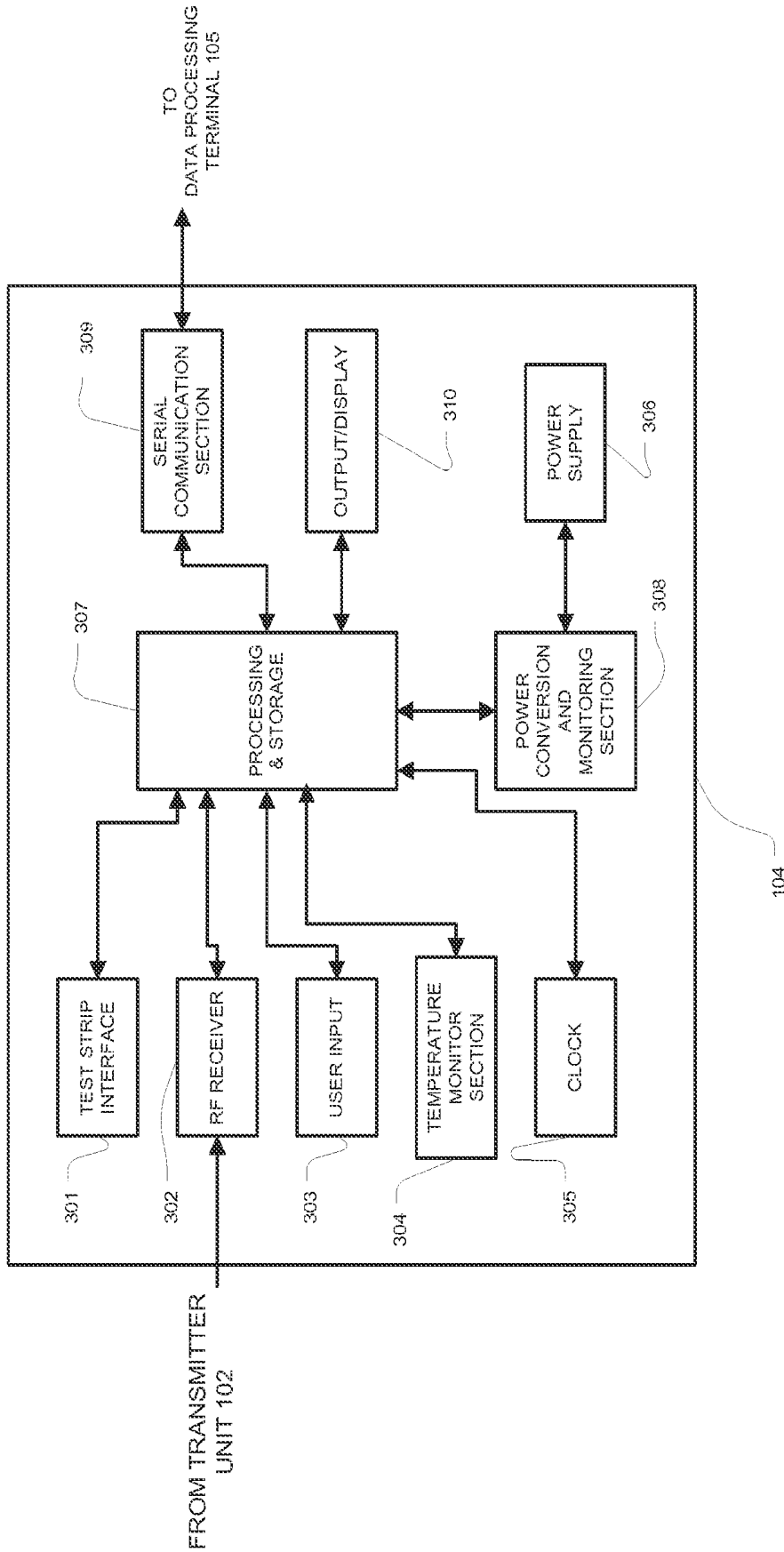


FIGURE 3

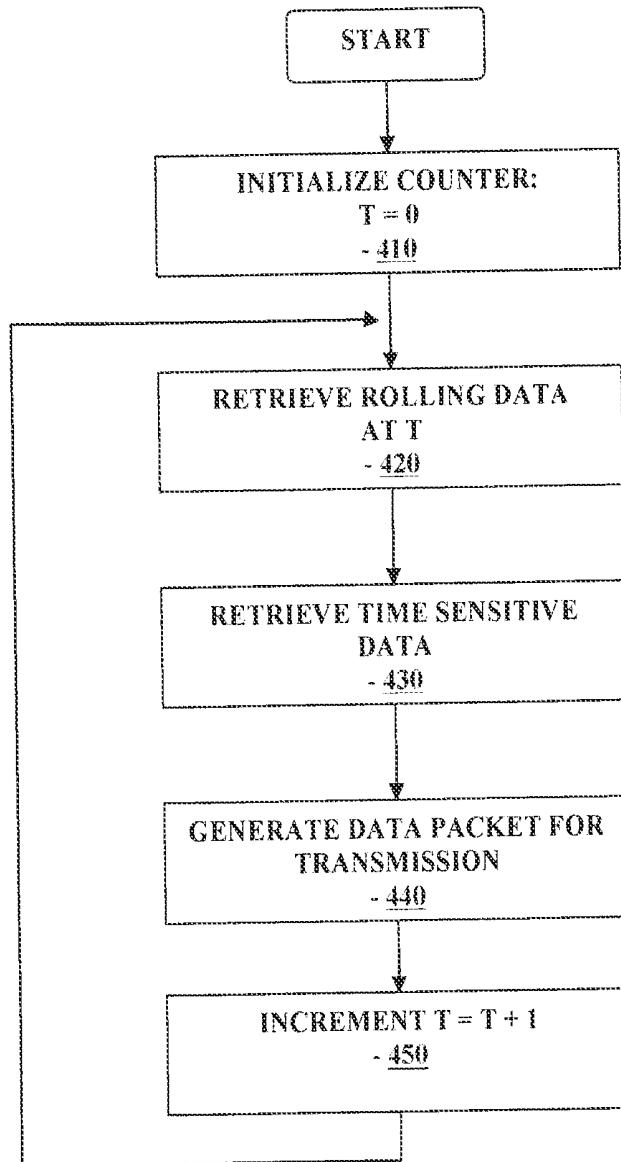


FIGURE 4

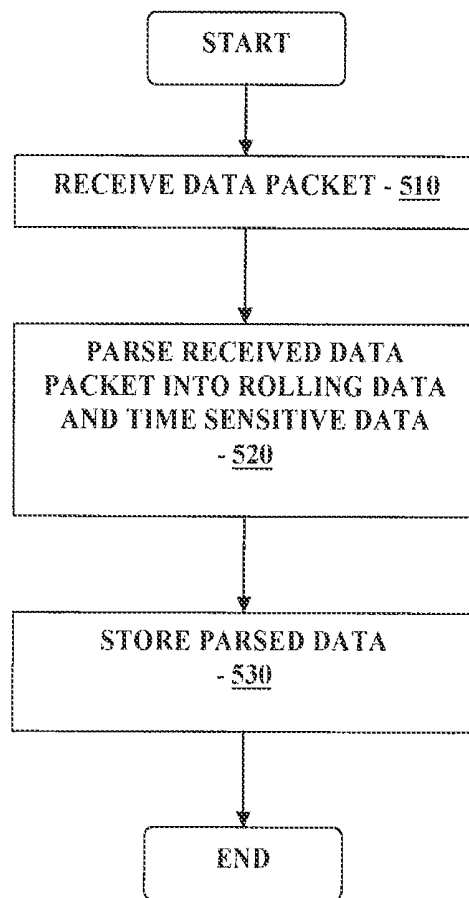


FIGURE 5

METHOD AND APPARATUS FOR PROVIDING ROLLING DATA IN COMMUNICATION SYSTEMS

RELATED APPLICATION

[0001] The present application is a continuation of U.S. patent application Ser. No. 13/406,528 filed Feb. 27, 2012, now U.S. Pat. No. 9,095,290, which is a continuation of U.S. patent application Ser. No. 11/681,133 filed Mar. 1, 2007, now U.S. Pat. No. 8,123,686, entitled "Method and Apparatus for Providing Rolling Data in Communication Systems," the disclosure of which is 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. RF signals may be used to transmit the collected data. One aspect of certain analyte monitoring systems include a transcutaneous or subcutaneous analyte sensor configuration which is, for example, at least partially positioned through the skin layer of a subject whose analyte level is to be monitored. The sensor 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] An analyte sensor may be configured so that a portion thereof is placed under the skin of the patient so as to contact analyte of the patient, and another portion or segment of the analyte sensor may be in communication with the transmitter unit. The transmitter unit may be 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 may perform data analysis, among other functions, on the received analyte levels to generate information pertaining to the monitored analyte levels.

[0004] Transmission of data over an RF communication link is often constrained to occur within a substantially short time duration. In turn, the time constraint in RF data communication imposes limits on the type and size of data that may be transmitted during the transmission time period.

[0005] In view of the foregoing, it would be desirable to have a method and apparatus for optimizing the RF communication link between two or more communication devices, for example, in a medical communication system.

SUMMARY OF THE INVENTION

[0006] Devices and methods for analyte monitoring, e.g., glucose monitoring, are provided. Embodiments include transmitting information from a first location to a second, e.g., using a telemetry system such as RF telemetry. Systems herein include continuous analyte monitoring systems and discrete analyte monitoring system.

[0007] In one embodiment, a method including retrieving a first data type, retrieving a second data type, transmitting a first data packet including the first data type and the second data type, updating the second data type, and generating a

second data packet including the first data type and the updated second data type, is disclosed, as well as devices and systems for the same.

[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 or more embodiments 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 packet procedure including rolling data for transmission in accordance with one embodiment of the present invention; and

[0013] FIG. 5 is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

[0014] As summarized above and as described in further detail below, in accordance with the various embodiments of the present invention, there is provided a method and system for retrieving a first data type, retrieving a second data type, transmitting a first data packet including the first data type and the second data type, updating the second data type, and generating a second data packet including the first data type and the updated second data type.

[0015] 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.

[0016] 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. More than one analyte may be monitored by a single system, e.g. a single analyte sensor.

[0017] The analyte monitoring system 100 includes a sensor 101, a transmitter unit 102 coupleable 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 evaluating the data received by the primary receiver unit 104. Moreover, the data processing terminal 105 in one embodi-

ment may be configured to receive data directly from the transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication. Accordingly, transmitter unit 102 and/or receiver unit 104 may include a transceiver.

[0018] Also shown in FIG. 1 is an optional 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 or one 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, pager, mobile phone, PDA, for example. Alternatively, the secondary receiver unit 106 may be configured with the same or substantially similar functionality as the primary receiver unit 104. The receiver unit may be configured to be used in conjunction with a docking cradle unit, for example for one or more of the following or other functions: placement by bedside, for re-charging, for data management, for night time monitoring, and/or bi-directional communication device.

[0019] In one aspect sensor 101 may include two or more sensors, each configured to communicate with transmitter unit 102. Furthermore, while only one, 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 sensors, multiple transmitter units 102, communication links 103, and data processing terminals 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.

[0020] 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 certain embodiments, the transmitter unit 102 may be physically coupled to the sensor 101 so that both devices are integrated in a single housing and positioned on the user's body. The transmitter unit 102 may perform data processing such as filtering and encoding on data signals and/or other functions, each of which corresponds to a sampled analyte level of the user, and in any event transmitter unit 102 transmits analyte information to the primary receiver unit 104 via the communication link 103.

[0021] 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.

[0022] 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.

[0023] 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 and/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.

[0024] 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.

[0025] Within the scope of the present invention, the data processing terminal 105 may include an infusion device such as an insulin infusion pump (external or implantable) 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 or otherwise couple to 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.

[0026] 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, where the communication link, as described above, may be configured for bi-directional communication.

[0027] 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 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPAA requirements) while avoiding potential data collision and interference.

[0028] 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 measurement 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 101 (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 or ablated, for example, such as carbon which may be printed, or a metal such as a metal foil (e.g., gold) or the like, which may be etched or ablated or otherwise processed to provide one or more electrodes. Fewer or greater electrodes and/or contact may be provided in certain embodiments.

[0029] 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.

[0030] 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.

[0031] 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, which may be a rechargeable battery.

[0032] In certain embodiments, 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, e.g., after having been stored for about eighteen months such as stored 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 μ A of current. Indeed, in one embodiment, a 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.

[0033] 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.

[0034] Referring yet again to FIG. 2, the temperature measurement 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. In certain

embodiments, 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 about 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit **104**.

[0035] Referring yet again to FIG. 2, also shown is a leak detection circuit **214** coupled to the guard contact (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.

[0036] Description of sensor, calibration (singlepoint), and/or exemplary analyte systems that may be employed are described in, for example, U.S. Pat. Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, and elsewhere.

[0037] 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 an analyte test strip, e.g., blood glucose test strip interface **301**, an RF receiver **302**, an input **303**, a temperature monitor 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**.

[0038] 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 may be used to calibrate the sensor **101** (FIG. 1) or otherwise. 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 monitor 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**.

[0039] 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 **04** 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.

[0040] 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 **309** 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.

[0041] 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** may be configured to synchronize with a transmitter, e.g., using Manchester decoding or the like, as well as error detection and correction upon the encoded data signals received from the transmitter unit **102** via the communication link **103**.

[0042] Additional description of the RF communication between the transmitter unit **102** and the primary receiver unit **104** (or with the secondary receiver unit **106**) that may be employed in embodiments of the subject invention is disclosed in application Ser. No. 11/060,365 filed Feb. 16, 2005, now U.S. Pat. No. 8,771,183 entitled "Method and System for Providing Data Communication in Continuous Glucose Monitoring and Management System" the disclosure of which is incorporated herein by reference for all purposes.

[0043] Referring to the Figures, in one embodiment, the transmitter unit **102** (FIG. 1) may be configured to generate data packets for periodic transmission to one or more of the receiver units **104**, **106**, where each data packet includes in one embodiment two categories of data—urgent data and non-urgent data. For example, urgent data such as for example glucose data from the sensor and/or temperature data associated with the sensor may be packed in each data packet in addition to non-urgent data, where the non-urgent data is rolled or varied with each data packet transmission.

[0044] That is, the non-urgent data is transmitted at a timed interval so as to maintain the integrity of the analyte monitoring system without being transmitted over the RF communication link with each data transmission packet from the transmitter unit **102**. In this manner, the non-urgent data, for

example that are not time sensitive, may be periodically transmitted (and not with each data packet transmission) or broken up into predetermined number of segments and sent or transmitted over multiple packets, while the urgent data is transmitted substantially in its entirety with each data transmission.

[0045] Referring again to the Figures, upon receiving the data packets from the transmitter unit 102, the one or more receiver units 104, 106 may be configured to parse the received the data packet to separate the urgent data from the non-urgent data, and also, may be configured to store the urgent data and the non-urgent data, e.g., in a hierarchical manner. In accordance with the particular configuration of the data packet or the data transmission protocol, more or less data may be transmitted as part of the urgent data, or the non-urgent rolling data. That is, within the scope of the present disclosure, the specific data packet implementation such as the number of bits per packet, and the like, may vary based on, among others, the communication protocol, data transmission time window, and so on.

[0046] In an exemplary embodiment, different types of data packets may be identified accordingly. For example, identification in certain exemplary embodiments may include—(1) single sensor, one minute of data, (2) two or multiple sensors, (3) dual sensor, alternate one minute data, and (4) response packet. For single sensor one minute data packet, in one embodiment, the transmitter unit 102 may be configured to generate the data packet in the manner, or similar to the manner, shown in Table 1 below.

TABLE 1

Single sensor, one minute of data	
Number of Bits	Data Field
8	Transmit Time
14	Sensor1 Current Data
14	Sensor1 Historic Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

[0047] As shown in Table 1 above, the transmitter data packet in one embodiment may include 8 bits of transmit time data, 14 bits of current sensor data, 14 bits of preceding sensor data, 8 bits of transmitter status data, 12 bits of auxiliary counter data, 12 bits of auxiliary thermistor 1 data, 12 bits of auxiliary thermistor 1 data and 8 bits of rolling data. In one embodiment of the present invention, the data packet generated by the transmitter for transmission over the RF communication link may include all or some of the data shown above in Table 1.

[0048] Referring back, the 14 bits of the current sensor data provides the real time or current sensor data associated with the detected analyte level, while the 14 bits of the sensor historic or preceding sensor data includes the sensor data associated with the detected analyte level one minute ago. In this manner, in the case where the receiver unit 104, 106 drops or fails to successfully receive the data packet from the transmitter unit 102 in the minute by minute transmission, the receiver unit 104, 106 may be able to capture the sensor data of a prior minute transmission from a subsequent minute transmission.

[0049] Referring again to Table 1, the Auxiliary data in one embodiment may include one or more of the patient’s skin temperature data, a temperature gradient data, reference data, and counter electrode voltage. The transmitter status field may include status data that is configured to indicate corrupt data for the current transmission (for example, if shown as BAD status (as opposed to GOOD status which indicates that the data in the current transmission is not corrupt)). Furthermore, the rolling data field is configured to include the non-urgent data, and in one embodiment, may be associated with the time-hop sequence number. In addition, the Transmitter Time field in one embodiment includes a protocol value that is configured to start at zero and is incremented by one with each data packet. In one aspect, the transmitter time data may be used to synchronize the data transmission window with the receiver unit 104, 106, and also, provide an index for the Rolling data field.

[0050] In a further embodiment, the transmitter data packet may be configured to provide or transmit analyte sensor data from two or more independent analyte sensors. The sensors may relate to the same or different analyte or property. In such a case, the data packet from the transmitter unit 102 may be configured to include 14 bits of the current sensor data from both sensors in the embodiment in which 2 sensors are employed. In this case, the data packet does not include the immediately preceding sensor data in the current data packet transmission. Instead, a second analyte sensor data is transmitted with a first analyte sensor data.

TABLE 2

Dual sensor data	
Number of Bits	Data Field
8	Transmit Time
14	Sensor1 Current Data
14	Sensor2 Current Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

[0051] In a further embodiment, the transmitter data packet may be alternated with each transmission between two analyte sensors, for example, alternating between the data packet shown in Table 3 and Table 4 below.

TABLE 3

Sensor Data Packet Alternate 1	
Number of Bits	Data Field
8	Transmitter Time
14	Sensor1 Current Data
14	Sensor1 Historic Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

TABLE 4

Sensor Data Packet Alternate 2	
Number of Bits	Data Field
8	Transmitter Time
14	Sensor1 Current Data
14	Sensor2 Current Data
8	Transmit Status
12	AUX Counter
12	AUX Thermistor 1
12	AUX Thermistor 2
8	Rolling-Data-1

[0052] As shown above in reference to Tables 3 and 4, the minute by minute data packet transmission from the transmitter unit 102 (FIG. 1) in one embodiment may alternate between the data packet shown in Table 3 and the data packet shown in Table 4. More specifically, the transmitter unit 102 may be configured in one embodiment to transmit the current sensor data of the first sensor and the preceding sensor data of the first sensor (Table 3), as well as the rolling data, and further, at the subsequent transmission, the transmitter unit 102 may be configured to transmit the current sensor data of the first and the second sensor in addition to the rolling data.

[0053] In one embodiment, the rolling data transmitted with each data packet may include a sequence of various predetermined types of data that are considered not-urgent or not time sensitive. That is, in one embodiment, the following list of data shown in Table 5 may be sequentially included in the 8 bits of transmitter data packet, and not transmitted with each data packet transmission of the transmitter (for example, with each 60 second data transmission from the transmitter unit 102).

TABLE 5

Rolling Data		
Time Slot	Bits	Rolling-Data
0	8	Mode
1	8	Glucose1 Slope
2	8	Glucose2 Slope
3	8	Ref-R
4	8	Hobbs Counter, Ref-R
5	8	Hobbs Counter
6	8	Hobbs Counter
7	8	Sensor Count

[0054] As can be seen from Table 5 above, in one embodiment, a sequence of rolling data is appended or added to the transmitter data packet with each data transmission time slot. In one embodiment, there may be 256 time slots for data transmission by the transmitter unit 102 (FIG. 1), and where, each time slot is separated by approximately 60 second interval. For example, referring to the Table 5 above, the data packet in transmission time slot 0 (zero) may include operational mode data (Mode) as the rolling data that is appended to the transmitted data packet. At the subsequent data transmission time slot (for example, approximately 60 seconds after the initial time slot (0)), the transmitted data packet may include the analyte sensor 1 calibration factor information (Glucose1 slope) as the rolling data. In this manner, with each data transmission, the rolling data may be updated over the 256 time slot cycle.

[0055] Referring again to Table 5, each rolling data field is described in further detail for various embodiments. For example, the Mode data may include information related to the different operating modes such as, but not limited to, the data packet type, the type of battery used, diagnostic routines, single sensor or multiple sensor input, type of data transmission (RF communication link or other data link such as serial connection). Further, the Glucose1-slope data may include an 8-bit scaling factor or calibration data for first sensor (scaling factor for sensor 1 data), while Glucose2-slope data may include an 8-bit scaling factor or calibration data for the second analyte sensor (in the embodiment including more than one analyte sensors).

[0056] In addition, the Ref-R data may include 12 bits of on-board reference resistor used to calibrate our temperature measurement in the thermistor circuit (where 8 bits are transmitted in time slot 3, and the remaining 4 bits are transmitted in time slot 4), and the 20-bit Hobbs counter data may be separately transmitted in three time slots (for example, in time slot 4, time slot 5 and time slot 6) to add up to 20 bits. In one embodiment, the Hobbs counter may be configured to count each occurrence of the data transmission (for example, a packet transmission at approximately 60 second intervals) and may be incremented by a count of one (1).

[0057] In one aspect, the Hobbs counter is stored in a non-volatile memory of the transmitter unit 102 (FIG. 1) and may be used to ascertain the power supply status information such as, for example, the estimated battery life remaining in the transmitter unit 102. That is, with each sensor replacement, the Hobbs counter is not reset, but rather, continues the count with each replacement of the sensor 101 to establish contact with the transmitter unit 102 such that, over an extended usage time period of the transmitter unit 102, it may be possible to determine, based on the Hobbs count information, the amount of consumed battery life in the transmitter unit 102, and also, an estimated remaining life of the battery in the transmitter unit 102.

[0058] FIG. 4 is a flowchart illustrating a data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention. Referring to FIG. 4, in one embodiment, a counter is initialized (for example, to T=0) (410). Thereafter the associated rolling data is retrieved from memory device, for example (420), and also, the time sensitive or urgent data is retrieved (430). In one embodiment, the retrieval of the rolling data (420) and the retrieval of the time sensitive data (430) may be retrieved at substantially the same time.

[0059] Referring back to FIG. 4, with the rolling data and the time sensitive data, for example, the data packet for transmission is generated (440), and upon transmission, the counter is incremented by one (450) and the routine returns to retrieval of the rolling data (420). In this manner, in one embodiment, the urgent time sensitive data as well as the non-urgent data may be incorporated in the same data packet and transmitted by the transmitter unit 102 (FIG. 1) to a remote device such as one or more of the receivers 104, 106. Furthermore, as discussed above, the rolling data may be updated at a predetermined time interval which is longer than the time interval for each data packet transmission from the transmitter unit 102 (FIG. 1).

[0060] FIG. 5 is a flowchart illustrating data processing of the received data packet including the rolling data in accordance with one embodiment of the present invention. Referring to FIG. 5, when the data packet is received (510) (for

example, by one or more of the receivers **104**, **106**, in one embodiment), the received data packet is parsed so that the urgent data may be separated from the not-urgent data (**520**) (stored in, for example, the rolling data field in the data packet). Thereafter the parsed data is suitably stored in an appropriate memory or storage device (**530**).

[0061] In the manner described above, in accordance with one embodiment of the present invention, there is provided method and apparatus for separating non-urgent type data (for example, data associated with calibration) from urgent type data (for example, monitored analyte related data) to be transmitted over the communication link to minimize the potential burden or constraint on the available transmission time. More specifically, in one embodiment, non-urgent data may be separated from data that is required by the communication system to be transmitted immediately, and transmitted over the communication link together while maintaining a minimum transmission time window. In one embodiment, the non-urgent data may be parsed or broken up into a number of data segments, and transmitted over multiple data packets. The time sensitive immediate data (for example, the analyte sensor data, temperature data etc.), may be transmitted over the communication link substantially in its entirety with each data packet or transmission.

[0062] Accordingly, in one embodiment, there is provided a method including retrieving a first data type, retrieving a second data type, transmitting a first data packet including the first data type and the second data type, updating the second data type, and generating a second data packet including the first data type and the updated second data type.

[0063] In one aspect, the first data type may be associated with urgent data, and further, where the second data type may be associated with non-urgent data.

[0064] In another aspect, the first data type may include real time analyte data associated with the monitored analyte level of a patient, and further, where the analyte may include glucose. Moreover, in one aspect, the first data type may be related to glucose level information, and the second data type may be related to a predetermined scaling factor associated with the glucose level information.

[0065] In still another aspect, the second data type may include one or more of a component status information, a calibration data, or an analyte sensor count information.

[0066] Moreover, the second data type and the updated second data type may be different.

[0067] The method may also include encrypting the first data packet before transmission. Moreover, the method may also include encrypting the second data packet.

[0068] Furthermore, in still another aspect, the method may include transmitting the encrypted second data packet, where the first data packet transmission and the second data packet transmission may be separated by one of approximately 60 seconds, less than five minutes, five minutes, or greater than five minutes.

[0069] Additionally, each of the first and second data packets may include a transmit time count which is incremented by an integer value with each subsequent transmission.

[0070] A method in accordance with another embodiment may include receiving a data packet, parsing the received data packet such that a first data type and a second data type are retrieved from the received data packet, and wherein the first data type is urgent type data, and the second data type is non-urgent type data.

[0071] The urgent type data in one embodiment may include analyte sensor data, and further, where the analyte may include glucose. Moreover, in one aspect, the first data type may be related to glucose level information, and the second data type may be related to a predetermined scaling factor associated with the glucose level information.

[0072] The method may further include storing the first data type and the second data type.

[0073] An apparatus in accordance with another embodiment of the present invention includes one or more processing units, and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processing units to retrieve a first data type, retrieve a second data type, transmit a first data packet including the first data type and the second data type, update the second data type, and generate a second data packet including the first data type and the updated second data type.

[0074] In another aspect, the apparatus may also include an RF transmitter coupled to the one or more processing units, and configured to transmit the first data packet, and the second data packet.

[0075] In still another aspect, the apparatus may include a medical module operatively coupled to the one or more processing units and the memory.

[0076] The medical module may include a continuous glucose monitoring device.

[0077] Furthermore, there may be provided a housing, where the medical module, the one or more processing units and the memory are integrated substantially within the housing.

[0078] The various processes described above including the processes performed by the processor **204** in the software application execution environment in the transmitter unit **102** as well as any other suitable or similar processing units embodied in the analyte monitoring system **100** including the processes and routines described in conjunction with FIGS. **4-5**, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in a memory or storage unit (not shown) of the processor **204** or the transmitter unit **102**, may be developed by a person of ordinary skill in the art and may include one or more computer program products.

[0079] 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.

What is claimed is:

1. A glucose monitoring device, comprising:
an in vivo glucose sensor that monitors glucose level; and
sensor electronics operatively coupled to the glucose sensor to receive and process signals from the glucose sensor, the sensor electronics generating a plurality of data packets for communication to a remote location, each generated data packet including one of a plurality of

- glucose monitoring device data, each glucose monitoring device data assigned with a communication time slot such that the sensor electronics sequentially communicates the plurality of generated data packets based on the assigned communication time slot, wherein each generated data packet includes the glucose data and the corresponding glucose monitoring device data assigned with the respective communication time slot.
2. The device of claim 1, wherein the sensor electronics communicates the plurality of generated data packets to the remote location such that each communicated data packet does not include all of the plurality of glucose monitoring device data.
 3. The device of claim 1, wherein the communication time slots assigned to each glucose monitoring device data are non-overlapping.
 4. The device of claim 1, wherein the glucose monitoring device data includes operational mode data including type of data communication.
 5. The device of claim 1, wherein the glucose monitoring device data includes glucose sensor calibration data.
 6. The device of claim 1, wherein the glucose monitoring device data includes glucose sensor temperature data.
 7. The device of claim 1, wherein the glucose monitoring device data includes glucose monitoring device power supply status data of sensor electronics power supply.
 8. The device of claim 7, wherein the power supply status data includes a count that increments with each communication of the generated data packet to the remote location and that corresponds to the remaining life of the power supply.
 9. The device of claim 1, wherein the glucose monitoring device data includes a communication count corresponding to the frequency of the sensor electronics data communication to the remote location.
 10. The device of claim 9, wherein the sensor electronics increments the communication count by an integer value with each subsequent communication.
 11. The device of claim 1, wherein the glucose data communicated to the remote location with each generated packet includes real time and historical glucose data.
 12. A glucose monitoring device, comprising:
 - an in vivo glucose sensor that monitors glucose level; and
 - sensor electronics operatively coupled to the glucose sensor to receive from the glucose sensor, the sensor electronics including:
 - a memory;
 - a communication unit; and
 - a processor operatively coupled to the memory, and the communication unit, the memory having stored therein a plurality of glucose monitoring data each assigned with a communication time slot, the processor configured to retrieve one of the plurality of glucose monitoring data from the memory and to generate a plurality of data packets where each generated data packet includes glucose data and one of the plurality of glucose monitoring device data;
 - wherein the communication unit serially communicates each of the plurality of generated data packets to a remote location in accordance with the assigned communication time slot.
 13. The device of claim 12, wherein each generated data packet communicated to the remote location does not include all of the plurality of glucose monitoring device data.
 14. The device of claim 12, wherein the glucose monitoring device data includes operational mode data including type of data communication.
 15. The device of claim 12, wherein the glucose monitoring device data includes glucose sensor calibration data.
 16. The device of claim 12, wherein the glucose monitoring device data includes glucose sensor temperature data.
 17. The device of claim 12, further including a power supply operatively coupled to the processor to provide power, wherein the glucose monitoring device data includes power supply status data of the power supply.
 18. The device of claim 17, wherein the power supply status data includes a count incremented with each communication of the generated data packet to the remote location and that corresponds to the remaining life of the power supply.
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摘要(译)

公开了用于在医疗系统中提供数据通信的方法和系统。

