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

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See application file for complete search history.

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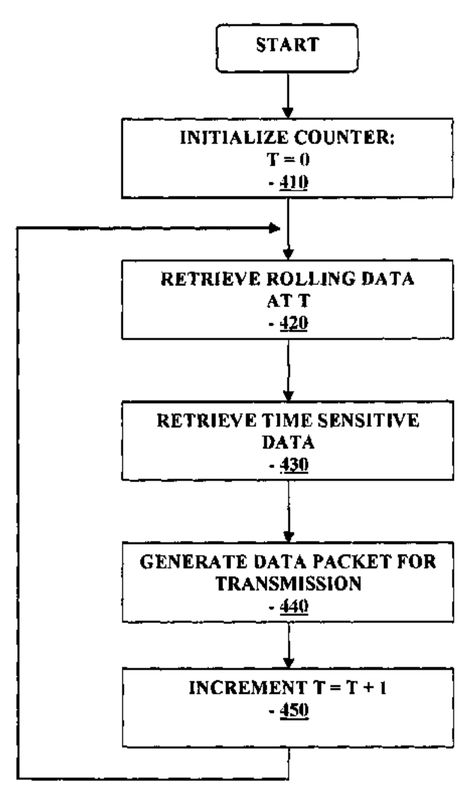
(57) **ABSTRACT**

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

20 Claims, 5 Drawing Sheets



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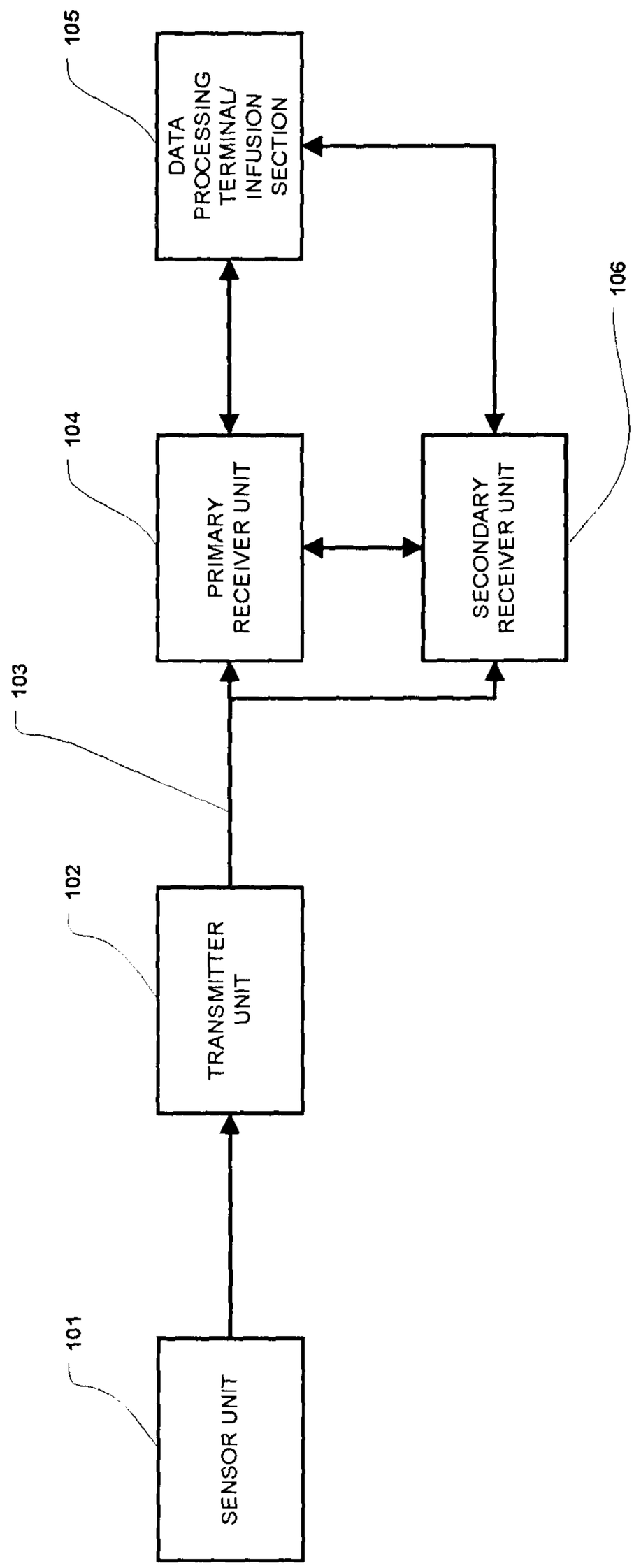
105
DATA PROCESSING TERMINAL/ INFUSION SECTION
106
104
PRIMARY RECEIVER UNIT
SECONDARY RECEIVER UNIT
103
102
TRANSMITTER UNIT
101
SENSOR UNIT

100

FIGURE 1

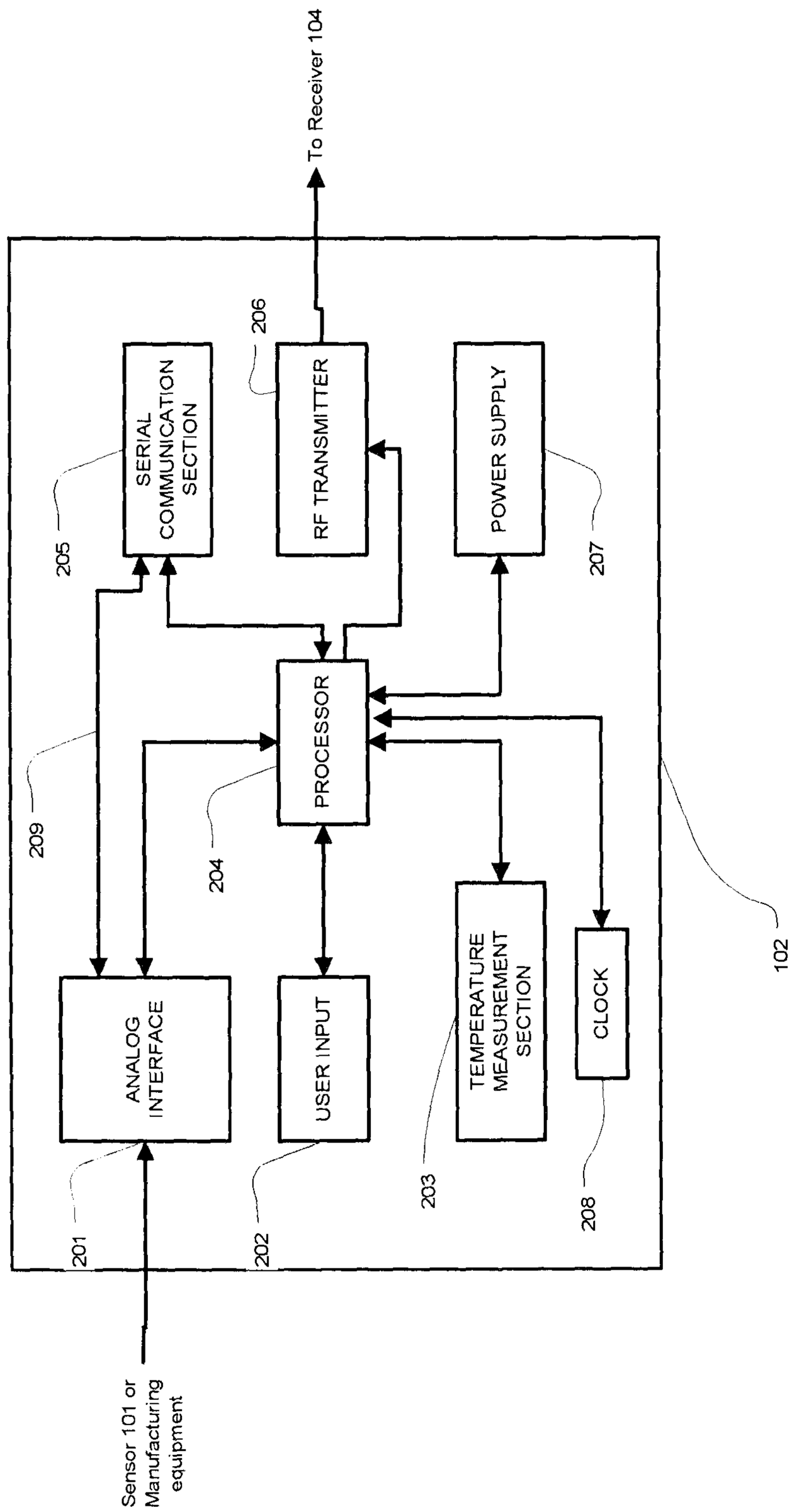
To Receiver 104
206
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
205
207
PROCESSOR
209
204
ANALOG INTERFACE
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
102
201
202
203
208
Sensor 101 or Manufacturing equipment

FIGURE 2

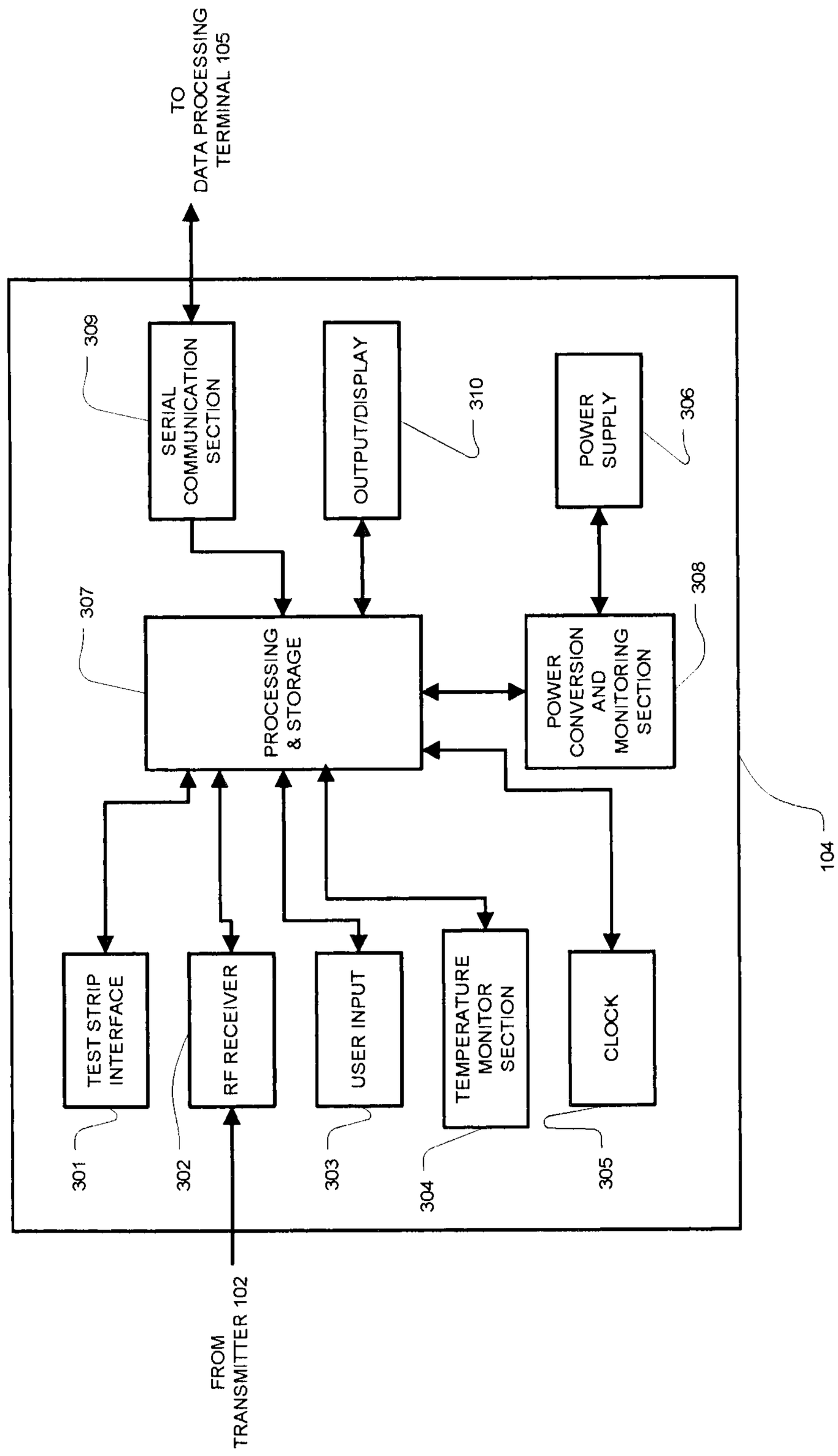
TO
DATA PROCESSING
TERMINAL 105
309
SERIAL
COMMUNICATION
SECTION
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
307
PROCESSING
& STORAGE
POWER
CONVERSION
AND
MONITORING
SECTION
308
104
TEST STRIP
INTERFACE
RF RECEIVER
USER INPUT
TEMPERATURE
MONITOR
SECTION
CLOCK
301
302
303
304
305
FROM
TRANSMITTER 102

FIGURE 3

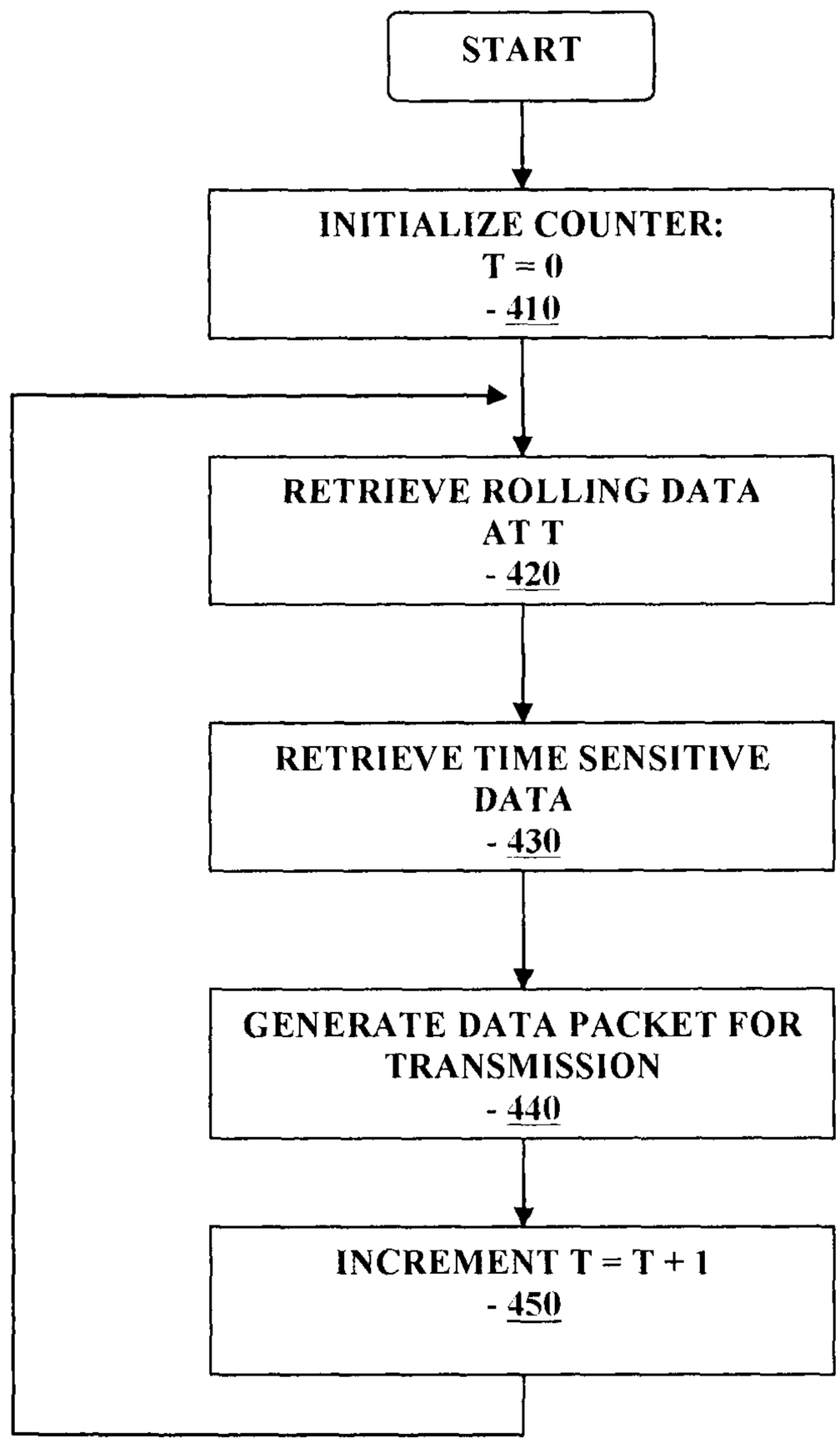
START
INITIALIZE COUNTER:
T = 0
- 410
RETRIEVE ROLLING DATA
AT T
- 420
RETRIEVE TIME SENSITIVE
DATA
- 430
GENERATE DATA PACKET FOR
TRANSMISSION
- 440
INCREMENT T = T + 1
- 450

FIGURE 4

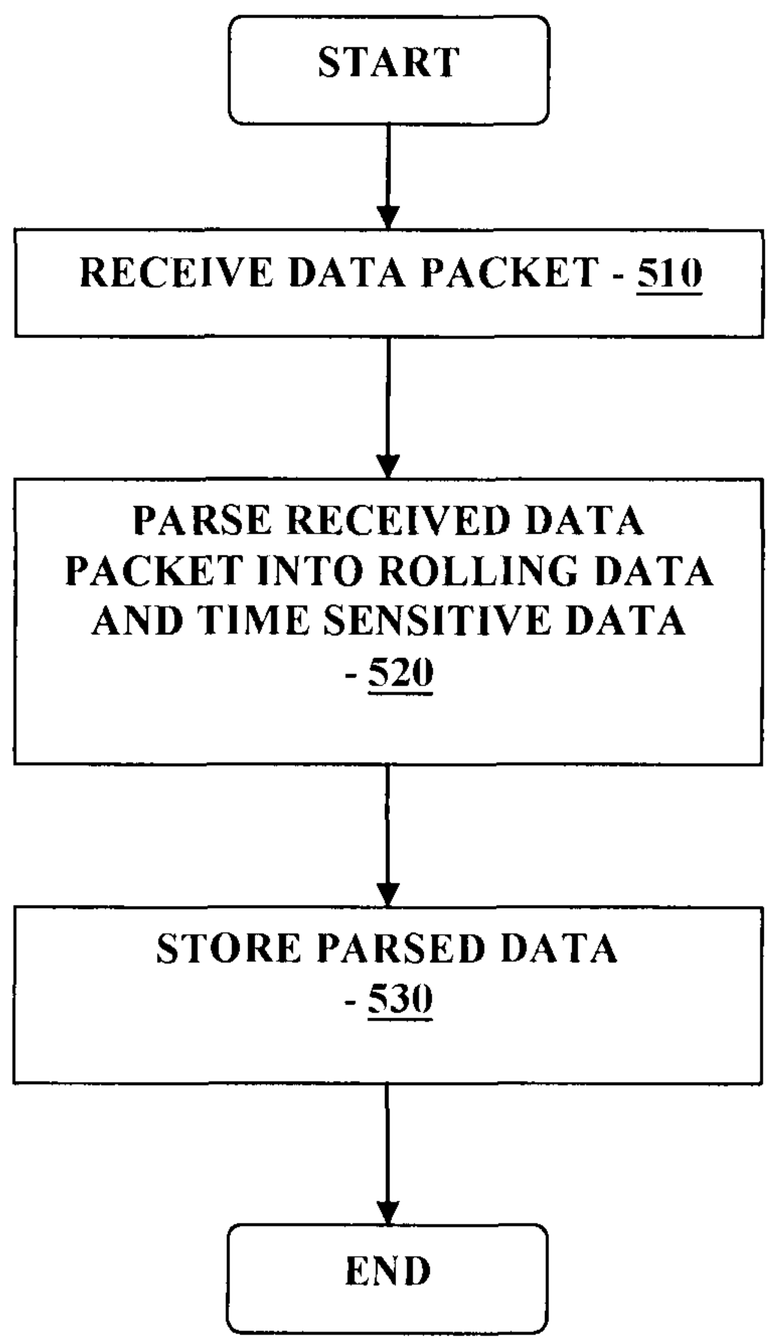
START
RECEIVE DATA PACKET - 510
PARSE RECEIVED DATA PACKET INTO ROLLING DATA AND TIME SENSITIVE DATA - 520
STORE PARSED DATA - 530
END

FIGURE 5

METHOD AND APPARATUS FOR PROVIDING ROLLING DATA IN COMMUNICATION SYSTEMS

RELATED APPLICATION

The present application 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

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.

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.

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.

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

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.

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.

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

FIG. **1** illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present invention;

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;

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;

FIG. **4** is a flowchart illustrating data packet procedure including rolling data for transmission in accordance with one embodiment of the present invention; and

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

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.

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.

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.

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 embodiment 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.

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 transmit-

ter 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.

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**.

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**.

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**.

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.

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.

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.

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**.

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.

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.

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.

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**.

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.

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.

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 μA 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**.

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.

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**.

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.

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.

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**.

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**.

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.

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.

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**.

Additional description of the RF communication between the transmitter **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.

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.

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.

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.

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

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.

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.

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.

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

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

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.

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

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.

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).

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).

In one aspect, the Hobbs counter is stored in a nonvolatile 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**.

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.

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**).

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**).

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.

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.

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.

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.

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.

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

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

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.

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.

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.

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.

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

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.

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.

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

The medical module may include a continuous glucose monitoring device.

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.

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.

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 computer implemented method for communicating rolling data in an analyte monitoring system, comprising:

retrieving with one or more processors a first data type from a storage device, wherein the first data type includes analyte sensor data obtained from an analyte sensor positioned in fluid contact with an interstitial fluid under a skin layer;

retrieving with the one or more processors a predetermined portion of a rolling data from the storage device, each predetermined portion of the rolling data assigned a transmission time slot and includes one or more of the following parameters: operational mode data, analyte sensor slope data, temperature related data, power supply status data, data transmission count data, or analyte sensor scaling factor data;

transmitting during a first transmission time slot a first data packet including the first data type and the predetermined portion of the rolling data assigned to the first transmission time slot to a remote location; and

transmitting during a second transmission time slot a second data packet to the remote location subsequent to the first data packet transmission, the second data packet including the first data type and the predetermined portion of the rolling data assigned to the second transmission time slot for transmission to the remote location;

wherein each transmitted data packet comprises the first data type and the predetermined portion of the rolling data.

2. The method of claim **1**, wherein the first data type is associated with urgent data, and further, wherein the rolling data is associated with non-urgent data.

3. The method of claim **1**, wherein the analyte sensor data includes real time analyte data associated with a monitored analyte level.

4. The method of claim **3**, wherein the analyte sensor data includes glucose, and further, wherein the first data type is related to glucose level information, and the rolling data is related to a predetermined scaling factor associated with the glucose level information.

5. The method of claim **1**, wherein each of the first and second data packets include a transmit time count which is incremented by an integer value with each subsequent transmission.

6. The method of claim **1**, wherein the first data type includes current sensor data and historic sensor data.

7. The method of claim **6**, wherein the first data type in the first data packet is current sensor data and the first data type in the second data packet is historic sensor data.

8. The method of claim **7**, wherein the historic sensor data includes sensor data that immediately precedes the current sensor data.

9. An apparatus, comprising:

one or more processors; and

a memory storing instructions which, when executed by the one or more processors, causes the one or more

processors to retrieve a first data type from a storage device, wherein the first data type includes analyte sensor data obtained from an analyte sensor positioned in fluid contact with an interstitial fluid under a skin layer, to retrieve a predetermined portion of a rolling data from the storage device, each predetermined portion of the rolling data assigned a transmission time slot and includes one or more of operational mode data, analyte sensor slope data, temperature related data, power supply status data, data transmission count data, or analyte sensor scaling factor data, to transmit during a first transmission time slot a first data packet including the first data type and the predetermined portion of the rolling data assigned to the first transmission time slot to a remote location, and to transmit during a second transmission time slot a second data packet to the remote location subsequent to the first data packet transmission, the second data packet including the first data type and the predetermined portion of the rolling data assigned to the second transmission time slot for transmission to the remote location, wherein each transmitted data packet comprises the first data type and the predetermined portion of the rolling data.

10. The apparatus of claim **9**, wherein the first data type is associated with urgent data, and further, wherein the rolling data is associated with non-urgent data.

11. The apparatus of claim **9**, wherein the analyte sensor data includes real time analyte data associated with the monitored analyte level.

12. The apparatus of claim **11**, wherein the analyte sensor data includes glucose, and further, wherein the first data type is related to glucose level information, and the rolling data is related to a predetermined scaling factor associated with the glucose level information.

13. The apparatus of claim **9**, wherein each of the first and second data packets include a transmit time count which is incremented by an integer value with each subsequent transmission.

14. The apparatus of claim **9**, wherein the first data type includes current sensor data and historic sensor data.

15. The apparatus of claim **14**, wherein the first data type in the first data packet is current sensor data and the first data type in the second data packet is historic sensor data.

16. The apparatus of claim **15**, wherein the historic sensor data includes sensor data that immediately precedes the current sensor data.

17. An apparatus, comprising:

one or more processors; and

a memory storing instructions which, when executed by the one or more processors, causes the one or more processors to retrieve a first data type from a storage device, wherein the first data type includes analyte sensor data obtained from an analyte sensor positioned in fluid contact with an interstitial fluid under a skin layer, to retrieve a predetermined portion of a rolling data from the storage device, each predetermined portion of the rolling data assigned a transmission time slot and includes one or more of operational mode data, analyte sensor slope data, temperature related data, power supply status data, data transmission count data, or analyte sensor scaling factor data, to transmit during a first transmission time slot a first data packet including the first data type and the predetermined portion of the rolling data assigned to the first transmission time slot to a remote location, to transmit during a second transmission time slot a second data packet to the remote location subsequent to the first data packet transmission, the second data packet including the first data type and the predetermined portion of the rolling data assigned to the second transmission time slot for transmission to the remote location, and to increment a counter value indicative of a power supply status of the apparatus, wherein each transmitted data packet comprises the first data type and the predetermined portion of the rolling data.

18. The apparatus of claim **17**, wherein the first data type is associated with urgent data, and further, wherein the rolling data is associated with non-urgent data.

19. The apparatus of claim **17**, wherein the first data type includes current sensor data and historic sensor data.

20. The apparatus of claim **19**, wherein the first data type in the first data packet is current sensor data and the first data type in the second data packet is historic sensor data.

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