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(54) **CONTINUOUS GLUCOSE MONITORING SYSTEM AND METHODS OF USE**

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See application file for complete search history.

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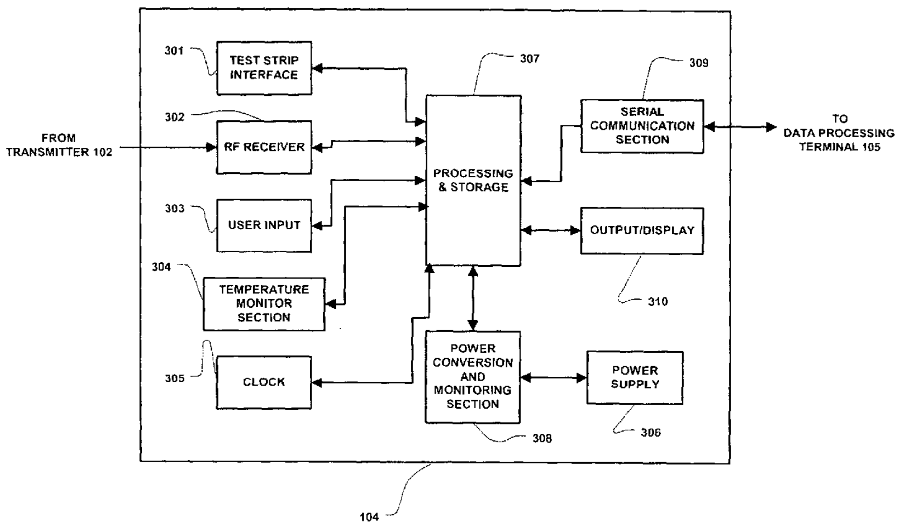
(57) **ABSTRACT**

A continuous glucose monitoring system including a sensor configured to detect one or more glucose levels, a transmitter operatively coupled to the sensor, the transmitter configured to receive the detected one or more glucose levels, the transmitter further configured to transmit signals corresponding to the detected one or more glucose levels, and a receiver operatively coupled to the transmitter configured to receive transmitted signals corresponding to the detected one or more glucose levels, and methods thereof, are disclosed. In one aspect, the transmitter may be configured to transmit a current data point and at least one previous data point, the current data point and the at least one previous data point corresponding to the detected one or more glucose levels.

21 Claims, 6 Drawing Sheets



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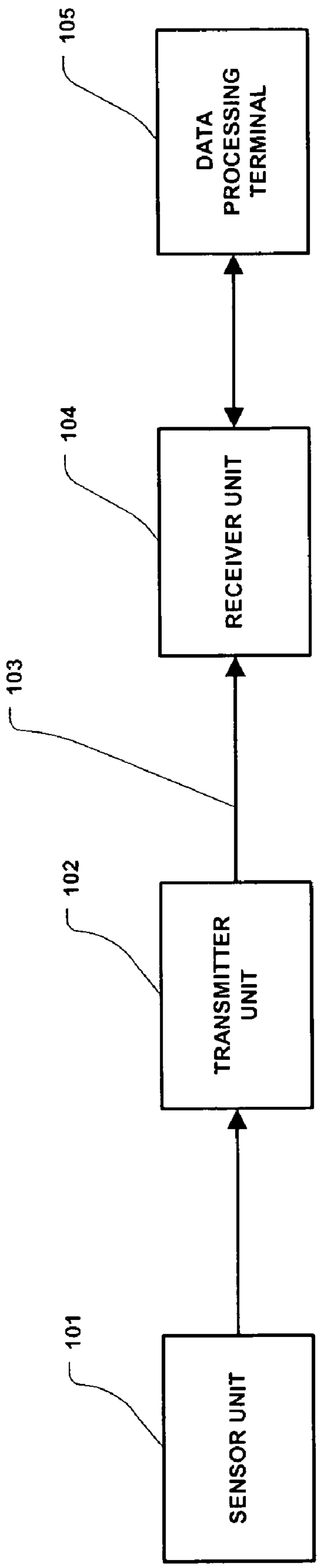
101
SENSOR UNIT
102
TRANSMITTER UNIT
103
104
RECEIVER UNIT
105
DATA PROCESSING TERMINAL

100

FIGURE 1

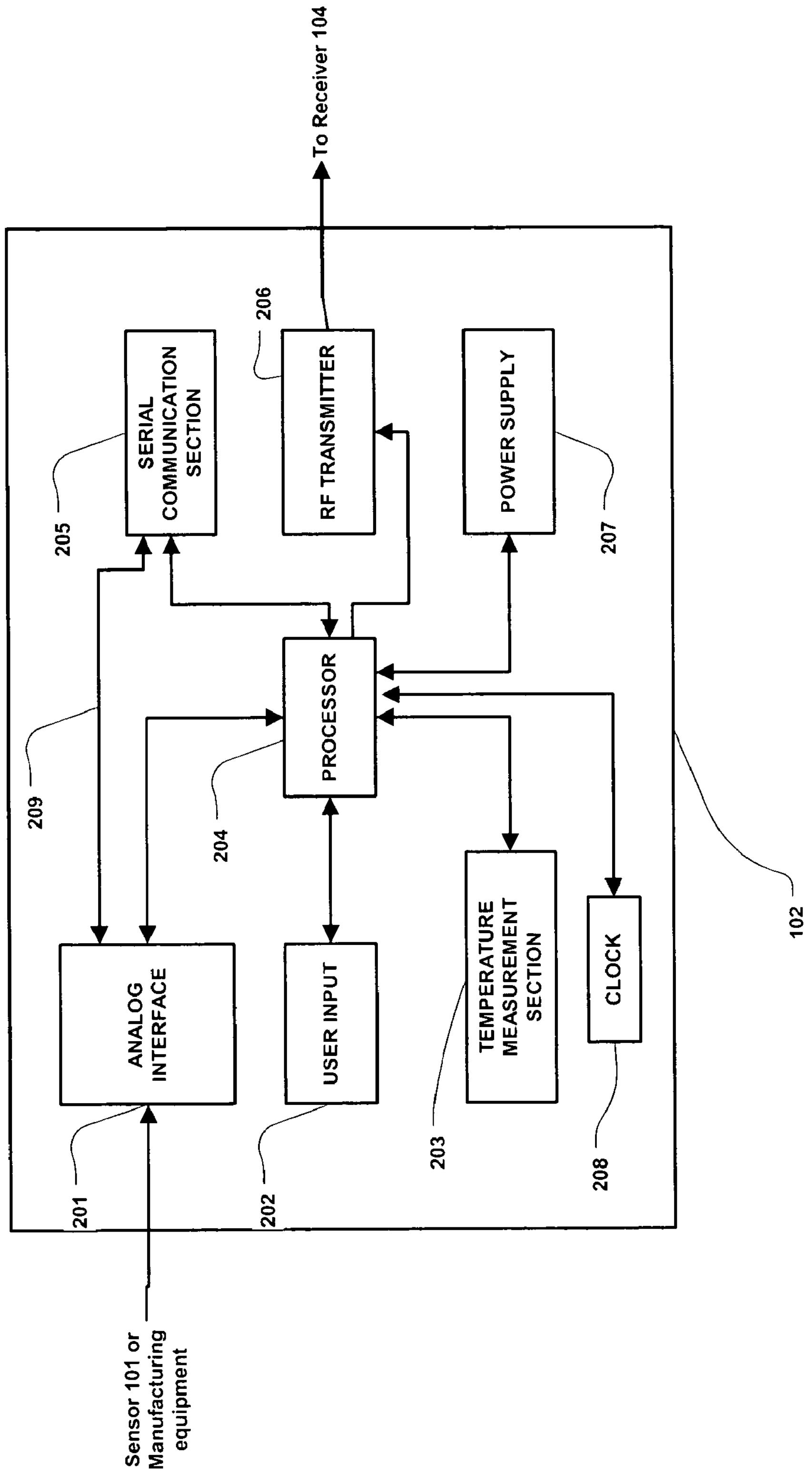
To Receiver 104
SERIAL COMMUNICATION SECTION
RF TRANSMITTER
POWER SUPPLY
PROCESSOR
ANALOG INTERFACE
USER INPUT
TEMPERATURE MEASUREMENT SECTION
CLOCK
Sensor 101 or Manufacturing equipment
201
202
203
204
205
206
207
208
209
102

FIGURE 2

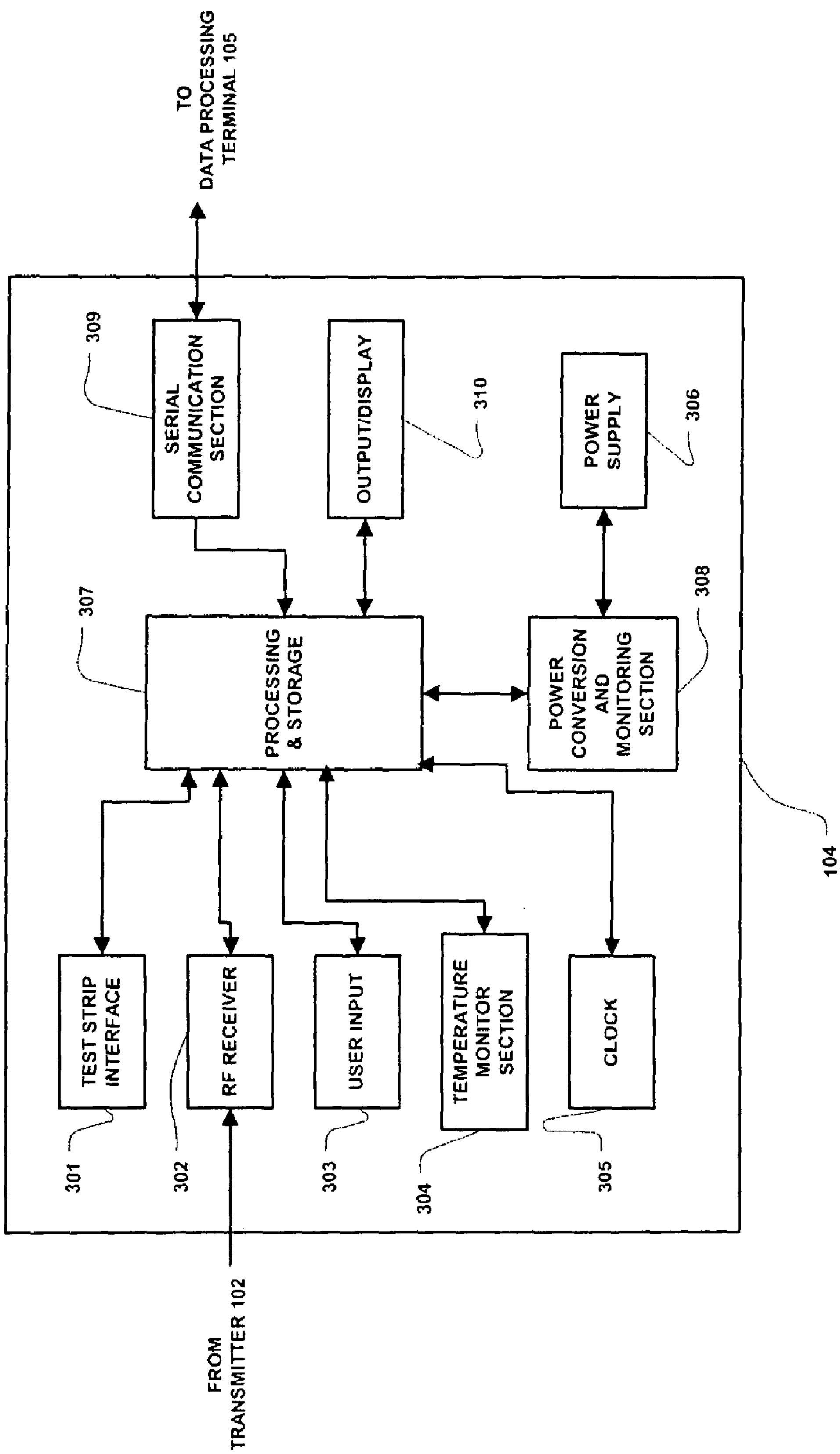
TO
DATA PROCESSING
TERMINAL 105
SERIAL
COMMUNICATION
SECTION
309
OUTPUT/DISPLAY
310
POWER
SUPPLY
306
PROCESSING
& STORAGE
307
POWER
CONVERSION
AND
MONITORING
SECTION
308
TEST STRIP
INTERFACE
301
RF RECEIVER
302
USER INPUT
303
TEMPERATURE
MONITOR
SECTION
304
CLOCK
305
104
FROM
TRANSMITTER 102

FIGURE 3

Byte		High Nibble	Low Nibble
0	TX ID (lsbyte)		
1	Tx Time		
2	Tx Status	Tx Status n1	Tx Status n0
3		Sensor n0	Tx Status n2
4		Sensor n2	Sensor n1
5		Tx Status-1 n1	Tx Status-1 n0
6		Sensor-1 n0	Tx Status-1 n2
7		Sensor-1 n2	Sensor-1 n1
8		Tx Status-2 n1	Tx Status-2 n0
9		Sensor-2 n0	Tx Status-2 n2
10		Sensor-2 n2	Sensor-2 n1
11		CV-1, Tx Status-1	CV, Tx Status
12		Tx Pending, Tx Batt	CV-2, Tx Status-2

FIGURE 4

1	Packed Data	13 bytes
2	Tx ID, middle sb	1 byte
3	Tx ID, msb	1 byte
4	Zero Pad	232 bytes
5	Parity Symbols	8 bytes
	Total	255 bytes

FIGURE 5A

1	Packed data	13 bytes
2	Parity Symbols	8 bytes
	Total	21 bytes

FIGURE 5B

1	0x00 0x00 0x12 0x34	4 bytes
1	Depadded Data Block Contents	21 bytes

FIGURE 5C

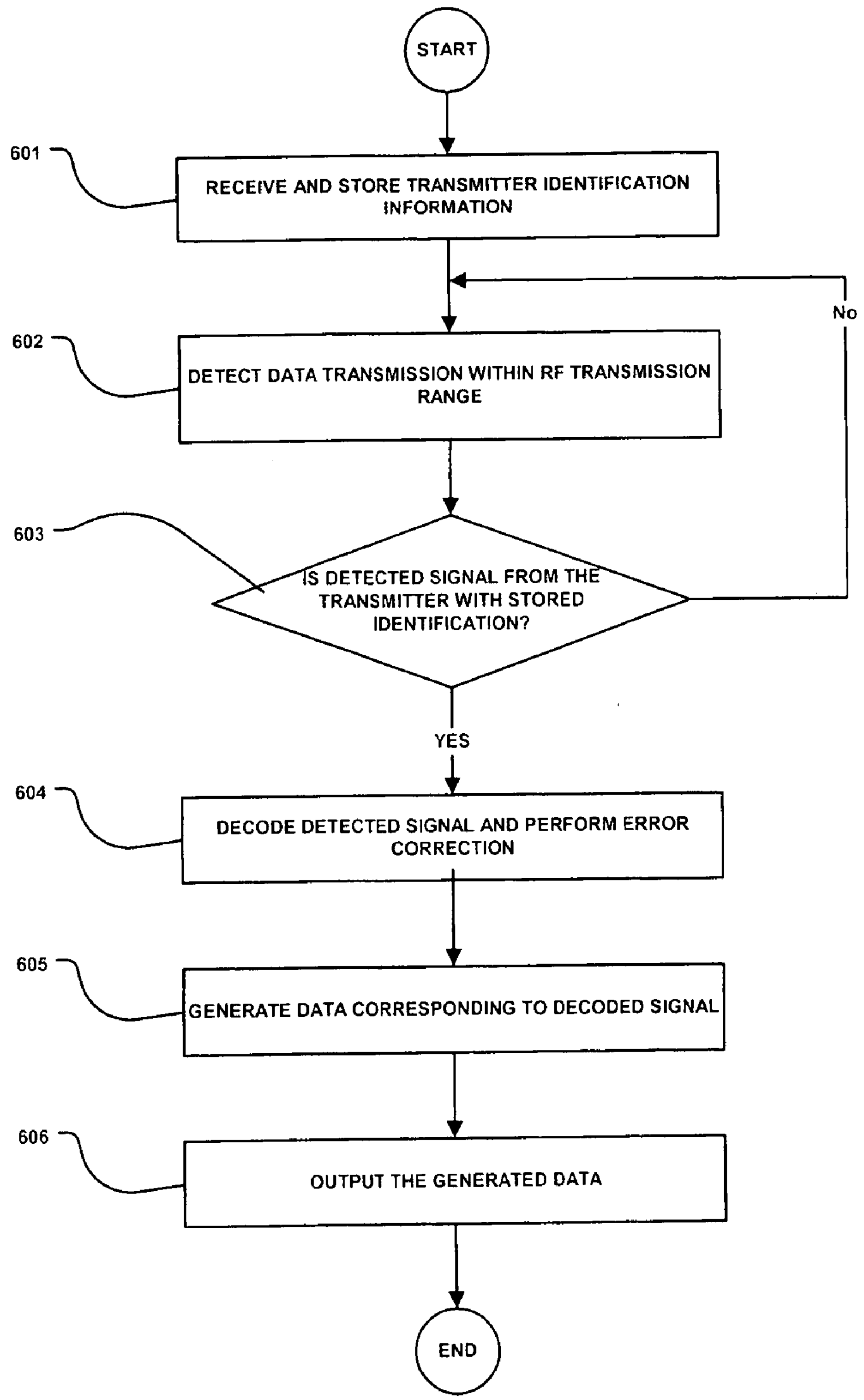
START
601
RECEIVE AND STORE TRANSMITTER IDENTIFICATION INFORMATION
602
DETECT DATA TRANSMISSION WITHIN RF TRANSMISSION RANGE
No
603
IS DETECTED SIGNAL FROM THE TRANSMITTER WITH STORED IDENTIFICATION?
YES
604
DECODE DETECTED SIGNAL AND PERFORM ERROR CORRECTION
605
GENERATE DATA CORRESPONDING TO DECODED SIGNAL
606
OUTPUT THE GENERATED DATA
END

FIGURE 6

CONTINUOUS GLUCOSE MONITORING SYSTEM AND METHODS OF USE

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 10/745,878 filed Dec. 26, 2003, entitled "Continuous Glucose Monitoring System and Methods of Use", which claims the benefit of U.S. Provisional Patent Application No. 60/437,374 filed Dec. 31, 2002, entitled "Continuous Glucose Monitoring System and Methods of Use", the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

The present invention relates to continuous glucose monitoring systems. More specifically, the present invention relates to an in-vivo continuous glucose monitoring system which detects glucose levels continuously and transfers the detected glucose level information at predetermined time intervals to data processing devices for monitoring, diagnosis and analysis.

SUMMARY OF THE INVENTION

A continuous glucose monitoring system in accordance with one embodiment of the present invention includes a sensor configured to detect one or more glucose levels, a transmitter operatively coupled to the sensor, the transmitter configured to receive the detected one or more glucose levels, the transmitter further configured to transmit signals corresponding to the detected one or more glucose levels, a receiver operatively coupled to the transmitter configured to receive transmitted signals corresponding to the detected one or more glucose levels, where the transmitter is configured to transmit a current data point and at least one previous data point, the current data point and the at least one previous data point corresponding to the detected one or more glucose levels.

The receiver may be operatively coupled to the transmitter via an RF communication link, and further, configured to decode the encoded signals received from the transmitter.

In one embodiment, the transmitter may be configured to periodically transmit a detected and processed glucose level from the sensor to the receiver via the RF data communication link. In one embodiment, the transmitter may be configured to sample four times every second to obtain 240 data points for each minute, and to transmit at a rate of one data point (e.g., an average value of the 240 sampled data points for the minute) per minute to the receiver.

The transmitter may be alternately configured to transmit three data points per minute to the receiver, the first data point representing the current sampled data, and the remaining two transmitted data points representing the immediately past two data points previously sent to the receiver. In this manner, in the case where the receiver does not successfully receive the sampled data from the transmitter, at the subsequent data transmission, the immediately prior transmitted data is received by the receiver. Thus, even with a faulty connection between the transmitter and the receiver, or a failed RF data link, the present approach ensures that missed data points may be ascertained from the subsequent data point transmissions without retransmission of the missed data points to the receiver.

The transmitter may be configured to encode the detected one or more glucose levels received from the sensor to generate encoded signals, and to transmit the encoded signals to the receiver. In one embodiment, the transmitter may be configured to transmit the encoded signals to the receiver at a transmission rate of one data point per minute. Further, the transmitter may be configured to transmit the current data point and the at least one previous data points in a single transmission per minute to the receiver. In one aspect, the current data point may correspond to a current glucose level, and where the at least one previous data point may include at least two previous data points corresponding respectively to at least two consecutive glucose levels, the one of the at least two consecutive glucose levels immediately preceding the current glucose level.

In a further embodiment, the receiver may include an output unit for outputting the received transmitted signals corresponding to one or more glucose levels. The output unit may include a display unit for displaying data corresponding to the one or more glucose levels, where the display unit may include one of a LCD display, a cathode ray tube display, and a plasma display.

The displayed data may include one or more of an alphanumeric representation corresponding to the one or more glucose levels, a graphical representation of the one or more glucose levels, and a three-dimensional representation of the one or more glucose levels. Moreover, the display unit may be configured to display the data corresponding to the one or more glucose levels substantially in real time.

Further, the output unit may include a speaker for outputting an audio signal corresponding to the one or more glucose levels.

In yet a further embodiment, the receiver may be configured to store an identification information corresponding to the transmitter.

The receiver may be further configured to perform a time hopping procedure for synchronizing with the transmitter. Alternatively, the receiver may be configured to synchronize with the transmitter based on the signal strength detected from the transmitter, where the detected signal strength exceeds a preset threshold level.

The transmitter in one embodiment may be encased in a substantially water-tight housing to ensure continuous operation even in the situation where the transmitter is in contact with water.

Furthermore, the transmitter may be configured with a disable switch which allows the user to temporarily disable the transmission of data to the receiver when the user is required to disable electronic devices, for example, when aboard an airplane. In another embodiment, the transmitter may be configured to operate in an additional third state (such as under Class B radiated emissions standard) in addition to the operational state and the disable state discussed above, so as to allow limited operation while aboard an airplane yet still complying with the Federal Aviation Administration (FAA) regulations. Additionally, the disable switch may also be configured to switch the transmitter between various operating modes such as fully functional transmission mode, post-manufacture sleep mode, and so on. In this manner, the power supply for the transmitter is optimized for prolonged usage by effectively managing the power usage.

Furthermore, the transmitter may be configured to transmit the data to the receiver in predetermined data packets, encoded, in one embodiment, using Reed Solomon encoding, and transmitted via the RF communication link. Additionally, in a further aspect of the present invention, the RF communication link between the transmitter and the receiver of the continuous glucose monitoring system may be implemented using a low cost, off the shelf remote keyless entry (RKE) chip set.

The receiver in an additional embodiment may be configured to perform, among others, data decoding, error detection and correction (using, for example, forward error correction) on the encoded data packets received from the transmitter to minimize transmission errors such as transmitter stabilization errors and preamble bit errors resulting from noise. The receiver is further configured to perform a synchronized time hopping procedure with the transmitter to identify and synchronize with the corresponding transmitter for data transmission.

Additionally, the receiver may include a graphical user interface (GUI) for displaying the data received from the transmitter for the user. The GUI may include a liquid crystal display (LCD) with backlighting feature to enable visual display in dark surroundings. The receiver may also include an output unit for generating and outputting audible signal alerts for the user, or placing the receiver in a vibration mode for alerting the user by vibrating the receiver.

More specifically, in a further aspect, the receiver may be configured to, among others, display the received glucose levels on a display section of the receiver either real time or in response to user request, and provide visual (and/or auditory) notification to the user of the detected glucose levels being monitored. To this end, the receiver is configured to identify the corresponding transmitter from which it is to receive data via the RF data link, by initially storing the identification information of the transmitter, and performing a time hopping procedure to isolate the data transmission from the transmitter corresponding to the stored identification information and thus to synchronize with the transmitter. Alternatively, the receiver may be configured to identify the corresponding transmitter based on the signal strength detected from the transmitter, determined to exceed a preset threshold level.

A method in accordance with one embodiment of the present invention includes the steps of receiving an identification information corresponding to a transmitter, detecting data within a predetermined RF transmission range, determining whether the detected data is transmitted from the transmitter, decoding the detected data, and generating an output signal corresponding to the decoded data.

In one embodiment, the step of determining whether the detected data transmission is transmitted from the transmitter may be based on the received identification information. In another embodiment, the step of determining whether the detected data transmission is transmitted from the transmitter may be based on the signal strength and duration of the detected data within the predetermined RF transmission range.

In a further embodiment, the step of decoding may also include the step of performing error correction on the decoded data. Moreover, the step of decoding may include the step of performing Reed-Solomon decoding on the detected data.

In the manner described, the present invention provides a continuous glucose monitoring system that is simple to use and substantially compact so as to minimize any interference with the user's daily activities. Furthermore, the continuous glucose monitoring system may be configured to be substantially water-resistant so that the user may freely bathe, swim, or enjoy other water related activities while using the monitoring system. Moreover, the components comprising the monitoring system including the transmitter and the receiver are configured to operate in various modes to enable power savings, and thus enhancing post-manufacture shelf life.

INCORPORATION BY REFERENCE

Applicants herein incorporate by reference application Ser. No. 09/753,746 filed on Jan. 2, 2001, and issued on May 6, 2003 as U.S. Pat. No. 6,560,471, entitled "Analyte Monitoring Device and Methods of Use" assigned to the Assignee of the present application for all purposes.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a continuous glucose monitoring system in accordance with one embodiment of the present invention;

FIG. **2** is a block diagram of the transmitter of the continuous glucose monitoring system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **3** is a block diagram of the receiver of the continuous glucose monitoring system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIG. **4** illustrates a data packet of the transmitter of the continuous glucose monitoring system shown in FIG. **1** in accordance with one embodiment of the present invention;

FIGS. **5**A, **5**B and **5**C illustrate a data packet table for Reed-Solomon encoding in the transmitter, a depadded data table, and a link prefix table, respectively, in accordance with one embodiment of the continuous glucose monitoring system of FIG. **1**; and

FIG. **6** is a flowchart illustrating the time hopping procedure for the receiver of the continuous glucose monitoring system shown in FIG. **1** in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION

FIG. **1** illustrates a continuous glucose monitoring system **100** in accordance with one embodiment of the present invention. In such embodiment, the continuous glucose monitoring system **100** includes a sensor **101**, a transmitter **102** coupled to the sensor **101**, and a receiver **104** which is configured to communicate with the transmitter **102** via a communication link **103**. The receiver **104** may be further configured to transmit data to a data processing terminal **105** for evaluating the data received by the receiver **104**. Only one sensor **101**, transmitter **102**, communication link **103**, receiver **104**, and data processing terminal **105** are shown in the embodiment of the continuous glucose monitoring system **100** illustrated in FIG. **1**. However, it will be appreciated by one of ordinary skill in the art that the continuous glucose monitoring system **100** may include one or more sensor **101**, transmitter **102**, communication link **103**, receiver **104**, and data processing terminal **105**, where each receiver **104** is uniquely synchronized with a respective transmitter **102**.

In one embodiment of the present invention, the sensor **101** is physically positioned on the body of a user whose glucose is being monitored. The term user as used herein is intended to include humans, animals, as well as any other who might benefit from the use of the glucose monitoring system **100**. The sensor **101** is configured to continuously sample the glucose level of the user and convert the sampled glucose level into a corresponding data signal for transmission by the transmitter **102**. In one embodiment, the transmitter **102** is mounted on the sensor **101** so that both devices are positioned on the user's body. The transmitter **102** performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled glucose level of the user, for transmission to the receiver **104** via the communication link **103**.

In one embodiment, the continuous glucose monitoring system **100** is configured as a one-way RF communication path from the transmitter **102** to the receiver **104**. In such embodiment, the transmitter **102** transmits the sampled data signals received from the sensor **101** without acknowledgement from the receiver **104** that the transmitted sampled data signals have been received. For example, the transmitter **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 receiver **104** may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals.

As discussed in further detail below, in one embodiment of the present invention the receiver **104** includes two sections. The first section is an analog interface section that is configured to communicate with the transmitter **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 **102**, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the receiver **104** is a data processing section which is configured to process the data signals received from the transmitter **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 receiver **104** is configured to detect the presence of the transmitter **102** within its range based on the strength of the detected data signals received from the transmitter **102**. For example, in one embodiment, the receiver **104** is configured to detect signals whose strength exceeds a predetermined level to identify the transmitter **102** from which the receiver **104** is to receive data. Alternatively, the receiver **104** in a further embodiment may be configured to respond to signal transmission for a predetermined transmitter identification information of a particular transmitter **102** such that, rather than detecting the signal strength of a transmitter **102** to identify the transmitter, the receiver **104** may be configured to detect transmitted signal of a predetermined transmitter **102** based on the transmitted transmitter identification information corresponding to the pre-assigned transmitter identification information for the particular receiver **104**.

In one embodiment, the identification information of the transmitters **102** includes a 16-bit ID number. In an alternate embodiment, the ID number may be a predetermined length including a 24-bit ID number or a 32-bit ID number. Further, any other length ID number may also be used. Thus, in the presence of multiple transmitters **102**, the receiver **104** will only recognize the transmitter **102** which corresponds to the stored identification information. Data signals transmitted from the other transmitters within the range of the receiver **104** are considered invalid signals.

Referring again to FIG. **1**, where the receiver **104** determines the corresponding transmitter **102** based on the signal strength of the transmitter **102**, when the receiver **104** is initially powered-on, the receiver **104** is configured to continuously sample the signal strength of the data signals received from the transmitters within its range. If the signal strength of the data signals meets or exceeds the signal strength threshold level and the transmission duration threshold level, the receiver **104** returns a positive indication for the transmitter **102** transmitting the data signals. That is, in one embodiment, the receiver **104** is configured to positively identify the transmitter **102** after one data signal transmission. Thereafter, the receiver **104** is configured to detect positive indications for three consecutive data signals transmissions for a predetermined time period. At such point, after three consecutive transmissions, the transmitter **102** is fully synchronized with the receiver **104**.

Upon identifying the appropriate transmitter **102**, the receiver **104** begins a decoding procedure to decode the received data signals. In one embodiment, a sampling clock signal may be obtained from the preamble portion of the received data signals. The decoded data signals, which include fixed length data fields, are then sampled with the sampling clock signal. In one embodiment of the present invention, based on the received data signals and the time interval between each of the three data signal transmissions, the receiver **104** determines the wait time period for receiving the next transmission from the identified and synchronized transmitter **102**. Upon successful synchronization, the receiver **104** begins receiving from the transmitter **102** data signals corresponding to the user's detected glucose level. As described in further detail below, the receiver **104** in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter **102** via the communication link **103** to obtain the user's detected glucose level.

Referring yet 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 is 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 glucose level of the user.

FIG. **2** is a block diagram of the transmitter **102** of the continuous glucose monitoring system **100** in accordance with one embodiment of the present invention. The transmitter **102** includes an analog interface **201** configured to communicate with the sensor **101** (FIG. **1**), a user input **202**, and a temperature detection section **203**, each of which is operatively coupled to a transmitter processor **204** such as a central processing unit (CPU). 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** is also provided in the transmitter **102** to provide the necessary power for the transmitter **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**, while a unidirectional output is established from the output of the RF transmitter **206**. 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, through the data path described above, the transmitter **102** is configured to transmit to the receiver **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 **102** for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

Referring back to FIG. **2**, the user input **202** includes a disable device that allows the operation of the transmitter **102** to be temporarily disabled, such as, by the user wearing the transmitter **102**. In an alternate embodiment, the disable device of the user input **202** may be configured to initiate the power-up procedure of the transmitter **102**.

As discussed above, the transmitter processor **204** is configured to transmit control signals to the various sections of the transmitter **102** during the operation of the transmitter **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 **102**, as well as the data signals received from the sensor **101**. The stored information may be retrieved and processed for transmission to the receiver **104** under the control of the transmitter processor **204**. Furthermore, the power supply **207** may include a commercially available battery pack.

The physical configuration of the transmitter **102** is designed to be substantially water resistant, so that it may be immersed in non-saline water for a brief period of time without degradation in performance. Furthermore, in one embodiment, the transmitter **102** is designed so that it is substantially compact and light-weight, not weighing more that a predetermined weight such as, for example, approximately 18 grams. Furthermore, the dimensions of the transmitter **102** in one embodiment includes 52 mm in length, 30 mm in width and 12 mm in thickness. Such small size and weight enable the user to easily carry the transmitter **102**.

The transmitter **102** is also configured such that the power supply section **207** is capable of providing power to the transmitter for a minimum of three months of continuous operation after having been stored for 18 months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor **204** operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter **102** places the transmitter **102** in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter **102** may be significantly improved.

Referring again to FIG. **2**, the analog interface **201** of the transmitter **102** in one embodiment includes a sensor interface (not shown) configured to physically couple to the various sensor electrodes (such as, for example, working electrode, reference electrode, counter electrode, (not shown)) of the sensor **101** (FIG. **1**) of the monitoring system **100**. The analog interface section **201** further includes a potentiostat circuit (not shown) which is configured to generate the Poise voltage determined from the current signals received from the sensor electrodes. In particular, the Poise voltage is determined by setting the voltage difference between the working electrode and the reference electrode (i.e., the offset voltage between the working electrode and the reference electrode of the sensor **102**). Further, the potentiostat circuit also includes a transimpedance amplifier for converting the current signal on the working electrode into a corresponding voltage signal proportional to the current. The signal from the potentiostat circuit is then low pass filtered with a predetermined cut-off frequency to provide anti-aliasing, and thereafter, passed through a gain stage to provide sufficient gain to allow accurate signal resolution detected from the sensor **101** for analog-to-digital conversion and encoding for transmission to the receiver **104**.

Referring yet again to FIG. **2**, the temperature detection section **203** of the transmitter **102** is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the glucose readings obtained from the analog interface **201**. As discussed above, the input section **202** of the transmitter **102** includes the disable device which allows the user to temporarily disable the transmitter **102** such as for, example, to comply with the FAA regulations when aboard an aircraft. Moreover, in a further embodiment, the disable device may be further configured to interrupt the transmitter processor **204** of the transmitter **102** while in the low power, non-operating mode to initiate operation thereof.

The RF transmitter **206** of the transmitter **102** may be configured for operation in the frequency band of 315 MHz to 322 MHz, for example, in the United States. Further, in one embodiment, the RF transmitter **206** is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is 19,200 symbols per second, with a minimum transmission range for communication with the receiver **104**.

FIG. **3** is a block diagram of the receiver **104** of the continuous glucose monitoring system **100** in accordance with one embodiment of the present invention. Referring to FIG. **3**, the receiver **104** includes a blood glucose test strip interface **301**, an RF receiver **302**, an input **303**, a temperature detection section **304**, and a clock **305**, each of which is operatively coupled to a receiver processor **307**. As can be further seen from the Figure, the receiver **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 testing strip, and thereby determine and display the glucose level of the testing strip on the output **310** of the receiver **104**. This manual testing of glucose can be used to calibrate sensor **101**. The RF receiver **302** is configured to communicate, via the communication link **103** (FIG. **1**) with the RF transmitter **206** of the transmitter **102**, to receive encoded data signals from the transmitter **102** for, among others, signal mixing, demodulation, and other data processing. The input **303** of the receiver **104** is configured to allow the user to enter information into the receiver **104** as needed. In one aspect, the input **303** may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section **304** is configured to provide temperature information of the receiver **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 receiver **104** shown in FIG. **3** are 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 receiver **104** for effective power management and to alert the user, for example, in the event of power usage which renders the receiver **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 receiver **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 receiver **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 receiver **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 receiver **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 receiver **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 receiver **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 receiver **104**, operatively coupled to the processor **307**. The processor **307** is further configured to perform Manchester decoding as well as error detection and correction upon the encoded data signals received from the transmitter **102** via the communication link **103**.

In conjunction with FIGS. **4**, **5**A, **5**B and **5**C, a description is provided of a data packet from the transmitter **102** to the receiver **104** via the communication link **103**.

FIG. **4** illustrates a data pack from the transmitter **102** (FIG. **1**) in accordance with one embodiment of the present invention. Referring to FIG. **4**, each data packet from the transmitter **102** includes 13 bytes as shown in the Figure. For example, the first byte (zero byte) includes the transmitter **102** identification information ("Tx ID"), while the third byte (byte two) provides transmitter status information, where a high nibble (byte) indicates an operating mode status, while a low nibble indicates a non-operating mode. In this manner, the signals received from the sensor **101** are packed into 13-byte data packs, for transmission to the receiver **104**.

FIGS. **5**A, **5**B and **5**C illustrate a data packet table for Reed-Solomon encoding in the transmitter, a depadded data table, and a link prefix table, respectively, in accordance with one embodiment of the continuous glucose monitoring system of FIG. **1**. Referring to FIG. **5**A, it can be seen that the Reed Solomon encoded data block contents include 13 bytes of packed data (FIG. **4**), one byte of the middle significant bit of the transmitter identification information (Tx ID), one byte of the most significant bit of the transmitter identification information, 232 bytes of zero pads, 8 bytes of parity symbols, to comprise a total of 255 bytes. In one embodiment, the Reed Solomon encode procedure at the transmitter **102** uses 8 bit symbols for a **255** symbol block to generate 8 parity symbols. Thereafter, the transmitter **102** is configured to remove the 232 bytes of zero pads, resulting in the 21 bytes of depadded data block including the 13 bytes of packed data as well as the 8 bytes of the parity symbols as shown in FIG. **5**B.

Thereafter, a link prefix is added to the depadded data block to complete the data packet for transmission to the receiver **104**. The link prefix allows the receiver **104** to synchronize with the transmitter **102** as described in further detail below. More specifically, as shown in FIG. **5**C, the transmitter **102** is configured to add 4 bytes of link prefix (0x00, 0x00, 0x12, and 0x34) to the 21 bytes of depadded data block to result in 24 bytes of data packet. Once powered up and enabled in operational mode, the transmitter **102** is configured to transmit the 24 byte data packet once every minute. More specifically, the transmitter **102** is configured to Manchester encode the data at 2 bits per data bit (0=10; 1=01), and transmit the Manchester bits at 19,200 symbols per second. The transmitter **102** is configured to transmit the data packets with the most significant bit of byte zero first.

FIG. **6** is a flowchart illustrating the time hopping procedure for the receiver of the continuous glucose monitoring system shown in FIG. **1** in accordance with one embodiment of the present invention.

Referring to FIG. **6**, upon completing the power up procedure as discussed above, the receiver **104** listens for the presence of a transmitter within the RF communication link range. At step **601**, when the transmitter **102** is detected within the RF communication link range, the receiver **104** is configured to receive and store the identification information corresponding to the detected transmitter **102**. Thereafter, at step **602**, the receiver **104** is configured to detect (or sample) data transmission within its RF communication range. In one aspect, the receiver **104** is configured to identify a positive data transmission upon ascertaining that the data transmission is above a predetermined strength level for a given period of time (for example, receiving three separate data signals above the predetermined strength level from the transmitter **102** at one minute intervals over a period of five minutes).

At step **603**, the receiver **104** is configured to determine whether the detected signals within the RF communication range is transmitted from the transmitter **102** having the transmitter identification information stored in the receiver **104**. If it is determined at step **603** that the detected data transmission at step **602** does not originate from the transmitter with the stored transmitter identification information, then the procedure returns to step **602** and awaits for the detection of the next data transmission.

On the other hand, if at step **603** it is determined that the detected data transmission is from the transmitter **102** corresponding to the stored transmitter identification information, then at step **604**, the receiver proceeds with decoding the received data and performing error correction thereon. In one embodiment, the receiver is configured to perform Reed-Solomon decoding, where the transmitted data received by the receiver is encoded with Reed-Solomon encoding. Furthermore, the receiver is configured to perform forward error correction to minimize data error due to, for example, external noise, transmission noise and so on.

Referring back to FIG. **6**, after decoding and error correcting the received data, the receiver **104** at step **605** generates output data corresponding to the decoded error corrected data received from the transmitter **102**, and thereafter, at step **606**, the receiver **104** outputs the generated output data for the user as a real time display of the output data, or alternatively, in response to the user operation requesting the display of the output data. Additionally, before displaying the output data for the user, other pre-processing procedures may be performed on the output data to for example, smooth out the output signals. In one aspect, the generated output data may include a visual graphical output displayed on the graphical user interface of the receiver. Alternatively, the output data may be numerically displayed representing the corresponding glucose level.

Referring now to FIGS. **4** and **6**, the time hopping procedure of one embodiment is described. More specifically, since more than one transmitter **102** may be within the receiving range of a particular receiver **104**, and each transmitting data every minute on the same frequency, transmitter units **102** are configured to transmit data packets at different times to avoid co-location collisions (that is, where one or more receivers **104** cannot discern the data signals transmitted by their respective associated transmitter units **102** because they are transmitting at the same time.)

In one aspect, transmitter **102** is configured to transmit once every minute randomly in a window of time of plus or minus 5 seconds (i.e., it time hops.) To conserve power, receiver **104** does not listen for its associated transmitter **102** during the entire 10 second receive window, but only at the predetermined time it knows the data packet will be coming from the corresponding transmitter **102**. In one embodiment, the 10 second window is divided into 400 different time segments of 25 milliseconds each. Before each RF transmission from the transmitter **102** takes place, both the transmitter **102** and the receiver **104** is configured to recognize in which one of the 400 time segments the data transmission will occur (or in which to start, if the transmission time exceeds 25 milliseconds.) Accordingly, receiver **104** only listens for a RF transmission in a single 25 millisecond time segment each minute, which varies from minute to minute within the 10 second time window.

Moreover, each transmitter **102** is configured to maintain a "master time" clock that the associated receiver unit **104** may reference to each minute (based on the time of transmission and known offset for that minute). A counter also on the transmitter **102** may be configured to keep track of a value "Tx Time" that increments by 1 each minute, from 0 to 255 and then repeats. This Tx Time value is transmitted in the data packet each minute, shown as Byte **1** in FIG. **4**. Using the Tx Time value and the transmitter's unique identification information (TX ID, shown as Byte **0** in FIG. **4**), both the transmitter **102** and the receiver **104** can calculate which of the 400 time segments will be used for the subsequent transmission. In one embodiment, the function that is used to calculate the offset from the master clock 1-minute tick is a pseudo-random number generator that uses both the Tx Time and the TX ID as seed numbers. Accordingly, the transmission time varies pseudo-randomly within the 10 second window for 256 minutes, and then repeats the same time hopping sequence again for that particular transmitter **102**.

In the manner described above, in accordance with one embodiment of the present invention, co-location collisions may be avoided with the above-described time hopping procedure. That is, in the event that two transmitters interfere with one another during a particular transmission, they are not likely to fall within the same time segment in the following minute. As previously described, three glucose date points are transmitted each minute (one current and two redundant/historical), so collisions or other interference must occur for 3 consecutive data transmissions for data to be lost. In one aspect, when a transmission is missed, the receiver **104** may be configured to successively widen its listening window until normal transmissions from the respective transmitter **102** resume. Under this approach, the transmitter listens for up to 70 seconds when first synchronizing with a transmitter **102** so it is assured of receiving a transmission from transmitter **102** under normal conditions.

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 system, comprising:

a sensor configured to sample glucose levels of a user;

a transmitter unit operatively coupled to the sensor, the transmitter unit comprising sensor electronics operatively coupled to the sensor to receive the sampled glucose levels and to transmit signals corresponding to the sampled glucose levels, a memory for storing a plurality of data points corresponding to the sampled glucose levels of the user, and a processor configured to generate one or more data packets for data transmission via the sensor electronics; and

a receiver unit operatively coupled to the transmitter unit, the receiver unit configured to establish a wireless communication range with the sensor electronics of the transmitter unit and receive the one or more data packets from the sensor electronics of the transmitter unit when the receiver unit is placed within the established wireless communication range;

wherein the sensor electronics include programming to transmit the one or more data packets with each data transmission, the one or more data packets including a current data point that corresponds to a glucose level of a current time period and at least one previous data point that corresponds to at least one glucose level of at least one previous time period, such that if the receiver unit does not successfully receive the current data point from the transmitter unit, at a subsequent data transmission, the current data point and the at least one previous data point are re-transmitted to the receiver unit with a new current data point, and the current data point is received at the receiver unit and ascertained from the subsequent data transmission.

2. The system of claim **1**, wherein the one or more data packets are transmitted using a radio frequency (RF) communication link.

3. The system of claim **1**, wherein the wireless communication range is established based on a wireless signal strength from the transmitter unit.

4. The system of claim **1**, wherein the transmitter unit further includes a temperature detection section configured to monitor a temperature of an insertion site of the sensor to obtain a temperature reading, wherein the temperature reading is used to adjust the sampled one or more glucose levels.

5. The system of claim **4**, wherein the receiver unit is further configured to receive at least one temperature reading related signal when the receiver unit is placed within the established wireless communication range.

6. The system of claim **1**, wherein the transmitter unit is configured to encode the one or more data packets.

7. The system of claim **6**, wherein the one or more data packets is encoded using Reed-Solomon encoding.

8. The system of claim **1**, wherein the glucose level from the at least one previous time period corresponds to at least one glucose level preceding the current glucose level.

9. The system of claim **1**, wherein the transmitter unit includes a switch configured to disable one or more functionalities of the transmitter unit.

10. The system of claim **1**, wherein the transmitter unit is configured to operate in a plurality of operating modes.

11. The system of claim **10**, wherein the plurality of operating modes include a disabled mode, a transmission mode, and a sleep mode.

12. A method of providing data communication in a glucose monitoring system, comprising:

establishing a wireless communication range between a transmitter unit operatively coupled to a sensor and a receiver unit; and

transmitting one or more data packets with at least one data transmission, the one or more data packets including a current data point that corresponds to a glucose level of a current time period and at least one previous data point that corresponds to at least one glucose level of at least one previous time period, such that if the receiver unit does not successfully receive the current data point from the transmitter unit, at a subsequent data transmission, the current data point and the at least one previous data point are re-transmitted to the receiver unit with a new current data point, and the current data point is received at the receiver unit and ascertained from the subsequent data transmission.

13. The method of claim **12**, wherein the at least one data packet is transmitted via a radio frequency (RF) communication link.

14. The method of claim **12**, further comprising detecting a temperature of an insertion site of the sensor to obtain a temperature reading, wherein the temperature reading is used to adjust the sampled one or more glucose levels.

15. The method of claim **14**, further comprising transmitting at least one temperature reading related signal to the receiver unit when the receiver unit is placed within the established wireless communication range.

16. The method of claim **12**, further comprising encoding the at least one data packet prior to transmitting the at least one data packet.

17. The method of claim **16**, wherein the at least one data packet is encoded using Reed-Solomon encoding.

18. The method of claim **12**, wherein establishing a wireless communication range includes determining a wireless signal strength from the transmitter unit and comparing the determined wireless signal strength to a wireless signal strength threshold level.

19. The method of claim **12**, wherein the at least one glucose level detected by the sensor at the at least one previous time period corresponds to a glucose level preceding the current glucose level.

20. The method of claim **12**, wherein the transmitter unit is configured to operate in a plurality of operating modes.

21. The method of claim **20**, wherein the plurality of operating modes includes a disabled mode, a transmission mode, and a sleep mode.

* * * * *

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摘要(译)

一种连续葡萄糖监测系统，包括配置成检测一个或多个葡萄糖水平的传感器，可操作地连接到传感器的发射器，发射器配置成接收检测到的一个或多个葡萄糖水平，发射器还配置成发送对应于检测到的一个葡萄糖水平的信号本发明公开了一种或多种葡萄糖水平，以及可操作地耦合到发射器的接收器，其配置成接收对应于检测到的一种或多种葡萄糖水平的发射信号，及其方法。在一个方面，发射器可以被配置为发送当前数据点和至少一个先前数据点，当前数据点和至少一个先前数据点对应于检测到的一个或多个葡萄糖水平。