METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 17/245,719, filed April 30, 2021, which is a continuation of U.S. Patent Application No. 16/228,910, filed December 21, 2018, now U.S. Patent No. 11,013,431, which is a continuation of U.S. Patent Application No. 15/061,774, filed March 4, 2016, now U.S. Patent No. 10,194,844, which is a continuation of U.S. Patent Application No. 13/925,694, filed June 24, 2013, now U.S. Patent No. 9,310,230, which is a continuation of U.S. Patent Application No. 12/769,635, filed April 28, 2010, now U.S. Patent No. 8,483,967, which claims the benefit of U.S. Provisional Patent Application No. 61/173,600, filed April 29, 2009, the disclosures of all of which are incorporated herein by reference in their entireties for all purposes.

BACKGROUND

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

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

SUMMARY

[0004] Devices and methods for analyte monitoring, e.g., glucose monitoring, and/or therapy management system including, for example, medication infusion devices 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, discrete analyte monitoring system, and therapy management systems.

[0005] Embodiments include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during a adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

[0006] Embodiments include detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period, disabling output of information associated with the analyte sensor, determining a successful calibration of the analyte sensor, retrieving one or more parameters associated with the successful calibration, processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration, and displaying the processed sensor data for the time period of disabled information output.

[0007] Embodiments include an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data, and a display unit coupled to the second memory and configured to display the processed sensor data, where the processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the

successful calibration, and display the processed sensor data for the time period of disabled information output.

[0008] These and other objects, features and advantages of the present disclosure will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

INCORPORATION BY REFERENCE

[0009] The following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Patent Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,167,818; and 7,299,082; U.S. Published Application Nos. 2004/0186365; 2005/0182306; 2007/0056858; 2007/0068807; 2007/0227911; 2007/0233013; 2008/0081977; 2008/0161666; and 2009/0054748; U.S. Patent Application Nos. 11/831,866; 11/831,881; 11/831,895; 12/102,839; 12/102,844; 12/102,847; 12/102,855; 12/102,856; 12/152,636; 12/152,648; 12/152,650; 12/152,652; 12/152,657; 12/152,662; 12/152,670; 12/152,673; 12/363,712; 12/131,012; 12/242,823; 12/363,712; 12/393,921; 12/495,709; 12/698,124; 12/699,653; 12/699,844; 12/714,439; 12/761,372; and 12/761,387 and U.S. Provisional Application Nos. 61/230,686 and 61/227,967.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present disclosure;

[0011] 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 disclosure;

[0012] 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 disclosure;

[0013] FIG. 4 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure;

[0014] FIG. 5 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure;

[0015] FIG. 6 illustrates backfilling gaps in sensor data in one embodiment of the present disclosure; and

[0016] FIGS. 7A and 7B illustrate backfill of gaps of a period of uncalibrated sensor data in one embodiment.

DETAILED DESCRIPTION

[0017] Before the present disclosure is described in additional detail, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[0018] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[0019] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0020] It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise.

[0021] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0022] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure.

[0023] The figures shown herein are not necessarily drawn to scale, with some components and features being exaggerated for clarity.

[0024] As described in further detail below, in accordance with the various embodiments of the present disclosure, there is provided a method and system for positioning a controller unit within a transmission range for close proximity communication, transmitting one or more predefined close proximity commands, and receiving a response packet in response to the transmitted one or more predefined close proximity commands. For example, in one aspect, close proximity communication includes short range wireless communication between communication components or devices, where the communication range is limited to about 10 inches or less, about 5 inches or less, or about 2 inches or less, or other suitable, short range or distance between the devices. The close proximity wireless communication in certain embodiments includes a bi-directional communication where a command sending communication device, when positioned within the short communication range or in close proximity to the command receiving communication device, is configured to transmit one or more commands to the command receiving communication device (for example, when a user activates or actuates a transmit command button or switch). In response, the command receiving communication device may be configured to perform one or more routines associated with the received command, and/or return or send back a response data packet or signal to the command sending communication device. Example of such functions and or commands may include, but not limited to activation of certain functions or routines such as analyte related data processing, and the like.

[0025] 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

disclosure. 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.

[0026] 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.

[0027] The analyte monitoring system 100 includes a sensor unit 101, a data processing and transmitter unit 102 coupleable to the sensor unit 101, and a primary receiver unit 104 which is configured to communicate with the data processing and transmitter unit 102 via a bi-directional 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 data processing and transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication. Accordingly, data processing and transmitter unit 102 and/or receiver unit 104 may include a transceiver.

[0028] 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 data processing and transmitter unit 102. Moreover, as shown in the Figure, the secondary receiver unit 106 is configured to communicate with the primary receiver unit 104 as well as the data processing terminal 105. Indeed, the secondary receiver unit 106 may be configured for bi-directional wireless communication with each or one of the primary receiver unit 104 and the data processing terminal 105. As discussed in further detail below, in one embodiment of the present disclosure, 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.

[0029] In one aspect sensor unit 101 may include two or more sensors, each configured to communicate with data processing and transmitter unit 102. Furthermore, while only one, data processing and 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 disclosure, 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.

[0030] In one embodiment of the present disclosure, the sensor unit 101 is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor unit 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 data processing and transmitter unit 102. In certain embodiments, the data processing and transmitter unit 102 may be physically coupled to the sensor unit 101 so that both devices are integrated in a single housing and positioned on the user's body. The data processing and 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 data processing and transmitter unit 102 transmits analyte information to the primary receiver unit 104 via the communication link 103. Examples of such integrated sensor and transmitter units can be found in, among others, U.S. Patent Application No. 12/698,124, incorporated herein by reference.

[0031] In one embodiment, the analyte monitoring system 100 is configured as a one-way RF communication path from the data processing and transmitter unit 102 to the primary receiver

unit 104. In such embodiment, the data processing and transmitter unit 102 transmits the sampled data signals received from the sensor unit 101 without acknowledgement from the primary receiver unit 104 that the transmitted sampled data signals have been received. For example, the data processing and 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 data processing and transmitter unit 102 and the primary receiver unit 104.

[0032] 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 data processing and 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 data processing and 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 data processing and transmitter unit 102 such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

[0033] In operation, upon completing the power-on procedure, the primary receiver unit 104 is configured to detect the presence of the data processing and transmitter unit 102 within its range based on, for example, the strength of the detected data signals received from the data processing and transmitter unit 102 and/or a predetermined transmitter identification information. Upon successful synchronization with the corresponding data processing and transmitter unit 102, the primary receiver unit 104 is configured to begin receiving from the data processing and 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 data processing and transmitter unit 102 via the communication link 103 to obtain the user's detected analyte level.

[0034] 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.

[0035] Within the scope of the present disclosure, 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 data processing and transmitter unit 102.

[0036] Additionally, the data processing and 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 data processing and 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 data processing and transmitter unit 102 via the communication link 103, where the communication link 103, as described above, may be configured for bi-directional communication.

[0037] In this embodiment, the data processing terminal 105 which may include an insulin pump, may be configured to receive the analyte signals from the data processing and transmitter unit 102, and thus, incorporate the functions of the receiver 104 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 HIPPA requirements) while avoiding potential data collision and interference.

[0038] 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 disclosure. Referring to the Figure, the data processing and transmitter unit 102 in one embodiment includes an analog interface 201 configured to communicate with the sensor unit 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 data processing and transmitter unit 102 for connection to the sensor unit 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.

[0039] 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 data processing and transmitter unit 102 to provide the necessary power for the data processing and transmitter unit 102. In certain embodiments, the power supply 207 also provides the power necessary to power the sensor 101. In other embodiments, the sensor is a self-powered sensor, such as the sensor described in U.S. Patent Application No. 12/393,921, incorporated herein by reference. Additionally, as can be seen from the Figure, clock 208 is provided to, among others, supply real time information to the transmitter processor 204.

[0040] In one embodiment, a unidirectional input path is established from the sensor unit 101 (FIG. 1) and/or manufacturing and testing equipment to the analog interface 201 of the data processing and transmitter unit 102, while a unidirectional output is established from the output of the RF transmitter 206 of the data processing and 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 data processing and 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 unit 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 data processing and transmitter unit 102 for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

[0041] As discussed above, the transmitter processor 204 is configured to transmit control signals to the various sections of the data processing and transmitter unit 102 during the operation of the data processing and 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 data processing and transmitter unit 102, as well as the data signals received from the sensor unit 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.

[0042] In certain embodiments, the data processing and 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 data processing and transmitter unit 102 may place the data processing and transmitter unit 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the data processing and 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 disclosure, the power supply unit 207 is configured to

provide the necessary power to each of the components of the data processing and transmitter unit 102 shown in FIG. 2.

[0043] Referring back to FIG. 2, the power supply section 207 of the data processing and 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 data processing and transmitter unit 102 may be powered for a longer period of usage time. Moreover, in one embodiment, the data processing and transmitter unit 102 may be configured without a battery in the power supply section 207, in which case the data processing and 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.

[0044] Referring yet again to FIG. 2, the temperature measurement section 203 of the data processing and 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 approximately 315 MHz to approximately 322 MHz, for example, in the United States. In certain embodiments, the RF transmitter 206 of the transmitter unit 102 may be configured for operation in the frequency band of approximately 400 MHz to approximately 470 MHz. 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.

[0045] Referring yet again to FIG. 2, also shown is a leak detection circuit 214 coupled to the guard electrode (G) 211 and the processor 204 in the transmitter unit 102 of the data monitoring and management system 100. The leak detection circuit 214 in accordance with one embodiment of the present disclosure may be configured to detect leakage current in the sensor unit 101 to determine whether the measured sensor data are corrupt or whether the measured data from the sensor 101 is accurate. Exemplary analyte systems that may be employed are described in, for example, U.S. Patent Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, and elsewhere, the disclosure of each of which are incorporated by reference for all purposes.

[0046] 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 disclosure. 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.

[0047] 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 unit 101 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.

[0048] 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.

[0049] The serial communication section 309 in the primary receiver unit 104 is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit 104. Serial communication section 104 can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output 310 of the primary receiver unit 104 is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit 104 also includes an electro-luminescent lamp configured to provide backlighting to the output 310 for output visual display in dark ambient surroundings.

[0050] 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.

[0051] Periodic calibration of the sensor unit 101 (FIG. 1) of an analyte monitoring system 100, in some embodiments, may be required for accurate calculation of a user's analyte level. Calibration, in some aspects, is used to ensure the analyte related data signals received at a transmitter unit 102 (and further transmitted to a receiver unit, such as the primary receiver unit 104) are correctly converted to corresponding analyte levels. Exemplary calibration protocols, routines and techniques are described, for example, in U.S. Patent No. 7,299,082, U.S. Patent Application No. 11/537,991 filed October 2, 2006, U.S. Patent Application No. 12/363,706 filed January 30, 2009, and in U.S. Patent Application No. 12/363,712 filed January 30, 2009, the disclosures of each of which are herein incorporated by reference for all purposes.

[0052] There are time periods where the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event. For example, the sensor may be configured for periodic calibration, such as, after 2 hours after insertion, 10 hours after insertion, 12 hours after insertion, 24 hours after insertion, 48 hours after insertion, or 72 hours after insertion, or one or more combinations thereof. If a predetermined calibration event is triggered but a successful calibration does not result, after a certain time period (for example, a predetermined grace period during which to calibrate), the receiver unit may no longer display the monitored and processed glucose information.

[0053] Other conditions may also result in rendering the condition unsuitable for sensor calibration including, but not limited to, detection of a failure mode of a sensor, sensor data values being outside a predetermined range, rate of change of sensor data values being above a predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.

[0054] FIG. 4 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure. Referring to FIG. 4, a transmitter unit 102 (FIG. 1) in operational contact with a sensor 101 receives analyte related sensor data (410) corresponding to a measured level of a biological fluid of the user. For example, the sensor 101 (FIG. 1) may be an analyte sensor configured to detect and measure the concentration of an analyte in a biological fluid, such as the blood of a user. Upon receipt of the analyte related sensor data, the transmitter unit 102 further transmits the analyte related sensor data to a receiver unit, such as primary receiver unit 104 (FIG. 1). It is to be noted that the reference to analyte related sensor data herein and throughout specification includes, for example, current signal received from the analyte sensor, as well as the current signal which has undergone predetermined data processing routines including, for example, filtering, clipping, digitizing, and/or encoding, and/or any other further processing and/or conditioning. In one aspect, the primary receiver unit 104 determines whether the sensor is calibrated and is in acceptable condition for further data processing (420). When sensor related conditions are unsuitable for calibration, the analyte related sensor data is stored (450) in a memory, for example, in the primary receiver unit 104.

[0055] Referring still to FIG. 4, if the sensor data is calibrated and in condition for further data processing, the sensor data is further processed (430) and output for display (440) to a user on a display unit 310 (FIG. 3) of the primary receiver unit 104. In one embodiment, the display of the

processed sensor data comprises a graphical representation of the processed sensor data. In other embodiments, the processed sensor data may be displayed as numerical values, visual indicators, auditory outputs, or combinations thereof. In one aspect, the processing routine described in conjunction with FIG. 4 is performed or executed in, for example, the transmitter unit 102, the secondary receiver unit 106 (FIG. 1), or the data processing terminal 105 (FIG. 1) of the analyte monitoring system 100 (FIG. 1) based on analyte data received from the sensor 101.

[0056] FIG. 5 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure. Referring to FIG. 5, in one embodiment, transmitter unit 102 (FIG. 1) receives analyte related sensor data (510) from a sensor 101 (FIG. 1). Upon receipt of the analyte related sensor data, the transmitter unit 102 transmits the analyte related sensor data (or processed, digitized, and/or filtered signals) to the primary receiver unit 104 (FIG. 1). The primary receiver unit 104 is configured to determine if calibration of the sensor data is suitable--that is, whether the conditions necessary for sensor calibration are met (520).

[0057] Still referring to FIG. 5, if it is determined that the sensor 101 is not calibrated or calibration condition for calibrating the sensor 101 is not met, in one aspect, the primary receiver unit stores the analyte related sensor data in a memory (550) and temporarily disables display of the sensor data (560) to the user (for example, if a calibration event has not occurred and the calibration grace period has expired). On the other hand, if the sensor 101 is calibrated, the sensor data is processed (530) by the primary receiver unit 104 and the processed sensor data is output to the user (540), for example via a display unit 310 (FIG. 3) of the primary receiver unit 104. In one aspect, the processing routine described in conjunction with FIG. 5 is performed or executed in, for example, the transmitter unit 102, the secondary receiver unit 106, or the data processing terminal 105 of the analyte monitoring system 100 based on analyte data received from the sensor 101 (FIG. 1).

[0058] In one aspect, the display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period (for example, including a predetermined grace period measured from the scheduled calibration). Thereafter, upon successful calibration, the system resumes display of the processed and calibrated analyte sensor data. However, there may be a time period or a gap in the output display during which the necessary calibration did not occur in a timely manner. For example, as shown in FIG. 7A, if sensor data is displayed as a graphical display, during time periods where the analyte monitoring

system 100 was not properly calibrated, analyte related sensor data was not processed and/or displayed, resulting in a gap in the graphical display.

[0059] FIG. 6 illustrates backfilling gaps in sensor data in one embodiment of the present disclosure. Referring to FIG. 6, when a scheduled calibration event fails and the associated grace period for calibration does not occur, the output display of the processed, calibrated sensor data is disabled (610). Referring to FIG. 6, once the system recovers after a successful calibration event, the calibrated sensor data is once again displayed (and stored). Furthermore, in one aspect, based on the parameters associated with the successful calibration, the previously unprocessed data during the display time out period may be retrieved (for example, the previously stored analyte related sensor signals during this period) and processed using calibration data, such as a sensitivity ratio for conversion of analyte related sensor data to analyte levels. For example, in one aspect, the subset of analyte related sensor data that were previously unprocessed or uncalibrated due to unsuccessful contemporaneous calibration may be processed using, for example, calibration data such as the sensitivity ratio determined from the most recent successful calibration event, and thereafter, the gap in output display illustrating the processed and calibrated signals may be filled.

[0060] In one aspect, once successful calibration of the sensor data occurs, the calibration parameters from this calibration event may be used to process the sensor data during the period of disabled output or display (620). Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630). By way of an example, FIGS. 7A and 7B illustrate the replacement of a period of unprocessed sensor data with corresponding backfilled processed sensor data, in one embodiment.

[0061] In one embodiment, the backfilled processed sensor data is displayed immediately upon calculation. In another embodiment, the backfilled processed sensor data is not displayed immediately, but rather, after waiting a predetermined period of time. The backfilled processed sensor data may not be displayed immediately to avoid possible unnecessary or incorrect action by a user in response to the backfilled processed sensor data. In this manner, in one aspect, the user or a healthcare provider may be provided with a continuous set of analyte data from the analyte monitoring system without any gaps in the processed signals for further analysis and/or therapy management.

[0062] In this manner, in accordance with the embodiments of the present disclosure, gaps in monitored analyte levels using an analyte monitoring system due to, for example, inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level, may be retrospectively filled or reprocessed so that the data gap is closed and the continuously monitored analyte level does not have any or substantially missing data. That is, in embodiments of the present disclosure, upon correction or rectification of the condition or conditions/parameters which resulted in the analyte monitoring system disabling the output results associated with the monitored real time analyte levels, the parameters associated with the correction or rectification may be used to retrospectively correct or process data or signals so that the missing gaps in analyte related data may be processed and backfilled.

[0063] In this manner, advantageously, in aspects of the present disclosure, additional robustness may be provided to the user and/or the healthcare provider to improve therapy or health management decisions.

[0064] In one embodiment, a method may include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during an adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

[0065] In one aspect, outputting the processed sensor data may include displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one or more combinations thereof.

[0066] The one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.

[0067] The sensor instability condition may include one or more of an early signal attenuation condition of the sensor, sensor misposition error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.

[0068] The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.

[0069] Furthermore, the method may include storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor.

[0070] In another embodiment, a method may include detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period, disabling output of information associated with the analyte sensor, determining a successful calibration of the analyte sensor, retrieving one or more parameters associated with the successful calibration, processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration, and displaying the processed sensor data for the time period of disabled information output.

[0071] The sensor data may be analyte concentration data.

[0072] The analyte concentration data may include blood glucose concentration data.

[0073] The sensor data may be processed in substantially real-time.

[0074] The condition unsuitable for calibration may include one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

[0075] The processed sensor data for the time period of disabled information output may be displayed substantially immediately upon processing.

[0076] The processed sensor data for the time period of disabled information output may be displayed only after waiting a predetermined period of time.

[0077] In another embodiment, an apparatus may include an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data, and a display unit coupled to the second memory and configured to display the processed sensor data, wherein the processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the

sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration, and display the processed sensor data for the time period of disabled information output.

[0078] The sensor may be an analyte sensor.

[0079] The analyte sensor may be a glucose sensor.

[0080] The sensor data may correspond to analyte concentration data.

[0081] The analyte concentration data may include blood glucose concentration data.

[0082] Furthermore, the apparatus may be configured to process and display the sensor data substantially in real-time.

[0083] In one aspect, the condition unsuitable for calibration may include one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

[0084] The display unit may be configured to display the processed sensor data for the time period of disabled information output substantially immediately upon processing the sensor data.

[0085] The display unit may be configured to display the processed sensor data for the time period of disabled information output only after waiting a predetermined period of time.

[0086] 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 disclosure and that structures and methods within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A method, comprising:

receiving sensor data from an analyte sensor of a sensor monitoring system;

processing the received sensor data with time corresponding calibration data;

outputting the processed sensor data;

detecting one or more adverse conditions associated with the sensor monitoring system;

disabling the output of the sensor data during an adverse condition time period;

determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system;

retrieving the sensor data during the adverse condition time period;

processing the retrieved sensor data during the adverse condition time period; and

outputting the processed retrieved sensor data.

2. The method of claim 1, wherein outputting the processed sensor data includes displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one or more combinations thereof.

3. The method of claim 1, wherein the one or more detected adverse conditions includes one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.

4. The method of claim 3, wherein the sensor instability condition includes one or more of an early signal attenuation condition of the sensor, sensor mis-position error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.

5. The method of claim 3, wherein the calibration failure condition includes one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.

6. The method of claim 1 including storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor.

7. A method, comprising:

detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period;

disabling output of information associated with the analyte sensor;

determining a successful calibration of the analyte sensor;

retrieving one or more parameters associated with the successful calibration;

processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration; and

displaying the processed sensor data for the time period of disabled information output.

8. The method of claim 7, wherein the sensor data is analyte concentration data.

9. The method of claim 8, wherein the analyte concentration data includes blood glucose concentration data.

10. The method of claim 7, wherein the sensor data is processed in substantially real-time.

11. The method of claim 7, wherein the condition unsuitable for calibration includes one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

12. The method of claim 7, wherein the processed sensor data for the time period of disabled information output is displayed substantially immediately upon processing.

13. The method of claim 7, wherein the processed sensor data for the time period of

disabled information output is displayed only after waiting a predetermined period of time.

14. An apparatus, comprising:

an interface configured to receive sensor data;

a first memory configured to store the received sensor data;

a processor coupled to the memory and configured to process the stored sensor data;

a second memory coupled to the processor and configured to store the processed sensor data; and

a display unit coupled to the second memory and configured to display the processed sensor data;

wherein the processor is further configured to:

detect a condition unsuitable for calibration of a sensor for a predetermined time period;

disable display of processed sensor data;

determine a successful calibration of the sensor; retrieve one or more parameters associated with the successful calibration;

process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration; and

display the processed sensor data for the time period of disabled information output.

15. The apparatus of claim 14, wherein the sensor is an analyte sensor.

16. The apparatus of claim 15, wherein the analyte sensor is a glucose sensor.

17. The apparatus of claim 15, wherein the sensor data corresponds to analyte concentration data.

18. The apparatus of claim 17, wherein the analyte concentration data includes blood glucose concentration data.

19. The apparatus of claim 14 configured to process and display the sensor data substantially in real-time.

20. The apparatus of claim 14, wherein the condition unsuitable for calibration includes one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

21. The apparatus of claim 14, wherein the display unit is configured to display the processed sensor data for the time period of disabled information output substantially immediately upon processing the sensor data.

22. The apparatus of claim 14, wherein the display unit is configured to display the processed sensor data for the time period of disabled information output only after waiting a predetermined period of time.

ABSTRACT OF THE DISCLOSURE

Provided are methods and apparatus for receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during the adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

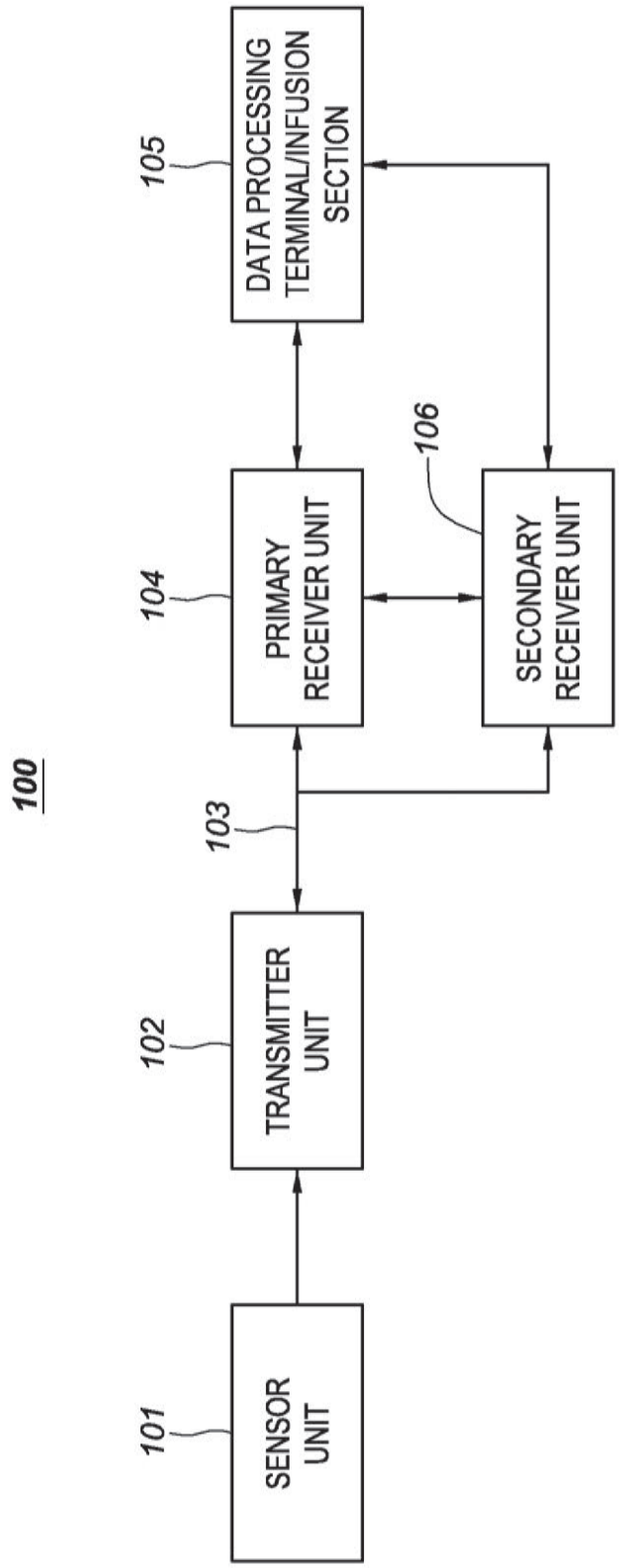
100
101
SENSOR UNIT
102
TRANSMITTER UNIT
103
104
PRIMARY RECEIVER UNIT
105
DATA PROCESSING TERMINAL/INFUSION SECTION
106
SECONDARY RECEIVER UNIT

FIG. 1

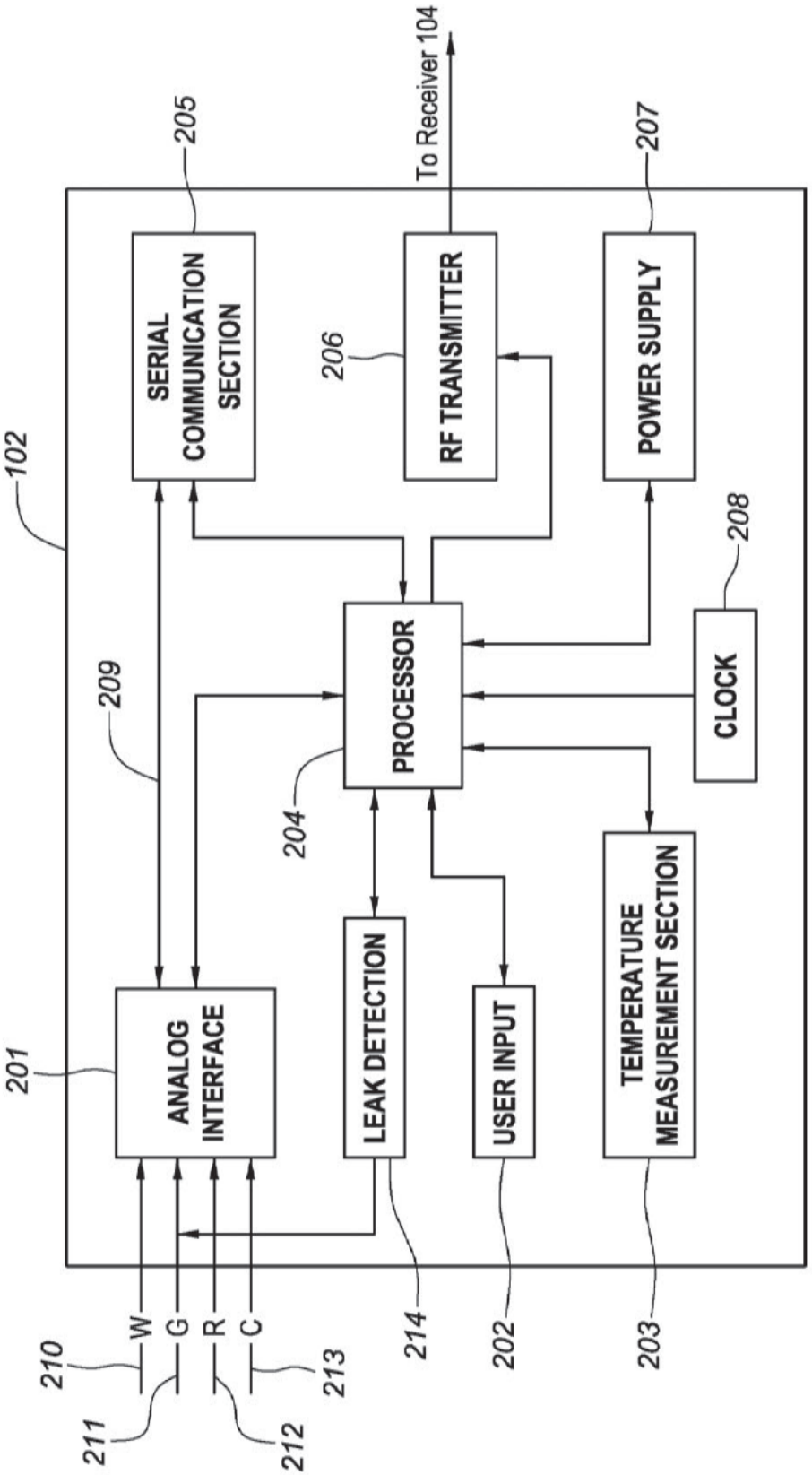
102
205
SERIAL COMMUNICATION SECTION
To Receiver 104
206
RF TRANSMITTER
207
POWER SUPPLY
208
CLOCK
209
PROCESSOR
204
201
ANALOG INTERFACE
LEAK DETECTION
USER INPUT
TEMPERATURE MEASUREMENT SECTION
W
G
R
C
210
211
212
213
214
202
203

FIG. 2

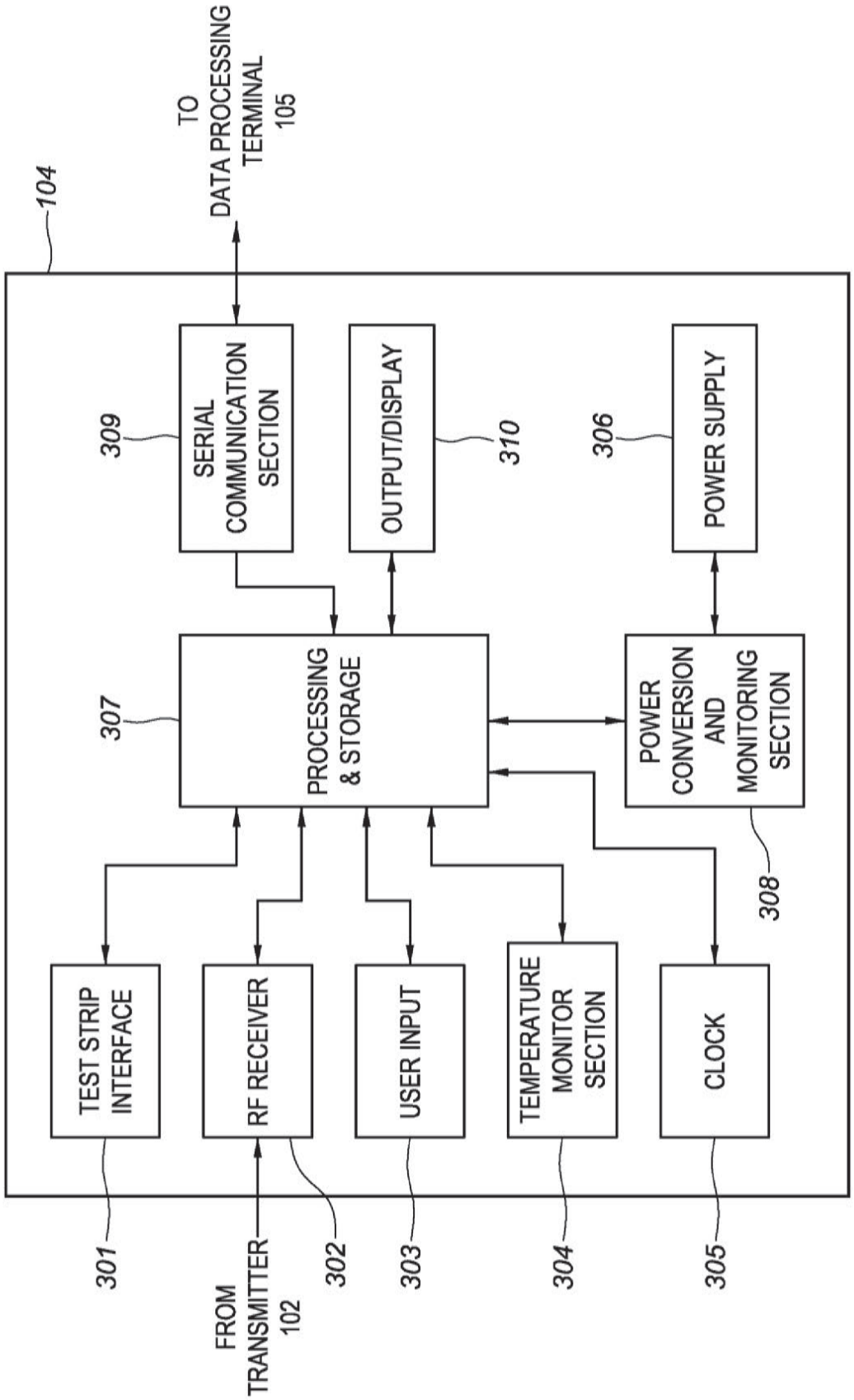
104
TO
DATA PROCESSING
TERMINAL
105
309
SERIAL
COMMUNICATION
SECTION
OUTPUT/DISPLAY
310
306
POWER SUPPLY
307
PROCESSING
& STORAGE
POWER
CONVERSION
AND
MONITORING
SECTION
308
TEST STRIP
INTERFACE
RF RECEIVER
USER INPUT
TEMPERATURE
MONITOR
SECTION
CLOCK
301
FROM
TRANSMITTER
102
302
303
304
305

FIG. 3

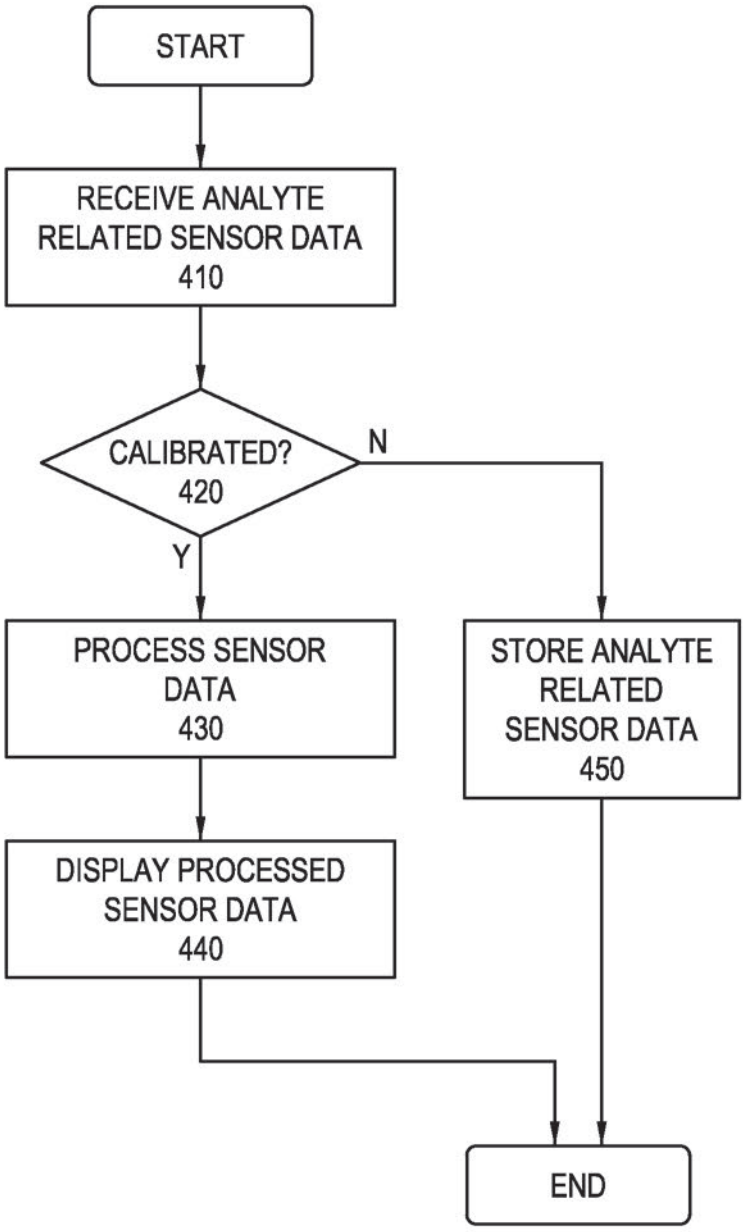
START
RECEIVE ANALYTE RELATED SENSOR DATA 410
CALIBRATED? 420
N
Y
PROCESS SENSOR DATA 430
STORE ANALYTE RELATED SENSOR DATA 450
DISPLAY PROCESSED SENSOR DATA 440
END

FIG. 4

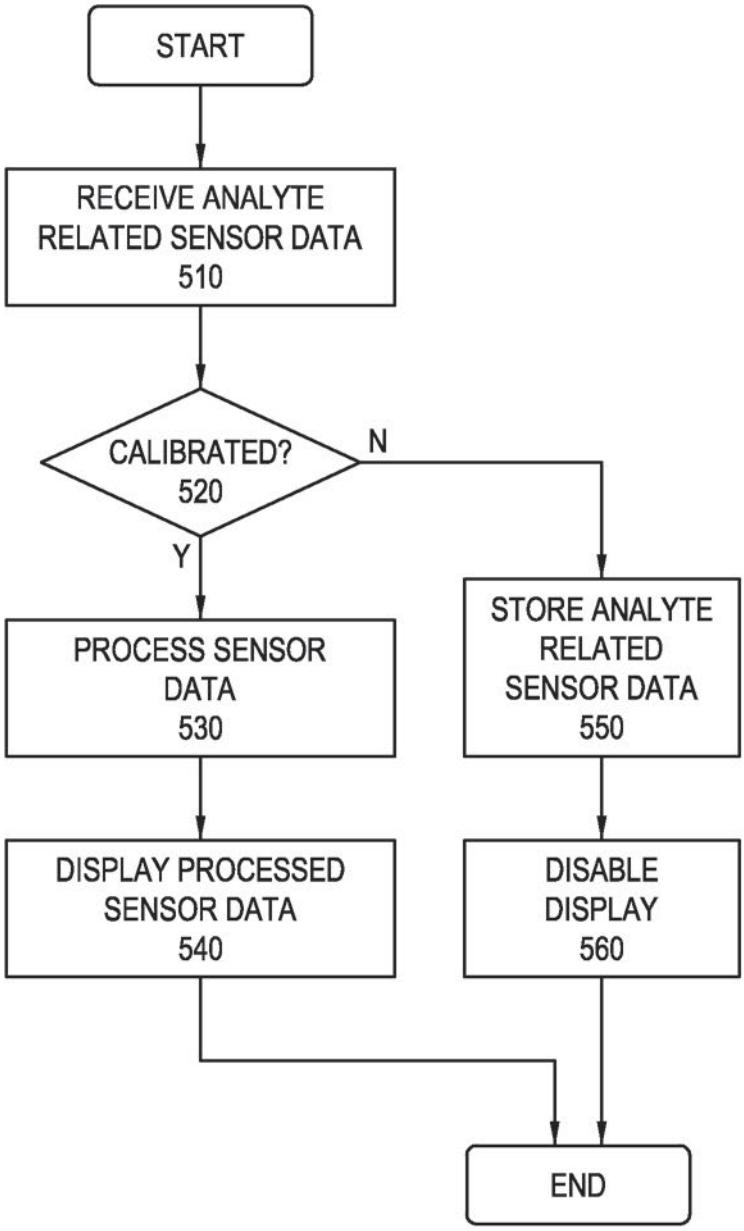
START
RECEIVE ANALYTE RELATED SENSOR DATA 510
CALIBRATED? 520
N
Y
PROCESS SENSOR DATA 530
STORE ANALYTE RELATED SENSOR DATA 550
DISPLAY PROCESSED SENSOR DATA 540
DISABLE DISPLAY 560
END

FIG. 5

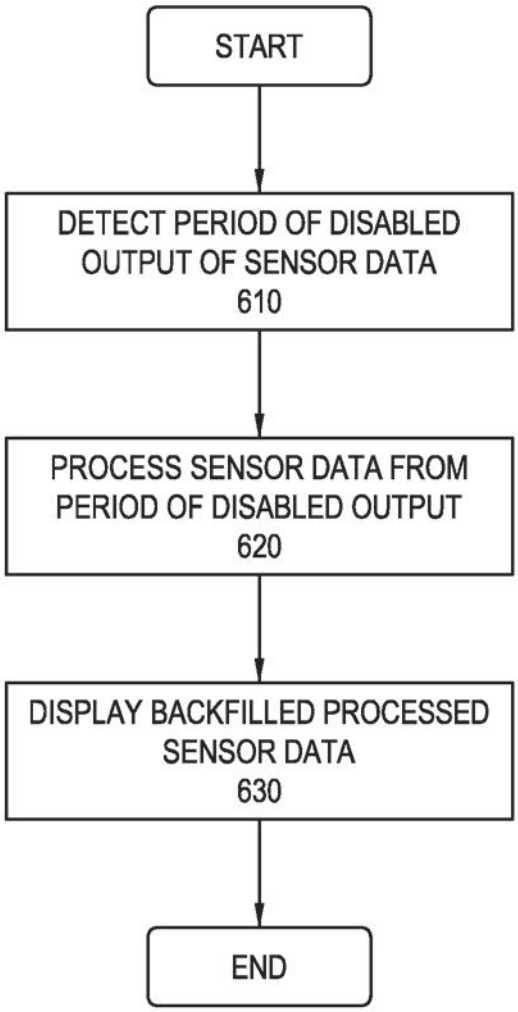
START
DETECT PERIOD OF DISABLED OUTPUT OF SENSOR DATA
610
PROCESS SENSOR DATA FROM PERIOD OF DISABLED OUTPUT
620
DISPLAY BACKFILLED PROCESSED SENSOR DATA
630
END

FIG. 6

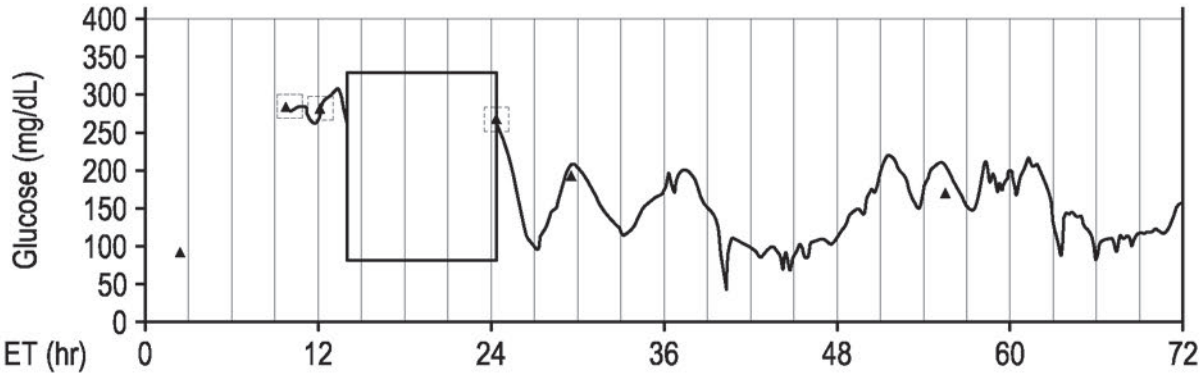
Glucose (mg/dL)
400
350
300
250
200
150
100
50
0
ET (hr)
0
12
24
36
48
60
72

FIG. 7A

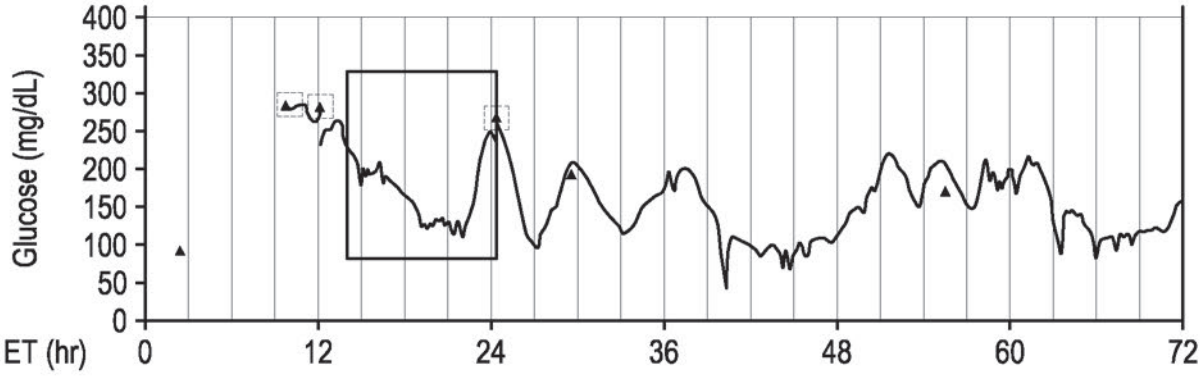
Glucose (mg/dL)
400
350
300
250
200
150
100
50
0
ET (hr)
0
12
24
36
48
60
72

FIG. 7B

PTO/AIA/08 (08-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing OR ■ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	TS-02-180C01
First Named Inventor	Wesley Scott Harper
COMPLETE IF KNOWN	
Application Number	13/925,694
Filing Date	June 24, 2013
Art Unit	1631
Examiner Name	Not Yet Assigned

Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application,

OR

■ United States Application Number or PCT International application number 13/925,694 filed on June 24, 2013

The above-identified application was made or authorized to be made by me.

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☒ The address associated with Customer Number: 30349 OR ☐ Correspondence address below

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Address		
City	State	Zip
Country	Telephone	Email

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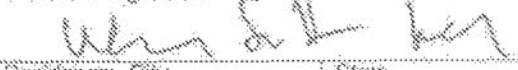
LEGAL NAME OF SOLE OR FIRST INVENTOR:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Wesley Scott Harper

Inventor's Signature	Date (Optional)
	31 Jul 2013

Residence: City	State	Country
Alameda	CA	US

Mailing Address: 15 Ferro Court

City	State	Zip	Country
Alameda	CA	94502	US

☐ Additional inventors are being named on the _____ supplemental sheet(s) PTO/AIA/08 attached hereto

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wesley Scott Harper

Application No.: To be assigned | Confirmation No.: To be assigned

Filed: August 25, 2021 | Art Unit: To be assigned

For: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING | Examiner: To be assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

EFS Web
Commissioner for Patents

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Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

☒ This IDS is being filed before the First Office Action.

☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action.

☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee.

Certifications:

If checked, the undersigned makes the following statement(s):

☐ Statement under 37 CFR § 1.97(e):

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

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Each item of information contained in this information disclosure statement was cited a counterpart application less than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of $260.00 set forth in 37 C.F.R. §1.17(p).

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In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

☒ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached.

This concise explanation is provided by way of:

☒ A translation of the relevant portions of the non-English language information;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and where not in the English language, a translation] of at least the relevant portion(s) of the communication from _____in which the information was cited; or

☐ This information is contained in the specification of the present application.

☒ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial Nos. 12/769,635, filed April 28, 2010, and 13/925,694, filed June 24, 2013, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: August 25, 2021

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Boulevard
East Tower, Suite 500
(949) 432-9993
Attorney for Applicants

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wesley Scott Harper

Application No.: To be assigned | Confirmation No.: To be assigned

Filed: August 25, 2021 | Art Unit: To be assigned

For: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING | Examiner: To be assigned

PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination on the merits, please see the following:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-22. (Canceled)

23. (New) A glucose monitoring system, comprising:

(1) an on body unit configured to be positioned on a user's body, the on body unit comprising:

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user and provide glucose related sensor data; and

a data processing and transmitter unit coupled with the glucose sensor, wherein the data processing and transmitter unit is configured to:

receive the glucose related sensor data from the glucose sensor;

process the glucose related sensor data to provide processed sensor data;

store, in memory of the data processing and transmitter unit during a time period associated with a failure mode condition, the glucose related sensor data, the processed sensor data, or both; and

transmit the processed sensor data over a Bluetooth wireless communication link; and

(2) a receiver unit, comprising:

a radio frequency receiver and an antenna configured to receive the processed sensor data transmitted by the data processing and transmitter unit over the Bluetooth wireless communication link;

a display configured to display numerical values and graphical representations of the processed sensor data; and

a processor coupled with memory of the receiver unit, wherein instructions stored in the memory of the receiver unit, when executed by the processor, cause the processor to:

detect the presence of the data processing and transmitter unit when the data processing and transmitter unit is within a range of the receiver unit,

establish the Bluetooth wireless communication link with the data processing and transmitter unit,

output a first graphical representation of the processed sensor data to the display of the receiver unit, wherein the first graphical representation comprises a first line graph, and wherein an end of the first line graph correlates with a time associated with a start of the failure mode condition, and

output a second graphical representation of the processed sensor data to the display of the receiver unit after the failure mode condition has been corrected, wherein the second graphical representation comprises a second line graph having a length greater than the first line graph.

24. (New) The glucose monitoring system of claim 23, wherein the first line graph comprises processed sensor data received before the start of the failure mode condition, and

wherein the second line graph comprises processed sensor data received before and after the start of the failure mode condition.

25. (New) The glucose monitoring system of claim 24, wherein the first line graph is outputted to the display of the receiver unit during a first time period, and wherein the second line graph is outputted to the display of the receiver unit during a second time period occurring after the first time period.

26. (New) The glucose monitoring system of claim 25, wherein the first line graph and the second line graph are outputted to a same graph comprising a first axis having a time unit of measurement and a second axis having a glucose concentration unit of measurement.

27. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor communication error.

28. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the glucose sensor.

29. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the data processing and transmitter unit.

30. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the receiver unit.

31. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a system malfunction associated with the data processing and transmitter unit or a system malfunction associated with the receiver unit.

32. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor dislodgement.

33. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an inability of the receiver unit to display or output the graphical representations of the processed sensor data to the display.

34. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an inability to calibrate the glucose sensor.

35. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor instability condition.

36. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a calibration failure condition.

37. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a monitoring system failure condition.

38. (New) The glucose monitoring system of claim 23, wherein the glucose sensor comprises a working electrode and a counter electrode.

39. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor misposition error.

40. (New) The glucose monitoring system of claim 23, wherein the on body unit further comprises a temperature sensor, and wherein the failure mode condition comprises a temperature measurement outside a predetermined range.

41. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an analyte level exceeding a predetermined threshold.

42. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a rate of change of an analyte level exceeding a predetermined threshold.

43. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with reference data.

44. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a data unavailability condition.

45. (New) The glucose monitoring system of claim 23, wherein the instructions stored in the memory of the receiver unit, when executed by the processor, further cause the processor to display the second line graph immediately after the correction of the failure mode condition.

46. (New) The glucose monitoring system of claim 23, wherein the instructions stored in the memory of the receiver unit, when executed by the processor, further cause the processor to wait a predetermined period of time after the correction of the failure mode condition before displaying the second line graph.

47. (New) The glucose monitoring system of claim 23, wherein the data processing and transmitter unit, the receiver unit, or both is further configured to store time information associated with the failure mode condition.

48. (New) The glucose monitoring system of claim 23, wherein the on body unit comprises a single integrated housing, and wherein the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within the single integrated housing.

49. (New) The glucose monitoring system of claim 23, wherein the receiver unit comprises a mobile phone.

50. (New) The glucose monitoring system of claim 23, wherein the time period associated with the failure mode condition comprises at least one hour.

51. (New) The glucose monitoring system of claim 23, wherein the first line graph is non-continuous before the failure mode has been corrected.

52. (New) The glucose monitoring system of claim 23, wherein the second line graph is continuous after the failure mode has been corrected.

REMARKS

Claims 23-52 are pending and claims 1-22 have been canceled without prejudice. Support for the new claims can be found, for example, at paragraphs [0030] to [0033] and [0052] to [0086], as well as Figures 4 to 6, 7A, and 7B, the original claims, and elsewhere throughout the application as filed. No new matter has been introduced. Examination of these new claims are respectfully requested.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: August 25, 2021

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0090.C7

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	10	100	1000
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**7160**

Electronic Acknowledgement Receipt

EFS ID:	43591634
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	25-AUG-2021
Filing Date:	
Time Stamp:	10:30:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$7160
RAM confirmation Number	E20218OA30494055
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	9368USC7_A0130_0090_C7_Track_One_Request.pdf	152461 97a35f53b2db19371611d31e00c5d6a2467c000c	no	2
Warnings:					
Information:					
2	Application Data Sheet	9368USC7_A0130_0090_C7_ADS.pdf	1256533 adcc083488c28251de22db049f3a7d9d2c1d3a7a	no	9
Warnings:					
Information:					
3		9368USC7_A0130_0090_C7_Specification.pdf	163591 02c4bdec2ee97c2192c04e0a9e3365e7f90d0784	yes	25

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	20
Claims	21	24
Abstract	25	25

Warnings:					
Information:					
4	Drawings-only black and white line drawings	9368USC7_A0130_0090_C7_Figures.pdf	210832 c8f4b5d0607abb09162e056bff2d32400703a4bc	no	7
Warnings:					
Information:					
5	Oath or Declaration filed	9368USC7_A0130_0090_C7_Declaration.pdf	508797 993c4a73e159a52a165d96ea04e9aa960809724c	no	2

Warnings:					
Information:					
6	Transmittal Letter	9368USC7_A0130_0090_C7_IDS_Transmittal.pdf	91693 a8bb1b18621f209ed5e6ff453fecc11b74c60935	no	4
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	9368USC7_A0130_0090_C7_IDS_1449.pdf	396814 6167ff4cf923c6cdd423982442b4e6a8e16b7687	no	21
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
8		9368USC7_A0130_0090_C7_Preliminary_Amendment.pdf	103758 e2fe4411baf39229073165d8e2d45df41cd89418	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	8

Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	53135 9b6d560642e4dec0232e7315d5ecca21e57f8c82	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2937614	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Wesley Scott Harper	Nonprovisional Application Number (if known):	
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Glen Liu/	Date 8/25/2021
Name (Print/Typed) Glen Liu	Practitioner Registration Number 75,058

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.