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(54) **OPTIMIZING ANALYTE SENSOR CALIBRATION**

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CPC ***A61B 5/1495*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/7221*** (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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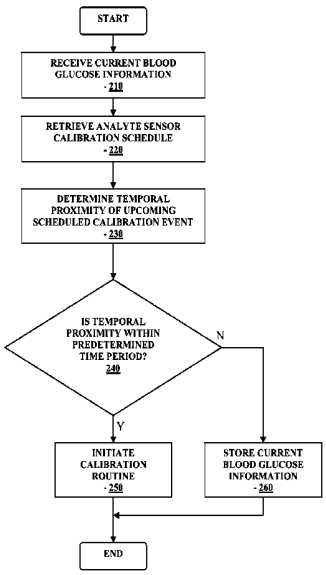
(57) **ABSTRACT**

Method and apparatus for optimizing analyte sensor calibration including receiving a current blood glucose measurement, retrieving a time information for an upcoming scheduled calibration event for calibrating an analyte sensor, determining temporal proximity between the current blood glucose measurement and the retrieved time information for the upcoming calibration event, initiating a calibration routine to calibrate the analyte sensor when the determined temporal proximity is within a predetermined time period, and overriding the upcoming scheduled calibration event using the current blood glucose measurement are provided.

22 Claims, 4 Drawing Sheets



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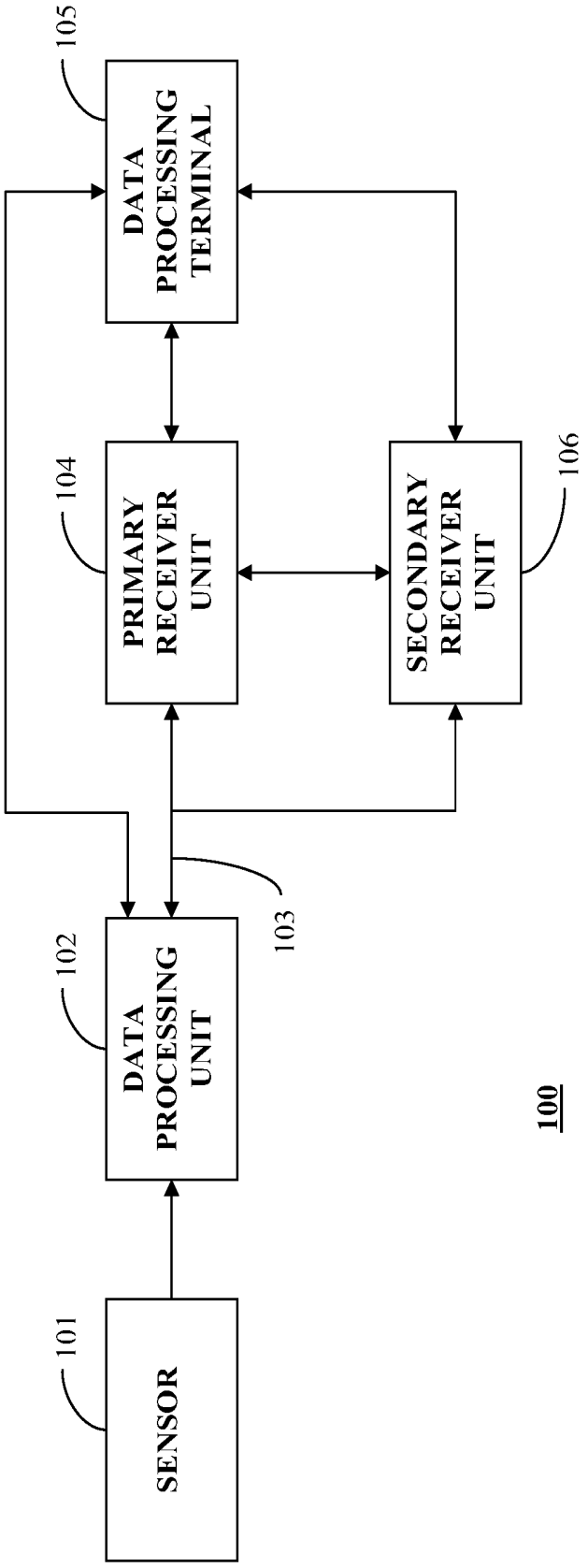
105
DATA PROCESSING TERMINAL
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106
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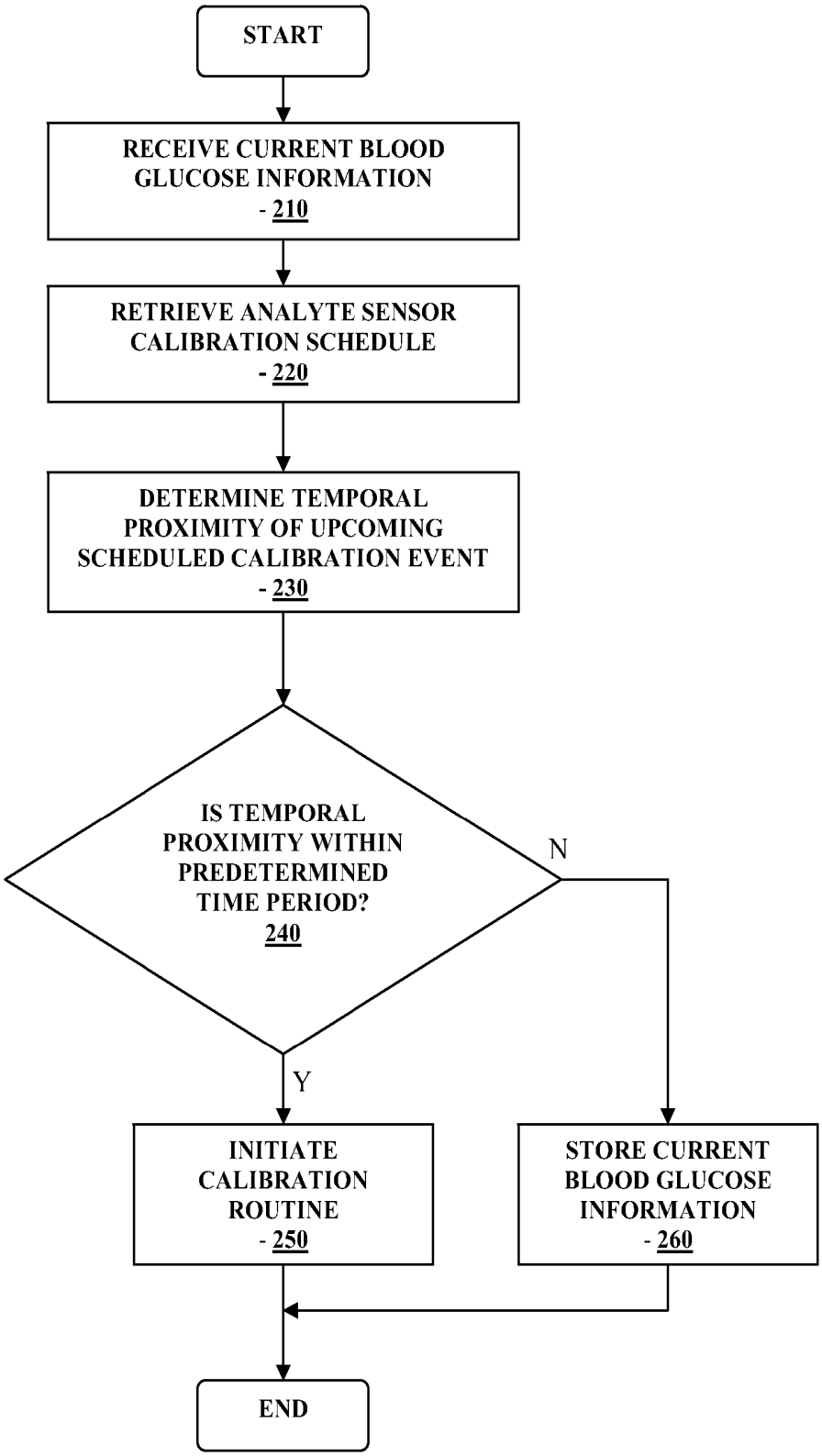
103
102
DATA PROCESSING UNIT
101
SENSOR

100

FIGURE 1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RETRIEVE ANALYTE SENSOR CALIBRATION SCHEDULE - 220
DETERMINE TEMPORAL PROXIMITY OF UPCOMING SCHEDULED CALIBRATION EVENT - 230
IS TEMPORAL PROXIMITY WITHIN PREDETERMINED TIME PERIOD? 240
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Y
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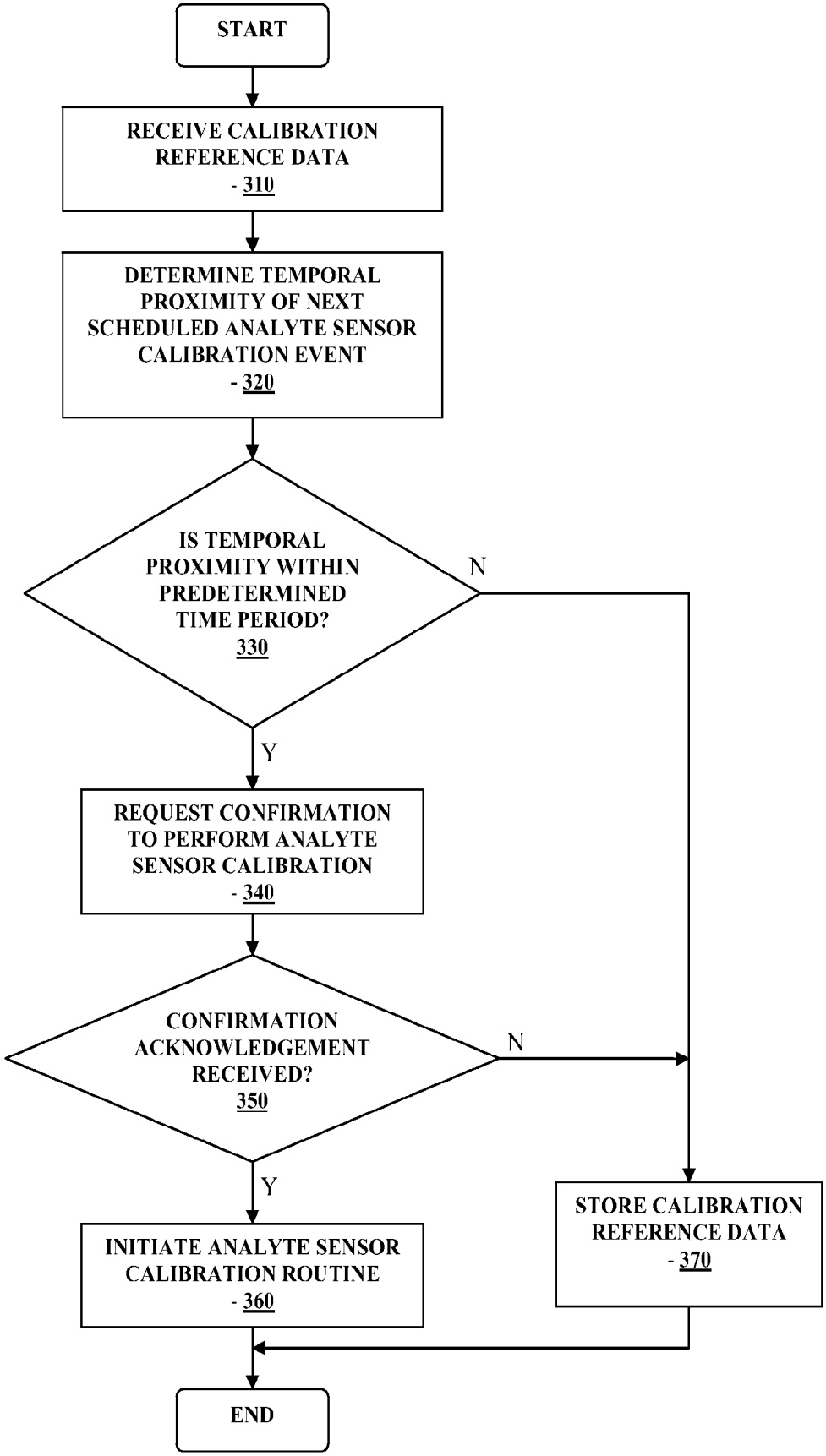
END

FIGURE 2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RECEIVE CALIBRATION REFERENCE DATA - 310
DETERMINE TEMPORAL PROXIMITY OF NEXT SCHEDULED ANALYTE SENSOR CALIBRATION EVENT - 320
IS TEMPORAL PROXIMITY WITHIN PREDETERMINED TIME PERIOD? 330
N
Y
REQUEST CONFIRMATION TO PERFORM ANALYTE SENSOR CALIBRATION - 340
CONFIRMATION ACKNOWLEDGEMENT RECEIVED? 350
N
Y
INITIATE ANALYTE SENSOR CALIBRATION ROUTINE - 360
STORE CALIBRATION REFERENCE DATA - 370
END

FIGURE 3

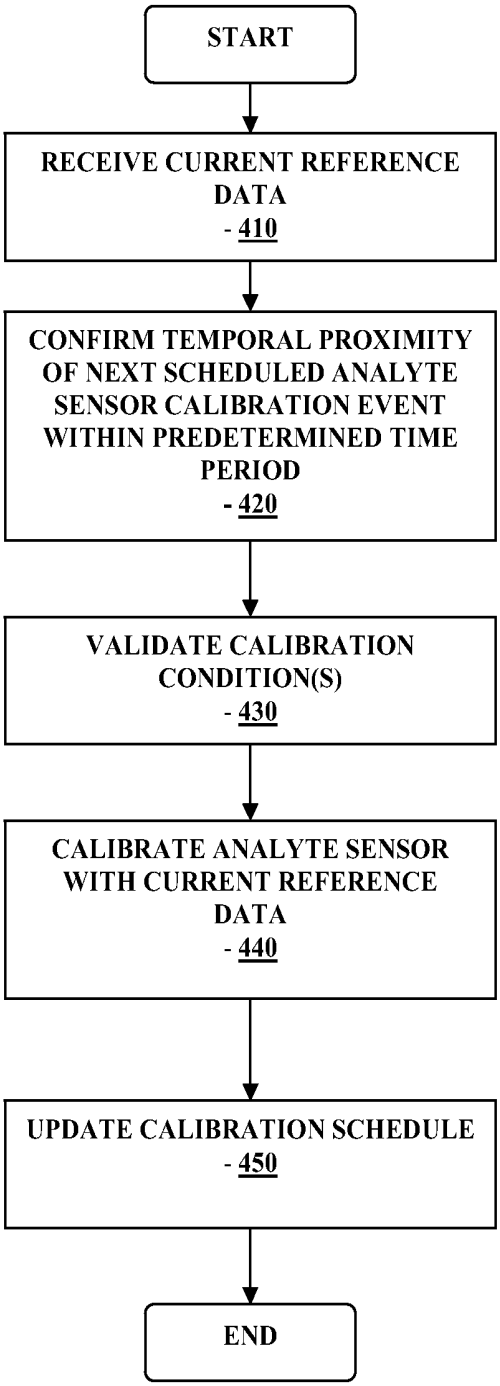
START
RECEIVE CURRENT REFERENCE DATA - 410
CONFIRM TEMPORAL PROXIMITY OF NEXT SCHEDULED ANALYTE SENSOR CALIBRATION EVENT WITHIN PREDETERMINED TIME PERIOD - 420
VALIDATE CALIBRATION CONDITION(S) - 430
CALIBRATE ANALYTE SENSOR WITH CURRENT REFERENCE DATA - 440
UPDATE CALIBRATION SCHEDULE - 450
END

FIGURE 4

OPTIMIZING ANALYTE SENSOR CALIBRATION

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13/544,934 filed Jul. 9, 2012, now U.S. Pat. No. 8,744,547, which is a continuation of U.S. patent application Ser. No. 12/242,823 filed Sep. 30, 2008, now U.S. Pat. No. 8,219,173, entitled "Optimizing Analyte Sensor Calibration", the disclosures of each of which are incorporated herein by reference for all purposes.

TECHNICAL FIELD

The present disclosure relates to analyte monitoring devices and systems. More specifically, the present disclosure relates to optimizing calibration of analyte sensors in analyte monitoring devices and systems.

BACKGROUND

There are significant therapeutic advantages for continuously monitoring analyte levels such as glucose levels of diabetic patients. Commercially available continuous glucose monitoring systems use analyte sensors that detect the glucose levels of the patients for a predetermined time period. During this time period, the analyte sensor is generally required to be periodically calibrated with a blood glucose measurement using, for example, an in vitro blood glucose meter.

Calibration of an analyte sensor typically follows a calibration schedule over the life of the analyte sensor, and are intended to maintain the accuracy of the analyte sensor during its useful life. Each calibration routine requires analysis of data from the analyte sensor in conjunction with a reference value, such as from a finger prick test using a lancing device in conjunction with a conventional blood glucose meter. While other areas of the body may be used to perform the blood glucose measurement, such measurement typically requires drawing a blood sample from the patient and applying the blood sample to a blood glucose test strip. This is often a painful experience, which must be performed periodically based on the calibration schedule of the analyte sensor.

SUMMARY

In accordance with the various embodiments of the present disclosure, there are provided method and apparatus for receiving a current blood glucose measurement, retrieving a time information for an upcoming scheduled calibration event for calibrating an analyte sensor, determining temporal proximity between the current blood glucose measurement and the retrieved time information for the upcoming calibration event, and initiating a calibration routine to calibrate the analyte sensor when the determined temporal proximity is within a predetermined time period.

In another aspect, method and apparatus include receiving a current reference data associated with a monitored analyte level, determining whether a next scheduled calibration event for calibrating an analyte sensor associated with the monitored analyte level is within a predetermined time period, validating one or more conditions associated with the calibration of the analyte sensor when the next scheduled calibration event is determined to be within the predetermined time period, and calibrating the analyte sensor based on the received current reference data.

In still a further aspect, an apparatus includes one or more processors; and a memory operatively coupled to the one or more processors for storing instructions which, when executed by the one or more processors, retrieves a time information for an upcoming scheduled calibration event for calibrating an analyte sensor when a current blood glucose measurement is received, determines a temporal proximity between the current blood glucose measurement and the retrieved time information for the upcoming calibration event, and initiates a calibration routine to calibrate the analyte sensor when the determined temporal proximity is within a predetermined time period.

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.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating an overall system for practicing one or more embodiments of the present disclosure;

FIG. **2** is an example flowchart for optimizing analyte sensor calibration in accordance with one embodiment of the present disclosure;

FIG. **3** is an example flowchart for optimizing analyte sensor calibration in accordance with another embodiment of the present disclosure; and

FIG. **4** is an example flowchart for optimizing analyte sensor calibration in accordance with yet another embodiment of the present disclosure.

DETAILED DESCRIPTION

Before the present disclosure is described, it is to be understood that this invention 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.

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 invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges as also encompassed within the invention, 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 invention.

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 invention 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.

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.

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 invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

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.

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

Generally, embodiments of the present disclosure relate to methods and devices for detecting at least one analyte such as glucose in body fluid. In certain embodiments, the present disclosure relates to the continuous and/or automatic in vivo monitoring of the level of an analyte using an analyte sensor.

Accordingly, embodiments include analyte monitoring devices and systems that include an analyte sensor—at least a portion of which is positionable beneath the skin of the user—for the in vivo detection, of an analyte, such as glucose, lactate, and the like, in a body fluid. Embodiments include wholly implantable analyte sensors and analyte sensors in which only a portion of the sensor is positioned under the skin and a portion of the sensor resides above the skin, e.g., for contact to a transmitter, receiver, transceiver, processor, etc. The sensor may be, for example, subcutaneously positionable in a patient for the continuous or periodic monitoring of a level of an analyte in a patient's interstitial fluid. For the purposes of this description, continuous monitoring and periodic monitoring will be used interchangeably, unless noted otherwise.

The analyte level may be correlated and/or converted to analyte levels in blood or other fluids. In certain embodiments, an analyte sensor may be positioned in contact with interstitial fluid to detect the level of glucose, which detected glucose may be used to infer the glucose level in the patient's bloodstream. Analyte sensors may be insertable into a vein, artery, or other portion of the body containing fluid. Embodiments of the analyte sensors of the subject invention may be configured for monitoring the level of the analyte over a time period which may range from minutes, hours, days, weeks, or longer.

Of interest are analyte sensors, such as glucose sensors, that are capable of in vivo detection of an analyte for about one hour or more, e.g., about a few hours or more, e.g., about a few days of more, e.g., about three or more days, e.g., about five days or more, e.g., about seven days or more, e.g., about several weeks or at least one month. Future analyte levels may be predicted based on information obtained, e.g., the current analyte level at time t_0, the rate of change of the analyte, etc. Predictive alarms may notify the user of predicted analyte levels that may be of concern prior in advance of the analyte level reaching the future level. This enables the user an opportunity to take corrective action.

As described in detail below, in accordance with the various embodiments of the present disclosure, there are provided method, apparatus and system for optimizing analyte sensor calibration to minimize the number of blood glucose measurements in conjunction with the sensor calibration schedule while maintaining the integrity of sensor accuracy.

FIG. **1** shows a data monitoring and management system such as, for example, an analyte (e.g., glucose) monitoring system **100** in accordance with certain embodiments. Embodiments of the subject invention are further described primarily with respect to glucose monitoring devices and systems, and methods of glucose detection, for convenience only 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 at the same time or at different times.

Analytes that may be monitored include, but are not limited to, 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. In those embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times.

The analyte monitoring system **100** in one embodiment includes a sensor **101**, a data processing unit **102** connectable to the sensor **101**, and a primary receiver unit **104** which is configured to communicate with the data processing unit **102** via a communication link **103**. In certain embodiments, the primary receiver unit **104** may be further configured to transmit data to a data processing terminal **105** to evaluate or otherwise process or format data received by the primary receiver unit **104**. The data processing terminal **105** may be configured to receive data directly from the data processing unit **102** via a communication link which may optionally be configured for bi-directional communication. Further, the data processing unit **102** may include a transmitter or a transceiver to transmit and/or receive data to and/or from the primary receiver unit **104**, the data processing terminal **105** or optionally the secondary receiver unit **106**.

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 unit **102**. The secondary receiver unit **106** may be configured to communicate with the primary receiver unit **104**, as well as the data processing terminal **105**. The secondary receiver unit **106** may be configured for bi-directional wireless communication with each of the primary receiver unit **104** and the data processing terminal **105**. As discussed in further detail below, in certain embodiments the secondary receiver unit **106** may be a de-featured receiver as compared to the primary receiver, i.e., the secondary receiver may include a limited or minimal number of functions and features as compared with the primary receiver unit **104**. As such, the secondary receiver unit **106** may include a smaller (in one or more, including all, dimensions), compact housing or embodied in a device such as a wrist watch, arm band, etc., for example. Alternatively, the secondary receiver unit **106** may be configured with the same or substantially similar functions and features as the primary receiver unit **104**. The secondary receiver unit **106** may include a docking portion to be mated with a docking cradle unit for placement by, e.g., the bedside for night time monitoring, and/or bi-directional communication device.

Only one sensor **101**, data processing unit **102** 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 more than one sensor **101** and/or more than one data processing unit **102**, and/or more than one data processing terminal **105**. Multiple sensors may be positioned in a patient for analyte monitoring at the same or different times. In certain embodiments, analyte information obtained by a first positioned sensor may be employed as a comparison to analyte information obtained by a second sensor. This may be useful to confirm or validate analyte information obtained from one or both of the sensors. Such redundancy may be useful if analyte information is contemplated in critical therapy-related decisions. In certain embodiments, a first sensor may be used to calibrate a second sensor.

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 component may be configured to be uniquely identified by one or more of the other components in the system so that communication conflict may be readily resolved between the various components within the analyte monitoring system **100**. For example, unique identification codes (IDs), communication channels, and the like, may be used.

In certain embodiments, the sensor **101** is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor **101** may be configured to at least periodically sample the analyte level of the user and convert the sampled analyte level into a corresponding signal for transmission by the data processing unit **102**. The data processing unit **102** is coupleable to the sensor **101** so that both devices are positioned in or on the user's body, with at least a portion of the analyte sensor **101** positioned transcutaneously. The data processing unit **102** performs data processing functions, where such functions may include but are not limited to, filtering and encoding of data signals, each of which corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit **104** via the communication link **103**. In one embodiment, the sensor **101** or the data processing unit **102** or a combined sensor/data processing unit may be wholly implantable under the skin layer of the user.

In one aspect, the primary receiver unit **104** may include an analog interface section including an RF receiver and an antenna that is configured to communicate with the data processing unit **102** via the communication link **103**, data processing unit **102** and a data processing section for processing the received data from the data processing unit **102** such as data decoding, error detection and correction, data clock generation, and/or data bit recovery.

In operation, the primary receiver unit **104** in certain embodiments is configured to synchronize with the data processing unit **102** to uniquely identify the data processing unit **102**, based on, for example, an identification information of the data processing unit **102**, and thereafter, to periodically receive signals transmitted from the data processing unit **102** associated with the monitored analyte levels detected by the sensor **101**.

Referring back to FIG. **1**, each of the primary receiver unit **104** and the secondary receiver unit **106** may include a blood glucose test strip port such that the user or the patient may perform finger prick tests using blood glucose test strips. Accordingly, in aspects of the present disclosure, the primary receiver unit **104** and the secondary receiver unit **106** may incorporate the functionalities of a blood glucose meter for processing a blood sample to determine a corresponding blood glucose measurement which may be performed by one or more controllers provided in the receiver unit including, for example, a microprocessor, application specific integrated circuit and/or a state machine for executing one or more routines associated with the processing and determination of blood glucose sample to determine the blood glucose level.

Exemplary analyte systems including calibration of analyte sensors that may be employed are described in, for example, U.S. Pat. Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, 7,299,082 and in application Ser. No. 10/745,878 filed Dec. 26, 2003, now U.S. Pat. No. 7,811,231, entitled "Continuous Glucose Monitoring System and Methods of Use", the disclosures of each of which are herein incorporated by reference.

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), telephone such as a cellular phone (e.g., a multimedia and Internet-enabled mobile phone such as an iPhone, Palm® device, Blackberry® device or similar device), mp3 player, pager, and the like), drug delivery device, 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 additionally storing, retrieving, updating, and/or analyzing data corresponding to the detected analyte level of the user.

In certain embodiments, the communication link **103** as well as one or more of the other communication interfaces shown in FIG. **1** to communicate data between the data processing unit **102**, the primary receiver unit **104**, secondary receiver unit **106** and the data processing terminal **105** may use one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth® enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPAA requirements) while avoiding potential data collision and interference.

Furthermore, data communication between the primary receiver unit **104** and the data processing terminal **105**, or between the secondary receiver unit **106** and the data processing terminal **105** may include wireless or wired connection such as USB connection, RS-232 connection, serial connection, and the like, to transfer data between the one or more of the primary and the secondary receiver units **104**, **106** to the data processing terminal **105**.

FIG. **2** is an example flowchart for optimizing analyte sensor calibration in accordance with one embodiment of the present disclosure. Referring to FIG. **2**, in one aspect, when a blood glucose information is received (**210**) for example, using a finger prick test using a blood glucose test strip, an analyte sensor calibration schedule associated with the analyte sensor **101** (FIG. **1**) is retrieved (**220**). In one aspect, the calibration schedule may include a predetermined time interval at which the sensor **101** is calibrated using a reference measurement such as a blood glucose measurement. In one aspect, one or more memory module or storage unit of the receiver unit **104**/**106** may store the calibration schedule associated with the sensor **101**.

Referring back to FIG. **2**, with the retrieved analyte sensor calibration schedule, a temporal proximity of the next upcoming scheduled calibration event is determined (**230**). That is, in one aspect, when a blood glucose measurement is received, the sensor calibration schedule is reviewed to

determine when the next scheduled calibration event is to occur. Thereafter, the temporal proximity is compared to a predetermined time period to determine whether the timing of when the current blood glucose measurement is within a time window associated with the next scheduled calibration event (**240**).

For example, given an exemplary calibration schedule of 10 hours, 12 hours, 24 hours and 72 hours measured from the analyte sensor positioning in the patient, when the reference blood glucose measurement is received at the 23rd hour from when the sensor was positioned in the patient, the temporal proximity is determined to be approximately one hour from the next scheduled calibration event (at the 24th hour). The temporal proximity is then compared to the predetermined time period which may be pre-programmed, for example, in the receiver unit (**104**/**106**) and may include, for example 90 minutes.

That is, in the example provided above, when a blood glucose measurement is received not in response to an execution of a calibration routine to calibrate the sensor **101**, it is determined whether the timing of the received blood glucose measurement is within the predetermined time period from the next scheduled calibration event. Referring back to FIG. **2**, if it is determined that the temporal proximity of the upcoming or next scheduled calibration event is within the predetermined time period, then the calibration routine to calibrate the analyte sensor is initiated (**250**).

In one embodiment, when the calibration routine is initiated, a preliminary check, the calibration conditions are evaluated to determine if calibration of the analyte sensor is appropriate, and when it is determined that the calibration conditions are appropriate, the routine proceeds with executing one or more functions associated with the calibration of the analyte sensor. Moreover, as part of the calibration routine, when initiated, the current blood glucose information as well as other data or information may be stored in a memory or storage unit of the receiver unit **104**/**106**.

Referring back to FIG. **2**, on the other hand, if it is determined that the temporal proximity is not within the predetermined time period (**240**), the current blood glucose measurement received is stored, for example, in a memory or storage unit of the receiver unit **104**/**106** (**260**). Additionally, the user or the patient may be notified of the successful calibration event, and further, that the successful calibration event overrides the upcoming scheduled calibration, and that the user or the patient will not be prompted or requested to perform the upcoming scheduled calibration including providing another blood glucose information.

In this manner, in one aspect, when the patient or the user of the analyte monitoring system **100** (FIG. **1**) performs a blood glucose measurement between the scheduled calibration time periods, a determination is made to accept the blood glucose measurement to perform calibration of the analyte sensor **101**. Thereafter, the upcoming or next scheduled calibration event may be overridden or updated with the calibration performed based on the blood glucose measurement received.

Accordingly, additional flexibility and robustness may be provided in the analyte monitoring system **100** while minimizing the number of blood glucose measurements to calibrate the analyte sensor **101** during its useful life. In other words, when the patient or the user of the analyte monitoring system **100** performs a self-initiated blood glucose measurement (for example, using a standard blood glucose meter, or using the receiver unit **104**/**106** having such functionality integrated therein), in one aspect, it is determined whether the blood glucose measurement may be used to perform calibration of the analyte sensor, and in which case, the next scheduled calibration event may be overridden or not performed as the conditions are such that the calibration routine using the received current blood glucose measurement may replace the upcoming scheduled calibration event.

By way of an example, there may be circumstances where patient motivated blood glucose measurements are performed sufficiently close to the next scheduled calibration of the analyte sensor **101** such that the next scheduled calibration event may be replaced with the calibration routine performed based on the patient motivated blood glucose measurements. Accordingly, in one aspect, the patient or the user of the analyte monitoring system **100** may be subject to one less finger prick test to determine blood glucose measurement to calibrate the analyte sensor **101**.

While particular examples are provided above for the predetermined time period used to compare the temporal proximity of the current blood glucose measurement to the next or upcoming scheduled calibration event, and further, while particular example calibration schedule is described above, within the scope of the present disclosure, the particular predetermined time period to compare the temporal proximity of the blood glucose measurement, or the particular calibration schedule may be varied. For example, the calibration schedule may be provided to require calibration routine once every 24 hours measured from the initial sensor insertion. Alternatively, the calibration schedule time periods may be different for each period during the life of the sensor (which may be 3 days, 5 days, 7 days or more), and further, each subsequent calibration routine after the initial calibration may be determined relative to the immediately preceding successful calibration routine performed, and not relative to the time associated with the initial sensor insertion. Moreover, the predetermined time period used to compare the temporal proximity may include other time periods such as approximately one hour, or approximately two hours, or any other suitable time period rather than approximately 90 minutes.

FIG. **3** is an example flowchart for optimizing analyte sensor calibration in accordance with another embodiment of the present disclosure. Referring to FIG. **3**, in a further aspect, after receiving calibration reference data (**310**), temporal proximity of the next scheduled analyte sensor calibration event is determined (**320**). Thereafter, the determined temporal proximity is compared to a predetermined time period as described above (**330**), and when it is determined that the temporal proximity is not within the predetermined time period, the received calibration reference data is stored (**370**) and the routine terminates.

On the other hand, referring back to FIG. **3**, when it is determined that the temporal proximity of the next scheduled analyte sensor calibration event is within the predetermined time period (relative to when the calibration reference data is received, for example), a request to confirm analyte sensor calibration may be generated and provided to the user or the patient (**340**). In this manner, the user or the patient may be provided with an opportunity to accept or decline the execution of the calibration routine based on the calibration reference data given the temporal proximity of the next or subsequent upcoming calibration schedule to calibrate the analyte sensor **101** (FIG. **1**).

In one aspect, using an output device such as a display on the receiver unit **104**/**106**, the user may be prompted to confirm the execution of the calibration routine in addition to providing information associated with when the next scheduled calibration is to occur. Referring yet again to FIG. **3**, when user confirmation acknowledgement is not received

(**350**), then the calibration reference data is stored (**370**) and the routine terminates. On the other hand, if the user confirmation acknowledgement is received (**350**), then the analyte sensor calibration routine is initiated (**360**) to execute the routine associated with the calibration of the analyte sensor. As discussed above, as part of the initiated calibration routine, the calibration reference data as well as other information and data may be stored in the memory or storage device of the receiver unit **104**/**106**.

Referring back to FIG. **3**, in a further aspect, when it is determined that the temporal proximity of the next scheduled analyte sensor calibration event is within the predetermined time period, prior to sending the request to confirm the calibration event, calibration conditions may be evaluated to determine whether analyte sensor calibration conditions are appropriate. Alternatively, evaluation of the calibration conditions may be performed after the user or the patient has provided acknowledgement confirmation to perform the calibration.

As discussed in further detail below, initiating the calibration routine may include, in one aspect, validating or confirming the acceptability of the received calibration reference data (for example, a determination that the blood glucose measurement used as the calibration reference data is within a predefined acceptable range such as 40 mg/dL to 400 mg/dL). Additionally, conditions or parameters associated with the execution of the calibration routine may be performed including, for example, determining the rate of the change of the analyte level to be within an acceptable range for calibration, the temperature information associated with the analyte sensor is within an acceptable range, or there are a sufficient number of analyte sensor data points to perform calibration.

FIG. **4** is an example flowchart for optimizing analyte sensor calibration in accordance with yet another embodiment of the present disclosure. Referring to FIG. **4**, in one aspect, when the current reference data is received (**410**), temporal proximity of the next scheduled analyte sensor calibration event is confirmed to be within a predetermined time period (for example, such as 90 minutes from when the current reference data is received) (**420**). Thereafter, calibration conditions are validated to determine that conditions associated with the patient and the analyte sensor, among others, are appropriate (**430**).

For example, in one aspect, the calibration condition may not be valid when the rate of change of the analyte level exceeds a predetermined threshold level or range. In another aspect, the calibration condition may be determined to be invalid when insufficient analyte sensor data points are present (whether due to data packet drop outs from the data processing unit **102** (FIG. **1**), or signal dropout events such as signal attenuation. Within the scope of the present disclosure, other parameters and/or conditions are reviewed and analyzed to determine whether the calibration condition is valid. Examples of such other parameters or conditions are further described in U.S. Pat. Nos. 6,175,752 and 7,299,083, among others, the disclosure of each of which are incorporated by reference for all purposes.

Referring back to FIG. **4**, upon validation of the calibration conditions (**430**), the analyte sensor is calibrated using the received current reference data (**440**). Moreover, after calibration, the stored calibration schedule in one aspect may be retrieved and updated to include the calibration performed based on the received current reference data (**450**). Moreover, in one aspect, the retrieved calibration schedule may be updated to replace the next scheduled analyte sensor calibration event with the calibration based on the current reference data.

In the manner provided, within the scope of the present disclosure, using the non-calibration prompted and user initiated blood glucose measurements, under certain conditions such as time proximity to the subsequent scheduled calibration event, among others, the number of required blood glucose measurement using a blood glucose test strip may be minimized.

Referring still to the various embodiments of the present disclosure, as discussed above, the analyte monitoring system may automatically perform the calibration of the analyte sensor based on the blood glucose measurement received, and thereafter, notify the user or the patient of the successful calibration of the sensor, or alternatively, provide the patient or the user with the option to confirm the performance of the calibration of the sensor based on the receive blood glucose measurement. Within the scope of the present disclosure, other variations or levels of user or patient interaction may be contemplated, such as, for example, notification (alarms or alerts that are visual, auditory, vibratory or one or more combinations thereof) to the user of calibration associated events such as updating the previously stored calibration schedule based on the calibration performed with the current reference or blood glucose data, notification of the next valid scheduled calibration, the number of calibrations remaining for the sensor prior to sensor replacement, failed calibration attempt, unsuitable calibration conditions, verified valid calibration conditions, and the like.

Accordingly, a method in one aspect includes receiving a current blood glucose measurement, retrieving a time information for an upcoming scheduled calibration event for calibrating an analyte sensor, determining temporal proximity between the current blood glucose measurement and the retrieved time information for the upcoming calibration event, and initiating a calibration routine to calibrate the analyte sensor when the determined temporal proximity is within a predetermined time period.

In one aspect, initiating the calibration routine may include calibrating the analyte sensor based on the received current blood glucose measurement.

Moreover, the method may include determining validity of the current blood glucose measurement, for example, by comparing the current blood glucose measurement to predetermined ranges or values.

Additionally, determining validity of the current blood glucose measurement may include analyzing the current blood glucose measurement based on a predetermined threshold range, a temperature information, or a combination thereof.

In still another aspect, the method may include determining the validity of an analyte sensor data, including one or more of analyzing the analyte sensor data based on one or more of a rate of change of the analyte level, a temperature information, a predetermined analyte level threshold range, or one or more combinations thereof.

In another aspect, the method may include overriding the upcoming scheduled calibration event when the calibration routine to calibrate the analyte sensor based on the received current blood glucose measurement is successful.

Also, initiating the calibration routine may include validating one or more calibration condition parameters associated with the calibration of the analyte sensor.

Yet still further aspect may include generating an output signal confirming completion of the upcoming scheduled calibration event.

In yet another aspect, the method may include updating a calibration schedule for calibrating the analyte sensor based on the initiated calibration routine.

Further, initiating calibration routine may include automatically performing the calibration routine to calibrate the analyte sensor when the determined temporal proximity is within the predetermined time period.

A method in accordance with another aspect of the present disclosure includes receiving a current reference data associated with a monitored analyte level, determining whether a next scheduled calibration event for calibrating an analyte sensor associated with the monitored analyte level is within a predetermined time period, validating one or more conditions associated with the calibration of the analyte sensor when the next scheduled calibration event is determined to be within the predetermined time period, and calibrating the analyte sensor based on the received current reference data.

The analyte sensor may be associated with a time spaced calibration schedule including the next scheduled calibration event.

The time spaced calibration schedule may include an unevenly time spaced calibration schedule during the life of the sensor.

In another aspect, the method may include updating the time spaced calibration schedule based on analyte sensor calibration using the received current reference data

Also, the method may include associating the current reference data with a corresponding calibrated analyte sensor data.

Additionally, in a further aspect, the method may include disabling a calibration routine associated with the next scheduled calibration event.

An apparatus in accordance with another aspect of the present disclosure includes one or more processors, and a memory operatively coupled to the one or more processors for storing instructions which, when executed by the one or more processors, retrieves a time information for an upcoming scheduled calibration event for calibrating an analyte sensor when a current blood glucose measurement is received, determines a temporal proximity between the current blood glucose measurement and the retrieved time information for the upcoming calibration event, and initiates a calibration routine to calibrate the analyte sensor when the determined temporal proximity is within a predetermined time period.

The apparatus may include a blood glucose strip port configured to receive a blood glucose test strip providing the current blood glucose measurement. That is, in one aspect, the receiver unit **104/106** (FIG. **1**) may include an integrated blood glucose test strip port and be configured to analyze the blood sample received from the test strip to determine the corresponding blood glucose level.

In still another aspect, the apparatus may include a housing coupled to the blood glucose strip port and further, wherein the one or more processors and the memory are provided in the housing.

The various processes described above including the processes performed by the one or more processors of the receiver unit **104/106**, or optionally the data processing unit **102** (FIG. **1**), in the software application execution environment as well as any other suitable or similar processing units embodied in the analyte monitoring system **100**, including the processes and routines described in conjunction with FIGS. **2-4**, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in a memory (or similar storage devices in the data processing unit **102**, or the receiver unit **104/106**) of the processor, may be developed by a person of ordinary skill in the art and may include one or more computer program products.

Various other modifications and alterations in the structure and method of operation of this present disclosure will be apparent to those skilled in the art without departing from the scope and spirit of the present disclosure. Although the present disclosure has been described in connection with specific preferred embodiments, it should be understood that the present disclosure 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:

determining, using one or more processors, a temporal proximity between when reference analyte data is received and a time information for an upcoming calibration event associated with an analyte sensor; and

calibrating one or more signals received from the analyte sensor when the determined temporal proximity is within a predetermined time period.

2. The method of claim **1**, wherein calibrating the one or more signals received from the analyte sensor includes calibrating based on an analyte level measurement of the reference analyte data.

3. The method of claim **2**, including determining, using the one or more processors, a validity of the reference analyte data.

4. The method of claim **3**, wherein determining the validity of the reference analyte data includes analyzing the reference analyte data based on a predetermined threshold range, a temperature information, or a combination thereof.

5. The method of claim **2**, further including determining, using the one or more processors, a validity of the one or more signals received from the analyte sensor.

6. The method of claim **5**, wherein determining the validity of the one or more signals received from the analyte sensor includes one or more of analyzing the one or more signals received from the analyte sensor based on one or more of a rate of change of an analyte level, a temperature information, a predetermined analyte level threshold range, or one or more combinations thereof.

7. The method of claim **2**, further including overriding the upcoming calibration event when the reference analyte data is accepted for calibrating the one or more signals received from the analyte sensor.

8. The method of claim **7**, wherein the upcoming calibration event is a scheduled calibration, and further comprising providing a notification to a user that the user will not be prompted to perform the scheduled calibration.

9. The method of claim **1**, further including validating one or more calibration condition parameters associated with the calibration of the one or more signals received from the analyte sensor.

10. The method of claim **1**, further including generating an output signal confirming completion of calibrating the one or more signals received from the analyte sensor.

11. The method of claim **1**, further including updating a calibration schedule based on calibrating the one or more signals received from the analyte sensor.

12. The method of claim **11**, wherein updating the calibration schedule comprises replacing an event in the cali-

bration schedule corresponding to the upcoming calibration event with an event for the calibrating of the one or more signals received from the analyte sensor.

13. The method of claim **1**, further including automatically calibrating the one or more signals received from the analyte sensor when the determined temporal proximity is within the predetermined time period.

14. A method, comprising:

validating, using one or more processors, one or more conditions associated with calibration of one or more signals received from an analyte sensor when an upcoming calibration event is within a predetermined time period from when reference analyte data is received; and

calibrating, using the one or more processors, the one or more signals received from the analyte sensor based on the received reference analyte data when the one or more conditions associated with the calibration of the one or more signals received from the analyte sensor is validated.

15. The method of claim **14**, wherein the analyte sensor is associated with a time spaced calibration schedule including the calibration event.

16. The method of claim **15**, wherein the time spaced calibration schedule includes unevenly time spaced calibration events during a life of the analyte sensor.

17. The method of claim **15**, further including updating, using the one or more processors, the time spaced calibration schedule based on the calibration of the one or more signals received from the analyte sensor using the received reference analyte data.

18. The method of claim **14**, further including associating, using the one or more processors, the reference analyte data with a corresponding one or more signals received from the analyte sensor.

19. The method of claim **14**, further including disabling, using the one or more processors, a calibration routine associated with the calibration event.

20. An apparatus, comprising:

one or more processors; and

a memory operatively coupled to the one or more processors for storing instructions which, when executed by the one or more processors, is configured to determine a temporal proximity between when reference analyte data is received and a time information for an upcoming calibration event, and to calibrate one or more signals from an analyte sensor when the determined temporal proximity is within a predetermined time period.

21. The apparatus of claim **20**, further including an input unit to receive the reference analyte data.

22. The apparatus of claim **21**, further including an output unit configured to output information associated with the one or more signals received from the analyte sensor, the reference analyte data, the temporal proximity, or the calibration event.

* * * * *

专利名称(译)	优化分析物传感器校准		
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[标]申请(专利权)人(译)	雅培糖尿病护理公司		
申请(专利权)人(译)	雅培糖尿病INC.		
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摘要(译)

用于优化分析物传感器校准的方法和设备包括接收当前血糖测量值，检索即将到来的预定校准事件的时间信息以校准分析物传感器，确定当前血糖测量值与所检索的时间信息之间的时间接近度以用于即将到来的校准事件，当确定的时间接近度在预定时间段内时启动校准例程以校准分析物传感器，并且提供使用当前血糖测量值覆盖即将到来的预定校准事件。