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(54) **METHOD AND APPARATUS FOR PROVIDING NOTIFICATION FUNCTION IN ANALYTE MONITORING SYSTEMS**

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(58) **Field of Classification Search**

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See application file for complete search history.

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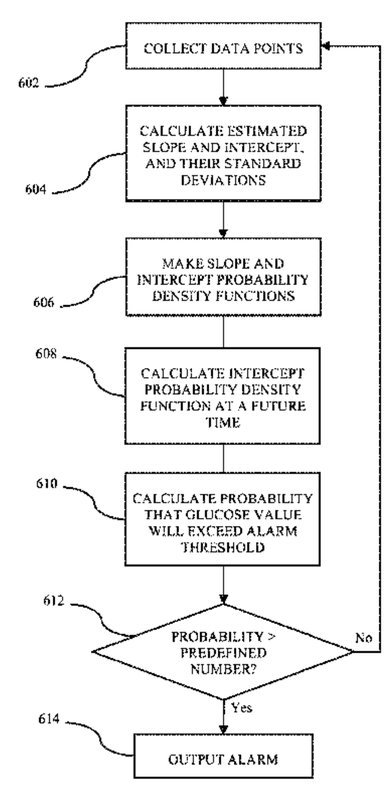
(57) **ABSTRACT**

Method and apparatus for determining and outputting projected alarms or notifications associated with anticipated hyperglycemic or hypoglycemic conditions are provided. Systems and kits employing the devices described herein executing the one or more routines described are also provided.

20 Claims, 8 Drawing Sheets



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U.S. Appl. No. 12/894,124, Office Action dated Sep. 23, 2013.
U.S. Appl. No. 15/094,991, Office Action dated Mar. 27, 2017.
U.S. Appl. No. 15/094,991, Office Action dated Sep. 2, 2016.

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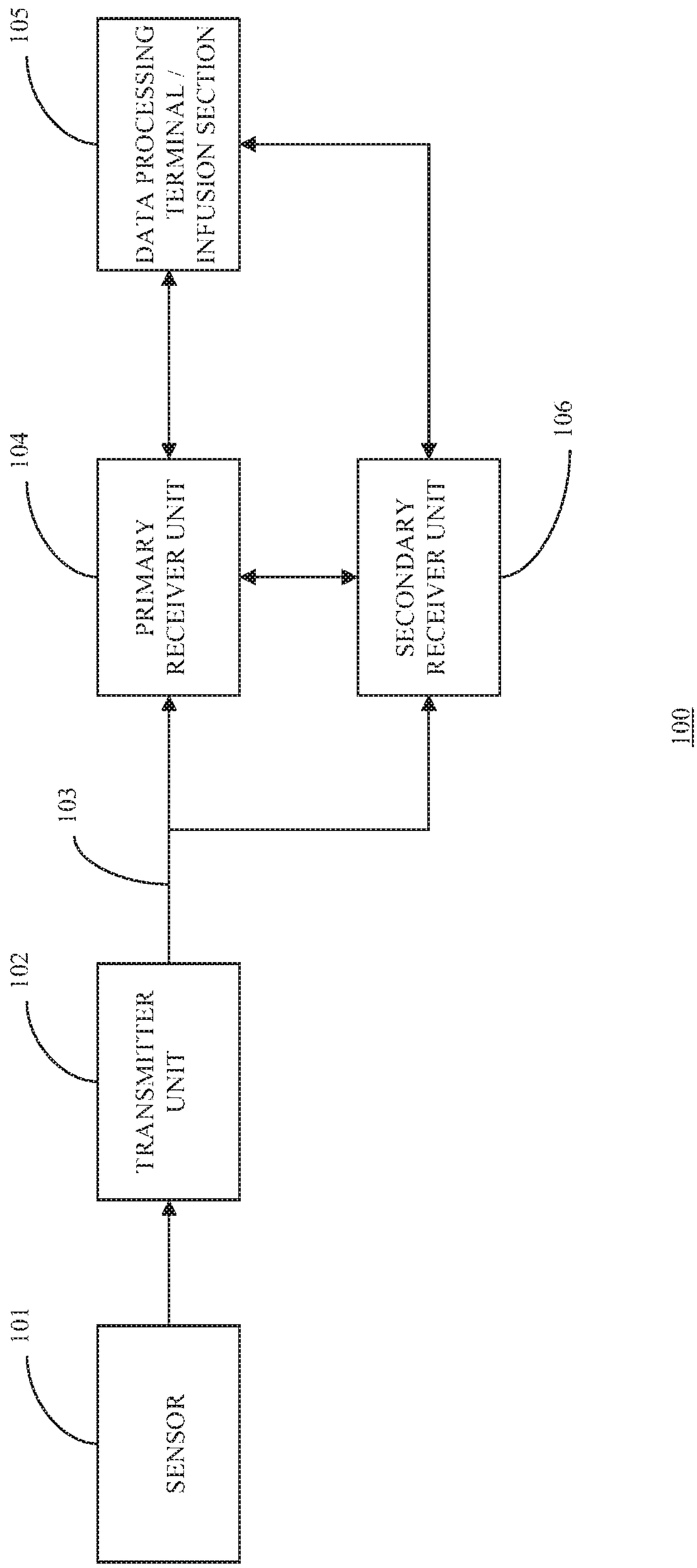
105
DATA PROCESSING TERMINAL / INFUSION SECTION
104
PRIMARY RECEIVER UNIT
106
SECONDARY RECEIVER UNIT
103
102
TRANSMITTER UNIT
101
SENSOR
100

FIG. 1A

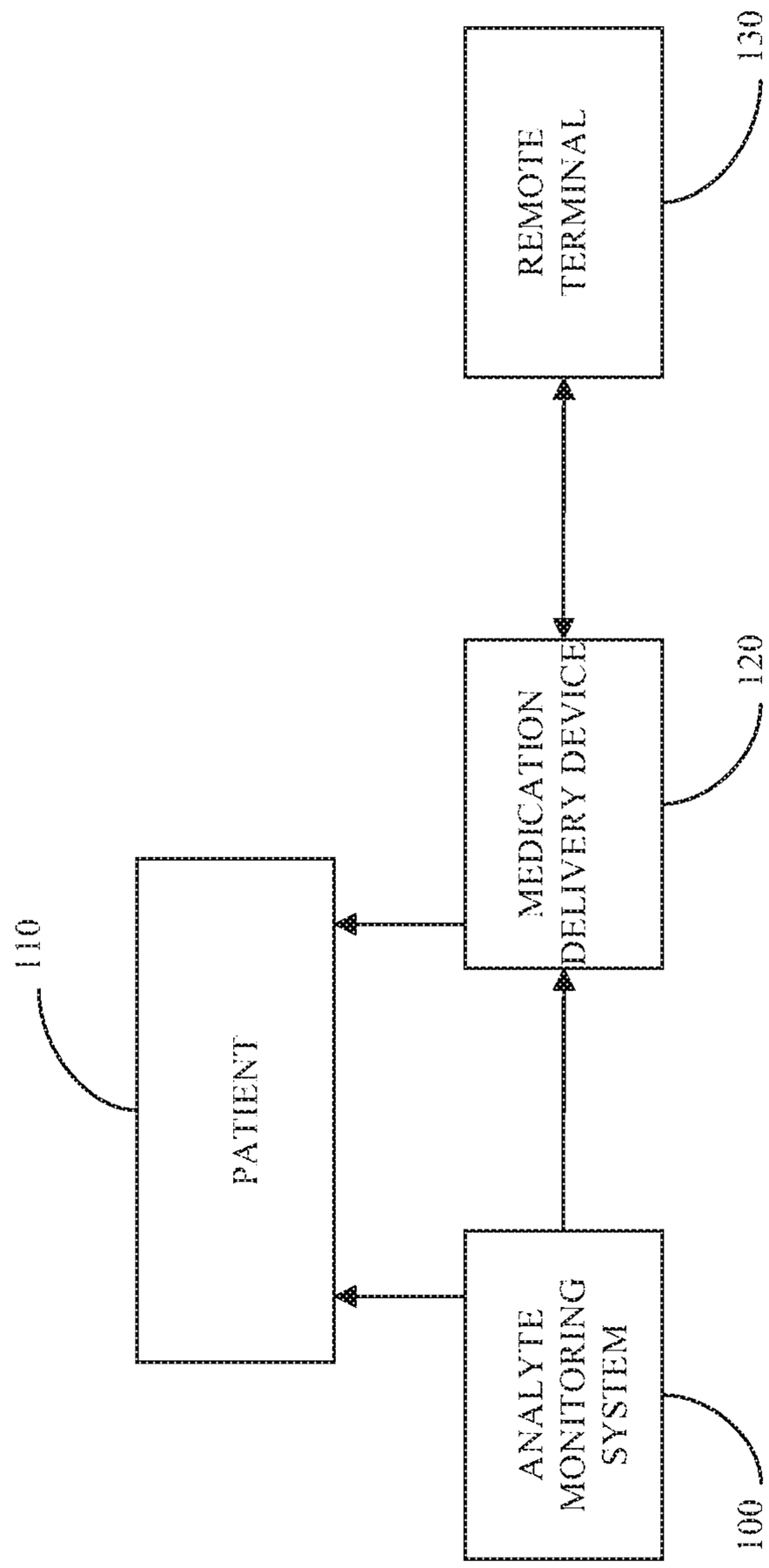
REMOTE TERMINAL
130
MEDICATION DELIVERY DEVICE
120
PATIENT
110
ANALYTE MONITORING SYSTEM
100

FIG. 1B

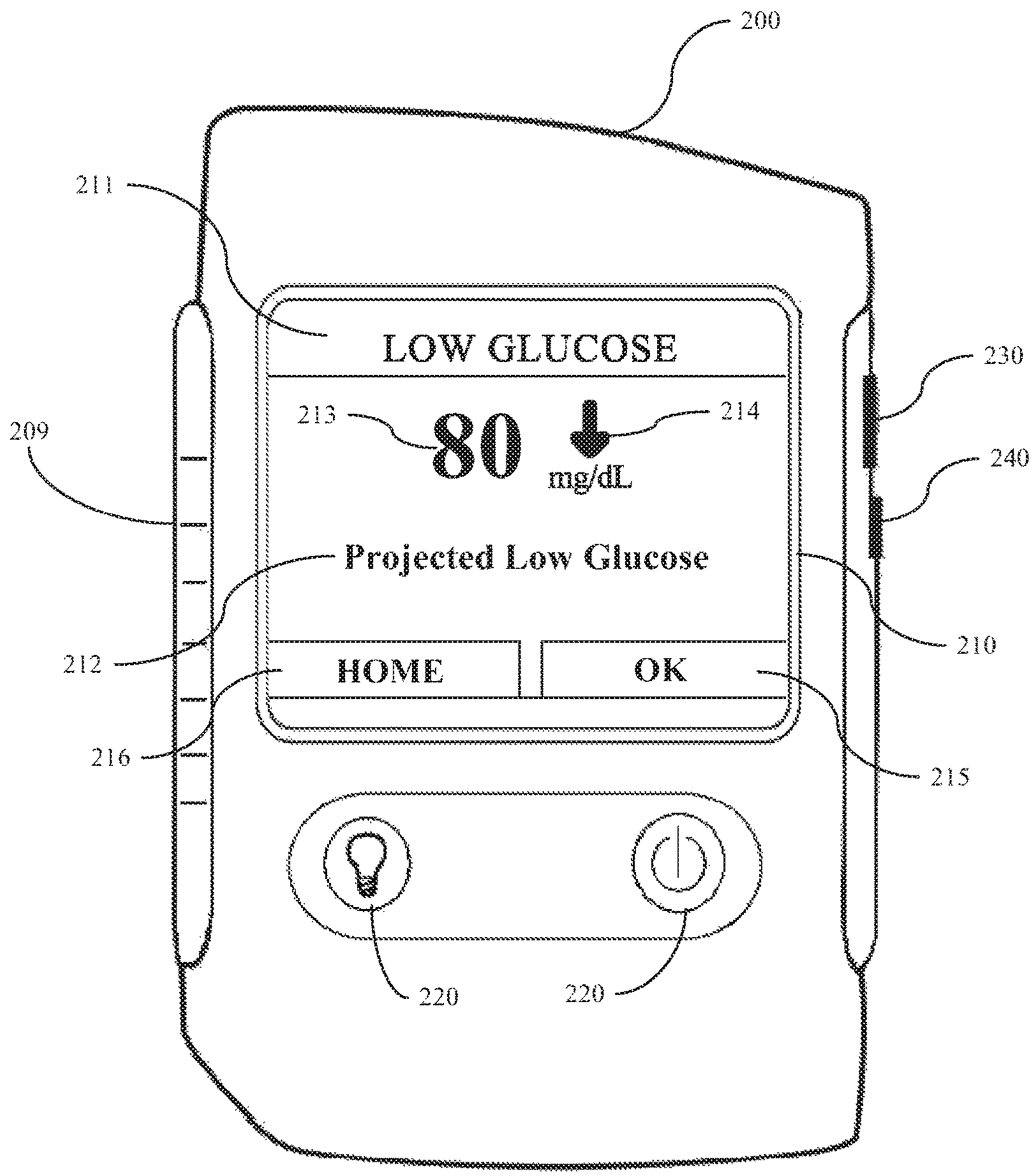
200
211
LOW GLUCOSE
213
80
214
mg/dL
209
Projected Low Glucose
212
HOME
OK
216
215
210
230
240
220
220

FIG. 2

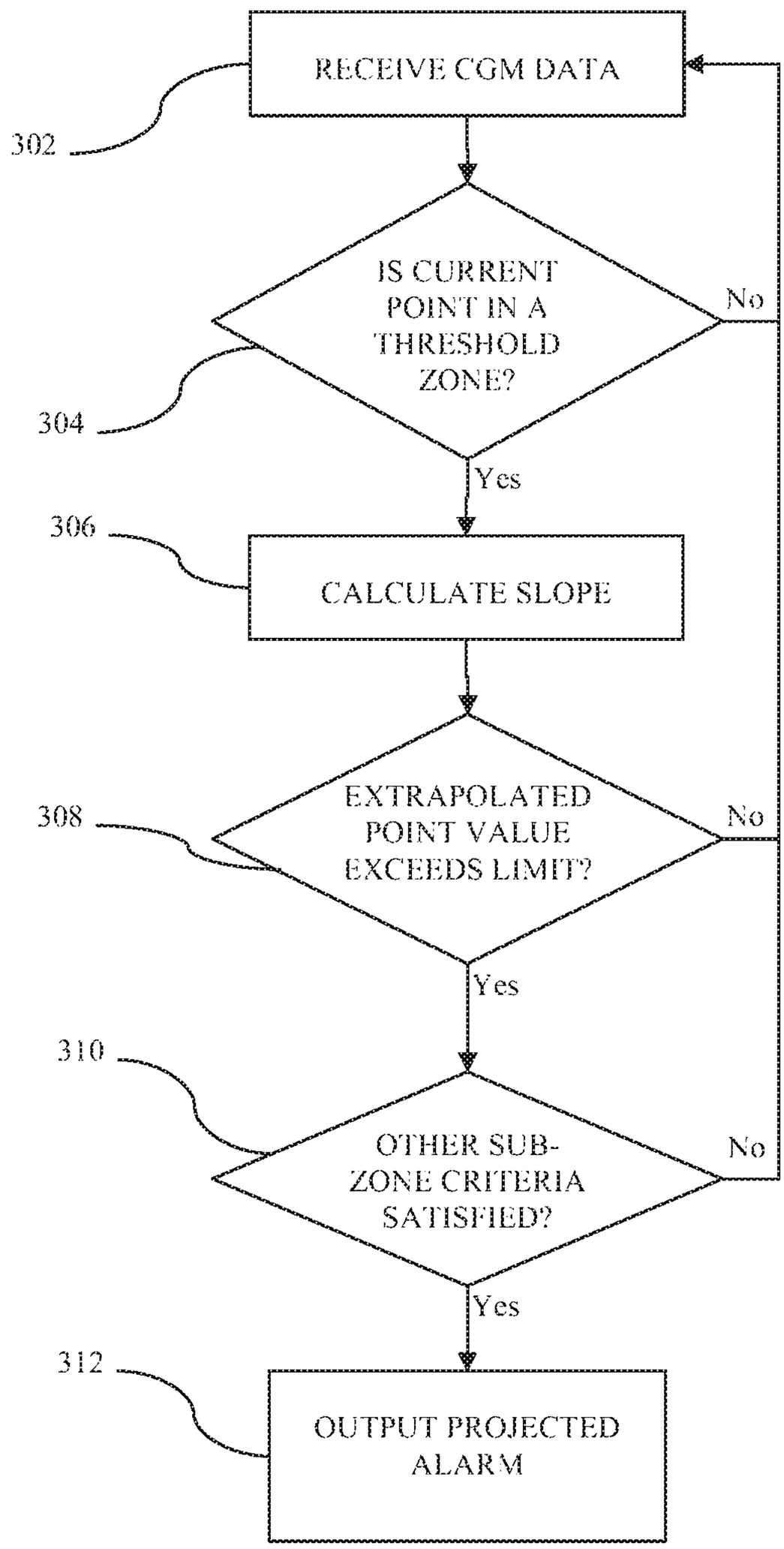
RECEIVE CGM DATA
302
IS CURRENT POINT IN A THRESHOLD ZONE?
No
304
Yes
306
CALCULATE SLOPE
EXTRAPOLATED POINT VALUE EXCEEDS LIMIT?
308
No
Yes
310
OTHER SUB-ZONE CRITERIA SATISFIED?
No
Yes
312
OUTPUT PROJECTED ALARM

FIG. 3

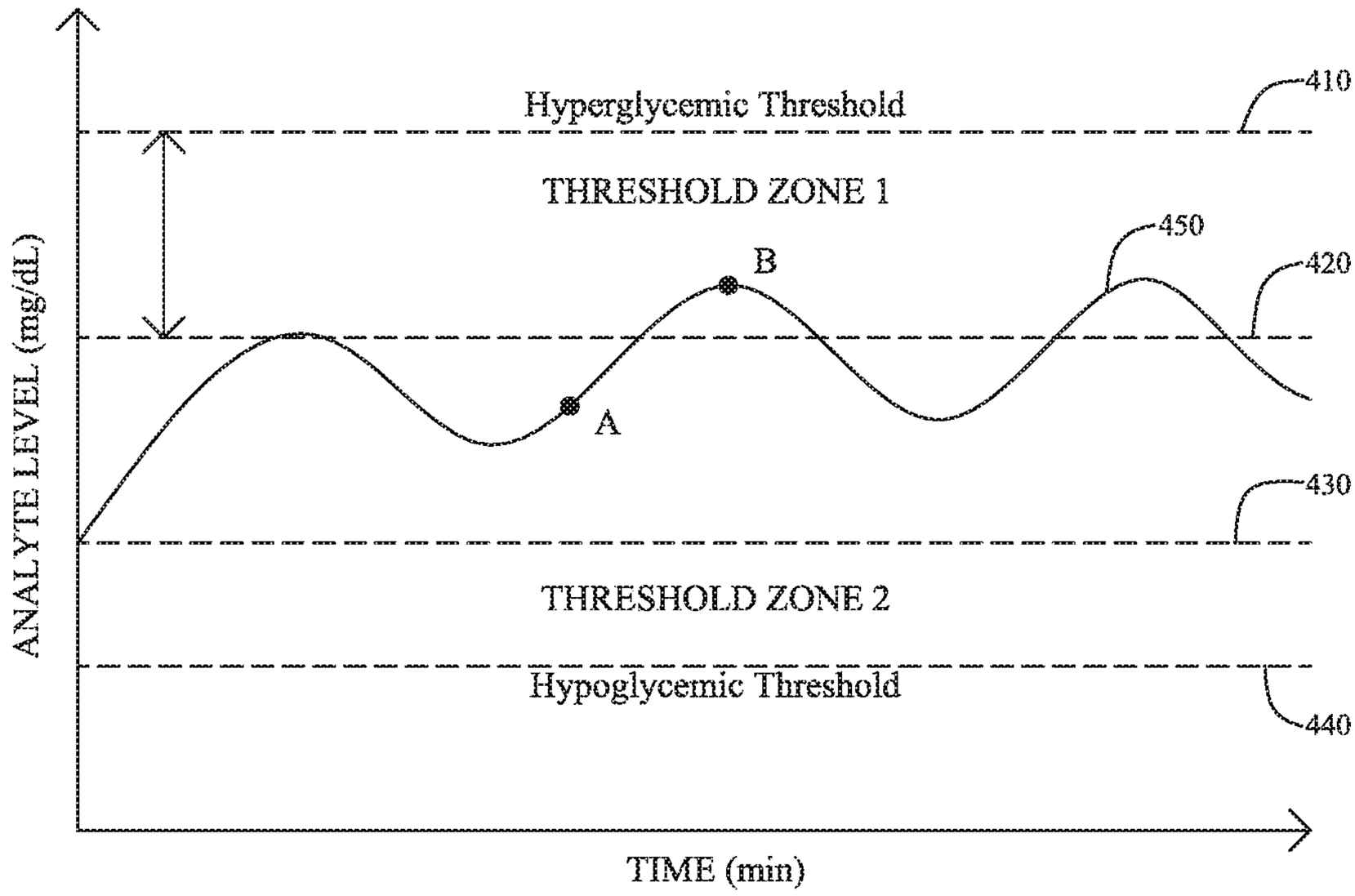
Hyperglycemic Threshold
410
THRESHOLD ZONE 1
450
B
420
A
430
THRESHOLD ZONE 2
Hypoglycemic Threshold
440
ANALYTE LEVEL (mg/dL)
TIME (min)

FIG. 4A

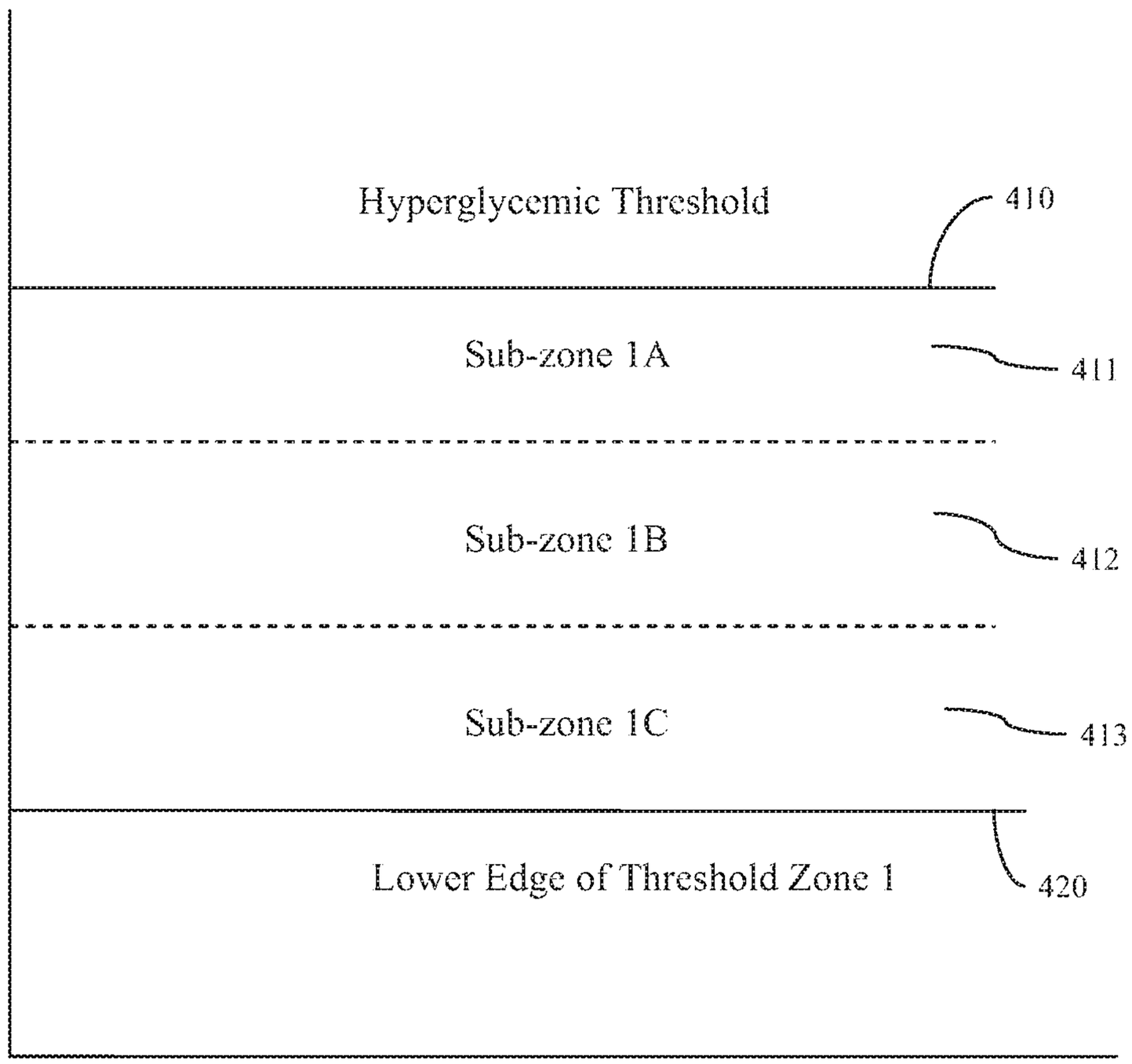
Hyperglycemic Threshold
410
Sub-zone 1A
411
Sub-zone 1B
412
Sub-zone 1C
413
Lower Edge of Threshold Zone 1
420

FIG. 4B

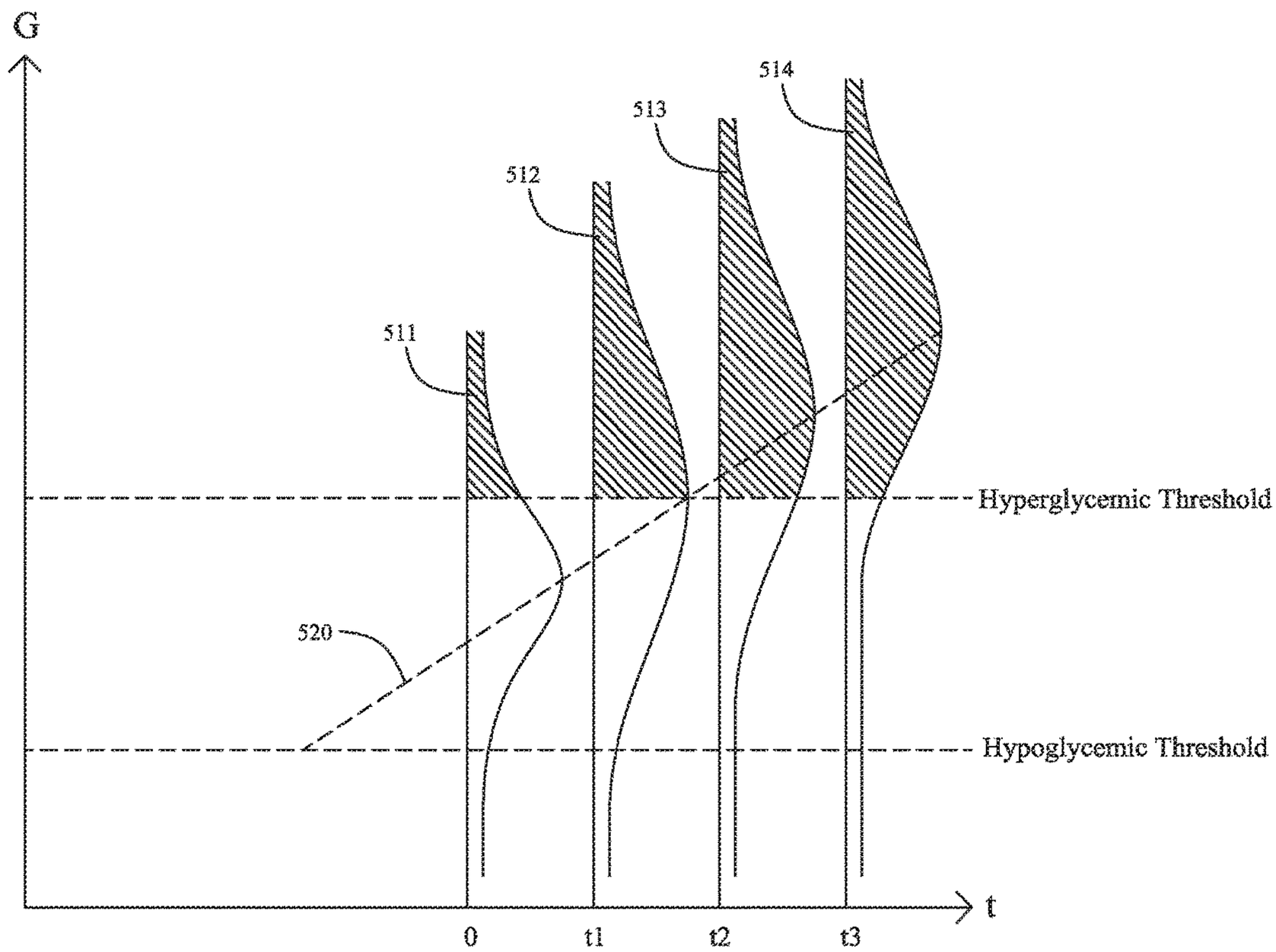
G
514
513
512
511
Hyperglycemic Threshold
520
Hypoglycemic Threshold
t
0
t1
t2
t3

FIG. 5

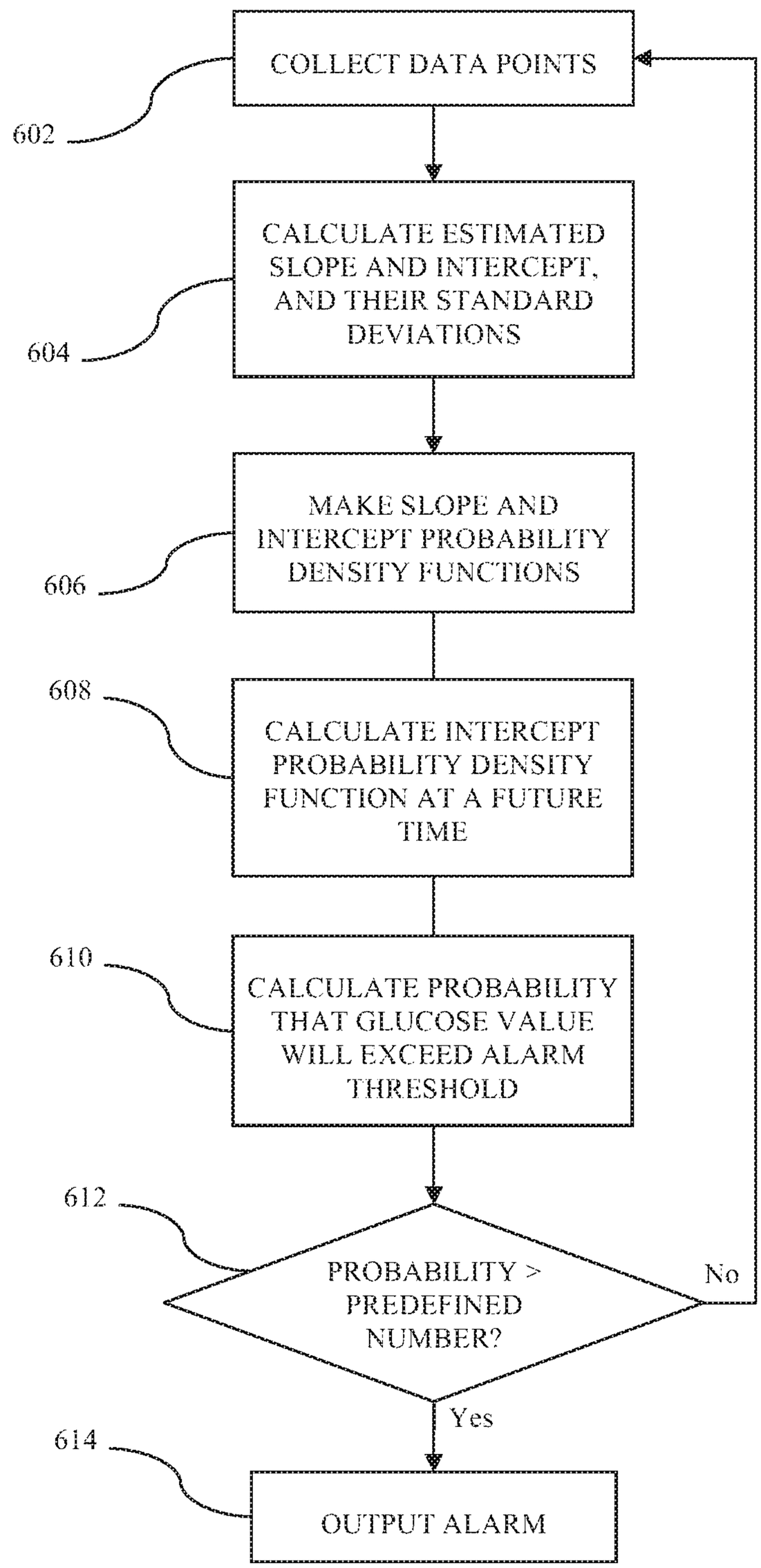
COLLECT DATA POINTS
602
CALCULATE ESTIMATED SLOPE AND INTERCEPT, AND THEIR STANDARD DEVIATIONS
604
MAKE SLOPE AND INTERCEPT PROBABILITY DENSITY FUNCTIONS
606
608
CALCULATE INTERCEPT PROBABILITY DENSITY FUNCTION AT A FUTURE TIME
610
CALCULATE PROBABILITY THAT GLUCOSE VALUE WILL EXCEED ALARM THRESHOLD
612
PROBABILITY > PREDEFINED NUMBER?
No
Yes
614
OUTPUT ALARM

FIG. 6

METHOD AND APPARATUS FOR PROVIDING NOTIFICATION FUNCTION IN ANALYTE MONITORING SYSTEMS

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 15/094,991 filed Apr. 8, 2016, now U.S. Pat. No. 9,750,439, which is a continuation of U.S. patent application Ser. No. 12/894,124 filed Sep. 29, 2010, now U.S. Pat. No. 9,320,461, which claims priority under § 35 U.S.C. 119(e) to U.S. Provisional Application No. 61/246,811 filed Sep. 29, 2009, entitled "Calculation of Projected Alarms", the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

Diabetes mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood glucose. In particular, when blood glucose levels rise, e.g., after a meal, insulin lowers the blood glucose levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type I diabetes) or does not properly utilize insulin (a condition known as Type II diabetes), the blood glucose remains in the blood resulting in hyperglycemia or abnormally high blood sugar levels.

People suffering from diabetes often experience long-term complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), which often leads to stroke, coronary heart disease, and other diseases, which can be life threatening.

The severity of the complications caused by both persistent high glucose levels and blood glucose level fluctuations has provided the impetus to develop diabetes management systems and treatment plans. In this regard, diabetes management plans historically included multiple daily testing of blood glucose levels, typically by a finger-stick to draw and test blood. The disadvantage with finger-stick management of diabetes is that the user becomes aware of his blood glucose level only when he performs the finger-stick. Thus, blood glucose trends and blood glucose snapshots over a period of time is unknowable. More recently, diabetes management has included the implementation of analyte monitoring systems, such as glucose monitoring systems which use in vivo sensors that continuously or intermittently generate signals indicative of the fluctuation in the analyte levels. Analyte monitoring systems have the capability to continuously monitor a user's glucose levels, and thus have the ability to illustrate not only present glucose levels but a snapshot of glucose levels and glucose fluctuations over a period of time.

Analyte monitoring systems also have the capability to output alarm notifications, such as an audible alarm, to alert the user to a condition that may require medical attention. Such alarms are usually triggered when the blood glucose level of a patient exceed a preset glucose level threshold. Some analyte monitoring systems also include projected alarms that warn the user of an impending high or low glucose level.

The method of calculating the projected alarms varies according to the glucose monitoring system being used. For example, some glucose monitoring systems use the present glucose level and its rate of change (slope) to make a straight-line extrapolation of the glucose value at times in the future. If the glucose value is projected to be above or below a certain threshold within a certain time period, the projected alarm is sounded. The user experience is very much affected by the frequency of the projected alarms.

For example, some analyte monitoring systems only utilize a small sampling of data points to calculate the glucose level rate of change. In other analyte monitoring systems, a high uncertainty value might disqualify an alarm activation even if the probability of a glycemic condition occurring is very high. Furthermore, some analyte monitoring systems assign an arbitrary penalty to missing glucose level data points that increase uncertainty. If ineffective calculation techniques are utilized to calculate the projected glucose level, such as those just described, the analyte monitoring system may output false projected alarms.

INCORPORATION BY REFERENCE

Patents, applications and/or publications described herein, including the following patents, applications and/or publications, are incorporated herein by reference for all purposes: U.S. Pat. Nos. 4,545,382, 4,711,245, 5,262,035, 5,262,305, 5,264,104, 5,320,715, 5,356,786, 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, 7,041,468, 7,167,818, and 7,299,082, U.S. Published Application Nos. 2004/0186365, now U.S. Pat. No. 7,811,231, 2005/0182306, now U.S. Pat. No. 8,771,183, 2006/0025662, now U.S. Pat. No. 7,740,581, 2006/0091006, 2007/0056858, now U.S. Pat. No. 8,298,389, 2007/0068807, now U.S. Pat. No. 7,846,311, 2007/0095661, 2007/0108048, now U.S. Pat. No. 7,918,975, 2007/0199818, now U.S. Pat. No. 7,811,430, 2007/0227911, now U.S. Pat. No. 7,887,682, 2007/0233013, 2008/0066305, now U.S. Pat. No. 7,895,740, 2008/0081977, now U.S. Pat. No. 7,618,369, 2008/0102441, now U.S. Pat. No. 7,822,557, 2008/0148873, now U.S. Pat. No. 7,802,467, 2008/0161666, 2008/0267823, and 2009/0054748, now U.S. Pat. No. 7,885,698, U.S. patent application Ser. No. 11/461,725, now U.S. Pat. No. 7,866,026, Ser. Nos. 12/131,012, 12/393,921, 12/242,823, now U.S. Pat. No. 8,219,173, Ser. No. 12/363,712, now U.S. Pat. No. 8,346,335, Ser. Nos. 12/495,709, 12/698,124, 12/698,129, now U.S. Pat. No. 9,402,544, Ser. Nos. 12/714,439, 12/794,721, now U.S. Pat. No. 8,595,607, Ser. Nos. 12/807,278, 12/842,013, and 12/871,901, now U.S. Pat. No. 8,514,086, and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, 61/317,243, 61/345,562, and 61/361,374.

SUMMARY

Generally, embodiments of the present disclosure provide an analyte measurement or monitoring system, which includes an analyte sensor in operative contact with an analyte and configured to generate a plurality of data points relative to the concentrations of analyte in a subject. The system also includes a processor adapted to process the data

signals generated by the sensor and logic to determine a mean value and a standard deviation value based on the plurality of data points. In certain embodiments, determined mean and standard deviations are used to determine a probability of an occurrence of an event such as a predetermined alarm condition based upon weighted deviations from the mean over the plurality of data points.

In certain embodiments, the processor is configured to determine the value of the analyte and the uncertainty in the determined value, and the rate of change of analyte and the uncertainty in that rate of change, and model the result as probability distributions. In certain embodiments, the rate of change and its uncertainty are determined using a least squares technique. In some embodiments, for example, at least fifteen data points may be used to determine a line fit for determining the rate of change and its uncertainty. However, at least three data points are needed to use the least squares technique.

In certain embodiments, the line fit may be determined based on autoregressive analysis, moving average analysis or other suitable time series forecasting techniques. In certain embodiments, the probability distribution is Gaussian. In certain embodiments, the probability may be determined based on Gamma distribution, Beta distribution, exponential distribution, or Bernoulli distribution.

Systems and kits for implementing the methods described above are also contemplated.

These and other features, objects and advantages of the present disclosure will become apparent to those persons skilled in the art upon reading the details of the present disclosure as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1**A and **1**B illustrate block diagrams of data monitoring and management systems for practicing one or more embodiments of the present disclosure;

FIG. **2** illustrates a receiver unit in accordance with certain embodiments of the present disclosure;

FIG. **3** is a flowchart illustrating a method for outputting a projected alarm in accordance with certain embodiments of the present disclosure;

FIG. **4**A is a graph illustrating glucose levels versus time in certain embodiments;

FIG. **4**B is a graph illustrating sub-zones of threshold zone **1** of FIG. **4**A in certain embodiments;

FIG. **5** depicts a graph showing different probability density functions at different time intervals in certain embodiments; and

FIG. **6** is a flowchart illustrating a method for outputting a projected alarm in accordance with certain embodiments of the present disclosure.

DETAILED DESCRIPTION

Before the present disclosure is described in 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.

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 and 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.

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.

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.

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.

Reference will now be made in detail to the exemplary embodiments of the present disclosure, an example of which is illustrated in the accompanying figures. The present disclosure will be described in conjunction with the detailed description of the device. However, the scope of the present disclosure is not limited to the specific embodiments described therein.

Various exemplary embodiments of analyte measurement systems and methods for the measuring analyte levels and concentrations and projecting physiological characteristics relating to the analyte concentrations are described in further detail below. The analyte measurement system is capable of continuously or intermittently monitoring an analyte in a biological fluid. Although the present disclosure is described primarily with respect to a glucose measurement system, the present disclosure can be employed in a wide variety of analyte measurement systems. Accordingly, it is to be understood that such description should not be construed to limit the scope of the present disclosure, and it is to be understood that the analyte measurement system can be configured to monitor a variety of analytes, as described below.

Turning now to the Figures, FIGS. **1**A and **1**B illustrate block diagrams of data monitoring and management systems for use in certain embodiments of the present disclosure. As shown, analyte measurement system **100** can generally include, in accordance with one embodiment, a sensor **101**, transmitter unit **102**, and a receiver unit **104**. The system can further include a data processing terminal **105** and/or a secondary receiver unit **106**, if desired. Generally, analyte sensor **101** operatively contacts an analyte to be measured in a biological fluid, such as blood or interstitial fluid, and converts the contacted analyte level into a data signal

relating to the amount or concentration of the analyte. The term "analyte" refers to a substance or chemical constituent in a biological fluid, such as for example, blood or interstitial fluid. For example and not limitation, the analyte can be glucose, lactate, 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. However, other analytes can be monitored as would be understood by one of ordinary skill in the art. Furthermore, analyte measurement system **100** can be configured to monitor the concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, theophylline, warfarin, and the like.

Signals generated by analyte sensor **101** are communicated to transmitter unit **102**, which is in electrical communication with analyte sensor **101**. Transmitter unit **102** may be configured to process the signals, for example encode the signals, received from analyte sensor **101** and transmit the processed data signals to receiver unit **104** along a communication link **103**. The communication between transmitter unit **102** and receiver unit **104** can be either unidirectional or bidirectional. In certain embodiments, the system can further include a display device for displaying information regarding the analyte measurement. The display device can further include the functionality to issue alarm notifications, for example, if the analyte levels are at a critical level. The display device can be part of primary receiver unit **104**, secondary receiver unit **106**, transmitter unit **102**, or can be a separate component.

As illustrated in FIG. **1**A, data processing terminal **105** may include an infusion section for infusing an agent to a user, such as an insulin infusion system. Such infusion section may be wholly implantable systems or external systems. External infusion devices are typically connected to an infusion set which includes a cannula that is placed transcutaneously through the skin of the patient to infuse a select dosage of an agent. The user can administer a select dosage of insulin based on the infusion device's programmed basal rates or any other medication delivery rates as prescribed by the user's health care provider. A user may be able to control the insulin infusion device to administer additional doses of insulin during the course of wearing and operating the infusion device, such as for administering a carbohydrate bolus prior to a meal or a correction bolus when high blood sugar level is present or anticipated. Certain infusion devices may include a food database that has associated therewith an amount of carbohydrate, so that the patient may better estimate the level of insulin dosage needed for, for example, calculating a bolus amount.

An exemplary infusion device or system is further described in U.S. Patent Publication No. 2008/0103447, now U.S. Pat. No. 8,579,853, the disclosure of which is incorporated herein by reference.

FIG. **1**B illustrates analyte monitoring system **100** in conjunction with the user/patient **110** and also in use, for example, with medication delivery device **120** that is also configured for communication with a remote terminal **130**. The remote terminal **130** may be similar to the data processing terminal **105** which, in certain embodiments, may be configured to process data received from medication delivery device **120** such as retrospectively or prospectively analyzing data received from medication delivery device **120** for therapy analysis and/or modification to the existing medication delivery profile associated, for example, with patient/user **110**, and/or medication delivery device **120**. As shown in FIG. **1**A, medication delivery device **120** and remote terminal **130** of FIG. **1**B in certain embodiments may be integrated in a single housing as data processing terminal/infusion section **105** (FIG. **1**A).

FIG. **2** illustrates an exemplary analyte monitoring device **200**, such as primary receiver unit **104** of analyte monitoring system **100** (FIG. **1**) that may be used with certain embodiments of the present disclosure. In certain embodiments, the analyte monitoring device **200** is shaped and sized to fit comfortably in one hand of a user. However, it is contemplated that the analyte monitoring device **200** may have various other shapes and sizes depending on, for example, a particular user or environment. For example, analyte monitoring device **200** may have a first size (larger) and shape for an adult user, and a second size (smaller) and shape for a child user. In certain embodiments, analyte monitoring device **200** may also include grip portions **209** disposed on lateral sides of the housing. Grip portions **209** may be made of rubber, plastic or other similar material that may improve or assist in a user's grip.

In certain embodiments, a user interface is disposed on the analyte monitoring device **200**. As used herein, user interface refers to one or more components that assist a user in interacting with analyte monitoring device **200**. Referring still to FIG. **2**, in certain embodiments, user interface may include display **210** and a plurality of input buttons **220** on the front surface of analyte monitoring device **200**. In certain embodiments, input buttons **220** may include a backlight function to illuminate the display **210** in dark ambient setting, and an on/off switch function to turn on or off the analyte monitoring device **200**. Although two input buttons **220** are shown, it is contemplated that in certain embodiments, a keypad or keyboard may be disposed on the front surface of analyte monitoring device **200**, or only a single button or no buttons may be included.

In certain embodiments, the user interface also includes a jog wheel **230** and a secondary button **240** disposed on one of the lateral sides of the analyte monitoring device **200** that may be operated to input data or commands via the user interface to the analyte monitoring device **200**. In certain embodiments, the user interface may also include a test strip port (not shown) for receiving an in vitro test strip to perform in vitro blood glucose testing, and a data port (not shown), such as a USB or serial port for data communication with, for example, data processing terminal/infusion section **105** (FIG. **1**A), medication delivery device **120** (FIG. **1**B), and/or remote terminal **130** (FIG. **1**B).

In certain embodiments, a sound system (not shown) may also be included with the user interface for outputting audible signals. In certain embodiments, a vibratory system may be included and configured for outputting, among others, a vibratory or other tactile alert. Although specific components are mentioned, it is contemplated that the user interface may include fewer or additional components than those specifically discussed.

Still referring to FIG. **2**, display **210** may be configured to display an alert screen. As shown in FIG. **2**, an alert screen may be output on the entire surface area of the display **210** of analyte monitoring device **200**. In certain embodiments, the alert screen includes a top portion **211** that indicates the nature of the alert (e.g., "Low Glucose"). The alert screen may also include information regarding the condition that triggered the alert. For example, and as shown in FIG. **2**, the displayed information indicates that the user is currently approaching a projected low glucose level **212**, including an indication of the current glucose level **213** and an indication

of the direction of the rate of change of glucose level, illustrated by a directional arrow **214**. In the embodiment shown in FIG. **2**, the alert screen shows that the user's glucose level is currently at 80 mg/dL and rapidly decreasing as indicated by the downward arrow **214**. The alert screen may include, in certain embodiments, menu buttons, which may be triggered by utilizing input buttons **220**.

As shown in FIG. **2**, menu buttons may include a "Home" button **216**, which may shift the display to a home screen, and an acknowledgement button, indicated as an "OK" button **215**. Further description of various alert screens and other screens displayable on the display **210** can be found in, among others, U.S. patent application Ser. No. 12/871,901, now U.S. Pat. No. 8,514,086, the disclosure of which is incorporated herein by reference, for all purposes.

In certain embodiments, techniques for identifying or determining hypoglycemic and/or hyperglycemic conditions are provided using receiver unit **104** (FIG. **1**) that is programmed or programmable to execute one or more software algorithms or functions stored therein or received from a remote location, to analyze data received from analyte sensor **101** (FIG. **1**). Within the scope of the present disclosure, any device comprising one or more microprocessors and/or logic or routines provided to one or more application specific integrated circuit (ASICs) capable of executing or implementing one or more logical operations can be utilized to execute the routines or algorithms for determining the conditions associated with the programmed alarm, alerts, or notifications, or projected alarms, alerts or notifications.

Referring to FIG. **3**, in certain embodiments, an operative component, such as receiver unit **104** receives continuous glucose monitoring (CGM) or analyte sensor data (**302**) including the current analyte level (e.g., glucose level). With the received current CGM data, it is determined whether the current analyte level based on the received current CGM data is within a particular threshold zone (**304**). If the analyte level is not within the particular threshold zone, then the routine returns to the beginning and awaits receipt of new CGM data (**302**) indicating the new or subsequent current glucose level.

Referring to FIGS. **3** and **4**A, as used herein the phrase "threshold zone" refers to a continuous range between a hyperglycemic or hypoglycemic value and predetermined threshold values. For example, as shown in FIG. **4**A, threshold zone **1** defined by boundaries **410** and **420** (e.g., spanning a predetermined range such as 50 mg/dL, 60 mg/dL, 70 mg/dL, 80 mg/dL, 90 mg/dL, 100 mg/dL, etc.) is a continuous range that includes one data point A outside the threshold zone **1**, and a second data point B within the threshold zone **1** on curve **450**. As described, in certain embodiments, if the monitored glucose level is outside the threshold zone, then the routine waits for the next CGM data (**302**) (FIG. **3**). For example, a determination may be made if the current glucose value is greater than an alarm threshold and less than the alarm threshold plus 90 mg/dl (for example) to define the threshold zone. If the glucose value is within a threshold zone, received sensor data is used to calculate a slope that indicates a rate of change of the monitored analyte level (**306**). For example, in certain embodiments, the slope may be determined based on the current CGM data received and a predetermined number of prior CGM data received and stored.

Referring to FIG. **3**, with the determined slope or rate of change information, a determination is made as to whether a straight-line extrapolation (or other suitable extrapolation) will cause the glucose value to pass the alarm threshold value within a predetermined amount of time (**308**). If not, then alarm or alert condition is not satisfied, and thus, the alarm or alert associated with the condition is not asserted nor presented to the user. On other hand, if the extrapolation analysis indicates the future glucose value will pass or cross the alarm threshold value within the predetermined amount of time (preprogrammed or programmable) (**308**), then it is determined whether other sub-zone criteria is satisfied (**310**) as described in further detail below.

More specifically, a threshold zone (as shown in FIG. **4**A) may be split or divided into two or more sub-zones, as shown in FIG. **4**B, and a determination may be made if the sub-zone criteria is satisfied (**310**). For example, in certain embodiments in each sub-zone, there may be additional criteria to be satisfied before an alarm is asserted or output. The sub-zone criteria may be more stringent as the distance of the sub-zone to the alarm threshold increases. For example, referring to FIG. **4**B, sub-zone **1**A **411** may not need any additional criteria to raise a projected hyperglycemic alarm as it is closest to the hyperglycemic threshold **410**. However, sub-zone **1**B **412** which is farther from the hyperglycemic threshold **410** than sub-zone **1**A **411**, may require that the straight line extrapolation fit the analyte data to an acceptable or predetermined degree or level before asserting or outputting the alarm. For example, the mean square error based on the monitored analyte data points deviating from the slope (or rate of change line) may have to be less than a predetermined value before asserting or outputting the alarm. In certain embodiments, the alarm triggering slope may be required to persist for a minimum amount of time to satisfy the condition for asserting the alarm. In certain embodiments, combinations of these two criteria could also be used. If all of the determinations yield an affirmative result, a projected alarm is output (**312**), for example, by receiver unit **104**, to notify or alert the user or the patient that the alarm condition (such as hyperglycemia or hypoglycemia) is approaching. That is, the outputted projected alarm is indicative of a future hyperglycemic event or a future hypoglycemic event.

Referring back to FIG. **4**B, as shown, sub-zone **1**C **413** is furthest from the hyperglycemic threshold **410**, but closest to the lower edge of threshold zone **1** (FIG. **4**A), and as such, the sub-zone criteria associated with sub-zone **1**C **413** may be more stringent than the criteria associated with sub-zone **1**A **411** or sub-zone **1**B **412**.

Moreover, referring to FIGS. **4**A and **4**B, the sub-zones as described above may be also provided in conjunction with the hypoglycemic threshold **440** (FIG. **4**A) with, differing criteria for evaluating the alarm conditions and thereby asserting the associated projected alarm/alert. For example, at the lower range of the analyte levels as shown in FIG. **4**A, threshold zone **2** defined by boundaries **440** (defining hypoglycemic threshold) and **430** may be divided into two or more sub-zones, such that, when the current analyte level is determined to be within a predetermined sub-zone within threshold zone **2**, then the criteria or condition associated with the predetermined sub-zone must be met before the projected hypoglycemia alarm is asserted or output.

In this manner, in certain embodiments, based on the current analyte level determined from the CGM data received and the analyte level slope or rate of change determination (based on prior and current analyte data), if it is determined that the calculated slope does not result in an acceptable level of line fit, but the determined slope or the rate of change indicates that the alarm condition threshold level (e.g., hyperglycemic threshold **410** (FIG. **4**A) or hypoglycemic threshold **440** (FIG. **4**A)) is within a predetermined range of the alarm condition threshold level (for

example, within a sub-zone discussed above (e.g., about 30 mg/dL or 40 mg/dL, etc.), the projected alarm is asserted or output regardless of whether the calculated slope or rate of change results in a line fit that is within the acceptable level of line fit. In other words, if the current analyte level monitored is close to the alarm condition threshold level, even if the line fit for the slope determination is not within a desired or acceptable level, the projected alarm is still asserted, as even the determined slope that does not provide an acceptable line fit (based on a predetermined criteria (e.g., acceptable level of mean square error)) still indicates that the alarm condition will be met—i.e., the alarm threshold will likely be crossed within a certain time period in the future.

In certain embodiments, in cases where the determined slope or rate of change indicates that the alarm threshold will likely be crossed within a predetermined time period, if the current analyte level (based on the received CGM data) is sufficiently far from the alarm threshold level (e.g., at sub-zone **1C** **413** relative to the hyperglycemic threshold **410** (FIG. **4**B)), then the line fit analysis is evaluated for the determined slope or rate of change. More specifically, in certain embodiments, it is determined whether the mean square error (which is the sum of the square of the deviations of each data point from the determined slope/line squared) divided by the number of data points is outside an acceptable level (for example, greater than 10%, or 15%, etc.). If it is determined that the line fit for the slope does not fall within the acceptable level indicating, for example, that despite initial condition for projected alarm being satisfied, because the current analyte level is sufficiently far from the alarm threshold level, and the line fit indicates a level that is outside the acceptable range, the projected alarm is not asserted or presented to the user or the patient.

In certain embodiments, when the current analyte level is determined to be sufficiently far from the alarm threshold level, instead of performing a line fit analysis of the determined slope, it is determined whether the detected condition (associated with the programmed or programmable projected alarm) persists continuously, for example, over a predetermined time period (e.g., 5 minutes, 10 minutes, 15 minutes, etc.) to determine whether or not to output the projected alarm associated with the detected analyte level condition. That is, when the current analyte level is sufficiently far from the alarm threshold level, but the extrapolation (straight line or other suitable extrapolation) of the determined slope indicates that the analyte level will meet or cross the alarm threshold level within a predetermined time period, a corresponding slope for each successive analyte level data is determined (for example, for current analyte level data, and each of the next 15 minutes (or some other suitable time interval) of analyte level data received). If the determined slope indicates that the projected alarm condition is met or satisfied over the predetermined time period, in certain embodiments, the line fit criteria may be deemphasized (or weighted less) and the projected alarm is output.

In this manner, in certain embodiments, when the current analyte level is determined to be within a certain or programmed distance from the alarm threshold level, regardless of the line fit analysis of the determined slope, if it is determined that the slope for consecutive analyte data indicates that the alarm threshold level will be satisfied within a predetermined time period, the projected alarm is output.

In certain embodiments, when the current analyte level is determined to be within a certain or programmed distance from the alarm threshold level, both the slope line fit analysis and the persistence of the consecutive alarm threshold level crossing within the predetermined time period are evaluated to determine whether the projected alarm is to be output or asserted. For example, for each analyte sensor data point, the line fit of the determined slope is evaluated (e.g., based on the mean value error analysis discussed above), and also, whether the analyte sensor data points over the predetermined time period such as 15 minutes, 10 minutes or the like indicates that the alarm threshold level (e.g., hyperglycemic threshold level **410** (FIG. **4**A) or hypoglycemic threshold level **440** (FIG. **4**A)) is crossed or met by the determined slope for each analyte sensor data point. Where it is determined that a certain predetermined number of the determined slope crosses the alarm threshold level consecutively (e.g., 5 out of 15 minutes of analyte sensor data, or some other suitable number), the projected alarm is asserted or output.

Referring now to FIG. **5**, in certain embodiments, probabilistic analysis may be used to determine or control projected alarms. For example, the value of the current analyte or glucose concentration may be modeled as a Gaussian distribution with a mean μ and a standard deviation σ. At a time point t in the future, the glucose concentration may be predicted or anticipated to be a second Gaussian distribution, with its mean μ at the extrapolated value given by the least squares analysis result and its standard deviation σ derived from the uncertainty in the determined slope and intercept. As shown graphically in FIG. **5**, different Gaussian functions at a succession of times starting from the present time (e.g., 0, t1, t2 and t3 minutes) are illustrated. Also shown in FIG. **5** is mean μ **520** which is the peak or the center of each Gaussian distribution shown.

In certain embodiments, the extrapolated mean of the intercept μ_t at time t, and the extrapolated standard deviation of the intercept σ_i at time t may be determined in accordance with the following expressions:

$$\sigma_t=\sqrt{\sigma_{intercept}^2+\sigma_{slope}^2(\Delta_t^2)} \quad (1)$$

where $\sigma_{intercept}$ is the standard deviation of the intercept, σ_{slope} is the standard deviation of the slope, and Δ_t is the extrapolated time (projected into the future); and

$$\mu_t=\mu_{intercept}+\mu_{slope}(\Delta_t) \quad (2)$$

where $\mu_{intercept}$ is the mean of the intercept, μ_{slope} is the mean of the slope, and Δ_t is the extrapolated time, and further, where both expressions (1) and (2) provide a straight line projection based on the extrapolated time projected into the future.

For each Gaussian distribution shown in FIG. **5**, shaded areas **511**, **512**, **513**, **514** under the respective distribution function provides the probability of the analyte level exceeding the alarm threshold level. For example, the probability of the glucose level exceeding the hyperglycemia threshold level G_{HYPER} may be determined by calculating the shaded area under the probability distribution from hyperglycemia threshold level G_{HYPER} to infinity. In certain embodiments, this calculated value provides the probability at each time period that the glucose level will exceed hyperglycemia threshold level G_{HYPER}. In certain embodiments, similar probabilistic determination may be made in conjunction with the hypoglycemia threshold level G_{HYPO}.

FIG. **6** is a flowchart illustrating a routine to determine the probability of the occurrence of a condition or event such as hypoglycemia or hyperglycemia. Referring to FIG. **6**, multiple data points relating to analyte levels, such as glucose levels, are received by receiver unit **104** (FIG. **1**A) (**602**). Next, the received data points are fit to a line so that a slope and intercept may be calculated (**604**) utilizing least squares

technique, for example. In certain embodiments, the intercept is a glucose value indicative of a hyperglycemic or hypoglycemic condition. For each set of data points, the mean μ, and standard deviation σ, can be calculated using a least squares method. The standard deviation σ changes based upon uncertainty at the time value along the calculated line. The further in the future the prediction is, the greater the uncertainty.

The probability of the glucose level at time t can then be calculated (**606**) utilizing standard probability calculation techniques (e.g., using a probability density function). For example, the probability P, that the glucose concentration G at a time tin the future, is greater than the hyperglycemia threshold level G_{HYPER}, can be determined (**608**) according to the following expression:

$$P(G > G_{HYPER}) = \frac{1}{\sqrt{2\pi\sigma}} \int_{G_{HYPER}}^{\infty} \exp\left[-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2\right] dx \quad (3)$$

where μ is the mean and σ is the standard deviation given by the least squares method and extrapolated into a future time period, and further, where x is a variable of integration for performing the integration in the probability determination.

In certain embodiments, the system may be configured such that if the probability P is larger than a predefined threshold (programmed in the system during manufacture, or programmable or programmed by the user), an alarm is output to alert the user of impending or anticipated hyperglycemic condition. In certain embodiments, hyperglycemia threshold G_{HYPER} is in the range of about 140 to about 300 mg/dl. Within the scope of the present disclosure, other ranges for hyperglycemia threshold G_{HYPER} may be provided that are narrower in range, or shifted to encompass a different range, or provide other overlapping ranges.

In certain embodiments, the probability P that the glucose concentration G at a time tin the future is less than the hypoglycemia threshold G_{HYPO} may be determined according to the following expression:

$$P(G \le G_{HYPO}) = \frac{1}{\sqrt{2\pi\sigma}} \int_{-\infty}^{G_{HYPO}} \exp\left[-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2\right] dx \quad (4)$$

where μ is the mean and σ is the standard deviation given by the least squares method and extrapolated into the future, and further, where x is a variable of integration for performing the integration in the probability determination.

In certain embodiments, the system may be configured such that if the probability P is larger than a predefined threshold (programmed in the system during manufacture, or programmable or programmed by the user), an alarm is output to alert the user of impending or anticipated hypoglycemic condition. In certain embodiments, hypoglycemia threshold G_{HYPO} is in the range of about 60 to about 139 mg/dl. Again, within the scope of the present disclosure, other suitable ranges for hypoglycemia threshold G_{HYPO} may be provided.

Referring back to FIG. **6**, after the probability at the future/projected time has been calculated (**608**), a determination is made whether the calculated probability is greater than an alarm threshold (**610**). If the calculated probability is greater than the alarm threshold (**612**), a projected alarm is output (**614**). For example, if the probability generated by expression (3) is greater than the alarm threshold, receiver unit **104** (FIG. **1**A) may be configured to output an alarm warning the user of the projected hyperglycemia event.

In the manner described above, in certain embodiments, analyte level is monitored and projected alarm conditions are evaluated using, for example, line fit analysis of slope, zone and subzone criteria, probability determination and the like, to output one or more indications associated with projected or anticipated alarm conditions such as hyperglycemic condition or hypoglycemic condition such that the user or the patient may take prompt corrective action prior to the physiological condition in the alarm condition state.

As described above, embodiments of the present disclosure may not be limited to an analyte measurement device or system. Referring back to FIGS. **1**A and **1**B, analyte sensor **101** and transmitter unit **102** can be separate components physically integrated in a mounting unit to define an on-body monitoring device. In certain embodiments, the sensor and the electronics may be integrated to define a single on-body component. The on-body analyte measurement device can be worn by a subject for a period of time during which the analyte of interest is monitored, e.g., continuously. In this regard, the analyte sensor can be implanted into a subject's body for a period of time to contact and monitor an analyte present in a biological fluid.

Analyte sensor **101** can be disposed in a subject at a variety of sites, including intramuscularly, transcutaneously, intravascularly, or in a body cavity. Preferably, analyte sensor **101** is at least partially implanted under the dermis layer of the skin. In one embodiment, analyte sensor **101** can be a transcutaneous glucose sensor. Alternatively, analyte sensor **101** can be a subcutaneous glucose sensor. The term "transcutaneous" as used herein refers to an analyte sensor that is only partially inserted under one or more layers of the skin of the user, whereas the term "subcutaneous" refers to an analyte sensor that is completely inserted under one or more layers of the skin of the user.

In some embodiments, the sensor is a self-powered analyte sensor, which is capable of spontaneously passing a currently directly proportional to analyte concentration in the absence of an external power source. Any exemplary sensor is described in U.S. patent application Ser. No. 12/393,921, filed Feb. 26, 2009, entitled "Self-Powered Analyte Sensor," which is hereby incorporated by reference in its entirety herein for all purposes.

In certain embodiments of the present disclosure, an analyte monitoring system may comprise an analyte sensor in operative contact with an analyte, the sensor adapted to generate a plurality of data points associated with a monitored analyte concentration, a processor adapted to process the plurality of data points generated by the analyte sensor, and logic implemented by the processor to determine whether a current data point of the plurality of data points is within a predetermined threshold zone, wherein if it is determined that the current data point is within the predetermined threshold zone, the logic implemented by the processor determines a rate of change of the analyte level based on the received plurality of data points, to determine if the rate of change indicates the projected glucose value exceeding the alarm threshold within a predetermined amount of time, and to perform one or more of a line fit analysis of a slope or anticipated alarm condition persistence evaluation when the determined rate of change indicates that the projected glucose level exceeds the alarm threshold within the predetermined amount of time.

In certain embodiments, the line fit analysis of the slope may include determining mean value error based on the plurality of data points within a predetermined deviation range.

In certain embodiments, the predetermined deviation range may be about 10%.

In certain embodiments, the anticipated alarm condition persistence evaluation may include determining whether the determined rate of change indicates that the projected glucose level exceeds the alarm condition during a predetermined time period.

In certain embodiments, the predetermined time period may include a consecutive time period spanning about 30 minutes or less, about 25 minutes or less, about 20 minutes or less, about 15 minutes or less, or about 10 minutes or less.

In certain embodiments, the rate of change may be determined based on a least squares technique.

In certain embodiments, the anticipated alarm condition may be one of an anticipated hypoglycemia alarm or an anticipated hyperglycemia alarm.

In certain embodiments, the plurality of data points may include at least 15 consecutive data points to determine the rate of change of the analyte.

Certain embodiments of the present disclosure may include generating a plurality of data points associated with a monitored analyte concentration, and determining whether a current data point of the plurality of data points is within a predetermined threshold zone, wherein if it is determined that the current data point is within the predetermined threshold zone, determining a rate of change of the analyte level based on the received plurality of data points, to determine if the rate of change indicates the projected glucose value exceeding the alarm threshold within a predetermined amount of time, and to perform one or more of a line fit analysis of a slope or anticipated alarm condition persistence evaluation when the determined rate of change indicates that the projected glucose level exceeds the alarm threshold within the predetermined amount of time.

In certain embodiments, performing the line fit analysis of the slope may include determining mean value error based on the plurality of data points within a predetermined deviation range.

In certain embodiments, the predetermined deviation range may be about 10%.

In certain embodiments, evaluating the anticipated alarm condition persistence may include determining whether the determined rate of change indicates that the projected glucose level exceeds the alarm condition during a predetermined time period.

In certain embodiments, the predetermined time period may include a consecutive time period spanning about 30 minutes or less, about 25 minutes or less, about 20 minutes or less, about 15 minutes or less, or about 10 minutes or less.

In certain embodiments, the rate of change may be determined based on a least squares technique.

In certain embodiments, the anticipated alarm condition may be one of an anticipated hypoglycemia alarm or an anticipated hyperglycemia alarm.

Certain embodiments of the present disclosure may include receiving a plurality of data points relating to analyte levels measured by a sensor, determining a least squares fit based on the received plurality of data points, determining an estimate of a slope and an intercept of the analyte level at a predetermined time based on the received plurality of data points and the determined least squares fit, determining a standard deviation of the slope and the intercept based on the determined estimated slope and the intercept, extrapolating a mean intercept and a standard deviation intercept in time at a future time, and determining a probability of the analyte level at the future time at or exceeding an alarm threshold level, and outputting an alarm if the determined probability at the future time is at or exceeds the alarm threshold level.

In certain embodiments, the analyte may be glucose.

In certain embodiments, the mean and the standard deviation may be calculated by a least squares analysis.

In certain embodiments, the output alarm may indicate an anticipated hyperglycemic condition or an anticipated hypoglycemic condition.

In certain embodiments, determining the least squares fit may be performed based on linear regression.

In certain embodiments, an apparatus may comprise one or more processors, and a memory for storing instructions which, when executed by the one or more processors, causes the one or more processors to receive a plurality of data points relating to analyte levels measured by a sensor, determine a least squares fit based on the received plurality of data points, determine an estimate of a slope and an intercept of the analyte level at a predetermined time based on the received plurality of data points and the determined least squares fit, determine a standard deviation of the slope and the intercept based on the determined estimated slope and the intercept, extrapolate a mean intercept and a standard deviation intercept in time at a future time, and determine a probability of the analyte level at the future time at or exceeding an alarm threshold level, and output an alarm if the determined probability at the future time is at or exceeds the alarm threshold level.

The foregoing only illustrates the principles of the disclosed subject matter. Various modifications and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will be appreciated that those skilled in the art will be able to devise numerous modifications which, although not explicitly described herein, embody the principles of the disclosed subject matter and are thus within the spirit and scope of the disclosed subject matter.

As for other details of the present disclosure, materials and alternate related configurations may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the disclosure in terms of additional acts as commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention. Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Any number of the individual parts or subassemblies shown may be integrated in their design. Such changes or others may be undertaken or guided by the principles of design for assembly.

Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms “a,” “an,” “said,” and “the” include plural referents unless the specifically stated otherwise. In other words, use of the articles allow for “at

least one" of the subject item in the description above as well as the claims below. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Without the use of such exclusive terminology, the term "comprising" in the claims shall allow for the inclusion of any additional element—irrespective of whether a given number of elements are enumerated in the claim, or the addition of a feature could be regarded as transforming the nature of an element set forth in the claims. Stated otherwise, unless specifically defined herein, all technical and scientific terms used herein are to be given as broad a commonly understood meaning as possible while maintaining claim validity.

Various other modifications and alterations in the structure and method of operation of the embodiments of the 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 certain embodiments, it should be understood that the present disclosure as claimed should not be unduly limited to such 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. An analyte monitoring system, comprising:

an in vivo analyte sensor in operative contact with an analyte, the analyte sensor adapted to generate a plurality of data points associated with a monitored analyte level and a corresponding time;

a receiving device adapted to receive the plurality of data points generated by the analyte sensor; and

logic implemented by the receiving device, to:

determine a rate of change of the analyte level based on the received plurality of data points;

determine if the rate of change indicates a projected analyte level exceeds an alarm threshold within a predetermined amount of time;

perform an anticipated alarm condition persistence evaluation when the determined rate of change indicates that the projected analyte level exceeds the alarm threshold within the predetermined amount of time, by at least: fitting the plurality of data points generated by the analyte sensor to a line; determining a standard deviation for the plurality of data points generated by the analyte sensor based at least on the line and the corresponding times for each data point of the plurality of data points; determining that a probability that an analyte level at a future time is greater than a predetermined threshold associated with a glycemic condition, based at least in part on the standard deviation; and

when the probability is greater than an alarm threshold, output an alarm to alert a user of the glycemic condition.

2. The system of claim **1**, wherein the analyte sensor is one of a lactate sensor or a glucose sensor.

3. The system of claim **1**, wherein the logic implemented by the receiving device is further to determine the standard deviation by at least weighting the corresponding times for each data point of the plurality of data points according to the line, wherein data points further in the future according to the line are weighted to have greater uncertainty.

4. The system of claim **1**, wherein the glycemic condition corresponds to one of hyperglycemia or hypoglycemia.

5. The system of claim **1**, wherein the alarm is configured to alert the user that the glycemic condition is impending.

6. The system of claim **1**, wherein the in vivo analyte sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

7. The system of claim **6**, wherein the analyte-responsive enzyme is chemically bonded to the polymer.

8. The system of claim **6**, wherein the working electrode further comprises a mediator.

9. The system of claim **1**, wherein the in vivo analyte sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

10. The system of claim **9**, wherein the mediator is chemically bonded to the polymer.

11. A method, comprising:

generating, by an in vivo analyte sensor in operative contact with an analyte, a plurality of data points associated with a monitored analyte level and a corresponding time;

receiving, at a receiving device, the plurality of data points;

determining a rate of change of the analyte level based on the received plurality of data points;

determining if the rate of change indicates a projected analyte level exceeds an alarm threshold within a predetermined amount of time;

performing an anticipated alarm condition persistence evaluation when the determined rate of change indicates that the projected analyte level exceeds the alarm threshold within the predetermined amount of time, by at least: fitting the plurality of data points generated by the analyte sensor to a line; determining a standard deviation for the plurality of data points generated by the analyte sensor based at least on the line and the corresponding times for each data point of the plurality of data points; determining that a probability that an analyte level at a future time is greater than a predetermined threshold associated with a glycemic condition, based at least in part on the standard deviation; and

when the probability is greater than an alarm threshold, outputting an alarm to alert a user of the glycemic condition.

12. The method of claim **11**, wherein the analyte sensor is one of a lactate sensor or a glucose sensor.

13. The method of claim **11**, wherein determining the standard deviation comprises weighting the corresponding times for each data point of the plurality of data points according to the line, wherein data points further in the future according to the line are weighted to have greater uncertainty.

14. The method of claim **11**, wherein the glycemic condition corresponds to one of hyperglycemia or hypoglycemia.

15. The method of claim **11**, wherein the alarm alerts the user that the glycemic condition is impending.

16. The method of claim **11**, wherein the in vivo analyte sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

17. The method of claim **16**, wherein the analyte-responsive enzyme is chemically bonded to the polymer.

18. The method of claim **16**, wherein the working electrode further comprises a mediator.

19. The method of claim **11**, wherein the in vivo analyte sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

20. The method of claim **19**, wherein the mediator is chemically bonded to the polymer.

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