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Systems and methods for ensuring sufficient bolus dosing for meal compensation

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ABSTRACT

Disclosed herein are systems and methods for providing safeguards, in an automatic drug delivery system, to prevent or compensate for insufficient delivery of bolus doses of a liquid drug. The safeguards include, for example, features built into the medication delivery algorithm to allow the medication delivery algorithm to ensure that proper bolus doses are delivered, either manually by the user or automatically by the drug delivery system. In addition, various methods are described for providing the medication delivery algorithm with a means for determining when a meal has been ingested and, in some embodiments, for providing an automatic bolus dose of the liquid drug in response to the determination.

**SYSTEMS AND METHODS FOR ENSURING SUFFICIENT
BOLUS DOSING FOR MEAL COMPENSATION**

RELATED APPLICATIONS

[0001] This application is a divisional application of Australian Patent Application No. 2023209422, which claims priority of U.S. Provisional Patent Application No. 63/300,460, filed January 18, 2022, the disclosures of which, as originally filed and as amended, are incorporated by reference herein in their entireties.

BACKGROUND

[0002] Many conventional automatic drug delivery systems are well known, including, for example, wearable drug delivery devices of the type shown in **FIG. 2**. The drug delivery device 102 can be designed to deliver any type of liquid drug to a user. In specific embodiments, the drug delivery device 102 can be, for example, an OmniPod® drug delivery device manufactured by Insulet Corporation of Acton, Massachusetts. The drug delivery device 102 can be a drug delivery device such as those described in U.S. Pat. No. 7,303,549, U.S. Pat. No. 7,137,964, or U.S. Pat. No. 6,740,059, each of which is incorporated herein by reference in its entirety.

[0003] Wearable drug delivery devices 102 are typically configured with a processor and memory and may execute a medication delivery algorithm (MDA). Alternatively, the medication delivery application may be executed on or via a remote device, such as a remote personal diabetes manager (PDM) or a smartphone, for example, which may be

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configured to transmit drug delivery instructions to the wearable drug delivery device 102.

[0004] The MDA may provide for basal dosing of a liquid drug. For example, for diabetics, the MDA may provide for basal doses of insulin or co-formulations of insulin and other drugs, to be delivered to the user, while allowing the user to self-administer bolus doses of the liquid drug to compensate for post-prandial excursions in the blood glucose level of the user.

[0005] The usual procedure for a user to self-administer a meal bolus is to use a bolus calculator to calculate the proper bolus dose to compensate for the ingested meal. To use the bolus calculator, the user enters the number of carbohydrates in the meal and the bolus dose is calculated based on the user's insulin to carbohydrate ratio. Typically, the bolus dose is the number of grams of carbohydrates in the meal divided by the insulin to carbohydrate ratio).

$$\text{Bolus Insulin} = \frac{\text{Number of Grams of Carbohydrates}}{\text{Insulin to Carbohydrate Ratio}}$$

[0006] However, the inventors determined that this method is error prone, as the user often mis-estimates the number of carbohydrates in the meal. Additionally, the insulin to carbohydrate ratio may vary throughout the day, depending on recent exercise activity, stress levels and hormonal variations. A dangerous situation could arise if the user administers an excessive or insufficient amount of insulin.

[0007] In addition, experienced users may become comfortable with the use of automatic insulin delivery (AID) systems and may become complacent in the self-administration of bolus doses of the liquid drug by inadvertently decreasing the number

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of times they bolus for their meals. The user may therefore have increased instances where their meals may not be sufficiently manually compensated with boluses. In addition, there may be occasions when a meal bolus is delayed, or a bolus is taken in anticipation of a meal, but the meal is delayed.

[0008] Given the many variables surrounding the self-administration of bolus doses, it is desirable to provide some level of safety for the user by building in several safeguards to the MDA which may be capable of compensating for, or at least alerting the user of, anomalous situations which may arise due to the shortcomings inherent in the self-administration of bolus doses.

DEFINITIONS

[0009] As used herein, the term “***liquid drug***” should be interpreted to include any drug in liquid form capable of being administered by a drug delivery device via a subcutaneous cannula, including, for example, insulin, GLP-1, pramlintide, morphine, blood pressure medicines, chemotherapy drugs, fertility drugs or the like or co-formulations of two or more of GLP-1, pramlintide, and insulin.

[0010] It is desired to address or alleviate one or more disadvantages or limitations of the prior art, or to at least provide a useful alternative.

SUMMARY

[0011] According to an aspect, there is provided a drug delivery system comprising a processor configured to execute a method of compensating for meal ingestion, the method comprising: receiving notification of a meal event; calculating a safe bolus dose to be delivered to a user, wherein calculation of the safe bolus is performed without the user entering a carbohydrate profile of the meal; delivering the safe bolus dose;

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monitoring blood glucose levels of the user; and compensating for further excursions in the blood glucose levels of the user in accordance with a medication delivery algorithm of the drug delivery system.

[0012] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended as an aid in determining the scope of the claimed subject matter.

[0013] In a first embodiment, the MDA may be configured to provide safeguards against or compensate for insufficient deliveries of bolus doses of the liquid drug. In a first aspect, various innovative features may be built into the MDA to provide for a safe calculation of a bolus dose to be automatically administered by the drug delivery device. The innovative features will be discussed in greater detail below. In a second aspect of the invention, the MDA may be able to assess past glucose history to automatically determine whether the user has ingested a meal that was not manually compensated for or was under-compensated for. When it has been determined that the user has ingested a meal, in a third aspect of the invention, the MDA may provide metrics to the user and may increase the aggressiveness of the MDA for high glucose concentrations during these periods. In a fourth aspect of the invention, when the MDA determines that a meal

has been ingested, a bolus dose of insulin may be automatically delivered by drug delivery device 102.

[0014] In various embodiments, the medication delivery algorithm may provide all or any combination of the above noted aspects of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] One or more embodiments of the present invention are hereinafter described, by way of example only, with reference to the accompanying drawings.

[0016] In the drawings, like reference characters generally refer to the same parts throughout the different views. In the following description, various embodiments of the present invention are described with reference to the following drawings, in which:

[0017] **FIG. 1** illustrates a functional block diagram of an exemplary system suitable for implementing the systems and methods disclosed herein.

[0018] **FIG. 2** is a depiction of a prior art wearable drug delivery device of the type in which the invention disclosed herein would be used.

[0019] **FIG. 3** is an exemplary user interface screen showing a “Going to Eat” button used to inform the system software that the user is about to ingest a meal.

[0020] **FIG. 4** is a histogram showing insulin delivered for each meal as a percentage of the user’s TDI.

[0021] **FIG. 5** is an exemplary user interface screen showing a “Set Nighttime Mode” button and fields for entering the start and end times of nighttime mode.

[0022] **FIG. 6** is a flowchart showing how the nighttime factor is adjusted based on the previous delivery of insulin.

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[0023] FIG. 7 is a plot of blood glucose readings having a sliding window superimposed thereon used to detect meals.

[0024] FIG. 8 is a plot of blood glucose readings over a period of the day showing rising glucose levels when meals have been ingested and the portions of the plot used to detect the meals.

[0025] FIG. 9 is a schematic representation of the machine learning pipeline.

[0026] FIG. 10 shows the supervised training process for 10-minute, 15-minute and 20-minute meal detectors.

[0027] FIG. 11 is a flowchart showing the pooling of the results from the 10-, 15- and 20-minute meal detectors to provide a robust meal detection result.

[0028] FIG. 12 is a flowchart showing the process for administering an automatic bolus of insulin.

DETAILED DESCRIPTION

[0029] This disclosure presents various systems, components and methods for providing safeguards against inadequate bolus dosing when the user is self-administering the bolus doses. The embodiments described herein provide one or more advantages over conventional, prior art systems, components and methods, namely, the provision of a safety net for the user in the event that the user's self-administering of bolus doses is inadequate through safeguards built into the medication delivery algorithm.

[0030] Various embodiments of the present invention include systems and methods for delivering a medication to a user using a drug delivery device (sometimes referred to herein as a "pod"), either autonomously, or in accordance with a wireless signal received from an electronic device. In various embodiments, the electronic device may be a user

device comprising a smartphone, a smart watch, smart jewelry, a module attached to the drug delivery device, or any other type or sort of electronic device that may be carried by the user or worn on the body of the user and that executes an algorithm that computes the times and dosages of delivery of the medication.

[0031] For example, the user device may execute an “artificial-pancreas” algorithm that computes the times and dosages of delivery of insulin. The user device may also be in communication with a sensor, such as a glucose sensor, that collects data on a physical attribute or condition of the user, such as a glucose level. The sensor may be disposed in or on the body of the user and may be part of the drug delivery device or may be a separate device.

[0032] Alternatively, the drug delivery device may be in communication with the sensor in lieu of or in addition to the communication between the sensor and the user device. The communication may be direct (if, e.g., the sensor is integrated with or otherwise a part of the drug delivery device) or remote/wireless (if, e.g., the sensor is disposed in a different housing than the drug delivery device). In these embodiments, the drug delivery device contains computing hardware (e.g., a processor, memory, firmware, etc.) that executes some or all of the algorithm that computes the times and dosages of delivery of the medication.

[0033] **FIG. 1** illustrates a functional block diagram of an exemplary drug delivery system 100 suitable for implementing the systems and methods described herein. The drug delivery system 100 may implement (and/or provide functionality for) a medication delivery algorithm, such as an artificial pancreas (AP) application, to govern or control the automated delivery of a drug or medication, such as insulin, to a user (e.g., to maintain euglycemia – a normal level of glucose in the blood). The drug delivery system

100 may be an automated drug delivery system that may include a drug delivery device 102 (which may be wearable), an analyte sensor 108 (which may also be wearable), and a user device 105.

[0034] Drug delivery system 100, in an optional example, may also include an accessory device 106, such as a smartwatch, a personal assistant device, or the like, which may communicate with the other components of system 100 via either a wired or wireless communication links 191-193.

User Device

[0035] The user device 105 may be a computing device such as a smartphone, a tablet, a personal diabetes management (PDM) device, a dedicated diabetes therapy management device, or the like. In an example, user device 105 may include a processor 151, device memory 153, a user interface 158, and a communication interface 154. The user device 105 may also contain analog and/or digital circuitry that may be implemented as a processor 151 for executing processes based on programming code stored in device memory 153, such as user application 160 to manage a user's blood glucose levels and for controlling the delivery of the drug, medication, or therapeutic agent to the user, as well for providing other functions, such as calculating carbohydrate-compensation dosage, a correction bolus dosage and the like, as discussed below. The user device 105 may be used to program, adjust settings, and/or control operation of drug delivery device 102 and/or the analyte sensor 108 as well as the optional smart accessory device 106.

[0036] The processor 151 may also be configured to execute programming code stored in device memory 153, such as the user app 160. The user app 160 may be a computer application that is operable to deliver a drug based on information received from the analyte sensor 108, the cloud-based services 111 and/or the user device 105 or

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optional accessory device 106. The memory 153 may also store programming code to, for example, operate the user interface 158 (e.g., a touchscreen device, a camera or the like), the communication interface 154 and the like. The processor 151, when executing user app 160, may be configured to implement indications and notifications related to meal ingestion, blood glucose measurements, and the like. The user interface 158 may be under the control of the processor 151 and be configured to present a graphical user interface that enables the input of a meal announcement, adjust setting selections and the like as described herein.

[0037] In a specific example, when the user app 160 is an AP application, the processor 151 is also configured to execute a diabetes treatment plan (which may be stored in a memory) that is managed by user app 160. In addition to the functions mentioned above, when user app 160 is an AP application, it may provide further functionality to determine a carbohydrate-compensation dosage, a correction bolus dosage and determine a basal dosage according to a diabetes treatment plan. In addition, as an AP application, user app 160 provides functionality to output signals to the drug delivery device 102 via communications interface 154 to deliver the determined bolus and basal dosages.

[0038] The communication interface 154 may include one or more transceivers that operate according to one or more radio-frequency protocols. In one embodiment, the transceivers may comprise a cellular transceiver and a Bluetooth® transceiver. The communication interface 154 may be configured to receive and transmit signals containing information usable by user app 160.

[0039] User device 105 may be further provided with one or more output devices 155 which may be, for example, a speaker or a vibration transducer, to provide various signals to the user.

Drug Delivery Device

[0040] In various exemplary embodiments, drug delivery device 102 may include a reservoir 124 and drive mechanism 125, which are controllable by controller 121, executing a medication delivery algorithm (MDA) 129 stored in memory 123 onboard the drug delivery device (and in exemplary embodiments, a wearable drug delivery device). Alternatively, controller 121 may act to control reservoir 124 and drive mechanism 125 based on signals received from user app 160 executing on a user device 105 and communicated to drug delivery device 102 via communication link 194. Drive mechanism 125 operates to longitudinally translate a plunger through the reservoir, such as to force the liquid drug through an outlet fluid port to needle / cannula 186.

[0041] In an alternate embodiment, drug delivery device 102 may also include an optional second reservoir 124-2 and second drive mechanism 125-2 which enables the independent delivery of two different liquid drugs. As an example, reservoir 124 may be filled with insulin, while reservoir 124-2 may be filled with Pramlintide or GLP-1. In some embodiments, each of reservoirs 124, 124-2 may be configured with a separate drive mechanism 125, 125-2, respectively, which may be separately controllable by controller 121 under the direction of MDA 129. Both reservoirs 124, 124-2 may be connected to a common needle / cannula 186.

[0042] Drug delivery device 102 may be optionally configured with a user interface 127 providing a means for receiving input from the user and a means for outputting information to the user. User interface 127 may include, for example, light-emitting

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diodes, buttons on a housing of drug delivery device 102, a sound transducer, a micro-display, a microphone, an accelerometer for detecting motions of the device or user gestures (e.g., tapping on a housing of the device) or any other type of interface device that is configured to allow a user to enter information and/or allow drug delivery device 102 to output information for presentation to the user (e.g., alarm signals or the like).

[0043] Drug delivery device 102 includes a patient interface 186 for interfacing with the user to deliver the liquid drug. Patient interface 186 may be, for example, a needle or cannula for delivering the drug into the body of the user (which may be done subcutaneously, intraperitoneally, or intravenously). Drug delivery device 102 may further include a mechanism for inserting the needle / cannula 186 into the body of the user, which may be integral with or attachable to drug delivery device 102. The insertion mechanism may comprise, in one embodiment, an actuator that inserts the needle / cannula 186 under the skin of the user and thereafter retracts the needle, leaving the cannula in place.

[0044] In one embodiment, drug delivery device 102 includes a communication interface 126, which may be a transceiver that operates according to one or more radio-frequency protocols, such as Bluetooth®, Wi-Fi, near-field communication, cellular, or the like. The controller 121 may, for example, communicate with user device 105 and an analyte sensor 108 via the communication interface 126.

[0045] In some embodiments, drug delivery device 102 may be provided with one or more sensors 184. The sensors 184 may include one or more of a pressure sensor, a power sensor, or the like that are communicatively coupled to the controller 121 and provide various signals. For example, a pressure sensor may be configured to provide an indication of the fluid pressure detected in a fluid pathway between the patient interface

186 and reservoir 124. The pressure sensor may be coupled to or integral with the actuator for inserting the patient interface 186 into the user. In an example, the controller 121 may be operable to determine a rate of drug infusion based on the indication of the fluid pressure. The rate of drug infusion may be compared to an infusion rate threshold, and the comparison result may be usable in determining an amount of insulin onboard (IOB) or a total daily insulin (TDI) amount. In one embodiment, analyte sensor 108 may be integral with drug delivery device 102.

[0046] Drug delivery device 102 further includes a power source 128, such as a battery, a piezoelectric device, an energy harvesting device, or the like, for supplying electrical power to controller 121, memory 123, drive mechanisms 125 and/or other components of drug delivery device 102.

[0047] Drug delivery device 102 may be configured to perform and execute processes required to deliver doses of the medication to the user without input from the user device 105 or the optional accessory device 106. As explained in more detail, MDA 129 may be operable, for example, to determine an amount of insulin to be delivered, IOB, insulin remaining, and the like, and to cause controller 121 to activate drive mechanism 125 to deliver the medication from reservoir 124. MDA 129 may take as input data received from the analyte sensor 108 or from user app 160.

[0048] The reservoirs 124, 124-2 may be configured to store drugs, medications or therapeutic agents suitable for automated delivery, such as insulin, Pramlintide, GLP-1, co-formulations of insulin and GLP-1, morphine, blood pressure medicines, chemotherapy drugs, fertility drugs or the like.

[0049] Drug delivery device 102 may be a wearable device and may be attached to the body of a user at an attachment location and may deliver any therapeutic agent,

including any drug or medicine, such as insulin or the like, to a user at or around the attachment location. A surface of drug delivery device 102 may include an adhesive to facilitate attachment to the skin of a user.

[0050] When configured to communicate with an external device, such as the user device 105 or the analyte sensor 108, drug delivery device 102 may receive signals over the wired or wireless link 194 from the user device 105 or from the analyte sensor 108. The controller 121 of drug delivery device 102 may receive and process the signals from the respective external devices as well as implementing delivery of a drug to the user according to a diabetes treatment plan or other drug delivery regimen.

Accessory Device

[0051] Optional accessory device 107 may be a wearable smart device, for example, a smart watch (e.g., an Apple Watch®), smart eyeglasses, smart jewelry, a global positioning system-enabled wearable, a wearable fitness device, smart clothing, or the like. Similar to user device 105, the accessory device 107 may also be configured to perform various functions including controlling drug delivery device 102. For example, the accessory device 107 may include a communication interface 174, a processor 171, a user interface 178 and a memory 173. The user interface 178 may be a graphical user interface presented on a touchscreen display of the smart accessory device 107. The memory 173 may store programming code to operate different functions of the smart accessory device 107 as well as an instance of the user app 160, or a pared-down version of user app 160 with reduced functionality. In some instances, accessory device 107 may also include sensors of various types.

Analyte Sensor

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[0052] The analyte sensor 108 may include a controller 131, a memory 132, a sensing/measuring device 133, an optional user interface 137, a power source/energy harvesting circuitry 134, and a communication interface 135. The analyte sensor 108 may be communicatively coupled to the processor 151 of the management device 105 or controller 121 of drug delivery device 102. The memory 132 may be configured to store information and programming code 136.

[0053] The analyte sensor 108 may be configured to detect multiple different analytes, such as glucose, lactate, ketones, uric acid, sodium, potassium, alcohol levels or the like, and output results of the detections, such as measurement values or the like. The analyte sensor 108 may, in an exemplary embodiment, be a continuous glucose monitor (CGM) configured to measure a blood glucose value at a predetermined time interval, such as every 5 minutes, every 1 minute, or the like. The communication interface 135 of analyte sensor 108 may have circuitry that operates as a transceiver for communicating the measured blood glucose values to the user device 105 over a wireless link 195 or with drug delivery device 102 over the wireless communication link 108. While referred to herein as an analyte sensor 108, the sensing/measuring device 133 of the analyte sensor 108 may include one or more additional sensing elements, such as a glucose measurement element, a heart rate monitor, a pressure sensor, or the like. The controller 131 may include discrete, specialized logic and/or components, an application-specific integrated circuit, a microcontroller or processor that executes software instructions, firmware, programming instructions stored in memory (such as memory 132), or any combination thereof.

[0054] Similar to the controller 121 of drug delivery device 102, the controller 131 of the analyte sensor 108 may be operable to perform many functions. For example, the

controller 131 may be configured by programming code 136 to manage the collection and analysis of data detected by the sensing and measuring device 133.

[0055] Although the analyte sensor 108 is depicted in **FIG. 1** as separate from drug delivery device 102, in various embodiments, the analyte sensor 108 and drug delivery device 102 may be incorporated into the same unit. That is, in various examples, the analyte sensor 108 may be a part of and integral with drug delivery device 102 and contained within the same housing as drug delivery device 102 or in a housing attachable to the housing of drug delivery device 102 or otherwise adjacent thereto. In such an example configuration, the controller 121 may be able to implement the functions required for the proper delivery of the medication alone without any external inputs from user device 105, the cloud-based services 111, another sensor (not shown), the optional accessory device 106, or the like.

Cloud-Based Services

[0056] Drug delivery system 100 may communicate with or receive services from cloud-based services 111. Services provided by cloud-based services 111 may include data storage that stores personal or anonymized data, such as blood glucose measurement values, historical IOB or TDI, prior carbohydrate-compensation dosage, and other forms of data. In addition, the cloud-based services 111 may process anonymized data from multiple users to provide generalized information related to TDI, insulin sensitivity, IOB and the like. The communication link 115 that couples the cloud-based services 111 to the respective devices 102, 105, 106, 108 of system 100 may be a cellular link, a Wi-Fi link, a Bluetooth® link, or a combination thereof.

Communication Links

[0057] The wireless communication links 115 and 191-196 may be any type of wireless link operating using known wireless communication standards or proprietary standards. As an example, the wireless communication links 191-196 may provide communication links based on Bluetooth®, Zigbee®, Wi-Fi, a near-field communication standard, a cellular standard, or any other wireless protocol via the respective communication interfaces 126, 135, 154 and 174.

Operational Example

[0058] In an operational example, user application 160 implements a graphical user interface that is the primary interface with the user and is used to start and stop drug delivery device 102, program basal and bolus calculator settings for manual mode as well as program settings specific for automated mode (hybrid closed-loop or closed-loop).

[0059] User app 160, provides a graphical user interface 158 that allows for the use of large text, graphics, and on-screen instructions to prompt the user through the set-up processes and the use of system 100. It will also be used to program the user's custom basal insulin delivery profile, check the status, of drug delivery device 102, initiate bolus doses of insulin, make changes to a patient's insulin delivery profile, handle system alerts and alarms, and allow the user to switch between automated mode and manual mode.

[0060] User app 160 may be configured to operate in a manual mode in which user app 160 will deliver insulin at programmed basal rates and bolus amounts with the option to set basal profiles for different times of day or temporary basal profiles. The controller 121 will also have the ability to function as a sensor-augmented pump in manual mode, using sensor glucose data provided by the analyte sensor 108 to populate the bolus calculator.

[0061] User app 160 may be configured to operate in an automated mode in which user app 160 supports the use of multiple target blood glucose values. For example, in

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one embodiment, target blood glucose values can range from 110-150 mg/dL, in 10 mg/dL increments, in 5 mg/dL increments, or other increments, but preferably 10 mg/dL increments. The experience for the user will reflect current setup flows whereby the healthcare provider assists the user to program basal rates, glucose targets and bolus calculator settings. These in turn will inform the user app 160 for insulin dosing parameters. The insulin dosing parameters will be adapted over time based on the total daily insulin (TDI) delivered during each use of drug delivery device 102. A temporary hypoglycemia protection mode may be implemented by the user for various time durations in automated mode. With hypoglycemia protection mode, the algorithm reduces insulin delivery and is intended for use over temporary durations when insulin sensitivity is expected to be higher, such as during exercise.

[0062] The user app 160 (or MDA 129) may provide periodic insulin micro-boluses based upon past glucose measurements and/or a predicted glucose over a prediction horizon (e.g., 60 minutes). Optimal post-prandial control may require the user to give meal boluses in the same manner as current pump therapy, but normal operation of the user app 160 will compensate for missed meal boluses and mitigate prolonged hyperglycemia. The user app 160 uses a control-to-target strategy that attempts to achieve and maintain a set target glucose value, thereby reducing the duration of prolonged hyperglycemia and hypoglycemia.

[0063] In some embodiments, user device 105 and the analyte sensor 108 may not communicate directly with one another. Instead, data (e.g., blood glucose readings) from analyte sensor may be communicated to drug delivery device 102 via link 196 and then relayed to user device 105 via link 194. In some embodiments, to enable communication

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between analyte sensor 108 and user device 105, the serial number of the analyte sensor must be entered into user app 160.

[0064] User app 160 may provide the ability to calculate a suggested bolus dose through the use of a bolus calculator. The bolus calculator is provided as a convenience to the user to aid in determining the suggested bolus dose based on ingested carbohydrates, most-recent blood glucose readings (or a blood glucose reading if using fingerstick), programmable correction factor, insulin to carbohydrate ratio, target glucose value and insulin on board (IOB). IOB is estimated by user app 160 taking into account any manual bolus and insulin delivered by the algorithm, and IOB may be divided between a basal IOB and a bolus IOB, the basal IOB accounting for insulin delivered by the algorithm, and the bolus IOB accounting for any bolus deliveries.

Description of Embodiments

[0065] The primary embodiment of the invention is directed to improvements implemented in an automatic drug delivery system 100, an example of which is shown in **FIG. 1**. The improvements are designed to make it easier for a user to maintain safe blood glucose levels. In one embodiment, the improvements eliminate the necessity for the user calculate and administer a bolus dose by providing a safe bolus dose to the user upon a notification of a meal event and thereafter providing further required dosing of the liquid drug in accordance with MDA 129. In other embodiments, drug delivery system 100 will automatically maintain acceptable glucose levels even when the user fails to self-administer a bolus dose of insulin prior to or after ingesting a meal.

[0066] The improvements may be implemented, for example, by modifications to the software executing as part of drug delivery system 100 (i.e., user application 160 or MDA 129). In certain embodiments, certain features may be implemented in user app 160

executing on user device 105, while other features may be implemented in MDA 129 executing on drug delivery device 102. Because various functions may be shared between user application 160 and MDA 129, the user application 160 and MDA 129 will be referred to herein collectively as the “system software”.

[0067] In one embodiment, the user is provided with a “Going to Eat” user selectable button 302, shown in **FIG. 3**, which, when selected by the user, indicates a meal event to the system software. (i.e., that the user intends to eat a meal). In certain embodiments, MDA 129, upon receipt of a notification of a meal event, may replace the bolus calculator and eliminate the need for the user to enter the carbohydrate profile of the intended meal. In preferred embodiments of the invention, button 302 may be displayed in user interface 158 of user device 105 or, in alternate embodiments, in user interface 178 on accessory device 106. In other embodiments, when drug delivery device 102 is provided with a user interface 127, the user may notify the system software of a meal event by providing input directly to drug delivery device 102 via user interface 127 (in this instance, however, no graphical representation of button 302 will be displayed). Upon a user selection of “Going to Eat” button 302 (or, upon provision of an indication to drug delivery device 102 of a meal event) a safe bolus insulin dose will be calculated and delivered to the user, the calculation of the safe bolus does takes into consideration the user’s current blood glucose level, the insulin-on-board (IOB), the user’s glucose trend during a predetermined past period of time (in preferred embodiments, 30 minutes) and, whether nighttime mode is enabled. Each of these considerations will be explained later herein.

[0068] An analysis of the insulin delivered prior to meals is depicted in the histogram shown in **FIG. 4**. The histogram shows the insulin delivered as a percentage of the total daily insulin (TDI) versus density for a typical user. A safe nominal insulin dose, which

may be adjusted by various considerations to determine a safe bolus dose, may be expressed as a percentage of the user's total daily insulin (TDI) as:

$$\text{Safe Nominal Insulin Dose} = x * TDI \tag{1}$$

where:

x is the desired percentage; and

TDI is the user's total daily insulin.

In one embodiment, x may be chosen as, for example, 8%, although other percentages may be chosen on a user-by-user basis. For example, a percentage between 5% to 15% (inclusive of endpoints) may be used for x .

[0069] In another aspect of the invention, a safe correction dose of insulin (*IOB Required Safe*) may be calculated based on the user's current blood glucose level, an elevated threshold glucose value and a correction factor (based on, for example, the 1600 rule, which estimates the drop in blood glucose level per unit of insulin by dividing a 1600 factor by the TDI, as shown in Eq. 2 below). A safe correction dose may, in some embodiments, be expressed as:

$$\text{IOB Required Safe} = \frac{BG_{\text{current}} - T_{\text{Elevated}}}{1600/TDI} \tag{2}$$

Where:

BG_{current} is the user's current blood glucose reading; and

T_{Elevated} is an elevated threshold.

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[0070] In one embodiment, $T_{Elevated}$ may be set, for example, to 150 mg/dl, although any value for the $T_{Elevated}$ may be used. The elevated threshold is used in combination with the safe nominal insulin dose and the IOB to determine the safe bolus dose. The safe correction dose serves two purposes. First, it makes the insulin requirement safe and, second, it allows some flexibility for any delays in the ingestion of the meal after the user has indicated the intention to ingest a meal by selection of the “Going to Eat” button 302.

[0071] In the event that data from the CGM is missing, a minimum CGM value in the past 30 minutes may be used for the $BG_{current}$ value. In the event no valid CGM data is available for the last 30 minutes, the *IOB Required Safe* could be calculated as:

$$IOB\ Required\ Safe = \frac{T_{Low} - T_{Elevated}}{1600/TDI} \tag{3}$$

where:

T_{Low} is a low threshold.

[0072] The value of T_{Low} may be set, in certain embodiments, to 100 ml/dl 70 ml/dl or 40 ml/dl, although any value for the low threshold may be used. Because the low threshold is always less than the elevated threshold, the use of the low threshold will lead to the *IOB Required Safe* to be negative and will reduce the total insulin.

[0073] In some embodiments, the safe bolus dose calculated and delivered after the user presses the “Going to Eat” button 302 can be further adjusted by a trend correction factor (CF_T) which depends on the trend of the blood glucose readings of the user for a predetermined time period prior to the selection of button 302. In certain embodiments, the predetermined time period may be, for example, 30 minutes. In preferred embodiments of the invention, blood glucose readings are periodically received from the CGM every five minutes, although, in other embodiments, other periods may be used.

For embodiments wherein the receipt of the CGM readings occurs in five minute intervals, a prior 30 minute time period will result in 7 blood glucose readings, starting with the current blood glucose reading BG_i .

[0074] A trend may be detected by calculating a coarse slope and coarse curvature of the blood glucose readings over time. In one embodiment, the trend may be calculated by first calculating averages of ranges of blood glucose readings over 15-minute blocks as:

$$BG_{avg1} = \frac{BG_i + BG_{i-1} + BG_{i-2} + BG_{i-3}}{4} \tag{4}$$

$$BG_{avg2} = \frac{BG_{i-3} + BG_{i-4} + BG_{i-5} + BG_{i-6}}{4} \tag{5}$$

$$Range1 = BG_{i-3} - BG_i \tag{6}$$

$$Range2 = BG_{i-6} - BG_{i-4} \tag{7}$$

[0075] The coarse slope and coarse curvature may thereafter be defined as:

$$Slope_{coarse} = BG_{avg1} - BG_{avg2} \tag{8}$$

$$Curvature_{coarse} = Range2 - Range1 \tag{10}$$

[0076] In certain embodiments, a trend correction factor CF_T may be determined using a set of rules. Although any set of rules may be used, in an exemplary embodiment, the set of rules may determine CF_T as follows:

$$\text{If } Slope_{coarse} < 0 \text{ AND } Curvature_{coarse} < 0 \text{ then } CF_T = 0.5 \tag{11}$$

$$\text{If } Range1 < 0 \text{ AND } Range2 < 0 \text{ then } CF_T = 0.5 \tag{12}$$

$$\text{If } Slope_{coarse} < 0 \text{ then } CF_T = 0.5 \tag{13}$$

[0077] In the event that one or more CGM values during the predetermined past time period are missing or unavailable, a data quality metric may be used to determine if adequate CGM data is available make a trend decision. Such metrics may be, for example, no more than $x\%$ (e.g., 30%) of data points are missing in the last 30 minutes. If the data quality is unacceptable, no trend correction is made, and the CF_T is set to 1.

[0078] If the user has experienced a hypoglycemic event just prior to the bolus dosing triggered by the notification of the meal event, (e.g., hypoglycemia within an hour or within a threshold time limit), then a rebound from hypo factor ($HF_{Rebound}$) that reduces the safe bolus dose can be applied. The hypo rebound factor may be specified as:

$$HF_{Rebound} = z$$

where:

$z = 0.75$ in some embodiments or any other constant in other embodiments.

[0079] In some embodiments, a nighttime mode setting may be provided. The nighttime mode setting, if enabled, will further reduce the safe bolus dose to further reduce the risk of hypoglycemia. In one embodiment, the user is provided with a nighttime mode user interface screen 500, shown in **FIG 5**, which includes a “Set Nighttime Mode” user selectable button 502 which, when selected by the user, indicates

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to the system software that nighttime mode is enabled. The user may set a start time 504 and an end time 506 to indicate when nighttime mode will be enforced.

[0080] In an alternative embodiment, nighttime mode can be enabled automatically by using an inertial measurement unit (IMU) sensor on the pump. The IMU may comprise one or more of an accelerometer, a gyro and, often, magnetometers. These sensors, together, can determine motion, orientation (or tilt) of the device in one or more of x, y, and z axes. For sustained activity such as running, swimming or sleeping, the IMU generates a unique profile of signal activity on each of the axes. By decoding these signals, a unique signature is identified which can be mapped to an activity. Thus, if it is determined that the user is sleeping, a unique signature would be detected along the 3 axes, and, together with time-zone information, a determination of “nighttime” mode for the user can be made.

[0081] In preferred embodiments of the invention, the nighttime mode user interface screen 500 may be displayed in user interface 158 of user device 105 or, in alternate embodiments, in user interface 178 on accessory device 106. In other embodiments, when drug delivery device 102 is provided with a user interface 127, the user may initiate nighttime mode directly to drug delivery device 102 via user interface 127 (in this instance, however, the nighttime mode user interface screen 500 will not be displayed).

[0082] If the nighttime mode is in effect and the “Going to Eat” button 302 is pressed, then a nighttime factor (*NF*) can be set which can vary from, for example, 0.6 to 0.9. In some embodiments, a value of 0.75 may be set as the default. The value can be reduced if, in past occurrences, the current value had created an additional risk of hypoglycemia. Conversely the current value can be increased if, in past occurrences, the blood glucose was elevated.

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[0083] The flowchart shown in **FIG. 6** may be used to determine any adjustments to the *NF* based on readings of the user’s blood glucose levels over a three-hour time period in past occurrences when the safe bolus dose was delivered. Starting with the current *NF*, a safe bolus dose is delivered and the blood glucose is monitored for a predetermined time period, for example, for 3 hours. If the blood glucose became elevated, the current *NF* is increased by, for example, 10%, for the next calculation. Elevated blood glucose can be defined, in some embodiments, as blood glucose greater than 80 mg/dl over the setpoint at the 3-hour mark. Other values may be used, such as 50 mg/dl, 60 mg/dl, 70 mg/dl, 90 mg/dl, or 100 mg/dl over the setpoint at the 3-hour mark. In other embodiments, other criteria may be used. If the blood glucose is not elevated, it is determined if the blood glucose fell below a low setpoint. If not, no changes are made to the current *NF*. However, if the blood glucose fell below the setpoint, the *NF* may be reduced by, for example, 10% for the next calculation.

[0084] In certain embodiments, any combination of the trend factor, the rebound hypo factor and the nighttime factor may be applied to the safe bolus dose to modify the quantity of the liquid drug represented by the safe bolus dose and which is delivered to the user in response to the user selection of button 302. When using all factors previously explained, the safe bolus insulin dose can be expressed as:

$$(CF_T * HF_{Rebound} * NF * x * TDI) + IOB_{Required\ Safe} - IOB \tag{14}$$

where:

the CF_T , the $HF_{Rebound}$ and the NF modify the value of x for safety. In various embodiments, a safe bolus dose may take into account the trend factor, the rebound hypo

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factor, and the nighttime factor, or any combination (including none of these factors) thereof to calculate a safe bolus dose.

[0085] The IOB is the insulin-on-board from prior insulin deliveries. If the IOB is negative, then it is truncated to 0.

[0086] The safe bolus dose is best suited for closed loop systems where the algorithmic (basal) insulin can be safely increased to compensate for the safe bolus dose and greatly reduces the risk of hypoglycemia in closed loop systems. After the safe bolus dose is administered upon notification of the meal event, the system software of drug delivery device 100 will compensate for further post-prandial excursions in the user's blood glucose levels in accordance with algorithmic basal insulin delivery embodied by MDA 129.

[0087] Insulin may be delivered in accordance with Eq. (14) multiple times when the value of x is reduced. For example, x may be set or reduced to 3.5% due to the application of the various previously-explained factors and the initial bolus insulin delivery can administered when the user selects the "Going to Eat" button 302, with a second bolus administered 10 minutes thereafter and a third bolus 20 minutes thereafter. Trends in the blood glucose can be used to deliver insulin safely. The IOB safeguards against excess insulin delivery.

[0088] Detecting Un-bolused or Under-bolused Meals - In this aspect of the invention, a method is disclosed to assess past glucose history and to determine whether the user had a meal that was not manually compensated for or was undercompensated for via a self-administered bolus dose and for situations where the user fails to inform drug delivery system 100 of a meal and event by selection of button 302. In an extension of this embodiment, should an uncompensated or undercompensated meal be detected, the

system software may provide metrics for the user, and may also increase the aggressiveness of MDA 129 for high glucose concentrations during those periods.

[0089] A typical un-bolused or under-bolused meals can result in significant increases in the user’s glucose, and significant increases in the automated insulin delivery beyond basal. In one embodiment of this aspect of the invention, the system software can review 5-hour windows at a 5-minute moving increment across each 24-hour period, as follows:

$$W_{post,i=1...228} = \sum_{j=1}^{60} I_{alg}(i + j) \tag{15}$$

$$G_{post,i=1...228} = \frac{\sum_{j=1}^{60} G(i + j)}{60} \tag{16}$$

where:

W_{post} is the total insulin delivered during the most recent 5-hour window;

G_{post} is the average of the glucose readings for the most recent 5-hour window; and

I_{alg} is the insulin recommended by the medication delivery algorithm;

228 is the number of 5-hour windows in one day; and

60 is a number of 5-minute cycles in 5 hours.

[0090] As would be realized by one of skill in the art, the constants in the above equations are tunable parameters. Different periodic intervals for evaluating the equations or a different window size would dictate the use of appropriately different constants.

[0091] If W_{post} and G_{post} meet certain criteria, all data points for that specific period can be considered to meet the definition of an unannounced meal detection. In one embodiment, these criteria can be, for example:

$$P_i = \begin{cases} True & W_{post,i} > \frac{TDI}{48} \cdot 2 \cdot 5 \text{ AND } G_{post,i} > 180 \\ False & W_{post,i} \leq \frac{TDI}{48} \cdot 2 \cdot 5 \text{ OR } G_{post,i} \leq 180 \end{cases} \quad (17)$$

[0092] Here, the thresholds are at least 2 times the user’s *TDI*-based basal being delivered over the most recent 5-hour window and the user’s mean glucose is above 180 over the most recent 5-hour window. It is important to note that the specific numerical values introduced in this embodiment are all variable parameters. For instance, both the increments and total duration of moving windows can vary, such as reviewing 6-hour windows in every 30-minute increments, or 3-hour windows in every 15-minute increments, or other values. Moreover, the thresholds of selection criteria may also vary. For instance, the threshold of total increased automated insulin delivery can be of 1.5, 3 or 4 times basal compared to 2 times basal delivery. The final glucose concentration can also vary as different values, such as 150 mg/dL, 250 mg/dL, the user’s final glucose target, other values.

[0093] The user’s mean glucose concentration during each moving window can also be included as a condition, as an addition, or in replacement of, the ending glucose condition, with associated thresholds of detection. For example, the condition may be stated as a mean glucose higher than 150 mg/dL during the moving window.

[0094] Rather than a binary detection of meals during this period, the system may instead provide a probabilistic calculation of the occurrence of meals depending on the extent over which each condition is exceeded. For instance, the system may provide a 50% chance that an unannounced or under-bolused meal had occurred if the automated insulin delivery exceeded 1.5x basal over the 5-hour window, which may rise to 100%

chance if the delivery exceeded 3x basal during this same period. Each condition may provide a probability of meal delivery, and the final determination of the probability of occurrence of a meal can be calculated as a mean, a sum, or other combination of the assessment of probability of a meal across all conditions.

[0095] For each period where an unannounced meal is detected, the user can be informed that the system detected that the user had an unannounced meal. In addition, the system software can provide a recommended amount of insulin based on the user's final glucose at the end of the period that, had the user self-administered a bolus of that amount, the user's glucose control outcomes would have been improved:

$$I_{rec,i} = \frac{G(i + 60) - target(i + 60)}{CF(i)} \tag{18}$$

[0096] Further, the system software may respond more aggressively to glucose deviations during the first 90 minutes of this period, by reducing the Q:R ratio (relative cost of insulin deviation -vs- glucose deviation) during this period based on the additional required insulin, as follows:

$$Q_{new,i...i+18} = \max \left(Q_{base} \left(\frac{I_{rec,i}}{\frac{TDI}{48} \cdot 2 \cdot 1.5} \right), Q_{base} \right) \tag{19}$$

[0097] In another aspect of the invention, a machine learning approach may be used to perform the detection of a meal. In this embodiment, a meal can be detected based on machine learning models that detect the characteristic rising profile of the blood sugar levels. The meal detection models are preferably trained on a closed loop control dataset.

Blood glucose profiles from closed loop data with prescribed rising characteristics are labeled to be used as training data. In one embodiment, the rise characteristics can be, for example, 20 ml/dl within a 15 minute period, 40 ml/dl within a 30 minute period and 60 ml/dl within a 60 minute period.

[0098] In one embodiment, two-hour periods of blood glucose data that go back in time from 10 minutes after the initial blood glucose rise, 15 minutes after the initial blood glucose rise and 20 minutes after the initial blood glucose rise, are trained using decision trees for detecting meals.

[0099] **FIG. 7** shows a sliding window over a plot of the blood glucose levels used to detect meals. As the window indexes through time, a meal is detected, in this example, when the sliding window reaches *BG* points 23, 24, 25 and beyond. **FIG. 8** shows a relationship between blood glucose rise and meal detection. A three-meal day pattern is shown.

[0100] To detect meals, certain features will be detected in the blood glucose data. In one embodiment, a 2-hour history of blood glucose data is maintained. In this embodiment, blood glucose may be sampled every five minutes, resulting in 25 data points. In embodiments wherein a different history period or different intervals for the sampling of the blood glucose levels are used, a different number of data points will be available for analysis. In one embodiment of the invention, the following features may be detected: 15 minute averages (average blood glucose in every 15 minute period during the most recent two-hour history); range features (differences in the blood glucose levels every 15 minutes); delta values (differences of 15 minute averages, providing coarse slopes of the plot of the blood glucose levels); slope values (differences between consecutive values of the slope of the plot of the blood glucose levels); and second

derivatives (the differences of the slopes of the plot of the blood glucose levels). In other embodiments of the invention, other features may be used.

[0101] In the training phase, blood glucose data is identified with rise characteristics such as 20 ml/dl within a 15 minute period, 40 ml/dl within a 30 minute period and 60 ml/dl within a 60 minute period. The identified data is presented to a machine learning model to develop meal detection rules. It should be noted that, while the full upward rising portion of the blood glucose curve is used to recognize a post-prandial rise in the glucose levels, in one embodiment, only 10-minutes, 15-minutes and 20-minutes of the rising blood glucose curve (and values earlier for a total of 25 data points at each instant), are presented to the machine learning system. The objective is to detect meals with minimal latency.

[0102] The machine learning pipeline is depicted in **FIG. 9**, which shows data generation for 10-minute, 15-minute and 20-minute meal detection classifiers. The *BG* rise points must be inside low and high thresholds. The 10-minute classifier looks forward 10 minutes and backward 110 minutes to extract 2 hours of data, the 15-minute classifier looks forward 15 minutes and backward 105 minutes to extract 2 hours of data and the 20-minute classifier looks forward 20 minutes and backward 100 minutes to extract 2 hours of data. **FIG. 10** shows supervised training for the 10-minute, 15-minute and 20-minute meal classifiers.

[0103] In certain embodiments, decision trees may be used for meal detection. In one embodiment, the meals are detected using three different delay periods. These are the 10-minute delay detector, the 15-minute delay detector and the 20-minute delay detector. The 10-, 15- and 20-minute delay detectors recognize rising blood glucose values with an assumption that the post-prandial blood glucose rise started 10, 15 and 20 minutes prior

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to the current time, respectively. The exact rules used in the meal detection decision trees may vary based on differing embodiments of the invention. In addition, detectors using different time periods may also be developed.

[0104] Models may be cascaded and/or combined to make the meal detection more robust. At each 5 minute interval, as a new blood glucose value is received from CGM 108, the 10-, 15 and 20-minute meal detectors are fired to detect meals. These results are then synthesized, resulting in a robust meal detection model, an example of which is shown in **FIG. 11**. At 1100, the most recent cycle of the MDA 129 begins and, at 1102, the most recent blood glucose reading is received and added to the most recent 2-hour history. The 10-minute delay meal detector 1104, the 15-minute delay meal detector 1106 and the 20-minute delay meal detectors 1108 2-hour history of blood glucose readings. At 1110, the results from each of the delayed meal detectors 1104, 1106 and 1108 are pooled and, at 1112, the meal detection result is output. Various rules may be enforced by the pool classifier at 1110 to determine whether a meal detection is *TRUE* or *FALSE* based on the combination of results from delayed meal detectors 1104, 1106, 1108.

[0105] As an example, if, in the current cycle, the 10-minute delay meal detector returns True, it is expected that the 15-minute meal detector will return True in the next cycle (it is conceivable the 10-minute detector may return True at this cycle as well), and that, in the next cycle, the 20-minute meal detector will return True. For robustness a period of time in which these detectors may return True is allowed and the final meal detection result is synthesized by pulling the outputs of the 10-, 15-, and 20-minute detectors, as shown in **FIG. 11**.

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[0106] Auto-Bolusing - In certain embodiments, when an un-bolused or under-bolused meal is detected, regardless of the method used for detection, an automatic bolus dose of insulin will be fired. FIG. 12 shows the logic flow for determining whether an automatic bolus should be administered. At 1200, the cycle begins. As previously discussed, in preferred embodiments of the invention, each cycle is five minutes in length and a new blood glucose reading is received from the CGM during each five minute cycle. In certain embodiments of the invention, the receipt of a new *BG* reading will trigger the beginning of the next cycle. At 1202, the most recent blood glucose reading is received and, at 1204, the meal detectors previously described are run on the most recent blood glucose readings, including the most recently received reading. At 1206, if a meal has been detected, the auto bolus will be administered as described above at 1208. If no meal is detected control returns to 1200, to await the start of the next cycle.

[0107] The auto bolus may have a nominal insulin delivery volume. In one embodiment, the auto bolus may be the safe bolus dose described in detail above. In other exemplary embodiments, the insulin volume required will nominally be a percentage (e.g., 8%) of the *TDI* for the user. This amount of insulin will be adjusted by a safe IOB requirement (IOB_{SR}) for correction and modulated by the current IOB. The safe IOB requirement indicates the insulin needed for correcting the blood glucose (however, instead of using the insulin setpoint, for improved safety, an elevated value, for example, 150 mg/dl, may be used for improved safety).

$$AutoBolus = (x * TDI) + IOB_{SR} - IOB$$

(20)

where:

$$IOB_{SR} = \frac{(CurrentBG - 150)}{CF} \tag{21}$$

where:

CF is a correction factor defined as $1600/TDI$.

[0108] In the event that a manual bolus has been administered prior to the triggering of the auto bolus, the IOB will modulate the insulin delivery. If the IOB is sufficiently high, then the auto bolus may deliver 0 units of insulin. On the other hand, if the user has under-bolused, then a suitable amount of insulin will be provided according to the IOB.

[0109] The auto bolus delivers a safe amount of insulin for post-prandial blood glucose compensation. The core closed loop control algorithm will continue to deliver the appropriate amount of basal insulin to maximize time in range for the user.

[0110] The following examples pertain to various embodiments of the systems and methods disclosed herein for providing a method for determining an optimal delivery of a drug by providing a stepwise exploration of a search space of possible quantities of the drug to be delivered to the user.

[0111] Example 1 is a method of a first embodiment of the invention comprising the steps of receiving notification of a meal event, calculating a safe bolus dose to be delivered to the user, delivering the safe bolus dose, moderating blood glucose levels of the user, and compensating for further excursions in the blood glucose levels of the user by a medication delivery algorithm of the drug delivery system.

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[0112] Example 2 is an extension of Example 1, or any other example disclosed herein, wherein notification of the meal event comprises a user selection of a button in a user interface.

[0113] Example 3 is an extension of Example 1, or any other example disclosed herein, wherein the safe bolus dose is calculated as a function of a safe nominal insulin delivery amount and the current insulin on board.

[0114] Example 4 is an extension of Example 3, or any other example disclosed herein, wherein the safe nominal insulin delivery amount is calculated as a percentage of the user's total daily insulin requirement.

[0115] Example 5 is an extension of Example 4, or any other example disclosed herein, wherein the safe bolus dose is modified by a blood glucose correction factor that takes into account the current blood glucose levels of the user.

[0116] Example 6 is an extension of Example 5, or any other example disclosed herein, wherein the safe bolus dose is modified by a trend correction factor which corrects for trends in the user's blood glucose values for a past predetermined period of time.

[0117] Example 7, is an extension of Example 6, or any other example disclosed herein, wherein the trend correction factor is based on a slope and a curvature of the user's blood glucose values for the past predetermined period of time.

[0118] Example 8 is an extension of Example 5, or any other example disclosed herein, wherein when the safe bolus dose is modified by a rebound from hypo factor which reduces the safe bolus dose by a predetermined amount if the user has experienced a hypoglycemic event within a predetermined time period prior to delivery of the safe bolus dose.

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[0119] Example 9 is an extension of Example 5, or any other example disclosed herein, wherein the safe bolus dose is modified by nighttime factor which reduces the safe bolus dose by calculated amount if the bolus dose is being administered during a nighttime period.

[0120] Example 10 is an extension of Example 9, or any other example disclosed herein, wherein a current value of the nighttime factor is lowered if, in past occurrences, the current value created an additional risk of hypoglycemia or is raised if, in past occurrences, the current value caused blood glucose values of the user to be elevated.

[0121] Example 11 is an extension of Example 3, or any other example disclosed herein, wherein the safe bolus dose may be modified by any combination of a blood glucose correction factor, a trend correction factor, a rebound from hypo factor and a nighttime factor.

[0122] Example 12 is an extension of Example 1, or any other example disclosed herein, wherein delivering the safe bolus dose further comprises splitting the safe bolus dose into multiple staged doses delivered at predetermined times after notification of the meal event.

[0123] Example 13 is an extension of Example 12, or any other example disclosed herein, wherein the safe bolus dose is recalculated at each staged delivery.

[0124] Example 14 is an extension of Example 1, or any other example disclosed herein, wherein the notification of a meal event comprises an automatic detection of ingestion of a meal based on blood glucose levels of the user received from a continuous glucose monitor.

[0125] Example 15 is an extension of Example 14, or any other example disclosed herein, wherein the automatic detection of the ingestion of a meal is based on detection of

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a significant increase in the user's blood glucose levels in a significant increase in automatic delivery of a liquid drug as calculated by a medication delivery algorithm of the drug delivery system.

[0126] Example 16 is an extension of Example 15, or any other example disclosed herein, wherein the increase in user's blood glucose levels and the increase in the automatic delivery of the liquid drug are evaluated for a moving window of a predetermined with evaluated each time a new blood glucose reading is received from the continuous blood glucose monitor.

[0127] Example 17 is an extension of Example 14, or any other example disclosed herein, wherein the automatic detection of the ingestion of a meal is based on an analysis of the plot of the user's blood glucose levels by one or more machine learning model trained is meal detection classifiers.

[0128] Example 18 is extension of Example 17, or any other example disclosed herein, wherein the one or more machine learning models are trained to detect post-prandial rises in blood glucose levels of the user beginning at various times prior to the current time

[0129] Example 19 is an extension of Example 18, or any other example disclosed herein, wherein the one or more machine learning models comprise a 10-minute delay detector, 15-minute delay detector and a 20-minute delay detector.

[0130] Example 20 is an extension of Example 17, or any other example disclosed herein, wherein the one or more machine learning models are cascaded to provide a final determination of a meal ingestion.

[0131] Example 21 is an extension of Example 14, or any other example disclosed herein, wherein the automatic detection of the ingestion of a meal is based on an analysis of the plot of the user's blood glucose levels by one or more decision trees.

[0132] Example 22 is an extension of Example 21, or any other example disclosed herein, wherein the decision trees use multiple delay detectors to recognize rising blood glucose values with an assumption that a rise in the blood glucose levels started at various times prior to the current time.

[0133] Example 23 is an extension of Example 22, or any other example disclosed herein, wherein the multiple delay detectors comprise 10-, 15- and 20-minute delay detectors.

[0134] Example 24 is an extension of Example 22, or any other example disclosed herein, wherein the results of the multiple delay detectors are pooled to synthesize a final meal detection decision.

[0135] Example 25 is an extension of example 14, or any other example disclosed herein, wherein, in response to the notification of a meal event, the method further comprises informing the user of the inner unannounced detection of a meal and providing a recommended bolus dose to the user.

[0136] Example 26 is an extension of Example 25, or any other example disclosed herein, wherein, in response to the notification of the meal event, the method further comprises adjusting a medication delivery algorithm of the drug delivery system to respond more aggressively to glucose deviations based on the recommended bolus dose.

[0137] Example 27 is a method of a second embodiment of the invention comprising the steps of automatically detecting ingestion of a meal based on blood glucose levels of the user received from a continuous glucose monitor, informing the user of the

unannounced detection of a meal, providing a recommended bolus dose to the user and adjusting them a medication delivery algorithm of the drug delivery system to respond more aggressively to glucose deviations based on the recommended bolus dose.

[0138] Example 28 is a system of third embodiment comprising a processor and software, executing on the processor providing the functions of receiving notification of a meal event, calculating a safe bolus dose to be delivered to the user, delivering the safe bolus dose, monitoring blood glucose levels of the user, and compensating for further excursions in the blood glucose levels of the user in accordance with the medication delivery algorithm of the drug delivery system.

[0139] Example 29 is an extension of Example 28, or any other example disclosed herein, wherein the notification of a meal event comprises a user selection of a button in the user interface of the drug delivery system.

[0140] Example 30 is an extension of Example 28, or any other example disclosed herein, further comprising a continuous glucose monitor, wherein the notification of a meal event comprises automatic detection of the ingestion of a meal based on blood glucose levels of the user received from the continuous glucose monitor.

[0141] Software related implementations of the techniques described herein may include, but are not limited to, firmware, application specific software, or any other type of computer readable instructions that may be executed by one or more processors. The computer readable instructions may be provided via non-transitory computer-readable media. Hardware related implementations of the techniques described herein may include, but are not limited to, integrated circuits (ICs), application specific ICs (ASICs), field programmable arrays (FPGAs), and/or programmable logic devices (PLDs). In some examples, the techniques described herein, and/or any system or constituent

component described herein may be implemented with a processor executing computer readable instructions stored on one or more memory components.

[0142] To those skilled in the art to which the invention relates, many modifications and adaptations of the invention may be realized. Implementations provided herein, including values of tunable parameters, should be considered exemplary only and are not meant to limit the invention in any way. As one of skill in the art would realize, many variations on implementations discussed herein which fall within the scope of the invention are possible. Moreover, it is to be understood that the features of the various embodiments described herein were not mutually exclusive and can exist in various combinations and permutations, even if such combinations or permutations were not made express herein, without departing from the spirit and scope of the invention.

Accordingly, the method and apparatus disclosed herein are not to be taken as limitations on the invention but as an illustration thereof. The scope of the invention is defined by the claims which follow.

[0143] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[0144] The reference in this specification to any prior publication (or information derived from it), or to any matter which is known, is not, and should not be taken as an acknowledgment or admission or any form of suggestion that that prior publication (or information derived from it) or known matter forms part of the common general knowledge in the field of endeavour to which this specification relates.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A drug delivery system comprising a processor configured to execute a method of compensating for meal ingestion, the method comprising:
 - receiving notification of a meal event;
 - calculating a safe bolus dose to be delivered to a user, wherein calculation of the safe bolus is performed without the user entering a carbohydrate profile of the meal;
 - delivering the safe bolus dose;
 - monitoring blood glucose levels of the user; and
 - compensating for further excursions in the blood glucose levels of the user in accordance with a medication delivery algorithm of the drug delivery system.
2. The drug delivery system of claim 1 wherein the notification of a meal event comprises a user selection of a button in a user interface of the drug delivery system.
3. The drug delivery system of claim 1 wherein the safe bolus dose is calculated as a function of a safe nominal insulin delivery amount and the current insulin on board.
4. The drug delivery system of claim 3 wherein the safe nominal insulin delivery amount is calculated as a percentage of a total daily insulin requirement (TDI) of the user.

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5. The drug delivery system of claim 4 wherein the safe bolus dose is modified by one or more of:
 - a blood glucose correction factor that takes into account the current blood glucose levels of the user;
 - a trend correction factor, wherein the trend correction factor corrects for trends in the user's blood glucose values for a past predetermined period of time;
 - a rebound from hypo factor, wherein the rebound from hypo factor reduces the safe bolus dose by a predetermined amount if the user has experienced a hypoglycemic event within a predetermined time period prior to delivery of the safe bolus dose; or
 - a nighttime factor, wherein the nighttime factor reduces the safe bolus dose by a calculated amount if the bolus dose is being administered during a nighttime period.
6. The drug delivery system of claim 5 wherein the trend correction factor is based on a slope and a curvature of the user's blood glucose values for the past predetermined period of time.
7. The drug delivery system of claim 5 wherein nighttime mode is automatically detected using a motion profile provided by an IMU and time zone information.
8. The drug delivery system of claim 5 wherein a current value of the nighttime factor is lowered if, in past occurrences, the current value created an additional risk of hypoglycemia or is raised if, in past occurrences, the current value caused blood

glucose values of the user to be elevated.

9. The drug delivery system of claim 1 wherein delivering the safe bolus dose further comprises:

splitting the safe bolus dose into multiple staged doses delivered at predetermined times after notification of the meal event.

10. The drug delivery system of claim 9 wherein the safe bolus dose is recalculated at each staged delivery.

11. The drug delivery system of claim 1 wherein the notification of a meal event comprises an automatic detection of ingestion of a meal based on blood glucose levels of the user received from a continuous glucose monitor.

12. The drug delivery system of claim 11 wherein the automatic detection of the ingestion of a meal is based on detection of a significant increase in the user's blood glucose levels and a significant increase in automatic delivery of a liquid drug as calculated by a medication delivery algorithm of the drug delivery system.

13. The drug delivery system of claim 12 wherein the increase in the user's blood glucose levels and the increase in the automatic delivery of the liquid drug are evaluated for a moving window of a predetermined width evaluated each time a new blood glucose reading is received from the continuous glucose monitor.

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14. The drug delivery system of claim 11 wherein the automatic detection of the ingestion of a meal is based on an analysis of the plot of the user's blood glucose levels by one or more machine learning models trained as meal detection classifiers.
15. The drug delivery system of claim 14 wherein the one or more machine learning models are trained to detect post-prandial rises in blood glucose levels of the user beginning at various times prior to the current time.
16. The drug delivery system of claim 15 wherein the one or more machine learning models comprise a 10-minute detector, a 15-minute detector and a 20-minute detector, wherein the one or more machine learning models are cascaded to provide a final determination of a meal ingestion.
17. The drug delivery system of claim 11 wherein the automatic detection of the ingestion of a meal is based on an analysis of the plot of the user's blood glucose levels by one or more decision trees that use multiple delay detectors to recognize rising blood glucose values with an assumption that a rise in the blood glucose levels started at various times prior to the current time.
18. The drug delivery system of claim 17 wherein the results of the multiple delay detectors are pooled to synthesize a final meal detection decision.
19. The drug delivery system of claim 1 wherein, in response to the notification of the meal event, the method further comprises:

informing the user of the unannounced detection of a meal; and
providing a recommended bolus dose to the user.

20. The drug delivery system of claim 1 wherein, in response to the notification of the meal event, the method further comprises:

adjusting a medication delivery algorithm of the drug delivery system to respond more aggressively to glucose deviations based on the recommended bolus dose.

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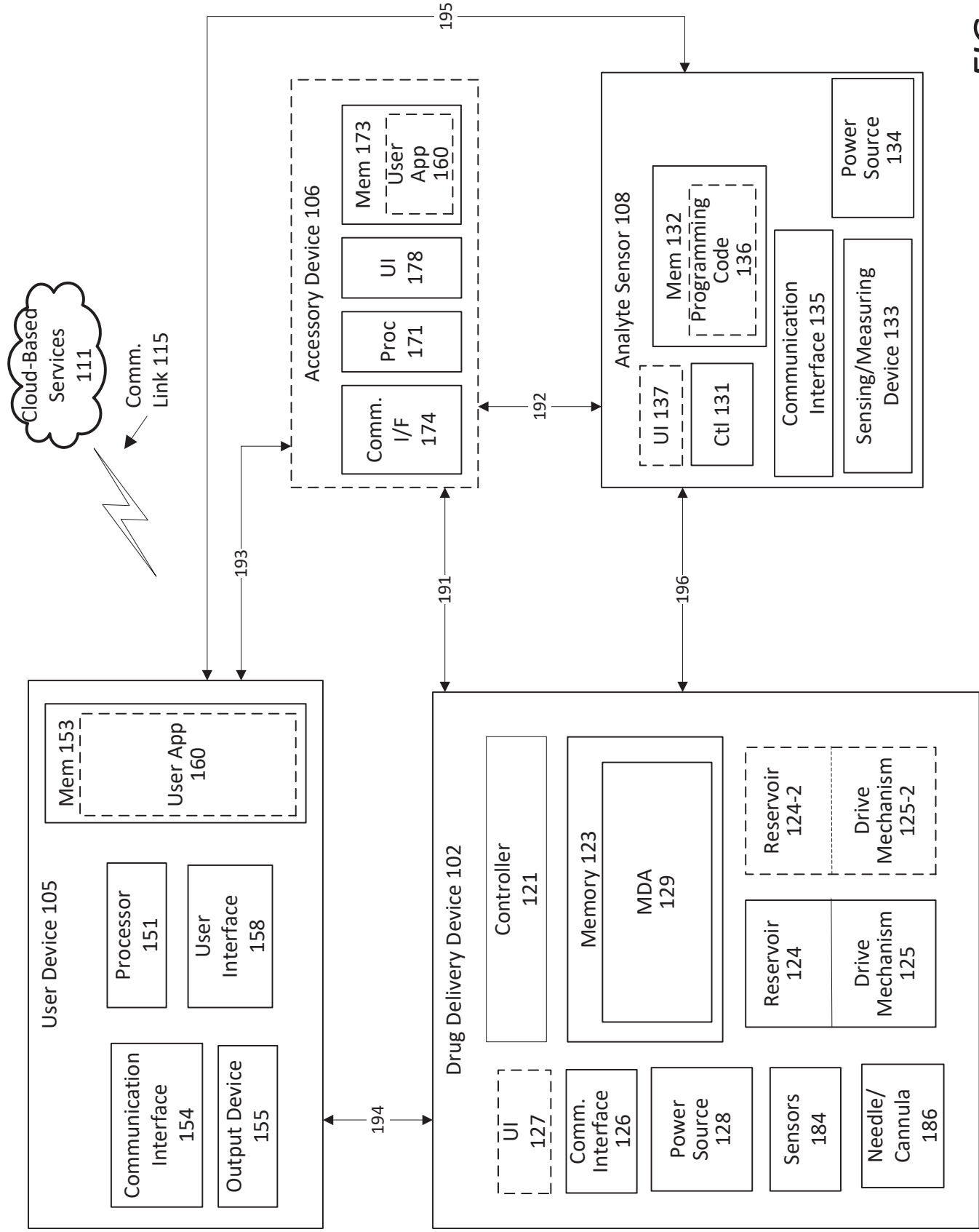


FIG. 1

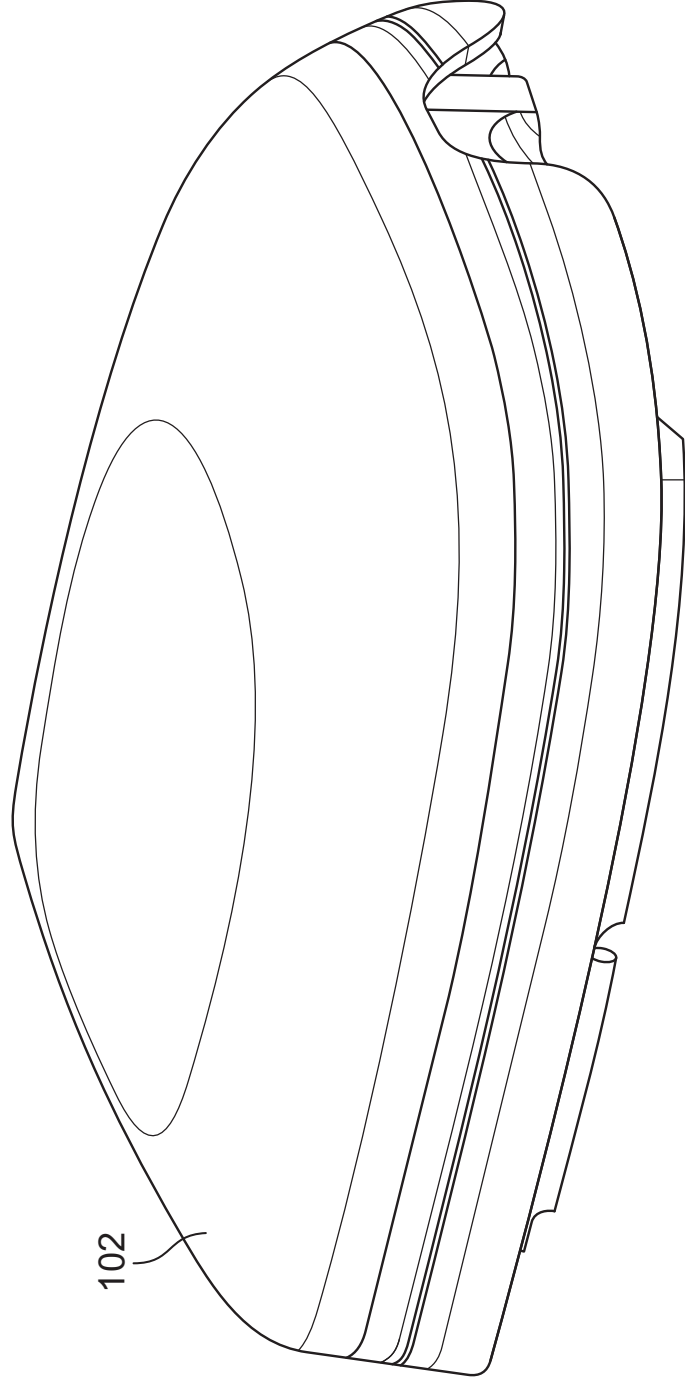


FIG. 2

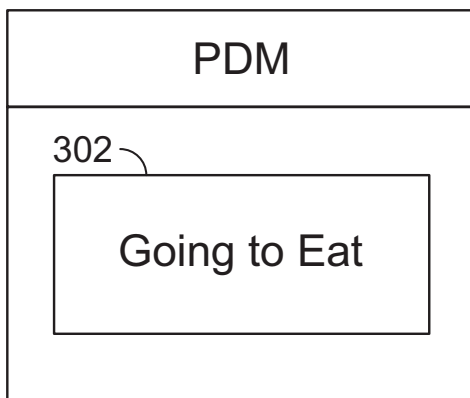


FIG. 3

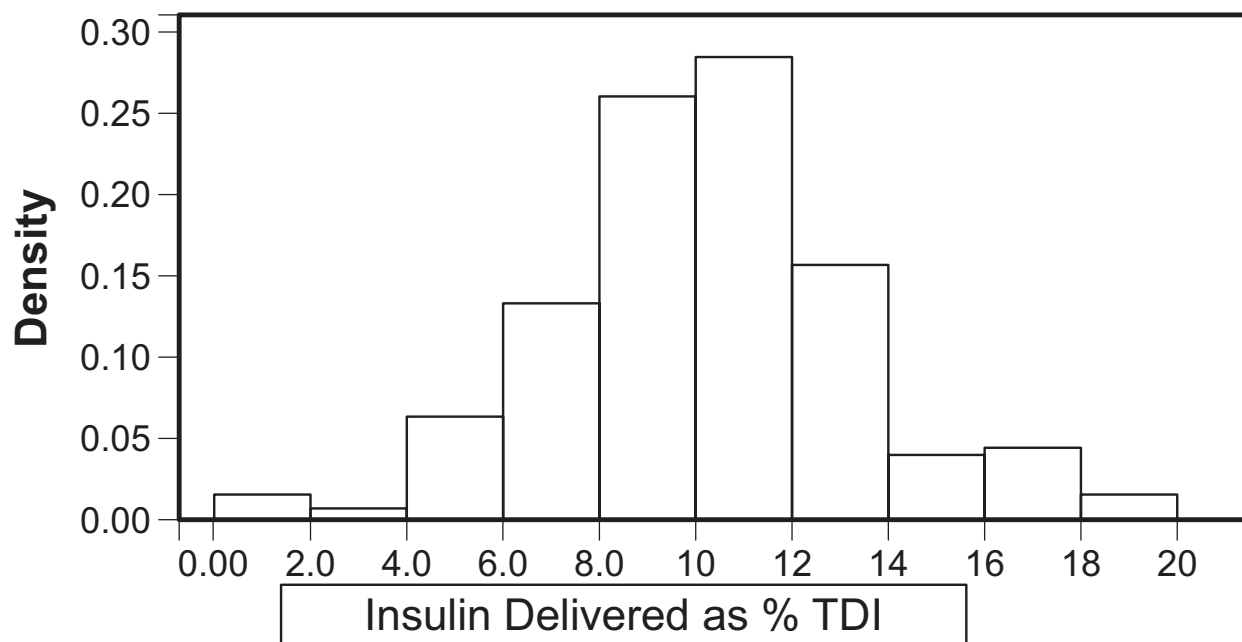


FIG. 4

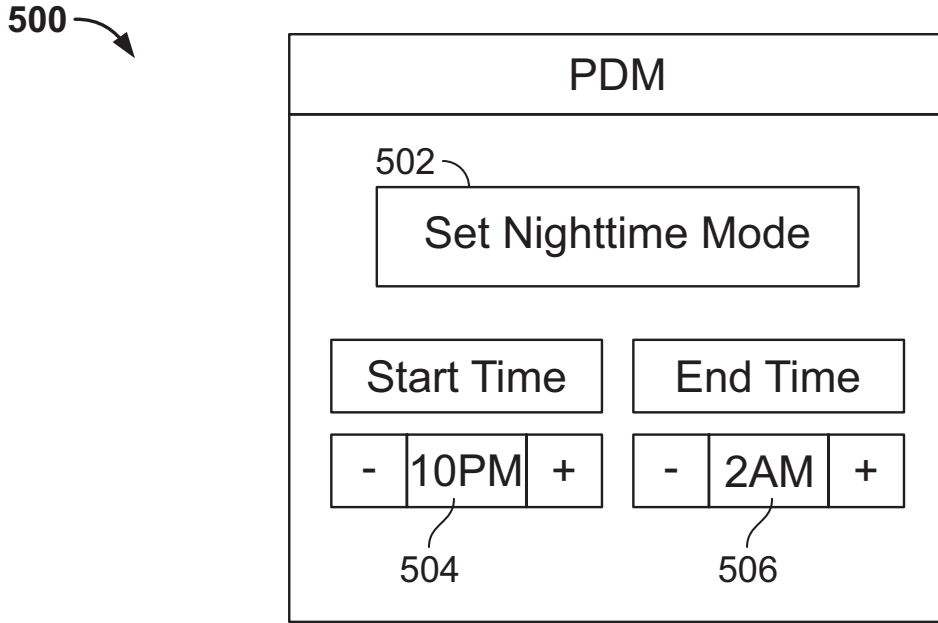


FIG. 5

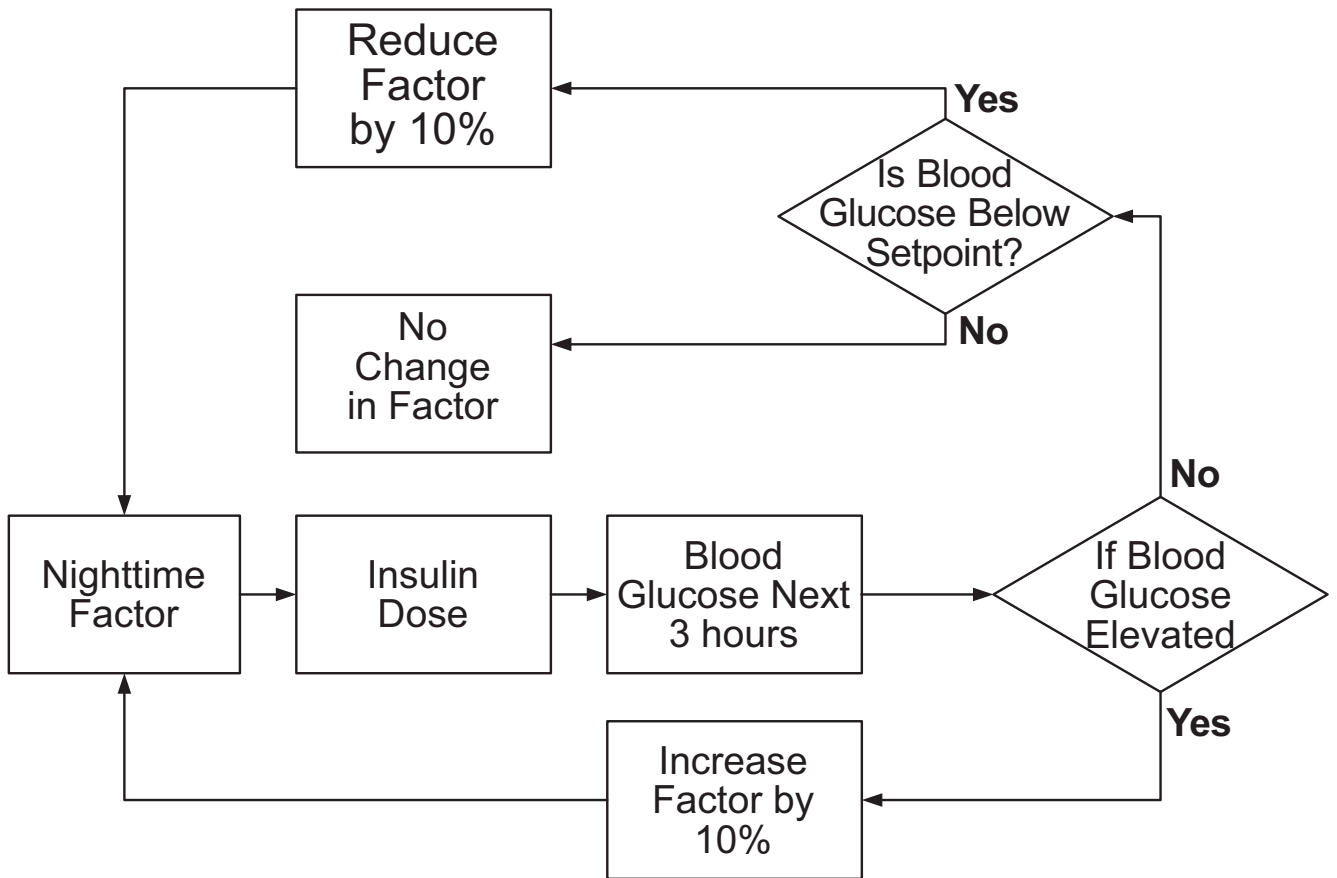


FIG. 6

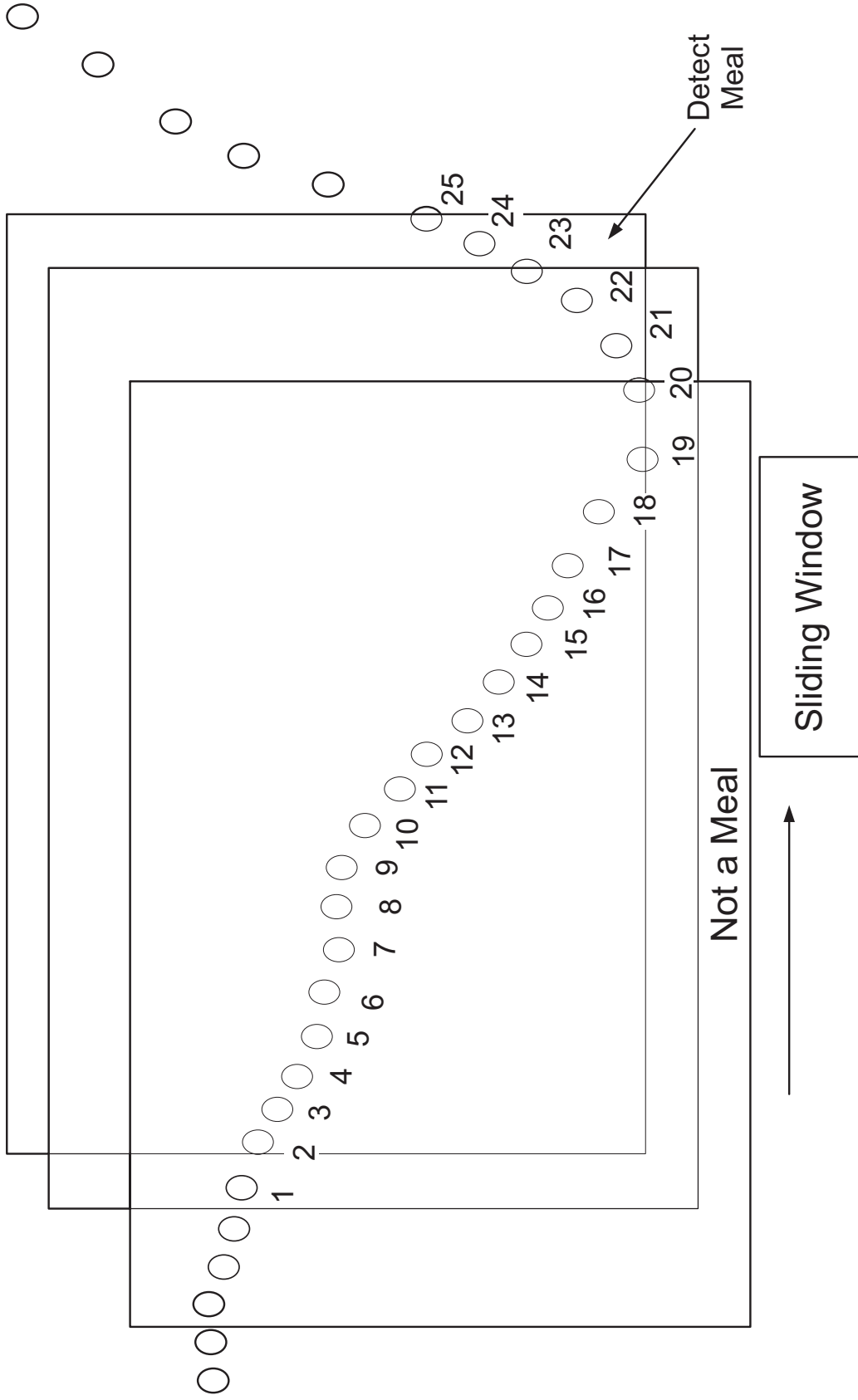


FIG. 7

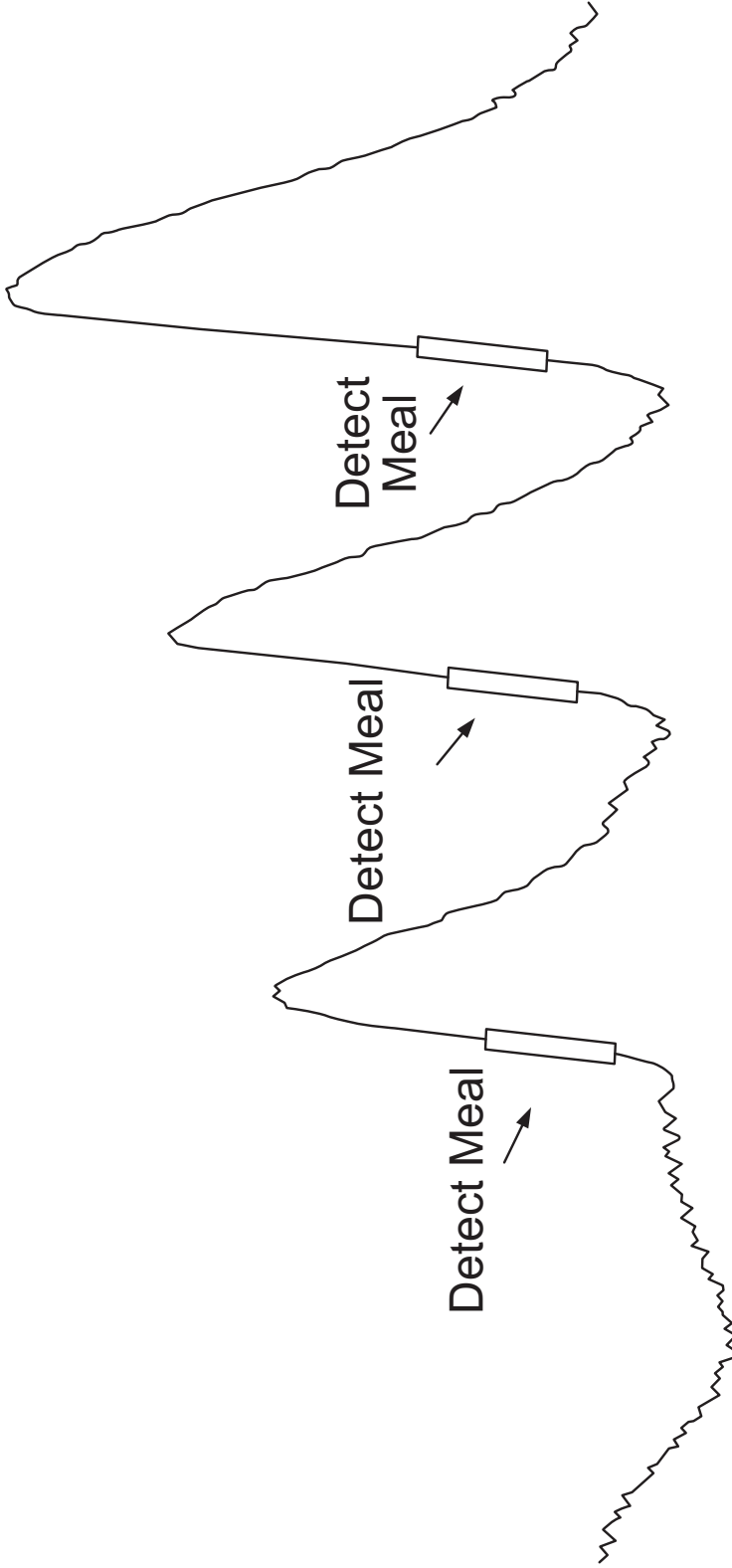


FIG. 8

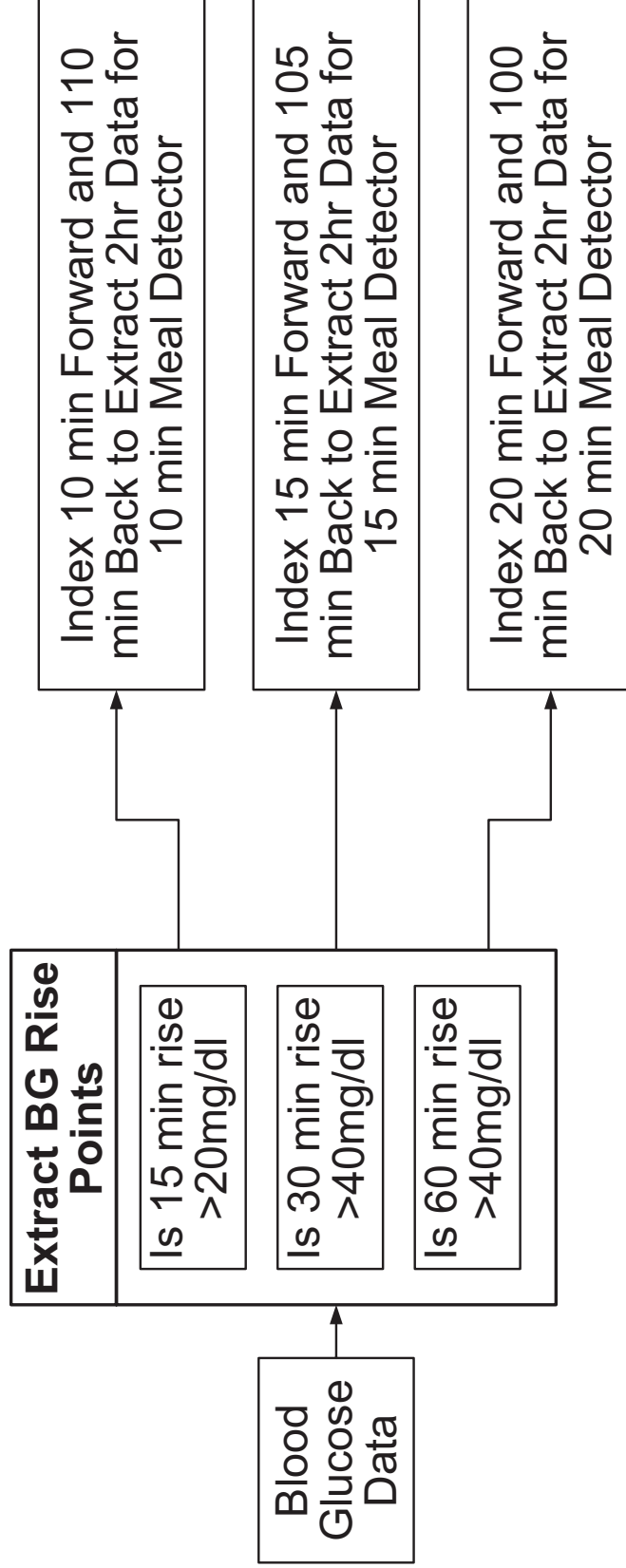


FIG. 9

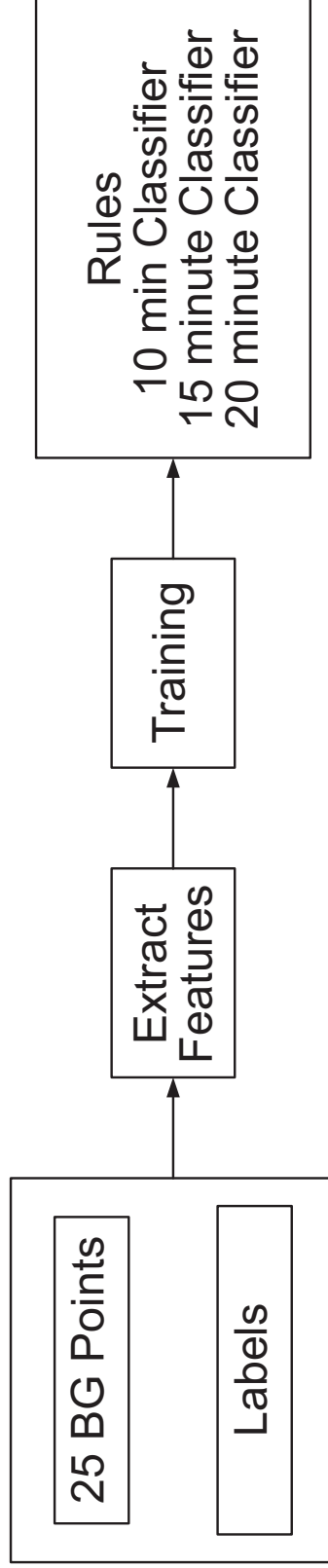


FIG. 10

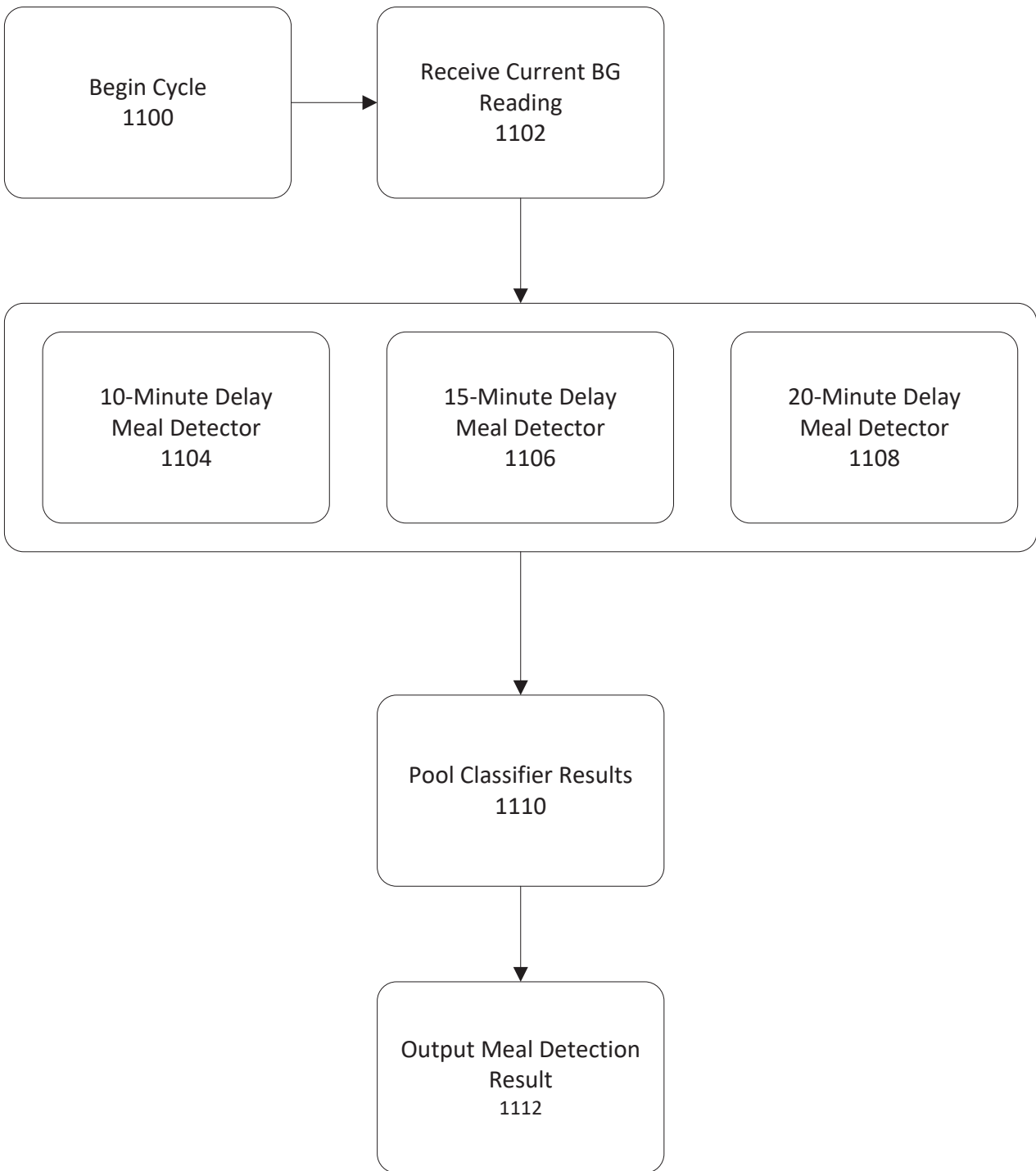


FIG. 11

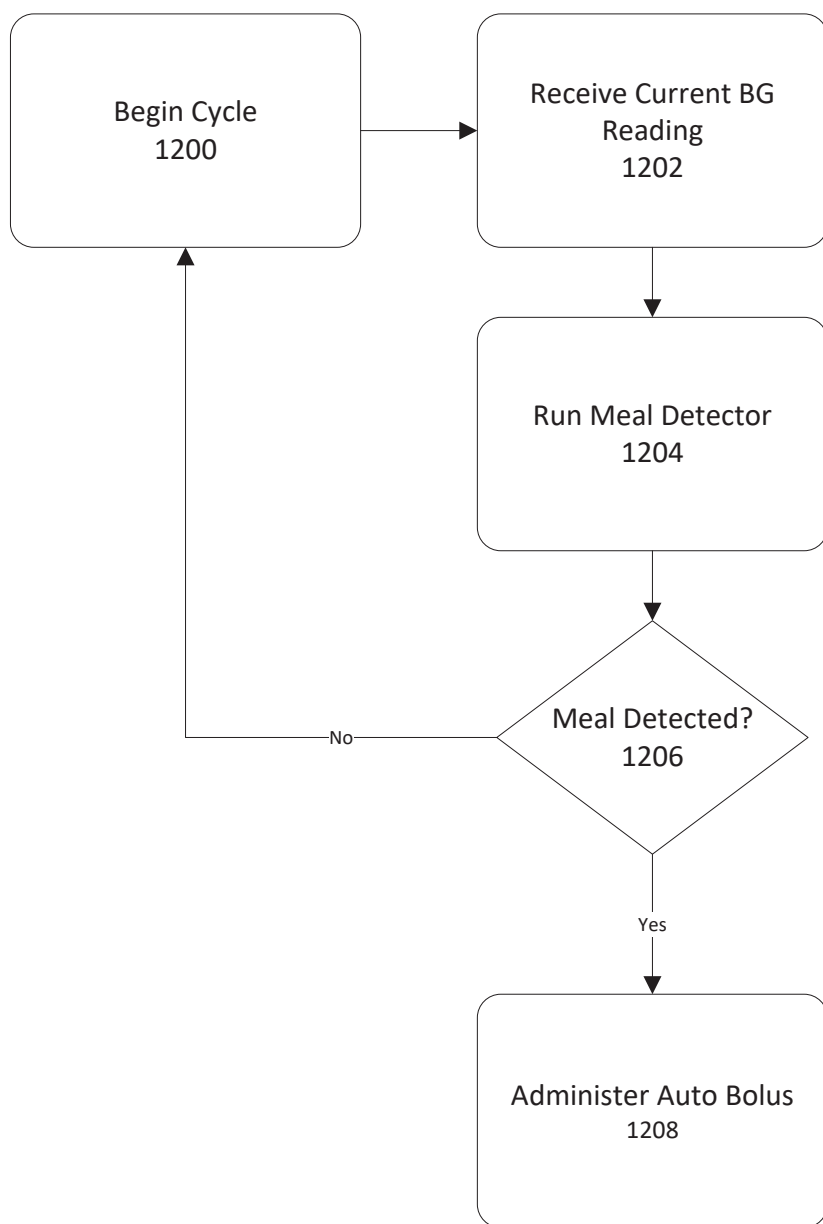


FIG. 12