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(54) **MEDICAMENT ADAPTATION AND SAFETY MONITORING**

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(57) **ABSTRACT**

Disclosed are exemplary drug delivery systems that include controllers, drug delivery devices, and the like. The disclosed drug delivery system and controllers may include a processor, a user interface, a memory, and communication circuitry. An automated drug delivery algorithm is operable to receive a number of different inputs related to a user's glucose and/or ketone levels. The automated drug delivery algorithm(s) of the described drug delivery systems and controllers are operable to adjust to when a user partakes in fasting for a period of time that lasts a day or multiple days. The period of time may be a fasting event, such as a religious holiday or diet regimen. For example, the disclosed automated drug delivery algorithm(s) are operable to receive an indication of initiation of a fasting mode; and modify a drug delivery schedule based on the period of fasting or while in fasting mode.
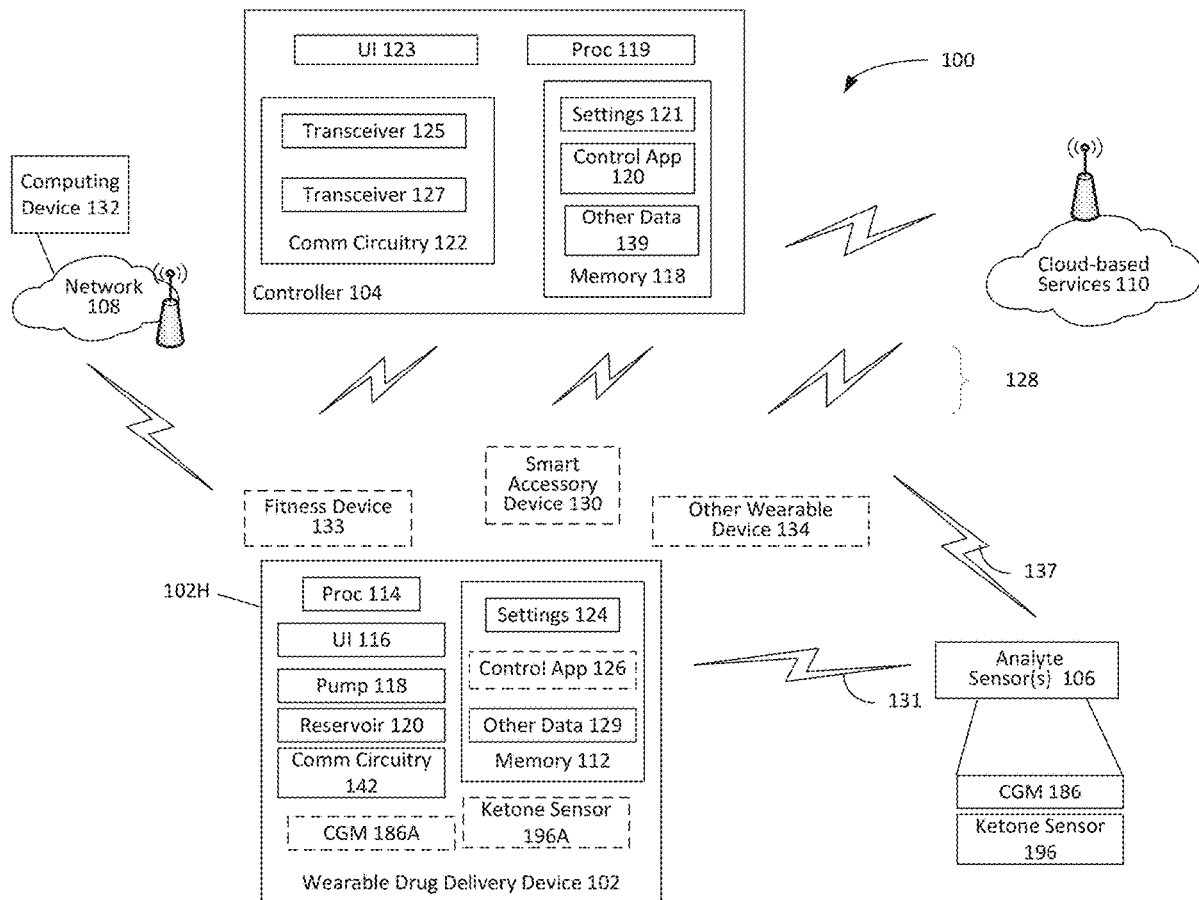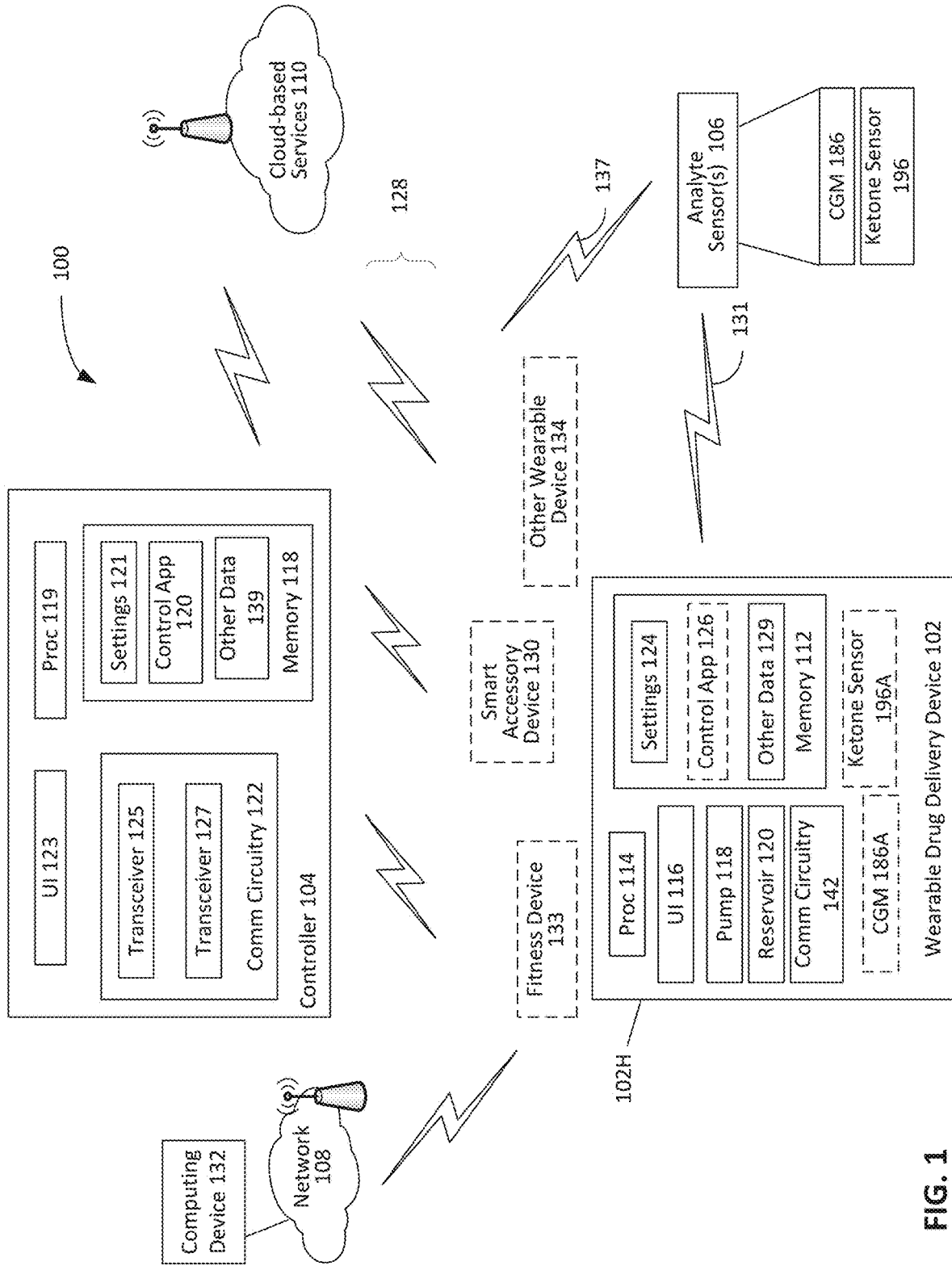
FIG. 1

FIG. 2

Sehar & Iftar Time April / May 2022

Fiqh Jafria: Suhoor Time -10min | Iftar Time + 10min

☾	Day	Sehar	Dhuhr	Asr	Iftar	Isha
1	02, Sat	04:14 AM	11:53 AM	03:24 PM	**06:08 PM**	07:38 PM
2	03, Sun	04:14 AM	11:53 AM	03:24 PM	**06:08 PM**	07:38 PM
3	04, Mon	04:12 AM	11:52 AM	03:24 PM	**06:09 PM**	07:39 PM
4	05, Tue	04:10 AM	11:52 AM	03:24 PM	**06:10 PM**	07:40 PM
5	06, Wed	04:09 AM	11:52 AM	03:24 PM	**06:10 PM**	07:40 PM
6	07, Thu	04:08 AM	11:51 AM	03:24 PM	**06:11 PM**	07:41 PM
7	08, Fri	04:07 AM	11:51 AM	03:24 PM	**06:12 PM**	07:42 PM

FIG. 3

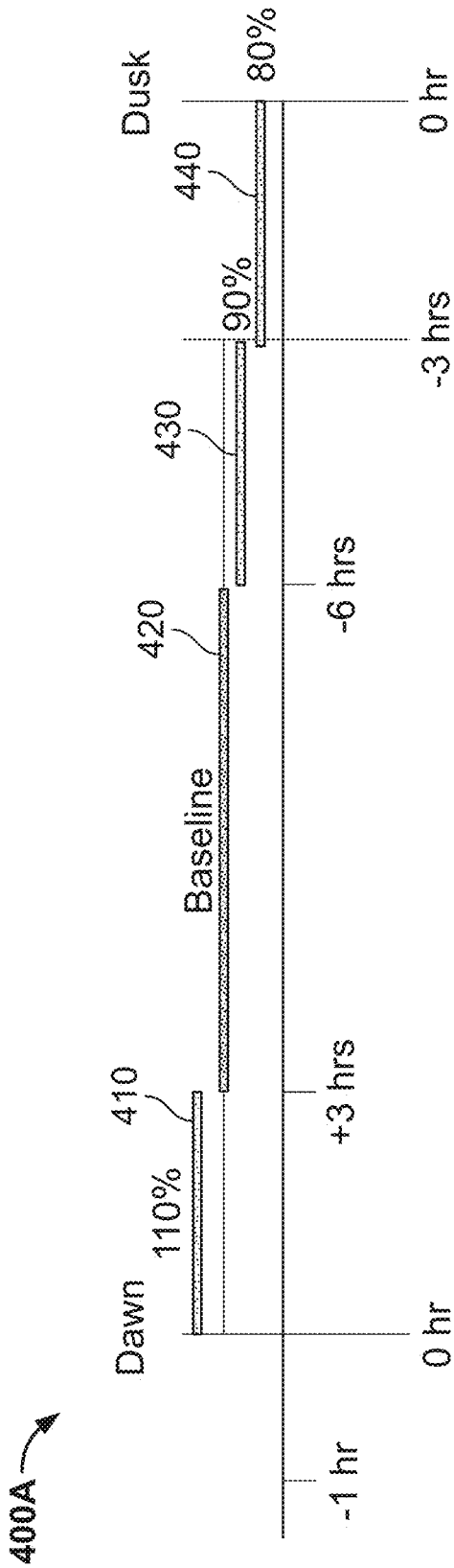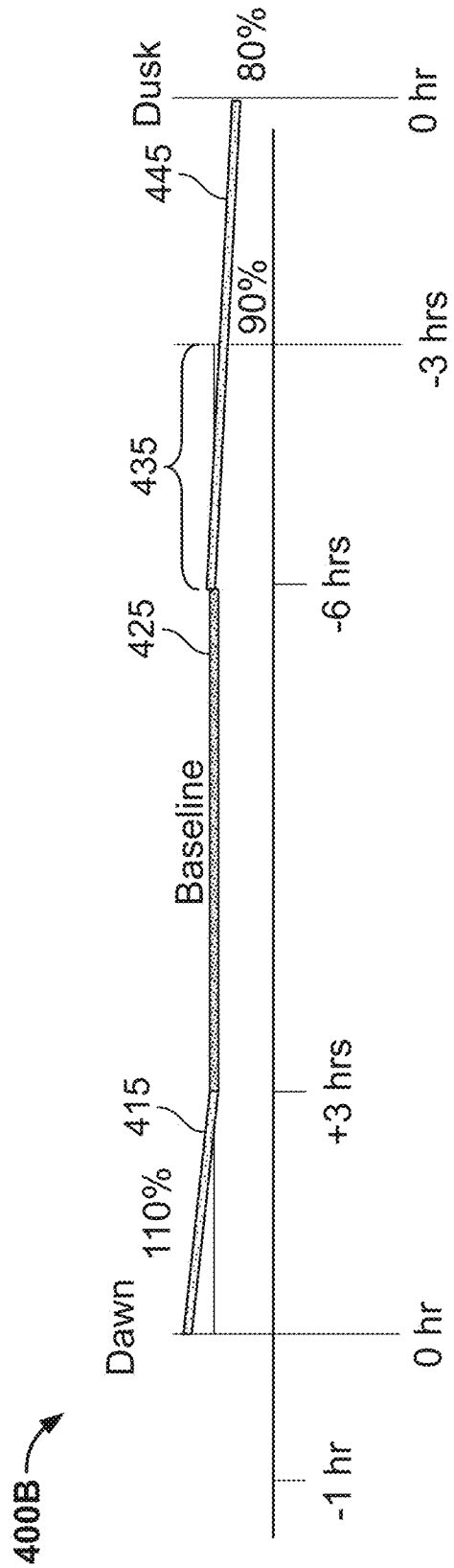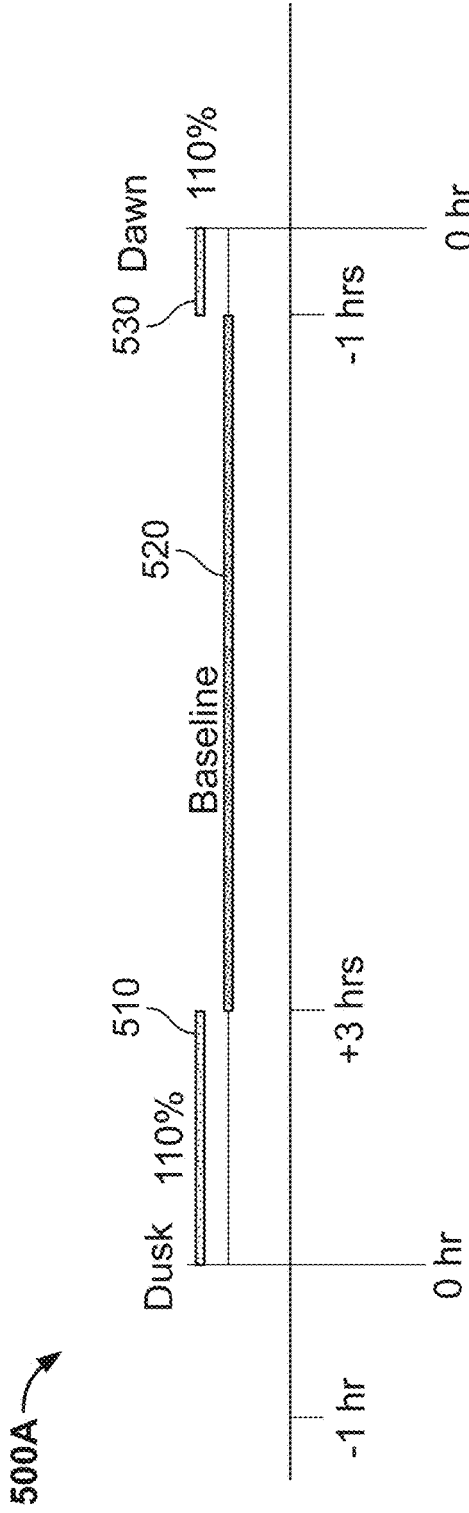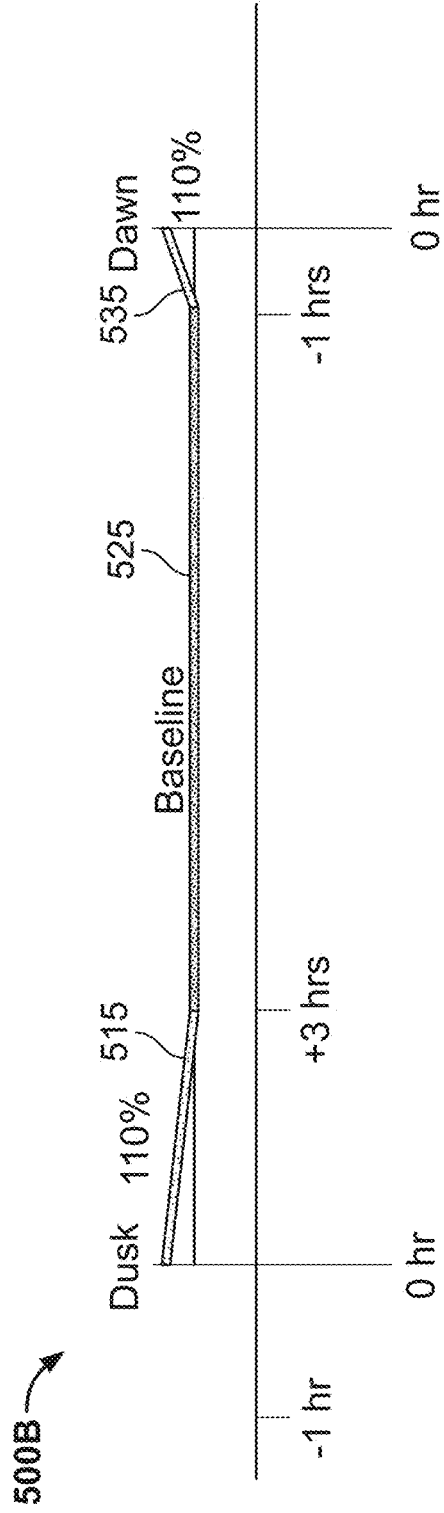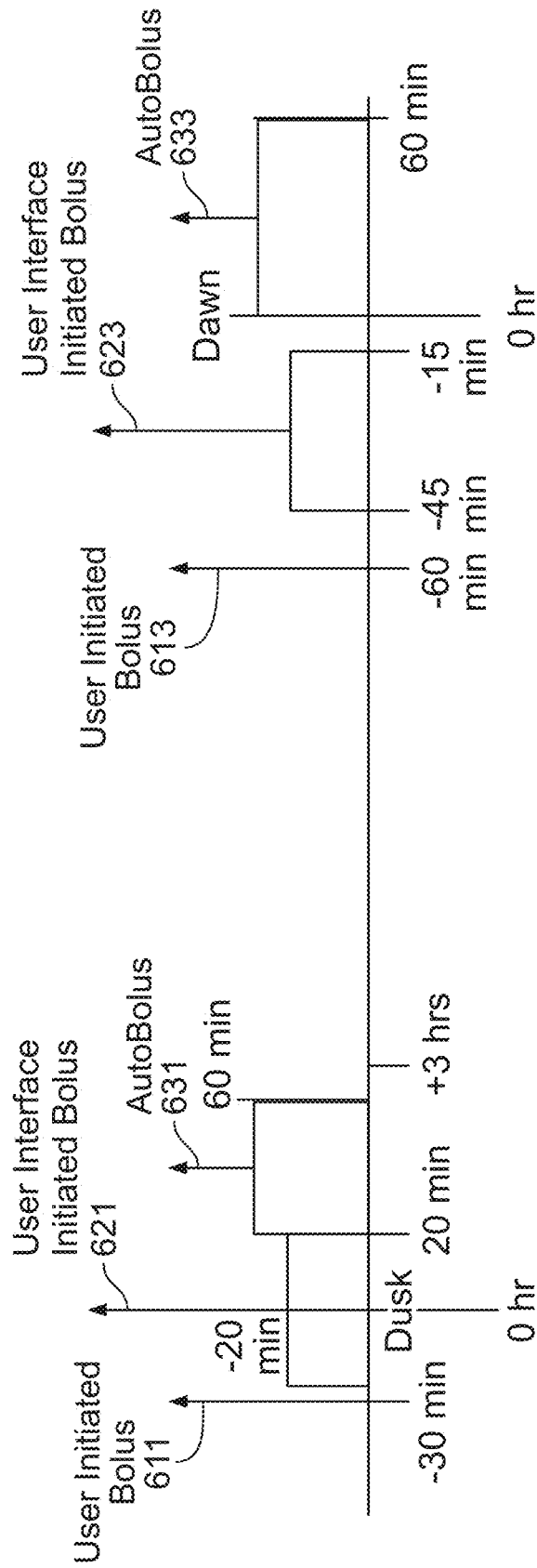FIG. 4A

FIG. 4B

FIG. 5A

FIG. 5B

FIG. 6

FIG. 7

FIG. 8

900

911 — Activity Level

913 — Blood Glucose

920 — HypoAlert
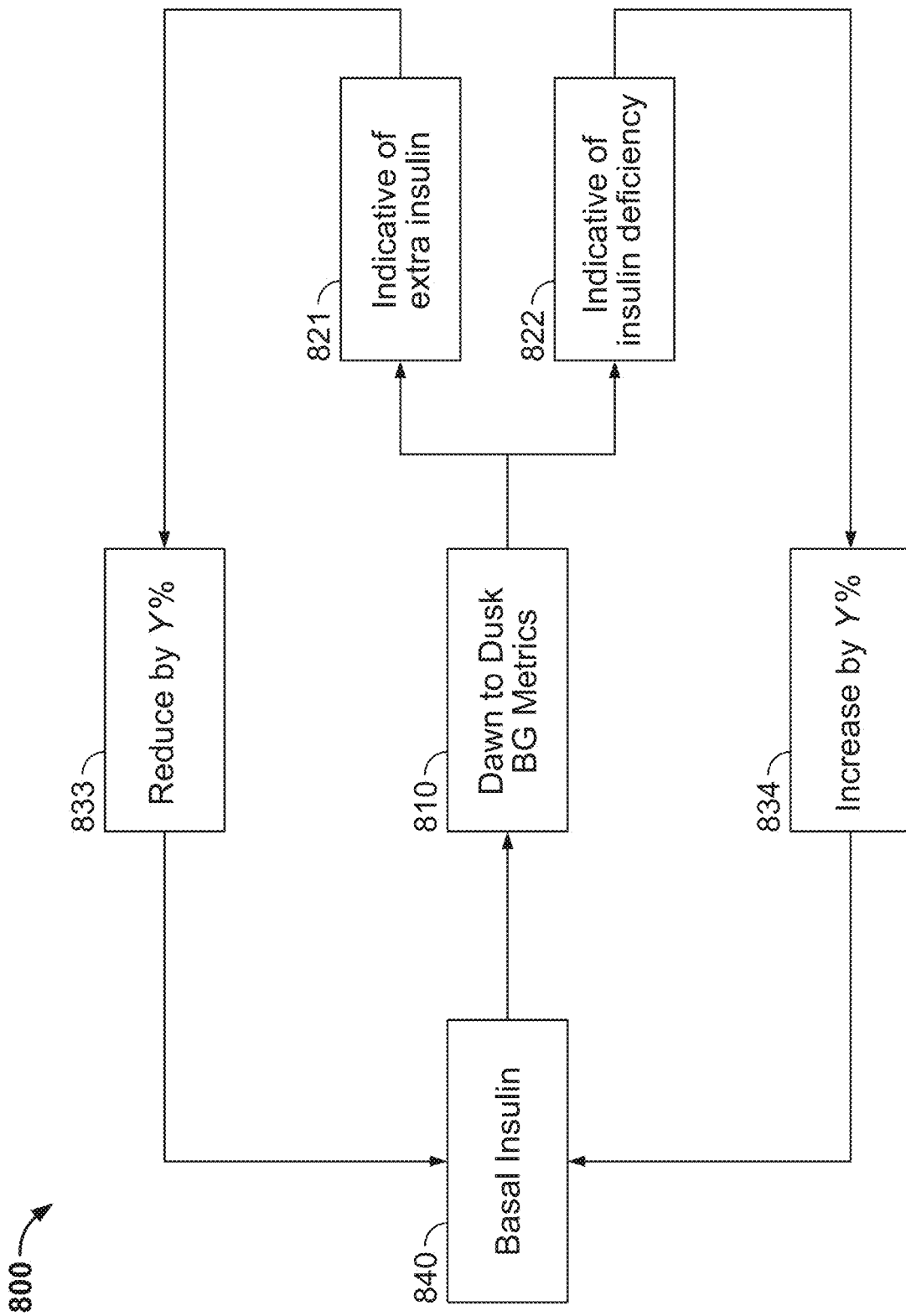
933 —
- Take Rest
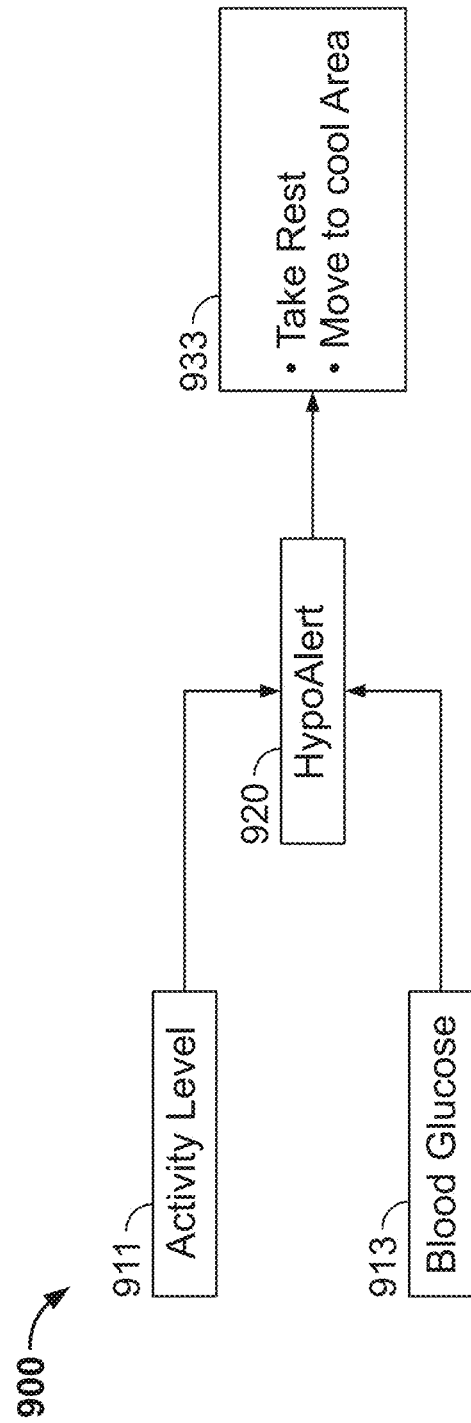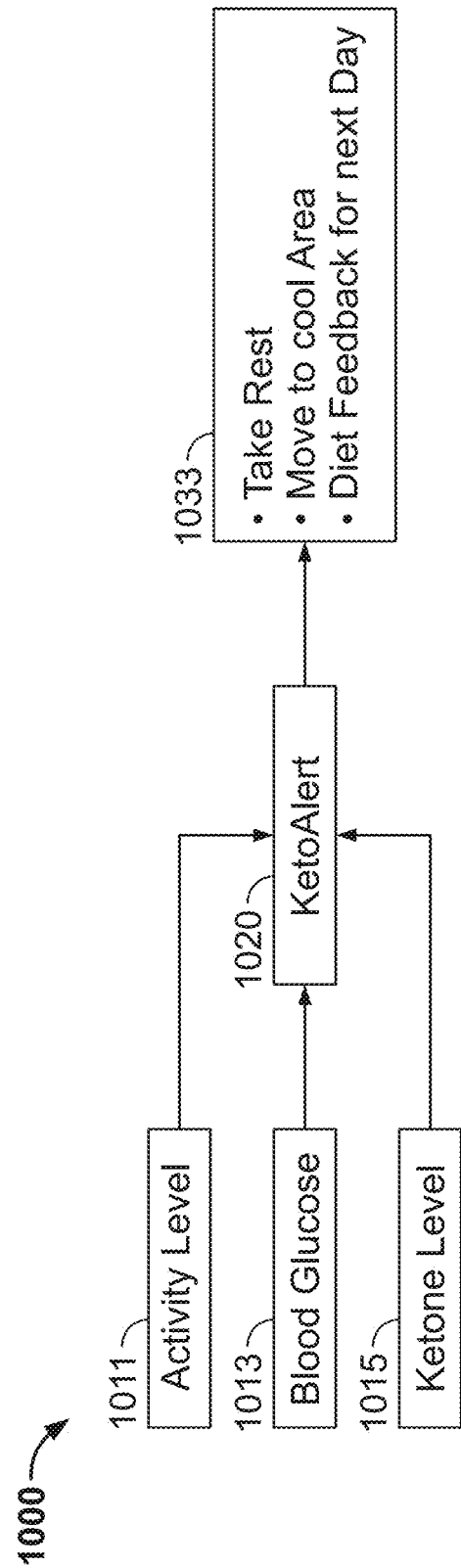- Move to cool Area
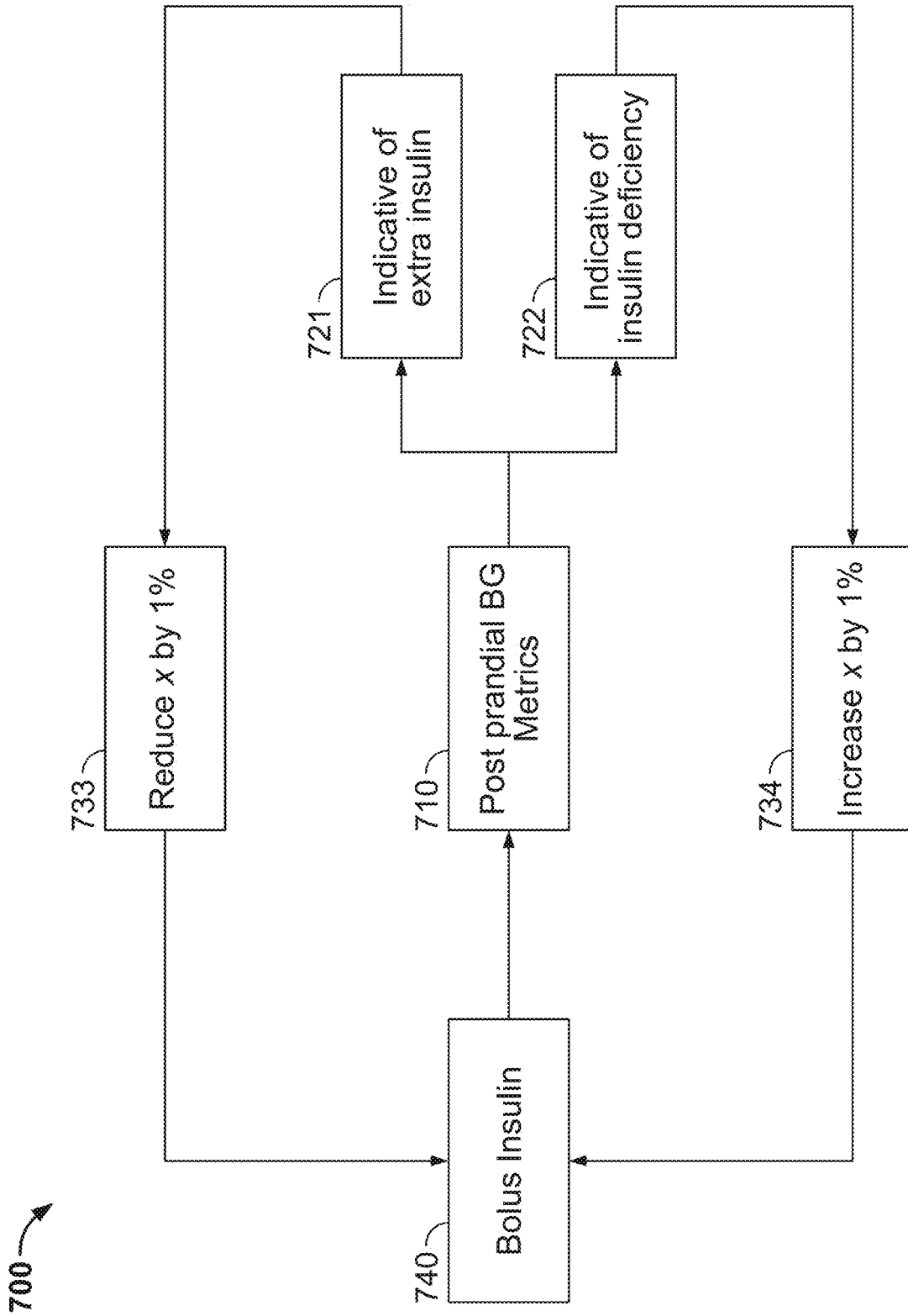
FIG. 9

FIG. 10

MEDICAMENT ADAPTATION AND SAFETY MONITORING

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/333,149, filed Apr. 21, 2022, the entire contents of which are incorporated herein by reference in their entirety.

BACKGROUND

[0002] Assessment of the performance of a medication delivery algorithm, such as automated drug delivery (ADD) algorithms, are often executed in a stepwise process, where a significant amount of drug delivery data and glucose measurement data is processed. Changes in the ADD algorithm that can result in improved glucose control outcome.

[0003] Fasting over predictive patterns changes insulin requirements. The specific challenges in diabetic patients when fasting is used as part of a dieting technique may potentially induce changes in glucose metabolism and drug sensitivity because the fasting may entail distinctive changes in food and fluids consumption. Similarly, the undertaking of fasting during a religious event, such as Ramadan, Lent, Passover, or a similar event may impact blood glucose measurement data over a lengthy period of time (e.g., 1 month). Diabetes patients who fast are predisposed to excessive glycogenolysis, gluconeogenesis and increased ketogenesis. Risks for hypoglycemia, hyperglycemia, diabetic ketoacidosis, and dehydration are elevated.

[0004] It would be beneficial if there were processes and systems to adapt medication delivery during fasting periods and non-fasting periods as well as processes and systems to monitor a user's safety as they undertake periods of fasting.

BRIEF SUMMARY

[0005] 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.

[0006] Disclosed is a controller of a drug delivery system. The controller includes a processor, a user interface, a memory, and a communication circuitry. The processor is operable to execute programming instructions. The user interface includes a display and user input circuitry. The memory is operable to store the programming instructions. The communication circuitry is coupled to the processor operable to receive and transmit wireless communication signals. The processor is operable to receive, via the user interface, an indication of a fasting event or a period of fasting for a user; and modify a drug delivery schedule based on the fasting event or the period of fasting, where such modifications can occur before, during, and/or after the period of fasting or fasting event.

[0007] In a further exemplary aspect, a drug delivery system is provided. The drug delivery system includes a processor, a user interface, a memory, and a communication circuitry. The processor is operable to execute programming instructions. The user interface includes a display and user input circuitry. The memory is operable to store the programming instructions. The communication circuitry is coupled to the processor operable to receive and transmit wireless communication signals. The processor is operable to receive, via the user interface, an indication of a period of fasting for a user; and modify a drug delivery schedule based on the period of fasting.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 illustrates an example of a system that is suitable to implement the subject matter described herein.

[0009] FIG. 2 illustrates another block diagram of the graphical user interface suitable for use to indicate fasting.

[0010] FIG. 3 illustrates an example of a portion of a calendar suitable for use by a fasting application in the examples disclosed herein.

[0011] FIG. 4A illustrates an example of a dawn-to-dusk basal modulation delivery schedule according to the disclosed subject matter.

[0012] FIG. 4B illustrates an alternative example of a dawn-to-dusk basal delivery schedule modulated according to the disclosed subject matter.

[0013] FIG. 5A illustrates an example of a dusk-to-dawn basal delivery schedule modulated according to the disclosed subject matter.

[0014] FIG. 5B illustrates an alternative example of a dusk-to-dawn basal delivery schedule modulated according to the disclosed subject matter.

[0015] FIG. 6 illustrates an example of a bolus delivery schedule according to the examples discussed with reference to FIGS. 2 and 3.

[0016] FIG. 7 illustrates a flowchart of an example process for adjusting bolus insulin based on the excursions in the glucose measurements.

[0017] FIG. 8 illustrates a flowchart of an example process for adjusting basal insulin based on the excursions in the glucose measurements.

[0018] FIG. 9 is a process flow diagram illustrating the process flow that monitors for hypoglycemia and generates alerts based on the results of the monitoring.

[0019] FIG. 10 is a process flow diagram illustrating the process flow that monitors for excessive ketone levels and generates alerts based on the results of the monitoring.

DETAILED DESCRIPTION

[0020] The following discussion provides a framework of an ADD algorithm to adjust to when a user partakes in fasting for a period of time, which may last for a period of hours or for multiple days.

[0021] A type of medication delivery algorithm (MDA) may include an "artificial pancreas" algorithm-based system, or more generally, an artificial pancreas (AP) application. For ease of discussion, the computer programs and computer applications that implement the medication delivery algorithms or applications may be referred to herein as an "AP application," an "ADD algorithm," or an "MDA." An AP application may be configured to provide automated delivery of medicament based on an analyte sensor(s) input, such as signals received from an analyte sensor(s), such as a continuous glucose monitor, ketone sensor or the like. The signals from the analyte sensor(s) may contain glucose measurement values, ketone measurement values, timestamps, or the like.

[0022] In addition, or alternatively, while the disclosed examples may have been described with reference to a closed loop algorithmic implementation, variations of the

disclosed examples may be implemented to enable open loop or hybrid closed loop use. These implementations allow for use of different modalities of delivery of insulin such as smart pen, syringe or the like. For example, the disclosed AP application and algorithms may be operable to perform various functions related to open loop operations, such as the generation of prompts requesting the input of information such as diabetes type, weight, or age. Similarly, a requested dosage amount of medicament, such as insulin, may be received by the AP application or algorithm from a user via a user interface. Other open-loop actions may also be implemented by adjusting user settings or the like in an AP application or algorithm.

[0023] Systems, devices, computer readable media and methods in accordance with the present disclosure are now described more fully hereinafter with reference to the accompanying drawings, where one or more examples are shown. The systems, devices, and methods described herein may be embodied in many different forms and are not to be construed as being limited to the examples set forth herein. Instead, these examples are provided so the disclosure is thorough and complete, and may fully convey the scope of the techniques and devices to those skilled in the art. Each of the systems, devices, media, and methods disclosed herein provides one or more advantages over conventional systems, components, and methods.

[0024] FIG. 1 illustrates an exemplary drug delivery system operable to implement the examples disclosed herein.

[0025] In some examples, the drug delivery system 100 is suitable for delivering a liquid medicament, such as insulin to a user in accordance with the disclosed embodiments. The drug delivery system 100 may include a wearable drug delivery device 102, a controller 104 and an analyte sensor (s) 106.

[0026] The wearable drug delivery device 102 may be a wearable device that is worn on the body of the user. The wearable drug delivery device 102 may be directly coupled to a user (e.g., directly attached to a body part and/or skin of the user via an adhesive, or the like). In an example, a surface of the wearable drug delivery device 102 may include an adhesive to facilitate attachment to the skin of a user.

[0027] The wearable drug delivery device 102 may include a processor 114. The processor 114 may be implemented in hardware, software, or any combination thereof. The processor 114 may, for example, be a microprocessor, a logic circuit, a field programmable gate array (FPGA), an application specific integrated circuit (ASIC) or a microprocessor coupled to a memory. The processor 114 may maintain a date and time as well as be operable to perform other functions (e.g., calculations or the like). The processor 114 may be operable to execute a control application 126 stored in the memory 112 that enables the processor 114 to direct operation of the wearable drug delivery device 102. The control application 126 may control insulin delivery to the user per an ADD control approach as describe herein. For example, the control application 126 may be an ADD algorithm. The memory 112 may hold settings 124 for a user, such as ADD algorithm settings, such as maximum insulin delivery, insulin sensitivity settings, total daily insulin (TDI) settings and the like. The memory may also store other data 129, such as ketone values, total daily insulin values, glucose measurement values from analyte sensor(s) 106 or controller 104, insulin dosage amounts (both basal and

bolus) and the like from previous minutes, hours, days, weeks, or months. The analyte sensor(s) 106 may be operable to collect physiological condition data, such as ketone values, ketone values with a time stamp, glucose measurement values (also referred to herein as "blood glucose values" or "blood glucose"), glucose measurement values and a timestamp, both ketone values and glucose values that may be shared with the wearable drug delivery device 102, the controller 104 or both. In an additional example, the analyte sensor(s) 106 may include multiple sensors, such as a continuous glucose monitor 186 and a ketone sensor(s) 196. In a further example, the wearable drug delivery device 102 may optionally include a continuous glucose monitor 186A and a ketone sensor 196A, which may be removably incorporated or fully integrated within the wearable drug delivery device 102. For example, the continuous glucose monitor 186A and the ketone sensor 196A may be incorporated in one or more housings 102H of the wearable drug delivery device 102. Note that ketones may also be detected using a breath sensor (which is not shown but may be incorporated in the controller 104) or urine content sensor and stored in the respective memories 118 and 112 via a user input of the ketone levels; however, a subcutaneous ketone sensor(s) gives more accurate information and is more continuous. As described herein, the MDA and ADD system is described based on receiving ketone values received subcutaneously. Use of a ketone breath sensor or urine sensor as part of or in addition to the analyte sensor(s) 106 may delay receipt of the ketone values and modifications to the system 100 may be made.

[0028] For example, the communication circuitry 142 of the wearable drug delivery device 102 may be operable to communicate with the analyte sensor(s) 106 and the controller 104 as well as the devices 130, 133 and 134. The communication circuitry 142 may be operable to communicate via Bluetooth, cellular communication, near field communication (NFC) and/or other wireless protocols. While not shown, the memory 112 may include both primary memory and secondary memory. The memory 112 may include random access memory (RAM), read only memory (ROM), optical storage, magnetic storage, removable storage media, solid state storage or the like.

[0029] The wearable drug delivery device 102 may include a reservoir 120. The reservoir 120 may be operable to store liquid drugs, medicaments, or therapeutic agents suitable for automated delivery, such as, insulin, glucagon-like peptide-1 (GLP-1) receptor agonist, pramlintide, glucose-dependent insulinotropic polypeptide (GIP), other hormones, or co-formulations of two or more of glucagon, GLP-1, pramlintide, and insulin; as well as pain relief drugs, such as opioids or narcotics (e.g., morphine, or the like), methadone, blood pressure medicines, chemotherapy drugs, fertility drugs, or the like.

[0030] A fluid path to the user may be provided via tubing and a needle/cannula (not shown). The fluid path may, for example, include tubing coupling the wearable drug delivery device 102 to the user (e.g., via tubing coupling a needle or cannula to the reservoir 120). The wearable drug delivery device 102 may be operable based on control signals from the processor 114 to expel the liquid drugs, medicaments, or therapeutic agents, such as insulin, from the reservoir 120 to deliver doses of the drugs, medicaments, or therapeutic agents, such as the insulin, to the user via the fluid path. The

processor **114** may be operable to cause insulin to be expelled from the reservoir **120**.

[0031] There may be one or more communications links **128** with one or more devices physically separated from the wearable drug delivery device **102** including, for example, a controller **104** of the user and/or a caregiver of the user and/or a sensor(s) **106**. The communication links **128** may include any wired or wireless communication link operating according to any known communications protocol or standard, such as Bluetooth®, NFC, Wi-Fi, a near-field communication standard, a cellular standard, or any other wireless protocol. The analyte sensor(s) **106** may communicate with the wearable drug delivery device **102** via a wireless communication link **131** and/or may communicate with the controller **104** via a wireless communication link **137**.

[0032] The wearable drug delivery device **102** may also include a user interface **116**, such as an integrated display device for displaying information to the user, and in some embodiments, receiving information from the user. For example, the user interface **116** may include a touchscreen and/or one or more input devices, such as buttons, knob(s), or a keyboard that enable a user to provide an input.

[0033] In addition, the processor **114** may be operable to receive data or information from the analyte sensor(s) **106** as well as other devices that may be operable to communicate with the wearable drug delivery device **102**.

[0034] The wearable drug delivery device **102** may interface with a network **108**. The network **108** may include a local area network (LAN), a wide area network (WAN) or a combination therein. A computing device **132** may be interfaced with the network, and the computing device may communicate with the insulin delivery device **102**. The computing device **132** may be a healthcare provider device through which a user's controller **104** may interact to obtain information, store settings and the like. The ADD algorithm operating, as or in cooperation with, the control application **120** may present a graphical user interface on the computing device **132** enabling the input and presentation of information related to the ADD algorithm and the example techniques and processes described herein.

[0035] The drug delivery system **100** may include an analyte sensor(s) **106** for sensing the levels of one or more analytes of a user. The analyte levels may be used as physiological condition data and be sent to the controller **104** and/or the wearable drug delivery device **102**. The sensor(s) **106** may be coupled to the user by, for example, adhesive or the like and may provide information or data on one or more medical conditions and/or physical attributes of the user. The sensor(s) **106** may be a continuous glucose monitor (CGM), ketone sensor, or another type of device or sensor(s) that provides glucose measurements and/or ketone measurements. The sensor(s) **106** may be physically separate from the wearable drug delivery device **102** or may be an integrated component thereof. The sensor(s) **106** may provide the processor **114** and/or processor **119** with physiological condition data indicative of measured or detected glucose levels of the user. The information or data provided by the sensor(s) **106** may be used to modify a medicament delivery schedule and thereby cause the adjustment of drug delivery operations of the wearable drug delivery device **102**.

[0036] The drug delivery system **100** may also include the controller **104**. In the depicted example, the controller **104** may include a processor **119** and a memory **118**. The

controller **104** may be a special purpose device, such as a dedicated personal diabetes manager (PDM) device. The controller **104** may be a programmed general-purpose device that is a portable electronic device, such as any portable electronic device, smartphone, smartwatch, fitness device, tablet or the like including, for example, a dedicated processor, such as processor, a micro-processor or the like. The controller **104** may be used to program or adjust operation of the wearable drug delivery device **102** and/or the sensor(s) **106**. The processor **119** may execute processes to control the delivery of the medicament, drug, or therapeutic agent to the user for the purpose of managing a user's blood glucose and/or ketone levels. The processor **119** may also be operable to execute programming code stored in the memory **118**. For example, the memory **118** may be operable to store a control application **120**, such as an ADD algorithm for execution by the processor **119**. The control application **120** may be responsible for controlling the wearable drug delivery device **102**, including the automated delivery of medicament, a drug, or therapeutic agent based on recommendations and instructions from the ADD algorithm, such as those recommendations and instructions described herein.

[0037] The memory **118** may store one or more applications, such as control application **120**, and settings **121** for the drug delivery device **102** like those described above. In addition, the memory **118** may be operable to store other data **139** and/or computer programs, such as drug delivery history, glucose measurement values over a period of time, total daily insulin values, ketone values, and the like. For example, the memory **118** is coupled to the processor **119** and operable to store programming instructions, such as the control application **120** and settings **121**, and data, such as other data **139**, related to a glucose of a user and/or data related to an amount of insulin expelled by the wearable drug delivery device **102**.

[0038] The controller **104** may include a user interface (UI) **123** for communicating with the user. The user interface **123** may include a display, such as a touchscreen, for displaying information. The touchscreen may also be used to receive input when it is a touch screen. The user interface **123** may also include input elements, such as a keyboard, button, knob or the like. In an operational example, the user interface **123** may include a touchscreen display (including a display and user input circuitry, such as touch sensitive circuits and the like) controllable by the processor **119** and be operable to present a graphical user interface and receive inputs via the user input circuitry, the touchscreen display may be operable to generate a signal indicative of the respective diet types, number of days, diet cycles, keto days, sick day mode, sickness symptoms, intermittent fasting mode, fasting mode, religious fasting mode, location information, calendar information, or the like. The touchscreen display, under control of the processor **119**, may be operable to, in response to the received input, generate a response to a user's drug treatment regimen as well as cause the presentation of prompts on a graphical user interface as described with reference to the later examples described with reference to FIGS. **2-10**. The graphical user interfaces discussed herein with respect to the later examples may be generated by the processor **119** of the controller **104** and be presented on the UI **123**.

[0039] The controller **104** may interface via a wireless communication link of the wireless communication links **128** with a network, such as a LAN or WAN or combination

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of such networks that provides one or more servers or cloud-based services **110** via communication circuitry **122**. The communication circuitry **122**, which may include transceivers **127** and **125**, may be coupled to the processor **119**. The communication circuitry **122** may be operable to transmit communication signals (e.g., command and control signals) to and receive communication signals (e.g., via transceivers **127** or **125**) from the wearable drug delivery device **102** and the analyte sensor(s) **106**. In an example, the communication circuitry **122** may include a first transceiver, such as **125**, that may be a Bluetooth transceiver, which is operable to communicate with the communication circuitry **122** of the wearable drug delivery device **102**, and a second transceiver, such as **127**, that may be a cellular or Wi-Fi transceiver operable to communicate via the network **108** with computing device **132** or with cloud-based services **110**.

[0040] The cloud-based services **110** may be operable to receive and store user history information, such as glucose measurement values over a set period of time (e.g., days, months, years), a drug delivery history that includes insulin delivery amounts (both basal and bolus dosages) and insulin delivery times, types of insulin delivered, indicated meal times, glucose measurement value trends or excursions or other user-related diabetes treatment information, specific factor settings including default settings, present settings and past settings, or the like.

[0041] Other devices, like smart accessory device **130** (e.g., a smartwatch or the like), fitness device **133** and other wearable device **134** may be part of the drug delivery system **100**. These devices may communicate with the wearable drug delivery device **102** to receive information and/or issue commands to the wearable drug delivery device **102**. These devices **130**, **133** and **134** may execute computer programming instructions to perform some of the control functions otherwise performed by processor **114** or processor **119**. These devices **130**, **133** and **134** may include user interfaces, such as touchscreen displays for displaying information such as current glucose level, medicament on board such as insulin on board, drug delivery history, or other parameters or treatment-related information and/or receiving inputs, such as those described with reference to the examples of FIGS. **1-10**. The display may, for example, be operable to present a graphical user interface for providing input, such as request a change in basal insulin dosage or delivery of a bolus of insulin. These devices **130**, **133** and **134** may also have wireless communication connections with the sensor(s) **106** to directly receive glucose level data or receive in parallel a presentation of the graphical user interface as shown in FIG. **1**.

[0042] In another operational example, the controller **104** may be operable to execute programming code that causes the processor **119** of the controller **104** to perform the following functions. The processor **119** of the controller **104** may execute an ADD algorithm that is one of the control applications **120** stored in the memory **118**. The processor may be operable to present graphical user interfaces as described herein on a user interface that is at least one component of the user interface **123**. The user interface **123** may be a touchscreen display controlled by the processor **119**, and the user interface **123** is operable to present a graphical user interface that offers an input of a subjective insulin need parameter usable by the ADD algorithm. The processor **119** may cause presentation on a user interface of

a user device, a graphical user interface offering an input device that enables input of a subjective medicament need parameter (e.g., subjective to the user, or based on the user's desire). The ADD algorithm may generate instructions for the pump **118** to deliver basal medicament to the user or the like.

[0043] The processor **119** is also operable to collect physiological condition data related to the user from sensors, such as the analyte sensor(s) **106** or heart rate data, for example, from the fitness device **133** or the smart accessory device **130**. In an example, the processor **119** executing the ADD algorithm may determine a dosage of medicament to be delivered based on the collected physiological condition of the user and/or a specific factor determined based on the subjective medicament need parameter. The processor **119** may output a control signal via one of the transceivers **125** or **127** to the wearable drug delivery device **102**. The outputted signal may cause the processor **114** to deliver command signals to the pump **118** to deliver an amount of the determined dosage of medicament in the reservoir **120** to the user based on an output of the ADD algorithm. The processor **119** may also be operable to perform calculations to update or establish settings of the ADD algorithm as discussed as herein. Modifications to the ADD algorithm settings may be stored in the memory **118**, for example, as settings **121**.

[0044] A wearable drug delivery device **102**, typically, has a lifecycle that is based on the amount of liquid drug that is stored in a reservoir **120** of the wearable drug delivery device **102** and/or the amount of the liquid drug delivered to the user. An ADD application or algorithm may use a number of parameters, such as glucose measurement values, total daily medicament, medicament onboard, and the like, when making the determination of an amount of the liquid drug to have delivered. In an operational example, the processor **119** of the controller **104** may be operable to receive evaluate the effectiveness of the ADD algorithm's control of the drug delivery device **102**. For example, the processor **119** may be operable to utilize historical data accessible by the processor in an evaluation of past performance of the ADD algorithm and generate recommendations for adjusting settings of the ADD algorithm accordingly as described in more detail with reference to the examples in the figures.

[0045] While the system **100** is described with reference to delivery of insulin and the use of an ADD algorithm, the system **100** may be operable to implement a drug delivery regimen via a medication delivery algorithm using a number of different liquid or therapeutic drugs/medicaments. A liquid drug may be or include any drug in liquid form capable of being administered by a drug delivery device via a subcutaneous cannula, including, for example, insulin, glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic polypeptide (GIP), pramlintide, glucagon, co-formulations of two or more of GLP-1, GIP, pramlintide, and insulin; as well as pain relief drugs, such as opioids or narcotics (e.g., morphine, or the like), methadone, blood pressure medicines, chemotherapy drugs, fertility drugs, or the like.

Insulin Delivery Adaptation for Predictive Fasting Patterns

[0046] Type 1 diabetics may be adversely affected by periods of fasting. The following discussion addresses the specific challenges in diabetic patients undertaking fasting

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as a diet or wellness technique (e.g., intermittent fasting, time restricted eating (e.g., eating only during 6-8 hours per day), 5:2 diet (5 days one diet/2 days different diet), warrior diet, Keto diet, or the like) as well as during a holiday, such as Ramadan, Passover, or Lent. In more detail, wellness technique fasting entails distinctive changes in food and/or fluids consumption that could potentially induce changes in glucose metabolism and insulin sensitivity. Diabetic patients who fast are predisposed to excessive glycogenolysis (e.g., production of glucose from glycogen), gluconeogenesis (e.g., production of glucose from non-carbohydrate sources) and increased ketogenesis (e.g., production of ketones from fatty acids and ketogenic amino acids). Additionally, risks for hypoglycemia, hyperglycemia, diabetic ketoacidosis, and dehydration are also elevated. The following discussion provides techniques implemented through a computer application that interacts with the MDA of the ADD system.

[0047] FIG. 2 illustrates a block diagram of the graphical user interface suitable for use to indicate fasting or to initiate a fasting mode, such as during a religious holiday.

[0048] The graphical user interface 200 is operable to present one or more different windows to collect information related to the user's fasting. For example, window 210 may be a prompt presented to the user that enables the user to initiate a fast or fasting mode. In response to the input at window 210, the computer application may begin modifying a drug delivery schedule based on the indication of fasting. For example, after the fast mode has been enabled, the computer application may generate a prompt, such as "Input Period of Fasting," "Fasting Event," or "Enter location," or a prompt to enter the type of fast, or a combination of the foregoing, which is presented in another window, such as 220. The period of fasting may be several hours, such as 8 PM-12 PM, Sunset to Sunrise, Sunrise to Sunset, 6 AM-4 PM, or the like. The location of the user may be useful to determine time zones, the times for Sunrise and Sunset at the user's location, and the like.

[0049] Alternatively, or additionally, the computer application, at 230, may generate a further prompt that produces a request to enter a calendar service, such as Google® calendar, Yahoo® calendar or Outlook® calendar. The calendar service may also be coupled to a service (e.g., a cloud based or internet based service) that indicates the times for Sunrise and Sunset on a daily basis. Alternatively, the system may store in memory different fasting periods that correspond to different fasting events, such as religious holidays or dieting regimens. The system may receive a time and date from other applications running on the system (e.g., a clock and calendar on a smartphone) and if the user selects to initiate a fasting mode, the system may ask the user via a GUI whether the fasting mode corresponds to a particular event (e.g., a fasting event) based on the current date and time or an upcoming date and time.

[0050] At 240, the computer application may, for example, at the end of the period of fasting or on occasion (e.g., every 24 hours or every couple of days or after each indicated fasting period), generate a prompt inquiring if the user would like to "Exit Fasting Mode."

[0051] A more detailed discussion of GUI window 230 is made with reference to FIG. 3, which illustrates an example of a portion of a calendar suitable for use in a fasting application of the examples disclosed herein.

[0052] In the FIG. 3 example, the fasting application may be operable to receive an indication of a holiday that requires

fasting, such as Ramadan or Lent. As shown in FIG. 3, a calendar 300 of the dawn (Sehar) and dusk (Iftar) times for the portion of the year and location (based on Doha, Kuwait) can be extracted from a calendar. Of course, other calendars and locations may be used to determine dawn or dusk as well as other times, such as work start or work end times, or the like. For example, fasting during Ramadan lasts 29 to 30 days each year, and the glycemic outcomes of diabetic patients on ADD systems can be significantly improved during this time of prolonged fasting if the system is aware that the user is fasting. In the case of Ramadan, the times for dawn (Sehar) and dusk (Iftar) are those times shown in the week during April and May of the calendar 300. The Sehar or dawn is when fasting starts and Iftar or dusk is when fasting ends. Typically, adherents to Ramadan eat a meal approximately prior to dawn and do not eat another meal until approximately dusk. As a result of the fasting, basal medicament needs are typically lower in the day (reduced by 20% up to 40% from baseline). Hyperglycemia is a challenge after the evening meal (Iftar) and the predawn meal (Sehar). Of course, the described examples may be used at other times as well.

[0053] In fasting situations, glycemic outcomes may be improved by the MDA of the ADD system by addressing and/or providing a GUI for fasting, a daytime medicament adaptivity algorithm, a dusk-to-dawn adaptivity algorithm, auxiliary sensors and/or safety monitoring and alerts. While the following examples of FIGS. 4-6 refer to dawn and dusk and to an approximately 12 hour fasting period, the fasting period may vary and the described intervals may be altered proportionately. In other fasting examples, "dawn" may be analogous to time for a pre-fasting period meal and "dusk" may be analogous to a post-fasting period meal, or the like. The system may receive a time, such as a current time and/or a dawn and dusk time, from other applications running on the system (e.g., a weather and/or clock and calendar app running on a smartphone) and may adjust medicament delivery settings accordingly if the particular user fast is influenced by time of day or calendar day. Thus, after initiating a "fasting mode," the user may be prompted to indicate whether the fast corresponds to an X, Y, or Z event based on the current time and/or day. If the user confirms that the fast corresponds to X event, and X event corresponds to fasting during particular periods of the day and/or particular days, the system will know that the user intends to fast during those particular periods of day and/or days and can adjust medicament delivery, accordingly, as explained further below.

[0054] Referring back to FIG. 2, in an operational example of the GUI 200 for fasting, the GUI 200 allows the user to set a fasting mode. For example, a user can invoke the Fast Mode (at window 210) as show in the GUI 200 through the portable diabetes manager (PDM) or controller, such as 106 of FIG. 1. The user may enable fast mode (210). The user may also set their location (220) via the GUI; alternatively, the user's location may be determined based on the location of the device or controller 104, e.g., from a geolocation service or app running on the device or controller 104. In an example, the location may be used to interface with a calendar service (at 230) running on the device or controller 104 or retrieved from a cloud-based service 110 that has the dawn (Sehar) and dusk times (Iftar) for the location which may be used to automatically determine a mealtime after dusk and a dawn mealtime for each day. Exemplary times

are shown in FIG. **3**. At the conclusion of a fasting period, the user may exit Fast Mode (**240**) at which time the processor may return the medicament delivery settings to baseline. In an example, if a number of fasting days (e.g., 28 to 30 days or a recurring 1 day or another period of time) have elapsed and the user has not requested an exit from Fast Mode, the Fast Mode may be automatically exited by the PDM or controller. The fast exit mode may also be used by the user in case there is a particular reason to exit the fast early. The user may restart again if the user wishes by pressing "Enable Fasting Mode" or a similar type of soft button, again (e.g., as presented in window **210** of FIG. **2**).

Day Time Medicament Adaptivity

[0055] When fasting (including intermittent fasting) occurs for an extended period of time, such as 2-3 days or longer, a user's daily medicament requirements may change. Since fasting during Ramadan, for example, is for an extended period of time, a user's medicament requirements are likely altered at least during that period of time. The manner in which the computer application and MDA respond may be configured to respond is described with reference to FIGS. **4A-6**. For example, during the day, the 3 hours after start of a dawn or a sunrise meal (Sehar) and 3 hours prior to the start of a dusk meal (Iftar), may be referred to as fasting period modification points. The nominal or baseline medicament need will only correspond to fasting basal medicament needs that are typical for the user when fasting. However, during prolonged fasting periods (e.g., 14 hours or longer) the medicament needs may be further reduced several hours into the fasting period. As such, the MDA when modifying a drug delivery schedule based on the period of fasting may make multiple modifications to the drug delivery schedule. As used herein, "the drug delivery schedule" may include an amount of drug to be delivered over particular time periods during a treatment period (e.g., 12, 16, 24 or 48 hours or other periods). For example, the fasting basal medicament dosage (e.g., a baseline dosage) may be 2 Units (U) per hour during the time period.

[0056] The processor may adjust basal medicament delivery according to a drug delivery schedule for basal delivery of medicament as illustrated in FIG. **4A** and outlined in Table 1 below.

TABLE 1

Basal Delivery Dawn to Dusk			
Dawn to Dawn + 3 hrs.	Dawn + 3 hrs. to dawn + 6 hrs.	Dawn + 6 hrs. to Dusk − 3 hrs.	Dusk − 3 hrs. to Dusk
Baseline*110%	Baseline	Baseline*90%	80%*Baseline

[0057] The example drug delivery schedule as shown in basal delivery schedule **400A** may begin increasing a basal rate for a first time threshold after receipt of the indication of the period of fasting. For example, the MDA may increase the basal rate by approximately 10% above a baseline insulin (shown as 110%) delivery rate (e.g., 8 U/hour), at **410**, for 3 hours after dawn (0 dawn hour to +3 hrs (where +3 indicates the number of hours since the start of the fasting period)) to act as a supplement to the bolus for the dawn meal taken at approximately 0 hour. The delivery of the bolus dosage is not shown in this example, but is described in another section herein. For the next 3 hours of the fasting

period (e.g., from +3 hrs until −6 hours (where −6 indicates the number of remaining hours in the fasting period)), the basal medicament delivery rate is set to the baseline medicament delivery rate of the user (**420**). In the example, at **420**, the MDA maintains the basal rate at a baseline value between a first time threshold after receipt of the indication of the period of fasting and a second time threshold after receipt of the indication of the period of fasting.

[0058] The processor executing the MDA, when modifying the drug delivery schedule based on the period of fasting, may be operable to reduce a basal delivery rate for a period of time prior to an end of the period of fasting. For example, after the baseline medicament delivery rate has been delivered for the 3 hours from +3 hrs to −6 hrs of the fasting period, the basal medicament delivery rate may be reduced by 10% (shown as 90%) from the baseline medicament delivery rate (**430**). The basal delivery schedule is further modified from the baseline medicament delivery rate after the 3 hours (or up to 3 hours before dusk (−3 hrs to 0 dusk hour)). The basal medicament delivery rate is decreased, at **440**, by 20% (shown as 80%) from the baseline basal medicament delivery rate (i.e., 100%) for 3 hours prior to dusk to start of dusk (i.e., −3 hrs to 0 dusk hour). The reductions in basal delivery rate may function as a safeguard against hypoglycemia. While the increases and decreases of basal delivery rate are described in percentage increments of 10%, these increments may have been other percentage increments, such as 12%, 8%, 20% or the like. Additionally, or alternatively, the percentage increments may have varied across time thresholds, where a time threshold may be a time start point such as 0 hours (hr), or a time duration, such as 3 hours or 0 hr to +3 hrs. For example, a first percentage increase may be a first percentage increment, such as 10% at a first time threshold, a second percentage increment, such as 5% at a second time threshold, and a third percentage increment, such as 15% at a third time threshold.

[0059] FIG. **4B** illustrates an alternative example of a dawn-to-dusk basal modulation delivery schedule according to the examples discussed with reference to FIGS. **2** and **3**. In the alternative example of FIG. **4B**, the processor, when modifying the drug delivery schedule based on the period of fasting, may be operable to adjust a basal delivery rate according to a function that decreases basal rate delivery from a set percentage (e.g., 10%) to a baseline basal delivery rate, and from the baseline basal delivery rate to the set percentage (i.e., 10%) or another set percentage (e.g., 5%, 12% or 20%) under the baseline basal delivery rate over a duration of the period of fasting.

[0060] The drug delivery schedule **400B** has similar time markings as those presented in **400A** of FIG. **4A** so a discussion of the similar features is not repeated.

[0061] In the basal delivery schedule **400B** of FIG. **4B**, the basal rate at 0 dawn hour (0 hr) is initially increased approximately 10% above baseline basal medicament delivery rate for the user during 415. In contrast to **410** of FIG. **4A**, the initial 10% increase in basal rate in **415** is allowed to decrease to baseline basal medicament delivery rate after 3 hours (i.e., form time 0 hr to +3 hours). In the drug delivery schedule of FIG. **4B**, the initial basal rate setting at 110% of the baseline medicament delivery rate may linearly decrease over 3 hours to the baseline medicament delivery rate (i.e., 100%). At the end of the initial 3 hours after dawn (e.g., at +3 hrs), the MDA may deliver medicament at the baseline basal delivery rate of the user (**425**). The delivery of medi-

cament at the baseline basal delivery rate of the user may last for another 3 hours until time mark minus (—) 6 hours. At the −6 hour mark, the MDA may linearly decrease the basal rate (at **435**) from the baseline basal medicament delivery rate (i.e., 100%) to end at 90% of the baseline basal delivery rate when the time mark −3 hrs is reached. From the −3 hrs time mark, the MDA may permit the basal rate to continue to linearly decrease from the 90% of the baseline basal delivery rate to 80% of the baseline basal delivery rate over the following 3 hours until the dusk 0 hr is reached (**445**).

[0062] While a linear decrease is shown in the example FIG. **4B**, the decrease may follow any sort of function, such as a stair-step, exponential, logarithmic, or the like, that is reasonable for the drug treatment of the user.

[0063] The medicament delivered by the ADD algorithm may start with these nominal delivery schedules shown in FIGS. **4A** and **4B**, which may be adapted to deliver additional or reduced medicament based on a prediction of the user's glucose level and the user's current medicament on board (e.g., insulin on board (JOB)). The medicament delivery may be adapted by examining excursions in the glucose level as indicated by glucose measurements.

[0064] In addition to modifying the user's drug delivery schedule during the day (i.e., dawn to dusk), the MDA is also operable to modify the user's drug delivery schedule from dusk to dawn as part of a dusk-to-dawn medicament adaptivity process. For example, the processor may be operable to modify the can occur before, during, and/or after the period of fasting or fasting event.

[0065] FIG. **5A** illustrates an example of a dusk-to-dawn modulated basal delivery schedule according to the disclosed subject matter.

[0066] The MDA executed by the processor may, at an end of the period of fasting, be operable to adjust a basal delivery rate up or down by a set percentage over a baseline basal rate for a first period of time, set the basal delivery rate to the baseline basal rate delivery for a second period of time, and/or increase or decrease the baseline basal delivery rate by a preset percentage over the baseline basal delivery rate for a third period of time.

[0067] As shown in more detail in the basal delivery schedule example of FIG. **5A**, the processor when executing the MDA to implement the basal insulin delivery schedule **500**A may keep the basal medicament delivery at approximately 110% of nominal basal for approximately 3 hours after the start of dusk (**510**). At the +3 hours' time mark, the basal delivery rate may be kept at the baseline basal delivery rate for the user, for example, from approximately +3 hours after dusk to approximately 1 hour prior to dawn (i.e., −1 hr. time mark) (**520**). At the −1 hr. time mark, the MDA may again increase the basal delivery rate 10% to 110% of the baseline basal delivery rate (**530**). The increased basal delivery rate of 110% of the basal delivery rate at 530 may continue until dawn (i.e., 0 hr. dawn).

[0068] FIG. **5B** illustrates an alternative example of a dusk-to-dawn basal delivery schedule modulated according to the disclosed subject matter. In the examples, the period of fasting is dawn-to-dusk.

[0069] In the alternative basal delivery schedule **500B** of FIG. **5B**, the MDA as implemented by the processor may be operable, at the end of the period of fasting (i.e., dusk), to adjust basal delivery rate according to a function that decreases basal rate delivery from a preset percentage increase over a baseline basal delivery rate to the baseline

basal delivery rate over a first period of time. The MDA may also set the basal delivery rate to the baseline basal rate delivery for a second period of time, and increase the baseline basal delivery rate to the preset percentage over the baseline basal delivery rate for a third period of time.

[0070] In an operational example, the MDA may gradually decrease (e.g., linearly in this example) the basal rate, for example, over the 3 hours after dusk from approximately 110% of the baseline basal delivery rate of the user. In the example, the MDA may cause the basal delivery rate at 0 hr dusk to be set initially at approximately 110% of the baseline basal delivery rate (**515**). In this and other examples, the baseline basal delivery rate may be a default value, may be input by the user, or preferably may be determined based on a total daily medicament delivered over a prior period (e.g., the total medicament delivered one day prior and divided by 2 (assuming a 50-50 split between basal and bolus medicament) and further divided by 24 (to determine an hourly basal baseline)). As time progresses, the basal delivery rate decreases (e.g., linearly) from the 110% of the baseline basal delivery rate to the baseline delivery rate at +3 hr. after dusk time mark (**515**). The decrease in the basal delivery rate may be a linear decrease. From the +3 hr. after dusk time mark until one hour prior to dawn (i.e., the −1 hrs. time mark), the basal delivery rate may remain at the basal baseline delivery rate of the user (**525**). At approximately 1 hour prior to dawn (i.e., the −1 hrs. time mark), the MDA may increase (e.g., linearly) the basal delivery rate from the baseline basal delivery rate to approximately 110% of the baseline basal delivery rate (**535**) as shown in basal medicament delivery schedule **500B**.

[0071] While a linear decrease and a linear increase are shown in FIG. **5B**, the decrease and increase may follow any sort of function, such as a stair-step, exponential, logarithmic, or the like, that is reasonable for the drug treatment of the user.

[0072] Since participants in the fast usually have a meal prior to the beginning of the period of fasting (e.g., dawn), and a daytime fast is typically broken at the end of the period of fasting (e.g., dusk), a bolus dosage of insulin may be given by the MDA for meal compensation at these times. The dosage of bolus insulin may be calculated as follows in Equation 1:

$$\text{Bolus Insulin} = x\,\%\;TDI + \frac{(\text{Blood Glucose} - \text{SetPoint})}{1800/TDI} - IOB$$

where the 1800 rule (i.e., 1800/TDI) is used for the correction factor, TDI is total daily insulin, the SetPoint variable is the user's target blood glucose level, variable x is any positive number (e.g., 5%, 8%, 10%, 12%, up to 20%, or the like), and IOB is the insulin on board (alternatively the 1600 rule (i.e., 1600/TDI) may be used in place of the 1800 rule). The correction factor and the IOB terms are expected to be small because of the already tapered basal insulin leading up to dusk.

[0073] FIG. **6** illustrates an example of a bolus delivery schedule in relation to the examples discussed with reference to FIGS. **4A**, **4B**, **5A** and **5B**. This bolus delivery schedule may operate automatically (or with user confirmation) when the system is in Fast Mode.

[0074] In an example, the bolus may be delivered to the user via three modalities, which are shown in FIG. **6** for ease

of description and understanding. In the first modality (referred to as a user initiated bolus) **611** and **613**, the bolus may be user initiated by the user signaling to the MDA that a meal has been consumed, is being consumed or is about to be consumed.

[0075] The second modality (referred to as a user interface initiated bolus), such as **621** and **623**, can be a time bound initiation that may cause a bolus to be administered to a user automatically via a setting made in the user interface. For example, when the period of fasting is based on when dawn and dusk occur, the automated setting of when the bolus will be delivered may be determined via the calendar service that is called and set according to the times for dawn and dusk as shown in window **230** of FIG. **2**. The second modality **621** and **623** may differ in the times they are implemented with respect to the end of the period of fasting and the beginning of the period of fasting, which are shown in this example, as dusk and dawn, respectively. For example, via the second modality **621**, the approximate start of dusk and dawn may be based on a calendar service called and the obtained daily for sunrise and sunset. The bolus medicament may be administered automatically by the MDA, for example, within a window of time that is equally divided at the approximate start of dusk. The bolus medicament may be administered only after the user confirms the bolus delivery (e.g., after an automatic prompt by the system at the determined time (e.g., dusk or dawn)). Meanwhile, the second modality **623** may be scheduled to deliver a bolus that is also approximately near dawn, but accounts for a meal being consumed before the beginning of the period of fasting. As a result, the second modality **623** may be implemented in a manner different from second modality **621**. The user interface initiated bolus **623** (or second modality **623**) may be administered prior to the dawn, or beginning of the fasting period, for example, between 45 minutes prior to dawn (−45 min) and 15 minutes prior to dawn (−15 min).

[0076] When setting up the user interface initiated bolus **621** or **623**, the processor may provide in the graphical user interface (similar to those shown in FIG. **2**) suggested times for administering a bolus based on the times that the user indicates they will be starting the period of fasting and a time when they will be ending the period of fasting. Based on the user indicated starting and ending times the processor may set a window of time during which the user interface initiated bolus **621** is delivered and another window of time during which the user interface initiated bolus **623** is delivered. Alternatively, the processor may provide in the graphical user interface fields that allow the user to input a window of time that corresponds to delivery of the user interface initiated bolus **621** and the delivery of the user interface initiated bolus **623**.

[0077] In the third modality **631** and **633**, the bolus medicament may be administered as an AutoBolus function that is based on meal detection. Meal detection may be implemented by monitoring a user's glucose levels to detect changes in glucose levels that correspond or correlate with a user's consumption of a meal. A meal detection threshold may be a rate of change of the user's glucose (e.g., increases of 15%-25% or greater within 30 minutes, a change from 120 mg/dL to 180 mg/dL in 30 minutes, or the like), an elevated glucose meal threshold (e.g., 200 mg/dL, 220 mg/dL, or the like), or the like. In some embodiments, machine learning classifiers (e.g., a decision tree) trained on prior meal-glucose responses may be utilized for triggering

an AutoBolus. The meal detection threshold at the end of the period of fasting may be kept low (e.g., at a low end of a range, such as a rate of change of 15% or 195 mg/dL) for a short window (e.g., 40 minutes) starting from 20 minutes after dusk and ending at 60 minutes after dusk. Similarly, the meal detection threshold at the beginning of the period of fasting may be kept low for a longer window starting at dawn and ending at 60 minutes after dawn.

[0078] In an operational example, the controller of the drug delivery system such as that shown in FIG. **1** may have a processor that, when executing programming instructions to implement the processes and function described herein, may be operable to deliver a bolus dosage proximate to a beginning of the period of fasting and proximate to an end of the period of fasting.

[0079] For a further operational example, the processor, when delivering the bolus dosage prior to the beginning of the period of fasting, may initiate delivery of the bolus dosage in response to receipt of an indication, via the user interface (e.g., the user initiated bolus **611**), that the period of fasting is beginning. Alternatively, when the processor is delivering the bolus dosage in response to the beginning of the period of fasting, the processor is further operable to initiate delivery of the bolus dosage upon receipt of a meal detection indication (e.g., Autobolus **631**).

[0080] In yet a further operational example, when the processor is delivering the bolus dosage at the end of the period of fasting, the processor may be operable automatically initiate (e.g., the user interface initiated bolus **623**) delivery of the bolus dosage at a predetermined time period proximate to the beginning of the period of fasting.

[0081] The other delivery modalities **613**, **621**, and **633** may be implemented in similar manners as those described above but with respect to their respective beginning time or end time for the period of fasting.

[0082] As discussed above with reference to FIG. **6**, bolus insulin for the dawn meal can again be delivered similar to the dusk bolus, either by user initiation, or by time bound initiation (e.g., 30 minutes prior to dawn) or by AutoBolus based on meal detection.

[0083] FIG. **7** illustrates a flowchart of an example process for adjusting bolus insulin based on the excursions in the glucose level.

[0084] In the example of FIG. **7**, the insulin delivered will follow the similar form described above with the value of x (of Equation 1 above) again being chosen as 10 (for a 10% TDI value in Equation 1). The bolus delivery **600** for dusk and dawn are illustrated in the example of FIG. **6**.

[0085] The process **700** to evaluate the determination of a dosage for bolus insulin delivery may begin at **710**. At **710**, the processor may, for example, since a last bolus dosage, examine excursions in the glucose (BG) levels of the user as indicated by BG metrics determined from or based on data received from a continuous glucose sensor(s) or a glucose monitor. For example, at **710**, the processor evaluate, for example, post prandial BG metrics that may include time above range (e.g., >180 mg/dl), time below range (e.g., <70 mg/dl), time T within range (e.g., 70 mg/dL<T<180 mg/dL), or the like. Depending on whether the evaluation of the post prandial BG metrics indicate extra insulin (**721**) or an insulin deficiency (**722**), the process **700** causes the processor to take a respective action to adjust the bolus insulin dosage and/or delivery schedule shown in FIG. **6**. For example, in response to the indication of extra insulin at **721**, the process

700 causes the processor to reduce x in Equation 1 above by 1. So, if x is initially 10, the processor would reduce x to 9 (for a 9% TDI value in Equation 1). The process 700 proceeds to 740 where a bolus dosage is calculated using Equation 1 with the 9% TDI value. Conversely, in response to the indication of insulin deficiency at 722, the process 700 causes the processor to increase x in Equation 1 above by 1. So, if x is initially 10, the processor would increase x to 11 (for a 11% TDI value in Equation 1). The process 700 proceeds to 740 where a bolus dosage is calculated using Equation 1 with the 11% TDI value. Process 700 may repeat approximately twice a day, three times a day or more, but may be less, to confirm that a proper bolus dosage is provided to compensate for meals outside the period of fasting.

[0086] FIG. 8 illustrates a flowchart of an example process for adjusting basal insulin based on excursions in the glucose (BG) as indicated by BG metrics. For example, the process 800 may enable basal insulin dosages to be adjusted by examining (810) dawn to dusk BG metrics of the user determined from or based on data received from a continuous glucose sensor(s) or a glucose monitor. In the 810, the processor may evaluate, for example, the dawn-to-dusk BG metrics that may include time above range (>180 mg/dL), time below range (<70 mg/dL), time T within range (70 mg/dL<T<180 mg/dL), or the like. Depending on whether the evaluation of the dawn-to-dusk BG metrics indicate extra insulin (821) or an insulin deficiency (822), the process 800 takes a respective action to adjust the basal insulin dosage and/or delivery schedule. For example, in response to the indication of extra insulin at 821, the process 800 causes the processor to reduce basal insulin delivery by Y %, which may be a tunable variable and have values such as 2.5%, 2%, 3% or a range of values, such as 1%-2.5% or 1.5%-3%, or the like. In an example, if the basal insulin delivery during the fasting period was delivered according to the basal delivery schedule shown in FIG. 4A or 4B, the basal insulin delivered during the respective time marks by be reduced by Y %. Thus, the basal baseline may be reduced by Y % and the other percentages under/over the basal baseline may also be reduced. For example, if Y is 2.5, the 110% of 410 of FIG. 4A may be reduced to 107.5%. Conversely, in response to the indication of insulin deficiency at 822, the process 800 causes the processor to increase basal insulin delivery by Y %. For example, if Y is 2.5, the 110% of 410 of FIG. 4A may be increased to 112.5%.

[0087] The process 800 may repeat for each operational cycle of a drug delivery device during the period of fasting to confirm that a proper basal dosage is provided during the period of fasting, which in this example was dawn-to-dusk. Of course, other periods of fasting may be used, such as 6 hours (e.g., noon to 6 pm), 16 hours (8 pm until noon), 24 hours, 3 hours, 1 meal, 2 meals, 3 meals, or the like. A "meal" period of fasting (e.g., 1 meal) may be based on the assumption that the user typically eats three meals a day. So, a fasting period of "1 meal" may correspond to a continuous fasting period of 4 hours, 5 hours, or 6 hours, for example.

[0088] It is also envisioned that auxiliary sensors may be utilized to assist the fasting user with remaining within range during their period of fasting and for the number of days over which the user will be fasting. For example, Ramadan lasts 28-30 days during which the user is fasting.

[0089] Auxiliary sensor(s) that may be helpful during a fast is a ketone sensor, such as 196 or 196A of FIG. 1. A user when consuming a normal diet without fasting may have ketone levels that are typically approximately <0.5 mmol/L. Exercise and low carbohydrate levels can increase a user's ketone levels to approximately 3.0 mmol/L. Starvation ketosis may elevate ketone levels up to 5 mmol/L.

[0090] In an example, an ADD system may be equipped with a continuous subcutaneous ketone sensor, such as 196 or 196A of FIG. 1. For example, a concentration of 3-hydroxybutyrate can be measured using the 3-hydroxybutyrate dehydrogenase (3HBDH) enzyme which can be integrated with the CGM sensor. Hydrogel membranes have been used to improve ketone concentration and reduce electrode fouling.

[0091] Ketone levels with a physiological status are summarized in Table 2 below:

TABLE 2

Ketone Levels with Physiological Status	
Physiological Status	Ketone Level
Acceptable	0-1.4 mmol/L
Above normal	1.5-3.0 mmol/L
High	$>_3$ mmol/L
Danger	$>_{10}$ mmol/L

[0092] In other examples, the ketone sensor and the CGM sensor may be integrated within the insulin delivery system as one physical unit. In still other examples, urine ketone levels or serum ketone levels may be used.

[0093] Auxiliary sensors may be used to monitor exercise of the user. Exercise monitoring may be accomplished via sensors, such as a heart rate monitor and/or accelerometer. The data from one or both of these sensors may provide data to related to an activity level and type of exercise performed by the user to the MDA. In other embodiments, activity data from fitness devices, such as a Fitbit® or the like, may be used.

[0094] Using a continuous glucose monitor and/or one or more of the auxiliary sensors the processor may be operable to perform safety monitoring and provide alerts to the user.

[0095] FIG. 9 is a process flow diagram illustrating the process flow that monitors for hypoglycemia and generates alerts based on the results of the monitoring. The monitoring process 900 may be implemented when the processor enables a "HypoAlert" mode or similar type mode. For example, the processor may have different modes that utilize different algorithms to provide distinct functions related to the management of the user's glucose and diabetes. In the process 900 of FIG. 9, the processor may receive inputs from sensors that monitor a user's activity level 911, such as sensors 130, 133 and/or 134 of FIG. 1, and sensors that monitor the user's glucose levels, such as CGM 186 or 186A. An example of the indication of activity level may be low, medium, or high, or heart rate levels of 65 beats per minute (bpm), 95 bpm and 110 bpm may be respective thresholds for the low, medium, and high activity levels. For example, the activity level 911 and glucose levels 913 may be received by the processor and input to the hypoalert algorithm 920. The processor may be operable to execute the

hypoalert algorithm **920**. Based on the output of the hypoalert algorithm **920**, the process **900** either performs step **933** or returns to **911** and **913**.

[0096] For example, if the processor determines that the glucose is expected to fall below 70 mg/dl between the start of the period of fasting (e.g., dawn) until the end of the period of fasting (e.g., dusk), the processor may be operable to output via a graphical user interface an alert **933** to take rest and curtail physical activity (e.g., "move to a cool area" or the like). Also, if they are in unfavorable weather conditions (e.g., hot temperatures or the like), they will be encouraged to move to a favorable weather environment that allows the user to cool off. In addition, the processor may cause insulin delivery to be suspended or reduced to mitigate the hypoglycemic risk. Additional feedback provided via the GUI to the user may be to consider adding extra nutrition/balance in their pre-fast meals (e.g., pre-dawn meal) and post-fast meal (e.g., meal at dusk) to have better glycemic outcomes.

[0097] Other algorithms may provide different alerts such as a "RestAlert" and a "KetoAlert." In an example, a rest alert may be, similar to the hypoalert example of FIG. **9** and may be performed if the user is exerting themselves physically while starving for caloric intake or losing water, for example, due to excessive sweating, the rest alert process may cause the presentation of prompts to encourage the user to move to cooler environment and reduce physical activity, similar to the presentation of the prompts at **933** of FIG. **9**.

[0098] FIG. **10** illustrates a process flow diagram illustrating the process flow that monitors the user's ketone levels and generates an alert when the user's ketone levels are over a predetermined threshold. In addition to the HypoAlert and RestAlert processes, the processor may be operable to implement a "KetoAlert" process **1000** as shown in the example of FIG. **10**. For example, the processor may receive inputs related to activity level **1013**, glucose values **1015**, and ketone levels **1017**. The processor may use the inputs **1013**, **1015** and **1017** in a ketoalert algorithm **1020**. The ketoalert process **1020** may evaluate the activity level **1011** and glucose **1013** in a manner similar to the activity level **911** and glucose **913**. With regard to the ketone level **1015**, the processor may evaluate the ketone level **1015** provided by a ketone sensor(s), such as **196** or **196A** of FIG. **1** and generate a ketoalert if the user's ketone levels are higher than 3 mmol/L or the like. In response to the ketoalert indicating the user's ketone levels are higher than 3 mmol/L, the processor at **1033** may cause a prompt on a GUI recommending the user to take a rest, move to a cooler area, and/or provide dietary feedback for the future or a following day. As feedback to the user also provided via the GUI, the processor may cause a recommendation to be presented on the GUI for the user to modify their dusk and dawn meals to be less prone to ketosis. In a further example, the processor may continue to monitor ketone levels closely and if the ketone levels rise above 10 mmol/L, the processor may be operable to request medical attention via communication circuitry coupled to the processor or may cause the generation of prompt as part of step **1033** for the user to seek medical attention. Should the ketoalert **1020** process not identify any activity, glucose or ketones above their respective alert thresholds, the process **1000** repeats with updated activity level data, glucose level data, and/or ketone level data.

[0099] Software related implementations of the techniques described herein, such as the processes examples described with reference to the above discussion and figures 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. The various elements of the processes described with reference to the figures may be implemented in devices, apparatuses or systems that may include various hardware elements, software elements, or a combination of both. Examples of hardware elements may include structural members, logic devices, components, processors, microprocessors, circuits, processors, circuit elements (e.g., transistors, resistors, capacitors, inductors, and so forth), integrated circuits, application specific integrated circuits (ASIC), programmable logic devices (PLD), digital signal processors (DSP), field programmable gate array (FPGA), memory units, logic gates, registers, semiconductor device, chips, microchips, chip sets, and so forth. Examples of software elements may include software components, programs, applications, computer programs, application programs, system programs, software development programs, machine programs, operating system software, middleware, firmware, software modules, routines, subroutines, functions, processes, procedures, software interfaces, application program interfaces (API), instruction sets, computing code, computer code, code segments, computer code segments, words, values, symbols, or any combination thereof.

[0100] Some examples of the disclosed device or processes may be implemented, for example, using a storage medium, a computer-readable medium, or an article of manufacture which may store an instruction or a set of instructions that, if executed by a machine (i.e., processor or controller), may cause the machine to perform a method and/or operation in accordance with examples of the disclosure. Such a machine may include, for example, any suitable processing platform, computing platform, computing device, processing device, computing system, processing system, computer, processor, or the like, and may be implemented using any suitable combination of hardware and/or software. The computer-readable medium or article may include, for example, any suitable type of memory unit, memory, memory article, memory medium, storage device, storage article, storage medium and/or storage unit, for example, memory (including non-transitory memory), removable or non-removable media, erasable or non-erasable media, writeable or re-writeable media, digital or analog media, hard disk, floppy disk, Compact Disk Read Only Memory (CD-ROM), Compact Disk Recordable (CD-R), Compact Disk Rewriteable (CD-RW), optical disk, magnetic media, magneto-optical media, removable memory cards or disks, various types of Digital Versatile Disk (DVD), a tape, a cassette, or the like. The instructions may include any suitable type of code, such as source code, compiled code, interpreted code, executable code, static code, dynamic code, encrypted code, programming code, and the like, implemented using any suitable high-level, low-level, object-oriented, visual, compiled and/or interpreted programming language. The non-transitory computer readable medium embodied programming code may cause a processor when executing the programming code to perform functions, such as those described herein.

[0101] Certain examples of the present disclosure were described above. It is, however, expressly noted that the present disclosure is not limited to those examples, but rather the intention is that additions and modifications to what was expressly described herein are also included within the scope of the disclosed examples. Moreover, it is to be understood that the features of the numerous examples described herein were not mutually exclusive and may 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 disclosed examples. In fact, variations, modifications, and other implementations of what was described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the disclosed examples. As such, the disclosed examples are not to be defined only by the preceding illustrative description.

[0102] Program aspects of the technology may be thought of as "products" or "articles of manufacture" typically in the form of executable code and/or associated data that is carried on or embodied in a type of non-transitory, machine readable medium. Storage type media include any or all of the tangible memory of the computers, processors or the like, or associated modules thereof, such as various semiconductor memories, tape drives, disk drives and the like, which may provide non-transitory storage at any time for the software programming. It is emphasized that the Abstract of the Disclosure is provided to allow a reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, various features are grouped together in a single example for streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed examples require more features than are expressly recited in each claim. Rather, as the following claims reflect, novel subject matter lies in less than all features of a single disclosed example. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate example. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein," respectively. Moreover, the terms "first," "second," "third," and so forth, are used merely as labels and are not intended to impose numerical requirements on their objects.

[0103] The foregoing description of examples has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the present disclosure to the precise forms disclosed. Many modifications and variations are possible considering this disclosure. It is intended that the scope of the present disclosure be limited not by this detailed description, but by the claims appended hereto. Future filed applications claiming priority to this application may claim the disclosed subject matter in a different manner and may include any set of one or more features as variously disclosed or otherwise demonstrated herein.

What is claimed is:

1. A controller of a drug delivery system, comprising:
a processor operable to execute programming instructions;
a user interface including a display and user input circuitry;
a memory operable to store the programming instructions; and
a communication circuitry coupled to the processor operable to receive and transmit wireless communication signals, wherein the processor is operable to:
receive, via the user interface, an indication of fasting event or a period of fasting for a user; and
modify a drug delivery schedule based on the period of fasting.

2. The controller of the drug delivery system of claim 1, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:
increase a basal delivery rate for a first time threshold after receipt of the indication of the period of fasting.

3. The controller of the drug delivery system of claim 1, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:
maintain a basal delivery rate at a baseline value between a first time threshold after receipt of the indication of the period of fasting and a second time threshold after receipt of the indication of the period of fasting.

4. The controller of the drug delivery system of claim 1, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:
reduce a basal delivery rate for a period of time prior to an end of the period of fasting.

5. The controller of the drug delivery system of claim 1, wherein the processor is further operable to:
deliver a bolus dosage in close proximity to an end of the period of fasting.

6. The controller of the drug delivery system of claim 5, wherein the processor, when delivering the bolus dosage in response to the end of the period of fasting, is further operable to:
initiate delivery of the bolus dosage in response to receipt of an indication, via the user interface, that the period of fasting has ended.

7. The controller of the drug delivery system of claim 5, wherein the processor, when delivering the bolus dosage at the end of the period of fasting, is further operable to:
initiate delivery of the bolus dosage automatically in response to the end of the period of fasting.

8. The controller of the drug delivery system of claim 5, wherein the processor, when delivering the bolus dosage in response to the end of the period of fasting, is further operable to:
automatically initiate delivery of the bolus dosage upon receipt of a meal detection indication.

9. The controller of the drug delivery system of claim 1, wherein the processor is further operable to:
deliver a bolus dosage proximate to a beginning of the period of fasting.

10. The controller of the drug delivery system of claim 9, wherein the processor, when delivering the bolus dosage prior to the beginning of the period of fasting, is further operable to:
initiate delivery of the bolus dosage in response to receipt of an indication, via the user interface, that the period of fasting is beginning.

11. The controller of the drug delivery system of claim **9**, wherein the processor, when delivering the bolus dosage at the end of the period of fasting, is further operable to:

automatically initiate delivery of the bolus dosage at a predetermined time period proximate to the beginning of the period of fasting.

12. The controller of the drug delivery system of claim **9**, wherein the processor, when delivering the bolus dosage in response to the beginning of the period of fasting, is further operable to:

initiate delivery of the bolus dosage upon receipt of a meal detection indication.

13. The controller of the drug delivery system of claim **1**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

adjust a basal delivery rate according to a function that decreases the basal rate delivery from a set percentage increase of a baseline basal delivery rate down to the baseline basal delivery rate, and from the baseline basal delivery rate to the set percentage or another set percentage under the baseline basal delivery rate during the period of fasting.

14. The controller of the drug delivery system of claim **1**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

at an end of the period of fasting, adjust a basal delivery rate to a basal rate delivery increased by a set percentage over a baseline basal rate for a first period of time, set the basal delivery rate to the baseline basal rate delivery for a second period of time, and increase the baseline basal delivery rate by the preset percentage over the baseline basal delivery rate for a third period of time.

15. The controller of the drug delivery system of claim **1**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

at an end of the period of fasting, adjust a basal delivery rate according to a function that decreases a basal delivery rate from a preset percentage increase over a

baseline basal delivery rate to the baseline basal delivery rate over a first period of time, maintain the basal delivery rate at the baseline basal delivery rate for a second period of time, and increase the basal delivery rate again by the preset percentage over baseline basal delivery rate for a third period of time.

16. A drug delivery system, comprising:

a processor operable to execute programming instructions;

a user interface including a display and user input circuitry;

a memory operable to store the programming instructions; and

a communication circuitry coupled to the processor operable to receive and transmit wireless communication signals, wherein the processor is operable to:

receive, via the user interface, an indication of a period of fasting for a user; and

modify a drug delivery schedule based on the period of fasting.

17. The drug delivery system of claim **16**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

increase a basal delivery rate for a first time threshold after receipt of the indication of the period of fasting.

18. The drug delivery system of claim **16**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

maintain a basal delivery rate at a baseline value between a first time threshold after receipt of the indication of the period of fasting and a second time threshold after receipt of the indication of the period of fasting.

19. The drug delivery system of claim **16**, wherein the processor, when modifying the drug delivery schedule based on the period of fasting, is further operable to:

reduce a basal delivery rate for a period of time prior to an end of the period of fasting.

20. The drug delivery system of claim **16**, wherein the processor is further operable to:

deliver a bolus dosage in close proximity to an end of the period of fasting.

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