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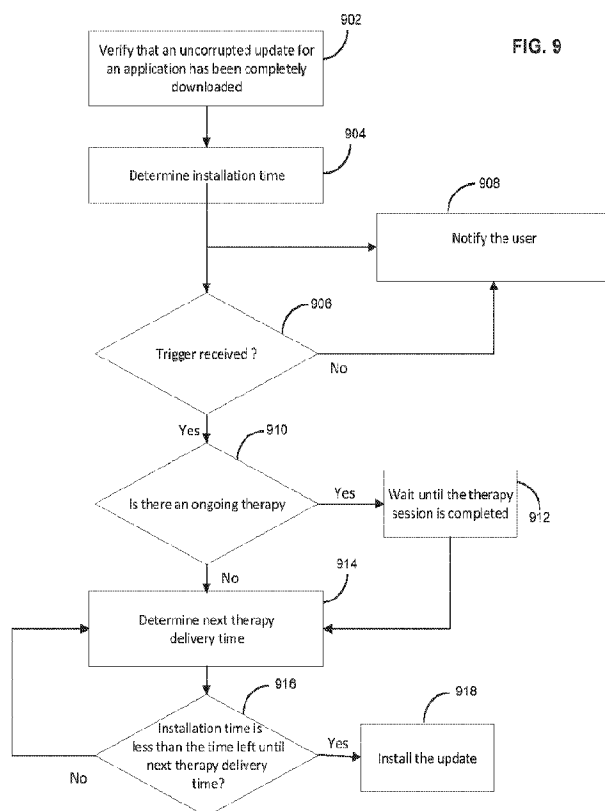
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(54) Titre : SYSTEME DE CONTROLE DE LA GLYCEMIE

(54) Title: BLOOD GLUCOSE CONTROL SYSTEM



(57) Abrégé/Abstract:

Blood glucose control systems and ambulatory medical devices that provide therapy to a subject, such as blood glucose control, are disclosed. Disclosed systems and devices can implement one or more features that improve the user experience, such as software update techniques that avoid interrupting delivery of therapy, gesture-based control of therapy delivery, automatic resumption of therapy after a user-initiated pause, improved alarm management, display of autonomously calculated dosing recommendations, wide area network connectivity, and security features.

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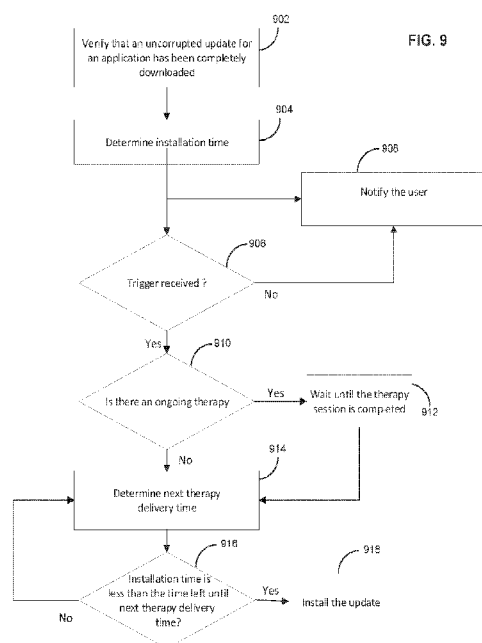
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(54) Title: BLOOD GLUCOSE CONTROL SYSTEM



(57) Abstract: Blood glucose control systems and ambulatory medical devices that provide therapy to a subject, such as blood glucose control, are disclosed. Disclosed systems and devices can implement one or more features that improve the user experience, such as software update techniques that avoid interrupting delivery of therapy, gesture-based control of therapy delivery, automatic resumption of therapy after a user-initiated pause, improved alarm management, display of autonomously calculated dosing recommendations, wide area network connectivity, and security features.

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WO 2021/011697 A1

WO 2021/011697 A1



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PATENT

BLOOD GLUCOSE CONTROL SYSTEM**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR
DEVELOPMENT**

This invention was made with U.S. Government support under Contract No. DK120234, awarded by the National Institutes of Health. The Government has certain rights in the invention.

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Nos. 62/987,842, filed March 10, 2020; 63/037,472, filed June 10, 2020; 62/874,934, filed July 16, 2019; 62/874,950, filed July 16, 2019; 62/874,968, filed July 16, 2019; 62/910,970, filed October 4, 2019; 62/911,017, filed October 4, 2019; and 62/911,143, filed October 4, 2019. The entire contents of each application referenced in this paragraph are incorporated by reference herein and made part of this specification.

BACKGROUNDTechnical Field

[0002] This disclosure relates to blood glucose control systems and to ambulatory medical devices that provide therapy to a subject.

Description of Related Art

[0003] Sustained delivery, pump driven medicament injection devices generally include a delivery cannula mounted in a subcutaneous manner through the skin of the subject at an infusion site. The pump draws medicine from a reservoir and delivers it to the subject via the cannula. The injection device typically includes a channel that transmits a medicament from an inlet port to the delivery cannula which results in delivery to the subcutaneous tissue layer where the delivery cannula terminates. Some infusion devices are configured to deliver one medicament to a subject while others are configured to deliver multiple medicaments to a subject.

SUMMARY

[0004] Blood glucose control systems and ambulatory medical devices that provide therapy to a subject, such as blood glucose control, are disclosed. Disclosed systems and devices can implement one or more features that improve the user experience, such as software update techniques that avoid interrupting delivery of therapy, gesture-based control of therapy delivery, automatic resumption of therapy after a user-initiated pause, improved alarm management, display of autonomously calculated dosing recommendations, wide area network connectivity, and security features.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] The systems, methods, and devices of this disclosure each have several innovative aspects, no single one of which is solely responsible for the all of the desirable attributes disclosed herein. Details of one or more implementations of the subject matter described in this specification are set forth in the accompanying drawings and the description below.

[0006] FIG. 1A illustrates an example blood glucose control system that provides blood glucose control via an ambulatory medicament pump.

[0007] FIG. 1B illustrates another example blood glucose control system that provides blood glucose control via an ambulatory medicament pump.

[0008] FIG. 1C illustrates a further example blood glucose control system that provides blood glucose control via an ambulatory medicament pump.

[0009] FIG. 2A shows a block diagram of an example blood glucose control system.

[0010] FIG. 2B shows a block diagram of another example blood glucose control system.

[0011] FIG. 2C shows a block diagram of another example blood glucose control system.

[0012] FIG. 2D shows a block diagram of another example blood glucose control system.

[0013] FIG. 3 is a schematic of an example glucose control system that includes an electronic communications interface.

[0014] FIG. 4A shows a block diagram of an example blood glucose control system in online operation mode.

[0015] FIG. 4B shows a block diagram of an example blood glucose control system in offline operation mode.

[0016] FIG. 5A illustrates a perspective view of an example ambulatory medical device.

[0017] FIG. 5B illustrates a cross sectional view of the ambulatory medical device shown in FIG. 5A.

[0018] FIG. 6 illustrates different modules that may be included in an example ambulatory medical device.

[0019] FIG. 7 illustrates various methods and links that AMD may establish a connection with a host computing system.

[0020] FIG. 8 is a flow diagram showing an example of a computer-implemented method that may be used by an AMD in order to detect and download an application update.

[0021] FIG. 9 is a flow diagram showing an example of a computer-implemented method that may be used by an AMD to install a down-loaded application update without interrupting the therapy provided to a subject.

[0022] FIG. 10 is a flow diagram showing an example of a computer-implemented method that may be used by an AMD to install a second update downloaded from a host computing system and switch control of the AMD from a first application to the second application without interrupting the therapy provided to a subject.

[0023] FIG. 11 is a flow diagram showing an example of a computer-implemented method that may be used by an AMD to install a second application downloaded from a host computing system, verify and switch control of the AMD from a first application to the second application without interrupting the therapy provided to a subject, only if the second application satisfies a minimum set of operation conditions.

[0024] FIG. 12 is a flow diagram showing an example of a computer-implemented method that may be used to respond to detection of an application fault during the execution of a first version of an application and switching control of the AMD to a second version an application installed on the AMD.

[0025] FIG. 13 is a flow diagram showing an example of a computer-implemented method that may be used to respond to detection of an application fault during the execution of a first version of an application and switching control of the AMD to a second version an application installed on the AMD and/or downloading a third version of the application.

[0026] FIG. 14. is a block diagram, illustrating an example network configuration wherein the AMD is directly connected to a computing system and the computing system shares the therapy reports with one or more display systems and the AMD.

[0027] FIG. 15 is a flow diagram illustrating an example method that may be used by a computing system, to generate and share a therapy report based on encrypted therapy data received from an AMD.

[0028] FIG. 16. is a block diagram, illustrating an example network and data flow configuration wherein the AMD is directly connected to a computing system and the computing system generates and sends alerts to one or more display systems and the AMD.

[0029] FIG. 17 is a flow diagram illustrating an example method that may be used by a computing system, to generate and send an alert to one or more authorized devices.

[0030] FIG. 18 illustrates the interconnection among modules and procedures in AMD involved in receiving, accepting and/or canceling therapy change request.

[0031] FIG. 19 is a flow diagram illustrating an example method that may be used by an AMD to allow a user to change the configuration of the ambulatory medicament device using a touch screen user interface.

[0032] FIG. 20A is an illustration of the touchscreen display of an example AMD after the touch screen is waked/unlocked by a wake action of a user and before the first user gesture is received.

[0033] FIG. 20B is an illustration of an example touchscreen display that may prompt the user to enter a predetermined series of inputs for the first gesture or second gesture.

[0034] FIG. 20C is an illustration of an example therapy change user interface.

[0035] FIG. 20D is an illustration of another therapy change user interface on a touchscreen display.

[0036] FIG. 21 is a flow diagram illustrating an example method that may be used by an AMD to generate an alarm status indicator.

[0037] FIG. 22 is a flow diagram illustrating an example method that may be used to cancel a therapy change using a touchscreen interface.

[0038] FIG. 23A is an illustration of a touchscreen display alerting the user that the delivery of one or more medicaments will occur.

[0039] FIG. 23B is an illustration of a touchscreen display showing that a medicament is being delivered to the user.

[0040] FIG. 24 is a block diagram illustrating the interconnection among modules and procedures in AMD involved in receiving, accepting and/or canceling a therapy suspension request.

[0041] FIG. 25 is a flow diagram illustrating an example method for receiving and implementing a suspension request, which may be implemented by an AMD

[0042] FIG. 26 illustrates a plurality of screens that the ambulatory medical device may display when a user pauses therapy.

[0043] FIG. 27 is a flow diagram illustrating an example method of resuming a suspended therapy that may be implemented by an AMD.

[0044] FIG. 28 illustrates a plurality of screens that the ambulatory medical device may display when a user resumes therapy.

[0045] FIG. 29 is a block diagram illustrating the interconnection among modules and procedures in AMD involved in changing the settings of the AMD.

[0046] FIG. 30 is a flow diagram illustrating an example method that may be used by an AMD to allow a user to change a setting of the AMD using a user generated passcode or an override passcode.

[0047] FIG. 31 is a flow diagram illustrating an example method that may be used by an AMD to allow a user to change a setting of the AMD using a user generated passcode or an override passcode.

[0048] FIG. 32 is a schematic diagram illustrating the interconnection among modules and procedures in AMD involved in monitoring the status of the AMD and/or the subject and generate alarms when an alarm condition is met.

[0049] FIG. 33 is a flow diagram illustrating an example procedure that may be used by the alarm system of an AMD to annunciate an alarm condition upon receiving a status information that satisfies an alarm condition.

[0050] FIG. 34 is a block diagram illustrating the interconnection among modules and procedures in AMD involved in monitoring the condition of the AMD and generating alerts when a device malfunction is detected.

[0051] FIG. 35 is a flow diagram illustrating an example procedure that may be used by the alert system of an AMD to monitor the operation of an AMD and generate alerts when a device malfunction is detected.

[0052] FIG. 36 is a schematic diagram illustrating an ambulatory medical device that provides the user with various options for providing medicament.

[0053] FIG. 37 is a flow diagram of a process for providing options for meal dosage selection on an ambulatory device.

[0054] FIG. 38 is another flow diagram of a process for providing options for meal dosage selection on an ambulatory device.

[0055] FIG. 39 is a series of screen displays showing a user initiating the activation of meal dosage on an ambulatory device.

[0056] FIG. 40 is a series of screen displays showing a user activating meal dosage on an ambulatory device.

[0057] FIG. 41 is a series of screen displays showing a user activating meal announcement on an ambulatory device.

[0058] FIG. 42 is a series of screen displays showing a user inputting the total number of units on an ambulatory device.

[0059] FIG. 43 is a series of screen displays showing an ambulatory medical device delivering the units and cancelling the delivery of the units.

[0060] FIG. 44 is a schematic illustrating a computer system that can be implemented in various embodiments of the described subject matter.

DETAILED DESCRIPTION

[0061] Some embodiments described herein pertain to medicament infusion systems for one or more medicaments and the components of such systems (e.g., infusion

pumps, medicament cartridges, cartridge connectors, lumen assemblies, infusion connectors, infusion sets, etc.). Some embodiments pertain to methods of manufacturing infusion systems and components thereof. Some embodiments pertain to methods of using any of the foregoing systems or components for infusing one or more medicaments (e.g., pharmaceutical, hormone, etc.) to a subject. As an exemplary illustration, an infusion system may include an infusion pump, which can include one or more medicament cartridges or can have an integrated reservoir of medicament. An infusion system may include medicament cartridges and cartridge connectors, but not a pump. An infusion system may include cartridge connectors and an infusion pump, but not medicament cartridges. An infusion system may include infusion connectors, a lumen assembly, cartridge connectors, an infusion pump, but not medicament cartridges or an infusion set. A blood glucose control system can operate in conjunction with an infusion system to infuse one or more medicaments, including at least one blood glucose control agent, into a subject. Any feature, structure, component, material, step, or method that is described and/or illustrated in any embodiment in this specification can be used with or instead of any feature, structure, component, material, step, or method that is described and/or illustrated in any other embodiment in this specification. Additionally, any feature, structure, component, material, step, or method that is described and/or illustrated in one embodiment may be absent from another embodiment.

Blood Glucose Control System Overview

[0062] A blood glucose control system (BGCS) is used to control blood glucose level in a subject. Blood glucose control systems can include a controller configured to generate dose control signals for one or more glucose control agents that can be infused into the subject. Glucose control agents include regulatory agents that tend to decrease blood glucose level, such as insulin and insulin analogs, and counter-regulatory agents that tend to increase blood glucose level, such as glucagon or dextrose. A blood glucose control system configured to be used with two or more glucose control agents can generate a dose control signal for each of the agents. In some embodiments, a blood glucose control system can generate a dose control signal for an agent even though the agent may not be available for dosing via a medicament pump connected to the subject.

[0063] Glucose control agents can be delivered to a subject via subcutaneous injection, via intravenous injection, or via another suitable delivery method. In the case of blood glucose control therapy via an ambulatory medicament pump, subcutaneous injection is most common. An ambulatory medicament pump 100 is a type of ambulatory medical device, which is sometimes referred to herein as an ambulatory device, an ambulatory medicament device, a mobile ambulatory device, or an AMD. Ambulatory medical devices include ambulatory medicament pumps and other devices configured to be carried by a subject and to deliver therapy to the subject.

[0064] In some examples, the ambulatory medical device (AMD) is an electrical stimulation device, and therapy delivery includes providing electrical stimulation to a subject. An example of an electrical stimulation device is a cardiac pacemaker. A cardiac pacemaker generates electrical stimulation of the cardiac muscle to control heart rhythms. Another example of an electrical stimulation device is a deep brain stimulator to treat Parkinson's disease or movement disorders.

[0065] FIGS. 1A-1C show examples of blood glucose control systems that provide blood glucose control via an ambulatory medicament pump connected to a subject. In FIG. 1A, the medicament pump 100 is connected to an infusion site 102 using an infusion set 104. The medicament pump has integrated pump controls 106a that permit a user to view pump data and change therapy settings via user interaction with the pump controls 106a. A glucose level sensor 110 generates a glucose level signal that is received by the blood glucose control system.

[0066] In FIG. 1B, the medicament pump 100 communicates with an external electronic device 108 (such as, for example, a smartphone) via a wireless data connection. At least some of the pump controls 106a and 106b can be manipulated via user interaction with user interface elements of the external electronic device 108. The glucose level sensor 110 can also communicate with the medicament pump 100 via a wireless data connection.

[0067] In FIG. 1C, the medicament pump 100 includes an integrated cannula that inserts into the infusion site 102 without a separate infusion set. At least some of the pump controls 106b can be manipulated via user interaction with user interface elements of an external electronic device 108. In some instances, pump controls can be manipulated via user interaction with user interface elements generated by a remote computing environment (not

shown), such as, for example, a cloud computing service, that connects to the medicament pump 100 via a direct or indirect electronic data connection.

[0068] Glucose control systems typically include a user interface configured to provide one or more of therapy information, glucose level information, and/or therapy control elements capable of changing therapy settings via user interaction with interface controls. The user interface can be implemented via an electronic device that includes a display and one or more buttons, switches, dials, capacitive touch interfaces, or touchscreen interfaces. In some embodiments, at least a portion of the user interface is integrated with an ambulatory medicament pump that can be tethered to a body of a subject via an infusion set configured to facilitate subcutaneous injection of one or more glucose control agents. In certain embodiments, at least a portion of the user interface is implemented via an electronic device separate from the ambulatory medicament pump, such as a smartphone.

[0069] FIGS. 2A-2D illustrate block diagrams showing example configurations of a glucose control system 200. As shown in FIG. 2A, a glucose control system 200a can include a controller 202a having an electronic processor 204a and a memory 210a that stores instructions 208a executable by the processor 204a. The controller 202a and a pump 212 can be integrated with into an ambulatory medical device (AMD) 100. The AMD 100 can include a transceiver 214a for wireless digital data communications with external electronic devices. When the instructions 208a stored in memory 210a are executed by the electronic processor 204a, the controller 202a can implement at least a portion of a control algorithm that generates dose control signals for one or more glucose control agents based on time-varying glucose levels of the subject and one or more control parameters. The dose control signals, when delivered to the pump 212, result in dosing operations that control the blood glucose of a subject.

[0070] As shown in FIG. 2B, a glucose control system 200b can operate at least partially via execution of instructions 208b by an electronic processor 204b of an electronic device 108 separate from the ambulatory medical device 100. The electronic device 108 can include a transceiver 214b capable of establishing a wireless digital data connection to the AMD 100, and a controller 202b can implement at least a portion of a control algorithm via execution of instructions 208b stored in memory 210b. When the instructions 208b stored in memory 210b are executed by the electronic processor 204b, the controller 202b can

implement at least a portion of a control algorithm that generates dose control signals for one or more glucose control agents based on time-varying glucose levels of the subject and one or more control parameters. The dose control signals, when delivered to the pump 212, result in dosing operations that control the blood glucose of a subject. In some embodiments, the dose control signals are transmitted from the device transceiver 214b to the AMD transceiver 214a over a short-range wireless data connection 216. The AMD 100 receives the dose control signals and passes them to the pump 212 for dosing operations.

[0071] As shown in FIG. 2C, a glucose control system 200c can operate at least partially via execution of instructions 208c on an electronic processor 204c integrated with a remote computer 206, such as, for example, a cloud service. When the instructions 208c stored in memory 210c are executed by the electronic processor 204c, the controller 202c can implement at least a portion of a control algorithm that generates dose control signals for one or more glucose control agents based on time-varying glucose levels of the subject and one or more control parameters. The dose control signals, when delivered to the pump 212, result in dosing operations that control the blood glucose of a subject. In some embodiments, the dose control signals are transmitted from the remote computer WAN connection interface 220c to the AMD WAN connection interface 220a over an end-to-end wireless data connection 218. The AMD 100 receives the dose control signals and passes them to the pump 212 for dosing operations.

[0072] As shown in FIG. 2D, a glucose control system 200d can have two or more controllers 202a, 202b, 202c that cooperate to generate a dose control signal for dosing operations by the pump 212. A remote computer 206 can transmit or receive data or instructions passed through a WAN connection interface 220c via a WAN wireless data connection 218 to a WAN connection interface 220b of an electronic device 108. The electronic device 108 can transmit or receive data or instructions passed through a transceiver 214b via a short-range wireless data connection 216 to a transceiver 214a of an AMD 100. In some embodiments, the electronic device can be omitted, and the controllers 202a, 202c of the AMD 100 and the remote computer 206 cooperate to generate dose control signals that are passed to the pump 212. In such embodiments, the AMD 100 may have its own WAN connection interface 220a to support a direct end-to-end wireless data connection to the remote computer 206.

[0073] As shown in FIG. 3, in some embodiments, the glucose control system 200 includes circuitry that implements an electronic communications interface (ECI) 302 configured to send and receive electronic data from one or more electronic devices. The ECI includes a sensor interface 304 configured to receive a glucose level signal from a sensor 110 such as a continuous glucose monitor (CGM). Some CGMs generate the glucose level signal at fixed measurement intervals, such as five-minute intervals. The sensor 110 can be operatively connected to a subject in order to generate a glucose level signal that corresponds to a blood glucose estimate or measurement of the subject. The glucose level signal can be used by the controller 202 to generate a dose control signal. The dose control signal can be provided to a pump 212 via a pump interface 306. In some embodiments, the sensor interface 304 connects to the sensor 110 via a short-range wireless connection 308. In some embodiments, the pump interface 306 connects to the pump 212 via a short-range wireless connection 310. In other embodiments, the pump interface 306 connects to the pump 212 via a local data bus, such as when the controller 202, the ECI 306, and the pump 212 are integrated into an AMD 100.

[0074] The controller can be configured to generate the dose control signal using a control algorithm that generates at least one of a basal dose, a correction dose, and/or a meal dose. Examples of control algorithms that can be used to generate these doses are disclosed in U.S. Patent Application Publication Nos. 2008/0208113, 2013/0245547, 2016/0331898, and 2018/0220942 (referenced herein as the “Controller Disclosures”), the entire contents of which are incorporated by reference herein and made a part of this specification. The correction dose can include regulatory or counter-regulatory agent and can be generated using a model-predictive control (MPC) algorithm such as the one disclosed in the Controller Disclosures. The basal dose can include regulatory agent and can be generated using a basal control algorithm such as disclosed in the Controller Disclosures. The meal dose can include regulatory agent and can be generated using a meal control algorithm such as disclosed in the Controller Disclosures. Additional aspects and improvements for at least some of these controllers are disclosed herein. The dose control signal can be transmitted to an infusion motor 306 via the ECI 302 or can be transmitted to the infusion motor 306 via an electrical conductor when the controller 202a is integrated in the same housing as the infusion motor 306.

[0075] As shown in FIG. 4A, the controller 400 can be configured to operate in “online mode” during time periods when the controller receives a glucose level signal 402 from a sensor 110. In online mode, the control algorithm generates a dose control signal 404 that implements regular correction doses based on values of the glucose level signal 402 and control parameters of the control algorithm. The pump 212 is configured to deliver at least correction doses and basal doses to the subject without substantial user intervention while the controller 400 remains in online mode.

[0076] As shown in FIG. 4B, the controller 400 can be configured to operate in “offline mode” during time periods when the controller does not receive a glucose level signal 402 from a sensor 110, at least during periods when the glucose level signal 402 is expected but not received. In offline mode, the control algorithm generates a dose control signal 404 that implements correction doses in response to isolated glucose measurements 406 (such as, for example, measurements obtained from the subject using glucose test strips) and based on control parameters of the control algorithm. The pump 212 is configured to deliver basal doses to the subject without substantial user intervention and can deliver correction doses to the subject in response to isolated glucose measurements 406 while the controller 400 remains in offline mode.

Example Ambulatory Medical Device

[0077] In some embodiments, the ambulatory medicament device (AMD) can be a portable or wearable device that provides life-saving treatment to subjects or subjects by delivering one or more medicaments (e.g., insulin and/or glucagon) to a subject or a subject. Some AMDs may continuously monitor the health condition of a subject using a sensor and deliver one or more medicaments based on the condition of the subject. Certain ambulatory medicament devices may be worn by subjects constantly (e.g., all day), or for a large portion of the day (e.g., during waking hours, during sleep hours, when not swimming, etc.) to enable continuous monitoring of the health condition of the subject and to deliver medicament as necessary.

[0078] FIG. 5A illustrates a three-dimensional (3D) view of an example ambulatory medical device 500 comprising a housing 502 with a wake button 506 and a touchscreen display 504. FIG. 5B is an illustration of a cross sectional view of the

ambulatory medical device 500 shown in part A. In this example, all the electronic modules 508 are included inside the housing, for example, as a single integrated electronic board. The wake button 506 may be any type of button (e.g., capacitive, mechanical) that registers an input generated by user interaction with the wake button 506 to generate a wake signal. In some embodiments, the wake signal is generated by a sensor (e.g., a biometric sensor such as a fingerprint reader or a retinal scanner, an optical or RF proximity sensor, and the like). In various embodiments, the wake signal may be generated by user interaction with the touch screen display 50 or with an alphanumeric pad (not shown). In some other examples, wake signal may be generated based on facial recognition or other biometric indicia. In yet other examples, the wake signal may be generated by a wireless signal such as RFID or Bluetooth signals or by detection of movement using one or more motion sensors such as an accelerometer. The wake button 506, if touched, pressed, or held for a certain period of time, may generate a wake signal that activates the touchscreen display 504. In some examples, touches on the touchscreen display 504 are not registered until the wake button activates the touchscreen display. In some such examples, the AMD remains locked from accepting at least certain types of user interaction or settings modification until a gesture (such as, for example, any of the gesture interactions described with reference to any of the embodiments disclosed herein) is received after the touchscreen display 504 is activated by the wake button 506.

[0079] FIG. 6 illustrates different modules that may be included in an example AMD 500. In some examples, all these modules may be integrated together inside a single housing (as shown in FIG. 5B). In some other examples, one or more modules may be individual modules contained in separate housings that communicate with the main unit via a wired or wireless communication links (e.g., Bluetooth). The modules included in the AMD may include a communication module 602, signal processing module 604, a therapy delivery module 606, a user interface module 608, and a control and computing module 610.

[0080] The control and computing module 610 may include one or more processors 614, a main memory 616, a storage 618 that may comprise one or more non-transitory memories and an interface 612 that enables data and signal communication among the components within the control and computing module 610 as well as communication between the control and computing module and all other modules of the AMD. The main

memory and the storage each may be divided into two or more memory locations or segments. The main memory 616 may communicate with the other components of the control and computing module 610 as well as other modules through the interface 612. Instructions may be transmitted to the main memory (e.g., from the storage) and the processor 614 executes instructions that are communicated to the processor through the main memory 616. The storage 618 may store data while the control and computing system 610 is powered or unpowered. The storage 618 may exchange data with the main memory directly or through the interface 612. The main memory 616 can be any type of memory that can store instructions and communicate them to the processor 614 and receive executed instructions from the processor 614. Types of main memory include but are not limited to random access memory ("RAM") and read-only memory ("ROM"). The processor 614 may be any type of general purpose central processing unit ("CPU"). In some embodiments, the control and computing module may include more than one processor of any type including, but not limited to complex programmable logic devices ("CPLDs"), field programmable gate arrays ("FPGAs"), application-specific integrated circuits ("ASICs") or the like. The storage 618 can be any type of computer storage that can receive data, store data, and transmit data to the main memory 616 and possibly other modules of AMD. Types of storage 618 that can be used in the control and computing system 610 include, but are not limited to, magnetic disk memory, optical disk memory, flash memory and the like. The interface 612 may include data transfer buses and electronic circuits configured to support data exchange among different components within the control and computing system 610. In some examples, the interface 612 may also support data and signal exchange among other modules as well as data exchange between any of the modules and the control and computing module 610.

[0081] The signal processing module 604 may include a plurality of interconnected electronic modules for signal conditioning and signal conversion (e.g., A-to-D and D-to-A conversion) configured to support communication and data exchange between different modules. For example, the signal processing 604 module may convert an analog signal received from the communication module 602 and convert it to a digital signal that can be transmitted to the control and computing module 610 (e.g., via the interface 612). As another example, the signal processing module may receive a digital control signal from the

control and computing module 610 and convert it to an analog signal that can be transmitted to the therapy delivery module 506, for example, to control one or more pumps.

[0082] The therapy delivery module 606 may comprise one or more infusion pumps configured to deliver one or more medicaments to a subject. The medicaments may be stored in one or more medicament cartridges housed in the therapy module 606. In some examples, the therapy delivery module may include electronic and mechanical components configured to control the infusion pumps based on the signals received from control and computing module 610 (e.g., via the signal processing module 604).

[0083] The user interface module 608 may include a display to show various information about the AMD, medicament type and delivery schedule, software status, and the like. Graphic images and text may be shown by any display technology including, but not limited to OLED, LCD, or e-ink. In some embodiments, the AMD, may include a user interface (e.g., an alphanumeric pad) that lets a user enter information or interact with the AMD to modify the settings of the AMD, respond to request for certain actions (i.e., installing a software) and the like. The alphanumeric pad may include a multitude of keys with numerical, alphabetical, and symbol characters. Keys of the alphanumeric pad may be capacitive or mechanical. The user may be a subject receiving medicament or therapy, or may be another user, such as a clinician or healthcare provider, or a parent or guardian of the subject. In some other embodiments, the AMD may include a touchscreen display that produces output and also accepts input enabling a two-way interaction between the user and the AMD. The touchscreen display may be any input surface that shows graphic images and text and also registers the position of touches on the input surface. The touchscreen display may accept input via capacitive touch, resistive touch, or other touch technology. The input surface of the touchscreen display can register the position of touches on the surface. In some examples, the touchscreen display can register multiple touches at once. In some embodiments, the alphanumeric pad is displayed on the touchscreen display. The touchscreen may present one or more user-interface screens to a user enabling the user to modify one or more therapy settings of the ambulatory medicament device.

[0084] The communication module 602, may include one or more wireless transceivers, one or more antennas and plurality of electronic modules. Each transceiver may be configured to receive or transmit different types of signals based on different wireless

standards via the antenna (e.g., an antenna chip). The transceiver may support communication using a low power wide area network (LPWAN) communication standard. In some examples, the transceiver may support communication with wide area networks such as a cellular network transceiver that enables 3G, 4G, 4G-LTE, or 5G. Further, the transceiver may support communication via a Narrowband Long-Term Evolution (NB-LTE), a Narrowband Internet-of-Things (NB-IoT), or a Long-Term Evolution Machine Type Communication (LTE-MTC) communication connection with the wireless wide area network. In yet other cases, the transceiver may support Wi-Fi® communication. In some examples, the transceiver may be capable of down-converting and up-converting a baseband or data signal from and to a carrier signal. In some examples, the communication module may wirelessly exchange data between other components of the ambulatory medical system (e.g., a sensor), a mobile device (e.g., smart phone), a Wi-Fi network, WLAN, a wireless router, a cellular tower, a Bluetooth device and the like. The antenna chip may be capable of sending and receiving various types of wireless signals including, but not limited to, Bluetooth, LTE, or 3G. In some examples, the communication module may support direct communication between the AMD and a server or a cloud network. In some other examples the AMD may communicate with an intermediary device (e.g., a smart phone). In some embodiments, the AMD may include an eSIM card that stores all of the information necessary to identify and authenticate a mobile subscriber. The eSIM card may allow the ambulatory device to transmit data on a very inexpensive IOT device basis. In other embodiments, the ambulatory medical device may be configured to transmit data in a narrowband communication protocol such as 2G or EDGE. Using the cellular connection the ambulatory medical device may be paired with the mobile device at inception and permit real-time data access to the ambulatory medical device by a healthcare provider. In certain implementations, the ambulatory medical device may include a geolocation receiver or transceiver, such as a global positioning system (GPS) receiver.

Example Operation of the AMD

[0085] In some embodiments, the AMD may continuously, periodically, or intermittently receive information about one or more parameters that are correlated with a health condition of a subject (e.g., glucose level, glucose trend, heart rate, body movement

indicia, etc.). This information may be encoded to a signal provided to AMD by a subject sensor 620 (e.g., a wearable sensor that measured an analyte in the interstitial fluid) that is connected to the main unit 600 via a wired or wireless link (e.g., Bluetooth). In some examples, the signal sent by the sensor may be received by the communication module 602 and transmitted to a signal processing module 604 that converts the signal to a machine-readable signal (e.g., a digital signal). The signal processed by the signal processor module 604 may be transmitted to the control and computing module 610 where it is analyzed to determine whether medicament should be delivered to the subject. If it is determined that medicament is needed, the control and computing module the volume of the medicament may calculate required dosage based on the information received from the subject sensor 620 and send a signal to the therapy module (e.g., via the signal processing module) to initiate the medicament delivery process to the subject.

[0086] All the procedures within the control and processing module 610 are executed by the processor 614 (or a plurality of processors) based on instructions provided by one or more software applications installed in one of the memories (e.g., the main memory) of control and computing module 610. These procedures include, but are not limited to, determining the need for delivering medicament, determining the type of medicament and the required dose, determining the rate of delivery during a therapy session, providing information (e.g., device status, next delivery time, level of certain analytes in the subject's blood and the like) via the user interface module 108, processing the information received from a subject sensor 620 via the user interface 608, and the like. In some embodiments, a first software application may control the AMD and may be installed on the main memory 616 while a second software application (e.g., different version) may be stored in the storage 618. In some examples, the first and second software applications may be both installed in the main memory 616 but in different locations or segments. In these examples, if needed, the control of the device can be switched from the first software application to the second software application.

[0087] In some embodiments, the ambulatory medical device 600 may deliver multiple types of therapies that are selectable by a user or the control and computing module 610. For example, the ambulatory medical device 600 may deliver the therapy of infusing insulin into a user and may also deliver the therapy of infusing glucagon into a user. In some

examples, the user interface may include an option for the user to select an infusion of insulin, glucagon, or both insulin and glucagon. In other embodiments, other hormones, liquids or therapies may be delivered. In some examples, the software application executed by the control and computing module 610, may determine the type of hormone that needs to be delivered, at least partly based on the information received from the sensor 620.

Communication and Networking

[0088] FIG. 7 illustrates various methods and links that AMD 702 may use to establish a connection with a host computing system 704 in order to obtain an application update. The host computing system 704 may be a server 706 or a computing system within a cloud computing network 708 or other networked computing environment. The host computing system 704 may be part of a data center (e.g., the data center of a health care provider).

[0089] To obtain the application update, the AMD may establish a connection (e.g., using its communication module) with the host computing system through an intermediary device 710, such as a desktop computer, a mobile device (e.g., a smart phone, a laptop, and the like). In some such examples, the AMD may receive the application update from a local device 712 of a user (e.g., a clinical computer, a subject's home computer, a smartphone, etc.) that has obtained a copy of the application update from the host computing system directly or via internet 714. In some other examples the AMD may communicate with the host computing system 704 through a local area network (LAN) through a Wi-Fi connection. Alternatively, or in addition, the ambulatory medical device may establish a connection to the host computing system 704 via a wide area network 716. Moreover, the communication connection established between the ambulatory medical device and the cloud computing service may be encrypted.

[0090] In some embodiments, the ambulatory medical device may establish a direct end-to-end connection over a wide area network 716 (e.g., a cellular network) with the host computing system 704. The method may include receiving a public key from the ambulatory medical device. The public key and a private key stored in the host computing system 704 can be used to permit the host computing system 704 to decrypt data communications transmitted by the ambulatory medical device. In some implementations,

establishing the direct end-to-end data connection comprises receiving a device identifier associated with the ambulatory medical device. The device identifier may be a unique identifier specific to the ambulatory medical device. Further, establishing the direct end-to-end data connection may include determining that the ambulatory medical device is permitted to communicate with the computing system based at least in part on the device identifier. The device identifier may be initially provided to the networked-computing environment prior to provisioning of the ambulatory medical device to the subject. For example, the device identifier may be initially provided to the networked-computing environment as part of a manufacturing process for manufacturing the ambulatory medical device. The device identifier may include or may be based on one or more of an Internet Protocol (IP) address, a Media Access Control (MAC) address, a serial number, or a subject identifier of a subject that receives therapy from the ambulatory medical device. In some cases, the subject or a user establishes or initiates establishing the direct end-to-end data connection with the computing system. In other cases, the direct end-to-end data connection may be initiated or established without action by the subject or the user. For example, the direct end-to-end data connection may occur automatically at particular times or when the ambulatory medical device is in particular locations. This automatic connection may occur using information supplied to the ambulatory medical device at a time of manufacture, shipment, sale, or prescription to the subject. In some cases, the wide area network may include, or may communicate with, the internet 714.

[0091] In some embodiments, the ambulatory medical device may be configured to communicate via the wide area network during manufacture or prior to being provisioned to the subject. For example, a manufacturer can register the ambulatory medical device with a wireless wide-area network provider (e.g., T-Mobile or Verizon) and provide an International Mobile Equipment Identity (IMEI) number or serial number for the ambulatory medical device to the network provider. Moreover, any fees can be negotiated or paid between the manufacturer and the network provider or between the subject's health insurance and the network provider. Thus, the subject's ambulatory medical device may be configured to communicate via the network of the network provider without any action by the subject.

[0092] In some other examples, the ambulatory medical device may be pre-registered or authenticated with a computing network of the cloud services provider as part of

the manufacturing process or before the ambulatory medical device is provided to the subject. This enables the ambulatory medical device to communicate over the wide area network with the computing system of the cloud services provider from day one without any or with minimal configuration by the subject. In some cases, a user, such as a healthcare provider may register or associate the ambulatory medical device with the subject at the computing network of the cloud services provider.

[0093] To enhance security, the ambulatory medical device may use a whitelist that identifies via a unique identifier (e.g., via an IP address, a MAC address, or a URL) permitted cloud servers or computing system of the cloud computing system. Further, the cloud computing service may have a whitelist that uses unique identifiers to specify ambulatory medical devices and/or other computing systems (e.g., remote display systems) that are permitted to communicate with the cloud computing system.

[0094] To enhance security, the ambulatory medical device may use a whitelist that identifies via a unique identifier (e.g., via an IP address, a MAC address, or a URL) permitted cloud servers or computing system of the cloud computing system. Further, the cloud computing service may have a whitelist that uses unique identifiers to specify ambulatory medical devices and/or other computing systems (e.g., remote display systems) that are permitted to communicate with the cloud computing system. The whitelist may be stored in a memory of the ambulatory medical device. Further, the whitelist may be configured during manufacture of the ambulatory medical device. For example, the whitelist may be configured with connection information to establish communication with one or more computing systems of a networked-computing environment. Further, the ambulatory medical device may be configured to execute the specific computer-executable instructions to at least obtain an address of the computing system from the whitelist and to establish a direct end-to-end data connection to the computing system of the networked-computing environment via a wireless wide area network using the address. Moreover, the ambulatory medical device may be configured to execute the specific computer-executable instructions to at least receive a public key from the computing system of the networked-computing environment.

Software Update of Ambulatory Medical Device

[0095] It is often the case that a computer application is updated after it is released. In some cases, the application is updated to patch bugs or vulnerabilities. In other cases, the application is updated or replaced with a new version to introduce new features or improve existing features. Regardless of the reason, it is often the case that an application is shutdown or is not executing while the application is updated. For most applications, there is minimal to no harm in shutting down or not executing an application while it is updated or otherwise replaced. For example, it is inconsequential that a video game, word processing, or edutainment application is not executing while it is updated.

[0096] However, it can be inconvenient, harmful, or, in some cases, life-threatening to cause an application on an ambulatory medical device to cease executing while it is updated or replaced by a new version of the application. If a subject or subject that is receiving therapy from the ambulatory medical device enters a state where therapy is desired or needed while an application or control software of the ambulatory medical device is being updated or replaced, harm may occur to the subject. For example, suppose the ambulatory medical device is an insulin pump, such as those that may be used by a type-1 diabetic. If the insulin pump becomes inoperative due to a software update process occurring at a time when a subject's blood glucose level exceeds a set-point or target range, the user may not receive a necessary insulin bolus from the ambulatory medical device. Thus, it is desirable to reduce or eliminate disruption to subject care or therapy when updating applications, such as control software, of an ambulatory medical device.

[0097] In some embodiments, an ambulatory medical device includes a computer-implemented method of updating an application executing on the ambulatory medical device without interrupting, or while causing minimal interruption, to therapy provided by the ambulatory medical device to a subject or subject. The method may generally be performed by a hardware processor, (e.g., a controller, and the like), included in an ambulatory medical device and based on a set of instructions that may be stored, for example, in a non-transitory memory of the AMD. The application update may be a new version of the application, a replacement or substitute application, or an application patch. In some examples, the application may be an older version of the application that has been used by instances of the ambulatory medical device for more than a threshold period of time and has experienced less than a threshold number of faults. The application update may be stored in one or more host

computing systems. The application update may be pushed to the host computing systems by a company that manages or manufactured the ambulatory medical device or other software company that is authorized by the manufacturer or licensee of the device.

[0098] FIG. 8 is a flow diagram showing an example of a computer-implemented method that may be used by the AMD in order to detect and download an application update from a host computing system or other computer readable media in which a copy of the application update is stored. In certain aspects, an ambulatory medical device, such as a medicament delivery device or a medicament pump may receive an indication 802 that an update is available for an application, such as control software or other software that controls or facilitates the operation of the ambulatory medical device. The software update may include a binary executable file for various processors of the ambulatory medical device. In some embodiments, the indication may be a determination made by a software or hardware module included in an ambulatory medical device of AMD. For example, the AMD may access a particular host computing system (e.g., using its communication module) to determine whether an update is available, based on set of update trigger conditions stored in a memory of AMD. The set of update trigger conditions may be defined/changed by a user and/or received by AMD from a host computing system. For example, a trigger condition may push the AMD to periodically search for an update at time intervals set by the user or received from a host computing system. Alternatively, or in addition, in response to a trigger (such as a user command, the replacement of medicament within the ambulatory medical device, the connecting to a particular network, or the connecting to a network using a particular communication transceiver (e.g., Wi-Fi) or the like), the ambulatory medical device may access a particular host computing system to determine whether an update is available to an application installed on the AMD. The software to be updated on the AMD may be currently executing on the ambulatory medical device or may be executed in future.

[0099] In some embodiments, the indication may a query received from the host computing system that may access the AMD to read and compare the software versions and the hardware configuration (and warranty) to determine the eligibility of the ambulatory medical device for a software upgrade. The serial number, the model number, and/or the software version may be used to determine software upgrade eligibility. In some embodiments, the eligibility may be determined based on the geoposition of the device

and/or whether the device is connected to a local area network (such as for example, a Wi-Fi network) or a wide area network (such as, for example, a cellular network). In various embodiments, the ambulatory medical device may have an antenna that provides the device with GPS, text or picture messaging, telephone calling, and data transfer capabilities. Software update may be provided on a limited release with test groups of varying sizes, e.g., 1-100 or 1-1000 or 1-10000. There may be a phase rollout of the software updates. In some embodiments, the AMD may responds to an upgrade eligibility request with a version of the first software or a model identification information of the ambulatory medical device or a manufacturing date of the ambulatory medical device.

[0100] If it is determined that an update is available to the application executing on the ambulatory medical device, the ambulatory medical device may establish a connection 804 to a host computing system that hosts the update to the application. Such connection may be established via one or more links or methods discussed above with reference to FIG. 7.

[0101] Once a connection is established, the ambulatory medical device may download the application update or application update from the host computing system over the connection 806. In some examples, the ambulatory medical device may download an image of the application update from the host computing system. While the application update is being downloaded, an existing version of the application on the ambulatory medical device may continue to execute. Thus, there is little or no interruption to therapy provided by the ambulatory medical device while the application update is being obtained by the ambulatory medical device.

[0102] Once the application update is obtained, the ambulatory medical device (using its control and computing module) may perform one or more operations to confirm that the application update was successfully downloaded from the application host system and that the download was not corrupted 808. For example, the ambulatory medical device may calculate a hash or checksum value from the downloaded application update. This hash or checksum value may be compared with one received from the application host system. If the calculated hash or checksum value matches the received hash or checksum value, then it may be determined that the download is both complete and not corrupt. Further, the ambulatory medical device may use the checksum, a tag, a payload size, or any other method to confirm that the download of the application update is complete and not corrupt. If it is

determined that the download is corrupt, the AMD discards the corrupt copy and downloads another copy of the update. If it is determined that the download is complete and not corrupt, the AMD may proceed to the installation step wherein the application update may be installed on the AMD without interrupting the ongoing or upcoming therapy sessions.

[0103] FIG. 9-11 are flow diagrams illustrating examples of computer-implemented methods that may be used by the AMD to install a downloaded application update without disrupting the therapy provided to a subject.

[0104] In the example method illustrated in FIG. 9, if it is verified that an uncorrupted copy of the update for an application is successfully downloaded 902 (e.g., using the procedure described above with reference to FIG. 8), the control and computing module (CCM) of the AMD may determine the amount of time required to install the application update 904 and wait for a trigger signal 906 to initiate installation process. In some examples, the CCM may notify to the user 908 through a user interface (e.g., a touchscreen display), that an update is ready for installation. The notification may include the installation time and information about the update. In such examples, if a trigger is not received, CCM may send one or more notifications to the user indicating that a new update is ready for installation. In some examples, the trigger may be the confirmation that the application was successfully downloaded. Alternatively, or in addition, the trigger may be a user command received based on an interaction by a user or subject with a user interface that is part of or that communicates with the ambulatory medical device.

[0105] The installation time may be determined by the CCM based on data or metadata provided with the downloaded application update. For example, the application update may include a file (e.g., a text file or configuration file) that includes the install time. The installation time may be determined by the manufacturer of the ambulatory medical device or the publisher of the application update. For example, the developer of the software update may average the install time across several test devices to determine the install time metadata that is provided with the software update. General purpose computers have a wide variety of configurations and the performance of a general purpose computer may vary depending on the applications executing at a particular time. Thus, the determination of install time for an application based on the measurement of install time on a test device is typically unreliable. However, as an ambulatory medical device is often a special-purpose

device that is designed to perform a specific function (e.g., provide insulin to a subject), an install time determined during testing by a manufacturer may in many cases be a reliable determination of install time on an ambulatory medical device of a subject. Alternatively, or in addition, to determining the install time based on testing by a manufacturer, the install time of an application update may be determined or estimated based on a size of the application update. In some cases, the provided or estimated install time may include a buffer. In other words, an additional amount of time may be added to the install time to account for variances in operating condition of the ambulatory medical device or inaccuracies in the estimated install time.

[0106] If a trigger is received 906, the CCM may check for any ongoing therapy session 910. If the no therapy is currently being administered, the CCM determines the next therapy time 914 (or the time left until the next therapy session). If therapy is currently being administered the installation will be delayed 912 until the therapy session is complete. Once the current therapy session is complete, the CCM may determine the time remaining until next therapy session 914 (e.g., during which medicament, such as insulin is delivered to a subject).

[0107] In some cases, the determination of the next time that therapy is to be delivered may be an estimate based on historical delivery of therapy, a present condition of the subject (e.g., when a glucose level is of a subject is at the center of a desired range, the next therapy delivery time may be estimated to be further off than when the glucose level is at the edge of the desired range), and/or an indication provided by a user or subject (e.g., an indication that the user is planning to have a meal, to exercise, or to go to sleep). Alternatively, or in addition, the determination of the next time that therapy is to be delivered may be based on a scheduled delivery of therapy (e.g., every 5 minutes or every hour).

[0108] As previously described, it is desirable to prevent disruption to therapy during the application update process. Thus, after the next therapy time is determined 914, the estimated install time may be compared 916 to the determined or estimated next therapy delivery time to determine whether the installation of the application update can be completed before the next therapy delivery to the subject. If it is determined that the time left until the next therapy session is sufficiently longer than the determined time for completing the installation, installation of the application updated may be initiated 918. In some

examples, the determined time to the next therapy session has to be longer than the determined installation time by a threshold value. Such threshold value may be different for different application updates and/or the type of next therapy session. If it is determined that the application installation cannot be completed before the next therapy delivery (or the time left until the next therapy is not larger than that estimated installation time by a threshold value), the installation of the application may be delayed, regardless of receipt of the trigger. In this case, the CCM may wait for the next therapy to be completed and then determine a new therapy time 914. This process may be repeated until CCM determines that the update can be installed without interrupting an expected or scheduled therapy by the ambulatory medical device. In some examples, a new determination may be made before completion of the next therapy, to determine whether installation may be completed prior to a subsequent therapy time after the next therapy time.

[0109] In some cases, a time when the application can be installed without interrupting therapy may not be identified. In some such cases, a user (e.g., a clinician or other medical provider, or a subject) may be provided with an alert that an application update is available and/or that the application update cannot be installed without interrupting therapy. The user may be provide with an option as to whether to permit the update and/or when to install the application update. The option may include presenting the user with the estimated install time enabling the user to schedule the application update at a time when interruptions to therapy may be minimal or when an alternative source of therapy (e.g., injection therapy) can be utilized.

[0110] In some embodiments, once it is verified that an uncorrupted copy of the update for an application is successfully downloaded 902, the AMD's control and computing module (CCM) may notify the user and wait for a trigger signal before determining the installation time. Once the trigger has been received, the CCM initiates the installation process of the downloaded copy of the application update without interrupting therapy provided by the ambulatory medical device to the subject. In such embodiments, the application update may be installed in a different memory location than the memory location where the original application is installed and executed.

[0111] FIG. 10 is flow diagram illustrating an example of a computer-implemented method that may be used by the AMD in order to install a second application

that is an update to a first application executing on the ambulatory medical device, without disrupting the therapy provided to a subject. In this example, once the control and computing module (CCM) of the AMD verifies that an uncorrupted copy of the second application is successfully downloaded 1002 (e.g., using the procedure described above with reference to FIG. 8), the CCM may initiate the installation process of the second application 1004 without interrupting the execution of the first application. The CCM may confirm 1006 the successful installation of the second application and wait for a trigger signal 1010 to initiate the execution of the second application in place of the first application. In some examples, the installation of the second application may be confirmed by sending a notification the user 1008 via a user interface of the AMD. In some examples, the CCM may determine the amount of time required for switching the control of AMD to from the first application to the second application. The notification may include information about the update and the time required for switching between the applications. In some examples, the trigger may be a user command received based on an interaction by a user or subject with a user interface that is part of or that communicates with the ambulatory medical device. In such examples, if a trigger is not received the AMD may send one or more notifications to the user indicating that a new update is ready for installation. If a trigger is received, the CCM may check for any ongoing therapy session 1012. If the no therapy is currently being administered, the CCM determines the next therapy time 1016 (or the time left until the next therapy session). If therapy is currently being administered the installation will be delayed 1014 until the therapy session is complete. Once the current therapy session is complete, the CCM may determine the time remaining until next therapy session 1016. The estimated next therapy delivery time may be compared to a set threshold time to determine whether the switching from the first application to the second application can be performed without interfering with the next therapy session. If it is determined that the time left until the next therapy session is longer than the set threshold time, the execution of the second application will be initiated and the execution of the first application will be halted 1020. In some examples, the set threshold time may be determined by the CCM at least partly based on the time required to execute of the second application and halt the first application. In some other examples, the set threshold time may be received from a host computing system.

[0112] In some embodiments, the performance of an application update may be tested before switching control of the AMD to the application update. FIG. 11 illustrate an example method that may be used by such embodiment. First the AMD verifies that an uncorrupted copy of the update for a first application is successfully downloaded 1102 (e.g., using the procedure described above with reference to FIG. 8). Next the AMD may install 1104 and execute 1106 the downloaded copy of the second application without interrupting the execution of the first application and therefore the therapy that might be provided by the ambulatory medical device to the subject. In some examples, the second application update may be installed to a separate portion (e.g., a separate execution space or separate memory) from the portion where the first application is installed and is being executed. The Control and computing module (CCM) of the AMD may determine that a minimum set of operating conditions are satisfied by the second application 1110, wherein the minimum set of operating conditions relate to maintaining therapy provided by the ambulatory medical device to the subject. If it is determined that the minimum set of operating conditions are not satisfied by the second application, the AMD may wait for an indication that a third application is available and repeat the procedure described above to evaluate the performance of the third application. If it is determined that the minimum set of operating conditions are satisfied by the second application, the AMD may check for an ongoing therapy session 1114. If it is determined that currently no therapy is provided to a subject, CCM may switch the control of the ambulatory medical device from the first application to the second application 1118. If currently therapy is provided to a subject, the CCM may wait until the therapy session is completed 1116 and then switch the control of the AMD from the first application to the second application.

[0113] In some cases, the ambulatory medical device may be updated (or downgraded) to add (or remove) features from the ambulatory medical device. For example, the ambulatory medical device may initially provide only insulin therapy. At some point in time, the ambulatory medical device may be upgraded to include bi-hormonal control (e.g., to provide both insulin therapy and counter-regulatory agent (e.g., Glucagon) therapy). The upgrade may be based on newly available features and/or based on a decision by a user to purchase or otherwise obtain additional features. Similarly, a user may opt to downgrade therapy from bi-hormonal to insulin-only therapy. Alternatively, the upgrade or downgrade

may be made based on the availability of medicament. In some examples, a first update can be a first application version comprising a first feature set (e.g., providing insulin therapy) and a second update can be a second application version comprising a second feature set (e.g., provide both insulin therapy and Glucagon therapy). In some such examples the first feature set may comprise a subset of the second feature set. In some other examples, the first feature set may comprise a partially overlapping set of features with the second feature set.

[0114] In some examples a computer-implemented method that may be used by the AMD in order to detect, download and install an update to an application executing on the ambulatory medical device wherein the application comprises one of a first application version comprising a first feature set or a second application version comprising a second feature set. In some examples, the first feature set may comprise partially overlapping set of features with the second feature set. In some other examples, the first feature set may comprise partially overlapping set of features with the second feature set. The AMD may receive an indication of availability of the application update, download the application update and verify that an uncorrupted image of the application update is successfully downloaded (e.g., using the procedure described above with reference to FIG. 8). Next, the control and computing module (CMM) of the AMD may initiate the installation process of the application update image without interrupting the execution of the application. In some examples, the indication received by the AMD 802 (with reference to FIG. 8), may include information about application update being an update to the first application version or to the second application version. In some such examples, the CCM may determine the version of the application update and download the application update image based on the determined version

[0115] In some embodiments, any downloaded application update may be installed to a separate portion (e.g., a separate execution space or separate memory) from a currently executing version of the application. Once installation of the application is complete and the application is verified as being successfully installed, the active version of the application can be switched. For example, control of the ambulatory medical device can be provided to the updated application, the previously executing application can be ceased or halted. The old application can then be removed, or kept as backup. Determining when to switch which version of the application is active may follow a similar process as previously

described for identifying a next therapy delivery time and selecting a time to switch active versions of the application when there will not be an interruption to the therapy provided by the ambulatory medical device.

[0116] In some embodiments, the ambulatory medical device may be configured to store multiple instances of an application (e.g., ambulatory medical device control software). For example, the ambulatory medical device may have a current, or first, version of the application that it is installed in a first memory location (e.g., in the main memory 616) and is executing to, for example, control therapy provided by a subject. Further, the ambulatory medical device may include an updated, or second version of the application installed in a second memory location (e.g., in the main memory 616). The update of the second version may have been downloaded and installed (e.g., in a prior to detection of the fault). In such embodiments, when a fault is detected during execution of the first version of the application, the ambulatory medical device may initiate the execution of the second version of the application and then switch control of the AMD to the second version of the application to maintain therapy to the subject.

[0117] In some examples, the second version of the application installed on the AMD may be a version older than the first version, or version that may not have track a record of stability and reliability. FIG. 12 is a flow diagram for such examples. Once an application-fault is detected during execution of the first version 1202, the control and computing module (CMM) of the AMD may switch the control of the AMD to the second version of the application 1204 while establishing a connection with a host computing system configured to host a third update and download the third update 1206. The third version of the application may be a new version, a version prior to the first version, an update to the first application that addresses the detected application-fault or an older version that satisfies the conditions to be classified as a “safe version” (e.g., less than a threshold number or rate of faults over a minimum period of time). The second version (installed in the device) may control the AMD while the third version is being downloaded and installed 1208 without interrupting the therapy. Once the download of the third version is complete, the CCM may initiate the installation process of the downloaded copy of the third application and switch control of the ambulatory medical device from the second application to the third application 1210 without interrupting therapy provided by the ambulatory medical device to the subject.

[0118] In yet other embodiments, a “safe version” of the application may have been installed on the ambulatory medical device prior to detection of a fault. The safe version of the application may include a version of the application that has been used by instances of the ambulatory medical device for more than a threshold period of time and has experienced less than a threshold number of faults. For example, the safe version of the application may be a two-year old version of the application that has demonstrably had less than a threshold number of faults occur over the period of two years. This safe version of the application may have less features than the first or second version of the application. However, when a fault is detected during execution of the first or second version of the application, the ambulatory medical device may switch control of the device to the safe version of the application to maintain therapy to the subject.

[0119] In some cases, if there is an issue installing an updated version of the application, the ambulatory medical device may revert to the current version or a safe version installed on the AMD.

[0120] In some other examples, the AMD may be triggered to establish a connection with the host computing system and search for the second version once a fault is detected during execution of the first version. In these examples, the ambulatory medical device may revert to the safe version (installed in the device) while downloading and installing the second version without interrupting the therapy.

[0121] FIG. 13 is a flow diagram illustrating yet another example of a method of responding to a fault detection by the AMD. In this example, once an application-fault is detected during execution of the first version of an application 1302, the control and computing module (CCM) of the AMD may look for a second version of the application 1304 in the main memory or the storage. If it is determined that the second version has been already downloaded, the CCM will determine 1306 whether the second version of the application is installed in a memory location and is ready to be executed. If it is determined that the second version of the application is installed, the control of the AMD will be switch to the second version of the application. With reference to block 1306, if CCM determines that the second version exists in eth memory but it is not installed, it will switch eth control of eth AMD to a safe version that may be already installed and then initiates the installation 1318 of the second version. Once the installation of the second version is complete, the CCM

may switch control of the AMD from the safe version of the application to the second version of the application. In some embodiments, after the control of the AMD is switched to the second version of the application, the CCM may search for a third version of the application 1310 that may be an update to the previously downloaded second version. If a third version is found, the CCM may download and install the third version 1312 and switch the control of the AMD to the third version 1314. With reference to block 1304, if the CCM cannot find a second version of the application in a memory or storage location, it will switch the control of the AMD to a safe version of the application 1320 that may be installed in a memory location (e.g., in the main memory or in the storage) and then search for a third version of the application 1310. If a third version is found, the system may download and install the third version 1312 and switch the control of the device to the third version 1314.

[0122] In some embodiments, when an application-fault of an application executing on the ambulatory medical device is detected, the AMD may transmit an indication of the application-fault to the host computing system of a manufacturer or maintenance service of the ambulatory medical device. In some other embodiments, the AMD may notify the user when an application-fault occurs through a user interface of the AMD or user interface communicating with the AMD.

Direct Network-Connected Medical Device Communication and Remote Viewing

[0123] An ambulatory medical device, such as an ambulatory medicament device (e.g., blood glucose control system (e.g., an insulin pump or a bi-hormonal pump that includes insulin and a counter-regulatory agent), a pacemaker, or any type of medical device that may be connected to a subject to provide therapy to the subject, can generate a significant amount of data related to therapy provided to a subject (therapy data). This therapy data may be useful for the subject, a healthcare provider, or other users (e.g., parent or guardian) to actively manage the subject's health condition. For example, the therapy data may be useful to determine whether a modification to therapy may be desirable or to confirm that intended therapy is being delivered at the right time. In other examples the data may be used to generate an alerts about the health condition of the subject when therapy data indicates that immediate attention is needed with regards to subject' health condition.

[0124] Various aspects of accessing the therapy data or other types of data stored in a memory of the AMD needs proper management in order to provide uninterrupted, secure and easy access to authorized users. As described above, the procedures and task performed by an AMD, including those associated with data transfer management, may be associated with certain computer-executable instructions stored and executed by the control and computing module 610 of the AMD 600. As such, different AMD configurations used for various data transfer management tasks, may be configurations of the control and computing module 610 of the AMD 600.

[0125] Accessing the data from the ambulatory medical device can be problematic in some cases. For example, accessing the data may require a user to connect the ambulatory medical device to a computer to upload the data. This places a burden on the user to remember to connect the ambulatory medical device. Further, during the period when the device is connected to the computer, the subject may not be receiving therapy from the ambulatory medical device. In some cases, the subject may not be capable of connecting the device to the computer (e.g., when the AMD is not within range of the local device) and may not have someone available to assist the subject. Thus, a direct end-to-end connection to a *computing system* that (e.g., computing system of a healthcare provider) can safely share data (e.g., therapy data) with authorized users may facilitate data management and access.

[0126] FIG. 14 is a block diagram illustrating an example network configuration wherein the AMD 1402 is directly connected to a computing system 1404. The computing system 1404 may be part of networked computing environment 1408 (e.g., a data center, networked computing system), or cloud network 1406 or cloud computing system of a cloud service provider. The computing system may include one or more non-transitional memories and one or more hardware processors configured to execute the computer-executable instructions stored in one or more non-transitional memories. In some such examples, the procedures performed by the computing system may be associated with the execution of certain computer-executable instructions stored in a memory of the computing system by a hardware processor of the computing system.

[0127] In some examples, the direct end-to-end data connection may be supported by one or more transceivers in AMD's communication module 602. For examples, a direct connection may be established between the AMD 1402 and the computing system 1404 over

a wide area network (e.g., a cellular network) without using an intermediary system using various wireless standards and technologies (e.g., 4G, 5G and the like). In some examples, the transceiver may support communication via communication standards, including but not limited to, low power wide area network (LPWAN), Narrowband Long-Term Evolution (NB-LTE), Narrowband Internet-of-Things (NB-IoT), or Long-Term Evolution Machine Type Communication (LTE-MTC). In some cases, the transceiver is always on, and in other cases, the transceiver may be activated when a data transfer is scheduled, requested or activated. In some cases, the capability of the ambulatory medical device 1402 to communicate with the computing system may be activated during manufacture or before providing the device to a subject.

[0128] In some cases, the subject or a user establishes or initiates establishing the direct end-to-end data connection with the computing system. For example, the subject may interact with a user interface to cause the ambulatory medical device to communicate with the cloud computing service. In other cases, the direct end-to-end data connection may be initiated or established without action by the subject or the user. For example, the direct end-to-end data connection may occur automatically at particular times or when the ambulatory medical device is in particular locations. This automatic connection may occur using information supplied to the ambulatory medical device at a time of manufacture, shipment, sale, or prescription to the subject. Further, in some cases, the ambulatory medical device can communicate with the computing system without having access to a wifi network or a local area network (LAN). For example, the ambulatory medical device may communicate using a cellular or other wide area network. Further, in some cases, the interaction by the user with the ambulatory medical device may be relatively minimal or simple compared to traditional network communication. For example, a user may push a single button (e.g., an “upload” button) to trigger establishing of a connection with the cloud computing service and causing data to be provided from the ambulatory medical device to the cloud computing service.

[0129] In some cases, the ambulatory medical device may be turned on and paired with the wireless wide area network (e.g., a cellular network) at the time of manufacture, or prior to being provided to a subject. Further, the ambulatory medical device may be authenticated with the networked-computing environment as part of the manufacturing process

[0130] Further, establishing the direct end-to-end data connection may include determining that the ambulatory medical device is permitted to communicate with the computing system based at least in part on the device identifier.

[0131] In some implementations, establishing the direct end-to-end data connection may include determining that the ambulatory medical device is permitted to communicate with the computing system based at least in part on a *device identifier* associated with the ambulatory medical device. The device identifier may be a unique identifier specific to the ambulatory medical device. The device identifier may include or may be based on one or more of an Internet Protocol (IP) address, a Media Access Control (MAC) address, a serial number, or a subject identifier of a subject that receives therapy from the ambulatory medical device.

[0132] Further, establishing the direct end-to-end data connection may include determining that the ambulatory medical device is permitted to communicate with the computing system based at least in part on the device identifier. The device identifier may be initially provided to the networked-computing environment prior to provisioning of the ambulatory medical device to the subject. For example, the device identifier may be initially provided to the networked-computing environment as part of a manufacturing process for manufacturing the ambulatory medical device. The request may include a device identifier associated with the ambulatory medical device.

[0133] The ambulatory medical device may be configured to at least identify a computing system 1404 of a networked-computing environment 1408 based on a whitelist of one or more approved computing systems. The whitelist may be stored in a memory of the ambulatory medical device 1402 (e.g., a memory in the control and computing module of the AMD). Further, the whitelist may be configured during manufacture of the ambulatory medical device. For example, the whitelist may be configured with connection information to establish communication with one or more computing systems of a networked-computing environment. Further, the ambulatory medical device may be configured to at least obtain an address of the computing system from the whitelist and to establish a direct end-to-end data connection to the computing system of the networked-computing environment via a wireless wide area network using the address. The whitelist may include unique identifiers, such as

MAC addresses or static IP addresses that are associated with computing systems of the cloud services provider.

[0134] To enhance security, the ambulatory medical device may use a whitelist that identifies via a unique identifier (e.g., via an IP address, a MAC address, or a URL) permitted cloud servers or computing systems in networked computing environment. Further, the cloud computing service may have a whitelist that uses unique identifiers to specify ambulatory medical devices and/or other computing systems (e.g., remote display systems) that are permitted to communicate with the cloud computing system.

[0135] When the AMD communicates data over a network, there is a risk of a data breach. Thus, to improve security, all communication between the ambulatory medical device and the computing may be based on a secure data transmission method. For example, the ambulatory medical device may encrypt all data using an asymmetric key.

[0136] In some examples, the therapy data may be encrypted before being transferred to the computing system. In these examples, AMD may have a public key and a private key stored in one of its memories permitting the AMD to encrypt data communications transmitted by the ambulatory medical device to the computing system. In these examples, AMD may transmit the public key along with the therapy data to the computing system. The public key provided by the AMD and a private key stored on the computing system may permit the computing system to decrypt the data received from the ambulatory medical device. In some such cases, the public key may timeout and a new public key may be obtained from the ambulatory medical device to facilitate decrypting subsequent communications from the ambulatory medical device. In some cases, the public key may be associated with a time-to-live (TTL) value. In some such cases, the public key may timeout and a new public key may be obtained from the ambulatory medical device to facilitate decrypting subsequent communications from the ambulatory medical device.

[0137] Moreover, the secure data transmission may include generating a shared secret based at least in part on the public key and the private key. In some such cases, decrypting the encrypted data comprises using the shared secret to decrypt the encrypted data. In some examples, shared secret may be established using public key exchange algorithm (e.g., Diffie-Hellman key exchange algorithm).

[0138] In some cases, the computing system may be configured to transfer the data after receiving a request to transfer data stored on the ambulatory medical device to the computing system over the direct end-to-end data connection via the wireless wide area network. Responsive to receiving the request to transfer data stored on the ambulatory medical device to the computing system, the computing system may be configured to receive, via the direct end-to-end data connection.

[0139] Once a connection is established and the therapy data is transferred to the computing system, the computing system may analyze the therapy data received from the ambulatory medical device and generate a therapy report. Further, the computing system may detect an alarm condition, based on therapy data analysis, and generate an alarm that may be provided to the subject, authorized user (e.g., healthcare provider). In some cases, the therapy data may trigger an automatic response by the computing system. For example, the AMD may determine that a medicament or another disposable is running low based on the received data and may automatically reorder the medicament or the disposable.

[0140] In some cases, the computing system may periodically receive data from the ambulatory medical device based on a regular schedule. Alternatively, or in addition, the data may be received in response to a command or when the ambulatory medical device determines it is within a certain location. For example, when the ambulatory medical device determines it is within a subject's home or at a healthcare provider's office based on a local area network connection or based on a geolocation system (e.g., a global positioning system (GPS)). In some implementations, additional encrypted data is received from the ambulatory medical device on an intermittent basis. Alternatively, or in addition, additional encrypted data is received from the ambulatory medical device on a continuous basis for at least a time period. The ambulatory medical device may be configured to transmit data as it is generated, or shortly thereafter, (e.g., in real or near real-time (e.g., within a few millisecond, seconds, or minutes of the data being generated)), or in bulk at specified periods of time. Transmitting the data in bulk at particular time periods may extend battery life, but may provide for less up-to-date analysis. Data can be made available on-demand by keeping the transceiver always on, but this may consume more power. Thus, the scheduling of data transfer may be balanced based on different considerations, such as: (1) power consumption and (2) need to share information with authorized users or systems.

[0141] In some cases, the computing system may be used as a backup for the ambulatory medical device. For example, the ambulatory medical device can backup data to the computing system every night, when it is charging, or when it is in proximity to home or a physician's office (e.g., when subject is in waiting room, the device may upload data that the physician can then access). Moreover, if the ambulatory medical device is replaced (e.g., for a new model or to replace a damaged device), the device can automatically synchronize with the computing system to obtain subject-specific configuration or therapy control data.

Therapy Data and Therapy Report

[0142] In some examples, *the therapy data* comprises dose or dosage data corresponding to one or more doses of medicament provided by the ambulatory medical device to the subject. Further, the therapy data may comprise subject data corresponding to a medical or physiological state of the subject as determined by the ambulatory medical device.

[0143] In other examples, the data provided to computing system may include any type of data that may be measured or obtained by the ambulatory medical device and may include a record of therapy provided by the ambulatory medical device. For example, the data may include a time that therapy was provided, an amount of medicament provided as part of the therapy, a measure of one or more vital signs of the subject, a measure of blood glucose levels at different times for the subject, a location of the subject, and the like.

[0144] In some cases, the therapy data may be used to track the use of disposables, such as insulin or other medicament, or insulin pump site kits. In some cases, the computing system may automatically order or reorder disposables at a particular time based on tracking the use of the disposable. Alternatively, or in addition, the reordering of the disposables may be initiated or performed from the ambulatory medical device (e.g., via a wireless wide area network or via a local connection through a separate electronic device).

[0145] In some cases, the data transferred to the computing systems may comprise operation data corresponding to operation of the ambulatory medical device. Alternatively, or in addition, the data may further comprise error data corresponding to an error in operation of the ambulatory medical device.

[0146] In some examples, the data, therapy data and/or the therapy report may be stored in a memory of the computing system and/or at a storage of the networked-computing environment.

[0147] In some cases, the method may include converting the therapy data from one format to another format. For example, the method may include converting the therapy data from a format used to store and/or present data on ambulatory medical device to a format that can be stored or processed on the computing system. In some cases, the therapy data is converted from a machine-readable format to a human-readable format. The data may be stored in a more easily interpreted format that can be understood by different types of users. For example, the data may be presented in one format for a healthcare provider (e.g., sensor readings), a simplified format for a subject or parent of a subject, other data formats for displaying data to different types of users.

[0148] In some examples, the therapy data collected from different AMDs associated with plurality of subjects may be aggregated for a group of subjects based on their association with an institution or organization (e.g., a clinic, an insurance company, and the like)

[0149] In some other examples, a *therapy report* based at least in part on the therapy data may be generated by the computing system. The therapy report may comprise time-series therapy data relating to the therapy delivered by the ambulatory medical device over a particular time period.

[0150] In some examples, the therapy report may be sent to AMD wherein the subject can see the report via a user interface (e.g., a touchscreen display).

[0151] In some cases, the ambulatory device data and/or data generated by the computing system based on the ambulatory device data can be viewed on a secondary display system from the computing system. For example, a clinician or parent can access the data from their personal device. The communication between the computing systems and the viewing device may be encrypted. Moreover, permission for sharing of end user data with a 'follower' (e.g., family member) or clinician may be granted or controlled by the end user (e.g., the subject or a guardian).

[0152] An association between a subject, a clinic, and/or an ambulatory medical device may be performed by association of a device serial number of the ambulatory medical

device with the subject and/or clinic. Further, a user (e.g., a subject, clinician, or parent) can access therapeutic recommendations through the cloud in case either the ambulatory medical device (e.g., an insulin pump) or the CGM sensor fails to function.

[0153] In some cases, the computing system may be configured to at least receive a request from one or more display systems 1410 that are separate from the networked computing environment to access the therapy report, therapy data or other data received by or stored in the AMD. In some cases, the display system may be a computing system of a medical practitioner 1414 (e.g., such as a doctor, nurse,...), a guardian of the subject 1416 (e.g., subject's parents), an authorized user 1418 (e.g., a user authorized by the subject such as spouse, relative, friend, and the like), a healthcare provides 1410, or a device of the subject 1412 (e.g., cell phone, personal computer, tablet and the like).

[0154] In some examples, the display system can be a therapy data management system that analyses a therapy data associated with a specific type health problem (e.g., data associated with managing diabetes) and provides useful information to the subject or an authorized user to monitor and manage the corresponding ailment.

[0155] The request may comprise an *account identifier* associated with a user that generated the request. In some examples, the account identifier may comprise a unique identifier associated with the subject. Alternatively, or in addition, the account identifier comprises a unique identifier associated with a user that is authorized to access the therapy report. The user may or may not be the subject. In some aspects of the present disclosure, the method may further include associating the therapy data with the account identifier at a storage of the networked-computing environment. Further, the computing system may be configured to determine whether an account associated with the account identifier is permitted to view the therapy report. In some examples, account permissions may be granted and/or modified by the subject. For example, the subject can access an account at a networked computing environment 1408, for example, a cloud service provider associated with the subject, and provide one or more identifiers associated with one or more other users to give them permission to access the subject's therapy data or report stored on the computing system.

[0156] Responsive to determining that the account is permitted to view the therapy report, the hardware processor may be configured to transmit the therapy report to the display system over an encrypted communication channel.

[0157] In some cases, the method may include receiving an identity or identification information of one or more users that are authorized to access therapy data stored at the networked-computing environment. For example, a user or subject may authorize a clinician or other healthcare provider, a parent or guardian, or other users that the subject desires to have access to the therapy data. The identity information of the one or more users may include any type of information that may identify the user or enable the user to be authenticated. For example, the identity information may include a name, unique identifier (e.g., social security number), an email, an address, a phone number, account information for the user at the networked-computing environment, or any other identifying information.

[0158] FIG. 15 is a flow diagram that illustrates an example method that may be used by computing system 1404, to generate and share a therapy report based on encrypted therapy data received from an AMD 1402. In some examples, the AMD 1402 may generate the encrypted therapy data using a public key and a private key. The method may include establishing a direct end-to-end data connection 1502 to an ambulatory medical device, for example, via a wireless wide area network (WAN) using a Narrowband Long-Term Evolution (NB-LTE) transceiver included in the AMD 1402. Once a direct end-to-end data connection between the AMD 1402 and the computing system 1404 is established, the computing system may receive a public key 1504 (e.g., associated with encrypted data), from the AMD 1402 over the established connection. Next, the computing system may receive a request from the AMD 1506 to transfer data (e.g., therapy data) stored on the ambulatory medical device 1402 to the computing system 1404 over the direct end-to-end data connection. In some examples, the computing system 1404 may use the device ID associated with the AMD 1402 to determine whether the AMD 1402 is authorized to transfer data to the computing system 1504. If, based on the device ID, it is determined that the AMD 1402 is authorized to transfer data to the computing system, the encrypted therapy data may be transferred 1512 to the computing system. If, based on the device ID, it is determined that the AMD 1402 is not authorized to transfer data to the computing system, the request may be denied 1510. The computing system may decrypt the encrypted therapy data 1514 using a

private key (e.g., stored in a memory of the computing system) and a public key received from the AMD 1402. In some examples, the therapy data may be used to generate a therapy report 1516. In some examples, the decrypted therapy data and/or therapy report may be stored in a memory of the computing system 1404.

[0159] The example method may further include receiving a request from a display system 1410 that is separate from the networked computing environment, to access the therapy report 1518. The request may comprise an account identifier associated with a user that generated the request. The method may include determining using the account identifier to determine whether the account associated with the account identifier is permitted to view the therapy report. In the computing system determines that the account associated with the received account identifier does not have the required permission, the request will be denied 1524. Responsive to determining that the account is permitted to view the therapy report, the method may include transmitting the therapy report to the display system over an encrypted communication channel.

[0160] In certain implementations, the method may further include determining that the therapy data or other data received from the AMD satisfy an *alert threshold* condition. In these implementations, it is determined that the therapy data or other data received from the AMD satisfy an alert threshold condition, the computing system may send an alert to one or more display systems designated to receive alerts from the computing system.

[0161] In some examples, alert threshold condition may be associated with the health condition of the subject. For example, alert threshold condition may include subject's blood sugar level is above or below a set value (hyperglycemia or hypoglycemia). In some other examples the alert threshold condition may be associated with the operation of the AMD. For example, alert threshold condition may include the rate of therapy (e.g., the rate at which insulin is provided to a subject) being above or below a set value.

[0162] In some other examples, alert threshold condition may be associated with the temporal behavior of therapy data over a period of time. For example, the alert threshold condition may include the fluctuations or variations of the subject's blood sugar level being above a set value.

[0163] In some examples, the alert threshold condition may be defined or set by health provider. In some such examples, the health provider may change one or more alert threshold conditions based on the health condition of the subject.

[0164] FIG. 16 is block diagram, illustrating an example network and data flow configuration where an AMD 1602, which is directly connected to a computing system 1604 (e.g., computing system within a cloud network 1606), may generate and send alerts 1619 (e.g., alert messages, alert signals and the like) upon determining that data received from the AMD 1607 satisfies a threshold condition. The computing system 1604 may be part of networked computing environment 1608 (e.g., a data center, networked computing system), or cloud network 1606 or cloud computing system of a cloud service provider. The computing system may include one or more non-transitional memories and one or more hardware processors configured to execute the computer-executable instructions stored in one or more non-transitional memories. The AMD may receive data from one or more medical sensors 1605 (e.g., analyte sensor, temperature sensor, heart beat sensor, and the like) and/or one or more environmental sensors (e.g., geolocation receiver, motions sensor, accelerometer and the like.). These sensors may be included in the AMD unit or may be connected to the AMD via a wired or wireless link.

[0165] In some cases, the display systems receiving the alert 1611, may be display systems that have already received therapy reports from the computing system 1604. In other examples, a group of display systems may be selected and authorized by the subject, who is receiving therapy from the AMD, to receive alerts 1611. The display systems that may receive alerts 1611 from the AMD may include: a medical practitioner 1614 (e.g., such as a doctor, nurse,...), a guardian of the subject 1616 (e.g., subject's parents), an emergency service provider 1618, an authorized user 1420 (e.g., a user authorized by the subject such as spouse, relative, friend, and the like), a healthcare provider 1622, or a device of the subject 1612 (e.g., cell phone, personal computer, tablet and the like). In some examples, when it is determined that received data the AMD 1607 satisfies a threshold condition, in addition to sending a alerts to one or more display systems 1610, the computing system 1604 may send an alert 1609 to the AMD 1602.

[0166] In some examples, the AMD 1602 may be configured to establish a connection to support continuous data transfer to the computing system 1604 for a given

period of time (e.g., provided to the AMD by the subject), in order to capture any data that is generated over that period and satisfies an alert threshold condition. For example, the subject may request a continuous connection between AMD and the computing system when going for hike alone to make sure that if his/her health condition deteriorate during the hike, an alert is sent to authorized display systems.

[0167] In some examples, a geolocation sensor (e.g., a Global Positioning System (GPS) receiver) and/or a proximity sensor can be used to enable location-activated features such as automatic upload of data at certain locations.

[0168] In some cases, the ambulatory medical device may include or be connected to an accelerometer or a geolocation system. This velocity of the ambulatory medical device may be determined based at least in part on the accelerometer or geolocation system. Using the data obtained 1607 from the ambulatory medical device 1602 including the location and/or velocity information, the computing system 1604 can provide intelligent alerts. For example, if the data indicates that a user is travelling at a high rate of speed (e.g., likely in a car) and the user's blood glucose level is low (e.g., below 55 mg/dl), the computing system may automatically alert emergency services 1618 that a subject is at risk of hypoglycemia and may be driving. Further, the computing system can provide a location of the subject to the emergency services provider 1618.

[0169] In some examples, the computing system can generate alerts based on a trend of the aggregated therapy data or based on therapy data that is an outlier to the aggregate therapy data or an outlier to a time-based average of the therapy data.

[0170] Further, the geolocation sensor and/or a motion sensor (e.g., an accelerometer) can be used to detect velocity of a subject to enable intelligent motion-sensitive alerts. For example, if the subject is moving at 60 mph and experiences low blood glucose, the system may enable a set of driving alerts and schedule possibly therapy in the future. The driving alerts may inform the subject to pull over immediately due to a risk of a hypoglycemic event. Further, an emergency responder may be informed of a subject location using based on information obtained from the geolocation sensor. If the subject is moving at 6-7 mph, exercise alerts may be enabled to, for example, alert the user to pause exercising and attend to low blood sugar. If the subject hasn't moved for 3 hours and has low blood sugar, the system can enable automatic notification to emergency services. Further, a

determination of the subject's motion can be used to automatically adjust setpoint (e.g., raise setpoint during exercise). The activity level of the subject can be sensed and use to improve alerts and therapy.

[0171] Additionally, the cloud server can send a text message or call to a follower's and/or end user's phone or smart device in case the therapy data satisfies an alert threshold. These messages may be provided from the cloud computing system to a third-party device in case roaming or disabling of the data plan on the ambulatory medical device occurs (e.g., no TCP/IP available). Further, the cloud computing service may send a text message or call 911 in case of a detected emergency. The cloud server can track, for example, via GPS, the end user's most recent location and share that information with a follower and/or emergency personnel. Moreover, the cloud computing system may enable an end user to order and re-order medical supplies directly from the viewing device.

[0172] Moreover, the computing system can generate notifications (e.g., generate a message when there is a risk of hypoglycemia). Further, more detailed processing in the cloud can result in improved recommendations (e.g., Tmax, setpoint, or other control parameters)

[0173] FIG. 17 is a flow diagram illustrating an example method that may be used by computing system 1604, to generate and send alerts (e.g., alert messages, alert signals and the like) to one or more authorized devices and to the AMD. The method may include establishing a direct end-to-end data connection 1702 to an ambulatory medical device, for example, via a wireless wide area network (WAN) using a Narrowband Long-Term Evolution (NB-LTE) transceiver included in the AMD 1602. In some examples, the direct end-to-end connection may be established for a given period of time set by the subject or an authorized user (e.g., a guardian of the subject). Once a direct end-to-end data connection between the AMD 1602 and the computing system 1604 is established, the computing system may receive a public key 1704, from the AMD 1602 over the established connection. Next, the computing system may receive a request from the AMD 1706 to transfer data (e.g., therapy data, medical sensor data or environmental sensor data) generated by the ambulatory medical device 1602 to the computing system 1604 over the direct end-to-end data connection. In some cases, the request may include a time period during which AMD continuously transmits any data generated by the AMD 1602 or obtained from one or more

sensors (e.g., medical sensors 1603 or environmental sensors 1605), to the computing system 1604. In some such cases, the time period for continuous data transfer from the AMD 1602 to the computing system 1604, may be provided by the subject or a guardian of the subject to the AMD. In some examples, the computing system 1604 may use the device ID associated with the AMD 1602 to determine whether the AMD 1602 is authorized to transfer data to the computing system 1604. If, based on the device ID, it is determined that the AMD 1602 is authorized to transfer data to the computing system 1604, the encrypted therapy data may be transferred 1712 to the computing system 1604. If, based on the device ID, it is determined that the AMD 1602 is not authorized to transfer data to the computing system, the request may be denied 1610. The computing system 1604 may decrypt the received data 1714 using a private key (e.g., stored in a memory of the computing system 1604) and a public key received 1702 from the AMD 1602. In some examples, the computing system 1604 may determine whether the received data (e.g., therapy data, medical sensor data or the environmental sensor data), satisfies a threshold condition 1716. In some cases, the threshold condition may be provided to the AMD by the subject or an authorized user (e.g., a guardian of the subject). In some other examples, the threshold condition may be provided by a healthcare provider. In some such examples, the threshold condition may be stored in a memory of the AMD. If it is determined that the data satisfies a threshold condition, an alert may be generated and sent 1718 to one or more display systems 1610 that are authorized (e.g., by the subject or a guardian of the subject) to receive alerts. In some examples, the subject or the guardian may authorize one or more display systems 1610 to receive alerts by providing the account IDs of the one or more displays systems to the computing system 1604 or the networked computing environment 1608.

Preventing Inadvertent Therapy Changes

[0174] As described above, the ambulatory medicament device may include a user interface (e.g., touchscreen interface or a non-touchscreen interface) that may present one or more user-interface screens to a user enabling the user to modify one or more therapy settings of the ambulatory medicament device, such as a quantity of medicament delivered when a condition is met or the condition that triggers the delivery of medicament to a subject. The user may be a subject receiving medicament or therapy, or may be another user, such as

a clinician or healthcare provider, or a parent or guardian. For ambulatory medicament devices that include a user interface, there is a risk that a setting is accidentally modified or is modified (intentionally or unintentionally) by a user that does not fully comprehend his or her action (e.g., a child or a user with a reduced mental capacity). Further, ambulatory medicament devices may accidentally have settings modified by inadvertent interactions with a user interface, such as may occur when an ambulatory medicament device is worn against the body of a subject.

[0175] This section relates to an ambulatory medicament device (AMD) to prevent an inadvertent modification in medicament deliver, for example, in the event of a setting of the AMD being accidentally modified by a user or inadvertent interactions with a user interface.

[0176] As mention above, in some embodiments the user may modify the control or configuration the AMD using a user interface. There is a possibility that the control or configuration of the AMD is accidentally modified through the user interface. For example, as the user may transport the ambulatory medical device, there is a danger that the user will inadvertently activate input in the ambulatory medical device that initiates a therapy change input (e.g., by applying pressure on the ambulatory medical device that may be placed in the jacket pocket of the user).

[0177] With reference to FIG. 18, in some such embodiments, the control and computing module (CCM) of the AMD may include a set of therapy change procedures 1828 implemented to prevent therapy change inputs 1829 that are inadvertent. The therapy change procedures 1828 may be implemented as instructions stored in a memory of CCM (e.g., the main memory 616) and executed by the processor 614. The therapy change input 1829, received from a user 1827, may be verified by the therapy change procedures 1828 before the ambulatory medical device 600 provides the therapy change delivery 1807. All the user interactions with the user interface module 1808 may be controlled and analyzed by the control and computing module (CCM) 610 via one or more therapy change procedures 1828.

[0178] In these embodiments, the user 1827 may wake or unlock the AMD by interacting with a wake interface 1822. The wake interface 1822 can be any of the additional user interfaces mentioned above, configured to generate a wake input to the CCM when detecting a pre-set user interaction.

[0179] The therapy change input 1829 can be an input provided by the user 1827 to change a therapy that is currently being delivered to the user 1827. In some embodiments, the therapy change input 1829 may cause the insulin or glucagon infusion pump to start infusing an amount of insulin or glucagon into the user 1827. Alternatively, the therapy change input 1829 may modify the rate of insulin or glucagon infusion into the user 1827. The therapy change input 1829 may also cancel insulin or glucagon infusion into the user 1827 from the insulin or glucagon infusion pump.

[0180] When a wake action is detected by the wake interface 1822, a wake input is sent to the control and computing module 610 wherein it imitates a wake control procedure 1834 that generates a wake signal to wake/unlock the user interface (e.g., a touch screen display).

[0181] When in the wake and/or unlocked state, a user may interact with the touchscreen 1824, alphanumeric pad 1826 or other types of user interfaces that may be included in the user interface module 1808, to obtain access to therapy change user interface.

[0182] The therapy change user interface may be activated by a first user interaction with the user interface (e.g., touchscreen display 1824). When the first user interaction is detected, the user interface module 1808 sends an input signal to the control and computing module 610 wherein it is analyzed by a therapy change control procedure 1836. If it is determined that the first user interaction satisfies a set of predefined conditions, the therapy change control procedure 1836 generates a signal to the user interface module 1808 to activate the therapy change user interface.

[0183] In some embodiments, the therapy change user interface may be limited based on the first user interaction. For example, the therapy change control procedure 1836 may send one of two signals to the user interface module 1808. The therapy change user interface may then unlock one of two different therapy change user interfaces that result in different options of therapy change selections for the user 1827. In an implementation of this example, a therapy change selection to make a significant therapy change, such as dramatically increase the rate of insulin or glucagon infusion rate, requires a first user interaction that is different from the first user interaction that would be required for an insulin or glucagon infusion at a normal or prescribed rate. In some examples, the first user interaction may be a simple interaction (e.g., a simple gesture) that unlocks a therapy change

user interface with therapy change selections that are limited. Another first user interaction may be a complicated interaction (e.g., a series of complex gestures) that unlocks a therapy change user interface with therapy change selections that have no limits. An example of this implementation may be useful for child users. The child user may perform the first gesture that is made up of a series of simple inputs to unlock therapy change selections that are limited. An adult user may perform the first gesture that is made up of a series of complex inputs to unlock the therapy change user interface with therapy change selections that have no limits.

[0184] Once activated, the therapy change user interface that may provide one or more control or configuration elements that enable the user to modify the control or configuration of the ambulatory medicament device. The control or configuration element may include any type of user interface screen on the touchscreen, or other type of user interface in the non-touchscreen context, that enables or permits a user to change a configuration of the ambulatory medicament device. This change in configuration of the ambulatory medicament device may relate to a change in the therapy provided or in the detection of a triggering event that causes therapy (e.g., medicament) to be provided to a subject. For example, the change in configuration may include a selection between one or more hormones that regulate blood sugar level (e.g., insulin or glucagon) of a user, an amount of the one or more hormones that regulate blood sugar level of the user.

[0185] In some cases, a change to the configuration of the ambulatory medicament device is automatically and/or instantly recognized or implemented by the ambulatory medicament device, and/or transmitted to the ambulatory medicament device. In other cases, a confirmation of the change may be required before the change is implemented by or transmitted to the ambulatory medicament device.

[0186] This confirmation may be entered based on a second user interaction with a user interface (e.g., touchscreen display 1824). When the second user interaction is detected, the user interface module 1808 sends an input signal to the control and computing module 2110 wherein it is analyzed by a therapy change control procedure 1836. If it is determined that the second user interaction satisfies a set of predefined conditions, the therapy change control procedure 1836 implements the change to the configuration of the AMD.

[0187] The first and/or second user interactions may include the selection of an icon, a series of taps or inputs, one or more gestures (e.g., a linear swipe, an arcuate swipe, a circular swipe, or other simple or complex movement across the touchscreen), performing a pattern or sequence on the touchscreen (e.g., drawing an image), a multi-touch or multi-input interaction, a combination of the foregoing, or any other type of interaction with a touchscreen, or portion thereof. The series of inputs may be any combination of touch movements, touch points, numerical characters, alphabetical characters, and other symbols. Gesture interactions can be guided by visual indicia displayed or printed on the AMD. In some embodiments, the visual indicia can include animations that suggest or guide user interactions with a touchscreen. For example, the first user interaction can include an arcuate swipe around at least a portion of a generally circular icon or logo. In some examples, the first and/or second user interactions may include a predetermined sequence of numerical or alphabetical inputs. In some examples, a series of multiple inputs, the range of parameters for an input may be dependent on other inputs in the series. For example, required start position of a touch movement may be dependent on the position of the previous touch movement. The time that the series of inputs are entered may also be a part of the range of parameters. For example, a series of inputs may need to be entered in no less than 3 seconds or more than 3 seconds, and no more than 15 seconds or less than 15 seconds.

[0188] Further, one or more of the interactions may include interacting with a sensor as an optical sensor (e.g., visible light or IR sensor), biometric sensor (e.g., a fingerprint or retinal scanner), a proximity sensor, a gyroscope, or a combination of accelerometer and gyroscope, and the like. Also, in an exemplary embodiment, the second user interaction may be made through a wireless signal such as RFID or Bluetooth. In some embodiments, the second user interaction may include receiving a selection of an indicator box that correspond to either insulin or glucagon and receiving a predetermined sequence of numerical inputs in order to deliver the therapy change selection.

[0189] The type of user interaction that unlocks the touchscreen, provides access to a configuration screen, and/or confirms a change to the configuration of the ambulatory medicament device may be the same or may differ.

[0190] In an exemplary embodiment, the system may have a time-out such that if no interaction occurs for a set period of time, the user interface will turn off and the therapy

change request process has to start again. In one implementation of the time-out, if no interaction occurs for more than 30 seconds after the system is waked/unlocked before the second user interaction is received by the user interface, the user interface will be deactivated.

[0191] Once the configuration change is confirmed, implemented, or transmitted, the ambulatory medicament device may begin operating with the changed configuration.

[0192] This operation may include triggering therapy based on the new configuration or providing therapy based on the new configuration. For example, the ambulatory medicament device may generate a dose control signal based at least in part on the modified configuration or control parameter, or may detect a trigger based at least in part on the modified configuration or control parameter that leads to the provisioning of therapy.

[0193] With reference to FIG. 18, in some embodiments, the changes made through the therapy change user interface are sent to CCM wherein the therapy control change procedure 1836 in CCM transfers the changes to the device and subject monitoring procedure 1832. The device and subject monitoring procedure 1832 may be implemented in the CCM 610 to monitor the status of the AMD (e.g., therapy delivery configuration) and the health condition of the user 1827 (or a subject). For example, the subject monitoring procedure 1832 may receive information about a therapy change requested by a user 1827 through a user interface (a touch screen display 1824 or alphanumeric pad 1826) or information about glucose level in subject's blood from the subject sensor 1820. Subsequently, the device and subject monitoring procedure 1832 may transmit the information pertaining a health condition of the subject and/or the AMD configuration, to the medicament dose control procedure 1830. In some examples, the parameters in the medicament dose control procedure 1830 may be adjusted based on the changes and/or information captured by the device and subject monitoring procedure 1832. The medicament dose control procedure 1830, controls the medicament delivery interface 1806 by providing a medicament dose signal. The medicament dose control may be generated based on detected conditions or physiological characteristics of the subject (e.g., provided by the readings of the subject sensor 1820) and according to parameter values received from the therapy change control procedure 1836. The medicament delivery interface 1806 may provide a therapy

change delivery to the user according to the information received by device and subject monitoring procedure 1832.

[0194] In some examples, the dose control signals may be produced based on time (e.g., medicament may be delivered on a periodic basis), one or more a command, indication that the subject is planning to engage or is engaging in a particular activity (e.g., eating a meal, exercising, sleeping, fasting, etc.), or any other factor that may relate to or cause the triggering of therapy (e.g., medicament delivery).

[0195] FIG. 19 is a flow diagram illustrating an example method that may be used by an AMD to allow a user to change the configuration of the ambulatory medicament device using a touch screen user interface. The user may initiate the configuration change process by waking/unlocking the touch screen using a wake action. Once the wake action is received by the wake interface 1902, the wake interface sends a wake input to CCM 1904. Within CCM, the wake procedure generates a wake signal 1906 that unlocks the touch screen 1908. Next, in response to receiving a first gesture by the user 1910, the therapy change user interface is unlocked 1912. Using one or more therapy control or configuration elements provided in the therapy change user interface, the user may change the therapy configuration 1914. The user may confirm the changes made, by providing a second gesture on the touch screen 1916. Once the confirmation is received 1916 the requested changes will be implemented, and the ambulatory medicament device may begin operating with the changed configuration. In some examples, once the user confirms the changes made, a dose control signal may be sent to the medicament delivery interface 1806 that triggers a therapy change delivery to the subject.

[0196] In some cases, the ambulatory medicament device, or a control device that enables a user to modify a configuration of the ambulatory medicament device, may have a timeout feature. The timeout feature may cause the ambulatory medicament device or the control device to enter a sleep or locked state after a period of time of inactivity by the user. In some cases, the timeout feature may cause the ambulatory medicament device or the control device to enter a sleep or locked state after a particular period of time regardless of whether the user is interacting with the ambulatory medicament device or control device. Thus, a user may have a limited period of time to modify he configuration of the ambulatory medicament device.

[0197] In some examples, the therapy change made by a user may trigger the delivery of a medicament according to the therapy change received and confirmed by a user. This therapy change delivery may occur after a set time from period from receiving the confirmation.

[0198] In some embodiments of the AMD, an alarm status indicator may be presented to the user via the user interface. The alarm status indicator, can be an alert message or an alert symbol. The alarm status indicator may be related to a configuration change made by a user, a change in the status of the AMD not related to a user input, or the condition of the subject (e.g., detected by the subject sensor).

[0199] FIG. 20A is an illustration of the touchscreen display 2000 of an example AMD after the touch screen is waked/unlocked by a wake action of a user and before the first user gesture is received. Even while the touchscreen display is locked, the touchscreen display 2000 may display any images, animations, text, or other graphics. The first gesture prompt 2005 displays to the user 1827 the input required to unlock the therapy change user interface. Here, the first gesture prompt 2005 shows the user 1827 that a touch movement that begins at the greater-than symbol and moves right across the “Unlock” text is the acceptable first gesture. In addition to the first gesture prompt, the refill status of the ambulatory medical device 600 is shown in a graphic representation 2010. Here, the graphic representation 2010 shows that the insulin cartridge in the ambulatory medical device 600 is almost full. A current blood sugar level 2015 is shown at the top of the touchscreen display 2000, which can inform the user 1827 of the need for a hormone that regulates blood sugar levels. The touchscreen display 2000 also shows a graphic representation 2020 of a cartridge of glucagon. The graphic representation of an alarm 2025 in the touchscreen display 2000 shows that an alert is set on the ambulatory medical device 600.

[0200] FIG. 20B is an illustration of an example touchscreen display 2050 that may prompt the user to enter a predetermined series of inputs for the first gesture or second gesture. In various embodiments, such as the embodiment shown in FIG. 20B, the touchscreen display 2050 may display touchable number keys 2055. In various embodiments, the touchscreen display 2050 prompts the user 1827 to enter the series of inputs that complete the first gesture or second gesture. The text Enter Code 2060 prompts the user 1827 to enter a predetermined or preselected numerical sequence as part of the first gesture or

second gesture. The numerical sequence being typed by the user 1827 is displayed in field 2065 as it is entered as an aid to the user 1827. The input 2070 of the touchscreen display 2050 shows that a touch movement of a swipe right across the bottom of the screen is required to complete the predetermined series of inputs for the first gesture or second gesture. A Bluetooth connection symbol 2075 shows that the ambulatory medical device 600 is paired or can be paired to another electronic device.

[0201] FIG. 20C is an illustration of an example therapy change user interface (in this case a touchscreen display 2002). The touch screen display may the user 1827 prompt to select a hormone that regulates blood sugar level. The touchscreen display 2002 presents the user 1827 with an option to select between two hormones. The touchscreen display 2002 aids the user 1827 by showing the selection 2008 for the user 1827. The selected hormone is “insulin Only” 2008. The user 1827 is also given the options of selecting the hormone glucagon only button 2012 or both insulin & glucagon button 2004 to regulate blood sugar level. Once the user 1827 selects between the one or more hormones that regulate blood sugar level. The Next button 2014 may be selected to complete the therapy change selection or select more options. In one embodiment, to select more options, the therapy change user interface prompts the user 1827 to select an amount of the one or more hormones that regulate blood sugar level of the user 1827. In other embodiments, the user 1827 may be prompted to select a blood sugar level and the ambulatory medical device 200 may choose the hormone and the amount of the hormone.

[0202] FIG. 20D is an illustration of another therapy change user interface on a touchscreen display 2016. Here, the user 1827 is given a multitude of options. One or more options in the therapy change user interface allow the user 1827 to make a therapy change selection. Other options are related to the therapy change selection. A Deliver Hormone Button 2030 allows the user 1827 to select a therapy change that delivers a hormone that regulates blood sugar to the user 1827. A Test Blood Sugar Button 2018 allows the user 1827 to test the blood sugar level of the user 1827. A Generate Report Button 2020 generates a document that reports the therapy changes that have been delivered to the user 1827. A Refill Cartridge Button 2022 allows the user 1827 to fill a cartridge in the ambulatory medical device 600 with medicament. An Upload to Cloud Button 2026 allows the user 1827 to transmit therapy change information to a cloud-based server. A Sound Control Button 2024

allows the user 1827 to control the sounds emitted by the ambulatory medical device 600. A Settings Button 2028 allows the user 1827 to manipulate other settings of the ambulatory medical device 600.

[0203] As mentioned above, in some embodiments of the AMD, an alarm status indicator may be presented to the user via the user interface to alert the user about a change made or occurred in the AMD configuration.

[0204] For example, with reference to FIG. 18, the user 1827 may make a therapy change 1829 using the user interface and based on the procedure illustrated in FIG. 19. Once therapy change procedure 1836 implements the therapy change, the AMD may alert the user that a therapy change is implemented. The alert message or symbol may be presented on a user interface (e.g., touch screen display) before and/or during the therapy change delivery 1807. For example, alarm indicator may inform the user 1827 that a therapy change is about to occur. Any number of details of the therapy change may be displayed as part of the alert message or symbol. In some cases the alarm status indicator may appear after the user unlocks or wakes the user interface using a wake action.

[0205] FIG. 21 is a flow diagram illustrating an example method that may be used by an AMD to generate an alarm status indicator. In some embodiments the device and subject monitoring procedure (excused within CCM), may continuously monitor the status of the AMD (e.g., the user interface, different modules of the AMD and the like) as well as the health condition of a subject (e.g., using various subject sensors such as analyte sensors). Once a status information is received 2104, the device and subject monitoring procedure may determine whether the received status information satisfies an alarm condition 2106. If the received status information does not satisfy an alarm condition, no action will be taken and device and subject monitoring procedure continuous monitoring the AMD and the subject. If it is determined that the received status information satisfies an alarm condition, the system search for a wake signal 2108. If no wake signal is detected, the systems waits for a wake signal to be received 2110. Once a wake signal is received via one or more user interfaces or sensors, the CCM may generate a display of a touchscreen lock screen interface 2112 and display one or more alarm status indicators, corresponding to the detected alarm condition, on the lock screen.

[0206] In some embodiments, the AMD may allow the user to provide a therapy change and then cancel the therapy change. FIG. 22 is a flow diagram illustrating an example method that may be used to cancel a therapy change using a touchscreen interface. The user may unlock the touchscreen display 2202 using a wake action and get access to a therapy change user interface 2204 (e.g., using a first gesture), where one or more therapy control elements may be displayed. Next, an indication of a modification to a therapy control element may be received 2206 by the user interface followed by a confirmation of the modification made 2208 (e.g., a second gesture). In response to receiving an indication and confirmation of a modification to a therapy control element, the corresponding control parameter may be changes from a first setting to a second setting 2210. In some examples, once the change is implemented 2210, the user may decide to cancel it, for example, after realizing that requested change is erroneous. In these examples the user may provide a third gesture 2212 on the touch screen. In response to receiving eth third gesture from eth user interface the therapy change procedure may restore the modified control parameter to the first setting 2214. In some examples the third gesture may a restore gesture. In some cases, the restore gesture may be a swipe gesture. In some examples the swipe gesture may be performed near or in a region of the therapy change user interface that is occupied by the therapy control element. An example of a restore swipe gesture may be performed from a starting swipe position to an ending swipe position located closer to a left edge of the touchscreen than the starting swipe position. In some embodiments, the restore gesture is received on a different user interface screen than a therapy change user interface wherein one or more therapy control element are provided. In various examples, the restore gesture is performed in the opposite direction from a therapy change confirmation gesture that confirms the modification to the therapy control element.

[0207] In some examples, in order to cancel a therapy change request, the restore gesture has to be provided within a set time period after the confirmation gesture is received by the user interface. In some such examples, during the set time period one or more dose control signals may be provided to the medicament delivery interface resulting in one or more therapy change deliveries.

[0208] In some cases, the system may allow the user, to modify a therapy change before confirmation. In these cases, the user may modify a therapy control element for a

second time to change the corresponding control parameter from a second setting to a third setting.

[0209] In some examples, the third setting may be the same as the first setting. In some cases the first setting or the third setting may be a default setting. In some other cases, the first setting or the third setting may be a restore setting.

[0210] FIG. 23A is an illustration of a touchscreen display 2300 alerting the user that the delivery of one or more medicaments will occur. The alert may be accompanied by sound or vibration effects. Here, the alert informs the user 1827 a delivery of medicament will occur in 2 seconds 2305. The touchscreen display 2300 is further allowing the user 1827 to perform a gesture to cancel the therapy change. The gesture to cancel the delivery is a touch movement that starts at the less-than symbol 2310 and swipes left across the “Cancel” text. In the embodiment shown in FIG. 23A, a single gesture by the user 1827 may cancel the therapy change. In an exemplary embodiment, input of the wake signal, the first gesture, the therapy change selection, and the second gesture are all required to cancel a therapy that is being delivered.

[0211] In some examples, the user may be able to cancel a therapy change delivery triggered based on therapy change made by the user. In these examples, the user may get access to the user interface using a wake action and provide a gesture to cancel the ongoing therapy corresponding to a therapy change delivery.

[0212] FIG. 23B is an illustration of a touchscreen display 2350 showing that a medicament is being delivered to the user 1827. The text Delivering 2355 informs the user 1827 that a medicament is currently being delivered to the user 1827. The progress bar 2360 is a graphic representation of the progress of the delivery. As shown in FIG. 23B, the delivery is only starting and zero progress has been completed. The touchscreen display 2350 is allowing the user 1827 to perform a gesture to cancel the delivery, which includes interrupting and discontinuing the delivery if it had already begun but has not yet been completed. The gesture to cancel the delivery is a touch movement that starts at the less-than symbol 2365 and swipes left across the “Cancel” text. In an exemplary embodiment that is shown in FIG. 23B, the therapy change delivery 1807 may be canceled by an input by the user 1827. The input to cancel a therapy change delivery 1807 may be any input such as a wake signal input or a series of touch inputs such as a gesture.

[0213] Additional embodiments relating to interacting with an ambulatory medicament device that can be combined with one or more embodiments of the present disclosure are described in U.S. Provisional Application No. 62/874,950, which was filed on July 16, 2019 and is titled “PREVENTING INADVERTENT THERAPY CHANGES ON AN AMBULATORY MEDICAL DEVICE,” the disclosure of which is hereby incorporated by reference in its entirety herein for all purposes, and in U.S. Provisional Application No. 62/874,954, which was filed on July 16, 2019 and is titled “CAPACITIVE TOUCH WAKE BUTTON FOR AN AMBULATORY MEDICAL DEVICE,” the disclosure of which is hereby incorporated by reference in its entirety herein for all purposes.

Automatic Resumption of Medicament Delivery Following Manual Suspension

[0214] In some cases, it may be desirable to suspend operation of the ambulatory medicament device or to suspend at least the delivery of medicament by the ambulatory medicament device for a period of time. For example, it may be desirable to suspend an operation associated with the delivery of medicament when the medicament reservoir or cartridge in the ambulatory medicament device is empty or needs replacing. As another example, it may be desirable to suspend delivery of medicament when the ambulatory medicament device is removed or is being moved to another site on the subject. In yet another example, it may be desirable to suspend delivery of the medicament when the subject is taking or ingesting another medicament that may produce a contraindication with the medicament provided by the ambulatory medicament device. In some cases, when a subject suspends the treatment delivered by a medical device, the subject may forget to resume the treatment delivered by the medical device. In other cases, the health condition of the subject may deteriorate during the suspension period requiring therapy delivery prior to end of the suspension period. As such, there is a need for AMDs that allows subjects to safely suspend treatment for temporary amounts of time.

[0215] In some embodiments, the AMD may support a therapy suspension and resumption procedure allowing a user to suspend all therapies or a subset of therapies for a period of time defined by the user as well as automatic resumption of one or more therapies at the end of the requested suspension period or when a threshold condition is met (e.g., a threshold condition associated with the health condition of the subject).

[0216] In AMDs that support therapy suspension, inadvertent activation and/or resumption of therapy delivery can be dangerous (e.g., when the AMD is an insulin and/or glucagon infusion device). In some examples to mitigate this risk, the AMD may be configured to avoid inadvertent suspension or resumption of therapies. For example, inadvertent activations of suspensions of medicament delivery may be prevented by requiring a user to perform gestures to activate suspension on the ambulatory medical device. The gestures must be entered at a particular prompt to activate a therapy suspension.

[0217] One particular application of the therapy suspension with automatic resumption feature in an AMD can be in the field of diabetes drug delivery. For example, the may need the ability to suspend delivery of insulin during situations such as exercise, which has a blood glucose lowering effect. Suspension of insulin delivery can prevent a subject from entering a hypoglycemic state (extreme low blood glucose), which carries severe complications. Once the therapy is suspended the user may be at the risk of entering a hyperglycemic state (high blood glucose that may result in complications such as diabetic ketoacidosis or neurovascular complications), if the user forgets to reactivate the drug delivery after exercise. Further, the subject's blood glucose level may raise above or below a dangerous level during the period of exercise. In these situations, the automatic medicament delivery resumption may improve the health of the subject.

[0218] In certain cases, the AMD may suspend one or more therapy deliveries when the AMD receives an indication that therapy (e.g., delivery of medicament) is to be suspended. The indication that therapy is to be suspended may be a command from a user. Often the user is the subject, but the user may also include other users that may have a say or interest in the care of the subject. For example, the user may be a clinician or other healthcare provider, or a parent or guardian.

[0219] In some examples, the indication that the therapy or medicament delivery is to be suspended may be a command received via an interface of the ambulatory medicament device or from another device that provides the user with an interface to request that medicament delivery be suspended. For example, the device may be a smartwatch, smartphone, laptop or desktop, or other control device that can communicate via a wired or wireless connection with the ambulatory medical device.

[0220] In some cases, the indication that the therapy or medicament delivery is to be suspended may be received from the ambulatory medicament device itself. For example, if the quantity of medicament available to the ambulatory medicament device drops below a threshold (e.g., the cartridge or reservoir is empty or below a minimum dosage amount), a signal may be generated to suspend medicament delivery. In some embodiments, suspension of therapy occurs based on a loss of a sensor signal, such as the loss of a glucose level signal.

[0221] FIG. 24 illustrates the interconnection among modules and procedures involved in receiving, accepting and/or canceling a therapy suspension request, in an example AMD. In some embodiments, a request for suspending one or more therapies (e.g., delivery of one or more medicament to the subject) can be made by a user 2427 by providing an input 2429 (e.g., the start and stop time for therapy suspension, selecting the type of therapy that should be suspended, and the like), through a therapy suspension user interface provided by the user interface module 2408. The therapy suspension user interface sends the suspension request along with the corresponding information to CCM wherein the suspension control procedure 2436, implemented in CCM, processes and sends a therapy suspension signal to the device and subject monitoring procedure 2432. To prevent therapy suspension request inputs 2429 that are inadvertent, the therapy suspension control procedure may include a therapy suspension request verification procedure to verify the therapy suspension request.

[0222] The device and subject monitoring procedure 2432 may be implemented in the CCM 210 to monitor the status of the AMD (e.g., therapy delivery configuration) and the health condition of the user 2427 (or a subject). For example, when the subject monitoring procedure 2432 receives the request for therapy suspension, it may send a signal to the medicament dose control procedure 2430 indicating that no dose control signal should be sent to the medicament delivery interface 2406 during the period requested by the user 2427. In some cases, if during the suspension period, certain pre-set conditions are satisfied, the device and subject monitoring procedure 2432 automatically resumes the therapy delivery by sending a signal to the medicament dose control 2430. For example, if during the suspension period the subject sensor 2420 detects an elevation of the level of one or more analytes in subject's blood and/or interstitial fluid beyond a set threshold, it may resume the

medicament delivery to the subject 2427 by a sending a dose control signal to the medicament delivery interface 2406.

[0223] In order to prevent inadvertent activation of a suspension, the user may initiate a therapy suspension request starting with a wake action (e.g., received by the wake interface 2422 and processed by the wake control procedure 2434), that activates the user interface module 2408. Using a first interaction with a user interface (e.g., a touchscreen display) the user may unlock a therapy suspension user interface where the information pertaining therapy suspension is provided. Next, the user may confirm the requested therapy suspension using a second interaction with the user interface. In some examples, the system may allow access to the therapy suspension user interface and accept the suspension request, only if the first and second interaction with the user interface are verified by the therapy suspension control procedure 2436.

[0224] In some examples, the therapy suspension control procedure 2436 may receive the request for suspension and suspension information from another device connected to the ambulatory medical device 600 (e.g., through the communication module).

[0225] The suspension information provided by the user may include a set of parameters needed for a suspension. For example, the suspension information may include the dates and/or times for starting and ending the therapy suspension, threshold values needed to define a threshold condition that may trigger an early resumption of the therapy delivery, and the like. In some other examples, suspension information may indicate that the suspension of therapy should happen at a particular time or after a particular event (e.g., after the next dose of medicament is delivered or after the condition of the subject reaches a particular state, such as the middle of a desired blood glucose range). In some examples, the threshold values may be associated with input provided by the subject sensor 2420 or other types of sensors that may be used to monitor one or more parameters associated with the health condition of the user 2427.

[0226] The parameters for a suspension may include the start and stop conditions for a suspension. The start condition for a suspension may be a condition that, when met, activates a suspension. In some such examples, the start condition is met when a timer runs out. Similarly, the stop condition is a condition that, when met, ends the suspension. In one example, the stop condition is met when a timer runs out. In another example, the stop

condition is met when a threshold is met. A threshold may be related to a measurement taken by ambulatory medical device (e.g., by a subject sensor 2420), such as a glucose concentration of the blood of a user. The threshold may be met if the glucose concentration goes above, goes below, or matches a set concentration. Multiple conditions may be set by the suspension request interface component. For example, a time condition and a threshold condition may be set simultaneously. A user may specify that a suspension will end after a set time. However, the suspension may end sooner than the set time if the glucose concentration of the user meets a threshold.

[0227] In some cases, the request to suspend therapy may include an indefinite suspension period. In other words, the request may not include a time period specified by a user or an identity of a resumption condition. In some other cases, the indication may include a request to temporarily suspend delivery of therapy for a defined period of time or until a further interaction or event occurs. Thus, the resumption condition can include an expiration of time or an active event (e.g., a command or a determined condition of a subject). Further, the therapy to be suspended may include any type of therapy. For example, the therapy to be suspended may be the suspension of the delivery of medicament, which may include insulin, counter-regulatory agent (e.g., Glucagon), or both insulin and a counter-regulatory agent. In some cases, the ambulatory medicament device may be capable of and/or configured to administer multiple medicaments (e.g., both insulin and a counter-regulatory agent). In some such cases, the request to suspend therapy may include a request to suspend one (e.g., insulin or the counter-regulatory agent) or both of the medicaments.

[0228] The interactions with the user interface may include the selection of an icon, a series of taps or inputs, one or more gestures (e.g., a swipe or other simple or complex movement across the touchscreen), performing a pattern or sequence on the touchscreen (e.g., drawing an image), a multi-touch or multi-input interaction, a combination of the foregoing, or any other type of interaction with a touchscreen, or portion thereof. The series of inputs may be any combination of touch movements, touch points, numerical characters, alphabetical characters, and other symbols. In some examples, the first and/or second user interactions may include a predetermined sequence of numerical or alphabetical inputs. In some examples, a series of multiple inputs, the range of parameters for an input may be dependent on other inputs in the series. For example, required start position of a touch

movement may be dependent on the position of the previous touch movement. The time that the series of inputs are entered may also be a part of the range of parameters. For example, a series of inputs may need to be entered in no less than 3 seconds or more than 3 seconds, and no more than 15 seconds or less than 15 seconds. In some cases, a visual guide may assist the user in generating the user interaction. For example, one or more arrows or images may be presented to the user to guide the user in providing the command to suspend the delivery of therapy.

[0229] Further, one or more of the interactions may include interacting with a sensor as an optical sensor (e.g., visible light or IR sensor), biometric sensor (e.g., a fingerprint or retinal scanner), a proximity sensor, a gyroscope, or a combination of accelerometer and gyroscope, and the like. Also, in an exemplary embodiment, the second user interaction may be made through a wireless signal such as RFID or Bluetooth. In some embodiments, the second user interaction may include receiving a selection of an indicator box that correspond to either insulin or glucagon and receiving a predetermined sequence of numerical inputs in order to deliver the therapy change selection.

[0230] The type of user interaction that unlocks the touchscreen, provides access to a therapy suspension user interface or confirms a suspension request may be the same or may differ.

[0231] In an exemplary embodiment, the system may have a time-out such that if no interaction occurs for a set period of time at each step during the therapy suspension request process, the user interface will turn off and the therapy suspension request process has to start again. In one implementation of the time-out, if no interaction occurs for more than 30 seconds after the system is waked/unlocked before the second user interaction is received by the user interface, the user interface will be deactivated.

[0232] FIG. 25 is a flow diagram illustrating an example method for receiving and implementing a suspension request, which may be implemented by an AMD. In this example the user may use a touchscreen interface to request and confirm a therapy suspension. Once the user activates the touchscreen using a wake action 2502, the AMD may wait for a first gesture on the touchscreen. After the user provides the first gesture and the gesture is verified by the therapy suspension control procedure 2436, a therapy user interface may be activated 2506 where the user can request a therapy suspension and provide 2508 the

suspension information (e.g., a start day/time and stop day/time and/or a resumption condition). Next, the AMD may wait for second gesture on the user interface 2510. If the second gesture is received and verified by the therapy suspension control procedure 2436, the therapy delivery will be suspended 2512. If the second gesture is not received or not verified by the therapy suspension control procedure 2436, the therapy suspension control procedure 2436, may determine if a set time has passed since receiving the therapy suspension request 2514. If it is determined that a set time has passed since receiving the therapy suspension request, the request will be canceled and the touch screen will be locked 2516. If it is determined that time from receiving the therapy suspension is less than a set time the AMD may wait for the second gesture to be received.

[0233] In some examples, once a wake action is received 2502, the AMD may automatically activate a therapy suspension user interface 2506, without the need for a first gesture 2504. In these examples, once the request for therapy suspension is received 2508, a gesture (e.g., a first gesture) may be required to verify the request. In some such examples, once the therapy delivery is suspended, a second gesture may stop a suspension before any of the conditions of the stop parameter are met. This allows the user the versatility of being able to modify a suspension that has been activated.

[0234] FIG. 26 is an illustration 2600 of a plurality of screens that the ambulatory medical device may display when a user activates a therapy suspension user interface. Screen 2602 shows a user interface that an ambulatory medical device may display to a user 2427. The display may be a touchscreen display 2424 that can accept input that includes the first and second gestures. The therapy suspension system 600 is not limited to the displays shown in FIG. 26. Various displays may communicate, to the user 2427, the same information shown in FIG. 26. The screen 2602 allows the user 2427 to select various functions. The pause button 2603, shown on screen 2602 is a function that suspends the delivery of a medicament to the user 2427. When the pause button 2603 is selected, the user 2427 is treated to the pause screen 2604. The pause screen 2604 allows the user 2427 to select a duration of the medicament suspension. The ambulatory medical device 600 may display various interfaces to allow the user 2427 to select a duration of the medicament suspension. The pause screen 2604 shows a simple interface, giving the user 2427 one of two duration options.

[0235] When the user 2427 has made a duration selection on the pause screen 2604, the pause screen 2606 shows the user 2427 the duration 2607 that the user 2427 selected (e.g., in the figure the user 2427 selected 1 hour. Thus the medicament delivery is suspended for 1 hour after the suspension begins). The pause screen 2606 has a prompt 2608 for the user to make a gesture to confirm the requested suspension before the medicament suspension begins. As shown by the prompt 2608, the user 2427 is being prompted to swipe right across the bottom of the screen. Once the user 2427 performs the gesture to begin the medicament suspension, the suspension screen 2610 is displayed on the touchscreen. The suspension screen 2610 informs the user 2427 that the medicament is paused. The user 2427 has the option of performing another gesture to unlock the ambulatory medical device. The prompt 2612 for the user 2427 to unlock the device forces the user to perform another swipe to execute more functions on the ambulatory medical device 600.

[0236] Suspending the medicament delivery may occur by not generating a dose control signal to deliver a dose of medicament. Alternatively, or in addition, suspending the medicament delivery may occur by sending a signal to the medicament pump to cease providing therapy or medicament to the subject.

[0237] In some cases, the ambulatory medicament device may not immediately suspend therapy upon receiving a command to suspend therapy. For example, if the ambulatory medicament device is in the process of delivering medicament or determines that a condition of the subject indicates that medicament may soon be required to maintain the subject's condition (e.g., blood glucose) within a particular state (e.g., within a desired blood glucose range), the suspension of therapy may be delayed until at least such time that medicament is not being delivered, is predicted to not be required during the suspension period, or the next therapy has been delivered. In some such cases, the ambulatory medicament device may inform that user that the suspension of therapy is being delayed. Further, the ambulatory medicament device may indicate the reason for the delay. In some cases, the user may be able to override the delay and request immediate suspension of therapy. For example, if the user is replacing the medicament cartridge, the user may override an indication that the suspension of therapy should be delayed. In some cases, the requested start time may be overridden by a determined condition of the subject.

[0238] The suspension of therapy or the suspension of the delivery of medicament may continue until a resumption condition occurs. In certain cases, when a resumption condition is met, the suspension period may automatically end without action by the user or subject.

[0239] The resumption condition may include the expiration of a time period, a command from a user (e.g., the subject), detection that the ambulatory medicament device satisfies a condition (e.g., that medicament has been refilled), that the condition of the subject meets certain criteria (e.g., the subject's blood glucose level drops below a threshold range or rises above a threshold range), or any other condition that may satisfy the reason for suspension of therapy or that overrides the request for suspension of therapy. For example, the drug delivery device may be configured to automatically resume drug delivery when a glucose threshold is reached or exceeded. This threshold could be set to 300mg/dl for example. The resumption condition may include detection of an impending risk of hypoglycemia or hyperglycemia, or a hypoglycemia or hyperglycemia event. Further, the resumption condition may include a meal announcement, or an "exercise concluded announcement," a motion sensing event, a pause of other administered medicament, a conclusion of an undefined suspension length (e.g., during cartridge change), a speed-based resumption event, a location-based resumption, a remote resumption in case of an emergency (e.g., commanded from caregiver admin software or clinician), or any other type of resumption event. In some cases, the resumption condition can include a combination of criteria.

[0240] In some cases, automatically resuming therapy may include discontinuing the suspension of therapy before the expiration of the suspension period. For example, if a condition that caused therapy to be suspended is resolved prior to the expiration of the suspension period, therapy may be resumed.

[0241] In some cases, when a resumption condition (provided by the user) is met, the ambulatory medicament device may confirm that one or more additional condition of the ambulatory medicament device are satisfied before therapy is resumed. For example, if the ambulatory medicament device determines that medicament has not been refilled or if there is a problem with the refill (e.g., cartridge is incorrectly installed), the ambulatory

medicament device may continue to maintain the suspension of therapy despite the trigger to resume therapy.

[0242] In some examples, a therapy suspension may be ended if a third interaction with a user interface (e.g., a gesture) is detected. The third user interface interaction may be detected by the user interface module 2408 and sent to the therapy suspension procedure 2436. If the therapy suspension procedure 2436 verifies that third interaction with the user interface is a predetermined third user interface interaction, it may send a signal to the device and subject monitoring procedure 2432 to activate the medicament dose procedure 2430. This allows the user the versatility of being able to end a suspension that has been activated, during the suspension period set by the user before the confirmation (second interface with the user interface). In some cases, a user may decide to end a therapy suspension to modify one or more suspension conditions set prior to activation of the current therapy suspension. In some other examples, user may decide to end a therapy suspension due to change in user's health condition not included in one or more therapy resumption conditions provided before activating the current therapy suspension.

[0243] FIG. 27 is a flow diagram illustrating an example method of resuming a suspended therapy that may be implemented by an AMD. Once a therapy suspension has been requested and confirmed by a user (e.g., using the procedure illustrated in FIG. 10) 2702, the AMD suspends one or more therapies selected for suspension at suspension initiation time received as part of the suspension information. For example, therapy suspension control module 2436 deactivates the medicament dose control procedure 2430 using the device and subject monitoring procedure 2432. During the suspension period, the therapy suspension control module 2436 continuously monitors the system clock and the subject and device condition (e.g., using medicament dose control procedure 2430).

[0244] If the therapy suspension control module 2436 determines that the time passed since the suspension initiation is less than the requested suspension time period 2706 and none of condition for resumption has been met 2708, the therapy suspension continues.

[0245] If the therapy suspension control module 2436 determines that the time passed since the suspension initiation is equal to the requested suspension time period 2706, or one or more resumption conditions have been met 2708, it may check other AMD or subject conditions (not included in the therapy suspension information), in order to determine

whether the therapy delivery can be safely resumed 2710. If it is determined that the therapy delivery cannot be safely resumed, an alert message will be send to the user interface to inform the about the reason for such determination. If it is determined that the therapy delivery can be safely resumed, the one or more suspended therapies will be resumed.

[0246] FIG. 28 is an illustration 2800 of a plurality of screens that may be displayed, for example, on a touchscreen display when a user 2427 resumes a suspended therapy. Screen 2802 informs the user that the delivery of medicament is currently in a suspended mode. The screen 2803 also shows the user 2427 the current glucose concentration of the blood of the user 2427. The ambulatory medical device 600 may display various vital measurements that are useful to the user 2427. In one implementation, the medicament suspension ends if the glucose concentration of the blood of the user meets or passes a threshold.

[0247] The interface screen 2804 allows the user 2427 to select and execute various functions on the ambulatory medical device 600. The resume button 2805 is a function that ends a medicament suspension. When the resume button 2805 is selected, the ambulatory medical device 600 displays a resume screen 2806. The resume screen 2806 has a prompt 2807 that prompts the user 2427 to perform a gesture. In the examples shown, the user 2427 is being prompted in the resume screen 2807 to swipe right across the bottom of the resume screen 2806. The requirement to perform the gesture to resume medicament delivery prevents the user 2427 from inadvertently resuming medicament delivery in the ambulatory medical device 600.

[0248] Once the user 2427 performs the gesture to resume medicament delivery, the medicament suspension ends. The resumption screen 2808 shows the user 2427 that the regular medicament delivery has resumed. Once the resumption screen 2808 has been displayed to the user 2427 for a sufficient amount of time to inform the user 2427 that the suspension is ending, the ambulatory medical device 600 may display a lock screen 2810. The lock screen 2810 prevents the user 2427 from inadvertently executing more functions on the ambulatory medical device 600.

[0249] In one embodiment, the ambulatory medical device 600 must receive a second gesture to end the suspension before the one or more conditions to end the suspension are met. The purpose of the second gesture is to ensure that the user 2427 does not

inadvertently end the suspension. Like the first gesture, the second gesture may be simple or complex.

[0250] With reference to FIG. 24, once the AMD device is instructed to resume therapy and/or determines that therapy is to be resumed, the ambulatory medicament device may determine whether a dose of medicament should be supplied to the user based on a control algorithm used by the ambulatory medicament device to control the provisioning of medicament to the subject. For example, the therapy suspension procedure 2436 may determine a resumption condition has been satisfied or receive a user input from the user interface module 2408 (a third interaction with a user interface) indicating that therapy suspension should be ended. Subsequently the therapy suspension control procedure 2436 may send a signal to the device and subject monitoring procedure 2432 to activate the medicament dose procedure 2430. If medicament is to be supplied, the Medicament does control may generate and send a dose control signal to the medicament delivery interface 2406.

[0251] In some cases, the ambulatory medicament device may alert the user and/or the subject that therapy is being resumed. This alert may occur before generating a dose control signal and/or after a resumption condition is satisfied (e.g., a suspension time expires). In some cases, the user may request that the suspension of therapy end early. The user may request the early resumption of therapy be interacting with the aforementioned user interface using one or more of the previously described interaction methods (e.g., gestures or taps).

[0252] Additional embodiments relating to suspending medicament delivery to a subject that can be combined with one or more embodiments of the present disclosure are described in U.S. Provisional Application No. 62/910,970, which was filed on October 4, 2019 and is titled "METHOD FOR SUSPENDING DELIVERY OF A DRUG INFUSION DEVICE WITH AUTOMATIC RESUMPTION OF DELIVERY," the disclosure of which is hereby incorporated by reference in its entirety herein for all purposes.

AMD with Security Functionality

[0253] An ambulatory medicament device (AMD), such as, but not limited to, an insulin pump, that provides life-saving treatment to subjects or subjects based on the

condition of the subject, may include a user interface (e.g., a touchscreen display) that lets a user to modify the settings of the ambulatory medicament device. The setting may include, but not limited to, a condition that triggers the delivery of medicament to a subject, the quantity of medicament delivered when a condition is met, type of the medicament and the like. The setting may also include features of the AMD that may not be directly related to the medicament delivery (e.g., the screen brightness, an alarm sound, and the like). In some examples, it is desirable to manage access to various settings of AMD in order to avoid inadvertent changes while enabling changes that may be necessary for uninterrupted and proper operation of the AMD. For example, it may be desirable to limit the access to some settings to certain authorized users (e.g., a healthcare provider) while enable access to some other settings other authorized users (e.g., the subject, a guardian or parent of the subject).

[0254] In many cases, a healthcare provider can modify the settings of the ambulatory medicament device. However, it is often desirable that a non-healthcare provider modify at least some settings of the ambulatory medicament device. For example, when the ambulatory medicament device runs out of or has below a threshold amount of medicament, it is often desirable that a user be able to refill or change a medicament cartridge without visiting a healthcare provider. In some cases, changing the medicament cartridge may include interacting with a user interface and/or one or more settings of the ambulatory medicament device. Another example of when it is desirable for a non-healthcare user (e.g., a subject, parent, or guardian) to modify settings of the ambulatory medicament device is when the initial settings of the ambulatory medicament device are not providing the desired effect (e.g., sufficient medicament, too much medicament, providing the medicament too slowly or too fast, etc.). In some cases, normal maintenance of the ambulatory medicament device and/or subject may require interaction with the ambulatory medicament device settings and/or controls. For example, negative consequences may being to occur when an ambulatory medicament device remains connected to a subject at the same site for more than a threshold period of time (e.g., for more than 2-3 days, more than 5 days, more than a week, etc.). Thus, the ambulatory medicament device may need to be periodically moved from one site on the subject to another site on the subject (e.g., from left-side to right-side, from arm to leg, from stomach to back, etc.). The change in site location may require interaction with

settings of the ambulatory medicament device (e.g., pausing operation until the site change is completed).

[0255] Although, as explained above, there are a number of reasons it is desirable to enable a user other than a healthcare provider (e.g., the subject receiving therapy, a parent, or a guardian) to have access to at least some user settings of an ambulatory medicament device, it is also desirable to regulate access to at least some of the ambulatory medicament device settings. For example, it is generally undesirable that a child (subject or otherwise), or a user below a particular age, have access to ambulatory medicament device settings that could cause harm to the subject if modified. Further, it may be undesirable for certain subjects who have diminished mental capacity regardless of age to have access to at least some ambulatory medicament settings.

[0256] The user may be a subject receiving medicament or therapy, or may be another user, such as a clinician or healthcare provider, or a parent or guardian of the subject. In some examples, the passcode required for changing one or more setting via an intermediary device may be different than the passcode required for changing the same settings directly using the AMD's user interface.

[0257] One solution to regulating access to settings of the ambulatory medicament device is to implement a lock feature to require that a user provide a passcode, a passcode, or other information before the user is permitted to modify a setting of the AMD, such as a control parameter. To simplify discussion, the disclosure will describe using a passcode. However, it should be understood that the passcode can be substituted for a passcode or any other type of secret or semi-secret information. In some examples, when the AMD is in the locked state, it may continue delivering therapy to the subject at the same rate as unlocked state.

[0258] The lock feature may be activated by default, or may be activated by a user. In some examples, the lock feature can be enabled through a setting in a control menu of the AMD device provided on a user interface (i.e., touchscreen display). The setting may include an on/off toggle (e.g., a software interface element or a hardware interface element) so when the toggle is on, a passcode (e.g., 4 to 8 numeric digits) may be required. In some cases, if the lock feature is on, the passcode (e.g., a 4 to 8 numeric digit code) may be required to turn the lock feature off. When the lock feature is activated, the user may program

the ambulatory medicament device with a user passcode selected by the user. Alternatively, or in addition, the user passcode may be set in response to a passcode change request. In some cases, a user passcode may expire. In such cases, a user may be required to generate a new passcode after the previous passcode expires or before the previous passcode is permitted to expire. In other cases, the ambulatory medicament device may periodically generate a new passcode (e.g., an override passcode), or may generate the passcode at a time when a user supplies the passcode.

[0259] In some cases, the user interface element used for accessing a user interface that enable changing one or more settings of the AMD may differ from the a user interface for modifying the control parameters associated with that setting. For example, a keypad may be used to enter a passcode for unlocking a user interface for changing a control parameter and a touchscreen may be used to modify the control parameter.

[0260] When the lock feature is enabled, the user interface screen may look and function the same as if the lock feature were not enabled. If the lock feature is enabled, when a visual guide for unlocking the device (such as, for example, a linear unlock slider, an arcuate unlock slider, or another unlock user interface element) is activated, a passcode entry interface (e.g., a keypad user interface element) may be displayed. If either the user passcode or the global override passcode is entered, the user interface may proceed as normal. Otherwise, the user interface may revert back to the original lock screen.

[0261] In some examples, the user action that permits a user to change one or more settings of the AMD may be different from the wake action that activates a user interface. For example, a wake action may be used to activate a touchscreen display that may display a plurality of user selectable elements some of which may be accessible without a passcode. In such examples, a subset of the user selectable elements, for example those allowing the user to change therapy control parameters, may require a passcode. In some cases, access to each user parameter control element may require a different passcode. In some other examples, providing a passcode may to an AMD in locked state, may directly enable access to a subset of control parameter elements.

[0262] To help recall the passcode, the passcode may be set by the user enabling the user to select a passcode the user is more likely to remember. However, regardless of who sets the passcode, there is a risk that the user will not remember the passcode. Due to the

nature of the device (e.g., a device that may provide life-saving treatment), it is desirable that certain user's not be restricted from accessing particular settings of the ambulatory medicament device, and be able to quickly (e.g., within seconds, minutes, prior to a next therapy event, or before harm may occur to the subject) obtain access to the particular settings when required. Thus, while some non-medical devices may implement lockout periods or other restrictions to prevent a malicious user from trying to brute-force determine a passcode for a device, such features are generally undesirable for an ambulatory medicament device. Accordingly, embodiments disclosed herein include an ambulatory medicament device that includes an override passcode that enables access to the ambulatory medicament device (or control settings thereof) regardless of whether the user passcode is provided.

[0263] In some examples the passcode or the override passcode can be a series of taps, series of inputs, a complex or a simple gesture (e.g., a swipe or other movement across the touchscreen), The series of inputs may be any combination of touch movements, touch points, numerical characters, alphabetical characters, and other symbols. In some examples, the time that the series of inputs are entered may also be a part of the range of parameters. For example, a series of inputs may need to be entered in no less than 3 seconds or more than 3 seconds, and no more than 15 seconds or less than 15 seconds. One example of the complex gesture is a swipe.

[0264] In some other examples the passcode or the override passcode can be a complex or a simple gesture (e.g., a swipe or other movement across the touchscreen), performing a pattern or sequence on the touchscreen (e.g., drawing an image), a multi-touch interaction, a combination of the foregoing, or any other type of interaction with a touchscreen, or portion thereof. Another example of a complex gesture is entering a predetermined sequence of touches. In some cases, the passcode may include a quiz or set of questions,

[0265] In some examples, the ambulatory medicament device may be configured to receive therapy settings or modifications to therapy settings from an intermediary device via a communication connection. In some cases, this feature may be supported in addition to providing the user with option of modifying one or more settings with a user interface of the AMD. The communication connection between the intermediary device and the AMD may

be a direct connection via, for example, Bluetooth®, or a connection via a network, such as over a local area network or a wide area network. In some such cases, the ambulatory medicament device may include a wireless transceiver, such as an NB-LTE transceiver, a Wi-Fi transceiver, or a Bluetooth transceiver. The intermediary device, that provides the user with a user interface to modify settings of the AMD, include any type of device (e.g., a computing device) that can communicate with an ambulatory medicament device. For example, the intermediary device may be a laptop or desktop computer, a smartwatch, a smartphone, or a hardware control device that may be configured to interact with the ambulatory medicament device. Embodiments disclosed herein are applicable regardless of whether the user interface for modifying therapy settings or the configuration of the ambulatory medicament device is generated or presented by the ambulatory medicament device to the user or via another device. In some such cases, a user may provide a user-generated passcode or an override passcode via an interface of the computing device. The computing device may then provide the user-generated passcode or the override passcode to the ambulatory medicament device via the network connection between the devices.

[0266] In some examples, even if the AMD is in locked state, certain intermediary devices may have access to user interfaces that may be used to change one or more settings (e.g., therapy settings) of the AMD. For example, the smart phone of a guardian or a parent of the subject may be used to change one or more settings of the AMD while the AMD is in the locked state.

[0267] In some examples, the AMD may be configured to receive a passcode from or via a computing systems (e.g., a cloud computing system). In these examples, the AMD may receive passcode through a direct end-to-end connection (e.g., a wireless connection over a wide area network) established with the computing system. In some such examples, another computing device (e.g., a smartphone, a laptop, a personal computer, and the like) connected to the computing system, may send a passcode to the AMD and be able to change one or more settings of the AMD if the passcode is validated by the AMD.

[0268] In cases where the user cannot recall the user passcode, the user can obtain access to the user interface that permits modification of the control parameter by supplying an override passcode. In some examples, the override passcode may be a universal fixed passcode (e.g., an 8-digit override passcode) that can be used instead of the user set passcode.

The override passcode can be stored in the ambulatory medicament device at the time of manufacture and may be shared among multiple ambulatory medicament devices (e.g., a global override passcode), or may be unique to a particular ambulatory medicament device. The override passcode may be managed by the manufacturer or by a third-party service. To obtain the override passcode, the user may contact the manufacturer or passcode managing service. Generally, enabling the passcode may exist to prevent a user with a diminished mental capacity (e.g., a child) from modifying settings of the ambulatory medicament device. Thus, security may be less of a concern and any user can contact the manufacturer or passcode managing service to obtain the override passcode. In some such cases, a single global override may be used for all devices produced by the manufacturer. However, in some cases, a level of security may be desired. In some such cases, it may be necessary for the user to authenticate him or herself. Further, the user may be required to provide a serial number of the ambulatory medicament device. In some cases, each model or each unit of the ambulatory medicament device may have a different override passcode. The user may provide authorization information and a serial number of the ambulatory medicament device to the manufacturer or passcode managing service to obtain the override passcode.

[0269] In some examples, may periodically generate a new override passcode or may generate an override passcode at a time when a user supplies the passcode. In these examples, the ambulatory medicament device may use the same parametric values to generate the override passcode as another device may use thereby ensuring a match between the override passcodes. Advantageously, in some cases, by using an algorithm to generate the override passcode, the override passcode can be obtained regardless of whether a user is able to contact a manufacturer or other passcode managing service. In some cases, the user may generate the override passcode without access to a network or phone using, for example, a computing device that can access a common parameter value as the ambulatory medicament device.

[0270] In some cases, the override passcode may change over time or be a rotating passcode. For example, in some cases, the override passcode may change every thirty seconds, every minute, every hour, etc. In some such cases, the override passcode may be determined from an algorithm executed by an application. The ambulatory medicament device may store a copy of the algorithm in a memory of the ambulatory medicament device

and may execute the algorithm to determine the override passcode that is currently valid. A copy of the algorithm may be executed by another computing device accessible by the user. The output of the algorithm may be based on a value that is commonly accessible by the ambulatory medicament device and the copy of the algorithm accessible by the computing device. For example, the output of the algorithm may be generated based on a time, a user identifier, a provided value, or any other factor that may be used to repeatedly generate the same output. In some cases, the override passcode may be calculated based on a combination of factors. For example, the override passcode may be calculated based on a portion of a serial number or model number for the ambulatory medicament device and the time. The determination of the override passcode may be calculated by the ambulatory medicament device, a computer server, and/or an application on a user device.

[0271] In some cases, the override code can be automatically received by the ambulatory medicament device. Thus, a user may not need to see or enter the override code. In some cases, the override code may be transmitted to another device of the user (e.g., a smartphone or laptop). For example, the override code can be texted to a user's smartphone. In some cases, the override code may be received in a coded manner that may not be understandable by a child or user with diminished mental capacity.

[0272] In some cases, the override passcode may be linked to a location. For example, the override passcode may only be enterable at a healthcare provider's office or at the subject's place of residence. The determination of the location of the ambulatory medicament device may be based on a geolocation system (e.g., a Global positioning System (GPS)) available to the ambulatory medicament device.

[0273] In some examples, at least for a subset of therapy settings, the passcode may provide a second level of security in addition to other interactions with the user interface (e.g., a first and a second gesture on a touchscreen display) that may be used to change the therapy settings and/or accept the change made to a therapy setting. In some other examples, at least for a subset of settings, the passcode may be used instead of other interactions with the user interface (described above).

[0274] As mentioned above, interacting with the user interface may cause the ambulatory medicament device, or other device that can modify a control of the ambulatory medicament device, to present a passcode input screen to the user. The user may enter the

passcode to unlock additional user interface features including, for example, a user interface that enables the user to modify at least one control parameter of the ambulatory medicament device. The control parameter can be modified based on an interaction with a parameter control element of the user interface. Further, modification of the control parameter may cause modification of the generation of a dose control signal that is generated by a control algorithm based at least in part on the control parameter.

[0275] In some embodiments, the ambulatory medicament device may have an advanced therapy screen, or other user interface, that permits a healthcare provider, or other user, to obtain additional details relating to therapy provided by the ambulatory medicament device. Although the advanced therapy screen may generally be intended for a knowledgeable user, such as a clinician, in some cases, any user may obtain access to the advanced therapy screen. The advanced therapy screen may permit the healthcare provider to modify control parameters that may not be modifiable by other users. For example, the healthcare provider may be able to control parameters that relate to the calculation of a rate of insulin accumulation, the rate the insulin diminishes within the blood of the subject, the setting of a glucose setpoint, an aggression level or factor of therapy relating to an amount of insulin provided when the subject's glucose level is outside the setpoint range, or when the insulin reaches a point of maximum concentration within the blood of the subject (e.g., T_{max}).

[0276] Access to the advanced therapy screen may be limited by requirement of a passcode, which may be referred to as a clinician passcode to distinguish it from the user-generated passcode and/or the override passcode. This clinician passcode may or may not be user-generated. However, the clinician passcode may be a separate passcode from the user-generated passcode that permits access to the non-advanced therapy screen interface. Further, the clinician passcode may be separate from the override passcode that permits a user to override the user-generated passcode to obtain access to the non-advanced therapy screen interface. In some cases, the clinician passcode may be used as an override passcode. In some example the clinician passcode can be valid for period of time (e.g., set by a subject or another authorized user such as the guardian or apparent of eth subject). For example, the clinician passcode may be valid for a day, a week or a month. In some examples, the AMD may allow certain authorized users to terminate the clinician access at any time.

[0277] In some cases, access to the advanced therapy screen may be limited to a particular period of time. After the time period expires, the ambulatory medicament device may automatically restrict access to the advanced therapy screen. In some cases, the window of access may be extended. For example, if the healthcare provider is continuing to interact with the advanced therapy screen, the screen may remain accessible.

[0278] In some cases, the advanced therapy screen may provide additional features. For example, while a user may be able to indicate that an amount of insulin provided for a meal or as a correction factor should be higher or lower, the healthcare provider may be able to specifically adjust the amount of insulin. Moreover, while a user's direction may or may not be followed depending, for example, if the request exceeds a threshold or may cause blood glucose to not satisfy a setpoint range, an indication provided via the advanced therapy screen may be followed regardless, or may have a wider range or different threshold that may control whether the instruction is followed. Further, the advanced therapy screen may be used to temporarily pause therapy and/or may prevent subject access.

[0279] In some cases, the manufacturer of the ambulatory medicament device may provide a remote unlock signal that can be used to unlock access to the ambulatory medicament device and/or to an advanced therapy screen of the ambulatory medicament device.

[0280] As described above, the passcode may be desired to prevent particular users from inadvertently changing certain control parameters of the ambulatory medicament device. However, features of the ambulatory medicament device that do not affect therapy may remain accessible to a user when the ambulatory medicament device is in a locked state. For example, a user may be able to access therapy history, screen brightness settings or colors, or any other feature that is unlikely to harm a subject if modified in a particular manner. Further, as the passcode feature is generally to prevent control parameter changes, the ambulatory medicament device may provide therapy and continue to provide therapy at the same rate and under the same condition, whether or not the ambulatory medicament device is locked or unlocked.

[0281] When the ambulatory medicament device receives the user passcode or the override passcode, the ambulatory medicament device validates the passcode. The passcode

may be validated by comparing the received passcode to a passcode stored in a memory of the ambulatory medicament device or generated by the ambulatory medicament device. If the passcode received from the user is successfully validated, the user may be granted access to a user interface to modify one or more control parameters. In some cases, the user may be requested to re-enter a passcode to confirm a change to a control parameter. In some other examples, the user may be requested to provide a gesture on a touchscreen to confirm a change to a control parameter.

[0282] If the passcode is not validated, the ambulatory medicament device, or other control device that can provide access to control parameters of the ambulatory medicament device, may prevent access to the user interface to modify the one or more control parameters. In some cases, the user interface that presents the user with the ability to enter the passcode may permit the user a particular number of tries or a particular number of tries within a particular time period to enter the user passcode. If the correct user passcode is not entered within the provided number of tries or within the particular time period, the user interface may enter a lock state (e.g., the screen will be turned off) and prevent further attempts to enter a passcode for at least a period of time. In some cases, the user passcode option may be indefinitely locked or blocked. In some such cases, the control parameters of the ambulatory medical device may only be accessible if the override passcode is provided. Alternatively, or in addition, a user passcode of a different user may be used to provide access to the control parameters of the ambulatory medical device. In some examples, if the correct override passcode is not entered within the provided number of tries or within the particular time period, the user interface may block any attempt to change the override passcode for at least a period of time.

[0283] In some cases, once the passcode is successfully entered or validated, a user may deactivate the passcode feature of the ambulatory medicament device. Deactivating the passcode feature may require use of a separate passcode or the override passcode in addition to the user passcode.

[0284] In some cases, the passcode may be optional or omitted based on the computing device connected to the ambulatory medicament device. For example, if the end-to-end connection is established between a smartphone registered to a particular user (e.g., a parent of the subject), the ambulatory medicament device may unlock automatically without

requiring a passcode. In other cases, the smartphone, or other computing device, may automatically provide the user-generated passcode or the override passcode to the ambulatory medicament device upon establishing a connection. In some cases, the ambulatory medicament device may automatically be unlocked when connected to a charger or when in a particular geographic area. For example, a geo-fence may be configured in one or more locations, such as the subject's house or the clinician's office. When the ambulatory medicament device determines it is within the geo-fence, the ambulatory medicament device may automatically be unlocked. Similarly, when the ambulatory medicament device determines that it is not within the geo-fenced region, it may automatically be locked. The determination of the location of the ambulatory medicament device may be made based on a geo-location system, such as the Global Positioning System (GPS).

[0285] In some cases, after a certain number of unsuccessful passcodes are entered (e.g., after 5 tries), the user interface screen may be turned off or may accept only the global override passcode

Example AMD with Security Codes

[0286] FIG. 29 is a block diagram illustrating the interconnection among modules and procedures in AMD involved in changing the settings of the AMD. In some cases, one or more settings of the AMD may be changed using one more parameter control elements 2941/2943/2945 presented on one or more setting control screens 2940/2942/2944 provided by the user interface module 2908. In some examples, when the lock feature is activated, access to one or more setting control screens 2940/2942/2944 and/or one or more parameter control elements 2941/2943/2945, may be protected by a passcode. In order to a control parameter 2941/2943/2945, the user may provide a passcode 2933 (e.g., a user generated passcode or an override passcode), via the user interface module 2908 (e.g., using a touchscreen display 2924 or alphanumeric pad 2926). Alternatively or in addition the user 2927 may provide a passcode 2946 using an intermediary device (e.g., a laptop, a smart phone and the like) that is connected to the AMD (e.g., via a wireless link). In some examples, the access to one or more setting control screens 2940/2942/2944 and/or parameter control elements 2941/2943/2945, may be managed by setting change procedures 2928

stored in a memory in the CCM of the AMD. A hard processor may execute the machine readable instructions associated with the setting change procedures 2928.

[0287] In some examples, the option to provide a passcode may become available, when the user 2927 performs a wake action on a wake interface 2922. In these examples if the wake control module 2934 of the CCM determines that a valid wake action is performed, it may present selectable elements associated with the setting control screens 2940/2942/2944, for example, on a touchscreen display. In some other examples, the first screen presented on the touchscreen display, may provide other selectable elements including an element to change the settings of the AMD. In such examples, selecting element associated with settings change may activate a second screen that presents selectable elements associated with the setting control screens 2940/2942/2944. When the lock feature is activated, access to any of the setting control screens 2940/2942/2944 and/or parameter control elements 2941/2943/2945 may require a passcode. In some examples, each one of the control screens 2940/2942/2944 and/or parameter control elements 2941/2943/2945 may require a different passcode. In some other examples, one or more control screens 2940/2942/2944 and/or parameter control elements 2941/2943/2945 may not require a passcode. For example, access to the first screen 2940 may require a first passcode, the access to the second screen 2942 may require a second passcode and the access to the third screen 2944 may not need a passcode. In yet another examples, all the control screens 2940/2942/2944 may be presented without the need for providing a passcode, but access to the one or more control elements in a control screen may require a passcode. For example, the user may select the second screen 2942 without entering a passcode but in order to select one or more parameter control elements 2943 on that screen, the user may need to enter one or more passcodes.

[0288] In some examples, once a passcode or override passcode received from the intermediary device 2922 or the interface module 2908, the passcode may be transmitted to the control and computing unit of the AMD where the setting change control procedure 2935 determines the validity of the passcode by comparing it to the one or more user generated passcodes 2939 or override passcodes 2937 stored in a memory of the CCM.

[0289] FIG. 30 is a flow diagram illustrating an example method that may be used by an AMD to allow a user to change a setting of the AMD using a user generated passcode

or an override passcode. Once the AMD (e.g., the wake action procedure in the CCM) receives a valid wake action 3002, a user interface may be activated. In some example, the wake action may directly activate a setting change interface 3004 (e.g., a setting change screen presented on a touchscreen display). In some examples, a specific wake action may activate the setting change interface. On the setting change interface 3006, the AMD (e.g., the setting change procedure in the CCM) may request a passcode (e.g., by presenting a window to enter a passcode). Once a passcode is received, the AMD (e.g., the setting change procedure in the CCM) may determine whether the passcode matches a user generated passcode 3008. If it is determined the passcode matches with a user generated passcode, the AMD may provide access 3010 to one or more control parameter elements associated with the received passcode. If the received passcode dose not match with any of the stored user generated passcode, the AMD may determine whether the passcode matches with an override passcode. If it is determined the passcode matches an override passcode stored in a memory of AMD or a memory of an authorized computing device, the AMD may provide access 3014 to one or more control parameter elements associated with the received override passcode. If it is determined the passcode does not matches an override passcode, the AMD denies access to one or more passcode protected control elements.

[0290] FIG. 31 is a flow diagram illustrating another example method that may be used by an AMD to allow a user to change a setting of the AMD using a user generated passcode or an override passcode. Once the AMD (e.g., the wake action procedure in the CCM) receives a valid wake action 3102, the AMD may provide a user interface (e.g., a touchscreen display) on which the user can provide a first gesture to activate a setting change interface or screen. When a first gesture is received from a user or subject 3104, the AMD may activate a setting change interface or a screen. In some examples, the setting change interface or a screen may include one or more parameter control elements associated with one or more settings of the AMD. In some other examples, the setting change interface or a screen may include one or more selectable elements each associated with a setting change screen (e.g., a screen provided on a touchscreen display) that may include one or more control parameters. When a request for setting change is received 3108, the AMD may determine whether the requested setting change is passcode protected or not. In some examples, the request for setting change may include selecting a parameter control element.

In some other examples, the request for setting change may include selecting a list of parameter control elements (e.g., included in a separate screen provided on a touchscreen display).

[0291] If the AMD determines that the requested setting change is not protected by a passcode, it may permit access to one or more parameter control elements associated with the requested setting change 3112. In some examples, once the changes are received via parameter control elements 3114, the user may need to provide a second gesture on the user interface (e.g., touchscreen display) to confirm the changes made. In response to receiving the second gesture 3116, the AMD may change one or more settings according to the requested and confirmed changes.

[0292] If the AMD determines that the requested setting change is protected by a passcode, it may request a passcode 3120 via a passcode display (e.g., provided on a touchscreen display). In some examples, the request for the passcode may be presented on a display but the passcode may be received via a physical keypad. Once a passcode is received 3122 from the user or subject, the AMD may validate the passcode 3124 by comparing it with one or more user generated passcodes or an override passcode. If it is determined that the passcode matches with a user generated passcode or an override passcode, the AMD may activate 3126 one or more parameter control elements associated with the requested setting change. Subsequently, the AMD may receive a setting change via the selected control parameter element 3128. In some examples, the user may need to provide a second gesture on the user interface (e.g., touchscreen display) to confirm the changes made. In response to receiving the second gesture 3130, the AMD may change one or more settings according to the requested and confirmed changes 3132.

AMD with Alarm System

[0293] In some cases, a condition may occur that impacts the operation of the ambulatory medicament device. This condition may be associated with the ability of the ambulatory medicament device to operate as intended by the manufacturer, a subject receiving therapy from the ambulatory medicament device, and/or user (e.g., healthcare provider, parent, or guardian of the subject). In some cases, the ambulatory medicament device may be operating as intended, but the condition of the subject may not satisfy a

desired level of health. In either case, it is generally desirable to generate an alarm to inform the subject and/or one or more users of the condition of the ambulatory medicament device and/or the subject. Moreover, it is desirable to track the alarm until the condition that caused the alarm is resolved. Further, it is desirable to issue different types of alarms for different conditions to enable a subject or user to easily distinguish the severity of the condition that triggered the alarm. The user may be a subject receiving medicament or therapy, or may be another user, such as a clinician or healthcare provider, or a parent or guardian.

[0294] This section of the disclosure relates to an ambulatory medicament device, such as an insulin pump or a combined insulin and counter-regulatory agent (e.g., Glucagon) pump, configured to generate a dose control signal configured to cause a medicament pump to infuse medicament into a subject. Moreover, the present disclosure relates to an ambulatory medicament device configured to detect a condition of the ambulatory medicament device and/or the subject, and to generate an alarm when it is determined that the detected condition satisfies an alarm condition.

[0295] As mention above, an ambulatory medicament device may include an alarm system configured to monitor the ambulatory medicament device and/or the subject, and to generate an alarm when it is determined that a condition has been detected that satisfies an alarm condition. In some examples, the alarm system that may organize a list of alarms, notifying a user of these alarms, and allowing the user to acknowledge alarms.

[0296] In some embodiments, the alarm system may comprise a plurality of sensors that monitor the AMD or the subject, a monitoring system interface that receives the data from sensors, and alarm generation module that process the received data and generate alarms if an alarm condition is met. In some examples, the monitoring system interface and the alarm generation module are implemented using one or more hardware processors and machine readable. In some other examples, the monitoring system interface and the alarm generation module are separate hard ware modules.

[0297] With reference to FIG. 32, in some embodiments, an alarm control system 3222 implements alarm control procedures in the control and computing module 210 (CCM) of the AMD. The alarm control system 3222 can be implemented as instructions stored in a memory of the CCM (e.g., the main memory 216) and executed by a hardware processor 214 to generate an alarm upon detection of a condition of the ambulatory medicament device

and/or the subject. In some cases, the hardware processor of the monitoring system is a hardware processor of the ambulatory medicament device that controls medicament delivery. In other cases, the hardware processor of the monitoring system may be a separate hardware processor.

[0298] In some examples, the alarm control system 3222 includes a monitoring system 3226 and an alarm annunciation system 3228. The monitoring system 3226 monitors the condition or status of the AMD and/or the subject at least partially based on signals or status values received from a set of device sensors 3224 and a set of subject sensors 3220. In some examples, the device sensors may be configured to track the status of the components or the elements of the ambulatory medicament device, and the subject sensors can be configured to obtain measurements of one or more physiological characteristics of the subject

[0299] In some examples, a device sensor 3224 is a sensor that generates a signal or status value associated with the condition of modules, interfaces, accessories, disposables of the AMD. In some examples, a device sensor 3224 may generate a signal that corresponds to a parameter associated with a component in a module or interface. For example, one device sensor may record the voltage of a battery and another device sensor may record the follow rate of a pump the medicament delivery interface 3206.

[0300] In some examples, a subject sensor 3220 may be any sensor that generates a signal or status value associated with one or more physiological indicators (or parameters) of a subject (e.g., heart rate, blood pressure, body temperature, level of blood sugar, serum levels of various hormones or other analytes). The device and subject monitoring system 3226 can include continuously receiving and analyzing signals received from device sensors 3224 and subject sensors 3206 to determine the condition of the ambulatory medicament device, the subject, a sensor, and/or other accessories.

[0301] In some cases, a single sensor may be used to monitor both the condition of the subject and the ambulatory medicament device or accessories and sensors connected to AMD. For example, a continuous glucose monitoring CGM sensor may be used to monitor the condition of the subject, and may also be monitored to determine whether the condition of the CGM satisfies an alarm condition (e.g., to alarm a user that the CGM should be replaced).

[0302] Although described as sensors of the ambulatory medicament device, one or more of the sensors may be accessories that may or may not be part of the ambulatory medicament device, but that may communicate with the ambulatory medicament device.

[0303] In some examples, alarm processing system 3222 implements procedures for allowing a user or the subject to change the alarm settings and/or acknowledging an alarm annunciation via the user interface 3208. In some examples, the user may be able to see one or more alarms annunciated on a user interface (e.g., as a list of alarms), even if the AMD is in locked state. In these examples, the user may not be able to acknowledge or respond to alarm when the AMD is in locked state.

[0304] In some such examples, a user or the subject may get access to an alarm setting screen or acknowledge an alarm annunciation by providing a wake signal and a first gesture (e.g., on a touchscreen display). In some cases, the first gesture may be created by entering predetermined characters on the alphanumeric pad. In some such examples, the alarm control system 3222 distinguishes inadvertent alarm control inputs from intentional alarm control inputs. An inadvertent alarm control input is an alarm acknowledgment input that was made without the intent of the user to acknowledge the alarm that the ambulatory medical device 600 is delivering to the user.

[0305] In some examples, the alarm control system 3222 implements processes for determination and categorization of an alarm condition based on its severity level (e.g., a severity level between 0 and 5), according to the information received through the monitoring system 3226.

[0306] In some other examples, the alarm control system 3222 implements procedures for controlling the annunciation of alarm conditions via the user interface module 3208, at least partially, based on their severity level. In some such examples, a user interface (e.g., a touchscreen display) may be configured to allow the user to navigate directly to the issue or fault for which an alarm is being delivered. This capability provides the user with access to address the fault causing the alarm so that it could be corrected thereby stopping the alarm.

Alarm Conditions

[0307] In some examples, the device and subject monitoring module 3226 may provide the status information received from the device 3224 and/or subject sensors 3220 to the alarm annunciation system 3228. In some examples, the status information may comprise one or more status values. In some such examples, the alarm generation system 3228 is configured to determine based at least in part on the status information received from the subject monitoring module 3226, whether an alarm condition is satisfied.

[0308] Determining whether the alarm condition is satisfied may include comparing one or more status values associated with the ambulatory medicament device and/or the subject to one or more alarm thresholds or alarm conditions. In some cases, each alarm threshold or alarm condition may be associated with an alarm profile. In some such cases, determining whether the alarm condition is satisfied may include comparing the status information to one or more alarm thresholds or alarm conditions included in one or more alarm profiles. In some examples, the alarm profile may be stored in the storage 218 of the CCM 210. In some such examples, at least some of the alarm profiles may be provided to the CCM by an authorized user or the subject via a user interface or directly transferred from another device to the storage (e.g., from USB drive, a laptop, smart phone, PC and the like). In some other examples, at least some of the alarm profiles may be stored in the storage 218 at the time of manufacture,

[0309] Each of the alarm profiles may indicate the characteristics or status of the ambulatory medicament device and/or subject that triggers an alarm corresponding to the alarm profile. For example, at least some alarm profiles may indicate the threshold status values below of above which an alarm should be triggered. For example, one alarm profile may indicate that when a blood glucose level of the subject exceeds a particular threshold, a particular alarm is to be generated and/or annunciated. As another example, an alarm profile may indicate that when an available amount of medicament is below a particular threshold, a particular alarm is to be generated and/or annunciated. The type of alarm and/or the alarm frequency or intensity associated with the medicament level may differ from the alarm triggered based on the blood glucose level. Although the previous examples, described a single condition associated with a single alarm profile, it should be understood that multiple conditions may be associated with an alarm profile. For example, a blood glucose level that exceeds an upper threshold or is below a lower threshold may be associated with different

alarm profiles or the same alarm profile. As another example, a blood glucose level that is above an upper threshold or a medicament pump that is unable to supply insulin may be associated with the same alarm profile. On the other hand, a medicament pump that is unable to supply insulin due to an empty insulin cartridge may be associated with a different alarm profile than if the medicament pump is unable to supply insulin due to damage to the medicament pump.

[0310] Some non-limiting examples of conditions of the ambulatory medicament device or of the subject that may be associated with an alarm profile include conditions relating to a battery capacity (e.g., below a threshold charge capacity or below a capacity associated with a particular amount of operating time (e.g., one day)), a battery condition (e.g., high temperature or low voltage), a medicament or drug delivery condition (e.g., medicament is empty or below a threshold, motor is stalled, catheter is occluded, etc.), subject sensor condition (e.g., blood glucose sensor is expiring, or signal was not received from sensor), calibration failure, high or low glucose levels, network (e.g., Bluetooth® or BN-LTE) communication errors, haptic interface errors (e.g., motor non-responsive), speaker errors (e.g., noise or low volume), medicament cartridge errors (e.g., empty cartridge, cartridge detection error, etc.), and the like. As explained below, each of these errors or conditions may be associated with different severity levels that cause the annunciation of different alarms.

[0311] In some cases, each alarm profile may be associated with a severity level of the alarm. The severity level may be associated with how urgently the condition that triggered the alarm should be addressed or resolved. Further, the severity level may be associated with an amount of harm that may be caused to a subject if the condition that triggered the alarm is not resolved or is not resolved within a particular time period. The number of severity levels may vary based on the type of ambulatory medicament device. Generally, there is no limit to the number of severity levels. However, there may be a point of diminishing returns as the number of severity levels exceeds a particular number because, for example, it may be difficult for a user to distinguish between the different numbers of severity levels or to identify with which severity level a particular alarm is associated. Thus, the number of severity levels may be limited to a particular number, such as 3, 5, 6, 9, or some number in between. However, it is possible for there to be more than 9 severity levels.

[0312] There may be multiple alarm profiles associated with the severity level. Or each condition of the ambulatory medicament device and/or subject that is associated with the same severity level may be associated with the same alarm profile.

[0313] The ambulatory medicament device may determine a severity of an alarm condition based on the condition of the ambulatory medicament device and/or the subject that triggered the alarm condition. In some cases, the ambulatory medicament device may determine the severity of the alarm condition based at least in part on an alarm profile associated with the alarm condition.

[0314] Generally, if the alarm condition does not prevent the ambulatory medicament device from providing therapy, the ambulatory medicament device may continue to provide therapy. However, if the alarm condition interferes with the delivery of therapy, operation of the ambulatory medicament device may be suspended or partially suspended. Generally, alarm conditions that interfere with the provisioning of therapy may be associated with a higher severity level. However, some alarm conditions that interfere with the provisioning of therapy may be associated with lower severity levels. For example, a determination that the ambulatory medicament device cannot supply insulin may normally be associated with a highest severity alarm. But if a user indicates that the site location is currently in process of being changed, the alarm condition may be associated with a lower severity level (e.g., an informational alarm reminding the user that insulin cannot be delivered during site change).

Alarm Annunciation

[0315] The alarm annunciation system 3228 can implement an annunciation pattern selected based at least in part on the status information generated by and received from the monitoring interface 3226, whether an alarm condition is satisfied. Determining whether the alarm condition is satisfied may include comparing one or more status values associated with the ambulatory medicament device and/or the subject to one or more alarm thresholds or alarm conditions associated with an alarm profile.

[0316] Upon verifying that an alarm condition associate with an alarm profile is satisfied, the alarm annunciation system 3228 annunciates the alarm condition.

[0317] In some examples, the alarm system may generate a list of pending alarm conditions and store it in a memory of the AMD (e.g., storage 218 in CCM 210). In these examples, any time an alarm condition associated with an alarm profile is satisfied, the alarm system may update the list of pending alarm condition by adding the new alarm condition to the list of pending alarm conditions.

[0318] In some examples, the list of pending alarm conditions may be sorted according to the severity level associated with the alarm conditions.

[0319] In some examples, the alarm system may annunciate the alarm conditions via the user interface module 3208 of the AMD 600. For example, the alarm condition may be annunciated via one or more user interfaces (e.g., a display, a speaker, and the like). In some such examples, an alarm may comprise an audio alarm, a text message, a graphical message, a text or graphical message with audio, vibrations, flashing light and any combination of these.

[0320] In some other examples, the alarm conditions may be transmitted to other devices, via the communication module 3202 of the AMD where, for example, an authorized user (e.g., guardians or parents of the subject), the subject or an emergency provider can view the alarm condition. In yet other examples, the alarm annunciation system 3228, may establish a direct end-to-end connection with a computing system (e.g., a cloud computing system) using the communication module 3202 and send the alarm condition to the computing system through the end-to-end connection.

[0321] Based on the severity of the alarm condition and/or the alarm profile corresponding to the alarm condition, an alarm may be generated and/or annunciated that is associated with the severity of the alarm condition and/or the type of alarm condition. Different alarm conditions and/or alarm profiles may result in different types of alarms or different annunciations of the alarm. For example, an alarm associated with the highest severity level may include an audible alarm with a loudness that exceeds a particular decibel level (e.g., above 70 or 80 decibels), a visible alarm (e.g., a flashing or steady light) with a luminance above a particular luminance value (e.g., a luminance between 10^5 or 10^6 candelas per square meter), and/or a vibrational alarm. Further, the alarm associated with the highest severity level may not be snoozed or dismissed. Alternatively, the alarm associated with the highest severity level may be snoozed for a shorter time period than alarms of lower severity

levels (e.g., for 5 minutes, for 10 minutes, etc.). An alarm associated with a different severity level than the highest severity level may include a different combination of audible, visible, and vibrational alarms. Not only may the existence of audible, visible, and vibrational alarms differ for different severity levels, but so may the characteristics of each of the alarm types. For example, audible alarms may have different sound patterns, loudness, frequencies, etc. Visible alarm may be of different intensity, color, pattern, etc. Vibrational alarms may be of different pattern, intensity, etc. Further, an alarm with a different severity level than the highest severity level may be permitted to be snoozed or dismisses, or snoozed for a longer period of time. In some examples, the severity of the alarm condition may determine the type of type of the alarm generated (e.g., audio, text, graphical, or any combination of these).

[0322] Further, the display of alarm conditions on the user interface may include an icon for each type of alarm condition. The user interface may display the number of alarm conditions and/or the number of alarm conditions of a particular type or severity level. In some cases, a duplicate alarm may be omitted from the list of alarms. In other cases, a count of the occurrence of alarms may be increased to reflect the duplicate alarm. In some cases, a duplicate alarm may result in the annunciation of the duplicate alarm. In other cases, the duplicate alarm is ignored. In some cases, the occurrence of a duplicate alarm may cause an escalation of the existing alarm. For example, if an alarm condition that causes an annunciation of an alarm with a first severity level is detected as occurring a second time, the alarm may be annunciated with a second severity level that indicates a greater degree of severity than the first severity level. It should be understood that an alarm occurring after an alarm condition is resolved may not be considered a duplicate alarm, but instead may be a reoccurrence of the alarm condition and/or an indicator that the resolution for the alarm condition failed (e.g., an insulin cartridge replacement is faulty or is empty).\

[0323] In some cases, the list of alarms may be accessed when the ambulatory medicament device is locked. Further, details about the alarms may be accessible when the ambulatory medicament device is locked.

[0324] Each of the alarm conditions, or information associated therewith, may be added to an indicator or user interface (e.g., a list, or other data structure or user interface element) that may be accessed by a user. This user interface may maintain the alarm condition on the user interface until the alarm condition is resolved. Further, the alarm

conditions may be sorted or ranked based on the severity level of the alarm condition, the time that the alarm condition occurred, whether the alarm condition relates to the subject or the ambulatory medicament device, any combination of the foregoing, or any other factor for sorting or ranking the alarm conditions.

[0325] In some cases wherein the alarm is presented on a display, the displayed information may include details about what caused the alarm, the severity of the alarm, how to respond to or address the alarm, or any other information that may be informative regarding why the alarm was generated and/or how to respond to the alarm. In some cases, the information may provide a workflow or instructions on how to respond to the alarm. The instructions may include a link to a workflow provided by a manufacturer of the ambulatory medicament device or of another entity, such as an entity that provides medicament or site changing kits.

[0326] In some cases, different views of an alarm or different information associated with the alarm may be provided based on an identity of the user, or a role of the user, viewing the alarm. For example, a child may be instructed to contact a parent to address an alarm. But a parent may be provided with information to resolve the alarm. The parent may receive simplified information (e.g., blood glucose level is high) about what caused the alarm, but a healthcare provider may receive more detailed information regarding the alarm (e.g., internal control parameter values, insulin flow rates, curvature of insulin diminishment predictions, etc.) that facilitates the healthcare provider caring for the subject.

[0327] The alarm conditions may be displayed on a display of the ambulatory medicament device. Alternatively, or in addition, the alarm conditions may be displayed on a remote display that is separate from the ambulatory medicament device. The remote display may be a display that is authenticated or associated with a computing device that is authenticated to access data, such as alarm conditions, from the ambulatory medicament device. In some cases, the list of alarms may be presented on a mobile device (e.g., a smartwatch or smartphone) or on a computing device (e.g., a laptop or desktop) that can obtain data directly or indirectly from the ambulatory medicament device.

[0328] In some cases, annunciating the alarm may include contacting a manufacturer and/or user (e.g., a healthcare worker, a parent or guardian, or other registered user). Further, the alarm may include instructions on repairing the ambulatory medicament

device and/or on addressing the alarm condition. For example, the alarm may provide a user with instructions to replace the insulin cartridge and how to replace the insulin cartridge. As another example, the alarm may provide instructions on how to change the battery of the device or on how to change a site where the insulin pump connects to the subject. In some cases, the alarm may include one or more operations associated with the alarm. For example, the alarm may trigger reordering of insulin or may request that the user confirm a reorder request to reorder insulin.

[0329] A user may be able to acknowledge and/or snooze alarms. Certain alarms, such as informational alarms, may be dismissible. However, generally the alarm may remain on the alarm list until the condition that caused the alarm is resolved.

[0330] Resolving the alarm may include any action that addresses the condition that caused the alarm to be generated. For example, resolving the alarm may include replacing an insulin cartridge, changing a site where the ambulatory medicament device is connected to the subject, charging a battery of the ambulatory medicament device, providing insulin or a counter-regulatory agent to the subject and/or the ambulatory medicament device, or any other action that may be performed to address an alarm condition. In some cases, the resolution action may be acknowledging the alarm. For example, if the alarm is informational (e.g., to inform the user that more insulin has been ordered), acknowledging the alarm may be a sufficient resolution action.

[0331] In some cases, whether the alarm condition is resolved may depend on an identity of the user. For example, if a child interacts with an alarm related to reordering of insulin, the alarm may remain until a parent or guardian acknowledges the alarm. However, the child may be able to snooze the alarm. In some cases, a user interface that displays alarms may differ based on who is viewing the alarm. For example, a child may view the alarms, but may not be able to interact with the alarms. However, a parent or guardian may be able to snooze or dismiss an alarm. Further, a child may be instructed to bring the device to a parent or adult to address an alarm. In some cases, the child may be informed of how urgently to contact the parent (e.g., contact a parent immediately, within a day, within a week, etc.). Moreover, a designated adult may separately be alarmed (e.g., via a text or email alarm). The parent or guardian may receive additional information not provided to the child or subject (e.g., a link to repair instructions or a workflow to address the alarm condition).

[0332] In some cases, certain conditions may self-resolve over time. For example, a low battery alarm may resolve as the battery is charged. In such cases, the alarm may be cancelled automatically as the battery charge level exceeds a particular threshold. Further, in some cases, one or more alarms and/or the alarm list can be viewed and/or accessed on a home screen, a main screen, or other non-alarm based user interface screen in addition to a user-interface screen designated for display alarms. The alarm list may be accessed from the ambulatory medicament device and/or a computing system in communication with the ambulatory medicament device.

[0333] However, in some cases, the alarm condition may or may not be resolvable when the ambulatory medicament device is locked.

[0334] A user may interact with the alarms generated based on the alarm condition. In some cases the user can only interact with the alarms when the ambulatory medicament device is unlocked. In other cases, the user can interact with the alarms to snooze them or to obtain further information. However, the user may not be able to dismiss the alarm without unlocking the ambulatory medicament device. Interacting with the alarms may include providing information associated with the alarm to a user in response to the user interacting with the alarm, or an indicator representative of the alarm.

Example AMD with Alarm Management System

[0335] FIG. 33 shows a flow diagram illustrating an example procedure that may be used by the alarm system of an AMD to annunciate an alarm condition upon receiving a status information that satisfies an alarm condition. In some examples, the alarm annunciation system 3228 implements an annunciation process by execution of instructions by a processor in CCM of the AMD, where the instructions can be stored in the main memory, storage of the AMD, or in a memory of a connected electronic device or computing system.

[0336] The alarm system may receive status information 3302 using the device and subject monitoring interface 3226, one or more device sensors and/or one or more subject sensors. In some examples, the alarm annunciation system 3228 determines whether the received status information satisfies an alarm condition. In some examples, the alarm condition may be an alarm condition in an alarm profile. If the received status information

does not satisfy an alarm condition, no action may be taken 3306. If the received status information satisfies an alarm condition, the alarm system may determine whether the alarm condition is already present in the list of pending alarm conditions or not 3308. If the alarm condition is not present in the list of pending alarm conditions, the alarm system may add the alarm condition to the list of pending alarm conditions 3310. Next the alarm system, may determine the severity of the alarm condition 3312. Based on the determined level of severity, the alarm annunciation system 3228 can select an annunciation pattern 3314 and annunciate the alarm condition using the selected annunciation pattern. If the alarm condition is present in the list of pending alarm conditions, the alarm system may select an annunciation pattern and annunciate the alarm condition using the selected annunciation pattern. In some examples, the annunciation pattern selected at block 3318, may be an annunciation pattern that is different than the previously used annunciation patterns for the alarm condition. In some such examples, the annunciation pattern selected at block 3318, may be selected based on number of times that the same alarm condition is satisfied by a received status information. The process of the alarm detection and control function may repeat each processing cycle so long as the ambulatory medical device is in use. In some examples, after an alarm is annunciated, the alarm system may wait for user acknowledgment of the alarm. If the user acknowledges the alarm, the system proceeds to perform alarm processing. However, if the user fails to acknowledge the alarm, the annunciation continues and may escalate depending on the level of the alarm.

[0337] As mentioned above, the alarm conditions may be categorized based and annunciated based on their severity level. In some examples, the alarms are categorized numerically in descending order with the highest priority fault displayed at the top of the list.

[0338] In some examples, a level 0 severity, may be for a trivial fault that does not require any action by the user thus not warranting an alarm notification. In some other examples, a level 1 severity may be an informational type notification that repeats at a certain frequency (e.g. every 30 minutes) until acknowledged by user which results in it being reset. The annunciation may include a brief vibration and a beep, for example. In some examples, a level 2 severity, may be one relating to an imminent loss of system function. Thus, such an annunciation may include two brief vibrations and two beeps, for example, and repeating at a certain frequency (e.g. every 30 minutes). Thus, the user would still need to address the

situation creating the fault to completely stop the annunciation. In some other examples, a level 3 fault may be for when the system is no longer fully functional thus requiring user intervention to correct the issue. The annunciation may begin with a base level intensity with three brief vibrations and three audio beeps, for example, and repeating at a certain frequency (e.g. every 5 minutes). The annunciation escalates at a second frequency, e.g. every 30 minutes, up to a maximum intensity level. The escalation may be a change in vibration intensity and/or audio level, for example. The escalation may be cleared to base level when the user acknowledges the fault; however, the base alarm remains if underlying condition persists. Thus, the user would still need to address the situation creating the fault to completely stop the annunciation. In some examples, a level 4 severity, may be for when the system is no longer functional and not correctable by the user. The annunciation may begin with a base level intensity with three audio beeps, for example, and repeating at a certain frequency (e.g. every 5 minutes). The annunciation escalates at a second frequency, e.g. every 30 minutes, up to a maximum intensity level. The escalation may be a change in audio level, for example. The escalation may be cleared when the user acknowledges the fault; however, the base alarm remains because the underlying condition persists. In some other examples, a level 5 severity, may be for high priority alarms per IEC 60601-1-8. The annunciation when activated may be cleared only when the underlying issue is resolved, e.g. glucose level is raised.

[0339] Additional embodiments relating to determining a severity of an alarm condition and annunciating the alarm based at least in part on the severity of the alarm condition that can be combined with one or more embodiments of the present disclosure are described in U.S. Provisional Application No. 62/911,017, which was filed on October 4, 2019 and is titled “ALARM SYSTEM AND METHOD IN A DRUG INFUSION DEVICE,” the disclosure of which is hereby incorporated by reference in its entirety herein for all purposes.

Non-critical AMD Condition Management

[0340] In some cases, a condition may occur that impacts the operation of the ambulatory medicament device. This condition may be associated with the ability of the ambulatory medicament device to operate as intended by the manufacturer, a subject

receiving therapy from the ambulatory medicament device, and/or user (e.g., healthcare provider, parent, or guardian of the subject). In some cases, the condition or malfunction of the ambulatory medical device may prevent the ambulatory medical device from providing therapy to the subject. In other cases, the condition or malfunction may permit, at least for a period of time, the ambulatory medical device to continue providing at least partial therapy to the subject. In either case, it is generally desirable to generate an alert to inform the subject and/or one or more users of the condition of the ambulatory medical device and/or the subject. Moreover, it is desirable to track the alert until the condition that caused the alert is resolved. Further, it is desirable to issue different types of alerts for different conditions to enable a subject or user to easily distinguish the severity of the condition that triggered the alert.

[0341] In many cases, if the nature of the alert is non-critical, it may be safer to continue the underlying therapy and notify the user of the condition than to cease therapy. In some such cases, the best response to a problem with the device for a subject is to notify the device manufacturer, or other user that can address the problem, while the subject continues to receive therapy until a replacement device can be obtained or a repair can be made.

[0342] Additionally, alert fatigue can be an issue with medical devices due to excessive alerts which do not necessarily require user interaction. Alert fatigue can be dangerous because it can lead users to ignore serious alerts or alerts that require action in the short term.

[0343] The method described herein may be performed by an AMD (e.g., by one or more processor of the AMD) to detect device malfunctions for the AMD and that can generate alerts corresponding to the ambulatory medical device and prioritize the alerts to enable the subject or user to quickly and easily determine whether the device malfunction will impact therapy, should be addressed in the short-term (e.g., immediately, in 1-2 hours, within the day, etc.), and/or can be addressed at the subject's convenience (e.g., within a month, or more). In some cases, the method may be used by other systems.

[0344] In certain embodiments, the system disclosed herein can detect a condition in which the ambulatory medical device does not meet a manufacturer's specification (e.g. a failure of a haptic annunciator, a Bluetooth® radio malfunction, glucagon or insulin runs out, there is a medicament delivery malfunction, a touchscreen failure, etc.). In some cases, there

can be several tiers of critical and/or non-critical faults. If it is determined that the underlying condition is not sufficient to stop therapy (e.g., delivery of insulin is not stopped), the fault may be deemed non-critical. In some cases, the fault may not be a fault of the device, but may be indicative of required maintenance (e.g., recharge battery indicator, order more medicament indicator, etc.). The condition may be annunciated to the user with appropriate instructions (e.g., call manufacturer for replacement medicament or parts) for addressing the fault or issue.

[0345] After the annunciation is acknowledged, the alert may be re-annunciated as a reminder at some later period in time (e.g. the alert may be re-annunciated daily at 4:00 PM or on Saturdays at noon). The length of time between annunciations may depend on the severity of the fault. In some cases, the re-annunciation cannot be stopped by the user, but may only cease if the underlying condition is resolved.

[0346] The method may include detecting a condition of the ambulatory medical device. The condition of the ambulatory medical device may be determined by one or more sensors of the ambulatory medical device. Further, the condition of the ambulatory medical device may be determined by the presence or absence of one or more errors when performing one or more functions of the ambulatory medical device. For example, if the ambulatory medical device fails to establish a communication connection with a control system or a data storage system, it may be determined that there is a possible malfunction with the ambulatory medical device. As another example, if the ambulatory medical device fails to deliver medicament or detects an error when attempting to deliver medicament, there may be a malfunction with the medicament pump. In some cases, the condition of the ambulatory medical device may be determined based on one or more configuration values being outside a normal operating range. For example, if the speed of delivery of medicament is faster or slower than a configured operating range, then it may be determined that there is a malfunction with the medicament pump or a connection with a medicament delivery tube (e.g., a catheter).

[0347] The method may include comparing the detected condition of the ambulatory medical device to a set of normal operating parameters. The set of normal operating parameters may be the specifications set by the manufacturer for when the ambulatory medical device is operating as intended by the manufacturer. In some cases, the

normal operating parameters may be associated with a range of values. For example, the operating parameter for a speed of medicament delivery may be associated with a range of speeds, which may vary based on user settings, medicament type, site location of medicament delivery, or manufacturing tolerances, among other parameters. Comparing the detected condition of the ambulatory medical device to the set of normal operating parameters may include comparing each operating parameter in the specification to a corresponding detected operating parameter of the ambulatory medical device. The ambulatory medical device may generate a user alert based on the determined condition of the ambulatory medical device. For example, the AMD may generate an alert when the detected condition of the ambulatory medical device does not satisfy a set of normal operating parameters.

[0348] The method may further include determining whether the detected condition satisfies a minimum set of operating parameters. In some cases, the minimum set of operating parameters may match the normal operating parameters. However, typically the minimum set of operating parameters differ from the normal operating parameters. The minimum operating parameters may include the minimum specifications, minimum parameters, or minimum condition required by the ambulatory medical device to maintain or continue providing therapy to the subject. In other words, the minimum operating parameters are the operating parameters sufficient to provide therapy. However, the minimum operating parameters may not be sufficient to enable all features of the ambulatory medical device. For example, the minimum operating parameters may permit the ambulatory medical device to deliver insulin to the subject, but may not be sufficient to deliver the insulin at a normal delivery speed for the particular ambulatory medical device. As another example, the minimum operating parameters may permit the delivery of therapy, but may not be sufficient to track a log of therapy or to transmit a therapy log to another computing system. In some cases the normal operating parameters and/or minimum operating parameters may be specified by a subject or healthcare provider (e.g., the minimum amount of medicament that is to be provided in each bolus may be specified by a healthcare provider). In some cases, the normal or minimum operating parameters may be modified.

[0349] When it is determined that the condition of the ambulatory medical device satisfies at least the minimum operating parameters, the ambulatory medical device may be

configured to maintain delivery of therapy to the subject. Maintaining delivery of therapy may include maintaining therapy at the same rate, at a reduced rate (e.g., providing only basal therapy and therapy responsive to a meal announcement), or at a minimum maintenance rate (e.g., providing only basal insulin). Advantageously, the ability of the ambulatory medical device to distinguish between a minimum set of operating parameters and a normal set of operating parameters enables an ambulatory medical device with a malfunction to continue providing therapy, which sometimes includes life-saving treatment, to a subject until the ambulatory medical device can be repaired or until the condition of the device worsens to a point where the minimum operating parameters cannot be maintained. In some cases, the ambulatory medical device may temporarily maintain delivery of therapy. Temporarily maintaining therapy may provide a subject time to address the issue that caused the ambulatory medical device to not satisfy the normal operating parameters before the subject loses access to therapy. In some cases, the ambulatory medical device temporarily maintains therapy until the device condition makes it no longer possible to maintain therapy.

[0350] FIG. 34 is a block diagram illustrating the interconnection among modules and procedures in AMD involved in monitoring the condition of the AMD and generating an alert when a device malfunction is detected. In some examples, the condition of AMD may include the status of the modules and components of the AMD and/or operation of modules and procedures of the AMD. In some embodiments, the alert system may be implemented as a set of alert control procedures 3422 in the control and computing module 610 (CCM) of the AMD. The alert control procedures 3422, may be implemented as instructions stored in a memory of CCM (e.g., the main memory 616) and executed by a hardware processor 614 to generate an alert upon detection of a malfunction of the ambulatory medicament device. In some cases, the hardware processor may be a hardware processor of the ambulatory medicament device that controls medicament delivery. In other cases, the hardware processor of the monitoring system may be a separate hardware processor.

[0351] In some examples, the alert control procedures 3422 may include a monitoring interface 3426, an operation monitor procedure 3425 and alert generation procedure 3428. The monitoring interface 3426 may monitor and evaluate the condition of the AMD and/or the subject at least partially based on the information received from the operation monitoring procedure 3425 and device sensors 3424. In some examples, the device

sensors may be configured to track the status of the components or the modules of the ambulatory medicament device and the operation monitoring procedure 3425 may be configured to monitor the operation of the modules and other procedures. In some examples, the detected of the AMD may be provided to the alert generation procedure monitoring interface. The alert generation procedure 3428 may compare the detected condition of the AMD with a set of normal operating parameter. In some examples, the alert generation procedure may also determine whether the detected condition of the AMD satisfies a minimum set of operating parameters. In some examples, if it is determined that the detection condition of the AMD does not satisfy the normal operating parameters, the alert generation procedure may generate an alert. In some examples, the alert may be transmitted to the user interface module 3408 and displayed on a display of the AMD (e.g., a touchscreen display). In some other examples, once an alert is generated the AMD may establish a connection (e.g., a wireless connection) with another device. This other device may include a local device (e.g., a laptop, smartphone or smartwatch of the user) or a computing system of a cloud-based service. In some such examples, the alert may be transmitted by the communication module 3402 to the computing systems where it may be displayed on user interface associated with the computing system. In some cases, the additional device may receive data from the ambulatory medical device enabling it to monitor the condition of the ambulatory medical device.

[0352] The type of the alert, and the frequency at which the alert is repeated, or whether an alert is dismissible or not, may be determined by the alert generation procedure based on the detected condition of the AMD and the alert information stored in a memory of the AMD. In some examples, the alert information may be provided by the subject, an authorized user or a healthcare provider. In some other examples, the alert information may be stored in the AMD at time of manufacturing.

[0353] In some examples, upon determination that the detected AMD condition does not satisfy a set of normal operating parameters, the alert generation procedure may cause the medicament delivery interface 606 to stop therapy delivery or modify one or more delivery parameters (e.g., therapy delivery rate). In some examples, upon determination that the detected AMD condition does not satisfy a set of normal operating parameters, but

satisfies a set of minimum operating parameters, the therapy delivery may be maintained at a normal rate.

[0354] The alert may include any type of alert. For example, the alert may be a visual alert (e.g., a light or changing light), an audible alert (e.g., a beep or series of beeps), a haptic or vibration alert, an email alert, a text alert, or any other type of alert. Different device conditions may be associated with or may trigger different alerts. Thus, the user alert may enable the user to determine the device condition of the ambulatory medical device based on the alert. For example, an indication that the ambulatory medical device failed to deliver a medicament may trigger one type of alert while an indication that the ambulatory medical device has below a particular level of medicament available may trigger a different alert. In some cases, the user alert is dismissible and/or may be snoozed by the user. In other cases, such as when the ambulatory medical device fails to satisfy a set of minimum operating parameters, the user alert may not be dismissible or cannot be snoozed.

[0355] A dismissible alert may be scheduled to repeat on a particular schedule until an alert modification condition occurs. The frequency with which the dismissible alert repeats may depend on the severity of the condition or the particular operating parameters that do not satisfy normal or minimum operating parameters. More urgent device conditions may result in alerts that repeat more frequently. Further, alerts may vary based on when the condition was detected, the time of day, or the detected activity of a subject (e.g., sleep, abnormal activity, or elevated activity, such as exercise). Similarly, the snooze options may vary for different alerts or any of the aforementioned conditions. In some cases, the ambulatory medical device may escalate an alert if it detects that the condition of the ambulatory medical device has become more critical.

[0356] The alert frequency may be for a static time period (e.g., every 5 hours) or may ramp towards more frequency (e.g., every 5 hrs for 1 to 3 reminders, every 4 hours for 3 to 6 reminders, etc.), or may change based on time of day (e.g., snooze alerts during sleeping hours for non-urgent alerts), etc.

[0357] The alert modification condition may include any action that causes the operating parameters of the ambulatory medical device to return to normal operating parameters. For example, the alert modification condition may be a repair or replacement of a faulty component. In some cases, the alert modification condition may comprises an

acknowledgement of the alert. In other cases, the alert modification condition may include a worsening of the ambulatory medical device condition. In such cases, the modification to the alert may include the substitution of the alert to a different alert that indicates a different or more serious condition of the ambulatory medical device. For example, an urgent condition may become critical if the detected malfunction is addressed after generating certain number of alerts. When an urgent condition becomes critical, it may trigger a different alert type (e.g., a louder sound, or brighter image) and/or escalation in the alert frequency. For example, the audible alert may become louder and may be combined with a vibration alert from a haptic annunciator. Moreover, if the condition reaches a critical state, the ambulatory medical device may cease providing therapy to the subject.

[0358] In some cases, generating the alert may further include contacting a manufacturer and/or healthcare provider (e.g., clinician). Further, generating the alert may include ordering replacement parts. In some cases, the alert may instruct a subject or user on how to repair the ambulatory medical device.

[0359] Once the malfunction is addressed, the ambulatory medical device is repaired, or the condition that caused the alert is resolved, a user may permanently (or until the next time a device condition triggers the alert) dismiss the alert. Alternatively, or in addition, the ambulatory medical device may automatically dismiss the alert if it senses that the device condition that caused the alert has been resolved. In some cases, the ambulatory medical device may periodically recheck the device condition to determine whether the alert condition has been resolved.

[0360] In some cases, the manufacturer or healthcare provider may remotely clear or stop an alert using, for example, an NB-LTE connection. In some cases, only the manufacturer and/or healthcare provider can clear or stop the alert. Further, in some cases, a manufacturer and/or a healthcare provider may notify a user (e.g., a subject, or parent or guardian) of an issue or impending issue with the ambulatory medical device. The notification may be received by the ambulatory medical device via the NB—LTE connection. Alternatively, or in addition, the notification may be received via a computing device, such as a smartphone or laptop.

[0361] FIG. 35 is a flow diagram illustrating an example procedure that may be used by the alert system of an AMD to monitor the operation of an AMD and generate alerts

when a device malfunction is detected. In some examples, the alert system continuously monitors the status of all modules and components associated with AMD as well as the operation of all modules and procedures of the AMD. When a device condition is detected 3502, the alert system may determine whether the detected device condition satisfies a set of normal operating parameters 3504. If it is determined that the detected device condition satisfies a set of normal operating parameters, the alert system takes no action and continuous monitoring the AMD. If it is determined that the device condition does not satisfy a set of normal operating parameters, the alert system determines whether the detected device condition satisfies a set of minimum operating parameters. If, at block 3508, it is determined that the device condition does not satisfy a set of minimum operating parameters, the alert system may send a signal to the therapy delivery module to stop delivery of therapy to the subject 3509, and immediately generate a critical user alert 3511 indicating that immediate action is required. In some examples, upon generation of a critical alert the alarm system of the AMD, may contact a healthcare provider or certified user (e.g., parent or guardian of the subject) and also send the critical alert to one or more computing devices (e.g., laptop, cell phone, personal computer, and the like) of the healthcare provider or certified user. If, at block 3508, it is determined that the device condition satisfies a set of minimum operating parameters, the alert system may maintain the delivery of therapy to the subject 3510 and generate a user alert 3512. In some such examples, the alert system may maintain the delivery of the therapy at rate associated with the detected condition of the AMD (e.g., normal rate or minimum maintenance rate) until an alert modification condition is detected 3514. Upon detection of an alert modification condition 3514, the alert system may determine whether the new device condition satisfies a normal set parameters 3516. If, at block 3516, it is determined that the new device condition satisfies a set of normal operating parameters, the alert system may resume the normal operation of the AMD 3518 (e.g., deliver the therapy at a normal rate). If at block 3516, it is determined that the new device condition does not satisfy a set of normal operating parameters, the alert system may determine whether the new device condition satisfies a minimum set parameters 3520. If, at block 3520, it is determined that the new device condition satisfy a set of minimum operating parameters. The alert system may maintain or modify the rate of therapy delivery according to the new device condition 3522 and generate a user alert 3524 according to the according to

the new device condition. If, at block 3520, it is determined that the new device condition does not satisfy a set of minimum operating parameters, the alert system may send a signal to the therapy delivery module to stop delivery of therapy to the subject 3509, and immediately generate a critical user alert 3511 indicating that immediate action is required. In some examples, upon generation of a critical alert the alarm system of the AMD, may contact a healthcare provider or certified user (e.g., parent or guardian of the subject) and also send the critical alert to one or more computing devices (e.g., laptop, cell phone, personal computer, and the like) of the healthcare provider or certified user.

Managing Doses of Glucose Control Agents

[0362] Ambulatory medical devices allow subjects the freedom to treat themselves while being mobile. Self-managed medical treatment comes with inherent risks to the subject.

[0363] An automated blood glucose control system may automatically provide insulin and/or a counter-regulatory agent (e.g., Glucagon) to a subject to help control the blood glucose level of the subject. Generally, a control algorithm is implemented by an automated blood glucose control system (BGCS) to determine when to deliver one or more glucose control agents and how much agent to provide to the subject. Further, the control algorithm may control both an ongoing or periodic delivery of insulin (e.g., a basal dose), and a correction bolus that may be provided to adjust a subject's blood glucose level to within a desired range. The control algorithm may use blood glucose level readings obtained from a sensor, such as a continuous glucose monitoring (CGM) sensor, that obtained automated blood glucose measurements from the subject. Moreover, in some cases, the control algorithm may deliver a bolus of insulin in response to an indication of a meal to be consumed or being consumed by the subject.

[0364] Insulin may be administered subcutaneously into blood of a subject. There is often a delay between when the insulin is provided and when the amount of insulin in the subject's blood plasma reaches maximum concentration. This amount of time may vary based on the type of insulin and on the physiology of the particular subject. For example, with a fast-acting insulin, it may take approximately 65 minutes for a bolus of insulin to reach maximum concentration in the blood plasma of the subject. For some other types of

insulin, it may take anywhere from 3-5 hours to reach maximum concentration in the blood plasma of the subject. Accordingly, the blood glucose control system may implement a predictive algorithm that implements a bi-exponential pharmacokinetic (PK) model that models the accumulation of insulin doses in the blood plasma of the subject. The blood glucose control system may modify its predictions based on the type of insulin, one or more blood glucose readings, and/or characteristics of the subject.

[0365] In some cases, a subject may receive a manual bolus of insulin or medicament. For example, a user (e.g., healthcare provider, parent, or guardian) or subject may inject a dose of insulin into the subject. As another example, the user or subject may manually direct the automated blood glucose control system to provide a bolus of insulin to the subject.

[0366] It is generally undesirable to have too much insulin. An excess of insulin can lead to Hypoglycemia. As described above, it may take time for insulin to reach maximum concentration in the blood plasma of the subject. Thus, a blood glucose level reading from a sensor may not immediately, or even after a particular period of time, reflect the amount of insulin within a subject. Thus, a manual bolus of insulin may not be detected by the automated blood glucose control system. As a result, if the automated blood glucose control system is operating during delivery of a manual bolus, or is configured to operate on the subject prior to blood glucose level readings reflecting the effect of the manual bolus on the subject, the automated blood glucose control system may unnecessarily administer additional insulin to the subject potentially leading to hypoglycemia.

[0367] The present disclosure relates to an automated blood glucose control system configured to provide automatic delivery of glucose control therapy to a subject and receive information about manual glucose control therapy provided to the subject. Using the received information about the manual glucose therapy, the automated blood glucose control system can adjust the blood glucose control algorithm to account for the manual dosing of insulin (or counter-therapy agents). The manual glucose control therapy may be provided by injection therapy, or it may be provided by an insulin pump.

[0368] In some cases, the automated blood glucose control system may receive an indication of insulin or medicament to administer to a subject in place of an automatically calculated dose of insulin. For example, the automated blood glucose control system may

receive an indication that a subject is consuming or will consume a meal. The indication may include a type of meal to be consumed (e.g., breakfast, lunch, or dinner) and an estimate of the quantity of food or carbohydrates to be consumed (e.g., less than usual, a usual amount, more than usual, 30-40 grams of carbohydrates, 45-60 grams of carbohydrates, etc.). Based on the indication, or meal announcement, the automated blood glucose control system may calculate an amount of insulin to administer to the subject. The calculation may be based on an insulin to carbohydrate ratio provided by a clinician and/or determined by the automated blood glucose control system. Moreover, the calculation may be based at least in part on a history of blood glucose level measurements for the subject when consuming particular meals.

[0369] The calculated amount of insulin for the meal announced by the user may be presented to the user. The user (e.g., the subject) may modify the amount of insulin to administer. For example, the user may determine that for the size meal the subject is consuming or planning to consume, more or less insulin should be administered. In such cases, the user may modify the calculated insulin dosage to match the user's determination of the amount of insulin to administer. In some cases, the automated blood glucose control system may modify its control algorithm based on the user's input. Thus, future meal announcements may result in a calculation of insulin that satisfies the subject's insulin needs and/or preferences.

[0370] In some cases, the indication of an amount of a manual bolus may be received by a user entering a numerical value (e.g., an amount of insulin, a number of carbohydrates, or another calculation) associated with administering insulin. As described above, the automated blood glucose control system may automatically-calculate a meal dose of insulin and present it to a user via a user interface where a user may enter the manual bolus information. At the time of making the meal announcement, the user may have an option to enter the manual bolus. The meal controller of the blood glucose pump can provide a recommendation against the manual entry if there is a prior history of online operation or a basis for making the recommendation.

[0371] The information may be received from a user via a user interface. This user interface may be provided by the automated blood glucose control system. Alternatively, or in addition, the user interface may be generated by another device, such as a laptop or

desktop, a smartphone, a smartwatch, or any other computing device that can communicate via wired or wireless communication with the automated blood glucose control system. The information may include one or more of: an indication of delivery of a manual bolus (e.g., via injection therapy), an amount of the manual bolus, a type of the insulin (or other medicament), a time when the manual bolus was delivered, a general location that the manual bolus was administered to the subject (e.g., back, stomach, arm, leg, etc.), a reason for the manual bolus (e.g., a meal, a maintenance dose, a blood glucose level reading, in advance of exercise, etc.), and any other information that may be useable by the blood glucose control system in controlling the blood glucose level of the subject.

[0372] Advantageously, in certain embodiments, providing manual dosing information to the automated blood glucose control system can help the blood glucose control system maintain the blood glucose level of the subject within a desired range when the automated features of the blood glucose control system are active or operational. For example, if the automated blood glucose control system determines from a CGM sensor reading that a subject's blood glucose level is high, the automated blood glucose control system might normally administer a bolus of insulin. However, if the automated blood glucose control system receives an indication that a manual bolus of insulin was administered recently (e.g., within the past thirty minutes), the automated blood glucose control system may reduce or not administer a bolus of insulin, thereby preventing a Hypoglycemic event. In some such cases, the automated blood glucose control system may continue monitoring the blood glucose level of the subject and may administer additional insulin at a later time if the blood glucose level readings do not reflect an expected blood glucose level based on the reported manual bolus of insulin.

[0373] In some cases, it may be unnecessary to receive an indication of the manual bolus because, for example, a user may cause the automated blood glucose control system to provide the manual bolus. In such cases, the automated blood glucose control system may track the amount of insulin delivered and the timing of the administering of the bolus. To track the manual bolus, the automated blood glucose control system may store the information associated with the manual bolus in a therapy log. Accordingly, when the automated blood glucose control system is operating in an automatic mode, the automated

blood glucose control system can access the therapy log to determine whether any manual bolus were administered and, if so, the timing and amount of the manual bolus.

[0374] In some cases, the automated blood glucose control system may model the diminishing of insulin, or other medicament, in the blood plasma over time based on the information associated with the manual bolus. Modeling the diminishing of medicament over time may be used to estimate a future effect of the medicament previously administered. In some cases, the model may account for previously administered medicament by the automated blood glucose control system. Further, in some cases, the model may account for physiological characteristics of the subject, such as the subject's weight or an input parameter related to the subject's weight (e.g., body mass index). Moreover, the model may account for perfusion over time of the medicament bolus from a subcutaneous infusion site into the blood plasma of the subject. Further, the automated blood glucose control system may model an accumulation of insulin, model time course of activity of insulin, or model a finite rate of utilization of insulin.

[0375] Based on the model, the automated blood glucose control system may adjust the automated administering of insulin, or other medicament when operating in an automatic mode. Further, the automated blood glucose control system may operate the administering of medicament (e.g., by controlling a medicament pump) based on a glucose level of the subject and the modeled concentration of medicament in the subject.

[0376] In some cases, the automated blood glucose control system may confirm that the manual bolus was delivered to the subject. The confirmation may be determined based at least in part on whether blood glucose level readings by the CGM sensor match or are within a threshold level anticipated by the automated blood glucose control system based on the manual dosing information. Alternatively, or in addition, the automated blood glucose control system may request, via a user interface, that a user confirm that the manual bolus was delivered. In cases where the manual bolus is delivered by the automated blood glucose control system, a user may be requested to confirm the administering of the manual bolus by using a particular gesture or sequence of interactions with a user interface (e.g., a touchscreen) of the automated blood glucose control system or of a device (e.g., laptop or smartphone, etc.) that communicates with the automated blood glucose control system.

[0377] As previously described, in some cases, the information relating to the manual bolus may include an amount of insulin and a reason the manual bolus was administered (e.g., for a meal of a particular size). In some such cases, the automated blood glucose control system may determine an amount of insulin the automated blood glucose control system would administer in an automatic operating mode based on the manual dosing information if the manual bolus had not been supplied. If the automated blood glucose control system determines it would have supplied a different quantity of the medicament, and if the difference exceeds a threshold, the automated blood glucose control system may adjust a blood glucose control algorithm to account for the difference. For example, the automated blood glucose control system may change the operating setpoint or range of insulin the automated blood glucose control system attempts to maintain in the subject. As another example, the automated blood glucose control system may supplement the manual bolus with additional insulin to account for an under-administering of insulin, or may reduce a subsequent dosage of insulin to account for an over-administering of insulin.

[0378] As previously indicated, the automated blood glucose control system may maintain a therapy log of manual insulin therapy. This therapy log may be maintained based on the use of the automated blood glucose control system to provide a manual bolus, or based on information provided by the user based on manual administering of insulin (e.g., via injection). The manual boluses may be supplied when the automated blood glucose control system is not operating, is not operating in an automatic mode, or is not connected to the subject. Once the automated blood glucose control system is connected to the subject and is configured in automatic mode, the automated blood glucose control system may determine therapy, if any, to provide to the subject based on a combination of the therapy log and the glucose control algorithm implemented by the automated blood glucose control system.

[0379] The automated blood glucose control system may generate a dose control signal based on the determined therapy. This dose control signal may be supplied to a medicament pump, which may control delivery of the medicament (e.g., insulin) to the subject.

[0380] In some cases, a user may control whether the automated blood glucose control system is operating in a manual mode or an automatic mode by interacting with a user interface of the automated blood glucose control system or of a device that communicate

with the automated blood glucose control system. The user interaction may include any type of user interaction with a user interface. For example, the user interaction may include interaction with physical buttons or interactions with a touchscreen including gestures or taps on the touchscreen.

[0381] Additional embodiments relating to managing meal medicament doses and manual dosing that can be combined with one or more embodiments of the present disclosure are described in U.S. Provisional Application No. 62/911,143, which was filed on October 4, 2019 and is titled "SYSTEM AND METHOD OF MANAGING MEAL DOSES IN AN AMBULATORY MEDICAL DEVICE," the disclosure of which is hereby incorporated by reference in its entirety herein for all purposes.

[0382] A system of one or more computers can be configured to perform particular operations or actions by virtue of having software, firmware, hardware, or a combination of them installed on the system that in operation causes or cause the system to perform the actions. One or more computer programs can be configured to perform particular operations or actions by virtue of including instructions that, when executed by data processing apparatus, cause the apparatus to perform the actions. One general aspect includes a method including: providing an option to a user to select between receiving medicament using a manual delivery component or an automated delivery system. The method also includes receiving, by the automated delivery system, subjective information regarding the activity or action that may alter the blood-glucose level. The method also includes receiving, by the manual delivery component, an amount of the medicament to be infused. The method also includes storing a time and the amount of medicament that is infused into the automated delivery system that controls blood glucose level. Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

[0383] Implementations may include one or more of the following features. The method where the automated delivery system modifies medicament delivery based on the time and the amount of medicament that was received from either the manual delivery component or the automated delivery system. The method where the manual delivery component includes a keypad which allows the user to type in the dosage amount of the desired medicament. The method where providing the option to select is provided prior to a

user performing the activity that may alter the blood-glucose level. The method where the activity that may alter the blood-glucose level includes of consuming food or exercising. The method where the subjective information regarding the activity of consuming food includes the approximate relative size of the food that is to be digested. The method where the approximate relative size of the food is compared to the recommended meal doses for the user, and depending on whether the approximate relative size is the same, larger, or smaller than the recommended doses, the model predictive control component is able to determine the actions that is required to regulate the glucose level of the blood. The method where the subjective information regarding the activity of exercising includes the intensity and the duration of the exercise. The method where the intensity and the duration of the exercise is compared to the recommended intensity and duration, and depending on whether it is the same, larger, or smaller than the recommended intensity and duration, the automated delivery system is able to determine the actions that is required to regulate the glucose level of the blood. Implementations of the described techniques may include hardware, a method or process, or computer software on a computer-accessible medium.

[0384] One general aspect includes a system having a medical device configured to provide an option to a user to select between receiving medicament using a manual delivery component or an automated delivery system. The system also includes automated delivery system configured to receive subjective information regarding the activity that may alter the blood-glucose level. The system also includes a manual delivery component configured to receive an amount of the medicament to be infused. The system also includes where the medical device storing a time and the amount of medicament that is infused into an automated delivery system that controls blood glucose levels. Other embodiments of this aspect include corresponding computer systems, apparatus, and computer programs recorded on one or more computer storage devices, each configured to perform the actions of the methods.

[0385] Upon utilizing an ambulatory medical device to request for a therapy change, users may have different preferences. Therefore, it is desirable for modern technology, specially the ambulatory medical devices to be equipped with optionality features. These optionality features may fulfill the different preferences of the users and subjects. The optionality features may allow users to control the therapy changes more

closely and may allow them to be more engaged with the medical assistance of the ambulatory medical device.

[0386] In order to fulfill the variety of preferences, an ambulatory medical device needs to provide options which allows the user to either manually request the amount of the desired medicament or chose an automated delivery system that automatically delivers the right amount of the medicament at the right time without further assistance. For the manual component, the user may personally input the desired amount on a keypad that is provided by the medical device. The medical device further confirms and delivers the requested medicament. After the medicament is infused through a manual delivery component, the data is stored into a model predicative control component which is further used to control and regulate the blood glucose level. However, if the user decides to use the automated delivery system, the user must provide subjective information regarding the activity or the action that may alter the blood-glucose level. For example, if the blood-glucose level changing activity is consuming food, the user must provide the time and the dosage amount of the food that is going to be digested. This information is tied to the automated delivery system, and the subjective information is further stored into a model predicative control component.

[0387] Embodiments described herein include an ambulatory medical device that has a keypad which allows a user to type in a dose of insulin or glucagon to be administered to a user. A user may wish to receive a single dose of insulin prior to consuming food and decide how much insulin need to be administered. In other embodiments, the user may choose to receive a burst of glucagon due to low blood sugar because of physical activities. Embodiments may include the options for manual inputs of medicament and automated delivery system of medicament. In various implementations, the automated delivery system of medicament is driven by the blood glucose level or related trends. Embodiments herein address a problem that may arise when the user has just received a manual dose and has switched on the automated delivery system. In such cases, the automated delivery system may be made aware of all manual medicament infusion amounts and the timing of such infusions. Accordingly, the manual delivery component may inform the automated delivery system upon delivering any medicament the type of medicament delivered, the amount of medicament and the timing of the medicament delivered. By having the above information, the automated delivery system may determine the amount of medicament that is the user's

blood stream and adjust the automated delivery of medicament and the timing of the automated delivery. Accordingly, embodiments are directed to allows for a risk free transition from the manual delivery component and the automated delivery system.

[0388] Differences from other system may include that the manual delivery may be tied to an automated delivery system, the dose input from the user is then stored into the MPC algorithm (Model Predictive Control) instead of the meal delivery algorithm and is handled by the MPC algorithm. Other embodiments may include selection being able to have a relativistic algorithmically tuned value. Other embodiments may include a learning algorithm that includes a usual size meal or larger size meal or small size meal. Embodiments may include correlating the manual inputs to asking the user what was the size of the meal and learning how the insulin affects the user. Embodiments may include correlating the manual inputs to asking the user what activity the user performed and learning how the glucagon affects the user for a particular activity.

BGCS with Manual Dose Management

[0389] FIG. 36 illustrates a schematic of the therapy change delivery system 3600 in an ambulatory medical device 3602 that allows the user the choice of receiving manual delivery of medicament or automated delivery of medicament. Moreover, the therapy change delivery system 3600 allow the user to transition between the manual mode and the automated mode with ease. The therapy change delivery system 3600 includes the ambulatory medical device 3602, a signal processing component 3603, a user 3604, a therapy delivery component 3605, a therapy change input 3606, input components 3607, activity change component 3608, and a therapy change delivery 3610. When the user intends to receive a therapy from an ambulatory medical device 3602, the user 3604 may initiate a therapy change input 3606 to request the manual or automated medicament.

[0390] The ambulatory medical device 3602 is any medical device that a user 3604 may carry around and use with the approval of a medical professional. There are many different types of ambulatory medical devices 3602. In one embodiment, the ambulatory medical device 3602 is an insulin and/or glucagon infusion device for user 3604 that have type I diabetes. Ambulatory medical devices 3602 allow users 3604 the freedom to receive medical care in any setting at their convenience. However, the drawback of using an

ambulatory medical device 3602 could be the user 3604 making mistakes when the user is away from the medical professionals. One possible issue may be caused the user 3604 switches from a manual delivery mode to an automated delivery mode when the automated delivery mode is unable to determine the amount of medicament in the user's blood stream. Embodiments are directed to the manual medicament delivery information being provided to the automated medicament delivery system so that it can adjust its operations based on the current and future medicament in the user's blood stream. In some cases, such as the embodiment where the ambulatory medical device 3602 is an insulin and/or glucagon infusion device, doing automated delivery of medicament can be problematic.

[0391] The ambulatory medical device 3602 includes a signal processing component 3603, a therapy delivery component 3605, and input components 3607. The signal processing component 3603, therapy delivery component 3605, and input components 3607 may be physically connected, wirelessly connected, connected via a cloud-based computer system, or connected in any other way.

[0392] The signal processing component 3603 is a computing system that performs the computing functions for the ambulatory medical device 3602. The signal processing component 3603 includes a processor, memory, and storage. The signal processing component 3603 may be a single computing system or may be made up of several computing systems. The signal processing component 3603 may perform the computing functions for a single ambulatory medical device 3602 or many ambulatory medical device 3602. The signal processing component 3603 receives signals from the therapy delivery component 3605 and from the input components 3607. The signal processing component 3603 also transmits signals to the therapy delivery component 3605 and the input components 3607. Signals of the therapy change input 3606, the therapy change delivery 3610, and all steps of the 3608 may be received or transmitted by the signal processing component 3603.

[0393] The user 3604 is any individual that uses the ambulatory medical device 3602. In one embodiment the user 3604 is an individual with diabetes that requires a periodic infusion of insulin or glucagon to maintain healthy blood sugar levels. In various embodiments, the ambulatory medical device 3602 infuses insulin or glucagon into the user 3604. The user 3604 may transport the ambulatory medical device 3602. Thus, as the user

3604 moves around, there is a danger that the user 3604 will inadvertently activate input in the ambulatory medical device 3602 that initiates a therapy change input 3606.

[0394] The therapy delivery component 3605 provides medicaments to the user 3604. Signals received from the signal processing component 3603 are executed by the therapy delivery component 3605 to change therapy such as starting, modifying, or stopping a therapy. The therapy delivery component 3605 may have a computing component for interpreting and executing instructions from the signal processing component 3603. Thus, the therapy delivery component 3605 can follow a program that is controlled by the signal processing component 3603. In one embodiment, the therapy delivery component 3605 is one or more infusion pumps. An infusion pump is capable of delivering fluids at varying rates to a user 3604. The infusion pump may deliver any fluid, including medicaments. The infusion pump may be connected to a user 3604 through any means. In one example, the infusion pump is connected to the body through a cannula. In an exemplary embodiment, the therapy delivery component 3605 is an insulin infusion pump. Also, in an exemplary embodiment, the therapy delivery component 3605 is an insulin and glucagon infusion pump. Signals received from the signal processing component 3603 may be interpreted by an insulin and glucagon pump to start, stop, or change the rate of insulin and glucagon being delivered into a user 3604.

[0395] In an exemplary embodiment, the therapy delivery component 3605 is an electrical stimulation device. An example of an electrical stimulation device is a cardiac pacemaker. A cardiac pacemaker stimulates the cardiac muscle to control heart rhythms. Instructions received from the signal processing component 3603 may be interpreted by a cardiac pacemaker to start stimulating a cardiac muscle, stop stimulating a cardiac muscle, or change the rate of stimulation of a cardiac muscle. Another example of an electrical stimulation device is a deep brain stimulator to treat Parkinson's disease or movement disorders. Instructions received from the signal processing component 3603 may be interpreted by the deep brain stimulator to start, stop, or modify the stimulation of the brain.

[0396] The therapy change input 3606 is an input provided by the user 3604 to change a therapy that is currently being delivered to the user 3604. The change of therapy may be to start a therapy, modify a therapy, or cancel a therapy. There are many types of possible therapy changes, and the types of therapy changes are dependent on the type of

ambulatory medical device 3602. In one embodiment, the ambulatory medical device 3602 is an insulin or glucagon infusion device. However, there are many possible embodiments of ambulatory medical devices 3602 for the disclosed subject matter. The therapy change input 3606 in an insulin or glucagon infusion device may be an instruction, that when executed, causes the insulin or glucagon infusion device to start infusing an amount of insulin or glucagon into the user 3604. Alternatively, the therapy change input 3606 may be an instruction to modify the rate of insulin or glucagon infusion into the user 3604. The therapy change input 3606 may also be an instruction to cancel insulin or glucagon infusion into the user 3604 from the insulin or glucagon infusion device. In an exemplary embodiment, the ambulatory medical device 3602 is an electrical implant, that when operated, stimulates a part of the body. An example is an electrical brain implant for users 3604 with Parkinson's disease or for pain management. The implementation of the therapy change can be to modify the rate of electrical stimulation to the body.

[0397] The therapy change delivery 3610 is the performance, by the ambulatory medical device 3602, of the therapy change input 3606 that was verified by the 3608. The therapy change that is delivered by the therapy change delivery 3610 corresponds to the therapy change selection made by the user 3604. In one embodiment, the ambulatory medical device 3602 alerts the user 3604 that it is performing a therapy change delivery 3610. In an example of various embodiments, the ambulatory medical device 3602 displays the therapy change during the therapy change delivery 3610. Any number of details of the therapy change may be displayed during the therapy change delivery 3610. As shown in FIG. 43B, a simple message of "Delivering" may be displayed during the therapy change delivery 3610. Alternatively, more exact details, such as "Delivering 2 units of insulin" or "Delivering insulin at 2 units per minute" may be displayed. In another example, the ambulatory medical device 3602 plays a sound effect during the therapy change delivery 3610. In an exemplary embodiment that is shown in FIG. 43B, the therapy change delivery 3610 may be canceled by an input by the user 3604. The input to cancel a therapy change delivery 3610 may be any input such as a wake signal input or a series of touch inputs such as a gesture.

[0398] The input components 3607 allow the user 3604 to interact with and control the ambulatory medical device 3602. The amount of control that a user 3604 has may vary based on the type of ambulatory medical device 3602 and the user 3604. For example,

an ambulatory medical device 3602 that delivers pain medication may allow the user more control than an ambulatory medical device 3602 that controls heart rhythms. In another example, a user 3604 that is a young child (less than about 10, 11 or 12 years) may be allowed less control over an ambulatory medical device 3602 than a user 3604 that is a teen or an adult. The input components 3607 include a wake button 3620, a touchscreen display 3622, and an alphanumeric pad 3624.

[0399] The wake button 3620 is activated by a user 3604 to create a wake signal input to unlock an ambulatory medical device 3602. The wake button 3620 may be any input button. In one embodiment, the wake button 3620 is a capacitive button that detects a change in capacitance. The wake button 3620 may have a computing component for interpreting and executing instructions from the signal processing component 3603. Thus, the wake button 3620 can follow a program that is dictated by the signal processing component 3603.

[0400] The touchscreen display 3622 may display a therapy change user interface for the user 3604 and receive user 3604 inputs on the touchscreen display 3622 input surface. Inputs on the touchscreen display 3622 may be registered by any touch technology including, but not limited to capacitive and resistive sensing. The touchscreen display 3622 may be a part of a mobile computing device, such as a cellular phone, tablet, laptop, computer or the like. The touchscreen display 3622 may have a computing component for interpreting and executing instructions from the signal processing component 3603. Thus, the touchscreen display 3622 can follow instructions that are directed by the signal processing component 3603. To receive input, the touchscreen display 3622 may display buttons, alphanumeric characters, symbols, graphical images, animations, or videos. The touchscreen display 3622 may display an image to indicate when the ambulatory medical device 3602 is locked or inaccessible via the touchscreen display 3622. The touchscreen display may receive the series of inputs that make up the first gesture and the second gesture.

[0401] The alphanumeric pad 3624 registers numerical inputs, alphabetical inputs, and symbol inputs. The alphanumeric pad 3624 includes a multitude of keys corresponding to numerical, alphabetical, and symbol inputs. The alphanumeric pad 3624 may have a computing component for interpreting and executing instructions from the signal processing component 3603. Thus, the alphanumeric pad 3624 can follow instructions that are dictated by the signal processing component 3603. The alphanumeric pad 3624 may be

configured to provide haptic feedback from its keys. The alphanumeric pad or pads 3624 may have any number of keys and any number of characters and may span multiple screens that the user 3604 can toggle between in order to find all of their sought-after characters. In one embodiment, the wake button 3620 is incorporated into the alphanumeric pad 3624. In various embodiments, the wake button 3620 may be any one or more keys of the alphanumeric pad 3624. In an exemplary embodiment, the alphanumeric pad 3624 is displayed as part of the touchscreen display 3622. Characters from the alphanumeric pad 3624 may be used as input for the wake signal input, first gesture, therapy change selection, and second gesture. In an exemplary embodiment, the first gesture and/or second gesture are created by entering predetermined characters on the alphanumeric pad 3624.

[0402] The activity change component 3608 may be part of a specialized software that is executed on an ambulatory medical device or include a specialized hardware that performs the various functions described here. The activity change component 3608 may receive inputs from the user regarding whether the user is about to conduct activities that will change the blood glucose of the user. For example, the user may provide input using the input components 3607 that the user is about to perform exercise that may lower their blood sugar or eat a meal that will increase their blood sugar. Upon receiving the activity change from the input components 3607, the activity change component 3608 offers the user the option via the mode controller 3613 to select between the automated delivery system 3612 or the manual delivery component 3614. As shown in FIG. 36, the manual delivery system may inform the automated delivery system 3612 and the model predictive control component 3616 regarding any manual medicament deliveries of insulin or glucagon.

[0403] In various embodiments, the user may choose the dosage amount, the drug type (insulin or glucagon; fast or slow acting) and the time of the delivery and the manual delivery component 3614 may receive such information and deliver the medicament(s) accordingly. In one embodiment, the manual delivery component 3614 may inform the automated delivery system 3612 and the model predictive control component 3616 regarding the drug type (insulin or glucagon; fast or slow acting) and the time of the delivery.

[0404] When the user activates the automated delivery system 3612, the data from previous manual medicament infusions can be readily available so that the automated delivery system 3612 may be able to determine how much medicament is still in the user's

blood stream. The automated delivery system 3612 may make that determination by tracking the finite rate of utilization of infused insulin by the subject based on the time and amount of any manual medicament infusions reported to the automated delivery system 3612.

[0405] FIG. 37 is a flow chart of a process 3700 detailing a medicament selection process, according to an exemplary embodiment. In step 3710, the medical device provides an option to a user to select between receiving medicament using a manual delivery component or an automated delivery system. By using the mode controller 113, the user can select the method for the therapy change request between manual delivery component and the automated delivery system.

[0406] In step 3720, the medical device may receive subjective information regarding the activity or action that may alter the blood-glucose level. Subjective information may include the size of the meal and/or the type of physical activity. In step 3730, the manual delivery component may receive an amount of the medicament to be infused. The medicament may be a plurality of hormones, including but not limited to, glucagon or insulin. At step 3740, the medical device may store a time and the amount of medicament that was infused into the automated delivery component that controls the blood glucose level. The systems that are disclosed in FIG. 36 will be utilized to accomplish each and every step from steps 3710, 3720, 3730 and 3740.

[0407] FIG. 38 is another flow diagram of a process 3800 for providing options for meal dosage selection or physical activity of the user on an ambulatory device. Embodiments described herein include an ambulatory medical device that has a keypad which allows a user to type in a dose of insulin or glucagon to be administered to a user. A user may wish to receive a single dose of insulin prior to consuming food and decide how much insulin need to be administered. In other embodiments, the user may choose to receive a burst of glucagon due to low blood sugar because of physical activities. Embodiments may include the options for manual inputs of medicament and automated delivery system of medicament. In various implementations, the automated delivery system of medicament is driven by the blood glucose level or related trends. Embodiments herein address a problem that may arise when the user has just received a manual dose and has switched on the automated delivery system. In such cases, the automated delivery system may be made aware of all manual medicament infusion amounts and the timing of such infusions. Accordingly,

the manual delivery component may inform the automated delivery system upon delivering any medicament the type of medicament delivered, the amount of medicament and the timing of the medicament delivered. By having the above information, the automated delivery system may determine the amount of medicament that is the user's blood stream and adjust the automated delivery of medicament and the timing of the automated delivery. Accordingly, embodiments are directed to allows for a risk free transition from the manual delivery component and the automated delivery system.

[0408] At block 3810, the user may inform the activity change component 108 that the user is about to engage in activities that may alter the blood-glucose level of the user. The mode controller 108 may be activated at decision block 3820 and ask whether the user wants to use the manual delivery component 3830 or the automated system 3850. If the user chooses to use the manual delivery component 3830 and the user provides an input to infuse medicament, the ambulatory device 3602 may delivery the medicament to the user. Upon the manual delivery process completion, the manual delivery component 3830 may inform at least one of the model predictive control component 3840 and the automated delivery system 3850 regarding the type of medicament, amount of medicament and the time when the medicament was delivery. The predictive control component 3840 and automated delivery system 3850 may track these manual infusions of medicament and determine that based on the rate of decay or the half-life of the medicament the total amount of medicament that remains in the user's blood stream at a particular time or a period of time. Accordingly, when the automated delivery system 3850 is activated by the user, the automated delivery system 3850 may change its medicament infusion based on the medicament that remains in the user's blood stream after a manual infusion by the user.

[0409] Differences from other system may include that the manual delivery may be tied to an automated delivery system, the dose input from the user is then stored into the MPC algorithm (Model Predictive Control) instead of the meal delivery algorithm and is handled by the MPC algorithm. Other embodiments may include selection being able to have a relativistic algorithmically tuned value. Other embodiments may include a learning algorithm that includes a usual size meal or larger size meal or small size mean. Embodiments may include correlating the manual inputs to asking the user what was the size of the meal and learning how the insulin affects the user. Embodiments may include

corelating the manual inputs to asking the user what activity the user performed and learning how the glucagon affects the user for a particular activity.

[0410] FIG. 39 illustrates a plurality of screens 3900 that may be produced by the ambulatory medical device 102. The plurality of screens 3900 demonstrates a process that a user may take in order to enter meal doses. When the mode controller 3608 is activated, the enter meal doses screen 3910 may be displayed. Once the screen 3910 is displayed, a warning text may be displayed for the user to ensure safety. The warning text states that entering a dose may be unsafe and the device will not adapt its meal doses. This warning text cautions the user of the risks that may be involved in the process of using the ambulatory medical device 3602. After a user acknowledges the warning sign and choses to proceed, a password screen 3920 may be displayed. Once the password screen 3920 is displayed, a keypad is provided for the user to enter a predetermined sequence of numbers to ensure that the user is the actual registered user of the ambulatory medical device 3602. When the ambulatory medical device 3602 receives the correct predetermined password from the user, the enter meal doses official screen 3930 and meal doses official screen 3940 may be displayed. The user may decide to access the advanced screen 3960, and upon doing so, the advanced screen 3960 will allow the user to double check the CGM Insulin levels and change the speed of the of the insulin pump. In screen 3930 and screen 3940, the user is provided the option to have the meal keypad on or off. If the user selects to have the keypad on, then an option may be provided for the user to choose the max dose limit. If the user decides to choose the max dose limit, the official max dose limit screen 3950 is displayed, where the user may enter up to 10 units of the dose. The provided number of units is then stored in the model predictive control component 116 for further regulation of the blood glucose level.

[0411] FIG. 40 illustrates a plurality of screens 4000 that may be produced by the ambulatory medical device 3602. Upon activating the ambulatory medical device 102, the initial menu screen 4010 may be displayed. In the menu screen 4010, options regarding functionalities of the ambulatory medical device 3602 is provided. The list of functionalities may cover all the aspects of the ambulatory medical device 3602. The user may access and control many aspects of the device by choosing the setting option. The setting option will allow the user to further assess and regulate the adjustable functionalities of the ambulatory medical device 3602. Upon selecting the setting option, the setting screen 4020 may be

displayed and the user may select the advanced setting option. Upon selecting the advanced option, the advanced setting screen 4030 is displayed, and the user is provided the option to double check the CGM insulin levels and change the speed of the of the insulin pump. The user may speed up the process or slow down the process depending on the regulation stats that are provided by the model predictive control component 3616.

[0412] FIG. 41 illustrates a plurality of screens 4100 that may be produced by the ambulatory medical device 3602. The plurality of screens 4100 is the process that a user may take in order to enter meal announcements. The home screen 610 provides information and stats regarding the cartridge of the ambulatory medical device 3602. The user may select the meal button with or without an installation of a new cartridge. If a user selects the meal button without installing a new cartridge, the ambulatory device 3602 will display the warning screen 4130, where the user is warned that the insulin cartridge is empty, and the device further advises the user to change the cartridge. However, if a new cartridge is already installed and the food button is pressed, the ambulatory medical device 3602 will display the carbs screen 4120, where the user is provided the option to choose a meal dose option. The carbs screen 4120 allows the user to provide subjective information regarding the food that is to be digested. This subjective data provided by the user is further stored in the model predictive control component 3616 for further regulation of the blood glucose level.

[0413] FIG. 42 illustrates a plurality of screens 4200 that may be produced by the ambulatory medical device 3602. The plurality of screens 4200 demonstrates the process of the user being alerted about the empty cartridge and having the option to replace the cartridge and further enter the meal doses. Warning screen 4210 alerts the user that the insulin cartridge is empty and the fact that it needs to be replaced. Upon replacing the cartridge, screens 4220 and 4230 will be displayed. Screen 4220 is initially displayed, and a user may enter a specified dose for each meal on a numerical pad. Upon inserting a numerical specified dose, screen 4230 is displayed where a next button is provided for the user to further complete the therapy change. The numerical specified dose is further stored in the model predictive control component 3616 for further regulation of the blood glucose level.

[0414] FIG. 43 illustrates a plurality of screens 4300 that may be produced by the ambulatory medical device 3602. Upon selecting the delivery request, a user may cancel the delivery of the medicaments prior to the completion of the delivery. The ambulatory medical

device 3602 displays a countdown prior to delivery. The initial countdown screen 4310 is proceeded by the secondary countdown screen 4330. During these countdown screens, a cancel button is provided for the user to cancel the therapy change. During the initial countdown screen 4310 or the secondary countdown screen 4330, the user may cancel the delivery at any time. By swiping the cancel button, the user may officially stop the delivery of the therapy change. If the user does not cancel, the therapy change may be delivered successfully. Furthermore, the time and the amount of the therapy change delivery is stored in the model predictive control component 3616 for further regulation of the blood glucose level. However, if the user decides to cancel the delivery, the delivery will be canceled and the screen 4320 will be provided. Once the delivery cancelation is requested and the screen 4320 is displayed, upon pressing the ok button, the ambulatory medical device 3602 will display a lock screen 4340 and take the time to officially cancel the therapy change request.

[0415] FIG. 44 is a block diagram illustrating a computer system 4400 that may be implemented in the various embodiments in the described subject matter. The computer system 4400 includes a processor 4402, main memory 4404, storage 4406, a bus 4408, and input 4410. The processor 4402 may be one or more processors. The processor 4402 executes instructions that are communicated to the processor through the main memory 4404. The main memory 4404 feeds instructions to the processor 4402. The main memory 4404 is also connected to the bus 4408. The main memory 4404 may communicate with the other components of the computer system through the bus 4408. Instructions for the computer system 4400 are transmitted to the main memory 4404 through the bus 4408. Those instructions may be executed by the processor 4402. Executed instructions may be passed back to the main memory 4404 to be disseminated to other components of the computer system 4400. The storage 4406 may hold large amounts of data and retain that data while the computer system 4400 is unpowered. The storage 4406 is connected to the bus 4408 and can communicate data that the storage holds to the main memory 4404 through the bus 4408.

[0416] The processor 4402 may be any type of general purpose processor including, but not limited to a central processing unit ("CPU"), a graphics processing unit ("GPU"), a complex programmable logic device ("CPLD"), a field programmable gate array ("FPGA"), or an application-specific integrated circuit ("ASIC"). One embodiment of the computer system 4400 in the ambulatory medical device 102 features a CPU as the processor

4402. However, embodiments may be envisioned for the computer system of the ambulatory medical device 102 that incorporate other types of processors 4402.

[0417] The main memory 4404 can be any type of main memory that can communicate instructions to the processor 4402 and receive executed instructions from the processor 4402. Types of main memory 4404 include but are not limited to random access memory ("RAM") and read only memory ("ROM"). In one embodiment, the computer system 4400 incorporates RAM as the form of main memory 4404 to communicate instructions to the processor 4402 and receive executed instructions from the processor 4402. Other embodiments may be envisioned that incorporate other types of main memory 4404 in the computer system 4400.

[0418] The storage 4406 can be any type of computer storage that can receive data, store data, and transmit data to the main memory 4404 via the bus 4408. Types of storage 4406 that can be used in the computer system 4400 include, but are not limited to, magnetic disk memory, optical disk memory, and flash memory. In one embodiment, flash memory is used as the storage 4406 in the computer system 4400 of the ambulatory medical device 102. Other embodiments that use other types of storage 4406 for the computer system 4400 may be envisioned.

[0419] The bus 4408 connects the internal components of the computer system 4400. The bus 4408 may include a multitude of wires that are connected to the components of the computer system 4400. The wires of the bus 4408 may differ based on the components of the computer system 4400 to which the bus 4408 connects. In various embodiments, the bus 4408 connects the processor 4402 to the main memory 4404. In various embodiments, the processor 4402 is directly connected to the main memory 4404.

[0420] The input 4410 of the computer system 4400 includes a touchscreen display 4412, an alphanumeric pad 4414, and buttons 4416. The touchscreen display 4412 both produces output and accepts input. The bus 4408 may be coupled to the touchscreen display 4412 to produce visual output. The touchscreen display 4412 may also accept input via capacitive touch, resistive touch, or other touch technology. The input surface of the touchscreen display 4412 can register the position of touches on the surface. Some types of touchscreen display 4412 can register multiple touches at once. The alphanumeric pad 4414 includes a multitude of keys with numerical, alphabetical, and symbol characters. Signals

from the alphanumeric pad 4414 are communicated by the bus 4408 to the main memory 4404. Keys of the alphanumeric pad 4414 may be capacitive or mechanical. In some embodiments, the alphanumeric pad 4414 is displayed on the touchscreen display 4412. Buttons 4416, such as the wake button 120, may be capacitive, mechanical, or other types of input buttons.

Terminology

[0421] It is to be understood that not necessarily all objects or advantages may be achieved in accordance with any particular embodiment described herein. Thus, for example, those skilled in the art will recognize that certain embodiments may be configured to operate in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

[0422] All of the processes described herein may be embodied in, and fully automated via, software code modules executed by a computing system that includes one or more computers or processors. The code modules may be stored in any type of non-transitory computer-readable medium or other computer storage device. Some or all the methods may be embodied in specialized computer hardware. Further, the computing system may include, be implemented as part of, or communicate with an automated blood glucose system, an ambulatory medicament system, or an ambulatory medical device.

[0423] Many other variations than those described herein will be apparent from this disclosure. For example, depending on the embodiment, certain acts, events, or functions of any of the algorithms described herein can be performed in a different sequence, can be added, merged, or left out altogether (for example, not all described acts or events are necessary for the practice of the algorithms). Moreover, in certain embodiments, acts or events can be performed concurrently, for example, through multi-threaded processing, interrupt processing, or multiple processors or processor cores or on other parallel architectures, rather than sequentially. In addition, different tasks or processes can be performed by different machines and/or computing systems that can function together.

[0424] The various illustrative logical blocks and modules described in connection with the embodiments disclosed herein can be implemented or performed by a machine, such as a processing unit or processor, a digital signal processor (DSP), an

application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A processor can be a microprocessor, but in the alternative, the processor can be a controller, microcontroller, or state machine, combinations of the same, or the like. A processor can include electrical circuitry configured to process computer-executable instructions. In another embodiment, a processor includes an FPGA or other programmable device that performs logic operations without processing computer-executable instructions. A processor can also be implemented as a combination of computing devices, for example, a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. Although described herein primarily with respect to digital technology, a processor may also include primarily analog components. A computing environment can include any type of computer system, including, but not limited to, a computer system based on a microprocessor, a mainframe computer, a digital signal processor, a portable computing device, a device controller, or a computational engine within an appliance, to name a few.

[0425] Conditional language such as, among others, “can,” “could,” “might” or “may,” unless specifically stated otherwise, are otherwise understood within the context as used in general to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without user input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment.

[0426] Disjunctive language such as the phrase “at least one of X, Y, or Z,” unless specifically stated otherwise, is otherwise understood with the context as used in general to present that an item, term, etc., may be either X, Y, or Z, or any combination thereof (for example, X, Y, and/or Z). Thus, such disjunctive language is not generally intended to, and should not, imply that certain embodiments require at least one of X, at least one of Y, or at least one of Z to each be present.

[0427] Any process descriptions, elements or blocks in the flow diagrams described herein and/or depicted in the attached figures should be understood as potentially representing modules, segments, or portions of code which include one or more executable instructions for implementing specific logical functions or elements in the process. Alternate implementations are included within the scope of the embodiments described herein in which elements or functions may be deleted, executed out of order from that shown, or discussed, including substantially concurrently or in reverse order, depending on the functionality involved as would be understood by those skilled in the art.

[0428] Unless otherwise explicitly stated, articles such as “a” or “an” should generally be interpreted to include one or more described items. Accordingly, phrases such as “a device configured to” are intended to include one or more recited devices. Such one or more recited devices can also be collectively configured to carry out the stated recitations. For example, “a processor configured to carry out recitations A, B and C” can include a first processor configured to carry out recitation A working in conjunction with a second processor configured to carry out recitations B and C.

[0429] Many variations and modifications may be made to the above-described embodiments, the elements of which are to be understood as being among other acceptable examples. All such modifications and variations are intended to be included herein within the scope of this disclosure.

WHAT IS CLAIMED IS:

1. A computer-implemented method of updating an application executing on an ambulatory medical device without interrupting therapy provided by the ambulatory medical device to a subject, the method comprising:

by a hardware processor of an ambulatory medical device,

receiving an indication that an application update comprising an update to an application executing on the ambulatory medical device is available;

establishing a communication connection to a host computing system configured to host the application update;

downloading the application update from the host computing system;

confirming that a downloaded copy of the application update is complete;

confirming that the downloaded copy of the application update is not corrupted;

determining an install time of an installation process that installs the downloaded copy of the application update at the ambulatory medical device;

receiving a trigger to install the downloaded copy of the application update;

responsive to the trigger, determining a next therapy delivery time associated with delivering therapy by the ambulatory medical device to a subject;

determining that the installation process will complete prior to the next therapy delivery time; and

initiating the installation process of the downloaded copy of the application update without interrupting therapy provided by the ambulatory medical device to the subject.

2. A computer-implemented method of updating an application executing on an ambulatory medical device without interrupting therapy provided by the ambulatory medical device to a subject, the method comprising:

by a hardware processor of an ambulatory medical device,

receiving an indication that an application update comprising an update to a first application executing on the ambulatory medical device is available;

establishing a communication connection to a host computing system configured to host the application update;

downloading a second application from the host computing system, wherein the second application is a version of the first application that includes the application update;

installing the second application while maintaining execution of the first application on the ambulatory medical device;

confirming successful installation of the second application on the ambulatory medical device;

receiving a trigger to execute the second application in place of the first application;

responsive to the trigger, determining a next therapy delivery time associated with delivering therapy by the ambulatory medical device to a subject; and

responsive to determining that an amount of time until the next therapy delivery time satisfies a threshold time period, initiating execution of the second application and halting execution of the first application.

3. The computer-implemented method of claim 1 or 2, wherein the next therapy delivery time is determined based on scheduled therapy delivery.

4. The computer-implemented method of claim 1 or 2, wherein the next therapy delivery time is determined based on a medical condition of the subject.

5. A computer-implemented method of updating an application executing on an ambulatory medical device without interrupting therapy provided by the ambulatory medical device to a subject, the method comprising:

by a hardware processor of an ambulatory medical device,

receiving an indication that an application update comprising an update to an application executing on the ambulatory medical device is available;

establishing a direct end-to-end data connection to a host computing system configured to host the application update, wherein the direct end-to-end data connection is established via a wireless wide area network;

downloading the application update from the host computing system over the direct end-to-end data connection;

confirming that a downloaded copy of the application update is complete;

confirming that the downloaded copy of the application update is not corrupted;

receiving a trigger to install the downloaded copy of the application update; and

responsive to the trigger, initiating the installation process of the downloaded copy of the application update without interrupting therapy provided by the ambulatory medical device to the subject.

6. The computer-implemented method of claim 1, 2 or 5, wherein the indication that an application update is available is received via an electronic communications interface configured to connect to a remote electronic device.

7. The computer-implemented method of claim 1, 2 or 5, wherein the indication that an application update is available is received when the ambulatory medical device establishes a connection to a network.

8. The computer-implemented method of claim 1, 2 or 5, wherein the indication that an application update is available is received responsive to an update request.

9. The computer-implemented method of claim 1, 2 or 5, wherein the application update is a new version of the application.

10. The computer-implemented method of claim 1, 2 or 5, wherein the application update is a replacement application.

11. The computer-implemented method of claim 1, 2 or 5, wherein the application update is a patch to the application.

12. The computer-implemented method of claim 1, 2 or 5, wherein the communication connection to the host computing system is a direct end-to-end wireless connection over a wide area network (WAN).

13. The computer-implemented method of claim 1 or 5, wherein the size of the downloaded application update is used to confirm that the downloaded application update is not corrupted.

14. A computer-implemented method of maintaining therapy provided by an ambulatory medical device during an occurrence of an application-fault of an application executing on the ambulatory medical device, the method comprising:

by a hardware processor of an ambulatory medical device,

detecting an application-fault associated with a first application executing on the ambulatory medical device, wherein the first application is configured to control therapy provided by the ambulatory medical device; and responsive to detecting the application-fault,

initiating execution of a second application on the ambulatory medical device, wherein the second application is configured to control therapy provide by the ambulatory medical device, and wherein the second application comprises an older version of the first application; and

switching control of the ambulatory medical device from the first application to the second application.

15. The computer-implemented method of claim 14, further comprising transmitting an indication of the application-fault to a computing device of a manufacturer or maintenance service of the ambulatory medical device.

16. The computer-implemented method of claim 14, further comprising alerting a user to an occurrence of the application-fault.

17. The computer-implemented method of claim 14, further comprising

receiving an indication that a third application is available, wherein the third application is configured to control therapy provide by the ambulatory medical device;

establishing a direct end-to-end data connection to a host computing system configured to host the third update, wherein the direct end-to-end data connection is established via a wireless wide area network;

downloading the third application from the host computing system over the direct end-to-end data connection;

initiating an installation process of the downloaded copy of the third application without interrupting therapy provided by the ambulatory medical device to the subject; and

switching control of the ambulatory medical device from the second application to the third application.

18. The computer-implemented method of claim 17, wherein the third application comprises an update to the first application that addresses the application-fault.

19. A computer-implemented method of updating an application executing on an ambulatory medical device without interrupting therapy provided by the ambulatory medical device to a subject, the method comprising:

by a hardware processor of an ambulatory medical device,

receiving an indication that an application update comprising an update to a first application executing on the ambulatory medical device is available;

establishing a communication connection to a host computing system configured to host a second application comprising the application update;

downloading the second application from the host computing system;

initiating an installation process of the downloaded copy of the second application without interrupting therapy provided by the ambulatory medical device to the subject;

executing the second application;

determining that a minimum set of operating conditions are satisfied, wherein the minimum set of operating conditions relate to maintaining therapy provided by the ambulatory medical device to the subject; and

responsive to determining that the minimum set of operating conditions are satisfied, switching control of the ambulatory medical device from the first application to the second application.

20. The computer-implemented method of claim 19, wherein determining that the minimum set of operating conditions are satisfied comprises determining that the ambulatory medical device is not currently administering a medicament.

21. A computer-implemented method of updating an application executing on an ambulatory medical device without interrupting therapy provided by the ambulatory medical device to a subject, the method comprising:

by a hardware processor of an ambulatory medical device,

receiving an indication that an application update comprising an update to an application executing on the ambulatory medical device is available, wherein the application comprises one of a first application version comprising a first feature set or a second application version comprising a second feature set;

establishing a communication connection to a host computing system configured to host the application update;

downloading an application update image corresponding to the application update from the host computing system, wherein the application update image is one of a first application update image corresponding to the first application version or a second application update image corresponding to the second application version;

confirming that the application update image has downloaded successfully; and

responsive at least in part to confirming that the application update image has downloaded successfully, initiating an installation process to install the application update image without interrupting therapy provided by the ambulatory medical device to the subject.

22. The computer-implemented method of claim 21, wherein the indication that the application update is available comprises an indicator of whether the application update corresponds to the first application version or the second application version.

23. The computer-implemented method of claim 21, wherein the first feature set comprises a subset of the second feature set.

24. The computer-implemented method of claim 21, wherein the first feature set comprises a partially overlapping set of features with the second feature set.

25. The computer-implemented method of claim 21, further comprising:
determining an application version of the application; and
downloading the application update image based at least in part on the application version of the application.

26. The computer-implemented method of claim 21, wherein confirming that the application update image has downloaded successfully comprises determining that the application update image is not corrupted.

27. The computer-implemented method of claim 21, wherein the first application update image comprises instructions for generating a glucagon dose control signal, and the second application update images lacks instructions for generating a glucagon dose control signal.

28. A computer-implemented method of managing ambulatory device data access, the method comprising:

by a computing system of a networked-computing environment,
establishing a direct end-to-end data connection to an ambulatory medical device via a wireless wide area network;
receiving a public key from the ambulatory medical device, wherein the public key and a private key stored on the computing system permit the computing system to decrypt data communications transmitted by the ambulatory medical device;
receiving, from the ambulatory medical device, a request to transfer data stored on the ambulatory medical device to the computing system over the direct end-to-end data connection via the wireless wide area network, and
responsive to receiving the request to transfer data stored on the ambulatory medical device to the computing system:
receiving, via the direct end-to-end data connection, encrypted data from the ambulatory medical device;
decrypting the encrypted data to obtain therapy data related to therapy delivered by the ambulatory medical device to a subject;

generating a therapy report based at least in part on the therapy data, the therapy report comprising time-series therapy data relating to the therapy delivered by the ambulatory medical device over a particular time period;

receiving a request from a display system that is separate from the networked computing environment to access the therapy report, wherein the request comprises an account identifier associated with a user that generated the request;

determining whether an account associated with the account identifier is permitted to view the therapy report based on permissions modified by the subject at the networked-computing environment; and

responsive to determining that the account is permitted to view the therapy report, transmitting the therapy report to the display system over an encrypted communication channel.

29. The computer-implemented method of claim 28, wherein the request comprises a device identifier associated with the ambulatory medical device, and wherein the device identifier is a unique identifier specific to the ambulatory medical device.

30. The computer-implemented method of claim 29, further comprising determining whether the ambulatory medical device is authorized to transfer data to the computing system based at least in part on the device identifier.

31. The computer-implemented method of claim 29, wherein the device identifier is initially provided to the networked-computing environment prior to provisioning of the ambulatory medical device to the subject.

32. The computer-implemented method of claim 29, wherein the device identifier is initially provided to the networked-computing environment as part of a manufacturing process for manufacturing the ambulatory medical device.

33. The computer-implemented method of claim 29, wherein the device identifier comprises an Internet Protocol (IP) address.

34. The computer-implemented method of claim 29, wherein the device identifier comprises a Media Access Control (MAC) address.

35. The computer-implemented method of claim 29, wherein the device identifier comprises a serial number.

36. The computer-implemented method of claim 29, wherein the device identifier comprises a subject identifier.

37. The computer-implemented method of claim 28, wherein establishing the direct end-to-end data connection comprises:

receiving a device identifier associated with the ambulatory medical device, wherein the device identifier is a unique identifier specific to the ambulatory medical device; and

determining that the ambulatory medical device is permitted to communicate with the computing system based at least in part on the device identifier.

38. The computer-implemented method of claim 37, wherein the device identifier is initially provided to the networked-computing environment prior to provisioning of the ambulatory medical device to the subject.

39. The computer-implemented method of claim 37, wherein the device identifier is initially provided to the networked-computing environment as part of a manufacturing process for manufacturing the ambulatory medical device.

40. The computer-implemented method of claim 37, wherein the device identifier comprises an Internet Protocol (IP) address.

41. The computer-implemented method of claim 37, wherein the device identifier comprises a Media Access Control (MAC) address.

42. The computer-implemented method of claim 37, wherein the device identifier comprises a serial number.

43. The computer-implemented method of claim 37, wherein the device identifier comprises a subject identifier.

44. The computer-implemented method of claim 28, further comprising associating the therapy data with the account identifier at a storage of the networked-computing environment.

45. The computer-implemented method of claim 28, further comprising generating a shared secret based at least in part on the public key and the private key, and

wherein decrypting the encrypted data comprises using the shared secret to decrypt the encrypted data.

46. The computer-implemented method of claim 28, further comprising storing the therapy data at a storage of the computing system.

47. The computer-implemented method of claim 28, further comprising storing the therapy data at a storage of the networked-computing environment.

48. The computer-implemented method of claim 28, wherein the computing system is located at a data center that hosts at least some computing systems of the networked-computing environment.

49. The computer-implemented method of claim 28, wherein the networked-computing environment comprises a cloud computing environment.

50. The computer-implemented method of claim 28, wherein the ambulatory medical device comprises a medicament pump.

51. The computer-implemented method of claim 50, wherein the medicament pump comprises an insulin pump.

52. The computer-implemented method of claim 28, wherein the ambulatory medical device comprises a pacemaker.

53. The computer-implemented method of claim 28, wherein the ambulatory medical device comprises a transceiver.

54. The computer-implemented method of claim 53, wherein the transceiver supports communication using a low power wide area network (LPWAN) communication standard.

55. The computer-implemented method of claim 53, wherein the transceiver supports communication via a Narrowband Long-Term Evolution (NB-LTE), a Narrowband Internet-of-Things (NB-IoT), or a Long-Term Evolution Machine Type Communication (LTE-MTC) communication connection with the wireless wide area network.

56. The computer-implemented method of claim 28, wherein the therapy data comprises dose data corresponding to one or more doses of medicament provided by the ambulatory medical device to the subject.

57. The computer-implemented method of claim 28, wherein the therapy data comprises subject data corresponding to a medical or physiological state of the subject as determined by the ambulatory medical device.

58. The computer-implemented method of claim 28, wherein the encrypted data further comprises operation data corresponding to operation of the ambulatory medical device.

59. The computer-implemented method of claim 28, wherein the encrypted data further comprises error data corresponding to an error in operation of the ambulatory medical device.

60. The computer-implemented method of claim 28, wherein the direct end-to-end data connection enable communication with the ambulatory medical device without communicating with an intermediary computing device.

61. The computer-implemented method of claim 28, wherein the account identifier comprises a unique identifier associated with the subject.

62. The computer-implemented method of claim 28, wherein the account identifier comprises a unique identifier associated with a user that is authorized to access the therapy report.

63. The computer-implemented method of claim 28, wherein additional encrypted data is received from the ambulatory medical device on an intermittent basis.

64. The computer-implemented method of claim 28, wherein additional encrypted data is received from the ambulatory medical device on a regularly scheduled basis.

65. The computer-implemented method of claim 28, wherein additional encrypted data is received from the ambulatory medical device on a continuous basis for at least a time period.

66. The computer-implemented method of claim 28, wherein the display system comprises a computing system of a medical provider.

67. The computer-implemented method of claim 28, wherein the display system comprises a computing system of a guardian of the subject.

68. The computer-implemented method of claim 28, further comprising determining that the therapy data satisfies an alert threshold.

69. The computer-implemented method of claim 68, further comprising generating an alert responsive to the therapy data satisfying the alert threshold.

70. The computer-implemented method of claim 69, further comprising outputting the alert to a user device of a medical practitioner.

71. The computer-implemented method of claim 69, further comprising outputting the alert to the ambulatory medical device.

72. The computer-implemented method of claim 69, further comprising outputting the alert to a user device of an emergency services provider.

73. The computer-implemented method of claim 69, further comprising outputting the alert to a user device of the subject.

74. The computer-implemented method of claim 69, further comprising outputting the alert to a user device of an authorized user associated with the subject.

75. A computing system included in a networked-computing environment, the computing system comprising:

- a memory configured to store specific computer-executable instructions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- establish a direct end-to-end data connection to an ambulatory medical device via a wireless wide area network;

- receive a public key from the ambulatory medical device, wherein the public key and a private key stored on the computing system permit the computing system to decrypt data communications transmitted by the ambulatory medical device;

- receive, from the ambulatory medical device, a request to transfer data stored on the ambulatory medical device to the computing system over the direct end-to-end data connection via the wireless wide area network; and

- responsive to receiving the request to transfer data stored on the ambulatory medical device to the computing system, the hardware processor is further configured to execute the specific computer-executable instructions to at least:

receive, via the direct end-to-end data connection, encrypted data from the ambulatory medical device;

decrypt the encrypted data to obtain therapy data related to therapy delivered by the ambulatory medical device to a subject;

generate a therapy report based at least in part on the therapy data, the therapy report comprising time-series therapy data relating to the therapy delivered by the ambulatory medical device over a particular time period;

receive a request from a display system that is separate from the networked computing environment to access the therapy report, wherein the request comprises an account identifier associated with a user that generated the request;

determine whether an account associated with the account identifier is permitted to view the therapy report based on permissions modified by the subject at the networked-computing environment; and

responsive to determining that the account is permitted to view the therapy report, transmit the therapy report to the display system over an encrypted communication channel.

76. An ambulatory medical device configured to provide therapy to a subject and to share therapy data related to the therapy with a networked-computing environment, the ambulatory medical device comprising:

a memory configured to store specific computer-executable instructions; and

a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

identify a computing system of a networked-computing environment based on a whitelist of one or more approved computing systems, wherein the whitelist is stored in a memory of the ambulatory medical device;

obtain an address of the computing system from the whitelist;

establish a direct end-to-end data connection to the computing system of the networked-computing environment via a wireless wide area network using the address;

receive a public key from the computing system of the networked-computing environment, wherein the public key and a private key stored on the ambulatory medical device permit the ambulatory medical device to encrypt data communications transmitted by the ambulatory medical device to the computing system;

encrypt therapy data related to therapy delivered by the ambulatory medical device to the subject to obtain encrypted therapy data; and

transmit the encrypted therapy data to the computing system over the direct end-to-end connection.

77. An ambulatory medicament device configured to generate a dose control signal for delivery of medicament into a subject, the ambulatory medicament device comprising:

a monitoring system interface configured to receive status information, wherein the status information comprises at least one of device information pertaining to a condition of the ambulatory medicament device or subject information pertaining to a condition of the subject;

a medicament delivery interface configured to operatively connect to a medicament pump configured to infuse medicament into the subject in response to receiving the dose control signal;

a touchscreen controller configured to output display signals configured to generate user interface screens on a touchscreen and to receive user input signals corresponding to user interaction with the touchscreen;

a memory configured to store specific computer-executable instructions; and

a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

receive the status information via the monitoring system interface;

determine that the status information satisfies an alarm condition for the ambulatory medicament device or for the subject; and

in response to a wake interaction with a wake interface element when the ambulatory medicament device is in a sleep state, wherein the touchscreen controller does not receive user input signals when the ambulatory medicament device is in the sleep state,

generate a display of a touchscreen lock screen interface; and
display on the touchscreen lock screen interface one or more
alarm status indicators corresponding to the alarm condition.

78. The ambulatory medicament device of claim 77, wherein:

in response to an unlock gesture interaction with the touchscreen lock screen interface, the hardware processor is further configured to execute the specific computer-executable instructions to:

permit access to a therapy control element of the ambulatory medicament device, wherein the therapy control element permits a user to modify a control parameter used in a control algorithm for generating a dose control signal;

receive an indication of a modification to the therapy control element;

and

in response to receiving the indication,

modify the control parameter based on the indication to obtain a modified control parameter;

generate the dose control signal based at least in part on the modified control parameter; and

provide, via the medicament delivery interface, the dose control signal to the medicament pump.

79. The ambulatory medicament device of claim 77, wherein the wake interface element comprises a motion sensor, and wherein the wake interaction comprises movement of the ambulatory medicament device.

80. The ambulatory medicament device of claim 79, wherein the motion sensor comprises an accelerometer.

81. The ambulatory medicament device of claim 79, wherein the movement of the ambulatory medicament device corresponds to a particular motion.

82. The ambulatory medicament device of claim 81, wherein the particular motion is indicative of the user moving the ambulatory medicament device within visual range of the user.

83. The ambulatory medicament device of claim 79, wherein the wake interaction further comprises receiving a biometric input.

84. An ambulatory medicament device configured to generate a dose control signal for delivery of medicament into a subject and to cancel a modification of medicament delivery initiated by a user, the ambulatory medicament device comprising:

- a medicament delivery interface configured to operatively connect to a medicament pump configured to infuse medicament into the subject in response to receiving the dose control signal;

- a touchscreen controller configured to output display signals configured to generate user interface screens on a touchscreen and to receive user input signals corresponding to user interaction with the touchscreen;

- a memory configured to store specific computer-executable instructions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- generate a display of a therapy control element on the touchscreen, wherein the therapy control element permits a user to modify a control parameter having a first setting used in a control algorithm for generating a dose control signal;

- receive an indication of a modification to the therapy control element;

- in response to receiving the indication, modify at a first time the control parameter from a first setting to a second setting based on the indication of the modification to the therapy control element;

- receive a restore gesture on the touchscreen at a second time, wherein the restore gesture indicates that the control parameter is to be restored to the first setting, and wherein the restore gesture comprises a swipe gesture performed by a user; and

- in response to receiving the restore gesture, restore the control parameter to the first setting.

85. The ambulatory medicament device of claim 84, wherein the swipe gesture is performed at least in part in a region of the touchscreen occupied by the therapy control element.

86. The ambulatory medicament device of claim 84, wherein the swipe gesture is performed from a starting swipe position to an ending swipe position located closer to a left edge of the touchscreen than the starting swipe position.

87. The ambulatory medicament device of claim 84, wherein the restore gesture is received on a user interface screen that presents the therapy control element.

88. The ambulatory medicament device of claim 84, wherein the restore gesture is received on a different user interface screen than a user interface screen that presents the therapy control element.

89. The ambulatory medicament device of claim 84, wherein the restore gesture is performed in the opposite direction from a therapy change confirmation gesture that confirms the modification to the therapy control element.

90. The ambulatory medicament device of claim 84, wherein the second time is later than the first time.

91. The ambulatory medicament device of claim 84, wherein the second time is after one or more dose control signals are provided to the medicament pump.

92. The ambulatory medicament device of claim 84, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least:

receive a second indication of a second modification to the therapy control element; and

in response to receiving the second indication, modify at a third time the control parameter from the second setting to a third setting based on the second indication of the second modification to the therapy control element.

93. The ambulatory medicament device of claim 92, wherein the third time is after the first time, but before the second time.

94. The ambulatory medicament device of claim 92, wherein the first setting comprises a default setting or a designated restore setting.

95. The ambulatory medicament device of claim 84, wherein the first setting comprises a setting immediately preceding the second setting.

96. The ambulatory medicament device of claim 84, wherein the first setting comprises a default setting or a designated restore setting.

97. An ambulatory medicament device configured to suspend medicament delivery to a subject, the ambulatory medicament device comprising:

- a medicament pump configured to receive dose control signals configured to cause the medicament pump to deliver medicament to the subject;

- a memory configured to store specific computer-executable instructions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- receive a request to temporarily suspend delivery of the medicament to the subject, wherein the request comprises an indication of a temporary suspension period associated with a length of time that the delivery of the medicament is to be suspended;

- suspend delivery of the medicament to the subject, wherein suspending delivery of the medicament includes not generating a dose control signal during the suspension period;

- determine that a resumption condition has occurred during the temporary suspension period, wherein the resumption condition requires no user action to trigger the resumption condition;

- generate a dose control signal after occurrence of the resumption condition, thereby discontinuing the temporary suspension; and

- provide the dose control signal to the medicament pump.

98. The ambulatory medicament device of claim 97, wherein the resumption condition occurs during the temporary suspension period.

99. The ambulatory medicament device of claim 97, wherein the resumption condition comprises the expiration of the temporary suspension period.

100. The ambulatory medicament device of claim 97, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least generate an alert prior to generating the dose control signal, wherein the alert indicates that the temporary suspension period has ended.

101. The ambulatory medicament device of claim 97, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at

least generate an alert upon determining that the resumption condition has occurred, wherein the alert indicates that the temporary suspension period has ended.

102. The ambulatory medicament device of claim 97, wherein receiving the request comprises receiving a first user interaction.

103. The ambulatory medicament device of claim 102, wherein receiving the request comprises receiving a confirmation.

104. The ambulatory medicament device of claim 103, wherein receiving the confirmation comprises receiving a second user interaction.

105. The ambulatory medicament device of claim 102, wherein the first user interaction comprises a gesture performed on a touchscreen display of the ambulatory medicament device.

106. The ambulatory medicament device of claim 97, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least generate an alert prior to suspending delivery of the medicament to the subject, wherein the alert indicates the time at which the delivery of the medicament will be suspended.

107. The ambulatory medicament device of claim 97, wherein the resumption condition occurs responsive to determining that a medical condition of the subject satisfies a threshold condition.

108. The ambulatory medicament device of claim 107, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least generate an alert, wherein the alert indicates a resumption condition has occurred.

109. The ambulatory medicament device of claim 97, wherein the resumption condition occurs responsive to receiving a trigger from a user or the subject to discontinue temporary suspension.

110. The ambulatory medicament device of claim 97, wherein the medicament pump comprises an insulin pump.

111. The ambulatory medicament device of claim 97, wherein the medicament pump comprises an insulin pump and a gluconate pump.

112. The ambulatory medicament device of claim 97, wherein receiving a request comprises receiving from the subject or a user, a suspension time to suspend delivery of the medicament to the subject.

113. The ambulatory medicament device of claim 112, wherein the delivery of the medicament to the subject is suspended at the suspension time.

114. The ambulatory medicament device of claim 113, wherein the delivery of the medicament to the subject is not suspended if a medical condition of the subject satisfies a threshold condition.

115. The ambulatory medicament device of claim 97 or 109, wherein the dose control signal is generated after a resumption period following the resumption condition has elapsed.

116. The ambulatory medicament device of claim 107, wherein the dose control signal is generated immediately after the resumption condition has occurred.

117. An ambulatory medicament device configured to generate a dose control signal for delivery of medicament to a subject and configured to secure at least some functionality of a user interface of the ambulatory medicament device, the ambulatory medicament device comprising:

- a medicament delivery interface configured to operatively connect to a medicament pump for infusing medicament into the subject;

- a display interface configured to output display signals configured to generate user interface screens on a display device;

- a memory configured to store specific computer-executable instructions, a user-generated passcode that is selected by a user during a passcode-setting process, and an override passcode that is not selected by the user; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- generate the dose control signal using a control algorithm employing control parameters, wherein at least one control parameter can be modified by user interaction with a parameter control element displayed via at least one of the user interface screens, wherein the ambulatory medicament device does not permit modification of the at least one control parameter via the parameter control element when the ambulatory medicament device is in a locked state;

- in response to user interaction with a user input element of the ambulatory medicament device when the ambulatory medicament device is in

the locked state, generate a passcode display of a keypad comprising user-selectable letters, numbers, symbols, or a combination thereof, wherein the keypad is configured to accept user input of a security code;

validate the security code to confirm that the user is authorized to modify the locked state of the ambulatory medicament device by confirming that the security code matches the user-generated passcode or the override passcode; and

in response to validating the security code, cause the ambulatory medicament device to enter an unlocked state, wherein the ambulatory medicament device permits modification of the at least one control parameter via the parameter control element when the ambulatory medicament device is in the unlocked state.

118. An ambulatory medicament device configured to generate a dose control signal for delivery of medicament to a subject and configured to secure at least some functionality of a user interface of the ambulatory medicament device, the ambulatory medicament device comprising:

a medicament delivery interface configured to operatively connect to a medicament pump for infusing medicament into the subject;

a memory configured to store specific computer-executable instructions, a user-generated passcode that is selected by a user during a passcode-setting process, and an override passcode that is not selected by the user; and

a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

generate the dose control signal using a control algorithm employing control parameters, wherein at least one control parameter can be modified by user interaction with a parameter control element, wherein the ambulatory medicament device does not permit modification of the at least one control parameter via the parameter control element when the ambulatory medicament device is in a locked state;

receive a request from a computing system over a direct end-to-end connection with the computing system to unlock the ambulatory medicament device, wherein the request includes a security code;

validate the security code to confirm that the user is authorized to modify the locked state of the ambulatory medicament device by confirming that the security code matches the user-generated passcode or the override passcode; and

in response to validating the security code, cause the ambulatory medicament device to enter an unlocked state, wherein the ambulatory medicament device permits modification of the at least one control parameter via the parameter control element when the ambulatory medicament device is in the unlocked state.

119. The ambulatory medicament device of claim 118, wherein the parameter control element is access via the computing system over the direct end-to-end connection.

120. The ambulatory medicament device of claim 118, wherein the direct end-to-end connection is established over a wide area network.

121. The ambulatory medicament device of claim 117 or 118, wherein access to at least some functionality of the user interface is permitted without validating the security code.

122. The ambulatory medicament device of claim 117, wherein the passcode display comprises a graph of glucose level of the subject over time.

123. The ambulatory medicament device of claim 117 or 118, wherein ambulatory medicament device comprises an insulin pump.

124. The ambulatory medicament device of claim 117 or 118, wherein the security code comprises at least one of a numeric code, an alphanumeric code, a shape, an answer to a question, a gesture interaction with a touch-sensitive surface, or a biometric identifier.

125. The ambulatory medicament device of claim 117, wherein the input element comprises an element displayed on a touchscreen display.

126. The ambulatory medicament device of claim 117, wherein the input element comprises a touch-sensitive surface comprising one or more visual indicia.

127. The ambulatory medicament device of claim 117, wherein at least some information associated with therapy delivery is accessible to the user in the locked state.

128. The ambulatory medicament device of claim 117 or 118, wherein the override passcode changes at periodic intervals.

129. The ambulatory medicament device of claim 117, wherein the hardware processor is configured to execute the specific computer-executable instructions to:

validate an advanced settings security code to confirm that the user is authorized to modify advanced settings of the ambulatory medicament device by confirming that the advanced settings security code matches an advanced settings passcode; and

in response to validating the advanced settings security code, cause the ambulatory medicament device to enter an advanced settings state, wherein the ambulatory medicament device permits modification of at least one advanced control parameter via an advanced parameter control element when the ambulatory medicament device is in the advanced settings state.

130. The ambulatory medicament device of claim 129, wherein the advanced settings security code expires after a predetermined period.

131. The ambulatory medicament device of claim 130, wherein the advanced settings security code expires at least once per week.

132. The ambulatory medicament device of claim 117, wherein the security code comprises a gesture interaction with a touchscreen display.

133. The ambulatory medicament device of claim 117, wherein if the security code cannot be validated after a predetermined number of security code entry attempts, further security code entry attempts are denied for a period of time.

134. The ambulatory medicament device of claim 117 or 118, wherein the override passcode is fixed during a manufacturing process.

135. The ambulatory medicament device of claim 117 or 118, wherein the override passcode is valid for at least some other ambulatory medicament devices

136. The ambulatory medicament device of claim 117 or 118, wherein, upon expiration of the override passcode, a new override passcode is generated algorithmically.

137. An ambulatory medicament device configured to generate a dose control signal configured to cause a medicament pump to infuse medicament into a subject, the ambulatory medicament device comprising:

- a monitoring system interface configured to receive status information, wherein the status information comprises at least one of device information pertaining to a condition of the ambulatory medicament device or subject information pertaining to a condition of the subject;

- a memory configured to store specific computer-executable instructions and a list of pending alarm conditions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- receive a first status information via the monitoring system interface;

- in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device or for the subject and determining that the alarm condition is not already present in the list of pending alarm conditions, modify the list of pending alarm conditions based on the alarm condition;

- determine a severity level of the alarm condition, wherein the severity level is one of a plurality of severity levels;

- annunciate the alarm condition using one or more annunciation patterns, wherein the one or more annunciation patterns are selected based on the severity level of the alarm condition for the medicament pump or for the subject; and

- maintain the alarm condition on the list of pending alarm conditions until the alarm condition is resolved.

138. The ambulatory medicament device of claim 137, wherein the ambulatory medicament device comprises an insulin pump.

139. The ambulatory medicament device of claim 137 or 138, wherein the ambulatory medicament device comprises a counter-regulatory agent pump.

140. The ambulatory medicament device of claim 137, wherein each severity level of the plurality of severity levels is associated with a unique annunciation pattern of the plurality of annunciation patterns.

141. The ambulatory medicament device of claim 137, wherein the list of pending alarm conditions is sorted according to severity level of the alarm condition.

142. The ambulatory medicament device of claim 137, wherein the list of pending alarm conditions is displayed on a user interface of the ambulatory medicament device.

143. The ambulatory medicament device of claim 142, wherein the list of pending alarm conditions is available when the ambulatory medicament device is in a locked state.

144. The ambulatory medicament device of claim 137, further comprising a wireless electronic communications interface configured to connect the ambulatory medicament device to a remote electronic device, wherein the ambulatory medicament device is configured to transmit an alarm signal via the wireless electronic communications interface to annunciate the alarm condition on the remote electronic device.

145. The ambulatory medicament device of claim 144, wherein the ambulatory medicament device transmits the list of pending alarm conditions to the remote electronic device.

146. The ambulatory medicament device of claim 137, wherein the ambulatory medicament device generates a display of an alarm state icon comprising a visual indication of a count of alarm conditions on the list of pending alarm conditions.

147. The ambulatory medicament device of claim 137, wherein
the ambulatory medicament device receives a second status information via the monitoring system interface; and

in response to determining that the second status information satisfies an alarm condition for the ambulatory medicament device or for the subject and determining that the alarm condition is already present in the list of pending alarm conditions, the ambulatory changes the one or more annunciation patterns previously used to announce the alarm condition.

148. The ambulatory medicament device of claim 137, wherein status information, is received from one or more sensors that measure characteristics of the ambulatory medicament device.

149. The ambulatory medicament device of claim 137, wherein status information, is received from one or more sensors that measure health conditions of the subject.

150. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device or for the subject, the ambulatory medicament device contacts a healthcare provider.

151. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device, the ambulatory medicament device contacts a manufacturer of the ambulatory medicament device.

152. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies a low medicament alarm condition for the ambulatory medicament device, the ambulatory medicament device contacts a provider of a medicament associated with the low medicament alarm condition; and places an order for the medicament.

153. The ambulatory medicament device of claim 137, wherein in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device, the ambulatory medicament device displays repair instructions on a user interface of the ambulatory medicament device.

154. The ambulatory medicament device of claim 137, wherein the annunciation pattern comprises textual information about the alarm condition.

155. The ambulatory medicament device of claim 137, wherein the annunciation pattern comprises an audible alarm.

156. The ambulatory medicament device of claim 137, wherein the annunciation pattern comprises a visual alarm.

157. The ambulatory medicament device of claim 137, wherein the annunciation pattern comprises a haptic alarm.

158. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies an alarm condition and determining that the alarm condition is already present in the list of pending alarm conditions, the ambulatory device:

modifies a severity level of the alarm condition to an elevated severity level,
and

based on the elevated severity level, modifies the annunciation pattern of the
alarm condition.

159. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device, the ambulatory medicament device determines a severity level of the alarm condition and at least partially based on the severity level of the alarm condition, suspends the delivery of the medicament to the subject.

160. The ambulatory medicament device of claim 137, wherein, in response to determining that the status information satisfies an alarm condition for the ambulatory medicament device, the ambulatory medicament device determines a severity level of the alarm condition and at least partially based on the severity level of the alarm condition, continues the delivery of the medicament to the subject.

161. The ambulatory medicament device of claim 137, wherein the annunciation pattern can be perceived by a user when the ambulatory medicament device is in a locked state.

162. The ambulatory medicament device of claim 137, wherein the ambulatory medicament device comprises a control element that allows a user to acknowledge the alarm condition.

163. The ambulatory medicament device of claim 137, wherein the ambulatory medicament device comprises a control element that allows a user to dismiss an alarm.

164. A computer-implemented method of device malfunction alert prioritization within an ambulatory medical device, the method comprising:

by a processor of the ambulatory medical device,

detecting a device condition of the ambulatory medical device;

determining that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device;

determining that the device condition satisfies a set of minimum operating parameters, wherein the minimum operating parameters are

sufficient to permit delivery of therapy by the ambulatory medical device to a subject; and

responsive to determining that the device condition satisfies the set of minimum operating parameters:

maintaining the delivery of therapy by the ambulatory medical device to the subject; and

generating a user alert based at least in part on the device condition, wherein the user alert enables a user to determine the device condition of the ambulatory medical device, wherein the user alert is dismissible by the user, and wherein the user alert is scheduled to repeat on a particular schedule until an alert modification condition occurs.

165. The computer-implemented method of claim 164, wherein the ambulatory medical device is a medicament pump.

166. The computer-implemented method of claim 165, wherein the medicament pump comprises at least one of an insulin pump or a counter-regulatory agent pump.

167. The computer-implemented method of claim 164, wherein at least some of the minimum operating parameters are provided by a manufacturer of the ambulatory medical device.

168. The computer-implemented method of claim 164, wherein at least some of the normal operating parameters are provided by a healthcare provider.

169. The computer-implemented method of claim 164, wherein at least some of the minimum operating parameters or the normal operating parameters are provided by the subject or an authorized user.

170. The computer-implemented method of claim 164, wherein the user alert type and frequency at a given time depend on the detected device condition that triggered the generation of the user alert and/or the number of times the user alert has been generated before the given time.

171. The computer-implemented method of claim 164, wherein the therapy delivery is stopped based, at least partially, on the detected device condition.

172. The computer-implemented method of claim 164, wherein the user alert is repeated at a fixed static time period.

173. The computer-implemented method of claim 164, wherein the user alert is repeated at time periods that gradually increase.

174. The computer-implemented method of claim 164, wherein the user alert is repeated at time periods that change during the day based on time of day.

175. The computer-implemented method of claim 164, wherein the alert modification condition comprises a change in the detected condition of the ambulatory medicament device.

176. The computer-implemented method of claim 164, wherein generating a user alert comprises contacting a manufacturer.

177. The computer-implemented method of claim 164, wherein generating a user alert comprises contacting a healthcare provider.

178. The computer-implemented method of claim 164, wherein generating a user alert comprises ordering medicament.

179. The computer-implemented method of claim 164, wherein generating a user alert comprises providing instructions for fixing the detected condition of the ambulatory medicament device.

180. The computer-implemented method of claim 164, wherein, in response to determining that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device, the delivery of therapy by the ambulatory medical device to the subject is maintained at a normal rate.

181. The computer-implemented method of claim 164, wherein, in response to determining that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device, the delivery of therapy by the ambulatory medical device to the subject is maintained at a minimum rate.

182. An ambulatory medical device configured to provide therapy to a subject, the ambulatory medical device comprising:

a memory configured to store specific computer-executable instructions; and

a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

detect a device condition of the ambulatory medical device;

determine that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device;

determine that the device condition satisfies a set of minimum operating parameters, wherein the minimum operating parameters are sufficient to permit delivery of therapy by the ambulatory medical device to a subject; and

responsive to determining that the device condition satisfies the set of minimum operating parameters, the hardware processor is further configured to execute the specific computer-executable instructions to at least:

maintain the delivery of therapy by the ambulatory medical device to the subject; and

generate a user alert based at least in part on the device condition, wherein the user alert enables a user to determine the device condition of the ambulatory medical device, wherein the user alert is dismissible by the user, and wherein the user alert is scheduled to repeat on a particular schedule until an alert modification condition occurs.

183. The ambulatory medical device of claim 182, comprising a medicament pump.

184. The ambulatory medical device of claim 183, wherein the medicament pump comprises at least one of an insulin pump or a counter-regulatory agent pump.

185. The ambulatory medical device of claim 182, wherein the minimum and/or normal operating parameters are provided by the manufacturer of the ambulatory medical device.

186. The ambulatory medical device of claim 182, wherein the minimum and/or normal operating parameters are provided by a healthcare provider.

187. The ambulatory medical device of claim 182, wherein the minimum and/or normal operating parameters are provided by the subject or an authorized user.

188. The ambulatory medical device of claim 182, wherein the user alert type and frequency at a given time depend on the detected device condition that triggered the

generation user alert and/or the number of times the user alert has been generated before the given time.

189. The ambulatory medical device of claim 182, wherein the ambulatory medicament device stops the therapy delivery based at least partially on the detected device condition.

190. The ambulatory medical device of claim 182, wherein ambulatory medicament device repeats the user alert at fixed intervals.

191. The ambulatory medical device of claim 182, wherein ambulatory medicament device repeats the user alert at intervals that vary over time.

192. The ambulatory medical device of claim 182, wherein ambulatory medicament device repeats the user alert at intervals that vary based on a time of day.

193. The ambulatory medical device of claim 182, wherein the alert modification condition comprises a change in the detected condition of the ambulatory medicament device.

194. The ambulatory medical device of claim 182, wherein generating a user alert comprises contacting a manufacturer.

195. The ambulatory medical device of claim 182, wherein generating a user alert comprises contacting a healthcare provider.

196. The ambulatory medical device of claim 182, wherein generating a user alert comprises ordering medicament.

197. The ambulatory medical device of claim 182, wherein generating a user alert comprises generating a display of instructions for resolving the detected condition.

198. The ambulatory medical device of claim 182, wherein, in response to determining that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device, the ambulatory medicament device maintains the delivery of therapy to the subject at a normal rate.

199. The ambulatory medical device of claim 182, wherein, in response to determining that the device condition does not satisfy a set of normal operating parameters for the ambulatory medical device, the ambulatory medicament device maintains the delivery of therapy to the subject at a reduced rate.

200. An automated blood glucose control system configured to provide automatic delivery of glucose control therapy to a subject and receive information about manual glucose control therapy provided to the subject, the automated blood glucose control system comprising:

- a medicament delivery interface configured to operatively connect to a medicament pump configured to infuse medicament into the subject;

- a user interface controller configured to receive input signals corresponding to user interaction with a user interface;

- a memory configured to store specific computer-executable instructions and a therapy log; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- generate an indication of an amount of a bolus of medicament via a control algorithm configured to control blood glucose level in the subject, wherein the bolus of medicament corresponds to a meal bolus of medicament or a correction bolus of medicament, and wherein the amount of the bolus of medicament is selected by the control algorithm based at least in part on preceding periods of glycemic control in the subject;

- generate a display of a manual bolus screen comprising a manual bolus control element and a bolus recommendation comprising the indication of the amount of the bolus of medicament generated by the control algorithm;

- receive, via user interaction with the manual bolus control element, an indication of an amount of a manual bolus of medicament;

- store, in the therapy log, the indication of the amount of the manual bolus of medicament supplied to the subject and an indication of a time when the manual bolus of medicament was supplied to the subject;

- model a diminishing of the medicament in the subject over time based at least in part on the manual bolus; and

- operate the control algorithm for automatic generation of an insulin dosing signal configured to operate the medicament pump to control blood glucose level in the subject based at least in part on a glucose level signal

received from a glucose level sensor operatively connected to the subject and a time course of activity of the medicament in the subject due to a finite rate of utilization of the medicament.

201. An ambulatory medical device comprising the automated blood glucose control system of claim 200 and a medicament pump.

202. The ambulatory medical device of claim 201, wherein the medicament pump comprises at least one of an insulin pump or a counter-regulatory agent pump.

203. The automated blood glucose control system of claim 200, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least model an accumulation of the manual bolus of the medicament in blood of the subject following subcutaneous infusion of the medicament.

204. The automated blood glucose control system of claim 200, further comprising a wireless electronic communications interface configured to receive the indication of the amount of the manual bolus of medicament from an electronic device remote from the medicament pump.

205. The automated blood glucose control system of claim 200, wherein receiving the indication of the amount of the manual bolus of medicament comprises detecting a gesture interaction made by a user.

206. The automated blood glucose control system of claim 205, wherein detecting the gesture interaction made by the user comprises confirming that the gesture interaction matches a specified gesture interaction required for entry of the manual bolus.

207. The automated blood glucose control system of claim 200, wherein receiving the indication of the amount of the manual bolus of medicament comprises receiving an estimate of a meal size or an estimate of a number of carbohydrates consumed by the subject.

208. The automated blood glucose control system of claim 200, wherein receiving the indication of the amount of the manual bolus of medicament comprises receiving an estimate of an intensity of exercise engaged in by the subject.

209. The automated blood glucose control system of claim 200, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least generate a dose control signal based at least in part on the indication of the amount of the manual bolus of medicament.

210. The automated blood glucose control system of claim 209, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least provide the dose control signal to the medicament pump.

211. The automated blood glucose control system of claim 209, wherein the manual bolus is infused through injection therapy or pump therapy.

212. The automated blood glucose control system of claim 209, wherein modeling the diminishing of the medicament in the subject over time enables an estimate of a future effect of medicament previously infused into the subject.

213. An automated blood glucose control system configured to provide automatic delivery of glucose control therapy to a subject and receive information about manual glucose control therapy provided to the subject, the automated blood glucose control system comprising:

- a glucose sensor interface operative to receive a glucose level signal from a sensor operative to determine a glucose level of the subject at periodic measurement intervals;

- a delivery device interface configured to transmit an insulin dose control signal to a medicament pump operative to deliver doses of insulin to the subject; and

- a memory configured to store specific computer-executable instructions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- receive an indication of an amount of a manual bolus of insulin from a user interface; and

- automatically generate the insulin dose control signal based at least in part on the glucose level signal, an accumulation of insulin in the subject due to finite rate of utilization of the insulin, an input parameter corresponding to a weight of the subject, the indication of the amount of the manual bolus, and an indication of a time when the manual bolus of insulin was supplied to the subject.

214. The automated blood glucose control system of claim 213, wherein the input parameter comprises a measure of weight, a body mass value, or a body mass index value.

215. The automated blood glucose control system of claim 213, wherein the insulin dose control signal is automatically adjusted based on the amount of the manual bolus.

216. The automated blood glucose control system of claim 213, wherein the hardware processor is further configured to execute the specific computer-executable instructions to at least generate a glucagon dose control signal based at least in part on the indication of the amount of the manual bolus.

217. An automated blood glucose control system configured to provide automatic delivery of glucose control therapy to a subject and receive information about manual glucose control therapy provided to the subject, the automated blood glucose control system comprising:

- a medicament delivery interface configured to operatively connect to a medicament pump configured to infuse medicament into the subject;

- a user interface controller configured to receive input signals corresponding to user interaction with a user interface;

- a memory configured to store specific computer-executable instructions; and

- a hardware processor in communication with the memory and configured to execute the specific computer-executable instructions to at least:

- receive a meal announcement from a user responsive to the user interaction with the user interface, wherein the meal announcement comprises an indication of a size of a meal consumed or to be consumed by the subject;

- determine a meal bolus of insulin to administer to the subject based at least in part on the meal announcement, the meal bolus comprising an amount of insulin to administer to the subject to compensate for a change in blood glucose attributable to the meal;

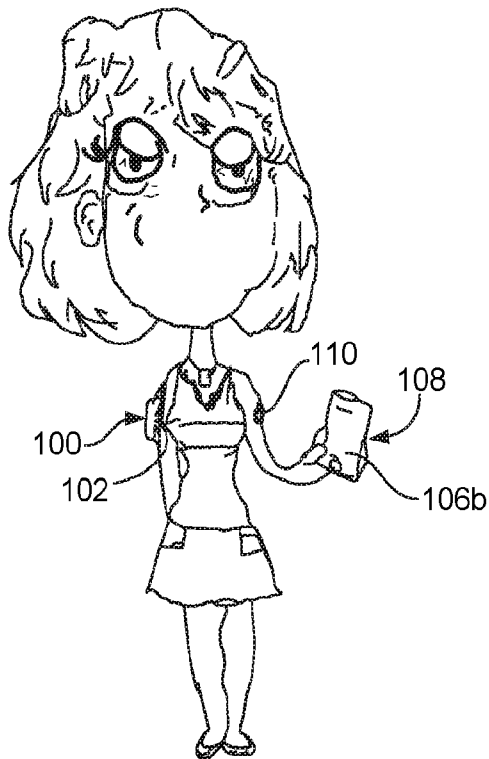
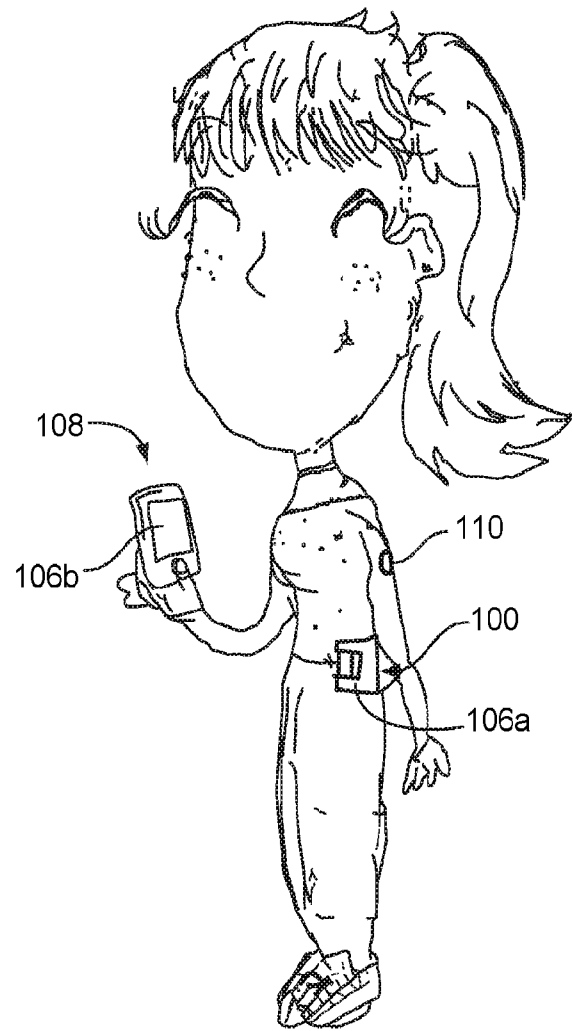
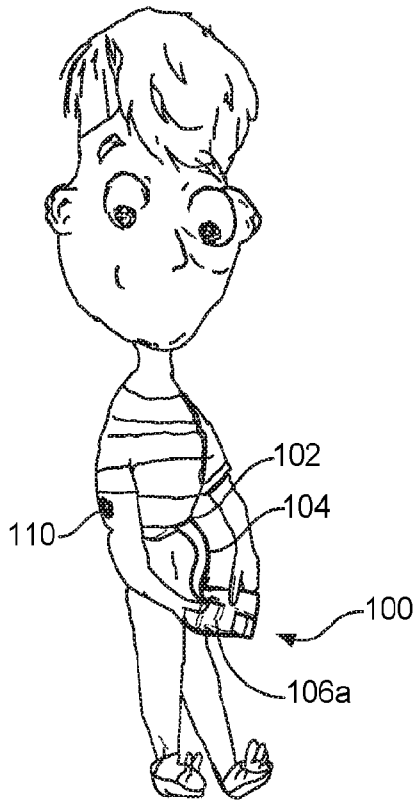
- output for display an indication of the meal bolus;

- receive an indication of a requested modification to the meal bolus from the user; and

- operate a control algorithm for automatic generation of an insulin dosing signal configured to operate the medicament pump to control blood glucose level in the subject based at least in part on a glucose level of the subject and the modification to the meal bolus.

218. The automated blood glucose control system of claim 217, wherein the user is the subject or a caregiver of the subject.

219. The automated blood glucose control system of claim 217, wherein the meal announcement is received via a wireless electronic communications interface configured to connect to a remote electronic device.



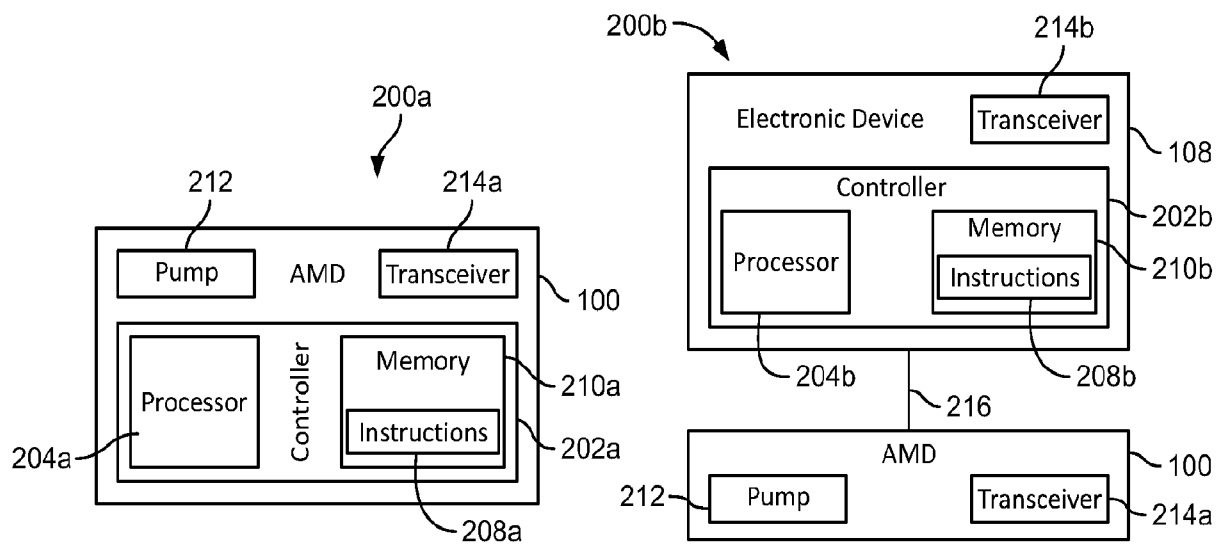


FIG. 2A

FIG. 2B

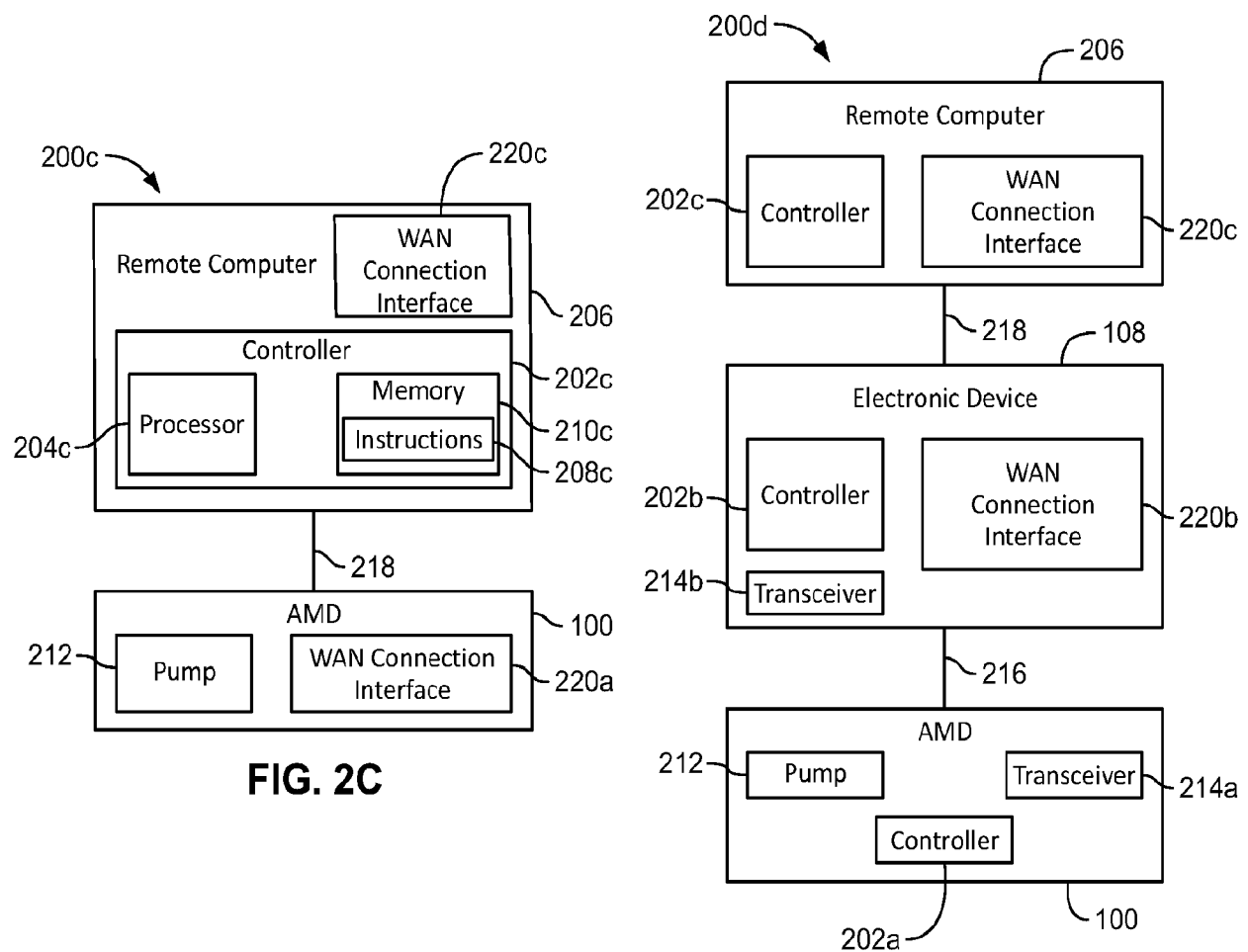
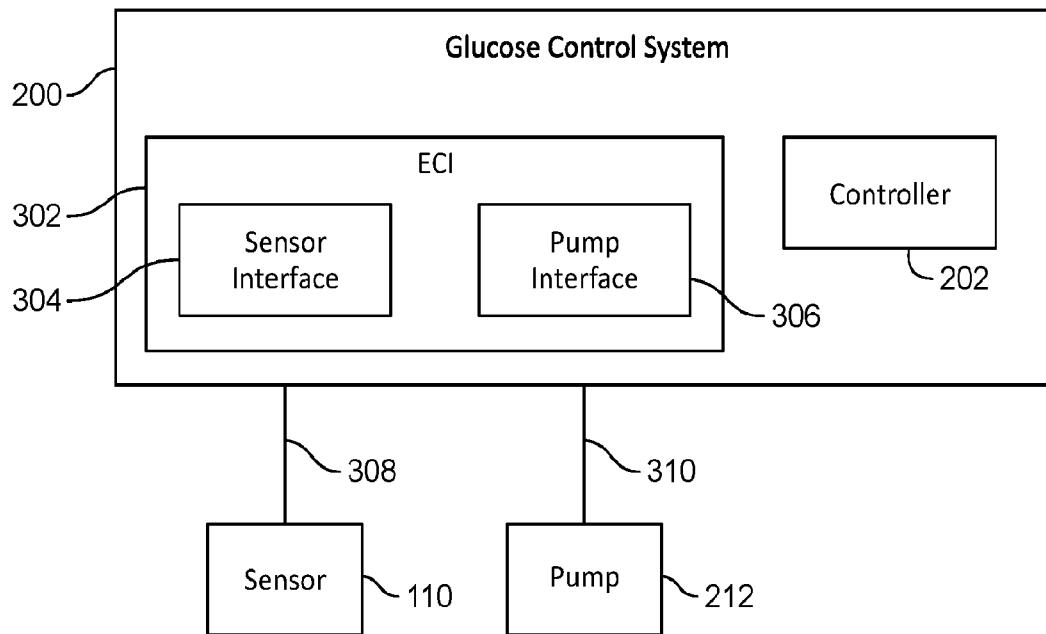


FIG. 2C

FIG. 2D

**FIG. 3**

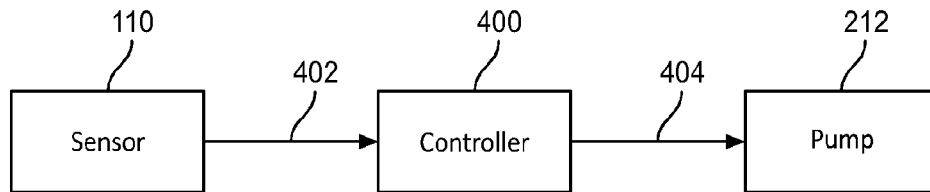
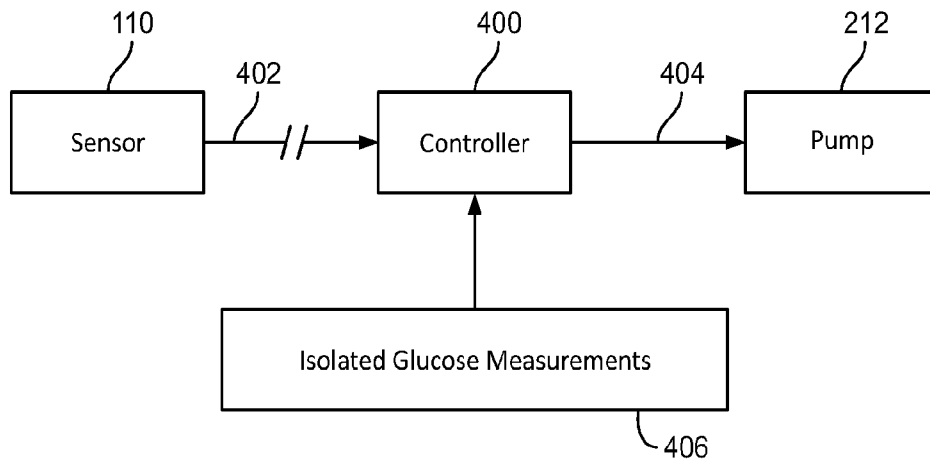
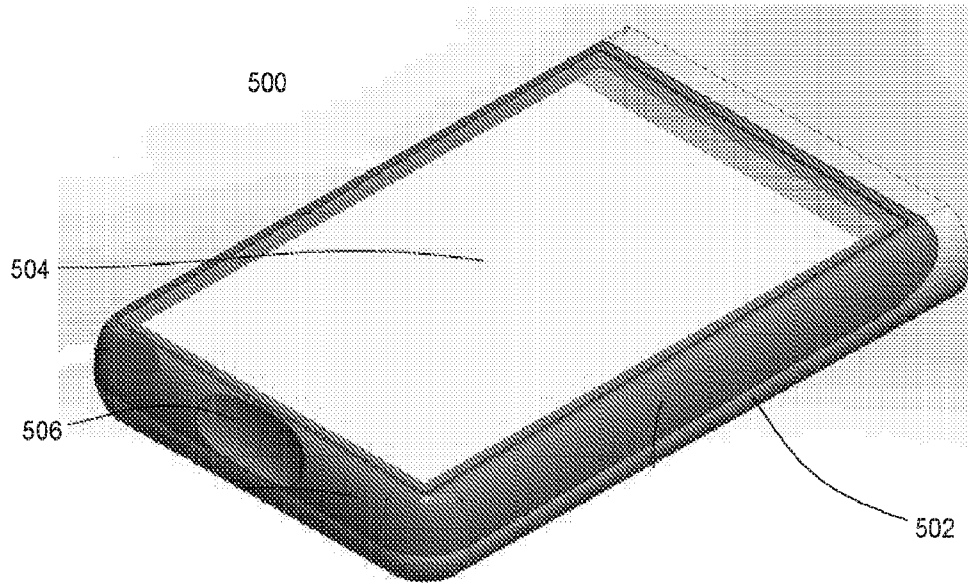
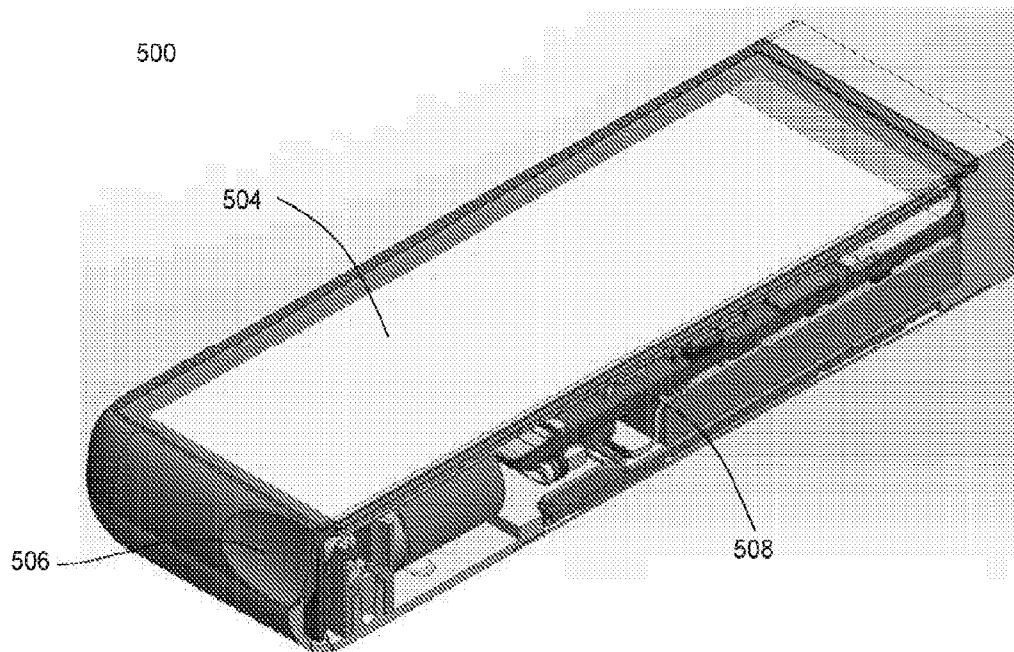
**FIG. 4A****FIG. 4B**

FIG. 5



(A)



(B)

FIG. 6

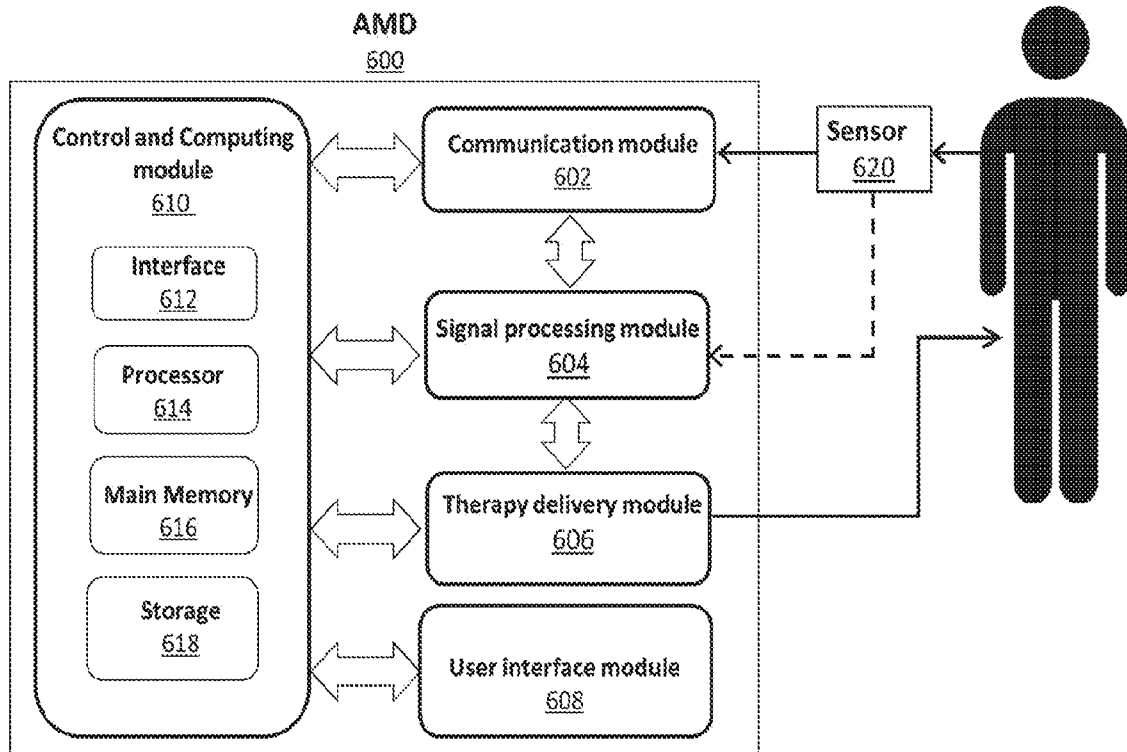


FIG. 7

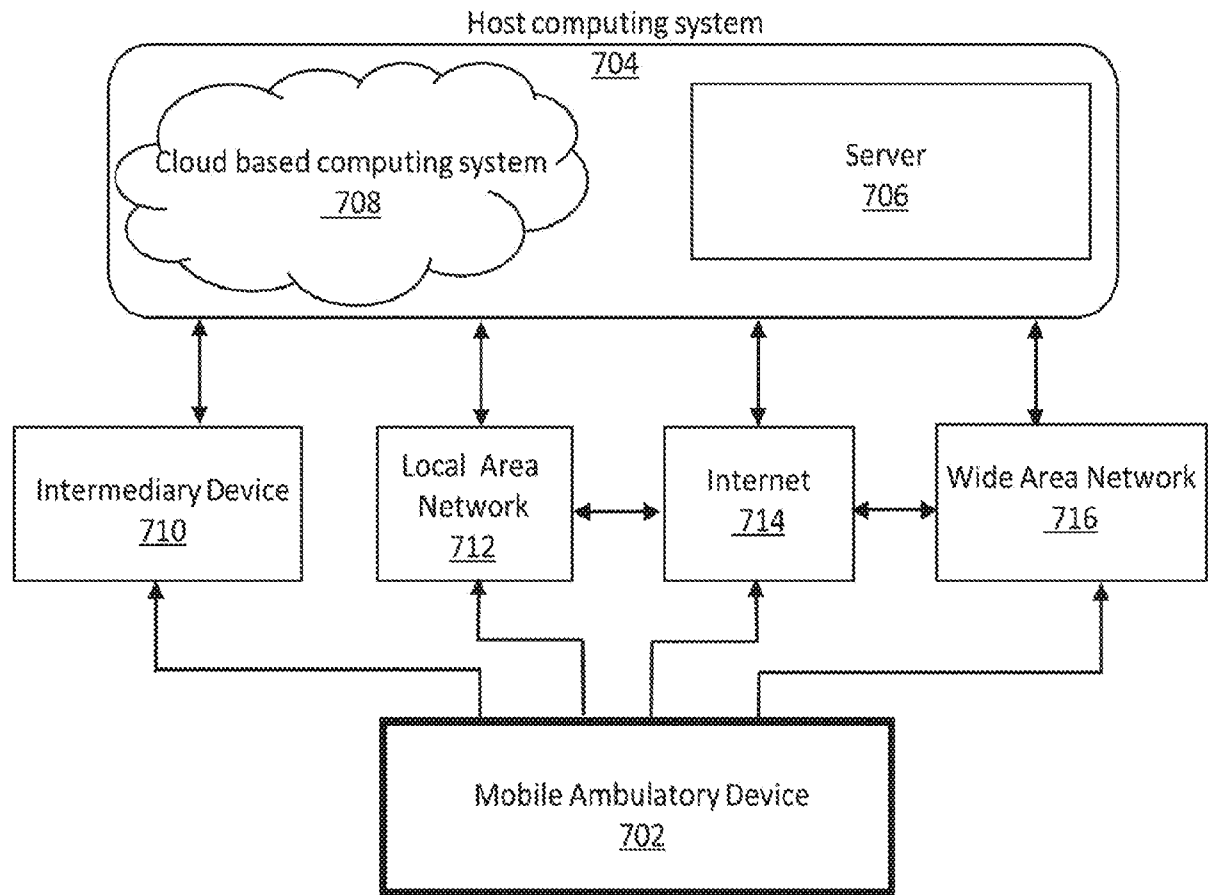


FIG. 8

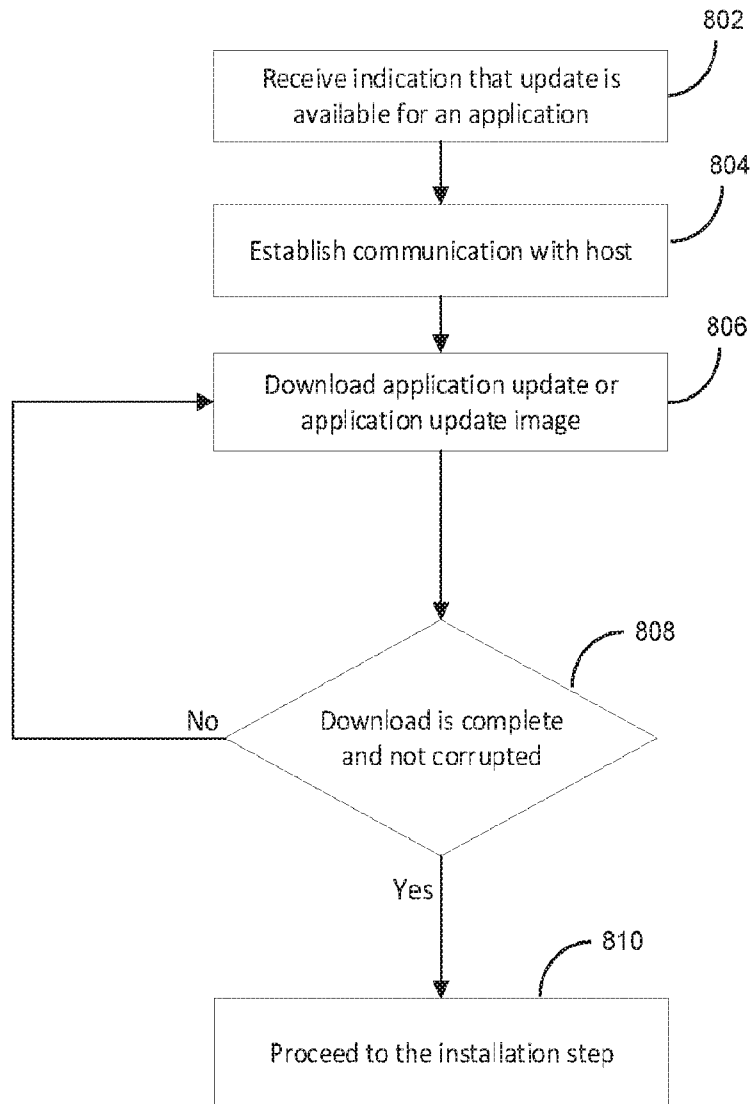


FIG. 9

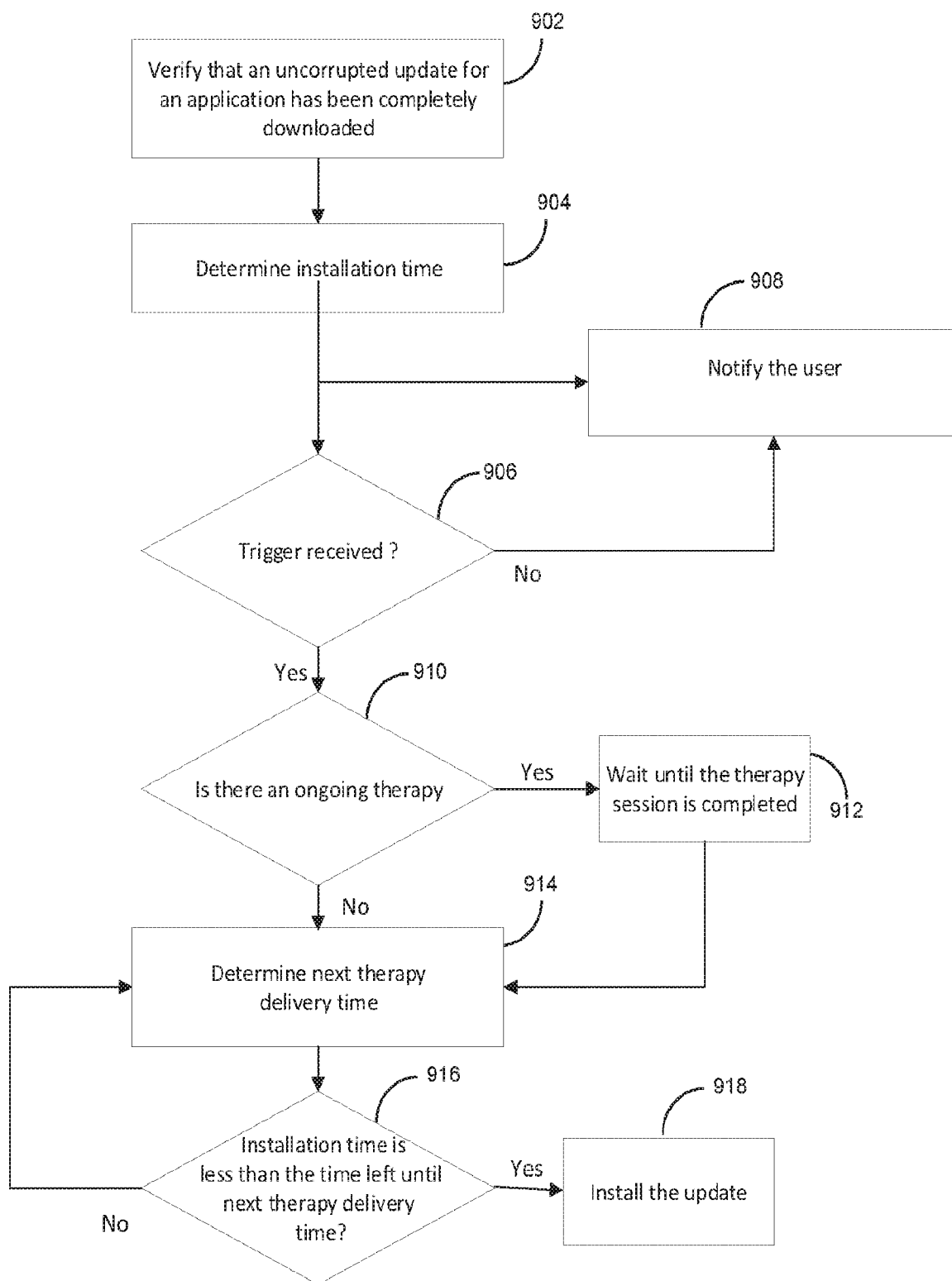


FIG. 10

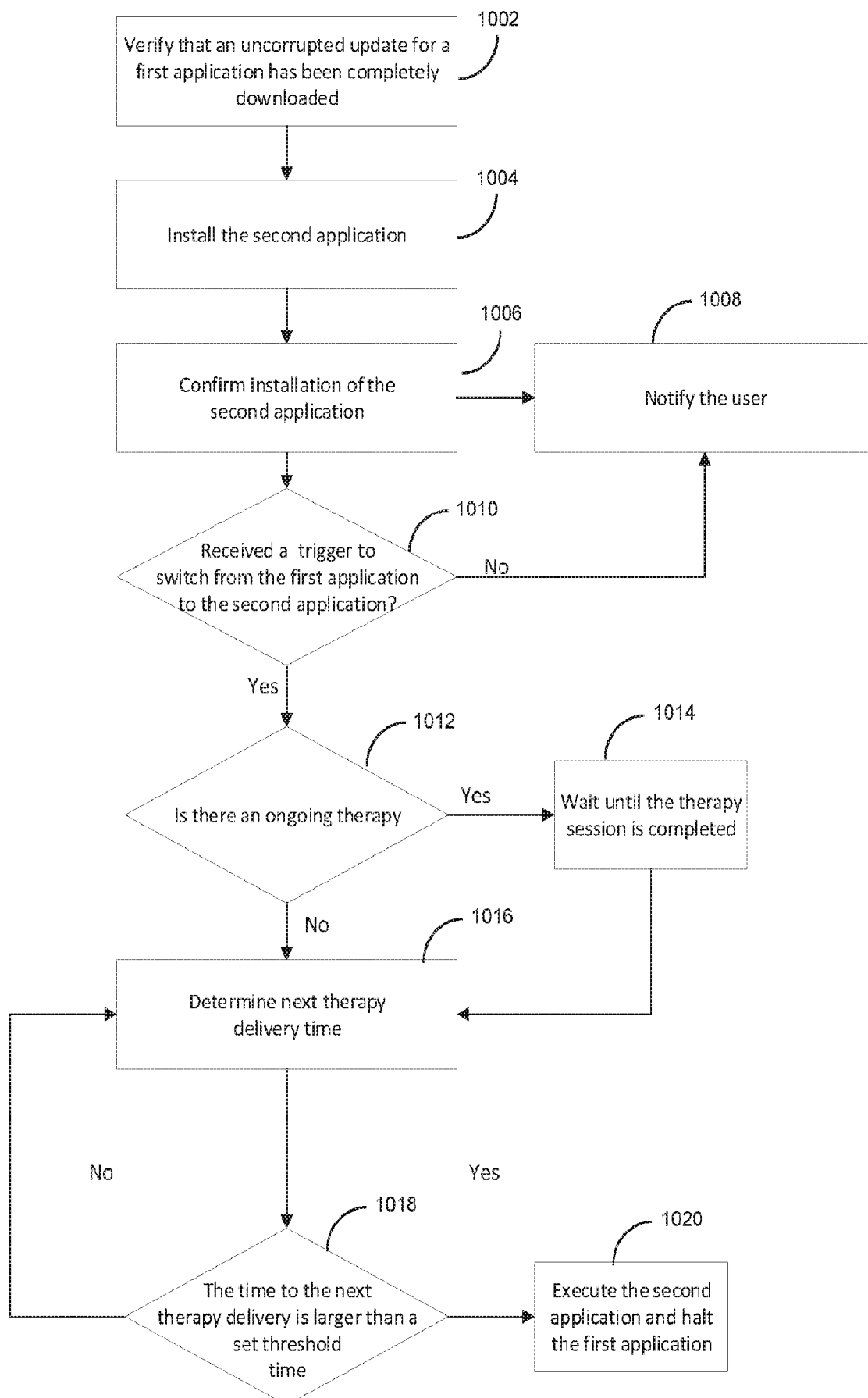
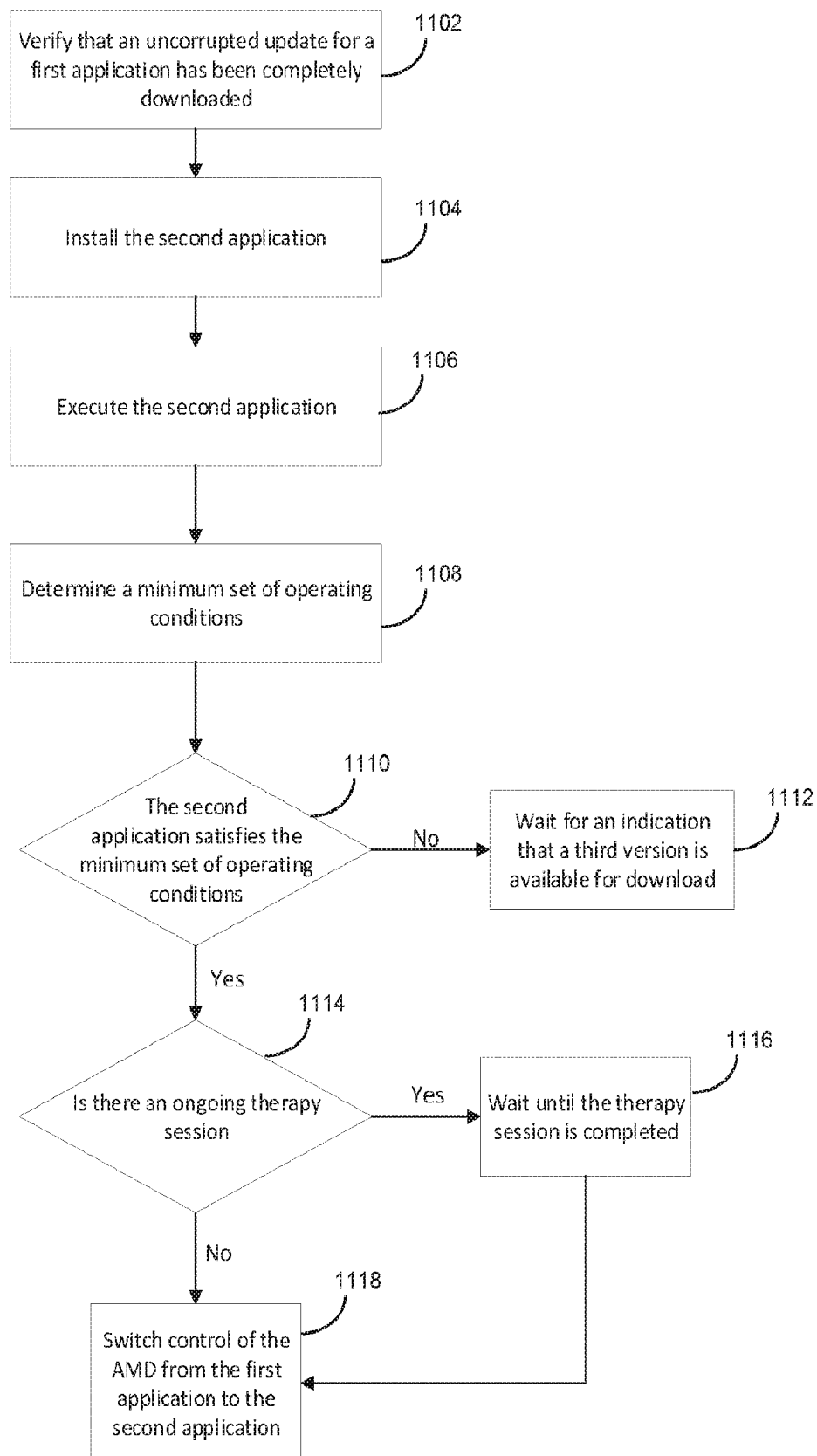


FIG. 11



12/44

FIG. 12

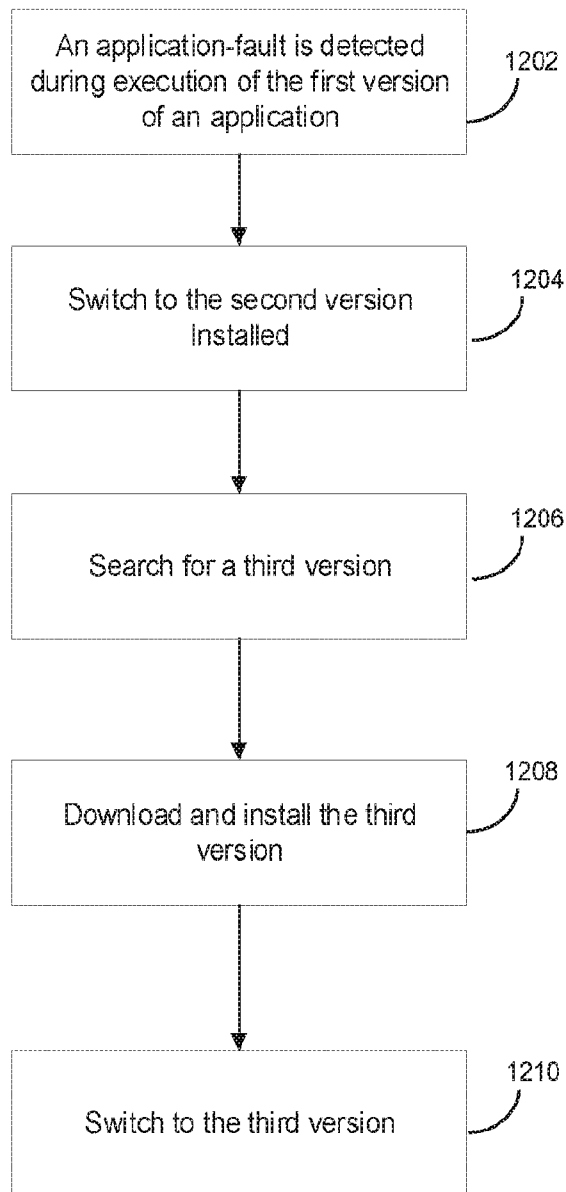


FIG. 13

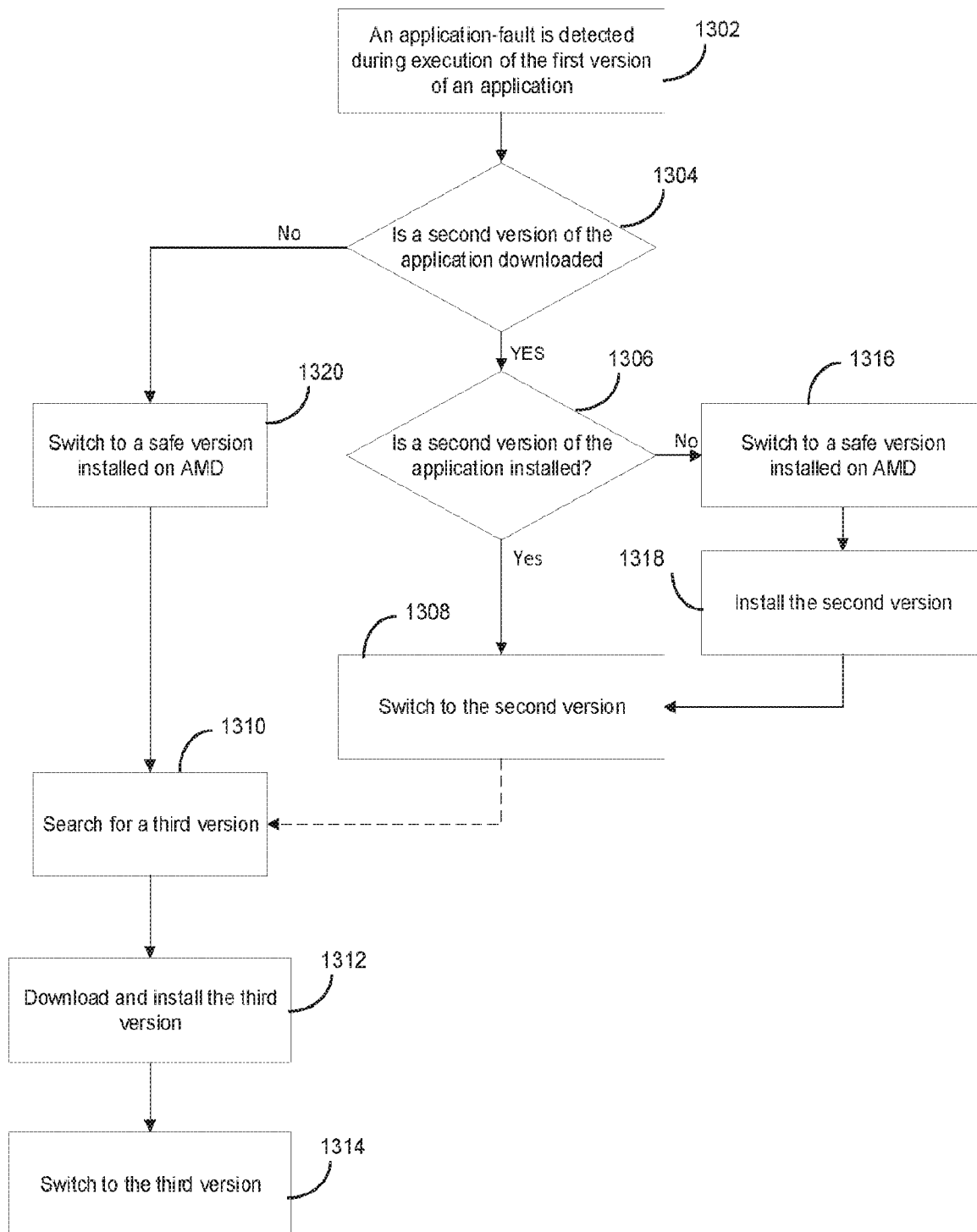
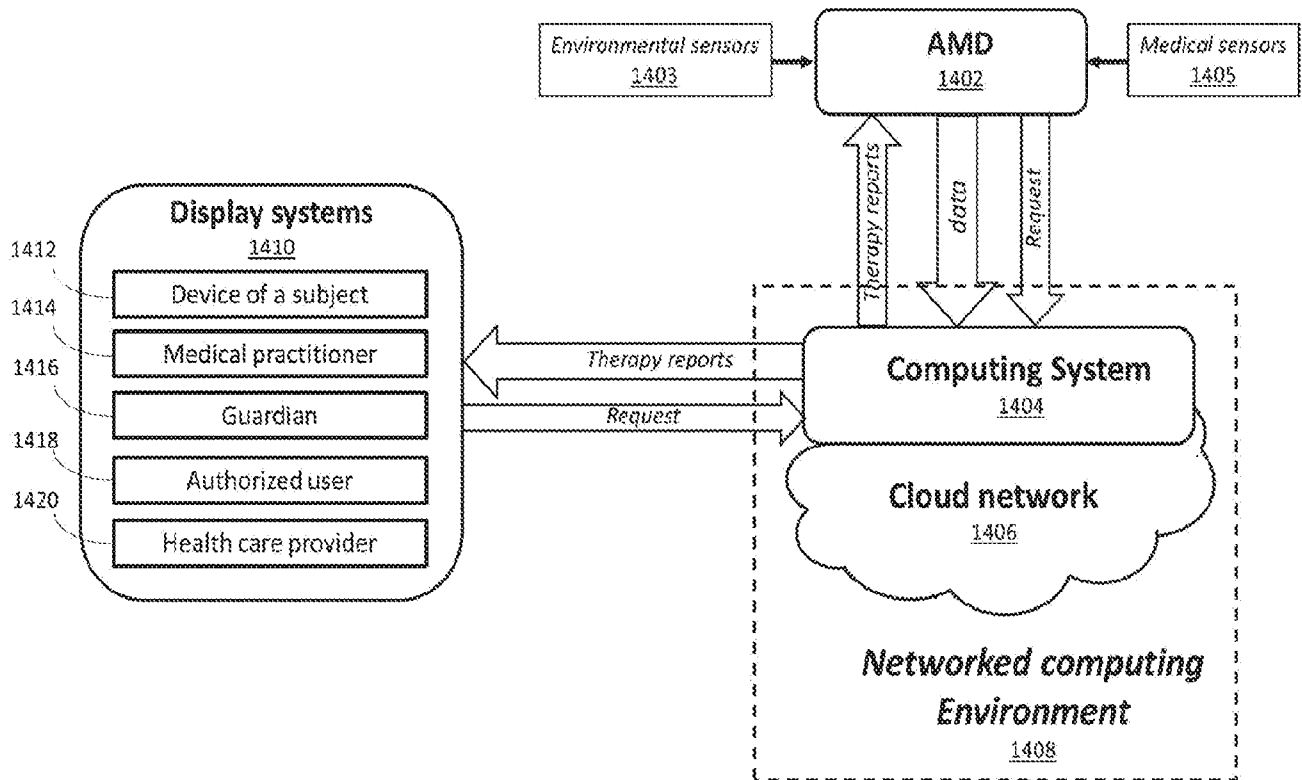


FIG. 14



15/44

FIG. 15

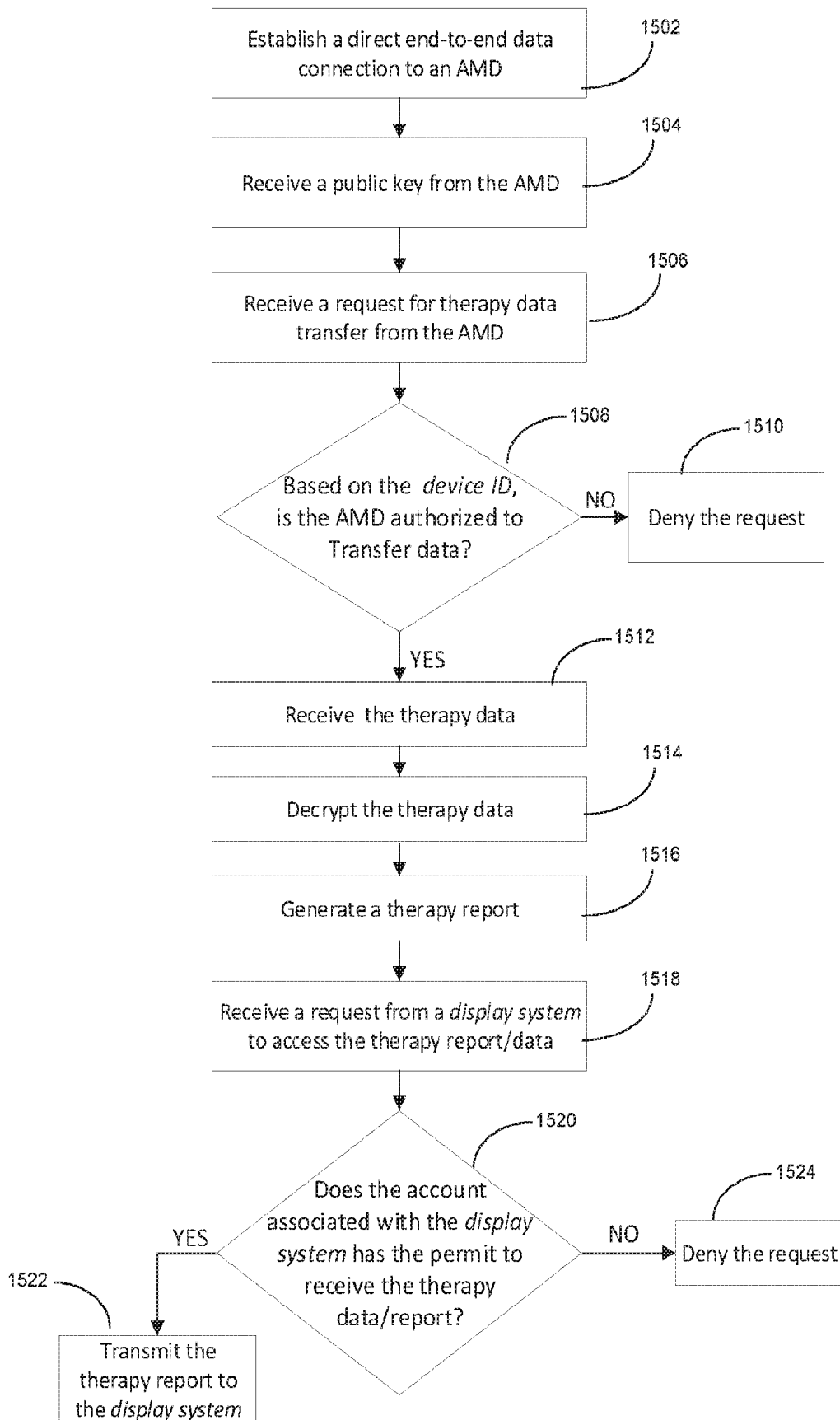


FIG. 16

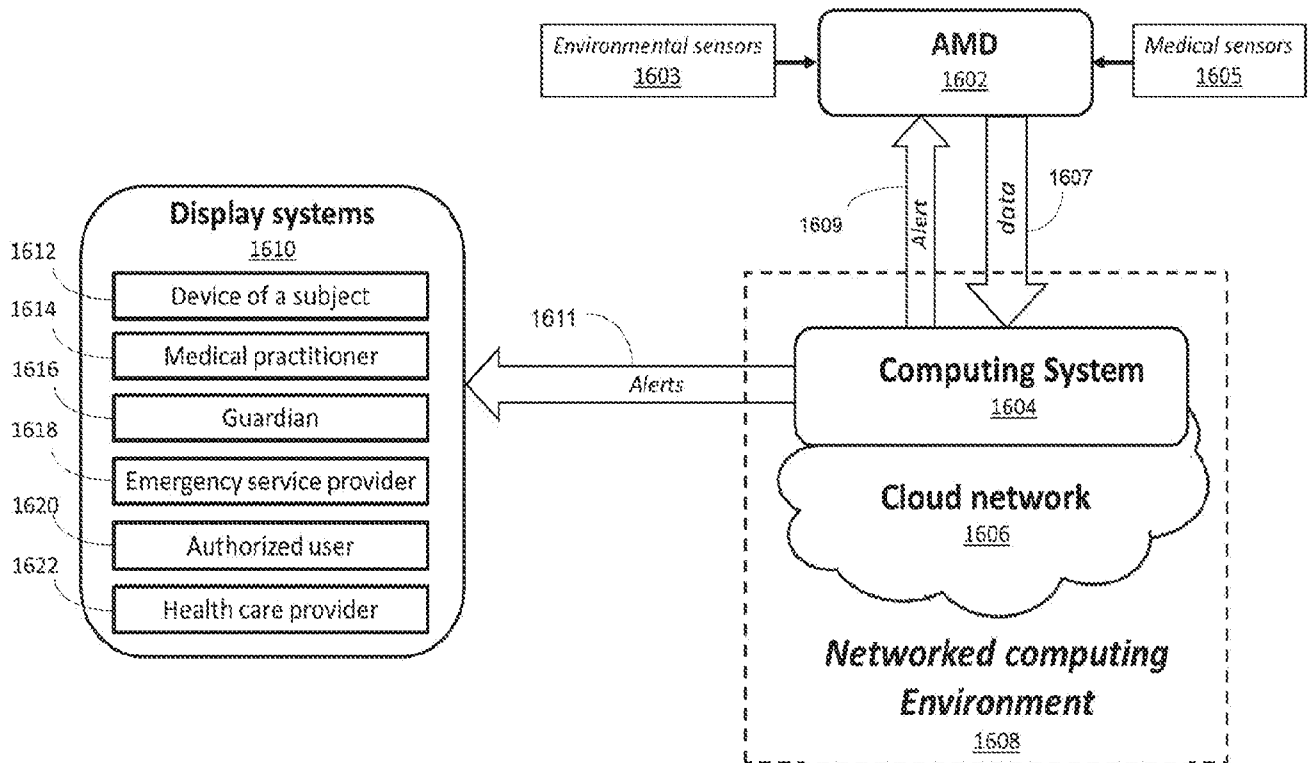


FIG. 17

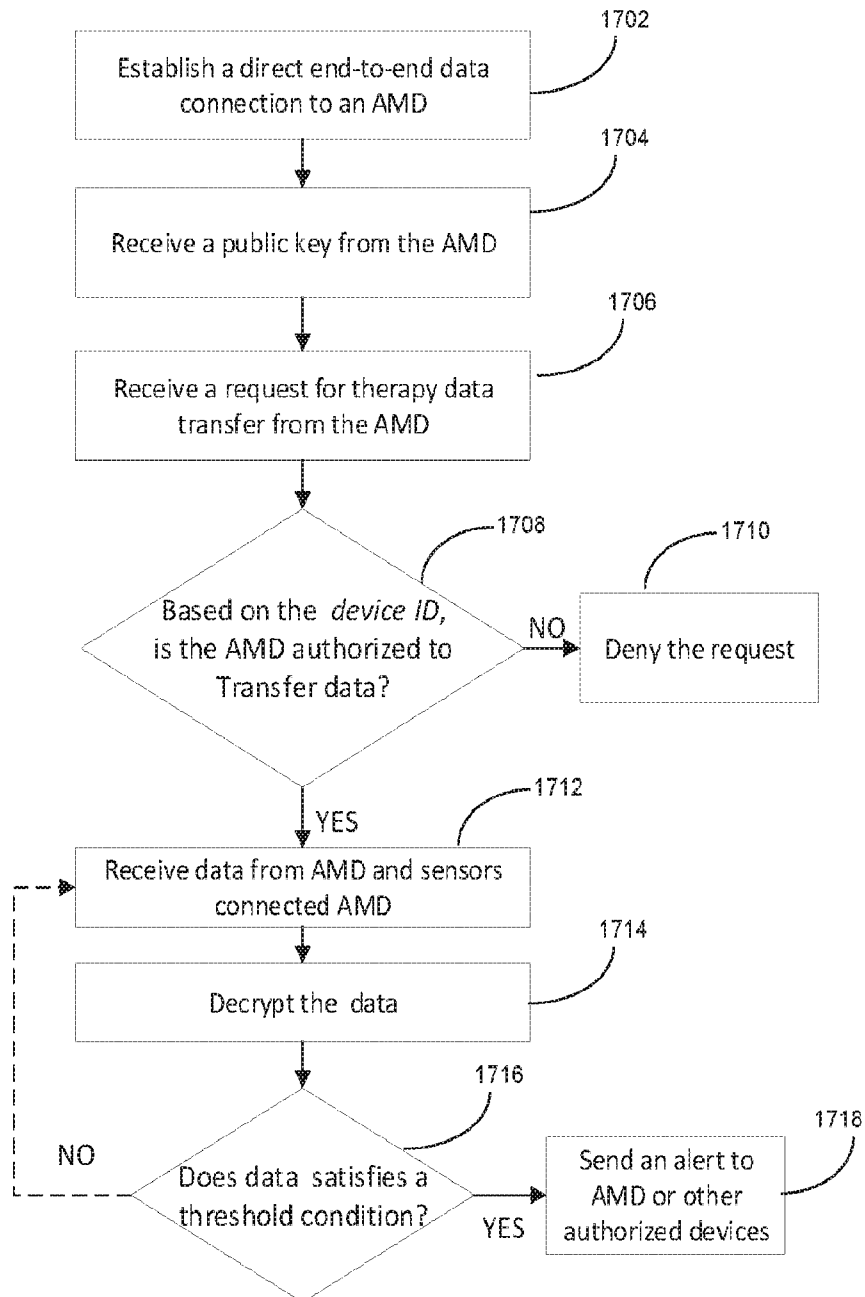
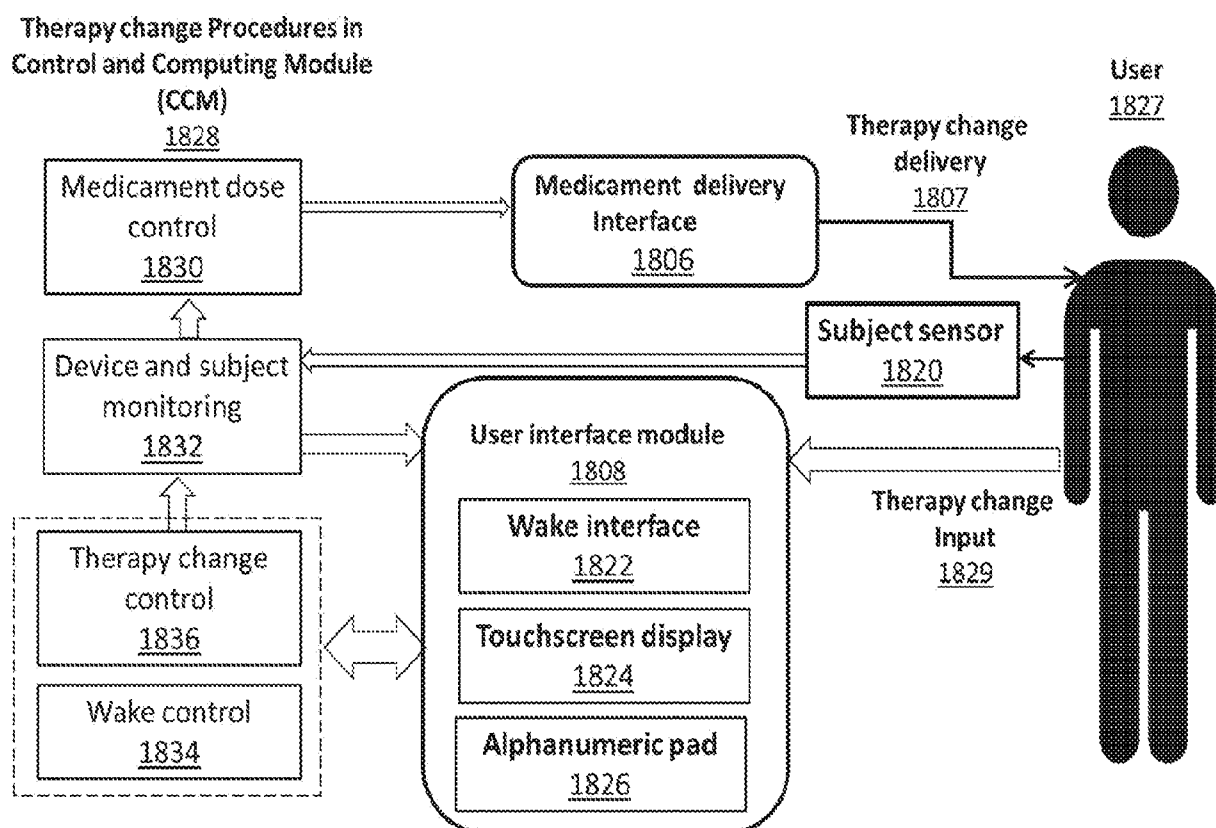


FIG. 18



19/44

FIG. 19

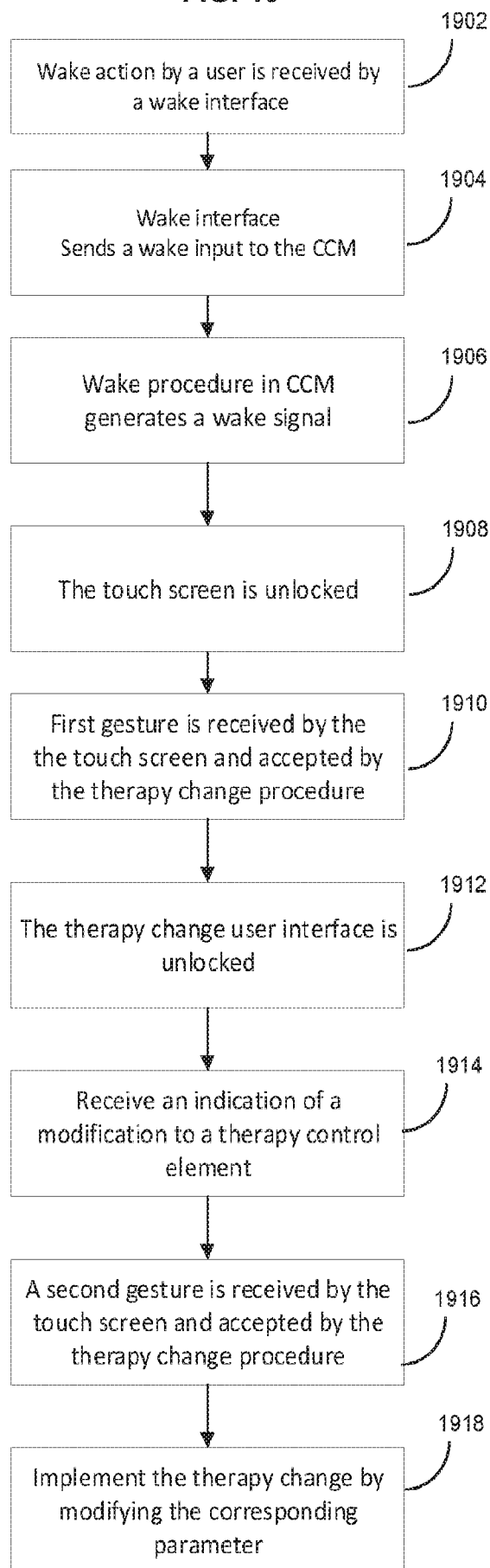
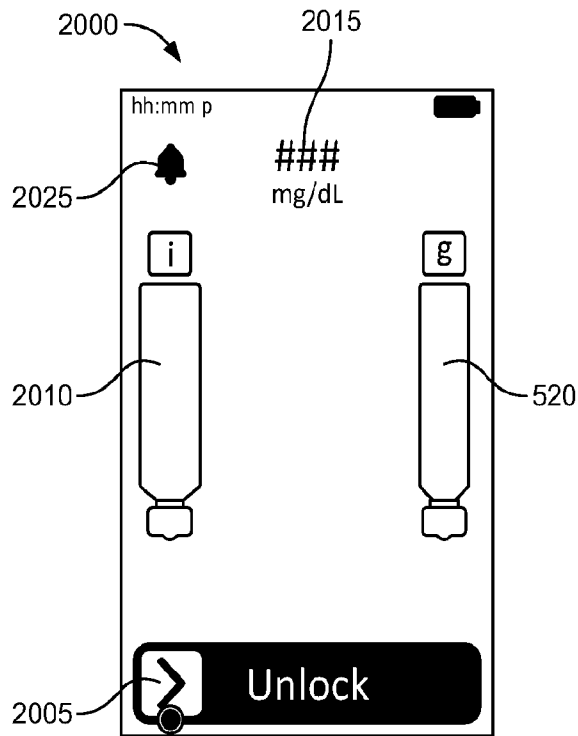
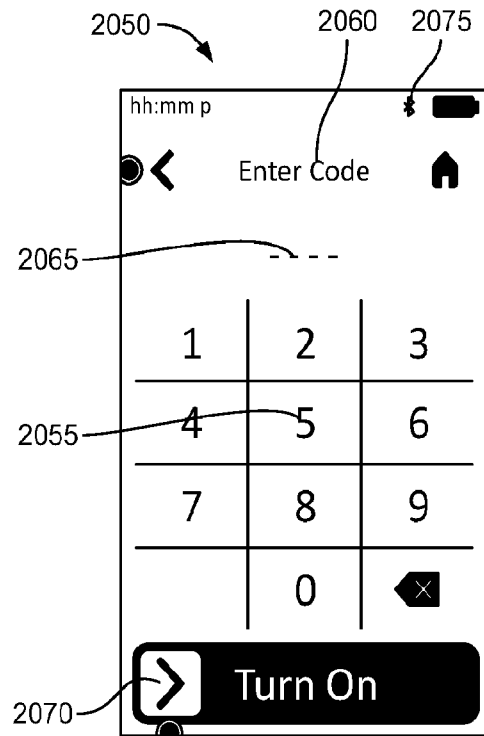


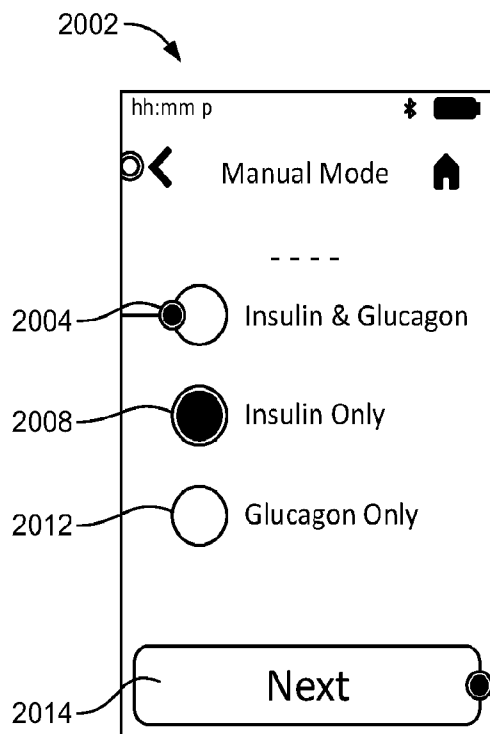
FIG. 20



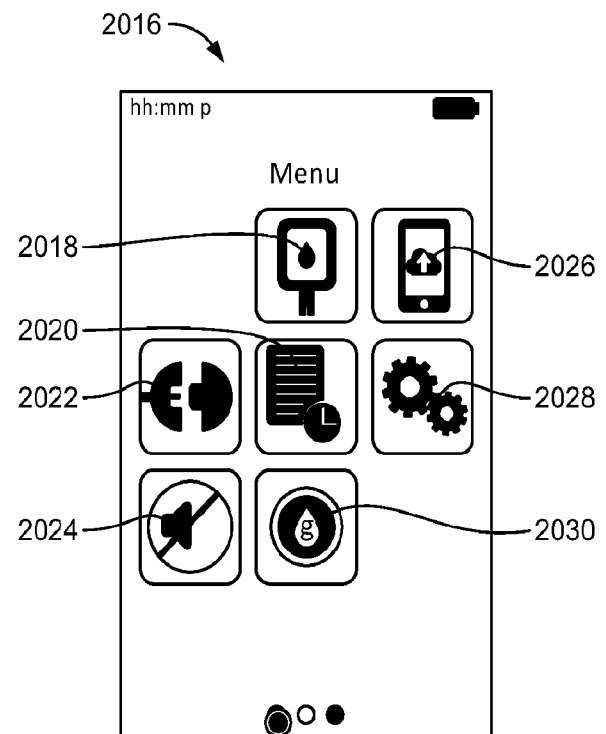
(A)



(B)

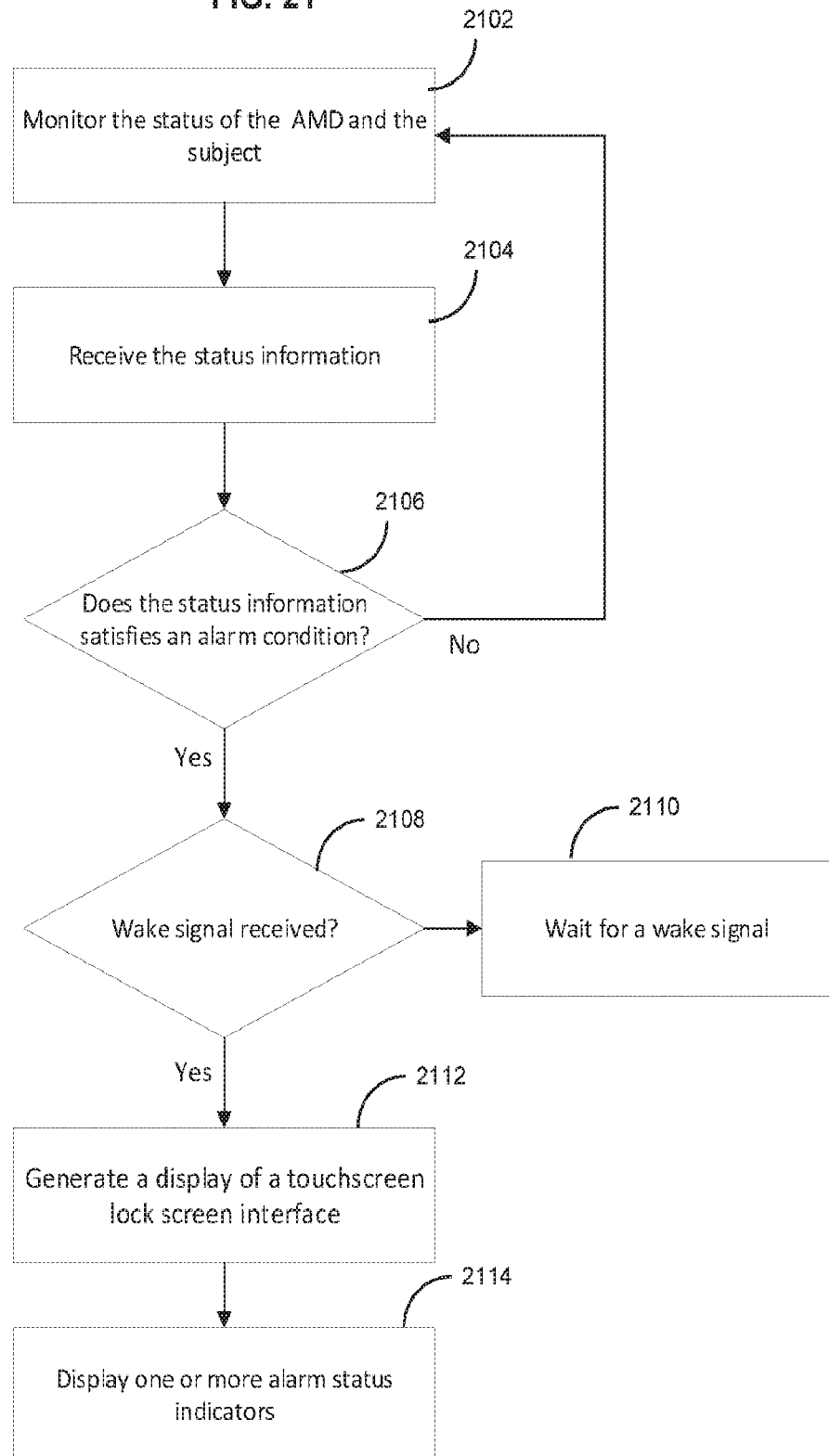


(C)



(D)

FIG. 21



22/44

FIG. 22

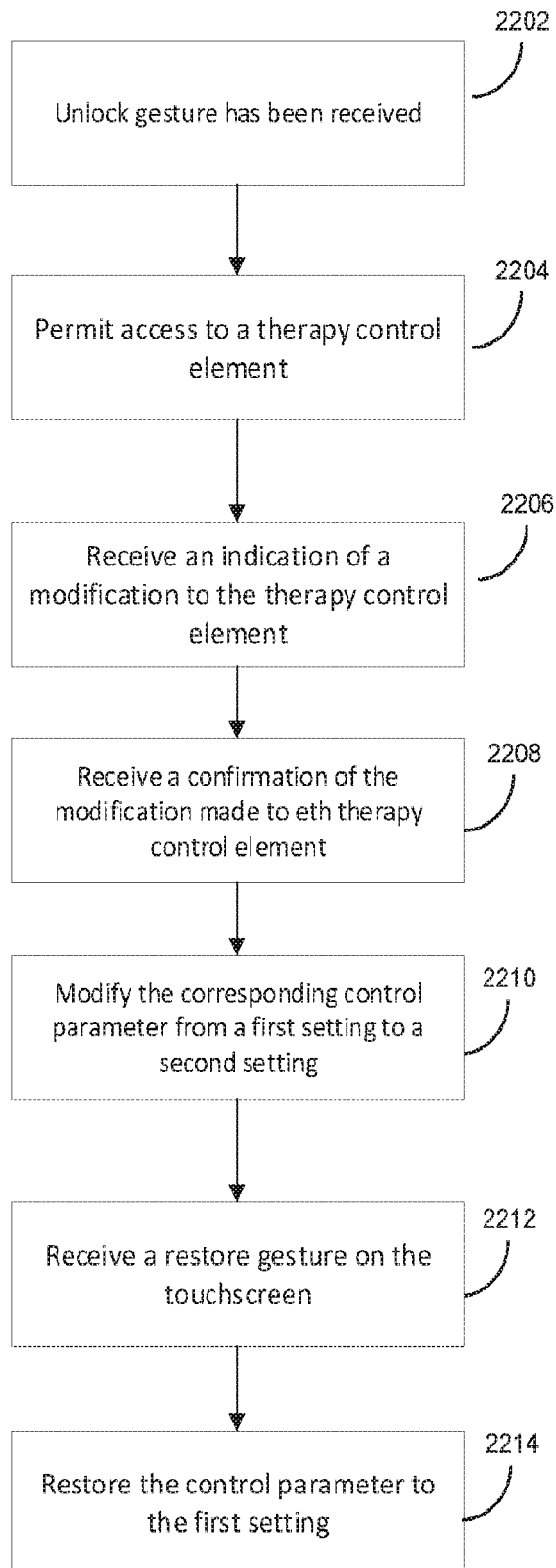


FIG. 23

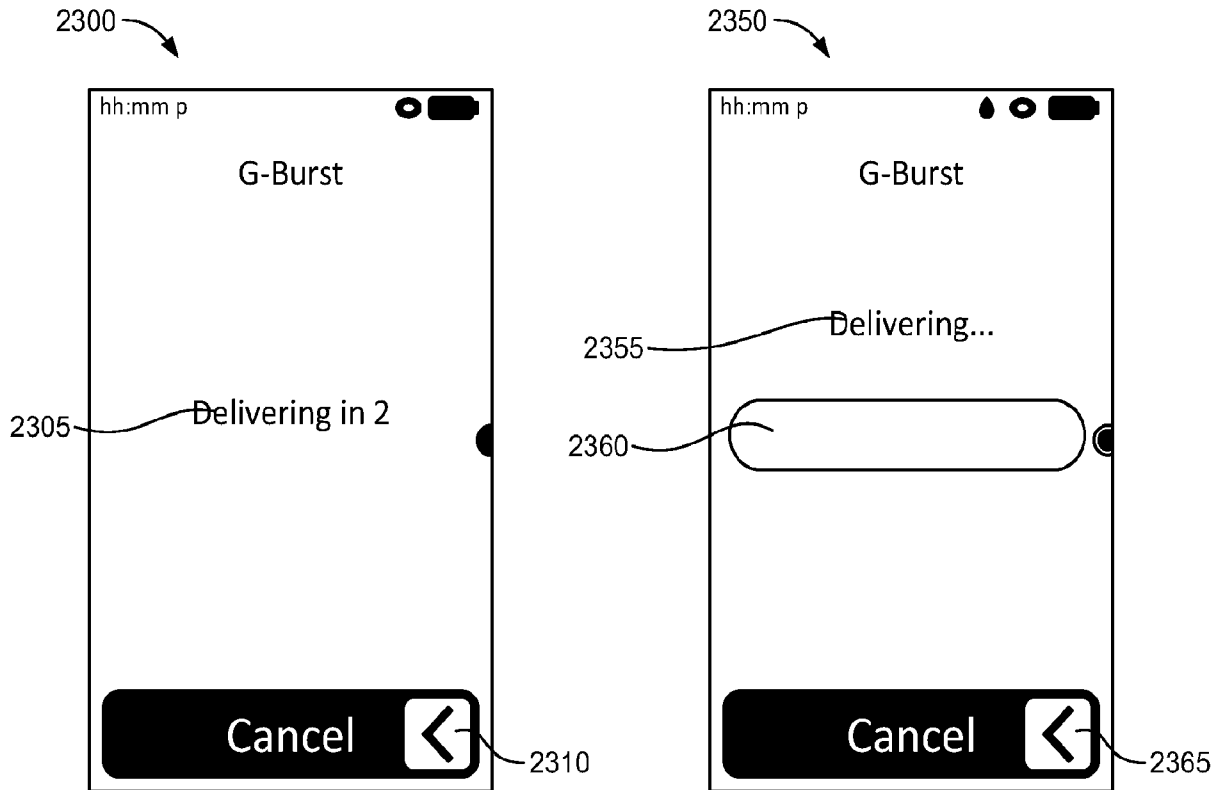


FIG. 24

Therapy Suspension Procedures in
Control and Computing Module
(CCM)
2428

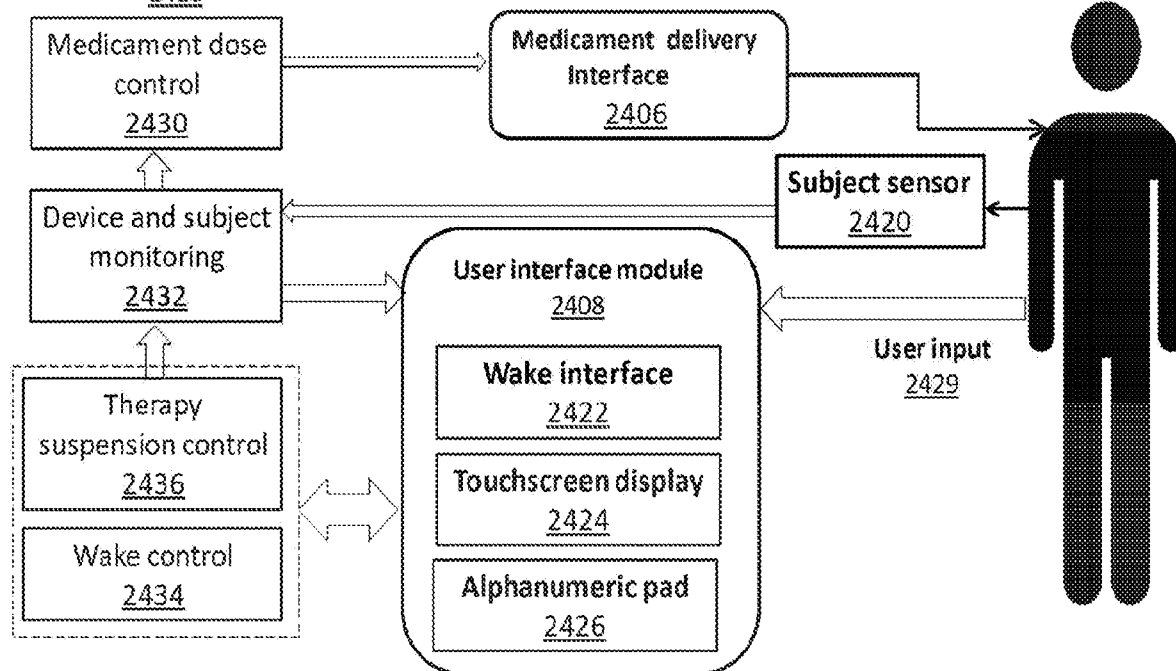


FIG. 25

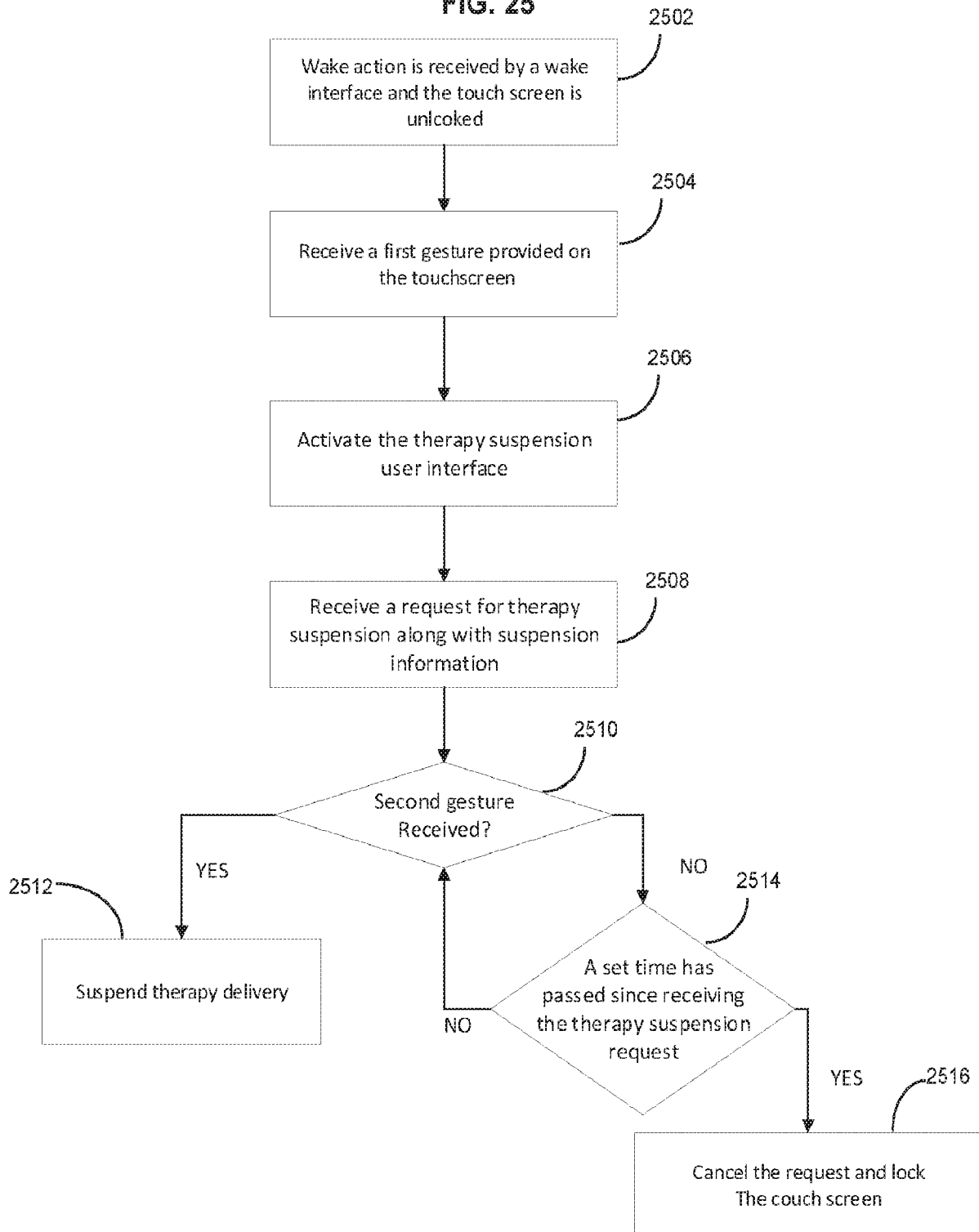


FIG. 26

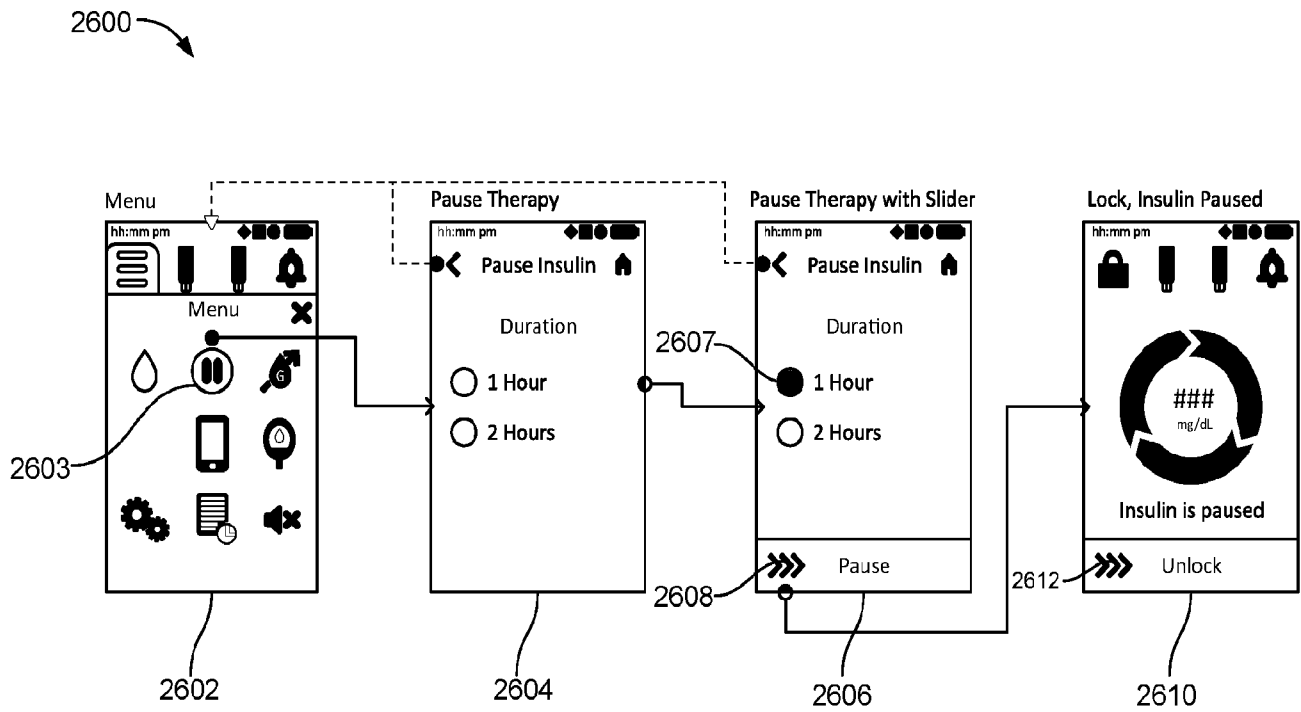


FIG. 27

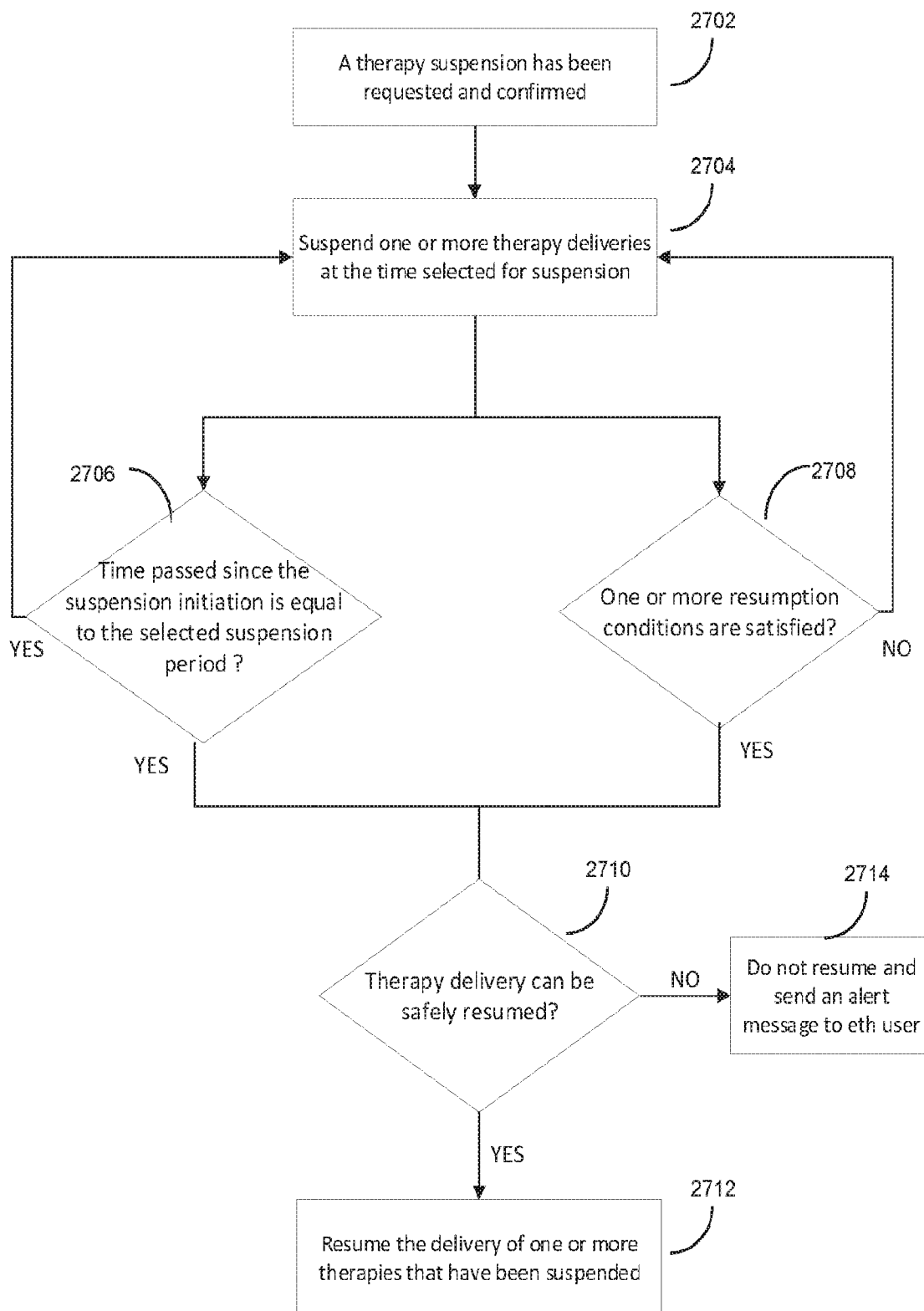


FIG. 28

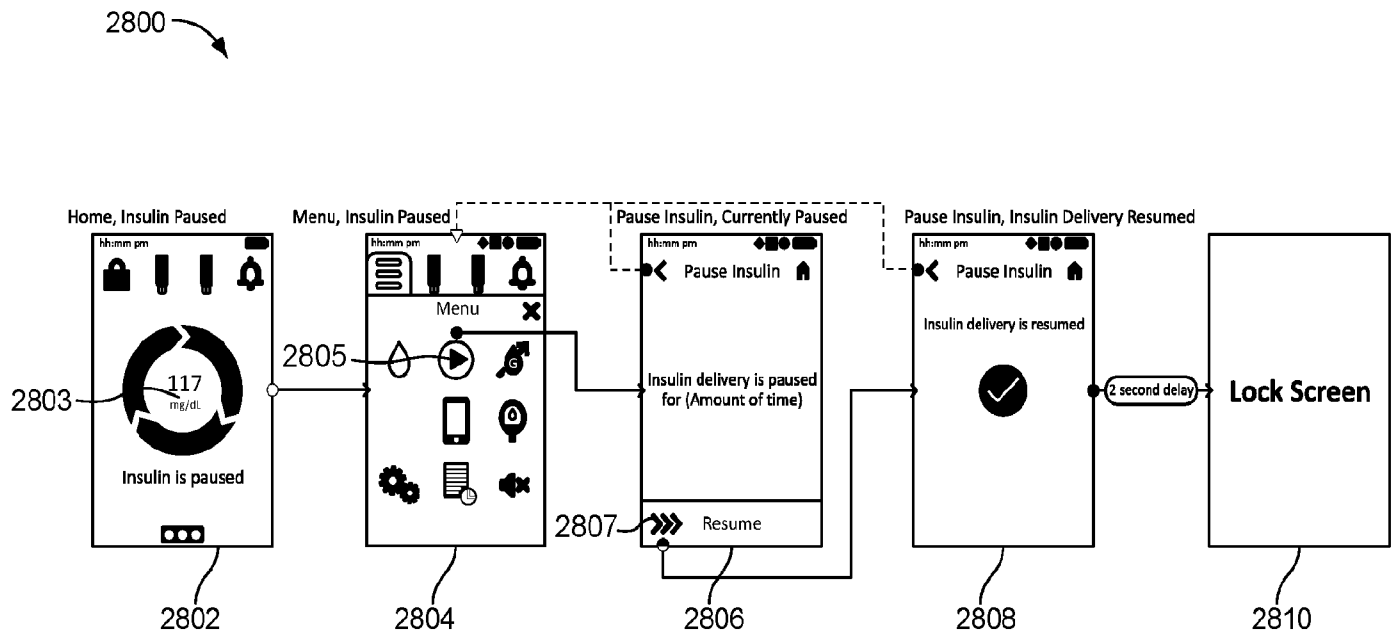


FIG. 29

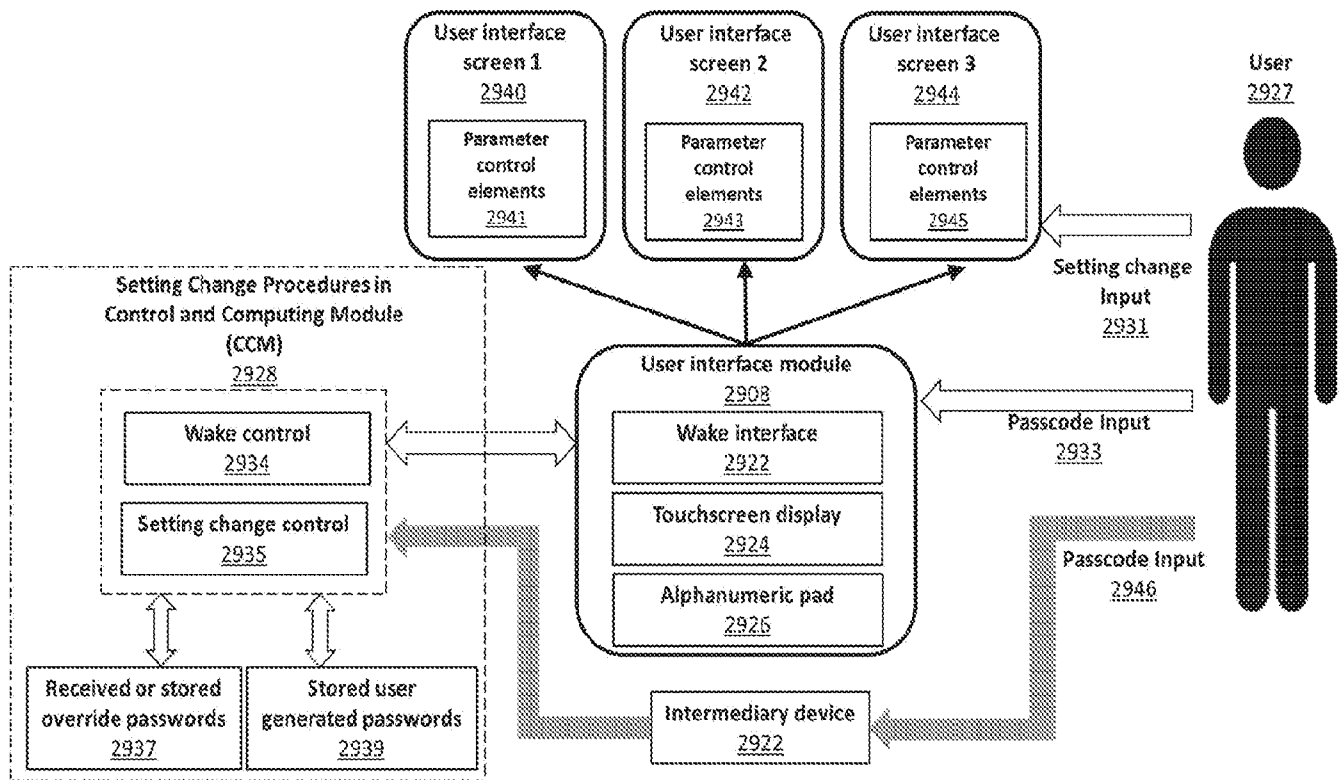


FIG. 30

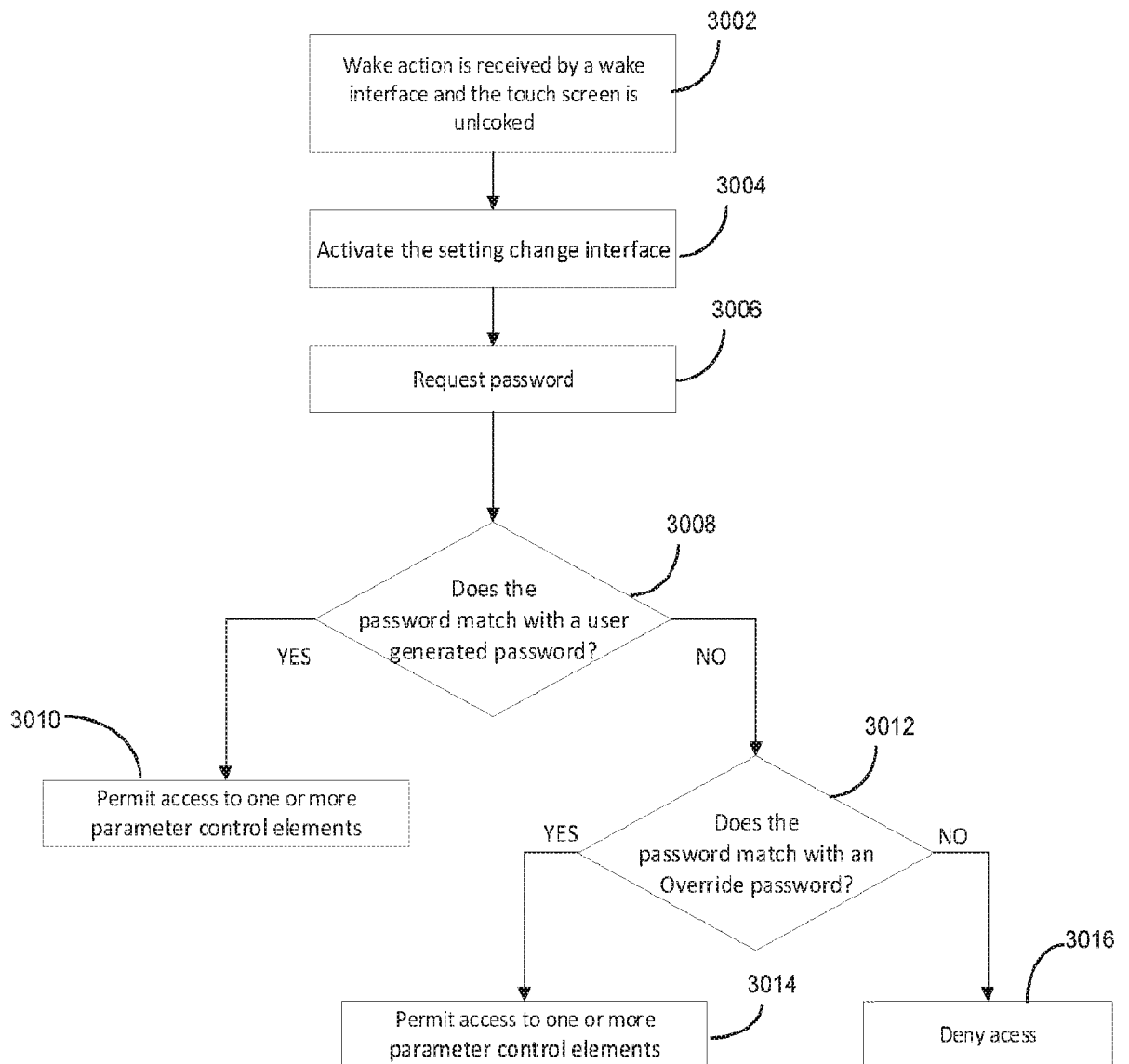


FIG. 31

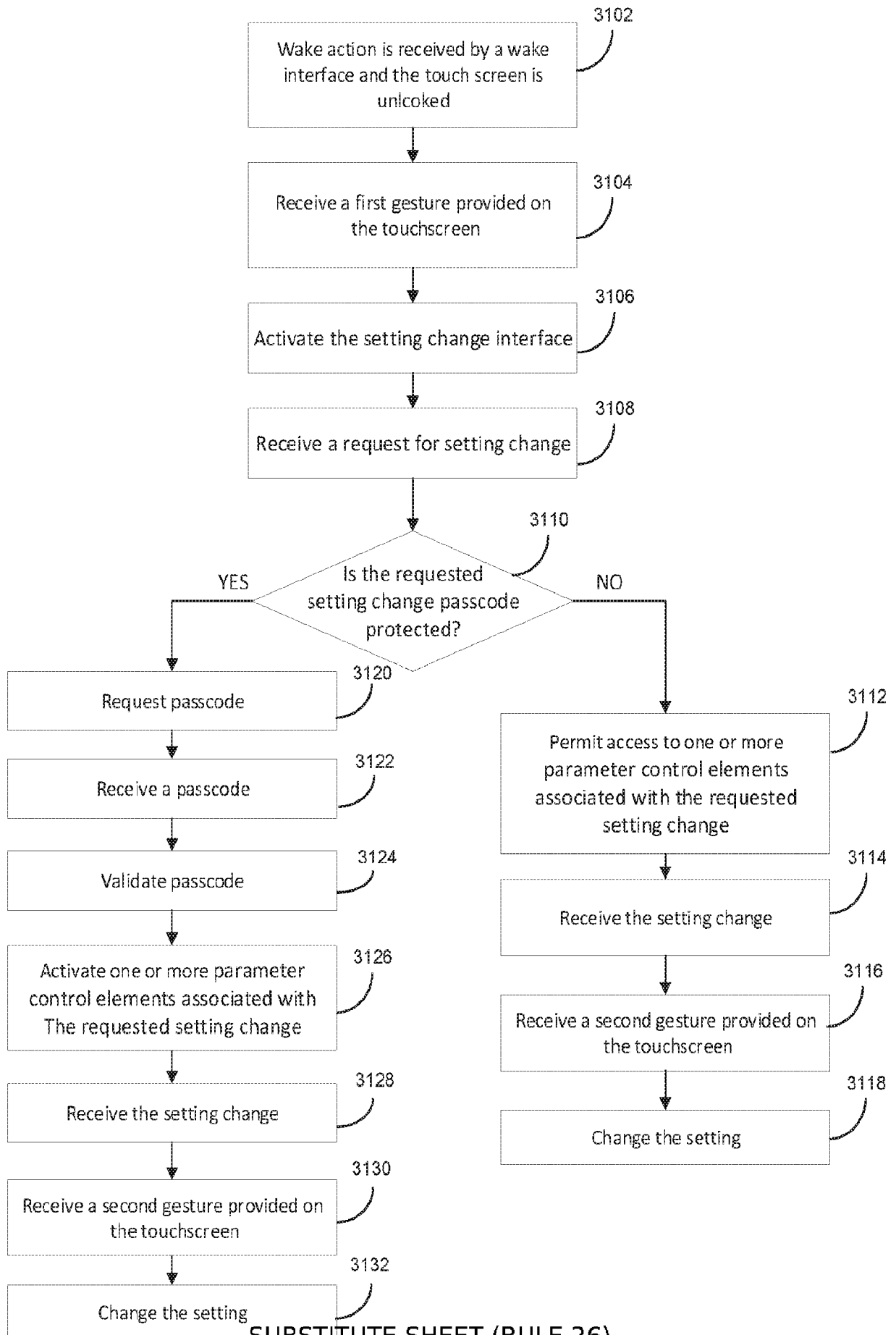


FIG. 32

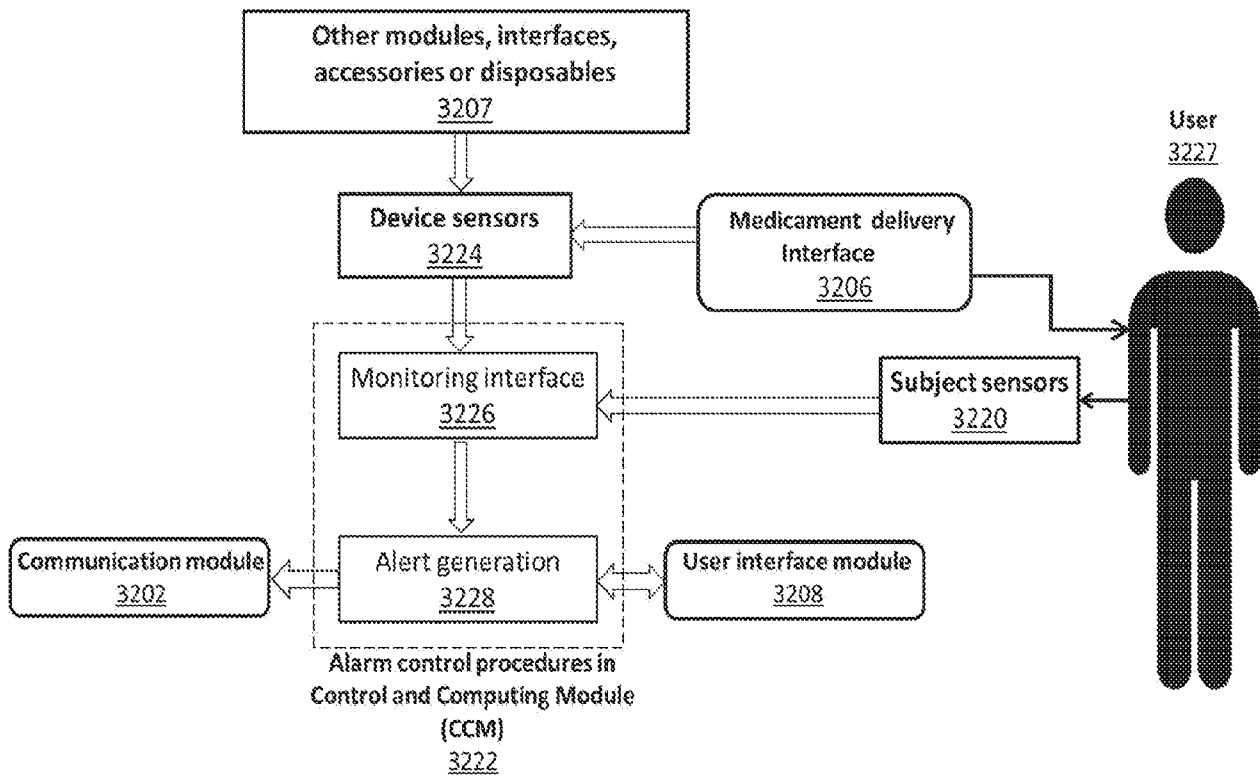


FIG. 33

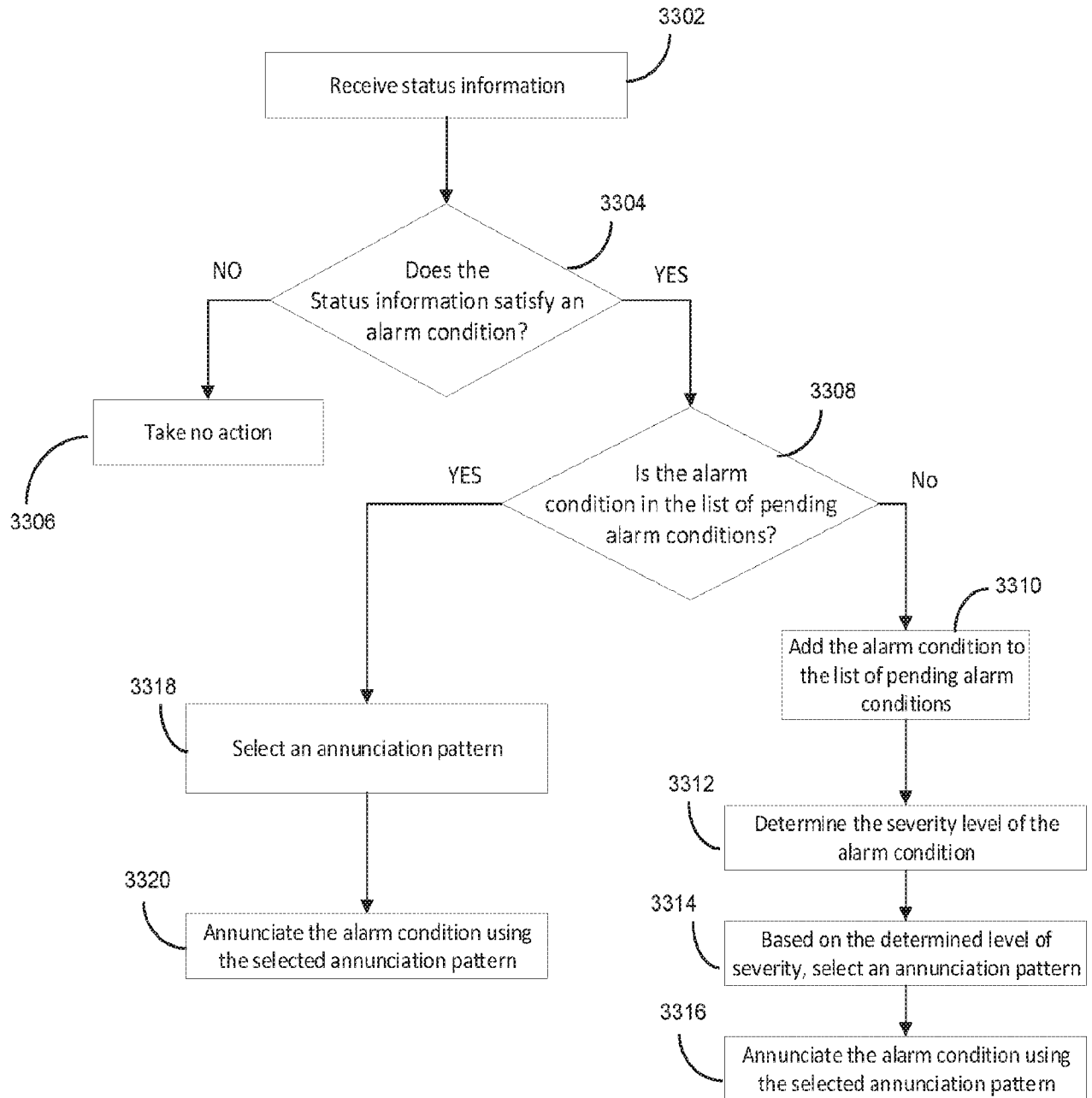


FIG. 34

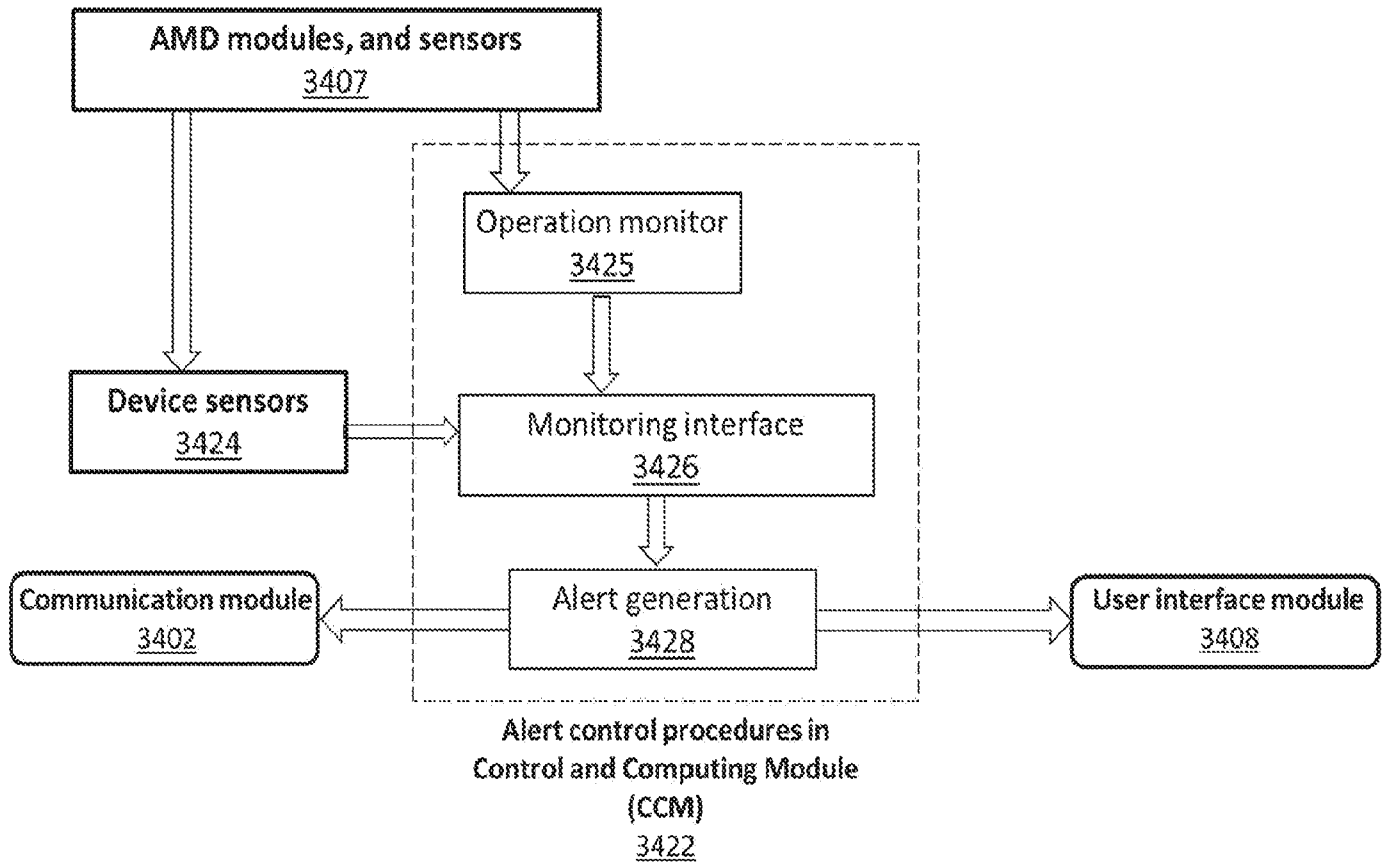


FIG. 35

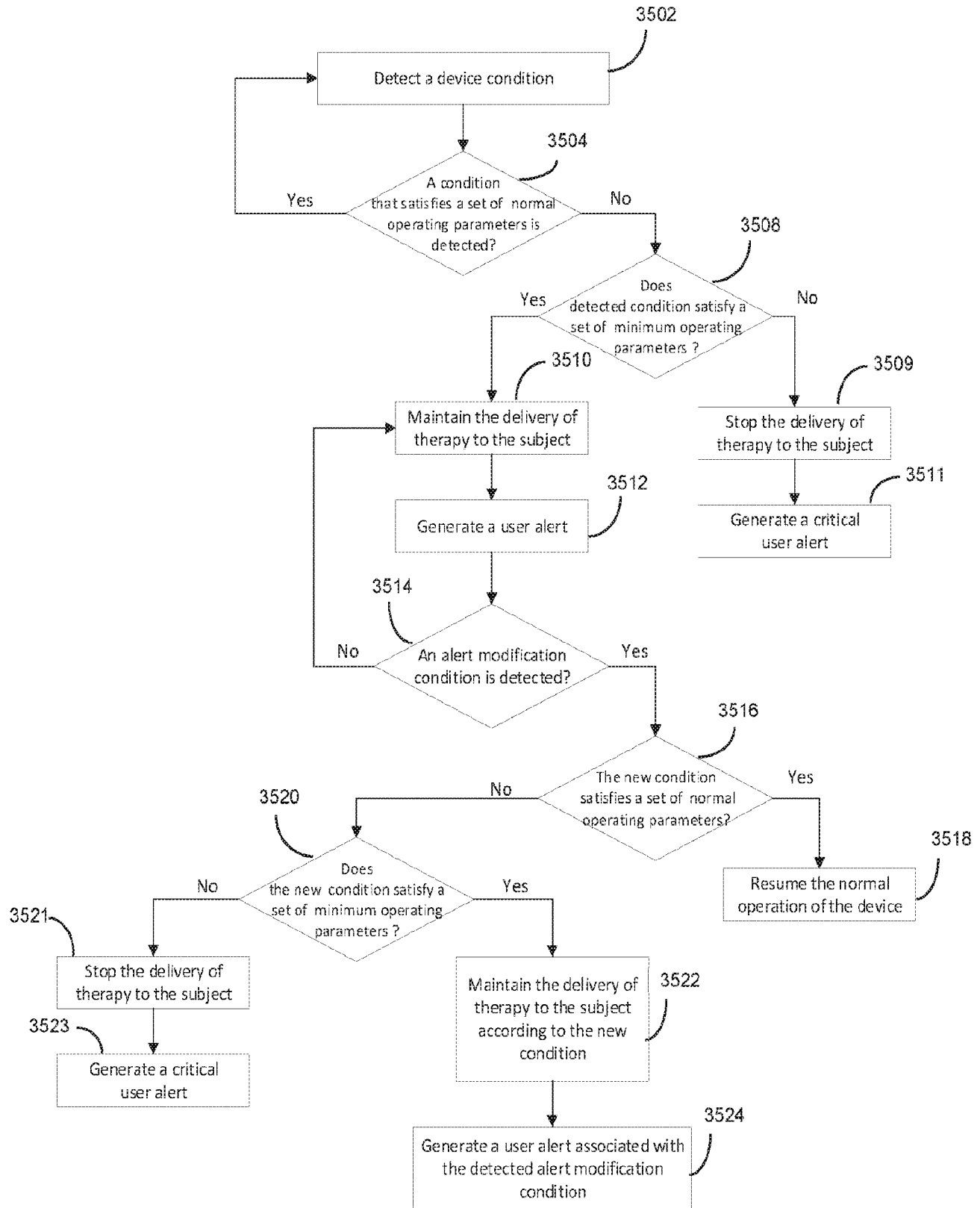


FIG. 36

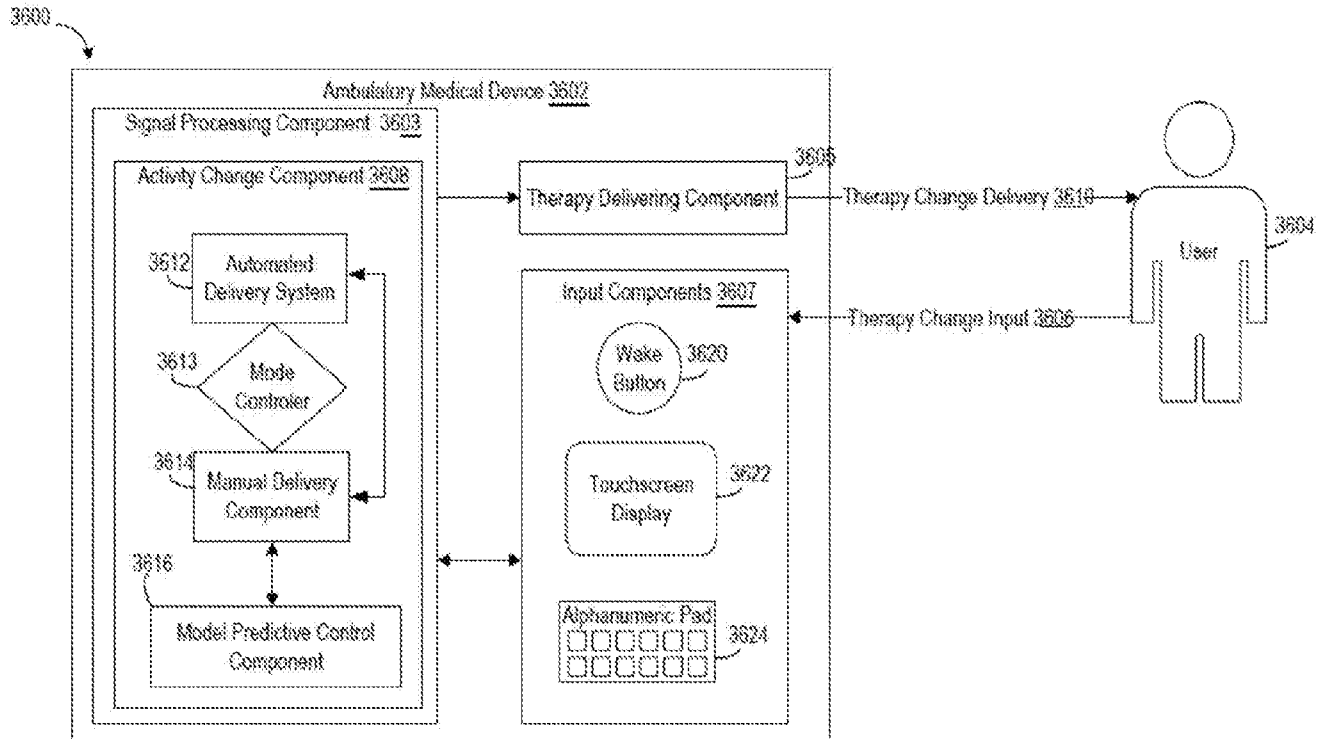


FIG. 37

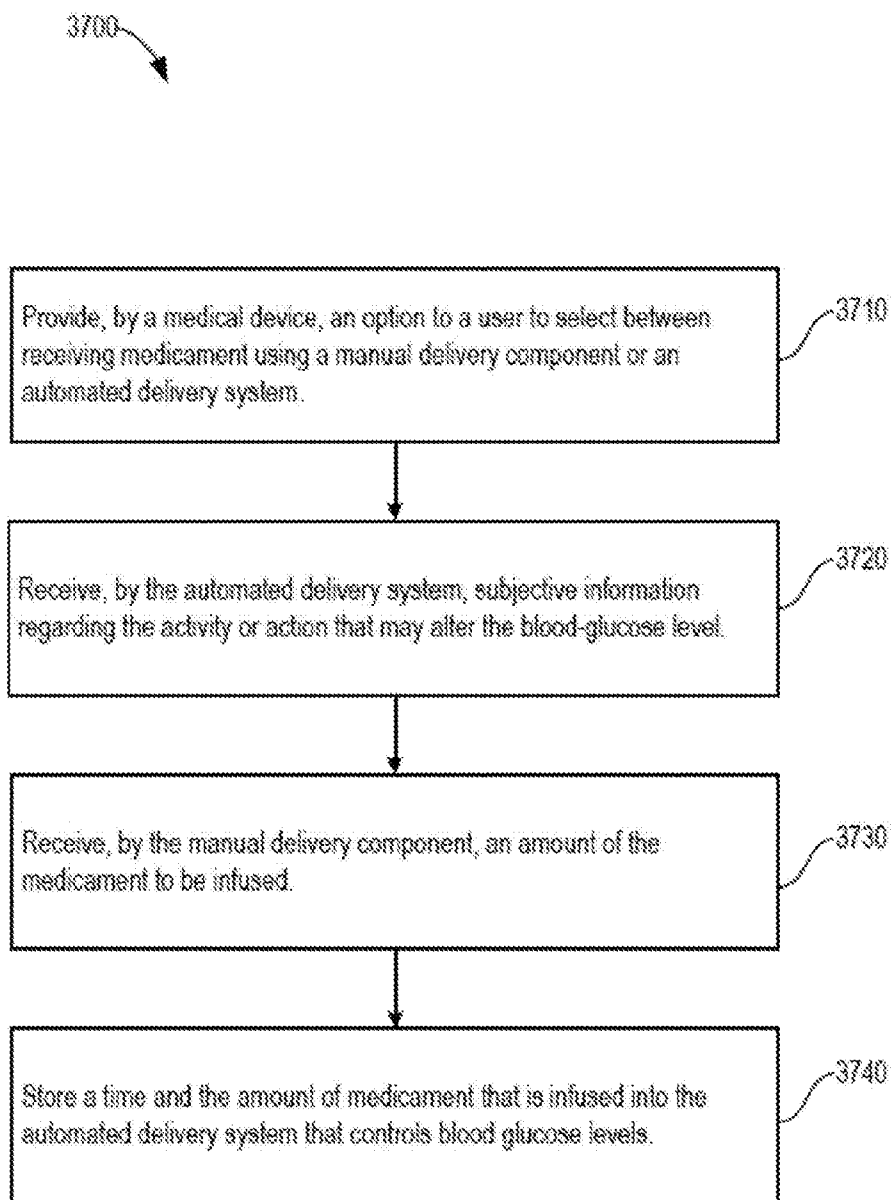


FIG. 38

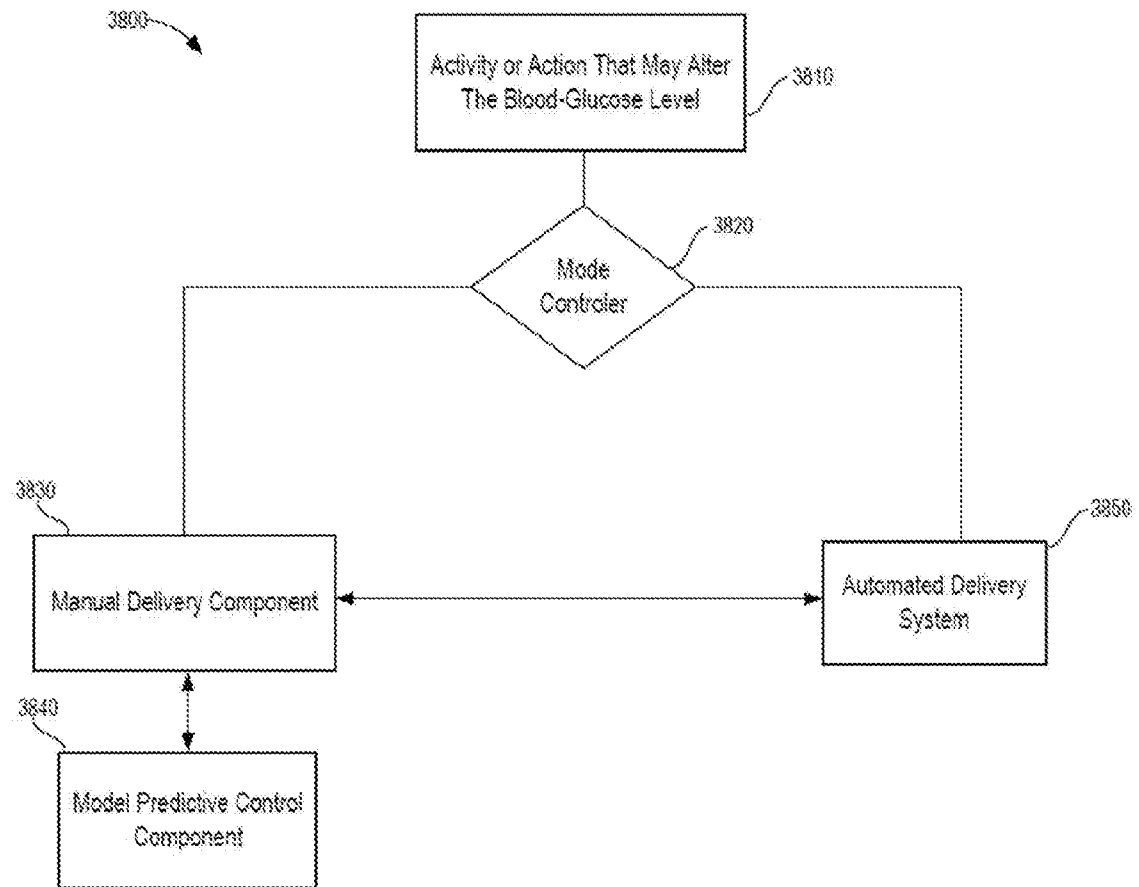


FIG. 39

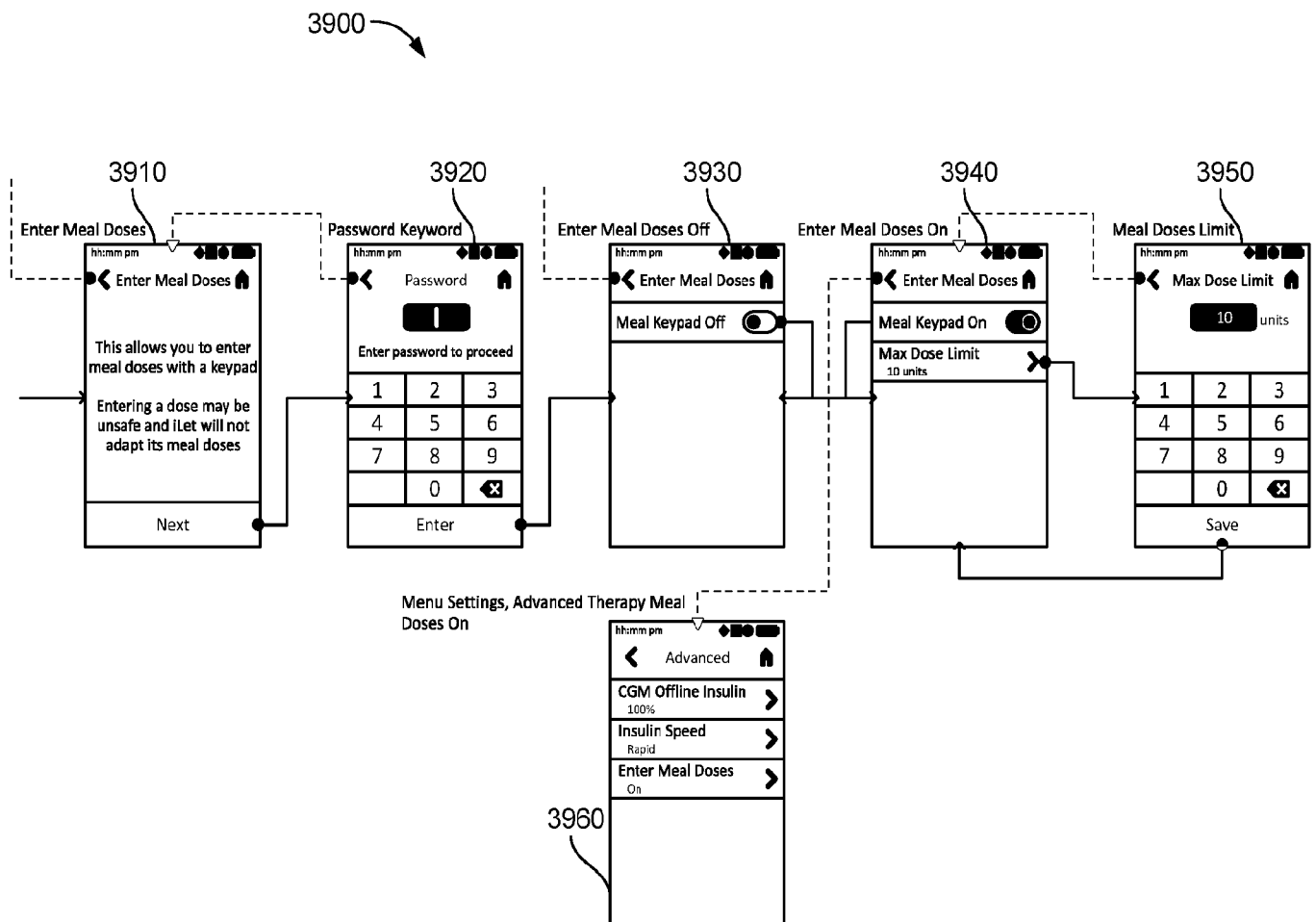


FIG. 40

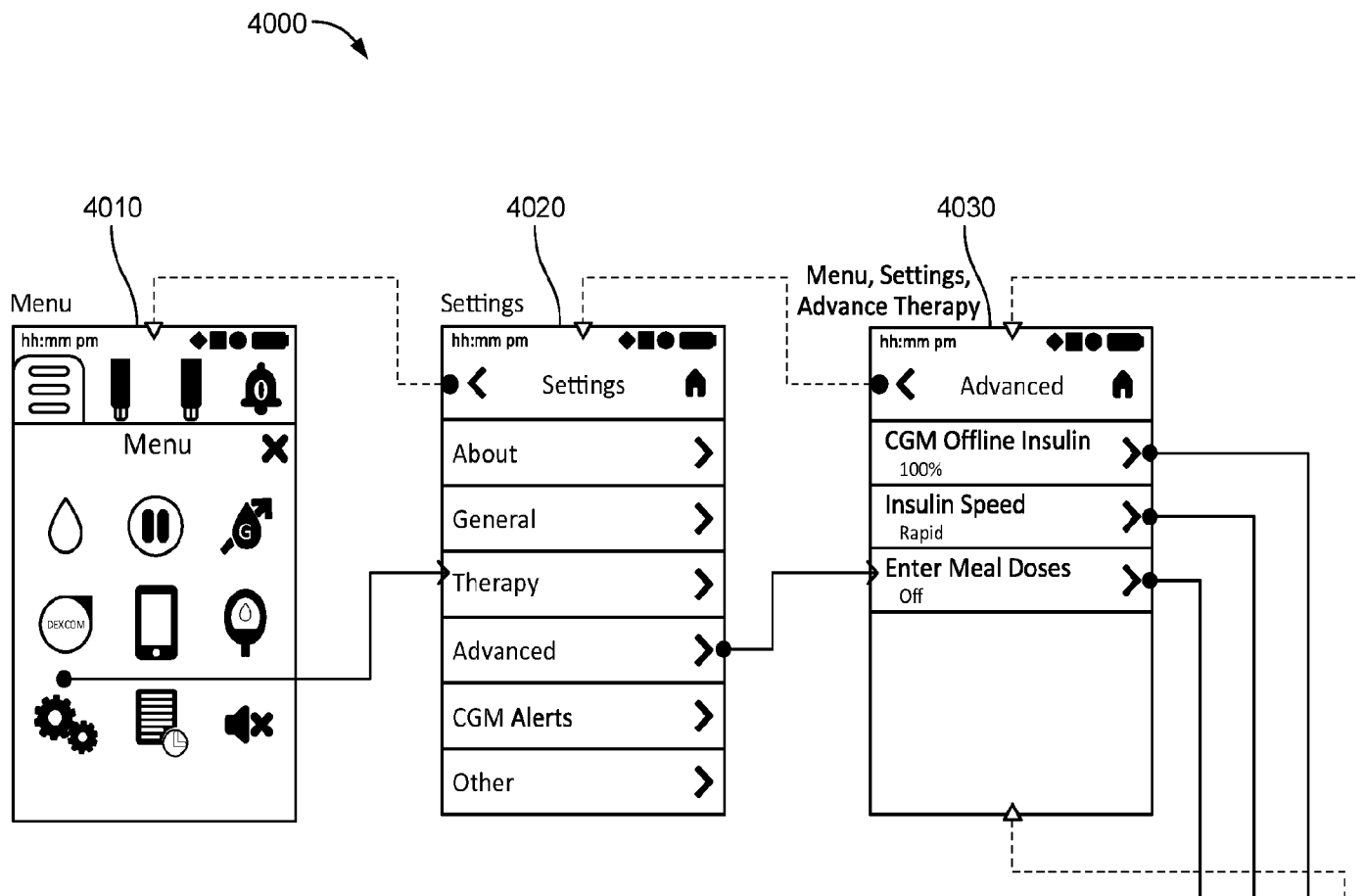


FIG. 41

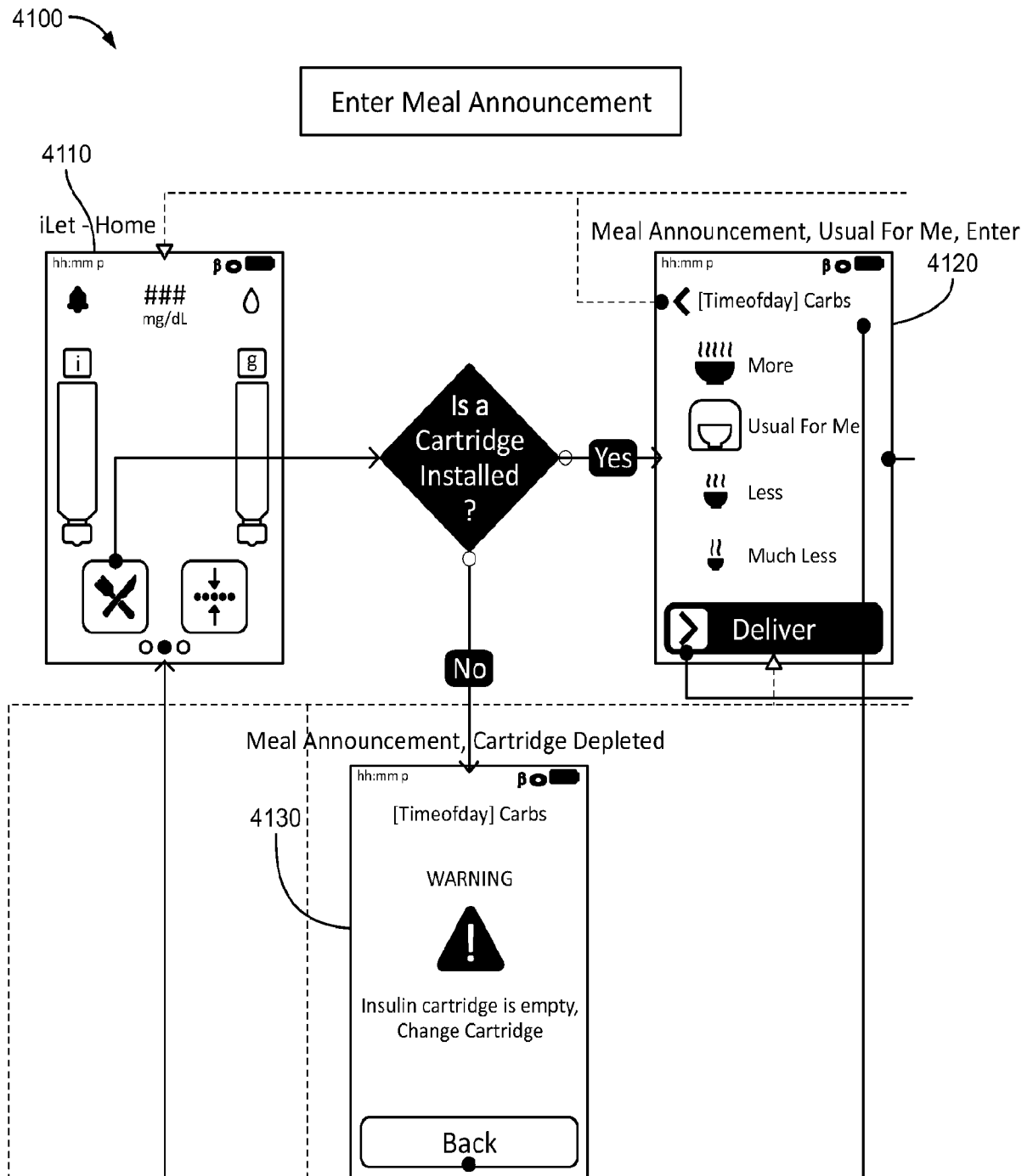


FIG. 42

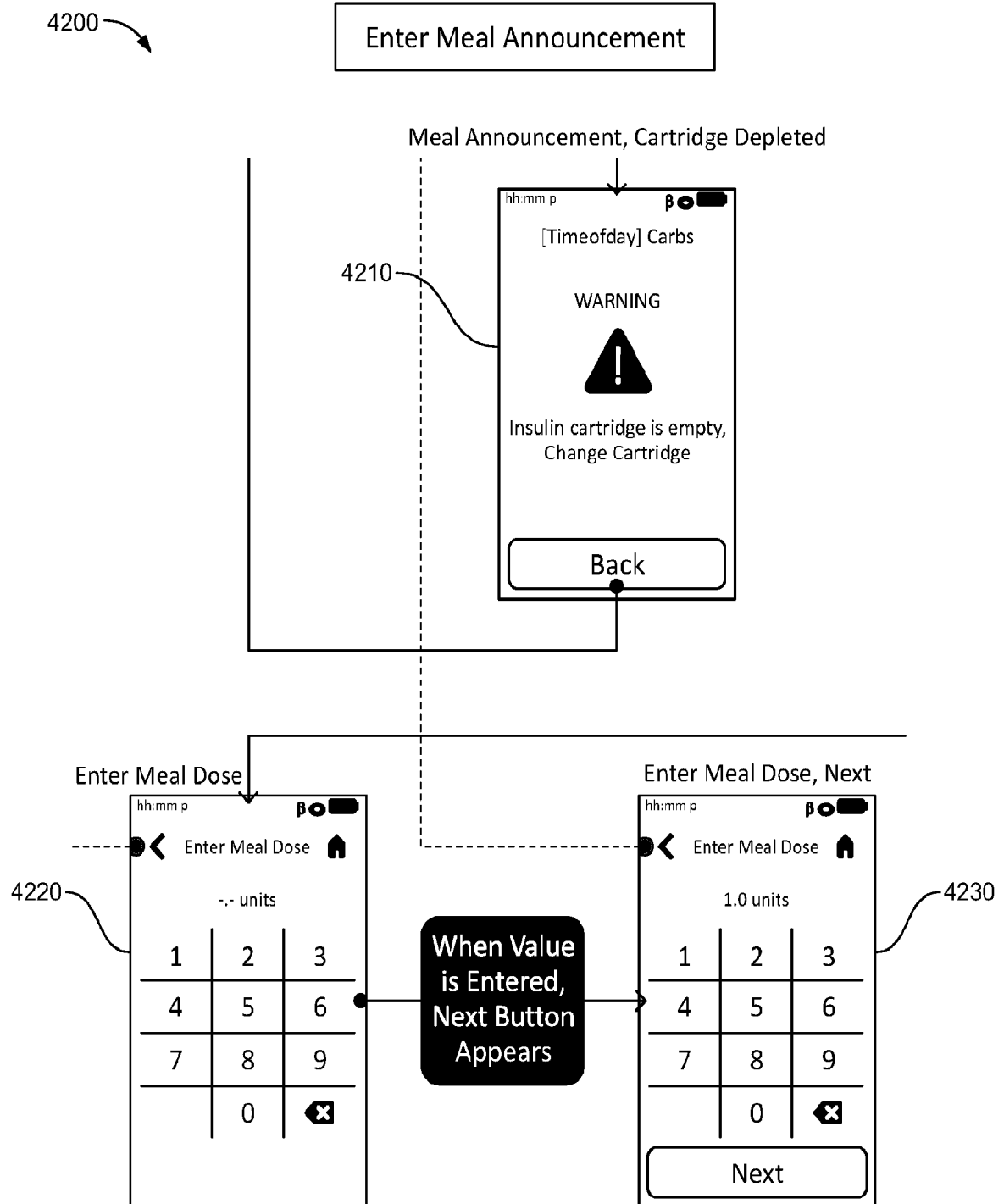


FIG. 43

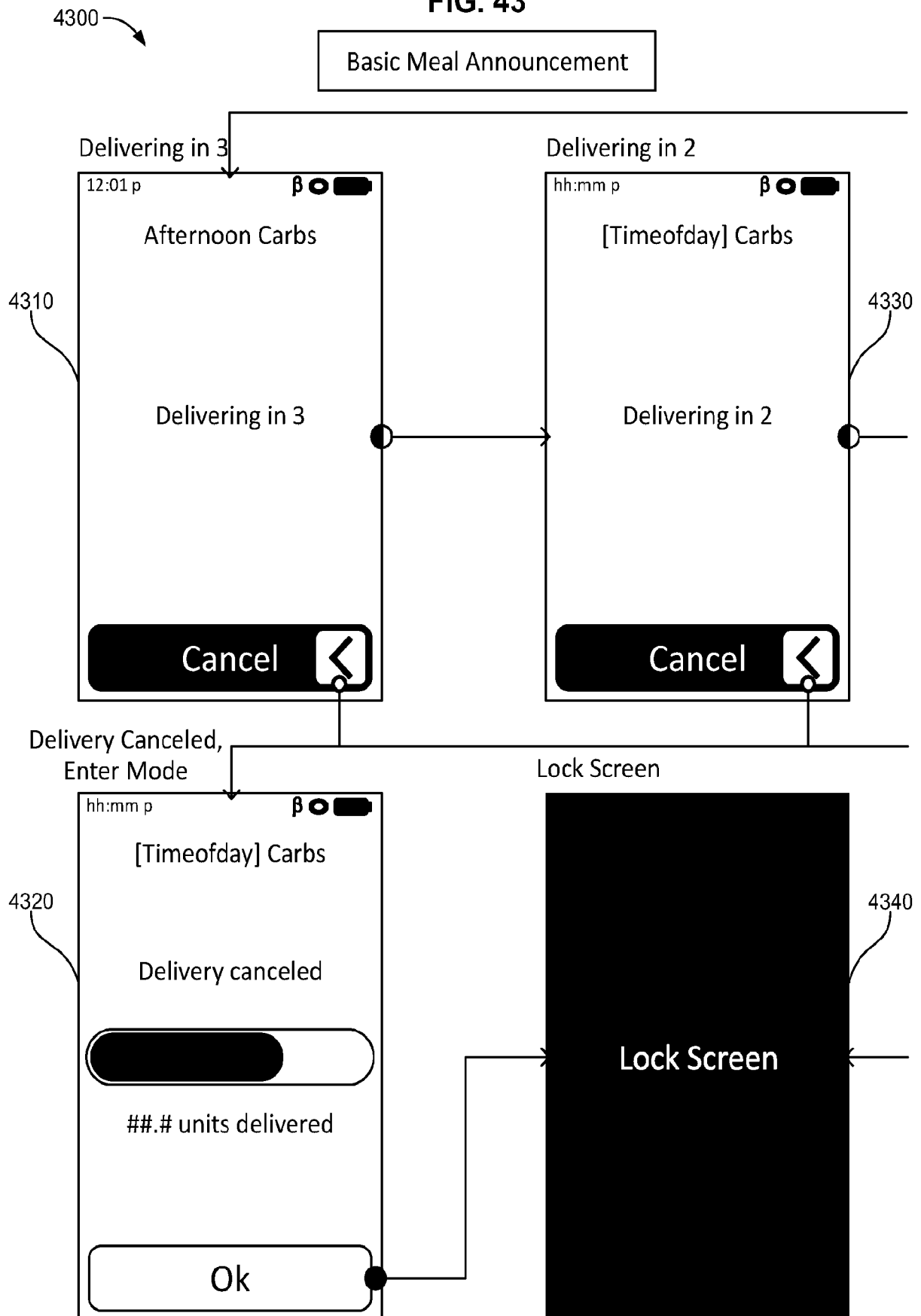


FIG. 44

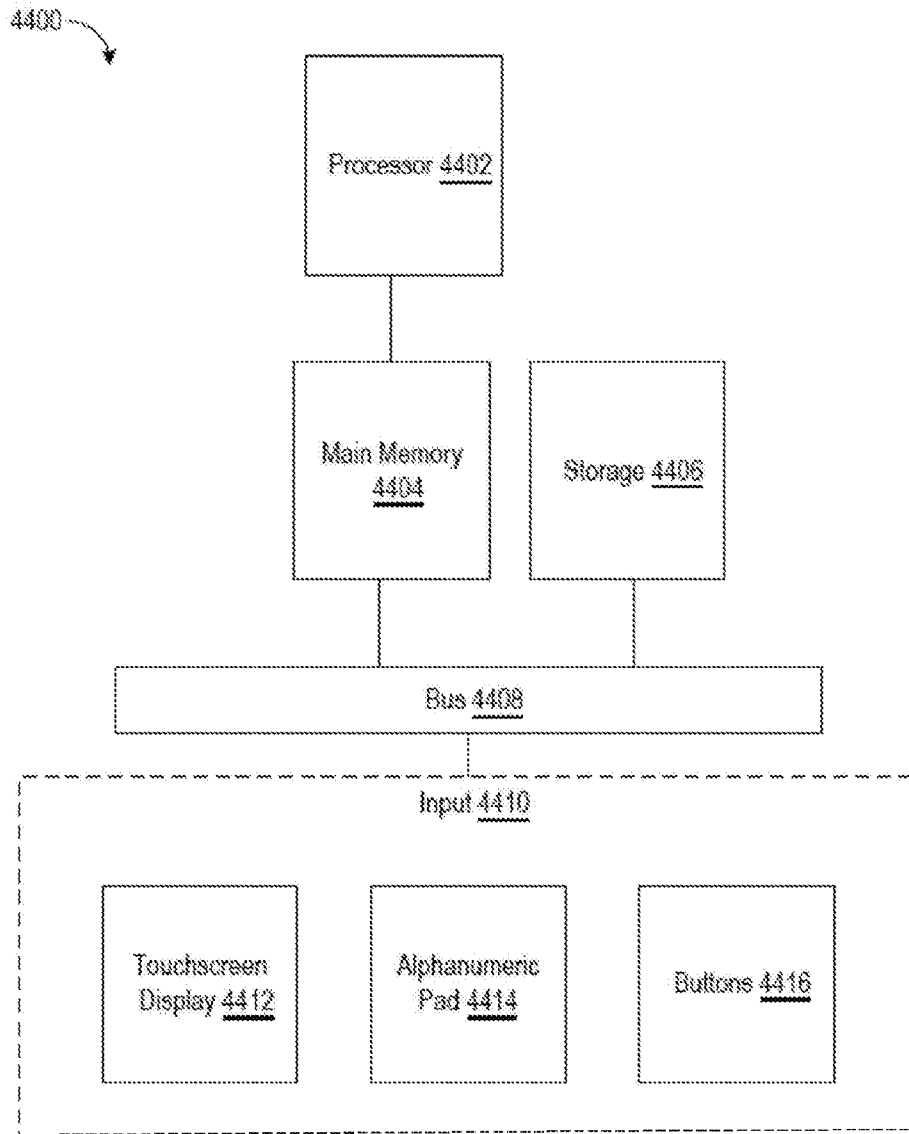


FIG. 9

