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(54) Title: DEVICES, SYSTEMS, AND METHODS ASSOCIATED WITH ANALYTE MONITORING DEVICES AND DEVICES INCORPORATING THE SAME

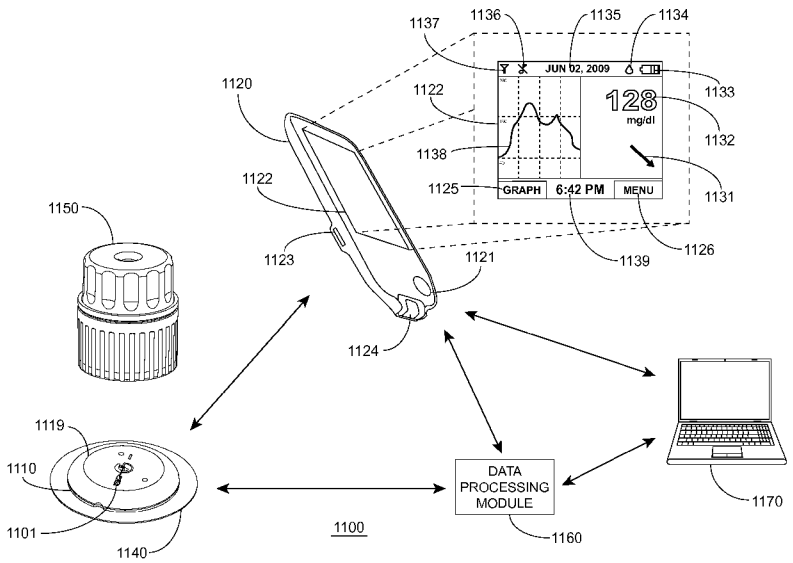

FIG. 1

(57) Abstract: Analyte monitoring systems, devices, and methods associated with analyte monitoring devices, and devices incorporating the same are provided. Various graphical user interfaces (GUI) and navigation flows are provided for performing various features, activities, functions, etc., associated with the analyte monitoring device or system. Intuitive navigation is provided to enhance the interpretation of analyte measurements.

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DEVICES, SYSTEMS, AND METHODS ASSOCIATED WITH ANALYTE MONITORING DEVICES AND DEVICES INCORPORATING THE SAME

PRIORITY

[0001] This application claims the benefit of priority under 35 U.S.C. §119(e) to U.S. Provisional Application Nos. 61/447,645 filed Feb. 28, 2011; 61/489,098 filed May 23, 2011; and 61/492,266 filed June 1, 2011, the disclosures of which are each incorporated by reference herein in their entirety.

BACKGROUND OF THE INVENTION

[0002] Analyte monitoring devices have been used as medical diagnostic devices to determine a level of analyte from a sample. One common application is glucose measurements. For example, an analyte monitoring device is used with a remote sensor to perform an analyte reading. The sensor may be configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient. The analyte monitoring device processes signals from the remote sensor to determine the concentration or level of analyte in the subcutaneous tissue and may display the current level of the analyte.

BRIEF DESCRIPTION OF THE DRAWINGS AND APPENDICES

[0003] The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to-scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included are the following:

[0004] **FIG. 1** illustrates an In-Vivo Analyte Monitoring System, according to one embodiment.

[0005] **FIG. 2** illustrates a block diagram of a system including an analyte monitoring device and remote data processing device, according to one embodiment.

[0006] **FIG. 3** illustrates an analyte monitoring device used with a remote sensor, according to one embodiment.

[0007] **FIG. 4** illustrates a method of powering on an analyte monitoring device, such as a glucose monitoring device, according to one embodiment.

[0008] **FIG. 5A** illustrates a method of navigating to a home screen from other screens on an analyte monitoring device, according to one embodiment.

[0009] **FIG. 5B** illustrates a method of powering an analyte monitoring device off, according to one embodiment.

[0010] **FIG. 5C** illustrates a method of powering an analyte monitoring device off, according to one embodiment.

[0011] **FIG. 5D** illustrates a method of powering off an analyte monitoring device, according to one embodiment.

[0012] **FIG. 5E** illustrates a battery low screen for an analyte monitoring device that indicates that the battery of the device is low, according to one embodiment.

[0013] **FIG. 5F** illustrates a method for linking an analyte monitoring device to a PC and transferring data between the two, according to one embodiment.

[0014] **FIG. 5G** illustrates a method for charging a battery for an analyte monitoring device, according to one embodiment.

[0015] **FIG. 6A** illustrates a method for performing a sensor scan or system check, according to one embodiment.

[0016] **FIG. 6B** illustrates a method for activating a sensor, according to one embodiment.

[0017] **FIG. 6C** illustrates a method for activating a sensor, according to one embodiment.

[0018] **FIG. 6D** illustrates a method 252 for scanning a sensor if the sensor is nearing expiration, according to one embodiment.

[0019] **FIG. 7** illustrates a method for activating a sensor after the device is powered on, according to one embodiment.

[0020] **FIG. 8** illustrates a method for scanning a sensor with an analyte monitoring device, according to one embodiment.

[0021] **FIG. 9A** illustrates a method for performing two scans within a predetermined period of time with the analyte reader, according to one embodiment.

[0022] **FIG. 9B** illustrates a method of logging a dose calculation, according to one embodiment.

[0023] **FIG. 9C** illustrates a method for enabling two consecutive scans, according to one embodiment.

[0024] **FIG. 10A** illustrates an example Sensor Results screen, according to one embodiment.

[0025] **FIG. 10B** illustrates an example Results Non-Actionable screen, according to one embodiment.

[0026] **FIG. 10C** illustrates an example Results - Masked screen, according to one embodiment.

[0027] **FIG. 10D** illustrates an interface for indicating that the sensor temperature is too high, according to one embodiment.

[0028] **FIG. 10E** illustrates an interface for indicating that the sensor temperature is too low, according to one embodiment.

[0029] **FIG. 10F** illustrates an interface for indicating that the sensor reading is out of range, according to one embodiment.

[0030] **FIG. 10G** illustrates an interface for indicating that the sensor reading is out of range, according to one embodiment.

[0031] **FIG. 10H** illustrates an interface for indicating that the sensor reading is high, according to one embodiment.

[0032] **FIG. 10I** illustrates an interface for indicating that the sensor reading is low, according to one embodiment.

[0033] **FIG. 10J** illustrates an interface for indicating that a high analyte level is projected, according to one embodiment.

[0034] **FIG. 10K** illustrates an interface for indicating that a low analyte level is projected, according to one embodiment.

[0035] **FIG. 11** illustrates an example method for performing a blood glucose test with a test strip, according to one embodiment.

[0036] **FIG. 12A** illustrates an example Blood Glucose Results screen, according to one embodiment.

[0037] **FIG. 12B** illustrates an example interface for indicating the results of a blood glucose control solution test, according to one embodiment.

[0038] **FIG. 12C** illustrates example interfaces for indicating that the analyte monitoring device's temperature is too high or too low, according to one embodiment.

[0039] **FIG. 12D** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment.

[0040] **FIG. 12E** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment.

[0041] **FIG. 12F** illustrates an interface for indicating that the measurement reading is high, according to one embodiment.

[0042] **FIG. 12G** illustrates an interface for indicating that the measurement reading is low, according to one embodiment.

[0043] **FIG. 13** illustrates an example method for performing a ketone test with a ketone test strip, according to one embodiment.

[0044] **FIG. 14A** illustrates an example Ketone Results screen, according to one embodiment.

[0045] **FIG. 14B** illustrates an example interface for indicating the results of a ketone control solution test, according to one embodiment.

[0046] **FIG. 14C** illustrates example interfaces for indicating that the analyte monitoring device's temperature is too high or too low, according to one embodiment.

[0047] **FIG. 14D** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment.

[0048] **FIG. 14E** illustrates an interface for indicating that the ketone measurement reading is high, according to one embodiment.

[0049] **FIGS. 15A-15E** illustrate a Notes Interface for entering notes on a Reader, according to embodiments of the present disclosure.

[0050] **FIGS. 16A-16C** illustrate an Insulin on Board Interface for entering insulin on board information on a Reader, according to embodiments of the present disclosure.

[0051] **FIGS. 17A-17E** illustrate an Insulin Calculator Interface for using an insulin calculator on a Reader, according to embodiments of the present disclosure.

[0052] **FIGS. 18A and 18B** illustrate a Dose Detail Interface for displaying insulin dose details on a Reader, according to embodiments of the present disclosure.

[0053] **FIGS. 19A-19D** illustrate a Reminders Interface for setting reminders on a Reader, according to embodiments of the present disclosure.

[0054] **FIGS. 20A and 20B** illustrate a Receive Reminder Interface for receiving reminders on a Reader, according to embodiments of the present disclosure.

[0055] **FIG. 21A** illustrates an exemplary interface for providing a summaries menu on the analyte monitoring device, according to one embodiment.

[0056] **FIG. 21B** illustrates a Daily Graph screen for showing a daily graph of sensor readings obtained over a single day or 24 hour time period, according to one embodiment.

[0057] **FIG. 21C** illustrates an exemplary Average Glucose Summary interface for providing a graph of sensor readings obtained over a time period that is summarized with respect to a predetermined time period, according to one embodiment.

[0058] **FIG. 21D** illustrates an exemplary screen for showing the percentage of time the sensor readings were within a target zone, according to one embodiment.

[0059] **FIG. 21E** illustrates an exemplary screen for showing a graph of the number of events associated with sensor readings obtained over a time period, wherein the events are summarized with respect to a predetermined time period, according to one embodiment.

[0060] **FIG. 21F** illustrates an exemplary screen for indicating information associated with the use of the sensor over a time period, according to one embodiment.

[0061] **FIG. 21G** illustrates an example interface for providing a summaries menu on the analyte monitoring device, when the device is in masked mode, according to one embodiment.

[0062] **FIGS. 22A-22D** illustrate a Logbook Interface for displaying, adding and/or editing logbook entries on a Reader, according to embodiments of the present disclosure.

[0063] **FIGS 23A and 23B** illustrate a Strip/Hardware Errors Interface for displaying error messages on a Reader, according to embodiments of the present disclosure.

[0064] **FIG. 24** illustrates methods for first starting an analyte monitoring device, according to one embodiment.

[0065] **FIG. 25** illustrates a method of entering settings on an analyte monitoring device, according to one embodiment.

[0066] **FIG. 26** illustrates methods of entering settings on an analyte monitoring device, according to one embodiment.

[0067] **FIG. 27** illustrates methods of checking the system status of an analyte monitoring device, according to one embodiment.

[0068] **FIG. 28** illustrates a method of setting a masked mode for an analyte monitoring device, according to one embodiment.

[0069] **FIG. 29** illustrates a method of activtating a calculator feature on an analyte monitoring device, according to one embodiment.

[0070] **FIG. 30** illustrates a method of setting up a calculator on an analyte monitoring device, according to one embodiment.

[0071] **FIG. 31** illustrates a method of setting up a calculator on an analyte monitoring device, according to one embodiment.

[0072] **FIG. 32** illustrates a method for a correction setup, according to one embodiment.

[0073] **FIG. 33** illustrates a method for an insuling on board setup and a method for saving settings, according to one embodiment.

[0074] **FIG. 34** illustrates example animation interfaces, according to certain embodiments.

[0075] **FIG. 35** illustrates example animation interfaces, according to certain embodiments.

[0076] **FIG. 36** illustrates a method when starting up Remote Device (RD) software on an remote data processing device, according to one embodiment.

[0077] **FIG. 37** illustrates a flowchart for the Auto-Assist Startup process, according to one embodiment.

[0078] **FIG. 38** illustrates an example Welcome screen, according to one embodiment.

[0079] **FIG. 39** illustrates a flowchart for a method of navigating through the Reader mode for accessing setting and functions that are used to setup and control the Reader device, according to one embodiment.

[0080] **FIG. 40** illustrates an example Reader Landing screen, according to one embodiment.

[0081] **FIG. 41** illustrates a screen indicating that the Reader is out of sync, according to one embodiment.

[0082] **FIG. 42** illustrates a Profile screen, according to one embodiment.

[0083] **FIG. 43** illustrates an Insulin Calculator Setup Interface for health management software configured for an easy insulin calculator, according to embodiments of the present disclosure.

[0084] **FIG. 44** illustrates an Insulin Calculator Setup Interface for health management software configured for an advanced insulin calculator set to count carbs by grams of carbs, according to embodiments of the present disclosure.

[0085] **FIGS. 45A and 45B** illustrate an Insulin Calculator Setup Interface for health management software configured for an advanced insulin calculator set to count carbs by grams of carbs and by time of day, according to embodiments of the present disclosure.

[0086] **FIGS. 46A and 46B** illustrate an Insulin Calculator Setup Interface for health management software configured for an advanced insulin calculator set to count carbs by servings of carbs and by time of day, according to embodiments of the present disclosure.

[0087] **FIG. 47** illustrates a Masked Mode setup screen, according to one embodiment.

[0088] **FIG. 48** illustrates a method for syncing a Reader device with a remote device, according to one embodiment.

[0089] **FIG. 49** illustrates a method for a Guided Reader Setup interface, according to one embodiment.

[0090] **FIG. 50** illustrates a single screen of a Guided Reader setup interface, according to one embodiment

[0091] **FIG. 51** illustrates a flowchart for navigating through the Reports mode of the RD software, according to one embodiment.

[0092] **FIG. 52** illustrates an example Reports landing screen, according to one embodiment.

[0093] **FIG. 53** illustrates an example Create Reports screen, according to one embodiment.

[0094] **FIG. 54** illustrates an example Logbook Report screen when viewed from the Reports Mode, according to one embodiment.

[0095] **FIG. 55** illustrates a flowchart for a Guided Reports Setup interface, according to one embodiment.

[0096] **FIG. 56** illustrates a method for exporting Reader data, according to one embodiment.

[0097] **FIG. 57** illustrates an exemplary Snapshot report for a specific time frame, according to certain embodiments.

[0098] **FIG. 58** illustrates a Calendar report, according to certain embodiments.

[0099] **FIG. 59** illustrates a Daily Patterns report, according to one embodiment.

[00100] **FIG. 60** illustrates a Meal Patterns report, according to one embodiment.

[00101] **FIG. 61** illustrates the first page of a Daily Statistics report for a given time period, according to one embodiment.

[00102] **FIG. 62** illustrates an exemplary Logbook report, according to one embodiment.

[00103] **FIG. 63** illustrates an exemplary Logbook report, according to one embodiment.

[00104] **FIG. 64** illustrates an example Reader Settings Report, according to one embodiment.

[00105] **FIG. 65** illustrates a Reader Settings Report, according to one embodiment.

DETAILED DESCRIPTION OF THE INVENTION

[00106] Before the present inventions are described, it is to be understood that this invention is not limited to particular aspects described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular aspects only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

[00107] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes

one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[00108] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can be used in the practice or testing of the present invention, some potential and preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. It is understood that the present disclosure supercedes any disclosure of an incorporated publication to the extent there is a contradiction.

[00109] It must be noted that as used herein and in the appended claims, the singular forms "a", "an", and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a program update" includes a plurality of such program updates and reference to "the program update" includes reference to one or more program updates and equivalents thereof known to those skilled in the art, and so forth.

[00110] Generally, embodiments of the present disclosure relate to in vivo methods and devices for detecting at least one analyte such as glucose in body fluid. Accordingly, embodiments include in vivo analyte sensors configured so that at least a portion of the sensor is positioned in the body of a user (e.g., within the ISF), to obtain information about at least one analyte of the body, e.g., transcutaneously positioned in user's body. In certain embodiments, an in vivo analyte sensor is coupled to an electronics unit that is maintained on the body of the user such as on a skin surface, where such coupling provides on body, in vivo analyte sensor electronics assemblies.

[00111] In certain embodiments, analyte information is communicated from a first device such as an on body electronics unit to a second analyte monitoring device which may include user interface features, including a display, and/or the like.

[00112] In many embodiments of the system, analyte information derived by the sensor/on body electronics (for example, on body electronics assembly) is made available in a user-usable or viewable form only when queried by the user such

that the timing of data communication is selected by the user. The on-body electronics may take periodic measurement and record such data until an on-demand reading is taken by the user (e.g., the display device brought in close vicinity of the on-body electronics and sensor). Upon communication, the on-body electronics may communicate the recorded data for a set time period. For example, the on-body electronics may have 8 hours of memory in which it stores periodic measurements taken every 15 minutes. When an on-demand reading is taken, the entire 8 hours is transferred to the device. It should be appreciated that if the user does not take an on-demand reading for longer than 8 hours, some of the data may be lost.

[00113] Accordingly, in certain embodiments once a sensor electronics assembly is placed on the body so that at least a portion of the in vivo sensor is in contact with bodily fluid such as ISF and the sensor is electrically coupled to the electronics unit, sensor derived analyte information may be communicated from the on body electronics to a display device on-demand by powering on the display device, and executing a software algorithm stored in and accessed from a memory of the display device, to generate one or more request commands, control signal or data packet to send to the on body electronics. The software algorithm executed under, for example, the control of the microprocessor or application specific integrated circuit (ASIC) of the display device may include routines to detect the position of the on body electronics relative to the display device to initiate the transmission of the generated request command, control signal and/or data packet.

[00114] Display devices may also include programming stored in memory for execution by one or more microprocessors and/or ASICs to generate and transmit the one or more request command, control signal or data packet to send to the on body electronics in response to a user activation of an input mechanism on the display device such as depressing a button on the display device, triggering a soft button associated with the data communication function, and so on. The input mechanism may be alternatively or additionally provided on or in the on body electronics which may be configured for user activation. In certain embodiments, voice commands or audible signals may be used to prompt or instruct the microprocessor or ASIC to execute the software routine(s) stored in the memory to generate and transmit the one or more request

command, control signal or data packet to the on body device. In the embodiments that are voice activated or responsive to voice commands or audible signals, on body electronics and/or display device includes a microphone, a speaker, and processing routines stored in the respective memories of the on body electronics and/or the display device to process the voice commands and/or audible signals. In certain embodiments, positioning the on body device and the display device within a predetermined distance (e.g., close proximity) relative to each other initiates one or more software routines stored in the memory of the display device to generate and transmit a request command, control signal or data packet.

[00115] Different types and/or forms and/or amounts of information may be sent for each on demand reading, including but not limited to one or more of current analyte level information (i.e., real time or the most recently obtained analyte level information temporally corresponding to the time the reading is initiated), rate of change of an analyte over a predetermined time period, rate of the rate of change of an analyte (acceleration in the rate of change), historical analyte information corresponding to analyte information obtained prior to a given reading and stored in memory of the assembly. Some or all of real time, historical, rate of change, rate of rate of change (such as acceleration or deceleration) information may be sent to a display device for a given reading. In certain embodiments, the type and/or form and/or amount of information sent to a display device may be preprogrammed and/or unchangeable (e.g., preset at manufacturing), or may not be preprogrammed and/or unchangeable so that it may be selectable and/or changeable in the field one or more times (e.g., by activating a switch of the system, etc). Accordingly, in certain embodiments, for each on demand reading, a display device will output a current (real time) sensor-derived analyte value (e.g., in numerical format), a current rate of analyte change (e.g., in the form of an analyte rate indicator such as a arrow pointing in a direction to indicate the current rate), and analyte trend history data based on sensor readings acquired by and stored in memory of on body electronics (e.g., in the form of a graphical trace). Additionally, the on skin or sensor temperature reading or measurement associated with each on demand reading may be communicated from the on body electronics to the display device. The temperature reading or measurement, however, may not be output or displayed

on the display device, but rather, used in conjunction with a software routine executed by the display device to correct or compensate the analyte measurement output to the user on the display device.

[00116] As described, embodiments include in vivo analyte sensors and on body electronics that together provide body wearable sensor electronics assemblies (also referred to herein as a "patch"). In certain embodiments, in vivo analyte sensors are fully integrated with on body electronics (fixedly connected during manufacture), while in other embodiments they are separate but connectable post manufacture (e.g., before, during or after sensor insertion into a body). On body electronics may include an in vivo glucose sensor, electronics, battery, and antenna encased (except for the sensor portion that is for in vivo positioning) in a waterproof housing that includes or is attachable to an adhesive pad.

[00117] Embodiments include sensor insertion devices, which also may be referred to herein as sensor delivery units, or the like. Insertion devices may retain on body electronics assemblies completely in an interior compartment, i.e., an insertion device may be "pre-loaded" with on body electronics assemblies during the manufacturing process (e.g., on body electronics may be packaged in a sterile interior compartment of an insertion device). In such embodiments, insertion devices may form sensor assembly packages (including sterile packages) for pre-use or new on body electronics assemblies, and insertion devices configured to apply on body electronics assemblies to recipient bodies.

[00118] Embodiments include portable handheld display devices, as separate devices and spaced apart from an on body electronics assembly, that collects information from the assemblies and provide sensor derived analyte readings to users. Such devices may also be referred to as meters, readers, monitors, receivers, human interface devices, companions, or the like. Certain embodiments may include an integrated in vitro analyte meter. In certain embodiments, display devices include one or more wired or wireless communications ports such as USB, serial, parallel, or the like, configured to establish communication between a display device and another unit (e.g., on body electronics, power unit to recharge a battery, a PC, etc).

[00119] Compatible informatics software in certain embodiments include, for example, but not limited to stand alone or network connection enabled data management software program, resident or running on a display device,

personal computer, a server terminal, for example, to perform data analysis, charting, data storage, data archiving and data communication as well as data synchronization. Informatics software in certain embodiments may also include software for executing field upgradable functions to upgrade firmware of a display device and/or on body electronics unit to upgrade the resident software on the display device and/or the on body electronics unit, e.g., with versions of firmware that include additional features and/or include software bugs or errors fixed, etc.

[00120] Embodiments may include a haptic feedback feature such as a vibration motor or the like, configured so that corresponding notifications (e.g., a successful on-demand reading received at a display device), may be delivered in the form of haptic feedback.

[00121] Embodiments include programming embedded on a computer readable medium, i.e., computer-based application software (may also be referred to herein as informatics software or programming or the like) that processes analyte information obtained from the system and/or user self-reported data. Application software may be installed on a host computer such as a mobile telephone, PC, an Internet-enabled human interface device such as an Internet-enabled phone, personal digital assistant, or the like, by a display device or an on body electronics unit. Informatics programming may transform data acquired and stored on a display device or on body unit for use by a user.

[00122] Embodiments of the subject disclosure are described primarily with respect to glucose monitoring devices and systems, and methods of glucose monitoring, for convenience only and such description is in no way intended to limit the scope of the disclosure. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes at the same time or at different times.

[00123] For example, analytes that may be monitored include, but are not limited to, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, oxygen, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and

warfarin, may also be monitored. In those embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times, with a single sensor or with a plurality of sensors which may use the same on body electronics (e.g., simultaneously) or with different on body electronics.

[00124] As described in detail below, embodiments include devices, systems, kits and/or methods to monitor one or more physiological parameters such as, for example, but not limited to, analyte levels, temperature levels, heart rate, user activity level, over a predetermined monitoring time period. Also provided are methods of manufacturing. Predetermined monitoring time periods may be less than about 1 hour, or may include about 1 hour or more, e.g., about a few hours or more, e.g., about a few days of more, e.g., about 3 or more days, e.g., about 5 days or more, e.g., about 7 days or more, e.g., about 10 days or more, e.g., about 14 days or more, e.g., about several weeks, e.g., about 1 month or more. In certain embodiments, after the expiration of the predetermined monitoring time period, one or more features of the system may be automatically deactivated or disabled at the on body electronics assembly and/or display device.

[00125] For example, a predetermined monitoring time period may begin with positioning the sensor in vivo and in contact with a body fluid such as ISF, and/or with the initiation (or powering on to full operational mode) of the on body electronics. Initialization of on body electronics may be implemented with a command generated and transmitted by a display device in response to the activation of a switch and/or by placing the display device within a predetermined distance (e.g., close proximity) to the on body electronics, or by user manual activation of a switch on the on body electronics unit, e.g., depressing a button, or such activation may be caused by the insertion device, e.g., as described in U.S. Patent Application No. 12/698,129 filed on February 1, 2010 and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, 61/317,243, 61/345,562, and 61/361,374, the disclosures of each of which are incorporated herein by reference for all purposes.

[00126] When initialized in response to a received command from a display device, the on body electronics retrieves and executes from its memory software routine to fully power on the components of the on body electronics, effectively placing the on body electronics in full operational mode in response to receiving

the activation command from the display device. For example, prior to the receipt of the command from the display device, a portion of the components in the on body electronics may be powered by its internal power supply such as a battery while another portion of the components in the on body electronics may be in powered down or low power including no power, inactive mode, or all components may be in an inactive mode, powered down mode. Upon receipt of the command, the remaining portion (or all) of the components of the on body electronics is switched to active, fully operational mode.

[00127] Embodiments include transcutaneous sensors and also wholly implantable sensors and wholly implantable assemblies in which a single assembly including the analyte sensor and electronics are provided in a sealed housing (e.g., hermetically sealed biocompatible housing) for implantation in a user's body for monitoring one or more physiological parameters.

[00128] Exemplary analyte monitoring systems that relate to the present disclosure an that may be utilized in connection with the disclosed analyte measurement system include those described in U.S. Patent No. 7,041,468; U.S. Pat. No. 5,356,786; U.S. Pat. No. 6,175,752; U.S. Pat. No. 6,560,471; U.S. Pat. No. 5,262,035; U.S. Pat. No. 6,881,551; U.S. Pat. No. 6,121,009; U.S. Pat. No. 7,167,818; U.S. Pat. No. 6,270,455; U.S. Pat. No. 6,161,095; U.S. Pat. No. 5,918,603; U.S. Pat. No. 6,144,837; U.S. Pat. No. 5,601,435; U.S. Pat. No. 5,822,715; U.S. Pat. No. 5,899,855; U.S. Pat. No. 6,071,391; U.S. Pat. No. 6,120,676; U.S. Pat. No. 6,143,164; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,338,790; U.S. Pat. No. 6,377,894; U.S. Pat. No. 6,600,997; U.S. Pat. No. 6,773,671; U.S. Pat. No. 6,514,460; U.S. Pat. No. 6,592,745; U.S. Pat. No. 5,628,890; U.S. Pat. No. 5,820,551; U.S. Pat. No. 6,736,957; U.S. Pat. No. 4,545,382; U.S. Pat. No. 4,711,245; U.S. Pat. No. 5,509,410; U.S. Pat. No. 6,540,891; U.S. Pat. No. 6,730,200; U.S. Pat. No. 6,764,581; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,461,496; U.S. Pat. No. 6,503,381; U.S. Pat. No. 6,591,125; U.S. Pat. No. 6,616,819; U.S. Pat. No. 6,618,934; U.S. Pat. No. 6,676,816; U.S. Pat. No. 6,749,740; U.S. Pat. No. 6,893,545; U.S. Pat. No. 6,942,518; U.S. Pat. No. 6,514,718; U.S. Pat. No. 5,264,014; U.S. Pat. No. 5,262,305; U.S. Pat. No. 5,320,715; U.S. Pat. No. 5,593,852; U.S. Pat. No. 6,746,582; U.S. Pat. No. 6,284,478; U.S. Pat. No. 7,299,082; U.S. Patent Application No. 61/149,639, entitled "Compact On-Body Physiological Monitoring

Device and Methods Thereof", U.S. Patent Application No. 11/461,725, filed August 1, 2006, entitled "Analyte Sensors and Methods"; U.S. Patent Application No. 12/495,709, filed June 30, 2009, entitled "Extruded Electrode Structures and Methods of Using Same"; U.S. Patent Application Publication No. US2004/0186365; U.S. Patent Application Publication No. 2007/0095661; U.S. Patent Application Publication No. 2006/0091006; U.S. Patent Application Publication No. 2006/0025662; U.S. Patent Application Publication No. 2008/0267823; U.S. Patent Application Publication No. 2007/0108048; U.S. Patent Application Publication No. 2008/0102441; U.S. Patent Application Publication No. 2008/0066305; U.S. Patent Application Publication No. 2007/0199818; U.S. Patent Application Publication No. 2008/0148873; U.S. Patent Application Publication No. 2007/0068807; US patent Application Publication No. 2010/0198034; and US provisional application no. 61/149,639 titled "Compact On-Body Physiological Monitoring Device and Methods Thereof", the disclosures of each of which are incorporated herein by reference in their entirety.

[00129] Additional relevant subject matter is provided in the following disclosures: U.S. Provisional Application Nos. 61/498,142 filed June 17, 2011; U.S. Application Nos. 13/071,461, 13/071,487, and 13/071,497, which were all filed on March 24, 2011, and 13/091,557 which was filed on April 21, 2011; US Patent Application Publication No. US 2010/0081905, 2011/0021889, 2010/0230285, and 2011/0021889; and U.S. Patent Nos. 6,736,957, 7,501,053 and 7,754,093; the disclosures of which are each incorporated by reference herein in their entirety and for all purposes.

[00130] **FIG. 1** illustrates an example embodiment of In-Vivo Analyte Monitoring System and is described below. FIG. 1 shows an exemplary in vivo-based analyte monitoring system 1100 in accordance with embodiments of the present disclosure. As shown, in certain embodiments, analyte monitoring system 1100 includes on body electronics 1110 electrically coupled to in vivo analyte sensor 1101 (a proximal portion of which is shown in FIG. 1) and attached to adhesive layer 1140 for attachment on a skin surface on the body of a user. On body electronics 1110 includes on body housing 1119, that defines an interior compartment. Also shown in FIG. 1 is insertion device 1150 that, when operated, transcutaneously positions a portion of analyte sensor 1101 through a skin

surface and in fluid contact with ISF , and positions on body electronics 1110 and adhesive layer 1140 on a skin surface In certain embodiments, on body electronics 1110, analyte sensor 1101 and adhesive layer 1140 are sealed within the housing of insertion device 150 before use, and in certain embodiments, adhesive layer 1140 is also sealed within the housing or itself provides a terminal seal of the insertion device 1150. Devices, systems and methods that maybe used with embodiments herein are described, e.g., in U.S. Patent Application No. 12/698,129 and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, 61/317,243, 61/345,562, and 61/361,374, the disclosures of each of which are incorporated herein by reference for all purposes.

[00131] Referring back to the FIG. 1, analyte monitoring system 100 includes display device 1120 which includes a display 1122 to output information to the user, an input component 1121 such as a button, actuator, a touch sensitive switch, a capacitive switch, pressure sensitive switch, jog wheel or the like, to input data or command to display device 1120 or otherwise control the operation of display device 1120. It is noted that some embodiments may include display-less devices or devices without any user interface components. These devices may be functionalized to store data as a data logger and/or provide a conduit to transfer data from on body electronics and/or a display-less device to another device and/or location. Embodiments will be described herein as display devices for exemplary purposes which are in no way intended to limit the embodiments of the present disclosure. It will be apparent that display-less devices may also be used in certain embodiments.

[00132] In certain embodiments, display 1122 and input component 1121 may be integrated into a single component, for example a display that can detect the presence and location of a physical contact touch upon the display such as a touch screen user interface. In such embodiments, the user may control the operation of display device 1120 by utilizing a set of pre-programmed motion commands, including, but not limited to, single or double tapping the display, dragging a finger or instrument across the display, motioning multiple fingers or instruments toward one another, motioning multiple fingers or instruments away from one another, etc. In certain embodiments, a display includes a touch screen

having areas of pixels with single or dual function capacitive elements that serve as LCD elements and touch sensors.

[00133] Display device 1120 also includes data communication port 1123 for wired data communication with external devices such as remote terminal (personal computer) 1170, for example. Example embodiments of the data communication port 1123 include USB port, mini USB port, RS-232 port, Ethernet port, Firewire port, or other similar data communication ports configured to connect to the compatible data cables. Display device 1120 may also include an integrated in vitro glucose meter, including in vitro test strip port 1124 to receive an in vitro glucose test strip for performing in vitro blood glucose measurements.

[00134] Referring still to FIG. 1, display 1122 in certain embodiments is configured to display a variety of information - some or all of which may be displayed at the same or different time on display 1122. Display 1122 may include but is not limited to graphical display 1138, for example, providing a graphical output of glucose values over a monitored time period (which may show important markers such as meals, exercise, sleep, heart rate, blood pressure, etc, numerical display 1132, for example, providing monitored glucose values (acquired or received in response to the request for the information), and trend or directional arrow display 1131 that indicates a rate of analyte change and/or a rate of the rate of analyte change, e.g., by moving locations on display 1122.

[00135] As further shown in FIG. 1, display 1122 may also include date display 1135 providing for example, date information for the user, time of day information display 1139 providing time of day information to the user, battery level indicator display 1133 which graphically shows the condition of the battery (rechargeable or disposable) of the display device 1120, sensor calibration status icon display 1134 for example, in monitoring systems that require periodic, routine or a predetermined number of user calibration events, notifying the user that the analyte sensor calibration is necessary, audio/vibratory settings icon display 1136 for displaying the status of the audio/vibratory output or alarm state, and wireless connectivity status icon display 1137 that provides indication of wireless communication connection with other devices such as on body electronics, data processing module1160, and/or remote terminal 1170. As additionally shown in FIG. 1, display 1122 may further include simulated touch screen buttons

1125,1126 for accessing menus, changing display graph output configurations or otherwise for controlling the operation of display device 1120.

[00136] Referring back to FIG. 1, in certain embodiments, display 1122 of display device 1120 may be additionally, or instead of visual display, configured to output alarms notifications such as alarm and/or alert notifications, glucose values etc, which may be audible, tactile, or any combination thereof. In one aspect, the display device 1120 may include other output components such as a speaker, vibratory output component and the like to provide audible and/or vibratory output indication to the user in addition to the visual output indication provided on display 1122. Further details and other display embodiments can be found in, e.g., U.S. Patent Application No. 12/871,901, U.S. provisional application nos. 61/238,672, 61/247,541, 61/297,625, the disclosures of each of which are incorporated herein by reference for all purposes.

[00137] After the positioning of on body electronics 1110 on the skin surface and analyte sensor 1101 in vivo to establish fluid contact with ISF (or other appropriate body fluid), on body electronics 1110 in certain embodiments is configured to wirelessly communicate analyte related data (such as, for example, data corresponding to monitored analyte level and/or monitored temperature data, and/or stored historical analyte related data) when on body electronics 1110 receives a command or request signal from display device 120. In certain embodiments, on body electronics 1110 may be configured to at least periodically broadcast real time data associated with monitored analyte level which is received by display device 1120 when display device 1120 is within communication range of the data broadcast from on body electronics 1110, i.e., it does not need a command or request from a display device to send information.

[00138] For example, display device 1120 may be configured to transmit one or more commands to on body electronics 1110 to initiate data transfer, and in response, on body electronics 1110 may be configured to wirelessly transmit stored analyte related data collected during the monitoring time period to display device 1120. Display device 1120 may in turn be connected to a remote terminal 1170 such as a personal computer and functions as a data conduit to transfer the stored analyte level information from the on body electronics 1110 to remote terminal 1170. In certain embodiments, the received data from the on body

electronics 1110 may be stored (permanently or temporarily) in one or more memory of the display device 1120. In certain other embodiments, display device 1120 is configured as a data conduit to pass the data received from on body electronics 1110 to remote terminal 1170 that is connected to display device 1120.

[00139] Referring still to FIG. 1, also shown in analyte monitoring system 1100 are data processing module 1160 and remote terminal 1170. Remote terminal 1170 may include a personal computer, a server terminal a laptop computer or other suitable data processing devices including software for data management and analysis and communication with the components in the analyte monitoring system 1100. For example, remote terminal 1170 may be connected to a local area network (LAN), a wide area network (WAN), or other data network for uni-directional or bi-directional data communication between remote terminal 1170 and display device 1120 and/or data processing module 1160.

[00140] Remote terminal 1170 in certain embodiments may include one or more computer terminals located at a physician's office or a hospital. For example, remote terminal 1170 may be located at a location other than the location of display device 1120. Remote terminal 1170 and display device 1120 could be in different rooms or different buildings. Remote terminal 1170 and display device 1120 could be at least about one mile apart, e.g., at least about 110 miles apart, e.g., at least about 1100 miles apart. For example, remote terminal 1170 could be in the same city as display device 1120, remote terminal 1170 could be in a different city than display device 1120, remote terminal 1170 could be in the same state as display device 1120, remote terminal 1170 could be in a different state than display device 1120, remote terminal 1170 could be in the same country as display device 1120, or remote terminal 1170 could be in a different country than display device 1120, for example. In certain embodiments, a separate, optional data communication/processing device such as data processing module 1160 may be provided in analyte monitoring system 1100. Data processing module 160 may include components to communicate using one or more wireless communication protocols such as, for example, but not limited to, infrared (IR) protocol, Bluetooth protocol, Zigbee protocol, and 802.11 wireless LAN protocol. Additional description of communication protocols including those based on Bluetooth protocol and/or Zigbee protocol can be found

in U.S. Patent Publication No. 2006/0193375 incorporated herein by reference for all purposes. Data processing module 1160 may further include communication ports, drivers or connectors to establish wired communication with one or more of display device1120, on body electronics 1110, or remote terminal 1170 including, for example, but not limited to USB connector and/or USB port, Ethernet connector and/or port, FireWire connector and/or port, or RS-232 port and/or connector.

[00141] In certain embodiments, control logic or microprocessors of on body electronics 1110 include software programs to determine future or anticipated analyte levels based on information obtained from analyte sensor 1101, e.g., the current analyte level, the rate of change of the analyte level, the acceleration of the analyte level change, and/or analyte trend information determined based on stored monitored analyte data providing a historical trend or direction of analyte level fluctuation as function time during monitored time period. Predictive alarm parameters may be programmed or programmable in display device 1120, or the on body electronics 1110, or both, and output to the user in advance of anticipating the user's analyte level reaching the future level. This provides the user an opportunity to take timely corrective action.

[00142] Information, such as variation or fluctuation of the monitored analyte level as a function of time over the monitored time period providing analyte trend information, for example, may be determined by one or more control logic or microprocessors of display device 1120, data processing module 160, and/or remote terminal 1170, and/or on body electronics 1110. Such information may be displayed as, for example, a graph (such as a line graph) to indicate to the user the current and/or historical and/or and predicted future analyte levels as measured and predicted by the analyte monitoring system 1100. Such information may also be displayed as directional arrows (for example, see trend or directional arrow display 1131) or other icon(s), e.g., the position of which on the screen relative to a reference point indicated whether the analyte level is increasing or decreasing as well as the acceleration or deceleration of the increase or decrease in analyte level. This information may be utilized by the user to determine any necessary corrective actions to ensure the analyte level remains within an acceptable and/or clinically safe range. Other visual indicators, including colors, flashing, fading, etc., as well as audio indicators including a

change in pitch, volume, or tone of an audio output and/or vibratory or other tactile indicators may also be incorporated into the display of trend data as means of notifying the user of the current level and/or direction and/or rate of change of the monitored analyte level. For example, based on a determined rate of glucose change, programmed clinically significant glucose threshold levels (e.g., hyperglycemic and/or hypoglycemic levels), and current analyte level derived by an in vivo analyte sensor, the system 1100 may include an algorithm stored on computer readable medium to determine the time it will take to reach a clinically significant level and will output notification in advance of reaching the clinically significant level, e.g., 30 minutes before a clinically significant level is anticipated, and/or 20 minutes, and/or 10 minutes, and/or 5 minutes, and/or 3 minutes, and/or 1 minute, and so on, with outputs increasing in intensity or the like.

[00143] Referring again back to FIG. 1, in certain embodiments, software algorithm(s) for execution by data processing module 1160 may be stored in an external memory device such as an SD card, microSD card, compact flash card, XD card, Memory Stick card, Memory Stick Duo card, or USB memory stick/device including executable programs stored in such devices for execution upon connection to the respective one or more of the on body electronics 1110, remote terminal 1170 or display device 1120. In a further aspect, software algorithms for execution by data processing module 160 may be provided to a communication device such as a mobile telephone including, for example, WiFi or Internet enabled smart phones or personal digital assistants (PDAs) as a downloadable application for execution by the downloading communication device.

[00144] Examples of smart phones include Windows®, AndroidTM, iPhone® operating system, Palm® WebOSTM, Blackberry® operating system, or Symbian® operating system based mobile telephones with data network connectivity functionality for data communication over an internet connection and/or a local area network (LAN). PDAs as described above include, for example, portable electronic devices including one or more microprocessors and data communication capability with a user interface (e.g., display/output unit and/or input unit, and configured for performing data processing, data upload/download over the internet, for example. In such embodiments, remote

terminal 170 may be configured to provide the executable application software to the one or more of the communication devices described above when communication between the remote terminal 1170 and the devices are established.

[00145] In still further embodiments, executable software applications may be provided over-the-air (OTA) as an OTA download such that wired connection to remote terminal 1170 is not necessary. For example, executable applications may be automatically downloaded as software download to the communication device, and depending upon the configuration of the communication device, installed on the device for use automatically, or based on user confirmation or acknowledgement on the communication device to execute the installation of the application. The OTA download and installation of software may include software applications and/or routines that are updates or upgrades to the existing functions or features of data processing module 1160 and/or display device 1120.

[00146] Referring back to remote terminal 1170 of FIG. 1, in certain embodiments, new software and/or software updates such as software patches or fixes, firmware updates or software driver upgrades, among others, for display device 1120 and/or on body electronics 1110 and/or data processing module 1160 may be provided by remote terminal 1170 when communication between the remote terminal 1170 and display device 1120 and/or data processing module 1160 is established. For example, software upgrades, executable programming changes or modification for on body electronics 1110 may be received from remote terminal 1170 by one or more of display device 1120 or data processing module 1160, and thereafter, provided to on body electronics 1110 to update its software or programmable functions. For example, in certain embodiments, software received and installed in on body electronics 1110 may include software bug fixes, modification to the previously stalled software parameters (modification to analyte related data storage time interval, resetting or adjusting time base or information of on body electronics 1110, modification to the transmitted data type, data transmission sequence, or data storage time period, among others). Additional details describing field upgradability of software of portable electronic devices, and data processing are provided in U.S. Application Nos. 12/698,124, 12/794,721, 12/699,653, and 12/699,844, and U.S. Provisional Application Nos.

61,359,265, and 61/325,155 the disclosure of which is incorporated by reference herein for all purposes.

[00147] In some aspects, the display device (also referred to herein as "analyte monitoring device" or simply "device") is configured to receive a signal from a remote sensor using radio-frequency identification (RFID) technology.

[00148] This configuration may be used to provide glucose on demand capabilities, for example, in which case when a measurement reading is desired, the analyte monitoring device is brought within close vicinity of the implantable sensor. It should be appreciated that in other embodiments the wireless communication unit may communicate with the sensor using a different wireless communication technology than RFID. When within range, the device may be configured to verify that the sensor is the appropriate sensor that it has been configured to operate with. If not, the device ignores the sensor and does not initiate operation with the sensor. If so, the device initiates operation with the sensor.

[00149] The analyte monitoring device may perform a variety of functions, including for example: modifying the signals from the sensor using calibration data and/or measurements from a temperature probe (not shown); determining a level of an analyte in the interstitial fluid; determining a level of an analyte in the bloodstream based on the sensor measurements in the interstitial fluid; determining if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values; activating an alarm system if a threshold value is met or exceeded; evaluating trends in the level of an analyte based on a series of sensor signals; therapy management (e.g., determine a dose of a medication, etc.); and reduce noise or error contributions (e.g., through signal averaging or comparing readings from multiple electrodes); etc. The analyte monitoring device may be simple and perform only one or a small number of these functions or the analyte monitoring device may perform all or most of these functions.

Software for the Remote Device

[00150] In some aspects, the analyte monitoring device may be communicatively coupled to a remote data processing device for management purposes. Remote device may include, for example, a personal computer, laptop, PDA, cellular

phone, smartphone, set-top box, etc. The remote device may include, for example, a control unit including any variety of processor, microprocessor, microcontroller, etc. The remote device may also include a memory unit comprising non-volatile memory and volatile memory.

[00151] The term "remote device" is used herein to represent any device that is external to the analyte monitoring device. The remote device may require software to fully communicate with the analyte monitoring device, manage data from the analyte monitoring device, modify settings on the analyte monitoring device, or otherwise operate with analyte monitoring device. This auto-assisting user interface software is referred to herein as "remote device software" or "RD software" or "Auto-Assist software" to distinguish it from the user interface software running on the analyte monitoring device. The RD software may be obtained from one or more methods such as downloading from the web, CD-ROM, memory stick, etc. The RD software is generally discussed here and additional details regarding various flows and screens are provided later.

[00152] In some embodiments, the analyte monitoring device includes the RD software programs and/or applications to be run on the remote device. In some instances, the RD software may be configured to automatically launch when the analyte monitoring device is coupled to the computer. For example, the analyte monitoring device may include an installer program that is stored in non-volatile memory and executed when the analyte monitoring device is coupled to the remote device. The installer program may be executed when the user couples the analyte monitoring device to the remote device. The installer program may then initiate the launch of the RD software on the remote device.

[00153] In some embodiments, the RD software is not stored in non-volatile memory on the remote device. The RD software is stored on the analyte monitoring device and used to launch the RD software on the remote device is coupled to the analyte monitoring device.

[00154] In some embodiments, the RD software may be downloaded and stored in non-volatile memory on the remote device. For example, the RD software may be downloaded via a network connection (e.g., via an internet connection), by storage device (e.g., CD-ROM, memory stick, etc.), and/or downloaded from the analyte monitoring device. In some instances, the RD software is capable of being run even when the device is not coupled to the computer.

[00155] It should be understood that the RD software may be compatible with various hardware systems (e.g., PC, MAC) and various operating systems (e.g., Windows, MAC OS, Linux).

[00156] The analyte monitoring device may be communicatively coupled to the remote device via wired technologies. Example wired technologies may include, but are not limited to, the following technologies, or family of technologies: USB, FireWire, SPI, SDIO, RS-232 port, etc.

[00157] The analyte monitoring device may include, for example, a communication connector unit to permit wired communication and coupling to the remote device. The communication connector unit provides the capability to communicate with a remote device having an appropriate interface to operatively couple with the communication connector. In some embodiments, the communication connector is configured to communicate with a smartphone such as an iPhone or Blackberry.

[00158] The communication connector unit may be any variety of connection interfaces—e.g., male or female connection interfaces. Using USB as an example, the communication connector may be any of the variety of USB plugs or USB receptacles/ports. As USB receptacles are typically located on computer and other devices, a corresponding USB plug used as a communication connector unit will enable the analyte monitoring device to be plugged directly into the USB receptacle, avoiding the use of cables. In other instances, the appropriate USB receptacle may be used on the analyte monitoring device to enable communication using a USB cable (similar to many other devices such as digital cameras, cellular phones, smartphones, etc.).

[00159] It should be appreciated that the in some embodiments the analyte monitoring device may be communicably coupled to the remote device via wireless technology. In such instances, the analyte monitoring device may include corresponding transmitters, receivers, and/or transceivers. The analyte monitoring device may be configured to wirelessly communicate using a technology including, but not limited to, radio frequency (RF) communication, Zigbee communication protocols, WiFi, infrared, wireless Universal Serial Bus (USB), Ultra Wide Band (UWB), Bluetooth® communication protocols, and cellular communication, such as code division multiple access (CDMA) or Global System for Mobile communications (GSM), etc.

[00160] The functionality of the RD software launched on the remote device may include a variety of functions relating to, for example, data acquisition; data management; management of features, settings, configurations, etc., of the analyte monitoring device; generation, saving, transmitting, and/or printing of reports, management of updates (e.g., field updates to device firmware and RD software); access to training content, web-based content, web-based marketing; etc.

[00161] The RD software may be launched on a remote device and used by the user (e.g., the patient) and/or a health care provider (HCP) (e.g., physician, hospital staff, etc.). For example, the HCP and/or patient may use the RD software on a remote device to analyze the patient data, view and print reports, view and change device settings, update device firmware and application software, etc.

[00162] In some instances, the RD software may initiate a comparison between the time date on the analyte monitoring device and that on the remote device and/or remote time server accessed via an internet connection from the remote device. The RD software may account for discrepancies and take action accordingly. For example, thresholds may be set (e.g., 5 minute difference) and if the threshold is reached, the analyte monitoring device prompts the user with a warning, question, indicator, etc., to acknowledge the discrepancy and/or remedy the discrepancy (e.g., adjust the time on one of the devices). In some instances, a similar comparison may be performed by the RD software to account for other discrepancies between the analyte monitoring device and remote device—e.g., discrepancies between data logs, data values, stored files, device and/or user interface configurations and settings, etc. The appropriate action can then be taken or requested.

[00163] Various defaults and customized configurations and settings may be established for generating, printing, saving, exporting, etc., reports. For example, the various formats for the report may be established (e.g., layout, style, themes, color, etc.); various file types to save the report as (e.g., PDF, Word document, Excel spreadsheet, etc. In some instances, for example, the RD software may provide the user with the ability to export tab-delimited text files or XML exports of the meter data (e.g., including blood glucose, ketones, carbs, insulin, and event tags, etc.). In some instances, the RD software may enable the user to

save, print, and/or export preferences, including favorite reports, target blood glucose ranges, auto save, auto print, color/black and white printing, device/software update settings for multiple devices, etc.

[00164] In some aspects, the RD software is used to control the configuration of the device and data from the device. This control may be utilized by the user and/or HCP. In some instances, the RD software shall provide access to one or more informative documents, trainings, tutorials, etc. For example, the RD software application may provide links or to manufacturer sponsored websites intended for any variety of purposes such as marketing and training content.

[00165] In some aspects, the RD software may include an update management function to help facilitate the detection, download, and installation of updates (e.g., firmware, informatics application updates, etc.) for the analyte meter device and/or the RD software. The updates may be detected and downloaded automatically in some instances (e.g., when an internet connection is active) and/or detected and downloaded upon user confirmation or request. In some instances, updates to the software shall also update its installation files stored on the device. Moreover, in some instances, when the device firmware is updated, required labeling/user documentation is also updated on the device. In some instances, when device firmware is updated, the existing device settings and testing history (e.g., blood glucose, insulin, carb data, etc.) is preserved.

[00166] In some aspects of the present disclosure, Auto-Assist software may be loaded and launched on a remote data processing device to operate with a coupled analyte monitoring device. The Auto-Assist software may include one or more GUI's for communicating with the analyte monitoring device. It should be appreciated a GUI may be used to represent one or more of graphical elements displayed on the display of the remote device for interfacing with the user. Thus, "graphical user interface" or "GUI" may encompass the entire display, an application window, pop-up windows, menus, progress and status bars, buttons, etc.

[00167] In some aspects of the present disclosure, the Auto-Assist software provides a meter mode to provide access to settings and functions that are used to setup and control the analyte monitoring device. The Auto-Assist software may also provide a meter setup mode to guide the user through the initial setup of the analyte monitoring device. The Auto-Assist software may provide a reports

mode to provide access to settings and function for creating, viewing, saving, and/or printing various reports. In addition, the Auto-Assist software may provide a reports setup mode to guide a user through the initial reports setup and creation process. The Auto-Assist software may also provide the function for users to export data from the analyte monitoring device—e.g., as a tab-delimited file or other spreadsheet-compatible format. In some instances, the Auto-Assist software may provide functions for providing help documents, tutorials, etc. to the user. The Auto-Assist software may provide functions for checking for software update and for acquiring updates. For example, checks may be automatically initiated and/or initiated by the user. In some instances, the software updates may be checked for and acquired via a network connection on the remote device.

Example Devices & Systems

[00168] **FIG. 2** illustrates a block diagram of a system including an analyte monitoring device and remote data processing device, according to some embodiments. System 1500 is shown to comprising analyte monitoring device 1501 communicably coupled to remote device 1505. In some instances, as shown, remote device 1505 may have network access to a network 1510 in which a second remote device 1515 is shown coupled to. It should be understood that network 1510 may include one or more networks, including LANs, WANs, and/or the internet.

[00169] Analyte monitoring device 1501 is shown removably coupled to remote device 1505 via communication connector unit 1422. Communication connector unit, for example, includes a USB plug which couples with a USB receptacle 1507 in remote device 1505. Remote device 1505 may include peripheral devices, such as printer, keyboard, monitor, CD drive, etc. Remote device 1505 may also include, as shown, a network interface 1530 which connects it to network 510. Remote device 1515 is also connected to network 1510 and may communicate with remote device1 505 via network 1510.

[00170] The following paragraphs describe system 1500 during operation, according to some embodiments. In some instances, the analyte monitoring device described is a glucose monitoring device which measures the glucose concentration level of a blood sample. It should be understood that the description applies equally to other analytes and to other forms of samples.

[00171] In use, analyte monitoring device 1501 receives a test strip 1525 for measuring an analyte level of a sample applied to test strip 1525. Test strip 1525 is received at strip port unit 1520. Analyte monitoring device 1501 performs a measurement computation on the sample and the user can view the measurement reading on, for example, a touchsreen display (not shown). The user may also be presented with a menu on the touchscreen display to view and select—e.g., menus for storing data, downloading data, performing bolus calculations based on the measurement, etc.

[00172] The user may couple the analyte monitoring device 1501 to remote device 505 (e.g., a personal computer) via a communication connector unit. For example, the user may decide to store the measurement data and then choose to download stored test data (including stored measurement readings) to a remote device 1505.

[00173] Analyte monitoring device1 501 may then be coupled to remote device 1505 via communication connector unit 1422. Communication connector unit 1422 may, for example, include a USB plug which couples to a USB receptacle 1507 on remote device 1505.

[00174] In some instances, the analyte monitoring device 1501 may be powered by the remote device 1505 when coupled via the communication connector unit 1422. In such case, the user would couple the analyte monitoring device 1501 to the remote device 1505 and then insert test strip 1525 into the strip port 1520 to take a measurement reading. In some instances, the analyte monitoring device includes its own power source, such as button or AAA-size batteries, for example, and is not powered by the remote device 1505.

[00175] In some instances, the analyte monitoring device may be “locked” or prevented from performing a test while coupled to the remote device 1505. For example, medical device regulations such as high voltage isolation testing may be required if the analyte monitoring device is configured to perform tests while coupled to a remote device. Thus, “locking” or preventing the analyte monitoring device from performing a test while coupled to the remote device allows the analyte monitoring device to not be subjected to the additional testing, if so desired.

[00176] In some aspects, the analyte monitoring device 1501 may initiate a user interface application (e.g., RD software) to execute on the analyte monitoring

device, and/or the remote device 1505 when coupled to the remote device 1505. The user interface application may be stored in a memory unit on the analyte monitoring device 1501, for example. In some aspects, the user is not required to have previously loaded software on the remote device 1505 to operate with the analyte monitoring device 1501. In some aspects, the analyte monitoring device may be configured to initiate the user interface application automatically upon coupling to the remote device. It should be understood that the user interface application may be configured to be compatible with various hardware systems (e.g., PC, MAC) and various operating systems (e.g., Windows, MAC OS, Linux).

[00177] The user interface application may include, for example, diabetes management related applications. The user interface application may provide a variety of menus, selections, charts, alarms, reminders, visual indicators, etc. For example, the user may be presented with menus and options, such as whether to take a measurement reading, to view stored measurement readings, to store data, to download data, to perform bolus calculation based on the measurement, etc.

[00178] The user interface program may, for example, allow the user to perform the following steps: (1) create a replica of the test data stored on the analyte monitoring device 1501, on the remote device 1505; and (2) synchronize test data from the analyte monitoring device 1501 to the database on the remote device 1505. Meter settings and/or user settings/preferences from the analyte monitoring device may also be included in the test data and synchronized with the remote device. Date and time for the remote device 1505 and analyte monitoring device 1501 may also be synched.

[00179] To read test data from the analyte monitoring device 1501 and write it to the remote device 1505, it is recognized herein that data in the remote device may be organized into tables, which may be organized into records, which may be broken down into predefined fields. Similarly, at some level data will be organized into records with a consistent field structure on the analyte monitoring device 1501. The user interface application may read test data from the analyte monitoring device and write it out to tables on the remote device 1505. The user interface application may also read data from table in the remote device 1505 and write them out to the analyte monitoring device 1501. Various types of data

conversion may be used. For example, data residing in fields in the analyte monitoring device may be converted from the format it exists in the analyte monitoring device to a format compatible with the remote device, and vice versa. The logical structure of the records in the two systems may be different.

[00180] Remote device 1505 may include peripheral devices, such as printer, keyboard, monitor, CD drive, etc. Remote device 1505 includes a network interface which connects it to network 1510 (e.g., the internet). The user interface application may provide the user with the option to view test data on the monitor, to store test data on storage media (e.g., CD-ROM, memory card, etc.), further analyze and/or manipulate test data, transmit data to another device), and/or print out test data such as charts, reports, etc., on the printer.

[00181] As shown, remote device 1505 may also include a network interface 1530 (e.g., network interface card (NIC), modem, router, RF front end, etc.) used to connect the remote device 1505 to network 1510. For example, in some aspects, analyte monitoring device 1501 may couple via a USB connection to the remote device which may be a personal computer or laptop connected to the internet using a wireless modem and/or router. In some aspects, analyte monitoring device 1501 may couple via a micro USB connection to a remote device 1505 which is a smartphone having an RF front end to access a mobile network. The user interface application may provide a user interface for using the network connection of the remote device 1505—e.g., to forward test data to a physician, hospital, health provider, and/or other third party located at a second remote device 1515 on network 1510. Appropriate action may then be taken by the receiving party at the second remote device 1515.

[00182] Referring back to FIG. 2, the analyte monitoring device may include a wireless communication unit, for example, which may include, for example, a receiver and/or transmitter for communicating with another device, e.g., remote device 1505, a medication delivery device, and/or a patient monitoring device (e.g., a continuous glucose monitoring device or a health management system, such as the CoPilot™ system available from Abbott Diabetes Care Inc., Alameda, CA), etc. The wireless communication unit may be configured to wirelessly communicate using a technology including, but not limited to, radio frequency (RF) communication, Zigbee communication protocols, WiFi, infrared, wireless Universal Serial Bus (USB), Ultra Wide Band (UWB), Bluetooth®

communication protocols, and cellular communication, such as code division multiple access (CDMA) or Global System for Mobile communications (GSM), etc. In some aspects, the wireless communication unit is configured for bi-directional radio frequency (RF) communication with another device to transmit and/or receive data to and from the analyte monitoring device 1501.

[00183] In some aspects, the wireless communication unit may be used to communicate with a remote device as described above for the communication connector unit. In some aspects where the analyte monitoring device includes a communication connector unit, the wireless communication unit may replace or provide an optional channel of communication for the functions provided by the communication connector unit discussed above. Referring back to FIG. 2, analyte monitoring device 1501 may be coupled to remote device 1505 via a wireless communication unit and provide an optional alternative communication channel with remote device 1505. In some aspects, analyte monitoring device 1501 may not include a communication connector unit 1422, and instead only communicate with the remote device 1505 via a wireless communication unit present on analyte monitoring device 1501. In some aspects, the analyte monitoring device is configured to receive a program update from a remote device via the wireless communication unit.

[00184] In some aspects, the wireless communication module may be configured to communicate with a smartphone (e.g., iPhone, Blackberry, etc). It is typical for smartphones to include various wireless technologies such as Wi-Fi, infrared, Bluetooth®, etc.

[00185] In some aspects, the analyte monitoring device may be configured to wirelessly communicate via the wireless communication unit with a server device, e.g., using a common standard such as 802.11 or Bluetooth® RF protocol, or an IrDA infrared protocol. The server device could be another portable device, such as a Personal Digital Assistant (PDA) or notebook computer, or a larger device such as a desktop computer, appliance, etc. In some aspects, the server device has a display, such as a liquid crystal display (LCD), as well as an input device, such as buttons, a keyboard, mouse or touchscreen. With such an arrangement, the user can control the meter indirectly by interacting with the user interface(s) of the server device, which in turn interacts with the meter across a wireless link.

[00186] In some aspects, the wireless communication module is used to communicate with a remote sensor--e.g., a sensor configured for implantation into a patient or user. Examples of sensors for use in the analyte monitoring systems of the present disclosure are described in U.S. Patent No. 6,175,752; and U.S. Patent Application, Ser. No. 09/034,372, incorporated herein by reference. Additional information regarding sensors and continuous analyte monitoring systems and devices are described in U.S. Patent Nos. 5,356,786; U.S. Pat. No. 6,175,752; U.S. Pat. No. 6,560,471; U.S. Pat. No. 5,262,035; U.S. Pat. No. 6,881,551; U.S. Pat. No. 6,121,009; U.S. Pat. No. 7,167,818; U.S. Pat. No. 6,270,455; U.S. Pat. No. 6,161,095; U.S. Pat. No. 5,918,603; U.S. Pat. No. 6,144,837; U.S. Pat. No. 5,601,435; U.S. Pat. No. 5,822,715; U.S. Pat. No. 5,899,855; U.S. Pat. No. 6,071,391; U.S. Pat. No. 6,120,676; U.S. Pat. No. 6,143,164; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,338,790; U.S. Pat. No. 6,377,894; U.S. Pat. No. 6,600,997; U.S. Pat. No. 6,773,671; U.S. Pat. No. 6,514,460; U.S. Pat. No. 6,592,745; U.S. Pat. No. 5,628,890; U.S. Pat. No. 5,820,551; U.S. Pat. No. 6,736,957; U.S. Pat. No. 4,545,382; U.S. Pat. No. 4,711,245; U.S. Pat. No. 5,509,410; U.S. Pat. No. 6,540,891; U.S. Pat. No. 6,730,100; U.S. Pat. No. 6,764,581; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,461,496; U.S. Pat. No. 6,503,381; U.S. Pat. No. 6,591,125; U.S. Pat. No. 6,616,819; U.S. Pat. No. 6,618,934; U.S. Pat. No. 6,676,816; U.S. Pat. No. 6,749,740; U.S. Pat. No. 6,893,545; U.S. Pat. No. 6,942,518; U.S. Pat. No. 6,514,718; U.S. Pat. No. 5,264,014; U.S. Pat. No. 5,262,305; U.S. Pat. No. 5,320,715; U.S. Pat. No. 5,593,852; U.S. Pat. No. 6,746,582; U.S. Pat. No. 6,284,478; U.S. Pat. No. 7,299,082; U.S. patent application Ser. No. 10/745,878 filed Dec. 26, 1003 entitled "Continuous Glucose Monitoring System and Methods of Use"; and U.S. Application No. 61/149,639 entitled “Compact On-Body Physiological Monitoring Device and Methods Thereof”, the disclosures of each which are incorporated by reference herein.

[00187] **FIG. 3** illustrates an analyte monitoring device used with a remote sensor, according to some embodiments. Sensor 1605 may be configured for implantation (e.g., subcutaneous, venous, or arterial implantation) into a patient. The sensor 1605 is coupled to sensor control unit 1610 which is typically attached to the skin of a patient. The sensor control unit 1610 operates the sensor 1605, including, for example, providing a voltage across the electrodes of

the sensor 1605 and collecting signals from the sensor 1605. The sensor control unit 1610 may evaluate the signals from the sensor 605 and/or transmit the signals to wireless communication unit 1423 on analyte monitoring device 1501 for evaluation.

[00188] In some aspects, the wireless communication unit 1423 is configured to receive a signal from a remote sensor using radio-frequency identification (RFID) technology. This configuration may be used to provide glucose on demand capabilities, in which case when a measurement reading is desired, the analyte monitoring device is brought within close vicinity of the implantable sensor. In some instances, RFID technology may be used in continuous glucose monitoring (CGM) applications.

[00189] The analyte monitoring device 1501 processes the signals from the on-skin sensor control unit 1610 to determine the concentration or level of analyte in the subcutaneous tissue and may display the current level of the analyte via display unit 1421. Furthermore, the sensor control unit 1610 and/or the analyte monitoring device 1501 may indicate to the patient, via, for example, an audible, visual, or other sensory-stimulating alarm, when the level of the analyte is at or near a threshold level. For example, if glucose is monitored then an alarm may be used to alert the patient to a hypoglycemic or hyperglycemic glucose level and/or to impending hypoglycemia or hyperglycemia.

[00190] The analyte monitoring device 1501 may perform a variety of functions, including for example: modifying the signals from the sensor 605 using calibration data and/or measurements from a temperature probe (not shown); determining a level of an analyte in the interstitial fluid; determining a level of an analyte in the bloodstream based on the sensor measurements in the interstitial fluid; determining if the level, rate of change, and/or acceleration in the rate of change of the analyte exceeds or meets one or more threshold values; activating an alarm system if a threshold value is met or exceeded; evaluating trends in the level of an analyte based on a series of sensor signals; therapy management (e.g., determine a dose of a medication, etc.); and reduce noise or error contributions (e.g., through signal averaging or comparing readings from multiple electrodes); etc. The analyte monitoring device may be simple and perform only one or a small number of these functions or the analyte monitoring device may perform all or most of these functions.

[00191] Analyte monitoring device 1501 may communicate with a remote device 505 via communication connector unit 1422, and/or wireless communication unit 1423, and/or a second wireless communication unit (not shown), as described earlier. It should also be understood that the analyte monitoring device may be configured with one or more wireless communication units.

User Interface for the Analyte Monitoring Device

[00192] In some aspects, the analyte monitoring device includes software used to perform various operation and functions with the device, such as, but not limited to, the functions described above. The device may include, for example, software instructions that are stored within a machine-readable storage medium (e.g., flash memory or other non-volatile memory) and executed by one or more general-purpose or special-purpose programmable microprocessors and/or microcontrollers, or other type of processing device. It should be appreciated that machine-readable storage medium may include any variety of non-volatile memory (e.g., Flash memory) or volatile memory (e.g., random access memory (RAM)), and may include one or more memory components.

[00193] In some aspects, the analyte monitoring device may include software that is used to provide the overall user interface for operation of the device and general user-experience with the device. The user interface may encompass graphical user interfaces (GUIs) that are displayed for a variety of features that may be provided by the device—e.g., Home screen, Glucose Reading screen, Logbook screen, Reader Summary screens, Reader Usage screens, etc. The user interface also encompasses screen navigation/flows for various operations that may be performed by the device—e.g., on-demand readings; activating a patch; replacing a patch; providing the status of a patch; notification of patch expiration; activating various information screens such as logbooks, summary screens, usage reports, etc.; creation of reports for display, communication, printing, etc.; etc.

[00194] It should be noted that the term “sensor” and “patch” are used herein to refer generally to the implanted sensor and on-body electronics together.

[00195] In some aspects of the present disclosure, the analyte monitoring device provides various graphical user interfaces (GUIs) or screens that are displayed on a display of the analyte monitoring device to assist the user with operation of

the device or provide information to the user. It should be understood that the terms “graphical user interface”, “‘GUI”, “interface” and “screen” are used broadly herein to represent any graphical interface element displayed on the display, and are used interchangeably. For example, the graphical user interface may comprise a graphical icon, element, picture, video, text box, pop-up window, application window, home screen, etc.

[00196] Furthermore, it must be noted that the terms “graphical user interface”, “GUI”, “interface”, and “screen” are used broadly herein and may include plural referents unless the context clearly dictates otherwise. Therefore, for example, reference to a “Setup screen” may include one or more screens in the setup process, and reference to "the Setup screen" may include reference to one or more program updates and equivalents thereof known to those skilled in the art, and so forth.

[00197] Furthermore, it should be understood that one or more GUIs may be implemented for various features, functions and/or settings. Further, different GUIs may be combined in some instances without compromising the underlying principles of the disclosure. Still further, the term

[00198] The user may navigate through branches of various screens via trigger elements on the device. The trigger elements may be any variety of trigger elements—e.g., buttons, keys, toggle switches, wheels, arrows, etc. The trigger elements may be physical and tangible trigger elements located on the device (e.g., hardware buttons or keys on the housing or keyboard, etc.) and/or may be nontangible trigger elements (e.g., graphical user interface elements) displayed on the device. It should also be understood that the branches of navigation may be displayed on the home screen (e.g., as icons on the display) and triggered by corresponding physical and tangible trigger elements on the housing of keyboard.

[00199] In some embodiments, a touchscreen display is implemented and the trigger elements are icons displayed on the touchscreen. The trigger element is activated by the user touching the corresponding trigger element (e.g., icon). It should be understood that icons is used broadly herein to represent any text, image, video, graphic, etc. For example, the trigger element may be suggestive of its function or feature—e.g., an image of a gear representing a trigger element

for accessing the setup menu, an arrow keys, check boxes, toggle switches, buttons (e.g., with identifying text or image inside), etc.

[00200] Home Screen:

[00201] In some aspects of the present disclosure a Home screen is provided. The home screen or landing screen is displayed on the display of the analyte monitoring device and functions as a reference point or relative reference point to perform various functions or features on the device. From the home screen the user can navigate to any of the various GUI's to perform or access various functions and features of the device. For instance, the user can navigate to a screen enabling the user to access a logbook, setup menu, reminders, etc. From that point, the user may access additional features and functions related to the selected item.

[00202] Active Screens:

[00203] In some aspects of the present disclosure an Active screen is provided. The Active Screen (e.g., Scan Prompt screen) awaits the user to perform an on-demand reading or otherwise "ping", "scan", or "swipe" the sensor. It should be appreciated that the term "ping", "scan", and "swipe" are used interchangeably herein and refer broadly to bringing the analyte monitoring device in sufficiently close distance of the sensor to perform a communication (e.g., on-demand reading, sensor activation, etc.).

[00204] On-Demand Reader Screens:

[00205] In some aspects of the present disclosure, On-Demand Reader screens are provided to convey information pertaining to analyte readings (e.g., glucose levels). While embodiments are described in relation to on-demand glucose readings, it should be appreciated that other analytes may be implemented in other embodiments.

[00206] In some instances, the On-Demand Reader screens may include one or more of the following: a reading, trend symbol, trigger element for calculating insulin, trigger element for food intake, trigger element for adding notes, trigger element for switching between screens, patch status information, trail information, the current time, battery status, etc. The reading provides glucose levels for a current reading. The trend symbol provides trending information related to increasing or decreasing patterns of glucose levels. When activated, the trigger element for calculating insulin displays a screen for providing an

insulin calculation for the user—e.g., based on the current glucose reading. When activated, the trigger element for food intake displays a screen for entering food intake and/or displaying food intake. When activated, the trigger element for notes displays a screen for entering notes and/or displaying previously entered notes. The trail information displays readings leading up to the current reading.

[00207] Some of the embodiments have a single screen layout in which all the information for the on-demand glucose reading is displayed on a single screen. Other embodiments include a dual screen layout which provides the information for the on-demand glucose reading over two screens. The user may switch between the two-screens with a trigger element such as an icon or box on the screen. In some instances, the user may be able to switch between screens by sliding a finger across the display of the device.

[00208] Reader Summary/Reports Screens:

[00209] In some aspects of the present disclosure, the analyte monitoring device displays summary screens that convey a collection of information associated with readings that have been performed.

[00210] Event Summary Views:

[00211] The Event Summary screen displays summarized information regarding the history of the user's readings.

[00212] Event Detail View:

[00213] The Event Detail screen displays a detailed view of the user's readings associated with an event—e.g., a hypoglycemic event.

[00214] Logbook screen:

[00215] The Logbook screen displays recorded readings and associated data regarding the user's readings.

[00216] Usage Report:

[00217] The Usage Report screen displays the meter utilization to indicate user engagement. Any gaps in time (e.g., extended durations where the user did not take any readings) are recorded and shown in the Usage Report.

[00218] Personalization Picture:

[00219] In some embodiments, the analyte monitoring device includes a personalization screen that displays a personalized image—e.g., selected or uploaded by the user. The personalized screen may be displayed at specific times. For example, the personalized screen may be displayed after the device

is powered on. Once the power up process is complete, the analyte monitoring device displays another screen, such as an active screen. In another embodiment, the home screen is displayed after the power up process.

[00220] Screen Qualities:

[00221] It should be appreciated that the analyte monitoring device may be implemented with different screen qualities—e.g., gray-scale and higher-resolution. In some embodiments, the analyte monitoring device may be capable of being operated in different screen qualities. For example, the analyte monitoring device may include a color touchscreen and be capable of being run in color mode or gray-scale mode.

[00222] The following paragraphs describe various navigation flows between user screens for performing various functions and features of the device.

NAVIGATION FLOWS

[00223] The following paragraphs describe various navigation flows between user screens for performing various functions and features of the analyte monitoring device. For example, software or firmware implementing flows introduced herein may be stored on a machine-readable storage medium and may be executed by one or more general-purpose or special-purpose programmable microprocessors.

Hardware

[00224] An exemplary embodiment of a graphical user interface which may be utilized in connection with an analyte monitoring device (e.g., analyte reader device) as described herein and which functions to perform various hardware-related actions is provided.

Hardware – Power On Interface

[00225] **FIG. 4** illustrates a method 100 of powering on an analyte monitoring device, such as a glucose monitoring device, according to one embodiment. The analyte monitoring device may also be referred to herein as a "reader" which takes measurement readings from the analyte sensor. From the off state, as represented by block 102, the device can be powered on by depressing a power button—e.g., by a "short" press or a "long press", as represented by block 104. At block 106, a test is performed to determine if the batter is depleted. If so, the device is powered off, as shown by block 108. In some instances, when the

device recovers from a power loss, it can remember "sensor" status information and resume use of the same sensor if the sensor has not expired—e.g., a 14-day period, or other predetermined period. If the battery is determined to not be depleted, then the device is powered on, as shown at block 110.

[00226] At block 112, it is determined if this is the first time the device is to be set up. If it is the first time, then a First Start procedure is initiated to begin the setup of the device, as shown at block 114. If it is determined that this is not a first time setup, then it is determined if the sensor has already been activated. If not activated, then the home screen is displayed, as shown at block 118. If already activated, then it is determined whether the sensor is expired, as shown at block 120. If the sensor is expired, it is determined if the sensor expiration message has been previously displayed, as shown at block 130. If so, then the home screen is displayed, as shown at block 134. If not, then a sensor expiration screen is displayed, as shown at block 132. In some instances, an audible notification may also be provided. The sensor expiration screen may also inform the use that a new sensor must be started to take a glucose reading. Once confirmed by the user, for example by pressing "ok", the home screen is displayed on the device.

[00227] Referring back to block 120, if the sensor is not expired, then it is determined if the sensor is warming up, as shown by block 122. If not, then a prompt is displayed for a sensor scan. If the sensor is warming up, then a warm-up message screen is displayed that informs the user that the sensor is warming up, as shown at block 126. In some instances, such as shown, the warm-up message screen indicates the time remaining before the sensor can be used. An audible reminder may also be present, as shown. Once confirmed by the user, for example by pressing "ok", the home screen is displayed on the device.

Go Home / Off Interface

[00228] **FIG. 5A** illustrates a method 140 of navigating to a home screen from other screens for an analyte monitoring device, according to one embodiment. AT block 142, the device is displaying a screen other than the home screen. At block 144 the home trigger button is pressed (e.g., by a short press) and the home screen is displayed, as shown at block 146. An alternative home screen 148 is shown that does not include a reminder. In some instances, a short press of the trigger button for the home screen is inactive when a test strip is inserted

within the device an prior to receiving a result. It should be appreciated that there may be some screens in which the home trigger button does not lead to a display of the home screen.

[00229] **FIG. 5B** illustrates a method 150 of powering an analyte monitoring device off, according to one embodiment. At block 152, a current screen is displayed on the device. When a screen has been displayed for a predetermined period of time—e.g., 45 seconds or some other period of time, the screen brightness may dim to say power, as shown at block 154. If the user touches the dimmed screen the display returns to full brightness and the timeout timer resets. After the screen is dimmed, if another predetermined period of time has passed without any activity—e.g., 15 seconds or other time period—then the device will power off. It should be appreciated that there may be certain screens in which such method does not apply.

[00230] **FIG. 5C** illustrates a method 160 of powering an analyte monitoring device off, according to one embodiment. From the home screen, shown at block 162, the pressing (e.g., short or long) of the home trigger button, as shown at block 164, will trigger the display of a screen indicating the device is to powering off. The user may be provided with an option to cancel the power down process. If no selection is detected, as shown at block 168, then the device may power down after a predetermined period of time—e.g., 5 seconds or some other time period, as represented by block 172. If at block 166 the trigger button is pressed, as shown at block 170, then the device is powered off, as represented by block 172.

[00231] **FIG. 5D** illustrates a method 180 of powering off an analyte monitoring device, according to one embodiment. From a current screen, shown at block 182, the depression of the trigger button (e.g., a long depression) triggers the display of a power down screen shown at block 186. The user may be provided with an option to cancel the power down process. If no selection is detected, as shown at block 188, then the device may power down after a predetermined period of time—e.g., 5 seconds or some other time period, as represented by block 192. If at block 186 the trigger button is pressed, as shown at block 190, then the device is powered off, as represented by block 192.

Low Battery Interface

[00232] **FIG. 5E** illustrates a battery low screen 196 for an analyte monitoring device that indicates that the battery of the device is low, according to one embodiment. In one embodiment, for example, this screen may appear after scanning of the sensor or a strip test, but before the results are shown. In some instance, this screen will start appearing when the battery capacity reaches a level equivalent to 1 day of typical use. This may be a predetermined value or based on a user history. In some instances, when the screen is display, a reminder auditory/vibratory signal is the only signal broadcast. The standard confirmation signal is omitted. A user confirmation element may be displayed that directs the user to scan results when the user confirms. In some instances, if the charger is plugged in from the battery low screen, the device will transition to the results screen.

PC link / Data Transfer Interface

[00233] **FIG. 5F** illustrates a method 200 for linking an analyte monitoring device to a PC and transferring data between the two, according to one embodiment. At block 202, the device is connected to the PC via a wired or wireless connection, and data is transferred between the device and the PC. When data is being transferred, a data transfer screen is displayed and indicates that the data transfer is in process. The example shown also instructs the user not to unplug the device from the computer. If the data transfer completes or the connection between the device and PC (e.g., USB connection) is disconnected, then the home screen is displayed. In one embodiment, if the initial Reader settings have not been saved the Reader will go to the First Start procedure after attempting to transfer data. It should be appreciated that engineering implementation may dictate changes to these screens in other embodiments. In some instances, if the device is plugged into a computer before initial setup, the language will default to English until it is set by PC App.

Charging Battery Interface

[00234] **FIG. 5G** illustrates a method 210 for charging a battery for an analyte monitoring device, according to one embodiment. The device may be charged by connecting the device to a PC or other device (e.g., via a USB connection, etc.) or by connecting the device to an AC adapter that is plugged into an AC outlet, for example. When the charger is plugged in from the off state, the home screen

is displayed and indicates the device is charging—e.g., via a charging icon or symbol, such as a battery symbol—such as shown at block 212. In one embodiment, while charging every screen is subject to a standard time-out period, such as a 60 second time-out period for instance.

[00235] If the device is disconnected from the charger (e.g., from the USB connection port), shown at 216, then the home screen continues to be displayed without the charging symbol or icon. This may be replaced by an icon or symbol indicating the current state of the battery life. In one embodiment, if the device is displaying any screen, including the home screen, it will remain on that screen when the charger is disconnected, and the predetermined timeout period will reset when the charger is disconnected.

Home Screen

[00236] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which functions to navigate the device in relation to the Home screen is provided.

Sensor Scan or System Check Interface

[00237] **FIG. 6A** illustrates a method 220 for performing a sensor scan or system check, according to one embodiment. From the home screen at block 222, if a glucose check is initiated, it is determined if a system check is required, as shown at block 230. If so, then a system check is performed, as shown at block 232. If a system check is not required, then a sensor scan prompt is displayed, as shown at block 234. The home screen may enable other features to be initiated as well. For example, a readers summaries menu screen may be displayed when the corresponding icon is triggered at the home screen, as shown by block 224. Also, a settings screen may be displayed when the corresponding icon is triggered at the home screen, as shown by block 226.

[00238] In addition, an insulin on board screen may be displayed when the corresponding icon is triggered at the home screen, as shown by block 236. The insulin on board screen provides information related to the estimated active insulin remaining in a user's body according to insulin data previously entered. Additional details may be provided when a corresponding icon is initiated from the insulin on board screen. In one embodiment, a timer counts down from time of dose for insulin duration as set in a calculator setup. In one embodiment, the insulin on board screen with active countdown appears if the insulin on board is

enabled in the calculator setup and the insulin on board is calculated to be present. The icon shown provides a visual indication that reflects the amount of rapid-acting insulin estimated to be still in body—e.g., a percentage of the body-shaped icon filled corresponding to a percentage of the active insulin remaining in the body.

[00239] Also, a reminder screen may be displayed when the corresponding icon is triggered at the home screen, as shown by block 228. In one embodiment, when a reminder is set, the time at which the alarm will sound appears next to a reminders icon. If, for example, multiple reminders are active, the time shown is the time of the reminder that will sound soonest.

Expired/No Sensor Interface

[00240] **FIG. 6B** illustrates a method for activating a sensor, according to one embodiment. In the embodiment shown, the home screen 242 indicates that no sensor is currently paired to the analyte monitoring device is displayed on the device. For example, a sensor may have never been paired to the device, or a previously paired sensor may have expired. From home screen 242, the user may trigger the activation of a sensor by pressing or otherwise selecting a corresponding icon or other trigger element displayed on the display of the device.

Sensor Warming Up Interface

[00241] **FIG. 6C** illustrates a method 246 for activating a sensor, according to one embodiment. After a user initiates the activation of a sensor, e.g., as represented by block 250, the device may indicate if the sensor is warming up. As illustrated, during the warm up period, the home screen 248 indicates that the sensor is warming up. For example, home screen 248 indicates the time remaining before the sensor is ready, as shown in screen 248—e.g., “Ready in 60 min”.

Sensor Near Expiration Interface

[00242] **FIG. 6D** illustrates a method 252 for scanning a sensor if the sensor is nearing expiration, according to one embodiment. In the embodiment shown, a screen 254 indicates the time remaining before the currently paired sensor is expired—e.g., in 16 hours. From home screen 254, the user may still trigger the activation of a sensor by pressing or otherwise selecting a corresponding icon or other trigger element displayed on the display of the device, since the sensor is not yet expired.

Sensor Activation

[00243] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which functions activate the sensor is provided.

[00244] **FIG. 7** illustrates a method 260 for activating a sensor after the device is powered on, according to one embodiment. At block 262, the device is powered on. Once powered, a home screen 264 is displayed. The home screen 264 indicates that there is no active sensor, and further includes an icon or other trigger element 265 that enables the start of a new sensor. Once icon 265 is selected by the user, as represented by block 266, a "Start New Sensor" screen 268 for starting the sensor is displayed. The start new sensor screen 268 enables the user to start a new sensor—e.g., by informing the user to scan the sensor to start it. The user may then scan a sensor to start a pairing, as indicated by block 270. If an expired sensor is scanned, the device may display a screen indicating the sensor is expired. If the scan fails, the device may display a screen informing the user that the scan failed.

[00245] In some instances, the device may include a masked mode that enables the user to take readings of a paired sensor, but does not display the resulting readings to the user, or otherwise limits the resulting data to the user. As shown by reference pathway B, after a non-expired sensor has been successfully scanned, the device may display a masked mode screen to indicate or configure a masked mode. For example, masked mode screen 272 indicates that the device will operate in the masked mode, unless otherwise changed by the user. Screen 272 enables the user to make a selection and be taken to a settings screen to edit the masked mode setting, as shown at block 274. In some instances, the initial configuration may be set up by the doctor or other health care profession for the patient. If the user wishes to remain in the masked mode, then it may be determined if the sensor has been already activated, as shown at block 276.

[00246] If the sensor has not been previously activated by another analyte monitoring device, then a warmup message screen 282 is displayed that indicates that the sensor is warming up. The remaining time may also be displayed. If the user confirms the message, for example by selecting the "ok" icon, then the home screen 284 is displayed and indicates the sensor is warming

up—e.g., by showing the remaining time until the sensor is ready. If the user attempts to perform a sensor scan as shown by block 286—e.g., by selecting the check glucose icon, then the warmup message screen 282 is displayed again. In some instances, the home screen may be displayed after a predetermined time showing the warmup message, after the sensor is ready, etc.

[00247] Referring back to block 276, if the sensor has already been activated by another device, then a screen 278 indicating that the sensor is already paired with another device is displayed. Upon user confirmation, the home screen is displayed, as shown at block 280.

Sensor Scan and Results

[00248] Exemplary embodiment of a graphical user interfaces which may be utilized in connection with a reader as described herein and which function to scan and to provide results are provided.

Sensor Scan Interface

[00249] **FIG. 8** illustrates a method 290 for scanning a sensor with an analyte monitoring device, according to one embodiment. At block 292, the device is powered on. A scan prompt screen 294 is displayed and indicates to the user to scan the sensor to check an analyte level (e.g., glucose level).

[00250] In the embodiment shown, an icon or trigger element is provided on screen 294 for going to the home screen 296. If selected by the user, the home screen 296 is displayed. From the home screen 296, the user may initiate a sensor scan thereafter and return to the scan prompt screen 294.

[00251] If a sensor is scanned, as shown at block 298, it is determined if the scan is successful, as shown at block 300. If the scan is not successful, it is determined whether there was an error or whether the sensor was deactivated, as shown at block 302. If there was an error, then a scan error screen 304 is displayed indicating to the user that an error occurred. If the sensor was deactivated, then a start sensor again screen 306 may be displayed to enable the user to restart the sensor. If it is determined that the sensor has fallen out, then a sensor fall out screen 308 is displayed and indicates that the sensor may have fallen loose and that a new sensor may be required. Screens 304, 306, and 308, provide a user confirmation element—e.g., an “ok” element. Upon selection, the home screen 296 is displayed.

[00252] Returning to block 300, if the scan is successful, then it is determined whether the sensor is new and has not been previously activated, as represented by reference pathway C and block 310. If the sensor is a new inactive sensor, then a new sensor detected screen 312 is shown and indicates that the sensor is a new sensor. Screen 312 provides the user with an option to start the new sensor or not. If the user elects to start the new sensor, then the device initiates the sensor activation process, as shown by block 316. If the user elects to not start the new sensor, then the device displays the home screen, as shown by block 314.

[00253] Returning to block 310, if the scanned sensor is determined to not be a new inactive sensor, then it is determined if the sensor is the current sensor paired with the device, as shown at block 318. If the sensor is not the current sensor for the device, and is instead already paired with another device, then a screen 320 is displayed that indicates that the sensor is already in use with another device and is not the current sensor for this device. Upon user confirmation, the home screen is displayed, as shown at block 322. If at block 318, it is determined that the sensor is the current sensor paired with the device, then it is determined if the sensor is expiring within a predetermined amount of time—e.g., 3 days in the embodiment shown—as shown by block 324. It should be appreciated that the amount of time may vary in other embodiments, and in one embodiment check to see if the sensor is expired. It should also be appreciated that the predetermined amount of time may be preprogrammed in manufacturing, and/or set within the settings, etc.

[00254] If at block 324, it is determined that the sensor is expiring within the predetermined amount of time, then a sensor near expiration screen 326 is displayed to indicate the sensor is close to expiring. The remaining time until the sensor expires may be displayed, for example.

[00255] If at block 324, it is determined that the sensor is not expiring within the predetermined amount of time, then it is determined whether the sensor battery is low, as represented by reference pathway D and block 328. If the battery is low, then at block 330, the device indicates that the battery is low—e.g., via a low battery screen, or a low battery icon, etc. In some instances, a reading is not taken and no results are shown for the scan.

[00256] If the battery is not low, then at block 332, it is determined if the skin temperature is too hot or cold—e.g., using a "safe" range of temperatures. The sensor may provide the temperature data to the device. If the temperature is determined to be too hot or cold, then the device displays the resulting reading and indicates that the sensor temperature was too hot or too cold, respectively, as shown at block 334.

[00257] If the skin temperature is not too hot or cold, then it is determined whether the resulting reading is out of range, as shown at block 336.

[00258] If the sensor is out of range, then it is determined if a high or low glucose condition has occurred, as shown at block 340. For example, a target range or acceptable range may be preset by the manufacturer or customizable by the user. If a high or low condition is present, then the user is taken to the Sensor Results screen and the high or low condition may be indicated on the Sensor Results screen (e.g., via a message, icon, etc.) along with the sensor results, as shown at block 342.

[00259] If a high or low condition is not present, then it is determined whether a high or low condition is projected, as shown at block 344. A high or low condition may be projected, for example, by trends in the measurement readings. If a high or low condition is projected, then the user is taken to the Sensor Results screen and the projected high or low condition is indicated on the Sensor Results screen along with the sensor results, as shown at block 346.

[00260] In some instances, the device is programmed such that the skin temperature test takes priority over other test conditions (e.g., out-of-range test, high/low glucose test, projected high/low glucose test, etc.) that may occur simultaneously.

Consecutive Scans Interface

[00261] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which functions to provide navigation when consecutive scans are present is provided.

Two Scans within Predetermined Period of Time

[00262] In some aspects, the analyte reader device is programmed to perform specific navigations when the device is scanned multiple times within a predetermined period of time.

[00263] **FIG. 9A** illustrates a method 350 for performing two scans within a predetermined period of time with the analyte reader, according to one embodiment. After the first scan is performed, a Sensor Results screen is displayed, as shown at block 352. If the power is turned off or the Sensor Results screen is left before a predetermined period of time (e.g., 3 minutes in the example embodiment shown), the results from the first scan are saved, as represented by block 354. If the device is powered back on, or another scan is attempted, within the predetermined period of time, the device will prevent the user from performing a new scan and display a No New Scan screen indicating that the a new sensor reading is not available at this time., as shown by blocks 356 and 358. The No New Scan screen may also indicate the time remaining until another scan, as well as, enable the user to view the last Sensor Results screen if desired, as represented by Sensor Results screen 362.

Device Timeout at the Suggest Dose Screen from BG Result

[00264] In some aspects, the analyte reader device is programmed to return to a saved suggested dose screen if the reader is powered off or leaves a "Calculator/Suggested Dose" screen when a dose has been calculated but not logged, and the device is powered back on or another scan is attempted within a predetermined period of time.

[00265] **FIG. 9B** illustrates a method 364 of logging a dose calculation, according to one embodiment. After a glucose reading is taken, a "Calculator/Suggested Dose" (CALC SGTD) screen 366 may be displayed to calculate and log a suggested dose of insulin. From screen 366, the user can adjust the suggested does if desired and log the dose. However, if within a predetermined period of time (e.g., 3 minutes in the embodiment shown), the device is powered off, or screen 366 is left, after a suggested dose has been calculated but not logged, then the suggested dose data is saved, as shown at block 368. If the device is powered back on, or another glucose scan is attempted, within the predetermined period of time, as shown by block 370, then the user is returned to the CALC SGTD screen 372 having the saved suggested dose data. From here, the user may continue with the dose calculation and log the calculated dose. If a dose is logged at this point, the dose is stored within the Logbook along with the test results. In one embodiment, the dose is logged as having been taken at the time the test was taken rather than at the time the dose was

actually logged. The insulin in body countdown, however, starts from the time at which the does is actually logged.

Suggested Dose from BG Result Logged

[00266] In some aspects of the present disclosure, after a first scan and calculated insulin dose logged, the device is programmed to prevent a second scan within a predetermined period of time from a first scan. The user will not be able to perform the second scan, but will be able to view the Logbook.

[00267] **FIG. 9C** illustrates a method 374 for enabling two consecutive scans, according to one embodiment. At block 376, the reader is powered off, or the Sensor Results screen is left, within a predetermined period of time after a first scan was taken (e.g., 3 minutes in the embodiment shown). If the device is powered back on, or another scan is attempted, within the predetermined period of time from the first scan, as shown at block 378, then the second scan is prevented from occurring until the predetermined period of time has lapsed. A No New Scan screen 380 is displayed indicating that another scan is not currently permitted. In some instances, as shown, screen 380 provides the time remaining until the another scan can be taken. In the embodiment shown, user confirmation form screen 380 takes the user to the Home screen as shown at block 382. Screen 380 may also provide a selection to allow the user to view the last reading in the Logbook, as shown at block 384.

Sensor Results Interface

[00268] In some aspects of the present disclosure, a graphical user interface is provided that may be utilized in connection with a reader as described herein and which functions generally to provide sensor results.

Results

[00269] **FIG. 10A** illustrates an example Sensor Results screen 388, according to one embodiment. Screen 388 may be provided, for example, after a scan has been successfully performed. The example sensor results screen 388 is shown to include a sensor reading 389a, a graph 389b of glucose readings taken, and various reader/sensor related information, such as a trending arrow, current time, battery life, sensor expiration, etc. A trigger element 389c for navigating to the Notes interface is also provided to take the user to the Notes screen as shown by block 390. It should be appreciated that other combinations of these, and other, features and trigger elements may be included in other embodiments.

[00270] In one embodiment, graph 389b does not display if the current glucose value is unavailable. Instead, a screen indicating that the glucose results are unavailable is displayed.

[00271] In one embodiment, graph 389b displays the past resulting readings for a given time period. The total time period may be sectionalized into a first predetermined period of time 389d, and a second predetermined period of time 389f. The second predetermined period 389f is subsequent to the first predetermined period of time 389d and includes more recent readings than the first predetermined period of time389d. For example, in the embodiment shown, at time 10:23pm, graph 389b displays readings in a first predetermined time period 389d of 8 hours (e.g., 2pm to 10pm), and also displays more recent readings within the second predetermined time period 389f of 1 hour (e.g., 10pm to 11pm). As graph 389b is displayed at 10:23pm, readings for the last 23 minutes (e.g., 10pm to 10:23pm) are shown in the second predetermined time period 389f. As subsequent readings are taken, graph 389b will track the readings within the second predetermined time period 389f. Once subsequent readings are taken for the entire second predetermined period of time 389f, the entire plot of readings are shifted in time by the second predetermined period of time 389f (e.g., 1 hour). In other words, once subsequent readings are obtained up to 11pm, the plot of readings from 3pm to 11pm will shift to the first predetermined period of time 389d, and the second predetermined time period 389f will begin without any readings and start to track subsequent readings between 11pm and 12pm. Once subsequent readings are obtained up to 12pm, then entire plot of readings are again shifted by the second predetermined period of time 389f (e.g., 1 hour), and the process repeats.

[00272] In one embodiment, when scanning is first started and no data has been obtained for the graph 389b, the graph 389b is not displayed until the device has obtained sensor readings for at least the first predetermined period of time 389d (e.g., 8 hours).

[00273] Thus, graph 389b begins with readings for at least the entire first predetermined period of time 389d. For example, in one embodiment, this threshold time period is equal to the first predetermined period of time 389d. In another embodiment, the threshold time period is longer than the first

predetermined period of time such that sensor readings have been obtained for part or all of the second predetermined period of time.

[00274] It is appreciated that in other embodiments, a template of the graph may be displayed at first, but no sensor readings are shown on the graph until the device has obtained sensor readings for at least the first predetermined period of time 389d.

Non-Actionable Reading

[00275] **FIG. 10B** illustrates an example Results Non-Actionable screen 388, according to one embodiment. When a scan is performed and the resulting reading is non-actionable, a Results Non-Actionable screen 388 indicates to the user that the result is non-actionable and that the result should be confirmed. For example, a non-actionable result is a reading that is determined to be too high or too low for a therapy treatment, decision, or recommendation to be made—e.g., an insulin calculation. Screen 388 includes a trigger element for providing more information to the user regarding the non-actionable reading. When selected by the user, a Non-Actionable Message screen 396 is provided additional details, recommendations, etc., such as recommending that the user take a test strip measurement before making any treatment decisions. User confirmation (e.g., by touching the "OK" button 396a) will return the user to the previously displayed Results screen.

Results – Masked Mode

[00276] **FIG. 10C** illustrates an example Results - Masked screen 398, according to one embodiment. When a scan is performed while the device is set for the Masked Mode, a Results – Masked screen 398 is displayed and indicates to the user that the reading was successful. Screen 398 does not provide the resulting reading to the user. The resulting reading is stored along with resulting readings from other scans in the device. These stored readings can later be accessed by a physician or other health care professional at a later time. For example, the physician or HCP may download the data during the next patient visit (e.g., via a wired or wireless connection between the reader and the physician's or HCP's computer,); or the data may be transferred via the internet from the reader (or patient's PC) to the physician's or HCP's computer or server; etc.

Sensor Temperature (Too Hot / Too Cold)

[00277] **FIG. 10D** illustrates an interface for indicating that the sensor temperature is too high, according to one embodiment. The Results Sensor Temp High screen 402 is displayed to indicate to the user that the sensor temperature is too high, such as with respect to a predetermined "safe" range of temperatures. For example, screen 402 may have a warning message and/or icon indicating a high sensor temperature and may further indicate that a glucose reading is not available, as shown. Screen 402 provides a trigger element 402a for providing additional information regarding the high sensor temperature. For example, when the user touches the touch-sensitive button 402a, another screen 404 is displayed to provide additional details or information, such as that the sensor temperature is too high and that the user should try again later.

[00278] **FIG. 10E** illustrates an interface for indicating that the sensor temperature is too low, according to one embodiment. The Results Sensor Temp Low screen 406 is displayed to indicate to the user that the sensor temperature is too low, such as with respect to a predetermined "safe" range of temperatures. For example, screen 406 may have a warning message and/or icon indicating a low sensor temperature and may further indicate that a glucose reading is not available, as shown. Screen 406 provides a trigger element 406a for providing additional information regarding the high sensor temperature. For example, when the user touches the touch-sensitive button 406a, another screen 408 is displayed to provide additional details or information, such as that the sensor temperature is too high and that the user should try again later.

Out of Range High/Low Readings

[00279] **FIG. 10F** illustrates an interface for indicating that the sensor reading is out of range, according to one embodiment. The Results Sensor HI screen 412 is displayed to indicate to the user that the sensor reading is too high and out of range of readings. Instead of a sensor reading being displayed, screen 412 displays an indicator element 412a, such as a message, icon, symbol, etc. For example, in the embodiment shown, the term "HI" 412a is shown in place of a sensor reading to indicate that the reading is out of range and too high.

[00280] The predetermined upper threshold reading value may be determined based on a predetermined number (e.g., 500 mg/dL), or may be determined relative to a predetermined "acceptable" range of readings to display (e.g., 40

mg/dL to 500 mg/dL), or with respect to a target range (e.g., 350 mg/dL over the target range), etc.

[00281] Screen 412 may also include a graph 412b of sensor readings that also indicates a target range 412D. Screen 412 provides a trigger element 412c for providing additional information, warning, instructions, etc., regarding the out of range and high sensor reading. For example, when the user touches the touch-sensitive button 412c, another screen 414 is displayed to provide additional details or information, such as that the glucose level is out of range high, that a high glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 412.

[00282] **FIG. 10G** illustrates an interface for indicating that the sensor reading is out of range, according to one embodiment. The Results Sensor LO screen 416 is displayed to indicate to the user that the sensor reading is out of range and too low. Instead of a sensor reading being displayed, screen 416 displays an indicator element 416a, such as a message, icon, symbol, etc. For example, in the embodiment shown, the term "LO" 416a is shown in place of a sensor reading to indicate that the reading is out of range and too low.

[00283] The predetermined lower threshold reading value may be determined based on a predetermined number (e.g., 40 mg/dL), or may be determined relative to a determined "acceptable" range of readings to display (e.g., 40 mg/dL to 500 mg/dL), or with respect to a target range (e.g., 20 mg/dL below the target range), etc.

[00284] Screen 416 may also include a graph 416b of sensor readings that also indicates a target range 416D. Screen 416 provides a trigger element 416c for providing additional information, warning, instructions, etc., regarding the out of range and low sensor reading. For example, when the user touches the touch-sensitive button 416c, another screen 418 is displayed to provide additional details or information, such as that the glucose level is out of range low, that a low glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 416.

High/Low Sensor Readings

[00285] **FIG. 10H** illustrates an interface for indicating that the sensor reading is high, according to one embodiment. The Results Sensor High screen 422 is displayed to indicate to the user that the sensor reading is a high reading, such as via a message, icon, symbol, etc., 422c. For example, in the embodiment shown, after a high reading is obtained, screen 422 is displayed and the sensor reading 422a is shown. In addition to showing the sensor reading 422a, screen 422 includes a trigger element 422c for indicating the high reading and for accessing additional information, warning, instructions, etc., regarding the high sensor reading. For example, when the user touches the touch-sensitive button 422c, another screen 424 is displayed to provide additional details or information about the high reading, such as that the glucose level is high, that a high glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 422.

[00286] The predetermined upper threshold reading value may be determined based on a predetermined number (e.g., 240 mg/dL), or may be determined relative to a predetermined range of readings (e.g., 70mg/dL to 240 mg/dL), or with respect to a target range (e.g., 120 mg/dL over the target range), etc.

[00287] Screen 422 may also include a graph 422b of sensor readings that also indicates a target range 422d. In addition, screen 422 may include a distinguishing element 422f for identifying the high reading on the graph 422b—e.g., in the embodiment shown, an encircled dot 422f. Screen 422 may also include other trigger elements, such as a trigger element 422e for initiating the Notes interface.

[00288] **FIG. 10I** illustrates an interface for indicating that the sensor reading is low, according to one embodiment. The Results Sensor Low screen 426 is displayed to indicate to the user that the sensor reading is a low reading (e.g., with respect to a predetermined "acceptable" reading range), such as via a message, icon, symbol, etc., 426c. For example, in the embodiment shown, after a low reading is obtained, screen 426 is displayed and the sensor reading 426a is shown. In addition to showing the sensor reading 426a, screen 426 includes a trigger element 426c for indicating the low reading and for accessing additional information, warning, instructions, etc., regarding the low sensor reading. For

example, when the user touches the touch-sensitive button 426c, another screen 428 is displayed to provide additional details or information about the low reading, such as that the glucose level is low, that a low glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 426.

[00289] The predetermined lower threshold reading value may be determined based on a predetermined number (e.g., 70 mg/dL), or may be determined relative to a predetermined range of readings (e.g., 70mg/dL to 240 mg/dL), or with respect to a target range (e.g., 10 mg/dL below the target range), etc.

[00290] Screen 426 may also include a graph 426b of sensor readings that also indicates a target range 426d. In addition, screen 426 may include a distinguishing element 426f for identifying the low reading on the graph 426b—e.g., in the embodiment shown, an encircled dot 426f. Screen 426 may also include other trigger elements, such as a trigger element 426e for initiating the Notes interface.

Projected High/Low Sensor Readings

[00291] **FIG. 10J** illustrates an interface for indicating that a high analyte level is projected, according to one embodiment. The Results Sensor Projected High screen 432 is displayed to indicate to the user that a high analyte level is projected based on the current sensor reading and trend, such as via a message, icon, symbol, etc., 432c. For example, in the embodiment shown, after a sensor reading is obtained, screen 432 is displayed and the sensor reading 432a is shown. In addition to showing the sensor reading 432a, screen 432 includes a trigger element 432c for indicating a projected high analyte level and for accessing additional information, warning, instructions, etc., regarding the projected high analyte level. For example, when the user touches the touch-sensitive button 432c, another screen 434 is displayed to provide additional details or information about the projected high analyte level, such as that the glucose level is high, that a high glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 432.

[00292] Screen 432 may also include a graph 432b of sensor readings that also indicates a target range 432d. In addition, screen 432 may include a distinguishing element 432f for identifying the projected high reading on the graph 432b—e.g., in the embodiment shown, an encircled dot 432f. Screen 432 may also include other trigger elements, such as a trigger element 432e for initiating the Notes interface.

[00293] **FIG. 10K** illustrates an interface for indicating that a low analyte level is projected, according to one embodiment. The Results Sensor Projected Low screen 436 is displayed to indicate to the user that a low analyte level is projected based on the current sensor reading and trend, such as via a message, icon, symbol, etc., 436c. For example, in the embodiment shown, after a sensor reading is obtained, screen 426 is displayed and the sensor reading 436a is shown. In addition to showing the sensor reading 436a, screen 436 includes a trigger element 436c for indicating the projected low analyte level and for accessing additional information, warning, instructions, etc., regarding the projected low analyte level. For example, when the user touches the touch-sensitive button 436c, another screen 438 is displayed to provide additional details or information about the projected low analyte level, such as that the glucose level is low, that a low glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the “OK” button) the user is taken back to screen 436.

[00294] Screen 436 may also include a graph 436b of sensor readings that also indicates a target range 436d. In addition, screen 436 may include a distinguishing element 436f for identifying the projected low reading on the graph 436b—e.g., in the embodiment shown, an encircled dot 436f. Screen 436 may also include other trigger elements, such as a trigger element 436e for initiating the Notes interface.

Blood Glucose Test & Results

[00295] In some aspects of the present disclosure, a graphical user interface is provided that may be utilized in connection with a reader as described herein and which functions generally to provide perform an analyte test and provide test results.

Blood Glucose Strip Test Interface

[00296] **FIG. 11** illustrates an example method 440 for performing a blood glucose test with a test strip, according to one embodiment. At block 442, a test strip is inserted within an analyte monitoring device that is powered off. Once inserted into the device, the device powers on, as shown at block 444. The strip port light, such as a light emitting diode for example, turns on and provides light to the strip port, as shown at block 446. At block 448, it is determined whether a universal serial bus (USB) connection is established with the device. It should be appreciated that other communication technologies may be implemented in other embodiments—e.g., micro-USB, mini USB, RS-232, Ethernet, Firewire, or other data communication connections. If a USB connection is established, then the strip test is prevented and a Strip Test Disabled screen 450 is displayed to indicate that the strip test is not permitted and that the user should unplug the device to perform a glucose test. If the test strip or the USB connection is removed, then the Reader will display the Home screen.

[00297] If at block 448, it is determined that a USB connection is not established, then it is determined if the inserted test strip is a blood glucose test strip or a ketone test strip, as shown at block 452. The test strip may include an identifying element, such as a specific contact configuration, to enable the device to identify what type of test strip it is. If it is determined that the test strip is a ketone test strip, then the device initiates the Ketone Test interface to perform a ketone test measurement, as shown by block 454. If, on the other hand, the test strip is determined to be a blood glucose test strip, then it is determined if the device temperature is outside of the device's operating range, as represented by block 456 and reference path F.

[00298] If it is determined that the temperature is above or below the device's operating range, then the port light is turned off, as shown by block 458, and the Strip Test Results interface is initiated and indicates that the temperature is too high or too low, as shown by Strip Test Results screen 460 and 462, respectively.

[00299] If at block 456, it is determined that the temperature is within the device's operating range, then Add Blood interface 464 is displayed to indicate that blood may be applied to the test strip. If the test strip is removed at this point, as shown by block 466, then the port light turns off and the Home screen is displayed, as

represented by blocks 468 and 470, respectively. If at screen 464, blood is applied to the test strip, as shown by block 472, then it is determined if there was sufficient blood applied to accurately perform a test measurement, as shown by block 474. It should be appreciated that the timing of this determination may vary. If not enough blood is present, then the Strip/Hardware Errors interface is displayed to indicate that not enough blood was applied or that there was an error, as shown by block 476.

[00300] If it is determined that sufficient blood has been applied to the test strip, then the port light turns off, as shown by block 478, and a test measurement is performed. A Waiting interface 480 may be displayed while the test measurement is being performed. At block 482, it is determined if the results are ready. If ready, then the Strips Test Results screen 486 is displayed to indicate the resulting reading. If not ready (e.g., after a predetermined timeout period), then the Strip/Hardware Errors screen 484 is displayed to indicate that there was an error in the measurement.

[00301] Looking ahead to **FIG. 34**, an example Waiting interface according to one embodiment is illustrated. Waiting interface 2400 is animated. For example, the a first screen 2402 includes a butterfly 2401 at the bottom left corner. As the next screen 2404 is displayed, the butterfly 2401 is located in a different position. Similarly, at the next screen 2406, the butterfly 2401 is again moved to a different position. When displayed consecutively, an animated sequence results.

[00302] FIG. 34 also illustrates an example animation interface 2408 to instruct the user to add blood, according to one embodiment. Screens 2410, 2412, and 2414 display an image of a finger with blood on it and an analyte monitoring device with test strip inserted into the strip port. The finger and test strip move closer as the sequence of screens 2410, 2412, and 2414 progress to animate the application of blood process. Animation interface 2408 may be displayed, for example, when the analyte monitoring device is ready to receive blood

[00303] FIG. 34 also illustrates an example animation interface 2415 to instruct the user to add blood during a ketone test, according to one embodiment. Simiarly to animation interface 2408, screens 2416, 2418, and 2420 display an image of a finger with blood on it and an analyte monitoring device with test strip inserted into the strip port. The finger and test strip move closer as the sequence of screens 2416, 2418, and 2420 progress to animate the application of blood

process. Animation interface 2408, however includes an indication that a Ketone test is being performed—e.g., displaying the words, "Ketone Test".

Blood Glucose Strip Test Results Interface

[00304] In some aspects of the present disclosure, a graphical user interface is provided that may be utilized in connection with a reader as described herein and which functions generally to provide blood glucose strip test results.

Results Screen

[00305] **FIG. 12A** illustrates an example blood glucose results (Results BG) screen 490, according to one embodiment. Screen 490 may be provided, for example, after a test strip measurement has been successfully performed. The example Results BG screen 490 is shown to include a test strip measurement 490a and various analyte and device related information, such as indicator elements for a blood glucose strip test 490b, current time 490d, battery life 490e, etc. A trigger element 490c for navigating to the Notes interface is also provided to take the user to the Notes screen as shown by block 494. It should be appreciated that other combinations of these, and other, features and trigger elements may be included in other embodiments.

[00306] For analyte monitoring devices with an active insulin calculator, Screen 492 may be provided, for example, after a test strip measurement has been successfully performed. The example Results BG screen 492 is shown to include a test strip measurement 492a and various analyte and device related information, such as indicator elements for a blood glucose strip test 492b, current time 492d, battery life 492e, etc. A trigger element 492c for navigating to the Notes interface is also provided to take the user to the Notes screen as shown by block 494. A trigger element 492f for navigating to an Insulin Calculation interface is also provided as shown by block 496 to provide a calculated insulin dose based on the test measurement 492a. It should be appreciated that other combinations of these, and other, features and trigger elements may be included in other embodiments.

Control Solution Screen

[00307] **FIG. 12B** illustrates an example interface for indicating the results of a blood glucose control solution test, according to one embodiment. The Results Control Solution (CTRL SLTN) screen 498 includes the results 498a of a blood glucose control solution test and various analyte and device related information,

such as indicator elements for indicating the blood glucose control solution test 498b, indicating the current time 498d, indicating the battery life 498e, etc.

Reader Temperature Warning (Too Hot / Too Cold) Screen

[00308] **FIG. 12C** illustrates example interfaces for indicating that the analyte monitoring device's temperature is too high or too low, according to one embodiment. Results BG Temp High2/Low2 screen 502 is displayed to indicate to the user that the device temperature is either too high or too low to provide a reading, such as with respect to a predetermined "safe" range of temperatures to perform an accurate test measurement. For example, screen 502 may have a warning message and/or icon 502a indicating too high or too low of a temperature and may further indicate that a glucose reading is not available, as shown. Screen 502 provides a trigger element 502b for providing additional information regarding the too high or too low device temperature. For example, when the user touches the touch-sensitive button 502b, another screen 504 or 506 is displayed to provide additional details or information, such as that the device temperature is too low or too high, respectively, and that the user should try again later. The user can confirm by pressing the "OK" button and return to the previously displayed Results screen, for instance.

[00309] Results BG Temp High1/Low1 screen 508 is an example interface that is displayed when a test measurement is available, but also indicates to the user that the device temperature is either high or low, such as with respect to a predetermined "safe" range of temperatures. For example, screen 508 displays the resulting test measurement 508a and also displays a warning message and/or icon 502b indicating a high or low device temperature. Icon 502b also serves as a trigger element for providing additional information regarding the high or low device temperature. For example, when the user touches the touch-sensitive button 502b, another screen 512 or 510 is displayed to provide additional details or information, such as that the device temperature is too low or too high, respectively, and that the user should try again later. In one embodiment, the device is programmed such that the temperature error takes precedence over other notifications that may be implemented.

Out of Range High/Low Screen

[00310] **FIG. 12D** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment. The Results BG HI

screen 516 is displayed to indicate to the user that the sensor reading is too high and out of range of readings. Instead of a measurement reading being displayed, screen 516 displays an indicator element 516a, such as a message, icon, symbol, etc. For example, in the embodiment shown, the term "HI" 516a is shown in place of a measurement reading to indicate that the reading is out of range and too high.

[00311] The predetermined upper threshold reading value may be determined based on a predetermined number (e.g., 500 mg/dL), or may be determined relative to a predetermined "acceptable" range of readings to display (e.g., 20 mg/dL to 500 mg/dL), or with respect to a target range (e.g., 350 mg/dL over the target range), etc.

[00312] Screen 516 provides a trigger element 516 for providing additional information, warning, instructions, etc., regarding the out of range and high measurement reading. For example, when the user touches the touch-sensitive button 516b, another screen 518 is displayed to provide additional details or information, such as that the glucose level is out of range high, that a high glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 516.

[00313] **FIG. 12E** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment. The Results BG LO screen 520 is displayed to indicate to the user that the measurement reading is out of range and too low. Instead of a sensor reading being displayed, screen 520 displays an indicator element 520q, such as a message, icon, symbol, etc. For example, in the embodiment shown, the term "LO" 520a is shown in place of a measurement reading to indicate that the reading is out of range and too low.

[00314] The predetermined lower threshold reading value may be determined based on a predetermined number (e.g., 20 mg/dL), or may be determined relative to a determined "acceptable" range of readings to display (e.g., 20 mg/dL to 500 mg/dL), or with respect to a target range (e.g., 40 mg/dL below the target range), etc.

[00315] Screen 520 provides a trigger element 520a for providing additional information, warning, instructions, etc., regarding the out of range and low measurement reading. For example, when the user touches the touch-sensitive

button 520b, another screen 522 is displayed to provide additional details or information, such as that the glucose level is out of range low, that a low glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 520.

High/Low Glucose Screen

[00316] **FIG. 12F** illustrates an interface for indicating that the measurement reading is high, according to one embodiment. The Results BG High screen 526 is displayed to indicate to the user that the measurement reading is a high reading, such as via a message, icon, symbol, trigger element, etc., 526c. For example, in the embodiment shown, after a high reading is obtained, screen 526 is displayed and the measurement reading 526a is shown. In addition to showing the sensor reading 526a, screen 526 includes a trigger element 526c for indicating the high reading and for accessing additional information, warning, instructions, etc., regarding the high measurement reading. For example, when the user touches the touch-sensitive button 422c, another screen 528 is displayed to provide additional details or information about the high reading, such as that the glucose level is high, that a high glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 526.

[00317] The predetermined upper threshold reading value may be determined based on a predetermined number (e.g., 240 mg/dL), or may be determined relative to a predetermined range of readings (e.g., 70mg/dL to 240 mg/dL), or with respect to a target range (e.g., 120 mg/dL over the target range), etc.

[00318] Screen 526 may also include an indicator element (e.g., icon, symbol, etc.) 526b that indicates that the measurement reading pertains to a blood glucose strip test. In the embodiment shown, a symbol of a blood drop 526b is used. Screen 526 may also include other trigger elements, such as a trigger element 526e for initiating the Notes interface.

[00319] **FIG. 12G** illustrates an interface for indicating that the measurement reading is low, according to one embodiment. The Results BG Low screen 530 is displayed to indicate to the user that the measurement reading is a low reading (e.g., with respect to a predetermined "acceptable" reading range), such as via a

message, icon, symbol, trigger element, etc., 530c. For example, in the embodiment shown, after a low reading is obtained, screen 530 is displayed and the measurement reading 530a is shown. In addition to showing the measurement reading 530a, screen 530 includes a trigger element 530c for indicating the low reading and for accessing additional information, warning, instructions, etc., regarding the low sensor reading. For example, when the user touches the touch-sensitive button 530c, another screen 532 is displayed to provide additional details or information about the low reading, such as that the glucose level is low, that a low glucose level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 530.

[00320] The predetermined lower threshold reading value may be determined based on a predetermined number (e.g., 70 mg/dL), or may be determined relative to a predetermined range of readings (e.g., 70mg/dL to 240 mg/dL), or with respect to a target range (e.g., 10 mg/dL below the target range), etc.

[00321] Screen 530 may also include an indicator element (e.g., icon, symbol, etc.) 530b that indicates that the measurement reading pertains to a blood glucose strip test. In the embodiment shown, a symbol of a blood drop 530b is used. Screen 530 may also include other trigger elements, such as a trigger element 530e for initiating the Notes interface.

Ketone Test & Results

[00322] In some aspects of the present disclosure, a graphical user interface is provided that may be utilized in connection with a reader as described herein and which functions generally to provide perform an ketone strip test measurement and provide test results.

Ketone Strip Test Interface

[00323] **FIG. 13** illustrates an example method 534 for performing a ketone test with a ketone test strip, according to one embodiment.At block 536, a ketone test strip is inserted within an analyte monitoring device that is powered off. Once inserted into the device, the device powers on, as shown at block 538. The strip port light, such as a light emitting diode for example, turns on and provides light to the strip port, as shown at block 540. At block 542, it is determined whether a universal serial bus (USB) connection is established with the device. Again, it

should be appreciated that other communication technologies may be implemented in other embodiments—e.g., micro-USB, mini USB, RS-232, Ethernet, Firewire, or other data communication connections. If a USB connection is established, then the strip test is prevented and a Strip Test Disabled screen 544 is displayed to indicate that the strip test is not permitted and that the user should unplug the device to perform a ketone or blood glucose test. If the test strip or the USB connection is removed, then the Reader will display the Home screen.

[00324] If at block 542, it is determined that a USB connection is not established, then it is determined if the inserted test strip is a blood glucose test strip or a ketone test strip, as shown at block 546. The test strip may include an identifying element, such as a specific contact configuration, to enable the device to identify what type of test strip it is. If it is determined that the test strip is a blood glucose test strip, then the device initiates the Blood Glucose Strip Test interface to perform a blood glucose test measurement, as shown by block 548. If, on the other hand, the test strip is determined to be a ketone test strip, then it is determined if the device temperature is outside of the device's operating range, as represented by block 550 and reference path H.

[00325] If it is determined that the temperature is above or below the device's operating range, then the port light is turned off, as shown by block 551, and the Ketone Results interface is initiated and indicates that the temperature is too high or too low, as shown by Ketone Results screen 552 and 554, respectively.

[00326] If at block 550, it is determined that the temperature is within the device's operating range, then P K Add Blood interface 556 is displayed to indicate that blood may be applied to the test strip. If the test strip is removed at this point, as shown by block 558, then the port light turns off and the Home screen is displayed, as represented by blocks 560 and 562, respectively. If at screen 556, blood is applied to the test strip, as shown by block 564, then it is determined if there was sufficient blood applied to accurately perform a test measurement, as shown by block 566 and reference path I. It should be appreciated that the timing of this determination may vary. If not enough blood is present, then the Strip/Hardware Errors interface is displayed to indicate that not enough blood was applied or that there was an error, as shown by block 568.

[00327] If it is determined that sufficient blood has been applied to the test strip, then a Waiting interface 570 is displayed while a test measurement is being performed. At block 572, it is determined if the results are ready. If ready, then the Strips Test Results screen 576 is displayed to indicate the resulting reading. If not ready (e.g., after a predetermined timeout period), then the Strip/Hardware Errors screen 574 is displayed to indicate that there was an error in calculating a measurement.

Ketone Strip Test Results Interface

[00328] In some aspects of the present disclosure, a graphical user interface is provided that may be utilized in connection with a reader as described herein and which functions generally to provide ketone strip test results.

[00329] Results Screen

[00330] **FIG. 14A** illustrates an example Ketone Results screen 580, according to one embodiment. Screen 580 may be provided, for example, after a ketone test strip measurement has been successfully performed. The example Ketone Results screen 580 is shown to include a ketone test strip measurement 580a and various analyte and device related information, such as indicator elements for indicating the ketone strip test 580b, indicating the current time 580d, indicating the battery life 580e, etc. In one embodiment, the indicator element 580b for identifying the ketone test strip measurement is the same symbol as the indicator element for a blood glucose test strip measurement. In such case, the indicator element 580b is generally indicating a test strip measurement result versus a sensor reading result. It should be appreciated that in other embodiments, different indicator elements may be used for the ketone strip test and the blood glucose strip test to distinguish between the two tests.

[00331] A trigger element 580c for navigating to the Notes interface is also provided to take the user to the Notes screen as shown by block 582. It should be appreciated that other combinations of these, and other, features and trigger elements may be included in other embodiments.

[00332] In one embodiment, the insulin calculator is enabled if the setting is enabled and if both of the following are met: 1) the ketone test has been performed within a predetermined period of time (e.g., 15 minutes) of successful strip test or another predetermined period of time (e.g., 3 minutes) of a

successful sensor test; and 2) insulin was not logged with that recent glucose test. Unless both conditions are met, the insulin calculator button is not provided.

Control Solution Screen

[00333] **FIG. 14B** illustrates an example interface for indicating the results of a ketone control solution test, according to one embodiment. The Ketone Control Solution Results screen 584 includes the results 584a of a ketone control solution test and various analyte and device related information, such as indicator elements for indicating a control solution test 584b, indicating the current time 584d, indicating the battery life 584e, etc. In one embodiment, the indicator element 584b for identifying the ketone control solution test is the same symbol as the indicator element for a blood glucose control solution test. In such case, the indicator element 584b is generally indicating a control solution test. It should be appreciated that in other embodiments, different indicator elements may be used for the ketone control solution test and the blood glucose control solution test to distinguish between the two tests.

Reader Temperature Warning (Too Hot / Too Cold) Screen

[00334] **FIG. 14C** illustrates example interfaces for indicating that the analyte monitoring device's temperature is too high or too low, according to one embodiment. Results Ketone Temp High2/Low2 screen 588 is displayed to indicate to the user that the device temperature is either too high or too low to provide a ketone reading, such as with respect to a predetermined "safe" range of temperatures to perform an accurate ketone test measurement. For example, screen 588 may have a warning message and/or icon 588a indicating too high or too low of a temperature and may further indicate that a ketone reading is not available, as shown. Screen 588 provides a trigger element 588b for providing additional information regarding the too high or too low device temperature. For example, when the user touches the touch-sensitive button 588b, another screen 590 or 592 is displayed to provide additional details or information, such as that the device temperature is too low or too high, respectively, and that the user should try again later.

[00335] Results Ketone Temp High1/Low1 screen 594 is an example interface that is displayed when a ketone test measurement is available, but also indicates to the user that the device temperature is either high or low, such as with respect to a predetermined "safe" range of temperatures. For example, screen 594

displays the resulting test measurement 594a and also displays a warning message and/or icon 594b indicating a high or low device temperature. Icon 502b also serves as a trigger element for providing additional information regarding the high or low device temperature. For example, when the user touches the touch-sensitive button 502b, another screen 598 or 596 is displayed to provide additional details or information, such as that the device temperature is too low or too high, respectively, and that the user should try again later.

Out of Range High Screen

[00336] **FIG. 14D** illustrates an interface for indicating that the measurement reading is out of range, according to one embodiment. The Ketone Results Out of Range High screen 602 is displayed to indicate to the user that the ketone measurement reading is too high and out of range of readings. Instead of a ketone measurement reading being displayed, screen 602 displays an indicator element 602a, such as a message, icon, symbol, etc. For example, in the embodiment shown, the term "HI" 602a is shown in place of a measurement reading to indicate that the reading is out of range and too high.

[00337] The predetermined upper threshold reading value may be determined based on a predetermined number, or may be determined relative to a predetermined "acceptable" range of readings to display, or with respect to a target range, etc.

[00338] Screen 602 provides a trigger element 602b for providing additional information, warning, instructions, etc., regarding the out of range and high ketone measurement reading. For example, when the user touches the touch-sensitive button 602b, another screen 604 is displayed to provide additional details or information, such as that the ketone level is out of range high, that a high ketone level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. Upon user confirmation (e.g., via selection of the "OK" button) the user is taken back to screen 602.

High Ketones Screen

[00339] **FIG. 14E** illustrates an interface for indicating that the ketone measurement reading is high, according to one embodiment. The Ketone Result – High Ketones screen 608 is displayed to indicate to the user that the ketone

measurement reading is a high reading, such as via a message, icon, symbol, trigger element, etc., 608c.

[00340] The predetermined upper threshold reading value may be determined based on a predetermined number, or may be determined relative to a predetermined range of readings, or with respect to a target range, etc.

[00341] In the embodiment shown, after a high ketone reading is obtained, screen 608 is displayed and the measurement reading 608a is shown. In addition to showing the sensor reading 608a, screen 608 includes a trigger element 608c for indicating the high ketone reading and for accessing additional information, warning, instructions, etc., regarding the high measurement reading. For example, when the user touches the touch-sensitive button 608c, another screen 610 or 612 is displayed to provide additional details or information about the high reading, such as that the ketone level is high, that a high ketone level may be dangerous, and that the user should check again later and treat as recommended by their health care professional. In the embodiment shown, screen 610 is displayed if the ketone reading is between a predetermined range (e.g., .6 to 1.5) and the second screen 612 is displayed if the ketone reading is between a high predetermined range (e.g., 1.6 to 8).

[00342] Screen 608 may also include an indicator element (e.g., icon, symbol, etc.) 608b that indicates that the measurement reading pertains to a strip test measurement (e.g., ketone test strip measurement). In the embodiment shown, a symbol of a blood drop 608b is used. Screen 608 may also include other trigger elements, such as a trigger element 608e for initiating the Notes interface.

Notes Interface

[00343] An exemplary embodiment of a graphical user interface which may be utilized in connection with a Reader as described herein and which facilitates a Notes procedure 3000 for entering notes into the logbook is provided. This graphical user interface is now described in greater detail with reference to FIG. 15.

[00344] A graphical user interface which facilitates the Notes procedure 3000 of the reader may include two different notes interfaces; a first notes interface for embodiments where the insulin calculator is disabled 3002, and a second notes interface for embodiments where the insulin calculator is enabled 3004. The Note (Insulin Calculator Disabled) Interface 3002, shown in FIG. 15A, begins

with the display of an “Add to Logbook” screen 3006. This “Add to Logbook” screen 3006 includes a list of several different notes that may be entered into the Logbook. The list of user selectable notes may include default (e.g., preset notes) and, in some instances, custom (e.g., user-defined) notes. For example, the default notes may include one or more of the following: rapid-acting insulin 3008, long-acting insulin 3010, food 3012, exercise 3014, and medication 3016. The custom notes may include any notes created by the user through the associated informatics software. In some cases, 12 notes may be included in the list of user-selectable notes. For example, 5 default notes and 7 custom notes may be included. In certain embodiments, 4 user-selectable notes are displayed on the touchscreen at once. If there are more than 4 user-selectable notes, the list of notes may be scrolled as necessary to view the list using scroll touchscreen buttons, such as down arrow (e.g., down triangle) touchscreen button 3018 and up arrow (e.g., up triangle) touchscreen button 3020. One or more user-selectable notes may be selected by touching the touchscreen checkbox adjacent the note desired to be selected. Touching a touchscreen checkbox will toggle the checkbox from a checked to unchecked state indicating whether the associated not is selected or not selected, respectively. For instance, the rapid-acting insulin note may be selected by touching the touchscreen checkbox 3022, which then displays a check mark in the touchscreen checkbox to indicate that the rapid-acting insulin note has been selected. The other user-selectable notes may be selected or unselected (e.g., checked or unchecked) as desired in an analogous manner.

[00345] The selection of notes may be saved by touching the “OK” touchscreen button 3024, which saves the selection of user-selectable notes and returns the graphical user interface to the previous screen. If the “OK” touchscreen button 3024 is pressed without changing the selection of user-selectable notes, then the previous selection of user-selectable notes is retained and saved.

[00346] In some embodiments, the amount of rapid-acting insulin, long-acting insulin, food, exercise, and medication may be entered by touching the numerical input touchscreen button (e.g., the “1 2 3” touchscreen button) associated with the desired selection. In some cases, the numerical input touchscreen button may not be displayed if the corresponding touchscreen checkbox is not checked, and may only be displayed if the corresponding

touchscreen checkbox is checked. For example, when rapid-acting insulin checkbox 3008 is unchecked, the numerical input touchscreen button 3026 for rapid-acting insulin is not displayed. When the rapid-acting insulin checkbox is checked 3022, the numerical input touchscreen button 3026 for rapid-acting insulin is displayed and may be selected.

[00347] The amount of rapid-acting insulin may be entered by pressing the numerical input touchscreen button 3026 associated with the rapid-acting insulin note selection. Pressing the numerical input touchscreen button 3026 for rapid-acting insulin will cause a numerical input screen 3028 for rapid acting insulin (e.g., the "Enter Rapid-Acting Insulin" screen) to be displayed, as shown by reference path (J) (see FIG. 15B). In the numerical input screen 3028 for rapid-acting insulin, the amount (e.g., units) of rapid-acting insulin may be entered. The numerical input screen initially displays no value (e.g., "- -" is displayed in place of any numbers), however, the amount of rapid-acting insulin may be adjusted by pressing the up arrow 3030 (e.g., "+") touchscreen button or the down arrow 3032 (e.g., "-") touchscreen button to increase or decrease, respectively, the amount of rapid-acting insulin as desired. For example, the amount of rapid-acting insulin 3034 may be adjusted by 1 unit increments by tapping the up arrow 3030 or the down arrow 3032. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Once the desired amount of rapid-acting insulin is entered, the amount may be saved by pressing the "OK" touchscreen button 3036, which saves the entered amount of rapid-acting insulin and then returns the graphical user interface to the "Add to Logbook" screen 3006, as shown by reference path (J). Numerical values for long-acting insulin may be entered in an analogous manner by pressing the numerical input touchscreen button 3038 (e.g., the "1 2 3" touchscreen button) associated with the long-acting insulin selection on the "Add to Logbook" screen 3006.

[00348] Numerical values for food may be entered by pressing the numerical input touchscreen button 3040 (e.g., the "1 2 3" touchscreen button) associated with the food selection on the "Add to Logbook" screen 3006. Pressing the numerical input touchscreen button 3040 for food will cause a numerical input screen 3042 for carbohydrates to be displayed (e.g., the "Enter Carbs" screen), as shown by

reference path (J) (see FIG. 15C). In the numerical input screen 3042 for food, the amount (e.g., grams) of carbs may be entered. The numerical input screen initially displays no value (e.g., "- -" is displayed in place of any numbers), however, the amount of carbs may be adjusted by pressing the up arrow 3044 (e.g., "+") touchscreen button or the down arrow 3046 (e.g., "-") touchscreen button to increase or decrease, respectively, the amount of carbs as desired. For example, the amount of carbs 3048 may be adjusted by 1 gram increments by tapping the up arrow 3044 or the down arrow 3046. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Once the desired amount of carbs is entered, the amount may be saved by pressing the "OK" touchscreen button 3050, which saves the entered amount of carbs and then returns the graphical user interface to the "Add to Logbook" screen 3006, as shown by reference path (J).

[00349] In certain embodiments, instead of entering the amount of food as grams of carbs, the amount of food may be entered as servings of carbs, as shown in FIG. 15E. In the numerical input screen 3068 for servings of carbs, the screen initially displays no value (e.g., "- -" is displayed in place of any numbers), however, the servings of carbs may be adjusted by pressing the up arrow 3070 (e.g., "+") touchscreen button or the down arrow 3072 (e.g., "-") touchscreen button to increase or decrease, respectively, the servings of carbs as desired. For example, the servings of carbs 3074 may be adjusted by 0.5 serving increments by tapping the up arrow 3070 or the down arrow 3072. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. In some cases, the numerical input screen 3068 for servings of carbs may include a display of the grams of carbs 3076 that corresponds to the number of servings entered. In some cases, the numerical input screen 3068 for servings of carbs may include a display of the energy (e.g., kcal) of carbs 3078 that corresponds to the number of servings entered. Once the desired servings of carbs is entered, the value may be saved by pressing the "OK" touchscreen button 3080, which saves the entered servings of carbs and then returns the graphical user interface to the "Add to Logbook" screen 3006.

[00350] Referring back to the numerical input screen 3042 for the amount (e.g., grams) of carbs (see FIG. 15C), the numerical input screen 3042 also includes two touchscreen checkboxes configured to allow the selection of reminders to check a user's glucose. For example, the numerical input screen 3042 includes a "1 hr" touchscreen checkbox 3052 and a "2 hr" touchscreen checkbox 3054. None, one or both of the touchscreen checkboxes may be selected as desired. Pressing the "1 hr" touchscreen checkbox 3052 will display a check mark in the "1 hr" touchscreen checkbox 3052 indicating that the "1 hr" touchscreen checkbox 3052 has been selected and will set the Reader to alert the user to check the user's glucose level after 1 hour. Pressing the "2 hr" touchscreen checkbox 3054 will display a check mark in the "2 hr" touchscreen checkbox 3054 indicating that the "2 hr" touchscreen checkbox 3054 has been selected and will set the Reader to alert the user to check the user's glucose level after 2 hours. The check glucose reminder checkboxes may also be displayed on the numerical input screen 3068 for entering the servings of carbs as described above (see FIG. 15E).

[00351] As indicated above, a second notes interface may be provided for embodiments where the insulin calculator is enabled 3004. The Note (Insulin Calculator Enabled) Interface 3004, shown in FIG. 15D, begins with the display of an "Add to Logbook" screen 3056. This "Add to Logbook" screen 3056 includes a list of several different notes that may be entered into the Logbook, similar to the "Add to Logbook" screen 3006 in the Note (Insulin Calculator Disabled) Interface 3002 described above. In the "Add to Logbook" screen 3056 of the Note (Insulin Calculator Enabled) Interface 3004, the user-selectable notes (e.g., default and custom notes) may be selected (e.g., checked) or unselected (e.g., unchecked) as desired in an analogous manner as described above in relation to the Note (Insulin Calculator Disabled) Interface 3002. In addition, the numerical input touchscreen buttons (e.g., the "1 2 3" touchscreen buttons) of the Note (Insulin Calculator Enabled) Interface 3004 function in an analogous manner as described above in relation to the Note (Insulin Calculator Disabled) Interface 3002.

[00352] In the Note (Insulin Calculator Enabled) Interface 3004, the insulin on board and rapid-acting insulin calculator features of the graphical user interface are enabled. For instance, in the Note (Insulin Calculator Enabled) Interface

3004, rather than displaying a numerical input touchscreen button for rapid-acting insulin, a calculator touchscreen button 3058 is displayed with the rapid-acting insulin selection. Pressing the calculator touchscreen button 3058 will cause the graphical user interface to display the Insulin on Board Interface 3060 (see FIG.16) and the Insulin Calculator Interface 3062 (see FIG. 17). In some embodiments, if food information (e.g., amount of carbs) is entered as described above, then when the calculator touchscreen button 3058 is pressed, the amount of carbs that was previously entered will automatically be displayed in the corresponding insulin on board and calculator interface screens.

[00353] In certain embodiments, the Notes – From Logbook Entry Interface 3064 may be displayed from the Logbook Entry screen if the "add or edit notes" touchscreen button is pressed. The Notes – From Logbook Entry Interface 3064 begins with the display of an "Add to Logbook" screen 3066. This "Add to Logbook" screen 3066 includes a list of several different user-selectable notes that may be entered into the Logbook, similar to user-selectable notes described above. In certain embodiments, the "Add to Logbook" screen 3066 of the Notes – From Logbook Entry Interface 3064 does not include a user-selectable note for rapid-acting insulin or food. The other default notes (e.g., long-acting insulin, exercise, medication) and custom notes may still be available for selection by the user as desired.

Insulin on Board Interface

[00354] As described above, pressing the calculator touchscreen button 3058 from the "Add to Logbook" screen 3056 of the Notes (Insulin Calculator Enabled) Interface 3004, will cause the graphical user interface to display the Insulin on Board Interface 3060 (see FIG.16). Regarding FIG. 16A, in certain embodiments, a user's insulin on board (IOB) information is used in the calculation of a recommended rapid-acting insulin dosage amount. For example, if an insulin dosage has been logged (e.g., logged as a calculated dose, or entered into the logbook as a rapid-acting dose), then the insulin dosage information may be used in the calculation of a recommended rapid-acting insulin dosage amount 3082.

[00355] In certain embodiments, a user's insulin on board information is used in the calculation of a recommended rapid-acting insulin dosage amount if the user's most recent insulin dose was administered within a certain time period. In

some instances, the insulin calculator may be partially locked out if the difference between the current time and the time the most recent rapid-acting insulin was administered is less than a lock out time period (e.g., the most recent insulin dose was administered within a preceding lockout time period, such as within the past 2 hours). During the lockout time period, the insulin calculator may be programmed to only calculate a meal bolus and may not calculate an additional correction bolus 3084. During the lockout time period, the insulin calculator may not include insulin on board into the calculation of a meal bolus.

[00356] If the difference between the current time and the time the most recent insulin bolus was administered is greater than a threshold time period (e.g., the lockout time period) and less than the duration of insulin action, then the insulin calculator may be programmed to include the user's IOB into the calculation of the recommended rapid-acting insulin dosage amount 3086. In the time period between the end of the lockout time period and the end of the user's duration of insulin action, the insulin calculator may be programmed to determine the recommended rapid-acting insulin dosage amount based on the determined analyte concentration and the insulin on board information. For instance, in the time period between the end of the lockout time period and the end of the user's duration of insulin action, the insulin calculator may be programmed to subtract the user's IOB from the rapid-acting insulin dosage based upon the current glucose concentration level to determine the recommended rapid-acting insulin dosage amount.

[00357] In certain instances, if the difference between the current time and the time the most recent insulin bolus was administered is greater than the user's duration of insulin action, then the insulin calculator will not include insulin on board into the calculation of a recommended rapid-acting insulin dosage amount 3088. In the time period after the user's duration of insulin action has expired (and before the next dose of insulin is administered), the insulin calculator may assume the user's insulin on board is zero. In the time period after the user's duration of insulin action has expired (and before the next dose of insulin is administered), the insulin calculator may be programmed to determine the rapid-acting insulin dosage amount based on the determined glucose concentration (without including the insulin on board information).

[00358] Regarding FIG. 16B, the Insulin on Board Interface is shown, and begins with a prompt screen 3090 prompting the user with a question asking if the user has forgotten to log any rapid-acting insulin the user has taken since a prior predetermined time point. The prior predetermined time point corresponds to the most recent of either: (a) the current time minus the set insulin duration of action, or (b) the time of the last logged dose of rapid-acting insulin. The prompt screen 3090 has a "Yes" touchscreen button 3092 and a "No" touchscreen button 3094 to select a yes or no answer to the prompted question. If the "No" touchscreen button 3094 is pressed, then the graphical user interface displays the Insulin Calculator Interface 3062 (see FIG. 17). If the "Yes" touchscreen button is pressed, then the graphical user interface displays a numerical input screen 3096 in the Insulin on Board Interface. On the numerical input screen 3096, the amount of rapid-acting insulin that the user has forgotten to log since the prior predetermined time point may be entered. The amount (e.g., units) of rapid-acting insulin may be adjusted by pressing the up arrow 3098 (e.g., "+") touchscreen button or the down arrow 3100 (e.g., "-") touchscreen button to increase or decrease, respectively, the amount of rapid acting insulin as desired. For example, the amount of rapid acting insulin 3102 may be adjusted by 1 unit increments by tapping the up arrow 3098 or the down arrow 3100. In some embodiments, the amount of rapid-acting insulin may be adjusted by 0.5 unit increments (not shown) if the calculator is set to allow half-unit increments. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Numerical input screen may also include a "?" touchscreen button 3104, which, when pressed, provides a help screen 3106 that includes additional instructions to the user. For example, the help screen 3106 may instruct the user to enter the sum total of insulin units that the user has taken over the last X hours that the user has not already logged, where X is the insulin duration of action time. The help screen 3106 may also inform the user that the Reader will use the entered amount of rapid-acting insulin to calculate the user's next rapid-acting insulin dose. The help screen 3106 includes an "OK" touchscreen button 3108, which, when pressed, returns the display to the numerical input screen 3096.

[00359] On the numerical input screen 3096, once the desired amount of rapid-acting insulin has been entered, the "Next" touchscreen button 3110 may be pressed to advance the graphical user interface to a time input screen 3114, as shown by reference path (M) (see FIG. 16C). Alternatively, on the numerical input screen 3096, the "Back" touchscreen button 3112 may be pressed, which returns the graphical user interface to the prompt screen 3090.

[00360] Regarding FIG. 16C, on the time input screen 3114, the display presents a question asking the user how long ago was the unlogged dose of rapid-acting insulin. On the time input screen 3114, the time since the last unlogged rapid-acting insulin dose may be adjusted by pressing the up arrow 3116 (e.g., "+") touchscreen button or the down arrow 3118 (e.g., "-") touchscreen button to increase or decrease, respectively, the time as desired. For example, the time 3120 may be adjusted by 15 minute increments by tapping the up arrow 3116 or the down arrow 3118. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. In some instances, the default time is 15 minutes (e.g., displayed as "15 minutes or less"). In some cases, the maximum time is the time value set for the insulin duration of action. If the user presses the up arrow 3116 once while the time is at the maximum value, then the time displayed may be shown as "[insulin duration] hours or more", and the up arrow 3116 may be displayed as greyed out and may be un-selectable by the user.

[00361] The time input screen 3114 also includes a "?" touchscreen button 3122, which, when pressed, provides a help screen 3106 that includes additional instructions to the user as described above and as indicated by reference path (K). The time input screen includes a "Back" touchscreen button 3124, which, when pressed, returns the display to the numerical input screen 3096 as shown by reference path (L). Once the desired time since the last unlogged rapid-acting insulin dose has been entered on the time input screen 3114, the "Next" touchscreen button 3126 may be pressed to advance the graphical user interface to the next screen in the Insulin on Board Interface, such as screen 3128. Pressing the "Next" touchscreen button will save the entered rapid-acting insulin dose with a time stamp reflecting the time calculated based on the interval since the dose was taken as indicated by the user in the previous time

input screen 3114. Screen 3128 informs the user that the entered dose of rapid-acting insulin will be used in the calculation of the user's suggested insulin dose, and that the next screen will allow the user to enter what the user plans to eat. Screen 3128 includes a "Back" touchscreen button 3130, which, when pressed, returns the display to the time input screen 3114. Screen 3128 includes a "Next" touchscreen button 3132, which, when pressed, causes the graphical user interface to display the Insulin Calculator Interface 3062 (see FIG. 17).

Insulin Calculator Interface

[00362] An Insulin Calculator Interface 3062 begins with the display of an "Enter Carbs" screen (see FIG. 17B). On the "Enter Carbs" screen, the amount of carbs may be entered. The amount of carbs may be entered as grams, servings, or by meal, depending on the settings of the Reader.

[00363] For example, the amount of carbs may be entered as grams of carbs on the "Enter Carbs" (grams) screen 3200. The "Enter Carbs" (grams) screen 3200 initially displays no value (e.g., "- -" or "0" is displayed), however, the grams of carbs may be adjusted by pressing the up arrow 3202 (e.g., "+") touchscreen button or the down arrow 3204 (e.g., "-") touchscreen button to increase or decrease, respectively, the grams of carbs as desired, as shown by reference path (T) (see FIG. 17C). For example, the grams of carbs 3206 may be adjusted by 1 gram increments by tapping the up arrow 3202 or the down arrow 3204. In some cases, the minimum grams of carbs that may be entered is zero carbs, and the maximum grams of carbs that may be entered is 200 grams of carbs. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Once the desired amount is entered, the amount may be saved by pressing the "Done" touchscreen button 3208, which saves the entered grams of carbs and then advances the graphical user interface to the Insulin Calculation Interface 3212, as shown by reference paths (S and V) (see FIGS. 17B, 17C and 17E). The "Enter Carbs" (grams) screen 3200 includes a "Back" touchscreen button 3210, which, when pressed, returns the display to the Results screen.

[00364] In certain embodiments, the amount of carbs may be entered as servings of carbs on the "Enter Carbs" (servings) screen 3216. The "Enter Carbs" (servings) screen 3216 initially displays no value (e.g., "- -" or "0" or "0.0" is

displayed), however, the servings of carbs may be adjusted by pressing the up arrow 3218 (e.g., "+") touchscreen button or the down arrow 3220 (e.g., "-") touchscreen button to increase or decrease, respectively, the servings of carbs as desired, as shown by reference path (T) (see FIG. 17C). For example, the servings of carbs 3222 may be adjusted by 0.5 serving increments by tapping the up arrow 3218 or the down arrow 3220. In some cases, the minimum servings of carbs that may be entered is zero servings. In some instances, the serving size may be set to 10 or 12 grams of carbs per serving and the maximum servings of carbs that may be entered is 20 servings. In some instances, the serving size may be set to 15 grams of carbs per serving and the maximum servings of carbs that may be entered is 15 servings. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. In some cases, the "Enter Carbs" (servings) screen 3216 may include a display of the grams of carbs 3228 that corresponds to the number of servings entered (see FIG. 17C). In some cases, the "Enter Carbs" (servings) screen 3216 may include a display of the energy (e.g., kcal) of carbs 3230 that corresponds to the number of servings entered (see FIG. 17C). Once the desired amount is entered, the amount may be saved by pressing the "Done" touchscreen button 3224, which saves the entered servings of carbs and then advances the graphical user interface to the Insulin Calculation Interface 3212, as shown by reference paths (S and V) (see FIGS. 17B, 17C and 17E). The "Enter Carbs" (servings) screen 3216 includes a "Back" touchscreen button 3226, which, when pressed, returns the display to the Results screen.

[00365] In certain embodiments, the amount of carbs may be entered by meal on the "Enter Carbs" (meal) screen 3232. The "Enter Carbs" (meal) screen 3232 displays a list of meals, such as breakfast, lunch, dinner, or no meal. Each selection includes a corresponding touchscreen radio button. For example, to select the "Dinner" meal, the touchscreen radio button 3234 associated with the "Dinner" selection may be pressed. The "Enter Carbs" (meal) screen 3232 includes a "Back" touchscreen button 3238, which, when pressed, returns the display to the Results screen. The "Enter Carbs" (meal) screen 3232 includes a "Next" touchscreen button 3236, which, when pressed, may advance the

graphical user interface to the "Double Check" screen 3240 via reference path (Z), as shown in FIG. 17C.

[00366] The "Double Check" screen 3240 (see FIG. 17C) is displayed if the user has marked the same meal since midnight (12:00AM) of the current day. The "Double Check" screen 3240 displays a warning to the user indicating that the user has already logged insulin for the selected meal that day, and asks the user if the user wants to log more insulin for the same meal that day. The "Double Check" screen 3240 includes a "No" touchscreen button, which, when pressed, returns the graphical user interface to the "Enter Carbs" (meal) screen 3232 via reference path (A1). The "Double Check" screen 3240 includes a "Yes" touchscreen button, which, when pressed, advances the graphical user interface to the Insulin Calculation Interface 3212 via reference path (Q) (see FIG. 17E).

[00367] Referring again to FIG. 17B, the "Enter "Carbs" screens (e.g., the "Enter Carbs" (grams) screen 3200, and the "Enter Carbs" (servings) screen 3216) both include a "?" touchscreen button 3214, which, when pressed, causes the graphical user interface to display help screens 3246, as shown by reference path (O) in FIG. 17B, or by reference path (N) in FIG. 17C. Help screens 3246 (see FIG. 17A) may display information to the user depending on whether the Reader is set to display carbs as grams, servings by grams of carbs, or servings by kcal of carbs. For example, a help screen 3248 may be shown that displays a set of help information to the user regarding carbohydrates when the Reader is set to display carbs as grams. In other instances, the help screen 3250 may be shown that displays a different set of help information to the user regarding carbohydrates as servings by grams of carbs when the Reader is set to display servings by grams of carbs. In other instances, the help screen 3252 may be shown that displays yet a different set of help information to the user regarding carbohydrates as servings by kcal of carbs when the Reader is set to display servings by kcal of carbs. In certain instances, if the help information includes more text than is able to be displayed on a single help screen, the help screen may include a down arrow 3254, which, when pressed, causes the graphical user interface to display the remaining text on a second help screen 3256. The second help screen 3256 includes an up arrow 3258, which, when pressed, returns the graphical user interface to the first help screen 3248, 3250 or 3252 depending on the settings of the Reader as described above. The help screens

3248, 3250, 3252 and 3256 include an "OK" touchscreen button 3260, which, when pressed, returns the graphical user interface to the "Enter "Carbs" screen (e.g., the "Enter Carbs" (grams) screen 3200, or the "Enter Carbs" (servings) screen 3216) from which the help screen was launched, via reference path (P).

[00368] Referring to FIG. 17B, once the desired amount of carbs is entered, the amount may be saved by pressing the "Done" touchscreen button 3208 or 3224, which saves the entered amount of carbs (e.g., grams of carbs or servings of carbs) and then advances the graphical user interface to the appropriate Insulin Calculation Interface 3212, as shown by reference path (S) (see FIG. 17E). The Insulin Calculation Interface 3212 displays the suggested dose of insulin based on the amount of carbs entered by the user on the previous screens as described above and/or the user's insulin on board, if any, as described above. The Insulin Calculation Interface 3212 may vary in appearance depending on whether the Reader is set to display whole units of insulin, half units of insulin, or a decimal point or a comma between the whole and half units of insulin.

[00369] Referring to FIG. 17E, in embodiments of the Insulin Calculation Interface 3212 where the Reader is set to display whole units of insulin, the Insulin Calculation Interface 3212 will appear as Suggested Dose screen 3262. Suggested Dose screen 3262 displays the suggested dose of insulin 3264 as units of insulin. The suggested dose of insulin may be adjusted in 1 insulin unit increments by pressing the up arrow 3266 (e.g., "+") touchscreen button or the down arrow 3268 (e.g., "-") touchscreen button to increase or decrease, respectively, the suggested dose of insulin as desired. The minimum and maximum values for the suggested dose of insulin are 0 and 99, respectively. If the suggested dose of insulin is adjusted by the user from its initial value, the amount of units increased or decreased by the user 3270 will be shown below the suggested insulin dose 3264. If the user adjustment of the suggested dose of insulin is calculated to reduce the user's blood glucose below the target range, then the graphical user interface will display a warning screen 3292 that displays a caution to the user that the insulin dose entered may take the user's blood glucose lower than the user's target range and put the user at risk for a low glucose event (see FIG. 17D). The warning screen 3292 includes an "OK" touchscreen button, which, when pressed, returns the graphical user interface to the Suggested Dose screen 3262 via reference path (W). The Suggested Dose

screen 3262 includes a “Back” touchscreen button 3272, which, when pressed, returns the user to the prior “Enter “Carbs” screen (e.g., the “Enter Carbs” (grams) screen 3200, or the “Enter Carbs” (servings) screen 3216) via reference path (R). The Suggested Dose screen 3262 also includes a “Log dose” touchscreen button 3274, which, when pressed, saves the suggested insulin dose in the logbook along with an associated glucose test result and the time the test was taken (e.g., the insulin dose is not saved as delivered at the time the “Log dose” touchscreen button is pressed) and advances the graphical user interface to the Logbook via reference path (Y) (see FIG. 17D).

[00370] Referring to FIG. 17E, in embodiments of the Insulin Calculation Interface 3212 where the Reader is set to display half unit increments of insulin and a decimal point between the whole and half units, the Insulin Calculation Interface 3212 will appear as Suggested Dose screen 3276. Suggested Dose screen 3276 displays the suggested dose of insulin 3278 as units of insulin in 0.5 unit increments. The suggested dose of insulin may be adjusted in 0.5 insulin unit increments by pressing the up arrow 3280 (e.g., “+”) touchscreen button or the down arrow 3282 (e.g., “-”) touchscreen button to increase or decrease, respectively, the suggested dose of insulin as desired. The minimum and maximum values for the suggested dose of insulin are 0 and 50, respectively. If the suggested dose of insulin is adjusted by the user from its initial value, the amount of units increased or decreased by the user 3284 will be shown below the suggested insulin dose 3278. If the user adjustment of the suggested dose of insulin is calculated to reduce the user’s blood glucose below the target range, then the graphical user interface will display a warning screen 3292 that displays a caution to the user that the insulin dose entered may take the user’s blood glucose lower than the user’s target range and put the user at risk for a low glucose event (see FIG. 17D). The warning screen 3292 includes an “OK” touchscreen button, which, when pressed, returns the graphical user interface to the Suggested Dose screen 3276 via reference path (W). The Suggested Dose screen 3276 includes a “Back” touchscreen button 3286, which, when pressed, returns the user to the prior “Enter “Carbs” screen (e.g., the “Enter Carbs” (grams) screen 3200, or the “Enter Carbs” (servings) screen 3216) via reference path (R). The Suggested Dose screen 3276 also includes a “Log dose” touchscreen button 3288, which, when pressed, saves the suggested insulin

dose in the logbook along with an associated glucose test result and the time the test was taken (e.g., the insulin dose is not saved as delivered at the time the "Log dose" touchscreen button is pressed) and advances the graphical user interface to the Logbook via reference path (Y) (see FIG. 17D).

[00371] Referring to FIG. 17E, in embodiments of the Insulin Calculation Interface 3212 where the Reader is set to display half unit increments of insulin and a comma between the whole and half units, the Insulin Calculation Interface 3212 will appear as Suggested Dose screen 3290. The functions of Suggested Dose screen 3290 are analogous to those described for Suggested Dose screen 3276 above.

[00372] If the insulin calculator of the Reader determines that no insulin dose is suggested, then the Insulin Calculation Interface 3212 will be displayed as No Suggested Dose screen 3298, which displays information indicating that based on the user's current glucose level, no rapid-acting insulin is being suggested. The No Suggested Dose screen includes a "Back" touchscreen button 3300, which, when pressed, returns the user to the prior "Enter "Carbs" screen (e.g., the "Enter Carbs" (grams) screen 3200, or the "Enter Carbs" (servings) screen 3216) via reference path (R). The No Suggested Dose screen 3298 includes a "Next" touchscreen button 3302, which, when pressed, advances the graphical user interface to Suggested Dose screen 3304. Suggested Dose screen 3304 begins by displaying a suggested does of insulin 3306 as 0 units of insulin. The suggested dose of insulin may be adjusted in 1 unit or 0.5 insulin unit increments, depending on the Reader settings, by pressing the up arrow 3308 (e.g., "+") touchscreen button or the down arrow 3310 (e.g., "-") touchscreen button to increase or decrease, respectively, the suggested dose of insulin as desired. If the suggested dose of insulin is adjusted by the user from its initial value, the amount of units increased or decreased by the user will be shown below the suggested insulin dose 3306. If the user adjustment of the suggested dose of insulin is calculated to reduce the user's blood glucose below the target range, then the graphical user interface will display a warning screen 3292 that displays a caution to the user that the insulin dose entered may take the user's blood glucose lower than the user's target range and put the user at risk for a low glucose event (see FIG. 17D). The warning screen 3292 includes an "OK" touchscreen button, which, when pressed, returns the graphical user interface to

the Suggested Dose screen 3304 via reference path (W). The Suggested Dose screen 3304 includes a "Back" touchscreen button 3312, which, when pressed, returns the user to the prior No Suggested Dose screen 3298. The Suggested Dose screen 3304 also includes a "Log dose" touchscreen button 3314, which, when pressed, saves the suggested insulin dose in the logbook along with an associated glucose test result and the time the test was taken (e.g., the insulin dose is not saved as delivered at the time the "Log dose" touchscreen button is pressed) and advances the graphical user interface to the Logbook via reference path (Y) (see FIG. 17D).

[00373] Suggested Dose screens 3262, 3276, 3290 and 3304 include a "Dose details" touchscreen button 3294 (e.g., an "i" touchscreen button), which, when pressed, causes graphical user interface to display Dose Details Interface via reference path (X) (see FIG. 17D).

[00374] Dose Details Interface 3296 is shown in FIGS. 18A and 18B. Dose Details Interface begins a Dose Details screen (e.g., 3316, 3318 and 3320) that displays a summary of the calculated insulin dose. The Dose Details screen (e.g., 3316, 3318 and 3320) may have various appearances depending on the settings of the Reader (e.g., whether the Reader is set to display carbs as grams of carbs, servings of carbs, or by meal) and the data input by the user or calculated by the Reader (e.g., amount of carbs, insulin on board, user adjustment to the suggested dose of insulin, etc.). The Dose Details screen displays the amount of carbs by meal 3322, as grams of carbs 3324, or as servings of carbs 3326. If insulin correction is enabled on the Reader, the Dose Details screen will display the suggested insulin dose 3328. If insulin correction is disabled on the Reader (e.g., the Easy setup sets "no correction insulin") then the suggested insulin dose is not displayed. If the Reader determines that insulin on board is present, then the Dose Details screen displays the amount of insulin on board 3330. In the Reader determines that no insulin on board is present, then the amount of insulin on board is not displayed. If the user adjusted the suggested insulin dose, the Dose Details screen will display the amount the user adjusted the suggested insulin dose 3332. Based on the above data, the Dose Details screen displays the calculated insulin dose 3334.

[00375] The Dose Details screen includes a down arrow touchscreen button 3336, which, when pressed, advances the Dose Details screen to the second page of

the Dose Details screen via reference path (B1) (see FIG. 18B). The information displayed on the second page of the Dose Details screen may vary depending on whether insulin on board is present and whether the suggested dose of insulin only accounts for carbs in the user's meal. If insulin on board is not present, then the second page of the Dose Details screen 3338 displays information indicating that the suggested dose of rapid-acting insulin covers the carbs in the user's meal and corrects for the user's current glucose level. If insulin on board is present and the user has taken insulin within the past 2 hours, then the second Dose Details screen 3340 displays information indicating that the user has taken rapid-acting insulin in the past 2 hours, and the suggested dose of insulin covers the carbs in the user's meal but does not correct for the user's current glucose level. If insulin on board is present and the time when the user has last taken insulin is more than 2 hours from the current time but less than the duration of insulin action, then the second Dose Details screen 3342 displays information indicating that the user has taken rapid-acting insulin in the past 4 hours, and the suggested dose of insulin covers the carbs in the user's meal, corrects for the user's current glucose level, and accounts for insulin that was previously logged. The second Dose Details screen (e.g., 3338. 3340 and 3342) include an up arrow touchscreen button 3344, which, when pressed, returns the graphical user interface to the previous Dose Details screen.

Reminders Interface

[00376] An exemplary embodiment of a graphical user interface which may be utilized in connection with a Reader as described herein and which facilitates a Reminders procedure 3400 for setting reminders is provided. This graphical user interface is now described in greater detail with reference to FIG. 19.

[00377] The Reminder Interface 3400, shown in FIG. 19A, begins with the display of a Home Screen 3402 of the Reader. The Home Screen includes a reminders touchscreen button 3404 (e.g., a bell shaped icon, an alarm clock icon, a clock icon, etc.), which, when pressed, begins the procedure to set and/or adjust reminders. If a reminder has been previously set, then next reminder time 3406 is displayed next to the reminders touchscreen button 3404.

[00378] Referring to FIG. 19A, if no reminder has been previously set, then pressing the reminders touchscreen button 3404 advances the graphical user interface to the Remind Me screen 3408 via reference path (D1) (see FIG. 19B).

Remind Me screen 3408 includes selections for the type of reminder, the schedule for the reminder, and the time of the reminder.

[00379] For example, on the Remind Me screen 3408, the type of reminder may be selected by pressing the Reminder Type touchscreen button 3410. The reminder selection touchscreen button 3410 displays the currently selected reminder type, which has a default value of "Check Glucose". The Reminder Type touchscreen button 3410, when pressed, advances the graphical user interface to the Reminder Type screen 3412 via reference path (K1) (see FIG. 19D). The Reminder Type screen 3412 lists the available types of reminders that may be set. The Reminder Type screen 3412 displays the 3 default reminders as the "Check Glucose" touchscreen button 3414, the "Take Insulin" touchscreen button 3416, the and "Alarm" touchscreen button 3418. The default types of reminders can be reordered using the PC interface, but not deleted from the Reader. Each default reminder touchscreen button includes text describing the type of reminder, as described above, and an icon associated with each different type of default reminder. Additional custom reminders can be setup using the PC interface. If additional custom reminders have been previously setup, then they will be displayed on the Reminder Type screen 3420. The custom reminders can by any type of reminder desired by the user. The additional custom reminders can be displayed by pressing the down arrow touchscreen button 3422 on reminder Type screen 3420. For example, the list of types of reminders may be scrolled through by tapping the down arrow 3422 or the up arrow 3424. In some embodiments, the pages scroll page by page by a single press of the up or down arrow and at a slow rate after 2 seconds when the up or down arrow is pressed and held. Once a type of reminder is selected by pressing the desired type of reminder, the graphical user interface returns to the Remind Me screen 3408 via reference path (J1) (see FIG. 19B).

[00380] On the Remind Me screen 3408, the schedule of the reminder may be selected by pressing the Repeat touchscreen button 3426. The Repeat touchscreen button 3426 displays the currently selected schedule for the reminder, which has a default value of "Daily", indicating that the reminder will be repeated daily at the selected time. The Repeat touchscreen button 3426, when pressed, advances the graphical user interface to the Reminder Schedule screen 3428 via reference path (N1) (see FIG. 19C). The Reminder Schedule

screen 3428 lists the available types of schedules that may be set for the reminder. The Reminder Schedule screen 3428 displays 3 types of reminder schedules as the “Daily” touchscreen button 3430, the “Once” touchscreen button 3432, the and “Countdown Timer” touchscreen button 3434. Pressing the “Daily” touchscreen button 3430 sets the reminder schedule to daily and returns the graphical user interface to the Remind Me screen 3408 via reference path (L1). Pressing the “Once” touchscreen button 3432 sets the reminder schedule to once (e.g., the reminder will not repeat) and returns the graphical user interface to the Remind Me screen 3408 via reference path (M1). Pressing the “Countdown Timer” touchscreen button 3434 sets the reminder schedule to a countdown timer and advances the graphical user interface to the Timer Duration screen 3436 (see FIG. 19C). The countdown timer may be set using the Timer Duration screen 3436. For example, the Timer Duration screen 3436 displays the current amount of time left on the countdown timer in hours and minutes. The default value for the countdown timer is 15 minutes. The amount of minutes may be adjusted by pressing the up arrow 3438 (e.g., “+”) touchscreen button or the down arrow 3440 (e.g., “-”) touchscreen button to increase or decrease, respectively, the amount of minutes as desired. For example, the amount of minutes may be adjusted by 1 minute increments by tapping the up arrow 3438 or the down arrow 3440. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. The amount of hours may be adjusted by pressing the up arrow 3442 (e.g., “+”) touchscreen button or the down arrow 3444 (e.g., “-”) touchscreen button to increase or decrease, respectively, the amount of minutes as desired. For example, the amount of hours may be adjusted by 1 hour increments by tapping the up arrow 3442 or the down arrow 3444. In some embodiments, the amount increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Once the desired amount of time for the countdown timer is entered, the amount may be saved by pressing the “OK” touchscreen button 3446, which saves the entered amount of time and then returns the graphical user interface to the Remind Me screen 3448, as shown by reference path (Q1) (see FIG. 19B). From the Remind Me screen 3448 (see FIG. 19B), the amount of time for the

countdown timer may be adjusted by pressing the Time touchscreen button 3464, which, when pressed, advances the graphical user interface to the Timer Duration screen 3436 via reference path (R1) (see FIG. 19C). On the Timer Duration screen 3436, the time for the countdown timer may be adjusted as described above.

[00381] On the Remind Me screen 3408, the time of the reminder may be selected by pressing the Time touchscreen button 3450. The Time touchscreen button 3450 displays the currently set time for the reminder, which has a default value of 12:00 am, indicating that the reminder will be activated at the selected time. The Time touchscreen button 3450, when pressed, advances the graphical user interface to the Reminder Time screen 3452 via reference path (P1) (see FIG. 19C). The Reminder Time screen 3452 allows the user to set the time when the reminder will be activated. For example, the Reminder Time screen 3452 displays the currently set time for the reminder in hours and minutes. The reminder time may be adjusted by pressing the minutes up arrow 3454 (e.g., "+") touchscreen button or the minutes down arrow 3456 (e.g., "-") touchscreen button to increase or decrease, respectively, the minutes as desired, and the hours up arrow 3458 (e.g., "+") touchscreen button or the hours down arrow 3460 (e.g., "-") touchscreen button to increase or decrease, respectively, the hours as desired. In some embodiments, the hours and minutes increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. Once the desired time for the reminder is entered, the time may be saved by pressing the "OK" touchscreen button 3462, which saves the entered time and then returns the graphical user interface to the Remind Me screen 3408, as shown by reference path (O1) (see FIG. 19B).

[00382] Referring to FIG. 19B, after the desired reminder type, reminder schedule and reminder time has been selected as desired, the reminder settings may be saved by pressing the "Save" touchscreen button 3466, which, when pressed, advances the graphical user interface to the Reminder List screen 3468 via reference path (E1) (see FIG. 19A). Referring back to FIG. 19B, the reminder settings may be discarded by pressing "Cancel" touchscreen button 3470. If no previous reminder have been set, then pressing "Cancel" touchscreen button 3470 returns the graphical user interface to the Home Screen 3402 via reference

path (C1) (see FIG. 19A). If one or more reminders has been previously set, then pressing "Cancel" touchscreen button advances the graphical user interface to the Reminders List screen 3468 via reference path (H1) or (I1) (see FIG. 19A). In certain embodiments, if the settings for a previously set reminder are being adjusted from the Remind Me screen 3408, then "Cancel" touchscreen button 3470 may be displayed as a "Delete" touchscreen button.

[00383] Referring to FIG. 19A, from the Home Screen 3402, if one or more reminders has been previously set, then pressing the reminders touchscreen button 3404 or, in some instances, the next reminder time 3406 advances the graphical user interface to the Reminders List screen 3468. The Reminders List screen 3468 displays a list of the previously set reminders. The list of previously set reminders displays the reminder time 3472 for each previously set reminder and a corresponding "On"/"Off" toggle touchscreen button 3474 for each previously set reminder. Pressing the reminder time 3472 advances the graphical user interface to the Remind Me screen 3408 via reference path (G1), from which the reminder settings may be adjusted as described above. Pressing the "On"/"Off" toggle touchscreen button 3474 turns the corresponding reminder on or off.

[00384] The Reminders List screen includes an "Add New" touchscreen button 3476, which, when pressed, advances the graphical user interface to the Remind Me screen 3408 via reference path (F1), from which a new reminder may be setup as desired, as described above. The Reminders List screen includes a "Done" touchscreen button 3478, which, when pressed, returns the graphical user interface to the Home Screen 3402.

Receive Reminders Interface

[00385] An exemplary embodiment of a graphical user interface which may be utilized in connection with a Reader as described herein and which facilitates a Receive Reminder procedure 3500 for receiving reminders is provided. This graphical user interface is now described in greater detail with reference to FIG. 20.

[00386] The Receive Reminder Interface 3500, shown in FIG. 20B, begins when a reminder (e.g., a reminder that has been set using the Reminders Interface 3400 described above) is activated, such as when the time or triggering event of a scheduled reminder is reached. A scheduled reminder should be displayed when

the time / triggering event of the reminder is reached even if the Reader display is off. In certain embodiments, a scheduled reminder is not displayed on the Reader if the time / triggering event of the reminder is reached: (1) During a blood glucose test using a strip – instead the reminder is presented after the results have been displayed; (2) When the battery is critically low – instead the reminder is presented when the battery is sufficiently charged, and the Reader is powered on; (3) During error conditions – instead the reminder is presented the next time the Reader is powered on; or (4) When the Reader is connected to a computer and data transfer is in process – instead the reminder is presented when the data transfer is completed.

[00387] When the time / triggering event of the reminder is reached, a Reminder screen is 3502 displayed (FIG. 20B). The Reminder screen 3502 includes display of the reminder with a reminder icon 3504 representing the type of reminder. For example, the reminder icon may be an “Alarm” reminder icon 3504 (e.g., a picture of a bell or alarm clock, etc.), indicating that the type of reminder is an alarm. In some instances, the reminder icon is a “Take Insulin” reminder icon 3506 (e.g., a picture of a syringe) (see FIG. 20A), indicating that the type of reminder is a reminder to the user to take insulin. In some instances, the reminder icon is a “Check Glucose” reminder icon 3508 (e.g., a picture of a glucose Reader) (see FIG. 20A), indicating that the type of reminder is a reminder to the user to check their glucose level. Other types of icons and reminders are possible.

[00388] If the Reminder sound is set to on, a beep sounds with appearance of any reminders screen. If a reminder is ignored, the reminder will appear on the screen with the next power on (whether by hardware button or strip insertion). If multiple reminders are active, the reminder screens will stack up with the most recent reminder showing first. The reminder screens will require dismissal one by one. If daily repeated reminders have been missed, once a new day’s reminder is current, the previous day’s reminder for that time is no longer active and is not part of the stack-up of reminder screens.

[00389] The Reminder screen 3502 includes a “Snooze 15 min” touchscreen button 3510, which, when pressed, sets the active reminder to re-active in 15 minutes, and returns the graphical user interface to the next active reminder or, if there are no other active reminders, to the previously displayed screen before

the reminder was activated. The Reminder screen 3502 also includes an "OK" touchscreen button 3512, which, when pressed cancels the active reminder and returns the graphical user interface to the next active reminder or, if there are no other active reminders, returns the graphical user interface to the Home Screen. In the Reader powers off automatically due to a timeout while displaying the Reminder screen, the reminder that was active when the Reader timed-out will be displayed again the next time the Reader is powered on.

Reader Summaries

[00390] In some aspects of the present disclosure, the analyte monitoring device may be programmed with software to provide summaries of information and data related to obtain readings. The software provides an interface to view and manage features related to generated reports. Different types of summaries may be generated. For example, FIGS. 21A-D illustrate various types of interfaces for displaying summaries on the analyte monitoring device, according to certain embodiments. It should be appreciated that the summary screens illustrated are exemplary and should not be interpreted as limiting.

[00391] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which functions to provide the user with summaries of information and data related to obtained readings.

Summaries Menu Interface

[00392] **FIG. 21A** illustrates an exemplary interface for providing a summaries menu on the analyte monitoring device. History Menu01 screen 622 is shown in FIG. 21A and provides a menu of summary options that the user can select. Option 622a takes the user to a Logbook screen for viewing logged data, as shown by block 626. Option 622b takes the user to a Daily Graph screen which provides a summary of data in a daily graph format. Option 622c provides a screen for averages for glucose readings obtained for a period of time. If more options are available that can fit on a single screen shot, then a trigger element 622h (e.g., an arrow symbol) for scrolling or otherwise viewing the remaining options may be selected. When arrow 622h is selected, the user is taken to screen 624 wherein the remaining options are displayed. For example, option 624 provides a summary screen of low glucose events for a period of time. Option 622d provides a screen showing a summary of time that obtained

readings were in the target zone. Option 622f provides a screen showing summarizing information related to the user of the reader device. Option 622g provides a summary screen of daily patterns that have been determined or identified based on reading acquired for a period of time. Trigger element 622i takes the user back to screen 622.

[00393] When one of the options are selected, it is determined if sensor data is present, as shown at block 628. If no data is present, a No Sensor Data screen 630 is displayed to indicate to the user that no sensor data is available for the summary. In one embodiment, the all summaries except for logbook include sensor data only (e.g., glucose data obtained from the sensor). If the device includes only strip data and insufficient sensor data, then the No Sensor Data screen is still provided when a summary option is selected.

[00394] If sensor data is provided, then the corresponding screen for the selected summary option is displayed, as represented by reference path T1. From the selected summary screen, the user can navigate back to the menu options screens 622,624 to select another menu option if desired, as shown by reference path S1.

[00395] **FIG. 21B** illustrates a Daily Graph screen 632 for showing a daily graph 632a of sensor readings obtained over a single day or 24 hour time period. For example, graph 632a illustrates the readings obtained on Wednesday, February 22. The horizontal axis of graph 632a represents time throughout the day, while the vertical axis represents sensor reading values. A target zone 632d may also be provided on graph 632 to represent the target zone for readings. Also shown, are event indicators 632b which indicate various events with symbols or icons on the graph 632a. For example, the needle icon represents a logged insulin event indicating that an insulin dose was taken, and the apple icon represents a logged food event indicating that food was eaten. More details may be stored or logged for the given event, and in one embodiment, the event indicators 632b may be selected by the user to provide additional details regarding the event.

[00396] In the embodiment shown, trigger elements 632c (e.g., left and right arrows) are also provided to enable the user to navigate forwards and backwards to another day or 24-hour time period. For example, the user could navigate to the next day after Wednesday using the right arrow, or go to the previous day by selecting the left arrow.

[00397] **FIG. 21C** illustrates an exemplary Average Glucose Summary interface for providing a graph of sensor readings obtained over a time period that is summarized with respect to a predetermined time period such as single day or 24 hour time period as shown. For example, Average Glucose (GLUC) 01 screen provides a bar graph 634a for sensor readings taken over the last 7 days. The bar graph 634a includes bars for various increments of time throughout a single day. Each bar represents the average glucose reading that was obtained at that increment of time of day for the last 7 days. For example, the average of all the sensor readings obtained between 12am and 6am over the last 7 days, is 121 mg/dL. For 6am to 12, the average glucose reading was 152 mg/dL, etc.

[00398] Screen 634 also includes an average glucose value 634b for the time period of data. For example, the average glucose reading for all readings obtained over the last 7 days was 119 mg/dL. Screen 634 also includes a trigger element 634c (e.g., an arrow icon) for changing the different time period of obtained data. For example, if the user selects the right arrow icon 634c, the user is taken to AVG GLUC02 screen 636, which similarly displays a bar graph 636a and average glucose value 636b, but for a different time period, such as the last 14 days as shown. Similarly, screen 636 also includes trigger elements 634c for again increasing the time period. In this way, the user can change to AVG GLUC03 screen 638, which similarly displays a bar graph 638a and average glucose value 638b, but for a different time period, such as the last 30 days as shown. Similarly, the user can change to AVG GLUC04 screen 640, which similarly displays a bar graph 640a and average glucose value 640b, but for a different time period, such as the last 90 days as shown. Trigger elements 634c enable the user to navigate forwards and backwards between screens 634,636,638,640 to change the time periods as desired. From any of the screens, user confirmation (e.g., by selecting the “ok” button) will take the user back to the options menu interface 622,624.

[00399] **FIG. 21D** illustrates an exemplary screen for showing the percentage of time the sensor readings were within a target zone. Time In Target screen 642 displays a representation 642a of the percentage of time within a target zone, above a target zone, and below a target zone, for sensor readings obtained for a period of time (e.g., 7 days in the embodiment shown). Trigger element 642c is provided to enable the user to change the time period—e.g., similarly as

described in FIG. 21c. Representation 642a also includes bar graphs for the associated percentages.

Summaries Menu – Masked Mode Interface

[00400] **FIG. 21E** illustrates an exemplary screen 644 for showing a graph 644a of the number of events associated with sensor readings obtained over a time period, wherein the events are summarized with respect to a predetermined time period, such as single day or 24 hour time period as shown. For example, screen 644 indicates a graph 644a for sensor readings obtained over the last 7 days, wherein 1 event occurred between 12am and 6am, 0 events occurred between 6am and 12pm, 3 events between 12pm and 6am, etc. In the embodiment shown, the event corresponds to a low glucose reading—e.g., with respect to a target zone. Other events may also be implemented—e.g., high glucose readings, insulin dosages, food intake events, etc. Trigger element 644c is provided to enable the user to change the time period.

[00401] **FIG. 21F** illustrates an exemplary screen 648 for indicating information associated with the use of the sensor over a time period. For example, screen 648 indicates the average scans per day, and the number of days with sensor data, for sensor readings obtained over the last 7 days. Similarly, trigger element 648c is provided to enable the user to change the time period.

[00402] **FIG. 21G** illustrates an example interface for providing a summaries menu on the analyte monitoring device, when the device is in masked mode. History Menu Masked screen 620 is shown provides a menu of summary options that the user can select. Option 620a takes the user to a Logbook screen for viewing logged data. Option 620b provides a screen showing summarizing information related to the use of the reader device. Since the device is in masked mode and does not permit the user from viewing sensor readings, summary screens related to obtained readings are also not available.

Logbook Interface

[00403] An exemplary embodiment of a graphical user interface which may be utilized in connection with a Reader as described herein and which facilitates a Logbook procedure 3600 for displaying, adding and/or editing logbook entries is provided. This graphical user interface is now described in greater detail with reference to FIG. 22.

[00404] The Logbook Interface 3600, shown in FIG. 22A, may be accessed from the Consecutive Scans Interface (see FIG. 9), the Insulin Calculator Interface (see FIG. 17), and the Reader Summaries Interface (see FIG. 21). From the Reader Summaries Menu screen (see FIG. 21), pressing the Logbook touchscreen button advances the graphical user interface into the Logbook Interface 3600 (see FIG. 22). If there are no entries in the logbook, the Logbook Empty screen 3602 is displayed, indicating that there is no data to report in the logbook (see FIG. 22A). If there are one or more entries in the logbook, then the Logbook List screen 3604 is displayed via reference path (V1) (see FIG. 22B). FIG. 22B shows various examples of Logbook List screens and the type of logbook entries that may be displayed. Each logbook entry displays the date 3606 and time 3608 associated with its corresponding logbook entry. Three logbook entries may be displayed per screen. The Logbook List screen includes a down arrow 3610, and in some embodiments an up arrow (not shown) that may be pressed to scroll down or up, respectively, through the logbook entries in the Logbook List screens. The Logbook List screen may be scrolled page by page by pressing the up arrow (not shown) touchscreen button or the down arrow 3610 touchscreen button to scroll through the Logbook List screens as desired. For example, the Logbook List screens may be scrolled page by page by tapping the up arrow (not shown) or the down arrow 3610. In some embodiments, the pages scroll at a slow rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held.

[00405] Referring to FIG. 22B, various examples of Logbook List screens and the type of logbook entries that may be displayed are shown. For example, the Logbook List screen may display a logged glucose level 3612. The logged glucose level 3612 may be displayed as a number corresponding to the user's glucose level in mg/dL. The glucose level may have an upward trend arrow or a downward trend arrow associated with the glucose level, indicating a rising trend in glucose readings or a decreasing trend in glucose readings, respectively. In some cases, if the logged glucose reading was above a maximum threshold level, "HI" may be displayed instead of a numerical glucose level, indicating that the glucose level exceeded a maximum threshold level. Similarly, if the logged glucose reading was below a minimum threshold level, "LO" may be displayed instead of a numerical glucose level, indicating that the glucose level was below

a minimum threshold level. In some instances, the glucose reading may be associated with a Note icon (e.g., a picture of a pencil), indicating that a note was entered with the logged glucose level.

[00406] In some instances, the Logbook List screen may display a logged ketone level 3614. The logged ketone level 3614 may be displayed as a number corresponding to the user's ketone level in mmol/L. In some instances, the Logbook List screen may display a logged glucose control solution test level 3616. The logged glucose control solution test level 3616 may be displayed as a number corresponding to the glucose control solution level in mg/dL. The glucose control solution test level 3616 may be associated with a corresponding control solution icon (e.g., a picture of a bottle of control solution). In some instances, the Logbook List screen may display a logged ketone control solution test level 3704. The logged ketone control solution test level 3704 may be displayed as a number corresponding to the ketone control solution level in mmol/L. The ketone control solution test level 3704 may be associated with a corresponding control solution icon (e.g., a picture of a bottle of control solution). In some instances, the Logbook List screen may display a logged temperature error 3618. The temperature error may be a low temperature error associated with a low temperature error icon (e.g., a picture of a blue thermometer), or a high temperature error associated with a high temperature error icon (e.g., a picture of a red thermometer). In some instances, the Logbook List screen may display a logged masked reading 3620. The logged masked reading may be associated with a masked reading icon (e.g., a checkmark icon). The Logbook List screen 3604 includes an "OK" touchscreen button 3622, which, when pressed, returns the graphical user interface to the previous screen displayed before entering the Logbook Interface 3600 (e.g., the Consecutive Scans Interface (see FIG. 9), the Insulin Calculator Interface (see FIG. 17), or the Reader Summaries Interface (see FIG. 21)). For example, pressing "OK" touchscreen button 3622 may cause the graphical user interface to return to the Reader Summaries Interface (see FIG. 21) via reference path (U1) (see FIG. 22A).

[00407] Each logbook entry on the Logbook List screen 3604 is a touchscreen button. Pressing a logbook entry on the Logbook List screen 3604 advances the graphical user interface to the Individual Logbook Entry screen 3624 associated

with the selected logbook entry via reference path (W1) (see FIGS. 22C and 22D). Various examples of Individual Logbook Entry screens 3624 are shown in FIGS. 22C and 22D.

[00408] If a logged glucose level is selected from the Logbook List screen 3604, the glucose level individual logbook entry screen 3626 is displayed. The glucose level individual logbook entry screen 3626 includes one or more of the following information: the date and time 3628 of the logged glucose level; the glucose reading 3630 in mg/dL; the amount of carbs 3632 (if any); an meal icon 3634 indicating whether the logged glucose reading was pre-meal or post-meal (e.g., a whole apple icon for pre-meal readings or a eaten apple icon for post-meal readings); a suggested insulin dose 3636 (if any) and/or a suggested insulin dose icon 3638 (e.g., a syringe icon); notes 3640 that were associated with the logged glucose reading (if any); a glucose level trend arrow 3642 (e.g., an upward or a downward trend arrow), as appropriate; an non-actionable icon 3644 indicating that the glucose reading is non-actionable; a high glucose level warning 3646 (as text and/or a warning icon); a low glucose level warning 3648 (as text and/or a warning icon); an masked icon 3650 indicating that the glucose reading is masked (e.g., a checkmark icon); suggested insulin dose details (e.g., amount of carbs 3652, suggested insulin dose 3654, IOB 3656, user adjustments to the suggested insulin dose 3658); a low temperature error warning 3660 (e.g., as text and/or a low temperature warning icon 3666, such as a blue thermometer icon); a high temperature error warning 3662 (e.g., as text and/or a high temperature warning icon 3668, such as a red thermometer icon); an icon indicating that the glucose reading was obtained via test strip or via sensor (e.g., a drop of blood icon 3664 for readings obtained via test strip); a sensor low temperature error warning 3670 (e.g., as text and/or a sensor low temperature warning icon 3672, such as a blue thermometer); and a sensor high temperature error warning 3674 (e.g., as text and/or a sensor high temperature warning icon 3676, such as a blue thermometer icon).

[00409] If notes are associated with the logged glucose reading and the notes will not all fit on one screen, the Individual Logbook Entry screen 3626 may include a down arrow 3678 (see FIG. 22C), and in some embodiments an up arrow 3680 (see FIG. 22D) that may be pressed to scroll down or up, respectively, through the notes. The Individual Logbook Entry screen 3626 may include an “Add or

edit notes" touchscreen button 3682, which, when pressed, causes graphical user interface to display the Add to Logbook screen 3684. The Add to Logbook screen 3684 includes a list of several different user selectable notes that may be entered into the Logbook. The list of user selectable notes may include one or more of the following: long-acting insulin 3686, exercise 3688, medication 3690, and the like. In certain embodiments, 3 user-selectable notes are displayed on the touchscreen at once. If there are more than 3 user-selectable notes, the list of notes may be scrolled as necessary to view the list using scroll touchscreen buttons, such as down arrow (e.g., down triangle) touchscreen button 3692 and up arrow (e.g., up triangle) touchscreen button (not shown). One or more user-selectable notes may be selected by touching the touchscreen checkbox adjacent the note desired to be selected. Touching a touchscreen checkbox will toggle the checkbox from a checked to unchecked state indicating whether the associated not is selected or not selected, respectively. For instance, the long-acting insulin note may be selected by touching the touchscreen checkbox 3694, which then displays a check mark in the touchscreen checkbox to indicate that the rapid-acting insulin note has been selected. The other user-selectable notes may be selected or unselected (e.g., checked or unchecked) as desired in an analogous manner. The selection of notes may be saved by pressing the "OK" touchscreen button 3696, which saves the selection of user-selectable notes and returns the graphical user interface to the previous individual logbook entry screen 3626.

[00410] If a logged ketone level is selected from the Logbook List screen 3604, the ketone level individual logbook entry screen 3698 is displayed, which displays the logged ketone reading in mmol/L. If a logged glucose control solution test is selected from the Logbook List screen 3604, the glucose control solution test level individual logbook entry screen 3700 is displayed, which displays the logged glucose control solution test reading in mg/dL. If a logged ketone control solution test is selected from the Logbook List screen 3604, the ketone control solution test level individual logbook entry screen 3702 is displayed, which displays the logged ketone control solution test reading in mmol/L.

[00411] The Individual Logbook Entry screen 3626 includes an "OK" touchscreen button 3706, which, when pressed, returns the graphical user interface to the Logbook List screen 3604 via reference path (X1).

Strip/Hardware Errors Interface

[00412] An exemplary embodiment of a graphical user interface which may be utilized in connection with a Reader as described herein and which facilitates a procedure for displaying strip/hardware errors 3710 is provided. This graphical user interface is now described in greater detail with reference to FIG. 23.

[00413] The Strip/Hardware Errors Interface 3710, shown in FIGS. 23A and 23B, may display strip and/or hardware errors as necessary as any relevant errors occur. A variety of different error messages may be displayed. For example, an "Error 1" screen 3712 may be displayed if the Reader detects a temperature error. The "Error 1" screen may display a message indicating that the Reader may be too hot or too cold, and that the user should move the Reader and strips to the appropriate environment and check glucose again with a new strip. "Error 1" screen may also display a message indicating that if this message appears again, the user should call Customer Service.

[00414] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 2" screen 3714 if the Reader may not be functioning properly. The "Error 2" screen 3714 may display a message indicating that the Reader may not be functioning properly and that the user should turn off the Reader and try again. The "Error 2" screen 3714 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00415] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 3" screen 3716 if the test strip may not be working properly or if the user's glucose may be too low. The "Error 3" screen 3716 may display a message indicating that the test strip may not be working properly or the user's glucose may be too low. The "Error 3" screen 3716 may also display a message indicating that low glucose can be dangerous and that the user should check their glucose again with a new strip and treat as recommended by the user's health care professional. The "Error 3" screen 3716 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00416] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 4" screen 3718 if the test strip may not be working properly or if the user's glucose/ketones may be too high. The "Error 4" screen 3718 may display a message indicating that the test strip may not be working properly or the user's glucose/ketones may be too high. The "Error 4" screen 3718 may also display a message indicating that high glucose/ketones can be dangerous and that the user should check their glucose or ketones again with a new strip and treat as recommended by the user's health care professional. The "Error 4" screen 3718 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00417] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 5" screen 3720 if blood may have been applied to the test strip too soon or the test strip may have already been used. The "Error 5" screen 3720 may display a message indicating that blood may have been applied to the test strip too soon or the test strip may have already been used. The "Error 5" screen 3720 may also display a message indicating that the user should check their glucose again with a new strip. The "Error 5" screen 3720 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00418] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 7" screen 3722 if the test strip may be damaged, used, or unrecognizable be the Reader. The "Error 7" screen 3722 may display a message indicating that the test strip may be damaged, used, or unrecognizable be the Reader. The "Error 7" screen 3722 may also display a message indicating that the user should check their glucose again with a new strip. The "Error 7" screen 3722 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00419] In certain embodiments, the Strip/Hardware Errors Interface 3710 may display an "Error 9" screen 3724 if the Reader is not working properly. The "Error 9" screen 3724 may display a message indicating that the Reader is not working properly. The "Error 9" screen 3724 may also display a message indicating that the user should turn off the Reader and try again. The "Error 9" screen 3724 may also display a message indicating that if this message appears again, the user should call Customer Service.

[00420] The error screens include an "OK" touchscreen button 3726, which, when pressed, returns the graphical user interface to the Home Screen. In certain embodiments, pressing the "OK" touchscreen button 3726 from either the "Error 2" screen 3714 or the "Error 9" screen 3724 will cause the Reader display to turn off. The Reader may be activated by inserting a test strip or by pressing the hardware power button.

Setup

[00421] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which facilitates a Setup procedure 2000 is provided. This graphical user interface is now described in greater detail with reference to FIGS. 24-27 and 29-33.

First Start Interface

[00422] A graphical user interface which facilitates a Setup procedure 2000 of the reader may include a First Start Interface 2001. First Start Interface 2001 begins with the display of an introduction screen 2002, e.g., for approximately 3 seconds. This introduction screen 2002 may include text and/or graphics designed to identify the manufacturer of the reader and/or the graphical user interface, e.g., the introduction screen 2002 may include the FreeStyle® butterfly trademark depicted in FIG. 24.

Language Selection

[00423] Following display of the introduction screen 2002, one or more Language Selection Screens 2003 are provided. In one embodiment, there is no default selection and the "OK" touch-screen button 2004 appears only after a language selection has been made, e.g., by touching the empty circle 2006 next to the language to be selected. The language selection options may be displayed in alphabetical order. If the list of language selection options includes more than 4 languages, the list may be scrolled as necessary to view the list using scroll touch-screen buttons 2005. The language list may be minimized by region and the order of language selection may be modified at a later time.

Date Selection

[00424] Once the language selection has been made by pressing an empty circle 2006 next to a language to be selected followed by the "OK" touch-screen button 2004, a First Date Selection Screen 2008 is displayed. This is depicted in FIG. 24 by reference path (Y1) 2007. At this stage, a user may return to the one or

more Language Selection Screens via reference path (Z1) 2009 by pressing touch-screen "back" button 2010 if desired. First Date Selection Screen 2008 provides a prompt 2011 to enter the current date along with a sample date 2012 which can be adjusted to the current date by the user. First Date Selection Screen 2008 also includes touchscreen up-arrow 2013 and touchscreen down-arrow 2014 by which the sample date 2012 may be adjusted by the user. For example, the sample date 2012 may be adjusted by 1 day increments by tapping the up arrow 2013 or the down arrow 2014. In one embodiment, the date increases or decreases as appropriate at a slow-rate for the first 2 seconds and at a faster rate after 2 seconds when the up or down arrow is pressed and held. The date format is set for SKU by region (U.S. format depicted in FIG. 24), which applies to all screens showing date.

Clock Style Selection

[00425] The user may move to the next screen in the graphical user interface Setup procedure 2000 by pressing touchscreen "next" button 2015, which causes First Clock Style Selection Screen 2016 to be displayed. At this stage, a user may return to the First Date Selection Screen 2008 by pressing touch-screen "back" button 2018 if desired. First Clock Style Selection Screen 2016 provides a prompt 2017 to select a clock style, e.g., 12-hour (am/pm) or 24-hour by touching the empty circle 2019 next to the clock style to be selected. Note that FIG. 24 depicts a selection of 12-hour (am/pm) as the clock style.

Time Selection

[00426] The user may move to the next screen in the graphical user interface Setup procedure 2000 by pressing touchscreen "next" button 2020, which causes First Time Selection Screen 2021 to be displayed. At this stage, a user may return to the First Clock Style Selection Screen 2016 by pressing touch-screen "back" button 2022 if desired. First Time Selection Screen 2021 provides a prompt 2023 to enter the current time. As depicted in FIG. 24, First Time Selection Screen 2021 includes a first touchscreen up-arrow 2024 and a first touchscreen down-arrow 2025 for adjusting the hour increments of time 2026. First Time Selection Screen 2021 also includes a second touchscreen up-arrow 2027 and a second touchscreen down-arrow 2028 for adjusting the minute increments of time 2026. The initial time format (12 or 24 hour) is displayed as set for the appropriate region. Using the relevant up and down-arrows Time

adjusts by 1 minute or 1 hour increments with arrow click. When pressing and holding the up or down-arrows, the appropriate time increments scroll at slow rate for the first 2 seconds and at faster rate after 2 seconds.

Target Glucose Range Selection

[00427] Once the current time has been entered on First Time Selection Screen 2021, the user can move to the next screen in the Setup procedure 2000 by pressing touchscreen "next" button 2029, which causes First Target Range Selection Screen 2033 to be displayed. This is depicted in FIG. 24 by reference path (A2) 2030. At this stage, the user may return to the First Time Selection Screen 2021 via reference path (B2) 2031 by pressing touchscreen "back" button 2032 if desired. First Target Range Selection Screen 2033 provides a first touchscreen up-arrow 2034 and a first touchscreen down-arrow 2035 for adjusting the low end (e.g., 80 mg/dL) of target glucose range 2036. First Target Range Selection Screen 2033 also provides a second touchscreen up-arrow 2037 and a second touchscreen down-arrow 2038 for adjusting the high end (e.g., 140 mg/dL) of target glucose range 2036. First Target Range Selection Screen 2033 also provides a touchscreen button "?" 2039, which, when pressed, provides a Target Range Details (DTL) screen 2040, which may display additional information related to the target glucose range 2036. Target Range Details (DTL) screen 2040 includes a touchscreen "OK" button 2041, which, when pressed, returns the user to the First Target Range Selection Screen 2033.

First Home Button

[00428] Once the target glucose range has been entered on First Target Range Selection Screen 2033, the user can move to the next screen in the Setup procedure 2000 by pressing touchscreen "next" button 2042, which causes First Home Button (BTTN) Screen 2043 to be displayed. The First Home Button (BTTN) Screen 2043 includes a prompt describing the function of the home button of the reader. For example, the prompt may be a text prompt which states "While using the Reader, press the button to return to the home screen" or the equivalent. This text may be provided with a graphical depiction of the location of the home button on the reader as shown in FIG. 24. At this stage, the user may return to the First Target Range Selection Screen 2033 by pressing touchscreen "back" button 2044 if desired. No "back" button will be displayed if the user arrives at the First Home Button Screen 2043 from the Settings Menu (discussed

in greater detail below) If the reader powers off after this screen is viewed, the next power on event will not result in display of the First Start Interface startup sequence described above. If this screen has not been displayed, the First Start Interface startup sequence will start at the beginning, and any settings made are NOT retained.

Arrow Description Screen

[00429] Pressing the touchscreen "next" button 2045 displayed on the First Home Button Screen 2043 results in the display of Arrow Description Screen 2046, which includes a description of various trending arrows utilized by the graphical user interface to convey glucose trend information. For example, the Arrow Description Screen 2046 may display a text prompt which states "When you scan your Sensor an arrow will indicate your recent glucose trend" or the equivalent. This text prompt may be followed by various arrows and associated descriptions of the trending information conveyed thereby. For example, a first arrow 2047 pointing straight up may indicate that the user's glucose level is "Rising quickly", a second arrow 2048 pointing up and to the right at an approximately 45 degree angle may indicate that the user's glucose level is "Rising" or the equivalent, a third arrow 2049 pointing straight to the right may indicate that the user's glucose level is "Stable" or the equivalent, a fourth arrow 2050 pointing down and to the right at an approximately 45 degree angle may indicate that the user's glucose level is "Falling" or the equivalent, and a fifth arrow 2051 may indicate that the user's glucose level is "Falling quickly" or the equivalent. At this stage, the user may return to the First Home Button Screen 2043 by pressing touchscreen "back" button 2052 if desired.

Charge Description Screen

[00430] Pressing the touchscreen "next" button 2053 displayed on Arrow Description Screen 2046 results in the display of Charge Description Screen 2054. Charge Description Screen 2054 provides a text prompt reminding the user to recharge the reader on a regular basis. For example, Charge Description Screen 2054 may display the text prompt "Recharge the Reader regularly" or the equivalent. Charge Description Screen 2054 may also display a graphic demonstrating to the user how to connect the reader to a power source for recharging purposes. At this stage, the user may return to the Arrow Description Screen 2046 by pressing touchscreen "back" button 2055 if desired. Charge

Description Screen 2054 also includes a touchscreen "done" button 2056, which, when pressed, completes the First Start Interface 2001. At this point, a sensor activation procedure may be implemented.

Settings Interface

[00431] A graphical user interface which facilitates a Setup procedure 2000 may include a Settings Interface 2057 which includes a Settings Menu 2058 which may be displayed on the reader. Settings Menu 2058 includes a first settings screen 2059, a second settings screen 2060, and a third settings screen 2061. First settings screen 2059 includes the following menu items: "Sounds", "Target Range", and "Control Solution Test." Each of these menu items is represented by a corresponding touchscreen button (touchscreen buttons 2062, 2063 and 2064 respectively). Second settings screen 2060 includes the following menu items: "Time & Date", "Display Brightness", and "Language". Each of these menu items is represented by a corresponding touchscreen button (touchscreen buttons 2065, 2066 and 2067 respectively). Finally, third settings screen 261 includes the following menu items: "System Status", "Calculator Settings", "Reader Basics", and "Professional Options". Each of these menu items is represented by a corresponding touchscreen button (touchscreen buttons 2068, 2069, 2070 and 2071 respectively). Touchscreen scroll buttons 2072, 2073, 2074 and 2075 may be used as appropriate to scroll between the first, second and third settings screens.

Sounds

[00432] Pressing touchscreen button 2062 ("Sounds") results in the display of sound settings screen 2076.This is depicted in FIG. 25 by reference path (C2) 2077. Sound settings screen 2076 includes touchscreen toggle settings for "Volume" 2078, "Notification Tone" 2079, "Notification Vibrate" 2080, and "Button Tone" 2081. Sounds and vibration can be toggled on or off with these settings. Button sounds include, e.g., keypresses and interactive notifications (e.g., result ready). The first two options impact screens that broadcast Notification, Confirmation and Reminder signals. Default button sound is Off. Default notification sound is On while vibration is Off. For hold-down scrolling, a sound is made for the initial touch only. Once the desired sound settings selections have been made using the touchscreen toggle settings, the settings can be accepted by touching touchscreen "OK" button 2082.

Target Range

[00433] Pressing touchscreen button 2063 ("Target Range") results in the display of Target Range settings screen 2083.This is depicted in FIG. 25 by reference path (D2) 2084. Target Range settings screen 2083 provides a first touchscreen up-arrow 2085 and a first touchscreen down-arrow 2086 for adjusting the low end (e.g., 70 mg/dL) of target glucose range 2089. Target Range settings screen 2083 also provides a second touchscreen up-arrow 2087 and a second touchscreen down-arrow 2088 for adjusting the high end (e.g., 130 mg/dL) of target glucose range 2089. At this stage, the user may return to first settings screen 2059 via reference path (D2) 202084 by pressing touchscreen "back" button 2093 if desired. The current settings can be selected by pressing touchscreen "done" button 2094. Target Range settings screen 2083 also provides a touchscreen button "?" 2090, which, when pressed, provides a Target Range Details (DTL) screen 2091, which may display additional information related to the target glucose range 2089. Target Range Details (DTL) screen 2091 includes a touchscreen "OK" button 2092, which, when pressed, returns the user to the Target Range settings screen 2083.

Display Brightness

[00434] Pressing touchscreen button 2066 ("Display Brightness") results in the display of Display Brightness settings screen 2095.This is depicted in FIG. 25 by reference path (G2) 2096. Display Brightness settings screen 2095 provides settings for "High", "Medium", and "Low" display brightness, which can be selected by touching one of empty circles 2097. Note that FIG. 25 shows the "High" brightness setting selected. Once the desired display brightness has been selected by pressing one of the empty circles 2097, the setting can be accepted by touching touchscreen "OK" button 2098.

Control Solution Test

[00435] Pressing touchscreen button 2064 ("Control Solution Test") results in the display of an "Insert Test Strip" (or the equivalent) prompt 2099 and initiates a Control Solution Test protocol as shown in flow-diagram 2100.This is depicted in FIG. 25 by reference path (E2) 2101. Generally, a test strip is inserted into the reader (Step 2102). Depending on whether the test strip is a blood glucose (BG) or ketone test strip, a corresponding Precision Control Solution animation (Step 2103) or a Ketone Control Solution animation (Step 2104) is displayed. See,

e.g., FIG. 35 for respective Precision Control Solution animation and Ketone Control Solution animation. Once the appropriate control solution is applied (Step 2105), a waiting animation is displayed (Step 2106) while the results are processed. See, e.g., FIG. 34, described earlier in the Blood Glucose Strip Test and Ketone Strip Test section earlier. Once the results are ready (Step 2107), the blood glucose control results (Step 2108) or the ketone results (Step 2109) are provided. These results may be displayed or stored, e.g., in a log-book application of the reader.

[00436] **FIG. 35** illustrates an example animation interface 2430 to instruct the user to apply control solution, according to one embodiment. Screens 2432, 2434, and 2436 display an image of a control solution dropper and an analyte monitoring device with test strip inserted into the strip port. The dropper and test strip move closer as the sequence of screens 2432, 2434, and 2436 progress to animate the application of the dropper on the test strip. Animation interface 2430 may be displayed, for example, when the analyte monitoring device is ready to receive the control solution.

[00437] FIG. 35 also illustrates an example animation interface 2438 to instruct the user to apply a ketone control solution, according to one embodiment. Similar to interface 2430, screens 2440, 2442, and 2444 display an image of a control solution dropper and an analyte monitoring device with test strip inserted into the strip port. The dropper and test strip move closer as the sequence of screens 2440, 2442, and 2444 progress to animate the application of the dropper on the test strip. Animation interface 2438, however, includes an indication that a Ketone test is being performed—e.g., displaying the words, "Ketone Test".

Time & Date

[00438] Pressing touchscreen button 2065 ("Time & Date") results in the display of Time & Date settings screen 2110.This is depicted in FIG. 25 by reference path (F2) 2111. Time & Date settings screen 2110 provides a touchscreen time button 2112 and a touchscreen date button 2113.

[00439] Pressing touchscreen time button 2112 results in the display of a Set Time 12 2114 or a Set Time 24 2115 screen. The Set Time 12 2114 screen includes a first touchscreen up-arrow 2118 and a first touchscreen down-arrow 2119 for adjusting the hour increments of time 2122. Set Time 12 screen 2114

also includes a second touchscreen up-arrow 2120 and a second touchscreen down-arrow 2121 for adjusting the minute increments of time 2122. The Set Time 24 screen 2115 includes a first touchscreen up-arrow 2123 and a first touchscreen down-arrow 2124 for adjusting the hour increments of time 2127. Set Time 24 screen 2115 also includes a second touchscreen up-arrow 2125 and a second touchscreen down-arrow 2126 for adjusting the minute increments of time 2127. The user can toggle between the Set Time 12 2114 and the Set Time 24 2115 screen by use of touchscreen toggle buttons 2115 and 2116 as appropriate. In addition, the Set Time 12 2114 and the Set Time 24 2115 screens include touchscreen "OK" buttons 2128 and 2129 respectively for accepting the entered time.

[00440] Pressing touchscreen date button 2113 results in the display of Set Date screen 2130. Set Date screen 2130 includes a touchscreen up-arrow button 2131 and a touchscreen down-arrow button 2132 for adjusting the day of the factory set date 2133. Set Date screen 2130 also includes touchscreen "OK" button 2134 for accepting the entered time.

[00441] Time & Date settings screen 2110 also includes touchscreen "done" button 2135, which, when pressed, returns the user to the Settings Menu 2058 via reference path (H2) 2136.

Language Settings

[00442] Pressing touchscreen button 2067 ("Language") results in the display of one or more Language Setting screens 2137. This is depicted in FIG. 26 by reference path (I2) 2138. The one or more Language Setting screens 2137 include language options which can be selected by pressing the empty circle next to the corresponding language choice. Note that FIG. 26 shows the English language option selected. The user may scroll between the language setting screens using the displayed up or down-arrows 2139 as appropriate. The Language Setting screens 2137 also include touchscreen "OK" button 2140 for accepting the selected language.

Calculator Settings

[00443] Pressing touchscreen button 2069 ("Calculator Settings") results in the display of Calculator Setting screens 2141. This is depicted in FIG. 26 by reference path (K2) 2142. The Calculator Setting screens 2141 include, e.g., an Insulin Calculator Settings – Easy Mode screen 2142 and an Insulin Calculator

Settings – Advanced Mode screen 2143. Insulin Calculator Settings – Easy Mode screen 2142 includes, e.g., insulin unit measurements of 18u associated with breakfast, 20u associated with lunch, 24u associated with dinner, a correction target of 70 to 130 mg/dL and a correction factor of 10 mg/dL. Insulin Calculator Settings – Advanced Mode screen 2143 includes, e.g., a carbohydrate (Carb) ratio of 1u for 10g, a correction target of 70 to 130 mg/dL, and a correction factor of 1u for 10 mg/dL. The Calculator Setting screens 2141 also include touchscreen "OK" button 2144 for accepting the indicated calculator settings.

[00444] Pressing touchscreen button 2070 ("Reader Basics") results in the display of the First Start Interface First Home Button screen 2043 discussed previously herein. This is depicted in FIG. 26 by reference path (L2) 2145.

Professional Options

[00445] As shown in FIG. 26, pressing touchscreen button 2071 ("Professional Options") results in the display of a HCP Ask screen 2146. This is depicted in FIG. 26 by reference path (J2) 2147. The HCP Ask screen 2146 displays a prompt asking whether the user is a health care professional. This question can be answered by touching the empty circle 2148 next to either the "Yes" or "No" option. Note that FIG. 26 shows the "Yes" option has been selected. No default selection is provided and touchscreen "next" button 2149 is not displayed until an option is selected. HCP Ask screen 2146 also includes a touchscreen "back" button 2150, which, when pressed, returns the user to the Settings Menu 2058 via reference path (J2) 2147. As indicated in FIG. 26, if the "No" option is selected a Not HCP screen 2151 is displayed which indicates, e.g., that "Professional Options can only be used by a health care professional." The Not HCP screen 2151 also includes a touchscreen "done" button 2152 which, e.g., returns the user to the Settings Menu 2058 via reference path (J2) 2147. If the "Yes" option is selected, a passcode entry screen 2153 is displayed which prompts the user to enter a passcode. Entry of an incorrect passcode will result in, e.g., an "Incorrect Code" prompt. Entry of the correct passcode allows the user access to the Professional Options screen 2154. Professional Options screen 2154 includes three touchscreen button options, a System Reset 2155 option, a Masked Mode 2156 option, and an Insulin Calculator 2157 option. Pressing the touchscreen button for the System Reset 2155 option results in the

display of a Reset System (SYS) screen 2158. Selecting the "reset" option from this screen restores all reader settings to the factory defaults and deletes all patient data stored in the reader. The user is then returned to the First Start Interface 2001. Pressing the touchscreen button for the Masked Mode 2156 option initiates a Masked Mode interface which is discussed elsewhere herein.

[00446] Pressing the touchscreen button for the Insulin Calculator 2157 option initiates an Insulin Calculator Start interface which is discussed in greater detail below.

[00447] Professional Options screen 2154 also includes a touchscreen "OK" button 2159, which, when pressed, returns the user to the Settings Menu 2058 via reference path (J2) 2147.

System Status

[00448] Pressing touchscreen button 2068 ("System Status") initiates a System Status Interface 2160. This aspect of the graphical user interface is discussed in greater detail below.

System Status Interface

[00449] A graphical user interface which facilitates a Setup procedure 2000 may include a System Status Interface 2160 which includes a System Status menu 2161, which may be displayed on the reader. System Status menu 2161 includes the following items: "System Info", "Self-Test", "Touchscreen Test", and "Error Log", which can be selected by touching corresponding touchscreen buttons 2162, 2163, 2164, and 2165 respectively. System Status menu 2161 includes a touchscreen "OK" button 2169, which, when pressed, returns the user to the Settings Interface 2057.

[00450] Pressing the touchscreen button 2162 for System Info results in display of System Info screen 2166, which may display information such as reader serial no., reader software no., reader hardware no., sensor ID, sensor software no., sensor count, strip count, date of last scan, last reset, and the like. This is depicted in FIG. 27 by reference path (N2) 2167. System Info screen 2166 includes a touchscreen "OK" button 2168, which, when pressed, returns the user to the System Status menu 2161 via reference path (M2) 2170.

[00451] Pressing the touchscreen button 2163 for Self-Test results in display of Self-Test screen 2171 and initiation of a self-diagnostics protocol. This is depicted in FIG. 27 by reference path (O2) 2172. The self-diagnostics protocol

can also be initiated by a press of the power button and a double-tap anywhere on the screen. Self-Test screen 2171 includes a touchscreen "LCD Test" button 2173. Pressing touchscreen "LCD Test" button 2173 results in display of an LCD Test Intro screen 2174A. LCD Test Intro screen 2174A includes, e.g., a prompt indicating "On the next screen check for missing pixels. Press 'start' to begin the test." LCD Test Intro screen 2174A also includes a touchscreen "start" button 2175 and a touchscreen "back" button 2176. When pressed, the touchscreen "back" button 2176 returns the user to Self-Test screen 2171. Pressing the touchscreen "start" button 2175 initiates an LCD test and results in the display of an LCD Test Results screen 2174B. The LCD Test Results screen 2174B may include a prompt indicating that the LCD test has been completed. The LCD Test Results screen 2174B may also include a touchscreen "done" button 2177, which, when pressed returns the user to Self-Test screen 2171 or the System Status menu 2161 via reference path (M2) 2170. Self-Test screen 2171 also includes a touchscreen "OK" button 2168, which, when pressed, returns the user to the System Status menu 2161 via reference path (M2) 2170.

[00452] Pressing the touchscreen button 2164 for Touchscreen Test results in display of Touch Sense Test screen 2178. This is depicted in FIG. 27 by reference path (P2) 2179. Touch Sense Test screen 2178 may display a prompt indicating, e.g., "Press start button to test display touch zone grid and test all the touch zones. Press the Power button in the touch sense grid to navigate back to the Diagnostic Menu." Touch Sense Test screen 2178 includes a touchscreen "start" button 2180, which, when pressed, results in display of a touch sense grid 2181 for testing the responsiveness of the various zones of the touch sense grid 2181. Touch Sense Test screen 2178 also includes a touchscreen "back" button which, when pressed, returns the user to the System Status menu 2161 via reference path (M2) 2170.

[00453] Pressing the touchscreen button 2165 for Error Log results in display of an Error Log Empty screen 2182 or an Error Log screen 2184. This is depicted in FIG. 27 by reference paths (Q2) 2183 and (R2) 2185 respectively depending on whether any error entries are present in the logbook. Error Log screen 2184 may include one or more down or up-arrows to scroll between pages of the error log if necessary.

Masked Mode Interface

[00454] An exemplary embodiment of a graphical user interface which may be utilized in connection with a reader as described herein and which functions to enable the operation of the analyte monitoring device in a masked mode.

[00455] **FIG. 28** illustrates a Professional Options screen 2502 that displays a menu of options for customizing the operation of the device. For example, the menu of options may be geared more for a physician or other health care professional to set up or otherwise configure the device for the patient. In one embodiment, the Professional Options screen 2502 may require a code or password to access, which the physician has but the patient does not. In another embodiment, the Professional Options screen 2502 may not be restrict access and the patient may also change the configuration.

[00456] Professional Options screen 2502 includes a Masked Mode option 2504 for navigating to a Masked Mode interface 2510 that enables activation or deactivation of the Masked Mode. Examples of other options is an Insulin Calculator option 2508 for navigating to an interface for activating or deactivating the insulin calculator. A System Reset Option 2502 is also included to reset the option to a default setting.

[00457] Masked Mode interface 2510 includes an activation icon, symbol, trigger element, etc., that may be selected to activate the Masked Mode. Masked Mode interface 2510 may also provide additional information about the Masked Mode to inform the user of its use. Masked Mode interface 2510 also includes trigger element 2514a for navigating back to the Professional Options screen 2502. Trigger element 2514b takes the user to a screen for setting a reminder to take a sensor reading, as shown by reference path T2.

[00458] Upon selection of trigger element 2514b, Masked Rem screen 2516 is displayed to enable setting the device to provide reminders to the user to perform a reading. For example, element 2518 may be selected to activate or deactivate the reminder feature on the device. Additional information may also be provided to inform the user of the reminder option. If the reminder is “off” and the user selects trigger element 2520a takes the user back to the Professional Options screen 2502. If the reminder is “on” and the user selects trigger element 2520b, then a Masked REM – Time screen 2522 is displayed to enable the user to set times for initiating a reminder. Once the time is set, the user can select

trigger element 2522b to trigger the Masked Complete (Comp) screen 2524 which indicates that the Masked Mode is activated. Upon user confirmation of the trigger element 2524, the device navigates back to the Professional Options screen 2502.

Calculator Start Interface

[00459] A graphical user interface which facilitates a Setup procedure 2000 may include a Calculator Start Interface 2186 as mentioned previously herein. Calculator Start Interface 2186 may be initiated by pressing the touchscreen button for the Insulin Calculator 2157 option located on the Professional Options screen 2154. Pressing the touchscreen button for the Insulin Calculator 2157 option results in a calculator On/Off status determination. If the calculator is On, reference path (X2) 2187 is initiated, which results in display of a Calculation Edit screen 2188. Calculation Edit screen 2188 includes a touchscreen "Turn Off Calculator" button 2189. Pressing the "Turn Off Calculator" button 2189 results in display of a Calculation Off screen 2190, which provides a prompt indicating that the insulin calculator is turned off. In this case, the calculator button will no longer be available when checking glucose levels. The Calculation Off screen 2190 includes a touchscreen "done" button, which, when pressed, initiates reference path (V2) 2192, which returns the user to the Professional Options screen 2154.

[00460] Calculation Edit screen 2188 also includes a touchscreen "Change Calculator Settings" button 2193. Pressing the touchscreen "Change Calculator Settings" button 2193 results in initiation of reference path (B3) 2194 discussed in greater detail below. Calculation Edit screen 2188 also includes a touchscreen "back" button 2195, which, when pressed, initiates reference path (W2) 2196 which returns the user to the Professional Options screen 2154.

[00461] As discussed above, pressing the touchscreen button for the Insulin Calculator 2157 option results in a calculator On/Off status determination. If the calculator is Off, a I Take screen 2197 is displayed. The I Take screen 2197 includes a prompt, "Does your patient take rapid-acting (short acting) insulin at meals?" The I Take screen 2197 also includes empty circles 2198 which may be pressed so as to indicate a Yes or No answer to the above prompt. Note that **FIG. 29** shows the Yes option selected. The I Take screen 2197 also includes a

touchscreen “next” button 2199, which initiates a reference path (Z2) 2200 (discussed in greater detail below) in the event the Yes option was selected.

[00462] Reference path (B3) 2194 and reference path (Z2) 2200 result in display of Calculation Type 01 screen 2201 or a Calculation Type 02 screen 2202 depending on whether an “Easy” or “Advanced” Setup Option is selected respectively using touchscreen toggle element 2203. The “Easy” Setup Option is utilized for patients who start with a fixed dose of rapid-acting insulin at meals while the “Advanced” Setup Option is utilized for patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals. Calculation Type 01 screen 2201 and Calculation Type 02 screen 2202 each include a touchscreen “back” button 2204 and a touchscreen “next” button 2205. Pressing “back” button 2204 returns the user to I Take 2197 via reference path (Y2) 2206 if I Take 2197was the previously viewed screen. Pressing “back” button 2204 returns the user to Calculation Edit 2188 via reference path (A3) 2207 if Calculation Edit 2188 was the previously viewed screen. Touching touchscreen “next” button 2205 initiates reference path D3 2208 or E3 2209 depending on whether the Easy or Advanced Setup option is selected respectively.

[00463] Reference path D3 2208 results in display of a Calculation Steps EZ screen 2210, including the following prompts: “This setup has two parts: 1) Enter each of your patient’s meal-time insulin doses; and 2) Enter your patient’s correction settings.” Calculation Steps EZ screen 2210 includes a touchscreen “back” button 2211 and a touchscreen “next” button 2212. Pressing touchscreen “back” button 2211 returns the user to Calculation Type 01 screen 2201 and Calculation Type 02 screen 2202 via reference path (C3) 2213. Pressing touchscreen “next” button 2212 results in initiation of an Easy Calculation Setup interface 2214 described in greater detail below.

[00464] Reference path E3 2209 results in display of a Calculation Steps Advanced screen 2215, including the following prompts: “This setup has two parts: 1) Enter your patient’s meal-time insulin settings; and 2) Enter your patient’s correction settings.” Calculation Steps Advanced screen 2215 includes a touchscreen “back” button 2216 and a touchscreen “next” button 2217. Pressing touchscreen “back” button 2216 returns the user to Calculation Type 01 screen 2201 and Calculation Type 02 screen 2202 via reference path (C3) 2213. Pressing touchscreen “next” button 2217 results in display of a Food Units 01

screen 2218. Food Units 01 screen 2218 includes a prompt "Enter food by:" and includes two options "Grams of carbs" and "Servings" which can be selected by pressing one of corresponding empty circles 2219. Note that FIG. 29 shows the "Grams of carbs" option selected. Food Units 01 screen 2218 includes a touchscreen "back" button 2220 and a touchscreen "next" button 2221. Pressing touchscreen "back" button 2220 returns the user to Calculation Steps Advanced screen 2215. Pressing touchscreen "next" button 2221 results in initiation of an Advanced Calculation Setup interface 2222, discussed in greater detail below. Food Units 01 screen 2218 also includes a touchscreen "?" button, which, when pressed, initiates reference path (F3) 2223, which provides additional information regarding the selection of "Grams of carbs" or "Servings" as shown in FIG. 29 with reference to screens H01 2224, H02 2225 and H03 2226.

Easy Calculation Setup Interface

[00465] Easy Calculation Setup interface 2214 is described with reference to FIG. 30. Three Meal Calculation screens are provided, one each for Breakfast 2227, Lunch 2228, and Dinner 2229. Each of these screens includes up and down-arrows 2230 for adjusting the displayed units of insulin associated with each meal. Each of these screens also includes touchscreen "back" and "next" buttons for navigating between screens of the Easy Calculation Setup interface 2214. Finally, each of these screens includes a touchscreen "?" button 2231, which, when pressed, initiates reference path G3 2232. Reference path G3 2232 results in display of a screen 2233 including the prompt: "Enter the units of rapid-acting insulin you recommended to cover this meal." Pressing the touchscreen "next" button from the Dinner 2229 screen results in display of a Correction Target screen 2234.

[00466] Correction Target screen 2234 includes first up and down-arrows (2235 and 2236) for adjusting a low target, e.g., 70 mg/dL, of the target glucose range 2237; and second up and down-arrows (2238 and 2239) for adjusting a high target, e.g., 130 mg/dL of the target glucose range 2237. Correction Target screen 2234 includes a touchscreen "?" button 2240, which, when pressed, initiates a reference path (H3) 2241. Reference path H3 2241 results in display of a screen 2242 including the prompt: "Target is the desired glucose value if extra rapid-acting insulin is needed to correct high glucose reading." Pressing the touchscreen "next" button from the Correction Target screen 2234 results in

display of a Correction Factor screen 2243. Correction Factor screen 2243 includes up and down-arrows 2244 for adjusting the insulin correction factor 2245. If the set Correction Factor scrolls below 1, a No Correction screen 2249 is displayed with the prompt "No correction insulin". Correction Factor screen 2243 includes a touchscreen "?" button 2246, which, when pressed, initiates a reference path (I3) 2247. Reference path I3 2247 results in display of a screen 2248 including the prompt: "The Reader uses this value to determine how many units of rapid-acting insulin is needed to lower high glucose to a target value or range." Pressing the touchscreen "next" button from the Correction Factor screen 2243 screen results in initiation of an Insulin On Board (IOB) Setup interface 2250, which is described in greater detail below.

Advanced Calculation Setup Interface

[00467] Advanced Calculation Setup interface 2222 is described with reference to FIG. 31. Initiation of Advanced Calculation Setup interface 2222 with "By grams of carbs" selected on screen 2218 results in display of a Set Carb Ratio screen 2251. Set Carb Ratio screen 2251 includes touchscreen up and down-arrows 2252 for adjusting correction factor 2253. Set Carb Ratio screen 2251 also includes a touchscreen "by time of day" button 2254.

[00468] Pressing the touchscreen "by time of day" button 2254 results in display of a CR Time List screen 2255. CR Time List screen 2255 includes touchscreen buttons 2256 which may be used to select a time period, e.g., morning, midday, evening, or night for the correction factor 2253. Pressing one of touchscreen buttons 2256 results in display of a CR Time screen 2257, which includes touchscreen up and down-arrows 2258 for adjusting correction factor 2253 by time of day. CR Time screen 2257 includes a touchscreen "OK" button 2259, which, when pressed, results in selection of the displayed correction factor 2253 by time of day and returns the user to the CR Time List screen 2255. Time List screen 2255 includes a touchscreen "back" button 2260 for returning to the Set Carb Ratio screen 2251 and a touchscreen "done" button 2261 for indicating completion of the correction factor 2253 by time of day setup and, in some embodiments, for initiating the Correction Setup interface 2268, discussed in greater detail below.

[00469] Set Carb Ratio screen 2251 and CR Time List screen 2255 each include a touchscreen "?" button 2264, which, when pressed, results in display of a Carb

Ratio information screen 2265. Carb Ratio information screen 2265 displays a prompt indicating "Carbohydrate ratio is the amount of carbohydrates that 1 unit of insulin will cover." Pressing the touchscreen "OK" button 2266 from Carb Ratio information screen 2265 returns the user to the Set Carb Ratio screen 2251 or the CR Time List screen 2255 as appropriate.

[00470] Set Carb Ratio screen 2251 includes a touchscreen "back" button 2262 and a touchscreen "done" button 2263. Pressing touchscreen "back" button 2262 returns the user to the Calculation Start interface 2186 as described previously herein via reference path (J3) 2267. Pressing touchscreen "done" button 2263 initiates a Correction Setup interface 2268 via reference path (K3) 2269.

[00471] Initiation of Advanced Calculation Setup interface 2222 with "By servings" selected on screen 2218 results in display of a Servings Definition screen 2270. Servings Definition screen 2270 includes touchscreen up and down-arrows 2271 for adjusting servings definition 2272 (e.g., 1 serving = 10.0 grams carbs). Servings Definition screen 2270 also includes a touchscreen "back" button 2273 and a touchscreen "next" button 2274. Pressing touchscreen "back" button 2273 returns the user to the Calculation Start interface 2186 as described previously herein. Pressing touchscreen "next" button 2274 results in display of a Set Carb Ratio Servings screen 2275. Set Carb Ratio Servings screen 2275 includes touchscreen up and down-arrows 2276 for adjusting servings ratio 2277 (e.g., For 1 serving: 1.5 units insulin). Set Carb Ratio Servings screen 2275 also includes a touchscreen "by time of day" button 2278.

[00472] Pressing the touchscreen "by time of day" button 2278 results in display of a CR Servings Time List screen 2279. CR Servings Time List screen 2279 includes touchscreen buttons 2280 which may be used to select a time period, e.g., morning, midday, evening, or night for the servings ratio 2277. Pressing one of touchscreen buttons 2280 results in display of a CR Servings Time screen 2281, which includes touchscreen up and down-arrows 2282 for adjusting servings ratio 2277 by time of day. CR Servings Time screen 2281 includes a touchscreen "OK" button 2283, which, when pressed, results in selection of the displayed servings ratio 2277 by time of day and returns the user to the CR Servings Time List screen 2279. CR Servings Time List screen 2279 includes a touchscreen "back" button 2284 for returning to the Set Carb Ratio Servings

screen 2275 and a touchscreen "done" button 2285 for initiating the Correction Setup interface 2268, discussed in greater detail below.

[00473] Set Carb Ratio Servings screen 2275 includes a touchscreen "back" button 2286 and a touchscreen "next" button 2287. Pressing touchscreen "back" button 2286 returns the user to the Servings Definition screen 2270. Pressing touchscreen "next" button 2287 results in initiation of the Correction Setup interface 2268, discussed in greater detail below.

[00474] Servings Definition screen 2270, Set Carb Ratio Servings screen 2275, and CR Servings Time List screen 2279 each include a touchscreen "?" button 2288, which, when pressed, results in display of a Servings Ratio information screen 2289 via reference path (L3) 2290. Servings Ratio information screen 2289 displays a prompt indicating "Servings ratio is the amount of insulin that will cover 1 serving" or the equivalent. Pressing the touchscreen "OK" button 2291 from Servings Ratio information screen 2289 returns the user to the Servings Definition screen 2270, Set Carb Ratio Servings screen 2275, or CR Servings Time List screen 2279 as appropriate.

Correction Setup Interface

[00475] Correction Setup interface 2268 is described with reference to FIG. 32. Initiation of Correction Setup interface 2268 results in display of Target Type screen 2292. Target Type screen 2292 includes a prompt "How does your patient correct their glucose" or the equivalent. Target Type screen 2292 includes the following two options or their equivalent: 1) To a single target; and 2) To a target range, one of which may be selected by pressing one of the corresponding empty circles 2293 associated with the options. Note that FIG. 32 shows the "To a single target" options selected. Target Type screen 2292 also includes a touchscreen "back" button 2294 and a touchscreen "next" button 2295. Pressing touchscreen "back" button 2294 returns the user to the previously viewed screen (Set Carb Ratio screen 2251, CR Time List screen 2255, Set Carb Ratio Servings screen 2275, or CR Servings Time List screen 2279.

[00476] When the "To a single target" option is selected on screen 2292, pressing the touchscreen "next" button 2295 results in display of a Correction Target screen 2296. Correction Target screen 2296 includes touchscreen up and down-arrows 2297 for adjusting correction target 2298 (e.g., 100 mg/dL). Correction

Target screen 2296 also includes a touchscreen “by time of day” button 2299. Pressing the touchscreen “by time of day” button 2299 results in initiation of reference pathway (P3) 2300, discussed in greater detail below. Correction Target screen 2296 also includes touchscreen “back” button 2301 and touchscreen “next” button 2302. Pressing touchscreen “back” button 2301 returns the user to Target Type screen 2292. Pressing touchscreen “next” button 2302 results in initiation of reference path (O3) 2303, discussed in greater detail below.

[00477] When the “To a target range” option is selected on screen 2292, pressing the touchscreen “next” button 2295 results in display of a Correction Target Range screen 2304. Correction Target Range screen 2304 includes first touchscreen up and down-arrows 2305A for adjusting the low end (e.g., 70 mg/dL) of correction target range 2306. Correction Target Range screen 2304 also includes second touchscreen up and down-arrows 2305B for adjusting the high end (e.g., 130 mg/dL) of correction target range 2306. Correction Target Range screen 2304 also includes a touchscreen “by time of day” button 2307. Pressing the touchscreen “by time of day” button 2307 results in initiation of reference pathway (M3) 2308, discussed in greater detail below. Correction Target Range screen 2304 also includes touchscreen “back” button 2309 and touchscreen “next” button 2310. Pressing touchscreen “back” button 2309 returns the user to Target Type screen 2292. Pressing touchscreen “next” button 2310 results in initiation of reference path (O3) 2303, discussed in greater detail below. Target Type screen 2292, includes a touchscreen “?” button 2311, which, when pressed, displays a target information screen 2312, including a prompt indicating that “The calculator can determine how much insulin is needed to bring the glucose to either a single number or within a range” or the equivalent. Pressing the touchscreen “OK” button 2313 returns the user to the Target Type screen 2292.

[00478] Each of Correction Target screen 2296, and Correction Target Range screen 2304 includes a touchscreen “?” button 2314, which, when pressed, displays a target information screen 2315, including a prompt indicating that “The correction target setting allows you to set a glucose target that will adjust your patient’s insulin dose if their glucose readings is above or below the target” or the equivalent. Pressing the touchscreen “OK” button 2316 returns the user to

the Correction Target screen 2296 or the Correction Target Range screen 2304 as appropriate.

[00479] As discussed above, pressing the touchscreen "by time of day" button 2299 on screen 2296 results in initiation of reference pathway (P3) 2300. Initiation of reference pathway (P3) 2300 results in display of Target Time List screen 2317, which includes touchscreen buttons 2318 for selecting a time of day (e.g., morning, midday, evening or night) for correction target 2298. Pressing one of touchscreen buttons 2318 results in display of a Target Time screen 2319. Target Time screen 2319 includes touchscreen up and down-arrows 2320 for adjusting correction target 2298 for the selected time of day. Target Time screen 2319 also includes touchscreen "OK" button 2320 for accepting the adjusted correction target 2298 for the selected time of day and returning the user to Target Time List screen 2317. Target Time List screen 2317 includes a touchscreen "back" button 2321 and a touchscreen "done" button 2322. Pressing touchscreen "back" button 2321 initiates reference pathway (Q3) 2323, which returns the user to the Correction Target screen 2296. Pressing touchscreen "done" button 2322 initiates reference path (S3) 2324, discussed in greater detail below.

[00480] As discussed above, pressing the touchscreen "by time of day" button 2307 on screen 2304 results in initiation of reference pathway (M3) 2308. Initiation of reference pathway (M3) 2308 results in display of Target Range Time List screen 2325, which includes touchscreen buttons 2326 for selecting a time of day (e.g., morning, midday, evening or night) for correction target range 2306. Pressing one of touchscreen buttons 2326 results in display of a Target Range Time screen 2327. Target Range Time screen 2327 includes first touchscreen up and down-arrows 2328 for adjusting the low end of correction target range 2306 for the selected time of day. Target Range Time screen 2327 includes second touchscreen up and down-arrows 2329 for adjusting the high end of correction target range 2306 for the selected time of day. Target Range Time screen 2327 also includes touchscreen "OK" button 2330 for accepting the adjusted correction target range 2306 for the selected time of day and returning the user to Target Range Time List screen 2325. Target Range Time List screen 2325 includes a touchscreen "back" button 2331 and a touchscreen "done" button 2332. Pressing touchscreen "back" button 2331 initiates reference

pathway (N3) 2333, which returns the user to the Correction Target Range screen 2304. Pressing touchscreen "done" button 2332 initiates reference path (S3) 2324, discussed in greater detail below.

[00481] Each of Target Time List screen 2317 and Target Range Time List screen 2325 includes a touchscreen "OK" button 2334, which, when pressed, results in display of target information screen 2315, including a prompt indicating that "The correction target setting allows you to set a glucose target that will adjust your patient's insulin dose if their glucose readings is above or below the target" or the equivalent. Pressing the touchscreen "OK" button 2316 returns the user to the Target Time List screen 2317 or the Target Range Time List screen 2325 as appropriate.

[00482] As discussed above, pressing touchscreen "next" button 2302 or 2310 initiates reference path (O3) 2303. Similarly, pressing "done" button 2322 or 2332 initiates reference path (S3) 2324. Reference paths (O3) 2303 and (S3) 2324 both result in display of a Set Correction Factor screen 2335. Set Correction Factor screen 2335 includes touchscreen up and down-arrows 2336 for adjusting insulin correction factor 2337 (e.g., 1 u insulin for 10 mg/dL). Set Correction Factor screen 2335 also includes a touchscreen "By time of day" button 2338, which, when pressed, results in display of a Correction Factor Time List screen 2339. Correction Factor Time List screen 2339 includes touchscreen buttons 2340 for selecting a time of day (e.g., morning, midday, evening or night) for correction factor 2337.

[00483] Pressing one of touchscreen buttons 2340 results in display of a Correction Factor by Time screen 2341. Correction Factor by Time screen 2341 includes touchscreen up and down-arrows 2342 for adjusting correction factor 2337 for the selected time of day. Correction Factor by Time screen 2341 also includes a touchscreen "OK" button 2343 for accepting the adjusted correction factor 2337 for the selected time of day and returning the user to Correction Factor Time List screen 2339.

[00484] Correction Factor Time List screen 2339 includes a touchscreen "back" button 2344 and a touchscreen "done" button 2345. Pressing touchscreen "back" button 2344 returns the user to the Set Correction Factor screen 2335. Pressing touchscreen "done" button 2345 initiates an Insulin On Board (IOB) interface 2346, discussed in greater detail below.

[00485] Set Correction Factor screen 2335 includes a touchscreen "back" button 2347 and a touchscreen "next" button 2348. Pressing touchscreen "back" button 2347 initiates reference path (T3) 2348 or (R3) 2347, respectively, depending on whether the optional "target by time of day" format has been selected or not. Pressing touchscreen "next" button 2348 initiates the Insulin On Board (IOB) interface 2346. Reference path (R3) 2347 returns the user to the Correction Target Range screen 2304 or the Correction Target screen 2296 as appropriate. Reference path (T3) 2348 returns the user to the Target Range Time List screen 2325 or the Target Time List screen 2317 as appropriate.

[00486] Each of Set Correction Factor screen 2335 and Correction Factor Time List screen 2339 includes a touchscreen "?" button 2349, which, when pressed, results in display of informational screen 2350. Informational screen 2350 displays a prompt indicating "The Reader uses this value to determine how many units of rapid-acting insulin is needed to lower high glucose to a target value or range" or the equivalent. Informational screen 2350 also includes a touchscreen "OK" button 2351 for returning the user to Set Correction Factor screen 2335 or Correction Factor Time List screen 2339 as appropriate.

Insulin On Board (IOB) Setup Interface

[00487] The Insulin On Board (IOB) Setup interface 2346 is described with reference to FIG. 33. Initiation of the IOB Setup interface 2346 results in display of Set Insulin Duration screen 2352. Set Insulin Duration screen 2352 includes touchscreen up and down-buttons 2353 for adjusting insulin duration (e.g., 4hrs:30min). Set Insulin Duration screen 2352 also includes touchscreen "back" button 2355 and touchscreen "next" button 2356. Pressing touchscreen "back" button 2355 returns the user to the previously viewed screen, e.g. Set Correction Factor screen 2335 or Correction Factor Time List screen 2339. Pressing touchscreen "next" button 2356 results in display of IOB Ask screen 2357. Set Insulin Duration screen 2352 also includes touchscreen "?" button 2358, which, when pressed, results in display of insulin duration description screen 2359. Insulin duration description screen 2359 displays a prompt indicating "Insulin duration is the amount of time rapid-acting insulin remains active in a patient's body" or equivalent. "The Reader uses the insulin duration value and the time of your patient's last dose when it calculates an insulin dose" or equivalent" or equivalent. Insulin duration description screen 2359 includes a touchscreen "OK"

button which, when pressed, returns the user to Set Insulin Duration screen 2352.

[00488] IOB Ask screen 2357 displays a prompt indicating "Do you want the Active Insulin symbol to be displayed on the Home screen?" or equivalent. IOB Ask screen 2357 includes a Yes and a No option, one of which may be selected by pressing one of the corresponding empty circles 2361 associated with the option. Note that FIG. 33 shows the Yes option selected. IOB Ask screen 2357 includes a touchscreen "back" button 2362 and a touchscreen "next" button 2363. Pressing touchscreen "back" button 2362 returns the user to Set Insulin Duration screen 2352. Pressing touchscreen "next" button 2363 results in display of a Calculation Done screen 2364. IOB Ask screen 2357 also includes a touchscreen "?" button 2365, which, when pressed, results in display of an insulin calculator description screen 2366. Insulin calculator description screen 2366 displays a prompt indicating that "The insulin calculator estimates the amount of rapid-acting insulin still in your patients body" or equivalent and "If you select yes, this estimate will be shown on the Home screen as a symbol" or equivalent. Note the symbol 2367 depicted in FIG. 33. The insulin calculator description screen 2366 includes a touchscreen "OK" button, which, when pressed, returns the user to the IOB Ask screen 2357.

[00489] Calculation Done screen 2364 includes a prompt indicating that setup is complete and may include a prompt indicating "When checking glucose, the insulin calculator will now be available" or equivalent. Calculation Done screen 2364 also includes a touchscreen "back" button 2368 and a touchscreen "done" button 2369. Pressing touchscreen "back" button 2368 returns the user to IOB Ask screen 2357. Pressing touchscreen "done" button 2369 returns the user to the reader Home Screen as described herein.

Save Changes Interface

[00490] A Save Changes interface 2370 operates to remind the user to save changes in the event a strip is inserted 2371 into the reader or the Home button is pressed 2372 before a sequence is completed. In the event a strip is inserted 2371 into the reader, reference path (U3) 2373 is initiated. Reference path (U3) 2373 results in display of a reminder prompt 2374 to the user. A Save Changes screen 2375 is displayed which includes a prompt indicating "Do you want to save your changes?" or equivalent. Save Changes screen 2375 includes a

touchscreen "Yes" button 2376 and a touchscreen "No" button 2377. If the "No" button 2377 is pressed or a selection is not made in 10 seconds the settings return to their previous values. If the "Yes" button 2376 is pressed, the new settings are saved. In either case, either a Blood Glucose Strip Test interface or a Ketone Strip Test interface is initiated as appropriate based on the identity of the inserted test strip.

[00491] Reference path (V3) 2378 results in display of a reminder prompt 2379 to the user. A Save Changes screen 2380 is displayed which includes a prompt indicating "Do you want to save your changes?" or equivalent. Save Changes screen 2380 includes a touchscreen "Yes" button 2381 and a touchscreen "No" button 2382. If the "No" button 2382 is pressed, the settings return to their previous values. If the "Yes" button 2381 is pressed, the new settings are saved. In either case, the user is returned to the Home screen as described herein.

Additional Information Regarding Auto-Assist Software

[00492] Additional information for the Auto Assist Software is provided in the following paragraphs and figures. It should be appreciated that the example interface flows are exemplary and should not be interpreted as limiting.

Example Interface Flows

Application Startup

[00493] **FIG. 36** illustrates a method 4000 when starting up the RD software, according to one embodiment. At block 4002, the Reader is coupled to a remote processing device, such as the user's computer. At block 4004 it is determined whether the software is installed on the remote processing device. If not, then the user is prompted to run an installer file stored on the reader, as shown at block 4006. If the user accepts, a default browser is launched with the Auto-Assist software (RD software) install website, as shown at block 4008. The user may elect to start the installation of the RD software and an installer application is downloaded to the remote device to install the complete installer application, as shown by blocks 1010 and 1012. The standard operation system (OS) installer application is run and the RD software is launched, as shown at block 4012 and 4014.

[00494] Referring back to block 4004, if the RD software is already installed on the remote device, then it is determined if the RD software is currently running. If so, then the user is taken to the Reader Landing screen at block 4026.

[00495] If the RD software is not currently running, then it is determined if an auto-launch is enabled to automatically launch the RD software if the analyte monitoring device is coupled to the remote device, as shown at block 4020. If the auto-launch is enabled, then the RD software is launched on the remote device. If the auto-launch is not enabled, then the user may manually launch the software when desired, as shown at block 4022.

[00496] When the RD software is launched, the software may automatically perform or ask to determine if updates to the software are available, as represented by block 4034. The RD software may, for example, access a server via the internet to determine what updates are currently available, and then compare the version of the software and any previous updates to see if any additional updates are missing. If new updates are not available, then the RD software application continues with the Auto-Assist Startup process to enable the user to use the RD software, as represented at block 4036.

[00497] If new updates are available, then the Reader Landing screen is displayed, as shown at block 4026. If the user elects not to run the update routines at this time, the RD software application continues with the Auto-Assist Startup process to enable the user to use the RD software, as represented at block 4036. If the user elects to install the updates, then the update routines are run, as shown at block 4024, before continuing on with the Auto-Assist Startup process at block 4036

[00498] If instead of starting at block 4002, the user launches RD software already installed on a remote device, as shown at block 4028, then it is determined if the analyte monitoring device is coupled to the remote device, as shown at block 4030. If the reader device is not connected, then a Reader Welcome screen is displayed to assist the user as the RD software is running, as shown at block 4032. If the reader is coupled to the remote device, then it is determined if any updates are available as shown and discussed for block 4034.

[00499] **FIG. 37** illustrates a flowchart for the Auto-Assist Startup process 4036, according to one embodiment. As the RD software starts up, it is determined if there is date (e.g., sensor readings) on the reader device, as shown at block 4042. If there is no data on the reader device, then it is determined if the reader device has already been set up, as shown at block 4044. If not, then the user is taken to a Guided Reader Setup – Welcome screen for guiding the user through

the reader setup process, as shown at block 4046. If the reader device has been setup before, then it is determined if the reader device and remote device are out of sync (e.g., the time on the Reader device and the remote device are different) If the reader device is out of sync, then a Reader Out of Sync screen is provided, as shown at block 4052, to inform the user and to enable synchronization. If the reader device is not out of sync, then the Reader Landing Screen is displayed, as shown at block 4050.

[00500] Referring back to block 4042, if sensor reading data is on the reader device, then the data may be downloaded to the remote device, either automatically or upon user confirmation, as shown by block 4054. At block 4054, it is determined if the reader device and remote device are out of sync. If so, then the Reader Out of Sync screen is displayed. If no out of sync, then it is determined if it is the first time creating reports on the remote device, as shown at block 4058., If so, then a Guided Reports Setup – Welcome screen is displayed, as shown at block 4060, to assist the user with setting up reports. If it is not the first time creating reports on the remote device, then it is determined if a quick print feature is enabled to allow quick display and/or printing of predetermined or pre-customized reports. If the quick printing feature is not enabled, then the user is taken to a Create Reports screen to enable the user to create reports, as shown at block 4068.

[00501] **FIG. 38** illustrates an example Welcome screen, according to one embodiment. The Welcome screen 5000, may be shown after the user launches the software prior to connecting the Reader device, for example, to inform the user that the system does not currently recognize a connected Reader and prompts them to connect one. Screen 5000 includes a Reader tab 5002 and a Reports tab 5004 that corresponds to a Reader Mode and a Reports mode, respectively, of the RD software. The tabs 5002,5004 are maintained on other screens for the RD software. In one embodiment, the Reader mode and Reports mode are not accessible to the user if a Reader is not connected to the remote device.

Reader Mode

[00502] **FIG. 39** illustrates a flowchart for a method 4080 of navigating through the Reader mode for accessing setting and functions that are used to setup and control the Reader device. Reader setting are directly read form or saved back to

the Reader device via functions primarily originating form the Reader mode and collection of screens.

[00503] Block 4082 represents a Reader Landing screen, wherein details regarding the Reader may be accessed. **FIG. 40** illustrates an example screen displayed when the Reader device is connected, according to one embodiment. Screen 5050 includes the update notification 5056, as well as, a quick synopsis of the profile of the Reader that is connected.The screen 5050 also includes a menu 5058 of trigger elements for initiating other Reader Mode screens, such as a Profile screen, Settings screen, Custom Notes screen, Reminders screen, Professional Options screen, and a Backups screen, which are all discussed further later.

[00504] **FIG. 41** illustrates an example screen that is displayed to indicate that the Reader device is out of sync, according to one embodiment. Screen 5050 displays an Out of Sync content notification 5080 that informs the user that the Reader device may be out of sync, and may further provide additional details about the sync (e.g., the time on both the Reader and the remote device) and enable the user to sync the Reader device. For example, trigger element 5081 is provided to enable the user to elect to sync the Reader device.

[00505] As shown in FIG. 39, from the Reader Landing screen at block 4082, the user may select from a menu 5058 of trigger elements for initiating other Reader Mode screens, such as a Profile screen at block 4084, Settings screen at block 4086, Custom Notes screen at block 4088, Reminders screen at block 4090, Professional Options screen at block 4092, and a Backups screen at block 4094, are accessible from the Reader Landing screen.

[00506] At block 4084, the user is taken to a Profile screen. **FIG. 42** illustrates a Profile screen 5086, according to one embodiment. As shown, Profile screen 5086 provides a section 5058 in which the user can set a name and patient ID, for example, to be associated with the Reader device. As shown, the menu 5058 of trigger elements for initiating various screens is maintained in the Profile screen 5086.

[00507] Referring back to FIG. 39, at block 4084, the user is taken to a Settings screen. The Settings screen provides screens for enabling the user to adjust general settings—e.g., as time, date, clock, style, language, sound and vibration

options, sync settings—as well as target zone settings (e.g., glucose target zone settings.

[00508] At block 4084, the user is taken to a Custom Notes screen where the user can view, edit, and/or delete notes from the Reader device. These notes can be default notes or customized notes by the user.

[00509] At block 4086, the user is taken to a Reminders screen where the user can view, edit, and/or delete reminders from the Reader device. The reminders may be provided to remind the user to check glucose readings, take insulin, etc.

[00510] At block 4088, the user is taken to a Professional Options screen where the user can access restricted features that should only be accessed by trained health care professionals (HCP). A password or code only given to the HCP's may be required to access the settings. Example features that may be restricted are the activation and setting of an insulin calculation feature, a masked mode operation of the device, the resetting of the system and/or settings on the device, etc.

Insulin Calculator Setup Interface:

[00511] An exemplary embodiment of a graphical user interface which may be utilized in connection with Health Management Software for a Reader as described herein and which facilitates a procedure for inputting the insulin calculator settings via the Health Management Software is provided. This graphical user interface is now described in greater detail with reference to FIGS. 43-46.

[00512] In some cases, the Health Management Software for the Reader may include programming for two or more types of medication dosage calculators. During setup of the Health Management Software, the Health Management Software may prompt the user and/or the health care professional to select a type of medication dosage calculator (e.g., insulin bolus calculator). The initial selection of the type of medication dosage calculator may be changed as desired by the user or the health care professional. In certain embodiments, the two or more types of medication dosage calculators include two types of bolus calculators. For instance, the two types of bolus calculators can include an easy bolus calculator and an advanced bolus calculator.

[00513] By "easy calculator", "easy bolus calculator", "simple bolus calculator", "easy insulin calculator" or "simple insulin calculator" is meant a bolus calculator

that includes basic features for determining a recommended medication dosage amount, such as a recommended insulin dosage amount. For example, an easy bolus calculator may include algorithms configured to determine a recommended medication dosage amount based on a fixed medication dosage amount. In these instances, the easy bolus calculator may be appropriate for a user that administers a fixed medication dosage amount (e.g., a fixed insulin dosage amount) for each meal. In some embodiments, the easy bolus calculator only takes into account the fixed medication dosage amount when recommending the medication dosage amount to the user, and thus functions as a reminder and/or log for the fixed medication dosage amount.

[00514] The insulin calculator setup procedure begins on the Insulin Calculator Interface Setup screen 3800, where the user can select an Insulin Calculator On/Off toggle button 3802 to turn the insulin calculator on or off. When the Insulin Calculator On/Off toggle button is selected into the "On" position, the insulin calculator is activated and may be set up as described below. The desired type of insulin calculator (e.g., easy or advanced calculator) can be selected by selecting the insulin calculator selection box 3804, which allows the selection of "Easy" to activate the easy insulin calculator, and "Advanced" to activate the advanced insulin calculator.

[00515] If the user selects the "Easy" selection in the insulin calculator selection box 3804, the Insulin Calculator Setup Interface screen 3800 displays the set up options for the easy bolus calculator. Set up for the easy bolus calculator is shown in FIG. 43.

[00516] In certain embodiments, the easy bolus calculator may determine a recommended medication dosage amount (e.g., a recommended rapid-acting insulin dosage amount) based on information, such as, but not limited to, a fixed medication dosage amount, a target blood glucose range (e.g., correction target), and an insulin sensitivity (e.g., correction factor). In some instances, the easy bolus calculator may also include information, such as the patient's insulin on board, in the determination of a recommended medication dosage amount. For example, a fixed medication dosage amount may be entered by meal (e.g., breakfast, lunch and dinner).

[00517] The Insulin Calculator Setup Interface screen 3800 includes amount entry boxes for each meal. A fixed medication dosage amount may be entered into the

breakfast amount entry box 3806, the lunch amount entry box 3808 and the dinner amount entry box 3810 as units of insulin. In some embodiments, the correction target range may be entered. The Insulin Calculator Setup Interface screen 3800 includes correction target range amount entry boxes for the minimum target range value 3812 and the maximum target range value 3814. In some embodiments, the Insulin Calculator Setup Interface screen 3800 includes a correction factor amount entry box 3816 in which the insulin sensitivity (e.g., correction factor) may be entered as 1 unit per X mg/dL, where X is the amount entered for the correction factor. In some embodiments, the Insulin Calculator Setup Interface screen 3800 includes radio buttons for enabling or disabling insulin calculator trend correction by selecting either the trend correction enabled radio button 3818 or the trend correction disabled radio button 3820, respectively.

[00518] If the user selects the "Advanced" selection in the insulin calculator selection box 3824, the Insulin Calculator Setup Interface screen 3822 displays the set up options for the advanced bolus calculator. Set up for the advanced bolus calculator is shown in FIG. 44, which shows advanced bolus calculator settings available when the insulin calculator is set to count carbs by grams of carbs.

[00519] By "advanced calculator", "advanced bolus calculator" or "advanced insulin calculator" is meant a bolus calculator that includes additional information, such as, but not limited to, the amount of carbohydrates consumed, the carbohydrate ratio, a target blood glucose range (e.g., correction target), and an insulin sensitivity (e.g., correction factor), in determining a recommended medication dosage amount (e.g., a recommended insulin dosage amount). For example, rather than using a fixed medication dosage amount for each meal as in the easy calculator, the advanced bolus calculator may use dose determination information entered by the user, such as the amount of carbohydrates consumed, to determine a recommended medication dosage amount. The advanced bolus calculator may also include additional dose determination information into the determination of the recommended medication dosage amount, such as but not limited to, a patient's the current blood glucose level, an amount of exercise, a target analyte concentration (e.g., a target blood glucose range), an insulin sensitivity (e.g., correction factor), a duration of insulin

action, a carbohydrate ratio, and insulin on board information, such as an administered medication dose time information, an administered dose frequency information over a predetermined time period, and an administered medication dose amount.

[00520] The Insulin Calculator Setup Interface screen 3822 includes an "Enter Food By" selection box 3826, which, when selected, allows the user to set the insulin calculator to enter food by grams of carbs or by servings. If "Grams of Carbs" is selected in the "Enter Food By" selection box 3826, then Insulin Calculator Setup Interface screen 3822 displays the set up options for the advanced bolus calculator by grams of carbs.

[00521] In some embodiments, the carbohydrate ratio may be entered. The Insulin Calculator Setup Interface screen 3822 includes a carbohydrate ratio amount entry box 3828 for entering the amount of the user's carbohydrate ratio as 1 unit per X grams of carbs, where X is the amount entered. In some embodiments, the correction target range may be entered. The Insulin Calculator Setup Interface screen 3822 includes correction target range amount entry boxes for the minimum target range value 3832 and the maximum target range value 3834. In some instances, the correction target may be entered as a single target value rather than a target range by selecting "Single Target" (not shown) from the correction target selection box 3830. In some embodiments, the Insulin Calculator Setup Interface screen 3822 includes a correction factor amount entry box 3836 in which the insulin sensitivity (e.g., correction factor) may be entered as 1 unit per X mg/dL, where X is the amount entered for the correction factor. In some embodiments, the Insulin Calculator Setup Interface screen 3822 includes radio buttons for enabling or disabling insulin calculator trend correction by selecting either the trend correction enabled radio button 3838 or the trend correction disabled radio button 3840, respectively.

[00522] In certain instances, the carbohydrate ratio, the target range, and/or the correction factor may be entered by time of day, as shown in FIG. 45. To enable the carbohydrate ratio time of day settings, the carbohydrate ratio "By Time of Day" checkbox 3842 may be selected. To enable the target range time of day settings, the target range "By Time of Day" checkbox 3844 may be selected. To enable the correction factor time of day settings, the correction factor "By Time of Day" checkbox 3846 may be selected.

[00523] If the carbohydrate ratio "By Time of Day" checkbox 3842 is selected, Insulin Calculator Setup Interface screen 3848 displays the time of day settings for the carbohydrate ratio (see FIG. 45A). The carbohydrate ratio may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). The morning carbohydrate ratio may be entered in the morning carbohydrate ratio amount entry box 3850, the midday carbohydrate ratio may be entered in the midday carbohydrate ratio amount entry box 3852, the evening carbohydrate ratio may be entered in the evening carbohydrate ratio amount entry box 3854, and the night carbohydrate ratio may be entered in the night carbohydrate ratio amount entry box 3856.

[00524] If the correction target range "By Time of Day" checkbox 3844 is selected, Insulin Calculator Setup Interface screen 3848 displays the time of day settings for the target range (see FIG. 45B). The target range may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). The morning target range may be entered in the minimum value morning target range amount entry box 3858 and the maximum value morning target range amount entry box 3860, the midday target range may be entered in the minimum value midday target range amount entry box 3862 and the maximum value midday target range amount entry box 3864, the evening target range may be entered in the minimum value evening target range amount entry box 3866 and the maximum value evening target range amount entry box 3868, and the night target range may be entered in the minimum value night target range amount entry box 3870 and the maximum value night target range amount entry box 3872.

[00525] If the correction factor "By Time of Day" checkbox 3846 is selected, Insulin Calculator Setup Interface screen 3848 displays the time of day settings for the correction factor (see FIG. 45B). The correction factor may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). The morning correction factor may be entered in the morning correction factor amount entry box 3874, the midday correction factor may be entered in the midday correction factor amount entry box 3876, the evening

correction factor may be entered in the evening correction factor amount entry box 3878, and the night correction factor may be entered in the night correction factor amount entry box 3880.

[00526] The Insulin Calculator Setup Interface screen 3882 includes an "Enter Food By" selection box 3884, which, when selected, allows the user to set the insulin calculator to enter food by grams of carbs or by servings (see FIG. 46A). If "Servings" is selected in the "Enter Food By" selection box 3884, then Insulin Calculator Setup Interface screen 3882 displays the set up options for the advanced bolus calculator by servings of carbs.

[00527] **FIGS. 43-46** show the Insulin Calculator Setup Interface screen 3882 when the carbohydrate ratio, the target range, and the correction factor are selected to be entered by time of day by selecting the carbohydrate ratio "By Time of Day" checkbox 3886, the target range "By Time of Day" checkbox 3888, and the correction factor "By Time of Day" checkbox 3890.

[00528] Insulin Calculator Setup Interface screen 3882 displays the time of day settings for the carbohydrate ratio (see FIG. 46A). The carbohydrate ratio may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). The morning carbohydrate ratio may be entered in the morning carbohydrate ratio amount entry box 3892, the midday carbohydrate ratio may be entered in the midday carbohydrate ratio amount entry box 3894, the evening carbohydrate ratio may be entered in the evening carbohydrate ratio amount entry box 3896, and the night carbohydrate ratio may be entered in the night carbohydrate ratio amount entry box 3898. The number of grams of carbs per 1 serving may be selected from the servings selection box 3900.

[00529] Insulin Calculator Setup Interface screen 3882 displays the time of day settings for the target range (see FIG. 46B). The target range may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). As shown in FIG. 46B, the target range is selected to be entered as a "Single Target" rather than a target range, as shown in the correction target selection box 3902. The morning target value may be entered the morning target value amount entry box 3904, the midday target value may be entered in the midday target value amount entry box 3906, the evening target value may be

entered in the evening target value amount entry box 3908, and the night target value may be entered in the night target value amount entry box 3910.

[00530] Insulin Calculator Setup Interface screen 3882 displays the time of day settings for the correction factor (see FIG. 46B). The correction factor may be set to the same or different values at 4 different times of day, such as morning (e.g., 4am-10am), midday (e.g., 10am-4pm), evening (e.g., 4pm-10pm), and night (e.g., 10pm-4am). The morning correction factor may be entered in the morning correction factor amount entry box 3912, the midday correction factor may be entered in the midday correction factor amount entry box 3914, the evening correction factor may be entered in the evening correction factor amount entry box 3916, and the night correction factor may be entered in the night correction factor amount entry box 3918.

Masked Mode Setup Interface:

[00531] The Professional Options screen also enables the Masked Mode setup to be viewed and set on the remote device. The setup screen provided functions similar to the Masked Mode setup discussed earlier, except that the setup takes place via the RD software application.

[00532] **FIG. 47** illustrates a Masked Mode setup screen 5090, according to one embodiment. As shown, Masked Mode setup screen 5090 provides a section 5092 in which the user can activate the Masked Mode and set reminders to check glucose at preset intervals. For example, the reminder is reset every time the sensor is scanned. As shown, the menu 5058 of trigger elements for initiating various screens is maintained in the Profile screen 5086.

Reset System:

[00533] The Professional Options screen also enables the user reset settings of the Reader device. The Reset System interface may permit reset of all settings at once, and/or permit the user to selectively reset specific setting on the device.

[00534] Referring back to FIG. 39, at block 4094, the user is taken to a Backups screen where the user can save a backup file of a current Reader setting. In one embodiment, the backup files do not save glucose results or other Reader logbook entries.

[00535] Thus, from the menu 5058 of trigger elements for initiating various Reader Mode screens, which remains on the various Reader Mode screens to enable quick reference and access to those screens, the user is able to navigate to the

desired Reader Mode screen. Once the settings are viewed, edited, or deleted, the user can save the setting to the reader, as shown by reference path X3. At block 4096, a Reader Status screen is displayed to indicate to the user that a save is in progress. In block 4098, a Progress screen is shown to indicate a save to the reader, and after the save the user is taken to a Reader Landing – Settings saved screen to indicate that the save was successful, as shown by block 4100.

[00536] If changes to any settings in menu 5058 are cancelled, as shown by reference path Y3, or the user navigates away, as shown by reference path A4, then the user is taken to a warming Alert screen to alert the user that changes will be lost, as shown at 4102 via reference path Z3. If changes are cancelled, then the user is navigated back to the Reader Landing screen 4082. If the user elects to save the changes, then to blocks 4096 and 4098 as previous described. If the user elects to not save the settings, then the user is taken to the Reader Landing – Setting saved screen 4100.

[00537] From the Backups screen, the user can save a backup file, as shown at block 4104. Progress screen 4106 is displayed while the save is in progress. If the save should be cancelled before complete, then the user is taken back to the Backups screen 4108.

[00538] If the save is determined to be not valid, as shown at block 4105, then the user is taken to an Alert screen 4110 to indicate to the user that a save is not valid. For example, if the filename already exists, then the user can elect to either save it and overwrite the previous file, and will be taken to the Progress screen 4106. If the user elects not to save it, then the user is then back to the Backups screen 4112.

[00539] From the Backups screen at block 4094, the user can select a backup file to restore, as shown by block 4114 and reference path C4. Once the backup file is selected the user is taken to a Progress screen 4116 that indicates that the backup file is being processed. If the processing of the backup file is determined to not be valid or encounters an error, then the Alert screen 4120 is displayed to indicate that there was an error with the backup file (e.g., that the file is damaged). The user is then taken back to the Backups screen, as shown by block 4122. If the processing of the backup file is valid, then the Restore Reader Setting is displayed to indicate that the Reader settings are being restored to the

settings on the backup file. If the restore should be cancelled, then the user is taken back to the Backups screen, as shown by block 4126. If the restore is not cancelled, then the user is taken to either a Reader Status screen 4128, or to a Progress screen 4130 and Backups screen 4132, similarly as described above.

Out of Sync Flow

[00540] **FIG. 48** illustrates a method 5100 for a flow for syncing the Reader device when the Reader is coupled to the remote device and determined to be out of sync with the remote device. For example, when out of sync, the time on the Reader is different than the time on the remote device.

[00541] If the Reader is coupled to the remote device and determined to be out of sync with the remote device, then the Reader Out of Sync screen at 5102 is initiated, as shown by block 5102. An Alert screen is displayed to alert the user of the sync and ask if the user wishes to synch the Reader with the remote device. The user is also taken to the Alert screen at 5106 from the General Reader Settings screen when it is determined that the two devices are out of sync, as shown by block 5104.

[00542] If the user elects to sync the two devices, then a Reader Status screen at 5108 and Progress screen at 5110 are displayed while the update is in progress. When the update is complete, the user is taken back to the Reader Landing – Reader updated screen, as shown at block 5112.

Guided Reader Setup Flow

[00543] When a new Reader that has never been used is connected to the remote device, the user is guided through the initial setup of that Reader in a step-by-step fashion. Along the way, basic Reader configuration settings such as name, patient ID, date, time, and language are collected for the purpose of initializing the Reader. In one embodiment, the patient name and ID are optional settings while the date, time, and language options must be set to complete the setup process.

[00544] **FIG. 49** illustrates a method 5100 for a flow for the Guided Reader Setup interface, according to one embodiment. When a new Reader that has never been used is connected to the remote device, the New Reader Welcome screen is displayed to start the guided setup process, as shown at block 5116. The Start/Patient info screen is initiated to receive patient info, as shown at block 5118. The Confirm Date/Time/Language screen is initiated to receive the

appropriate entries from the user, as shown at block 5118. Once entered, the Ready to Save screen is initiated to indicate to the user that the entries are to be saved. As the save is in progress, the Reader Status screen at 5130 or the Progress screen at 5128 is displayed. From the Progress screen at block 5128, the Reader Landing – Reader ready screen at block 5132 is displayed when the save is complete.

[00545] If the setup process is interrupted or exited from any of blocks 5118,5120,5122, then the Alert screen at block 5124 is displayed to alert the user that any changes will be lost if not saved. After the Alert screen is displayed at block 5124, the user is taken to the New Reader Welcome screen so that the initial setup can be completed, as shown by blocks 5116,5126.

[00546] **FIG. 50** illustrates a single screen of the Guided Reader setup interface, according to one embodiment. The initial screen of the Guided Reader setup interface includes information regarding the guided setup and provides a trigger element 5136 that enables the user to begin the guided setup.

Reader Mode

Reports Mode Flow

[00547] **FIG. 51** illustrates a flowchart for a method 4080 of navigating through the Reports mode of the RD software, according to one embodiment. The reports mode of the application provides access to settings and functions for creating, viewing, saving, and printing reports. In the examples shown, the Reports mode is provided as a tab on the interface screens for the RD software, along with the tab for the Reader mode.

[00548] At block 5140, the Reports Landing screen is displayed on the remote device when the Reports tab is selected. The user is provided with the option to create reports or to view or edit Report Preferences—e.g., the user may select, for example, between corresponding trigger elements on the Landing Screen to navigate to the Create Reports interface or the Report Preferences interface.

[00549] From the Create Reports screen at block 5142, the user can select the parameter of the particular Report to be created. The Choose screen at block 5146 enables the user to set the destination of the directory for auto-saving. When a report is created, the Progress screen at block 5144 is displayed while the report is being created. When complete, the View reports screen at block 5148 displays the created report, or provides a menu to select from various

reports created. The Reports can be saved via a Save window screen at block 5152 and the progress screen at block 5154 will be displayed when the save is in progress. After the save is complete, the user is taken back to the View Reports screen at block 5148.

[00550] If the View Reports screen at block 5148 is closed, then the user is taken back to the Create Reports screen at block 5142. The user may also print one or more Reports from the View Reports screen 5148 via Print screen at block 5150.

[00551] From the Reports Landing screen at block 5140, the user may elect to navigate to the Report Set screen at block 5156. The Set Reports screen at block 5156 enable the user to pre-select reports to be created each time the user creates reports with the Auto-Assist software. Example reports may include, a Snapshot, Calendar, Average Day, Logbook, Daily Statistics, Mealtime Averages, and Reader Settings, as will be discussed further later. The various reports are selectable and will be set as the default preferences for the creation of reports from the Reader. The Calendar may default to a predetermined time period, such as 3 months for example. If the user selects the Mealtime Averages report they are presented with an overly that allows them to set the default pre and post meal target ranges.

[00552] From the Reports Landing screen at block 5140, the user may also elect to navigate to: Timeframe screen at block 5158 to enable the user to establish default timeframes used when reports are created; Glucose Targets screen at block 5160 to enable the user to establish the default setting for the glucose target range and hypoglycemia threshold to be applied to created reports; Auto-Save Options screen at block 5162 to enable the user to activate and set the auto save feature, as well as, choose the file name format, and save location (as shown at block 5174) that will used during report creation; Print Color screen at block 5164 that enables the user to choose default print color options; and Quick Print screen at block 5166 which allows the user to enable or disable the quick print feature, which causes the software to immediately generate reports once a Reader with data is connect to the computer.

[00553] Settings or changes made to the screens 5156, 5158, 5160, 5162, 5164, and 5166 can be saved, at which point the Progress screen at block 5172 is displayed during the save. If the user cancels or navigates away from any of

screens 5156, 5158, 5160, 5162, 5164, and 5166, it is determined if any changes were made, as shown at block 5168. If not, the user is able to navigate away to the desired screen. If changes were made, then an Alert screen is displayed to alert the user that changes may be lost and to provide the user with the option to save, as represented by the Progress screen at block 5172.

[00554] **FIG. 52** illustrates an example Reports landing screen that is displayed when the user first connects a Reader with stored data, according to one embodiment. As shown, Reports landing screen 5220 includes trigger elements 5222 and 5224 to initiate the Create Reports interface and Report Preferences interface, respectively.

[00555] **FIG. 53** illustrates an example Create Reports screen, according to one embodiment. Creates Reports screen 5230 is shown providing information regarding the current settings for creation of reports, as well as providing the user with navigation options (e.g., trigger elements) to make changes to the current settings—e.g., patient information 5232, timeframe 5234, reports 5236 selected to print or view, glucose targets 5238, and auto-save options 5240. Screen 5230 also provides trigger elements 5240,5242 to print the reports or view them, respectively.

[00556] FIG. 54 illustrates an example Logbook Report screen when viewed from the Reports Mode, according to one embodiment. As show, Logbook Report screen includes a table 5252 of the data in the Logbook Report as well as trigger elements 5254,5256 for printing and saving the report, respectively.

Guided Reports Setup Interface

[00557] The first time a user accesses the printing features of the application, they are guided through the reports setup and creation process in a step-by-step fashion by a Guided Reports Setup interface. Along the way, the RD software collects default reports preferences such as patient information, timeframe, report set, glucose targets, and auto-save options, as well as prepares the first set of reports fro viewing, saving, and printing.

[00558] **FIG. 55** illustrates a flowchart for a Guided Reports Setup interface, according to one embodiment. The first time a user accesses the printing features of the application, user is taken to the First-Use Reports Welcome screen to begin the guided setup. The Start/Patient info screen is initiated to receive patient info, as shown at block 5182. Then the user is navigated through

the following screens: Timeframe screen at block 5186 to enable the user to establish default timeframes used when reports are created; Set Reports screen at block 5188 enable the user to pre-select reports to be created each time the user creates reports with the Auto-Assist software; Glucose Targets screen at block 5190 to enable the user to establish the default setting for the glucose target range and hypoglycemia threshold to be applied to created reports; Auto-Save Options screen at block 5192 to enable the user to activate and set the auto save feature, as well as, choose the file name format, and save location that will used during report creation; and Ready to Create Reports screen at block 5194 which allows the user to create the selected reports and either view them or print them.

[00559] When printing the selected reports, the Progress screen at block 5196 is displayed while the report is being created. When complete, the View reports screen at block 5198 displays the created report, or provides a menu to select from various reports created. The Reports are then immediately printed via a Print window screen at block 5200. If auto save is set, once the reports are created at block 5196, the selected reports are automatically saved to the selected destination, as shown at block 5204. If the creation at block 5196 is interrupted or cancelled, then the user is taken back to the Create Reports screen at block 5202.

[00560] When electing to view the selected reports form block 5194, the Progress screen at block 5206 is displayed while the report is being created. When complete, the View reports screen at block 5210 displays the created report, or provides a menu to select from various reports created. If auto save is set, once the reports are created at block 5206, the selected reports are automatically saved to the selected destination, as shown at block 5204. If the creation at block 5206 is interrupted or cancelled, then the user is taken back to the Create Reports screen at block 5208.

Export Reader Flow

[00561] The RD software provides a function for users to export data from a Reader coupled to the computer as a tab-delimited file or other spreadsheet-compatible format, for example. The Export function may be accessed, for example, via the “File” menu of the application..

[00562] **FIG. 56** illustrates a method for exporting Reader data, according to one embodiment. At block 5252 of Export Meter Data interface 5250, it is determined if the Reader device is coupled to the remote device. If not coupled, then the Export data feature is disabled (e.g., in the File menu) as shown at block 4254. If the Reader device is coupled to the remote device, then it is determined if the Reader device has sensor data stored, as shown at block 5256. If the Reader has no data stored, then the Export data feature is disabled at block 4254. If the Reader does have data, then it is determined if the Reader is downloading data. If so, then the Export data feature is disabled at block 4254. If the Reader is not downloading data, then the Export data feature is enabled (e.g., in the File menu).

[00563] Once enabled, the user can select to export data from the Reader, as represented by block 5262. Once selected, the meter export file is saved as shown at block 5264. If the save is determined to be valid, then the Progress screen 5272 is shown to indicate that the process of exporting data is in progress. If no error occurs, the user is taken back to the originating screen as shown at block 5276. If an error occurs, an Alert screen is provided to notify the user of the failed export, as shown at block 5274.

[00564] If at block 5266, it is determined that the saving of the meter export file was not valid, then an Alert screen is provided to notify that the save was not valid (e.g., the file already exists), as shown at block 5268. The user is provided with the option to overwrite the existing file, which navigates the user to the Progress screen at block 5272. The user is also provided the option to not save the invalid file, in which case the user is taken back to the originating screen, as shown at block 5270.

REPORTS

[00565] In some embodiments, the RD software provides a user interface to manage and/or control features related to reports. For example, the RD software provides a reports mode for creating, editing, viewing, printing, and for performing any other functions associated with report generation and management.

[00566] Different types of reports may be generated. For example, FIGS. 45-53 illustrate various types of reports, according to certain embodiments. It should be appreciated that the reports illustrated are exemplary and should not be

interpreted as limiting. Further details regarding various reports that may be implemented with the software is described in US Patent Application No. 11.146,897, filed on June 6, 2005, and US Provisional Application Nos. 61/451,488, filed March 10, 2011; and 60/577,064, filed Jun. 4, 2004, the entireties of which are incorporated herein by reference.

[00567] As stated above, reports may be generated and communicated to a remote device—e.g., for display on the remote device and/or printing on the remote device. The remote device may be, for example, a desktop computer, laptop, cell phone, etc. For example, the remote device may be a personal computer accessed by the user, enabling the user to view and/or printout the reports. In other instances, the remote device may be a computer accessed by another party, such as a physician or health care professional. The user may, for example, bring the device to their physician so that the physician could transfer the data to his or her computer for display and/or printing of the reports.

[00568] The analyte monitoring device may communicate the reports to the remote device using any variety of wired (e.g., USB, FireWire, SPI, SDIO, RS-232 port, etc.) or wireless technologies (e.g., radio frequency (RF) communication, Zigbee communication protocols, WiFi, infrared, wireless Universal Serial Bus (USB), Ultra Wide Band (UWB), Bluetooth® communication protocols, and cellular communication, such as code division multiple access (CDMA) or Global System for Mobile communications (GSM), etc).

[00569] In some instances, the analyte monitoring device may include software that is loaded onto the remote device—e.g., the first time connecting to the remote device. In other instances, the software may be loaded to the remote device via the internet or storage device (e.g., CD-ROM, FLASH memory drive, etc.).

[00570] In some instances, the reports may be communicated to a remote device and thereafter communicated to another remote device. For example, the user may download the data to his own computer and thereafter transmit the data to the physician for further analysis. Upon receipt, the physician could view and download reports to assess the activities and events of the user.

EXAMPLE REPORTS

[00571] In the following paragraphs, example reports are provided and described. The various reports may include general identification information for the

associated patient (e.g., name of the patient, identification number, etc.) and/or associated device (e.g., name of the device; model of the device, etc.).

Snapshot:

[00572] In some aspects of the present disclosure, a Snapshot report is provided. The Snapshot report captures the overall condition of the patient's health management (e.g., diabetes management). For instance, the report may highlight the key metrics for the user's activities over a specific time period. In some embodiments, the Snapshot report provides significant pieces of information related to one or more of the following: utilization, glucose levels, events, and notes.

[00573] **FIG. 57** illustrates an exemplary Snapshot report for a specific time frame (e.g., a two week period as shown), according to certain embodiments. The Snapshot report 5300 includes key metrics associated with the user's history over the two week period of time. For example, Snapshot report includes: section 5302 displaying metrics 5308 regarding the user's glucose, insulin, and carbohydrate intake are provided for the given two-week time period; section 5304 displaying metrics 5312 regarding low glucose events for the two-week time period; section 5306 displaying metrics 5316 regarding glucose readings for the two-week time period; and section 5307 displaying the estimated A1c percentage for the two week period.

[00574] In the embodiment shown, metrics 5308 includes average glucose value; time above, in, and below the target zone, average carb intake per day; average rapid-acting insulin intake per day; and average long-acting insulin intake per day. Section 5302 also includes a graph 5310 of glucose values for the two week period that have been averaged with respect to specific times throughout the day. Graph 5310 also indicates the range of glucose readings for the specific time throughout the day.

[00575] Metrics 5312 includes the total number of low glucose events, the average duration of a low glucose event, and the low glucose threshold. Section 5304 also includes a graph 5314 of a summary of low glucose events for the two week period that have been averaged with respect to specific times throughout the day.

[00576] Metrics 5316 includes the average number of scans per day and the percentage of available sensor data. Section 5306 also includes a graph 5318 of

the percentage high glucose readings of sensor data recorded for the two week period, categorized with respect to specific times throughout the day.

[00577] Snapshot Screen 5300 also includes a Comments section 5320 that indicates any comments that the user has logged. In some embodiments, the comments section provides software generated comments generated from analysis of the sensor data. Snapshot Screen 5300 also includes a section for identifying the Report, the time period applicable to the reports, and the target range.

Calendar:

[00578] In some aspects of the present disclosure, a Calendar report is provided. The Calendar report provides an overview of the patient's involvement and highlights points of concern (e.g., hypoglycemic events).

[00579] For example, **FIG. 58** illustrates a Calendar report that highlights the key metrics for the user's activities in calendar format, according to certain embodiments. The events of each day of the selected month are detailed in calendar-format. The Calendar report is provided for a one-month period, e.g., March, with the following events indicated: average glucose readings for the given day 5352; number of scans per the given day 5354; and the occurrence of low glucose events for the given day. For example, on March 7, the average glucose reading was 171 mg/dL; there were 7 scans; and 2 low glucose events.

Daily Patterns:

[00580] In some aspects of the present disclosure, a Daily Patterns report is provided. A Daily Patterns report communicates the trend in glucose levels for the given time period, with respect to times throughout the day.

[00581] **FIG. 59** illustrates a Daily Patterns report, according to one embodiment. Daily Patterns Report 5360 includes a graph 5362 displaying the median glucose values 5364 with respect to time periods throughout a day; the range of glucose values associated with the 25th to 75th percentile of readings 5366;and the range of glucose values associated with the 10th to 90th percentile of readings 68.

[00582] Below graph 5362, and aligned with respect to the time periods, is a graph of carbs taken and logged 5370, as represented above the horizontal axis, and of rapid-acting insulin taken and logged 5372, as represented below the horizontal axis.

[00583] Daily Patterns Report 5360 also includes sections 5374, 5376, and 5378 next to graph 5362 and aligned with respect to time periods throughout the day. Section 5374 indicates the daily average glucose value for each time period throughout the day. Section 5376 indicates the daily average carb intake per time period, as well as the number of related notes taken. Section 5378 indicates the daily averages for intake of rapid-acting insulin and long-acting insulin for each time period throughout the day, as well as the number of related notes.

Mealtime Patterns:

[00584] In some aspects of the present disclosure, a Mealtime Patterns report is provided. A Mealtime Patterns report communicates the rise and fall in glucose levels relative to meals.

[00585] **FIG. 60** illustrates a Meal Patterns report, according to one embodiment. The report includes data for a given time period 5414 (e.g., two weeks) and includes plots of the glucose values before and after specific meals of the day.

[00586] The report includes plots 5402, 5404, and 5406 for three different meal events—e.g., meals occurring at different time periods 5416a, 5416b, 5416c of the day (e.g., Morning, Midday, and Evening, respectively). The number of notes logged for food intake and insulin intake are also provided at sections 5418a, 5418b, and 5418c. Furthermore, the average carbs taken and logged 5420a, 5420b, and 5420c for the respective time period is also shown. The average insulin taken and logged 5422a, 5422b, and 5422c for the respective time period is also shown.

[00587] The meal time reference points 5412a, 5412b, and 5412c indicate the time at which the meal was taken. One hour incremental time periods before and after the reference points are provided. Median glucose plots 5408a, 5408b, and 5408c are displayed for the respective periods. The 10^{th} to 90^{th} Percentile range 5410a, 5410b, and 5410c are also provided on plots 5402, 5404, and 5406, respectively. The average glucose values 5426a, 5426b, and 5426c for the respective incremental time periods are also provided below and aligned with the respective plots.

Daily Statistics:

[00588] In some aspects of the present disclosure, a Daily Statistics report is provided. The Daily Statistics report highlights glucose readings for days within the given time period (e.g., 2 weeks). The data may be used to assist in the

identification of causes of hypoglycemic events and other abnormalities, for example.

[00589] **FIG. 61** illustrates the first page of a Daily Statistics report 5500 for a given time period (e.g., two week period). The first page includes the daily statistics for the first seven days of the given two-week time period. Plots 5502, 5504, 5506, 5508, 5510, 5512, and 5514 of glucose values for each of the seven days are displayed.

[00590] The day is broken up into incremental time periods (e.g., two hour periods as shown) and event information may be indicated on the chart. For example, a carb intake event 5502b is indicated at the corresponding incremental time period in which it occurred.

[00591] Rapid and long acting insulin intake events 5502c and 5502e, respectively, are indicated at the corresponding incremental time period in which it occurred.

[00592] Events associated with food intake and insulin logged without a value 5502f and 5502i, respectively, are indicated at the corresponding incremental time period in which it occurred.

[00593] User Time change event 5502g is indicated at the corresponding incremental time period in which it occurred. For example, if the user changes the time on the Reader device, this event would be indicated at the appropriate time and day.

[00594] Sensor scan event 5502h is indicated at the corresponding incremental time period in which it occurred. In this way, any discontinuities in glucose readings are also displayed, as represented as breaks in the glucose plot.

[00595] Furthermore, Daily Totals section 5516 displays daily totals of additional glucose related data. For example, section 5516 provides daily totals for the first day—March 17th. Section 5516 includes the average glucose for the day, the total number of carbs for the day, the amount of rap-acting insulin taken for the day, and the amount of long-acting insulin taken from the day.

Logbook:

[00596] In some aspects of the present disclosure, a Logbook report is provided. A Logbook report provides a detailed look at obtained sensor readings and, in some cases, other relevant data—e.g., insulin dosages, meal events, notes, strip

glucose measurements, and ketone events—categorized by time period (e.g., by day).

[00597] **FIG. 62** illustrates an exemplary Logbook report, according to one embodiment. The exemplary Logbook report 5520 illustrates the first page of the Logbook report 5520 and shows glucose related data in tables 5522, 5524, and 5526 for first 3 days of the two week time period. Glucose readings, carb intake, insulin data (e.g., intake for rapid and long acting insulin) are provided for time periods (e.g., hourly time periods as shown) throughout the day. Various events are also represented in the table (e.g., via shading, symbols, icons, etc.), such as a low glucose readings 5428, high glucose readings 5530, food intake 5532 and insulin intake 5534 that was logged without a value. Notes are also indicated in the table—e.g., notes indicating exercise or other relevant events.

[00598] Graphs 5540, 5542, and 5544 of the glucose values throughout the associated day are also provided for each day shown. The daily average is also indicated for each day.

[00599] **FIG. 63** illustrates another exemplary Logbook report, according to one embodiment. The exemplary Logbook report 5550 is similar to the Logbook report 5520 in FIG. 62, and similar features will not be repeated for FIG. 63 for the sake of clarity and brevity. Logbook report 5550 includes strip glucose measurements 5552 and ketone measurements 5554 in the associated tables at the associated time and day.

Reader Settings:

[00600] In some aspects of the present disclosure, a Reader Settings Report is provided. A Reader Settings Report provides a summary of settings that are currently set for the Reader device.

[00601] **FIG. 64** illustrates an example Reader Settings Report, according to one embodiment. Reader Settings Report 5600 includes a Profile section 5602, which displays profile settings, such as the patients name and ID. Reader Settings Report 5600 includes a Settings section 5604, which displays general settings on the Reader, such as date, time, clock style, notification sound, button tone, vibration, and target glucose range. Reader Settings Report 5600 also includes a Notes section 5606, which displays Notes settings, such as which categories of notes are available. Example categories of notes may relate to rapid acting insulin, long acting insulin, food, exercise, medication, control

solution, stress, etc. Reader Settings Report 5600 also includes a Reminders section 5608, which displays Reminder settings, such as alarms to check glucose and to take insulin dosages. Reader Settings Report 5600 also includes a Changes section 5610, which displays any changes to the Reader settings within a given time period (e.g., the last 30 days as shown).

[00602] If insulin calculation or masked mode operation are available on the Reader device, the Reader Setting Report may also include summary sections for these settings as well. For example, **FIG. 65** illustrates a Reader Settings Report 5620 including an Insulin Calculator section 5622, which displays Insulin Calculator settings—e.g., whether rapid or long acting insulin calculator is on, a calculator mode (e.g., advanced or easy as discussed earlier), carbohydrate ration, correction target, and correction factors. Reader Settings Report 5620 also includes a Masked Mode section 5624, which displays Masked Mode settings, such as whether the Masked Mode is activated, whether the check glucose reminder is activated, and the frequency or time settings for the reminder, etc.

EXAMPLE EMBODIMENTS

[00603] In some aspects of the present disclosure, methods of operating an analyte monitoring device are provided that include receiving an indication for powering on an analyte monitoring device; powering on the analyte monitoring device; providing power to an RF reader element within the analyte monitoring device; activating a scan state for scanning an analyte sensor; receiving an indication of a predetermined event; and powering off the RF reader and maintaining power to the analyte monitoring device.

[00604] In one embodiment, the scan state comprises displaying a prompt to scan the analyte sensor on a display of the analyte monitoring device. I

[00605] In one embodiment, the predetermined event is a lapse of a predetermined period of time without performing a scan. In some instances, the predetermined event is a deactivation of the scan state. In some instances, the predetermined event is a user-initiated change from a scan prompt screen to a home screen. In some instances, the predetermined event is an occurrence of a scan error or failed scan.

[00606] In one embodiment, the methods comprise: receiving an indication to perform a sensor scan; repowering the RF reader; and reactivating the scan state for scanning the analyte sensor.

[00607] In one embodiment, the methods comprise: detecting the analyte sensor; and scanning the analyte sensor to perform an analyte reading.

[00608] In one embodiment, the analyte is glucose or a ketone body.

[00609] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00610] In some aspects of the present disclosure, methods of operating an analyte monitoring device are provided that include performing a first scan of an analyte sensor; displaying a reading resulting from the first scan; preventing performance of a second scan for a predetermined period of time; and enabling performance of a second scan after lapse of the predetermined period of time.

[00611] In one embodiment, the methods include powering the analyte monitoring device off after the reading is displayed; and powering on the analyte monitoring device before the lapse of the predetermined period of time.

[00612] In one embodiment, the methods include receiving an indication of an attempt of a second scan before the lapse of the predetermined period of time; and indicating that the second scan cannot be performed. In some instances, the methods include indicating an estimated time remaining before performance of a second scan is enabled.

[00613] In one embodiment, the methods include exiting a screen displaying the reading; and indicating that any results displayed before the lapse of the predetermined period of time is for the first scan.

[00614] In one embodiment, the methods include performing the second scan of the analyte sensor after the lapse of the predetermined period of time.

[00615] In one embodiment, the predetermined period of time is between 1 and 5 minutes.

[00616] In one embodiment, the analyte is glucose or a ketone body.

[00617] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory

operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00618] In some aspects of the present disclosure, methods of operating an analyte monitoring device are provided that include performing a first scan of an analyte sensor; displaying a screen for calculating a suggested insulin dose based on a result of the first scan; exiting the screen for calculating a suggested dose before logging the suggested dose calculation; enabling logging of the suggested dose calculation for a predetermined period of time; and preventing logging of the suggested dose calculation for the first scan after a lapse of the predetermined period of time.

[00619] In one embodiment, the methods include powering the device off and then back on after displaying the screen for calculating the suggest dose and before the lapse of the predetermined period of time; wherein the exiting of the screen results from powering the analyte monitoring device off. In some instances, the screen for calculating the suggested dose is displayed when the device is powered back on, and wherein the screen for calculating the suggested dose enables the user to log the suggested dose calculation.

[00620] In one embodiment, the methods include receiving an indication to log the suggested dose calculation; and associating the suggested dose calculation with the first scan and with a time the first scan was performed; wherein a countdown for an estimated amount of insulin remaining in-body starts at a time of the logging of the suggested dose calculation.

[00621] In one embodiment, the methods include powering the device off after displaying the screen for calculating the suggest dose and before lapse of the predetermined period of time, wherein the exiting of the screen results from powering the analyte monitoring device off; and powering the device back on after the lapse of the predetermined period of time.

[00622] In one embodiment, the methods include displaying a prompt to scan the analyte sensor for a second scan when the device is powered back on.

[00623] In one embodiment, the analyte is glucose or a ketone body.

[00624] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions

stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00625] In some aspects of the present disclosure, methods are provided that include performing consecutive scans of an analyte sensor; displaying, on a display of the analyte monitoring device, a resulting reading for each of the consecutive scans; displaying a graph on the display of the analyte monitoring device, the graph displaying resulting readings for a first predetermined period of time and tracking subsequent resulting readings during a second predetermined period of time following the first predetermined period of time; and after the subsequent resulting readings are tracked for the entire second predetermined period of time, shifting the subsequent resulting readings into the first predetermined period of time and continuing to track subsequent resulting readings during the second period of time; and repeatedly shifting the subsequent resulting readings after tracking occurs for the entire second period of time.

[00626] In one embodiment, the graph is displayed on the display after resulting readings are obtained for the first predetermined period of time.

[00627] In one embodiment, before resulting readings are obtained for the first predetermined period of time, the graph is displayed without any resulting readings; and the resulting readings for the first predetermined period of time are displayed on the graph after the resulting readings are obtained for the first predetermined period of time. In some instances, the first predetermined period of time is a multiple of the second predetermined period of time. In some instances, the first predetermined period of time is 8 hours and the second predetermined period of time is 1 hour.

[00628] In one embodiment, the analyte is glucose or a ketone body.

[00629] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein, the instructions comprising instructions for performing the previously described methods.

[00630] In some aspects of the present disclosure, methods of displaying analyte sensor readings on an analyte monitoring device are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display

on the analyte monitoring device, a graph of sensor readings obtained over a prior 24-hour period.

[00631] In one embodiment, the methods include displaying a trigger element for shifting the graph forward or backward by 24 hours; receiving an indication that the trigger element was initiated by a user; and shifting the graph forward or backward by 24 hours.

[00632] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00633] In some aspects of the present disclosure, methods of displaying analyte sensor readings on an analyte monitoring device are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display on the analyte monitoring device, a summary of average sensor readings for a prior predetermined period of time, wherein the average sensor readings include an average sensor reading for a plurality of divisions within a day.

[00634] In one embodiment, the prior predetermined period of time is a 7 day period, and the average sensor readings include an average sensor reading for four divisions within a day.

[00635] In one embodiment, the methods include displaying a total average of each average sensor reading for the plurality of divisions within a day.

[00636] In one embodiment, the methods include displaying a trigger element for shifting the graph forward or backward by the predetermined period of time; receiving an indication that the trigger element was triggered by a user; and shifting the graph forward or backward by the predetermined period of time.

[00637] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00638] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions including instructions for instructions for obtaining sensor readings from an analyte sensor; and instructions for displaying on a display on the analyte monitoring device, a summary of average sensor readings for a prior predetermined period of time, wherein the average sensor readings include an average sensor reading for a plurality of divisions within a day.

[00639] In one embodiment, the prior predetermined period of time is a 7 day period, and the average sensor readings include an average sensor reading for four divisions within a day.

[00640] In one embodiment, the instructions include instructions for displaying a total average of each average sensor reading for the plurality of divisions within a day.

[00641] In one embodiment, the instructions include instructions for displaying a trigger element for shifting the graph forward or backward by the predetermined period of time; instructions for receiving an indication that the trigger element was triggered by a user; and instructions for shifting the graph forward or backward by the predetermined period of time.

[00642] In some aspects of the present disclosure, methods of displaying analyte sensor readings on an analyte monitoring device are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display on the analyte monitoring device, a summary of average events associated with the sensor readings obtained for a prior predetermined period of time, wherein the average events include an average event for a plurality of divisions within a day; wherein the summary is displayed upon user-selection.

[00643] In one embodiment, the prior predetermined period of time is a 7 day period, and the average event include an average event for four divisions within a day.

[00644] In one embodiment, the methods include displaying a total average of each average event for the plurality of divisions within a day.

[00645] In one embodiment, the methods include displaying a trigger element for shifting the summary forward or backward by the predetermined period of time;

receiving an indication that the trigger element was triggered by a user; and shifting the summary forward or backward by the predetermined period of time.

[00646] In one embodiment, the event is a low glucose reading.

[00647] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00648] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions including instructions for obtaining sensor readings from an analyte sensor; and instructions for displaying on a display on the analyte monitoring device, a summary of average events associated with the sensor readings obtained for a prior predetermined period of time, wherein the average events include an average event for a plurality of divisions within a day; wherein the summary is displayed upon user-selection.

[00649] In one embodiment, the prior predetermined period of time is a 7 day period, and the average event include an average event for four divisions within a day.

[00650] In one embodiment, the analyte monitoring devices include instructions for displaying a total average of each average event for the plurality of divisions within a day.

[00651] In one embodiment, the analyte monitoring devices include instructions for displaying a trigger element for shifting the summary forward or backward by the predetermined period of time; instructions for receiving an indication that the trigger element was triggered by a user; and instructions for shifting the summary forward or backward by the predetermined period of time.

[00652] In one embodiment, the event is a low glucose reading.

[00653] In some aspects of the present disclosure, methods of displaying analyte sensor readings on an analyte monitoring device are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display

on the analyte monitoring device, a summary of sensor readings obtained for a prior predetermined period of time, wherein the summary of sensor readings include one or more numbers or percentages of sensor readings with respect to a target range; wherein the summary is displayed upon user-selection.

[00654] In one embodiment, a number or percentage of sensor readings above, below, and within a target range are included in the summary.

[00655] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00656] In some aspects of the present disclosure, methods are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display on the analyte monitoring device, a summary of data associated with use of the sensor for a prior predetermined period of time, wherein the use of the sensor includes an average number of scans per day; wherein the summary is displayed upon user-selection.

[00657] In one embodiment, the use of the sensor includes a number of days having sensor data within the prior predetermined period of time.

[00658] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising instructions for obtaining sensor readings from an analyte sensor; and instructions for displaying on a display on the analyte monitoring device, a summary of data associated with use of the sensor for a prior predetermined period of time, wherein the use of the sensor includes an average number of scans per day; wherein the summary is displayed upon user-selection.

[00659] In one embodiment, the use of the sensor includes a number of days having sensor data within the prior predetermined period of time.

[00660] In some aspects of the present disclosure, methods are provided that include obtaining sensor readings from an analyte sensor; and displaying on a display on the analyte monitoring device, a graph of daily patterns for a prior

predetermined period of time, wherein the graph of daily patterns includes an average sensor reading for a plurality of divisions within a day; wherein the graph is displayed upon user-selection.

[00661] In one embodiment, the prior predetermined period of time is a 7 day period, and the graph of daily patterns includes an average sensor reading for four divisions within a day.

[00662] In one embodiment, the chart of daily patterns indicates a range of average sensor readings for the plurality of divisions within a day.

[00663] In one embodiment, the methods include displaying a trigger element for shifting the graph forward or backward by the predetermined period of time; instructions for receiving an indication that the trigger element was triggered by a user; and shifting the graph forward or backward by the predetermined period of time.

[00664] In one embodiment, the analyte is glucose or a ketone body.

[00665] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions including instructions for obtaining sensor readings from an analyte sensor; and instructions for displaying on a display on the analyte monitoring device, a graph of daily patterns for a prior predetermined period of time, wherein the graph of daily patterns includes an average sensor reading for a plurality of divisions within a day; wherein the graph is displayed upon user-selection.

[00666] In one embodiment, the prior predetermined period of time is a 7 day period, and the graph of daily patterns includes an average sensor reading for four divisions within a day.

[00667] In one embodiment, the chart of daily patterns indicates a range of average sensor readings for the plurality of divisions within a day.

[00668] In one embodiment, the instructions include instructions for displaying a trigger element for shifting the graph forward or backward by the predetermined period of time; instructions for receiving an indication that the trigger element was triggered by a user; and instructions for shifting the graph forward or backward by the predetermined period of time.

[00669] In one embodiment, the analyte is glucose or a ketone body.

[00670] In some aspect of the present disclosure, methods of operating an analyte monitoring device are provided that include receiving an indication to operate in a masked mode; performing scans of an analyte sensor; and storing sensor readings obtained from the scans without displaying the sensor readings on a display of the analyte monitoring device.

[00671] In one embodiment, the methods include receiving an indication to operate in a non-masked mode; performing scans of an analyte sensor; and displaying sensor readings on a display of the analyte monitoring device.

[00672] In one embodiment, the methods include transmitting the stored sensor readings to a remote device.

[00673] In one embodiment, the methods include the analyte is glucose or a ketone body.

[00674] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00675] In some aspect of the present disclosure, methods of operating an analyte sensor are provided that include communicating between an analyte sensor and a first analyte monitoring device; establishing a pairing with the first analyte monitoring device to enable the first analyte monitoring device to perform analyte readings with the analyte sensor; receiving an identification code for the first analyte monitoring device from the first analyte monitoring device; and storing the device identification code in memory to indicate the established pairing with the first analyte monitoring device.

[00676] In one embodiment, the methods include receiving a request for the device identification form a second analyte monitoring device; and transmitting the device identification code for the first analyte monitoring device to the second analyte monitoring device.

[00677] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions

stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00678] In some aspects of the present disclosure, methods for operating an analyte monitoring device are provided that include communicating between a first analyte monitoring device and a first sensor; determining, with a processor of the first analyte monitoring device, that the first sensor is not paired with any analyte monitoring device; determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor; and pairing the first analyte monitoring device with the first sensor to enable the first analyte monitoring device to perform analyte readings with the first sensor; and transmitting an identification code for the first analyte monitoring device to the first sensor to indicate the pairing.

[00679] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00680] In some aspects of the present disclosure, methods of operating an analyte monitoring device are provided that include communicating between a first analyte monitoring device and a first sensor; determining, with a processor of the first analyte monitoring device, that the first sensor is paired with a second analyte monitoring device; and preventing, with the processor, the first analyte monitoring device from performing analyte readings with the first sensor; wherein the determining that the first sensor is paired comprises receiving, with the processor, an indication that the first sensor contains an identification (ID) code for the second analyte monitoring device that is paired to the first sensor.

[00681] In one embodiment, the methods include visually indicating on a display on the first analyte monitoring device that the first sensor cannot be used.

[00682] In one embodiment, the methods include communicating between the first analyte monitoring device and a second sensor; determining, with the processor, that the second sensor is not paired with any analyte monitoring device; determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor; pairing the first analyte monitoring device with the second sensor to enable the first analyte monitoring device to perform

analyte readings with the second sensor; and transmitting an identification code for the first analyte monitoring device to the second sensor for storage on the second sensor, the identification code indicating a pairing of the first analyte monitoring device with the second sensor.

[00683] In one embodiment, the methods include communicating between the first analyte monitoring device and a third sensor; determining, with the processor, that the third sensor is not paired with any analyte monitoring device; and preventing, with the processor, the first analyte monitoring from performing analyte readings with the second sensor.

[00684] In some aspects of the present disclosure, analyte monitoring devices are provided. The analyte monitoring devices include a processor; and memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising instructions for performing the previously described methods.

[00685] It should be understood that techniques introduced herein can be implemented by programmable circuitry programmed or configured by software and/or firmware, or they can be implemented entirely by special-purpose "hardwired" circuitry, or in a combination of such forms. Such special-purpose circuitry (if any) can be in the form of, for example, one or more application-specific integrated circuits (ASICS), programmable logic devices (PLDs), field-programmable gate arrays (FPGAs), etc.

[00686] Software or firmware implementing the techniques introduced herein may be stored on a machine-readable storage medium and may be executed by one or more general-purpose or special-purpose programmable microprocessors. A "machine-readable medium" ", as the term is used herein, includes any mechanism that can store information in a form accessible by a machine (a machine may be, for example, a computer, network device, cellular phone, personal digital assistant (PDA), manufacturing took, any device with one or more processors, etc.). For example, a machine-accessible medium includes recordable/non-recordable media (e.g., read-only memory (ROM); random access memory (RAM); magnetic disk storage media; optical storage media; flash memory devices; etc.), etc. The term "logic", as used herein, can include, for example, special purpose hardwired circuitry, software and/or firmware in conjunction with programmable circuitry, or a combination thereof.

[00687] The preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope. Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and aspects of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary aspects shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

THAT WHICH IS CLAIMED IS:

1. A method of operating an analyte monitoring device, comprising:
receiving an indication for powering on an analyte monitoring device;
powering on the analyte monitoring device;
providing power to an RF reader element within the analyte monitoring device;
activating a scan state for scanning an analyte sensor;
receiving an indication of a predetermined event; and
powering off the RF reader and maintaining power to the analyte monitoring device.

2. The method of claim 1, wherein the scan state comprises displaying a prompt to scan the analyte sensor on a display of the analyte monitoring device.

3. The method of claim 1, wherein the predetermined event is a lapse of a predetermined period of time without performing a scan.

4. The method of claim 3, wherein the predetermined event is a deactivation of the scan state.

5. The method of claim 3, wherein the predetermined event is a user-initiated change from a scan prompt screen to a home screen.

6. The method of claim 3, wherein the predetermined event is an occurrence of a scan error or failed scan.

7. The method of claim 1, comprising:
receiving an indication to perform a sensor scan;
repowering the RF reader; and
reactivating the scan state for scanning the analyte sensor.

8. The method of claim 1, comprising:

detecting the analyte sensor; and

scanning the analyte sensor to perform an analyte reading.

9. The method of claim 1, wherein the analyte is glucose or a ketone body.

10. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for powering on the analyte monitoring device;

instructions for providing power to an RF reader element within the analyte monitoring device;

instructions for activating a scan state for scanning an analyte sensor;

instructions for receiving an indication of a predetermined event; and

instructions for powering off the RF reader and maintaining power to the analyte monitoring device.

11. The analyte monitoring device of claim 10, wherein the scan state comprises displaying a prompt to scan the analyte sensor on a display of the analyte monitoring device.

12. The analyte monitoring device of claim 10, wherein the predetermined event is a lapse of a predetermined period of time without performing a scan.

13. The analyte monitoring device of claim 12, wherein the predetermined event is a deactivation of the scan state.

14. The analyte monitoring device of claim 12, wherein the predetermined event is a user-initiated change from a scan prompt screen to a home screen.

15. The analyte monitoring device of claim 12, wherein the predetermined event is an occurrence of a scan error or failed scan.

16. The analyte monitoring device of claim 10, wherein the instructions comprise:

instructions for receiving an indication to perform a sensor scan;

instructions for repowering the RF reader; and

instructions for reactivating the scan state for scanning the analyte sensor.

17. The analyte monitoring device of claim 10, wherein the instructions comprise:

instructions for detecting the analyte sensor; and

instructions for scanning the analyte sensor to perform an analyte reading.

18. The analyte monitoring device of claim 10, wherein the analyte is glucose or a ketone body.

19. A method of operating an analyte monitoring device, comprising:

performing a first scan of an analyte sensor;

displaying a reading resulting from the first scan;

preventing performance of a second scan for a predetermined period of time; and

enabling performance of a second scan after lapse of the predetermined period of time.

20. The method of claim 19, comprising:

powering the analyte monitoring device off after the reading is displayed; and

powering on the analyte monitoring device before the lapse of the predetermined period of time.

21. The method of claim 19, comprising:

receiving an indication of an attempt of a second scan before the lapse of the predetermined period of time; and

indicating that the second scan cannot be performed.

22. The method of claim 21, comprising:

indicating an estimated time remaining before performance of a second scan is enabled.

23. The method of claim 19, comprising:

exiting a screen displaying the reading; and

indicating that any results displayed before the lapse of the predetermined period of time is for the first scan.

24. The method of claim 19, comprising;

performing the second scan of the analyte sensor after the lapse of the predetermined period of time.

25. The method of claim 19, wherein the predetermined period of time is between 1 and 5 minutes.

26. The method of claim 19, wherein the analyte is glucose or a ketone body.

27. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for performing a first scan of an analyte sensor;

instructions for displaying a reading resulting from the first scan;

instructions for preventing performance of a second scan for a predetermined period of time; and

instructions for enabling performance of a second scan after lapse of the predetermined period of time.

28. The analyte monitoring device of claim 27, wherein the instructions comprise:

instructions for powering the analyte monitoring device off after the reading is displayed; and

instructions for powering on the analyte monitoring device before the lapse of the predetermined period of time.

29. The analyte monitoring device of claim 27, wherein the instructions comprise:

instructions for receiving an indication of an attempt of a second scan before the lapse of the predetermined period of time; and

instructions for indicating that the second scan cannot be performed.

30. The analyte monitoring device of claim 29, wherein the instructions comprise:

instructions for indicating an estimated time remaining before performance of a second scan is enabled.

31. The analyte monitoring device of claim 27, wherein the instructions comprise:

instructions for exiting a screen displaying the reading; and

instructions for indicating that any results displayed before the lapse of the predetermined period of time is for the first scan.

32. The analyte monitoring device of claim 27, wherein the instructions comprise;

instructions for performing the second scan of the analyte sensor after the lapse of the predetermined period of time.

33. The analyte monitoring device of claim 27, wherein the predetermined period of time is between 1 and 5 minutes.

34. The analyte monitoring device of claim 27, wherein the analyte is glucose or a ketone body.

35. A method of operating an analyte monitoring device, comprising:

performing a first scan of an analyte sensor;

displaying a screen for calculating a suggested insulin dose based on a result of the first scan;

exiting the screen for calculating a suggested dose before logging the suggested dose calculation;

enabling logging of the suggested dose calculation for a predetermined period of time; and

preventing logging of the suggested dose calculation for the first scan after a lapse of the predetermined period of time.

36. The method of claim 35, comprising powering the device off and then back on after displaying the screen for calculating the suggest dose and before the lapse of the predetermined period of time;

wherein the exiting of the screen results from powering the analyte monitoring device off.

37. The method of claim 36, wherein the screen for calculating the suggested dose is displayed when the device is powered back on, and wherein the screen for calculating the suggested dose enables the user to log the suggested dose calculation.

38. The method of claim 35, comprising;

receiving an indication to log the suggested dose calculation; and

associating the suggested dose calculation with the first scan and with a time the first scan was performed;

wherein a countdown for an estimated amount of insulin remaining in-body starts at a time of the logging of the suggested dose calculation.

39. The method of claim 35, comprising:

powering the device off after displaying the screen for calculating the suggest dose and before lapse of the predetermined period of time, wherein the exiting of the screen results from powering the analyte monitoring device off; and

powering the device back on after the lapse of the predetermined period of time.

40. The method of claim 35, comprising displaying a prompt to scan the analyte sensor for a second scan when the device is powered back on.

41. The analyte monitoring device of claim 35, wherein the analyte is glucose or a ketone body.

42. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for performing a first scan of an analyte sensor;

instructions for displaying a screen for calculating a suggested insulin dose based on a result of the first scan;

instructions for exiting the screen for calculating a suggested dose before logging the suggested dose calculation;

instructions for enabling logging of the suggested dose calculation for a predetermined period of time; and

instructions for preventing logging of the suggested dose calculation for the first scan after a lapse of the predetermined period of time.

43. The analyte monitoring device of claim 42, wherein the instruction comprise instructions for powering the device off and then back on after displaying the screen for calculating the suggest dose and before the lapse of the predetermined period of time;

wherein the exiting of the screen results from powering the analyte monitoring device off.

44. The analyte monitoring device of claim 43, wherein the screen for calculating the suggested dose is displayed when the device is powered back on, and wherein the screen for calculating the suggested dose enables the user to log the suggested dose calculation.

45. The analyte monitoring device of claim 42, wherein the instruction comprise;

instructions for receiving an indication to log the suggested dose calculation; and

instructions for associating the suggested dose calculation with the first scan and with a time the first scan was performed;

instructions for wherein a countdown for an estimated amount of insulin remaining in-body starts at a time of the logging of the suggested dose calculation.

46. The analyte monitoring device of claim 42, wherein the instruction comprise:

instructions for powering the device off after displaying the screen for calculating the suggest dose and before lapse of the predetermined period of time, wherein the exiting of the screen results from powering the analyte monitoring device off; and

instructions for powering the device back on after the lapse of the predetermined period of time.

47. The analyte monitoring device of claim 42, wherein the instruction comprise instructions for displaying a prompt to scan the analyte sensor for a second scan when the device is powered back on.

48. The analyte monitoring device of claim 42, wherein the analyte is glucose or a ketone body.

49. A method of displaying analyte sensor readings on an analyte monitoring device, comprising:

performing consecutive scans of an analyte sensor;

displaying, on a display of the analyte monitoring device, a resulting reading for each of the consecutive scans;

displaying a graph on the display of the analyte monitoring device, the graph displaying resulting readings for a first predetermined period of time and tracking subsequent resulting readings during a second predetermined period of time following the first predetermined period of time; and

after the subsequent resulting readings are tracked for the entire second predetermined period of time, shifting the subsequent resulting readings into the first predetermined period of time and continuing to track subsequent resulting readings during the second period of time; and

repeatedly shifting the subsequent resulting readings after tracking occurs for the entire second period of time.

50. The method of claim 49, wherein the graph is displayed on the display after resulting readings are obtained for the first predetermined period of time.

51. The method of claim 49, wherein before resulting readings are obtained for the first predetermined period of time, the graph is displayed without any resulting readings; and

wherein the resulting readings for the first predetermined period of time are displayed on the graph after the resulting readings are obtained for the first predetermined period of time.

52. The method of claim 51, wherein the first predetermined period of time is a multiple of the second predetermined period of time.

53. The method of claim 51, wherein the first predetermined period of time is 8 hours and the second predetermined period of time is 1 hour.

54. The analyte monitoring device of claim 49, wherein the analyte is glucose or a ketone body.

55. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for performing consecutive scans of an analyte sensor;

instructions for displaying, on a display of the analyte monitoring device, a resulting reading for each of the consecutive scans;

instructions for displaying a graph on the display of the analyte monitoring device, the graph displaying resulting readings for a first predetermined period of time and tracking subsequent resulting readings during a second predetermined period of time following the first predetermined period of time; and

after the subsequent resulting readings are tracked for the entire second predetermined period of time, instructions for shifting the subsequent resulting readings into the first predetermined period of time and continuing to track subsequent resulting readings during the second period of time;

instructions for repeatedly shifting the subsequent resulting readings after tracking occurs for the entire second period of time.

56. The analyte monitoring device of claim 55, wherein the graph is displayed on the display after resulting readings are obtained for the first predetermined period of time.

57. The analyte monitoring device of claim 55, wherein before resulting readings are obtained for the first predetermined period of time, the graph is displayed without any resulting readings; and

wherein the resulting readings for the first predetermined period of time are displayed on the graph after the resulting readings are obtained for the first predetermined period of time.

58. The analyte monitoring device of claim 57, wherein the first predetermined period of time is a multiple of the second predetermined period of time.

59. The analyte monitoring device of claim 57, wherein the first predetermined period of time is 8 hours and the second predetermined period of time is 1 hour.

60. The analyte monitoring device of claim 55, wherein the analyte is glucose or a ketone body.

61. A method of displaying analyte sensor readings on an analyte monitoring device, comprising:

obtaining sensor readings from an analyte sensor; and

displaying on a display on the analyte monitoring device, a graph of sensor readings obtained over a prior 24-hour period.

62. The method of claim 61, comprising:

displaying a trigger element for shifting the graph forward or backward by 24 hours;

receiving an indication that the trigger element was initiated by a user; and

shifting the graph forward or backward by 24 hours.

63. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a graph of sensor readings obtained over a prior 24-hour period.

64. The analyte monitoring device of claim 63, wherein the instructions comprise:

instructions for displaying a trigger element for shifting the graph forward or backward by 24 hours;

instructions for receiving an indication that the trigger element was initiated by a user; and

instructions for shifting the graph forward or backward by 24 hours.

65. A method of displaying analyte sensor readings on an analyte monitoring device, comprising:

obtaining sensor readings from an analyte sensor; and

displaying on a display on the analyte monitoring device, a summary of average sensor readings for a prior predetermined period of time, wherein the average sensor readings include an average sensor reading for a plurality of divisions within a day.

66. The method of claim 65, wherein the prior predetermined period of time is a 7 day period, and the average sensor readings include an average sensor reading for four divisions within a day.

67. The method of claim 65, comprising displaying a total average of each average sensor reading for the plurality of divisions within a day.

68. The method of claim 65, comprising:

displaying a trigger element for shifting the graph forward or backward by the predetermined period of time;

receiving an indication that the trigger element was triggered by a user; and

shifting the graph forward or backward by the predetermined period of time.

69. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a summary of average sensor readings for a prior predetermined period of time, wherein the average sensor readings include an average sensor reading for a plurality of divisions within a day.

70. The analyte monitoring device of claim 69, wherein the prior predetermined period of time is a 7 day period, and the average sensor readings include an average sensor reading for four divisions within a day.

71. The analyte monitoring device of claim 69, wherein the instructions comprise instructions for displaying a total average of each average sensor reading for the plurality of divisions within a day.

72. The analyte monitoring device of claim 69, wherein the instructions comprise:

instructions for displaying a trigger element for shifting the graph forward or backward by the predetermined period of time;

instructions for receiving an indication that the trigger element was triggered by a user; and

instructions for shifting the graph forward or backward by the predetermined period of time.

73. The method of displaying analyte sensor readings on an analyte monitoring device, comprising:

obtaining sensor readings from an analyte sensor; and

displaying on a display on the analyte monitoring device, a summary of average events associated with the sensor readings obtained for a prior predetermined period of

time, wherein the average events include an average event for a plurality of divisions within a day;

wherein the summary is displayed upon user-selection.

74. The method of claim 73, wherein the prior predetermined period of time is a 7 day period, and the average event include an average event for four divisions within a day.

75. The method of claim 73, comprising displaying a total average of each average event for the plurality of divisions within a day.

76. The method of claim 73, comprising:

displaying a trigger element for shifting the summary forward or backward by the predetermined period of time;

receiving an indication that the trigger element was triggered by a user; and

shifting the summary forward or backward by the predetermined period of time.

77. The method of claim 73, wherein the event is a low glucose reading.

78. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a summary of average events associated with the sensor readings obtained for a prior predetermined period of time, wherein the average events include an average event for a plurality of divisions within a day;

wherein the summary is displayed upon user-selection.

79. The analyte monitoring device of claim 78, wherein the prior predetermined period of time is a 7 day period, and the average event include an average event for four divisions within a day.

80. The analyte monitoring device of claim 78, wherein the instructions comprise instructions for displaying a total average of each average event for the plurality of divisions within a day.

81. The analyte monitoring device of claim 78, wherein the instructions comprise:

instructions for displaying a trigger element for shifting the summary forward or backward by the predetermined period of time;

instructions for receiving an indication that the trigger element was triggered by a user; and

instructions for shifting the summary forward or backward by the predetermined period of time.

82. The analyte monitoring device of claim 78, wherein the event is a low glucose reading.

83. The method of displaying analyte sensor readings on an analyte monitoring device, comprising:

obtaining sensor readings from an analyte sensor; and

displaying on a display on the analyte monitoring device, a summary of sensor readings obtained for a prior predetermined period of time, wherein the summary of sensor readings include one or more numbers or percentages of sensor readings with respect to a target range;

wherein the summary is displayed upon user-selection.

84. The method of claim 83, wherein a number or percentage of sensor readings above, below, and within a target range are included in the summary.

85. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a summary of sensor readings obtained for a prior predetermined period of time, wherein the summary of sensor readings include one or more numbers or percentages of sensor readings with respect to a target range;

wherein the summary is displayed upon user-selection.

86. The analyte monitoring device of claim 85, wherein a number or percentage of sensor readings above, below, and within a target range are included in the summary.

87. The analyte monitoring device of displaying analyte sensor readings on an analyte monitoring device, wherein the instructions comprise:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a summary of data associated with use of the sensor for a prior predetermined period of time, wherein the use of the sensor includes an average number of scans per day;

wherein the summary is displayed upon user-selection.

88. The analyte monitoring device of claim 87, wherein the use of the sensor includes a number of days having sensor data within the prior predetermined period of time.

89. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a summary of data associated with use of the sensor for a prior predetermined period of time, wherein the use of the sensor includes an average number of scans per day;

wherein the summary is displayed upon user-selection.

90. The analyte monitoring device of claim 89, wherein the use of the sensor includes a number of days having sensor data within the prior predetermined period of time.

91. The method of displaying analyte sensor readings on an analyte monitoring device, comprising:

obtaining sensor readings from an analyte sensor; and

displaying on a display on the analyte monitoring device, a graph of daily patterns for a prior predetermined period of time, wherein the graph of daily patterns includes an average sensor reading for a plurality of divisions within a day;

wherein the graph is displayed upon user-selection.

92. The method of claim 91, wherein the prior predetermined period of time is a 7 day period, and the graph of daily patterns includes an average sensor reading for four divisions within a day.

93. The method of claim 91, wherein the chart of daily patterns indicates a range of average sensor readings for the plurality of divisions within a day.

94. The method of claim 91, wherein the instructions comprise:

displaying a trigger element for shifting the graph forward or backward by the predetermined period of time;

receiving an indication that the trigger element was triggered by a user; and

shifting the graph forward or backward by the predetermined period of time.

95. The method of claim 91, wherein the analyte is glucose or a ketone body.

96. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for displaying analyte sensor readings on an analyte monitoring device, the instructions comprising:

instructions for obtaining sensor readings from an analyte sensor; and

instructions for displaying on a display on the analyte monitoring device, a graph of daily patterns for a prior predetermined period of time, wherein the graph of daily patterns includes an average sensor reading for a plurality of divisions within a day;

wherein the graph is displayed upon user-selection.

97. The analyte monitoring device of claim 96, wherein the prior predetermined period of time is a 7 day period, and the graph of daily patterns includes an average sensor reading for four divisions within a day.

98. The analyte monitoring device of claim 96, wherein the chart of daily patterns indicates a range of average sensor readings for the plurality of divisions within a day.

99. The analyte monitoring device of claim 96, wherein the instructions comprise:

instructions for displaying a trigger element for shifting the graph forward or backward by the predetermined period of time;

instructions for receiving an indication that the trigger element was triggered by a user; and

instructions for shifting the graph forward or backward by the predetermined period of time.

100. The analyte monitoring device of claim 96, wherein the analyte is glucose or a ketone body.

101. A method of operating an analyte monitoring device, comprising:

receiving an indication to operate in a masked mode;

performing scans of an analyte sensor; and

storing sensor readings obtained from the scans without displaying the sensor readings on a display of the analyte monitoring device.

102. The method of claim 101, comprising:

receiving an indication to operate in a non-masked mode;

performing scans of an analyte sensor; and

displaying sensor readings on a display of the analyte monitoring device.

103. The method of claim 101, comprising transmitting the stored sensor readings to a remote device.

104. The method of claim 101, wherein the analyte is glucose or a ketone body.

105. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for receiving an indication to operate in a masked mode;

instructions for performing scans of an analyte sensor; and

instructions for storing sensor readings obtained from the scans without displaying the sensor readings on a display of the analyte monitoring device.

106. The analyte monitoring device of claim 105, wherein the instructions comprise:

instructions for receiving an indication to operate in a non-masked mode;

instructions for performing scans of an analyte sensor; and

instructions for displaying sensor readings on a display of the analyte monitoring device.

107. The analyte monitoring device of claim 105, wherein the instructions comprise instructions for transmitting the stored sensor readings to a remote device.

108. The analyte monitoring device of claim 105, wherein the analyte is glucose or a ketone body.

109. A method of operating an analyte sensor, comprising;

communicating between an analyte sensor and a first analyte monitoring device;

establishing a pairing with the first analyte monitoring device to enable the first analyte monitoring device to perform analyte readings with the analyte sensor;

receiving an identification code for the first analyte monitoring device from the first analyte monitoring device; and

storing the device identification code in memory to indicate the established pairing with the first analyte monitoring device.

110. The method of claim 109, comprising:

receiving a request for the device identification form a second analyte monitoring device; and

transmitting the device identification code for the first analyte monitoring device to the second analyte monitoring device.

111. An analyte sensor, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte sensor, the instructions comprising:

instructions for communicating between an analyte sensor and a first analyte monitoring device;

instructions for establishing a pairing with the first analyte monitoring device to enable the first analyte monitoring device to perform analyte readings with the analyte sensor;

instructions for receiving an identification code for the first analyte monitoring device from the first analyte monitoring device; and

instructions for storing the device identification code in memory to indicate the established pairing with the first analyte monitoring device.

112. The analyte sensor of claim 111, wherein the instruction comprise:

instructions for receiving a request for the device identification form a second analyte monitoring device; and

instructions for transmitting the device identification code for the first analyte monitoring device to the second analyte monitoring device.

113. A method for operating an analyte monitoring device, comprising;

communicating between a first analyte monitoring device and a first sensor;

determining, with a processor of the first analyte monitoring device, that the first sensor is not paired with any analyte monitoring device;

determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor; and

pairing the first analyte monitoring device with the first sensor to enable the first analyte monitoring device to perform analyte readings with the first sensor; and

transmitting an identification code for the first analyte monitoring device to the first sensor to indicate the pairing.

114. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for communicating between a first analyte monitoring device and a first sensor;

instructions for determining, with a processor of the first analyte monitoring device, that the first sensor is not paired with any analyte monitoring device;

instructions for determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor; and

instructions for pairing the first analyte monitoring device with the first sensor to enable the first analyte monitoring device to perform analyte readings with the first sensor; and

instructions for transmitting an identification code for the first analyte monitoring device to the first sensor to indicate the pairing.

115. A method for operating an analyte monitoring device, comprising;

communicating between a first analyte monitoring device and a first sensor;

determining, with a processor of the first analyte monitoring device, that the first sensor is paired with a second analyte monitoring device; and

preventing, with the processor, the first analyte monitoring device from performing analyte readings with the first sensor;

wherein the determining that the first sensor is paired comprises receiving, with the processor, an indication that the first sensor contains an identification (ID) code for the second analyte monitoring device that is paired to the first sensor.

116. The method of claim 115, comprising visually indicating on a display on the first analyte monitoring device that the first sensor cannot be used.

117. The method of claim 115, comprising:

communicating between the first analyte monitoring device and a second sensor;

determining, with the processor, that the second sensor is not paired with any analyte monitoring device;

determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor;

pairing the first analyte monitoring device with the second sensor to enable the first analyte monitoring device to perform analyte readings with the second sensor; and

transmitting an identification code for the first analyte monitoring device to the second sensor for storage on the second sensor, the identification code indicating a pairing of the first analyte monitoring device with the second sensor.

118. The method of claim 117, comprising:

communicating between the first analyte monitoring device and a third sensor;

determining, with the processor, that the third sensor is not paired with any analyte monitoring device; and

preventing, with the processor, the first analyte monitoring from performing analyte readings with the second sensor.

119. An analyte monitoring device, comprising:

a processor; and

memory operably coupled to the processor, wherein the memory includes instructions stored therein for operating an analyte monitoring device, the instructions comprising:

instructions for communicating between a first analyte monitoring device and a first sensor;

instructions for determining, with a processor of the first analyte monitoring device, that the first sensor is paired with a second analyte monitoring device; and

instructions for preventing, with the processor, the first analyte monitoring device from performing analyte readings with the first sensor;

wherein the determining that the first sensor is paired comprises receiving, with the processor, an indication that the first sensor contains an identification (ID) code for the second analyte monitoring device that is paired to the first sensor.

120. The analyte monitoring device of claim 119, wherein the instructions comprise instructions for visually indicating on a display on the first analyte monitoring device that the first sensor cannot be used.

121. The analyte monitoring device of claim 119, wherein the instructions comprise instructions:

instructions for communicating between the first analyte monitoring device and a second sensor;

instructions for determining, with the processor, that the second sensor is not paired with any analyte monitoring device;

instructions for determining, with the processor, that the first analyte monitoring device is not paired with any analyte sensor;

instructions for pairing the first analyte monitoring device with the second sensor to enable the first analyte monitoring device to perform analyte readings with the second sensor; and

instructions for transmitting an identification code for the first analyte monitoring device to the second sensor for storage on the second sensor, the identification code indicating a pairing of the first analyte monitoring device with the second sensor.

122. The analyte monitoring device of claim 121, wherein the instructions comprise instructions:

instructions for communicating between the first analyte monitoring device and a third sensor;

instructions for determining, with the processor, that the third sensor is not paired with any analyte monitoring device; and

instructions for preventing, with the processor, the first analyte monitoring from performing analyte readings with the second sensor.

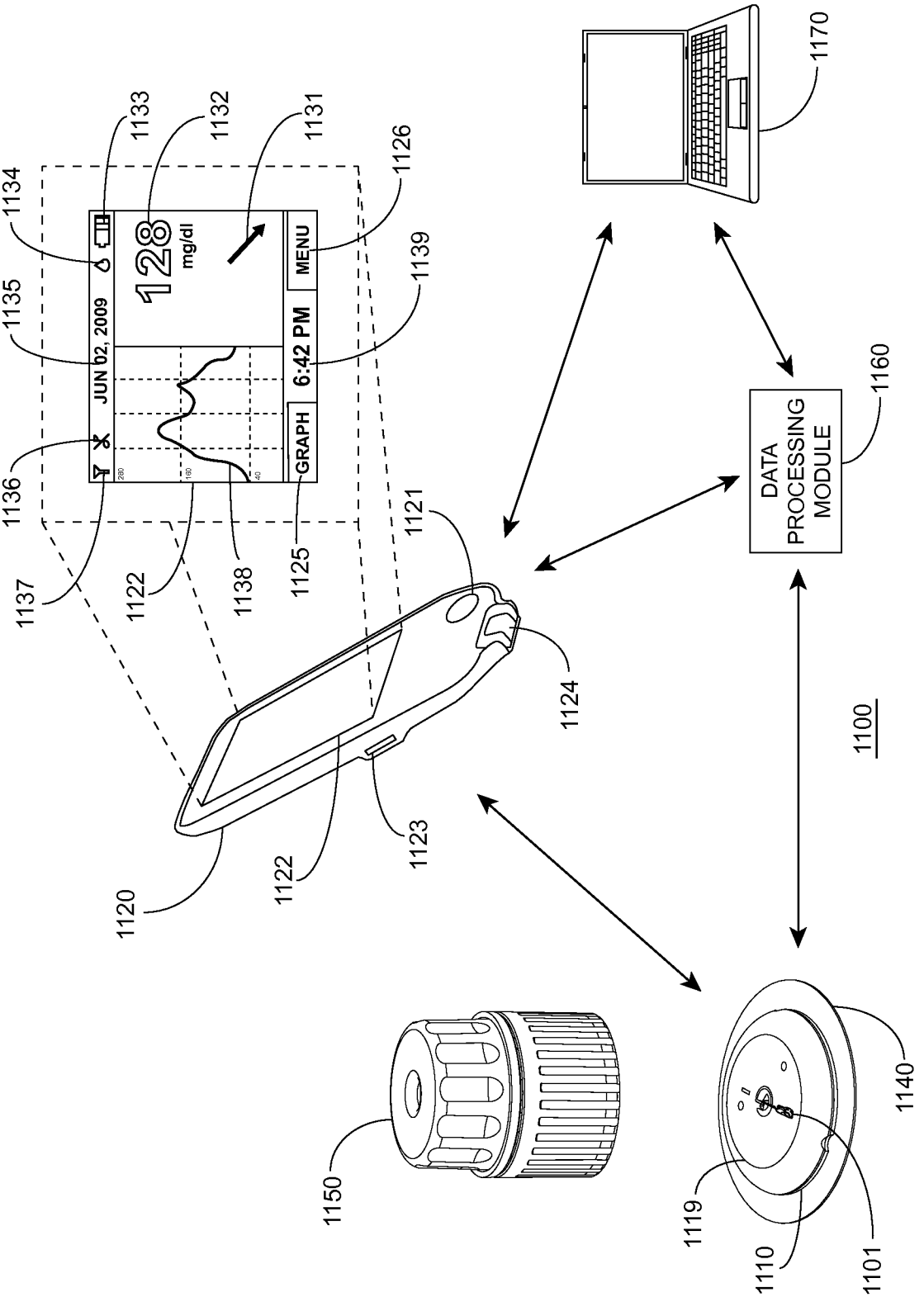

1170
1133
1132
1131
1126
1134
128
mg/dl
MENU
1135
JUN 02, 2009
6:42 PM
1139
1136
GRAPH
1137
1122
1138
1125
1121
DATA PROCESSING MODULE
1160
1124
1100
1120
1122
1123
1150
1119
1110
1101
1140

FIG. 1

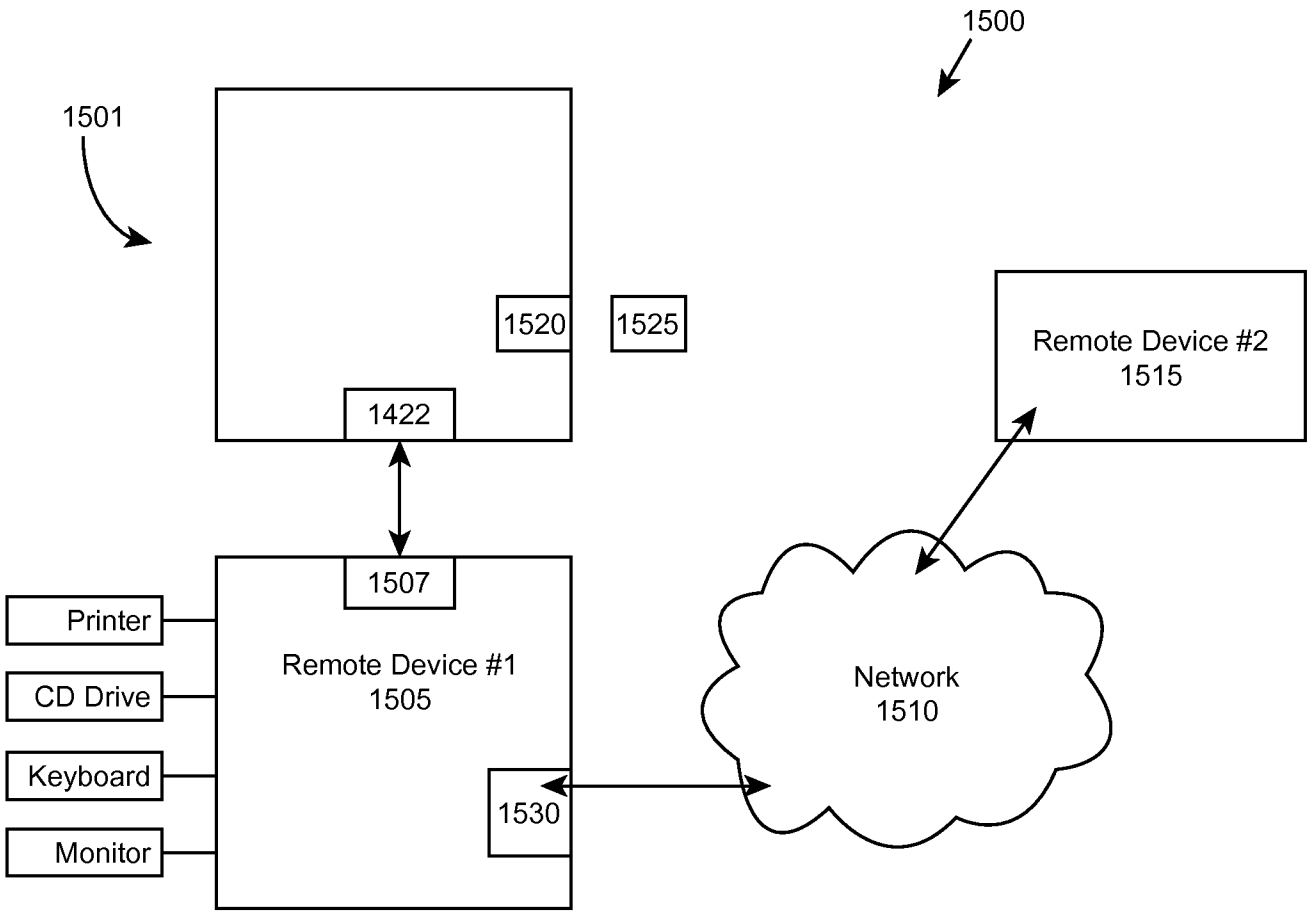

1500
1501
1520
1525
1422
Remote Device #2
1515
1507
Printer
CD Drive
Keyboard
Monitor
Remote Device #1
1505
Network
1510
1530

FIG. 2

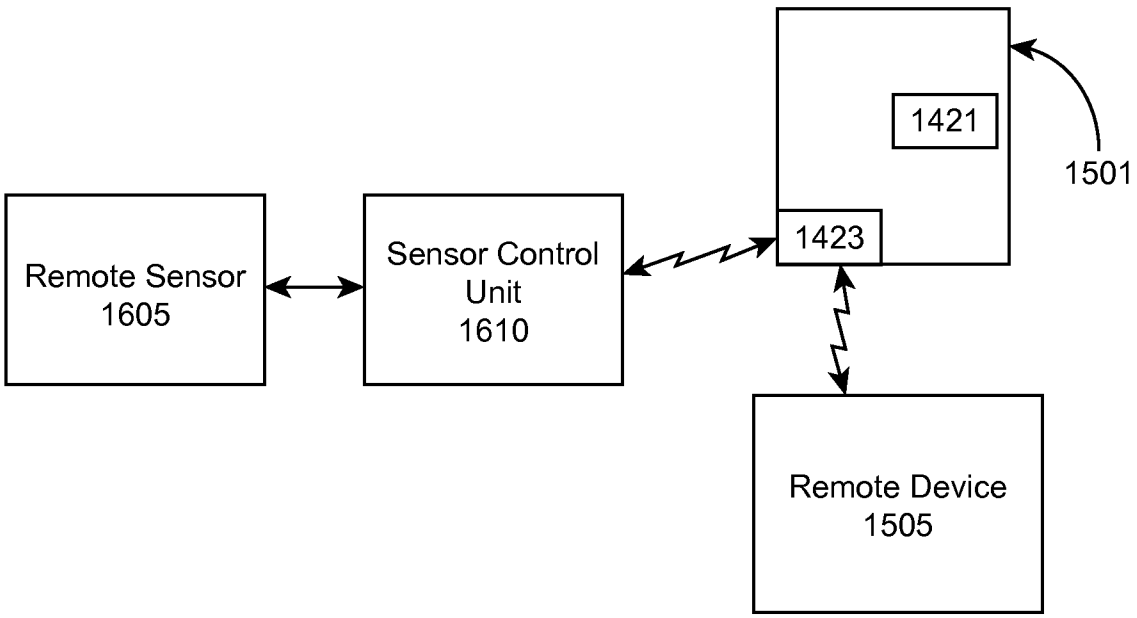

1421
1501
Remote Sensor
1605
Sensor Control
Unit
1610
1423
Remote Device
1505

FIG. 3

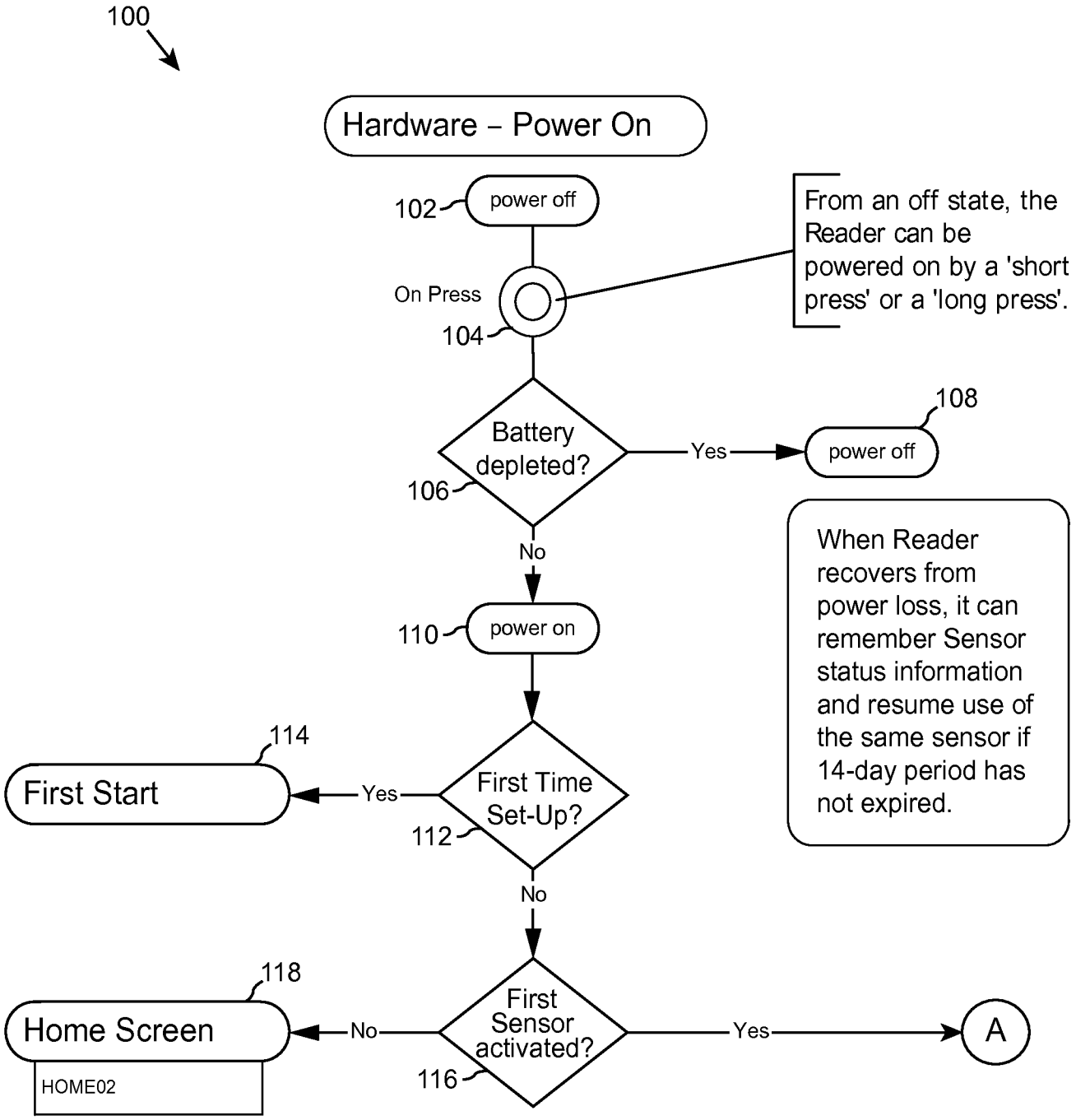

100
Hardware – Power On
102
power off
From an off state, the Reader can be powered on by a 'short press' or a 'long press'.
On Press
104
Battery depleted?
106
Yes
108
power off
No
When Reader recovers from power loss, it can remember Sensor status information and resume use of the same sensor if 14-day period has not expired.
110
power on
114
First Start
Yes
First Time Set-Up?
112
No
118
Home Screen
HOME02
No
First Sensor activated?
116
Yes
A

FIG. 4

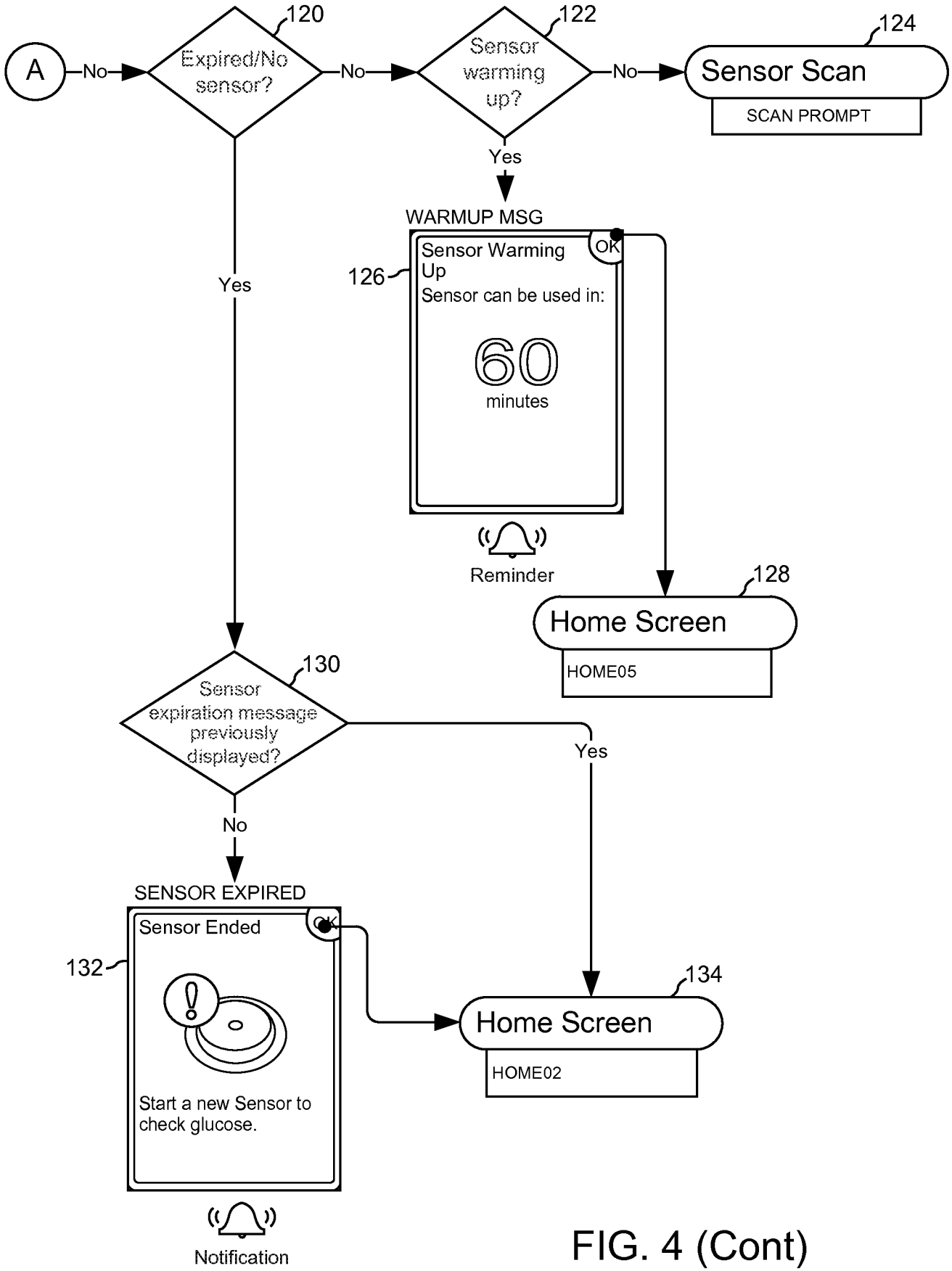

A
No
Expired/No sensor?
120
No
Sensor warming up?
122
No
Sensor Scan
124
SCAN PROMPT
Yes
WARMUP MSG
Sensor Warming Up
Sensor can be used in:
60
minutes
OK
126
Reminder
Yes
128
Home Screen
HOME05
130
Sensor expiration message previously displayed?
Yes
No
SENSOR EXPIRED
Sensor Ended
OK
132
Start a new Sensor to check glucose.
Notification
134
Home Screen
HOME02

FIG. 4 (Cont)

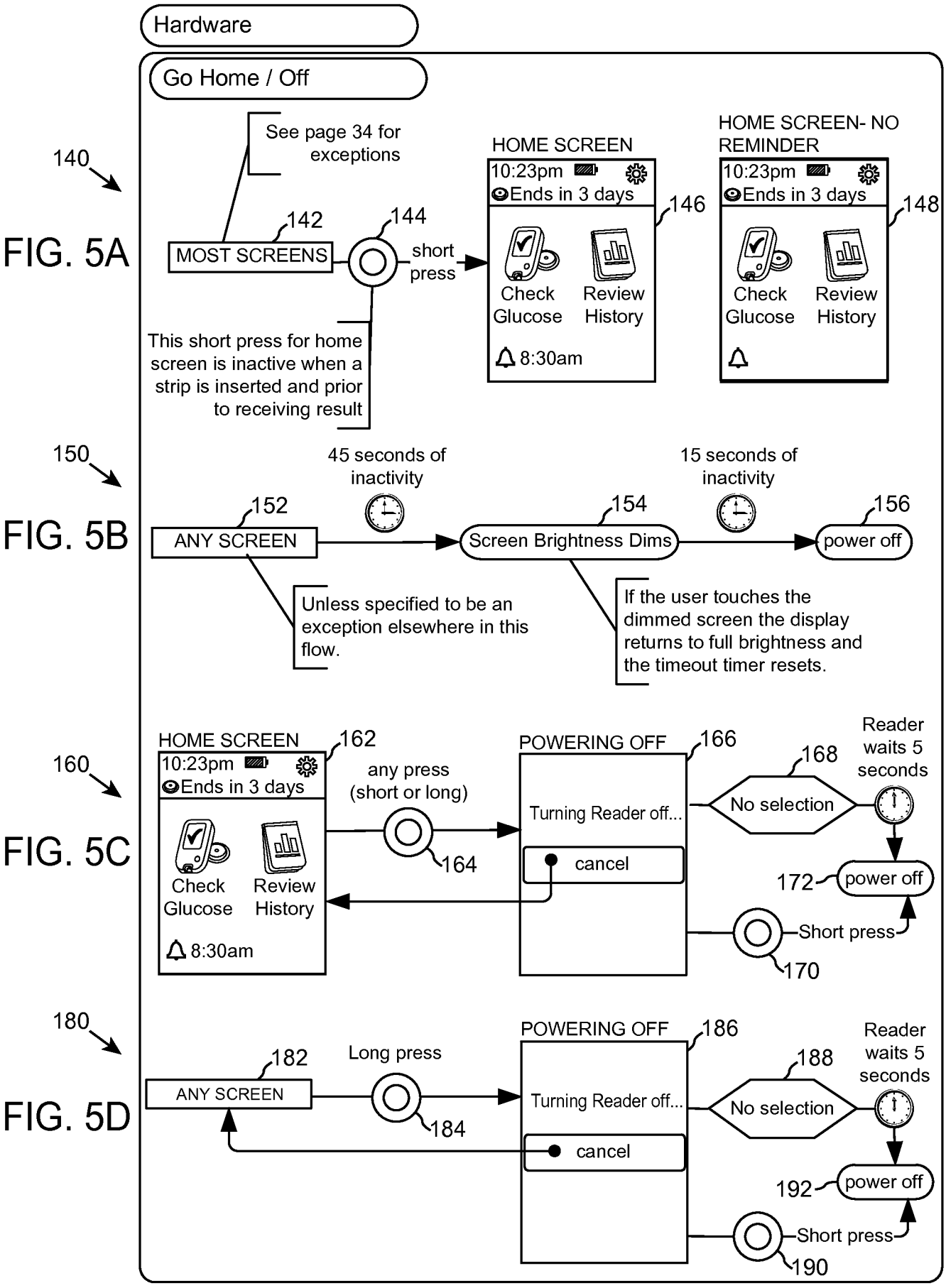


FIG. 5A

FIG. 5B

FIG. 5C

FIG. 5D

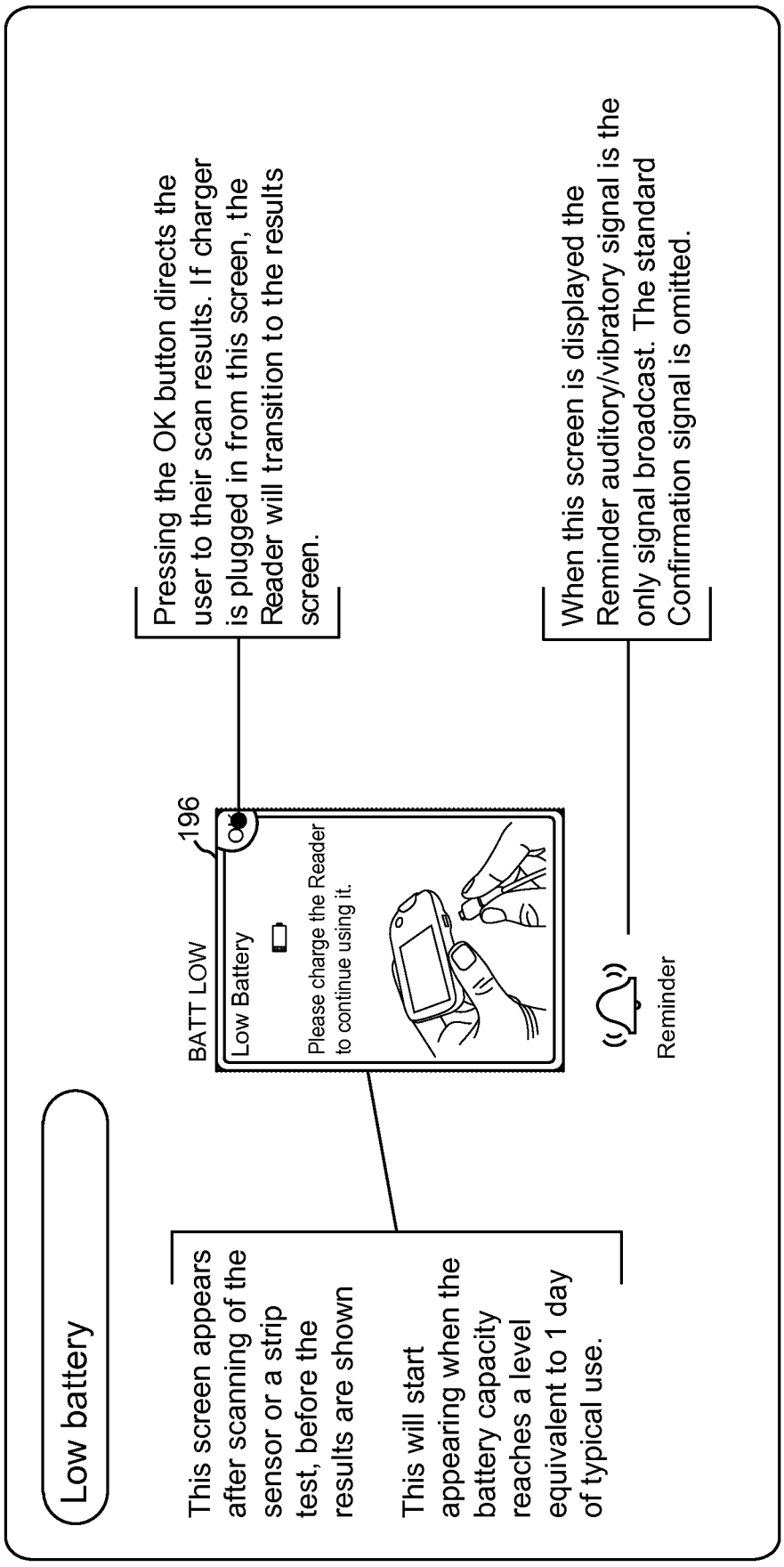

Low battery
This screen appears after scanning of the sensor or a strip test, before the results are shown
This will start appearing when the battery capacity reaches a level equivalent to 1 day of typical use.
196
BATT LOW
OK
Low Battery
Please charge the Reader to continue using it.
Pressing the OK button directs the user to their scan results. If charger is plugged in from this screen, the Reader will transition to the results screen.
When this screen is displayed the Reminder auditory/vibratory signal is the only signal broadcast. The standard Confirmation signal is omitted.
Reminder

FIG. 5E

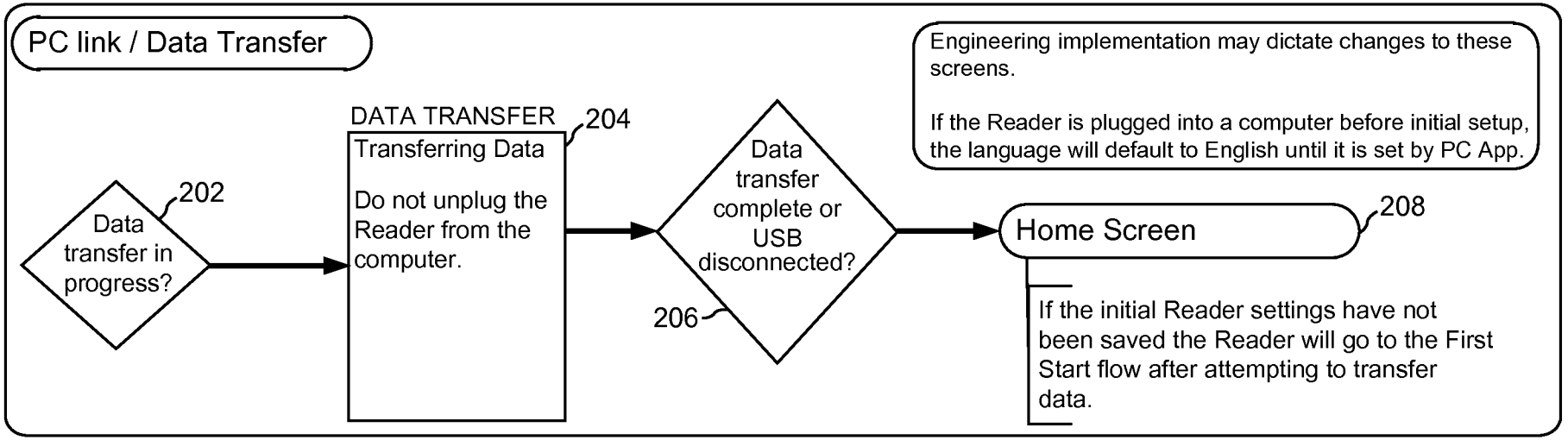

PC link / Data Transfer
Engineering implementation may dictate changes to these screens.
If the Reader is plugged into a computer before initial setup, the language will default to English until it is set by PC App.
DATA TRANSFER
204
Transferring Data
Do not unplug the Reader from the computer.
202
Data transfer in progress?
Data transfer complete or USB disconnected?
206
Home Screen
208
If the initial Reader settings have not been saved the Reader will go to the First Start flow after attempting to transfer data.
200

FIG. 5F

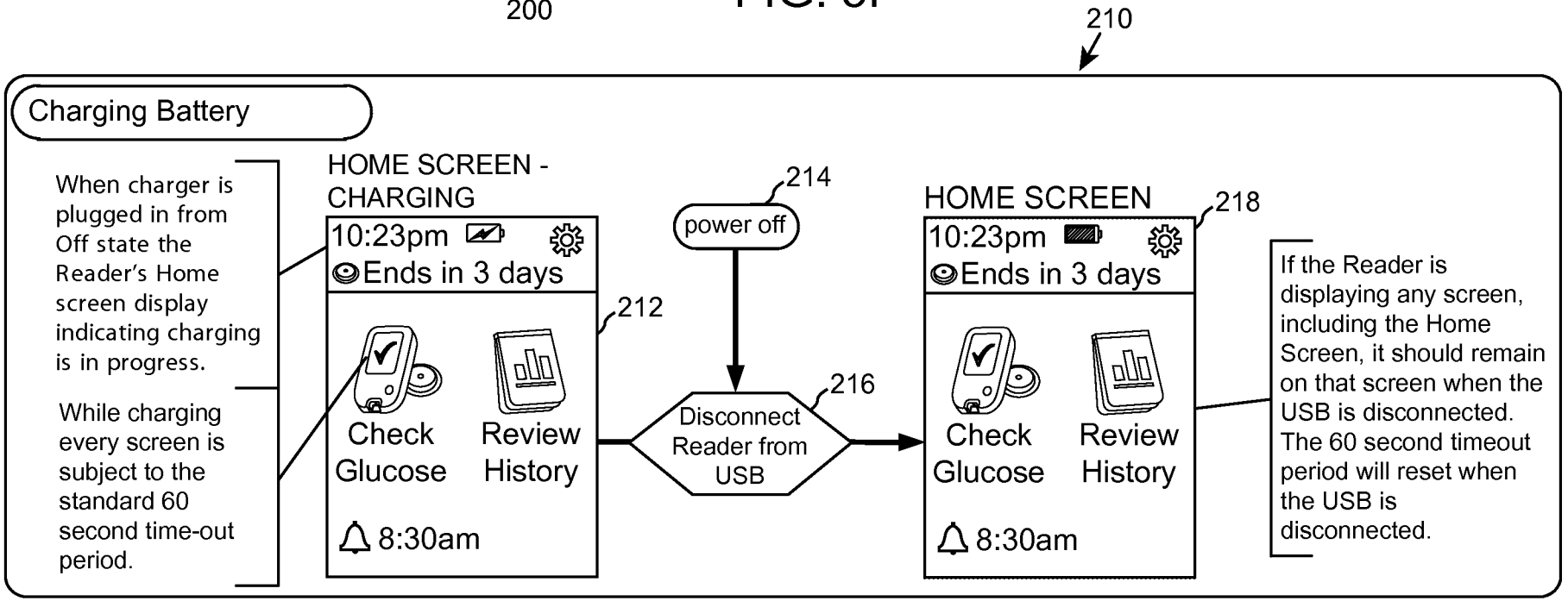
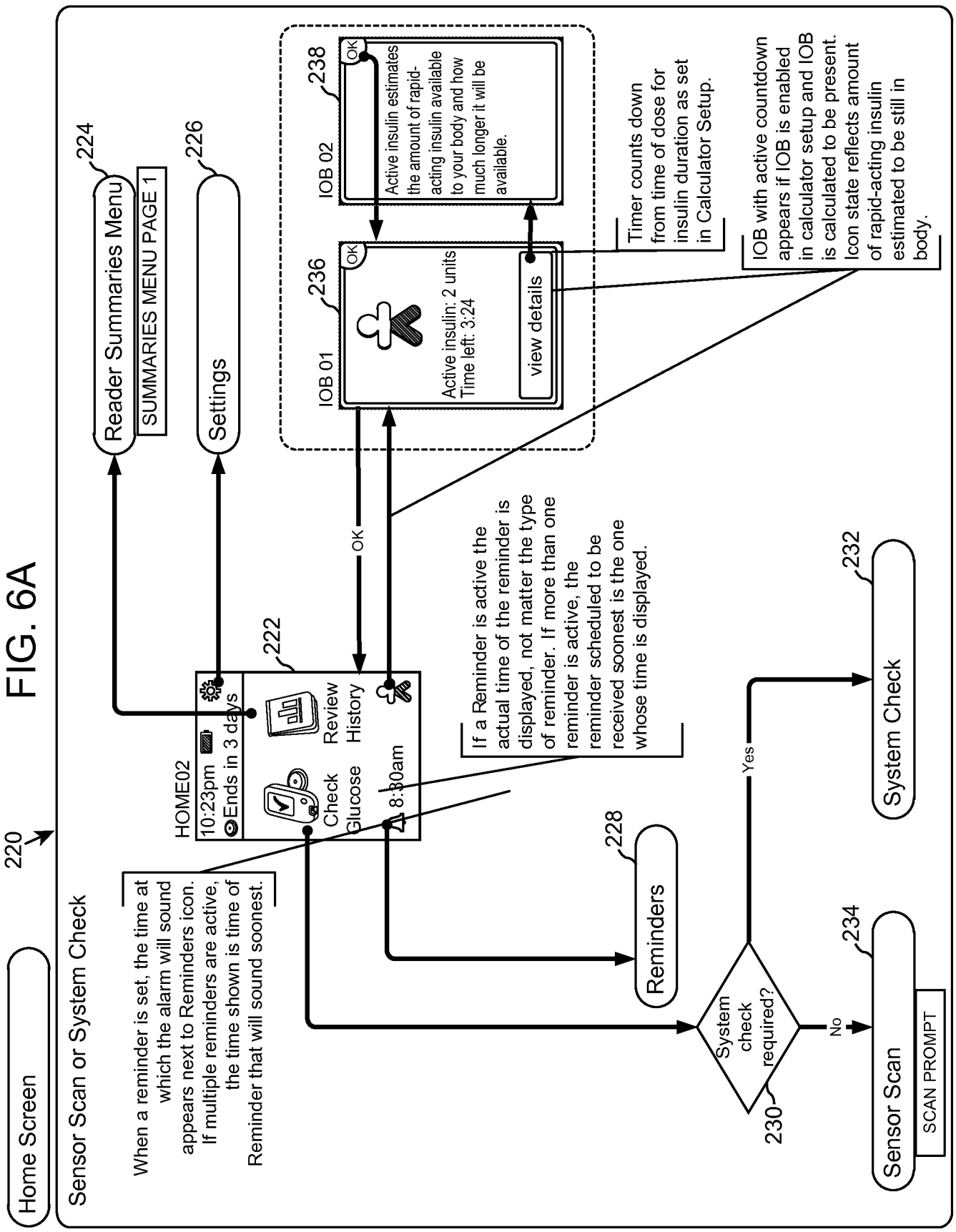

210
Charging Battery
When charger is plugged in from Off state the Reader's Home screen display indicating charging is in progress.
While charging every screen is subject to the standard 60 second time-out period.
HOME SCREEN - CHARGING
10:23pm
Ends in 3 days
212
Check Glucose
Review History
8:30am
214
power off
216
Disconnect Reader from USB
HOME SCREEN
218
10:23pm
Ends in 3 days
Check Glucose
Review History
8:30am
If the Reader is displaying any screen, including the Home Screen, it should remain on that screen when the USB is disconnected. The 60 second timeout period will reset when the USB is disconnected.

FIG. 5G

FIG. 6A


Home Screen
220
Sensor Scan or System Check
When a reminder is set, the time at which the alarm will sound appears next to Reminders icon. If multiple reminders are active, the time shown is time of Reminder that will sound soonest.
HOME02
10:23pm
Ends in 3 days
Check Glucose
Review History
8:30am
222
224
Reader Summaries Menu
SUMMARIES MENU PAGE 1
226
Settings
228
Reminders
If a Reminder is active the actual time of the reminder is displayed, not matter the type of reminder. If more than one reminder is active, the reminder scheduled to be received soonest is the one whose time is displayed.
OK
IOB 01
Active insulin: 2 units
Time left: 3:24
view details
236
IOB 02
Active insulin estimates the amount of rapid-acting insulin available to your body and how much longer it will be available.
238
Timer counts down from time of dose for insulin duration as set in Calculator Setup.
IOB with active countdown appears if IOB is enabled in calculator setup and IOB is calculated to be present. Icon state reflects amount of rapid-acting insulin estimated to be still in body.
System check required?
230
Yes
No
232
System Check
234
Sensor Scan
SCAN PROMPT

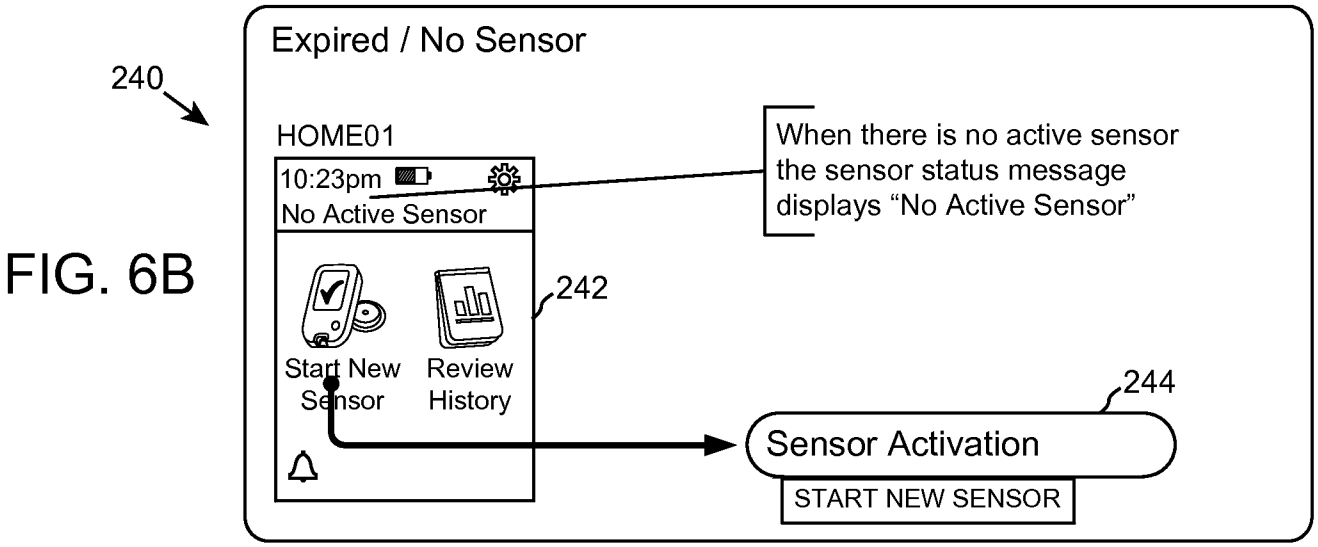


FIG. 6B

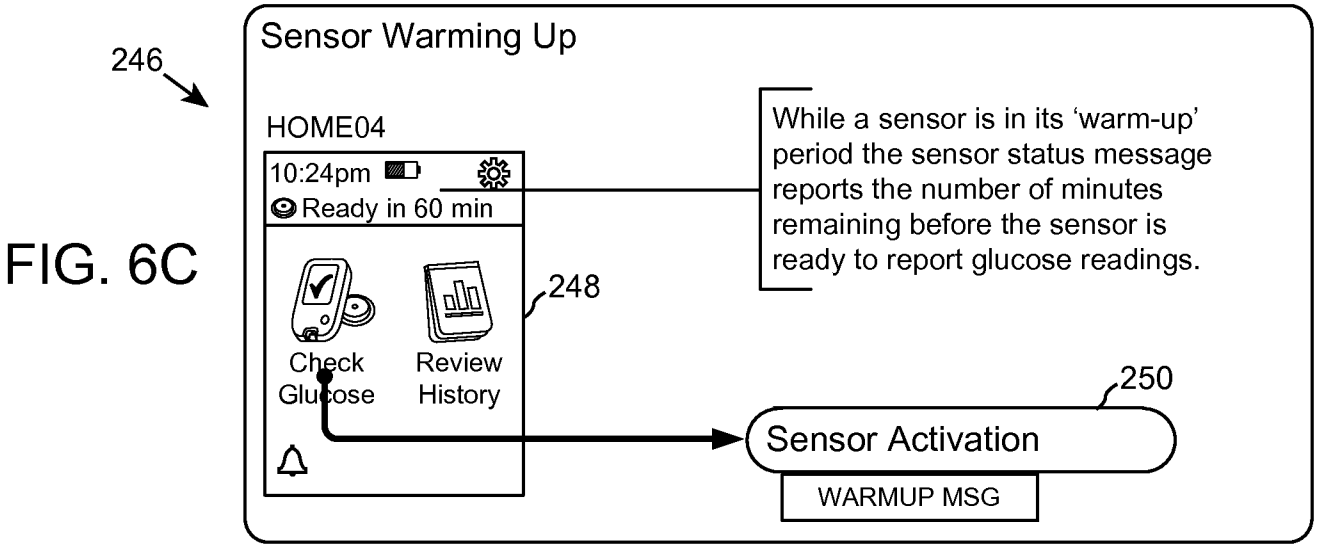


FIG. 6C

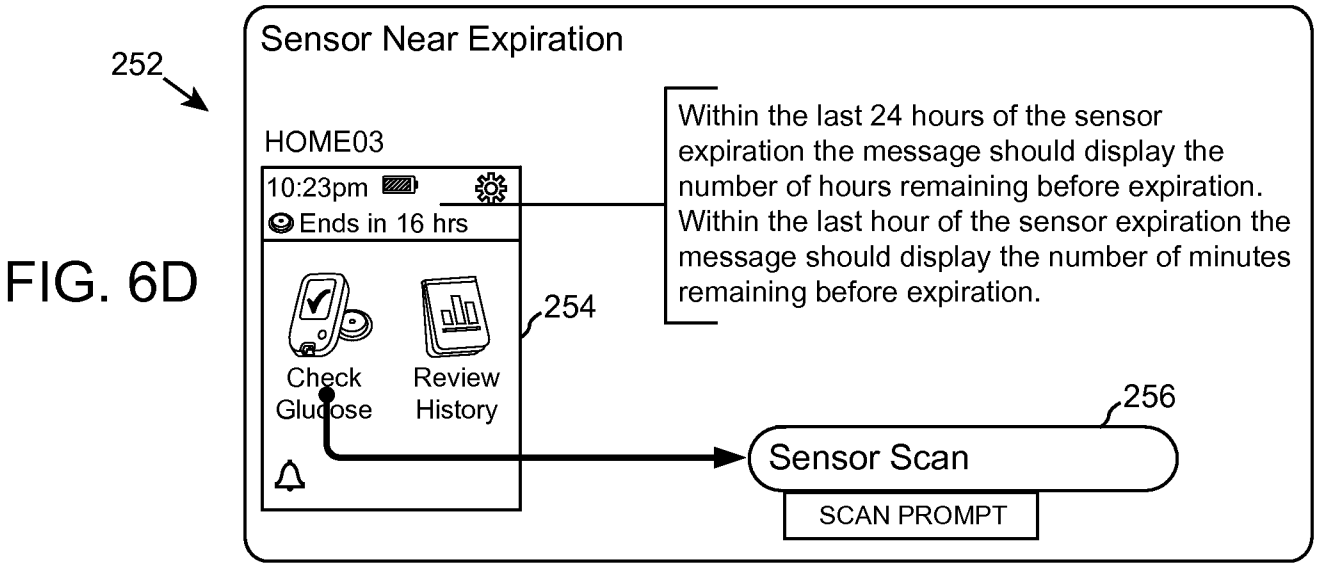


FIG. 6D

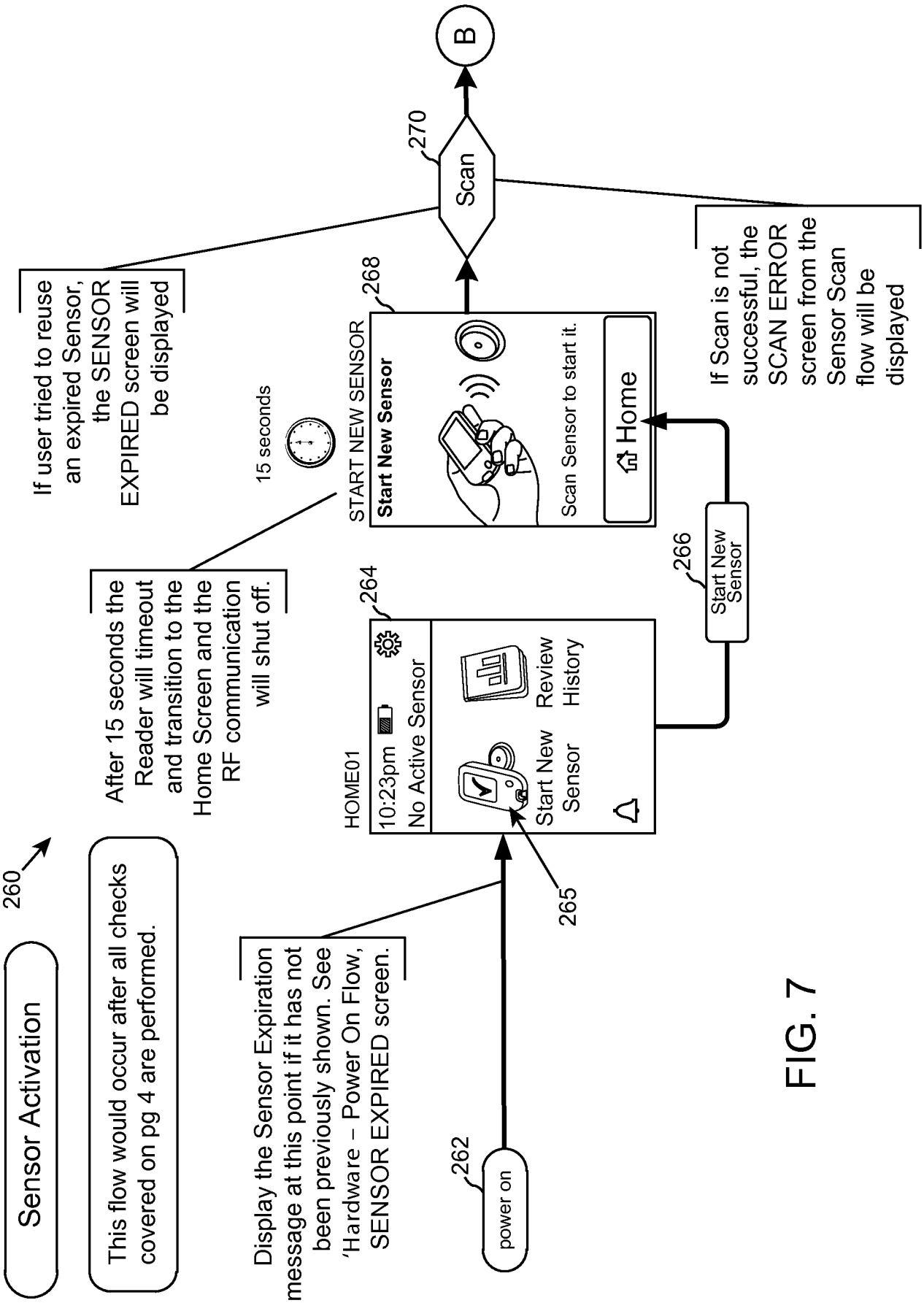

Sensor Activation
260
This flow would occur after all checks covered on pg 4 are performed.
Display the Sensor Expiration message at this point if it has not been previously shown. See 'Hardware – Power On Flow, SENSOR EXPIRED screen.
power on
262
HOME01
10:23pm
No Active Sensor
Start New Sensor
Review History
264
265
Start New Sensor
266
START NEW SENSOR
Start New Sensor
Scan Sensor to start it.
Home
268
15 seconds
After 15 seconds the Reader will timeout and transition to the Home Screen and the RF communication will shut off.
If user tried to reuse an expired Sensor, the SENSOR EXPIRED screen will be displayed
Scan
270
B
If Scan is not successful, the SCAN ERROR screen from the Sensor Scan flow will be displayed

FIG. 7

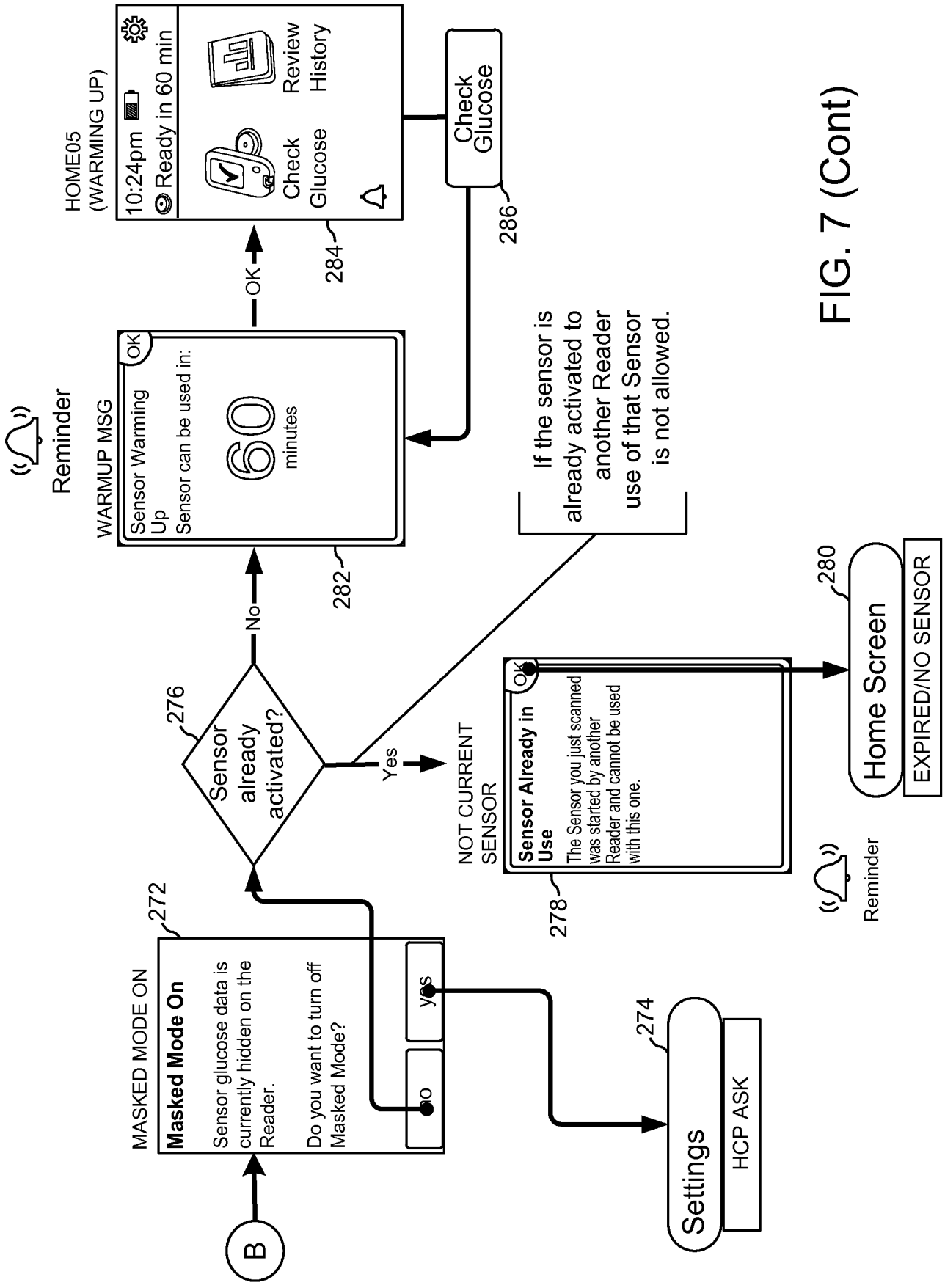

B
MASKED MODE ON
272
Masked Mode On
Sensor glucose data is currently hidden on the Reader.
Do you want to turn off Masked Mode?
no
yes
Settings
274
HCP ASK
Sensor already activated?
276
No
Yes
WARMUP MSG
OK
Sensor Warming Up
Sensor can be used in:
60
minutes
282
OK
HOME05
(WARMING UP)
10:24pm
Ready in 60 min
Check Glucose
Review History
284
Check Glucose
286
Reminder
NOT CURRENT SENSOR
OK
Sensor Already in Use
The Sensor you just scanned was started by another Reader and cannot be used with this one.
278
If the sensor is already activated to another Reader use of that Sensor is not allowed.
Reminder
280
Home Screen
EXPIRED/NO SENSOR

FIG. 7 (Cont)

FIG. 8

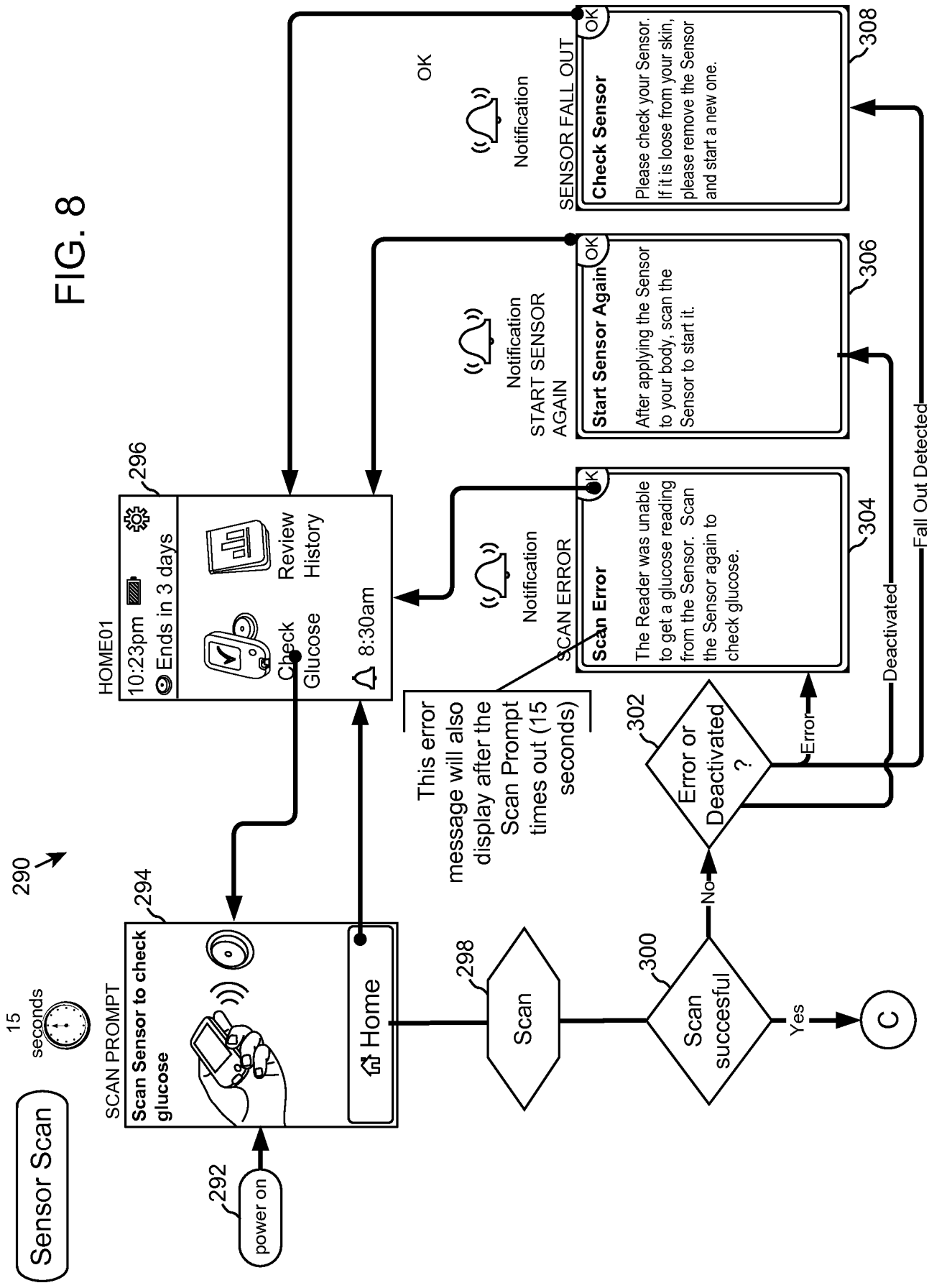
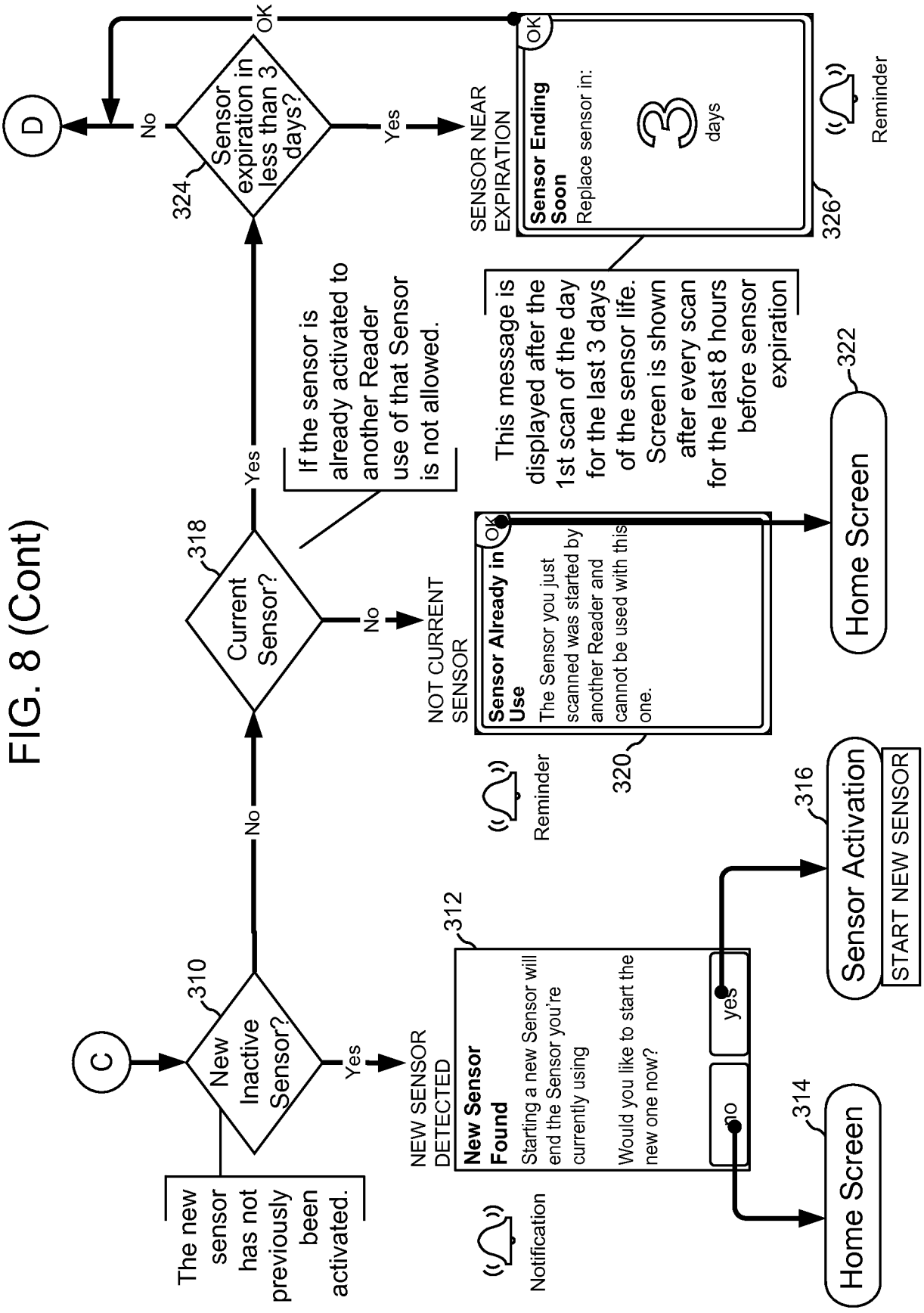

Sensor Scan
290
15 seconds
292
power on
SCAN PROMPT
Scan Sensor to check glucose
294
Home
298
Scan
300
Scan succesful
No
Yes
C
302
Error or Deactivated ?
Error
Deactivated
Fall Out Detected
This error message will also display after the Scan Prompt times out (15 seconds)
HOME01
10:23pm
Ends in 3 days
Check Glucose
Review History
8:30am
296
Notification
SCAN ERROR
OK
Scan Error
The Reader was unable to get a glucose reading from the Sensor. Scan the Sensor again to check glucose.
304
Notification
START SENSOR AGAIN
Start Sensor Again
After applying the Sensor to your body, scan the Sensor to start it.
306
Notification
SENSOR FALL OUT
Check Sensor
Please check your Sensor. If it is loose from your skin, please remove the Sensor and start a new one.
308

FIG. 8 (Cont)


C
D
New Inactive Sensor?
310
Yes
No
The new sensor has not previously been activated.
NEW SENSOR DETECTED
New Sensor Found
Starting a new Sensor will end the Sensor you're currently using
Would you like to start the new one now?
yes
no
312
Notification
Sensor Activation
START NEW SENSOR
316
Home Screen
314
Current Sensor?
318
Yes
No
If the sensor is already activated to another Reader use of that Sensor is not allowed.
NOT CURRENT SENSOR
Sensor Already in Use
The Sensor you just scanned was started by another Reader and cannot be used with this one.
OK
320
Reminder
Home Screen
322
Sensor expiration in less than 3 days?
324
Yes
No
OK
SENSOR NEAR EXPIRATION
Sensor Ending Soon
Replace sensor in:
3
days
OK
326
Reminder
This message is displayed after the 1st scan of the day for the last 3 days of the sensor life. Screen is shown after every scan for the last 8 hours before sensor expiration

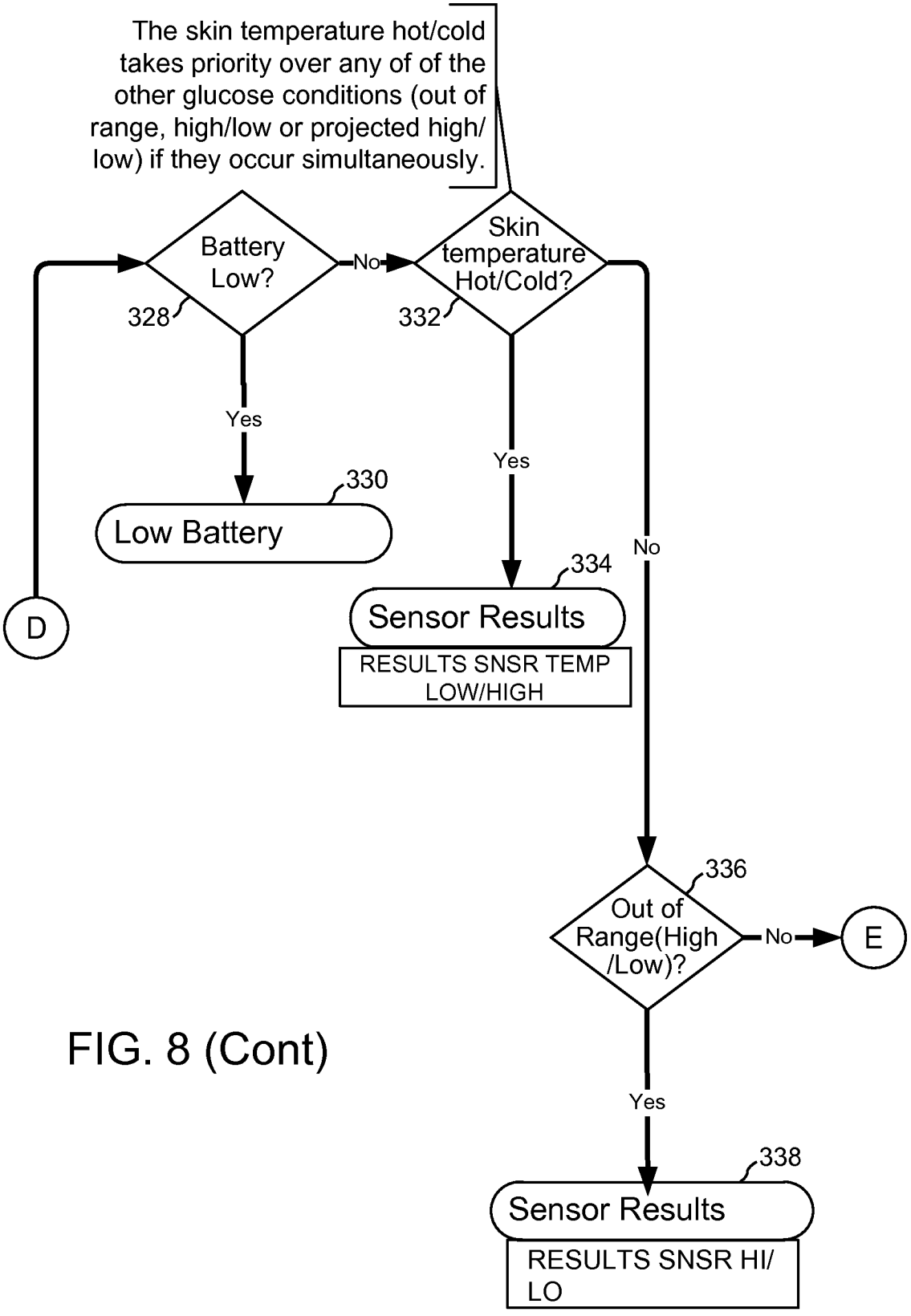

The skin temperature hot/cold takes priority over any of of the other glucose conditions (out of range, high/low or projected high/ low) if they occur simultaneously.
Battery Low?
328
No
Skin temperature Hot/Cold?
332
Yes
Yes
No
330
Low Battery
334
Sensor Results
RESULTS SNSR TEMP LOW/HIGH
D
336
Out of Range(High /Low)?
No
E
Yes
338
Sensor Results
RESULTS SNSR HI/ LO

FIG. 8 (Cont)

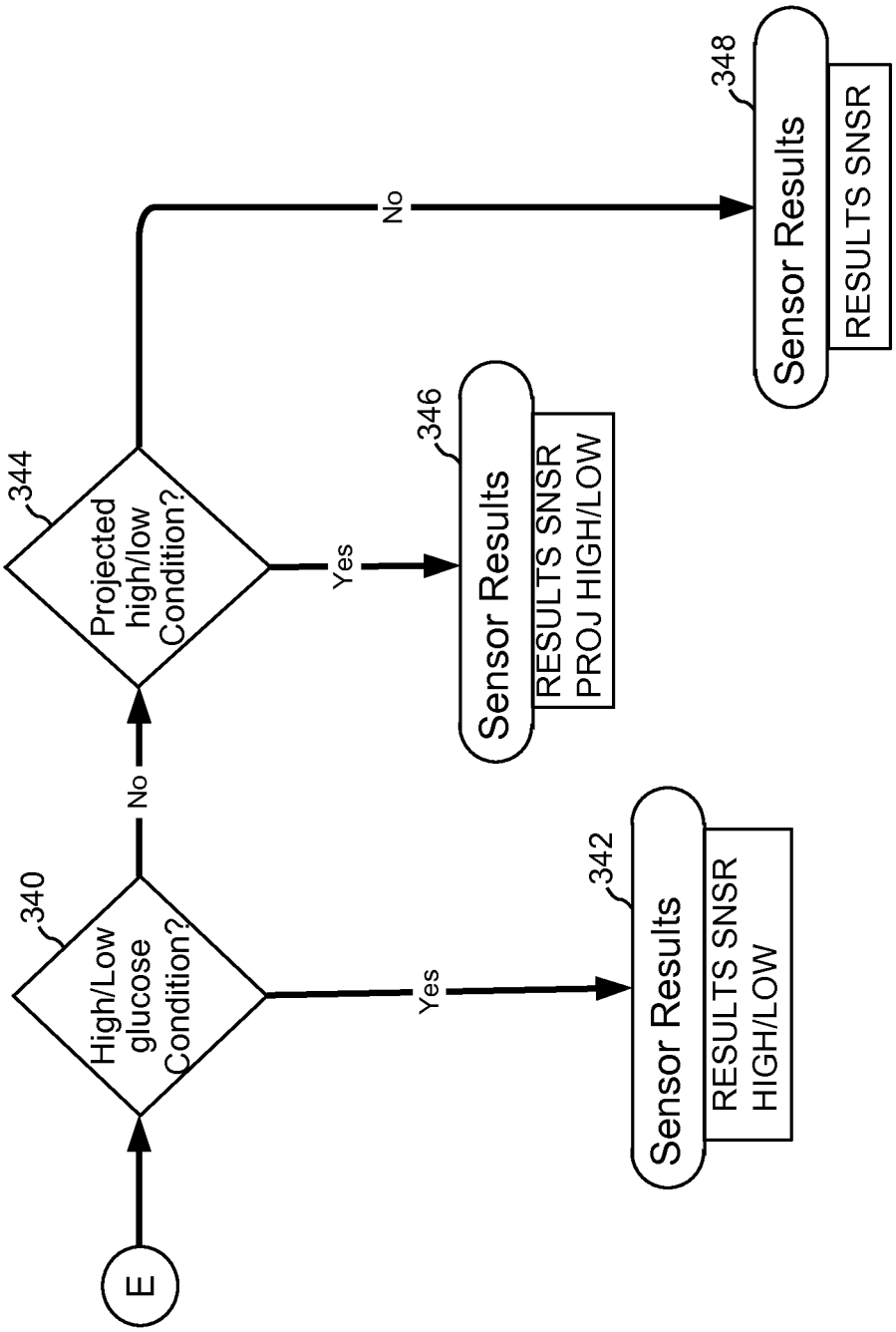

E
340
High/Low glucose Condition?
Yes
342
Sensor Results
RESULTS SNSR HIGH/LOW
No
344
Projected high/low Condition?
Yes
346
Sensor Results
RESULTS SNSR PROJ HIGH/LOW
No
348
Sensor Results
RESULTS SNSR

FIG. 8 (Cont)

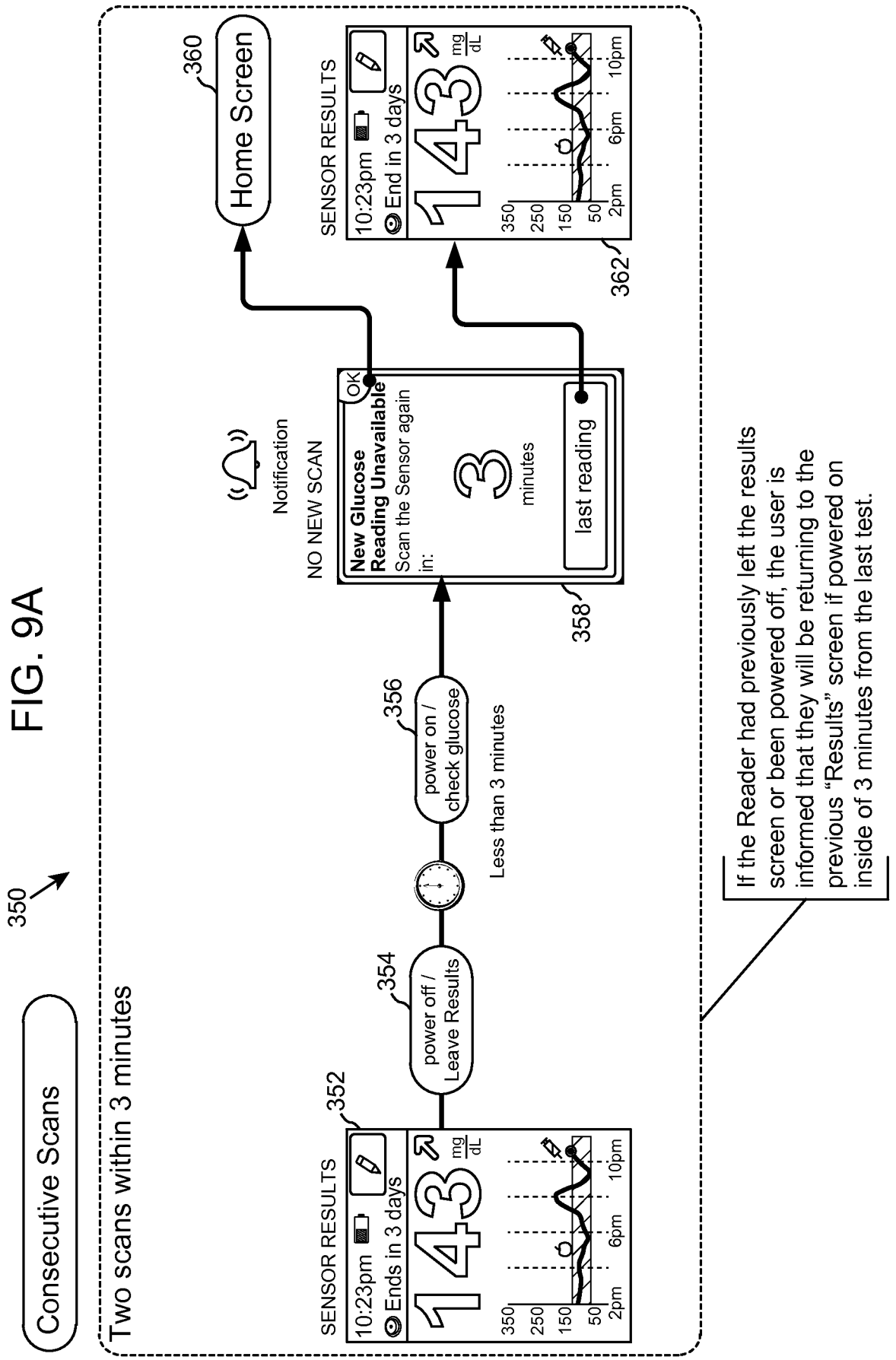


FIG. 9A

Performs BG Check in between 2 consecutive scans

FIG. 9B

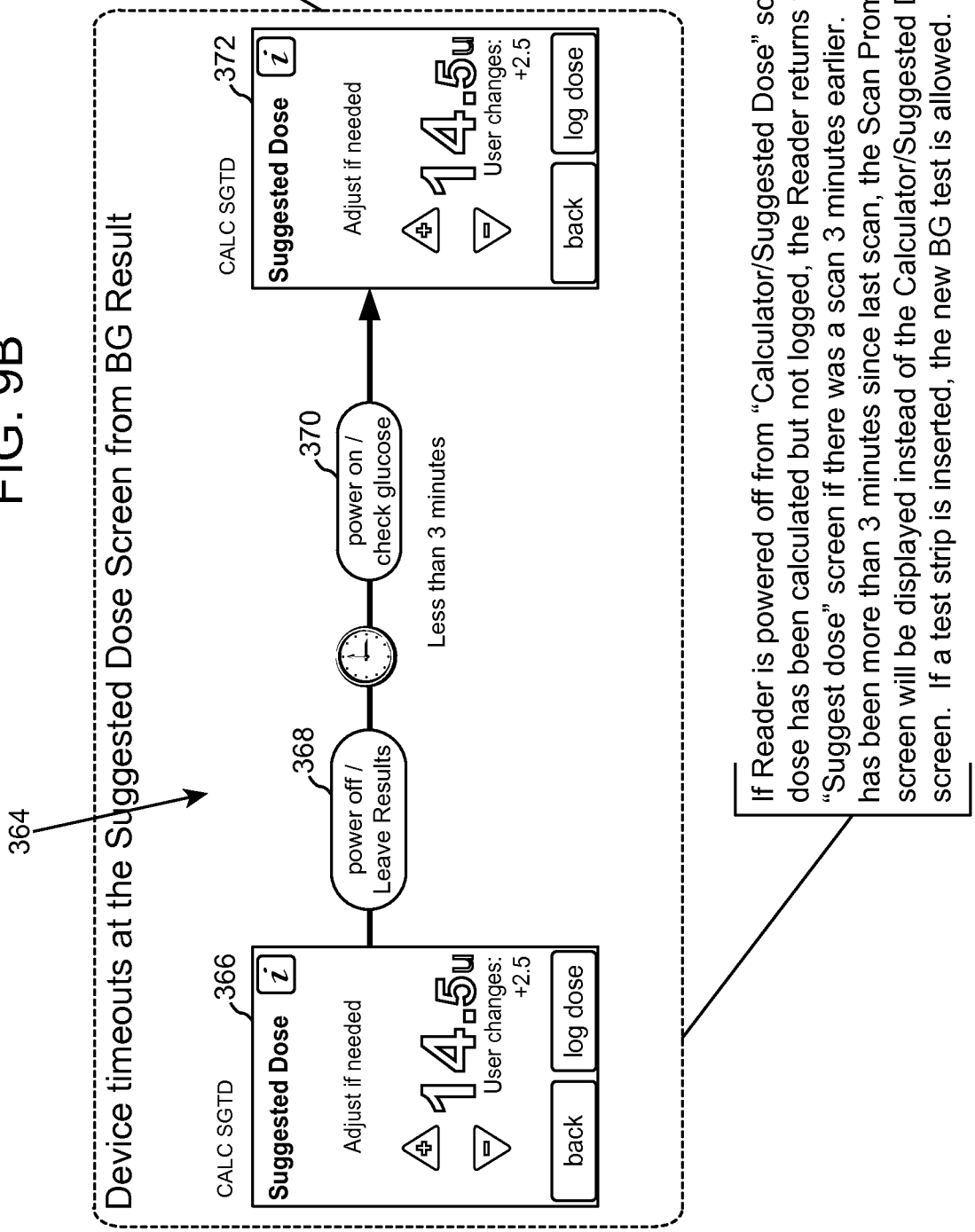
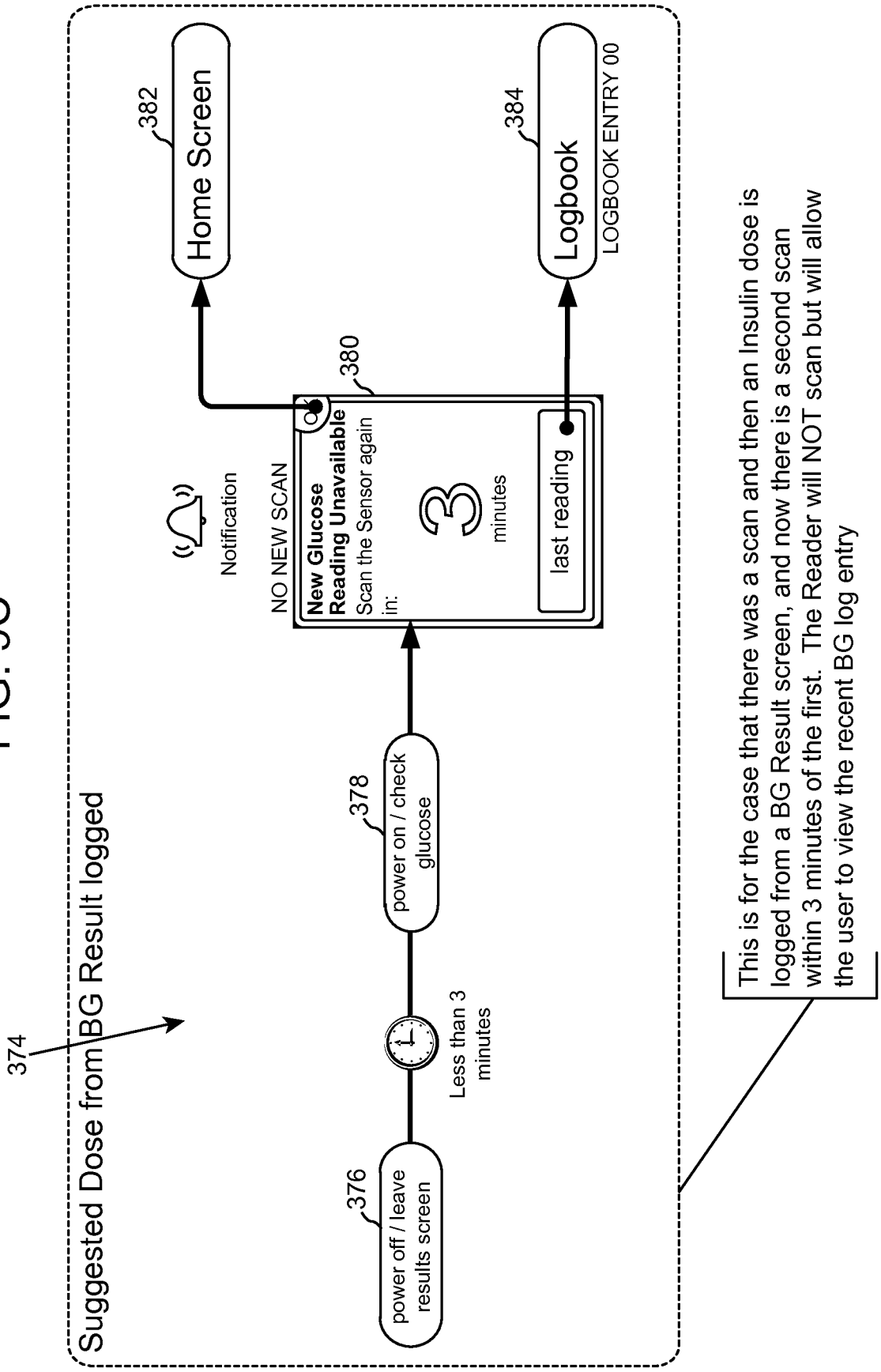

Device timeouts at the Suggested Dose Screen from BG Result
364
366
CALC SGTD
Suggested Dose
Adjust if needed
14.5u
User changes: +2.5
back
log dose
368
power off / Leave Results
Less than 3 minutes
370
power on / check glucose
372
CALC SGTD
Suggested Dose
Adjust if needed
14.5u
User changes: +2.5
back
log dose
If a dose is logged at the end of this flow, the dose is stored in the logbook with the test at the time the test was taken (the dose is not logged as delivered at the time "log dose" is selected); however insulin in body countdown starts from time at which dose is actually logged.
If Reader is powered off from "Calculator/Suggested Dose" screen and dose has been calculated but not logged, the Reader returns to the "Suggest dose" screen if there was a scan 3 minutes earlier. If its has been more than 3 minutes since last scan, the Scan Prompt screen will be displayed instead of the Calculator/Suggested Dose" screen. If a test strip is inserted, the new BG test is allowed.

FIG. 9C


374
Suggested Dose from BG Result logged
376
power off / leave results screen
Less than 3 minutes
378
power on / check glucose
NO NEW SCAN
Notification
New Glucose Reading Unavailable
Scan the Sensor again in:
3
minutes
last reading
380
382
Home Screen
384
Logbook
LOGBOOK ENTRY 00
This is for the case that there was a scan and then an Insulin dose is logged from a BG Result screen, and now there is a second scan within 3 minutes of the first. The Reader will NOT scan but will allow the user to view the recent BG log entry

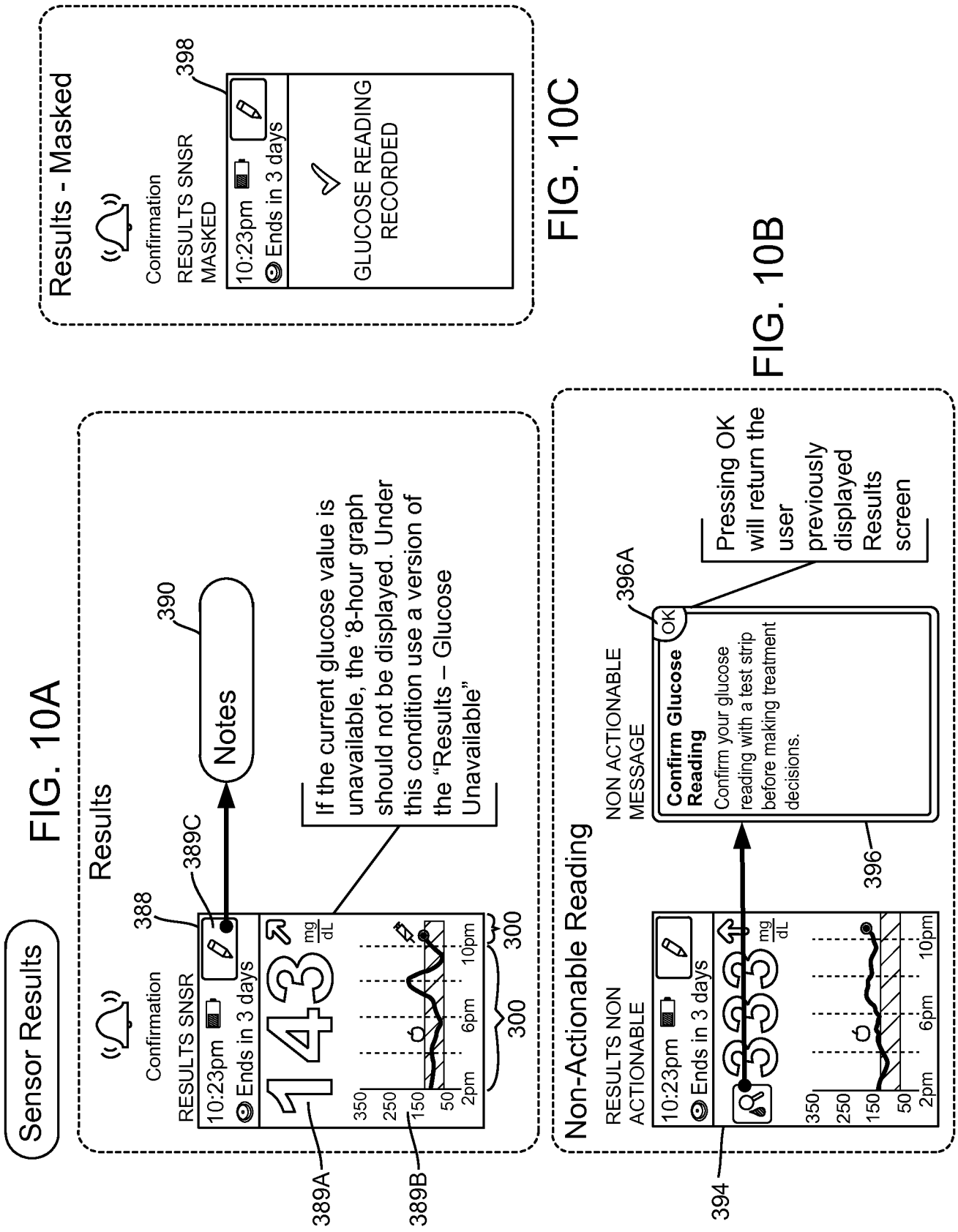


FIG. 10A

FIG. 10B

FIG. 10C

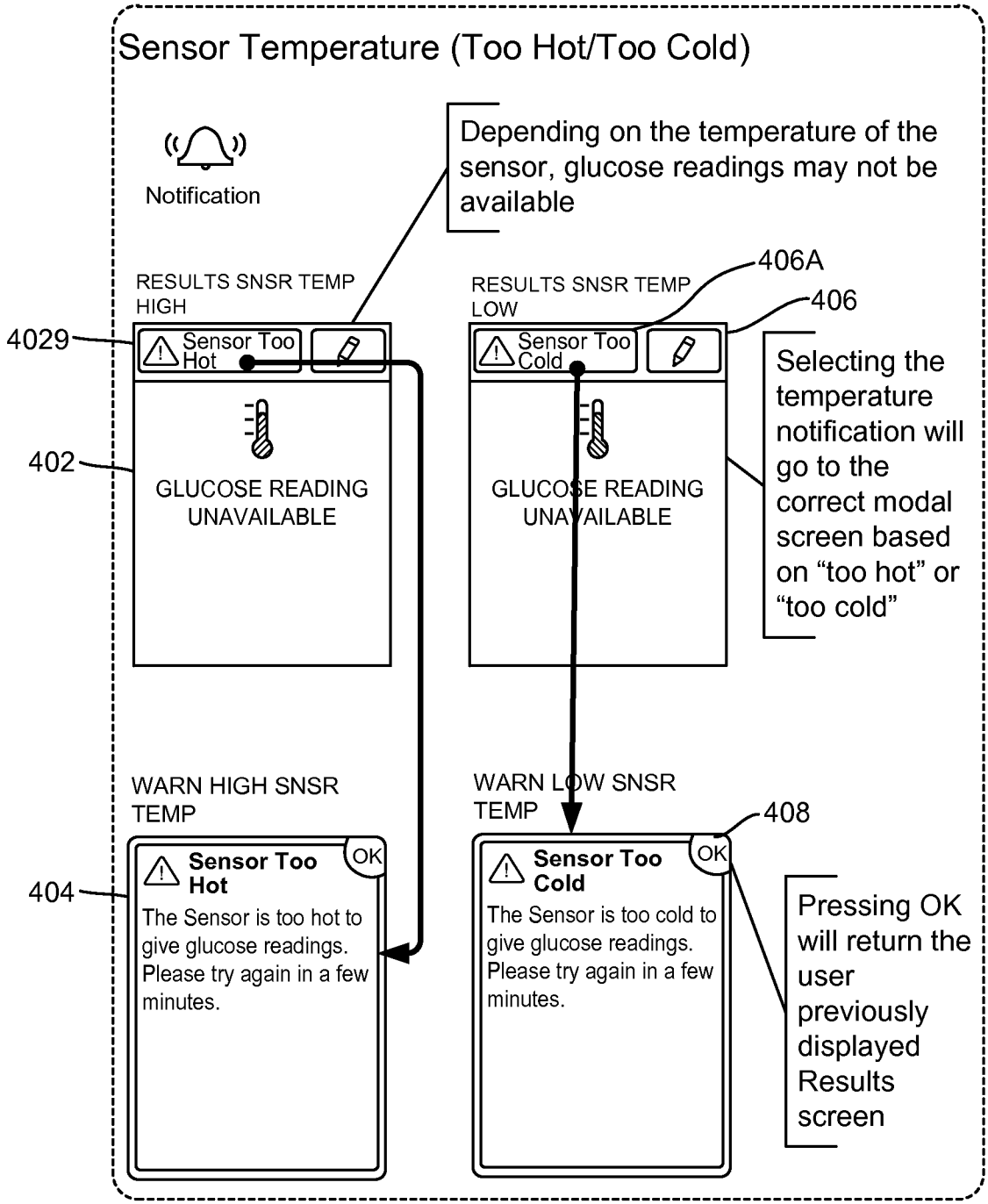


FIG. 10D FIG. 10E

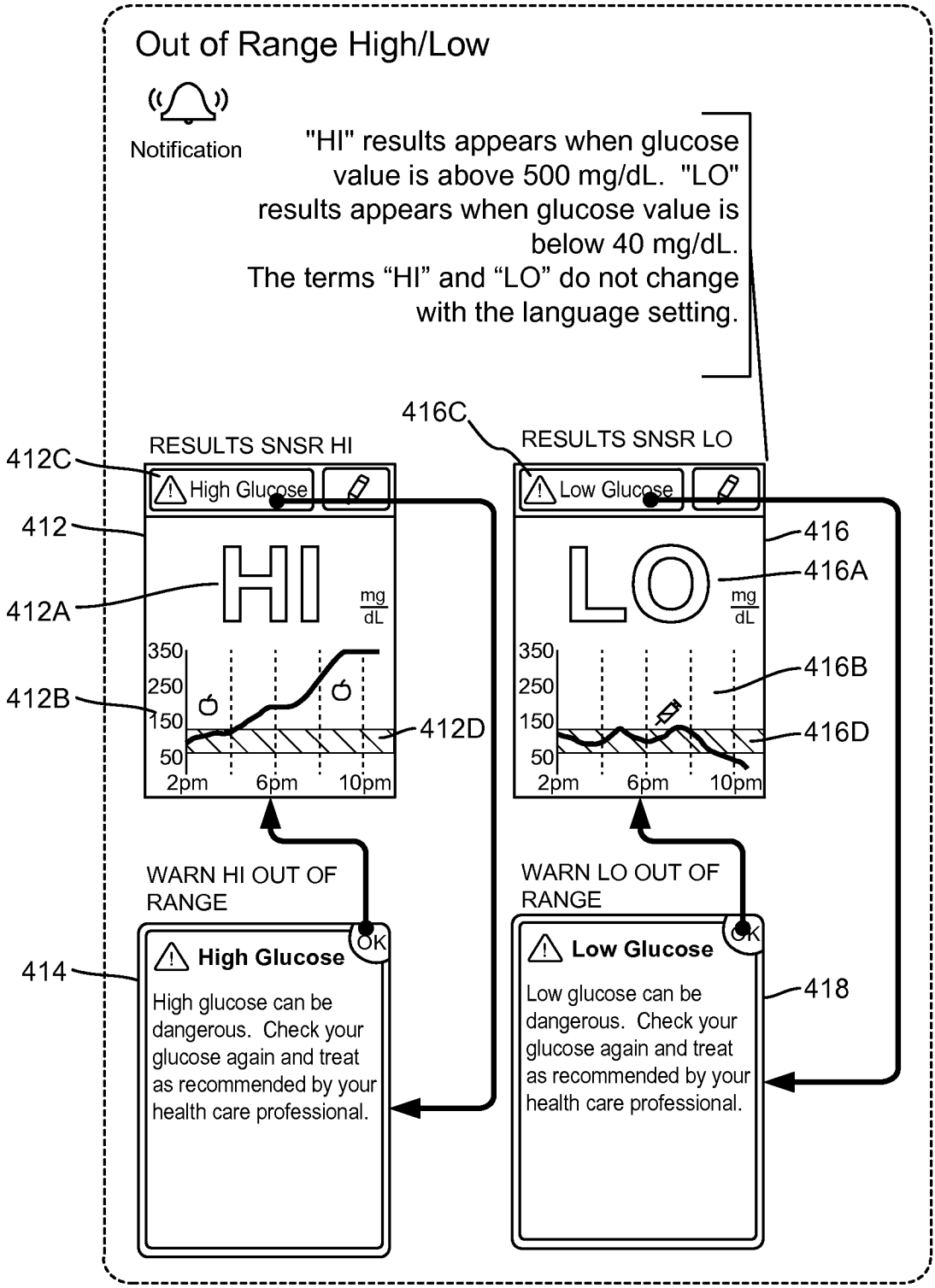


FIG. 10F FIG. 10G

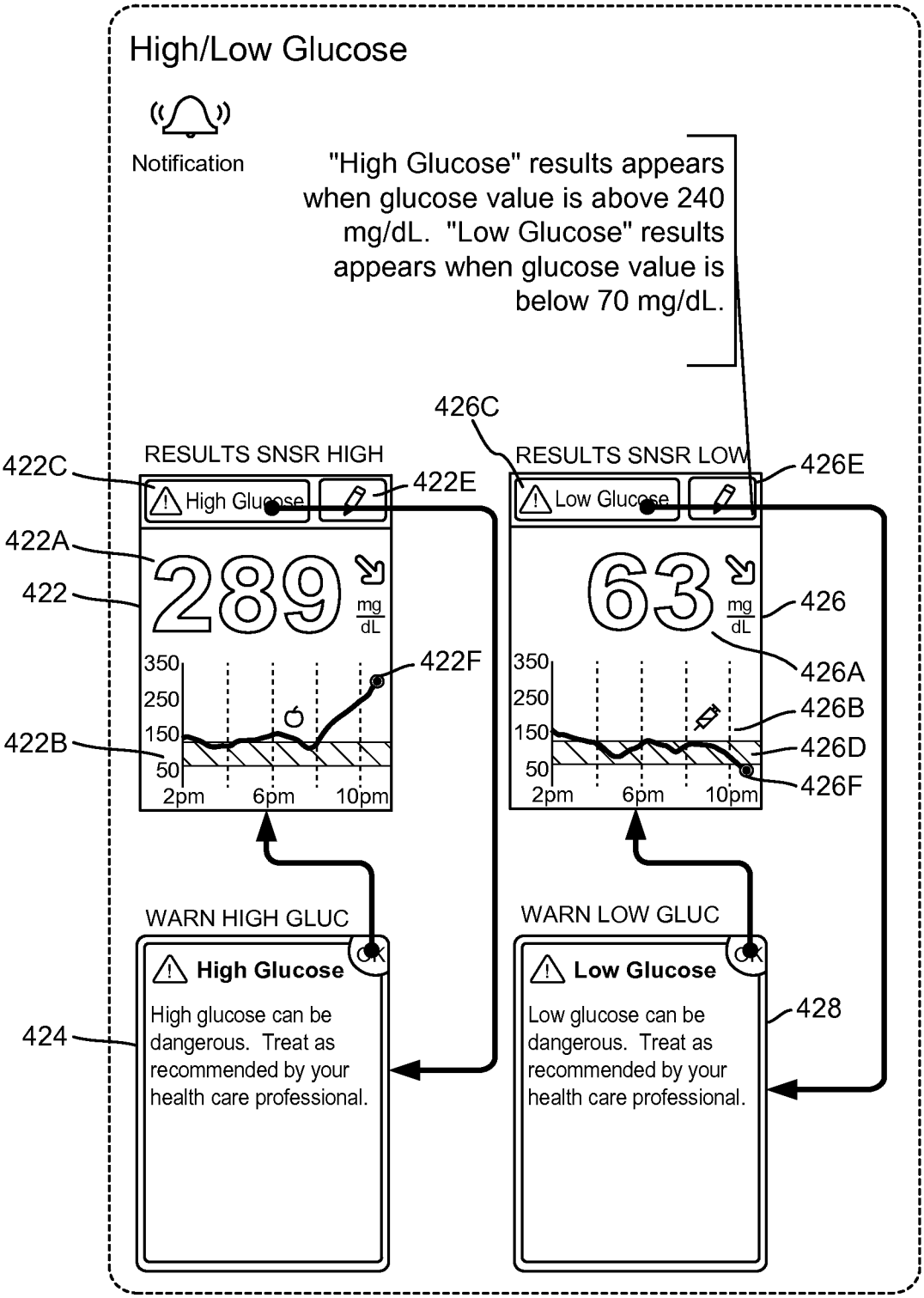


FIG. 10H FIG. 10I

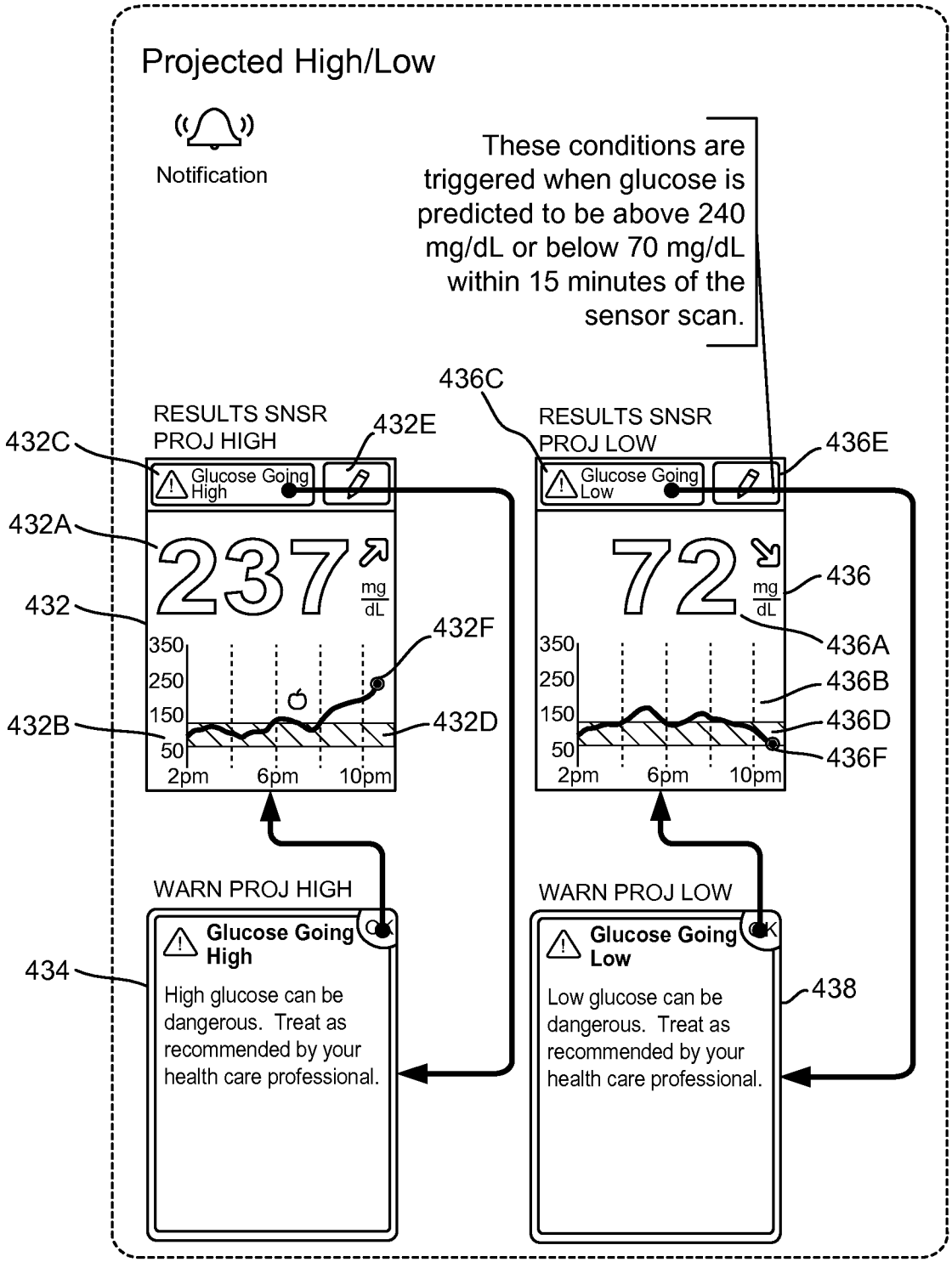


FIG. 10J FIG. 10K

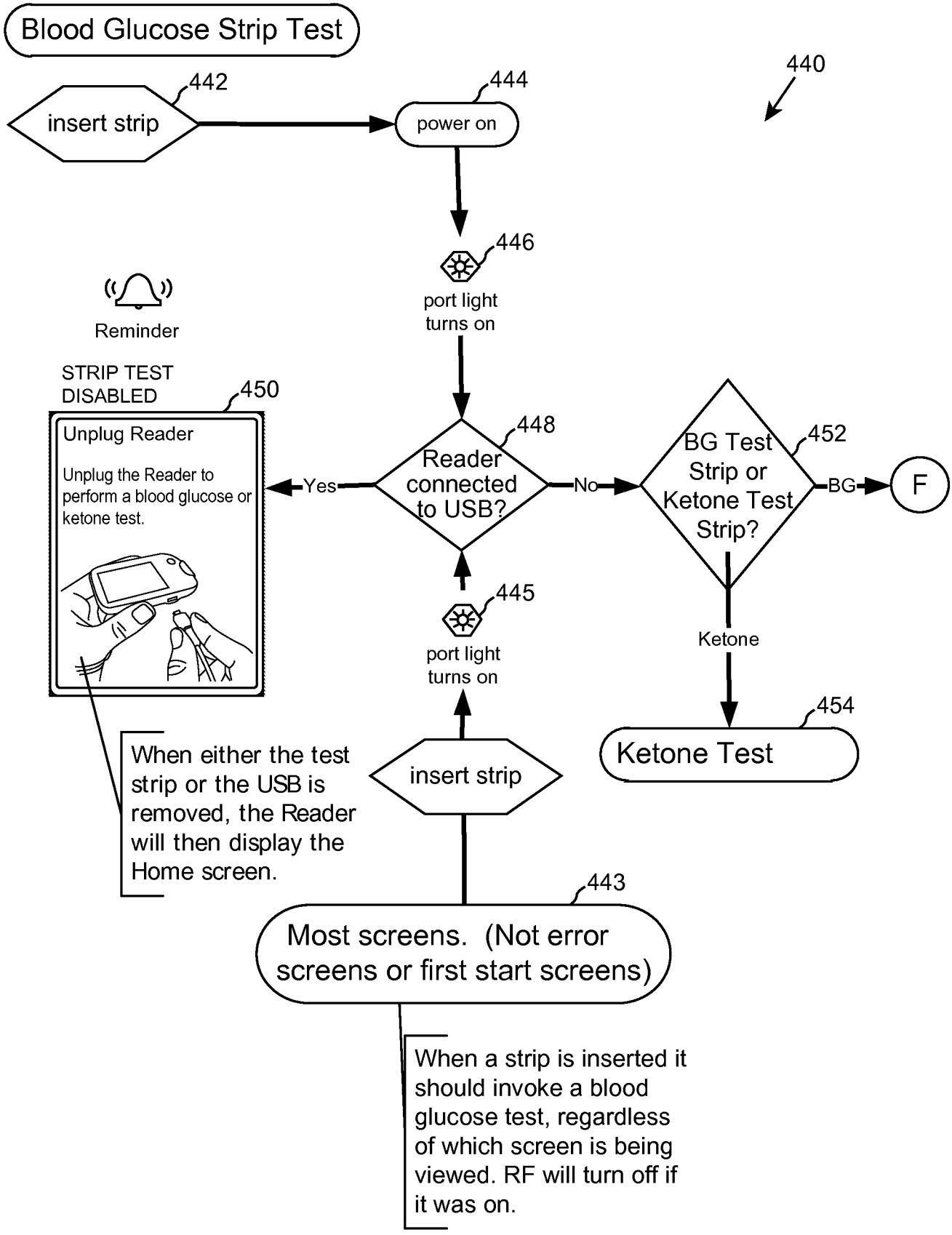

Blood Glucose Strip Test
440
442
insert strip
444
power on
446
port light turns on
Reminder
STRIP TEST DISABLED
450
Unplug Reader
Unplug the Reader to perform a blood glucose or ketone test.
448
Reader connected to USB?
Yes
No
452
BG Test Strip or Ketone Test Strip?
BG
F
Ketone
454
Ketone Test
445
port light turns on
insert strip
When either the test strip or the USB is removed, the Reader will then display the Home screen.
443
Most screens. (Not error screens or first start screens)
When a strip is inserted it should invoke a blood glucose test, regardless of which screen is being viewed. RF will turn off if it was on.

FIG. 11

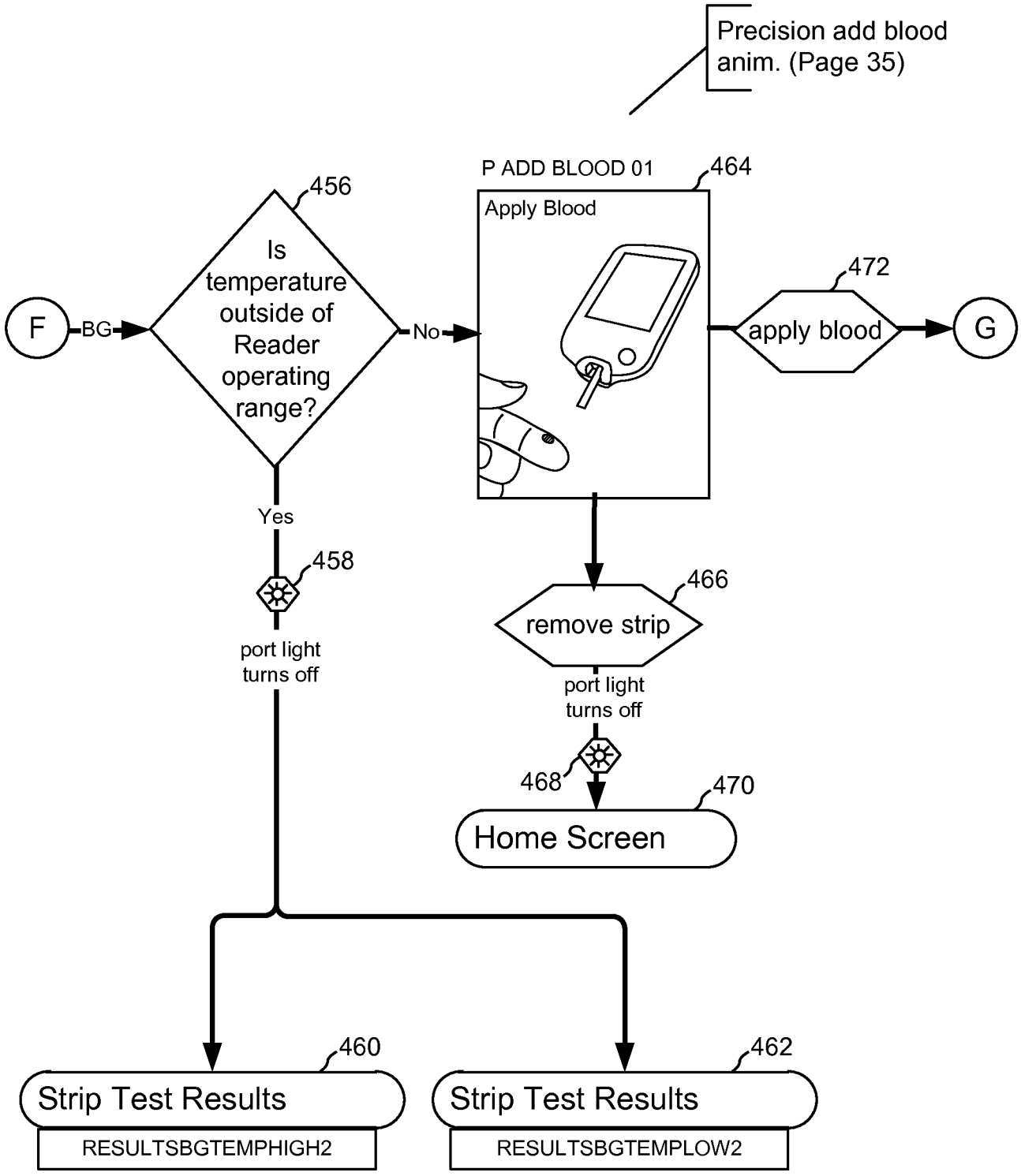

Precision add blood anim. (Page 35)
P ADD BLOOD 01
464
Apply Blood
456
Is temperature outside of Reader operating range?
F
BG
No
472
apply blood
G
Yes
458
port light turns off
466
remove strip
port light turns off
468
470
Home Screen
460
Strip Test Results
RESULTSBGTEMPHIGH2
462
Strip Test Results
RESULTSBGTEMPLOW2

FIG. 11 (Cont)

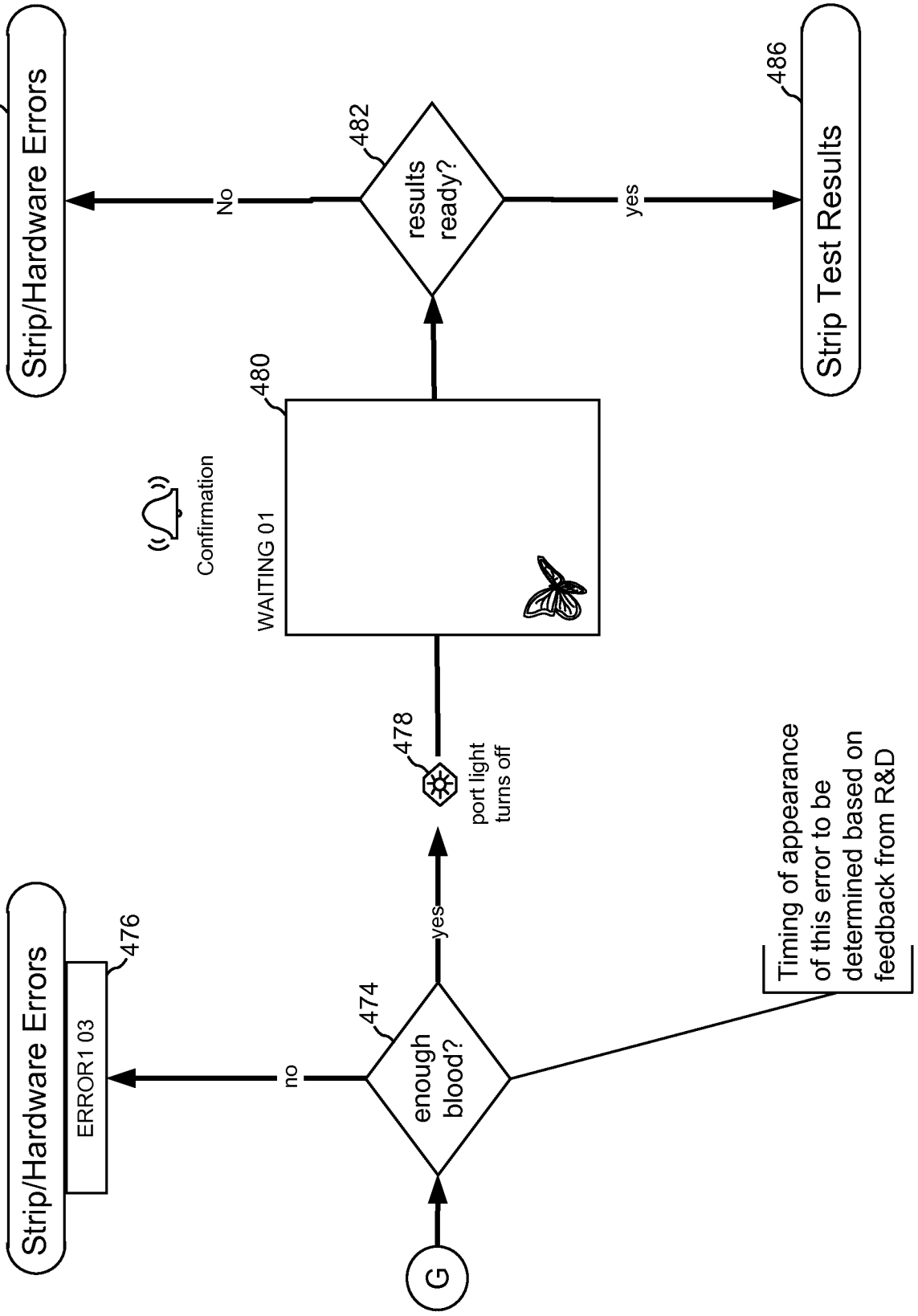

Strip/Hardware Errors
484
No
482
results ready?
yes
486
Strip Test Results
480
WAITING 01
Confirmation
478
port light turns off
yes
474
enough blood?
no
476
ERROR1 03
Strip/Hardware Errors
G
Timing of appearance of this error to be determined based on feedback from R&D

FIG. 11 (Cont)

Blood Glucose Strip Test Results

FIG. 12A

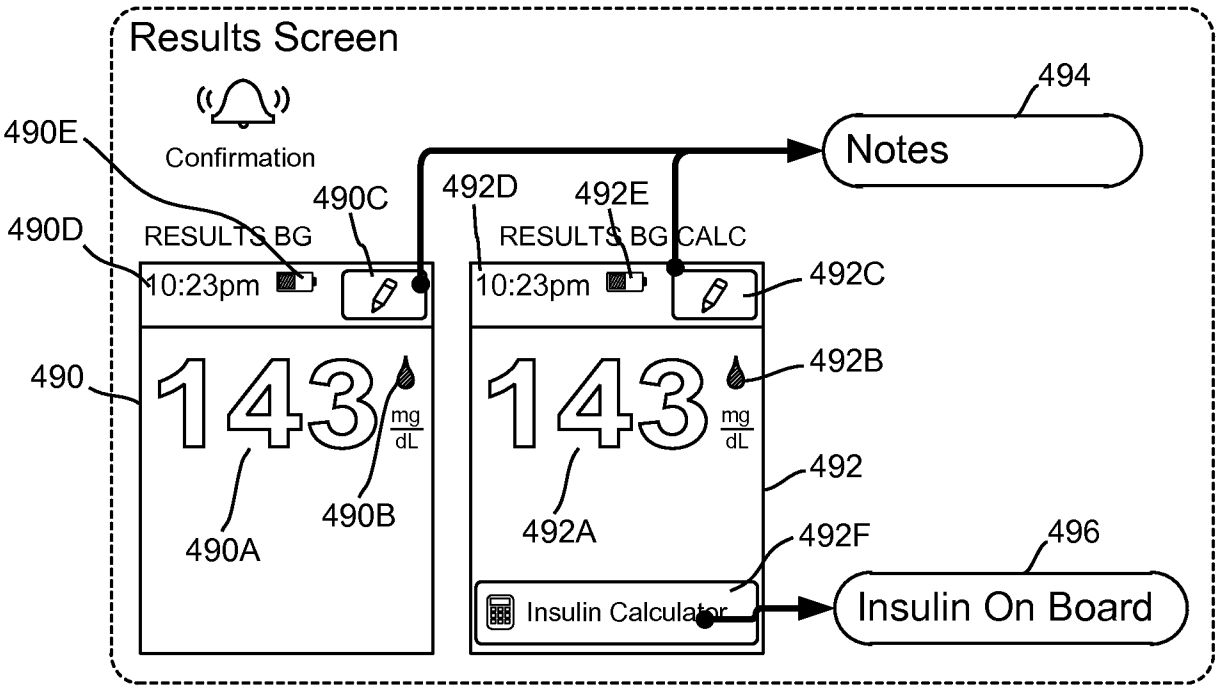
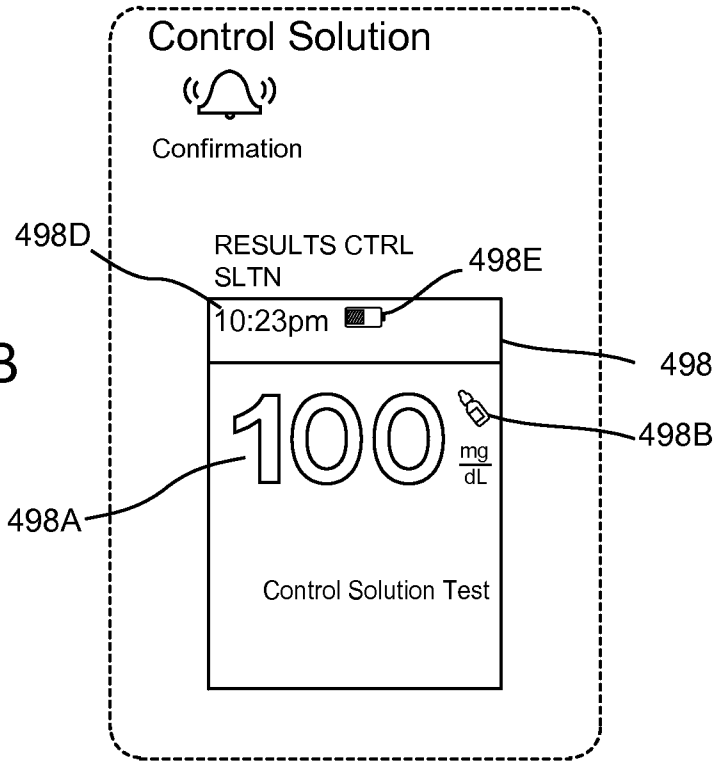


FIG. 12B



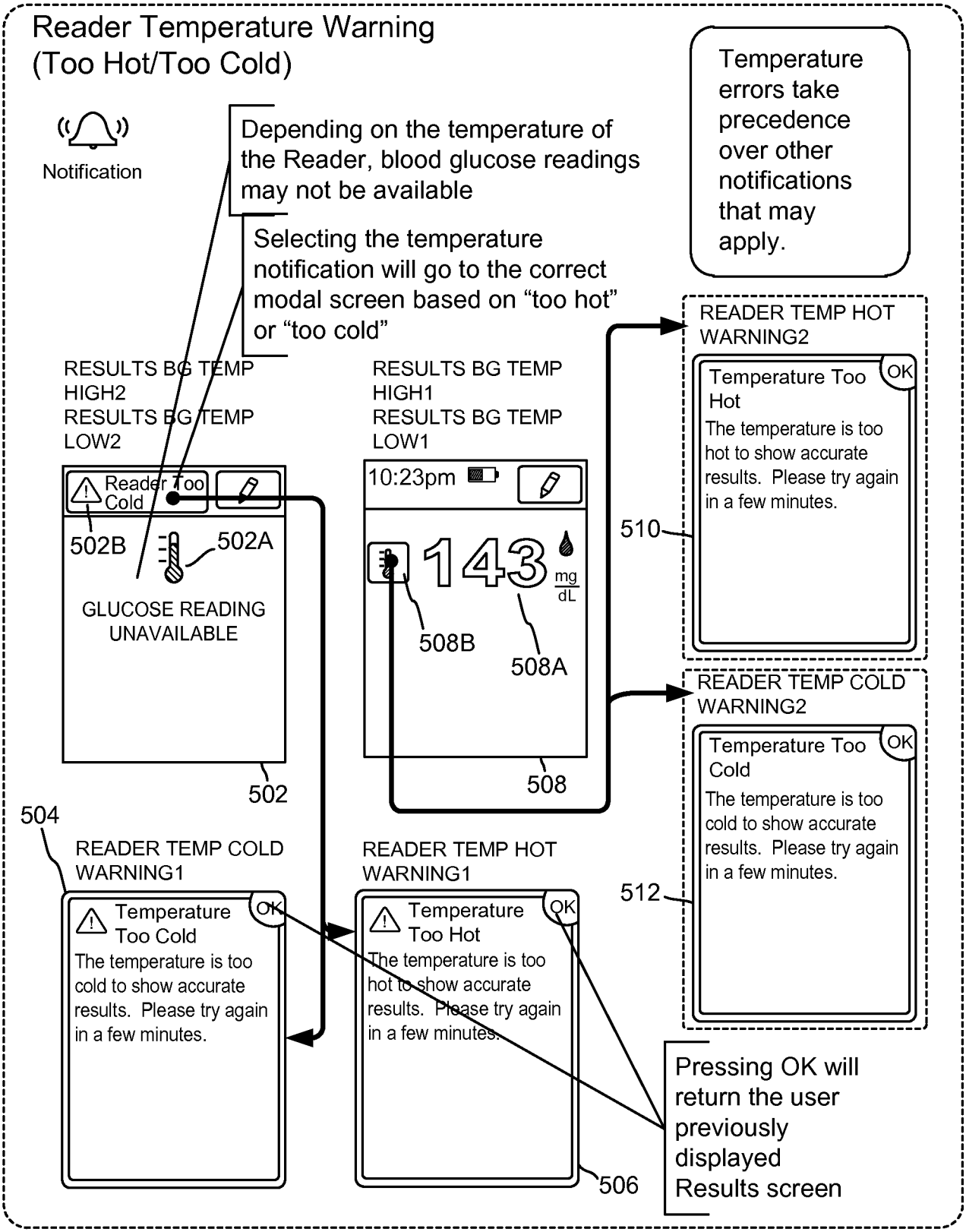

Reader Temperature Warning
(Too Hot/Too Cold)
Notification
Depending on the temperature of the Reader, blood glucose readings may not be available
Selecting the temperature notification will go to the correct modal screen based on "too hot" or "too cold"
Temperature errors take precedence over other notifications that may apply.
RESULTS BG TEMP HIGH2
RESULTS BG TEMP LOW2
Reader Too Cold
502B
502A
GLUCOSE READING UNAVAILABLE
502
RESULTS BG TEMP HIGH1
RESULTS BG TEMP LOW1
10:23pm
143
mg dL
508B
508A
508
READER TEMP HOT WARNING2
Temperature Too Hot
OK
The temperature is too hot to show accurate results. Please try again in a few minutes.
510
READER TEMP COLD WARNING2
Temperature Too Cold
OK
The temperature is too cold to show accurate results. Please try again in a few minutes.
512
504
READER TEMP COLD WARNING1
Temperature Too Cold
OK
The temperature is too cold to show accurate results. Please try again in a few minutes.
READER TEMP HOT WARNING1
Temperature Too Hot
OK
The temperature is too hot to show accurate results. Please try again in a few minutes.
506
Pressing OK will return the user previously displayed Results screen

FIG. 12C

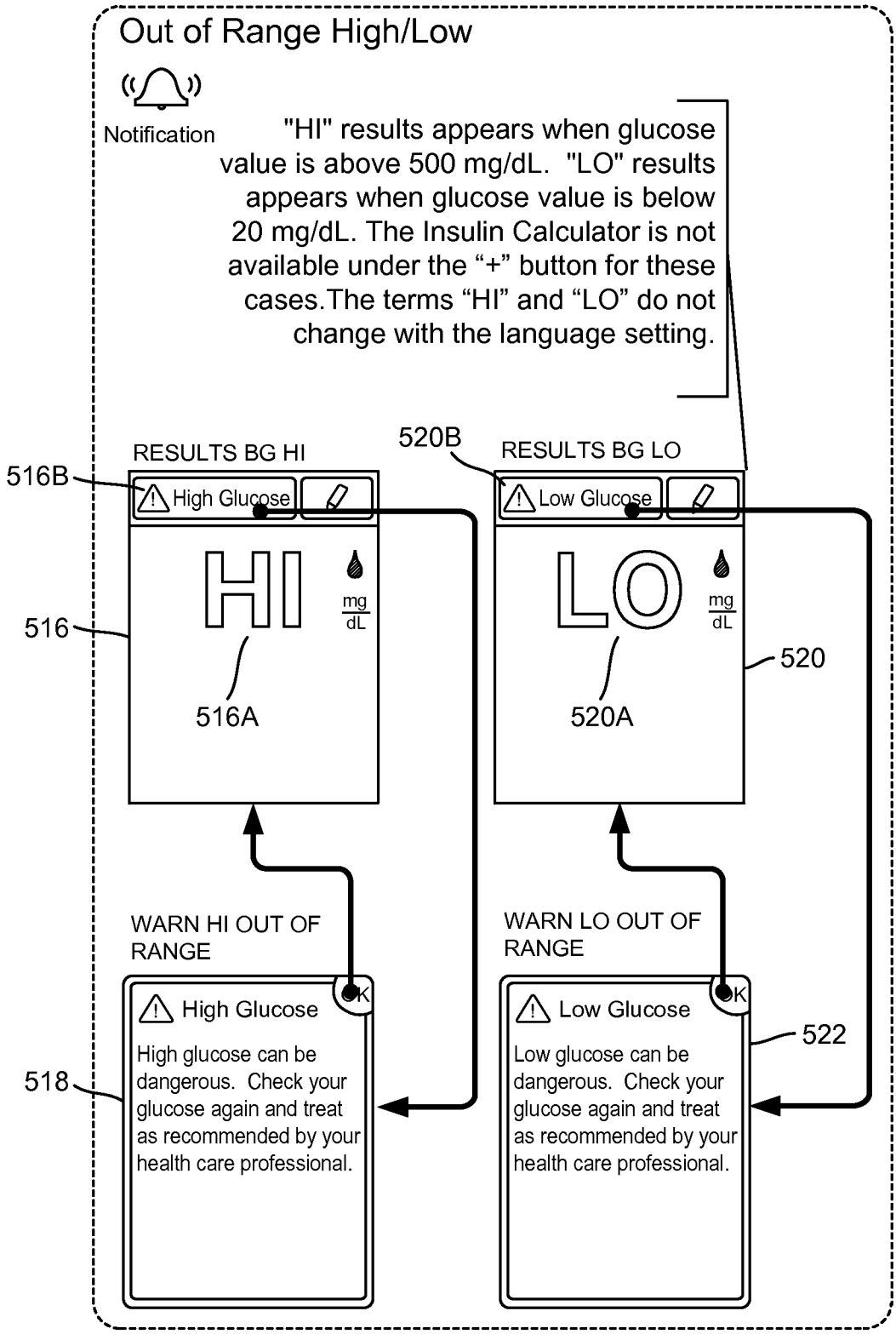


FIG. 12D FIG. 12E

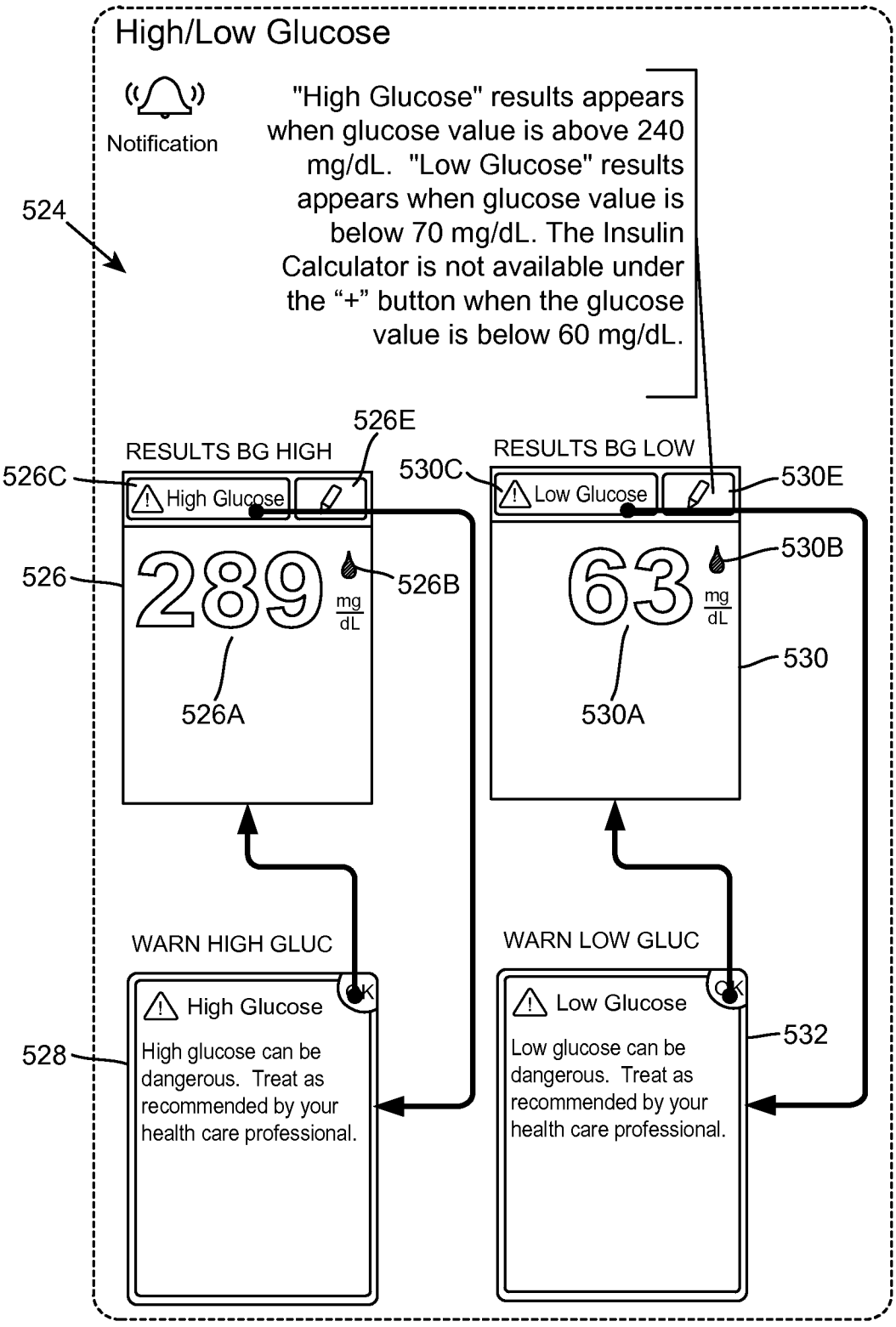


FIG. 12F FIG. 12G

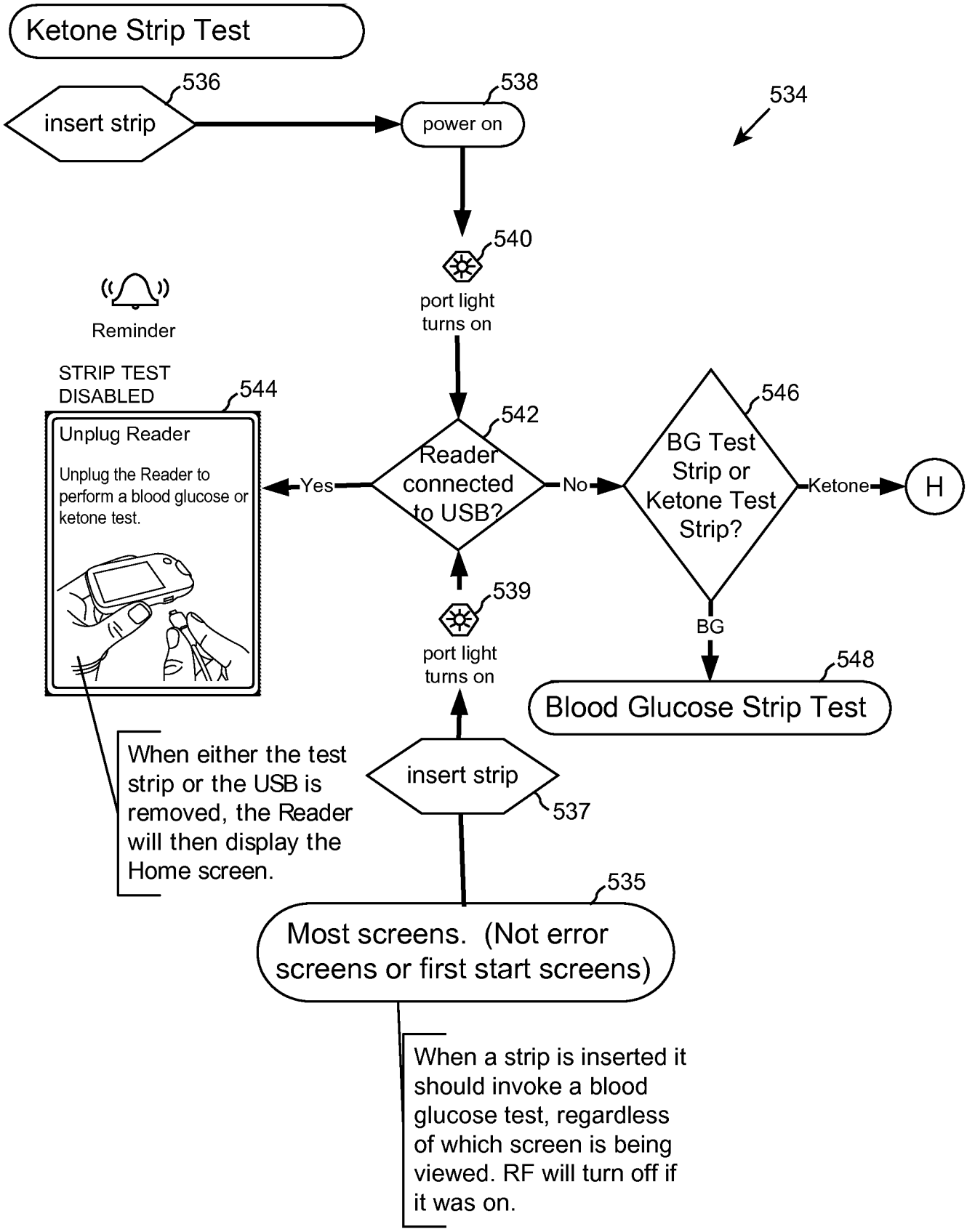

Ketone Strip Test
536
insert strip
538
power on
534
540
port light turns on
Reminder
STRIP TEST DISABLED
544
Unplug Reader
Unplug the Reader to perform a blood glucose or ketone test.
542
Reader connected to USB?
Yes
No
546
BG Test Strip or Ketone Test Strip?
Ketone
H
539
port light turns on
BG
548
Blood Glucose Strip Test
When either the test strip or the USB is removed, the Reader will then display the Home screen.
insert strip
537
535
Most screens. (Not error screens or first start screens)
When a strip is inserted it should invoke a blood glucose test, regardless of which screen is being viewed. RF will turn off if it was on.

FIG. 13

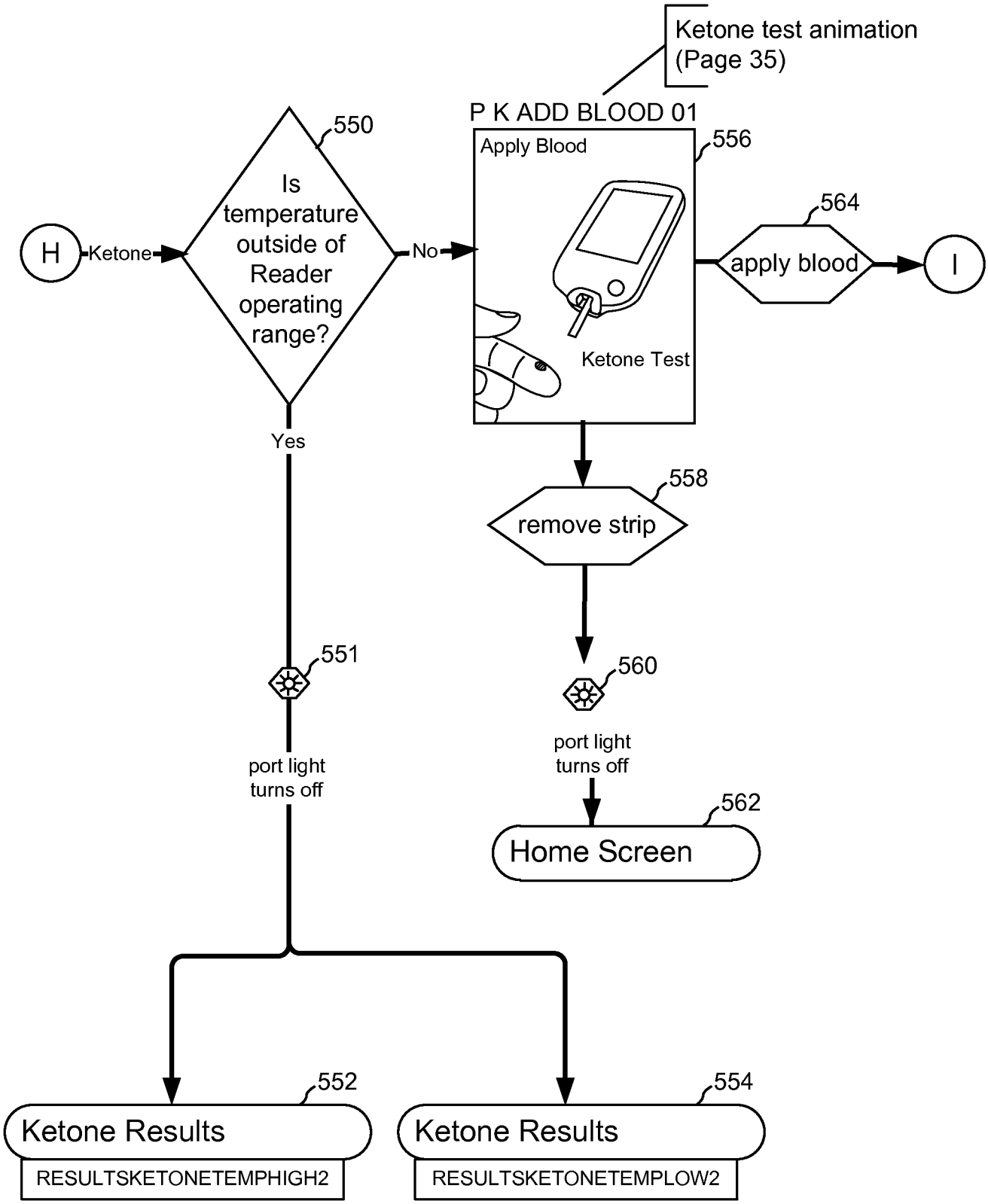

Ketone test animation
(Page 35)
P K ADD BLOOD 01
550
Is temperature outside of Reader operating range?
H
Ketone
No
Yes
Apply Blood
556
Ketone Test
564
apply blood
I
558
remove strip
560
port light turns off
551
port light turns off
562
Home Screen
552
Ketone Results
RESULTSKETONETEMPHIGH2
554
Ketone Results
RESULTSKETONETEMPLOW2

FIG. 13 (Cont)

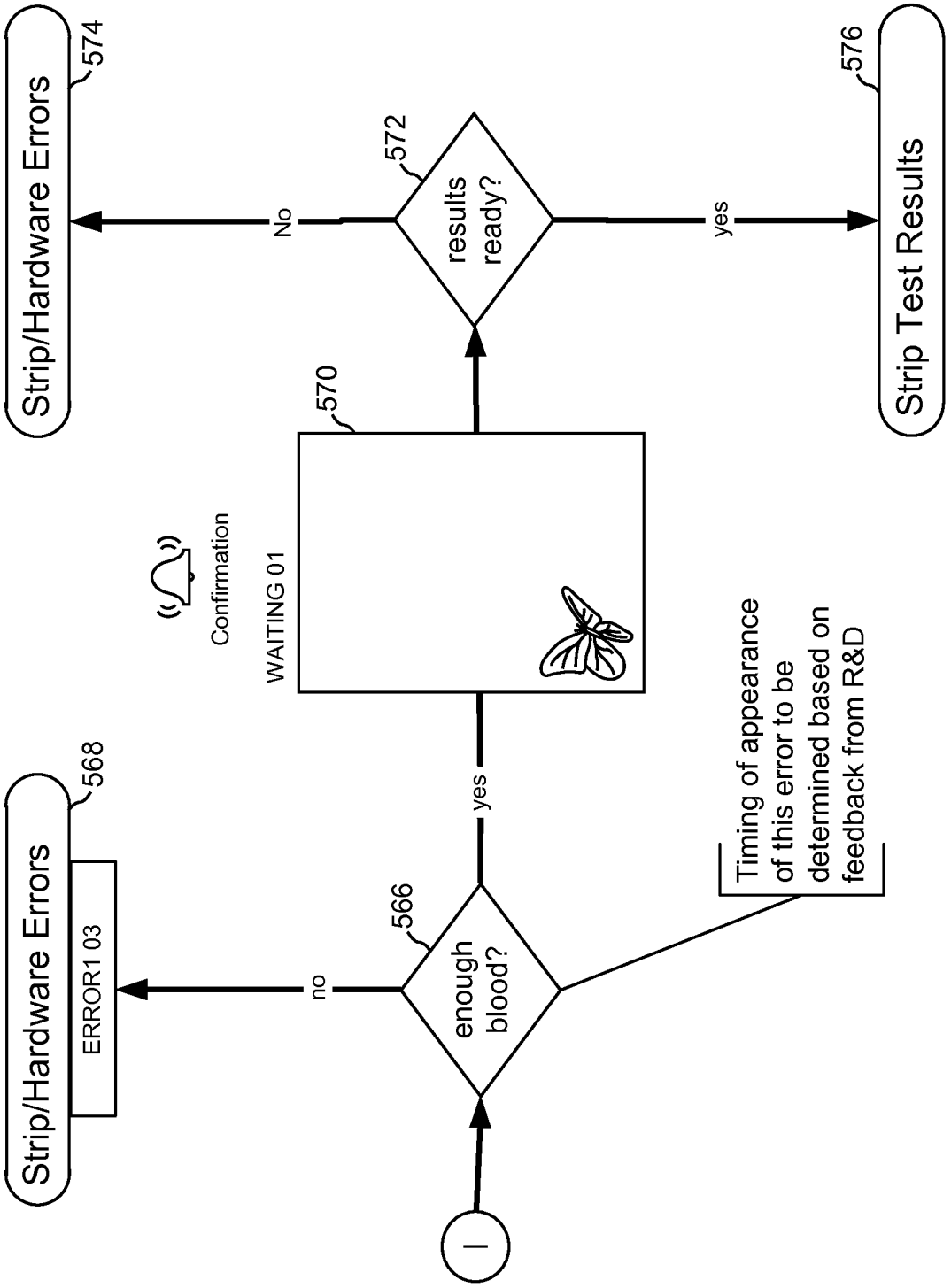

Strip/Hardware Errors
574
No
572
results ready?
yes
576
Strip Test Results
570
Confirmation
WAITING 01
Strip/Hardware Errors
568
ERROR1 03
no
566
enough blood?
yes
Timing of appearance of this error to be determined based on feedback from R&D
I

FIG. 13 (Cont)

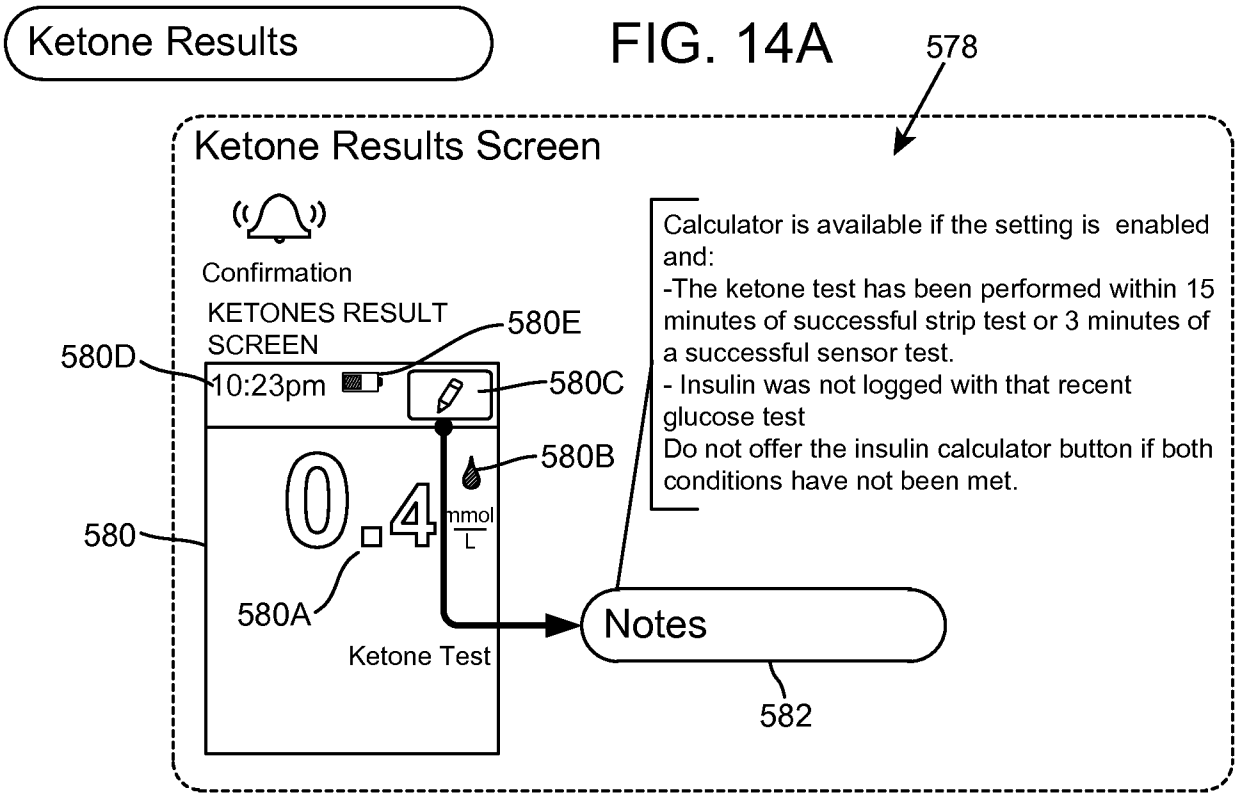
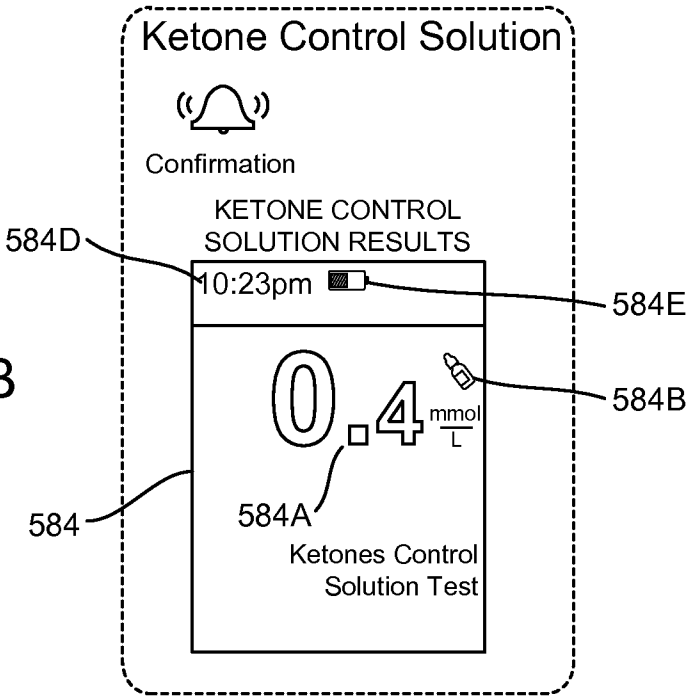

Ketone Results
FIG. 14A
578
Ketone Results Screen
Confirmation
KETONES RESULT SCREEN
580D
580E
10:23pm
580C
580B
0.4
mmol/L
580
580A
Ketone Test
Notes
582
Calculator is available if the setting is enabled and:
-The ketone test has been performed within 15 minutes of successful strip test or 3 minutes of a successful sensor test.
- Insulin was not logged with that recent glucose test
Do not offer the insulin calculator button if both conditions have not been met.

FIG. 14B


Ketone Control Solution
Confirmation
KETONE CONTROL SOLUTION RESULTS
584D
10:23pm
584E
584B
0.4
mmol/L
584
584A
Ketones Control Solution Test

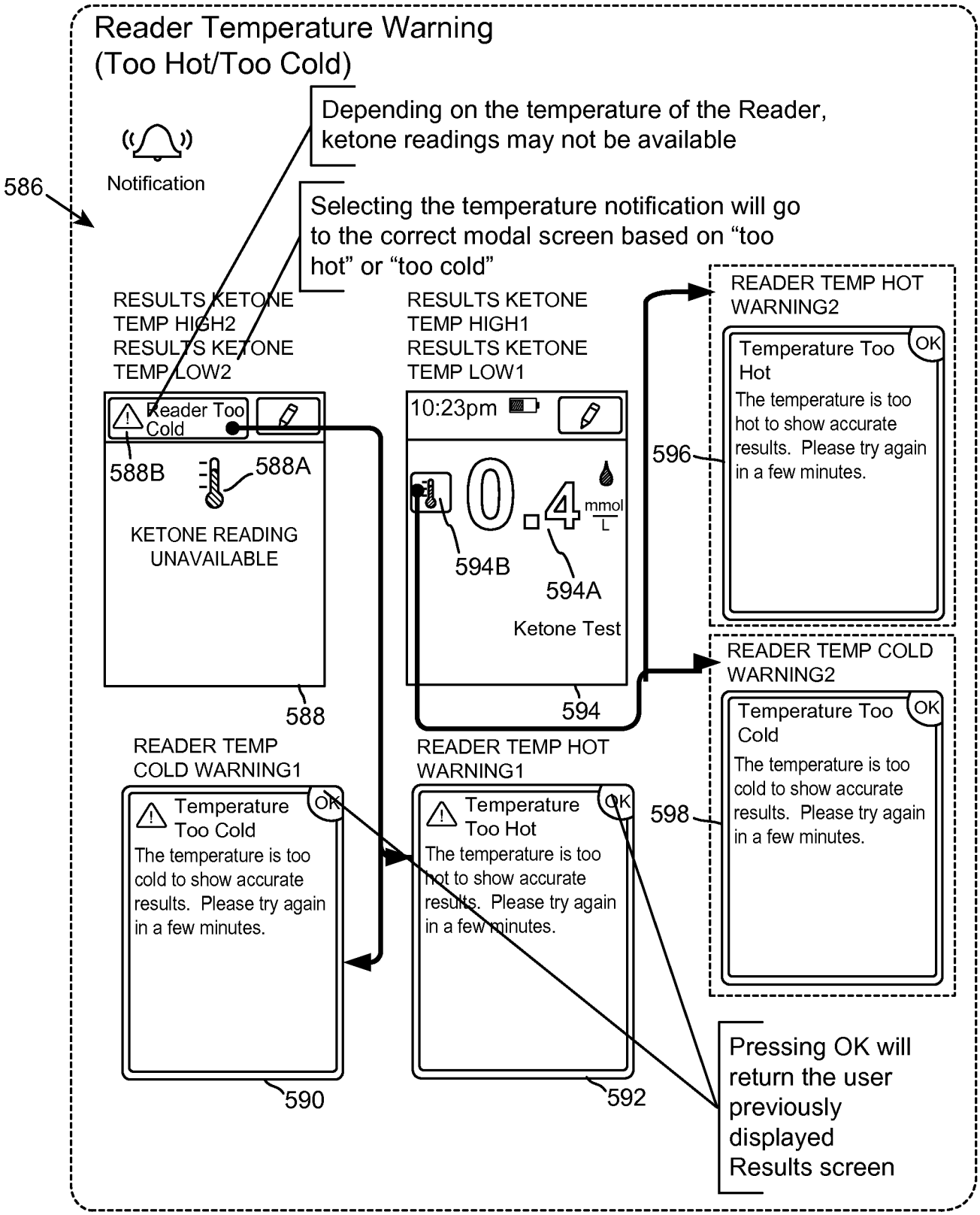

Reader Temperature Warning
(Too Hot/Too Cold)
Depending on the temperature of the Reader, ketone readings may not be available
Notification
586
Selecting the temperature notification will go to the correct modal screen based on "too hot" or "too cold"
RESULTS KETONE TEMP HIGH2
RESULTS KETONE TEMP LOW2
Reader Too Cold
588B
588A
KETONE READING UNAVAILABLE
588
RESULTS KETONE TEMP HIGH1
RESULTS KETONE TEMP LOW1
10:23pm
0.4 mmol/L
594B
594A
Ketone Test
594
READER TEMP HOT WARNING2
Temperature Too Hot
OK
The temperature is too hot to show accurate results. Please try again in a few minutes.
596
READER TEMP COLD WARNING2
Temperature Too Cold
OK
The temperature is too cold to show accurate results. Please try again in a few minutes.
598
READER TEMP COLD WARNING1
Temperature Too Cold
OK
The temperature is too cold to show accurate results. Please try again in a few minutes.
590
READER TEMP HOT WARNING1
Temperature Too Hot
OK
The temperature is too hot to show accurate results. Please try again in a few minutes.
592
Pressing OK will return the user previously displayed Results screen

FIG. 14C

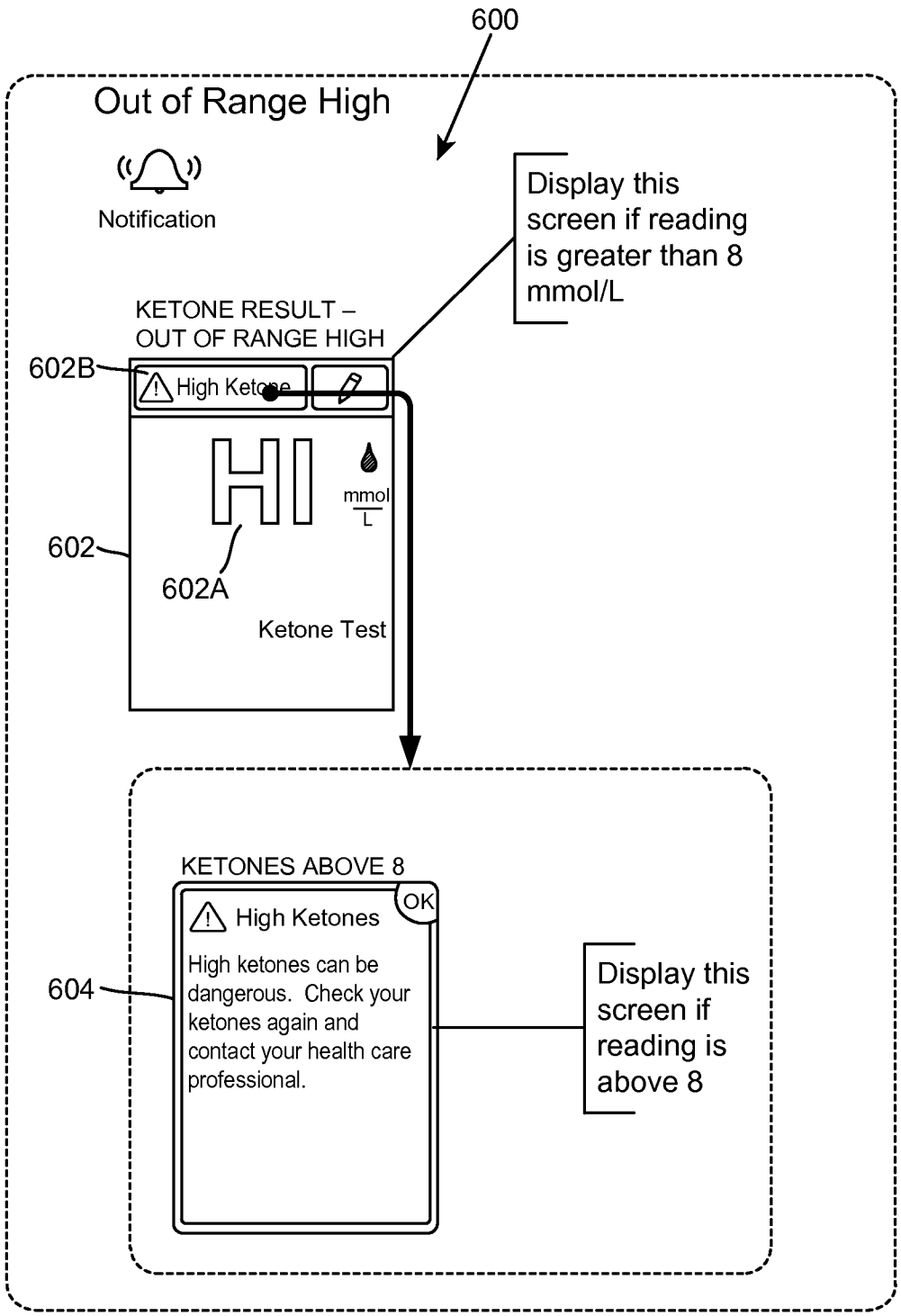

600
Out of Range High
Notification
Display this screen if reading is greater than 8 mmol/L
KETONE RESULT – OUT OF RANGE HIGH
602B
High Ketone
HI
mmol/L
602
602A
Ketone Test
KETONES ABOVE 8
OK
High Ketones
High ketones can be dangerous. Check your ketones again and contact your health care professional.
604
Display this screen if reading is above 8

FIG. 14D

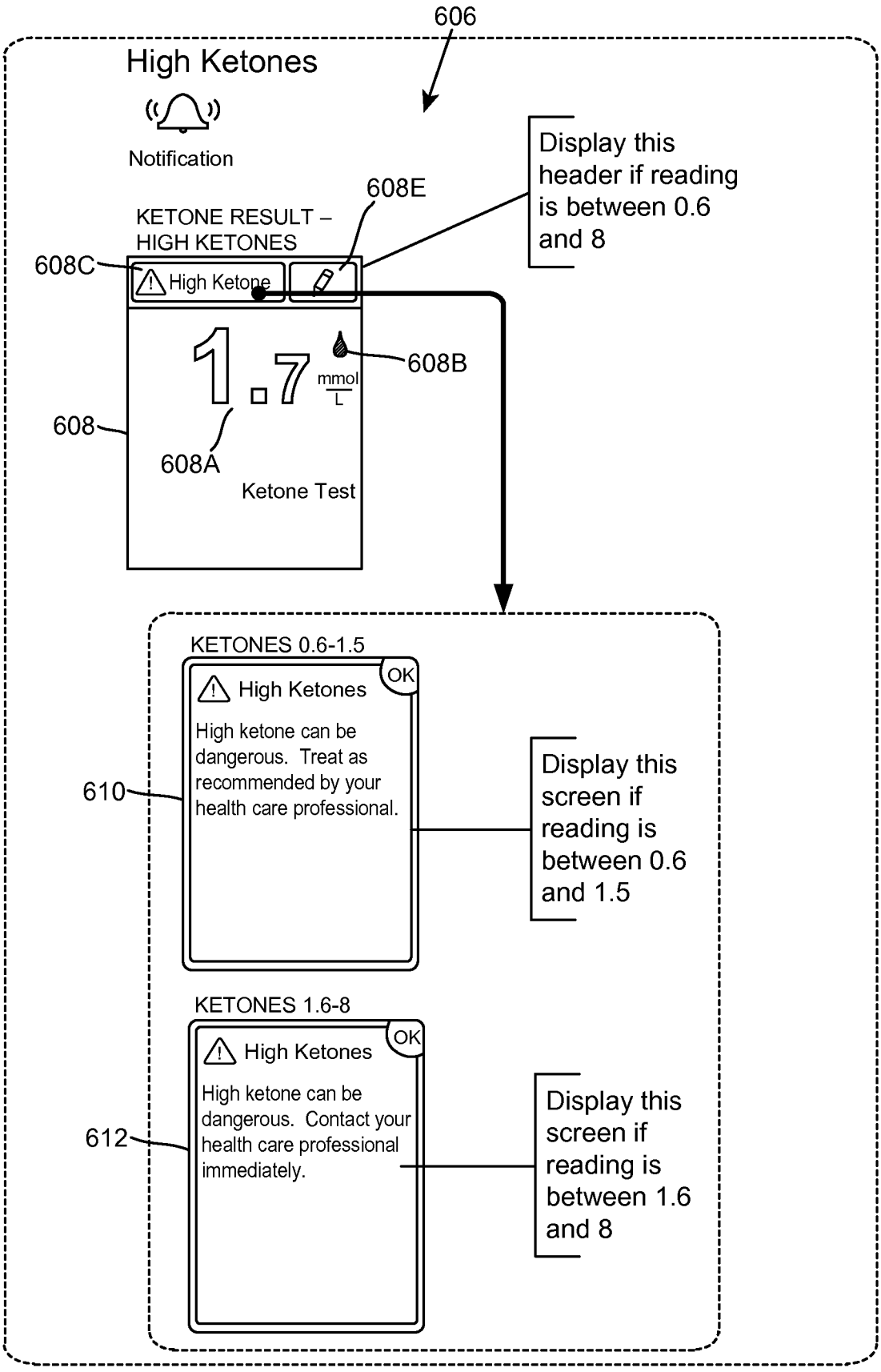

606
High Ketones
Notification
Display this header if reading is between 0.6 and 8
608E
KETONE RESULT – HIGH KETONES
608C
High Ketone
1.7
mmol/L
608B
608
608A
Ketone Test
KETONES 0.6-1.5
OK
High Ketones
High ketone can be dangerous. Treat as recommended by your health care professional.
610
Display this screen if reading is between 0.6 and 1.5
KETONES 1.6-8
OK
High Ketones
High ketone can be dangerous. Contact your health care professional immediately.
612
Display this screen if reading is between 1.6 and 8

FIG. 14E

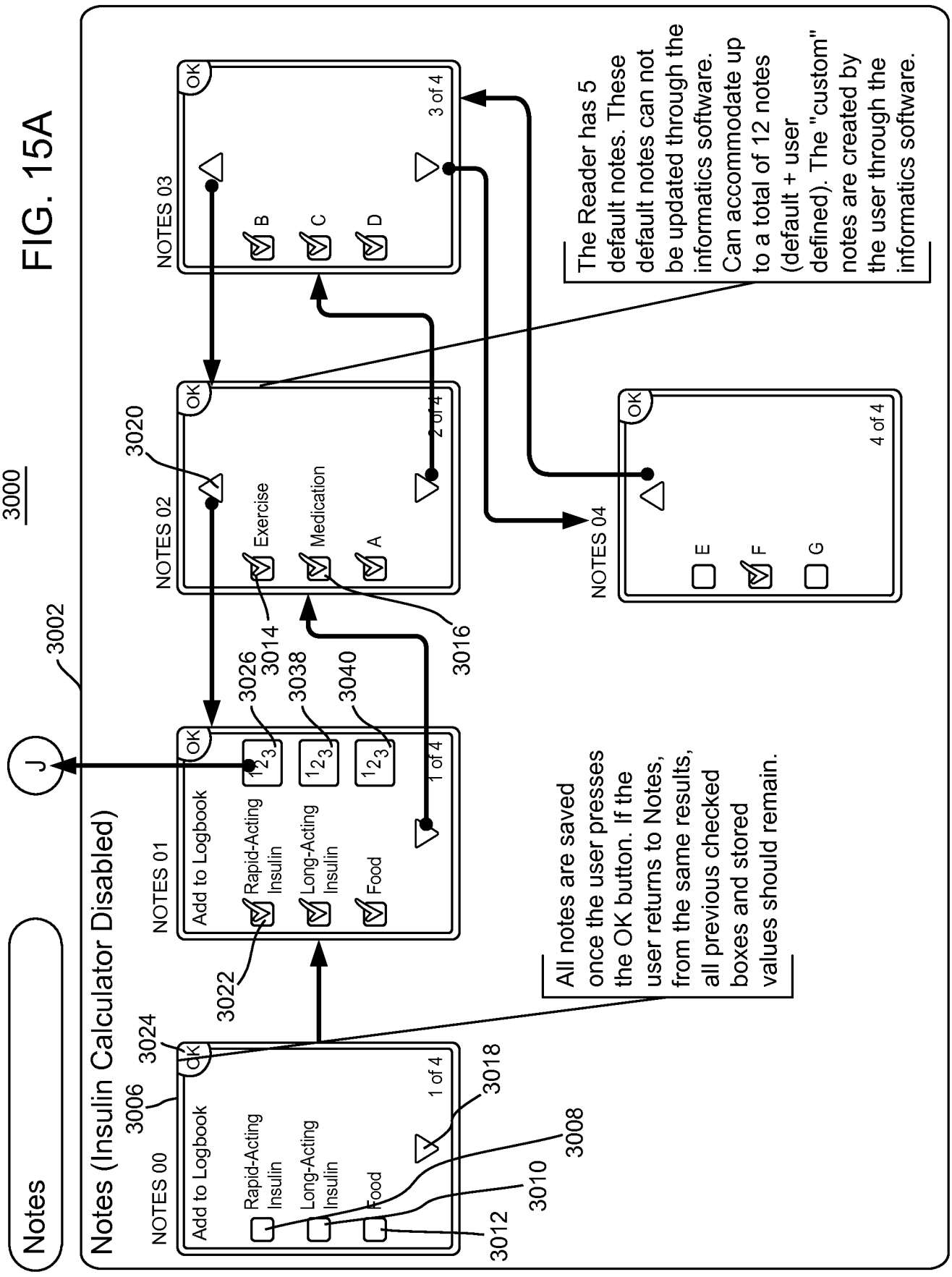

Notes
3000
Notes (Insulin Calculator Disabled)
3002
J
NOTES 00
Add to Logbook
Rapid-Acting Insulin
Long-Acting Insulin
Food
1 of 4
3006
3024
OK
3018
3008
3010
3012
NOTES 01
Add to Logbook
Rapid-Acting Insulin
Long-Acting Insulin
Food
1 of 4
3022
3026
3014
3038
3040
3016
NOTES 02
Exercise
Medication
A
2 of 4
3020
NOTES 03
B
C
D
3 of 4
NOTES 04
E
F
G
4 of 4
All notes are saved once the user presses the OK button. If the user returns to Notes, from the same results, all previous checked boxes and stored values should remain.
The Reader has 5 default notes. These default notes can not be updated through the informatics software. Can accommodate up to a total of 12 notes (default + user defined). The "custom" notes are created by the user through the informatics software.

FIG. 15A

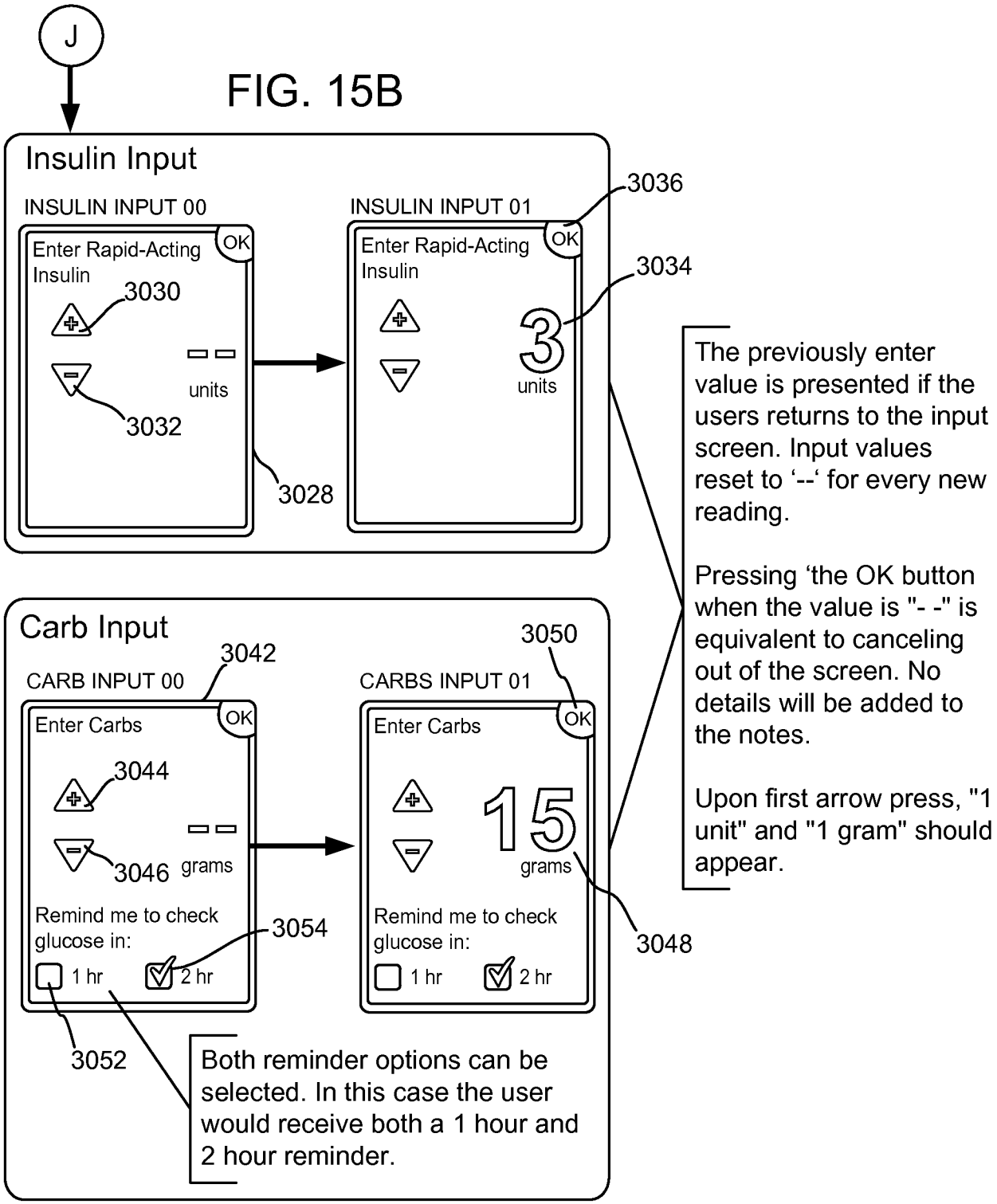


FIG. 15B

FIG. 15C

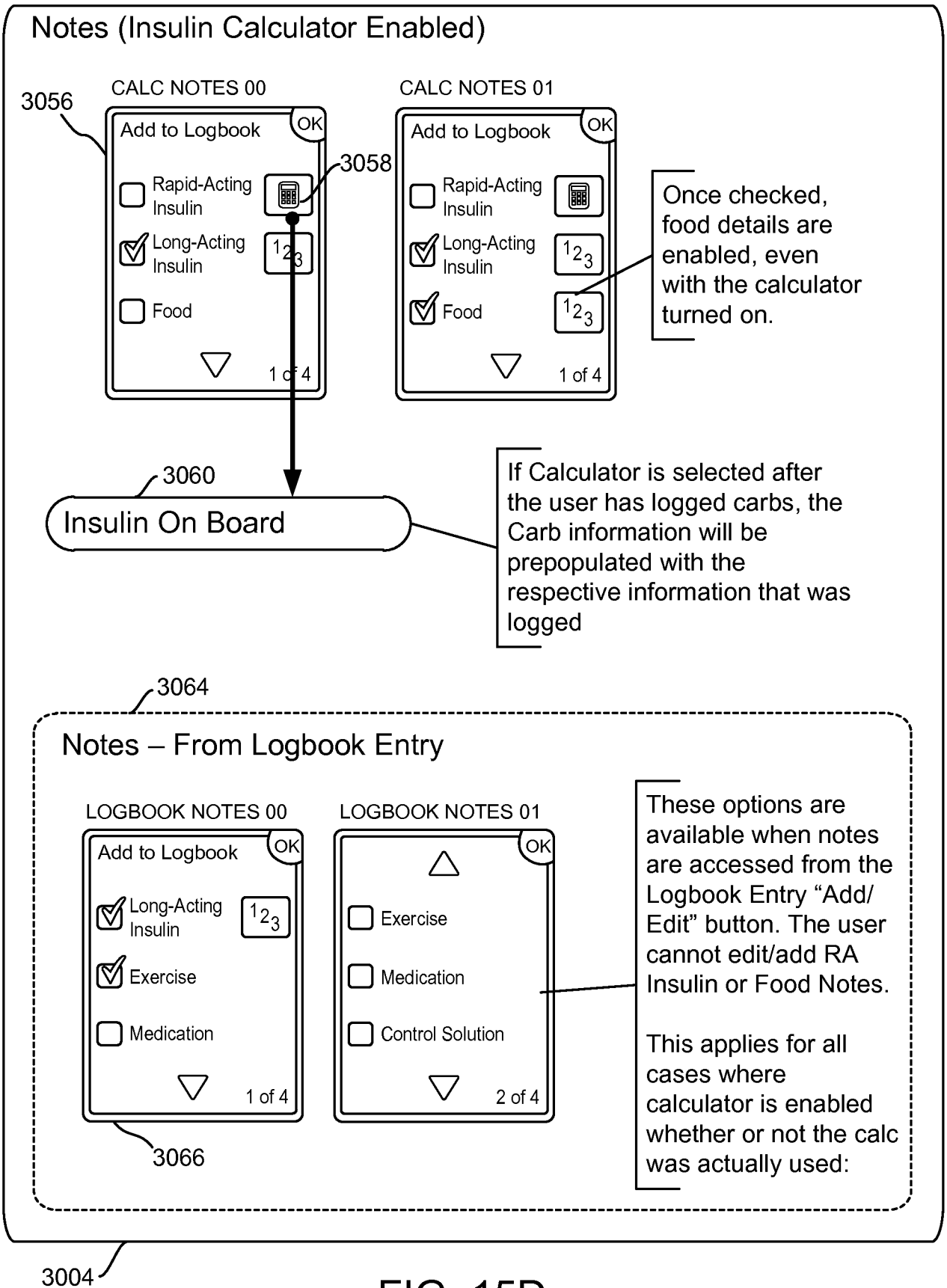

Notes (Insulin Calculator Enabled)
3056
CALC NOTES 00
Add to Logbook
OK
Rapid-Acting Insulin
Long-Acting Insulin
Food
1 of 4
3058
CALC NOTES 01
Add to Logbook
OK
Rapid-Acting Insulin
Long-Acting Insulin
Food
1 of 4
Once checked, food details are enabled, even with the calculator turned on.
3060
Insulin On Board
If Calculator is selected after the user has logged carbs, the Carb information will be prepopulated with the respective information that was logged
3064
Notes – From Logbook Entry
LOGBOOK NOTES 00
Add to Logbook
OK
Long-Acting Insulin
Exercise
Medication
1 of 4
3066
LOGBOOK NOTES 01
OK
Exercise
Medication
Control Solution
2 of 4
These options are available when notes are accessed from the Logbook Entry "Add/ Edit" button. The user cannot edit/add RA Insulin or Food Notes.
This applies for all cases where calculator is enabled whether or not the calc was actually used:
3004

FIG. 15D

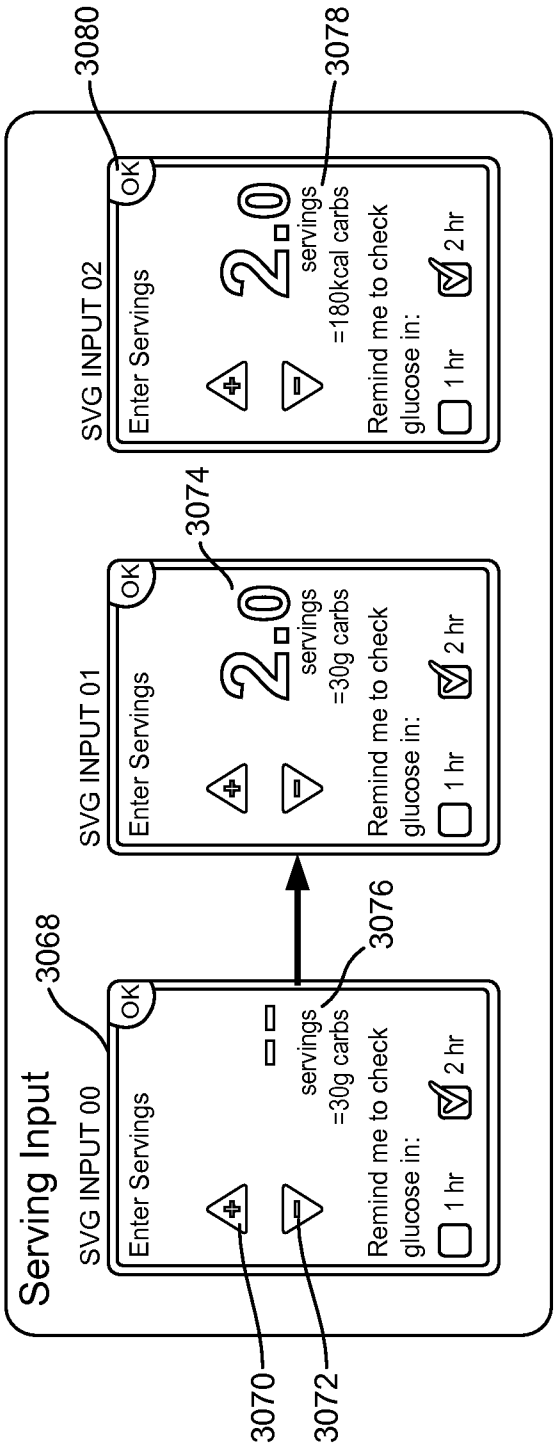

Serving Input
SVG INPUT 00
Enter Servings
servings
=30g carbs
Remind me to check glucose in:
1 hr
2 hr
OK
SVG INPUT 01
Enter Servings
2.0
servings
=30g carbs
Remind me to check glucose in:
1 hr
2 hr
OK
SVG INPUT 02
Enter Servings
2.0
servings
=180kcal carbs
Remind me to check glucose in:
1 hr
2 hr
OK
3068
3070
3072
3074
3076
3078
3080

FIG. 15E

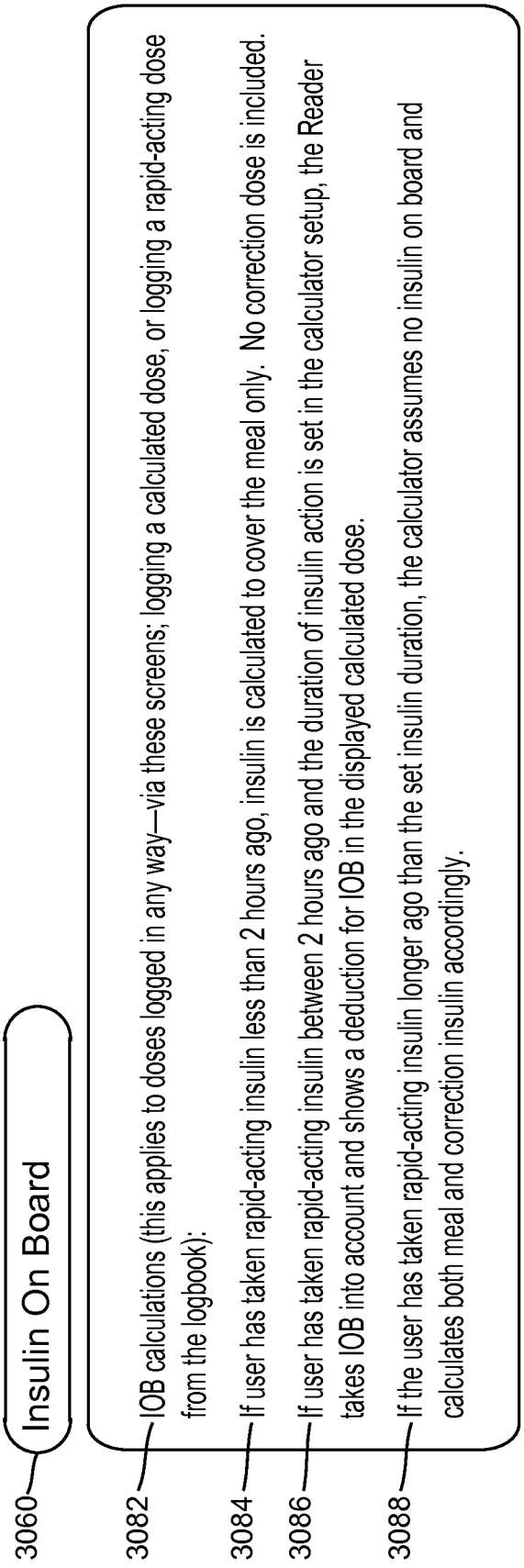

3060
Insulin On Board
3082
IOB calculations (this applies to doses logged in any way—via these screens; logging a calculated dose, or logging a rapid-acting dose from the logbook):
3084
If user has taken rapid-acting insulin less than 2 hours ago, insulin is calculated to cover the meal only. No correction dose is included.
3086
If user has taken rapid-acting insulin between 2 hours ago and the duration of insulin action is set in the calculator setup, the Reader takes IOB into account and shows a deduction for IOB in the displayed calculated dose.
3088
If the user has taken rapid-acting insulin longer ago than the set insulin duration, the calculator assumes no insulin on board and calculates both meal and correction insulin accordingly.

FIG. 16A

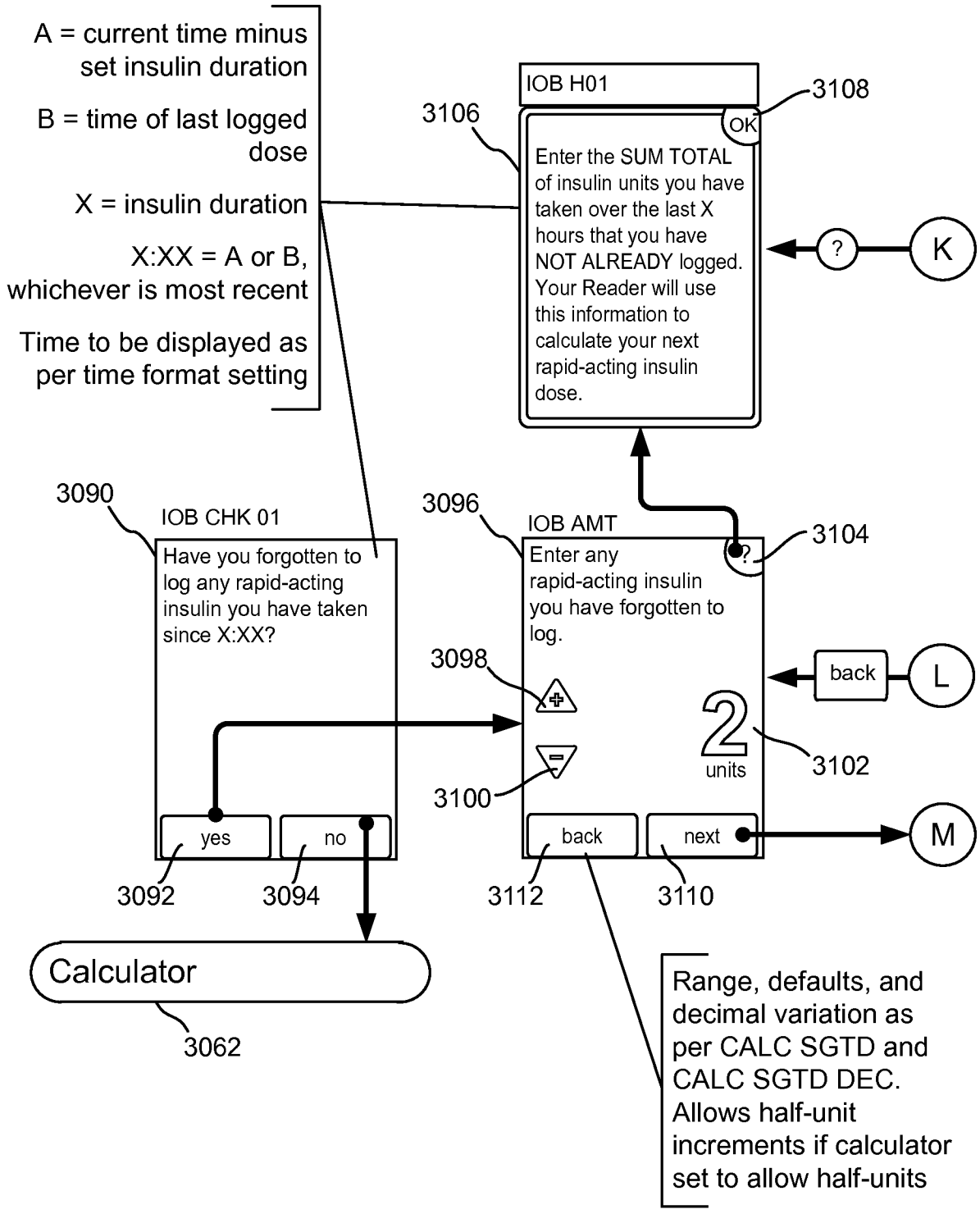

A = current time minus set insulin duration
B = time of last logged dose
X = insulin duration
X:XX = A or B, whichever is most recent
Time to be displayed as per time format setting
IOB H01
3106
3108
OK
Enter the SUM TOTAL of insulin units you have taken over the last X hours that you have NOT ALREADY logged. Your Reader will use this information to calculate your next rapid-acting insulin dose.
?
K
3090
IOB CHK 01
Have you forgotten to log any rapid-acting insulin you have taken since X:XX?
3096
IOB AMT
Enter any rapid-acting insulin you have forgotten to log.
?
3104
3098
back
L
2
units
3102
3100
yes
no
back
next
M
3092
3094
3112
3110
Calculator
3062
Range, defaults, and decimal variation as per CALC SGTD and CALC SGTD DEC. Allows half-unit increments if calculator set to allow half-units

FIG. 16B

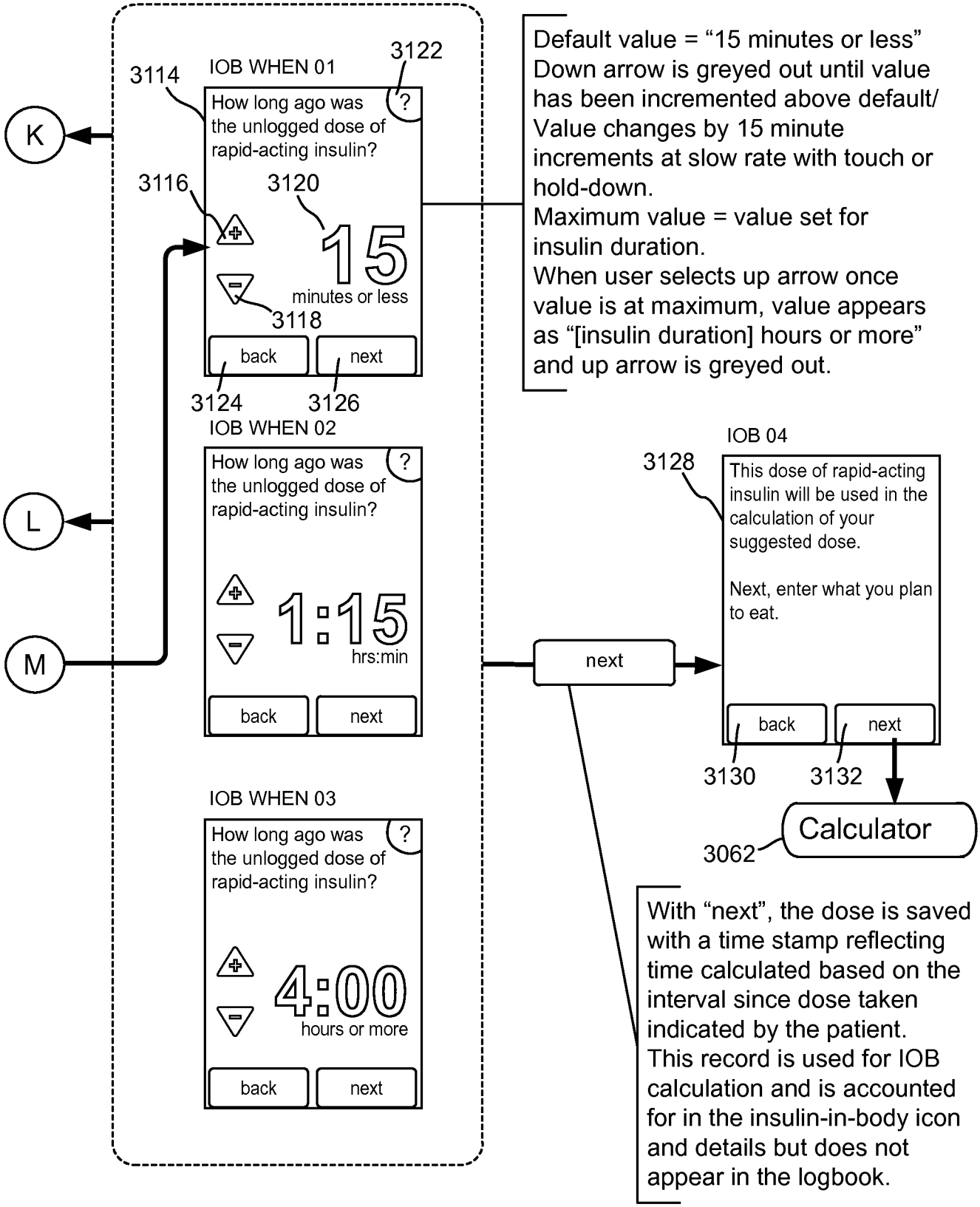
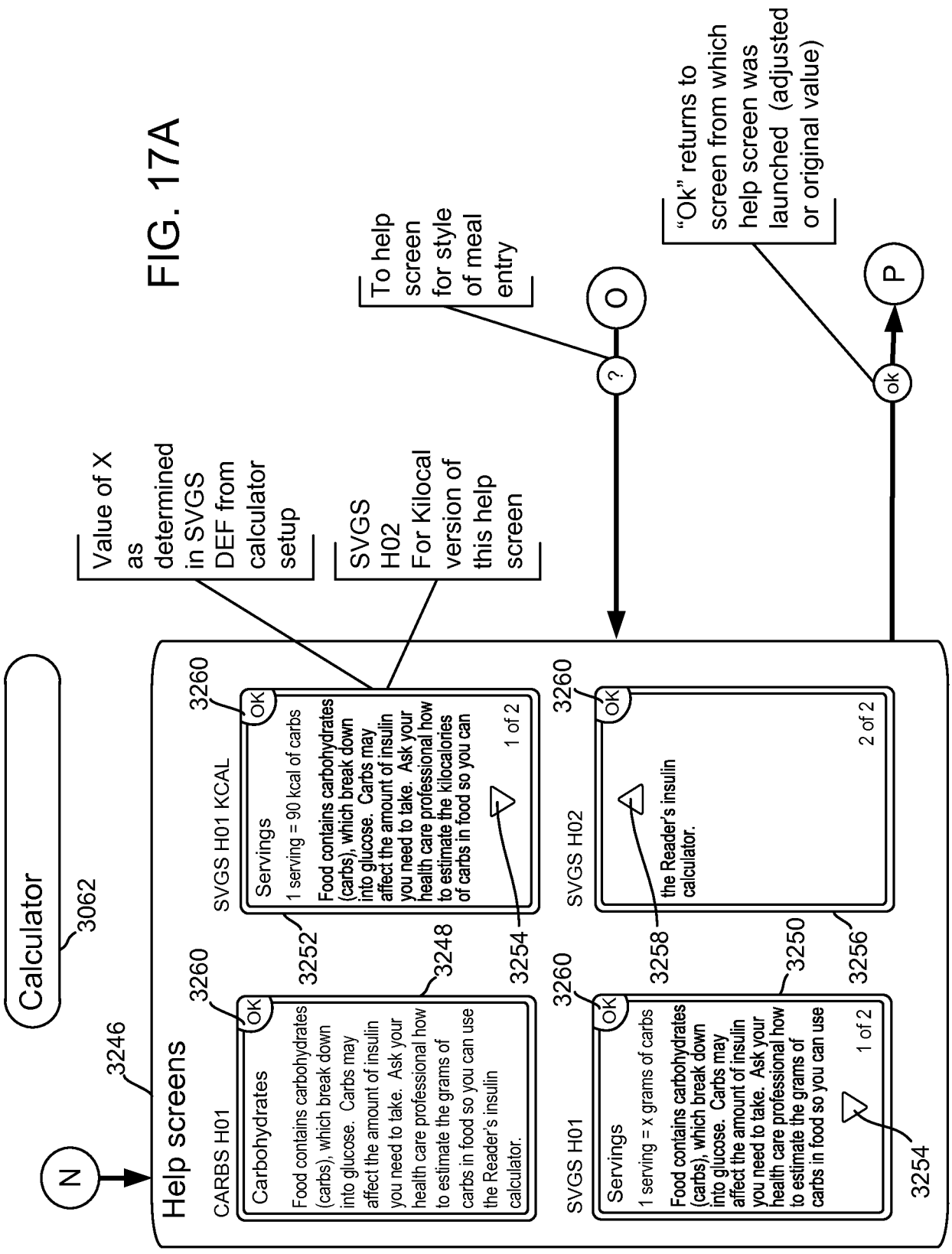

K
L
M
3114
IOB WHEN 01
3122
How long ago was the unlogged dose of rapid-acting insulin?
?
3116
3120
15
minutes or less
3118
back
next
3124
3126
IOB WHEN 02
How long ago was the unlogged dose of rapid-acting insulin?
?
1:15
hrs:min
back
next
IOB WHEN 03
How long ago was the unlogged dose of rapid-acting insulin?
?
4:00
hours or more
back
next
Default value = “15 minutes or less”
Down arrow is greyed out until value has been incremented above default/
Value changes by 15 minute increments at slow rate with touch or hold-down.
Maximum value = value set for insulin duration.
When user selects up arrow once value is at maximum, value appears as “[insulin duration] hours or more” and up arrow is greyed out.
next
IOB 04
3128
This dose of rapid-acting insulin will be used in the calculation of your suggested dose.
Next, enter what you plan to eat.
back
next
3130
3132
Calculator
3062
With “next”, the dose is saved with a time stamp reflecting time calculated based on the interval since dose taken indicated by the patient.
This record is used for IOB calculation and is accounted for in the insulin-in-body icon and details but does not appear in the logbook.

FIG. 16C

FIG. 17A


Calculator
3062
N
3246
Help screens
CARBS H01
3260
OK
Carbohydrates
Food contains carbohydrates (carbs), which break down into glucose. Carbs may affect the amount of insulin you need to take. Ask your health care professional how to estimate the grams of carbs in food so you can use the Reader's insulin calculator.
3248
SVGS H01 KCAL
3260
OK
Servings
1 serving = 90 kcal of carbs
Food contains carbohydrates (carbs), which break down into glucose. Carbs may affect the amount of insulin you need to take. Ask your health care professional how to estimate the kilocalories of carbs in food so you can
1 of 2
3252
3254
Value of X as determined in SVGS DEF from calculator setup
SVGS H02 For Kilocal version of this help screen
To help screen for style of meal entry
?
O
SVGS H01
3260
OK
Servings
1 serving = x grams of carbs
Food contains carbohydrates (carbs), which break down into glucose. Carbs may affect the amount of insulin you need to take. Ask your health care professional how to estimate the grams of carbs in food so you can use
1 of 2
3254
3250
SVGS H02
3260
OK
the Reader's insulin calculator.
2 of 2
3256
3258
"Ok" returns to screen from which help screen was launched (adjusted or original value)
ok
P

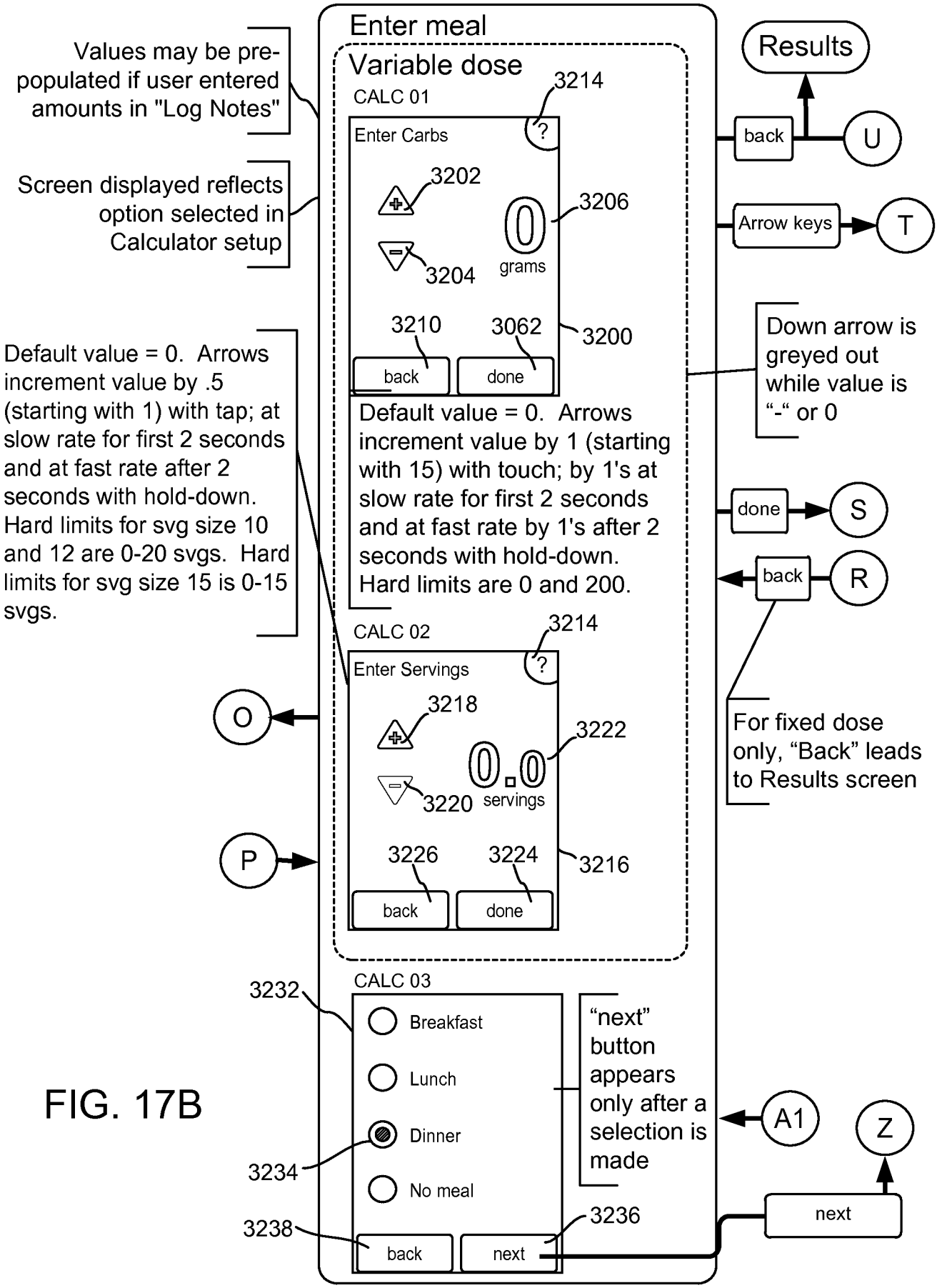
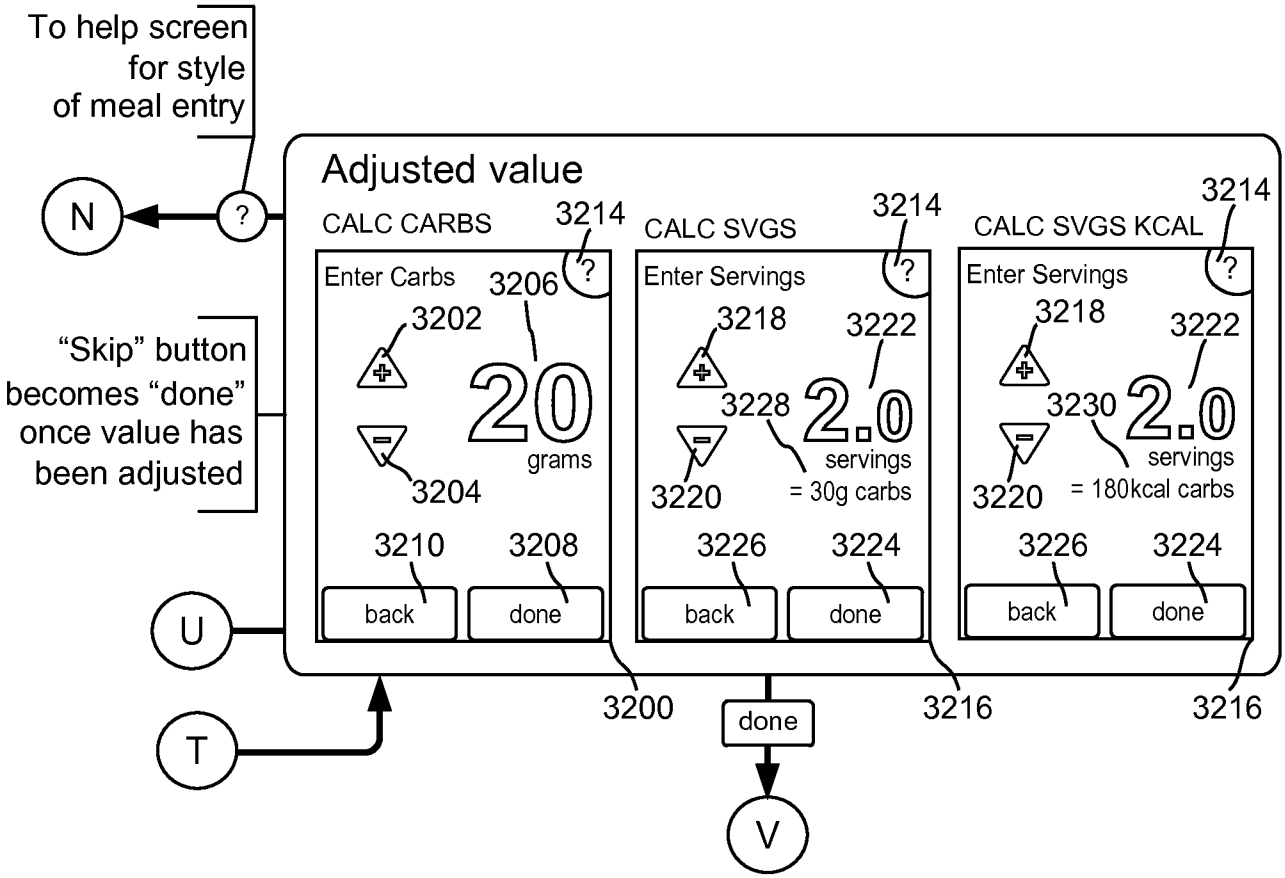

Enter meal
Variable dose
CALC 01
3214
Enter Carbs
3202
3206
0
grams
3204
3210
3062
3200
back
done
Default value = 0. Arrows increment value by 1 (starting with 15) with touch; by 1's at slow rate for first 2 seconds and at fast rate by 1's after 2 seconds with hold-down. Hard limits are 0 and 200.
CALC 02
3214
Enter Servings
3218
3222
0.0
servings
3220
3226
3224
3216
back
done
CALC 03
3232
Breakfast
Lunch
Dinner
No meal
3234
3238
3236
back
next
Values may be pre-populated if user entered amounts in "Log Notes"
Screen displayed reflects option selected in Calculator setup
Default value = 0. Arrows increment value by .5 (starting with 1) with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits for svg size 10 and 12 are 0-20 svgs. Hard limits for svg size 15 is 0-15 svgs.
Results
back
U
Arrow keys
T
Down arrow is greyed out while value is "-" or 0
done
S
back
R
For fixed dose only, "Back" leads to Results screen
O
P
"next" button appears only after a selection is made
A1
Z
next

FIG. 17B


To help screen for style of meal entry
"Skip" button becomes "done" once value has been adjusted
Adjusted value
CALC CARBS
CALC SVGS
CALC SVGS KCAL
Enter Carbs
Enter Servings
Enter Servings
3202
3204
3206
20
grams
3214
3218
3220
3222
3228
2.0
servings
= 30g carbs
3230
= 180kcal carbs
3208
3210
3224
3226
back
done
N
U
T
V
3200
3216

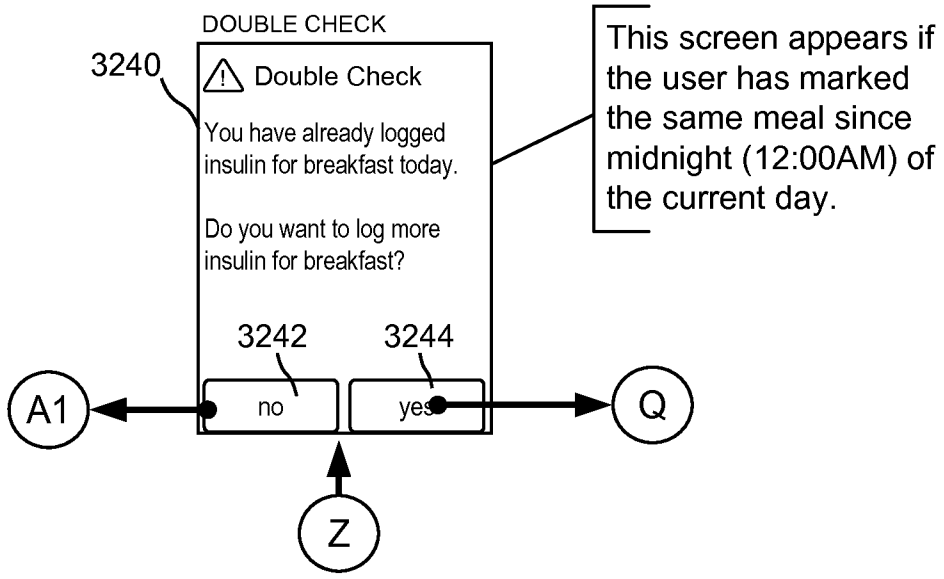

DOUBLE CHECK
3240
Double Check
You have already logged insulin for breakfast today.
Do you want to log more insulin for breakfast?
3242
3244
no
yes
A1
Q
Z
This screen appears if the user has marked the same meal since midnight (12:00AM) of the current day.

FIG. 17C

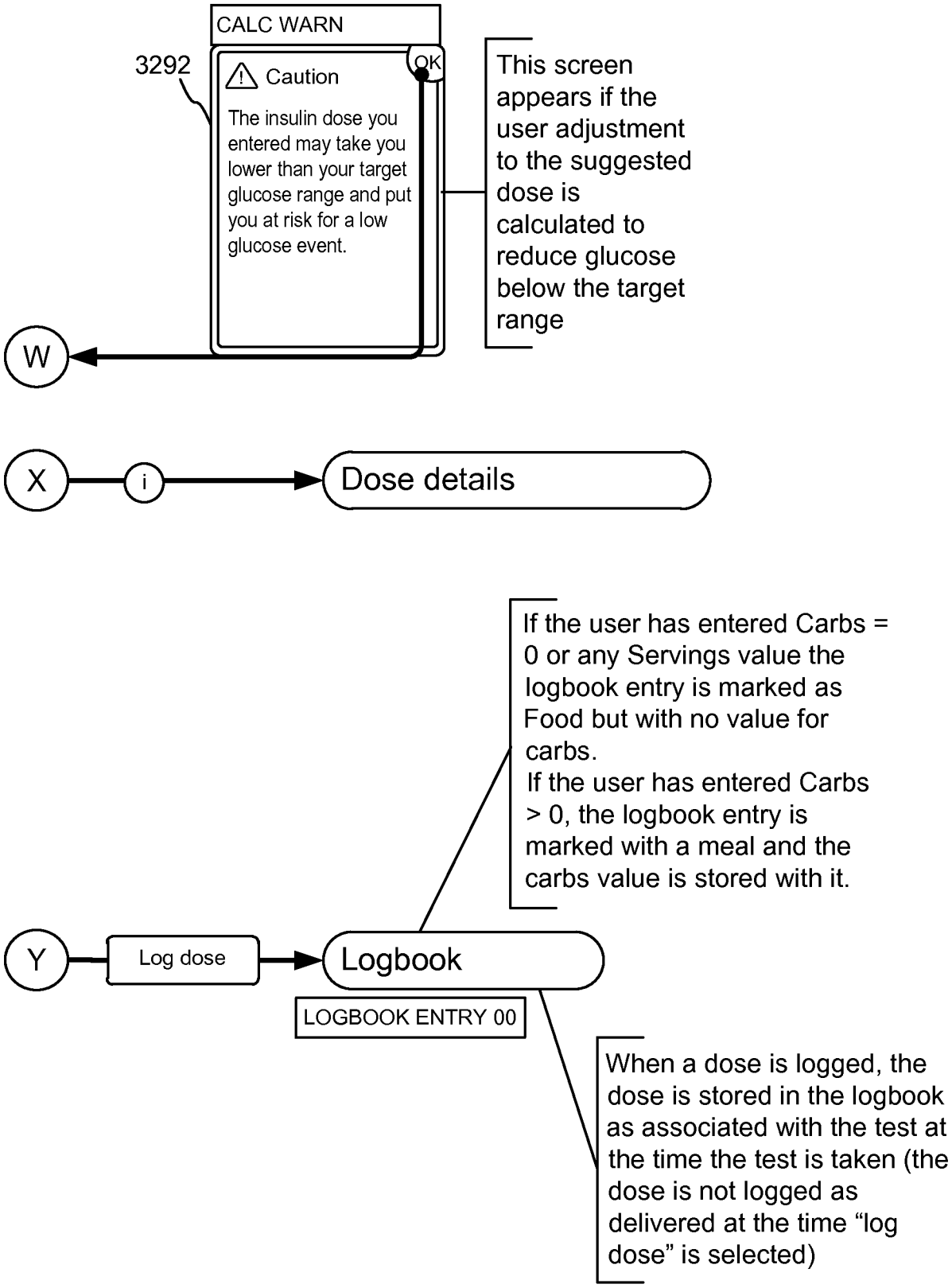

CALC WARN
3292
Caution
The insulin dose you entered may take you lower than your target glucose range and put you at risk for a low glucose event.
OK
This screen appears if the user adjustment to the suggested dose is calculated to reduce glucose below the target range
W
X
i
Dose details
If the user has entered Carbs = 0 or any Servings value the logbook entry is marked as Food but with no value for carbs.
If the user has entered Carbs > 0, the logbook entry is marked with a meal and the carbs value is stored with it.
Y
Log dose
Logbook
LOGBOOK ENTRY 00
When a dose is logged, the dose is stored in the logbook as associated with the test at the time the test is taken (the dose is not logged as delivered at the time “log dose” is selected)

FIG. 17D

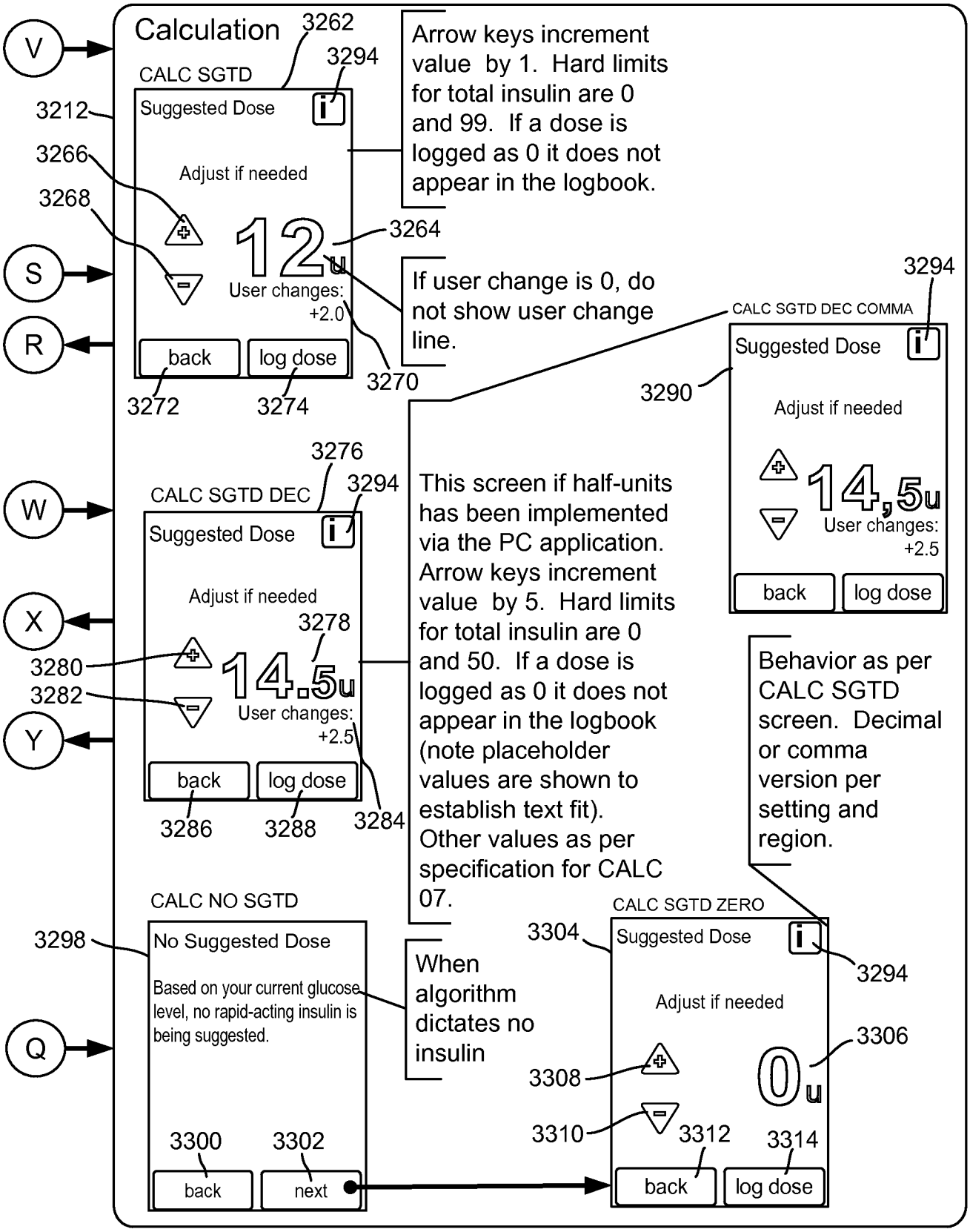

Calculation
3262
CALC SGTD
3294
Suggested Dose
3212
Adjust if needed
3266
3268
12u
3264
User changes:
+2.0
back
log dose
3272
3274
3270
V
S
R
Arrow keys increment value by 1. Hard limits for total insulin are 0 and 99. If a dose is logged as 0 it does not appear in the logbook.
If user change is 0, do not show user change line.
CALC SGTD DEC COMMA
3294
Suggested Dose
3290
Adjust if needed
14,5u
User changes:
+2.5
back
log dose
3276
CALC SGTD DEC
3294
Suggested Dose
Adjust if needed
3278
3280
14.5u
3282
User changes:
+2.5
back
log dose
3286
3288
3284
W
X
Y
This screen if half-units has been implemented via the PC application. Arrow keys increment value by 5. Hard limits for total insulin are 0 and 50. If a dose is logged as 0 it does not appear in the logbook (note placeholder values are shown to establish text fit). Other values as per specification for CALC 07.
Behavior as per CALC SGTD screen. Decimal or comma version per setting and region.
CALC NO SGTD
3298
No Suggested Dose
Based on your current glucose level, no rapid-acting insulin is being suggested.
3300
3302
back
next
Q
When algorithm dictates no insulin
CALC SGTD ZERO
3304
Suggested Dose
3294
Adjust if needed
3306
3308
0u
3310
3312
3314
back
log dose

FIG. 17E

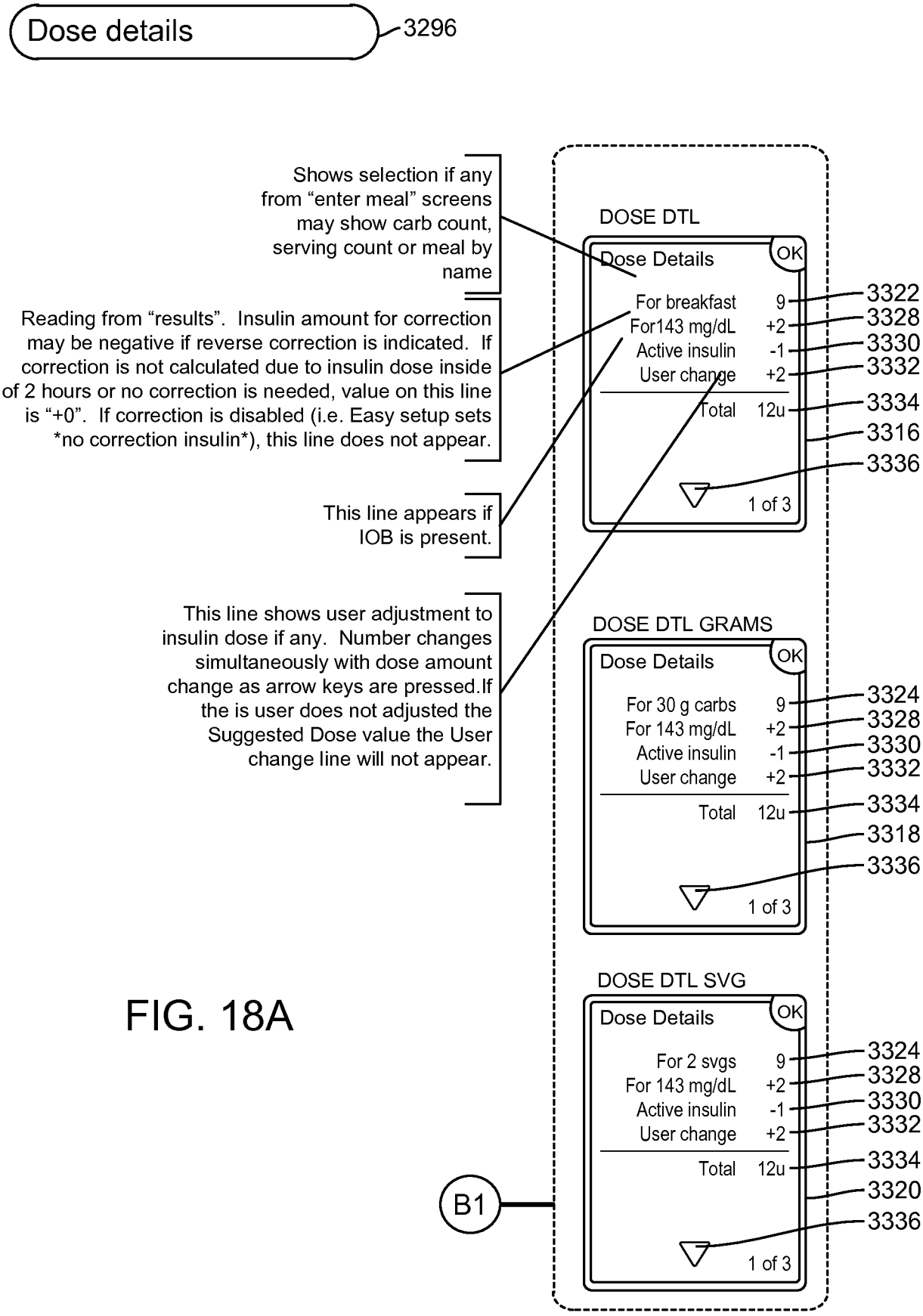

Dose details
3296
Shows selection if any from "enter meal" screens may show carb count, serving count or meal by name
Reading from "results". Insulin amount for correction may be negative if reverse correction is indicated. If correction is not calculated due to insulin dose inside of 2 hours or no correction is needed, value on this line is "+0". If correction is disabled (i.e. Easy setup sets *no correction insulin*), this line does not appear.
This line appears if IOB is present.
This line shows user adjustment to insulin dose if any. Number changes simultaneously with dose amount change as arrow keys are pressed.If the is user does not adjusted the Suggested Dose value the User change line will not appear.
DOSE DTL
Dose Details
OK
For breakfast 9
For143 mg/dL +2
Active insulin -1
User change +2
Total 12u
1 of 3
3322
3328
3330
3332
3334
3316
3336
DOSE DTL GRAMS
Dose Details
OK
For 30 g carbs 9
For 143 mg/dL +2
Active insulin -1
User change +2
Total 12u
1 of 3
3324
3328
3330
3332
3334
3318
3336
DOSE DTL SVG
Dose Details
OK
For 2 svgs 9
For 143 mg/dL +2
Active insulin -1
User change +2
Total 12u
1 of 3
3324
3328
3330
3332
3334
3320
3336
B1

FIG. 18A

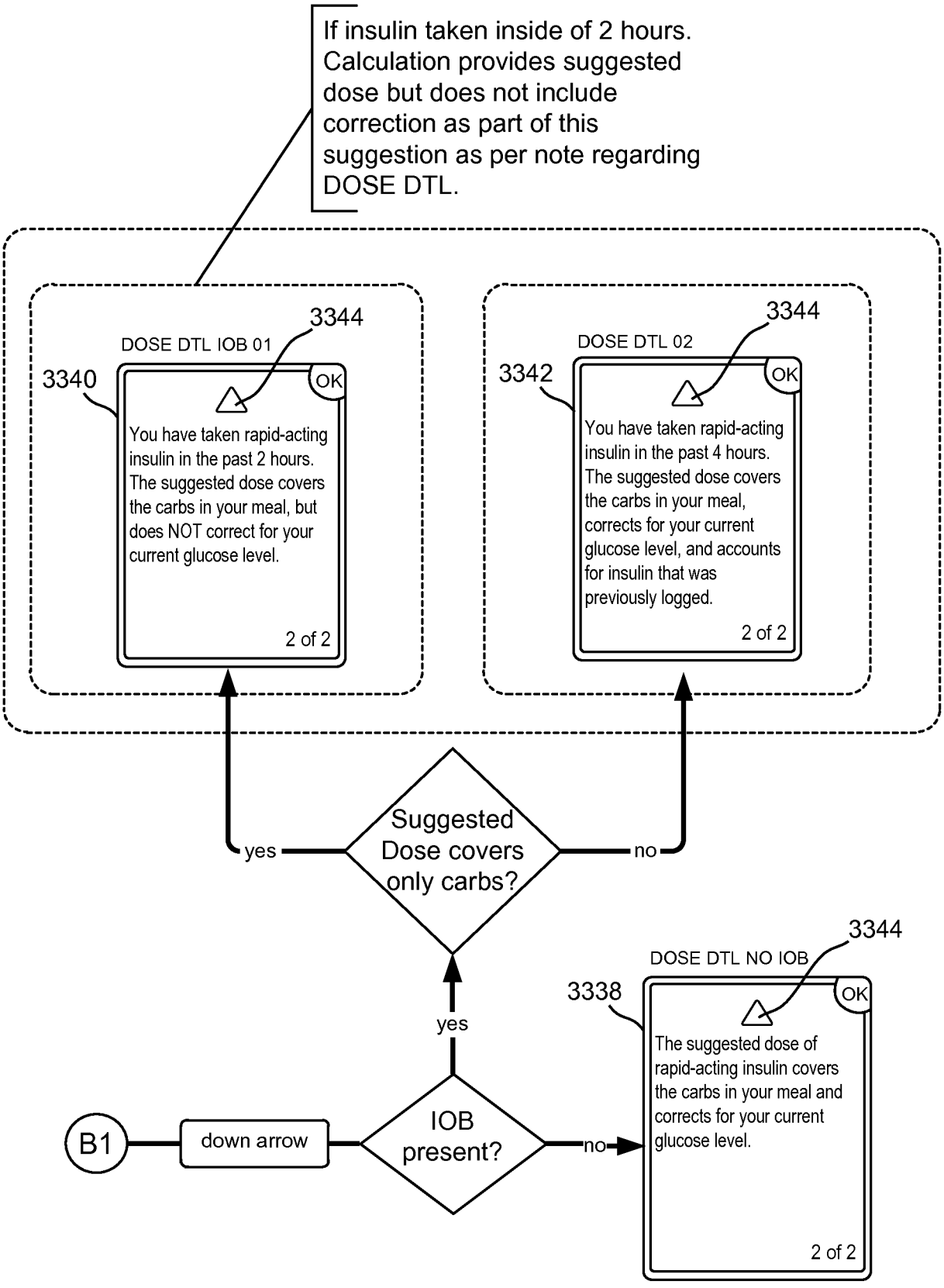

If insulin taken inside of 2 hours. Calculation provides suggested dose but does not include correction as part of this suggestion as per note regarding DOSE DTL.
3344
DOSE DTL IOB 01
3340
OK
You have taken rapid-acting insulin in the past 2 hours. The suggested dose covers the carbs in your meal, but does NOT correct for your current glucose level.
2 of 2
3344
DOSE DTL 02
3342
OK
You have taken rapid-acting insulin in the past 4 hours. The suggested dose covers the carbs in your meal, corrects for your current glucose level, and accounts for insulin that was previously logged.
2 of 2
yes
Suggested Dose covers only carbs?
no
3344
DOSE DTL NO IOB
3338
OK
The suggested dose of rapid-acting insulin covers the carbs in your meal and corrects for your current glucose level.
2 of 2
yes
IOB present?
no
B1
down arrow

FIG. 18B

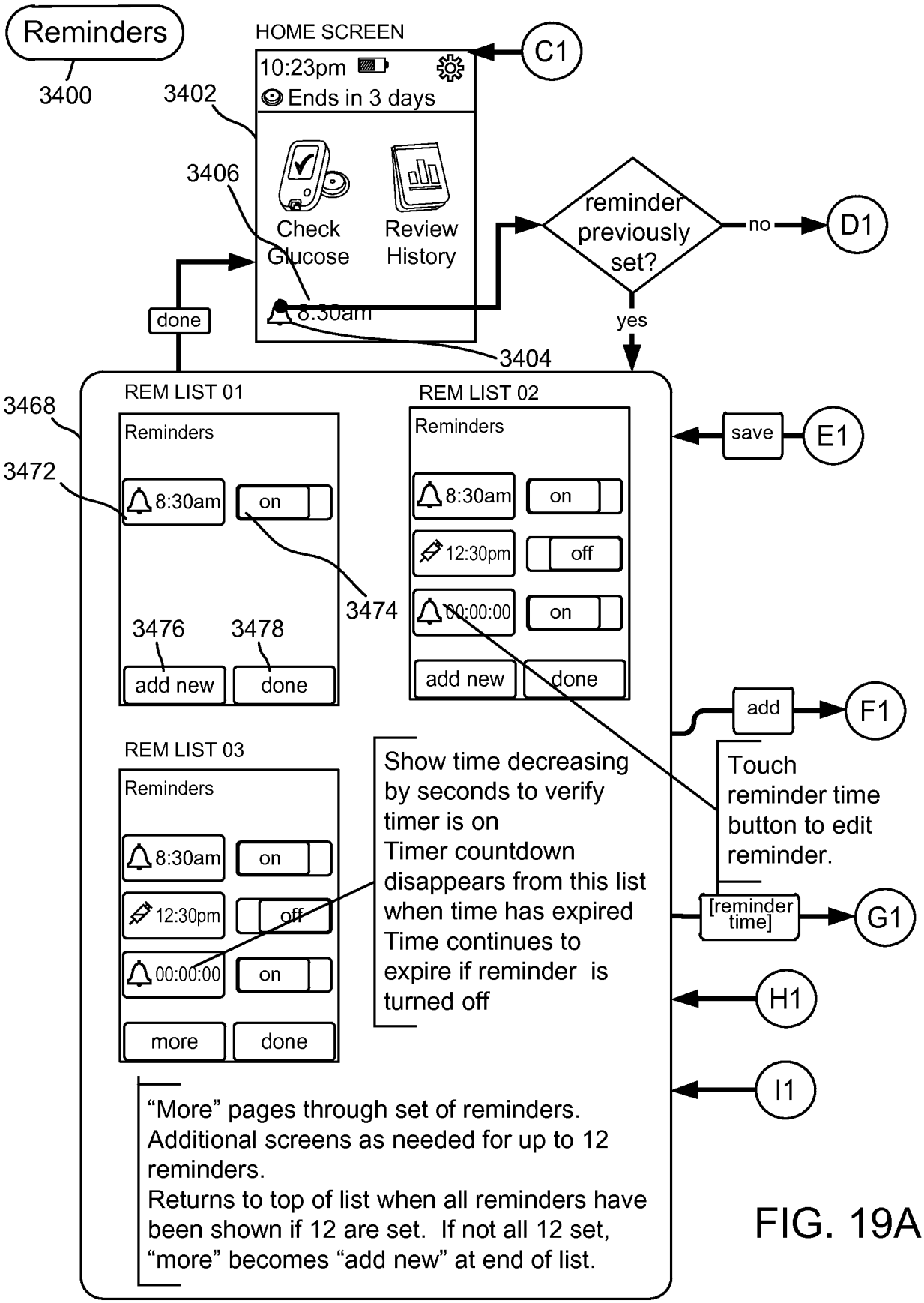
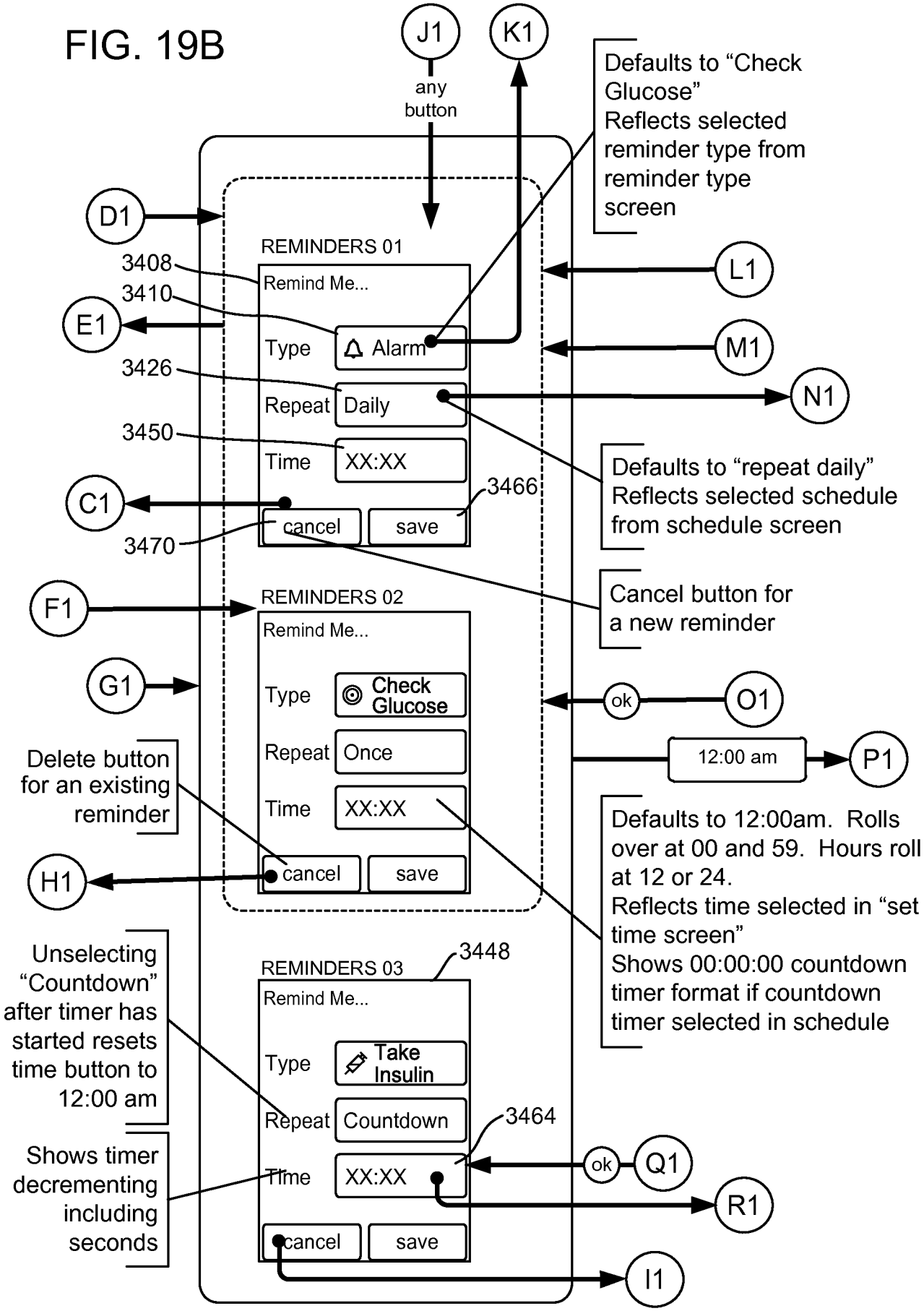

Reminders
3400
HOME SCREEN
C1
10:23pm
Ends in 3 days
3402
3406
Check Glucose
Review History
8:30am
reminder previously set?
no
D1
yes
done
3404
REM LIST 01
3468
Reminders
3472
8:30am
on
3474
3476
3478
add new
done
REM LIST 02
Reminders
save
E1
8:30am
on
12:30pm
off
00:00:00
on
add new
done
add
F1
REM LIST 03
Reminders
8:30am
on
12:30pm
off
00:00:00
on
more
done
Show time decreasing by seconds to verify timer is on
Timer countdown disappears from this list when time has expired
Time continues to expire if reminder is turned off
Touch reminder time button to edit reminder.
[reminder time]
G1
H1
I1
"More" pages through set of reminders.
Additional screens as needed for up to 12 reminders.
Returns to top of list when all reminders have been shown if 12 are set. If not all 12 set, "more" becomes "add new" at end of list.

FIG. 19A

FIG. 19B


J1
K1
any button
Defaults to "Check Glucose"
Reflects selected reminder type from reminder type screen
D1
REMINDERS 01
3408
Remind Me...
3410
L1
E1
Type
Alarm
M1
3426
Repeat
Daily
N1
3450
Time
XX:XX
Defaults to "repeat daily"
Reflects selected schedule from schedule screen
C1
3466
cancel
save
3470
Cancel button for a new reminder
F1
REMINDERS 02
Remind Me...
G1
Type
Check Glucose
ok
O1
Repeat
Once
12:00 am
P1
Delete button for an existing reminder
Time
XX:XX
Defaults to 12:00am. Rolls over at 00 and 59. Hours roll at 12 or 24.
Reflects time selected in "set time screen"
Shows 00:00:00 countdown timer format if countdown timer selected in schedule
H1
cancel
save
Unselecting "Countdown" after timer has started resets time button to 12:00 am
3448
REMINDERS 03
Remind Me...
Type
Take Insulin
Repeat
Countdown
3464
Shows timer decrementing including seconds
Time
XX:XX
ok
Q1
R1
cancel
save
I1

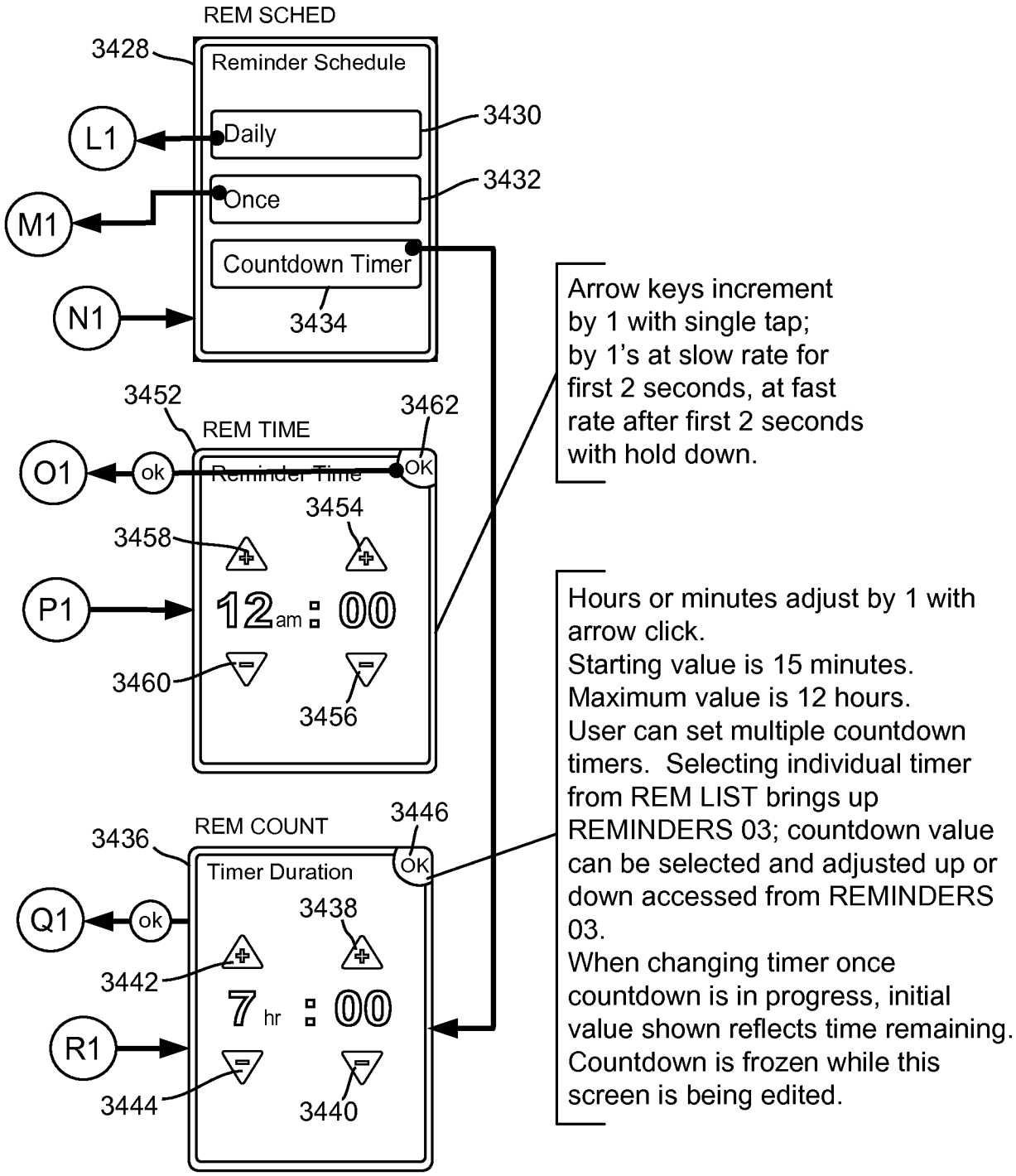

REM SCHED
3428
Reminder Schedule
L1
Daily
3430
M1
Once
3432
Countdown Timer
N1
3434
3452
REM TIME
3462
O1
ok
Reminder Time
OK
3454
3458
P1
12 am : 00
3460
3456
REM COUNT
3446
3436
Timer Duration
OK
Q1
ok
3438
3442
7 hr : 00
R1
3444
3440
Arrow keys increment by 1 with single tap; by 1's at slow rate for first 2 seconds, at fast rate after first 2 seconds with hold down.
Hours or minutes adjust by 1 with arrow click.
Starting value is 15 minutes.
Maximum value is 12 hours.
User can set multiple countdown timers. Selecting individual timer from REM LIST brings up REMINDERS 03; countdown value can be selected and adjusted up or down accessed from REMINDERS 03.
When changing timer once countdown is in progress, initial value shown reflects time remaining.
Countdown is frozen while this screen is being edited.

FIG. 19C

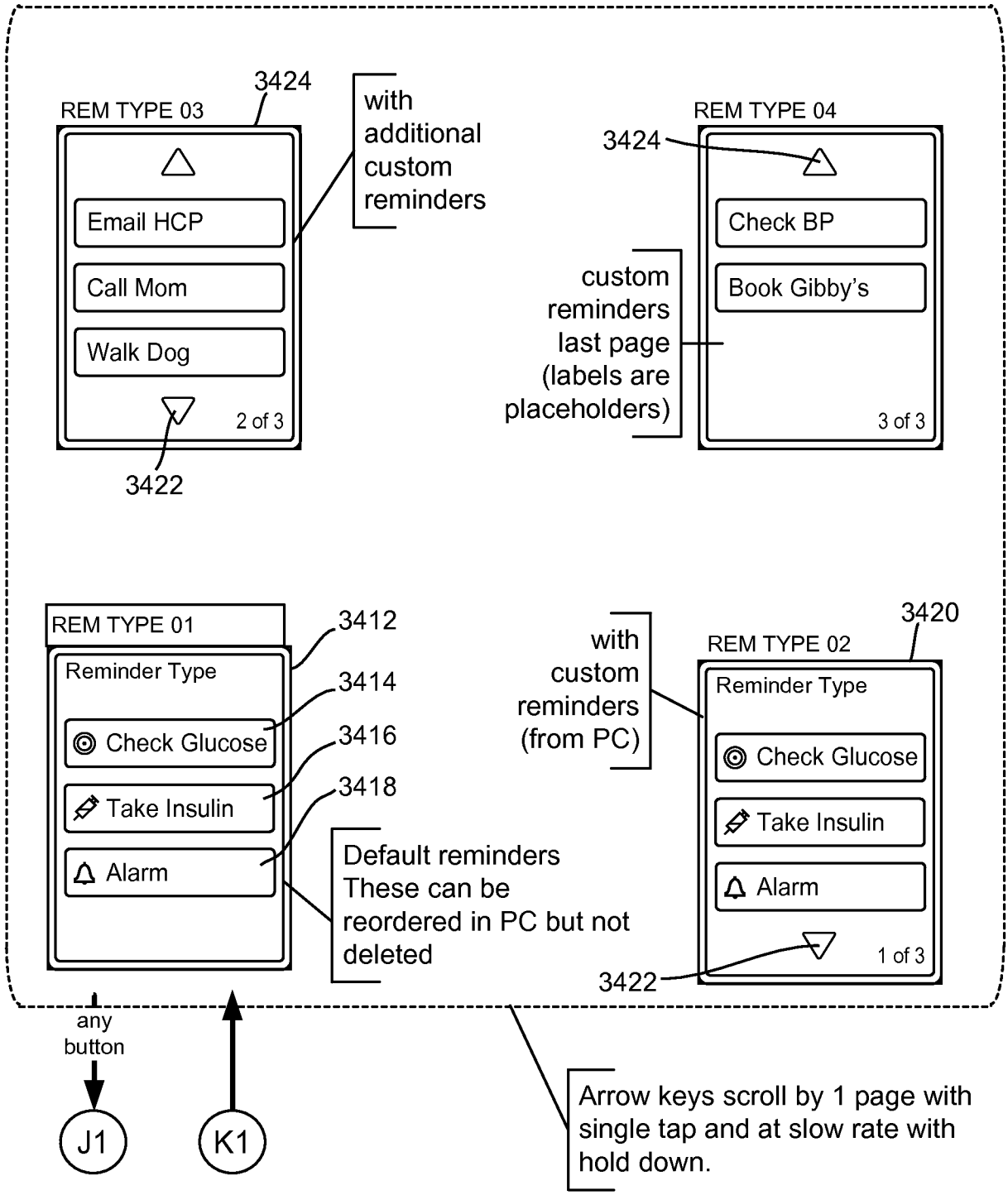

REM TYPE 03
3424
with additional custom reminders
Email HCP
Call Mom
Walk Dog
2 of 3
3422
REM TYPE 04
3424
Check BP
Book Gibby's
custom reminders last page (labels are placeholders)
3 of 3
REM TYPE 01
3412
Reminder Type
3414
Check Glucose
3416
Take Insulin
3418
Alarm
Default reminders These can be reordered in PC but not deleted
with custom reminders (from PC)
3420
REM TYPE 02
Reminder Type
Check Glucose
Take Insulin
Alarm
1 of 3
3422
any button
J1
K1
Arrow keys scroll by 1 page with single tap and at slow rate with hold down.

FIG. 19D

Receive reminder 3500

If Reminder sound is set to on, beep sounds with appearance of any reminders screen.

See “symbols and notes” for specifications of duration of reminder sounds.

If a reminder is ignored, the reminder will appear on screen with the next power on (whether by hardware button or strip insertion).

If multiple reminders are active, “Receive reminder” screens will stack up with the most recent reminder showing first. They will require dismissal one by one.

If daily repeated reminders have been missed, once a new day’s reminder is current the previous day’s reminder for that time is no longer active and is not part of that stack-up.

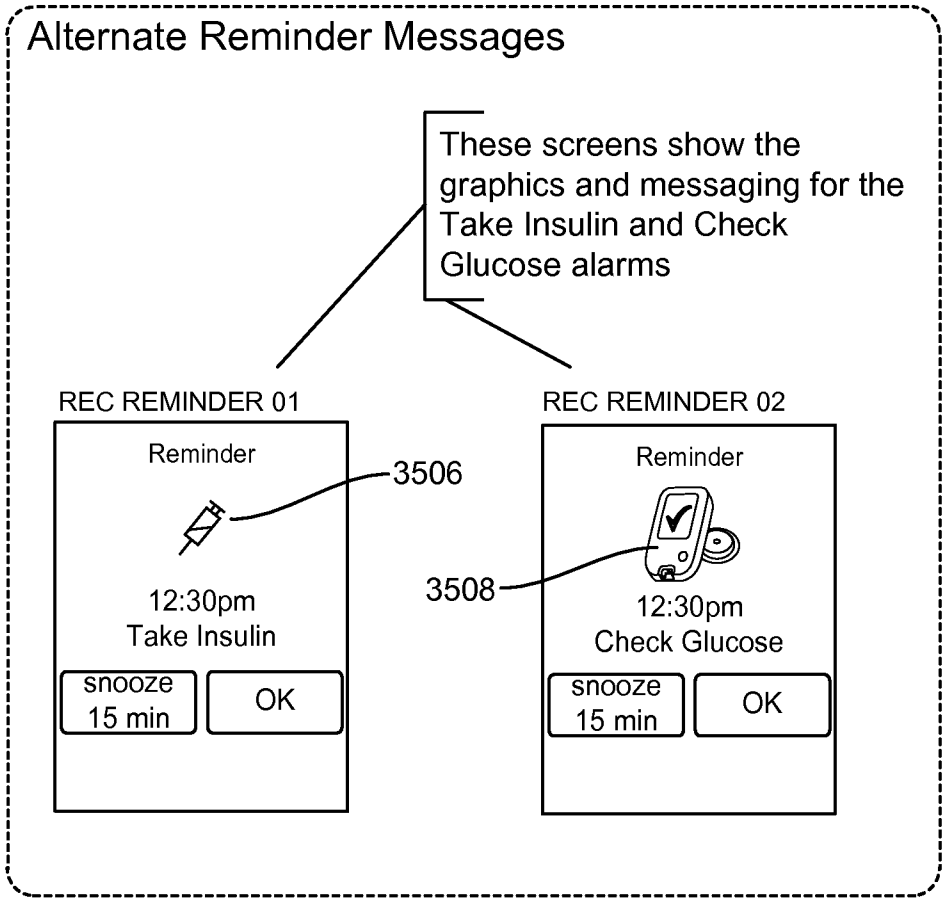
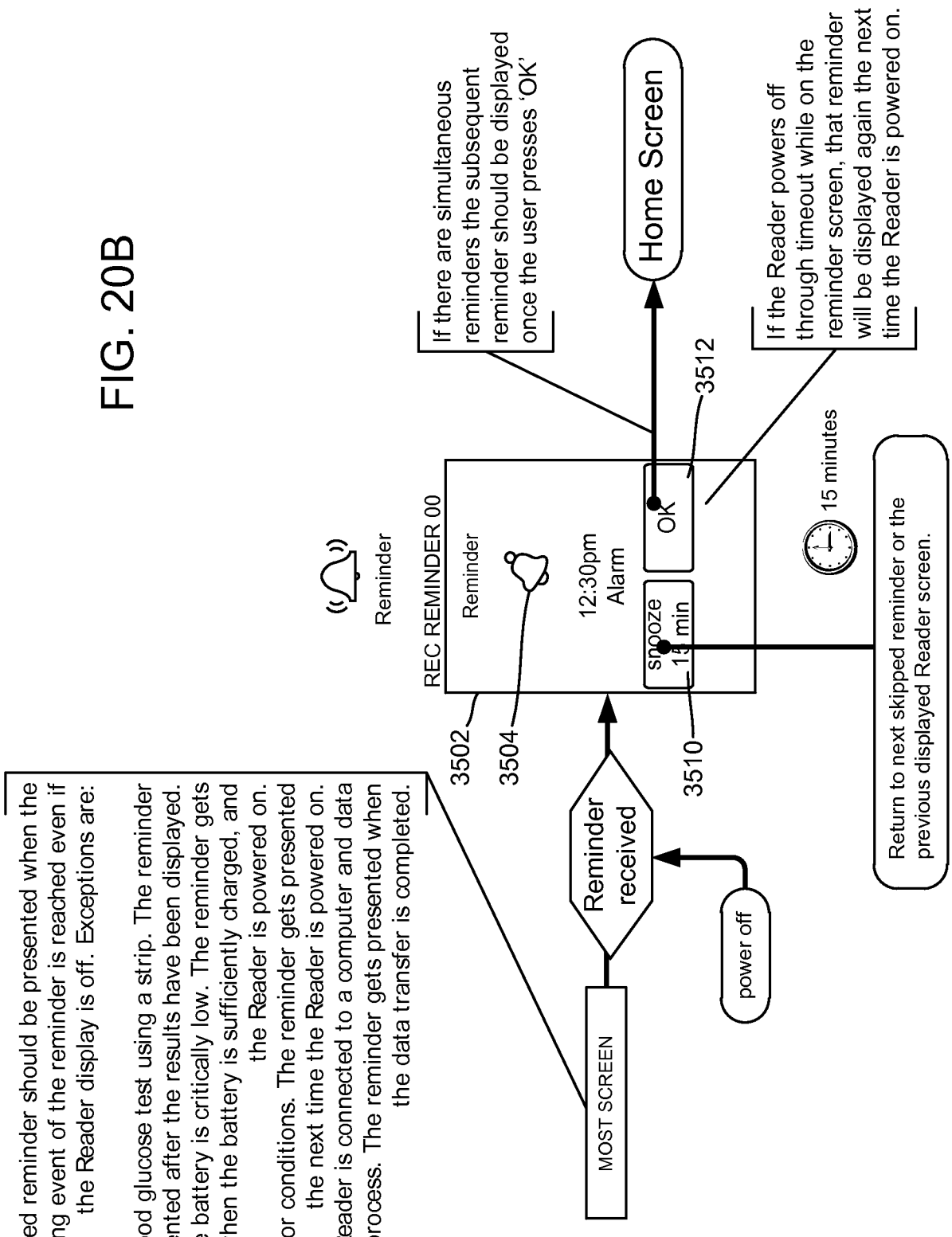


FIG. 20A

FIG. 20B


A scheduled reminder should be presented when the time / triggering event of the reminder is reached even if the Reader display is off. Exceptions are:
1. During a blood glucose test using a strip. The reminder gets presented after the results have been displayed.
2. When the battery is critically low. The reminder gets presented when the battery is sufficiently charged, and the Reader is powered on.
3. During error conditions. The reminder gets presented the next time the Reader is powered on.
4. When the Reader is connected to a computer and data transfer is in process. The reminder gets presented when the data transfer is completed.
MOST SCREEN
Reminder received
power off
Reminder
REC REMINDER 00
Reminder
12:30pm
Alarm
snooze
15 min
OK
3502
3504
3510
3512
15 minutes
Home Screen
If there are simultaneous reminders the subsequent reminder should be displayed once the user presses 'OK'
If the Reader powers off through timeout while on the reminder screen, that reminder will be displayed again the next time the Reader is powered on.
Return to next skipped reminder or the previous displayed Reader screen.

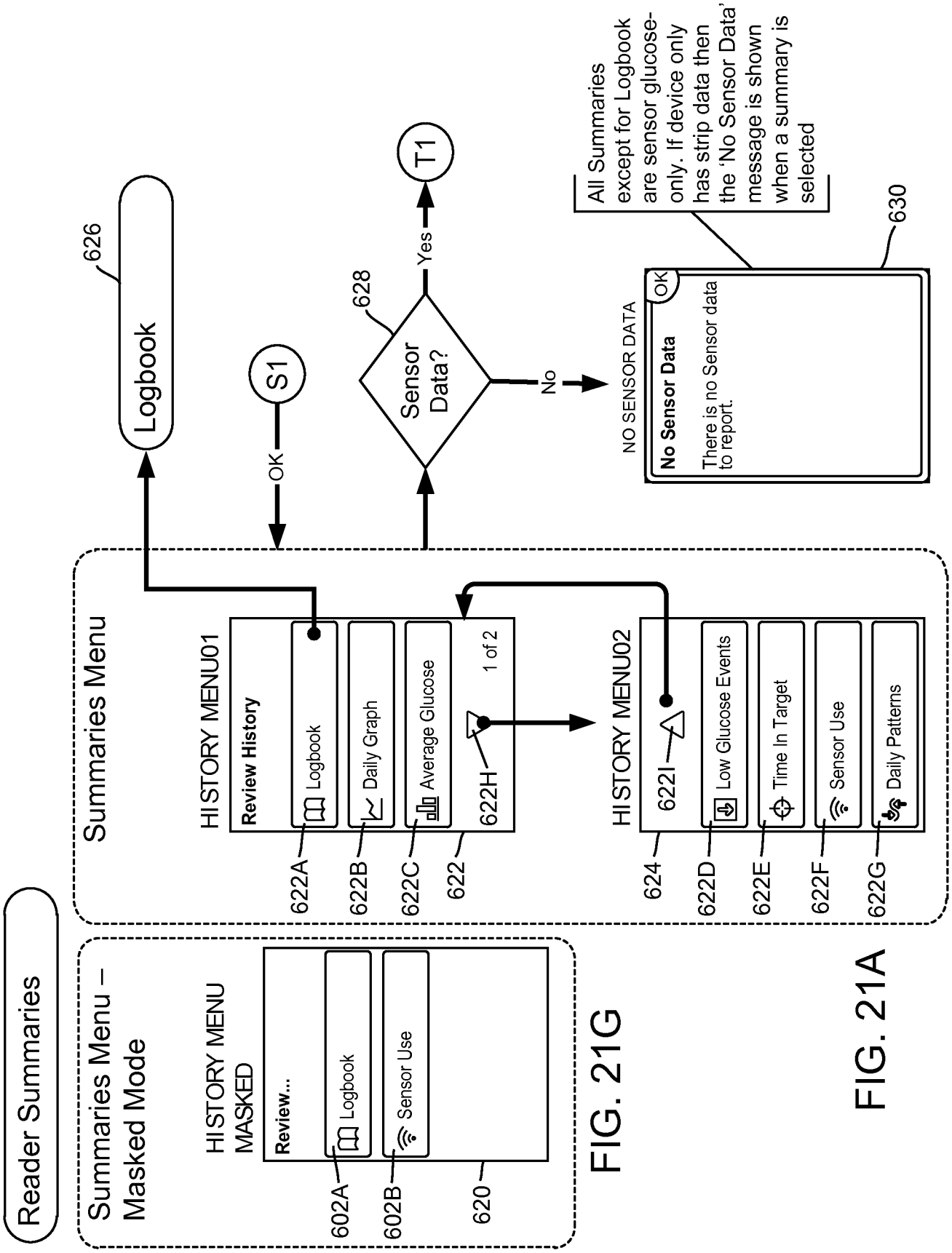
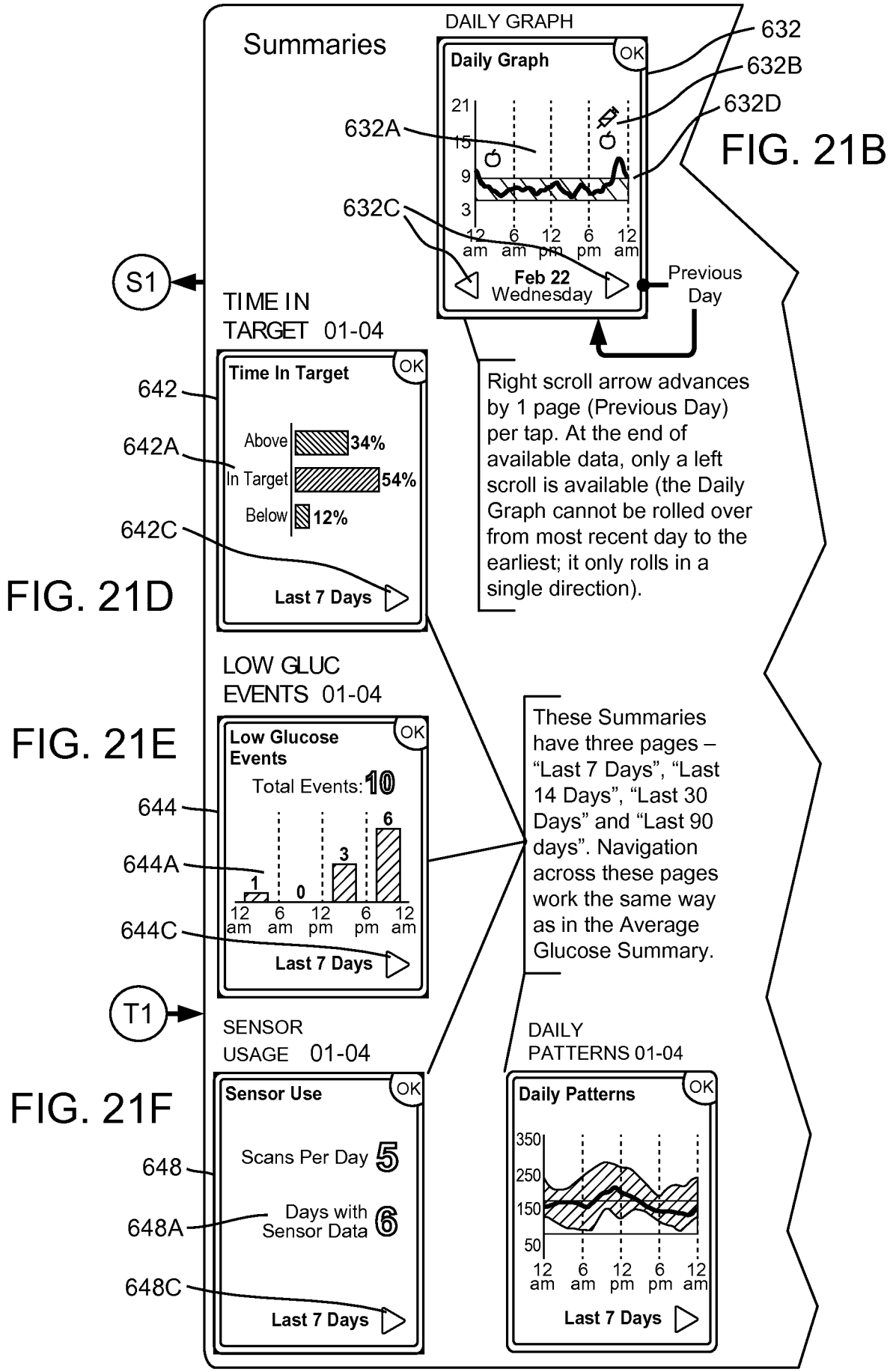


FIG. 21G

FIG. 21A


Summaries
DAILY GRAPH
Daily Graph
OK
632
632B
632D
632A
632C
21
15
9
3
12 am
6 am
12 pm
6 pm
12 am
Feb 22
Wednesday
Previous Day
FIG. 21B
S1
TIME IN TARGET 01-04
Time In Target
642
642A
642C
Above 34%
In Target 54%
Below 12%
Last 7 Days
FIG. 21D
Right scroll arrow advances by 1 page (Previous Day) per tap. At the end of available data, only a left scroll is available (the Daily Graph cannot be rolled over from most recent day to the earliest; it only rolls in a single direction).
LOW GLUC EVENTS 01-04
Low Glucose Events
Total Events: 10
644
644A
644C
1
0
3
6
Last 7 Days
FIG. 21E
These Summaries have three pages – “Last 7 Days”, “Last 14 Days”, “Last 30 Days” and “Last 90 days”. Navigation across these pages work the same way as in the Average Glucose Summary.
T1
SENSOR USAGE 01-04
Sensor Use
Scans Per Day 5
Days with Sensor Data 6
648
648A
648C
Last 7 Days
FIG. 21F
DAILY PATTERNS 01-04
Daily Patterns
350
250
150
50
Last 7 Days

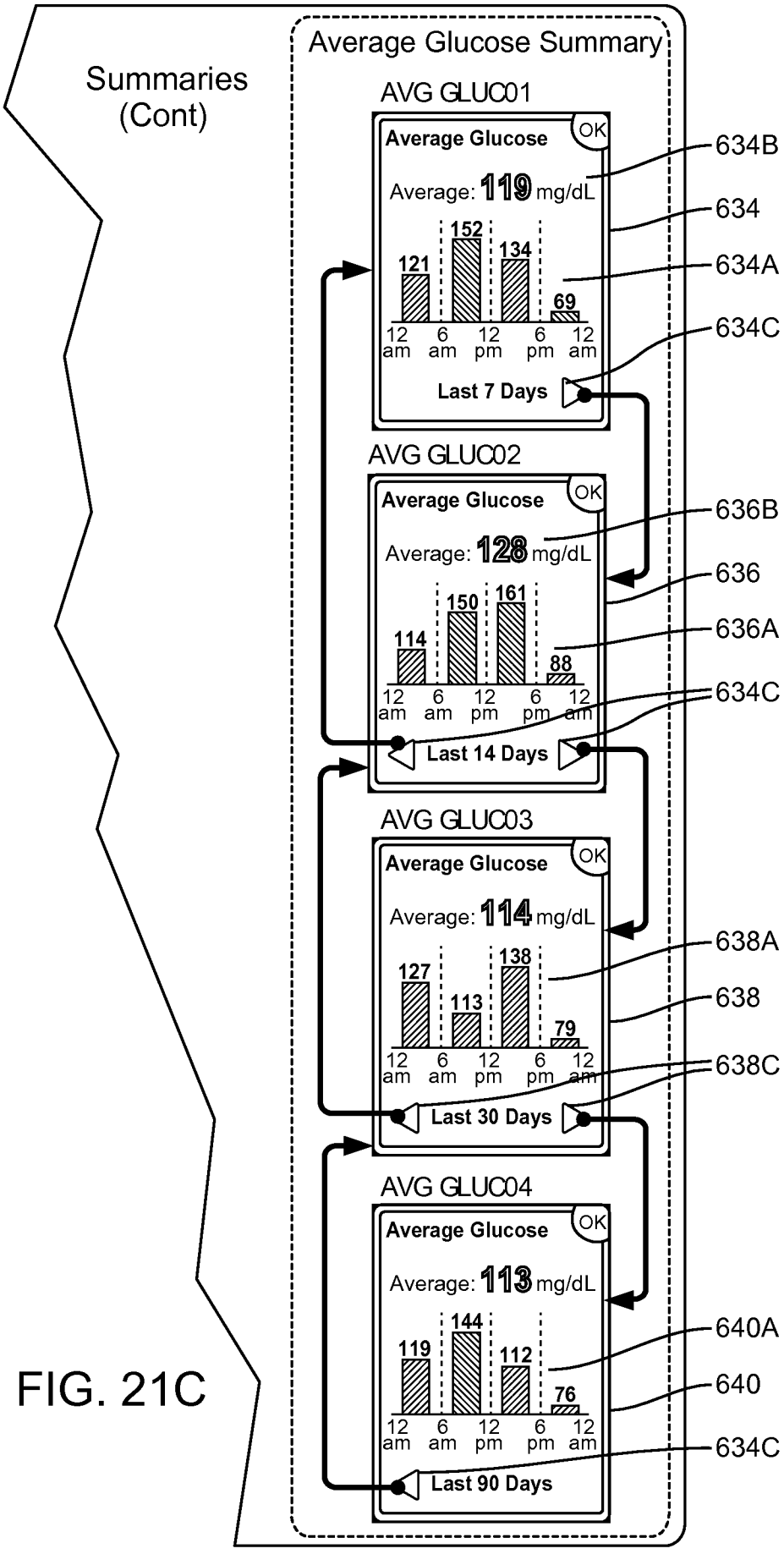

Summaries (Cont)
Average Glucose Summary
AVG GLUC01
Average Glucose
OK
Average: 119 mg/dL
121
152
134
69
12 am
6 am
12 pm
6 pm
12 am
Last 7 Days
AVG GLUC02
Average Glucose
OK
Average: 128 mg/dL
114
150
161
88
Last 14 Days
AVG GLUC03
Average Glucose
OK
Average: 114 mg/dL
127
113
138
79
Last 30 Days
AVG GLUC04
Average Glucose
OK
Average: 113 mg/dL
119
144
112
76
Last 90 Days
634B
634
634A
634C
636B
636
636A
634C
638A
638
638C
640A
640
634C

FIG. 21C

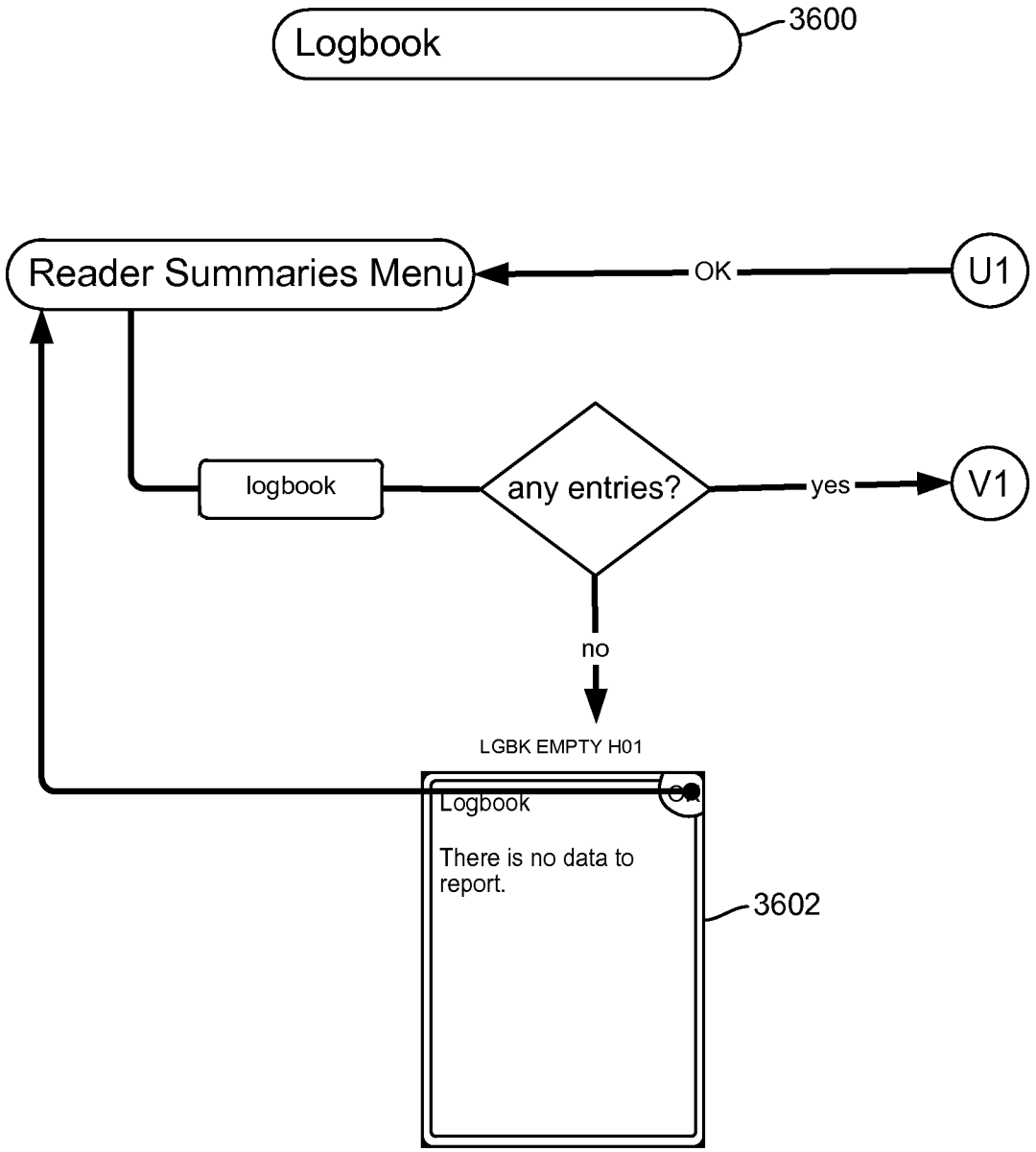

Logbook
3600
Reader Summaries Menu
OK
U1
logbook
any entries?
yes
V1
no
LGBK EMPTY H01
OK
Logbook
There is no data to report.
3602

FIG. 22A

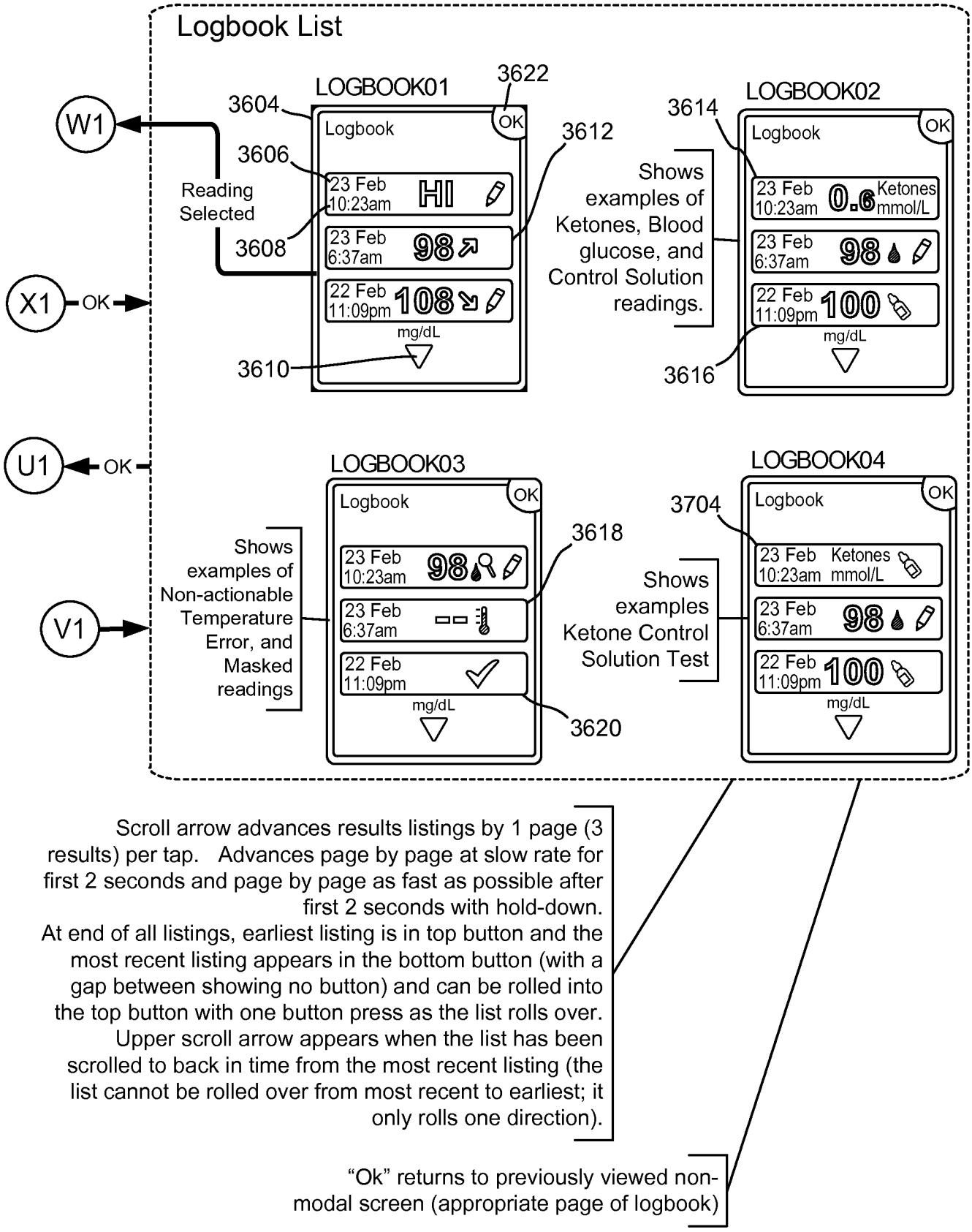

Logbook List
LOGBOOK01
3622
3604
Logbook
OK
3606
23 Feb 10:23am HI
23 Feb 6:37am 98
22 Feb 11:09pm 108
mg/dL
3610
3608
3612
W1
Reading Selected
X1
OK
LOGBOOK02
3614
Logbook
OK
23 Feb 10:23am 0.6 Ketones mmol/L
23 Feb 6:37am 98
22 Feb 11:09pm 100
mg/dL
3616
Shows examples of Ketones, Blood glucose, and Control Solution readings.
U1
OK
LOGBOOK03
Logbook
OK
23 Feb 10:23am 98
23 Feb 6:37am
22 Feb 11:09pm
mg/dL
3618
3620
V1
Shows examples of Non-actionable Temperature Error, and Masked readings
LOGBOOK04
3704
Logbook
OK
23 Feb 10:23am Ketones mmol/L
23 Feb 6:37am 98
22 Feb 11:09pm 100
mg/dL
Shows examples Ketone Control Solution Test
Scroll arrow advances results listings by 1 page (3 results) per tap. Advances page by page at slow rate for first 2 seconds and page by page as fast as possible after first 2 seconds with hold-down.
At end of all listings, earliest listing is in top button and the most recent listing appears in the bottom button (with a gap between showing no button) and can be rolled into the top button with one button press as the list rolls over.
Upper scroll arrow appears when the list has been scrolled to back in time from the most recent listing (the list cannot be rolled over from most recent to earliest; it only rolls one direction).
"Ok" returns to previously viewed non-modal screen (appropriate page of logbook)

FIG. 22B

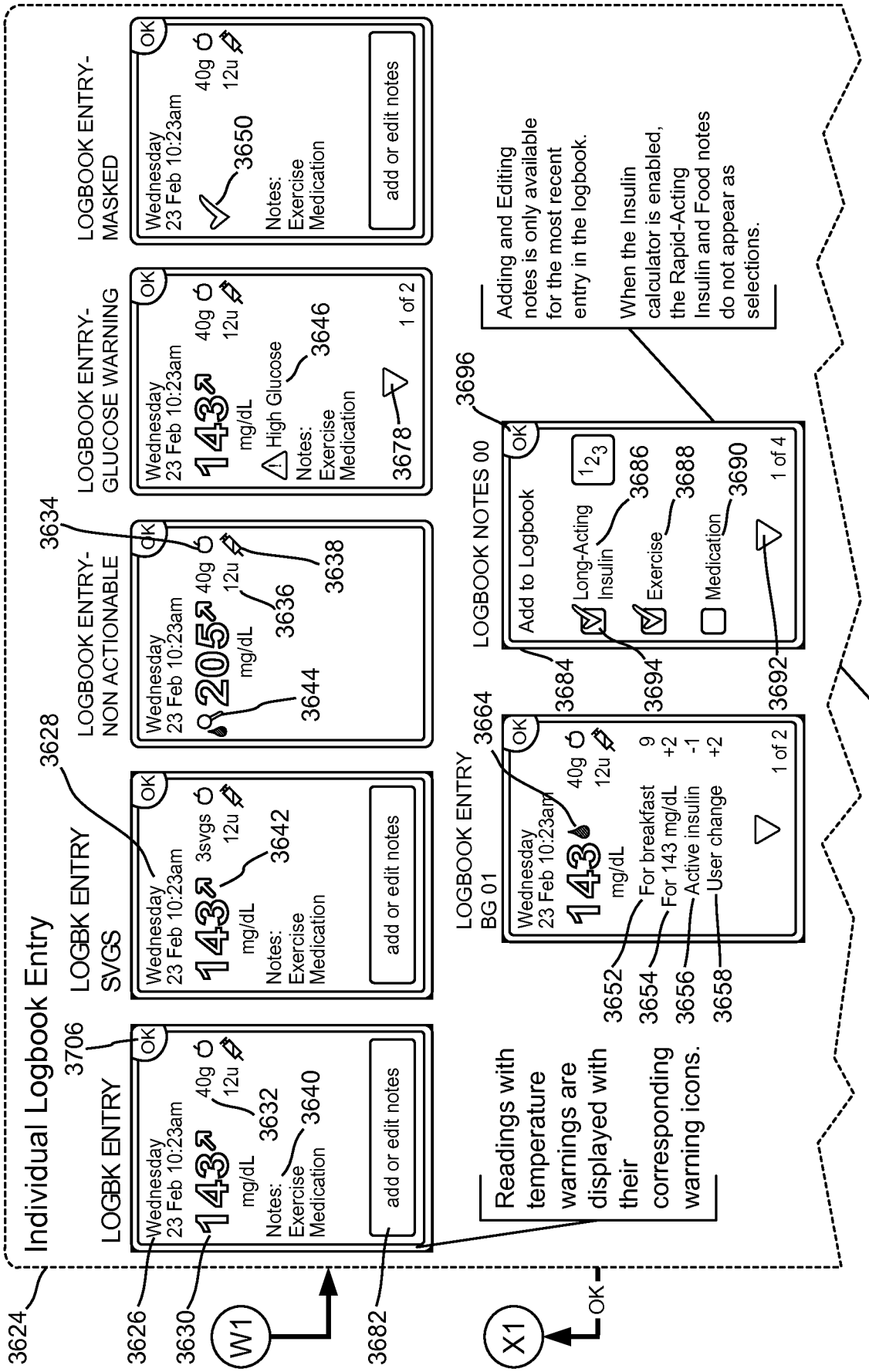

Individual Logbook Entry
3624
LOGBK ENTRY
3706
OK
Wednesday
23 Feb 10:23am
143
mg/dL
40g
12u
Notes:
Exercise
Medication
3632
3640
add or edit notes
3626
3630
3682
W1
LOGBK ENTRY SVGS
3628
3svgs
3642
LOGBOOK ENTRY- NON ACTIONABLE
3634
205
3644
3636
3638
LOGBOOK ENTRY- GLUCOSE WARNING
High Glucose
3646
1 of 2
3678
LOGBOOK ENTRY- MASKED
3650
LOGBOOK ENTRY BG 01
3664
For breakfast 9
For 143 mg/dL +2
Active insulin -1
User change +2
1 of 2
3652
3654
3656
3658
LOGBOOK NOTES 00
3696
Add to Logbook
Long-Acting Insulin
Exercise
Medication
3686
3688
3690
1 of 4
3684
3694
3692
Adding and Editing notes is only available for the most recent entry in the logbook.
When the Insulin calculator is enabled, the Rapid-Acting Insulin and Food notes do not appear as selections.
Readings with temperature warnings are displayed with their corresponding warning icons.
X1
OK
"Ok" returns to previously viewed non-modal screen (appropriate page of logbook)

FIG. 22C

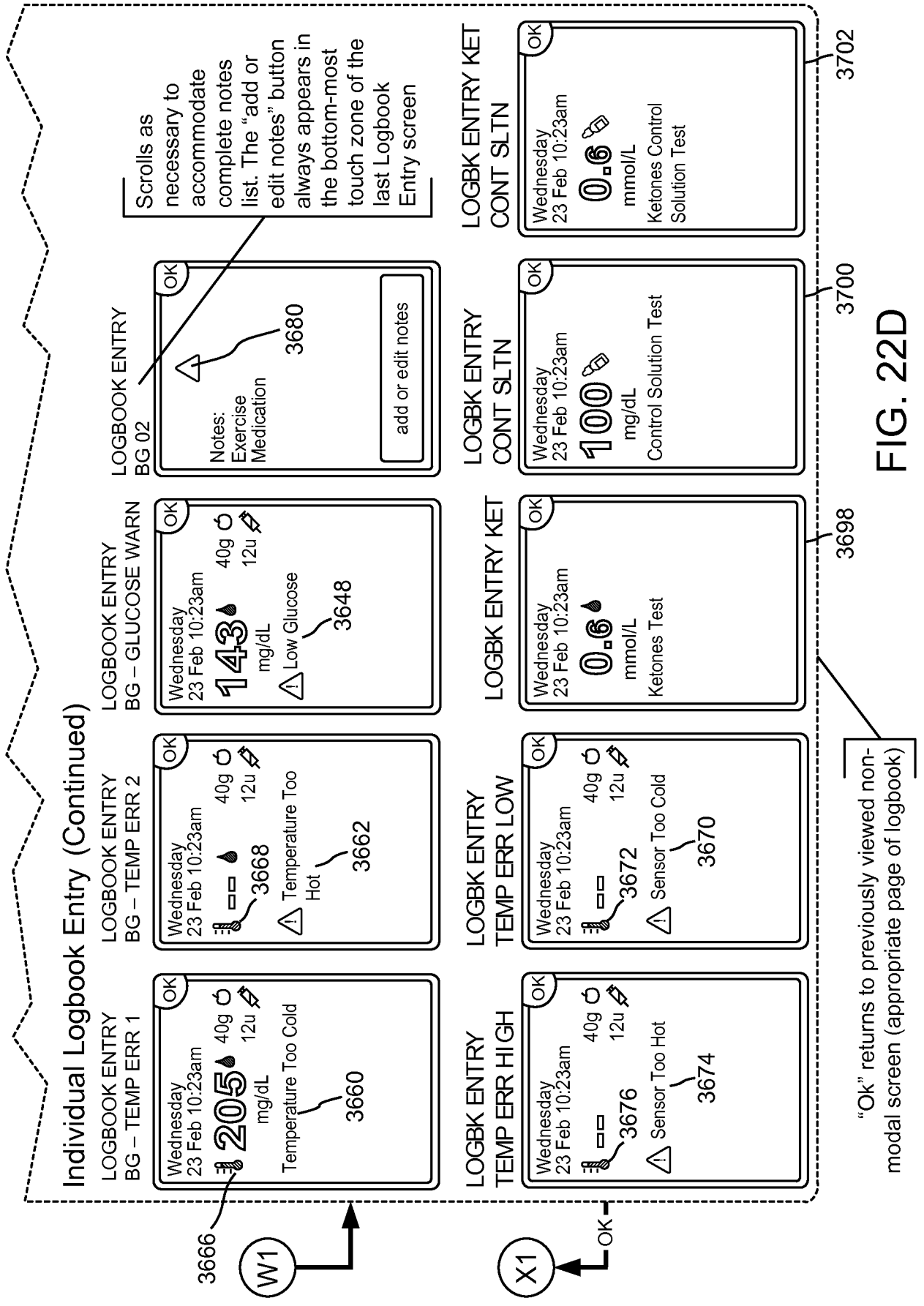

Individual Logbook Entry (Continued)
LOGBOOK ENTRY BG – TEMP ERR 1
Wednesday 23 Feb 10:23am
205 mg/dL
40g 12u
Temperature Too Cold
3660
3666
LOGBOOK ENTRY BG – TEMP ERR 2
Wednesday 23 Feb 10:23am
3668
40g 12u
Temperature Too Hot
3662
LOGBOOK ENTRY BG – GLUCOSE WARN
Wednesday 23 Feb 10:23am
143 mg/dL
40g 12u
Low Glucose
3648
LOGBOOK ENTRY BG 02
Notes: Exercise Medication
3680
add or edit notes
Scrolls as necessary to accommodate complete notes list. The "add or edit notes" button always appears in the bottom-most touch zone of the last Logbook Entry screen
LOGBK ENTRY TEMP ERR HIGH
Wednesday 23 Feb 10:23am
3676
40g 12u
Sensor Too Hot
3674
LOGBK ENTRY TEMP ERR LOW
Wednesday 23 Feb 10:23am
3672
40g 12u
Sensor Too Cold
3670
LOGBK ENTRY KET
Wednesday 23 Feb 10:23am
0.6 mmol/L
Ketones Test
3698
LOGBK ENTRY CONT SLTN
Wednesday 23 Feb 10:23am
100 mg/dL
Control Solution Test
3700
LOGBK ENTRY KET CONT SLTN
Wednesday 23 Feb 10:23am
0.6 mmol/L
Ketones Control Solution Test
3702
OK
W1
X1
OK
"Ok" returns to previously viewed non-modal screen (appropriate page of logbook)

FIG. 22D

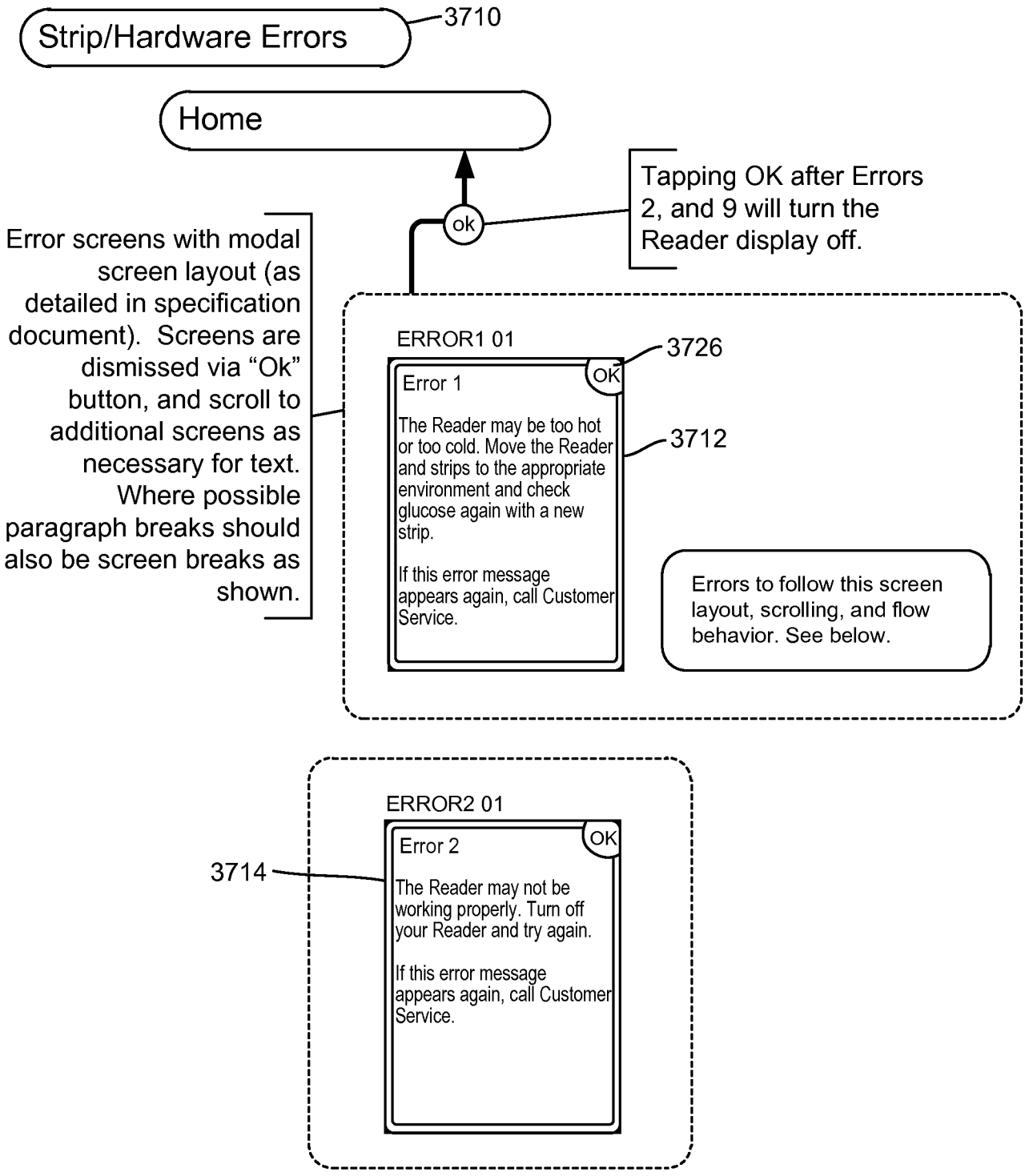

Strip/Hardware Errors
3710
Home
ok
Tapping OK after Errors 2, and 9 will turn the Reader display off.
Error screens with modal screen layout (as detailed in specification document). Screens are dismissed via "Ok" button, and scroll to additional screens as necessary for text. Where possible paragraph breaks should also be screen breaks as shown.
ERROR1 01
3726
OK
Error 1
The Reader may be too hot or too cold. Move the Reader and strips to the appropriate environment and check glucose again with a new strip.
If this error message appears again, call Customer Service.
3712
Errors to follow this screen layout, scrolling, and flow behavior. See below.
ERROR2 01
OK
Error 2
The Reader may not be working properly. Turn off your Reader and try again.
If this error message appears again, call Customer Service.
3714

FIG. 23A

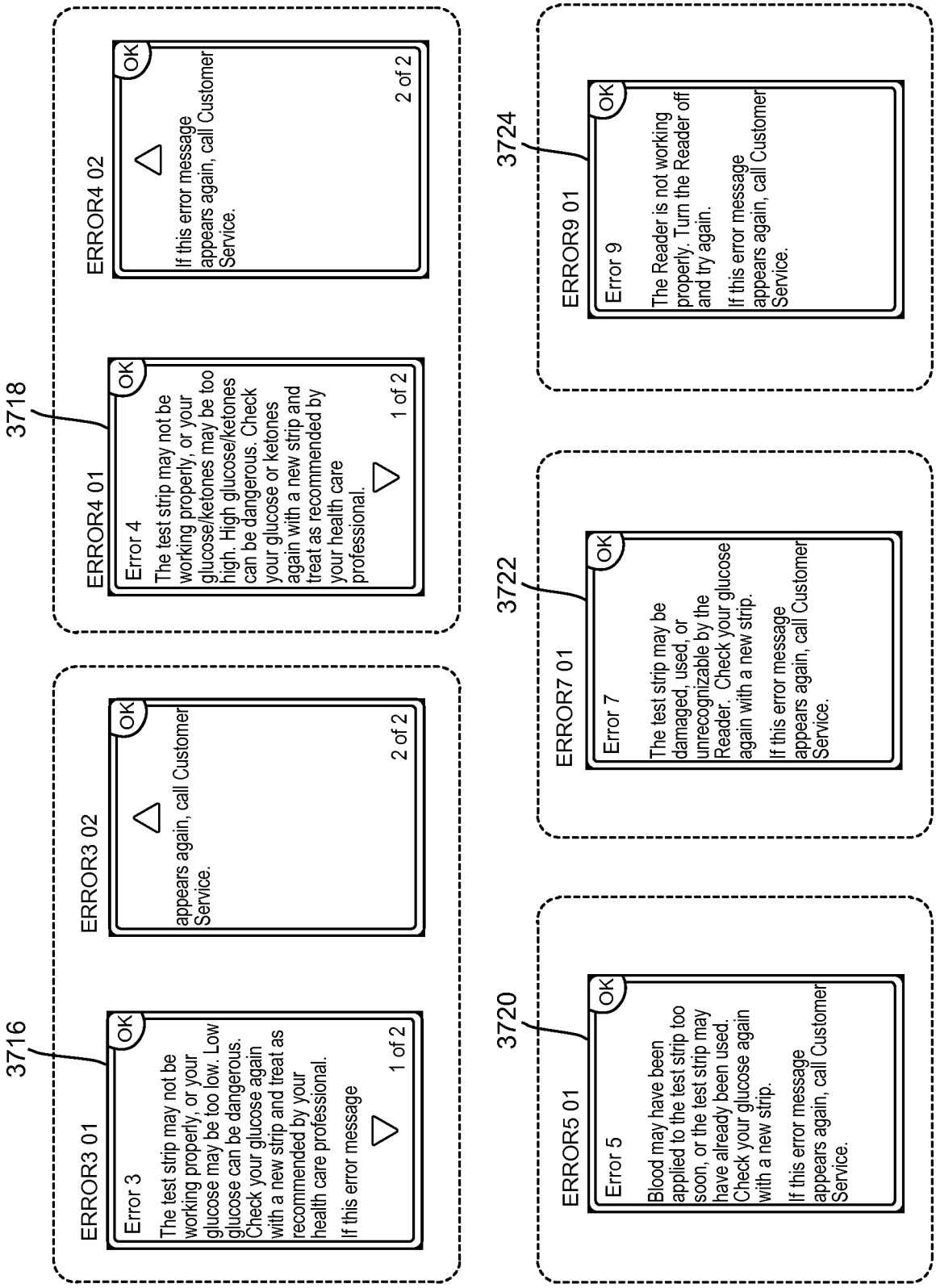

3716
ERROR3 01
OK
Error 3
The test strip may not be working properly, or your glucose may be too low. Low glucose can be dangerous. Check your glucose again with a new strip and treat as recommended by your health care professional.
If this error message
1 of 2
ERROR3 02
OK
appears again, call Customer Service.
2 of 2
3718
ERROR4 01
OK
Error 4
The test strip may not be working properly, or your glucose/ketones may be too high. High glucose/ketones can be dangerous. Check your glucose or ketones again with a new strip and treat as recommended by your health care professional.
1 of 2
ERROR4 02
OK
If this error message appears again, call Customer Service.
2 of 2
3720
ERROR5 01
OK
Error 5
Blood may have been applied to the test strip too soon, or the test strip may have already been used. Check your glucose again with a new strip.
If this error message appears again, call Customer Service.
3722
ERROR7 01
OK
Error 7
The test strip may be damaged, used, or unrecognizable by the Reader. Check your glucose again with a new strip.
If this error message appears again, call Customer Service.
3724
ERROR9 01
OK
Error 9
The Reader is not working properly. Turn the Reader off and try again.
If this error message appears again, call Customer Service.

FIG. 23B

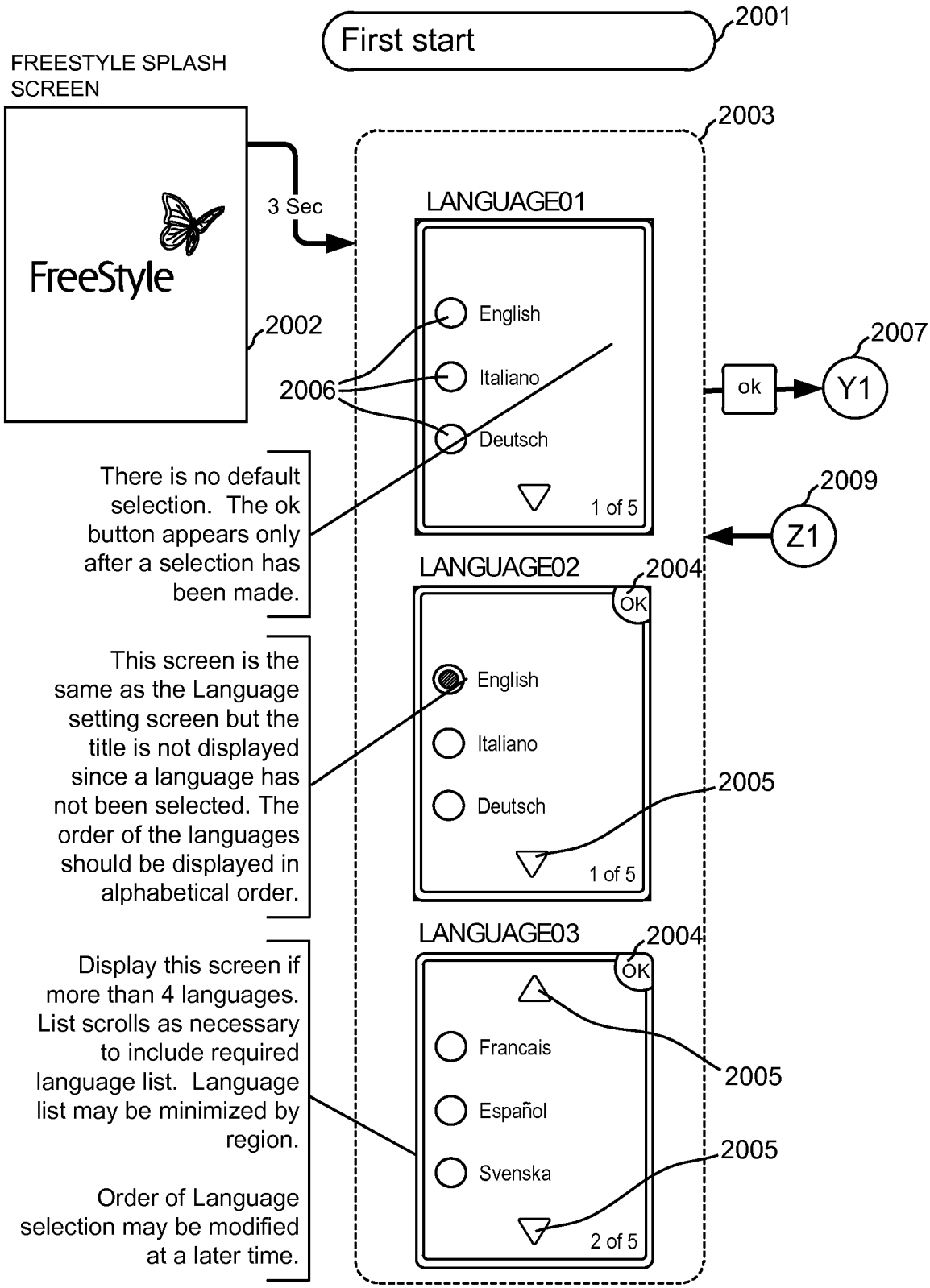
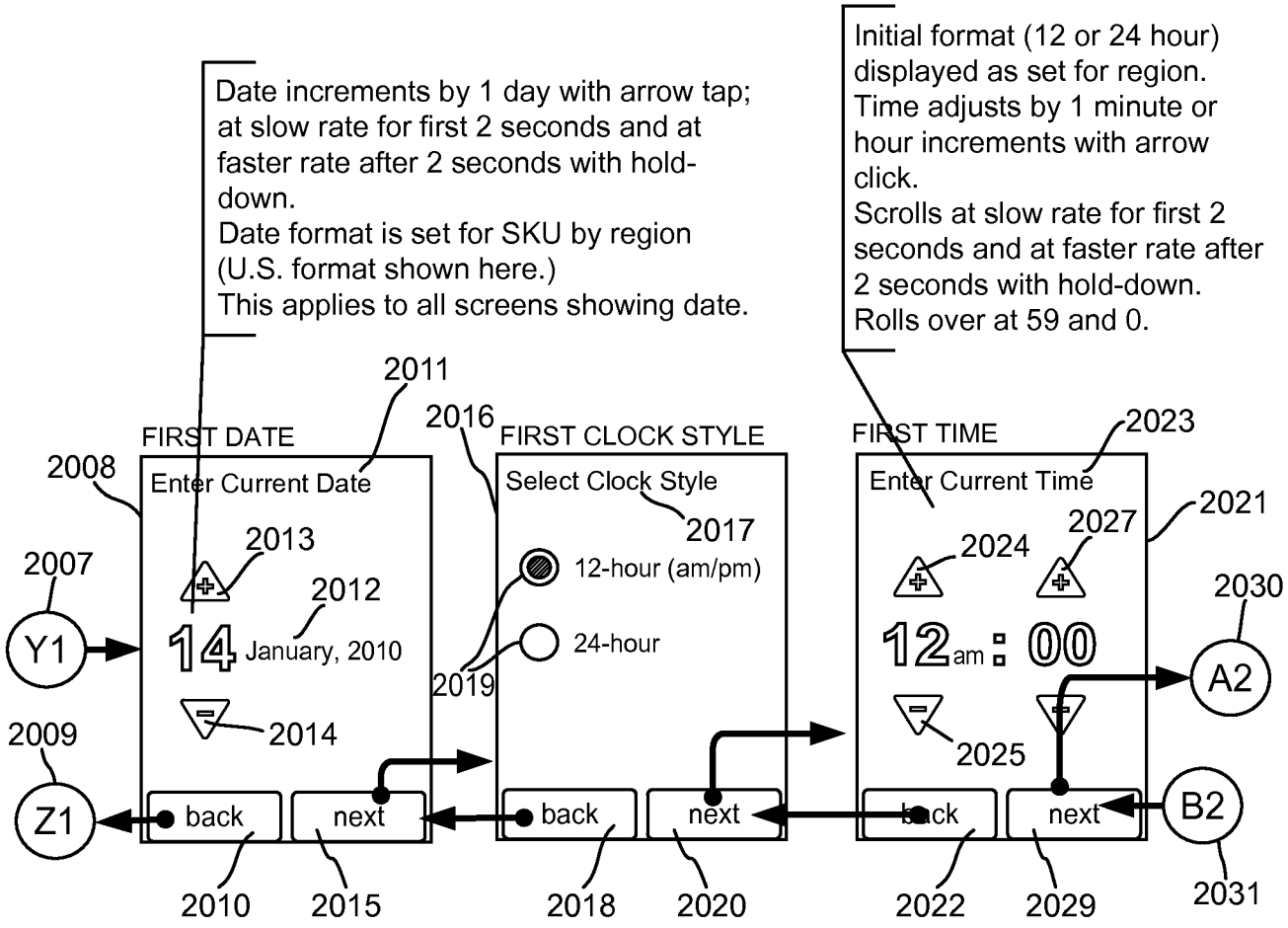

First start
2001
FREESTYLE SPLASH SCREEN
FreeStyle
3 Sec
2002
2003
LANGUAGE01
English
Italiano
Deutsch
1 of 5
2006
ok
Y1
2007
2009
Z1
There is no default selection. The ok button appears only after a selection has been made.
LANGUAGE02
OK
2004
English
Italiano
Deutsch
1 of 5
2005
This screen is the same as the Language setting screen but the title is not displayed since a language has not been selected. The order of the languages should be displayed in alphabetical order.
LANGUAGE03
OK
2004
Francais
Español
Svenska
2 of 5
2005
2005
Display this screen if more than 4 languages. List scrolls as necessary to include required language list. Language list may be minimized by region.
Order of Language selection may be modified at a later time.

FIG. 24



Note: Reader can be turned off by a single Home button press during LANG, FIRST DATE, or FIRST TIME. These settings will not be saved.

Note: if a strip is inserted before language, date, and time are set up, strip insertion launches the First Start sequence which aborts after FIRST TIME is completed (FIRST HOME BTTN and FIRST DONE are not displayed) and goes to the Test sequence (APPLY BLOOD). FIRST HOME BTTN and FIRST DONE will not ever be seen by this user.

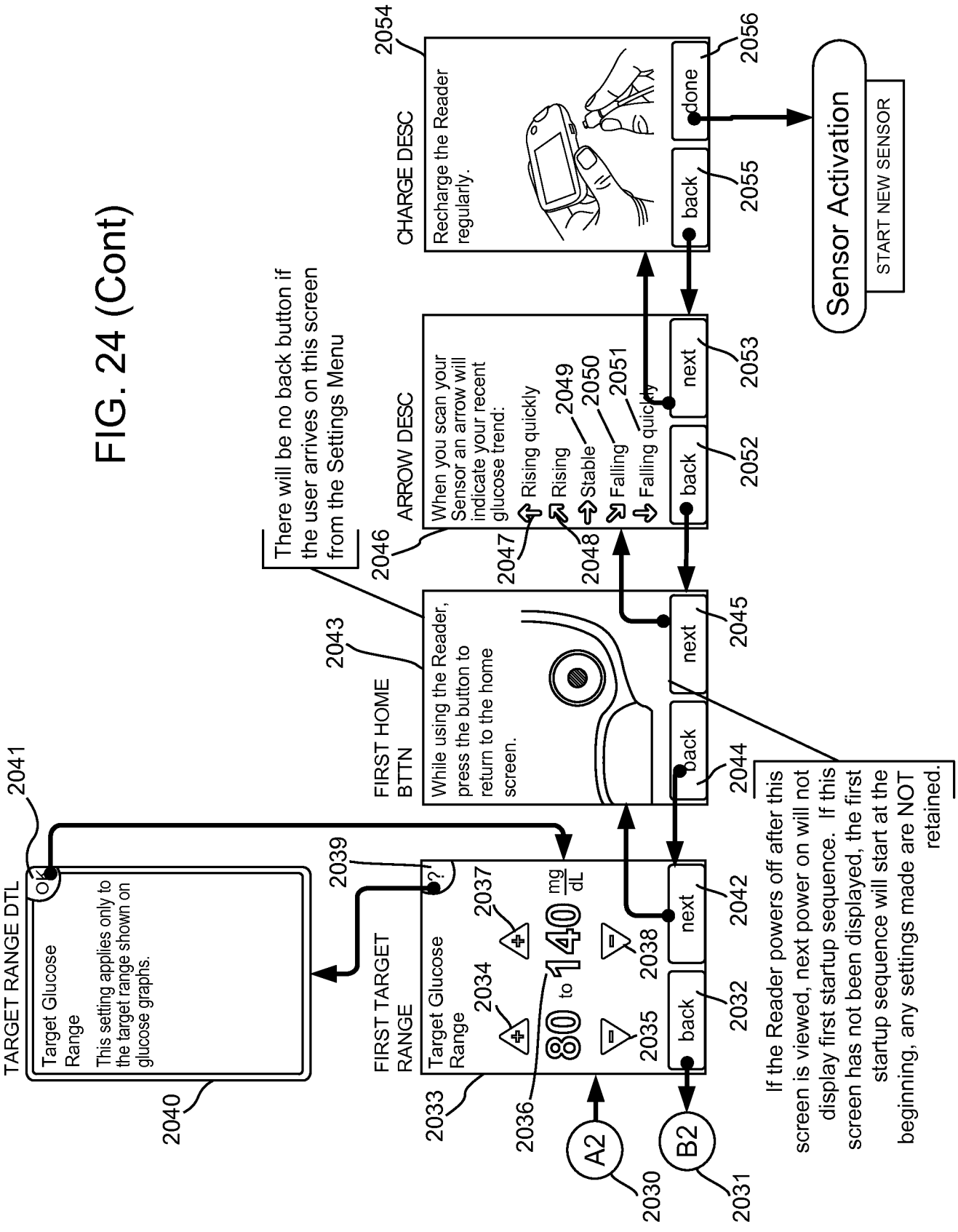
If a USB-to-PC is inserted before the First Start sequence, the Reader displays DATA TRANSFER in English. First Start sequence will be displayed on the PC Application.

If a USB-to-AC Power is inserted, the First Start sequence will initiate as if the Reader was powered on using the Power button.

If the First Start sequence is not completed, settings are NOT retained. Successive Reader activation (via strip insertion, power button or USB insertion (from AC-only)) will bring up the first step in the sequence until it is complete.

FIG. 24 (Cont)

FIG. 24 (Cont)


TARGET RANGE DTL
2041
OK
Target Glucose Range
This setting applies only to the target range shown on glucose graphs.
2040
2039
?
FIRST TARGET RANGE
Target Glucose Range
2034
2037
80 to 140 mg/dL
2036
2035
2038
back
next
2032
2042
2033
A2
2030
B2
2031
There will be no back button if the user arrives on this screen from the Settings Menu
FIRST HOME BTTN
2043
While using the Reader, press the button to return to the home screen.
back
next
2044
2045
ARROW DESC
2046
When you scan your Sensor an arrow will indicate your recent glucose trend:
Rising quickly
Rising
Stable
Falling
Falling quickly
2047
2048
2049
2050
2051
back
next
2052
2053
CHARGE DESC
2054
Recharge the Reader regularly.
back
done
2055
2056
Sensor Activation
START NEW SENSOR
If the Reader powers off after this screen is viewed, next power on will not display first startup sequence. If this screen has not been displayed, the first startup sequence will start at the beginning, any settings made are NOT retained.

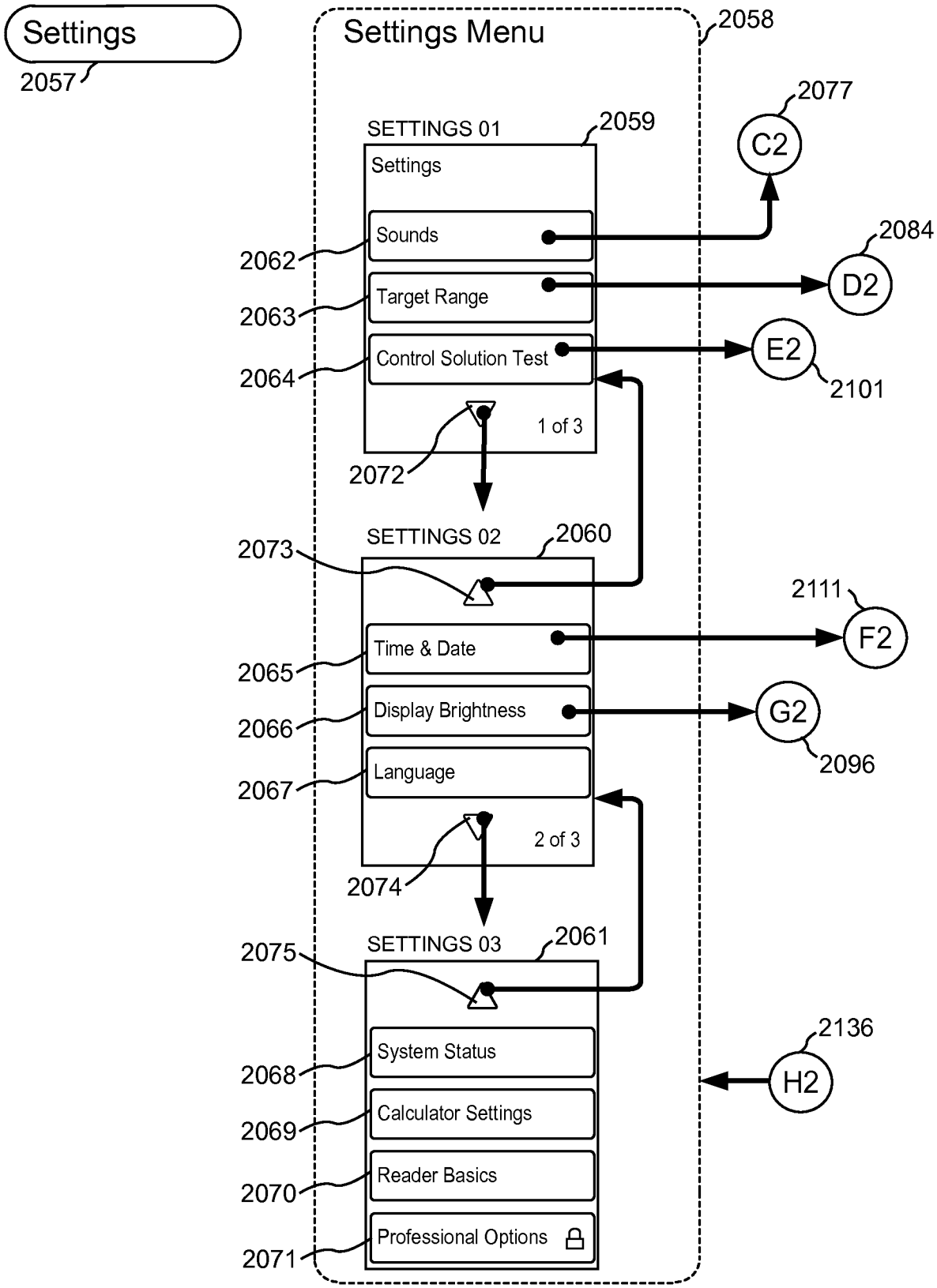

Settings
2057
Settings Menu
2058
SETTINGS 01
2059
Settings
Sounds
Target Range
Control Solution Test
1 of 3
2062
2063
2064
2072
2077
C2
2084
D2
E2
2101
SETTINGS 02
2060
2073
Time & Date
Display Brightness
Language
2 of 3
2065
2066
2067
2074
2111
F2
G2
2096
SETTINGS 03
2061
2075
System Status
Calculator Settings
Reader Basics
Professional Options
2068
2069
2070
2071
2136
H2

FIG. 25

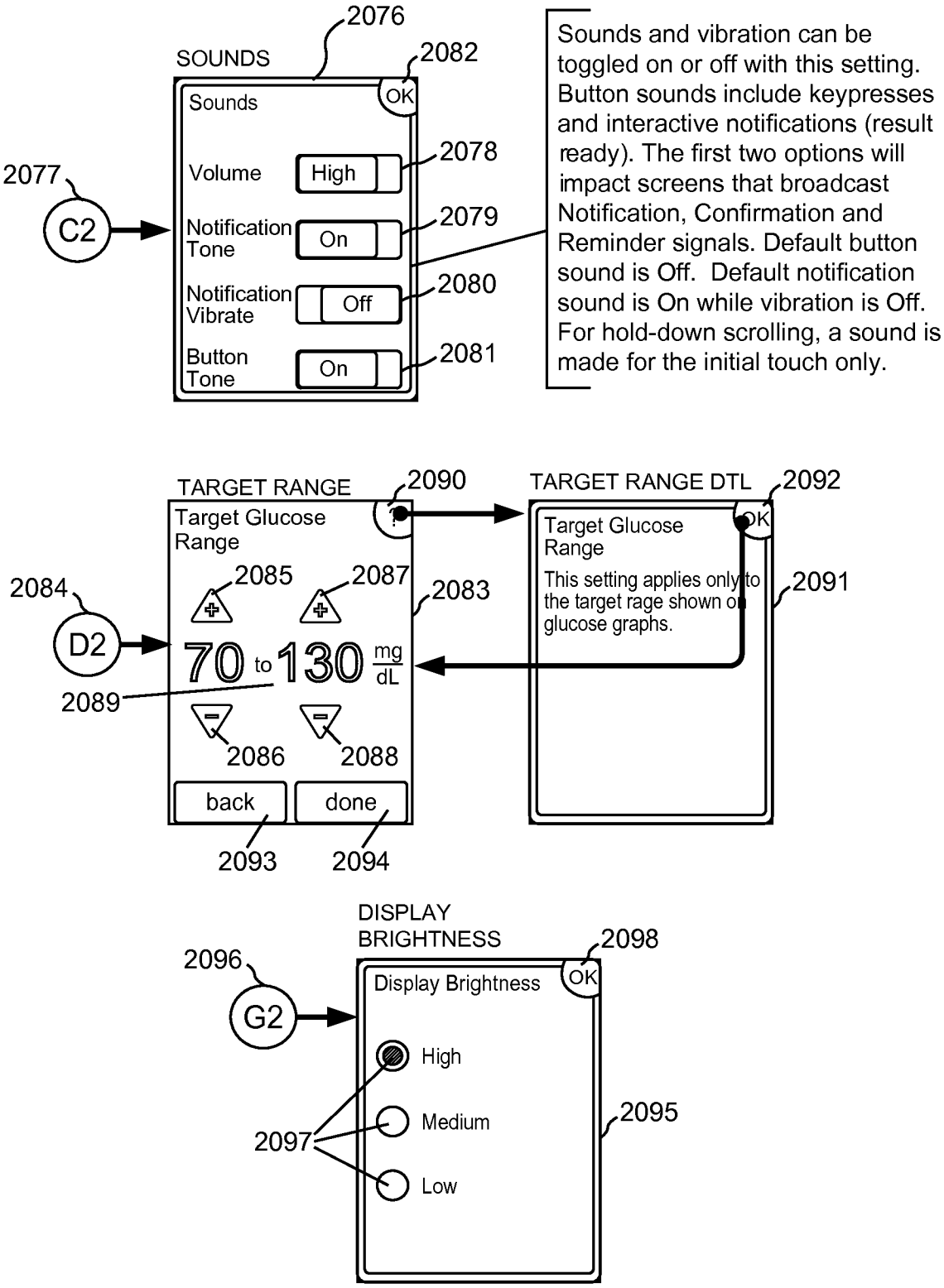

2076
SOUNDS
2082
Sounds
OK
2077
C2
Volume
High
2078
Notification Tone
On
2079
Notification Vibrate
Off
2080
Button Tone
On
2081
Sounds and vibration can be toggled on or off with this setting. Button sounds include keypresses and interactive notifications (result ready). The first two options will impact screens that broadcast Notification, Confirmation and Reminder signals. Default button sound is Off. Default notification sound is On while vibration is Off. For hold-down scrolling, a sound is made for the initial touch only.
TARGET RANGE
2090
Target Glucose Range
2084
D2
2085
2087
2083
70 to 130 mg dL
2089
2086
2088
back
done
2093
2094
TARGET RANGE DTL
2092
Target Glucose Range
OK
This setting applies only to the target rage shown on glucose graphs.
2091
DISPLAY BRIGHTNESS
2098
2096
G2
Display Brightness
OK
High
Medium
Low
2097
2095

FIG. 25 (Cont)

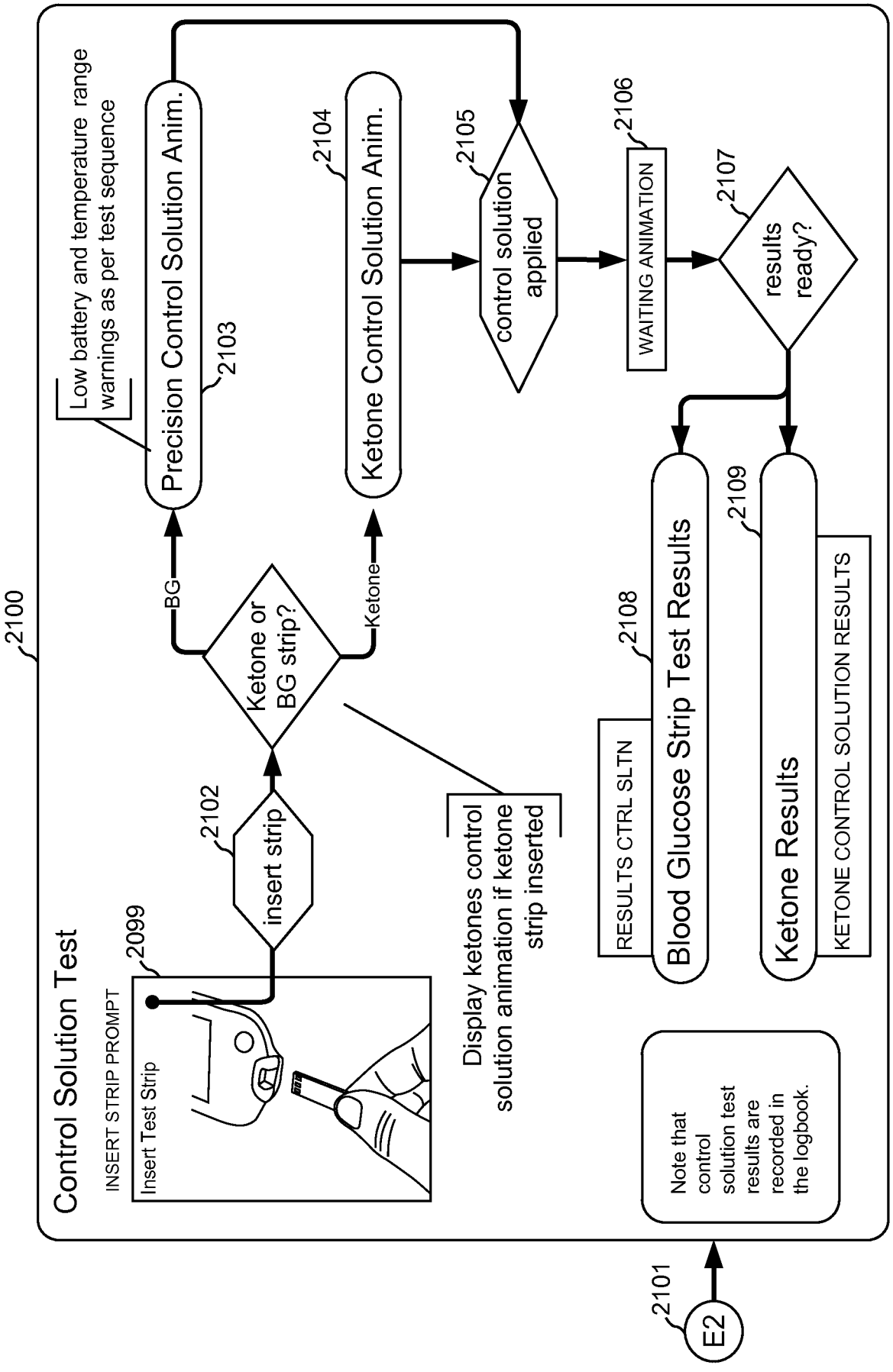

2100
Control Solution Test
INSERT STRIP PROMPT
Insert Test Strip
2099
2102
insert strip
Ketone or BG strip?
BG
Ketone
Low battery and temperature range warnings as per test sequence
Precision Control Solution Anim.
2103
Ketone Control Solution Anim.
2104
Display ketones control solution animation if ketone strip inserted
2105
control solution applied
2106
WAITING ANIMATION
2107
results ready?
RESULTS CTRL SLTN
2108
Blood Glucose Strip Test Results
2109
Ketone Results
KETONE CONTROL SOLUTION RESULTS
Note that control solution test results are recorded in the logbook.
2101
E2

FIG. 25 (Cont)

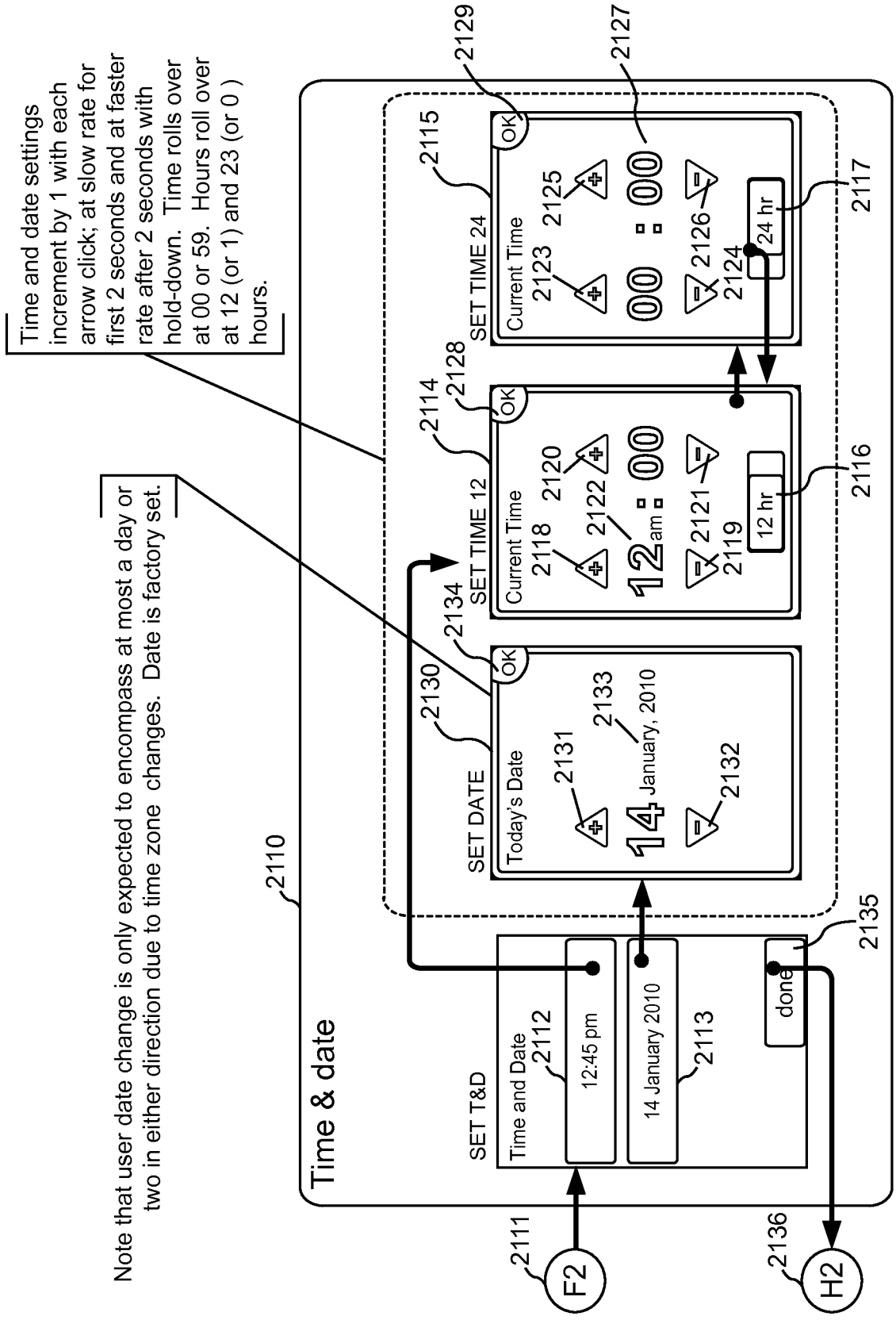

Time and date settings increment by 1 with each arrow click; at slow rate for first 2 seconds and at faster rate after 2 seconds with hold-down. Time rolls over at 00 or 59. Hours roll over at 12 (or 1) and 23 (or 0) hours.
Note that user date change is only expected to encompass at most a day or two in either direction due to time zone changes. Date is factory set.
Time & date
2110
SET T&D
Time and Date
2112
12:45 pm
14 January 2010
2113
done
2135
SET DATE
Today's Date
2131
14 January, 2010
2133
2132
OK
2130
2134
SET TIME 12
Current Time
2118
2120
2122
12 am : 00
2121
2119
12 hr
2116
OK
2114
2128
SET TIME 24
Current Time
2123
2125
00 : 00
2126
2124
24 hr
2117
OK
2115
2129
2127
F2
2111
H2
2136

FIG. 25 (Cont)

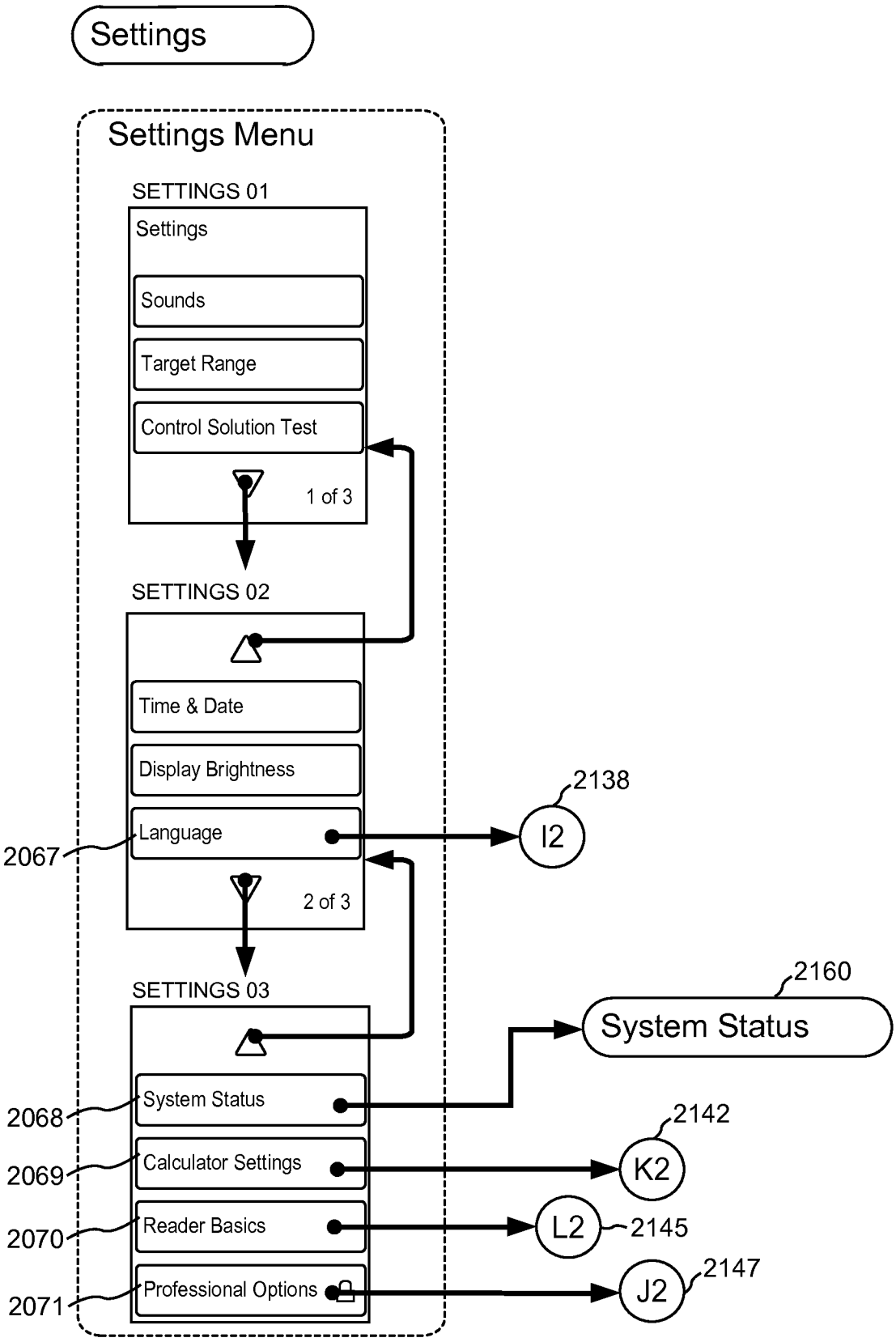

Settings
Settings Menu
SETTINGS 01
Settings
Sounds
Target Range
Control Solution Test
1 of 3
SETTINGS 02
Time & Date
Display Brightness
Language
2 of 3
SETTINGS 03
System Status
Calculator Settings
Reader Basics
Professional Options
2067
2068
2069
2070
2071
2138
I2
2160
System Status
2142
K2
L2
2145
J2
2147

FIG. 26

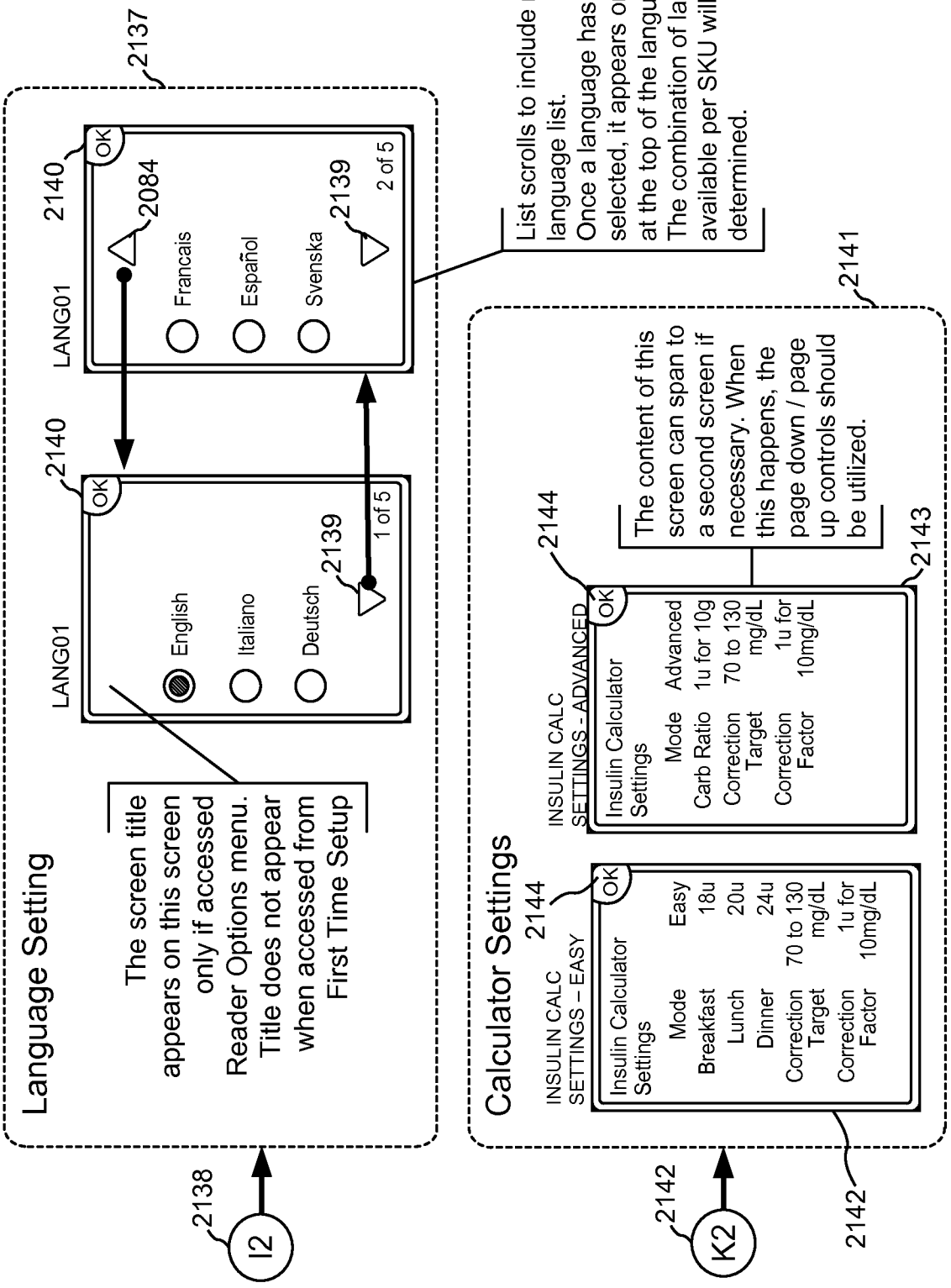

2137
Language Setting
The screen title appears on this screen only if accessed Reader Options menu. Title does not appear when accessed from First Time Setup
LANG01
English
Italiano
Deutsch
2139
1 of 5
OK
2140
LANG01
Francais
Español
Svenska
2084
2139
2 of 5
OK
2140
List scrolls to include required language list. Once a language has been selected, it appears on the first page at the top of the language list. The combination of languages to be available per SKU will be determined.
2141
Calculator Settings
INSULIN CALC SETTINGS – EASY
2144
OK
Insulin Calculator Settings
Mode Easy
Breakfast 18u
Lunch 20u
Dinner 24u
Correction Target 70 to 130 mg/dL
Correction Factor 1u for 10mg/dL
2142
INSULIN CALC SETTINGS - ADVANCED
2144
OK
Insulin Calculator Settings
Mode Advanced
Carb Ratio 1u for 10g
Correction Target 70 to 130 mg/dL
Correction Factor 1u for 10mg/dL
2143
The content of this screen can span to a second screen if necessary. When this happens, the page down / page up controls should be utilized.
2138
I2
2142
K2

FIG. 26 (Cont)

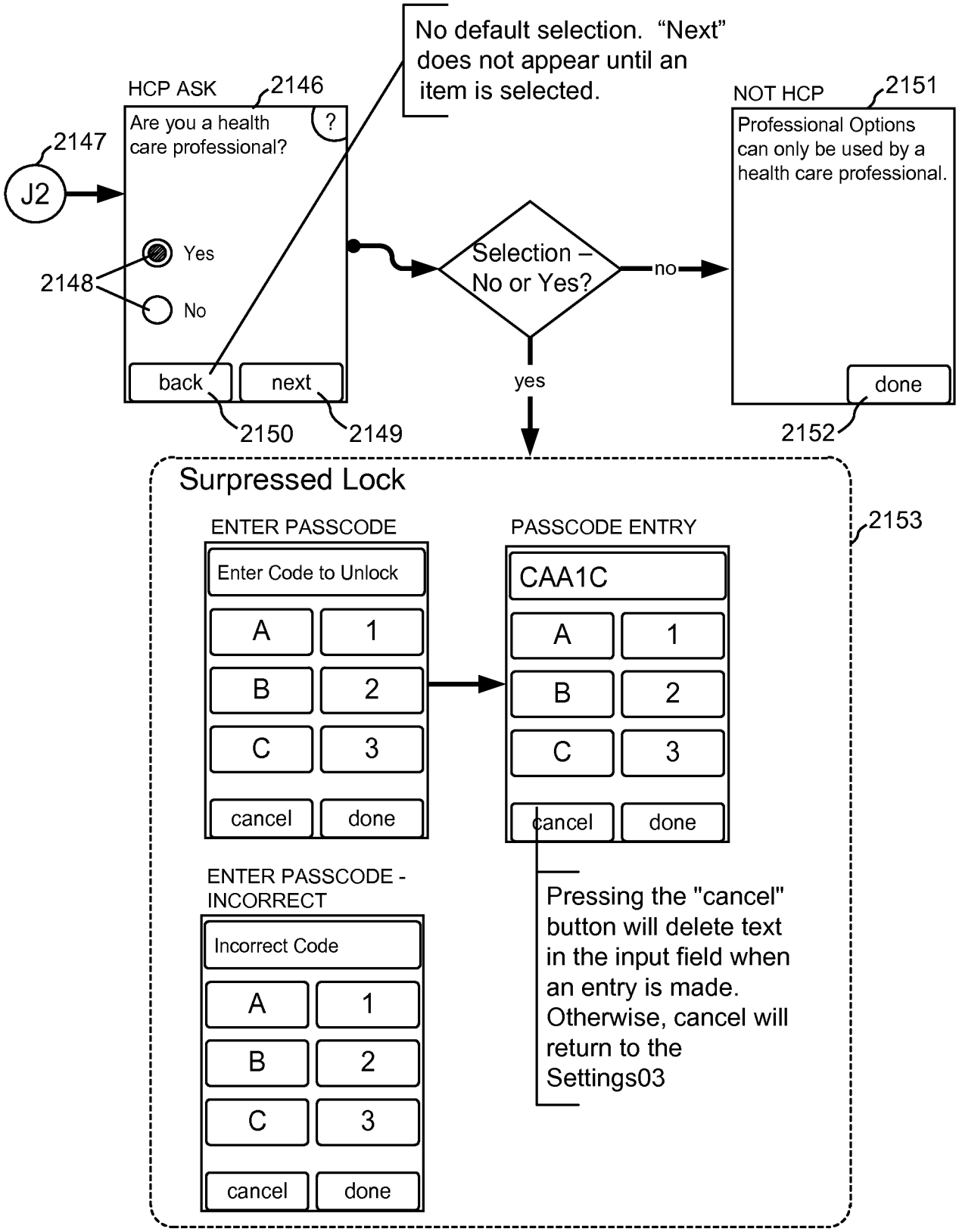

No default selection. "Next" does not appear until an item is selected.
HCP ASK
2146
Are you a health care professional?
?
2147
J2
Yes
2148
No
back
next
2150
2149
Selection – No or Yes?
no
yes
NOT HCP
2151
Professional Options can only be used by a health care professional.
done
2152
Surpressed Lock
2153
ENTER PASSCODE
Enter Code to Unlock
A 1
B 2
C 3
cancel done
PASSCODE ENTRY
CAA1C
A 1
B 2
C 3
cancel done
ENTER PASSCODE - INCORRECT
Incorrect Code
A 1
B 2
C 3
cancel done
Pressing the "cancel" button will delete text in the input field when an entry is made. Otherwise, cancel will return to the Settings03

FIG. 26 (Cont)

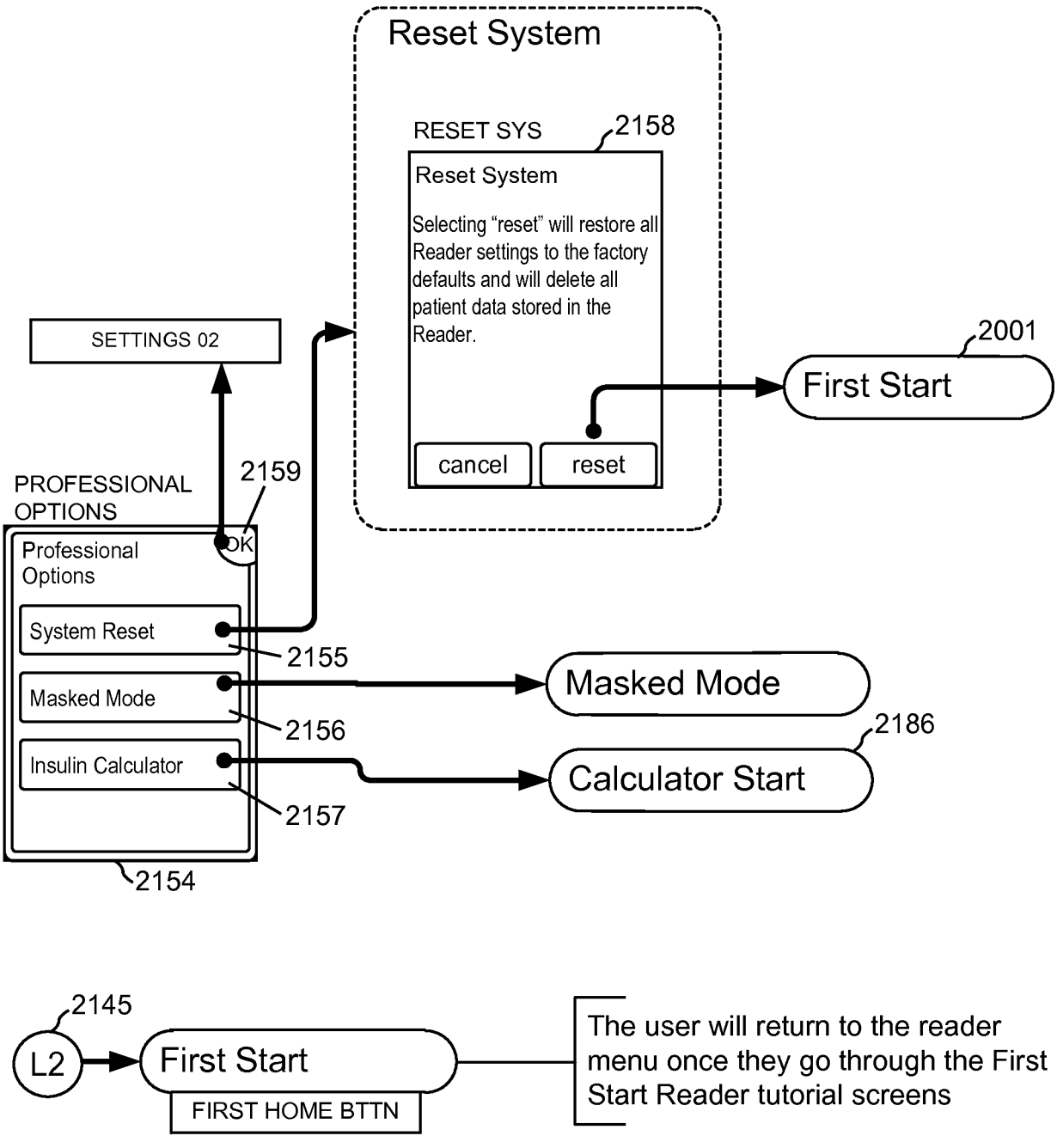

Reset System
RESET SYS
2158
Reset System
Selecting "reset" will restore all Reader settings to the factory defaults and will delete all patient data stored in the Reader.
cancel
reset
2001
First Start
SETTINGS 02
PROFESSIONAL OPTIONS
2159
OK
Professional Options
System Reset
2155
Masked Mode
2156
Insulin Calculator
2157
2154
Masked Mode
2186
Calculator Start
2145
L2
First Start
FIRST HOME BTTN
The user will return to the reader menu once they go through the First Start Reader tutorial screens

FIG. 26 (Cont)

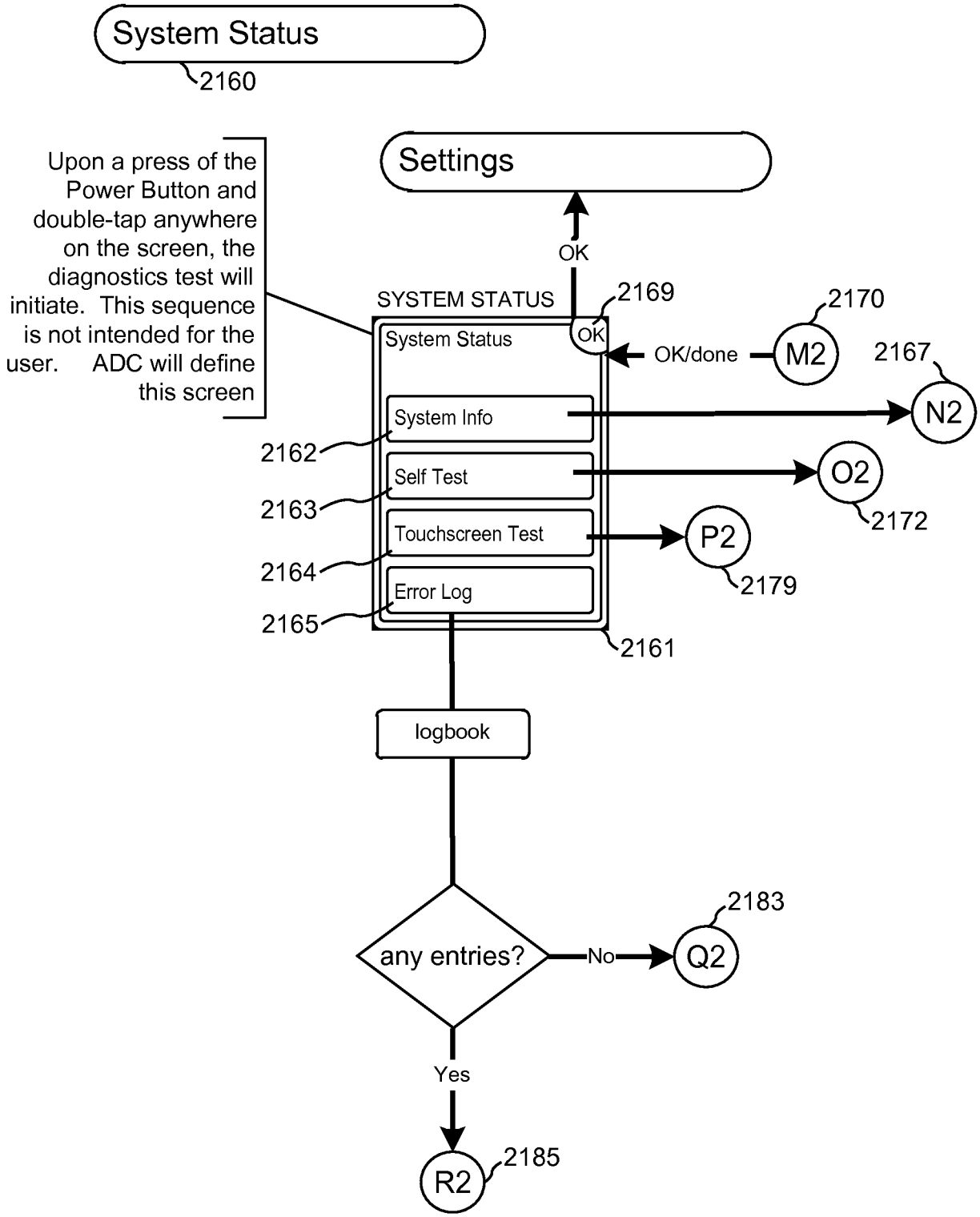

System Status
2160
Upon a press of the Power Button and double-tap anywhere on the screen, the diagnostics test will initiate. This sequence is not intended for the user. ADC will define this screen
Settings
OK
SYSTEM STATUS
2169
OK
System Status
OK/done
M2
2170
2167
N2
System Info
2162
Self Test
2163
O2
2172
Touchscreen Test
2164
P2
2179
Error Log
2165
2161
logbook
any entries?
No
Q2
2183
Yes
R2
2185

FIG. 27

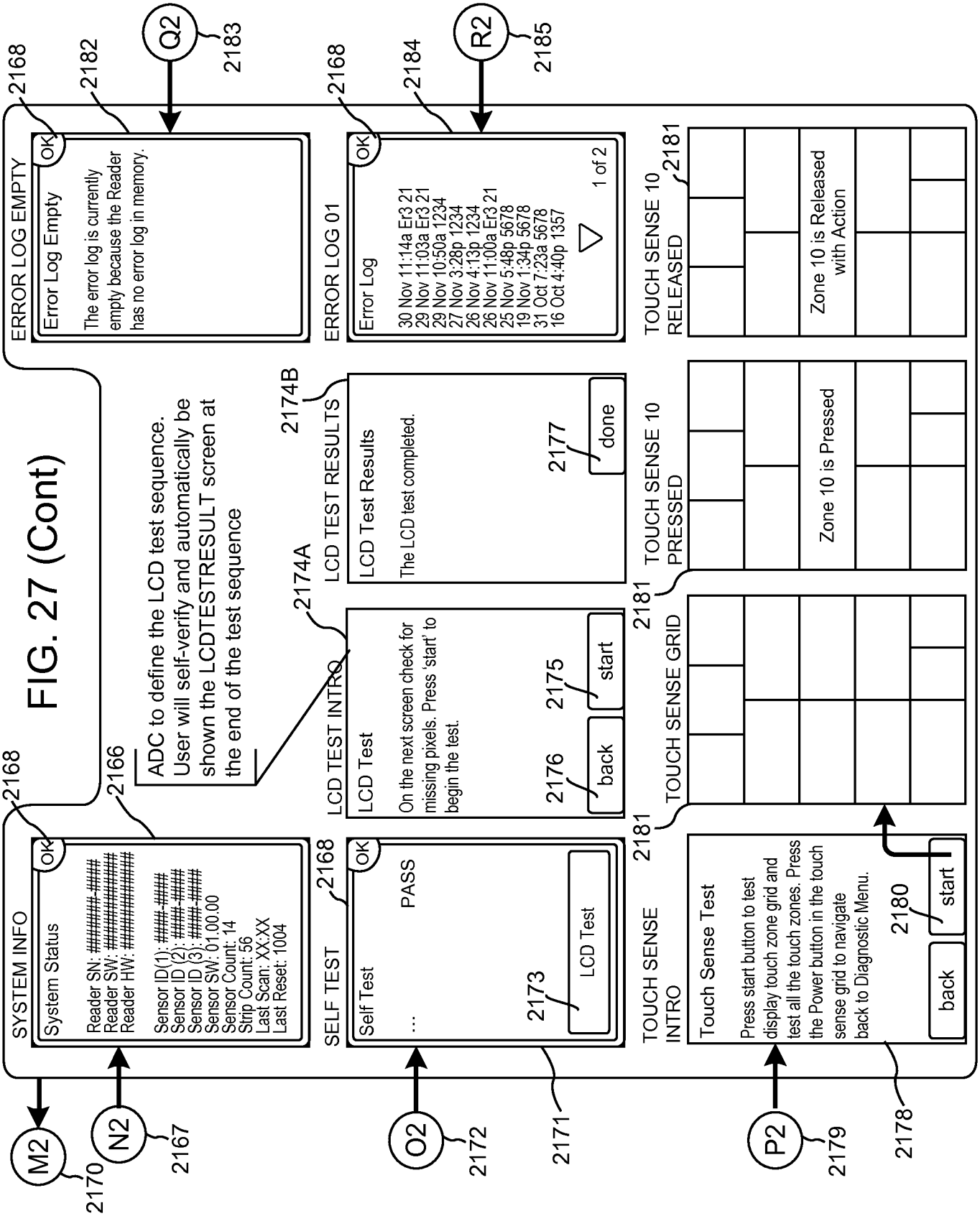


FIG. 27 (Cont)
SYSTEM INFO
OK
System Status
Reader SN: ##########
Reader SW: ##########
Reader HW: ##########
Sensor ID(1): ####-####
Sensor ID (2): ####-####
Sensor ID (3): ####-####
Sensor SW: 01.00.00
Sensor Count: 14
Strip Count: 56
Last Scan: XX:XX
Last Reset: 1004
2168
2166
ADC to define the LCD test sequence. User will self-verify and automatically be shown the LCDTESTRESULT screen at the end of the test sequence
SELF TEST
OK
Self Test
PASS
...
LCD Test
2173
2168
LCD TEST INTRO
LCD Test
On the next screen check for missing pixels. Press 'start' to begin the test.
back
start
2176
2175
2174A
LCD TEST RESULTS
LCD Test Results
The LCD test completed.
done
2177
2174B
TOUCH SENSE INTRO
Touch Sense Test
Press start button to test display touch zone grid and test all the touch zones. Press the Power button in the touch sense grid to navigate back to Diagnostic Menu.
back
start
2180
2181
TOUCH SENSE GRID
TOUCH SENSE 10 PRESSED
Zone 10 is Pressed
TOUCH SENSE 10 RELEASED
Zone 10 is Released with Action
ERROR LOG EMPTY
OK
Error Log Empty
The error log is currently empty because the Reader has no error log in memory.
2182
ERROR LOG 01
OK
Error Log
30 Nov 11:14a Er3 21
29 Nov 11:03a Er3 21
29 Nov 10:50a 1234
27 Nov 3:28p 1234
26 Nov 4:13p 1234
26 Nov 11:00a Er3 21
25 Nov 5:48p 5678
19 Nov 1:34p 5678
31 Oct 7:23a 5678
16 Oct 4:40p 1357
1 of 2
2184
2168
M2
2170
N2
2167
O2
2172
P2
2179
Q2
2183
R2
2185
2171
2178

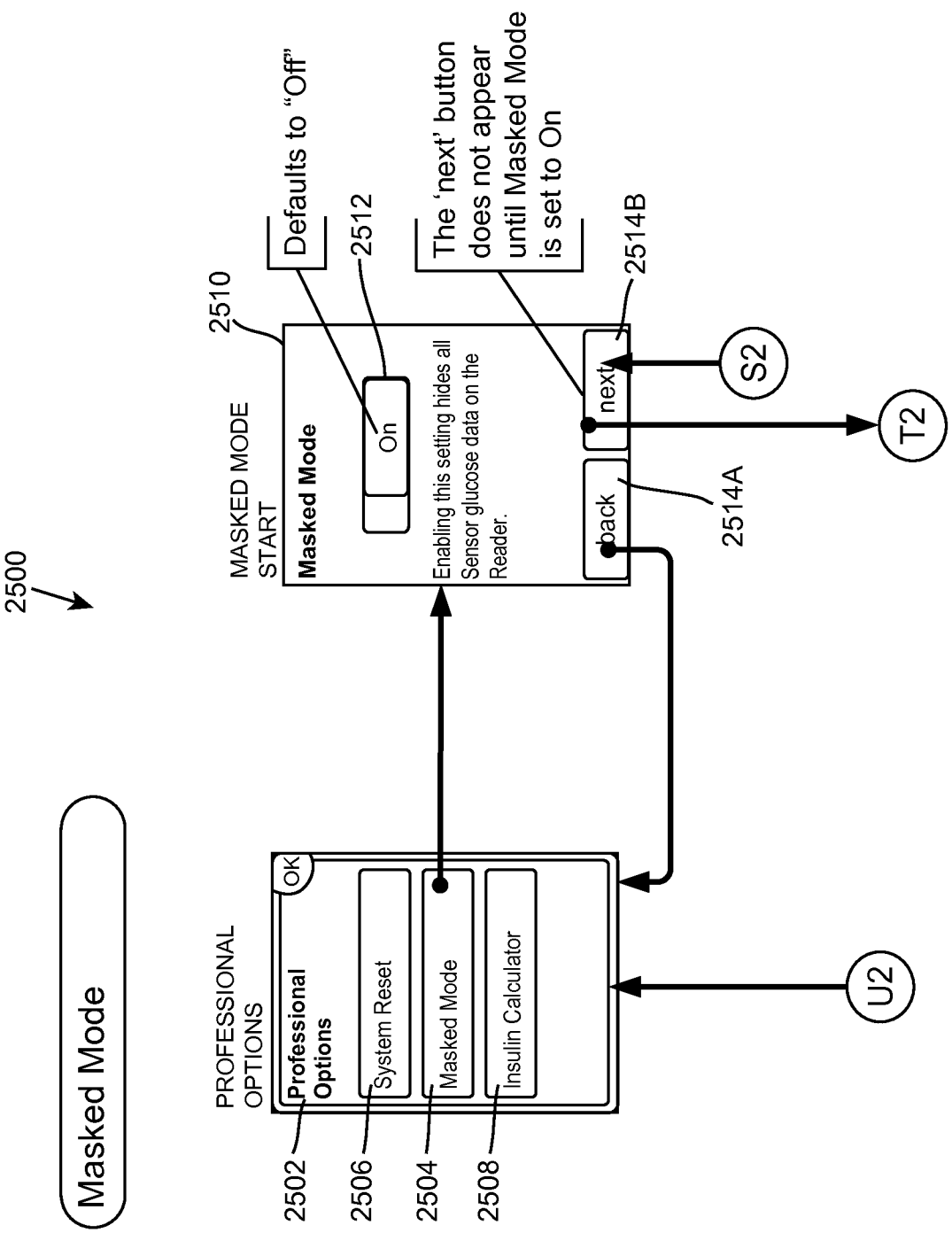

2500
Masked Mode
PROFESSIONAL OPTIONS
OK
Professional Options
System Reset
Masked Mode
Insulin Calculator
2502
2506
2504
2508
U2
MASKED MODE START
2510
Masked Mode
On
Defaults to "Off"
2512
Enabling this setting hides all Sensor glucose data on the Reader.
The 'next' button does not appear until Masked Mode is set to On
next
back
2514B
2514A
S2
T2

FIG. 28

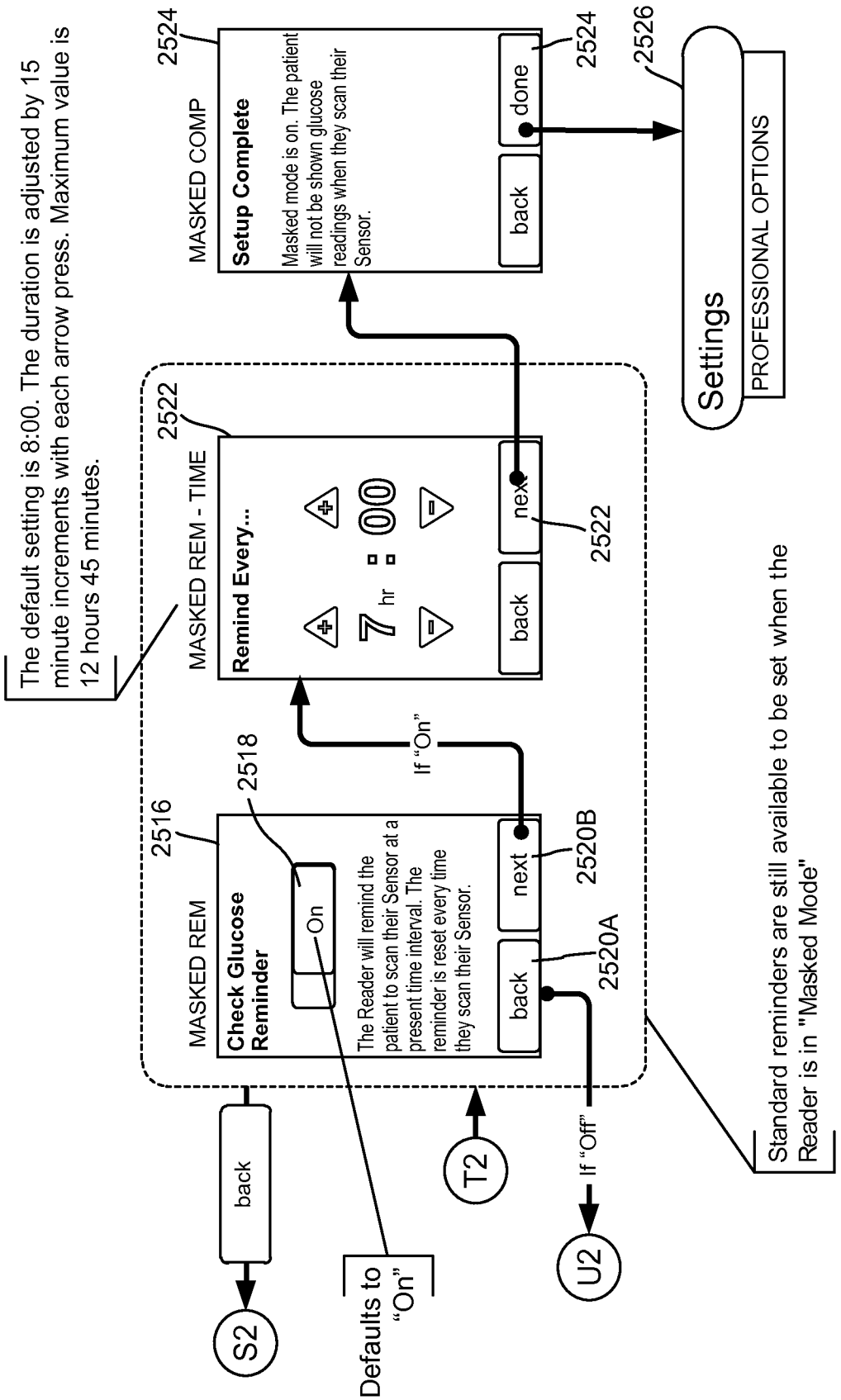

The default setting is 8:00. The duration is adjusted by 15 minute increments with each arrow press. Maximum value is 12 hours 45 minutes.
2524
MASKED COMP
Setup Complete
Masked mode is on. The patient will not be shown glucose readings when they scan their Sensor.
back
done
2524
2526
Settings
PROFESSIONAL OPTIONS
2522
MASKED REM - TIME
Remind Every...
7 hr 00
back
next
2522
2516
2518
MASKED REM
Check Glucose Reminder
On
The Reader will remind the patient to scan their Sensor at a present time interval. The reminder is reset every time they scan their Sensor.
back
next
2520B
2520A
If "On"
back
S2
Defaults to "On"
T2
If "Off"
U2
Standard reminders are still available to be set when the Reader is in "Masked Mode"

FIG. 28 (Cont)

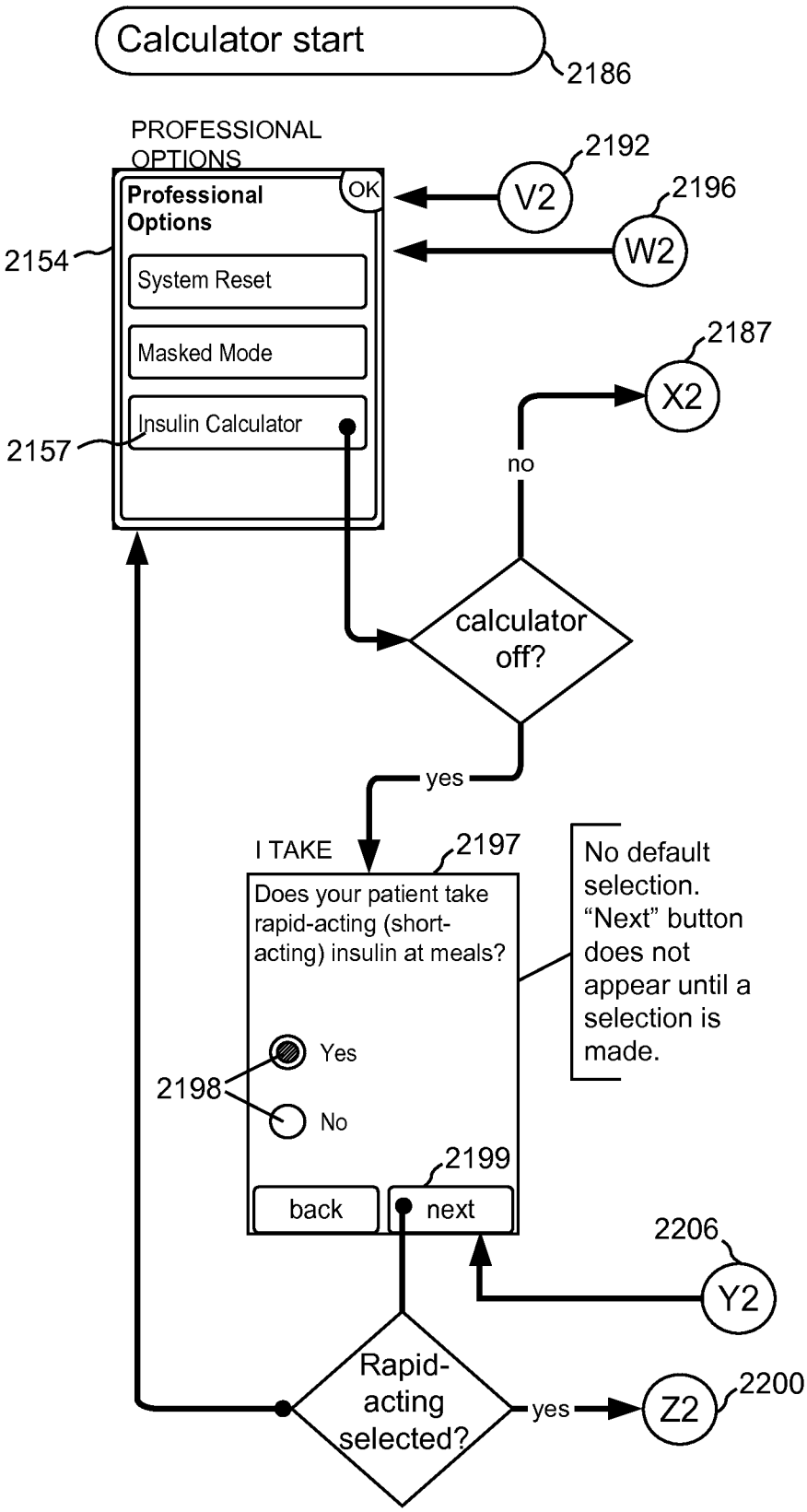
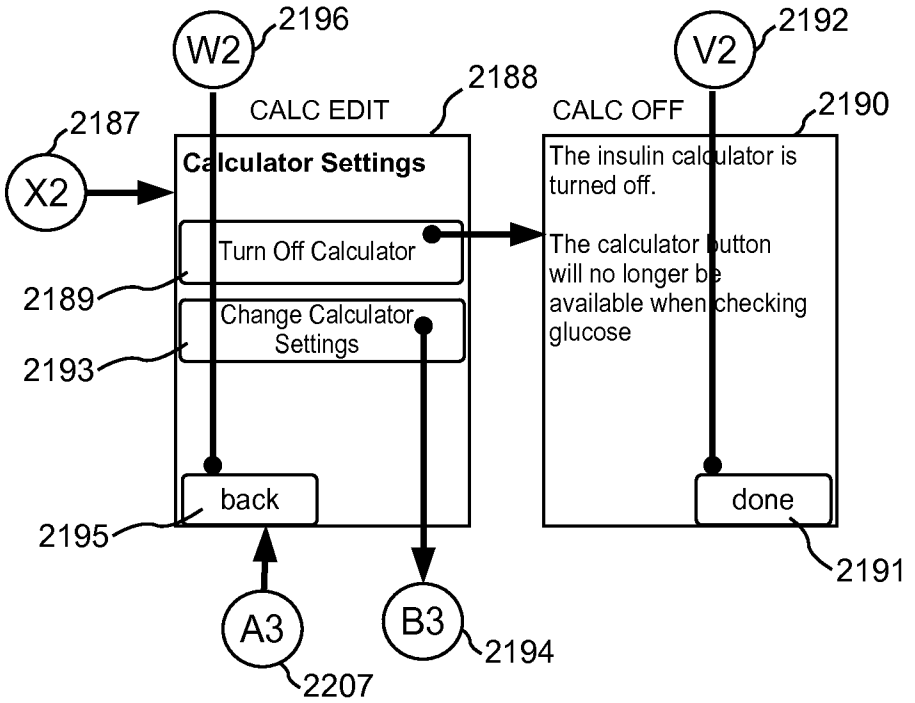

Calculator start
2186
PROFESSIONAL OPTIONS
Professional Options
OK
2154
System Reset
Masked Mode
Insulin Calculator
2157
2192
V2
2196
W2
2187
X2
no
calculator off?
yes
I TAKE
2197
Does your patient take rapid-acting (short-acting) insulin at meals?
Yes
No
2198
2199
back
next
No default selection. "Next" button does not appear until a selection is made.
2206
Y2
Rapid-acting selected?
yes
Z2
2200

FIG. 29


W2
2196
CALC EDIT
2188
2187
X2
Calculator Settings
Turn Off Calculator
2189
Change Calculator Settings
2193
back
2195
A3
2207
B3
2194
V2
2192
CALC OFF
2190
The insulin calculator is turned off.
The calculator button will no longer be available when checking glucose
done
2191

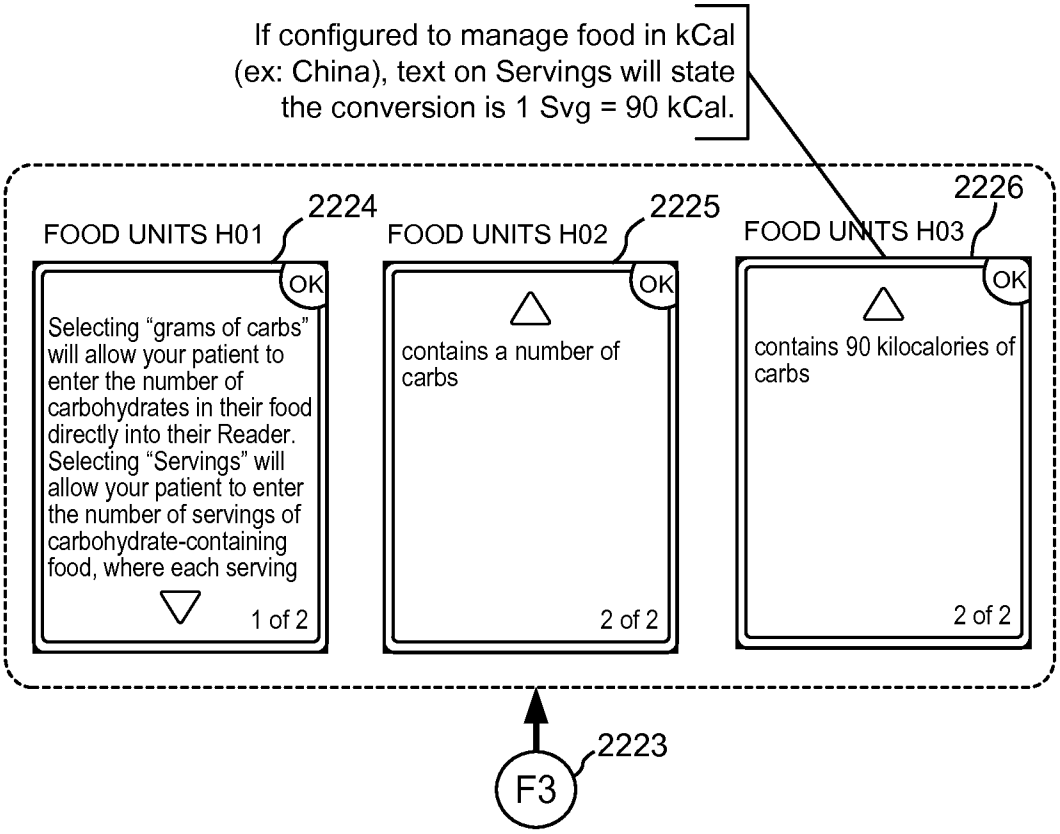

If configured to manage food in kCal (ex: China), text on Servings will state the conversion is 1 Svg = 90 kCal.
FOOD UNITS H01
2224
OK
Selecting "grams of carbs" will allow your patient to enter the number of carbohydrates in their food directly into their Reader. Selecting "Servings" will allow your patient to enter the number of servings of carbohydrate-containing food, where each serving
1 of 2
FOOD UNITS H02
2225
OK
contains a number of carbs
2 of 2
FOOD UNITS H03
2226
OK
contains 90 kilocalories of carbs
2 of 2
F3
2223

FIG. 29 (Cont)

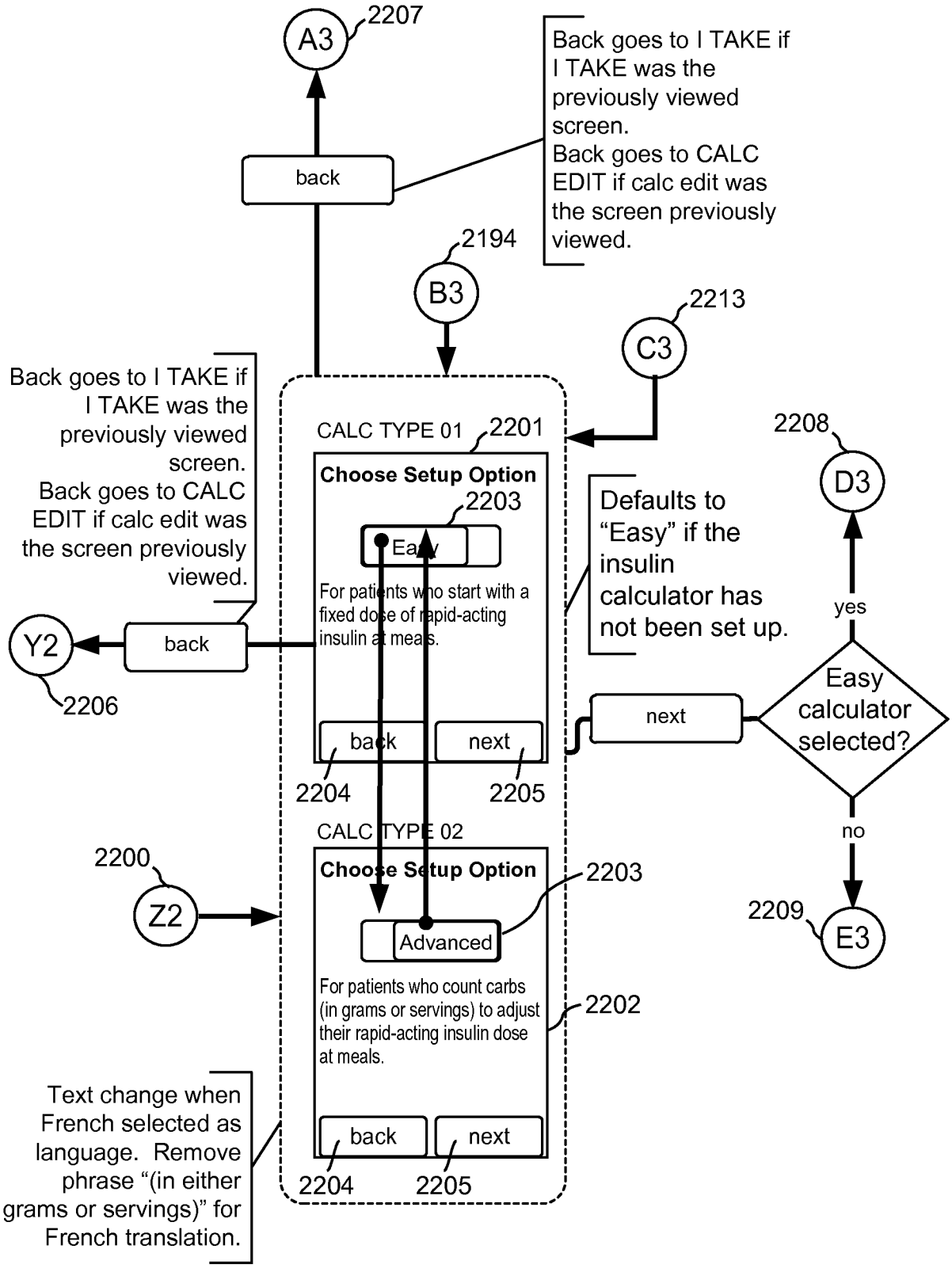

A3
2207
back
Back goes to I TAKE if I TAKE was the previously viewed screen.
Back goes to CALC EDIT if calc edit was the screen previously viewed.
2194
B3
2213
C3
Back goes to I TAKE if I TAKE was the previously viewed screen.
Back goes to CALC EDIT if calc edit was the screen previously viewed.
CALC TYPE 01
2201
Choose Setup Option
2203
Easy
For patients who start with a fixed dose of rapid-acting insulin at meals.
Y2
back
2206
back
next
2204
2205
Defaults to "Easy" if the insulin calculator has not been set up.
2208
D3
yes
Easy calculator selected?
next
no
2209
E3
2200
Z2
CALC TYPE 02
Choose Setup Option
2203
Advanced
For patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
2202
back
next
2204
2205
Text change when French selected as language. Remove phrase "(in either grams or servings)" for French translation.

FIG. 29 (Cont)

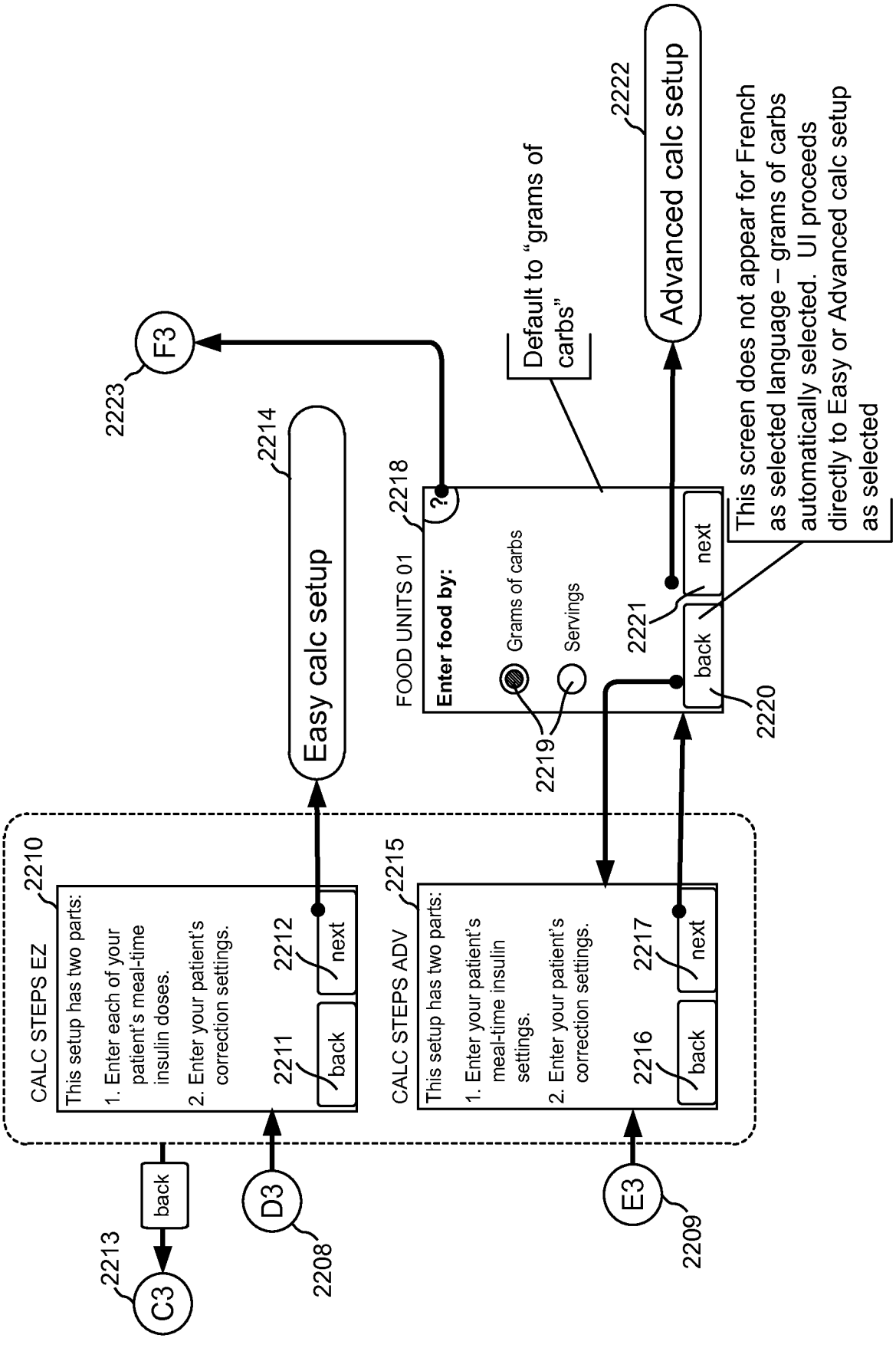

CALC STEPS EZ
2210
This setup has two parts:
1. Enter each of your patient's meal-time insulin doses.
2. Enter your patient's correction settings.
back
2211
next
2212
CALC STEPS ADV
2215
This setup has two parts:
1. Enter your patient's meal-time insulin settings.
2. Enter your patient's correction settings.
back
2216
next
2217
Easy calc setup
2214
Advanced calc setup
2222
FOOD UNITS 01
2218
Enter food by:
Grams of carbs
Servings
2219
back
next
2221
2220
Default to "grams of carbs"
This screen does not appear for French as selected language – grams of carbs automatically selected. UI proceeds directly to Easy or Advanced calc setup as selected
F3
2223
C3
2213
back
D3
2208
E3
2209

FIG. 29 (Cont)

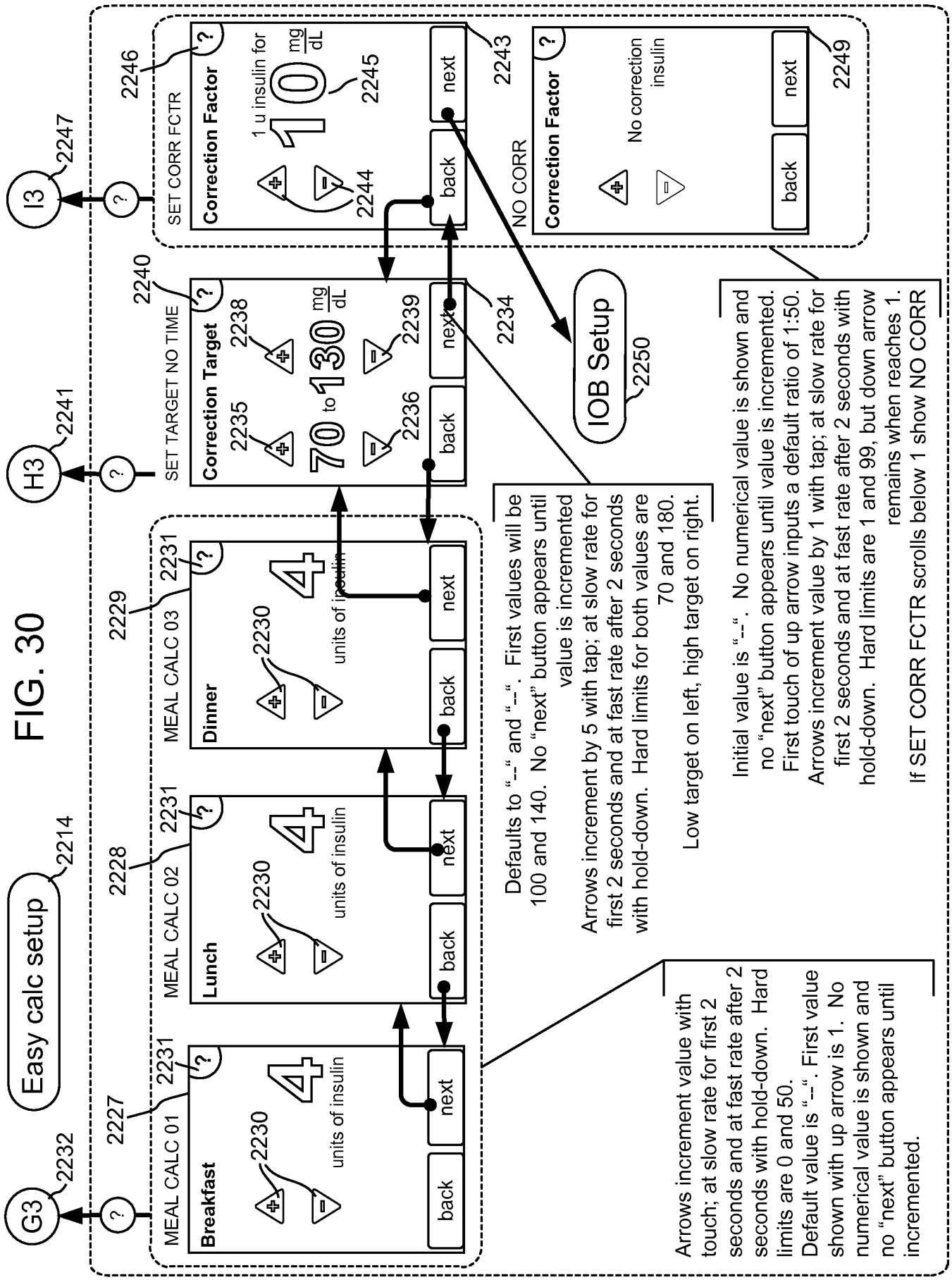


FIG. 30
Easy calc setup
2214
G3
2232
H3
2241
I3
2247
MEAL CALC 01
Breakfast
2227
2231
MEAL CALC 02
Lunch
2228
MEAL CALC 03
Dinner
2229
SET TARGET NO TIME
Correction Target
2240
SET CORR FCTR
Correction Factor
2246
NO CORR
Correction Factor
No correction insulin
IOB Setup
2250
units of insulin
1 u insulin for
mg/dL
70 to 130
back
next
2230
2231
2234
2235
2236
2238
2239
2243
2244
2245
2249
Arrows increment value with touch; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits are 0 and 50.
Default value is "--". First value shown with up arrow is 1. No numerical value is shown and no "next" button appears until incremented.
Defaults to "--" and "--". First values will be 100 and 140. No "next" button appears until value is incremented
Arrows increment by 5 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits for both values are 70 and 180.
Low target on left, high target on right.
Initial value is "--". No numerical value is shown and no "next" button appears until value is incremented.
First touch of up arrow inputs a default ratio of 1:50.
Arrows increment value by 1 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits are 1 and 99, but down arrow remains when reaches 1.
If SET CORR FCTR scrolls below 1 show NO CORR

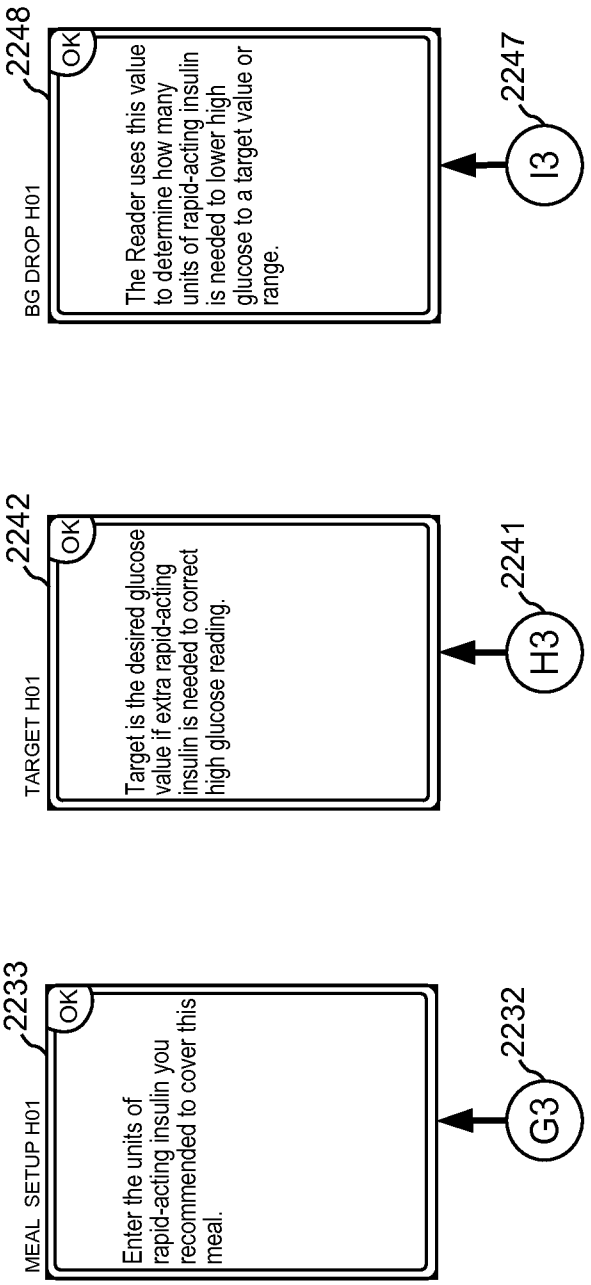

2248
BG DROP H01
OK
The Reader uses this value to determine how many units of rapid-acting insulin is needed to lower high glucose to a target value or range.
2247
I3
2242
TARGET H01
OK
Target is the desired glucose value if extra rapid-acting insulin is needed to correct high glucose reading.
2241
H3
2233
MEAL SETUP H01
OK
Enter the units of rapid-acting insulin you recommended to cover this meal.
2232
G3

FIG. 30 (Cont)

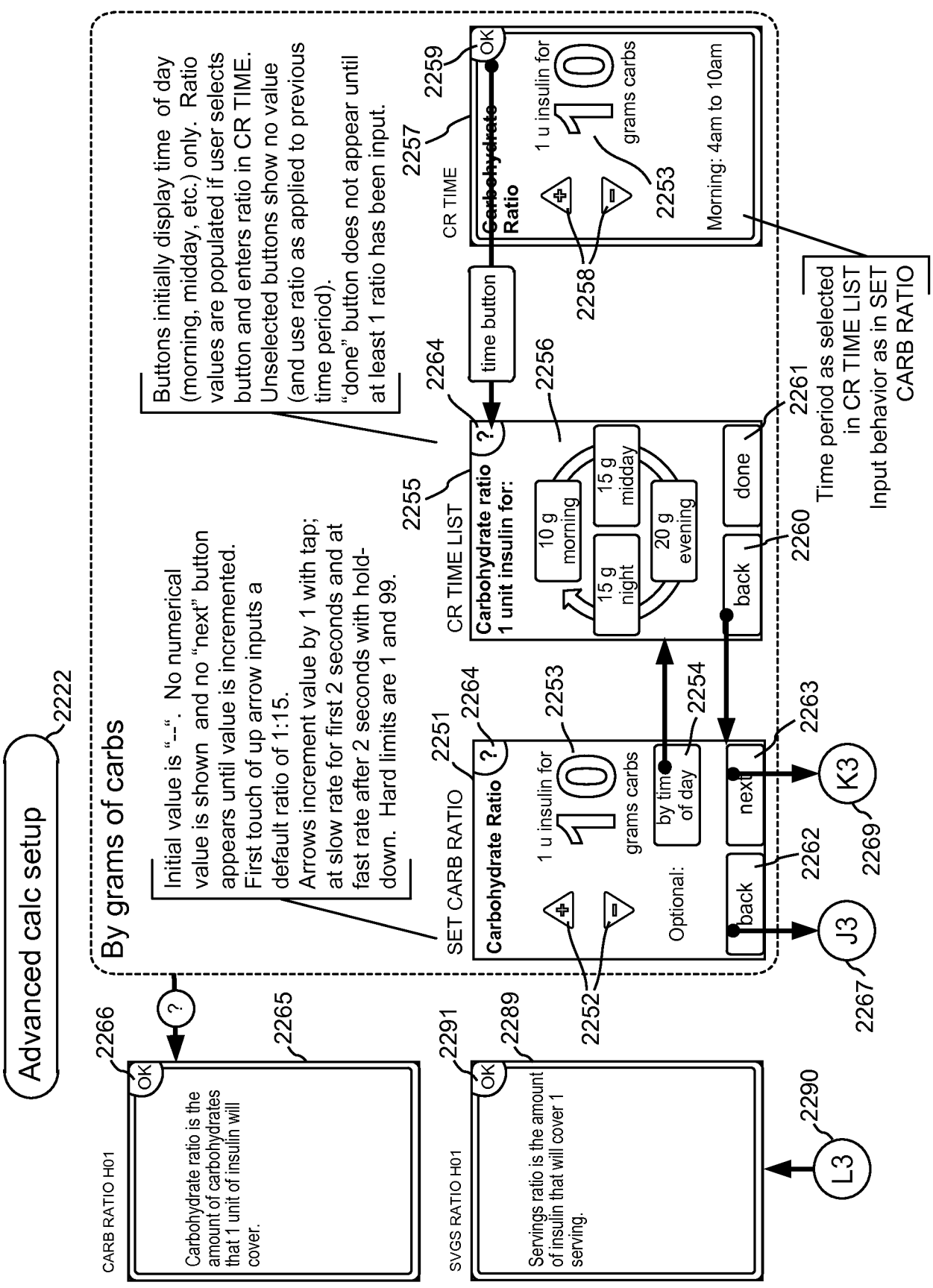

Advanced calc setup
2222
By grams of carbs
Initial value is "--". No numerical value is shown and no "next" button appears until value is incremented. First touch of up arrow inputs a default ratio of 1:15. Arrows increment value by 1 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits are 1 and 99.
Buttons initially display time of day (morning, midday, etc.) only. Ratio values are populated if user selects button and enters ratio in CR TIME. Unselected buttons show no value (and use ratio as applied to previous time period). "done" button does not appear until at least 1 ratio has been input.
SET CARB RATIO
2251
2264
Carbohydrate Ratio
1 u insulin for
10
grams carbs
2253
Optional:
by time of day
2254
back
next
2252
2262
2263
2269
J3
2267
K3
CR TIME LIST
2255
Carbohydrate ratio 1 unit insulin for:
10 g morning
15 g midday
15 g night
20 g evening
2256
back
done
2260
2261
Time period as selected in CR TIME LIST
Input behavior as in SET CARB RATIO
CR TIME
2257
Carbohydrate Ratio
OK
2259
1 u insulin for
10
grams carbs
2253
2258
Morning: 4am to 10am
time button
2264
CARB RATIO H01
2266
OK
Carbohydrate ratio is the amount of carbohydrates that 1 unit of insulin will cover.
2265
SVGS RATIO H01
2291
OK
2289
Servings ratio is the amount of insulin that will cover 1 serving.
2290
L3

FIG. 31

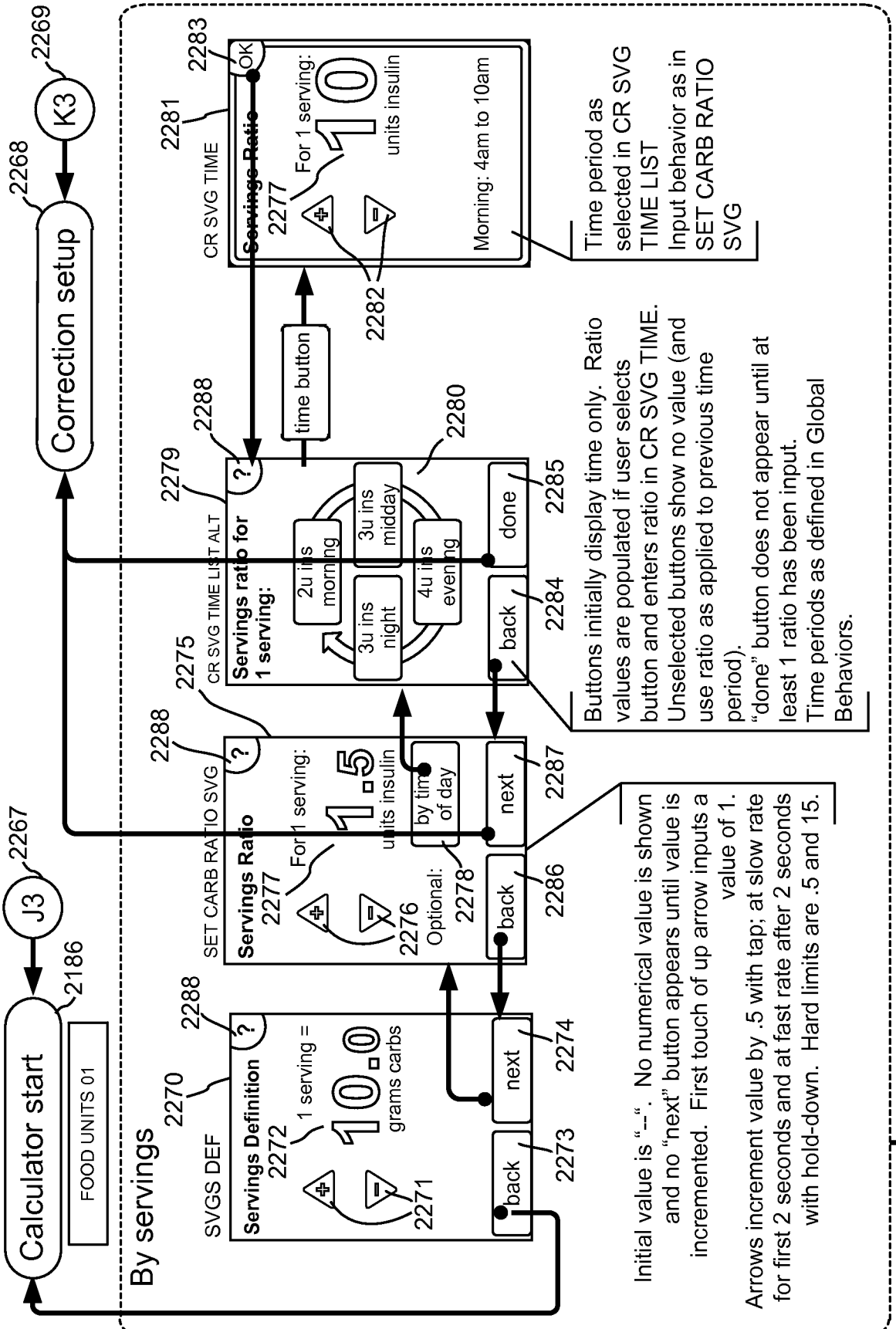

Calculator start
2186
FOOD UNITS 01
J3
2267
Correction setup
2268
K3
2269
By servings
SVGS DEF
Servings Definition
2270
2272
1 serving =
10.0
grams carbs
2271
back
next
2273
2274
2288
SET CARB RATIO SVG
Servings Ratio
2277
For 1 serving:
1.5
units insulin
2276
Optional:
by time of day
2278
back
next
2286
2287
2275
CR SVG TIME LIST ALT
Servings ratio for 1 serving:
2279
2280
2u ins morning
3u ins midday
3u ins night
4u ins evening
back
done
2284
2285
time button
2281
CR SVG TIME
Servings Ratio
OK
2283
For 1 serving:
10
units insulin
2277
2282
Morning: 4am to 10am
Time period as selected in CR SVG TIME LIST
Input behavior as in SET CARB RATIO SVG
Buttons initially display time only. Ratio values are populated if user selects button and enters ratio in CR SVG TIME. Unselected buttons show no value (and use ratio as applied to previous time period).
"done" button does not appear until at least 1 ratio has been input.
Time periods as defined in Global Behaviors.
Initial value is "--". No numerical value is shown and no "next" button appears until value is incremented. First touch of up arrow inputs a value of 1.
Arrows increment value by .5 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits are .5 and 15.
L3
2290

FIG. 31 (Cont)

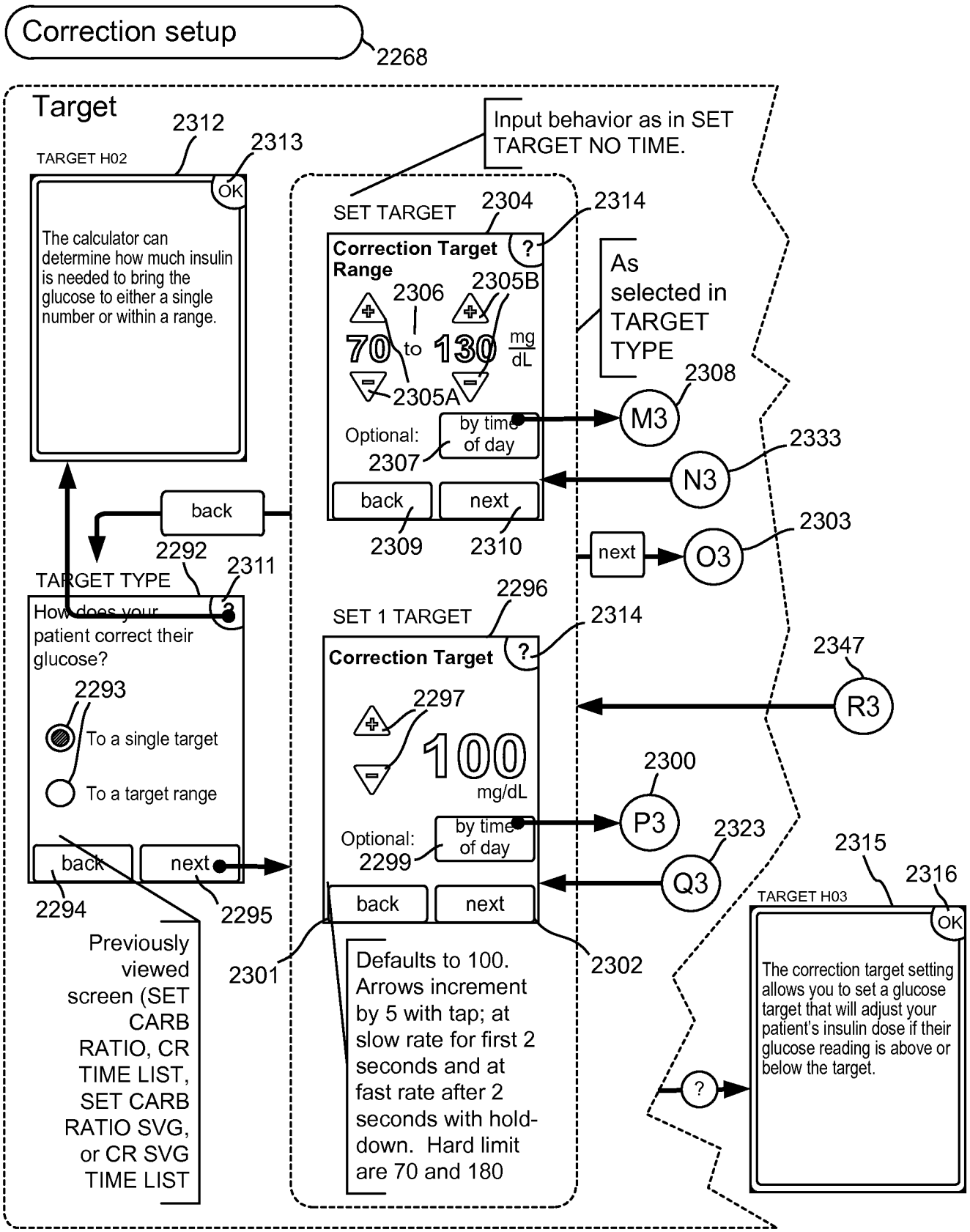

Correction setup
2268
Target
2312
2313
TARGET H02
OK
The calculator can determine how much insulin is needed to bring the glucose to either a single number or within a range.
Input behavior as in SET TARGET NO TIME.
SET TARGET
2304
2314
Correction Target Range
?
2306
2305B
70
to
130
mg
dL
2305A
As selected in TARGET TYPE
2308
M3
Optional:
by time of day
2307
2333
N3
back
next
2309
2310
2303
next
O3
back
2292
2311
TARGET TYPE
How does your patient correct their glucose?
3
2293
To a single target
To a target range
back
next
2294
2295
2296
SET 1 TARGET
2314
Correction Target
?
2347
R3
2297
100
mg/dL
2300
P3
Optional:
by time of day
2299
2323
Q3
back
next
2315
2316
TARGET H03
OK
The correction target setting allows you to set a glucose target that will adjust your patient's insulin dose if their glucose reading is above or below the target.
?
Previously viewed screen (SET CARB RATIO, CR TIME LIST, SET CARB RATIO SVG, or CR SVG TIME LIST
2301
Defaults to 100. Arrows increment by 5 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limit are 70 and 180
2302

FIG. 32

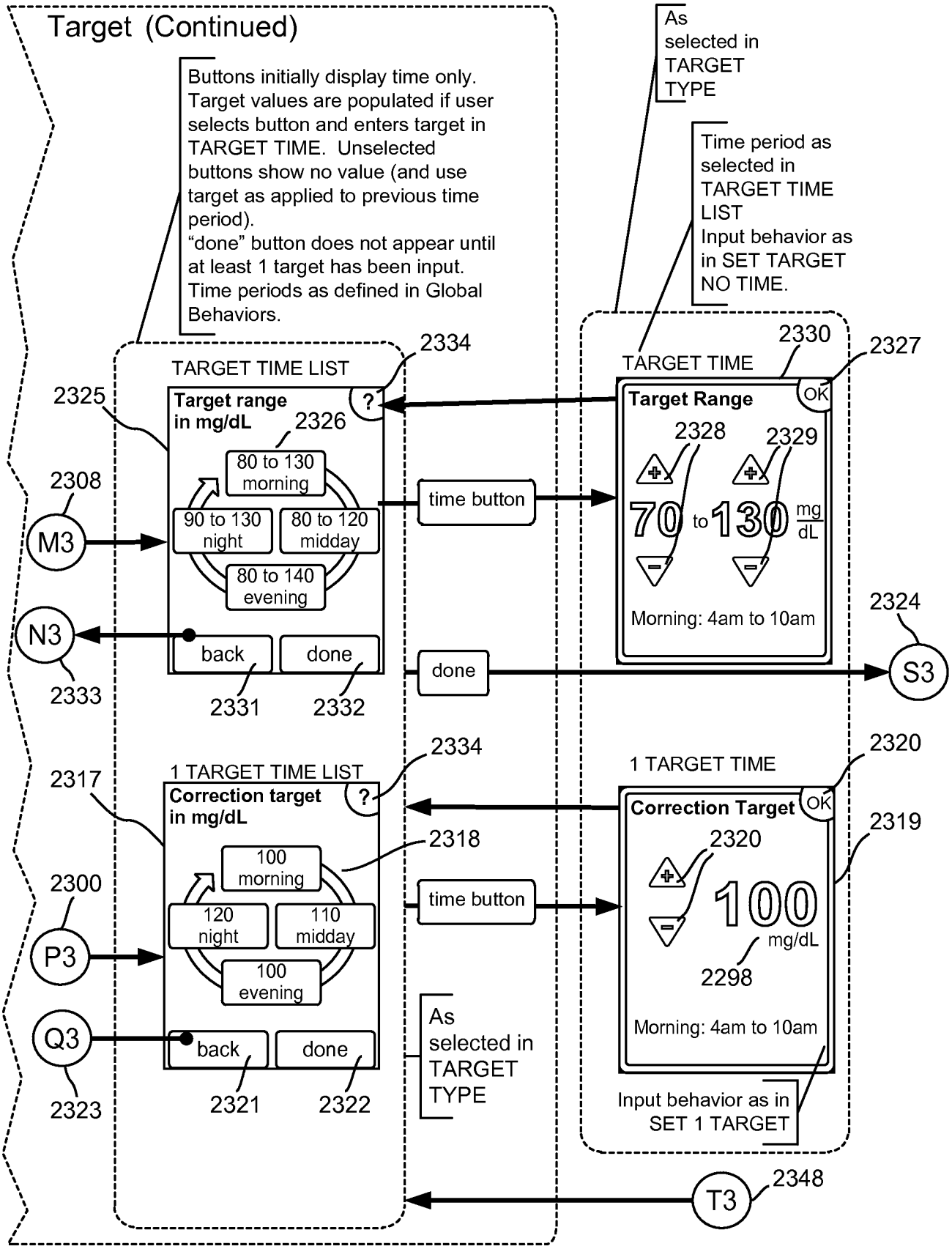

Target (Continued)
Buttons initially display time only. Target values are populated if user selects button and enters target in TARGET TIME. Unselected buttons show no value (and use target as applied to previous time period).
"done" button does not appear until at least 1 target has been input.
Time periods as defined in Global Behaviors.
As selected in TARGET TYPE
Time period as selected in TARGET TIME LIST
Input behavior as in SET TARGET NO TIME.
TARGET TIME LIST
Target range in mg/dL
80 to 130 morning
90 to 130 night
80 to 120 midday
80 to 140 evening
back
done
TARGET TIME
Target Range
OK
70 to 130 mg/dL
Morning: 4am to 10am
time button
done
1 TARGET TIME LIST
Correction target in mg/dL
100 morning
120 night
110 midday
100 evening
back
done
1 TARGET TIME
Correction Target
100 mg/dL
Morning: 4am to 10am
Input behavior as in SET 1 TARGET
As selected in TARGET TYPE
M3
N3
P3
Q3
S3
T3
2308
2333
2300
2323
2324
2348
2325
2326
2327
2328
2329
2330
2331
2332
2334
2317
2318
2319
2320
2321
2322
2298

FIG. 32 (Cont)

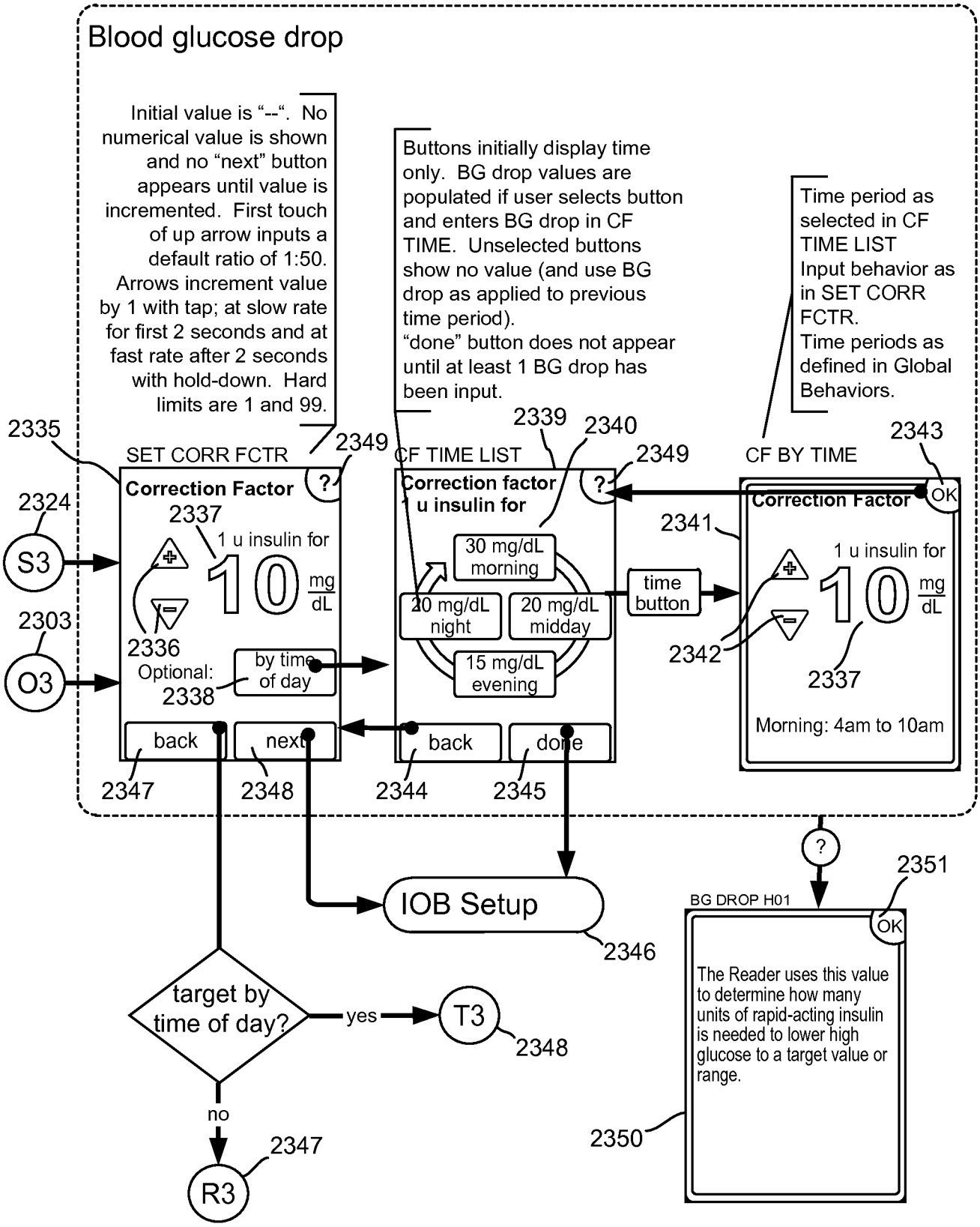

Blood glucose drop
Initial value is "--". No numerical value is shown and no "next" button appears until value is incremented. First touch of up arrow inputs a default ratio of 1:50. Arrows increment value by 1 with tap; at slow rate for first 2 seconds and at fast rate after 2 seconds with hold-down. Hard limits are 1 and 99.
Buttons initially display time only. BG drop values are populated if user selects button and enters BG drop in CF TIME. Unselected buttons show no value (and use BG drop as applied to previous time period).
"done" button does not appear until at least 1 BG drop has been input.
Time period as selected in CF TIME LIST
Input behavior as in SET CORR FCTR.
Time periods as defined in Global Behaviors.
2335
SET CORR FCTR
2349
Correction Factor
1 u insulin for
10
mg/dL
2337
2336
2324
S3
2303
O3
Optional:
2338
by time of day
back
next
2347
2348
2339
2340
CF TIME LIST
2349
Correction factor 1 u insulin for
30 mg/dL morning
20 mg/dL night
20 mg/dL midday
15 mg/dL evening
time button
back
done
2344
2345
2343
CF BY TIME
Correction Factor
OK
2341
1 u insulin for
10
mg/dL
2342
2337
Morning: 4am to 10am
IOB Setup
2346
target by time of day?
yes
T3
2348
no
2347
R3
2351
BG DROP H01
OK
The Reader uses this value to determine how many units of rapid-acting insulin is needed to lower high glucose to a target value or range.
2350

FIG. 32 (Cont)

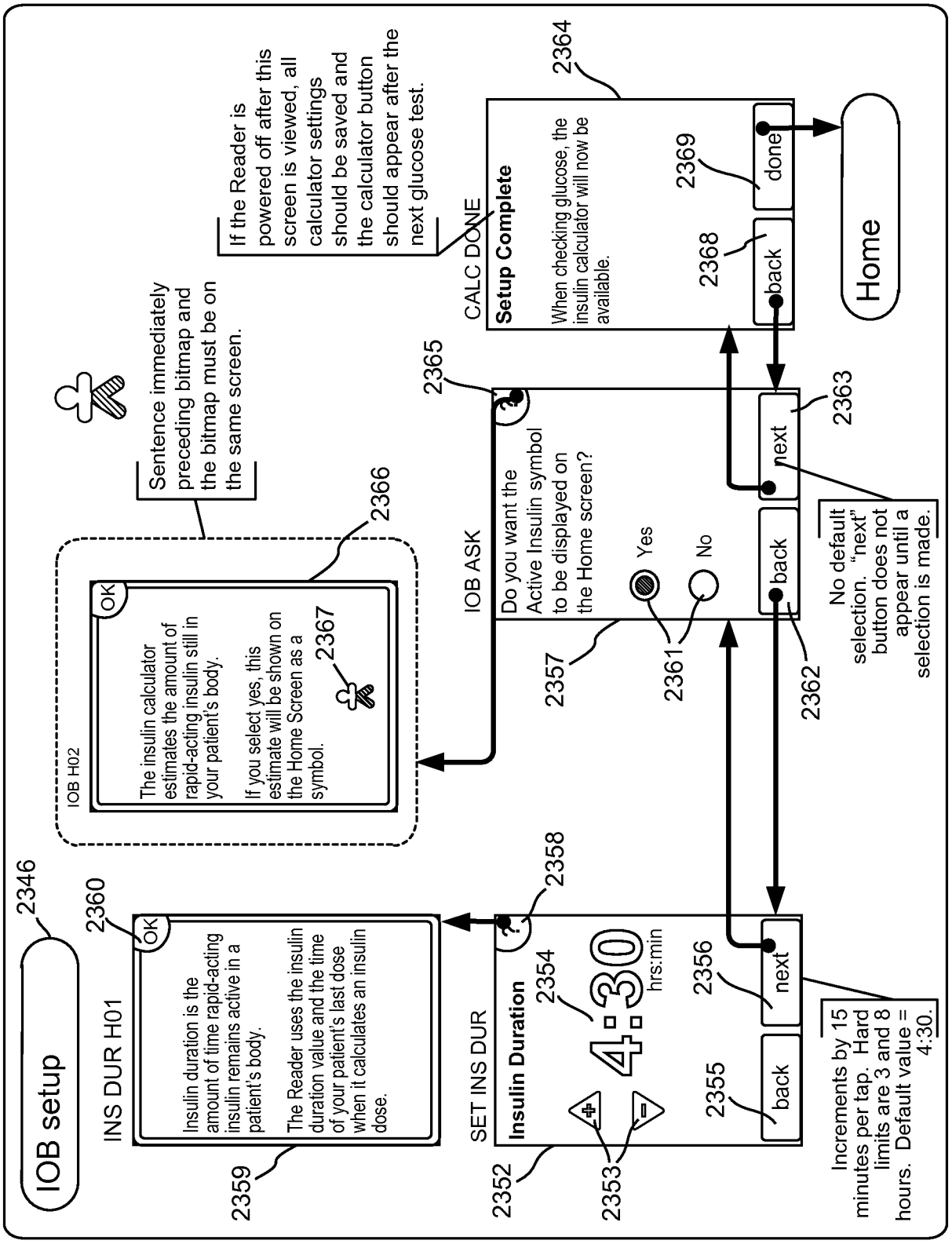

IOB setup
2346
INS DUR H01
2360
OK
Insulin duration is the amount of time rapid-acting insulin remains active in a patient's body.
The Reader uses the insulin duration value and the time of your patient's last dose when it calculates an insulin dose.
2359
SET INS DUR
2358
Insulin Duration
2354
4:30
hrs:min
2352
2353
2356
2355
back
next
Increments by 15 minutes per tap. Hard limits are 3 and 8 hours. Default value = 4:30.
IOB H02
OK
The insulin calculator estimates the amount of rapid-acting insulin still in your patient's body.
If you select yes, this estimate will be shown on the Home Screen as a symbol.
2367
2366
Sentence immediately preceding bitmap and the bitmap must be on the same screen.
IOB ASK
2365
Do you want the Active Insulin symbol to be displayed on the Home screen?
Yes
No
2357
2361
back
next
2362
2363
No default selection. "next" button does not appear until a selection is made.
If the Reader is powered off after this screen is viewed, all calculator settings should be saved and the calculator button should appear after the next glucose test.
CALC DONE
2364
Setup Complete
When checking glucose, the insulin calculator will now be available.
2368
back
2369
done
Home

FIG. 33

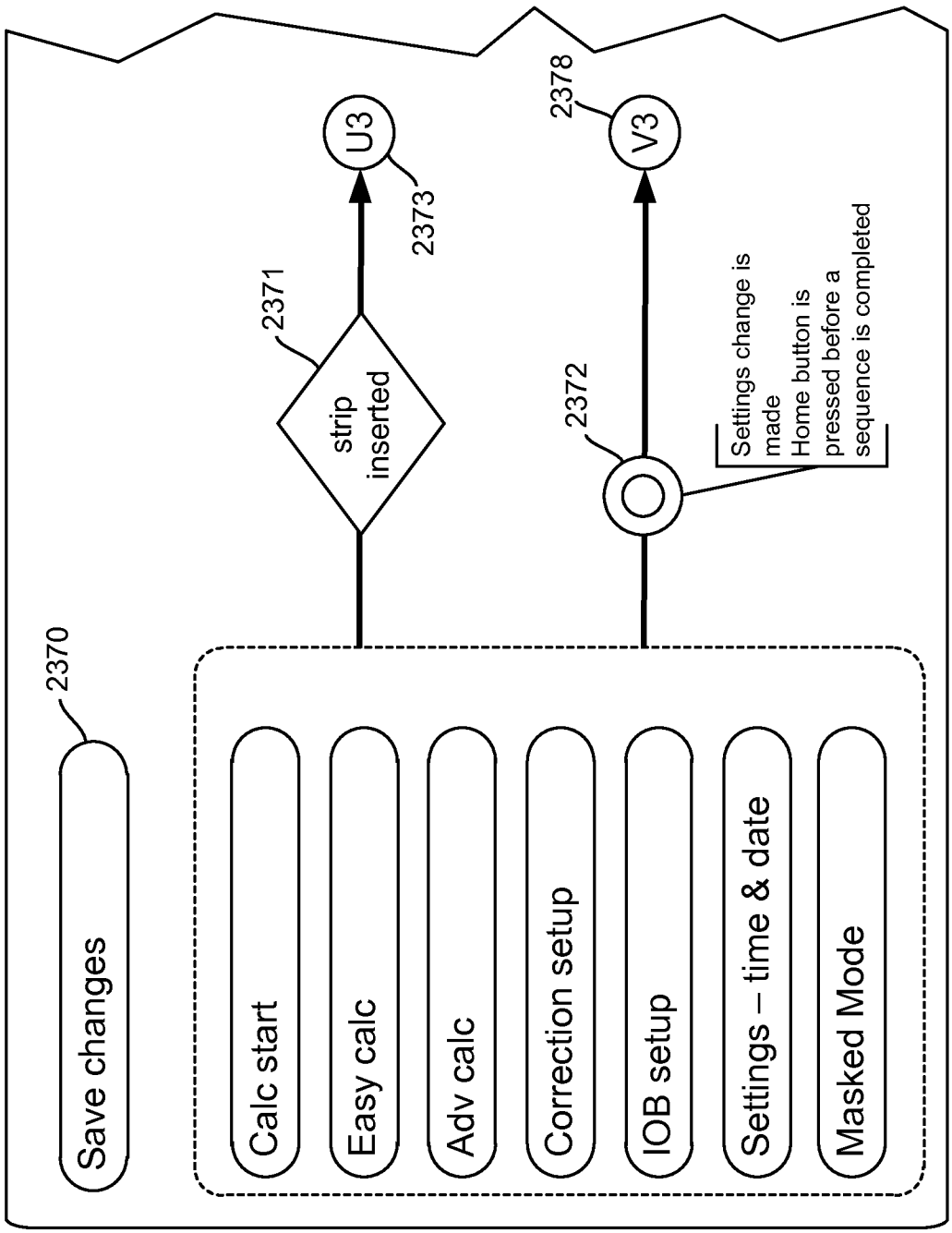

2370
Save changes
Calc start
Easy calc
Adv calc
Correction setup
IOB setup
Settings – time & date
Masked Mode
2371
strip inserted
U3
2373
2372
2378
V3
Settings change is made
Home button is pressed before a sequence is completed

FIG. 33 (Cont)

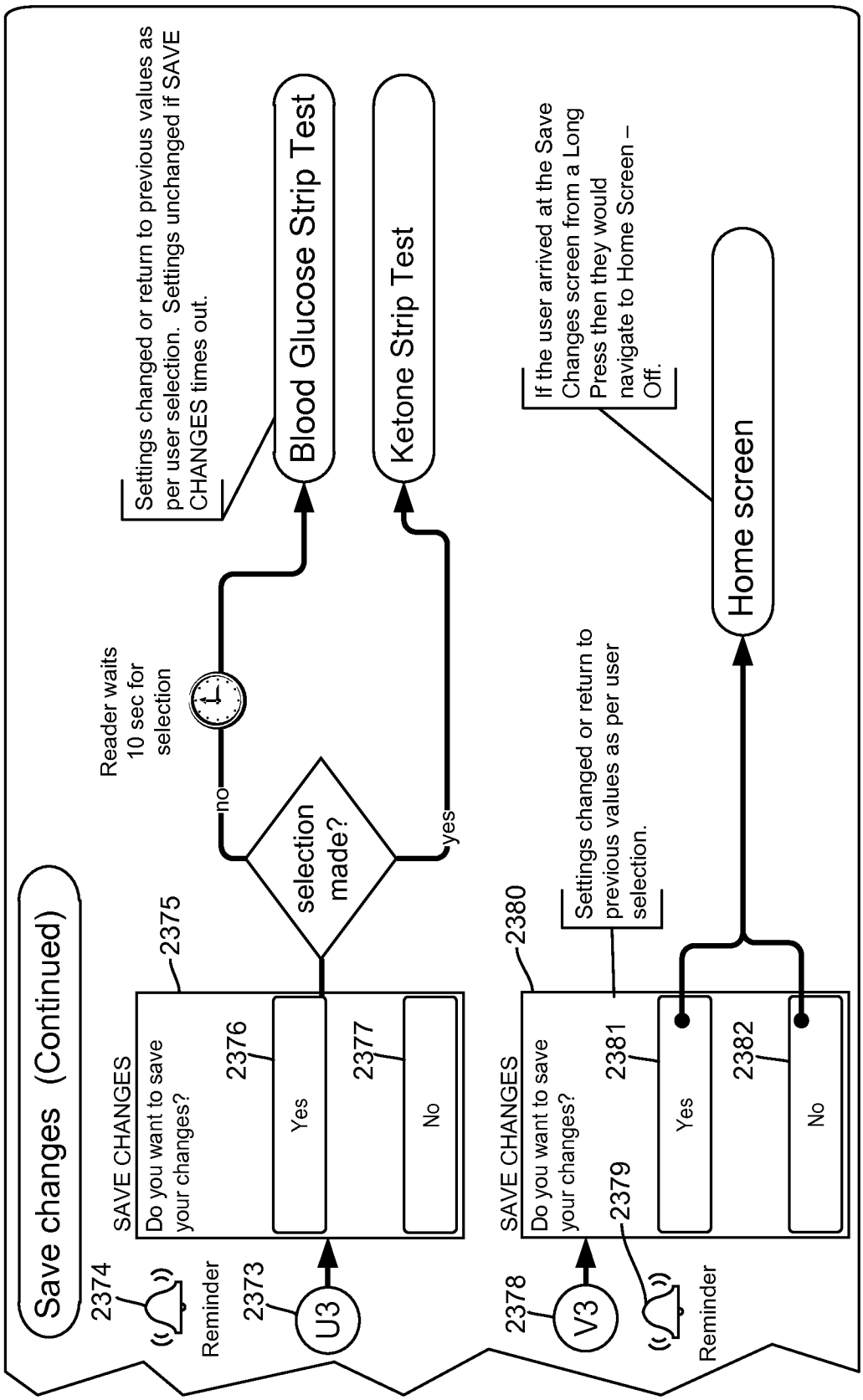

Save changes (Continued)
2374
Reminder
2373
U3
SAVE CHANGES
Do you want to save your changes?
2375
2376
Yes
2377
No
Reader waits 10 sec for selection
selection made?
no
yes
Settings changed or return to previous values as per user selection. Settings unchanged if SAVE CHANGES times out.
Blood Glucose Strip Test
Ketone Strip Test
2378
V3
Reminder
2379
SAVE CHANGES
Do you want to save your changes?
2380
2381
Yes
2382
No
Settings changed or return to previous values as per user selection.
If the user arrived at the Save Changes screen from a Long Press then they would navigate to Home Screen – Off.
Home screen

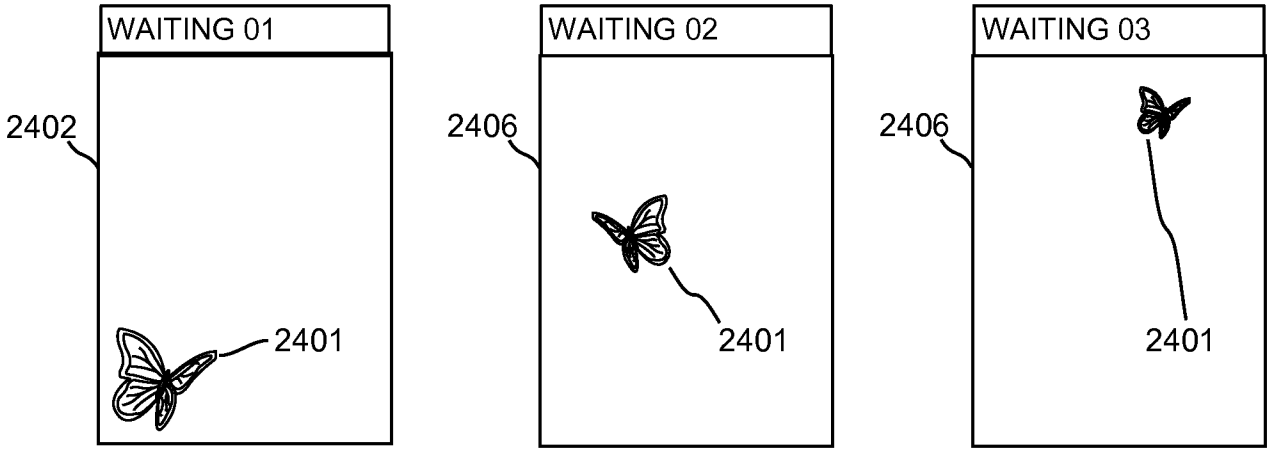
FIG. 33 (Cont)

FIG. 34

Waiting animation

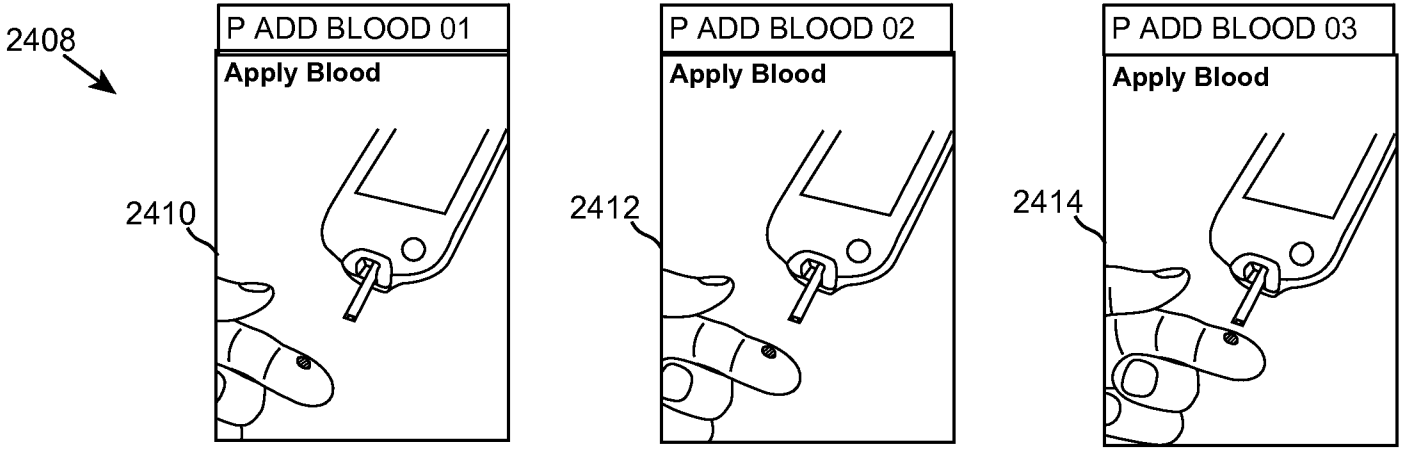
2400

Display animation at animation frame rate.



Precision add blood anim.

Animation duration is 2-3 seconds. Animation loops. Display animation at animation frame rate.



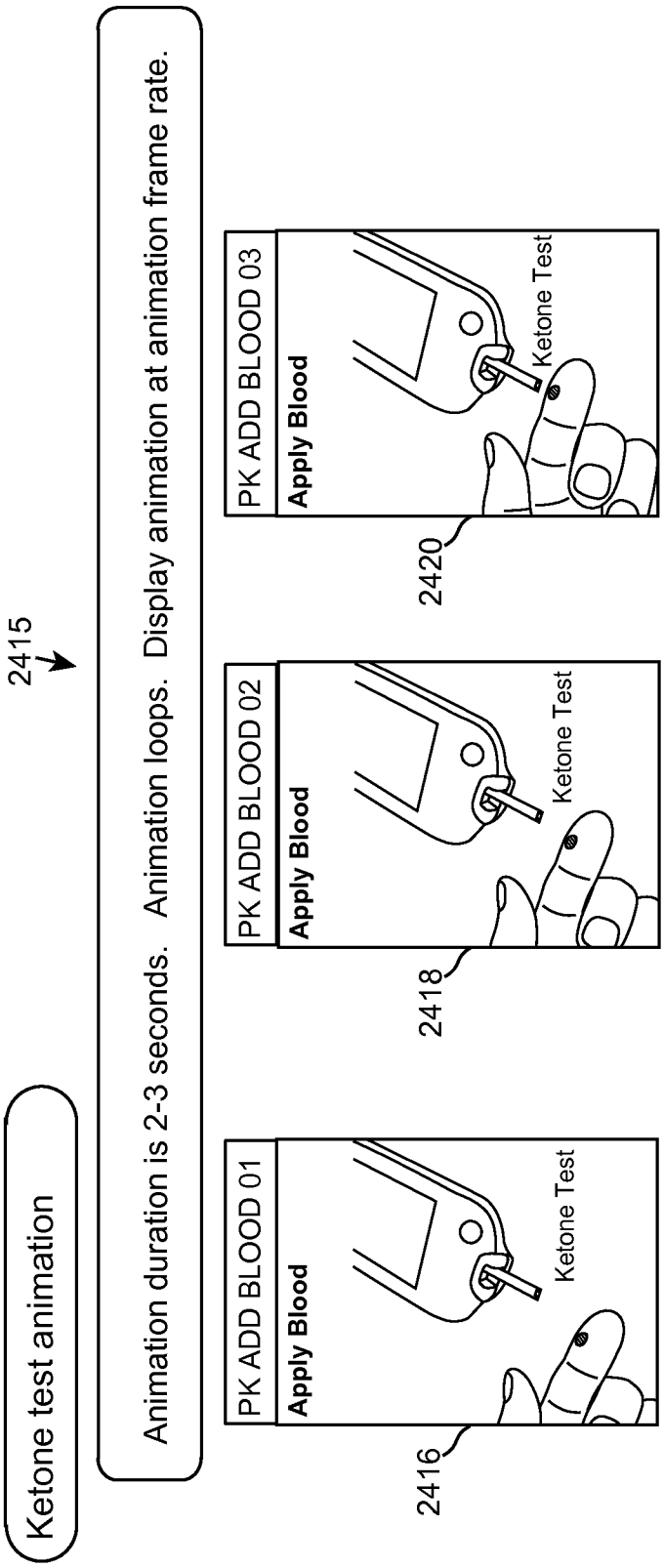

Ketone test animation
2415
Animation duration is 2-3 seconds. Animation loops. Display animation at animation frame rate.
PK ADD BLOOD 01
Apply Blood
Ketone Test
2416
PK ADD BLOOD 02
Apply Blood
Ketone Test
2418
PK ADD BLOOD 03
Apply Blood
Ketone Test
2420

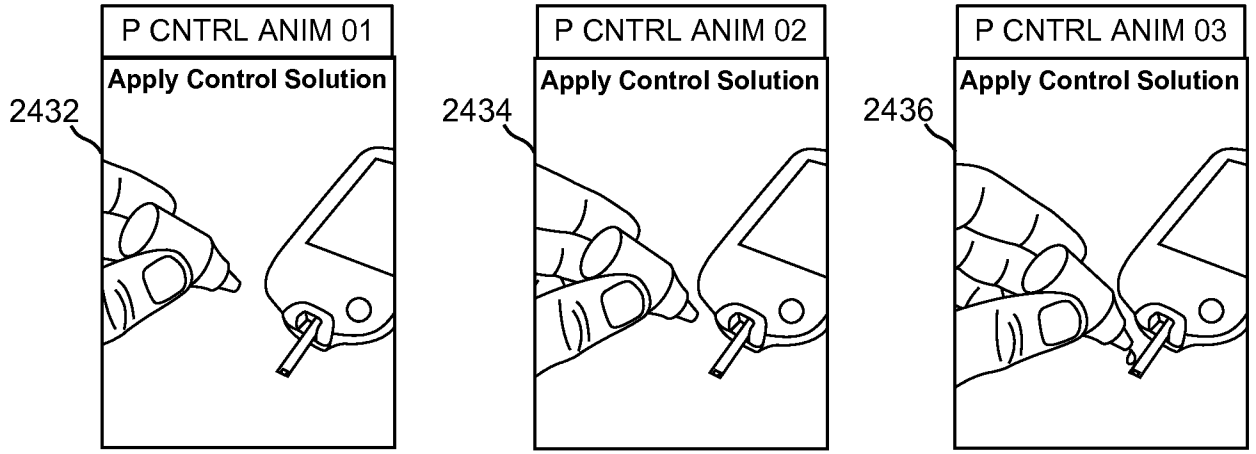
FIG. 34 (Cont)

FIG. 35

Precision control solution anim.

2430

Animation duration is 2-3 seconds. Animation loops. Display animation at animation frame rate.



Ketone control solution anim.

Animation duration is 2-3 seconds. Animation loops. Display animation at animation frame rate.

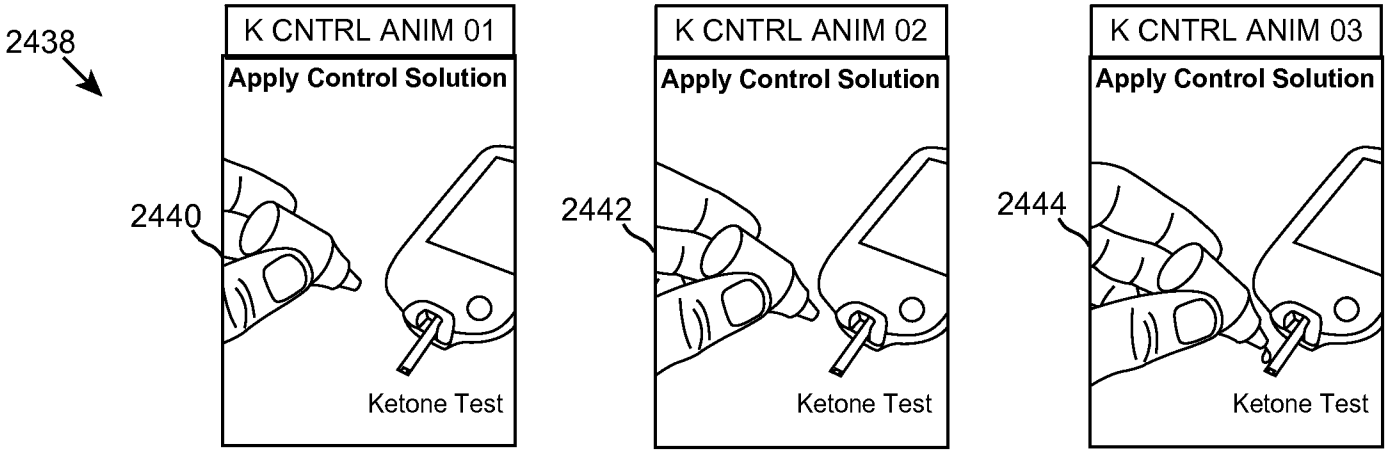


FIG. 36

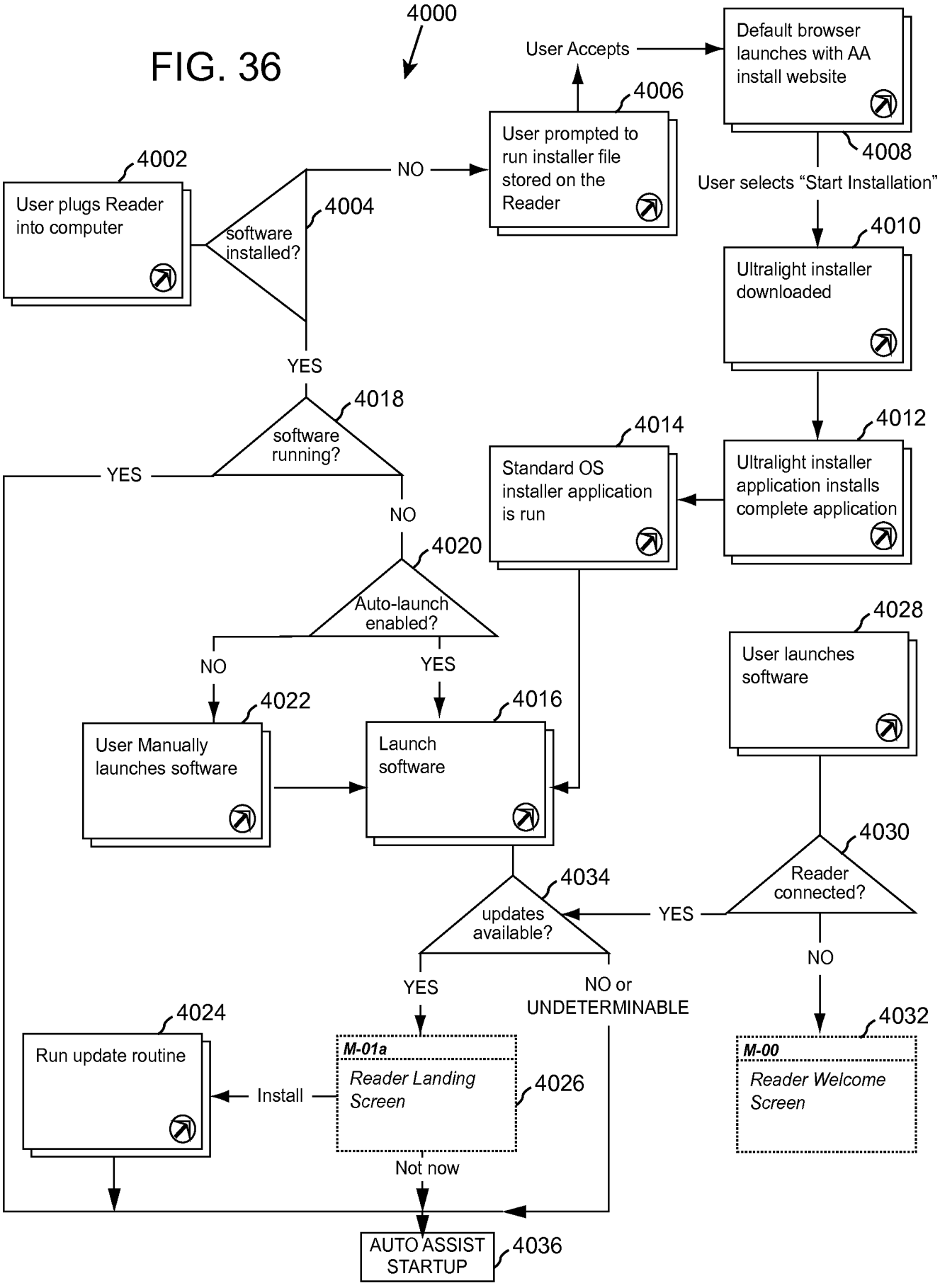
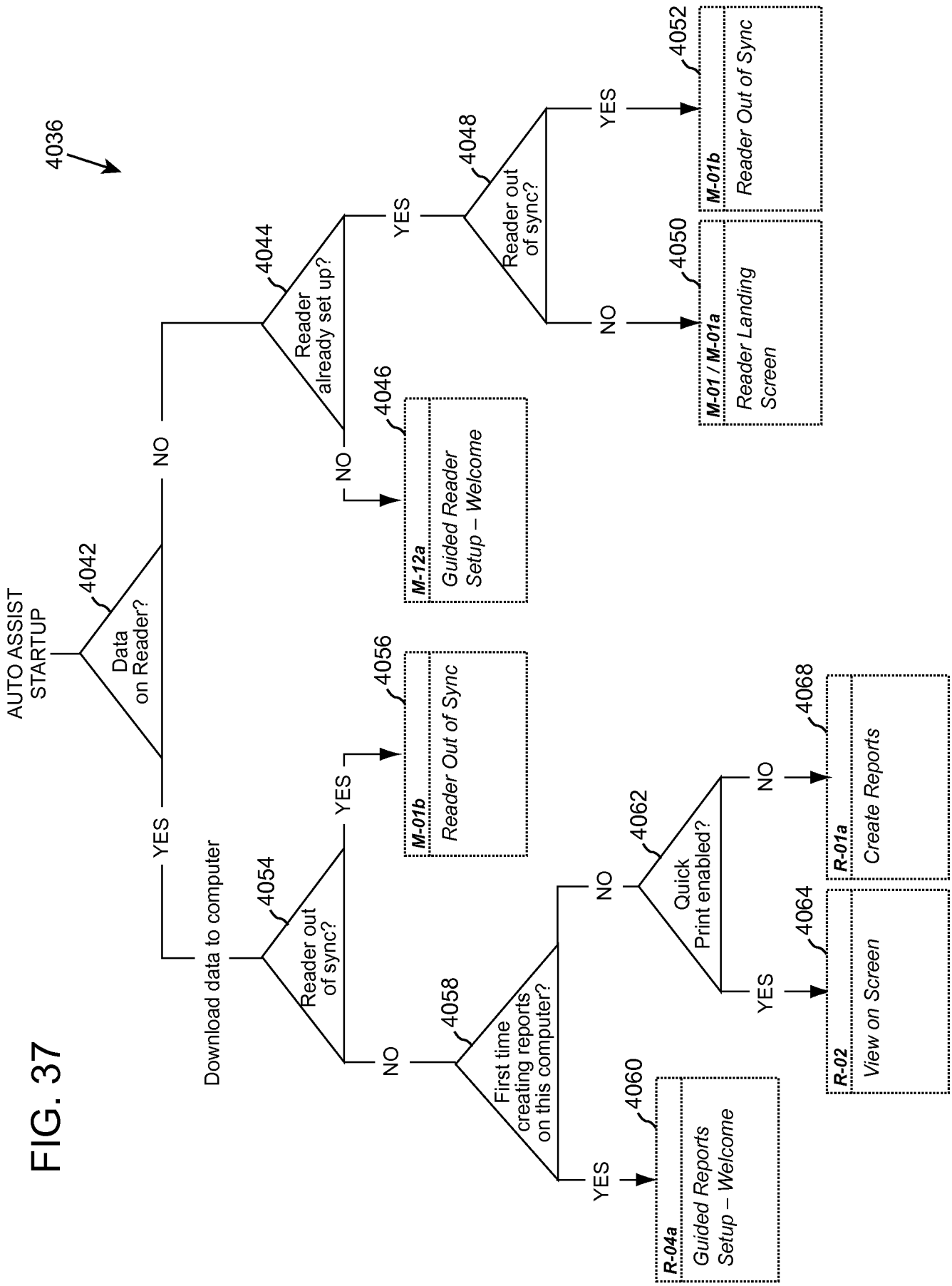

4000
User plugs Reader into computer
4002
software installed?
4004
NO
User prompted to run installer file stored on the Reader
4006
User Accepts
Default browser launches with AA install website
4008
User selects "Start Installation"
Ultralight installer downloaded
4010
Ultralight installer application installs complete application
4012
Standard OS installer application is run
4014
YES
software running?
4018
YES
NO
Auto-launch enabled?
4020
NO
YES
User Manually launches software
4022
Launch software
4016
User launches software
4028
Reader connected?
4030
YES
NO
updates available?
4034
YES
NO or UNDETERMINABLE
Run update routine
4024
Install
M-01a
Reader Landing Screen
4026
Not now
M-00
Reader Welcome Screen
4032
AUTO ASSIST STARTUP
4036

FIG. 37


4036
AUTO ASSIST STARTUP
4042
Data on Reader?
YES
NO
Download data to computer
4044
Reader already set up?
YES
NO
4046
M-12a
Guided Reader Setup – Welcome
4048
Reader out of sync?
YES
NO
4050
M-01 / M-01a
Reader Landing Screen
4052
M-01b
Reader Out of Sync
4054
Reader out of sync?
YES
NO
4056
M-01b
Reader Out of Sync
4058
First time creating reports on this computer?
YES
NO
4060
R-04a
Guided Reports Setup – Welcome
4062
Quick Print enabled?
YES
NO
4064
R-02
View on Screen
4068
R-01a
Create Reports

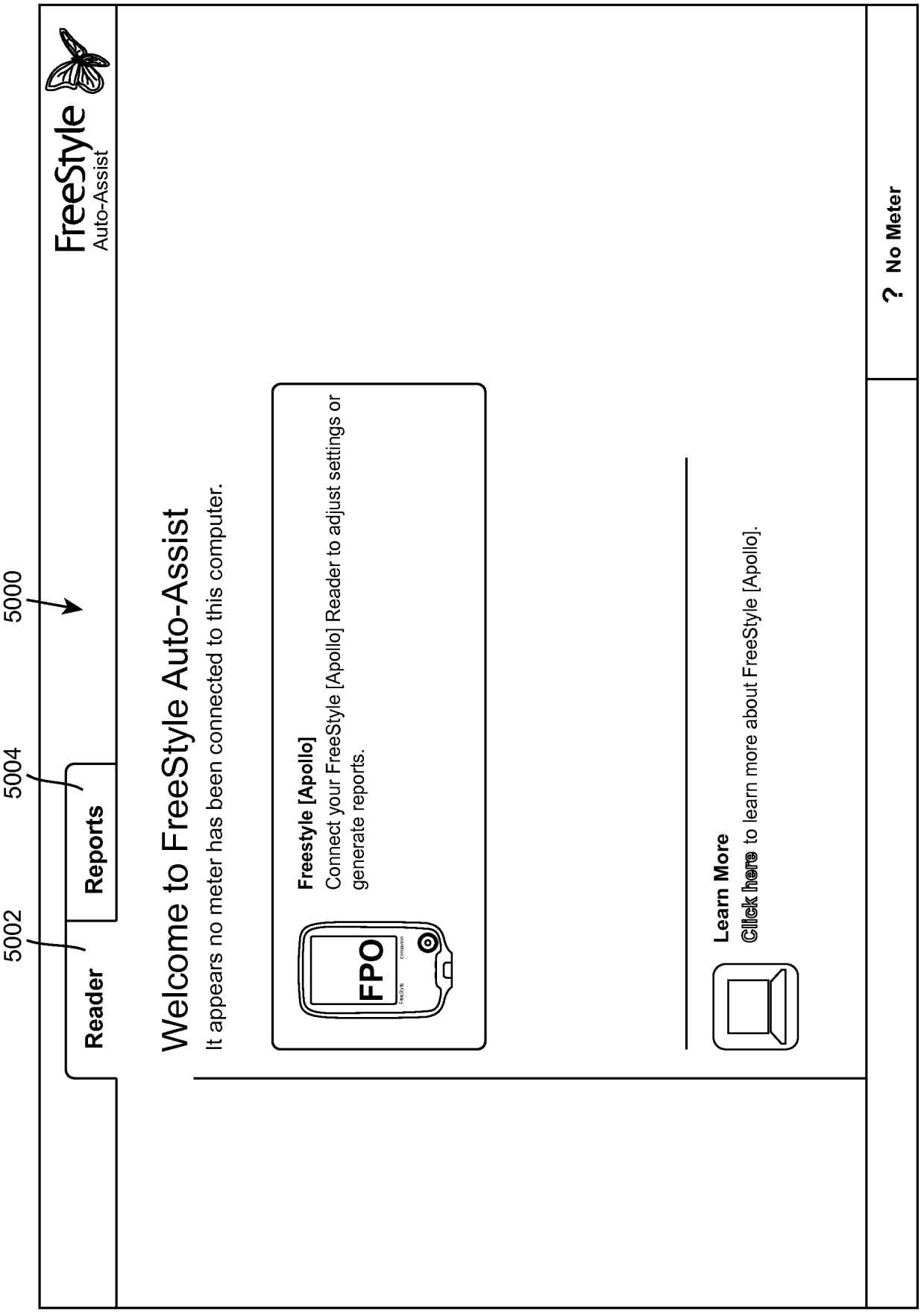

5000
5002
5004
Reader
Reports
FreeStyle
Auto-Assist
Welcome to FreeStyle Auto-Assist
It appears no meter has been connected to this computer.
Freestyle [Apollo]
Connect your FreeStyle [Apollo] Reader to adjust settings or generate reports.
FPO
Learn More
Click here to learn more about FreeStyle [Apollo].
? No Meter

FIG. 38

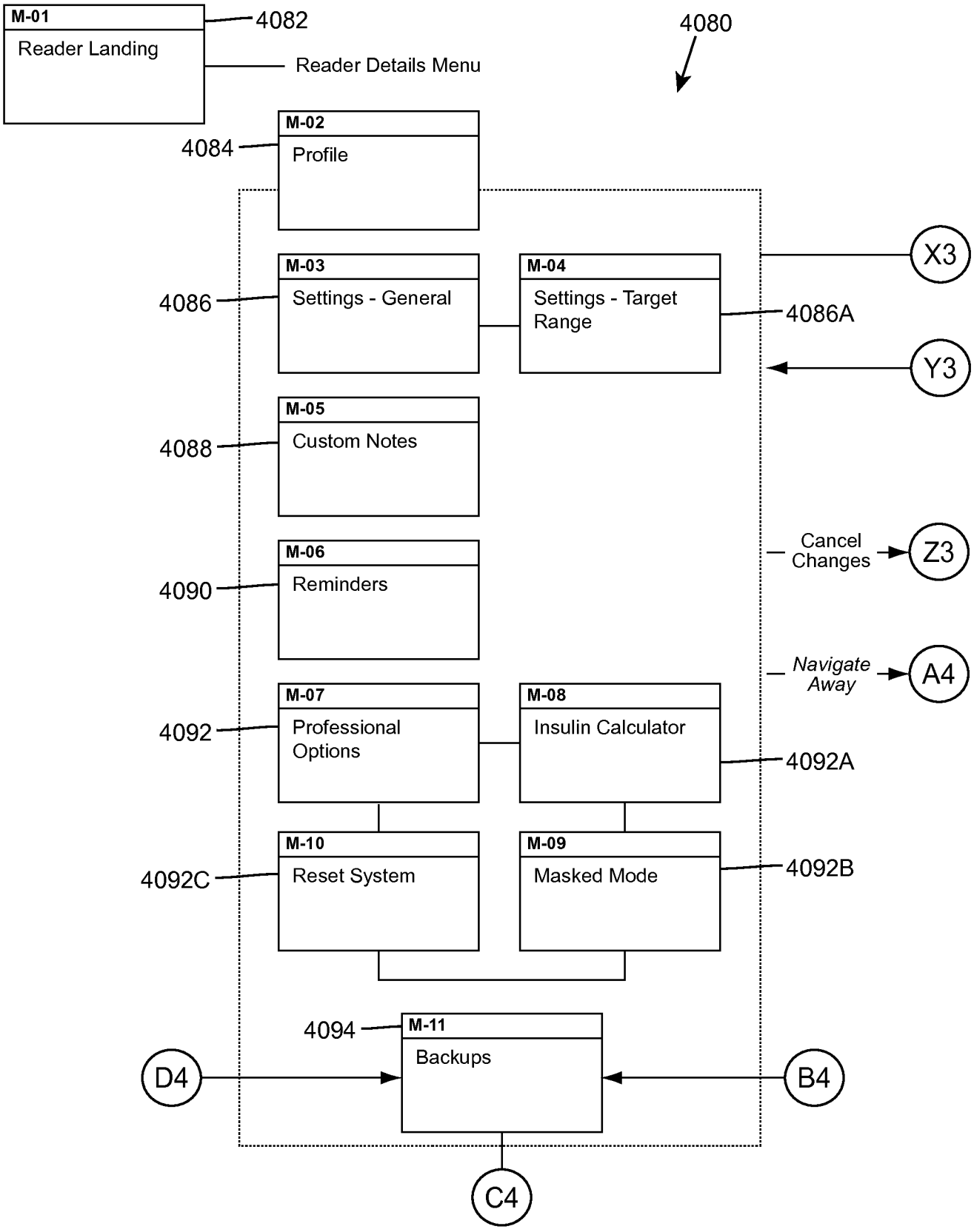

M-01
Reader Landing
4082
Reader Details Menu
4080
M-02
4084
Profile
M-03
4086
Settings - General
M-04
Settings - Target Range
4086A
X3
Y3
M-05
4088
Custom Notes
M-06
4090
Reminders
Cancel Changes
Z3
Navigate Away
A4
M-07
4092
Professional Options
M-08
Insulin Calculator
4092A
M-10
4092C
Reset System
M-09
Masked Mode
4092B
4094
M-11
Backups
D4
B4
C4

FIG. 39

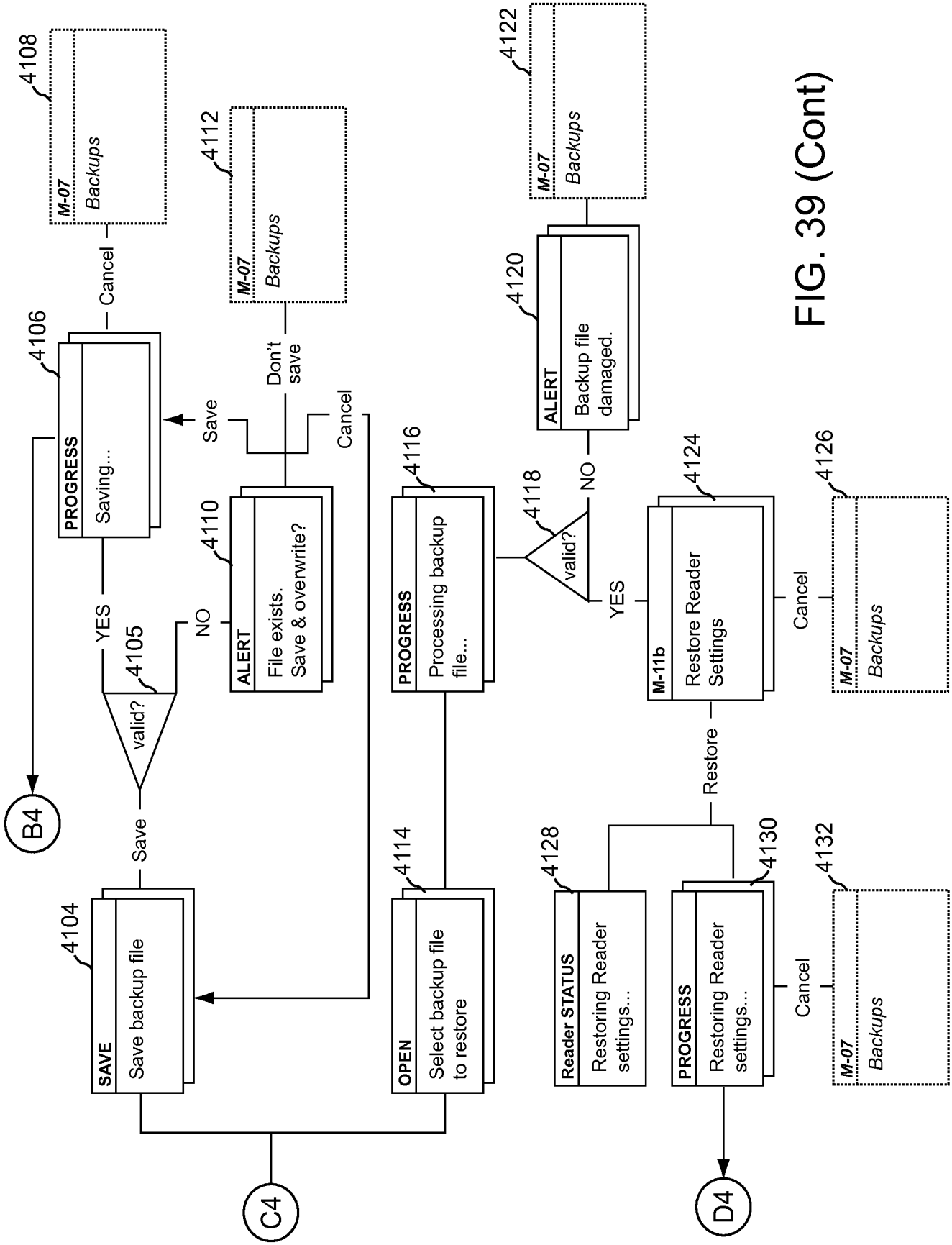

4108
M-07
Backups
Cancel
4106
PROGRESS
Saving...
YES
4105
valid?
NO
4110
ALERT
File exists.
Save & overwrite?
Save
Don't save
Cancel
4112
M-07
Backups
B4
Save
4104
SAVE
Save backup file
C4
4114
OPEN
Select backup file to restore
4116
PROGRESS
Processing backup file...
4118
valid?
NO
YES
4120
ALERT
Backup file damaged.
4122
M-07
Backups
4124
M-11b
Restore Reader Settings
Cancel
4126
M-07
Backups
Restore
4128
Reader STATUS
Restoring Reader settings...
4130
PROGRESS
Restoring Reader settings...
Cancel
4132
M-07
Backups
D4

FIG. 39 (Cont)

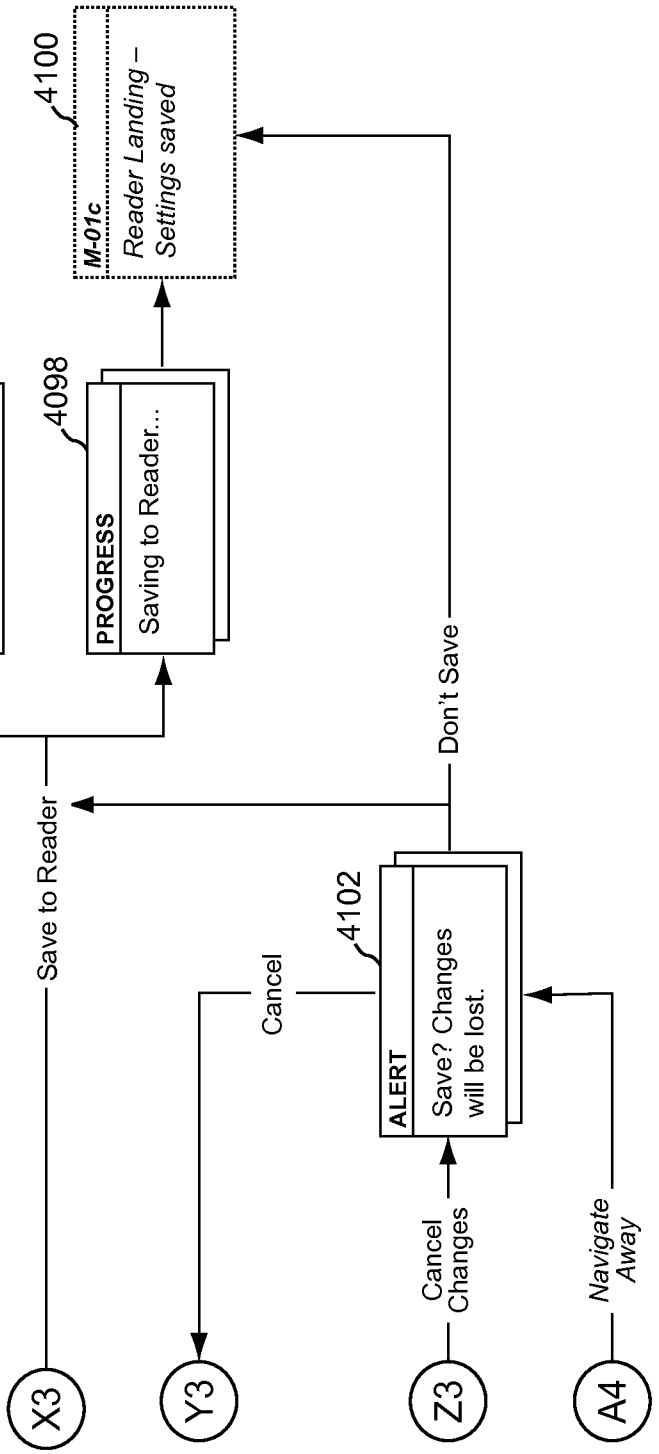

4100
M-01c
Reader Landing – Settings saved
4096
Reader STATUS
Saving to Reader...
4098
PROGRESS
Saving to Reader...
Save to Reader
Don't Save
Cancel
4102
ALERT
Save? Changes will be lost.
Cancel Changes
Navigate Away
X3
Y3
Z3
A4

FIG. 39 (Cont)

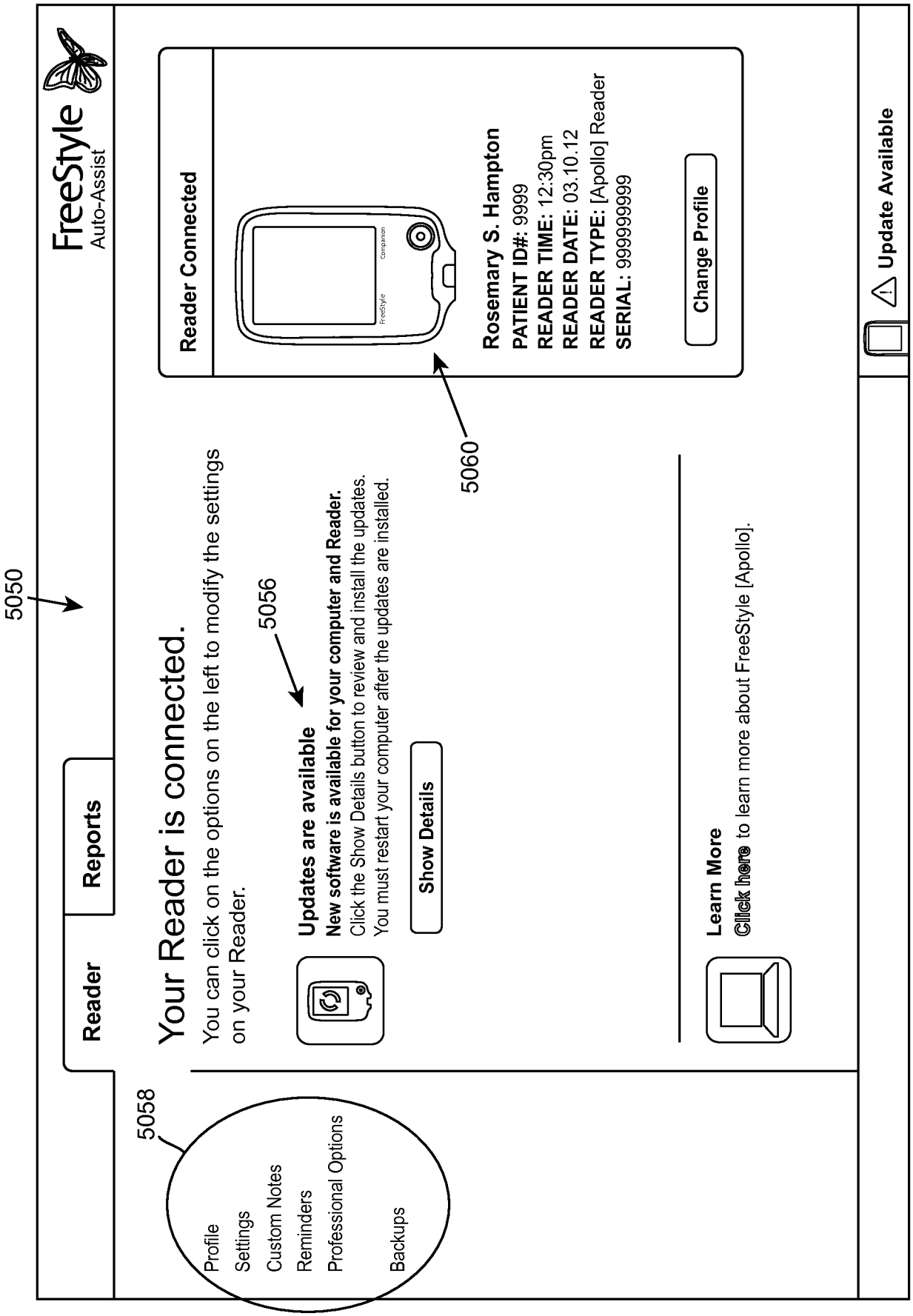

5050
FreeStyle
Auto-Assist
Reader
Reports
Your Reader is connected.
You can click on the options on the left to modify the settings on your Reader.
5056
Updates are available
New software is available for your computer and Reader.
Click the Show Details button to review and install the updates.
You must restart your computer after the updates are installed.
Show Details
Learn More
Click here to learn more about FreeStyle [Apollo].
5058
Profile
Settings
Custom Notes
Reminders
Professional Options
Backups
Reader Connected
5060
Rosemary S. Hampton
PATIENT ID#: 9999
READER TIME: 12:30pm
READER DATE: 03.10.12
READER TYPE: [Apollo] Reader
SERIAL: 999999999
Change Profile
Update Available

FIG. 40

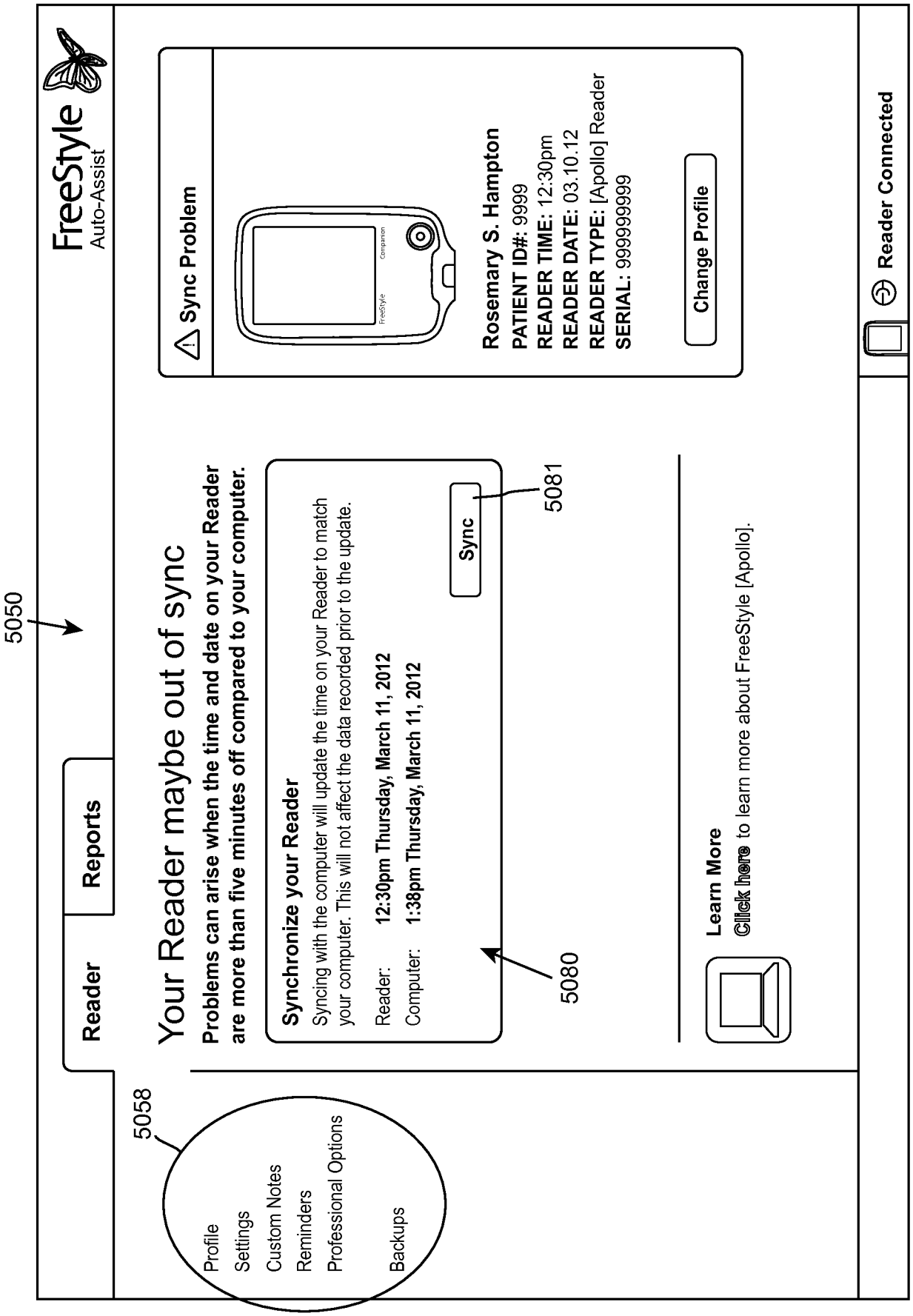

5050
FreeStyle
Auto-Assist
Reader
Reports
Your Reader maybe out of sync
Problems can arise when the time and date on your Reader are more than five minutes off compared to your computer.
Synchronize your Reader
Syncing with the computer will update the time on your Reader to match your computer. This will not affect the data recorded prior to the update.
Reader: 12:30pm Thursday, March 11, 2012
Computer: 1:38pm Thursday, March 11, 2012
Sync
5080
5081
Learn More
Click here to learn more about FreeStyle [Apollo].
Sync Problem
Rosemary S. Hampton
PATIENT ID#: 9999
READER TIME: 12:30pm
READER DATE: 03.10.12
READER TYPE: [Apollo] Reader
SERIAL: 999999999
Change Profile
Reader Connected
5058
Profile
Settings
Custom Notes
Reminders
Professional Options
Backups

FIG. 41

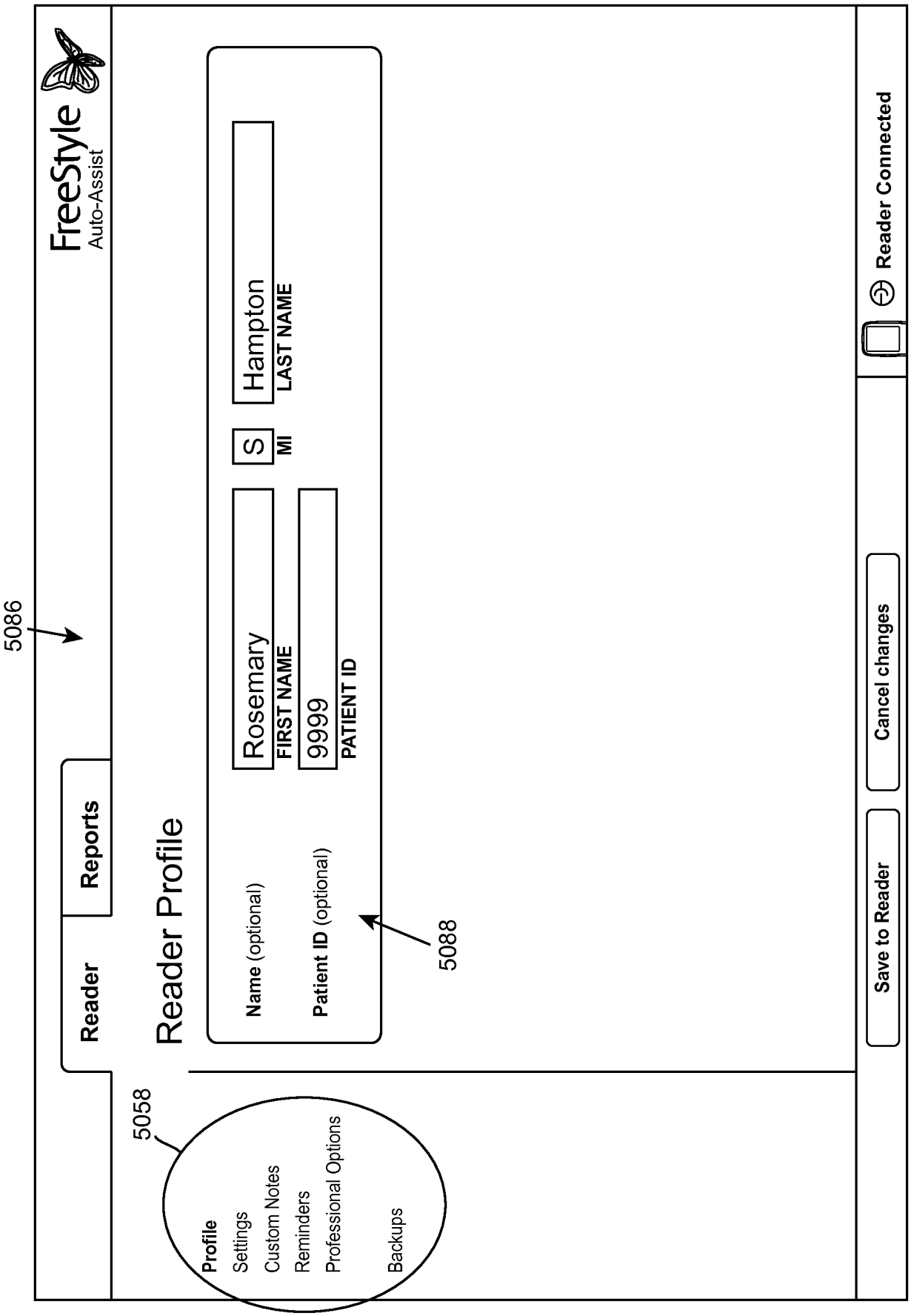

5086
FreeStyle
Auto-Assist
Reader
Reports
Reader Profile
5058
Profile
Settings
Custom Notes
Reminders
Professional Options
Backups
Name (optional)
Rosemary
FIRST NAME
S
MI
Hampton
LAST NAME
Patient ID (optional)
9999
PATIENT ID
5088
Save to Reader
Cancel changes
Reader Connected

FIG. 42

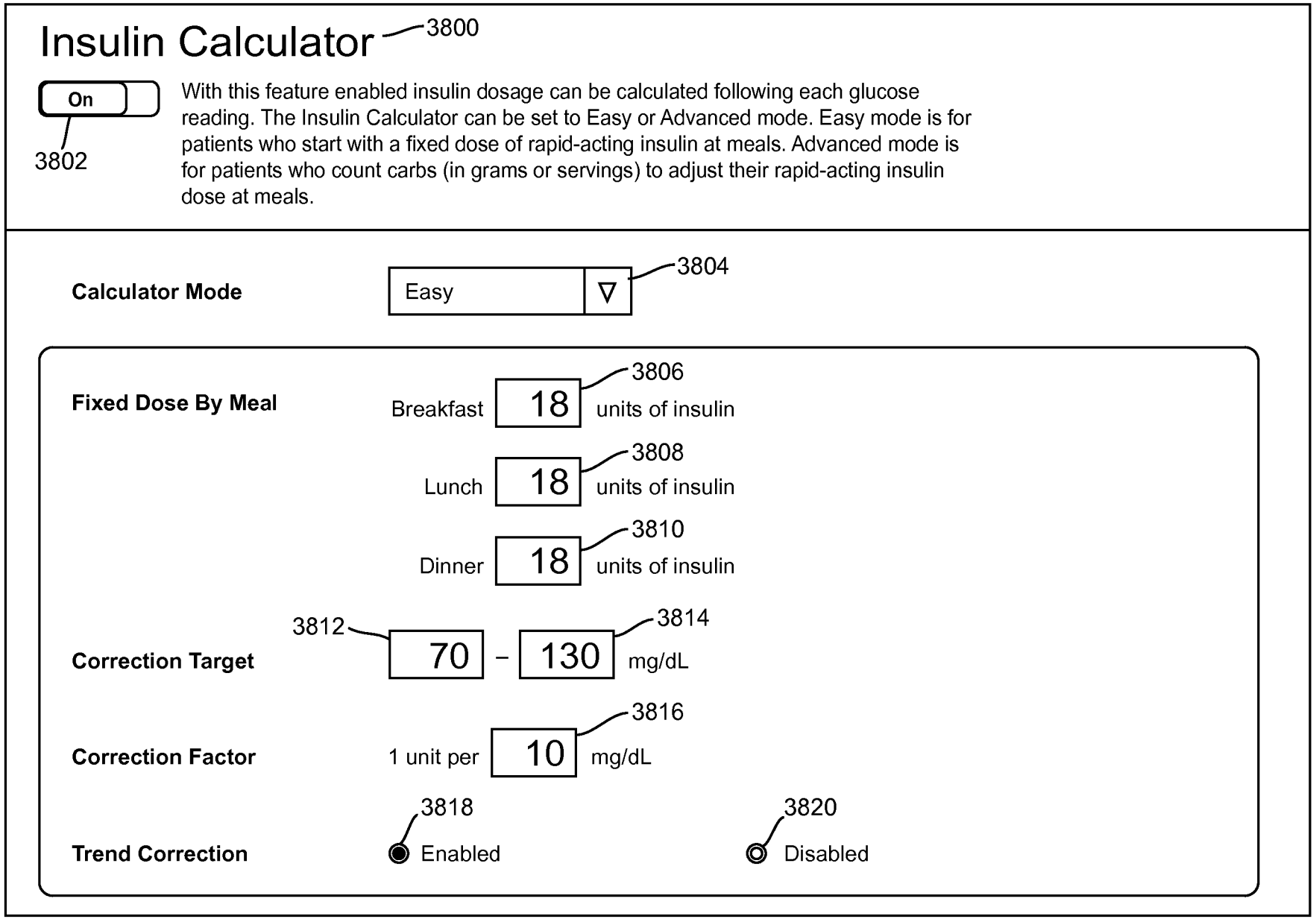

Insulin Calculator
3800
On
3802
With this feature enabled insulin dosage can be calculated following each glucose reading. The Insulin Calculator can be set to Easy or Advanced mode. Easy mode is for patients who start with a fixed dose of rapid-acting insulin at meals. Advanced mode is for patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
Calculator Mode
Easy
3804
Fixed Dose By Meal
Breakfast
18
3806
units of insulin
Lunch
18
3808
units of insulin
Dinner
18
3810
units of insulin
Correction Target
3812
70
-
130
3814
mg/dL
Correction Factor
1 unit per
10
3816
mg/dL
Trend Correction
3818
Enabled
3820
Disabled

FIG. 43

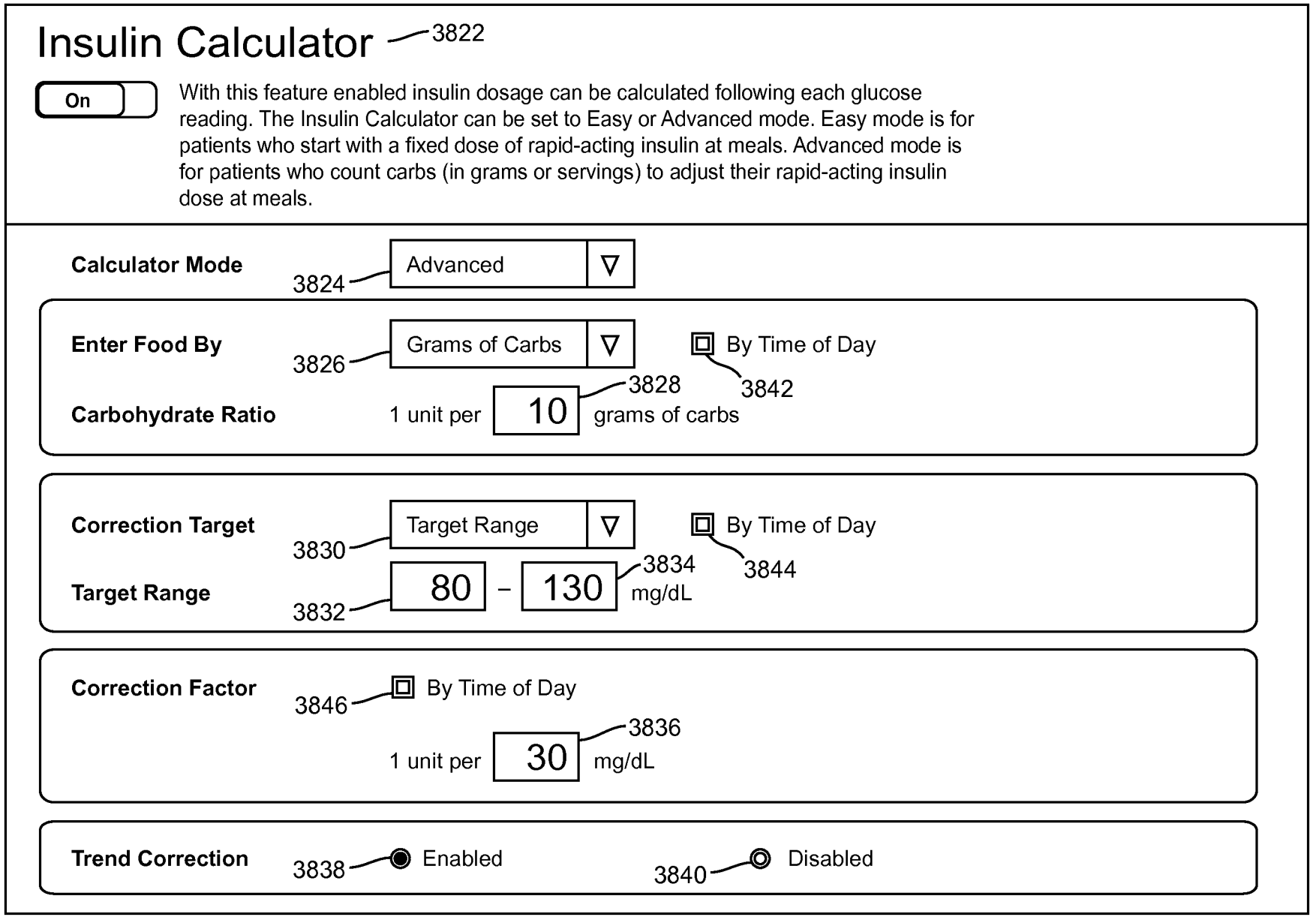

Insulin Calculator
3822
On
With this feature enabled insulin dosage can be calculated following each glucose reading. The Insulin Calculator can be set to Easy or Advanced mode. Easy mode is for patients who start with a fixed dose of rapid-acting insulin at meals. Advanced mode is for patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
Calculator Mode
3824
Advanced
Enter Food By
3826
Grams of Carbs
By Time of Day
3842
Carbohydrate Ratio
1 unit per
10
3828
grams of carbs
Correction Target
3830
Target Range
By Time of Day
3844
Target Range
3832
80
130
3834
mg/dL
Correction Factor
3846
By Time of Day
1 unit per
30
3836
mg/dL
Trend Correction
3838
Enabled
3840
Disabled

FIG. 44

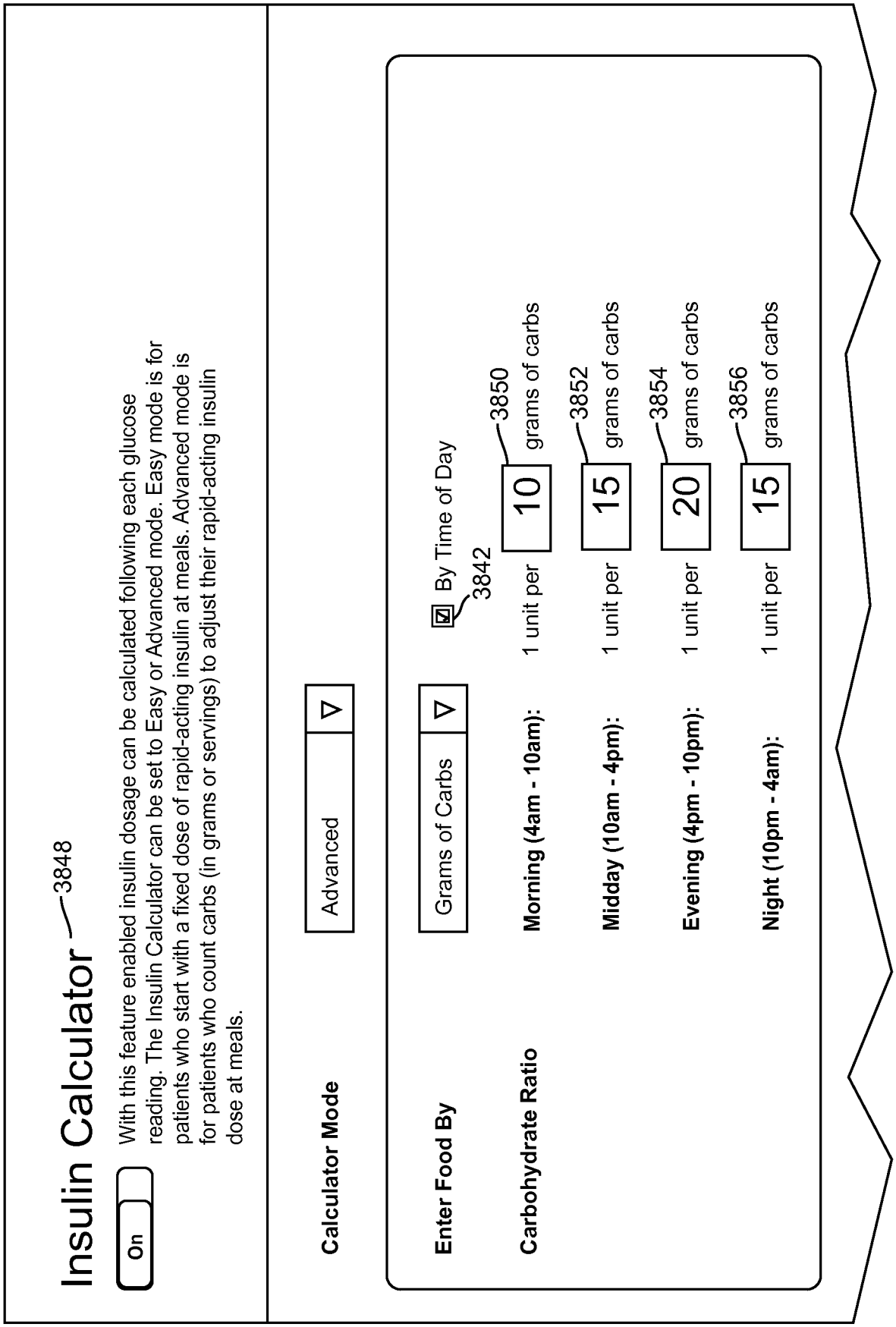

Insulin Calculator
3848
On
With this feature enabled insulin dosage can be calculated following each glucose reading. The Insulin Calculator can be set to Easy or Advanced mode. Easy mode is for patients who start with a fixed dose of rapid-acting insulin at meals. Advanced mode is for patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
Calculator Mode
Advanced
Enter Food By
Grams of Carbs
By Time of Day
3842
Carbohydrate Ratio
Morning (4am - 10am):
1 unit per
10
grams of carbs
3850
Midday (10am - 4pm):
1 unit per
15
grams of carbs
3852
Evening (4pm - 10pm):
1 unit per
20
grams of carbs
3854
Night (10pm - 4am):
1 unit per
15
grams of carbs
3856

FIG. 45A

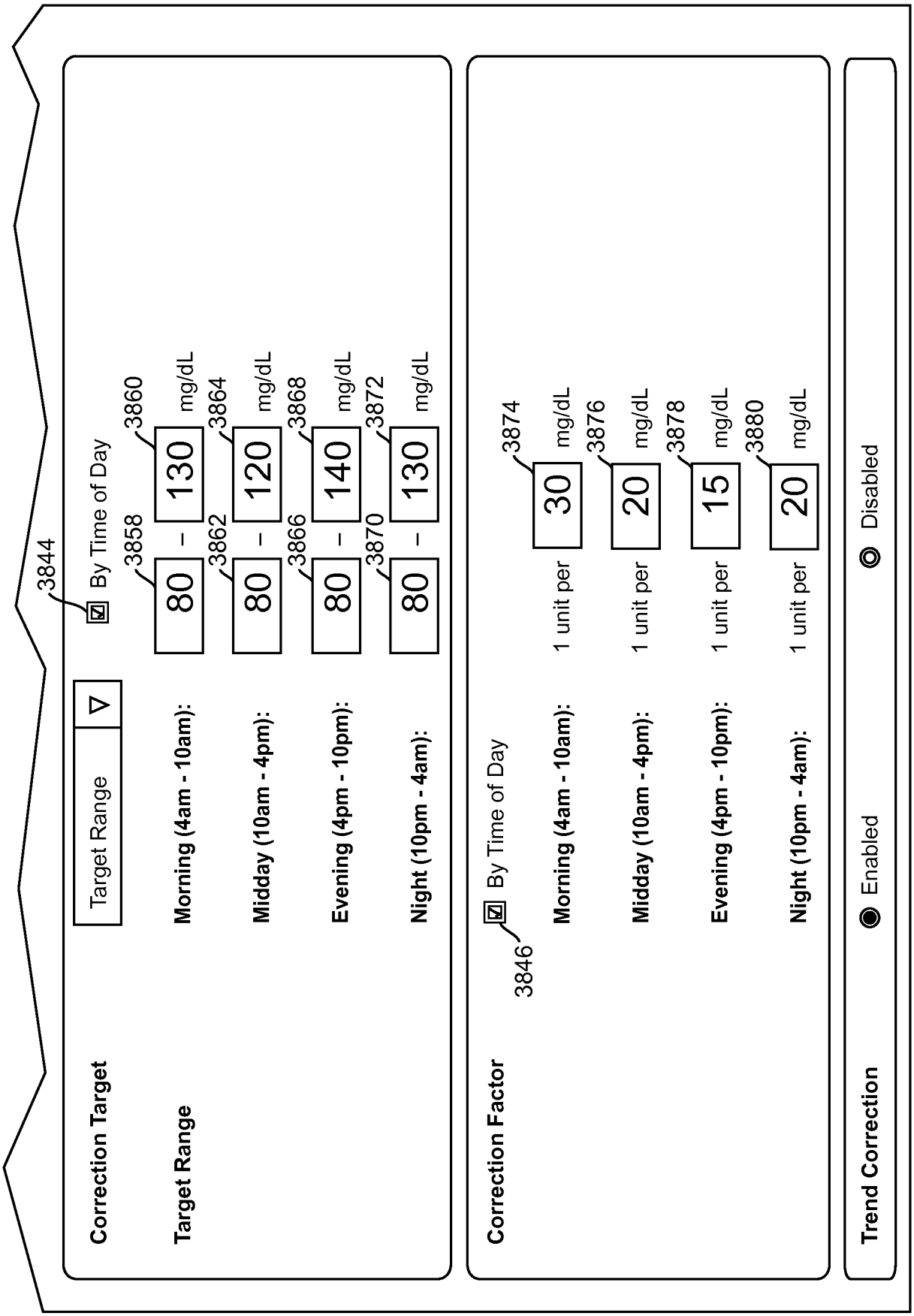

Correction Target
Target Range
Target Range
By Time of Day
3844
Morning (4am - 10am):
80 – 130 mg/dL
3858
3860
Midday (10am - 4pm):
80 – 120 mg/dL
3862
3864
Evening (4pm - 10pm):
80 – 140 mg/dL
3866
3868
Night (10pm - 4am):
80 – 130 mg/dL
3870
3872
Correction Factor
By Time of Day
3846
Morning (4am - 10am):
1 unit per 30 mg/dL
3874
Midday (10am - 4pm):
1 unit per 20 mg/dL
3876
Evening (4pm - 10pm):
1 unit per 15 mg/dL
3878
Night (10pm - 4am):
1 unit per 20 mg/dL
3880
Trend Correction
Enabled
Disabled

FIG. 45B

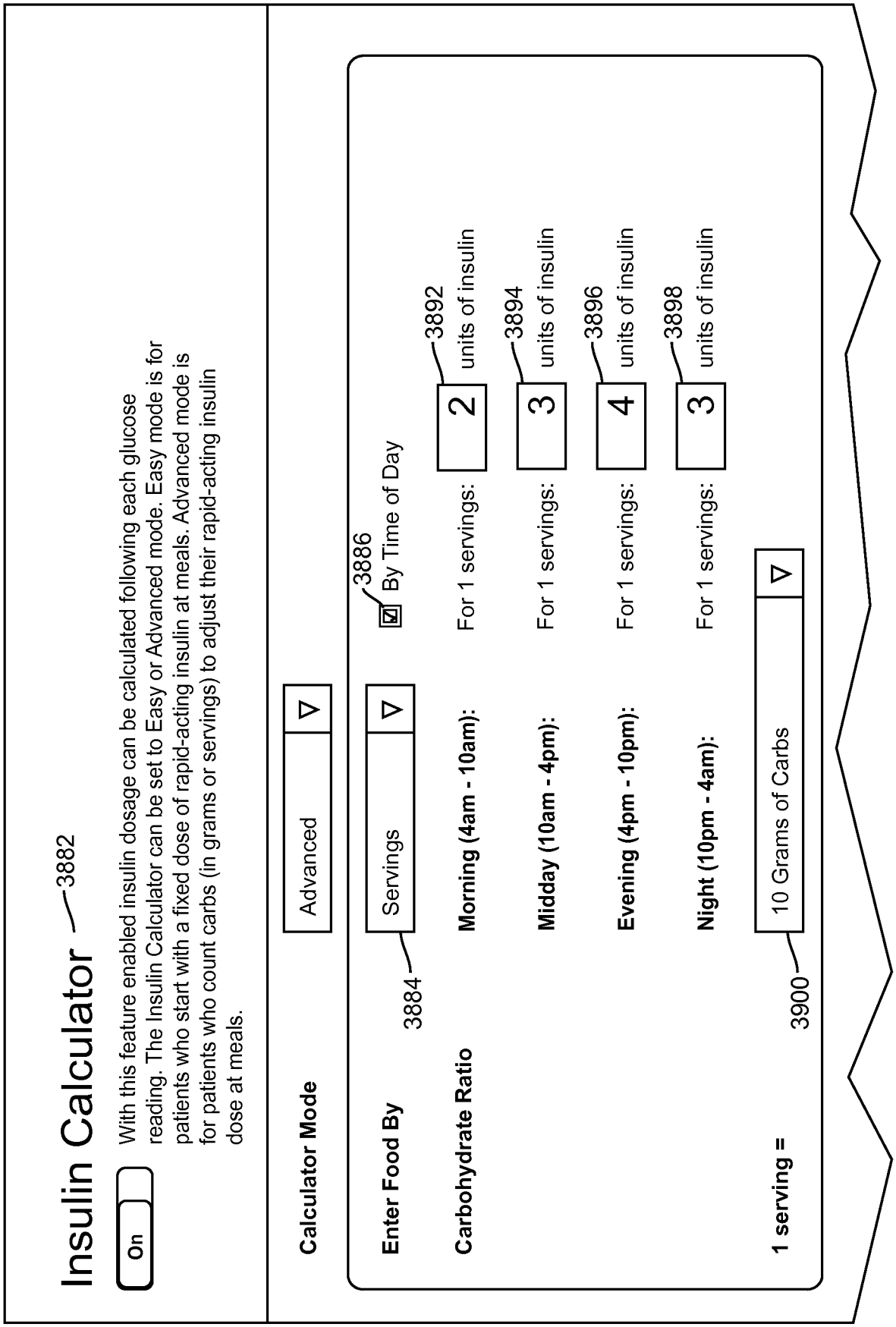

Insulin Calculator
3882
On
With this feature enabled insulin dosage can be calculated following each glucose reading. The Insulin Calculator can be set to Easy or Advanced mode. Easy mode is for patients who start with a fixed dose of rapid-acting insulin at meals. Advanced mode is for patients who count carbs (in grams or servings) to adjust their rapid-acting insulin dose at meals.
Calculator Mode
Advanced
Enter Food By
3884
Servings
3886
By Time of Day
Carbohydrate Ratio
Morning (4am - 10am):
For 1 servings:
2
3892
units of insulin
Midday (10am - 4pm):
For 1 servings:
3
3894
units of insulin
Evening (4pm - 10pm):
For 1 servings:
4
3896
units of insulin
Night (10pm - 4am):
For 1 servings:
3
3898
units of insulin
1 serving =
3900
10 Grams of Carbs

FIG. 46A

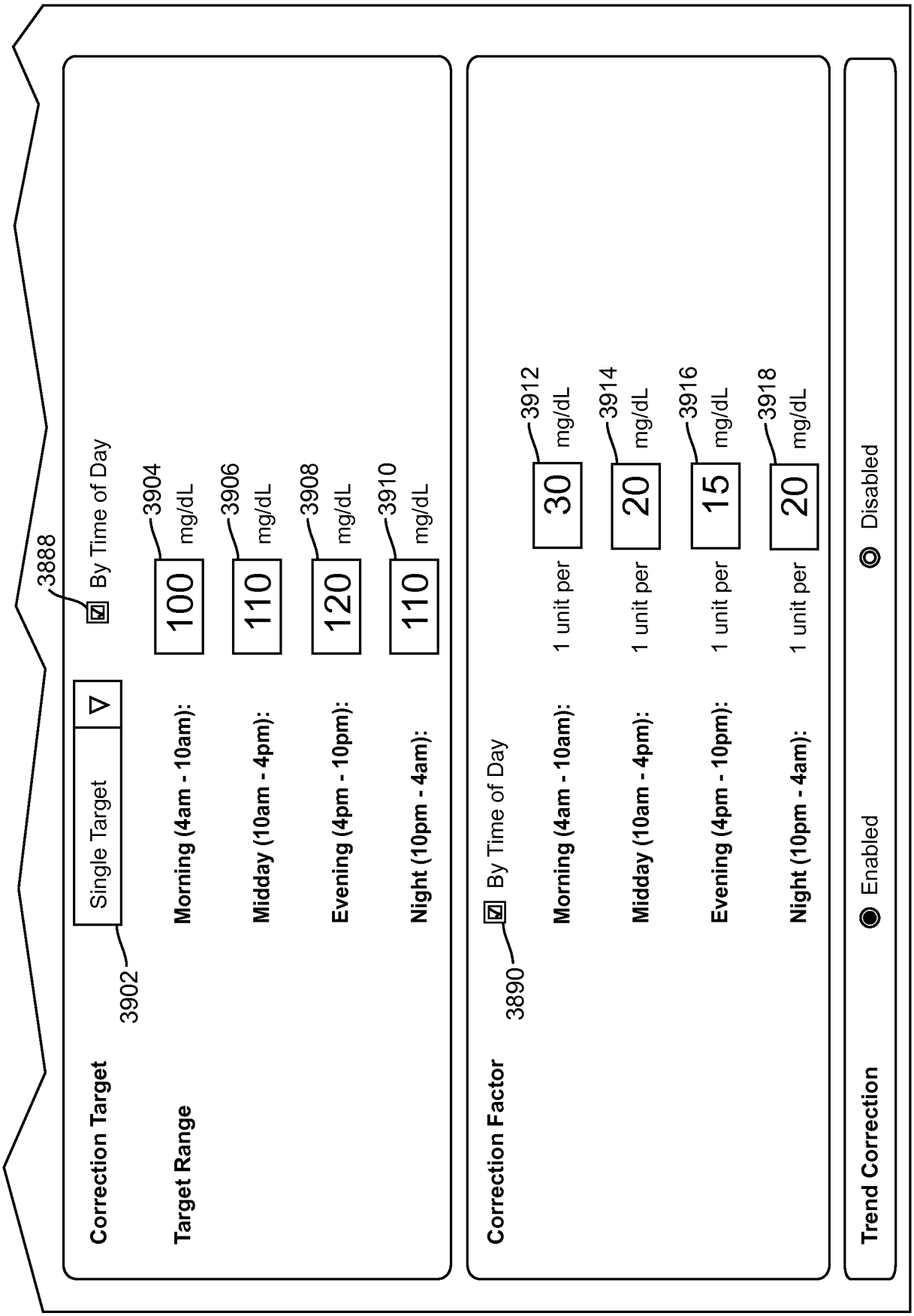

Correction Target
3902
Single Target
3888
By Time of Day
Target Range
Morning (4am - 10am):
100
3904
mg/dL
Midday (10am - 4pm):
110
3906
mg/dL
Evening (4pm - 10pm):
120
3908
mg/dL
Night (10pm - 4am):
110
3910
mg/dL
Correction Factor
3890
By Time of Day
Morning (4am - 10am):
1 unit per
30
3912
mg/dL
Midday (10am - 4pm):
1 unit per
20
3914
mg/dL
Evening (4pm - 10pm):
1 unit per
15
3916
mg/dL
Night (10pm - 4am):
1 unit per
20
3918
mg/dL
Trend Correction
Enabled
Disabled

FIG. 46B

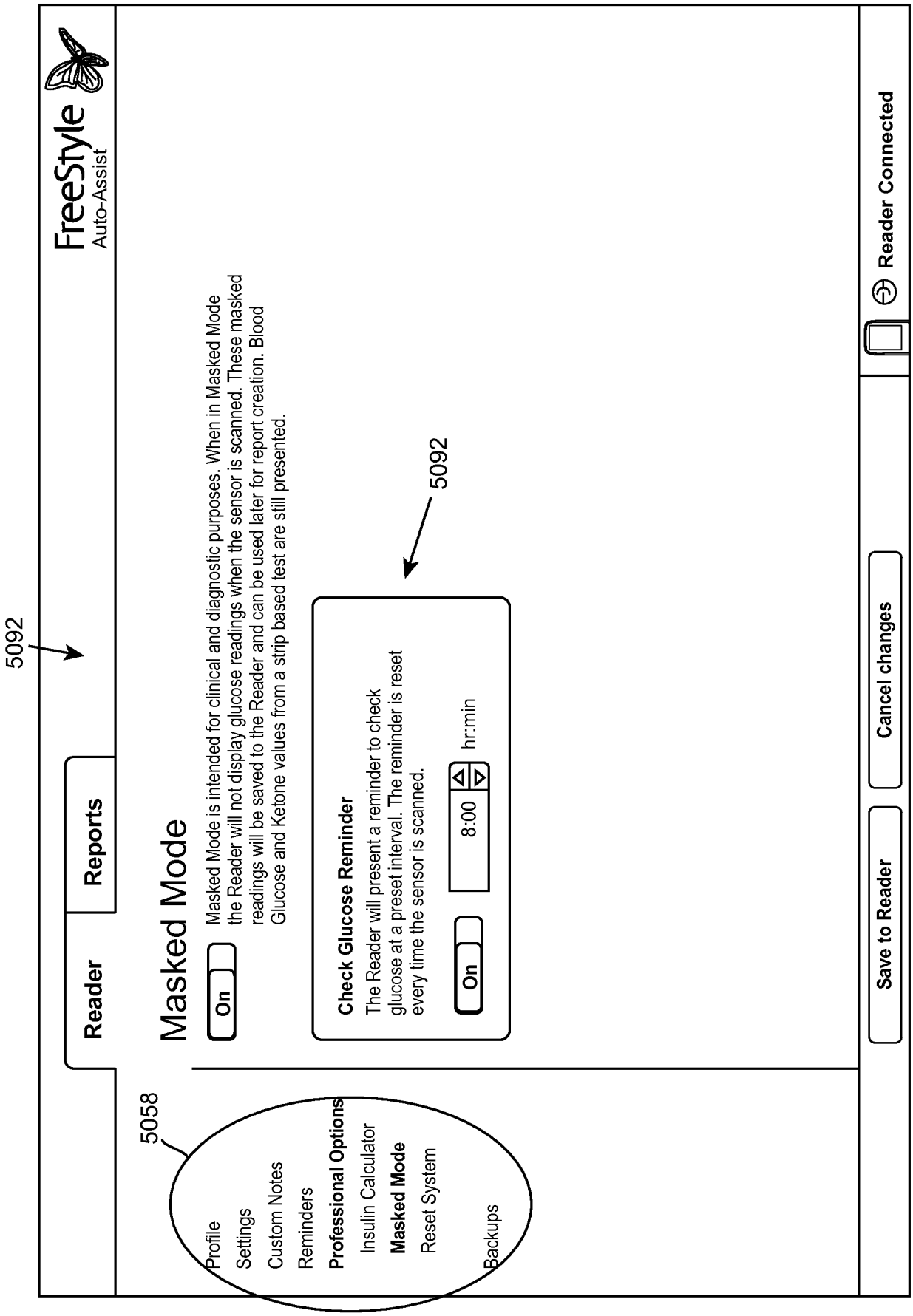

5092
FreeStyle
Auto-Assist
Reader
Reports
Masked Mode
On
Masked Mode is intended for clinical and diagnostic purposes. When in Masked Mode the Reader will not display glucose readings when the sensor is scanned. These masked readings will be saved to the Reader and can be used later for report creation. Blood Glucose and Ketone values from a strip based test are still presented.
5092
Check Glucose Reminder
The Reader will present a reminder to check glucose at a preset interval. The reminder is reset every time the sensor is scanned.
On
8:00
hr:min
5058
Profile
Settings
Custom Notes
Reminders
Professional Options
Insulin Calculator
Masked Mode
Reset System
Backups
Save to Reader
Cancel changes
Reader Connected

FIG. 47

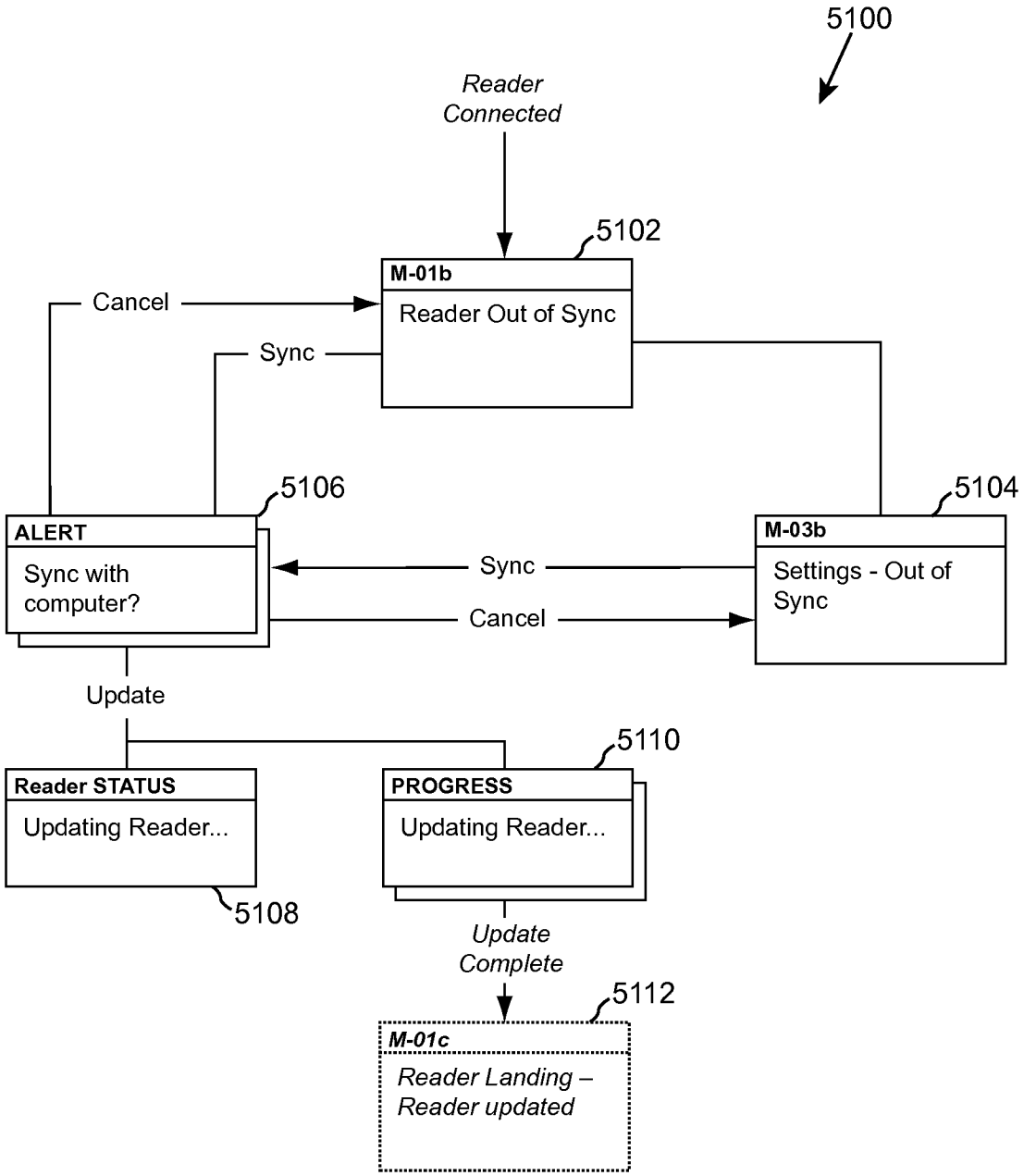

5100
Reader Connected
5102
M-01b
Reader Out of Sync
Cancel
Sync
5106
ALERT
Sync with computer?
5104
M-03b
Settings - Out of Sync
Sync
Cancel
Update
5110
Reader STATUS
Updating Reader...
PROGRESS
Updating Reader...
5108
Update Complete
5112
M-01c
Reader Landing – Reader updated

FIG. 48

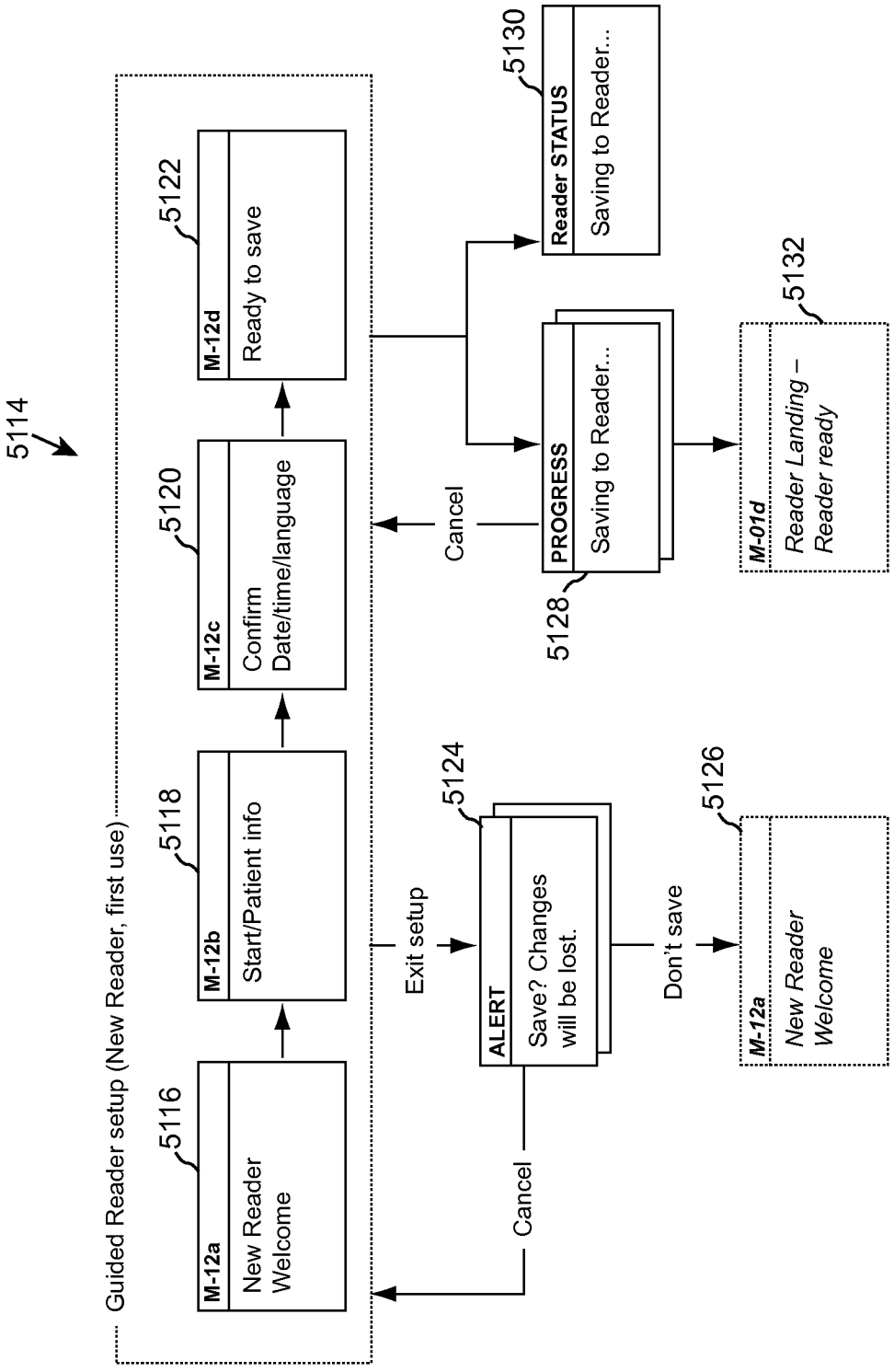

5114
Guided Reader setup (New Reader, first use)
5116
M-12a
New Reader Welcome
5118
M-12b
Start/Patient info
5120
M-12c
Confirm Date/time/language
5122
M-12d
Ready to save
Exit setup
Cancel
5124
ALERT
Save? Changes will be lost.
Cancel
Don't save
5126
M-12a
New Reader Welcome
5128
PROGRESS
Saving to Reader...
5130
Reader STATUS
Saving to Reader...
5132
M-01d
Reader Landing – Reader ready

FIG. 49

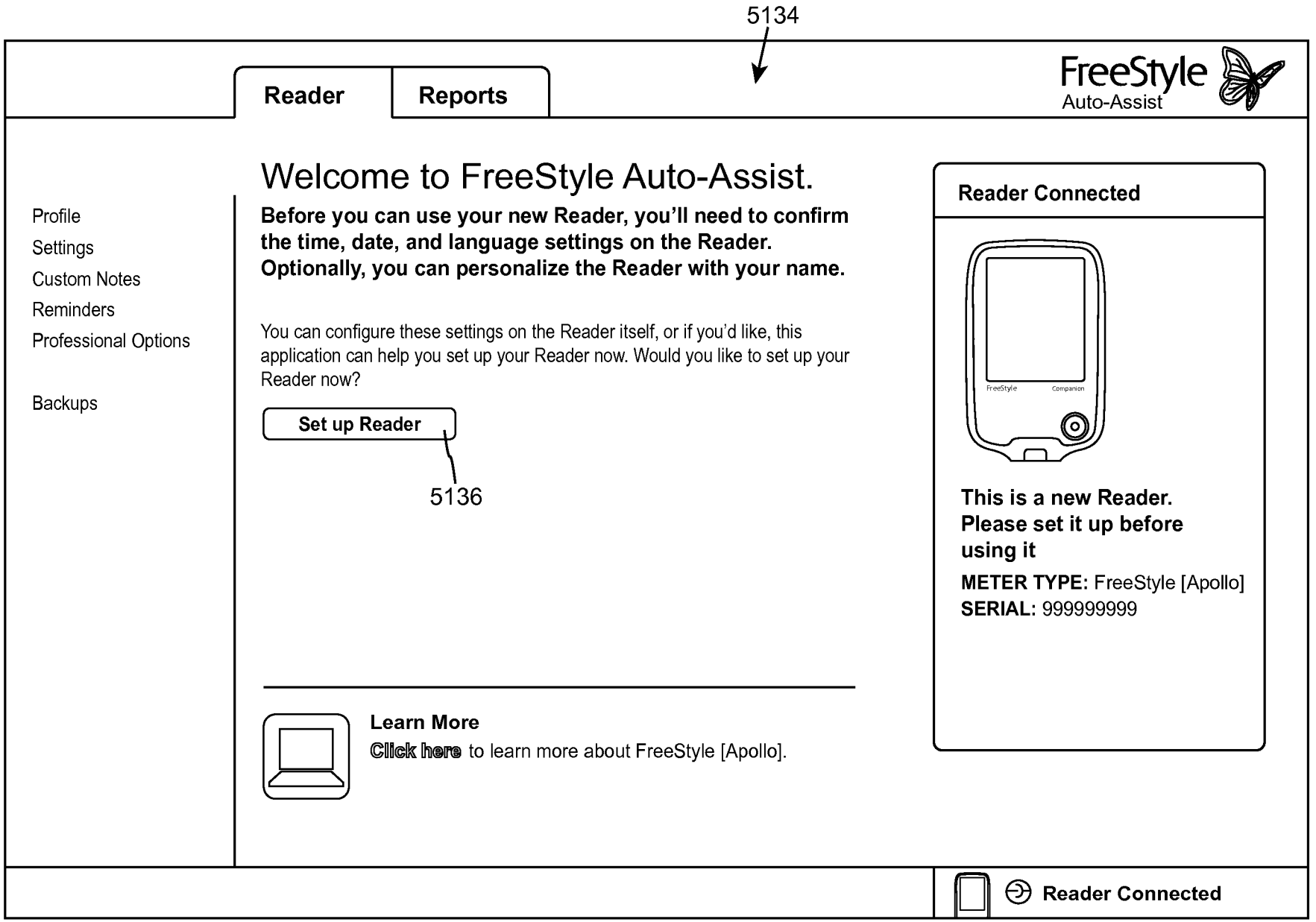

5134
Reader
Reports
FreeStyle
Auto-Assist
Welcome to FreeStyle Auto-Assist.
Profile
Settings
Custom Notes
Reminders
Professional Options
Backups
Before you can use your new Reader, you'll need to confirm the time, date, and language settings on the Reader. Optionally, you can personalize the Reader with your name.
You can configure these settings on the Reader itself, or if you'd like, this application can help you set up your Reader now. Would you like to set up your Reader now?
Set up Reader
5136
Learn More
Click here to learn more about FreeStyle [Apollo].
Reader Connected
FreeStyle
Companion
This is a new Reader. Please set it up before using it
METER TYPE: FreeStyle [Apollo]
SERIAL: 999999999
Reader Connected

FIG. 50

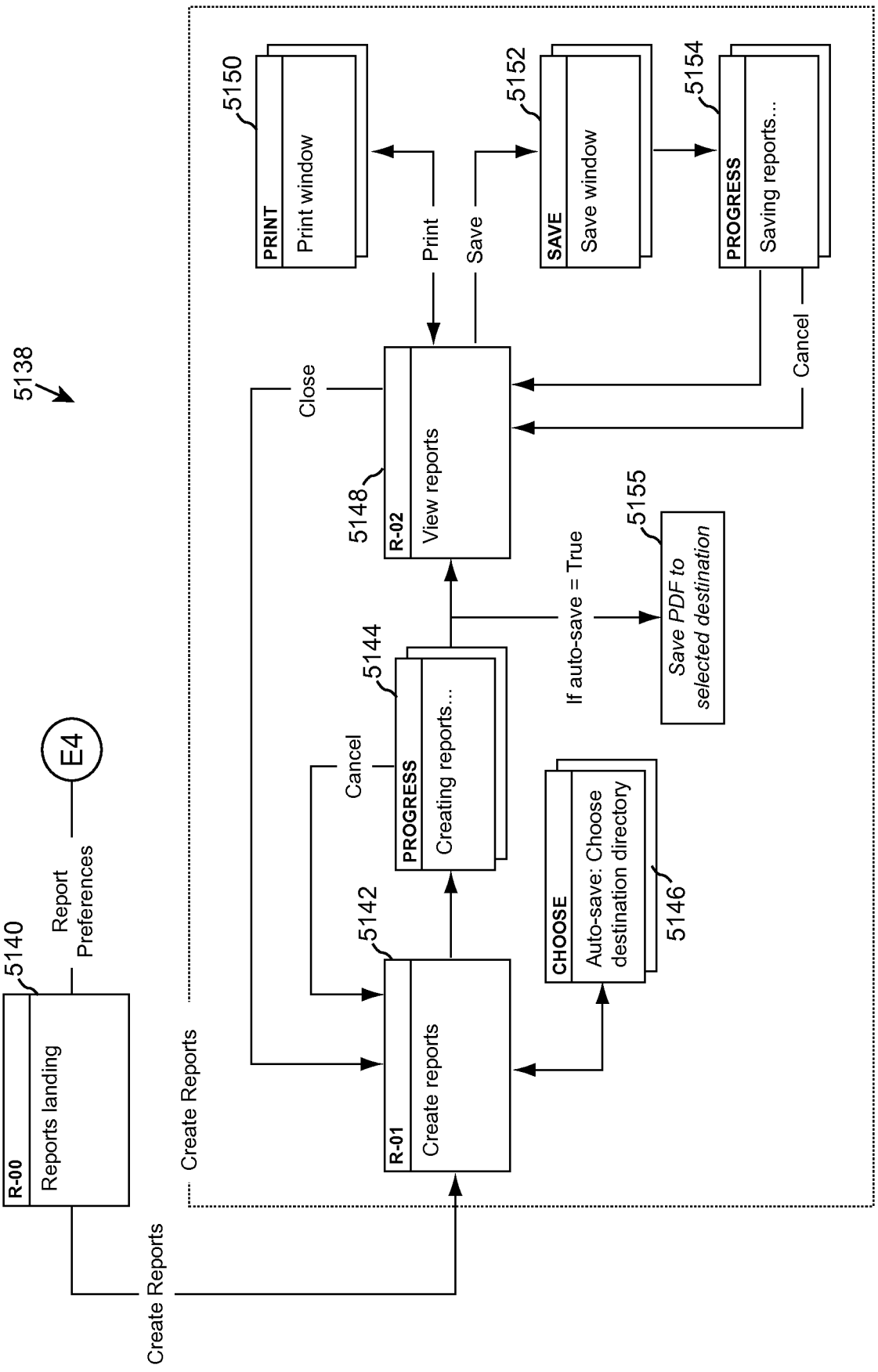

5138
R-00
Reports landing
5140
Report Preferences
E4
Create Reports
Create Reports
R-01
Create reports
5142
PROGRESS
Creating reports...
5144
Cancel
If auto-save = True
Save PDF to selected destination
5155
CHOOSE
Auto-save: Choose destination directory
5146
R-02
View reports
5148
Close
Print
Save
Cancel
PRINT
Print window
5150
SAVE
Save window
5152
PROGRESS
Saving reports...
5154

FIG. 51

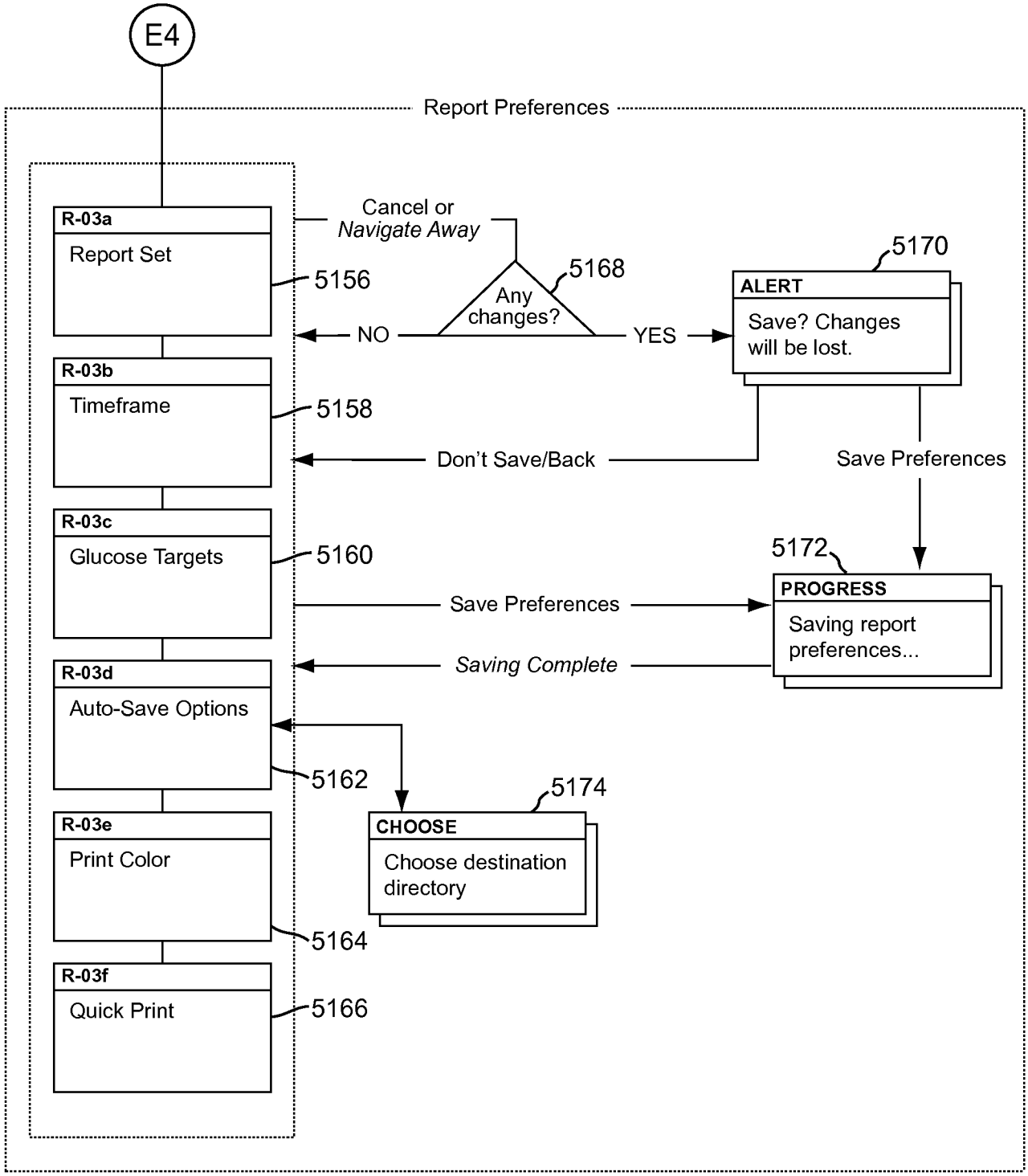

E4
Report Preferences
R-03a
Report Set
5156
Cancel or
Navigate Away
5168
Any
changes?
NO
YES
5170
ALERT
Save? Changes
will be lost.
R-03b
Timeframe
5158
Don't Save/Back
Save Preferences
R-03c
Glucose Targets
5160
5172
PROGRESS
Saving report
preferences...
Save Preferences
Saving Complete
R-03d
Auto-Save Options
5162
5174
CHOOSE
Choose destination
directory
R-03e
Print Color
5164
R-03f
Quick Print
5166

FIG. 51 (Cont)

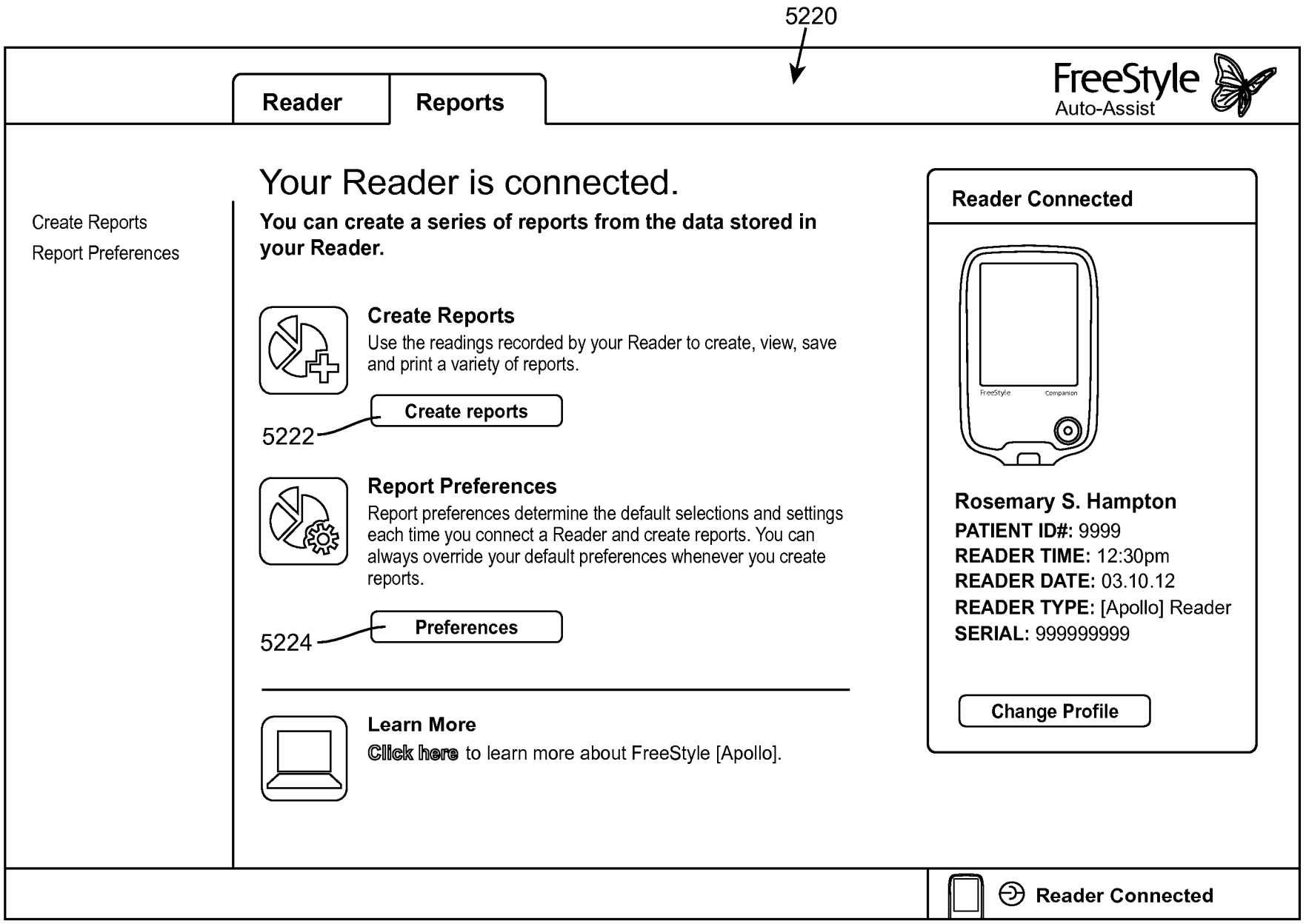

5220
Reader
Reports
FreeStyle
Auto-Assist
Your Reader is connected.
Create Reports
Report Preferences
You can create a series of reports from the data stored in your Reader.
Create Reports
Use the readings recorded by your Reader to create, view, save and print a variety of reports.
Create reports
5222
Report Preferences
Report preferences determine the default selections and settings each time you connect a Reader and create reports. You can always override your default preferences whenever you create reports.
Preferences
5224
Learn More
Click here to learn more about FreeStyle [Apollo].
Reader Connected
FreeStyle
Companion
Rosemary S. Hampton
PATIENT ID#: 9999
READER TIME: 12:30pm
READER DATE: 03.10.12
READER TYPE: [Apollo] Reader
SERIAL: 999999999
Change Profile
Reader Connected

FIG. 52

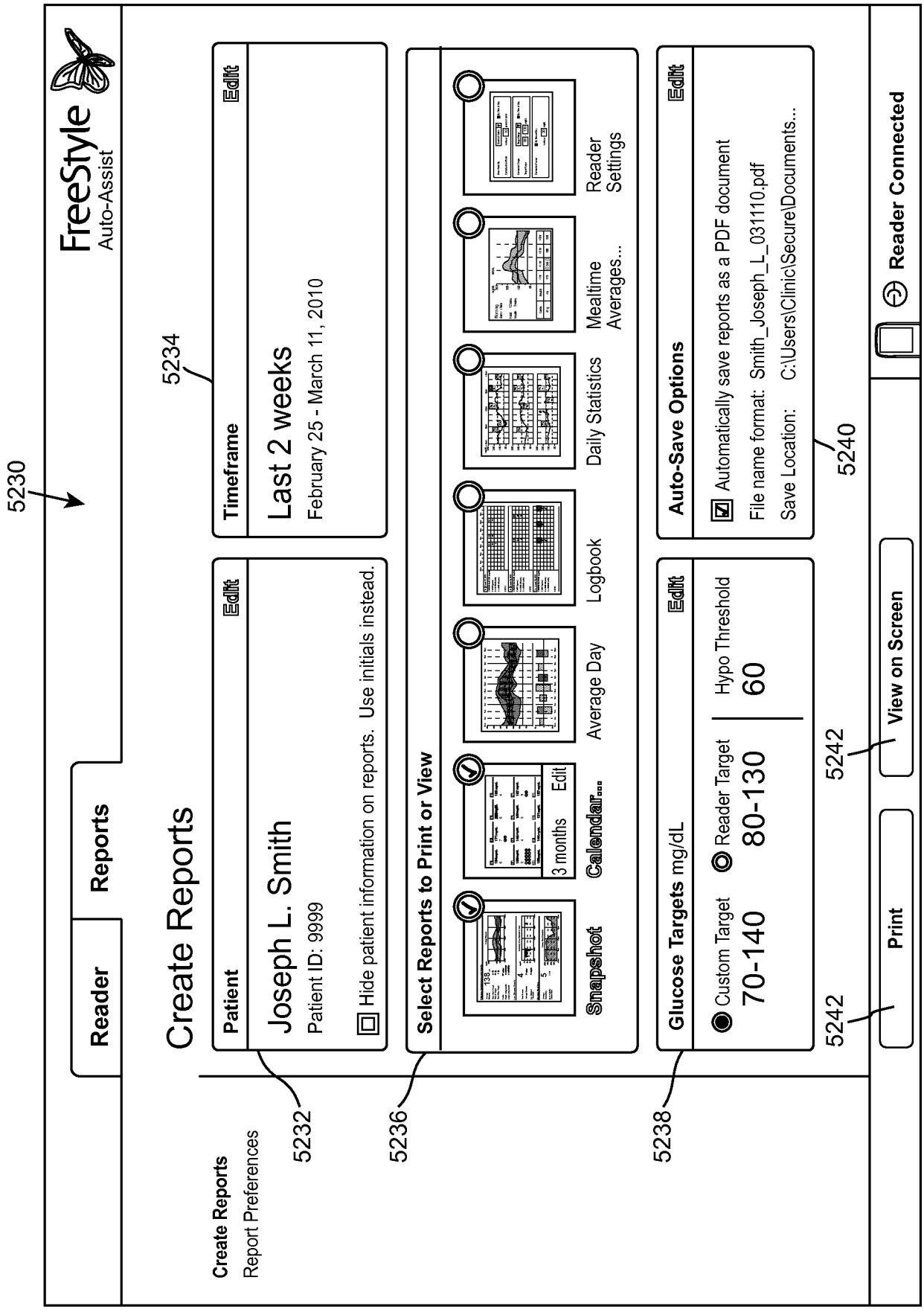

5230
FreeStyle
Auto-Assist
Reader
Reports
Create Reports
Create Reports
Report Preferences
Patient
Edit
Joseph L. Smith
Patient ID: 9999
Hide patient information on reports. Use initials instead.
5232
5234
Timeframe
Edit
Last 2 weeks
February 25 - March 11, 2010
5236
Select Reports to Print or View
Snapshot
3 months
Edit
Calendar...
Average Day
Logbook
Daily Statistics
Mealtime Averages...
Reader Settings
5238
Glucose Targets mg/dL
Edit
Custom Target
70-140
Reader Target
80-130
Hypo Threshold
60
5240
Auto-Save Options
Edit
Automatically save reports as a PDF document
File name format: Smith_Joseph_L_031110.pdf
Save Location: C:\Users\Clinic\Secure\Documents...
5242
Print
View on Screen
Reader Connected

FIG. 53

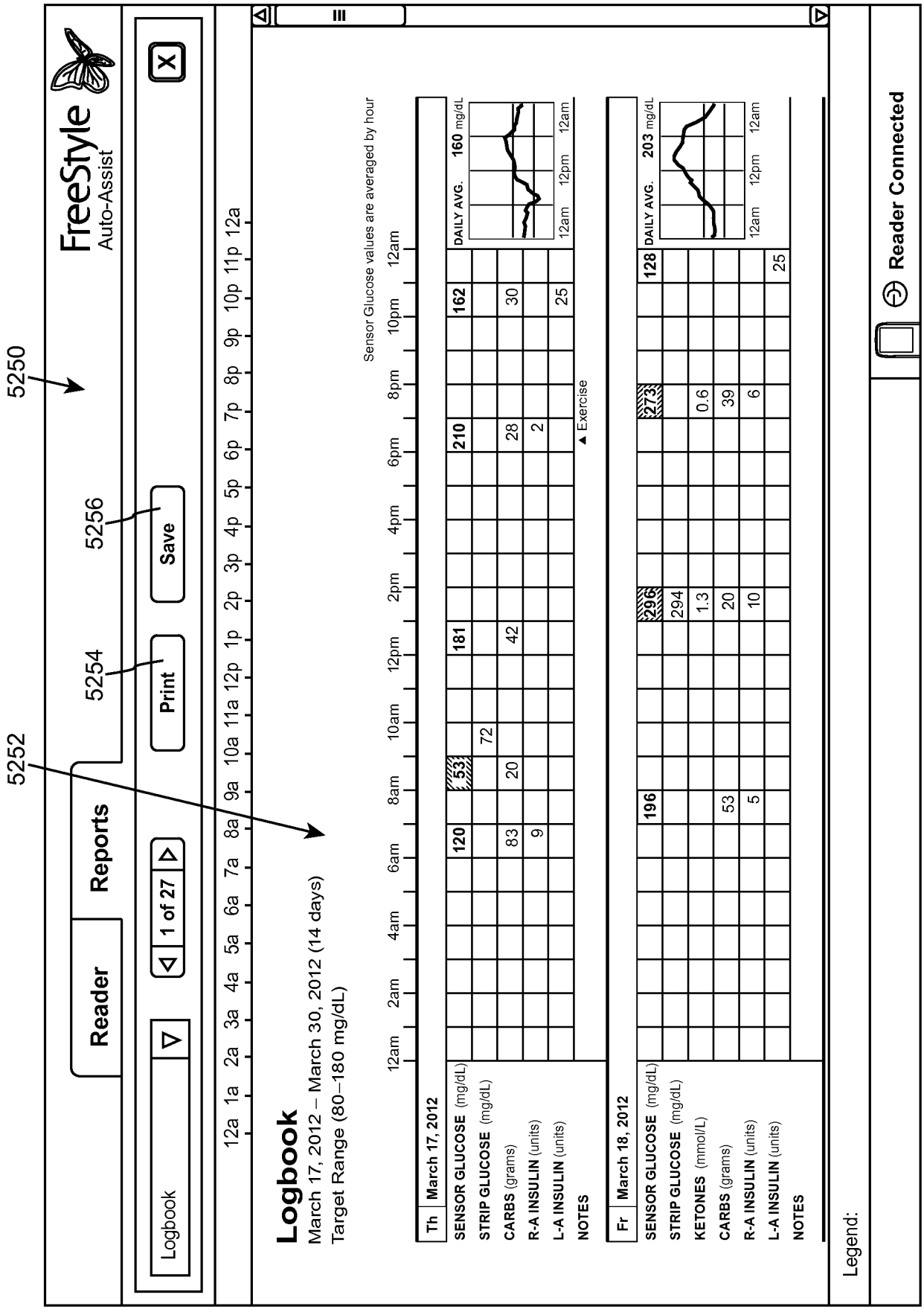

5250
5252
5254
5256
FreeStyle
Auto-Assist
Reader
Reports
Logbook
1 of 27
Print
Save
12a 1a 2a 3a 4a 5a 6a 7a 8a 9a 10a 11a 12p 1p 2p 3p 4p 5p 6p 7p 8p 9p 10p 11p 12a
Logbook
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
Sensor Glucose values are averaged by hour
12am 2am 4am 6am 8am 10am 12pm 2pm 4pm 6pm 8pm 10pm 12am
Th March 17, 2012
SENSOR GLUCOSE (mg/dL)
STRIP GLUCOSE (mg/dL)
CARBS (grams)
R-A INSULIN (units)
L-A INSULIN (units)
NOTES
120 53 181 210 162
72
83 20 42 28 30
9 2
25
Exercise
DAILY AVG. 160 mg/dL
12am 12pm 12am
Fr March 18, 2012
SENSOR GLUCOSE (mg/dL)
STRIP GLUCOSE (mg/dL)
KETONES (mmol/L)
CARBS (grams)
R-A INSULIN (units)
L-A INSULIN (units)
NOTES
196 296 273 128
294
1.3 0.6
53 20 39
5 10 6
25
DAILY AVG. 203 mg/dL
12am 12pm 12am
Legend:
Reader Connected

FIG. 54

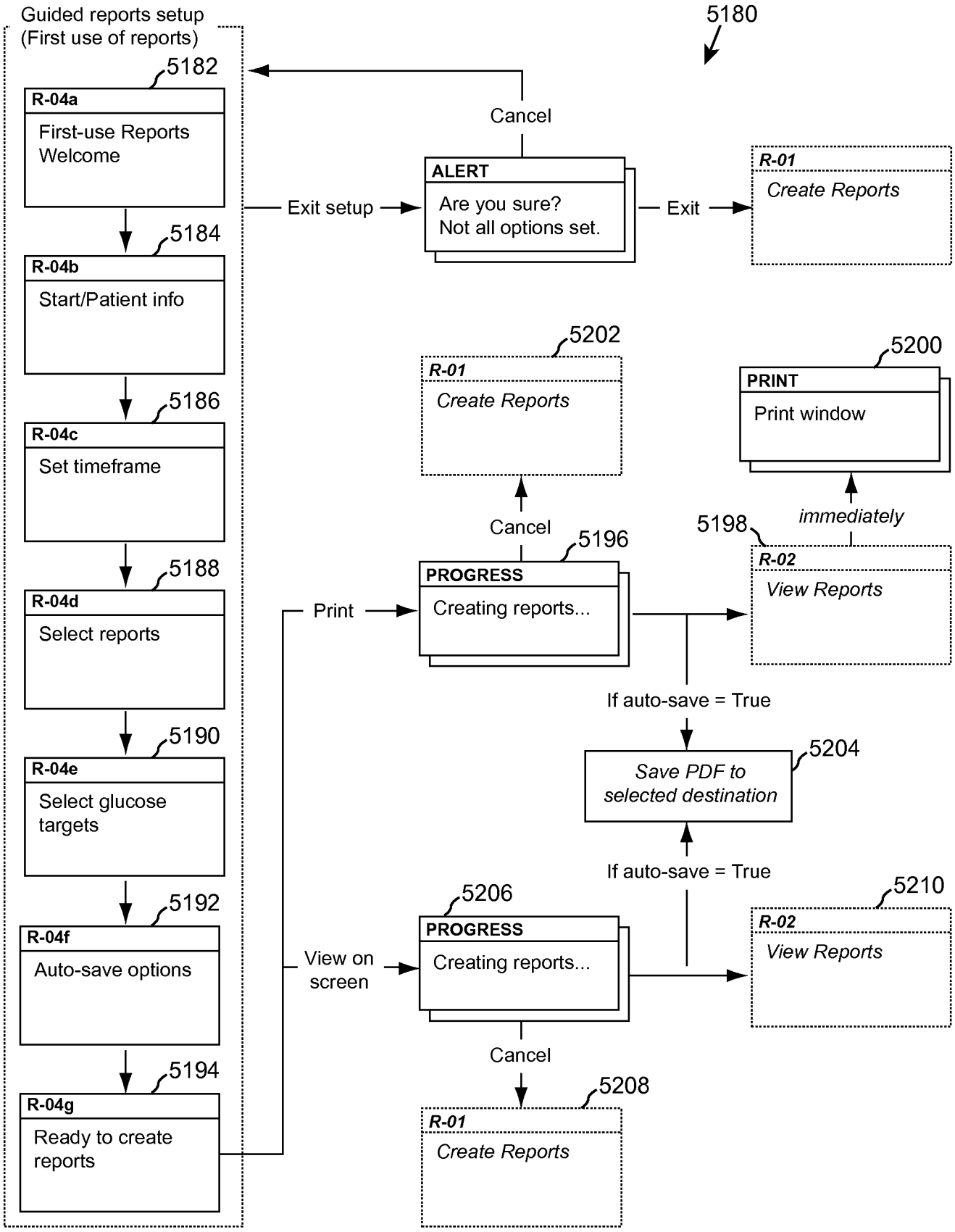

Guided reports setup
(First use of reports)
5180
5182
R-04a
First-use Reports Welcome
5184
R-04b
Start/Patient info
5186
R-04c
Set timeframe
5188
R-04d
Select reports
5190
R-04e
Select glucose targets
5192
R-04f
Auto-save options
5194
R-04g
Ready to create reports
Cancel
Exit setup
ALERT
Are you sure?
Not all options set.
Exit
R-01
Create Reports
5202
R-01
Create Reports
5200
PRINT
Print window
immediately
Cancel
5196
PROGRESS
Creating reports...
5198
R-02
View Reports
Print
If auto-save = True
5204
Save PDF to selected destination
If auto-save = True
5206
PROGRESS
Creating reports...
View on screen
5210
R-02
View Reports
Cancel
5208
R-01
Create Reports

FIG. 55

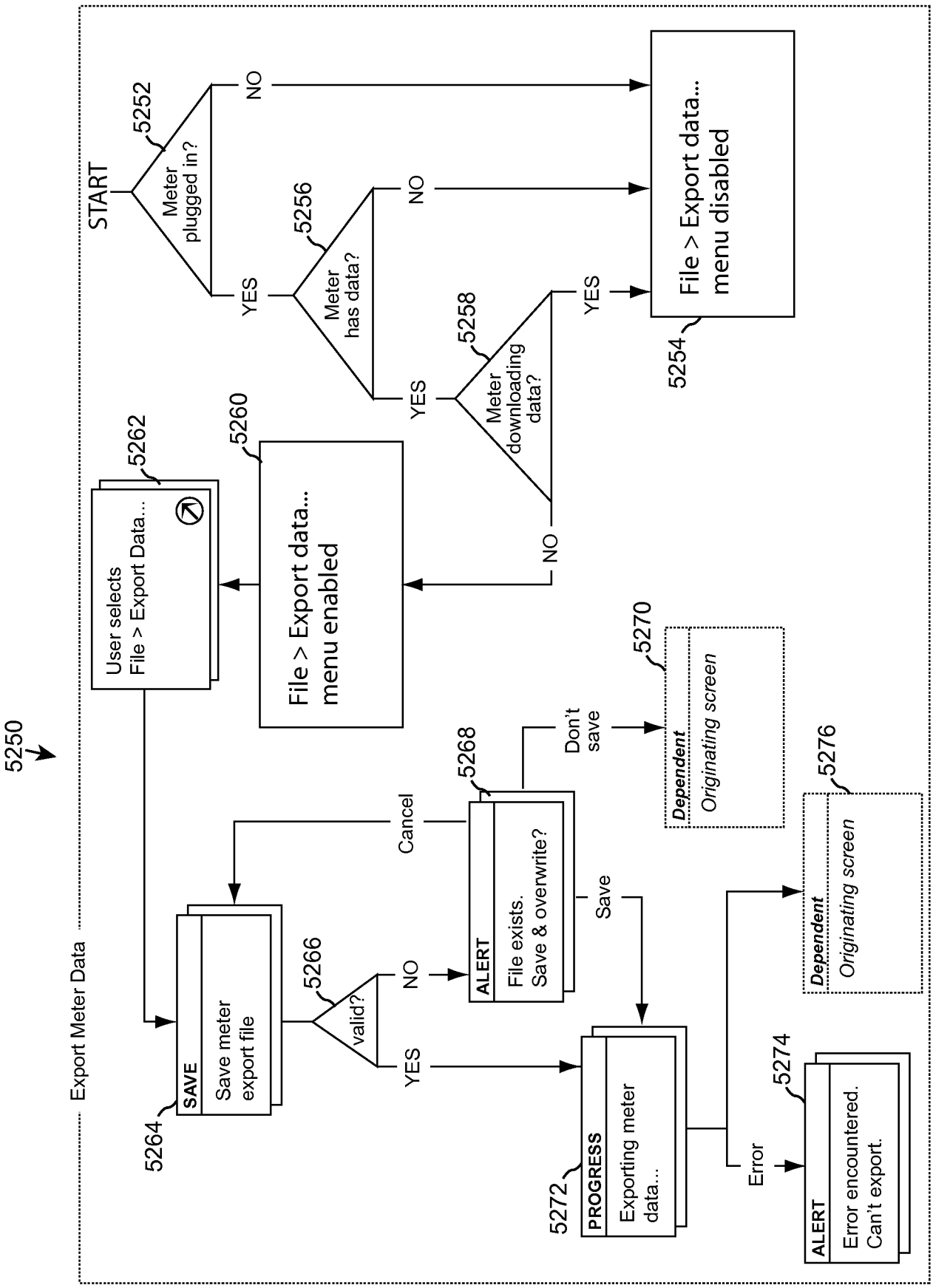

5250
Export Meter Data
START
5252
Meter plugged in?
NO
YES
5256
Meter has data?
NO
YES
5258
Meter downloading data?
YES
NO
File > Export data... menu disabled
5254
File > Export data... menu enabled
5260
User selects File > Export Data...
5262
SAVE
Save meter export file
5264
5266
valid?
NO
YES
Cancel
ALERT
File exists. Save & overwrite?
5268
Don't save
Save
Dependent
Originating screen
5270
PROGRESS
Exporting meter data...
5272
Error
ALERT
Error encountered. Can't export.
5274
Dependent
Originating screen
5276

FIG. 56

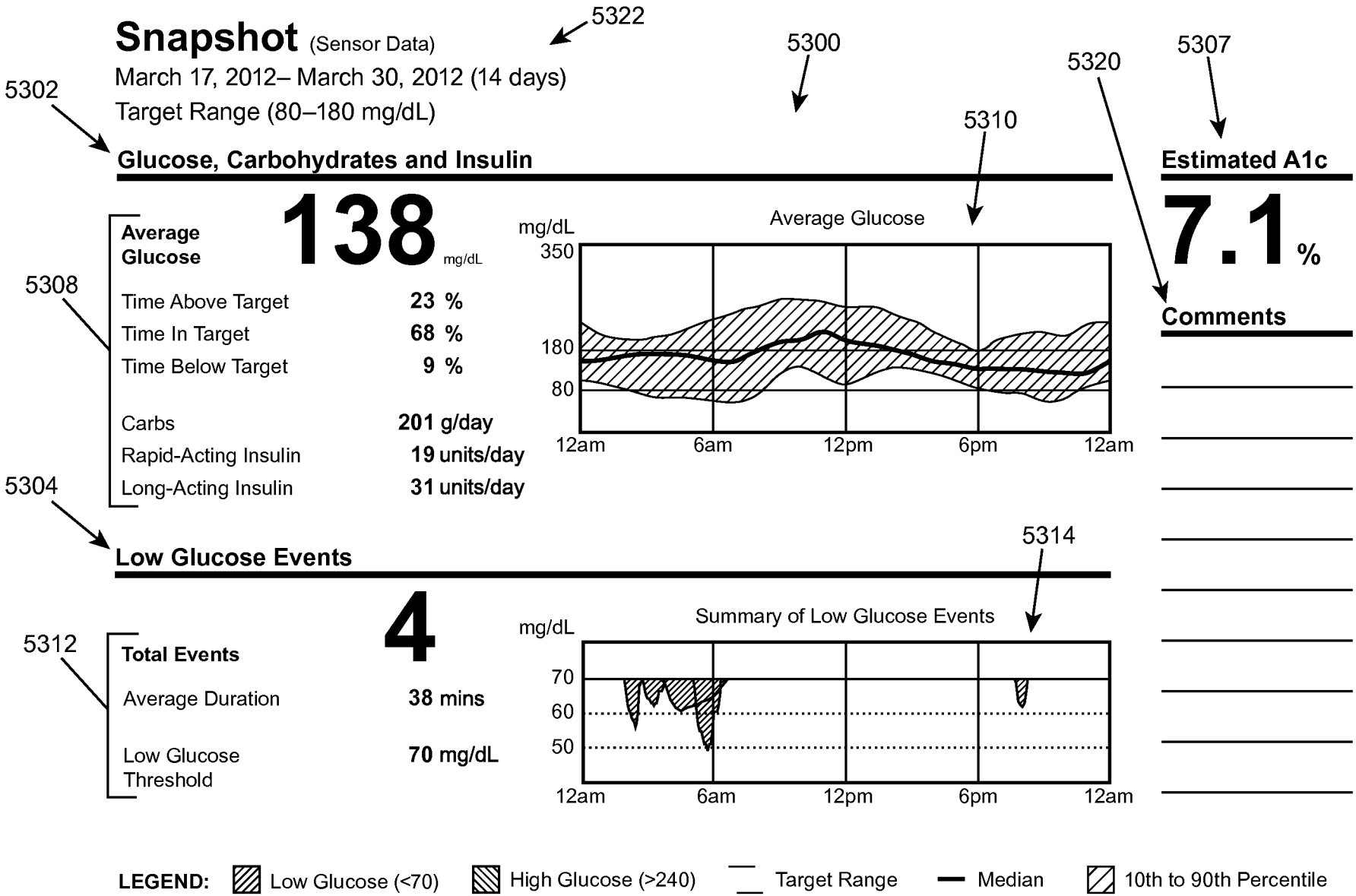

Snapshot (Sensor Data)
March 17, 2012– March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5322
5300
5320
5307
5302
5310
Glucose, Carbohydrates and Insulin
Estimated A1c
7.1 %
Average Glucose
138 mg/dL
mg/dL
350
180
80
Average Glucose
12am
6am
12pm
6pm
12am
Comments
5308
Time Above Target 23 %
Time In Target 68 %
Time Below Target 9 %
Carbs 201 g/day
Rapid-Acting Insulin 19 units/day
Long-Acting Insulin 31 units/day
5304
Low Glucose Events
5314
4
Summary of Low Glucose Events
mg/dL
70
60
50
5312
Total Events
Average Duration 38 mins
Low Glucose Threshold 70 mg/dL
12am
6am
12pm
6pm
12am
LEGEND:
Low Glucose (<70)
High Glucose (>240)
Target Range
Median
10th to 90th Percentile

FIG. 57

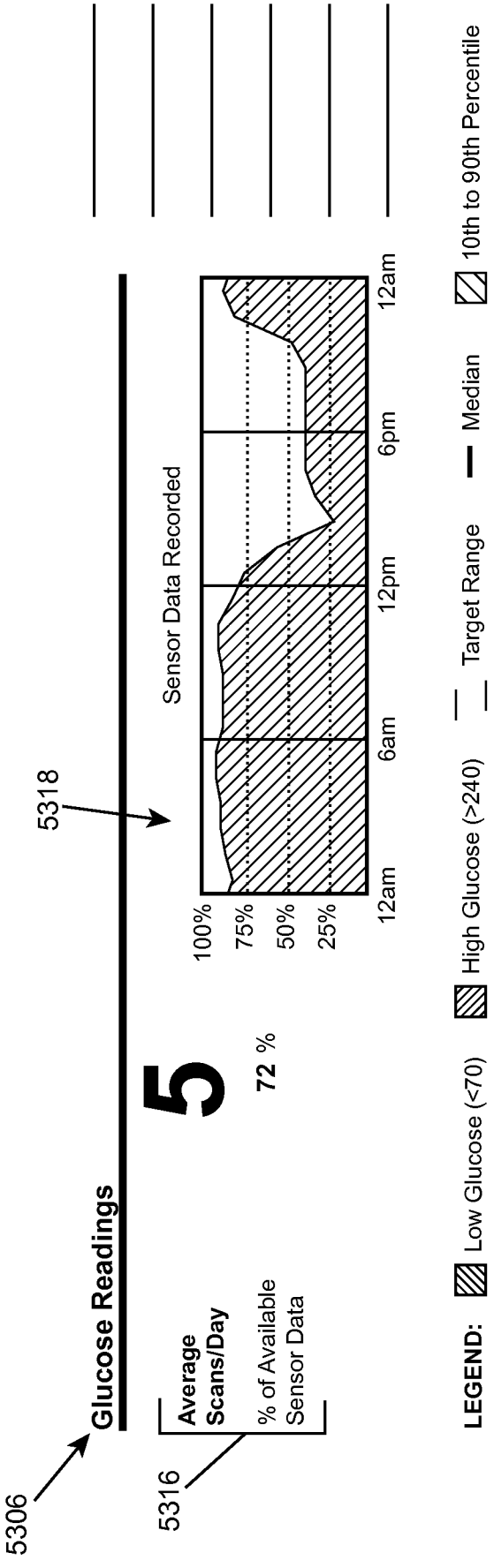

5306
Glucose Readings
5316
Average Scans/Day
5
% of Available Sensor Data
72 %
5318
Sensor Data Recorded
100%
75%
50%
25%
12am
6am
12pm
6pm
12am
LEGEND:
Low Glucose (<70)
High Glucose (>240)
Target Range
Median
10th to 90th Percentile

FIG. 57 (Cont)

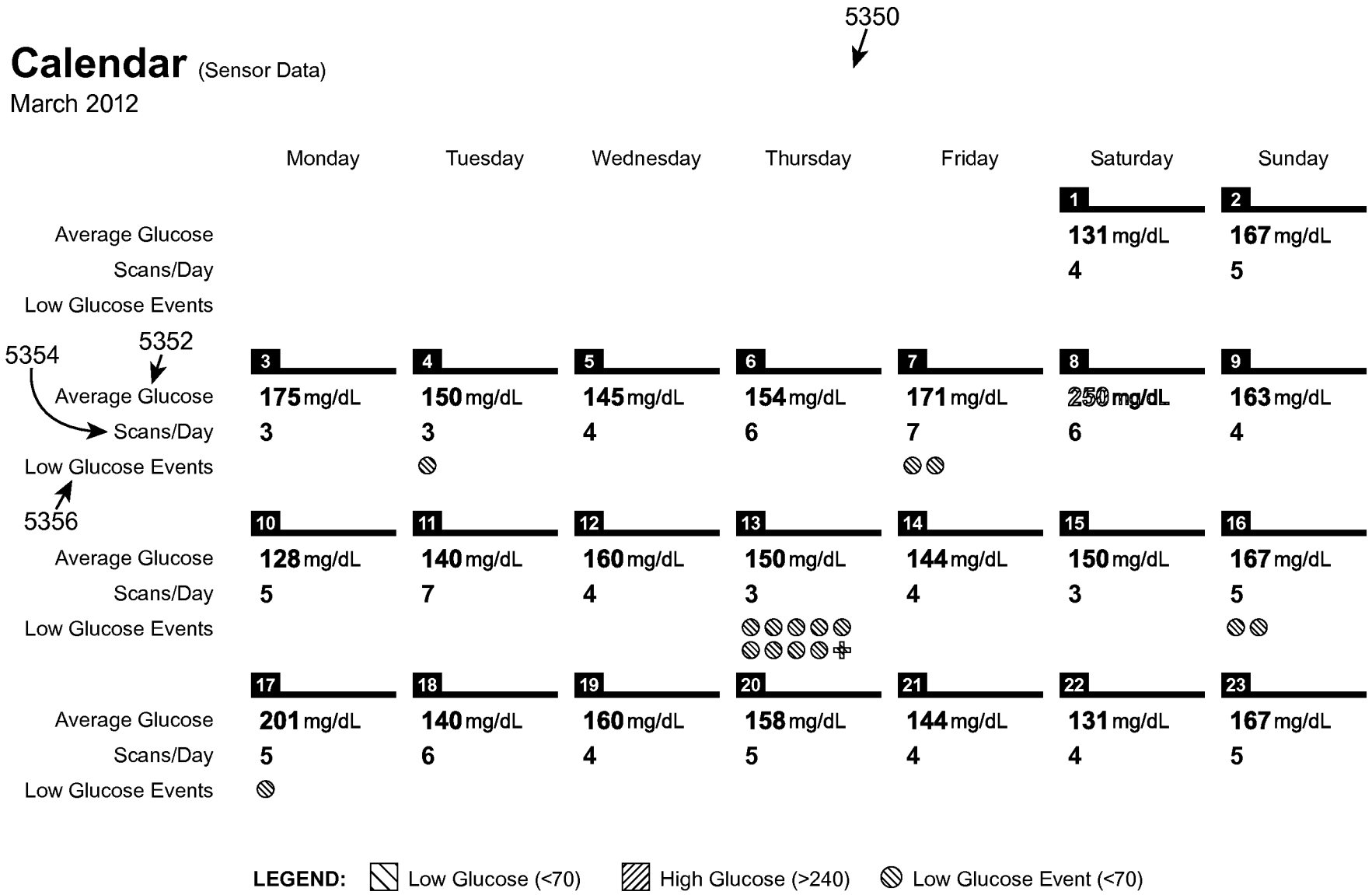

5350
Calendar (Sensor Data)
March 2012
Monday
Tuesday
Wednesday
Thursday
Friday
Saturday
Sunday
1
2
Average Glucose
131 mg/dL
167 mg/dL
Scans/Day
4
5
Low Glucose Events
5354
5352
3
4
5
6
7
8
9
Average Glucose
175 mg/dL
150 mg/dL
145 mg/dL
154 mg/dL
171 mg/dL
250 mg/dL
163 mg/dL
Scans/Day
3
3
4
6
7
6
4
Low Glucose Events
5356
10
11
12
13
14
15
16
Average Glucose
128 mg/dL
140 mg/dL
160 mg/dL
150 mg/dL
144 mg/dL
150 mg/dL
167 mg/dL
Scans/Day
5
7
4
3
4
3
5
Low Glucose Events
17
18
19
20
21
22
23
Average Glucose
201 mg/dL
140 mg/dL
160 mg/dL
158 mg/dL
144 mg/dL
131 mg/dL
167 mg/dL
Scans/Day
5
6
4
5
4
4
5
Low Glucose Events
LEGEND:
Low Glucose (<70)
High Glucose (>240)
Low Glucose Event (<70)

FIG. 58

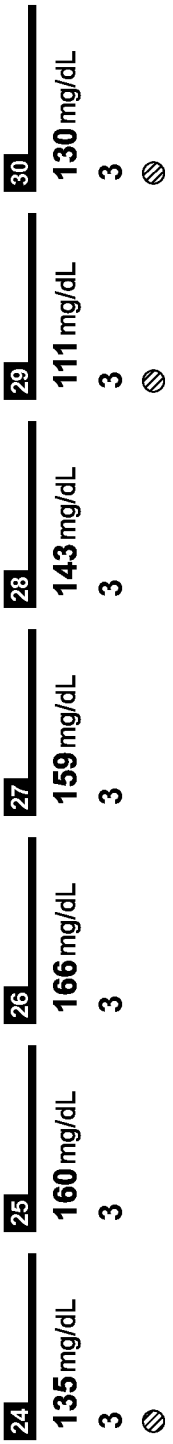

24
25
26
27
28
29
30
31
Average Glucose
Scans/Day
Low Glucose Events
135 mg/dL
3
160 mg/dL
3
166 mg/dL
3
159 mg/dL
3
143 mg/dL
3
111 mg/dL
3
130 mg/dL
3
135 mg/dL
8
LEGEND:
Low Glucose (<70)
High Glucose (>240)
Low Glucose Event (<70)

FIG. 58 (Cont)

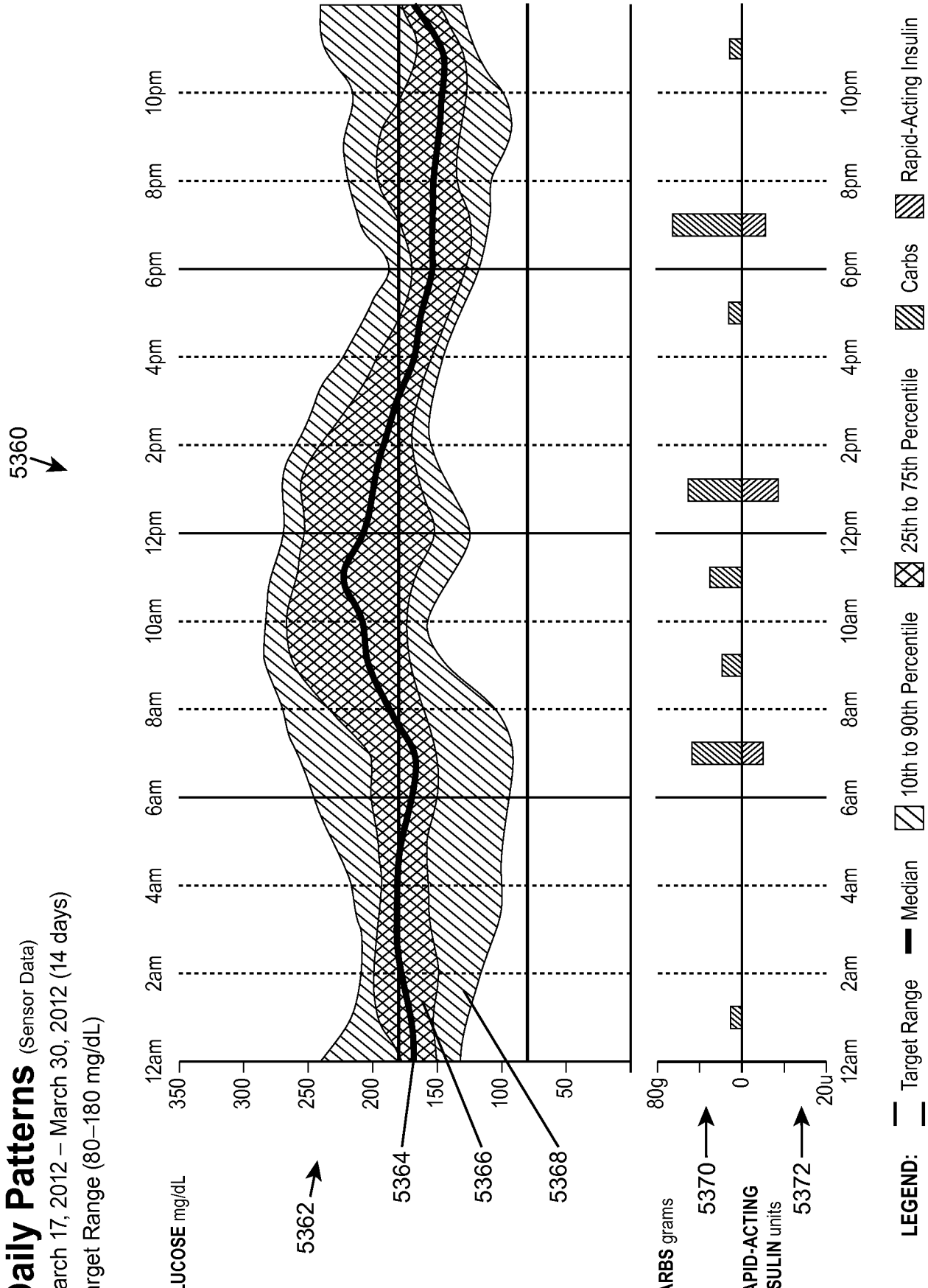

Daily Patterns (Sensor Data)
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5360
GLUCOSE mg/dL
350
300
250
200
150
100
50
5362
5364
5366
5368
12am
2am
4am
6am
8am
10am
12pm
2pm
4pm
6pm
8pm
10pm
CARBS grams
80g
5370
RAPID-ACTING INSULIN units
0
20u
5372
LEGEND:
Target Range
Median
10th to 90th Percentile
25th to 75th Percentile
Carbs
Rapid-Acting Insulin

FIG. 59

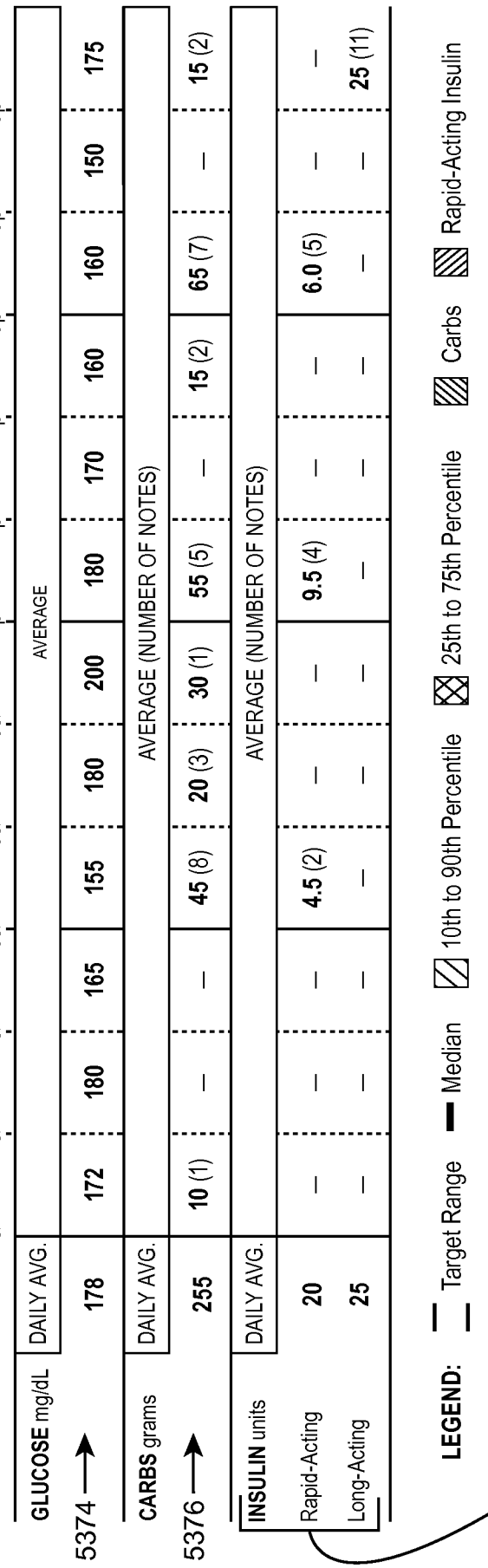
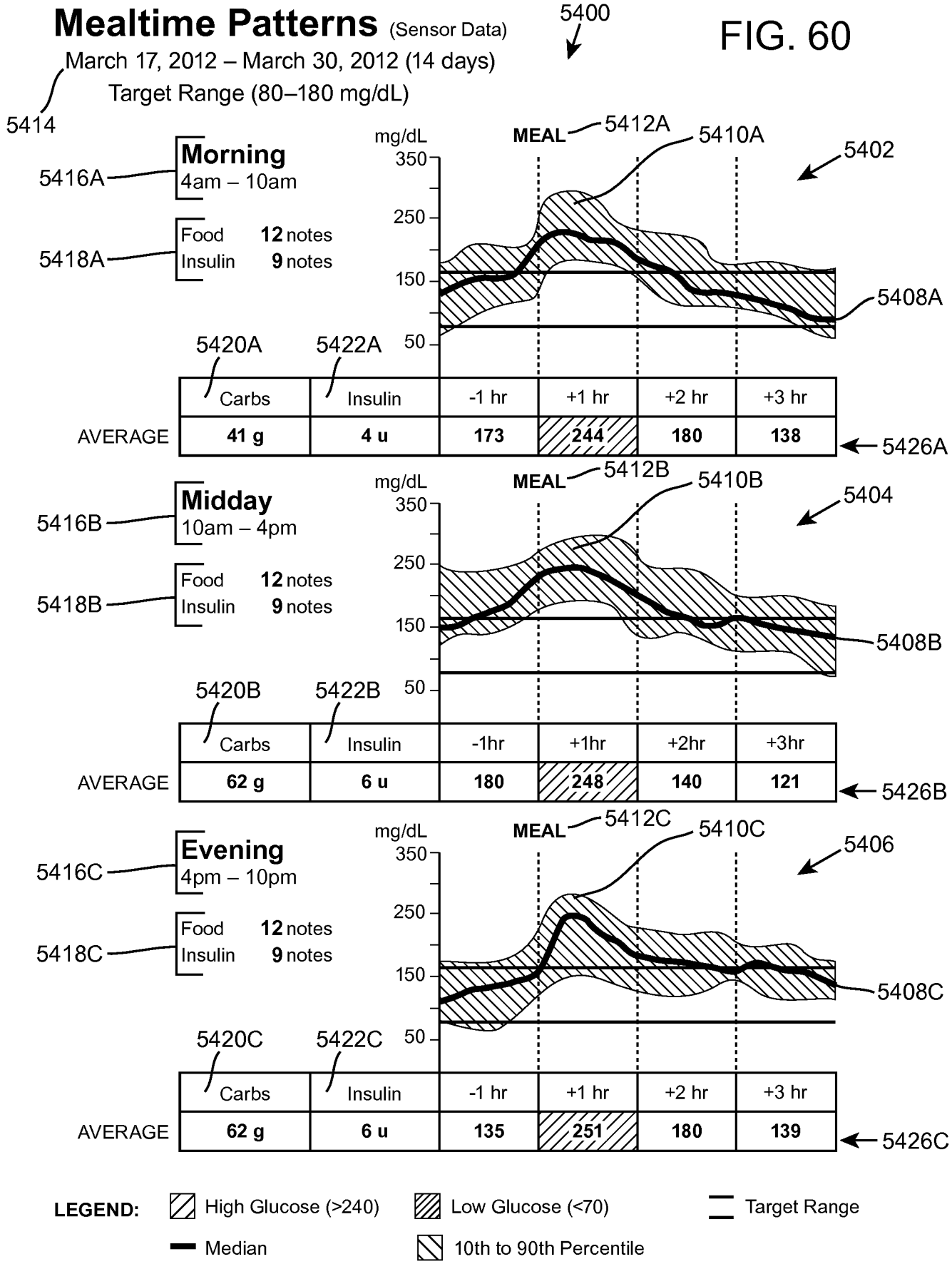

12am 2am 4am 6am 8am 10am 12pm 2pm 4pm 6pm 8pm 10pm
GLUCOSE mg/dL
DAILY AVG.
AVERAGE
5374
178
172 180 165 155 180 200 180 170 160 160 150 175
CARBS grams
DAILY AVG.
AVERAGE (NUMBER OF NOTES)
5376
255
10 (1) — — 45 (8) 20 (3) 30 (1) 55 (5) — 15 (2) 65 (7) — 15 (2)
INSULIN units
DAILY AVG.
AVERAGE (NUMBER OF NOTES)
Rapid-Acting
20
— — — 4.5 (2) — — 9.5 (4) — — 6.0 (5) — —
Long-Acting
25
— — — — — — — — — — — 25 (11)
LEGEND:
Target Range
Median
10th to 90th Percentile
25th to 75th Percentile
Carbs
Rapid-Acting Insulin
5378

FIG. 59 (Cont)

FIG. 60


Mealtime Patterns (Sensor Data)
5400
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5414
Morning
4am – 10am
5416A
Food 12 notes
Insulin 9 notes
5418A
mg/dL
350
250
150
50
MEAL
5412A
5410A
5402
5408A
5420A
5422A
Carbs
Insulin
-1 hr
+1 hr
+2 hr
+3 hr
AVERAGE
41 g
4 u
173
244
180
138
5426A
Midday
10am – 4pm
5416B
Food 12 notes
Insulin 9 notes
5418B
MEAL
5412B
5410B
5404
5408B
5420B
5422B
Carbs
Insulin
-1hr
+1hr
+2hr
+3hr
AVERAGE
62 g
6 u
180
248
140
121
5426B
Evening
4pm – 10pm
5416C
Food 12 notes
Insulin 9 notes
5418C
MEAL
5412C
5410C
5406
5408C
5420C
5422C
Carbs
Insulin
-1 hr
+1 hr
+2 hr
+3 hr
AVERAGE
62 g
6 u
135
251
180
139
5426C
LEGEND:
High Glucose (>240)
Low Glucose (<70)
Target Range
Median
10th to 90th Percentile

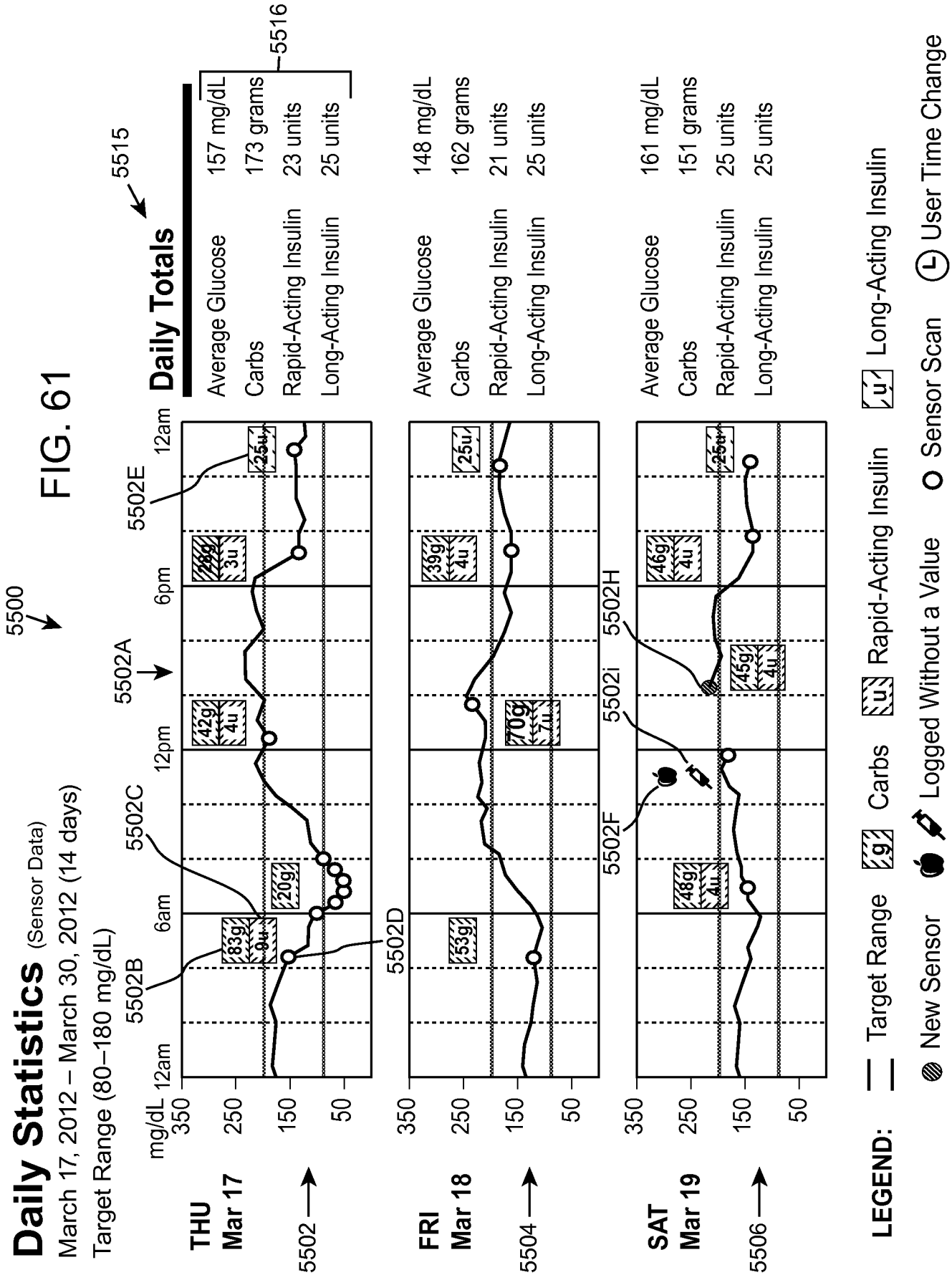

Daily Statistics (Sensor Data)
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5500
5515
Daily Totals
Average Glucose 157 mg/dL
Carbs 173 grams
Rapid-Acting Insulin 23 units
Long-Acting Insulin 25 units
5516
Average Glucose 148 mg/dL
Carbs 162 grams
Rapid-Acting Insulin 21 units
Long-Acting Insulin 25 units
Average Glucose 161 mg/dL
Carbs 151 grams
Rapid-Acting Insulin 25 units
Long-Acting Insulin 25 units
mg/dL
350
250
150
50
12am
6am
12pm
6pm
12am
5502A
5502B
5502C
5502D
5502E
5502F
5502H
5502i
THU Mar 17
FRI Mar 18
SAT Mar 19
5502
5504
5506
83g
0u
20g
42g
4u
3u
25u
53g
39g
4u
70g
7u
48g
4u
46g
4u
45g
4u
LEGEND:
Target Range
g Carbs
u Rapid-Acting Insulin
u Long-Acting Insulin
New Sensor
Logged Without a Value
Sensor Scan
User Time Change

FIG. 61

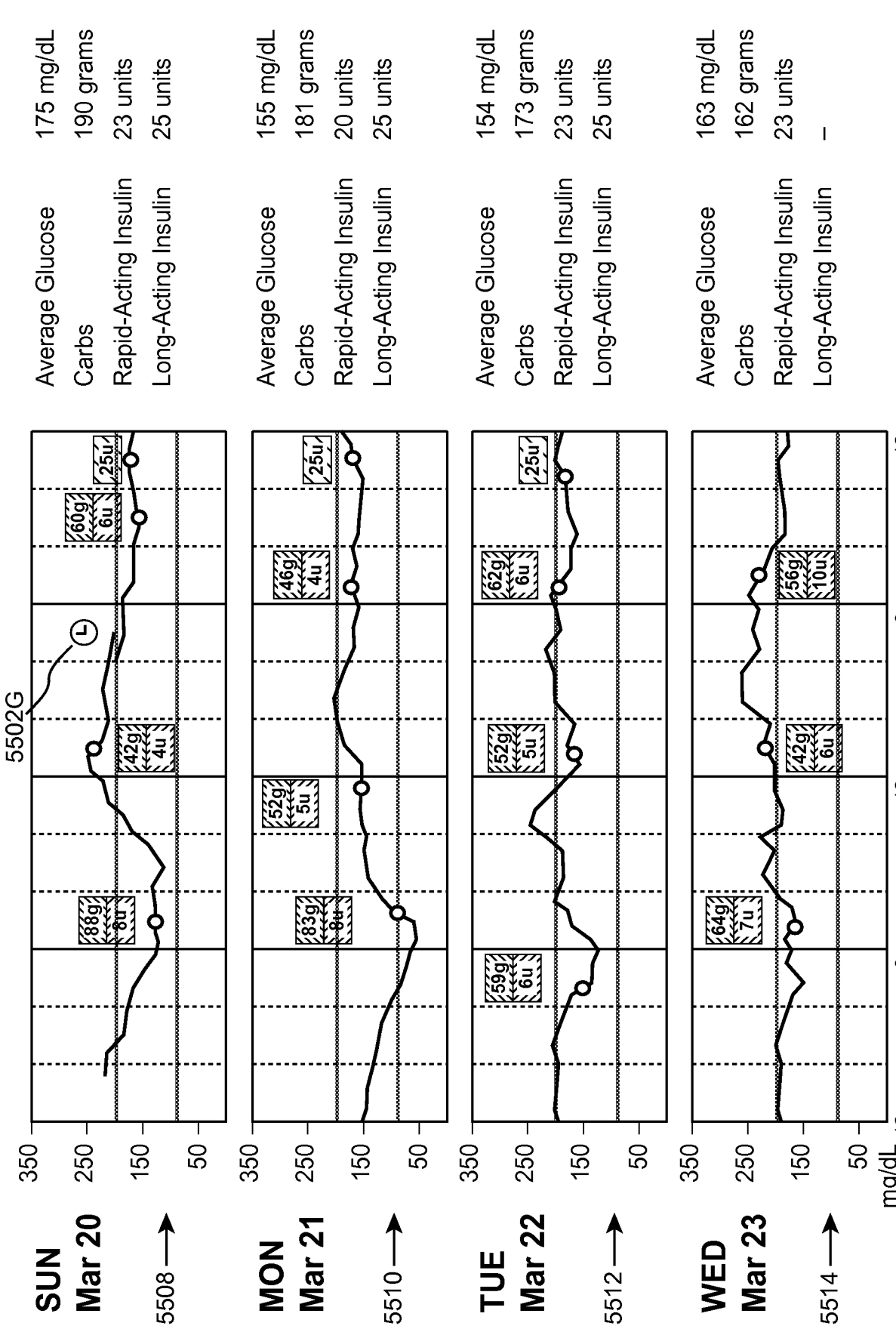

SUN
Mar 20
5508
MON
Mar 21
5510
TUE
Mar 22
5512
WED
Mar 23
5514
5502G
88g 8u
42g 4u
60g 6u
25u
83g 8u
52g 5u
46g 4u
25u
59g 6u
52g 5u
62g 6u
25u
64g 7u
42g 6u
56g 10u
350
250
150
50
mg/dL
12am
6am
12pm
6pm
12am
Average Glucose 175 mg/dL
Carbs 190 grams
Rapid-Acting Insulin 23 units
Long-Acting Insulin 25 units
Average Glucose 155 mg/dL
Carbs 181 grams
Rapid-Acting Insulin 20 units
Long-Acting Insulin 25 units
Average Glucose 154 mg/dL
Carbs 173 grams
Rapid-Acting Insulin 23 units
Long-Acting Insulin 25 units
Average Glucose 163 mg/dL
Carbs 162 grams
Rapid-Acting Insulin 23 units
Long-Acting Insulin –
LEGEND:
Target Range
Carbs
Rapid-Acting Insulin
Long-Acting Insulin
New Sensor
Logged Without a Value
Sensor Scan
User Time Change

FIG. 61 (Cont)

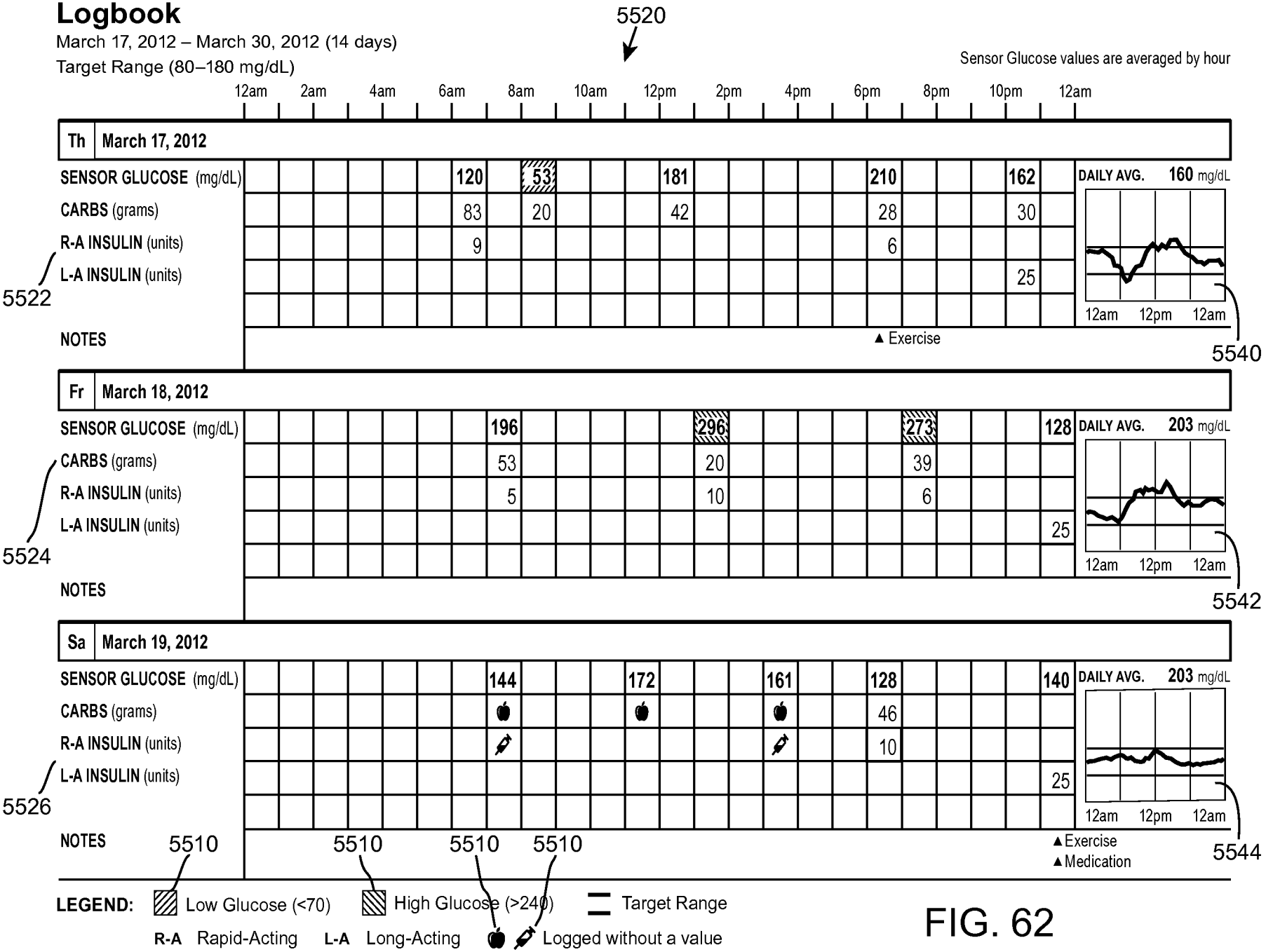

Logbook
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5520
Sensor Glucose values are averaged by hour
12am 2am 4am 6am 8am 10am 12pm 2pm 4pm 6pm 8pm 10pm 12am
Th March 17, 2012
SENSOR GLUCOSE (mg/dL) 120 53 181 210 162
CARBS (grams) 83 20 42 28 30
R-A INSULIN (units) 9 6
L-A INSULIN (units) 25
NOTES ▲ Exercise
DAILY AVG. 160 mg/dL
12am 12pm 12am
5522
5540
Fr March 18, 2012
SENSOR GLUCOSE (mg/dL) 196 296 273 128
CARBS (grams) 53 20 39
R-A INSULIN (units) 5 10 6
L-A INSULIN (units) 25
NOTES
DAILY AVG. 203 mg/dL
12am 12pm 12am
5524
5542
Sa March 19, 2012
SENSOR GLUCOSE (mg/dL) 144 172 161 128 140
CARBS (grams) 46
R-A INSULIN (units) 10
L-A INSULIN (units) 25
NOTES ▲ Exercise ▲ Medication
DAILY AVG. 203 mg/dL
12am 12pm 12am
5526
5544
5510 5510 5510 5510
LEGEND: Low Glucose (<70) High Glucose (>240) Target Range
R-A Rapid-Acting L-A Long-Acting Logged without a value

FIG. 62

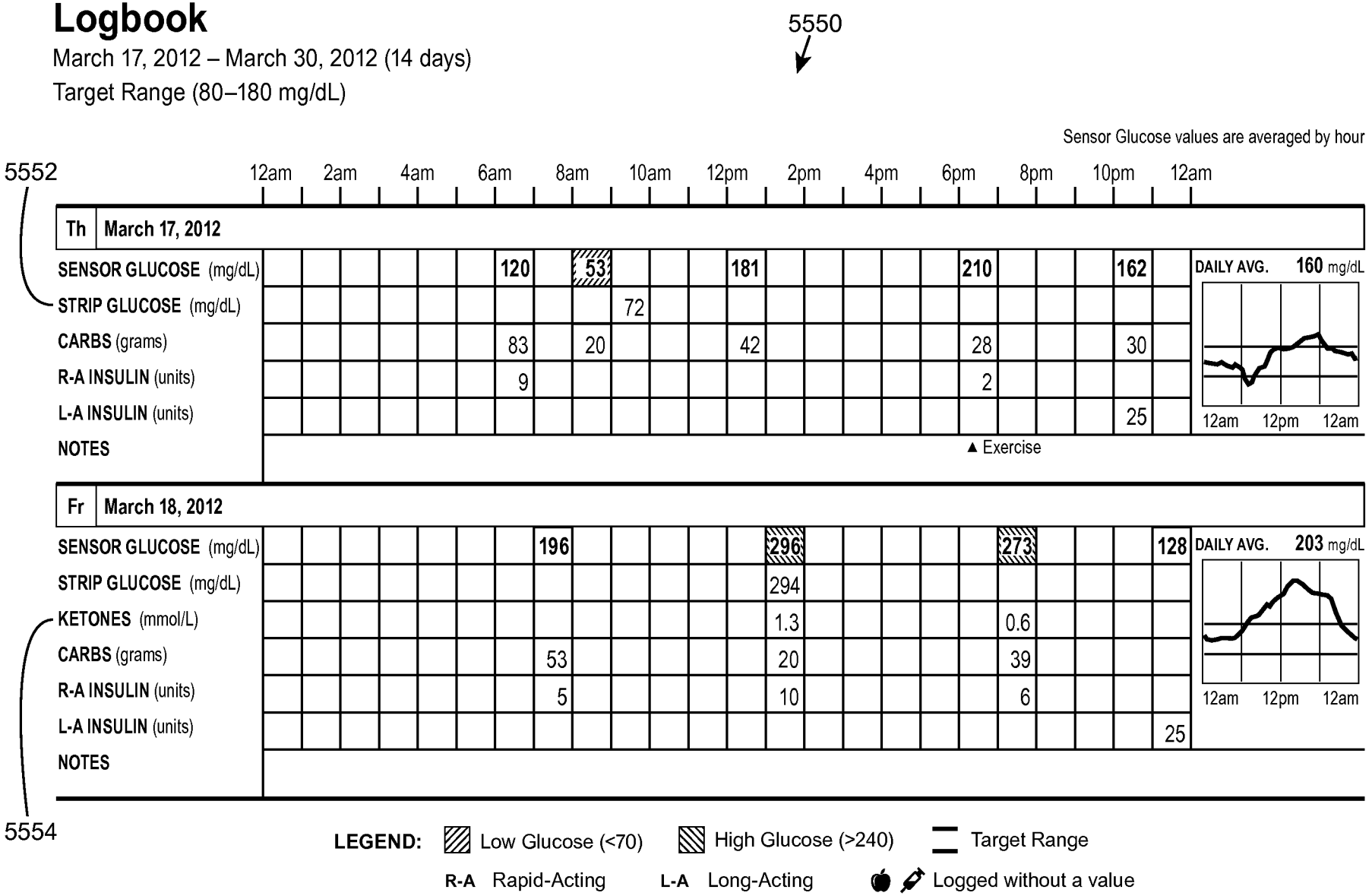

Logbook
March 17, 2012 – March 30, 2012 (14 days)
Target Range (80–180 mg/dL)
5550
Sensor Glucose values are averaged by hour
5552
12am 2am 4am 6am 8am 10am 12pm 2pm 4pm 6pm 8pm 10pm 12am
Th March 17, 2012
SENSOR GLUCOSE (mg/dL) 120 53 181 210 162
STRIP GLUCOSE (mg/dL) 72
CARBS (grams) 83 20 42 28 30
R-A INSULIN (units) 9 2
L-A INSULIN (units) 25
NOTES ▲ Exercise
DAILY AVG. 160 mg/dL
12am 12pm 12am
Fr March 18, 2012
SENSOR GLUCOSE (mg/dL) 196 296 273 128
STRIP GLUCOSE (mg/dL) 294
KETONES (mmol/L) 1.3 0.6
CARBS (grams) 53 20 39
R-A INSULIN (units) 5 10 6
L-A INSULIN (units) 25
NOTES
DAILY AVG. 203 mg/dL
12am 12pm 12am
5554
LEGEND: Low Glucose (<70) High Glucose (>240) Target Range
R-A Rapid-Acting L-A Long-Acting Logged without a value

FIG. 63

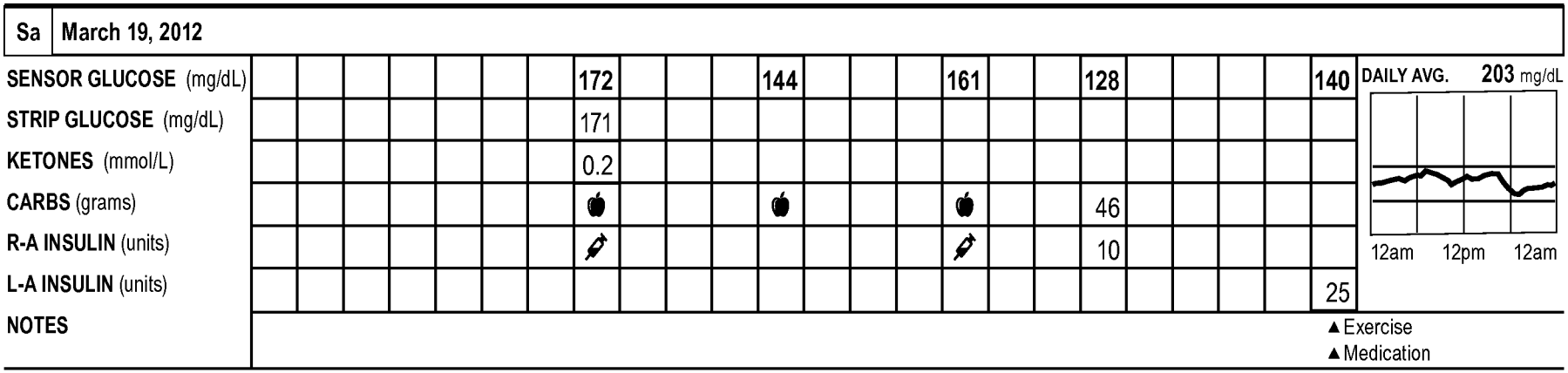

Sa March 19, 2012
SENSOR GLUCOSE (mg/dL)
STRIP GLUCOSE (mg/dL)
KETONES (mmol/L)
CARBS (grams)
R-A INSULIN (units)
L-A INSULIN (units)
NOTES
172
171
0.2
144
161
128
140
46
10
25
DAILY AVG. 203 mg/dL
12am
12pm
12am
▲Exercise
▲Medication
LEGEND:
Low Glucose (<70)
High Glucose (>240)
Target Range
R-A Rapid-Acting
L-A Long-Acting
Logged without a value

FIG. 63 (Cont)

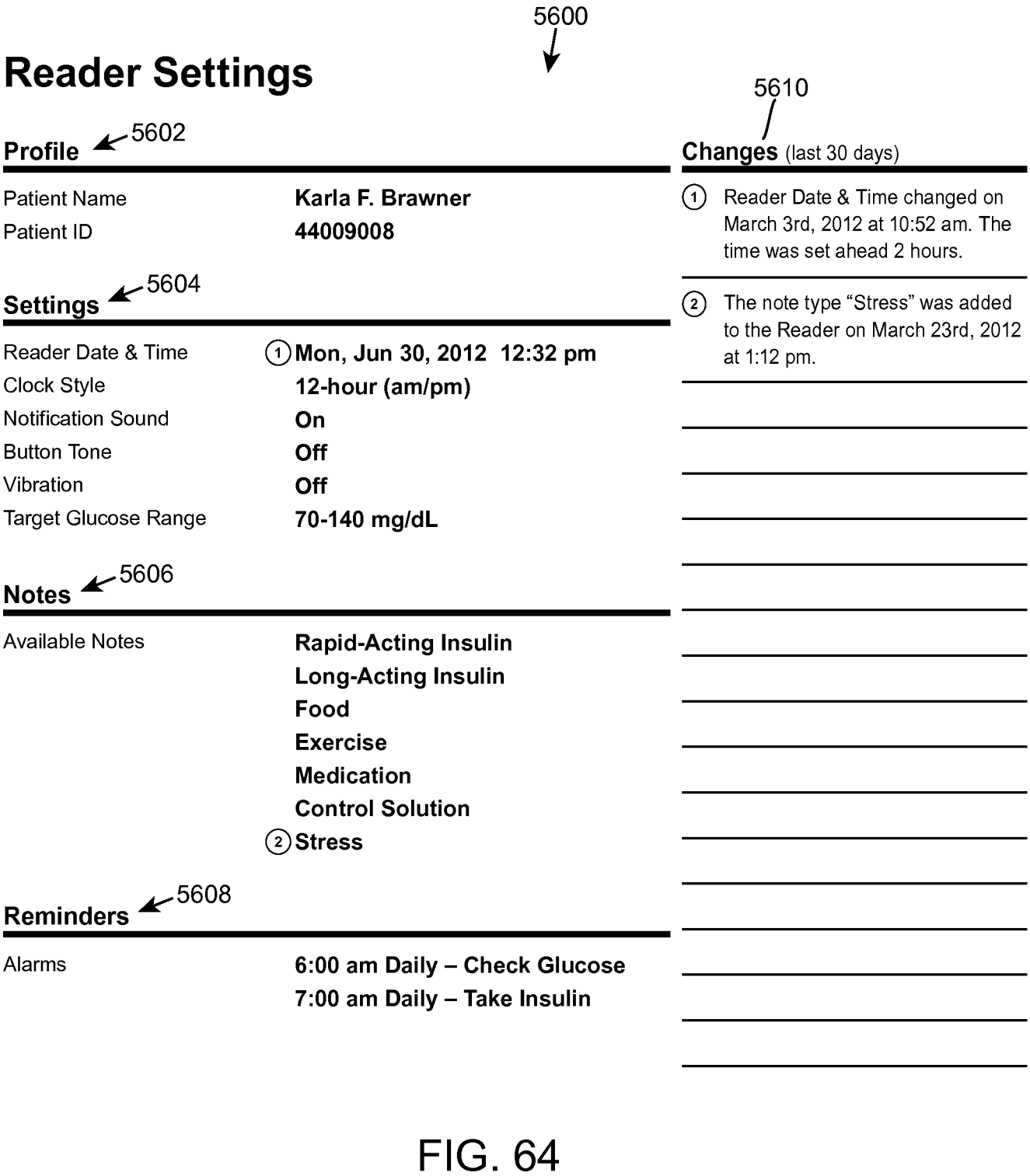
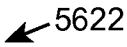

5600
Reader Settings
5610
Profile
5602
Changes (last 30 days)
Patient Name
Karla F. Brawner
Patient ID
44009008
1 Reader Date & Time changed on March 3rd, 2012 at 10:52 am. The time was set ahead 2 hours.
Settings
5604
2 The note type "Stress" was added to the Reader on March 23rd, 2012 at 1:12 pm.
Reader Date & Time
1 Mon, Jun 30, 2012 12:32 pm
Clock Style
12-hour (am/pm)
Notification Sound
On
Button Tone
Off
Vibration
Off
Target Glucose Range
70-140 mg/dL
Notes
5606
Available Notes
Rapid-Acting Insulin
Long-Acting Insulin
Food
Exercise
Medication
Control Solution
2 Stress
Reminders
5608
Alarms
6:00 am Daily – Check Glucose
7:00 am Daily – Take Insulin

FIG. 64

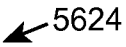
Reader Settings

Insulin Calculator



Rapid-Acting Insulin Calculator	**On**
Calculator Mode	**Advanced**
Carbohydrate Ratio	**1 unit per 10 grams of carbs**
Correction Target	**70-130 mg/dL**
Correction Factor	
Morning (4am-10am)	**1 unit per 30 mg/dL**
Midday (10am-4pm)	**1 unit per 20 mg/dL**
Evening (4pm-10pm)	**1 unit per 20 mg/dL**
Night (10am-4pm)	**1 unit per 50 mg/dL**

Masked Mode



③

Masked Sensor Reading	**On**
Check Glucose Reminder	**On**
Remind Every	**8:00 (hr:min)**

Changes (last 30 days)

③ Masked Mode was enabled March 30th, 2012 at 3:14 pm.

FIG. 65

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/027022

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/157 (2012.01)
USPC - 600/365
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 145, 15, 155, 157 (2012.01)
USPC - 600/309, 347, 365, 573, 584; 604/317, 318

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/0213080 A1 (CELENTANO et al) 26 August 2010 (26.08.2010) entire document	1-18
Y	US 2007/0017983 A1 (FRANK et al) 25 January 2007 (25.01.2007) entire document	1-18
Y	US 2008/0092638 A1 (BRENNEMAN et al) 24 April 2008 (24.04.2008) entire document	6, 15
A	US 5,748,103 A (FLACH et al) 05 May 1998 (05.05.1998) entire document	1-18
A	US 2010/0010329 A1 (TAUB et al) 14 January 2010 (14.01.2010) entire document	1-18
A	US 2009/0216100 A1 (EBNER et al) 27 August 2009 (27.08.2009) entire document	1-18
A	US 2007/0100222 A1 (MASTROTOTARO et al) 03 May 2007 (03.05.2007) paragraphs [0067], [0071], [0102]	1-18

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 August 2012	24 AUG 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/027022

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See extra sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-18

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/027022

Continuation of Box III.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.
Group I, claims 1-18, drawn to a method for operating and an analyte monitoring device, comprising receiving an indication for powering on an analyte monitoring device, providing power to the device and an RF reader element, and powering off the RF reader and maintaining power to the analyte monitoring device.
Group II, claims 19-34, drawn to a method for operating and an analyte monitoring device, comprising preventing performance of a second scan for a predetermined period of time, and enabling performance of a second scan after lapse of the predetermined period of time.
Group III, claims 35-48, drawn to a method for operating and an analyte monitoring device, comprising displaying a screen for calculating a suggested dose insulin dose based on a first scan.
Group IV, claims 49-60, drawn to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying a resulting reading for each of consecutive scans; displaying a graph on the display of the analyte measuring device, the graph displaying readings for a first predetermined period of time and subsequent resulting readings for a second period of time; after the readings are tracked for the entire second period of time, shifting the subsequent readings into the first period of time and continuing to track and shift the readings.
Group V, claims 61-64, drawn to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying a graph of readings obtained over a 24 hour period.
Group VI, claims 65-82, drawn to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying on a display of the analyte monitoring device a summary of average sensor readings for a prior predetermined time.
Group VII, claims 83-86, drawn to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying on a display of an analyte sensor, a summary of sensor readings including one or more numbers or percentages of sensor readings with respect to a target range.
Group VIII, claims 87-90, drawn to to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying on the display of an analyte sensor a summary of data associated with use of the sensor for a predetermined period of time, wherein the use of the sensor includes an average number of scans per day.
Group IX, claims 91-100, drawn to a method for displaying analyte sensor readings and an analyte monitoring device, comprising displaying on the display of an analyte sensor a graph of daily patterns.
Group X, claims 101-108, drawn to a method for operating and an analyte monitoring device, comprising receiving an indication to operate in masked mode; storing readings from the scans without displaying the sensor reading on a display of the device.
Group XI, claims 109-122, drawn to a method for operating and an analyte monitoring device, comprising communicating between an analyte sensor and a first analyte monitoring device; establishing a pairing with the first analyte monitoring device; receiving identification code for the first device; and storing the code in memory to indicate the established pairing with the first analyte monitoring device.
The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:
the special technical feature of the Group I invention: providing power to the device and an RF reader element, and powering off the RF reader and maintaining power to the analyte monitoring device as claimed therein is not present in the invention of Groups II-XI.
The special technical feature of the Group II invention: preventing performance of a second scan for a predetermined period of time, and enabling performance of a second scan after lapse of the predetermined period of time as claimed therein is not present in the invention of Groups I, III-XI.
The special technical feature of the Group III invention: displaying a screen for calculating a suggested dose insulin dose based on a first scan as claimed therein is not present in the invention of Groups I, II, IV-XI.
The special technical feature of the Group IV invention: a graph displaying readings for a first predetermined period of time and subsequent resulting readings for a second period of time; after the readings are tracked for the entire second period of time, shifting the subsequent readings into the first period of time and continuing to track and shift the readings as claimed therein is not present in the invention of Groups I, II, III or V-XI.
The special technical feature of the Group V invention: displaying a graph of readings obtained over a 24 hour period as claimed therein is not present in the invention of Groups I-IV, VI-XI.
The special technical feature of the Group VI invention: displaying a summary of average sensor readings for a prior predetermined time as claimed therein is not present in the invention of Groups I-V, VII-XI.
The special technical feature of the Group VII invention: displaying a summary of sensor readings including one or more numbers or percentages of sensor readings with respect to a target range as claimed therein is not present in the invention of Groups I-VI or VIII-XI.
The special technical feature of the Group VIII invention: displaying a summary of data associated with use of the sensor for a predetermined period of time, wherein the use of the sensor includes an average number of scans per day as claimed therein is not present in the invention of Groups I-VII, IX-XI.
The special technical feature of the Group IX invention: displaying a graph of daily patterns as claimed therein is not present in the invention of Groups I-VIII, X-XI.
The special technical feature of the Group X invention: receiving an indication to operate in masked mode; storing readings from the scans without displaying the sensor reading on a display of the device as claimed therein is not present in the invention of Groups I-IX, XI.
The special technical feature of the Group XI invention: communicating between an analyte sensor and a first analyte monitoring device; establishing a pairing with the first analyte monitoring device; receiving identification code for the first device; and storing the code in memory to indicate the established pairing with the first analyte monitoring device as claimed therein is not present in the invention of Groups I-X.
Groups I to XI lack unity of invention because even though the inventions of these groups require the technical feature of an analyte monitoring device and sensor and method for operating, taking scans of an analyte for predetermined periods of time, processing scan data and displaying scan data and results, where the display of the analyte monitoring device displays graphs, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of US 2007/0100222 A1 (MASTROTOTARO et al) 03 May 2007 (03.05.2007) paragraphs [0067], [0071], [0102].
Since none of the special technical features of the Group I to XI inventions are found in more than one of the inventions, unity of invention is lacking.