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[Continued on next page]

(54) **Title**: ANALYTE TESTING METHOD AND SYSTEM

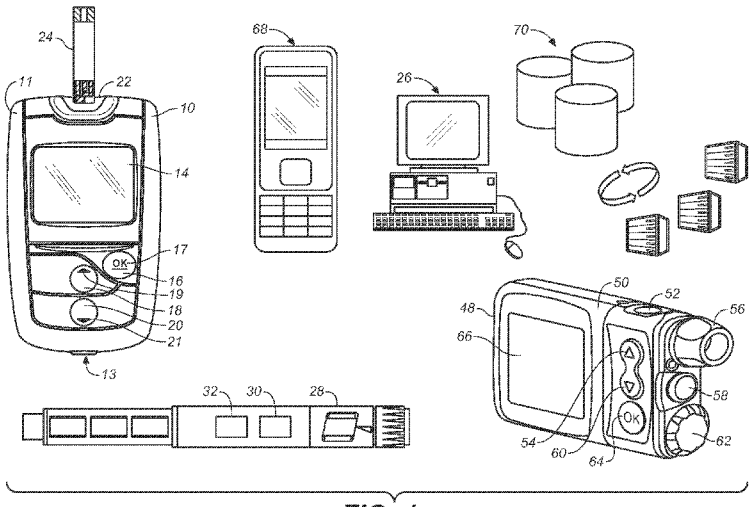

FIG. 1

(57) **Abstract**: Various methods and systems to manage diabetes using data relating to testing compliance, bolus dosing, or cannula usage are described and illustrated.

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ANALYTE TESTING METHOD AND SYSTEM

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[0001] This application claims the benefits of priority under 35 USC§ 119 and/or §120 from prior filed U.S. Provisional Application Serial No. 61/297,573 filed on January 22, 2010 (Attorney Docket No. LFS-5211PSP), which application is incorporated by reference in their entirety into this application.

Background

[0002] Glucose monitoring is a fact of everyday life for people with diabetes. The accuracy of such monitoring can significantly affect the health and ultimately the quality of life for people with diabetes. Generally, a person with diabetes should measure blood glucose levels several times a day to monitor and control blood sugar levels. Failure to test blood glucose levels accurately and on a regular basis can result in serious diabetes-related complications, including cardiovascular disease, kidney disease, nerve damage and blindness. There are a number of electronic devices currently available which enable an individual to test the glucose level in a small sample of blood. One such glucose meter is the OneTouch® Ultra® glucose meter, a product which is manufactured by LifeScan.

[0003] In addition to glucose monitoring, people with diabetes often have to perform drug therapy such as, for example, insulin dosing. People with diabetes may self-administer insulin to reduce their blood glucose concentration. There are a number of mechanical devices currently available which enable an individual to dose a predetermined quantity of insulin such as, for example, a hypodermic syringe, an insulin pen, and an insulin pump. One such insulin pump is the Animas® 2020, a product which is manufactured by Animas Inc.

[0004] People with diabetes should maintain tight control over their lifestyle, so that they are not adversely affected by, for example, irregular food consumption or exercise.

In addition, a physician dealing with a particular individual with diabetes may require detailed information on the individual's lifestyle to provide effective treatment or modification of treatment for controlling diabetes. Currently, one of the ways of monitoring the lifestyle of an individual with diabetes has been for the individual to keep a paper logbook of their lifestyle. Another way is for an individual to simply rely on remembering facts about their lifestyle and then relay these details to their physician on each visit.

[0005] The aforementioned methods of recording lifestyle information are inherently difficult, time consuming, and possibly inaccurate. Paper logbooks are not necessarily always carried by an individual and may not be accurately completed when required. Such paper logbooks are small and it is therefore difficult to enter detailed information requiring detailed descriptors of lifestyle events. Furthermore, an individual may often forget key facts about their lifestyle when questioned by a physician who has to manually review and interpret information from a hand-written notebook. There is no analysis provided by the paper logbook to distill or separate the component information. Also, there are no graphical reductions or summary of the information. Entry of data into a secondary data storage system, such as a database or other electronic system, requires a laborious transcription of information, including lifestyle data, into this secondary data storage. Difficulty of data recordation encourages retrospective entry of pertinent information that results in inaccurate and incomplete records.

[0006] There currently exist a number of portable electronic devices that can measure glucose levels in an individual and store the levels for recalling or uploading to another computer for analysis. One such device is the Accu-Check™ Complete™ System from Roche Diagnostics, which provides limited functionality for storing lifestyle data. However, the Accu-Check™ Complete™ System only permits a limited selection of lifestyle variables to be stored in a meter. There is a no intelligent feedback from values previously entered into the meter and the user interface is unintuitive for an infrequent user of the meter.

Summary of the Disclosure

[0007] In one embodiment, a method of monitoring therapeutic bolus compliance with an analyte testing device and a therapeutic dispensing device is provided. Each of both devices includes a microprocessor coupled to a memory. The method may be achieved by: obtaining from the memory of the analyte testing device data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences; collecting from the memory of the therapeutic dispensing device a time stamp for each bolus of dispensed therapeutic; identifying a hyperglycemic occurrence that does not have at least one bolus of dispensed therapeutic within a predetermined time range of the hypoglycemic occurrence; calculating a percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range; and annunciating the percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range.

[0008] In yet another embodiment, a method of monitoring insulin bolus compliance with an analyte testing device and a therapeutic dispensing device is provided. Each of both devices includes a microprocessor coupled to a memory. The method may be achieved by: obtaining from the memory of the analyte testing device data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences; collecting from the memory of the therapeutic dispensing device a time stamp for each bolus of dispensed therapeutic; identifying a hyperglycemic occurrence that has at least one bolus of dispensed therapeutic within a predetermined time range of the hypoglycemic occurrence; calculating a percentage of hyperglycemic occurrences that have at least one bolus of dispensed therapeutic within the predetermined time range; and annunciating the percentage of hyperglycemic occurrences that have at least one bolus of dispensed therapeutic within the predetermined time range.

[0009] In yet a further embodiment, a diabetes management system is provided that includes a plurality of glucose test strips, test strip port connector, data management device. Each test strip is configured to receive a physiological sample. The test strip port connector is configured to receive the plurality of test strips. The data management device includes a housing, microprocessor, memory, display and power supply. The microprocessor is coupled to a memory, display, and power supply. The microprocessor

is coupled to the test strip sensor to obtain data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences. The microprocessor is configured to collect a time stamp for each bolus of dispensed therapeutic so that a percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range is determined by the microprocessor.

[0010] In yet another embodiment, a method of monitoring analyte-testing compliance with an analyte testing device and a therapeutic dispensing device is provided. Each of both devices includes a microprocessor coupled to a memory. The method may be achieved by: obtaining from the memory of the analyte testing device a time stamp for each of the glucose measurements; collecting from the memory of the therapeutic dispensing device data including a number of bolus events and a time stamp for each bolus event; identifying a bolus event that does not have at least one glucose measurement within a predetermined time range of the bolus event; calculating a percentage of bolus events that do not have at least one glucose measurement within the predetermined time range; and annunciating the percentage of bolus events that do not have at least one glucose measurement within the predetermined time range.

[0011] In a further embodiment, a method of monitoring insulin bolus compliance with an analyte testing device and a therapeutic dispensing device is provided. Each of both devices includes a microprocessor coupled to a memory. The method may be achieved by: obtaining from the memory of the analyte testing device data including a number of glucose measurements and a time stamp for each of the glucose measurements; collecting from the memory of the therapeutic dispensing device data including a number of bolus events and a time stamp for each bolus event; identifying a bolus event that has at least one glucose measurement within a predetermined time range of the bolus event; calculating a percentage of bolus events that do have at least one glucose measurement within the predetermined time range; and annunciating a percentage of bolus events that do have at least one glucose measurement within the predetermined time range.

[0012] In another further embodiment, a diabetes management system is provided that includes a plurality of glucose test strips, test strip port, and data management unit. Each of the test strips is configured to receive a physiological sample. The test strip port connector is configured to receive the plurality of test strips. The data management device includes a housing, microprocessor, memory, display and power supply. The microprocessor is coupled to a memory, display, and power supply with the microprocessor being disposed proximate the housing. The microprocessor is also coupled to the test strip sensor to obtain a time stamp for each of the glucose measurements. The microprocessor is configured to collect data including a number of bolus events and a time stamp for each bolus event so that a percentage of bolus events that do not have at least one glucose measurement within the predetermined time range are determined by the microprocessor.

[0013] In another embodiment, a method of monitoring an average number of days in between cannula fills of a therapeutic dispensing device that delivers a therapeutic agent to a user via a cannula is provided. The method may be achieved by: (i) selecting a user interface option to perform a cannula fill procedure when a cannula is coupled to the therapeutic dispensing device; (ii) pumping an amount of therapeutic agent to fill the cannula; (iii) saving to a memory of the therapeutic dispensing device or an analyte-testing device a time stamp in which the cannula fill procedure was performed; (iv) repeating steps (i) to (iii) three or more times; (v) calculating an average number of days in between cannula fills; and (vi) annunciating the average number of days in between cannula fills.

[0014] In a further embodiment, a method of monitoring bolus overrides with an analyte-testing device and a therapeutic dispensing device is provided. Each of both devices includes a microprocessor coupled to a memory. The method may be achieved by: (i) annunciating a recommended bolus amount on a display of either the analyte testing device or a therapeutic dispensing device;(ii) inputting a different bolus amount that is either higher or lower than the recommended bolus amount; (iii) saving to a memory of the therapeutic dispensing device or an analyte testing device the different bolus amount and a time stamp; and (iv) displaying the different bolus amount with

either a first indicia indicating a bolus amount higher than the recommended bolus amount or a second indicia indicating a bolus amount lower than the recommended bolus amount.

[0015] These and other embodiments, features and advantages will become apparent to those skilled in the art when taken with reference to the following more detailed description of various exemplary embodiments of the invention in conjunction with the accompanying drawings that are first briefly described.

Brief Description of the Figures

[0016] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate presently preferred embodiments of the invention, and, together with the general description given above and the detailed description given below, serve to explain features of the invention (wherein like numerals represent like elements).

[0017] Figure 1 illustrates a diabetes management system that includes an analyte measurement and management device and data communication devices.

[0018] Figure 2 illustrates a user interface of the analyte measurement and management device where data is transferred between a therapeutic dosing device and the analyte measurement and management device.

[0019] Figure 3A illustrates a top portion of a circuit board of the analyte measurement and management device.

[0020] Figure 3B illustrates a bottom portion of the circuit board of the analyte measurement and management device.

[0021] Figure 4 illustrates a schematic of the functional components of a therapeutic dosing device.

[0022] Figure 5 is a flow chart illustrating a method for performing a glucose test.

[0023] Figure 6 is a flow chart illustrating a method for setting up a bolus calculator.

[0024] Figure 7 is a flow chart illustrating a method for calculating an insulin bolus.

[0025] Figure 8 is a flow chart illustrating a method of monitoring therapeutic bolus compliance with the measurement and management device and the therapeutic dosing device.

[0026] Figure 9 is a flow chart illustrating a method of monitoring analyte-testing compliance with the measurement and management device and the therapeutic dosing device.

[0027] Figure 10 is a flow chart illustrating a method of monitoring an average number of days in between cannula fills.

[0028] Figure 11 illustrates an output on a report that provides a percentage of hyperglycemic results that have no boluses within +/- one hour, a percentage of boluses that have no glucose results within +/- one hour, and the average number of days in between cannula fills.

[0029] Figure 12 illustrates a cannula that is configured to be fluidically coupled to an insulin pump.

[0030] Figure 13 is a flow chart illustrating a method of indicating a bolus override that differs from a recommended bolus amount.

[0031] Figure 14 illustrates a screen-shot of a logbook that includes a bolus override, as indicated with either an up arrow or down arrow.

Detailed Description of the Exemplary Figures

[0032] The following detailed description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0033] As used herein, the terms “about” or “approximately” for any numerical values or ranges indicate a suitable dimensional tolerance that allows the part or collection of components to function for its intended purpose as described herein. In addition, as

used herein, the terms "patient," "host," "user," and "subject" refer to any human or animal subject and are not intended to limit the systems or methods to human use, although use of the subject invention in a human patient represents a preferred embodiment.

[0034] Figure 1 illustrates a diabetes management system that includes an analyte measurement and management device 10, therapeutic dosing devices (28 or 48), and data/communication devices (68, 26, or 70). Analyte measurement and management device 10 can be configured to wirelessly communicate with a handheld glucose-insulin data management unit or DMU such as, for example, an insulin pen 28, an insulin pump 48, a mobile phone 68, or through a combination of the exemplary handheld glucose-insulin data management unit devices in communication with a personal computer 26 or network server 70, as described herein. As used herein, the nomenclature "DMU" represents either individual unit 10, 28, 48, 68, separately or all of the handheld glucose-insulin data management units (28, 48, 68) usable together in a disease management system. Further, the analyte measurement and management device or DMU 10 is intended to include a glucose meter, a meter, an analyte measurement device, an insulin delivery device or a combination of or an analyte testing and drug delivery device. In an embodiment, analyte measurement and management device 10 may be connected to personal computer 26 with a cable. Alternatively, the device 10 may connect to the computer 26 or server via a suitable wireless technology.

[0035] Figure 2 illustrates a user interface 200 of analyte measurement and management device 10. A microprocessor can be programmed to generally carry out the steps of user interface 200. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. Devices (10 and 48) can both be configured for bi-directional data transfer through a wireless signal 204. In an exemplary implementation, user interface 200 may provide recommendations, warnings, and compliance updates to a user as part of the user's diabetes management. In such embodiment, programs and methods for conducting user interface 200 may be stored on a non-volatile memory portion of glucose meter 10. Alternatively, interface 200 may be stored on a non-volatile memory portion of computer 26, cell phone 68, pump 48, or

server 70. Steps and instructions of user interface 200 may be communicated on a communication output unit such as, for example, a display 14 of glucose meter 10 or the display 66 of the pump 48.

[0036] In such embodiment, the software for user interface 200 may be implemented using meter 10 and pump 48 without the need for an external computer, personal digital assistant, or mobile phone. However, in another embodiment, diabetes management 200 may be implemented using a personal computer where data is transferred bi-directionally from meter 10 and pump 48.

[0037] Note that recommendations, warnings, and compliance updates may be annunciated to a user. As used herein, the term "user" is intended to indicate primarily a mammalian subject (e.g., a person) who has diabetes but which term may also include a caretaker or a healthcare provider who is operating the meter 10 on behalf of the diabetes subject. As used here, the term "annunciated" and variations on the root term indicate that an announcement may be provided via text, audio, visual or a combination of all modes of communication to a user, a caretaker of the user, or a healthcare provider.

[0038] Glucose meter 10 can include a housing 11, user interface buttons (16, 18, and 20), a display 14, a strip port connector 22, and a data port 13, as illustrated in Figure 1. User interface buttons (16, 18, and 20) can be configured to allow the entry of data, navigation of menus, and execution of commands. Data can include values representative of analyte concentration, and/or information, which are related to the everyday lifestyle of an individual. Information, which is related to the everyday lifestyle, can include food intake, medication use, occurrence of health check-ups, and general health condition and exercise levels of an individual. Specifically, user interface buttons (16, 18, and 20) include a first user interface button 16, a second user interface button 18, and a third user interface button 20. User interface buttons (16, 18, and 20) include a first marking 17, a second marking 19, and a third marking 21, respectively, which allow a user to navigate through the user interface.

[0039] The electronic components of meter 10 can be disposed on a circuit board 34 that is within housing 11. Figures 3A and 3B illustrate the electronic components disposed on a top surface and a bottom surface of circuit board 34, respectively. On the top surface, the electronic components include a strip port connector 22, an operational amplifier

circuit 35, a microcontroller 38, a display connector 14a, a non-volatile memory 40, a clock 42, and a first wireless module 46. On the bottom surface, the electronic components include a battery connector 44a and a data port 13. Microcontroller 38 can be electrically connected to strip port connector 22, operational amplifier circuit 35, first wireless module 46, display 14, non-volatile memory 40, clock 42, battery connector 44a, data port 13, and user interface buttons (16, 18, and 20).

[0040] Referring to Figure 3A, operational amplifier circuit 35 can include two or more operational amplifiers configured to provide a portion of the potentiostat function and the current measurement function. The potentiostat function can refer to the application of a test voltage between at least two electrodes of a test strip. The current function can refer to the measurement of a test current resulting from the applied test voltage. The current measurement may be performed with a current-to-voltage converter. Microcontroller 38 can be in the form of a mixed signal microprocessor (MSP) such as, for example, the Texas Instrument MSP 430. The MSP 430 can be configured to also perform a portion of the potentiostat function and the current measurement function. In addition, the MSP 430 can also include volatile and non-volatile memory. In another embodiment, many of the electronic components can be integrated with the microcontroller in the form of an application specific integrated circuit (ASIC).

[0041] Strip port connector 22 can be configured to form an electrical connection to the test strip. Display connector 14a can be configured to attach to display 14. Display 14 can be in the form of a liquid crystal display for reporting measured glucose levels, and for facilitating entry of lifestyle related information. Display 14 can optionally include a backlight. Data port 13 can accept a suitable connector attached to a connecting lead, thereby allowing glucose meter 10 to be linked to an external device such as a personal computer. Data port 13 can be any port that allows for transmission of data such as, for example, a serial, USB, or a parallel port. Clock 42 can be configured for measuring time and be in the form of an oscillating crystal. Battery connector 44a can be configured to be electrically connected to a power supply.

[0042] In one exemplary embodiment, test strip 24 can be in the form of an electrochemical glucose test strip, as illustrated in Figure 1. Test strip 24 can include one or more working electrodes and a counter electrode. Test strip 24 can also include a

plurality of electrical contact pads, in which each electrode can be in electrical communication with at least one electrical contact pad. Strip port connector 22 can be configured to electrically interface to the electrical contact pads and form electrical communication with the electrodes. Test strip 24 can include a reagent layer that is disposed over at least one electrode. The reagent layer can include an enzyme and a mediator. Exemplary enzymes suitable for use in the reagent layer include glucose oxidase, glucose dehydrogenase (with pyrroloquinoline quinone co-factor, "PQQ"), and glucose dehydrogenase (with flavin adenine dinucleotide co-factor, "FAD"). An exemplary mediator suitable for use in the reagent layer includes ferricyanide, which in this case is in the oxidized form. The reagent layer can be configured to physically transform glucose into an enzymatic by-product and in the process generate an amount of reduced mediator (e.g., ferrocyanide) that is proportional to the glucose concentration. The working electrode can then measure a concentration of the reduced mediator in the form of a current. In turn, glucose meter 10 can convert the current magnitude into a glucose concentration.

[0043] Referring back to Figure 1, insulin pen 28 can include a housing, preferably elongated and of sufficient size to be handled by a human hand comfortably. The device 28 can be provided with an electronic module 30 to record dosage amounts delivered by the user. The device 28 may include a second wireless module 32 disposed in the housing that, automatically without prompting from a user, transmits a signal to first wireless module 46 of the DMU 10. The wireless signal can include, in an exemplary embodiment, data to (a) type of therapeutic agent delivered; (b) amount of therapeutic agent delivered to the user; or (c) time and date of therapeutic agent delivery.

[0044] In one embodiment, a therapeutic delivery device can be in the form of a "user-activated" therapeutic delivery device, which requires a manual interaction between the device and a user (for example, by a user pushing a button on the device) to initiate a single therapeutic agent delivery event and that in the absence of such manual interaction deliver no therapeutic agent to the user. A non-limiting example of such a user-activated therapeutic agent delivery device is described in co-pending U.S. Non-Provisional Application No. 12/407173 (tentatively identified by Attorney Docket No. LFS-5180USNP); 12/417875 (tentatively identified by Attorney Docket No. LFS-5183USNP);

and 12/540217 (tentatively identified by Attorney Docket No. DDI-5176USNP), which is hereby incorporated in whole by reference. Another non-limiting example of such a user-activated therapeutic agent delivery device is an insulin pen 28. Insulin pens can be loaded with a vial or cartridge of insulin, and can be attached to a disposable needle. Portions of the insulin pen can be reusable, or the insulin pen can be completely disposable. Insulin pens are commercially available from companies such as Novo Nordisk, Aventis, and Eli Lilly, and can be used with a variety of insulin, such as Novolog, Humalog, Levemir, and Lantus.

[0045] Referring to Figure 1, the therapeutic dosing device can also be a pump 48 that includes a housing 50, a backlight button 52, an up button 54, a cartridge cap 56, a bolus button 58, a down button 60, a battery cap 62, an OK button 64, and a display 66. Pump 48 can be configured to dispense medication such as, for example, insulin for regulating glucose levels.

[0046] Referring to Figure 4, pump 48 includes the following functional components that are a display (DIS) 66, navigational buttons (NAV) 72, a reservoir (RES) 74, an infrared communication port (IR) 76, a radio frequency module (RF) 78, a battery (BAT) 80, an alarm module (AL) 82, and a microprocessor (MP) 84. Note that navigational buttons 72 can include up button 54, down button 60, and ok button 64.

[0047] People with diabetes will often have to perform several glucose tests and bolus several insulin doses to effectively manage the disease. The glucose concentration amount, time that the test was performed, and lifestyle data (e.g., meals and exercise) are factors often taken into account when calculating a proper insulin-dosing regimen. Applicant believes that users have difficulty determining the effectiveness and compliance with the insulin-dosing regimen. The following will describe a series of methods (500, 600, 700, 800, 900, 1000, and 1300) that a user may select within a main menu 202 for helping users better understand their compliance with managing their disease and guiding them to improving their compliance. As illustrated in Figure 2, the menu may include the following methods that are to perform a glucose test 500, provide an insulin bolus compliance update 600, a glucose testing compliance update 700, configure settings for insulin bolus calculator 800, calculate an insulin bolus 900, provide a cannula fill time average 1000, and output a bolus override flag 1300.

[0048] The glucose test 500 may include inserting an electrochemical test strip 24 into strip port connector 22 of glucose meter 10, as illustrated in a step 502 of Figure 5. A microprocessor can be programmed to generally carry out the steps of method 500. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. Once user interface prompts a user to dose blood, the user can dose a sample onto test strip 24, illustrated in a step 504. Glucose meter 10 can then perform the measurement and output a glucose result on display 14, as illustrated in a step 506. After the result is calculated, the glucose result and time stamp can be saved to a memory in the glucose meter 10, as illustrated in a step 508. The term time stamp can refer to the date and time that an event was performed, which in this case is a glucose measurement.

[0049] Figure 6 illustrates an embodiment 600 for configuring the set up of the bolus calculator 700. A microprocessor can be programmed to generally carry out the steps of method 600. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. A user may select an insulin sensitivity value, an insulin-to-carbohydrate ratio, and a target blood glucose value, as shown in steps 602, 604, and 605. More specifically, the user may select a discrete insulin sensitivity value and an insulin-to-carbohydrate ratio for a particular meal such as breakfast, lunch, or dinner. Insulin sensitivity values may range from about 5 mg/dL (or its conversion into mmol/L unit or millimole per liter) to about 300 mg/dL (or its conversion into mmol/L unit or millimole per liter). Insulin-to-carbohydrate ratio may range from about 5 grams to about 50 grams. Target blood glucose values may range from about 60 mg/dL (or its conversion into mmol/L unit or millimole per liter) to about 290 mg/dL (or its conversion into mmol/L unit or millimole per liter). Next, a confirmation of the insulin sensitivity value and an insulin-to-carbohydrate ratio may be annunciated to the user, as shown in a step 606, which is then followed by returning to main menu 202.

[0050] Briefly, three types of insulin boluses are described herein, which are an insulin bolus amount for: (a) carbohydrate coverage, (b) glucose correction, or (c) a combination thereof. The insulin bolus amount for carbohydrate coverage may be an amount of

insulin needed to account for carbohydrates about to be consumed at a meal. The insulin bolus amount for a glucose measurement correction may be an amount of insulin needed to account for a user's measured glucose value that is greater than a targeted euglycemic glucose value. The combination (e.g., carbohydrate value and measured glucose value) correction may be an amount of insulin needed to account for carbohydrates about to be consumed and the user's measured glucose value.

[0051] Three types of insulin boluses are described herein, which are a Glucose Correction Dose, a Carbohydrate Coverage Dose, and a combination thereof. The Glucose Correction Dose is an amount of insulin needed to account for a user's recently measured glucose value that is greater than the euglycemic zone. The Carbohydrate Coverage Dose is an amount of insulin calculated based on the amount of carbohydrates to be consumed. The combination (e.g., carbohydrate value and measured glucose value) correction may be an amount of insulin needed to account for carbohydrates about to be consumed and the user's measured glucose value.

[0052] An embodiment of a Glucose Correction Dose is shown in Equation 1.

Eq. 1 Glucose Correction Dose = (Current G – Target G) x Insulin Sensitivity Factor

[0053] The Glucose Correction Dose may be the amount of insulin needed to adjust the current measured glucose value or concentration to the euglycemic zone. The Current G and Target G may be the current measured glucose value or concentration and the target glucose value or concentration, respectively. The Insulin Sensitivity Factor may be a constant that is special to the user that relates to the proportional effectiveness of insulin.

[0054] The insulin bolus amount for carbohydrate coverage dose may be calculated by using Equation 2.

[0055] Eq. 2 Insulin bolus amount for carbohydrate coverage Dose = Carbohydrate Estimate x Insulin-to-Carbohydrate Ratio

[0056] The Carbohydrate Estimate may be the amount consumed by the user and the Insulin-to-Carbohydrate Ratio may be a constant that is special to the user relating to the proportional effectiveness of insulin on consumed carbohydrates. A total insulin dose may be calculated by summing together the Glucose Correction Dose and the Carbohydrate Anticipatory Dose.

[0057] Figure 7 is a flow chart illustrating an embodiment of a method 700 for calculating an insulin bolus with a carbohydrate coverage and glucose correction. A microprocessor can be programmed to generally carry out the steps of method 700. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. Initially, the meter may determine whether the insulin calculator is already setup, as shown in a step 702. If the insulin calculator is not setup, then the method may move to an insulin bolus calculator settings function 600 (described above). If the insulin calculator has been setup, then the user interface 200 (which is implemented exemplarily in meter 10) may determine whether the last glucose value or concentration of the user measured is less than about 90 minutes to about 120 minutes old, as shown in a step 704. A message may be annunciated that another glucose test must be performed to use the bolus calculator, as shown in a step 705, when the last glucose value or concentration of the user measured is not less than about 90 minutes to about 120 minutes old.

[0058] A recommended amount of carbohydrates may be annunciated, as shown in a step 708, where the glucose value or concentration of the user is less than about 90 minutes to about 120 minutes old. The amount of carbohydrate may represent an amount that is about to be consumed by the user. The user has the option to input the recommended amount of carbohydrates or a different value, as shown in a step 710. As a non-limiting example, the amount of carbohydrates inputted may range from about zero to about 999 grams.

[0059] After inputting the amount of carbohydrates, a recommended insulin bolus may be annunciated, as shown in a step 712. Note that the recommended insulin bolus amount includes both an insulin bolus amount for carbohydrate coverage and an insulin correction of a recent measured glucose value of the user. The user has the option to input the recommended amount of insulin or a different value, as shown in a step 714,

such as, for example, about zero to about 999 units. Next, the actual bolus amount and a time stamp may be saved to memory, as illustrated in a step 718. A confirmation of the inputted bolus amount may be annunciated to the user, as shown in a step 716, which is then followed by returning to main menu 202.

[0060] Figure 8 is a flow chart illustrating a method 800 of monitoring therapeutic bolus compliance with the measurement and management device 10 and the therapeutic dosing device 48. A microprocessor can be programmed to generally carry out the steps of method 800. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. As a general rule, a person with diabetes should take a bolus of insulin every time a hyperglycemic event is identified because clinical outcomes for individuals dramatically improve when a user reduces the duration of a hyperglycemic state. In an embodiment, a therapeutic bolus may represent an amount of insulin or an amount of drug for treating a disease such as, for example, diabetes. Typically, a bolus of therapeutic may be injected in its entirety into a user over a relatively short period of time such as, for example, about less than one minute.

[0061] Method 800 includes obtaining from the memory of the analyte testing device 10 data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences, as illustrated in a step 802. Before step 802, a user may assay a plurality of blood samples for glucose using a plurality of test strips 24 with glucose meter 10. In an embodiment, microcontroller 38 of glucose meter 10 may automatically identify glucose measurements that are hyperglycemic (e.g., glucose concentrations greater than about 200 milligrams per deciliter).

[0062] Method 800 also includes collecting from the memory of the therapeutic dispensing device 48 a time stamp for each bolus of dispensed therapeutic, as illustrated in a step 804. A user can initiate a bolus on pump 48 by manually inputting a bolus amount with navigational 72 buttons or by using method 700. The microprocessor 84 of pump 48 can record the date and time in which the bolus was dispensed and also the amount of insulin.

[0063] After steps 802 and 804, a microprocessor can identify a hyperglycemic occurrence that does not have at least one bolus of dispensed therapeutic within a

predetermined time range of the hypoglycemic occurrence, as illustrated in a step 806. In an embodiment, the predetermined time range may be from about one hour before to about one hour after the time stamp of the hyperglycemic occurrence. For each hyperglycemic occurrence, the microprocessor may analyze all boluses to determine if at least one bolus has a time stamp that is within the predetermined time range. For example, if there is a hyperglycemic occurrence with a 2:00 pm time stamp, then the microprocessor can search for at least one bolus having a time stamp with a predetermined time range of +/- one hour, which in this case would be from about 1:00 pm to about 3:00 pm. If no bolus was found from about 1:00 pm to about 3:00, then the hyperglycemic occurrence would be identified as having no associated bolus within the predetermined time range of +/- one hour.

[0064] A percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range can be calculated, as illustrated in a step 808. The calculating can include determining the total number of hyperglycemic occurrences and the number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range. Next, the number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range can be divided by a total number of hyperglycemic occurrences. The calculation of step 808 can be calculated using Equation 3.

$$\text{Eq. 3} \quad \%H_{NB} = [H_{NB} / H_T] \times 100$$

[0065] The terms $\%H_{NB}$ is the percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range, H_{NB} is the number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range, and H_T is the total number of hyperglycemic occurrences.

[0066] Once the percentage of step 808 has been calculated, the percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range can be annunciated, as illustrated in a step 810.

Figure 11 illustrates an exemplary output on a portion 1102 of a report that provides a percentage of hyperglycemic results that have no boluses within +/- one hour. The output of step 810 may display on a screen of a personal computer configured into a special purpose health monitoring device, the analyte testing device, the therapeutic dispensing device, or other DMU (described above).

[0067] In an alternative embodiment to method 800, a percentage of hyperglycemic occurrences that "have" at least one bolus of dispensed therapeutic within a predetermined time range can be calculated instead of the percentage of hyperglycemic occurrences that "do not have" at least one bolus of dispensed therapeutic within a predetermined time range. The term $\%H_{WB}$ can be defined to be the percentage of hyperglycemic occurrences that "have" at least one bolus of dispensed therapeutic within a predetermined time range. The sum of the terms $\%H_{NB}$ and $\%H_{WB}$ will be about unity. In terms of providing an update to insulin bolus compliance, a user can employ either $\%H_{NB}$ or $\%H_{WB}$ for determining the adherence to recommended insulin therapy guidelines. In an embodiment, a user may have a target goal of a $\%H_{NB}$ of about zero or alternatively a $\%H_{WB}$ of about one.

[0068] Figure 9 is a flow chart illustrating a method 900 of monitoring analyte-testing compliance with the measurement and management device 10 and the therapeutic dosing device 48. A microprocessor can be programmed to generally carry out the steps of method 900. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. As a general rule, a person with diabetes should measure their glucose contemporaneous with an insulin bolus so that the amount of the bolus can be tailored to the amount of glucose in the person's blood. Implementing a more intelligent insulin-dosing regimen, based on current glucose measurements, that increases the duration of euglycemia, will dramatically improve clinical outcomes.

[0069] Method 900 includes obtaining from the memory of the analyte-testing device 10 a time stamp for each of the glucose measurements, as illustrated in a step 902. Before step 902, a user may assay a plurality of blood samples for glucose using a plurality of test strips 24 with glucose meter 10.

[0070] Method 900 also includes collecting from the memory of the therapeutic dispensing device 48 data including a number of bolus events and a time stamp for each bolus event, as illustrated in a step 904. A user can initiate a bolus on pump 48 by manually inputting a bolus amount with navigational 72 buttons or by using method 700. The microprocessor 84 of pump 48 can record the date and time in which the bolus was dispensed, the amount of insulin, and a total number of bolus events.

[0071] After steps 902 and 904, a microprocessor can identify a bolus event that does not have at least one glucose measurement within a predetermined time range of the bolus event, as illustrated in a step 906. In an embodiment, the predetermined time range may be from about one hour before to about one hour after the time stamp of the bolus event. For each bolus event, the microprocessor may analyze all glucose concentrations to determine if at least one glucose concentration has a time stamp that is within the predetermined time range. For example, if there is a bolus event with a 2:00 pm time stamp, then the microprocessor can search for at least one glucose measurement having a time stamp with a predetermined time range of +/- one hour, which in this case would be from about 1:00 pm to about 3:00 pm. Thus, if no glucose measurement was found from about 1:00 pm to about 3:00, then the bolus event would be identified as having no associated glucose measurement within the predetermined time range of +/- one hour.

[0072] A percentage of boluses that do not have at least one glucose measurement within the predetermined time range can be calculated, as illustrated in a step 908. The calculating can include determining the total number of bolus events and the number of bolus events that do not have at least one glucose measurement within the predetermined time range. Next, the number of bolus events that do not have at least one glucose measurement within the predetermined time range can be divided by a total number of bolus events. The calculation of step 908 can be calculated using Equation 4.

$$\text{Eq. 4} \quad \%B_{NG} = [B_{NG} / B_T] \times 100$$

[0073] The terms $\%B_{NG}$ is the percentage of bolus events that do not have at least one glucose measurement within the predetermined time range, B_{NG} is the number of bolus

events that do not have at least one glucose measurement within the predetermined time range, and B_T is the total number of bolus events.

[0074] Once the percentage of step 908 has been calculated, the percentage of bolus events that do not have at least one glucose measurement within the predetermined time range can be annunciated, as illustrated in a step 910. Figure 11 illustrates an exemplary output on a portion 1104 of a report that provides a percentage of bolus events that have glucose measurements within +/- one hour. The output of step 910 may display on a screen of a personal computer, the analyte testing device, the therapeutic dispensing device, or other DMU (described above).

[0075] In an alternative embodiment to method 900, a percentage of bolus events that "have" at least one glucose measurement within a predetermined time range can be calculated instead of the percentage of bolus events that "do not have" at least one glucose measurements within a predetermined time range. The term $\%B_{WG}$ can be defined to be the percentage of bolus events that "have" at least one glucose measurement within a predetermined time range. As a result, the sum of the terms $\%B_{NG}$ and $\%B_{WG}$ will be about unity. In terms of providing an update to glucose testing compliance, a user can employ either $\%B_{NG}$ or $\%B_{WG}$ for determining the adherence to recommended insulin therapy guidelines. In an embodiment, a user may have a target goal of a $\%B_{NG}$ of about zero or alternatively a $\%B_{WG}$ of about one.

[0076] Figure 10 is a flow chart illustrating a method 1000 of monitoring an average number of days in between cannula fills. A microprocessor can be programmed to generally carry out the steps of method 1000. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. A cannula is a small tube that is fluidically connected to an insulin pump for dispensing drug into the body. Figure 12 illustrates a side view of a cannula 1202 that has been inserted into a subcutaneous layer 1204 of the skin. Cannula 1202 may be attached to a cannula housing 1204 that is fluidically connected to a luer fitting 1206. An insulin pump can then connect to luer fitting 1206. The cannula may remain in the body after being inserted with a needle that is subsequently removed. In some systems, the cannula should be changed with a particular frequency (every 3 days) to mitigate the risk of clogging.

Additional details may be found regarding cannulas in U.S. Patent No.'s 7,052,483 and 6,572,586, which are hereby fully incorporated herein.

[0077] Method 1000 includes selecting a user interface option to perform a cannula fill procedure when a cannula is coupled to a therapeutic dispensing device, as illustrated in a step 1002. After the cannula fill option is selected, a user must physically attach a new cannula to the pump and if necessary remove the old cannula.

[0078] Once the new cannula is attached an amount of therapeutic is pumped so that the cannula is filled, as illustrated in a step 1004. In an embodiment, a user can select a user interface option to prime the cannula. Next, a time stamp in which the cannula fill procedure was performed can be saved to a memory, as illustrated in a step 1006. Note that the time stamp may be saved to a memory of the therapeutic dispensing device, the analyte testing device, a personal computer, or other DMU. The steps 1002, 1004, and 1006 can be repeated three or more times, as illustrated in a step 1008.

[0079] After step 1008, a microprocessor can calculate an average number of days in between cannula fills, as illustrated in a step 1010. The calculation of step 1010 can be calculated using Equation 5.

$$\text{Eq. 5} \quad C_{avg} = \frac{\sum_{i=1}^{N} C_i}{(N-1)}$$

[0080] The terms C_{avg} is an average number of days between cannula fills, C_i is the number of days between two consecutive cannula fills, and N is a total number of cannula fills.

[0081] Once the average number of days in between cannula fills for step 1010 has been calculated, it can be annunciated, as illustrated in a step 1012. The output of step 1012 may display on a screen of a personal computer, the analyte testing device, the therapeutic dispensing device, or other DMU (described above). In an embodiment, an alert can be annunciated to a user where the average number of days in between cannula fills is greater than about three days.

[0082] Under certain circumstances, a user may adjust a recommended bolus to be lower or higher due to factors not typically accounted for in a basic insulin calculator. For

instance, the type of insulin (e.g., fast or slow acting) or type of carbohydrate (e.g., simple or complex) may cause a user to adjust the recommended bolus amount. However, if the adjusted bolus amount results in hypo or hyperglycemia, the user or HCP may want to review a logbook of adjusted insulin boluses to see whether a particular adjustment was higher or lower.

[0083] Figure 13 is a flow chart illustrating a method 1300 for indicating a bolus override that differs from a recommended bolus amount. A microprocessor can be programmed to generally carry out the steps of method 1300. The microprocessor can be part of a particular device, such as, for example, a glucose meter, an insulin pen, an insulin pump, a server, a mobile phone, personal computer, or mobile hand held device. When using an insulin bolus calculator, a recommended bolus amount can be displayed on a display of a special purpose computer 26, either an analyte testing device 10 or a therapeutic dispensing device 48, as shown in a step 1302. A user can either accept the recommended bolus amount, or alternatively can override the bolus amount by inputting a different bolus amount that is either higher or lower, as shown in a step 1304. Where the bolus amount is overridden, the different bolus amount and a time stamp can be saved to a memory of either analyte testing device 10 or therapeutic dispensing device 48, as shown in a step 1306. Next, the different bolus amount can be displayed with either a first indicia or second indicia to indicate that the adjusted bolus amount was lower or higher than the recommended amount, as shown in a step 1308.

[0084] In an embodiment, the different bolus amount with either first or second indicia can be displayed on a display of a special purpose computer 26, analyte testing device 10 or therapeutic dispensing device 48. In another embodiment, the different bolus amount with either first or second indicia can displayed on a display of personal computer 26 after the data has been transferred. The first and second indicia may be represented by an up arrow or down arrow, as illustrated in sections 1404 and 1402 of the screen-shot of Figure 14. The first or the second indicia may be located immediately adjacent to the recommended bolus amount.

[0085] The different bolus amount can be located within a cell of a logbook. More specifically, different bolus amounts with either an up or down arrow are shown in the medication column (denoted as “Med”) of Figure 14. A logbook can include a plurality of

cells organized into a two dimensional array where a first dimension represents time intervals during one day and a second dimension represents time intervals of several days. For example, the time intervals of the first dimension can be represented in columns labeled as "Overnight," "Early Morning," "Late Morning," "Early Afternoon," "Late Afternoon," "Early Evening," "Late Evening," and "Bedtime." The time intervals of the second dimension can be represented as a plurality of rows in which each row is a single day.

[0086] It is noted that the various methods described herein can be used to generate software codes using off-the-shelf software development tools such as, for example, Visual Studio 6.0, Windows 2000 Server, and SQL Server 2000. The methods, however, may be transformed into other software languages depending on the requirements and the availability of new software languages for coding the methods. Additionally, the various methods described, once transformed into suitable software codes, may be embodied in any computer-readable storage medium that, when executed by a suitable microprocessor or computer, are operable to carry out the steps described in these methods along with any other necessary steps.

[0087] While the invention has been described in terms of particular variations and illustrative figures, those of ordinary skill in the art will recognize that the invention is not limited to the variations or figures described. In addition, where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art will recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Therefore, to the extent there are variations of the invention, which are within the spirit of the disclosure or equivalent to the inventions found in the claims, it is the intent that this patent will cover those variations as well.

WHAT IS CLAIMED IS:

1. A method of monitoring therapeutic bolus compliance with an analyte testing device and a therapeutic dispensing device, in which each of both devices each includes a microprocessor coupled to a memory, the method comprising:

obtaining from the memory of the analyte testing device data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences;

collecting from the memory of the therapeutic dispensing device a time stamp for each bolus of dispensed therapeutic;

identifying a hyperglycemic occurrence that does not have at least one bolus of dispensed therapeutic within a predetermined time range of the hypoglycemic occurrence;

calculating a percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range; and

annunciating the percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range.

2. The method of claim 1, in which the predetermined time range comprises about one hour before to about one hour after the time stamp of the hyperglycemic occurrence.

3. The method of claim 1, in which the calculating comprises:

determining data including a total number of hyperglycemic occurrences and a number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range; and

dividing the number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range by a total number of hyperglycemic occurrences.

4. The method of Claim 1, in which the calculating comprises determining a result for a following equation:

$$\%H_{NB} = [H_{NB} / H_T] \times 100, \text{ where}$$

$\%H_{NB}$ is the percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range,

H_{NB} is the number of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range, and

H_T is the total number of hyperglycemic occurrences.

5. The method of Claim 1, in which the hyperglycemic occurrence comprises a glucose concentration greater than about 200 milligrams per deciliter.

6. The method of Claim 1, in which the identifying comprises automatically determining whether a glucose measurement comprises a hypoglycemic occurrence.

7. The method of claim 1 further comprising:

assaying a plurality of blood samples to measure glucose before the obtaining from the memory of the analyte testing device.

8. The method claim 1, in which the therapeutic dispensing device comprises a device selected from the group consisting of an insulin pump and an insulin pen and combinations thereof.

9. The method of claim 1, in which the annunciating comprises displaying on a screen of a device selected from the group consisting of a personal computer, the analyte testing device, or the therapeutic dispensing device and combinations thereof.

10. A method of monitoring insulin bolus compliance with an analyte testing device and a therapeutic dispensing device, in which each of both devices each includes a microprocessor coupled to a memory, the method comprising:

obtaining from the memory of the analyte testing device data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences;

collecting from the memory of the therapeutic dispensing device a time stamp for each bolus of dispensed therapeutic;

identifying a hyperglycemic occurrence that has at least one bolus of dispensed therapeutic within a predetermined time range of the hypoglycemic occurrence;

calculating a percentage of hyperglycemic occurrences that have at least one bolus of dispensed therapeutic within the predetermined time range; and

annunciating the percentage of hyperglycemic occurrences that have at least one bolus of dispensed therapeutic within the predetermined time range.

11. A diabetes management system comprising:

a plurality of glucose test strips, each test strip configured to receive a physiological sample;

a test strip port connector configured to receive the plurality of test strips; and

a data management device comprising:

a housing;

a microprocessor coupled to a memory, display, and power supply disposed proximate the housing, the microprocessor coupled to the test strip sensor to obtain data including a number of hyperglycemic occurrences and a time stamp for each of the hyperglycemic occurrences, the microprocessor configured to collect a time stamp for each bolus of dispensed therapeutic so that a percentage of hyperglycemic occurrences that do not have at least one bolus of dispensed therapeutic within the predetermined time range is determined by the microprocessor.

12. A method of monitoring analyte testing compliance with an analyte testing device and a therapeutic dispensing device, in which each of both devices each includes a microprocessor coupled to a memory, the method comprising:

obtaining from the memory of the analyte testing device a time stamp for each of the glucose measurements;

collecting from the memory of the therapeutic dispensing device data including a number of bolus events and a time stamp for each bolus event;

identifying a bolus event that does not have at least one glucose measurement within a predetermined time range of the bolus event;

calculating a percentage of bolus events that do not have at least one glucose measurement within the predetermined time range; and

annunciating the percentage of bolus events that do not have at least one glucose measurement within the predetermined time range.

13. The method of claim 12, in which the predetermined time range comprises about one hour before to about one hour after the time stamp of the bolus event.

14. The method of claim 12, in which the calculating comprises:

determining data including a total number of bolus events and a number of bolus events that do not have at least one glucose measurement within the predetermined time range;

dividing the number of bolus events that do not have at least one glucose measurement within the predetermined time range by a total number of bolus events.

15. The method of Claim 12, in which the calculating comprises determining a result of a following equation:

$\%B_{NG} = [B_{NG} / B_T] \times 100$, where

$\%B_{NG}$ is the percentage of bolus events that do not have at least one glucose measurement within the predetermined time range,

B_{NG} is the number of bolus events that do not have at least one glucose measurement within the predetermined time range, and

B_T is the total number of bolus events.

16. The method of Claim 12, in which a bolus event comprises a predetermined amount of insulin injected with the therapeutic dispensing device.

17. The method claim 12 further comprising:

assaying a plurality of blood samples to measure glucose before the obtaining from the memory of the analyte testing device.

18. The method claim 12, in which the therapeutic dispensing device comprises an insulin pump or insulin pen.

19. The method of claim 12, in which the annunciating comprises displaying on a screen of a device selected from the group consisting of a personal computer, the analyte testing device, or the therapeutic dispensing device and combinations thereof.

20. A method of monitoring insulin bolus compliance with an analyte testing device and a therapeutic dispensing device, in which each of both devices each includes a microprocessor coupled to a memory, the method comprising:

obtaining from the memory of the analyte testing device data including a number of glucose measurements and a time stamp for each of the glucose measurements;

collecting from the memory of the therapeutic dispensing device data including a number of bolus events and a time stamp for each bolus event;

identifying a bolus event that has at least one glucose measurement within a predetermined time range of the bolus event;

calculating a percentage of bolus events that do have at least one glucose measurement within the predetermined time range; and

annunciating a percentage of bolus events that do have at least one glucose measurement within the predetermined time range.

21. A diabetes management system comprising:

a plurality of glucose test strips, each test strip configured to receive a physiological sample;

a test strip port connector configured to receive the plurality of test strips; and

a data management device comprising:

a housing;

a microprocessor coupled to a memory, display, and power supply disposed proximate the housing, the microprocessor coupled to the test strip sensor to obtain a time stamp for each of the glucose measurements, the microprocessor configured to collect data including a number of bolus events and a time stamp for each bolus event so that a percentage of bolus events that do not have at least one glucose measurement within the predetermined time range is determined by the microprocessor.

22. A method of monitoring an average number of days in between cannula fills of a therapeutic dispensing device that delivers a therapeutic agent to a user via a cannula, the method comprising:

(i) selecting a user interface option to perform a cannula fill procedure when a cannula is coupled to the therapeutic dispensing device;

(ii) pumping an amount of therapeutic agent to fill the cannula;

(iii) saving to a memory of the therapeutic dispensing device or an analyte-testing device a time stamp in which the cannula fill procedure was performed;

(iv) repeating steps (i) to (iii) three or more times;

(v) calculating an average number of days in between cannula fills; and

(vi) annunciating the average number of days in between cannula fills.

23. The method of Claim 22, in which the annunciating comprises alerting a user where the average number of days in between cannula fills is greater than about three days.

24. The method of Claim 22, in which the annunciating comprises displaying on a screen of a device, the device selected from the group consisting of a personal computer, the therapeutic dispensing device, or the analyte testing device, and combinations thereof.

25. The method of Claim 22, in which the calculating of the average number of days in between cannula fills comprises determining a result for the following equation:

$$C_{avg} = \frac{\sum_{i=1}^{N} C_i}{(N-1)}, \text{ where}$$

C_{avg} is an average number of days between cannula fills

C_i is the number of days between two consecutive cannula fills

N is a total number of cannula fills.

26. A method of monitoring bolus overrides with an analyte testing device and a therapeutic dispensing device, in which each of both devices includes a microprocessor coupled to a memory, the method comprising:

(i) annunciating a recommended bolus amount on a display of either the analyte testing device or a therapeutic dispensing device;

(ii) inputting a different bolus amount that is either higher or lower than the recommended bolus amount;

(iii) saving to a memory of the therapeutic dispensing device or an analyte testing device the different bolus amount and a time stamp; and

(iv) displaying the different bolus amount with either a first indicia indicating a bolus amount higher than the recommended bolus amount or a second indicia indicating a bolus amount lower than the recommended bolus amount.

27. The method of Claim 26, in which the first or the second indicia is immediately adjacent to the recommended bolus amount.

28. The method of Claim 26, in which the displaying of the different bolus amount is located within a cell of a logbook, the logbook comprising a plurality of cells organized into a two dimensional array where a first dimension represents time intervals during one day and a second dimension represents time intervals of several days.

29. The method of Claim 26, in which the first indicia comprises an up arrow and the second indicia comprises a down arrow.

30. The method of Claim 26 further comprising:

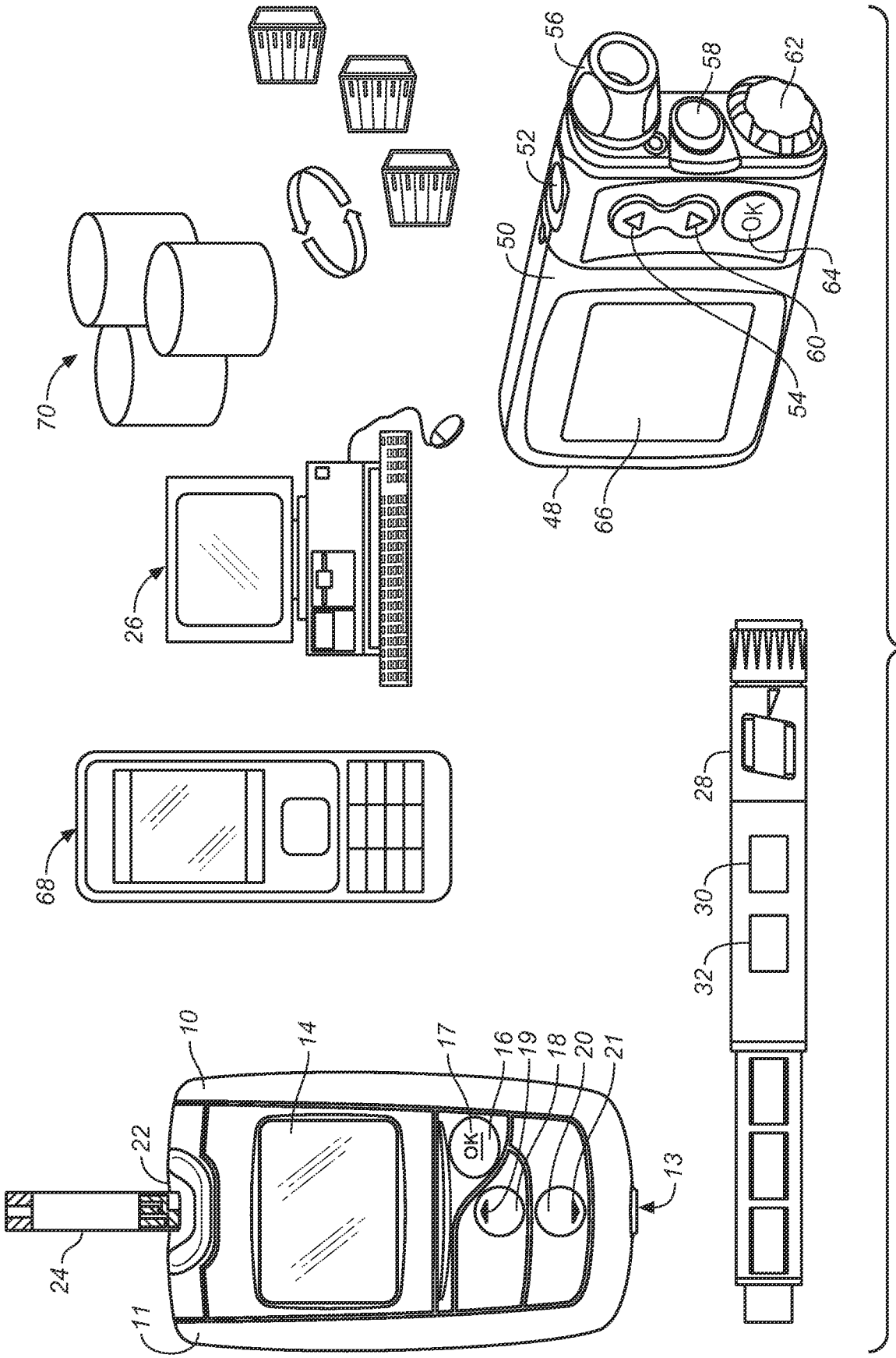
before the annunciating, assaying a blood sample to measure a glucose concentration; and

calculating the recommended bolus amount based on the measured glucose concentration, an insulin sensitivity value, and a target glucose concentration.

31. The method of Claim 26 further comprising:

before the annunciating, inputting an amount of carbohydrate into the analyte testing device or the therapeutic dispensing device; and

calculating the recommended bolus amount based on the measured glucose concentration, an insulin to carbohydrate ratio, and a target glucose concentration.


70
26
68
24
11
10
14
17
16
19
18
20
21
22
13
OK
28
30
32
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58
62
52
50
64
60
54
48
66
OK

FIG. 1

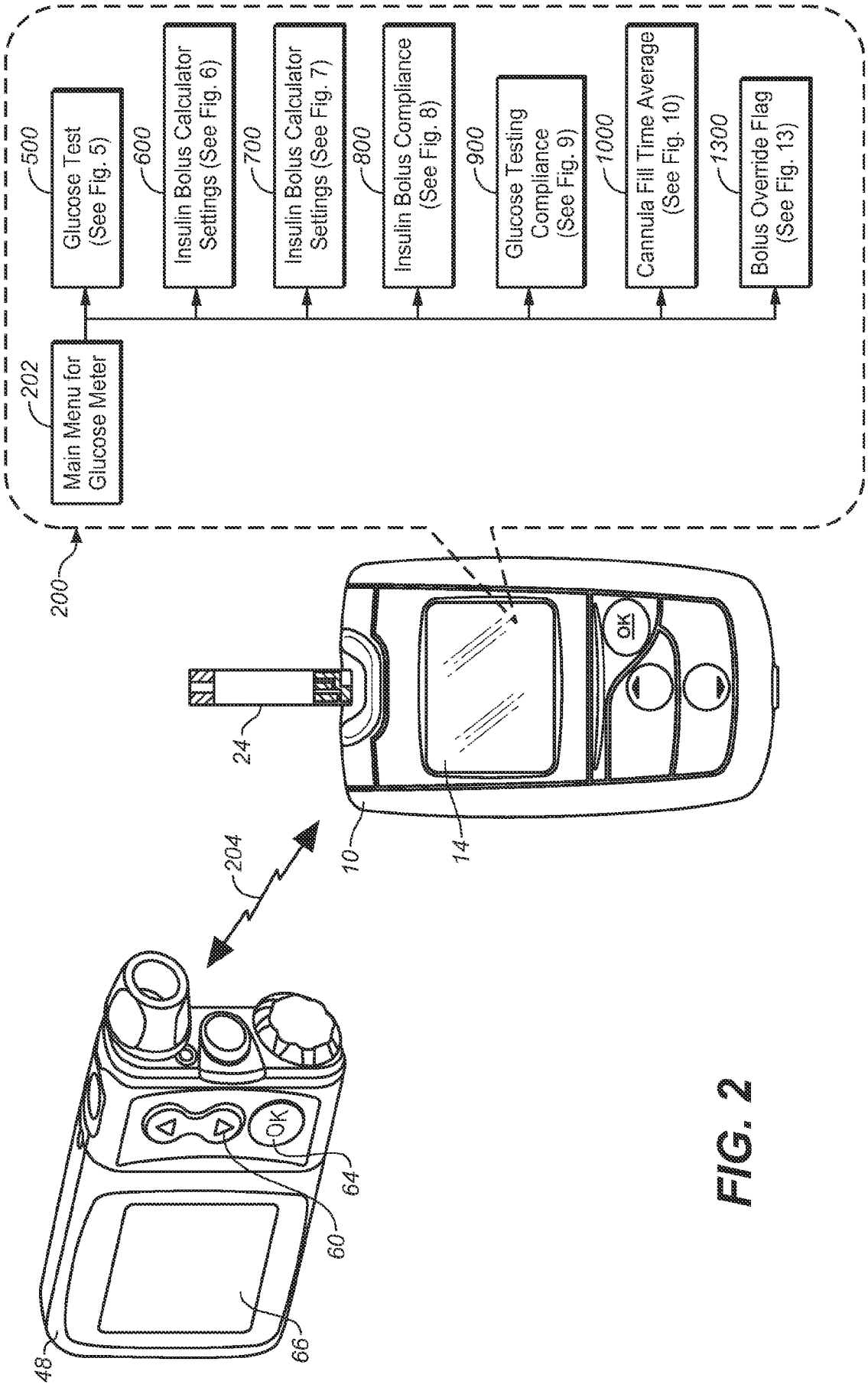

200
202
Main Menu for Glucose Meter
500
Glucose Test (See Fig. 5)
600
Insulin Bolus Calculator Settings (See Fig. 6)
700
Insulin Bolus Calculator Settings (See Fig. 7)
800
Insulin Bolus Compliance (See Fig. 8)
900
Glucose Testing Compliance (See Fig. 9)
1000
Cannula Fill Time Average (See Fig. 10)
1300
Bolus Override Flag (See Fig. 13)
24
10
14
OK
204
48
66
60
64
OK

FIG. 2

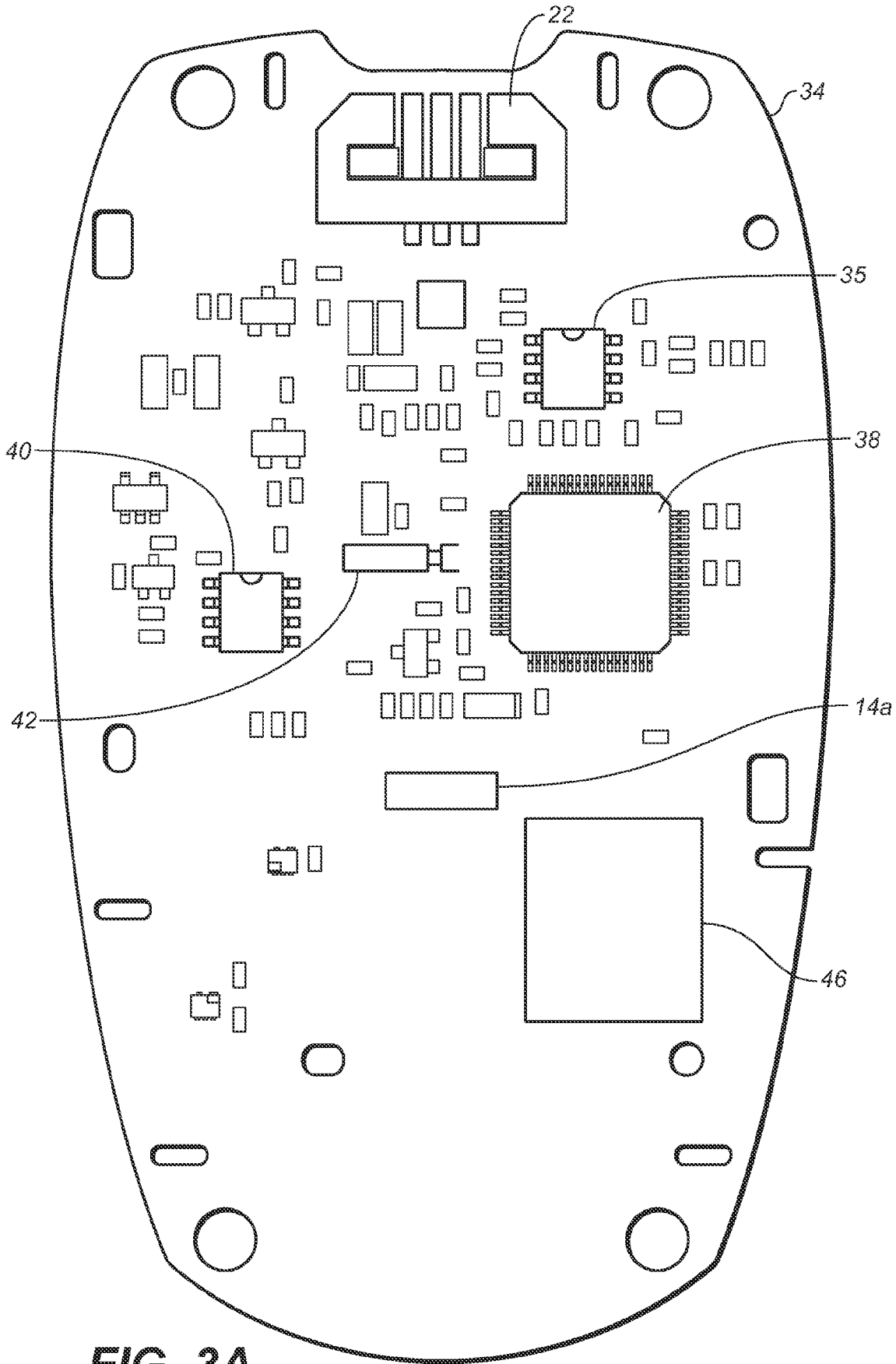


FIG. 3A

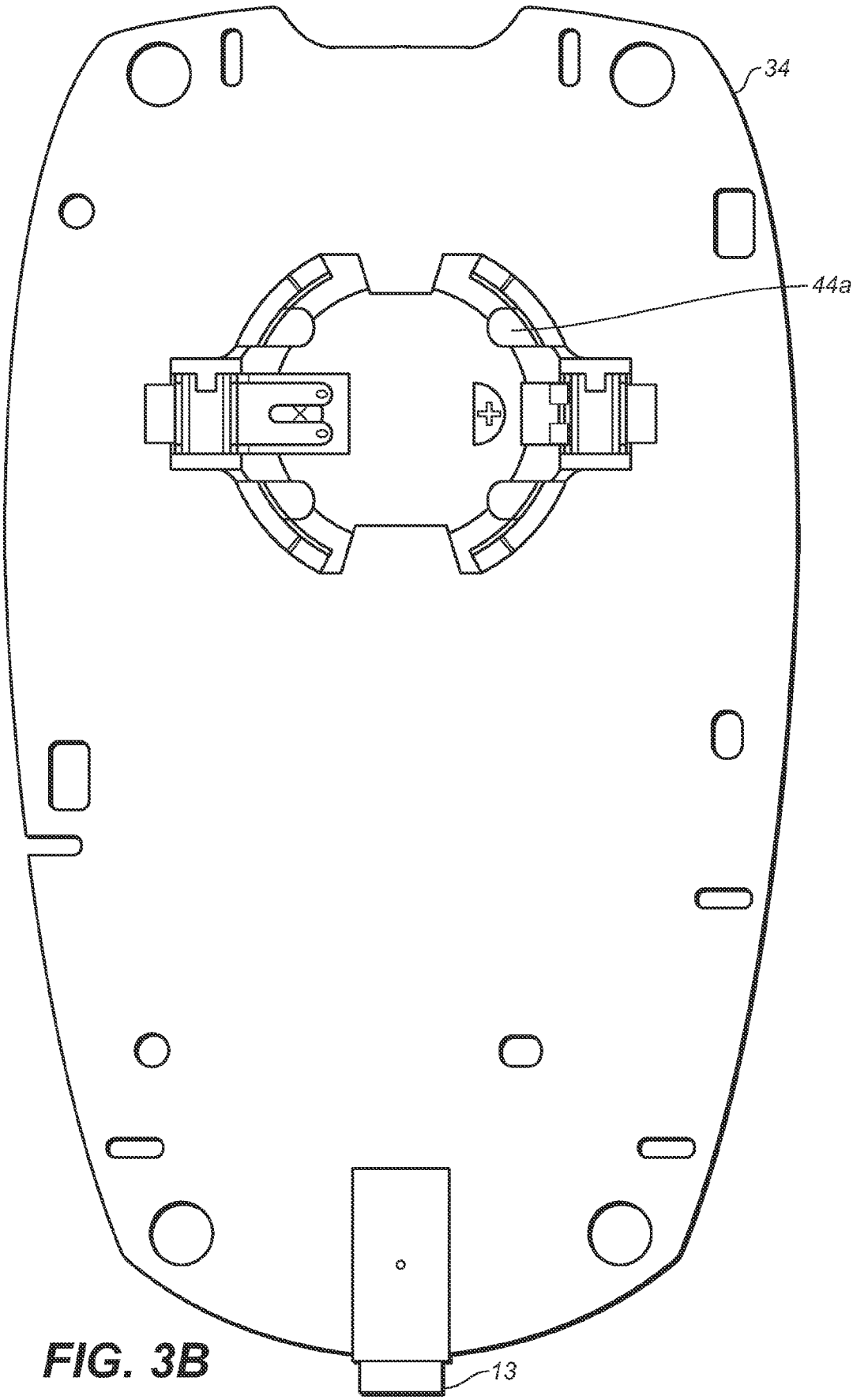


FIG. 3B

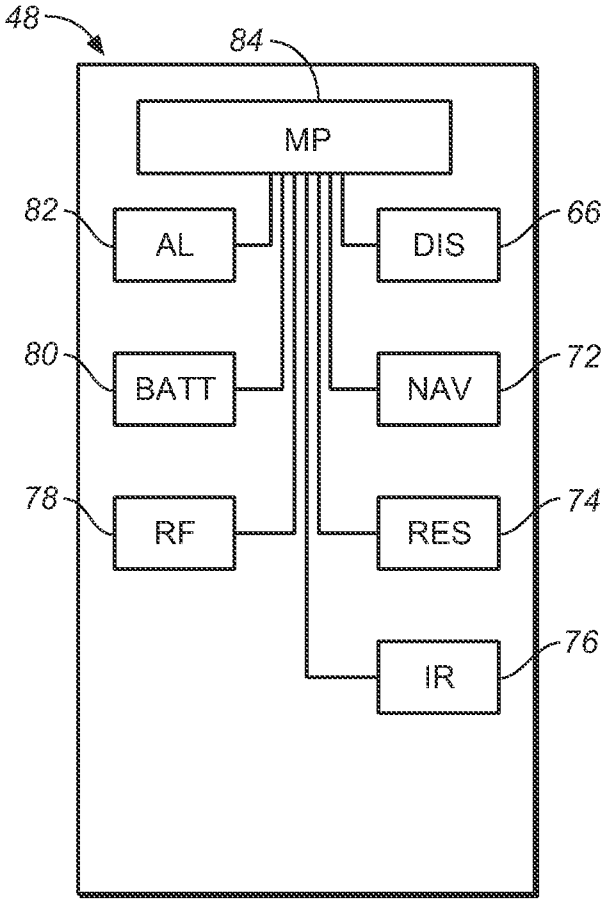


FIG. 4

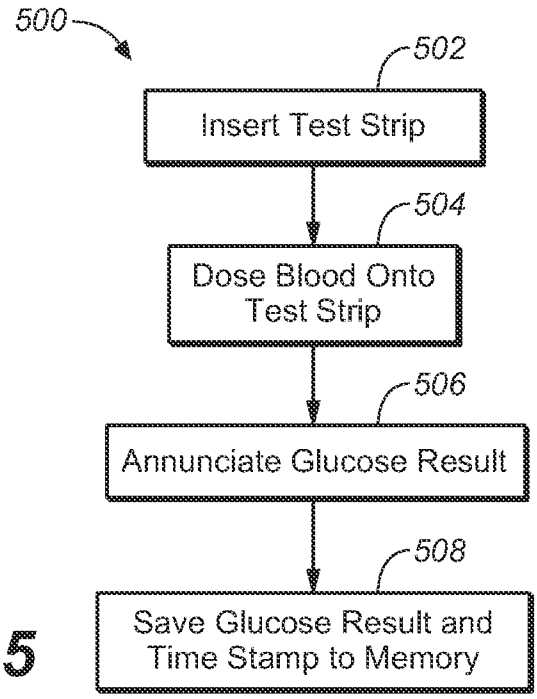

500
502
Insert Test Strip
504
Dose Blood Onto Test Strip
506
Annunciate Glucose Result
508
Save Glucose Result and Time Stamp to Memory

FIG. 5

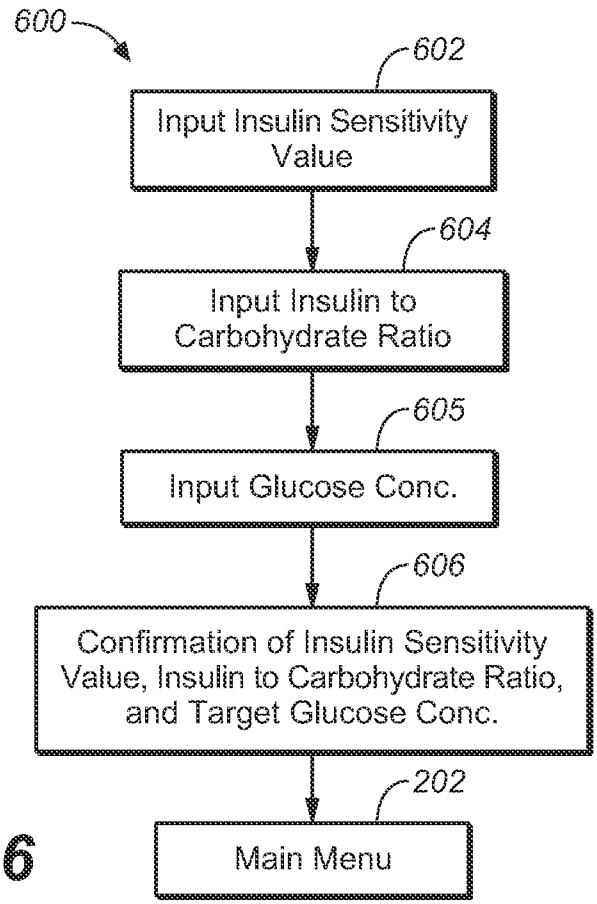

600
602
Input Insulin Sensitivity Value
604
Input Insulin to Carbohydrate Ratio
605
Input Glucose Conc.
606
Confirmation of Insulin Sensitivity Value, Insulin to Carbohydrate Ratio, and Target Glucose Conc.
202
Main Menu

FIG. 6

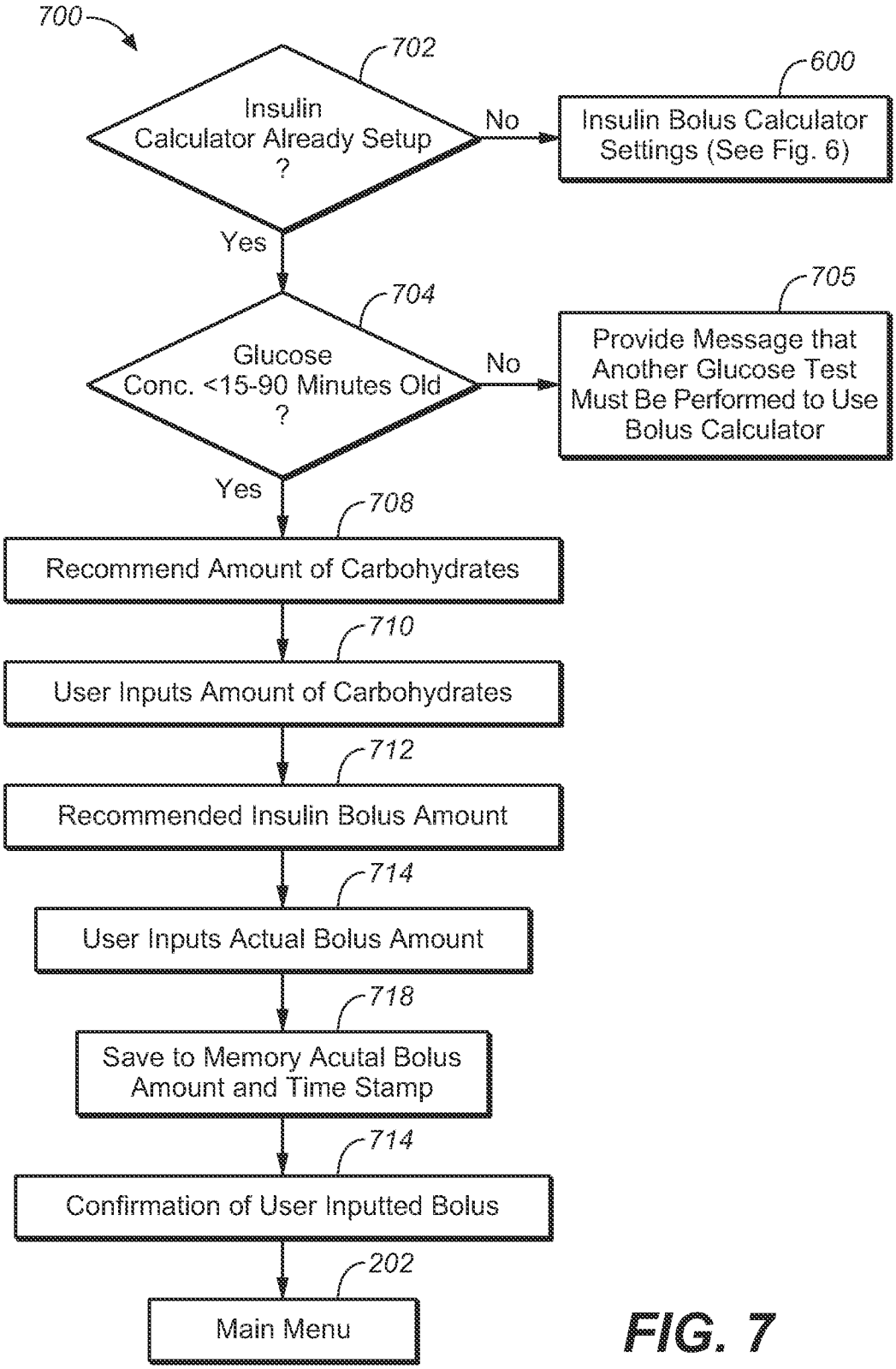

700
702
Insulin Calculator Already Setup ?
No
600
Insulin Bolus Calculator Settings (See Fig. 6)
Yes
704
Glucose Conc. <15-90 Minutes Old ?
No
705
Provide Message that Another Glucose Test Must Be Performed to Use Bolus Calculator
Yes
708
Recommend Amount of Carbohydrates
710
User Inputs Amount of Carbohydrates
712
Recommended Insulin Bolus Amount
714
User Inputs Actual Bolus Amount
718
Save to Memory Acutal Bolus Amount and Time Stamp
714
Confirmation of User Inputted Bolus
202
Main Menu

FIG. 7

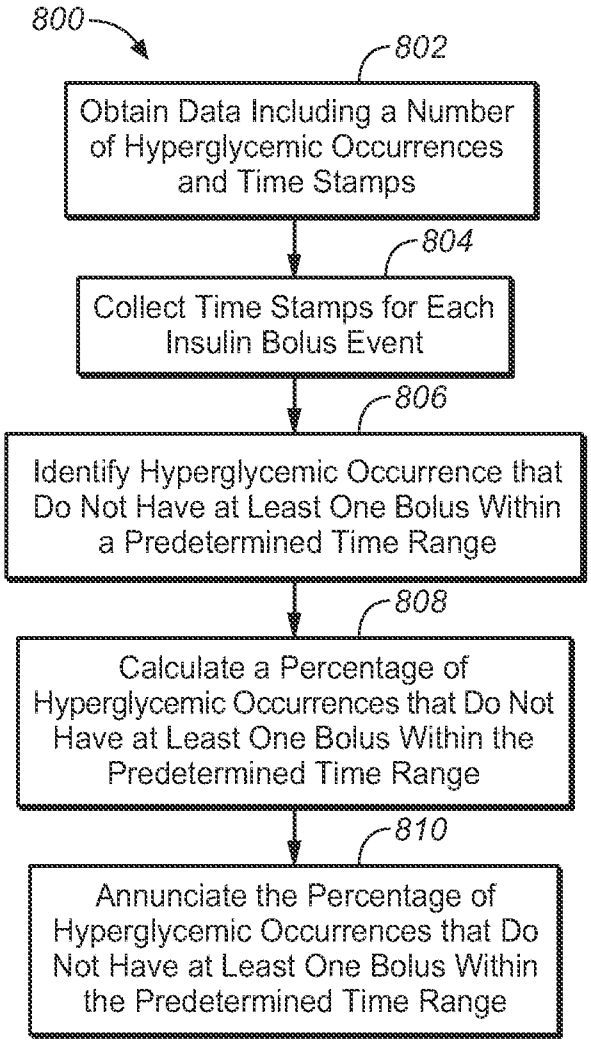

800
802
Obtain Data Including a Number of Hyperglycemic Occurrences and Time Stamps
804
Collect Time Stamps for Each Insulin Bolus Event
806
Identify Hyperglycemic Occurrence that Do Not Have at Least One Bolus Within a Predetermined Time Range
808
Calculate a Percentage of Hyperglycemic Occurrences that Do Not Have at Least One Bolus Within the Predetermined Time Range
810
Annunciate the Percentage of Hyperglycemic Occurrences that Do Not Have at Least One Bolus Within the Predetermined Time Range

FIG. 8

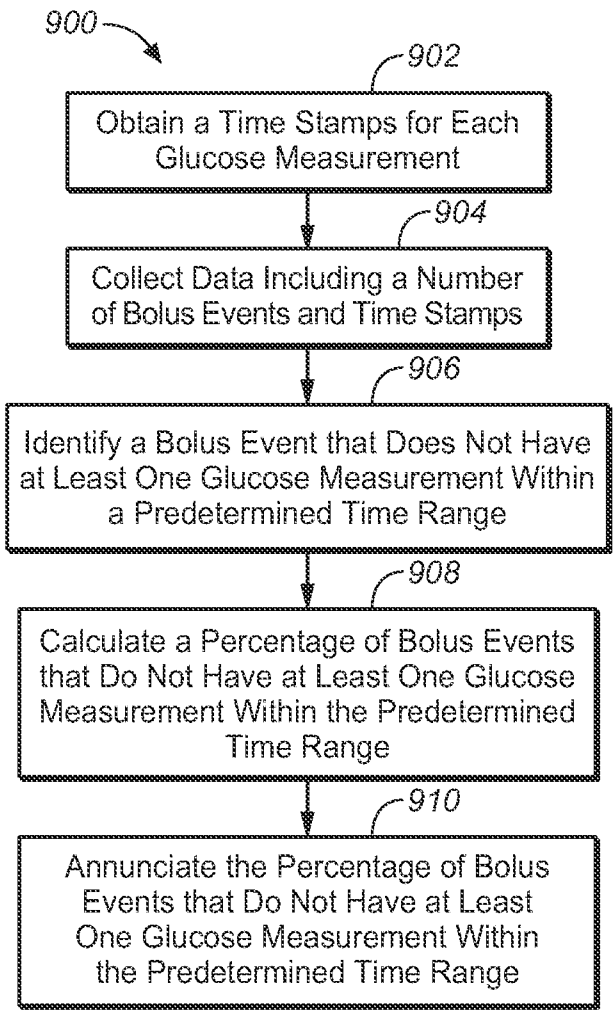

900
902
Obtain a Time Stamps for Each Glucose Measurement
904
Collect Data Including a Number of Bolus Events and Time Stamps
906
Identify a Bolus Event that Does Not Have at Least One Glucose Measurement Within a Predetermined Time Range
908
Calculate a Percentage of Bolus Events that Do Not Have at Least One Glucose Measurement Within the Predetermined Time Range
910
Annunciate the Percentage of Bolus Events that Do Not Have at Least One Glucose Measurement Within the Predetermined Time Range

FIG. 9

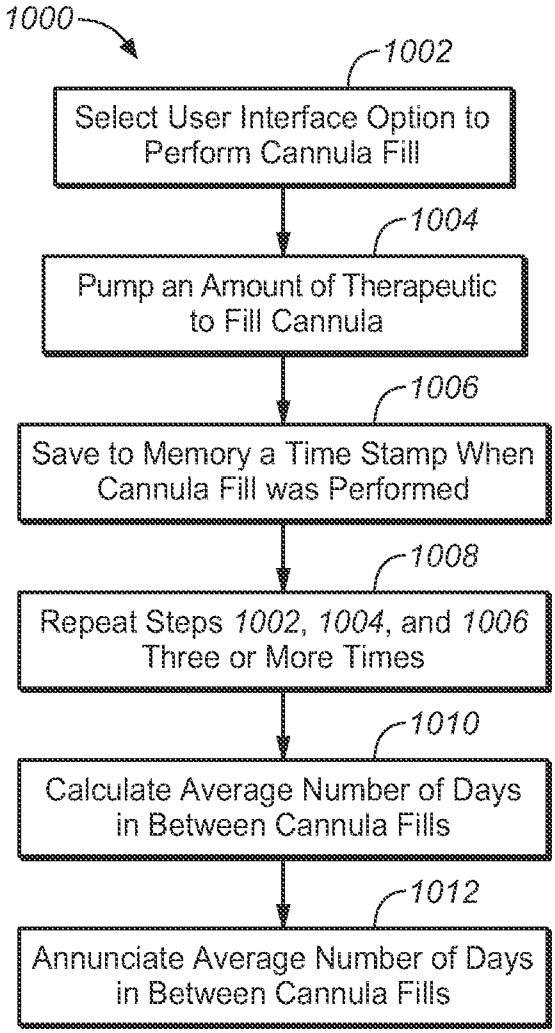
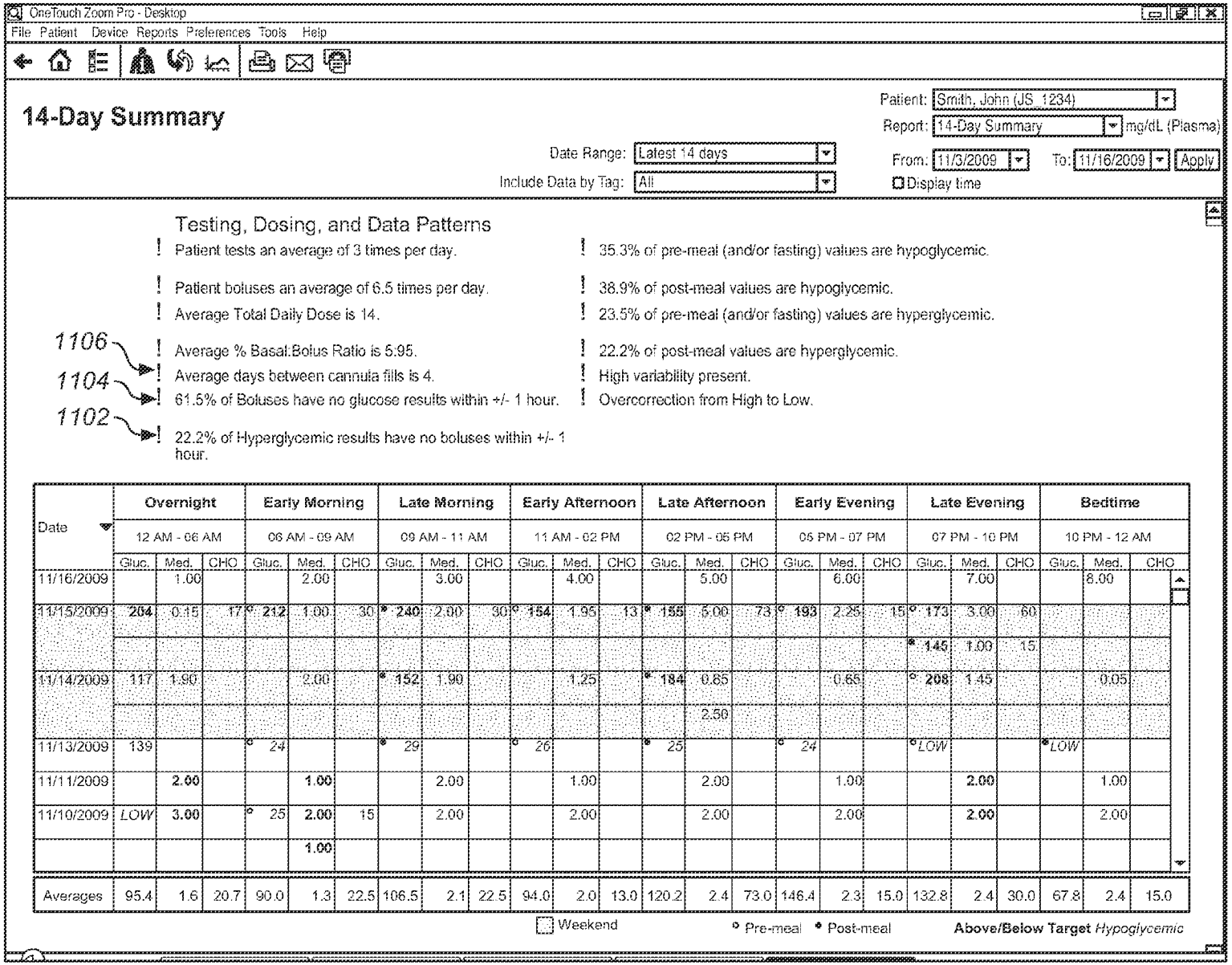

1000
1002
Select User Interface Option to Perform Cannula Fill
1004
Pump an Amount of Therapeutic to Fill Cannula
1006
Save to Memory a Time Stamp When Cannula Fill was Performed
1008
Repeat Steps 1002, 1004, and 1006 Three or More Times
1010
Calculate Average Number of Days in Between Cannula Fills
1012
Annunciate Average Number of Days in Between Cannula Fills

FIG. 10



Date	Overnight			Early Morning			Late Morning			Early Afternoon			Late Afternoon			Early Evening			Late Evening			Bedtime		
	12 AM - 06 AM			06 AM - 09 AM			09 AM - 11 AM			11 AM - 02 PM			02 PM - 05 PM			05 PM - 07 PM			07 PM - 10 PM			10 PM - 12 AM		
	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO
11/16/2009		1.00			2.00			3.00			4.00			5.00			6.00			7.00			8.00	
11/15/2009	204	0.15	17	° 212	1.00	30	* 240	2.00	30	° 154	1.95	13	* 155	5.00	73	* 193	2.25	15	° 173	3.00	60			
																			* 145	1.00	15			
11/14/2009	117	1.90			2.00		* 152	1.90			1.25		* 184	0.65			0.65		° 208	1.45			0.05	
														2.50										
11/13/2009	139			° 24			* 29			° 26			* 25			° 24			°LOW			*LOW		
11/11/2009		2.00			1.00			2.00			1.00			2.00			1.00			2.00			1.00	
11/10/2009	LOW	3.00		° 25	2.00	15		2.00			2.00			2.00			2.00			2.00			2.00	
					1.00																			
Averages	95.4	1.6	20.7	90.0	1.3	22.5	106.5	2.1	22.5	94.0	2.0	13.0	120.2	2.4	73.0	146.4	2.3	15.0	132.8	2.4	30.0	67.8	2.4	15.0

FIG. 11

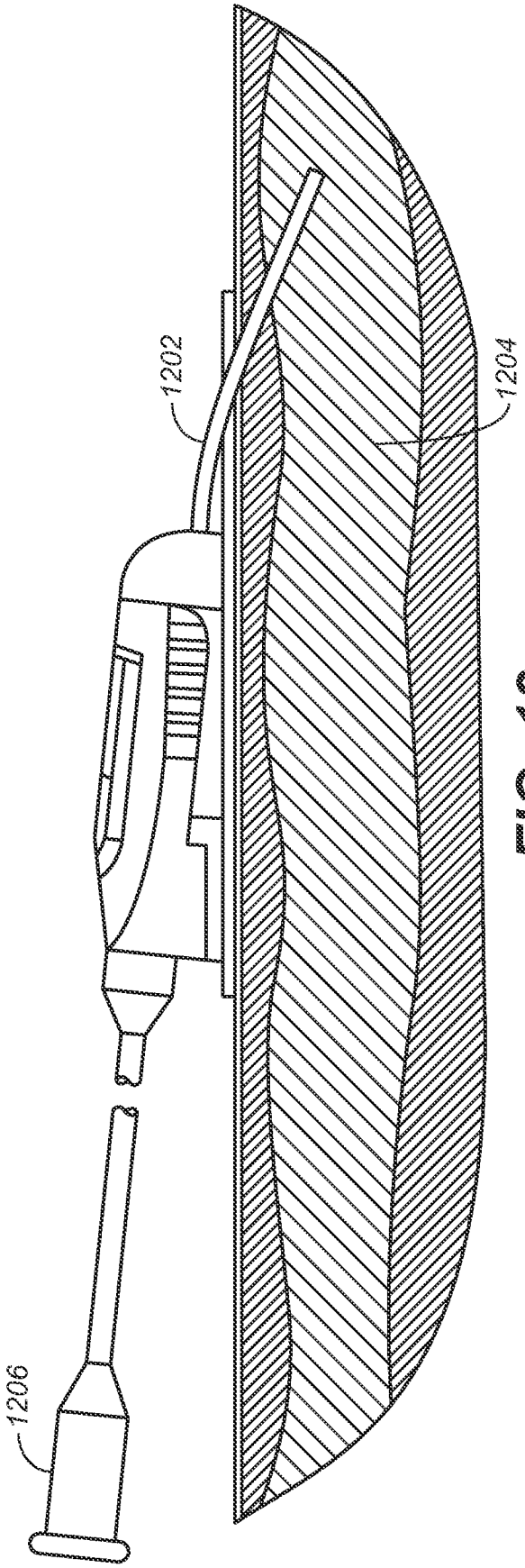


FIG. 12

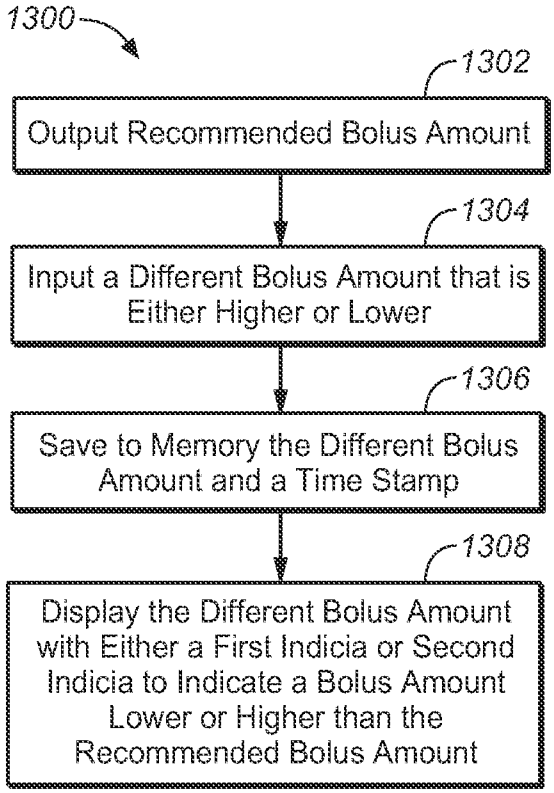
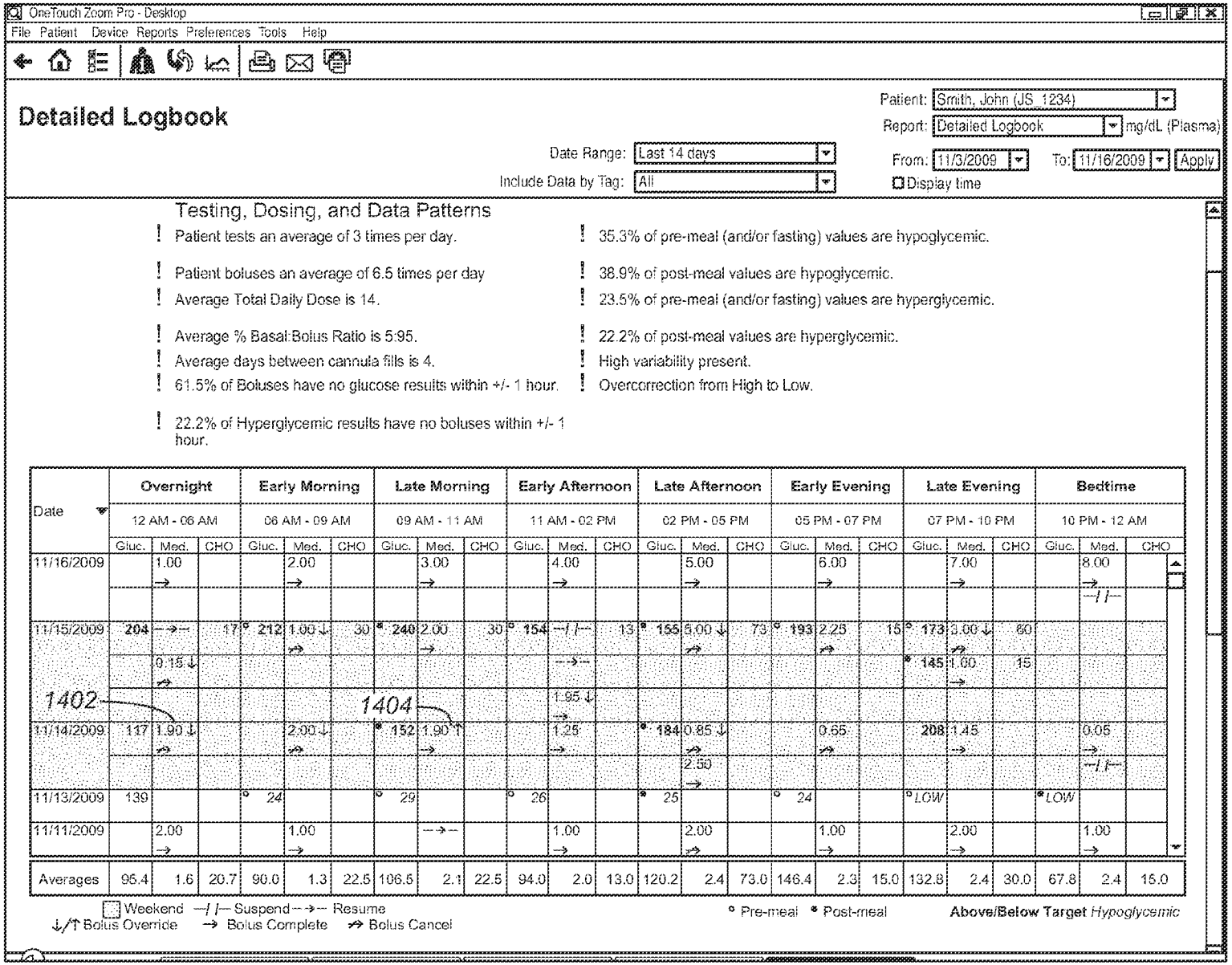

1300
1302
Output Recommended Bolus Amount
1304
Input a Different Bolus Amount that is Either Higher or Lower
1306
Save to Memory the Different Bolus Amount and a Time Stamp
1308
Display the Different Bolus Amount with Either a First Indicia or Second Indicia to Indicate a Bolus Amount Lower or Higher than the Recommended Bolus Amount

FIG. 13



Date	Overnight 12 AM - 06 AM			Early Morning 06 AM - 09 AM			Late Morning 09 AM - 11 AM			Early Afternoon 11 AM - 02 PM			Late Afternoon 02 PM - 05 PM			Early Evening 05 PM - 07 PM			Late Evening 07 PM - 10 PM			Bedtime 10 PM - 12 AM		
	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO	Gluc.	Med.	CHO
11/16/2009		1.00 →			2.00 →			3.00 →			4.00 →			5.00 →			6.00 →			7.00 →			8.00 → —//—	
11/15/2009	204	—→—	17	° 212	1.00 ↓ ↛	30	* 240	2.00 →	30	° 154	—//—	13	* 155	5.00 ↓ ↛	73	° 193	2.25 ↛	15	* 173	3.00 ↓ ↛	60			
		0.15 ↓ ↛									—→—								* 145	1.00 →	15			
											1.95 ↓ →													
11/14/2009	117	1.90 ↓ ↛			2.00 ↓ ↛		* 152	1.90 ↑ →			1.25 →		* 184	0.85 ↓ ↛			0.65 ↛		208	1.45 →			0.05 → —//—	
														2.50 →										
11/13/2009	139			° 24			° 29			° 26			* 25			° 24			°LOW			*LOW		
11/11/2009		2.00 →			1.00 →			—→—			1.00 →			2.00 ↛			1.00 →			2.00 →			1.00 →	
Averages	96.4	1.6	20.7	90.0	1.3	22.5	106.5	2.1	22.5	94.0	2.0	13.0	120.2	2.4	73.0	146.4	2.3	15.0	132.8	2.4	30.0	67.8	2.4	15.0

FIG. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/022039

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/145 A61B5/1486 A61M5/142 G06F19/00
ADD.

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)
A61B A61M G06F

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2009/137661 A1 (LIFESCAN INC [US]; SIEH ZARA [US]; HORWITZ DAVID [US]; PRICE DAVID [US) 12 November 2009 (2009-11-12)	26-31
A	paragraphs [0030] - [0039], [0048], [0049]	1-21

A	WO 2006/001929 A1 (MEDTRONIC MINIMED INC [US]) 5 January 2006 (2006-01-05) paragraphs [0007] - [0014], [0047] - [0049], [0059] - [0060], [0071] - [0073]	1-21

A	US 2008/235053 A1 (RAY PINAKI [US] ET AL) 25 September 2008 (2008-09-25) paragraphs [0034] - [0035], [0082] - [0085]	1-21

	-/--	

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* 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 document 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
20 June 2011	12/07/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Manschot, Jan

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/022039

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 additional 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 an 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.:

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/US2011/022039

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2008/200897 A1 (HOSS UDO [US] ET AL) 21 August 2008 (2008-08-21) paragraphs [0036], [0100] -----	22
A	US 6 554 798 B1 (MANN ALFRED E [US] ET AL) 29 April 2003 (2003-04-29) column 10, line 65 - column 12, line 65 column 15, line 65 - column 18, line 64 -----	26,30,31

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/022039

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2009137661 A1	12-11-2009	AU 2009244268 A1	12-11-2009
		CA 2723352 A1	12-11-2009
		CN 102088898 A	08-06-2011
		EP 2320787 A1	18-05-2011
		KR 20110014176 A	10-02-2011
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		JP 2008229331 A	02-10-2008
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		WO 2008103620 A2	28-08-2008
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		DE 69921833 D1	16-12-2004
		DE 69921833 T2	08-12-2005
		DK 1473050 T3	12-04-2010
		DK 1109586 T3	21-03-2005
		EP 1473050 A1	03-11-2004
		EP 2106815 A2	07-10-2009
		EP 2243506 A2	27-10-2010
		EP 2266644 A2	29-12-2010
		EP 2266645 A2	29-12-2010
		EP 1109586 A2	27-06-2001
		JP 2002523149 T	30-07-2002
		WO 0010628 A2	02-03-2000
		US 6551276 B1	22-04-2003

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-21

   Monitoring therapeutic bolus compliance by relating dispensed bolus events with measured glucose/hyperglycemic occurrences

   ---

2. claims: 22-25

   Monitoring an average number of days between cannula fills

   ---

3. claims: 26-31

   Monitoring and indicating a recommended bolus override
