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(54) **Title:** A HANDHELD DIABETES MANAGER WITH A FLIGHT MODE

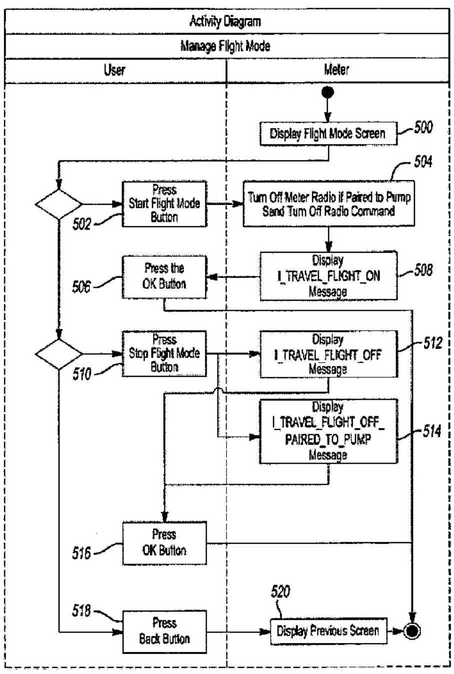

Fig-5

(57) Abstract: A handheld diabetes manager has a flight mode that cooperatively interacts with an external medical device and includes a port configured to receive a test strip for blood glucose measurement, a blood glucose measurement module operable with the test strip, a communications module and a user interface module. The communications module selectively communicates wirelessly with an external medical device. The user interface module communicates with the blood glucose measurement module and the communications module and operates to provide a graphical user interface on a display of the diabetes manager. The graphical user interface includes a screen with a flight mode option. When the flight mode option is enabled and the external medical device is paired and currently communicating with the diabetes manager, the user interface module interacts with the communication module to send a command to the external medical device to turn off wireless communication of the external medical device.

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A HANDHELD DIABETES MANAGER WITH A FLIGHT MODE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. provisional application 61/581 149 filed on December 29, 201 1. The disclosure of the above application is incorporated herein by reference in its entirety.

FIELD

[0002] The present disclosure relates to a handheld diabetes manager that has a flight mode for an external medical device, such as an insulin pump, communicating with the diabetes manager.

BACKGROUND

[0003] Diabetes mellitus, often referred to as diabetes, is a chronic condition in which a person has elevated blood glucose levels that result from defects in the body's ability to produce and/or use insulin. There are three main types of diabetes. Type 1 diabetes usually strikes children and young adults, and may be autoimmune, genetic, and/or environmental. Type 2 diabetes accounts for 90-95% of diabetes cases and is linked to obesity and physical inactivity. Gestational diabetes is a form of glucose intolerance diagnosed during pregnancy and usually resolves spontaneously after delivery.

[0004] Diabetes is managed primarily by controlling the level of glucose in the bloodstream. This level is dynamic and complex, and is affected by multiple factors including the amount and type of food consumed, and the amount of insulin (which mediates transport of glucose across cell membranes) in the blood. Blood glucose levels are also sensitive to exercise, sleep, stress, smoking, travel, illness, menses, and other psychological and- lifestyle factors unique to individual patients. The dynamic nature of blood glucose and insulin, and all other factors affecting blood glucose, often require a person with diabetes to forecast blood glucose levels. Therefore, therapy in the form of insulin or oral medications, or both, can be timed to maintain blood glucose levels in an appropriate range.

[0005] Management of diabetes is time-consuming for patients because of the need to consistently obtain reliable diagnostic information, follow prescribed therapy, and manage lifestyle on a daily basis. Diagnostic information, such as blood glucose, is typically obtained from a capillary blood sample with a lancing device and is then measured with a handheld blood glucose meter. Interstitial glucose levels may be obtained from a continuous glucose sensor worn on the body. Prescribed therapies may include insulin, oral medications, or both. Insulin can be delivered with a syringe, an ambulatory infusion pump, or a combination of both. With insulin therapy, determining the amount of insulin to be injected can require forecasting meal composition of fat, carbohydrates and proteins along with effects of exercise or other physiologic states. The management of lifestyle factors such as body weight, diet, and exercise can significantly influence the type and effectiveness of a therapy.

[0006] Management of diabetes involves large amounts of diagnostic data and prescriptive data acquired in a variety of ways: from medical devices, from personal healthcare devices, from patient-recorded logs, from laboratory tests, and from healthcare professional recommendations. Medical devices include patient-owned bG meters, continuous glucose monitors, ambulatory insulin infusion pumps, diabetes analysis software, and diabetes device configuration software. Each of these systems generates and/or manages large amounts of diagnostic and prescriptive data. Personal healthcare devices include weight scales, blood pressure cuffs, exercise machines, thermometers, and weight management software. Patient recorded logs include information relating bG levels, meals, exercise and lifestyle. Lab test results include HbAlC, cholesterol, triglycerides, and glucose tolerance. Healthcare professional recommendations include prescriptions, diets, test plans, therapy changes and other information relating to the patient's treatment.

[0007] The present teachings are directed to a handheld diabetes manager that includes a user interface with a travel mode for an external medical device, such as an insulin pump, communicating with the diabetes manager.

SUMMARY

[0008] This section provides a general summary of the disclosure, and is not a comprehensive disclosure of its full scope or all of its features.

[0009] The present teachings provide a handheld diabetes manager that has a flight mode that cooperatively interacts with an external medical device and includes a port configured to receive a test strip for blood glucose measurement, a blood glucose measurement module cooperatively operable with the test strip, a communications module and a user interface module. The communications module selectively communicates wirelessly with the external medical device. The user interface module is in data communication with the blood glucose measurement module and the communications module and operates to provide a graphical user interface on a display of the diabetes manager. The graphical user interface includes a screen with a flight mode option. When the flight mode option is enabled and the external medical device is paired and currently communicating with the diabetes manager, the user interface module interacts with the communication module to send a command to the external medical device to turn off wireless communication of the external medical device.

[0010] The present teachings provide a handheld diabetes manager that has a flight mode that cooperatively interacts with an external medical device and includes a port configured to receive a test strip for blood glucose measurement, a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement, a bolus advice module, a communications module, a travel module and a user interface module. The bolus advice module is configured to receive blood glucose measurements from the blood glucose measurement module and operates, in response to an input, to compute an insulin recommendation for a patient based in part on the blood glucose measurements. The communications module selectively communicates via a wireless data link with an external medical device. The travel module cooperatively operates with the communications module to effectuate a flight mode. The user interface module is in data communication with the travel module and operates to provide a graphical user interface on a display of the diabetes manager. The graphical user interface includes a travel screen that allows a user to selectively enable or disable a flight mode. The user interface module presents, in response to user input to access bolus advice and while the flight mode is enabled, a notification on the display that an insulin recommendation from the bolus advice module may be based on data that is outdated.

[0011] The present teachings also provide an alternative embodiment wherein the flight mode option is enabled by sending a flight mode command to the external medical device during a periodic listening window of the external medical device. Periodic listening windows of the external medical device are associated with corresponding periodic beacons from the external medical device to the diabetes manager. In response to the flight mode command from the diabetes manager, the external medical device enters a listening only mode having periodic listening windows without sending beacons.

[0012] Further areas of applicability will become apparent from the description provided herein. The description and specific examples in this summary are intended for purposes of illustration only and are not intended to limit the scope of the present disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The drawings described herein are for illustrative purposes only of selected embodiments and not all possible implementations, and are not intended to limit the scope of the present disclosure.

[0014] FIG. 1 shows a patient with a continuous glucose monitoring (CGM) patch, an ambulatory durable insulin infusion pump, an ambulatory non-durable insulin infusion pump, and a diabetes manager;

[0015] FIG. 2 shows a diabetes management system used by patients and clinicians to manage diabetes;

[0016] FIG. 3 is a functional block diagram of a diabetes manager according to the present teachings;

[0017] FIG. 4 is a block diagram illustrating a user interface with a travel module for a diabetes manager according to the present teachings;

[0018] FIG. 5 is an activity diagram illustrating behavior flow for managing a flight mode according to the present teachings;

[0019] Fig. 6 illustrates a representative flight mode screen according to the present teachings;

[0020] FIG. 7 illustrates a representative screen indicating that flight mode is turned on according to the present teachings;

[0021] FIG. 8A illustrates an exemplary main menu screen of a diabetes manager according to the present teachings;

[0022] FIG. 8B illustrates a representative screen illustrating a bolus warning when the flight mode is turned on according to the present teachings;

[0023] FIG. 8C illustrates a representative screen detailed screen for bolus advice according to the present teachings;

[0024] FIG. 8D illustrates a representative screen showing a bolus advice warning when the flight mode is turned on according to the present teachings;

[0025] Fig. 9 illustrates a representative screen showing device connectivity according to the present teachings; and

[0026] FIG. 10 is an activity diagram illustrating an alternative embodiment for managing a flight mode according to the present teachings.

[0027] Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION

[0028] The following description is merely illustrative in nature and is in no way intended to limit the disclosure, its application, or uses. For purposes of clarity, the same reference numbers will be used in the drawings to identify similar elements. As used herein, the phrase at least one of A, B, and C should be construed to mean a logical (A or B or C), using a non-exclusive logical "or". It should be understood that steps within a method may be executed in different order without altering the principles of the present disclosure.

[0029] Referring now to FIG. 1, a person with diabetes 100 using various medical devices is illustrated. Persons with diabetes include persons with metabolic syndrome, persons with pre-diabetes, type 1 diabetes, type 2 diabetes, and gestational diabetes, and are collectively referred to as a patient. Healthcare providers for diabetes are diverse and include nurses, nurse practitioners, physicians, diabetes nurse educators, nutritionists and endocrinologists and are collectively referred to as a clinician.

[0030] During a healthcare consultation, the patient 100 typically shares with the clinician a variety of patient data including blood glucose measurements, continuous glucose monitor data, amounts of insulin infused, amounts of food and beverages consumed, exercise schedules, and other lifestyle information. The clinician may obtain additional patient data that includes measurements of HbAlC, cholesterol levels, triglycerides, blood pressure, and weight of the patient 100. The patient data can be recorded manually or electronically on a handheld diabetes management device 104 having a display 103, a diabetes analysis software executed on a personal computer (PC not shown), and/or a web-based diabetes analysis site (not shown). The clinician can analyze the patient data manually or electronically using the diabetes management device 104, the diabetes analysis software and/or the web-based diabetes analysis site. After analyzing the patient data and reviewing adherence of the patient 100 to previously prescribed therapy, the clinician can decide whether to modify the therapy for the patient 100.

[0031] Referring now to FIG. 1, the patient 100 can use a continuous glucose monitoring (CGM) device or CGM patch 200, an ambulatory non-durable insulin infusion pump 202 or an ambulatory durable insulin infusion pump 204 (hereinafter insulin pump 202 or 204), and the handheld diabetes management device 104 (hereinafter the diabetes manager or meter 104). The CGM patch 200 includes a body mount, a reusable component and a subcutaneous sensor to sense and monitor the amount of glucose in interstitial fluid of the patient 100 and communicates corresponding data to the diabetes manager 104.

[0032] The diabetes manager 104 can perform various tasks including measuring and recording blood glucose levels, determining an amount of insulin to be administered to the patient 100 via the insulin pump 202 or 204, receiving patient data via a user interface, archiving the patient data, etc. The diabetes manager 104 periodically receives glucose levels of the patient 100 from the CGM patch 200, or data from which glucose levels of the patient 100 may be computed. The diabetes manager 104 transmits instructions to the insulin pump 202 or 204, which delivers insulin to the patient 100. Insulin can be delivered in a scheduled manner in the form of a basal dose, which maintains a predetermined insulin dose to the patient 100. Additionally, insulin can be delivered in the form of a bolus dose, which raises the amount of insulin delivered to the patient 100 by a determined amount.

[0033] Generally, and referring now to FIG. 2, a diabetes management system 300 used by the patient 100 and the clinician can include one or more of the following devices: the diabetes manager 104, the continuous glucose monitor (CGM patch) 200, the insulin pump 202 or 204, a mobile device 302, the PC 106 with diabetes analysis and/or configuaration software, and other healthcare devices 304. The diabetes manager 104 can be configured as a system hub that communicates with the devices of the diabetes management system 300. Alternatively, the mobile device 302 can serve as the system hub. Communication between the devices in the diabetes management system 300 can be performed using wireless interfaces (e.g., Bluetooth) and/or wireline interfaces (e.g., USB). Communication protocols used by these devices can include protocols compliant with the IEEE 11073 standard, as extended using guidelines provided by Continua® Health Alliance Design Guidelines. Further, healthcare records systems such as Microsoft® HealthVault™ and Google™ Health can be used by the patient 100 and clinician to exchange information.

[0034] The diabetes manager 104 can receive glucose readings from one or more sources (e.g., from the CGM patch 200). The CGM patch 200 regularly monitors the interstitial glucose level of the patient 100. The CGM patch 200 periodically communicates glucose levels to the diabetes manager 104. The diabetes manager 104 and the CGM patch 200 communicate wirelessly using generally a wireless protocol, such as, for example, the standard Bluetooth Low Energy wireless protocol. Any other suitable wireless protocol can be used instead.

[0035] Additionally, the diabetes manager 104 includes a blood glucose meter (BGM) and a port that communicates with the BGM (not shown). The port can receive a blood glucose measurement strip 306. The patient 100 deposits a sample of blood on the blood glucose measurement strip 306. The BGM analyzes the sample and measures the blood glucose level in the sample. The blood glucose level measured from the sample is used to determine the amount of insulin to be administered to the patient 100 using, for example, the insulin pump 202, 204.

[0036] The diabetes manager 104 also communicates with the insulin pump 202 or 204. The insulin pump 202 or 204 can be configured to receive instructions from the diabetes manager 104 to deliver a predetermined amount of insulin to the patient 100 in the form of basal dose or bolus dose. Additionally, the insulin pump 202 or 204 can receive other information including meal and/or exercise schedules of the patient 100. The insulin pump 202 or 204 or the diabetes manager 104 can determine the amount of insulin to administer based on the additional information as a basal dose or bolus dose.

[0037] The insulin pump 202 or 204 can also communicate data to the diabetes manager 104 via wireless communication module including, for example, a pump transceiver or a communications radio. The data can include amounts of insulin delivered to the patient 100, corresponding times of delivery, and pump status. The diabetes manager 104 and the insulin pump 202 or 204 can communicate using a wireless communication protocol such as Bluetooth. Other wireless communication protocols can also be used.

[0038] In addition, the diabetes manager 104 can communicate with the other healthcare devices 304. For example, the other healthcare devices 304 can include a blood pressure meter, a weight scale, a pedometer, a fingertip pulse oximeter, a thermometer, etc. The other healthcare devices 304 obtain and communicate personal health information of the patient 100 to the diabetes manager 104 through wireless, USB, or other interfaces. The other healthcare devices 304 may use communication protocols compliant with ISO/IEEE 11073 extended using guidelines from Continua® Health Alliance. The diabetes manager 104 can communicate with the other healthcare devices 304 using interfaces including Bluetooth, USB, etc. Further, the devices of the diabetes management system 300 can communicate with each other via the diabetes manager 104.

[0039] The diabetes manager 104 can communicate with the PC 106 using Bluetooth, USB, or other wireless interfaces. A diabetes management software running on the PC 106 includes an analyzer-configurator that stores configuration information of the devices of the diabetes management system 300. The configurator has a database to store configuration information of the diabetes manager 104 and the other devices. The configurator can communicate with users through standard web or computer screens in non-web applications. The configurator transmits user-approved configurations to the devices of the diabetes management system 300. The analyzer retrieves data from the diabetes manager 104, stores the data in a database, and outputs analysis results through standard web pages or computer screens in non-web based applications.

[0040] The diabetes manager 104 can communicate with the mobile device 302 using Bluetooth or another suitable wireless communication protocol. The mobile device 302 may include a cellular phone, a pager, or a personal digital assistant (PDA). The diabetes manager 104 can send messages to an external network through the mobile device 302. The mobile device 302 can transmit messages to the external network upon receiving requests from the diabetes manager 104.

[0041] Referring now to FIG. 3, the diabetes manager 104 includes a blood glucose measuring (BGM) module 400, a communication module 402, a user interface module 404, various user interface elements 406, a processing module 408, a memory 410, and a power module 412. The user interface module 404 and the processing module 408 can be implemented by an application processing module 409. The BGM module 400 includes a blood glucose measuring engine that analyzes samples provided by the patient 100 on the blood glucose measurement strip 306 and measures the amount of blood glucose in the samples. The communication module 402 can include a transceiver and/or multiple radios that communicate with different devices of the diabetes management system 300. The user interface module 404 interfaces the diabetes manager 104 to various user interface elements 406 that the patient 100 can use to interact with the diabetes manager 104. For example, the user interface elements 406 can include a touchscreen or other display, touchscreen or other keys, switches, a speaker, a microphone, a secure digital (SD) card port, a USB port, etc. (not shown).

[0042] The processing module 408 processes data received from the BGM module 400, the communication module 402, and the user interface module 404. The processing module 408 uses memory 410 for processing and storing data. The memory 410 can include volatile and nonvolatile memory. The processing module 408 outputs data to and receives data from the user interface elements 406 via the user interface module 404. The processing module 408 outputs data to and receives data from the devices of the diabetes management system 300 via the communication module 402. The power module 412 supplies power to the components of the diabetes manager 104. The power module 412 can include a rechargeable battery. The battery can be charged via the USB port of the diabetes manager 104 using an adapter that plugs into a wall outlet or using a cable that plugs into a PC.

[0043] Referring to FIG. 4, a logical navigation architecture of the user interface module for handheld diabetes manager 104 is illustrated. The following modules can be integrated in the navigation architecture of the handheld diabetes manager 104: a startup module 150, a home module 152, a meter module 154, a bolus advice module 156, a "my data" module 158, a system settings module 160, a device connectivity module 162, a travel module 16, a pump module 166 166 and a data module 140. The data module 140 includes databases, settings and configurations, and acts as a central hub that communicates with the other modules to store and provide information related regarding data, settings, configuration related to the other modules. In some embodiments, some of the modules can be removed or inactivated or additional modules can be added. For example, the pump module 166 may be removed or inactivated in models of the handheld diabetes manager 104 for non-pump users. In other modules, a continuous glucose monitoring module (CGM) 168 can be added, as illustrated in dashed lines.

[0044] As briefly outlined in reference to FIG. 4, the handheld diabetes manager 104 of the present teachings integrates in a single handheld device various functions, controls, calculations, tests and reports that, in prior art devices, are typically split among different specialized devices, such as single-purpose bG meters, single-purpose remote devices for insulin pumps and other similar single or limited-purpose diabetes managers. Integrating the multiple tasks and functions of the plurality of modules of the handheld diabetes manager 104 of the present teachings requires a user interface that does not simply superpose various functions in an additive manner, but anticipates behaviors and use case scenarios that are unique and emerge from the interaction of the multiplicity of modules when all these modules are integrated in the same handheld device. Such interactions arise not just from the hardware aspects of the device, but from the various possibilities or use scenarios that a user may subject the device based in the user-perceived and/or actual capabilities of the device. For example, although portability is common to many prior art diabetes devices, portability and use in restricted or semi-restricted environments, such as during air travel, requires anticipation of alternative use case or use scenarios to avoid conflicts, without totally disabling the device. In the following, the term pump is used interchangeably for an insulin pump, a micropump, and insulin patch with a CGM device or a combination, unless differentiation is required.

[0045] In the context of the user interface for the handheld diabetes manager 104, a use case is an observable result based upon an action by a user. A use case describes the behavior and navigation along a primary or alternate path including any standard business rules for diabetes management and is graphically represented in an activity or behavior diagram, as shown, for example, in FIG. 5.

[0046] Referring to FIG. 4, the present teachings are directed generally to the travel module 164 of the user interface. Generally, the travel module 164 interacts with the meter module 154, the bolus advice module 156 and pump module 166 (and/or the CGM module 168). The travel module 164 can be accessed, for example, via a travel/flight mode button 688 of a main menus screen 660, shown in FIG. 8A and described below. The bolus advice module 156 receives blood glucose measurements from the blood glucose measurement module 400 (FIG. 3) and determines various insulin recommendations in the form of a bolus for a patient based in part on the blood glucose measurements, meals, lifestyle factors, health events, etc.

[0047] Referring to FIG. 5, an activity diagram of behavioral flow for the travel module 164 is illustrated. From a home screen or a main screen 660 (FIG. 8A), the flight mode button 688 (FIG. 8A) can be selected to display flight mode screen (block 500) that includes a button to start flight mode, a button to stop flight mode and a button to go back. Pressing the start flight mode button (block 502), the wireless communication with an external medical device, such as the insulin pump 202, 204 or CGM 200 that is paired with the diabetes manager 104 and currently communicating with the diabetes manager 104, will be stopped. Specifically, if the insulin pump 202, 204 is paired and currently communicating with the diabetes manager 104, the diabetes manager 104 will send a command via the communications module 402 (block 504) to the insulin pump 202, 204 (or other external medical device) to turn off the pump's wireless radio or transceiver and stop the communication. When the diabetes manager 104 sends a command to the pump 202, 204 to turn the radio off and in response an error is received from the pump 202, 204, a warning message that the flight mode failed at the pump will be displayed 202, 204. The diabetes manager 104 will also disable the diabetes manager's 104 own wireless communication, such as turn off Bluetooth radio, for example. If the diabetes manager 104 is not set up to communicate with an external medical device, pressing the start flight mode button (block 502) will simply disable the diabetes manager's 104 own wireless communication. The diabetes manager 104 displays a screen with a notification that the travel/flight mode is on (block 508). If the diabetes manager 104 is paired with the pump 202, the notification also includes a "paired to pump" text message. Additionally, the start flight mode button (block 502) is disabled and grayed out and the stop flight mode button is enabled (block 510). Pressing a confirming or OK button (block 506) returns the diabetes manager 104 to the previous screen (block 520).

[0048] With continued reference to FIG. 5, pressing the stop flight mode button (block 510) while flight mode is enabled, enables the wireless communication and displays a screen with the notification that the travel/flight mode is off (block 512). If the insulin pump 202, 204 is paired with the diabetes manager 104, a notification that the travel/flight mode is off and that the pump is paired will be displayed (block 514). Pressing an OK button (block 516) from the travel mode screens (blocks 512 and 514) displays the previous screen (block 520). Pressing a back button (block 518) from the flight mode screen (block 500) will also display the previous screen (block 520).

[0049] Referring to FIG. 8A, a main menu screen 660 can display time and date information, and various status icons, such as, for example a temperature icon 662, sound icon 664 (including vibrate mode), battery status icon 668 and flight mode icon 670. Some status icons are only displayed when they are enabled or active. For example, if flight mode is enabled, the flight mode icon 670 is displayed. Similarly, the sound and sound/vibrate icons 664 are displayed when the corresponding functions are enabled. The temperature icon 662 is displayed when the diabetes manager 104 detects that the temperature is outside a bG test warning temperature or a bG test lockout range, as defined by a code key for the test strip 306. The battery icon 668 displays the current charge condition of the battery. The main menu screen 660 includes various buttons (mechanical or touch buttons) that can be activated by touch or stylus or other selector device to display a corresponding detailed screen. The button labeled meter 672 represents a graphical user interface for the meter module 154 and interfaces with the BGM module 400. The button labeled pump 676 illustrates a graphical user interface for an external medical device, in this case a pump, as shown in the pump module 166 (FIG. 4) and in FIG. 2 at 202 and 204. The pump button 676 is used to represent graphically any such external medical device, with the insulin infusion pumps 202, 204 and the CGM patch 200 being exemplary external medical devices.

[0050] With continued reference to FIG. 8A, the main menu screen 660 can include a bolus button 674 corresponding to the bolus advice module 156, a "my data" button 678 corresponding to the "my data" module 158, a communications button 680 corresponding to the "device connectivity" (or communications) module 162, and a settings button 682 corresponding to the system setting module 160. The main menu screen 660 can also include a status button 684, and a quick notes button 686. A flight mode button 688 and a help button 690 (indicated as a question mark) can be presented and accessed by swiping the screen along its length to shift the buttons on the main menu screen 660. Some of the preceding set of buttons may go out of view as a result.

[0051] Referring now to FIGS. 6-9, pressing the flight mode button 688 from the main menu screen 660 (FIG. 8A) displays a flight mode screen 600 (FIG. 6) indicating the current status of the flight mode. The flight mode screen 600 includes a "flight mode" heading 602, a "flight mode on" button 604 and a "flight mode off "button 606. If flight mode is enabled, pressing the flight mode on button 604 displays a flight mode on screen 630 (FIG. 7). The flight mode on screen 630 can display a "meter information" heading 632, a flight mode on icon and text at 634 and a text message that meter communication is disabled at 636. Pressing an OK button 638 displays the main menu screen 660. Similarly, if flight mode is not enabled, a screen indicating that the flight mode is off will be displayed (not shown). From the main menu screen 660, pressing the bolus button 674, displays a bolus advice screen. When bolus advice has been programmed in the diabetes manager 104 and set to on status (bolus advice on), the bolus advice screen 720 of FIG. 8C is displayed. Screen 720 includes a heading 722 labeled bolus input with a bolus on icon and temperature icon, and various bolus-related buttons that when pressed display more detailed screens. These buttons include a bG test button 726, a meal time button 728, a carbohydrates button 730, a health events button 732, a basal insulin button 734, and note button 736. Pressing a confirming button 738 displays the previous screen. Pressing a bolus button 740 while in flight mode will display a warning screen 742 (FIG. 8D) with the message that bolus information may be out of date. Similarly, pressing the meter button 672 from the main menu screen 660 while in flight mode will display a warning screen 742 (FIG. 8D) with the message that bolus information may be out of date.

[0052] Referring to FIG. 8B, pressing the bolus button 674 while in flight mode displays a screen 700 having a meter information heading 702 and displaying a bolus warning message at 704 and a text message 706 that there is no communication with the pump and that the bolus history may be out of date. Pressing an OK button 708 displays the previous screen. The warning screens 700 and 742 of FIGS. 8B and 8D may be also displayed from other screens when the user attempts to access information related to the current status of the bolus and bolus history.

[0053] When the flight mode is on, the pump button 676 in the main screen 660, and in any other detailed or status screen where it may be displayed, is disabled and grayed out. Additionally, in flight mode, connectivity to a PC and pairing with devices, and corresponding connectivity buttons are disabled. For example, in the device connectivity screen 750 of FIG. 5, a "manage paired devices" button 758 is disabled and grayed out. Similarly, a pair new devices button 754 for pairing new devices is also disabled and grayed out. Other buttons, such as a connect settings button 756 and a "connect to PC" button 752 can remain enabled in the connectivity screen 750. The device connectivity screen 750 is displayed, for example, by pressing the communications button 680 of the main menu screen 660. Additionally, when the flight mode is on, only status screens with bG status information are displayed. Any status screens that include pump (or other external medical device) status are either not displayed or the pump information is suppressed or grayed out.

[0054] Referring to FIG. 10, an alternative embodiment for managing a flight mode is diagrammatically illustrated. In this embodiment, the handheld diabetes manager 104 can communicate with an external medical device 200A, such as an insulin pump 202, 204 or a CGM patch 200 using radio frequency signals at periodic intervals. Specifically, during usual, non-flight mode, the external medical device 200A and the diabetes manager 104 can communicate with signals (beacon or notification or advertisement signals) 800 initiated and emitted by the external medical device 200A at periodic intervals of time ti. The external medical device 200A then listens for a response or message from the diabetes manager 104 during a short, predetermined listening internal or window. Accordingly, the diabetes manager 104 can communicate with the external medical device 200A during the external medical device's listening period after a beacon 800 is sent. If the listening window associated with a specific beacon is missed, the diabetes manger 104 can communicate with the external medical device 200A during the next listening window. This arrangement conserves power in the external medical device 200A, which typically has great power constraints than the diabetes manager 104.

[0055] To enter flight mode, the diabetes manager sends a command or message 802 to the external medical device 200A to enter a flight or airplane mode during its regular listening window. The external medical device 200A is programmed such that upon receiving the message 802 enters a flight mode that includes listening only windows 804 at periodic intervals t_2 that are typically greater than the regular interval ti. No beacons 800 are transmitted while the external medical device 200A is in flight mode. When it is determined that flight mode can be safely exited, the diabetes manager 104 sends a command 806 to the external medical device 200A during one of its listening windows and instructs the external medical device 200A to resume a regular non-flight mode. Alternatively, a specific time interval after which the external medical device 200A can exit the flight mode can be sent to the external medical device 200A together with the initial command 802 to enter the flight mode. Typically, the interval for exiting flight mode is set for the known duration of the flight and possibly an additional safety interval. After exiting the flight mode, the external medical device 200A then resumes the transmission of beacons 800 at regular periodic intervals ti.

[0056] As used herein, the term module may refer to, be part of, or include an Application Specific Integrated Circuit (ASIC); an electronic circuit; a combinational logic circuit; a field programmable gate array (FPGA); a processor (shared, dedicated, or group) that executes code; other suitable components that provide the described functionality; or a combination of some or all of the above, such as in a system-on-chip. The term module may include memory (shared, dedicated, or group) that stores code executed by the processor.

[0057] The term code, as used above, may include software, firmware, and/or microcode, and may refer to programs, routines, functions, classes, and/or objects. The term shared, as used above, means that some or all code from multiple modules may be executed using a single (shared) processor. In addition, some or all code from multiple modules may be stored by a single (shared) memory. The term group, as used above, means that some or all code from a single module may be executed using a group of processors. In addition, some or all code from a single module may be stored using a group of memories. .

[0058] The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer-readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage.

There is disclosed a handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising: a port configured to receive a test strip for blood glucose measurement; a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement; a communications module that selectively communicates via a wireless data link with an external medical device, the external medical device being physically separated from the diabetes manager; and a user interface module in data communication with the blood glucose measurement module and the communications module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface includes a screen with a flight mode option and wherein when the flight mode option is enabled and the external medical device is paired and currently communicating with the diabetes manager, the user interface module interacts with the communication module to send a command via the wireless data link to the external medical device to turn off wireless communication of the external medical device.

In a development, the external medical device is an insulin pump.

In a development, the external medical device is a continuous glucose monitoring device.

In a development, the flight mode is enabled, pairing with new devices is disabled and corresponding buttons are grayed out in a connectivity screen.

In a development, when the flight mode is enabled, managing of paired devices is disabled and corresponding buttons are grayed out in a connectivity screen.

In a development, when the flight mode is enabled and the diabetes manager sends a command to the external medical device to turn off wireless communication, a failure warning is displayed if the external medical device responds with an error message.

In a development, when the flight mode is enabled and a bolus advice module is accessed via the user interface a warning that the bolus information may be out of date is displayed on the display.

In a development, when the flight mode is enabled and the diabetes manager is not paired with the external medical device, the diabetes manager disables wireless communication of the communications module.

In a development, when the flight mode is enabled and the diabetes manager is paired but not currently communicating with the external medical device, the diabetes manager disables wireless communication of the communications module.

In a development, when the flight mode is enabled, the diabetes manager displays a notification that travel and flight mode is on.

In a development, when the diabetes manager is paired to the external medical device, the notification includes pairing information.

There is disclosed a handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising: a port configured to receive a test strip for blood glucose measurement; a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement; a bolus advice module configured to receive blood glucose measurements from the blood glucose measurement module and operating, in response to an input, to compute an insulin recommendation for a patient based in part on the blood glucose measurements; a communications module that selectively communicates via a wireless data link with an external medical device, the external medical device being physically separated from the diabetes manager; a travel module that cooperatively operates with the communications module to effectuate a flight mode; and a user interface module in data communication with the travel module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface includes a travel screen that allows a user to selectively enable or disable a flight mode, and wherein the user interface module presents, in response to user input to access bolus advice and while the flight mode is enabled, a notification on the display, wherein the notification indicates that an insulin recommendation from the bolus advice module may be based on data that is outdated.

In a development, the external medical device is an insulin pump.

In a development, the external medical device is a continuous glucose monitoring device.

In a development, when the flight mode is enabled, pairing with new devices is disabled and corresponding buttons are grayed out in a connectivity screen.

In a development, when the flight mode is enabled, managing of paired devices is disabled and corresponding buttons are grayed out in a connectivity screen.

In a development, when the flight mode is enabled and the diabetes manager is paired and currently communicating with the external medical devices, the diabetes manager sends a command to the external medical device to turn off wireless communication.

In a development, a failure warning is displayed if the external medical device sends an error message in response to the command to turn off wireless communication.

In a development, when the flight mode is enabled and the diabetes manager is either not paired with the external medical device or paired but currently not communicating with the external medical device, the diabetes manager disables wireless communication of the communications module.

There is disclosed a handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising: a port configured to receive a test strip for blood glucose measurement; a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement; a communications module that selectively communicates via a wireless data link with an external medical device to receive status data pertaining to the operation of the external medical device, the external medical device being physically separated from the diabetes manager; and a user interface module in data communication with the blood glucose measurement module and the communications module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface allows a user to enable or disable a flight mode of the diabetes manager.

In a development, when the flight mode is enabled wireless communication with the external medical device is disabled.

In a development, when the flight mode is enabled, a notification that bolus information may be outdated is displayed when a user inputs a request for bolus advice information.

There is disclosed a handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising: a port configured to receive a test strip for blood glucose measurement; a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement; a communications module that selectively communicates via a wireless data link with an external medical device, the external medical device being physically separated from the diabetes manager; and a user interface module in data communication with the blood glucose measurement module and the communications module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface includes a screen with a flight mode option and wherein the flight mode option is enabled by sending a fl ight mode command to the external medical device during a periodic listening window of the external medical device, the periodic listening window associated with a corresponding periodic beacon from the external medical device to the diabetes manager, and wherein, in response to the flight mode command, the external medical device enters a listening only mode having periodic listening windows and stops sending beacons.

In a development, during the flight mode the periodic listening windows are separated by greater intervals of time in comparison to the listening windows associated with beacons.

In a development, when the diabetes manager sends a command to the external medical device during a listening window to exit flight mode, the external medical device resumes sending beacons at periodic time intervals.
In a development, the diabetes manager is configured to send instructions to exit the flight mode after a specified time interval when sending the flight mode command to the external medical device.

There is disclosed a handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising: a port configured to receive a test strip for blood glucose measurement; a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement; a communications module that selectively communicates via a wireless data link with an external medical device, the external medical device being physically separated from the diabetes manager; and a user interface module in data communication with the blood glucose measurement module and the communications module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface includes a screen with a flight mode option and wherein when the flight mode option is enabled and the external medical device is paired and currently communicating with the diabetes manager, the user interface module interacts with the communication module to send a command via the wireless data link to the external medical device to turn off wireless communication of the external medical device.

In a development, the graphical user interface includes a screen with a flight mode option and wherein the flight mode option is enabled by sending a flight mode command to the external medical device during a periodic listening window of the external medical device, the periodic listening window associated with a corresponding periodic beacon from the external medical device to the diabetes manager, and wherein, in response to the flight mode command, the external medical device enters a listening only mode having periodic listening windows and stops sending beacons.

In a development, during the flight mode the periodic listening windows are separated by greater intervals of time in comparison to the listening windows associated with beacons.

In a development, when the diabetes manager sends a command to the external medical device during a listening window to exit flight mode, the external medical device resumes sending beacons at periodic time intervals.

In a development, the diabetes manager is configured to send instructions to exit the flight mode after a specified time interval when sending the flight mode command to the external medical device.

There is disclosed a method which steps can correspond to instructions and/or operations and/or actions and/or events occuring in or carried out by the system presently described and claimed. There is disclosed a computer program comprising instructions for carrying out one or more steps of the method when said computer program is executed on a suitable computer or medical device. There is disclosed a computer readable medium having encoded thereon such a computer program. There is also disclosed a system comprising means or computer devices and/or medical devices and/or servers adapted to carry out the steps of the method.

The invention can take form of an entirely hardware embodiment, an entirely software embodiment or an embodiment containing both hardware and software elements. Software, includes but is not limited to firmware, resident software, microcode, etc. A computer readable medium may be a computer readable signal medium or a computer readable storage medium. A storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination thereof. A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein. A computer readable signal medium can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device. The computer program may execute entirely on the user's or patient's computer device, partly on the user's or patient's computer device, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server via a network such as the Internet.

[0059] The broad teachings of the disclosure can be implemented in a variety of forms. Therefore, while this disclosure includes particular examples, the scope of the disclosure should not be so limited since other modifications will become apparent to the skilled practitioner upon a study of the drawings, the specification, and the following claims.

CLAIMS

What is claimed is:

1. A handheld diabetes manager having a flight mode that cooperatively interacts with an external medical device, comprising:

a port configured to receive a test strip for blood glucose measurement;

a blood glucose measurement module cooperatively operable with a test strip inserted in the port for blood glucose measurement;

a communications module that selectively communicates via a wireless data link with an external medical device, the external medical device being physically separated from the diabetes manager; and

a user interface module in data communication with the blood glucose measurement module and the communications module and operable to provide a graphical user interface on a display of the diabetes manager, wherein the graphical user interface includes a screen with a flight mode option and wherein when the flight mode option is enabled and the external medical device is paired and currently communicating with the diabetes manager, the user interface module interacts with the communication module to send a command via the wireless data link to the external medical device to turn off wireless communication of the external medical device.

2. The diabetes manager of claim 1, wherein the external medical device is an insulin pump.

3. The diabetes manager of claim 1, wherein the external medical device is a continuous glucose monitoring device.

4. The diabetes manager of claim 1, wherein when the flight mode is enabled, pairing with new devices is disabled and corresponding buttons are grayed out in a connectivity screen.

5. The diabetes manager of claim 1, wherein when the flight mode is enabled, managing of paired devices is disabled and corresponding buttons are grayed out in a connectivity screen.

6. The diabetes manager of claim 1, wherein when the flight mode is enabled and the diabetes manager sends a command to the external medical device to turn off wireless communication, a failure warning is displayed if the external medical device responds with an error message.

7. The diabetes manager of claim 1, wherein when the flight mode is enabled and a bolus advice module is accessed via the user interface a warning that the bolus information may be out of date is displayed on the display.

8. The diabetes manager of claim 1, wherein when the flight mode is enabled and the diabetes manager is not paired with the external medical device, the diabetes manager disables wireless communication of the communications module.

9. The diabetes manager of claim 1, wherein when the flight mode is enabled and the diabetes manager is paired but not currently communicating with the external medical device, the diabetes manager disables wireless communication of the communications module.

10. The diabetes manager of claim 1, wherein when the flight mode is enabled, the diabetes manager displays a notification that travel and flight mode is on.

11. The diabetes manager of claim 10, wherein when the diabetes manager is paired to the external medical device, the notification includes pairing information.

12. The diabetes manager of claim 1, wherein the graphical user interface includes a screen with a flight mode option and wherein the flight mode option is enabled by sending a flight mode command to the external medical device during a periodic listening window of the external medical device, the periodic listening window associated with a corresponding periodic

beacon from the external medical device to the diabetes manager, and wherein, in response to the flight mode command, the external medical device enters a listening only mode having periodic listening windows and stops sending beacons.

13. The handheld diabetes manager of claim 12, wherein during the flight mode the periodic listening windows are separated by greater intervals of time in comparison to the listening windows associated with beacons.

14. The handheld diabetes manager of claim 13, wherein when the diabetes manager sends a command to the external medical device during a listening window to exit flight mode, the external medical device resumes sending beacons at periodic time intervals.

15. The handheld diabetes manager of claim 13, wherein the diabetes manager is configured to send instructions to exit the flight mode after a specified time interval when sending the flight mode command to the external medical device.

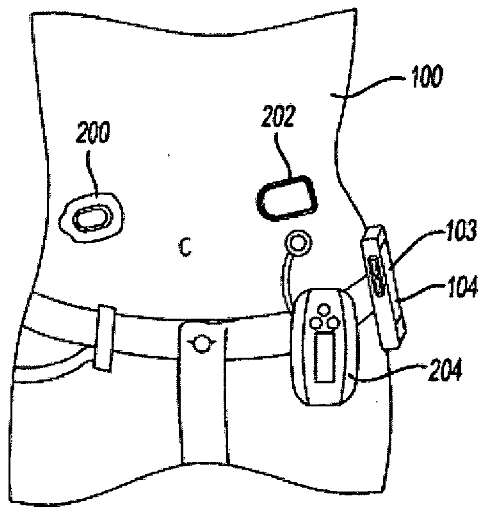

100
200
202
103
104
204

Fig-1

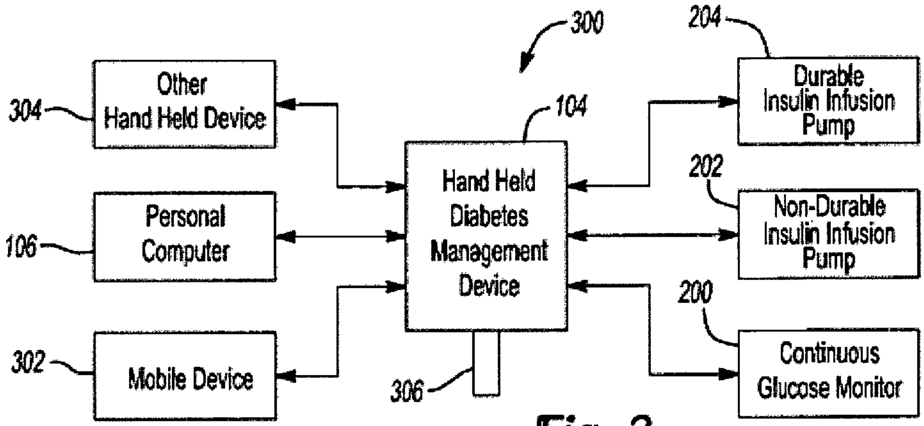

300
204
Other
Hand Held Device
304
104
Durable
Insulin Infusion
Pump
202
Hand Held
Diabetes
Management
Device
106
Personal
Computer
Non-Durable
Insulin Infusion
Pump
200
302
Mobile Device
Continuous
Glucose Monitor
306

Fig-2

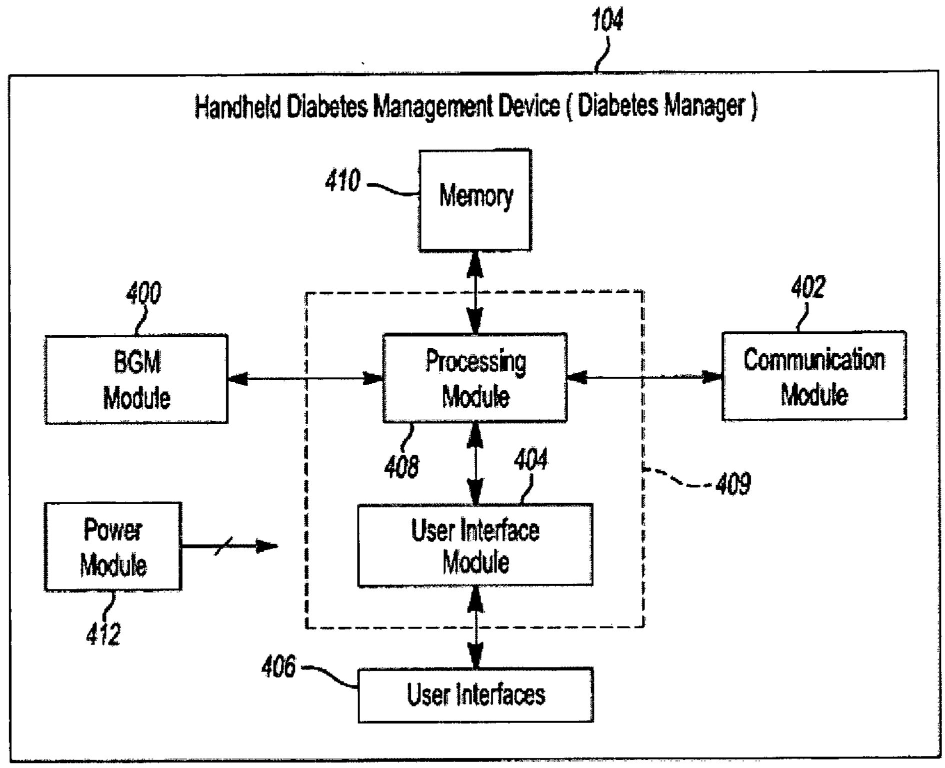

104
Handheld Diabetes Management Device (Diabetes Manager)
410
Memory
400
BGM Module
Processing Module
402
Communication Module
408
404
409
Power Module
User Interface Module
412
406
User Interfaces

Fig-3

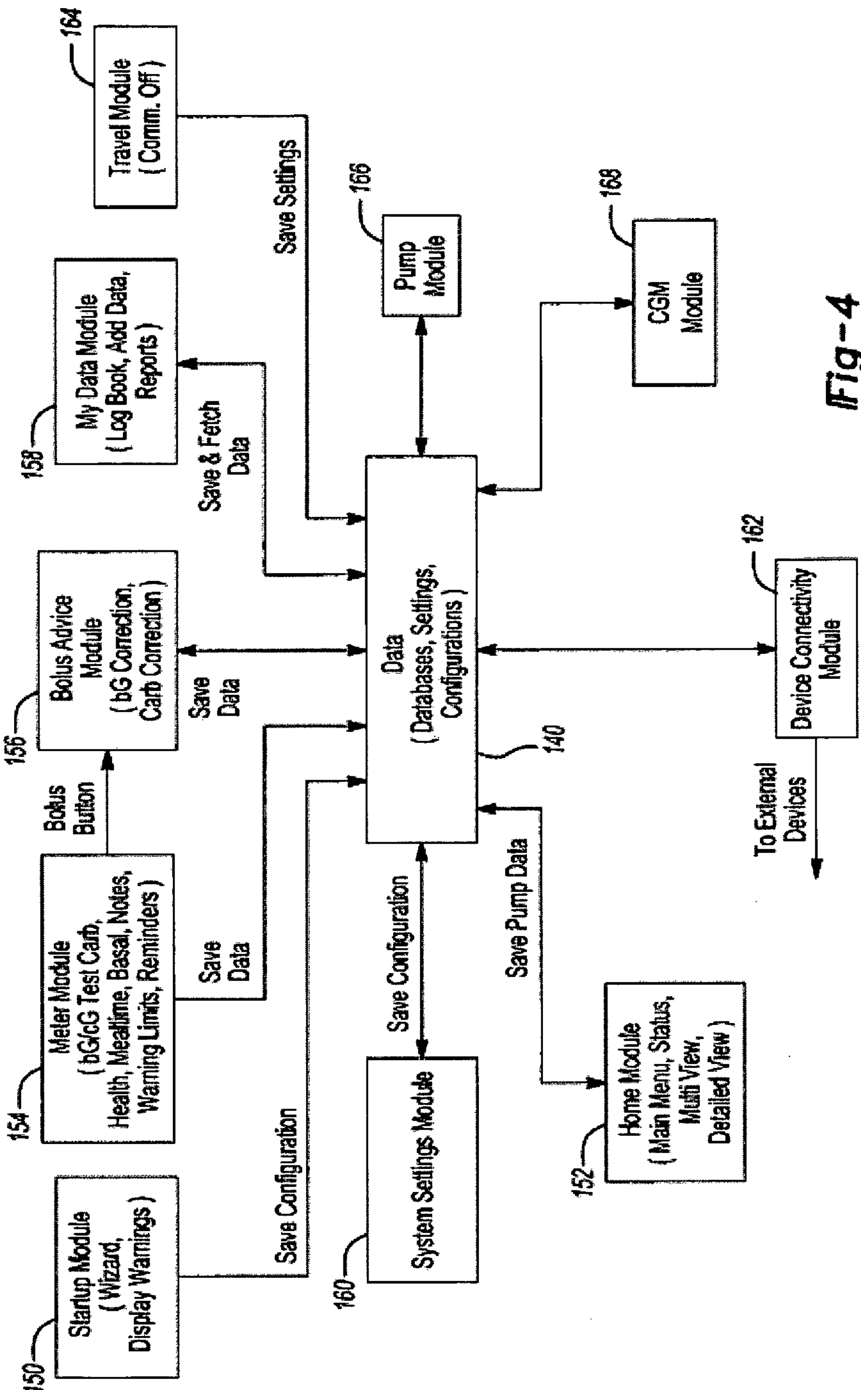

Startup Module (Wizard, Display Warnings)
150
Meter Module (bG/cG Test Carb, Health, Mealtime, Basal, Notes, Warning Limits, Reminders)
154
Bolus Advice Module (bG Correction, Carb Correction)
156
My Data Module (Log Book, Add Data, Reports)
158
Travel Module (Comm. Off)
164
Bolus Button
Save Data
Save Data
Save & Fetch Data
Save Settings
Save Configuration
Save Configuration
Save Pump Data
Pump Module
166
CGM Module
168
Data (Databases, Settings, Configurations)
140
System Settings Module
160
Home Module (Main Menu, Status, Multi View, Detailed View)
152
Device Connectivity Module
162
To External Devices

Fig-4

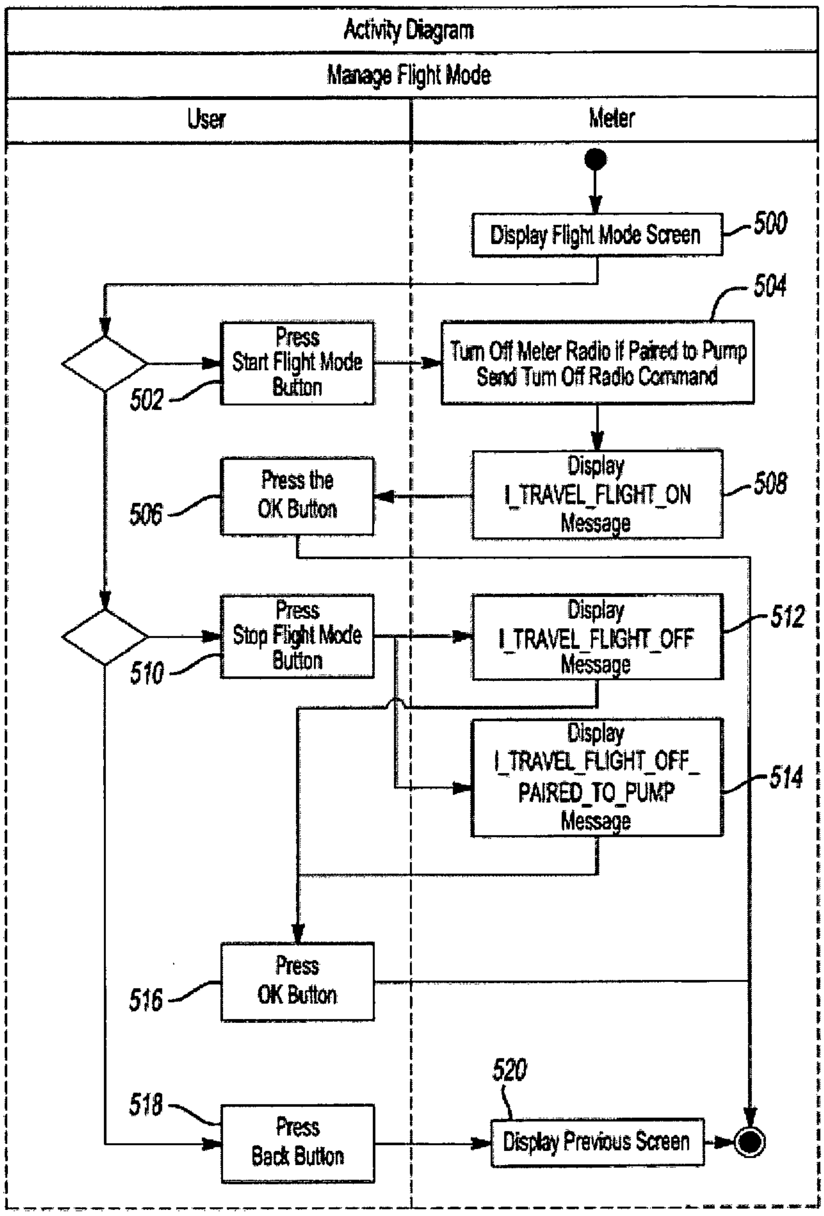

Activity Diagram
Manage Flight Mode
User
Meter
Display Flight Mode Screen
500
504
Press
Start Flight Mode
Button
502
Turn Off Meter Radio If Paired to Pump
Send Turn Off Radio Command
Press the
OK Button
506
Display
I_TRAVEL_FLIGHT_ON
Message
508
Press
Stop Flight Mode
Button
510
Display
I_TRAVEL_FLIGHT_OFF
Message
512
Display
I_TRAVEL_FLIGHT_OFF_
PAIRED_TO_PUMP
Message
514
Press
OK Button
516
518
Press
Back Button
520
Display Previous Screen

Fig-5

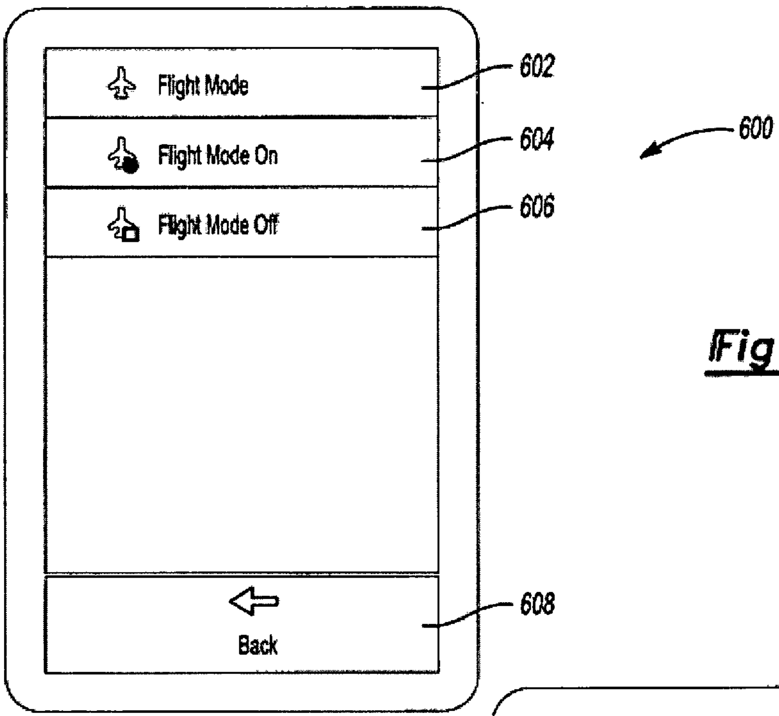

Flight Mode
Flight Mode On
Flight Mode Off
Back
602
604
606
608
600

Fig-6

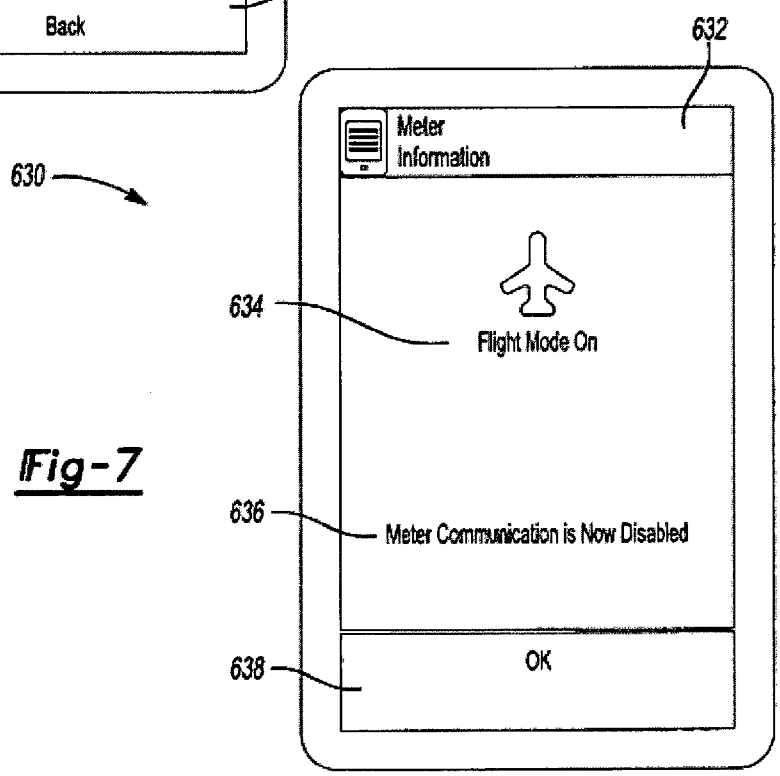
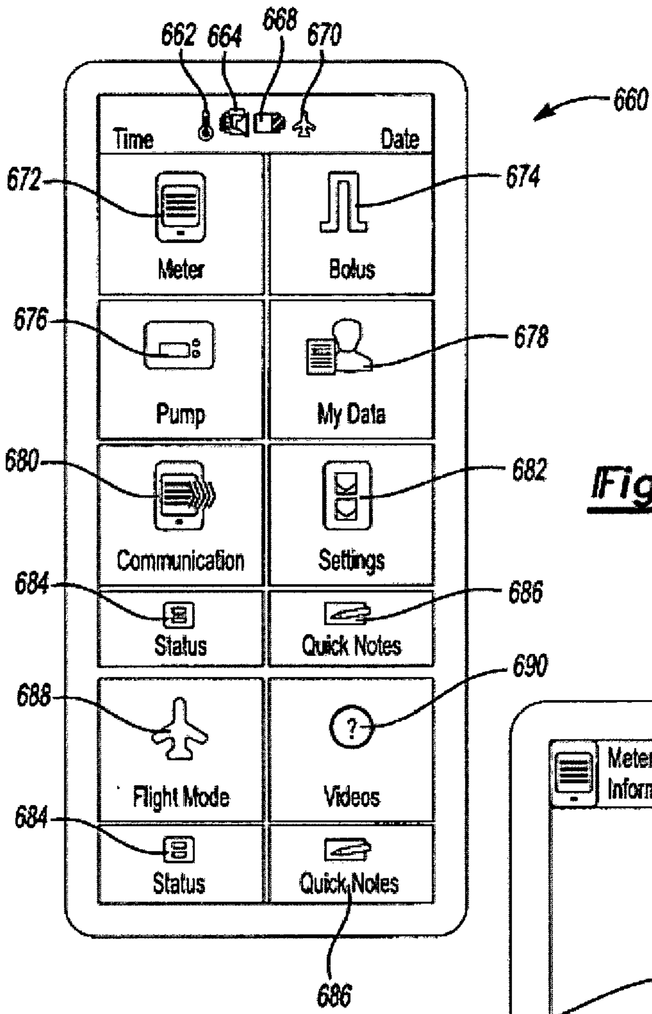
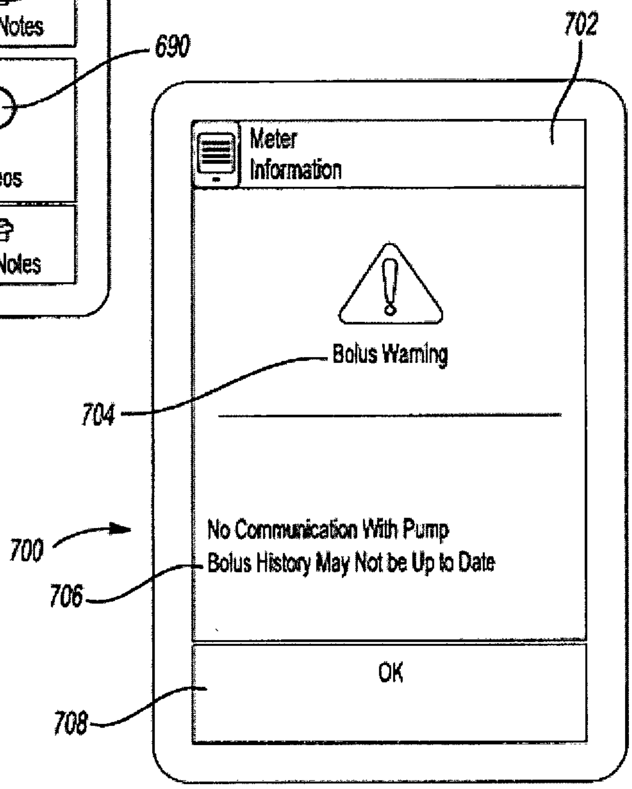

Meter
Information
Flight Mode On
Meter Communication is Now Disabled
OK
630
632
634
636
638

Fig-7



662 664 668 670
660
Time
Date
672
674
Meter
Bolus
676
678
Pump
My Data
680
682
Communication
Settings
684
686
Status
Quick Notes
688
690
Flight Mode
Videos
684
Status
Quick Notes
686

Fig-8A



702
Meter
Information
Bolus Warning
704
700
No Communication With Pump
Bolus History May Not be Up to Date
706
OK
708

Fig-8B

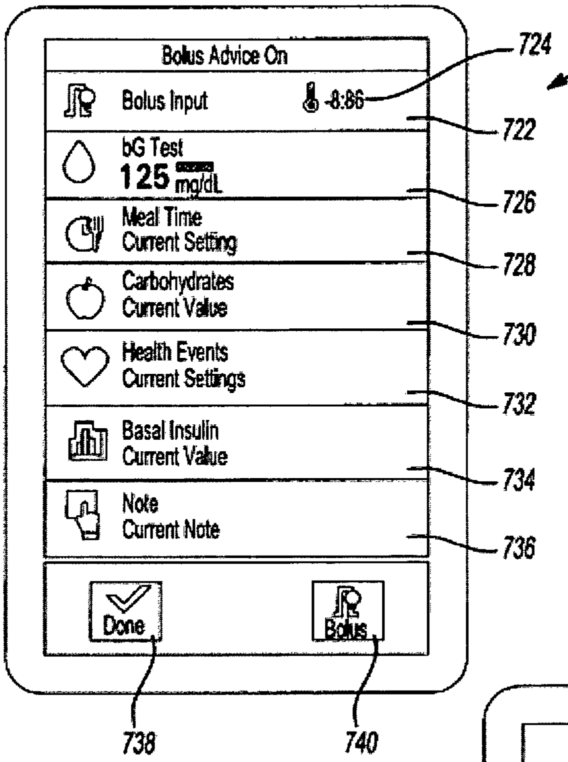

Bolus Advice On
Bolus Input
-8:86
bG Test
125 mg/dL
Meal Time
Current Setting
Carbohydrates
Current Value
Health Events
Current Settings
Basal Insulin
Current Value
Note
Current Note
Done
Bolus
724
720
722
726
728
730
732
734
736
738
740

Fig-8C

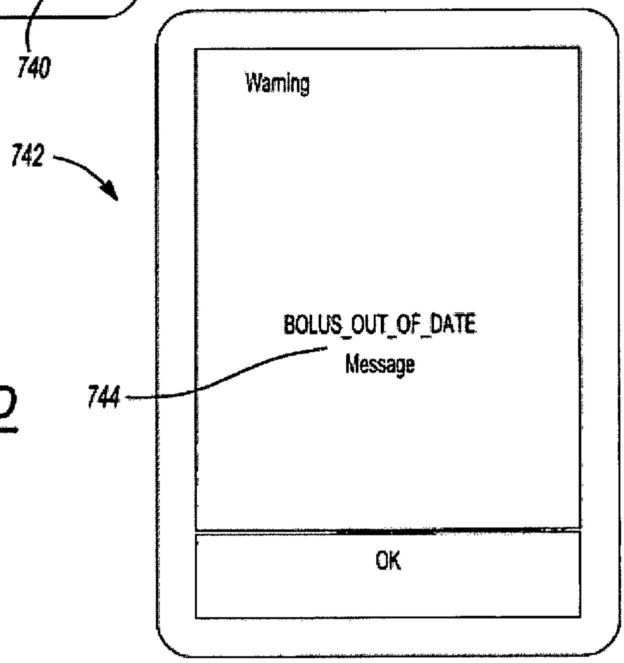

742
Warning
BOLUS_OUT_OF_DATE
Message
744
OK

Fig-8D

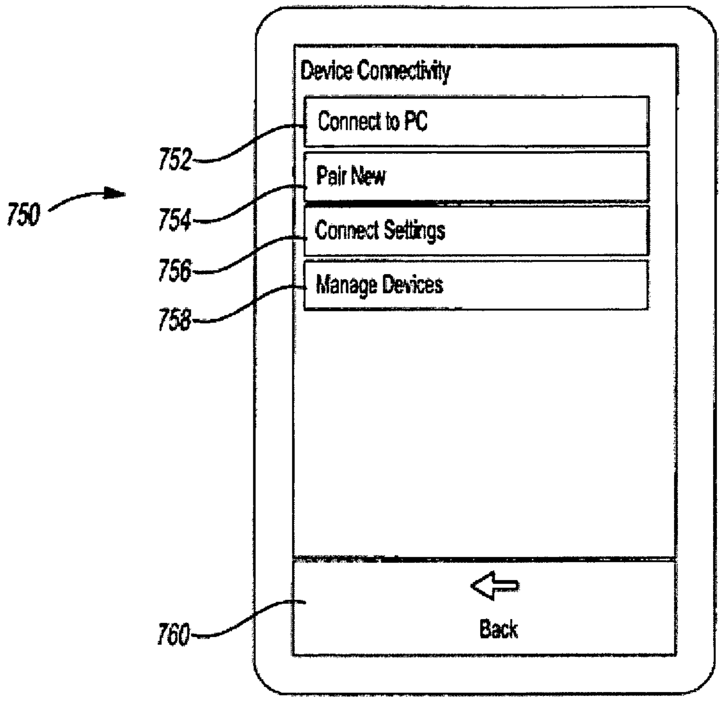

Device Connectivity
Connect to PC
Pair New
Connect Settings
Manage Devices
Back
750
752
754
756
758
760

Fig-9

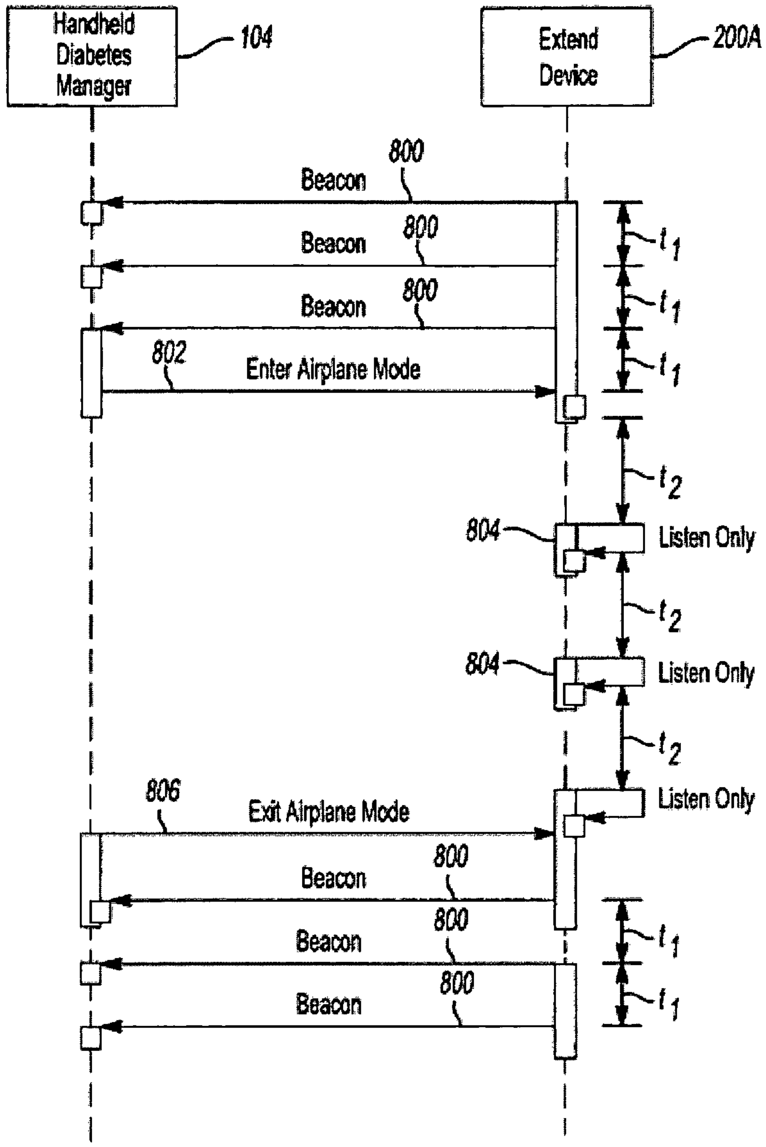

Handheld Diabetes Manager
104
Extend Device
200A
Beacon
800
Beacon
800
Beacon
800
802
Enter Airplane Mode
t_1
t_1
t_1
t_2
804
Listen Only
t_2
804
Listen Only
t_2
Listen Only
806
Exit Airplane Mode
Beacon
800
Beacon
800
Beacon
800
t_1
t_1

Fig-10

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/005186

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/145 A61M5/142
ADD. H04W84/18 H04W84/20

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

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)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011/152970 A1 (JOLLOTA JAMES [US] ET AL) 23 June 2011 (2011-06-23) paragraphs [0001] - [0004], [0020] - [0031], [0034], [0045], [0046]; figure 1 paragraphs [0062] - [0068] -----	1,2,4-6, 8-14
Y	US 2010/052899 A1 (BRUCE ROBERT [US]) 4 March 2010 (2010-03-04) paragraphs [0002], [0003], [0022] - [0027], [0038] - [0041]; figures 1,5 -----	1-15

-/--

[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 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
13 February 2013	11/03/2013

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	Kronberger, Raphael

3

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/312585 A1 (BRUKALO KRZYSZTOF Z [US] ET AL) 18 December 2008 (2008-12-18) paragraphs [0063] - [0064], [0083] - [0084]; figures 13-15,17-20 paragraphs [0039] - [0041], [0043] - [0045], [0050] - [0052]; figures 1-4 paragraph [0053]; figure 6 paragraphs [0056] - [0058] paragraph [0059]; figures 9a,9b -----	1-15
X	US 2010/198143 A1 (ESTES MARK C [US] ET AL) 5 August 2010 (2010-08-05) paragraphs [0062] - [0066], [0073] - [0074], [0077] - [0079] -----	1
X	WO 2009/005957 A1 (ROCHE DIAGNOSTICS GMBH [DE]; HOFFMANN LA ROCHE [CH]; MEIERTOBERENS ULF) 8 January 2009 (2009-01-08) page 22, line 12 - page 27, line 15 page 8, line 26 - page 9, line 21; figures 1,4,5,8 page 14, line 29 - page 16, line 7 -----	1
X	US 2010/292556 A1 (GOLDEN MICHAEL [US]) 18 November 2010 (2010-11-18) paragraphs [0177] - [0179] paragraphs [0012], [0051], [0095], [0107] - [0113], [0120] -----	1
A	EP 2 120 173 A1 (LG ELECTRONICS INC [KR]) 18 November 2009 (2009-11-18) paragraphs [0136] - [0144]; figures 7a,,9,10,11a-11d -----	4,5,10

3

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/ EP2012/0O5 186

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