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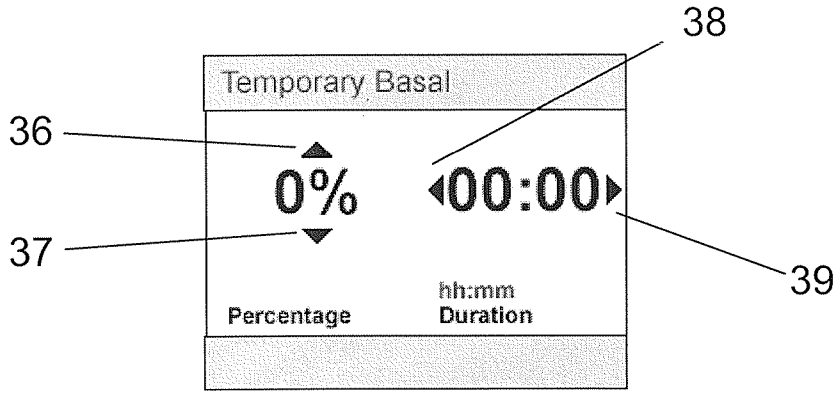

(57) Abstract: The invention provides a user input device (1) for operating a drug delivery- system comprising display means (30) adapted to simultaneously display at least two user controllable settings (65, 66) , and user input means (11, 12, 13, 14) allowing a user to simultaneously and directly set each of the simultaneously displayed user controllable settings. By this arrangement a user can effectively and safely enter related information without having to jump between two or more input screens.

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USER INTERFACE FOR DELIVERY SYSTEM PROVIDING DUAL SETTING OF PARAMETERS

The present invention generally relates to electronically controlled drug delivery systems and devices. In a specific embodiment the invention relates to a medical delivery device in combination with a user operated control interface for controlling the delivery device, however, the different aspects of the present invention is applicable for all types of devices or systems for which a user has to input information in order to control the device or system.

BACKGROUND OF THE INVENTION

In the disclosure of the present invention reference is mostly made to the treatment of diabetes by infusion of insulin, however, this is only an exemplary use of the present invention.

Drug delivery devices for delivering a drug such as insulin to a patient are well known and generally comprise a reservoir adapted to contain a liquid drug, a pump assembly for expelling a drug out of the reservoir to the patient. Such devices are often termed infusion pumps and are normally provided with a user interface allowing a user to control the operation of the pump. The user interface provided on some of the first pumps allowed the user to change a basal infusion rate and program a bolus infusion of a desired size. More recent infusion pumps have provided a number of more advanced features such as a number of basal rates to choose among, temporal basal, bolus calculations based on blood glucose (BG) input and/or meal size, diary functions, food data bases, connectivity to external devices, e.g. BG meter (BGM), PC, PDA or mobile phone.

An infusion pump may basically be a remotely controlled implantable pump or an external pump carried outside the human body and connected thereto by a transcutaneous access device such as a soft cannula or a needle. The external pump may be a traditional durable pump adapted to e.g. be worn in a belt at the waist of the user, this allowing the user to operate the pump by directly accessing the user interface on the pump, e.g. in order to change infusion rate or to program a bolus infusion. However, the pump may also be worn hidden under clothing this making operation more difficult. Correspondingly, it has been proposed to provide an infusion pump of the durable type with a wireless remote controller allowing the user to access some or all of the functionality of the pump, see for example US patent 6,551,276, US 2005/0022274 and US 2003/0065308, which are hereby incorporated by ref-

erence, the latter disclosing an ambulatory medical device (MD) adapted to receive control messages from a communication device (CD).

As traditional durable external pumps are relatively expensive it has been proposed to provide disposable pumps which may be attached directly to the skin of the user by means of an adhesive at a lower surface of such a device. A disposable pump may be provided to the user prefilled or it may be adapted to be filled by the user. Correspondingly, the pump may be a unitary fully disposable device or it may comprise two or more portions adapted to be used for different periods of time. Thus, for a skin-mountable device, typically comprising an adhesive allowing the device to be attached directly to the skin of the user, a remote controller would appear even more desirable as it would reduce the cost of providing a full user interface on the pump. Correspondingly, EP 1 177 802 and US patent 6,740,059, which are hereby incorporated by reference, disclose semi-disposable and fully disposable infusion devices (which may be termed a local device or unit) which are intended to be operated primarily or entirely by a wireless remote controller (which may be termed a remote device or unit). As the delivery device thus does not have to be provided with a user interface such as a display and keyboard, the semi-disposable or disposable infusion can be provided more cost-effectively.

Having regard to the above, it is the object of the present invention to provide a user interface for and methods of operation for a drug delivery device which assures one or more of the following: easy to learn, intuitive and easy to use, fast to use, ease of entering information, ease of navigating, easy of retrieving information. It is a further object to provide a user interface including enhanced display/patient notification features, safety features, and/or medical device programming/communication features.

DISCLOSURE OF THE INVENTION

In the disclosure of the present invention, embodiments and aspects will be described which will address one or more of the above objects or which will address objects apparent from the below disclosure as well as from the description of exemplary embodiments.

Thus, in a first aspect a user input device for programming a parameter profile for a drug delivery system is provided, comprising display means adapted to graphically display a parameter profile showing a parameter value as a function of time, the profile comprising at

least one segment, each segment indicating a period of time and an associated parameter value, each segment having a starting point of time and an ending point of time, the display means being adapted to also show an indicator (or cursor) arranged corresponding to a given parameter value for a given point of time. The input device further comprises first user input means allowing a user to move the indicator corresponding to a desired point of time, and second user input means allowing a user to move the indicator corresponding to a desired parameter value. By this arrangement the user can graphically draw a continuous profile for a desired period of time by moving the indicator on the display corresponding to the desired period of time, the drawn profile graphically displaying the infusion profile. This arrangement provides both ease of use as well as it requires a positive action of the user (i.e. to move the indicator) to program a parameter for any period of time, this preventing that incorrect values are erroneously accepted. The term "given point of time" also embraces given period of time depending e.g. of the resolution of the indicator and/or display means. The profile may be displayed in any convenient way, e.g. using line segments or columns, e.g. a segment may be represented by a line or one or more columns representing e.g. 30 or 60 minutes. The display means may be of any suitable type, e.g. in the form of one or more LCD screens.

The display means may be adapted to display a first axis representing time and a second axis representing the parameter, wherein the first user input means allows the user to move the indicator corresponding to the first axis, and the second user input means allows the user to move the indicator corresponding to the second axis. The first axis may be oriented "horizontally" for a preferred user orientation of the device with the second axis oriented "vertically". In a specific embodiment the parameter profile is an infusion profile and the parameter value is an infusion rate. For such a device the display may show a profile for a 24 hour period, e.g. from 0:00 to 24:00 with the first input means moving the indicator (e.g. a cursor) in steps of e.g. 30 or 60 minutes. For such a configuration a single segment may span from 24 hours to 30 or 60 minutes. Typically the x-axis will be used to indicate time and the y-axis to indicate infusion rate. A starting point of time may conventionally be a lower time value, e.g. 4:30, and an ending point of time is a higher time value, e.g. 7:00. The user input means may be uni-directional, e.g. allowing the indicator to move in only one direction and then jumping from 24:00 to 0:00, or the first user input means may be bi-directional comprising a first pair of input means allowing a user to move the indicator in opposite directions in respect of time, and the second user input means may comprise a second pair of input means allowing a user to move the indicator in opposite directions in respect of the parameter value.

The input device may be adapted to program a first segment for a parameter profile by (i) moving the indicator to a first parameter value, and (ii) moving the indicator from a first starting point of time to a first ending point of time, thereby programming a first segment for a parameter profile having the first parameter value between the first starting point of time and the first ending point of time. The input device may be further be adapted to program a second segment for an parameter profile by (iii) moving the indicator from the first to a second parameter value, and (iv) moving the indicator from the first ending point of time, representing a second starting point of time, to a second ending point of time, thereby programming a second segment for an infusion profile having the second parameter value between the second starting point of time and the second ending point of time.

In a further embodiment the user input device may be adapted to program a change for an existing parameter profile by (i) arranging the indicator on the graphically displayed existing parameter profile at a desired location representing a change starting point of time and an initial parameter value, (ii) moving the indicator to a desired change parameter value, and (iii) moving the indicator from the change starting point of time to a change ending point of time, thereby programming a changed segment for a parameter profile having the change parameter value between the change starting point of time and the change ending point of time. The user input device allow the further step of (iv) moving the indicator from the change parameter value to the initial parameter value corresponding to the change ending point of time. As appears, the drawing of the final “vertical” portion of the graphical profile may be either automatic or manual.

The first user input means may comprise a first pair of input means allowing a user to move the indicator in opposite directions in respect of time, and the second user input means comprises a second pair of input means allowing a user to move the indicator in opposite directions in respect of the parameter value. The first and second pair of input means may be provided by either a four-way rocker switch or a four-way joystick providing the.

In the above disclosure of an aspect of the invention, a user input device for creating a profile showing a parameter value (e.g. infusion rate) as function of time, however, in a more general aspect user input device for programming a profile for a drug delivery system is provided, comprising display means adapted to graphically display a first parameter as a function of a second parameter, the profile comprising at least one segment, each segment indi-

cating an interval for the second parameter and an associated value for the first parameter, each segment having a starting value and an ending value for the first parameter, the display means being adapted to show an indicator arranged corresponding to a given value for the first respectively the second parameter. The device further comprises first user input means allowing a user to move the indicator corresponding to a desired value for the second parameter, and second user input means allowing a user to move the indicator corresponding to a desired value for the first parameter, whereby the user graphically can draw a continuous profile for a desired interval for the second parameter by moving the indicator on the display corresponding to the desired interval, the drawn profile graphically displaying the programmed profile.

In a yet further aspect a drug delivery system is provided, comprising a user input device as in any of the previous claims, a reservoir adapted to contain a drug, an expelling assembly adapted for cooperation with the reservoir to expel drug out of the reservoir, and at least one processor adapted to control the expelling device in accordance with a programmed infusion profile.

Depending on the system configuration the system may comprises one or more processors wherein the different tasks of supporting the user interface and controlling the delivery means may be performed by a single processor or two or more processors in combination.

In the context of the present application and as used in the specification and claim, the term processor covers any combination of electronic circuitry suitable for providing the specified functionality, e.g. processing data and controlling memory as well as all connected input and output devices. A processor will typically comprise one or more CPUs or microprocessors which may be supplemented by additional devices for support or control functions. For example, in case a communication interface is provided (e.g. wireless), the transmitter and receiver may be fully or partly integrated with a processor, or may be provided by individual units. Each of the components making up the processor circuitry may be special purpose or general purpose devices.

The system may comprise a delivery unit in which the reservoir and the expelling assembly are arranged, and a control unit comprising the display and user input means, the delivery and control units being adapted to communicate with each other, e.g. by wire, RF or IR. Al-

ternatively, the system comprises a delivery unit in which the reservoir and the expelling assembly are arranged, the delivery unit further comprising the display and user input means.

The drug may be in the form of a fluid drug or a powder drug. For a fluid drug the expelling assembly may be in the form of a pump forcing or drawing drug from the reservoir and into a patient through a transcutaneous access device. For a fluid drug or a powder drug the expelling assembly may also be semi-automatic dispensing a given amount of drug from a reservoir after which a flow of air created by the person using the system will transport the powder drug to the desired location, e.g. the lungs or other portion of the airways.

The reservoir for a fluid drug may be any suitable structure adapted to hold an amount of a fluid drug, e.g. a hard reservoir, a flexible reservoir, a distensible or elastic reservoir. The reservoir may e.g. be prefilled, user fillable or in the form of a replaceable cartridge which again may be prefilled or fillable. The reservoir may also be in the form of a pressurized aerosol container. For a powder drug the reservoir may in the form of a blister or a plurality of individual blisters.

For a fluid drug the system may comprise or be adapted to cooperate with a transcutaneous access device which may e.g. be in the form of a hollow steel needle, a soft cannula in combination with an external or internal introduction needle, or a micro-needle array.

The user input means may be in the form of a keyboard comprising one or more user accessible keys, however, alternative a touch display or voice recognition may be used. The user input means may allow a user to bi-directionally set each of the simultaneously displayed user controllable settings, e.g. dial up and down. For example, when setting a temporal basal infusion comprising the two parameters duration and adjustment percentage, the actually displayed duration, e.g. 1:00 hour may be placed between a set of arrows (as in < 1:00 >) with the input means corresponding to a corresponding set of arrow-markings. The adjustment percentage may be provided with a pair of up-down arrows arranged above and below that value. In case a touch sensitive display is used, the user may tap directly on the arrow indices.

In a further aspect the invention provides a method for programming a parameter profile, comprising the steps of: (a) providing a user input device including display means adapted to graphically display a parameter profile showing a parameter value as a function of time, and

(b) graphically drawing a continuous profile for a desired period of time, the drawn profile graphically displaying the programmed infusion profile. The display means may be adapted to display a profile comprising at least one segment, each segment indicating a period of time and an associated parameter value, each segment having a starting point of time and an ending point of time. The display means may further be adapted to show an indicator arranged corresponding to a given parameter value for a given point of time. The continuous profile may be drawn by moving the indicator using the steps of: (i) moving the indicator to a desired point of time using first user input means, and (ii) moving the indicator to a desired parameter using second user input means. As for the user input device the parameter profile may be an infusion profile and the parameter value an infusion rate.

In a second aspect a user input device for operating a drug delivery system is provided, comprising display means adapted to simultaneously display a plurality of menu items, display means adapted to display at least one user settable drug delivery parameter, and user input means allowing a user to directly select each of the simultaneously displayed menu items, wherein the user input means comprises a keyboard comprising at least one pair of user input keys, each pair allowing a user to bi-directionally set a user settable drug delivery parameter when user controllable settings are displayed. By this arrangement a compact and economical yet easy to use user interface is provided.

The keyboard may comprise two pairs of user input keys, each pair allowing a user to bi-directionally set a user settable drug delivery parameter, the two pairs being arranged graphically with an upper and a lower key respectively a left and a right key. The user input means may comprise either a four-way rocker switch or a four-way joystick, the respectively ways corresponding to four user input keys. The rocker switch may also be “virtual” and provided by a membrane keyboard. To allow easy and intuitively selection of a given menu item, the individual menu items may have a predefined location on the display means, the system comprising correspondingly arranged user input means allowing a given menu item to be selected by activating the correspondingly arranged user input means.

In a specific embodiment the display menu items are graphically arranged corresponding to the user input keys and being directly selectable by the corresponding key.

At least one menu item may give direct access to a user settable drug delivery parameter. For example, at least one user settable drug delivery parameter is taken from the group

comprising: (a) a bolus size to be delivered, (b) an infusion profile for a bolus to be delivered, (c) a duration for an infusion profile, (d) an infusion rate for an infusion profile, (e) a selectable pre-programmed infusion profile, (f) a profile segment for a pre-programmed infusion profile (e.g. a temporal basal rate), (g) a time-location (e.g. a start and stop time) for an infusion profile or rate, and (h) an infusion rate for an infusion profile. Further, at least one menu item may give direct access to a pair of user settable drug delivery parameters from the group comprising: (a) a bolus size to be delivered and an infusion profile therefore, (b) a duration for an infusion profile or segment and infusion rate or change therefore, (c) a selectable pre-programmed infusion profile and profile segment therefore, and (d) a time-location for an infusion profile and an infusion rate therefore (e.g. when programming an infusion profile).

In a specific embodiment the display means is adapted to simultaneously display at least two user controllable settings, and the user input means allows a user to simultaneously and directly set each of the simultaneously displayed user controllable settings.

To aid the user in relating a displayed user settable drug delivery parameter with the input keys provided for setting the parameter, at least one displayed user settable drug delivery parameter may be associated with a pair of indices indicating bi-directional adjustment of a setting, a pair of user input keys being correspondingly marked, e.g. up-down or left-right.

The above-described input device for operating a drug delivery system may be provided as part of a drug delivery system is provided. The actual configuration of the system, the reservoir, the expelling assembly, the display and input means, and the processors may be provided as described above in respect of the first aspect.

In a third aspect a user input device for operating a drug delivery system is provided, comprising display means adapted to simultaneously display at least two user controllable settings, and user input means allowing a user to simultaneously and directly set each of the simultaneously displayed user controllable settings. By this arrangement a user can effectively and safely enter related information without having to jump between two or more input screens.

The term “user controllable setting” covers different kind of “settings”, e.g.: (1) “Operational settings”, i.e. entering of parameters (e.g. a numeral value or a time value for e.g. a bolus, a

bolus calculation, a temporal basal rate, an infusion profile, a CIR or ISF value), or the election of options having a direct influence of the infusion of a drug (e.g. direct or extended bolus), (2) "Information settings", e.g. entering of diary information, e.g. time and amount for medication, meal or exercise, and (3) "presentational settings", e.g. setting a display to display a desired kind of information, e.g. to display a given kind of information (e.g. a BG value) for a give time period, e.g. for a day or for a week. By the definition "simultaneously and directly" is meant that the settings can be set without having to navigate through a menu or pre-select items.

The user input means may be adapted to allow a user to bi-directionally set each of the simultaneously displayed user controllable settings, using up-down or back-forth input keys. As stated above, at least one user controllable setting may represent a drug delivery parameter.

To aid the user in relating a displayed user settable drug delivery parameter with the input keys provided for setting the parameter, at least one displayed user settable drug delivery parameter may be associated with a pair of indices indicating bi-directional adjustment of a setting, a pair of user input keys being correspondingly marked, e.g. up-down or left-right.

Two user controllable settings may represent a pair of drug delivery parameters from the group comprising: (i) a bolus size to be delivered and an infusion profile therefore, (ii) a duration for an infusion profile and infusion rate therefore, (iii) a time-location for an infusion profile and an infusion rate therefore.

The user input device may comprise a memory for storing data, wherein at least two user controllable settings are used to locate data, e.g. they may represent a pair of data storage parameters from the group comprising: (i) a type of data and a period of time related thereto, or (ii) a value for a parameter and a period of time related thereto.

The above-described input device for operating a drug delivery system may be provided as part of a drug delivery system is provided. The actual configuration of the system, the reservoir, the expelling assembly, the display and input means, and the processors may be provided as described above in respect of the first aspect.

As used herein, the term "drug" is meant to encompass any drug-containing flowable medicine capable of being passed through a delivery means such as a cannula, hollow needle or

inhalation conduit in a controlled manner, such as a liquid, solution, gel, fine suspension or a powder. Representative drugs include pharmaceuticals such as peptides, proteins, and hormones, biologically derived or active agents, hormonal and gene based agents, nutritional formulas and other substances in both solid (dispensed) or liquid form. In the description of the exemplary embodiments reference will be made to the use of insulin. Correspondingly, the term "subcutaneous" infusion is meant to encompass any method of transcutaneous delivery to a subject.

BRIEF DESCRIPTION OF THE DRAWINGS

In the following the invention will be further described with reference to the drawings, wherein

fig. 1 shows a user input device in the form of a remote control (RC),
figs. 2A and 2B show shortcut menu (SM) respectively main menu (mm) screens for a RC,
fig. 3 shows a flowchart for a RC user interface architecture,
fig. 4 shows different paths to an “edit bolus” menu,
fig. 5 shows use of the build-in BG meter in order to enter a bolus,
fig. 6 shows temporal basal (TB) options by which the user can set or cancel a TB,
figs. 7A and 7B show how the user can view, edit or redefine the basal rate (BR),
fig. 8 shows the options available to the user for the diary function,
fig. 9 shows the options available to the user for the reminder function,
fig.10 shows the options available to the user for the statistics function,
fig.11 shows the different set-up options,
fig. 12 shows a dual-mode bolus input screen,
fig. 13 shows how a TB rate is programmed using a dual-mode screen,
fig. 14 shows a status screen indicating that both a bolus and a TB rate are being delivered,
figs. 15-18 show further types of dual-mode screens,
figs. 19-23 show aspects of the diary function,
fig. 24 shows the patch unit of fig. 5 in greater detail,
fig. 25 shows the patch unit of fig. 7 in an actuated state,
fig. 26 shows a patch unit with a pump unit partly attached,
fig. 27 shows the pump unit of fig. 9 fully attached to the patch unit,
fig. 28 shows in an exploded view a pump unit,
fig. 29 shows a schematic representation of a process unit and a control unit,
figs. 30A and 30B show a general information architecture for a drug delivery system, and

figs. 31A and 31B show the information structure for an initial setup of the system.

In the figures like structures are mainly identified by like reference numerals.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

When in the following terms such as "upper" and "lower", "right" and "left", "horizontal" and "vertical" or similar relative expressions are used, these only refer to the appended figures and not to an actual situation of use. The shown figures are schematic representations for which reason the configuration of the different structures as well as there relative dimensions are intended to serve illustrative purposes only.

The present invention relates to a user input device adapted to cooperate with a drug delivery device (e.g. a drug delivery pump) in a drug delivery system.

Fig. 1 shows a user input device 1 in the form of a remote control (RC) comprising an LCD display 30 arranged at the upper portion of the unit and buttons arranged beneath the display. The placement close to the centre line is chosen for ergonomic reasons. The remote comprises a rocker switch 10 and a left ACCEPT key 21 as well as a right ESCAPE key 22. The rocker switch is the fundamental navigation button and is a four-way switch having four areas 11, 12, 13, 14 supporting respectively the directions: UP-DOWN and LEFT-RIGHT. Indeed, the four areas of the rocker switch may be replaced with a number of keys arranged in any desired configuration. The vertical axis functions to e.g. (i) scroll up/down in a menu, and (ii) increase or decrease a number. The horizontal axis LEFT RIGHT is used for e.g. (i) scrolling in time, and (ii) changing time related or secondary parameters. The accept button is the fundamental "Yes" button and functions as (i) go forth, enter, select, accept or confirm, and (ii) zoom-in in views. The Escape button is the fundamental "No" button and has the functions (i) no, escape, step back, exit or undo, and (ii) zoom-out in views. Additional functions may be added to the ones described. The display is a dot matrix display and may be a monochrome, greyscale or colour display. The display shows the main screen (MS) which normally is displayed when the RC is turned on. The MS serves to indicate to the user the status of the system controlled by the RC. The screen has a general configuration also used in many other situations of use (see below). More specifically, the MS comprises a central "split screen" area with left and right portions 31, 32 as well as an upper and a lower information bar 33, 34. In the shown view the MS displays in the upper bar the remaining amount of

insulin in the insulin pump to which the RC is currently paired as well as the battery status for the RC. The split screen shows the current time and date, and the lower bar shows the current basal infusion rate for the paired pump. Depending on the selected mode of the RC, the split screen can have a "dual mode" configuration (see below) used for a number of input screens.

Depending on the status of the system other information may be displayed, e.g. status indication for an ongoing bolus and/or an ongoing temporal basal infusion rate.

The RC is further provided with an upper port 40 for a build-in BG meter allowing a BG strip to be inserted and a BG value to be determined. The RC may further be provided with one or more keys at e.g. the sides allowing less commonly used functions to be activated, e.g. on-off and keyboard lock. The RC may be powered by replaceable or rechargeable batteries.

When the remote is turned on it will check whether an initial setup has taken place (e.g. entering personal limits and alarm settings) and if so go to the main or "status screen" as described above. When pressing any key the display will show a shortcut menu (SM) screen having a number of items 51, 52, 53, 54 at predefined locations as shown in fig. 2A. As described below the text in this screen will depend on the actual bolus condition or basal setting. Using the rocker switch the user can go directly to any of the four indicated items: bolus, profiles, temp (i.e. temporal) basal, or menu screens. When the menu screen is selected a main menu is shown (see fig. 2B) allowing the user to scroll to a desired menu item 55 and select it, e.g. diary, statistics, reminders or setup. Having a section with a traditional menu makes it easy to add or remove features without breaking up the entire structure. Further, such a menu structure is also makes it easy to provide a customizable interface allowing health care professionals to control how much functionality should be available to a given user. This said, the shortcut menu type of fig. 2A may be used also for one or more sub-levels of menus, e.g. the four menu items of fig. 2B may be displayed corresponding to fig. 2A. One or more of the four sub-level shortcut menus may then be provided with a further level of shortcut menus.

As appears, the four-way rocker switch and the SM screen represents a concrete embodiment of a user input device in which a display is adapted to simultaneously display a plurality of menu items having a predefined location on the display means, and user input means allowing a user to directly select each of the simultaneously displayed menu items. However,

as will be explained in detail below, the present user interface provides a high degree of user friendliness by combining the menu selection means (e.g. the rocker key), with a second user interface in which the display means is adapted to display at least one user settable drug delivery parameter, wherein the user input means comprises a keyboard comprising at least one pair of user input keys, each pair allowing a user to bi-directionally set a user settable drug delivery parameter when user controllable settings are displayed.

Fig. 3 shows an embodiment for a general user interface (UI) architecture for the remote controller (RC). The UI has a main screen (MS) which normally is displayed when the RC is turned on. The MS may be the standard MS or it may show additional information relating to an ongoing bolus or temporal basal (TB) rate. When the RC is switched on for the first time, the user is guided to the initial setup menu. From the MS the user can by pressing any key go to the shortcut menu (SM) from which the specific main functions can be chosen, either directly or via a main menu (MM). As indicated, an ongoing bolus or TB rate will influence the options in the SM.

Turning to the individual main functions, fig. 4 shows how the user can be guided to the "edit bolus" menu in three different ways: (1) after having determined a blood glucose value (BG) using the RC strip port (or alternatively by an external BG meter), (2) directly by the user, or (3) by using the bolus calculator (selected via the MM). In addition, a running bolus can be aborted.

Fig. 5 shows how the build-in BG meter is used and how it can be used to enter the bolus menu. When a BG strip is inserted the user is asked for calibration and type data, however, with no input the RC swiftly proceeds to the "request blood". If a sufficient amount of blood is placed on the strip and a BG within the set normal range is produced and displayed, the user is offered the option to go to the bolus calculator or leave the BG menu. If the bolus option is chosen the user is requested to enter meal carbohydrates (if any) and the RC will calculate and display a suggested bolus size. The user can then use this information as guidance when freely setting a bolus of a desired size.

Fig. 6 shows the two TB options by which the user can set or cancel a TB. How to set a temp basal is described below with reference to figs. 13.

Figs. 7A and 7B show how the user can either: (1) view the basal rate (BR) profile, (2) edit the BR profile, or (3) redefine the BR profile. Instead of a recurring one-day BR profile the disclosed system uses a 7-day BR profile which is set for the first time during the initial set-up. Via the "edit BR profile" function the user can select a single day and change the BR profile of that day. Alternatively, the user can decide to re-set the entire 7-day profile. If the profile is the same for every day, once the first (e.g. Monday) BR profile is entered, the user can copy the profile for the subsequent days. How to set a daily BR profile is described below with reference to figs. 17 and 18.

In the MM the user can select between "bolus calculator" (see above), "diary" (in the flow charts also named "log book"), "reminder", "statistics" and "setup".

Fig.8 shows the options available to the user for the diary function. In the "view" option the display opens with a 7-day view showing a pre-selected type of information, e.g. BG values, or combination of types of information, e.g. BG values and bolus. For a given type of information, each event is represented by a specific icon. The user now has to two options, either to select another type of information to be displayed or select a day view showing essentially the same information but in a higher resolution over the 24 hours of the day. The user can also select a different type of information when in the day view state. When in the day view the user can select any of the displayed icons by browsing and then request the associated detailed information to be displayed in an "action card" view. When an action card is displayed the user can browse through the previous or next card for the selected type of information, both for the selected day but also for the previous or subsequent day. When a given action card is selected the user can choose (if allowed) between different options for the displayed information: edit, delete or hide. In the "add" option the user selects a day and a type of information. The user is then presented with an "edit action card" view allowing the user to enter the relevant type of information for the selected type of information, e.g. meal size and time.

Fig. 9 shows the options available to the user for the reminder function. The reminder function works essentially the same way as the diary function, i.e. the user is presented with week view, day view and "reminder card" (instead of action card) options as well as type of reminders. Correspondingly, the user can edit and add reminders as set out above for the action card information. In addition, when setting a new reminder, the user has a recurrence option, i.e. daily or weekly.

Fig.10 shows the options available to the user for the statistics function. The statistics function can display one or more average values, e.g. for 14 or 30 days, for a selected type of information, e.g. daily basal or daily bolus.

Fig.11 shows the different options available to the user for the setup function, e.g. time and date, regional settings and alarms.

As described with reference to figs. 29 the pump is controlled via the RC, this allowing new settings to be transmitted to the pump, however, the communication is two-way allowing also the pump to transmit information to the RC, e.g. alarms. Especially for the latter, it is important that communication is upheld between the two units. As shown in fig. 23, when communication is lost for more than a first predetermined amount of time, e.g. 10 minutes, a first "connection lost" warning will appear in the main screen. If communication is not re-established within a second predetermined amount of time, e.g. 2 hours, a second "connection lost" warning will appear in the main screen and an audible and/or tactile alarm will be sounded.

In the following some of the input options will be described in order to illustrate different user oriented aspects of above described user input device.

When the user desires to directly enter a bolus to be infused, i.e. without using the bolus calculator, the bolus menu point in the SM is selected by using the UP key which brings the user to the set bolus input screen which is of the "dual mode" configuration, see e.g. fig. 13. A dual mode screen displays two user controllable settings, e.g. two parameters, which at the same time (i.e. using the same screen) can be directly set by the user using a keyboard provided on the remote. In the present embodiment a four-way rocker switch is provided allowing two settings 65, 66 to be controlled in an "up-down" or scrolling fashion. As can be seen, on the screen image two set of arrows 36, 37, 38, 39 are provided to assist the user when operating the four-way switch. As two different settings can be controlled as well as displayed at the same time a user interface providing ease and safety of use is provided. The display further comprises an upper and a lower bar for additional information.

More specifically, the bolus input screen in fig. 12 shows to the left a numerical value (initially showing 0.0) indicating the selected amount of e.g. insulin unit and associated with a set of

UP-DOWN arrows. To the right is shown a symbol indicating the selected type of bolus infusion, e.g. "direct" (e.g. as fast as possible), "extended" or "sawtooth" (also called dual-phase), and an associated set of LEFT-RIGHT arrows. As follows, when setting a bolus the user enter the amount of drug using the UP-DOWN keys, and selects the type of infusion by scrolling in the "type menu". To activate the desired bolus ACCEPT is pressed which is then followed by a checkmark on the screen, this indicating that the pump unit has confirmed that the instruction has been received and will be performed, where after the remote automatically returns to the status screen now indicating bolus (remaining time and insulin-amount) as long as bolus is being delivered. In the lower bar a bolus suggestion may be displayed if the edit bolus screen has been entered via the bolus calculator.

When the user will cancel a running bolus infusion using the SM screen is selected which now display "abort bolus" instead of bolus. The user selects the "abort bolus" menu item and confirms abortion by pressing ACCEPT.

Fig. 13 shows another use of the dual-mode screen in which a TB rate is programmed. More specifically, the TB input screen shows to the left a numerical % value 65 (initially showing 0%) indicating the selected percentage adjustment of the running basal rate or profile, and an associated set of UP-DOWN arrows. To the right is shown the selected duration of time 66 for the TB expressed in hours and minutes, and an associated set of LEFT-RIGHT arrows. As follows, when setting a TB rate the user enters the percentage adjustment, selectable from e.g. (-100) % to (+100) % as well as the desired time period for the TB rate. To activate the desired TB rate ACCEPT is pressed which is then followed by a checkmark on the screen, this indicating that the pump unit has confirmed that the instruction has been received and will be performed, where after the remote automatically returns to the status screen now indicating the TB rate in a split screen view (percentage change and remaining time) as long as TB rate is being delivered. Fig. 14 shows a status screen indicating that both a bolus and a TB rate are being delivered.

Using the programming of a new BR profile as an example, figs. 15-18 show further types of dual-mode screens. In either the initial setup or in case it is desired to redefine the BR profile the user is brought to a "define profile" screen.

More specifically, when actuating the "basal profile" in the SM the user is brought to a "week view" screen for the BR profile, see fig. 15. This screen comprises two sets of arrows, a first

set being used in a "spinner bar" 35 arranged below the upper information bar, the second set being used for a given selected day. Using the corresponding UP-DOWN keys on the RC the user can toggle between the options in the spinner bar, e.g. "view", "edit" or "redefine". Correspondingly, using the LEFT-RIGHT keys the user can select a given day. When "redefine" is selected (see fig. 16) the second set of arrows disappears as in the shown embodiment the BR profile can only be redefined for an entire week. Thus, when pressing ACCEPT the user is taken to the redefine BR profile screen, see fig. 17.

In accordance with an aspect of the invention, the edit BR profile screen is adapted to graphically display an infusion profile showing an infusion rate as a function of time. The profile comprises a number of consecutive segments, each segment indicating a period of time and an associated infusion rate (BR). In the shown embodiment 24 segments are used for a 24 hours period and the profile is shown as a full line. The screen further shows an indicator 61 (here a circle with a dot) arranged corresponding to a given infusion rate for a given point of time, initially a time 0 and indicating an infusion rate of 0. The indicator is associated with two sets of arrows indicating that the indicator can be moved up-down corresponding to a desired BR as well as forth-back corresponding to a desired segment, i.e. desired point of or time. Using the rocker switch the RC is thus provided with first user input means allowing the user to move the indicator corresponding to a desired point of time, and second user input means allowing the user to move the indicator corresponding to a desired infusion rate, whereby the user graphically can draw a continuous profile 62 for a desired period of time by moving the indicator on the screen corresponding to the desired period of time, the drawn profile graphically displaying the BR profile. The actual time and BR corresponding to the indicator is shown in the lower bar. When the profile is completed the user presses ACCEPT, however, if the profile is not completed this will be indicated, e.g. by the "missing" profile portion blinking, see fig. 18.

In the disclosed embodiment of the RC the BR profile is defined as a 7-day profile. When the first days (e.g. Mondays) profile is programmed, accept of the profile will bring the user to a screen for the next day showing a "pre-set" identical profile which can then be accepted (and so forth until completion of the week), this being expedient as the profile is often the same for a number of day or even all 7 days of the week. In case it is not desirable to copy a profile for the next day, the user simply start to redraw a new profile or change the profile for the previous day.

Next, with reference to figs. 19-23, aspects of the diary function will be described, this function providing further implementations of a dual-mode screen.

More specifically, using the MM the user selects the diary function which via a view/add "diary-options" menu brings the user to the "diary – week view" screen, see fig. 19. This screen is similar to the above-described week view for the basal profile, see fig. 15, i.e. comprising a spinner bar and week view with selectable days, both being selectable using the two sets of keys provided by the 4-way rocker key. Using the UP-DOWN keys the user can select between the following diary item options to be displayed: Blood glucose (BG), BG and bolus (see fig. 20), BG and basal (i.e. BR profile), and miscellaneous. The diary item options can represent either a single type of data, e.g. BG, or a combination of one or more data types, e.g. BG and basal. Also the miscellaneous item can comprise a number of data types, e.g. meal, medication or exercise. Using the LEFT-RIGHT keys and subsequently the ACCEPT key the user can select a day view, see fig. 21. Both in the week and day view the individual data units are represented by a symbol 63, e.g. for BG a drop or blood, or for basal a change in the displayed profile. When in the day view the second set of arrows is used to indicate a single symbol, the LEFT-RIGHT keys allowing the user to scroll back and forth to previous or next symbol, this including the symbols of the "neighbouring" days. Using the ACCEPT key for a given selected symbol, the user is brought to a "diary action card" screen displaying data associated with the selected symbol, see fig. 22. A given symbol and its associated data can be considered a data unit which may comprise data from one of the following groups of data: (i) a symbol representing a blood glucose value, time data representing a point of time, and a blood glucose value, (ii) a symbol representing a meal, time data representing a point of time, and a value representing a characteristic of the meal, (iii) a symbol representing a bolus delivery, time data representing a point of time, and a size of a bolus, (iv) a symbol representing exercise, time data representing a point of time, and a value representing the level of exercise, and (v) a symbol representing one of an amount of change in a basal delivery rate, taking of medication, or illness, and time data representing a point of time. Indeed, it may be desirable to store other types of data. Also the "diary action card" screen comprises a spinner bar, this allowing the user to toggle between "edit", "delete", and "hide/show". Depending on the type of data, one or more of these actions may be allowable, e.g. some kind of data cannot be deleted or edited.

If the user selects "add" in the "diary-options" menu, the user is brought to a week view screen similar to the screen for the view option, e.g. comprising a spinner bar and a day se-

lector feature. However, when a day and a type of data is selected from the spinner bar, pressing the ACCEPT key takes the user directly to an action card edit screen corresponding to the selected type of data to be entered, see fig. 23 showing how a level and a time is entered for an exercise item to be added.

In the above aspects of a user interface for a drug delivery device has been described. Thus, in the following an illustrative drug delivery system suitable to be used in combination with a user interface incorporating one or more of the described aspects or features will be described. Although the present invention will be described with reference to the pump unit and the remote controller unit disclosed in figs. 24-29, it should be understood that the present disclosure is broadly applicable to any form of system comprising a pump unit in combination with a controller unit or other external unit, e.g. a PC or PDA. For example, aspects of the present invention may be used with programmable ambulatory insulin infusion pumps of the sort currently commercially available from a number of manufacturers, including without limitation and by way of example, Medtronic MiniMed under the trademark PARADIGM, Insulet Corporation under the trademark OmniPod, Smiths Medical under the trademark Deltec COZMO, and others, these pumps either being provided with a remote control or being adaptable to be used with one.

Fig. 24 shows a skin-mountable device in the form of a patch (or cannula) unit 400. The patch unit comprises a relatively rigid body portion 414 arranged on a flexible sheet member 430 with a lower mounting surface 431 provided with an adhesive allowing the sheet to be adhered to a skin surface of a subject. The sheet member comprises a central opening 432 through which a cannula can be inserted. The body portion comprises a housing portion 412 in which a cannula inserting mechanism is arranged, see below. The body portion further comprises two slider leg members 413 extending from the housing, the legs adding stiffness to the patch and further serves as guiding means when a pump/reservoir unit is attached the patch unit, see below. The housing is provided with a set of opposed grooves 420 serving as attachment means for a packaging and subsequently for a pump unit. The housing further comprises a fluid inlet 415 adapted to be mounted in fluid communication with a corresponding fluid outlet from an attached pump unit 450, an actuator 416 for actuating an electrical contact on the attached pump, and a release member 417 adapted to release a cannula inserting mechanism when the pump unit is attached for the first time, the cannula being inserted through the opening 432. The housing portion 412 also comprises a catch 419 adapted to engage a corresponding coupling structure on the pump unit. As appears, when

the cannula 951 is inserted (see fig. 25), it is protected by the pump unit, however, the pump unit can be removed for subsequent inspection of the insertion site as shown in fig. 26.

Fig. 26 shows an alternative embodiment of a patch unit 1010 with a pump unit 1050 by its side, and fig. 27 shows the pump unit fully but releasably attached. More specifically, fig. 26 shows an embodiment of a medical device 1000, comprising a cannula unit 1010 of the type shown in fig. 24 and a thereto mountable pump (or reservoir) unit 1050. In the shown embodiment the cannula unit comprises a housing 1015 with a shaft into which a portion 1051 of the pump unit is inserted. The shaft has a lid portion 1011 with an opening 1012, the free end of the lid forming a flexible latch member 1013 with a lower protrusion (not shown) adapted to engage a corresponding depression 1052 in the pump unit, whereby a snap-action coupling is provided when the pump unit is inserted into the shaft of the cannula unit. Also a vent opening 1054 can be seen. The housing 1015 is provided with a pair of opposed legs 1018 and is mounted on top of a flexible sheet member 1019 with a lower adhesive surface 1020 serving as a mounting surface, the sheet member comprising an opening 1016 for the cannula 1017.

As appears, from the housing of the cannula unit extends a cannula at an inclined angle, the cannula being arranged in such a way that its insertion site through a skin surface can be inspected (in the figure the full cannula can be seen), e.g. just after insertion. In the shown embodiment the opening in the lid provides improved inspectability of the insertion site. When the pump unit is connected to the cannula unit it fully covers and protects the cannula and the insertion site from influences from the outside, e.g. water, dirt and mechanical forces (see fig. 27), however, as the pump unit is detachable connected to the cannula unit, it can be released (by lifting the latch member) and withdrawn fully or partly from the cannula unit, this allowing the insertion site to be inspected at any desired point of time. By this arrangement a drug delivery device is provided which has a transcutaneous device, e.g. a soft cannula as shown, which is very well protected during normal use, however, which by fully or partly detachment of the pump unit can be inspected as desired. Indeed, a given device may be formed in such a way that the insertion site can also be inspected, at least to a certain degree, during attachment of the pump, e.g. by corresponding openings or transparent areas, however, the attached pump provides a high degree of protection during use irrespective of the insertion site being fully or partly occluded for inspection during attachment of the pump. In the shown embodiment an inclined cannula is used, however, in alternative em-

bodiments a needle or cannula may be inserted perpendicularly relative to the mounting surface.

Fig. 28 shows in an exploded view a pump unit 300 of the same type as in fig. 12. The pump unit comprises an upper housing portion 310 and a lower housing portion 320 which in an assembled state provides a water-protected enclosure for the additional components of the reservoir unit: A pump assembly 330, an actuator 340, a reservoir 350, and electronic control means 360. In an initial state as supplied to the user, a protective cap assembly 370 is attached to the unit.

The lower housing portion is made from a transparent material allowing a reservoir (see below) to be inspected by a user from the outside, and comprises an opening 321 in which a water repelling vent 322 is arranged. A sheet member 325 with a window opening 326 is attached to the lower surface of the lower housing portion, this masking the transparent portion except for a window over the reservoir. The sheet member may be used to display user information, e.g. type and amount of drug.

The pump assembly 330 is in the form of a membrane pump comprising a piston-actuated pump membrane with flow-controlled inlet- and outlet-valves. The pump has a general layered construction comprising a number of body members between which are interposed flexible membrane layers, whereby a pump chamber, inlet and outlet valves, and one or more safety valves can be formed, the layers being hold together with clamps 338. The pump further comprises a fluid connector 335 in the form of hollow connection needle slidably positioned within the pump (for illustrative purposes shown outside of the pump), this allowing the pump to be connected with reservoir when the protective cap assembly 370 is activated. For a more detailed description of such a membrane pump reference is made to applicants co-pending application PCT/EP2006/060277, which is hereby incorporated by reference.

The pump actuator is in the form of a coil actuator to which the pump assembly is attached by a clamp. For a more detailed description of such a coil actuator reference is made to the description of figs. 1-9 above and applicants co-pending application WO 2005/094919, which is hereby incorporated by reference.

The drug reservoir is in the form of a flexible, pre-filled collapsible pouch 350 comprising a needle-penetratable septum 354 allowing the fluid connector to be pushed into the reservoir without leakage, thereby providing a fluid communication with the pump. A clip holder 352 is attached to the reservoir, this allowing the reservoir to be attached to the housing without influencing the reservoir *per se*. Under the reservoir (as seen from the lower surface of the unit) is arranged a sheet (not shown) comprising a contrast-enhancing pattern, e.g. a black line on a white background, allowing for easier visual identification of impurities in the drug, e.g. fibrillation in insulin.

The electronic control means 360 comprises a PCB or flex-print 362 with a processor 361 for controlling the pump assembly, a battery 366, an acoustic transducer 365 providing an alarm and communication interface with the user, as well as a contact mounted on the actuator allowing the control means to be activated by the user when taken into use for the first time (via the actuator 216). The control means may comprise a receiver and/or a transmitter allowing the reservoir to communicate wirelessly with a remote controller.

The protective cap assembly 370 comprises an attachment member 371 initially locked to the reservoir unit and an activation "push button" member 372 slidingly attached to the attachment member. When the reservoir unit is removed from its primary packaging (not shown) the user depresses the activation member towards the reservoir unit. This actuation results in three actions taking place: A first protrusion on the activation member will actuate a contact on the reservoir unit, this activating the electronics, and a second protrusion will engage the pump assembly and push the fluid connector 335 out from the pump assembly and into the reservoir, thereby establishing a fluid communication between the reservoir and the pump. Thirdly, depression of the activation member will "unlock" the attachment member and allow it, and thereby the activation member, to be removed from the reservoir unit. Thereafter the reservoir unit can be connected to the patch unit.

Fig. 29 shows a schematic representation of a process unit 200 (here corresponding to the pump unit 1050 of fig. 26) and a controller unit 100 (here in the form of a wireless "remote controller" or "external communication device" for the pump unit). It is considered that the general design of such units is well known to the skilled person, however, for a more detailed description of the circuitry necessary to provide the desired functionality of the present invention reference is made to US 2003/0065308 which is hereby incorporated by reference.

More specifically, fig. 29 depicts a simplified block diagram of various functional components or modules (i.e. single components or groups of components) included in the pump unit 200 and remote controller 100. The remote controller unit includes a housing 101, a remote processor 110 including a CPU, memory elements for storing control programs and operation data and a clock, an LCD display 120 for providing operation for information to the user, a keypad 130 for taking input from the user, an audio alarm 140 for providing information to the user, a vibrator 150 for providing information to the user, a main battery 160 for supplying power to the controller, a backup battery 161 to provide memory maintenance for the controller, a remote radio frequency (RF) telemetry transmitter 170 for sending signals to the pump unit, a remote radio frequency (RF) telemetry receiver 180 for receiving signals from the pump unit, and a second transmitter 190. The controller further comprises a port 185, e.g. an infrared (IR) or RF input/output system, or a USB port for communicating with a further device, e.g. a blood glucose meter (BGM), a continuous blood glucose meter (CGM), a PC or a PDA.

As also depicted in fig. 29, the pump unit 200 includes a housing 201, local processor electronics 210 including a CPU and memory elements for storing control programs and operation data, battery 260 for providing power to the system, a process unit RF telemetry transmitter 270 for sending communication signals to the remote unit, a process unit radio frequency (RF) telemetry receiver 280 for receiving signals from the remote unit, a second process unit receiver 240 (which may be in the form of a coil of an acoustic transducer used in an audio alarm for providing feedback to the user), a reservoir 230 for storing a drug, and a pump assembly 220 for expelling drug from the reservoir through a transcutaneous device to the body of a patient. In alternative embodiments the pump unit may also comprise an LCD display for providing information to the user, a keypad for taking input from the user, and a vibrator or other tactile actuator for providing information to the user. RF transmission may be in accordance with a standard protocol such as Bluetooth ®.

As appears, the system of fig. 29 comprises first and second means of communication allowing a first and second group of data types to be transmitted between the two units. In this way different properties of the two means of communication can be used to secure that certain data, e.g. during pairing of the two devices using near-field communication, can be transmitted in a more controlled way whereas other data can be transmitted in a less controlled way using longer-distance communication.

In the above a number of features have been described for a user interface for a drug delivery system. In figs. 30A and 30B the different features are shown as being part of a general information architecture (figs. 30A and 30B showing the left respectively the right portion of the architecture). Figs. 31A and 31B correspondingly shows the information structure for the initial setup of the system. A detailed disclosure of the different screens can be found in applicants co-pending application WO___ (NN ref. 7230).

In the above description of the preferred embodiments, the different structures and means providing the described functionality for the different components have been described to a degree to which the concept of the present invention will be apparent to the skilled reader. The detailed construction and specification for the different components are considered the object of a normal design procedure performed by the skilled person along the lines set out in the present specification.

*****

CLAIMS

1. A user input device (1) for operating a drug delivery system, comprising:
- display means (30) adapted to simultaneously display at least two user controllable settings (65, 66),
- user input means (11, 12, 13, 14) allowing a user to simultaneously and directly set each of the simultaneously displayed user controllable settings.

2. A user input device as in claim 1, wherein the user input means allows a user to bi-directionally set each of the simultaneously displayed user controllable settings.

3. A user input device as in claim 1, wherein at least one user controllable setting represents a drug delivery parameter.

4. A user input device as in claim 1, wherein at least two user controllable settings represent a pair of drug delivery parameters.

5. A user input device as in claim 1, wherein two user controllable settings represent a pair of drug delivery parameters from the group comprising:
- a bolus size to be delivered and an infusion profile therefore,
- an infusion rate and a duration therefore,
- a percentage for a pre-programmed infusion rate or profile and a duration therefore,
- a selectable pre-programmed infusion profile and profile segment therefore, and
- a time-location for an infusion profile and an infusion rate therefore.

6. A user input device as in claim 1, further comprising a memory for storing data, wherein at least two user controllable settings are used to locate data.

7. A user input device as in claim 1, wherein two user controllable settings represent a pair of data storage parameters from the group comprising:
- a type of data and a period of time related thereto
- a type of data and a time location therefore.

8. A user input device as in any of the previous claims, wherein each of the simultaneously displayed user controllable settings is associated with a pair of indices indicating bi-

directional adjustment of a setting, the system further comprising correspondingly marked user input means.

9. A user input device as in claim 8, wherein the indices are pairs of oppositely directed arrows.

10. A drug delivery system comprising:

- a user input device (1, 100) as in any of the previous claims,
- a reservoir (350) adapted to contain a drug,
- an expelling assembly (330) adapted for cooperation with the reservoir to expel drug out of the reservoir, and
- at least one processor (361) adapted to control the expelling device in accordance with a user set drug delivery parameter.

11. A system as in any claim 10, comprising a delivery unit (1050) in which the reservoir and the expelling assembly are arranged, and a control unit (1, 100) comprising the display and user input means, the delivery and control units being adapted to communicate with each other.

12. A system as in claim 10 or 11, comprising a delivery unit in which the reservoir and the expelling assembly are arranged, the delivery unit further comprising the display and user input means.

13. A system as in claim 11, comprising a delivery unit (1050) in which the reservoir and the expelling assembly are arranged, and a control unit (1, 100) comprising the display and user input means, the delivery and control units being adapted to communicate with each other.

14. A medical system as in claim 12 or 13, further comprising a transcutaneous device unit (1015), the transcutaneous device unit comprising:

- a transcutaneous device (1017), and
- a mounting surface (1020) adapted for application to the skin of a subject,
- wherein the transcutaneous device unit and the delivery unit (1050) are adapted to be secured to each other to form a combined device.

15. A method for operating a drug delivery system, comprising the steps of:

- providing a user input device comprising display means (30) adapted to simultaneously display at least two user controllable settings (65, 66), and user input means (11, 12, 13, 14),
- operating the user input means to simultaneously and directly set each of the simultaneously displayed user controllable settings.

*****

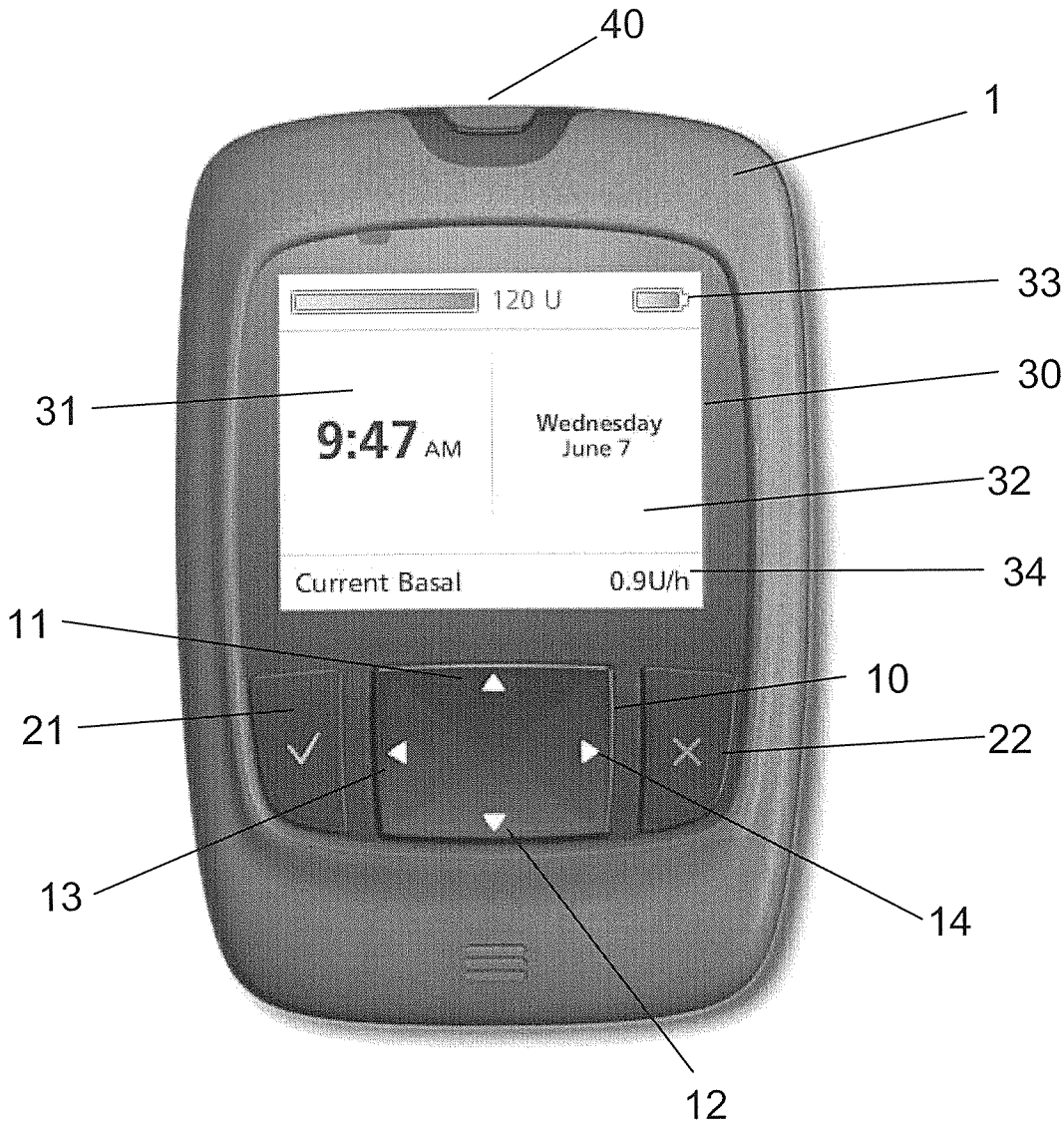
40
1
33
30
31
32
34
11
10
21
22
13
14
12
120 U
9:47 AM
Wednesday
June 7
Current Basal
0.9U/h

Fig. 1

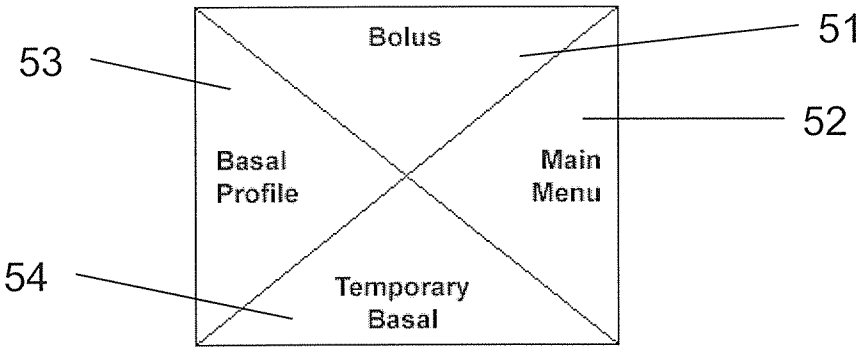
Bolus
Basal Profile
Main Menu
Temporary Basal
51
52
53
54

Fig. 2A

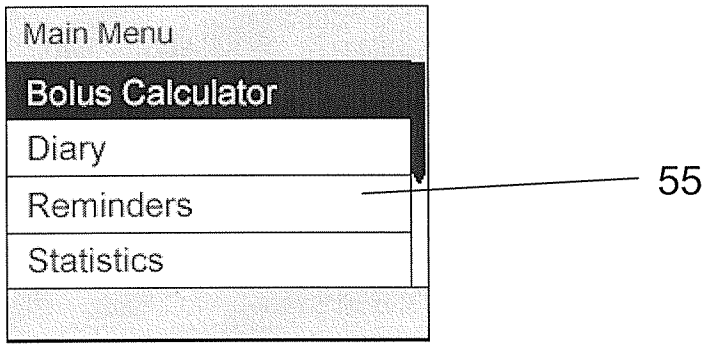
Main Menu
Bolus Calculator
Diary
Reminders
Statistics
55

Fig. 2B

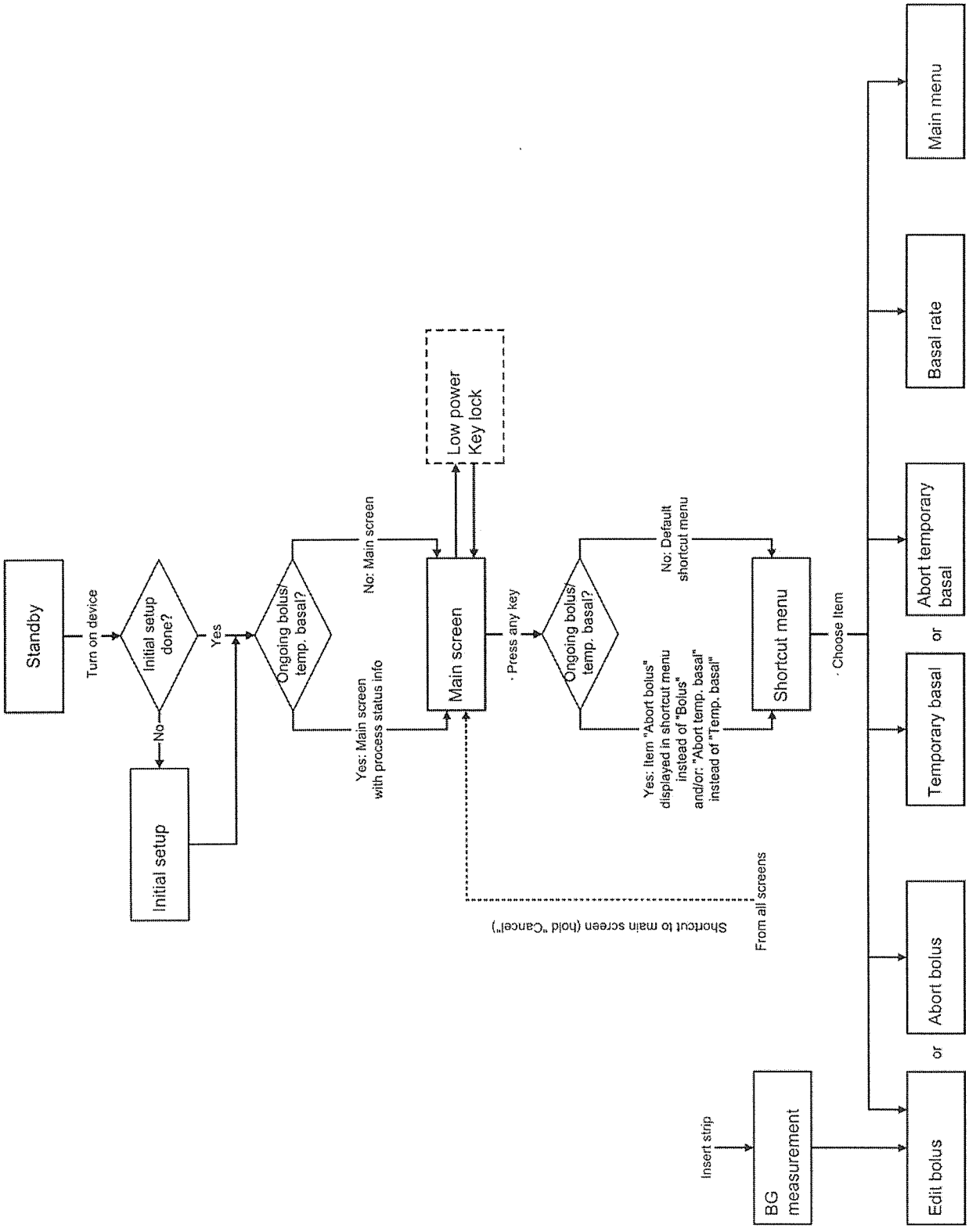
Standby
Turn on device
Initial setup done?
No
Yes
Initial setup
Ongoing bolus/ temp. basal?
No: Main screen
Yes: Main screen with process status info
Low power
Key lock
Main screen
· Press any key
Ongoing bolus/ temp. basal?
No: Default shortcut menu
Yes: Item "Abort bolus" displayed in shortcut menu instead of "Bolus" and/or: "Abort temp. basal" instead of "Temp. basal"
Shortcut menu
· Choose item
Main menu
Basal rate
Abort temporary basal
or
Temporary basal
Abort bolus
or
Edit bolus
Insert strip
BG measurement
From all screens
Shortcut to main screen (hold "Cancel")

Fig. 3

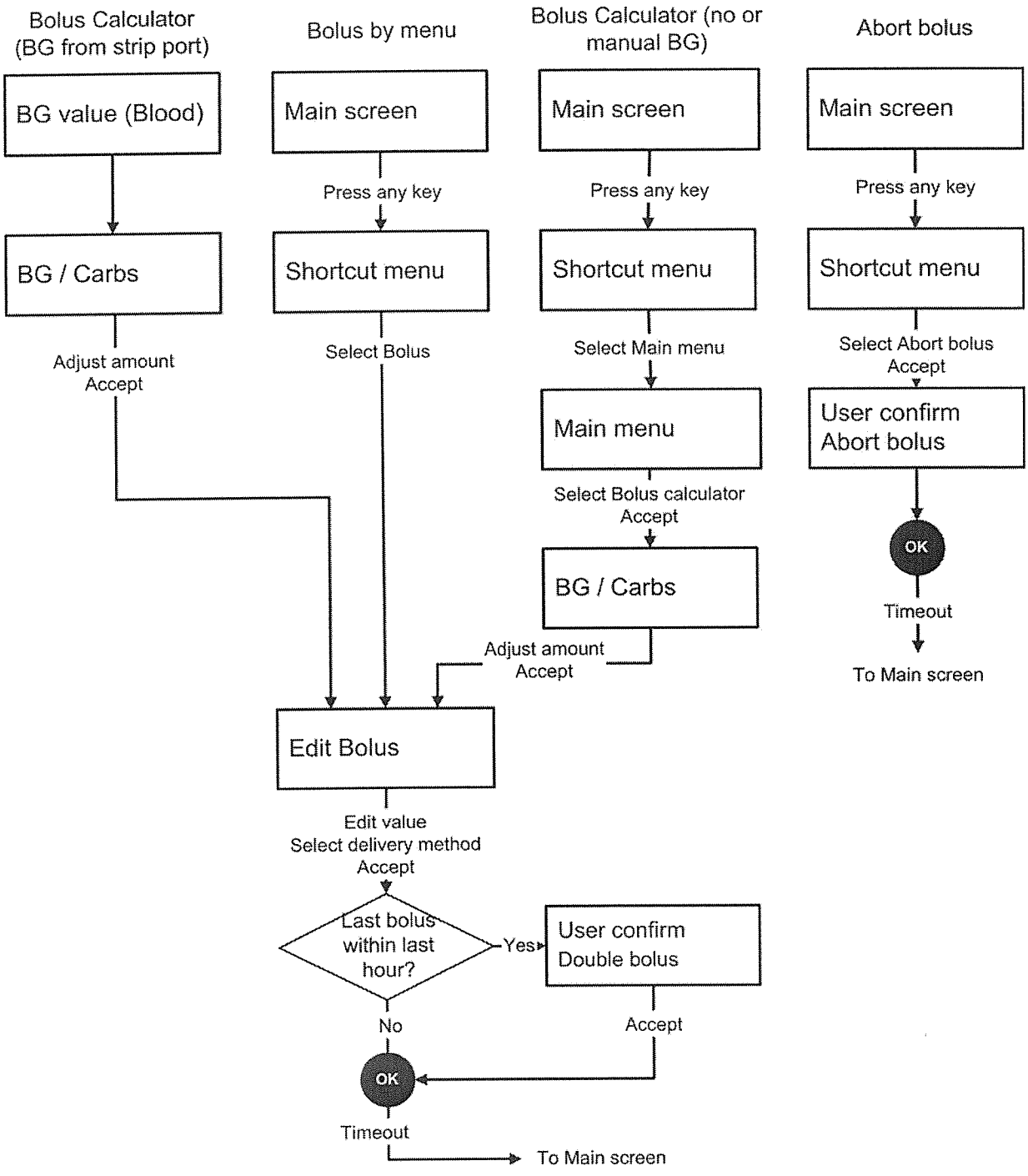
Bolus Calculator (BG from strip port)
BG value (Blood)
BG / Carbs
Adjust amount
Accept
Bolus by menu
Main screen
Press any key
Shortcut menu
Select Bolus
Bolus Calculator (no or manual BG)
Main screen
Press any key
Shortcut menu
Select Main menu
Main menu
Select Bolus calculator
Accept
BG / Carbs
Adjust amount
Accept
Abort bolus
Main screen
Press any key
Shortcut menu
Select Abort bolus
Accept
User confirm Abort bolus
OK
Timeout
To Main screen
Edit Bolus
Edit value
Select delivery method
Accept
Last bolus within last hour?
Yes
User confirm Double bolus
Accept
No
OK
Timeout
To Main screen

Fig. 4

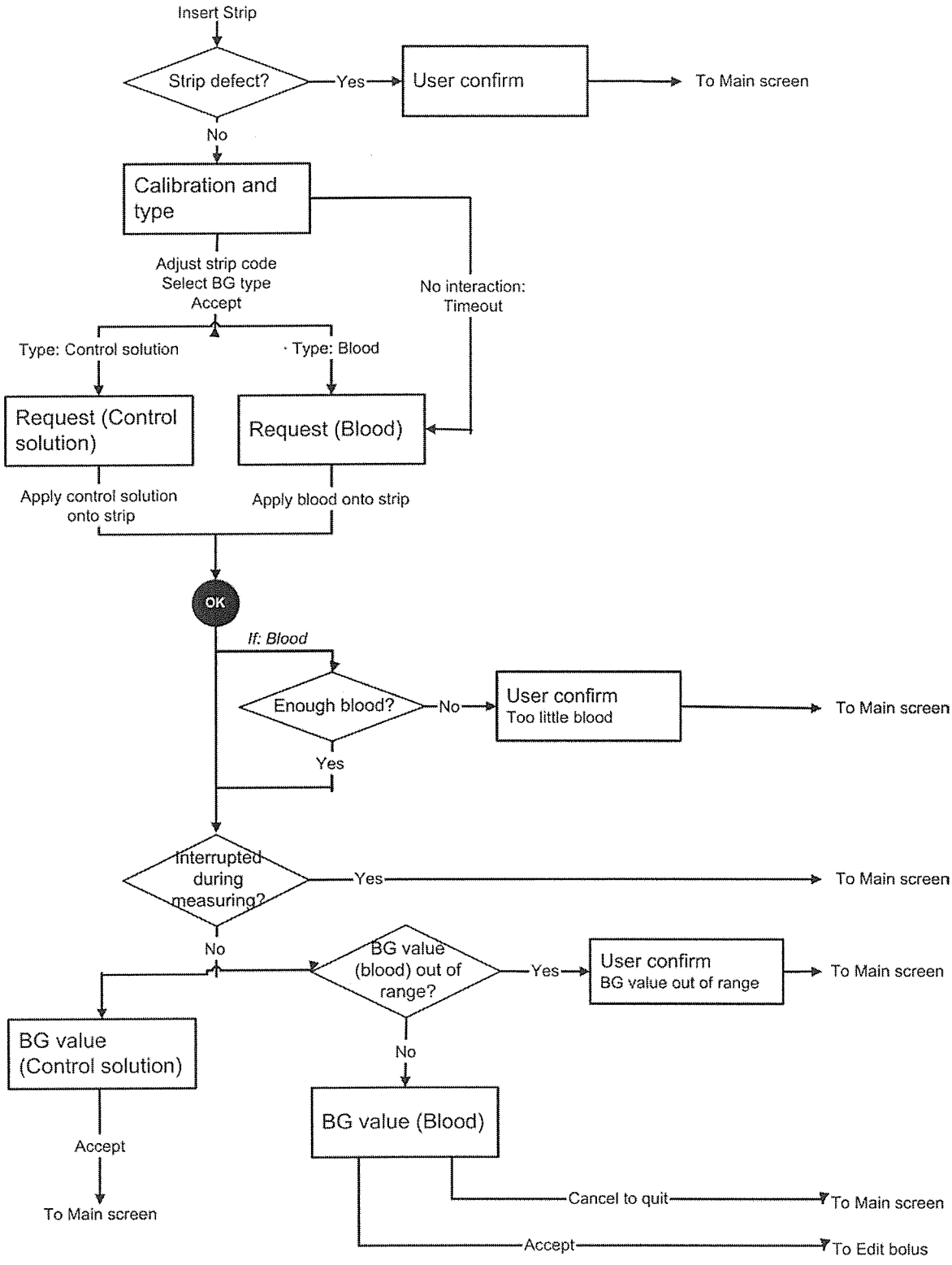
Insert Strip
Strip defect?
Yes
User confirm
To Main screen
No
Calibration and type
Adjust strip code
Select BG type
Accept
No interaction:
Timeout
Type: Control solution
Type: Blood
Request (Control solution)
Request (Blood)
Apply control solution onto strip
Apply blood onto strip
OK
If: Blood
Enough blood?
No
User confirm
Too little blood
To Main screen
Yes
Interrupted during measuring?
Yes
To Main screen
No
BG value (blood) out of range?
Yes
User confirm
BG value out of range
To Main screen
BG value (Control solution)
No
BG value (Blood)
Accept
To Main screen
Cancel to quit
To Main screen
Accept
To Edit bolus

Fig. 5

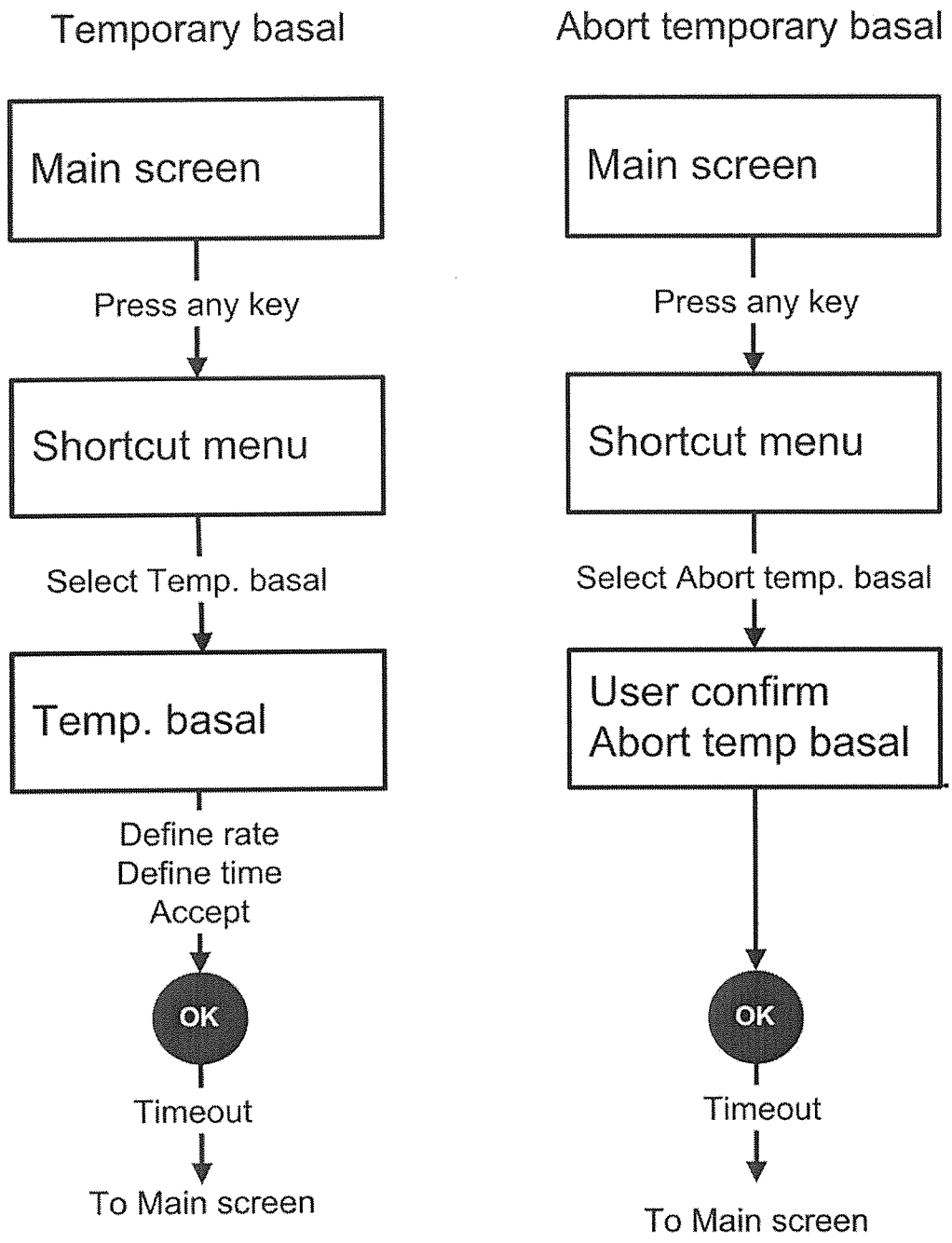
Temporary basal
Main screen
Press any key
Shortcut menu
Select Temp. basal
Temp. basal
Define rate
Define time
Accept
OK
Timeout
To Main screen
Abort temporary basal
Main screen
Press any key
Shortcut menu
Select Abort temp. basal
User confirm
Abort temp basal
OK
Timeout
To Main screen

Fig. 6

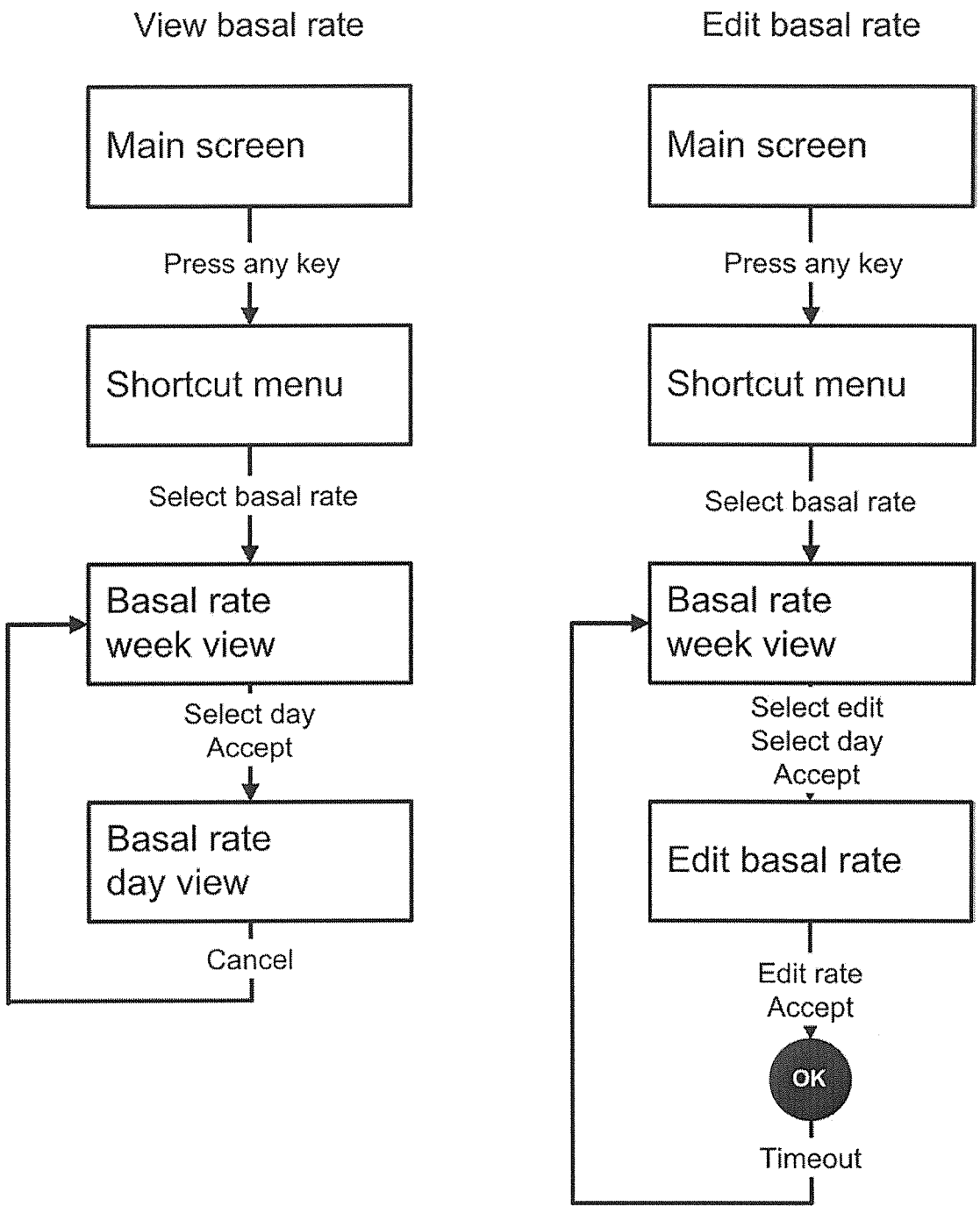
View basal rate
Main screen
Press any key
Shortcut menu
Select basal rate
Basal rate week view
Select day
Accept
Basal rate day view
Cancel
Edit basal rate
Main screen
Press any key
Shortcut menu
Select basal rate
Basal rate week view
Select edit
Select day
Accept
Edit basal rate
Edit rate
Accept
OK
Timeout

Fig. 7A

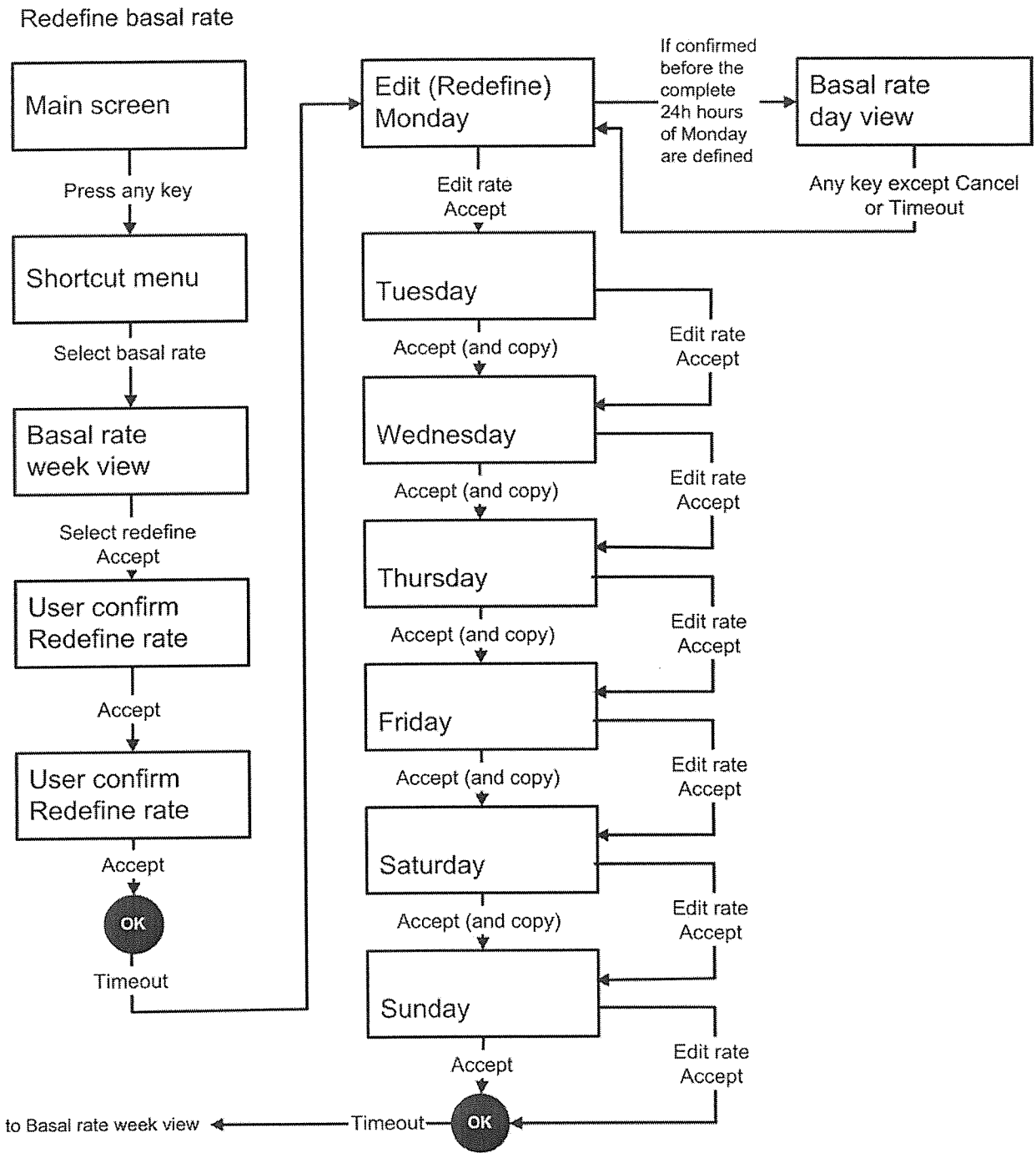
Redefine basal rate
Main screen
Press any key
Shortcut menu
Select basal rate
Basal rate week view
Select redefine Accept
User confirm Redefine rate
Accept
User confirm Redefine rate
Accept
OK
Timeout
Edit (Redefine) Monday
If confirmed before the complete 24h hours of Monday are defined
Basal rate day view
Any key except Cancel or Timeout
Edit rate Accept
Tuesday
Accept (and copy)
Edit rate Accept
Wednesday
Accept (and copy)
Edit rate Accept
Thursday
Accept (and copy)
Edit rate Accept
Friday
Accept (and copy)
Edit rate Accept
Saturday
Accept (and copy)
Edit rate Accept
Sunday
Accept
Edit rate Accept
OK
Timeout
to Basal rate week view

Fig. 7B

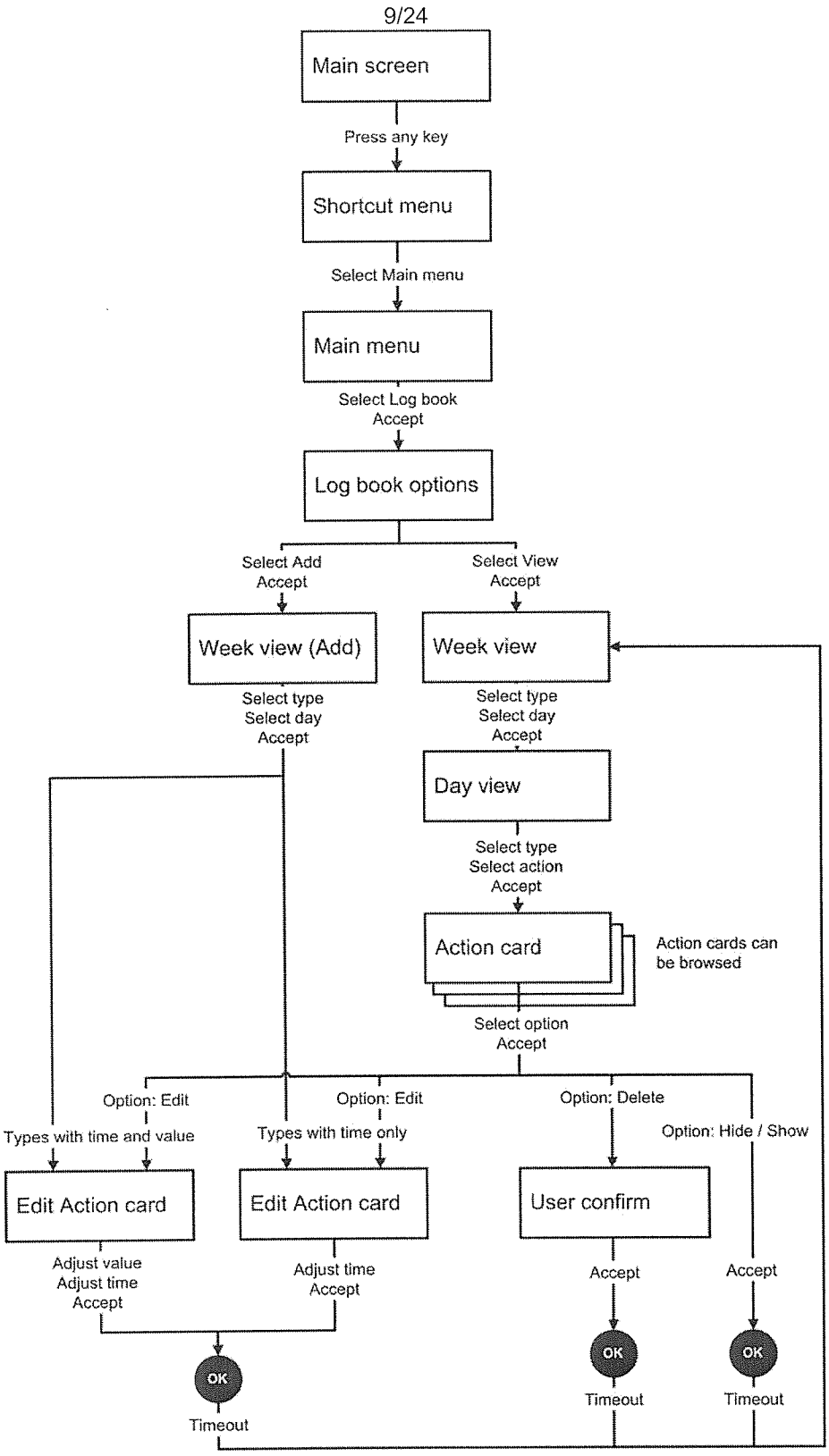
Main screen
Press any key
Shortcut menu
Select Main menu
Main menu
Select Log book
Accept
Log book options
Select Add
Accept
Select View
Accept
Week view (Add)
Week view
Select type
Select day
Accept
Select type
Select day
Accept
Day view
Select type
Select action
Accept
Action card
Action cards can be browsed
Select option
Accept
Option: Edit
Types with time and value
Option: Edit
Types with time only
Option: Delete
Option: Hide / Show
Edit Action card
Edit Action card
User confirm
Adjust value
Adjust time
Accept
Adjust time
Accept
Accept
Accept
OK
OK
OK
Timeout
Timeout
Timeout

Fig. 8

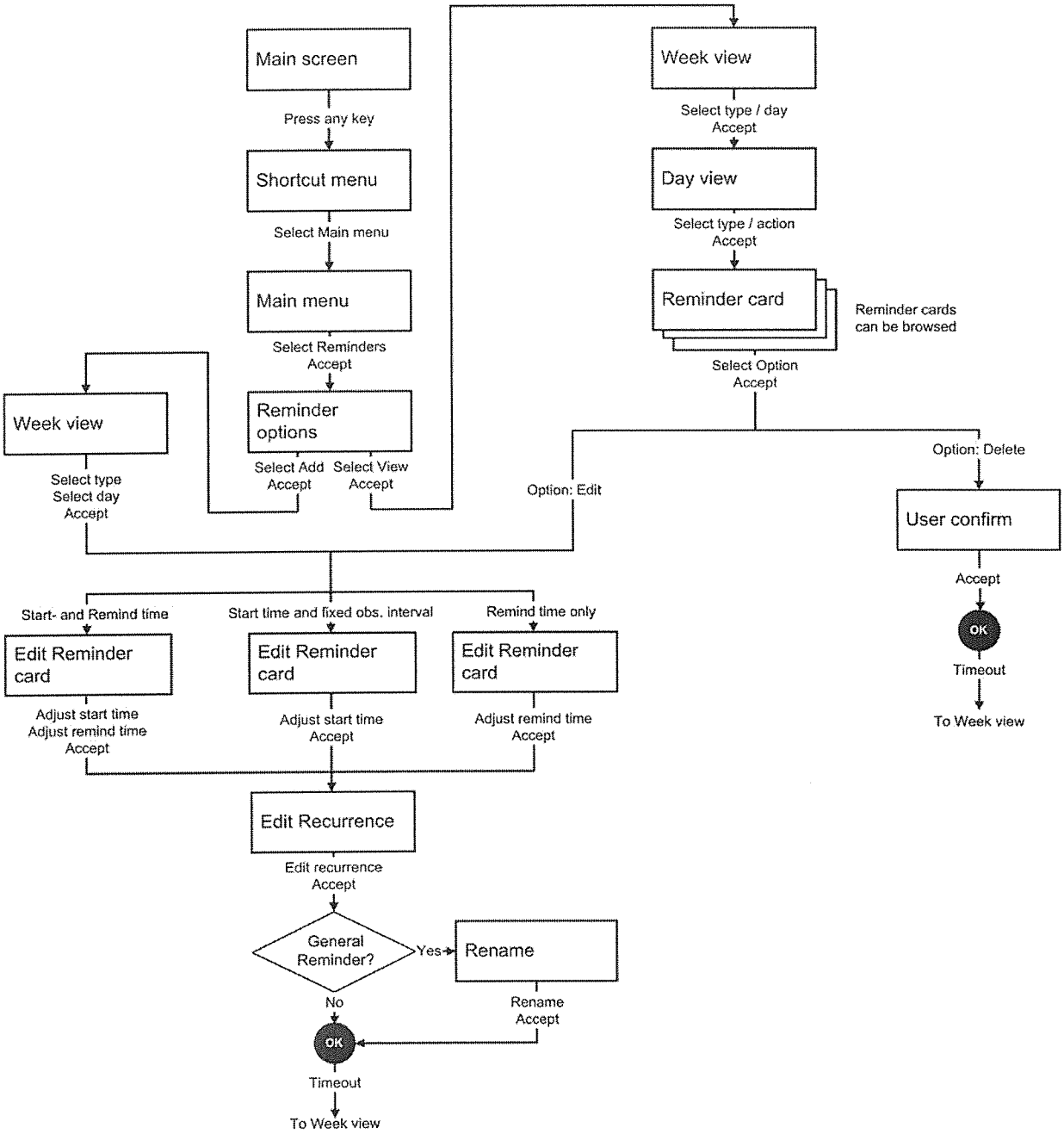
Main screen
Press any key
Shortcut menu
Select Main menu
Main menu
Select Reminders
Accept
Reminder options
Select Add
Accept
Select View
Accept
Week view
Select type
Select day
Accept
Week view
Select type / day
Accept
Day view
Select type / action
Accept
Reminder card
Reminder cards can be browsed
Select Option
Accept
Option: Edit
Option: Delete
User confirm
Accept
OK
Timeout
To Week view
Start- and Remind time
Start time and fixed obs. interval
Remind time only
Edit Reminder card
Edit Reminder card
Edit Reminder card
Adjust start time
Adjust remind time
Accept
Adjust start time
Accept
Adjust remind time
Accept
Edit Recurrence
Edit recurrence
Accept
General Reminder?
Yes
Rename
Rename
Accept
No
OK
Timeout
To Week view

Fig. 9

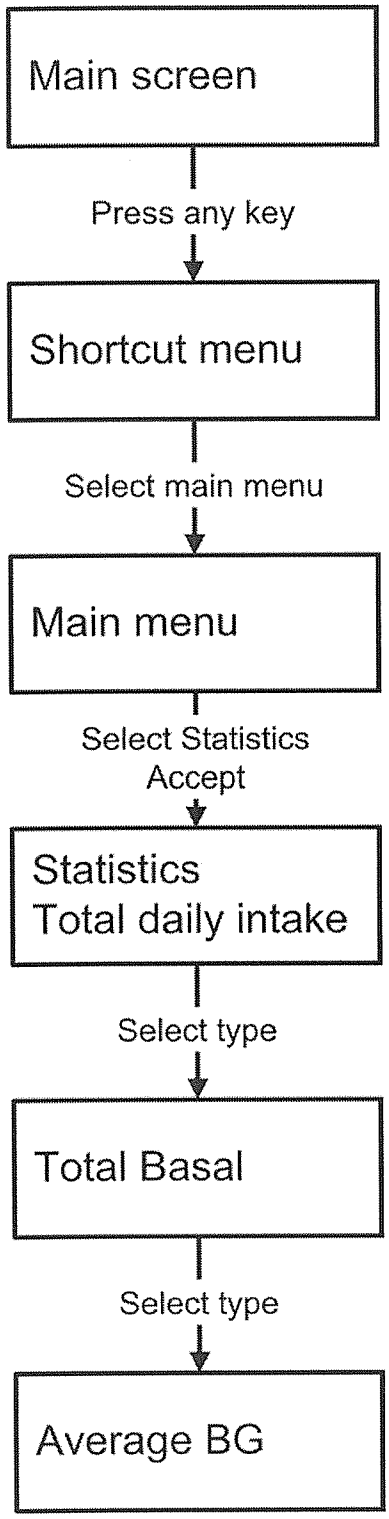
Main screen
Press any key
Shortcut menu
Select main menu
Main menu
Select Statistics
Accept
Statistics
Total daily intake
Select type
Total Basal
Select type
Average BG

Fig. 10

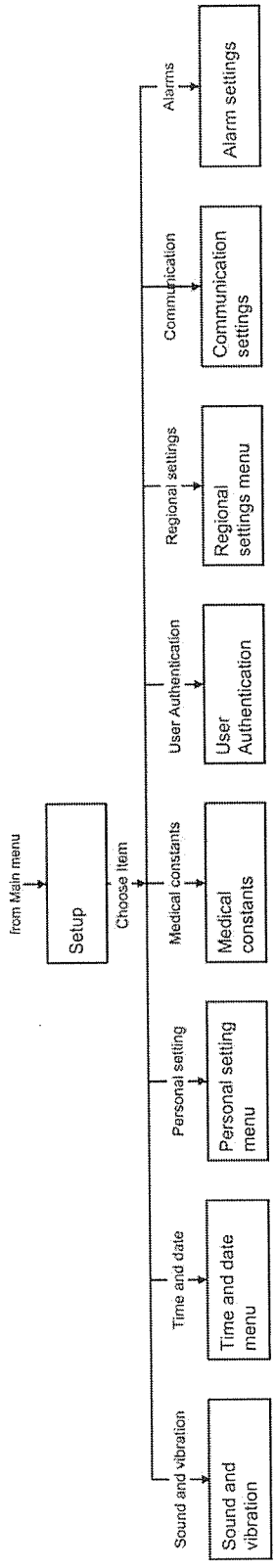
from Main menu
Setup
Choose item
Sound and vibration
Sound and vibration
Time and date
Time and date menu
Personal setting
Personal setting menu
Medical constants
Medical constants
User Authentication
User Authentication
Regional settings
Regional settings menu
Communication
Communication settings
Alarms
Alarm settings

Fig. 11

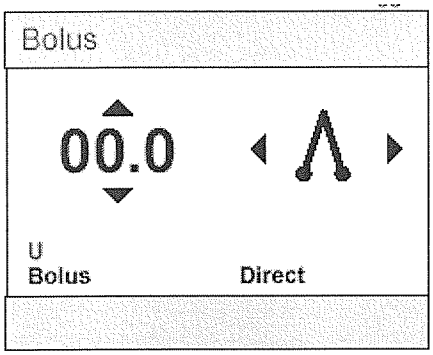

Fig. 12

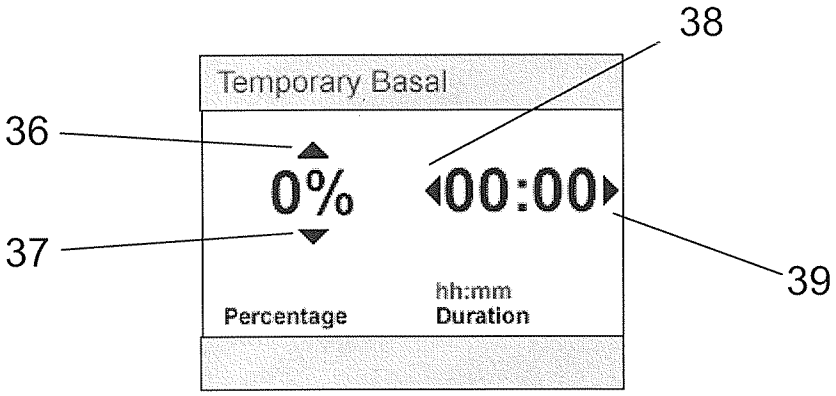

Fig. 13

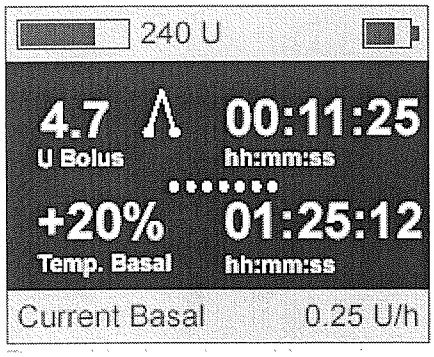

Fig. 14

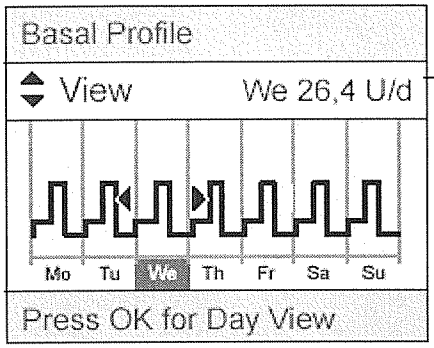

Fig. 15

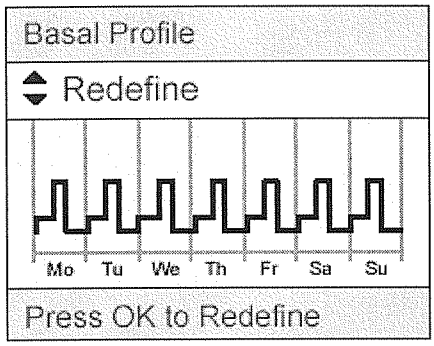

Fig. 16

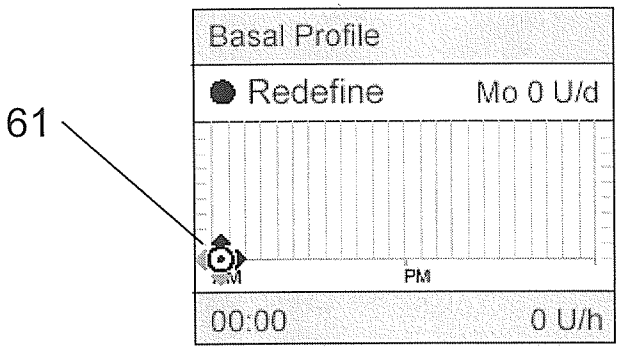

Fig. 17

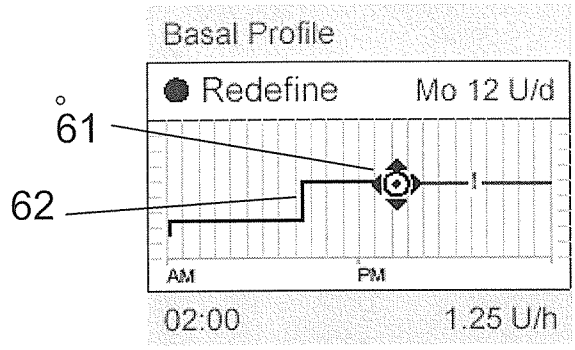

Fig. 18

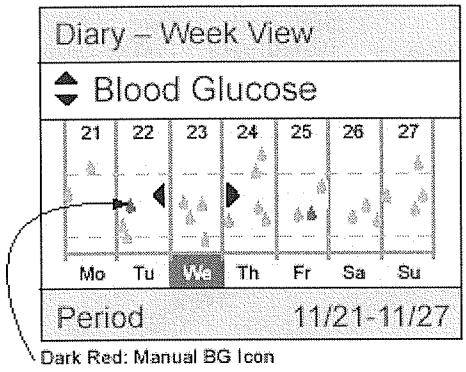

Fig. 19

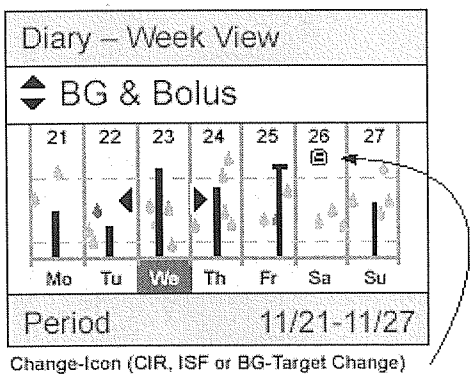

Fig. 20

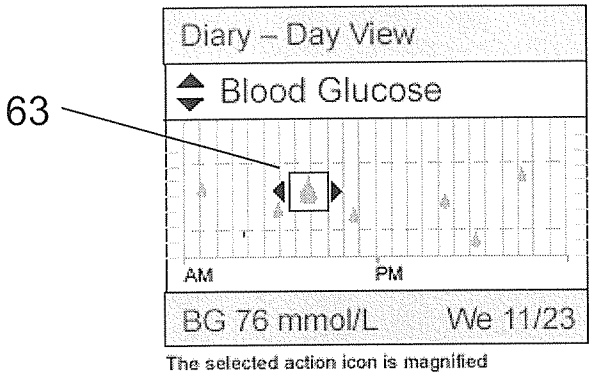

Fig. 21

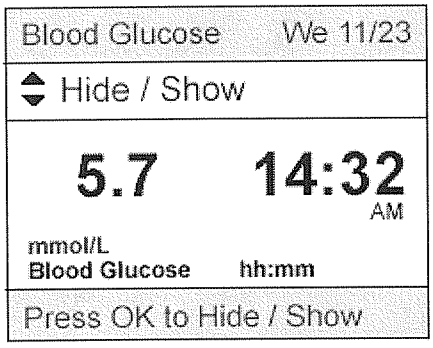

Fig. 22

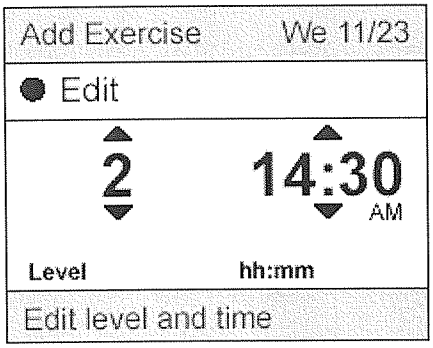

Fig. 23

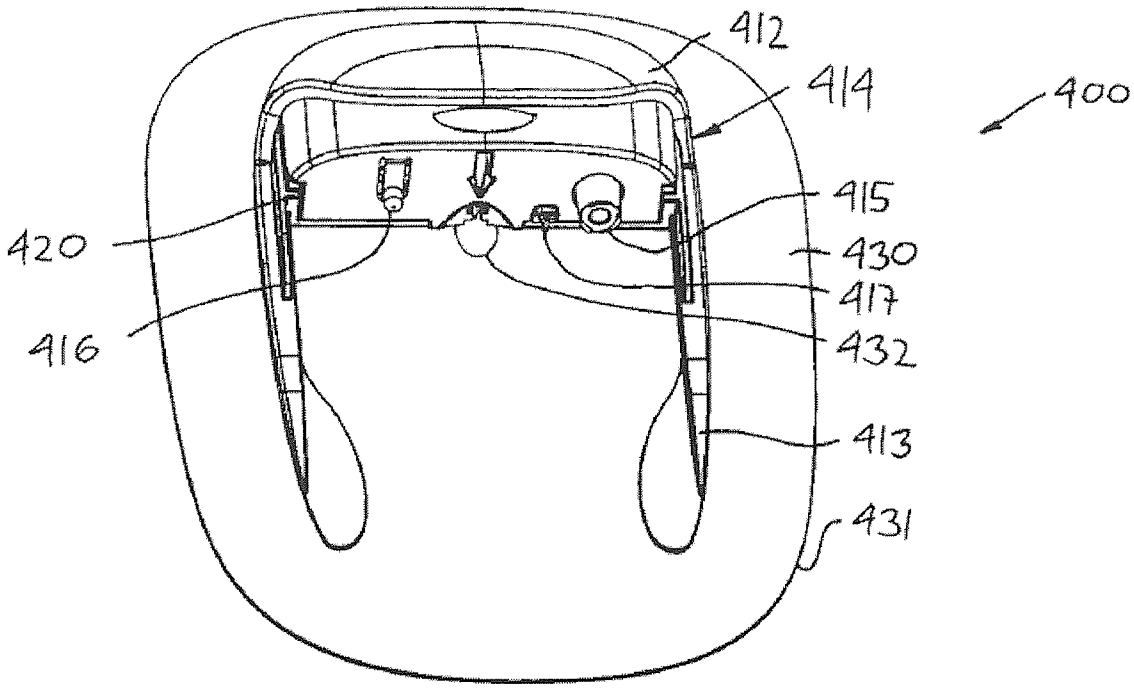

Fig. 24

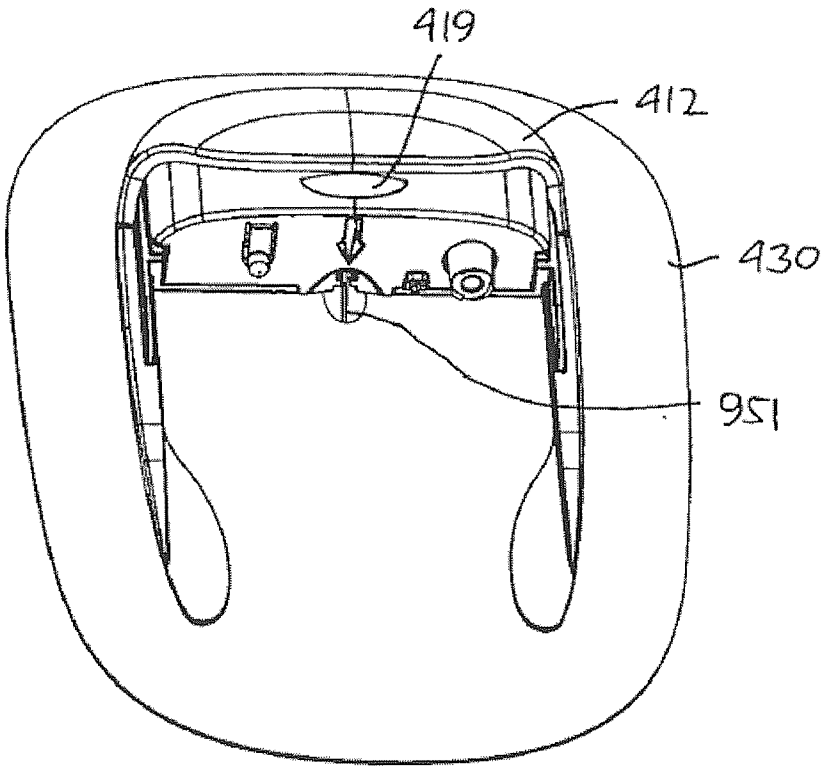

Fig. 25

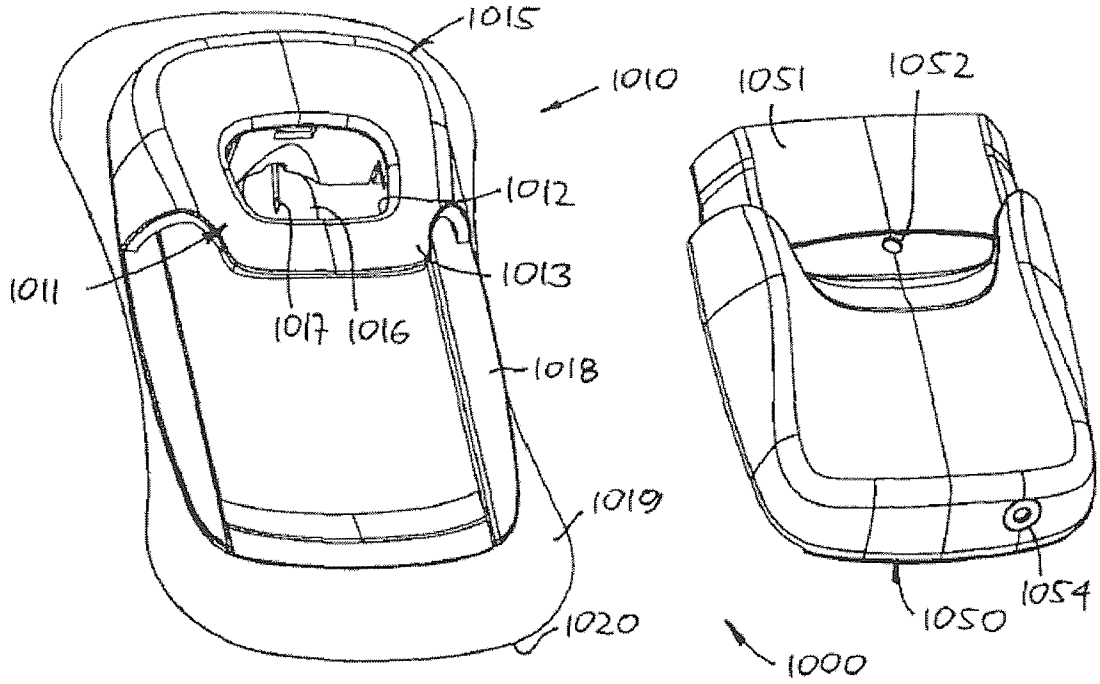
1015
1010
1051
1052
1012
1011
1013
1017
1016
1018
1019
1020
1050
1054
1000

Fig. 26

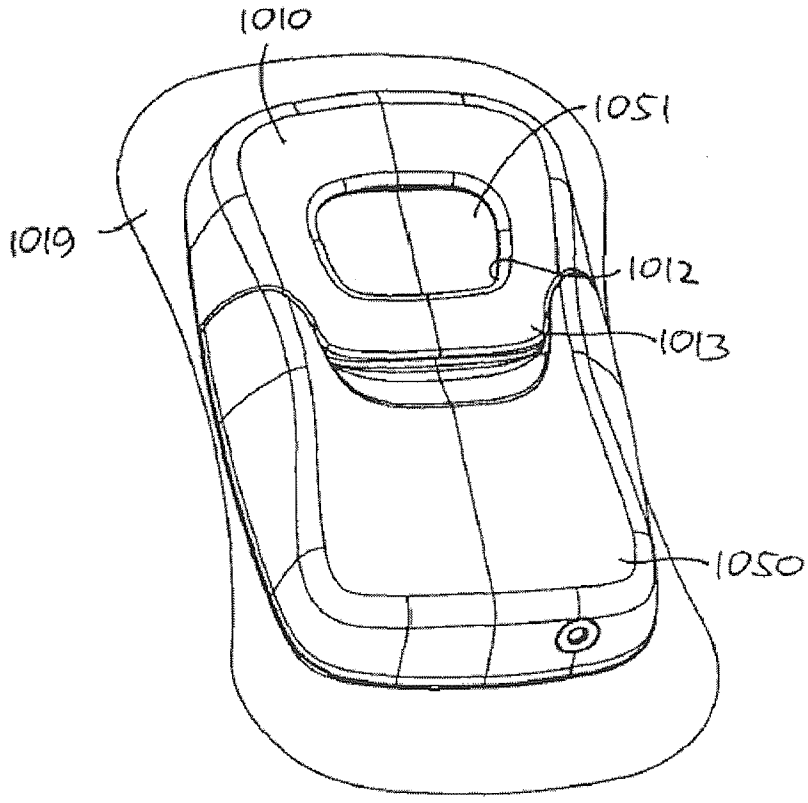
1010
1051
1019
1012
1013
1050

Fig. 27

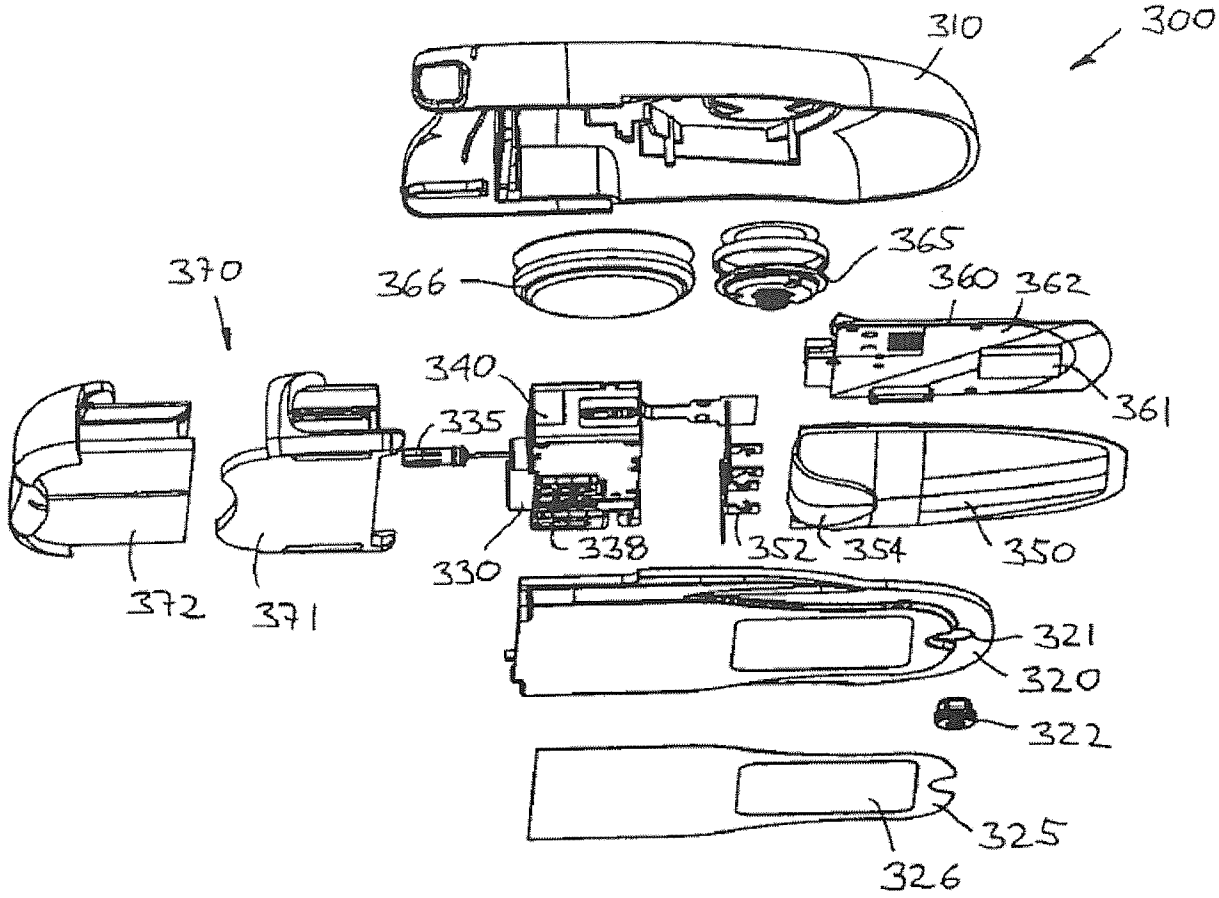
310
300
370
366
365
360
362
340
335
361
372
371
330
338
352
354
350
321
320
322
325
326

Fig. 28

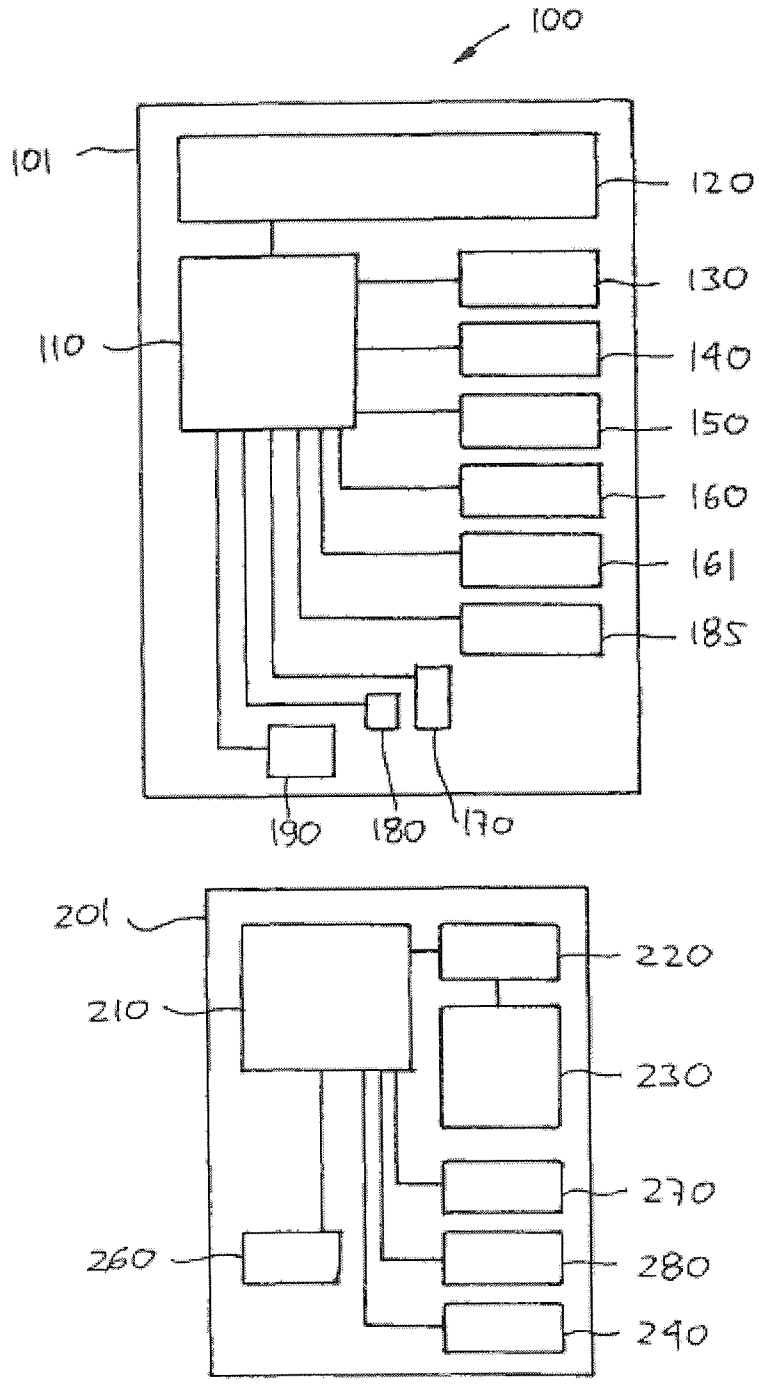
100
101
120
130
110
140
150
160
161
185
190
180
170
201
220
210
230
270
260
280
240

Fig. 29

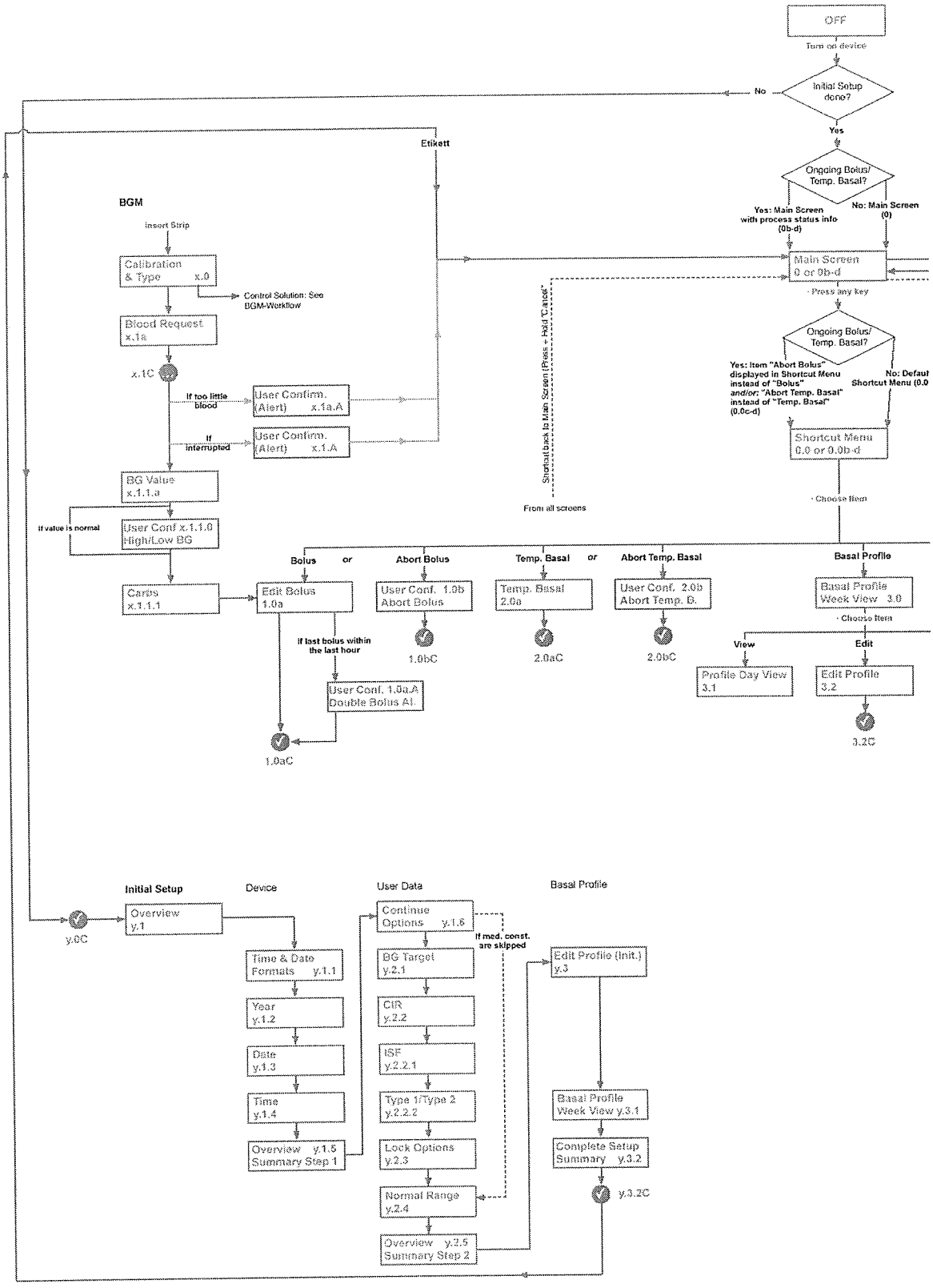
OFF
Turn on device
Initial Setup done?
No
Yes
Ongoing Bolus/ Temp. Basal?
Yes: Main Screen with process status info (0b-d)
No: Main Screen (0)
Main Screen 0 or 0b-d
Press any key
Ongoing Bolus/ Temp. Basal?
Yes: Item "Abort Bolus" displayed in Shortcut Menu instead of "Bolus" and/or: "Abort Temp. Basal" instead of "Temp. Basal" (0.0c-d)
No: Defaut Shortcut Menu (0.0
Shortcut Menu 0.0 or 0.0b-d
Choose Item
Shortcut back to Main Screen (Press + Hold 'Cancel')
From all screens
Etikett
BGM
Insert Strip
Calibration & Type x.0
Control Solution: See BGM-Workflow
Blood Request x.1a
x.1C
If too little blood
User Confirm. (Alert) x.1a.A
If interrupted
User Confirm. (Alert) x.1.A
BG Value x.1.1.a
If value is normal
User Conf x.1.1.0 High/Low BG
Carbs x.1.1.1
Bolus or Abort Bolus
Edit Bolus 1.0a
User Conf. 1.0b Abort Bolus
If last bolus within the last hour
User Conf. 1.0a.A Double Bolus Al.
1.0aC
1.0bC
Temp. Basal or Abort Temp. Basal
Temp. Basal 2.0a
User Conf. 2.0b Abort Temp. B.
2.0aC
2.0bC
Basal Profile
Basal Profile Week View 3.0
Choose Item
View
Edit
Profile Day View 3.1
Edit Profile 3.2
3.2C
Initial Setup
Overview y.1
y.0C
Device
Time & Date Formats y.1.1
Year y.1.2
Date y.1.3
Time y.1.4
Overview y.1.5 Summary Step 1
User Data
Continue Options y.1.6
If med. const. are skipped
BG Target y.2.1
CIR y.2.2
ISF y.2.2.1
Type 1/Type 2 y.2.2.2
Lock Options y.2.3
Normal Range y.2.4
Overview y.2.5 Summary Step 2
Basal Profile
Edit Profile (Init.) y.3
Basal Profile Week View y.3.1
Complete Setup Summary y.3.2
y.3.2C

Fig. 30A

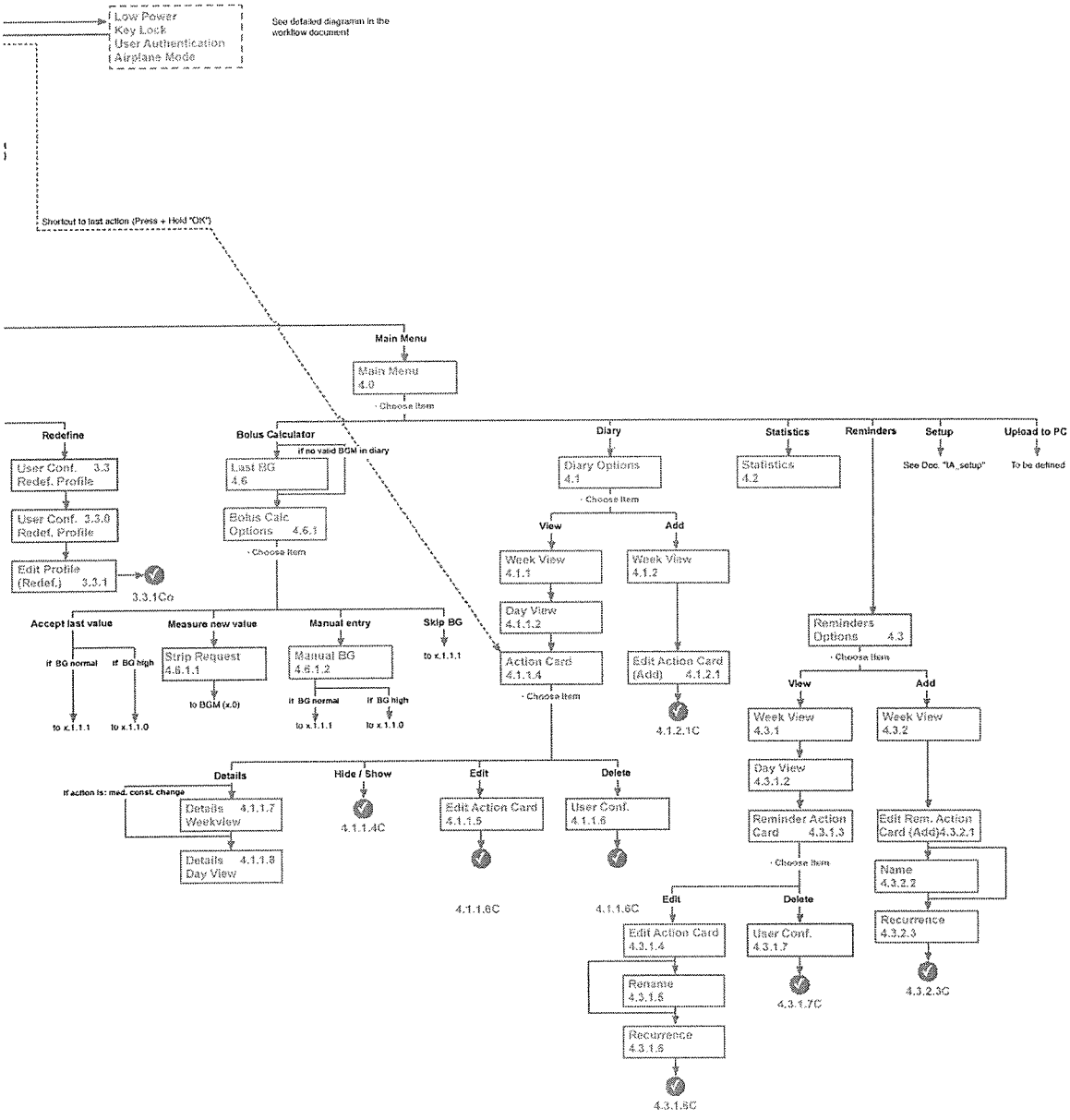
Low Power
Key Lock
User Authentication
Airplane Mode
See detailed diagramm in the workflow document
Shortcut to last action (Press + Hold "OK")
Main Menu
Main Menu 4.0
- Choose Item
Redefine
Bolus Calculator
Diary
Statistics
Reminders
Setup
Upload to PC
See Doc. "IA_setup"
To be defined
User Conf. 3.3 Redef. Profile
User Conf. 3.3.0 Redef. Profile
Edit Profile (Redef.) 3.3.1
3.3.1Co
if no valid BGM in diary
Last BG 4.6
Bolus Calc Options 4.6.1
Diary Options 4.1
Statistics 4.2
View
Add
Week View 4.1.1
Week View 4.1.2
Day View 4.1.1.2
Action Card 4.1.1.4
Edit Action Card (Add) 4.1.2.1
4.1.2.1C
Accept last value
Measure new value
Manual entry
Skip BG
if BG normal
if BG high
to x.1.1.1
to x.1.1.0
Strip Request 4.6.1.1
to BGM (x.0)
Manual BG 4.6.1.2
Reminders Options 4.3
Week View 4.3.1
Week View 4.3.2
Day View 4.3.1.2
Reminder Action Card 4.3.1.3
Edit Rem. Action Card (Add)4.3.2.1
Name 4.3.2.2
Recurrence 4.3.2.3
4.3.2.3C
Details
Hide / Show
Edit
Delete
if action is: med. const. change
Details 4.1.1.7 Weekview
Details 4.1.1.8 Day View
4.1.1.4C
Edit Action Card 4.1.1.5
User Conf. 4.1.1.6
4.1.1.6C
4.1.1.6C
Edit
Delete
Edit Action Card 4.3.1.4
User Conf. 4.3.1.7
Rename 4.3.1.5
Recurrence 4.3.1.6
4.3.1.7C
4.3.1.8C

Fig. 30B

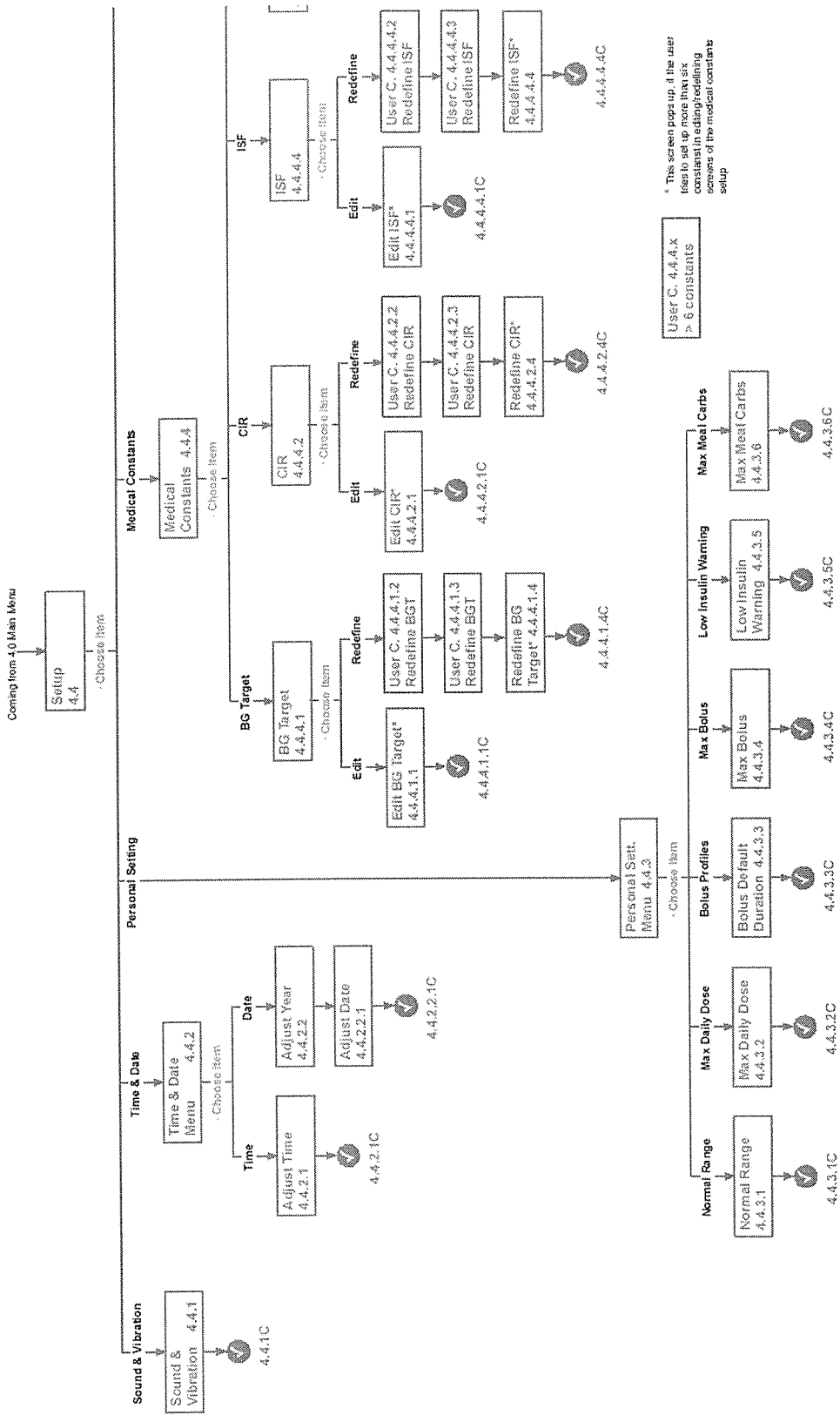
Coming from 4.0 Main Menu
Setup 4.4
Choose Item
Sound & Vibration
Sound & Vibration 4.4.1
4.4.1C
Time & Date
Time & Date Menu 4.4.2
Choose Item
Time
Adjust Time 4.4.2.1
4.4.2.1C
Date
Adjust Year 4.4.2.2
Adjust Date 4.4.2.2.1
4.4.2.2.1C
Personal Setting
Personal Sett. Menu 4.4.3
Choose Item
Normal Range
Normal Range 4.4.3.1
4.4.3.1C
Max Daily Dose
Max Daily Dose 4.4.3.2
4.4.3.2C
Bolus Profiles
Bolus Default Duration 4.4.3.3
4.4.3.3C
Max Bolus
Max Bolus 4.4.3.4
4.4.3.4C
Low Insulin Warning
Low Insulin Warning 4.4.3.5
4.4.3.5C
Max Meal Carbs
Max Meal Carbs 4.4.3.6
4.4.3.6C
Medical Constants
Medical Constants 4.4.4
Choose Item
BG Target
BG Target 4.4.4.1
Choose Item
Edit
Edit BG Target* 4.4.4.1.1
4.4.4.1.1C
Redefine
User C. 4.4.4.1.2 Redefine BGT
User C. 4.4.4.1.3 Redefine BGT
Redefine BG Target* 4.4.4.1.4
4.4.4.1.4C
CIR
CIR 4.4.4.2
Choose Item
Edit
Edit CIR* 4.4.4.2.1
4.4.4.2.1C
Redefine
User C. 4.4.4.2.2 Redefine CIR
User C. 4.4.4.2.3 Redefine CIR
Redefine CIR* 4.4.4.2.4
4.4.4.2.4C
ISF
ISF 4.4.4.4
Choose Item
Edit
Edit ISF* 4.4.4.4.1
4.4.4.4.1C
Redefine
User C. 4.4.4.4.2 Redefine ISF
User C. 4.4.4.4.3 Redefine ISF
Redefine ISF* 4.4.4.4.4
4.4.4.4.4C
User C. 4.4.4.x > 6 constants
* This screen pops up, if the user tries to set up more than six constants in editing/redefining screens of the medical constants setup

Fig. 31A

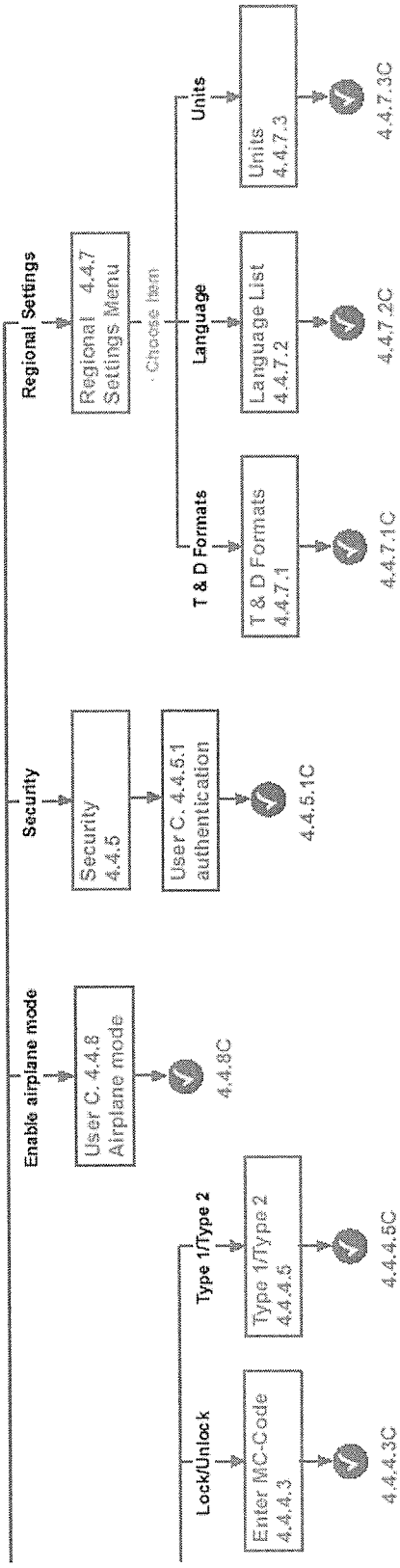
Enable airplane mode
User C. 4.4.8 Airplane mode
4.4.8C
Security
Security 4.4.5
User C. 4.4.5.1 authentication
4.4.5.1C
Regional Settings
Regional 4.4.7 Settings Menu
Choose item
T & D Formats
T & D Formats 4.4.7.1
4.4.7.1C
Language
Language List 4.4.7.2
4.4.7.2C
Units
Units 4.4.7.3
4.4.7.3C
Lock/Unlock
Enter MC-Code 4.4.4.3
4.4.4.3C
Type 1/Type 2
Type 1/Type 2 4.4.4.5
4.4.4.5C

Fig. 31B

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/063523

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00

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)
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 2005/018716 A (TERUMO CORP [JP]; KUTSUZAWA AKIO [JP]) 3 March 2005 (2005-03-03) paragraph [0020]; figure 2	1-15
X	DE 198 40 965 A1 (DISETRONIC LICENSING AG [CH]) 9 March 2000 (2000-03-09) column 9, lines 23-29 column 11, lines 17-54; figures 2,4	1-15
X	US 2003/163789 A1 (BLOMQUIST MICHAEL L [US]) 28 August 2003 (2003-08-28) paragraphs [0225] - [0273]; figures 29-30E	1-15

-/--

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

[X] See patent family annex.

* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
27 October 2006	07/11/2006

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, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Ceccarelli, David

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/063523

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 553 958 A (LECOCQ ANDREW D [US]) 19 November 1985 (1985-11-19) column 4, line 9 - column 5, line 2 column 5, line 53 - column 6, line 31; figure 2A	1-15
X	EP 0 424 687 A (STORZ INSTR CO [US]; AMERICAN CYANAMID CO [US]) 2 May 1991 (1991-05-02) abstract; figure 13	1,2,6,8, 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/063523

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005018716 A	03-03-2005	JP 2005095577 A	14-04-2005
		US 2006140798 A1	29-06-2006
DE 19840965 A1	09-03-2000	AT 284033 T	15-12-2004
		AU 5404899 A	27-03-2000
		AU 5404999 A	27-03-2000
		WO 0013725 A1	16-03-2000
		WO 0014533 A1	16-03-2000
		EP 1110085 A1	27-06-2001
		ES 2234286 T3	16-06-2005
		JP 2002524735 T	06-08-2002
		US 2001025189 A1	27-09-2001
US 2003163789 A1	28-08-2003	NONE	
US 4553958 A	19-11-1985	NONE	
EP 0424687 A	02-05-1991	JP 2938176 B2	23-08-1999
		JP 3151967 A	28-06-1991
		US 5249121 A	28-09-1993