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(54) **Title:** LIQUID INFUSION PUMP

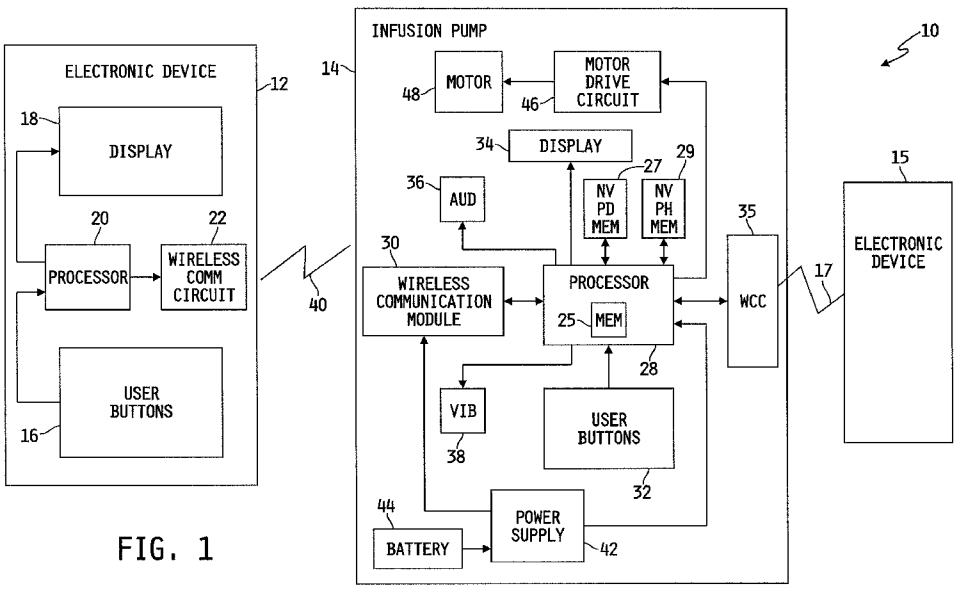

FIG. 1

(57) **Abstract:** A method is provided for controlling change access to a display menu of an ambulatory liquid infusion pump. A programmed menu of the infusion pump may be displayed and a menu lock flag may be monitored. Changes to at least one active item of the programmed menu may be disabled if the menu lock flag is activated.

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LIQUID INFUSION PUMP

CROSS REFERENCE TO RELATED APPLICATIONS

This patent application claims priority to and the benefit of U.S. Provisional Patent Application Ser. No. 60/937,933 filed June 29, 2007, the disclosure of which is incorporated herein by reference.

FIELD OF THE INVENTION:

The present invention relates generally to devices for selectively delivering liquid to a living body, and more specifically to liquid infusion pumps for controllably delivering liquid to a living body.

BACKGROUND

Devices for selectively and controllably delivering liquid, such as a drug, to a living body are known. Such devices may typically be configured to controllably deliver the drug to the living body at different rates during different times of the day and according to one or more user selectable drug delivery profiles that may be programmed by the user.

SUMMARY

The present invention may comprise one or more of the features recited in the attached claims, and/or one or more of the following features and combinations thereof. A method of controlling change access to a display menu of an ambulatory liquid infusion pump may comprise displaying a programmed menu of the infusion pump, monitoring a menu lock flag, and disabling changes to at least one active item of the programmed menu if the menu lock flag is activated.

Disabling changes may comprise disabling changes to all active items of the programmed menu.

The method may further comprise displaying a warning message upon detection of attempted changes to the at least one active item of the programmed menu if the menu lock flag is activated.

The method may further comprise enabling changes to the at least one active item of the programmed menu if the menu lock flag is deactivated.

Enabling changes may comprise enabling changes to all of the active items of the programmed menu.

The method may be carried out on the ambulatory liquid infusion pump. In this embodiment, displaying may comprise displaying the programmed menu on a display device of the ambulatory liquid infusion pump. Alternatively or additionally, the method may be carried out on an electronic device that is separate and remote from the ambulatory liquid infusion pump. In this embodiment, displaying may comprise displaying the programmed menu on a display device of the electronic device.

A first version of application software containing the menu may be available to users of the ambulatory liquid infusion pump, and a second version of the application software containing the menu may be available only to health care professionals. In one embodiment, the menu lock flag may be activated in the first version of application software and may be deactivated in the second version of the application software. Alternatively, the menu lock flag may be activated in the first version of application software, and the second version of the application software may not include the menu lock flag.

A method of extending a pre-programmed lifetime of an ambulatory liquid infusion pump may comprise monitoring a pre-programmed lifetime timer resident in the liquid infusion pump, allowing the liquid infusion pump to continue operating after the lifetime timer expires, and disabling operation of the liquid infusion pump if a liquid infusion pump operating error is detected after the lifetime timer expires.

The method may further comprise displaying a message on a display device of the liquid infusion pump when the lifetime timer expires. The message may illustratively identify expiration of the lifetime of the liquid infusion pump.

The method may further comprise activating at least one of an audible indicator and a vibratory device when the lifetime timer expires.

A method of storing information relating to operation of a liquid infusion pump may comprise periodically storing in a storage location of a non-volatile memory information relating to delivery by the pump of a commanded liquid

amount throughout delivery by the pump of the commanded liquid amount, transferring the information relating to delivery by the pump of the commanded liquid amount from the storage location of the non-volatile memory to a pump history database when delivery by the pump of the commanded liquid amount is complete, and automatically transferring any information relating to delivery by the pump of a commanded liquid amount that is accumulated in the storage location of the non-volatile memory to the pump history database upon power up of the liquid infusion pump.

The information relating to delivery by the pump of a commanded liquid amount may include any one or more of a delivered liquid quantity, a percentage of a delivered liquid quantity relative to 100%, one or more associated liquid delivery limits, a liquid delivery type, whether the delivered liquid was locally or remotely commanded, and the time and date of liquid delivery. The one or more liquid delivery limits may illustratively include one or more of a maximum liquid amount, a minimum liquid amount, a maximum delivery duration and a minimum delivery duration. The liquid delivery type may illustratively include at least one of a basal rate, a temporary basal rate a standard bolus, an extended bolus, a multi-wave bolus and a quick bolus.

The method may further comprise clearing the non-volatile memory after automatically transferring information from the non-volatile memory to the pump history database.

The commanded liquid amount may be one of a locally commanded liquid amount and a remotely commanded liquid amount.

In one embodiment, periodically storing information relating to delivery by the pump of a commanded liquid amount throughout delivery by the pump of the commanded liquid amount may comprise storing information periodically in time. Alternatively or additionally, periodically storing information relating to delivery by the pump of a commanded liquid amount throughout delivery by the pump of the commanded liquid amount may comprise storing the information after each delivery of by the pump of an incremental amount of the commanded liquid amount.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of one illustrative embodiment of a wireless communication system including a liquid infusion pump and a remote electronic device that are both configured to wirelessly communicate with each other.

FIG. 2 is a diagram of one illustrative embodiment of the liquid infusion pump of FIG. 1.

FIG. 3 is a diagram of the liquid infusion pump of FIG. 2 shown with a liquid cartridge inserted therein.

FIG. 4 is a flowchart of one illustrative embodiment of a process for controlling change access to one or more active items of a displayed menu.

FIG. 5 is a flowchart of one illustrative embodiment of a process for extending the pre-programmed lifetime of the liquid infusion pump.

FIG. 6 is a flowchart of one illustrative embodiment of a process for storing current pump operating information in non-volatile memory during and throughout delivery of a currently commanded liquid amount.

DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to a number of illustrative embodiments shown in the attached drawings and specific language will be used to describe the same.

The following co-pending patent applications are incorporated herein by reference: PCT Patent Application No. _____, entitled APPARATUS AND METHOD FOR REMOTELY CONTROLLING AN AMBULATORY MEDICAL DEVICE and having attorney docket no. 5727-205462, PCT Patent Application No. _____, entitled COMBINATION COMMUNICATION DEVICE AND MEDICAL DEVICE FOR COMMUNICATING WIRELESSLY WITH A REMOTE MEDICAL DEVICE, and having attorney docket no. 5727-205463, PCT Patent Application No. _____, entitled METHOD AND APPARATUS FOR DETERMINING AND DELIVERING A DRUG BOLUS, and having attorney docket no. 5727-205464, PCT Patent Application No. _____, entitled USER INTERFACE FEATURES FOR AN ELECTRONIC DEVICE, and having attorney docket no. 5727-205466, PCT Patent Application No. _____, entitled METHOD FOR PAIRING AND AUTHENTICATING ONE OR MORE

MEDICAL DEVICES AND ONE OR MORE REMOTE ELECTRONIC DEVICES, and having attorney docket no. 5727-205470, PCT Patent Application No. _____, entitled DEVICE AND METHODS FOR OPTIMIZING COMMUNICATIONS BETWEEN A MEDICAL DEVICE AND A REMOTE ELECTRONIC DEVICE, and having attorney docket no. 5727-204710/WP-24993PCT, and U.S. Provisional Patent Application Ser. No. _____, entitled DEVICE AND METHODS FOR OPTIMIZING COMMUNICATIONS BETWEEN AN ELECTRONIC DEVICE AND A MEDICAL DEVICE, and having attorney docket no. 5727-204710/WP-24993US.

Referring now to FIG. 1, a block diagram is shown of one illustrative embodiment of a wireless communication system 10 including a liquid infusion pump 14 and a remote electronic device 12 that are both configured to wirelessly communicate with each other. The electronic device 12 has a housing through which a user button section 16 extends. The user button section 16 defines a number of user buttons, keys or switches that may be manually manipulated by a user to provide input to the remote electronic device 12. A visual display unit 18 is also carried by the housing of the electronic device 12. In one embodiment, the visual display unit 18 is provided in the form of a conventional liquid crystal display (LCD), although this disclosure contemplates using other conventional display units. Examples include, but are not limited to, plasma displays, light emitting diode (LED) based displays, vacuum fluorescent (VF) displays, and the like. In any case, the visual display unit 18 is controlled by the electronic device 12 to display information to a user of the device 12. The user buttons 16 and the display device 18 are both electrically connected to a conventional processor 20 that is also electrically connected to a conventional wireless communication circuit or module 22. In some embodiments, the remote electronic device 12 may further include a conventional glucose meter that is configured to receive therein a carrier upon which an analyte containing liquid sample may be deposited. The remote electronic device 12 may be operable in a conventional manner to determine the concentration of the analyte in the liquid sample, and to display the result on the display unit 18 and/or use the result in one or more algorithms executed by the processor 20.

The liquid infusion pump 14 has a conventional processor 28 that includes a conventional memory unit 25. In the illustrated embodiment, the infusion

pump 14 further includes conventional non-volatile memory units 27 and 29. In one embodiment, the non-volatile memory unit 27 is provided in the form of a conventional ferroelectric random access memory (FRAM) and the non-volatile memory unit 29 is provided in the form of a conventional electrically erasable programmable read only memory (EEPROM), although either memory unit 27, 29 may alternatively be provided in the form of one or more other conventional non-volatile memory units. In any case, the memory units 27 and 29 are each external to the processor 28 and are each electrically connected to the processor 28. As will be described in greater detail hereinafter, the memory unit 27 is a pump delivery (PD) memory unit in which the processor 28 stores current pump delivery information, and the memory unit 29 is a pump history (PH) memory unit that has stored therein pump history information in a pump history database, e.g., in the form of event records each corresponding to an operational event of the pump 14. The processor 28 is also electrically connected to a wireless communication circuit or module 30. The wireless communication module 30 is configured to communicate wirelessly with the wireless communication module 22 of the remote electronic device 12 via a wireless communication link 40 in a conventional manner. In one embodiment, as will be illustrated by example throughout this disclosure, the wireless communication module 30 and the wireless communication module 22 of the electronic device 12 are both conventional BlueTooth® modules configured to wirelessly communicate according to a conventional BlueTooth® communication protocol. It will be understood, however, that the wireless communication circuit or module 30 and the wireless communication circuit or module 22 of the electronic device 12 may alternatively be configured to wirelessly communicate according to one or more other conventional communication protocols.

The processor 28 is also electrically connected to another wireless communication circuit or module 35. The wireless communication circuit 35 is configured to communicate wirelessly with another remote electronic device 15 via a wireless communication link 17 in a conventional manner. In one embodiment, the wireless communication circuit 35 includes a conventional infrared (IR) transceiver, and the wireless communication circuit 35 is configured to communicate with the electronic device 15 via a conventional IR communications protocol. In this embodiment, the electronic device 15 also includes a conventional IR transceiver, and

the wireless communication link 17 is therefore an IR communication link. In one embodiment, the electronic device 15 is a conventional personal computer (PC), although the electronic device 15 may alternatively be a conventional laptop, notebook or other computer, a personal data assistant (PDA) or the like. In the illustrated embodiment, the wireless communication circuit 35 is used by the liquid infusion pump 14 to download pump-related data to the electronic device 15 for analysis and/or observation. The wireless communication circuit 35 may alternatively or additionally be used to download data or code from the electronic device 15, such as new software, software updates, software version updates or the like, pump configuration data, language files, current time and data information, and the like. It will be understood, however, that while the wireless communication circuit 35 has been described as including a conventional infrared transceiver, the wireless communication circuit 35 and the electronic device 15 may alternatively or additionally be configured to wirelessly communicate via other conventional media including for example, but not limited to, a radio frequency (RF) communication link, a microwave frequency communication link, inductive coupling, or the like.

The liquid infusion pump 14 includes a housing through which a number of user buttons 32 extend. The user buttons 32 may be provided in the form of any number of user selectable buttons, keys or switches that are electrically connected to the processor 28. The liquid infusion pump 14 further includes a visual display unit 34 that is carried by the housing and that is electrically connected to the processor 28. The visual display unit 34 may be, for example, a conventional liquid crystal display (LCD), plasma displays, light emitting diode (LED) based display, vacuum fluorescent (VF) display, or the like. The visual display unit 34 is controlled by the processor 28 to display information to a user of the liquid infusion pump 14.

The processor 28 of the liquid infusion pump 14 is further electrically connected to a conventional audible indication device 36 and/or to a conventional vibratory device 38. The processor 28 is generally operable to control the audible indication device 36 and/or the vibratory device 38 to produce one or more audible sounds and/or vibrations respectively to notify the user of various operational aspects of the liquid infusion pump 14 and to also notify the user of any alarm and/or warning conditions associated with the liquid infusion pump 14. The memory unit 25 has one or more sets of instructions stored therein that are executable by the processor 28 to

carry out one or more processes associated with the liquid infusion pump 14. The liquid infusion pump 14 further includes a power supply 42 that is configured to derive a supply voltage from one or more chargeable or non-chargeable batteries 44, and to provide the supply voltage to at least the processor 28 and the wireless communication module 30. In one embodiment, the insulin infusion pump 14 uses a single AA 1.5V rechargeable battery or a lithium or alkaline non-rechargeable battery, having a minimum capacity of 2500 mAh, although this disclosure contemplates other embodiments which use more, fewer and/or different chargeable and/or non-rechargeable batteries. A conventional motor drive circuit 46 is electrically connected to the processor 28, and the motor drive circuit 46 is responsive to control signals produced by the processor 28 to drive a pump motor 48. In one embodiment, the pump motor 48 is a brushless DC motor, although the pump motor 48 may alternatively be a conventional DC motor or a stepper motor or other conventional drive mechanism.

Referring now to FIG. 2, a diagram is shown of one illustrative embodiment of some of the exterior and/or readily visible features of the liquid infusion pump 14. In the illustrated embodiment, the pump 14 has a housing 50 through which a display 34 extends. In alternative embodiments, the pump 14 may not include a display and/or may include other visual indicators such as one or more lamps, light emitting diodes (LEDs), or the like. The housing 50 defines a liquid cartridge chamber 52 into which a conventional liquid drive mechanism 54 is configured to extend. In one embodiment, the liquid drive mechanism 54 is a conventional telescoping drive mechanism that is configured to move linearly within the chamber 52, although this disclosure contemplates alternative embodiments in which the liquid drive mechanism 54 rotatably advances into and out of the chamber 52 in a conventional manner.

As shown in FIG. 3, the chamber 52 is sized to hold a cartridge 70 of liquid, e.g., drug, to be infused by the pump 14 into a body. The drive mechanism 54 is sized to be received within one end of the liquid cartridge 70 and to engage a plug 72 that forms a movable liquid seal with the cartridge 70. The opposite end of the liquid cartridge 70 is secured to the housing 50 via releasably engageable, e.g., threaded, adapter 74 through which a conventional Luer lock fitting 76 extends. The Luer lock fitting 76 is configured to be fluidly connected to an infusion set (not

shown) that extends into a body of a user. Under the control of the processor 28, the pump motor 48 drives the liquid drive mechanism 54 to controllably advance into the liquid cartridge 70 and thereby force liquid from the cartridge 70 into the body of the user via the Luer lock fitting 76 and infusion set.

The user buttons 32 of the liquid infusion pump 14 are distributed in groups of two buttons or keys 60, 62 and 64, 66 each near opposite sides of the display unit 34. In the illustrated embodiment, the key 60 is a MENU key, the key 62 is a "check" or "OK" key, the key 64 is an up key and the key 66 is a down key. The MENU key 60 allows the user to select and move through menus, function screens and information screens, and may also act an on/off key for the infusion pump 14. The check or OK key 62 allows the user to select menus, to save changes, to exit function and information screens and to view one or more quick information screens. The up key 64 allows the user to move forward in the information screens, to increase a displayed setting, to turn on a backlight of the display device 34, to program a quick bolus, to cancel a quick bolus and to turn off a stop warning. The stop warning is generally activated periodically, e.g., once per minute, when liquid delivery by the pump 14 is stopped. By pressing and holding the up key 64 for approximately 3 seconds, this stop warning may be turned off or disabled. The down key 66 allows the user to move backward in the information screens, to decrease a displayed setting, to program a quick bolus, to cancel a quick bolus and to turn off the stop warning by pressing and holding the down key 36 for approximately 3 seconds. By simultaneously pressing the MENU key 60 and the up key 64, the user can exit menus, function screens and information screens without saving changes, and to sequentially navigate back through the previous menus. By simultaneously pressing the menu key 60 and the down key 66, e.g., until 3 beeps occur, the user can unlock the user keys 32. By simultaneously pressing the up key 64 and the down key 66, the user can copy an hourly basal rate to the following hour.

The processor 28 is generally operable to control the display unit 34 within various menus to allow the user to enter information, such as an infusion amount, infusion duration, or the like, via one or more editable menu screens. By repeatedly pressing the up key 64 or the down key 66 when an editable menu screen is selected on the display unit 34, the numerical value in the editable menu screen is correspondingly incremented or decremented respectively. The pump 14 also

includes a smart scroll function that provides for rapid scrolling through values that the user may enter in any of the editable menu screens. For example, by pressing and holding the up key 64 or the down key 66, the value displayed in the editable menu screen is, in one illustrative embodiment, automatically incremented or decremented respectively at a high increment or decrement rate. Alternatively or additionally, the step size of the increment or decrement may increase to a larger incremental value, .e.g., from 0.1 to 0.5, when the up key 64 or the down key 66 is pressed and held. In either case, the desired value in an editable menu screen may be selected or confirmed by pressing the OK key 62.

EXAMPLE

The following is a description of example features of one illustrative embodiment of the liquid infusion pump 14 of FIGS. 1-3. It will be understood that such features are provided only by way of example, and should not be considered limiting in any way. By way of overview, the example infusion pump 14 provides for the choice of three different user menus of varying complexity. A standard menu provides for basic functionality and programming of the pump 14, an advanced menu provides for full functionality and programming of the pump 14 and a custom menu option allows the user to define a menu structure having desired functionality and programming options.

Generally, the example infusion pump 14 provides for five basal rate profiles, and for the programming of three different bolus types. Illustratively, the three different bolus types include a standard (STD) bolus, corresponding to a specified bolus quantity that is delivered immediately and all at once, an extended bolus (EXT), corresponding to a specified bolus quantity that is delivered over a specified period of time, and a multi-wave bolus (MW), corresponding to a specified bolus quantity of which a portion is delivered immediately and another portion of which is thereafter delivered over a specified time period. Additionally, a quick bolus, which is a specific form of a standard bolus, may also be programmed without having to view the display device 34. Warnings and errors are signaled using the combination of audible tones or beeps and tactile vibrations, and the beep tones of the audible device 36 are fully adjustable in volume. Historical information relating to operation of the pump 14 may be transferred from the pump 14 to the electronic device 15 via the wireless communication circuit 35. The display device 34 may be

configured to display information in a default orientation or in an orientation that is rotated 180° relative to the default rotation. In addition to the warnings and errors, the pump 14 may be programmed to signal various reminders. The user keys 32 may be locked to prevent accidental activation of functions, such as during sleep or certain activities, and may be unlocked using a combination of the user keys 32 as described above.

The screen displayed on the display device 34 relate to four general categories: 1) run, stop and quick information, 2) information, 3) function and 4) setup. Generally, the display device 34 is deactivated by the processor 28 to conserve battery life, and becomes active by pressing any of the user keys 32. When any such key is pressed, the RUN screen is displayed when the pump 14 is in the RUN mode, meaning that insulin is being delivered by the pump 14 according to the programmed basal rate. Illustratively, the RUN screen displays a basal rate indication icon, the current hourly basal rate, the time of day and the active basal rate profile. Additional icons that may be displayed on the display device 34 during the RUN mode include, but should not be limited to, a battery life indicator, a cartridge volume indicator, a pump timer indicator and a key lock indicator.

A STOP screen is displayed when the pump 14 is in the STOP mode, meaning that insulin is no longer being delivered by the pump 14. Illustratively, the STOP screen displays the current time of day, the date and a stop symbol. The STOP screen may further be configured to display any one or more of a battery life indicator, a cartridge volume indicator, a pump timer, and a key lock indicator. Illustratively, programming specific functions, changing the cartridge and/or the infusion set, priming the infusion set, and transferring data to and from the pump 14 all require the pump 14 to be in the STOP mode. Additionally, it is illustratively recommended for the pump to be in the STOP mode when changing the battery 44

The pump 14 further includes a quick information screen, which may be displayed by pressing the OK or check key 62. Generally, the quick information screen shows the remaining liquid content in the cartridge 70 in suitable liquid units. By again pressing the OK or check key 62, the bolus data function is displayed, and the most recent 30 boluses may be viewed by pressing the up and down keys 64 and 66 respectively.

The screens displayed on the display device 34 may generally be navigated by pressing the menu key 60 until reaching a screen of choice, and then pressing the OK or check button 62. After pressing the OK or check button 62, one or more function screens become available. The value displayed within each function screen may be changed by pressing the up and down keys 64 and 66 respectively, and the next function screen may be displayed by pressing the menu key 60. A user may also move backwards through the menu structure as described hereinabove. In any case, the OK or check button 62 may be pressed to save changes.

Information relating to operation of the pump 14 is generally stored in memory by the processor 28 along with the time and date of occurrence thereof. Illustratively, the time may be selected to be American time or European/military time. In embodiments in which the pump 14 communicates wirelessly with the electronic device 12 as illustrated in FIG. 1, the time and date of the pump 14 is the master time and date, and is used to periodically update the time and date of the electronic device 12.

BASAL RATE PROFILE

In this example, the pump 14 delivers liquid every three minutes, in 20 equal doses each hour, 24 hours per day. The flow of liquid, e.g., insulin, is measured in international units per hour (U/h), and is called the basal rate profile. The pump 14 can store up to five different basal rate profiles each consisting of 24 different hourly basal rates. Each hourly basal rate may be changed independently, and the total of all 24 basal rates in any one basal rate profile is referred to as the daily basal rate total. By pressing the menu key 60, basal rate profile programming screens are available in which basal rates may be programmed for each hour of consecutive 24 hour periods. The basal rate programming screens further allow for the copying of hourly basal rates to one or more additional hours for situations in which the basal rate will be unchanged for multiple consecutive hours. Changes to the basal rate programming screens may be made in either the RUN mode or the STOP mode. These changes are saved by pressing the OK or check key 62. If changes are made in the RUN mode, the display device 34 returns to the RUN screen after pressing the OK or check key 62. If changes are made in the STOP mode, the display device 34 returns to the STOP screen after pressing the OK or check key 62. If the user does not press the OK or check key 62 when attempting to make changes to a basal rate, the screen timer

will eventually time out and the processor 28 will return the display device 34 to the RUN or STOP screen without implementing the change to the basal rate. Generally, changes may be undone by simultaneously pressing the menu key 60 and the up key 64 when the display device 34 returns to the main menu or to the RUN or STOP screen. During normal use, the pump 14 is in the RUN mode, and liquid, e.g., insulin, is continually delivered to the user's body according to the programmed basal rate profile. Bolus amounts may be programmed and delivered as deemed necessary by the user, as will be described hereinafter.

The display screens of the pump 14 include a START and a STOP screen that may be accessed by successively pressing the menu key 60. After the user starts the pump 14 by accessing the START menu and pressing the OK or check key 62, the RUN screen is thereafter displayed. Likewise, by accessing the STOP screen via successively presses of the menu key 60, the STOP function may be activated by pressing the OK or check button 62, after which the STOP screen is displayed on the display device 34.

The liquid infusion pump 14 further provides for the temporary increase or decrease of the programmed basal rate. For example, a basal rate initially set to 100% can be increased up to 250% for up to 24 hours or decreased down to 0% for up to 24 hours, although other percentage and/or time values may be used. In one alternative embodiment, for example, a basal rate initially set to 100% may be increased up to 500% for up to 50 hours or decreased down to 0% for up to 50 hours. By increasing or decreasing the basal rate by the temporary basal rate amount, each hourly basal rate for the duration of the increase or decrease is likewise increased or decreased. The characteristic shape of the existing basal rate profile remains intact with the temporary basal rate. A temporary basal rate may be programmed only when the pump is in the RUN mode, and is implemented by successively pressing the menu key 60 to a temporary basal rate screen. By pressing the OK or check key 62, the temporary basal rate percentage value may be changed by pressing the up or down key 64 or 66 respectively. The duration of the temporary basal rate may be set by similarly accessing a temporary basal rate duration screen, and setting the duration value to a desired temporary basal rate duration.

The temporary basal rate may be canceled during programming in one of three ways. First, failure to press any of the user keys 32 for 20 seconds will cause

the pump 14 to return to the RUN screen. Additionally, the temporary basal rate screen may be exited by simultaneously pressing the menu key 60 and the up key 64. Finally, the temporary basal rate percentage may be set to the default value of 100%, after which the temporary basal rate value may be saved by pressing the OK or check key 62. During delivery, there are two ways to cancel a temporary basal rate. For example, the temporary basal rate programming screen may be accessed, and the temporary basal rate value may be changed to 100% as described above. Alternatively, the pump 14 may be put into the STOP mode as described above, which automatically cancels the temporary basal rate being delivered. A temporary basal rate cancel warning is displayed in each case, which may or may not be accompanied by an audible and/or vibratory indication.

PROGRAMMING BOLUSES

It is generally understood that a bolus is an amount of insulin delivered to compensate for the intake of food and/or to correct high blood glucose levels. The liquid infusion pump 14 is capable of being programmed to deliver three different types of bolus as described above. Illustratively, the three different bolus types include a standard (STD) bolus, corresponding to a specified bolus quantity that is delivered immediately and all at once, an extended bolus (EXT), corresponding to a specified bolus quantity that is delivered over a specified period of time, and a multi-wave bolus (MW), corresponding to a specified bolus quantity of which a portion is delivered immediately and another portion of which is thereafter delivered over a specified time period. Additionally, a quick bolus, which is a specific form of a standard bolus, may also be programmed without having to view the display device 34.

The liquid infusion pump 14 provides for two different types of standard bolus as just described. A quick bolus may be programmed when the pump 14 is operating in the RUN mode by pressing and holding the up key 64 or the down key 66 for several seconds until a beep sequence and vibration occur. Thereafter, a quick bolus screen appears on the display device 34, and the user may press the up key 64 or the down key 66 to increment the displayed bolus amount until the desired bolus value is reached. Generally, if the up key 64 was used to enter the quick bolus screen, the down key 66 must be used to increment the desired bolus value, and vice versa. In either case, each press of the up key 64 or the down key 66 causes the pump

14 to simultaneously beep and vibrate to indicate the incremental increase in the bolus amount. Five seconds after the last press of the up key 64 or the down key 66, the pump 14 confirms the total quick bolus amount by activating one beep and vibration for each bolus increment that was programmed. The standard bolus symbol in the display 34 then blinks for approximately five seconds, after which the pump 14 begins to deliver the programmed quick bolus. After the delay period, the pump 14 beeps and vibrates three times and then begins to deliver the total quick bolus that was programmed, and the display 34 simultaneously counts down the remaining bolus to be delivered until the full programmed quick bolus amount is delivered. Because the pump 14 beeps and vibrates to guide the user through the programming steps, the quick bolus amounts may be programmed without viewing the pump display 34.

During programming, the quick bolus amount may be canceled by decrementing the quick bolus amount to 0.0 units using the opposite one of the up or down key 64, 66 that was used to increment the quick bolus amount. If the display remains at 0.0 units for approximately five seconds, no new bolus will be delivered and the pump display 34 returns to the RUN screen which may or may not be accompanied by an audible and/or vibratory indication. The quick bolus may also be canceled during confirmation of the total bolus amount (when one beep and vibration occurs for each bolus increment programmed) or during start delay (when the standard bolus symbol blinks for approximately five seconds), by pressing either of the up or down keys 64 and 66 respectively. When this occurs, the display device 34 returns to the RUN screen, and a bolus cancel warning then appears on the screen which may or may not be accompanied by an audible and/or vibratory indication. The user may press the OK or check key 62 twice to confirm and turn off the alert. The quick bolus may also be canceled during bolus delivery by pressing either the up key 64 or the down key 66 for approximately three seconds, after which the display 34 will display a bolus cancel warning which may or may not be accompanied by an audible and/or vibratory indication. The OK or check key 62 may be pressed twice to confirm and turn off the alert. The actual bolus amount delivered prior to being canceled may be viewed by accessing the bolus history as will be described hereinafter.

A standard bolus may be programmed by accessing the standard bolus menu via successive presses of the menu key 60. Pressing the OK or check key 62

when the standard bolus menu is displayed causes a standard bolus amount to be displayed on the display device 34. The user may press the up key 64 to increase or the down key 66 to decrease the bolus amount, and the OK or check key 62 is pressed to confirm the bolus amount. After pressing the OK or check key 62, the display device 34 may be controlled to indicate the change, for example by flashing the standard bolus symbol in the display 34 for some time period, e.g., for approximately five seconds, after which the delivery of the standard bolus amount will begin. The pump 14 may illustratively produce an audible and/or vibratory indication when the programmed bolus amount is being delivered, and the display 34 counts down the remaining bolus yet to be delivered.

During programming of the standard bolus, cancellation of the bolus may occur in one of three ways. If no key is pressed for approximately 20 seconds during programming, no bolus amount will be delivered and the display 34 returns to the previous screen. Also, if during programming of the standard bolus amount, the menu key 60 and the up key 64 are simultaneously pressed, the pump 14 exits the standard bolus menu and returns to the previous screen. Finally, if the bolus amount is set to 0.0 units, pressing the OK or check key 62, will return the display 34 to the previous screen with no bolus amount being delivered. In any of these cases, the user may then press the up key 64 three times to display the RUN screen or wait until the screen timer times out after which the processor 28 will automatically display the RUN screen. During the start delay (when the standard bolus symbol blinks for approximately five seconds) the programmed standard bolus amount may be canceled by pressing the up key 64 or the down key 66 until a beep sequence is heard, after which the display 34 displays a bolus cancel warning. Pressing the OK or check key 62 twice confirms and turns off this alert. During delivery of the programmed standard bolus amount, the user may press and hold the up key 64 or the down key 66 for approximately three seconds until a beep sequence is heard. A bolus cancel warning will again appear, and the OK or check key 62 may be pressed twice to confirm and turn off this alert. The actual bolus amount delivered prior to cancellation can be viewed by accessing the bolus history as will be described hereinafter.

Extended boluses may be programmed in intervals, e.g., 15, 30 or 60 minute intervals, up to some number of time units, e.g., 50 hours, and will begin

immediately after confirmation of the programmed bolus amount. Throughout delivery of an extended bolus, the remaining time and bolus amount yet to be delivered will be displayed, along with the current hourly basal rate, on the display 34 in the RUN screen. An extended bolus may be programmed by accessing an extended bolus screen via successive presses of the menu key 60, and then by pressing the OK or check key 62 when the extended bolus appears. The bolus amount may be selected by pressing the up key 64 to increase the bolus amount or by selecting the down key 66 to decrease the bolus amount. The duration of the last extended bolus that was delivered appears on the screen, and by pressing the menu key 60 the display 34 displays the bolus duration screen. The bolus duration may be increased or decreased by pressing the up key 64 and the down key 66 respectively. Successive pressing the menu key 60 will switch the display 34 between the programmed bolus amount and programmed bolus duration. When the extended bolus amount and extended bolus duration are selected, the OK or check key 62 is pressed to confirm the bolus amount and duration. A beep sequence and/or vibration may occur when the OK or check key 62 is pressed. Bolus delivery thereafter begins, e.g., within the next three minutes. If a temporary basal rate is active at the same time as an extended bolus, the remaining time and amount of the bolus as well as the amount of the increased or decreased hourly basal rate will be displayed together on the RUN screen. A standard bolus can be added to an ongoing extended bolus, and if the standard bolus is canceled, the extended bolus will continue to run. However, during the delivery of an extended bolus, the programming of another extended bolus or of a multi-wave bolus will be blocked, and an error message indicating that a bolus is currently running will appear on the display 34. To program a different extended bolus when an extended bolus is currently running, the pump 14 must be put into the STOP mode to cancel the current extended bolus and then to reprogram a new extended bolus.

An extended bolus may be canceled during programming identically as described hereinabove with respect to the standard bolus. After delivery of the bolus has begun, the extended bolus may be canceled only by putting the pump 14 in the STOP mode. This cancels delivery of the standard bolus, and displays a bolus cancel warning in the display 34. The OK or check key 62 may be pressed twice to confirm and turn off the alert. The amount of extended bolus delivered prior to the

cancellation may be viewed in the bolus history screen as will be described hereinafter.

A multi-wave bolus may be programmed in intervals, e.g., 15, 30 or 60 minute intervals, for up to some number of time units, e.g., 50 hours. Programming of a multi-wave bolus is only available in the advanced or custom user menus, as will be described in greater detail hereinafter, and in these menus successive presses of the menu key 60 will display the multi-wave bolus screen. Pressing the OK or check key 62 then causes a bolus amount screen to appear, and the user may select the bolus amount by pressing the up key 64 and down key 66 to increase or decrease respectively the total bolus amount. Illustratively, the first press of the up key 64 will cause the bolus duration of the last multi-wave bolus to appear on the screen. When the total bolus amount is programmed, the menu key 60 may be pressed to move to the immediate bolus screen which displays the immediate portion of the multi-wave bolus. Illustratively, the first press of the up key 64 will cause the amount of the last immediate portion of a multi-wave bolus to appear on the screen. The user may press the up key 64 and the down key 66 to increment and decrement the immediate bolus amount. The user may then press the menu key 60 again to move to the bolus duration screen by pressing the up key 64 and the down key 66. The duration of the extended portion of the multi-wave bolus may be set in increments, e.g., in increments of 15, 30 or 60 minutes, up to some number of time units, e.g., 50 hours. Again, the menu key 60 may be pressed repeatedly to switch the display device 34 between the bolus amount, immediate bolus and bolus duration screens. When these three values have been selected, the user may press the OK or check key 62 to confirm the multi-wave bolus parameters, and the display device 34 may then be controlled to indicate the confirmation, for example by flashing the multi-wave bolus symbol on the display 34 for some time period, e.g., approximately five seconds. At the end of the delay, e.g., a five second delay, the immediate portion of the multi-wave bolus will be delivered by the pump 14. This may or may not be accompanied by an audible and/or vibratory indication. The display 34 will then be controlled to display a count down of the remaining portion of the bolus.

The multi-wave bolus may be canceled during the programming mode identically as described with respect to the programming of the standard and extended bolus. During the START delay (in which the multi-wave bolus symbol illustratively

flashes), the multi-wave bolus may be canceled identically as described above with respect to the standard bolus. Likewise, the immediate portion of the multi-wave bolus may be canceled during delivery thereof identically as described above with respect to the standard bolus. Finally, cancellation of the multi-wave bolus during delivery of the extended portion of the multi-wave bolus may be canceled identically as described above with respect to delivery of the extended bolus.

Insulin delivery may stop if a mechanical or an electrical error is discovered during the routine automatic system check. Insertion of a new battery will also cause a power interrupt error to occur if the pump 14 is operating in the RUN mode. A user may turn off either the beeps or vibrations for the initial alarm indication, but not both. Generally, if a warning or error is not confirmed by the user in 60 seconds, it will occur again. The OK or check key 62 will generally be pressed twice to confirm a warning or an error. The first press acknowledges the warning or error, and the second press confirms the warning or error. If the warning or error is acknowledged but not confirmed, e.g., by pressing the OK or check key 62 only once, the warning or error will not be cleared and it will generally occur again. If the warning or error is acknowledged and confirmed, e.g., by pressing the OK or check key 62 twice, the warning or error will be cleared and will not occur again unless the condition that caused the warning or error thereafter occurs.

The user may turn off the beeps and vibrations by pressing the OK or check key 62, after which the warning or error continues to be displayed on the display device 34. By pressing the OK or check key 62 again, the warning or error will disappear from the display 34. If more than one warning and/or error occurs simultaneously, the user will be required to press the OK or check key 62 twice for each warning or error to confirm and turn off. However, a number of warnings or errors will continue to be displayed in the RUN screen or the STOP screen after they have been confirmed. Examples of such warnings or errors that will be continued to be displayed in the RUN screen or STOP screen include, but may not be limited to, a cartridge low warning, a cartridge empty error, a battery low warning, a battery depleted error, a pump timer warning, and an end of operation error.

The following is a list of warnings and errors that will be identified and displayed by the pump 14, each followed by a short description thereof.

A cartridge low warning will occur when the contents of the cartridge 70 have dropped to approximately 20 units of insulin.

A battery low warning will occur when the voltage supplied by the battery 44 is less than a threshold voltage. Failure to replace the battery will generally result in additional error messages.

When the pump 14 has been without power for more than one hour, a review time warning will occur. With this warning, the user is prompted to check and correct if necessary, the current date and time.

When the pump 14 is coming to the end of its predetermined lifetime, a lifetime error will occur. Related to this is a pump lifetime timer warning that will occur when the operating time of the pump 14 will soon expire. When this error occurs, the display 34 may or may not be activated to display an approximate number of days remaining in the operation of the pump 14. In this embodiment, when the pump lifetime timer reaches zero, the pump 14 will change to the STOP mode and no longer operate. Alternatively, the pump 14 may be configured to operate after the pump lifetime timer reaches zero as will be described hereinafter with respect to FIG. 5.

When a temporarily increased or decreased basal rate has been canceled, a temporary basal rate cancellation warning will occur. Similarly, when a temporary basal rate has ended, a temporary basal rate over warning will occur, and the original basal rate (100%) will resume automatically.

When a bolus has been canceled during the start delay or after delivery has begun, as described hereinabove, a bolus cancellation warning will occur.

If authentication data associated with the pairing and authentication of an electronic device 12 is or becomes corrupt, or if operation of the wireless communication module 30, illustratively provided in the form of a BlueTooth® module, is compromised, operation of the pump 14 thereafter will result in a wireless communication fault warning. This warning generally will not occur after pump 14 is either re-paired with the electronic device 12 to which it was previously paired, or after the pump 14 is paired with a new electronic device.

When the insulin cartridge 70 is empty, a cartridge empty error will occur. Similarly, if the battery 44 is depleted, a battery depleted error will occur.

If no keys are pressed within a specified time period in the RUN mode, an automatic off error will occur if this feature of the pump 14 is activated.

On some occasions, insulin may not be delivered by the pump 14 as a result of a blocked infusion set, a damaged cartridge 70, and/or a dirty or damaged piston rod. In this case, an occlusion error will occur. Similarly, cartridge change function was not correctly performed, a cartridge error will occur, and if the cartridge has been changed but the infusion set has not been primed, a set not primed error will occur.

If data transfer via the wireless communication circuit 35 has been interrupted, a data interruption error will occur.

Additionally, a number of different alarm clock functions may be programmed in the pump 14, and an alarm error will occur when any of the programmed alarm clock functions expires.

Generally, it will be understood that the occurrence of any of the errors or warnings described herein by example, may or may not be accompanied by any type of message displayed on the display device 34, any single one of, plurality of or sequence of an audible indication and/or any single one of, plurality of or sequence of a vibratory indication.

VIEWING PUMP DATA

The external pump history (PH) memory unit 29 of the pump 14 stores historical information associated with the operation of the pump 14. The pump history information may include, for example, but should not be limited to, all events relating to the operation of the pump 14, e.g., warnings and errors, programming operations and insulin delivery records. Up to approximately 4500 events may be stored, which corresponds to approximately the previous 90 days of use. This data may be downloaded to the electronic device 15 via the wireless communication circuit 35 as described hereinabove. While still present within the PH memory unit 29, the following data categories can be reviewed directly on the display device 34: 1) bolus history (last 30 boluses), 2) alarm history (last thirty warnings and errors), 3) history of daily insulin totals (last 30 daily totals of insulin delivered), and 4) temporary basal rate history (last 30 increases and decreases in basal rate). Additionally, if the pump 14 is configured to do so, the pump timer (remaining timing days until the pump timer expires) information may be reviewed via the display

device 34. Generally, the menu key 60 may be successively pressed to display a "my data" screen from which the foregoing pump data categories may be accessed. In the bolus history screen, for example, the bolus amount and type, bolus time, date and entry number may be displayed. In the alarm history screen, the number and type of the warning or error may be displayed along with a text description of the warning or error, the time, date and entry number of the warning or error. In the daily insulin total history screen, total daily insulin delivered by date and entry number may be displayed, and in the temporary basal rate history screen, the temporary basal rate increase or decrease (in percentage), total basal rate duration, time and date may be displayed. In the pump timer screen, the total number of days remaining of pump operation are displayed.

The pump 14 additionally has a data transfer menu that may be accessed through repeated presses of the menu key 60 and when the data transfer menu is selected, the user may press the OK or check key 62 to enabled downloading of information to the electronic device 15. Generally, the electronic device 15 will include one or more software applications configured to request the downloading of pump data from the PH memory unit 29 to the electronic device 15 via the wireless communication circuit 35.

AVAILABLE MENUS

More or fewer of the foregoing menus are available on the pump screen depending upon which of three menus are selected for use. The three choices are standard, advanced and custom. If the standard menu is selected, all menus required for the basic functions for the pump 14 will be available to the user via the display 34. If the advanced menu option is selected, the complete range of functions of the pump 14 are provided in menus available to the user via the display 34, and in the custom menu option, the user may select which menu is available from the full range of menus. The user may select the standard, advanced or custom menu settings by successively pressing the menu key 60 to a menu settings display. If the standard user menu is selected, the following menu settings are available; therapy settings, pump settings, time and date settings, and my data. In the RUN mode, the programmed basal rate, stop command, standard bolus, extended bolus, temporary basal rate and basal rate programming displays are available. In the STOP mode, the STOP display, start pump, cartridge change, infusion set priming, data transfer and

basal rate one through five selection screens are available. In the advanced user menu setting, the following menu settings are available: Bluetooth settings, therapy settings, pump settings, time and date settings, reminder settings and my data. In the RUN mode, the basal rate display, stop command, standard bolus, extended bolus, multi-wave bolus, temporary basal rate programming and basal rate profiles one through five programming screens are available. In the STOP mode, the stop display, start command, cartridge change, infusion set priming, data transfer and basal rate one through five selection screens are available. In the custom menu setting, the desired ones of the advanced menu settings may be selected for display.

Referring now to FIG. 4, a flowchart is shown of one illustrative embodiment or process for controlling change access to one or more active items of a menu display of the display device 34 of the insulin infusion pump 14. In one embodiment, the process 80 is illustratively stored within the memory unit 25 of the processor 28, or in either of the memory units 27 and 29, in the form of instructions that are executable by the processor 28 to carry out the features of the process 80. In an alternate embodiment, the process 80 is illustratively stored in a memory unit of the electronic device 15 in the form of instructions that are executable by a processor of the electronic device 15 to carry out the features of the process 80. In this latter embodiment, the electronic device 15 is illustratively a PC, laptop or notebook computer, although the electronic device 15 may alternatively be any conventional computer, hand-held electronic device or other conventional electronic device. While the process 80 will be described with respect to FIG. 4 as being carried out on the liquid infusion pump 14, i.e., executed by the processor 28, it will be understood that the process 80 may alternatively be carried out on the electronic device 15, i.e., executed by a processor included in the electronic device 15.

In the illustrated embodiment, the process 80 presumes that a menu for display on the display device 34 of the liquid infusion pump 14 has been programmed and stored in the memory unit 25. At step 82 of the process 80, the processor 28 is operable to control the display device 34 to display the program menu thereon. Following step 82, the processor 28 is operable at step 84 to monitor a menu lock flag that is stored in the memory unit 25, or alternatively in the memory unit 27 or 29. Thereafter at step 86, the processor 28 is operable to determine the status, e.g., locked

(activated) or unlocked (deactivated), of the menu lock flag stored in the memory unit 25.

If the processor 28 determines at step 86 that the menu lock flag is locked or activated, the processor 28 is operable at step 88 to disable changes to any one or more of the active menu items of the currently displayed menu. In one illustrative embodiment, step 88 may further include the act of displaying via the display device 34 a warning message, that may or may not be accompanied by an audible or vibratory indication, upon detection of attempted changes to the one or more active menu items of the currently displayed window when the menu lock flag is locked or activated. If, at step 86, the processor 28 determines that the menu lock flag status is unlocked or deactivated, the processor 28 is thereafter operable at step 90 to enable changes to one or more active menu items in the currently displayed menu. At either of steps 88 or 90, the process 80 ends.

Illustratively, a different menu lock flag exists for each pre-programmed menu of the liquid infusion pump 14. Alternatively, a single menu lock flag may exist for all of the pre-programmed menus of the liquid infusion pump. In one embodiment, all of the one or more menu lock flags are initially locked or activated so that a user may not change one or more active menu items of any of the displayable menus. In one embodiment, the menu lock flag for any one or more of the displayable menus may be unlocked or deactivated by entering a suitable code or password into processor 28 via one or more of the user keys 32. Such a password may, for example, be known to a healthcare provider or other restricted person who may unlock or deactivate the menu lock flag for one or more menus so that one or more such menus may be customized for the user. Unlocking or deactivating any such menu lock flag may illustratively allow the healthcare professional or other restricted person to modify one of a certain one or more active menu items of any displayed menu, or may alternatively unlock or deactivate all active menu items of the selected display so that the healthcare professional or other restricted person may modify any active display item.

In an alternative embodiment, two different versions of application software containing the menu or menus may exist; one that is available to users and another that is available only to health care professionals. In this embodiment, the menu lock flag is illustratively activated in the version that is available to users so that

users do not have change access to one or more active menu items in one or more menus, and illustratively deactivated or non-existent in the version that is available to health care professionals so that health care professionals do have change access to the one or more active menu items in one or more menus. In this embodiment, the version that is available to users may, but need not, provide for menu change access by entering a suitable password or other access code.

Referring now to FIG. 5, a flow chart is shown of one illustrative embodiment of a process 100 for extending the preprogrammed lifetime of the liquid infusion pump 14. In one embodiment, as described hereinabove, the pump 14 includes a pump lifetime timer that allows the pump 14 to operate for a predetermined time, e.g., four years, after which operation of the pump 14 is disabled. In the embodiment illustrated in FIG. 5, in contrast, operation of the pump 14 may be extended beyond expiration of the pump lifetime timer. The process 100 is illustratively stored in the memory unit 25, or in the memory unit 27 or 29, in the form of instructions that are executable by the processor 28 to carry out the various features of the process 100.

The process 100 begins at step 102 where the processor 28 monitors the pump lifetime timer. Thereafter at step 104, the processor 28 is operable to determine whether the lifetime timer has expired. If not, the process 100 loops back to step 102. If, at step 104, the processor 28 determines that the pump lifetime timer has expired the process 100 advances to step 106 where the processor 28 is operable to control the display device 34 to display a message indicating that the pump 14 has passed its lifetime. Thereafter at step 108, the processor 28 is operable to control the audible indicator 36 and/or the vibratory device 38 to provide a corresponding audible and/or vibratory indication when the lifetime timer expires. Step 108 is illustrated in FIG. 5 as a dashed-line step to indicate that this step is optional. In any case, the process 100 advances to step 110 where the processor 28 is operable to determine whether an operating error associated with the operation of the pump 14 has been detected. Illustratively, the operating error monitored at step 110 may be or include any one or more of the pump errors described hereinabove. If such an error is not detected, the process 100 loop back to the beginning of step 110. If, at step 110, the processor 28 determines that an operating error has been detected, the process 100

advances from step 110 to step 112, where processor 28 is operable to disable, e.g., permanently, operation of the pump 14. Following step 112, the process 100 ends.

Referring now to FIG. 6, a flowchart is shown of one illustrative embodiment of a process 120 for periodically storing pump operating information in the non-volatile PD memory unit 27 during delivery of liquid by the liquid infusion pump 14. The process 120 is illustratively stored in the memory unit 25, or in the memory unit 27 or 29, in the form of instructions that are executable by the processor 28 to carry out the process 120. The process 120 begins at step 122 where the processor 28 is operable to determine whether the liquid infusion pump 14 is currently delivering liquid, either as a result of being locally commanded to deliver liquid or of being remotely commanded to do so. In either case, if the processor 28 determines at step 122 that the liquid infusion pump 14 is not currently delivering liquid, the process 120 loops back to the beginning of step 122. If, at step 122, the processor 28 otherwise determines that the liquid infusion pump 14 is currently delivering liquid, the process 120 advances to step 124 where the processor 28 is operable to periodically store pump operating information in a predefined storage location of the non-volatile pump delivery (PD) memory unit 27. Alternatively, the processor 28 may be operable at step 124 to periodically store the pump operating information in a predefined storage location of the non-volatile pump history (PH) memory unit 29. Illustratively, the term "periodically" may be time-based and may be any time value between a few microseconds and one or more seconds. Alternatively or additionally, the term "periodically" may correspond to units or sub-units of liquid that is delivered by the liquid infusion pump 14. One specific example of the former case may be 1-10 milliseconds, and one specific example of the latter case may be 1/10 – 1/2 units of liquid, e.g., IU, although neither of these examples should be considered to be limiting in any way. In any case, the term "pump operating information" may be or include, but should not be limited to, delivered liquid quantity, e.g., in IU, a percentage of a delivered liquid quantity relative to 100%, one or more associated liquid delivery limits, e.g., maximum and/or minimum quantity and/or duration, delivery type (or profile), e.g., basal, temporary basal, standard bolus, extended bolus, multi-wave bolus, quick bolus or the like, whether the delivered liquid was locally or remotely commanded, time and date of liquid delivery, and the like.

Following step 124, the processor 28 is operable at step 126 to determine whether the current liquid delivery profile is complete, i.e., whether delivery of the currently commanded liquid delivery type is complete. If not, the process 120 loops back to the beginning of step 124. If, at step 126, the processor 28 determines that the current liquid delivery profile is complete, the process 120 advances to step 128 where the processor 28 transfers all of the pump operating information relating to the currently commanded liquid delivery profile from the predefined location of the non-volatile memory unit 27 to a pump history database resident in the non-volatile PH memory unit 29. Alternatively, the pump history database may be resident in the non-volatile memory unit 27 at a location that is different from that of the current pump operating information. In any case, the process 120 advances from step 128 to step 132 where the processor 28 is operable to clear the predefined location of the non-volatile memory unit 27 to thereby remove the pump operating information relating to the currently commanded liquid delivery profile from the non-volatile memory unit 27. The process 100 ends after the completion of step 132.

The processor 28 is operable according to the process 120 just described to illustratively store in a predefined location of the non-volatile memory unit 27 pump operating information that relates to a liquid delivery profile that is currently being delivered by the pump 14. After delivery of the profile is complete, the processor 28 illustratively transfers the pump operating information relating the completed delivery profile from the predefined location of the non-volatile memory unit 27 to the pump history database in the non-volatile memory unit 29. One purpose for periodically storing the pump operating information as the commanded liquid amount is being delivered is to retain pump operating information in the event of a power down or power failure of the pump 14. Illustratively, the on/off function (e.g., the menu key 60) is disabled so that the pump 14 cannot be turned off during delivery of liquid. However, a power failure may occur that relates to the one more batteries 44 and/or power supply circuit 42 and that causes disruption of electrical power supplied by the power supply circuit 42 to the processor 28. Likewise, power supplied by the power supply circuit 42 to the processor 28 will be disrupted if the one or more batteries 44 is/are removed. In either case, current liquid delivery

information is retained by periodically storing the pump operating information in the non-volatile memory unit 27 as the commanded liquid amount is being delivered.

Because such a power failure or power disruption may occur at any time, the process 120 further includes an additional step 130 that is repeatedly executed by the processor 28. At step 130, the processor 28 is operable to determine whether the pump 14 has just powered up. If the processor 28 determines that the pump 14 has not just powered up, the process 120 loops back to the beginning of step 130. If, at step 130, the processor 28 determines that the pump 14 has just powered up, step 130 advances to step 128 where the processor 28 is operable to transfer any pump operating information that corresponds to current delivery of liquid from the predefined location of the non-volatile memory unit 27 to the pump history database resident within the non-volatile memory unit 29. During normal operation of the pump 14, the predefined location of the non-volatile memory unit 27 generally will not have any information stored therein upon power up of the pump 14 that relates to liquid currently being delivered by the pump 14, and in such cases the execution of step 128 after power up of the pump 14 will not result in the transfer of any current liquid delivery information from the predefined location of the non-volatile memory unit 27 to the pump history database resident within the non-volatile memory unit 29. However, in cases where a power failure or disruption occurs as described above, execution of step 128 following subsequent power up of the pump 14 will typically result in the transfer of current liquid delivery information from the predefined location of the non-volatile memory unit 27 to the pump history database resident within the non-volatile memory unit 29 if the pump 14 was delivering liquid at the time of the power failure or disruption. The current liquid delivery information that is transferred at step 128 will, in such cases, correspond to the liquid delivery information that was accumulated in the predefined location of the non-volatile memory unit 27 prior to the power failure or disruption.

While the invention has been illustrated and described in detail in the foregoing drawings and description, the same is to be considered as illustrative and not restrictive in character, it being understood that only illustrative embodiments thereof have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected. For example, while various operations of the liquid infusion pump 14 have been described herein as

being accompanied by a general or specific display on the display device 34, a general or specific audible indication and/or a general or specific vibratory indication, it will be understood that the entering of any information into the pump 14, any wireless communication with the pump 14 and/or any operation carried out by the pump, delayed or otherwise, including but not limited to basal or bolus delivery, error conditions, warning conditions, or the like, may or may not be accompanied by any type of message displayed on the display device 34, any single one of, plurality of or sequence of an audible indication and/or any single one of, plurality of or sequence of a vibratory indication.

WHAT IS CLAIMED IS:

1. A method of controlling change access to a display menu of an ambulatory liquid infusion pump, the method comprising:

displaying a programmed menu of the infusion pump,

monitoring a menu lock flag, and

disabling changes to at least one active item of the programmed menu if the menu lock flag is activated.

2. The method of claim 1 wherein disabling changes comprises disabling changes to all active items of the programmed menu.

3. The method of claim 1 further comprising displaying a warning message upon detection of attempted changes to the at least one active item of the programmed menu if the menu lock flag is activated.

4. The method of claim 1 further comprising enabling changes to the at least one active item of the programmed menu if the menu lock flag is deactivated.

5. The method of claim 1 wherein enabling changes comprises enabling changes to all of the active items of the programmed menu.

6. The method of claim 1 wherein the method is carried out on the ambulatory liquid infusion pump,

and wherein displaying comprises displaying the programmed menu on a display device of the ambulatory liquid infusion pump.

7. The method of claim 1 wherein the method is carried out on an electronic device that is separate and remote from the ambulatory liquid infusion pump,

and wherein displaying comprises displaying the programmed menu on a display device of the electronic device.

8. The method of claim 1 wherein a first version of application software containing the menu is available to users of the ambulatory liquid infusion pump and a second version of the application software containing the menu is available only to health care professionals,

and wherein the menu lock flag is activated in the first version of application software and is deactivated in the second version of the application software.

9. The method of claim 1 wherein a first version of application software containing the menu is available to users of the ambulatory liquid infusion pump and a second version of the application software containing the menu is available only to health care professionals,

and wherein the menu lock flag is activated in the first version of application software,

and wherein the second version of the application software does not include the menu lock flag.

10. A method of extending a pre-programmed lifetime of an ambulatory liquid infusion pump, the method comprising:

monitoring a pre-programmed lifetime timer resident in the liquid infusion pump,

allowing the liquid infusion pump to continue operating after the lifetime timer expires, and

disabling operation of the liquid infusion pump if a liquid infusion pump operating error is detected after the lifetime timer expires.

11. The method of claim 10 further comprising displaying a message on a display device of the liquid infusion pump when the lifetime timer expires.

12. The method of claim 11 wherein the message identifies expiration of the lifetime of the liquid infusion pump.

13. The method of claim 10 further comprising activating at least one of an audible indicator and a vibratory device when the lifetime timer expires.

14. A method of storing information relating to operation of a liquid infusion pump, the method comprising:

periodically storing in a storage location of a non-volatile memory information relating to delivery by the pump of a commanded liquid amount throughout delivery by the pump of the commanded liquid amount,

transferring the information relating to delivery by the pump of the commanded liquid amount from the storage location of the non-volatile memory to a pump history database when delivery by the pump of the commanded liquid amount is complete, and

automatically transferring any information relating to delivery by the pump of a commanded liquid amount that is accumulated in the storage location of the non-volatile memory to the pump history database upon power up of the liquid infusion pump.

15. The method of claim 14 wherein the information relating to delivery by the pump of a commanded liquid amount includes any one or more of a delivered liquid quantity, a percentage of a delivered liquid quantity relative to 100%, one or more associated liquid delivery limits, a liquid delivery type, whether the delivered liquid was locally or remotely commanded, and the time and date of liquid delivery.

16. The method of claim 15 wherein the one or more liquid delivery limits includes one or more of a maximum liquid amount, a minimum liquid amount, a maximum delivery duration and a minimum delivery duration.

17. The method of claim 15 wherein the liquid delivery type is at least one of a basal rate, a temporary basal rate a standard bolus, an extended bolus, a multi-wave bolus and a quick bolus.

18. The method of claim 14 further comprising clearing the non-volatile memory after automatically transferring information from the non-volatile memory to the pump history database.

19. The method of claim 14 wherein the commanded liquid amount is one of a locally commanded liquid amount and a remotely commanded liquid amount.

20. The method of claim 14 wherein periodically storing information relating to delivery by the pump of a commanded liquid amount throughout delivery by the pump of the commanded liquid amount comprises storing information periodically in time.

21. The method of claim 14 wherein periodically storing information relating to delivery by the pump of a commanded liquid amount throughout delivery by the pump of the commanded liquid amount comprises storing the information after each delivery of by the pump of an incremental amount of the commanded liquid amount.

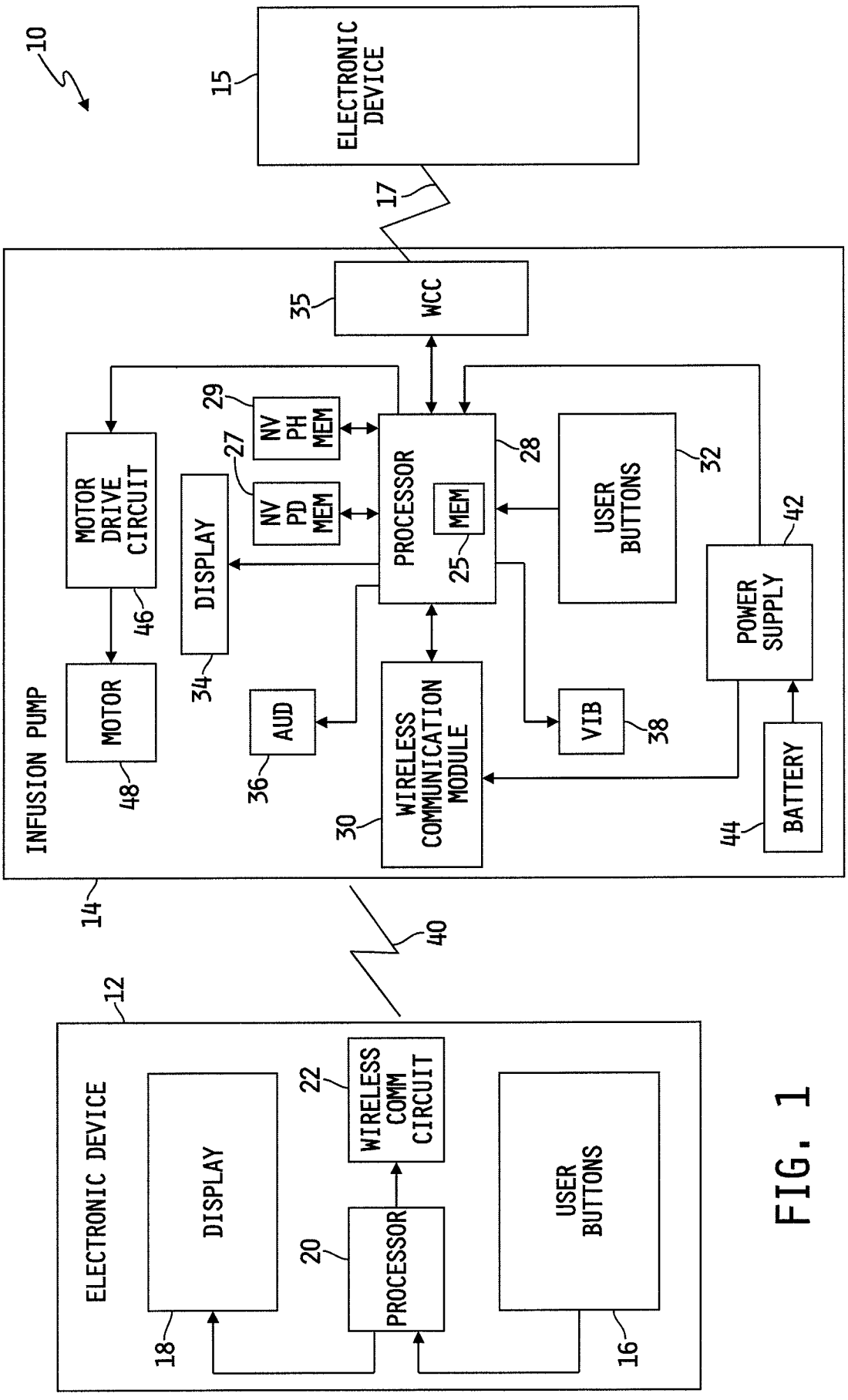
10
15
ELECTRONIC DEVICE
17
35
WCC
INFUSION PUMP
29
NV PH MEM
27
NV PD MEM
PROCESSOR
MEM
25
28
USER BUTTONS
32
MOTOR DRIVE CIRCUIT
46
DISPLAY
34
POWER SUPPLY
42
MOTOR
48
AUD
36
WIRELESS COMMUNICATION MODULE
30
VIB
38
BATTERY
44
14
40
12
ELECTRONIC DEVICE
DISPLAY
18
22
WIRELESS COMM CIRCUIT
20
PROCESSOR
USER BUTTONS
16

FIG. 1

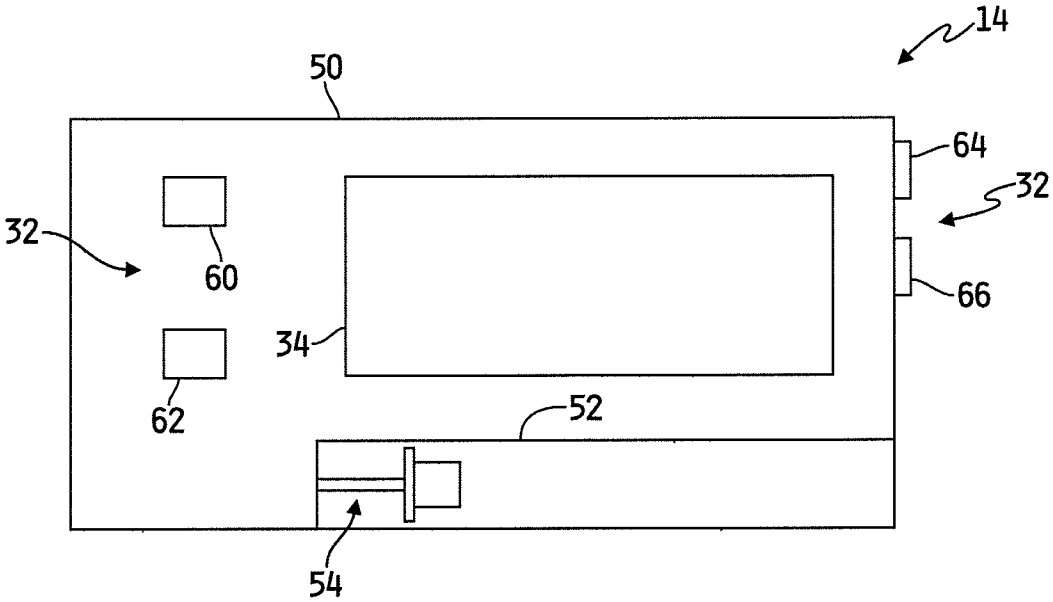
14
50
64
32
32
60
34
66
62
52
54

FIG. 2

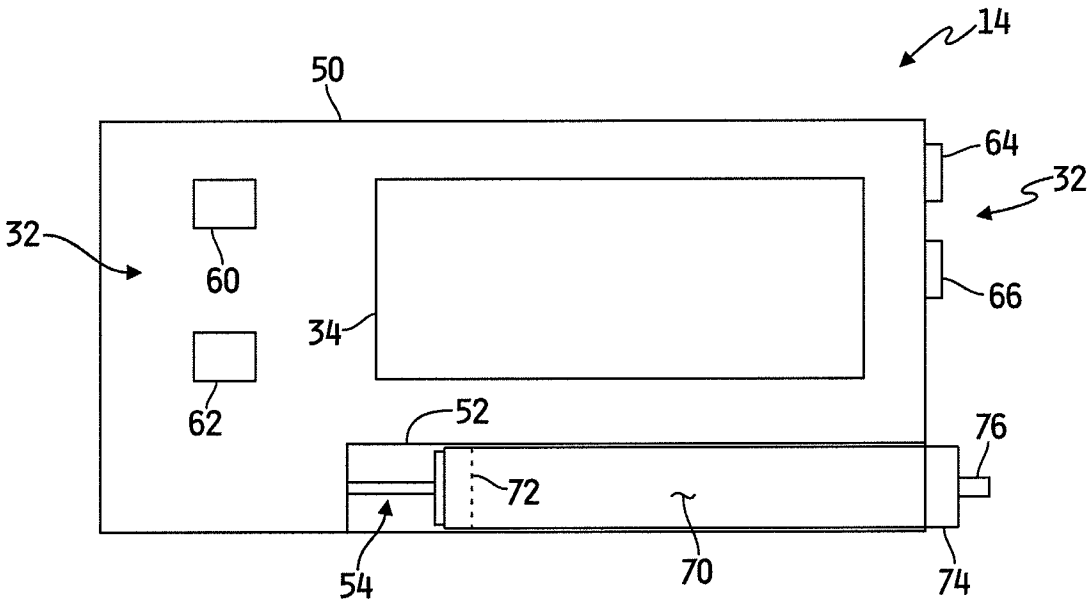
14
50
64
32
32
60
34
66
62
52
76
72
54
70
74

FIG. 3

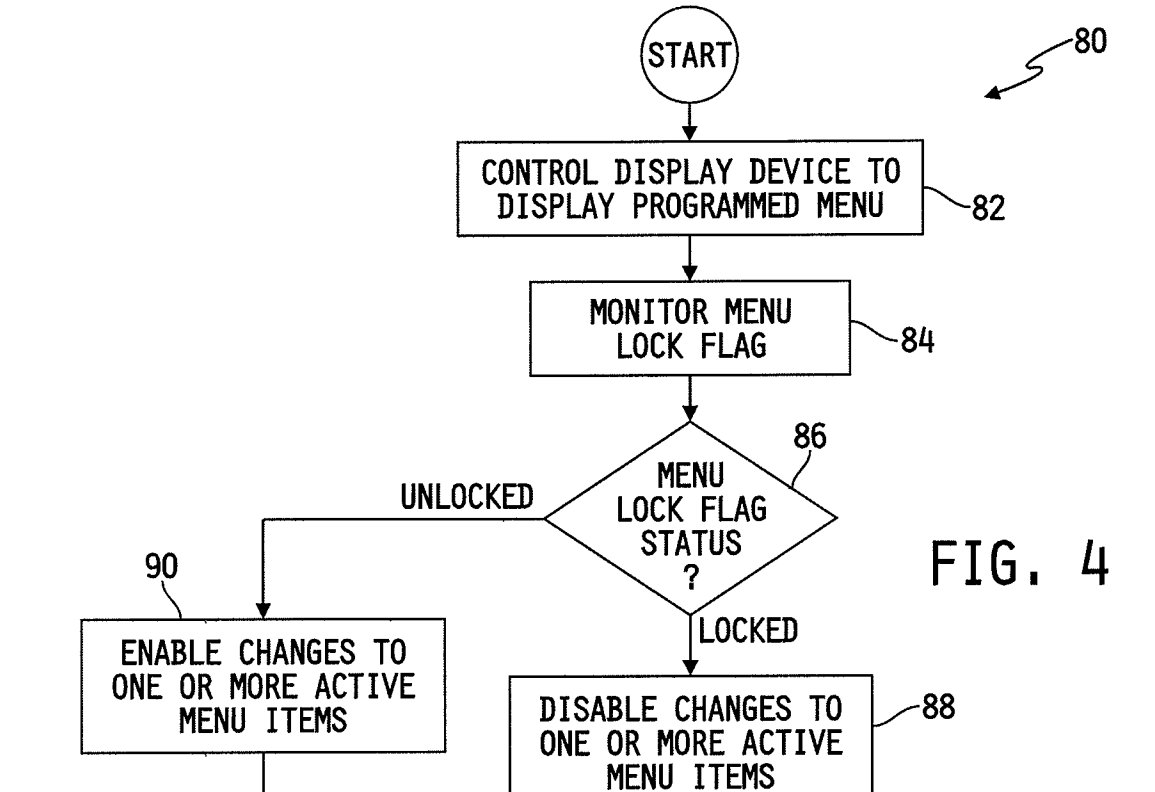
START
80
CONTROL DISPLAY DEVICE TO DISPLAY PROGRAMMED MENU
82
MONITOR MENU LOCK FLAG
84
86
MENU LOCK FLAG STATUS ?
UNLOCKED
LOCKED
90
ENABLE CHANGES TO ONE OR MORE ACTIVE MENU ITEMS
DISABLE CHANGES TO ONE OR MORE ACTIVE MENU ITEMS
88
END

FIG. 4

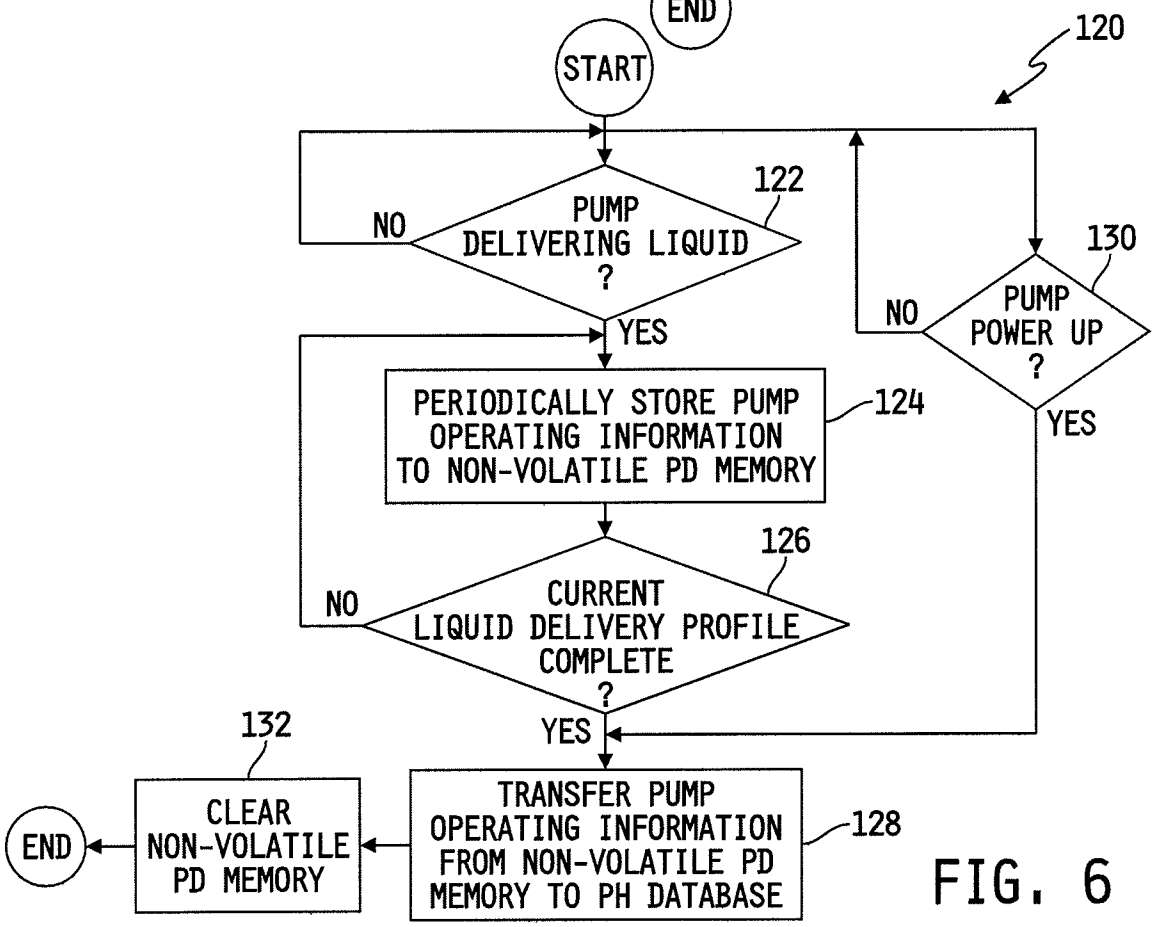
START
120
122
PUMP DELIVERING LIQUID ?
NO
YES
130
PUMP POWER UP ?
NO
YES
PERIODICALLY STORE PUMP OPERATING INFORMATION TO NON-VOLATILE PD MEMORY
124
126
CURRENT LIQUID DELIVERY PROFILE COMPLETE ?
NO
YES
TRANSFER PUMP OPERATING INFORMATION FROM NON-VOLATILE PD MEMORY TO PH DATABASE
128
CLEAR NON-VOLATILE PD MEMORY
132
END

FIG. 6

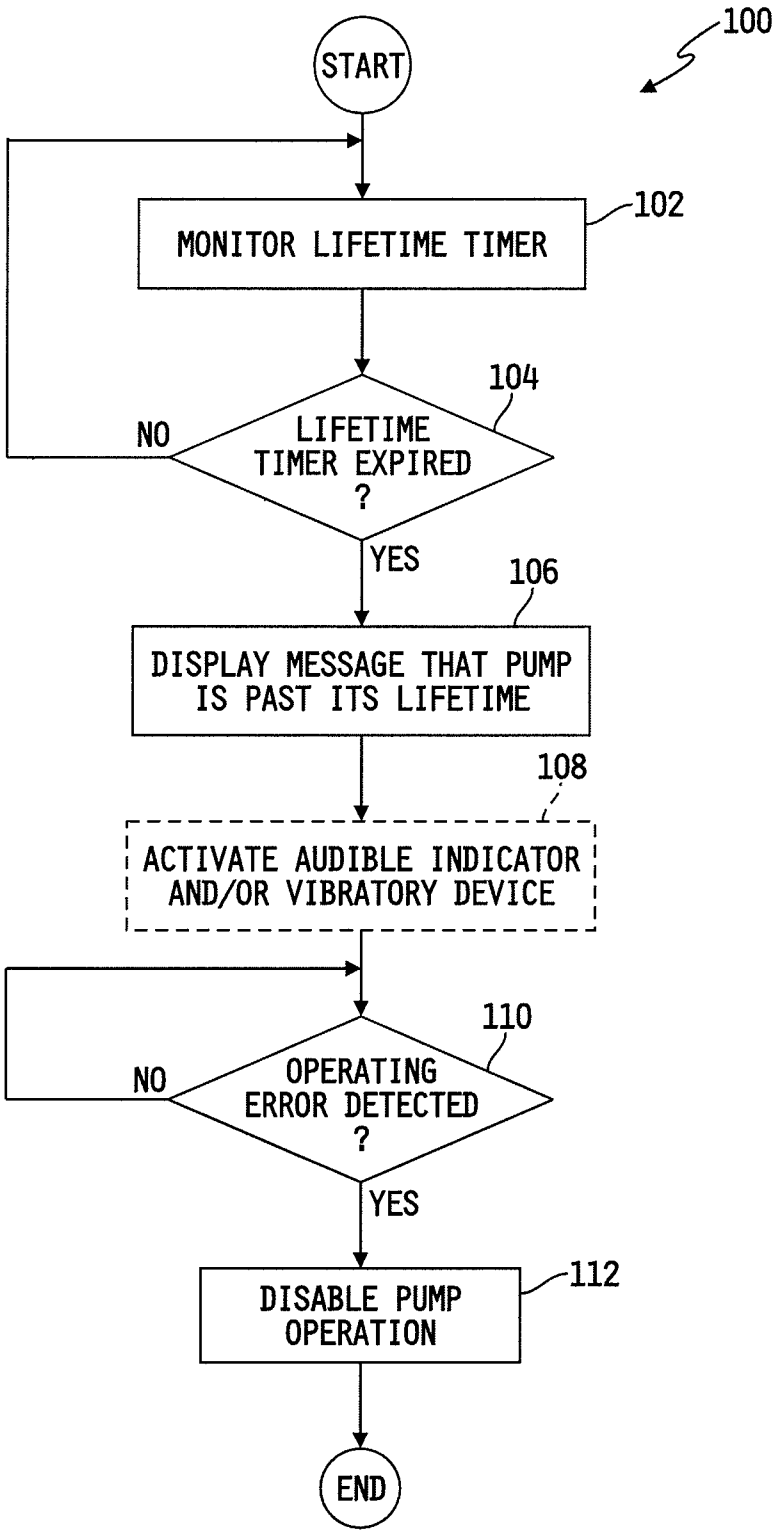
100
START
MONITOR LIFETIME TIMER
102
104
NO
LIFETIME TIMER EXPIRED ?
YES
106
DISPLAY MESSAGE THAT PUMP IS PAST ITS LIFETIME
108
ACTIVATE AUDIBLE INDICATOR AND/OR VIBRATORY DEVICE
110
NO
OPERATING ERROR DETECTED ?
YES
112
DISABLE PUMP OPERATION
END

FIG. 5