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(54) **SYSTEMS, DEVICES AND METHODS FOR MANAGING GLUCOSE LEVELS**

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CPC ***G06F 3/0362*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61M 5/1723*** (2013.01); ***G06F 3/016*** (2013.01); *A61B 5/746* (2013.01); *A61B 5/7455* (2013.01); *A61B 2560/0276* (2013.01); *A61M 2205/18* (2013.01); *A61M 2205/3584* (2013.01); *A61M 2205/505* (2013.01); *A61M 2205/582* (2013.01); *A61M 2230/201* (2013.01); *H01H 2003/008* (2013.01)

(58) **Field of Classification Search**

CPC G06F 3/016; H01H 2003/008

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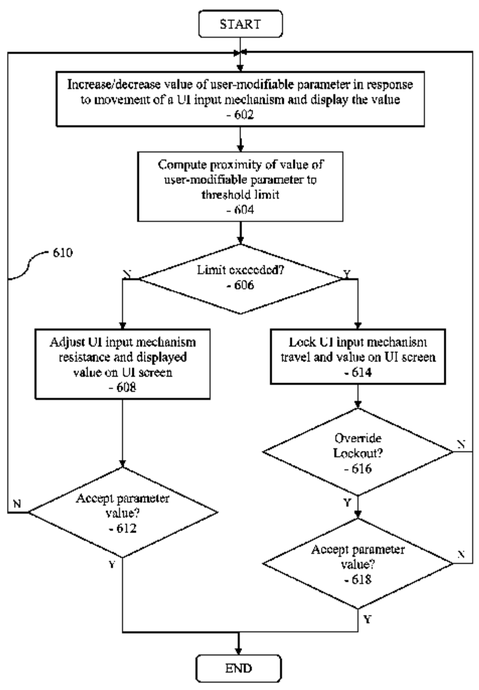
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(57) **ABSTRACT**

Systems, devices and methods for the management of glucose levels in the body of patient featuring user interface input mechanisms configured to provide haptic feedback to the user are provided.

20 Claims, 4 Drawing Sheets



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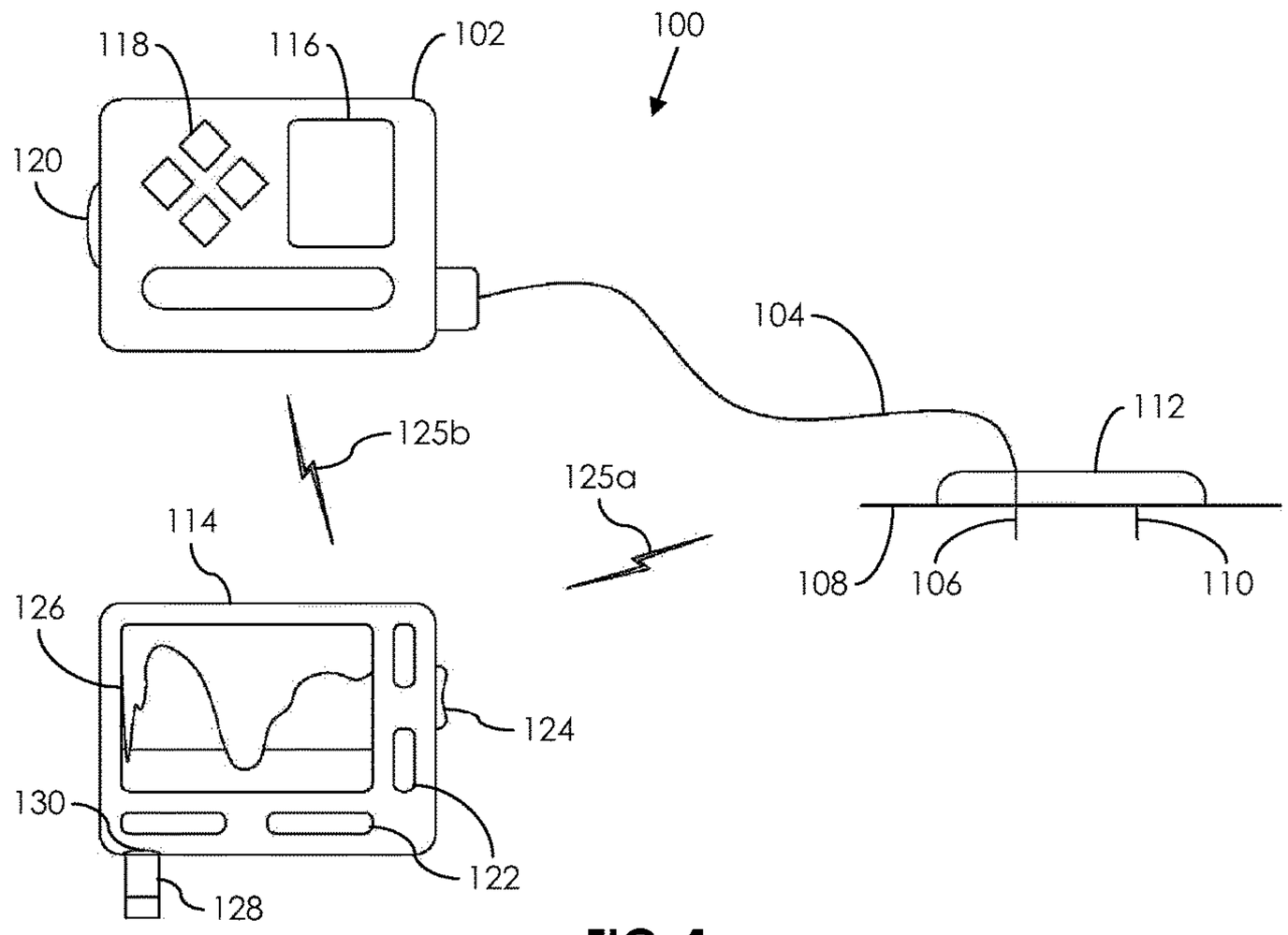

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FIG. 1

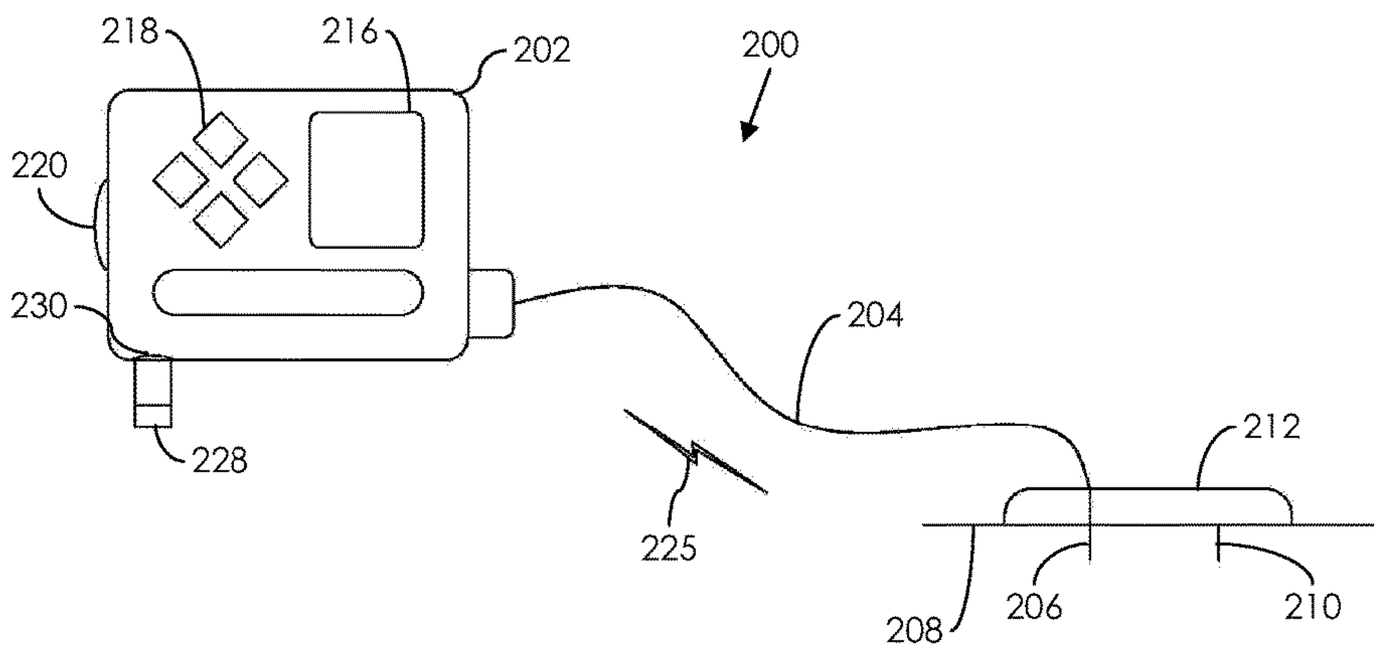

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FIG. 2

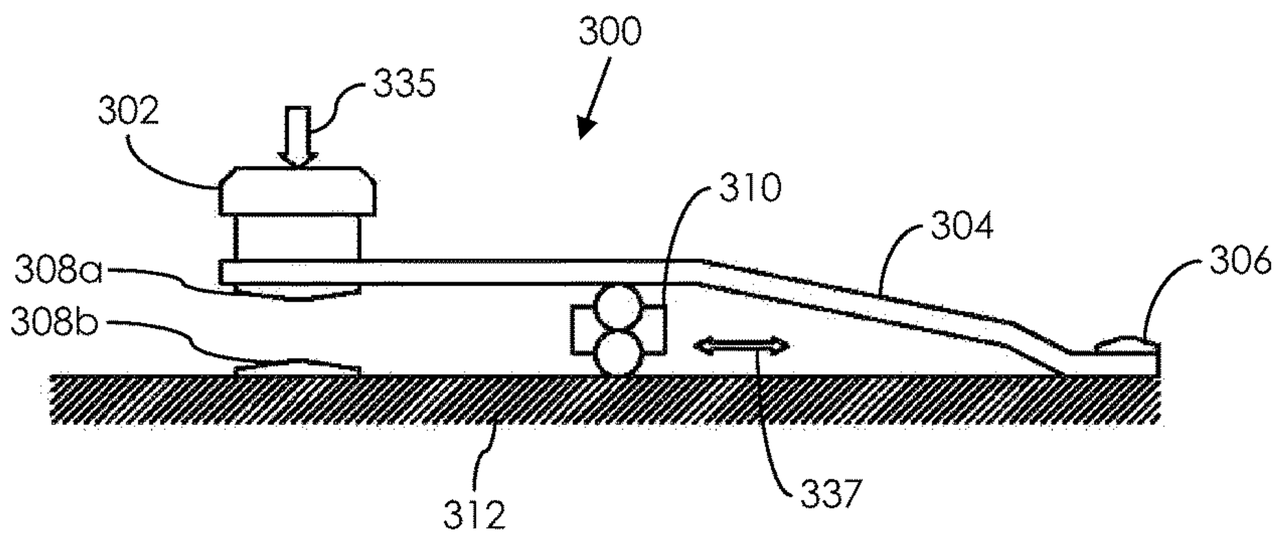


FIG. 3

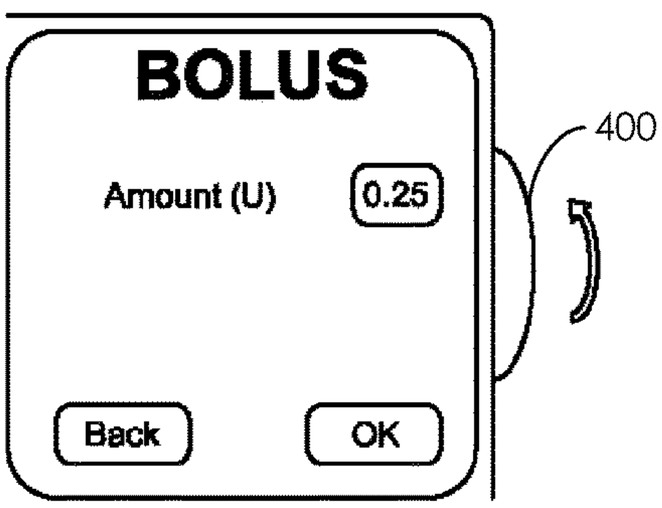


FIG. 4A

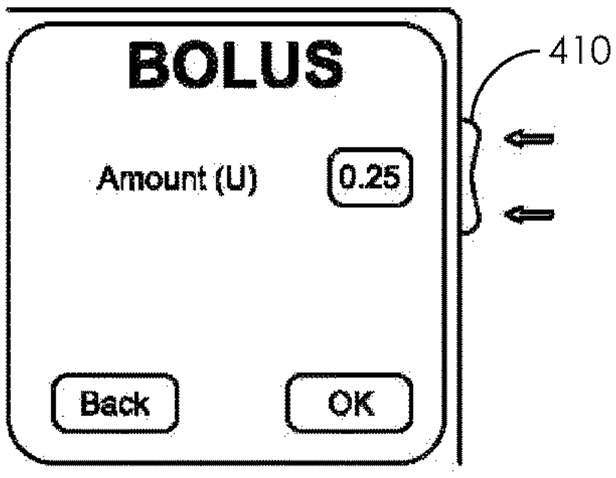


FIG. 4B

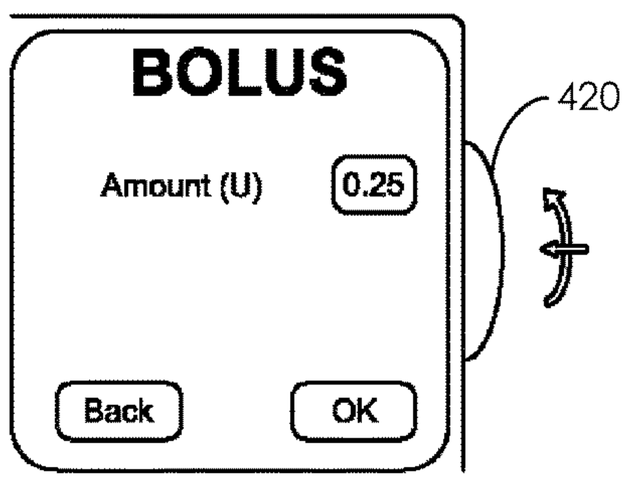


FIG. 4C

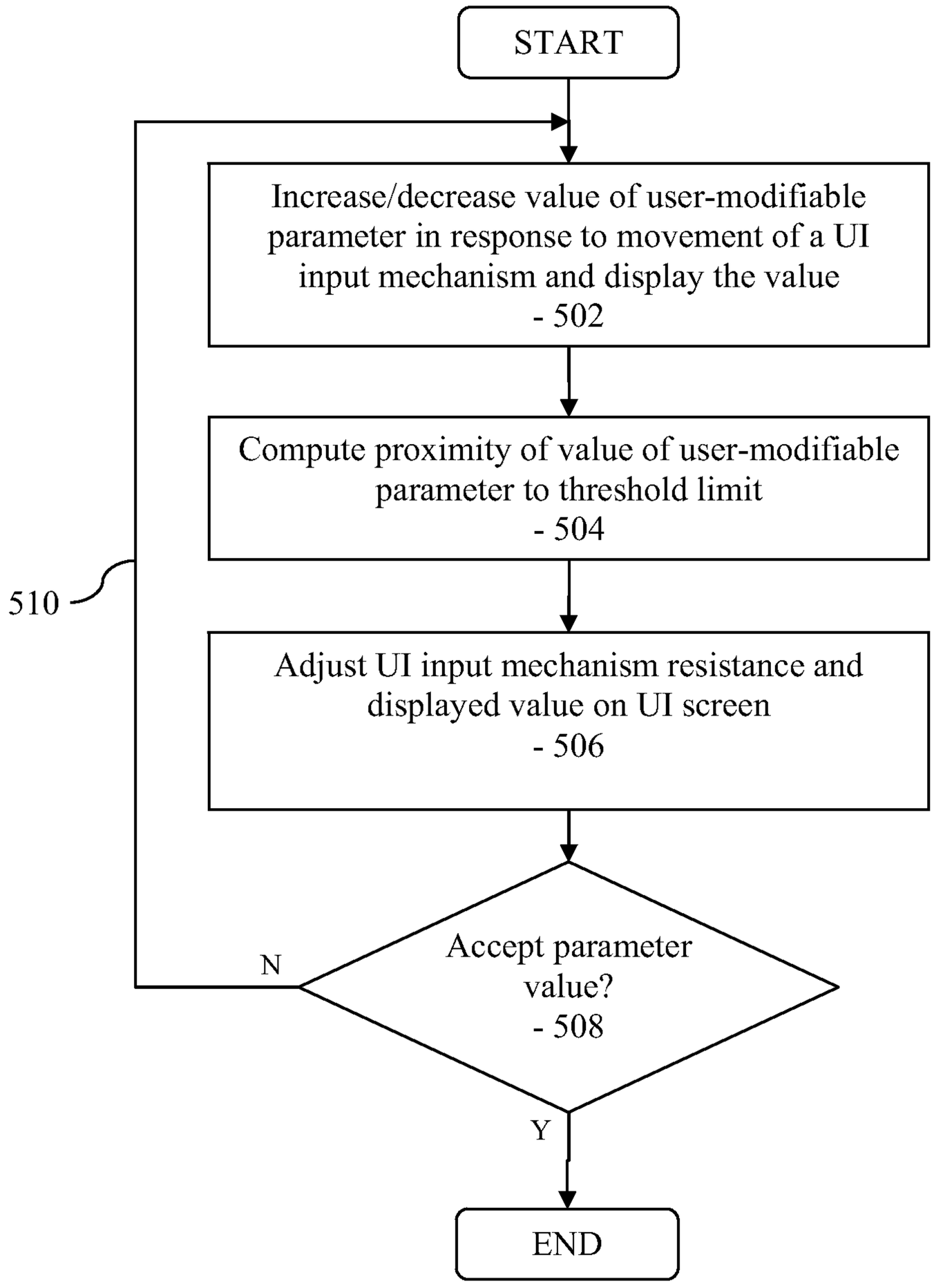

START
Increase/decrease value of user-modifiable parameter in response to movement of a UI input mechanism and display the value
- 502
Compute proximity of value of user-modifiable parameter to threshold limit
- 504
Adjust UI input mechanism resistance and displayed value on UI screen
- 506
Accept parameter value?
- 508
N
Y
510
END

FIG. 5

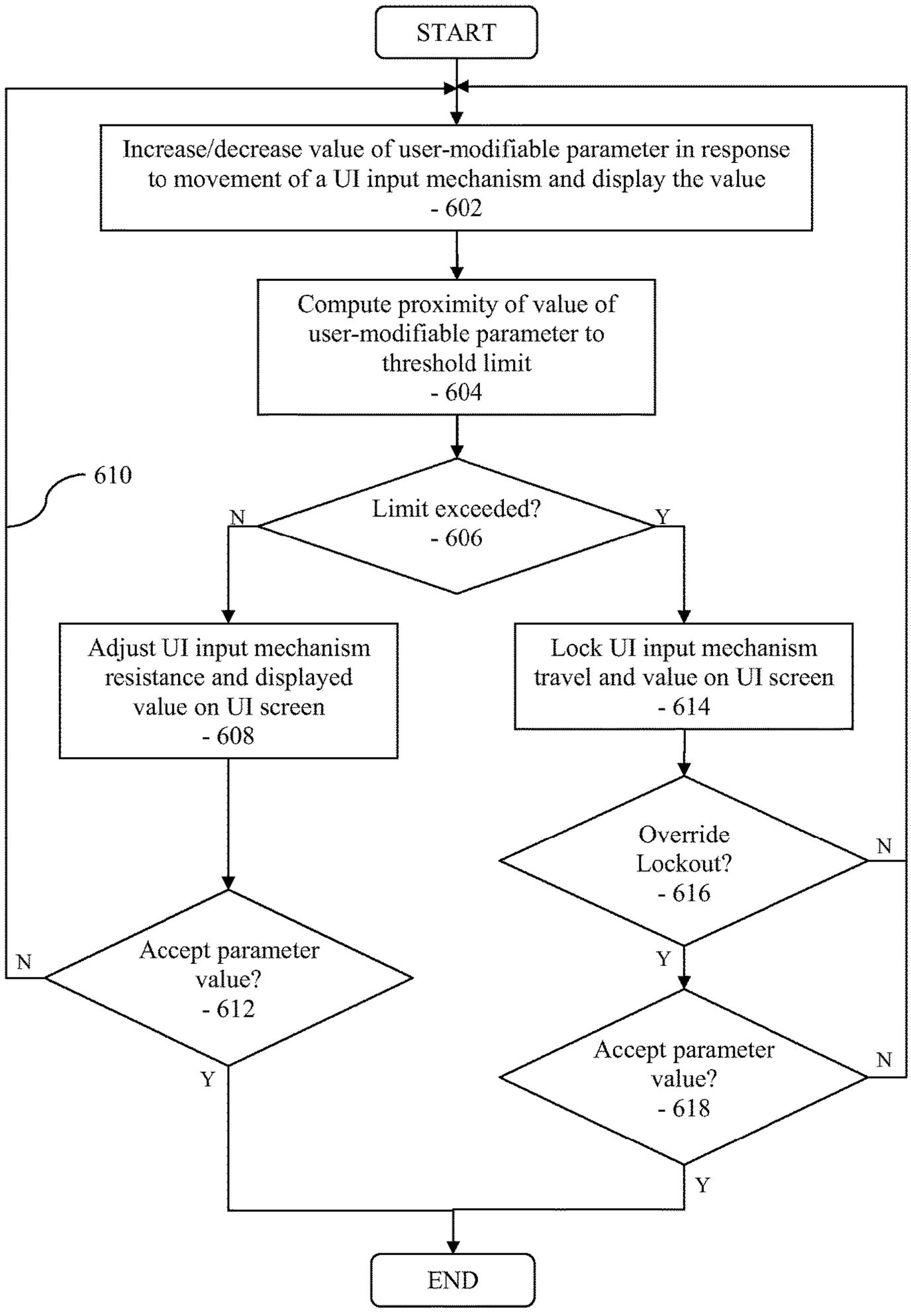

START
Increase/decrease value of user-modifiable parameter in response to movement of a UI input mechanism and display the value - 602
Compute proximity of value of user-modifiable parameter to threshold limit - 604
610
Limit exceeded? - 606
N
Y
Adjust UI input mechanism resistance and displayed value on UI screen - 608
Lock UI input mechanism travel and value on UI screen - 614
Override Lockout? - 616
N
Y
Accept parameter value? - 612
N
Y
Accept parameter value? - 618
N
Y
END

FIG. 6

SYSTEMS, DEVICES AND METHODS FOR MANAGING GLUCOSE LEVELS

RELATED APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 13/044,521, filed Mar. 9, 2011, which claims the benefit of U.S. Provisional Patent Application No. 61/312,644, filed Mar. 10, 2010, entitled "Systems, Devices and Methods for Managing Glucose Levels", the disclosures of all of which are incorporated herein by reference in their entireties for all purposes.

BACKGROUND

Individuals with Type 1 diabetes mellitus (T1DM) must periodically administer insulin to sustain their physiological conditions. Some persons with diabetes, other than T1DM patients, might also require administration of insulin. Typically, these patients administer doses of either fast-acting or slow-acting insulin using needle type syringes, for example, prior to meals or exercising, and/or at suitable times throughout the course of each day. The administration of insulin is often performed contemporaneously with the testing of a patient's blood glucose level where such level is measured discretely using fingerstick testing or continuously using an in vivo sensor. If insulin is not appropriately administered, the diabetic patient risks serious damage to the body which may result in death.

Continued developments and improvements in recent years have made infusion device therapy, such as external infusion pump therapy, much more appealing to persons with diabetes due to the added flexibility and freedom it offers and the improvement in regulating and controlling insulin levels on an ongoing basis. The infusion devices, such as external infusion pumps, are typically connected to an infusion set, which includes a cannula, that is placed transcutaneously through the skin of the patient and infusion tubing which fluidly connects the cannula to the infusion device. An insulin infusion device is often used in conjunction with periodic discrete testing by the patient of his or her current glucose levels using an in vitro blood test strip and a blood glucose meter such as the Freestyle® and Precision® blood glucose monitoring systems available from Abbott Diabetes Care Inc., of Alameda, Calif. The infusion device may also be used with a continuous glucose monitoring (CGM) system in which a glucose sensor is transcutaneously positioned in the subcutaneous tissue of a patient, and the continuously monitored glucose levels are transmitted, often wirelessly, from the sensor to a receiver unit by way of a skin-mounted sensor control unit, e.g., the FreeStyle Navigator® continuous glucose monitoring system from Abbott Diabetes Care Inc. The infusion device may be configured to communicate with the CGM system wirelessly or via a wired connection. Alternatively, the infusion device and CGM control unit may be integrated in the same device housing and share user interface mechanisms (i.e., a common display and input keys) and certain functionalities including data storage and processing.

Use of such infusion devices involves the administration of insulin to the patient throughout the day based on preprogrammed patterns, referred to as basal profiles. The basal profiles are generally determined by a physician based on a number of factors, including the patient's insulin sensitivity and other physiological conditions, and are intended to maintain, as accurately as possible, the patient's glucose levels over a predetermined time period. The infusion devices also include databases and computational capabilities to assist the patient in determining if and when additional insulin doses, referred to as bolus doses, are required by the patient. Such dosages include carbohydrate boluses and correction boluses to accommodate for meals and exercise.

The infusion devices and/or analyte monitoring systems typically include a user interface which includes an input mechanism such as buttons and/or a thumb wheel through which the patient may program and control the infusion device. The user interface also typically includes a display which is configured to display digital and graphical information relevant to the patient's infusion progress and the status of various components of the device, as well as other programmable information such as patient-specific basal profiles and bolus doses. In the course of using the analyte monitoring system and the infusion device, data associated with a patient's physiological condition such as monitored analyte levels or insulin dosage information, for example, may be stored and processed. As the complexity of these systems and devices increase, so do the amount of data and information associated with them.

In view of the foregoing, it would be desirable to have a user interface for a diabetes management system or device that provides the user with greater control, functionality, and convenience. It would be additionally advantageous to provide such a user interface, which does not require visual or auditory feedback, to ensure the patient's privacy in managing his or her diabetes.

SUMMARY

The present disclosure provides systems, devices and methods for managing diabetes. An aspect of the present disclosure is the provision of user interface input mechanisms with haptic feedback capabilities to improve the functionality and provided enhanced privacy to a patient when desired.

Glucose management devices of the present disclosure include at least one user interface controlled by a processor in which the user interface has a user input mechanism configured for tactile contact and movement by the user for entering values of parameters for controlling certain functions of the device. The user input mechanism is configured to provide a haptic feedback response to the user as the entered value of a selected parameter approaches a predefined limit or moves away from a preferred value.

With embodiments in which the user interface mechanism is responsive to approaching a predefined limit, the haptic feedback response may be a damping or stiffness of movement of the user input mechanism wherein the extent of damping or stiffness increases the closer the entered value approaches the predefined limit. In certain embodiments, the device may be configured to lock the user input mechanism against further movement upon the entered value exceeding this predefined limit. With embodiments in which the user input mechanism is responsive to moving away from a preferred value for a parameter, the haptic feedback response may provide a spring biasing of the input mechanism toward a centered position defining a preferred value, where the extent of spring bias increases the further the entered value moves away from the predefined preferred value. Alternately or additionally to a change in the intensity or extent of perceived opposing force of the haptic response felt by a user, the haptic feedback response may also provide

a detented sensation to the user where one detent corresponds to a predefined unit of the entered value of the selected parameter.

A variety of types of user input mechanisms are suitable for use with embodiments of the present disclosure where the input mechanism provides movement in one, two, three or more degrees of freedom. The type of movement may be linear, rotational, or both, and may have any suitable physical configuration, for example, a button, keypad, knob, dial, thumb wheel, scroll ball, track ball, floating disc, touch screen, etc., to provide the desired type of movement. Movement in any one particular direction may be associated with increasing or decreasing the value of the selected parameter of the glucose management device. The parameter value being entered or changed may also be visually displayed on a screen or display of the user interface, where the displayed digital value is associated with an extent of damping or stiffness of the user input mechanism as a pre-selected limit of the parameter is approached.

The glucose management systems of the present disclosure include at least one glucose management device, such as an insulin infusion pump, a discrete or continuous glucose monitoring device, or an integrated insulin infusion pump and glucose monitoring device, where the device includes one or more user input mechanisms configured to provide a haptic feedback response to a user as described above. With an insulin infusion pump, the various selectable parameters by a user via the user interface mechanism may include any type of bolus dose or basal rate related to the delivery of insulin to a patient, wherein a predefined limit may be a maximum or minimum dosage or rate. With a glucose monitoring device, the selectable parameters may include the patient's measured glucose levels, which may be provided in graphical format on a user interface display including an axis corresponding to time and an axis corresponding to the monitored glucose level wherein movement of the user input mechanism moves a cursor on the display along either or both of the axes.

The present disclosure also includes methods for using the subject systems and devices, as well as methods for infusing an agent or medicament to within a patient, or continuously monitoring selected analyte levels in a patient, or both. One such method provides for managing the level of an analyte within a patient by providing an apparatus or system as described above, moving the user interface input mechanism in a first direction toward a target value of the selected parameter, computing the proximity of the entered parameter value to a predefined or preselected limit of the selected parameter, increasing the stiffness of the input mechanism and changing the displayed value if the entered parameter value is within the predefined limit. The method may further include steps associated with additional features of the haptic response, including for example, locking the input mechanism from further movement if the entered parameter value is equal to the predefined limit, enabling the user to continue to move the input mechanism to change the entered parameter value, enabling the user to change the predefined limit of the selected parameter, moving the user interface input mechanism in a second direction toward a target value of the selected parameter, decreasing the stiffness of the input mechanism when moved in the second direction, and changing the displayed value corresponding to the currently selected value of the parameter. The subject methods, in addition to providing a feedback response, may also include the provision of an audible or visual warning to the user via the user interface.

These and other features, objects and advantages of the present disclosure will become apparent to those persons skilled in the art upon reading the details of embodiments of the present disclosure as described below.

INCORPORATION BY REFERENCE

The following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Pat. Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,676,819; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,167,818; and 7,299,082; U.S. Published Application Nos. 2004/0186365, now U.S. Pat. No. 7,811,231; 2005/0182306, now U.S. Pat. No. 8,771,183; 2007/0056858, now U.S. Pat. No. 8,298,389; 2007/0068807, now U.S. Pat. No. 7,846,311; 2007/0227911, now U.S. Pat. No. 7,887,682; 2007/0233013; 2008/0081977, now U.S. Pat. No. 7,618,369; 2008/0161666; and 2009/0054748, now U.S. Pat. No. 7,885,698; U.S. patent application Ser. Nos. 11/396,135, now U.S. Pat. No. 7,620,438, Ser. Nos. 11/537,984, 12/131,012; 12/242,823, now U.S. Pat. No. 8,219,173; Ser. No. 12/363,712, now U.S. Pat. No. 8,346,335; Ser. Nos. 12/698,124; 12/714,439; 12/807,278; 12/842,013; and 12/848,075, now U.S. Pat. No. 8,478,557.

BRIEF DESCRIPTION OF THE DRAWINGS

A detailed description of various aspects, features and embodiments of the present disclosure is provided herein with reference to the accompanying drawings, which are briefly described below. The drawings are illustrative and are not necessarily drawn to scale, with some components and features being exaggerated for clarity. A reference numeral, letter, and/or symbol that is used in one drawing to refer to a particular element or feature may be used in another drawing to refer to a like element or feature. Included in the drawings are the following:

FIG. **1** illustrates one embodiment of a glucose management system of the present disclosure which includes separately housed insulin infusion and analyte monitoring devices;

FIG. **2** illustrates another embodiment of a glucose management system of the present disclosure which provides insulin infusion and analyte monitoring devices housed in the same unit;

FIG. **3** is a schematic illustration of a haptic feedback-enabled switch or actuator for application in the user interface (UI) input mechanisms in certain embodiments;

FIGS. **4**A-**4**C illustrate exemplary user interface (UI) input mechanisms usable with the control devices of the systems in certain embodiments;

FIG. **5** is a flow chart illustrating an exemplary process of haptic feedback implementable by the systems and devices of the present disclosure; and

FIG. **6** is a flow chart illustrating another exemplary process of haptic feedback implementable by the systems and devices of the present disclosure.

DETAILED DESCRIPTION

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

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges, and are also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, the preferred methods and materials are described.

All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure.

The subject systems, devices and methods of the present disclosure are configured for the management of one or more analyte, such as glucose, levels in the body of a patient. Certain devices include an infusion device or pump for delivering one or more agents, drugs or medicaments to within the body of a patient for maintaining a desired level of the one or more analyte levels. Other devices include a continuous or discrete analyte monitor, or a monitor that is capable of both continuous and discrete monitoring. The systems may include at least one infusion pump or may include complementary devices such as one or more analyte monitoring devices, the functions of which may be housed separately from the infusion device or integrated or housed in a single unit.

Embodiments include implantable or external infusion devices or medication delivery devices that may be controlled or controllable by a separate wireless communication device such as microprocessor driven or controlled devices that are configured for wired or wireless communication with the implantable or external infusion devices. Such infusion devices may also include dedicated control units or features such as user interface buttons and/or actuators integrated with the infusion devices for the control and/or operation of the infusion devices. Furthermore, certain embodiments include on skin patch type infusion devices that are provided or configured with a compact housing and designed for placement on the skin surface of a patient or a user to deliver drug or medication. Exemplary embodiments of infusion devices and systems including the same are provided in US Patent Publication Nos. 2004/0254434, now U.S. Pat. No. 8,460,243, 2006/0224141, 2007/0213657, now U.S. Pat. No. 7,981,034, 2008/0004515, 2008/0103447, now U.S. Pat. No. 8,579,853, 2008/0200897, 2009/0054745, 2009/0054750, now U.S. Pat. No. 8,206,296, 2009/0105658, now U.S. Pat. No. 8,353,881, and 2009/0171269, and others, the disclosures of each of which are incorporated by reference for all purposes.

Due to the prevalence of diabetes, the present disclosure is described and illustrated herein in the context of glucose management in which the agent to be administered is insulin and the analyte to be monitored is glucose; however, the following description is intended to be exemplary of the present disclosure and not limited thereby as the present disclosure may be applied to other applications in which other analytes are monitored and other therapeutic agents are administered to manage those analytes.

Additional analytes that may be monitored by the subject systems include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be determined. Where the monitored drug concentration is that of a therapeutic drug, which may also be that which is being administered by the management system.

Referring now to the figures, FIG. **1** illustrates one embodiment of a glucose management system of the present disclosure which includes separately housed insulin infusion and analyte monitoring devices. Referring to FIG. **1**, glucose management system **100** includes an insulin infusion unit **102**. The insulin infusion unit **102** utilizes an infusion set for transporting insulin from a reservoir (not shown) housed within the insulin infusion unit **102**, transcutaneously into a patient. The infusion set includes infusion tubing **104** for liquid transport of the insulin to a cannula **106** which is configured for transcutaneous placement within a patient. In one embodiment, the systems may be a stand-alone pump including only the insulin infusion unit **102** and the associated infusion set. In other embodiments, the systems may include additional devices which provide additional control in the management of a patient's glucose levels. Referring again to FIG. **1**, system **100** also includes an analyte monitoring device **114**, which may be configured to continuously monitor a patient's analyte, such as glucose, levels by means of an implantable or in vivo sensor **110** coupled to a sensor control unit **112** mounted to the patient's skin by way of an adhesive patch **108**. Analyte monitoring unit **114** is configured to wirelessly receive signals associated with analyte levels detected by the analyte sensor **110** which are periodically and/or intermittently received by the analyte monitoring unit **114** from sensor control unit **112** over communication path **125***a*. Analyte monitoring unit **114** may be configured to include a transceiver unit (not shown) for bidirectional communication over the communication path

125*a*, or in certain embodiments may include radio frequency identification (RFID) components for, e.g., passive or active RFID systems, and sensor control unit **112** may likewise be configured to include RFID components to communicate with an RFID-enabled analyte monitoring unit **114**.

In other embodiments, analyte monitoring unit **114** may be configured for discrete monitoring of analyte levels by the use of an in vitro test strip **128** with analyte sample provided thereon, which is receivable at a port **130** within the housing of analyte monitoring unit **114**. In yet another configuration, as shown in FIG. **1**, analyte monitoring unit **114** is designed for both continuous and discrete monitoring of analyte levels by means of a transcutaneous in vivo sensor **110** and in vitro test strip **128**, respectively. In any of the aforementioned configurations, the analyte monitoring unit **114** may be configured to communicate unidirectionally or bidirectionally with insulin infusion unit **102** over communication path **125***b*, which may be a wireless or wired connection.

Examples of continuous monitoring systems and discrete analyte monitoring systems and data management systems that may be employed can be found in U.S. Pat. No. 6,175,752; U.S. Pat. No. 6,560,471; U.S. Pat. No. 5,262,035; U.S. Pat. No. 6,881,551; U.S. Pat. No. 6,121,009; U.S. Pat. No. 7,167,818; U.S. Pat. No. 6,270,455; U.S. Pat. No. 6,161,095; U.S. Pat. No. 5,918,603; U.S. Pat. No. 6,144,837; U.S. Pat. No. 5,601,435; U.S. Pat. No. 5,822,715; U.S. Pat. No. 5,899,855; U.S. Pat. No. 6,071,391; U.S. Pat. No. 6,120,676; U.S. Pat. No. 6,143,164; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,338,790; U.S. Pat. No. 6,377,894; U.S. Pat. No. 6,600,997; U.S. Pat. No. 6,773,671; U.S. Pat. No. 6,514,460; U.S. Pat. No. 6,592,745; U.S. Pat. No. 5,628,890; U.S. Pat. No. 5,820,551; U.S. Pat. No. 6,736,957; U.S. Pat. No. 4,545,382; U.S. Pat. No. 4,711,245; U.S. Pat. No. 5,509,410; U.S. Pat. No. 6,540,891; U.S. Pat. No. 6,730,200; U.S. Pat. No. 6,764,581; U.S. Pat. No. 6,299,757; U.S. Pat. No. 6,461,496; U.S. Pat. No. 6,503,381; U.S. Pat. No. 6,591,125; U.S. Pat. No. 6,616,819; U.S. Pat. No. 6,618,934; U.S. Pat. No. 6,676,816; U.S. Pat. No. 6,749,740; U.S. Pat. No. 6,893,545; U.S. Pat. No. 6,942,518; U.S. Pat. No. 6,514,718; and U.S. Pat. No. 7,811,231, and elsewhere, the disclosures of each which are incorporated herein by reference for all purposes.

FIG. **2** shows another glucose management system **200** of the present disclosure in which the insulin infusion and analyte monitoring devices are integrated into a single integrated infusion and monitoring device **202**. By providing many of the information associated with analyte, such as glucose, levels and insulin infusion information in one integrated infusion and monitoring device **202**, the patient may be provided with the additional convenience and discreteness in managing diabetes and improving insulin therapy. The integrated infusion and monitoring device **202** houses an insulin reservoir (not shown) which is coupled to an infusion tubing **204** connected to a cannula **206** which is configured for transcutaneous placement through a skin layer of a patient. Integrated infusion and monitoring device **202** may be configured to communicate unidirectionally or bidirectionally with a sensor control unit **212** over a communication path **225**, which may be a wireless connection or a wired connection provided via direct coupling between the two components by means of a cable (not shown). The sensor control unit **212**, which is in electrical contact with an in vivo analyte sensor **210** subcutaneously positioned under the skin of the patient, is retained in position by an adhesive layer or patch **208** provided on the bottom surface of the sensor control unit **212**. Integrated infusion and monitoring device **202** may also be configured for discrete monitoring of glucose levels by means of in vitro test strip **228** with analyte sample provided thereon and received at a test port **230** in the housing of the integrated infusion and monitoring device **202**.

The communication paths **125***a*, **225** between the respective sensor control units **112**, **212** and the respective analyte monitoring unit **114** or integrated infusion and monitoring device **202**, respectively of FIGS. **1** and **2**, as well as the communication path **125***b* between the analyte monitoring unit **114** and insulin infusion unit **102** of FIG. **1**, may include a radio frequency (RF) communication link, WiFi communication link, Bluetooth® communication link, infrared (IR) communication link, RFID communication link, or any other type of suitable wireless communication link or protocol between two or more electronic devices. Alternatively, the various data communication links may be a wired cable connection such as, for example, but not limited to, an RS-232 connection, universal serial bus (USB) connection, or serial cable connection.

The analyte monitoring unit **114** or the insulin infusion device **102** of FIG. **1**, or both, and the integrated infusion and monitoring device **202** of FIG. **2** may be configured to further communicate with a data processing terminal (not shown) which may include a desktop computer terminal, a data communication enabled kiosk, a laptop computer, a handheld computing device such as a personal digital assistant (PDA), or a data communication enabled mobile telephone, and the like, each of which may be configured for data communication via a wired or a wireless connection. A data processing terminal may include a physician's terminal and/or a bedside terminal in a hospital or home environment, for example.

With each of the embodiments of FIGS. **1** and **2**, the respective infusion cannulas **106**, **206** and infusion tubing **104**, **204** are coupled through the control unit **112**, **212** and the adhesive patch **108**, **208** to minimize the area of the skin occupied by the system components. However, the infusion components (i.e., cannula and infusion tubing) may be transcutaneously positioned at a distance away from the monitoring components (transmitter and sensor) or even on different areas of the body, in which case two separate patches may be used. In the illustrated embodiments, the respective control unit, in vivo sensor and cannula may be configured to be positioned simultaneously, or the sensor and cannula may be configured to be placed first with the control unit then mounted over and in electrical contact with the sensor. In another embodiment, the control unit may be mounted first and configured to receive the cannula and/or the sensor and facilitate positioning of the cannula and/or sensor through the skin of the patient. The infusion tubing may be configured to operatively couple with a port (not shown) within the housing of the respective control units so as to be in fluid alignment with the cannula and to provide a substantially fluid-tight seal between the tubing and cannula.

Each of the insulin infusion unit **102** and analyte monitoring unit **114** of FIG. **1** and the integrated infusion and analyte monitoring device **202** of FIG. **2** have one or more processors (e.g., application specific integrated circuits (ASICs), microprocessors, etc.) or control units (not shown) which are configured to perform data storage and processing based on one or more preprogrammed or predetermined processes. For example, a processor of analyte monitoring unit **114** of FIG. **1** or an analyte monitoring processor of integrated infusion and analyte monitoring device **202** of

FIG. **2** may be configured to store the received signals associated with analyte levels in a data storage unit, such as a memory (not shown). Alternatively or additionally, the processor may be configured to process the signals associated with the analyte levels to generate trend indication by, for example, display of a line chart or an angular icon based display for visual output on display **126** (FIG. **1**), **216** (FIG. **2**). In certain embodiments, a processor is programmed to determine the rate of change of an analyte and/or the rate of the rate of change of an analyte over time based on current and historical analyte information obtained from the sensor **110**, **210** via the control unit **112**, **212** and stored in a memory. Additional information which may be processed, stored and displayed by the analyte monitor includes, but is not limited to, the substantially contemporaneous and real time analyte levels of the patient received from respective control unit **112**, **212** as detected by the respective sensor **110**, **210**. The real time analyte level may be displayed in a numeric format or in any other suitable format which provides the patient with the accurate measurement of the substantially real time analyte level detected by the sensor.

The processor of insulin infusion unit **102** or an infusion-specific processor within integrated infusion and analyte monitoring device **202** may include capabilities for programming basal profiles and for calculating bolus doses including, but not limited to, correction boluses, carbohydrate boluses, extended boluses, and dual boluses, which may be based on one or more factors including the patient's insulin sensitivity, insulin on board, intended carbohydrate intake (for example, for the carbohydrate bolus calculation prior to a meal), the patient's measured or detected glucose level, and the patient's glucose trend information. Such calculations may be performed by the patient using the user interface (UI) displays **116**, **216** and keypads **118**, **218** of insulin infusion unit **102** and integrated infusion and analyte monitoring device **202**, respectively. In a further variation of system **100** of FIG. **1**, the bolus calculation capabilities may also be provided in the analyte monitor unit **114**.

In each of the system embodiments, the individual functional units, i.e., the insulin infusion unit **102** of system **100** (FIG. **1**), the analyte monitoring unit **114** of system **100** and the integrated infusion and analyte monitoring device **202** of system **200** (FIG. **2**), are configured with a substantially compact housing that can be easily carried by the patient or conveniently worn on the patient's clothing (for example, housed in a holster or a carrying device worn or clipped to the patient's belt or other parts of the clothing). As mentioned earlier, each unit or only some units of the system may include a user interface (UI) on the housing for outputting information to the user or patient and inputting information by the user or patient.

Output mechanisms include a visual output, such as displays **116**, **126** (FIG. **1**) and **216** (FIG. **2**), which may be configured to display digital data and/or graphical and/or analog data. Other output mechanisms may include one or more audio output devices such as speakers or buzzers (not shown) integrated with the device housings so as to output audible alerts or alarms based on the occurrence of one or more predetermined conditions associated with insulin infusion unit **102**, analyte monitoring unit **114** or integrated infusion and analyte monitoring device **202**. For example, insulin infusion unit **102** may be configured to output an audible alarm or alert to the patient upon detection of an occlusion in the infusion tubing **104** or upon the occurrence of a timed event such as a reminder to prime the infusion tubing **104** upon replacement of the cannula **106**, and the like. Analyte monitoring unit **114** may similarly be configured to output an audible alarm or alert when a predetermined condition or a pre-programmed event occurs, such as, for example, a reminder to replace sensor **110** after its useful life (e.g., of 3 days, 5 days, 7 days, 10 days, 14 days or more), or one or more alerts associated with the data received from the sensor control unit **112** corresponding to the patient's monitored analyte levels. Such alerts or alarms may include a warning alert to the patient when the detected analyte level is beyond a predetermined threshold level or when the trend of the detected analyte levels within a given time period is indicative of a significant condition, such as potential hyperglycemia or hypoglycemia, which require attention or corrective action. The audible alarms may be output alone or in combination with one or more visual alerts such as an output on the display units **116**, **126** (FIG. **1**) or **216** (FIG. **2**), or with a vibratory alert which would provide a tactile indication to the patient of the associated alarm and/or alert. Accordingly, alarms and/or alerts may be audible and/or visual and/or tactile.

Referring still to FIGS. **1** and **2**, user interface input mechanisms may include one or more of keypads **118**, **218**, buttons **122**, **124** and thumb wheels or jog dials **120**, **220**, as well as displays **116**, **126** and **216** where the displays may be touch screens. The interface inputs may be used by the user/patient to input data, select menus, and perform the various bolus calculations discussed above. With a stand-alone pump, the patient may have to key in real-time glucose levels (as well as other information) obtained by discrete testing or by a continuous monitor not in automatic communication with the pump. On the other hand, the glucose management system **100** of FIG. **1** and the glucose management system **200** of FIG. **2** provide enhanced functionality by having substantially continuous real time glucose data and trend information automatically provided to the infusion device/processor by the continuous analyte monitoring device/process. Accordingly, bolus doses of insulin are more easily quantified and the pre-programmed basal profiles more easily adjusted by the patient.

Embodiments of the user interface input elements of the present disclosure are configured to provide force (kinesthetic) feedback and/or tactile feedback to the user in response to an activating motion or input, e.g., pressing a button or rotating a jog dial, by the user. These feedbacks are collectively referred to herein as "haptic feedback." Haptic technology or haptics takes advantage of a user's sense of touch by applying forces, vibrations, and/or motions upon the user which is felt as a physical sensation to the touch, typically in response to a user-initiated action or motion. Accordingly, embodiments of the subject systems include haptic feedback so that the physical sensation is felt by the user manipulating an input unit of the interface device, such as a joystick, a mouse button, etc., used to control the system. One or more motors or other actuators controlled by the computer system are coupled to the input unit. The computer controls forces on the input unit and/or device housing in conjunction and coordinated with displayed events and interactions by sending control signals or commands to the actuators. The computer system thus conveys physical force sensations to the user in conjunction with other supplied feedback as the user is grasping or contacting the input unit.

Certain embodiments of haptic feedback use electromagnetic technologies such as vibratory motors, such as the pager motor or voice coils, in which an offset mass is moved by a magnetic field. The electromagnetic motors typically operate at a resonance frequency and provide strong feedback, but have limited range of sensations. Other actuator

technologies which offer a wider range of effects and more rapid response times include electroactive polymers, piezoelectrics, and electrostatic surface actuation. Electroactive polymers or EAPs are polymers whose shape is modified when a voltage is applied to them. Piezoelectricity is the ability of some materials (notably crystals and certain ceramics) to generate an electric field or electric potential in response to applied mechanical stress. The effect is closely related to a change of polarization density within the material's volume. Electrostatics involves the buildup of charge on the surface of objects due to contact with other surfaces. When at least one of the surfaces has a high resistance to electrical flow, the effects of charge exchange are usually noticeable. This is because the charges that transfer to or from the highly resistive surface are more or less trapped there for a long enough time for their effects to be observed.

Other embodiments use the active elements such as motors or piezoactuators to alter the passive mechanical property in the path of the human interface. One example is to alter the effective pivot point of a flexible cantilever that provides stiffness and/or damping to a mechanical switch. FIG. **3** illustrates a schematic representation of such a haptic feedback-enabled switch **300**, the functional principles of which are suitable for use for certain user interface input applications of the present disclosure and may be implemented by any of the aforementioned haptic technologies. Switch **300** includes a button **302** positioned on the free end of a cantilever **304** secured to a ground reference **312** at a fixed or pivot end **306**. A first electrical contact **308***a* is provided on the underside of cantilevered button **302** and a second electrical contact **308***b* is provided on the ground reference **312** opposite to and in alignment with electrical contact **308***a*. When the two contacts **308***a*, **308***b* meet, the switch is closed, effecting an action, e.g., incremental increase or decrease of a value or quantity, selection of a specific value or range of values, scrolling of a cursor, etc. A double-roller mechanism **310** is frictionally engaged between the underside of cantilever **304** and ground **312** and is configured to translate linearly along the length of cantilever **304** between fixed or pivot end **306** of the cantilever and electrical contacts **308***a*, **308***b*, as shown by arrow **337**. Linear movement of mechanism **310** is controlled by an actuator mechanism (not shown). Upon application of a downward force **335** on button **302** in order to establish physical contact between the electrical contacts **308***a*, **308***b*, (in addition to the resulting action identified above) the actuator may be incrementally activated to incrementally move double-roller mechanism **310** closer to or farther away from button **302**. Movement of mechanism **310** closer towards button **302** increases the responsive stiffness felt by the user pressing on button **302**, and movement away from button **302** decreases the stiffness felt by the user. The increasing stiffness felt by the user, for example, may indicate relative advancement to a fixed threshold. In one variation, when double-roller mechanism **310** is moved toward button **302** and reaches some specified lateral distance from button **302** or is placed directly between the electrical contacts **308***a*, **308***b*, it provides a hard stop where the button can no longer be pressed and/or the electrical contacts will no longer be able to touch each other, indicating that a threshold limit has been reached.

The switch of FIG. **3** is merely intended to be a simple schematic example of how a haptic feedback mechanism works. For purposes of the present disclosure, however, user interface input mechanisms may include, but are not limited to, buttons, keypads, knobs, dials, thumb wheels, scroll balls, touch screens, etc. integrated with the housing of a glucose management device, such as an insulin infusion unit, analyte monitoring unit, or a unit integrating control of insulin infusion and analyte monitoring. The input mechanisms may be a continuous one degree-of-freedom type, as shown in FIG. **4**A, e.g., the dial **400** can be rotated continuously. Alternatively, the input mechanism may have one degree-of-freedom but enable binary movement in which it can be moved in two, usually opposite, directions, e.g., as shown in FIG. **4**B, button **410** can be toggled in two directions. A multi-directional mechanism, such as a scroll ball, track ball or floating disc, usually providing movement with three or four degrees-of-freedom, may also be employed. Certain mechanism may provide more than one type of input motion. For example, as shown in FIG. **4**C, a jog wheel **420** may be configured to be depressed like a button in addition to being rotatable about an axis.

The amount of responsive force of the haptic feedback may be the same regardless of the number of depressions or the extent of travel of an input mechanism, where one level, value or point of adjustment is met by the equivalent physical sensation of a "click", such as riding over a detent or the like. The "resolution" or magnitude of such detents may be predefined or variable. One useful application for a detent-action input mechanism is for providing user feedback upon the user-initiated incrementing or decrementing of a value, with or without threshold or safety limits, where movement of the input mechanism in one direction increments a value, for example, of a dose of a medicament to be administered to a patient, and movement in a second direction decrements the value of that dose.

Alternatively or additionally, the haptic feedback sensation may be one of a gradual stiffening of the input mechanism such that continued movement of it by the user in one direction is met with greater and greater resistance to prevent an input error hazard and to make the user more aware of certain safety-based limits. For example, if a jog wheel or scroll ball input mechanism is used, the ability of the wheel or ball to roll freely given a certain "spin" will diminish as the selected value nears a threshold or safety limits. This can be achieved by coupling the jog wheel or scroll ball about its axis of rotation, i.e., at its axle, to a motor which outputs a torque on the axle in a direction opposite to the motion of the axle and in an amount which increases proportionately as the axial velocity of the wheel or ball increases.

Where a model-based system is employed which provides for a preferred or target value for certain parameters, the UI input mechanism may be spring-biased toward a "center" position representative of the preferred or target value. When the input mechanism, such as a jog wheel or roller ball, is rotated or spun away from this default center position, the wheel or ball will slowly or gradually return to the default position. This haptic effect may be implemented by connecting the wheel or ball's axle to a motor. The amount of torque exerted on the axle is configured to increase proportionately as the axle deviates from the default position in either or any direction, thereby acting as a virtual spring. Alternatively, the virtual spring effect may be configured to keep the input mechanism within a preferred or acceptable range of motion rather than a discrete center position. Still yet, there may be two or more such center positions which correspond to favorite or commonly used user settings, which, for example, may correspond to typical carbohydrate boluses to be administered for breakfast, lunch, dinner and snacks, respectively.

The haptic response of the input mechanisms of embodiments of the present disclosure may have any one or more of the following features: (1) the input mechanism provides

tactile feedback simulating discrete detents where one detent corresponds to a predefined unit, typically a single unit, of the value of a given user-modifiable or user-selected parameter; (2) the apparent damping or resistance of the mechanism's movement (whether a gradual rotation of a wheel or an incremental or stepped input of a button) increases as a limit is approached—a virtual damper mechanism; (3) upon being advanced to a position or being depressed a number of times beyond a set limit, the mechanism's apparent resistance or stiffness causes it to return to a position representing the closest allowable value of the parameter being adjusted; (4) with or without gradual or incremental resistance, when advanced beyond a position or point representing a set limit, travel of the mechanism ceases or is locked altogether; and (5) the input mechanism is physically biased toward one or more discrete positions or to within a range of acceptable movement rather than having or in addition to having set limits—a virtual spring mechanism. The input mechanisms may be further configured to unlock the user input mechanism and/or cease further haptic responses if the user activates an override of the set limits or otherwise conforms to within the currently-set limitations.

Unlike a system having only absolute hard limits on its parameters (which in some cases is absolutely necessary), a system having modifiable parameters allows use of a dynamic range limit that may be modified for reasons specific to a particular user or to accommodate an urgent exception. Haptic feedback capability enables a more dynamic user interface for a system in which certain parameters, and in some cases, limits on parameter ranges, may be user-modified. In the context of the user interface input (UI) mechanisms of the subject diabetic management systems of the present disclosure, haptic feedback capabilities, in addition to enhancing usability, are provided to prevent hazardous outcomes, such as under- or overdosing, which may be caused by user error. Various haptic applications include, but are not limited to, insulin delivery threshold settings, i.e., maximum or minimum thresholds, being approached or achieved upon user "request of" or input to an infusion pump. More specifically, when a user's input, via a user interface (UI) input mechanism configured with haptic feedback, either to affect a change in basal rate or for the administration of one or more bolus doses, approaches or attempts to surpass or override a pre-defined maximum (or minimum) volume of insulin already delivered or to be delivered by an insulin pump, the input mechanism provides a resistive or opposite force which may increase or decrease in some sort of linear fashion as the quantity of insulin selected by the user increases or decreases, respectively.

A flow chart of the above process is illustrated in FIG. **5**. Referring to FIG. **5**, upon deciding to increase/decrease user-modifiable value, e.g., the volume of a bolus dose of insulin, the user moves, e.g., presses, spins, rolls, etc., a UI input mechanism (**502**), e.g., a button, wheel, roller ball, etc., presented on the housing of an insulin infusion device one or more times or detents to adjust a digital value of the parameter being adjusted (incremented or decremented), e.g., to increase a bolus dose to be delivered, which value is also presented on the pump's UI display. For each incremental movement of the UI input mechanism, i.e., for each press of the button, a processor within the control system, e.g., infusion device, computes the proximity of the user requested value, e.g., bolus volume, to a predefined or a dynamically computed threshold limit (**504**), which limit may be based on one or more parameters including, for the bolus dose example, the total daily dosage (TDD) entered by the user, recent bolus history, the preset basal rate, carbohydrate intake, exercise events, etc. The processor then activates an actuator or the like which adjusts the tactile resistance, e.g., stiffness, of the user interface mechanism (**506**) to reflect the relative proximity of the requested bolus dose value to the predefined or computed limit. The processor also then, substantially simultaneously, adjusts the digital value of the requested value, e.g., bolus dose, on the UI display (**506**). If the adjusted bolus amount is acceptable to the user, the user may be required to further acknowledge such by depressing the same or another user interface mechanism (**508**), and the haptic response cycle is ended. If the process is not acceptable to the user (**508**) the process is repeated (**510**) for each increment/decrement of the UI input mechanism and, without any automatic locks provided by the system, may allow the user to override the predefined limits by further movement of the UI input mechanism.

In another embodiment, as illustrated in FIG. **6**, a process may be configured with automatic safety lockouts where continued movement of the UI mechanism by the user results in a hard stop in which further movement of the UI mechanism is impossible without overriding the system, for example, when a pre-defined insulin threshold has been met or exceeded. The initial steps of moving the UI mechanism (**602**) to achieve a desired parameter value, e.g., bolus dose, and computing the proximity of the incremented/decremented parameter value (**604**), e.g., bolus dose, to a predefined or a dynamically computed limit are substantially the same as for the process of FIG. **5**. If the selected parameter value, e.g., bolus dose, does not exceed the predefined or preselected limit (**606**), the UI input mechanism resistance, e.g., button stiffness, and the corresponding digital value in the UI display are each adjusted accordingly (**608**). At this point, the user may accept the last selected, non-limit-exceeding amount (**612**) or may attempt to further increment/decremented the selected parameter value (**610**), e.g., the selected bolus dose amount. However, should the selected parameter value, e.g., bolus dose, exceed the predefined limit (**606**), the processor may activate an actuator or the like to lock UI input mechanism travel, and the digital value of the previously selected, non-exceeding parameter value, e.g., bolus dose amount, will remain on the UI display screen (**614**). It is noted that with the input mechanism lockout feature (**614**) to ensure against a hazardous dosing situation or the like, it may not be necessary for the UI mechanism to have an adjustable tactile resistance feature. Upon lockout (**614**) the user may have the option to override the lockout (**616**). The system, via the user interface, may be configured to provide an audible or visual warning to the user, or a textual notice to the user of the risk of overriding the lockout (if such an override is available) or requesting the user to redefine the safety or threshold limits in the case where one or more of the user-entered parameters (but not system-based or physician-set parameters) is/are allowed to be adjusted. Should the acceptable range of the parameter be increased or decreased, the resulting range of resistance, stiffness or damping will also be increased or decreased, respectively. It is noted that adjusting one such parameter may in turn require other parameter or parameter ranges to be adjusted. The system may be configured to automatically adjust such other dependent parameters or otherwise notify the user of the need to adjust such. Once the parameter threshold(s) are redefined, the user may re-enter or re-select the desired parameter value using the UI input mechanism (i.e., repeating or redoing the parameter entry process) (**618**). Otherwise, the lockout may continue until the user selects a non-limit-exceeding value of the selected parameter by decrementing/incrementing (as the case may be) the

currently-displayed, over-limit parameter value (**618**) (i.e., repeating the parameter entry process), cancels the operation, or manually overrides the system (**616**) if the system is configured to allow such an override.

Other aspects of diabetes management devices and systems which involve user input in which haptic feedback capabilities are suitable or useful include, but are not limited to, CGM graphical applications in which a user-controlled cursor is scrollable over the respective graph axes. For example, a UI input dial may be employed to scroll a cursor along the time-based axis (e.g., the x-axis) of the graph wherein detent sensations are provided when certain pre-programmed events, e.g. meals and exercise, are passed. The system may be further configured such that the dial's resistance increases along the time-based axis as the cursor approaches glucose values representative of hypoglycemic or hyperglycemic limits. Additionally or alternatively, the extent of resistance or stiffness of the jog wheel may be relatively associated with rising and falling glucose levels. Additionally or alternatively, movement of an input mechanism may correspond to movement of a cursor along the axis representing glucose level (e.g., the y-axis), wherein detent sensations are provided at each unit change, i.e., increase or decrease, in glucose level.

In certain embodiments, the diabetes management device may include an analyte monitoring device, such as a glucose monitoring device, including a discrete or continuous glucose monitoring device, which may be used in conjunction with or independently from a medication infusion device, such as an insulin pump. The analyte monitoring device may be configured to include a user interface (UI) including selectable menu parameters. Such parameters may include selectable or adjustable thresholds and intervals, such as, but not limited to, a time interval between analyte, such as glucose, check reminders, thresholds for high and/or low glucose level alerts, the projection time for projected high and/or low glucose level alerts, and other parameters associated with a patient's needs. Parameters including scheduling parameters, threshold levels, and UI personalized configurations may be selectable or adjustable based on the patient's particular medical condition, such as, for example, louder alarms, lower hyperglycemic threshold levels, or larger display preferences for patients with advanced medical conditions effecting the patient's sight, hearing, or other medical and health conditions. Similar to the haptic feedback embodiments described above associated with an infusion device, the user interface of the analyte monitoring device may be configured such that actuation of the user interface, such as buttons, wheels, or the like, may increase in perceived stiffness as the selected parameters approach a programmed or chosen limit. In other aspects, selection through menu choices or available parameter values may be associated with simulated discrete detents where one detent corresponds to a predefined unit or menu choice.

The user interface mechanisms of the present disclosure may be configured wherein haptic-type feedback may be the only form of user feedback or the haptic feedback may be complemented by another form of feedback such as audio feedback, e.g., a buzzing noise or pinging sound from a speaker on the user interface, visual feedback, e.g., a flashing light, a change in color or a blinking symbol on the user interface display, or another type of tactile feedback such as a vibration of the user interface or device housing. Where discreteness or silence is necessary or desired (such as when in a meeting or at the movies), a haptic-only feedback response will allow a user to make adjustments to parameters without needing to see or hear the UI device and, as such, the user is able to manipulate the device while the device is kept concealed within a pocket or on a belt loop.

One aspect of the present disclosure includes a glucose management device having a processor and a user interface controlled by the processor comprising a user input mechanism configured for tactile contact and movement by a user for entering values of one or more parameters for controlling the glucose management device, wherein the user input mechanism is configured to provide a haptic feedback response to the user as the entered value of a selected parameter approaches a predefined limit.

In one embodiment, the haptic feedback response comprises a damping of movement of the user input mechanism wherein the extent of damping increases the closer the entered value approaches the predefined limit.

In a further embodiment, the haptic feedback response further comprises locking the user input mechanism against further movement upon the entered value of the selected parameter exceeding the predefined limit.

In another embodiment, the user input mechanism is movable in at least two directions wherein movement in a first direction increases the value of the selected parameter and movement in a second direction decreases the value of the selected parameter.

In a further embodiment, the user input mechanism is rotatable about an axis and the movement of the user input mechanism is rotational.

In yet a further embodiment, the user input mechanism is further moveable in a linear direction transverse to the axis of rotation.

The user input mechanism is a toggle button in other embodiments.

In another embodiment, the user interface comprises a display for displaying the values of the one or more parameters for controlling the glucose management device, wherein the display is configured to display the entered value of the selected parameter.

In a further embodiment the display is configured to provide visual feedback to the user when the entered value of the selected parameter exceeds the predefined limit.

In other embodiments, the haptic feedback response further comprises providing a detented sensation to the user wherein one detent corresponds to a predefined unit of the entered value of the selected parameter.

Another aspect includes a glucose management device having a processor, and a user interface controlled by the processor comprising a user input mechanism configured for tactile contact and movement by a user for entering values of one or more parameters for controlling the glucose management device, wherein the user input mechanism is configured to provide a haptic feedback response to the user as the entered value of a selected parameter moves away from at least one predefined preferred value for the selected parameter.

In one embodiment, the haptic feedback response comprises a spring biased movement of the user input mechanism toward a centered position corresponding to the at least one predefined preferred value.

In a further embodiment, the extent of spring bias increases the further the entered value of the selected parameter moves away from the at least one predefined preferred value.

In another embodiment, the user input mechanism is rotatable in at least two directions.

In one embodiment, the user input mechanism is one or more of a dial, knob, scroll ball, track ball and floating disc.

Another aspect includes a glucose management system having an insulin infusion device comprising a user interface controlled by at least one processor, the user interface comprising a user input mechanism configured for tactile contact by a user for entering values of one or more parameters for controlling, at least in part, the infusion of insulin to a patient, wherein the user input mechanism is configured to provide a haptic feedback response to the user as the entered value of a selected parameter approaches a predefined limit.

In one embodiment, the selected parameter of the system is the bolus dosing of insulin, and wherein the predefined limit is a maximum bolus dose.

In another embodiment, the user input mechanism comprises at least one of a button, keypad, knob, dial, thumb wheel, scroll ball, floating disc or touch screen.

Another aspect includes a glucose monitoring device in communication with the insulin infusion device.

In one embodiment, the glucose monitoring device provides discrete, continuous or both discrete and continuous measurement of the patient's glucose level.

In certain embodiments, the insulin infusion device and the glucose monitoring device are provided within the same housing, and the user interface is further configured for entering values of parameters for controlling, at least in part, the monitoring of glucose levels of the patient.

In yet another aspect, a glucose management system having a glucose monitoring device including a user interface controlled by at least one processor, the user interface comprising a display for displaying glucose levels of a patient and a user input mechanism configured for tactile contact by a user for evaluating displayed glucose levels, wherein the user input mechanism is configured to provide a haptic feedback response to the user as a monitored glucose level approaches a predefined limit is provided.

In one embodiment, the displayed glucose levels are provided in graphical format comprising an axis corresponding to time and an axis corresponding to the monitored glucose level and wherein movement of the user input mechanism moves a cursor on the display along the axis corresponding to time.

In other embodiments, the predefined limit comprises a hypoglycemic level, a hyperglycemic level, or both.

In certain embodiments, the glucose monitoring device monitors glucose continuously.

In one aspect, the glucose monitoring device and the insulin infusion device are provided within the same housing, and the user interface is further configured for entering values of parameters for controlling, at least in part, the infusion of insulin to the patient.

Another aspect of the present disclosure includes a method for managing the level of an analyte of a patient including providing an apparatus for managing the level of an analyte of a patient comprising a processor and a user interface controlled by the processor, the user interface comprising a user input mechanism configured for tactile contact and movement by the user for entering values of one or more parameters for controlling the apparatus, wherein movement of the input mechanism changes the value of a selected parameter, and a display for displaying values of the one or more parameters for controlling the apparatus, wherein the display is configured to display digital values corresponding to the user-entered values of the selected parameter, displaying a digital value on the display corresponding to the current value of the selected parameter, moving the user interface input mechanism in a first direction toward a target value of the selected parameter, computing the proximity of the entered selected parameter value to a predefined limit of the selected parameter, and increasing the stiffness of the input mechanism and changing the displayed value of the selected parameter if the entered selected parameter value is within the predefined limit.

A further embodiment includes locking the input mechanism from further movement if the entered selected parameter value is equal to the predefined limit.

Another further embodiment includes enabling the user to continue to move the input mechanism to change the entered selected parameter value.

Yet another further embodiment includes enabling the user to change the predefined limit of the selected parameter.

Other embodiments include providing an audible or visual warning to the user via the user interface when the entered selected parameter value is equal to the predefined limit.

A further aspect includes moving the user interface input mechanism in a second direction toward a target value of the selected parameter, computing the proximity of the entered selected parameter value to the target value of the selected parameter, and decreasing the stiffness of the input mechanism and changing the displayed value.

In one embodiment, the analyte is glucose, the apparatus comprises an insulin infusion pump, and the selected parameter is a bolus dose.

In another embodiment, movement of the user interface input mechanism in the first direction increases the value of the target bolus dose and the predefined limit is a maximum value of a bolus dose.

In one embodiment, the analyte is glucose, the apparatus comprises an insulin infusion pump, and the selected parameter is a basal rate.

In another embodiment, movement of the user interface input mechanism in the first direction increases the value of the target basal rate and the predefined limit is a maximum value of a basal rate.

While the present disclosure has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the disclosure. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present disclosure. All such modifications are intended to be within the scope of the claims appended hereto.

The invention claimed is:

1. A glucose management device, comprising:

a processor;

a user interface controllable by the processor, the user interface configured for tactile contact by a user for entering a value of one or more parameters of the glucose management device; and

a feedback mechanism, wherein the processor controls the feedback mechanism to provide a haptic feedback response to the user as the entered value of a selected parameter approaches or moves away from at least one set value of the selected parameter.

2. The glucose management device of claim **1**, wherein the user interface is further configured to allow the user to adjust the value of the selected parameter in at least two directions, wherein adjustment in the first direction increases the entered value of the selected parameter and adjustment in the second direction decreases the entered value of the selected parameter.

3. The glucose management device of claim 2, wherein the processor controls the feedback mechanism to increase the intensity of the haptic feedback response as the entered value of the selected parameter approaches the at least one set value of the selected parameter, and to decrease the intensity of the haptic feedback response as the entered value of the selected parameter moves away from the at least one set value of the selected parameter.

4. The glucose management device of claim 2, wherein the processor controls the feedback mechanism to decrease the intensity of the haptic feedback response as the entered value of the selected parameter approaches the at least one set value of the selected parameter, and to increase the intensity of the haptic feedback response as the entered value of the selected parameter moves away from the at least one set value of the selected parameter.

5. The glucose management device of claim 2, wherein the processor controls the feedback mechanism to increase the intensity of the haptic feedback response as the entered value of the selected parameter approaches the at least one set value of the selected parameter, and to decrease the intensity of the haptic feedback response as the entered value of the selected parameter moves away from the at least one set value of the selected parameter.

6. The glucose management device of claim 5, wherein the processor controls the user interface to prevent further adjustment of the entered value of the selected parameter beyond the at least one set value of the selected parameter.

7. The glucose management device of claim 1, wherein the processor controls the feedback mechanism to provide a detent sensation to the user.

8. The glucose measurement device of claim 7, wherein the processor controls the feedback mechanism to apply the detent sensation each time a predefined unit of the entered value of the selected parameter is reached.

9. The glucose management device of claim 1, wherein the user interface includes a touch screen configured to display the entered value of the selected parameter.

10. The glucose management device of claim 1, wherein the user interface comprises a touch screen and the haptic feedback response is vibration.

11. The glucose management device of claim 1, further comprising an infusion pump, wherein the one or more parameters relate to the administration of insulin by the infusion pump.

12. The glucose management device of claim 11, wherein the selected parameter is insulin dosage, and wherein the set value is a maximum dose.

13. The glucose management device of claim 1, wherein the at least one set value is at least one target value or at least one predefined limit.

14. A glucose management device, comprising:

a processor;

a user interface controllable by the processor, the user interface configured for tactile contact by a user for entering a value of one or more parameters of the glucose management device; and

a feedback mechanism, wherein the processor controls the feedback mechanism to provide haptic feedback in the form of a detent sensation each time a predefined unit of the entered value of the selected parameter is reached.

15. The glucose management device of claim 14, wherein the processor controls the feedback mechanism to increase the detent sensation to the user as the entered value of the selected parameter approaches at least one set value of the selected parameter, and to decrease the detent sensation to the user as the value of the selected parameter moves away from the at least one set value of the selected parameter.

16. The glucose management device of claim 14, wherein the processor controls the feedback mechanism to decrease the detent sensation to the user as the entered value of the selected parameter approaches at least one set value of the selected parameter, and to increase the detent sensation to the user as the entered value of the selected parameter moves away from the at least one set value of the selected parameter.

17. The glucose management device of claim 14, wherein the processor controls the feedback mechanism to increase the detent sensation to the user as the entered value of the selected parameter approaches at least one set value of the selected parameter, and to decrease the detent sensation to the user as the entered value of the selected parameter moves away from the at least one set value of the selected parameter.

18. The glucose management device of claim 14, wherein the user interface is further configured to allow the user to adjust the entered value of the selected parameter in at least two directions, wherein adjustment in the first direction increases the entered value of the selected parameter and adjustment in the second direction decreases the entered value of the selected parameter.

19. The glucose management device of claim 14, wherein the processor controls the feedback mechanism to provide haptic feedback to the user as the entered value of the selected parameter approaches or moves away from at least one set value of the selected parameter.

20. The glucose management device of claim 14, wherein the selected parameter is insulin dosage.

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