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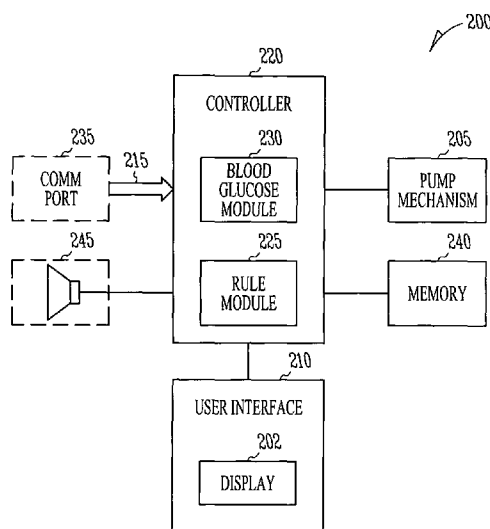(54) **Title:** INSULIN PUMP BASED EXPERT SYSTEM

FIG. 2

(57) **Abstract:** An apparatus comprising a pump configured to deliver insulin, an input configured to receive blood glucose data, a user interface, and a controller communicatively coupled to the pump, the input, and the user interface. The controller includes a blood glucose data module to compare the blood glucose data to a target blood glucose level for an insulin pump user. The controller is configured to present a question related to the blood glucose level via the user interface when the blood glucose level is different than the target blood glucose level, receive a response to the question via the user interface, and present a recommended user action based at least in part on the response. Other devices, systems, and methods are disclosed.

INSULIN PUMP BASED EXPERT SYSTEM

5   <u>Technical Field</u>

[0001]   The field generally relates to patient insulin management devices and, in particular, but not by way of limitation, to systems, devices and methods for managing insulin therapy.

10   <u>Background</u>

[0002]   People who suffer from diabetes require insulin to keep their blood glucose level as close as possible to normal levels. It is essential for people with diabetes to manage their blood glucose level to within a normal range. Complications from diabetes can include heart disease (cardiovascular

15   disease), blindness (retinopathy), nerve damage (neuropathy), and kidney damage (nephropathy). Insulin is a hormone that reduces the level of blood glucose in the body. Normally, insulin is produced by beta cells in the pancreas. In non-diabetic people, the beta cells release insulin to satisfy two types of insulin needs. The first type is a low-level of background insulin that is released

20   throughout the day. The second type is a quick release of a higher-level of insulin in response to eating. Insulin therapy replaces or supplements insulin produced by the pancreas.

[0003]   Conventional insulin therapy typically involves one or two injections a day. The low number of injections has the disadvantage of allowing

25   larger variations in a person's insulin levels. Some people with diabetes manage their blood glucose level with multiple daily injections (MDI). MDI may involve more than three injections a day and four or more blood glucose tests a day. MDI offers better control than conventional therapy. However, insulin injections are inconvenient and require a diabetic person to track the insulin doses, the

30   amount of carbohydrates eaten, and their blood glucose levels among other information critical to control.

[0004]   It is important for a diabetic person to be treated with the proper amount of insulin. As discussed previously, high blood sugar can lead to serious

complications. Conversely, a person with low blood sugar can develop

hypoglycemia. Ideally, insulin therapy mimics the way the body works. An

insulin pump is one way to mimic the body's insulin production. An insulin

pump can provide a background or basal infusion of insulin throughout the day

5   and provide a quick release or bolus of insulin when carbohydrates are eaten. If

a person develops high blood sugar, a correction bolus can be delivered by the

pump to correct it. While insulin pumps improve convenience and flexibility for

a diabetic person, they can be sophisticated devices. Some insulin pumps can be

difficult to program. Proper use of an insulin pump requires a user to go through

10   a learning curve to properly treat their diabetes using the insulin pump.

Summary

[0005]   This document discusses, among other things, devices and

methods for managing insulin therapy. A device example includes a pump

15   configured to deliver insulin, an input configured to receive blood glucose data, a

user interface, and a controller communicatively coupled to the pump, the input,

and the user interface. The controller includes a blood glucose data module to

compare the blood glucose data to a target blood glucose level for an insulin

pump user. The controller is configured to present a question related to the

20   blood glucose level via the user interface when the blood glucose level is

different than the target blood glucose level, receive a response to the question

via the user interface, and present a recommended user action based at least in

part on the response.

[0006]   A method example includes receiving blood glucose data into a

25   device that includes an insulin pump, presenting a question related to a blood

glucose level of an insulin pump user when determining, from the blood glucose

data, that the blood glucose level is different from a target blood glucose level,

receiving at least one response to the question into the insulin pump device, and

presenting a recommended action for a user to take based, at least in part, on the

30   response.

[0007]   A system example includes a first device and a second device.

The first device includes a pump configured to deliver insulin, an input that

includes a communication port configured to receive blood glucose data, a user

interface, and a controller communicatively coupled to the pump mechanism, the input, and the user interface. The controller includes a blood glucose data module configured to compare the blood glucose data to a target blood glucose level for an insulin pump user. The controller is configured for presenting a

5   question related to the blood glucose level when the blood glucose level is different from a target blood glucose level, receiving a response to the question via the user interface, and presenting a recommended action for the user to take based at least in part on the response. The second device includes a user interface, a processor that includes a rule development module configured for

10   developing the rule via the user interface, and a communication port configured to communicate the rule to the first device.

[0008]   This summary is intended to provide an overview of the subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The detailed description is

15   included to provide further information about the subject matter of the present patent application.

Brief Description of the Drawings

[0009]   FIGS. 1A and 1B illustrate portions of a device that includes an

20   insulin pump.

[0010]   FIG. 2 is a block diagram of an example of portions of an insulin pump device.

[0011]   FIG. 3 shows an example of a method for managing insulin therapy.

25   [0012]   FIG. 4 shows a portion of an example of a decision tree to determine one or more questions for the user of an insulin pump device.

[0013]   FIG. 5 shows an example of a portion of a system that provides an environment to customize a rule for an insulin pump device.

Detailed Description

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[0014]   The following detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the

invention may be practiced. These embodiments, which are also referred to
herein as "examples," are described in enough detail to enable those skilled in
the art to practice the invention. The embodiments may be combined, other
embodiments may be utilized, or structural, logical and electrical changes may be

5   made without departing from the scope of the present invention. The following
detailed description is, therefore, not to be taken in a limiting sense, and the
scope of the present invention is defined by the appended claims and their
equivalents.

[0015]   In this document, the terms "a" or "an" are used, as is common

10   in patent documents, to include one or more than one. In this document, the term
"or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not
B," "B but not A," and "A and B," unless otherwise indicated. Furthermore, all
publications, patents, and patent documents referred to in this document are
incorporated by reference herein in their entirety, as though individually

15   incorporated by reference. In the event of inconsistent usages between this
document and those documents so incorporated by reference, the usage in the
incorporated reference(s) should be considered supplementary to that of this
document; for irreconcilable inconsistencies, the usage in this document
controls.

20   [0016]   FIGS. 1A and 1B illustrate portions of a device 100 that
includes an insulin pump. The device 100 includes a cassette or cartridge of
insulin. The cartridge is connectable to infusion tubing 140 connectable to a
patient such as by a Luer lock 145 or infusion set 142. The device 100 includes a
display 102 and a user interface that may include the display 102 and include one

25   or more keys 104. Because proper use of an insulin pump requires a user to go
through a learning curve to properly treat their diabetes using the pump, it is
desirable for a pump to provide assistance to the user, whether the user is a
diabetic patient, a caregiver, or a clinician. Providing an expert system in an
insulin pump device will provide assistance to the user to effectively treat their

30   diabetes using the insulin pump device.

[0017]   FIG. 2 is a block diagram of an example of portions of an
insulin pump device 200. The insulin pump device 200 includes a pump 205 or
pump mechanism to deliver insulin to a subject, such as a positive displacement

pump for example. The insulin pump device 200 also includes a user interface 210, an input 215, and a controller 220. The user interface 210 receives manual input from a user and may include one or more pushbuttons or a keypad. The user interface 210 may include a display 202 to provide instructions to the user.

5   The user of the device may be a clinician or a diabetic patient. The display 202 may include a touch-screen.

[0018]   The input 215 is configured to receive blood glucose data of a patient or subject. The input 215 may be coupled to a blood glucose monitor (GM) included in the insulin pump device 200 or the input 215 may include a

10 communication port to receive the blood glucose data from a second separate device. In some embodiments, the communication port 235 is a wireless communication port configured to receive the blood glucose data from the separate device wirelessly. If the GM is a continuous GM, the continuous GM automatically collects the sampled blood glucose data in real time. The insulin

15 pump device 200 may receive the blood glucose in real time as it is obtained, or communicated at a later time. If the data is communicated at a later time, a timestamp may be included with the blood glucose data to indicate at what time the data was collected. In some embodiments, the input 215 is coupled to the user interface 210, and the user may manually input the data into the insulin

20 pump device 200 through a keypad included in the user interface 210.

[0019]   In some examples, the GM may require a prompt from the user to begin a blood glucose data measurement to obtain the blood glucose data. For example, the GM may require diabetes test strips to take a blood glucose measurement. The controller 220 recurrently presents a prompt to the user to

25 begin a blood glucose measurement using the GM and obtain blood glucose data. In certain examples, the prompt is presented periodically. The prompt may be presented via the display 202. The prompt may be presented by activating a light emitting diode (LED) included in the insulin pump device 200. In some examples, the prompt is presented by audibly such as by a transducer or by a

30 speaker instructing the user. The user then provides a new test strip to the GM when prompted during the correction factor test. In another example, the GM may include a drum of diabetes test strips and the user advances the drum to a fresh or unused test strip when prompted by the controller 220.

[0020]   If the insulin pump device 200 includes a continuous GM, the input 215 may be coupled to blood glucose sensor circuit. The blood glucose sensor circuit includes a blood glucose sensor to produce a blood glucose signal representative of a blood glucose level of the patient. The blood glucose sensor may sense blood glucose concentration from blood or interstitial fluid. The blood glucose sensor circuit may include a sensor interface circuit to sample the blood glucose signal and may provide additional signal processing such as filtering or amplification for example. The blood glucose sensor circuit may provide sampled blood glucose data to the input 215. A description of a blood glucose sensor circuit can be found in Steil et al., U.S. Patent No. 6,558,351, filed June 1, 2000.

[0021]   The controller 220 is operatively coupled to the pump mechanism 205, the input 215, and the user interface 210. The controller 220 can be implemented using hardware circuits, firmware, software or any combination of hardware, firmware and software. Examples, include a microcontroller, a logical state machine, and a processor such as a microprocessor, application specific integrated circuit (ASIC), or other type of processor. The controller 220 is configured to perform or execute a function or functions. Such functions correspond to modules, which are software, hardware, firmware or any combination thereof. Multiple functions are performed in one or more modules.

[0022]   The controller 220 monitors the blood glucose data of the subject. The controller 220 includes a blood glucose data module 230. The blood glucose data module 230 uses the blood glucose data to determine whether a blood glucose level of the subject is different from a target blood glucose level. The target blood glucose level may include a specified range of blood glucose levels and the blood glucose data module 230 may determine whether the blood glucose data indicates the blood glucose of the pump user is outside of a specified range of blood glucose levels. Being outside of a range may include having a blood glucose level that is too high or too low. The blood glucose data module 230 may determine whether a blood glucose level is above an acceptable range of higher blood glucose level, or below an acceptable range of low blood glucose levels. The target or range may be stored in memory and be a

programmable parameter available to the blood glucose data module 230. A

clinician would specify the range of blood glucose levels for the patient. The

range would depend on various factors for the patient such as weight, age, and

level of activity of the patient for example.

5   [0023]   If the blood glucose data module 230 determines that the blood

glucose level of the subject is different from the target or the specified range of

blood glucose levels, the controller 220 presents one or more questions related to

the blood glucose level via the user interface 210. Preferably, the question is

presented using the display 202. However, in some examples, the question may

10   be presented audibly. Presenting the question audibly may be useful if the

insulin pump user has difficulty seeing the display 202. The questions are

designed to help a user to properly treat their diabetes using the insulin pump

device 200 and even by programming the insulin pump device 200. In some

examples, the controller 220 presents different questions according to different

15   blood glucose levels. For example, the controller 220 may present different

questions according to whether the blood glucose level of the patient is above

200 mg/dl, or above 300mg/dl, or above 400mg/dl. The clinician may program

the different levels into the insulin pump device 200.

[0024]   The user responds to the question through the user interface

20   210. Based at least in part on one or more responses, the controller 220 displays

at least one recommended action for the user to take. As is discussed below, the

recommended action may involve various user actions such as troubleshooting

the insulin pump device 200, delivering insulin using the insulin pump device

200, initiating a measurement or test using the insulin pump device 200, or

25   making lifestyle changes for example. In some examples, the recommended

action for display may include contacting a physician. In some examples, the

recommended action may be different according to the blood glucose level of the

patient. For example, the controller 220 may present different actions according

to whether the blood glucose level of the patient is above 200 mg/dl, or above

30   300mg/dl, or above 400mg/dl.

[0025]   If the question is presented using a display 202, the device may

include an alarm circuit 245 coupled to the controller 220 to draw the attention

of the user to the display 202. The alarm circuit 245 may include an audible

alarm, a visual indication such as a flashing light or flashing icon on the display, or the alarm circuit may mechanically vibrate the insulin pump device to draw attention of the user. The controller 220 activates the alarm circuit 245 if it is determined that the blood glucose level of the subject is outside of the specified

5   range of blood glucose levels.

[0026]   FIG. 3 shows an example of a method 300 for managing insulin therapy. At block 305, blood glucose data is received into an insulin pump device 200. At block 310, at least one question related to a blood glucose level of a patient is presented when determining, from the blood glucose data, that the

10   blood glucose level is outside of a range of blood glucose levels. The question may be presented on a display 202 included with the insulin pump device 200, or the question may be transmitted to a second device for display, such as a computer for example. This is may be useful if a display 202 on the insulin pump device 200 is difficult for the user to read. In some examples, the second

15   device presents the question audibly. The insulin pump and the second device may communicate wirelessly such as by radio frequency (RF) or infrared red (IR) communication. At block 315, at least one response to the question is received into the insulin pump device 200. The response may be received through a user interface. At block 320, at least one recommended action is presented for a user

20   to take based, at least in part, on the response. The action may be presented audibly or visually, such as by a display for example.

[0027]   Returning to FIG. 2, in some embodiments, the controller 220 includes a rule module 225 to apply at least one rule to the blood glucose data to determine the question to be presented. In some embodiments, the rule includes

25   a decision tree. FIG. 4 shows a portion of an example of a decision tree 400 to determine one or more questions for the user of the insulin pump device 200. In certain examples, the decision tree 400 may implemented with a series of IF-Then logic statements. The controller 220 traverses the decision tree 400 using various information such as the blood glucose data, responses from the user, or

30   other data. If the blood glucose is high, the left portion of the decision tree 400 is traversed at block 405. The controller 220 may display a recommended action, such as the user taking a correction bolus at block 410, before asking one or more questions. If the blood glucose is low, the right portion of the decision tree

400 is traversed at block 415. The controller 220 may display a recommended action, such as the user eating food at block 420 before asking one or more questions. The controller 220 may display a picture or icon of food when making the recommendation.

5   [0028]   In some examples, the rule module 225 applies the rule to the blood glucose data and to at least one user response to the question to determine the recommended action for display. For example, using the decision tree 400, if the blood glucose level is high, the controller 220 may display a question asking if the infusion site is red at block 425. If the user interface 210 receives a

10   response from the user that the site is red, the controller 220 may display a recommendation that the user change the infusion site at block 430.

[0029]   In some embodiments, the rule module 225 may include a look-up table stored in a memory. For example, if the blood glucose is low, the look up table may include a question as to whether the patient had a high activity

15   level. If the user interface 210 receives a response that the activity level was high, the look up table includes a recommended action corresponding to a table entry for low blood glucose and high activity. The table entry may include a recommended action that the patient eat before the activity or lower a programmable basal rate of insulin before or during the activity. The table may

20   include multiple dimensions to take into account multiple factors, responses, or other data. In some examples, the rule module 225 assigns weights to corresponding table entries. For example, receiving a response that the infusion set has visible blood may by weighted as a stronger indication to change the infusion site than if a response is received that the infusion site is red. In some

25   examples, the rule module 225 uses one or more fuzzy logic rules to determine the question for display and any recommended action. The fuzzy logic rules may be used to blend any weighted questions, responses, or actions. In some examples, the rule module 225 uses a rule involving application of artificial intelligence methods to determine the questions and the actions to be presented.

30   [0030]   In some examples, the rule module 225 may apply the rule to the blood glucose data and present a recommendation that the user initiate at least one blood glucose measurement. The measurement may be made using a second separate device that includes a GM, or the action may recommend

making the measurement with the insulin pump device 200 if the device includes a GM.

[0031]   Note that application of the rule by the rule module 225 may result in a series of questions displayed, responses by the user, and recommend actions. For example, the insulin pump device 200 may receive an indication that a recommended action was taken. The rule module 225 may apply the rule to the blood glucose data, the response to the question, and the indication that the action was taken to determine at least one of a further question and a further recommended action to be presented.

[0032]   In some examples, the rule module 225 may apply the rule to the blood glucose data and present a recommendation that the user initiate a basal rate test. Basal rate refers to a type of twenty-four hour background infusion of insulin by an insulin pump that mimics the continuous background release of insulin from a normal pancreas. It is the rate of insulin delivery the patient normally needs independent of the consumption of meals. If the basal rate is inappropriate, blood glucose concentration levels may result that are out of a recommended or desired range. An insulin pump user may go through several iterations of trial and error before finding appropriate basal rates. Because a patient's basal insulin needs may change over time, such as with weight change or with a change in fitness level, basal rate testing may be performed periodically to ensure that an appropriate basal rate is being delivered by an insulin pump. Based on the blood glucose level, the rule module 225 determines that a recommendation to run a basal rate test (by either the insulin pump device 200 or a separate device) should be presented (such as by display). As a result of the basal rate test, the controller may display a recommendation to change a programmable basal rate pattern or profile of the insulin pump device 200. Descriptions of devices and methods that perform a basal rate test are found in Blomquist et al., "Basal Rate Testing Using Frequent Blood Glucose Input," U.S. Patent Application Serial No. 11/685,617, filed March 13, 2007, which is incorporated herein by reference.

[0033]   In some examples, the rule module 225 may apply the rule to the blood glucose data and present a recommendation that the user initiate a carbohydrate ratio test if the blood glucose level is outside a desired range. A

carbohydrate ratio refers to the amount of carbohydrates covered by a unit of
insulin. It is sometimes referred to as a carbohydrate factor, or carb factor, and is
typically specified as grams of carbohydrates per unit of insulin. The insulin
pump device 200 may use the carbohydrate ratio to automatically determine a

5   carbohydrate insulin bolus amount required to match a number of carbohydrates
ingested by the patient, or at least to keep post-meal blood glucose within a range
that is healthy for a patient. For example, the patient may plan to eat seventy
grams of carbohydrates. If the carbohydrate ratio is ten grams of carbohydrates
per unit of insulin, the insulin pump device 200 would determine that seven units

10   of insulin are required to cover the carbohydrates.

[0034]   The appropriate carbohydrate ratio may vary from person to
person, yet it is important for an insulin pump to use an appropriate carbohydrate
ratio. If a carbohydrate ratio is too small, the pump may determine a
carbohydrate bolus that is too large for the carbohydrates consumed. This may

15   cause a low blood glucose level within a few hours of the carbohydrate bolus
(e.g., the blood glucose level drops below 70mg/dl). If a carbohydrate bolus is
too large, the insulin pump device 200 may determine a carbohydrate bolus that
is too small for the carbohydrates consumed. This may cause a high blood
glucose level within a few hours of a carbohydrate bolus. Based on the blood

20   glucose level, the rule module 225 determines that a recommendation to run a
carbohydrate ratio test should be presented. As a result of the carbohydrate ratio
test, the controller 220 may present a recommendation to change a carbohydrate
insulin bolus pattern or profile delivered by the insulin pump device 200. For
example, the controller 220 may recommend a carbohydrate bolus pattern that

25   includes an extended carbohydrate bolus or a combination bolus. Descriptions
of devices and methods that perform a carbohydrate ratio test are found in
Blomquist, "Carbohydrate Ratio Testing Using Frequent Blood Glucose Input,"
U.S. Patent Application Serial No. 11/679,712, filed February 27, 2007, which is
incorporated herein by reference.

30   [0035]   In some examples, the rule module 225 may apply the rule to
the blood glucose data and present a recommendation that the user initiate a
correction factor test. A correction factor refers to the amount in drop in blood
sugar, or blood glucose, for one unit of insulin. It is measured in milligrams per

deciliter (mg/dl) per unit in the U.S. and in millimoles (mmol) per unit in other

countries. The insulin pump device 200 may use the correction factor to

automatically determine a bolus amount required for a high reading or a

reduction in a meal bolus for a below-target reading. The insulin pump device

5   200 may also use the correction factor to calculate the amount of carbohydrates a

patient should eat to bring low blood sugar up to a target blood sugar level. An

appropriate correction factor brings a high blood glucose reading down using an

automatically determined correction bolus without a risk of going low.

[0036]   The appropriate correction factor varies from person to person.

10   It is important for an insulin pump to use an effective correction factor. If a

correction factor for a pump is set too high, the blood glucose may not actually

be dropping as much as estimated and could lead to high blood glucose levels. If

the correction factor is set too low, a correction bolus may provide too much

insulin and result in a low blood glucose level. As a result of the carbohydrate

15   ratio test, the controller 220 may display a recommendation to change an insulin

correction bolus pattern or profile, such as to include an extended bolus or a

combination bolus for example. Descriptions of devices and methods that

perform a carbohydrate ratio test are found in Blomquist et al., "Correction

Factor Testing Using Frequent Blood Glucose Input," U.S. Patent Application

20   Serial No. 11/626,653, filed January 24, 2007, which is incorporated herein by

reference.

[0037]   In some embodiments, the rule module 225 may receive an

updated or new rule or a modification to the rule. In certain embodiments, the

insulin pump device 200 includes a communication port 235 coupled to the input

25   215. The communication port 235 receives the rule into the insulin pump device

200 from a second separate device. In some examples, the communication port

235 is a wireless port and receives the rule wirelessly. The second device may

be a computer or a personal data assistant (PDA). The second device may

provide an environment (e.g., such as through software) for a diabetes

30   professional, clinician, or other caregiver to customize the rule. In some

examples, the environment allows the clinician to customize a decision tree or

look up table.

[0038]   FIG. 5 shows an embodiment of a portion of a system 500 that provides an environment to customize rules in the rule module 225. The system 500 includes an insulin pump device 200 and a computing device 550. The insulin pump device 200 includes a communication port 235 to communicate

5   information with the computing device 550. The communication port 235 shown is a wireless port that communicates wirelessly with the computing device 550, such as a radio frequency (RF) port or infrared (IR) port for example. The communication port 235 may receive blood glucose data from a third device, such as a GM for example. In certain examples, the insulin pump device 200

10   receives the blood glucose data from a GM when the GM is communicatively coupled to the communication port 235. The insulin pump device 200 is able to communicate information with the computing device 550 when the GM is not communicatively coupled to the insulin pump device 200. In some examples, the communication port 235 may be a wired port, such as a serial port for

15   example, to communicate with the computing device 550.

[0039]   The computing device 550 may be a personal computer (PC), laptop computer, or a personal data assistant (PDA). The computing device 550 includes a user interface 555 that includes a display and may include at least one of a keyboard or keypad and a computer mouse. The computing device 550 also

20   includes a processor 560 communicatively coupled to the user interface 555. The processor 560 can be a microprocessor, application specific integrated circuit (ASIC), or other type of processor.

[0040]   The processor 560 includes a rule development module 565 that provides doctors or clinical experts the ability to develop and generate a new rule

25   or rule set or modify rules via the user interface 555. The computing device 550 includes software that provides a flexible framework to create or modify rules such as by updating a graphical decision tree, a multidimensional table, or other type of logical rule. The software may included in a computer readable medium, such as a compact disc (CD) for example, or the software may be downloaded to

30   the computing device 550 from remote storage, such as from a server for example. The rule development module 565 develops a rule to be applied to the blood glucose data received into the insulin pump device 200, and may develop a rule that is also applied to at least one of physiologic data, demographic data,

patient lifestyle data, insulin delivery history data, and blood glucose history data to generate a recommended action. The computing device 550 includes a communication port 535 to communicate information with the insulin pump device 200. The computing device 550 uses the communication port 535 to

5   communicate the rule to the insulin pump device 200.

[0041]   Once a rule is developed, the doctor or clinical expert could publish or otherwise share a rule or set of rules. In some embodiments, rule sets can be stored in remote storage, such as a server for example. The computing device 550 may be connected to a communication network, such as the internet

10   or a cell phone network for example. A doctor or clinical expert may download a rule or rule set from the remote storage and either download the rule set directly from the computing device 550 into the insulin pump device 200 or modify the rule or rule set before downloading the modified rule or rule set to the insulin pump device 200.

15   [0042]   Returning to FIG. 2, in some embodiments, the user interface 210 and the input 215 receive modifications to the rule that are entered into the insulin pump device 200 manually by the user via the user interface 210. For example, the user may step through the rule with the aid of the display 202. The user may then alter the rule with a keypad included in the user interface 210. For

20   example, the user may enter a new look up table entry using the key pad, or add another branch to a decision tree or edit a branch of the decision tree. In certain embodiments, an entire new rule or rule set is entered manually into the insulin pump device 200 via the user interface 210.

[0043]   In some embodiments, the insulin pump device 200 stores data

25   to track effectiveness of a new rule or modified rule. For example, the insulin pump device 200 may track the number of times the blood glucose level of the patient returned to the target blood glucose level or to within the target range of levels after application of the rule. The effectiveness may be displayed as a percentage or as X successes out of Y applications on either a display 202 of the

30   insulin pump or uploaded and displayed on a separate device, such as the computing device 550 in FIG. 5 for example.

[0044]   If a rule or rule set is downloaded into multiple devices, the effectiveness of the rule set for multiple device may be tracked. The stored data

related to the effectiveness may be uploaded to a remote server and the server tracks the overall effectiveness of the rule over the multiple devices. The overall effectiveness may be useful to a clinician in determining whether to download a particular rule or rule set to the insulin pump device 200.

5   [0045]   In some embodiments, controller 220 determines a rate of change of a blood glucose level of the subject from the blood glucose data. For example, the controller 220 may determine that the blood glucose concentration level is increasing or decreasing at a rate of 2 to 4 mg/dl/min (milligrams per deciliter per minute). The rule module 225 may apply one or more rules to the

10   rate of change of a blood glucose level to determine at least one of a question for display or one or more recommended actions for display. For example, the blood glucose level of the user may not be high, but the rate of change of blood glucose may be increasing at such a rate to indicate there is a risk of the blood glucose level going high. Conversely, the blood glucose level of the user may

15   not be below a blood glucose target, but the rate of change of blood glucose may be decreasing at such a rate to indicate there is a risk of the blood glucose level going low.

[0046]   In some examples, the rule module 225 may apply the rules to at least one of the blood glucose data, the rate of change of blood glucose data, and

20   a response to a question to determine a subsequent question or recommended action for display by the controller 220. For example, if the blood glucose level is high and increasing at a certain rate, the rule module 225 may apply the rule to determine that a recommended action to take a correction bolus should be presented before presenting a question. In another example, if the blood glucose

25   level is high and decreasing at a certain rate, the rule module 225 may apply the rule to determine that a recommended action to take a correction bolus should not be displayed and proceed to displaying a question such as whether the patient ate something where it was difficult to estimate the carbohydrates.

[0047]   According to some embodiments, the controller 220 may

30   display a recommendation that the patient consume carbohydrates if the blood glucose level is low or there is a risk of blood glucose level going low. In some examples, the memory 240 may store a database of food options in association with a known amount of carbohydrates. The recommended action presented by

the controller 220 may include displaying a food option for consumption that is included in the database.

[0048]   In some embodiments, the controller 220 determines an amount of carbohydrates for the patient to consume and presents a food option

5   accordingly. For example, assume that the blood glucose level of a patient is 40mg/dl below a desired range of blood glucose levels. The correction factor is stored in the insulin pump device 200 and is 1unit per 80mg/dl. The controller 220 determines that -0.5unit of insulin (-40/80) is required to bring the blood glucose level back to the target level or range. Further assume that the

10   carbohydrate ratio of the patient is 20 grams of carbohydrates per unit of insulin (20g/u). The controller 220 multiplies the amount of insulin by the carbohydrate ratio to determine that the patient should eat 10 grams of carbohydrates [(0.5)(20)]. The insulin calculation module 125 may take into account additional factors such as the health status of the patient and the activity level of the patient

15   in recommending the carbohydrate amount. In some example, the food option may be displayed using an icon or picture of food.

[0049]   According to some embodiments, the input 215 receives physiologic data into the insulin pump device 200 from a separate second device. The data may be received through the input 215 or another input. In some

20   embodiments, the insulin pump device 200 receives the physiologic data through a communication port 235. In some examples, the insulin pump device 200 receives the physiologic data through the same communication port 235 that receives the blood glucose data. In some examples, the second device includes a temperature monitor and the physiologic data includes a patient temperature. In

25   some examples, the second device includes an activity monitor and the physiologic data includes an indication of a level of patient activity.

[0050]   The rule module 225 may apply one or more rules to the physiologic data to determine a question for display. The rule module 225 may apply one or more rules to the physiologic data and a response to the question to

30   determine one or more recommended actions for display. In some examples, the rule module 225 may apply one or more rules to the physiologic data, the blood glucose data, at least one question response to determine a question or

recommended action for display. The controller 220 displays the questions and recommended actions.

[0051]   In some embodiments, the insulin pump device 200 includes a memory 240 communicatively coupled to the controller 220. The memory 240 may store demographic data of the subject. The demographic data includes such information as a patient's weight, age, and gender for example. The demographic data may be received from a second device or through the user interface 210. The rule module 225 may apply one or more rules to the demographic data to determine a question to be presented. The rule module 225 may apply one or more rules to the demographic data and a response to the question to determine and/or adjust one or more recommended actions. In some examples, the rule module 225 may apply one or more rules to the demographic data, the blood glucose data, at least one question response to determine a question or recommended action for display.

[0052]   In some embodiments, the controller 220 adjusts the questions and recommended actions based on the demographic data. For example, the controller 220 may use a different set of questions and recommended actions when the demographic data indicates that the patient is a child than when the demographic data indicates the patient is an adult.

[0053]   In some embodiments, the memory 240 may store lifestyle data of the subject. The lifestyle data includes such information as whether a patient tends to eat high glycemic index foods, drinks alcohol, smokes, eats a bedtime snack, a health status of the patient, whether the patient is typically under stress, whether the patient tends to be active, and the amount time he patient spends exercising, for example. The lifestyle data may be received from a second device or entered through the user interface 210. The rule module 225 may apply one or more rules to the lifestyle data to determine a question for display. The rule module 225 may apply one or more rules to the lifestyle data and a response to the question to determine one or more recommended actions for display. In some examples, the rule module 225 may apply one or more rules to the lifestyle data, the blood glucose data, at least one question response to determine a question or recommended action for display.

[0054]   A recommended action may include a change to at least one
aspect of the patient's lifestyle, such as to skip the bedtime snack or to eat lower
glycemic index meals, for example. In some examples, the recommended action
may include recommending patient training. In certain examples, the insulin

5   pump device 200 may present a recommendation that the patient be trained in
carbohydrate counting. In certain examples, the insulin pump device 200 may
recommend that the patient be trained in managing their exercise. In certain
examples, the insulin pump device 200 may recommend that the patient be
trained in using the insulin pump when the patient is sick. In certain examples,

10   the insulin pump device 200 may recommend that the patient be trained in proper
infusion site care.

[0055]   In some embodiments, the memory 240 may store insulin
delivery history data of the patient. Insulin delivery history data may include a
time duration since the last meal bolus, how long since the cartridge was

15   changed, and whether there have been any recent changes to programming
parameters and what those changes were for example. The rule module 225 may
apply one or more rules to the insulin delivery history data to determine a
question to be presented. The rule module 225 may apply one or more rules to at
least one of the insulin delivery history data, the blood glucose data, and a

20   response to a question to determine one or more recommended actions.

[0056]   In some embodiments, the memory 240 may store blood
glucose history data of the subject. Blood glucose history data may include
blood glucose data from a previous time period, such as two hours or 24 hours in
the past for example. The data may be received from a GM included in the

25   insulin pump device 200 or from a GM included in a separate device. In some
examples, the blood glucose history data may be received from a separate
computing device such as a PC, laptop, or PDA configured to communicate with
the insulin pump device 200. The controller 220 may generate a prompt to
download blood glucose history data from the second separate device, such as a

30   prompt on a display 202, an LED prompt, or an audible prompt. The rule
module 225 may apply one or more rules to the blood glucose history data to
determine a question to be presented. The rule module 225 may apply one or
more rules to at least one of the blood glucose history data, the blood glucose

data collected in real time, and a response to a question to determine one or more recommended actions.

[0057]   The patient may experience trouble with the insulin pump device 200 itself. According to some embodiments, the recommended action presented by the controller 220 includes actions for troubleshooting the insulin pump device 200. If the blood glucose level is low, the recommended actions may include checking or changing the insulin cartridge, the infusion set, the infusion set tubing, and/or the infusion site. For example, if the insulin pump device 200 stores the time since the cartridge was changed, the rule module 225 may determine that it is time for a new cartridge and display instructions to check whether the cartridge is low or change the cartridge. If it has been a short time since the cartridge was changed, the rule module 225 may eliminate the cartridge as the problem and display instructions to check or change the infusion set or the infusion site.

[0058]   In another example, the user may respond that the cartridge was checked. The rule module 225 may apply the rule to the blood glucose level and the response and eliminate the cartridge as the problem. The insulin pump device 200 and the user may then step through response and actions that instruct the user to troubleshoot the infusion set and site. The controller 220 may also present a recommendation to change the type of insulin. For example, the rule module 225 may determine that the delay for uptake is too slow and recommend that the patient use a type of insulin with faster uptake. The controller 220 may also present a recommendation to change an insulin pump executable program and to see a diabetes professional. The controller may present a question whether the infusion set has visible blood and recommend that the infusion site be changed if there is visible blood. In some examples, the controller 220 may display a device error code and a recommendation to see the diabetes professional rather than present instructions to the user or patient that the pump program should be changed. The diabetes professional interprets the error code to determine the recommended action.

[0059]   According to some examples, the blood glucose data module 230 may determine from the blood glucose data that a blood glucose level of the subject is at a target blood glucose level or within a specified range of blood

glucose levels. The rule module 225 may determine one or more recommend actions for the patient to take that are related to maintaining normoglycemia. The rule module 225 may apply the rule to the blood glucose data and at least one of the physiologic data, the demographic data, the lifestyle data, the blood

5   glucose history data, the insulin delivery history data, question responses, and previous actions taken to make the recommendation. The controller 220 displays the recommended action. For example, the controller 220 may ask lifestyle questions when blood glucose data is in the normoglycemic range. The controller 220 may aggregate insulin pump data and answers to the questions

10   from various times when the blood glucose data values were in range and help the patient identify lifestyle or therapy patterns that promote good glycemic control.

[0060]   It is to be understood that the above description is intended to be illustrative, and not restrictive. For example, the above-described

15   embodiments (and/or aspects thereof) may be used in combination with each other. Many other embodiments will be apparent to those of skill in the art upon reviewing the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled. In the appended claims, the

20   terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover,

25   in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

[0061]   The Abstract of the Disclosure is provided to comply with 37 C.F.R. §1.72(b), requiring an abstract that will allow the reader to quickly

30   ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, it can be seen that various features are grouped together in a single embodiment for the purpose

of streamlining the disclosure. This method of disclosure is not to be interpreted

as reflecting an intention that the claimed embodiments require more features

than are expressly recited in each claim. Rather, as the following claims reflect,

inventive subject matter lies in less than all features of a single disclosed

5   embodiment. Thus the following claims are hereby incorporated into the

Detailed Description, with each claim standing on its own.

What is claimed is:

1.   An apparatus comprising:

a pump configured to deliver insulin;

5   an input configured to receive blood glucose data;

a user interface; and

a controller communicatively coupled to the pump, the input, and the user

interface, wherein the controller includes:

a blood glucose data module configured to compare the blood

10   glucose data to a target blood glucose level for an insulin pump user; and

wherein the controller is configured to:

present a question related to the blood glucose level via the user

interface when the blood glucose level is different than the target blood

glucose level;

15   receive a response to the question via the user interface; and

present a recommended user action based at least in part on the

response.

2.   The apparatus of claim 1, wherein the controller includes a rule module

20   configured to apply a rule to the blood glucose data to determine the question.

3.   The apparatus of claim 2, wherein the rule module is configured to apply

the rule to the response to determine the recommended action.

25   4.   The apparatus of claim 2 or 3, wherein the input is configured to receive

physiologic data into the device from at least one second device,

wherein the rule module is configured to apply the rule to the physiologic

data to determine the question, and

wherein the controller is configured to determine the recommended

30   action based at least in part on the physiologic data.

5.   The apparatus of claim 2, 3, or 4 including:

a memory, communicatively coupled to the controller, to store

demographic data of the insulin pump user,

wherein the rule module is configured to apply the rule to the

demographic data to determine the question, and

5   wherein the controller is configured to adjust presentation of the

recommended action based on the demographic data.

6.   The apparatus of claim 2, 3, 4, or 5, including:

a memory, communicatively coupled to the controller, to store lifestyle

10   data of the insulin pump user,

wherein the rule module is configured to apply the rule to the lifestyle

data to determine the question, and

wherein the controller is configured to determine the recommended

action based at least in part on the lifestyle data.

15

7.   The apparatus of claim 2, 3, 4, 5, or 6, wherein the controller is

configured to present a recommended change to an aspect of a lifestyle of the

insulin pump user.

20   8.   The apparatus of claim 2, 3, 4, 5, 6, or 7, wherein the controller is

configured to determine a rate of change of a blood glucose level of the insulin

pump user from the blood glucose data, and

wherein the rule module is configured to apply the rule to the rate of

change of a blood glucose level to determine at least one of the question and the

25   recommended action.

9.   The apparatus of claim 2, 3, 4, 5, 6, 7, or 8, including:

a memory, communicatively coupled to the controller, to store insulin

delivery history data of the insulin pump user, and

30   wherein the rule module is configured to apply the rule to the blood

glucose data and the insulin delivery history data to determine at least one of the

question and the recommended action.

10. The apparatus of claim 2, 3, 4, 5, 6, 7, 8, or 9 including a communication port communicatively coupled to the controller, wherein the communication port is configured to receive the rule into the device from a second separate device.

5   11. The apparatus of claim 2, 3, 4, 5, 6, 7, 8, or 9 wherein the user interface and the input are configured to receive modifications to the rule.

12. The apparatus of any one of claims 1-11, wherein the recommended action includes troubleshooting at least one of the insulin pump device, an

10 insulin cartridge, an infusion set, infusion set tubing, and the infusion site.

13. The apparatus of any one of claims 1-12, wherein the recommended action includes changing at least one of an insulin cartridge, an infusion set, an insulin type, an insulin bolus pattern, an insulin basal rate pattern, and an insulin

15 pump executable program.

14. The apparatus of any one of claims 1-13, wherein the recommended action includes a recommendation to initiate a correction bolus when the blood glucose module determines the blood glucose level is at risk of being high.

20
15. The apparatus of any one of claims 1-14, wherein the recommended action includes a recommendation to initiate at least one blood glucose measurement.

25 16. The apparatus of any one of claims 1-15, wherein the recommended action includes a recommendation to perform at least one of a basal rate test, a carbohydrate ratio test, and a correction factor test.

17. The apparatus of any one of claims 1-16, wherein the recommended
30 action includes a recommendation to consume carbohydrates if the blood glucose level is at risk of being low.

18. The apparatus of claim 17, including:

a memory, communicatively coupled to the controller, to store a database

of food options in association with a known amount of carbohydrates, and

wherein the controller is configured to present a food option included in

the database.

5

19.   The apparatus of any one of claims 1-18, wherein the recommended

action includes contacting a physician.

20.   The apparatus of any one of claims 1-19, wherein the controller is

10   configured to:

present a question after receiving an indication via the user interface that

a recommended action was taken; and

present a further recommended action for the user to take based, at least

in part, on a response to the question presented after receiving the indication.

15

21.   The apparatus of any one of claims 1-20, including:

a memory, communicatively coupled to the controller, to store blood

glucose history data of the pump user, and

wherein the rule module is configured to apply the rule to the blood

20   glucose history data and the blood glucose data received by the input.

22.   The apparatus of claim 21, wherein the input includes a communication

port configured to receive blood glucose history data from a second separate

device, and wherein the controller is configured to present a prompt to download

25   blood glucose history data from the second separate device.

23.   The apparatus of any one of claims 1-22, including a blood glucose

monitor communicatively coupled to the input, wherein the input is configured

to receive the blood glucose data from the blood glucose monitor.

30

24.   The apparatus of claim 23, wherein the blood glucose monitor is a

continuous blood glucose monitor configured to automatically collect the

sampled blood glucose data in real time.

25.   The apparatus of any one of claims 1-22, wherein the input includes a
communication port configured to receive the blood glucose data from a second
separate device.

5

26.   The apparatus of claim 25, wherein the communication port is a wireless
communication port configured to receive the blood glucose data from the
second separate device wirelessly.

10   27.   The apparatus of claim 25 or 26, wherein the controller is configured to
recurrently prompt the user to obtain blood glucose data using the separate
device.

28.   The apparatus of any one of claims 1-22, wherein the user interface and
15   the input are configured to receive the blood glucose data.

29.   The apparatus of any one of claims 1-28, including an alarm circuit
coupled to the controller, wherein the controller is configured activating an
audible alarm if it is determined that the blood glucose level of the subject
20   different from a target blood glucose level.

30.   The apparatus of any one of claims 1-29, wherein the blood glucose data
module is configured to determine, from the blood glucose data, whether a blood
glucose level of the subject is at the target blood glucose level, and wherein the
25   controller is configured for displaying a recommended user action when the
blood glucose level is near the target blood glucose level, wherein the
recommended action is related to maintaining normoglycemia.

31.   A system comprising:
30   a first device including:
                        a pump configured to deliver insulin;
                        an input including a communication port configured to receive
                blood glucose data;

26

a user interface; and

a controller communicatively coupled to the pump, the input, and
the user interface, wherein the controller includes:

a blood glucose data module configured to compare the

5   blood glucose data to a target blood glucose level for an insulin

pump user; and

a rule module configured to:

receive a rule via the input;

determine a question related to the blood glucose

10   level via the user interface when the blood glucose level is

different than the target blood glucose level; and

determine a recommended action for the user to

take by applying the rule to the blood glucose data and a

response to the question received via the user interface,

15   wherein the controller is configured to present the question and

the recommended action; and

a second device comprising:

a user interface;

a processor, communicatively coupled to the user interface,

20   including a rule development module configured for developing the rule

via the user interface; and

a communication port, communicatively coupled to the processor,

configured to communicate the rule to the first device.

25   32.   The system of claim 31, wherein the rule development module is
configured to develop the rule, wherein the rule is applied to the blood glucose
data and at least one of physiologic data, demographic data, patient lifestyle data,
insulin delivery history data, and blood glucose history data to determine the
recommended action.

30

33.   The system of claim 31 or 32, wherein the input of the first device
includes a communication port configured to receive the blood glucose data from
a third device.

34.   The system of claim 31, 32, or 33, wherein the first device includes a blood glucose monitor communicatively coupled to the input to provide the blood glucose data.

35.   A method comprising:

receiving blood glucose data into a device that includes an insulin pump;

presenting a question, via the device, related to a blood glucose level of an insulin pump user when determining, from the blood glucose data, that the blood glucose level is different from a target blood glucose level;

receiving a response to the question into the insulin pump device; and

presenting a recommended action for the user to take based, at least in part, on the response.

36.   The method of claim 35, including applying a rule stored in the device to the blood glucose data to determine the question.

37.   The method of claim 36, including applying the rule to the blood glucose data to determine the recommended action.

38.   The method of claim 36 or 37, including:

receiving physiologic data into the device from a second device;

wherein the applying a rule includes applying the rule to the physiologic data to determine the question; and

wherein the displaying a recommended action includes displaying the recommended action based at least in part on the physiologic data.

39.   The method of claim 36, 37, or 38, including:

receiving user demographic data into the device;

wherein the applying a rule includes applying the rule to the demographic data to determine the question; and

wherein the presenting a recommended action includes adjusting presentation of the recommended action according to the demographic data.

40.   The method of claim 36, 37, 38, or 39, including:

receiving user lifestyle data into the device;

wherein the applying a rule includes applying the rule to the lifestyle data

5   to determine the question; and

wherein the presenting a recommended action includes displaying a

recommended action based at least in part on the lifestyle data.

41.   The method of claim 36, 37, 38, 39, or 40, including:

10   determining a rate of change of a blood glucose level of the user from the

blood glucose data; and

applying the rule to the rate of change of a blood glucose level to

determine at least one of the question and the recommended action.

15   42.   The method of claim 36, 37, 38, 39, or 40, including receiving the rule

into the device via a device communication port from a second separate device.

43.   The method of claim 36, 37, 38, 39, or 40, including receiving the rule

into the device via the user interface.

20

44.   The method of claim 36, 37, 38, 39, 40, 41, 42, or 43, including:

storing insulin delivery history data of the pump user in the insulin pump

device; and

applying the rule to the blood glucose data and the insulin delivery

25   history data to determine at least one of the question and the recommended

action.

45.   The method of any one of claims 35-44, wherein the presenting a

recommended action includes displaying a recommended change to at least one

30   aspect of user lifestyle.

46.   The method of any one of claims 35-45, wherein the presenting a

recommended action includes presenting a recommendation for troubleshooting

at least one of the insulin pump device, an insulin cartridge, an infusion set, infusion set tubing, an insulin basal rate pattern, and the infusion site.

47.   The method of any one of claims 35-46, wherein the presenting a recommended action includes presenting a recommendation to change at least one of an insulin cartridge, an infusion set, an insulin type, an insulin bolus pattern, and an insulin pump executable program.

48.   The method of any one of claims 35-47, wherein the presenting a recommended action includes presenting a recommendation to initiate a correction bolus from the insulin pump device when the blood glucose level is at risk of being high.

49.   The method of any one of claims 35-48, wherein the presenting a recommended action includes presenting a recommendation to initiate a blood glucose measurement.

50.   The method of any one of claims 35-49, wherein the presenting a recommended action includes presenting a recommendation to perform at least one of a basal rate test, a carbohydrate ratio test, and a correction factor test.

51.   The method of any one of claims 35-50, wherein the presenting a recommended action includes presenting a recommendation to consume carbohydrates when the blood glucose level is at risk of being low.

52.   The method of claim 51, including:
        storing a database of food options in association with a known amount of carbohydrates; and
        wherein presenting a recommendation to consume carbohydrates includes presenting a food option included in the database.

53.   The method of any one of claims 35-52, wherein the presenting a

recommended action includes presenting a recommendation to contact a

physician.

5   54.   The method of any one of claims 35-53, including:

        presenting a question after receiving an indication into the device that the

recommended action was taken; and

        presenting a further recommended action for the user to take based, at

least in part, on the response to the question presented after the indication was

10   received.

55.   The method of any one of claims 35-53, including:

        storing blood glucose history data of the user in the insulin pump device;

and

15   applying the rule to the blood glucose history data and the blood glucose

data received from the blood glucose monitor to determine the recommended

action.

56.   The method of claim 55, including presenting a prompt to the pump user

20   to download blood glucose history data from a separate second device to the

insulin pump device.

57.   The method of any one of claims 35-56, wherein receiving blood glucose

data includes automatically receiving the blood glucose data from a blood

25   glucose monitor included in the insulin pump device.

58.   The method of any one of claims 35-56, wherein receiving blood glucose

data includes:

        obtaining the blood glucose data using a second device separate from the

30   insulin pump device; and

        receiving the blood glucose data into the insulin pump device from the

second device through a communication port.

59.   The method of claim 58, wherein receiving blood glucose data includes wirelessly receiving the blood glucose data into the insulin pump device from the second device through a wireless communication port.

5   60.   The method of claim 58, wherein receiving blood glucose data includes receiving the blood glucose data into the insulin pump device in real time as the blood glucose data is obtained by the second device.

61.   The method of claim 58, wherein receiving blood glucose data includes
10   recurrently displaying a prompt to a user of the insulin pump device to obtain blood glucose data using the second device.

62.   The method of any one of claims 35-56, wherein receiving blood glucose data includes receiving the blood glucose data through a user interface of the
15   insulin pump device configured for manual entry of blood glucose data.

63.   The method of any one of claims 35-62, including activating an audible alarm if it is determined that the blood glucose level of the pump user is different from the target blood glucose level.
20

64.   The method of any one of claims 35-63, including presenting a recommended action for the user to take that is related to maintaining normoglycemia when determining, from the blood glucose data, that the blood glucose level is near the target blood glucose level.
25

65.   An apparatus comprising:
        means for receiving blood glucose data into a device that includes an insulin pump;
        means for presenting a question related to a blood glucose level of an
30   insulin pump user when determining, from the blood glucose data, that the blood glucose level is different from a target blood glucose level;
        means for receiving a response to the question into the insulin pump device; and

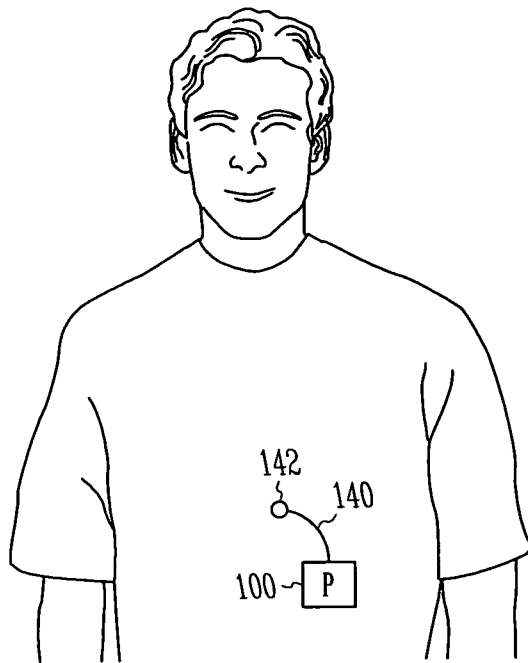means for presenting a recommended action for the user to take based, at least in part, on the response.

5
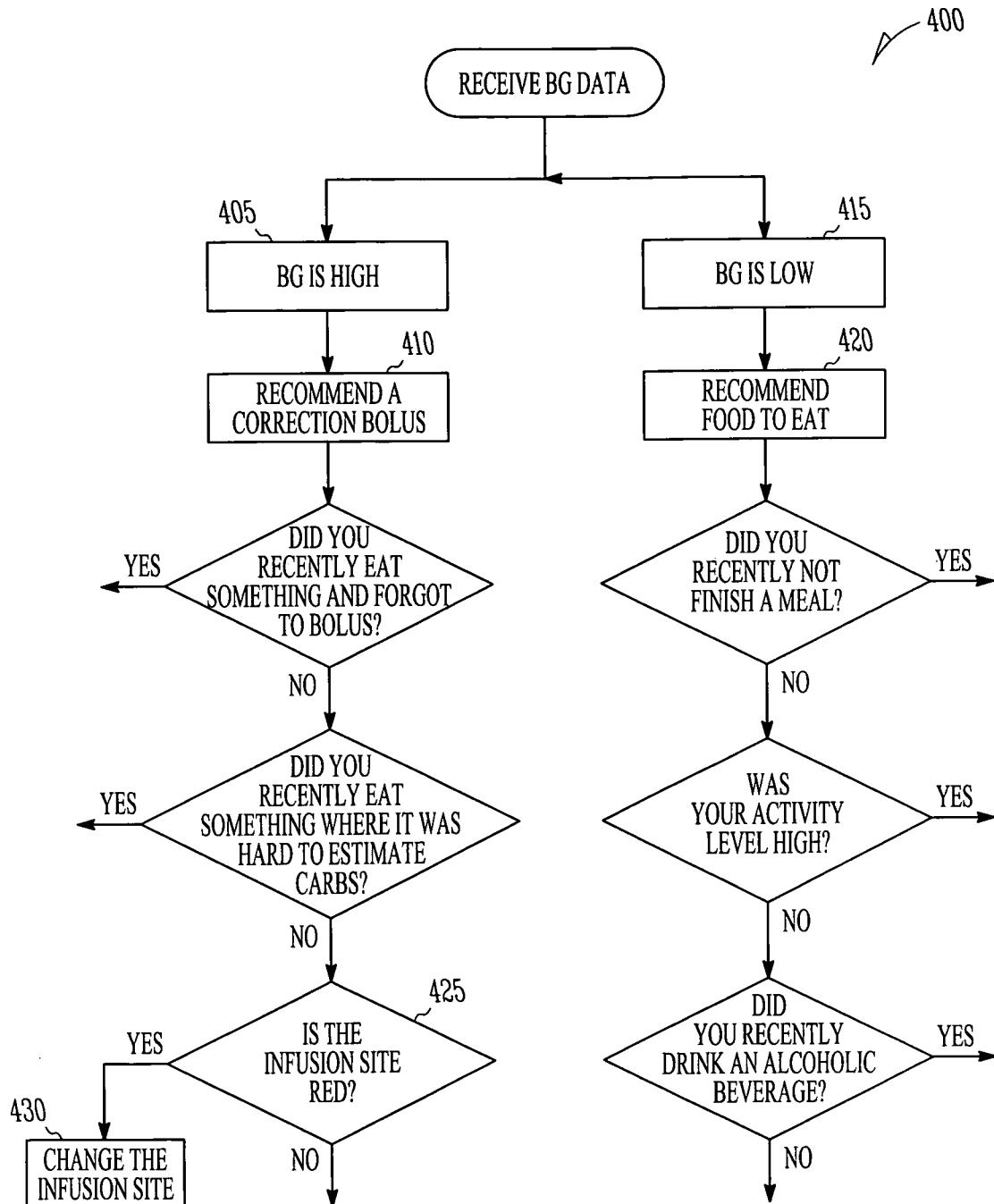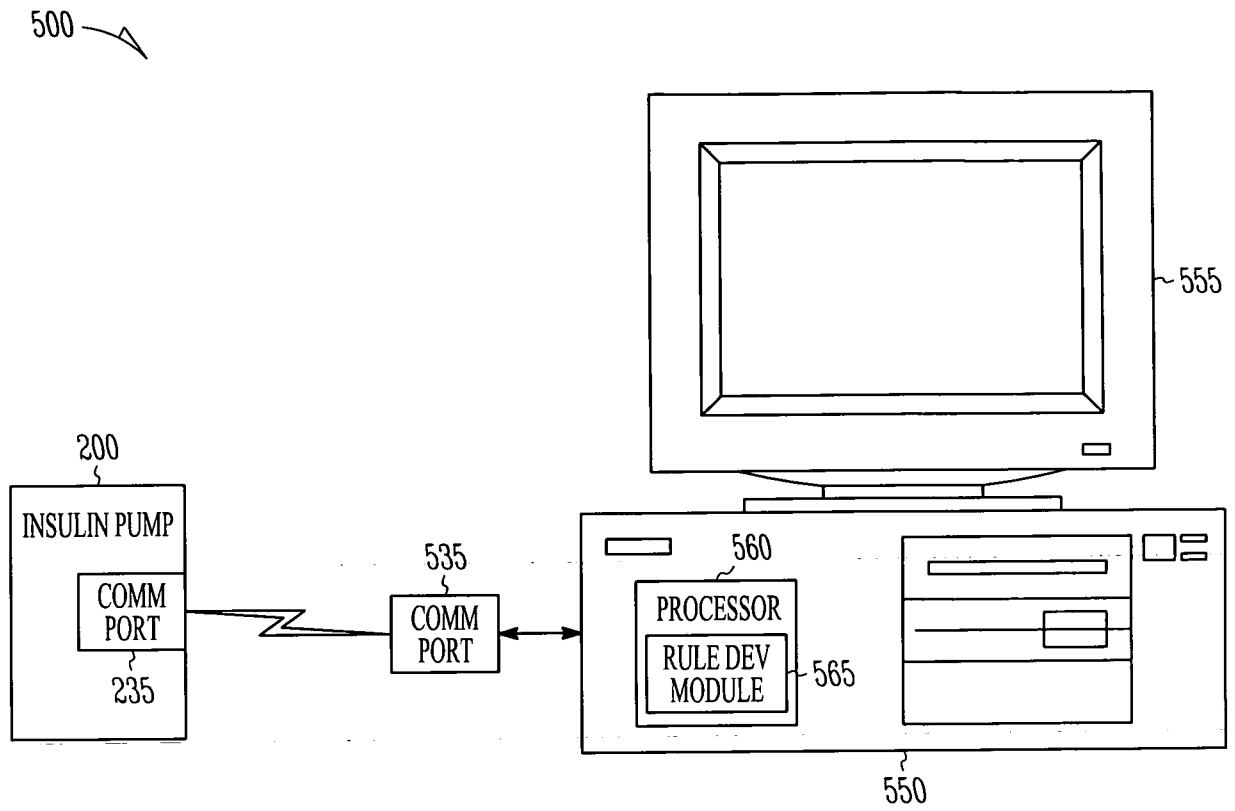
FIG. 1A

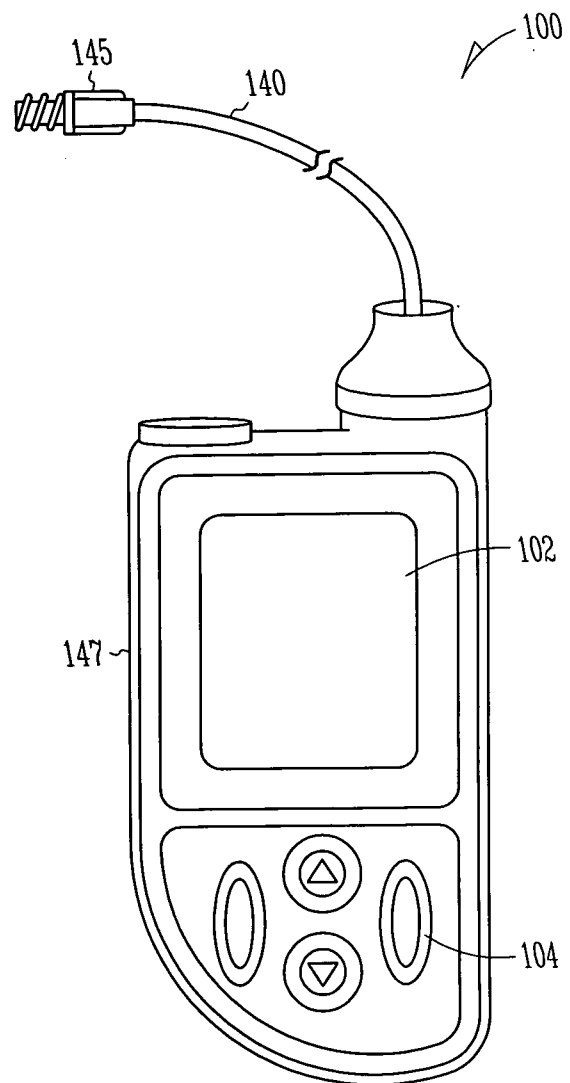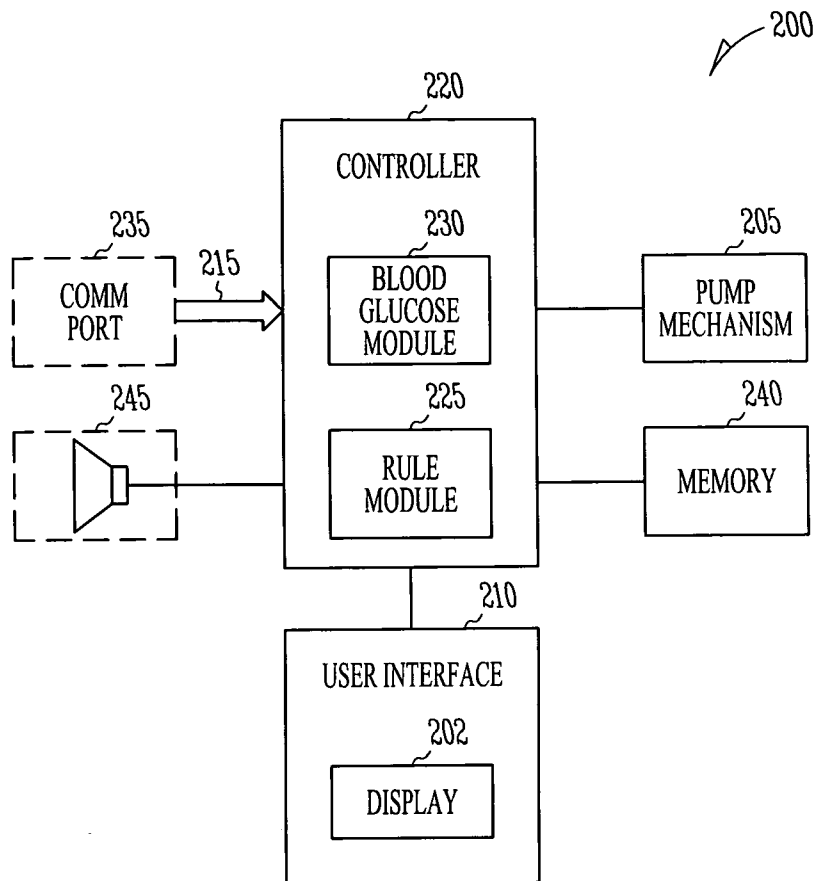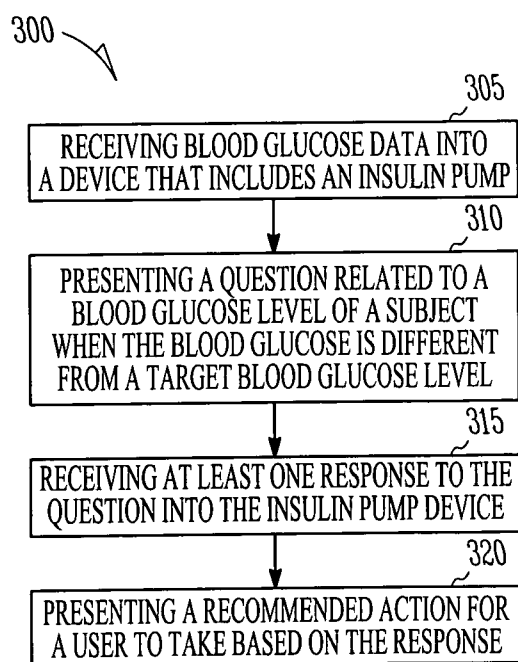

FIG. 1B

FIG. 2

FIG. 3

FIG. 4

FIG. 5

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M   A61B   G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/050621 A1 (LEBEL RONALD J [US] ET AL) 13 March 2003 (2003-03-13)	1,12-30, 65
Y	paragraphs [0037] - [0067]	2-11, 31-34
	paragraphs [0087] - [0089] figure 2	
Y	US 2007/100222 A1 (MASTROTOTARO JOHN J [US] ET AL) 3 May 2007 (2007-05-03)	1,65
A	paragraph [0061] paragraph [0073] paragraphs [0105] - [0107] paragraphs [0165], [0166] figures 1A-2S	2-34
	-/--	

X	Further documents are listed in the continuation of Box C.	X	See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 October 2008	30/10/2008

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

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	pages 3-7 pages 9-10 figures 1,2	12-30
A	US 2003/208113 A1 (MAULT JAMES R [US] ET AL) 6 November 2003 (2003-11-06)	1-11, 23-28, 30,33, 34,65
	paragraphs [0068] - [0096] paragraphs [0108] - [0118] figures 1,2	
A	US 2003/163090 A1 (BLOMQUIST MICHAEL L [US] ET AL BLOMQUIST MICHAEL L [US] ET AL) 28 August 2003 (2003-08-28) paragraph [0120]	12-14
A	US 5 822 715 A (WORTHINGTON DAVID R L [US] ET AL) 13 October 1998 (1998-10-13) column 4, lines 32-48 column 14, lines 27-49	13-18
A	US 2006/047538 A1 (CONDURSO JOSEPH [US] ET AL) 2 March 2006 (2006-03-02) paragraphs [0125] - [0127] paragraph [0138]	13,14
A	WO 2005/046559 A (LIFESCAN INC [US]; VEIT ERIC D [US]; BYLUND ADAM [US]; WEBER BARRY [US]) 26 May 2005 (2005-05-26) the whole document	1,31,65
A	US 2006/080059 A1 (STUPP STEVEN E [US] ET AL STUPP STEVEN ELLIOT [US] ET AL) 13 April 2006 (2006-04-13) the whole document	1,31,65

Box No. II   Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.:   35-64
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by
surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body
by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such
an extent that no meaningful International search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III   Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest   [ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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