(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
14 February 2013 (14.02.2013)

WIPO | PCT

(10) International Publication Number
WO 2013/023014 A1

(51) International Patent Classification: *A61B 5/00* (2006.01)

(21) International Application Number: PCT/US2012/050061

(22) International Filing Date: 9 August 2012 (09.08.2012)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/522,514 11 August 2011 (11.08.2011) US
61/594,557 3 February 2012 (03.02.2012) US

(72) Inventor; and
(71) Applicant : SCHERB, Cliff [US/US]; 287 Silvermine Avenue, Norwalk, CT 06858 (US).

(74) Agents: GORDON, David, P. et al.; Gordon & Jacobson, P.C., 60 Long Ridge Road, Suite 407, Stamford, CT 06902 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published**:
— *with international search report (Art. 21(3))*

(54) **Title**: SYSTEM AND METHOD FOR DETERMINING AN AMOUNT OF INSULIN TO ADMINISTER TO A DIABETIC PATIENT

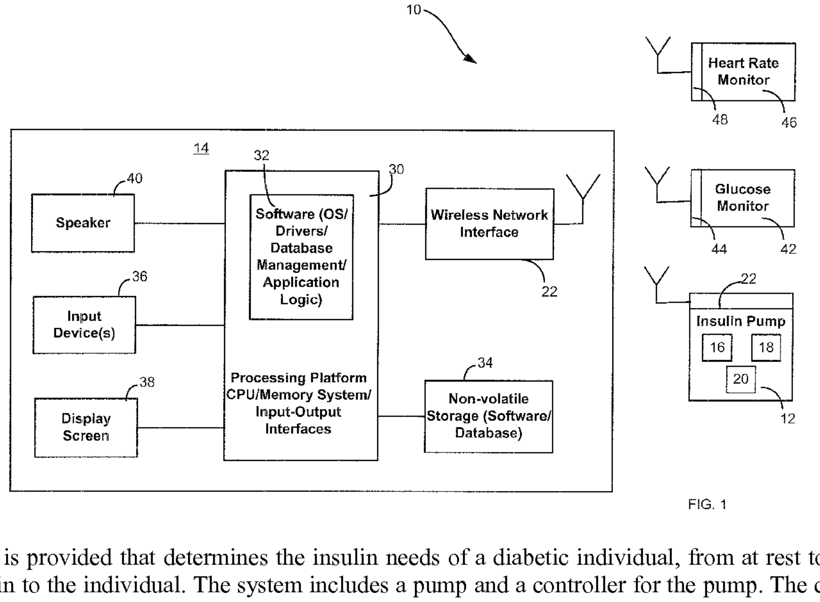



FIG. 1

(57) **Abstract**: A system is provided that determines the insulin needs of a diabetic individual, from at rest to any level of activity, and administers the insulin to the individual. The system includes a pump and a controller for the pump. The controller The controller includes a user interface that allows the user to input user data, including set-up information that personalizes the system to the needs of the user, to establish or select routines for insulin administration based on defined levels of activity, as well as interact with the controller on an ongoing basis to enter data relevant to modifying the routines based upon parameters.

WO 2013/023014 A1

# SYSTEM AND METHOD FOR DETERMINING AN AMOUNT OF INSULIN TO ADMINISTER TO A DIABETIC PATIENT

## BACKGROUND OF THE INVENTION

1. Field Of The Invention

**[0001]** The present invention relates to system and methods for treating diabetics. More particularly, the systems and methods are directed to controlling the amount of insulin administered to a diabetic.

2. State of the Art

**[0002]** The prevalence of diabetes has reached epidemic proportions. Diabetes is a disease in which the pancreas fails to properly function to produce insulin. Insulin allows the body to break down blood sugar. There are three primary types of diabetes: type 1 diabetes, type 2 diabetes, and gestational diabetes. In type 1 diabetes, the body fails to produce insulin. In type 2, the body's cells fail to use insulin properly, sometimes combined with an absolute insulin deficiency. Gestational diabetes is a temporal diabetic condition of high blood glucose levels during pregnancy. Both type 1 and type 2 diabetes are chronic conditions that cannot be cured. All forms of diabetes have been treatable, in some sense, since insulin became available in 1921. While type 2 diabetes may be controlled with medications and diet, treatment with insulin is the only effective treatment for individuals with type 1 diabetes, and is often ultimately required by individuals with type 2 diabetes.

**[0003]** When required, insulin is administered either by injection or by an infusion pump. Such administration balances an adjustable bolus administration of insulin relative to a prescribed basal (base) level that is administered at a steady rate (or maintained over time such as with a type 2 diabetic), with both the basal and bolus levels together attempting to meet ongoing needs to manage blood glucose levels to recommended levels. Management with insulin concentrates on keeping blood sugar levels as close to normal (euglycemia) as possible, without causing hypoglycemia. However, as diabetics attempt to live more active lifestyles, the current methods of calculating insulin administration are ineffective and prone to cause insulin and glucose levels to veer toward outlier levels of what is comfortable and safe for the patient. Patients, often frustrated with low energy and depression resulting from improper insulin levels, often manipulate their basal rates (or basal to bolus insulin ratio) which disrupts the prescribed regimen of their insulin administration. Furthermore, weight gain from lows, depression, and mood swings can be a part of a diabetic's life. Other diabetics may temporarily forgo insulin altogether in order to maintain a blood-sugar balance. In essence, such diabetics are removing insulin at times when they may need it and at other times are putting too much into their system when their body does not need it, resulting in an unhealthy "yo-yo effect".

## SUMMARY OF THE INVENTION

**[0004]** In accord with the invention, a system is provided that provides a novel manner of determining and providing administration of insulin to a diabetic individual. The system and method accommodate the insulin needs of a diabetic individual, from at rest to any level of activity.

**[0005]** The system may include (i) a software program stored and executed in association with a microprocessor, the software program providing for an individual to input data for predetermined parameters and, based upon such input data, the program determining a rate of administration of insulin for the individual, (ii) an insulin pump having a controller which based upon individual input data for the predetermined parameters, activates the pump to meter a determined dosage of rapid release insulin the user; i.e., at a determined relatively steady rate of administration or at bolus amounts, and (iii) an implantable or externally provided artificial pancreas including an insulin pump, a continuous glucose monitor, and a controller which based upon an individual's input data for predetermined parameters and the feedback of blood glucose data from the glucose monitor, activates the pump to meter a determined dosage of rapid release insulin to the user; i.e., at a determined relatively steady rate of administration or at bolus amounts.

**[0006]** Regardless of the type of system, the system is controlled by software instructions used in association with a microprocessor. In addition, in each system, a user interface is provided so that the user can interact with the controller to provide input data and select amongst various presets. More particularly, the user interface allows the user to input user data, including set-up information that personalizes the system to the needs of the user, to establish or select routines for insulin administration based on defined levels of activity, as well as interact with the controller on an ongoing basis to enter data relevant to modifying the routines based upon parameters discussed below.

**[0007]** The controller includes a setup routine in which (1) the daily at rest insulin needs (in units of rapid release insulin) for an individual (a user of the system) is established, (2) the number of grams of carbohydrate consumption that is covered by one unit of insulin for that individual is established, (3) and a total insulin to carbohydrate (I:C) ratio for the individual is calculated. The controller also implements a method in which (4) the daily basal insulin rates for various times over the curse of a day based on a cumulative level of activity over a rolling predetermined period, such as a rolling seven day period, is determined and (5) a bolus insulin need relative to the daily basal insulin need is determined in order to maintain the I:C ratio substantially constant, regardless of the level of individual activity. The controller also implements the method of: (6) determining temporary basal insulin rates correlated to recent levels of activity throughout a recent predetermined period, such as a day, and (7) temporarily adjusting the bolus insulin need in view of the temporary basal insulin need so that the I:C ratio is maintained substantially constant regardless of individual activity.

**[0008]** In accord with one embodiment of the invention, the daily at rest insulin need for a particular diabetic individual to maintain body weight is preferably determined from reference to data obtained from reliable reference material and is commonly based on such factors as age, gender, height, and weight of an individual. Similarly, the number of grams of carbohydrates covered by one unit of rapid release insulin for the individual is also obtained from suitably reliable data from reference materials and used to calculate the I:C ratio. Data for the entire potential user population is preferably stored in non-volatile memory in the controller for access during the set-up routine.

**[0009]** Next, the cumulative number of hours of activity during the prior rolling predetermined period is input at the user interface. Then, the system calculates an adjustment to the total daily basal insulin needs based on the cumulative number of hours of activity during the prior rolling predetermined period; i.e., a rolling daily basal need of insulin. With increased activity over the rolling predetermined period, the rolling daily basal need relative to an at-rest basal need is decreased. Further in accord with one aspect of the invention, the rolling daily basal need is not infused evenly throughout the day. Rather, in view of different insulin needs at different times of a day, e.g., due to early morning increases in blood sugar (“dawn phenomenon”) and hormonal changes throughout the day, the rolling daily basal need is metered to the individual at various rates throughout the day, rather than a constant rate. Together the various rates operate to provide the rolling daily basal need of insulin.

**[0010]** Given that basal rates are decreased with increased activity and that it is desirable to maintain the I:C ratio substantially constant, the percentage of insulin provided by bolus infusion increases as the percentage provided by basal infusion decreases. The bolus infusion, in distinction from the ‘background’ basal levels, is administered anytime carbohydrates are consumed, as well as provide a route to correction for high blood sugars.

**[0011]** In accord with another optional aspect of the system of the invention, modified exercise basal rates are provided based on the activity level of an exercise. The activity level may be determined, e.g., by a predetermined attribution of a level of exertion for a given time of exercise at a given exertion level, by a user-indicated level of exertion for one or more time periods over the course of the exercise, or for a monitored/measured heart rate over the course of the exercise.

**[0012]** In accord with yet another optional aspect of the system of the invention, exercise recovery basal rates are provided post-exercise. Based on the duration and intensity of the exercise, a temporary recovery basal rate is selected by the system. The preferred parameter to determine the recovery basal rate is heart rate, which can be obtained through real-time monitoring, or in the absence of heart rate monitoring, user perceived exertion.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0013]** Fig. 1 is a schematic diagram of an insulin pump system according to the invention.

**[0014]** Fig. 2 is a flow diagram of the set-up procedure for a user at the controller of the system.

**[0015]** Fig. 3 is a chart illustrating information input, calculated, and/or stored at the controller during the set-up procedure.

**[0016]** Fig. 4 is a flow diagram of the calculation by the controller of the adjusted rolling basal rates.

[0017] Fig. 5A is a chart illustrating the relationship of basal and bolus insulin as a percentage of total insulin needs as a user's activity level increases over the rolling period.

[0018] Fig. 5B is exemplar user data indicating the relationship of basal and bolus insulin as a percentage of total insulin needs as a user's activity level increases over the rolling period.

[0019] Fig. 6 is a chart illustrating the relationship of the different rates at which rolling basal insulin is administered at different time ranges over a day depending on user's activity level over the rolling period.

[0020] Fig. 7 is a flow diagram illustrating how the bolus needs are calculated and tracked by the controller.

[0021] Fig. 8 is a flow diagram illustrating how post-exercise recovery basal rates are calculated.

[0022] Fig. 9 is a chart of data for an exemplar user for any activity between inactivity through 24 hours activity in a rolling period, including adjusted rolling basal rates for time ranges throughout a day as well as various other data.

[0023] Figs. 10 – 14 provide data in chart form for adjusted basal rates for an exemplar user undertaking an exercise training schedule, in which Fig. 10 provides initial rolling basal rates, Fig. 11 provides recommended carbohydrate intake, Fig. 12 indicates the grams of carbohydrate to consume at different times during an exercise routine, Fig. 13 sets out post-exercise recovery basal rates, and Fig. 14 provides an updated set of rolling basal rates which is updated based on the current level of activity in the rolling period.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0024] For the following description, the term 'database' means one or more structured sets of persistent data associated with software to update and/or query the persistent data.

[0025] Turning now to Fig. 1, a schematic representation of an insulin pump system 10 in accord with the invention is shown. The system 10 includes a pump 12 and a controller 14 for the pump.

**[0026]** The pump 12 includes a user-fillable reservoir 16 to store insulin, an infusion pump 18 to meter the stored insulin to the user, a subcutaneous interface 20, such as a connector for a cannula and tubing set, to transfer the metered insulin to the user, and a communication interface 22 for communicating with the controller 14. The communication interface 22 is preferably wireless, but may be wired. Alternatively, the pump 12 and controller 14 may integrated as a single unit.

**[0027]** The controller 14 includes a processing platform 30 having a central processing unit (CPU), a memory system, and input/output interfaces. In addition, the processing platform 30 is provided with software 32, including database management logic and application logic. The processing platform 30 is coupled to non-volatile storage 34, which contains the software 32 and one or more databases. When the controller 14 is operational, the software 32 is loaded from non-volatile storage 34 to the processing platform 30 for execution on the processing platform 30. When executed on the processing platform 30, the application logic and database management logic of the software 32 cooperate to access the one or more databases stored in the non-volatile storage 34 in order to carry out the control methodologies described herein in detail.

**[0028]** In addition, the controller 14 includes input devices 36 such as buttons, scroll wheel, knobs, keypad, microphone, and/or any other device suitable for data input to the controller 14. The controller 14 also includes a display screen 38 and optionally a speaker 40 to provide visual as well as audio information to the user. Other output devices to present information to the user may be provided as well. A communication interface 42 is provided for communication with the pump. The interface 42 is preferably a wireless network interface, but may be a wired network interface. The system is preferably provided with the appropriate interface(s) to allow firmware and/or database updates.

**[0029]** The system 10 may optionally include a glucose monitor 42 to provide a measure of the glucose level of the patient on an automatic periodic basis (e.g., every minute or every five minutes) so as to be considered continuous monitoring. The glucose monitor includes a network interface 44 that preferably wirelessly communicates the measured glucose levels to the controller 14. The glucose monitor 42 preferably measures either the glucose level of interstitial fluid (which can be calibrated to indicate approximate blood glucose levels) or more preferably actual blood glucose levels.

**[0030]** In addition, the system 10 may include additional input devices to monitor other pertinent physiological parameters. By way of example, the system may include a heart rate monitor 46 with a network interface 48 that preferably wirelessly communicates measured heart rate to the controller 14. As discussed below, the measured or input heart rate of a user can be used to modify insulin rates for the user. By way of another example, the system may similarly include a pedometer that communicates its activity to the controller 14. As discussed below, such activity monitors can be used to modify insulin rates for the user.

**[0031]** With the system 10 having been briefly set forth, the method of the system is now described with respect to various exemplar users. It is appreciated that the system and method will similarly operate with other users that personalize the system with different 'set-up' information during a hereinafter described set-up routine and that undertake different levels of activity which, as described below, affects the insulin needs of the user.

**[0032]** Initially a set-up routine is performed at the controller 14 to personalize the system 10 for the particular user of the system. The set-up routine allows the controller 14 to determine or select a set of baseline basal insulin rates for the user from a set of basal rates in a database in the memory storage 34. The set-up routine includes determining (1) the daily 'at rest' insulin needs (in units of rapid release insulin) for the user 102, (2) the number of grams of carbohydrate consumption that is covered by one unit of rapid release insulin for the user at 106, and (3) a total desirable insulin to carbohydrate (I:C) ratio for the user at 110. In addition, as discussed in more detail below with reference to Fig. 4, an additional part of the set-up includes establishing an initial cumulative activity level for the user over a predetermined rolling period and establishing a corresponding rolling period basal need and corresponding daily basal rates.

**[0033]** With reference to Fig. 2, the daily 'at rest' insulin needs for a particular diabetic individual (by 'needs', it is meant 'to maintain body weight') is preferably established at 102 from reference to data obtained from reliable reference material and is commonly based on such factors as age, gender, height, and weight of an individual, as indicated at 104. For example, a tool to determine daily 'at rest' insulin needs is available from diabetesnet.com at www.diabetesnet.com/diabetes_tools/tools_tdd.php and such tool uses suitable reference data. The memory storage 34 preferably includes databases that similarly relate such factors or others to a daily 'at rest' insulin need. The numbers or entries corresponding to the factors (e.g., weight in kilograms, age, height) as well as selection of other factors from a defined list (male, female) can be input at input device 36 and displayed on screen 38 (Fig. 1). Referring to a data example shown in Fig. 3, based upon the values of a plurality of such factors or other factors, a daily 'at rest' insulin need (e.g., 40.8 units), shown at 120, is determined for a user, and from the total insulin need, the total 'at rest' basal insulin needs (e.g., 23.3 units—not shown) as well as an average 'at rest' basal rate (e.g., 0.97 units/hour) shown at 122 are read, calculated or otherwise determined from data in the corresponding database. In addition, the number of grams of carbohydrates covered by one unit of rapid release insulin for the user is obtained at 124 based on the 'set-up' factors from the corresponding database at 108 in Fig. 2. The number of grams of carbohydrates covered by one unit of rapid release insulin is used to calculate an insulin to carbohydrate (I:C) ratio. By way of the example shown in Fig. 3, if the number of grams of carbohydrates covered by one (1) unit of rapid insulin for the user are determined to be 22 grams, then the I:C ratio is 1/22 or 0.052 as shown at 126. Data for the entire potential user population of the system is preferably stored in databases in the non-volatile memory 34 in the controller for access during the set-up routine. Alternatively, equations may be established, e.g., as derived by polynomial curve-fit equations, that closely match the data relationship, with such equations stored in the controller and accessed to output the above-identified set-up parameters based on the input of the user data into the equations. In addition, referring to 128a, 128b, 128c, the total number of grams of carbohydrates that the user should consume daily to maintain body weight can be calculated based on a plurality of the same set-up factors used to determine the daily 'at rest' insulin needs. For example, the well-known Mifflin Equation determines an individual's daily energy requirements in calories based on age, height and weight, and can be further related to carbohydrate requirements. Further, experiential data is available setting forth the daily recommended caloric and carbohydrate intake for individuals based on the same or similar factors.

**[0034]** Turning now to Fig. 4, also during the initial set-up, the user inputs at 130 the cumulative number of hours of activity the user has undertaken during a current rolling period of predetermined length. The preferred rolling period is a 7-day period or week. Using the preferred rolling 7-day period, the user inputs the cumulative number of hours of activity (i.e., exercise) undertaken during the current 7-day period. In a preferred operation of the system, the user inputs an exact number of hours of activity, preferably ranging from 0 to 24 over the rolling period. In addition, for users of limited activity throughout the rolling period; i.e., that do not actively exercise, additional 'low activity' activity settings may be input or selected. For example, there are provided three available activity settings over the rolling period for individuals that are not particularly active but not on complete bed rest. A first low-level activity setting is designated AA and corresponds to bed rest at a basal metabolic rate. A second low-level activity setting is designated AB and corresponds to substantially complete rest with no more that 10 minutes of total movement a day. A third low-level activity setting is designated AC and corresponds to a resting state more active than AB but of no more than 30 minutes of daily movement. Then, the '0' hour of activity corresponds to more movement than AC but preferably no more than 90 minutes of daily movement, but not necessarily movement considered exercise. Fig. 5A is a chart illustrating the manner in which the basal need decreases as a proportion of overall daily insulin need, and that consequently the bolus insulin administration need as a percentage of the total insulin need increases, as a user's activity level over the rolling period increases. The percentage changes must be considered in the context that total insulin needs decrease as activity increases. Fig. 5B provides data for an exemplar user having total daily 'at rest' insulin needs of 31.1 units and an I:C ratio of 0.052. The relationship of the basal to bolus insulin needs corresponds to the relationship shown in Fig. 5A. It is recognized that fewer or additional low-level activity settings may be provided, or the controller may permit input of activity in minutes or other portion of an hour over the rolling period where the user is not active for at least one hour. Alternatively, the controller may be programmed to provide the option for the user to select from preferably continuous bracketed ranges of hours of activity, by way of example only: 0-3 hours, 3-5 hours, 5-8 hours, 8-12 hours, 12-15 hours, 15-18 hours, 18-21 hours, 21-24 hours, 24+ hours, all in the current rolling period. A fewer or greater number of brackets can be provided.

**[0035]** Regardless of how the cumulative hours of activity over the rolling period are input into the controller, based on the cumulative hours of activity during the current rolling period, the system determines an adjustment relative to the daily total 'at rest' basal insulin need (from step 120) and the average 'at rest' basal rate (from step 122) to determine a rolling daily basal insulin need at 132 and an average rolling daily basal insulin rate at 134. That is, referring again to the chart of Fig. 5A, it has been determined with increased activity over the rolling period, the rolling daily basal insulin need relative to an 'at rest' basal insulin need is decreased. The identification of the rolling daily basal insulin need is preferably determined by an adjustment relative to the daily total 'at rest' basal insulin need and more particularly is preferably determined from reference to data contained in databases in the memory 34. The data contained in the databases is preferably derived from experiential data of a sufficiently large diabetic population to render the respective adjustments valid for any user of the system. Alternatively, rather than reference data in databases, the adjustment may be calculated based on an established relationship or equation that preferably corresponds to the adjustment seen in experiential data. Such equations may be derived, e.g., by polynomial curve-fit equations, that closely match the data relationship, with such equations stored in the controller. In such case, the processing platform 30 carries out the calculation(s) necessary to effect the adjustment to determine the rolling daily basal insulin need. Once the rolling daily basal insulin need is determined (as a percentage of the total insulin need), the average rolling basal insulin rate per hour is optionally calculated at 134 as the rolling basal insulin need divided by 24 hours.

**[0036]** Further, in accord with another aspect of the invention, the rolling daily basal insulin need is preferably not infused evenly throughout the day; i.e., preferably not infused at the average rolling basal insulin rate calculated at 134. Rather, in view of different insulin needs at different times of a day, e.g., due to early morning increases in blood sugar ('dawn phenomenon') and hormonal changes throughout the day, the rolling daily basal insulin need is metered to the user at various rates throughout the day which depend on the time of day. 'Time of day' adjustment factors correlated with the user's level of activity are recalled at 136 from the database in memory 34. Together the adjustment factors operate to ensure that the rolling daily basal insulin need is metered in an optimum manner. In accord with a preferred manner of metering the basal insulin needs, each day is subdivided into a plurality, and preferably four, multi-hour ranges each having associated therewith a 'time of day' adjustment factor. Fig. 6 illustrates that the adjustment factors are preferred percentage decreases during each range relative to the average 'at rest' basal rate (as indicated at 122) for the various activity levels over the rolling period. (It is noted that in Fig. 6, the prefix 'B' corresponds to the prefix 'A' in Fig. 5A.)

**[0037]** In one exemplar day divided into four ranges, range 1 corresponds to 'sleep', range 2 corresponds to 'waking time and dawn phenomenon', range 3 corresponds 'daytime active hours', and range 4 corresponds to 'early evening hours'. It is appreciated that a different number of ranges could be used (fewer or more), and that the times of day during which each range starts can be specifically tailored to the user's daily habits (waking time, active hours, sleep time, etc.).

**[0038]** By way of further example, it is assumed that a user has an activity of 10 hours over the current rolling period. Each range is provided its own respective rolling basal insulin rate to accommodate the insulin needs generally required by the human body during that time of day. As such, for a rolling basal insulin need of 10.68 units per day (and a resulting average rolling basal rate of 0.445 units per hour), the first range has an adjustment factor of 0.60 which is multiplied by the 'at rest' basal rate of 0.97 units/hour to result in a Range 1 basal rate of 0.58 units/hour from 5:00 am – 8:59 am, the second range has an adjustment factor of 0.51 which is multiplied by the 'at rest' basal rate of 0.97 units/hour to result in a Range 2 rate of 0.39 units/hour from 9:00 am – 6:59 pm, the third range has an adjustment factor of 0.40 which is multiplied by the 'at rest' basal rate of 0.97 units/hour to result in a Range 3 rate of 0.40 units/hour from 7:00 pm – 11:59 pm, and the fourth range has an adjustment factor or 0.41 which is multiplied by the 'at rest' basal rate of 0.97 units/hour to result in a Range 4 rate of 0.50 units/hour from 12:00 am – 4:50 am. These adjusted rolling basal rates provides the basal insulin need of 10.68 units in an optimal manner for the level of activity of the user. Fig. 9 provides complete data for an exemplar user for any activity between inactive through 24 hours activity in a rolling period, including adjusted rolling basal rates for ranges throughout a day, as well as various other data.

**[0039]** It is appreciated that once the adjusted rolling basal rates for a day are initially established during set-up, such rates will be modified automatically based on the amount of activity during the rolling period. The amount of activity throughout a day is preferably recorded at 138. The amount of activity throughout a day can be recorded, by way of examples only, (i) at the end of each day by manual user input to the controller, (ii) more preferably by manual user input to the controller throughout each day, e.g., at the conclusion of each and every activity, and/or (iii) even more preferably automatically via controller interface with, e.g., a heart rate monitor 46, pedometer, etc. Options (ii) and (iii) are more preferred as they permit the timing of post-exercise recovery schedules relative to the activity performed. Upon receiving the updated activity, the controller automatically updates the current amount of activity in the current rolling period at 140, and subsequently updates the rolling daily basal need at 132, the average rolling basal rate at 134, and the adjusted rolling basal rates for different times of day at 136. Alternatively, the rolling daily basal need, rolling average basal rate, and rolling basal rates for different times of day are updated at defined intervals (e.g., at one or more preset times during the day), for example, daily at 12:00 am or four times daily at the times of day when the ranges transition for the basal rates, based on the now current amount of activity in the predetermined rolling period.

**[0040]** In a special situation when the user stops exercising during a rolling period, the rolling period basal rate is decreased by one basal rate level for every two hours that pass since the previous exercise. That is, referring to Fig. 5A, if the user had a cumulative activity level corresponding to A14 (that is, 14 hours over the prior 7 days) and then exercises for one hour, the activity level will increase to A15, representing the prior 14 hours of cumulative activity in addition to the one most recent hour of exercise. When the workout is complete, a temporary recovery basal rate will be applied, as discussed in detail below, based on the perceived exertion or heart rate, and applied for a predetermined number of hours. Then there will also be a calculation for the rolling seven day basal recovery rate post-workout, as also discussed in detail below. This rate also uses the end of the most recent workout as its timed starting point. For each subsequent two hours of time that passes post-workout the basal rate will drop by one basal rate level; that is, two hours post-activity the basal rate will drop from A15 to A14, and again two hours later from A14 to A13. This is in contrast to moving up basal rates by only one basal rate per hour of increased cumulative activity on a rolling seven day basis.

**[0041]** With the average rolling basal insulin need for any day determined at 132, the bolus insulin need for that day is next established. As discussed above, under the methodology disclosed herein, it is preferable to maintain the I:C ratio substantially constant; i.e., within ±10% of the initially calculated ratio. Given that the I:C ratio for the user is stored at the controller 14 during set-up, and the basal portion of the daily insulin need is established from the rolling daily basal insulin needs, the bolus insulin need for the day is established at 150 from its relationship relative to the rolling daily basal insulin need shown in Fig. 5A. It is preferred to maintain a determined relationship between the basal insulin need and the bolus insulin need (in relative percent of the total insulin need), which depends on the amount of activity within the rolling period.

**[0042]** Turning to Fig. 7, once the bolus insulin needs for a day are calculated, the bolus insulin is administered throughout the day, preferably whenever carbohydrates are consumed. In order to administer an appropriate amount of bolus insulin and to track the bolus insulin used each day, when the user is to consume carbohydrates, the user preferably enters one or both of (i) the carbohydrates at each meal or snack time at 152, and (ii) the number of units which the user intends to bolus at 154. If the number of grams of carbohydrates is entered, the controller includes the necessary tools to calculate for the user at 156 (given the user's I:C ratio) the units of insulin to bolus for the number of grams of carbohydrates entered. It is appreciated that the controller may additionally be provided with a food conversion system that allows the user to input various food menu options (either from generic type food selections such as "1 slice whole wheat bread" or brand-specific food selections such as a medium order french fries from a specific fast food chain). From the input menu option, the system can immediately display to the user the grams of carbohydrates contained therein, or tally and output the total amount of carbohydrates for several selected items. Databases can be provided within the controller containing the required information. In addition, the databases may be upgradeable by the user (e.g., via a USB or other data cable or a wireless connection connecting the controller to a computer and/or dedicated web site) to allow the controller to have a relatively current list of commercially available foods, specialty foods, ethnic foods, foods specific to a dieting program, foods specific to athletic training, etc. Once the number of grams of carbohydrates is determined, a recommended corresponding number of units of insulin to bolus is output. This recommended number of units to bolus can then be accepted at 158 or overridden at 160 by the user. If the number of units is overridden by the user, a warning may be displayed to the user (and optionally an audible warning tone) which the user can subsequently override. If the user does not accept or override, the controller enters a ready state at 162 to again track carbohydrate consumption or bolus administration without any updates to the calculated remaining bolus insulin for the day.

**[0043]** Alternatively, a user can mentally convert food to be consumed to grams of carbohydrates to units of insulin to bolus, and be provided the option to directly enter the number of units to bolus at 154. If the user directly enters a number of units of insulin to bolus, the system will calculate at 158 whether the number of units is acceptable within the calculated daily limits. If the number is calculated to be outside the daily limits, the system may display a warning to the user (and optionally an audible warning tone) which the user can override at 160.

**[0044]** In either case, once the user enters or accepts the number of units of insulin to bolus and the controller instructs the pump to administer the bolus, at 164 the controller deducts the units of insulin administered as bolus from the total units to bolus for the day and tracks the remaining units of insulin to bolus for the day. The process repeats each time the user consumes carbohydrates throughout the day, with the units of insulin to bolus deducted from the previously remaining units to bolus, and the remaining units of insulin to bolus is updated, preferably for display to the user. Once the maximum recommended grams of carbohydrates have been consumed; i.e., with the remaining insulin units to bolus at calculated at zero or below, the controller may present the user with an alert.

**[0045]** In accord with another optional aspect of the system of the invention, modified exercise basal rates are provided based on the activity level of an exercise. The activity level may be determined at 170, e.g., by a user-indicated level of exertion for one or more time periods over the course of the exercise, or more accurately and therefore preferably from a monitored heart rate over the course of or intermittently during the exercise. Therefore, it is advantageous for a user to use the heart rate monitor 46 to monitor the user's heart rate, and transmit heart rate measurements back to the controller 14 (Fig. 1). From the heart rate monitor 46 or optionally user feedback of the user's exertion level, the controller determines the heart rate zone for the user's activity, and the time at the respective heart rate zone.

**[0046]** The heart rate zones represent user effort and can be used to predict a post-exercise change in user blood sugars. In accord with standard convention, there are preferably five identifiable heart rate zones, each associated with a different amount of physiological exercise stimulus. However, additional zones may be recognized or implemented, or the level of activity may be measured on a continuum rather than at discrete zones. Using zones, it is preferable that the controller modify the basal and bolus rates post-activity, dependent on the heart rate zone of the activity. The controller 14 can be operated to select a 'zone training' mode which modifies the basal and bolus rates based on the measured or input heart rates at 170 (Fig. 8).

[0047] Zone 1 is preferably set at not exceeding 85 % of the lactate threshold heart rate and generally corresponds to very low level of exercise, such as an easy walk or hike. For user feedback, Zone 1 may be scored as a perceived exertion (PE) of between 1 – 3 on a scale of 1 - 10. It has been determined that insulin sensitivity is 2.0 – 3.5 times greater than at non-activity during this level of activity. Further, the post-exercise basal insulin rate is reduced by 30% - 70% (i.e., is set at 70% - 30% of the rolling basal rate) during the post-activity insulin sensitivity period.

[0048] Zone 2 is preferably set at 85 – 89 % of the lactate threshold heart rate and generally corresponds to a base level of training and for an endurance athlete, Zone 2 is where most training is performed. For user feedback, Zone 2 may be scored as a perceived exertion (PE) of between 4 – 5 on a scale of 1 - 10. Zone 2 has an insulin sensitivity similar to Zone 1. Thus, the insulin sensitivity is 2.0 – 3.5 times greater than at non-activity for Zone 2 activity. Further, the post-exercise basal insulin rate is reduced by 30% - 70% (i.e., is set at 70% - 30% of the rolling basal rate) during the post-activity insulin sensitivity period.

[0049] Zone 3 is preferably set at 90 – 94 % of the lactate threshold heart rate and generally corresponds to a level of training causing labored breathing. For user feedback, Zone 3 may be scored as a perceived exertion (PE) of between 6 – 7 on a scale of 1 - 10. It has been determined that post-activity insulin sensitivity will occur for 2.5 – 4.5 times the duration of the activity. Further, the post-exercise insulin basal rate is reduced by 60% - 85% (i.e., is set at 40% - 15% of the rolling basal rate) during the post-activity insulin sensitivity period.

[0050] Zone 4 is preferably set at 95 – 99 % of the lactate threshold heart rate (just below the lactate threshold). Like Zone 3, Zone 4 has a post-activity insulin sensitivity occurring for 2.5 – 4.5 times the duration of the activity. Also, the post-exercise insulin basal rate is reduced by 60% - 85% (i.e., is set at 40% - 15% of the rolling basal rate) during the post-activity insulin sensitivity period.

[0051] Zone 5 is preferably set at 100 – 106 % of the lactate threshold heart rate. For user feedback, Zone 5 may be scored as a perceived exertion (PE) of between 7 – 8.5 on a scale of 1 - 10. It has been determined that post-activity insulin sensitivity is 3.0 – 8.0 times the duration of the activity. Further, the post-exercise insulin basal rate is reduced by 75% - 90% (i.e., is set at 25% - 10% of the rolling basal rate) during the post-activity insulin sensitivity period.

**[0052]** Alternatively, Zones 1-5 (or a set of zones corresponding to the range thereof) may be established from metabolic heart testing, in which the user performs a test which determines the metabolic efficiency of each individual and determines their ability to burn fat versus carbohydrates which will determine heart rate training zones. As yet another alternative, other systems for determining the appropriate zone in which an individual is training may be used.

**[0053]** It is recognized that the above description describes Zones 1 and 2 as having similar durations of post-exercise insulin sensitivity and basal rate reductions, and that Zones 3 and 4 likewise have similar durations of post-exercise insulin sensitivity and the magnitude of the sensitivity. Such zone are further differentiated from each other based on the activity performed (e.g., swimming, bicycling, running), the size of the muscles used, and the numbers of muscles and muscle groups used. Activities that use larger muscles and more muscles will have greater durations of post-exercise insulin sensitivity and greater insulin sensitivity.

**[0054]** As discussed above and now with reference to Fig. 8, each heart rate zone or activity level at 170 has associated therewith a determined increased insulin sensitivity at 172 as well as a post-activity duration for the insulin sensitivity at 174. The higher the heart rate zone, the greater the insulin sensitivity as well as the longer the duration of the post-activity insulin sensitivity. A recovery basal rate is preferably implemented at 176 over the duration of the insulin sensitivity calculated as the rolling basal rate multiplied by a recovery multiplier that decreases the basal insulin to adjust for the increased insulin sensitivity, and administered to the user at 178. By way of example, if a user has a rolling basal rate of 0.46 units per hour, and the user undertakes a run for 0.5 hours with a measured or feedback heart rate in Zone 2 for a majority of the run that provides a recovery multiplier of 0.70,

**[0055]** the recovery basal rate = rolling basal rate x recovery multiplier

= 0.46 x 0.70 = 0.32 units per hour.

**[0056]** The duration of the recovery basal rate in Zone 2 can be set at three times the duration of the activity. As such, the 0.32 units per hour will be applied for 1.5 hours.

**[0057]** If a workout includes several activities carried out in different zones and for different times, an average recovery basal rate can be applied for the total time of the workout. By way of example, if a user has a rolling basal rate of 0.46 units per hour, and the user undertakes a 1.5 run, in which 0.5 hours was in Zone 2, 0.5 hours was in Zone 3, and 0.5 hours was in Zone 5, one manner of calculating the recovery basal rate is:

**[0058]** the recovery basal rate = 1/3 (rolling basal rate x recovery multiplier Zone 2) + 1/3 (rolling basal rate x recovery multiplier Zone 3) + 1/3 (rolling basal rate x recovery multiplier Zone 5); ie.,

**[0059]** = 1/3 (0.46 x 0.70) + 1/3 (0.46 x 0.30) + 1/3 (0.46 x 0.15)

= 0.32 units per hour.

**[0060]** The recovery basal rate is preferably applied for the longest applicable duration to any of the heart rate zones. That is, if a portion of the exercise occurs within Zone 5, and the recovery basal rate for Zone 5 is three times the duration of the exercise, then the entire recovery basal rate is applied for three times the duration of the entire exercise within all zones. Alternatively, the recovery basal rate can be applied in a weighted manner with additional weight applied to the exercise in zones of increased heart rate activity. As such, higher heart rate zone activity will have greater effect on the recovery basal rate.

**[0061]** In addition, if a user undertakes several workouts at different times during a day, the recovery basal rate for the earlier workout may affect the recovery basal rate of the later workout. By way of example, if the recovery rate for the earlier workout has expired then it will not affect the recovery rate for the later workout. However, if the recovery rate for the earlier workout is still active at the conclusion of the later workout, then the controller is programmed to (i) select the lower of the recovery rate of the earlier and later recovery rates, and (ii) use the selected recovery rate for a time equaling the sum the remaining time for the earlier recovery rate and the time for the later recovery rate. This has been shown to be an easy way to calculate the effective recovery rate and time for multiple workouts in a day. However, it is recognized that other systems (using different rates and/or recovery times) can be used.

**[0062]** An example relative to the above recovery basal system is now illustrated as follows. A user has been preparing for a half marathon. For the past rolling 7 days the user has exercised 8.5 hours. The user has entered these training hours into his controller and when the user exercises the user also uses a heart rate monitor which collects the user's efforts.

**[0063]** For a daily exercise the user plans a 1.5 hour run that consists of a run including each of easy, moderate, and full effort portions. The user's insulin and inputs and outputs would be calculated as follows:

**[0064]** Current rolling 7 day average of workout hours = 8.5

**[0065]** Current basal rate is .51 units/hour.

**[0066]** Prior to the workout and based on 8.5 hours of exercise, the controller would be running the correct rolling 7 day basal rate from the table in Fig. 10, with the appropriate recommended daily carbohydrate intake from the table in Fig. 11.

**[0067]** Five to ten minutes before the user's run, the user will bolus at 50% of the suggested insulin for 44 grams of carbohydrate in a medium to high glycemic form of carbohydrate. This information is entered into the controller. The user will also simultaneously turn the basal rate insulin OFF for the duration of the activity. The user's bolus before the workout = .05248 (units/grams) x 44 grams = 2.3 units.

**[0068]** After one hour of activity, the user will need to consume carbohydrates to maintain blood sugar based on the user's insulin on board. The amount to consume is calculated from the table in Fig. 12: 75 percent of the 44 grams originally consumed, or 33 grams.

**[0069]** After the user finishes the workout and based on the user's exercise activity recorded from a heart rate monitor, the heart rate has a distribution of 30 minutes Heart Rate Zone 2, 30 minutes in Zone 3, and 30 minutes in Zone 4. The controller multiplies a weighted distribution of these zones to administer basal insulin at a recovery basal rate.

**[0070]** According to a defined schedule shown in Fig. 13 and a weighted distribution based on the time at various heart rate zones, a recovery basal rate is calculated. In this case the recovery basal rate equals [((.44u x 70%) x 1/3))+((.44u x 30%) x 1/3)) + ((.44u x 15%) x 1/3)) = 0.176 units/hour.

**[0071]** In this example, recovery basal hours (i.e., the time at which the recovery basal rates are to be applied) are similarly weighted. Recovery basal hours are determined by [(.5hr at Z2) + (.5hr at Z3) + (.5hr at Z4)] = [(1.5 x 1/3) + (2.3 x 1/3) + (2.5 x 1/3)] = 6.3 hours to apply the recovery basal rate of 0.176 units/hour. Thus, based on the calculations, the system will apply a recovery basal rate of 0.176 units/hour for a total of 6.3 hours. Alternatively, the recovery basal rate can be applied for the longest duration indicated by any of the zones.

**[0072]** During this recovery basal rate any recovery meals are bolused at the predetermined Insulin to Carbohydrate (I:C) Ratio. The user's recovery meal bolus one hour post exercise is calculated as .0524 units/gram x 90 grams = 4.71 units.

**[0073]** After the recovery basal rate has been applied for the determined time, the system will apply the current rolling seven day basal rate of 0.44 units/hour. From the chart in Fig. 14, this corresponds to a basal rate based on 10 hours of cumulative weekly exercise.

**[0074]** For each hour after the conclusion application of the recovery basal rate, the basal rate level will drop by one basal level for every two hours. Assuming the user will not exercise again, the user would reach B0 after 20 hours of inactivity. The system automatically accommodates the change in basal level and basal rates.

**[0075]** There have been described and illustrated herein embodiments of a system and method for administering insulin to a diabetic individual as well as determining dosages of insulin to be administered. While particular embodiments of the invention have been described, it is not intended that the invention be limited thereto, as it is intended that the invention be as broad in scope as the art will allow and that the specification be read likewise. Thus, while particular systems have been disclosed implementing the system and method disclosed herein, it will be appreciated that the method ma be implemented in association with a different system. For example, the system may comprise a manually operated system that provides infusion rates from parameter data in look-up tables, such infusion rates correlated to a level of activity of a patient. It will therefore be appreciated by those skilled in the art that yet other modifications could be made to the provided invention without deviating from its spirit and scope as claimed.

WHAT IS CLAIMED IS:

1. A system for determining insulin needs of a diabetic user, from at rest to any level of user activity, comprising:

an insulin pump controller having a user interface that allows the user to input user data, the controller including software (i) for establishing baseline total insulin needs for the user, (ii) for determining basal insulin needs and basal insulin rates based on levels of user activity over a rolling period, and (iii) for determining bolus insulin needs relative to the basal insulin needs.

2. The system according to claim 1, further comprising:

a pump interfacing with the controller, the pump receiving instructions from the controller for the administration of a determined amount of insulin to the user.

3. The system according to claim 1, further comprises:

a continuous glucose monitor that transmits data corresponding to blood glucose concentrations to the controller.

4. The system according to claim 1, further comprising:

a heart rate monitor that transmits heart rate data to the controller.

5. The system according to claim 1, wherein:

the software sets the rolling period at 7 days.

6. The system according to claim 1, wherein:

the software of the controller includes a setup routine in which (1) the baseline daily insulin needs calculated is the daily at rest insulin needs, (2) the number of grams of carbohydrate consumption that is covered by one unit of insulin for that individual is established, (3) and a total insulin to carbohydrate (I:C) ratio for the individual is calculated.

7. The system according to claim 6, wherein:

the controller determines the bolus insulin need relative to the daily basal need so that the I:C ratio remains substantially constant.

8. The system according to claim 7, wherein:

the controller determines temporary basal insulin rates correlated to recent levels of user activity throughout a recent predetermined period shorter than the rolling period.

9. The system according to claim 8, wherein:

the recent predetermined period is a day.

10. The system according to claim 8, wherein:

the controller adjusts the bolus insulin rate in view of the temporary basal insulin rate so that the I:C ratio is maintained substantially constant regardless of the user activity.

11. The system according to claim 8, wherein:

following increased level of user activity, the controller adjusts the bolus insulin rate for an associated increased insulin sensitivity for a post-activity duration.

12. A method for determining insulin needs of a diabetic user, from at rest to any level of user activity, comprising:

a) establishing baseline total insulin needs for the user;

b) determining basal insulin needs and basal insulin rates based on levels of user activity over a rolling period of time; and

c) determining bolus insulin needs relative to the basal insulin needs.

13. A method according to claim 12, wherein:

said rolling period of time is one week.

14. A method according to claim 12, wherein:

the user activity is determined at least in part from activity performance within heart rate training zones.

15. A method according to claim 14, wherein:

the heart rate training zones for a user is determined at least in part by metabolic heart testing.

16. A method according to claim 12, wherein:

the bolus insulin needs are determined relative to the basal insulin needs so that a total insulin to carbohydrate ratio for the user remains substantially constant.

17. A method according to claim 12, further comprising:

after a user perform an exercise activity, calculating a temporary recovery basal rate for a calculated period of time.

18. A method according to claim 17, further comprising:

after the calculated period of time, reducing the basal insulin rate.

19. A method according to claim 18, wherein:

said basal insulin rates are organized in levels, and said basal insulin rate is reduced by one level for each hour after the calculated period of time.

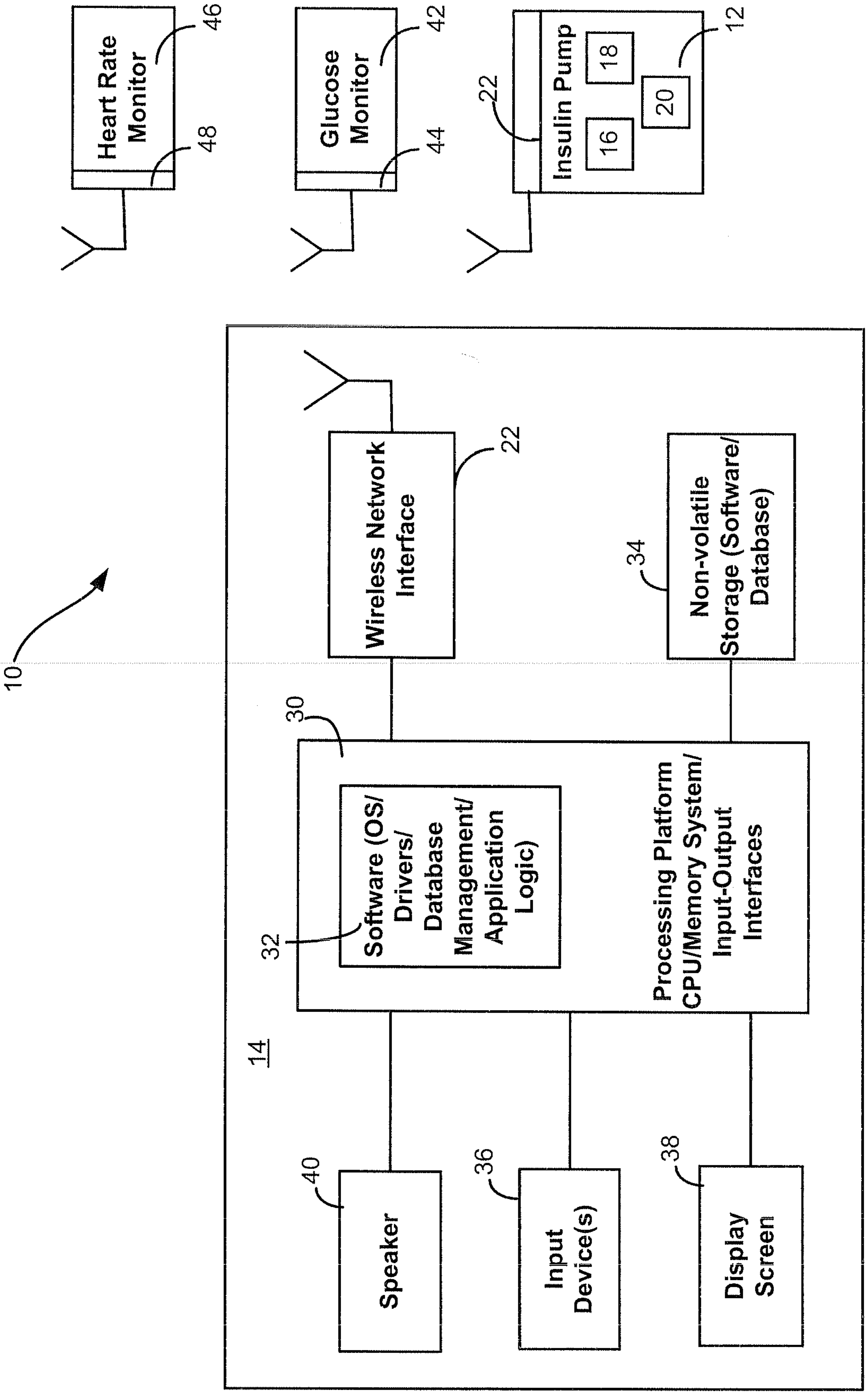

Heart Rate Monitor
46
48
Glucose Monitor
42
44
Insulin Pump
22
16
18
20
12
10
Wireless Network Interface
22
Non-volatile Storage (Software/ Database)
34
30
Software (OS/ Drivers/ Database Management/ Application Logic)
32
Processing Platform CPU/Memory System/ Input-Output Interfaces
14
Speaker
40
Input Device(s)
36
Display Screen
38

FIG. 1

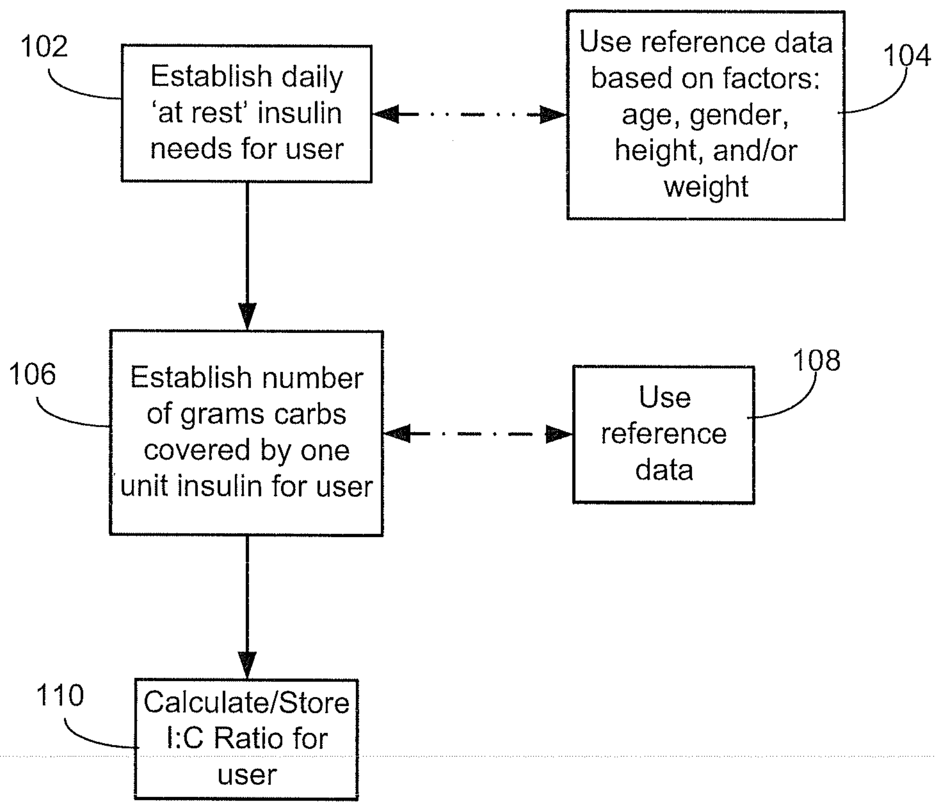

102
Establish daily 'at rest' insulin needs for user
Use reference data based on factors: age, gender, height, and/or weight
104
106
Establish number of grams carbs covered by one unit insulin for user
Use reference data
108
110
Calculate/Store I:C Ratio for user

FIG. 2

| | | |
|---|---|---|
| Total Insulin Needs | 40.8 | 120 |
| One Unit Rapid Insulin | 1 | |
| Carbs Covered By one unit of Insulin | 22 | 124 |
| Units Per Carb | 0.052485 | 126 |
| Weight | 163 | |
| Weight in Kilograms | 74.1 | |
| Hours of training Current rolling 7 days | 8 | |
| Basal Rate for a total rest day | 0.97 | 122 |
| Daily Basal Program: (Based on hrs of activity | 0.51 | |
| Consume grams of carbohydrate per kilogram of bo | 6.5 | 128a |
| Total daily carbohydrates to be consumed | 482 | 128b |
| Carbs to eat per hour of exercise based on weight | 31 | 128c |
| Carbohydrate Reductions during activity | 50.0% | |

FIG. 3

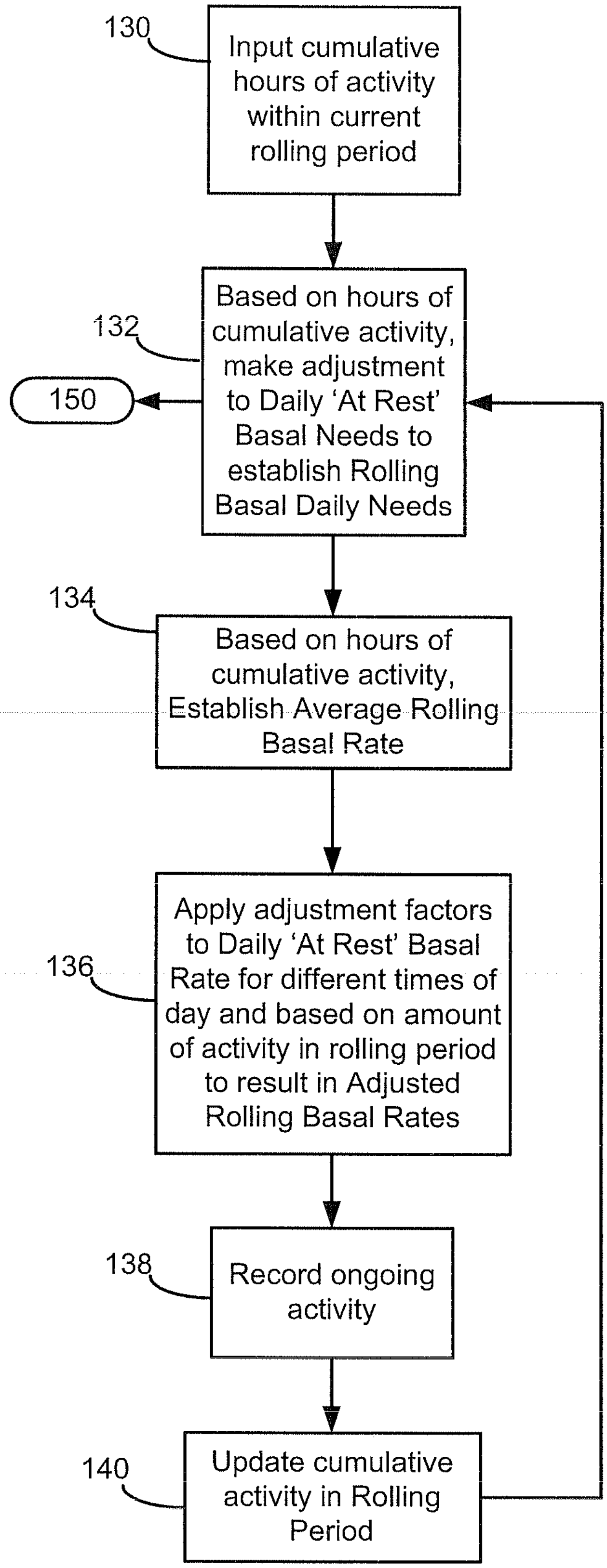

130
Input cumulative hours of activity within current rolling period
132
Based on hours of cumulative activity, make adjustment to Daily 'At Rest' Basal Needs to establish Rolling Basal Daily Needs
150
134
Based on hours of cumulative activity, Establish Average Rolling Basal Rate
136
Apply adjustment factors to Daily 'At Rest' Basal Rate for different times of day and based on amount of activity in rolling period to result in Adjusted Rolling Basal Rates
138
Record ongoing activity
140
Update cumulative activity in Rolling Period

FIG. 4

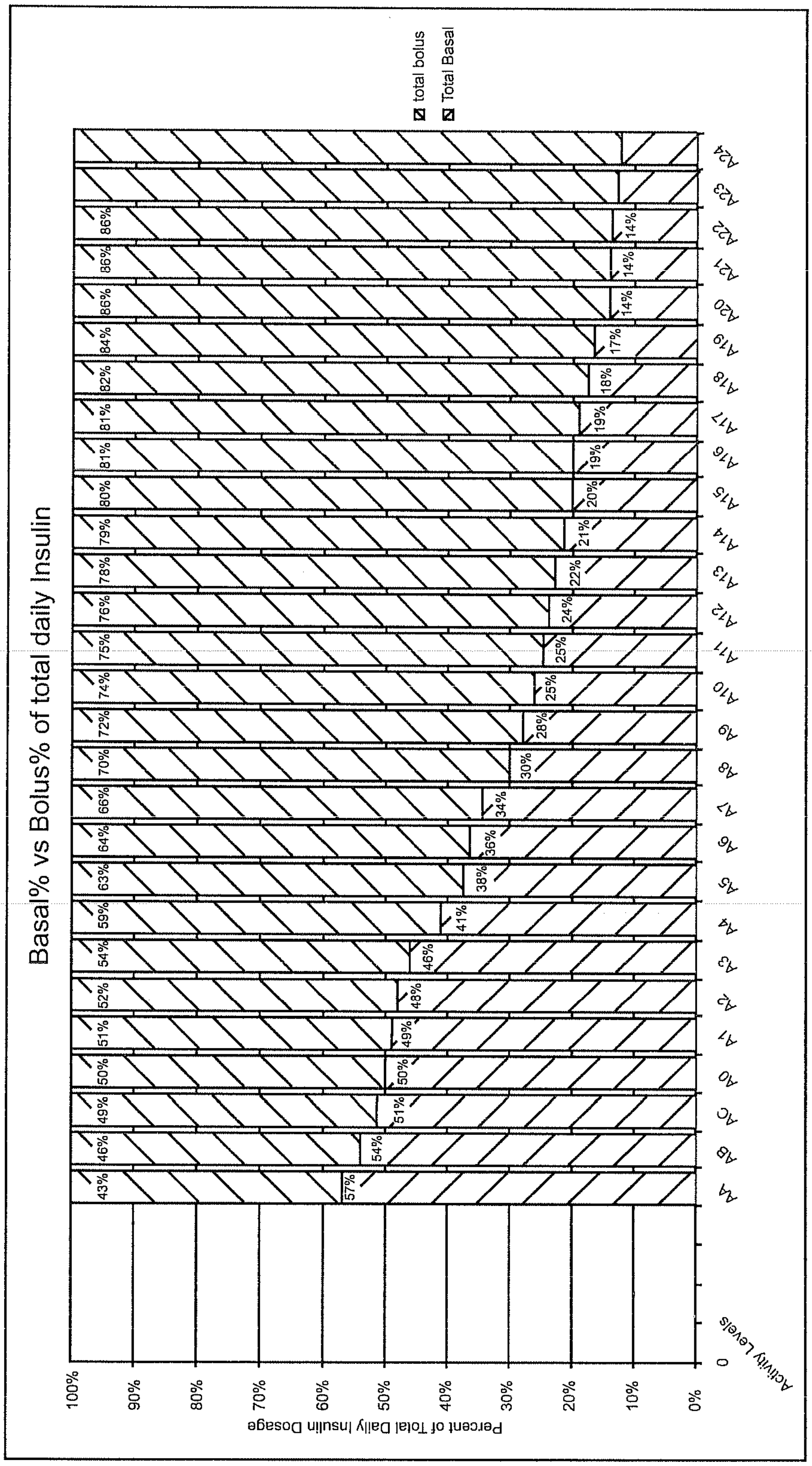

Basal% vs Bolus% of total daily Insulin
total bolus
Total Basal
Percent of Total Daily Insulin Dosage
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
Activity Levels
AA 43% 57%
AB 46% 54%
AC 49% 51%
A0 50% 50%
A1 51% 49%
A2 52% 48%
A3 54% 46%
A4 59% 41%
A5 63% 38%
A6 64% 36%
A7 66% 34%
A8 70% 30%
A9 72% 28%
A10 74% 25%
A11 75% 25%
A12 76% 24%
A13 78% 22%
A14 79% 21%
A15 80% 20%
A16 81% 19%
A17 81% 19%
A18 82% 18%
A19 84% 17%
A20 86% 14%
A21 86% 14%
A22 86% 14%
A23
A24

FIG. 5A

| Cumulative 7 days of Excercise | Activity Levels | Total Insulin | Total Basal | basa % of total | total bolus | bolus % of total | Total Carbs based on Weight | IC Ratio |
|---|---|---|---|---|---|---|---|---|
| 0 | AA | 31.1 | 23.30 | 57% | 7.78 | 43% | 148 | 0.052485 |
| 0 | AB | 33.7 | 22.03 | 54% | 11.67 | 46% | 222 | 0.052485 |
| 0 | AB | 34.4 | 20.81 | 51% | 13.61 | 49% | 259 | 0.052485 |
| 0 | A0 | 40.8 | 20.40 | 50% | 15.55 | 50% | 296 | 0.052485 |
| 1 | A1 | 35.5 | 19.99 | 49% | 15.55 | 51% | 296 | 0.052485 |
| 2 | A2 | 37.1 | 19.58 | 48% | 17.50 | 52% | 333 | 0.052485 |
| 3 | A3 | 38.2 | 18.77 | 46% | 19.44 | 54% | 370 | 0.052485 |
| 4 | A4 | 36.2 | 16.73 | 41% | 19.44 | 59% | 370 | 0.052485 |
| 5 | A5 | 36.7 | 15.30 | 38% | 21.39 | 63% | 408 | 0.052485 |
| 6 | A6 | 38.0 | 14.69 | 36% | 23.33 | 64% | 445 | 0.052485 |
| 7 | A7 | 39.2 | 13.95 | 34% | 25.28 | 66% | 482 | 0.052485 |
| 8 | A8 | 37.5 | 12.24 | 30% | 24.28 | 70% | 482 | 0.052485 |
| 9 | A9 | 38.6 | 11.34 | 28% | 27.22 | 72% | 519 | 0.052485 |
| 10 | A10 | 37.8 | 10.61 | 26% | 27.22 | 74% | 519 | 0.052485 |
| 11 | A11 | 39.3 | 10.12 | 25% | 29.17 | 75% | 556 | 0.052485 |
| 12 | A12 | 38.8 | 9.63 | 24% | 29.17 | 76% | 556 | 0.052485 |
| 13 | A13 | 40.2 | 9.14 | 22% | 31.11 | 78% | 593 | 0.052485 |
| 14 | A14 | 39.8 | 8.65 | 21% | 31.11 | 79% | 593 | 0.052485 |
| 15 | A15 | 41.2 | 8.16 | 20% | 33.05 | 80% | 630 | 0.052485 |
| 16 | A16 | 41.0 | 7.92 | 19% | 33.05 | 81% | 630 | 0.052485 |
| 17 | A17 | 42.7 | 7.67 | 19% | 35.00 | 81% | 667 | 0.052485 |
| 18 | A18 | 42.2 | 7.18 | 18% | 35 .00 | 82% | 667 | 0.052485 |
| 19 | A19 | 41.7 | 6.73 | 17% | 35.00 | 84% | 667 | 0.052485 |
| 20 | A20 | 42.8 | 5.88 | 14% | 36.94 | 86% | 704 | 0.052485 |
| 21 | A21 | 42.7 | 5.75 | 14% | 36.94 | 86% | 704 | 0.052485 |
| 22 | A22 | 44.5 | 5.63 | 14% | 38.89 | 85% | 741 | 0.052485 |
| 23 | A23 | 44.2 | 5.30 | 13% | 38.89 | 87% | 741 | 0.052485 |
| 24 | A24 | 45.9 | 5.10 | 13% | 40.83 | 88% | 778 | 0.052485 |

FIG. 5B

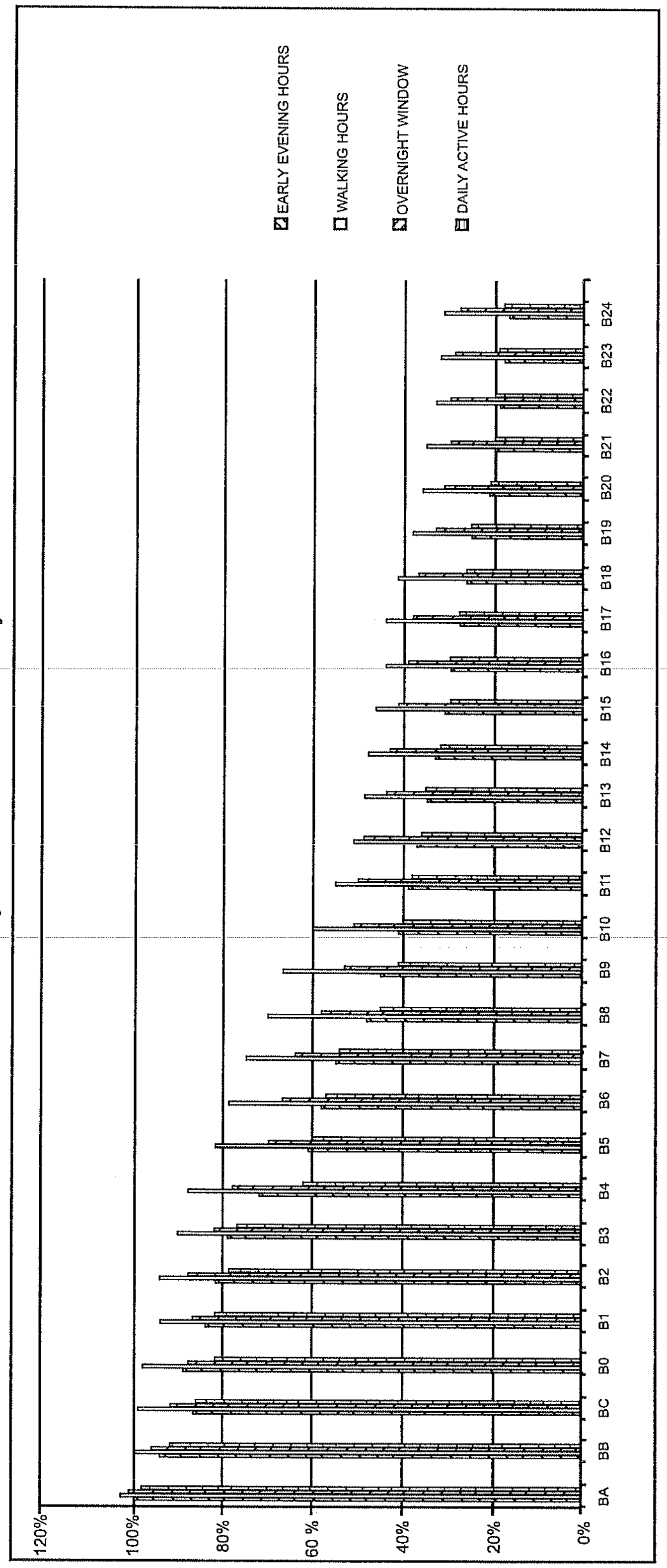

Rolling Basal Insulin Rates as a function of Activity Level and Time of Day
EARLY EVENING HOURS
WALKING HOURS
OVERNIGHT WINDOW
DAILY ACTIVE HOURS
120%
100%
80%
60 %
40%
20%
0%
BA BB BC B0 B1 B2 B3 B4 B5 B6 B7 B8 B9 B10 B11 B12 B13 B14 B15 B16 B17 B18 B19 B20 B21 B22 B23 B24

FIG. 6

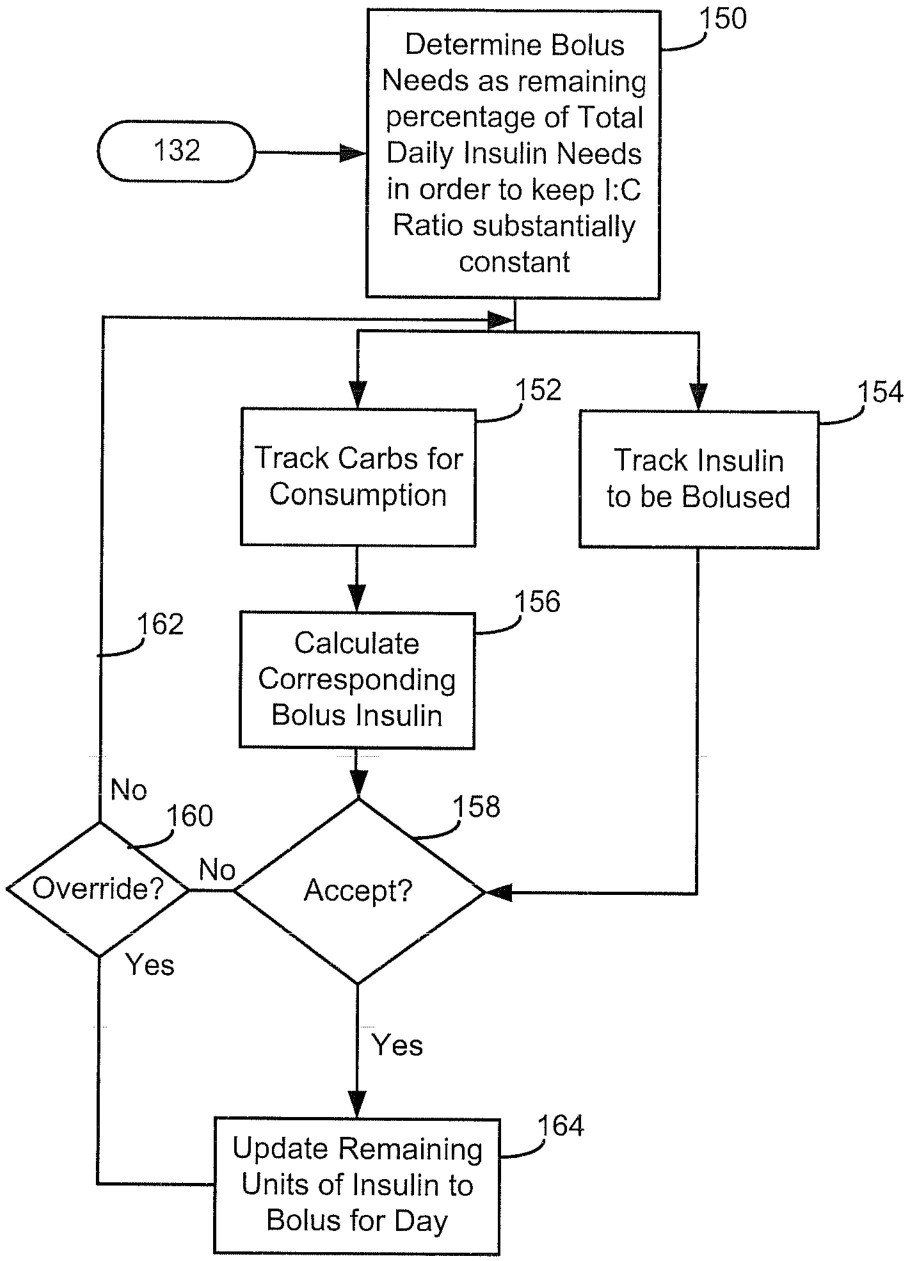
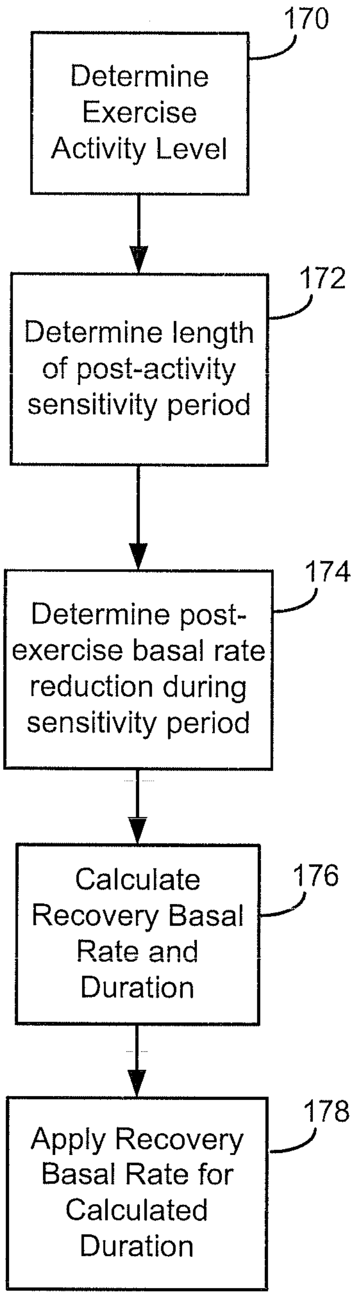

Determine Bolus Needs as remaining percentage of Total Daily Insulin Needs in order to keep I:C Ratio substantially constant
150
132
Track Carbs for Consumption
152
Track Insulin to be Bolused
154
Calculate Corresponding Bolus Insulin
156
162
No
160
Override?
No
Accept?
158
Yes
Yes
Update Remaining Units of Insulin to Bolus for Day
164

FIG. 7



170
Determine Exercise Activity Level
172
Determine length of post-activity sensitivity period
174
Determine post-exercise basal rate reduction during sensitivity period
176
Calculate Recovery Basal Rate and Duration
178
Apply Recovery Basal Rate for Calculated Duration


FIG. 8

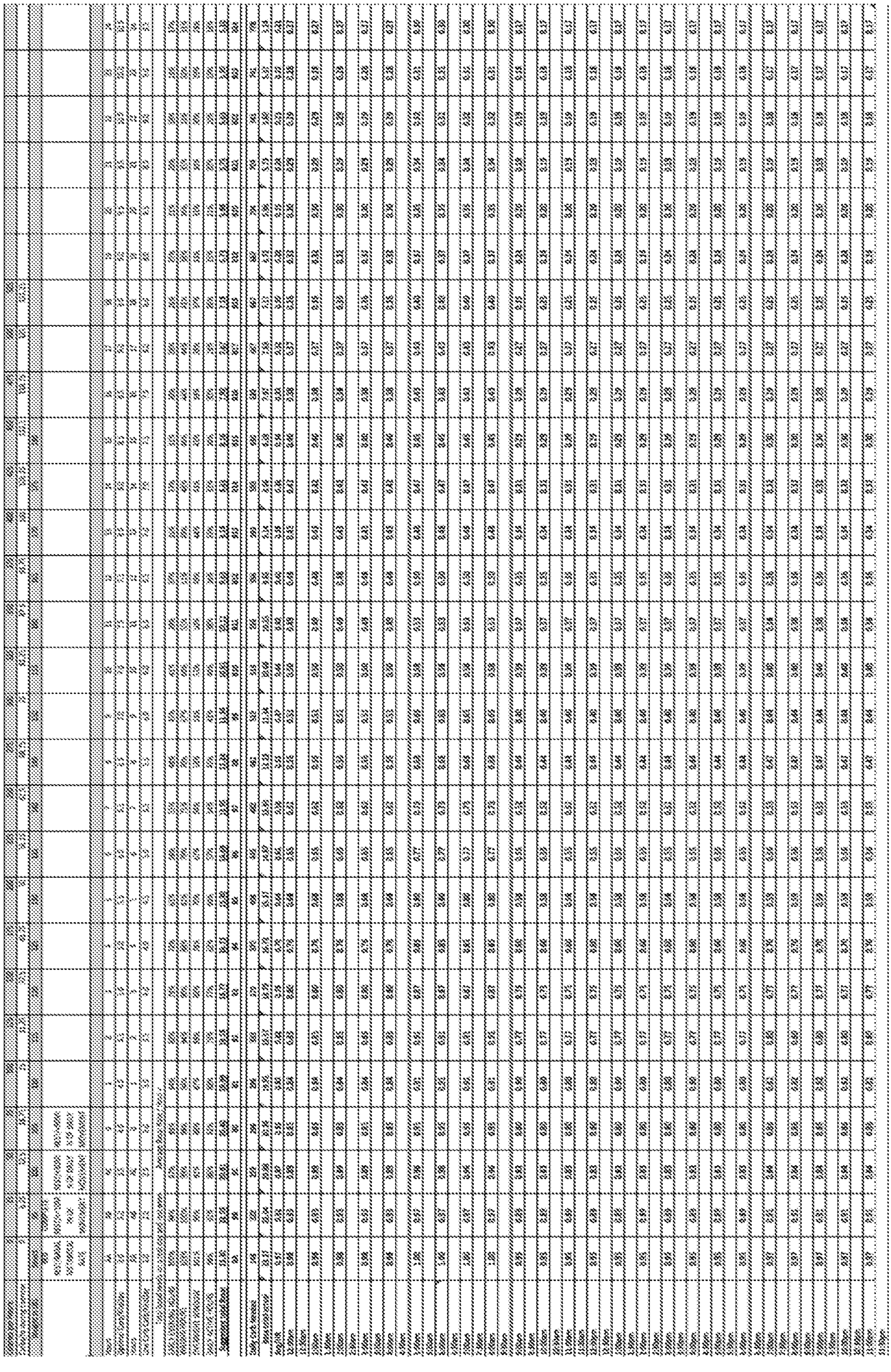


FIG. 9

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| EARLY EVENING HOUR | 100% | 94% | 87% | 89% | 84% | 82% | 79% | 7 |
| WAKING HOURS | 103% | 100% | 99% | 98% | 94% | 94% | 90% | 8 |
| OVERNIGHT WINDOW | 101% | 96% | 92% | 88% | 87% | 88% | 82% | 7 |
| DAILY ACTIVE HOURS | 98% | 92% | 86% | 82% | 82% | 79% | 77% | 8 |
| Suggested total Basal | 23.30 | 22.03 | 20.81 | 20.40 | 19.99 | 19.58 | 18.77 | 10 |
| | BA | BB | BC | BO | B1 | B2 | B3 | |
| Daily Carb Needed | 148 | 222 | 259 | 296 | 296 | 333 | 370 | 3 |
| Basa total-actual | 23.27 | 22.04 | 20.88 | 20.36 | 19.91 | 19.57 | 18.79 | 10 |
| Avg/HR | 0.97 | 0.92 | 0.87 | 0.85 | 0.83 | 0.82 | 0.78 | 0 |
| 12:00am | 0.98 | 0.93 | 0.89 | 0.85 | 0.84 | 0.85 | 0.80 | 0 |
| 12:30am | | | | | | | | |
| 1:00am | 0.98 | 0.93 | 0.89 | 0.85 | 0.84 | 0.85 | 0.80 | 0 |
| 1:30am | | | | | | | | |
| 2:00am | 0.98 | 0.93 | 0.89 | 0.85 | 0.84 | 0.85 | 0.80 | 0 |
| 2:30am | | | | | | | | |
| 3:00am | 0.98 | 0.93 | 0.89 | 0.85 | 0.84 | 0.85 | 0.80 | 0 |
| 3:30am | | | | | | | | |
| 4:00am | 0.98 | 0.93 | 0.89 | 0.85 | 0.84 | 0.85 | 0.80 | 0 |
| 4:30am | | | | | | | | |
| 5:00am | 1.00 | 0.97 | 0.96 | 0.95 | 0.91 | 0.91 | 0.87 | 0 |
| 5:30am | | | | | | | | |
| 6:00am | 1.00 | 0.97 | 0.96 | 0.95 | 0.91 | 0.91 | 0.87 | 0 |
| 6:30am | | | | | | | | |
| 7:00am | 1.00 | 0.97 | 0.96 | 0.95 | 0.91 | 0.91 | 0.97 | 0 |
| 7:30am | | | | | | | | |
| 8:00am | 1.00 | 0.97 | 0.96 | 0.95 | 0.91 | 0.91 | 0.87 | 0 |
| 8:30am | | | | | | | | |
| 9:00am | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |
| 9:30am | | | | | | | | |
| 10:00am | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |
| 10:30am | | | | | | | | |
| 11:00am | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |
| 11.30am | | | | | | | | |
| 12:00pm | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |
| 12:30pm | | | | | | | | |
| 1:00pm | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |
| 1:30pm | | | | | | | | |
| 2:00pm | 0.95 | 0.89 | 0.83 | 0.80 | 0.80 | 0.77 | 0.75 | 0 |

FIG. 10

| Basal or Bolus Strategy | Training or Race | Event | | | | Carbs Consumed /Mean Max Carb Intake | Carb on Board | Bolus#1 on board | Bolus#2 on board | weekly base basa/turn off | Total IOB | IOB;COB | Bolus Reduction During Exercise | Carb Reduction Multiplier | Bolus #1 Reduction Multiplier | Bolus #2 Reduction Multiplier | Weekly Base basal Reduction Rate | | IOB Multiplier |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bolus | Training | | | 0:00 | Z1-Z2 | 31 | 31 | 0.8 | | 0.51 | 1.3 | 0.04 | 50.0% | 100.0% | | | | | 100% |
| Bolus | Training | | | 0:05 | Z1-Z2 | | 30 | 0.8 | | 0.51 | 1.3 | 0.04 | | 95.0% | | | | | 100% |
| Bolus | Training | | | 0:10 | Z1-Z2 | | 28 | 0.8 | | 0.51 | 1.3 | 0.05 | | 90.0% | | | | | 100% |
| Bolus | Training | | | 0:15 | Z1-Z2 | | 25 | 0.8 | | 0.51 | 1.3 | 0.05 | | 80.0% | | | | | 100% |
| Bolus | Training | | | 0:20 | Z1-Z2 | | 22 | 0.8 | | 0.51 | 1.3 | 0.06 | | 70.0% | | | | | 100% |
| Bolus | Training | | | 0.25 | Z1-Z2 | | 19 | 0.8 | | 0.51 | 1.3 | 0.07 | | 60.0% | | | | | 100% |
| Bolus | Training | | | 0:30 | Z1-Z2 | | 16 | 0.8 | | 0.51 | 1.3 | 0.09 | | 50.0% | | | | | 100% |
| Bolus | Training | | | 0:35 | Z1-Z2 | | 12 | 0.8 | | 0.51 | 1.3 | 0.11 | | 40.0% | | | | | 100% |
| Bolus | Training | | | 0:40 | Z1-Z2 | | 9 | 0.8 | | 0.51 | 1.3 | 0.14 | | 30.0% | | | | | 100% |
| Bolus | Training | | | 0:45 | Z1-Z2 | | 6 | 0.8 | | 0.51 | 1.3 | 0.21 | | 20.0% | | | | | 100% |
| Bolus | Training | | | 0:50 | Z1-Z2 | | 3 | 0.8 | | 0.48 | 1.3 | 0.41 | | 10.0% | | | | | 95% |
| Bolus | Training | | | 0:55 | Z1-Z2 | | 2 | 0.7 | | 0.43 | 1.1 | 0.73 | | 5.0% | | | | | 85% |
| Bolus | Training | | | 1:00 | Z1-Z2 | | 0 | 0.6 | | 0.38 | 1.0 | 3.20 | | 1.0% | | | | | 75% |
| Bolus | Training | | | 1:05 | Z1-Z2 | 23 | 25 | 0.6 | | 0.38 | 1.0 | 0.04 | 0.0% | 100.0% | | | | | 74% |
| Bolus | Training | | | 1:10 | Z1-Z2 | | 22 | 0.6 | | 0.37 | 1.0 | 0.043 | | 95.0% | | | | | 72% |
| Bolus | Training | | | 1:15 | Z1-Z2 | | 21 | 0.6 | | 0.35 | 0.9 | 0.044 | | 90.0% | | | | | 100% |
| Bolus | Training | | | 1:20 | Z1-Z2 | | 19 | 0.5 | | 0.34 | 0.9 | 0.047 | | 80.0% | | | | | 100% |
| Bolus | Training | | | 1:25 | Z1-Z2 | | 16 | 0.5 | | 0.32 | 0.8 | 0.051 | | 70.0% | | | | | 100% |
| Bolus | Training | | | 1:30 | Z1-Z2 | | 14 | 0.5 | | 0.31 | 0.8 | 0.057 | | 60.0% | | | | | 100% |
| Bolus | Training | | | 1:35 | Z1-Z2 | | 12 | 0.5 | | 0.30 | 0.8 | 0.067 | | 50.0% | | | | | 100% |
| Bolus | Training | | | 1.40 | Z1-Z2 | | 9 | 0.5 | | 0.29 | 0.7 | 0.080 | | 40.0% | | | | | 100% |
| Bolus | Training | | | 1:45 | Z1-Z2 | | 7 | 0.4 | | 0.27 | 0.7 | 0.099 | | 30.0% | | | | | 100% |
| Bolus | Training | | | 1:50 | Z1-Z2 | | 5 | 0.4 | | 0.24 | 0.6 | 0.136 | | 20.0% | | | | | 100% |
| Bolus | Training | | | 1:55 | Z1-Z2 | | 2 | 0.4 | | 0.22 | 0.6 | 0.250 | | 10.0% | | | | | 100% |
| Bolus | Training | | | 2:00 | Z1-Z2 | | 1 | 0.3 | | 0.20 | 0.5 | 0.455 | | 5.0% | | | | | 100% |
| Bolus | Training | | | 2:05 | Z1-Z2 | 13 | 23 | 0.3 | | 0.20 | 0.5 | 0.040 | 0.0% | 100.0% | | | | | 95% |
| Bolus | Training | | | 2:10 | Z1-Z2 | | 12 | 0.3 | | 0.18 | 0.5 | 0.04 | | 95.0% | | | | | 85% |
| Bolus | Training | | | 2:15 | Z1-Z2 | | 12 | 0.3 | | 0.16 | 0.4 | 0.04 | | 90.0% | | | | | 75% |
| Bolus | Training | | | 2:20 | Z1-Z2 | | 10 | 0.2 | | 0.14 | 0.4 | 0.04 | | 80.0% | | | | | 74% |
| Bolus | Training | | | 2:15 | Z1-Z2 | | 9 | 0.2 | | 0.12 | 0.3 | 0.03 | | 70.0% | | | | | 72% |

FIG. 12

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Hours | 0 | 0 | 0 | 0 | 1 | 2 | 3 | 4 |
| Optimal Carb/KiloDay | 2.0 | 3.0 | 3.5 | 4.0 | 4.0 | 4.5 | 5.0 | 5.0 |

FIG. 11

| Personal Carbohydrate, bolus and basal plan based on weekly training activity rate. | | Exercise Type | Activ | Duartaion of Exerc | Heart Rate Zone | Carbs needed per hc | Total Carbs | Insulin Per hour based on Carb/hc | weekly base ba | basal adjustment during excercis | Recovery temp basal | temp basal duration in HRS | Bolus reduction during exercis | Reduction Multiplier During Exercis | Basal Reduction during exercis | exercise - temp basal multipli | Post Basal Exercise Reducti | Recovery duration multipli | IOB Insulin On Board |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Run <=30min | | Endurance | Run | 0.5 | Z1-Z2 | 31 | 16 | 0.4 | 0.51 | NA | 0.36 | 1.5 | 50.0% | NA | NA | 70.0% | 30.0% | 3.0 | |
| Run <=30min | | Muscle End | Run | 0.5 | Z3-Z4 | 31 | 16 | 0.4 | 0.51 | NA | 0.15 | 2.3 | 50.0% | NA | NA | 70.0% | 30.0% | 3.0 | |
| Run <=.5hr | | Threshold | Run | 0.5 | Z5a,b,c | 31 | 16 | 0.4 | 0.51 | NA | 0.08 | 2.5 | 50.0% | NA | NA | 15.0% | 85.0% | 5.0 | |

FIG. 13

| | Total | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| EARLY EVENING HOUR | 10% | 41% | 39% | 37% | 35% | 33% | 31% | 30% | 28% | 26% |
| WAKING HOURS | 10% | 60% | 55% | 51% | 49% | 48% | 46% | 44% | 44% | 41% |
| OVERNIGHT WINDOW | 10% | 51% | 50% | 49% | 44% | 43% | 41% | 39% | 38% | 37% |
| DAILY ACTIVE HOURS | 98% | 40% | 38% | 36% | 35% | 32% | 30% | 30% | 28% | 26% |
| Suggested total Basal | 23 34 | 10.61 | 10.12 | 9.63 | 9.14 | 8.65 | 8.16 | 7.92 | 7.67 | 7.18 |
| | B9 | B10 | B11 | B12 | B13 | B14 | B15 | B16 | B17 | B18 |
| Daily Carb Needed | 149 | 519 | 556 | 556 | 593 | 593 | 630 | 630 | 667 | 667 |
| Basa total-actual | 23 34 | 10.68 | 10.15 | 9.65 | 9.14 | 8.66 | 8.19 | 7.97 | 7.63 | 7.17 |
| Avg/HR | 0.47 | 0.44 | 0.42 | 0.40 | 0.38 | 0.36 | 0.34 | 0.33 | 0.32 | 0.30 |
| 12:00am | 0.51 | 0.50 | 0.49 | 0.48 | 0.43 | 0.42 | 0.40 | 0.38 | 0.37 | 0.36 |
| 12:30am | | | | | | | | | | |
| 1:00am | 0.51 | 0.50 | 0.49 | 0.48 | 0.43 | 0.42 | 0.40 | 0.38 | 0.37 | 0.36 |
| 1:30am | | | | | | | | | | |
| 2:00am | 0.51 | 0.50 | 0.49 | 0.48 | 0.43 | 0.42 | 0.40 | 0.38 | 0.37 | 0.36 |
| 2:30am | | | | | | | | | | |
| 3:00am | 0.51 | 0.50 | 0.49 | 0.48 | 0.43 | 0.42 | 0.40 | 0.38 | 0.37 | 0.36 |
| 3:30am | | | | | | | | | | |
| 4:00am | 0.51 | 0.50 | 0.49 | 0.48 | 0.43 | 0.42 | 0.40 | 0.38 | 0.37 | 0.36 |
| 4:30am | | | | | | | | | | |
| 5:00am | 1.55 | 0.58 | 0.53 | 0.50 | 0.48 | 0.47 | 0.45 | 0.43 | 0.43 | 0.40 |
| 5:30am | | | | | | | | | | |
| 6:00am | 1.55 | 0.58 | 0.53 | 0.50 | 0.48 | 0.47 | 0.45 | 0.43 | 0.43 | 0.40 |
| 6:30am | | | | | | | | | | |
| 7:00am | 1.55 | 0.58 | 0.53 | 0.50 | 0.48 | 0.47 | 0.45 | 0.43 | 0.43 | 0.40 |
| 7:30am | | | | | | | | | | |
| 8:00am | 1.55 | 0.58 | 0.53 | 0.50 | 0.48 | 0.47 | 0.45 | 0.43 | 0.43 | 0.40 |
| 8:30am | | | | | | | | | | |

FIG. 14

## INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 12/50061

**A. CLASSIFICATION OF SUBJECT MATTER**
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/365
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)
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/365

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/365, 366, 347

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB, USPT, EPAB, JPAB); Google (Patents, Scholar, Web)
Search Terms: Insulin, need, level, require, automatic, activity, exercise, controller, CPU, computer, processor, software, program, rolling, period, day, duration, week, pump, interface, input, total, basal, bolus, rate, inject, determined, calculated, base, baseline, daily,

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| Y | US 2011/0098548 A1 (BUDIMAN et al.) 28 April 2011 (28.04.2011) Fig. 1-3; Para [0012], [0047]-[0048], [0057], [0063], [0079]-[0082], [0112]-[0113], [0116]-[0117], [0122]-[0126], [0128], [0131], [0145]-[0150], [0215] | 1-19 |
| Y | US 2008/0194922 A1 (HOLDEN) 14 October 2010 (14.10.2010) Para [0047], [0051]-[0052], [0095]-[0101], [0125]-[0126] | 1-19 |
| Y | US 2006/0228681 A1 (CLARKE) 12 October 2006 (12.10.2006) Para [0030], [0036]-[0037] | 15 |
| Y | US 2008/0228056 A1 (BLOMQUIST et al.) 18 September 2008 (18.09.2008) Para [0034]-[0039] | 18-19 |
| A | US 2010/0262434 A1 (SHAYA) 14 October 2010 (14.10.2010) Abstract; Para [0089]-[0094], [0119], [0125]-[0128] | 1-19 |
| A | US 2010/0185175 A1 (KAMEN et al.) 22 July 2010 (22.07.2010) Para [0079]-[0084], [0123], [0145]-[0146], [0163]-[0172] | 1-19 |
| A | US 2007/0112298 A1 (MUELLER et al.) 17 May 2007 (17.05.2007) Abstract; Fig. 1-9; Para [0027], [0036], [0038], [0043]-[0063] | 1-19 |
| A | WO 2011/039741 A1 (ATLAS et al.) 07 April 2011 (07.04.2011) Abstract; Fig. 1-4; page 11, ln 14 to page 12, ln 11, page 13, ln 23 to page 16, ln 26, page 17, ln 15 to page 24, ln 11 | |
| A | US 2008/0172026 A1 (BLOMQUIST et al.) 17 July 2008 (17.07.2008) Abstract; Fig. 1-2, 7-9; Para [0021]-[0036], [0086]-[0107] | |

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 25 September 2012 (25.09.2012) | 15 OCT 2012 |

| Name and mailing address of the ISA/US | Authorized officer: |
|---|---|
| Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Lee W. Young<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |