Title: MANAGEMENT OF INHALABLE INSULIN DATA

(Continued on next page)

Abstract: Apparatus, system and machine readable medium are disclosed which manage insulin data. Some embodiments comprise an inhaler that administers inhalable insulin doses measured in milligrams and a diabetes management device to track such inhalable insulin doses. Some embodiments may further comprise a blood glucose meter that generates blood glucose readings and/or subcutaneous delivery devices that administer insulin preparations under the skin. The subcutaneous delivery devices administer insulin preparations in doses measured in standard units of biological activity. The diabetes management device may further track such blood glucose readings and the subcutaneously delivered insulin doses.
Declaration under Rule 4.17:
— of inventorship (Rule 4.17(iv))

Published:
— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
MANAGEMENT OF INHALABLE INSULIN DATA

CROSS REFERENCE TO RELATED APPLICATION

This application claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. provisional patent application Serial No. 60/915,323 filed May 1, 2007, the disclosure of which is incorporated herein by reference in its entirety.

BACKGROUND

Insulin preparations historically have been administered subcutaneously via syringes and/or infusion pumps which inject or otherwise deliver a diluent containing insulin below the skin of the recipient. Further, such subcutaneous insulin preparations are subscribed and administered in doses measured in standard units of biological activity (hereafter "Unit"). For example, a person may take a 3 Unit dose of insulin subcutaneously at certain times of day as part of their diabetes treatment regimen. As a result, current medical devices and diabetes management solutions only record insulin doses in Units.

Recently insulin powders have been developed that are administered to the lungs of the recipient via an inhaler. As a result of being delivered to the lungs instead of subcutaneously, insulin powders provide a different efficacy curve than their subcutaneous counterparts. In other words, a certain quantity of insulin inhaled to the lungs achieves a different effect on the blood glucose level of the recipient than the same quantity of insulin injected under skin. To better distinguish the differences been inhaled and subcutaneous insulin, a different unit of measure has been assigned to inhaled insulin doses. In particular, inhaled insulin doses are commonly prescribed and/or administered in doses measured in milligrams.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention described herein is illustrated by way of example and not by way of limitation in the accompanying figures. For simplicity and clarity of illustration, elements illustrated in the figures are not necessarily drawn to scale. For example, the dimensions of some elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference labels have been repeated among the figures to indicate corresponding or analogous elements.
FIG. 1 depicts a diabetes management system.
FIG. 2 depicts another diabetes management system.
FIGS. 3-6 depict mechanical aspects of the inhaler depicted in FIGS. 1 and 2.
FIG. 7 depicts a inhalable insulin dose that may be administered by the inhaler of FIGS. 3-6.
FIG. 8 depicts additional details of the inhaler depicted in FIGS. 1 and 2.
FIG. 9 depicts a computing device suitable for implementing the diabetes management device of FIGS. 1 and 2 and/or the storage device of FIG. 2.

DETAILED DESCRIPTION

The following description describes techniques of managing data regarding inhaled insulin. In the following description, numerous specific details such as logic implementations, opcodes, means to specify operands, resource partitioning/sharing/duplication implementations, types and interrelationships of system components, and logic partitioning/integration choices are set forth in order to provide a more thorough understanding of the present invention. It will be appreciated, however, by one skilled in the art that the invention may be practiced without such specific details. In other instances, control structures, gate level circuits and full software instruction sequences have not been shown in detail in order not to obscure the invention. Those of ordinary skill in the art, with the included descriptions, will be able to implement appropriate functionality without undue experimentation.

References in the specification to "one embodiment", "an embodiment", "an example embodiment", etc., indicate that the embodiment described may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in connection with an embodiment, it is submitted that it is within the knowledge of one skilled in the art to effect such feature, structure, or characteristic in connection with other embodiments whether or not explicitly described.
Embodiments of the invention may be implemented in hardware, firmware, software, or any combination thereof. Embodiments of the invention may also be implemented as instructions stored on a machine-readable medium, which may be read and executed by one or more processors. A machine-readable medium may include any mechanism for storing or transmitting information in a form readable by a machine (e.g., a computing device). For example, a machine-readable medium may include read only memory (ROM); random access memory (RAM); magnetic disk storage media; optical storage media; flash memory devices; and others.

Referring now FIG. 1, a diabetes management system 100 is depicted.

The diabetes management system 100 may include any combination of an inhaler 110, a subcutaneous delivery device 115, inhalable insulin doses 120, a blood glucose meter 130, and/or a diabetes management device 140. In particular, the present application contemplates diabetes management systems 100 which include the inhaler 110 and the diabetes management device 140; diabetes management systems 100 which include the inhaler 110, the subcutaneous delivery device 115, and the diabetes management device 140; diabetes management systems 100 which include the inhaler 110, the subcutaneous delivery device 115, the blood glucose meter 130, and/or the diabetes management device 140; and diabetes management systems 100 which include the inhaler 110, the blood glucose meter 130 and the diabetes management device 140. Diabetes management systems 100 that include other combinations are also contemplated.

A person may use the inhaler 110 to administer one or more doses 120 of inhalable insulin. Doses of inhalable insulin are measured in milligrams of insulin in one embodiment. The inhaler 110 may locally store inhaler data comprising data representative of the administered doses 120 and/or may transfer inhaler data representative of the administered doses 120 to another device.

The person may use a subcutaneous delivery device 115 such as a syringe or insulin pump to administer insulin under the skin of the person. Similar to the inhaler 110, the subcutaneous delivery device 115 may locally store injection data comprising data representative of the subcutaneously delivered insulin doses and/or may transfer such injection data to another device. However, insulin administered via the subcutaneous delivery device 115 is measured in standard units of biological activity, whereas inhalable insulin is measured in milligrams. A vial of insulin is a
combination of insulin hormone and a sterile liquid, called the diluent. The concentration of the insulin to the diluent determines its strength. Though U-100 insulin is the most common, insulin may be ordered in a variety of strengths, such as U-40. The "U" value of insulin indicates its strength - the number reflects the number of active insulin units in each milliliter of liquid. One may visualize 100 "units" as 100 tiny pieces of insulin floating in each milliliter of diluent. U-100 insulin comprises 100 units per milliliter, and U-40 comprises 40 units per milliliter. Thus, U-100 has 2.5 times the amount of active insulin per milliliter, and is therefore 2.5 times as strong as U-40 insulin. Appropriate syringes are made for use with the respective insulin, marked with the correct measure for dosage.

The person may further use the blood glucose meter 130 to obtain blood glucose readings. The blood glucose meter 130 may locally store meter data comprising the obtained blood glucose readings and/or may transfer meter data to another device. The blood glucose meter 130 may comprise sensors which generate a blood glucose reading based upon analyzing blood glucose test strips to which a blood sample from a person has been applied.

The diabetes management device 140 may transfer, store, manipulate, compare, and otherwise analyze inhaled insulin data measured in milligrams. The diabetes management device may further maintain other diabetes related data such as blood glucose values, blood pressure, weight of the person, and subcutaneously delivered insulin that is measured in units of biological activity. To this end, the diabetes management device 140 may receive data representative of the administered doses 120 and may receive blood glucose readings. In one embodiment, the diabetes management device 140 receives data representative of the administered doses 120 directly from the inhaler 110. Similarly, the diabetes management device 130 in one embodiment receives blood glucose readings directly from the blood glucose meter 130. However, in other embodiments, the diabetes management device 140 may receive data from the inhaler 110 and/or readings from the meter 130 indirectly. For example, the inhaler 110 may transfer data to the meter 130 which in turn transfers the inhaler data as well as the meter data to the diabetes management device 140. Similarly, in another embodiment, the meter 130 may transfer blood glucose readings to the inhaler 110 which in turn transfers the inhaler data as well as the meter data to the diabetes management device 140.
In one embodiment, the diabetes management device 140 receives inhaler data indicative the amount of insulin in milligrams inhaled by a person as well as meter data indicative of blood glucose levels of the person. The diabetes management device 140 may further support receiving injection data from the subcutaneous delivery device 115 which is indicative of insulin delivered subcutaneously to the person. In one embodiment, the diabetes management device 140 executes diabetes management software. The diabetes management software helps manage meter data received from glucose meter 130, inhaler data received from inhaler 110, and injection data received from subcutaneous delivery device 115. To this end, the diabetes management device 140 may store the blood glucose readings of the meter data, the inhaled milligram doses of the inhaler data, and the injected Unit doses of the injection data. The diabetes management device 140 may further enable a person to record the number of carbohydrates consumed, to manually enter information regarding exercise activities, and to perform various statistical and other analyses of the gathered data.

The diabetes management software may provide the diabetes management device 140 with an electronic blood glucose logbook that combines readings from multiple meters 130. The electronic blood glucose logbook may arrange readings such that trends in readings associated with breakfast, lunch, dinner and/or other periods of the day may be visually identified by the person. The electronic blood glucose logbook may further highlight readings associated with low blood sugar and high blood sugar to further aid the person in identifying trends. The electronic blood glucose logbook may further plot administered inhaled insulin as measured in milligrams and may also plot administered subcutaneous insulin as measured in Units delivered, thus providing the person with further feedback regarding the relationship of administered insulin in both inhaled and subcutaneous forms to blood glucose readings.

The diabetes management software may further provide the diabetes management device 140 with standard day data plots. In such plots, the diabetes management device may plot blood glucose levels versus the time of day with multiple days plotted on top of each other, creating a scatter of points. The diabetes management device 140 may further plot administered inhaled insulin as measured in milligrams and may also plot administered subcutaneous insulin as measured in Units
delivered versus time with multiple days of administered insulin plotted. Such a plot again provides the person with feedback regarding the relationship of administered insulin in both inhaled and subcutaneous forms to blood glucose readings over the course of day.

The diabetes management software may provide additional other types of plots, pie charts, reports, etc. which aid the person in analyzing the performance of their insulin deliver protocol in light of their dietary intake, exercise, and other information such as sleep patterns that might effect blood glucose levels of the person.

FIG. 2 depicts another diabetes management system 200. The diabetes management system 200 may include any combination of the inhaler 110, the subcutaneous delivery device 115, the inhalable insulin doses 120, the blood glucose meter 130, the diabetes management device 140, and a storage device 250. In particular, the present application contemplates diabetes management systems 200 which include the inhaler 110 and the storage device 250; diabetes management systems 200 which include the inhaler 110, the subcutaneous delivery device 115, and the storage device 250; diabetes management systems 200 which include the inhaler 110, the subcutaneous delivery device 115, the blood glucose meter 130, and the storage device 250; diabetes management systems 200 which include the inhaler 110, the subcutaneous delivery device 115, the diabetes management device 140 and the storage device 250; diabetes management systems 200 which include the inhaler 110, the blood glucose meter 130, and the storage device 250; and diabetes management systems 200 which include the inhaler 110, the blood glucose meter 130, the diabetes management device 140, and the storage device 250; and diabetes management system 200 which include the inhaler 110, the diabetes management device 140 and the storage device 250. Diabetes management systems comprising other combinations are also contemplated.

Like the diabetes management system 100 of FIG. 1, the diabetes management system 200 may support direct data transfer amongst the inhaler 110, the meter 130, and the diabetes management device 140. The diabetes management system 200 may further support data transfer between the inhaler 110 and the storage
device 250, data transfer between the meter 130 and the storage device 250, and data transfer between the diabetes management device 140 and the storage device 250. Thus, the storage device 250 may receive and store inhaler and/or meter data and may later transfer such inhaler and/or meter data to the diabetes management device 140 for further logging and/or processing.

The storage device 150 may be implemented as a computer readable medium such as, for example, a memory card, thumb drive, or hard drive which may be physically connected to the inhaler 110 and/or meter 130 to receive inhaler and/or meter data therefrom. In another embodiment, the storage device 150 may be implemented as a separate computing device having a computer readable medium and a wired or wireless interface for transferring data with the inhaler 110 and/or meter 130 and a wired or wireless interface for transferring data with the diabetes management device 140. In such an embodiment, the storage device 150 may be implemented as a personal data assistant (PDA), a cellular telephone, an audio player, or some other portable computing device having storage capabilities.

Mechanical aspects of an embodiment of the inhaler 110 are depicted in FIGS. 3-6. As depicted, the inhaler 110 may comprise a base 300 and a chamber 320. The base 300 may include a pull ring 302 positioned toward a first or lower end 304 of the base 300 and chamber release buttons 306 positioned along each side of the base 300 toward a second or upper end 308 of the base 300. In one embodiment, the chamber 320 may be slideably engaged with the base 300 such that a lower end 322 of the chamber 320 receives the upper end 308 of the base 300. In one embodiment, when in a closed position as depicted in FIG. 6, the lower end 322 of the chamber 320 is in close proximity to the lower end 304 of the base 300, and when in an opened position as depicted in FIGS. 3-5, the lower end 322 of the chamber is in close proximity to the upper end 308 of the base 300.

The pull ring 302 may aid a user in opening the inhaler 110. In particular, when the inhaler 110 is in a closed position, a user may grab the pull ring 302 to pull the lower end 304 of the base 300 away from the lower end 322 of the chamber 320 until the lower end 322 is in close proximity to the upper end 308 of the base 300. At which time, the chamber release buttons 306 click into place thus preventing the lower end 322 of chamber 320 from being slid further away from or toward the lower end 304 of the base 300. The user may later return the chamber 320
of the inhaler 110 to a closed position by squeezing the chamber release buttons 306 on each side of the base 300 and pushing the lower end 304 of the base 300 thus cause the upper end 308 of the base 300 to slide into the chamber 320 and toward an upper end 324 of the chamber 320. The slideably engagement between the base 300 and chamber 320 permits for compact storage of the inhaler 110 during periods of inactivity.

The base 300 may further comprise a slot 310 into which insulin doses 120 may be inserted and from which spent insulin doses 120 may be removed. An embodiment of an insulin dose 120 is depicted in FIG. 7 in the form of a blister pack. As depicted, the dose 120 comprises a substrate or card 350 and a blister 352 containing insulin. The dose 120 may further comprise identifying information 354 such as text, ridges, bar codes, RF ID tags, and the like which may be used by the user and/or the inhaler 110 to determine the amount of insulin provided by the dose 120.

In one embodiment, insulin doses 120 are provided in 1 milligram blister packs and 3 milligram blister packs. Further, the identifying information 354 of the 1 milligram blister packs in one embodiment comprise a single ridge, text indicating a 1 milligram dose, as well as a first color (e.g. green) associated with a 1 milligram dose. Similarly, the identifying information 354 of the 3 milligrams blister packs in one embodiment comprise three ridges, text indicating a 3 milligram dose, as well as a second color (e.g. blue) associated with a 3 milligram dose. Thus, a user and/or inhaler 110 may visually distinguish between a 1 milligram dose and a 3 milligram dose based upon the ridges, text, and/or color. Moreover, the user and/or inhaler 110 may physically distinguish between the 1 milligram dose and the 3 milligram dose based upon the ridges.

The base 300 may further comprise a handle 312. The handle 312 may move between an open position as depicted in FIG. 3 and a closed position as depicted in FIGS. 4 and 6. In one embodiment, a user moves the handle 312 from the closed position to the open position to fill a pressure chamber 314 with air and then squeezes the handle 312 to the closed position to pressurize the air within the pressure chamber 314.

The base 300 further comprises a dose release button 316. The dose release button 316 in one embodiment punctures the blister 352 of a dose 120 and
releases the pressurized air of the chamber 314. As a result of puncturing the blister 352 and releasing the air, a cloud of insulin powder is formed in the chamber 320.

As depicted, the chamber 314 also comprises a mouthpiece 326 which may be actuated between an open position depicted in FIG. 3 and a closed position (not shown). When in the closed position, the mouthpiece 326 forms an airtight seal with the chamber 314, thus closing the chamber 314 from the external environment. When in the open position, the mouthpiece 326 provides an airway between the external environment and the chamber 314. After creating an insulin cloud in the chamber 314, a user may move the mouthpiece 326 to the open position, place the mouthpiece 326 in her mouth, and inhale the insulin cloud from the chamber 314 into her lungs. Once inhaled, the user may move the mouthpiece 326 to the closed position in preparation for administering the next dose.

The base 300 further comprises a dose remove button 317. A user may depress or otherwise actuate the dose remove button 317 to eject or semi-eject the dose 120 from the slot 310. Thus, after inhaling the insulin cloud and closing the mouthpiece 326, the user may actuate the dose remove button 317 in order to remove the dose 120 from the slot 310 of the inhaler 110. Finally, as mentioned above, the user may then depress the chamber release buttons 322 and push the base 300 into the chamber 320 for compact storage.

Electrical aspects of the inhaler 110 are depicted in FIG. 8. As depicted, the inhaler 110 further includes a controller 400, a dose input device 402, a real-time clock 404, storage 406, and a communications interface 408. The controller 400 may control operation of other components of the inhaler 110 such as the dose input device 402, the real-time clock 404, the storage 406, and the communications interface 408. The controller 400 may further store in the storage 406 data for each administered dose 120. For example, the controller 400 may store the number of milligrams, the delivery time, and the delivery date of an administered dose 120. To this end, the controller 400, in one embodiment, comprises one or more processors that execute software and/or firmware instructions stored in the storage 406 and/or a separate memory of the controller 400. In other embodiments, the controller 400 may comprise other types of control circuitry such as, for example, discrete digital and/or analog circuit components, ASIC (application specific integrated circuit) devices, PAL (programmable array logic) devices, FPGA (field programmable gate array).
devices, microprocessors, digital signal processors, and application processors which may or may not execute instructions in order to control the operation of the inhaler 110.

The dose input device 402 may comprise one or more I/O devices that enable the inhaler 110 to receive dosage data regarding doses administered by the inhaler 110. For example, the dose input device 402 may comprise sensors such as, for example, physical switches, optical sensors, RF sensors, and/or electrical sensors that enable the inhaler 110 to determine the dosage amount of dose 120 that has been inserted in slot 310 of the inhaler 110 and delivered to the user. As mentioned above, the dose 120 includes identifying information 354 which indicates the dosage amount. Accordingly, the inhaler 110 may be equipped with an input device 402 capable of identifying the dose amount based upon the identifying information 354. For example, the input device 402 may include sensors that detect ridges, text, color or other identifying aspects of the dose 120. The input device 402 may further comprise user input devices such as keys, buttons, and switches which the user may actuate in order to enter the dosage amount.

The storage 406 may comprise various volatile and non-volatile data storage devices such as, for example, random accessory memory (RAM) devices, read only memory (ROM) devices, FLASH memory devices, and disk drives. The storage 406 may store software and/or firmware instructions which the controller 400 may execute. Furthermore, the controller 400 may store data in the storage 406 that is representative of doses administered by the inhaler 110.

The real-time clock 404 comprises an integrated circuit that keeps track of the current time. The controller 400 in one embodiment utilizes the real-time clock 404 to track not only the current time of day but also the date. As a result, the controller 400 may associate a date, time and/or a timestamp with each dose 120 administered by the inhaler 110.

The communication interface 408 of the inhaler 110 may provide an interface between the inhaler 110 and the storage device 150, the diabetes management device 140, and/or the glucose meter 130. In particular, the communication interface 408 may transfer inhaler data to and/or from the storage 406 of the inhaler 110 to other devices having compatible communication interfaces. To this end, the communication interface 408 may comprise a wired interface controller
such as, for example, a universal serial bus (USB) controller, a Firewire controller, a serial bus controller, a parallel bus controller, an Ethernet controller, and/or another type of wired interface controller. The communication interface 408 may also comprise a wireless interface controller such as a Bluetooth controller, a WiFi network controller, a WiMAX controller, an infrared controller, an RF controller, or some other wireless interface controller.

As mentioned above, the dose 120 provides inhalable insulin in doses measured in milligrams. Accordingly, the dose input device 402 generates and the storage 406 stores dosage data for the inhaler 120 that is indicative of the number of milligrams provided by the dose 120. Such dose data may comprise a number (e.g. 3) that indicates the milligram amount (e.g. 3 mg). Such dose data may further comprise a product ID number, SKU number, or other identifier (e.g. 12345-678-XB) associated with a dose 120 that provides a predetermined amount of milligrams of insulin. In another embodiment, the dose data may indicate a dose 120 has been delivered where the inhaler 110 has been configured to deliver doses of a predetermined or programmed number of milligrams. For example, the inhaler 120 may be programmed to deliver only 1 milligram doses 120 and the dose input device 402 may detect and record each 1 milligram dose delivered.

Referring now to FIG. 9, a computing device 500 is depicted. As depicted, the computing device 500 comprises a processor 510, a chipset 520, memory 530, a storage device 540, a communication interface 550, and a user interface 560. The computing device 500 may be suitable for the diabetes management device 140 and/or the storage device 150. However, computing devices of the diabetes management systems may utilize a different architecture than the architecture depicted in FIG. 9. The processor 510 may comprise one or more logic cores for executing instructions stored in memory 530. The processor 510 may further comprise various cache memories, firmware, microcode, interrupt controllers, memory controllers, timers, and/or other circuitry which aid or support the execution of instructions by the processor 510. The chipset 520 may comprises a memory controller, direct memory access controllers, audio controllers, network controllers, graphics controllers, disk controllers, interrupt controllers, real time clocks, and/or other support circuitry to control the flow of data between components (e.g. processor 510, memory 530, storage device 540, network interface 550, and user interface 560).
of the computing device 500. To this end, the chipset 520 may further comprise interface controllers that are compliant with interconnect technologies such as, for example, Universal Serial Bus (USB) controllers, Peripheral Component Interconnect (PCI) Express controllers, IEEE 1394 (Firewire) controllers, Serial ATA controllers, and others.

The memory 530 and/or storage device 540 may store firmware and/or software instructions which in response to being executed by the processor 510 results in the computing device 500 performing various operations of a diabetes management process. Such operations are presented in further detail below in regard to the flowcharts of FIGS. 10 and 11. The memory 530 may comprise various volatile memory devices such as, for example, random access memory (RAM) devices, synchronous dynamic RAM (SDRAM) devices, double data rate (DDR) SDRAM devices, and static RAM (SRAM) devices. The memory 530 may also comprise various non-volatile memory devices such as, for example, read only memory (ROM) devices, programmable ROM (PROM) devices, electronically erasable PROM (EEPROM) devices, and flash memory devices.

The storage device 540 may comprise various electromagnetic, optical, and/or some other mass storage technology devices such as hard disk drives, tape drives, redundant array of independent devices (RAID) devices, compact disc drives, and DVD drives. As mentioned above, the storage device 540 may store software which the processor 510 may execute in order to perform various operations of the invitation order process. In particular, the storage device 540 in an embodiment may store such software in a non-volatile manner for later execution by the processor 510. Furthermore, the storage device 540 may store data such as files, documents, web pages, databases, and the like which the processor 510 may read, write, or/otherwise access in support of the invitation order process.

The communication interface 550 may comprise wired and/or wireless interfaces for coupling the computing device with the network 140. For example, the communication interface 550 may be compliant with IEEE 802.3 (Ethernet), IEEE 802.11 (WiFi), IEEE 802.16 (WiMAX), Bluetooth, Firewire, USB, or some interconnect technology. The user interface 560 may comprise various input and/or output devices which enable a user of the computing device 500 to input data into the computing device 500 and receive data from the computing device 500. Example
input devices include but are not limited to mice, keyboards, touch screens, buttons, and microphones. Similarly, example output devices include but are not limited to printers, CRT displays, digital flat panel displaces, light emitting diodes, and audio speakers.

While certain features of the invention have been described with reference to various embodiments, the description is not intended to be construed in a limiting sense. Various modifications of the described embodiments, as well as other embodiments of the invention, which are apparent to persons skilled in the art to which the invention pertains are deemed to lie within the spirit and scope of the invention.
WHAT IS CLAIMED IS:

1. A method of managing data representative of inhalable insulin administered to a person, comprising
   receiving data indicative of doses of inhalable insulin administered to the person, and
   storing the data indicative of the doses of inhalable insulin administered to the person.

2. The method of claim 1, wherein
   receiving comprises receiving the data from an inhaler, and
   storing comprises storing the data in a storage device that is separate from the inhaler.

3. The method of claim 1, wherein
   receiving the data comprises receiving data that represents the doses of inhalable insulin in milligrams, and
   storing the data comprises storing the data such that the data represents the doses of inhalable insulin in milligrams.

4. The method of claim 1, wherein receiving the data comprises receiving the data from an inhaler that delivers a predetermined dose of inhalable insulin, the data representative of one or more deliveries of the predetermined dose.

5. The method of claim 1, wherein receiving the data comprises receiving the data from an inhaler that delivers a predetermined dose of inhalable insulin, the data representative of a time and a date at which the predetermined dose was delivered.

6. The method of claim 1, wherein receiving the data comprises receiving data that is representative of a dose in milligrams of inhalable insulin and data that is representative of a time and date at which the dose was delivered.
7. The method of claim 1, wherein receiving the data comprises receiving data that is representative of an inhalable insulin product and data that is representative of a time and date at which the inhalable insulin product was delivered.

8. An inhaler for delivery of inhalable insulin to the lungs of a person, comprising
   a chamber to receive a dose of inhalable insulin measured in milligrams;
   a mouthpiece coupled to the chamber via which the person inhales the dose from the chamber;
   a dose input device to receive an indication of the dose in milligrams;
   and
   storage to store, based upon the received indication, data indicative of the dose in milligrams.

9. The inhaler of claim 8 further comprising a communications interface to transfer the data indicative of the dose in milligrams from the storage to another device.

10. The inhaler of claim 8, further comprising a controller, wherein
   the inhaler is configured to deliver a predetermined dose of inhalable insulin, and
   the received indication comprises the dose input device detecting deliver of the dose.

11. The inhaler of claim 8, further comprising a real time clock, wherein the storage further stores data indicative of a time and a date at which the dose was delivered.

12. The inhaler of claim 8, wherein the dose input device generates the data that is representative of a dose in milligrams based upon identifying information provided by packaging of the dose.
13. The inhaler of claim 8, wherein the dose input device comprises a user input device that a user actuates to enter the data indicative of the dose in milligrams.

14. A computing device, comprising a communications interface to receive data that represents inhaled insulin doses as measured in milligrams, storage to store the data that represents inhaled insulin doses as measured in milligrams, and a processor to control the communications interface and the storage.

15. The computing device of claim 14, wherein the communications interface receives the data from an inhaler.

16. The computing device of claim 14, wherein the communications interface receives the data from another computing device having a computer readable medium to which the data was stored.

17. The computing device of claim 14, wherein the communications interface further receives data representative of blood glucose readings.

18. The computing device of claim 14, wherein the communications interface further receives data representative of subcutaneous insulin doses as measured in standard units of biological activity.

19. A diabetes management system, comprising a diabetes management device to track data regarding a diabetes treatment regimen, and an inhaler to deliver inhalable insulin to a person in doses measured in milligrams, to provide the diabetes management device with data representative of administered inhalable insulin doses as measured in milligrams.
20. The diabetes management system of claim 19 wherein the diabetes management device receives and stores data representing inhalable insulin doses measured in milligrams, data representing subcutaneous insulin doses measured in standard units of biological activity, and data representing blood glucose readings.
FIG. 8

DATA INPUT DEVICE 402

CONTROLLER 400

COM. INTERFACE 408

STORAGE 406

RTC 404

FIG. 9

PROCESSOR 510

STORAGE DEVICE 540

CHIPSET 520

MEMORY 530

COM. INT. 550

UI 560
INTERNATIONAL SEARCH REPORT
International application No
PCT/US2008/061860

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00

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

B. FIELDS SEARCHED

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

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>US 6 540 672 B1 (SIMONSEN JAN HENNING [DK]) ET AL 1 April 2003 (2003-04-01) the whole document</td>
<td>1-20</td>
</tr>
</tbody>
</table>

D

Further documents are listed in the continuation of Box C.

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

* Additional documents are listed in the continuation of Box C.

"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 prior 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.

"A" document member of the same patent family

Date of the actual completion of the international search
28 August 2008

Date of mailing of the international search report
04/09/2008

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, Tx. 31 651 epo nl
Fax: (+31-70) 340-3016
Bernardi, Luca
<table>
<thead>
<tr>
<th>Patent document cited in search report</th>
<th>Publication date</th>
<th>Patent family member(s)</th>
<th>Publication date</th>
</tr>
</thead>
<tbody>
<tr>
<td>US 6540672 B1</td>
<td>01-04-2003</td>
<td>NONE</td>
<td></td>
</tr>
<tr>
<td>US 2003163088 A1</td>
<td>28-08-2003</td>
<td>NONE</td>
<td></td>
</tr>
</tbody>
</table>