MEDICATION DELIVERY DEVICE HAVING COMMUNICATION CAPABILITY WITH GLUCOSE MONITOR

A method of treating a medical condition, such as diabetes, in a person. The method encompasses the steps of providing a blood glucose monitor either entirely or at least partially implanted within the person to determine a blood glucose level without manually drawing a blood sample, providing an injection pen including a multi-dose quantity of diabetes medication, receiving with the injection pen via a wireless communication from the blood glucose monitor the determined blood glucose level, displaying the blood glucose level on a display of the injection pen, setting the injection pen to deliver a dose of the diabetes medication based on the displayed blood glucose level, and operating the injection pen to administer to the person the set dose of diabetes medication.
as to the applicant’s entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, IC, IK, IR, IS, IT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, GC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, IS, MW, MZ, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
BACKGROUND OF THE INVENTION

The present invention pertains to medication delivery devices, and, in particular, to an injection pen that a user operates to selectively inject medication to treat a medical condition.

Patients suffering from a variety of diseases often are able to treat themselves by self-administering appropriate doses of medication. An assortment of differently configured portable injectors broadly known as injection pens have been developed to make it convenient for users to so administer medicine.

An injection pen loaded with a multi-dose cartridge of insulin frequently is just one device in a set of devices used by some people with diabetes to control their blood glucose levels. A blood glucose monitoring device may be part of this set and used to test blood glucose values in order for a determination to be made as to, for example, the proper amount of insulin to be injected with the injection pen, or the amount of orally administrable drugs to take, to treat the user’s condition.

One shortcoming of such sets is the difficulty of transporting, keeping track of and separately handling the various devices. To try and address this shortcoming, at least one proposed injection pen has been integrated with a blood glucose monitor. However, this integrated device can still require a user, in order to test her blood glucose value, to draw blood, such as by using a lancing device on her finger, for use with the monitor. This drawing of a blood sample is inconvenient, painful, and distasteful to many users, which can result in blood glucose values being tested less often than recommended.
Relatively recent developments in devices to aid users in controlling blood glucose levels include implanted blood glucose monitors, such as a continuous blood glucose monitor (cBGM). Available cBGMs have included a catheter sensor implanted under the user's skin or in an artery and connected to a base unit outside the body, and are being developed to instead include an equivalent sensor/base unit which is entirely implantable, that wirelessly communicates sensed blood glucose values to a pager-like device which can be attached to the belt of a user. This pager-like device displays the sensor values in a manner similar to more conventional blood glucose monitoring devices, and allows the user to determine what dosage of blood glucose lowering agent, such as insulin, should be administered based on this blood glucose value. For example, based upon this displayed output, the insulin injection pen can be retrieved and manipulated to deliver the dose of insulin calculated to be necessary by the user. Unfortunately, while cBGMs advantageously eliminate the need to draw blood, substituting such devices for more standard blood glucose monitoring devices does not adequately address handling type issues, as a user still may need to access both an injection pen and a separate pager-like device of the cBGM.

Thus, it would be desirable to provide an apparatus that overcome at least one of these shortcomings of the prior art.

**BRIEF SUMMARY OF THE INVENTION**

The present invention encompasses an injection pen including a wireless communications capability that allow instantaneous blood glucose data received from a transmitting blood glucose monitor to be displayed on an electronic screen of the injection pen. A user can then use this displayed data to determine a proper therapeutic dose.
of medicine, which dose can be administered by operation of the injection pen.

In one form thereof, the present invention provides a method of treating diabetes in a person, including the steps of: providing a blood glucose monitor either entirely or at least partially implanted within the person, whereby a blood glucose level of the person is determinable by the blood glucose monitor without manually drawing a blood sample, providing an injection pen including a multi-dose quantity of diabetes medication, receiving with the injection pen via a wireless communication from the blood glucose monitor the determined blood glucose level, displaying the blood glucose level on a display of the injection pen, setting the injection pen to deliver a dose of the diabetes medication based on the displayed blood glucose level, and operating the injection pen to administer to the person the set dose of diabetes medication.

One advantage of the present invention is that an injection pen is provided that can be used as part of a convenient diabetes management system that allows for the control of blood glucose levels without frequent finger-sticks or other blood draws.

Another advantage of an inventive injection pen is that it is capable of directly communicating with an implanted blood glucose monitor, thereby reducing the amount of equipment that has to be carried around by a user in order to control blood glucose levels by injection.

Still another advantage of an inventive injection pen is that it can be programmed to communicate sensed blood glucose levels and treatment history to an external database for review.

Yet another advantage of an inventive injection pen is that it can be part of a diabetes management system that promotes better blood glucose control by making it
convenient and painless to frequently determine blood glucose levels, and then conveniently administer medicine in view thereof, as many times per time as may be needed or recommended.

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BRIEF DESCRIPTION OF THE DRAWINGS

The above-mentioned and other advantages and objects of this invention, and the manner of attaining them, will become more apparent, and the invention itself will be better understood by reference to the following description of embodiments of the invention taking in conjunction with the accompanying drawings, wherein:

Fig. 1 is a front view of an exemplary embodiment of an injection pen of the present invention;

Fig. 2 is a schematic block diagram of components of the injection pen of Fig. 1;

Fig. 3 is a diagrammatic perspective view of the injection pen of Fig. 1 being used to obtain in a wireless fashion a blood glucose reading from a transmitting blood glucose monitor; and

Fig. 4 is a schematic block diagram of an injection pen of the present invention as part of a diabetes management system.

Corresponding reference characters indicate corresponding parts throughout the several views. Although the drawings represent embodiments of the present invention, the drawings are not necessarily to scale, and certain features may be exaggerated or omitted in some of the drawings in order to better illustrate and explain the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to Figs. 1 and 2, there is shown an exemplary embodiment of a portable injector or injection pen
of the present invention. The shown injection pen, generally designated 20, closely resembles a pen-type writing instrument in appearance, but the injection pen of the present invention may be configured to have a different appearance, including but not limited to the more compact, boxlike appearance of the injection pen known as Innovo® available from Novo Nordisk. Pen 20 is of a reusable or refillable variety, as opposed to a disposable variety in which the entire device would be discarded after its supply of medication is exhausted. As is generally known in reusable devices of its type, injection pen 20 includes a medication filled cartridge as part of a cartridge assembly, generally designated 24, which is connected to a reusable pen base, generally designated 26. The shown cartridge assembly is in the form of a reusable retainer 28 with a disposable cartridge 30 filled with multiple doses of medicine loaded therein. Retainer 28 is connectable to the pen base housing, such as via threads. Cartridge 30 is insertable into, and removable when empty for replacement from, the retainer through the open proximal end of the retainer when the retainer is not connected to pen base 26.

An injection needle assembly 32 is mountable on the distal end of cartridge assembly 24 such that the proximal end of its needle pierces a not shown septum of the cartridge. Although shown as having a single needle, the needle assembly may be of various types known in the art, including, but not limited to, assemblies with one or more shortened injection needles, including microneedle arrays. Medicine, such as insulin, is outlet from the internal volume of cartridge 30 through the needle when a piston 31 within the cartridge is moved toward the needle assembly in a conventional manner during injecting use of pen 20. The cartridge assembly may be differently configured, such as is known in the art. For example, the cartridge assembly may
include a distal cap that holds an inserted cartridge within a retainer portion extending from the pen housing, or may be assembled from component parts during its production into a unit handleable by a user as a single piece, and disposed of as a unit when the contained medicine is exhausted.

Pen base 26 includes components that function to allow any one of a number of quantities of medicine to be selected and then expelled from cartridge 30 at a given time through the attached injection needle assembly 32. As further represented in Fig. 2, those components include a manually operable dosage knob 34 and a mechanical drive mechanism 36 which is protectively housed within the pen base and operably connected to knob 34. Dosage knob 34 is rotatable in either direction to set the dose to be injected, or in other words control the distance the drive member will advance when the dosage knob 34 is plunged. Drive mechanism 36 includes a drive member that advances to shift piston 31 distally and force medication from cartridge 30 when dosage knob 34 is plunged after having been rotated to set a dose.

Although dosage knob 34 may move out relative to the pen base when rotated to increase the set dose, and then move in relative to the pen base when rotated to decrease the set dose, such axial motion during dose setting is a function of the drive mechanism to which it operatively attaches, and the dosage knob 34 need not so move to fall within the scope of the invention. In addition, the element actuated to cause the drive mechanism to advance the cartridge piston 31 is described herein as the knob 34 used to set the dose, but may be a different actuating element within the scope of the invention.

As shown in Fig. 2, a battery-powered electronics package of pen 20 includes a microprocessor 40 within pen base 26. Microprocessor 40 is circuited with one or more memory storage elements 42 and a display or screen 44 on
which displayed data is visible to a user. One or more control buttons 46, optionally as well as dosage knob 34, may be used to control the operation of pen 20, such as manually input data to the microprocessor, such as corrections to the time and date determined by a clock contained within the electronics package of pen 20. A sensor 48 senses knob 34 to input to microprocessor 40 the dosage selected by knob rotation, which sensed dosage can be displayed on screen 44. Microprocessor 40 causes the sensed dosage, as well as one or more previous dosages if desired, to be saved in memory storage elements 42 along with the time and day of their administrations for later recall.

The foregoing generally describes pen 20 as an electronic injection pen that automatically senses and displays a dose selected for injection, and which effects a dose delivery by a strictly mechanical interconnection between a plungable dose knob and the cartridge piston advancing drive member. Such general description, however, is merely provided as background and is intended to be illustrative and not limiting in any way. A variety of injection pens are known in the art which include different mechanisms for setting and administering doses, and these pens may be readily adapted to include the specific communications module and practice the invention as further described herein. Possible such pens are not limited to and include, for example, those disclosed in U.S. Patents No. 5,925,021 and 5,928,201 and European Patent Application EP 1095668 A1.

Injection pen 20 further includes a communications module 52 within pen base 26 and electrically circuited to microprocessor 40. Communications module 52 includes hardware that serves as an input port, and optionally an output port as described further below, for communicating as instructed by microprocessor 40 with a device distinct from
and external to the injection pen 20. Communications module 52 is preferably configured for wireless communications, with the external device, although infrared and direct plug-in physical connections may be employed in embodiments in which the external device is physically accessible.

Injection pen 20 receives input from a blood glucose monitor (BGM) 60 that is implanted in a person 62 who can use pen 20 to inject medication. BGM 60 is shown diagrammatically in Fig. 4, and includes a system for determining a blood glucose level and a transmitter for transmitting that blood glucose level to communications module 52 of pen 20. BGM 60 can be of the type entirely implanted under the skin of the user. Alternatively, BGM 60 can be of the type only partially implanted under the skin of the user, such as a sensor element within a cannula that implants under the skin to access blood within the user, and with other aspects of the BGM, such as the transmitter, being housed within a unit mounted to the user's skin. In any case, BGM 60 determines blood glucose levels without the user 62 having blood manually removed from her body, thereby eliminating the need for a blood-drawing via a conventional lancet finger-stick. BGM 60 can be an active unit, such as a continuous blood glucose monitor which continuously senses and transmits blood glucose levels to any pen with a communications module brought into the range of its transmitted signal. BGM 60 alternatively can be a passive unit that is only briefly activated when signaled by injection pen 20. For example, a signal from communications module 52 can turn on a power source within, or directly energize, the BGM that then sends a blood glucose indicating signal back to pen 20. For that passive BGM unit, communications module 52 provides both a transmitting function and a receiving function. Variously configured
BGMs of these general types are known in the art, such as disclosed in U.S. Patent No. 6,201,980 B1, and International Patent Applications WO 99/48419 and WO 00/49940, and are therefore only briefly described herein.

The structure of a diabetes management system using pen 20 will be further understood in view of the following explanation of its operation. When person 62 believes it appropriate to check her blood glucose level, she retrieves pen 20 and brings it into proximity with BGM 60. If BGM 60 is in a passive mode, injection pen 20 can be properly manipulated to send a signal that, for example, awakens BGM 60. BGM 60 determines and wirelessly transmits a signal as to the person's blood glucose level to pen 20, which signal is received by module 52 and processed by microprocessor 40 such that the blood glucose level is caused to be visually displayed on electronic screen 44. Person 62 is then able to read the displayed blood glucose level from screen 44 and, preferably after priming the pen with an air shot in a known manner, to manually rotate dosage knob 34 to set injection pen 20 to deliver a proper amount of medication, such as insulin, from pen cartridge 30 to treat the condition reflected by that blood glucose reading. After the proper dose has been set, injection pen 20 is manipulated such that needle 32 penetrates the skin of the user at the appropriate injection site, and dosage knob 34 is plunged to cause drive mechanism 36 to administer the set dose of medication through the needle to the patient. The administered dose, possibly along with prior administered doses as well as, for example, the times and dates at which such doses were administered, can be automatically stored in memory 42 for later reference.

Referring now to Fig. 4, an embodiment of an injection pen 20 of the present invention is shown as part of a diabetes management system in which it is utilized both to
collect data from a downstream, implanted blood glucose monitor 60, and then to transmit that collected data, along with data it may generate, to a second external device 70 which is upstream in a data chain. Thus, the shown injection pen can serve as an integral and intermediate part of a chain by which diabetes treatment history data can be communicated to, for example, a treating medical professional, for further consideration.

Specifically, as previously described, injection pen 20 is capable of storing blood glucose levels received from BGM 60, as well as dosing information it develops during use. That information is all communicated at 68 to an external device indicated at 70. For example, via communications module 52, pen 20 can transmit that information, preferably in a wireless fashion but alternatively via a plug-in style connection, to a device 70 that is a personal digital assistant (PDA) loaded with patient data software. The software allows the person to also directly enter into the PDA data such as food intake and physical activity. A treating physician can view the data on the PDA to assess the medical history of the person, or download the data from the PDA, such as via either a wireless or plug-in style connection, to, for example, a database on a stand-alone or networked computer for later consideration. Device 70 shown in Fig. 4 alternatively may be such stand-alone or networked computer. Still further, device 70 to which pen 20 is shown communicating in Fig. 4 alternatively may be a cell phone, or pager-style device similarly capable of transmitting information, which relays the data to, for example, a website or networked computer system, which cell phone or pager-style device also may possibly be used to relay other data such as food intake or physical activity. The cell phone or pager-style device alternatively may be used as an amplifier to get the data to a satellite for transmission,
and further the cell phone or pager-style device could have a capability for, at the touch of a single emergency button provided thereon, calling in an emergency, such as to locations further described below, if the patient recognized that the blood glucose value provided to pen 20 by BGM 60 indicates, for example, that the patient is having a hypoglycemic attack, and then the patient pressed such button. The cell phone or pager-style device, if provided with global positioning system capabilities, could also be used by a patient to signal where exactly he or she is located if the emergency button on the phone or device were pressed.

In addition, and in another embodiment represented by Fig. 4, the diabetes management system utilizing injection pen 20 can be adapted to signal for emergency assistance without action by the patient. In particular, injection pen 20 could be configured so as to automatically trigger a cell phone or pager-style device 70 to call (i.e., without patient intervention) for such exigent circumstances as could be envisioned when the patient’s blood glucose values get to such a low level that a patient could be at risk that imminent harm may ensue. One such system involves a continuously broadcasting blood glucose monitor 60, and an injection pen 20 constantly in a receiving mode and in communication with the monitor 60 when in sufficient proximity to the patient, preferably while in the patient’s pocket. When the blood glucose signal received from monitor 60 by pen 20 is recognized by pen 20 as being below a preset danger level, which preset danger level is patient-appropriate and set up or preprogrammed in the pen 20 by the patient’s physician and/or the equipment supplier, pen 20, besides possibly creating an audible alarm to notify the patient, automatically causes the cell phone or pager-style device 70 to signal for help without intervention by the
patient. The phone or pager-style device signals for help by contacting, for example, a doctor's office or pager, or an emergency service provider. Alternatively, rather than a pen which is always receiving values from a continuously broadcasting blood glucose monitor, the injection pen 20 could be configured to awaken periodically without intervention by the patient, and when awakened to energize the "sleeping" BGM in proximity thereto to cause a blood glucose value to be determined and broadcast to the pen, which pen, if necessary, then works to have an emergency signaled in the above-described manner.

The wireless communications protocol by which pen 20 communicates may be one known in the art, such as the "Bluetooth" protocol. Other suitable protocols by which pen 20 can communicate may be used, and include, but are not limited to, the IEEE 802.11 protocol.

While this invention has been shown and described as having preferred designs, the present invention may be modified within the spirit and scope of this disclosure. For example, the injection pen of the present invention may be a needle-free or jet injector device, and further may employ electromechanical components or biasing members such as springs to assist the dosing or injecting process. For example, the dose could be automatically set in the pen with an electric motor based on the communicated blood glucose level. In addition, the external device 70 could be provided with dosing information directly by the injection pen, and blood glucose level information directly by the blood glucose monitor. Still further, user operable medication delivery devices other than an injection pen, such as pulmonary devices like a dry power inhaler, may be adapted to practice the present invention. This application is therefore intended to cover any variations, uses or adaptations of the invention using its general principles.
Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains.
WE CLAIM:

1. A method of treating diabetes in a person, comprising the steps of:
   providing a blood glucose monitor either entirely or at least partially implanted within the person, whereby a blood glucose level of the person is determinable by the blood glucose monitor without manually drawing a blood sample;
   providing an injection pen including a multi-dose quantity of diabetes medication;
   receiving with the injection pen via a wireless communication from the blood glucose monitor the determined blood glucose level;
   displaying the blood glucose level on a display of the injection pen;
   setting the injection pen to deliver a dose of the diabetes medication based on the displayed blood glucose level; and
   operating the injection pen to administer to the person the set dose of diabetes medication.

2. The method of claim 1 wherein the step of setting the injection pen comprises manually rotating a dose setting knob of the injection pen.

3. The method of claim 2 wherein the step of operating the injection pen comprises plunging the dose setting knob from a first position to a second position relative to a housing of the injection pen.

4. The method of claim 1 further comprising the step of operating the injection pen to communicate glucose levels and dosing information stored in the injection pen to an external data collection device.

5. The method of claim 4 wherein the step of communicating with an external data collection device uses the Bluetooth communications protocol.
# INTERNATIONAL SEARCH REPORT

**A. CLASSIFICATION OF SUBJECT MATTER**

| IPC 7   | A61B5/00 | A61M5/172 |

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 7   | A61B | A61M |

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, INSPEC**

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<td>US 5 925 021 A (CASTELLANO THOMAS P ET AL) 20 July 1999 (1999-07-20) cited in the application column 6, line 36 -column 9, line 20</td>
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X Further documents are listed in the continuation of box C.  
X Patent family members are listed in annex.

**Date of the actual completion of the international search**

13 March 2003

**Date of mailing of the international search report**

19/03/2003

**Name and mailing address of the ISA**

European Patent Office, P.B. 5818 Patent ciudad 2 NL-2280 HV Rijswijk, Tel. (+31-70) 540-2040, Fax: (+31-70) 540-3016

**Authorized officer**

Manschot, J
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<td>US 5 569 186 A (LORD PETER C ET AL) 29 October 1996 (1996-10-29) column 3, line 49 - column 5, line 15</td>
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Continuation of Box I.1

Although claims 1–5 are directed to a method of treatment of the human/animal body, the search has been carried out to a device used for carrying out the method: i.e. blood glucose monitor and injection pen having wireless communication capability.

Continuation of Box I.1

Claims Nos.: 1–5

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
### INTERNATIONAL SEARCH REPORT

#### Box I  Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

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

1. **X** Claims Nos.: 1-5  
   because they relate to subject matter not required to be searched by this Authority, namely:  
   see FURTHER INFORMATION sheet PCT/ISA/210

2. **☐** Claims Nos.:  
   because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

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

#### Box II  Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

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

1. **☐** As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**  
☐ The additional search fees were accompanied by the applicant’s protest.  
☐ No protest accompanied the payment of additional search fees.

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Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)
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