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Galasso

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(54) **DEVICE AND METHOD FOR AUTOMATIC DATA ACQUISITION AND/OR DETECTION**

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This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
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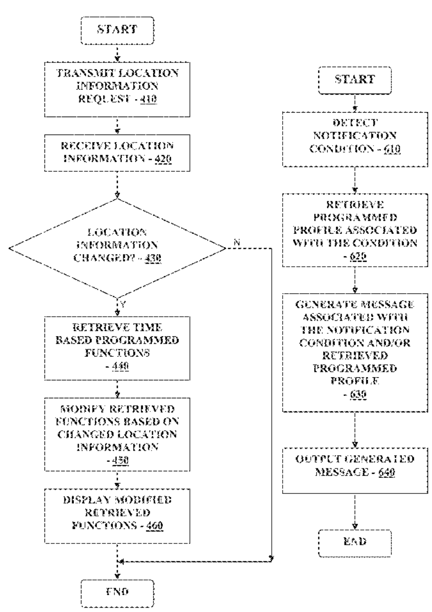
(57) **ABSTRACT**

Methods and system for providing diabetes management including automatic time acquisition protocol and expiration date detection are provided.

20 Claims, 9 Drawing Sheets



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(58) **Field of Classification Search**

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See application file for complete search history.

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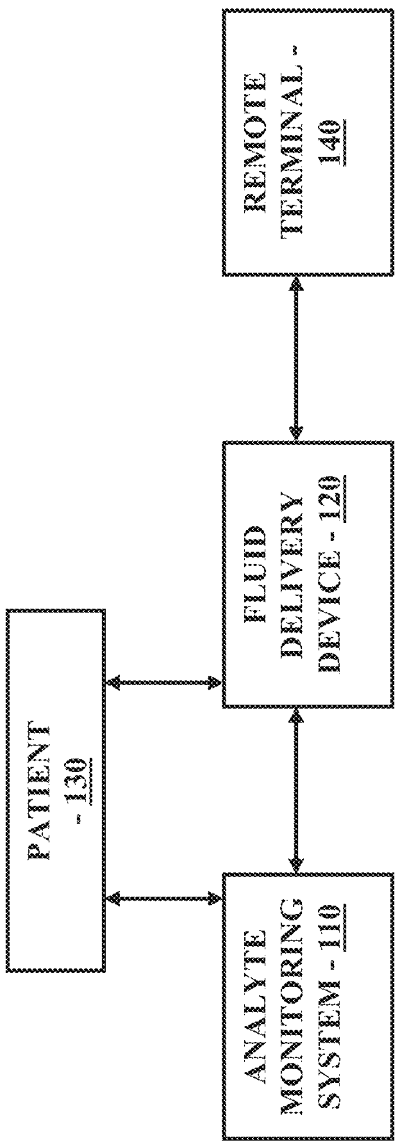

REMOTE TERMINAL - 140
FLUID DELIVERY DEVICE - 120
PATIENT - 130
ANALYTE MONITORING SYSTEM - 110

100

FIGURE 1

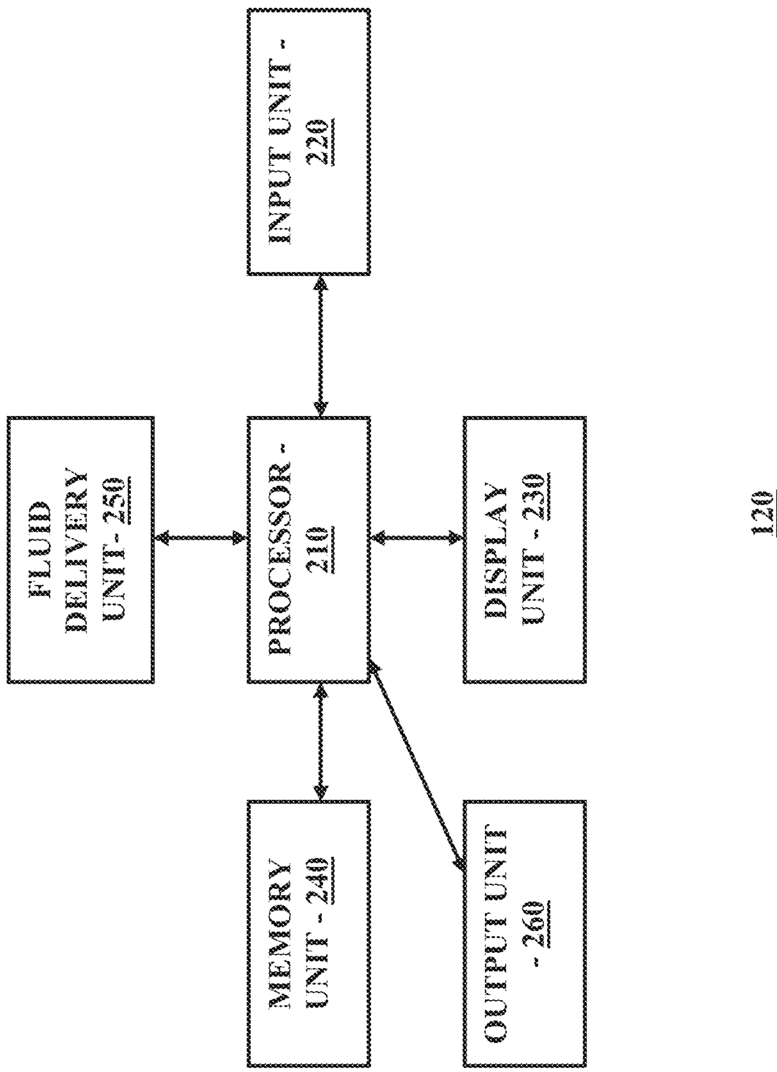
INPUT UNIT - 220
FLUID DELIVERY UNIT - 250
PROCESSOR - 210
DISPLAY UNIT - 230
MEMORY UNIT - 240
OUTPUT UNIT - 260
120

FIGURE 2

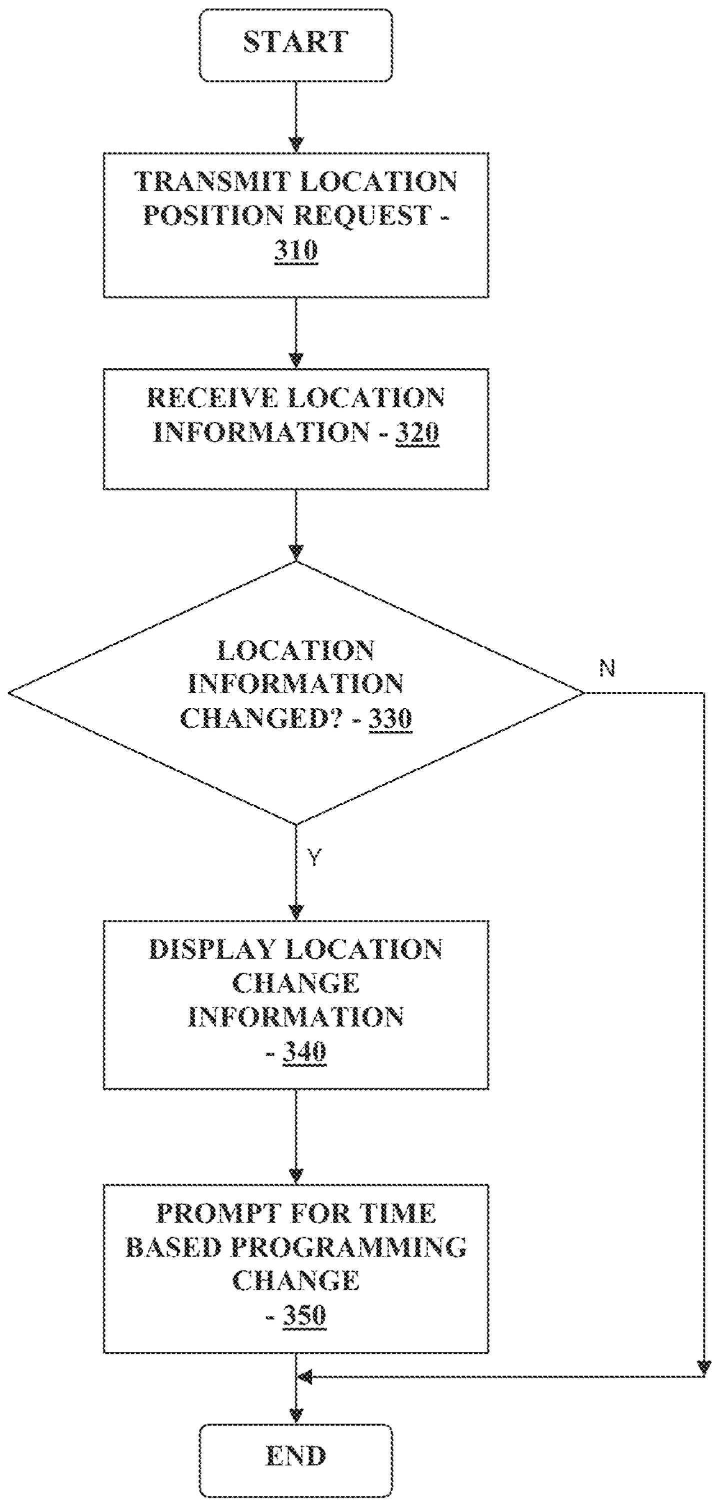
START
TRANSMIT LOCATION POSITION REQUEST - 310
RECEIVE LOCATION INFORMATION - 320
LOCATION INFORMATION CHANGED? - 330
N
Y
DISPLAY LOCATION CHANGE INFORMATION - 340
PROMPT FOR TIME BASED PROGRAMMING CHANGE - 350
END

FIGURE 3

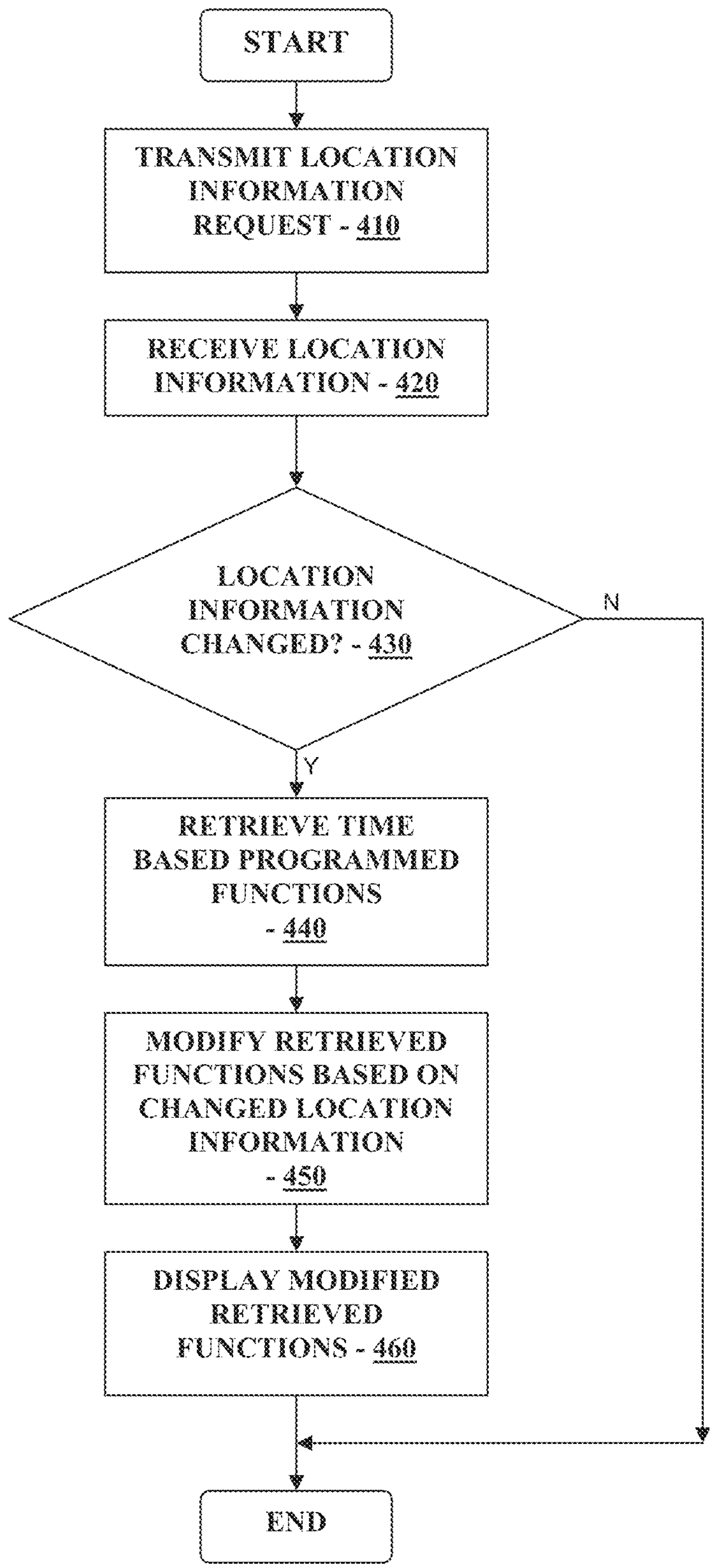
START
TRANSMIT LOCATION INFORMATION REQUEST - 410
RECEIVE LOCATION INFORMATION - 420
LOCATION INFORMATION CHANGED? - 430
N
Y
RETRIEVE TIME BASED PROGRAMMED FUNCTIONS - 440
MODIFY RETRIEVED FUNCTIONS BASED ON CHANGED LOCATION INFORMATION - 450
DISPLAY MODIFIED RETRIEVED FUNCTIONS - 460
END

FIGURE 4

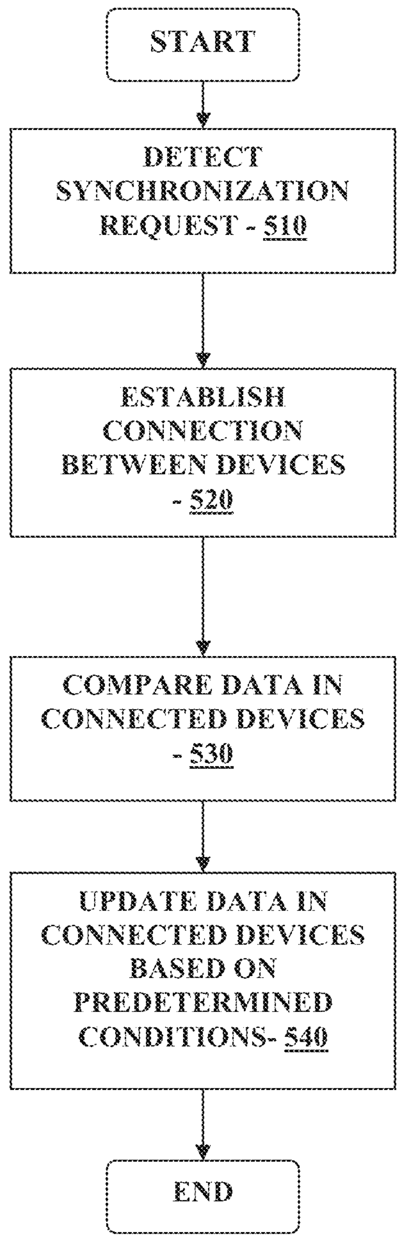
START
DETECT SYNCHRONIZATION REQUEST - 510
ESTABLISH CONNECTION BETWEEN DEVICES - 520
COMPARE DATA IN CONNECTED DEVICES - 530
UPDATE DATA IN CONNECTED DEVICES BASED ON PREDETERMINED CONDITIONS- 540
END

FIGURE 5

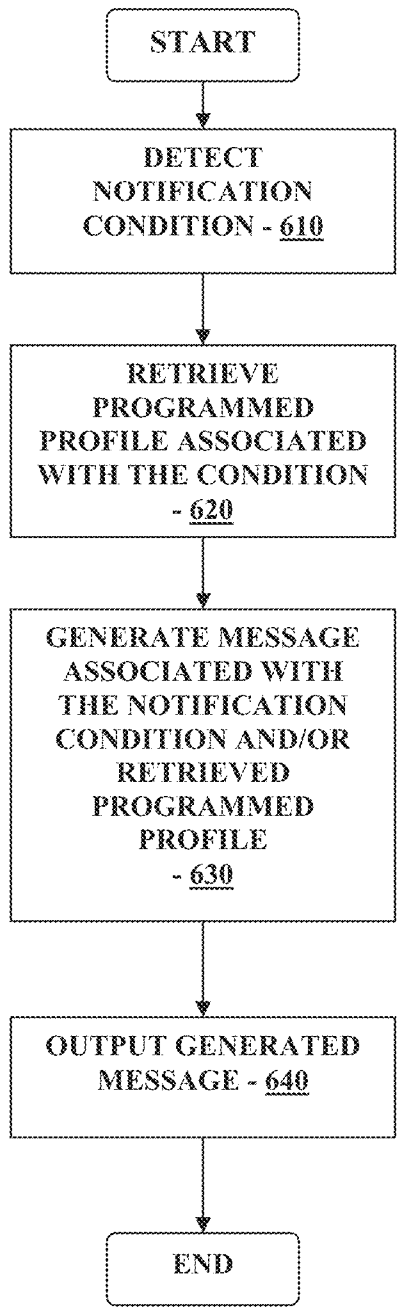
START
DETECT NOTIFICATION CONDITION - 610
RETRIEVE PROGRAMMED PROFILE ASSOCIATED WITH THE CONDITION - 620
GENERATE MESSAGE ASSOCIATED WITH THE NOTIFICATION CONDITION AND/OR RETRIEVED PROGRAMMED PROFILE - 630
OUTPUT GENERATED MESSAGE - 640
END

FIGURE 6

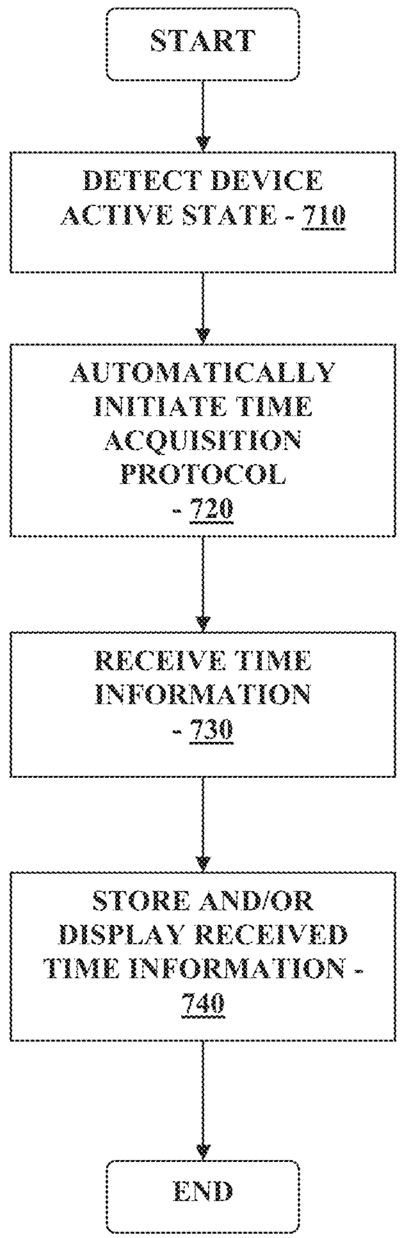
START
DETECT DEVICE ACTIVE STATE - 710
AUTOMATICALLY INITIATE TIME ACQUISITION PROTOCOL - 720
RECEIVE TIME INFORMATION - 730
STORE AND/OR DISPLAY RECEIVED TIME INFORMATION - 740
END

FIGURE 7

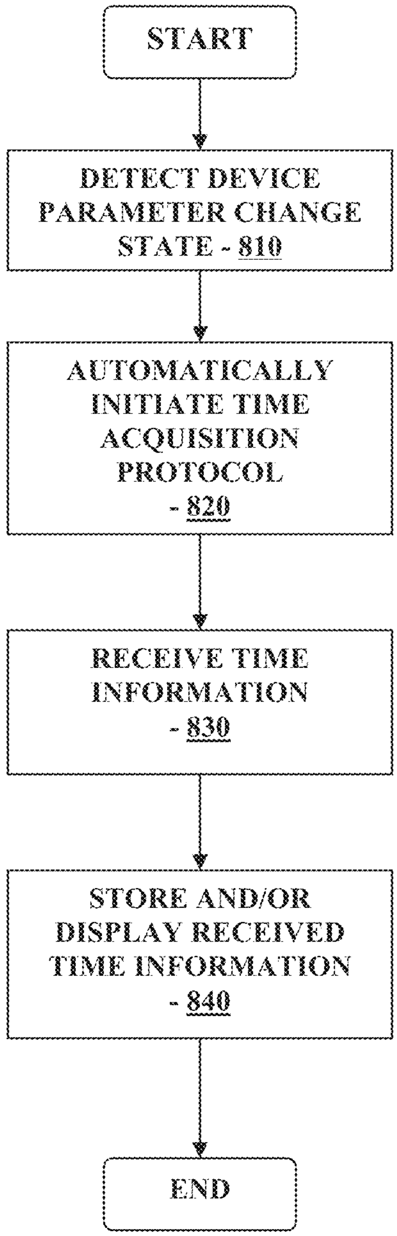
START
DETECT DEVICE PARAMETER CHANGE STATE - 810
AUTOMATICALLY INITIATE TIME ACQUISITION PROTOCOL - 820
RECEIVE TIME INFORMATION - 830
STORE AND/OR DISPLAY RECEIVED TIME INFORMATION - 840
END

FIGURE 8

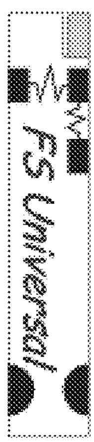

FIGURE 9A

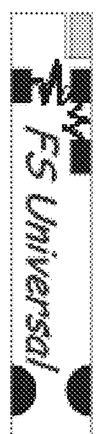

FIGURE 9B

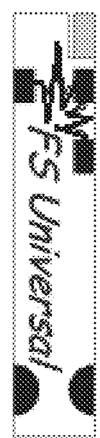

FIGURE 9C

DEVICE AND METHOD FOR AUTOMATIC DATA ACQUISITION AND/OR DETECTION

RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 14/829,611 filed Aug. 18, 2015, which is a continuation of U.S. patent application Ser. No. 12/031,660 filed Feb. 14, 2008, which claims priority under § 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/890,161 filed Feb. 15, 2007, entitled "Device And Method For Automatic Data Acquisition And/Or Detection", the disclosures of each of which are incorporated herein by reference for all purposes.

BACKGROUND

In diabetes management, there exist devices which allow diabetic patients to measure the blood glucose levels. One such device is a hand-held electronic meter such as blood glucose meters such as Freestyle® blood glucose monitoring system available from Abbott Diabetes Care Inc., of Alameda, Calif. which receives blood samples via enzyme-based test strips. Typically, the patient lances a finger or alternate body site to obtain a blood sample, applies the drawn blood sample to the test strip, and the strip is inserted into a test strip opening or port in the meter housing. The blood glucose meter converts a current generated by the enzymatic reaction in the test strip to a corresponding blood glucose value which is displayed or otherwise provided to the patient to show the level of glucose at the time of testing.

Such periodic discrete glucose testing helps diabetic patients to take any necessary corrective actions to better manage diabetic conditions. Presently available glucose meters have limited functionalities (for example, providing the glucose value measured using the test strip and storing the data for subsequent recall or display) and do not provide any additional information or capability to assist patients in managing diabetes. For example, Type-1 diabetic patients who require periodic infusion or injection of insulin, typically use glucose meters in addition to, for example, wearing an external infusion device, or a pen type injection device. Also, in the case of external infusion devices, because the strip port on the meter receives the test strip (which is generally not a water tight seal), it is not desirable to incorporate the discrete glucose meter functionalities to the housing of the external infusion devices.

Presently available external infusion devices typically include an input mechanism such as buttons through which the patient may program and control the infusion device. Such infusion devices also typically include a user interface such as a display which is configured to display information relevant to the patient's infusion progress, status of the various components of the infusion device, as well as other programmable information such as patient specific basal profiles.

The external infusion devices are typically connected to an infusion set which includes a cannula that is placed transcutaneously through the skin of the patient to infuse a select dosage of insulin based on the infusion device's programmed basal rates or any other infusion rates as prescribed by the patient's doctor. Generally, the patient is able to control the pump to administer additional doses of insulin during the course of wearing and operating the infusion device such as for, administering a carbohydrate bolus prior to a meal. Certain infusion devices include food database that has associated therewith, an amount of carbohydrate, so that the patient may better estimate the level of insulin dosage needed for, for example, calculating a bolus amount.

Programming and controlling the pump functions are typically performed by the patient using the pump user interface which includes input buttons and a display. Typically, depending on the type of the infusion device, the amount of information which is provided to the user generally focuses on infusion management such as programming temporary basals, bolus calculation, and the like, in addition to the device operational functions such as alerts for occlusion detection. Given the decreasing cost of microprocessor, communication and other electronic components, and increasing sophistication of patients and users of medical devices such as blood glucose meters, infusion devices, and continuous glucose monitoring systems, it would be desirable to provide additional features and functionalities to improve health related management by the user using these medical devices.

SUMMARY

In accordance with the various embodiments of the present disclosure, there are provided methods and system for providing robust functionalities for a therapy management system including infusion devices and analyte monitoring systems including continuous glucose monitoring systems and discrete blood glucose meters with improved capabilities.

These and other objects, features and advantages of the present disclosure will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating a therapy management system for practicing one embodiment of the present disclosure;

FIG. **2** is a block diagram of a fluid delivery device of FIG. **1** in one embodiment of the present disclosure;

FIG. **3** is a flowchart illustrating the time zone detection procedure in the therapy management system in one embodiment of the present disclosure;

FIG. **4** is a flowchart illustrating the time zone detection procedure in the therapy management system in another embodiment of the present disclosure;

FIG. **5** is a flowchart illustrating the device synchronization procedure in the therapy management system in one embodiment of the present disclosure;

FIG. **6** is a flowchart illustrating device condition notification function in the therapy management system in one embodiment of the present disclosure;

FIG. **7** is a flowchart illustrating automatic time information detection function incorporated in a medical device such as a blood glucose meter in one embodiment of the present disclosure;

FIG. **8** is a flowchart illustrating automatic time information detection function incorporated in a medical device such as a blood glucose meter in another embodiment of the present disclosure; and

FIGS. **9**A-**9**C illustrate embodiments of automatic expiration detection function on blood glucose meter test strips in accordance with one embodiment of the present disclosure.

DETAILED DESCRIPTION

As described below, within the scope of the present disclosure, there are provided user interface features associated with the operation of the various components or devices in a therapy management system such as automatic time change based functions, automatic expiration date detection on test strips, for example, synchronization of the components in the therapy management system, user interface changes based on the user configuration, notification functions for programmable events associated with the therapy management, and voice enabled communication between devices in the therapy management system.

FIG. **1** is a block diagram illustrating a therapy management system for practicing one embodiment of the present disclosure. Referring to FIG. **1**, the therapy management system **100** includes an analyte monitoring system **110** operatively coupled to a fluid delivery device **120**, which may be in turn, operatively coupled to a remote terminal **140**. As shown in the Figure, the analyte monitoring system **110** is, in one embodiment, coupled to the patient **130** so as to monitor or measure the analyte levels of the patient. Moreover, the fluid delivery device **120** is coupled to the patient using, for example, an infusion set and tubing connected to a cannula (not shown) that is placed transcutaneously through the skin of the patient so as to infuse medication such as, for example, insulin, to the patient.

Referring to FIG. **1**, the analyte monitoring system **110** in one embodiment may include one or more analyte sensors subcutaneously positioned such that at least a portion of the analyte sensors are maintained in fluid contact with the patient's analytes. The analyte sensors may include, but are not limited to short term subcutaneous analyte sensors or transdermal analyte sensors, for example, which are configured to detect analyte levels of a patient over a predetermined time period, and after which, a replacement of the sensors is necessary.

The one or more analyte sensors of the analyte monitoring system **110** is coupled to a respective one or more of a data transmitter unit which is configured to receive one or more signals from the respective analyte sensors corresponding to the detected analyte levels of the patient, and to transmit the information corresponding to the detected analyte levels to a receiver device, and/or fluid delivery device **120**. That is, over a communication link, the transmitter units may be configured to transmit data associated with the detected analyte levels periodically, and/or intermittently and repeatedly to one or more other devices such as the fluid delivery device **120** and/or the remote terminal **140** for further data processing and analysis.

In one aspect, each of the one or more receiver devices of the analyte monitoring system **110** and the fluid delivery device **120** includes a user interface unit which may include a display unit, an audio output unit such as, for example, a speaker, or any other suitable user interface mechanism for displaying or informing the user of such devices.

The transmitter units of the analyte monitoring system **110** may in one embodiment be configured to transmit the analyte related data substantially in real time to the fluid delivery device **120** and/or the remote terminal **140** after receiving it from the corresponding analyte sensors such that the analyte level such as glucose level of the patient **130** may be monitored in real time. In one aspect, the analyte levels of the patient may be obtained using one or more of discrete blood glucose testing devices such as blood glucose meters that employ glucose test strips, or continuous analyte monitoring systems such as continuous glucose monitoring systems. In a further embodiment, the analyte monitoring system **110** may include a blood glucose meter such as FreeStyle® and Precision meters available from Abbott Diabetes Care Inc., of Alameda Calif. The blood glucose meter may be used to calibrate the sensors in the analyte monitoring system **110**. Exemplary analyte systems that may be employed are described in, for example, U.S. Pat. Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, and elsewhere, the disclosures of which are herein incorporated by reference.

Analytes that may be monitored, determined or detected in the analyte monitoring system **110** include, for example, acetyl choline, amylase, amylin, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, measures for oxidative stress (such as 8-iso PGF2gamma), peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), biguanides, digitoxin, digoxin, drugs of abuse, GLP-1, insulin, PPAR agonists, sulfonylureas, theophylline, thiazolidinediones, and warfarin, may also be determined.

Moreover, within the scope of the present disclosure, the transmitter units of the analyte monitoring system **110** may be configured to directly communicate with one or more of the remote terminal **140** or the fluid delivery device **120**. Furthermore, within the scope of the present disclosure, additional devices may be provided for communication in the analyte monitoring system **110** including additional receiver/data processing units, remote terminals (such as a physician's terminal and/or a bedside terminal in a hospital environment, for example).

In addition, within the scope of the present disclosure, one or more of the analyte monitoring system **110**, the fluid delivery device **120** and the remote terminal **140** may be configured to communicate over a wireless data communication link such as, but not limited to RF communication link, Bluetooth® communication link, infrared communication link, or any other type of suitable wireless communication connection between two or more electronic devices, which may further be uni-directional or bi-directional communication between the two or more devices. Alternatively, the data communication link may include wired cable connections such as, for example, but not limited to RS232 connection, USB connection, or serial cable connection.

The fluid delivery device **120** may include in one embodiment, but not limited to, an external infusion device such as an external insulin infusion pump, an implantable pump, a pen-type insulin injector device, a patch pump, an inhalable infusion device for nasal insulin delivery, or any other type of suitable delivery system. In addition, the remote terminal **140** in one embodiment may include for example, a desktop computer terminal, a data communication enabled kiosk, a laptop computer, a handheld computing device such as a personal digital assistant (PDAs), or a data communication enabled mobile telephone.

Referring back to FIG. **1**, in one embodiment, the analyte monitoring system **110** includes a strip port configured to receive a test strip for capillary blood glucose testing. In one aspect, the glucose level measured using the test strip may in addition, be configured to provide periodic calibration of the analyte sensors of the analyte monitoring system **110** to assure and improve the accuracy of the analyte levels detected by the analyte sensors.

Referring yet again to FIG. **1**, in one embodiment of the present disclosure, the fluid delivery device **120** may be configured to include a voice signal activation/generation unit for voice communication with the remote terminal **140** configured as a voice device such as a mobile telephone, a voice enabled personal digital assistant, a Blackberry device, or the like. For example, in one embodiment, the communication between the fluid delivery device **120** and the remote terminal **140** may be voice based such that the information or data output to the user from the fluid delivery device **120** is configured to be transmitted to the user's telephone. In turn, the fluid delivery device **120** may additionally be configured to receive voice commands from the remote terminal **140** configured as a telephone or any other voice signal communication device (such as personal computers or PDAs with voice signal capabilities).

In this manner, in one embodiment, the user interface of the fluid delivery device **120** may be configured with the voice signal activation/generation unit such that, output information for the user is converted into a voice signal and transmitted to the voice signal enabled remote terminal **140**. For example, when the fluid delivery device **120** detects an alarm condition, the fluid delivery device **120** is configured to initiate a telephone call to the user's telephone (remote terminal **140**), and when the user picks up the telephone line, the user is provided with a voice signal representing the alarm condition.

In a further embodiment, for certain predetermined patient conditions, the fluid delivery device **120** may be configured to initiate a telephone call directly to a preprogrammed telephone number of a health care physician, a local hospital, or emergency medical care facilities, in addition to or instead of initiating a telephone call to the user of the fluid delivery device **120**.

In addition, within the scope of the present disclosure, interaction and programming of the fluid delivery device **120** may be exclusively or partially exclusively performed over the user's telephone in voice communication with the fluid delivery device **120**. That is, when the user wishes to calculate a carbohydrate bolus in the fluid delivery device **120**, the user may dial a predetermined number using the user's telephone (remote terminal **140**) to connect with the fluid delivery device **120**, and the user may provide voice commands to the fluid delivery device **120** via the telephone connection between the user's telephone (remote terminal **140**) and the fluid delivery device **120**.

FIG. **2** is a block diagram of a fluid delivery device of FIG. **1** in one embodiment of the present disclosure. Referring to FIG. **2**, the fluid delivery device **120** in one embodiment includes a processor **210** operatively coupled to a memory unit **240**, an input unit **220**, a display unit **230**, an output unit **260**, and a fluid delivery unit **250**. In one embodiment, the processor **210** includes a microprocessor that is configured to and capable of controlling the functions of the fluid delivery device **120** by controlling and/or accessing each of the various components of the fluid delivery device **120**. In one embodiment, multiple processors may be provided as safety measure and to provide redundancy in case of a single processor failure. Moreover, processing capabilities may be shared between multiple processor units within the fluid delivery device **120** such that pump functions and/or control may be performed faster and more accurately.

Referring back to FIG. **2**, the input unit **220** operatively coupled to the processor **210** may include a jog dial key pad buttons, a touch pad screen, or any other suitable input mechanism for providing input commands to the fluid delivery device **120**. More specifically, in case of a jog dial input device, or a touch pad screen, for example, the patient or user of the fluid delivery device **120** will manipulate the respective jog dial or touch pad in conjunction with the display unit **230** which performs as both a data input and output unit. The display unit **230** may include a touch sensitive screen, an LCD screen, or any other types of suitable display unit for the fluid delivery device **120** that is configured to display alphanumeric data as well as pictorial information such as icons associated with one or more predefined states of the fluid delivery device **120**, or graphical representation of data such as trend charts and graphs associated with the insulin infusion rates, trend data of monitored glucose levels over a period of time, or textual notification to the patients.

In one embodiment, the alphanumeric representation displayed on the display unit **230** may be configured to be modified by the user of the fluid delivery device such that the size of the displayed number or character may be adjusted to suit the user's visual needs. For example, in one embodiment, the user may apply font size adjustment request via the input unit **220** to instruct the processor **210** to modify the size of the displayed number or character on the display unit **230**. In one aspect, the font size may be increased or decreased for each character, value or word displayed on the display unit **230**. Alternatively, the font size adjustment may be applied globally to all output settings, for example, under the control of the processor **210** such that the user setting of the size adjustment may be configured to apply to substantially all displayed values or characters on the display unit **230** of the fluid delivery device **120** (FIG. **1**).

Moreover, referring back to FIG. **2**, in a further aspect of the present disclosure, the relative size adjustment of the displayed character or value may be determined by the processor **210** so that the relative size adjustment may be implemented to the output display on the display unit **230**. In this manner, depending upon the type or configuration of the display unit **230** (whether bit map or icon type display), in one embodiment, the display size adjustment may be implemented within the predetermined size restrictions for the respective value or character. For example, a 10% relative increase in the font size for display area designated for insulin dosage level may correspond to a 5% relative increase in the size of the display area designated for the insulin delivery time display. In one embodiment, the processor **210** may be configured to determine the relative size modification for each area of the display unit **230** based on the user inputted size adjustment values to appropriately apply the relative size differential adjustment.

In a further aspect, the processor **210** may be configured to temporarily increase the font size displayed on the display unit **230** based on the user input commands such that the user requested size modification on the display unit **230** may be implemented only for the displayed screen at the time the user input commands for size adjustment is received by the processor **210**. In this manner, the processor may be configured to revert to the previously programmed display size settings for the display unit **230** when the user is no longer viewing the particular displayed screen from which the user has requested font size adjustment.

In addition, the user interface of the receiver unit of the analyte monitoring system **110** (FIG. **1**) may be configured with similar size adjustment capabilities so as to allow the user to instruct the controller or processor of the analyte monitoring system **110** to appropriately adjust the size of the displayed character or value on the display unit of the analyte monitoring system **110**.

In a further embodiment, the display unit **230** may be configured to display an indication or marker for the type of insulin or other medication being used by the fluid delivery device **120** such as, for example, Symlin and Byetta. Such a marker may, in one embodiment, be associated with a predefined icon or character for display on the display unit

230. In addition, within the scope of the present disclosure, the information associated with the displayed marker or indication may be stored in the memory unit **240** so that the user may retrieve this information as desired. In addition, an indication or a marker for shift work may be programmed in the fluid delivery device **120** (FIG. **1**) such that shift workers using the fluid delivery device **120** may align days and nights upon command based on the markers.

For example, if a user worked nightshifts on Mondays and Tuesdays and dayshifts on Thursdays and Fridays, this daily work pattern information may be stored, identified or marked in the fluid delivery device **120** to provide additional data management functionalities and a more robust therapy analysis. For example, meal times such as breakfasts, for example, at 8 pm on Monday and 9 pm on Tuesday (during the nightshifts) may be aligned with the breakfasts at 7 am on Thursday and 8 am on Friday. In this manner, the user may conveniently access meal (e.g., breakfast) related data and associated therapy information in conjunction with the operation of the fluid delivery device **120**. This may assist the user in improving upon the user's diet such as the daily food intake.

Referring to FIG. **2**, the output unit **260** operatively coupled to the processor **210** may include an audible alarm or alarms including one or more tones and/or preprogrammed or programmable tunes or audio clips, or vibratory alert features having one or more preprogrammed or programmable vibratory alert levels.

In addition, in one embodiment of the present disclosure, each alert event or alarm event may be programmed with combined notification features such that, depending upon the level of importance associated with each alert or alarm, a combination of vibratory, audible, or displayed indications may be provided to the user using the display unit **230** in combination with the output unit **260**.

For example, the processor **210** may be configured to provide combined vibratory and increasingly audible alerts on the output unit **260** in addition to intermittently flashing background light on the display unit **230** for one or more predetermined alarms that require immediate user attention. An example may include unexpected pressure increase in the infusion tubing which may indicate an occlusion or other undesirable condition that the user should be immediately notified. The processor **210** may be configured such that the alarm or alert may be automatically reasserted within a predetermined time period in the event the associated alarm or alert condition has not been cleared by the user. In addition, each alert/alarm feature may be individually programmed to include a wide selection of tones, audible levels, vibratory strength, and intensity of visual display.

In a further aspect, the fluid delivery device **120** may be configured to provide an alarm or alert indication associated with a change in temperature. That is, when the fluid delivery device **120** which contains the insulin (for example, in a reservoir) experiences a rise or drop in temperature, such change in the temperature may have an adverse effect on the insulin contained within the device **120**. Accordingly, a temperature sensor may be coupled to the processor **210** of the fluid delivery device **120** to detect the operating condition of the fluid delivery device **120** and to notify the user of changes in the temperature, when, for example, the temperature change reaches a predetermined threshold level that may potentially have an adverse impact upon the efficacy of the insulin being delivered.

Also shown in FIG. **2** is the fluid delivery unit **250** which is operatively coupled to the processor **210** and configured to deliver the insulin doses or amounts to the patient from the insulin reservoir or any other types of suitable containment for insulin to be delivered (not shown) in the fluid delivery device **120** via an infusion set coupled to a subcutaneously positioned cannula under the skin of the patient.

Referring yet again to FIG. **2**, the memory unit **240** may include one or more of a random access memory (RAM), read only memory (ROM), or any other type of data storage unit that is configured to store data as well as program instructions for access by the processor **210** and execution to control the fluid delivery device **120** and/or to perform data processing based on data received from the analyte monitoring system **110**, the remote terminal **140**, the patient **130** or any other data input source.

FIG. **3** is a flowchart illustrating the time zone detection procedure in the therapy management system in one embodiment of the present disclosure. Referring to FIG. **3**, the fluid delivery device **120** (FIG. **1**) may be configured to transmit a location position request (**310**) to for example, a global positioning system (GPS). Thereafter, the location information is received (**320**) by the processor **210** of the fluid delivery device **120**. The processor **210** is further configured to determine whether the location information has changed (**330**). That is, the processor **210** in one embodiment is configured to compare the receive location information which may include a current time zone information associated with the location of the fluid delivery device **120**, with the previously stored and operating time zone information in the fluid delivery device **120** in operation.

Referring back, if it is determined that the location information has not changed, then the routine terminates. On the other hand, if it is determined that the fluid delivery device location information has changed, then, the location change information is output (**340**) to the user on the display unit **230**, for example. Thereafter, the processor **210** may be configured to generate a user prompt or notification to modify the time zone information (**350**) of the fluid delivery device **120** such that it is updated to the new location where the fluid delivery device **120** is operating.

For example, when the fluid delivery device **120** is programmed with predetermined basal profiles and/or bolus functions that are time based and associated with an internal clock of the fluid delivery device **120**, it may be desired to modify some or all of the time based insulin delivery profiles programmed in the fluid delivery device **120** so as to correspond to the location of the fluid delivery device **120**. More specifically, if a user is traveling from a first location to a second location in which one or more time zones are traversed, e.g., by way of example from San Francisco to Paris, given the time difference, the meal times, and sleep times, for example, will change. In this case, it may be desirable to modify the preprogrammed time based insulin delivery profiles so that they are synchronized with the user events such as meals and sleep times.

Referring back to FIG. **3**, in one embodiment, the user responds to the time based programming change prompt provided by the processor **210**, then the processor **210** may be configured in one embodiment, to propagate the time change associated with the preprogrammed insulin delivery profile and notify the user to confirm the changes, prior to implementing the modification to the delivery profiles and any associated alerts or notifications. For example, in the case where the user has programmed to be alerted at a particular time of day, e.g., noon each day, for a bolus determination prior to lunch, the processor **210** in one embodiment is configured to either modify the internal clock of the fluid delivery device **120** or alternatively, modify the programmed alert for bolus determination so as to correspond to the new location of the user and the fluid delivery device **120**.

In another embodiment, the fluid delivery device **120** may be configured to include a time zone detection unit, such as for example, the processor **210** may be configured to communicate with a geographical location change detection mechanism (e.g., an atomic clock) operatively coupled to the processor **210** for performing the time zone detection procedure as described above in conjunction with FIG. **3**. In addition, the analyte monitoring system **110** may be configured to include a time zone detection unit as described above to automatically or based on a preprogrammed procedure, detect any location change associated with the analyte monitoring system **110**. In this manner, the analyte monitoring system **110** may be configured to automatically or based on a preprogrammed procedure, implement modifications to functions associated with the operation of the analyte monitoring system **110** that are temporally associated with the time of day information.

FIG. **4** is a flowchart illustrating the time zone detection procedure in the therapy management system in another embodiment of the present disclosure. Referring to FIG. **4**, the fluid delivery device **120** (FIG. **1**) may be configured to transmit a location position request (**410**) to for example, a global positioning system (GPS). Thereafter, the location information is received (**420**) by the processor **210** of the fluid delivery device **120**. The processor **210** is further configured to determine whether the location information has changed (**430**). That is, the processor **210** in one embodiment is configured to compare the receive location information which may include a current time zone information associated with the location of the fluid delivery device **120**, with the previously stored and operating time zone information in the fluid delivery device **120** in operation.

Referring back, if it is determined that the location information has not changed, then the routine terminates. On the other hand, if it is determined that the fluid delivery device location information has changed, then, the processor **210** in one embodiment is configured to retrieve one or more time based programmed functions (**440**) from the memory unit **240** of the fluid delivery device **120**, for example.

Thereafter, the processor **210** may be further configured to modify the retrieved time based preprogrammed functions in accordance with the location change information received (**450**). Then, the modified retrieved functions are provided to the user (**460**) on the display unit **230**, for example, to request confirmation of the time based adjustments, prior to the processor **210** executing the modified retrieved functions.

In addition, in one embodiment of the present disclosure, the fluid delivery device **120** may be configured to detect for daylight savings time and the processor **210** may be configured to either automatically execute the time change in the internal clock of the fluid delivery device, and/or provide a user notification to accept such time based change so that the operation of the fluid delivery device **120** performing time based programs are updated with any time based change in the insulin delivery system **120** operating environment.

Within the scope of the present disclosure, the fluid delivery device **120** may be configured to receive location information from any positioning system which provides updated time information based on location. The fluid delivery device **120** may be configured with a positioning transceiver that is configured to transmit location information requests to a satellite network, for example, and to receive the location information therefrom.

Alternatively, the fluid delivery device **120** may be configured to update its location information locally upon synchronization with another device operating in the local (or at the new location). This may include a host computer terminal connectable to the fluid delivery device **120** such as, for example, the remote terminal **140** (FIG. **1**), the analyte monitoring system **110**, or any other electronic device operating in the new location with communication capabilities with the fluid delivery device **120** such as a cellular telephone, a personal digital assistant, and the like.

In addition, within the scope of the present disclosure, the procedure and processes described in conjunction with FIGS. **3-4** associated with location change information and corresponding modification to the time based preprogrammed functions in the fluid delivery device **120** may be provided to the analyte monitoring system **110** such that the analyte monitoring system **110** is also configured to receive new location information and correspondingly perform modifications to any time based preprogrammed functions.

FIG. **5** is a flowchart illustrating the device synchronization procedure in the therapy management system in one embodiment of the present disclosure. Referring to FIG. **5**, in one embodiment the fluid delivery device **120** (FIG. **1**) may be configured to detect a synchronization request (**510**) from another device such as the remote terminal **140** or the analyte monitoring system **110** (FIG. **1**). Thereafter, data communication connection is established (**520**) between the fluid delivery device **120** and the synchronization requesting device. In one embodiment, the fluid delivery device **120** is configured to verify the authenticity or identity of the device requesting synchronization, and upon synchronization approval, the fluid delivery device **120** is configured to establish communication with the synchronization requesting device.

In addition, within the scope of the present disclosure, the fluid delivery device **120** may be configured to periodically or at a predetermined time interval, establish communication connection with another device for synchronization. Alternatively, the fluid delivery device may be configured to attempt communication connection when another device for synchronization is detected within a predefined distance from the location of the fluid delivery device **120**.

Referring back to FIG. **5**, the fluid delivery device **120** is configured in one embodiment to transmit its programmed and operating settings to the connected device (**530**), and the connected device is configured to update and store the data received from the fluid delivery device **120** based on predetermined conditions (**540**). For example, the predetermined conditions may include a predefined set of rules associated with the type of data from the fluid delivery device **120** to be updated such as historical infusion related information, programmed functions in the fluid delivery device **120** such as bolus calculations, temporarily basal profiles, programmed basal profiles, insulin usage level, and any other information that is associated with the user.

In this manner, in one embodiment of the present disclosure, periodic synchronization of the fluid delivery device **120** settings and functions may be synchronized to another device so that when the user replaces the fluid delivery device **120**, the new or upgrade fluid delivery device may be easily and readily programmed to the user's specification. The synchronization described above may be configured to be performed periodically at a regular interval such as, once a week, once per day, when certain predefined criteria are met such as when the devices are within a predetermined distance from each other, and/or upon user command.

In addition, within the scope of the present disclosure, the fluid delivery device **120** may be configured with any communication protocol which would allow data transfer between the fluid delivery device **120** and the synchronizing device. This may include, wired or wireless communication including for example, Bluetooth® protocol, 802.1x protocol, USB cable connection and the like.

FIG. **6** is a flowchart illustrating device condition notification function in the therapy management system in one embodiment of the present disclosure. Referring to FIG. **6** the fluid delivery device **120** may be configured to detect a notification condition (**610**). For example, the processor **210** may be configured to detect such notification conditions at a preprogrammed time interval (such as about every 24 hours, for example). Thereafter, the programmed profile associated with the condition is retrieved (**620**). An example of the programmed profile associated with the condition includes a reminder to start an overnight fast for the user.

Referring back to FIG. **6**, the processor **210** in one embodiment is further configured to generate a message associated with the notification condition and/or the retrieved programmed profile (**630**), and, the generated message is provided to the user (**640**) on one or more of the display unit **230** or the output unit **260**. In this manner, in one embodiment of the present disclosure, the fluid delivery device **120** may be programmed with automatic reminders for conditions to assist the user to improve insulin therapy management.

In one embodiment, the notification condition detection may be skipped and the processor **210** may be configured to retrieve the appropriate programmed profile associated with notification conditions based on the user programming of the fluid delivery device **120**. Additionally, while a reminder for overnight fast is described as an example, any other therapy related reminders or device operating condition reminders may be programmed for execution by the processor **210** to remind the user. Examples of such reminders include, but are not limited to, infusion set replacement reminder, battery replacement reminder, data synchronization reminder, insulin replenishment reminder, glucose testing reminder, and the like. In addition, within the scope of the present disclosure, the procedure described in conjunction with FIG. **6** may be incorporated in the analyte monitoring system **110** for programming suitable automatic reminders such as, for example, sensor replacement reminder, sensor calibration reminder, and the like.

FIG. **7** is a flowchart illustrating automatic time information detection function incorporated in a medical device such as a blood glucose meter of the analyte monitoring system **110** in one embodiment of the present disclosure. Referring to FIG. **7**, when the medical device active state is detected (**710**) for example, by the user initiated power on procedure of the medical device such as a blood glucose meter, a routine is called by the processor of the medical device to automatically initiate time acquisition protocol. That is, upon power on of the medical device, the device is automatically configured to perform time acquisition protocol to, among others, transmit request for time and/or date information to available communication channels, and upon receiving the information, to store, update and/or otherwise set and/or display the received or acquired time/date information in the medical device (**720-740**).

Referring back to FIG. **7**, in one embodiment, the time information is received at step **730**, and thereafter, the received time information is stored and/or displayed on a display unit of the medical device. In one aspect, the medical device is configured to update all previously stored time associated data (for example, blood glucose readings taken at certain times of the day (or week, month, or any other time period)). More specifically, in one embodiment, when the medical device such as the blood glucose meter is activated by the user, the processor or controller of the glucose meter is configured to enable or activate time/date receiver (for example, a communication component such as a radio frequency transceiver coupled to the processor of the glucose meter). The time/date receiver in one embodiment is configured to seek or acquire automatically, upon activation, time and date information from one or more available communication networks within range. For example, the time/date receiver may be configured to detect the time/date information from one or more radio frequencies on public, government, or private airwaves using AM band short frequency or FM band long wave frequency. Alternatively, as discussed above, current local time/date information may be received from global positioning satellites, as well as cellular telephone networks such as GSM, CDMA, AMPS, and the like within range of the time/date receiver in the medical device. Additionally, WiFi network may be used to receive the time/data information, if available and within range.

In this manner, in one embodiment, the medical device such as a blood glucose meter, may be configured to automatically acquire time information that is continuously broadcast on a frequency in which the antenna and the receiver of the blood glucose meter are configured to operate. Upon obtaining and verifying the time and date information, the internal clock function or component is updated or adjusted with the acquired time/date information and displayed to the user, for example.

In a further embodiment, the medical device such as a blood glucose meter may be configured to use GMT time as the reference time for all log entry (for example, for each blood glucose test performed) timestamps associated with each data stored in the medical device. Thereafter, the medical device may be configured to convert the stored GMT based time information for each log entry stored in the medical device to the local time based on the location of the medical device.

FIG. **8** is a flowchart illustrating automatic time information detection function incorporated in a medical device such as a blood glucose meter in another embodiment of the present disclosure. Referring to FIG. **8**, in one embodiment, the automatic time acquisition protocol is initiated based on a detection of one or more changed or preconfigured parameters associated with the medical device and/or the user of the medical device (**810**). For example, the device parameter may include a preconfigured time for periodically checking for time and date information (such as every 24 hours, 48 hours, or based on a programmed calendar such as to compensate for daylight savings time change).

Alternatively, the device parameter may include an environmental condition change associated with the medical device or the user, such as a detection of the medical device location such as during travel by air or a vehicle. That is, in one embodiment, the medical device may be configured to include an altimeter which is coupled to the processor of the medical device to detect a change in altitude of the medical device location for example, when the user of the medical device is traveling by air. In such a case, the medical device may be configured to initiate the time acquisition protocol to confirm or verify the time and date information of the medical device (**820-840**).

Further, the medical device may include an accelerometer which may be configured to initiate the automatic time acquisition protocol on the medical device when a predetermined threshold level of acceleration force is reached. Within the scope of the present disclosure, other parameters may be used in conjunction with the medical device to trigger the automatic time acquisition protocol on the medical device (**820-840**) such that, without user intervention, prompting, or initiating, the medical device is configured to automatically initiate time and date information acquisition routine. In addition, the functionality of the automatic time and date information acquisition may be incorporated in other medical devices such as infusion pumps, continuous glucose monitoring devices, heart rate monitors, and the like that are configured to maintain a time associated log of physiological data (such as glucose levels, insulin infusion rates, cardiac signal levels and so on) of a patient or a user.

FIGS. **9**A-**9**C illustrate embodiments of automatic expiration detection function on blood glucose meter test strips in accordance with one embodiment of the present disclosure. Presently, test strips for use with blood glucose meters are sold or made available in containers that include the expiration date information of the test strips contained therein. For diabetic patients or healthcare providers using glucose meters, it is important to check the expiration information of the test strip before testing for glucose levels so that the obtained results are accurate.

Referring to FIGS. **9**A-**9**C, in one embodiment, test strips may be configured with predefined parameters to allow automatic expiration date detection of the test strip. In one aspect, resistance values are provided on the test strips such that when the test strip is inserted into the strip port of the blood glucose meter, the meter is configured to compare the detected resistance value to a stored value of resistance, and determine whether the inserted test strip has expired or not. More specifically, in one embodiment, using the resistance value on the test strip, the expiration date information may be coded, and the meter may be configured to detect the resistance value of the test strip and determine whether the test strip has expired.

In one aspect, the resistance value on the test strip may be controlled with the ink formulation on the wake up bar and/or patterns provided thereon. Silver, gold, carbon or any other suitable conductive material may be used to increase the resistance as may be desired. The blood glucose meter may be configured such that the strip port includes a current connector and predetermined control lines that may be configured to measure the resistance values coded on the test strips. More specifically, in one embodiment, the expiration dates may be coded using the resistance value on the wake-up bar in a logical sequence such as follows:

Resistance Value	Expiration Date
300-310 kOhm	Q1 of odd year
315-320 kOhm	Q2 of odd year
350-360 kOhm	Q1 of even year

Referring to FIGS. **9**A-**9**C, it can be seen that the wavy lines may increase in thickness or length to change the resistance on the test strip. Furthermore, the pads on the test strip are shown to make contact with the wake-up bar on the strip port. By way of an example, FIG. **9**A illustrates 300 KOhm trace width, FIG. **9**B illustrates 315 KOhm trace width, and FIG. **9**C illustrates 350 KOhm trace width, each associated with a predefined expiration date as described above.

In this manner, in one embodiment of the present disclosure, expiration date of test strips may be automatically detected so that the user is notified of expired date of a given test strip before it used to test for blood glucose levels. Moreover, while the automatic expiration detection is described in conjunction with test strip and blood glucose meters, within the scope of the present disclosure, other medical device or consumable items with expiration dates may benefit from the technique described herein.

Furthermore, within the scope of the present disclosure, the expiration time information may be provided on the test strip using techniques other than, for example, resistance values provided on the wake up bar. That is, the coded or stored expiration time information may be provided on the test strip or other medical components such as analyte sensors, catheters, medication cartridges, for example, using capacitance, or thermal coating. Accordingly, the expiration of the test strip or consumable medical components may be readily and easily ascertained.

A method in one aspect of the present disclosure includes detecting a presence of a medical component, determining a resistance value associated with the medical component, retrieving a stored resistance value associated with a predetermined time information, comparing the determined resistance value to the stored resistance value, and generating an output signal based on the comparison.

The predetermined time information may include expiration information associated with the medical component.

The medical component may include one or more of an analyte sensor, a blood glucose test strip, a medication cartridge, an infusion device infusion set, or a catheter.

The medical component may include a glucose test strip for determining a glucose level using a predetermined volume of blood sample, where the predetermined volume may include 1.0 microliter or less of blood sample, 0.5 microliter or less of blood sample, 0.25 microliter or less of blood sample, or 0.1 microliter or less of blood sample. Additional description related to using a small volume of sample to determine analyte levels using in vitro analyte sensor is provided in U.S. Pat. Nos. 6,143,164 and 6,592,745, the disclosure of which is incorporated herein by reference for all purposes.

The resistance value may be provided on the medical component, using for example, silver, gold, carbon, one or more combinations thereof, or ink formulation based thereon.

The medical component may include a glucose test strip having a wake up bar, and further, where the resistance value is provided using ink formulation on the wake up bar.

The method may include outputting the generated output signal, where the generated output signal may include one or more of an audible signal such as an audible alarm, a visual signal such as, for example, graphical or text display of the information, or a vibratory signal.

The generated output signal may include a notification of the medical component expiration.

An apparatus in a further aspect of the present disclosure includes a housing, a test strip port coupled to the housing for receiving a test strip, a memory unit coupled to the housing, and a processing unit operatively coupled to the memory unit, the test strip port and the housing, the processing unit configured to detect a resistance value associated with the test strip, to retrieve a predetermined time information associated with the detected resistance value, and to generate an output signal based on the retrieved predetermined time information.

The test strip may include a glucose test strip.

The memory unit may be configured to store a plurality of predetermined resistance values, each associated with a respective predetermined time information.

The predetermined time information may be associated with expiration information for the test strip.

The predetermined time information may include time and date information.

The apparatus may include an output unit coupled to the housing, the display unit configured to display the generated output signal, where the output unit may include one or more of an audible output unit, a textual output unit, a vibratory output unit, or a graphical output unit.

The generated output signal may include a notification of the test strip expiration information.

A method in a further embodiment may include detecting insertion of a glucose test strip, determining a resistance value associated with the test strip, retrieving an expiration information associated with the determined resistance value, and generating an expiration notification based on the expiration information.

The resistance value may be provided on the test strip, for example, using ink formulation.

A therapy management system in one embodiment of the present disclosure includes an infusion device including a processing unit configured to perform data processing, and a user interface unit operatively coupled to a processing unit, where the processing unit is configured to detect a location information associated with the infusion device for output to the user interface unit.

The location information in one embodiment is time based.

In one aspect, the location information is associated with a local time information based on the location of the infusion device, where the location information may be received from a global positioning system (GPS) or from another device, such as a mobile telephone, a GPS enabled personal digital assistant, which has received that information from a global positioning system.

In one aspect, a clock unit may be operatively coupled to the processing unit, where the clock unit is configured to dynamically adjust the location information based on the location of the infusion device.

In a further embodiment, the clock unit may include an atomic clock.

The processor unit may be configured to generate a notification associated with the detected location information for output to the user interface unit, where the notification may be output to the user interface unit as one or more of a date information and time information associated with the location of the infusion device.

The processing unit may be configured to retrieve one or more programmed procedures associated with time, where the one or more programmed procedures may include one or more basal profiles, a programmed bolus determination schedule, a time based condition alert.

The time based condition alert may include one or more of a time based reminder associated with the operation of the infusion device. Further, the time based condition alert may include one or more of a time based reminder associated with the condition of the infusion device user.

In a further aspect, the processor unit may be configured to automatically adjust one or more time based functions associated with the operation of the infusion device based on the detected location information.

A method in accordance with another embodiment includes detecting a change in the location information of a therapy management device, comparing the detected change with a stored location information, and executing one or more processes associated with the operation of the therapy management device based on the detected change.

The detected change in the location information may include one of a time zone change, a time standard change, a date change, or combinations thereof.

The one or more processes may include generating a notification associated with the detected change in the location information.

Further, the one or more processes may include modifying one or more programmed time based functions of the therapy management device and which may include one or more of a programmed time based alert, a programmed time based fluid delivery determination; a programmed time based fluid delivery profile, or a programmed time based operational condition of the therapy management device.

In still another aspect, the therapy management device may include one or more of an infusion device or an analyte monitoring unit.

A therapy management system in accordance with still another embodiment of the present disclosure includes an infusion device, and a communication unit operatively coupled to the infusion device over a wireless data network, the communication device configured to transmit a request for synchronization to the infusion device, where the infusion device may be configured to transmit one or more data to the communication unit in response to the received synchronization request.

The wireless data network may be based on one or more of a Bluetooth® communication protocol, an RF communication protocol, an infrared communication protocol, a Zigbee® communication protocol, an 802.1x communication protocol, or a wireless personal area network such as ANT protocol.

In a further aspect, the wireless data network may include one or more of a wireless local area network, or a WiFi network.

The communication unit may be configured to periodically transmit the synchronization request at a predetermined time interval.

Further, the infusion device may be configured to verify the received synchronization request before transmitting the one or more data to the communication unit.

The transmitted one or more data to the communication unit may be encrypted, and also, the communication unit may be configured to decrypt the received one or more encrypted data.

The transmitted one or more data may include one or more information associated with the stored user profile of the infusion device, an operating parameter of the infusion device, or infusion delivery information.

The communication unit may include one or more of an analyte monitoring unit, a personal digital assistant, a mobile telephone, a computer terminal, a server terminal or an additional infusion device.

A system for communicating with an infusion device in still another embodiment of the present disclosure includes a voice enabled device and an infusion device configured to communicate with the voice enabled device using one or more voice signals.

In one aspect, the voice enabled device may include one or more of a telephone set, a mobile telephone, a voice of IP (Internet Protocol) telephone, a voice enabled computing device, or a voice enabled computer terminal.

The infusion device may be configured to initiate a voice enabled communication to the voice enabled device. For example, the infusion device may be integrated with mobile telephone components.

In one aspect, the voice enabled communication may include a telephone call.

The infusion device may be configured to receive one or more voice commands from the voice enabled device, where the infusion device may be configured to process the one or more voice commands to execute one or more associated functions of the infusion device operation.

The one or more associated functions include a bolus dosage determination, a programmable notification, or a temporarily basal dosage determination.

A method in accordance with yet still another embodiment of the present disclosure includes initiating a voice signal based communication from an infusion device, and transmitting a voice signal associated with the operation of the infusion device.

The method may also include receiving a voice signal based request over a communication network, and executing one or more functions associated with the operation of the infusion device based on the received voice signal based request.

The voice signal based communication may include a telephone call.

A therapy management kit in accordance with still yet another embodiment includes an infusion device including a processing unit configured to perform data processing, and a user interface unit operatively coupled to a processing unit, where the processing unit is configured to detect a location information associated with the infusion device for output to the user interface unit.

The kit may further include a clock unit operatively coupled to the processing unit, where the clock unit is configured to dynamically adjust the location information based on the location of the infusion device.

The clock unit may include an atomic clock.

In a further aspect, the kit may also include a voice enabled device, where the infusion device may be further configured to communicate with the voice enabled device using one or more voice signals.

In one aspect, the voice enabled device may include one or more of a telephone set, a mobile telephone, a voice of IP (Internet Protocol) telephone, a voice enabled computing device, or a voice enabled computer terminal.

The various processes described above including the processes performed by the processor **210** in the software application execution environment in the fluid delivery device **120** as well as any other suitable or similar processing units embodied in the analyte monitoring system **120** and the remote terminal **140**, including the processes and routines described in conjunction with FIGS. **3-8**, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in the memory unit **240** (or similar storage devices in the analyte monitoring system **110** or the remote terminal **140**) of the processor **210**, may be developed by a person of ordinary skill in the art and may include one or more computer program products.

In addition, all references cited above herein, in addition to the background and summary of the invention sections, are hereby incorporated by reference into the detailed description of the preferred embodiments as disclosing alternative embodiments and components.

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present disclosure and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A device, comprising:
- a user interface to receive a user input, and to output information related to the operation of the device;
- a communication component to receive glucose data based on signals generated by an in vivo glucose sensor;
- one or more processors; and
- a memory storing instructions which, when executed by the one or more processors, cause the one or more processors to: store the information related to the operation of the device in the memory, and determine a change in environment in which the device is operating, and in response obtain time data and update the stored information based on the time data.

2. The device of claim **1**, wherein the change in environment corresponds to a change in time zone in which the device is operating.

3. The device of claim **1**, wherein the change in environment corresponds to a change in altitude of the device location.

4. The device of claim **1**, wherein the information related to the operation of the device is information for a therapy profile for a user.

5. The device of claim **1**, wherein the communication component is configured to receive the glucose data over at least one of an RF communication link, a Bluetooth communication link, or an infrared communication link.

6. The device of claim **1**, wherein the in vivo glucose sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

7. The device of claim **6**, wherein the analyte-responsive enzyme is chemically bonded to the polymer.

8. The device of claim **6**, wherein the working electrode further comprises a mediator.

9. The device of claim **1**, wherein the in vivo glucose sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

10. The device of claim **9**, wherein the mediator is chemically bonded to the polymer.

11. A system, comprising:
- an in vivo glucose sensor; and
- a receiving device, comprising:
  - a user interface to receive a user input, and to output information related to the operation of the receiving device;
  - a communication component to receive glucose data based on signals generated by the in vivo glucose sensor;
  - one or more processors; and
  - a memory storing instructions which, when executed by the one or more processors, cause the one or more

processors to: store the information related to the operation of the receiving device in the memory, and determine a change in environment in which the receiving device is operating, and in response obtain time data and update the stored information based on the time data.

12. The system of claim **11**, wherein the change in environment corresponds to a change in time zone in which the receiving device is operating.

13. The system of claim **11**, wherein the change in environment corresponds to a change in altitude of the receiving device location.

14. The system of claim **11**, wherein the information related to the operation of the receiving device is information for a therapy profile for a user.

15. The system of claim **11**, wherein the communication component is configured to receive the glucose data over at least one of an RF communication link, a Bluetooth communication link, or an infrared communication link.

16. The system of claim **11**, wherein the in vivo glucose sensor comprises a plurality of electrodes including a working electrode comprising an analyte-responsive enzyme bonded to a polymer disposed on the working electrode.

17. The system of claim **16**, wherein the analyte-responsive enzyme is chemically bonded to the polymer.

18. The system of claim **16**, wherein the working electrode further comprises a mediator.

19. The system of claim **11**, wherein the in vivo glucose sensor comprises a plurality of electrodes including a working electrode comprising a mediator bonded to a polymer disposed on the working electrode.

20. The system of claim **19**, wherein the mediator is chemically bonded to the polymer.

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