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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 August 2012 (16.08.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/108935 A1

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

(21) **International Application Number**:
PCT/US2011/066418

(22) **International Filing Date**:
21 December 2011 (21.12.2011)

(25) **Filing Language**: English

(26) **Publication Language**: English

(30) **Priority Data**:
61/442,093 11 February 2011 (11.02.2011) US

(71) **Applicant** *(for all designated States except US)*: **ABBOTT DIABETES CARE INC.** [US/US]; 1360 South Loop Road, Alameda, California 94502 (US).

(72) **Inventors; and**

(75) **Inventors/Applicants** *(for US only)*: **BRADRICK, Brittany K.** [US/US]; 425 1st Street, #1508, San Francisco, California 94105 (US). **BERNSTEIN, Daniel M.** [US/US]; P.O. Box 1236, El Granada, California 94018 (US). **DAVIS, Eric** [US/US]; 3380 Sydney Way, Castro Valley, California 94546 (US). **DUNN, Timothy C.** [US/US]; 812 Clayton Street, San Francisco, California 94117 (US). **GOLDSMITH, Joel** [US/US]; 8410 Pine Hills Drive, Oakland, California 94611 (US). **GOPAL, Mani** [IN/US]; 1520 Oak Rim Drive, Hillsborough, California 94010 (US). **HAYTER, Gary A.** [US/US]; 4409 Harbord Drive, Oakland, California 94618 (US). **WINKLER, Todd** [US/US]; 3185 Aeronca Way, Cameron Park, California 95682 (US).

(74) **Agent**: **BABA, Edward J.**; 1900 University Avenue, Suite 200, East Palo Alto, California 94303 (US).

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

[Continued on next page]

(54) **Title**: SENSOR-BASED INFORMATICS TELEMEDICINE DISEASE MANAGEMENT SOLUTION

(57) **Abstract**: Provided herein are systems and associated devices configured to capture biometric patient data; e.g., blood glucose data; transmit such data to a location-independent "cloud", the Internet, or other shared server system, hereinafter referred to as "the Cloud"; and provide automated data-based algorithms to analyze data and deliver therapy recommendations, related output, and/or therapy recommendation decision support to one or more authorized stakeholders.

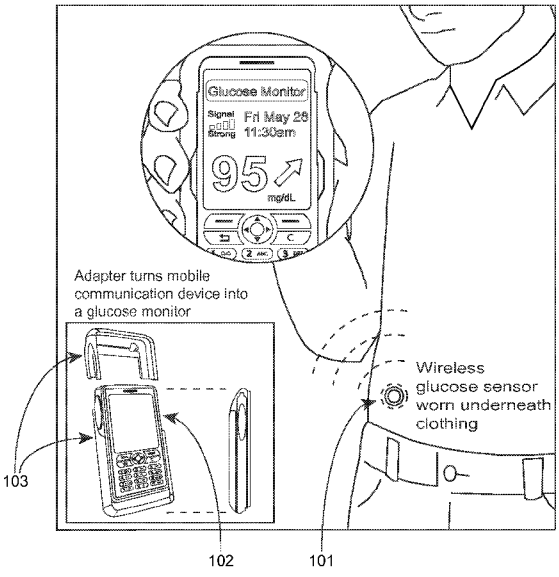

FIG. 6

WO 2012/108935 A1

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

Published:

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

SENSOR-BASED INFORMATICS TELEMEDICINE DISEASE MANAGEMENT SOLUTION

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] Pursuant to 35 U.S.C. § 119(e), this application claims priority to U.S. Provisional Application No. 61/442,093 filed on February 11, 2011, the disclosure of which is herein incorporated by reference in its entirety.

[0002] This application is related to U.S. Provisional Application No. 61/442,085 filed on February 11, 2011; U.S. Provisional Application No. 61/486,117 filed on May 13, 2011; U.S. Provisional Patent Application No. 61/442,063 filed on February 11, 2011; U.S. Provisional Application No. 61/442,092 filed on February 11, 2011; U.S. Provisional Application No. 61/485,840 filed on May 13, 2011; and U.S. Provisional Application No. 61/442,097 filed on February 11, 2011, the disclosures of which are all incorporated herein by reference in their entirety and for all purposes.

BACKGROUND OF THE INVENTION

The Field of the Invention

[0003] The present disclosure relates to the field of informatics-based telemedicine disease management solutions.

Background

[0004] Current approaches to disease management include systems designed to provide greater connectivity between patients and health care providers (HCPs) or other stakeholders. These systems may analyze biometric patient data and provide feedback to the patient, HCP or other stakeholder. However such systems may be limited by the quantity and/or quality of the biometric patient data provided as input and/or the ability of one or more system components to provide meaningful therapy recommendations in response to such data. The present disclosure addresses these issues and provides related advantages.

BRIEF SUMMARY

[0005] The present disclosure provides systems and associated devices configured to capture biometric patient data; e.g., blood glucose data; transmit such data to a location-independent "cloud", the Internet, or other shared server system, hereinafter referred to as "the Cloud"; and provide automated data-based algorithms to analyze data and deliver therapy recommendations, related output, and/or therapy recommendation decision support to one or more authorized stakeholders.

[0006] It should be noted that two or more of the embodiments described herein may be combined to produce one or more additional embodiments which include the combined features of the individual embodiments.

BRIEF DESCRIPTION OF THE FIGURES

[0007] The accompanying drawings, which are incorporated herein, form part of the specification. Together with this written description, the drawings further serve to explain the principles of, and to enable a person skilled in the relevant art(s), to make and use the present invention.

[0008] **FIG. 1** provides a diagram of a first embodiment of a health management system according to the present disclosure. The arrows depict information and/or data flow between system components.

[0009] **FIG. 2** provides a diagram of a second embodiment of a health management system according to the present disclosure. The arrows depict information and/or data flow between system components.

[0010] **FIG. 3** provides a diagram of a third embodiment of a health management system according to the present disclosure. The arrows depict information and/or data flow between system components.

[0011] **FIG. 4** provides a diagram of a fourth embodiment of a health management system according to the present disclosure. The arrows depict information and/or data flow between system components.

[0012] **FIG. 5** provides a diagram of a fifth embodiment of a health management system according to the present disclosure. The arrows depict information and/or data flow between system components.

[0013] **FIG. 6** provides a depiction of a system in which a mobile communication device is fitted with an adapter to allow for wireless communication of sensor data from a biometric sensor to the mobile communication device.

[0014] **FIG. 7** provides a depiction of a system in which a mobile communication device is fitted with an adapter to allow for wireless communication of sensor data from a biometric sensor to the mobile communication device. The mobile communication device can then communicate the sensor data or associated information to one or more authorized stakeholders, e.g., an HCP, family member, etc., via the Cloud or one or more wireless networks.

DETAILED DESCRIPTION OF THE INVENTION

[0015] Before the embodiments of the present disclosure are described, it is to be understood that this invention is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the embodiments of the invention will be limited only by the appended claims.

[0016] Several system embodiments are now described with reference to the figures. One embodiment of a system according to the present disclosure may be described generally with reference to FIG. 1, which depicts a system **100** including system components **101**-**107**. The flow of information and/or data between the system components may be as indicated by the arrows. It should be noted that the flow of information and/or data between any two system components described herein may be unidirectional or bidirectional as appropriate. System **100** includes one or more biometric sensors **101** which are used to acquire biometric information and/or data from a patient. Biometric information and/or data which may be acquired by the biometric sensors **101** includes, e.g., glucose levels (e.g., blood glucose levels), cholesterol levels, basal metabolic rate and/or calorie output. Suitable sensors which may be utilized as the biometric sensors **101** include, e.g., continuous and on-demand glucose sensors. These glucose sensors are described in greater detail below as well as in various documents incorporated by reference herein. In some embodiments, the biometric sensors **101** are wireless sensors capable of wirelessly transferring information and/or data collected by the sensor to one or more remote devices.

[0017] Mobile communication device **102** is a remote device which may be configured to wirelessly receive biometric information and/or data from the one or more biometric sensors **101**. In one embodiment, mobile communication device **102** is configured to receive biometric information and/or data directly from the one or more biometric

sensors **101**. Such an embodiment is depicted, e.g., in the form of system **200** of FIG. 2. In another embodiment, the system **100** includes an adapter **103** for the mobile communication device **102**, which adapter is configured to receive the biometric information and/or data from the biometric sensor **101** and transfer the biometric information and/or data from the adapter **103** to the mobile communication device **102**. See, e.g., FIG. 1. It should be noted that while FIG. 1 depicts both the direct transfer of information and/or data from the biometric sensor **101** to the mobile communication device **102** and the indirect transfer of information and/or data through adapter **103**, these may be alternative embodiments. Accordingly, in some embodiments, adapter **103** will not be included in the system as depicted in system **200** of FIG. 2.

[0018] In one embodiment, e.g., as depicted in system **300** of FIG. 3, adapter **103** is not configured to communicate with a biometric sensor **101** but is instead configured as a biometric monitoring device, for example, the adapter **103** may be configured as a discrete analyte monitoring device which includes a test strip port for receiving an analyte test strip, e.g. a glucose test strip. A more detailed description of adapter **103** is provided below.

[0019] In another embodiment, e.g., as depicted system **400** of FIG. 4, the mobile communication device **102** is configured to receive biometric information and/or data solely from the one or more additional biometric data sources **104** as described herein.

[0020] A variety of mobile communication devices may be suitable for use as mobile communication device **102**. For example, suitable devices may include mobile phones, laptop computers; mobile devices, such as personal digital assistants (PDA)s, iPhone® devices, iPad® devices, Blackberry® devices, tablet computers, etc.; communication-enabled analyte meters; and other such devices known in the art.

[0021] Where biometric information and/or data is communicated by the one or more biometric sensors **101** to the mobile communication device **102**, either directly or via adapter **103**, such information and/or data may be communicated to a patient, e.g., visually via an integrated display of the mobile communication device **102**, audibly via an integrated speaker of the mobile communication device **102** or via an external speaker in communication with the mobile communication device **102**, and/or via a vibratory output of the communication device **102**.

[0022] In addition to receiving biometric sensor information and/or data from one or more biometric sensors **101**, mobile communication device **102** may be configured to receive biometric information and/or data from additional biometric data sources **104**. In

this manner, mobile communication device **102** may operate as a "hub" for a variety of other devices and/or sensors. Additional sources **104** may include, e.g., discreet glucose monitoring devices, insulin pumps, insulin pen devices, blood pressure cuffs, scales, respirometers, pedometers, pulse oximeters, medical imaging devices (e.g., retinal scanners), and additional patient monitoring devices known in the art. This additional biometric information and/or data may be transmitted directly from one of the above devices, e.g., via wired or wireless communication means, in the event such devices are configured for wired and/or wireless communication. Alternatively, or in addition, such information and/or data may be entered manually using one or more inputs devices of the mobile communication device **102**, e.g. a key pad or touch screen of mobile communication device **102**. Additional information related to a disease and/or health condition of the patient may be communicated directly from one or more additional biometric data sources **104** or entered manually into the mobile communication device **102**, such information may include, e.g., carbohydrate intake information; information relating to the frequency, type, or intensity of exercise by the patient; insulin information resulting from a bolus calculation, and any other suitable information related to the health of the patient.

[0023] Mobile communication device **102** may be configured to communicate information and/or data to the Cloud **105**. This information and/or data may include biometric sensor information and/or data received from one or more biometric sensors **101**, biometric information and/or data received from adapter **103**, biometric information and/or data received from one or more additional biometric data sources **104**, biometric information and/or data generated by mobile communication device **102** (e.g., where the mobile communication device **102** is a communication-enabled analyte meter) and/or any additional health related information received by mobile communication device **102**.

[0024] Cloud **105** may be configured to run one or more automated or semi-automated data-based algorithms in response to the inputs provided by mobile communication device **102**, processing device **502**, electronic medical record (EMR) **107** and/or one or more authorized stakeholders **106**. These automated or semi-automated data-based algorithms may in turn provide outputs which facilitate management of a disease and/or health condition of the patient. These outputs may be communicated to one or more components of systems **100-500**, e.g., to the patient via mobile communication device **102**, to one or more authorized stakeholders **106** (e.g., an HCP, health plan administrator, disease management case manager, government entity, payor, family member, etc.), to a

processing device **106**, and/or to the patient's EMR **107**. Suitable outputs of the automated of semi-automated data-based algorithms may include, e.g.: reminders to the patient to take various medications/drugs (adherence program); communication to authorized stakeholder, e.g., HCP, that a hypoglycemic state is imminent; recommendation for an HCP to consider prescribing a new drug for the patient; medication recommendations and/or considerations, including, e.g., titration and/or change in amount, timing or type, e.g., recommendation for an HCP to consider changing the dose of a patient's medication/drug or time of day when the medication/drug is administered; indication to an HCP that a new medication has been ineffective for the patient; recommendation and/or consideration with respect to a change in diet; patient coaching/encouragement with respect to various goals (e.g., lose weight, start exercising, reduce cholesterol); reminders to the patient to refill a prescription, obtain additional testing materials; a prediction of the patient's HbA1c level; a forecast of a patient's future blood glucose level; patient stratification, e.g., risk stratification based on predictive biometric patient data; real-time or retrospective analysis for clinical trials; real-time data updates; etc.

[0025] As indicated above, some data-based algorithms may be semi-automated. For example, some algorithms may require certain information in addition to biometric information and/or data received, e.g., from a biometric sensor **101**, in order to provide a desired algorithm output. Such information may include inputs provide by one or more authorized stakeholders, for example. This may be important where, e.g., a patient's biometric information and/or data falls outside a normal or expected range for a particular condition.

[0026] The Cloud-based systems described herein may, in some embodiments, facilitate structured testing protocols. For example, an HCP may perform a patient-specific drug trial by utilizing biometric data and/or information obtained from the Cloud to determine how the patient reacts to a new medication and/or change in dosage. In some embodiments, the Cloud may provide automated or semi-automated therapy recommendations and/or considerations based on an analysis of the results of such a structured testing protocol.

[0027] In one embodiment, as depicted in system **500** of FIG. 5, biometric information and/or data is communicated from a biometric monitoring device **501** to a processing device **502**. Biometric monitoring device **501**, may be an analyte monitor, e.g., a discrete analyte monitor such as a blood glucose monitor configured to receive a glucose test

strip. Alternatively, or in addition, biometric monitoring device **501** may be a portable hand-held component of a continuous or on demand analyte monitoring system, which systems are described in greater detail in the documents incorporated by reference herein. For example, biometric monitoring device **501** may be configured to communicate with an on-body portion of an analyte measurement system, e.g., an implanted or partially implanted analyte sensor or an RF-powered measurement circuit coupled to an implanted or partially implanted analyte sensor.

[0028] In some embodiments, biometric monitoring device **501** may be configured to receive biometric information and/or data from additional biometric data sources **104**, such as those described previously herein. Thus, biometric monitoring device **501** may operate as a "hub" for a variety of other devices and/or sensors.

[0029] Processing device **502** may be relatively non-mobile as compared with mobile communication device **102** discussed previously herein and may be, for example, a desktop computer such as a personal computer (PC) or Macintosh® computer.

[0030] In system **500**, biometric monitoring device **501** is configured to communicate biometric information and/or data to processing device **502**, e.g., via any suitable wired (e.g., USB) or wireless (e.g., Bluetooth) connection described herein or known in the art. Processing device **502** is in turn configured to communicate with Cloud **105** utilizing one or more wired and/or wireless communication means. Communication between the Cloud **105**, EMR **107**, and authorized stakeholders **106** may be as described herein for systems **100-400**. In addition, authorized stakeholders **106** may communicate with a patient by sending one or more messages, e.g., one or more treatment recommendations, to the patient either through the Cloud **105** to the processing device **502** and/or the biometric monitoring device **501**; directly to the patient's biometric monitoring device **501**, where the biometric monitoring device **501** is suitably enabled; or directly to the patient via any other suitable form of communication, e.g., telephone communication. In addition, in some embodiments, real-time feedback may be provided to the patient by the Cloud **105** or one or more authorized stakeholders **106**, e.g., by sending a text message to a patient's mobile phone (not shown in system **500**).

[0031] The automated or semi-automated data-based algorithms discussed herein may be configured to analyze the patient's data in view of standard protocols endorsed by authorities, such as the American Diabetes Association (ADA), European Association for the Study of Diabetes (EASD), International Diabetes Center (IDC), Joslin Diabetes Center, etc.

[0032] In some embodiments, as described previously herein, a system according to the present disclosure includes an optional component in the form of the patient's EMR **107**. In these embodiments, outputs of the automated or semi-automated data-based algorithms and/or therapy decisions made based on such outputs by one or more authorized stakeholders may be communicated to the patient's EMR. In addition, patient information stored in the EMR **107** may be communicated from the EMR **107** to the Cloud **105**, e.g., for use in one or more automated data-based algorithms, and/or by one or more authorized stakeholders **106**.

[0033] Authorized stakeholders **106** may in some embodiments include endocrinologists or other HCPs with specialized training. The Cloud automated data-based algorithms may be designed to communicate selected patient records to these specialized HCPs. This would allow the specialized HCPs to confirm selected therapy recommendations made by the algorithm or analyze abnormal data patterns. A health plan may apply a variety of filtering parameters to identify patients or patient groups to be evaluated by the specialized HCPs. In some embodiments, the specialized HCPs may provide feedback (e.g., general coaching and/or drug therapy recommendations) directly to the patient, e.g., via mobile communication device **102** or processing device **502**. In other embodiments, the specialized HCPs may provide feedback to the patient's primary care physician (PCP) or to a health plan's diabetes management case manager.

[0034] In one embodiment, the automated or semi-automated data-based algorithms may be designed to communicate certain patient records to a health plan's disease management department. The Cloud may analyze inbound patient data using the automated or semi-automated data-based algorithms in order to segment patients based on certain recommended disease management actions and/or to stratify patients based on priority of action.

[0035] Additional benefits of the Cloud-based system structure disclosed herein include the ability of authorized stakeholders to use data captured on the Cloud for real-time clinical trials or health outcomes research. In addition, historic data captured in the Cloud may be analyzed retrospectively on a patient de-identified basis to enable retrospective health outcomes studies.

[0036] Additional disclosure related to cloud-based systems and associated algorithms can be found in the U.S. Provisional Application entitled "*FEEDBACK FROM CLOUD OR HCP TO PAYER OR PATIENT VIA METER OR CELL PHONE*", Attorney Docket No. ADCI-240PRV, filed on the same day as the instant application, and U.S.

Provisional Application entitled "*ANALYTICS AND DATA MINING IN CLOUD FOLLOWING UPLOAD OF ANALYTE DATA VIA GSM OR CDM*", Attorney Docket No. ADCI-244PRV, filed on the same day as the instant application, which applications are incorporated by reference herein in their entirety and for all purposes.

Mobile Communication Devices

[0037] As discussed previously herein, a variety of mobile communication devices may be suitable for use as mobile communication device **102**. For example, suitable devices may include mobile phones, laptop computers; mobile devices, such as personal digital assistants (PDA)s, iPhone® devices, iPad® devices, Blackberry® devices, tablet computers, etc.; communication-enabled analyte meters; and other such devices known in the art. Additional information related to communication-enabled analyte meters can be found, e.g., in U.S. Application Publication No. 2010/0198142, the disclosure of which is incorporated herein by reference in its entirety and for all purposes.

[0038] In some embodiments, where the mobile communication device **102** is a communication-enabled analyte meter, the mobile communication device **102** may be configured as one or more of a discrete analyte measurement device (e.g., a glucose meter configured to receive a glucose test strip), a component of an analyte measurement system which system includes an implanted or partially implanted analyte sensor (e.g., a component of a continuous glucose measurement system), a component of an on-demand analyte measurement system, or a component of a medication delivery system (e.g., an insulin delivery system including an insulin pump or insulin pen device).

[0039] In some embodiments, where the mobile communication device **102** is configured as a discrete analyte measurement device, it may include a test strip port, e.g., a test strip port as described herein.

[0040] In some embodiments, where the mobile communication device **102** is configured as a component of an analyte measurement system, which system includes an implanted or partially implanted analyte sensor (e.g., a continuous analyte sensor), the mobile communication device **102** provides a portable hand-held component of the measurement system. In such embodiments, the mobile communication device **102** may be configured to include a communication unit which provides for wireless, e.g., RF, communication with an on-body portion of the analyte measurement system, e.g., an implanted or partially implanted analyte sensor or an RF-powered measurement circuit coupled to an implanted or partially implanted analyte sensor. In one embodiment,

analyte readings (e.g., glucose readings) are performed automatically every minute, and the real time results are wirelessly transferred to the mobile communication device **102**.

[0041] In some embodiments, a user interface of mobile communication device **102** may be utilized by a user to request a display of the current analyte measurement data or provide analyte measurement trending information.

[0042] In some embodiments, where the mobile communication device **102** is configured as a component of an on-demand analyte measurement system, the mobile communication device **102** provides a portable hand-held component of the measurement system. In such embodiments, mobile communication device **102** may be configured to include a communication interface which provides for wireless, e.g., RF, communication with an on-body portion of the on-demand analyte measurement system when the portable hand-held component is positioned in proximity to the on-body portion of the on-demand analyte measurement system. In this manner, periodic or intermittent analyte readings may be obtained and communicated to a user. In some embodiments, a user interface of the mobile communication device **102** may be utilized by a user to initiate the on-demand acquisition of measurement data.

[0043] In some embodiments, where the mobile communication device **102** is configured as a component of a medication delivery system, e.g., an insulin delivery system, the mobile communication device **102** provides a portable hand-held component of the medication delivery system. In such embodiments, the mobile communication device **102** may be configured to include a communication interface which provides for wireless, e.g., RF, communication with a medication delivery device, e.g., an insulin pump.

[0044] As discussed above, in embodiments of the present disclosure, a strip port for receiving an analyte test strip, e.g., a glucose test strip, may be integrated with the housing of the mobile communication device **102**. Additional information is provided in US Patent No. 7,041,468 and in US Patent Application Publication No. 20040245534, the disclosures of which are incorporated herein by reference in their entirety and for all purposes.

Mobile Communication Device Applications

[0045] Mobile communication device **102** may be configured to run one or more software and/or firmware applications ("app.")s to provide functionalities which facilitate the functioning of system **100**. For example, mobile communication device

102, may include and be configured to run an app. which is programmed to capture patient-supplied information, such as a summary of recent exercise, diet, and/or exception events (e.g., stress, flu, trouble sleeping).

[0046] In one embodiment, mobile communication device **102**, includes and is configured to determine an analyte level, e.g., a blood glucose level, based on signals received from an integrated test strip port or from an adapter **103** including an integrated test strip port. In such embodiments, e.g., as depicted in FIGS. 3 and 4, the system may not include a biometric sensor **101**.

[0047] In one embodiment, mobile communication device **102**, includes and is configured to run an app. which is configured to provide one or more feedback outputs to the patient, e.g., feedback on recent glucose control. Such feedback may be communicated to the patient, e.g., via text or audio communication and may include one or messages, e.g., "good job, your average fasting glucose has improved since last month. Additional feedback outputs include, e.g., forecasted HbA1c, recommended mealtime insulin (e.g., based on patient-supplied carbs and data from insulin pen), reminder to take other drugs, reminder of upcoming doctor's visit, and broadcasting of patient-specific educational content.

[0048] In one embodiment, mobile communication device **102**, includes and is configured to run an app. which is configured to relay messages from other stakeholders; such as secure message or questions from a PCP, e.g., ("I'm proud of you for staying on the exercise plan we agreed to."); and secure messages or questions from a diabetes management case manager or health plan, e.g., ("Have you had a foot exam this year?").

[0049] In one embodiment, apps. are licensed, acquired, or otherwise built by third-parties to be incorporated into mobile communication device **102**.

[0050] Mobile communication device **102** may include one or more of the software applications described in U.S. Patent Application No. 7,766,829; and U.S. Provisional Patent Application Nos. 61/015,185; 61/262,849; 61/290,841; 61/254,156; and 61/325,155; the disclosures of which are incorporated herein by reference in their entirety and for all purposes. Additional software applications suitable for use in connection with mobile communication device **102** are described in the U.S. Provisional Application entitled "*SOFTWARE APPLICATIONS RESIDING ON HANDHELD ANALYTE DETERMINING DEVICES*", Attorney Docket No. ADCI-242PRV, filed on the same day as the instant application, and incorporated by reference herein in its entirety and for all purposes.

[0051] In some embodiments, the mobile communication device **102** is an uncontrolled data processing device (UDPD). In such embodiments, when a safety critical application (SCA) is to be run on the device, a system according to the present disclosure will include methods and/or articles of manufacture for hosting the SCA on the UDPD. Description of such methods and/or articles of manufacture can be found, e.g., in U.S. Patent Application No. 12/876,840, entitled "Methods and Articles of Manufacture for Hosting a Safety Critical Application on an Uncontrolled Data Processing Device", filed September 7, 2010, the disclosure of which is incorporated by reference herein its entirety and for all purposes.

[0052] While the above applications are described in the context of a mobile communication device **102**, it should be noted that any of the above applications may be run by a biometric monitoring device **501**.

Communication

[0053] Mobile communication device **102** may be configured for wired or wireless communication with one or more of the components of system **100**, e.g., one or more biometric sensors **101**, the Cloud **105**, additional biometric data sources **104**, or one or more authorized stakeholders **106**. For example, the mobile communication unit **102** may be configured for wireless communication, including, but not limited to, radio frequency (RF) communication (e.g., Radio-Frequency Identification (RFID), Zigbee communication protocols, WiFi, infrared, wireless Universal Serial Bus (USB), Ultra Wide Band (UWB), Bluetooth® communication protocols, and cellular communication, such as code division multiple access (CDMA) or Global System for Mobile communications (GSM).

[0054] In one embodiment, the mobile communication device **102** is configured for infrared communication, Bluetooth® communication, or any other suitable wireless communication protocol to enable communication with other devices such as computer terminals and/or networks, communication-enabled mobile telephones, PDAs, or any other communication-enabled devices which the patient or user may use in connection with managing the treatment of a health condition, such as diabetes.

[0055] In one embodiment, the mobile communication device **102** is configured to provide a connection for data transfer utilizing Internet Protocol (IP) through a cellular telephone network, Short Message Service (SMS), wireless connection to a personal

computer (PC) on a Local Area Network (LAN) which is connected to the internet, or WiFi connection to the internet at a WiFi hotspot.

[0056] In one embodiment, the mobile communication device **102** is configured to wirelessly communicate with a server device, e.g., using a common standard such as 802.11 or Bluetooth® RF protocol, or an IrDA infrared protocol.

[0057] The mobile communication device **102** may be configured to automatically or semi-automatically communicate data stored in the mobile communication device **102** to one or more of the components of system **100** using one or more of the communication protocols and/or mechanisms described above.

[0058] As discussed previously herein and as depicted in FIGS. 1, 2, 6 and 7, mobile communication device **102** may be configured to communicate with one or more biometric sensors **101**, either directly or via adapter **103**. This communication may be wired or wireless. Suitable wireless communication protocols and/or mechanisms may include one or more of those described above. In one embodiment, a mobile communication unit **102** is configured for wireless communication, e.g., RF, communication with an on-body portion of a biometric sensor **101**, e.g., an implanted or partially implanted analyte sensor or an RF-powered measurement circuit coupled to an implanted or partially implanted analyte sensor. In one embodiment, analyte readings (e.g., glucose readings) are performed automatically every minute, and the real time results are wirelessly transferred to the mobile communication device **102**, either directly or via adapter **103**.

Adapter

[0059] As depicted in FIGS. 1, 3, 6 and 7 mobile communication device **102** may optionally include an adapter **103** configured to be coupled therewith. In some embodiments, adapter **103** is configured to acquire biometric information and/or data (e.g., where the adapter **103** includes an integrated test strip port) or receive biometric information and/or data communicated from one or more biometric sensors **101** and transfer such information and/or data to mobile communication device **102**.

[0060] The adapter **103** may be in the form of a protective "skin" or case designed to fit a mobile communication device **102**. In some embodiments, the adapter may provide structural support for the integrated device combination. As shown in FIGS. 6 and 7, in some embodiments, the adapter may include two or more pieces which engage to form a complete adapter. In other embodiments the adapter may be a single unit.

[0061] As used herein the term "skin" refers to a flexible material, e.g., a flexible polymer material, configured to cover at least a portion of a mobile communication device **102**. In some embodiments, the skin is sized and shaped to fit one or more external dimensions of a mobile communication device **102**, while providing access to one or more features of the mobile communication device **102**, e.g., one or more input units, displays, speakers, microphones, headphone jacks, cameras, communication ports, etc. The skin may be configured to cover greater than 40%, e.g., greater than 50%, greater than 60%, greater than 70%, greater than 80% or greater than 90% of the exposed surface of a portable electronic device.

[0062] As used herein with reference to a portable electronic processing device, use of the term "case" as opposed to the term skin refers to a relatively rigid covering for a mobile communication device **102**. As with the skin, in some embodiments, a case is sized and shaped to fit one or more external dimensions of a mobile communication device **102**, while providing access to one or more features of the mobile communication device **102**, e.g., one or more input units, displays, speakers, microphones, headphone jacks, cameras, communication ports, etc. For example, a case may be configured to cover greater than 40%, e.g., greater than 50%, greater than 60%, greater than 70%, greater than 80% or greater than 90% of the exposed surface of a mobile communication device **102**.

[0063] Communication between the mobile communication device **102** and the optional adapter **103** may be accomplished using a wired connection between the adapter **103** and a hard-wired communication port positioned on the mobile communication device **102** (e.g., a USB port or a proprietary serial interface such as that found in the iPhone®). For example, the adapter **103** may include a male USB connector while mobile communication device **102** includes a corresponding female USB connector. Connection of the two connectors provides a physical and electrical connection between the adapter **103** and the mobile communication device **102**. Alternatively, communication between adapter **103** and mobile communication device **102** may be via one or more of the wireless communication protocols and/or mechanisms described herein.

[0064] The adapter **103** may be configured as one or more of a discrete analyte measurement device (e.g., a glucose meter configured to receive a glucose test strip), a component of an analyte measurement system which system includes an implanted or partially implanted analyte sensor (e.g., a component of a continuous glucose measurement system), a component of an on-demand analyte measurement system, or a

component of a medication delivery system (e.g., an insulin delivery system including an insulin pump).

[0065] In some embodiments, where the adapter **103** is configured as a discrete analyte measurement device, it may include a test strip port, e.g., a test strip port as described herein. In such embodiments, the discrete analyte measurement device may or may not include a display unit which is separated from a display unit of the mobile communication device **102**. Where the discrete analyte measurement device does not include a separate display unit, analyte measurement results obtained using the discrete analyte measurement device may be displayed on a display unit of the mobile communication device **102**.

[0066] In some embodiments, e.g., as depicted in FIGS. 1, 6 and 7, where the adapter **103** is configured as a component of an analyte measurement system, which system includes an implanted or partially implanted analyte sensor (e.g., a continuous analyte sensor), the adapter **103** in combination with the mobile communication device **102** coupled thereto provides a portable hand-held component of the measurement system. In such embodiments, the adapter **103** may be configured to include a communication unit which provides for wireless, e.g., RF, communication with an on-body portion of the analyte measurement system, e.g., an implanted or partially implanted analyte sensor or an RF-powered measurement circuit coupled to an implanted or partially implanted analyte sensor. In one embodiment, analyte readings (e.g., glucose readings) are performed automatically every minute, and the real time results are wirelessly transferred to the adapter **103**.

[0067] In some embodiments, a button or other input device on the adapter **103** may be utilized by a user to request a display of the current analyte measurement data or provide analyte measurement trending information. Alternatively, or in addition, the request for current measurement data may be made using a user interface of the mobile communication device **102**. The adapter **103** may be configured such that when it operates in combination with a mobile communication device **102** the normal functioning of the mobile communication device **102** is not impaired. For example, in some embodiments, where the adapter includes a test strip port integrated therein, a user may make or receive a call, text message, etc., using a mobile phone fitted to the adapter even when a test strip is inserted into the test strip port.

[0068] In some embodiments, where the adapter **103** is configured as a component of an on-demand analyte measurement system, the adapter **103** in combination with the mobile

communication device **102** coupled thereto provides a portable hand-held component of the measurement system. In such embodiments, the adapter **103** may be configured to include a communication interface which provides for wireless, e.g., RF, communication with an on-body portion of the on-demand analyte measurement system when the portable hand-held component is positioned in proximity to the on-body portion of the on-demand analyte measurement system. In this manner, periodic or intermittent analyte readings may be obtained and communicated to a user. In some embodiments, a button or other input device on the adapter **103** may be utilized by a user to initiate the on-demand acquisition of measurement data. Alternatively, or in addition, the acquisition of measurement data may be initiated using a user interface of the mobile communication device **102**. The adapter **103** may be configured such that when it operates in combination with a mobile communication device **102** the normal functioning of the mobile communication device **102** is not impaired.

[0069] In some embodiments, where the adapter **103** is configured as a component of a medication delivery system, e.g., an insulin delivery system, the adapter **103** in combination with the mobile communication device **102** coupled thereto provides a portable hand-held component of the medication delivery system. In such embodiments, the adapter **103** may be configured to include a communication interface which provides for wireless, e.g., RF, communication with a medication delivery device, e.g., an insulin pump.

[0070] In some embodiments, the adapter **103** is configured to be powered by the mobile communication device **102** to which the adapter **103** is coupled, e.g. via a USB connection. Alternatively, or in addition, the adapter **103** may include a separate power source, e.g., a disposable or rechargeable battery. Additional information related to the powering of an adapter coupled to a mobile communication device is provided in U.S. Patent No. 7,041,468, the disclosure of which is incorporated herein by reference in its entirety and for all purposes.

[0071] The adapter **103** may include a memory for storing one or more software applications designed to be uploaded and/or run by a processor of the mobile communication device **102** to which the adapter **103** is coupled.

[0072] As discussed above, in embodiments of the present disclosure, a strip port for receiving an analyte test strip, e.g., a glucose test strip, may be integrated with the housing of the adapter **103**. Additional information is provided in US Patent No.

7,041,468 and in US Patent Application Publication No. 20040245534, the disclosures of which are incorporated herein by reference in their entirety and for all purposes.

[0073] Additional information related to the use and structure of an adapter as disclosed herein can be found in Provisional Application No. 61/325,021, filed on April 16, 2010, and titled "Mobile Phone Display for Continuous Analyte Monitoring," the disclosure of which is incorporated by reference herein and for all purposes.

Sensors

[0074] The systems of the present disclosure may include one or more biometric sensors. The biometric sensors according to the present disclosure may be configured to be relatively small in size. For example, in some embodiments, the biometric sensors are approximately the size of a quarter or smaller. Such sensors may be attached to the body of a user, e.g., via an adhesive patch. In some embodiments, the sensor includes electrodes which are positioned below the surface of the skin, e.g., a few millimeters below the surface of the skin. Sensors of this type may be worn on the body for extended periods of time, e.g., periods of up to 10 days or more.

[0075] In some embodiments, a system according to the present disclosure may include a biometric sensor **101** which may be an on-body patch device with a thin profile that may be comfortably worn on the arm or other locations on the body (e.g., under clothing worn by the user or the patient). The on-body patch device may include a biometric sensor and circuitry and components for operating the sensor and processing and storing signals received from the sensor as well as for communication with the adapter **103** and/or the mobile communication device **102**. For example, in one embodiment the on-body patch device may include electronics configured to sample a voltage signal received from a biometric sensor in fluid contact with a body fluid, and to process the sampled voltage signals into corresponding analyte, e.g., glucose, values and/or store the sampled voltage signal as raw data.

[0076] The on-body patch device in one embodiment may include an antenna such as a loop antenna to receive RF power from an external device such as the adapter **103**, the mobile communication device **102** or the biometric monitoring device **501** described above; electronics to convert the RF power received via the antenna into DC (direct current) power for the on-body patch device circuitry; communication module or electronics to detect commands received from the adapter **103**, the mobile communication device **102** or the biometric monitoring device **501**; a communication

component such as an RF transmitter to transmit data to the adapter **103**, the mobile communication device **102** or the biometric monitoring device **501**; a low capacity battery for providing power to sensor sampling circuitry (for example, the analog front end circuitry of the on-body patch device in signal communication with the analyte sensor); and/or one or more non-volatile memory or storage devices to store data including raw signals from the sensor or processed data based on the raw sensor signals.

[0077] In some embodiments, a biometric sensor as described herein may be an implanted or partially implanted analyte sensor, e.g., an implanted or partially implanted glucose sensor. An adapter or mobile communication device as described herein may be configured to receive analyte data from the implanted or partially implanted glucose sensor either directly or through an intermediate device, e.g., an RF-powered measurement circuit coupled to an implanted or partially implanted analyte sensor. In some embodiments, where a system according to the present disclosure includes an implanted sensor, the system does not include a strip port for receiving an analyte test strip. In some embodiments, the analyte measurement system may be configured to communicate with the implanted or partially implanted analyte sensor via Radio Frequency Identification (RFID) and provide for intermittent or periodic interrogation of the implanted analyte sensor.

[0078] In some embodiments, the biometric sensor is a self-powered analyte sensor. Additional information related to self-powered analyte sensors and methods of communicating therewith are provided in U.S. Patent Application Publication No. 2010/0213057, the disclosure of which is incorporated by reference herein in its entirety and for all purposes.

[0079] Additional disclosure related to the structure and function of biometric sensors can be found, e.g., in the following patents, applications and/or publications which are incorporated herein by reference in their entirety and for all purposes: U.S. Patent Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,356,786; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,730,200; 6,736,957; 6,746,582; . 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892;

6,932,894; 6,942,518; 7,041,468; 7,167,818; 7,299,082; and 7,866,026; U.S. Published Application Nos. 2004/0186365; 2005/0182306; 2006/0025662; 2006/0091006; 2007/0056858; 2007/0068807; 2007/0095661; 2007/0108048; 2007/0199818; 2007/0227911; 2007/0233013; 2008/0066305; 2008/0081977; 2008/0102441; 2008/0148873; 2008/0161666;2008/0267823; 2009/0054748; 2009/0247857; 2009/0294277; 2010/0081909; 2010/0198034;2010/0213057; 2010/0230285; 2010/0313105; 2010/0326842; and 2010/0324392; U.S. Patent Application Serial Nos. 12/807,278; 12/842,013; and 12/871,901; and U.S. Provisional Application Nos. 61/238,646; 61/246,825; 61/247,516; 61/249,535; 61/317,243; 61/345,562; 61/361,374; and 61/415,174.

Integration with Medication Delivery Devices and/or Systems

[0080] In some embodiments, the systems disclosed herein may be integrated with a medication delivery device and/or system, e.g., an insulin pump module, such as an insulin pump or controller module thereof, or insulin injection pen. Additional information regarding medication delivery devices and/or systems, such as, for example, integrated systems, is provided in U.S. Patent Application Publication No. 20060224141, published on October 5, 2006, entitled "Method and System for Providing Integrated Medication Infusion and Analyte Monitoring System", and U.S. Patent Application Publication No. 20040254434, published on December 16, 2004, entitled "Glucose Measuring Module and Insulin Pump Combination," the disclosures of which are incorporated by reference herein in their entirety and for all purposes. Medication delivery devices which may be integrated with systems as described herein include, e.g., a needle, syringe, pump, catheter, inhaler, transdermal patch, or combination thereof. In some embodiments, the medication delivery device or system may be in the form of a drug delivery injection pen such as a pen-type injection device incorporated within the housing of an analyte measurement device. Additional information is provided in U.S. Patent Nos. 5,536,249 and 5,925,021, the disclosures of each of which are incorporated by reference herein in their entirety and for all purposes.

Analyte Test Strips

[0081] Analyte test strips for use in the disclosed devices and systems can be of any kind, size, or shape known to those skilled in the art; for example, FREESTYLE® and FREESTYLE LITE ™ test strips, as well as PRECISION™ test strips sold by ABBOTT

DIABETES CARE Inc. In addition to the embodiments specifically disclosed herein, devices of the present disclosure may be configured to work with a wide variety of analyte test strips, e.g., those disclosed in U.S. Patent Application Publication No. 20070095661; U.S. Patent Application Publication No. 20060091006; U.S. Patent Application Publication No. 20060025662; U.S. Patent Application Publication No. 20080267823; U.S. Patent Application Publication No. 20070108048; U.S. Patent Application Publication No. 20080102441; U.S. Patent Application Publication No. 20080066305; U.S. Patent Application Publication No. 20070199818; U.S. Patent Application Publication No. 20080148873; U.S. Patent Application Publication No. 20070068807; U.S. Patent Application No. 20090255811, and U.S. Patent Application Publication No. 20090095625; U.S. Patent No. 7,866,026; U.S. Patent No. 6,616,819; U.S. Patent No. 6,143,164; U.S. Patent No. 6,592,745; U.S. Patent No. 6,071,391 and U.S. Patent No. 6,893,545; the disclosures of each of which are incorporated by reference herein in their entirety and for all purposes.

Calculation of Medication Dosage

[0082] In one embodiment, one or more of the system components described herein may be configured to measure the blood glucose concentration of a patient and include instructions for a long-acting insulin dosage calculation function. Periodic injection or administration of long-acting insulin may be used to maintain a baseline blood glucose concentration in a patient with Type-1 or Type-2 diabetes. In one embodiment, the long-acting medication dosage calculation function may include an algorithm or routine based on the current blood glucose concentration of a diabetic patient, to compare the current measured blood glucose concentration value to a predetermined threshold or an individually tailored threshold as determined by a doctor or other treating professional to determine the appropriate dosage level for maintaining the baseline glucose level. In one embodiment, the long-acting insulin dosage calculation function may be based upon LANTUS® insulin, available from Sanofi-Aventis, also known as insulin glargine. LANTUS® is a long-acting insulin that has up to a 24 hour duration of action. Further information on LANTUS® insulin is available at the website located by placing "www" immediately in front of ".lantus.com". Other types of long-acting insulin include Levemir® insulin available from NovoNordisk (further information is available at the website located by placing "www" immediately in front of ".levemir-us.com". Examples of such embodiments are described in in US Published Patent Application No.

201001981142, the disclosure of which is incorporated by reference herein in its entirety and for all purposes.

Strip Port Configured to Receive Test Strips for Different Analytes

[0083] In one embodiment, the test strip ports described herein are capable of performing a multiplicity of testing functionalities. In such embodiments, the test ports may be adapted for use in combination with a multiplicity of different types of test strips and include a sensor capable of specifically interacting with the indicator(s) on the test strips, thereby selecting at least one of the multiplicity of testing functionalities corresponding to the type of test strip. For example, such a strip port may be used to read a test strip for glucose and a test strip for ketone bodies. Examples of such strip ports are provided in U.S. Patent No. 6,773,671, the disclosure of which is incorporated by reference herein in its entirety and for all purposes.

Strip Port Configured to Receive Test Strips Having Different Dimensions and/or Electrode Configurations

[0084] In some embodiments, the test strip ports discussed herein may be configured to receive test strips having different dimensions and/or electrode configurations, e.g., as described in the U.S. Patent Application No. 12/695,947 filed on January 28, 2010, and entitled "Universal Test Strip Port", the disclosure of which is incorporated by reference herein in its entirety and for all purposes.

Input Unit

[0085] An adapter, mobile communication device or biometric monitoring device as described herein can be configured to include an input unit and/or input buttons coupled to the housing of the adapter and/or a mobile communication device and in communication with a controller unit and/or processor of the adapter and/or mobile communication device. In some embodiments, the input unit includes one or more input buttons and/or keys, wherein each input button and/or key is designated for a specific task. Alternatively, or in addition, the input unit may include one or more input buttons and/or keys that can be 'soft buttons' or 'soft keys'. In the case where one or more of the input buttons and/or keys are 'soft buttons' or 'soft keys', these buttons and/or keys may be used for a variety of functions. The variety of functions may be determined based on the current mode of the adapter and/or a mobile communication device, and may be

distinguishable to a user by the use of button instructions shown on an optional display unit of the adapter and/or a mobile communication device. Yet another input method may be a touch-sensitive display unit, as described in greater detail below.

[0086] In addition, in some embodiments, the input unit is configured such that a user can operate the input unit to adjust time and/or date information, as well as other features or settings associated with the operation of the adapter and/or a mobile communication device.

Display Unit

[0087] As discussed previously herein, in some embodiments, an adapter, a mobile communication device or a biometric monitoring device according to the present disclosure includes an optional display unit or a port for coupling an optional display unit to the adapter and/or a mobile communication device. The display unit is in communication with a control unit and/or processor of the adapter and/or a mobile communication device. In some embodiments, the display unit is configured to display biometric sensor signals and/or results determined from biometric sensor signals including, for example, analyte concentration, rate of change of analyte concentration, and/or the exceeding of a threshold analyte concentration (indicating, for example, hypo- or hyperglycemia).

[0088] The display unit can be a dot-matrix display, e.g., a dot-matrix LCD display. In some embodiments, the display unit includes a liquid-crystal display (LCD), thin film transistor liquid crystal display (TFT-LCD), plasma display, light-emitting diode (LED) display, seven-segment display, E-ink (electronic paper) display or combination of two or more of the above. The display unit can be configured to provide, an alphanumeric display, a graphical display, a video display, an audio display, a vibratory output, or combinations thereof. The display can be a color display. In some embodiments, the display is a backlit display.

[0089] The display unit can also be configured to provide, for example, information related to a patient's current analyte concentration as well as predictive analyte concentrations, such as trending information.

[0090] In some embodiments an input unit and a display unit are integrated into a single unit, for example, the display unit can be configured as a touch sensitive display, e.g., a touch-screen display, where the user may enter information or commands via the display area using, for example, the user's finger, a stylus or any other suitable implement, and

where, the touch sensitive display is configured as the user interface in an icon driven environment, for example.

[0091] In some embodiments, the display unit does not include a screen designed to display results visually. Instead, in some embodiments the optional display unit is configured to communicate results audibly to a user of the analyte measurement system, e.g., via an integrated speaker, or via separate speakers through a headphone jack or Bluetooth® headset.

Analytes

[0092] A variety of analytes can be detected and quantified using the disclosed system. Analytes that may be determined include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones (e.g., ketone bodies), lactate, oxygen, 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), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be determined. Assays suitable for determining the concentration of DNA and/or RNA are disclosed in U.S. Patent No. 6,281,006 and U.S. Patent No. 6,638,716, the disclosures of each of which are incorporated by reference herein in their entirety.

Conclusion

[0093] The foregoing description of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Other modifications and variations may be possible in light of the above teachings. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, and to thereby enable others skilled in the art to best utilize the invention in various embodiments and various modifications as are suited to the particular use contemplated. It is intended that the appended claims be construed to include other alternative embodiments of the invention; including equivalent structures, components, methods, and means.

[0094] It is to be appreciated that the Detailed Description section, and not the Summary and Abstract sections, is intended to be used to interpret the claims. The Summary and Abstract sections may set forth one or more, but not all exemplary embodiments of the

present invention as contemplated by the inventor(s), and thus, are not intended to limit the present invention and the appended claims in any way.

[0095] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limits of that range is also specifically disclosed. Each smaller range between any stated value or intervening value in a stated range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included or excluded in the range, and each range where either, neither or both limits are included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

[0096] In the description of the invention herein, it will be understood that a word appearing in the singular encompasses its plural counterpart, and a word appearing in the plural encompasses its singular counterpart, unless implicitly or explicitly understood or stated otherwise. Merely by way of example, reference to "an" or "the" "analyte" encompasses a single analyte, as well as a combination and/or mixture of two or more different analytes, reference to "a" or "the" "biometric sensor" encompasses a single biometric sensor, as well as two or more biometric sensors, and the like, unless implicitly or explicitly understood or stated otherwise. Further, it will be understood that for any given component described herein, any of the possible candidates or alternatives listed for that component, may generally be used individually or in combination with one another, unless implicitly or explicitly understood or stated otherwise. Additionally, it will be understood that any list of such candidates or alternatives, is merely illustrative, not limiting, unless implicitly or explicitly understood or stated otherwise.

[0097] Various terms are described to facilitate an understanding of the invention. It will be understood that a corresponding description of these various terms applies to corresponding linguistic or grammatical variations or forms of these various terms. It will also be understood that the invention is not limited to the terminology used herein, or the descriptions thereof, for the description of particular embodiments. Merely by way of example, the invention is not limited to particular analytes, bodily or tissue fluids, blood or capillary blood, or sensor constructs or usages, unless implicitly or explicitly understood or stated otherwise, as such may vary.

[0098] The publications discussed herein are provided solely for their disclosure prior to the filing date of the application. Nothing herein is to be construed as an admission that the embodiments of the invention are not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0099] The detailed description of the figures refers to the accompanying drawings that illustrate an exemplary embodiment of an analyte measurement system. Other embodiments are possible. Modifications may be made to the embodiment described herein without departing from the spirit and scope of the present invention. Therefore, the following detailed description is not meant to be limiting.

[00100] Certain embodiments presented herein relate to electrical interfaces in measurement devices. Measurement devices often have electrical interfaces that allow them to electrically connect with another device or apparatus and perform an analysis of an analyte. A device that measures blood glucose levels, for example, includes electrical interfaces that allow the device to measure the blood glucose level from a small blood sample.

CLAIMS

What is claimed is:

1. A health management system, comprising:

a mobile communication device;

a biometric, on-body sensor, wherein the biometric, on-body sensor is configured to communicate biometric sensor data or associated biometric sensor data information to the mobile communication device;

a location-independent, shared server system,

wherein the mobile communication device is configured to communicate the biometric sensor data or associated biometric sensor data information to the location-independent, shared server system,

wherein the location-independent, shared server system is configured to run one or more automated or semi-automated data-based algorithms using the biometric sensor data or associated biometric sensor data information as input, and

wherein the location-independent, shared server system is configured to provide one or more outputs of the automated data-based algorithms to one or more authorized stakeholders.

2. The health management system of claim 1, wherein the biometric, on-body sensor is an implanted or partially implanted analyte sensor.

3. The health management system of claim 2, wherein the implanted or partially implanted analyte sensor is a glucose sensor.

4. The health management system of any of the preceding claims, wherein the on-body sensor is configured to wirelessly communicate the biometric sensor data or associated biometric data information to the mobile communication device.

5. The health management system of any of the preceding claims, wherein the mobile communication device is configured to wirelessly communicate the biometric sensor data or associated biometric data information to the location-independent, shared server system.

6. The health management system of any of the preceding claims, wherein the one or more authorized stakeholders are selected from the group consisting of: a patient, health care provider (HCP), health plan administrator, disease management case manager, government entity, payor, and a family member of the patient.

7. The health management system of any of the preceding claims, wherein the location-independent, shared server system is configured to automatically provide the one or more outputs of the automated data-based algorithms to a patient's electronic medical record (EMR).

8. The health management system of any of the preceding claims, further comprising an adapter configured to couple to the mobile communication device, wherein the on-body sensor, the adapter and the mobile communication device are configured such that the biometric sensor data or associated biometric sensor data information is communicated from the biometric, on-body sensor to the adapter and from the adapter to the mobile communication device.

9. The health management system of claim 8, wherein the information communication from the adapter to the mobile communication device is by way of a wired connection.

10. The health management system of claim 8, wherein adapter comprises a two-part housing configured to engage the mobile communication device.

11. The health management system of claim 8, wherein adapter comprises a test-strip port.

12. The health management system of any of the preceding claims, further comprising one or more additional biometric data sources, wherein the mobile communication device is configured to receive biometric data from the one or more additional biometric data sources.

13. The health management system of any of the preceding claims, wherein the one or more outputs of the automated data-based algorithms comprise one or more therapy recommendations.

14. A health management system, comprising:

a mobile communication device;

an adapter configured to couple to the mobile communication device, wherein the adapter comprises an analyte monitor and is configured to communicate analyte data or associated analyte data information to the mobile communication device;

a location-independent, shared server system,

wherein the mobile communication device is configured to communicate the analyte data or associated analyte data information to the location-independent, shared server system,

wherein the location-independent, shared server system is configured to run one or more automated or semi-automated data-based algorithms using the analyte data or associated analyte data information as input, and

wherein the location-independent, shared server system is configured to provide one or more outputs of the automated data-based algorithms to one or more authorized stakeholders.

15. A health management system, comprising:

a communication-enabled analyte meter;

a location-independent, shared server system,

wherein the communication-enabled analyte meter is configured to communicate analyte data or associated analyte data information from the communication-enabled analyte meter to the location-independent, shared server system,

wherein the location-independent, shared server system is configured to run one or more automated or semi-automated data-based algorithms using the analyte data or associated analyte data information as input, and

wherein the location-independent, shared server system is configured to provide one or more outputs of the automated data-based algorithms to one or more authorized stakeholders.

16. A health management system, comprising:

a biometric monitoring device;

a processing device;

a location-independent, shared server system,

wherein the biometric monitoring device is configured to communicate biometric data or associated biometric data information from the biometric monitoring device to the location-independent, shared server system via the processing device,

wherein the location-independent, shared server system is configured to run one or more automated or semi-automated data-based algorithms using the biometric data or associated biometric data information as input, and

wherein the location-independent, shared server system is configured to provide one or more outputs of the automated or semi-automated data-based algorithms to one or more authorized stakeholders.

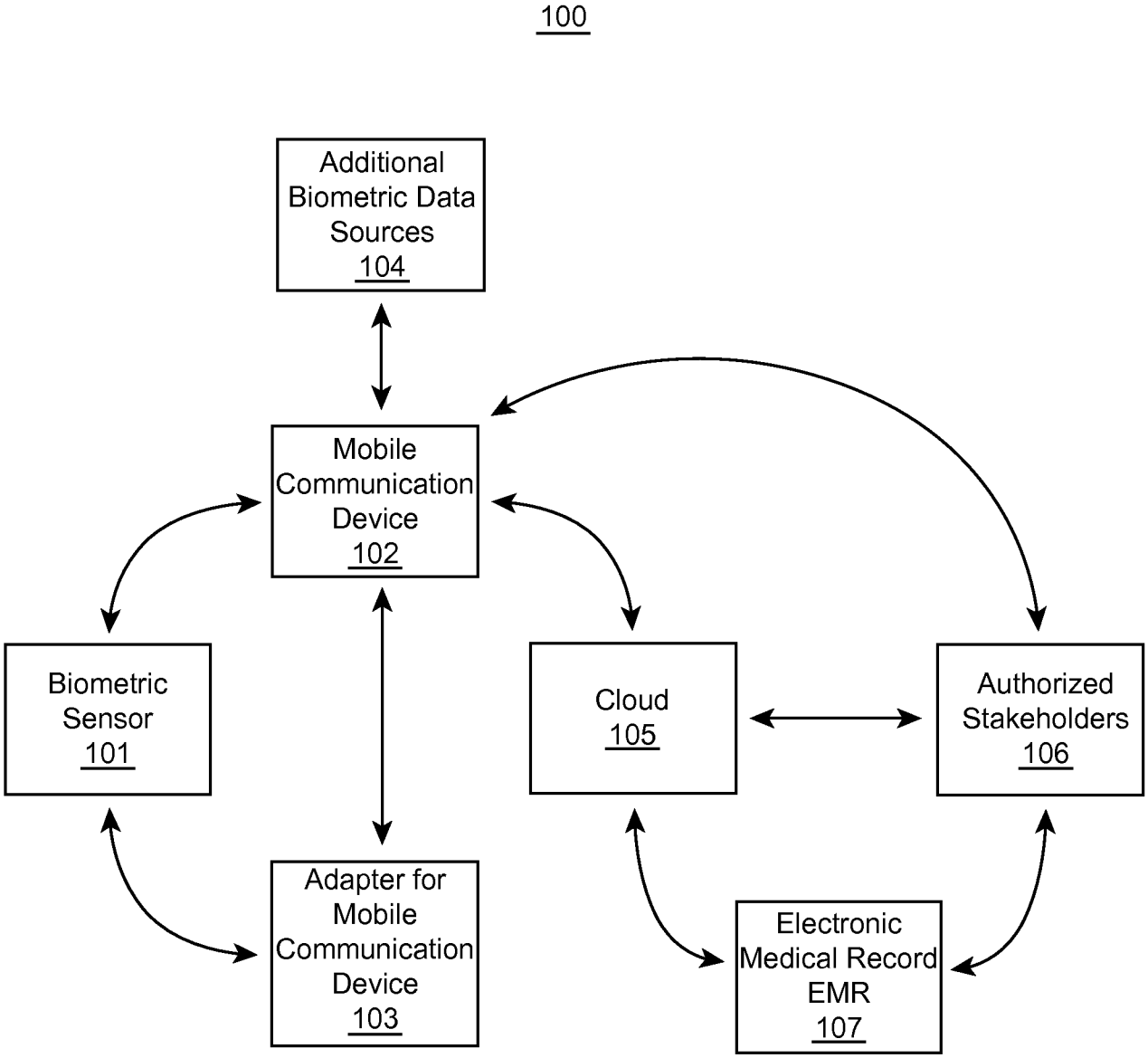
100
Additional Biometric Data Sources 104
Mobile Communication Device 102
Biometric Sensor 101
Cloud 105
Authorized Stakeholders 106
Adapter for Mobile Communication Device 103
Electronic Medical Record EMR 107

FIG. 1

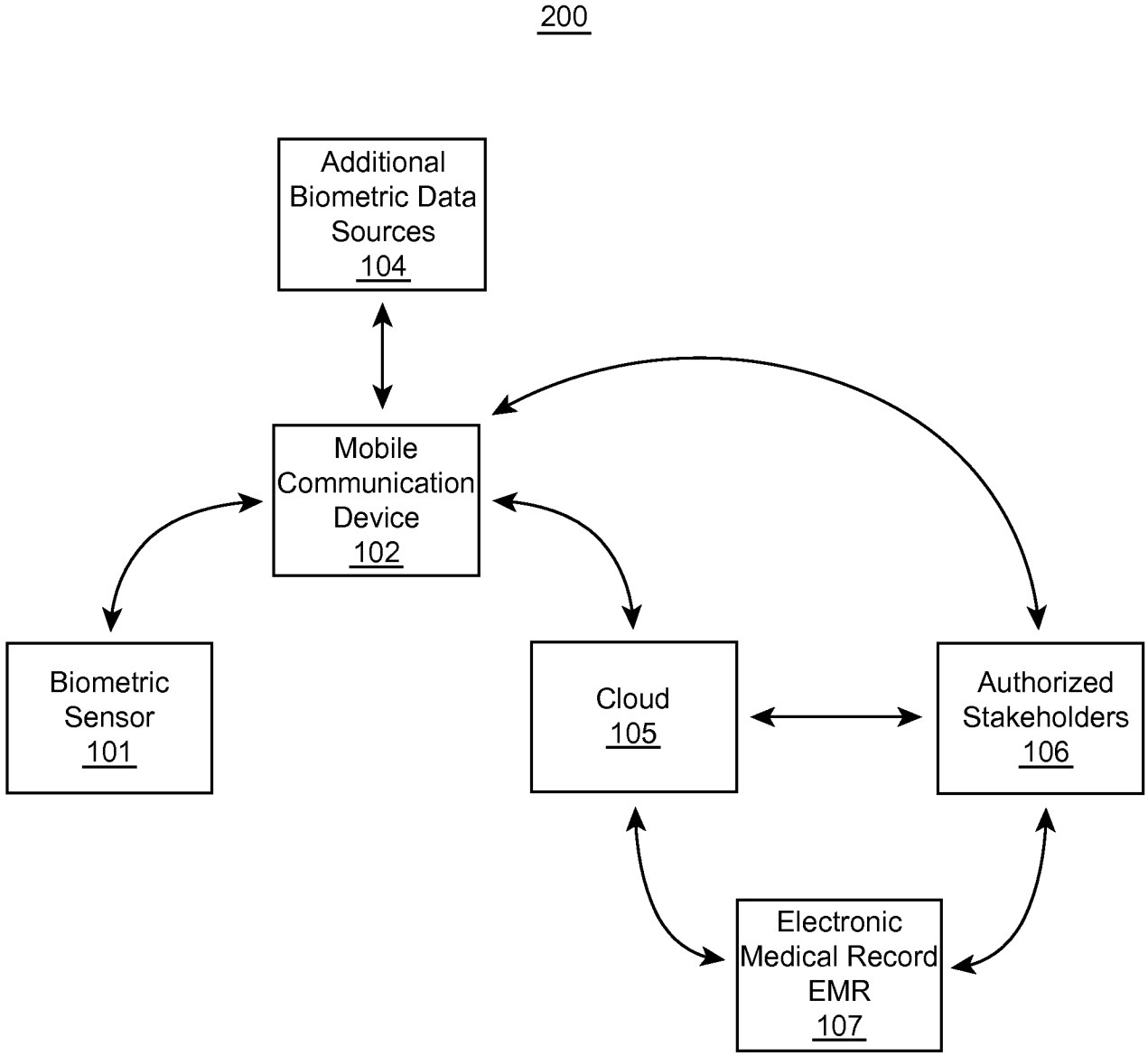
200
Additional Biometric Data Sources 104
Mobile Communication Device 102
Biometric Sensor 101
Cloud 105
Authorized Stakeholders 106
Electronic Medical Record EMR 107

FIG. 2

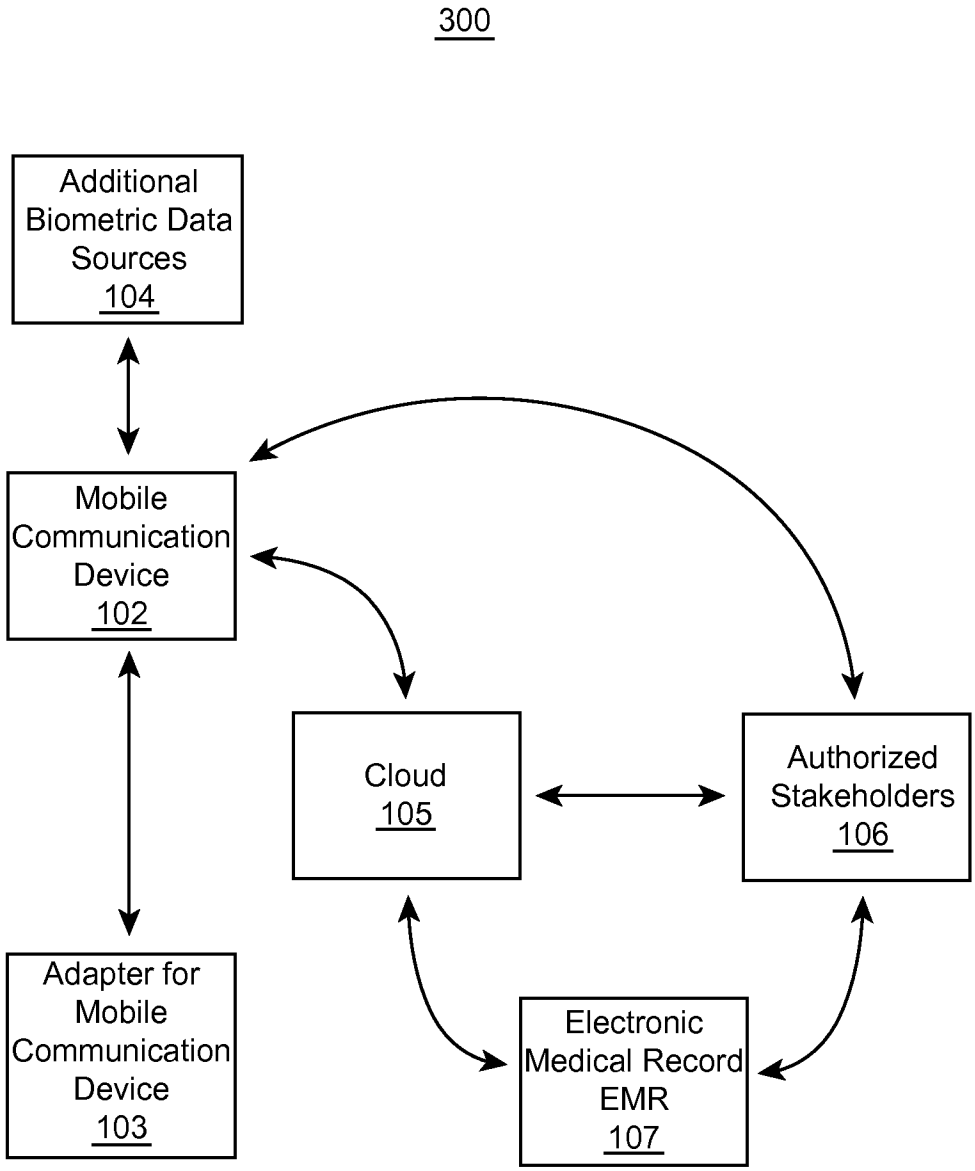
300
Additional Biometric Data Sources 104
Mobile Communication Device 102
Cloud 105
Authorized Stakeholders 106
Adapter for Mobile Communication Device 103
Electronic Medical Record EMR 107

FIG. 3

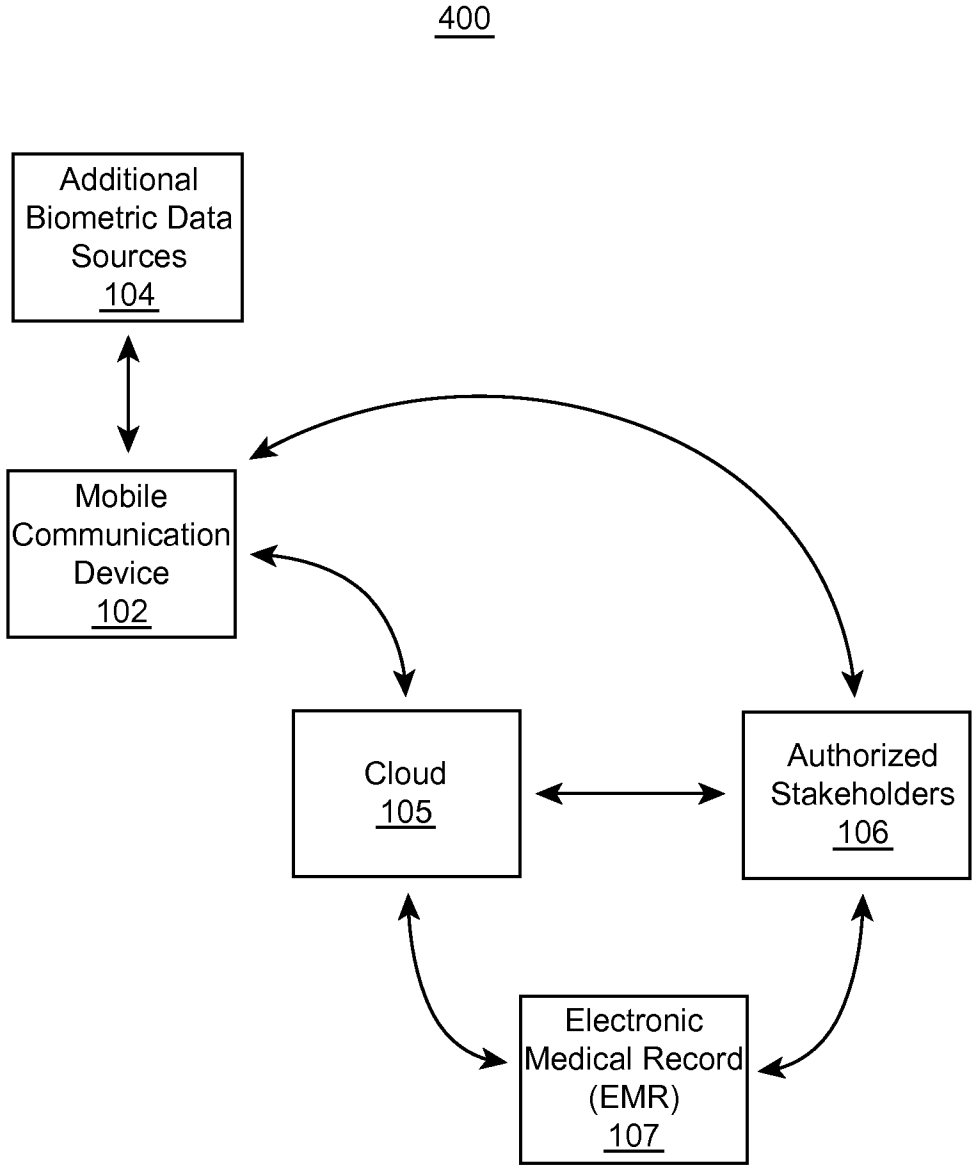
400
Additional Biometric Data Sources 104
Mobile Communication Device 102
Cloud 105
Authorized Stakeholders 106
Electronic Medical Record (EMR) 107

FIG. 4

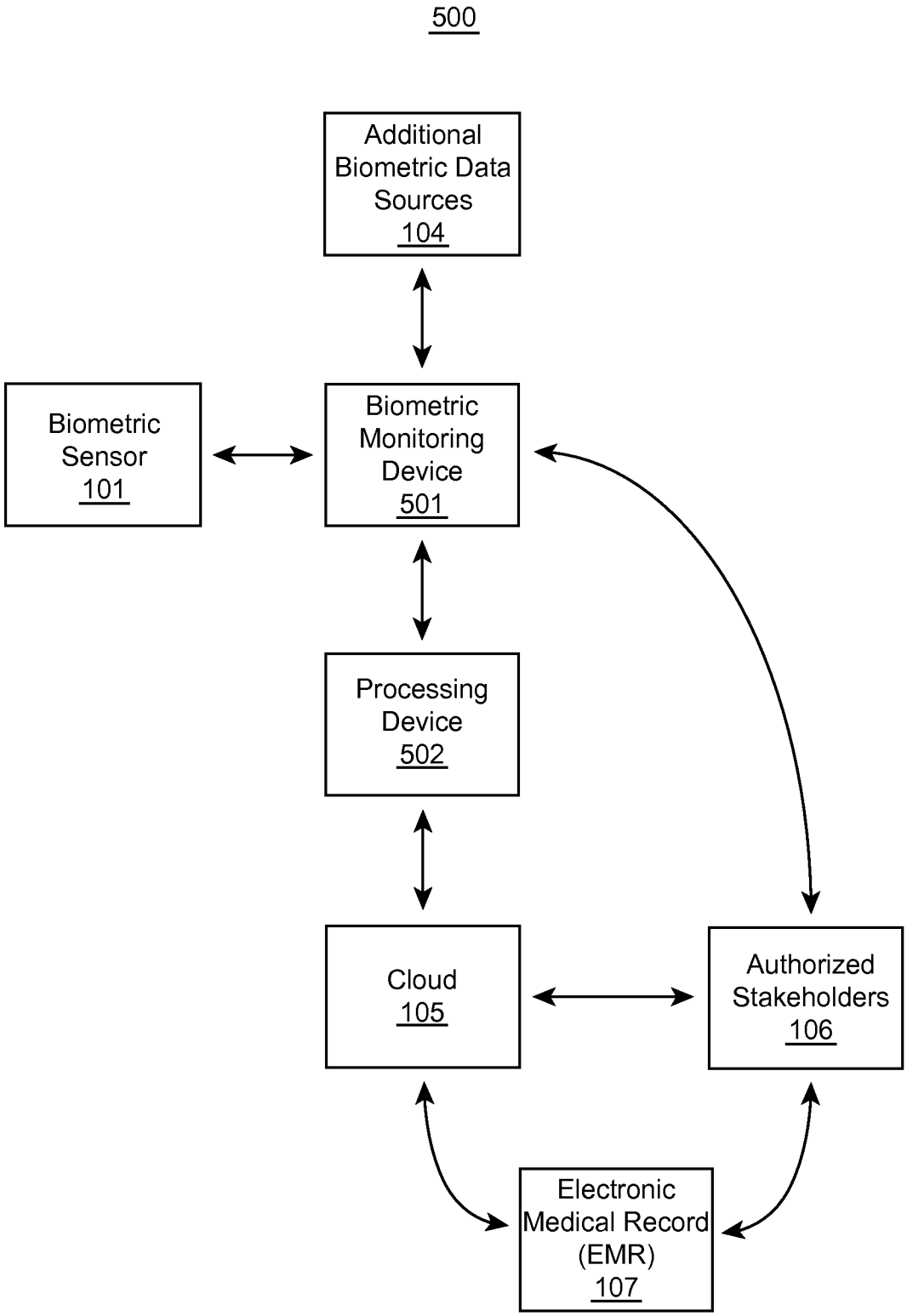
500
Additional Biometric Data Sources 104
Biometric Sensor 101
Biometric Monitoring Device 501
Processing Device 502
Cloud 105
Authorized Stakeholders 106
Electronic Medical Record (EMR) 107

FIG. 5

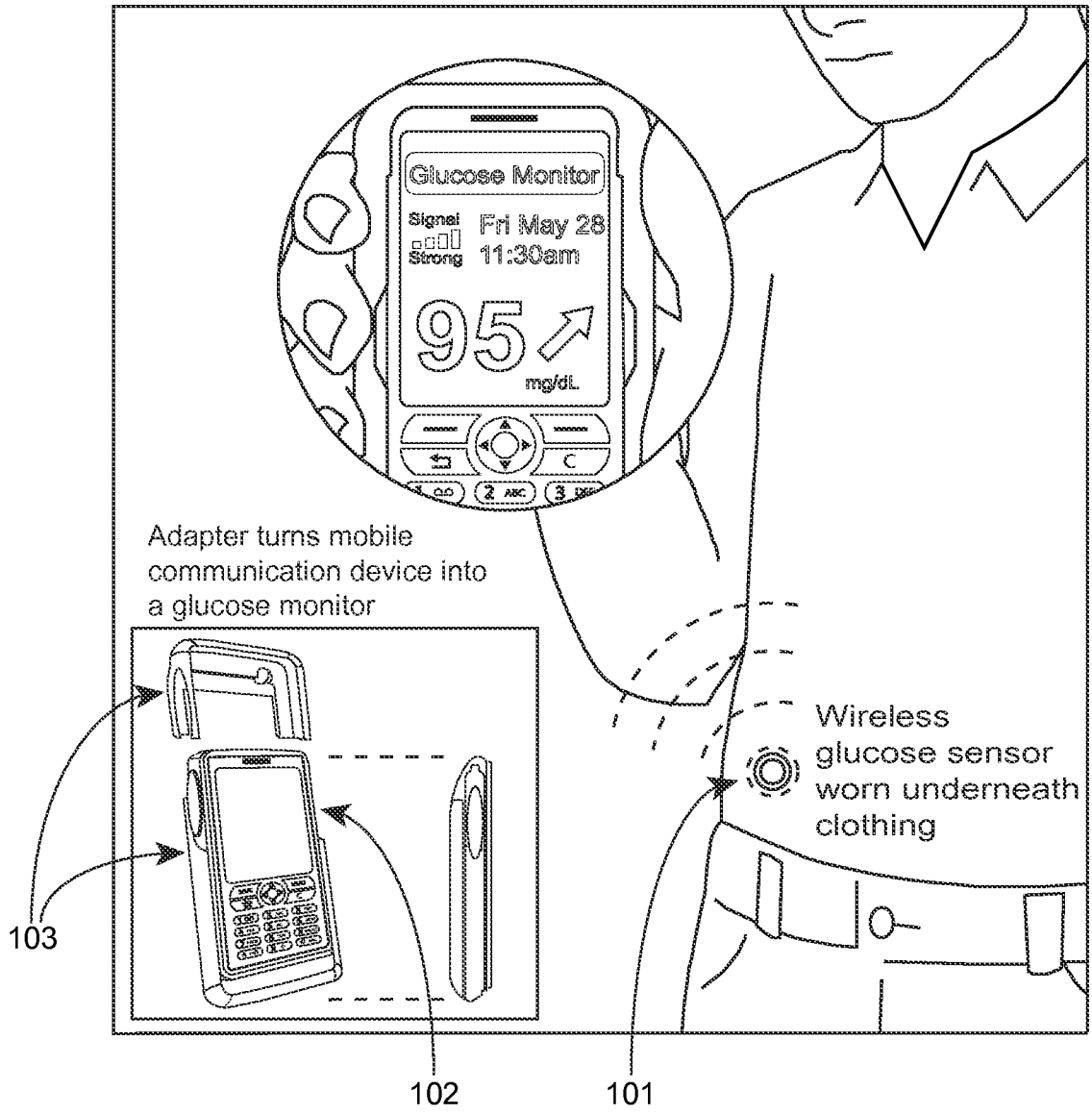
Glucose Monitor
Signal
Strong
Fri May 28
11:30am
95
mg/dL
Adapter turns mobile communication device into a glucose monitor
Wireless glucose sensor worn underneath clothing
103
102
101

FIG. 6

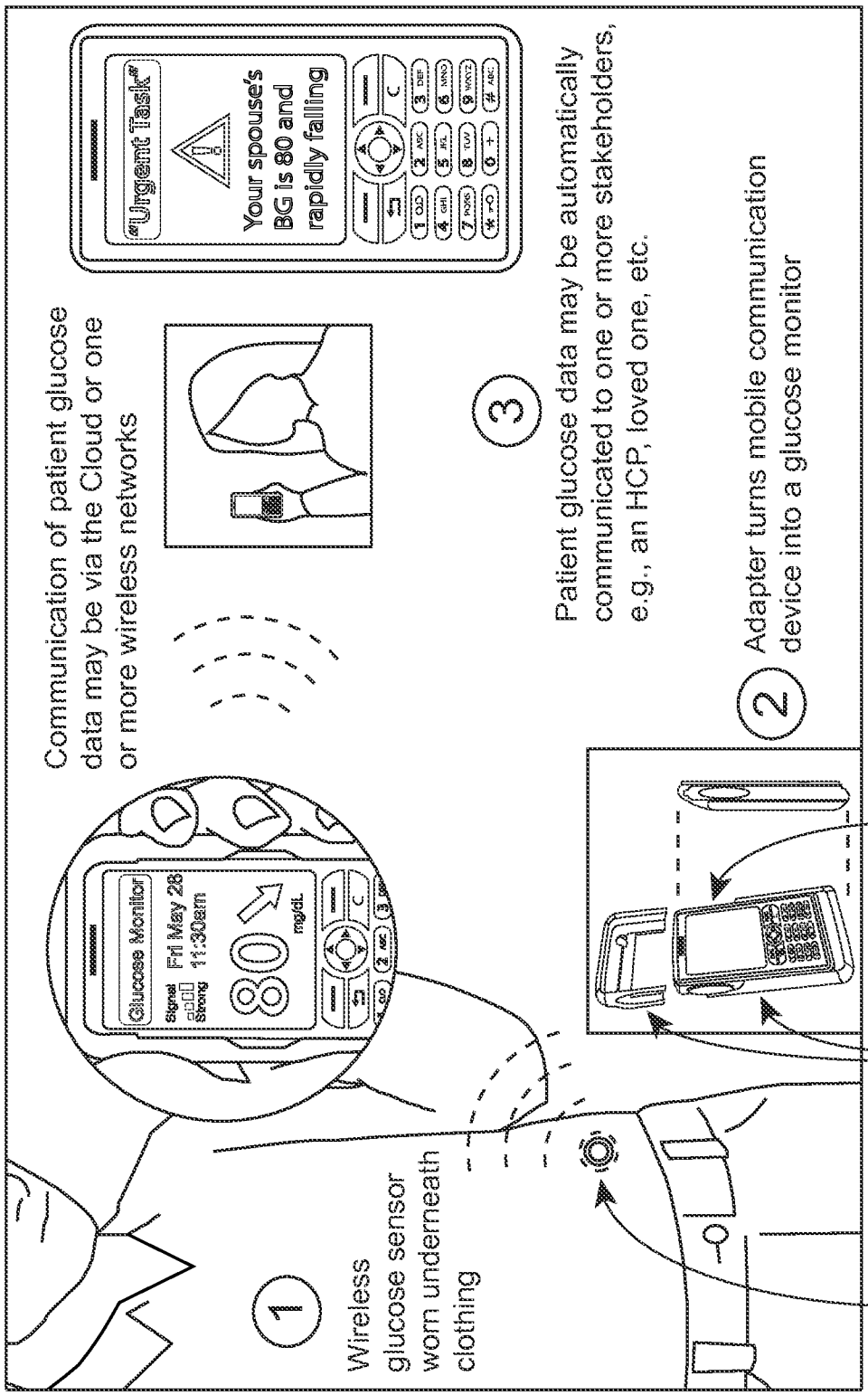
Glucose Monitor
Fri May 28
11:30am
80
mg/dL
Urgent Task
Your spouse's BG is 80 and rapidly falling
Communication of patient glucose data may be via the Cloud or one or more wireless networks
1
Wireless glucose sensor worn underneath clothing
2
Adapter turns mobile communication device into a glucose monitor
3
Patient glucose data may be automatically communicated to one or more stakeholders, e.g., an HCP, loved one, etc.
101
102
103

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/66418

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00 (2012.01)
USPC - 600/301
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61B 5/00 (2012.01)
USPC: 600/301

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/300; 604/19; 702/1, 19, 22; 705/1.1, 2 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST; Google Scholar; Google Patents; FreePatentsOnline. Search terms used: patient, sensor body-sensor attached-sensor implant-sensor embed-sensor, biometric glucose-level blood-glucose-level cholesterol-level basal-metabolism basal-metabolic-rate caloric-output analyte analyte-sensor analyte-meter, mobile wireless portable wifi ...

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0101841 A9 (KAYLOR et al.) 12 May 2005 (12.05.2005) entire document, especially Abstract; para [0003], [0030], [0041], [0058], [0060], [0061], [0066], [0076], [0077], [0097], [0118], [0202], [0246], [0262]	1-4, 14-16
X	US 20100198142 A1 (SLOAN et al.) 05 August 2010 (05.08.2010) entire document, especially Abstract; para [0066], [0176], [0177], [0214], [0295], [0327], [0331], [0373]	1, 14-16
A	US 2009/0240128 A1 (MENSINGER et al.) 24 September 2009 (24.09.2009) entire document	1-4, 14-16
A	US 2003/0208110 A1 (MAULT et al.) 06 November 2003 (06.11.2003) entire document	1-4, 14-16

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
09 April 2012 (09.04.2012)	20 APR 2012
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 11/66418

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

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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.: 5-13
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

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

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

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search 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 and, where applicable, the payment of a protest fee.

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

☐ No protest accompanied the payment of additional search fees.