

## DETAILED DESCRIPTION OF INVENTION

**[0018]** The present invention is directed to a system and methods for real-time or substantially real-time diabetes monitoring via a smart device and for allowing secure communications between a patient and a diabetes care provider.

**[0019]** In this detailed description, references to “one embodiment”, “an embodiment”, or “in embodiments” mean that the feature being referred to is included in at least one embodiment of the invention. Moreover, separate references to “one embodiment”, “an embodiment”, or “in embodiments” do not necessarily refer to the same embodiment; however, neither are such embodiments mutually exclusive, unless so stated, and except as will be readily apparent to those skilled in the art. Thus, the invention can include any variety of combinations and/or integrations of the embodiments described herein.

#### A. Real-Time Transmission of Diabetes Readings/Data Via Smart Device

**[0020]** According to the present invention, a smart device (e.g., smartphone, tablet computer, personal digital assistant, wearable digital devices such as a wrist, arm or eyewear devices) having wireless access to the Internet is provided with a software application. Through the software application (or “app”), the smart device is in wireless communication with at least one diabetes device, including, but not limited to, a glucometer, insulin pump, continuous glucose monitoring system (CGMS), implantable monitoring device, wristwatch device, or other wearable monitor, or the like. In specific embodiments, the smart device and at least one diabetes device may be enabled with Wi-Fi, Bluetooth, RF radio, infrared, or any other wireless technology.

**[0021]** According to the present invention, the smart device collects readings from the at least one diabetes device and transmits the results in real-time or near real-time over the internet to a server. Such readings may include, but are not limited to, blood sugar readings (e.g., logs), insulin pump settings, insulin treatment doses, CGMS readings, other insulin treatment data, or any combination thereof. The readings may be encrypted for transmission to the server. In specific embodiments, the server may be a secure server, for example a Health Insurance Portability and Accountability Act (HIPAA) compliant, secure server.

**[0022]** In specific embodiments, the smart device may continuously poll the at least one diabetes device or may periodically poll the at least one diabetes device for readings at a predetermined time (e.g., hourly, daily, weekly) or whenever internet access is or becomes available. No patient interaction is required in this mode. The wearer of the smart device can also manually prompt the device to poll the aforementioned diabetes devices to obtain new data.

**[0023]** The readings may be displayed on a graphical user interface of the patient’s smart device before and/or after the readings are transmitted to the server. In specific embodiments, the readings may be displayed, for example, as a table, pie chart, or summary graph.

**[0024]** According to an embodiment of the present invention, the transmitted diabetes readings are posted from the secure server to an administrative version of the app (discussed below) for review. The diabetes care provider’s smart device may display the patient’s data in the same display formats described above and may be synchronized with the patient’s device via the secure server. In this manner, the

readings that appear on both the patient’s and diabetes care provider’s devices show the same synchronized data and allow for further discussion, thereby obviating the need to post the data to a website or other intermediate device for viewing.

**[0025]** However, in specific embodiments, the system has the capability to and may also post the transmitted diabetes readings from the secure server to a secure website that is accessible by plurality of computers via a network. The network may comprise at least one of a wireless network, the internet, the World Wide Web, an intranet network, local area network, or wide area network. In specific embodiments, the secure website may be the Pediatric Diabetes Education Portal (PDEP) website of the Tripler Army Medical Center (TAMC) in Honolulu, Hi. See Pinsker et al., *A Pilot Project for Improving Paediatric Diabetes Outcomes using a Website: the Pediatric Diabetes Education Portal*, Journal of Telemedicine and Telecare, 2011, 226-30, vol. 17, no. 5 and Recupero, et al., *Emerging Technology in Diabetes Care: The Real-Time Diabetes Monitoring System*, Military Medicine, 2013, 218-21, vol. 178, the entireties of which are incorporated herein by reference.

**[0026]** According to an embodiment of the present invention, a diabetes care provider may be notified (e.g., via e-mail, phone, text, smart phone banners or alerts, etc.) that readings from a patient’s at least one diabetes device have been transmitted. The diabetes care provider may access the readings via an administrative version of the app (discussed below) that displays the transmitted readings on his or her smart device, and/or via a secure website. In specific embodiments, the readings may be displayed, for example, as a table, pie chart, or summary graph.

**[0027]** In specific embodiments, when diabetes readings are received by the server that are above at least one predetermined threshold for a particular patient, the system of the present invention may immediately communicate a warning message to the patient (e.g., “Have you taken your insulin?” or “Are you having low blood sugar?”) prior to, or contemporaneously with, notifying the patient’s diabetes care provider. The at least one predetermined threshold may be set by the diabetes care provider and, in embodiments, may be deactivated if a patient becomes capable of dealing with these issues on his or her own.

#### B. Secure Communication or Chat Module

**[0028]** According to the system and methods of the present invention, a patient and diabetes care provider may communicate in real-time, as opposed to waiting for an office or clinic visit, via the patient’s smart device. Thus, the app on the patient’s smart device and the administrative app on the diabetes care provider’s smart device may have a secure communication or chat module, thereby providing for two-way communications or messaging. In specific embodiments, the communications may use a smart device’s data plan and communicate through a server (e.g., a secure server) to which the transmitted readings/data are sent.

**[0029]** The diabetes care provider may review and interpret the transmitted readings from a patient’s at least one diabetes device and then send a message to the patient. In specific embodiments, the message may include, but is not limited to, at least one of discussion of the readings, recommendations for patient action, or reference to educational materials (e.g., accessible via a web link in the message or posted on a related secure website). Alternatively, or in addition thereto, the edu-