A system according to one aspect of the present invention comprises a processor, a medical device transceiver, a user interface, a data relay transceiver, a memory coupled to the processor, and storing instructions. The processor executes the instructions in the memory to receive data from a medical device using the medical device transceiver and transmits the data to an intermediary device using the data relay transceiver. This system can be implemented in a small, portable unit that is easy for a patient to transport. The system’s user interface may include a microphone and speaker to allow the communication of audible information between the system and a user.
REQUEST MEDICAL DEVICE ID

RECEIVE DATA WIRELESSLY FROM A MEDICAL DEVICE

VALIDATE DATA FROM MEDICAL DEVICE

AUTHENTICATE INTERMEDIARY DEVICE

ACTIVATE INTERMEDIARY DEVICE

TRANSMIT DATA TO INTERMEDIARY DEVICE

CONFIRM TRANSMISSION OF DATA TO INTERMEDIARY DEVICE

VALIDATE DATA TRANSMITTED TO INTERMEDIARY DEVICE

STORE DATA

FORMAT MESSAGE FOR TRANSMISSION TO MEDICAL DATA SERVER

TRANSMIT FORMATTED MESSAGE TO MEDICAL DATA SERVER

RECEIVE COMMAND FROM MEDICAL DATA SERVER

Figure 1
Figure 7

MEDICAL DATA SYSTEM

CLIENT/USER/PATIENT COMPONENT

701

GENERATE REQUEST TO AUTHENTICATE ACCESS

702

RECEIVE REQUEST TO AUTHENTICATE ACCESS

710

OBTAIN/GENERATE AUTHENTICATION TOKEN

730

SECURE AUTHENTICATION TOKEN

740

TRANSMIT TOKEN TO REQUESTING SYSTEM

750

760

GENERATE REQUEST TO AUTHENTICATE ACCESS

770

AUTHENTICATION SUCCESS?

780

GENERATE NOTICE OF AUTHENTICATION FAILURE/RETRY

790

RECEIVE NOTICE OF AUTHENTICATION FAILURE

EXIT
WIRELESS PROCESSING SYSTEMS AND METHODS FOR MEDICAL DEVICE MONITORING AND INTERFACE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to U.S. Provisional Patent Application Ser. No. 60/862,743, filed Oct. 24, 2006, the disclosure of which is incorporated by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] Not applicable.

NOTICE OF INCLUDED COPYRIGHTED MATERIAL

[0003] A portion of the disclosure of this patent document contains material which is subject to copyright protection. The copyright owner has no objection to the facsimile reproduction by anyone of the patent document or the patent disclosure, as it appears in the Patent and Trademark Office patent file or records, but otherwise reserves all copyright rights whatsoever. All trademarks and service marks identified herein are owned by the applicant.

DESCRIPTION OF THE INVENTION

[0004] 1. Field of the Invention

[0005] The present invention relates to systems and methods for medical device monitoring, and more particularly, to systems and methods for wirelessly monitoring medical devices.

[0006] 2. Background of the Invention

[0007] Historically, patient medical care was often provided for in the patient’s home or some other environment apart from a medical setting. Physicians, midwives, or other healthcare providers would make house calls, observe patient symptoms, formulate diagnoses, and provide treatment. As the state of the art of health care evolved over time, the number of house calls made by healthcare professionals diminished. In large part, healthcare providers conducted fewer and fewer house calls because it became impractical to bring bulky medical diagnosis and test equipment to the patient. Likewise, it was not cost effective or intellectually feasible for patients to purchase and operate the complicated and expensive medical machines in a home setting. Therefore, the healthcare model changed dramatically, emphasizing patient visits to healthcare facilities where an assortment of state-of-the-art test equipment would be available to assist doctors in more accurately assessing and treating patients. This meant that patients were now expected to come to the doctor, rather than the other way around.

[0008] Innovations in electronics in the last twenty years have made available a large number of more affordable and patient-operable medical devices that obviated, at least in part, the need for the patient to go to a facility each time a medical test or device checkup was required. Size and expense were not the only factors making this possible; since the new devices provided sophisticated processing in smaller form factors, the technical complexity required to operate the devices were reduced to a level that would not overwhelm a layperson’s knowledge. Unfortunately, although portable medical devices such as blood glucose meters now allow patients to perform tests outside the context of medical facilities, patients still need to meet with health care providers to discuss the results obtained.

[0009] Some medical devices include wireless transmitters for the communication of data to and from the medical device. For medical devices implanted in a patient, such as a pacemaker, wireless communication allows a healthcare provider to monitor the operation of the medical device, and to optionally monitor a patient’s biological and biometric information, the patient’s behavior, and other information pertinent to the treatment of the patient. However, the manner in which medical devices communicate varies depending on the type and manufacturer of the device, and therefore, proprietary equipment has been designed to wirelessly communicate with medical devices only on a specific frequency and using a particular data communication protocol based on the type of medical device being used.

[0010] In the United States, medical devices can broadcast on a wide range of frequencies. For example, older medical devices use frequencies ranging from 32 KHz to 175 KHz. The Federal Communications Commission (FCC) has allocated three frequency bands for use with wireless medical device communication, known as the Wireless Medical Telemetry System (WMTS). The WMTS frequency bands include the frequency ranges of 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz. Additionally, the FCC has allocated a band specifically for use by implanted medical devices. This band is known as the Medical Implant Communication Service (MICS) and includes the 402-405 MHz frequency band. It would be desirable to have the capability to communicate with medical devices using any of these frequency bands using a wide variety of wireless protocols that might be broadcast by the devices.

[0011] To make patient monitoring more convenient, Remote Patient Monitoring (RPM) was developed. Remote Patient Monitoring (RPM) generally refers to monitoring one or more conditions of a patient without requiring the patient to visit a hospital, doctor’s office, or other healthcare facility. RPM can increase the efficiency and effectiveness of providing care to patients while reducing costs. RPM can be particularly useful when a patient has a long-term or chronic disease that would otherwise require frequent visits to a healthcare facility and/or where a patient’s treatment regimen must be modified based on changing patient conditions that are monitored by one or more medical devices, such as a pacemaker or glucose meter. For example, Type-1 Diabetes patients (a lifelong condition) use glucose meters to monitor their blood sugar level to assist in determining when to take insulin—it would be desirable if such information could be quickly, easily, and effectively relayed to a health care provider for review and analysis.

[0012] Conventional RPM generally involves the use of a specific monitoring device installed in a patient’s home. The device collects data concerning the patient’s condition and relays the data to a healthcare provider. Some conventional systems require a patient to manually enter the data. For example, a diabetes patient using a conventional system for RPM may be required to sample their blood sugar level using a glucose meter, take note of the reading, and then manually enter the level in the conventional system. There are drawbacks with these conventional devices. Because of their complexity and proprietary interfaces, many are very expensive, which reduces the cost-savings benefit of RPM. Additionally, they often require a land-line connection (such as phone or
VPN) to transmit data and/or are physically bulky/heavy and therefore difficult to transport. Furthermore, conventional systems are often unable to provide data to healthcare providers quickly where data must be manually entered by a patient, which can reduce the level of benefit the patient receives from RPM. What is needed, then, is a system to allow health care providers to freely access patient-related health data, enabling the provider to conduct a virtual house call. What is also needed is a portable device and system that interoperates with a broad range of wireless-enabled medical devices to receive medical data, and provides for management and transport of that data to a healthcare provider.

SUMMARY OF THE INVENTION

[0013] Methods and systems according to the present invention may operate in conjunction with any desired frequency band, including those described above, and may operate in conjunction with multiple frequency bands. In exemplary embodiments, methods and systems according to the present invention may be configured to receive medical device data transmitted in any format and from any medical device. A system according to one aspect of the present invention comprises a processor, a medical device transceiver, a user interface, a data relay transceiver, a memory coupled to the processor, and storing instructions. Those of skill in the relevant arts understand that the transceivers referenced herein may comprise a receiver, a transmitter, or both a receiver and transmitter, and may receive and/or transmit electrical signals, radio frequency signals, modulated light signals, sonic signals, or other signals propagated through a suitable medium. The processor executes the instructions in the memory to receive data from a medical device using the medical device transceiver (which gathers data concerning the patient’s condition), and transmits the data to an intermediary device using the data relay transceiver. This system can be implemented in a small, portable unit that is easy for a patient to transport. For example, the unit could be the size of a cell phone or contained within a cell phone, or could be a small accessory device that is maintained in proximity to the medical device, such as in a container in which the medical device is also situated. The system’s user interface may include a microphone and speaker to allow the communication of audible information between the system and a user. While certain embodiments operate with radio frequency protocols such as BlueTooth and WiFi, other embodiments may utilize non-rf communications protocols such as modulated infrared light (e.g. IrDA).

[0014] A system according to another aspect of the present invention comprises a processor, a medical device transceiver, a user interface, a data relay transceiver, a memory coupled to the processor, and storing instructions. The medical device transceiver is configured to receive data wirelessly from one or more different medical different medical devices. The processor executes the instructions in the memory to receive data from one or more different medical devices using the medical device transceiver, and transmits the data to an intermediary device using the data relay transceiver. The system’s user interface may include a microphone and speaker to allow the communication of audible information between the system and a user. The method preferably functions without the need for the patient to manually enter information into a device. This method optionally allows for multiple different medical devices used by a single patient to be monitored, even if each of the devices communicate on different frequencies and/or use different communication protocols. While certain embodiments operate with radio frequency protocols such as BlueTooth and WiFi, other embodiments may utilize non-rf communications protocols such as modulated infrared light (e.g. IrDA).

[0015] Embodiments of the present invention may be used to wirelessly monitor any appropriate medical device from essentially any location from which a communications signal can be sent and received. This enables patients to enjoy an active lifestyle by not being tied to medical device monitoring equipment that is difficult or impossible to transport or having to routinely visit health care facilities. The present invention can be used to monitor any amount and type of data from any medical device.

[0016] The present invention can also be used for a variety of other monitoring purposes. For example, the present invention can be used to monitor a blood alcohol monitor, alcohol breathalyzer, or alcohol ignition interlock device to help insure a driver does not operate a motor vehicle under the influence of alcohol or other substance. The present invention can also be used in conjunction with a Global Positioning System (GPS) or other geolocation device to monitor the position of a patient. The present invention may also be used in a wide variety of military applications, such as remotely monitoring devices tracking the health status of soldiers on a battlefield in real-time in order to quickly dispatch aid to wounded soldiers. The present invention may be used to remotely monitor a chemical, biological, or radiation sensor carried by a soldier to detect an attack by unconventional weaponry.

[0017] Both the foregoing summary and the following detailed description are exemplary and explanatory only and are not restrictive of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the following illustrative figures.

[0019] FIG. 1 is a flow diagram depicting an exemplary process for medical device monitoring according to various aspects of the present invention.

[0020] FIG. 2 is a block diagram depicting an exemplary system for medical device monitoring according to various aspects of the present invention.

[0021] FIGS. 3A and 3B depict top and side views, respectively, of an external casing for a medical data translator device according to various aspects of the present invention.

[0022] FIGS. 3C and 3D depict perspective views of another embodiment of an external casing for a medical data translator according to various aspects of the present invention.

[0023] FIG. 3E depicts a perspective view of yet another embodiment of an external casing for a medical data translator according to various aspects of the present invention.

[0024] FIG. 4 depicts the interior of an exemplary container for holding a medical device and medical data translator according to various aspects of the present invention.

[0025] FIGS. 5A and 5B are a circuit diagrams depicting elements of exemplary medical data translators according to various aspects of the present invention.
FIG. 6 is a block diagram depicting a container including light and motion sensors for activating a medical data translator in accordance with various aspects of the present invention.

FIG. 7 is a flow diagram of an exemplary process for authenticating access to a system component of the present invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

An exemplary method according to an aspect of the present invention is depicted in FIG. 1. In this method, an identifier is requested from a medical device (105), and data from the medical device is received (110) and validated (115). An intermediary device such as a mobile phone or personal digital assistant is authenticated (120) and activated (125). The data is transmitted by the medical device to the intermediary device (130) and the transmission to the intermediary device is confirmed (135). The data is stored (140) in the intermediate device. A message is formatted (145) and transmitted to a medical data server (150). Optionally, a command can be received from the medical data server (155) and optionally relayed from the intermediary device. Any combination and/or subset of the elements of the method depicted in FIG. 1 may be practiced in any suitable order and in conjunction with any system, device, and/or process. The method shown in FIG. 1 can be implemented in any suitable manner, such as through software operating on one or more computer systems. Exemplary systems for performing elements of the method shown in FIG. 1 are discussed later in this description.

Request Medical Device Id

In the exemplary process according to aspects of the present invention depicted in FIG. 1, an identifier is requested from a medical device providing the data to be monitored (105). Any suitable identifier may be provided, such as the serial number of the medical device or a numeric, alphabetic, alphanumeric, or other identifier. The medical device identifier can be used to determine whether the correct medical device is being monitored. The medical device identifier can also be used to determine the manufacturer, model, type, characteristics, or other information pertinent to the medical device and/or the patient(s) it monitors. The medical device identifier may be received passively, such as from a medical device that automatically includes its identifier as part of its telemetry broadcast. Alternatively, the medical device can be polled to request the medical device identifier. The medical device identifier need not be requested from the medical device each time the medical device is being monitored. For example, the medical device identifier may be stored in a storage medium for future reference.

Receive Data Wirelessly from a Medical Device

In the exemplary method shown in FIG. 1, data is received wirelessly from the medical device (110). Accordingly, any system implementing the method of FIG. 1 does not need to be physically connected to the medical device to receive the data. Patients monitored by medical devices are thus able to lead active lifestyles without being forced to remain close to the system receiving the data from the medical device. Data can be received from any medical device, such as a blood glucose meter, a pacemaker, a blood pressure monitor, an insulin pump, a pulse oximeter, a Holter monitor, an electrocardiograph, an electroencephalograph, a blood alcohol monitor, an alcohol breathalyzer, an alcohol ignition interlock, a respiration monitor, an accelerometer, a skin galvanometer, a thermometer, a patient geolocation device, a scale, an intravenous flow regulator, patient height measuring device, a biochip assay device, a sphygmomanometer, a hazardous chemical agent monitor; an ionizing radiation sensor; a monitor for biological agents, a loop recorder, a spirometer, an event monitor, a prothrombin time (PT) monitor, an international normalized ratio (INR) monitor, a tremor sensor, a defibrillator, or any other medical device. A medical device that includes a combination of different medical devices (such as those listed previously) may be monitored in accordance with the present invention. The medical device can be partially or completely implanted in a patient, such as in the case of a pacemaker. The medical device may also be located externally to a patient. The medical device may be connected to a patient (for example, through one or more electrodes), or operate independently of any coupling to a patient, such as a scale. The medical device may also operate in conjunction with a temporary interfacing with a patient, such as the case of the cuff of a blood pressure monitor encompassing the arm of a patient to take a reading.

The medical device data can be received by any person, system, device, or other suitable recipient. The exemplary method in FIG. 1 may be practiced manually by a human being, automatically by a device, or a combination of the two. An exemplary device for performing the method depicted in FIG. 1 is depicted in FIG. 2 and is discussed in detail below.

Data can be received directly from a medical device. For example, some medical devices such as pacemakers and other devices implanted in a patient include wireless transmitters to wirelessly broadcast data. A medical device can also provide data wirelessly using another device. In one embodiment of the present invention, for example, a medical device provides data through a serial port (a wired connection) to a computing device. The computing device is in turn connected to a wireless router. The data can thus be received wirelessly after being retransmitted from the wireless router.

The medical device may transmit on any frequency using any format and protocol. For example, various medical devices transmit data in the Wireless Medical Telemetry Service (WMTS) frequency bands. There are three WMTS frequency bands, including frequencies from 608 MHz to 614 MHz, 1395 MHz to 1400 MHz, and 1427 MHz to 1432 MHz. In another example, the medical device may transmit using the Medical Implant Communications Service (MICs) frequency band, including frequencies from 402 MHz to 405 MHz. In yet another example, a medical device may transmit data in the 32 KHz to 175 KHz range.

The medical device data can be received from a plurality of different medical devices, where each medical device may perform any combination of functions. For example, data from a glucose meter, blood pressure monitor, and combination scale/height measuring device each transmitting data in different formats and on different frequencies may each be received in accordance with the present invention. In the case where a plurality of medical devices transmits data in response to a request for data, each device in the plurality of devices can be sent such a request separately. Alternatively, a plurality of medical devices automatically transmitting data on the same frequency, in the same format, and potentially at the same time (such as in the case of multiple devices of the same type and/or from the same manu-
facturer) can be received in accordance with the present invention by, for example, using a separate wireless receiver keyed to a unique identifier associated with each medical device. When data has been received from a plurality of medical devices, in one embodiment, a list of the medical devices may be displayed on a user interface, and optionally, the user may be prompted to select one, all, or none of the plurality of medical devices, whose data is desired to be transmitted to the medical data server. The data for the selected set of medical devices is then relayed as described with alternate embodiments as described herein. Any other suitable method for receiving data from a plurality of medical devices may also be used in conjunction with the present invention.

Any type of data may be received from a medical device. For example, the data may include information regarding a patient, such as the patient's biological and biometric information, the patient's behaviors, results of analysis of physical patient parameters, and information regarding the patient's environment. For example, a medical device such as a glucose meter could provide data regarding a patient's current (or last measured) blood glucose level, the date and time the patient last used the glucose meter, and the current temperature or other environmental factors that might affect a glucose test. Other possible environmental parameters that may be included in the data received from a medical device include a battery charge level, a temperature, a barometric pressure, a code relating to an accessory for the medical device, a data validity measurement, an elapsed time since a previous reading by the medical device, a test result parameter, a signal-to-noise parameter, and a quality of service (QoS), and combinations thereof. Data received from a medical device may also include any other suitable information, such as diagnostic information regarding the medical device.

The medical device data may provide data relating to a single patient or multiple patients. In the case where a single medical device provides data regarding multiple patients, the data can be identified with an individual patient either in the data received by medical device (such as by using a patient identifier) or through processing in accordance with the present invention.

The medical device can provide the data in any format. Different medical devices from different manufacturers often use different formats for providing data. For example, data from a glucose meter may be provided in a series of fixed-length data records followed by a terminator indicator (such as a null or other predefined character) and/or a checksum for validating the data. Any type of data may be provided. In the case of a glucose meter, the data may include one or more readings of a patient's blood glucose level and the date and time each reading was taken. The medical device identifier discussed previously may be used to determine a specific data format used by a medical device. Alternatively, a data format may be specified by a user or selected by analyzing the format of the data received and comparing it to a set of known medical device data formats.

Validate Data

In the exemplary process shown in FIG. 1, the data from the medical device is validated (115). The data from the medical device can be validated in any suitable manner to achieve any result. For example, the data from the medical device may be validated to ensure it was transmitted properly and completely. The medical device data may also be validated to ensure it was provided from a specific medical device or particular type of medical device. The data may also be validated to ensure that fields in the data correspond to pre-determined values and/or are within certain thresholds or tolerances. Any number, code, value or identifier can be used in conjunction with validating the medical device data. For example, the data can be validated by analyzing a medical device serial number, a medical device identifier, a patient identifier, one or more parity bits, a cyclic redundancy checking code, an error correction code, and/or any other suitable feature.

Authenticate Intermediary Device

In the exemplary method depicted in FIG. 1, an intermediary device receiving the data is authenticated (120). In the context of the present invention, the intermediary device includes any type of system or device capable of receiving the medical device data in any manner. Such intermediate devices may include, for example, personal computers, laptops, personal digital assistants, and mobile computing devices. The intermediary device may process the data in any manner, and can transmit some or all of the data to another recipient, such as a medical data server. For example, but not by way of limitation, the intermediary device may include a personal computer or a mobile computing device, such as a laptop computer, a mobile wireless telephone, or a personal digital assistant (PDA). In an exemplary embodiment of the present invention, the intermediary device further includes software for receiving the medical device data, formatting a message based on the data, and transmitting the formatted message to a medical data server. Such software can operate on any suitable mobile computing device and with any computer operating system. The intermediary device may also include any number of other systems and devices suitable for receiving data from the medical device, processing the data, and/or transmitting the data to a medical data server. Further discussion regarding exemplary embodiments of intermediary devices is presented later in this description.

The intermediary device can receive the data directly from the medical device, or from one or more other devices. In one exemplary embodiment of the present invention, the intermediary device comprises a mobile computing device including one or more wireless transceivers and is configured to receive data from the medical device directly. In another exemplary embodiment of the present invention, the medical device transmits the data to a first device, which in turn transmits the medical device data to the intermediary device (wirelessly or through a wired connection).

The intermediary device may be authenticated to achieve any result. For example, the intermediary device may be authenticated to restrict transmission of the data from the medical device to intermediary devices operating as part of the present invention. Authentication can also prevent sensitive medical data from being broadcast and viewed by unintended recipients. The intermediary device may also be authenticated to verify that the intermediary device is able to receive, process, and/or transmit the medical device data to a medical data server. During authentication, the authenticated device or devices may also be remotely commanded, and such commands may include steps that configure devices to inter-operate with components of the present invention. For example, but not by way of limitation, such steps may include the downloading of software applications, applets, embedded operating code, and/or data.
The intermediary device can be authenticated in any manner. For example, an intermediary device can be authenticated to receive data from one or more medical devices using an authorization code. The authorization code can be any number, code, value or identifier to allow the intermediary device to be identified as a valid recipient of the data from the medical device. In one exemplary embodiment of the present invention, an intermediary device stores an authorization code and broadcasts the authorization code in response to a request for authorization. Unless the authorization code matches a code stored by the transmitter of the medical device data (such as the medical device itself or another transmission device), the medical device data is not transmitted to the intermediary device. Transmission of the medical device data to the intermediary device need not necessarily be predicated upon successful authentication of the intermediary device, however.

In another exemplary embodiment of the present invention, an intermediary device receiving the medical device data using a wireless network protocol (such as Bluetooth) is authenticated based on whether the intermediary device advertises one or more services. In this context, advertised services reflect functions, utilities, and processes the intermediary device is capable of performing. The intermediary device broadcasts indicators of this functionality, thus “advertising” them to other systems and devices. In the present exemplary embodiment of the invention, unless the intermediary device advertises a service that is identifiable with the operation of the present invention (i.e. a process capable of broadcasting the medical device data to a medical data server, for example), the intermediary device is not authenticated and thus the medical device data is not transmitted to the intermediary device.

Activate Intermediary Device

In the exemplary process depicted in FIG. 1, the intermediary device can be activated (125) prior to transmitting the medical device data to the intermediary device. Many devices, particularly mobile computing devices running on batteries, employ power-saving features to conserve battery life when not in use. In the case where an intermediary device is in a power-saving or standby mode, it may be necessary to activate the intermediary device before it can receive the medical device data. The intermediary device can be activated in any suitable manner. For example, a signal configured to activate the device may be transmitted to prepare the intermediary device to receive the medical device data.

Transmit Data to Intermediary Device

The medical device data is transmitted to the intermediary device (130). The data can be transmitted in any suitable manner. In one exemplary embodiment of the present invention, the medical device data is transmitted to the intermediary device using a wired connection, such as an RS-232 serial cable, USB connector, Firewire connector, or other suitable wired connection. The medical device data can also be transmitted to the intermediary device wirelessly using a wireless transmitter. Any suitable method of wireless communication can be used to transmit the medical device data, such as a Bluetooth connection, infrared radiation, Zigbee protocol, Whireless protocol, IEEE 802.15 protocol, IEEE 802.11 protocol, IEEE 802.16 protocol, and/or ultra-wideband (UWB) protocol. If desired, the medical device data could be transmitted to the intermediary device using both a wired and wireless connection, such as to provide a redundant means of communication, for example.

Any amount of medical device data can be transmitted to the intermediary device in any manner. For example, data from the medical device can be transmitted to the intermediary device in real-time, or medical device data can be stored (such as in a memory storage device) for a period of time before being transmitted to the intermediary device. In some cases, for example, it may be more efficient to transmit blocks of medical device data at once rather than initiating communication with an intermediary device each time data is available from the medical device. In other cases, the intermediary device may be out of range or otherwise unavailable to receive the medical device data. The medical device data can be stored for any desired length of time, and/or until a particular event occurs. For example, the medical device data could be stored until it is verified that the intermediary device and/or the medical data server have received the data, allowing the data to be retransmitted if necessary.

The medical device data is transmitted to the intermediary device in any format. For example, the data from the medical device can be transmitted to the intermediary device exactly as it is transmitted from the medical device. This would be the case in embodiments of the present invention where the medical device itself is transmitting the data directly to the intermediary device. Alternatively, in embodiments of the present invention where the data is being received from the medical device and then retransmitted to the intermediary device, the medical device data can be reformatted, modified, combined with other data, or processed in any other suitable manner before being transmitted to the intermediary device. For example, the medical device data can be encrypted prior to transmission to the intermediary device, and this encryption may occur at any stage, for instance in the medical device itself or at a stage after being transmitted by the medical device. In cases where the medical device data is being combined with other data and transmitted to the intermediary device, all of the data may be encrypted or simply the medical device data itself. In an alternate embodiment, a digest of the medical data may be encrypted, to digitally “sign” the data contents to verify its authenticity. For example, but not by way of limitation, this digest may be produced by providing the received medical data to a hashing algorithm such as the MD5 or SHA-1 Secure Hashing Algorithm as specified in National Institute of Standards and Technology Federal Information Processing Standard Publication Number 180-1.

Asymmetric encryption algorithms and techniques are well known in the art. See, for example, RSA & Public Key Cryptography, by Richard A. Mollin, CRC Press, 2002, and U.S. Pat. No. 4,405,829, issued Sep. 20, 1983, the disclosures of which are fully incorporated by reference herein for all purposes. In an illustrative example, if two parties (for example, "Alice" and "Bob") wish to communicate securely using public key cryptography, each party begins by generating a unique key pair, where one of the keys is a private key that is kept in confidence by that party, and the other key is a public key that may be publicly distributed, published only to a message recipient, or made available through a public key infrastructure. The key generation step need be done by a party only once, provided that the party’s private key does not become compromised or known by another party. If Alice wants to send a message confidentially to Bob, she may use
Bob's public key to encrypt the message, and once sent, only Bob can decrypt and view the message using Bob's private key. But if Alice also wanted Bob to have assurance that the message was in fact coming from her, she could further encrypt the message with her private key before sending, then when Bob's private key and Alice's public key are used to decrypt the message, Bob knows for certain that he was the intended recipient and that Alice was the one who originated the message, and Alice knows that only Bob will be able to decrypt and read her message.

[0049] Asymmetric cryptography may be utilized to enhance security of certain implementations of the present invention. In an alternate embodiment, data transmitted by a medical device 250 is encrypted with a private key of the medical device user (or optionally with the private key of a health care provider that is operating the medical device), or with a public key of the intended recipient system such as the medical data server 270, or with both keys. The private and/or public keys may be delivered to the medical data translator 200 through a wired or wireless connection, allowing the translator 200 to be configured for secure operation. In one embodiment, the system or medical data server 270 may request that the public key of the medical device be forwarded to enable decryption of any medical information encoded with the user's private key. In this manner, the data may be authenticated as coming from the actual patient that is desired to be monitored, and optionally, the patient may also be assured that only the intended recipient system or medical device server 270 is capable of decrypting and gaining access to the patient's medical device data.

[0050] In alternate embodiment, encrypted or unencrypted data can be transmitted through an encrypted transmission protocol, such as the wireless encryption protocols (WEP, WPA and WPA2) associated with the IEEE 802.11 wireless protocols. Any number of other encryption methods can be used to encrypt the medical device data in conjunction with the present invention. The intermediary device may decrypt the medical device data, to allow processing of the data for example. Alternatively, to protect the data from unauthorized viewing, an intermediary device could simply retransmit the encrypted data to the medical data server.

Confirm Transmission of Data to Intermediary Device

[0051] The transmission of the medical device data can be confirmed (135) to verify the transmission was successful. The transmission can be confirmed in any suitable manner. For example, the intermediary device can transmit an acknowledgement once the transmission is received, otherwise the transmission can be rebroadcast.

Validate Data Transmitted to Intermediary Device

[0052] In the exemplary process shown in FIG. 1, the data transmitted to the intermediary device is validated (115). The data from the medical device can be validated in any suitable manner to achieve any result. For example, the data from the medical device may be validated to ensure it was transmitted properly and completely. The medical device data may also be validated to ensure it was provided from a specific medical device or particular type of medical device. The data may also be validated to ensure that fields in the data correspond to predetermined values and/or are within certain thresholds or tolerances. Any number, code, value or identifier can be used in conjunction with validating the medical device data. For example, the data can be validated by analyzing a medical device serial number, a medical device identifier, a patient identifier, one or more parity bits, a cyclic redundancy checking code, an error correction code, and/or any other suitable feature.

Store Data

[0053] The intermediary device may store the medical device data (145). The intermediary device may store the data in any suitable manner, such as by using a memory storage device. Any portion or amount of medical device data (or other forms of information) received or generated by the intermediary device may be stored for any length of time. The data may be stored for a predefined period of time and/or until an event occurs. For example, in one embodiment of the present invention the data is stored by the intermediary device until the data has been transmitted to the medical data server. In another embodiment, data is stored by the intermediary device until a predetermined data transmission record size has been reached, so as to reduce communication charges that may accrue during transmission. In yet another embodiment, the intermediary device stores the data until an acknowledgment from the medical data server is received, where the acknowledgment indicates that the stored data has been received by the medical data server.

Format Message for Transmission to Medical Data Server

[0054] In the exemplary method according to an aspect of the present invention depicted in FIG. 1, a message is formatted for transmission to the medical data server. The message can originate from any system operating in conjunction with the present invention. For example, the message may be created by the intermediary device, a device transmitting the medical device data to the intermediary device, or the medical device itself. The message can include some or all of the medical device data, as well as any other information useful to the medical data server. Multiple messages can be formatted to include any desired amount of medical device data. For example, in the case of data from a glucose meter, multiple messages may be formatted to each include a single glucose reading, or a single message could be formatted to include the last ten glucose readings taken by the meter. The message can include any other desired data from any suitable source. For example, real-time data from a medical device may be included in a message along with previously-transmitted data from the stored by the intermediary device creating the message. The message (in whole or in part) may be encrypted to protect the contents of the message from unintended viewers and/or the privacy of the patient being monitored.

[0055] The message provides the medical device information to the medical data server in a format the medical data server can recognize and utilize. The message can thus be formatted to only include portions of the medical device data needed by the server and/or additional information about a patient, the medical device, and/or the treatment regimen. The message can be of desired format. For example, the message can be included in a file having a tokenized format such as standard ASCII text format, or any other suitable standardized file format, such as an MS Word document, MS Excel file, Adobe PDF file, or binary picture file (JPEG, bmp, etc.). The data within such a file can be ordered in any manner and have any suitable delimiters, notations, or other features. For example, a list of multiple glucose level readings in a text
file message could be provided chronologically by when the readings were taken, with comma or tab delimiters to denote the start and end of each reading. The message may also have a unique and/or propriety format.

The format of the message can also be based on the method by which the message is transmitted to the medical data server. For example, where the message is transmitted to the medical data server using a wireless mobile telephone such as a cellular phone, the message can be formatted as an SMS text message. Similarly, the message may be formatted as an XML record, email, and/or facsimile. The message can include multiple formats and/or multiple messages may be formatted having different formats for transmission in a variety of methods or to a variety of recipient medical data servers.

Transmit Formatted Message to Medical Data Server

The message is transmitted to a medical data server (160) to allow the medical device data to be analyzed and processed. The message can be transmitted to a single medical data server, or to a plurality of medical data servers. The medical data server can be any suitable recipient of the medical device data. For example, the medical data server can be a computer system or other device as well as a human recipient (such as a doctor, nurse, or other healthcare provider).

The message can be transmitted to the medical data server in any suitable manner. For example, the message can be transmitted to the medical data server through a wired connection, such as a telephone line, fiber optic cable, and/or coaxial cable. The message may also be transmitted wirelessly using any suitable wireless system, such as a wireless mobile telephony network, General Packet Radio Service (GPRS) network, wireless Local Area Network (WLAN), Global System for Mobile Communications (GSM) network, Personal Communication Service (PCS) network, Advanced Mobile Phone System (AMPS) network, and/or a satellite communication network. The message may be transmitted using any suitable combination of multiple wired and wireless communication methods. The transmission method selected to transmit the message to the medical data server can be chosen according to any desired criteria. For example, one or more transmission methods can be selected from a plurality of possible transmission methods to send the message based on each method's cost, time required to transmit, reliability, security, or any other suitable factor.

Receive Command from Medical Data Server

In addition to receiving the medical device data, the medical data server can transmit a command (160). The command can be received by the intermediary device, the medical device, and/or any other suitable recipient. Any number of commands of any type may be transmitted by the medical data server. The command can be transmitted using the same variety of wired and wireless methods discussed previously for the transmission of the formatted message. The command need not be transmitted using the same communication method with which the formatted messages are transmitted to the medical data server.

In one embodiment of the present invention, for example, the medical data server issues a command to reconfigure a software application operating on the intermediary device. In another embodiment, the medical data server issues one or more commands to control the functionality of the medical device. In yet another embodiment, the medical data server issues one or more commands to request that a public encryption key corresponding to the patient using a medical device be forwarded to the medical data server, or that a device associated with the present invention receive a public encryption key corresponding to an intended recipient such as a particular health care service provider or other known destination such as the medical data server.

The commands need not be sent directly to a device they are intended to control. For example, a command could be transmitted to an intermediary device, which in turn retransmits it (unmodified) to the medical device to be controlled. Alternatively, the intermediary device could receive a command from the medical server, analyze it, and then transmit an appropriately formatted command tailored to the specific medical device to be controlled. In this manner, the medical data server need not be able to generate a command for each and every specific device it wishes to control, it can send a command appropriate to a class of devices (e.g., glucose meters) and the intermediary device will appropriately translate the command to control the medical device. The commands from the medical data server can initiate/run diagnostic programs, download data, request the patient's public encryption key, download the intended recipient's public encryption key, and perform any other suitable function on the intermediary device, medical device, or other devices operating in conjunction with systems and methods of the present invention.

A command from a medical data server can be in any appropriate format and may include any suitable information. For example, a command may include data received from one medical device 250 to be delivered to another medical device 250 through the medical data translator 200. In this manner, a variety of medical devices can share data whether they are in communication with the medical data translator 200 or not.

A command can also originate from an intermediary device. For example, a command to program or reconfigure one or more software programs on the medical data translator 200 depicted in FIG. 2 can be provided by an intermediary device 260 to the medical data translator 200 through the data relay transceiver 230. A command, as discussed above, may include multiple instructions, applets, or data elements to be processed, such as sections of executable code or interpretable scripts. Additionally, a user can program or configure a software program on any device operating in conjunction with the present invention through a suitable user interface, such as the user interface 290 of the medical data translator 200.

In any system where commands can be sent remotely, security is always a concern, especially when a wireless implementation may provide an entry vector for an interloper to gain access to components, observe confidential patient data, and control health-sensitive components such as pacemakers and insulin pumps. In any digital data network, it is also possible that commands intended for one recipient may be misrouted to a patient or health care provider that was not the intended recipient of the command. There are, however, a number of methods to provide for enhanced security in a remote command system while still allowing flexibility and minimal obtrusiveness.

In one embodiment, a command received by any of the components in FIG. 2 may be authenticated before the command is either acted upon by the destination component, or forwarded to another component in the system. Authentication may be directed to determining (1) whether the command came from a trusted or authorized source and (2) that the recipient is actually the intended recipient of the command. In one implementation, source command authentication is achieved by determining whether the origin of the command is a trusted component or server, and one way to accomplish this determination is analyzing whether a com-
mand is properly digitally signed by the originator, or some other authentication information is provided that assures the recipient component that the message or command is authentic and the recipient component is actually the intended recipient. In an alternate implementation, destination command authentication is accomplished by examining the contents of the message or an authentication tag to determine the intended recipient, or alternatively decrypting the command or a portion of the command to verify the intended recipient.

In one embodiment, when commands are created by a command originator, the originator provides for a means to verify the authenticity and/or validity of the command by at least one of the following methods: (1) encrypting the command with a private key of the command originator; (2) generating a digest of the command (through a method such as a hashing algorithm discussed above) and optionally encrypting the hashed digest with the command originator’s private key, or (3) utilizing a symmetric encryption scheme providing an authentication code (such as a cryptographically hashed password) that is compared to previously stored values. Then, when a system component receives the command along with any encrypted or cleartext certification data, the component may determine the command is valid by (1) attempting to decrypt an encrypted command message with the alleged originator’s public key, (2) attempting to decrypt an encrypted digest with the alleged originator’s public key, and comparing the result to a hashed value of the command, or (3) comparing a cryptographically hashed password for the alleged originator to known pre-stored values, and if a match is found, authorization is granted. As an additional step, if the command were optionally encrypted using the intended patient/provider’s public key, then only the recipient is capable of decrypting the command, ensuring that only the truly intended patient’s health-care devices were being issued commands, and not an unintended third party. For example, in one embodiment, authenticating the command comprises decrypting at least part of the command using at least one of: a public key associated with the medical data server; a private key associated with a user of the medical device; and a private key associated with the medical device.

Generation of an authentication token may be accomplished using alternative methods such as entry of a patient identifier, PIN, or password by a patient or healthcare provider after being prompted to do so. Alternatively, a biometric measurement of the patient or healthcare provider could be obtained and the measurement rendered into a digital representation. Once generated, for security purposes the authentication token may be secured by encrypting the token, digesting and encrypting the digest of the token, or cryptographically hashing the token before transmission to the requesting entity such as the medical data system or server. As discussed above in regards to the abovementioned command authentication, in one embodiment, when authentication tokens are created, the originating component of the token may create a certification of validity through at least one of the following methods: (1) encrypting the token with a private key associated with the token originator; (2) encrypting the token with a public key associated with the token requester or destination; (3) generating a digest of the token (through a method such as a hashing algorithm discussed above) and optionally encrypting the hashed digest with the token originator’s private key, or (4) providing an authentication code as at least part of the token (such as a cryptographically hashed password) that may be compared to previously stored values. Then, when a medical data system component receives the token along with any encrypted or cleartext certification data, the component may determine the access is valid by (1) attempting to decrypt an encrypted token with the alleged originator’s public key; (2) attempting to decrypt an encrypted token with the alleged originator’s public key; (3) attempting to decrypt an encrypted digest with the alleged originator’s public key, and comparing the result to a hashed value of the token, pin, code, or password, or (4) comparing a cryptographically hashed password for the alleged originator to known pre-stored values, and if a match is found, authorization is granted.

The medical data system component then receives and analyzes the validity of the authentication token as described above. If examination of the authentication token provides that the token is authentic, such as by comparing the analyzed token data to known pre-stored values such as the patient’s or the patient’s healthcare provider’s pre-stored hashed password or other identity datum, then access is successful and the process terminates. After analyzing the authentication token or a message containing or associated with the token, the medical data system may determine that access is either permitted or denied, and may communicate this status to the originator of the authentication token who then receives notice of the failure. At that point, the system may repeat the process, allowing the token originator to attempt access again.

Exemplary System

An exemplary system for use in conjunction with the present invention is depicted in FIG. 2. This system may be used in conjunction with the method described in FIG. 1, as well as with any subset or combination of the elements thereof. The system shown in FIG. 2 may also be used in conjunction with any other suitable embodiments of systems and methods for medical device monitoring according to an aspect of the present invention.

The exemplary system for medical device monitoring depicted in FIG. 2 includes a medical data translator that includes a processor coupled to a memory. A data relay transceiver wirelessly communicates with one or more intermediary devices via antenna, which in turn communicates with one or more medical device servers.
An adapter module 240 communicates with one or more medical devices 250 via antenna 243. The adapter module 240 includes a medical device transceiver 242 and an auxiliary communication system 244, both in communication with the processor 210. The auxiliary system 244 may include any number of wired or wireless connections to one or more computer systems 280, such as a universal serial bus (USB) connection, serial connection, parallel connection, Firewire connection, Ethernet connection, or any other suitable connection. The medical data translator 200 may include any suitable power connection for powering the translator and/or for recharging an energy storage device such as a battery (not shown). The components of the medical data translator 200 may receive electrical power from any other type of power supply. The medical device transceiver is coupled to an antenna 243, which may establish unidirectional or bidirectional wireless communications with one or more of the medical devices 250. The antenna 243 may be the same antenna as antenna 232, or one or more separate antennas. The antenna 243 may be located internally or externally to the adapter module 240, and may be configured in any suitable manner to operate with the medical data translator 200. The functionality of the medical data translator 200 can be implemented in any suitable manner, such as through the processor 210 executing software instructions stored in the memory 220. Functionality may also be implemented through various hardware components storing machine-readable instructions, such as application-specific integrated circuits (ASICs), field-programmable gate arrays (FPGAs) and/or complex programmable logic devices (CPLDs). Systems for medical device monitoring according to an aspect of the present invention may operate in conjunction with any desired combination of software and/or hardware components.

**Medical Data Translator 200**

[0072] Referring to FIGS. 3A and 3B, the medical data translator 200 depicted in FIG. 2 is shown enclosed within a case 300. A case holding a system for medical device monitoring according to aspects of the present invention may be of any size, shape and configuration. The system (and case enclosing it) is preferably small enough to be easily portable by a patient or person being monitored. For example, the exemplary case 300 depicted in FIGS. 3A and 3B is 2.5 inches long, 2 inches wide, and 0.5 inches deep. The top and bottom of the case 300 are 0.05 inches thick, while the sides of the case 300 are 0.075 inches thick. The case may be manufactured from any number of materials, such as plastic, metal, wood, composites, and/or any other suitable material. The case 300 shown in FIGS. 3A and 3B, for example, is manufactured from hard plastic.

[0073] The case 300 includes battery compartments 320 for powering the data translator 200. The case 300 also includes an interface module 310 that includes the adapter 240. The interface module 310 may include any suitable portion of the medical data translator 200. In the exemplary embodiment depicted in FIG. 2, the interface module 310 includes the adapter module 240 comprising a medical device transceiver 242 and auxiliary communication system 244. In this embodiment, the interface module 310 is detachably connected to the case 300 to allow different modules 310 to be interchangeably connected to the case 300 to communicate with different medical devices 250.

[0074] In another exemplary embodiment of the present invention, referring now to FIGS. 3C and 3D, a case 370 includes a removable adapter module 380 that includes an antenna 385 for communicating with a medical device 250 through a wireless connection. The adapter module 380 connects to the case 370 using plug 387. The plug 387 attaches to a corresponding port on the case 370 (not shown) to hold the adapter module 380 in place and allow the communication of data through the adapter module 380. The plug 387 can utilize any desired wired connection, such as a USB connection. The adapter module 380 connects to the case 370 using plug 387. The plug 387 attaches to a corresponding port on the case 370 (not shown) to hold the adapter module 380 in place and allow the communication of data through the adapter module 380.

[0075] The case can include any other suitable features. For example, the case may include a screen, lights, LEDs, keys, speaker, and microphone grill to support features of a user interface included in a system for medical device monitoring. The exemplary systems for medical device monitoring shown in FIGS. 2, 3A, 3B, 3C, 3D and 3E are all configured to fit in a container along with the medical device it communicates with to allow a user to easily transport the medical device and the data translator together.

[0076] Other embodiments of systems for medical device monitoring according to aspects of the present invention can be configured to be in small enough to be coupled with or integrated into a medical device 250 or an intermediary device 260. For example, a medical device 250 may be configured to include a medical data translator 200 within the packaging housing the medical device 250. Similarly, a medical device 250 can be integrated as part of an intermediary device 260 such as a cellular phone, PDA, or other mobile computing device. The intermediary device 260 could thus be configured to both receive data from a medical device 250 as well as transmit messages regarding the medical device 250 and/or patient to a medical data server 270.

[0077] Alternatively, a medical data translator 200 can be configured to be physically attached to a medical device 250 or intermediary device 260. For example, where an intermediary device 260 such as a mobile wireless telephone or PDA is used in conjunction with embodiments of the present invention, one exemplary embodiment of a medical data translator 200 and its case 300 is configured to match the size and shape of the of the intermediary device 260 and attach to the back of the intermediary device 260 using metal or plastic clips that wrap around the face and/or sides of the intermediary device 260. When attached, the medical data translator 200 conforms to the size and shape of the outline of the intermediary device 260, and is preferably shaped to conform to the dimensions of the back of the intermediary device 260 to avoid unnecessarily impacting the original size of the intermediary device 260. In this embodiment, the case of the medical data translator 200 may also include other desirable features, such as a belt clip to allow the data translator/intermediary device combination to be worn by a user.

[0078] Turning to FIG. 4, in another exemplary embodiment of the present invention, the medical data translator 200 is contained in a flexible, protective container 400 that opens to allow a medical device 250 and/or intermediary device 260 (such as a cellular phone, PDA, or other mobile computing device) to be likewise contained therein. This allows a medical data translator 200 to be used with a variety of intermediary devices 260, and may (in some cases) provide a more cost effective approach to integrate the medical data translator 200 with an intermediary device 260 or medical device 250. In this embodiment, the medical data translator 200 can be integrated within the protective container 400 itself, with the container acting as the case for the data translator 200.

[0079] Alternatively, as depicted in FIG. 4, the medical data translator 200 may simply be contained within a pouch or other structure within the container 400. The exemplary con-
container 400 depicted in FIG. 4 also includes a holder 420 for the medical device 250 formed from clear plastic to allow a user to read a display 422 and/or operate keys 424 on the medical device 250. The protective container 400 can also be sized to comfortably fit and protect any other desired item, such as a day planner, wallet, notepad, and/or writing utensil or PDA stylus. The protective container can be made from any desired material, such as leather, plastic, nylon, cordura, or other flexible material. The protective container can be sealed in any manner, such as by using snaps, hook-and-loop closures, buttons, and/or a zipper. The exemplary container 400 depicted in FIG. 4, for example, is sealed using a zipper 430. The container 400 can be waterproof, heat resistant, and/or include padding to protect the medical data translator and other contents from the shock of a fall. The container 400 may include any number of pockets, pouches, or other sub-containers inside or outside the case to hold accessories associated with the medical device 250, intermediary device 200, or other item(s) stored within the container 400.

[0080] The exemplary protective container 400 depicted in FIG. 4 is configured to hold a medical device 250 (specifically, a glucose meter) and a medical data translator 200 according to an aspect of the present invention. In this exemplary embodiment, the protective container 400 is closed using a zipper 430 that runs along the exterior of the sides of the container 400. A user unzips the two halves of the container 400 and opens the container 400 to display the glucose meter contained in the holder 420 attached to the interior of one half of the container 400, while the medical data translator 200 is contained in a pouch 410 attached to the interior of the other half of the container 400. The pouch 410 is formed from a nylon mesh material to allow a user to see and/or interact with user interface features of the medical data translator 200. The pouch 410 is sealed with a zipper 412. The container 400 includes a flexible elastic strap 440 to hold a container of blood sugar metering strips 442. The container 400 may include any number of other pouches or containers on the interior or exterior of the container for storing batteries and/or power cables for the glucose meter and/or medical data translator 200, and other items of use to the patient carrying the container, such as bottles of insulin and needles for use by the patient depending on the outcome of a reading by the glucose meter.

Processor 210

[0081] The processor 210 retrieves and executes instructions stored in the memory 220 to control the operation of the medical data translator 200. Any number and type of processor such as an integrated circuit microprocessor, microcontroller, and/or digital signal processor (DSP), can be used in conjunction with the present invention. Referring now to FIG. 5A, an exemplary medical data translator 200 according to an aspect of the present invention is implemented using a microcontroller 501. In the exemplary systems depicted in FIGS. 5A and 5B, the microcontrollers 501 and 530 include a Universal Asynchronous Receiver/Transmitter (UART) and Universal Serial Bus (USB). The microcontroller 530 depicted in FIG. 5B additionally includes a digital signal processor (DSP) for communication with a cellular RF Transceiver 540 as will be discussed in more detail below. The microcontrollers 501, 530 depicted in FIGS. 5A and 5B, respectively, can include any other suitable components and features, such as analog-to-digital converters (ADCs) (520), and/or digital-to-analog converters (DACs) (515), though these components have been shown outside the microcontrollers 501, 530 for clarity.

Power Source

[0082] Any number, combination, and type of suitable power sources can be utilized in accordance with aspects of the present invention. The exemplary systems depicted in FIGS. 5A and 5B are powered by a rechargeable 4.2V Lithium ion battery 506. One DC to DC converter 508 is used to step down the voltage from the battery 506 to 3.3V for use by some components in the system, while another DC to DC converter 509 is used to step up the voltage to 5V for use by other components. The battery 506 can be recharged through the VBUS lead of the USB connector 504 and charging circuit 507. Both converters 508, 509 can be enabled and disabled via signals from the microcontroller 501 on OUT1 and OUT2 to save power and extend the life of the battery 506. The microcontroller 501, 530 can monitor the voltage of the battery 506 using ADC 520, FET circuit 521, and voltage divider 522. The voltage divider 522 is used because the voltage of the battery 506 when fully charged (4.2V) is greater than the maximum 3.3V input that can be accepted by the ADC 520. The FET circuit 521 connects the battery 506 to the voltage divider 522 only when a battery test is being performed (i.e.—when pin OUT10 is grounded) to avoid a constant drain on the battery 506 when the system is otherwise powered down.

[0083] Any other suitable battery may be used according to any desired criteria. For example, a rechargeable battery or batteries integrated with the data translator may be selected to reduce the overall size of the medical data translator 200 and/or provide for the convenience of a user who would not need to replace batteries. One or more standard replaceable batteries (i.e. alkaline AA or AAA batteries) may be selected to reduce the price of the medical data translator 200. The power supply circuitry shown in FIGS. 5A and 5B is exemplary only, and may be implemented by using other conventional power supply approaches. The medical data translator 200 and other systems for medical device monitoring according to various aspects of the present invention can utilize any appropriate power supply devices, components, circuits, and systems.

Memory 220

[0084] The exemplary system in FIG. 2 includes a memory 220. The memory 220 stores instructions, medical device data, messages transmitted to or received from the medical data server 270, and any other suitable information. A memory operating in conjunction with the present invention may include any combination of different memory storage devices, such as hard drives, random access memory (RAM), read only memory (ROM), FLASH memory, or any other type of volatile and/or nonvolatile memory.

[0085] In the exemplary embodiments of medical data transmitters 200 depicted in FIGS. 5A and 5B, the microcontroller 501 and 530 each include an on-chip memory. In addition, the microcontroller 501, 530 is coupled to a flash memory 513. The flash memory 513 may be of any size to achieve any desired purpose. In this exemplary embodiment, the size of flash memory 513 is selected to adequately store pre-recorded voice recordings to be played through the speaker 518, discussed below. Any number of memory stor-
age devices of any size and configuration may also be used in conjunction with the present invention.

**Data Relay Transceiver 230**

The data relay transceiver 230 communicates with one or more intermediary devices 250, medical data servers 270, or other suitable systems. Any suitable communications device, component, system, and method may be used in conjunction with the present invention. In the exemplary circuits shown in FIGS. 5A and 5B, the data relay transceiver 230 comprises a Bluetooth transceiver 512 that is in bidirectional communication with the microcontroller 501, 530 through the UART interface on the microcontroller 501, 530.

The medical data translator 200 may also be used in conjunction with the present invention. In FIG. 51, for example the exemplary medical data translator 200 further includes a cellular radio frequency (RF) transceiver 540 in communication with the microcontroller 530. In this exemplary embodiment, the microcontroller 530 is a cellular baseband processor that includes a digital signal processor (DSP) which communicates data through a cellular RF power amplifier and front end connected to a cellular antenna 550. Data is transmitted by the microcontroller 530 on the CELL TX line and received by the microcontroller 530 on the CELL RX line. Additionally, the microcontroller 530 can control various features of the RF transceiver 540 via the CELL CTRL line. The RF power amplifier and front end 550 performs the necessary functions to transmit and receive cellular signals, such as power amplification, power detection, filtering, and input/output matching.

The medical data translator 200 depicted in FIG. 51 may be configured to communicate using any number and type of cellular protocols, such as General Packet Radio Service (GPRS), Global System for Mobile Communications (GSM), Enhanced Data rates for GSM Evolution (EDGE), Personal Communication Service (PCS), Advanced Mobile Phone System (AMPS), Code Division Multiple Access (CDMA), Wideband CDMA (W-CDMA), Time Division-Synchronous CDMA (TD-SCDMA), Universal Mobile Telecommunications System (UMTS), and/or Time Division Multiple Access (TDMA). A medical data translator 200 operating in conjunction with the present invention may alternatively (or additionally) include data relay transceiver 230 components to communicate using any other method of wired or wireless communication.

As discussed previously, the medical data translator 200 can transmit any data to any entity operating in conjunction with the present invention. For example, the medical data translators 200 depicted in FIGS. 5A and 5B may transmit medical data to one or more intermediary devices 260, as well as to one or more medical data servers 270.

**Adapter Module 240**

Referring again to FIG. 2, the exemplary medical data translator 200 includes an adapter module 240 for communicating with one or more medical devices 250 as well as other suitable systems. The adapter module 240 can be configured to communicate with any suitable class, type, and/or manufacturer of medical device 250. The adapter module 240 in this example includes a medical device transceiver 242 for communicating with one or more medical devices 250 and an auxiliary communication system 244 for communicating with an external personal computer system 280 to upload software to the data translator 200, store data, provide or update encryption keys, perform diagnostics, and other appropriate purposes. The adapter module 240 can be modular and removably attached to the body of the medical data translator 200, integrated as part of the data translator 200, or a combination of the two. Antenna 243 may optionally be included in the adapter module 240 assembly, or otherwise electrically coupled to the adapter module. In one exemplary embodiment of the present invention, the adapter module 240 is removably attached to the body of the medical data translator 200 to allow different medical devices 250 to interoperate with the data translator 200. As new medical devices 250 and/or new frequencies are utilized, an adapter module 240 configured to communicate with the new device or new frequency can be added to the existing system. In the exemplary circuits depicted in FIGS. 5A and 5B, any of the components used to communicate with other devices, such as the USB connector 504, MICS transceiver 510, and Bluetooth transceiver 512 can be included in an adapter module 240 that is removably attached to the body of the medical data translator 200.

Software running on or operating in conjunction with the adapter module 240 can be configured/updated through the auxiliary communication system 244, the user interface 290, or in response to a communication from an intermediary device 260 or medical data server 270 received through the data relay transceiver 230. This allows the functionality of the medical data translator 200 to be dynamically updated and avoids the expense of having to create custom hardware implementations for every type of medical device to be monitored.

**Medical Device Transceiver 242**

The medical device transceiver 242 wirelessly communicates with one or more medical devices 250. The medical device transceiver 242 may include any number and combination of hardware and/or software components. In the exemplary medical data translator 200 depicted in FIG. 2, the medical device transceiver 242 is integrated with the adapter 240 and communicates with medical devices 250 through an antenna 243. In this way, adapters 240 that allow connections to different medical devices can be used interchangeably with the same medical data translator 200.

Any number of transceivers may be used in conjunction with the present invention, for example to communicate with multiple medical devices 250 using different frequencies and/or communication protocols. The present invention may be used in conjunction with any communication protocol to communicate with one or more medical devices 250. For example, the medical data translator 200 may be configured to communicate with one or more medical devices using (without limit): the WMTS frequency bands (608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz), the MICS frequency band (402-405 MHz), 32 KHz-175 KHz, as well as any other suitable frequency band. The medical data translator 200 may communicate with medical devices using any other method of communication, such as infrared radiation, Zigbee protocol, WiBro protocol, Bluetooth connection, IEEE 802.11 protocol, IEEE 802.12 protocol, IEEE 802.16 protocol, and/or Ultra Wideband (UWB) protocol. In an alternate embodiment, the medical data translator 200 may selectively communicate with one or more medical devices by using time division multiple access (TDMA), frequency division multiple access (FDMA), code division multiple access (CDMA), or other multiple access protocols.

In the exemplary embodiment depicted in FIG. 2, the medical device transceiver 242 can be configured (e.g. through software program residing in memory 220 and executed by processor 210) to detect and switch to different frequencies emitted from one or more medical devices 243.
Take for example, a hypothetical case where a patient has an implanted loop recorder broadcasting data regarding the patient’s heart rate and rhythm using a MICs frequency, an implanted pacemaker broadcasting data at 32 KHz, and utilizes an external insulin pump communicating at 175 KHz. Each device could be produced by the same or separate manufacturers. The medical device transceiver 242 according to various aspects of the present invention can be configured to detect the three devices and switch to the appropriate frequencies to communicate with each, thus providing interoperability between types and manufacturers of a wide variety of medical devices.

The medical data translator 200 can be configured to automatically request data from one or more medical devices 250 at predetermined times using the medical device transceiver 242. Any appropriate date or time setting may be used. The data translator 200, medical device 250, or any other device operating in conjunction with the present invention can be configured to automatically request and/or transmit data in any suitable manner. For example, the medical data translator 200 depicted in FIG. 2 can be configured through the auxiliary communication system 244, the user interface 290, and/or from a command issued transmitted by an intermediary device 260 through the data relay transceiver 230. In the case of a command received through the data relay transceiver 230, the command can be generated by any suitable entity, such as from a medical data server 260 or a user of the intermediary device.

The automatic requesting/transmission of data by a device operating in conjunction with the present invention may be subject to any suitable conditions or rules that dictate whether the data is in fact requested/transmitted. For example, a medical data translator 200 programmed to request data from a medical device 250 at a set time may first check to verify that the medical device is within range, that the translator 200 has sufficient battery reserves to send the request and receive the data, whether the translator 200 has sufficient space in the memory 220 to store the data, and/or whether any other suitable condition is met.

In the exemplary circuits depicted in FIGS. 5A and 5B, the medical data transceiver 242 comprises a 405 MHz transceiver 510 in bidirectional communication with the microcontroller 501, 530 through an Inter-Inegrated Circuit (I2C) bus interface and a Serial Peripheral Interface (SPI) bus interface. The transceiver 510 sends and receives signals in the 402-205 MHz MICs band through antenna 560. In this exemplary embodiment, the microcontroller 501, 530 can activate the transceiver 510 periodically to monitor for incoming signals from one or more medical devices 250. This mode of operation is useful for collecting data from medical devices 250 that only broadcast data, but do not have the capability to receive requests for data. For medical devices 250 that can both send and receive information, the microcontroller 510, 530 can activate the transceiver 510 to send a request for data to one or more medical devices 250. Both modes of operation help reduce the amount of time the transceiver 510 is activated, and thus reduce the amount of power used by the system.

Auxiliary Communication System 244

The adapter module 240 depicted in FIG. 2 includes an auxiliary communication system 244 for communicating with additional systems and devices. The medical data translator 200 or other system operating in conjunction with the present invention can include any suitable circuit, component, device, and system for communicating with any other device. In the exemplary circuits depicted in FIGS. 5A and 5B, the auxiliary communication system 244 comprises a USB connector 504.

The auxiliary communication system 244 can be used to transfer data to and from the medical data translator 200, as well as for an external computer system 280 to configure or program software and hardware in the data translator 200. In one embodiment of the present invention, for example, a user operating computer system 280 can connect to the medical data translator 200 through the Internet to configure settings for the adapter module 240, relay transceiver 230, and user interface 290. The computer system 280 can also download data received by the data translator 200 from one or more medical devices 250. Additionally, the computer system 280 may communicate with the medical devices 250 in real-time through the medical device transceiver 240, such as to monitor or control one or more medical devices 250.

User Interface 290

The medical device 250, medical data translator 200, intermediary device 260, or other device operating in conjunction with the present invention may include a user interface. Referring to FIG. 2, an exemplary user interface 290 of a medical data translator 200 in accordance with aspects of the present invention includes an input device 292 and an output device 294. The input device 292 receives commands, data, and other suitable input from a user. The output device 294 provides the user with data, alerts, and other suitable information from the medical data translator 200.

Any number of input devices may be included in a user interface for one or more devices in the present invention. In one embodiment of the present invention, for example, the user interface 290 includes a touch pad, a touch screen, or an alphanumeric keypad to allow a user to enter instructions and data into the medical data translator 200. One or more buttons on the keypad or touch screen can be programmed or configured to perform specific functions, such as to request data from one or more medical devices. The user interface 290 can also include one or more multifunction switches, keys, or buttons that each allows a user to perform multiple functions.

The user interface may also include a microphone to allow the user to provide speech information to the medical data translator 200 verbally. In this exemplary embodiment, the medical data translator 200 also includes speech recognition software to process speech and input the speech through the user interface 290. The ability of the medical data translator to recognize speech from a patient can be particularly useful for users/patients who have vision problems, arthritis, or other impairments that would inhibit them from using a keypad or other input device. A microphone can be used in conjunction with audible (e.g., through sound waves perceivable by the human ear) data provided through a speaker, as discussed below, to allow a user to interact with any device operating in conjunction with the present invention in a completely auditory manner. In one nonlimiting example, audible input could also be sensed and analyzed by the medical data translator 200 that a patient has uttered a command, such as the command to turn on. Bidirectional audible communication, in addition to aiding impaired patients, allows users to operate devices in the present invention in a hands-free manner which can increase the speed, ease, and efficiency in which a device (such as the medical data translator 200) can be utilized.

Devices operating in conjunction with the present invention may include any number of suitable output devices. Referring to the exemplary medical data translator circuits depicted in FIGS. 5A and 5B, a user interface including two
lights 514 (LED1 and LED2) may be used to indicate the status of the data translator to the user, as well as other pertinent information. For example, a flashing LED can be used to indicate when data from a medical device is in the process of being transferred, while a solid LED can indicate the transfer of data is complete. The medical data translators 200 depicted in FIGS. 5A and 5B also provide auditory output through speaker 518. The microcontroller 501, 530 retrieves audio samples, such as recorded speech, from the EEPROM 513 and provides output to DAC 515, which converts the digital signal from the microcontroller 501, 530 to an analog signal that can be output on the speaker 518. The analog signal is provided to an audio amplifier 517 that amplifies the signal. The gain of the amplifier 517 is set by the ratio of resistors 516 and 519.

0104 Any other suitable user interface features may similarly be included in devices and systems operating in accordance with the present invention. In another exemplary embodiment, for example, the output device 294 includes a display screen to visually display information as well as a speaker (e.g. speaker 518 shown in FIGS. 5A and 5B) to provide auditory output. The output device 294 can include multiple transducers such as audio speakers or piezoelectric elements, amplifiers, and other appropriate devices and systems to provide the auditory output. The medical data translator 200 may be configured to provide words, phrases, tones, recorded music or any other type of auditory output to the user.

0105 Any type of information may be communicated through the user interface 290, such as the biological, biometric, or behavioral information for one or more patients. The user interface can provide receive any other suitable information, such as environmental information and/or diagnostic data for a medical device, a battery charge level, a temperature, a barometric pressure, a code relating to an accessory for the medical device, a biometric access measurement, a data validity measurement, an elapsed time since a previous reading by the medical device, a test result parameter, a signal-to-noise parameter, and a quality of service (QoS), and combinations thereof.

0106 Information provided or received by the user interface 290 may be in any appropriate format. For example, a user interface that communicates information to a user in an auditory format may first provide a data header followed by a data value to identify the data to the user. Similarly, an output device 294 providing information to a user visually may provide a series of measurements in the form of a spreadsheet with headers indicating the source of the measurements. The output device 294 can also provide information in any number of desired languages, regardless of whether the information is provided audibly or visually.

0107 Various features of the user interface can be implemented in hardware, software, or a combination of the two. In the medical data translator 200 depicted in FIG. 2, for example, the user interface 290 includes voice interface software stored in the memory 220, including tables of recorded words and phrases. When executed by the processor 210, the voice interface software plays the appropriate recorded words and phrases (such as enumerating the medical data) through a speaker such as one included in the output device 294 to provide information to the user. The voice interface software, like any software operating on the medical data translator 200, can be downloaded and configured through the auxiliary communication system 244. As discussed previously, any software program on any device operating in accordance with the present invention can be programmed or configured through any other suitable interface. In the medical data translator 200, for example, the voice interface software could also be downloaded and configured through the data relay receiver 230 in response to a command from a medical data server 270 and/or intermediary device 260, as well as from input from the user through the user interface 290. Accordingly, the voice interface software can be configured to include words and phrases in any number of different languages, and can be updated with new words and phrases as desired, such as to accommodate a new medical device 250 operating with the medical data translator 200. Non-verbal sounds, such as melodies and tones, can also be stored and used by the user interface 294 to provide alerts, indicators, and other information to the user.

0108 The user interface can also provide/receive information to a user in a machine-readable format. In one exemplary embodiment of the present invention, for example, the user interface 290 of a medical data translator 200 includes a fixed or retractable USB port to communicate with a thumb drive, memory stick, portable hard drive, an external computer system, or other USB-compatible device. This allows doctors and other healthcare providers to directly access the medical data translator 200 directly, having to retrieve the data from a medical data server. In this exemplary embodiment, the medical data translator 200 can be configured to send, receive, and process machine-readable data in any standard format (such as a MS Word document, Adobe PDF file, ASCII text file, JPEG, or other standard format) as well as any proprietary format. Machine-readable data can be stored on the user interface may also be encrypted to protect the data from unintended recipients and/or improper use. In an alternate embodiment, a user must enter a passcode to enable use of the USB port, and optionally, after a time period of non-use, the USB port is automatically disabled. Any other user interface feature may be utilized to allow a human or non-human user to interact with one or more devices operating in conjunction with the present invention.

Power Saving Features

0109 A medical data translator, intermediary device, medical device, or other system operating in accordance with aspects of the present invention may include any other suitable features, components, and/or systems. For example, the data translator 200 or other device may be configured to preserve the life of its battery by shutting off or going into a low-power mode when it, and/or the medical device it monitors, experiences a predetermined period of non-use, or a change in a measured parameter such as indication that a case holding the translator 200 has been actuated to a closed position. Such devices can also be configured to become active in response to any suitable event, such as receiving a signal from a device (such as a sensor).

0110 In one non-limiting embodiment of the present invention, referring now to FIG. 6, a medical data translator 200 communicates with a motion sensor 610 and a light sensor 620 to determine when a container 630 holding the data translator 200 and the medical device 250 it monitors is open or closed. In this exemplary embodiment, the data translator 200 can preserve the life of its battery by shutting off or going into a low-power mode when the container 630 is closed and, therefore, the medical device 250 held in the container 630, is not in use. Any type of motion sensor can be used in accordance with the present invention, such as an accelerometer, tilt switch, or other device that generates a signal in response to movement. Similarly, any type of light sensor may be used in conjunction with the present invention. The light sensor can be used to detect the amount of light entering a container 630 holding the medical device 250, medical data translator 200, or other device to activate the
device when the sensed amount of light exceeds a predetermined threshold, or if an increase in the amount of incident light exceeds a predetermined threshold. In an alternate embodiment, a microphone may receive audible signals that are analyzed by the medical data translator 200 to determine that a command has been uttered, and such a command may include instructions that the medical data translator 200 should be shut down or activated from a quiescent or low-power state.

A sensor may be integrated into the medical data translator 200, or operate externally to the data translator 200, communicating with the data translator 200 wirelessly or through a wired connection. For example, in the exemplary embodiment depicted in FIG. 9, the motion sensor 910 and light sensor 920 are integrated into the interior of the container 930 and communicate with a medical data translator 200 contained within to indicate when the container 930 is actuated from a closed position to an open position.

Security Measures

Systems and devices operating in accordance with aspects of the present invention may implement one or more security measures to protect data, restrict access, or provide any other desired security feature. For example, any device operating in conjunction with the present invention may encrypt transmitted data and/or protect data stored within the device itself. Such security measures may be implemented using hardware, software, or a combination thereof. Any method of data encryption or protection may be utilized in conjunction with the present invention, such as public/private key encryption systems, data scrambling methods, hardware and software firewalls, tamper-resistant or tamper-resistant memory storage devices or any other method or technique for protecting data. Similarly, passwords, biometrics, access cards or other hardware, or any other system, device, and/or method may be employed to restrict access to any device operating in conjunction with the present invention.

The particular implementations shown and described above are illustrative of the invention and its best mode and are not intended to otherwise limit the scope of the present invention in any way. Indeed, for the sake of brevity, conventional data storage, data transmission, and other functional aspects of the systems may not be described in detail. Methods illustrated in the various figures may include more, fewer, or other steps. Additionally, steps may be performed in any suitable order without departing from the scope of the invention. Furthermore, the connecting lines shown in the various figures are intended to represent exemplary functional relationships and/or physical connections between the various elements. Many alternative or additional functional relationships or physical connections may be present in a practical system.

Changes and modifications may be made to the disclosed embodiments without departing from the scope of the present invention. These and other changes or modifications are intended to be included within the scope of the present invention, as expressed in the following claims.

What is claimed is:

1. A medical data translator comprising:
   a processor;
   a medical device transceiver;
   a user interface;
   a data relay transceiver; and
   a memory coupled to the processor and storing instructions that, when executed by the processor, cause the processor to:

   - receive data wirelessly from a medical device using the medical device transceiver;
   - transmit the data to an intermediary device using the data relay transceiver.

2. The medical data translator of claim 1, wherein the data relay transceiver includes a wireless transmitter for transmitting the data wirelessly to the intermediary device.

3. The medical data translator of claim 1, wherein the medical device transmits the data in a frequency range selected from the group consisting of the medical implant communications service (MICS) frequency band, the frequency range of 402 MHz to 405 MHz, the Wireless Medical Telemetry Service (WMTS) frequency band, the frequency range of 608 MHz to 614 MHz, the frequency range of 1395 MHz to 1400 MHz, the frequency range of 1427 MHz to 1432 MHz, the frequency range 32 KHz to 175 KHz, and combinations thereof.

4. The medical data translator of claim 1, wherein the user interface includes an input device for receiving input from a user.

5. The medical data translator of claim 4, wherein the input device includes a microphone for receiving audible input from a user.

6. The medical data translator of claim 5, wherein the medical data translator is configured to:
   - receive an utterance through the microphone;
   - analyze the utterance to determine that a predetermined command was uttered.

7. The medical data translator of claim 6, wherein the predetermined command corresponds to one or more words in the English language.

8. The medical data translator of claim 6, wherein the medical data translator is configured to recognize commands in a language other than the English language.

9. The medical data translator of claim 1, wherein the user interface includes an output device for communicating output from the medical data translator to a user.

10. The medical data translator of claim 9, wherein the output device includes a speaker for communicating audible output to a user.

11. The medical data translator of claim 10, wherein the medical data translator is configured to communicate the audible output in a plurality of languages to a user through the speaker.

12. The medical data translator of claim 9, wherein the output from the medical data translator includes at least one of the data from the medical device, a status indicator for the medical device, and a command received by the medical data translator from the intermediary device.

13. A medical data translator comprising:
   a processor;
   a medical data transceiver configured to receive data wirelessly from one or more different medical devices;
   a user interface;
   a data relay transceiver; and
   a memory coupled to the processor and storing instructions that, when executed by the processor, cause the processor to:

   - receive data wirelessly from the one or more different medical devices using the medical data transceiver;
   - transmit the data to an intermediary device using the data relay transceiver.
14. The medical data translator of claim 13, wherein the one or more different medical devices include at least one of a blood glucose meter, a pacemaker, a blood pressure monitor, an insulin pump, a pulse oximeter, a holter monitor, an electrocardiograph, an electroencephalograph, a blood alcohol monitor, an alcohol breathalyzer, an alcohol ignition interlock, a respirator monitor, an accelerometer, a skin galvanometer, a thermometer, a patient geolocation device, a scale, an intravenous flow regulator, patient height measuring device, a biochip assay device, a sphygmomanometer, a hazardous chemical agent monitor, an ionizing radiation sensor; a monitor for biological agents, a loop recorder, a spirometer, an event monitor, a prothrombin time (PT) meter, an international normalized ratio (INR) meter, a tremor sensor, and a defibrillator.

15. The medical data translator of claim 13, farther comprising a plurality of wireless receivers, wherein each wireless receiver is configured to receive data from the one or more of the plurality of different medical devices.

16. The medical data translator of claim 15, wherein each wireless receiver is configured to receive data from the one or more of a plurality of different medical devices using an identifier associated with each of the plurality of different medical devices.

17. The medical data translator of claim 13, wherein the user interface includes an input device for receiving input from a user.

18. The medical data translator of claim 17, wherein the input device includes a microphone for receiving audible input from a user.

19. The medical data translator of claim 18, wherein the medical data translator is configured to:

- receive an utterance through the microphone;
- analyze the utterance to determine that a predetermined command was uttered.

20. The medical data translator of claim 19, wherein the predetermined command corresponds to one or more words in the English language.

21. The medical data translator of claim 19, wherein the medical data translator is configured to recognize commands in a language other than the English language.

22. The medical data translator of claim 13, wherein the user interface includes an output device for communicating output from the medical data translator to a user.

23. The medical data translator of claim 22, wherein the output device includes a speaker for communicating audible output to a user.

24. The medical data translator of claim 22, wherein the medical data translator is configured to communicate the audible output in a plurality of languages to a user through the speaker.

25. The medical data translator of claim 22, wherein the output from the medical data translator includes at least one of the data from the one or more different medical devices, a status indicator for the one or more different medical devices, and a command received by the medical data translator from the intermediary device.

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