



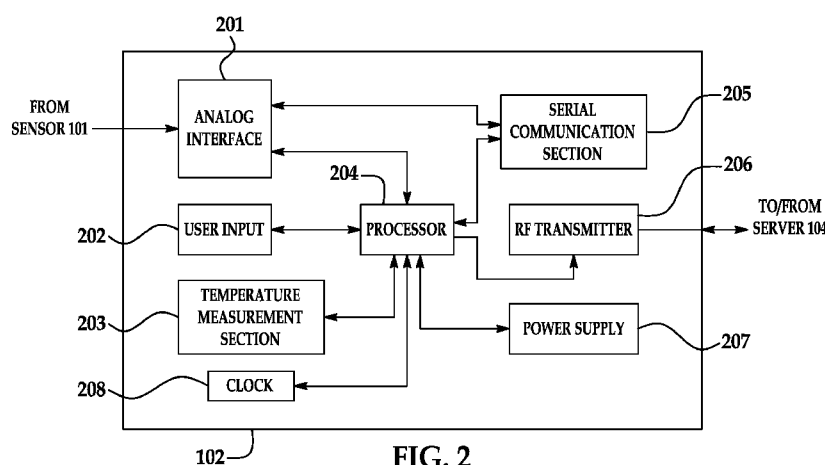
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(54) **Title:** LOW ENERGY COMMUNICATION OF MEDICAL MONITORING INFORMATION**FIG. 2**

(57) **Abstract:** Methods, systems, and devices for low energy communication of medical testing information are provided. Low energy communication of medical testing information may include detecting an analyte sample, determining an analyte concentration associated with the detected analyte sample, and transmitting an indication of the analyte concentration to an external device using a low energy wireless communication protocol. Transmitting an indication of the analyte concentration to an external device using a low energy wireless communication protocol may include generating an audio indication of the analyte concentration, packetizing the audio indication, and transmitting the packetized audio indication.

LOW ENERGY COMMUNICATION OF MEDICAL MONITORING INFORMATION

TECHNICAL FIELD

[0001] The embodiments herein relate in general to a device and method for determining and reporting glucose readings in wireless personal area networks for diabetics.

BACKGROUND

[0002] The number of diagnosed cases of diabetes continues to increase in the U.S. and throughout the world, creating enormous economic and public health consequences. Devices and therapies that improve the quality of life for the diabetic patient thus are important not only for the patient, but for society at large. One area in which recently developed technologies have been able to improve the standard of care has been in the maintenance of tight control over the blood glucose levels. It is well known that if a diabetic patient's blood glucose values can be maintained in a relatively narrow and normal range of from about 80 milligrams per deciliter (mg/dL) to about 120 mg/dL, the physiologically damaging consequences of unchecked diabetes can be minimized. With better blood glucose information, diabetic patients can better exercise tight control of their blood glucose level through a variety of means, including diet, exercise, and medication. For this reason a large industry has developed to provide the diabetic population with ever more convenient and accurate ways to measure blood glucose. There are many forms of these measuring devices; one common type is represented by hand-held electronic meters which receive blood samples via enzyme-based "test strips". In using these systems, the patient lances a finger or alternate body site to obtain a blood sample, the strip is inserted into a test strip opening in the meter housing, the sample is applied to the test strip and the electronics in the meter convert a current generated by the enzymatic reaction in the test strip to a blood glucose value. The result is displayed on the (typically) liquid crystal display of the meter. Usually, this display must be large so that diabetics, who often have deteriorating vision, can more easily see the result.

[0003] It is known that such hand-held meters can advantageously be manufactured to include wireless communication capability. Such capability can assist the user in downloading

data to a home computer or to a handheld computing device, for example. This minimizes the need for the user to write down data and transfer it later to an electronic record.

[0004] It is also known that hand-held meters are often given to users, so that suppliers of the strips used with the meters can generate greater strip sales. This makes the cost of the hand-held meters critical to profitability of the manufacturers. If the cost of a meter is relatively high, profits from the sale of strips will be small or worse yet, non-existent. If the cost of the meter can be reduced, profitability is improved.

[0005] Lastly, it is known that if a strip and meter system is convenient to use, patients will test more often and compliance with treatment programs will improve. Including wireless communication in the meter adds convenience, but at a cost. For these reasons, there is a continuing need for a low cost meter and strip glucose monitoring system that nevertheless has highly convenient features, including wireless communication capabilities.

BRIEF SUMMARY

[0006] In view of the foregoing, in accordance with the various embodiments of the present disclosure, there are provided methods, devices, and systems for providing low energy communication of medical testing information detected using a health monitor device.

[0007] In a first aspect, the present disclosure provides a device, including a housing, a processor coupled to the housing, a low energy wireless transmission unit, and a memory device coupled to the housing and the processor, wherein the memory device includes instructions which, when executed by the processor, cause the processor to detect an analyte sample, determine an analyte concentration associated with the detected analyte sample, and cause the low energy wireless transmission unit to transmit an indication of the analyte concentration to an external device.

[0008] In some embodiments of the first aspect, the low energy wireless transmission unit includes a Bluetooth® low energy unit.

[0009] In some embodiments of the first aspect, the indication of the analyte concentration includes a value indicating the analyte concentration.

[0010] In some embodiments of the first aspect, the memory device includes instructions

to cause the processor to generate an audio indication of the analyte concentration, wherein the indication of the analyte concentration includes the audio indication.

[0011] In some embodiments of the first aspect, the memory device includes instructions to cause the processor to packetize the audio indication to generate a plurality of application layer packets such that each packet in the plurality of application layer packets includes a portion of the audio indication; and wherein causing the low energy wireless transmission unit to transmit the indication of the analyte concentration includes causing the low energy wireless transmission unit to transmit the plurality of application layer packets such that the external device can present the audio indication.

[0012] In some embodiments of the first aspect, the audio indication includes a voice output.

[0013] In some embodiments of the first aspect, the memory device includes instructions to cause the processor to generate the voice output such that a tone of voice of the voice output indicates a degree of urgency.

[0014] In some embodiments of the first aspect, the memory device includes instructions to cause the processor to cause the low energy wireless transmission unit to transmit the indication of the analyte concentration to the external device using a low energy wireless transmission protocol.

[0015] In a second aspect, the present disclosure provides a method including detecting an analyte sample, determining an analyte concentration associated with the detected analyte sample, and transmitting an indication of the analyte concentration to an external device using a low energy wireless communication protocol.

[0016] In some embodiments of the second aspect, the low energy wireless communication protocol includes a Bluetooth® low energy wireless communication protocol.

[0017] In some embodiments of the second aspect, the indication of the analyte concentration includes a value indicating the analyte concentration.

[0018] In some embodiments of the second aspect, the method includes generating an audio indication of the analyte concentration, wherein the indication of the analyte concentration

includes the audio indication.

[0019] In some embodiments of the second aspect, the method includes packetizing the audio indication to generate a plurality of application layer packets such that each packet in the plurality of application layer packets includes a portion of the audio indication; and wherein transmitting the indication of the analyte concentration includes transmitting the plurality of application layer packets such that the external device can present the audio indication.

[0020] In some embodiments of the second aspect, the audio indication includes a voice output.

[0021] In some embodiments of the second aspect, generating the voice output includes generating the voice output such that a tone of voice of the voice output indicates a degree of urgency.

[0022] It should be noted that two or more of the embodiments described herein, including those described above, may be combined to produce one or more additional embodiments which include the combined features of the individual embodiments.

[0023] These and other objects, features, and advantages of the present disclosure will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The invention is best understood from the following detailed description when read in conjunction with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to-scale. On the contrary, the dimensions of the various features are arbitrarily expanded or reduced for clarity. Included in the drawings are the following figures.

[0025] FIG. 1 is a schematic view showing typical data signal flow between devices of a wireless system constructed according to one embodiment of the present invention.

[0026] FIG. 2 is a schematic view showing the client device of Fig. 1.

[0027] FIG. 3 is a schematic view showing the server device of Fig. 1.

[0028] FIG. 4 is a pectoral view showing a typical client device and typical server devices.

[0029] FIG. 5 is a perspective view showing an integrated device of an alternative embodiment.

[0030] FIG. 6 is a diagram of a health monitor device in accordance with some embodiments of this disclosure.

[0031] Fig. 7 is a diagram of an example of transmitting an audio indication of health monitoring information using a low energy wireless communication protocol in accordance with some embodiments of this disclosure.

DETAILED DESCRIPTION

[0032] Before the devices and methods of the present disclosure are described in greater detail, it is to be understood that the devices and methods are not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the sensors and methods will be limited only by the appended claims.

[0033] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the methods belong. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the devices and methods, representative illustrative devices, methods and materials are now described.

[0034] It is noted that, as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements, or use of a “negative” limitation.

[0035] Referring to Fig. 1, a wireless system constructed according to a preferred embodiment of the present invention will be described. Test strip 101 electrically communicates with client device 102, which wirelessly communicates with server device 104, such as by two-way radio frequency (RF) contact, infrared (IR) contact, Bluetooth® contact or other known wireless means 103. Optionally, server device 104 can also communicate with other devices such as data processing terminal 105 by direct electronic contact, via RF, IR, Bluetooth® or other wireless means.

[0036] Test strip 101 is a commonly known electrochemical analyte test strip, such as a blood glucose test strip as described in U.S. patent application number 09/434,026 filed November 4, 1999 entitled “Small Volume In Vitro Analyte Sensor and Methods”, incorporated herein by reference. It is mechanically received in a test strip port of a client device 102, similar to a commonly known hand-held blood glucose meter as described in the aforementioned patent application. In the preferred embodiment, client device 102 is constructed without a user interface or display to keep the size and cost of device 102 to a minimum. Client device 102 can take the form of a highlighter or easel-sized pen, as shown in Fig. 4, and can be powered by a single AA or AAA size battery.

[0037] Client device 102 wirelessly communicates with server device 104, preferably using a common standard such as 802.11 or Bluetooth® RF protocol, or an IrDA infrared protocol. Server device 104 can be another portable device, such as a Personal Digital Assistant (PDA) or notebook computer, or a larger device such as a desktop computer, appliance, etc. as shown by the examples in Fig. 4. Preferably, server device 104 does have a display, such as a liquid crystal display (LCD), as well as an input device, such as buttons, a keyboard, mouse or touch-screen. With this arrangement, the user can control client device 102 indirectly by interacting with the user interface(s) of server device 104, which in turn interacts with client device 102 across wireless link 103.

[0038] Server device 104 can also communicate with another device 105, such as for sending glucose data from devices 102 and 104 to data storage in device 105, and/or receiving instructions or an insulin pump protocol from a health care provider computer 105. Examples of such communication include a PDA 104 synching data with a personal computer (PC) 105, a

mobile phone 104 communicating over a cellular network with a computer 105 at the other end, or a household appliance 104 communicating with a computer system 105 at a physician's office.

[0039] Referring to Fig. 2, internal components of a blood glucose meter 102 of the preferred embodiment are shown. Alternatively, user input 202, such as push button(s), and other sections can be eliminated to reduce size and cost of client device 102. The glucose meter housing may contain any glucose sensing system of the type well known in the art that can be configured to fit into a small profile. Such a system can include, for example, the electrochemical glucose strip and meter sensing system sold by TheraSense, Inc. of Alameda, California under the FreeStyle® brand, or other strip and meter glucose measuring systems. The housing may thus encompass the sensor electronics and a strip connector, which connector is accessed via a test strip port opening in the housing. The housing will typically also include a battery or batteries.

[0040] Referring to Fig. 3, internal components of a server device 104 of the preferred embodiment are shown. Note that a redundant test strip interface 301 can be provided if desired for receiving test strips 101. Device 104 can be a proprietary unit designed specifically for use with blood glucose meters, or can be a generic, multipurpose device such as a standard PDA. An example of a similar device designed for blood glucose testing is disclosed in U.S. Patent No. 6,560,471 issued May 6, 2003 to TheraSense, Inc. entitled "Analyte Monitoring Device and Methods of Use", incorporated herein by reference.

[0041] Figure 4 shows examples of the devices to and from which the meter of the invention can communicate. Such devices will become part of an individual's personal area network and each becomes enabled with short range wireless communication capabilities. Desktop, laptop and handheld computers, as well as printers can be so enabled and will provide displays and printouts valuable as records for the diabetic. Telephones will also be enabled in this fashion and can be used for displaying glucose data as well as further transmitting the data over larger networks. Many of these devices can assist the diabetic by responding to glucose levels by providing alarms, or suggesting that action be taken to correct a hypo or hyperglycemic condition, or to call necessary medical assistance. Diabetics are aware of the risks involved in driving when glucose levels are out of range and particularly when they are too low. Thus, the

navigation computer in the diabetic's car may become part of the local area network and will download glucose data from the meter when the diabetic enters the car. For safety sake, the car computer system may be programmed to require that the diabetic perform a glucose test before driving, and more specifically the car may be disabled unless the diabetic takes the test and the result is in an appropriate range.

[0042] The pen shaped client device 102 shown in Fig. 4 preferably has a test strip port 201 (not shown in Fig. 4) located on its distal end. Because the sensitive analog "front end" circuitry associated with measuring the very small electrochemistry currents from test strips 101 is located adjacent strip port 201, it is advisable to not design a wireless link antenna too close to this distal end as it may interfere with the proper operation of the glucose sensing circuitry. On the other hand, if the wireless link antenna is located at the proximal end of the client device 102, it will likely be covered by the hand of the user holding it, which may limit the range of the low transmission power device to an unacceptable distance. Accordingly, it is preferable to design the layout of client device 102 such that an internal antenna is located in a middle section of the device away from the distal and proximal ends.

[0043] Referring to Fig. 5, an alternative embodiment of the present invention is shown. Due to the reduced size of a blood glucose meter 102 when it does not include a display or push buttons, it can be combined with a lancing device to form an integrated unit 102'. Test strip port 201 can be located in the side of integrated device 102' or wherever there is room available. A test strip storage compartment can also be located within integrated device 102' and accessed through a flip-lid 220 or other suitable closure means. If room permits, a second test strip storage compartment (not shown) can be included so that fresh strips and used strips can be separately stored. Preferably, a desiccant is provided in one of the storage compartments to preserve the fresh strips. The design and use of lancing devices is described in U.S. Patent Number 6,283,982 issued to TheraSense, Inc. on September 4, 2001 entitled "Lancing Device and Method of Sample Collection", incorporated herein by reference. By integrating these features together in a single device without a user interface, the typical test kit that is carried around by people with diabetes can be made much smaller, easier to handle, and less costly.

[0044] Thus, one of the important features of the invention is reliance of the

“displayless” glucose meter unit on a separate display device in order to minimize the complexity and cost of the meter unit. This permits the user to use the larger display units within his or her personal area network, all of which can be synchronized as they interact and communicate with the wireless enabled meter. When the meter is used, the sequences through which the user must “step” to complete the test are readily viewed on the larger display units (e.g. entering the calibration code, prompting application of the sample). At the same time the meter unit is simplified, smaller and less expensive to manufacture. Additionally, control buttons that are found on typical glucose meters can be eliminated, saving additional size and cost, since the user can rely on the user in out features of the server device instead. It is expected that the simplified, wireless enabled meters of the invention may ultimately become inexpensive enough to make them disposable after a specified number of uses, permitting the producer to routinely upgrade as appropriate.

[0045] Additionally, the system permits the user to include security coding at any time the meter unit accesses a display device, so that the user’s data is secure. That is, it is considered an important feature of the invention that when the “client” meter of the invention is used, that the system will require the user to enter an identity code in order to verify that the person handling the meter is indeed an authorized user. Of course, it is possible for the system to permit more than one user if the meter owner so desires. Moreover, the user’s data may optionally be encrypted prior to wireless transmission and thereafter respectively decrypted upon wireless reception.

[0046] While the module need not include a large or expensive display, it may nevertheless be advantageous to include some ability to advise the user of a glucose level which is determined when the module is used as a “stand-alone” unit. For example, the module could include a very low cost, small three digit LCD display. Alternatively, the module could include LED indicator lights (e.g. red for out of desired range, green for within desired range). Other possibilities include a red LED for below range, a green LED for within range, and a yellow LED for above range, or a column of LEDs or an electroluminescent strip (similar to those used on common batteries to indicate battery life) to indicate approximate or relative glucose levels.

[0047] FIG. 6 shows a diagram of a health monitor device 600 in accordance with some

embodiments of this disclosure. The health monitor device 600 may be used for determining a concentration of an analyte in blood or interstitial fluid. For example, the health monitor device 600 may be an analyte test meter, such as a glucose test meter that may be used for determining an analyte concentration, such as a blood glucose concentration, of a sample for determination of a blood glucose level of a patient, such as a patient with Type-1 or Type-2 diabetes. In some embodiments, the health monitor device 600 may be a blood glucose meter, a continuous monitor, an insulin pump, a blood pressure meter, a heart rate monitor, a thermometer, or any other health monitor device capable of measuring, monitoring, or storing raw or analyzed medical data electronically.

[0048] The health monitor device 600 may communicate in a wireless communication system, such as the wireless system shown in Fig. 1. For example, the health monitor device 600 may receive fluid samples, or sample data, from a sensor device 602, such as the test strip 101 shown in Fig. 1, and may wirelessly transmit data to an external device 604, such as the server device 104 shown in Fig. 1. The health monitor device 600 may include a housing 610, a processor 620, a sensor interface 630, a user interface 640, a clock 650, a data storage unit 660, a power supply 670, and a communication interface 680.

[0049] The housing 610 may physically enclose one or more of the processor 620, the sensor interface 630, the user interface 640, the clock 650, the data storage unit 660, the power supply 670, or the communication interface 680, and may be configured to fit into a small profile. Although the housing 610 is shown a single physical unit, the housing 610 may be implemented as one or more physical units that may be physically or electronically connected. Although not shown in Fig. 6, the housing 610 may include one or more ports, such as a test strip port, a power port, an audio connection port, or a data connection port. For example, the housing 610 may include a test strip port configured to receive a test strip, which may include a fluid sample, and may be connected to the sensor interface 630.

[0050] The processor 620 may include any device capable of manipulating or processing a signal or other information, including an optical processor, a quantum processor, a molecular processor, or a combination thereof. For example, the processor 620 may include a general purpose processor, a central processing unit (CPU), a special purpose processor, a plurality of

microprocessors, a controller, a microcontroller, an Application Specific Integrated Circuit (ASIC), a Field Programmable Gate Array (FPGA), a programmable logic array, programmable logic controller, microcode, firmware, any type of integrated circuit (IC), a state machine, or any combination thereof. As used herein, the term “processor” includes a single processor or multiple processors. The processor 620 may be operatively coupled to the sensor interface 630, the user interface 640, the clock 650, the data storage unit 660, the power supply 670, or the communication interface 680.

[0051] In some embodiments, the sensor interface 630 may receive a fluid sample, such as a fluid sample transported via the test strip 101 shown in Fig. 1, and the processor 620 may control the sensor interface 630 to analyze the fluid sample to determine an associated analyte level. In some embodiments, the sensor interface 630 may receive raw or analyzed data indicating an analyte level associated with a fluid sample analyzed at an external measurement device, such as a continuous analyte monitoring device, via a wireless communication medium, such as radio frequency identification (RFID). For example, the continuous analyte monitoring device may include a transcutaneously implanted sensor, such as an implantable glucose sensor, that may continually or substantially continually measure an analyte concentration of a bodily fluid. In some embodiments, the sensor interface 630 may receive analyte related data from the external measurement device periodically, based on a transmission schedule, or may request the data from the external measurement device.

[0052] The user interface 640 may include a display unit and one or more input elements, such as buttons, jogs, or dials. The user interface 640, or a portion thereof, may be integrated with the housing 610. For example, the user interface 640 may form a part of an external surface of the housing 610. The user interface 640, or a portion thereof, may be configured to allow a user of the health monitor device 600 to receive information, input information, or otherwise interact, with the health monitor device 600. For example, the user of the health monitor device 600 may operate the one or more input buttons to enter a calibration code associated with a test strip or other fluid sample reception device. In another example, the user interface 640 may present visual, tactile, or auditory information indicating, for example, a blood glucose measurement to the user. In some embodiments, the display unit may include a graphical display

unit, such as a LCD or an LED display, an auditory display unit, such as speaker, or both a graphical display and an audio display. In some embodiments, the user interface 640 may include a touch screen display. In some embodiments, the display unit, the input elements, or both may be omitted from the user interface 640.

[0053] The clock 650 may be operatively coupled to the processor 620 and may provide a clock signal at discreet clock frequencies to the processor 620. For example, the clock may include an oscillator, such as a quartz crystal oscillator, or any other device capable of producing a clock signal for indicating a real time clock.

[0054] The data storage unit 660 may store raw data, analyzed data, or both. In some embodiments, the data storage unit 660 may store instructions that may be executed by the processor to, for example, perform analysis, such as analyte concentration analysis and medication dosage calculation. The data storage unit 660 may include any non-transitory computer-usable or computer-readable medium, such as any tangible device that can, for example, contain, store, communicate, or transport instructions, or any information associated therewith, for use by or in connection with the processor 620. The non-transitory computer-usable or computer-readable medium may be, for example, a solid state drive, a memory card, removable media, a read only memory (ROM), a random access memory (RAM), any type of disk including a hard disk, a floppy disk, an optical disk, a magnetic or optical card, an application specific integrated circuits (ASICs), or any type of non-transitory media suitable for storing electronic information, or any combination thereof. The data storage unit 660 may be operatively connected to, for example, the processor 620 through, for example, a memory bus.

[0055] The power supply 670 may be any suitable device for powering the health monitor device 600, or any portion thereof. For example, the power supply 670 may include a wired power source; one or more dry cell batteries, such as nickel-cadmium (NiCd), nickel-zinc (NiZn), nickel metal hydride (NiMH), lithium-ion (Li-ion); solar cells; fuel cells; or any other device capable of powering the health monitor device 600. The processor 620, the sensor interface 630, the user interface 640, the clock 650, the data storage unit 660, or the communication interface 680, may be operatively coupled to the power supply 670.

[0056] The communication interface 680 may communicate with an external device 604,

such as the sever 104 shown in Fig. 1 and Fig. 4. For example, the communication interface 680 may be an RF transmitter, such as the RF transmitter 206 shown in Fig. 2, and may communicate using a wireless communication protocol, such as an 802.11 protocol, a Bluetooth® RF protocol, a cellular protocol, or any other wireless protocol. In some embodiments, the communication interface 680 may include a receiver, a transmitter, or a transceiver. For example, the communication interface 680 may include a wireless transmission unit, such as a Bluetooth® low energy wireless transmission unit. Although not expressly shown in Fig. 6, the communication interface 680 may include a wireless antenna, a wired communication port, such as an Ethernet port, an infrared port, a serial port, or any other wired or wireless unit capable of interfacing with a wired or wireless electronic communication medium. In some embodiments, the health monitor device 600 may communicate with the external device 604 indirectly via another device, or series of devices. For example, the health monitor device 600 may communicate with the external device 604 via a network, wherein the health monitor device 600 may transmit signals to, for example, an access point (not shown), and the access point may transmit the signals to the external device 604, in the same or a different format, via one or more other devices in a network.

[0057] In some embodiments, the communication interface 680 may communicate with the external device 604 using a low energy wireless communication protocol, such as Bluetooth® low energy. Communicating using a low energy wireless communication protocol may allow the communication interface 680 to use substantially less power than communicating using other wireless communication protocols, such as other versions of Bluetooth®. For example, using a low energy wireless communication protocol, the communication interface 680 may have a lower duty cycle and may actively operate less frequently, for shorter periods of time, or both.

[0058] In some embodiments, the processor 610, the communication interface 680, or a combination of the processor 610 and the communication interface 680, may determine whether to use a wireless communication protocol, such as Bluetooth®, or a low energy wireless communication protocol, such as Bluetooth® low energy. For example, the processor 610 may determine which wireless communication protocol to use based on network conditions, battery

conditions, sensed data, or a combination thereof.

[0059] In some embodiments, the health monitor device 600 may audibly present information, such as information indicating an analyte concentration, information indicating a rate of change of an analyte concentration, or information indicating the exceeding of a threshold of an analyte concentration, which may indicate, for example, hypo- or hyperglycemia. For example, the user interface 640 may include a speaker, and the health monitor device 600 may present the audio signal via the speaker. In some embodiments, the health monitor device 600 may transmit raw or analyzed analyte information to the external device 604 and the external device 604 may generate an audio signal for presentation. In some embodiments, the health monitor device 600 may generate an audio signal indicating the information and may transmit the audio indication to the external device 604 for audio presentation.

[0060] Although shown as separate elements, the processor 620, the sensor interface 630, the user interface 640, the clock 650, the data storage unit 660, the power supply 670, the communication interface 680, or any combination thereof, may be integrated in one or more electronic units, circuits, or chips.

[0061] Fig. 7 shows an example of transmitting an audio indication of health monitoring information using a low energy wireless communication protocol in accordance with some embodiments of this disclosure. For example, a health monitor device, such as the health monitor device 600 shown in Fig. 6, may transmit an audio indication of health monitoring information, such as analyte information, using a low energy wireless communication protocol. Transmitting an audio indication of health monitoring information using a low energy wireless communication protocol may include identifying a sample at 710, analyzing the sample at 720, identifying an analyte concentration at 730, storing analyte information at 740, generating an audio signal at 750, packetizing the audio signal at 760, transmitting the packetized audio signal at 770, regenerating the audio signal at 780, presenting the audio signal at 790, or a combination thereof.

[0062] A sample, such as a blood sample, may be identified at 710. For example, the health monitor device may include a sensor interface, such as the sensor interface 630 shown in Fig. 6, configured to receive a fluid sample, such as a fluid sample transported via a test strip, such as the test strip 101 shown in Fig. 1. In some embodiments, the sample may be

identified by an external measurement device, such as a continuous analyte monitoring device, configured to communicate with the health monitor device using, for example, a short range wireless communication method, such as RFID. For example, the continuous analyte monitoring device may include a transcutaneously implanted sensor that may continually or substantially continually measure an analyte concentration of a bodily fluid.

[0063] The sample may be analyzed to determine a corresponding analyte level, such as a glucose level, at 720. For example, the health monitor device may include a processor, such as the processor 620 shown in Fig. 6, configured to analyze the sample. In some embodiments, the sample may be analyzed by an external analysis device, such as a continuous analyte monitoring device, configured to communicate with the health monitor device.

[0064] An analyte concentration may be identified at 730. For example, the analyte concentration may be identified based on the sample analysis at 720. In some embodiments, the analyte concentration may be received from an external analysis device, such as a continuous analyte monitoring device, configured to communicate with the health monitor device. In some embodiments, the analyte concentration may be identified based on stored information, such as previously stored raw or analyzed sample data.

[0065] In some embodiments, raw or analyzed analyte information, such the analyte concentration identified at 730, may be stored at 740. For example, health monitor device may include a data storage unit, such as the memory 660 shown in Fig. 6, a processor, such as the processor 620 shown in Fig. 6, a sensor interface, such as the sensor interface 630 shown in Fig. 6, or a combination thereof, and the processor, the sensor interface, or a combination thereof, may identify the analyte concentration based on raw or analyzed analyte data stored on the data storage unit.

[0066] An audio signal may be generated based on the analyte concentration at 750. Generating the audio signal may include generating a voice output or sound tones. The voice output or may be configured to provide an audible indication of information including, for example, analyte concentration, rate of change of analyte concentration, or the exceeding of a threshold analyte concentration. In some embodiments, the audio signal may be stored on the health monitor device, such as on a data storage unit in the health monitor device.

[0067] The voice output may be generated using a synthesized voice, a pre-recorded voice, or a combination of a synthesized voice and a pre-recorded voice. For example, the voice output may be generated based on a set of pre-recorded terms stored on the health monitor device and any terms not included in the set of pre-recorded may be provided by a voice synthesizer. In some embodiments, the health monitor device may include pre-recorded terms in one or more languages and generating the audio signal may include using pre-recorded terms, a synthesized voice, or both, in a specified language. In some embodiments, the health monitor device may provide for voice output selection, which may be configured to allow the selection of various aspects of the voice output, such as, volume of the voice output, gender of the spoken voice, or language of the spoken voice.

[0068] In some embodiments, generating a voice output may include modulating the audio stream to use tone of voice to indicate urgency. For example, a healthy blood glucose level may be presented using a normal tone of voice and an unhealthy blood glucose level, such as a level indicating hypoglycemia or hyperglycemia, may be presented in an urgent tone of voice.

[0069] In some embodiments, generating the audio signal may include generating voice output of audio instructions. For example, the voice output may include audio instructions indicating how to clear an occlusion, or instructions to drink fruit juice to recover from hypoglycemia. In another example, the voice output may include audio instructions to assist the patient in gathering information for determining an adjusted dose level, such as an adjusted dose level for long-acting insulin based on fasting blood glucose levels. The audio instructions may indicate a series of actions, including, but not limited to, fasting and blood glucose tests, re-testing, insulin injections and food intake

[0070] Although Fig. 7 shows presenting an audio signal in conjunction with analyzing an analyte sample, an audio signal may be generated and presented independently of sample analysis. For example, an audio signal may be generated and presented to audibilize an alarm that is not related to sample measurement, or to present a reminder. For example, the health monitor device may allow entry and storage of reminders, such as a periodic reminder to perform sample analysis, and an audio signal may be generated and presented to audibilize the reminders.

[0071] The audio signal may be packetized at 760. For example, the health monitor

device may be configured to communicate the audio signal to an external device using a low energy wireless communication protocol, such as Bluetooth® low energy, which may not support transmission of an audio signal. In order to transmit the audio signal using a wireless communication protocol that does not support transmission of an audio signal, such as via audio streaming, the health monitor device may packetize the audio signal into a series of packets, which may be referred to as application layer packets, in a format that is supported by the wireless communication protocol. In some embodiments, the wireless communication protocol may support audio transmission and packetization may be omitted.

[0072] The audio signal may be transmitted to an external device at 770. For example, the health monitor device may include a communication unit, such as the transceiver 680 shown in Fig. 6, and the audio signal may be transmitted to an external device, such as the external device 604 shown in Fig. 6. For example, the packets generated by packetizing the audio signal at 760 may be transmitted to the external device using a low energy wireless communication protocol, such as Bluetooth® low energy. Transmitting the packetized audio signal may include performing signal processing, such as transport and physical layer packetization.

[0073] The wireless communication may be received by the external device and the audio signal may be regenerated at 780. For example, the external device may receive a signal using a low energy wireless communication protocol, such as Bluetooth® low energy. The received signal may include the packetized audio signal. The external device may recover the application layer packets from the received signal and may combine the application layer packets to regenerate the audio signal.

[0074] The audio signal may be presented at 790. For example, the external device may be a wireless headset, a car stereo, a television, a set top box, or any other device, or combination of devices, capable of receiving the wireless communication and audibly presenting the audio signal.

[0075] It is appreciated that certain features of the devices and methods, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the devices and methods, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in

any suitable sub-combination. All combinations of the embodiments are specifically embraced by the present invention and are disclosed herein just as if each and every combination was individually and explicitly disclosed, to the extent that such combinations embrace operable processes and/or devices/systems/kits. In addition, all sub-combinations listed in the embodiments describing such variables are also specifically embraced by the present devices and methods and are disclosed herein just as if each and every such sub-combination was individually and explicitly disclosed herein.

[0076] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present devices and methods. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

[0077] Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A device comprising:
 - a housing;
 - a processor coupled to the housing;
 - a low energy wireless transmission unit; and
 - a memory device coupled to the housing and the processor, wherein the memory device comprises instructions which, when executed by the processor, cause the processor to:
 - detect an analyte sample;
 - determine an analyte concentration associated with the detected analyte sample;
 - cause the low energy wireless transmission unit to transmit an indication of the analyte concentration to an external device.
2. The device of claim 1, wherein the low energy wireless transmission unit includes a Bluetooth® low energy unit.
3. The device of claim 1, wherein the indication of the analyte concentration includes a value indicating the analyte concentration.
4. The device of claim 1, wherein the memory device includes instructions to cause the processor to generate an audio indication of the analyte concentration, wherein the indication of the analyte concentration includes the audio indication.

5. The device of claim 4, wherein the memory device includes instructions to cause the processor to packetize the audio indication to generate a plurality of application layer packets such that each packet in the plurality of application layer packets includes a portion of the audio indication; and wherein causing the low energy wireless transmission unit to transmit the indication of the analyte concentration includes causing the low energy wireless transmission unit to transmit the plurality of application layer packets such that the external device can present the audio indication.

6. The device of claim 4, wherein the audio indication includes a voice output.

7. The device of claim 6, wherein the memory device includes instructions to cause the processor to generate the voice output such that a tone of voice of the voice output indicates a degree of urgency.

8. The device of claim 1, wherein the memory device includes instructions to cause the processor to cause the low energy wireless transmission unit to transmit the indication of the analyte concentration to the external device using a low energy wireless transmission protocol.

9. The device of claim 1, wherein the external device is a wireless headset, a car stereo, a television, or a set top box.

10. The device of claim 1, wherein the memory device includes instructions to cause the processor to detect the analyte sample by receiving an indication of the analyte sample, and to determine the analyte concentration associated with the detected analyte sample by receiving an indication of the analyte concentration.

11. A method comprising:
detecting an analyte sample;
determining an analyte concentration associated with the detected analyte sample; and
transmitting an indication of the analyte concentration to an external device using a low energy wireless communication protocol.

12. The method of claim 11, wherein the low energy wireless communication protocol includes a Bluetooth® low energy wireless communication protocol.

13. The method of claim 11, wherein the indication of the analyte concentration includes a value indicating the analyte concentration.

14. The method of claim 11, further comprising:
generating an audio indication of the analyte concentration, wherein the indication of the analyte concentration includes the audio indication.

15. The method of claim 14, further comprising:
packetizing the audio indication to generate a plurality of application layer packets such that each packet in the plurality of application layer packets includes a portion of the audio indication; and wherein transmitting the indication of the analyte concentration includes transmitting the plurality of application layer packets such that the external device can present the audio indication.

16. The method of claim 14, wherein the audio indication includes a voice output.

17. The method of claim 16, wherein generating the voice output includes generating the voice output such that a tone of voice of the voice output indicates a degree of urgency.

18. The method of claim 16, wherein the external device is a wireless headset, a car stereo, a television, or a set top box.

19. The method of claim 16, detecting the analyte sample includes receiving an indication of the analyte sample, and determining the analyte concentration associated with the detected analyte sample includes receiving an indication of the analyte concentration.

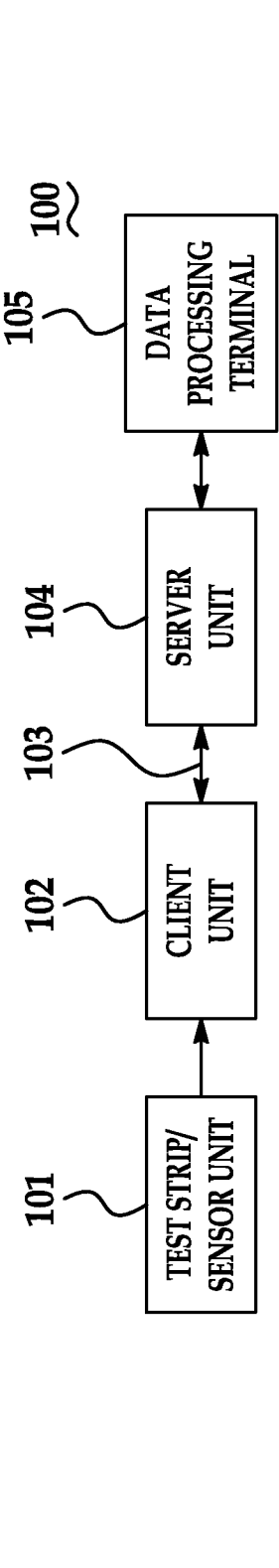


FIG. 1

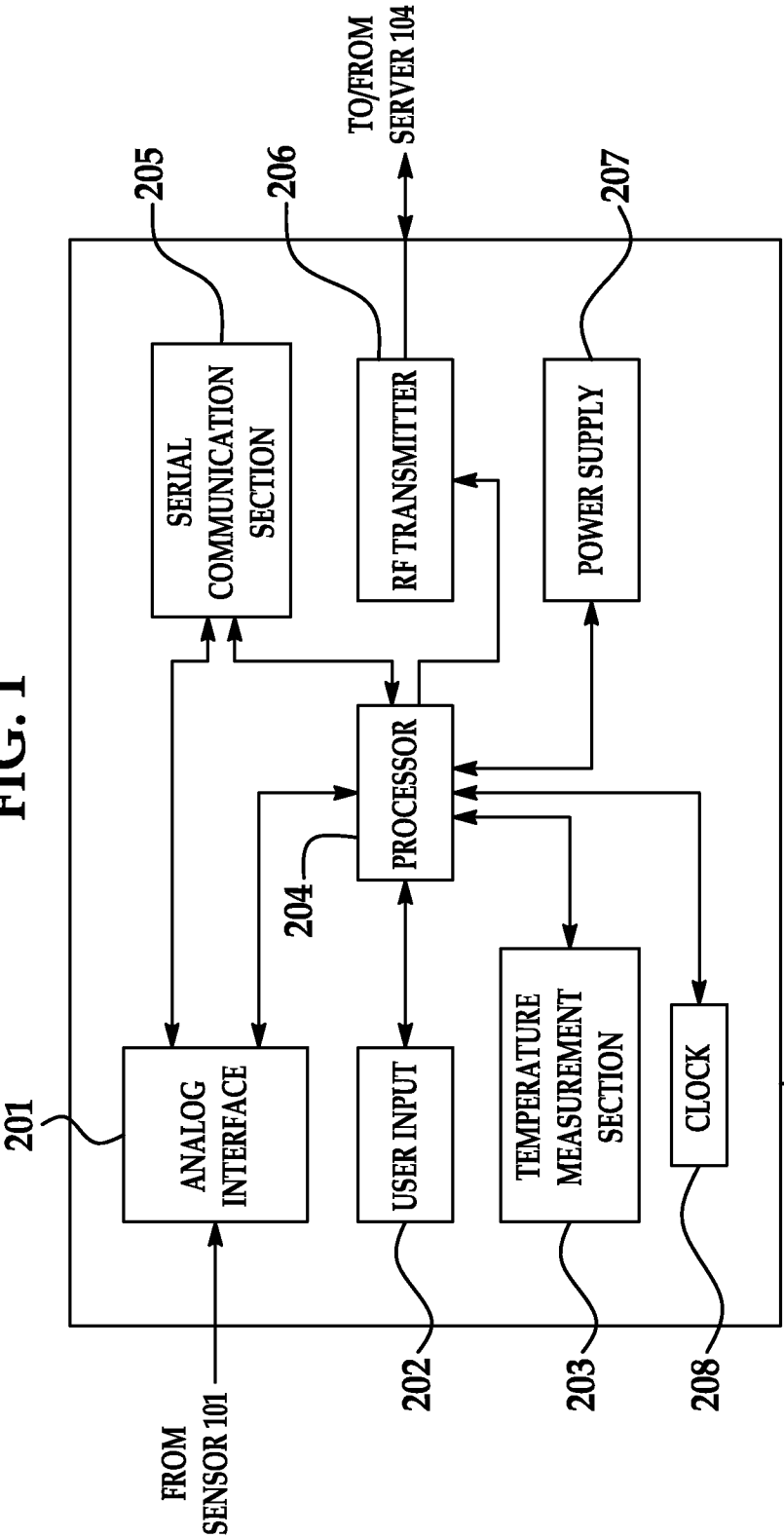


FIG. 2

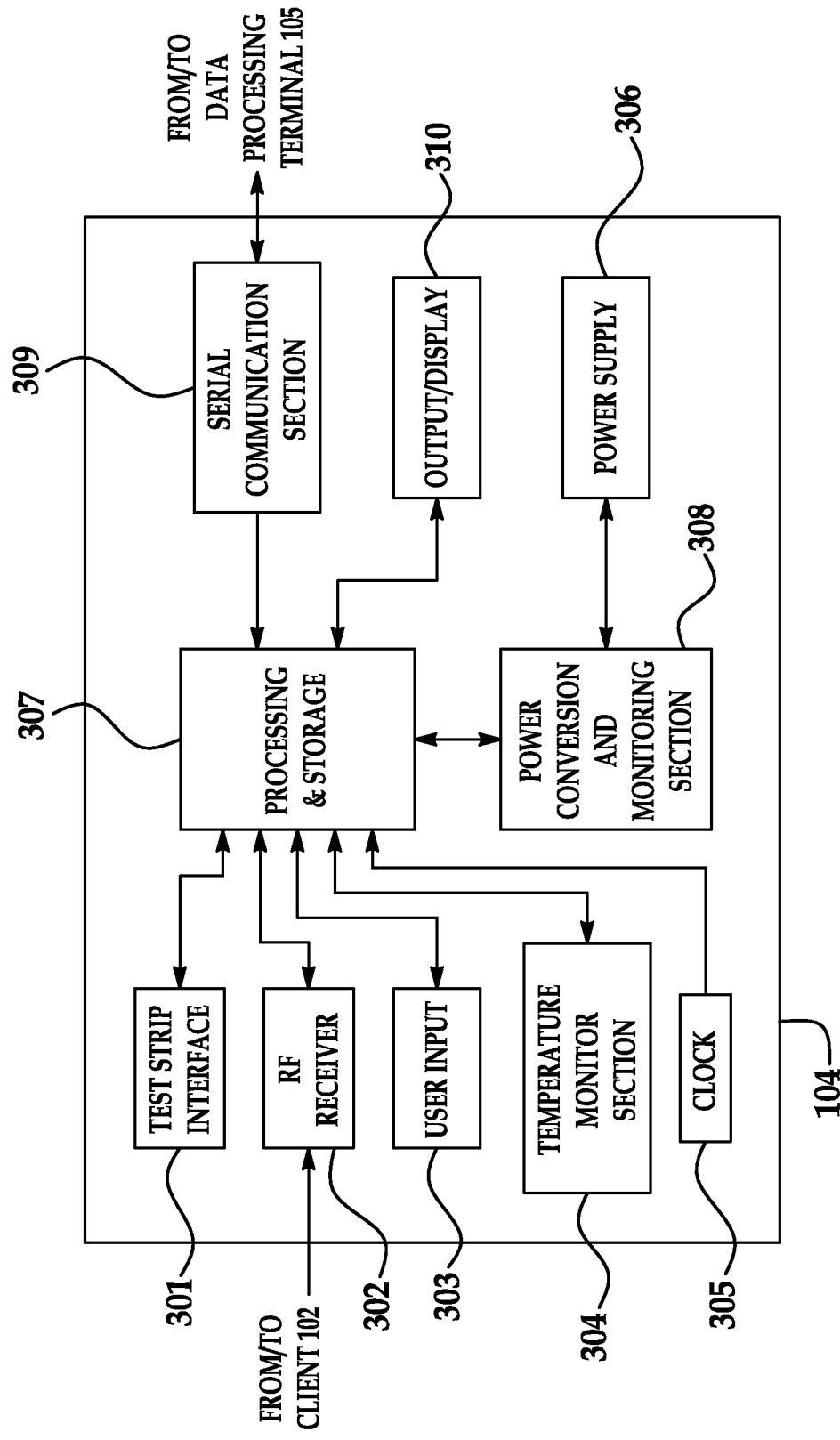
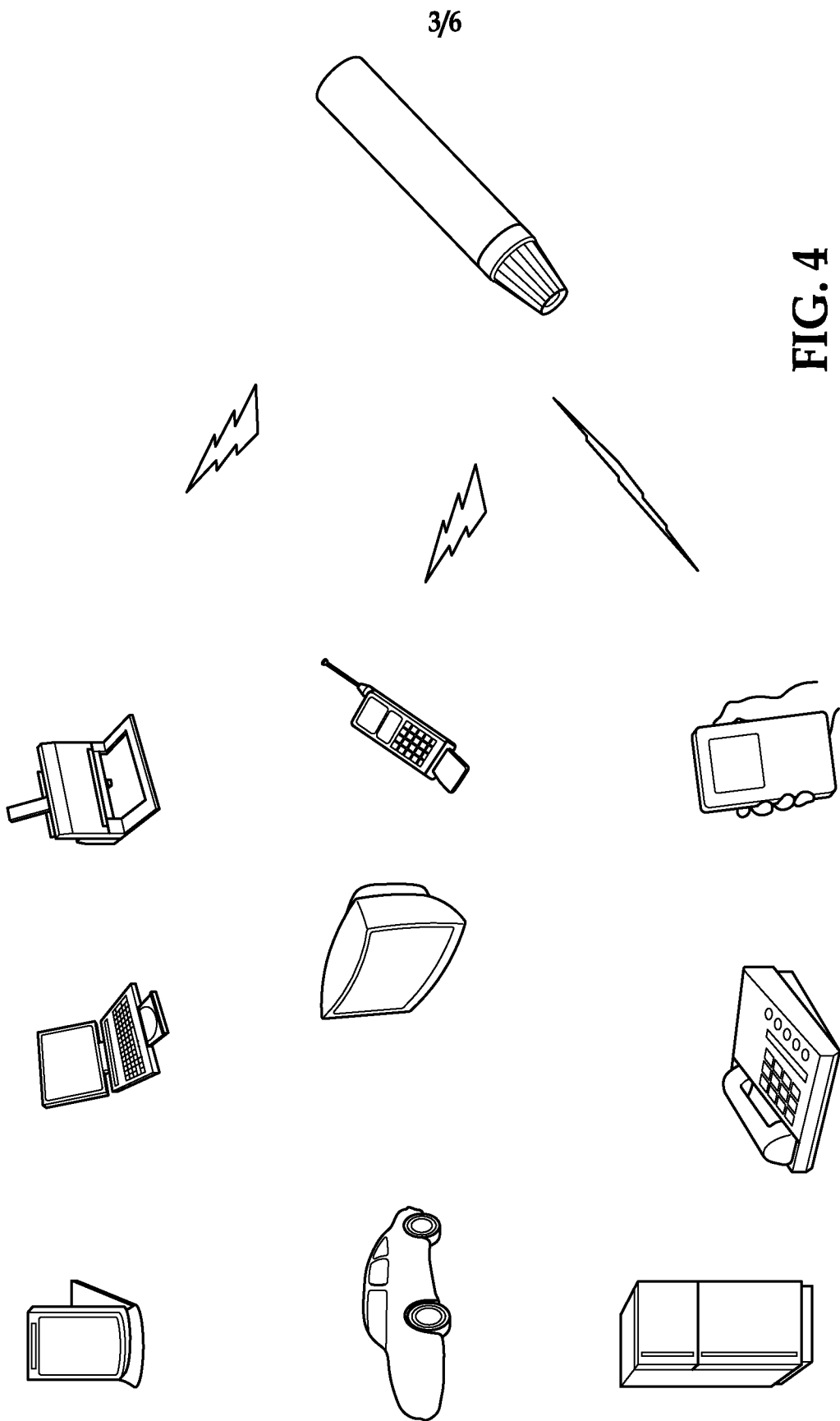


FIG. 3



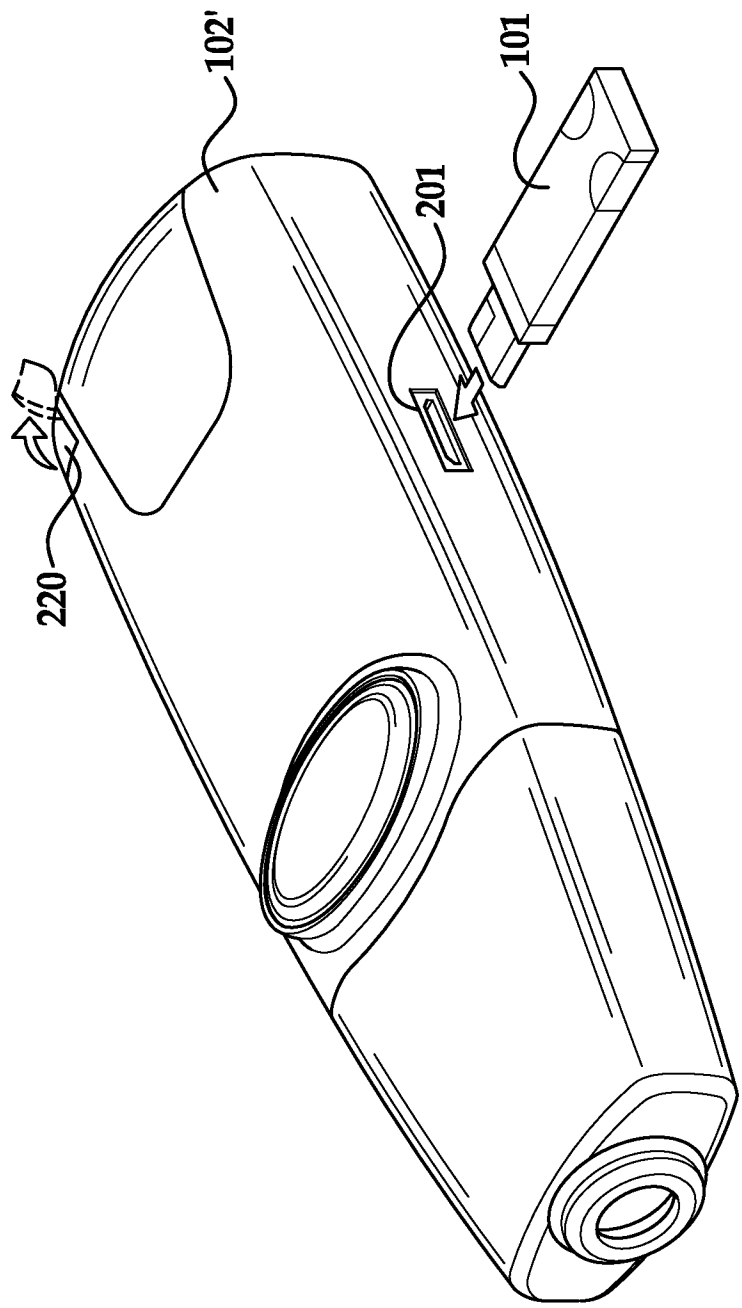


FIG. 5

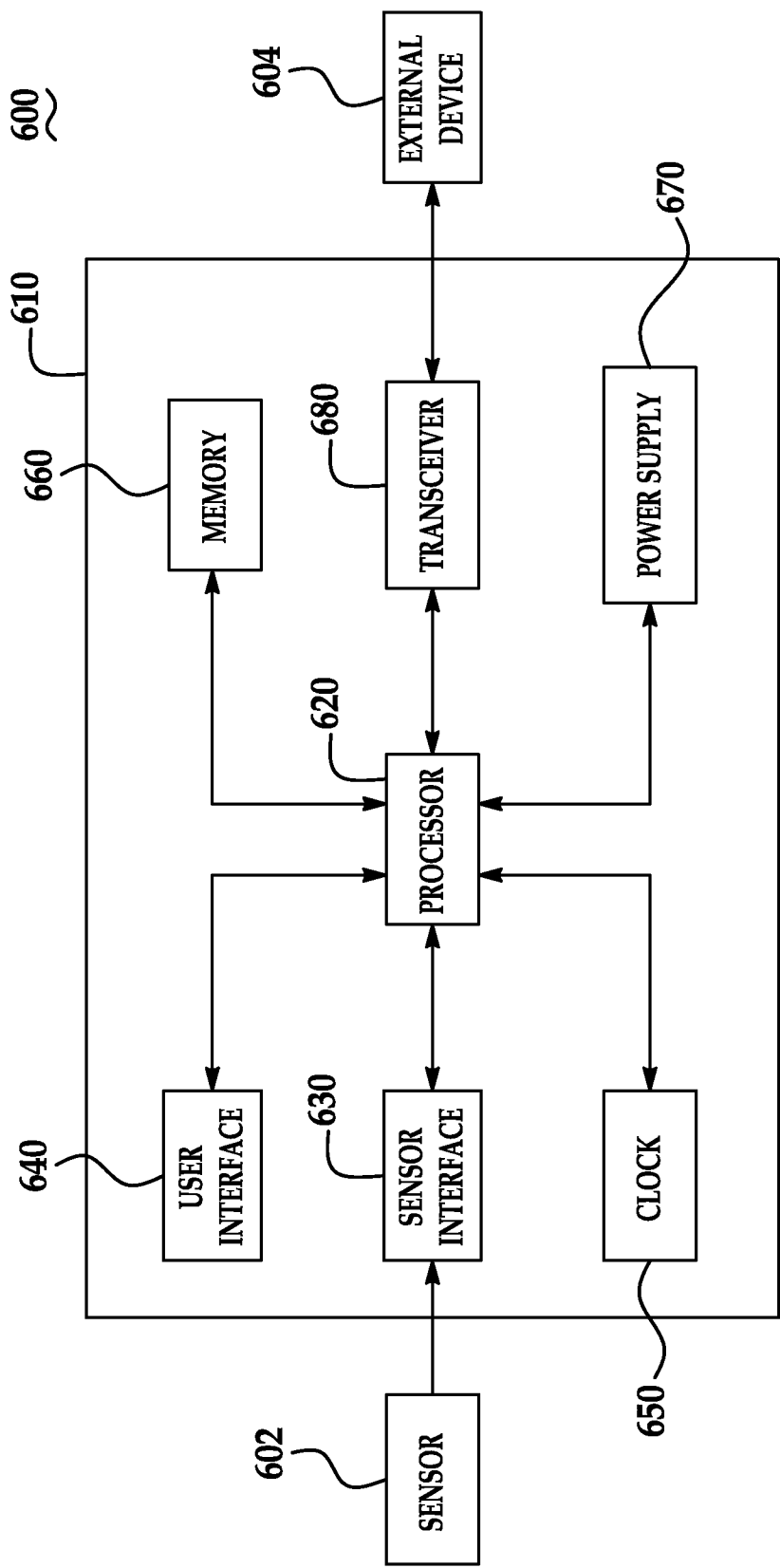


FIG. 6

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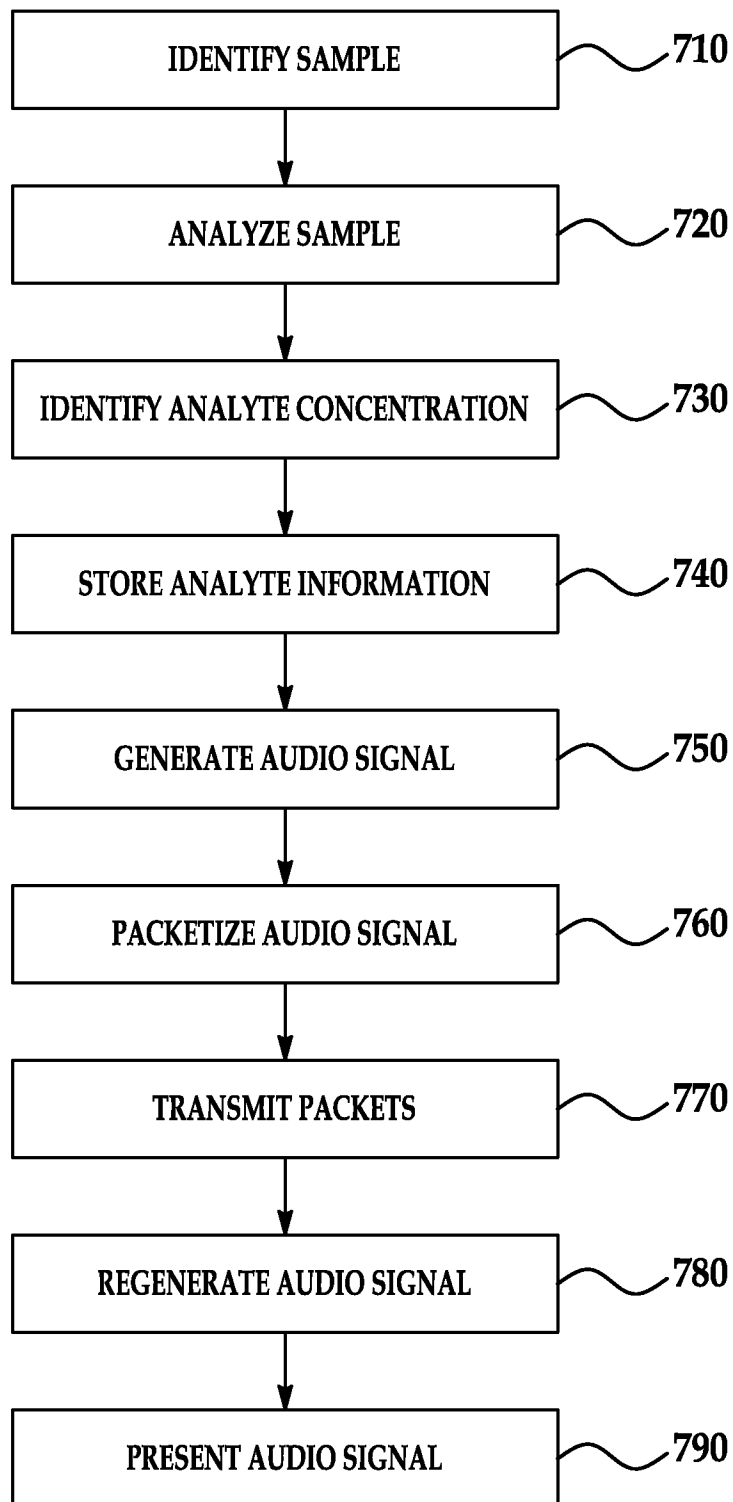


FIG. 7

A. CLASSIFICATION OF SUBJECT MATTER**A61B 5/145(2006.01)i, H04B 7/24(2006.01)i**

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/145; H04Q 7/24; A61M 31/00; A61B 5/1468; A61M 5/31; H04L 12/56; A61B 5/00; H04B 7/24

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models

Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & Keywords: analyte concentration, communication, transmit, processor

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2012-0232520 A1 (MARK K. SLOAN et al.) 13 September 2012	1-4, 6-14, 16-19
Y	See abstract, paragraphs [0288]-[0289], claims 13-44 and figures 1-3.	5, 15
Y	US 2008-0273508 A1 (SHERMAN LEE et al.) 06 November 2008	5, 15
	See abstract, paragraphs [0026]-[0029], claim 1 and figures 1, 2A.	
A	US 2010-0331657 A1 (MICHAEL ROBERT MENSINGER et al.) 30 December 2010	1-19
	See abstract, paragraphs [0100]-[0102] and figures 1, 2A.	
A	US 2010-0076288 A1 (BRIAN EDMOND CONNOLLY et al.) 25 March 2010	1-19
	See abstract, paragraphs [0083]-[0097] and figures 1, 7.	
A	US 2005-0065464 A1 (CARY, D. TALBOT et al.) 24 March 2005	1-19
	See abstract, paragraphs [0046]-[0050] and figures 1-4a.	



Further documents are listed in the continuation of Box C.



See patent family annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

21 February 2014 (21.02.2014)

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/065254

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2012-0232520 A1	13/09/2012	WO 2012-122520 A1	13/09/2012
US 2008-0273508 A1	06/11/2008	DE 60336607 D1	19/05/2011
		EP 1335532 A2	13/08/2003
		EP 1335532 A3	07/06/2006
		EP 1335532 B1	11/05/2011
		EP 1335533 A2	13/08/2003
		EP 1335533 A3	07/06/2006
		EP 1335533 B1	18/05/2011
		EP 1335542 A2	13/08/2003
		EP 1335542 A3	07/06/2006
		EP 1335542 B1	15/06/2011
		EP 1335543 A2	13/08/2003
		EP 1335543 A3	07/06/2006
		EP 1335543 B1	15/06/2011
		EP 1335544 A2	13/08/2003
		EP 1335544 A3	07/06/2006
		EP 1335544 B1	06/04/2011
		US 2003-0151534 A1	14/08/2003
		US 2003-0152055 A1	14/08/2003
		US 2003-0152056 A1	14/08/2003
		US 2003-0152057 A1	14/08/2003
		US 2003-0152161 A1	14/08/2003
		US 2004-0119619 A1	24/06/2004
		US 2007-0291723 A1	20/12/2007
		US 2008-0267155 A1	30/10/2008
		US 2010-0135271 A1	03/06/2010
		US 2011-228754 A1	22/09/2011
		US 6661360 B2	09/12/2003
		US 6917318 B2	12/07/2005
		US 7031401 B2	18/04/2006
		US 7277420 B2	02/10/2007
		US 7403141 B2	22/07/2008
		US 7411934 B2	12/08/2008
		US 7684377 B2	23/03/2010
		US 7944380 B2	17/05/2011
		US 7944907 B2	17/05/2011
		US 7953057 B2	31/05/2011
		US 8169990 B2	01/05/2012
US 2010-0331657 A1	30/12/2010	CA 2715628 A1	27/08/2009
		EP 2252196 A1	24/11/2010
		EP 2252196 A4	15/05/2013
		US 2009-0240120 A1	24/09/2009
		US 2009-0240128 A1	24/09/2009
		US 2009-0240193 A1	24/09/2009
		US 2010-0331656 A1	30/12/2010
		US 2011-0009727 A1	13/01/2011
		US 8229535 B2	24/07/2012

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2013/065254

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2010-0076288 A1	25/03/2010	US 8591455 B2	26/11/2013
		WO 2009-105709 A1	27/08/2009
US 2010-0076288 A1	25/03/2010	CA 2521494 A1	21/10/2004
		EP 1611500 A2	04/01/2006
		EP 1611500 A4	18/03/2009
		EP 1611500 B1	20/03/2013
		JP 04403176 B2	20/01/2010
		JP 2006-522346 A	28/09/2006
		US 2004-0249999 A1	09/12/2004
		US 2010-0082266 A1	01/04/2010
		US 2010-0121168 A1	13/05/2010
		US 2010-0309001 A1	09/12/2010
		US 7587287 B2	08/09/2009
		US 8437966 B2	07/05/2013
		US 8483974 B2	09/07/2013
		US 8560250 B2	15/10/2013
		WO 2004-090503 A2	21/10/2004
		WO 2004-090503 A3	16/12/2004
US 2005-0065464 A1	24/03/2005	AU 2003-252104 A1	09/02/2004
		AU 2003-252104 A8	09/02/2004
		CA 2571174 A1	05/01/2006
		CA 2571174 C	01/09/2009
		CA 2669294 A1	12/06/2008
		EP 1525014 A2	27/04/2005
		EP 1525014 B1	14/11/2012
		EP 1758625 A1	07/03/2007
		EP 2099356 A1	16/09/2009
		EP 2253346 A1	24/11/2010
		EP 2253347 A1	24/11/2010
		US 2004-0068230 A1	08/04/2004
		US 2007-0100222 A1	03/05/2007
		US 2009-0118664 A1	07/05/2009
		US 2009-0118665 A1	07/05/2009
		US 2009-0143662 A1	04/06/2009
		US 2009-0149803 A1	11/06/2009
		US 2010-0198143 A1	05/08/2010
		US 2013-303980 A1	14/11/2013
		US 8192395 B2	05/06/2012
		US 8512276 B2	20/08/2013
		WO 2004-008956 A2	29/01/2004
		WO 2004-008956 A3	22/04/2004
		WO 2006-001929 A1	05/01/2006
		WO 2008-069931 A1	12/06/2008