(54) Title: IMPROVING ANALYTE MONITORING USING ONE OR MORE ACCELEROMETERS
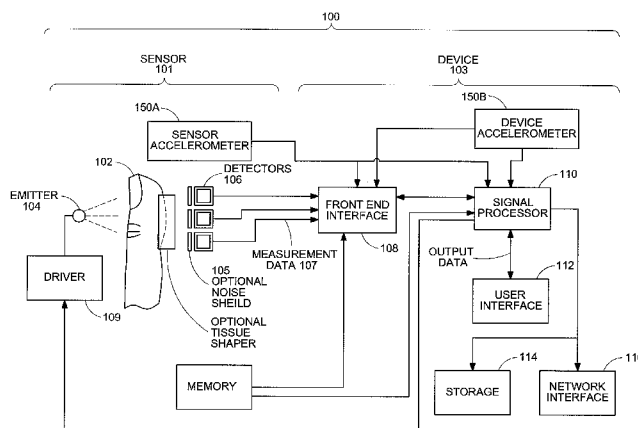
FIG. 1

(57) Abstract: The present disclosure relates to methods, devices, and systems for measuring a blood analyte, such as glucose. The disclosure relates more specifically to the use of one or more accelerometers in such methods, devices, and systems to aid in the collection of data, operation of the device, filtering, and other uses. In some embodiments, the accelerometers are three-dimensional accelerometers. An accelerometer can be used in conjunction with analyte monitoring that may be performed with infrared, near infrared, or other wavelength spectroscopy. The accelerometer may allow a monitoring instrument to expect noisy measurement data, indicate positioning of a measurement site for improved expected results, indicate position of the instrument, or help the user to properly place or control the instrument. It may also improve analyte monitoring by providing motion information that can be used to help determine and reduce or remove movement-related signal artifacts or noise that may be present within the monitoring signal.

IMPROVING ANALYTE MONITORING USING ONE OR MORE ACCELEROMETERS

REFERENCE TO RELATED APPLICATIONS

[0001]   The present application claims priority benefit under 35 U.S.C. §119 (e) from U.S. Provisional Application No. 61/243,507, filed September 17, 2009, entitled "Improving Analyte Monitoring Using One Or More Accelerometers," which is incorporated herein by reference.

FIELD

[0002]   The present disclosure relates to measuring a blood analyte, such as glucose.   The disclosure relates more specifically to the use in such measurements of an accelerometer to aid in the collection of data, operation of the device, filtering, and other uses.

BACKGROUND

[0003]   Measuring blood analytes, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) and other physiologically relevant patient characteristics can be difficult.   Consider for example, the measurement of blood glucose. Invasive techniques used to measure glucose levels can be painful and inconvenient to perform.   In addition, some patients, such as elderly or infant patients, cannot reliably perform these invasive tests on their own.   These shortcomings can be especially significant in diabetic patients who require frequent monitoring.   Failure to properly monitor and control blood glucose level can have serious consequences for a diabetic patient.

[0004]   Considerable efforts have been made to develop noninvasive techniques for measuring blood glucose.   For example, one noninvasive technique that has been attempted is infrared spectroscopy.   With infrared spectroscopy, blood glucose is measured based on the amount of optical radiation absorbed, transmitted, or reflected from the patient's tissue.

[0005]   Unfortunately, blood glucose can be difficult to measure using traditional infrared spectroscopy.   Biologic tissue and water have a high intrinsic absorption at the same wavelengths of light that are responsive to blood glucose. Blood glucose also exists in relatively low concentrations.   Furthermore, different patients will have large variations in the optical properties of their skin and blood composition.   In addition, any physical movement of the measurement site introduces noise in the measurement signal, making an accurate reading very difficult.   These and other challenges have made noninvasive glucose monitoring difficult.

[0006]   The issues exist beyond the measurement of glucose.   In certain conditions, similar problems may exist for the measurement of other analytes, such as oxygen, carbon monoxide, methemoglobin, total hemoglobin, glucose, proteins, glucose, lipids, a percentage thereof (e.g., saturation) or for measuring many other physiologically relevant patient characteristics.

SUMMARY

[0007]   The present disclosure relates to methods, devices, and systems for measuring a blood analyte, such as glucose.   The disclosure relates more specifically to the use in such methods, devices, and systems of one or more accelerometers to aid in the collection of data, operation of the device, filtering, and other uses.   In some embodiments, the accelerometer is a three-dimensional ("3D") accelerometer.

[0008]   The term 3D accelerometer as used herein includes its broad meaning known to a skilled artisan. Accelerometers may provide outputs responsive to acceleration of the device and three orthogonal axes, sometimes denoted the "X," "Y," and "Z" axes.   As discussed herein, an accelerometer can be used in conjunction with analyte monitoring that may be performed with infrared, near infrared, or other wavelength spectroscopy.   For example, the processing of data from an accelerometer may allow a monitoring instrument to expect noisy measurement data, indicate position of a measurement site for improved expected results, indicate position of the instrument, a combination of the same and the like. In some embodiments, the use of an accelerometer may improve analyte monitoring

by providing motion information that can be used to help determine movement-related signal artifacts or noise that may be present within the monitoring signal. In some embodiments, a 3D accelerometer is used to provide greater detail of the motion noise. The removal of artifacts and noise may improve the quality of the analyte monitoring signal. Additionally, in some embodiments, the information from the accelerometers can also be used to provide feedback to the patient, subject, or user of the device in order to aid them in, for example, moving the sensor to the correct position or orientation or keeping the sensor motionless or nearly motionless. In various embodiments, accelerometers can also be placed on the base or processing unit of the device to enable control of said device using device-centric motion.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009]   Figure 1 is a block diagram of an exemplary data collection system capable of noninvasively measuring one or more blood analytes in a monitored patient, including one or more accelerometers, according to an embodiment of the disclosure.

[0010]   Figures 2A, 2B, 2C, and 2D illustrate optional placements of accelerometers 150A, 150B, 150C, 150D, and 150E in varied locations in sensors 101A, 101B, 101C, and 101D.

[0011]   Figures 3A, 3B, and 3C illustrate the optional placement of accelerometers 150A, 150B, 150C, and 150D in varied locations in devices 103A, 103B, and 103C.

[0012]   Figure 4A is a block diagram depicting a first system for processing accelerometer data.

[0013]   Figure 4B is a block diagram depicting a second system for processing accelerometer data.

[0014]   Figure 5A is a block diagram depicting a third system for processing accelerometer data.

[0015]   Figure 5B is a block diagram depicting a fourth system for processing accelerometer data.

[0016]   Figure 6 is a flow chart depicting a process for indicating noise level for a signal obtained from the sensor device.

[0017]   Figure 7 is a flow chart depicting a process for prompting a patient to properly position and orient the sensor.

[0018]   Figure 8 is a block diagram depicting filtering of a noisy signal using information from a 3D accelerometer.

[0019]   Figure 9 is a block diagram depicting a system for subtracting a noise signal from an input signal.

DESCRIPTION OF EMBODIMENTS

[0020]   Generally, certain embodiments disclosed herein may include an analyte measuring system connected to a device designed to process the signal sent out from the sensor. Each of the sensor and the device may have thereto

attached one or more accelerometers. The accelerometers may be used to provide information to the system. For example, the accelerometer or accelerometers on the sensor may be used to indicate that the signal coming from the sensor is noisy or to indicate to the patient that his or her finger is not in the correct position or orientation, such as the finger being level and being below the patient's heart, with the location of the finger relative to the patient's heart being estimated, for example, from the orientation of the sensor and knowledge of the mechanics of the shoulder, elbow, wrist, and fingers. The device may also provide the user feedback on the movement of the sensor. When it is important that the user control or cease movement of the sensor, such feedback on movement of the sensor can be useful to control or cease movement and thereby improve the measurement accuracy. As another example, the accelerometer or accelerometers on the device may be used to control the device. The accelerometers on the device may be used to indicate the orientation of the device using a 3D object on the display of the device, shaking the device may clear the screen on the device, and other examples discussed herein.

[0021]   The remainder of the disclosure refers to the embodiments disclosed in the figures. For example, Figure 1 illustrates an exemplary data collection system 100. System 100 can be configured to noninvasively measure blood analytes, such as glucose, total hemoglobin, methemoglobin, oxygen content, etc. System 100 may be capable of measuring optical radiation from the measurement site. For example, in some embodiments, system 100 may employ photodiodes defined in terms of area from about 1 mm^2 – 5 mm^2 (or higher) that are capable of detecting about 100 nanoamps (nA) or less of current resulting from measured light at full scale. An artisan will recognize from the disclosure herein that the phrase "at full scale" includes its ordinary meaning, which includes light saturation of the photodiode amplifier.

[0022]   The artisan will also recognize from the disclosure herein, that the system 100 may measure a range of about 2 nA to about 100 nA full scale. System 100 may also include sensor front-ends that are capable of processing and amplifying current from the detector(s) at signal-to-noise ratios (SNRs) of about 100

decibels (dB) or more, e.g., about 120 dB in order to measure various desired analytes. An artisan will recognize that system 100 may operate with a lower SNR, if improved accuracy is desired for an analyte like glucose.

[0023]   As shown in Figure 1, the data collection system 100 may be configured to measure glucose concentrations based on detection of light attenuated by a measurement site 102. Measurement site 102 may be any location on patient's body, such as a finger, ear lobe, and the like. In other embodiments, the system 100 may measure various blood analytes, other physiological parameters, or other data or collection of data useful in determining a state or trend of wellness of a patient. As shown in Figure 1, the system 100 may include an optional tissue thickness adjuster or tissue shaper, such as a protrusion, bump, or other suitable tissue shaping mechanism. In an embodiment, the tissue shaper seeks to create a substantially flat surface proximate to the finger and apply sufficient pressure to cause the finger tissue to be flat. In an embodiment, the shaper balances the performance enhancement caused by reducing the finger thickness, with the desire to avoid occlusion or perhaps even attempt to avoid disrupting blood flow at all.

[0024]   Figure 1 also illustrates an optional noise shield 105. In an embodiment, the noise shield 105 may advantageously be adapted to reduce electromagnetic noise while attempting to increase the transmittance or minimize attenuation of light from the measurement site 102 to the detectors 106. For example, the shield 105 may advantageously comprise a conductive coated glass or metal grid electrically communicating with one or more other shields of the sensor 101. In an embodiment where the shield 105 comprises conductive coated glass, the coating may advantageously comprise indium tin oxide. In an embodiment, the indium tin oxide comprises a surface resistivity ranging from approximately 30 ohms per square inch to 500 ohms per square inch, or, in some embodiments, approximately 30, 200, or 500 ohms per square inch. Other conductive materials substantially transparent to light will be recognizable to an artisan from the disclosure herein.

[0025]   In some embodiments, system 100 may be configured to measure blood analytes like glucose at measurement sites somewhere along a non-dominant arm or from a patient's non-dominant hand, e.g., a right-handed person's left arm or left hand.   In some patients, the non-dominant arm or hand may have less musculature and higher fat content, which can result in less water content in that tissue of the patient. Tissue having less water content may provide less interference with the particular wavelengths that are absorbed in a useful manner by blood analytes like glucose.   Accordingly, in some embodiments, system 100 may be configured for use on a person's non-dominant hand or arm.

[0026]   Data collection system 100 may comprise one or more sensors, such as a sensor 101, that is coupled to a processing device 103.   In an embodiment, sensor 101 and device 103 may be integrated together into a single unit like a handheld device. In an embodiment, sensor 101 and device 103 may be separate from each other and communicate with one with another in any suitable manner, such as, for example, through wired or wireless communications, over one or more computing networks, combinations of the same, or the like. The sensor 101 and device 103 may be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like. Sensor 101 and device 103 will now be further described.

[0027]   As shown in Figure 1, sensor 101 may comprise an emitter 104, an optional tissue thickness adjuster, a set of detectors 106, and optionally, one or more optional front-end interfaces 108 (not pictured). Emitter 104 may serve as the source of optical radiation transmitted towards measurement site 102.   In some embodiments, emitter 104 is configured as a optical point source, and thus, the optical sources of emitter 104 may be located within a relatively close distance to each other, such as within about a 2 mm to about 4 mm diameter; however, an artisan will recognize from the disclosure herein other relative spatial relationships that effectively behave as a point source from the perspective of one or more photodetectors.   In an embodiment, emitter 104 may comprise sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

[0028]   An artisan will also recognize that other wavelength centroids or ranges may be useful in system 100 for distinguishing other types of tissue, fluids, tissue properties, fluid properties, combinations of the same, or the like. Disclosure of considerations and embodiments of wavelengths of light and emitters and receivers are disclosed in related U.S. Provisional Patent Application, serial number 61/078,228, filed July 3, 2008 to Kiani et al., incorporated herein in its entirety by reference and specifically incorporated as to disclosure related to foregoing considerations and other processing techniques.

[0029]   In an embodiment, driver 109 drives emitter 104. For example, driver 109 may be configured to provide pulses of current to emitter 104. In some embodiments, driver 109 is capable of driving emitter 104 to emit optical radiation in a pattern that varies by less than about 10 parts-per-million; however an artisan will also recognize from the disclosure herein other amounts of variation.

[0030]   Detectors 106 capture and measure light from measurement site 102. For example, detectors 106 may capture and measure light transmitted from emitter 104 that has been attenuated or reflected from the tissue in measurement site 102. Detectors 106 may then provide a detector signal 107 to indicate the light captured or measured. Detectors 106 may be implemented using one or more photodiodes. Many types of photodiodes are well known to an artisan, and from the disclosure herein, the artisan will recognize many different types of photodiodes may be used to emphasize that particular photodiode's design specifications, response attributes or the like. A skilled artisan will also recognize that a system for emission and capture of light could be built with small modifications to the above using photo conductors or photo resisters.

[0031]   In addition, detectors 106 may be arranged with spatial considerations also discussed in the foregoing incorporated application, which is also specifically incorporated for subject matter relating to detection and other considerations.

[0032]   Front-end interfaces 108 provide an interface that adapts the output of detectors 106, which is responsive to desired physiological parameters. For example, front-end interfaces 108 may adapt signal 107 from detectors 106 into

a form that can be handled by device 103, or signal processor 110 in device 103. As shown in Figure 1, front-end interfaces 108 may have components assembled in sensor 101, device 103, connecting cabling when relevant, combinations of the same, or the like. These embodiments may be chosen based on various factors including space desired for the components, desired noise reductions or limitations, desired heat maximums of the front-end interfaces, or the like.

[0033] The front-end interfaces 108 may also be connected to one or more accelerometers 150A and 150B. The front-end interface 108 may process the output from the accelerometers 150A and 150B in order to produce signals in a form that can be handled by the signal processor 110. Alternatively, the accelerometers 150A and 150B may be connected to and provide a signal directly to the signal processor 110. Accelerometer 150A may be coupled to or encased within sensor 101 or its housing. Accelerometer 150B may be coupled to or encased within device 103 or its housing. As depicted in Figures 2A-2D and 3A-3C, in some embodiments, one or more additional accelerometers 150A-150E may be associated with one or both of the sensor 101 and device 103 and may be placed in various positions.

[0034] The foregoing front-end interfaces 108 may be coupled to detectors 106, signal processor 110, and accelerometers 150A and 150B using a bus, wire, wireless, electrical or optical cable, flex circuit, or some other form of signal connection. An artisan may also recognize that front-end interfaces 108 may be at least partially integrated with other components, such as detectors 106 and/or accelerometers 150A or 150B. For example, front-end interfaces 108 may comprise integrated circuits that are on the same circuit board as detectors 106. Other configurations will be recognized by an artisan.

[0035] Considerations of specific exemplary embodiments of front-end interfaces 108 herein may parallel the considerations in specific embodiments of front-end interfaces 108 as disclosed in the incorporated application referred to above and the like.

[0036] As shown in Figure 1, device 103 may comprise a front-end interface 108, a signal processor 110, and a user interface, such as a user interface

112. Device 103 may also comprise optional outputs alone or in combination with user interface 112, such as storage 114 and a network interface 116. In an embodiment, signal processor 110 comprises the processing logic that determines measurements for desired analytes, such as glucose, based on the streams of signals from detectors 106. Signal processor 110 may be implemented using known technology, such as application specific integrated circuits, field programmable gate arrays, and other available processors. An artisan will recognize from the disclosure herein that signal processor 110 may comprise a number of processors and sub-processors to perform its functions.

[0037]   In addition, signal processor 110 may provide various signals that control the operation of sensor 101. For example, signal processor 110 may provide an emitter control signal to driver 109 for emitter 104. As also shown, an optional memory communicates with front-end interface 108, sensor 101, device 103, and/or signal processor 110. This memory may serve as a buffer or storage location for front-end interface 108 or signal processor 110. An artisan will recognize many uses for such a memory, including program or partial program storage, quality control measures, upgrade capability, or the like.

[0038]   User interface 112 serves as a user interface component and provides an output, for example, to a user of system 100. User interface 112 may be implemented using well known components, such as a touch-screen display, a liquid crystal display (LCD), and organic light emitting diode (LED) display. In addition, user interface 112 may be manipulated to allow for measurement on the non-dominant side of patient. For example, user interface 112 may include a flip screen, a screen that can be moved from one side or another on device 103, or may include an ability to reorient its display indicia responsive to user input or device orientation.

[0039]   Device 103 may execute various software and applications to provide results to the user, the results provided in a known or recognizable manner. Artisans will also recognize from the disclosure herein that system 100 may be provided without a display and simply provide an output signal to a separate display or system.

[0040] Storage 114 and network interface 116 represent other optional output connections that may be implemented. For example, system 100 may be coupled to storage 114 that is in the form of a hard disk, flash memory card, or other suitable computer accessible memory. System 100 may also comprise a network interface 116, such as a serial bus port, an Ethernet port, a wireless interface, or other suitable communication device(s) that allows system 100 to communicate and share data with other devices. Device 103 may comprise various other components, such as a general purpose processor or controller (not shown) to provide a user interface, control data communications, data trending computations, or other suitable data displays, whether indicative to individual parameter measurements or combined or aggregated data displays.

[0041] Although disclosed with reference to Figure 1, an artisan will recognize from the disclosure herein that the system 100 may include other components or may be configured in different ways. For example, system 100 may include a touch screen that is used by the user to control the operation of device 103. In addition, system 100 may be configured with both the emitter 104 and detectors 106 on the same side of the measurement site 102. System 100 may also include a sensor that measures the power of light emitted from emitter 104. System 100 may also integrate the sensor and its front-end interfaces into the same component. Alternatively, the sensor and its front-end interfaces may be provided in different components of system 100.

[0042] Figures 2A, 2B, 2C, and 2D illustrate optional placements of accelerometers 150A, 150B, 150C, 150D, and 150E in varied locations in sensors 101A, 101B, 101C, and 101D. An accelerometer 150A, 150B, 150C, 150D, or 150E may measure acceleration that it experiences relative to gravity or freefall. An accelerometer 150A, 150B, 150C, 150D, or 150E may provide acceleration information along three axes and may provide acceleration information which is the equivalent of inertial acceleration minus local gravitational acceleration. Accelerometers 150A, 150B, 150C, 150D, and 150E are well known to those skilled in the art. They may be micro-electromechanical systems and may include piezoresistors. The accelerometers 150A, 150B, 150C, 150D, and 150E may be

high impedance charge output or low impedance output accelerometers. In some embodiments, accelerometers 150A, 150B, 150C, 150D, and 150E may be tri-axis accelerometers and the output of the accelerometers 150A, 150B, 150C, 150D, and 150E may include three signals each of which represents acceleration in particular axis. The output of accelerometers 150A, 150B, 150C, 150D, and 150E may be 8 bit, 12 bit, or any other appropriate-sized output signal. The outputs of the accelerometers may be analog or digital.

[0043]   The accelerometers 150A, 150B, 150C, 150D, and 150E may be used to determine whether the portion of the patient to which the sensor 101A, 101B, 101C, or 101D is attached is in the correct position, such as a digit being level and positioned below the heart of patient, or to see whether the sensor 101A, 101B, 101C, or 101D is moving so much as to cause a signal obtained from the sensor to be too noisy to be accurate. The signals from the accelerometers 150A, 150B, 150C, 150D, and 150E may then be used to help guide the patient in placing and steadying the sensor 101A, 101B, 101C, or 101D.

[0044]   As depicted in these figures, one or more accelerometers 150A, 150B, 150C, 150D, and 150E can be placed in various positions in a sensor 101A, 101B, 101C, or 101D. In some embodiments, the accelerometers 150A, 150B, 150C, 150D, and 150E may be placed on the sensors 101A, 101B, 101C, and 101D in such a way that during motion of a sensor 101A, 101B, 101C, or 101D, the accelerometers 150A, 150B, 150C, 150D, and 150E are subject to the same or similar acceleration as the measurement site. For example, on a digit, sensor 101A, 101B, 101C, or 101D, the accelerometers 150A, 150B, 150C, 150D, and 150E might be placed near an emitter and / or detector close to the tip of the finger. For a forehead or ear sensor 101A, 101B, 101C, or 101D, the accelerometers 150A, 150B, 150C, 150D, and 150E might be placed near either the detector or emitter on the sensor 101A, 101B, 101C, or 101D.

[0045]   Figures 3A, 3B, and 3C illustrate optional placements of accelerometers 150A, 150B, 150C, and 150D in varied locations on or in devices 103A, 103B, and 103C. The accelerometers 150A, 150B, 150C, and 150D on the devices 103A, 103B, and 103C may be similar to those described above. The

accelerometers 150A, 150B, 150C, and 150D on the devices 103A, 103B, and 103C may allow the device to produce a 3D object that shows the relative orientation of the device 103A, 103B, and 103C. In some embodiments, for example, if the user looks up at the bottom of device 103A, 103B, and 103C, then the user may see the bottom of the 3D object. In some embodiments, the devices 103A, 103B, and 103C allow a person to make notations or to take notes. The accelerometers 150A, 150B, 150C, and 150D on the devices 103A, 103B, and 103C may allow one to clear a screen on the device 103A, 103B, and 103C by shaking the device 103A, 103B, and 103C. In some embodiments, the devices 103A, 103B, and 103C may also speak parameters that are displayed or displayable on the devices 103A, 103B, and 103C, such as date, measurements, and time.

[0046]   Figure 4A is a block diagram depicting a first system for processing accelerometer data. In some embodiments, the output signal or signals 450 of a 3D accelerometer are received at separate band pass filters 410, one for each component of signal 450 or for each separate signal 450. The band pass filters 410 may be low pass filters 410. As discussed above, the output signals 450 may comprise 8 bit, 12 bit, or any other appropriately-size output signal(s) if it is digital. The output signal 450 may also be analog. The output signals 450 may also include any other set or compilation of data that allows it to indicate a 3D acceleration. The band pass filters 410 may operate to remove low frequency acceleration changes from the output signals 450. Some 3D accelerometers may have a drift. That is, the 3D accelerometers may indicate a slow change over time that is not actually occurring. Passing the output signals 450 through the band pass filters 410 (embodied as low pass filters 410) may remove the drift from the accelerometers. The output of the band pass filters 410 may be fed into squaring mechanisms 420. The squaring mechanisms 420 may square the outputs of the band pass filters 410. The outputs of the squaring mechanisms 420 may be combined in combination mechanism 470. In some embodiments, the combination performed in combination mechanism 470 is a summation of the signals. The combination performed may also include combining the squared components into a vector. After the outputs of the squaring mechanisms 420 had been combined by combination mechanism 470.

The square root mechanism 480 may take the square root of the combination. The output of the square root mechanism 480 is a filtered acceleration signal 490.

[0047]   Figure 4B is a block diagram depicting a second system for processing accelerometer data. Figure 4B is similar to Figure 4A in that each takes output signals 450 and applies band pass filters 410. The difference between the two figures is that in Figure 4B an L_m normalization unit 425 processes output signal 450 in order to produce filtered acceleration signal 490. A general equation for L_m normalization may be:

$$\left| x \right|_m = \left(\sum_{k=1}^{n} \left| x_k \right|^m \right)^{1/m} ,$$

[0048]   Where m is the level of normalization and n is the number of component or 'x' signals. The system depicted in Figure 4A may be equivalent to an L_2 normalization, where x=3. In some embodiments, if m=1, then the result is the sum of the absolute values of x_k. If m=∞, then the result may be the maximum absolute value of x_k.

[0049]   In some embodiments, such as that depicted in Figure 4B, output signal 450 is processed by band pass filters 410 and the output of those filters are processed by the L_m normalization unit 425, which in turn produces filtered acceleration signal 490. The choice of value for the "m" for the L_m normalization unit 425 will depend on the needs of the system, the type of noise expected or found in the system, available and preferable hardware, and other considerations known to those skilled in the art.

[0050]   The filtered acceleration signal 490 in both Figures 4A and 4B may indicate the acceleration of the 3D accelerometers in question. As discussed above, in some embodiments, the filtered acceleration signal may be used to indicate that a sensor is moving too much and causing too much noise in the signal for the signal to be trusted. The filtered acceleration signal 490 may also be used to remove noise from a recorded signal. In some embodiments, when a captured analyte signal is graphed, the color of the signal may be change based on the filtered acceleration signal. For example, the analyte signal may be colored red if much noise is detected

with the filtered acceleration signal 490, yellow if there is only moderate noise, and green if there is little noise. In some embodiments, if there is low perfusion of blood, then the signal may be weak because it is hard to measure the oxygen or other analyte in the blood. If this is the case, then even a small amount of motion in the sensor, as detected with the filtered acceleration signal 490, may indicate a bad reading and may warrant graphing the analyte signal in red. If the perfusion is high, however, and even if some motion is detected with filtered acceleration signal 490, then the graph might still be colored green. As noted herein, the filtered acceleration signal 490 may also be used to interact with the user interface of the device or otherwise control a sensor or accompanying device.

[0051]   In some embodiments, the analyte signal and the filtered acceleration signal 490 from the sensor may be graphed together. This may allow a user to visually receive feedback that she should reduce or eliminate movement of the sensor if the signal is too noisy.

[0052]   In the embodiments where the filtered acceleration signal 490 is a vector, orientation may be obtainable. Orientation may be useful, as discussed above, because it will allow the system to indicate to user that the finger on which the sensor is attached is not level or otherwise oriented correctly.

[0053]   Figure 5A is a block diagram depicting a third system for processing accelerometer data. The system in Figure 5A is similar in some ways to that depicted in Figure 4A. A manner in which the two systems differ is that the band pass filtering on the data is performed last. That is, the 3D accelerometer output 450 is squared using the squaring mechanisms 420, combined using a combination mechanism 470, the square root of combination is taken with the square root mechanism 480, and then finally a band pass filter is applied with the band pass filters 410 in order to produce filtered acceleration signal 490. In some embodiments, a system such as system is that depicted in Figure 5A may require fewer band pass filters than the system depicted in Figure 4A.

[0054]   Figure 5B is a block diagram depicting a fourth system for processing accelerometer data. The system in Figure 5B is similar to that depicted in Figure 4B in some ways and to that depicted in Figure 5A in some ways. The

system in Figure 5A and in 5B both use a post-processing band pass filter, thereby, in some embodiments, requiring fewer band pass filters 410 in the system. The systems depicted in Figures 5B and 4B are similar in that each depicts a general L_m normalization unit 425. As above, the choice of which value to use for "m" for the L_m normalization unit 425 will depend on the situation and needs of the system, as will be recognized by the skilled artisan.

[0055] Embodiments such as those depicted in Figures 4A, 4B, 5A, and 5B may be implemented using an integrated circuit, a central processing unit, or any of many other options known to those skilled in the art. Referring Figure 1, the system's depicted in Figures 4A, 4B, 5A, and 5B may be implemented within the signal processor 110, front-end interface 108, or any other appropriate module.

[0056] Figure 6 is a flow chart depicting a process for indicating noise level for a signal obtained from the sensor device. For example, referring to Figure 1, the signal obtained at sensor 101 and sent to device 103 may have noise in it. Sensor accelerometer 150A may provide useful information for determining how much noise is in the signal from sensor 101. Returning now to Figure 6, in the first step, the sensor's accelerometer data is obtained. Accelerometer data is described elsewhere herein. After the accelerometer data is obtained in step 610, a determination is made as to potential noise in the signal based on accelerometer data in step 620. Some embodiments of processing of accelerometer data are described above with respect to Figures 4A, 4B, 5A, and 5B. In some embodiments, determining the noise metric may include subtracting out a gravity signal. Step 620 may include determining an overall measure of the accelerometer data, such as a single number that indicates the level of acceleration in the sensor. As discussed with respect to Figures 4A, 4B, 5A, and 5B, in some embodiments, determining a single number that indicates acceleration in the sensor may include squaring the incoming accelerometer data, summing the accelerometer data over multiple axes, passing the sum through a band pass filter, and / or performing L_m normalization on the signal.

[0057] After a noise metric has been determined in step 620, then in step 630 a determination is made as to whether the noise metric is above a threshold.

The noise threshold may be any appropriate number and may vary depending on the noise metric used. If it is determined in step 630 that the noise metric is above a certain threshold, then in step 640 noise is indicated to the user. The noise may be indicated in any number of ways. For example, in some embodiments, if the noise level is high, then there may be an indicator on the device that lights up or otherwise indicates that there is a high level of noise and that the signal received from the sensor should not be trusted. In some embodiments, if the noise level is above a certain threshold, then the graph indicating the received signal may be colored differently. In some embodiments, (not pictured) even if the noise level is below the threshold, then a low noise indication may be made on the device. For example, a red graph may indicate a high noise level, a green graph may indicate a low the noise level or no noise, and a yellow graph may indicate a noise level between high and low. In some embodiments, the data processing system may ignore data that is noisier than a certain threshold when calculating the level of the blood analyte. The calculation might be based solely on data received when the noise was below a certain threshold. Displaying movement feedback to the user wearing the sensor may be useful as the user will be made aware of even small movements of the sensor.

[0058] In some embodiments, after steps 610 – 640 have been performed, the cycle will repeat again starting in step 610.

[0059] Figure 7 is a flow chart depicting a process for prompting a patient to properly position and orient the sensor. In some embodiments, there is a proper position for the sensor that is on the patient's finger. This proper position for the sensor may be level or parallel with ground and below the patient's heart. In step 710, the sensor's accelerometer data is obtained. This is described above with respect to step 610. After the accelerometer sensor data has been obtained in step 710 then in step 720 a position is determined for the sensor. As is apparent to the skilled artisan, although accelerometer data cannot typically be used to determine position directly, it may be useful for estimating position based on the angle of the gravity vector and knowledge of the mechanics of the shoulder, elbow, wrist, and finger, for example. If an initial position is known, then the current position of the

sensor may be estimated based on cumulative acceleration data. In some embodiments, the position may be estimated based on the 3 acceleration axes when the sensor is at rest. When the sensor is at rest, the value of acceleration in the three axes may indicate the direction of gravity. The resultant vector may be the gravity vector and define the orientation of the sensor.

[0060]   After the sensor's position is determined in step 720, then in step 730 a determination is made as to whether the sensor's position is proper. In some embodiments, the sensor's position will be proper if it's within a broad range of positions, such as within 5°, 10°, or 30° of parallel with the ground and below the patient's heart.

[0061]   If the sensor's position is not proper, as determined in step 730, then in step 740 an indication is made on the device connected to the sensor that the patient should reposition the sensor area. The indication to the patient to reposition the sensor could take any appropriate form. For example, in some embodiments, a text message may be displayed on the device indicating to the patient that he or she should "reposition the sensor to be parallel to the ground and below your heart." In some embodiments, a graphical indication may be made in order to show the patient that the sensor should be repositioned or show a picture of how the sensor should be repositioned.

[0062]   After steps 710 – 740 have been performed, then in some embodiments, the cycle will begin again at step 710.

[0063]   Figure 8 is a block diagram depicting filtering of a noisy signal using information from a 3D accelerometer. In some embodiments, the output signal 850 from a 3D accelerometer is received at a movement reference unit 810. The movement reference unit 810 produces a noise reference signal 830. Examples of producing a noise reference signal are described in Figures 4A, 4B, 5A, 5B, and 9. An adaptive filter unit 820 receives the noise reference signal 830 and the plethysmograph signal 840. The adaptive filter unit 820 processes the plethysmograph signal 840 along with the noise reference signal 830 in order to produce the noise-reduced signal 860.

[0064]   In some embodiments, movement reference unit 810 and adaptive filter unit 820 may be implemented as part of a signal processor 110 of Figure 1 or using other appropriate computers, circuitry, or computational device. Accelerometer output signal 850 may be produced by an accelerometer 150A or front-end interface 108.

[0065]   Figure 9 is a block diagram depicting a system for subtracting a noise signal from an input signal. The system in Figure 9 takes as input the accelerometer data 950 and applies a band pass filter 910 on the accelerometer data 950. The system of Figure 9 also applies a tapped delay line to the accelerometer data 950. A tapped delay line 920 may be a delay line with at least one "tap." A delay-line tap extracts a signal output from somewhere within the delay line, optionally scales it, and may sum with other taps for form an output signal. A tap may be interpolating or non-interpolating. A non-interpolating tap extracts the signal at some fixed delay relative to the input signal.

[0066]   The output of the tapped delay lines 920 are combined in combination mechanism 930, which may be similar to combination mechanism 470 described above. The resultant motion noise reference signal 931 may then be combined with the input signal 941, which includes motion noise. In some embodiments, the result of combining these two signals is that the motion noise, as represented by the motion noise reference signal 931, is subtracted out of the input analyte measurement signal 941, to produce a motion-noise reduced output signal 951.

[0067]   Returning now to Figure 1, in some embodiments, one or more accelerometers, such as accelerometer 150B, may be associated with device 103. In some of those embodiments, the output of accelerometer 150B and any other accelerometers may be used to produce effects at the user interface 112. For example, in one embodiment, if a user moves or shakes the device 103, then device 103 may power up, show the user a subsequent menu, reorient the display, or provide other information.

[0068]   In some embodiments, one or more accelerometers, such as accelerometer 150A, are associated with sensor 101. The signal processor 110

may determine an orientation of sensor 101 based on information from accelerometer 150A. If, for example, the orientation of sensor 101 were important for the operation of the sensor 101 or the quality of the signal produced by the sensor 101, then the signal processor's 110 determination of orientation could be used to output feedback to the user via the user interface 112. For example, if holding the sensor 101 relatively motionless and parallel to the ground were important and the user was moving the sensor 101 and not holding it in the correct orientation, then the user interface 112 could indicate to the user that the sensor should correct the orientation or movement of the sensor 101.

[0069] The processes, computer readable medium, and systems described herein may be performed on various types of hardware, such as hand-held devices or computer systems. Hand-held devices may include personal data assistants, cell phones, portable music players, laptops, and any other portable computing device. Computer systems and hand-held devices may include a bus or other communication mechanism for communicating information, and a processor coupled with the bus for processing information. A hand-held device or computer system may have a main memory, such as a random access memory or other dynamic storage device, coupled to the bus. The main memory may be used to store instructions and temporary variables. The computer system may also include a read-only memory or other static storage device coupled to the bus for storing static information and instructions. The hand-held device or computer system may also be coupled to a display, such as a CRT or LCD monitor. Input devices may also be coupled to the computer system. These input devices may include a mouse, a trackball, or cursor direction keys. Computer systems or hand-held device described herein may include instrument 140, patient monitor 120, photocommunicative key 210, information module 370, and refill module 310. Each computer system may be implemented using one or more physical computers or computer systems or portions thereof. The instructions executed by the hand-held device or computer system may also be read in from a computer-readable medium. The computer-readable medium may be a CD, DVD, optical or magnetic disk, laserdisc, carrier wave, or any other medium that is readable by the computer

system. In some embodiments, hardwired circuitry may be used in place of or in combination with software instructions executed by the processor.

[0070] As will be apparent, the features and attributes of the specific embodiments disclosed above may be combined in different ways to form additional embodiments, all of which fall within the scope of the present disclosure.

[0071] Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment.

[0072] Any process descriptions, elements, or blocks in the flow diagrams described herein and/or depicted in the attached figures should be understood as potentially representing modules, segments, or portions of code which include one or more executable instructions for implementing specific logical functions or steps in the process. Alternate implementations are included within the scope of the embodiments described herein in which elements or functions may be deleted, executed out of order from that shown or discussed, including substantially concurrently or in reverse order, depending on the functionality involved, as would be understood by those skilled in the art.

[0073] All of the methods and processes described above may be embodied in, and fully automated via, software code modules executed by one or more general purpose computers or processors, such as those computer systems described above. The code modules may be stored in any type of computer-readable medium or other computer storage device. Some or all of the methods may alternatively be embodied in specialized computer hardware.

[0074]   It should be emphasized that many variations and modifications may be made to the above-described embodiments, the elements of which are to be understood as being among other acceptable examples. All such modifications and variations are intended to be included herein within the scope of this disclosure and protected by the following claims.

WHAT IS CLAIMED IS:

1.   A physiological monitoring system comprising:

        a sensor, comprising:

                a light source; and

                a photodetector capable of detecting light from said light source

        after attenuation by tissue of a measurement site; and

        a device coupled to the sensor, comprising:

                one or more accelerometers; and

                a signal processor which receives a signal generated by the one

        or more accelerometers, said signal processor capable of:

                        generating a movement signal based on the signal

                generated by `the one or more accelerometers; and

                        providing feedback to a user based on the movement

                signal for the device.

2.   The physiological monitoring system of claim 1, wherein the feedback provided to the user comprises turning on a user interface on the device.

3.   The physiological monitoring system of claim 1, wherein the feedback provided to the user comprises reorienting a user interface on the device.

4.   The physiological monitoring system of claim 1, wherein the feedback provided to the user comprises showing the user a new menu on an interface on the device.

5.   The physiological monitoring system of claim 1, wherein the physiological monitoring system further includes a user interface and the signal processor is further capable of providing data to the user interface.

6.   The physiological monitoring system of claim 1, wherein the signal processor is further configured to improve signal integrity based on the outputs of the one or more accelerometers.

7.   The physiological monitoring system of claim 6, wherein the signal processor signal processor improves signal integrity by adaptive filtering based on the outputs of the one or more accelerometers.

8.   The physiological monitoring system of claim 6, wherein the signal processor improves signal integrity by signaling the user based on the outputs of the one or more accelerometers.
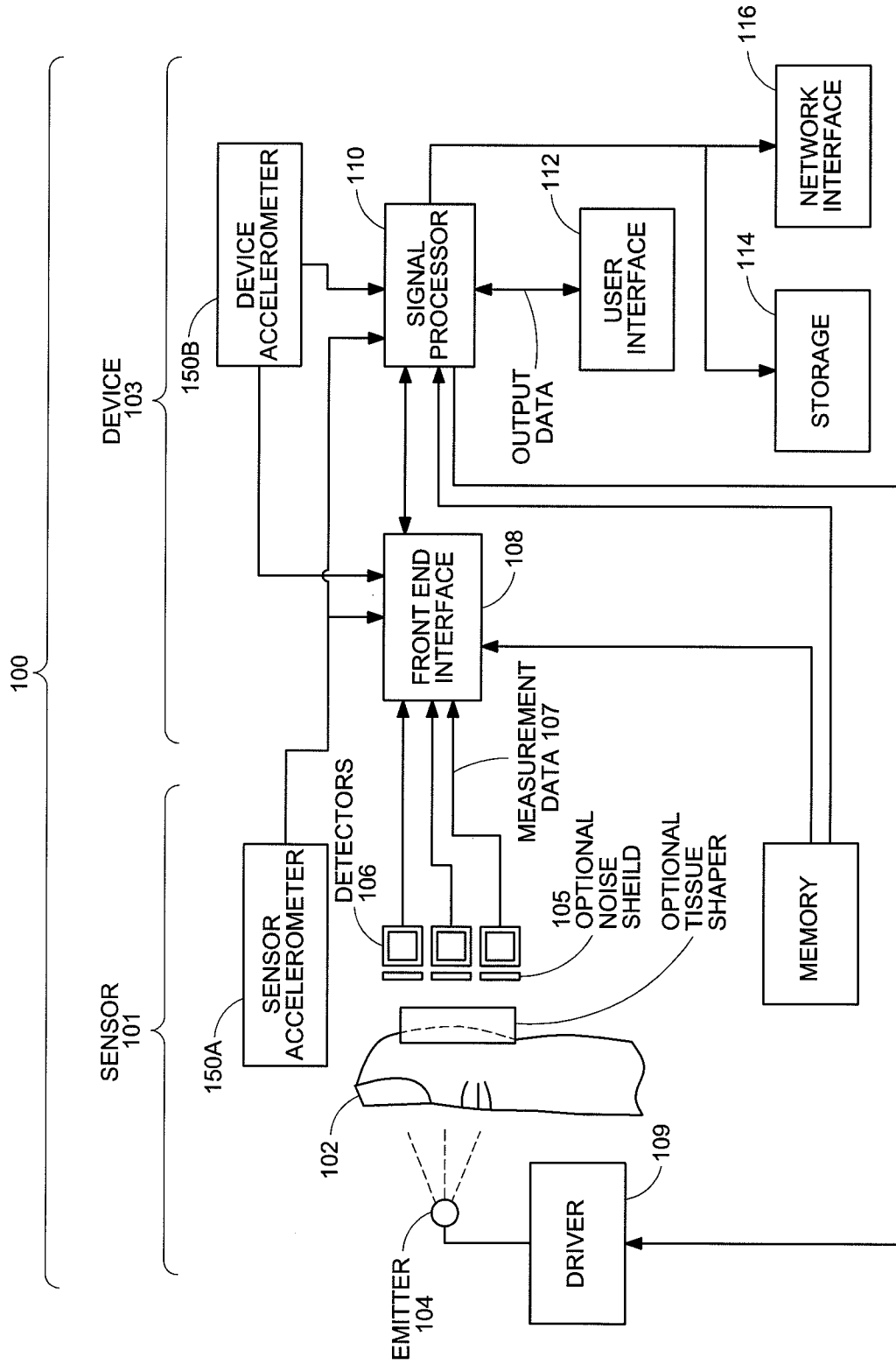
9.   A physiological monitoring system comprising:

a sensor, comprising:

an accelerometer;

a light source; and

a photodetector capable of detecting light from said light source after attenuation by tissue of a measurement site; and

a device coupled to the sensor, comprising:

a signal processor which receives a signal generated by the accelerometer, said signal processor capable of:

generating a movement signal based on the signal generated by the accelerometer; and

providing feedback to a user based on the movement signal for the device.

10.   The physiological monitoring system of claim 9, wherein the accelerometer; and wherein the signal processor is further capable of:

using the signal produced by the accelerometer to estimate a position of the sensor; and

indicating to an end user a desired position of the sensor relative to the estimated position of the sensor.

11.   The physiological monitoring system of claim 9, wherein the signal processor is further capable of:

using the signal produced by the accelerometer to determine the orientation of the sensor; and

indicating to an end user a desired orientation of the sensor relative to the current orientation of the sensor.

12.   The physiological monitoring system of claim 5, wherein the feedback provided to the user comprises showing the user a noise level of a signal obtained based on data from the accelerometer on a user interface on the device.

13.   The physiological monitoring system of claim 5, wherein the physiological monitoring system further includes a user interface and the signal processor is further capable of providing data to the user interface.

14.   A physiological monitoring system comprising:

a sensor, comprising:

one or more accelerometers;

a light source; and

a photodetector capable of detecting light from said light source after attenuation by tissue of a measurement site; and

a device coupled to the sensor, comprising

a signal processor which receives signal generated by the one or more accelerometers and an analyte signal detected by the device, said signal processor capable of:

generating a movement noise signal based on the signal generated by the one or more accelerometers; and

generating a noise-reduced signal based on the movement noise signal and the analyte signal.

15.   The physiological monitoring system of claim 14, wherein the physiological monitoring system further includes a user interface and the signal processor is further capable of providing data to the user interface.

16.   The physiological monitoring system of claim 14, wherein the signal processor is further configured to improve signal integrity based on the outputs of the one or more accelerometers.

17.   The physiological monitoring system of claim 16, wherein the signal processor improves signal integrity by adaptive filtering based on the outs of the one or more accelerometers.
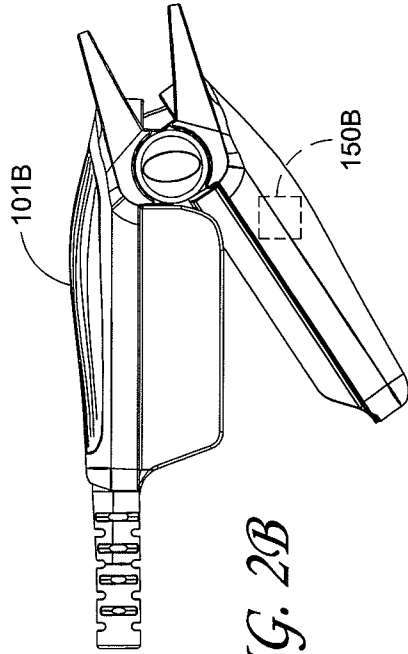
18.   The physiological monitoring system of claim 16, wherein the signal processor signal processor improves signal integrity by signaling the user based on the outs of the one or more accelerometers.
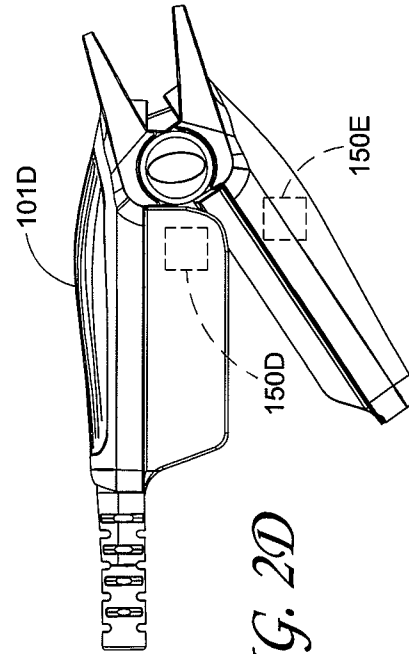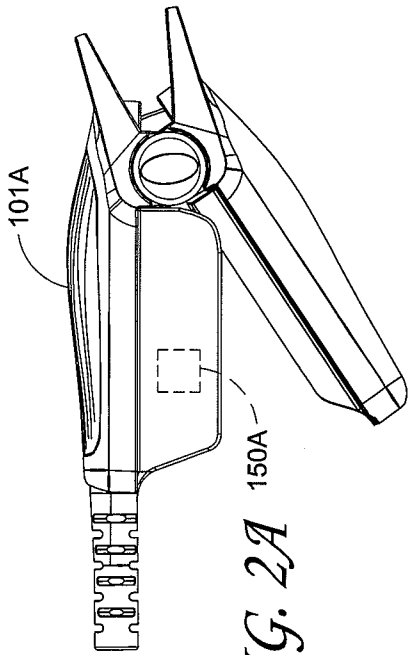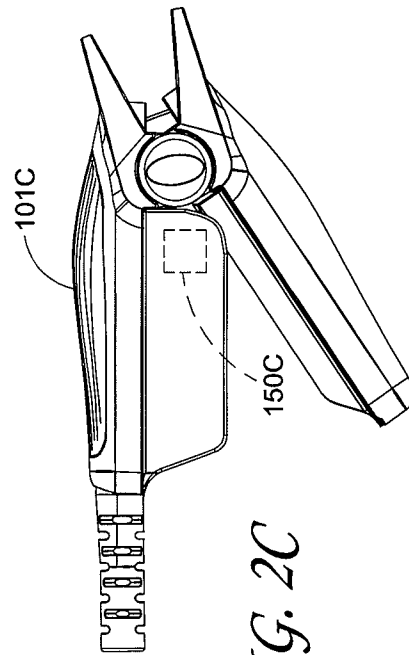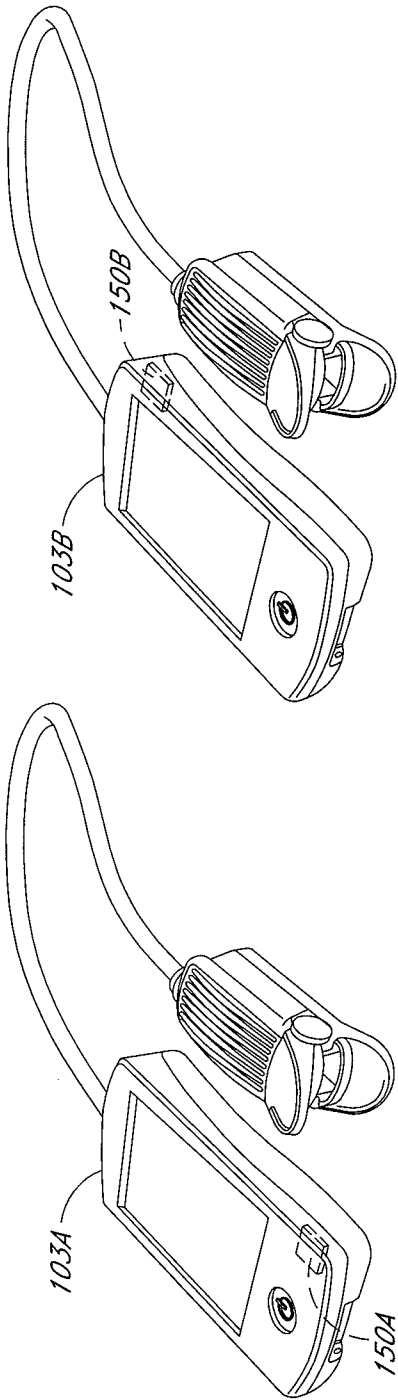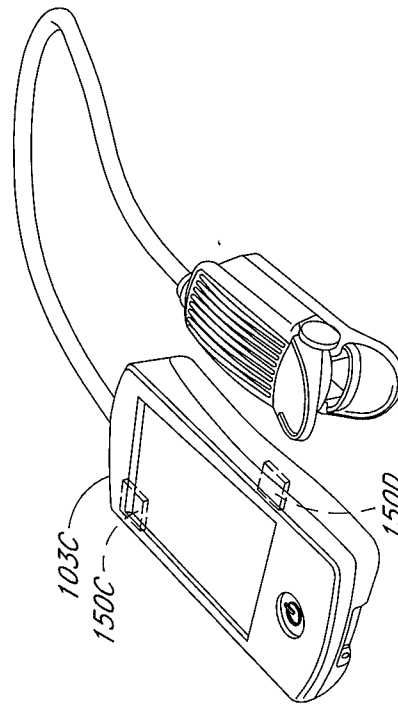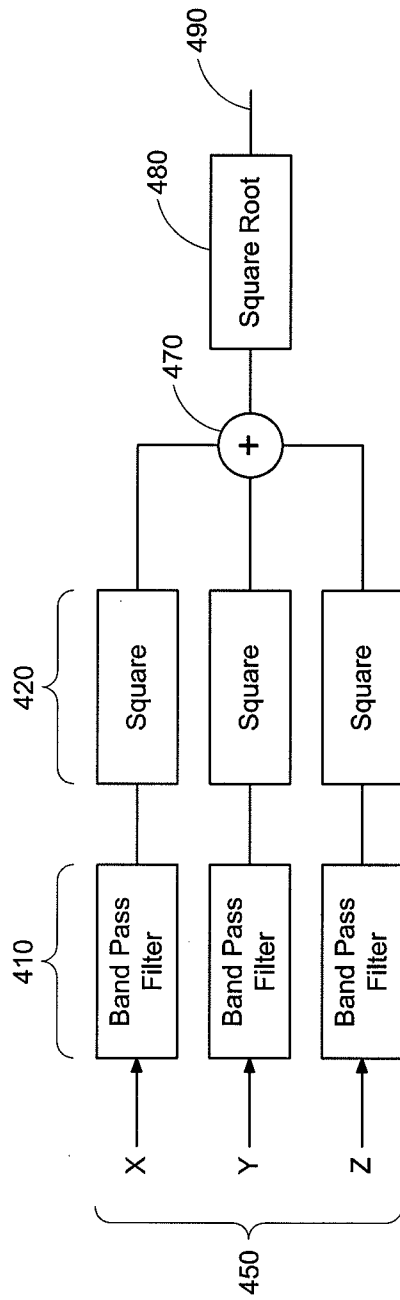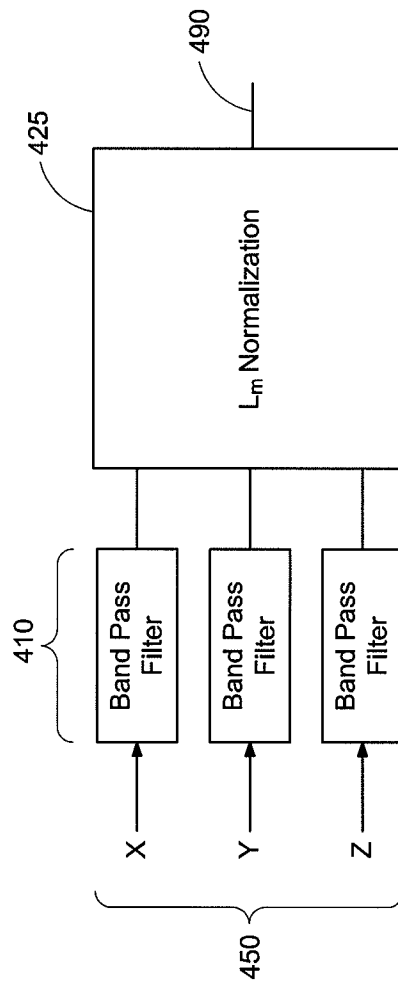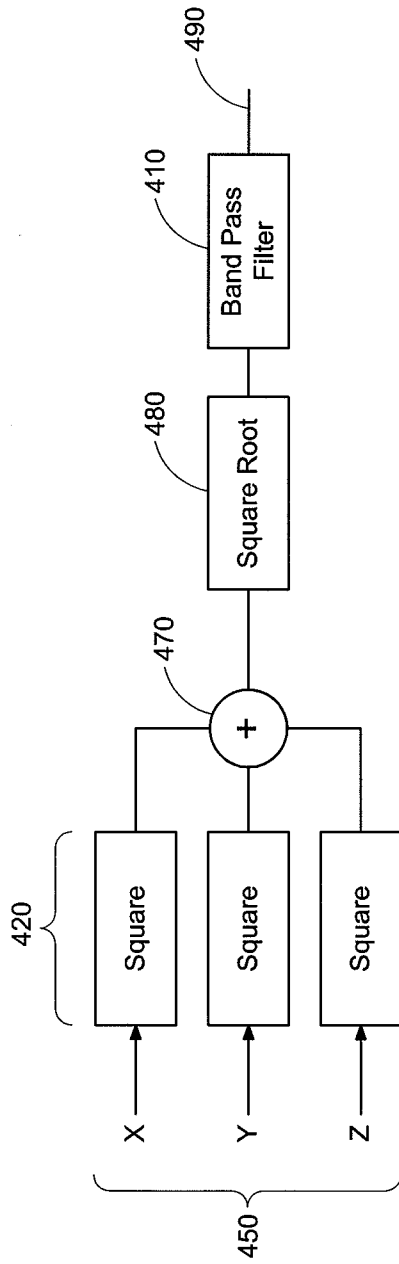
1/9

FIG. 1

FIG. 2B

FIG. 2D

FIG. 2A

FIG. 2C

FIG. 3A

FIG. 3B

FIG. 3C

FIG. 4A

FIG. 4B

FIG. 5A

FIG. 5B

FIG. 6

710 ── OBTAIN SENSOR'S
ACCELEROMETER DATA

720 ── DETERMINE SENSOR
POSITION

730 ── IS SENSOR
POSITION
PROPER?

N

Y

740 ── INDICATE THAT SENSOR
SHOULD BE REPOSITIONED

FIG. 7

8/9
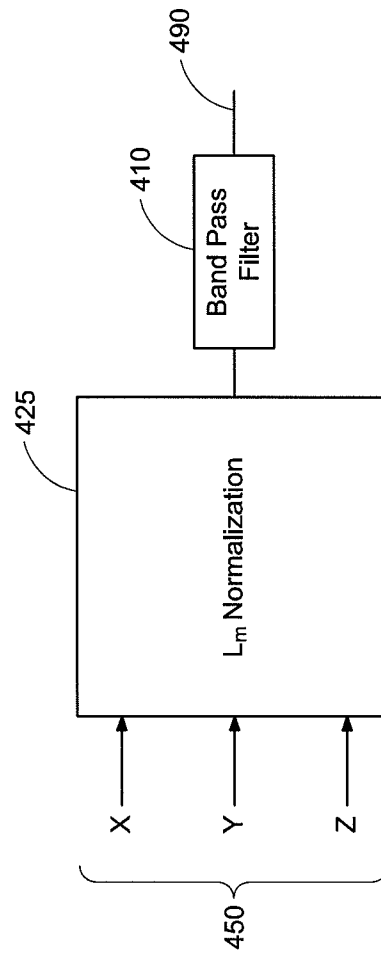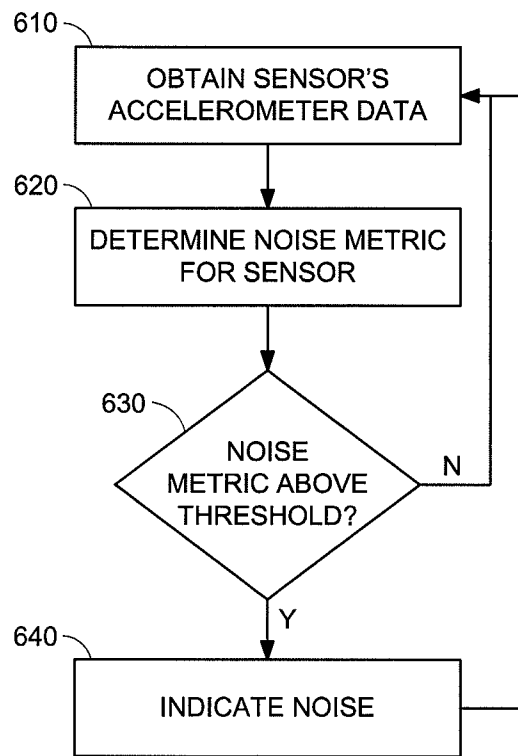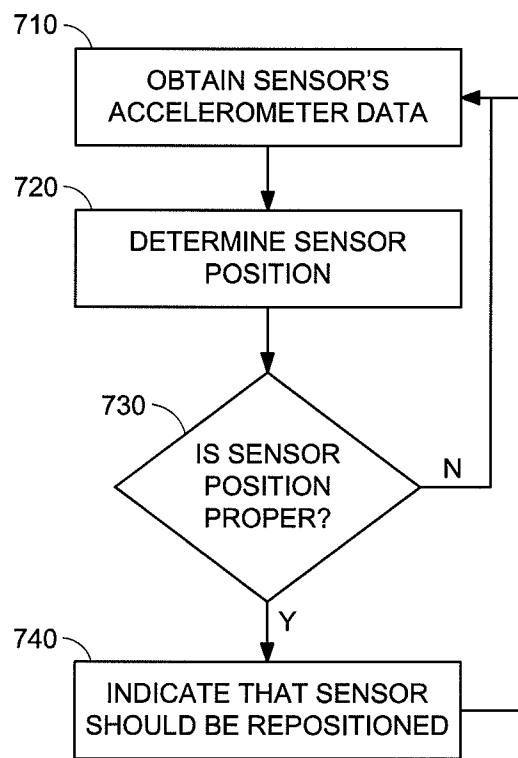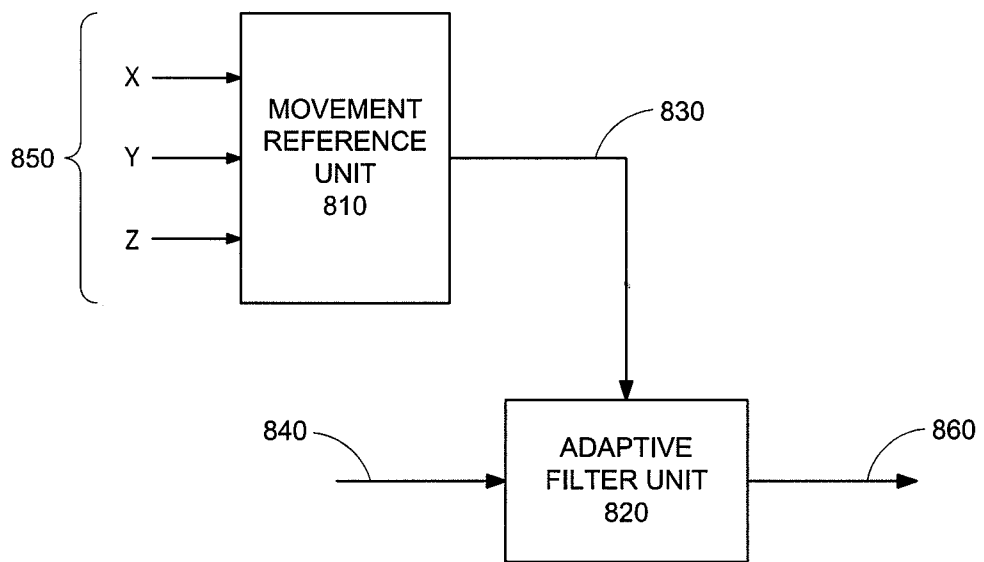
FIG. 8

FIG. 9

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00   G01P15/00
ADD.

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   G01P

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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| X | Further documents are listed in the continuation of Box C. |

| X | See patent family annex. |

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Date of the actual completion of the international search	Date of mailing of the international search report
29 November 2010	07/12/2010

| Name and mailing address of the ISA/
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 Mundakapadam, S |

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INTERNATIONAL SEARCH REPORT

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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