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(54) **SYSTEMS, DEVICES, AND METHODS WITH DURATION-BASED ADJUSTMENT OF SENSOR DATA**

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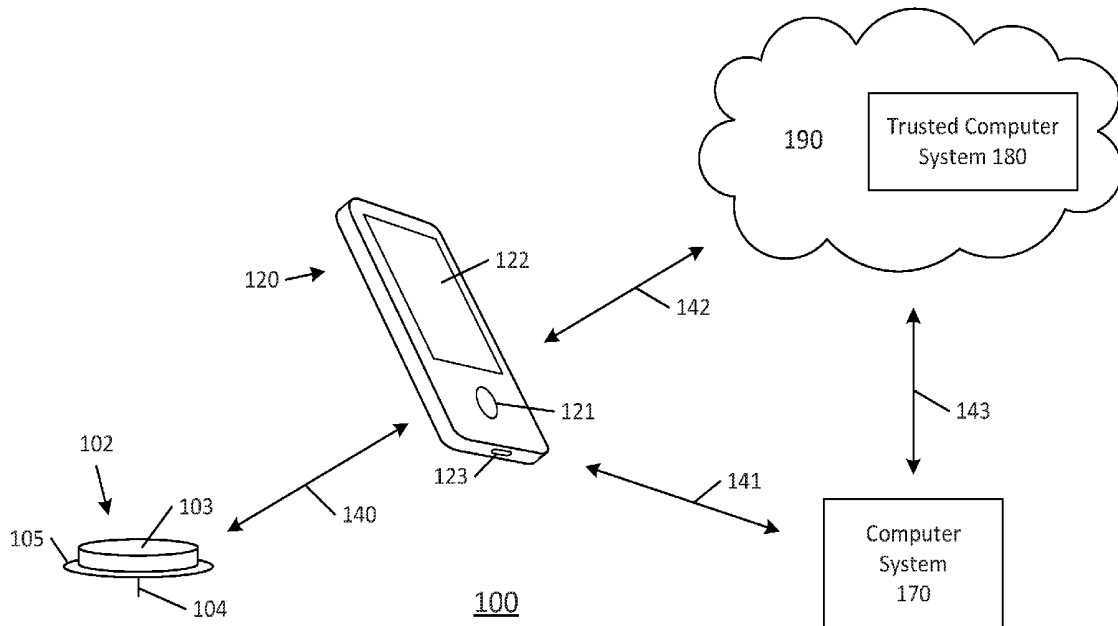
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(57) **ABSTRACT**

Embodiments that compensate for changes to sensor response characteristics (e.g., sensitivity) due to time durations are disclosed. The time durations can be the amount of time the sensor is in a post-manufacture packaged state prior to use, or the amount of time the sensor is in use. Sensor response changes due to other variables can also be compensated for.



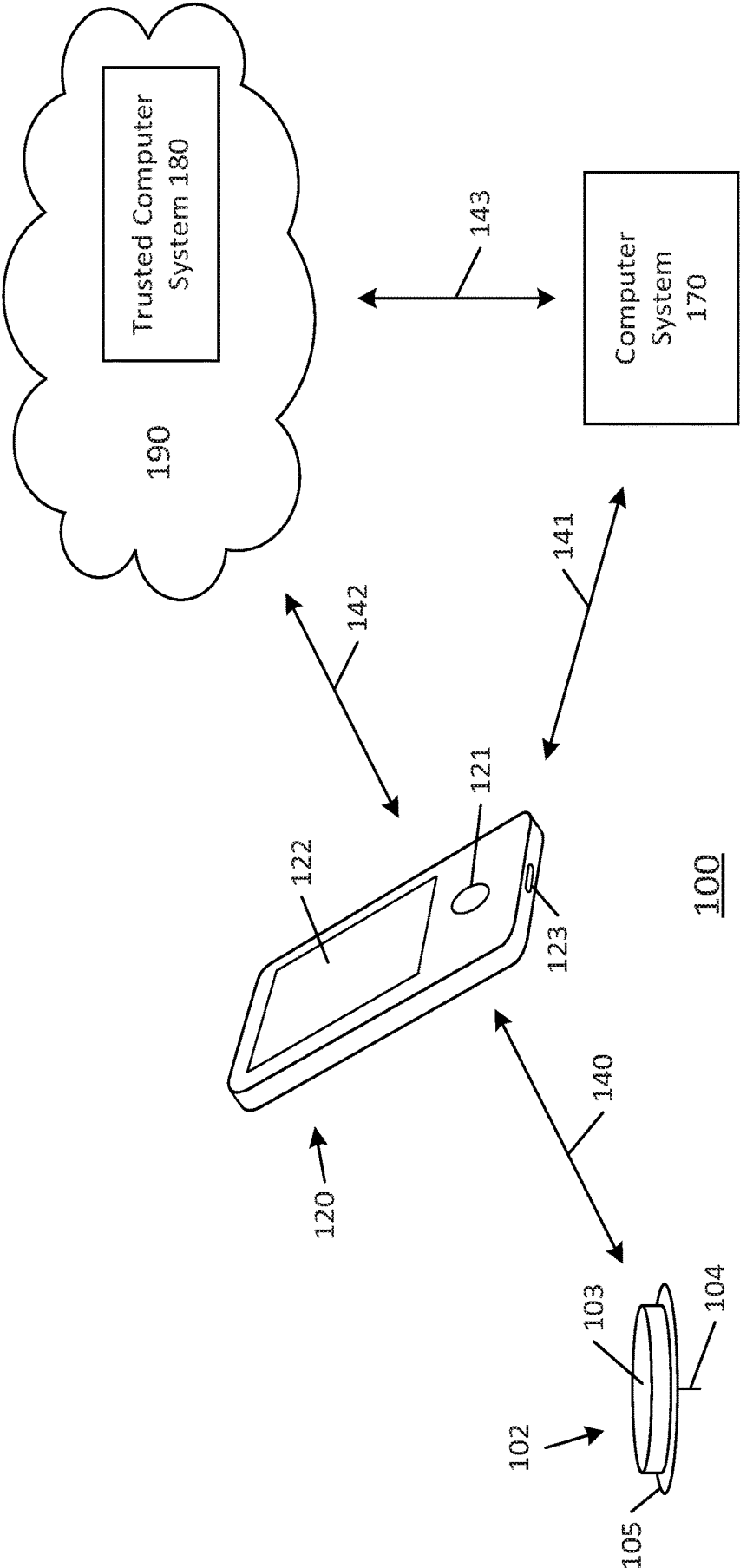


FIG. 1A

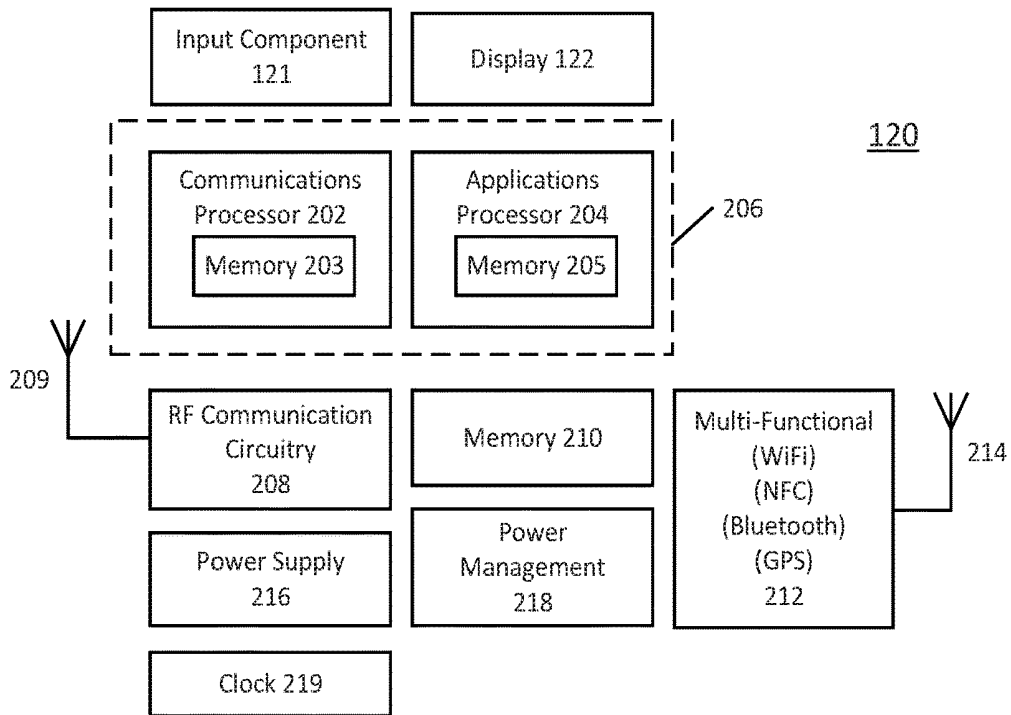


FIG. 1B

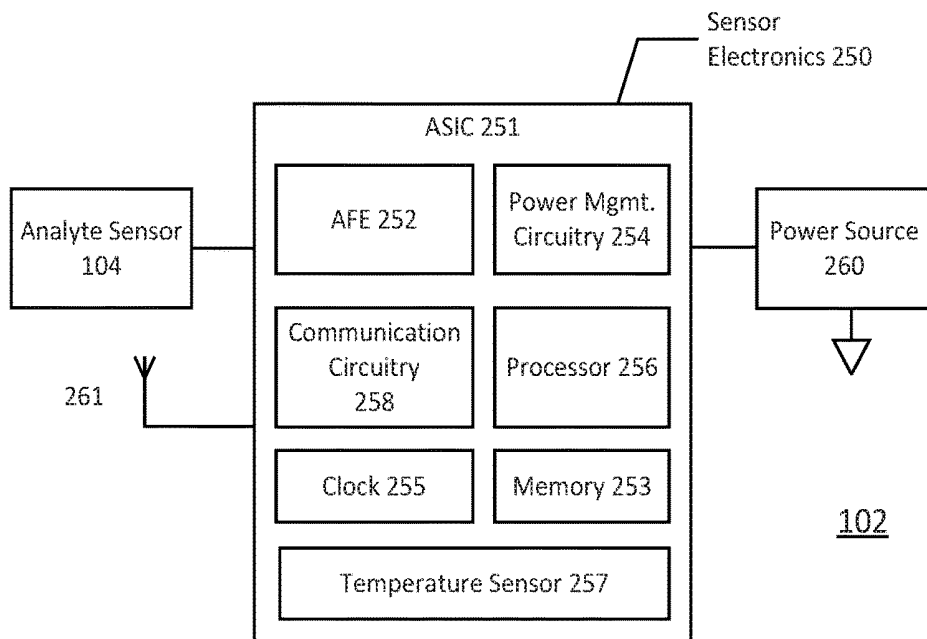


FIG. 1C

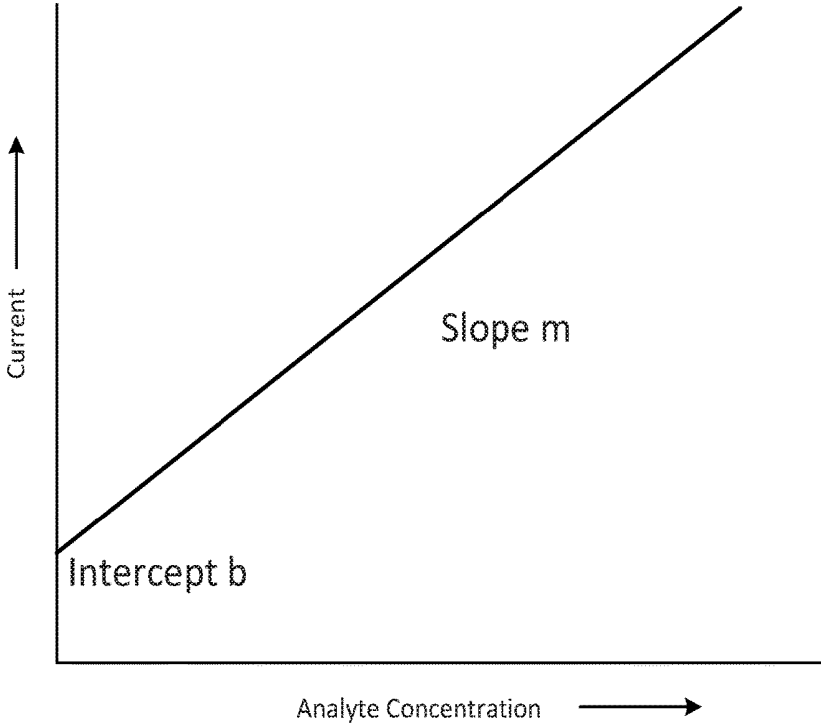


FIG. 2A

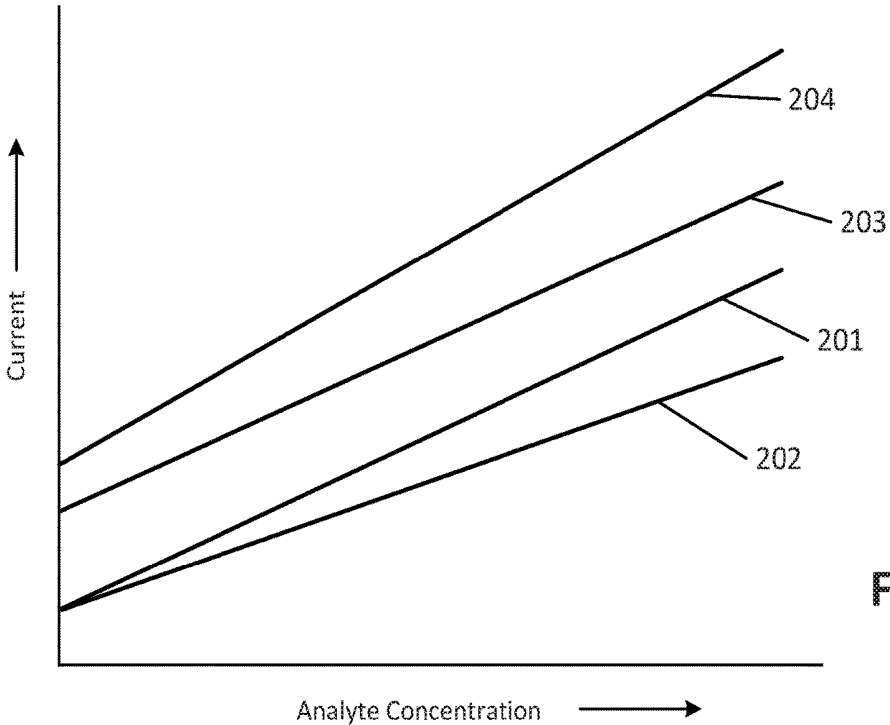


FIG. 2B

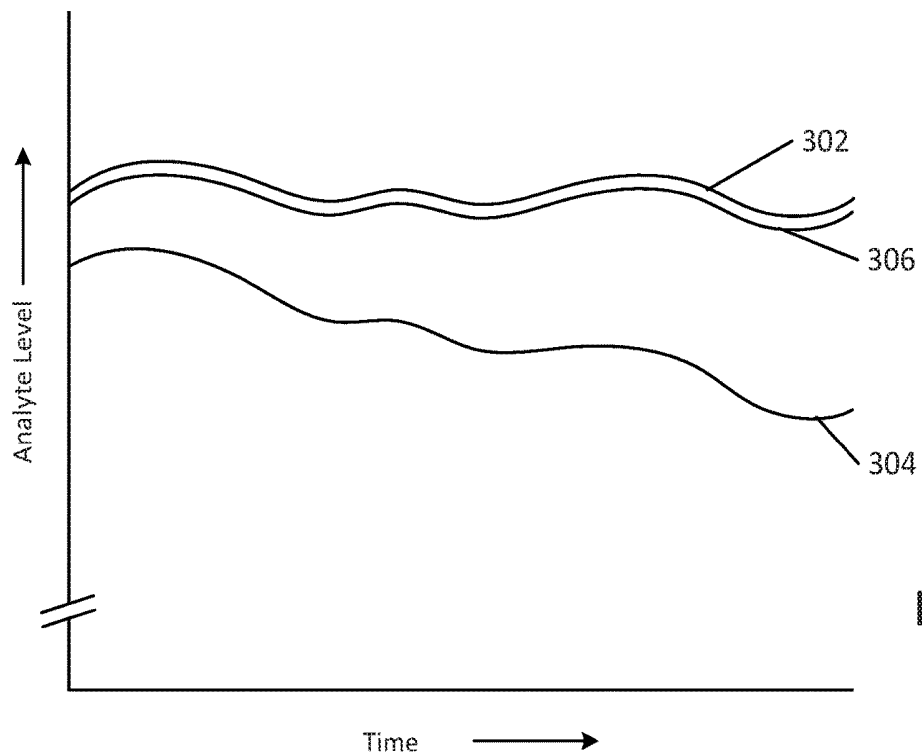


FIG. 3A

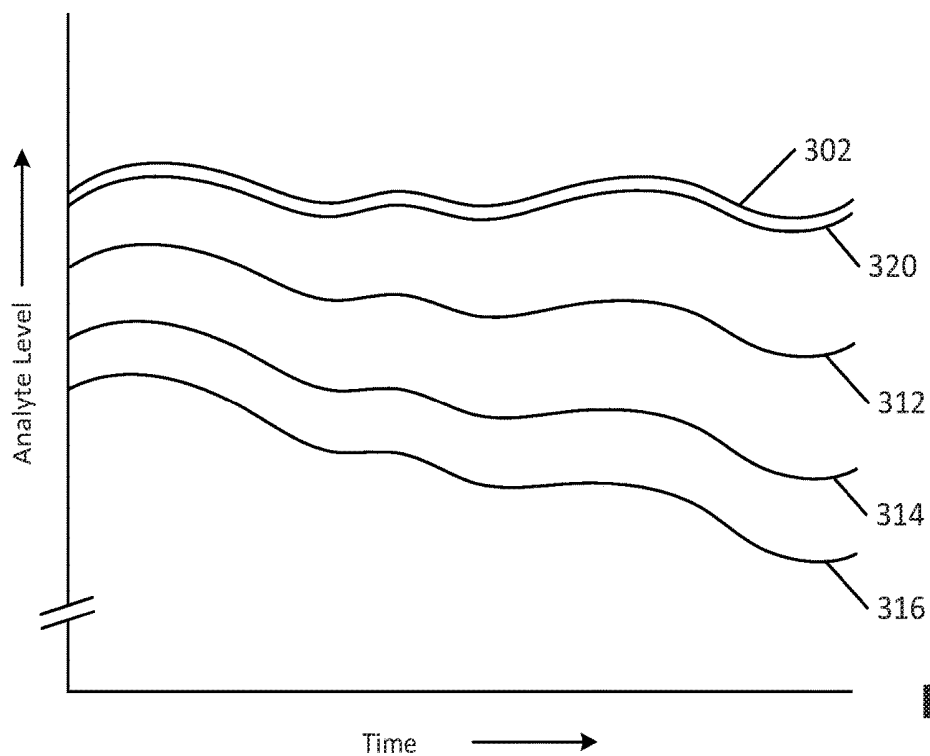


FIG. 3B

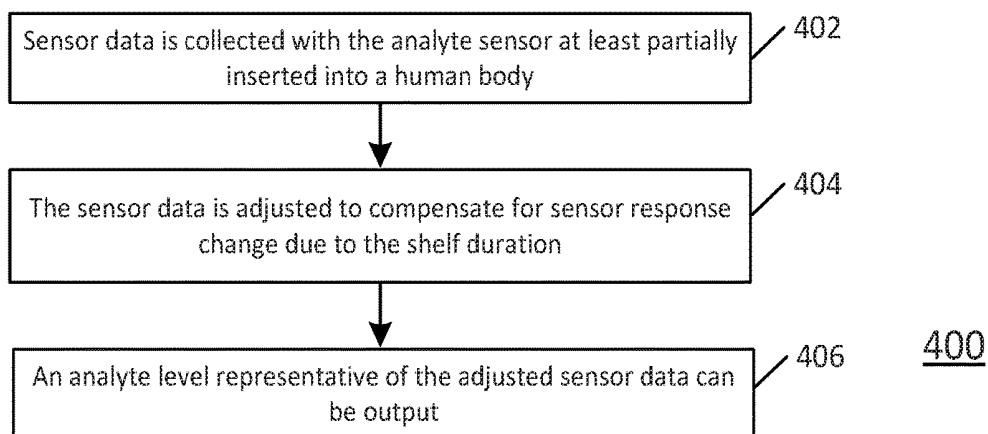


FIG. 4A

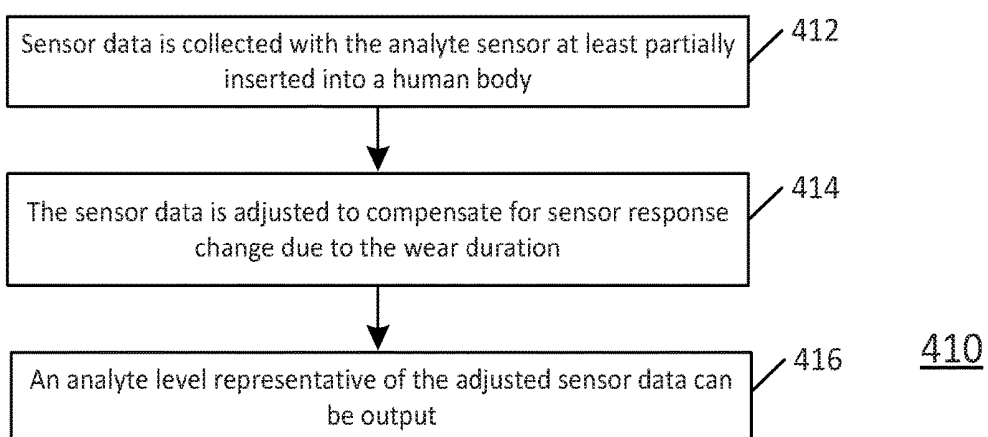


FIG. 4B

SYSTEMS, DEVICES, AND METHODS WITH DURATION-BASED ADJUSTMENT OF SENSOR DATA

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of International Patent Application No. PCT/US2018/030619, filed May 2, 2018, which claims priority to and the benefit of U.S. Provisional Patent Application No. 62/500,955, filed May 3, 2017, and U.S. Provisional Patent Application No. 62/624,665, filed Jan. 31, 2018, all of which are incorporated by reference herein in their entirety for all purposes.

FIELD

[0002] The subject matter described herein relates generally to systems, devices, and methods for performing duration-based adjustments of sensor data, and more particularly, to the improvement of analyte monitoring systems with analyte sensors that are subjected to various durations of post-manufacture storage and various durations of active (e.g., in vivo) use.

BACKGROUND

[0003] A vast and growing market exists for monitoring the health and condition of humans and other living animals. Information that describes the physical or physiological condition of humans can be used in countless ways to assist and improve quality of life and diagnose and treat undesirable human conditions.

[0004] A common device used to collect such information is a physiological sensor such as a biochemical analyte sensor, or a device capable of sensing a chemical analyte of a biological entity. Biochemical sensors come in many forms and can be used to sense analytes in fluids, tissues, or gases forming part of or produced by a biological entity, such as a human being. These analyte sensors can be used on or within the body itself, or they can be used on biological substances that have already been removed from the body.

[0005] The performance of an analyte sensor can be characterized in a number of ways, and a characteristic of particular importance can be the accuracy of the analyte sensor, or the degree to which the sensor correctly measures the concentration or content of the chemical analyte being measured.

[0006] Although analyte sensors often have a complex and well-studied design, they can still be subject to a degree of performance variation. For these and other reasons, needs exist for improvement to the performance of analyte sensors.

SUMMARY

[0007] Example embodiments of systems, devices, and methods are described herein for improving the performance of analyte sensors. These embodiments provide for the adjustment or calibration of data collected with analyte sensors based on one or more durations of time. A first example duration of time for which these embodiments can compensate pertains to changes in sensor response due to the period of time post-manufacture before a particular analyte sensor is put into use, e.g., a shelf duration. A second example duration of time for which these embodiments can compensate pertains to changes in sensor response due to the period of time during which the analyte sensor is used, e.g.,

a wear duration. Numerous examples of algorithms and methods for performing variations of one or both of these compensations are provided, as well as example embodiments of systems and devices for performing the same. Numerous example embodiments of various methods for measuring the time durations, and systems and devices for performing the same, are provided. Example embodiments compensating for other variables that can change sensor response, such as temperature, in addition to one or both durations of time are also provided, in addition to systems and devices for performing the same.

[0008] Other systems, devices, methods, features and advantages of the subject matter described herein will be or will become apparent to one with skill in the art upon examination of the following figures and detailed description. It is intended that all such additional systems, methods, features and advantages be included within this description, be within the scope of the subject matter described herein, and be protected by the accompanying claims. In no way should the features of the example embodiments be construed as limiting the appended claims, absent express recitation of those features in the claims.

BRIEF DESCRIPTION OF FIGURES

[0009] The details of the subject matter set forth herein, both as to its structure and operation, may be apparent by study of the accompanying figures, in which like reference numerals refer to like parts. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the subject matter. Moreover, all illustrations are intended to convey concepts, where relative sizes, shapes and other detailed attributes may be illustrated schematically rather than literally or precisely.

[0010] FIG. 1A is an illustrative view depicting an example embodiment of an in vivo analyte monitoring system.

[0011] FIG. 1B is a block diagram of an example embodiment of a reader device.

[0012] FIG. 1C is a block diagram depicting an example embodiment of sensor control device.

[0013] FIG. 2A is a graph depicting an example of an in vitro sensitivity of an analyte sensor.

[0014] FIG. 2B is a graph depicting examples of different sensitivities for analyte sensors.

[0015] FIG. 3A is a graph depicting example traces corresponding to actual analyte levels, analyte levels determined from data not compensated for wear duration, and analyte levels determined from data compensated for wear duration.

[0016] FIG. 3B is a graph depicting example traces corresponding to actual analyte levels, analyte levels determined from various sensors not compensated for shelf duration, and analyte levels determined from data compensated for shelf duration.

[0017] FIGS. 4A-4B are flow diagrams depicting example embodiments of methods for adjusting sensor data to compensate for shelf duration and wear duration, respectively.

DETAILED DESCRIPTION

[0018] Before the present subject matter is described in detail, it is to be understood that this disclosure is not limited to the 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 present disclosure will be limited only by the appended claims.

[0019] Generally, embodiments of the present disclosure are used with systems, devices, and methods for detecting at least one analyte, such as glucose, in a bodily fluid (e.g., subcutaneously within the interstitial fluid (“ISF”) or blood, within the dermal fluid of the dermal layer, or otherwise). Accordingly, many embodiments include in vivo analyte sensors structurally configured so that at least a portion of the sensor is, or can be, positioned in the body of a user to obtain information about at least one analyte of the body. However, the embodiments disclosed herein can be used with in vivo analyte monitoring systems that incorporate in vitro capability, as well as purely in vitro or ex vivo analyte monitoring systems, including those systems that are entirely non-invasive.

[0020] Before describing the embodiments in detail, however, it is first desirable to describe examples of devices that can be present within, for example, an in vivo analyte monitoring system, as well as examples of their operation, all of which can be used with the embodiments described herein.

Example Embodiments of Analyte Monitoring Systems

[0021] There are various types of analyte monitoring systems. “Continuous Analyte Monitoring” systems (or “Continuous Glucose Monitoring” systems), for example, are in vivo systems that can transmit data from a sensor control device to a reader device repeatedly or continuously without prompting, e.g., automatically according to a schedule. “Flash Analyte Monitoring” systems (or “Flash Glucose Monitoring” systems or simply “Flash” systems), as another example, are in vivo systems that can transfer data from a sensor control device in response to a scan or request for data by a reader device, such as with a Near Field Communication (NFC) or Radio Frequency Identification (RFID) protocol. In vivo analyte monitoring systems can also operate without the need for finger stick calibration.

[0022] In vivo monitoring systems can include a sensor that, while positioned in vivo, makes contact with the bodily fluid of the user and senses one or more analyte levels contained therein. The sensor can be part of a sensor control device that resides on the body of the user and contains the electronics and power supply that enable and control the analyte sensing. The sensor control device, and variations thereof, can also be referred to as a “sensor control unit,” an “on-body electronics” device or unit, an “on-body” device or unit, or a “sensor data communication” device or unit, to name a few. As used herein, these terms are not limited to devices with analyte sensors, and encompass devices that have sensors of other types, whether biometric or non-biometric. The term “on body” refers to any device that resides directly on the body or in close proximity to the body, such as a wearable device (e.g., glasses, watch, wristband or bracelet, neckband or necklace, etc.).

[0023] In vivo monitoring systems can also include one or more reader devices that receive sensed analyte data from the sensor control device. These reader devices can process and/or display the sensed analyte data, in any number of forms, to the user. These devices, and variations thereof, can be referred to as “handheld reader devices,” “reader devices” (or simply, “readers”), “handheld electronics” (or hand-

helds), “portable data processing” devices or units, “data receivers,” “receiver” devices or units (or simply receivers), “relay” devices or units, or “remote” devices or units, to name a few. Other devices such as personal computers have also been utilized with or incorporated into in vivo and in vitro monitoring systems.

[0024] In vivo analyte monitoring systems can be differentiated from “in vitro” systems that contact a biological sample outside of the body (or rather “ex vivo”) and that typically include a meter device that has a port for receiving an analyte test strip carrying a bodily fluid of the user, which can be analyzed to determine the user’s analyte level. As mentioned, the embodiments described herein can be used with in vivo systems, in vitro systems, and combinations thereof.

[0025] The embodiments described herein can be used to monitor and/or process information regarding any number of one or more different analytes. Analytes that may be monitored include, but are not limited to, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, glycosylated hemoglobin (HbA1c), creatine kinase (e.g., CK-MB), creatine, creatinine, DNA, fructosamine, glucose, glucose derivatives, glutamine, growth hormones, hormones, ketones, ketone bodies, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. In embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times

[0026] FIG. 1A is an illustrative view depicting an example embodiment of an in vivo analyte monitoring system **100** having a sensor control device **102** and a reader device **120** that communicate with each other over a local communication path (or link) **140**, which can be wired or wireless, and uni-directional or bi-directional. In embodiments where path **140** is wireless, a near field communication (NFC) protocol, RFID protocol, Bluetooth or Bluetooth Low Energy protocol, Wi-Fi protocol, proprietary protocol, or the like can be used, including those communication protocols in existence as of the date of this filing or their later developed variants.

[0027] Reader device **120** is also capable of wired, wireless, or combined communication with a computer system **170** (e.g., a local or remote computer system) over communication path (or link) **141** and with a network **190**, such as the internet or the cloud, over communication path (or link) **142**. Communication with network **190** can involve communication with trusted computer system **180** within network **190**, or through network **190** to computer system **170** via communication link (or path) **143**. Communication paths **141**, **142**, and **143** can be wireless, wired, or both, can be uni-directional or bi-directional, and can be part of a telecommunications network, such as a Wi-Fi network, a local area network (LAN), a wide area network (WAN), the internet, or other data network. In some cases, communication paths **141** and **142** can be the same path. All communications over paths **140**, **141**, and **142** can be encrypted and sensor control device **102**, reader device **120**, computer system **170**, and trusted computer system **180** can each be configured to encrypt and decrypt those communications sent and received.

[0028] Variants of devices **102** and **120**, as well as other components of an in vivo-based analyte monitoring system that are suitable for use with the system, device, and method embodiments set forth herein, are described in U.S. Patent Application Publ. No. 2011/0213225 (the '225 Publication), which is incorporated by reference herein in its entirety for all purposes.

[0029] Sensor control device **102** can include a housing **103** containing in vivo analyte monitoring circuitry and a power source. In this embodiment, the in vivo analyte monitoring circuitry is electrically coupled with an analyte sensor **104** that extends through an adhesive patch **105** and projects away from housing **103**. Adhesive patch **105** contains an adhesive layer (not shown) for attachment to a skin surface of the body of the user. Other forms of body attachment to the body may be used, in addition to or instead of adhesive.

[0030] Sensor **104** is adapted to be at least partially inserted into the body of the user, where it can make fluid contact with that user's bodily fluid (e.g., subcutaneous (subdermal) fluid, dermal fluid, or blood) and be used, along with the in vivo analyte monitoring circuitry, to measure analyte-related data of the user. Sensor **104** and any accompanying sensor control electronics can be applied to the body in any desired manner. For example, an insertion device (not shown) can be used to position all or a portion of analyte sensor **104** through an external surface of the user's skin and into contact with the user's bodily fluid. In doing so, the insertion device can also position sensor control device **102** with adhesive patch **105** onto the skin. In other embodiments, insertion device can position sensor **104** first, and then accompanying sensor control electronics can be coupled with sensor **104** afterwards, either manually or with the aid of a mechanical device. Examples of insertion devices are described in U.S. Publication Nos. 2008/0009692, 2011/0319729, 2015/0018639, 2015/0025345, and 2015/0173661, all which are incorporated by reference herein in their entireties and for all purposes.

[0031] After collecting raw data from the user's body, sensor control device **102** can apply analog signal conditioning to the data and convert the data into a digital form of the conditioned raw data. In some embodiments, this conditioned raw digital data can be encoded for transmission to another device, e.g., reader device **120**, which then algorithmically processes that digital raw data into a final form representative of the user's measured biometric (e.g., a form readily made suitable for display to the user). This algorithmically processed data can then be formatted or graphically processed for digital display to the user. In other embodiments, sensor control device **102** can algorithmically process the digital raw data into the final form that is representative of the user's measured biometric (e.g., analyte level) and then encode and wirelessly communicate that data to reader device **120**, which in turn can format or graphically process the received data for digital display to the user. In other embodiments, sensor control device **102** can graphically process the final form of the data such that it is ready for display, and display that data on a display of sensor control device **102** or transmit the data to reader device **120**. In some embodiments, the final form of the biometric data (prior to graphic processing) is used by the system (e.g., incorporated into a diabetes monitoring regime) without processing for display to the user. In some embodiments,

sensor control device **102** and reader device **120** transmit the digital raw data to another computer system for algorithmic processing and display.

[0032] Reader device **120** can include a display **122** to output information to the user and/or to accept an input from the user, and an optional input component **121** (or more), such as a button, actuator, touch sensitive switch, capacitive switch, pressure sensitive switch, jog wheel or the like, to input data, commands, or otherwise control the operation of reader device **120**. In certain embodiments, display **122** and input component **121** may be integrated into a single component, for example, where the display can detect the presence and location of a physical contact touch upon the display, such as a touch screen user interface. In certain embodiments, input component **121** of reader device **120** may include a microphone and reader device **120** may include software configured to analyze audio input received from the microphone, such that functions and operation of the reader device **120** may be controlled by voice commands. In certain embodiments, an output component of reader device **120** includes a speaker (not shown) for outputting information as audible signals. Similar voice responsive components such as a speaker, microphone and software routines to generate, process and store voice driven signals may be included in sensor control device **102**.

[0033] Reader device **120** can also include one or more data communication ports **123** for wired data communication with external devices such as computer system **170** or sensor control device **102**. Example data communication ports include USB ports, mini USB ports, USB Type-C ports, USB micro-A and/or micro-B ports, RS-232 ports, Ethernet ports, Firewire ports, or other similar data communication ports configured to connect to the compatible data cables. Reader device **120** may also include an integrated or attachable in vitro glucose meter, including an in vitro test strip port (not shown) to receive an in vitro glucose test strip for performing in vitro blood glucose measurements.

[0034] Reader device **120** can display the measured biometric data wirelessly received from sensor control device **102** and can also be configured to output alarms, alert notifications, glucose values, etc., which may be visual, audible, tactile, or any combination thereof. Further details and other display embodiments can be found in, e.g., U.S. Publication No. 2011/0193704, which is incorporated herein by reference in its entirety for all purposes.

[0035] Reader device **120** can function as a data conduit to transfer the measured data from sensor control device **102** to computer system **170** or trusted computer system **180**. In certain embodiments, the data received from sensor control device **102** may be stored (permanently or temporarily) in one or more memories of reader device **120** prior to uploading to system **170**, **180** or network **190**.

[0036] Computer system **170** may be a personal computer, a server terminal, a laptop computer, a tablet, or other suitable data processing device. Computer system **170** can be (or include) software for data management and analysis and communication with the components in analyte monitoring system **100**. Computer system **170** can be used by the user or a medical professional to display and/or analyze the biometric data measured by sensor control device **102**. In some embodiments, sensor control device **102** can communicate the biometric data directly to computer system **170** without an intermediary such as reader device **120**, or indirectly using an internet connection (also optionally with-

out first sending to reader device **120**). Operation and use of computer system **170** is further described in the '225 Publication incorporated herein. Analyte monitoring system **100** can also be configured to operate with a data processing module (not shown), also as described in the incorporated '225 Publication.

[0037] Trusted computer system **180** can be within the possession of the manufacturer or distributor of sensor control device **102**, either physically or virtually through a secured connection, and can be used to perform authentication of sensor control device **102**, for secure storage of the user's biometric data, and/or as a server that serves a data analytics program (e.g., accessible via a web browser) for performing analysis on the user's measured data.

Example Embodiments of Reader Devices

[0038] Reader device **120** can be a mobile communication device such as a dedicated reader device (configured for communication with a sensor control device **102**, and optionally a computer system **170**, but without mobile telephony communication capability) or a mobile telephone including, but not limited to, a Wi-Fi or internet enabled smart phone, tablet, or personal digital assistant (PDA). Examples of smart phones can include those mobile phones based on a Windows® operating system, Android™ operating system, iPhone® operating system, Palm® WebOSTM, Blackberry® operating system, or Symbian® operating system, with data network connectivity functionality for data communication over an internet connection and/or a local area network (LAN).

[0039] Reader device **120** can also be configured as a mobile smart wearable electronics assembly, such as an optical assembly that is worn over or adjacent to the user's eye (e.g., a smart glass or smart glasses, such as Google glasses, which is a mobile communication device). This optical assembly can have a transparent display that displays information about the user's analyte level (as described herein) to the user while at the same time allowing the user to see through the display such that the user's overall vision is minimally obstructed. The optical assembly may be capable of wireless communications similar to a smart phone. Other examples of wearable electronics include devices that are worn around or in the proximity of the user's wrist (e.g., a watch, etc.), neck (e.g., a necklace, etc.), head (e.g., a headband, hat, etc.), chest, or the like.

[0040] FIG. 1B is a block diagram of an example embodiment of a reader device **120** configured as a smart phone. Here, reader device **120** includes an input component **121**, display **122**, and processing circuitry **206**, which can include one or more processors, microprocessors, controllers, and/or microcontrollers, each of which can be a discrete chip or distributed amongst (and a portion of) a number of different chips. Here, processing circuitry **206** includes a communications processor **202** having on-board memory **203** and an applications processor **204** having on-board memory **205**. Reader device **120** further includes RF communication circuitry **208** coupled with an RF antenna **209**, a memory **210**, multi-functional circuitry **212** with one or more associated antennas **214**, a power supply **216**, power management circuitry **218**, and a clock **219**. FIG. 1B is an abbreviated representation of the typical hardware and functionality that resides within a smart phone and those of

ordinary skill in the art will readily recognize that other hardware and functionality (e.g., codecs, drivers, glue logic) can also be included.

[0041] Communications processor **202** can interface with RF communication circuitry **208** and perform analog-to-digital conversions, encoding and decoding, digital signal processing and other functions that facilitate the conversion of voice, video, and data signals into a format (e.g., in-phase and quadrature) suitable for provision to RF communication circuitry **208**, which can then transmit the signals wirelessly. Communications processor **202** can also interface with RF communication circuitry **208** to perform the reverse functions necessary to receive a wireless transmission and convert it into digital data, voice, and video. RF communication circuitry **208** can include a transmitter and a receiver (e.g., integrated as a transceiver) and associated encoder logic.

[0042] Applications processor **204** can be adapted to execute the operating system and any software applications that reside on reader device **120**, process video and graphics, and perform those other functions not related to the processing of communications transmitted and received over RF antenna **209**. The smart phone operating system will operate in conjunction with a number of applications on reader device **120**. Any number of applications (also known as "user interface applications") can be running on reader device **120** at any one time, and may include one or more applications that are related to a diabetes monitoring regime, in addition to the other commonly used applications that are unrelated to such a regime, e.g., email, calendar, weather, sports, games, etc. For example, the data indicative of a sensed analyte level and in vitro blood analyte measurements received by the reader device can be securely communicated to user interface applications residing in memory **210** of reader device **120**. Such communications can be securely performed, for example, through the use of mobile application containerization or wrapping technologies.

[0043] Memory **210** can be shared by one or more of the various functional units present within reader device **120**, or can be distributed amongst two or more of them (e.g., as separate memories present within different chips). Memory **210** can also be a separate chip of its own. Memories **203**, **205**, and **210** are non-transitory, and can be volatile (e.g., RAM, etc.) and/or non-volatile memory (e.g., ROM, flash memory, F-RAM, etc.).

[0044] Multi-functional circuitry **212** can be implemented as one or more chips and/or components (e.g., transmitter, receiver, transceiver, and/or other communication circuitry) that perform other functions such as local wireless communications, e.g., with sensor control device **102** under the appropriate protocol (e.g., Wi-Fi, Bluetooth, Bluetooth Low Energy, Near Field Communication (NFC), Radio Frequency Identification (RFID), proprietary protocols, and others) and determining the geographic position of reader device **120** (e.g., global positioning system (GPS) hardware). One or more other antennas **214** are associated with the functional circuitry **212** as needed to operate with the various protocols and circuits.

[0045] Power supply **216** can include one or more batteries, which can be rechargeable or single-use disposable batteries. Power management circuitry **218** can regulate battery charging and power supply monitoring, boost power, perform DC conversions, and the like.

[0046] Reader device **120** can also include or be integrated with a drug (e.g., insulin, etc.) delivery device such that they,

e.g., share a common housing. Examples of such drug delivery devices can include medication pumps having a cannula that remains in the body to allow infusion over a multi-hour or multi-day period (e.g., wearable pumps for the delivery of basal and bolus insulin). Reader device **120**, when combined with a medication pump, can include a reservoir to store the drug, a pump connectable to transfer tubing, and an infusion cannula. The pump can force the drug from the reservoir, through the tubing and into the diabetic's body by way of the cannula inserted therein. Other examples of drug delivery devices that can be included with (or integrated with) reader device **120** include portable injection devices that pierce the skin only for each delivery and are subsequently removed (e.g., insulin pens). A reader device **120**, when combined with a portable injection device, can include an injection needle, a cartridge for carrying the drug, an interface for controlling the amount of drug to be delivered, and an actuator to cause injection to occur. The device can be used repeatedly until the drug is exhausted, at which point the combined device can be discarded, or the cartridge can be replaced with a new one, at which point the combined device can be reused repeatedly. The needle can be replaced after each injection.

[0047] The combined device can function as part of a closed-loop system (e.g., an artificial pancreas system requiring no user intervention to operate) or semi-closed loop system (e.g., an insulin loop system requiring seldom user intervention to operate, such as to confirm changes in dose). For example, the diabetic's analyte level can be monitored in a repeated automatic fashion by sensor control device **102**, which can then communicate that monitored analyte level to reader device **120**, and the appropriate drug dosage to control the diabetic's analyte level can be automatically determined and subsequently delivered to the diabetic's body. Software instructions for controlling the pump and the amount of insulin delivered can be stored in the memory of reader device **120** and executed by the reader device's processing circuitry. These instructions can also cause calculation of drug delivery amounts and durations (e.g., a bolus infusion and/or a basal infusion profile) based on the analyte level measurements obtained directly or indirectly from sensor control device **102**. In some embodiments sensor control device **102** can determine the drug dosage and communicate that to reader device **120**.

Example Embodiments of Sensor Control Devices

[0048] FIG. 1C is a block diagram depicting an example embodiment of sensor control device **102** having analyte sensor **104** and sensor electronics **250** (including analyte monitoring circuitry) that can have the majority of the processing capability for rendering end-result data suitable for display to the user. In FIG. 1C, a single semiconductor chip **251** is depicted that can be a custom application specific integrated circuit (ASIC). Shown within ASIC **251** are certain high-level functional units, including an analog front end (AFE) **252**, power management (or control) circuitry **254**, processor **256**, and communication circuitry **258** (which can be implemented as a transmitter, receiver, transceiver, passive circuit, or otherwise according to the communication protocol). In this embodiment, both AFE **252** and processor **256** are used as analyte monitoring circuitry, but in other embodiments either circuit can perform the analyte monitoring function. Processor **256** can include one or more processors, microprocessors, controllers, and/or

microcontrollers, each of which can be a discrete chip or distributed amongst (and a portion of) a number of different chips.

[0049] A memory **253** is also included within ASIC **251** and can be shared by the various functional units present within ASIC **251**, or can be distributed amongst two or more of them. Memory **253** can also be a separate chip. Memory **253** is non-transitory and can be volatile and/or non-volatile memory. In this embodiment, ASIC **251** is coupled with power source **260**, which can be a coin cell battery, or the like. AFE **252** interfaces with in vivo analyte sensor **104** and receives measurement data therefrom and outputs the data to processor **256** in digital form, which in turn can, in some embodiments, process in any of the manners described elsewhere herein. This data can then be provided to communication circuitry **258** for sending, by way of antenna **261**, to reader device **120** (not shown), for example, where minimal further processing is needed by the resident software application to display the data. Antenna **261** can be configured according to the needs of the application and communication protocol. Antenna **261** can be, for example, a printed circuit board (PCB) trace antenna, a ceramic antenna, or a discrete metallic antenna. Antenna **261** can be configured as a monopole antenna, a dipole antenna, an F-type antenna, a loop antenna, and others.

[0050] Information may be communicated from sensor control device **102** to a second device (e.g., reader device **120**) at the initiative of sensor control device **102** or reader device **120**. For example, information can be communicated automatically and/or repeatedly (e.g., continuously) by sensor control device **102** when the analyte information is available, or according to a schedule (e.g., about every 1 minute, about every 5 minutes, about every 10 minutes, or the like), in which case the information can be stored or logged in a memory of sensor control device **102** for later communication. The information can be transmitted from sensor control device **102** in response to receipt of a request by the second device. This request can be an automated request, e.g., a request transmitted by the second device according to a schedule, or can be a request generated at the initiative of a user (e.g., an ad hoc or manual request). In some embodiments, a manual request for data is referred to as a "scan" of sensor control device **102** or an "on-demand" data transfer from device **102**. In some embodiments, the second device can transmit a polling signal or data packet to sensor control device **102**, and device **102** can treat each poll (or polls occurring at certain time intervals) as a request for data and, if data is available, then can transmit such data to the second device. In many embodiments, the communication between sensor control device **102** and the second device are secure (e.g., encrypted and/or between authenticated devices), but in some embodiments the data can be transmitted from sensor control device **102** in an unsecured manner, e.g., as a broadcast to all listening devices in range.

[0051] Different types and/or forms and/or amounts of information may be sent as part of each communication including, but not limited to, one or more of current sensor measurements (e.g., the most recently obtained analyte level information temporally corresponding to the time the reading is initiated), rate of change of the measured metric over a predetermined time period, rate of the rate of change of the metric (acceleration in the rate of change), or historical

metric information corresponding to metric information obtained prior to a given reading and stored in a memory of sensor control device 102.

[0052] Some or all of real time, historical, rate of change, rate of rate of change (such as acceleration or deceleration) information may be sent to reader device 120 in a given communication or transmission. In certain embodiments, the type and/or form and/or amount of information sent to reader device 120 may be preprogrammed and/or unchangeable (e.g., preset at manufacturing), or may not be preprogrammed and/or unchangeable so that it may be selectable and/or changeable in the field one or more times (e.g., by activating a switch of the system, etc.). Accordingly, in certain embodiments reader device 120 can output a current (real time) sensor-derived analyte value (e.g., in numerical format), a current rate of analyte change (e.g., in the form of an analyte rate indicator such as an arrow pointing in a direction to indicate the current rate), and analyte trend history data based on sensor readings acquired by and stored in memory of sensor control device 102 (e.g., in the form of a graphical trace). Additionally, an on-skin or sensor temperature reading or measurement may be collected by an optional temperature sensor 257. Those readings or measurements can be communicated (either individually or as an aggregated measurement over time) from sensor control device 102 to another device (e.g., reader 120). The temperature reading or measurement, however, may be used in conjunction with a software routine executed by reader device 120 to correct or compensate the analyte measurement output to the user, instead of or in addition to actually displaying the temperature measurement to the user.

Example Embodiments of Calibration

[0053] Analyte sensors can be described by one or more sensing characteristics. A common sensing characteristic is referred to as the analyte sensor's sensitivity, which is a measure of the sensor's responsiveness to the concentration of the chemical or composition it is designed to detect. For electrochemical sensors, this response can be in the form of an electrical current (amperometric) or electrical charge (coulometric). For other types of sensors, the response can be in a different form, such as a photonic intensity (e.g., optical light). The sensitivity of an analyte sensor can vary depending on a number of factors, including whether the sensor is in an in vitro state or an in vivo state.

[0054] FIG. 2A is a graph depicting the in vitro sensitivity of an amperometric analyte sensor. The in vitro sensitivity can be obtained by in vitro testing the sensor at various analyte concentrations and then performing a regression (e.g., linear or non-linear) or other curve fitting on the resulting data. In this example, the analyte sensor's sensitivity is linear, or substantially linear, and can be modeled according to the equation $y=mx+b$, where y is the sensor's electrical output current, x is the analyte level (or concentration), m is the slope of the sensitivity and b is the intercept of the sensitivity, where the intercept generally corresponds to a background signal (e.g., noise). For sensors with a linear or substantially linear response, the analyte level that corresponds to a given current can be determined from the slope and intercept of the sensitivity. Sensors with a non-linear sensitivity require additional information to determine the analyte level resulting from the sensor's output current, and those of ordinary skill in the art are familiar with manners by which to model non-linear sensitivities. In certain embodi-

ments of in vivo sensors, the in vitro sensitivity may be the same as the in vivo sensitivity, but in other embodiments a transfer (or conversion) function is used to translate the in vitro sensitivity into the in vivo sensitivity that is applicable to the sensor's intended in vivo use.

[0055] Analyte sensors of the same design undergoing the same manufacturing process can have different in vitro sensitivities (as well as in vivo sensitivities, if applicable) due to variations in that manufacturing process and the materials used for fabrication. FIG. 2B depicts examples of different sensitivities 201-204 for different analyte sensors of the same mechanical and electrochemical design. The sensitivities 201-204 in this example are linear for ease of illustration, but in other examples can be non-linear. Here, a first sensitivity 201 has the same intercept as a second sensitivity 202, but a greater slope. A third sensitivity 203 has generally the same slope as that of sensitivity 201, but a greater intercept. A fourth sensitivity 204 has a still greater slope and intercept than those of sensitivities 201-203.

[0056] In order to compensate for these variations, the sensor can be calibrated. Calibration is a technique for improving or maintaining accuracy by adjusting a sensor's measured output to reduce the differences with the sensor's expected output. One or more parameters that describe the sensor's sensing characteristics, like its sensitivity, are established for use in the calibration adjustment.

[0057] After using an in vivo sensor to obtain a raw measurement signal from the user's body, the on body electronics can apply analog signal conditioning to the raw signal and convert the signal into a digital form of the conditioned raw signal. For example, the digital raw data can be in counts converted by an A/D converter from the raw analog signal (for example, voltage or amps). In some embodiments, this conditioned raw digital data can be encoded for transmission to another device, e.g., a reader device as described herein, which then algorithmically processes that digital raw data into a processed result representative of the user's analyte level (e.g., a result readily made suitable for display to the user). This algorithmic processing utilizes the calibration information for the sensor to arrive at the processed result, and can utilize other one or more other variables depending upon the implementation. This algorithmically processed result can then be digitally formatted or graphically processed for digital display to the user. In other embodiments, the on body electronics itself can algorithmically process the digital raw data into the processed result that is representative of the user's measured analyte level, and then encode and wirelessly communicate that data to a reader device, which in turn can format or graphically process the received data for digital display to the user. In some such embodiments, the on body electronics can further graphically process the processed result of the data such that it is ready for display, and then display that data on a display of on body electronics or transmit the data to a display device. In some embodiments, the processed analyte data result (prior to graphic processing) is used by the system (e.g., incorporated into a diabetes monitoring regime) without processing for display to the user. In some embodiments, the on body electronics and/or the display device transmit the digital raw data to another computer system for algorithmic processing and display.

[0058] Certain embodiments of in vivo analyte monitoring systems require calibration to occur after implantation of the sensor into the user or patient, either by user interaction or

by the system itself in an automated fashion. For example, when user interaction is required, the user performs an in vitro measurement (e.g., a blood glucose (BG) measurement using a finger stick and an in vitro test strip) and enters this into the system, while the analyte sensor is implanted. The system then compares the in vitro measurement with the in vivo signal and, using the differential, determines an estimate of the sensor's in vivo sensitivity. The in vivo sensitivity can then be used in an algorithmic process to transform the data collected with the sensor to a value that indicates the user's analyte level. This and other processes that require a user to make an in vitro reference measurement to perform calibration are referred to as "user calibration." Multiple user calibrations (e.g., according to a periodic (e.g., daily) schedule or on an as-needed basis) may be required to maintain accuracy. While the embodiments described herein can incorporate a degree of user calibration for a particular implementation, generally this is not preferred as it requires the user to perform a painful or otherwise burdensome BG measurement, and can introduce user error.

[0059] Some embodiments of in vivo analyte monitoring systems operate with a sensor that is factory calibrated. Factory calibration refers to the determination or estimation of the one or more calibration parameters prior to distribution to the user or healthcare professional (HCP). The calibration parameter can be determined by the sensor manufacturer (or the manufacturer of the other components of the sensor control device if the two entities are different).

[0060] Factory calibration can be implemented with user calibration or without any user calibration. For example, in all of the embodiments described herein, the in vivo sensors can be calibrated by the manufacturer and then provided to the user, who can then use such sensors for the duration of their lifespan to accurately monitor the user's in vivo analyte levels, and no step of user calibration is performed during that lifespan. Such systems and methods determine clinically accurate analyte concentrations at least over the predetermined sensing period of analyte sensor systems without obtaining one or more independent analyte measurements (e.g., without using an in vitro test strip or other reference device) for calibration of a generated analyte related signal from the analyte sensor during the usage life of the sensor. In other words, once the analyte sensors are positioned in the body of the user, control logic or microprocessors in the sensor electronics, or the microprocessors in the display device include one or more algorithms or programming to accurately convert or correlate signals related to the sensed analyte (e.g., in nanoamps (nA), counts, or other appropriate units) to a corresponding analyte level (e.g., converted to an analyte level in milligrams per deciliter (mg/dL) or other appropriate units) without a reference value provided to the system, rendering sensor calibration "invisible" to the user such that the system does not require any human intervention for analyte sensor calibration.

[0061] The calibration information can be in the form of one or more calibration parameters, or one or more calibration codes, that can be stored in the memory of the corresponding sensor control device, such that when a user initiates operation of the sensor control device, the requisite calibration information is readily available. In some cases, the calibration information is made available to the user (e.g., such as a sensor code printed on packaging, etc.) and then manually input (or input using a scanner, e.g., optical or magnetic) into the reader or sensor control device.

Example Embodiments of Duration-Based Adjustment of Sensor Signals

[0062] The calibration information is representative of an attempt to accurately model the sensor's response or sensitivity. In certain analyte monitoring systems **100** however, the sensitivity of sensor **101** can change over time after sensor **101** is initially manufactured. This can be caused by a number of factors, including environmental exposure (e.g., temperature, humidity, air pressure), the duration of time the sensors are in existence post-manufacture and prior to use, or the duration of time the sensors are in use post-manufacture. These variations can cause sensors of the same design and manufacturing process to have measurable differences in their performance. If the sensor sensitivity changes and this change is not compensated for, such as by adjusting the calibration information, then the resulting analyte data will not be as accurate. The algorithmic scaling process performed on the data obtained from the sensor will result in analyte concentrations that deviate from those actually present.

[0063] The relevant time periods occurring post-manufacture can be referred to as the "shelf duration" and the "wear duration." Shelf duration generally refers to the time period after manufacture and before use of the sensor, during which the sensor is generally in a packaged state. Wear duration generally refers to the time period during which the sensor is used by the user, which in the case of in vivo sensor **101** is generally the time that the sensor is at least partially implanted within the body of the user.

[0064] Example embodiments described herein can compensate for a change in sensor response due to the length of shelf duration in order to achieve and maintain a higher degree of accuracy than without such compensation, which results in improved overall performance. In addition, or alternatively, example embodiments described herein can compensate for a change in sensor response due to the length of wear duration, in order to achieve and maintain a higher degree of accuracy than without such compensation, also resulting in improved overall performance.

[0065] The compensation can be applied by processing circuitry executing software instructions, where this processing circuitry is within sensor control device **102**, reader device **120**, computer system **170**, or elsewhere in system **100**. This compensation can occur in the same stage of processing where sensor-derived data is adjusted with the calibration information, but is not limited to such, and can occur at any processing stage where analyte data is manipulated.

[0066] For ease of description, the compensation embodiments will be described in the context of a sensor **101** modeled with a linear sensitivity having a slope and offset. However, the embodiments described herein are not limited to such, and can also be applied to sensors modeled with two or more linear sensitivities (e.g., for regions of different measurement magnitudes), one or more nonlinear sensitivities, or any combination thereof.

[0067] An example of a linear equation that converts or adjusts a first analyte value (G_{init}) to a second, calibrated value (G_{cal}) is as follows:

$$G_{cal} = G0 + \left[\frac{G_{init}}{Sc} \right] \quad (1)$$

where $G0$ and Sc are the offset (e.g., intercept) and the slope, respectively, of the linear sensitivity associated with a particular sensor, or group of sensors (e.g., in a sensor production lot). In some embodiments, the parameters $G0$ and Sc can be functions of other pre-determined parameters STI and STS associated with a particular sensor or group of sensors, e.g., $G0 = -STI/STS$ and $Sc = STS$. The values of $G0$ and Sc , or other pre-determined parameters, can be provided to sensor control device **102** (or other devices in system **100**) as a code (as discussed elsewhere herein). In some embodiments, these parameters are used over the lifetime of the sensor without modification. In other embodiments, at least one of $G0$ and Sc is modified one or more times with a user calibration, e.g., based on the results of a finger stick measurement made by the user. For clarity, it is noted that the embodiments described herein can be accomplished using only factory calibration, only user calibration, a combination of factory and user calibration, or otherwise.

[0068] G_{init} can any initial or intermediate analyte data value to which calibration is applied. For example, G_{init} can be a raw value that has not undergone any processing in the digital domain (e.g., representative of the counts from an analog-digital converter), or G_{init} can be a processed value that has been algorithmically adjusted in the digital domain but that still requires some calibration scaling. G_{cal} can be a final processed value, e.g., ready for output to the user, or can be subjected to further algorithmic processing for other purposes.

[0069] In many example embodiments, the equation (1) can be modified to account for shelf duration and/or wear duration. For example, a modified form of (1) that accounts for both shelf duration and wear duration is as follows:

$$G0 = \left[\frac{-STI}{STS} \right] + f_{gWear} + f_{gShelf} \quad (2)$$

$$Sc = STS \times [1 + f_{sWear} + f_{sShelf}] \quad (3)$$

[0070] where the functions f_{gWear} and f_{sWear} are $G0$ and Sc adjustments, respectively, to account for wear duration, and the functions f_{gShelf} and f_{sShelf} are $G0$ and Sc adjustments, respectively, to account for shelf duration. In certain embodiments, each of the adjustments can be a function of time:

$$f_{gWear} = K_{G0_wear} \times T_{wear} \quad (4)$$

$$f_{sWear} = R_{Sc_wear} \times T_{wear} \quad (5)$$

$$f_{gShelf} = K_{G0_shelf} \times T_{shelf} \quad (6)$$

$$f_{sShelf} = R_{Sc_shelf} \times T_{shelf} \quad (7)$$

where T_{wear} is the wear duration and T_{shelf} is the shelf duration, where K_{G0_wear} , R_{Sc_wear} are constant or variable parameters that provide adjustment to $G0$ and Sc for wear duration, and where K_{G0_shelf} and R_{Sc_shelf} are constant or variable parameters that provide adjustment to $G0$ and Sc for shelf duration. The functions f_{gWear} and f_{gShelf} can operate in the same units of analyte concen-

tration as $G0$ and G_{cal} . The functions f_{sWear} and f_{sShelf} can operate in the same units of the reciprocal of slope, $1/Sc$. **[0071]** In yet another embodiment, the adjustment for offset $G0$ over time can be a pair of functions that modify only the pre-determined parameter STI instead:

$$G0 = [-STI + f_{iWear} + f_{iShelf}] / STS \quad (2a)$$

Where the functions f_{iWear} and f_{iShelf} are similar to f_{gWear} and f_{gShelf} , respectively, but vary in the appropriate units scaled by STS relative to each other. For ease of discussion, many embodiments discussed below assume the use of equation (2) and not equation (2a), although those embodiments can be implemented using either equation (2) or (2a), or others.

[0072] In the embodiments described herein, system **100** can adjust for both wear duration and shelf duration as in example equations (2) and (3). However, the embodiments described herein can account for just wear duration if desired. In such embodiments, for example, only the terms f_{gWear} and f_{sWear} are included in equations (2) and (3), and the terms f_{gShelf} and f_{sShelf} are omitted. Conversely, the embodiments described herein can account for just shelf duration if desired. In such embodiments, for example, only the terms f_{gShelf} and f_{sShelf} are included in equations (2) and (3), and the terms f_{gWear} and f_{sWear} are omitted.

[0073] Similarly, the embodiments of system **100** can adjust one or both of $G0$ and Sc . For example, in certain embodiments, sensor **101** may only exhibit duration-based sensitivity change for $G0$, in which case equation (2) can be implemented with equation (1) but Sc remains equal to STS . Further, if only one of wear duration or shelf duration is compensated for $G0$, then only that corresponding function (f_{gWear} , f_{gShelf}) can be included in equation (2). In other embodiments, sensor **101** may only exhibit duration-based sensitivity change for Sc , in which case equation (3) can be implemented with equation (1) but $G0 = -STI/STS$. Further, if only one of wear duration or shelf duration is compensated for Sc , then only that corresponding function (f_{sWear} , f_{sShelf}) can be included in equation (2).

[0074] T_{wear} and T_{shelf} can be expressed in units of time (e.g., seconds, minutes, hours, days, weeks, months, etc.) or any other units that are representative of a particular duration (e.g., such as counts on a counter). T_{wear} is preferably representative of the amount or duration of time the sensor is in an in vivo state. T_{shelf} is preferably representative of the amount or duration of time that transpired between completion of the sensor's manufacture (shelf start time) and insertion of the sensor into the user's body (shelf stop time). There are various ways these durations can be measured, depending on what actions constitute the start and stop times, and these variations are discussed further below.

[0075] K_{G0_wear} , R_{Sc_wear} , K_{G0_shelf} , and R_{Sc_shelf} can be determined theoretically and/or empirically. In some embodiments, K_{G0_wear} and R_{Sc_wear} are determined empirically, e.g., through in vitro testing of sensors over time, in vivo testing of sensors over time, and/or a combination thereof, to assess the characteristics of the sensitivity change occurring while the sensor is being used in vivo. Values for K_{G0_wear} and R_{Sc_wear} can then be extrapolated from the resulting data set, e.g., through regression or curve-fitting analysis, and used as the parameters for other sensors. In other embodiments, values for K_{G0_wear} and R_{Sc_wear} can be determined from a theoretical model

that models sensor performance in vivo. In still other embodiments, values for K_G0_wear and R_Sc_wear can be determined from both empirical data and a theoretical model.

[0076] In some embodiments, K_G0_shelf and R_Sc_shelf are determined empirically, e.g., through in vitro or in vivo testing of sensors that have been subjected to differing amounts of shelf durations, and/or a combination thereof, to assess the characteristics of the sensitivity change occurring while the sensor is in storage. Values for K_G0_shelf and R_Sc_shelf can then be extrapolated from the resulting data set, e.g., through regression or curve-fitting analysis, and used as the parameters for other sensors. In other embodiments, values for K_G0_shelf and R_Sc_shelf can be determined from a theoretical model that models sensor sensitivity changes over time while ex vivo. In still other embodiments, values for K_G0_shelf and R_Sc_shelf can be determined from both empirical data and a theoretical model.

[0077] Depending on a variety of factors, including the degree of variation in K_G0_wear, R_Sc_wear, K_G0_shelf, and R_Sc_shelf, in some embodiments one set of these parameters can be determined and applied to an entire production line of sensors (e.g., across hundreds or thousands of production lots). In other embodiments, these parameters can be determined and applied for different groups or subsets of sensors within the production line, e.g., these parameters can be determined separately for each lot of sensors being manufactured, and applied only to those sensors in that lot.

[0078] Before performing functions (4)-(7), in many embodiments T_wear and/or T_shelf are first converted into a scaling factor without units, for example, an integer or decimal value. The conversion can be linear or nonlinear, or otherwise as described in further detail herein. T_wear and T_shelf can be determined each time a calibration is performed, or T_wear and T_shelf can be determined at regular or irregular intervals that have a lower frequency than the frequency at which calibrations are performed. For example, if calculation of analyte values such as G_cal is performed once per minute, T_wear can also be determined once per minute, or at a lower frequency (e.g., once per ten minutes, once per hour, etc.), depending on the needs of the particular implementation. T_shelf can be determined once and then used for all subsequent calibrations, which is efficient, since T_shelf will often be constant once in vivo sensor use has begun.

[0079] FIG. 3A is graph depicting an example adjustment to sensor data for wear duration. The y-axis represents measured in vivo analyte levels (e.g., G_cal) and the x-axis represents time. Trace 302 represents actual analyte levels over time for a user, and trace 304 represents average analyte levels collected from a sensor 101 for that user over time where no wear duration adjustment has been performed. (Any effects of in vivo sensor lag are ignored for ease of illustration.) Here, trace 304 exhibits generally lower values than the actual values of trace 302 due to a change in in vivo sensitivity over the duration of wear. Trace 306 represents the analyte levels of trace 304 after wear duration calibration has been performed according to the embodiments herein. As can be seen, application of wear duration calibration can adjust the values of trace 304 such that they more closely approximate the actual analyte levels of the user.

[0080] FIG. 3B is graph depicting an example adjustment to sensor data for shelf duration. The y-axis represents measured in vivo analyte levels (e.g., G_cal) and the x-axis represents time. Trace 302 represents actual analyte levels over time for a user. Traces 312, 314, and 316 represent average analyte levels collected from the user with three different sensors 101 over the same period of time where no shelf duration adjustment has been performed. (Any effects of in vivo sensor lag are ignored for ease of illustration.) Here, trace 312 was derived from a sensor 101 having a first shelf duration (A), trace 314 was derived from a sensor 101 having a second shelf duration (B), and trace 316 was derived from a sensor 101 having a third shelf duration (C), where C is greater than B, which is greater than A (C>B>A). Trace 320 represents the analyte levels of traces 312-316 after shelf duration calibration has been performed according to the embodiments herein. As can be seen, application of shelf duration calibration can adjust the values of traces 312-316 such that they more closely approximate the actual analyte levels of the user. Here, traces 312-316 have been adjusted to the same values 320, although in some actual implementations the adjusted forms of traces 312-316 may be different from each other, although still more closely approximating the actual analyte levels of trace 302. In some implementations, trace 320 and any other adjusted values align directly with trace 302.

Additional Examples of Determining Shelf Duration

[0081] There are various ways shelf duration (T_shelf) can be determined, depending on what actions constitute the start and stop times. For example, the T_shelf start time can be the time at which the sensor: completed manufacturing, completed testing, completed final assembly into sensor control device 102, completed the packaging procedure, or others. In many embodiments, the T_shelf start time can be stored in memory of sensor control device 102 at the time of manufacture or packing, such as in the form of a time and/or date stamp of manufacture. The T_shelf start time can be input to the memory using a wired or wireless communication link. In some embodiments, the T_shelf start time is linked to an identifier of the sensor (e.g., a unique serial number), and that identifier is communicated over an internet connection to a server (e.g., trusted computer system 180), which then provides the corresponding T-shelf start time for that sensor to the appropriate component of system 100 (e.g., sensor control device 102 or reader 120) making the T_shelf determination. In some embodiments, the T_shelf start time is printed on the packaging of the sensor 101 or sensor control device 102, and the user can input the T_shelf start time into the appropriate component of system 100. Various methods of user input of the T_shelf start time include manually keying the start time into system 100, reading the start time with an optical scanner (e.g., camera photo of alphanumeric code in combination with optical character recognition (OCR), camera photo of 2D or 3D barcode, etc.), wireless scanning (e.g., reading an RFID or NFC tag with reader 120), reading with a ROM calibrator, or others.

[0082] Similarly, the T_shelf stop time can be determined in various ways. For example, the T_shelf stop time can be the time at which sensor 101 is inserted into the patient's body, the time at which sensor control unit 102 is activated, the time a first measured analyte value is collected from sensor 101 from the user's body, the time a first analyte level

collected from sensor **101** (in an in vivo state) is displayed to the user on reader device **120**, or others. The clock used to determine the stop time of T_{shelf} can be determined from a present time supplied to system **100**, e.g., a network clock provided to a smart phone reader **120** by a mobile telephone network, or a time tracked or maintained by system **100**, e.g., a time entered into system **100** by the user (e.g., by a set time function) and then maintained by an internal clock, or the like.

[0083] Software instructions for determining the shelf start time and/or shelf stop time can be stored on the appropriate device (e.g., sensor control device **102** or reader device **120**), which can execute those instructions with processing circuitry and record the respective start and/or stop times when they occur, store them in memory, and/or communicate them to other devices within system **100**.

[0084] The devices within system **100** can determine T_{shelf} by subtracting the start time from the stop time. This may involve communication of the start time and/or stop time from one device in system **100** to another (e.g., between sensor control device **102** and reader device **120**). In one embodiment, sensor control device **102** has the T_{shelf} start time in memory and determines the T_{shelf} stop time, and then subtracts the T_{shelf} start time from the T_{shelf} stop time to determine T_{shelf} , which is then used by sensor control device **102** to calibrate the analyte signals. In another embodiment, sensor control device **102** communicates the shelf start and stop times to reader device **120** which then determines T_{shelf} and performs the calibration. In another embodiment, sensor control device **102** determines T_{shelf} and communicates it to reader device **120**, which then performs the calibration. In another embodiment, sensor control device **102** communicates the start time to reader device **120**, which determines the stop time, then determines T_{shelf} and then performs the calibration. In yet another embodiment, the start time is provided to reader device **120** in another manner (e.g., by user input to reader device **120**, by communication to reader device **120** over the internet from a server), and reader device **120** then determines the stop time, then determines T_{shelf} , and then performs the calibration. In still another embodiment, sensor control device **102** and/or reader device **120** communicate with a server (e.g., trusted computer system **180**), which determines T_{shelf} and communicates it over the internet to the appropriate device(s) in system **100** (e.g., sensor control device **102** and/or reader device **120**).

[0085] In some embodiments, a clock, counter, or other timer is started at the start time and operated (e.g., repeatedly incremented) to the stop time, and the final output of that clock is used to determine T_{shelf} . Such a clock could be located within sensor control device **102**, or could be maintained on a network, the output of which is then provided to the appropriate device of system **100**.

[0086] In the embodiments described herein, system **100** can be programmed to wait for a period of time (e.g., a wait period) before setting the T_{shelf} start time, or to automatically deduct this period of time from the shelf duration, or to otherwise determine T_{shelf} such that it is reduced by the wait period. For example, the calculation of T_{shelf} may start after the T_{shelf} wait period has elapsed. The T_{shelf} wait period can be, for example, a certain number of minutes, hours, days, weeks, or months, etc. For example, the T_{shelf} wait period can be a certain time period after completion of sensor manufacture, or sensor control device

102 packaging, etc. The value of this wait period can be pre-determined and stored in memory (e.g., of sensor control device **102** or reader **120**), or can be coded directly within the software instructions of the respective device, such that the analyte processing algorithm has access to it. In other embodiments, the value of the wait period can be communicated to the appropriate device in system **100** at the time of initial use or activation of sensor control device **102** (e.g., by sending the wait period value to reader **120** over the internet).

[0087] In embodiments where T_{shelf} start is delayed by the wait period, then T_{shelf} can then be determined by subtracting the start time from the stop time. In other embodiments, the delayed shelf start time can be determined by adding the wait period duration to the original start time (e.g., completion of manufacturing or packaging). In other embodiments, the shelf duration is determined by subtracting both the original start time and the wait period from the stop time. In still other embodiments, the shelf start time is stored (e.g., by a device of system **100**) as the original time incremented by the wait period, such that determination of T_{shelf} can be accomplished by subtracting this incremented time from the shelf stop time. In embodiments that use an active clock, counter, or timer to track shelf duration, this clock, counter, or timer can be incremented by the wait period.

[0088] In some embodiments, the length or magnitude of the wait period can be stored as an enumeration or code, which can then be translated into a length of time. For example, sensor control device **102** can store the wait period as one or more bits, which can then be referenced against a key or look-up table to determine the corresponding length of time (e.g., a two-bit number can be converted into a period of zero time, one or more minutes, one or more hours, one or more days, one or more weeks, etc.).

Additional Examples of Determining Wear Duration

[0089] Like shelf duration, there are various ways wear duration (T_{wear}) can be determined, depending on what actions constitute the wear start time and current time. System **100** can, in some embodiments, determine T_{wear} by subtracting a T_{wear} start time from a current time (or wear current time, which is the time used to approximate the current time).

[0090] For example, the T_{wear} start time can be the time of insertion of sensor **101** into the body of the patient or user, the time since activation of the sensor control unit **102** with the sensor **101** implanted within the user's body, the time since a first measured analyte value was collected from sensor **101** from the user's body, the time since a first analyte level collected from sensor **101** (in an in vivo state) was displayed to the user on reader device **120**, and so forth. In some embodiments, software instructions executed by the processing circuitry of a device in system **100** (e.g., sensor control device **102**, reader device **120**, etc.) can determine the wear start time automatically. In other embodiments, the user can manually input the wear start time into the device of system **100** (e.g., by input with a touchscreen or keypad of reader **120**). In other embodiments, the device of system **100** can prompt the user if the start time is the current time (or a particular time recently transpired), and upon confirmation can use that time as the start time.

[0091] Determine of T_{wear} by subtracting the wear start time from the wear current time may involve communica-

tion of the wear start time and/or wear current time from one device in system 100 to another (e.g., between sensor control device 102 and reader device 120). In one embodiment, sensor control device 102 has the T_{wear} start time in memory and determines the T_{wear} current time, and then subtracts the T_{wear} start time from the T_{wear} current time to determine T_{wear} , which is then used by sensor control device 102 to calibrate the analyte signals. In another embodiment, sensor control device 102 communicates the wear start and current times to reader device 120 which then determines T_{wear} and performs the calibration. In another embodiment, sensor control device 102 determines T_{wear} and communicates it to reader device 120, which then performs the calibration. In another embodiment, sensor control device 102 communicates the wear start time to reader device 120, which determines the wear current time, then determines T_{wear} and performs the calibration. In yet another embodiment, the wear start time is provided to reader device 120 in another manner (e.g., by user input to reader device 120, by communication to reader device 120 over the internet from a server), and reader device 120 then determines the wear current time, then determines T_{wear} , and then performs the calibration. In still another embodiment, sensor control device 102 and/or reader device 120 communicate with a server (e.g., trusted computer system 180), which determines T_{wear} and communicates it over the internet to the appropriate device(s) in system 100 (e.g., sensor control device 102 and/or reader device 120). In still yet another embodiment, reader device 120 determines the wear start time, and the wear current time, and determines T_{wear} and then performs the calibration.

[0092] The T_{wear} current time can be determined in various ways. For example, the T_{wear} current time can be the current time maintained by system 100, or the device in system 100 performing the T_{wear} calculation. The current time can be provided by a network clock, e.g., a clock provided to a smart phone reader 120 by a mobile telephony network. The current time can be tracked or maintained by a local clock within system 100, e.g., a time entered into system 100 by the user (e.g., by a set time function) or by another source and then maintained by an internal clock, or the like, present in one of the devices of system 100 (e.g., a clock of sensor control device 102, a clock of reader 120, etc.). The wear current time can be approximated depending on the desired degree of accuracy, e.g., multiple analyte measurements taken in relatively quick succession can be adjusted with the same current time.

[0093] Instead of tracking the wear start times and wear current time and then calculating the difference, in the embodiments described herein T_{wear} can be determined by use of a clock, counter, or other timer that is initiated at the wear start time or that otherwise represents the time since the wear start time. The present value of that clock, counter, or timer is representative of T_{wear} and can be used directly. Such a timing device could be located within sensor control device 102, reader device 120, or could be maintained on a network such that the output of which is then provided to the appropriate device of system 100.

[0094] Software instructions for determining the wear start time and/or wear current time can be stored on the appropriate device (e.g., sensor control device 102 or reader device 120), which can execute those instructions with processing circuitry and record the respective start and/or

current times when they occur, store them in memory, and/or communicate them to other devices within system 100.

[0095] In the embodiments described herein, system 100 can be programmed to wait for a period of time (e.g., a wait period) before setting the T_{wear} start time, or to automatically deduct this period of time from the wear duration, or to otherwise determine T_{wear} such that it is reduced by the wait period. For example, the calculation of T_{wear} may start after the T_{wear} wait period has elapsed. The T_{wear} wait period can be, for example, a certain number of seconds, minutes, hours, or days, or weeks, etc. For example, the T_{wear} wait period can be a certain time period after insertion of sensor 101 into the body, or activation of the electronics of sensor control device 102, etc. The value of this wait period can be pre-determined and stored in memory (e.g., of sensor control device 102 or reader 120), or can be coded directly within the software instructions of the respective device, such that the analyte processing algorithm has access to it. In other embodiments, the value of the wait period can be communicated to the appropriate device in system 100 at the time of initial use or activation of sensor control device 102 (e.g., by sending the wait period value to reader 120 over the internet).

[0096] In embodiments where T_{wear} start is delayed by the wait period, then T_{wear} can then be determined by subtracting the wear start time from the wear current time. In other embodiments, the delayed wear start time can be determined by adding the wait period duration to the original wear start time (e.g., insertion or activation). In other embodiments, the wear duration is determined by subtracting both the original start time and the wait period from the current wear time. In still other embodiments, the wear start time is stored (e.g., by a device of system 100) as the original time incremented by the wear wait period, such that determination of T_{wear} can be accomplished by subtracting this incremented time from the wear current time, where negative values can be treated as no adjustment since the wait period has not yet passed. In embodiments that use an active clock or timer to track wear duration, this clock or timer can be incremented by the wait period.

[0097] In some embodiments, the length or magnitude of the wear wait period can be stored as an enumeration or code, which can then be translated into a length of time. For example, sensor control device 102 can store the wait period as one or more bits, which can then be referenced against a key or look-up table to determine the corresponding length of time (e.g., a two-bit number can be converted into a period of zero time, one or more minutes, one or more hours, one or more days, one or more weeks, etc.).

Example Embodiments with Time Limitations and/or Time Delineations

[0098] In some example embodiments, the adjustment functions themselves (e.g., f_gWear , f_sWear , f_gShelf , f_sShelf , f_iWear , and f_iShelf) can vary. For example, the adjustment functions can have predetermined minimum and/or maximum limits that can be incorporated into the algorithms (and stored in the respective device, e.g., sensor control device 102 or reader 120). The minimum value can be zero or a number greater than zero. For example, regardless of how low the value of T_{shelf} is, the functions f_gShelf and f_sShelf will not be below a set minimum value, and regardless of how high the value of T_{shelf} is, the functions f_gShelf and f_sShelf will not exceed a set maximum value. The set minimum and maximum values for each

of the functions f_{gShelf} and f_{sShelf} can differ. Similarly, for example, regardless of how low the value of T_{wear} is, the functions f_{gWear} and f_{sWear} will not be below a set minimum value, and regardless of how high the value of T_{wear} is, the functions f_{gWear} and f_{sWear} will not exceed a set maximum value. The set minimum and maximum values for each of the functions f_{gWear} and f_{sWear} can differ. For example, in one embodiment, f_{gWear} is as follows:

$$\begin{aligned} f_{gWear} &= G_{w1} \text{ for } T_{wear} \text{ less than or equal to} \\ & T_{w1} \text{ days;} \\ f_{gWear} &= G_{w1} + [(t - T_{w1}) * (G_{w2} - G_{w1}) / (T_{w2} - T_{w1})] \\ & \text{ for } T_{wear} \text{ greater than } T_{w1} \text{ days and} \\ & \text{ less than or equal to } T_{w2} \text{ days;} \text{ and} \\ f_{gWear} &= G_{w2} \text{ for } T_{wear} \text{ greater than } T_{w2} \text{ days,} \end{aligned} \quad (8)$$

where G_{w1} is a minimum constant, G_{w2} is a maximum constant, and t is the current wear duration.

[0099] In some example embodiments, different adjustment functions (f_{gWear} , f_{sWear} , f_{gShelf} , and f_{sShelf}) can be used dependent on the magnitude of the respective duration. For example, with respect to wear duration, if T_{wear} is below a first value, then a first version of f_{gWear} and a first version of f_{sWear} can be used and, if T_{wear} is above the first value, then a second version of f_{gWear} and a second version of f_{sWear} can be used (which can be extended for T_{wear} being above a second value, a third value, and so on). Each of the different versions can be a constant value or a variable function (e.g., a linear or nonlinear equation).

[0100] In other embodiments, the adjustment functions (e.g., f_{gWear} , f_{sWear} , f_{gShelf} , f_{sShelf} , f_{iWear} , and f_{iShelf}) can be a function of time, but are nonlinear. For example, the wear duration adjustment can assume an exponential function with a pre-specified time constant and a pre-specified steady-state value. For example, $f_{gWear} = G_{wQ0} + [G_{wQ1} * T_{wear}] + [G_{wQ2} * T_{wear} * T_{wear}]$, where G_{wQ0} , G_{wQ1} , and G_{wQ2} are pre-determined quadratic polynomial parameters. In another example, $f_{gWear} = G_{wE1} * \exp(\text{Tau}_{wE1} * T_{wear})$, where the time constant Tau_{wE1} scales the wear duration T_{wear} for the exponential function, scaled by G_{wE1} . In another example, $f_{gWear} = G_{wP1} * A_{wP1}^{[T_{wear}]}$, where instead of an exponential function $\exp(x)$, a general power function with pre-determined base A_{wP1} is used.

Example Embodiments with Multiple Parameters for Duration-Based Adjustment

[0101] In some example embodiments, the duration-based adjustment algorithms can be modified to provide greater flexibility to accommodate sensors of different configurations or chemistries. For example, different chemistry formulations may result in one sensor **101** (or sensor control device **102**) requiring relatively greater shelf and/or wear duration adjustments than a second sensor **101** (or sensor control device **102**), where the durations themselves are equal. In these embodiments, secondary adjustment parameters can be used as follows:

$$f_{gWear} = K_{G0_wear} * Y_{G0_wear} * T_{wear} \quad (9)$$

$$f_{sWear} = R_{Sc_wear} * Y_{Sc_wear} * T_{wear} \quad (10)$$

$$f_{gShelf} = K_{G0_shelf} * Y_{G0_shelf} * T_{shelf} \quad (11)$$

$$f_{sShelf} = R_{Sc_shelf} * Y_{Sc_shelf} * T_{shelf} \quad (12)$$

where Y_{G0_wear} is a secondary adjustment factor for wear duration for the $G0$ parameter, Y_{Sc_wear} is a secondary adjustment factor for wear duration for the Sc parameter, Y_{G0_shelf} is a secondary adjustment factor for shelf duration for the $G0$ parameter, and Y_{Sc_shelf} is a secondary adjustment factor for shelf duration for the Sc parameter.

[0102] The secondary adjustment parameters can scale the resulting adjustment functions to compensate for the different tendencies of the sensitivities of different sensor configurations to change over time. For example, one sensor control device **102** could have a multiplier Y_{Sc_shelf} as 0.8, while another set can take on a more aggressive multiplier Y_{Sc_shelf} as 2.3, such that when the shelf duration adjustment is applied, the second set of sensor control devices **102** will see more adjustment over the same shelf life duration

Example Embodiments Incorporating One or More Additional Variables

[0103] In other embodiments, the determination of sensor response change can utilize other information in addition to time. For example, all of the embodiments of shelf and/or wear duration adjustments described herein can be modified to account for incremental temperature exposure by utilizing an available temperature measurement yT for sensor control device **102**. For example, with respect to wear duration:

$$f_{sWear} = R_{Sc_wear} * f_{sWearTemp}(yT, T_{wear}) \quad (13)$$

The function $f_{sWearTemp}$ can compensate for temperature exposure, for example, using an integral as follows:

$$f_{sWearTemp}(yT, T_{wear}) = [1 - [A_{sW} \exp(-E_{sW}/zT)]] \quad (14)$$

$$zT(\tau = T_{wear}) = \frac{1}{T_{wear}} \int_{\tau=0}^{\tau=T_{wear}} yT(\tau) d\tau \quad (15)$$

where zT is the accumulated temperature related exposure based on the temperature measurement yT . The temperature measurement yT can be collected by sensor control device **102** with a temperature sensor that measures the ambient temperature of sensor control device **102** or the temperature of the user's body.

[0104] With respect to shelf duration adjustments, while sensor control device **102** is in storage, it can be configured to periodically power up in order to measure the ambient temperature (yT), which can then be stored in memory or used to update a cumulative temperature assessment (zT , below), so that a shelf duration adjustment similar to the aforementioned wear duration adjustment can be made:

$$f_{sShelf} = R_{Sc_shelf} * f_{sShelfTemp}(yT, T_{shelf}) \quad (16)$$

The function $f_{sShelfTemp}$ can compensate for temperature exposure, for example, by estimating an integral exposure from the periodic sample in a zero-order-hold manner as follows:

$$f_{sShelfTemp}(yT, T_{shelf}) = [1 - [A_{sS} \exp(-E_{sS}/zT)]] \quad (17)$$

$$zT(\tau = T_{shelf}) = \frac{1}{T_{shelf}} \sum_{\tau=0}^{\tau=T_{shelf}} yT(\tau - \Delta\tau) \Delta\tau \quad (18)$$

where $\Delta\tau$ is the periodic interval of temperature measurement sampling. Those skilled in the art can determine the values A_{sW} , A_{sS} , E_{sW} , and E_{sS} from, e.g., a combination of first principles and empirical data.

[0105] In some embodiments, instead of using multiple discrete temperature measurements to estimate aggregated thermal exposure over time, a time temperature indicator (TTI) can be used to obtain a single estimated value for aggregate thermal exposure during storage. Examples of TTIs are described in “Time temperature indicators as devices intelligent packaging,” *Acta Universitatis Agriculturae et Silviculturae Mendelianae Brunensis*, 2013, LXI, No. 1, pp. 245-251, and in U.S. Pat. No. 6,950,028 (titled “Electronic Time-Temperature Indicator”), both of which are incorporated by reference herein. For example, a TTI can be included with sensor control device **102** (e.g., as a form of temperature sensor **257**, or on the packaging of sensor control device **102**) and used to collect information indicative of the aggregate temperature (optionally over a predetermined limit) to which sensor **101** is exposed post-manufacture. In some embodiments, the output of the TTI can be read optically by a user, and then subsequently entered into the appropriate device of system **100** (e.g., sensor control device **102**, reader **120**, etc.), the processing circuitry of which can then use the entered information to perform a shelf duration adjustment to the analyte data. In other embodiments, the output of the TTI can be electronic and obtainable by the processing circuitry (e.g., of sensor control device **102**) without intervention of the user and used to perform a shelf duration adjustment of the analyte data. In still other embodiments, the output of the TTI can be read over a wireless connection, e.g., by an RFID or NFC tag, and the user can obtain the measurement by scanning the TTI with a sensor control device **102** or reader device **120** having the appropriate wireless communication circuitry. In some embodiments, because the output of the TTI incorporates both time and temperature information, the shelf adjustment algorithm can use this information alone, without a separate time value input.

Example Embodiments of Parameter Coding

[0106] The various parameters described herein (e.g., STI, STS, K_{G0_wear} , R_{Sc_wear} , K_{G0_shelf} , R_{Sc_shelf} , Y_{G0_wear} , Y_{Sc_wear} , Y_{G0_shelf} , Y_{Sc_shelf} , G_{w1} , G_{w2} , any and all time values, time periods, temperature measurements, time temperature measurements, and so on) can be stored in the devices of system **100** in any desired format. In some embodiments, any and all of these parameters can be stored as their actual value (represented in digital format). In other embodiments, any and all of these parameters can be stored in a coded format. The coded format can be decoded by reference to a software algorithm or lookup table. In some embodiments, to conserve memory space, the parameters can be stored as one of a finite set of codes that can be decoded to a corresponding value. Each of the parameters can be nonzero values, or codes corresponding to nonzero values, such that the adjustment results in an actual change from the first analyte value (e.g., G_{init}) to the second analyte value (e.g., G_{cal}).

[0107] For example, the secondary adjustment factors (e.g., Y_{G0_wear} , Y_{Sc_wear} , Y_{G0_shelf} , Y_{Sc_shelf}) can be stored as one of a predetermined number of codes (e.g., 5 codes), each of which can be decoded as a particular value (e.g., where a 0 code is zero, a 1 code is 0.1, a 2 code

is 0.5, a 3 code is 1, and a 4 code is 1.2). Such an arrangement can conserve memory space.

[0108] Any and all parameters can be stored as a single code, e.g., a calibration code, that can be decoded to translate each of the respective parameters to their respective values. In some embodiments, various parameters are stored as different codes, e.g., a first code for STI and STS, a second code for the primary adjustment parameters (e.g., K_{G0_wear} , R_{Sc_wear} , K_{G0_shelf} , R_{Sc_shelf}), a third code for the secondary adjustment parameters (e.g., Y_{G0_wear} , Y_{Sc_wear} , Y_{G0_shelf} , Y_{Sc_shelf}), a fourth code for the shelf start time, and so forth. Each of these codes can be stored in sensor control device **102** at the time of manufacture and used as needed by sensor control device **102** to process the data, or communicated to a different device (e.g., reader **120**) for data processing.

[0109] In one embodiment, certain memory space reserved for the date of manufacture is used to store the adjustment factor. For example, the memory originally allocated to store the month (of the date of manufacture) no longer stores the day of the month, but stores the adjustment factor(s) instead.

Example Methods of Adjustment

[0110] Several example embodiments of methods of adjusting analyte sensor data are described with reference to FIGS. 4A-4B. FIG. 4A is a flow diagram depicting an example method **400** where sensor data is adjusted to compensate for a change in sensor response due to a shelf duration. At **402**, sensor data is collected with the analyte sensor at least partially inserted into a human body. In some embodiments, a shelf duration of the analyte sensor can be determined with processing circuitry (e.g., of a sensor control device **102**, a reader device **120**, or other device of system **100**). At **404**, the sensor data is adjusted, with processing circuitry (e.g., of a sensor control device **102**, a reader device **120**, or other device of system **100**), to compensate for the shelf duration. In some embodiments, the adjustment to the sensor data can be performed using the shelf duration (T_{shelf}) and one or more primary shelf duration adjustment parameters (e.g., K_{G0_shelf} , R_{Sc_shelf}), depending on the number of characteristics (e.g., slope, offset) being adjusted.

[0111] In some embodiments, temperature data representative of temperatures to which the analyte sensor was subjected during the shelf duration are collected, and then the sensor data is also adjusted to compensate for the temperature exposure during the shelf duration.

[0112] At **406**, an analyte level representative of the adjusted sensor data can be output. Outputting of the adjusted sensor data can include, for example, communicating the adjusted sensor data from sensor control device **102** to a second electronic device (e.g., reader device **120**) for further processing and/or display to a user, outputting the adjusted sensor data to the user directly from a display (e.g., of sensor control device **102** or reader device **120**), or others.

[0113] FIG. 4B is a flow diagram depicting an example method **410** where sensor data is adjusted to compensate for a change in sensor response due to a wear duration. At **412**, sensor data is collected with the analyte sensor at least partially inserted into a human body. In some embodiments, a wear duration of the analyte sensor can be determined with processing circuitry (e.g., of a sensor control device **102**, a reader device **120**, or other device of system **100**). At **414**,

the sensor data is adjusted, with processing circuitry (e.g., of a sensor control device **102**, a reader device **120**, or other device of system **100**), to compensate for the wear duration. In some embodiments, the adjustment to the sensor data can be performed using the wear duration (T_{wear}) and one or more primary wear duration adjustment parameters (e.g., K_{GO_wear} , R_{Sc_wear}), depending on the number of characteristics (e.g., slope, offset) being adjusted.

[0114] In some embodiments, temperature data representative of temperatures to which the analyte sensor was subjected during the wear duration are collected, and then the sensor data is also adjusted to compensate for the temperature exposure during the wear duration.

[0115] At **416**, an analyte level representative of the adjusted sensor data can be output. Outputting of the adjusted sensor data can include, for example, communicating the adjusted sensor data from sensor control device **102** to a second electronic device (e.g., reader device **120**) for further processing and/or display to a user, outputting the adjusted sensor data to the user directly from a display (e.g., of sensor control device **102** or reader device **120**), or others.

[0116] In another example embodiment, the collected sensor data is adjusting to compensate for sensor response changes for both shelf duration and wear duration.

[0117] The embodiments described herein are restated and expanded upon in the following paragraphs without explicit reference to the figures. In many embodiments, a method of adjusting analyte sensor data is provided, where the method includes: collecting sensor data with an analyte sensor at least partially inserted into a human body; adjusting, with processing circuitry, the sensor data to compensate for at least a first duration of time, where the first duration of time is one of a shelf duration or a wear duration; and outputting an analyte level representative of the adjusted sensor data. In many embodiments, the adjusted sensor data is different from the collected sensor data. In some embodiments, the analyte sensor is a glucose sensor.

[0118] In some embodiments, the method further includes adjusting, with processing circuitry, the sensor data to compensate for a first duration of time and a second duration of time, where the first duration of time is the shelf duration and the second duration of time is the wear duration.

[0119] In some embodiments, the first duration of time is the shelf duration, and the method further includes determining the shelf duration with processing circuitry. In some embodiments, the shelf duration can be representative of a period of time after the analyte sensor was manufactured and before the analyte sensor was inserted into the human body. In some embodiments, the shelf duration can include the entire time the analyte sensor was in a packaged state prior to insertion into the human body. In some embodiments, a wait period is implemented such that the shelf duration is representative of a time period less than the entire time the analyte sensor was in a packaged state prior to insertion.

[0120] In some embodiments, the analyte sensor has a sensitivity at least partially represented by a slope and/or an intercept, and the step of adjusting, with processing circuitry, the sensor data to compensate for the shelf duration includes adjusting at least one of the slope and the intercept.

[0121] In some embodiments, the method further includes collecting temperature data representative of a plurality of temperatures to which the analyte sensor was subjected during the shelf duration. In some embodiments, the method

further includes adjusting, with processing circuitry, the sensor data to compensate for the shelf duration and the plurality of temperatures.

[0122] In some embodiments, the first duration of time is the wear duration, the method further including determining the wear duration with processing circuitry. In some embodiments, the wear duration is representative of a period of time during which the analyte sensor is at least partially inserted into the human body. In some embodiments, the wear duration begins upon insertion of the analyte sensor into the human body. In some embodiments, a wait period is implemented such that the wear duration begins a period of time period after insertion of the analyte sensor into the human body. In some embodiments, a sensor control device includes the analyte sensor and sensor electronics, and the wear duration begins upon activation of the sensor control device.

[0123] In some embodiments, the analyte sensor has a sensitivity at least partially represented by a slope and/or an intercept, and the step of adjusting, with processing circuitry, the sensor data to compensate for the wear duration includes adjusting the slope, the intercept, or both.

[0124] In some embodiments, the method further includes collecting temperature data representative of a plurality of temperatures to which the analyte sensor was subjected during the wear duration. In some embodiments, the method further includes adjusting, with processing circuitry, the sensor data to compensate for the wear duration and the plurality of temperatures.

[0125] In some embodiments, adjusting, with processing circuitry, the sensor data to compensate for the shelf duration includes: adjusting, with processing circuitry, the sensor data with a function including an adjustment parameter and a value representative of time. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and the method further includes: decoding, with processing circuitry, the code to determine the adjustment parameter. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and the method further includes: communicating the code from a sensor control device to a reader device; decoding, with processing circuitry of the reader device, the code to determine the adjustment parameter; and adjusting, with processing circuitry of the reader device, the sensor data with the function including the adjustment parameter and the value representative of time. In some embodiments, the value representative of time is representative of a shelf duration. In some embodiments, the value representative of time is representative of a shelf duration less a wait period. In some embodiments, the adjustment factor is stored in memory in an unencoded form, and the method further includes: adjusting, with processing circuitry, the sensor data without decoding the adjustment factor.

[0126] In some embodiments, adjusting, with processing circuitry, the sensor data to compensate for the wear duration includes: adjusting, with processing circuitry, the sensor data with a function including an adjustment parameter and a value representative of time. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, the method further including: decoding, with processing circuitry, the code to determine the adjustment parameter. In some embodiments, the adjustment parameter corresponds to a code selected from one of

a plurality of codes, the method further including: communicating the code from a sensor control device to a reader device; decoding, with processing circuitry of the reader device, the code to determine the adjustment parameter; and adjusting, with processing circuitry of the reader device, the sensor data with the function including the adjustment parameter and the value representative of time. In some embodiments, the value representative of time is representative of a wear duration. In some embodiments, the value representative of time is representative of a wear duration less a wait period. In some embodiments, the adjustment factor is stored in memory in an unencoded form, the method further including: adjusting, with processing circuitry, the sensor data without decoding the adjustment factor.

[0127] In many embodiments, an analyte monitoring system is provided, the analyte monitoring system including: a sensor control device including an analyte sensor at least partially insertable into a human body, processing circuitry, and a non-transitory memory, where the sensor control device is configured to collect sensor data with the analyte sensor; and a reader device including processing circuitry and a non-transitory memory, where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust collected sensor data to compensate for at least a first duration of time, where the first duration of time is one of a shelf duration or a wear duration; and cause output of an analyte level representative of the adjusted sensor data. In many embodiments, the adjusted sensor data is different from the collected sensor data. In some embodiments, the analyte sensor is a glucose sensor.

[0128] In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust the collected sensor data to compensate for a first duration of time and a second duration of time, where the first duration of time is the shelf duration and the second duration of time is the wear duration.

[0129] In some embodiments, the first duration of time is the shelf duration, and where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the shelf duration.

[0130] In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the shelf duration such that the shelf duration is representative of a period of time after the analyte sensor was manufactured and before the analyte sensor was inserted into the human body. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the shelf duration such that the shelf duration includes the entire time the analyte sensor was in a packaged state prior to insertion into the human body.

In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the shelf duration such that it begins after a post-manufacture wait period.

[0131] In some embodiments, the sensor control device is programmed to communicate an adjustment parameter to the reader device, the adjustment parameter being representative of a nonzero value and usable with a shelf duration time value to compensate for shelf duration.

[0132] In some embodiments, the analyte sensor has a sensitivity at least partially represented by a slope and/or an intercept, and where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust at least one of the slope, the intercept, or both to compensate for the shelf duration.

[0133] In some embodiments, the sensor control device further includes a temperature sensor adapted to collect temperature data representative of a plurality of temperatures to which the analyte sensor is subjected during the shelf duration. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust the sensor data to compensate for the shelf duration and the plurality of temperatures.

[0134] In some embodiments, the first duration of time is the wear duration, and at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the wear duration. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the wear duration such that the wear duration is representative of a period of time during which the analyte sensor is at least partially inserted into the human body. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the wear duration from the time of insertion of the analyte sensor into the human body. In some embodiments, a sensor control device includes the analyte sensor and sensor electronics, and at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the wear duration from the time of activation of the sensor control device. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: determine the wear duration such that it begins after a post-insertion wait period.

[0135] In some embodiments, the sensor control device is programmed to communicate an adjustment parameter to the

reader device, the adjustment parameter being representative of a nonzero value and usable with a wear duration time value to compensate for wear duration.

[0136] In some embodiments, the analyte sensor has a sensitivity at least partially represented by a slope and/or an intercept, and where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust at least one of the slope, the intercept, or both to compensate for the wear duration.

[0137] In some embodiments, the sensor control device further includes a temperature sensor adapted to collect temperature data representative of a plurality of temperatures to which the analyte sensor is subjected during the wear duration. In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust the sensor data to compensate for the wear duration and the plurality of temperatures.

[0138] In some embodiments, the non-transitory memory of the sensor control device includes instructions that, when executed, cause the processing circuitry of the sensor control device to: adjust collected sensor data to compensate for at least a first duration of time, where the first duration of time is one of a shelf duration or a wear duration; and cause output an analyte level representative of the adjusted sensor data to the reader device or to a user.

[0139] In some embodiments, the non-transitory memory of the reader device includes instructions that, when executed, cause the processing circuitry of the reader device to: adjust collected sensor data to compensate for at least a first duration of time, where the first duration of time is one of a shelf duration or a wear duration; and cause output an analyte level representative of the adjusted sensor data.

[0140] In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust the sensor data, to compensate for shelf duration, with a function including an adjustment parameter and a value representative of time. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: decode the code to determine the adjustment parameter. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and where the sensor control device is programmed to communicate the code to the reader device. In some embodiments, the non-transitory memory of the reader device includes instructions that, when executed, causes the processing circuitry of the reader device to: decode the code to determine the adjustment parameter; and adjust the sensor data with the function including the adjustment parameter and the value representative of time. In some embodiments, the value representative of time is representative of a shelf duration. In some embodiments, the value representative of time is representative of a shelf duration less a wait period.

In some embodiments, the adjustment factor is stored in the non-transitory memory of the sensor control device in an unencoded form, and where the sensor control device is programmed to communicate the unencoded adjustment factor to the reader device.

[0141] In some embodiments, at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: adjust the sensor data, to compensate for wear duration, with a function including an adjustment parameter and a value representative of time. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and where at least one of the non-transitory memories of the sensor control device or reader device includes instructions that, when executed, cause at least one of the processing circuitries of the sensor control device or the reader device to: decode the code to determine the adjustment parameter. In some embodiments, the adjustment parameter corresponds to a code selected from one of a plurality of codes, and where the sensor control device is programmed to communicate the code to the reader device. In some embodiments, the non-transitory memory of the reader device includes instructions that, when executed, causes the processing circuitry of the reader device to: decode the code to determine the adjustment parameter; and adjust the sensor data with the function including the adjustment parameter and the value representative of time. In some embodiments, the value representative of time is representative of a wear duration. In some embodiments, the value representative of time is representative of a wear duration less a wait period. In some embodiments, the adjustment factor is stored in the non-transitory memory of the sensor control device in an unencoded form, and where the sensor control device is programmed to communicate the unencoded adjustment factor to the reader device.

[0142] For each and every embodiment of a method disclosed herein, systems and devices capable of performing each of those embodiments are covered within the scope of the present disclosure. For example, embodiments of sensor control devices are disclosed, and these devices can have one or more analyte sensors, analyte monitoring circuits (e.g., an analog circuit), memories (e.g., for storing instructions), power sources, communication circuits, transmitters, receivers, clocks, counters, times, temperature sensors, processors (e.g., for executing instructions) that can perform any and all method steps or facilitate the execution of any and all method steps. These sensor control device embodiments can be used and can be capable of use to implement those steps performed by a sensor control device from any and all of the methods described herein. Similarly, embodiments of reader devices are disclosed, and these devices can have one or more memories (e.g., for storing instructions), power sources, communication circuits, transmitters, receivers, clocks, counters, times, and processors (e.g., for executing instructions) that can perform any and all method steps or facilitate the execution of any and all method steps. These reader device embodiments can be used and can be capable of use to implement those steps performed by a reader device from any and all of the methods described herein. Embodiments of computer devices and servers are disclosed, and these devices can have one or more memories (e.g., for storing instructions), power sources, communica-

tion circuits, transmitters, receivers, clocks, counters, times, and processors (e.g., for executing instructions) that can perform any and all method steps or facilitate the execution of any and all method steps. These reader device embodiments can be used and can be capable of use to implement those steps performed by a reader device from any and all of the methods described herein.

[0143] Computer program instructions for carrying out operations in accordance with the described subject matter may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, JavaScript, Smalltalk, C++, C#, Transact-SQL, XML, PHP or the like and conventional procedural programming languages, such as the “C” programming language or similar programming languages. The program instructions may execute entirely on the user’s computing device, partly on the user’s computing device, as a stand-alone software package, partly on the user’s computing device and partly on a remote computing device or entirely on the remote computing device or server. In the latter scenario, the remote computing device may be connected to the user’s computing device through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

[0144] It should be noted that all features, elements, components, functions, and steps described with respect to any embodiment provided herein are intended to be freely combinable and substitutable with those from any other embodiment. If a certain feature, element, component, function, or step is described with respect to only one embodiment, then it should be understood that that feature, element, component, function, or step can be used with every other embodiment described herein unless explicitly stated otherwise. This paragraph therefore serves as antecedent basis and written support for the introduction of claims, at any time, that combine features, elements, components, functions, and steps from different embodiments, or that substitute features, elements, components, functions, and steps from one embodiment with those of another, even if the following description does not explicitly state, in a particular instance, that such combinations or substitutions are possible. It is explicitly acknowledged that express recitation of every possible combination and substitution is overly burdensome, especially given that the permissibility of each and every such combination and substitution will be readily recognized by those of ordinary skill in the art.

[0145] To the extent the embodiments disclosed herein include or operate in association with memory, storage, and/or computer readable media, then that memory, storage, and/or computer readable media are non-transitory. Accordingly, to the extent that memory, storage, and/or computer readable media are covered by one or more claims, then that memory, storage, and/or computer readable media is only non-transitory.

[0146] As used herein and in the appended claims, the singular forms “a,” “an,” and “the” include plural referents unless the context clearly dictates otherwise.

[0147] While the embodiments are susceptible to various modifications and alternative forms, specific examples thereof have been shown in the drawings and are herein described in detail. It should be understood, however, that these embodiments are not to be limited to the particular

form disclosed, but to the contrary, these embodiments are to cover all modifications, equivalents, and alternatives falling within the spirit of the disclosure. Furthermore, any features, functions, steps, or elements of the embodiments may be recited in or added to the claims, as well as negative limitations that define the inventive scope of the claims by features, functions, steps, or elements that are not within that scope.

1. A method of adjusting analyte sensor data, comprising: collecting sensor data with an analyte sensor at least partially inserted into a human body; adjusting, with processing circuitry, the sensor data to compensate for at least a first duration of time, wherein the first duration of time is one of a shelf duration or a wear duration; and outputting an analyte level representative of the adjusted sensor data.
2. (canceled)
3. The method of claim 1, wherein the first duration of time is the shelf duration, the method further comprising determining the shelf duration with processing circuitry.
4. The method of claim 3, wherein the shelf duration is representative of a period of time after the analyte sensor was manufactured and before the analyte sensor was inserted into the human body.
5. The method of claim 3, wherein the shelf duration includes the entire time the analyte sensor was in a packaged state prior to insertion into the human body.
6. The method of claim 5, wherein a wait period is implemented such that the shelf duration is representative of a time period less than the entire time the analyte sensor was in a packaged state prior to insertion.
7. The method of claim 3, wherein the adjusted sensor data is different from the collected sensor data.
8. The method of claim 3, wherein the analyte sensor has a sensitivity at least partially represented by a slope and/or an intercept, and wherein adjusting, with processing circuitry, the sensor data to compensate for the shelf duration comprises adjusting at least one of the slope and the intercept.
9. (canceled)
10. The method of claim 3, further comprising collecting temperature data representative of a plurality of temperatures to which the analyte sensor was subjected during the shelf duration.
11. The method of claim 10, further comprising adjusting, with processing circuitry, the sensor data to compensate for the shelf duration and the plurality of temperatures.
12. The method of claim 1, wherein the first duration of time is the wear duration, the method further comprising determining the wear duration with processing circuitry.
13. The method of claim 12, wherein the wear duration is representative of a period of time during which the analyte sensor is at least partially inserted into the human body.
14. The method of claim 12, wherein the wear duration begins upon insertion of the analyte sensor into the human body.
15. The method of claim 12, wherein a wait period is implemented such that the wear duration begins a period of time period after insertion of the analyte sensor into the human body.

16. The method of claim 12, wherein a sensor control device comprises the analyte sensor and sensor electronics, and wherein the wear duration begins upon activation of the sensor control device.

17-22. (canceled)

23. The method of claim 3, wherein adjusting, with processing circuitry, the sensor data to compensate for the shelf duration comprises:

adjusting, with processing circuitry, the sensor data with a function comprising an adjustment parameter and a value representative of time.

24. The method of claim 23, wherein the adjustment parameter corresponds to a code selected from one of a plurality of codes, the method further comprising:

decoding, with processing circuitry, the code to determine the adjustment parameter.

25. The method of claim 23, wherein the adjustment parameter corresponds to a code selected from one of a plurality of codes, the method further comprising:

communicating the code from a sensor control device to a reader device;

decoding, with processing circuitry of the reader device, the code to determine the adjustment parameter; and adjusting, with processing circuitry of the reader device, the sensor data with the function comprising the adjustment parameter and the value representative of time.

26. The method of claim 23, wherein the value representative of time is representative of a shelf duration.

27. The method of claim 23, wherein the value representative of time is representative of a shelf duration less a wait period.

28. The method of claim 23, wherein the adjustment factor is stored in memory in an unencoded form, the method further comprising:

adjusting, with processing circuitry, the sensor data without decoding the adjustment factor.

29-73. (canceled)

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摘要(译)

公开了补偿由于持续时间导致的传感器响应特性（例如，灵敏度）的变化的实施例。持续时间可以是传感器在使用之前处于制造后封装状态的时间量，或者传感器在使用中的时间量。也可以补偿由于其他变量引起的传感器响应变化。

