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Noise rejection methods and apparatus for sparsely sampled analyte sensor data

Abstract

Systems, methods and apparatus are provided for rejecting noise from sparsely sampled analyte sensor data. Embodiments of the present disclosure include receiving a raw set of sensor data from an on-body device including an in vivo analyte sensor, determining an interpolation-based estimate of an analyte level over time based on the raw set of sensor data, determining an extrapolation-based estimate of the analyte level over time based on the raw set of sensor data, determining a combined estimate of the analyte level over time based on the interpolation-based estimate and the extrapolation-based estimate, and displaying a representation of the combined estimate of the analyte level over time on an output device. Numerous additional aspects are disclosed.

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6936006	12/2004	Sabra	N/A	N/A

6940403	12/2004	Kail, IV	N/A	N/A
6941163	12/2004	Ford et al.	N/A	N/A
6942518	12/2004	Liamos et al.	N/A	N/A
6950708	12/2004	Bowman IV et al.	N/A	N/A
6958705	12/2004	Lebel et al.	N/A	N/A
6968294	12/2004	Gutta et al.	N/A	N/A
6971274	12/2004	Olin	N/A	N/A
6974437	12/2004	Lebel et al.	N/A	N/A
6990366	12/2005	Say et al.	N/A	N/A
6997907	12/2005	Safabash et al.	N/A	N/A
6998247	12/2005	Monfre et al.	N/A	N/A
7003336	12/2005	Holker et al.	N/A	N/A
7003340	12/2005	Say et al.	N/A	N/A
7003341	12/2005	Say et al.	N/A	N/A
7009511	12/2005	Mazar et al.	N/A	N/A
7010345	12/2005	Hill et al.	N/A	N/A
7011630	12/2005	Desai et al.	N/A	N/A
7016713	12/2005	Gardner et al.	N/A	N/A
7016720	12/2005	Kroll	N/A	N/A
7020508	12/2005	Stivoric et al.	N/A	N/A
7022072	12/2005	Fox et al.	N/A	N/A
7022219	12/2005	Mansouri et al.	N/A	N/A
7024236	12/2005	Ford et al.	N/A	N/A
7024245	12/2005	Lebel et al.	N/A	N/A
7025425	12/2005	Kovatchev et al.	N/A	N/A
7029443	12/2005	Kroll	N/A	N/A
7029444	12/2005	Shin et al.	N/A	N/A
7041068	12/2005	Freeman et al.	N/A	N/A
7041468	12/2005	Drucker et al.	N/A	N/A
7043287	12/2005	Khalil et al.	N/A	N/A
7043305	12/2005	KenKnight et al.	N/A	N/A
7052483	12/2005	Wojcik	N/A	N/A
7056302	12/2005	Douglas	N/A	N/A
7058453	12/2005	Nelson et al.	N/A	N/A
7060031	12/2005	Webb et al.	N/A	N/A
7074307	12/2005	Simpson et al.	N/A	N/A
7076300	12/2005	Kroll et al.	N/A	N/A
7081195	12/2005	Simpson et al.	N/A	N/A
7082334	12/2005	Boute et al.	N/A	N/A
7092891	12/2005	Maus et al.	N/A	N/A
7096064	12/2005	Deno et al.	N/A	N/A
7098803	12/2005	Mann et al.	N/A	N/A
7103412	12/2005	Kroll	N/A	N/A
7108778	12/2005	Simpson et al.	N/A	N/A
7110803	12/2005	Shults et al.	N/A	N/A
7113821	12/2005	Sun et al.	N/A	N/A
7118667	12/2005	Lee	N/A	N/A
7123950	12/2005	Mannheimer	N/A	N/A
7125382	12/2005	Zhou et al.	N/A	N/A
7134999	12/2005	Brauker et al.	N/A	N/A

7136689	12/2005	Shults et al.	N/A	N/A
7142911	12/2005	Boileau et al.	N/A	N/A
7153265	12/2005	Vachon	N/A	N/A
7167818	12/2006	Brown	N/A	N/A
7171274	12/2006	Starkweather et al.	N/A	N/A
7190988	12/2006	Say et al.	N/A	N/A
7192450	12/2006	Brauker et al.	N/A	N/A
7198606	12/2006	Boecker et al.	N/A	N/A
7203549	12/2006	Schommer et al.	N/A	N/A
7225535	12/2006	Feldman et al.	N/A	N/A
7226978	12/2006	Tapsak et al.	N/A	N/A
7228182	12/2006	Healy et al.	N/A	N/A
7237712	12/2006	DeRocco et al.	N/A	N/A
7258673	12/2006	Racchini et al.	N/A	N/A
7267665	12/2006	Steil et al.	N/A	N/A
7272436	12/2006	Gill et al.	N/A	N/A
7276029	12/2006	Goode, Jr. et al.	N/A	N/A
7278983	12/2006	Ireland et al.	N/A	N/A
7295867	12/2006	Berner et al.	N/A	N/A
7297114	12/2006	Gill et al.	N/A	N/A
7299082	12/2006	Feldman et al.	N/A	N/A
7310544	12/2006	Brister et al.	N/A	N/A
7317938	12/2007	Lorenz et al.	N/A	N/A
7318816	12/2007	Bobroff et al.	N/A	N/A
7324850	12/2007	Persen et al.	N/A	N/A
7335294	12/2007	Heller et al.	N/A	N/A
7347819	12/2007	Lebel et al.	N/A	N/A
7354420	12/2007	Steil et al.	N/A	N/A
7364592	12/2007	Carr-Brendel et al.	N/A	N/A
7366556	12/2007	Brister et al.	N/A	N/A
7379765	12/2007	Petisce et al.	N/A	N/A
7384397	12/2007	Zhang et al.	N/A	N/A
7387010	12/2007	Sunshine et al.	N/A	N/A
7399277	12/2007	Saidara et al.	N/A	N/A
7402153	12/2007	Steil et al.	N/A	N/A
7404796	12/2007	Ginsberg	N/A	N/A
7419573	12/2007	Gundel	N/A	N/A
7424318	12/2007	Brister et al.	N/A	N/A
7460898	12/2007	Brister et al.	N/A	N/A
7467003	12/2007	Brister et al.	N/A	N/A
7468125	12/2007	Kraft et al.	N/A	N/A
7471972	12/2007	Rhodes et al.	N/A	N/A
7474992	12/2008	Ariyur	N/A	N/A
7492254	12/2008	Bandy et al.	N/A	N/A
7494465	12/2008	Brister et al.	N/A	N/A
7497827	12/2008	Brister et al.	N/A	N/A
7499002	12/2008	Blasko et al.	N/A	N/A
7502644	12/2008	Gill et al.	N/A	N/A
7519408	12/2008	Rasdal et al.	N/A	N/A
7524287	12/2008	Bharmi	N/A	N/A

7547281	12/2008	Hayes et al.	N/A	N/A
7565197	12/2008	Haubrich et al.	N/A	N/A
7569030	12/2008	Lebel et al.	N/A	N/A
7574266	12/2008	Dudding et al.	N/A	N/A
7583990	12/2008	Goode, Jr. et al.	N/A	N/A
7591801	12/2008	Brauker et al.	N/A	N/A
7599726	12/2008	Goode, Jr. et al.	N/A	N/A
7602310	12/2008	Mann et al.	N/A	N/A
7604178	12/2008	Stewart	N/A	N/A
7613491	12/2008	Boock et al.	N/A	N/A
7615007	12/2008	Shults et al.	N/A	N/A
7618369	12/2008	Hayter et al.	N/A	N/A
7630748	12/2008	Budiman	N/A	N/A
7632228	12/2008	Brauker et al.	N/A	N/A
7635594	12/2008	Holmes et al.	N/A	N/A
7637868	12/2008	Saint et al.	N/A	N/A
7640048	12/2008	Dobbles et al.	N/A	N/A
7643798	12/2009	Ljung	N/A	N/A
7659823	12/2009	Killian et al.	N/A	N/A
7668596	12/2009	Von Arx et al.	N/A	N/A
7699775	12/2009	Desai et al.	N/A	N/A
7699964	12/2009	Feldman et al.	N/A	N/A
7736310	12/2009	Taub et al.	N/A	N/A
7741734	12/2009	Joannopoulos et al.	N/A	N/A
7766829	12/2009	Sloan et al.	N/A	N/A
7771352	12/2009	Shults et al.	N/A	N/A
7774145	12/2009	Bruaker et al.	N/A	N/A
7778680	12/2009	Goode, Jr. et al.	N/A	N/A
7779332	12/2009	Karr et al.	N/A	N/A
7782192	12/2009	Jeckelmann et al.	N/A	N/A
7783333	12/2009	Brister et al.	N/A	N/A
7791467	12/2009	Mazar et al.	N/A	N/A
7792562	12/2009	Shults et al.	N/A	N/A
7826981	12/2009	Goode, Jr. et al.	N/A	N/A
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7882611	12/2010	Shah et al.	N/A	N/A
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7899511	12/2010	Shults et al.	N/A	N/A
7905833	12/2010	Brister et al.	N/A	N/A
7912674	12/2010	Killoren Clark et al.	N/A	N/A
7914450	12/2010	Goode, Jr. et al.	N/A	N/A
7916013	12/2010	Stevenson	N/A	N/A
7938797	12/2010	Estes	N/A	N/A
7955258	12/2010	Goscha et al.	N/A	N/A
7970448	12/2010	Shults et al.	N/A	N/A
7974672	12/2010	Shults et al.	N/A	N/A
7999674	12/2010	Kamen	N/A	N/A
8072310	12/2010	Everhart	N/A	N/A

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8093991	12/2011	Stevenson et al.	N/A	N/A
8094009	12/2011	Allen et al.	N/A	N/A
8098159	12/2011	Batra et al.	N/A	N/A
8098160	12/2011	Howarth et al.	N/A	N/A
8098161	12/2011	Lavedas	N/A	N/A
8098201	12/2011	Choi et al.	N/A	N/A
8098208	12/2011	Ficker et al.	N/A	N/A
8102021	12/2011	Degani	N/A	N/A
8102154	12/2011	Bishop et al.	N/A	N/A
8102263	12/2011	Yeo et al.	N/A	N/A
8102789	12/2011	Rosar et al.	N/A	N/A
8103241	12/2011	Young et al.	N/A	N/A
8103325	12/2011	Swedlow et al.	N/A	N/A
8111042	12/2011	Bennett	N/A	N/A
8115488	12/2011	McDowell	N/A	N/A
8116681	12/2011	Baarman	N/A	N/A
8116683	12/2011	Baarman	N/A	N/A
8116837	12/2011	Huang	N/A	N/A
8117481	12/2011	Anselmi et al.	N/A	N/A
8120493	12/2011	Burr	N/A	N/A
8124452	12/2011	Sheats	N/A	N/A
8130093	12/2011	Mazar et al.	N/A	N/A
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8132037	12/2011	Fehr et al.	N/A	N/A
8135352	12/2011	Langsweirdt et al.	N/A	N/A
8136735	12/2011	Arai et al.	N/A	N/A
8138925	12/2011	Downie et al.	N/A	N/A
8140160	12/2011	Pless et al.	N/A	N/A
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8140299	12/2011	Siess	N/A	N/A
8150321	12/2011	Winter et al.	N/A	N/A
8150516	12/2011	Levine et al.	N/A	N/A
8160900	12/2011	Taub et al.	N/A	N/A
8179266	12/2011	Hermle	N/A	N/A
8211016	12/2011	Budiman	N/A	N/A
8216137	12/2011	Budiman	N/A	N/A
8216138	12/2011	McGarraugh et al.	N/A	N/A
8224415	12/2011	Budiman et al.	N/A	N/A
8231531	12/2011	Brister et al.	N/A	N/A
8255026	12/2011	Al-Ali	N/A	N/A
8282549	12/2011	Brauker et al.	N/A	N/A
8457703	12/2012	A1-Ali	N/A	N/A
8532935	12/2012	Budiman	N/A	N/A
9113828	12/2014	Budiman	N/A	N/A
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2006/0029177	12/2005	Cranford, Jr. et al.	N/A	N/A
2006/0031094	12/2005	Cohen et al.	N/A	N/A
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2006/0167365	12/2005	Bharmi	N/A	N/A
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Background/Summary

RELATED APPLICATION (1) The present application claims priority under 35 U.S.C. § 119 (e) to U.S. Provisional Application No. 61/794,549 filed Mar. 15, 2013, entitled “Noise Rejection Methods and Apparatus For Sparsely Sampled Analyte Sensor Data,” the disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND

(1) The detection of the concentration level of glucose or other analytes in certain individuals may be vitally important to their health. For example, the monitoring of glucose levels is particularly important to individuals with diabetes or pre-diabetes. People with diabetes may need to monitor their glucose levels to determine when medication (e.g., insulin) is needed to reduce their glucose levels or when additional glucose is needed.

(2) Devices have been developed for automated in vivo monitoring of analyte time series characteristics, such as glucose levels, in bodily fluids such as in the blood stream or in interstitial fluid. Some of these analyte level measuring devices are configured so that at least a portion of a sensor of an on-body device is positioned below a skin surface of a user, e.g., in a blood vessel or in the subcutaneous tissue of a user. As used herein, the term analyte monitoring system is used to refer to any type of in vivo monitoring system that uses a sensor disposed with at least a subcutaneous portion to measure and store sensor data representative of analyte concentration levels automatically over time. Analyte monitoring systems include both (1) systems such as continuous glucose monitors (CGMs) which transmit sensor data continuously or at regular time

intervals (e.g., once per minute) to a processor/display unit and (2) systems that transfer stored sensor data in one or more batches in response to data request from a processor/display unit (e.g., based on an activation action and/or proximity using, for example, a near field communications protocol).

(3) Some analyte monitoring systems may store samples relatively infrequently. For example, the sensor data may only include measurements or samples taken once every ten or fifteen minutes. In some cases, such sparsely sampled analyte sensor data may not accurately reflect the analyte concentration levels, particularly if signal noise is present. Thus, what are needed are systems, methods and apparatus that can reliably represent the analyte concentration level even of sparsely sampled data is used.

SUMMARY

(4) As mentioned above, accurate monitoring of analyte levels can be important to a person's health. To insure that sensor data does accurately reflect analyte concentration, embodiments of the present disclosure provide systems, methods, and apparatus for rejecting noise from sparsely sampled analyte sensor data that does not alter or distort true sensor data excursions. Conventional noise filtering from sparsely sampled sensor data can result in undesirable side effects such as over-filtering, particularly where an actual rapid change (e.g., a relatively fast change compared to the sample rate) in analyte concentration (i.e., a fast true sensor data excursion) occurs. In effect, conventional analyte sensor data filtering methods may not reliably distinguish between noise that should be rejected and rapid changes in analyte concentration that should be preserved. As a result, the analyte sensor can appear less responsive, and, in addition, can lag as compared to reference analyte measurements. The present disclosure provides novel noise rejection methods that take advantage of the similarities and differences of interpolation-based and extrapolation-based estimation methods to filter noise without attenuating fast true sensor data excursions.

(5) In some embodiments, the present disclosure provides systems, methods and apparatus for rejecting noise from sparsely sampled analyte sensor data. The invention includes receiving a raw set of sensor data from an on-body device including an in vivo analyte sensor, determining an interpolation-based estimate of an analyte level over time based on the raw set of sensor data, determining an extrapolation-based estimate of the analyte level over time based on the raw set of sensor data, determining a combined estimate of the analyte level over time based on the interpolation-based estimate and the extrapolation-based estimate, and displaying a representation of the combined estimate of the analyte level over time on an output device.

(6) The invention also includes a computer system and a computer program product for rejecting noise in sparsely sampled analyte monitoring system sensor data. Numerous other aspects and embodiments are provided. Other features and aspects of the present disclosure will become more fully apparent from the following detailed description, the appended claims, and the accompanying drawings.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The accompanying drawings, which are incorporated herein, form part of the specification. Together with this written description, the drawings further serve to explain the principles of, and to enable a person skilled in the relevant arts, to make and use the present disclosure.

(2) FIG. 1 depicts an example graph illustrating a Least Squares fit of a straight line to estimate a sensor data value in accordance with some embodiments of the present disclosure.

(3) FIG. 2 depicts an example graph illustrating the smoothing effect of the Least Squares fit based calculation in accordance with some embodiments of the present disclosure.

(4) FIG. 3 depicts an example graph illustrating the Least Squares fit based calculation applied

- outside the measurement window in accordance with some embodiments of the present disclosure.
- (5) FIG. 4 depicts an example graph illustrating the combination of an interpolation-based calculation and an extrapolation-based calculation in accordance with some embodiments of the present disclosure.
- (6) FIG. 5 depicts an example graph illustrating the effectiveness of applying methods of the present disclosure to noisy sensor data in accordance with some embodiments of the present disclosure.
- (7) FIG. 6 is a flow chart depicting an example method of noise rejection for sparsely sampled analyte sensor data in accordance with some embodiments of the present disclosure.

DETAILED DESCRIPTION

(8) Before the embodiments of the present disclosure are described, it is to be understood that this invention 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 embodiments of the invention will be limited only by the appended claims.

(9) The present disclosure provides systems, methods, and apparatus to reject noise from sparsely sampled analyte sensor data that does not alter or distort true sensor data excursions. As used herein, the term “sparsely sampled” is intended to mean a sample rate that is low enough such that first phase responses to meal and/or insulin may be difficult to discern in real-time. For example, based on average human physiology, a sample rate of once every ten minutes or slower is a sparsely sampled rate. The invention can be applied to sensor data from an analyte monitoring system, such as, for example, any type of in vivo monitoring system that uses a sensor disposed with at least a subcutaneous portion to measure and store sensor data representative of analyte concentration levels automatically over time. Analyte monitoring systems may include CGMs which are programmed to transmit sensor data according to a predetermined transmission schedule, continuously, or at regular time intervals to a processor/display unit and systems that transfer stored sensor data in one or more batches in response to a request from a processor/display unit, i.e., not according to a predetermined transmission schedule. Without requiring a patient to provide blood samples for in vitro reference glucose readings, the present disclosure is operable to reject noise from sparsely sampled data from an in vivo analyte sensor.

(10) According to some embodiments of the present disclosure, a dataset representative of a patient's monitored analyte concentration level (herein referred to as “sensor data”) over time is received from an on-body device that includes sensor electronics operatively coupled to an analyte sensor that is in fluid contact with interstitial fluid. In some embodiments, the sensor data may represent a collection of data received from the on-body device at several different times during a wear period of the on-body device. In some other embodiments, the sensor data may represent data collected and stored over an entire wear period of the on-body device and only received from the on-body device at the end of the wear period or at the end of the useful life of the on-body device. In other words, the sensor data can be transmitted continuously, on a regular schedule, in multiple batches over time, in batches on demand, or in a single batch.

(11) Embodiments of the present disclosure may be applied to any analyte concentration level determination system that may exhibit or at least be suspected of exhibiting, or that may be susceptible to noise in the sensor data. Embodiments of the invention are described primarily with respect to continuous glucose monitoring devices and systems but the present disclosure may be applied to other analytes and analyte characteristics, as well as data from measurement systems that transmit sensor data from a sensor unit to another unit such as a processing or display unit in response to a request from the other unit. For example, other analytes that may be monitored include, but are not limited to, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glutamine, growth hormones, hormones, ketones, 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 the embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times. The present disclosure also provides numerous additional embodiments.

(12) Embodiments of the present disclosure may include a programmed computer system adapted to receive and store data from an analyte monitoring system. The computer system may include one or more processors for executing instructions or programs that implement the methods described herein. The computer system may include memory and persistent storage devices to store and manipulate the instructions and sensor data received from the analyte monitoring system. The computer system may also include communications facilities (e.g., wireless and/or wired) to enable transfer of the sensor data from the analyte monitoring system to the computer. The computer system may include a display and/or output devices for identifying dropouts in the sensor data to a user. The computer system may include input devices and various other components (e.g., power supply, operating system, clock, etc.) that are typically found in a conventional computer system. In some embodiments, the computer system may be integral to the analyte monitoring system. For example, the computer system may be embodied as a handheld or portable receiver unit within the analyte monitoring system.

(13) The various methods described herein for performing one or more processes also described herein may be embodied as computer programs (e.g., computer executable instructions and data structures) developed using an object oriented programming language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. However, any practicable programming language and/or techniques may be used. The software for performing the inventive processes, which may be stored in a memory or storage device of the computer system described herein, may be developed by a person of ordinary skill in the art based upon the present disclosure and may include one or more computer program products. The computer program products may be stored on a computer readable medium such as a server memory, a computer network, the Internet, and/or a computer storage device. Note that in some cases the methods embodied as software may be described herein with respect to a particular order of operation or execution. However, it will be understood by one of ordinary skill that any practicable order of operation or execution is possible and such variations are contemplated by this specification of the present disclosure.

(14) Rejecting noise can be essential in generating an accurate representation of an analyte concentration level using an analyte monitoring system. In some analyte monitoring systems, for example, the sensor data can include a window of sparsely sampled data long enough to cover a significant portion of a day, e.g., a 6 to 12 hour window with datapoints every 10 to 20 minutes. In addition to noise, some of the data points may not be available due to data quality issues. A reliable analyte measurement system according to the present disclosure can reject noise and recover missing data using the remaining sparsely sampled data.

(15) Conventional filtering methods can apply a relatively simple approach that is robust to intermittent signal loss and noise. This method includes fitting one or more parameters of a pre-determined polynomial structure over a window of sensor data using the Least-Squares Error (LS) fit method. An analytical solution can be derived for each of the parameters, as long as there is sufficiency of excitation and the number of parameters identified remain small (e.g. up to 3 parameters). This means that polynomials with up to three degrees of freedom (e.g., linear (a straight line with 0 intercept); affine (straight line with general intercept); or parabolic) can be considered. For numerical robustness with respect to noise, affine functions are considered. Up to two parameters are estimated, namely the slope and intercept.

(16) FIG. 1 is a graph 100 of sensor data values plotted over time. The graph 100 illustrates an example of a LS fit of a straight line 102 to estimate a value at a time of interest 104 and the rate of

change (i.e. the slope of the LS fit), whether or not the source data at time of interest **104** is available. In the example shown in FIG. **1**, the time of interest **104** is inside the measurement window **106**. The filled solid circles represent available and valid data points within the measurement window **106**. As will be shown in more detail with respect to FIG. **2**, the LS fit method allows recovery of missing data based on neighboring raw sensor data. However, as will also be illustrated below, obtaining an estimate outside the window **106**, whose instance is relatively distant from the center of the measurement window **106** and large relative to the size of the measurement window **106**, can exaggerate the negative effects of extrapolation.

(17) LS fit of a straight line of data in a measurement window can be used to achieve robust signal recovery and noise rejection. For example, suppose an LS fit of a straight line is determined using three data points spaced fifteen minutes apart and the LS fit estimate at the center data point is used as the output. FIG. **2** depicts a graph **200** of an example of a raw sensor data set plot *z* stored at fifteen minute intervals. In this example, curve *y.sub.c* is the resulting LS fit estimate using the method described above with respect to FIG. **1**, based on three *z* neighboring values and estimating the center value. In general, curve *y.sub.c* is a smoother representation of the sensor data values compared to plot *z*. However, the values around fast transitions (e.g., around the peak at 26 Hr. and valley at 27 Hr.) are severely attenuated, which is evident from the reduced dynamic range (or roughly peak-to-peak distance) of the LS fit result compared to plot *z*.

(18) When the LS fit is used to estimate a value at the edge of the window or slightly outside of the window, the attenuation rounding effect is replaced by noise amplification associated with extrapolation. However, when results of two extrapolations (or near extrapolation in the case where the estimate lies on the edge of the window) are combined such that the estimate lies on the same sample instance, and one window uses past data while the other uses future data, the result is a reasonably smooth signal with exaggerated sharp apexes. This result is shown as curve *y.sub.s* in the graph **300** of FIG. **3**, which is generally smoother than plot *z*, but errs on the opposite side of plot *z* compared to curve *y.sub.c*.

(19) To overcome the attenuation around fast transitions introduced by interpolation filtering methods and the exaggerated fast transitions introduced by extrapolation filtering methods, the methods of the present disclosure combine interpolation based estimates and extrapolation based estimates. As shown in the graph **400** of FIG. **4**, when the interpolation-based calculation for curve *y.sub.c* (LS fit based calculation inside the measurement window) and the extrapolation-based calculation for curve *y.sub.s* (LS fit based calculation outside the measurement window) are combined, the result is curve *y.sub.a*. Note that curve *y.sub.a* traces plot *z* relatively accurately in this example that does not contain significant noise to reject and/or data loss to recover. However, turning now to FIG. **5**, the efficacy of this combination in rejecting noisy sensor data is graphically demonstrated.

(20) FIG. **5** is a graph **500** that depicts methods of the present disclosure applied to an example of a noisy sensor data segment. Plot *z* represents noisy raw sensor data sampled and presented in one minute increments. Curve *y.sub.b* represents reference glucose measurements taken every fifteen minutes, visually connected by dotted lines. When the noisy sensor data of plot *z* is used for a sensor output calculation that involves a rate of change calculation, the resulting output at fifteen minute intervals is shown as curve *y.sub.b'*. Plot *z.sub.c* represents conditioned sensor data sampled and presented in fifteen minute increments. If the same sensor output calculation uses the conditioning of the present disclosure (i.e., uses plot *z.sub.c* as the input data) instead of plot *z*, the resulting output at fifteen minute intervals is shown as curve *y.sub.b''*. As can be seen in FIG. **5**, using the methods of the present disclosure, there is a significant reduction of the noise in the analyte measurement system output in the presence of noisy raw analyte sensor data input. Further, as illustrated in FIG. **4**, the estimation methods of the present disclosure do not attenuate the amplitude of true analyte sensor data excursions and sensor data segments with low noise are not affected.

(21) Turning now to FIG. 6, a flow chart **600** depicting example methods of the present disclosure is provided. As indicated above, the methods of the present disclosure can be implemented on a computer or other processing device. In some embodiments, raw sensor data is received from an on-body device that includes an in vivo analyte sensor (**602**). The raw sensor data may represent data sampled over a period of time during the use of the on-body device. The sample rate may be less than ten or fifteen minutes such that the data collected is sparsely sampled as defined above. In some embodiments, the set of data received may include data collected and stored over an entire wear period.

(22) An interpolation-based estimate of the analyte level over time is determined based on the raw set of sensor data (**604**). The interpolation-based estimate can be computed based on a least squares fit based calculation of analyte sensor data values within a predefined measurement window. For example, given values $z(t_0)$, $z(t_1)$, $z(t_2)$, up to $z(t_N)$, the estimate $y_{\text{sub.c}}(t_e)$ at time t_e as well as the slope $v_{\text{sub.c}}(t_e)$ at time t_e based on a least-squares fit of a line can be computed by the following equation:

$$(23) \begin{bmatrix} y_{\text{c}}(t_e) \\ v_{\text{c}}(t_e) \end{bmatrix} = [\Phi^T \Phi]^{-1} \Phi^T Y$$

$$(24) Y = \begin{bmatrix} z(t_0) \\ \text{.Math.} \\ z(t_N) \end{bmatrix}, \quad \Phi = \begin{bmatrix} 1 & t_0 - t_e \\ \text{.Math.} & \text{.Math.} \\ 1 & t_N - t_e \end{bmatrix}$$

where:

Without loss of generality, suppose only up to three values of z are used to form a window at any time, and that the values are spaced at regular sample interval T_s . Then, for the least-squares estimate at the center:

$$t_1 = t_e - T_s$$

$$t_2 = t_e$$

$$t_3 = t_e + T_s$$

The estimated values $y_{\text{sub.c}}(t_e)$ and $v_{\text{sub.c}}(t_e)$ are then computed as follows:

$$(25) \begin{bmatrix} y_{\text{c}}(t_e) \\ v_{\text{c}}(t_e) \end{bmatrix} = [\Phi^T \Phi]^{-1} \Phi^T Y$$

$$(26) Y = \begin{bmatrix} z(t_1) \\ z(t_2) \\ z(t_3) \end{bmatrix}, \quad \Phi = \begin{bmatrix} 1 & t_1 - t_e \\ 1 & t_2 - t_e \\ 1 & t_3 - t_e \end{bmatrix} = \begin{bmatrix} 1 & -T_s \\ 1 & 0 \\ 1 & T_s \end{bmatrix}$$

where:

Likewise, an extrapolation-based estimate of the analyte level over time is determined based on the raw set of sensor data (**606**). The extrapolation-based estimate can be computed based on a least squares fit based calculation of analyte sensor data values outside or at the left edge of a predefined measurement window. Then, for the least-squares estimate $y_l(t_e)$ and $v_l(t_e)$ at the left of a window of data values $z(t_2)$, $z(t_3)$, $z(t_4)$ with t_e at t_2 :

$$t_2 = t_e$$

$$t_3 = t_e + T_s$$

$$t_4 = t_e + 2T_s$$

The estimated values $y_l(t_e)$ and $v_l(t_e)$ are then computed as follows:

$$(27) \begin{bmatrix} y_l(t_e) \\ v_l(t_e) \end{bmatrix} = [\Phi^T \Phi]^{-1} \Phi^T Y$$

$$(28) Y = \begin{bmatrix} z(t2) \\ z(t3) \\ z(t4) \end{bmatrix}, \Phi = \begin{bmatrix} 1 & t2 - te \\ 1 & t3 - te \\ 1 & t4 - te \end{bmatrix} = \begin{bmatrix} 1 & 0 \\ 1 & Ts \\ 1 & 2Ts \end{bmatrix}$$

where:

(29) Similarly, the extrapolation-based estimate of the analyte level over time can be computed based on a combination of an extrapolation using a least squares fit based calculation of analyte sensor data values from the right side or at the right edge of a predefined measurement window of preceding values and a second extrapolation using a least squares fit based calculation of analyte sensor data values from the right side or at the right edge of a predefined measurement window of succeeding values. Then, for the least-squares estimate $y_{sub.r}(te)$ and $v_{sub.r}(te)$ at the right of a window of data values $z(t0)$, $z(t1)$, $z(t2)$ with te at $t2$:

$$t0 = te - 2Ts$$

$$t1 = te - Ts$$

$$t2 = te$$

The estimated values $y_{sub.l}(te)$ and $v_{sub.l}(te)$ are then computed as follows:

$$(30) \begin{bmatrix} y_r(te) \\ v_r(te) \end{bmatrix} = [\Phi^T \Phi]^{-1} \Phi^T Y$$

$$(31) Y = \begin{bmatrix} z(t0) \\ z(t1) \\ z(t2) \end{bmatrix}, \Phi = \begin{bmatrix} 1 & t0 - te \\ 1 & t1 - te \\ 1 & t2 - te \end{bmatrix} = \begin{bmatrix} 1 & -2Ts \\ 1 & -Ts \\ 1 & 0 \end{bmatrix}$$

where:

(32) A combined estimate of the analyte level over time is determined based on the interpolation-based estimate and the extrapolation-based estimate (608). For example, when all calculations yc , yr , and yl are available, an estimate can be calculated by taking the average of the left and right:

$$ys(te) = [yr(te) + yl(te)]/2$$

Which is then combined with the interpolation based estimate to obtain a final estimated value:

$$ya(te) = [ys(te) + y_{sub.c}(te)]/2$$

Alternatively, a final estimate can be obtained by a weighted average of the calculations yc , yr and yl in a more general manner:

$$ya(te) = Kc y_{sub.c}(te) + Kl yl(te) + Kr yr(te)$$

where the sum of Kc , Kl and Kr equals 1.

(33) In a more general embodiment, when the number of analyte data points z within a predetermined window may vary, the weights applied to each element of the estimate, for example, yc , yl , and yr , can be a function of the number of available data points. The number of data points available can vary due to certain data points having been disqualified by an upstream data integrity check, having been disqualified by an upstream physiological feasibility check, or having been provided with varying time gaps by an upstream process. Conceptually, elements of the estimate such as yc , yl , or yr , whose number of available points are lower than the desired amount, will have a lower weighting factor in order for the less reliable measurement to exert less influence into the final estimate ya .

(34) In some embodiments, yc , yl , and yr are calculated in the same manner as previously described. Instead of fixed weights Kc , Kl , and Kr as previously described, Kc , Kl , and Kr can take on different values as a function of the number of available data points z in their respective windows. Let the number of available data points be denoted Qc , Ql , and Qr . Then, Kc , Kl , and Kr are such that when Qc , Ql , and Qr is equal to the maximum number of points, Kc , Kl , and Kr will take on their largest possible respective values. As Qc , Ql , and Qr approach zero, then Kc , Kl , and Kr will take on their smallest possible respective values, which may or may not be zero. One way

to achieve this is to use a smooth function that relates K_c , K_l , and K_r to Q_c , Q_l , and Q_r , respectively. Alternatively, Q_c , Q_l , and Q_r may affect the weights K_c , K_l , and K_r in stepwise thresholds.

(35) A numerical example of the embodiment described, using stepwise thresholds is described as follows. For the calculation of $y_{sub.c}$, find 3 available data points z as previously described. If the number of valid points is greater than 2 (i.e., $Q_c \geq 2$), set K_c to 5. If the number of valid points is equal to 2 (i.e., $Q_c = 2$), set K_c to 2.5. Otherwise, set K_c to 0. This can be achieved by using a function evaluated at the discrete available number of points Q_c , or by evaluating Q_c against threshold value 2. For the calculation of y_l , find 3 available data points z as previously described. If $Q_l > 2$, set K_l to 1. If $Q_l = 2$, set K_l to 0.4. Otherwise, since there is insufficient number of points, set K_l to 0. For the calculation of y_r , find 3 available data points z as previously described. If $Q_r > 2$, set K_r to 1. If $Q_r = 2$, set K_r to 0.4. Otherwise, set K_r to 0. In addition, if both y_l and y_r can be calculated, calculate the mean of both values, $y_m = [y_l + y_r] / 2$. A new weight K_m is assigned the value 6 if both can be calculated or 0 otherwise. Finally, an estimate that is robust to data loss and can generate results under partially missing data, y_f , can be computed by taking the weighted average:

$$y_f = [K_c * y_c + K_l * y_l + K_r * y_r + K_m * y_m] / [K_c + K_l + K_r + K_m],$$

when at least one of the weights K_c , K_l , K_r , or K_m is nonzero. If all of the weights are zero, there is insufficient data to generate a reliable estimate, and no estimate y_f is given.

(36) A representation of the combined estimate of the analyte level over time can then be displayed on an output device operatively coupled to the processor (610). The representation can be, for example, in the form of a graphical plot, a numerical display, or a combination thereof.

(37) In the manner described above, in certain embodiments of the present disclosure, there is provided a method of estimating an analyte level using sparsely sampled analyte sensor data comprising: determining, using a processor, a composite estimate of an analyte level over time based on a combination of an interpolated estimate of the analyte level and an extrapolated estimate of the analyte level, and displaying a representation of the composite estimate of the analyte level over time on an output device.

(38) In certain embodiments, the interpolated estimate of the analyte level and the extrapolated estimate of the analyte level are computed based on a raw set of sensor data.

(39) In certain embodiments, the raw set of sensor data is received from an on-body device including an in vivo analyte sensor.

(40) In certain embodiments, the interpolated estimate of the analyte level over time is computed based on a least squares fit based calculation of analyte sensor data values within a predefined measurement window, and further, wherein the extrapolated estimate of the analyte level over time is computed based on more than one least squares fit based calculation of analyte sensor data values outside or at the edge of the predefined measurement window.

(41) In certain embodiments, the interpolated estimate of the analyte level over time is computed based on a least squares fit based calculation of analyte sensor data values within a predefined measurement window, and further, wherein the extrapolated estimate of the analyte level over time is computed based on a combination of a first extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a first predefined measurement window and a second extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a second predefined measurement window.

(42) In certain embodiments, the first predefined measurement window uses analyte sensor data values from a time before a data point of interest and wherein the second predefined measurement window uses analyte sensor data values from a time after the data point of interest.

(43) A computer-implemented method in certain embodiments includes receiving a raw set of sensor data from an on-body device including an in vivo analyte sensor, determining an interpolation-based estimate of an analyte level over time based on the raw set of sensor data,

determining an extrapolation-based estimate of the analyte level over time based on the raw set of sensor data, determining a combined estimate of the analyte level over time based on the interpolation-based estimate and the extrapolation-based estimate, and displaying a representation of the combined estimate of the analyte level over time on an output device.

(44) In certain embodiments, the interpolation-based estimate of the analyte level over time based on the raw set of sensor data is computed based on a least squares fit based calculation of analyte sensor data values within a predefined measurement window.

(45) In certain embodiments, the extrapolation-based estimate of the analyte level over time based on the raw set of sensor data is computed based on more than one least squares fit based calculation of analyte sensor data values outside or at the edge of a predefined measurement window.

(46) In certain embodiments, the extrapolation-based estimate of the analyte level over time based on the raw set of sensor data is computed based on a combination of a first extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a first predefined measurement window and a second extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a second predefined measurement window.

(47) In certain embodiments, the first predefined measurement window uses analyte sensor data values from a time before a data point of interest and wherein the second predefined measurement window uses analyte sensor data values from a time after the data point of interest.

(48) In certain embodiments, the raw set of sensor data includes data sampled at a rate less than once per ten minutes.

(49) In certain embodiments, the representation of the combined estimate of the analyte level over time includes at least one of a graph and a numeric display.

(50) A system for monitoring analyte concentration in certain embodiments includes a processor, and a memory coupled to the processor, the memory storing processor executable instructions to: receive a raw set of sensor data from an on-body device including an in vivo analyte sensor, determine an interpolation-based estimate of an analyte level over time based on the raw set of sensor data, determine an extrapolation-based estimate of the analyte level over time based on the raw set of sensor data, determine a combined estimate of the analyte level over time based on the interpolation-based estimate and the extrapolation-based estimate, display a representation of the combined estimate of the analyte level over time on an output device operatively coupled to the processor.

(51) In certain embodiments, the instruction to determine the interpolation-based estimate of the analyte level over time based on the raw set of sensor data includes an instruction to determine the interpolation-based estimate based on a least squares fit based calculation of analyte sensor data values within a predefined measurement window.

(52) In certain embodiments, the instruction to determine the extrapolation-based estimate of the analyte level over time based on the raw set of sensor data includes an instruction to determine the extrapolation-based estimate based on more than one least squares fit based calculation of analyte sensor data values outside or at the edge of a predefined measurement window.

(53) In certain embodiments, the instruction to determine the extrapolation-based estimate of the analyte level over time based on the raw set of sensor data includes an instruction to determine the extrapolation-based estimate based on a combination of a first extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a first predefined measurement window and a second extrapolation using a least squares fit based calculation of analyte sensor data values outside or at the edge of a second predefined measurement window.

(54) In certain embodiments, the first predefined measurement window uses analyte sensor data values from a time before a data point of interest and wherein the second predefined measurement window uses analyte sensor data values from a time after the data point of interest.

(55) In certain embodiments, the raw set of sensor data includes data sampled at a rate less than

once per ten minutes.

(56) In certain embodiments, the instruction to display the representation of the combined estimate of the analyte level over time on the output device includes an instruction to display at least one of a graph and a numeric display.

(57) A computer-implemented method in certain embodiments includes receiving a raw set of sensor data from an on-body device including an in vivo analyte sensor, determining an interpolation-based estimate of an analyte level over time based on the raw set of sensor data, determining an extrapolation-based estimate of the analyte level over time based on the raw set of sensor data, determining weights of each estimate based on the number of available sensor data used to compute each estimate, determining a combined estimate of the analyte level over time based on the weighted average of the interpolation-based estimate and the extrapolation-based estimate, displaying a representation of the combined estimate of the analyte level over time on an output device.

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

Claims

1. A method of monitoring a glucose concentration using a glucose sensor having a processor configured to be positioned in contact with a fluid under a skin layer of a subject, the method comprising: receiving a plurality of data points within a period of time, the plurality of data points corresponding to a glucose level of the subject; determining, based on the plurality of data points, interpolated estimates of the glucose level of the subject; determining, based on a first portion of the plurality of data points, a first set of extrapolated estimates of the glucose level of the subject; determining, based on a second portion of the plurality of data points, a second set of extrapolated estimates of the glucose level of the subject, wherein the second portion of the plurality of data points correspond to time points associated with later time points than the first portion of the plurality of data points; determining, using the processor of the glucose sensor, composite estimates of the glucose level of the subject based on a combination of the interpolated estimates, the first set of extrapolated estimates, and the second set of extrapolated estimates, wherein determining the composite estimates comprises applying weights to the interpolated estimates and the first and second sets of extrapolated estimates, the weights being determined based on a function of a number of the plurality of data points; and providing, to a display associated with the glucose sensor, the composite estimate of the glucose level of the subject.
2. The method of claim 1, wherein the plurality of data points within the period of time are sparsely sampled data generated by the glucose sensor.
3. The method of claim 1, wherein the interpolated estimates of the glucose level and the first set and the second set of extrapolated estimates of the glucose level are computed based on a raw set of data from the glucose sensor.
4. The method of claim 3, wherein the raw set of data from the glucose sensor includes data sampled at a rate less than once per minute.
5. The method of claim 1, wherein glucose sensor is an in vivo analyte sensor.
6. The method of claim 1, wherein the interpolated estimates of the glucose level are based on a least squares fit based calculation.
7. The method of claim 1, wherein each of the first set and the second set of extrapolated estimates

of the glucose level are based on a more than one least squares fit based calculation.

8. The method of claim 1, wherein each of the first set and the second set of extrapolated estimates of the glucose level are based on a combination of a first extrapolation based on a least squares fit based calculation and a second extrapolation based on a least squares fit based calculation.

9. The method of claim 1, wherein the display associated with the glucose sensor is configured to display the first set of extrapolated estimates or the second set of extrapolated estimates based at least an estimated glucose value outside the period of time.

10. A system for monitoring glucose concentration, the system comprising: a processor; and memory coupled to the processor, the memory storing instructions to: receive a plurality of data points within a period of time, the plurality of data points corresponding to a glucose level of a subject; determine, based on the plurality of data points, interpolated estimates of the glucose level of the subject; determine, based on a first portion of the plurality of data points, a first set of extrapolated estimates of the glucose level of the subject; determine, based on a second portion of the plurality of data points, a second set of extrapolated estimates of the glucose level of the subject, wherein the second portion of the plurality of data points correspond to time points associated with later time points than the first portion of the plurality of data points; and determine composite estimates of a glucose level of the subject based on a combination of the interpolated estimates, the first set of extrapolated estimates, and the second set of extrapolated estimates, wherein the composite estimates of the glucose level are determined based on data sampled by a glucose sensor that is configured to be positioned in contact with a fluid under a skin layer of the subject, wherein determining the composite estimates comprises applying weights to the interpolated estimates and the first and second sets of extrapolated estimates, the weights being determined based on a function of a number of the plurality of data points.

11. The system of claim 10, wherein the instructions are further configured to cause the system to display a representation of the composite estimates of the glucose level.

12. The system of claim 10, wherein the plurality of data points within the period of time are sparsely sampled analyte sensor data generated by the glucose sensor.

13. The system of claim 10, wherein the interpolated estimates of the glucose level and the first set and the second set of extrapolated estimates of the glucose level are computed based on a raw set of data from the glucose sensor.

14. The system of claim 13, wherein the raw set of data from the glucose sensor includes data sampled at a rate less than once per minute.

15. The system of claim 10, wherein glucose sensor is an in vivo glucose sensor.

16. The system of claim 10, wherein the interpolated estimates of the glucose level are based on a least squares fit based calculation.

17. The system of claim 10, wherein each of the first set and the second set of extrapolated estimates of the glucose level are based on a more than one least squares fit based calculation.

18. The system of claim 10, wherein the instructions are further configured to cause the system to display the first set of extrapolated estimates or the second set of extrapolated estimates based at least an estimated glucose value outside the period of time.

19. An apparatus for monitoring analyte concentration, the apparatus comprising: an on-body device including an in vivo glucose sensor that is configured to be positioned in contact with a fluid under a skin layer of a subject, wherein the apparatus is configured to: receive a plurality of data points within a period of time, the plurality of data points corresponding to a glucose level of a subject; determine, based on the plurality of data points, interpolated estimates of the glucose level of the subject; determine, based on a first portion of the plurality of data points, a first set of extrapolated estimates of the glucose level of the subject; determine, based on a second portion of the plurality of data points, a second set of extrapolated estimates of the glucose level of the subject, wherein the second portion of the plurality of data points correspond to time points associated with later time points than the first portion of the plurality of data points; and determine

composite estimates of a glucose level based on a combination of the interpolated estimates, the first set of extrapolated estimates, and the second set of extrapolated estimates, wherein determining the composite estimates comprises applying weights to the interpolated estimates and the first and second sets of extrapolated estimates, the weights being determined based on a function of a number of the plurality of data points.

20. The apparatus of claim 19, wherein the apparatus is further configured to send instructions to an associated display for displaying the first set of extrapolated estimates or the second set of extrapolated estimates based at least an estimated glucose value outside the period of time.
