Docket Nos.: A0130.0090.C7
9368USC7

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wesley Scott Harper

Application No.: To be assigned

Confirmation No.: To be assigned

Filed: August 25, 2021

Art Unit: To be assigned

For: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

Examiner: To be assigned

PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination on the merits, please see the following:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 7 of this paper.

DEXCOM
EXHIBIT 1002

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-22. (Canceled)

23. (New) A glucose monitoring system, comprising:

(1) an on body unit configured to be positioned on a user's body, the on body unit comprising:

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user and provide glucose related sensor data; and

a data processing and transmitter unit coupled with the glucose sensor, wherein the data processing and transmitter unit is configured to:

receive the glucose related sensor data from the glucose sensor;

process the glucose related sensor data to provide processed sensor data;

store, in memory of the data processing and transmitter unit during a time period associated with a failure mode condition, the glucose related sensor data, the processed sensor data, or both; and

transmit the processed sensor data over a Bluetooth wireless communication link; and

(2) a receiver unit, comprising:

a radio frequency receiver and an antenna configured to receive the processed sensor data transmitted by the data processing and transmitter unit over the Bluetooth wireless communication link;

a display configured to display numerical values and graphical representations of the processed sensor data; and

a processor coupled with memory of the receiver unit, wherein instructions stored in the memory of the receiver unit, when executed by the processor, cause the processor to:

detect the presence of the data processing and transmitter unit when the data processing and transmitter unit is within a range of the receiver unit,

establish the Bluetooth wireless communication link with the data processing and transmitter unit,

output a first graphical representation of the processed sensor data to the display of the receiver unit, wherein the first graphical representation comprises a first line graph, and wherein an end of the first line graph correlates with a time associated with a start of the failure mode condition, and

output a second graphical representation of the processed sensor data to the display of the receiver unit after the failure mode condition has been corrected, wherein the second graphical representation comprises a second line graph having a length greater than the first line graph.

24. (New) The glucose monitoring system of claim 23, wherein the first line graph comprises processed sensor data received before the start of the failure mode condition, and

wherein the second line graph comprises processed sensor data received before and after the start of the failure mode condition.

25. (New) The glucose monitoring system of claim 24, wherein the first line graph is outputted to the display of the receiver unit during a first time period, and wherein the second line graph is outputted to the display of the receiver unit during a second time period occurring after the first time period.

26. (New) The glucose monitoring system of claim 25, wherein the first line graph and the second line graph are outputted to a same graph comprising a first axis having a time unit of measurement and a second axis having a glucose concentration unit of measurement.

27. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor communication error.

28. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the glucose sensor.

29. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the data processing and transmitter unit.

30. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with the receiver unit.

31. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a system malfunction associated with the data processing and transmitter unit or a system malfunction associated with the receiver unit.

32. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor dislodgement.

33. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an inability of the receiver unit to display or output the graphical representations of the processed sensor data to the display.

34. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an inability to calibrate the glucose sensor.

35. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor instability condition.

36. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a calibration failure condition.

37. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a monitoring system failure condition.

38. (New) The glucose monitoring system of claim 23, wherein the glucose sensor comprises a working electrode and a counter electrode.

39. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a sensor misposition error.

40. (New) The glucose monitoring system of claim 23, wherein the on body unit further comprises a temperature sensor, and wherein the failure mode condition comprises a temperature measurement outside a predetermined range.

41. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises an analyte level exceeding a predetermined threshold.

42. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a rate of change of an analyte level exceeding a predetermined threshold.

43. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a signal error associated with reference data.

44. (New) The glucose monitoring system of claim 23, wherein the failure mode condition comprises a data unavailability condition.

45. (New) The glucose monitoring system of claim 23, wherein the instructions stored in the memory of the receiver unit, when executed by the processor, further cause the processor to display the second line graph immediately after the correction of the failure mode condition.

46. (New) The glucose monitoring system of claim 23, wherein the instructions stored in the memory of the receiver unit, when executed by the processor, further cause the processor to wait a predetermined period of time after the correction of the failure mode condition before displaying the second line graph.

47. (New) The glucose monitoring system of claim 23, wherein the data processing and transmitter unit, the receiver unit, or both is further configured to store time information associated with the failure mode condition.

48. (New) The glucose monitoring system of claim 23, wherein the on body unit comprises a single integrated housing, and wherein the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within the single integrated housing.

49. (New) The glucose monitoring system of claim 23, wherein the receiver unit comprises a mobile phone.

50. (New) The glucose monitoring system of claim 23, wherein the time period associated with the failure mode condition comprises at least one hour.

51. (New) The glucose monitoring system of claim 23, wherein the first line graph is non-continuous before the failure mode has been corrected.

52. (New) The glucose monitoring system of claim 23, wherein the second line graph is continuous after the failure mode has been corrected.

REMARKS

Claims 23-52 are pending and claims 1-22 have been canceled without prejudice. Support for the new claims can be found, for example, at paragraphs [0030] to [0033] and [0052] to [0086], as well as Figures 4 to 6, 7A, and 7B, the original claims, and elsewhere throughout the application as filed. No new matter has been introduced. Examination of these new claims are respectfully requested.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: August 25, 2021

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0090.C7

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	10	100	1000
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**7160**

Electronic Acknowledgement Receipt

EFS ID:	43591634
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	25-AUG-2021
Filing Date:	
Time Stamp:	10:30:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$7160
RAM confirmation Number	E20218OA30494055
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	9368USC7_A0130_0090_C7_Track_One_Request.pdf	152461 97a35f53b2db19371611d31e00c5d6a2467c000c	no	2
Warnings:					
Information:					
2	Application Data Sheet	9368USC7_A0130_0090_C7_ADS.pdf	1256533 adcc083488c28251de22db049f3a7d9d2c1d3a7a	no	9
Warnings:					
Information:					
3		9368USC7_A0130_0090_C7_Specification.pdf	163591 02c4bdec2ee97c2192c04e0a9e3365e7f90d0784	yes	25

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	20
Claims	21	24
Abstract	25	25

Warnings:					
Information:					
4	Drawings-only black and white line drawings	9368USC7_A0130_0090_C7_Figures.pdf	210832 c8f4b5d0607abb09162e056bff2d32400703a4bc	no	7
Warnings:					
Information:					
5	Oath or Declaration filed	9368USC7_A0130_0090_C7_Declaration.pdf	508797 993c4a73e159a52a165d96ea04e9aa960809724c	no	2

Warnings:					
Information:					
6	Transmittal Letter	9368USC7_A0130_0090_C7_IDS_Transmittal.pdf	91693 a8bb1b18621f209ed5e6ff453fecc11b74c60935	no	4
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	9368USC7_A0130_0090_C7_IDS_1449.pdf	396814 6167ff4cf923c6cdd423982442b4e6a8e16b7687	no	21
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
8		9368USC7_A0130_0090_C7_Preliminary_Amendment.pdf	103758 e2fe4411baf39229073165d8e2d45df41cd89418	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	8

Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	53135 9b6d560642e4dec0232e7315d5ecca21e57f8c82	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	2937614	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Wesley Scott Harper	Nonprovisional Application Number (if known):	
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Glen Liu/	Date 8/25/2021
Name (Print/Typed) Glen Liu	Practitioner Registration Number 75,058

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Wesley	Scott	Harper	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	Alameda	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	15 Ferro Court		
Address 2			
City	Alameda	State/Province	CA
Postal Code	94502	Country	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	95508		
Email Address	ipdocketing@onellp.com	Add Email	Remove Email

Application Information:

Title of the Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING		
Attorney Docket Number	A0130.0090.C7	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	7	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	95508		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	17245719	2021-04-30

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Prior Application Status: Patented — Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
17245719	Continuation of	16228910	2018-12-21	11013431	2021-05-25

Prior Application Status: Patented — Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16228910	Continuation of	15061774	2016-03-04	10194844	2019-02-05

Prior Application Status: Patented — Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15061774	Continuation of	13925694	2013-06-24	9310230	2016-04-12

Prior Application Status: Patented — Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13925694	Continuation of	12769635	2010-04-28	8483967	2013-07-09

Prior Application Status: Expired — Remove

Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
12769635	Claims benefit of provisional	61173600	2009-04-29

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. — Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[j] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. — Add

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	ABBOTT DIABETES CARE INC.		
Mailing Address Information For Applicant:			
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Address 2			
City	Alameda	**State/Province**	CA
Country	US	Postal Code	94502
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

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This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Glen Liu/			Date (YYYY-MM-DD)	2021-08-25
First Name	Glen	Last Name	Liu	Registration Number	75058

Additional Signature may be generated within this form by selecting the Add button. Add

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0090.C7
	Application Number	
Title of Invention	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	

This collection of information is required by 37 CFR 1.76. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1 The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3 A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent CooperationTreaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 17/245,719, filed April 30, 2021, which is a continuation of U.S. Patent Application No. 16/228,910, filed December 21, 2018, now U.S. Patent No. 11,013,431, which is a continuation of U.S. Patent Application No. 15/061,774, filed March 4, 2016, now U.S. Patent No. 10,194,844, which is a continuation of U.S. Patent Application No. 13/925,694, filed June 24, 2013, now U.S. Patent No. 9,310,230, which is a continuation of U.S. Patent Application No. 12/769,635, filed April 28, 2010, now U.S. Patent No. 8,483,967, which claims the benefit of U.S. Provisional Patent Application No. 61/173,600, filed April 29, 2009, the disclosures of all of which are incorporated herein by reference in their entireties for all purposes.

BACKGROUND

[0002] Analyte, e.g., glucose monitoring systems including continuous and discrete monitoring systems generally include a small, lightweight battery powered and microprocessor controlled system which is configured to detect signals proportional to the corresponding measured glucose levels using an electrometer. RF signals may be used to transmit the collected data. One aspect of certain analyte monitoring systems includes a transcutaneous or subcutaneous analyte sensor configuration which is, for example, at least partially positioned through the skin layer of a subject whose analyte level is to be monitored. The sensor may use a two or three-electrode (work, reference and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit connected through a contact system.

[0003] An analyte sensor may be configured so that a portion thereof is placed under the skin of the patient so as to contact analyte of the patient, and another portion or segment of the analyte sensor may be in communication with the transmitter unit. The transmitter unit may be configured to transmit the analyte levels detected by the sensor over a wireless communication link such as an RF (radio frequency) communication link to a receiver/monitor unit. The receiver/monitor unit may perform data analysis, among other functions, on the received analyte levels to generate information pertaining to the monitored analyte levels.

SUMMARY

[0004] Devices and methods for analyte monitoring, e.g., glucose monitoring, and/or therapy management system including, for example, medication infusion devices are provided. Embodiments include transmitting information from a first location to a second, e.g., using a telemetry system such as RF telemetry. Systems herein include continuous analyte monitoring systems, discrete analyte monitoring system, and therapy management systems.

[0005] Embodiments include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during a adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

[0006] Embodiments include detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period, disabling output of information associated with the analyte sensor, determining a successful calibration of the analyte sensor, retrieving one or more parameters associated with the successful calibration, processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration, and displaying the processed sensor data for the time period of disabled information output.

[0007] Embodiments include an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data, and a display unit coupled to the second memory and configured to display the processed sensor data, where the processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the

successful calibration, and display the processed sensor data for the time period of disabled information output.

[0008] These and other objects, features and advantages of the present disclosure will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

INCORPORATION BY REFERENCE

[0009] The following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Patent Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,167,818; and 7,299,082; U.S. Published Application Nos. 2004/0186365; 2005/0182306; 2007/0056858; 2007/0068807; 2007/0227911; 2007/0233013; 2008/0081977; 2008/0161666; and 2009/0054748; U.S. Patent Application Nos. 11/831,866; 11/831,881; 11/831,895; 12/102,839; 12/102,844; 12/102,847; 12/102,855; 12/102,856; 12/152,636; 12/152,648; 12/152,650; 12/152,652; 12/152,657; 12/152,662; 12/152,670; 12/152,673; 12/363,712; 12/131,012; 12/242,823; 12/363,712; 12/393,921; 12/495,709; 12/698,124; 12/699,653; 12/699,844; 12/714,439; 12/761,372; and 12/761,387 and U.S. Provisional Application Nos. 61/230,686 and 61/227,967.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present disclosure;

[0011] FIG. 2 is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure;

[0012] FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure;

[0013] FIG. 4 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure;

[0014] FIG. 5 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure;

[0015] FIG. 6 illustrates backfilling gaps in sensor data in one embodiment of the present disclosure; and

[0016] FIGS. 7A and 7B illustrate backfill of gaps of a period of uncalibrated sensor data in one embodiment.

DETAILED DESCRIPTION

[0017] Before the present disclosure is described in additional detail, it is to be understood that this disclosure is not limited to particular embodiments described, as such may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present disclosure will be limited only by the appended claims.

[0018] Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the disclosure. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the disclosure, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the disclosure.

[0019] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosure, the preferred methods and materials are now described. All publications mentioned herein are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited.

[0020] It must be noted that as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise.

[0021] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosure is not entitled to antedate such publication by virtue of prior disclosure. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

[0022] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosure.

[0023] The figures shown herein are not necessarily drawn to scale, with some components and features being exaggerated for clarity.

[0024] As described in further detail below, in accordance with the various embodiments of the present disclosure, there is provided a method and system for positioning a controller unit within a transmission range for close proximity communication, transmitting one or more predefined close proximity commands, and receiving a response packet in response to the transmitted one or more predefined close proximity commands. For example, in one aspect, close proximity communication includes short range wireless communication between communication components or devices, where the communication range is limited to about 10 inches or less, about 5 inches or less, or about 2 inches or less, or other suitable, short range or distance between the devices. The close proximity wireless communication in certain embodiments includes a bi-directional communication where a command sending communication device, when positioned within the short communication range or in close proximity to the command receiving communication device, is configured to transmit one or more commands to the command receiving communication device (for example, when a user activates or actuates a transmit command button or switch). In response, the command receiving communication device may be configured to perform one or more routines associated with the received command, and/or return or send back a response data packet or signal to the command sending communication device. Example of such functions and or commands may include, but not limited to activation of certain functions or routines such as analyte related data processing, and the like.

[0025] FIG. 1 illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system 100 in accordance with one embodiment of the present

disclosure. The subject invention is further described primarily with respect to a glucose monitoring system for convenience and such description is in no way intended to limit the scope of the invention. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes, e.g., lactate, and the like.

[0026] Analytes that may be monitored include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, 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. More than one analyte may be monitored by a single system, e.g., a single analyte sensor.

[0027] The analyte monitoring system 100 includes a sensor unit 101, a data processing and transmitter unit 102 coupleable to the sensor unit 101, and a primary receiver unit 104 which is configured to communicate with the data processing and transmitter unit 102 via a bi-directional communication link 103. The primary receiver unit 104 may be further configured to transmit data to a data processing terminal 105 for evaluating the data received by the primary receiver unit 104. Moreover, the data processing terminal 105 in one embodiment may be configured to receive data directly from the data processing and transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication. Accordingly, data processing and transmitter unit 102 and/or receiver unit 104 may include a transceiver.

[0028] Also shown in FIG. 1 is an optional secondary receiver unit 106 which is operatively coupled to the communication link and configured to receive data transmitted from the data processing and transmitter unit 102. Moreover, as shown in the Figure, the secondary receiver unit 106 is configured to communicate with the primary receiver unit 104 as well as the data processing terminal 105. Indeed, the secondary receiver unit 106 may be configured for bi-directional wireless communication with each or one of the primary receiver unit 104 and the data processing terminal 105. As discussed in further detail below, in one embodiment of the present disclosure, the secondary receiver unit 106 may be configured to include a limited number of functions and features as compared with the primary receiver unit 104. As such, the secondary receiver unit 106 may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, pager, mobile phone, PDA, for example.

Alternatively, the secondary receiver unit 106 may be configured with the same or substantially similar functionality as the primary receiver unit 104. The receiver unit may be configured to be used in conjunction with a docking cradle unit, for example for one or more of the following or other functions: placement by bedside, for re-charging, for data management, for night time monitoring, and/or bi-directional communication device.

[0029] In one aspect sensor unit 101 may include two or more sensors, each configured to communicate with data processing and transmitter unit 102. Furthermore, while only one, data processing and transmitter unit 102, communication link 103, and data processing terminal 105 are shown in the embodiment of the analyte monitoring system 100 illustrated in FIG. 1. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system 100 may include one or more sensors, multiple transmitter units 102, communication links 103, and data processing terminals 105. Moreover, within the scope of the present disclosure, the analyte monitoring system 100 may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system 100.

[0030] In one embodiment of the present disclosure, the sensor unit 101 is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor unit 101 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the data processing and transmitter unit 102. In certain embodiments, the data processing and transmitter unit 102 may be physically coupled to the sensor unit 101 so that both devices are integrated in a single housing and positioned on the user's body. The data processing and transmitter unit 102 may perform data processing such as filtering and encoding on data signals and/or other functions, each of which corresponds to a sampled analyte level of the user, and in any event data processing and transmitter unit 102 transmits analyte information to the primary receiver unit 104 via the communication link 103. Examples of such integrated sensor and transmitter units can be found in, among others, U.S. Patent Application No. 12/698,124, incorporated herein by reference.

[0031] In one embodiment, the analyte monitoring system 100 is configured as a one-way RF communication path from the data processing and transmitter unit 102 to the primary receiver

unit 104. In such embodiment, the data processing and transmitter unit 102 transmits the sampled data signals received from the sensor unit 101 without acknowledgement from the primary receiver unit 104 that the transmitted sampled data signals have been received. For example, the data processing and transmitter unit 102 may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the primary receiver unit 104 may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the analyte monitoring system 100 may be configured with a bi-directional RF (or otherwise) communication between the data processing and transmitter unit 102 and the primary receiver unit 104.

[0032] Additionally, in one aspect, the primary receiver unit 104 may include two sections. The first section is an analog interface section that is configured to communicate with the data processing and transmitter unit 102 via the communication link 103. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the data processing and transmitter unit 102, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the primary receiver unit 104 is a data processing section which is configured to process the data signals received from the data processing and transmitter unit 102 such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

[0033] In operation, upon completing the power-on procedure, the primary receiver unit 104 is configured to detect the presence of the data processing and transmitter unit 102 within its range based on, for example, the strength of the detected data signals received from the data processing and transmitter unit 102 and/or a predetermined transmitter identification information. Upon successful synchronization with the corresponding data processing and transmitter unit 102, the primary receiver unit 104 is configured to begin receiving from the data processing and transmitter unit 102 data signals corresponding to the user's detected analyte level. More specifically, the primary receiver unit 104 in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized data processing and transmitter unit 102 via the communication link 103 to obtain the user's detected analyte level.

[0034] Referring again to FIG. 1, the data processing terminal 105 may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital

assistants (PDAs)), and the like, each of which may be configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal 105 may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected analyte level of the user.

[0035] Within the scope of the present disclosure, the data processing terminal 105 may include an infusion device such as an insulin infusion pump (external or implantable) or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit 104 for receiving, among others, the measured analyte level. Alternatively, the receiver unit 104 may be configured to integrate or otherwise couple to an infusion device therein so that the receiver unit 104 is configured to administer insulin therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the data processing and transmitter unit 102.

[0036] Additionally, the data processing and transmitter unit 102, the primary receiver unit 104 and the data processing terminal 105 may each be configured for bi-directional wireless communication such that each of the data processing and transmitter unit 102, the primary receiver unit 104 and the data processing terminal 105 may be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication link 103. More specifically, the data processing terminal 105 may in one embodiment be configured to receive data directly from the data processing and transmitter unit 102 via the communication link 103, where the communication link 103, as described above, may be configured for bi-directional communication.

[0037] In this embodiment, the data processing terminal 105 which may include an insulin pump, may be configured to receive the analyte signals from the data processing and transmitter unit 102, and thus, incorporate the functions of the receiver 104 including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link 103 may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth® enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements) while avoiding potential data collision and interference.

[0038] FIG. 2 is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. 1 in accordance with one embodiment of the present disclosure. Referring to the Figure, the data processing and transmitter unit 102 in one embodiment includes an analog interface 201 configured to communicate with the sensor unit 101 (FIG. 1), a user input 202, and a temperature measurement section 203, each of which is operatively coupled to a transmitter processor 204 such as a central processing unit (CPU). As can be seen from FIG. 2, there are provided four contacts, three of which are electrodes--work electrode (W) 210, guard contact (G) 211, reference electrode (R) 212, and counter electrode (C) 213, each operatively coupled to the analog interface 201 of the data processing and transmitter unit 102 for connection to the sensor unit 101 (FIG. 1). In one embodiment, each of the work electrode (W) 210, guard contact (G) 211, reference electrode (R) 212, and counter electrode (C) 213 may be made using a conductive material that is either printed or etched or ablated, for example, such as carbon which may be printed, or a metal such as a metal foil (e.g., gold) or the like, which may be etched or ablated or otherwise processed to provide one or more electrodes. Fewer or greater electrodes and/or contact may be provided in certain embodiments.

[0039] Further shown in FIG. 2 are a transmitter serial communication section 205 and an RF transmitter 206, each of which is also operatively coupled to the transmitter processor 204. Moreover, a power supply 207 such as a battery is also provided in the data processing and transmitter unit 102 to provide the necessary power for the data processing and transmitter unit 102. In certain embodiments, the power supply 207 also provides the power necessary to power the sensor 101. In other embodiments, the sensor is a self-powered sensor, such as the sensor described in U.S. Patent Application No. 12/393,921, incorporated herein by reference. Additionally, as can be seen from the Figure, clock 208 is provided to, among others, supply real time information to the transmitter processor 204.

[0040] In one embodiment, a unidirectional input path is established from the sensor unit 101 (FIG. 1) and/or manufacturing and testing equipment to the analog interface 201 of the data processing and transmitter unit 102, while a unidirectional output is established from the output of the RF transmitter 206 of the data processing and transmitter unit 102 for transmission to the primary receiver unit 104. In this manner, a data path is shown in FIG. 2 between the aforementioned unidirectional input and output via a dedicated link 209 from the analog interface 201 to serial communication section 205, thereafter to the processor 204, and then to

the RF transmitter 206. As such, in one embodiment, via the data path described above, the data processing and transmitter unit 102 is configured to transmit to the primary receiver unit 104 (FIG. 1), via the communication link 103 (FIG. 1), processed and encoded data signals received from the sensor unit 101 (FIG. 1). Additionally, the unidirectional communication data path between the analog interface 201 and the RF transmitter 206 discussed above allows for the configuration of the data processing and transmitter unit 102 for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

[0041] As discussed above, the transmitter processor 204 is configured to transmit control signals to the various sections of the data processing and transmitter unit 102 during the operation of the data processing and transmitter unit 102. In one embodiment, the transmitter processor 204 also includes a memory (not shown) for storing data such as the identification information for the data processing and transmitter unit 102, as well as the data signals received from the sensor unit 101. The stored information may be retrieved and processed for transmission to the primary receiver unit 104 under the control of the transmitter processor 204. Furthermore, the power supply 207 may include a commercially available battery, which may be a rechargeable battery.

[0042] In certain embodiments, the data processing and transmitter unit 102 is also configured such that the power supply section 207 is capable of providing power to the transmitter for a minimum of about three months of continuous operation, e.g., after having been stored for about eighteen months such as stored in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor 204 operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, a step during the manufacturing process of the data processing and transmitter unit 102 may place the data processing and transmitter unit 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the data processing and transmitter unit 102 may be significantly improved. Moreover, as shown in FIG. 2, while the power supply unit 207 is shown as coupled to the processor 204, and as such, the processor 204 is configured to provide control of the power supply unit 207, it should be noted that within the scope of the present disclosure, the power supply unit 207 is configured to

provide the necessary power to each of the components of the data processing and transmitter unit 102 shown in FIG. 2.

[0043] Referring back to FIG. 2, the power supply section 207 of the data processing and transmitter unit 102 in one embodiment may include a rechargeable battery unit that may be recharged by a separate power supply recharging unit (for example, provided in the receiver unit 104) so that the data processing and transmitter unit 102 may be powered for a longer period of usage time. Moreover, in one embodiment, the data processing and transmitter unit 102 may be configured without a battery in the power supply section 207, in which case the data processing and transmitter unit 102 may be configured to receive power from an external power supply source (for example, a battery) as discussed in further detail below.

[0044] Referring yet again to FIG. 2, the temperature measurement section 203 of the data processing and transmitter unit 102 is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface 201. In certain embodiments, the RF transmitter 206 of the transmitter unit 102 may be configured for operation in the frequency band of approximately 315 MHz to approximately 322 MHz, for example, in the United States. In certain embodiments, the RF transmitter 206 of the transmitter unit 102 may be configured for operation in the frequency band of approximately 400 MHz to approximately 470 MHz. Further, in one embodiment, the RF transmitter 206 is configured to modulate the carrier frequency by performing Frequency Shift Keying and Manchester encoding. In one embodiment, the data transmission rate is about 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit 104.

[0045] Referring yet again to FIG. 2, also shown is a leak detection circuit 214 coupled to the guard electrode (G) 211 and the processor 204 in the transmitter unit 102 of the data monitoring and management system 100. The leak detection circuit 214 in accordance with one embodiment of the present disclosure may be configured to detect leakage current in the sensor unit 101 to determine whether the measured sensor data are corrupt or whether the measured data from the sensor 101 is accurate. Exemplary analyte systems that may be employed are described in, for example, U.S. Patent Nos. 6,134,461, 6,175,752, 6,121,611, 6,560,471, 6,746,582, and elsewhere, the disclosure of each of which are incorporated by reference for all purposes.

[0046] FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure. Referring to FIG. 3, the primary receiver unit 104 includes an analyte test strip, e.g., blood glucose test strip, interface 301, an RF receiver 302, an input 303, a temperature monitor section 304, and a clock 305, each of which is operatively coupled to a receiver processor 307. As can be further seen from the Figure, the primary receiver unit 104 also includes a power supply 306 operatively coupled to a power conversion and monitoring section 308. Further, the power conversion and monitoring section 308 is also coupled to the receiver processor 307. Moreover, also shown are a receiver serial communication section 309, and an output 310, each operatively coupled to the receiver processor 307.

[0047] In one embodiment, the test strip interface 301 includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output 310 of the primary receiver unit 104. This manual testing of glucose may be used to calibrate the sensor unit 101 or otherwise. The RF receiver 302 is configured to communicate, via the communication link 103 (FIG. 1) with the RF transmitter 206 of the transmitter unit 102, to receive encoded data signals from the transmitter unit 102 for, among others, signal mixing, demodulation, and other data processing. The input 303 of the primary receiver unit 104 is configured to allow the user to enter information into the primary receiver unit 104 as needed. In one aspect, the input 303 may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature monitor section 304 is configured to provide temperature information of the primary receiver unit 104 to the receiver processor 307, while the clock 305 provides, among others, real time information to the receiver processor 307.

[0048] Each of the various components of the primary receiver unit 104 shown in FIG. 3 is powered by the power supply 306 which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section 308 is configured to monitor the power usage by the various components in the primary receiver unit 104 for effective power management and to alert the user, for example, in the event of power usage which renders the primary receiver unit 104 in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply 306 while the processor 307 (thus, the

primary receiver unit 104) is turned on. Moreover, the power conversion and monitoring section 308 may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

[0049] The serial communication section 309 in the primary receiver unit 104 is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit 104. Serial communication section 104 can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output 310 of the primary receiver unit 104 is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit 104 also includes an electro-luminescent lamp configured to provide backlighting to the output 310 for output visual display in dark ambient surroundings.

[0050] Referring back to FIG. 3, the primary receiver unit 104 in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor 307, or provided separately in the primary receiver unit 104, operatively coupled to the processor 307. The processor 307 may be configured to synchronize with a transmitter, e.g., using Manchester decoding or the like, as well as error detection and correction upon the encoded data signals received from the transmitter unit 102 via the communication link 103.

[0051] Periodic calibration of the sensor unit 101 (FIG. 1) of an analyte monitoring system 100, in some embodiments, may be required for accurate calculation of a user's analyte level. Calibration, in some aspects, is used to ensure the analyte related data signals received at a transmitter unit 102 (and further transmitted to a receiver unit, such as the primary receiver unit 104) are correctly converted to corresponding analyte levels. Exemplary calibration protocols, routines and techniques are described, for example, in U.S. Patent No. 7,299,082, U.S. Patent Application No. 11/537,991 filed October 2, 2006, U.S. Patent Application No. 12/363,706 filed January 30, 2009, and in U.S. Patent Application No. 12/363,712 filed January 30, 2009, the disclosures of each of which are herein incorporated by reference for all purposes.

[0052] There are time periods where the sensor characteristics or the user's physiological condition renders the condition unsuitable for a sensor calibration event. For example, the sensor may be configured for periodic calibration, such as, after 2 hours after insertion, 10 hours after insertion, 12 hours after insertion, 24 hours after insertion, 48 hours after insertion, or 72 hours after insertion, or one or more combinations thereof. If a predetermined calibration event is triggered but a successful calibration does not result, after a certain time period (for example, a predetermined grace period during which to calibrate), the receiver unit may no longer display the monitored and processed glucose information.

[0053] Other conditions may also result in rendering the condition unsuitable for sensor calibration including, but not limited to, detection of a failure mode of a sensor, sensor data values being outside a predetermined range, rate of change of sensor data values being above a predetermined threshold, a temperature measurement outside a predetermined range, or any combination thereof.

[0054] FIG. 4 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure. Referring to FIG. 4, a transmitter unit 102 (FIG. 1) in operational contact with a sensor 101 receives analyte related sensor data (410) corresponding to a measured level of a biological fluid of the user. For example, the sensor 101 (FIG. 1) may be an analyte sensor configured to detect and measure the concentration of an analyte in a biological fluid, such as the blood of a user. Upon receipt of the analyte related sensor data, the transmitter unit 102 further transmits the analyte related sensor data to a receiver unit, such as primary receiver unit 104 (FIG. 1). It is to be noted that the reference to analyte related sensor data herein and throughout specification includes, for example, current signal received from the analyte sensor, as well as the current signal which has undergone predetermined data processing routines including, for example, filtering, clipping, digitizing, and/or encoding, and/or any other further processing and/or conditioning. In one aspect, the primary receiver unit 104 determines whether the sensor is calibrated and is in acceptable condition for further data processing (420). When sensor related conditions are unsuitable for calibration, the analyte related sensor data is stored (450) in a memory, for example, in the primary receiver unit 104.

[0055] Referring still to FIG. 4, if the sensor data is calibrated and in condition for further data processing, the sensor data is further processed (430) and output for display (440) to a user on a display unit 310 (FIG. 3) of the primary receiver unit 104. In one embodiment, the display of the

processed sensor data comprises a graphical representation of the processed sensor data. In other embodiments, the processed sensor data may be displayed as numerical values, visual indicators, auditory outputs, or combinations thereof. In one aspect, the processing routine described in conjunction with FIG. 4 is performed or executed in, for example, the transmitter unit 102, the secondary receiver unit 106 (FIG. 1), or the data processing terminal 105 (FIG. 1) of the analyte monitoring system 100 (FIG. 1) based on analyte data received from the sensor 101.

[0056] FIG. 5 illustrates analyte sensor data processing in accordance with one embodiment of the present disclosure. Referring to FIG. 5, in one embodiment, transmitter unit 102 (FIG. 1) receives analyte related sensor data (510) from a sensor 101 (FIG. 1). Upon receipt of the analyte related sensor data, the transmitter unit 102 transmits the analyte related sensor data (or processed, digitized, and/or filtered signals) to the primary receiver unit 104 (FIG. 1). The primary receiver unit 104 is configured to determine if calibration of the sensor data is suitable--that is, whether the conditions necessary for sensor calibration are met (520).

[0057] Still referring to FIG. 5, if it is determined that the sensor 101 is not calibrated or calibration condition for calibrating the sensor 101 is not met, in one aspect, the primary receiver unit stores the analyte related sensor data in a memory (550) and temporarily disables display of the sensor data (560) to the user (for example, if a calibration event has not occurred and the calibration grace period has expired). On the other hand, if the sensor 101 is calibrated, the sensor data is processed (530) by the primary receiver unit 104 and the processed sensor data is output to the user (540), for example via a display unit 310 (FIG. 3) of the primary receiver unit 104. In one aspect, the processing routine described in conjunction with FIG. 5 is performed or executed in, for example, the transmitter unit 102, the secondary receiver unit 106, or the data processing terminal 105 of the analyte monitoring system 100 based on analyte data received from the sensor 101 (FIG. 1).

[0058] In one aspect, the display or output of processed sensor data may be disabled if a required calibration event is unsuccessful over a permitted time period (for example, including a predetermined grace period measured from the scheduled calibration). Thereafter, upon successful calibration, the system resumes display of the processed and calibrated analyte sensor data. However, there may be a time period or a gap in the output display during which the necessary calibration did not occur in a timely manner. For example, as shown in FIG. 7A, if sensor data is displayed as a graphical display, during time periods where the analyte monitoring

system 100 was not properly calibrated, analyte related sensor data was not processed and/or displayed, resulting in a gap in the graphical display.

[0059] FIG. 6 illustrates backfilling gaps in sensor data in one embodiment of the present disclosure. Referring to FIG. 6, when a scheduled calibration event fails and the associated grace period for calibration does not occur, the output display of the processed, calibrated sensor data is disabled (610). Referring to FIG. 6, once the system recovers after a successful calibration event, the calibrated sensor data is once again displayed (and stored). Furthermore, in one aspect, based on the parameters associated with the successful calibration, the previously unprocessed data during the display time out period may be retrieved (for example, the previously stored analyte related sensor signals during this period) and processed using calibration data, such as a sensitivity ratio for conversion of analyte related sensor data to analyte levels. For example, in one aspect, the subset of analyte related sensor data that were previously unprocessed or uncalibrated due to unsuccessful contemporaneous calibration may be processed using, for example, calibration data such as the sensitivity ratio determined from the most recent successful calibration event, and thereafter, the gap in output display illustrating the processed and calibrated signals may be filled.

[0060] In one aspect, once successful calibration of the sensor data occurs, the calibration parameters from this calibration event may be used to process the sensor data during the period of disabled output or display (620). Upon successful processing of the sensor data during the period of disabled output, the processed sensor data during this time period is backfilled, or the gap in the processed continuous sensor data are filled in the display (630). By way of an example, FIGS. 7A and 7B illustrate the replacement of a period of unprocessed sensor data with corresponding backfilled processed sensor data, in one embodiment.

[0061] In one embodiment, the backfilled processed sensor data is displayed immediately upon calculation. In another embodiment, the backfilled processed sensor data is not displayed immediately, but rather, after waiting a predetermined period of time. The backfilled processed sensor data may not be displayed immediately to avoid possible unnecessary or incorrect action by a user in response to the backfilled processed sensor data. In this manner, in one aspect, the user or a healthcare provider may be provided with a continuous set of analyte data from the analyte monitoring system without any gaps in the processed signals for further analysis and/or therapy management.

[0062] In this manner, in accordance with the embodiments of the present disclosure, gaps in monitored analyte levels using an analyte monitoring system due to, for example, inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level, may be retrospectively filled or reprocessed so that the data gap is closed and the continuously monitored analyte level does not have any or substantially missing data. That is, in embodiments of the present disclosure, upon correction or rectification of the condition or conditions/parameters which resulted in the analyte monitoring system disabling the output results associated with the monitored real time analyte levels, the parameters associated with the correction or rectification may be used to retrospectively correct or process data or signals so that the missing gaps in analyte related data may be processed and backfilled.

[0063] In this manner, advantageously, in aspects of the present disclosure, additional robustness may be provided to the user and/or the healthcare provider to improve therapy or health management decisions.

[0064] In one embodiment, a method may include receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during an adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

[0065] In one aspect, outputting the processed sensor data may include displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one or more combinations thereof.

[0066] The one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.

[0067] The sensor instability condition may include one or more of an early signal attenuation condition of the sensor, sensor misposition error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.

[0068] The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.

[0069] Furthermore, the method may include storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor.

[0070] In another embodiment, a method may include detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period, disabling output of information associated with the analyte sensor, determining a successful calibration of the analyte sensor, retrieving one or more parameters associated with the successful calibration, processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration, and displaying the processed sensor data for the time period of disabled information output.

[0071] The sensor data may be analyte concentration data.

[0072] The analyte concentration data may include blood glucose concentration data.

[0073] The sensor data may be processed in substantially real-time.

[0074] The condition unsuitable for calibration may include one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

[0075] The processed sensor data for the time period of disabled information output may be displayed substantially immediately upon processing.

[0076] The processed sensor data for the time period of disabled information output may be displayed only after waiting a predetermined period of time.

[0077] In another embodiment, an apparatus may include an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the memory and configured to process the stored sensor data, a second memory coupled to the processor and configured to store the processed sensor data, and a display unit coupled to the second memory and configured to display the processed sensor data, wherein the processor is further configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period, disable display of processed sensor data, determine a successful calibration of the

sensor, retrieve one or more parameters associated with the successful calibration, process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration, and display the processed sensor data for the time period of disabled information output.

[0078] The sensor may be an analyte sensor.

[0079] The analyte sensor may be a glucose sensor.

[0080] The sensor data may correspond to analyte concentration data.

[0081] The analyte concentration data may include blood glucose concentration data.

[0082] Furthermore, the apparatus may be configured to process and display the sensor data substantially in real-time.

[0083] In one aspect, the condition unsuitable for calibration may include one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

[0084] The display unit may be configured to display the processed sensor data for the time period of disabled information output substantially immediately upon processing the sensor data.

[0085] The display unit may be configured to display the processed sensor data for the time period of disabled information output only after waiting a predetermined period of time.

[0086] Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present disclosure and that structures and methods within the scope of these claims and their equivalents be covered thereby.

WHAT IS CLAIMED IS:

1. A method, comprising:

receiving sensor data from an analyte sensor of a sensor monitoring system;

processing the received sensor data with time corresponding calibration data;

outputting the processed sensor data;

detecting one or more adverse conditions associated with the sensor monitoring system;

disabling the output of the sensor data during an adverse condition time period;

determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system;

retrieving the sensor data during the adverse condition time period;

processing the retrieved sensor data during the adverse condition time period; and

outputting the processed retrieved sensor data.

2. The method of claim 1, wherein outputting the processed sensor data includes displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one or more combinations thereof.

3. The method of claim 1, wherein the one or more detected adverse conditions includes one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.

4. The method of claim 3, wherein the sensor instability condition includes one or more of an early signal attenuation condition of the sensor, sensor mis-position error, sensor communication error, temperature measurement outside a predetermined range, or a combination thereof.

5. The method of claim 3, wherein the calibration failure condition includes one or more of an analyte level exceeding a predetermined threshold, a rate of change of analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.

6. The method of claim 1 including storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor.

7. A method, comprising:

detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period;

disabling output of information associated with the analyte sensor;

determining a successful calibration of the analyte sensor;

retrieving one or more parameters associated with the successful calibration;

processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration; and

displaying the processed sensor data for the time period of disabled information output.

8. The method of claim 7, wherein the sensor data is analyte concentration data.

9. The method of claim 8, wherein the analyte concentration data includes blood glucose concentration data.

10. The method of claim 7, wherein the sensor data is processed in substantially real-time.

11. The method of claim 7, wherein the condition unsuitable for calibration includes one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

12. The method of claim 7, wherein the processed sensor data for the time period of disabled information output is displayed substantially immediately upon processing.

13. The method of claim 7, wherein the processed sensor data for the time period of

disabled information output is displayed only after waiting a predetermined period of time.

14. An apparatus, comprising:

an interface configured to receive sensor data;

a first memory configured to store the received sensor data;

a processor coupled to the memory and configured to process the stored sensor data;

a second memory coupled to the processor and configured to store the processed sensor data; and

a display unit coupled to the second memory and configured to display the processed sensor data;

wherein the processor is further configured to:

detect a condition unsuitable for calibration of a sensor for a predetermined time period;

disable display of processed sensor data;

determine a successful calibration of the sensor; retrieve one or more parameters associated with the successful calibration;

process the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration; and

display the processed sensor data for the time period of disabled information output.

15. The apparatus of claim 14, wherein the sensor is an analyte sensor.

16. The apparatus of claim 15, wherein the analyte sensor is a glucose sensor.

17. The apparatus of claim 15, wherein the sensor data corresponds to analyte concentration data.

18. The apparatus of claim 17, wherein the analyte concentration data includes blood glucose concentration data.

19. The apparatus of claim 14 configured to process and display the sensor data substantially in real-time.

20. The apparatus of claim 14, wherein the condition unsuitable for calibration includes one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof.

21. The apparatus of claim 14, wherein the display unit is configured to display the processed sensor data for the time period of disabled information output substantially immediately upon processing the sensor data.

22. The apparatus of claim 14, wherein the display unit is configured to display the processed sensor data for the time period of disabled information output only after waiting a predetermined period of time.

ABSTRACT OF THE DISCLOSURE

Provided are methods and apparatus for receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, outputting the processed sensor data, detecting one or more adverse conditions associated with the sensor monitoring system, disabling the output of the sensor data during the adverse condition time period, determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system, retrieving the sensor data during the adverse condition time period, processing the retrieved sensor data during the adverse condition time period, and outputting the processed retrieved sensor data.

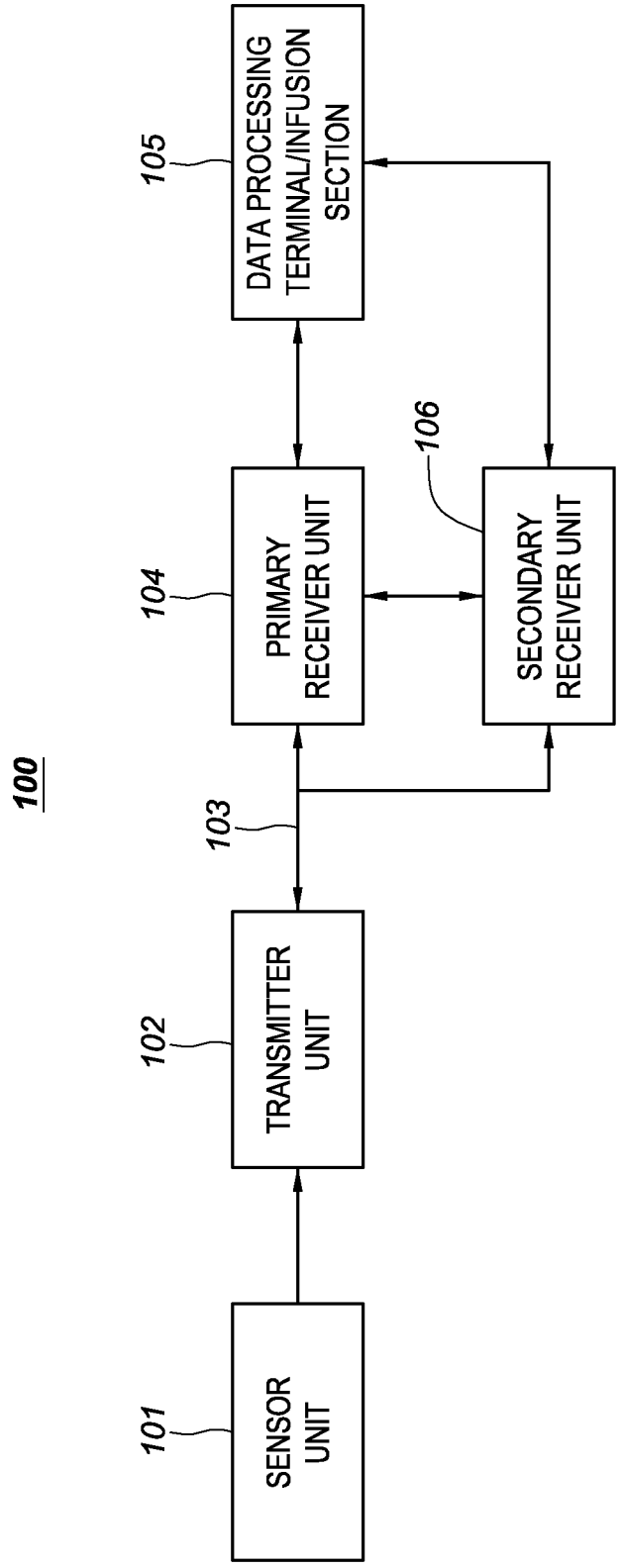

100
101
SENSOR UNIT
102
TRANSMITTER UNIT
103
104
PRIMARY RECEIVER UNIT
105
DATA PROCESSING TERMINAL/INFUSION SECTION
106
SECONDARY RECEIVER UNIT

FIG. 1

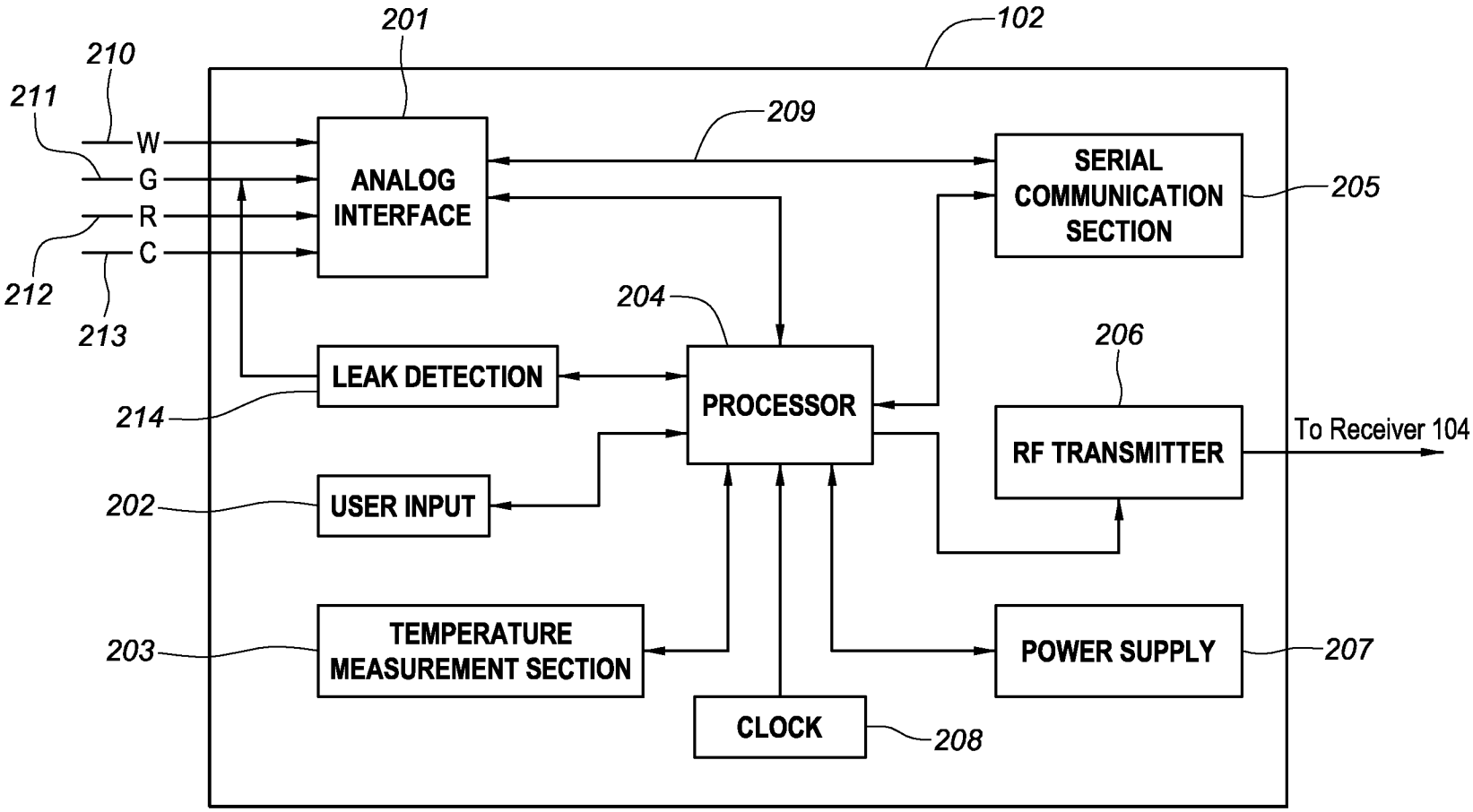

201
102
210
211
W
G
R
C
212
213
209
ANALOG INTERFACE
SERIAL COMMUNICATION SECTION
205
204
206
LEAK DETECTION
214
PROCESSOR
RF TRANSMITTER
To Receiver 104
202
USER INPUT
203
TEMPERATURE MEASUREMENT SECTION
POWER SUPPLY
207
CLOCK
208

FIG. 2

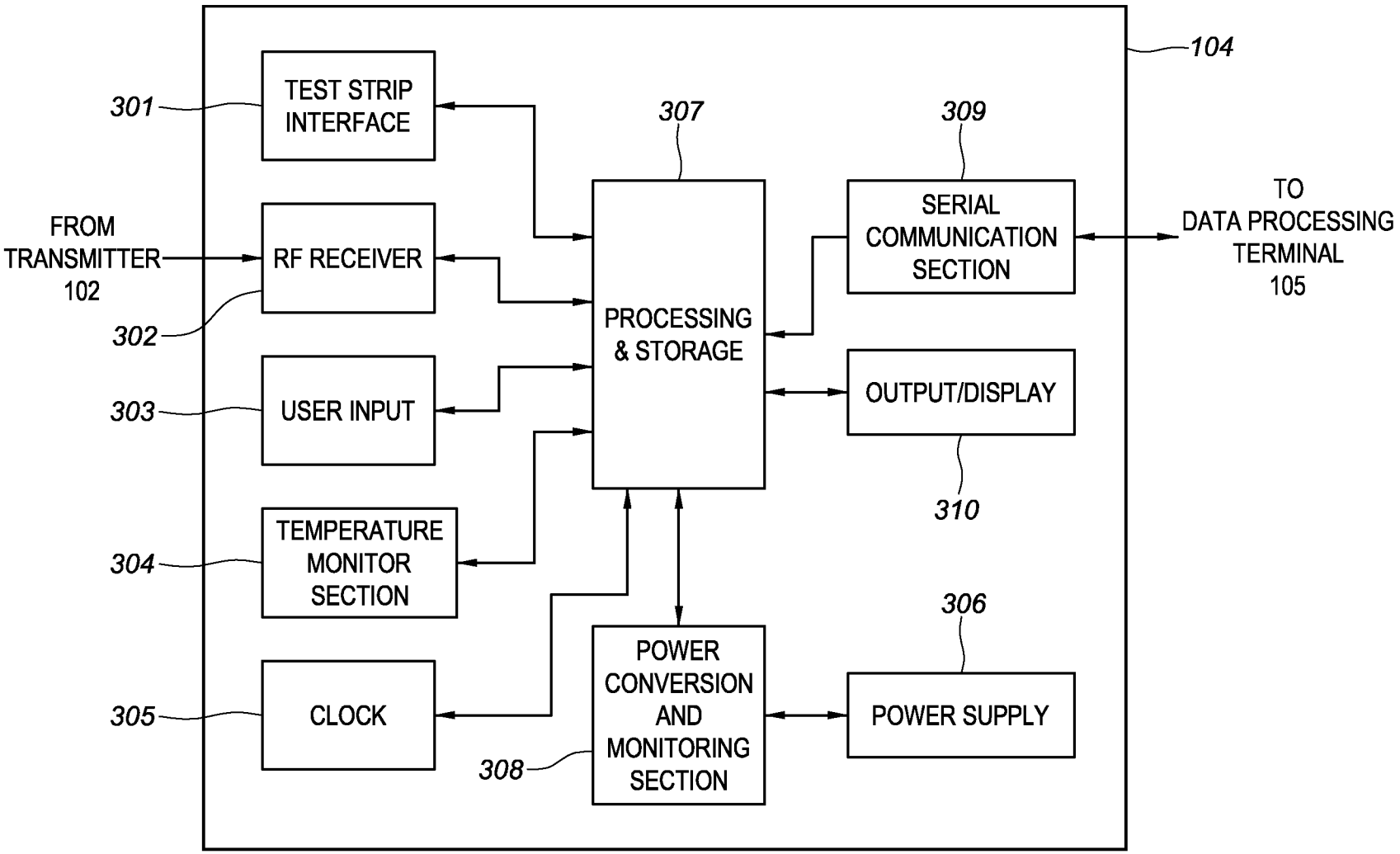

104
301
TEST STRIP INTERFACE
307
309
FROM TRANSMITTER 102
RF RECEIVER
PROCESSING & STORAGE
SERIAL COMMUNICATION SECTION
TO DATA PROCESSING TERMINAL 105
302
303
USER INPUT
OUTPUT/DISPLAY
310
304
TEMPERATURE MONITOR SECTION
306
305
CLOCK
POWER CONVERSION AND MONITORING SECTION
POWER SUPPLY
308

FIG. 3

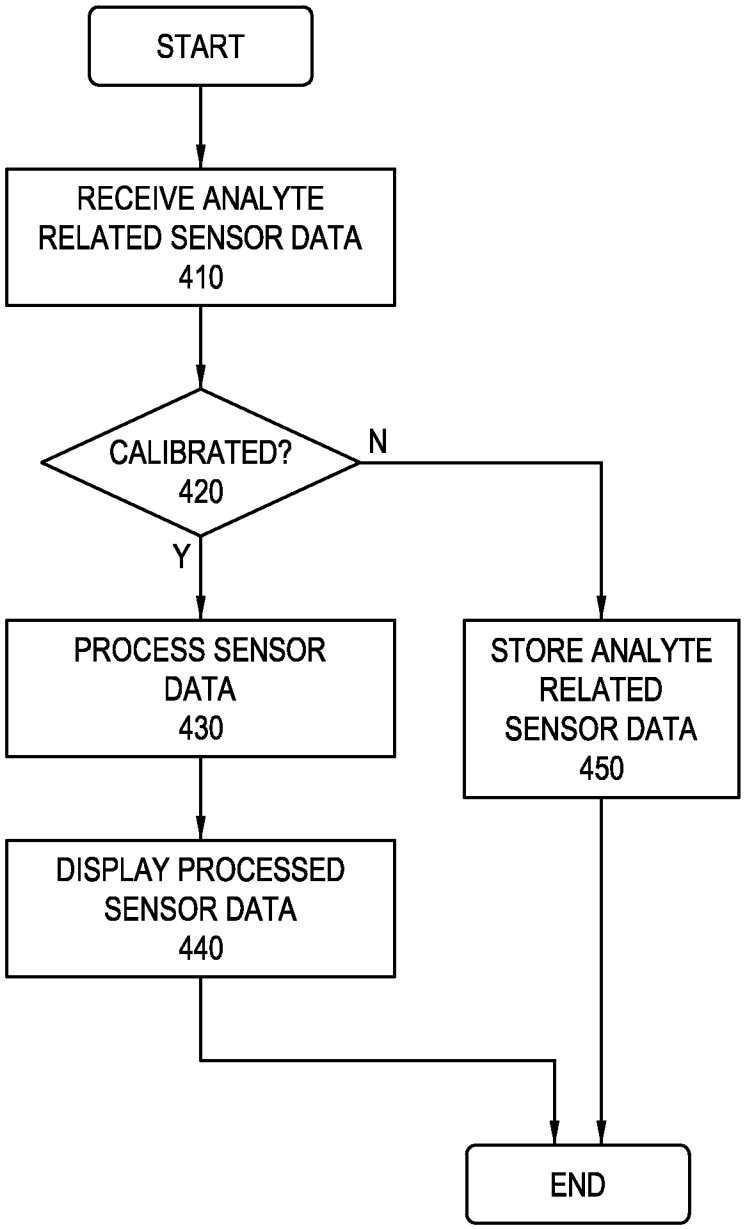

START
RECEIVE ANALYTE RELATED SENSOR DATA 410
CALIBRATED? 420
N
Y
PROCESS SENSOR DATA 430
STORE ANALYTE RELATED SENSOR DATA 450
DISPLAY PROCESSED SENSOR DATA 440
END

FIG. 4

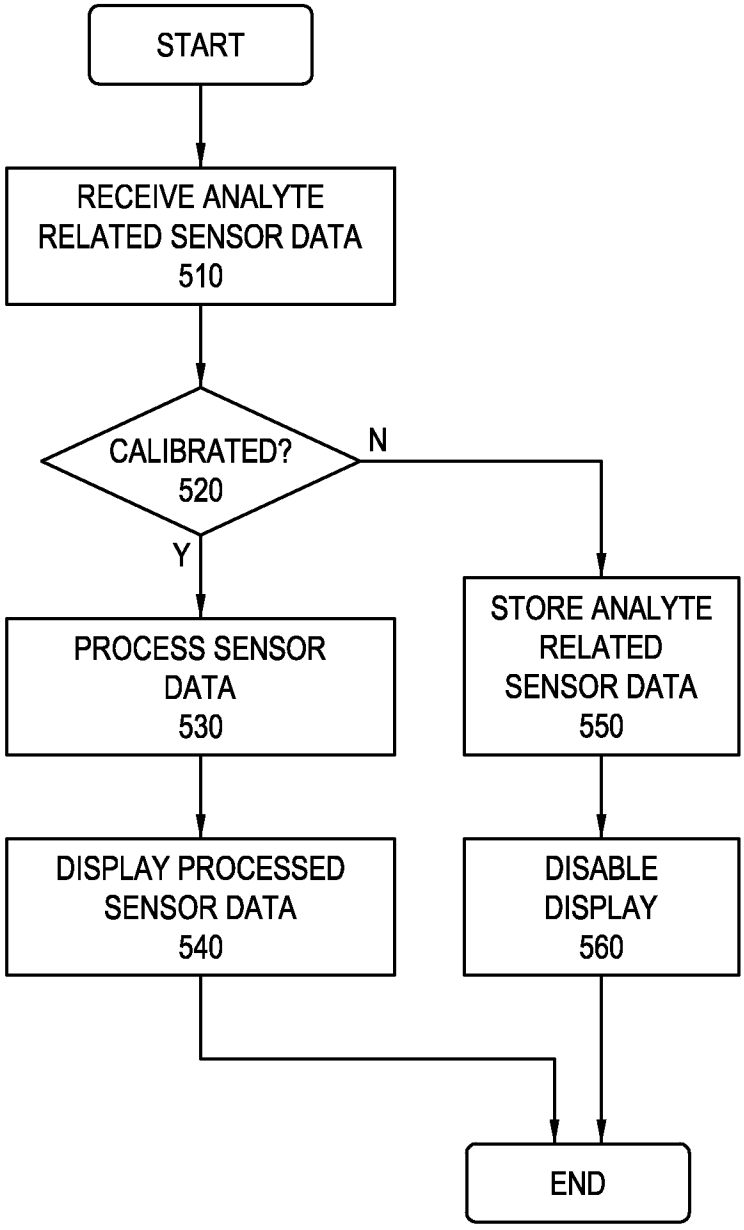

START
RECEIVE ANALYTE RELATED SENSOR DATA 510
CALIBRATED? 520
N
Y
PROCESS SENSOR DATA 530
STORE ANALYTE RELATED SENSOR DATA 550
DISPLAY PROCESSED SENSOR DATA 540
DISABLE DISPLAY 560
END

FIG. 5

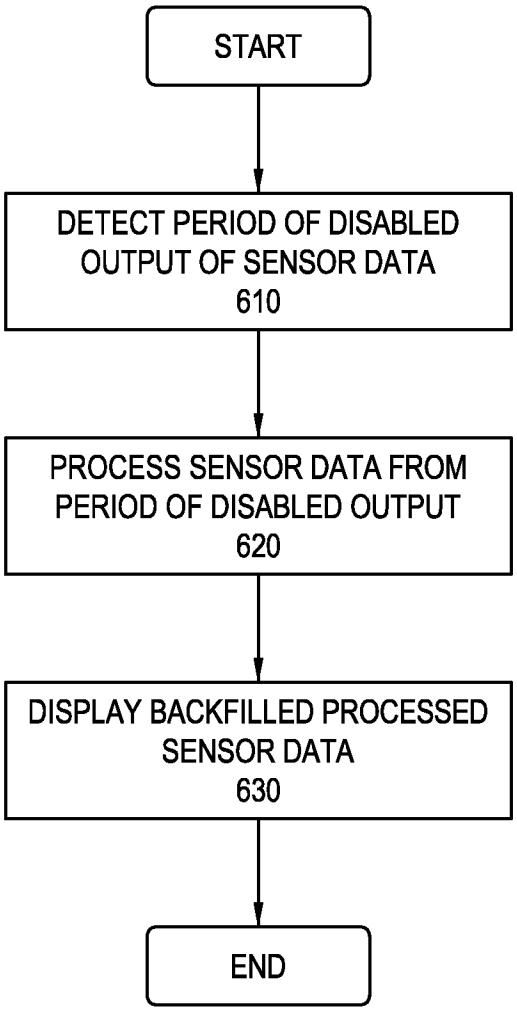

START
DETECT PERIOD OF DISABLED OUTPUT OF SENSOR DATA
610
PROCESS SENSOR DATA FROM PERIOD OF DISABLED OUTPUT
620
DISPLAY BACKFILLED PROCESSED SENSOR DATA
630
END

FIG. 6

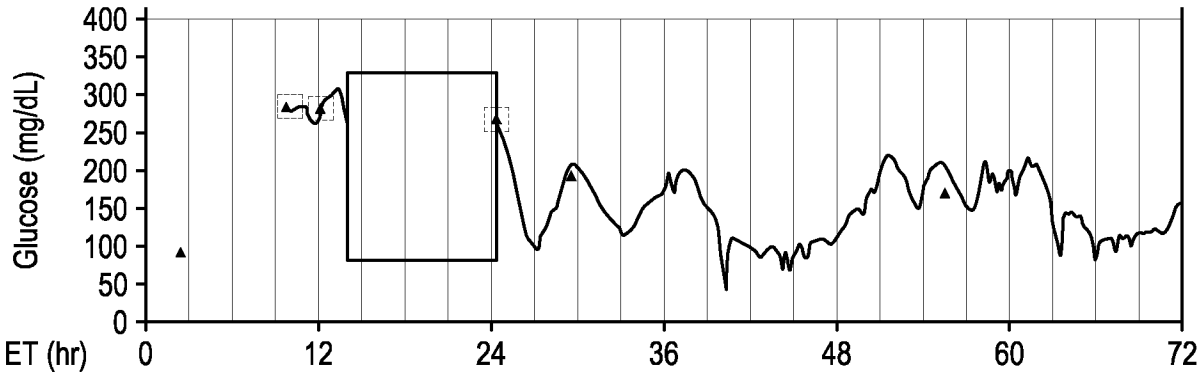

Glucose (mg/dL)
400
350
300
250
200
150
100
50
0
ET (hr)
0
12
24
36
48
60
72

FIG. 7A

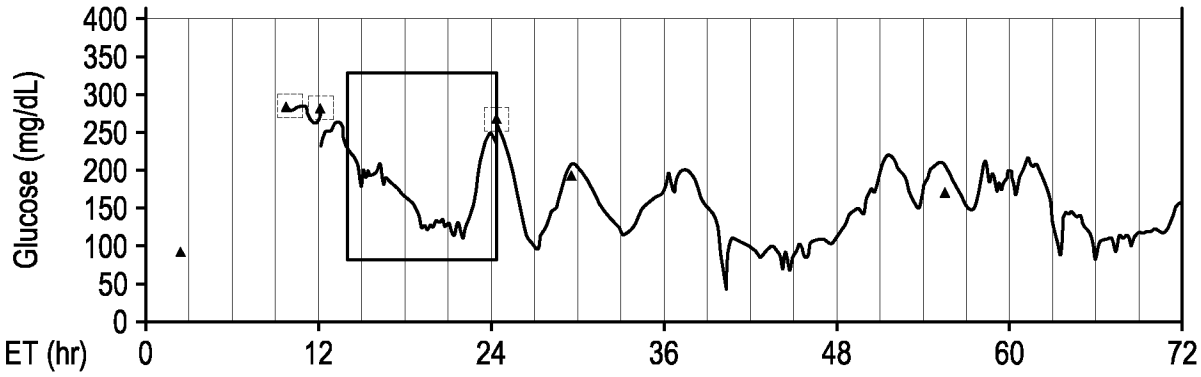

Glucose (mg/dL)
400
350
300
250
200
150
100
50
0
ET (hr)
0
12
24
36
48
60
72

FIG. 7B

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing OR ☒ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	TS-02-180C01
First Named Inventor	Wesley Scott Harper
COMPLETE IF KNOWN	
Application Number	13/925,694
Filing Date	June 24, 2013
Art Unit	1631
Examiner Name	Not Yet Assigned

Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

(Title of the Invention)

As a below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application,

OR

☒ United States Application Number or PCT International application number 13/925,694 filed on June 24, 2013.

The above-identified application was made or authorized to be made by me.

I believe I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

Authorization To Permit Access To Application by Participating Office

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified patent application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the above-identified patent application is filed to have access to the above-identified patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the above-identified patent application with respect to: 1) the above-identified patent application-as-filed; 2) any foreign application to which the above-identified patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified patent application; and 3) any U.S. application-as-filed from which benefit is sought in the above-identified patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 31 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☒ The address associated with Customer Number: 30349 OR ☐ Correspondence address below

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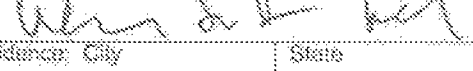
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LEGAL NAME OF SOLE OR FIRST INVENTOR:

(E.g., Given Name (first and middle (if any)) and Family Name or Surname)

Wesley Scott Harper

Inventor's Signature	Date (Optional)
	31 Jul 2013

Residence: City	State	Country
Alameda	CA	US

Mailing Address: 15 Ferro Court

City	State	Zip	Country
Alameda	CA	94502	US

☐ Additional inventors are being named on the _____ supplemental sheet(s) PTO/AIA/08 attached hereto

Docket Nos.: A0130.0090.C7
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wesley Scott Harper

Application No.: To be assigned	Confirmation No.: To be assigned
Filed: August 25, 2021	Art Unit: To be assigned
For: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING	Examiner: To be assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

EFS Web
Commissioner for Patents

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

☒ This IDS is being filed before the First Office Action.

☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action.

☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee.

Certifications:

If checked, the undersigned makes the following statement(s):

☐ Statement under 37 CFR § 1.97(e):

☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited a counterpart application less than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of $260.00 set forth in 37 C.F.R. §1.17(p).

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

☒ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most knowledgeable about the content of the information, is attached.

This concise explanation is provided by way of:

☒ A translation of the relevant portions of the non-English language information;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and where not in the English language, a translation] of at least the relevant portion(s) of the communication from _____in which the information was cited; or

☐ This information is contained in the specification of the present application.

☒ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial Nos. 12/769,635, filed April 28, 2010, and 13/925,694, filed June 24, 2013, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: August 25, 2021

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Boulevard
East Tower, Suite 500
(949) 432-9993
Attorney for Applicants

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	21

Complete if Known	
Application Number	To be assigned
Filing Date	August 25, 2021
First Named Inventor	Wesley Scott Harper
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket No: A0130.0090.C7	

US PATENT DOCUMENTS

*Examiner Initials**	*Cite No.*	*Document Number Number-Kind Code*	*Publication Date MM-DD-YYYY*	*Name of Patentee or Applicant of Cited Document*	*Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear*
		3,581,062	05-21-1971	Aston	
		3,926,760	12-16-1975	Allen, et al.	
		3,949,388	04-06-1976	Fuller	
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		4,986,271	01-22-1991	Wilkins	
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		5,002,054	03-26-1991	Ash, et al.	
		5,019,974	05-28-1991	Beckers	
		5,050,612	09-24-1991	Matsumura	
		5,051,688	09-24-1991	Murase, et al.	

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		5,055,171	10-08-1991	Peck	
		5,082,550	01-21-1992	Rishpon, et al.	
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		5,320,725	06-14-1994	Gregg, et al.	
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		5,472,317	12-05-1995	Field, et al.	
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Sheet	4	of	21	Attorney Docket No: A0130.0090.C7

US PATENT DOCUMENTS

*Examiner Initials**	*Cite No.*	*Document Number Number-Kind Code*	*Publication Date MM-DD-YYYY*	*Name of Patentee or Applicant of Cited Document*	*Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear*
		5,972,199	10-26-1999	Heller, et al.	
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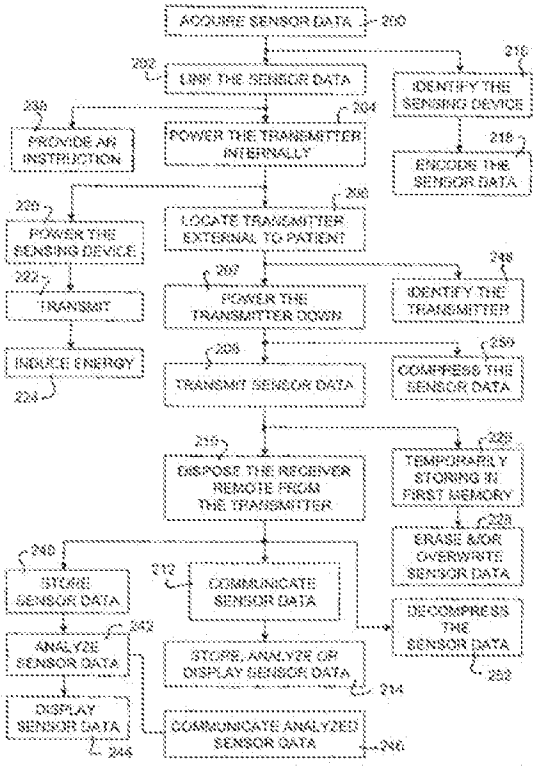
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(54) Wireless patient monitoring system

(57) A device and method for monitoring a patient having a sensing device taking sensor data continuously and a transmitter located on the patient and internally powered. The transmitter is normally in a power-down state and powered-up for transmitting the sensor data. A receiver is located remote from the patient and receives the sensor data transmitted wirelessly from the transmitter. The transmission is typically a burst and can also be initiated on a command. For the burst, the sensor data is accumulated over a first period. The transmitter can transmit the sensor data over a second period of time. The second period of time is shorter than the first period of time. Once the transmission is complete, transmitter can be powered down. A further step displays the sensor data at the receiver in pseudo real-time. The display is shifted by a sum of the first and the second period of time.

FIG. 2



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Description

1. Field of the Invention

[0001] This invention relates to a system and method for measuring, storing and communicating sensor readings from a patient to a central system for display and analysis.

2. Discussion of the Related Art

[0002] For certain medical conditions, such as head trauma, it is necessary to place sensors on and in a patient to take continuous sensor readings. One shortcoming of the prior art is the need to wire the sensors to receiving and recording units located near the patient. The wires, especially leading to implanted sensors, cause difficulty for caregivers to move and treat the patient, both in and out of bed. In response, wireless sensor systems were developed that record the sensor data and do not tether the patient to wired receivers. The sensor data is transmitted wirelessly to the receiver. However, continuous wireless data transmission draws a significant amount of power. Since the sensors are wireless, they must rely on battery power and the continuous wireless transmission shortens the battery life and thus the operational life of the sensor.

[0003] To overcome some of the above shortcomings, US-A-4,519,401 discloses a minimized "pulse" power scheme wherein the sensors and transmitters are placed in a low power cycle when readings are not being taken and then pulse powered up to take a sensor reading and transmit it to a receiver. This power conservation scheme is useful for sensor readings that are only taken at intervals and not continuously. Continuous data sampling would defeat US-A-4,519,401's pulse power scheme, as the sensors and transmitter can never power down.

[0004] US-A-6,533,733 discloses a sensing system wherein the sensor readings are continuously read and stored. The stored data is then periodically transmitted to a receiver. The sensors are continuously powered and transmitter is also continuously powered and draws additional power during power transmission. US-A-6,533,733 realizes that this system is power consumptive and solves the problem by using a combination of power supplies. US-A-6,533,733 is silent regarding powering down the system and US-A-6,533,733's system could not take continuous readings without constant power. Further, since US-A-6,533,733's sensor data is stored, the sensor readings are not resented to the caregiver in approximately real-time. Thus, there is a time lag between when the sensor data is taken and displayed. US-A-6,533,733 compensates for this lag by providing the sensor controller with an alarm function to notify a caregiver of an anomalous sensor reading.

[0005] US-A-6,731,976 discloses a passive sensing system wherein sensor readings are taken and transmitted only when powered externally. The sensing and transmission only last as long as the external power is supplied. This embodiment provides "real-time" sensor data but only while the system is externally powered. Further, US-A-6,731,976 discloses an embodiment of providing a power supply for the system but, as US-A-6,533,733 does, US-A-6,731,976 takes and stores the sensor data but does not disclose powering down the transmitter to conserve energy. Further, US-A-6,731,976 does not disclose how to compensate for the lag between when the sensor data is taken and when it is transmitted.

[0006] Thus, there is a need in the art for a sensor system that can take continuous readings and provide the sensor data to a caregiver is pseudo-real-time. Further, there is a need to conserve power of the sensing device and transmitter by powering down the transmitter and transmitting the sensor data only over bursts.

SUMMARY OF INVENTION

[0007] A device for monitoring a patient sensor has a sensing device disposed on or in the patient and takes sensor data continuously. A transmitter is located on the patient and internally powered. The transmitter is normally in a power-down state and typically only powered-up for transmitting the sensor data. A first link if formed between the sensing device and the transmitter so the transmitter can receive the sensor data. The first link can include a wired and a wireless link. Further, the wireless transmission can be sent over any known wireless frequencies and utilize any protocols known in the art. A receiver is located remote from the patient and receives the sensor data transmitted wirelessly from the transmitter. The transmission is typically a burst and can also be initiated on a command.

[0008] A method of monitoring a patent sensor having the steps of acquiring sensor data from the sensing device and linking the sensor data to the transmitter. The transmitter is powered internally and located on the patient. Typically, the transmitter is powered down in a normal state and powered up to transmit the sensor data from the transmitter to a receiver, which is disposed remote from the transmitter. The transmission can be sent by a burst or upon command.

[0009] Another embodiment of the present method includes acquiring sensor data from the sensing device. Typically sensor data is acquired continuously, but can also be taken at intervals. The sensor data is linked to a transmitter by the first communication link and the transmitter is powered internally by a power supply. The sensor data is accumulated over a first period of time which can be a few seconds to a few minutes and, in one embodiment, is a one minute interval. The transmitter can be powered-up and transmitting the sensor data from the transmitter to the receiver over a second period of time. The second period of time is shorter than the first period of time and is typically a factor of shorter. Once the transmission is complete, transmitter can be powered down. A further step displays the sensor data at the receiver in

pseudo real-time. The display is shifted by a sum of the first and the second period of time. For example, if the sensor data is accumulated over 1 minute and the burst transmission is 6 seconds, the displayed data is time shifted (or lagged) 66 seconds from real-time.

[0010] In a further embodiment, the sensor data can be compressed prior to transmitting the sensor data and then it can be decompressed prior to the displaying the sensor data. Compressing the sensor data can assist in shorting the second period of time and thus shortening the burst period and the lag time.

[0011] One or more sensing devices can be linked to a single transmitter. Each sensing device can include a unique sensing device ID which identifies each sensing device. The unique sensing device ID can include the serial number of the sensing device and an identifier to identify the type, model, manufacturer and calibration information of the sensing device. The unique sensing device ID can identify the sensing device for the transmitter. Furthermore, the transmitter can have a unique transmitter ID identifying the transmitter to a receiver and the receiver can also have a unique receiver ID. Receiver ID identifies the receiver to a central server and the sensor data can be encoded/encrypted with the unique receiver ID as outlined above regarding the other unique IDs.

[0012] In one embodiment, the receiver is located within 15 feet of the transmitter. The proximity of the receiver to the transmitter can prolong the life of power supply because less power is needed if the transmission is over a short distance. Also, the proximity prevents dropped signals and interference from outside sources.

[0013] In another embodiment, the sensor data can be encrypted before it is transmitted wirelessly to prevent unauthorized access or tampering with the sensor data. In a further embodiment, one or both of the unique sensing device ID and the transmitter ID can be used as base keys for encrypting the data. The IDs can be used as a public key and thus either every sensing device's or transmitter's sensor data can be uniquely encrypted.

[0014] Further to the above, the first link can include a power link to provide power to the sensing device from the transmitter. The receiver can send a confirmation signal to the transmitter to acknowledging receipt of the sensor data. The confirmation signal is a safety feature to assure that the sensor data is received by the receiver.

BRIEF DESCRIPTION OF THE DRAWING FIGURES

[0015] The above and still further objects, features and advantages of the present invention will become apparent upon consideration of the following detailed description of a specific embodiment thereof, especially when taken in conjunction with the accompanying drawings wherein like reference numerals in the various figures are utilized to designate like components, and wherein:

Figure 1 is schematic diagram of the system of the present invention;

Figure 2 is a flow chart of an embodiment of a method of the present invention;

Figure 3 is a flow chart of another embodiment of a method of the present invention; and

Figure 4 is a flow chart of a further embodiment of a method of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0016] Referring to Figure 1, a system 100 for monitoring a patient sensor is illustrated. The system 100 includes a sensing device 102 disposed on the surface of or implanted in the patient 10 that takes sensor data 104. The sensing device can be disposed or implanted anywhere on the patient 10, including implanted in the patient's brain. Sensing device 102 can be any medical sensing device, including a pressure sensor, an oxygen sensor, neural impulse sensor, temperature sensor, pH sensor, an electroencephalogram and a fetal heart monitor. The sensing device 102 can collect sensor data 104 over many different time periods. Sensor data 104 can be collected continuously, over either a predetermined or random interval, or upon a command issued from a caregiver. Sensing device 102 can be powered internally by, for example, disposable batteries, rechargeable batteries, or a capacitive device capable of storing energy transmitted through an inductive power coupling or directly through the inductive power coupling.

[0017] Sensing device 102 transmits the sensor data 104 to a transmitter 106 located outside the patient 10. The transmitter 106 is typically located on or very close to the patient 10 but not implanted in the patient 10. Typically, transmitter 106 can be strapped to the nearest appendage or adhered to the patient's skin. Transmitter 106 is internally powered by power supply 108. Power supply 108 can be, for example disposable batteries, rechargeable batteries, or a capacitive device capable of storing energy transmitted through an inductive power coupling.

[0018] The transmitter 106 receives the sensor data 104 over a first link 110 between the sensing device 102 and the transmitter 106. The first link 110 can be a wired 110a or a wireless link 110b. If the first link 110 is wired link 110a, the transmitter 106 can have multiple leads or ports to accept one or more wired links. The leads and ports can be any type known in the art to transmit at least analogue or digital data to allow the transmission of sensor data 104 to the transmitter 106. If the first link 110 is a wireless link 110b, the transmission can be sent over any known wireless frequencies and utilize any protocols known in the art. Further, wireless link 110b can be transmitted inductively by using the patient's body at the antenna.

[0019] Further, the sensing device 102 and the transmitter 106 can undergo handshake protocols to "introduce" the sensing device 102 to the transmitter 106. The handshake can be performed automatically upon the powering up or the plugging in of either the sensing de-

vice 102 or the transmitter 106. Alternately, the caregiver can initiate a handshake protocol manually.

[0020] One or more sensing devices 102 can be linked to a single transmitter 106. Each sensing device 102 can include a unique sensing device ID which identifies each sensing device 102. The unique sensing device ID can include the serial number of the sensing device 102 and an identifier to identify the type, model, manufacturer and calibration information of the sensing device 102. The unique sensing device ID can identify the sensing device 102 for the transmitter 106. Furthermore, the transmitter 106 can have a unique transmitter ID identifying the transmitter 106 to a receiver 112.

[0021] Transmitter 106 transmits the sensor data 104 to receiver 112. Receiver 112 is typically located remote from the patient 10. In one embodiment, the receiver 112 is located within 15 feet of the transmitter. The proximity of the receiver 112 to the transmitter 106 can prolong the life of power supply 108 because less power is needed if the transmission is over a short distance. Also, the proximity prevents dropped signals and interference from outside sources.

[0022] The receiver 112 and the transmitter 106 communicate wirelessly, thus allowing patient 10 the freedom to move around and shift position or be moved to aid caregivers activities without disrupting the communications between the two. The communication between the transmitter 106 and the receiver 112 can take place continuously, at an interval, or upon a command. The interval can be either predetermined or random and in one embodiment, the transmitter 106 provides a burst transmission at least every minute. Burst transmissions are used to conserve the power of the transmitter 106. Sending the transmission to the receiver 112 is power consumptive and minimizing the number of transmissions can extend the life of the internal power supply 108. Short interval bursts allow a caregiver to receive nearly real-time sensor data 104 and still conserve the power supply 108.

[0023] Further, transmitter 106 can process sensor data 104 through a compression algorithm to compress the data before transmitting it to receiver 112. Compressing sensor data 104 allows for a shorter burst period and assists in reducing the overall power consumption of the transmitter 106 and prolong the life of the power supply 108. Compressed sensor data 104 also conserves storage space on the receiver 112 or server 114. Compressed sensor data 104 can be stored compressed and decompressed for processing or display to the caregiver. Alternately, the receiver can decompress the sensor data 104 upon receipt and store it decompressed to reduce the wait time for processing or displaying.

[0024] Further, the wireless transmission can be sent over any known wireless frequencies and utilize any protocols known in the art. Additionally, the transmitter 106 and the receiver 112 can undergo handshake protocols to "introduce" the transmitter 106 to the receiver 112. The handshake can be performed automatically upon the powering up or the plugging in of either the transmitter 106 or the receiver 112. Alternately, the caregiver can initiate a handshake protocol manually.

[0025] In an embodiment, transmitter 106 communicates with receiver 112 utilizing a "burst mode." Burst mode collects and stores sensor data 104 in the transmitter 106 over a set period of time. Typically, the sensor data 104 is compressed to reduce the size of the data packet. Transmitter 106, at the predetermined time, powers up and transmit the stored sensor data 104 in a burst that is typically much, much shorter than the time period over which the sensor data 104 is collected. Transmitter 106 then powers down. The receiver 112 receives and collects the sensor data 104 from the transmitter 106 and decompresses the sensor data 104 back to the original timescale for display or analysis. The receiver 112 displays the data in pseudo real-time - the sensor data 104 is displayed in the same spatial resolution that it was collected with but delayed from real-time by the length of the time period over which it was originally collected plus the communications "burst" time. This embodiment allows transmitter 106 to limit the power expenditure overhead of powering on and establishing link 110 by not requiring the transmitter 106 to perform these tasks for each individual sensor reading taken.

[0026] The receiver 112 can be powered by any source, but typically is powered externally, i.e. plugged into the nearest electrical outlet. In an embodiment, receiver 112 can be designed as a permanent or semi-permanent device in the patent's room. Utilizing an external power source to power receiver 112 has advantages. Receiver 112 can be active continuously and can perform storage, analysis, and display functions. Receiver 112 can store and accumulate sensor data 104 for an extended period of time and can store sensor data 104 from numerous transmitters 106 and/or patients 10. Receiver 112 can analyze the sensor data 104 and display it for the caregiver. Additionally, an external power supply allows receiver 112 more flexibility in communicating the sensor data 104, analyzed or not, to a central server 114 located remote from the receiver 112.

[0027] Receiver 112 and central server 114 can be linked directly or through a network, LAN, WAN, or the Internet. The connection can be wired or wireless using any protocols known in the art. Central server 114 can be remote from the receiver, i.e. in another room, building or state and a patient 10 can be monitored by a caregiver remote from the patient's location.

[0028] In an embodiment, central server 114 can be a portable device (e.g. PDA, cell phone, beeper, Blackberry®) or a semi-portable device (laptop and desktop on wheels) that can be carried by the caregiver or kept in proximity to patent 10 so the caregiver can move into proximity with the patient 10 and display the sensor data 104 at, for example, the patient's bedside. Central server 114 can also store, analyze, and display the sensor data 104. In an embodiment, either the receiver 112 or the central server 114 analyzes the data, or receiver 112 can perform basic analysis and central server 114 performs

more detailed analysis if required.

[0029] Receiver 112 can also send notifications to central server 114 in response to a number of preset or programmed conditions. For example, if the sensor data 104 shows that there is a critical condition (e.g. the patient's heart stops beating) a notification can be sent (e.g. messaging a pager, ringing a cell phone) notifying the caregiver of the critical condition. As described below, the caregiver can then issue remote instructions to further monitor the patient 10.

[0030] If the receiver 112 and the central server 114 communicate wirelessly, all the protocols, handshake procedures and frequencies described above can be used here as described above.

[0031] In an embodiment, sensor data 104 can be encoded with the unique sensing device ID and the encoded sensor data is transmitted to the receiver 112 and to the central server 114. Using the unique sensing device ID can identify the specific sensor and thus the specific patient 10. This can help the organization of the sensor data 104 when stored and can assist in the search and retrieval of the sensor data 104 at a later time. Further, sensor data 104 can be encoded with the unique transmitter ID alone or in combination with the unique sensing device ID. The unique transmitter ID can further assist in storage, searching and retrieval.

[0032] In one embodiment, the sensor data 104 can be encrypted before it is transmitted wirelessly to prevent unauthorized access or tampering with the sensor data 104. In a further embodiment, one or both of the unique sensing device ID and the transmitter ID can be used as base keys for encrypting the data. The IDs can be used as a public key and thus either every sensing device's or transmitter's sensor data 104 can be uniquely encrypted.

[0033] Further to the above, the first link 110 can include a power link to provide power to the sensing device 102 from the transmitter 106. In this embodiment, sensing device 102 does not have a stand alone power supply. If first link 110 is wired 110a, the power can be transmitted directly to the sensing device 102 along the same wire or a different wire than the sensor data 104 is transmitted. Alternately, the power link can be an induced connection. An induction coil from the transmitter 106 can be placed in proximity to an inductance coil in the sensing device 102 to provide power to the sensing device 102. Power supply 108 can provide continuous power or act as a charging station to charge the sensing device 102 on demand. This can be used especially with implanted sensing devices 102. Since transmitter 106 is disposed outside of patient 10, it is easier to recharge power supply 108 and use the transmitter to power sensing device 102.

[0034] In an embodiment, transmitter 106 includes a first memory 116 that temporarily stores the sensor data 104 prior to the transmission to the receiver 112. The first memory 116 can be flash RAM or any other type of permanent or removable memory known in the art. First memory 116 can be kept small to allow transmitter 106 to be light weight. Once the sensor data 104 stored on first memory 116 is transmitted to the receiver 112, the sensor data can be erased or overwritten. The overwriting procedure can include overwriting the oldest data first.

[0035] Additionally, receiver 112 can include a confirmation signal 118 transmitted from the receiver 112 to the transmitter 106 to acknowledging receipt of the sensor data 104. The confirmation signal 118 is a safety feature to assure that the sensor data 104 is received by the receiver 112. The confirmation signal 118 can also be used as a trigger for the transmitter 106 to erase the first memory 116.

[0036] In an embodiment, if the transmitter 106 does not receive the confirmation signal 118, the transmitter 106 can repeat the transmission one or more times until the confirmation signal 118 is received. Also, the transmitter 106 can include an alarm 120 that can send an alarm signal when the confirmation signal 118 is not received once or for a period of time.

[0037] Alternately, transmitter 106 can resend the "old" sensor data 104 from the unconfirmed transmission as an add-on to the next transmission of "new" sensor data 104. If the transmitter 106 is set to burst transmissions, adding-on sensor data 104 can lengthen the transmission time but maintains the interval so keep power consumption at a minimum.

[0038] In another embodiment, transmitter 106 can be used to communicate with sensing device 102. First link 110 can provide an instruction to the sensing device 102. Examples of instructions can be to turn on/off, change data retrieval intervals, perform a diagnostic test, report power and/or communication status and to take sensor data essentially contemporaneous with the instruction. This allows a caregiver to receive real-time sensor data 104, if the caregiver deems it necessary. The instructions can be originated at the transmitter 106 or at the receiver 112 and/or central server 114 to be transmitted to the transmitter 106 to be relayed to sensing device 104. This configuration allows instructions to originate anywhere the caregiver is located.

[0039] Embodiments include using one transmitter 106 per patient 10 and linking multiple sensing devices 104 to the single transmitter 106. A second sensing device 122 can be implanted in the patient 10. The second sensing device 122 takes second sensor data 124 and can include any or all of the features described above for sensing device 102. In a further embodiment, second sensing device can include a unique second sensing device ID. Unique second sensing device ID can be used as above, to identify second sensing device and to encode or encrypt second sensor data 124.

[0040] A second link 126 between the second sensing device 122 and the transmitter 106 can be formed similarly to first link 110. Transmitter 106 can receive both sensor data 104 and second sensor data 124. In an embodiment, the transmitter 106 can be programmed to combine the sensor data 104, 124 into a single sensor data file to be transmitted to receiver 112 or can keep

the sensor data 104 and the second sensor data 124 separate. To assist in differentiating between the two sensor data, the unique sensing device ID and the unique second sensing device ID can be used to encode and separate the data.

[0041] A further embodiment includes using multiple transmitters with one receiver 112. Typically, a second transmitter 128 is linked to a second sensing device 122 implanted in a second patient 20. However, multiple transmitters can be used with the same patient 10, if the positioning of the sensing devices 102 or receiver 112 dictates. As above, second sensing device 122 takes second sensor data 124 and transmits it to second transmitter 128 via second link 126. Second transmitter 128 can include a unique second transmitter ID identifying it. Receiver 112 can receive sensor data 104 and second sensor data 124 from the transmitter 106 and the second transmitter 128, respectively. In an embodiment, the sensor data 104, 124 can be encoded or encrypted using the unique transmitter and second transmitter IDs. Furthermore, if multiple sensing devices are attached to each transmitter, the sensor data can be encoded with both the unique sensing device ID and the unique transmitter ID.

[0042] Receiver 112 can also have a unique receiver ID to identify the receiver to the central server 114 and the sensor data 104 can be encoded/encrypted with the unique receiver ID as outlined above regarding the other unique IDs.

[0043] Figure 2 illustrates a method of monitoring a patient sensor. Sensor data 104 can be acquired from sensing device 102 implanted in the patient (step 200) and linked to the transmitter 106 either continuously, at an interval, a burst, or upon command (step 202). The transmitter 106 is powered internally (step 204) and located external to the patient 10 (step 206). Typically, transmitter 106 is in a powered down condition (step 207). The transmitter 106 is powered up and then transmits the sensor data from the transmitter 106 to receiver 112 (step 208) and the receiver 112 is disposed remote from the transmitter 106 (step 210). The sensor data 104 is communicated from the receiver 112 to the central server 114 (step 212) and central server 114 can store, analyze, or display the sensor data 104 (step 214). In an alternate embodiment, the receiver 112 can store, analyze and display the sensor data 104 for an individual patient.

[0044] Embodiments include, identifying the sensing device 102 with a unique sensing device ID (step 216) and optionally encoding the sensor data 104 with the unique sensing device ID (Step 218). Further embodiments include powering the sensing device 102 from the transmitter 106 using a power link (step 220) by optionally, transmitting energy over a wire from the transmitter 106 to the sensing device 102 (step 222) or inducing energy through induction coils in the transmitter 106 and the sensing device 102 (step 224). Another embodiment is temporarily storing the sensor data 102 in a first memory 116 prior to the transmitting step (step 226) and erasing and/or overwriting the sensor data after the transmitting step (step 228).

[0045] Referring to Figure 3, the method can further include sending a confirmation signal acknowledging receipt of the sensor data 104 (step 230) and issuing an alarm upon failure to receive the confirmation signal (step 232). Additionally, the transmitter 106 can receive the confirmation signal (step 234) and erase the first memory 116 storing the sensor data 104 upon receipt of the confirmation signal (step 236).

[0046] Returning to Figure 2, the transmitter 106 can provide an instruction to the sensing device (step 238). Also, the receiver can optionally, store the sensor data 104 (step 240), analyze the sensor data 104 (step 242) or display the sensor data 104 (step 244). Further, the communicating step above can include communicating the analyzed sensor data 104 to the central server 114 (step 246). Also, the transmitter 106 can be identified with a unique transmitter ID (step 248). In an alternate embodiment, transmitter 106 can compress sensor data 104 (step 250) and receiver 112 can decompress the data (step 252). Alternately, central server 114 can decompress the sensor data.

[0047] Turning to Figure 4, another embodiment of the present method is illustrated. The method of monitoring a patent sensor includes acquiring sensor data 104 from a sensing device 102 disposed on the patient 10 (step 300). Typically sensor data 104 is acquired continuously, but can also be taken at intervals. The sensor data can be linked to a transmitter by the first communication link 110 (step 302). The transmitter is powered internally (step 304) by power supply 108 and is typically located on patient 10 (step 306). The sensor data can be accumulated over a first period of time (step 308). The first period of time can be a few seconds to a few minutes and, in one embodiment, is a one minute interval. Transmitter 106 is powered-up and transmits the sensor data 104 from the transmitter 106 to receiver 112 over a second period of time (step 310). The second period of time is shorter than the first period of time and is typically a factor of shorter. Once the transmission is complete, transmitter 106 is powered down (step 312). A further step is displaying the sensor data at the receiver in pseudo real-time (step 314). The display is shifted by a sum of the first and the second period of time. For example, if the sensor data is accumulated over 1 minute and the burst transmission is 6 seconds, the displayed data is time shifted (or lagged) 66 seconds from real-time.

[0048] In a further embodiment, the sensor data can be compressed prior to transmitting the sensor data 104 (step 316) and then it can be decompressed prior to the displaying the sensor data 104 (step 318). Compressing the sensor data 104 can assist in shorting the second period of time and thus shortening the burst period and the lag time. The compression compresses the waveform of the sensor data and the decompression returns the waveform of the sensor data back to its original data.

[0049] Further, it is know in the art that any analogue

signals can be converted to digital signals before transmission and converted back to analogue signals, if necessary, for display and analysis.

[0050] While there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps which perform substantially the same function, in substantially the same way, to achieve the same results are within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

Claims

1. A device for monitoring a patient sensor, comprising:

   a sensing device for disposal on or in the patient for taking sensor data continuously;
   an internally powered transmitter for location on the patient, which transmitter is normally in a power-down state and is powered-up for transmitting the sensor data;
   a wired or wireless first link between the sensing device and the transmitter wherein the transmitter receives the sensor data from the sensing device; and
   a receiver, for location remote from the patient, for receiving the sensor data transmitted wirelessly from the transmitter,
   wherein the sensor data transmission is a burst or is initiated on a command.

2. The device of claim 1, wherein the sensing device comprises a unique sensing device ID and the sensing device is identified by the transmitter using the unique sensing device ID.

3. The device of claim 2, wherein the sensor data is encoded with the unique sensing device ID and the encoded sensor data is transmitted to the receiver and to a central server.

4. The device of any one of claims 1 to 3, wherein the first link further comprises a power link to provide power to the sensing device from the transmitter, wherein the power link provides power by a direct connection or an induced connection.

5. The device of any one of claims 1 to 5, wherein the transmitter comprises a first memory temporarily storing the sensor data prior to the transmission to the receiver, wherein the first memory is overwritten or erased after the transmission of the sensor data to the receiver.

6. The device of any one of claims 1 to 5, further comprising a confirmation signal transmitted from the receiver to the transmitter acknowledging receipt of the sensor data.

7. The device of claim 6, wherein the transmitter further comprises an alarm for sending an alarm signal upon failure to receive the confirmation signal.

8. The device of claim 6 or claim 7, wherein the confirmation signal instructs the transmitter to erase a first memory temporally storing the sensor data prior to the transmission to the receiver.

9. The device of any one of claims 1 to 8, wherein the transmitter provides an instruction to the sensing device.

10. The device of any one of claims 1 to 9, further comprising a central server, for location remote from the receiver, for receiving the sensor data from the receiver and for storing, analyzing and/or displaying the sensor data wherein the receiver is adapted to transmit the sensor data to the central server continuously, at an interval or upon a command.

11. The device of any one of claims 1 to 10, wherein the receiver stores, analyzes and/or displays the sensor data.

12. The device of claim 11, wherein the receiver transmits the analyzed sensor data to a central server.

13. The device of any one of claims 1 to 12, wherein the transmitter comprises a unique transmitter ID and the transmitter is identified by the receiver using the unique transmitter ID.

14. The device of claim 13, wherein the sensing device comprises a unique sensing device ID and the sensing device is identified by the transmitter using the unique sensing device ID,
   wherein the sensor data is encoded with the unique sensing device ID and the unique transmitter ID and the encoded sensor data is transmitted to the receiver.

15. The device of any one of claims 1 to 14, further comprising:

   a second sensing device for implantation in the

patient, for taking second sensor data continuously, at an interval andor upon a command, comprising a unique second sensing device ID and the second sensing device is identified by the transmitter using the unique second sensor device ID, wherein the second sensor data is encoded with the unique second sensing device ID; and

a wired or wireless second link between the second sensing device and the transmitter wherein the transmitter receives the second sensor data from the second sensing device and the second link;

wherein the sensing device comprises a unique sensing device ID, the sensing device is identified by the transmitter using the unique sensing device ID, and the sensor data is encoded with the unique sensing device ID, and

wherein the encoded sensor data and the encoded second sensor data are transmitted to the receiver.

16. The device of any one of claims 1 to 15, further comprising:

a second sensing device for implantation in a second patient, for taking second sensor data continuously, at an interval and/or upon a command;

an , internally powered second transmitter for location outside the second patient, for transmitting the second sensor data to the receiver continuously, at an interval and/or upon a command and comprises a unique second transmitter ID and the second transmitter is identified by the receiver using the unique second transmitter ID; and

a wired or wireless second link between the second sensing device and the second transmitter wherein the second transmitter receives the second sensor data from the second sensing device.

17. The device of any one of claims 1 to 16, wherein the transmitter compresses the sensor data prior to transmitting to the receiver and wherein the receiver decompresses the compressed sensor data.

18. The device of claim 10, further comprising a notification, sent from the receiver to the central server upon a met condition.

19. The device of any one of claims 1 to 18, wherein the transmitter comprises a first memory for temporarily storing the sensor data prior to the transmission to the receiver, wherein the sensor data is compressed prior to transmission and decompressed by the receiver.

20. A method of monitoring a patent sensor, comprising the steps of:

acquiring sensor data from a sensing device on or in the patient;

linking the sensor data to a transmitter continuously, at an interval and/or upon a command;

powering the transmitter internally;

locating the transmitter on the patient;

powering the transmitter down in a normal state;

powering the transmitter up and transmitting the sensor data from the transmitter to a receiver by a burst and/or upon command; and

disposing the receiver remote from the transmitter.

21. The method of claim 20, further comprising the steps of:

communicating the sensor data from the receiver to a central server; and

storing, analyzing and/or displaying the sensor data at the central server.

22. The method of claim 20 or claim 21, further comprising the steps of:

identifying the sensing device with a unique sensing device ID; and

optionally, encoding the sensor data with the unique sensing device ID.

23. The method of any one of claims 20 to 22, further comprising the step of powering the sensing device from the transmitter by transmitting energy over a wire from the transmitter to the sensing device or inducing energy through induction coils in the transmitter and the sensing device.

24. The method of any one of claims 20 to 23, further comprising the steps of:

temporarily storing the sensor data in a first memory prior to the transmitting step; and

erasing and/or overwriting the sensor data after the transmitting step.

25. The method of any one of claims 20 to 24, further comprising the step of sending a confirmation signal acknowledging receipt of the sensor data.

26. The method of claim 25, further comprising the step of issuing an alarm upon failure to receive the confirmation signal.

27. The method of any one of claims 20 to 26, further comprising the steps of:

receiving a confirmation signal; and
erasing a first memory storing the sensor data upon receipt of the confirmation signal.

28. The method of any one of claims 20 to 27, further comprising the step of providing an instruction from the transmitter to the sensing device.

29. The method of any one of claims 20 to 28, further comprising storing the sensor data at the receiver, analyzing the sensor data at the receiver and/or displaying the sensor data at the receiver.

30. The method of any one of claims 20 to 29, which includes communicating the analyzed sensor data to a central server.

31. The method of any one of claims 20 to 30, further comprising the step of identifying the transmitter with a unique transmitter ID.

32. The method of any one of claims 20 to 31, further comprising the step of compressing the sensor data prior to the transmitting step.

33. The method of claim 32, further comprising the step of decompressing the sensor data prior to analysis.

34. The method of any one of claims 20 to 33, further comprising the step of communicating a notification to a central server.

35. A method of monitoring a patient sensor, comprising the steps of:

acquiring sensor data from a sensing device disposed on or in the patient;
linking the sensor data to a transmitter by a wireless or a wire link;
powering the transmitter internally;
locating the transmitter on the patient;
accumulating the sensor data over a first time;
powering on the transmitter and transmitting the sensor data from the transmitter to a receiver over a second time, shorter than the first time;
powering off the transmitter; and
displaying the sensor data at the receiver in pseudo real-time shifted by a sum of the first and the second times.

36. The method of claim 35, further comprising the steps of:

compressing the sensor data prior to the transmitting step; and
decompressing the sensor data prior to the displaying step.

FIG. 1

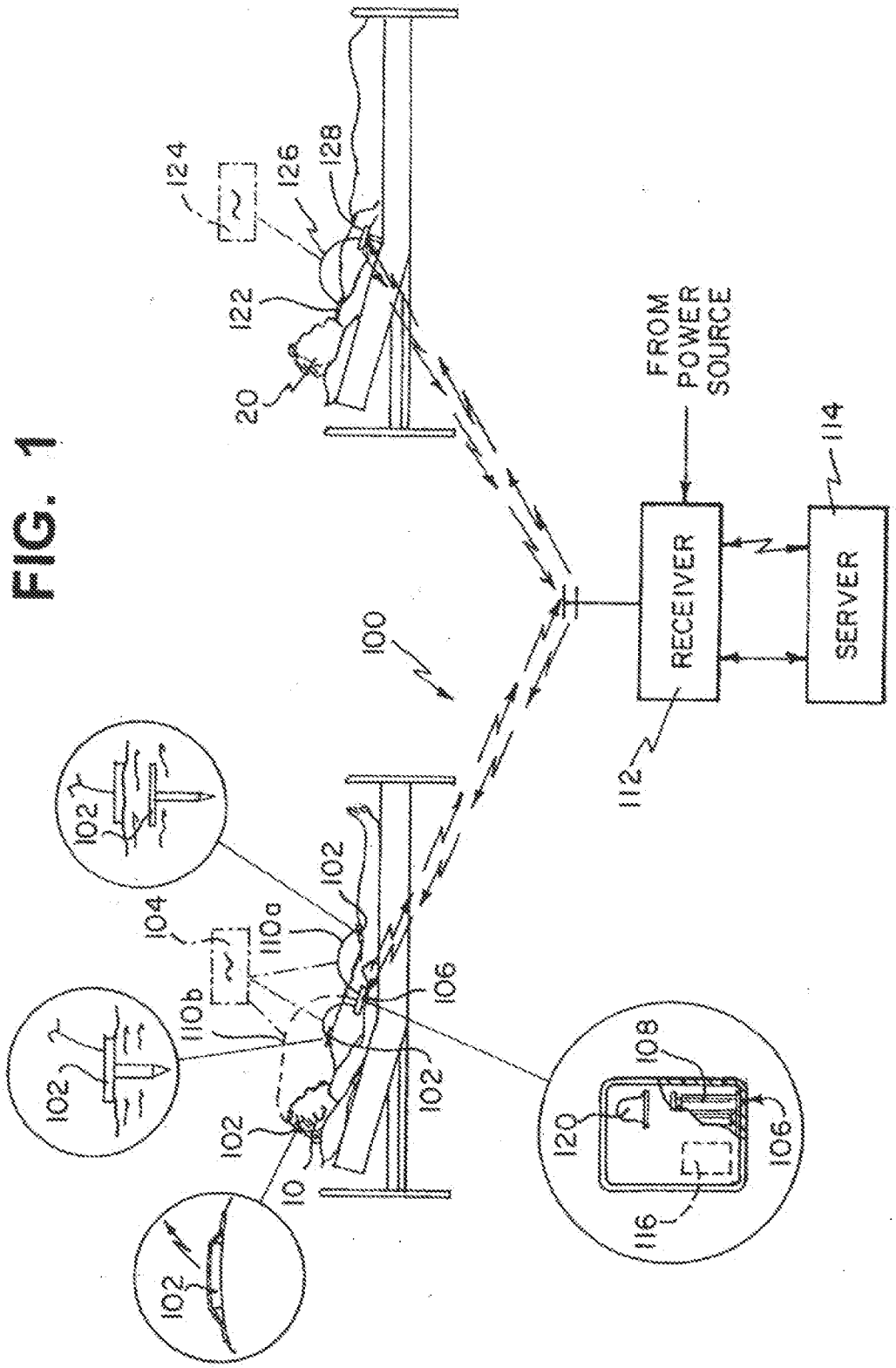

124
126
128
122
20
FROM POWER SOURCE
114
RECEIVER
SERVER
112
100
102
104
110a
110b
106
108
120
116
10

FIG. 2

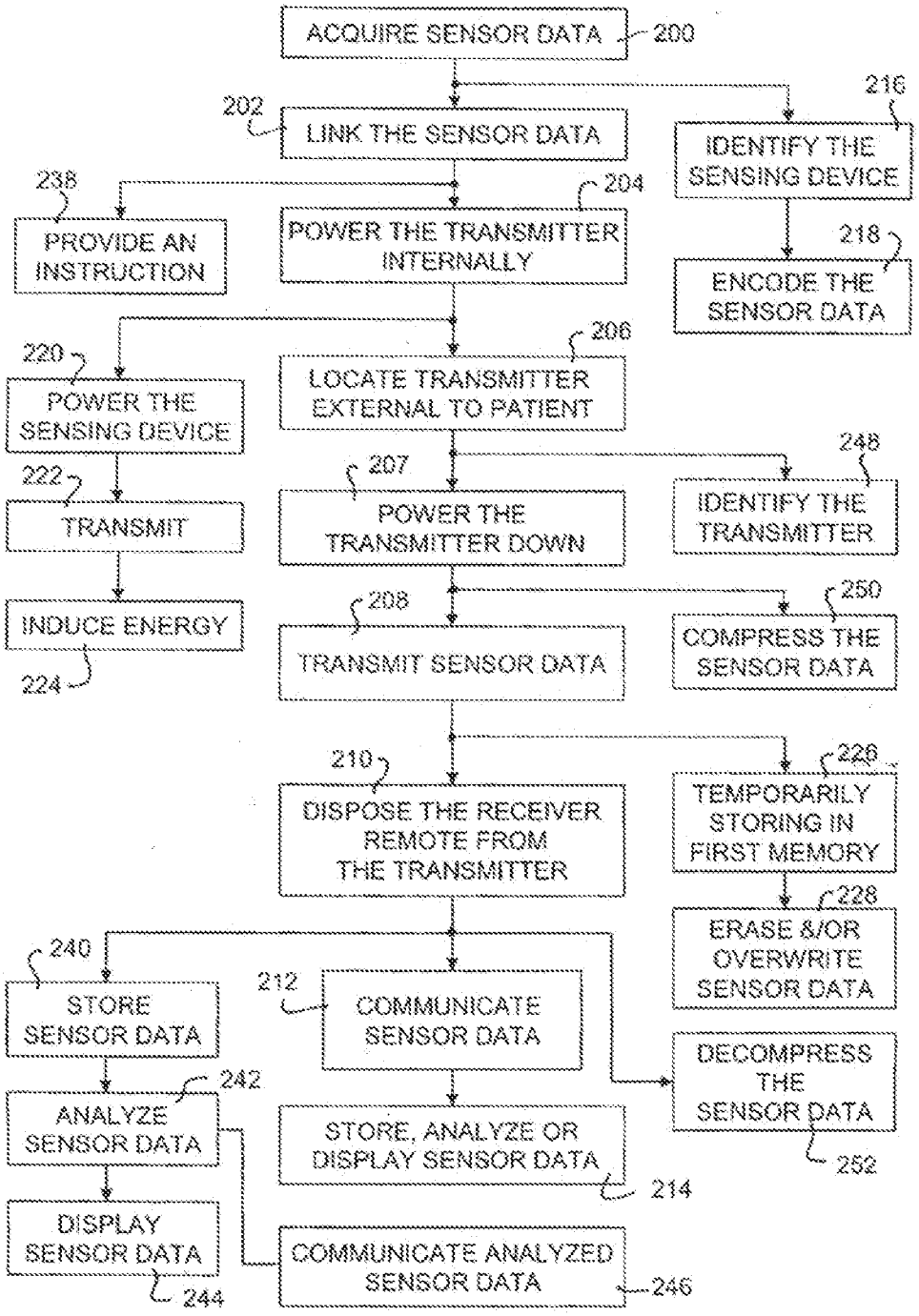

ACQUIRE SENSOR DATA
200
LINK THE SENSOR DATA
202
IDENTIFY THE SENSING DEVICE
216
PROVIDE AN INSTRUCTION
238
POWER THE TRANSMITTER INTERNALLY
204
ENCODE THE SENSOR DATA
218
LOCATE TRANSMITTER EXTERNAL TO PATIENT
206
POWER THE SENSING DEVICE
220
TRANSMIT
222
INDUCE ENERGY
224
POWER THE TRANSMITTER DOWN
207
IDENTIFY THE TRANSMITTER
248
TRANSMIT SENSOR DATA
208
COMPRESS THE SENSOR DATA
250
DISPOSE THE RECEIVER REMOTE FROM THE TRANSMITTER
210
TEMPORARILY STORING IN FIRST MEMORY
226
ERASE &/OR OVERWRITE SENSOR DATA
228
STORE SENSOR DATA
240
COMMUNICATE SENSOR DATA
212
DECOMPRESS THE SENSOR DATA
252
ANALYZE SENSOR DATA
242
STORE, ANALYZE OR DISPLAY SENSOR DATA
214
DISPLAY SENSOR DATA
244
COMMUNICATE ANALYZED SENSOR DATA
246

FIG. 3

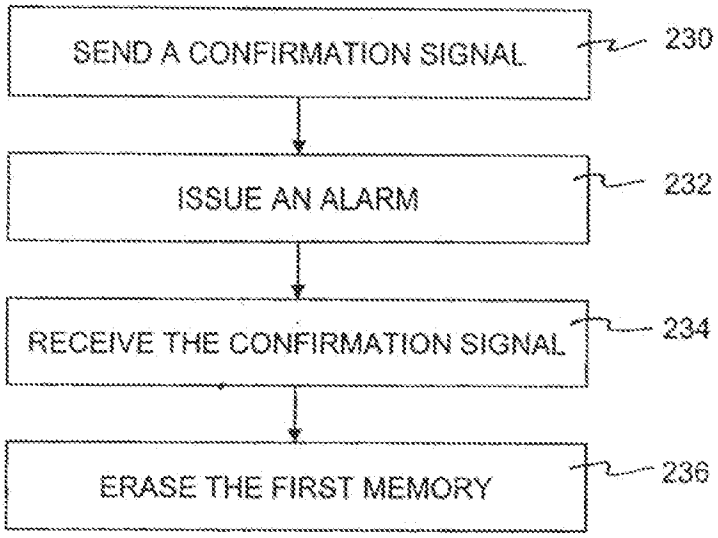
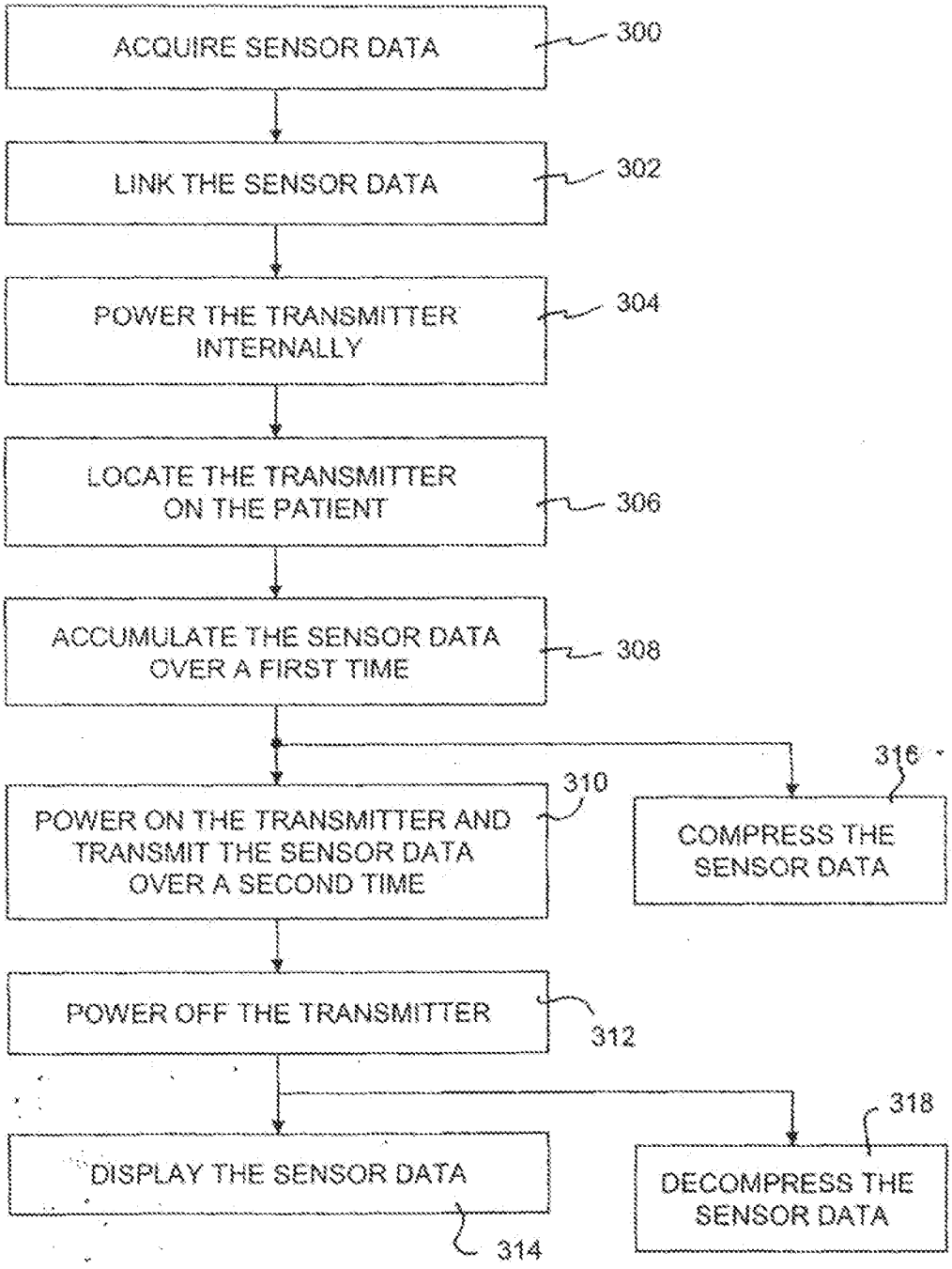

SEND A CONFIRMATION SIGNAL
230
ISSUE AN ALARM
232
RECEIVE THE CONFIRMATION SIGNAL
234
ERASE THE FIRST MEMORY
236

FIG. 4


ACQUIRE SENSOR DATA
300
LINK THE SENSOR DATA
302
POWER THE TRANSMITTER INTERNALLY
304
LOCATE THE TRANSMITTER ON THE PATIENT
306
ACCUMULATE THE SENSOR DATA OVER A FIRST TIME
308
POWER ON THE TRANSMITTER AND TRANSMIT THE SENSOR DATA OVER A SECOND TIME
310
COMPRESS THE SENSOR DATA
316
POWER OFF THE TRANSMITTER
312
DISPLAY THE SENSOR DATA
314
DECOMPRESS THE SENSOR DATA
318

REFERENCES CITED IN THE DESCRIPTION

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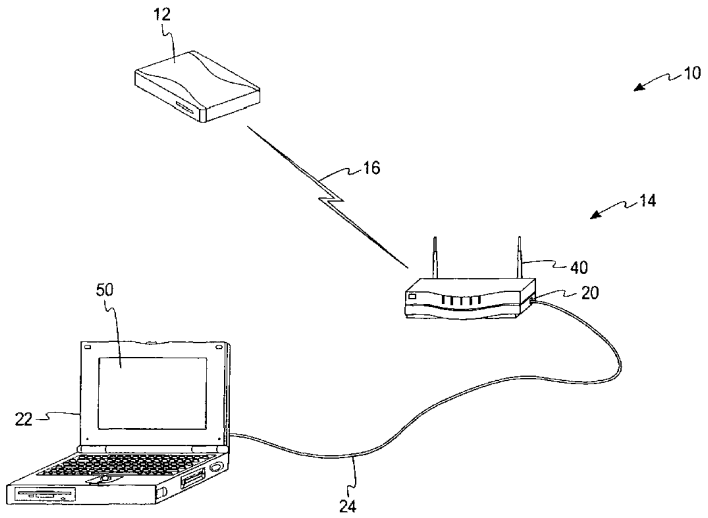
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[Continued on next page]

(54) Title: WIRELESS ANALYTE MONITORING SYSTEM



(57) Abstract: A system for monitoring a concentration of an analyte in a fluid or tissue sample. The system comprises a sensor module adapted to be borne on a patient. The sensor module includes a power supply adapted to provide a transmission power, a first transceiver adapted to transmit analyte-concentration information, and a memory. The system further comprises a remote monitoring device adapted to wirelessly communicate with the sensor module. The remote monitoring device includes a second transceiver adapted to receive the analyte- concentration information transmitted by the sensor module and adapted to transmit a signal to the sensor module confirming that the analyte-concentration information was received. The information is stored in the memory until the signal is received by the sensor module.

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WIRELESS ANALYTE MONITORING SYSTEM

FIELD OF THE INVENTION

[001] The present invention relates generally to a system and method for wirelessly monitoring the concentration of one or more analytes in a fluid or tissue sample.

BACKGROUND OF THE INVENTION

[002] The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. In particular, determining glucose in body fluids is important to diabetic individuals who must frequently check the glucose level in their body fluids to regulate the glucose intake in their diets.

[003] In one current type of blood glucose testing system, test sensors are used to test a sample of blood. The testing end of the test sensor is placed into the blood that has, for example, accumulated on a patient's finger after the finger has been pricked. Blood samples are often taken from a fingertip of a test subject because of the high concentration of capillaries, which can provide an effective blood supply. The blood may be drawn into a capillary channel that extends in the test sensor from the testing end to the reagent material by capillary action so that a sufficient amount of blood is drawn into the test sensor. A voltage is applied, causing the glucose in the blood to then chemically react with the reagent material in the test sensor, resulting in an electrical signal indicative of the glucose level in the blood. This signal is supplied to a sensor-dispensing instrument, or meter, via contact areas located near the rear or contact end of the test sensor and becomes the measured output.

[004] Drawing blood each time a glucose reading is desired is an inconvenient and invasive procedure. Moreover, drawing blood is undesirable because of the resulting pain, discomfort, and risk of infection often experienced by the patient each time a blood sample is taken.

[005] To assist in minimizing the disadvantages associated with invasive analyte-testing procedures, the concentration of a desired analyte may be continuously monitored. Continuous monitoring generally includes a portable test sensor module being borne by a patient. The sensor module collects data, which may include a parameter correlated with the concentration of the measured analyte. The sensor module may be placed over the patient's skin. Alternatively, a portion (e.g., the testing portion) of the sensor module may be placed under the patient's skin. Although placing the sensor module underneath the patient's skin

does not eliminate pain, discomfort, and/or risk of infection associated therewith, it may reduce these disadvantages because the patient need only be pricked once to obtain multiple measurement data or readings.

[006] For added convenience, continuous analyte monitoring systems may be wireless. A portable sensor module of a wireless continuous monitoring system includes a transmitter to wirelessly transmit data signals to a remote monitoring device (RMD). The RMD may, for example, be worn around the neck of a patient using a neck strap, shoulder strap, belt clip, or other suitable means. The RMD generally includes a wireless receiver to receive the data signals from the sensor module, a mechanism to interpret the data collected by the sensor module, and a data memory for storage of the interpreted data. The RMD may be equipped to communicate with other devices including, but not limited to, devices that may modify the rate of intravenous drip of drugs, glucose, insulin, drugs, pain killers, chemotherapeutic agents, or the like based on information received from the RMD.

[007] One problem associated with typical wireless continuous monitoring systems includes loss of data signals due to, for example, the receiver being out of range, being in an "off" position, interference in the communication link, or the like. Because the patient may become separated from the RMD, the data signal transmitted by the sensor module may not reach the RMD. Thus, analyte concentration measurements may be permanently lost. Thus, each sensor module must be maintained no more than a certain distance away from the RMD to ensure that each data measurement will be successfully transmitted.

[008] Furthermore, wireless continuous monitoring systems typically include a single sensor module associated with a single RMD. Thus, the patient is generally the only person who receives immediate notification if dangerous analyte concentration levels are reached. This may be undesirable for several reasons. For example, an RMD is generally kept on or near a child whose glucose levels are being monitored. Thus, a parent sleeping in another room generally may not monitor the glucose activity and generally will not be alerted when the child's glucose levels become dangerously low (hypoglycemic) or high (hyperglycemic).

[009] Similarly, requiring a separate RMD for each sensor module may be undesirable. For example, in an institutional (e.g., hospital) setting, it is typically necessary that a caregiver monitor a different RMD associated with each patient wearing a sensor module. This may be both costly and inconvenient. Moreover, the limited transmission distance associated with typical wireless continuous analyte monitoring systems makes it difficult, if

not impossible, for a caregiver to monitor the analyte concentration levels of a patient located at greater distances from the caregiver's station.

[0010] It would be desirable to have a wireless continuous monitoring system that assists in addressing one or more of the above disadvantages.

SUMMARY OF THE INVENTION

[0011] According to one embodiment of the present invention, a system for monitoring a concentration of an analyte in a fluid or tissue sample is disclosed. The system comprises a sensor module adapted to be borne on a patient. The sensor module includes a power supply adapted to provide a transmission power, a first transceiver adapted to transmit analyte-concentration information, and a memory. The system further comprises a remote monitoring device adapted to wirelessly communicate with the sensor module. The remote monitoring device includes a second transceiver adapted to receive the analyte-concentration information transmitted by the sensor module and adapted to transmit a signal to the sensor module confirming that the analyte-concentration information was received. The information is stored in the memory until the signal is received by the sensor module.

[0012] According to a process of the present invention, a method of monitoring a concentration of an analyte in a fluid or tissue sample is disclosed. The method comprises the act of obtaining a measurement corresponding with the analyte concentration using a sensor module. The sensor module includes a memory and a power supply adapted to supply a transmission power. The method further comprises the act of transmitting the measurement to a remote monitoring device using the transmission power. The method further comprises the act of, upon receiving the measurement, transmitting a signal from the remote monitoring device to the sensor module. The method further comprises the act of, upon receiving the signal, removing the measurement from the memory.

[0013] According to another embodiment of the present invention, a system for monitoring an analyte concentration of one or more patients is disclosed. The system comprises a first sensor module adapted to be borne on a first patient. The first sensor module includes a first transceiver adapted to transmit analyte-concentration data associated with the first patient. The system further comprises a second sensor module adapted to be borne on a second patient. The second sensor module includes a second transceiver adapted to transmit analyte-concentration data associated with the second patient. The system further comprises a remote monitoring device including a third transceiver adapted to receive the

analyte-concentration data wirelessly transmitted by one or more of the first and second sensor modules. The first and second transceivers are adapted to transmit data to one another and to the remote monitoring device.

[0014] According to another embodiment of the present invention, a system for monitoring an analyte concentration of one or more patients is disclosed. The system comprises a sensor module adapted to be borne on a patient. The sensor module includes a transceiver adapted to transmit analyte-concentration data associated with the patient. The system further comprises more than one remote monitoring device. Each of the remote monitoring devices includes a second transceiver adapted to receive the analyte-concentration data wirelessly transmitted by the sensor module.

[0015] The above summary of the present invention is not intended to represent each embodiment, or every aspect, of the present invention. Additional features and benefits of the present invention are apparent from the detailed description and figures set forth below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 is a perspective view of the components of a system according to one embodiment of the present invention.

[0017] FIG. 2 is a functional block diagram of the components according to one embodiment.

[0018] FIG. 3 is a flow diagram detailing a method according to one embodiment of the present invention.

[0019] FIG. 4 is a flow diagram detailing a method according to another embodiment of the present invention.

[0020] FIG. 5a is a perspective view of a system including multiple sensor modules and a single remote monitoring device, according to one embodiment of the present invention.

[0021] FIG. 5b is a perspective view of a system including a single sensor module and multiple remote monitoring devices, according to another embodiment of the present invention.

[0022] FIG. 5c is a perspective view of a system including multiple sensor modules and multiple remote monitoring devices, according to another embodiment of the present invention.

[0023] FIG. 5d is a perspective view of a system including multiple sensor modules and multiple remote monitoring devices, according to another embodiment of the present invention.

DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0024] The present invention is directed to a wireless continuous analyte monitoring system. The system may be used to assist in determining an analyte concentration in a fluid or tissue sample. Some examples of the types of analytes that may be collected and analyzed include glucose, lipid profiles (e.g., cholesterol, triglycerides, LDL, and HDL), microalbumin, fructose, lactate, or bilirubin. The present invention is not limited, however, to these specific analytes, and it is contemplated that other analyte concentrations may be determined. The analytes may be in, for example, a whole blood sample, a blood serum sample, a blood plasma sample, and/or other body fluids like ISF (interstitial fluid). One non-limiting example of a use of the wireless continuous monitoring system of the present invention is to determine the glucose concentration in a user's blood, plasma, or ISF. Although glucose is the analyte used in many of the examples described herein, it is contemplated that any suitable analyte may be used in the embodiments of the present invention.

[0025] Referring to FIG. 1, a wireless continuous monitoring system 10 according to one embodiment of the present invention is shown. The system 10 includes a portable sensor module 12 and a remote monitoring device (RMD) 14. The sensor module 12 and the RMD 14 are linked by a wireless data communication link 16. The sensor module 12 may include any of a variety of devices capable of monitoring one or more selected physiological conditions or analyte (e.g., glucose) concentrations of a patient and to transmit data taken by the sensor module 12 to the RMD 14. The sensor module 12 may be borne on any suitable portion of the patient's body including, but not limited to, the patient's arm or abdomen. The sensor module 12 may be placed over the patient's skin (i.e., a transdermal sensor), or the sensor module or a portion thereof may be implanted under the patient's skin (i.e., an insertable sensor). The sensor module 12 may be removably secured to the patient's body using any suitable means including, but not limited to, adhesive, a bandage, a body or arm band, or the like.

[0026] The sensor module 12 may be maintained on a patient's body for extended periods of time. For example, the patient may wear the sensor module 12 for up to five days or more.

To minimize the inconvenience to the patient, it is desirable for the sensor module 12 to be as small as possible. Small, battery-powered sensor modules allow the patient to move freely about while still permitting the continuous monitoring of relevant patient physiological conditions or analyte concentrations. Because of such size limitations and desired placement on a patient's body, it is often not feasible for the sensor module 12 to include a display for displaying data measurement values, a device capable of converting collected data into values useful to the patient, or the like. However, it is contemplated that a low power and/or an error indicator may be included on the sensor module 12. In one example, an LED is used to show that the sensor module 12 is working properly. The LED may display a green light if the sensor module 12 is functioning properly and a red light is the sensor module 12 is experiencing an error or problem. Other ways of indicating low power or errors in the sensor module 12 may also be used.

[0027] The RMD 14 may be carried by the patient in his or her pocket, worn around the patient's neck using a neck strap, shoulder strap, belt clip, or the like. Carrying the RMD 14 at all times, however, may be inconvenient, heavy, and/or bulky. Thus, the patient it may be desirable for the patient to remove the RMD 14 and place it in a stationary position (e.g., in the patient's home, workplace, or the like).

[0028] The RMD 14 may include a data port 20, which may be connected to a personal computer 22, a cellular telephone (not shown), or the like via a cable or cord 24. The data port 20 allows the RMD 14 to communicate with, for example, the personal computer 22 so that stored glucose readings, concentration trends, and corresponding information may be transferred to and displayed on the computer 22. The RMD 14 may also wirelessly communicate with the personal computer 22 (e.g., using Bluetooth or WiFi). The RMD 14 may also include a display (not shown) to display the measurement data, trends, and/or the like.

[0029] FIG. 2 is a block diagram of the functional components of the sensor module 12 and of the RMD 14. The sensor module 12 includes a unique identifier. The sensor module further includes an operation device 30 generally including elements required to operate the sensor module 12 and, thus, to measure a parameter correlating with, for example, the glucose concentration of the patient at the test site. The function of the operation device 30 is known to those skilled in the art and, therefore, will not be described further herein. The measurements are fed to a processor 32. The processor 32, which includes an analog-to-digital converter, converts the outputs received from the operation device 30 to a suitable

digital form for transmission to the RMD 14. It is also contemplated that the measurements may be transmitted using direct analog transmission. Depending on the sensor module 12, the processor 32 may also include selected information regarding the patient, error checking means, or the like. The processor 32 may also process received data to a more useful form and/or have other suitable functions. The sensor module 12 further includes a memory unit 39, which may be separate from or associated with the processor 32. The sensor module 12 also includes a power-supply battery 37. The battery 37 may be rechargeable and is adapted to provide a transmission power to the RMD 14. A voltage monitor (not shown) may be integrated into the sensor module 12 to alert the patient in a timely manner of the need for battery exchange or recharge.

[0030] Although not necessary, the sensor module 12 may further include an output unit 36. The output unit 36 may issue an audio, visual (e.g., a light), and/or vibrational alarm if a certain condition(s) is met. For example, an alarm may be activated if a dangerous glucose value (i.e., dangerously high or low) is detected by the sensor module 12 Alternatively or additionally, the alarm may be activated if the sensor module 12 loses communication with the RMD 14. Thus, the output unit 36 may provide additional protection for the patient. The output unit 36 may be chosen for minimum size and consumption of battery 37.

[0031] The output from the processor 32 is provided to a transceiver 38. Any suitable type of transceiver 38 may be built into the sensor module 12 including, but not limited to the MaxStream® Xbee™ OEM RF module (MaxStream, Inc., Lindon, Utah) ("the MaxStream® module"), which operates generally within the ISM 2.4 GHz frequency band. Low-power systems, such as the MaxStream® module, may be desirable for use in longer-term analyte sensor modules.

[0032] The transceiver 38 provides the output from the processor 32 to a receiving antenna 40 (see FIG. 1), which also operates to receive wireless data. The transceiver 38 and/or the antenna 40 may be infra-red (IR) elements, radio frequency (RF) elements, or other suitable radiation transceiving elements. Radiation outputted by the transceiver 38 is, thus, received by one or more of the antenna 40 or other receiving devices suitably positioned on or in the RMD 14.

[0033] The receiving devices (e.g., antenna 40) are connected to a second transceiver 42 positioned within the RMD 14. Information received at the second transceiver 42 is provided to a CPU 44. The CPU 44 may perform further processing on the received information. The CPU 44 may selectively store such information, either in received form or in processed form,

in temporary or bulk storage devices 48. Information is communicated between the transceiver 38 and the second transceiver 42 via the communication link 16, which is preferably a wireless communication link.

[0034] Furthermore, it may be desirable for a communications protocol facilitating communication with cellular phones, wireless computer networks, and the like, to be used. One non-limiting example of a communication protocol that may be used in the embodiments of the present invention is the 802.15.4 standard. The 802.15.4 standard offers a low data rate and power management functions to ensure low power consumption. Preferably, the transceiver 38 operates in the 2.4 GHz frequency band, in which there are 16 channels, each addressable by 16-bit or 64-bit addressing. For communication with cellular phones, the processor 32 and the CPU 44 are programmed to format data communicated across the communication link 16 according to any number of cellular data protocols, such as one compatible with the Short Message Service (SMS) of the CDMA or GSM cellular protocols. In one embodiment, data representative of the patient's monitored analyte concentrations may be sent as a text message across the SMS service to a cellular phone in lieu of or in addition to the RMD 14. Other information may also be sent, including information indicative of an alarm (for example, in response to a hypoglycemic or hyperglycemic glucose level), a signal indicative of a loss of communication with the RMD 14 (for example, if the patient leaves the RMD 14 at a location). Still other information that can be transmitted from the sensor module 12 to the RMD 14 is mentioned below and can also be transmitted to a cellular phone as a data message. In other aspects, the RMD 14 may communicate with a cellular phone by transmitting image data associated with the concentration levels (e.g., a graph showing historical measured levels over a period of time) or information indicating a loss of communication with the sensor module 12 (e.g., communication attempts between the RMD 14 and the sensor module 12 repeatedly failed over a period of time, whereupon the RMD 14 sends an SMS message to the cellular phone indicating the loss of communication with the sensor module 12).

[0035] The RMD 14 may then be linked to the computer 22 using the cable or cord 24. Upon linking the RMD 14 to the computer 22, the information is transferred from the storage device 48 to the computer 22 for further processing. Images indicative of such received information may be displayed on one or more displays (e.g., display 50 of FIG. 1) of the computer 22. Thus, the patient's relevant analyte concentration(s) and/or trends thereof may

be monitored. The computer 22 may display the data in any suitable way including alpha-numerically, graphically, combinations thereof, or the like.

[0036] A unique sequence identifier (e.g., an index number) is assigned to each data measurement. As measurement data are collected, the sequence identifier is incremented. Thus, the software of the RMD 14 has a sequence identifier linked to the measurement data. The RMD 14 generally includes a real-time clock such that a time and/or date may be associated with each sequence identifier and, thus, with each data measurement. In another embodiment, the sensor module 12 includes a real-time clock. The time/date stamp may alternatively be used as the sequence identifier, as each time/date stamp will be unique. The sequence identifier is used to keep track of what data is transmitted from the sensor module 12 to the remote monitoring device 14. When measurement data are transmitted, the sequence identifier associated with the most recent data measurement not yet transmitted is logged by the sensor module 12. Alternatively, the sensor module 12 stores the range of sequence identifiers associated with the measurement data transmitted from the sensor module 12.

[0037] In another aspect of the present invention, the RMD 14 may transmit a signal to the sensor module 12 indicative of a request for data measured during a certain time period, such as the previous two hours. According to this aspect, the processor 32 of the sensor module 12 analyzes the time/date stamps (or the sequence identifier in embodiments where the time/date stamp is used as the sequence identifier) to determine which measurement data fall within the requested time period. The sensor module 12 then transmits to the RMD 14 the measurement data associated with the requested time period.

[0038] The transmission distance between the sensor module 12 and the remote monitoring device 14 may generally range from about 1 foot to about 100 feet. More specifically, the transmission distance may range from about 5 feet to about 30 feet. For example, the MaxSteam® module has a transmission distance of about 100 feet.

[0039] As discussed above, the RMD 14 is often not carried by the patient at all times. According to the present invention, if the sensor module 12 loses communication with the RMD 14, all measurement data collected during the period of lost communication are stored in the memory 39 of the sensor module 12 until communication is restored. Communication may be lost, for example, when the RMD 14 is out of range (e.g., when a patient fitted with the sensor module 12 is outside of the transmission distance from the RMD 14), when the RMD 14 is in an "off" position, when there is interference with the signal, when the patient is

engaged in heavy exercise, or the like. Thus, when the sensor module 12 becomes sufficiently close to the RMD 14 such that the wireless exchange of data between the sensor module 12 and the RMD 14 is restored, the measurement data acquired during the period of non-communication are transferred from the memory 39 of the sensor module 12 into the second transceiver 42 of the RMD 14.

[0040] According to one embodiment, to further conserve power, a proximity sensor (e.g., a reed switch and a magnet) is utilized between the RMD 14 and the sensor module 12. When the sensor module 12 is within a certain distance from the RMD 14, communication between the sensor module 12 and the RMD 14 is restored. Alternatively or additionally, the proximity sensor may be used as a trigger to send data in an ultra low power version. In such an ultra low power version, to view the data, the displa y 50 must be within a certain proximity of the sensor module 12.

[0041] According to one aspect of the present invention, after the sensor module 12 transmits the measurement data to the RMD 14, the sensor module 12 awaits an acknowledgement signal from the RMD 14 that the measurement data have been successfully received. In one aspect, when the acknowledgement signal is received from the RMD 14, the sensor module 12 deletes the measurement data taken during the time period measured. In another aspect, the measurement data are not deleted until the next regular or scheduled transmission. The sensor module may store a range of sequence identifiers associated with the transmitted measurement data in the memory 39 or in the memory associated with the processor 32. The most recently stored sequence identifier is used as a "place holder" to keep track of what measurement data was already transmitted so that as the sensor module 12 continues to store subsequent measurement data, it has the ability to remember where the transmitted data ends and where the non-transmitted data begins. Thus, the sensor module 12 may continue to store subsequent measurement data while waiting for an acknowledgement from the RMD 14 that the transmitted data was received. Once that acknowledgment signal is received from the RMD 14 at the sensor module 12, the sensor module 12 may delete the measurement data associated with the stored sequence identifiers and all historical measurement data. Any newly stored but not yet transmitted measurement data are thus preserved in the sensor module 12 for transmission.

[0042] By buffering all measurement data and continuing to buffer measurement data following a transmission, loss of the measurement data is avoided in at least two ways. First, historical measurement data is preserved until it can be transmitted successfully to the RMD

14. In the event of a transmission failure, no measurement data is lost. Second, measurement data that is accumulated during or following a transmission is preserved until the next transmission can be made. The storage of the sequence identifiers prevents measurement data that is recorded during or following a transmission from being lost or erased. In other words, only that measurement data that is successfully transmitted and acknowledged by the RMD 14 as received will be deleted from the memory 39. All other measurement data (historical or future) is stored until it can be successfully transmitted.

[0043] FIG. 3 illustrates a method according to one embodiment of the present invention. At step s100, the test sensor module 12 obtains measurement (e.g., analyte concentration) data. The measurement data is associated with a unique sequence identifier, as described above, at step s102. The measurement data and corresponding sequence identifier are stored in the memory 39 of the sensor module 12 at step s104. At determining step s106, whether a data-transmission triggering event has occurred is determined. A data-transmission triggering event may include occurrence of an alarm condition (e.g., exceeding a threshold indicating a hypoglycemic or hyperglycemic condition), passage of a predetermined time interval, an update request from the RMD 14, or the like. Thus, the sensor module 12, the RMD 14, or a combination thereof may trigger data transmission. If a data-transmission triggering event has not occurred, the measurement data continues to be stored in the memory 39 of the sensor module 12 (step s104). On the other hand, if a data-transmission triggering event has occurred, measurement data is transmitted from the sensor module 12 to the RMD 14 at step s108. Once the measurement data has been transmitted at step s108, whether the sensor module 12 has received an acknowledgement signal from the RMD 14 that the measurement data has been received is determined at step s110. If an acknowledgement signal has not been received, the measurement data is continued to be stored in the memory 39 of the sensor module 12 (step s104). If, on the other hand, an acknowledgement signal is received, the measurement data may be deleted from the memory 39 of the sensor module 12.

[0044] The storage capacities of the memory 39 of the sensor module 12 and the storage device 48 of the RMD 14 match the particular applications for which they are intended. For example, the memory 39 of the sensor module 12 is used primarily for the intermediate storage of relatively small volumes of data, namely the measurement values stored since the last time that the sensor module 12 was in communication with the RMD 14. For example, the capacity of the memory 39 may be approximately 512 kilobits (kb). The memory 39 of the sensor module 12 may have the capacity to store measurement data for about 48 hours,

depending on how often concentration measurements are taken. The capacity of the memory 39 may also be less than or greater than the examples provided. For example, the memory 39 of the sensor module 12 may be increased to store, for example, several days of measurement data. The memory 48 of the RMD 14 is generally substantially larger than the memory 39 of the sensor module 12 and may store data generated over long time intervals (at least one week).

[0045] The memory 39 or the memory associated with the processor 32 in the sensor module 12 may store other data (in addition to measurement data and the sequence identifier) indicative of the following types of modifiable information, alone or in any combination: (1) the time and/or date of the last successful transmission; (2) the time and/or date of the last attempted transmission; (3) one or more alarm thresholds corresponding to one or more analyte concentration measurements; (4) the type of alarm to be indicated by the output unit 36 (e.g., audible, visual, vibrational, or no alarm); (5) a desired power output level of the antenna 40; (6) the time interval during which the operation device 30 is to take a measurement (e.g., every hour or every two hours); (7) the type of analyte to be monitored; (8) the amount of power remaining in the battery 37; (9) the unique network address of the sensor module 12, which is used for transmitting information on an available channel in the communication link 16; or (10) relative aggregate data including, for example, data obtained during the most recent 1,000 minutes, 1,000 hours, 1,000 days, or other suitable time period. The sensor module 12 may use the amount of power remaining in the battery 37 to dynamically adjust the power output of the antenna 40. For example, if the battery 37 power level is low, the power output of the antenna 40 can be reduced to save battery power. The output unit 36 may indicate when the power level of the battery 37 becomes too low to sustain reliable functioning.

[0046] The memory 48 in the RMD 14 device may store data indicative of the following types of modifiable information, alone or in any combination: (1) the measurement data transmitted by the sensor module 12 and/or the corresponding sequence identifier(s); (2) one or more types of errors, such as corrupted data, partially received data, no data, and the like; (3) a command to send immediately or within a specified time period (a) all measurement data stored since the last transmission, (b) a selected range of measurement data, or (c) measurement data conforming to one or more criteria (such as (i) only those measurement data representing glucose concentrations exceeding a specified level, or (ii) the data measurement(s) corresponding to the highest measured analyte concentrations); (4) an

analyte concentration threshold for triggering an alarm that is indicated by the output unit 36 of the sensor module 12; (5) one or more types of alarms to be indicated by the output unit 36 of the sensor module 12, such as an audible alarm, a visual alarm, a vibrational alarm, or no alarm; (6) a command to retransmit the measurement data; (7) a command for the sensor module 12 to erase part or all of its memory 39; (8) a command instructing the sensor module 12 to take a measurement immediately and transmit the measurement data to the RMD 14; (9) a command instructing the sensor module 12 to change its power output level and/or one or more power output levels (e.g., low, high, off); (10) data indicating that the RMD 14 will be unavailable for a specified or unspecified period of time and optionally the nature of the reason for such unavailability; (11) one or more time intervals during which the sensor module 12 is to take measurements (e.g., every two hours or every hour); (12) the type(s) of analyte(s) to be monitored by the sensor monitor 12 (e.g., glucose, lipids, fructose, bilirubin, and the like); (13) network administration information, such as (a) the network address of the RMD 14 or the sensor module 12 or (b) a command to the sensor module 12 to change its network address; (14) a command disallowing an attempted transmission by the sensor module 12 because it is an unauthorized device; (15) one or more SMS messages for transmission to a cellular telephone (such as a loss of communication with a sensor module, with an RMD), image data conveying information about the measurement data (e.g., a graph of measured analyte levels over a given period of time).

[0047] According to another embodiment of the present invention, the transmission power of the system 10 may be varied depending on the quality, level, and/or strength of communication between the sensor module 12 and the RMD 14. For example, the transmission power is decreased if the level of communication is strong or if battery power is low. Conversely, the transmission power is generally increased if the level of communication is weak. In the case where communication has been lost altogether and is not reestablished after a certain, predetermined time interval, the transmission power level may be reduced to its normal level, thereby assisting in conserving the life of the battery 37. In one embodiment, when communication has been lost altogether, the transmission power is reduced to a minimal level with an intermittent burst of high transmission power to seek to reestablish communication with the RMD 14. As described below, the transmission power can also be varied by the RMD 14 by issuing a command to the sensor module 12 to vary the power. In addition, the sensor module 12 may turn off the antenna 40 until the sensor module 12 needs to transmit data to the RMD 14.

[0048] In addition to the signals described above, the sensor module 12 may receive various other types of signals from the RMD 14. The signals sent from the RMD 14 to the sensor module 12 may include any one or more of the following: (1) a signal indicative of an acknowledgement that data transmitted from the sensor module 12 was received by the RMD 14; (2) a signal indicative of an error in the transmission of data received from the sensor module 12 (e.g., the data was corrupted during transmission); (3) a signal indicative of a command by the RMD 14 to the sensor module 12 to send now or within a specified time period (a) all measurement data stored since the last transmission, (b) a selected range of measurement data, or (c) measurement data conforming to one or more criteria (such as (i) only those measurement data representing glucose concentrations exceeding a specified level, or (ii) the data measurement(s) corresponding to the highest measured analyte concentrations); (4) a signal indicative of an analyte concentration threshold (e.g., a threshold indicating a hypoglycemic or hyperglycemic condition) for triggering an alarm that is indicated by the output unit 36 of the sensor module 12; (5) a signal indicative of the type of alarm to be indicated by the output unit 36 of the sensor module 12, such as an audible alarm, a visual alarm, a vibrational alarm, or no alarm; (6) a signal indicative of a command to the sensor module 12 to retransmit the measurement data; (7) a signal indicative of a command to erase part or all of the memory 39; (8) a signal indicative of a command instructing the sensor module 12 to take a measurement now and transmit the measurement data to the RMD 14; (9) a signal indicative of a command instructing the sensor module 12 to change its power output level; (10) a signal indicating that the RMD 14 will be unavailable for a specified or unspecified period of time and, optionally, the nature of the reason for such unavailability; (11) a signal indicative of the time interval during which the sensor module 12 is to take measurements (e.g., every two hours or every hour); (12) a signal indicative of the type(s) of analyte(s) to be monitored by the sensor monitor 12 (e.g., glucose, lipids, fructose, bilirubin, and the like); (13) a signal indicative of network administration, such as (a) a change in the network address of the RMD 14 or the sensor module 12 or (b) a command to the sensor module 12 to change its network address; (14) a signal disallowing the transmission because the sensor module 12 is an unauthorized device.

[0049] In response to receiving any of the above signals from the RMD 14, the sensor module may take the following respective actions: (1) erases the measurement data corresponding to the measurement data transmitted to and acknowledged as received by the RMD 14; (2) retransmits the measurement data; (3) transmits the requested measurement

data; (4) changes the analyte concentration threshold for triggering an alarm, which threshold may optionally be stored in the memory 39; (5) changes the type of alarm to be indicated by the output unit 36, which type may optionally be stored in the memory 39; (6) retransmits the measurement data; (7) erases part or all of the memory 39; (8) takes a measurement and then transmits that measurement data to the RMD 14; (9) changes its power output level, which may optionally be stored in the memory 39 (e.g., the sensor module 12 enters a "power saving" mode); (10) continues to buffer measurement data in the memory 39 until the RMD 14 is available again and thereafter transmitting all buffered measurement data when the RMD 14 is expected to be available again; (11) changes the time interval during which the sensor module 12 is to take measurements, which time interval may optionally be stored in the memory 39; (12) monitors the requested type of analyte; (13) changes the network address associated with the sensor module 12; (14) attempts to transmit to another RMD in the network or to another sensor module.

[0050] Referring to FIG. 4, a method according to one embodiment of the present invention is detailed. At step s200, the RMD 14 provides a signal to the sensor module 12. The signal may include any type of signal described above or combinations thereof. The sensor module 12 receives the signal at step s205. Depending on the type of signal produced and received, the sensor module 12 may modify a parameter of the sensor module software (step s210) or transmit measurement data from the sensor module 12 to the RMD 14 (step s215). Sensor parameters that may be modified at step s210 include, for example, analyte-concentration thresholds for triggering an alarm, the type of alarm, power output levels, the length of time between measurements, the type(s) of analyte(s) to be monitored, the sensor module's network address, combinations thereof, or the like. The transmitting data step (s215) may be conducted in accordance with the method illustrated in FIG. 3 and described above.

[0051] According to another embodiment, communication between the sensor module 12 and the RMD 14 are coordinated such that one transmits data at the same time the other is adapted to receive the data. This may be useful since power may be consumed by the devices when they are transmitting data as well as when they are receiving data. In one example, impromptu communication (e.g., an alarm condition) between the sensor module 12 and the RMD 14 may be preceded by a non-RF trigger to assist in synchronizing the communication between the sensor module 12 and the RMD 14.

[0052] According to yet another aspect of the present invention, the wireless continuous monitoring systems of the present invention may be tailored to the needs of a user. For example, in FIGs. 5a-d, the systems of the embodiments of the present invention may include hardware capable of establishing point-to-point communication (see FIG. 5a), point-to-multipoint communication (see FIGs. 5b, 5c), peer-to-peer communication (see peer-to-peer link between sensor modules 269, 270 in FIG. 5d), or mesh communication (see FIG. 5d).

[0053] In FIG. 5a, multiple sensor modules 260 may transmit respective measurement data to a single RMD 262. This may be useful, for example, in an institutional (e.g., hospital) setting where a caregiver may monitor the analyte concentrations of several different patients on a single RMD 262.

[0054] In FIG. 5b, a single sensor module 264 may transmit measurement data to multiple RMDs 266a,b. The embodiment of FIG. 5b has multiple advantages. For example, if the sensor module 264 is borne by a child, a first RMD 266a may be located near the child such that measurement data from the sensor module 12 may be readily transmitted from the sensor module 12 to the first RMD 266a. An alarm on the first RMD 266a may issue if the child's glucose concentration is outside of the normal limits. A second RMD 266b located near the child's parent may also (or alternatively) issue an alarm, thereby alerting the parent that the child's glucose concentration is outside of the normal limits. This may be particularly useful, for example, when the child is sleeping, engaged in sports, playing outside, or the like. According to the embodiment of FIG. 5b, the child's parent need not be in the same room or even in hearing range of an alarm on the child's RMD 266a to know that the child's glucose concentration is at a dangerous level. Instead of or in addition to an alarm, the parent may monitor the child's glucose level in other suitable ways. For example, the second RMD 266b may include a display for displaying glucose levels, may be connected to a computer, or the like.

[0055] In embodiments where a wireless continuous monitoring system includes more than one RMD, as in FIG. 5b, it is contemplated that in certain circumstances, the sensor module 264 may be in communication with less than all of the RMDs 266a,b. In such a circumstance, the sensor module may include internal software allowing it to store measurement data in a memory (as described above) until it receives a signal from each of the RMDs 266a,b with which it is intended to communicate, indicating that all of the RMDs have successfully received the transmitted measurement data. Once all of the signals are received, the measurement data may be erased from the memory.

[0056] Because each sensor module has its own unique identifier associated therewith, multiple sensor modules may communicate with a single RMD. FIG. 5c shows multiple sensor modules 267a,b communicating with multiple receivers. In the embodiment of FIG. 5c, a first sensor module 267a is in communication with a first RMD 268a and a common RMD 268b. A second sensor module 267b is in communication with a second RMD 268c and the common RMD 268b. Such an embodiment may be desirable, for example, where two children in the same household are monitoring their glucose levels (e.g., on RMDs 268a, 268c) and a parent is monitoring the glucose levels of both children (e.g., on the central RMD 268b). Alternatively, this embodiment may be desirable in an institutional setting where two patients are individually monitoring their glucose levels (e.g., on RMDs 268a, 268c) and a caregiver is monitoring the glucose levels of both patients (e.g., on the central RMD 268b).

[0057] Referring now to FIG. 5d, a mesh system is shown in which data may be transmitted peer-to-peer between multiple sensor modules (e.g., sensor module 269 to sensor module 270) and from a sensor module (e.g., sensor module 272) to an RMD (e.g., RMD 274). The mesh system shown in FIG. 5d can reconfigure broken or blocked communication links by hopping from sensor module to sensor module until the destination is reached. Thus, a sensor module may transmit measurement data to an RMD outside its range by passing the measurement data through other sensor modules located at distances closer to the RMD via internal software. The transmission distance between the sensor module (e.g., sensor module 269) and the RMD 274 is thereby significantly increased. This embodiment may be particularly useful, for example, in institutional settings (e.g., hospitals) in which patients wearing sensor modules are located generally near each other but are located a substantial distance from the RMD 274. Thus, a single RMD 274 at, for example, a nurse's station, may allow the caregiver to monitor many sensor modules on many different patients.

[0058] In networks such as the mesh network shown in FIG. 5d enabling peer-to-peer communication, each sensor module can communicate uni-directionally or bi-directionally with other sensor modules in the network. In one aspect, if a memory in one sensor module becomes too full to store any further measurement data, that sensor module can "forward" subsequent measurement data to a proxy sensor module for storage until the sensor module has successfully transmitted its measurement data to an available RMD and erased its memory contents. The proxy sensor module can then retransmit the forwarded measurement data back to the sending sensor module when it has free memory space. In another aspect, if a sensor module loses communication with an RMD, it can pass its data to another proxy

sensor module for transmission to an RMD. In this aspect, the originating sensor module also transmits identification information, such as its network address, along with the sequence identifiers and measurement data so that its origin can be ascertained by the RMD. The originating sensor module also sends a signal to the proxy sensor module indicative of a command to forward the forthcoming measurement data to the RMD. Thus, when the proxy sensor module receives the measurement data, it transmits the data to the RMD along with the identification information so that the RMD knows that this data is associated with a sensor module different from the sensor module sending the data.

[0059] Peer-to-peer configurations also allow the RMD to issue system-level commands or instructions to all sensor modules in the network without having to broadcast the command or instruction multiple times to each sensor module. In one aspect, the RMD sends a command or instruction to one sensor, which forwards it to all peers in the network in relay fashion.

[0060] In another embodiment, the RMD is adapted to receive data from a first sensor module to assist in calibrating a second sensor module. The first sensor module may, for example, have been used during a previous monitoring period, and the second sensor module may be used for a subsequent monitoring period. The RMD in this embodiment may inform a user when to replace the first sensor module with the second sensor module.

[0061] In yet another embodiment, the RMD may be adapted to communicate with an independent device that may be adjusted based on information transmitted from the RMD. For example, the RMD may communicate with a device connected to an intravenous drip providing, for example, glucose, insulin, drugs, pain killers, chemotherapeutic agents, or the like based on information received from the RMD.

[0062] The hardware of the sensor modules of the embodiments of the present invention may allow for multiple software-selectable frequencies. The 802.15.4 protocol operating in the 2.4 GHz frequency band allows for up to 16 different connections without sharing a channel. However, the 802.15.4 protocol includes two software addressing modes, 16-bit short and 64-bit IEEE addressing. By using software addressing within each channel, systems according to the present invention can accommodate 65,536 sensor modules (using 16-bit short addressing), each having its own network-addressable transceiver, on the same channel. In order to transmit on a channel, the sensor module would wait until it is addressed individually before using the channel. This may be useful, for example, in an institutional

(e.g., hospital or hospital ward) setting where hundreds or even thousands of sensor modules could be operating at any given time.

[0063] In any of the foregoing aspects or embodiments described herein, data communicated across the wireless communication link between the sensor modules and the one or more RMD units may be encrypted for increased security and compliance with privacy regulations. The sensor module and RMD would include encryption and decryption modules that would also include appropriate keys for ciphering/deciphering the data. Alternately, the data communicated across the wireless communication link may be ciphered in such a way that renders it very difficult to recreate the original message without the proper cipher.

ALTERNATIVE EMBODIMENT A

[0064] A system for monitoring a concentration of an analyte in a fluid or tissue sample comprising:

a sensor module adapted to be borne on a patient, the sensor module including a power supply adapted to provide a transmission power, a first transceiver adapted to transmit analyte-concentration information, and a memory; and

a remote monitoring device adapted to wirelessly communicate with the sensor module, the remote monitoring device including a second transceiver adapted to receive the analyte-concentration information transmitted by the sensor module and adapted to transmit a signal to the sensor module confirming that the analyte-concentration information was received,

wherein the information is stored in the memory until the signal is received by the sensor module.

ALTERNATIVE EMBODIMENT B

[0065] The system of Alternative Embodiment A, wherein the sensor module includes a transdermal test sensor or an insertable sensor.

ALTERNATIVE EMBODIMENT C

[0066] The system of Alternative Embodiment A, wherein the analyte is glucose.

ALTERNATIVE EMBODIMENT D

[0067] The system of Alternative Embodiment A, wherein the transmission power is fluctuated based on quality, level, or strength of the wireless communication.

ALTERNATIVE EMBODIMENT E

[0068] The system of Alternative Embodiment A, wherein the remote monitoring device further comprises a device adapted to interpret the analyte-concentration information and an

information storage device.

ALTERNATIVE EMBODIMENT F

[0069] The system of Alternative Embodiment A, wherein the analyte-concentration information is stored in the memory when wireless communication with the remote monitoring device is lost and the analyte-concentration information is transmitted to the remote monitoring device when the wireless communication is restored.

ALTERNATIVE EMBODIMENT G

[0070] The system of Alternative Embodiment A, wherein the analyte-concentration information includes measurement data having a sequence identifier being associated therewith, the sequence identifier being adapted to track whether the measurement data has been transmitted to the remote monitoring device.

ALTERNATIVE EMBODIMENT H

[0071] The system of Alternative Embodiment A, wherein the analyte-concentration information is transmitted in response to a transmission triggering event.

ALTERNATIVE EMBODIMENT I

[0072] The system of Alternative Process H, wherein the transmission triggering event includes exceeding a threshold analyte concentration, passage of a predetermined time interval, or a signal request from the remote monitoring device.

ALTERNATIVE EMBODIMENT J

[0073] The system of Alternative Embodiment A, further comprising a second sensor module.

ALTERNATIVE EMBODIMENT K

[0074] The system of Alternative Embodiment J, wherein the second sensor module is adapted to transmit analyte-concentration data to at least one of the sensor module and the remote monitoring device.

ALTERNATIVE EMBODIMENT L

[0075] The system of Alternative Embodiment A, further comprising a second remote monitoring device adapted to wirelessly communicate with the sensor module, the second remote monitoring device including a third transceiver adapted to receive the analyte-concentration information transmitted by the sensor module.

ALTERNATIVE EMBODIMENT M

[0076] The system of Alternative Embodiment A, wherein the remote monitoring device is adapted to be linked to a computer.

ALTERNATIVE PROCESS N

[0077] A method of monitoring a concentration of an analyte in a fluid or tissue sample, the method comprising the acts of:

obtaining a measurement corresponding with the analyte concentration using a sensor module, the sensor module including a memory and a power supply adapted to supply a transmission power;

transmitting the measurement to a remote monitoring device using the transmission power;

upon receiving the measurement, transmitting a signal from the remote monitoring device to the sensor module; and

upon receiving the signal, removing the measurement from the memory.

ALTERNATIVE PROCESS O

[0078] The method of Alternative Process N, further comprising varying the transmission power based on a level of communication between the sensor module and the remote monitoring device.

ALTERNATIVE PROCESS P

[0079] The method of Alternative Process N, further comprising storing the measurement in the memory when communication with the remote monitoring device is lost, and wherein the act of transmitting the measurement to the remote monitoring device is performed when the communication is restored.

ALTERNATIVE PROCESS Q

[0080] The method of Alternative Process N, further comprising associating the measurement with a sequence identifier, the sequence identifier being adapted to track whether the measurement has been transmitted to the remote monitoring device.

ALTERNATIVE PROCESS R

[0081] The method of Alternative Process N, wherein the act of transmitting the measurement to a remote monitoring device occurs in response to a transmission triggering event.

ALTERNATIVE PROCESS S

[0082] The method of Alternative Process R, wherein the transmission triggering event includes exceeding a threshold analyte concentration, passage of a predetermined time interval, or a signal request from the remote monitoring device.

ALTERNATIVE PROCESS T

[0083] The method of Alternative Process N, further comprising:

obtaining a second data measurement using a second sensor module, the second sensor module including a second memory; and

transmitting the second data measurement to one of the sensor module and the remote monitoring device.

ALTERNATIVE PROCESS U

[0084] The method of Alternative Process T, wherein the sensor module is borne by a first patient and the second sensor module is borne by a second patient.

ALTERNATIVE PROCESS V

[0085] The method of Alternative Process N, further comprising transmitting the data measurement to a second remote monitoring device.

ALTERNATIVE PROCESS W

[0086] The method of Alternative Process N, further comprising linking the remote monitoring device to a computer.

ALTERNATIVE EMBODIMENT X

[0087] A system for monitoring an analyte concentration of one or more patients, the system comprising:

a first sensor module adapted to be borne on a first patient, the first sensor module including a first transceiver adapted to transmit analyte-concentration data associated with the first patient;

a second sensor module adapted to be borne on a second patient, the second sensor module including a second transceiver adapted to transmit analyte-concentration data associated with the second patient; and

a remote monitoring device including a third transceiver adapted to receive the analyte-concentration data wirelessly transmitted by one or more of the first and second sensor modules,

wherein the first and second transceivers are adapted to transmit data to one another and to the remote monitoring device.

ALTERNATIVE EMBODIMENT Y

[0088] A system for monitoring an analyte concentration of one or more patients, the system comprising:

a sensor module adapted to be borne on a patient, the sensor module including a transceiver adapted to transmit analyte-concentration data associated with the patient; and

more than one remote monitoring device, each of the remote monitoring devices including a second transceiver adapted to receive the analyte-concentration data wirelessly transmitted by the sensor module.

[0089] While the invention is susceptible to various modifications and alternative forms, specific embodiments are shown by way of example in the drawings and are described in detail herein. It should be understood, however, that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

CLAIMS:

1. A system for monitoring a concentration of an analyte in a fluid or tissue sample comprising:

a sensor module adapted to be borne on a patient, the sensor module including a power supply adapted to provide a transmission power, a first transceiver adapted to transmit analyte-concentration information, and a memory; and

a remote monitoring device adapted to wirelessly communicate with the sensor module, the remote monitoring device including a second transceiver adapted to receive the analyte-concentration information transmitted by the sensor module and adapted to transmit a signal to the sensor module confirming that the analyte-concentration information was received,

wherein the information is stored in the memory until the signal is received by the sensor module.

2. The system of claim 1, wherein the sensor module includes a transdermal test sensor or an insertable sensor.

3. The system of claim 1, wherein the analyte is glucose.

4. The system of claim 1, wherein the transmission power is fluctuated based on quality, level, or strength of the wireless communication.

5. The system of claim 1, wherein the remote monitoring device further comprises a device adapted to interpret the analyte-concentration information and an information storage device.

6. The system of claim 1, wherein the analyte-concentration information is stored in the memory when wireless communication with the remote monitoring device is lost and the analyte-concentration information is transmitted to the remote monitoring device when the wireless communication is restored.

7. The system of claim 1, wherein the analyte-concentration information includes measurement data having a sequence identifier being associated therewith, the sequence identifier being adapted to track whether the measurement data has been transmitted to the remote monitoring device.

8. The system of claim 1, wherein the analyte-concentration information is transmitted in response to a transmission triggering event.

9. The system of claim 8, wherein the transmission triggering event includes exceeding a threshold analyte concentration, passage of a predetermined time interval, or a signal request from the remote monitoring device.

10. The system of claim 1, further comprising a second sensor module.

11. The system of claim 10, wherein the second sensor module is adapted to transmit analyte-concentration data to at least one of the sensor module and the remote monitoring device.

12. The system of claim 1, further comprising a second remote monitoring device adapted to wirelessly communicate with the sensor module, the second remote monitoring device including a third transceiver adapted to receive the analyte-concentration information transmitted by the sensor module.

13. The system of claim 1, wherein the remote monitoring device is adapted to be linked to a computer.

14. A method of monitoring a concentration of an analyte in a fluid or tissue sample, the method comprising the acts of:

obtaining a measurement corresponding with the analyte concentration using a sensor module, the sensor module including a memory and a power supply adapted to supply a transmission power;

transmitting the measurement to a remote monitoring device using the transmission power;

upon receiving the measurement, transmitting a signal from the remote monitoring device to the sensor module; and

upon receiving the signal, removing the measurement from the memory.

15. The method of claim 14, further comprising varying the transmission power based on a level of communication between the sensor module and the remote monitoring device.

16. The method of claim 14, further comprising storing the measurement in the memory when communication with the remote monitoring device is lost, and wherein the act of transmitting the measurement to the remote monitoring device is performed when the communication is restored.

17. The method of claim 14, further comprising associating the measurement with a sequence identifier, the sequence identifier being adapted to track whether the measurement has been transmitted to the remote monitoring device.

18. The method of claim 14, wherein the act of transmitting the measurement to a remote monitoring device occurs in response to a transmission triggering event.

19. The method of claim 18, wherein the transmission triggering event includes exceeding a threshold analyte concentration, passage of a predetermined time interval, or a signal request from the remote monitoring device.

20. The method of claim 14, further comprising:

obtaining a second data measurement using a second sensor module, the second sensor module including a second memory; and

transmitting the second data measurement to one of the sensor module and the remote monitoring device.

21. The method of claim 20, wherein the sensor module is borne by a first patient and the second sensor module is borne by a second patient.

22. The method of claim 14, further comprising transmitting the data measurement to a second remote monitoring device.

23. The method of claim 14, further comprising linking the remote monitoring device to a computer.

24. A system for monitoring an analyte concentration of one or more patients, the system comprising:

a first sensor module adapted to be borne on a first patient, the first sensor module including a first transceiver adapted to transmit analyte-concentration data associated with the first patient;

a second sensor module adapted to be borne on a second patient, the second sensor module including a second transceiver adapted to transmit analyte-concentration data associated with the second patient; and

a remote monitoring device including a third transceiver adapted to receive the analyte-concentration data wirelessly transmitted by one or more of the first and second sensor modules,

wherein the first and second transceivers are adapted to transmit data to one another and to the remote monitoring device.

25. A system for monitoring an analyte concentration of one or more patients, the system comprising:

a sensor module adapted to be borne on a patient, the sensor module including a transceiver adapted to transmit analyte-concentration data associated with the patient; and

more than one remote monitoring device, each of the remote monitoring devices including a second transceiver adapted to receive the analyte-concentration data wirelessly transmitted by the sensor module.

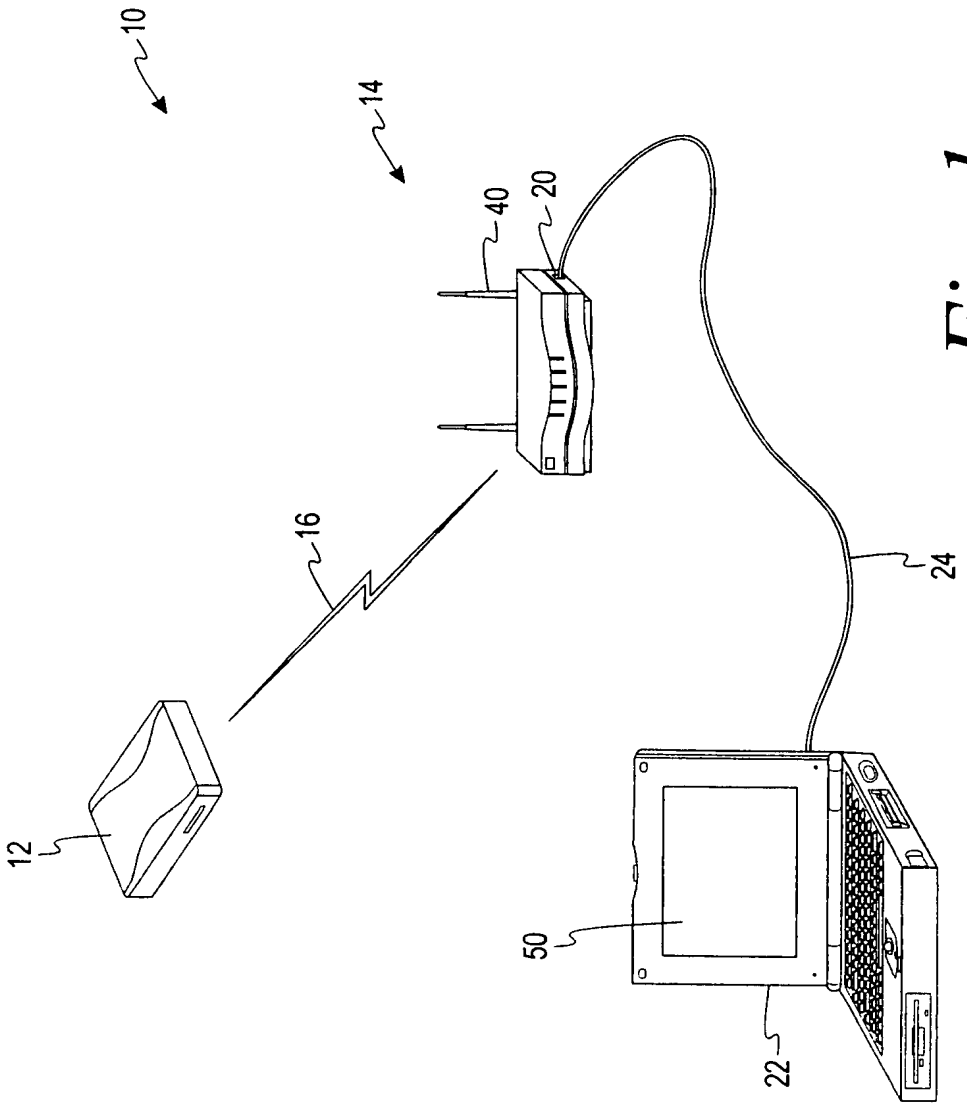


Fig. 1

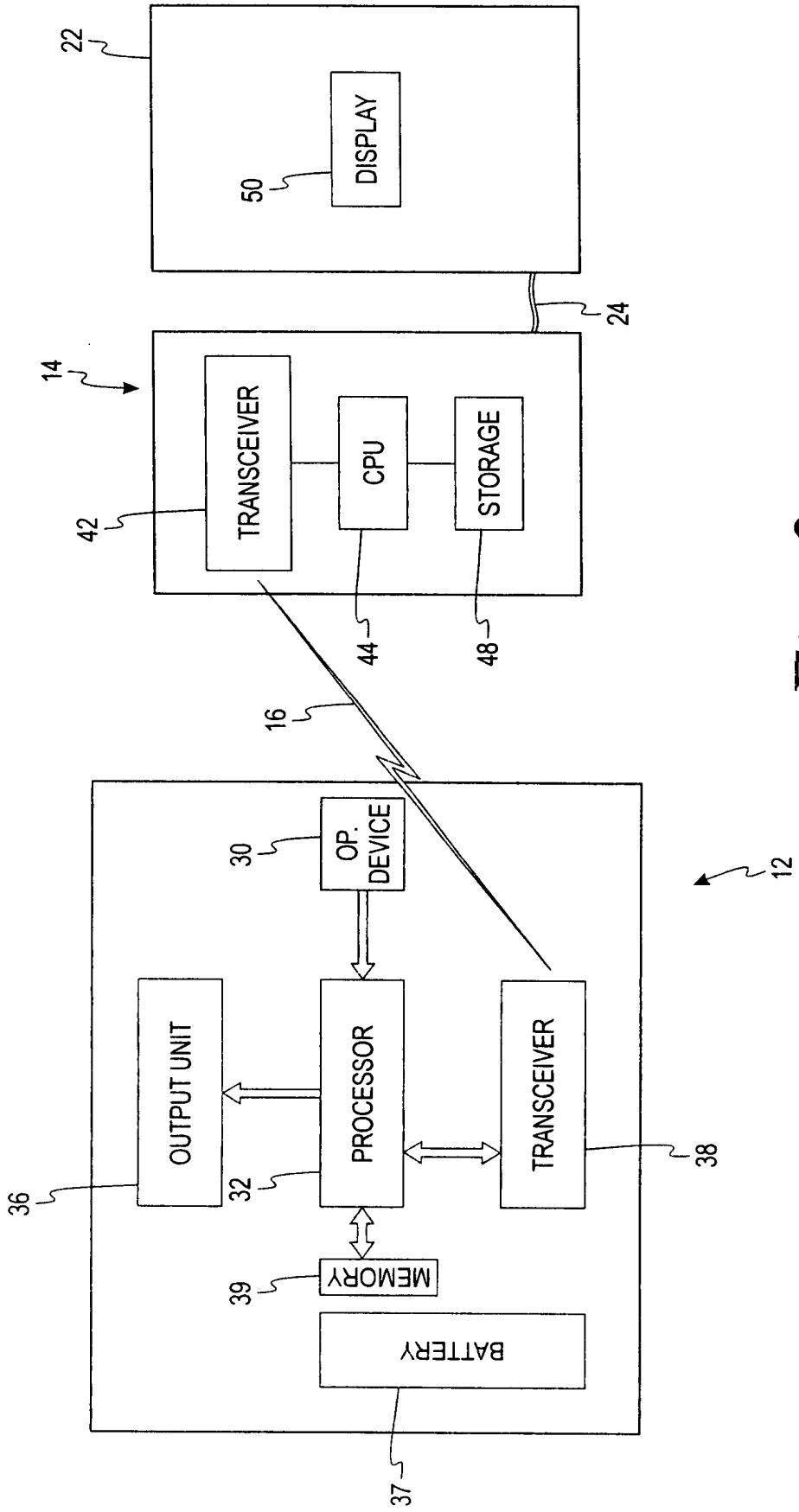

22
DISPLAY
50
24
14
TRANSCEIVER
CPU
STORAGE
42
44
48
16
12
OP. DEVICE
30
OUTPUT UNIT
PROCESSOR
TRANSCEIVER
36
32
38
MEMORY
39
BATTERY
37

Fig. 2

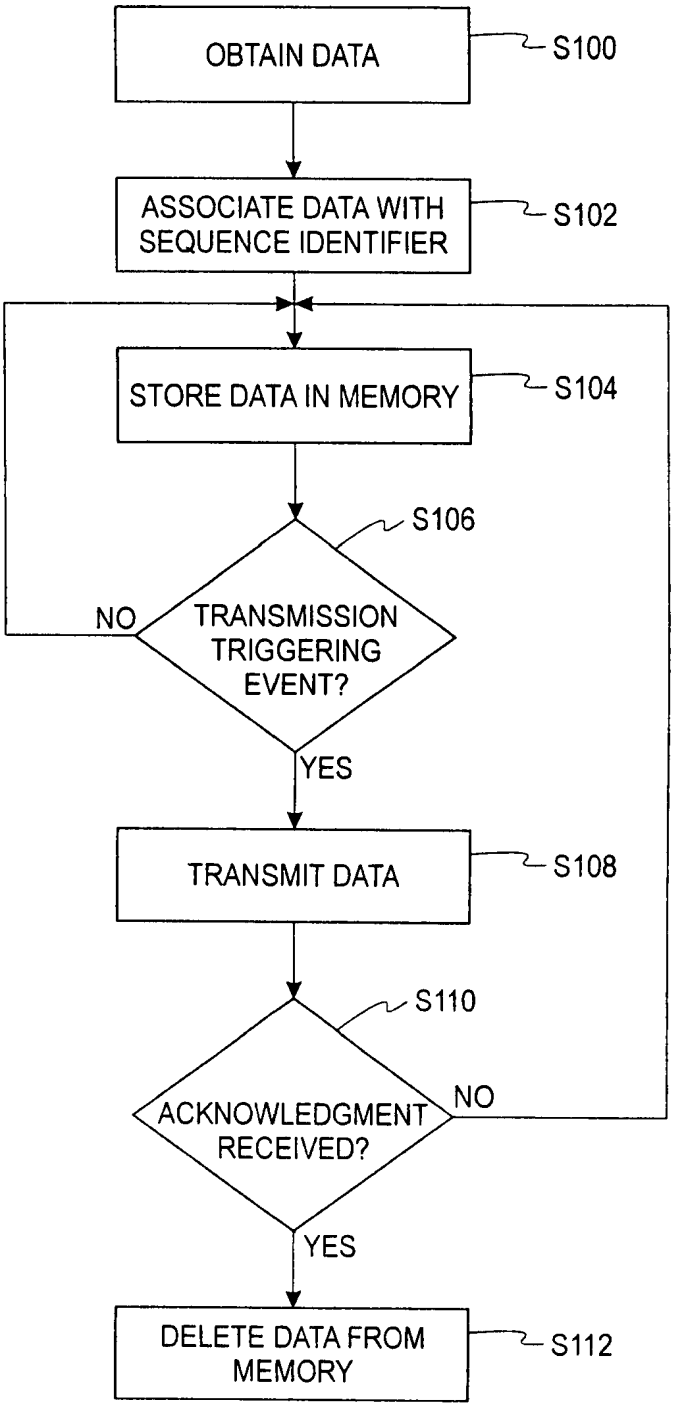

OBTAIN DATA
S100
ASSOCIATE DATA WITH SEQUENCE IDENTIFIER
S102
STORE DATA IN MEMORY
S104
S106
TRANSMISSION TRIGGERING EVENT?
NO
YES
TRANSMIT DATA
S108
S110
ACKNOWLEDGMENT RECEIVED?
NO
YES
DELETE DATA FROM MEMORY
S112

Fig. 3

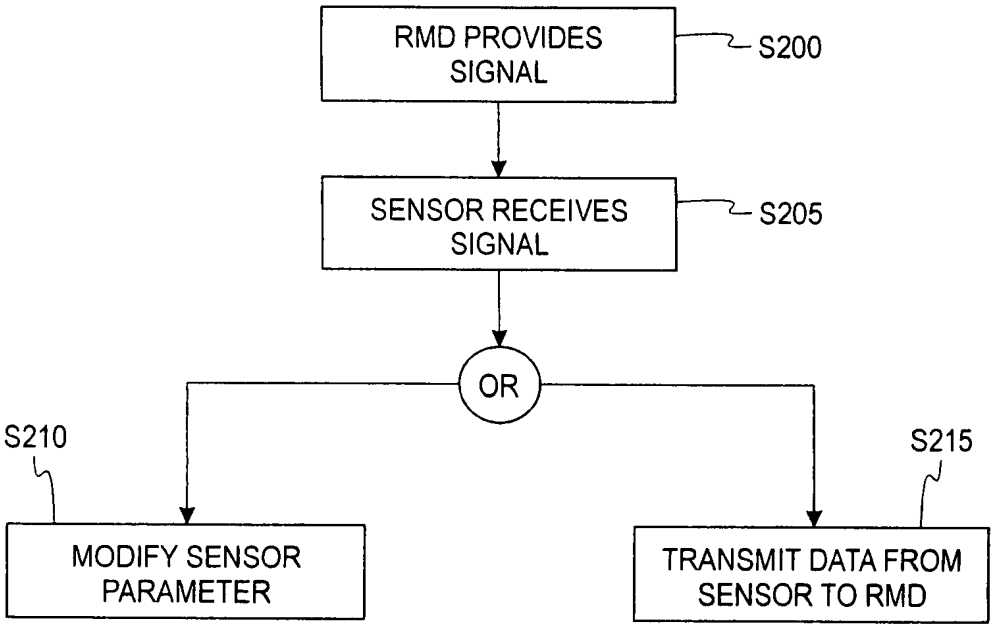

RMD PROVIDES SIGNAL
S200
SENSOR RECEIVES SIGNAL
S205
OR
S210
MODIFY SENSOR PARAMETER
S215
TRANSMIT DATA FROM SENSOR TO RMD

Fig. 4

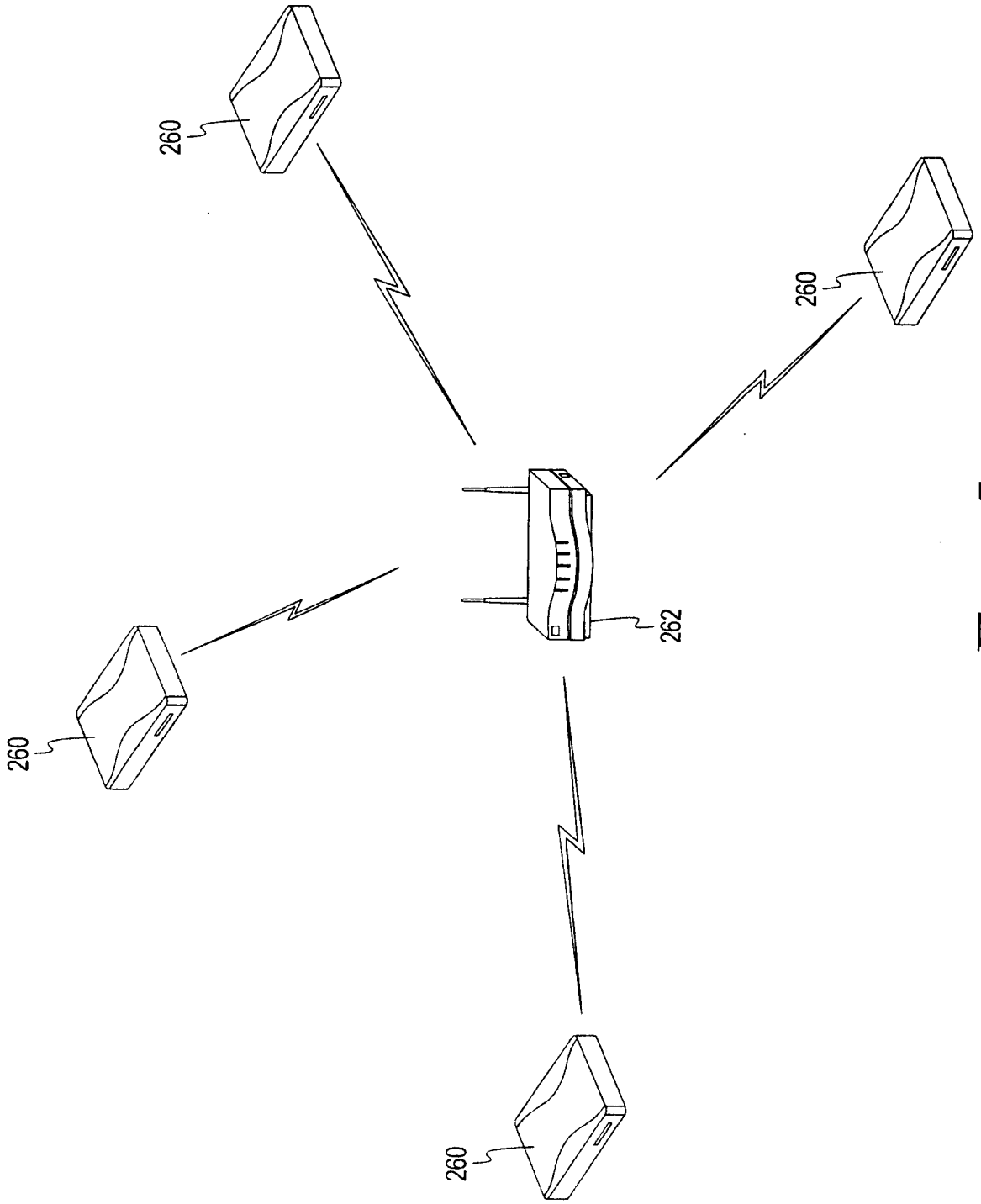


Fig. 5a

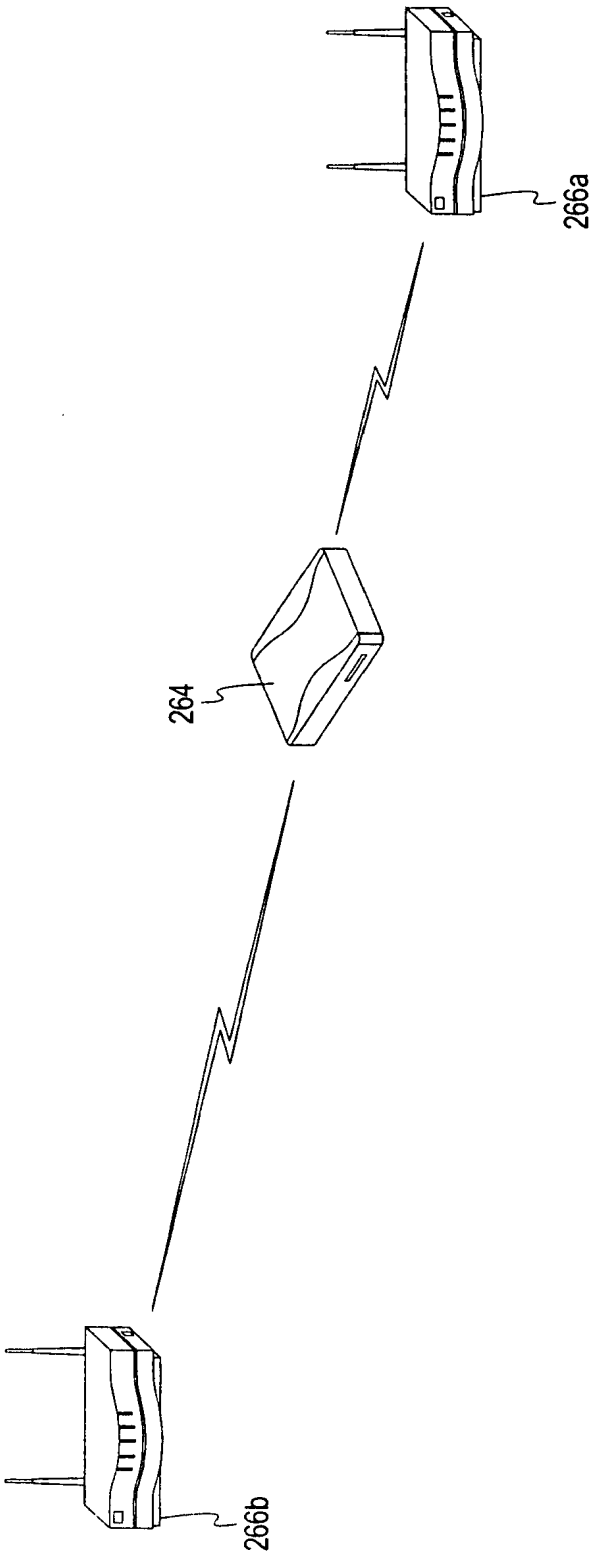


Fig. 5b

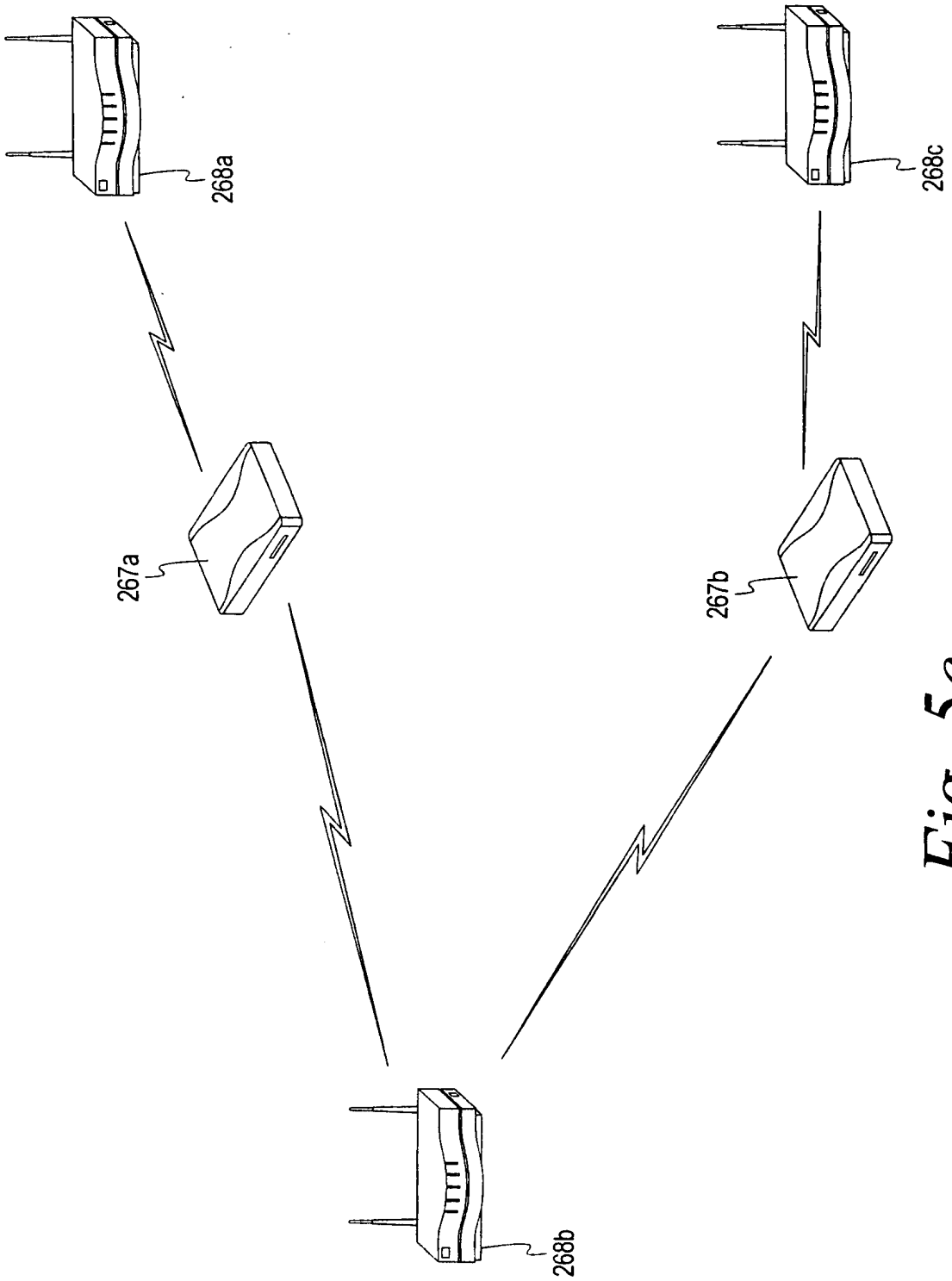


Fig. 5c

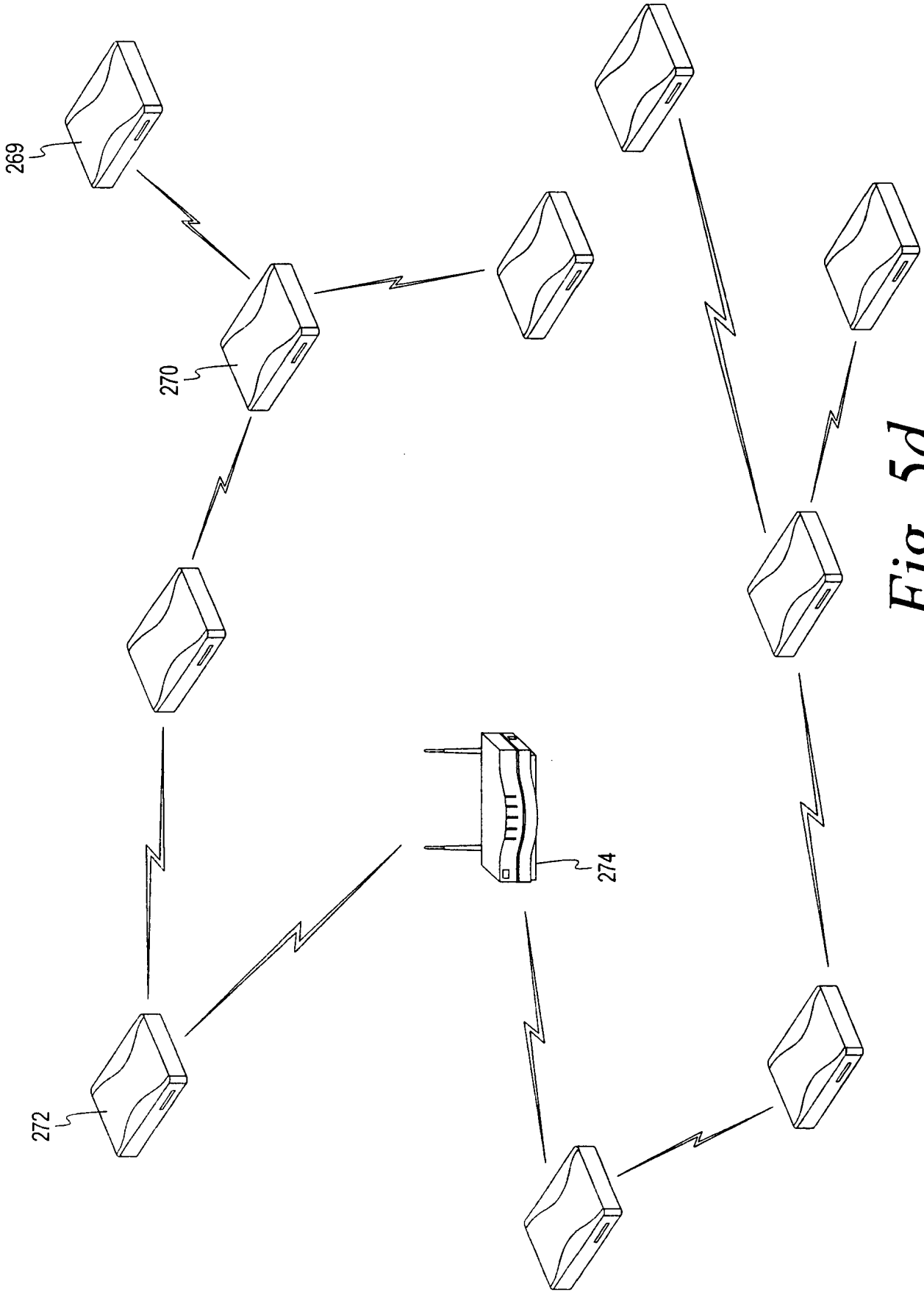


Fig. 5d

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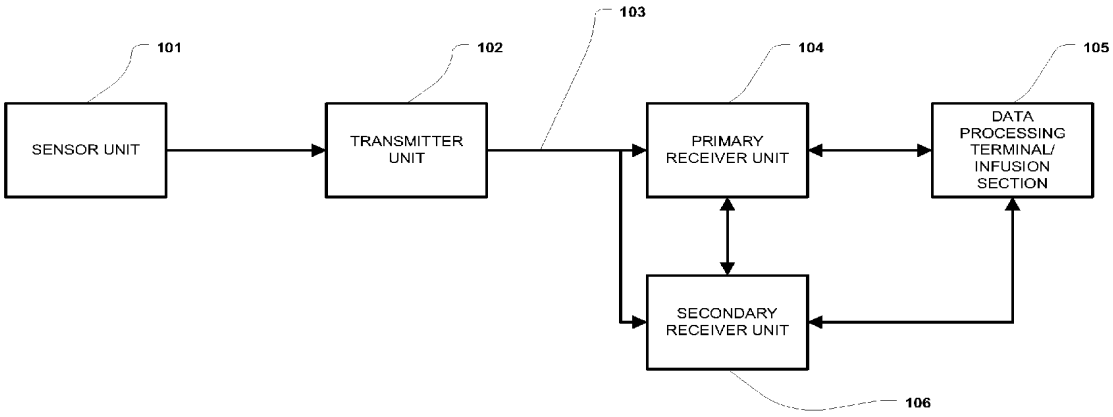
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(54) **Title:** METHOD, SYSTEM AND COMPUTER PROGRAM PRODUCT FOR REAL-TIME DETECTION OF SENSITIVITY DECLINE IN ANALYTE SENSORS



(57) **Abstract:** Method, system and computer program product for providing real time detection of analyte sensor sensitivity decline is continuous glucose monitoring systems are provided.

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METHOD, SYSTEM AND COMPUTER PROGRAM PRODUCT FOR REAL-TIME DETECTION OF SENSITIVITY DECLINE IN ANALYTE SENSORS

RELATED APPLICATION

This application claims priority to U.S. Provisional Application No. 60/854,566 entitled "Method, System and computer program product for real-time detection of sensitivity decline in continuous glucose sensors (CGS)" filed on October 26, 2006, the disclosure of which is incorporated herein by reference for all purposes. This application is related to U.S. Application No. 11/925,689 of Marc D. Breton et al., filed October 26, 2007, the disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND

Analyte, e.g., glucose monitoring systems including continuous and discrete monitoring systems generally include a small, lightweight battery powered and microprocessor controlled system which is configured to detect signals proportional to the corresponding measured glucose levels using an electrometer, and RF signals to transmit the collected data. One aspect of certain analyte monitoring systems include a transcutaneous or subcutaneous analyte sensor configuration which is, for example, partially mounted on the skin of a subject whose analyte level is to be monitored. The sensor cell may use a two or three-electrode (work, reference and counter electrodes) configuration driven by a controlled potential (potentiostat) analog circuit connected through a contact system.

The analyte sensor may be configured so that a portion thereof is placed under the skin of the patient so as to detect the analyte levels of the patient, and another portion of segment of the analyte sensor that is in communication with the transmitter unit. The transmitter unit is configured to transmit the analyte levels detected by the sensor over a wireless communication link such as an RF (radio frequency) communication link to a receiver/monitor unit. The receiver/monitor unit performs data analysis, among others on the received analyte levels to generate information pertaining to the monitored analyte levels.

In view of the foregoing, it would be desirable to have an accurate assessment of the glucose level fluctuations, and in particular, the detection of analyte sensor signal drop outs of sensor sensitivity referred to as Early Signal Attenuation (ESA).

SUMMARY OF THE DISCLOSURE

In one embodiment, method, system and computer program product for receiving a plurality of analyte sensor related signals, determining a probability of signal attenuation associated with the received plurality of analyte sensor related signals, verifying the presence of signal attenuation when the determined probability exceeds a predetermined threshold level, and generating a first output signal associated with the verification of the presence of signal attenuation, are disclosed.

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

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a block diagram of a data monitoring and management system for practicing one or more embodiments of the present disclosure;

FIG. 2 is a block diagram of the transmitter unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure;

FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure;

FIGS. 4A-4B illustrate a perspective view and a cross sectional view, respectively of an analyte sensor in accordance with one embodiment of the present disclosure;

FIG. 5 is a block diagram illustrating real time early signal attenuation (ESA) in one embodiment of the present disclosure;

FIG. 6 is a flowchart illustrating an overall ESA detection routine in accordance with one embodiment of the present disclosure;

FIG. 7 is a flowchart illustrating real-time detection of sensor current abnormalities described in conjunction with module 1 of FIG. 5 in accordance with one embodiment of the present disclosure;

FIG. 8 is a flowchart illustrating verification routine of module 2 in FIG. 5 to confirm or reject the output of module 1 in accordance with one embodiment of the present disclosure;

FIG. 9 illustrates a real time current signal characteristics evaluation approach based on a sliding window process of module 1 in FIG. 5 in accordance with one embodiment of the present disclosure;

FIG. 10 illustrates bootstrap estimation of coefficients for module 1 of FIG. 5 in accordance with one embodiment of the present disclosure;

FIG. 11 illustrates Gaussian kernel estimation of the normalized sensitivity density of module 2 of FIG. 5 in accordance with one embodiment of the present disclosure; and

FIG. 12 illustrates output curve of the first module compared with the output curve of the combined first and second modules of FIG. 5, based on a predetermined test data set and detection threshold of FIG. 7 in accordance with embodiment of the present disclosure.

DETAILED DESCRIPTION

As described in further detail below, in accordance with the various embodiments of the present disclosure, there is provided method, system and computer program product for real time detection of analyte sensor sensitivity decline in data processing and control systems including, for example, analyte monitoring systems. In particular, within the scope of the present disclosure, there are provided method, system and computer program product for the detection of episodes of low sensor sensitivity that may cause clinically significant sensor related errors, including, for example, early sensor attenuation (ESA) represented by sensor sensitivity (defined as the ratio between the analyte sensor current level and the blood glucose level) decline which may exist during the initial 12-24 hours of the sensor life, or during night time use of the analyte sensor ("night time drop outs").

FIG. 1 illustrates a data monitoring and management system such as, for example, analyte (e.g., glucose) monitoring system 100 in accordance with one embodiment of the present disclosure. The subject disclosure is further described primarily with respect to a glucose monitoring system for convenience and such description is in no way intended to limit the scope of the disclosure. It is to be

understood that the analyte monitoring system may be configured to monitor a variety of analytes, e.g., lactate, and the like.

Analytes that may be monitored include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, 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.

The analyte monitoring system 100 includes a sensor 101, a transmitter unit 102 coupled to the sensor 101, and a primary receiver unit 104 which is configured to communicate with the transmitter unit 102 via a communication link 103. The primary receiver unit 104 may be further configured to transmit data to a data processing terminal 105 for evaluating the data received by the primary receiver unit 104. Moreover, the data processing terminal in one embodiment may be configured to receive data directly from the transmitter unit 102 via a communication link which may optionally be configured for bi-directional communication.

Also shown in FIG. 1 is a secondary receiver unit 106 which is operatively coupled to the communication link 103 and configured to receive data transmitted from the transmitter unit 102. Moreover, as shown in the Figure, the secondary receiver unit 106 is configured to communicate with the primary receiver unit 104 as well as the data processing terminal 105. Indeed, the secondary receiver unit 106 may be configured for bi-directional wireless communication with each of the primary receiver unit 104 and the data processing terminal 105. As discussed in further detail below, in one embodiment of the present disclosure, the secondary receiver unit 106 may be configured to include a limited number of functions and features as compared with the primary receiver unit 104. As such, the secondary receiver unit 106 may be configured substantially in a smaller compact housing or embodied in a device such as a wrist watch, for example. Alternatively, the secondary receiver unit 106 may be configured with the same or substantially similar functionality as the primary receiver unit 104, and may be configured to be used in conjunction with a docking cradle unit for placement by bedside, for night time monitoring, and/or bi-directional communication device.

Only one sensor 101, transmitter unit 102, communication link 103, and data processing terminal 105 are shown in the embodiment of the analyte monitoring system 100 illustrated in FIG. 1. However, it will be appreciated by one of ordinary skill in the art that the analyte monitoring system 100 may include one or more sensor 101, transmitter unit 102, communication link 103, and data processing terminal 105. Moreover, within the scope of the present disclosure, the analyte monitoring system 100 may be a continuous monitoring system, or semi-continuous, or a discrete monitoring system. In a multi-component environment, each device is configured to be uniquely identified by each of the other devices in the system so that communication conflict is readily resolved between the various components within the analyte monitoring system 100.

In one embodiment of the present disclosure, the sensor 101 is physically positioned in or on the body of a user whose analyte level is being monitored. The sensor 101 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the transmitter unit 102. In one embodiment, the transmitter unit 102 is coupled to the sensor 101 so that both devices are positioned on the user's body, with at least a portion of the analyte sensor 101 positioned transcutaneously under the skin layer of the user. The transmitter unit 102 performs data processing such as filtering and encoding on data signals, each of which corresponds to a sampled analyte level of the user, for transmission to the primary receiver unit 104 via the communication link 103.

In one embodiment, the analyte monitoring system 100 is configured as a one-way RF communication path from the transmitter unit 102 to the primary receiver unit 104. In such embodiment, the transmitter unit 102 transmits the sampled data signals received from the sensor 101 without acknowledgement from the primary receiver unit 104 that the transmitted sampled data signals have been received. For example, the transmitter unit 102 may be configured to transmit the encoded sampled data signals at a fixed rate (e.g., at one minute intervals) after the completion of the initial power on procedure. Likewise, the primary receiver unit 104 may be configured to detect such transmitted encoded sampled data signals at predetermined time intervals. Alternatively, the analyte monitoring system 100 may be configured with a bi-directional RF (or otherwise) communication between the transmitter unit 102 and the primary receiver unit 104.

Additionally, in one aspect, the primary receiver unit 104 may include two sections. The first section is an analog interface section that is configured to communicate with the transmitter unit 102 via the communication link 103. In one embodiment, the analog interface section may include an RF receiver and an antenna for receiving and amplifying the data signals from the transmitter unit 102, which are thereafter, demodulated with a local oscillator and filtered through a band-pass filter. The second section of the primary receiver unit 104 is a data processing section which is configured to process the data signals received from the transmitter unit 102 such as by performing data decoding, error detection and correction, data clock generation, and data bit recovery.

In operation, upon completing the power-on procedure, the primary receiver unit 104 is configured to detect the presence of the transmitter unit 102 within its range based on, for example, the strength of the detected data signals received from the transmitter unit 102 or predetermined transmitter identification information. Upon successful synchronization with the corresponding transmitter unit 102, the primary receiver unit 104 is configured to begin receiving from the transmitter unit 102 data signals corresponding to the user's detected analyte level. More specifically, the primary receiver unit 104 in one embodiment is configured to perform synchronized time hopping with the corresponding synchronized transmitter unit 102 via the communication link 103 to obtain the user's detected analyte level.

Referring again to FIG. 1, the data processing terminal 105 may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., personal digital assistants (PDAs)), and the like, each of which may be configured for data communication with the receiver via a wired or a wireless connection. Additionally, the data processing terminal 105 may further be connected to a data network (not shown) for storing, retrieving and updating data corresponding to the detected analyte level of the user.

Within the scope of the present disclosure, the data processing terminal 105 may include an infusion device such as an insulin infusion pump or the like, which may be configured to administer insulin to patients, and which may be configured to communicate with the receiver unit 104 for receiving, among others, the measured analyte level. Alternatively, the receiver unit 104 may be configured to integrate an infusion device therein so that the receiver unit 104 is configured to administer insulin

therapy to patients, for example, for administering and modifying basal profiles, as well as for determining appropriate boluses for administration based on, among others, the detected analyte levels received from the transmitter unit 102.

Additionally, the transmitter unit 102, the primary receiver unit 104 and the data processing terminal 105 may each be configured for bi-directional wireless communication such that each of the transmitter unit 102, the primary receiver unit 104 and the data processing terminal 105 may be configured to communicate (that is, transmit data to and receive data from) with each other via the wireless communication link 103. More specifically, the data processing terminal 105 may in one embodiment be configured to receive data directly from the transmitter unit 102 via the communication link 106, where the communication link 106, as described above, may be configured for bi-directional communication.

In this embodiment, the data processing terminal 105 which may include an insulin pump, may be configured to receive the analyte signals from the transmitter unit 102, and thus, incorporate the functions of the receiver 103 including data processing for managing the patient's insulin therapy and analyte monitoring. In one embodiment, the communication link 103 may include one or more of an RF communication protocol, an infrared communication protocol, a Bluetooth enabled communication protocol, an 802.11x wireless communication protocol, or an equivalent wireless communication protocol which would allow secure, wireless communication of several units (for example, per HIPPA requirements) while avoiding potential data collision and interference.

FIG. 2 is a block diagram of the transmitter of the data monitoring and detection system shown in FIG. 1 in accordance with one embodiment of the present disclosure. Referring to the Figure, the transmitter unit 102 in one embodiment includes an analog interface 201 configured to communicate with the sensor 101 (FIG. 1), a user input 202, and a temperature measurement section 203, each of which is operatively coupled to a transmitter processor 204 such as a central processing unit (CPU).

Further shown in FIG. 2 are a transmitter serial communication section 205 and an RF transmitter 206, each of which is also operatively coupled to the transmitter processor 204. Moreover, a power supply 207 such as a battery is also provided in the transmitter unit 102 to provide the necessary power for the transmitter unit 102.

Additionally, as can be seen from the Figure, a clock 208 is provided to, among others, supply real time information to the transmitter processor 204.

As can be seen from FIG. 2, the sensor unit 101 (FIG. 1) is provided four contacts, three of which are electrodes - work electrode (W) 210, guard contact (G) 211, reference electrode (R) 212, and counter electrode (C) 213, each operatively coupled to the analog interface 201 of the transmitter unit 102. In one embodiment, each of the work electrode (W) 210, guard contact (G) 211, reference electrode (R) 212, and counter electrode (C) 213 may be made using a conductive material that is either printed or etched, for example, such as carbon which may be printed, or metal foil (e.g., gold) which may be etched, or alternatively provided on a substrate material using laser or photolithography.

In one embodiment, a unidirectional input path is established from the sensor 101 (FIG. 1) and/or manufacturing and testing equipment to the analog interface 201 of the transmitter unit 102, while a unidirectional output is established from the output of the RF transmitter 206 of the transmitter unit 102 for transmission to the primary receiver unit 104. In this manner, a data path is shown in FIG. 2 between the aforementioned unidirectional input and output via a dedicated link 209 from the analog interface 201 to serial communication section 205, thereafter to the processor 204, and then to the RF transmitter 206. As such, in one embodiment, via the data path described above, the transmitter unit 102 is configured to transmit to the primary receiver unit 104 (FIG. 1), via the communication link 103 (FIG. 1), processed and encoded data signals received from the sensor 101 (FIG. 1). Additionally, the unidirectional communication data path between the analog interface 201 and the RF transmitter 206 discussed above allows for the configuration of the transmitter unit 102 for operation upon completion of the manufacturing process as well as for direct communication for diagnostic and testing purposes.

As discussed above, the transmitter processor 204 is configured to transmit control signals to the various sections of the transmitter unit 102 during the operation of the transmitter unit 102. In one embodiment, the transmitter processor 204 also includes a memory (not shown) for storing data such as the identification information for the transmitter unit 102, as well as the data signals received from the sensor 101. The stored information may be retrieved and processed for transmission to the primary

receiver unit 104 under the control of the transmitter processor 204. Furthermore, the power supply 207 may include a commercially available battery.

The transmitter unit 102 is also configured such that the power supply section 207 is capable of providing power to the transmitter for a minimum of about three months of continuous operation after having been stored for about eighteen months in a low-power (non-operating) mode. In one embodiment, this may be achieved by the transmitter processor 204 operating in low power modes in the non-operating state, for example, drawing no more than approximately 1 μA of current. Indeed, in one embodiment, the final step during the manufacturing process of the transmitter unit 102 may place the transmitter unit 102 in the lower power, non-operating state (i.e., post-manufacture sleep mode). In this manner, the shelf life of the transmitter unit 102 may be significantly improved. Moreover, as shown in FIG. 2, while the power supply unit 207 is shown as coupled to the processor 204, and as such, the processor 204 is configured to provide control of the power supply unit 207, it should be noted that within the scope of the present disclosure, the power supply unit 207 is configured to provide the necessary power to each of the components of the transmitter unit 102 shown in FIG. 2.

Referring back to FIG. 2, the power supply section 207 of the transmitter unit 102 in one embodiment may include a rechargeable battery unit that may be recharged by a separate power supply recharging unit (for example, provided in the receiver unit 104) so that the transmitter unit 102 may be powered for a longer period of usage time. Moreover, in one embodiment, the transmitter unit 102 may be configured without a battery in the power supply section 207, in which case the transmitter unit 102 may be configured to receive power from an external power supply source (for example, a battery) as discussed in further detail below.

Referring yet again to FIG. 2, the temperature detection section 203 of the transmitter unit 102 is configured to monitor the temperature of the skin near the sensor insertion site. The temperature reading is used to adjust the analyte readings obtained from the analog interface 201. The RF transmitter 206 of the transmitter unit 102 may be configured for operation in the frequency band of 315 MHz to 322 MHz, for example, in the United States. Further, in one embodiment, the RF transmitter 206 is configured to modulate the carrier frequency by performing Frequency Shift Keying

and Manchester encoding. In one embodiment, the data transmission rate is 19,200 symbols per second, with a minimum transmission range for communication with the primary receiver unit 104.

Referring yet again to FIG. 2, also shown is a leak detection circuit 214 coupled to the guard electrode (G) 211 and the processor 204 in the transmitter unit 102 of the data monitoring and management system 100. The leak detection circuit 214 in accordance with one embodiment of the present disclosure may be configured to detect leakage current in the sensor 101 to determine whether the measured sensor data are corrupt or whether the measured data from the sensor 101 is accurate.

FIG. 3 is a block diagram of the receiver/monitor unit of the data monitoring and management system shown in FIG. 1 in accordance with one embodiment of the present disclosure. Referring to FIG. 3, the primary receiver unit 104 includes a blood glucose test strip interface 301, an RF receiver 302, an input 303, a temperature detection section 304, and a clock 305, each of which is operatively coupled to a receiver processor 307. As can be further seen from the Figure, the primary receiver unit 104 also includes a power supply 306 operatively coupled to a power conversion and monitoring section 308. Further, the power conversion and monitoring section 308 is also coupled to the receiver processor 307. Moreover, also shown are a receiver serial communication section 309, and an output 310, each operatively coupled to the receiver processor 307.

In one embodiment, the test strip interface 301 includes a glucose level testing portion to receive a manual insertion of a glucose test strip, and thereby determine and display the glucose level of the test strip on the output 310 of the primary receiver unit 104. This manual testing of glucose can be used to calibrate sensor 101. The RF receiver 302 is configured to communicate, via the communication link 103 (FIG. 1) with the RF transmitter 206 of the transmitter unit 102, to receive encoded data signals from the transmitter unit 102 for, among others, signal mixing, demodulation, and other data processing. The input 303 of the primary receiver unit 104 is configured to allow the user to enter information into the primary receiver unit 104 as needed. In one aspect, the input 303 may include one or more keys of a keypad, a touch-sensitive screen, or a voice-activated input command unit. The temperature detection section 304 is configured to provide temperature information of the primary receiver unit 104 to the

receiver processor 307, while the clock 305 provides, among others, real time information to the receiver processor 307.

Each of the various components of the primary receiver unit 104 shown in FIG. 3 is powered by the power supply 306 which, in one embodiment, includes a battery. Furthermore, the power conversion and monitoring section 308 is configured to monitor the power usage by the various components in the primary receiver unit 104 for effective power management and to alert the user, for example, in the event of power usage which renders the primary receiver unit 104 in sub-optimal operating conditions. An example of such sub-optimal operating condition may include, for example, operating the vibration output mode (as discussed below) for a period of time thus substantially draining the power supply 306 while the processor 307 (thus, the primary receiver unit 104) is turned on. Moreover, the power conversion and monitoring section 308 may additionally be configured to include a reverse polarity protection circuit such as a field effect transistor (FET) configured as a battery activated switch.

The serial communication section 309 in the primary receiver unit 104 is configured to provide a bi-directional communication path from the testing and/or manufacturing equipment for, among others, initialization, testing, and configuration of the primary receiver unit 104. Serial communication section 104 can also be used to upload data to a computer, such as time-stamped blood glucose data. The communication link with an external device (not shown) can be made, for example, by cable, infrared (IR) or RF link. The output 310 of the primary receiver unit 104 is configured to provide, among others, a graphical user interface (GUI) such as a liquid crystal display (LCD) for displaying information. Additionally, the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output as commonly found in handheld electronic devices, such as mobile telephones presently available. In a further embodiment, the primary receiver unit 104 also includes an electro-luminescent lamp configured to provide backlighting to the output 310 for output visual display in dark ambient surroundings.

Referring back to FIG. 3, the primary receiver unit 104 in one embodiment may also include a storage section such as a programmable, non-volatile memory device as part of the processor 307, or provided separately in the primary receiver unit 104, operatively coupled to the processor 307. The processor 307 is further configured to perform Manchester decoding as well as error detection and correction upon the

encoded data signals received from the transmitter unit 102 via the communication link 103.

In a further embodiment, the one or more of the transmitter unit 102, the primary receiver unit 104, secondary receiver unit 105, or the data processing terminal/infusion section 105 may be configured to receive the blood glucose value wirelessly over a communication link from, for example, a glucose meter. In still a further embodiment, the user or patient manipulating or using the analyte monitoring system 100 (FIG. 1) may manually input the blood glucose value using, for example, a user interface (for example, a keyboard, keypad, and the like) incorporated in the one or more of the transmitter unit 102, the primary receiver unit 104, secondary receiver unit 105, or the data processing terminal/infusion section 105.

Additional detailed description of the continuous analyte monitoring system, its various components including the functional descriptions of the transmitter are provided in U.S. Patent No. 6,175,752 issued January 16, 2001 entitled "Analyte Monitoring Device and Methods of Use", and in application No. 10/745,878 filed December 26, 2003 entitled "Continuous Glucose Monitoring System and Methods of Use", each assigned to Abbott Diabetes Care, Inc., of Alameda, California.

FIGS. 4A-4B illustrate a perspective view and a cross sectional view, respectively of an analyte sensor in accordance with one embodiment of the present disclosure. Referring to FIG. 4A, a perspective view of a sensor 400, the major portion of which is above the surface of the skin 410, with an insertion tip 430 penetrating through the skin and into the subcutaneous space 420 in contact with the user's biofluid such as interstitial fluid. Contact portions of a working electrode 401, a reference electrode 402, and a counter electrode 403 can be seen on the portion of the sensor 400 situated above the skin surface 410. Working electrode 401, a reference electrode 402, and a counter electrode 403 can be seen at the end of the insertion tip 403.

Referring now to FIG. 4B, a cross sectional view of the sensor 400 in one embodiment is shown. In particular, it can be seen that the various electrodes of the sensor 400 as well as the substrate and the dielectric layers are provided in a stacked or layered configuration or construction. For example, as shown in FIG. 4B, in one aspect, the sensor 400 (such as the sensor unit 101 FIG. 1), includes a substrate layer 404, and a first conducting layer 401 such as a carbon trace disposed on at least a portion of the

substrate layer 404, and which may comprise the working electrode. Also shown disposed on at least a portion of the first conducting layer 401 is a sensing layer 408.

Referring back to FIG. 4B, a first insulation layer such as a first dielectric layer 405 is disposed or stacked on at least a portion of the first conducting layer 401, and further, a second conducting layer 409 such as another carbon trace may be disposed or stacked on top of at least a portion of the first insulation layer (or dielectric layer) 405. As shown in FIG. 4B, the second conducting layer 409 may comprise the reference electrode 402, and in one aspect, may include a layer of silver/silver chloride (Ag/AgCl).

Referring still again to FIG. 4B, a second insulation layer 406 such as a dielectric layer in one embodiment may be disposed or stacked on at least a portion of the second conducting layer 409. Further, a third conducting layer 403 which may include carbon trace and that may comprise the counter electrode 403 may in one embodiment be disposed on at least a portion of the second insulation layer 406. Finally, a third insulation layer 407 is disposed or stacked on at least a portion of the third conducting layer 403. In this manner, the sensor 400 may be configured in a stacked or layered construction or configuration such that at least a portion of each of the conducting layers is separated by a respective insulation layer (for example, a dielectric layer).

Additionally, within the scope of the present disclosure, some or all of the electrodes 401, 402, 403 may be provided on the same side of the substrate 404 in a stacked construction as described above, or alternatively, may be provided in a co-planar manner such that each electrode is disposed on the same plane on the substrate 404, however, with a dielectric material or insulation material disposed between the conducting layers/electrodes. Furthermore, in still another aspect of the present disclosure, the one or more conducting layers such as the electrodes 401, 402, 403 may be disposed on opposing sides of the substrate 404.

FIG. 5 is a block diagram illustrating real time early signal attenuation (ESA) in one embodiment of the present disclosure. Referring to FIG. 5, in one embodiment, the overall sensitivity decline detector 500 includes a first module 510 configured to perform an estimation of the probability of sensitivity decline based on a window of analyte sensor measurements to determine whether a finger stick measurement of blood glucose level is necessary. Based on the estimated probability of the sensitivity decline

performed by the first module 510, when it is determined that the finger stick measurement of the blood glucose level is necessary, as shown in FIG. 5, in one aspect of the present disclosure, the second module 520 uses the measured blood glucose value to verify or otherwise confirm or reject the estimated probability of the sensitivity decline performed by the first module 510. In one aspect, the second module 520 may be configured to confirm or reject the results of the first module 510 (e.g., the estimated probability of sensitivity decline) based upon a statistical determination.

That is, in one aspect, the first module 510 of the sensitivity decline detector 500 of FIG. 5 may be configured to estimate the probability of the analyte sensor sensitivity decline based on an analysis of a window of sensor values (for example, current signals from the analyte sensor for a predetermined time period). More specifically, the first module 510 may be configured to estimate the probability of the sensor sensitivity decline based on a sliding window extractor of sensor current signal characteristics, a model based estimation of the probability of sensitivity decline based on the determined or retrieved sensor current signal characteristics, and/or a comparison of the estimated probability to a predetermined threshold value τ.

Referring back to FIG. 5, the logistic estimator 511 of the first module 510 may be configured in one embodiment to retrieve or extract a sliding window of sensor current signal characteristics, and to perform the estimation of the probability of the sensitivity decline based on the sensor current signal characteristics, and to compare the estimated probability of the sensitivity decline to a predetermined threshold τ to determine, whether verification of the estimated sensitivity decline is desired, or whether it can be confirmed that ESA or night time drop outs is not detected based on the estimated probability of the sensitivity decline.

Referring again to FIG. 5, as shown, when it is determined that confirmation or verification of the estimated probability of the sensitivity decline is desired (based on, for example, when the estimated probability exceeds the predetermined threshold value τ determined in the first module 510, hypothesis analysis module 521 of the second module 520 in the sensitivity decline detector 500 in one embodiment receives the capillary blood measurement from a blood glucose measurement device such as a blood glucose meter including FreesStyle® Lite, Freestyle Flash®, FreeStyle Freedom®, or Precision Xtra™ blood glucose meters commercially available from Abbott Diabetes Care, Inc., of Alameda, California. In one aspect, based on the received capillary blood

glucose measurement and the analyte sensor current characteristics or values, the estimated probability of the sensor sensitivity decline may be confirmed or rejected, thus confirming the presence of ESA or night time drop out (in the event the corresponding data point is associated with night time sensor current value), or alternatively, confirming that the ESA or night time drop out is not present.

In the manner described, in one aspect of the present disclosure, there is provided a real time detection routine based on sensor current signal characteristics, where the detector 500 (FIG. 5) includes a first module 510 configured in one embodiment to perform the detection and estimation of the probability of the sensor sensitivity decline, and a second module 520 configured in one aspect to verify the presence or absence of ESA or night time drop outs based on the probability estimations determined by the first module 510. Accordingly, in one aspect of the present disclosure, ESA episodes or night time declines or drop outs maybe accurately detected while minimizing the potential for false alarms or false negatives.

Referring again to FIG. 5, a sliding window process is used in the first module 510 of the sensor sensitivity estimator 500 in one embodiment to mitigate between the desire for a real time decision process and the necessity of redundancy for sensor current characteristics estimation. An example of the sliding window process is illustrated in accordance with one embodiment of the present disclosure in FIG. 9.

For instance, in one aspect, during the processing performed by the first module 510, at each iteration of the decision process, a time window is selected, and based on the sensor current signals determined during the selected time window, one or more predetermined sensor characteristics are determined. By way of nonlimiting examples, the one or more predetermined sensor characteristics may include the mean current signal level, the current signal variance, the average slope of the current signal, and the average sensor life (or the time elapsed since the insertion or transcutaneous positioning of the analyte sensor).

Thereafter, the selected time window is then slid by a fixed number of minutes for the next iteration. In one aspect, the width or duration of the time window and the incremental step size may be predetermined or established to 60 minutes, thus generating non-overlapping time window to minimize potential correlation between decisions. Within the scope of the present disclosure, other approaches may be

contemplated, for example, where the sliding time windows may include time duration of approximately 30 minutes with an incremental one minute step.

In one aspect, the following expressions may be used to determine the sensor characteristic estimations discussed above such as, for example, the sensor signal mean, the average slope and the variance values:

$$\begin{bmatrix} mean \\ slope \end{bmatrix} = (X'X)^{-1} X'Y$$

where X is a matrix with a column of 1s and a column of data index and Y is a column vector of current values

$$variance = \frac{1}{n-1} \sum_{i=0}^{width} (current_{t+i} - mean)^2$$ where t is the index of the first available data point in the time window

Referring back to FIG. 5, after estimating or determining the sensor characteristics described above, a four-dimensional feature vector corresponding to a time window of sensor current signal is generated. In one aspect, the generated feature vector and logistic regression approach may be used to estimate the probability that the sensor is undergoing or experiencing early signal attenuation (ESA) during each of the predetermined time window. In one aspect, the logistic regression approach for determination or estimation of the probability of ESA presence Pr[ESA] may be expressed as follows:

$$\Pr[ESA \mid x_n] = \frac{\exp\langle \beta, x_n \rangle}{1 + \exp\langle \beta, x_n \rangle}$$

$$x_n = \begin{bmatrix} 1 \\ \log(mean_n) \\ \log(variance_n) \\ slope_n \\ \log(sensorlife_n) \end{bmatrix} \quad (1)$$

In one aspect, the coefficient vector β plays a significant role in the efficiency of the sensor signal attenuation estimation. That is, in one embodiment, a predetermined number of sensor insertions may be used to empirically determine or estimate the model coefficients. More specifically, in one aspect, a bootstrap estimation procedure may be performed to add robustness to the model coefficients. For example, a generalized

linear model fit approach may be applied to a predetermined time period to determine the coefficient vector β. Based on a predefined number of iterations, an empirical probability distribution function of each coefficient may be determined, for example, as shown in FIG. 10, where each selected coefficient corresponds to the mode of the associated distribution.

After the determination of the one or more sensor current characteristics or parameters, and the determination of the corresponding coefficients, the probability of ESA presence Pr[ESA] is estimated based on, in one embodiment, the following expression:

$$\Pr[ESA|x_n] = \frac{\exp^{1.511-1.813\times\log(mean)+0.158\times slope+0.399\times\log(variance)-0.576\times\log(SensorLife)}}{1+\exp^{1.511-1.813\times\log(mean)+0.158\times slope+0.399\times\log(variance)-0.576\times\log(SensorLife)}} \quad (2)$$

It is to be noted that within the scope of the present disclosure, the estimation of the probability of the ESA presence Pr[ESA] as described by the function shown above may be modified depending upon the design or the associated underlying parameters, such as, for example, the time of day information, or the detrended variance of the sensor current signal, among others.

Referring yet again to FIG. 5, after the determination of the probability of ESA presence based on the estimation described above, in one aspect, the estimated probability is compared to a preselected threshold level, and based on the comparison, a request for capillary blood glucose measurement may be prompted. In one aspect, the predetermined threshold level may include 0.416 for comparison with the estimated probability of ESA presence. Alternatively, within the scope of the present disclosure, the predetermined threshold level may vary within the range of approximately 0.3 to 0.6.

As described above, in one aspect of the present disclosure, the first module 510 of the sensor sensitivity estimator 500 (FIG. 5) is configured to perform estimation of the probability of ESA presence based on the characteristics or parameters associated with the analyte sensor and the sensor current signals. In one embodiment, the second module 520 of the sensor sensitivity estimator 500 (FIG. 5) may be configured to perform additional processing based on capillary blood glucose measurement to provide

substantially real time estimation of the early sensor attenuation (ESA) of the analyte sensors. That is, since ESA is defined by a drop or decrease of sensitivity (that is, the current signal of the sensor over the blood glucose ratio), the distribution of the sensitivity during ESA occurrence is generally lower than the distribution during normal functioning conditions. Additionally, based on the non linear relation ship between the sensor current level and blood glucose measurements, the ESA presence probability estimation using capillary blood measurements may be determined using a bin (e.g., category) construction approach, as well as the estimation of the empirical distribution functions of the nominal sensitivity ratio.

More particularly, in one aspect of the present disclosure, the instantaneous sensitivity (IS) may be defined as the ratio of the actual current value of the analyte sensor and the actual blood glucose value at a given point in time (defined, for example, by the expression (a) below. However, due to noise in the signals, for example, particularly in the case of a stand alone measurement such as a single blood glucose measurement, the instantaneous sensitivity (IS) may be approximated by determining the average sensor current signal levels around the time of the fingerstick blood glucose determination, determines, for example, by the expression (b) shown below.

$$a. \qquad DS_t = \frac{current_t}{BG_t}$$

$$b. \qquad IS_t = \frac{\frac{1}{11}\sum_{i=-5}^{5} current_{t+i}}{BG_t} \qquad (3)$$

Given that each analyte sensor has a different sensitivity, and thus the instantaneous sensitivity (IS) is highly sensor dependent, the absolute value of the instantaneous sensitivity (IS) may not provide reliable indication of ESA presence. On the other hand, during manufacturing, each analyte sensor is associated with a nominal sensitivity value. Accordingly, the ratio of the instantaneous sensitivity over the sensor nominal sensitivity will result in a more sensor independent, reliable ESA detection mechanism. Accordingly, the sensitivity ratio $R_S(t)$ at time t may be defined in one aspect as follows:

$$R_{S(t)} = \frac{IS(t)}{S_{nominal}} = \frac{1}{11}\frac{\sum_{i=-5}^{5} current_{t+i}}{S_{nominal} \times BG_t} \qquad (4)$$

Referring to the discussion above, the blood glucose bin/category construction approach in one embodiment may include defining a transformation of the blood glucose measurement scale which rectifies a discrepancy between the measured and estimated blood glucose values. That is, in one aspect, the defined transformation approach corresponds to or is associated with a typical distribution of blood glucose levels. For example, the transformation approach defining the various bins/categories may be determined based on the following expression:

$$r = 1.509 \times e^{1.084 \times \log(\log(BG) - 5.381)} \qquad \text{where BG is in mg/dl} \qquad (5)$$

where the following scaled glucose bins may be defined:

1. r < -2, severe hypoglycemia
2. -2 <= r <-1, mild hypoglycemia
3. -1 <= r < 0, low euglycemia
4. 0 <= r < 1, high euglycemia
5. 1 <= r < 2, mild hyperglycemia
6. 2 <= r, severe hyperglycemia

Upon determination of the bin/category for use with the estimation of the probability of ESA presence, in one aspect, kernel density estimation (using Gaussian kernel, 24, for example) may be used to estimate the distribution of the sensitivity ratio Rs in each bin/category described above. In one aspect, this estimation of the distribution in sensitivity ratio Rs is shown in FIG. 11, where for each bin/category (including, for example, severe hypoglycemia (bin1), mild hypoglycemia (bin2), low euglycaemia (bin3), high euglycaemia (bin4), low hyperglycemia (bin5), and high hyperglycemia (bin6)), each chart illustrates the associated distribution where ESA presence is detected.

Referring again to the discussions above, based on the estimation of the probability density functions of the estimated distribution of the sensitivity ratio Rs in

each bin/category, in one aspect, a non-parametric hypothesis testing approach based on Bayes' law may be implemented. For example, in one aspect of the present disclosure, from Bayes' law, the estimated probability of ESA presence knowing the sensitivities ratio and the blood glucose bin/category may be decomposed based on the following expression:

$$\Pr[ESA \mid R_S = \rho \,\&\, r \in bin_i] = \frac{\pi_{ESA}\hat{f}_i(\rho)}{\pi_{ESA}\hat{f}_{ESA,i}(\rho) + \pi_{\overline{ESA}}\hat{f}_{\overline{ESA},i}(\rho)} \quad (6)$$

where π_a is the proportion of events in class a and $\hat{f}_{a,i}$ is the previously estimated probability density function of R_S in bin/category i for class a.

In addition, to minimize the overall probability of error the following decision rule may be applied:

$$\begin{aligned} &\text{sensor is ESA if } \frac{\Pr[ESA \mid R_S = \rho \,\&\, r \in bin_i]}{\Pr[\overline{ESA} \mid R_S = \rho \,\&\, r \in bin_i]} > 1 \\ \Rightarrow \quad &\frac{\hat{f}_{ESA,i}(\rho)}{\hat{f}_{\overline{ESA},i}(\rho)} > \frac{\pi_{\overline{ESA}}}{\pi_{ESA}} \\ &\text{assuming } \pi_{\overline{ESA}} = \pi_{ESA} = 0.5 \\ \Rightarrow \quad &\frac{\hat{f}_{ESA,i}(\rho)}{\hat{f}_{\overline{ESA},i}(\rho)} > 1 \quad \Rightarrow \quad \hat{f}_{ESA,i}(\rho) > \hat{f}_{\overline{ESA},i}(\rho) \end{aligned} \quad (7)$$

Accordingly, based on the above, the hypothesis analysis module (521) of the second module 520 shown in FIG. 5 in one embodiment may be configured to verify/confirm the presence of ESA for a given analyte sensor based on the capillary blood glucose level measurement reading, when the capillary blood glucose measurement is in bin/category i, when the sensitivity ratio Rs is less than the corresponding defined threshold level t_i. For example, given the six blood glucose bins/categories (bin1 to bin6) described above, the respective threshold level t_i is: t_1=1.138, t_2=0.853, t_3=0.783, t_4=0.784, t_5=0.829, and t_6=0.797.

In this manner, in one aspect of the present disclosure, the method, system and computer program product provides for, but not limited to, early detection of sensitivity drops in continuous glucose monitoring systems. Sensitivity drops can be found in the first 24 hours, for example, of the sensor life, and while the potential adverse impacts may be minimized by frequent calibration or sensor masking, such sensitivity drops have clinically significant effects on the accuracy of the sensor data, and in turn, potential danger to the patient using the sensor. Accordingly, in one aspect, there is provided method, system, and computer program product for estimating or determining the probability of the presence of ESA based on the sensor current signal characteristics, and thereafter, performing a confirmation or verification routine to determine whether the sensitivity drop probability estimated based on the sensor current signal characteristics corresponds to a real time occurrence of a corresponding sensitivity drop in the sensor.

Accordingly, sensor accuracy, and in particular in the critical hypoglycemic ranges may be improved, multiple calibrations and/or sensor masking may be avoided during the early stages of the sensor life, and further, sensor calibration during sensitivity drop occurrence which may result in undetected hypoglycemic events, may be avoided.

FIG. 6 is a flowchart illustrating an overall ESA detection routine in accordance with one embodiment of the present disclosure. Referring to FIG. 6, in one embodiment of the present disclosure, a predetermined number of sensor data is retrieved or collected (610), and thereafter, it is determined whether the probability estimation for the sensitivity decline determination is appropriate (620). In one aspect, one or more of the following parameters may be used to determine whether the determination of the probability estimation of the sensitivity decline is appropriate: presence or collection of sufficient data points associated with the analyte sensor, timing of the probability estimation relative to when the analyte sensor was inserted or subcutaneously positioned, time period since the most recent determination of the probability estimation for the sensitivity decline, among others.

If is determined that the probability estimation for the sensitivity decline determination is not appropriate (620), then the routine shown in FIG. 6 returns to collecting additional sensor data points. On the other hand, if it is determined that the probability estimation for the sensitivity decline determination is appropriate, then the

probability estimation for the sensitivity decline determination is performed (630). Thereafter, based upon the determined probability estimation for the sensitivity decline, it is determined whether ESA is present or not (640).

That is, based on the analysis performed, for example, by the first module 520 of the sensitivity decline detector 500 (FIG. 5), if ESA is not detected, then the routine returns to collection and/or retrieval of additional sensor current data (640). On the other hand, if based on the analysis described above ESA is detected (640), then a capillary blood measurement is requested (for example, by prompting the user to perform a fingerstick blood glucose test and input the blood glucose value) (650). Thereafter, the routine shown in FIG. 6 performs the routine for confirming the presence or absence of ESA by, for example, the hypothesis analysis module 521 (FIG. 5).

Referring again to FIG. 6, if based on the analysis using the capillary blood measurement determines that ESA is not present, the routine again returns to the data collection/retrieval mode (610). On the other hand, if ESA presence is determined, in one aspect, an alarm or notification may be generated and provided to the user (680) to alert the user.

FIG. 7 is a flowchart illustrating real-time detection of sensor current abnormalities described in conjunction with module 1 of FIG. 5 in accordance with one embodiment of the present disclosure. Referring to FIG. 7, in one embodiment, analyte sensor data for a defined time period is retrieved or selected. With the analyte sensor data, one or more data processing is performed to determine sensor signal characteristics, including, for example, the mean current signal, the least squares slope, a standard deviation, an average elapsed time since the analyte sensor insertion/positioning (or average sensor life), a variance about the least squares slope (710).

Referring to FIG. 7, predetermined coefficients based on the analyte sensor data may be retrieved (720), and applied to the analyte sensor signals to determine or estimate the probability of ESA presence (730). Additionally, further shown in FIG. 7 is a predetermined threshold (740) which in one embodiment may be compared to the determined estimated probability of ESA presence (750). In one aspect, the predetermined threshold may be determined as the minimum probability of ESA presence for declaring such condition, and may be a tradeoff between false alarms (false

positives, where the threshold may be easy to exceed) versus missed detections (false negatives, where the threshold is difficult to exceed).

Referring still again to FIG. 7, if it is determined that the estimated probability of ESA presence does not exceed the predetermined threshold (750), then it is determined that ESA is not present – that is, sensor current signal attenuation is not detected (760). On the other hand, if it is determined that estimated probability of ESA presence exceeds the predetermined threshold, it is determined that ESA is present – that is, sensor current signal attenuation is detected (770). In either case, where the ESA presence is determined to be present or not present, such determination is communicated or provided to the subsequent stage in the analysis (780) for further processing.

FIG. 8 is a flowchart illustrating verification routine of module 2 in FIG. 5 to confirm or reject the output of module 1 in accordance with one embodiment of the present disclosure. Referring to FIG. 8, with the continuous glucose data (801) and the capillary blood glucose measurement (802), an average function of one or more continuous glucose sensor current data point at around the same time or approximately contemporaneously with the blood glucose measurement is performed (803). In the case where the sensor current data point is a single value, average function will result in the value itself – therefore averaging routine is unnecessary.

Alternatively, in the case where the sensor data includes more than one data point, for example, 11 data points centered around the time of the blood glucose data point, the average function is performed resulting in an average value associated with the plurality of data points. Thereafter, as shown in FIG. 8, a sensitivity value (S) is determined based on the calculated average value of the sensor data points as described above and the capillary blood glucose measurement (805). For example, the sensitivity value (S) associated with the sensor may be determined as the ratio of the determined average sensor data point value to the blood glucose value.

Referring still to FIG. 8, a nominal sensor sensitivity typically determined at the time of sensor manufacturing (807) is retrieved and applied to the determined sensor sensitivity value (S) to attain a normalized sensitivity ratio Rs (808).

Referring back to FIG. 8, based on the measured or received capillary blood glucose measurement (802), a corresponding glucose bin described above is determined or calculated (804), for example, in one aspect, by applying the function described in

equation (5) above. Thereafter, a corresponding ESA test threshold t is determined (806) based on the calculated or determined glucose bin. For example, as described above, each glucose bin (bin1 to bin6), is associated with a respective threshold level t which may, in one aspect, be determined by prior analysis or training.

Referring still again to FIG. 8, with the normalized sensitivity ratio (808) and the calculated bin (806), a comparison is made between the normalized sensitivity ratio and the determined or calculated bin (809). For example, in the case where the comparison establishes the normalized sensitivity ratio (S) exceeds the calculated bin t, it is determined that early signal attenuation (ESA) is not present (811). On the other hand, when the normalized sensitivity ratio (S) is determined to be less than the calculated bin t, then it is determined that ESA in the sensor signals is present.

FIG. 9 illustrates a real time current signal characteristics evaluation approach based on a sliding window process of module 1 in FIG. 5 in accordance with one embodiment of the present disclosure.

FIG. 10 illustrates bootstrap estimation of coefficients for module 1 of FIG. 5 in accordance with one embodiment of the present disclosure. Referring to the Figures, the bootstrap estimation procedure performed to add robustness to the model coefficients may include, in one aspect, a generalized linear model fit applied to a predetermined time period to determine the coefficient vector β. Based on a predefined number of iterations, an empirical probability distribution function of each coefficient may be determined, for example, as shown in FIG. 10, where each selected coefficient corresponds to the mode of the associated distribution.

FIG. 11 illustrates Gaussian kernel estimation of the normalized sensitivity density of module 2 of FIG. 5 in accordance with one embodiment of the present disclosure. Referring to FIG. 11, as described above in conjunction with FIG. 5, in one aspect, kernel density estimation (using Gaussian kernel, 24, for example) may be used to estimate the distribution of the sensitivity ratio Rs in each bin/category described above. The estimation of the distribution in sensitivity ratio Rs in one aspect is shown in FIG. 11, where for each bin/category (including, for example, severe hypoglycemia (bin1), mild hypoglycemia (bin2), low euglycaemia (bin3), high euglycaemia (bin4), low hyperglycemia (bin5), and high hyperglycemia (bin6)), the corresponding chart

illustrates the associated distribution where ESA presence is detected as compared to the distribution where no ESA presence is detected.

FIG. 12 illustrates a comparison of rate of false alarms (false positives) and sensitivity decline detection rate in accordance with embodiment of the present disclosure. That is, FIG. 12 represents the relation between ESA detection rate and false alarm rate. In one aspect, curve 1210 illustrates the output results of the first module 510 in the sensitivity decline detector 500 (FIG. 5) based on the logistic regression classifier, while curve 1220 illustrates the combined output of the first module 510 and the second module 520 of the sensitivity decline detector 500 (FIG. 5) based, for example, on a logistic rule classifier prompting a blood glucose measurement in the case of ESA presence probability exceeding a predetermined threshold level. In one embodiment, based on a threshold level of 0.416 determining the ESA presence probability, the rate of ESA detection is approximately 87.5% and a false alarm rate is approximately 6.5%.

In the manner described above, in accordance with the various embodiments of the present disclosure, real time detection of ESA or night time drop outs of analyte sensor sensitivities are provided. For example, an analyte sensor with lower than normal sensitivity may report blood glucose values lower than the actual values, thus potentially underestimating hyperglycemia, and triggering false hypoglycemia alarms. Moreover, since the relationship between the sensor current level and the blood glucose level is estimated using a reference blood glucose value (for example, calibration points), if such calibration is performed during a low sensitivity period, once the period comes to an end, all glucose measurements will be positively biased, thus potentially masking hypoglycemia episodes. Accordingly, the occurrence of errors in the relation between the current signal output of the analyte sensor and the corresponding blood glucose level may be monitored and detected in real time such that the patients may be provided with the ability to take corrective actions.

Indeed, real time detection of variations in the glucose levels in patients using monitoring devices such as analyte monitoring devices provide temporal dimension of glucose level fluctuations provide the ability to tightly control glycemic variation to control diabetic conditions. More specifically, in accordance with the various embodiments of the present disclosure, the analyte monitoring systems may be configured to provide warnings about low glucose levels in real time in particular, when

the patient may not be suspecting hypoglycemia or impending hypoglycemia, and thus provide the ability to help patients avoid life-threatening situations and self- treat during hypoglycemic attacks.

Accordingly, in one aspect of the present disclosure, the detection of episodes of low sensor sensitivity includes a first module which may be configured to execute a real-time detection algorithm based on analyte sensor current signal characteristics, and further, a second module which may be configured to perform a statistical analysis based on a single blood glucose measurement to confirm or reject the initial detection of the sensor sensitivity decline performed by the first module. In this manner, in one aspect of the present disclosure, accurate detection of ESA episodes or night time drop outs or declines in sensor current signal levels may be provided with minimal false alarms.

Accordingly, a computer implemented method in one aspect includes receiving a plurality of analyte sensor related signals, determining a probability of signal attenuation associated with the received plurality of analyte sensor related signals, verifying the presence of signal attenuation when the determined probability exceeds a predetermined threshold level, and generating a first output signal associated with the verification of the presence of signal attenuation.

Further, determining the probability of signal attenuation may include determining one or more characteristics associated with the received plurality of analyte sensor related signals, and applying a predetermined coefficient to the plurality of analyte sensor related signals.

In another aspect, the determined one or more characteristics may include one or more mean value associated with the analyte sensor related signals, the least square slope associated with the analyte sensor related signals, a standard deviation associated with the analyte sensor related signals, an average elapsed time from positioning the analyte sensor, or a variance about a least squares slope associated with the analyte sensor related signals.

Also, in still another aspect, the predetermined threshold level may be user defined or defined by a system expert.

In still another aspect, when the determined probability does not exceed the predetermined threshold level, the method may further include generating a second output signal associated with absence of signal attenuation condition.

Additionally, in yet a further aspect, verifying the presence of signal attenuation may include selecting a signal attenuation threshold level, determining a sensitivity level associated with the analyte related sensor signals, and confirming the presence of signal attenuation based at least in part on a comparison of the determined sensitivity level and the selected signal attenuation threshold level, where the signal attenuation threshold level may be associated with a blood glucose measurement.

Also, the blood glucose measurement may in another aspect include a capillary blood glucose sampling.

In yet still another aspect, the sensitivity level associated with the analyte related sensor may include a ratio of nominal sensitivity associated with the analyte related sensor signals and the sensitivity value associated with the analyte related sensor signals, where the sensitivity value may be determined as a ratio of the average of the analyte related sensor signals and a blood glucose measurement.

Moreover, confirming the presence of signal attenuation in another aspect may include determining that the sensitivity level is less than the selected signal attenuation threshold level, which in one aspect, may be determined by a system expert.

An apparatus in accordance with another aspect of the present disclosure includes a data storage unit, and a processing unit operatively coupled to the data storage unit configured to receive a plurality of analyte sensor related signals, determine a probability of signal attenuation associated with the received plurality of analyte sensor related signals, verify the presence of signal attenuation when the determined probability exceeds a predetermined threshold level, and generate a first output signal associated with the verification of the presence of signal attenuation.

The processing unit may be configured to determine the probability of signal attenuation is configured to determine one or more characteristics associated with the received plurality of analyte sensor related signals, and to apply a predetermined coefficient to the plurality of analyte sensor related signals.

The determined one or more characteristics may include one or more mean value associated with the analyte sensor related signals, the least square slope associated with the analyte sensor related signals, a standard deviation associated with the analyte sensor related signals, an average elapsed time from positioning the analyte sensor, or a variance about a least squares slope associated with the analyte sensor related signals,

where the predetermined threshold level may be user defined, or defined by a system expert.

When the determined probability does not exceed the predetermined threshold level, the processing unit may be further configured to generate a second output signal associated with absence of signal attenuation condition.

In still another aspect, the processing unit may be further configured to select a signal attenuation threshold level, determine a sensitivity level associated with the analyte related sensor signals, and confirm the presence of signal attenuation based at least in part on a comparison of the determined sensitivity level and the selected signal attenuation threshold level.

The signal attenuation threshold level may be associated with a blood glucose measurement.

The blood glucose measurement may include a capillary blood glucose sampling.

The sensitivity level associated with the analyte related sensor may include a ratio of nominal sensitivity associated with the analyte related sensor signals and the sensitivity value associated with the analyte related sensor signals, where the sensitivity value may be determined as a ratio of the average of the analyte related sensor signals and a blood glucose measurement.

The processing unit may be further configured to determine that the sensitivity level is less than the selected signal attenuation threshold level, which may be, in one aspect determined by a system expert.

In still another aspect, the apparatus may include a user output unit operatively coupled to the processing unit to display the first output signal.

A system for detecting signal attenuation in a glucose sensor in still another aspect of the present disclosure includes an analyte sensor for transcutaneous positioning through a skin layer of a subject, a data processing device operatively coupled to the analyte sensor to periodically receive a signal associated with the analyte sensor, the data processing device configured to determine a probability of the early signal attenuation (ESA), and to verify the presence of early signal attenuation based on one or more predetermined criteria.

The data processing device may include a user interface to output one or more signals associated with the presence or absence of early signal attenuation associated with the analyte sensor.

Various other modifications and alterations in the structure and method of operation of this disclosure will be apparent to those skilled in the art without departing from the scope and spirit of the disclosure. Although the disclosure has been described in connection with specific preferred embodiments, it should be understood that the disclosure as claimed should not be unduly limited to such specific 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.

WHAT IS CLAIMED IS:

1. A computer implemented method, comprising:

receiving a plurality of analyte sensor related signals;

determining a probability of signal attenuation associated with the received plurality of analyte sensor related signals;

verifying the presence of signal attenuation when the determined probability exceeds a predetermined threshold level; and

generating a first output signal associated with the verification of the presence of signal attenuation.

2. The method of claim 1 wherein determining the probability of signal attenuation includes:

determining one or more characteristics associated with the received plurality of analyte sensor related signals; and

applying a predetermined coefficient to the plurality of analyte sensor related signals.

3. The method of claim 2 wherein the determined one or more characteristics includes one or more mean value associated with the analyte sensor related signals, the least square slope associated with the analyte sensor related signals, a standard deviation associated with the analyte sensor related signals, an average elapsed time from positioning the analyte sensor, or a variance about a least squares slope associated with the analyte sensor related signals.

4. The method of claim 1 wherein the predetermined threshold level is user defined.

5. The method of claim 1 wherein when the determined probability does not exceed the predetermined threshold level, generating a second output signal associated with absence of signal attenuation condition.

6. The method of claim 1 wherein verifying the presence of signal attenuation includes:

selecting a signal attenuation threshold level;

determining a sensitivity level associated with the analyte related sensor signals; and

confirming the presence of signal attenuation based at least in part on a comparison of the determined sensitivity level and the selected signal attenuation threshold level.

7. The method of claim 6 wherein the signal attenuation threshold level is associated with a blood glucose measurement.

8. The method of claim 7 wherein the blood glucose measurement include a capillary blood glucose sampling.

9. The method of claim 6 wherein the sensitivity level associated with the analyte related sensor includes a ratio of nominal sensitivity associated with the analyte related sensor signals and the sensitivity value associated with the analyte related sensor signals.

10. The method of claim 9 wherein the sensitivity value is determined as a ratio of the average of the analyte related sensor signals and a blood glucose measurement.

11. The method of claim 6 wherein confirming the presence of signal attenuation includes determining that the sensitivity level is less than the selected signal attenuation threshold level.

12. An apparatus, comprising:

a data storage unit; and

a processing unit operatively coupled to the data storage unit configured to receive a plurality of analyte sensor related signals, determine a probability of signal attenuation associated with the received plurality of analyte sensor related signals, verify the presence of signal attenuation when the determined probability exceeds a predetermined threshold level, and generate a first output signal associated with the verification of the presence of signal attenuation.

13. The apparatus of claim 12 wherein the processing unit configured to determine the probability of signal attenuation is configured to determine one or more characteristics associated with the received plurality of analyte sensor related signals, and to apply a predetermined coefficient to the plurality of analyte sensor related signals.

14. The apparatus of claim 13 wherein the determined one or more characteristics includes one or more mean value associated with the analyte sensor related signals, the least square slope associated with the analyte sensor related signals, a standard deviation associated with the analyte sensor related signals, an average elapsed time from positioning the analyte sensor, or a variance about a least squares slope associated with the analyte sensor related signals.

15. The apparatus of claim 12 wherein the predetermined threshold level is user defined.

16. The apparatus of claim 12 wherein when the determined probability does not exceed the predetermined threshold level, the processing unit is further configured to generate a second output signal associated with absence of signal attenuation condition.

17. The apparatus of claim 12 wherein the processing unit is further configured to select a signal attenuation threshold level, determine a sensitivity level associated with the analyte related sensor signals, and confirm the presence of signal attenuation based at least in part on a comparison of the determined sensitivity level and the selected signal attenuation threshold level.

18. The apparatus of claim 17 wherein the signal attenuation threshold level is associated with a blood glucose measurement.

19. The apparatus of claim 18 wherein the blood glucose measurement include a capillary blood glucose sampling.

20. The apparatus of claim 17 wherein the sensitivity level associated with the analyte related sensor includes a ratio of nominal sensitivity associated with the analyte related sensor signals and the sensitivity value associated with the analyte related sensor signals.

21. The apparatus of claim 20 wherein the sensitivity value is determined as a ratio of the average of the analyte related sensor signals and a blood glucose measurement.

22. The apparatus of claim 17 wherein the processing unit is further configured to determine that the sensitivity level is less than the selected signal attenuation threshold level.

23. The apparatus of claim 12 including a user output unit operatively coupled to the processing unit to display the first output signal.

24. A system for detecting signal attenuation in an analyte sensor, comprising:

an analyte sensor for transcutaneous positioning through a skin layer of a subject; and

a data processing device operatively coupled to the analyte sensor to periodically receive a signal associated with the analyte sensor, the data processing device configured to determine a probability of the early signal attenuation (ESA), and to verify the presence of early signal attenuation based on one or more predetermined criteria.

25. The system of claim 24 wherein the data processing device includes a user interface to output one or more signals associated with the presence or absence of early signal attenuation associated with the analyte sensor.

101
102
103
104
105
SENSOR UNIT
TRANSMITTER UNIT
PRIMARY RECEIVER UNIT
DATA PROCESSING TERMINAL/ INFUSION SECTION
SECONDARY RECEIVER UNIT
106
100

FIGURE 1

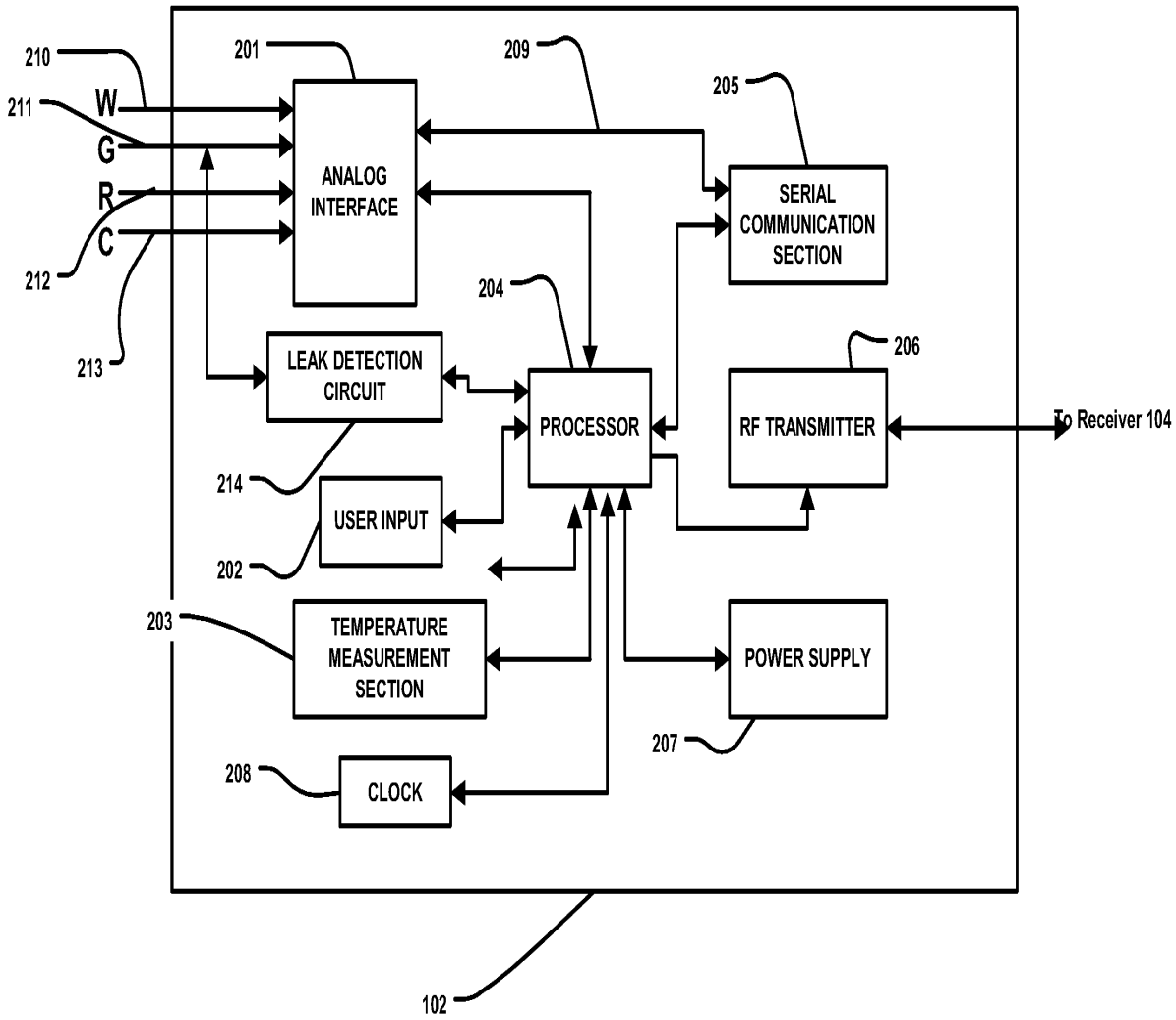

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209
205
ANALOG INTERFACE
SERIAL COMMUNICATION SECTION
204
206
LEAK DETECTION CIRCUIT
PROCESSOR
RF TRANSMITTER
To Receiver 104
214
USER INPUT
202
203
TEMPERATURE MEASUREMENT SECTION
POWER SUPPLY
207
208
CLOCK
102

FIGURE 2

301
TEST STRIP INTERFACE
307
309
SERIAL COMMUNICATION SECTION
TO DATA PROCESSING TERMINAL 105
302
FROM TRANSMITTER 102
RF RECEIVER
PROCESSING & STORAGE
303
USER INPUT
OUTPUT/DISPLAY
304
TEMPERATURE MONITOR SECTION
310
POWER CONVERSION AND MONITORING SECTION
POWER SUPPLY
305
CLOCK
308
306
104

FIGURE 3

FIGURE 4A

FIGURE 4B

520
510
Module 2
Finger Stick Measure
Module 1
CGS Current
Detection
yes
521
Hypothesis
Analysis Module
yes
Pr[ESA]
Logic Estimator
>τ
no
no
No detection
511
No detection
500

FIGURE 5

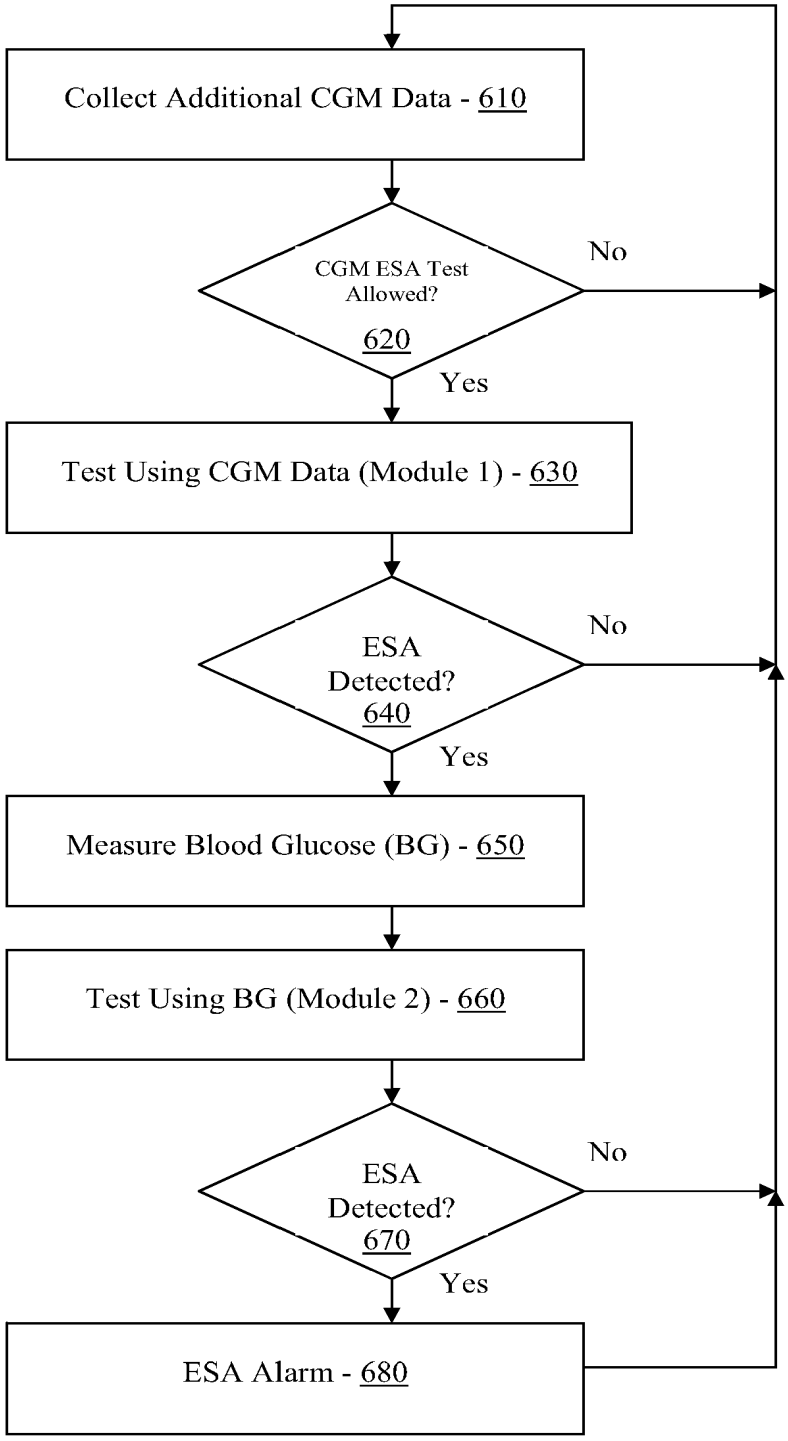

Collect Additional CGM Data - 610
CGM ESA Test Allowed? 620
No
Yes
Test Using CGM Data (Module 1) - 630
ESA Detected? 640
No
Yes
Measure Blood Glucose (BG) - 650
Test Using BG (Module 2) - 660
ESA Detected? 670
No
Yes
ESA Alarm - 680

FIGURE 6

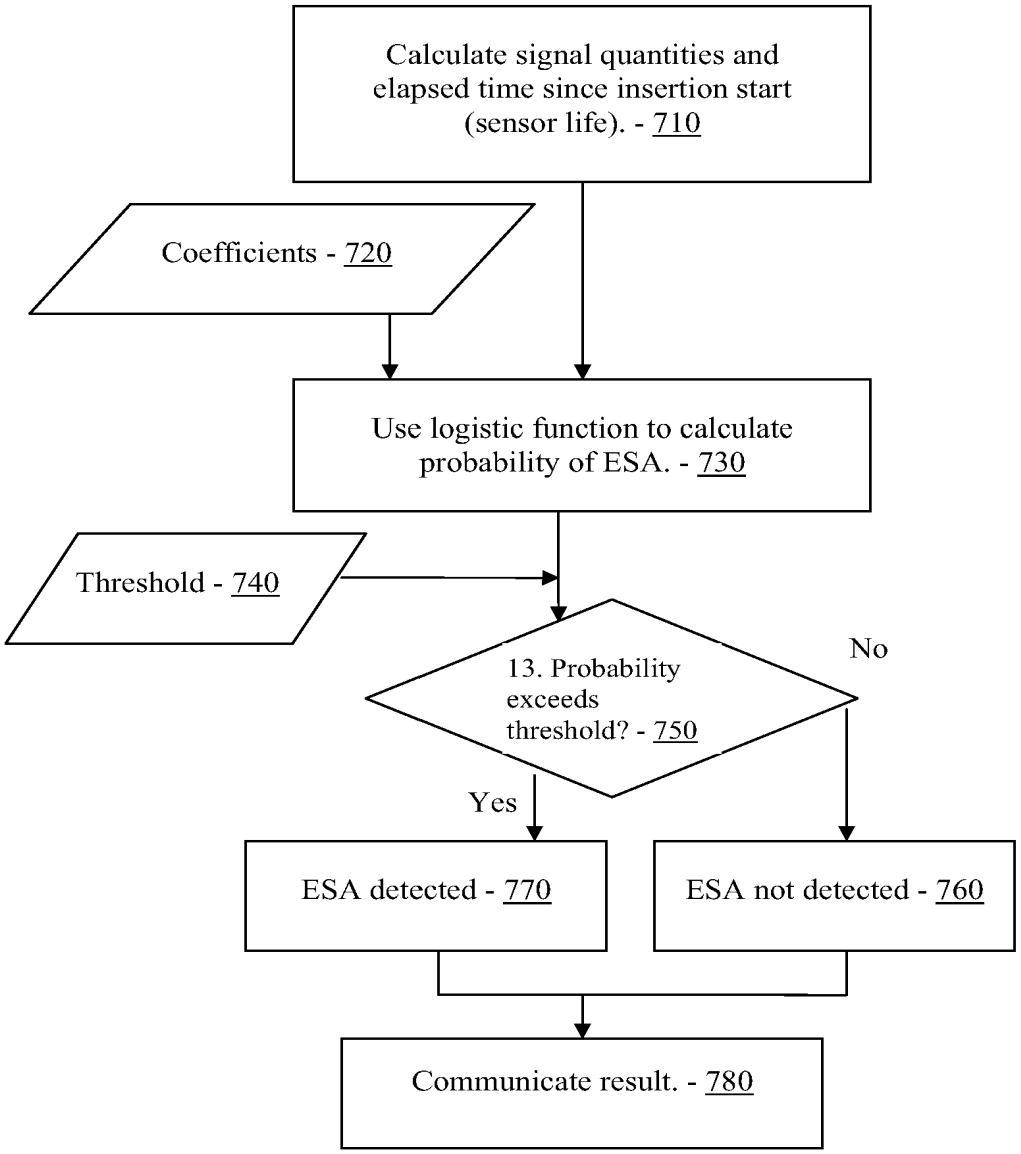

Calculate signal quantities and elapsed time since insertion start (sensor life). - 710
Coefficients - 720
Use logistic function to calculate probability of ESA. - 730
Threshold - 740
13. Probability exceeds threshold? - 750
No
Yes
ESA detected - 770
ESA not detected - 760
Communicate result. - 780

FIGURE 7

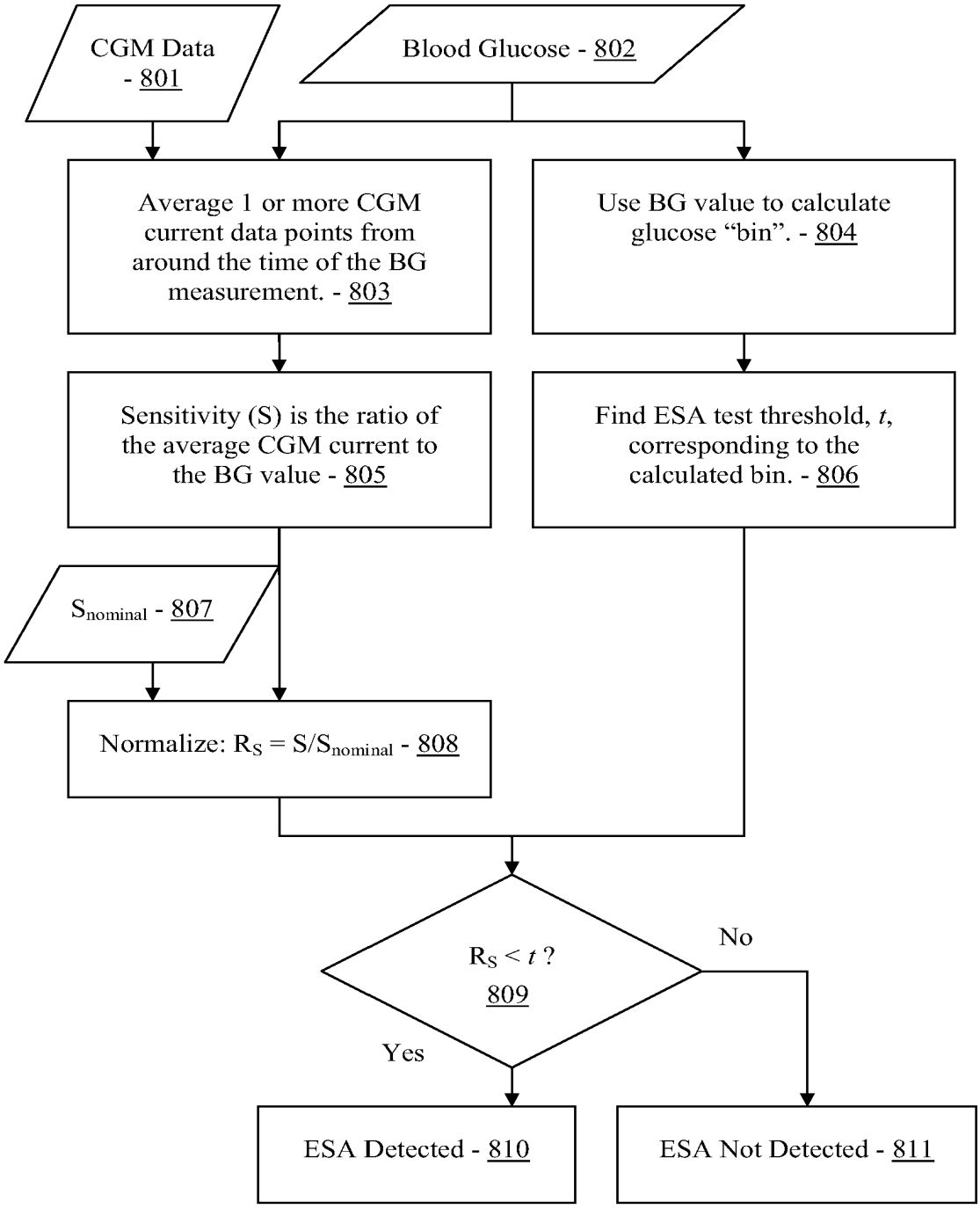

CGM Data - 801
Blood Glucose - 802
Average 1 or more CGM current data points from around the time of the BG measurement. - 803
Use BG value to calculate glucose "bin". - 804
Sensitivity (S) is the ratio of the average CGM current to the BG value - 805
Find ESA test threshold, t, corresponding to the calculated bin. - 806
$S_{nominal}$ - 807
Normalize: $R_S = S/S_{nominal}$ - 808
$R_S < t$? 809
No
Yes
ESA Detected - 810
ESA Not Detected - 811

FIGURE 8

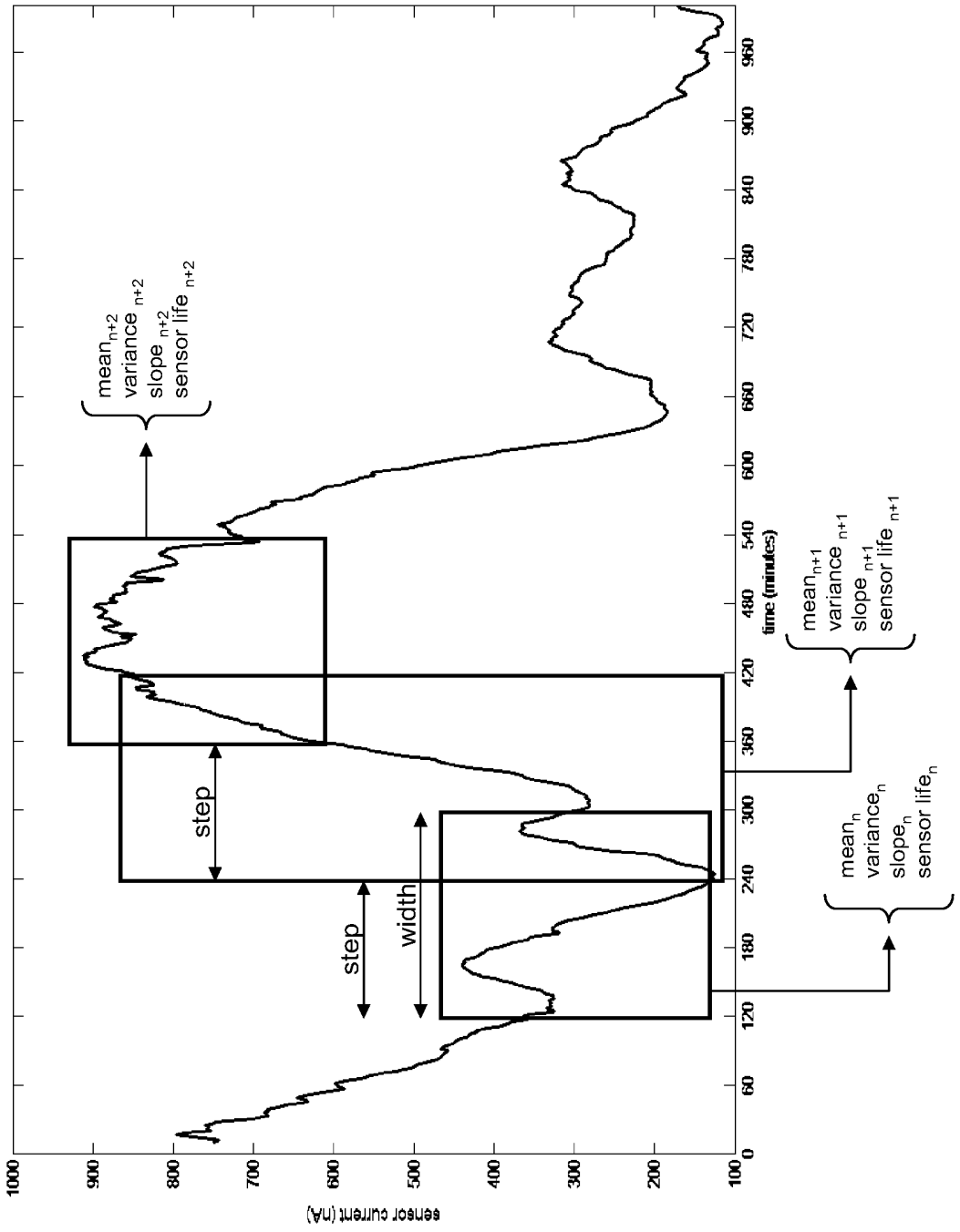

sensor current (nA)
time (minutes)
step
step
width
mean$_{n+2}$
variance $_{n+2}$
slope $_{n+2}$
sensor life $_{n+2}$
mean$_{n+1}$
variance $_{n+1}$
slope $_{n+1}$
sensor life $_{n+1}$
mean$_n$
variance$_n$
slope$_n$
sensor life$_n$

FIGURE 9

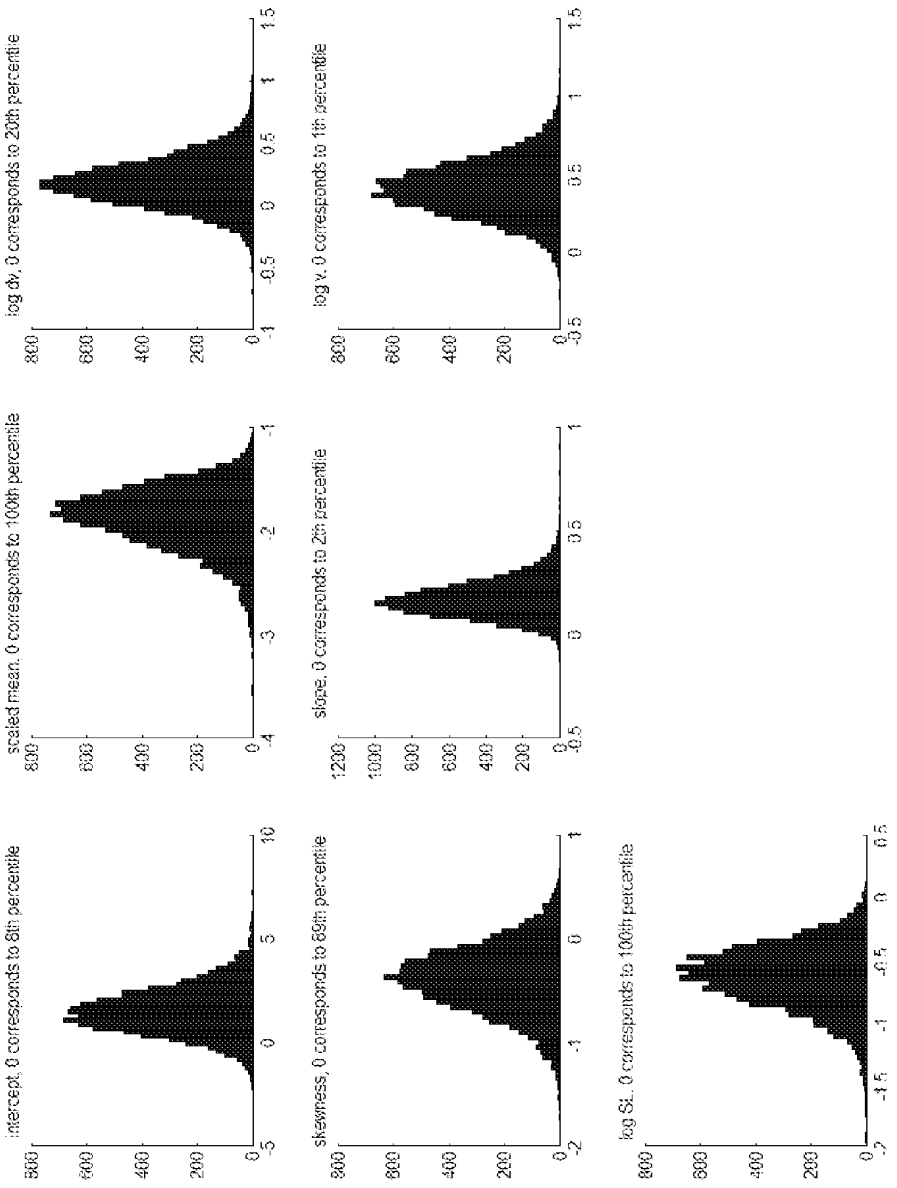

log dv, 0 corresponds to 20th percentile
log v, 0 corresponds to 1th percentile
scaled mean, 0 corresponds to 100th percentile
slope, 0 corresponds to 2th percentile
intercept, 0 corresponds to 8th percentile
skewness, 0 corresponds to 89th percentile
log SI, 0 corresponds to 100th percentile

FIGURE 10

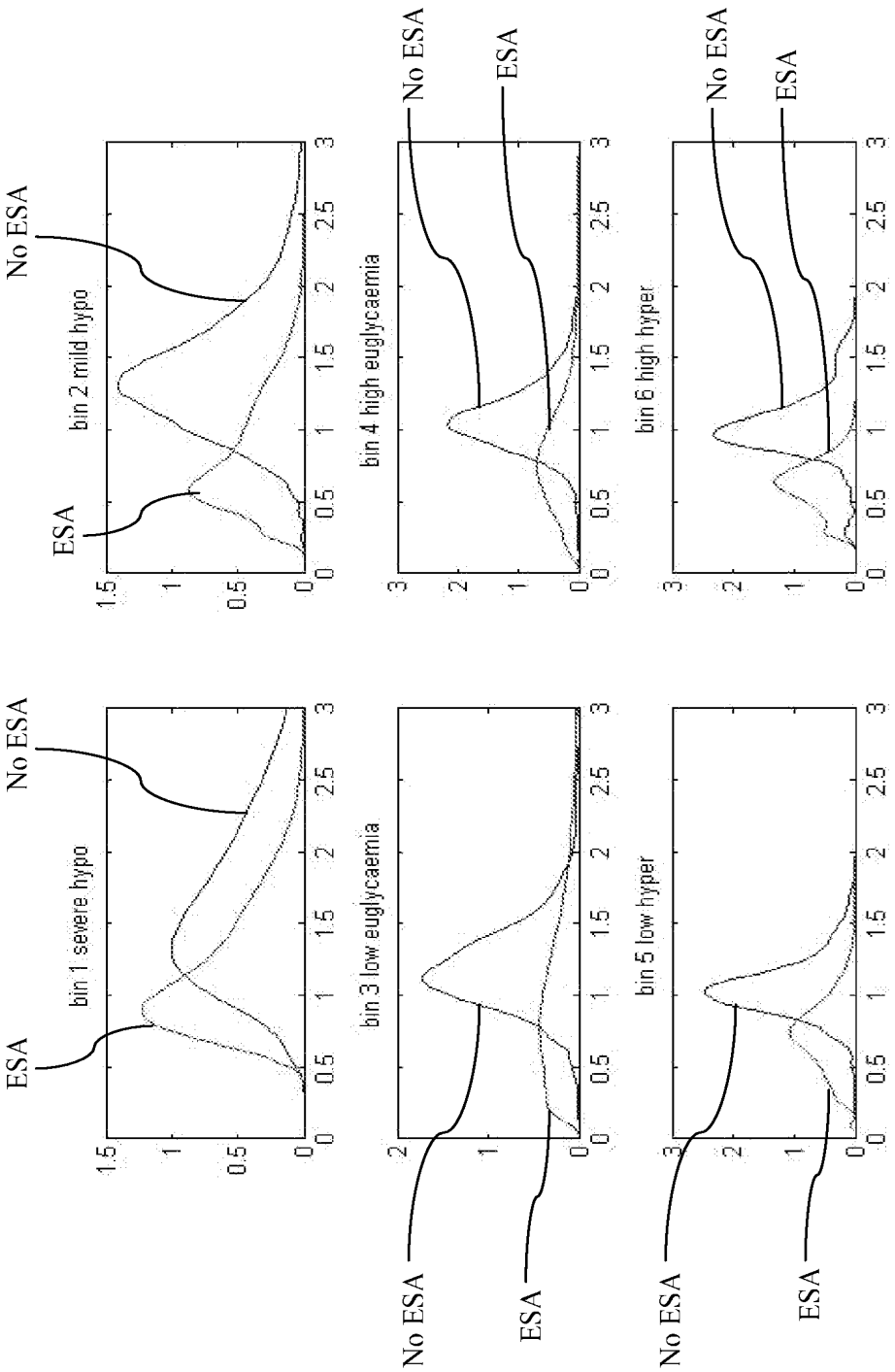

bin 1 severe hypo
bin 2 mild hypo
bin 3 low euglycaemia
bin 4 high euglycaemia
bin 5 low hyper
bin 6 high hyper
No ESA
ESA

FIGURE 11

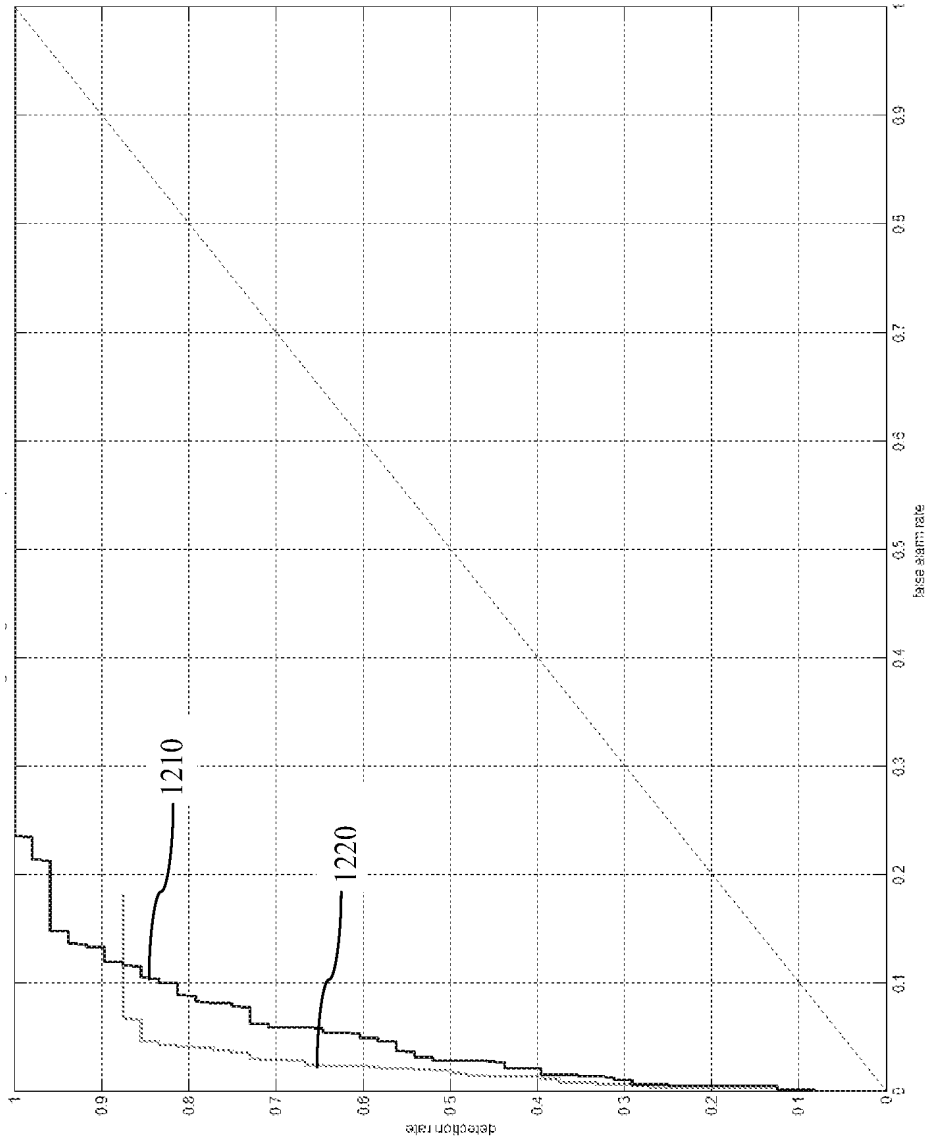


FIGURE 12

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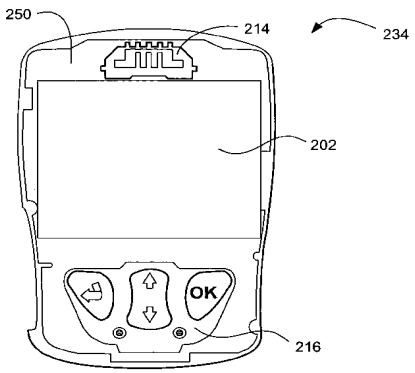
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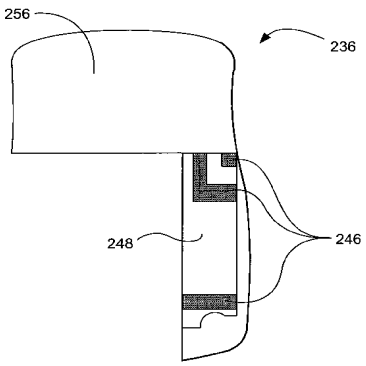
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[Continued on next page]

(54) Title: BLOOD GLUCOSE METER CAPABLE OF WIRELESS COMMUNICATION





(57) Abstract: The present invention relates to a blood glucose meter (200) comprising a blood glucose measuring module (234) for performing a blood glucose measuring function and a wireless communication module (236) adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol. The blood glucose measuring module (234) and the wireless communication module (236) are physically- separate units electrically connected in order to allow for an exchange of electrical signals corresponding to information to be transmitted by the wireless communication module and/or information received by the wireless communication module (236). According to the invention, the blood glucose measuring module (234) and the wireless communication module (236) both comprise a connector component (238, 240), wherein the two connector components (238, 240) are adapted to releasably establish the electrical connection between the blood glucose measuring module (234) and the wireless communication module (236).

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Blood glucose meter capable of wireless communication

The present invention relates to a blood glucose meter comprising a blood glucose measuring module for performing a blood glucose measuring function and a wireless communication module adapted for wireless communication with an external device, and to a method of constructing such a blood glucose meter.

Diabetes mellitus is a chronic metabolic disorder caused by an inability of the pancreas to produce sufficient amounts of the hormone insulin so that the metabolism is unable to provide for the proper absorption of sugar and starch. This failure leads to hyperglycemia, i.e. the presence of an excessive amount of glucose within the blood plasma. Persistent hyperglycemia causes a variety of serious symptoms and life threatening long term complications such as dehydration, ketoacidosis, diabetic coma, cardiovascular diseases, chronic renal failure, retinal damage and nerve damages with the risk of amputation of extremities. Because healing is not yet possible, a permanent therapy is necessary which provides constant glycemic control in order to always maintain the level of blood glucose within normal limits. Such glycemic control is achieved by regularly supplying external insulin to the body of the patient to thereby reduce the elevated levels of blood glucose.

External insulin was commonly administered by means of typically one or two injections of a mixture of rapid and intermediate acting insulin per day via a hypodermic syringe. While this treatment does not require the frequent estimation of blood glucose, it has been found that the degree of glycemic control achievable in this way is suboptimal because the delivery is unlike physiological insulin production, according to which insulin enters the bloodstream at a lower rate and

over a more extended period of time. Improved glycemic control may be achieved by the so-called intensive insulinotherapy which is based on multiple daily injections, including one or two injections per day of long acting insulin for providing basal insulin and additional injections of rapidly acting insulin before each meal in an amount proportional to the size of the meal. Although traditional syringes have at least partly been replaced by insulin pens, the frequent injections are nevertheless very inconvenient for the patient.

Substantial improvements in diabetes therapy have been achieved by the development of blood glucose systems relieving the patient of the daily use of syringes or insulin pens. Such blood glucose systems usually comprise a battery-operated blood glucose meter and one or more separate further devices, such as a battery-operated insulin pump. Further, such blood glucose systems usually comprise a control unit which is often provided as an integral part of the blood glucose meter, but may also be provided as a separate device communicating with the blood glucose meter and the remaining devices.

In such systems, the blood glucose meter is used to determine the blood glucose concentration, e.g. by receiving blood samples via enzyme-based test strips and calculating the blood glucose value based on the enzymatic reaction. Advantageously, the blood glucose system is configured such that the measured value is automatically delivered to the control unit. The insulin pump allows for the delivery of insulin in a more physiological manner and can be controlled to follow standard or individually modified protocols to give the patient a better glycemic control over the course of a day. It can be constructed as an implantable device for subcutaneous arrangement or can be constructed as an external device that is carried on the body of the patient.

The operation of the insulin pump and of other devices can be controlled and modified by means of the control unit. For example, delivery of suitable amounts of insulin by the insulin pump requires that the patient frequently determines his or her blood glucose level and inputs this value into the control unit, which then calculates a suitable modification to the default or currently in use insulin delivery protocol, i.e. dosage and timing, and subsequently communicates with the insulin pump to adjust its operation accordingly. In this regard, it may be necessary to use the control unit each time the patient eats to instruct the pump to administer a specified amount of insulin to cover that meal. Recently, a more or less closed-loop control has been realized in which the control unit modifies the insulin delivery protocol automatically.

In view of the permanence of the therapy, it is desirable to provide the diabetic patient with flexibility, convenience and ease of use in order to increase the quality of his or her life. In this regard, it is evident that cable connections between the individual devices of a blood glucose system are disadvantageous. Thus, it is known to provide a blood glucose meter with wireless communication capabilities.

In some of such meters, care has been taken to separate the part that is responsible for the measuring functionality yielding a metered value corresponding to blood glucose level from the part that is responsible for establishing a wireless communication link and receiving and/or transmitting information via this link. This arrangement has the advantage that in case changes to the wireless communication part are made upon further development of the blood glucose meter, such changes do not have an influence on the blood glucose measuring functionality. In this way, it is ensured that a modification which only relates to the wireless communication part does not have an impact on the critical medical functionality so that a

new testing and validation of the blood glucose measuring part is avoided. In blood glucose meters, this issue is of great importance, because uncertainties with regard to the correct measurement of blood glucose level cannot be accepted.

One exemplary blood glucose meter constructed in this way is described in US 2003/0065536 A1. This reference discloses a blood glucose meter capable of communicating medically relevant data information to another device such as e.g. a central server or a mobile terminal. The blood glucose meter includes a blood glucose measuring part for executing a blood glucose measuring function and a communication part responsible for wireless communication according to e.g. radio frequency communication, infrared communication, the Bluetooth protocol and/or the TCP/IP protocol. Both parts are connected in such a manner that they can exchange data information according to a predetermined protocol under the control of the blood glucose measuring part. Otherwise, the functionalities of both parts are separated in order to obtain two physically and functionally separated parts for the above reasons. While this blood glucose meter may facilitate advancement to the next product cycle to some degree, it lacks desired flexibility for the meter to be easily adapted to operation in different environments. The communication device part has predetermined functions, and in case a particular application requires a deviating wireless approach, a complex modification procedure is necessary.

In a different field of medical devices, US 6,731,962 discloses a finger oximeter with remote telecommunication capabilities enabling the oximeter to transmit measurement data from a patient to a remote device. The oximetry circuitry and the transmission circuitry may be provided on a single or on two separate printed circuit boards. This device has the same

disadvantages mentioned above for the known blood glucose meter.

It is the object of the present invention to provide a blood glucose meter providing a high degree of flexibility with regard to adapting it to operation in different wireless communication environments and that remedies the disadvantages found in the prior art, and to provide a blood glucose system including such a blood glucose meter as well as a method of constructing such a blood glucose meter.

This object is achieved by a blood glucose meter with the features of claim 1, by a blood glucose system with the features of claim 23, and by a method with the features of claim 25. Further preferred embodiments of the invention are the subject-matter of the respective dependent claims.

The blood glucose meter of the present invention comprises a blood glucose measuring module for performing a blood glucose measuring function, i.e. the module includes a means for performing such function, such as e.g. a means that is able to analyze blood samples on enzyme-based test strips, that can be inserted into a test strip receiving slot of the meter in order to determine the blood glucose level based on the enzymatic reaction. This blood glucose measuring module may be adapted to perform all steps necessary to measure, calculate and provide a value of blood glucose level. For some applications, however, it may be advantageous if the blood glucose measuring module is adapted to perform only a part of these steps, while one or more additional devices, connected to the blood glucose meter by means of e.g. a wireless or cable connection, are provided to perform the remaining steps. For example, an external sensor may be provided for transmitting a signal characteristic of blood glucose level to the blood glu-

cose meter, from which signal the blood glucose meter calculates and displays the blood glucose level.

The blood glucose meter further comprises a wireless communication module adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol. In the context of the present invention, the term frequency format refers to the physical characteristics of the wireless signals such as frequency or modulation. Although the wireless communication link will usually be bidirectional, for simple applications the link can also be unidirectional, i.e. the wireless communication module may be configured to only transmit or to only receive messages to or from the external device.

The blood glucose measuring module and the wireless communication module are physically separate units. In the context of the present invention, this means that the two modules as a whole are distinct structural parts which may be completely spatially separated from each other. However, they are releasably electrically connected in order to allow for an exchange of electrical signals corresponding to information to be transmitted by the wireless communication module and/or information received by the wireless communication module, i.e. in accordance with the considerations mentioned above the exchange of signals may be bidirectional or unidirectional.

It is to be noted that in addition to a means for performing a blood glucose measuring function, the blood glucose measuring module may also include other means for performing other functions relevant to the operation of the blood glucose meter. Only means relating to the wireless communication are necessarily disposed separate from this module and are located in

the wireless communication module. In case the blood glucose measuring module includes a substantial part of the functional means or substantially all functional means of the blood glucose meter, the blood glucose measuring module could also be referred to as the main module of the meter.

According to the present invention, the blood glucose measuring module and the wireless communication module both comprise a connector component adapted to releasably establish the electrical connection between the blood glucose measuring module and the wireless communication module. Thus, the connector component of the blood glucose measuring module and the connector component of the wireless communication module can cooperate to effect the electrical connection between the two modules. This electrical connection is releasable, i.e. it can be selectively and repeatedly disconnected and re-established.

This construction provides the advantage that any connection and functional cooperation between the two physically separate modules can be easily and readily broken in case it is desired to replace one of the modules with another similar module providing a different functionality. Thus, while the above-referenced advantages due to separation of the blood glucose measuring functionality and the wireless communication functionality into two distinct units, i.e. the functional independence of this units, found in prior art blood glucose meters are retained, it is very simple to quickly replace a first wireless communication module, which is e.g. adapted for communication according to the Bluetooth standard, with a second wireless communication module, which is e.g. adapted for communication according to the ZigBee or ISM standard, thereby adapting the blood glucose meter to a different wireless communication environment. This advantageous flexibility can be utilized at the manufacturing stage or even later-on by the user. Thus, advantageously the blood glucose meter is con-

structed such that the frequency format and/or protocol according to which the blood glucose meter can communicate with an external device can be changed by replacing the wireless communication module with another wireless communication module which can be connected to the connector component of the blood glucose measuring module by means of its own connector component and which is adapted to communicate according to a different frequency format and/or protocol.

Moreover, the construction according to the invention provides further advantages during the quality control procedure. Because the electrical connection between the blood glucose measuring module and the wireless communication module is releasable and the blood glucose measuring functionality and the wireless communication functionality are compartmentalized in different modules, separate quality control tests can be performed on the modules after spatially separating the modules. This avoids problems and a complicated procedure due to the two modules being electrically connected and in close proximity to each other. Otherwise, problems could arise e.g. due to the wireless signal generated by the wireless communication module interfering with the quality control testing of the blood glucose measuring module. Thus, the likelihood of encountering interferences during quality control testing can be reduced by performing the two quality control tests entirely separately in such a manner that the blood glucose measuring module and the wireless communication module are not electrically connected and not in close proximity to each other.

In an advantageous version of the invention, the blood glucose meter is constructed such that the frequency format and/or protocol according to which the blood glucose meter can communicate with an external device can be changed solely by replacing the wireless communication module with another wireless communication module which is adapted to communicate ac-

cording to a different frequency format and/or protocol. Thus, in order to adapt the meter to a different wireless communication environment, no other steps but disconnecting the present wireless communication module from the blood glucose measuring module, removing the wireless communication module and connecting a different wireless communication module having the desired wireless communication capabilities to the blood glucose measuring module are necessary for the adaptation. In particular, no changes whatsoever have to be made to the blood glucose measuring module. For this purpose, the electrical signals provided and expected by the blood glucose measuring module at its connector component are predetermined, and the new wireless communication module has to operate in accordance with the standard constituted by the corresponding set of predetermined signals.

In a preferred embodiment of the blood glucose meter, the blood glucose measuring module comprises a control means operable to control the electrical signals provided by the blood glucose measuring module at its connector component.

It is further preferred if the wireless communication module comprises a memory chip connector for electrically connecting the wireless communication module with a non-volatile semiconductor memory card or a so-called smart card, wherein the control means of the blood glucose measuring module is adapted to operate in accordance with information stored in a non-volatile semiconductor memory card or smart card connected to the memory chip connector of the wireless communication module. In this regard, it is also possible that the memory card or smart card includes circuitry which is connected via the memory chip connector and the connector components of the two modules to the control means of the blood glucose measuring device and then forms part of the control means to thereby change or adapt the operation of the control means to the par-

ticular wireless communication module. In any case, the provision of a memory chip connector results in increased flexibility because the signals provided and expected by the blood glucose measuring module at its connector may be modified to thereby improve the capabilities of the wireless communication module and the meter as a whole.

In the alternative, it is preferred if the control means can be reprogrammed in order to change the electrical signals provided and/or expected during operation by the blood glucose measuring module at its connector component, i.e. the electrical signals can be reprogrammed in their functions. In a preferred embodiment such reprogramming can be effected by the wireless communication module. For this purpose, the wireless communication module may comprise a memory chip connector for electrically connecting the wireless communication module with a non-volatile semi-conductor memory card or smart card, wherein the control means of the blood glucose measuring module can be reprogrammed in accordance with information stored in a non-volatile semiconductor memory card or smart card connected to the memory chip connector of the wireless communication module. For example, the meter may be constructed such that this reprogramming is effected automatically upon establishing the releasable electrical connection between the blood glucose measuring module and the wireless communication module or by inserting a memory card or smart card into the memory chip connector. This design provides additional flexibility because the memory card or smart card does not always have to be present in the wireless communication module. In any case, the frequency format and/or protocol according to which the blood glucose meter can communicate with an external device can advantageously be changed by replacing the wireless communication module with another wireless communication module which is adapted to communicate according to a different fre-

quency format and/or protocol and suitably reprogramming the control means of the blood glucose measuring module.

It should be noted that each of the memory chip connectors mentioned above could also be provided not in the wireless communication module, but at a different location in the blood glucose meter of the present invention. For example, they could be provided in the blood glucose measuring module. In any case, in the assembled state of the blood glucose meter the memory chip connectors have to be connected to the control means of the blood glucose measuring module. However, in most cases, disposing the memory chip connector in the wireless communication module provides the advantages of particular flexibility and space economy within the blood glucose measuring module.

It is preferred that the wireless communication module comprises a memory chip connector for electrically connecting the wireless communication module with a non-volatile semiconductor memory card. This memory chip connector can be one of the memory chip connectors mentioned above or an additional memory chip connector. In this way a variety of different functions of the wireless communication module and/or the blood glucose measuring module may be modified and adapted in a particularly simple manner. Further, a memory card or smart card can also serve as a storage means for storing various information relating to the measurement results obtained by the meter. In addition or in the alternative, one or more memory chip connectors for connecting a non-volatile semiconductor memory card with the blood glucose meter and fulfilling one or more of the above or one or more other functions could also be provided at other locations in the blood glucose meter of the present invention, e.g. in the blood glucose measuring module.

For any memory chip connector present in the wireless communication module (or at a different location), it is advantageous if the memory chip connector is orientated such that a set of contacts on a memory card connected to the memory chip connector face downwards allowing a user to more easily observe upward facing artwork on the memory card as it is inserted into said blood glucose meter. In this way, the identity of the card can be easily verified without a need to remove the card from the memory chip connector.

According to a preferred embodiment of the invention, the wireless communication module does not comprise an own power supply. Rather, a corresponding power supply for operating the wireless communication module is disposed in the blood glucose measuring module. This power supply can be the power supply of the blood glucose measuring module or a separate, dedicated power supply. In any case, the electrical signals provided during operation by the blood glucose measuring module at its connector component include signals for supplying power to the wireless communication module. This construction provides the advantage of the possibility of a particularly simple and low-cost design of the wireless communication module, which is highly advantageous in view of the wireless communication modules being envisaged for interchangeability.

It is preferred that the wireless communication module comprises a transceiver, an antenna impedance matching network and an antenna, and possibly also an electrostatic discharge (ESD) protection circuit. In this manner, the wireless communication module is a self-contained unit. Arrangement of the antenna in close proximity to the remaining components of the wireless communication module is highly advantageous.

It is further preferred that the blood glucose meter comprises a housing in which the blood glucose measuring module and the

wireless communication module are enclosed to provide a meter which is compact and easily manageable for the user.

In a preferred embodiment of the invention, the blood glucose measuring module comprises or consists of a first printed circuit board on which blood glucose measuring circuitry - and possibly further circuitry if the first printed circuit board is the main board of the meter - is mounted or provided, and the wireless communication module comprises or consists of a second printed circuit board, different from the first printed circuit board, on which wireless communication circuitry is mounted or provided. In this case, it is advantageous if the wireless communication module comprises a transceiver, an antenna impedance matching network and an antenna as well as possibly an ESD protection circuit, and if all these elements of the wireless communication module are mounted or provided on the second printed circuit board. Further, a particularly simple and efficient design can be realized if the first printed circuit board is a motherboard and the second printed circuit board is a daughterboard. Further, it is preferred if the second printed circuit board is disposed on the first printed circuit board. In any case, it is an advantage of this construction that the second printed circuit board or daughter board helps to economize space on the first printed circuit board or mother board.

It is preferred if one of the connector components of the blood glucose measuring module and the wireless communication module is the plug component of a plug and socket connector and the other connector component is the socket component of the plug and socket connection. Such a plug and socket connection is particularly easy to operate and simple in construction. The releasable electrical connection may be established by directly connecting the plug and the socket, i.e. by inserting the plug on the wireless communication module or the

blood glucose measuring module into the socket on the blood glucose measuring module or wireless communication module, respectively, or by connecting them via an adapter or a cable.

The connector components of the blood glucose measuring module and the wireless communication module may also be adapted to be connected by a cable having suitable connector components at its ends. Such a construction provides flexibility with regard to the physical arrangement of the two modules within the meter.

The wireless communication module may advantageously be adapted to communicate according to the ISM, Bluetooth, ZigBee or WLAN standard or even according to two or more of these standards.

The blood glucose meter of the invention described above may advantageously be part of a blood glucose meter system further comprising at least one further wireless communication module similar to the wireless communication module but adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol different from the frequency format and/or protocol of the wireless communication module. As is evident from the above description, with such a system the frequency format and/or protocol according to which the blood glucose meter can communicate with an external device can be changed by replacing the wireless communication module with one of the at least one further wireless communication module by establishing a releasable connection between the blood glucose measuring module and the new wireless communication module by means of their connector components. Of course, such a system can also be regarded as comprising a blood glucose meter as described above with or without a wireless com-

munication module connected to the blood glucose measuring module as well as a number or set of wireless communication modules which are adapted for different wireless communication capabilities. This set of wireless communication modules may e.g. include wireless communication modules adapted to communicate according to the ISM, Bluetooth, ZigBee or WLAN standard or even according to two or more of these standards.

Any of the blood glucose meters of the present invention described above may advantageously be constructed by a method in which a blood glucose measuring module for performing a blood glucose measuring function is provided and a plurality of wireless communication modules are provided, each adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol different from the frequency format and/or protocol of the other wireless communication modules. As noted in detail above, the blood glucose measuring modules and the wireless communication module are physically separate units and the blood glucose measuring module and each wireless communication module comprise respective connector components by means of which a selected one of the wireless communication modules may be releasably electrically connected in order to allow for an exchange of electrical signals corresponding to information to be transmitted by the respective wireless communication module and/or information received by the respective wireless communication module. Subsequently, one of the plurality of wireless communication modules is selected in accordance with the desired frequency format and protocol, and an electrical connection between the selected wireless communication module and the blood glucose measuring module is established by means of the respective connector components to thereby form the blood glucose meter. By this method, a manufacturer or even a user may easily and in a

flexibly manner construct a blood glucose meter tailored to a particular application.

In the following, the invention is explained in more detail for preferred embodiments with reference to the figures.

Figure 1 is a top perspective view of a blood glucose meter according to the present invention.

Figure 2 is a schematic diagram showing the blood glucose meter of Figure 1 wirelessly communicating with a plurality of external medical devices.

Figure 3 is a simplified bottom plan view of a motherboard of the blood glucose meter shown in Figure 1.

Figure 4 is a simplified top plan view of the motherboard shown in Figure 3.

Figure 5 is a simplified top plan view of a daughterboard of the blood glucose meter shown in Figure 1.

Figure 6 is a simplified bottom plan view of the daughterboard shown in Figure 5.

Figure 7 is a bottom plan view of a memory chip for use with the daughterboard shown in Figures 5 and 6.

Figure 8 is a top plan view of the memory chip shown in Figure 7.

Figure 9 is a simplified bottom perspective view of the daughterboard shown in Figures 5 and 6.

Figure 10 is a simplified bottom perspective view of the blood glucose meter with a bottom housing half removed.

Figure 1 is a perspective view of a blood glucose measurement device or meter in accordance with the present invention, which in a particular embodiment of the invention is provided in the form of a remote controller 200. This remote controller 200 may e.g. be part of the blood glucose system schematically shown in Figure 2. A medical device such as, for example, this glucose measurement device 200 may have the ability to wirelessly communicate with one or more peripheral medical devices. In the embodiment of this invention shown in Figure 2, the blood glucose measurement device or remote controller 200 communicates via a wireless signal 310 with peripheral medical devices such as, for example, an insulin pump 300 for dispensing insulin to the blood circuit of a patient, a continuous glucose monitor (CGM) 400, an insulin pen 500, or a combination thereof. The insulin pump 300 may be an external device to be worn on the body of a patient, or it may be constructed as an implantable device to be disposed subcutaneously.

Recently, there has been a continuing development in the field of wireless communications and it is likely that these improvements will continue in the future. There will also likely be a need for additional types of peripheral medical devices to wirelessly communicate with a blood glucose measurement device for facilitating the therapy of people with diabetes. This has led to a need for designing a medical device such as a blood glucose meter which can have its hardware easily adapted to a new wireless communication environment or application or upgraded by using a modular architecture. In an embodiment of this invention, the wireless circuitry is compartmentalized from the blood glucose measuring circuitry. Thus, in such a design, only the wireless circuitry must be replaced while the blood glucose measuring circuitry will require lit-

tle or no modification. In general, this will make adapting, changing or upgrading the wireless functionality of a blood glucose measurement device faster and easier to perform.

Remote controller 200 may be used to episodically measure blood glucose and to wirelessly control insulin pump 300 and/or other peripheral medical device(s). In an embodiment of this invention, remote controller 200 may be a master and insulin pump 300 and/or other peripheral medical device(s) may be a slave. As shown in Figure 1, remote controller 200 includes a first housing half 201, a display 202, an OK button 204, a universal port connector 205, a down button 206, a second housing half 207, a back button 208, a port cover 209, an up button 210, light emitting diode (LED) 212, and a strip port connector (SPC) 214. In an embodiment of this invention, a first housing half 201 and second housing half 207 may adapt to join together to form an ergonomically shaped handheld glucose meter which encloses both a motherboard and a daughterboard which will be described in detail below.

Figures 3 and 4 show a simplified schematic bottom and top plan view, respectively, of an embodiment of a motherboard 234 having a bottom surface 252 and a top surface 250. As shown in Figure 4, motherboard 234 has mounted on top surface 250, the strip port connector 214, the display 202, and a plurality of navigation buttons 216, namely the OK button 204, the down button 206, the back button 208 and the up button 210 (see Figure 1) for effecting user entries e.g. by navigating through a menu structure of a user interface. The navigation buttons 216 may be utilized for initiating a particular action by the remote controller 200 or to input data into the remote controller 200, e.g. in order to adjust the operation of the insulin pump 300 with regard to various patient parameters such as e.g. his or her weight. As shown in Figure 3, motherboard 234 has mounted on bottom surface 252 an alarm 226, a

blood glucose measurement means 220 for determining the level of blood glucose, a wired communication port 224, a memory 230, a first connector 238, a motherboard electrostatic discharge (ESD) circuitry 242, and a microprocessor 228.

Figures 5 and 6 show a simplified schematic top and bottom plan view, respectively, of an embodiment of a daughterboard 236 having a top surface 254 and a bottom surface 256. As shown in Figure 5, daughterboard 236 has mounted on its top surface 254, a memory chip port 232, a daughterboard ESD circuitry 244, an antenna impedance matching network 219, a radio frequency transceiver 218, and a second connector 240. As shown in Figure 6, daughterboard 236 has mounted on its bottom surface 256, a dielectric material 248 and an antenna element 246 coupled to the transceiver 218. It should be noted that a combination of dielectric material 248 and antenna element 246 may be simply referred to as an antenna. Antenna element 246 may be a contiguous conductive material having a 3-dimensional shape which is disposed on a portion of dielectric material 248 as also shown in Figure 9. The use of daughterboard 236 provides an additional set of two surfaces (i.e. top surface 254 and bottom surface 256) in which electronic components can be mounted. This allows more electronics to be efficiently enclosed within first housing half 201 and second housing half 207. The daughterboard 236 may also include control electronics, e.g. in the form of a microprocessor, operable to compose data frames to be transmitted by means of the transceiver 218, to analyze data frames received by the transceiver 218, and to activate and deactivate the transceiver 218 to transmit and/or receive data frames.

Motherboard 234 includes all of the functional circuitry required for performing an episodic glucose measurement test, whereas daughterboard 236 includes all of the functional circuitry required for a wireless communication with one or more

peripheral medical devices such as insulin pump 300. From the above description, it is evident that the motherboard 234 forms a blood glucose measuring module in accordance with the present invention and that the daughterboard 236 forms a wireless communication module in accordance with the present invention. In the shown embodiment, motherboard 234 and daughterboard 236 are electrically connected, respectively, by the first connector 238 and the second connector 240, both of which are adapted to reversibly mate and to effect a releasable electrical connection which can be repeatedly and selectively disconnected and re-established. In an embodiment of this invention, motherboard 234 and daughterboard 236 are disposed in a stacking orientation such that when they are mated together by means of connectors 238 and 240 bottom surface 252 of motherboard 234 is orientated in a spaced apart and facing arrangement with top surface 254 of daughterboard 236 (see Figures 3, 5, and 10).

Figure 9 shows two batteries 222 which are disposed in a position such that a major axis of antenna element 246 is parallel to a major axis of batteries 222. Batteries 222 may be disposed in a battery compartment which is integrated as a portion of second housing half 207 (not shown). In the embodiment shown in Figures 5, 6 and 9, daughterboard 236 has an "L" shape to provide room for batteries 222 which in this case are two AAA alkaline batteries as shown in Figures 5 and 9.

Remote controller 200 may be designed such that it can be operated while on a tabletop or while being held by a user's hand. First housing half 201 may be a top surface of remote controller 200 and second housing half 207 may be a bottom surface of remote controller 200. During the use of remote controller 200, its bottom surface should be disposed on either a tabletop or the user's hand and thus should not be viewable by a user. However, the top surface of remote con-

troller 200 should be viewable by a user during use. Therefore, display 202 and navigation buttons 216 should be mounted on top surface 250 of motherboard 234. In addition, top surface 250 of motherboard 234 should be disposed immediately underneath first housing half 201 such that corresponding apertures within first housing half 201 adapt to the shape of display 202 and navigation buttons 216. This allows display 202 and navigation buttons 216 to be viewable on the top surface of remote controller 200.

It is desirable to make the size of remote controller 200 relatively small so that it can easily fit into a palm of a user's hand. In general, a length and a width of motherboard 234 must be about the same as remote controller 200 in order to efficiently use all of the usable space available within remote controller 200 for mounting electronic components. Typically, there is a desire to have sufficiently large navigation buttons 216 and display 202 so that a user can easily see and handle them. Therefore, in order to design remote controller 200 as small as possible and have sufficiently large navigation buttons 216 and display 202, motherboard 234 should have an efficiently packed set of electronic components leaving little to no usable space. In an embodiment of this invention, the set of electronic components mounted to top surface 250 on motherboard 234 may include display 202, navigation buttons 216, and strip port connector 214. Figure 4 shows that the set of electronic components occupy nearly all of the usable area of the top surface of motherboard 234 making it difficult to mount additional electronic components without increasing the size of motherboard 234.

Display 202 may be a liquid crystal display (LCD) to show both textual and graphical information to a user. A user interface (UI) may be a software driven menu that is shown on display 202 that enables the user to operate remote controller 200. A

user can navigate through the UI using navigation buttons 216 which include up button 210, down button 206, OK button 204, and back button 208. In an embodiment of this invention, the UI allows a user to operate an insulin pump, query the status of the insulin pump, measure blood glucose episodically, and to display data on display 202 (e.g. glucose concentration versus time).

Alarm 226 which may be in a variety of forms to warn a user of various statuses that might need an actionable response. For example, alarm 226 may include an audio alarm (monophonic beeps or polyphonic tones), a vibratory alarm, or a LED 212 which may be a multi-colored LED that can illuminate red, yellow, and green light. In an embodiment of this invention, an alarm signal my be used to warn a user that there is a low blood glucose reading, a partially filled blood glucose test strip, a low reservoir of insulin, an occlusion in insulin pump 300, a low battery status for insulin pump 300, a low battery status for remote controller 200, and/or an improperly filled test strip.

Blood glucose measurement means 220 may be a potentiostat designed for performing an episodic electrochemical measurement of a physiological fluid. In an embodiment of this invention, blood glucose measurement means 220 may apply a constant potential such as, for example, about +0.4 V between a working electrode and a reference electrode of a disposable test strip. A disposable test strip which may be suitable for use in the present invention is the OneTouch Ultra test strip which is commercially available from LifeScan, Inc. in Milpitas, California, U.S.A. The disposable test strip may be inserted into and electrically connected with strip port connector 214. After insertion, a physiological fluid such as blood may be applied to the disposable test strip causing the test to initiate. A reagent layer on the disposable test strip

may proportionally convert an oxidized mediator to a reduced mediator allowing a current to be measured. A portion of the current may be sampled and mathematically converted to the glucose concentration which is displayed on display 202.

Port cover 209 in Figure 1 is an elastomeric material that covers over a wired connection port 224 and a memory chip port 232. Examples of a wired connection port may be a universal serial bus (USB) or a serial RS232. Wired connection port 224 may used to connect to a personal computer for transferring/receiving data and/or a software code.

Radio frequency (RF) transceiver 218 may be an electronic circuit capable of receiving and sending a wireless signal to a peripheral medical device. RF transceiver 218 may include a microprocessor for managing and processing a wireless signal. In an embodiment of this invention, RF transceiver 218 may use one of a variety of frequency formats and/or protocols such as, for example, an Industry-Scientific-Medical (ISM) frequency band, a Bluetooth format, a ZigBee format, and a WLAN format. In the ISM frequency band, the frequency may range from about 868 MHz to about 928 MHz. Antenna element 246 may be mounted to dielectric material 248 which in turn is mounted to bottom surface 256 of daughterboard 236. Antenna element 246 may be used as a conduit for sending and receiving wireless signals 310. Antenna impedance matching network 219 may be used to compensate for non-idealities or variations in the impedance of antenna element 246. Electrical signals corresponding to wireless signals 310 received by transceiver 218 are provided, following suitable processing, at connector 240 of daughterboard 236. Electrical signals corresponding to wireless signals 310 to be transmitted by transceiver 218 are provided by motherboard 234 at its connector 238.

Figures 7 and 8 show a bottom and top plan view, respectively, of a memory chip 290 having a bottom surface 260 and a top surface 258. Memory chip 290 may be in the form of a non-volatile semiconductor memory such as, for example, a flash memory or an electrically erasable programmable read only memory (EEPROM). In an embodiment of this invention, memory chip 290 may be a type of flash memory called a Smart Card as shown in Figure 7 and 8.

Figure 10 is a simplified schematic bottom perspective view of remote controller 200 with second housing half 207 removed. Memory chip 290 shown in Figures 7 and 8 may be inserted into memory chip port 232 for storing data and/or upgrading the software in remote controller 200, such as the software in microprocessor 228. Memory chip port 232 may be in the form of a slot on a side portion of remote controller 200 underneath port cover 209. Figure 10 shows a partial insertion of memory chip 290 into the slot. Memory chip port 232 is a connector having a plurality of memory chip port contacts 233 to electrically connect to a corresponding plurality of memory chip contacts 292 which are disposed on memory chip 290. Memory chip port 232 may be mounted on top surface 254 of daughterboard 236 allowing memory chip port contacts 233 to be facing upwards when inserted.

Memory chip 290 must be inserted into memory chip port 232 in a particular orientation such that a proper electrical connection can be established between memory chip 290 and remote controller 200. However, there are several orientations in which memory chip 290 may be inserted into memory chip port 232 and it may not be obvious to a user which way is proper. For example, there are four different permutations in which memory chip 290 may be inserted into memory chip port which are 1) top surface 258 facing upward towards a user and inserting initially a first end 294, 2) top surface 258 facing

upward towards a user and inserting initially a second end 296, 3) bottom surface 260 facing upwards towards a user and inserting initially first end 294, and 4) bottom surface 260 facing upwards towards a user and inserting initially second end 296.

In an embodiment of this invention, memory chip 290 should have some printed artwork, such as an arrow and/or some text on either top surface 258 or bottom surface 260, to guide the user towards the proper orientation in inserting memory chip 290 and to clearly identify the memory chip 290. However, bottom surface 260 of memory chip 290 is substantially covered by memory chip contacts 292 making it difficult to print the artwork on bottom surface 260. Thus, the artwork should be printed on top surface 258 of memory chip 290. This will allow a user to view the artwork on top surface 258 of memory chip 290 while inserting it into memory chip port 232. In this configuration, memory chip contacts 292 should be facing downward and memory chip port contacts 233 should be facing upwards to allow for proper electrical connection.

It should be noted that daughterboard 236 provide an additional top surface 254 in which memory chip port 232 can be mounted such that memory chip port contacts 233 face upwards. It is not practical to mount memory chip port to top surface 250 of motherboard 234 because of a lack of usable space. As mentioned earlier, top surface 250 of motherboard 234 was predominantly occupied by navigational buttons 216 and display 202. Thus, the use of daughterboard 236 helps conserve space by allowing memory chip port 232 to mounted to it with memory chip connector contacts 233 facing upwards. This prevents having to mount memory chip port 232 to top surface 250 of motherboard 234 which would increase the size of motherboard 234 which is undesirable increase because this would, in turn, increase the size of remote controller 200.

It is an advantage of this invention that remote controller 200 can adapt or upgrade its wireless hardware in a simple and flexible manner. Because the wireless circuitry is compartmentalized from the blood glucose measuring circuitry, it is a simple procedure to replace the wireless circuitry which in this case is located on daughterboard 236. Thus, daughterboard 236 may be swapped with a new one having a different set of wireless components mounted thereon while retaining the circuitry located on the motherboard 234 for measuring glucose.

It is another advantage of this invention that a modular glucose meter having a wireless functionality can have a simpler to perform quality control procedure. Because the functional circuitry for the wireless capability and the glucose measurement are on separate circuit boards, separate quality control tests can be performed on the spatially separated circuit boards. The wireless signal generated by the wireless circuitry may interfere with the quality control testing for the glucose measuring circuitry. This would make the quality control procedure complicated to perform if both sets of circuits are electrically connected and in close proximity to each other. Thus, the likelihood of encountering interferences during quality control testing will be reduced by performing the two quality control tests separately such that motherboard 234 and daughterboard 236 are not in close proximity to each other.

It is yet another advantage of this invention that daughterboard 236 helps economizes space on motherboard 234. A sufficiently large LCD and navigation buttons can be mounted to top surface 250 of motherboard 234 that are easy for a user to see while at the same time allowing remote controller 200 to have a relatively small footprint. Further, daughterboard 236 allows memory chip port 232 to be mounted such that the memory

chip 290 can be inserted with memory chip contacts 292 facing downward. This makes the insertion of memory chip 290 easier because the artwork can be placed on top surface 258 of memory chip 290 prompting and guiding the user to insert memory chip 290 with the proper orientation.

Claims

1. A blood glucose meter (200) comprising:
a blood glucose measuring module (234) for performing a blood glucose measuring function and
a wireless communication module (236) adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol,
wherein the blood glucose measuring module (234) and the wireless communication module (236) are physically separate units electrically connected in order to allow for an exchange of electrical signals corresponding to information to be transmitted by the wireless communication module (236) and/or information received by the wireless communication module (236),
characterized in that the blood glucose measuring module (234) and the wireless communication module (236) both comprise a connector component (238, 240), wherein the two connector components (238, 240) are adapted to releasably establish the electrical connection between the blood glucose measuring module (234) and the wireless communication module (236).

2. The blood glucose meter according to claim 1, wherein the frequency format and/or protocol according to which the blood glucose meter (200) can communicate with an external device can be changed by replacing the wireless communication module (236) with another wireless communication module (236) which is adapted to communicate according to a different frequency format and/or protocol.

3. The blood glucose meter according to claim 1 or claim 2, wherein the blood glucose measuring module (234) comprises

a control means (228) operable to control the electrical signals provided by the blood glucose measuring module (234) at its connector component (238).

4. The blood glucose meter according to any of the preceding claims, wherein the frequency format and/or protocol according to which the blood glucose meter (200) can communicate with an external device can be changed solely by replacing the wireless communication module (236) with another wireless communication module (236) which is adapted to communicate according to a different frequency format and/or protocol.

5. The blood glucose meter according to claim 3, wherein the wireless communication module (236) comprises a memory chip connector (232) for electrically connecting the wireless communication module (236) with a non-volatile semiconductor memory card (290), and wherein the control means (228) of the blood glucose measuring module (234) is adapted to operate in accordance with information stored in a non-volatile semiconductor memory card (290) connected to the memory chip connector (232) of the wireless communication module (236).

6. The blood glucose meter according to claim 3, wherein the control means (228) can be reprogrammed in order to change the electrical signals provided during operation by the blood glucose measuring module (234) at its connector component (238).

7. The blood glucose meter according to claim 6, wherein the wireless communication module (236) comprises a memory chip connector (232) for electrically connecting the wireless communication module (236) with a non-volatile semiconductor memory card (290) , and wherein the control

means (228) of the blood glucose measuring module (234) can be reprogrammed in accordance with information stored in a non-volatile semiconductor memory card (290) connected to the memory chip connector (232) of the wireless communication module (236).

8. The blood glucose meter according to claim 6 or claim 7, wherein the frequency format and/or protocol according to which the blood glucose meter (200) can communicate with an external device can be changed by replacing the wireless communication module (236) with another wireless communication module (236) which is adapted to communicate according to a different frequency format and/or protocol and reprogramming the control means (228) of the blood glucose measuring module (234).

9. The blood glucose meter according to any of the preceding claims, wherein the wireless communication module (236) comprises a memory chip connector (232) for electrically connecting the wireless communication module (236) with a non-volatile semi-conductor memory card (290).

10. The blood glucose meter according to any of claims 5, 7, and 9, wherein the memory chip connector (232) is orientated such that a set of contacts (292) on a memory card (290) connected to the memory chip connector (232) face downwards allowing a user to more easily observe upward facing artwork on the memory card (290) as it is inserted into said blood glucose meter (200).

11. The blood glucose meter according to any of the preceding claims, wherein the blood glucose measuring module (234) comprises a power supply for operating the wireless communication module (236), and wherein the electrical signals provided during operation by the blood glucose measuring

module (234) at its connector component (238) include signals for supplying power to the wireless communication module (236).

12. The blood glucose meter according to any of the preceding claims, wherein the wireless communication module (236) comprises a transceiver (218), an antenna impedance matching network (21) and an antenna (246, 248).

13. The blood glucose meter according to claim 12, wherein the wireless communication module (236) further includes an electrostatic discharge (ESD) protection circuit (244).

14. The blood glucose meter according to any of the preceding claims, wherein the blood glucose meter (200) comprises a housing (201, 207) in which the blood glucose measuring module (234) and the wireless communication module (236) are enclosed.

15. The blood glucose meter according to any of the preceding claims, wherein the blood glucose measuring module (234) comprises a first printed circuit board on which blood glucose measuring circuitry (220) is mounted, and the wireless communication module (236) comprises a second printed circuit board on which wireless communication circuitry (218, 219, 246) is mounted.

16. The blood glucose meter according to claims 12 and 15, wherein the transceiver (218), the antenna impedance matching network (219) and the antenna (246, 248) are mounted on the second printed circuit board.

17. The blood glucose meter according to claims 13 and 16, wherein the ESD protection circuit (244) is mounted on the second printed circuit board.

18. The blood glucose meter according to any of claims 15 to 17, wherein the first printed circuit board is a mother-board and the second printed circuit board is a daughter-board.

19. The blood glucose meter according to any of claims 15 to 18, wherein the second printed circuit board is disposed on the first printed circuit board.

20. The blood glucose meter according to any of the preceding claims, wherein one of the connector components (238, 240) of the blood glucose measuring module (234) and the wireless communication module (236) is the plug component of a plug and socket connector and the other connector component (238, 240) is the socket component of the plug and socket connection.

21. The blood glucose meter according to any of claims 1 to 19, wherein the connector components (238, 240) of the blood glucose measuring module (234) and the wireless communication module (236) are adapted to be connected by a cable having suitable connector components at its ends.

22. The blood glucose meter according to any of the preceding claims, wherein the wireless communication module (236) is adapted to communicate according to the ISM, Bluetooth, ZigBee or WLAN standard.

23. A blood glucose meter system comprising:
a blood glucose meter (200) according to any of claims 1 to 19, and
at least one further wireless communication module (236) similar to the wireless communication module (236) but adapted for establishing a wireless communication link

with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol different from the frequency format and/or protocol of the wireless communication module (236),
wherein the frequency format and/or protocol according to which the blood glucose meter (200) can communicate with an external device can be changed by replacing the wireless communication module (236) with one of the at least one further wireless communication module (236).

24. The blood glucose meter system according to claim 23, wherein the wireless communication module (236) and the at least one further wireless communication module (236) include wireless communication modules (236) adapted to communicate according to the ISM, Bluetooth, ZigBee or WLAN standard.

25. A method of constructing a blood glucose meter (200) according to any of claims 1 to 22 comprising the steps of:
providing a blood glucose measuring module (234) for performing a blood glucose measuring function,
providing a plurality of wireless communication modules (236), each adapted for establishing a wireless communication link with an external device and exchanging information with the external device via the wireless communication link according to a predetermined frequency format and protocol different from the frequency format and/or protocol of the other wireless communication modules (236), wherein the blood glucose measuring module (234) and the wireless communication modules (236) are physically separate units and wherein the blood glucose measuring module (234) and each wireless communication module (236) comprise respective connector components (238, 240) by means of which a selected one of the wireless communi-

cation modules (236) may be releasably electrically connected to the blood glucose measuring module (234) in order to allow for an exchange of electrical signals corresponding to information to be transmitted by the respective wireless communication module (236) and/or information received by the respective wireless communication module (236),

selecting one of the plurality of wireless communication modules (236) in accordance with the desired frequency format and protocol, and

establishing an electrical connection between the selected wireless communication module (236) and the blood glucose measuring module (234) by means of the respective connector components (238, 240).

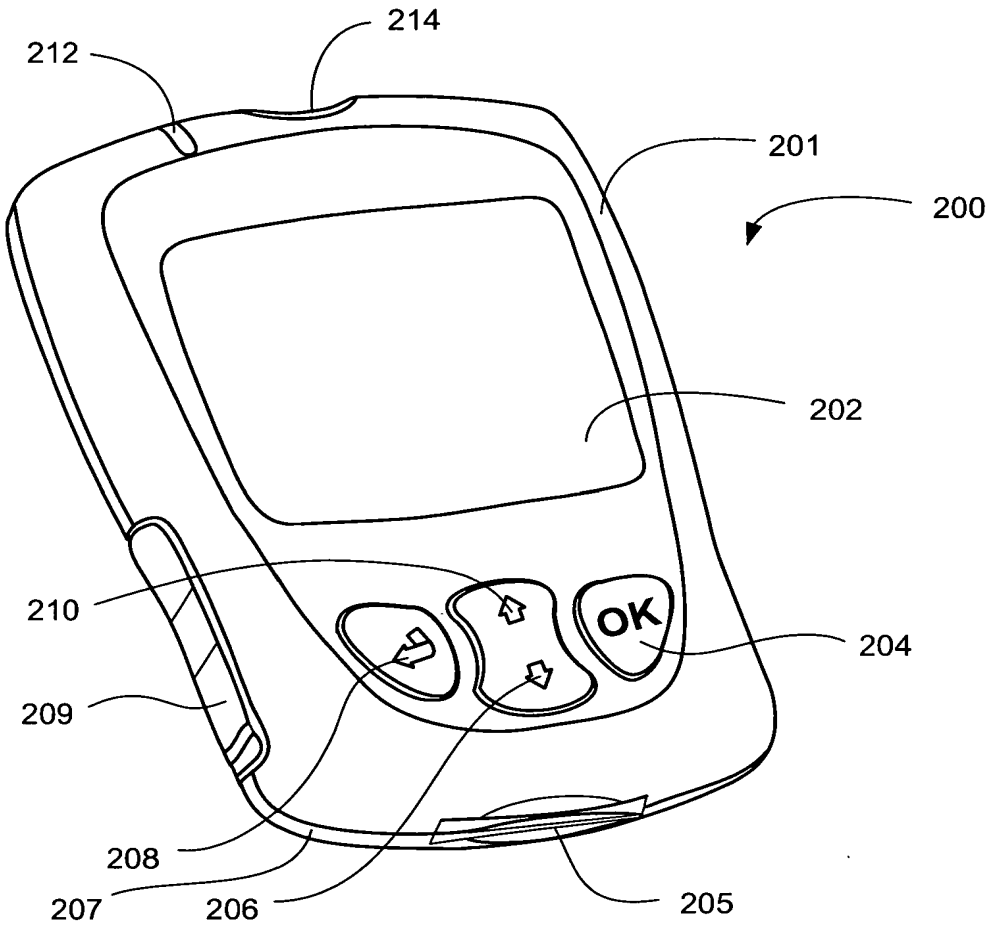


FIG. 1

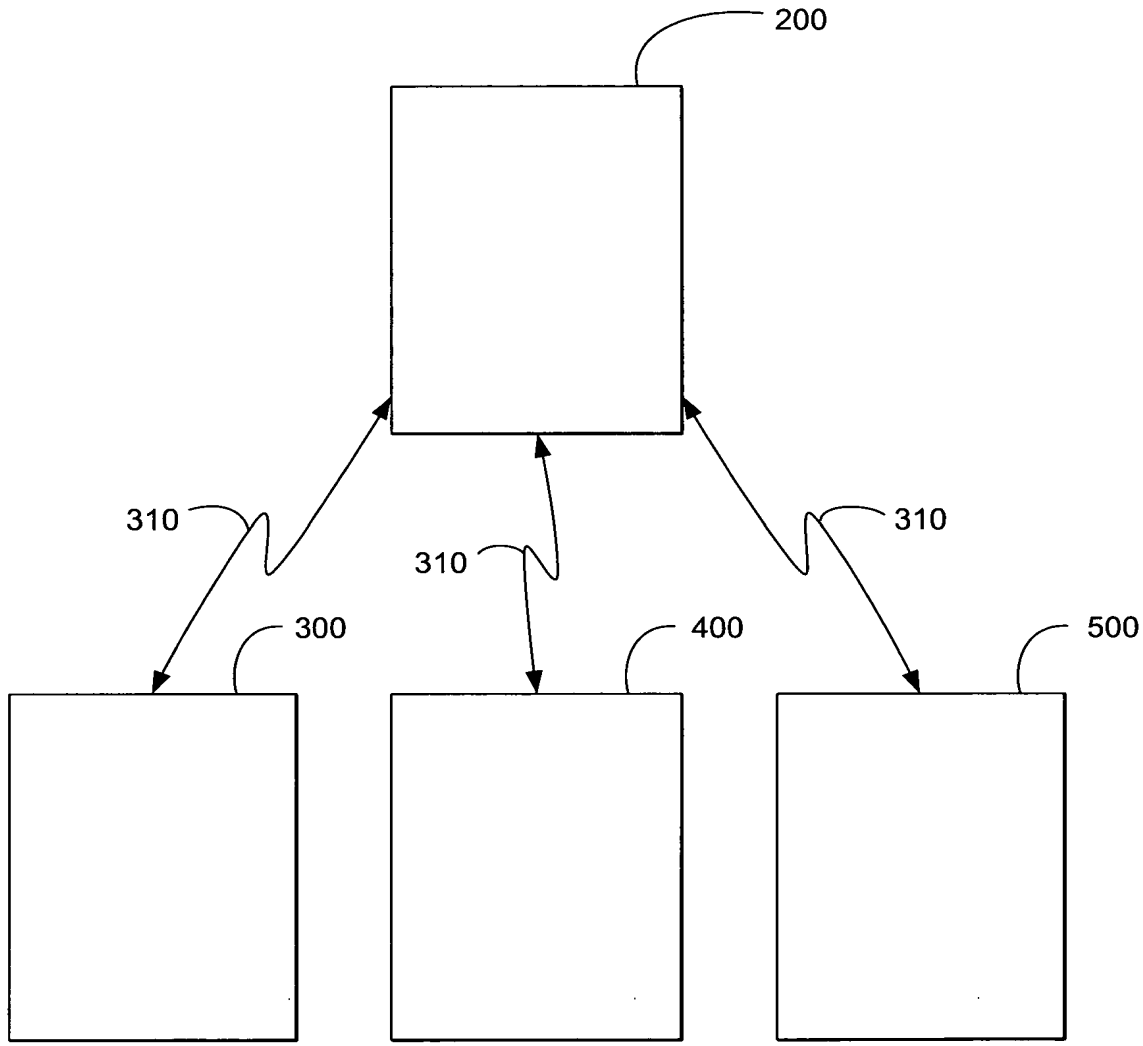


FIG. 2

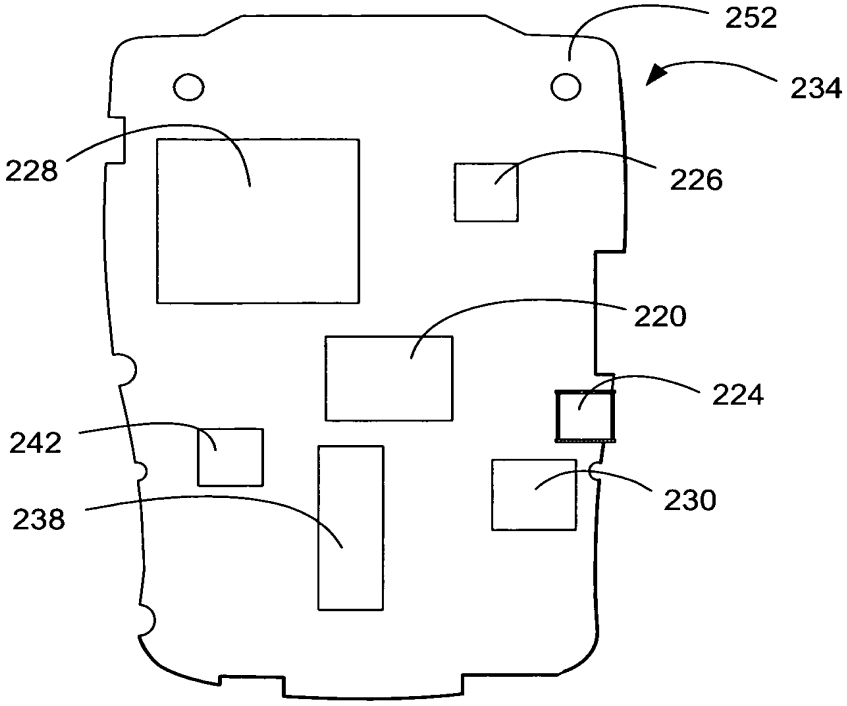

252
234
228
226
220
224
242
230
238

FIG. 3

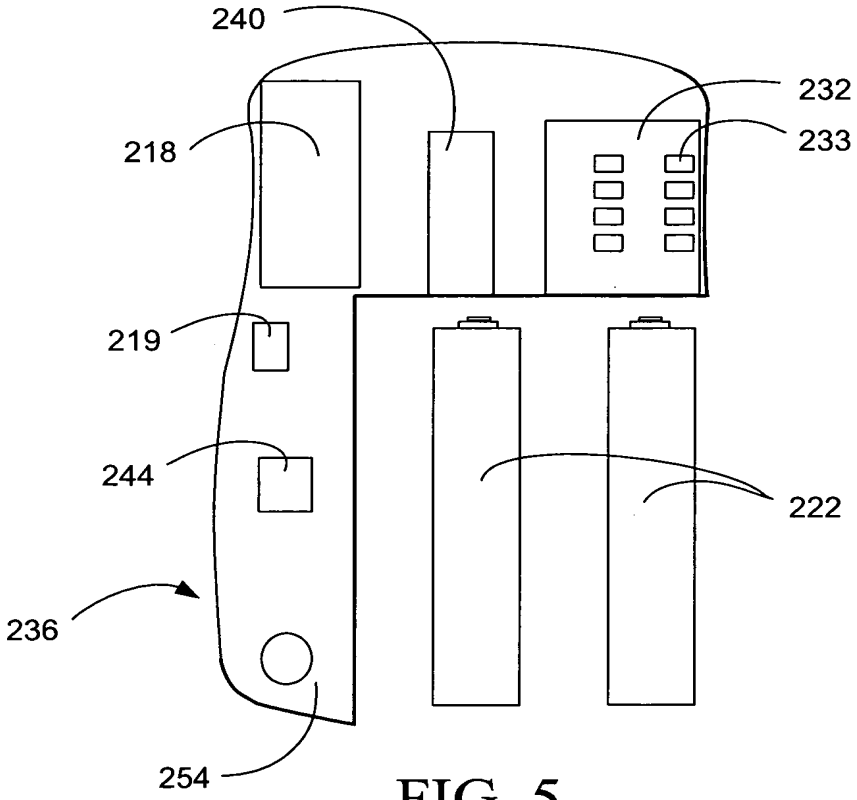

240
232
218
233
219
244
222
236
254

FIG. 5

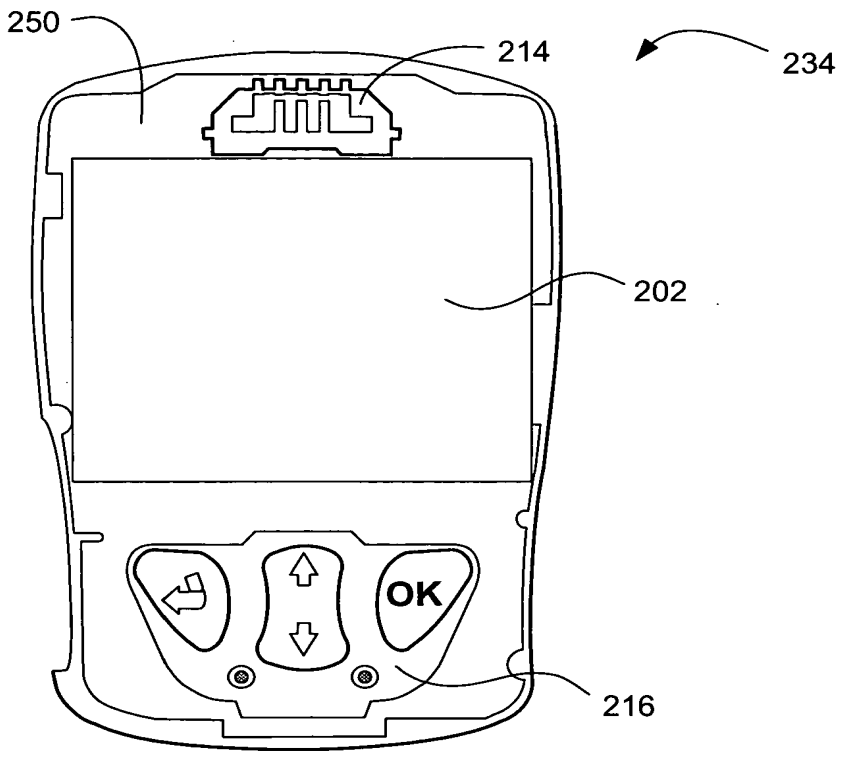


FIG. 4

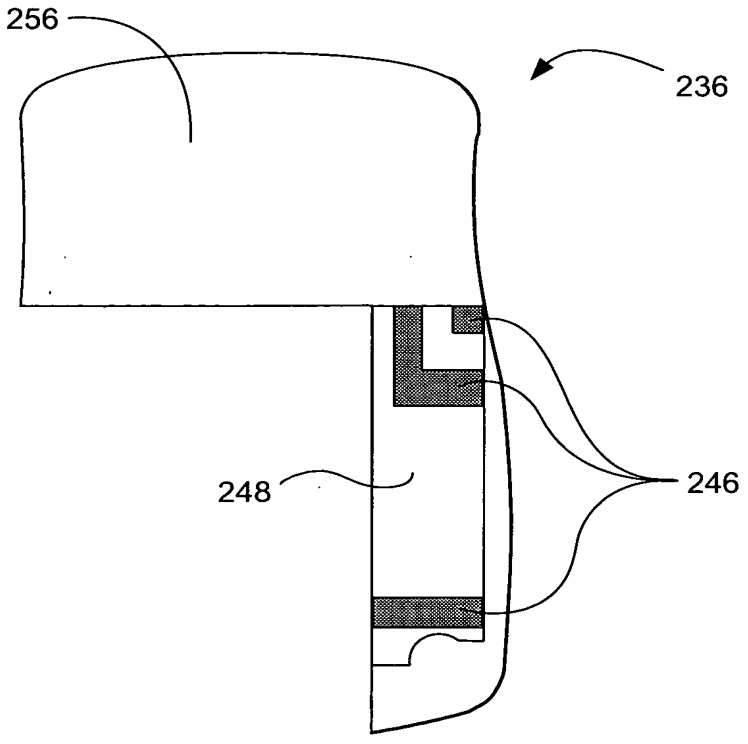


FIG. 6

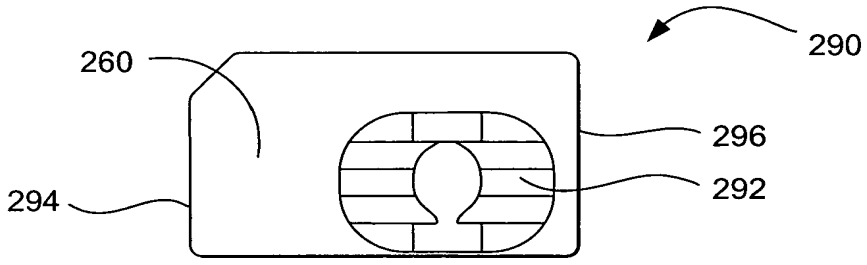


FIG. 7

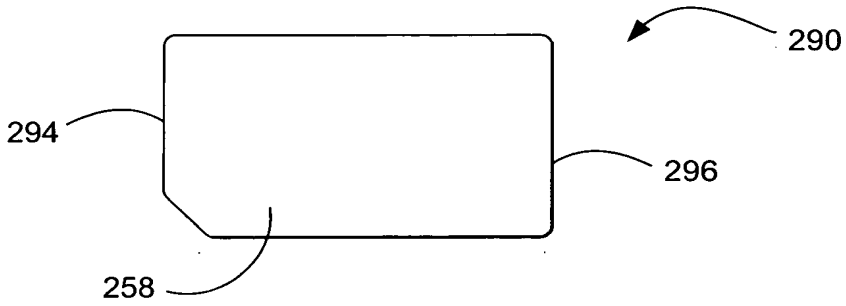


FIG. 8

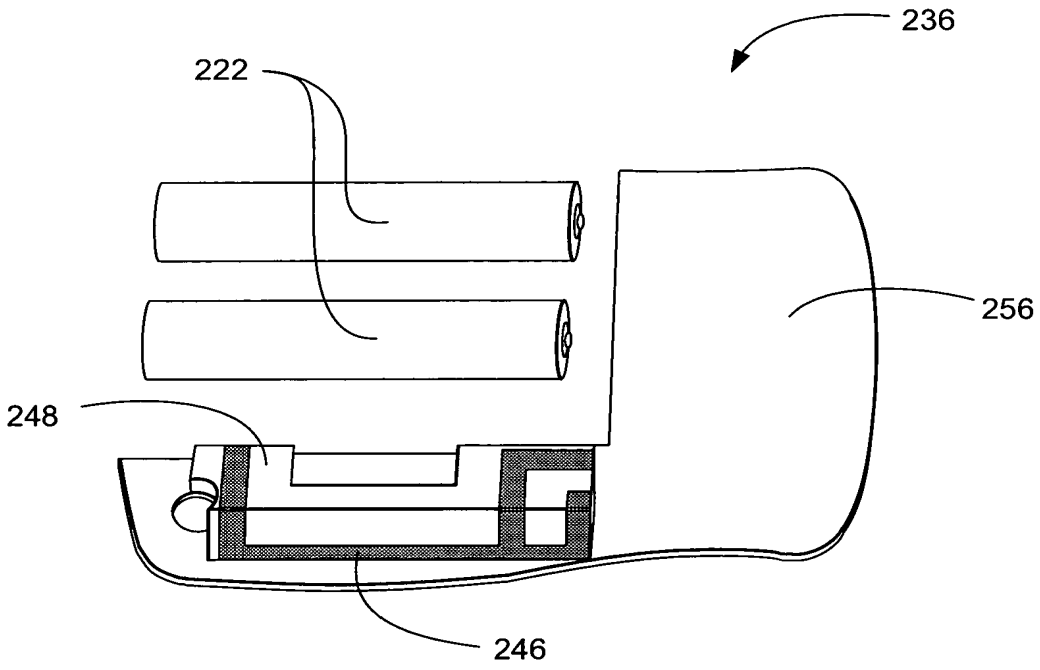


FIG. 9

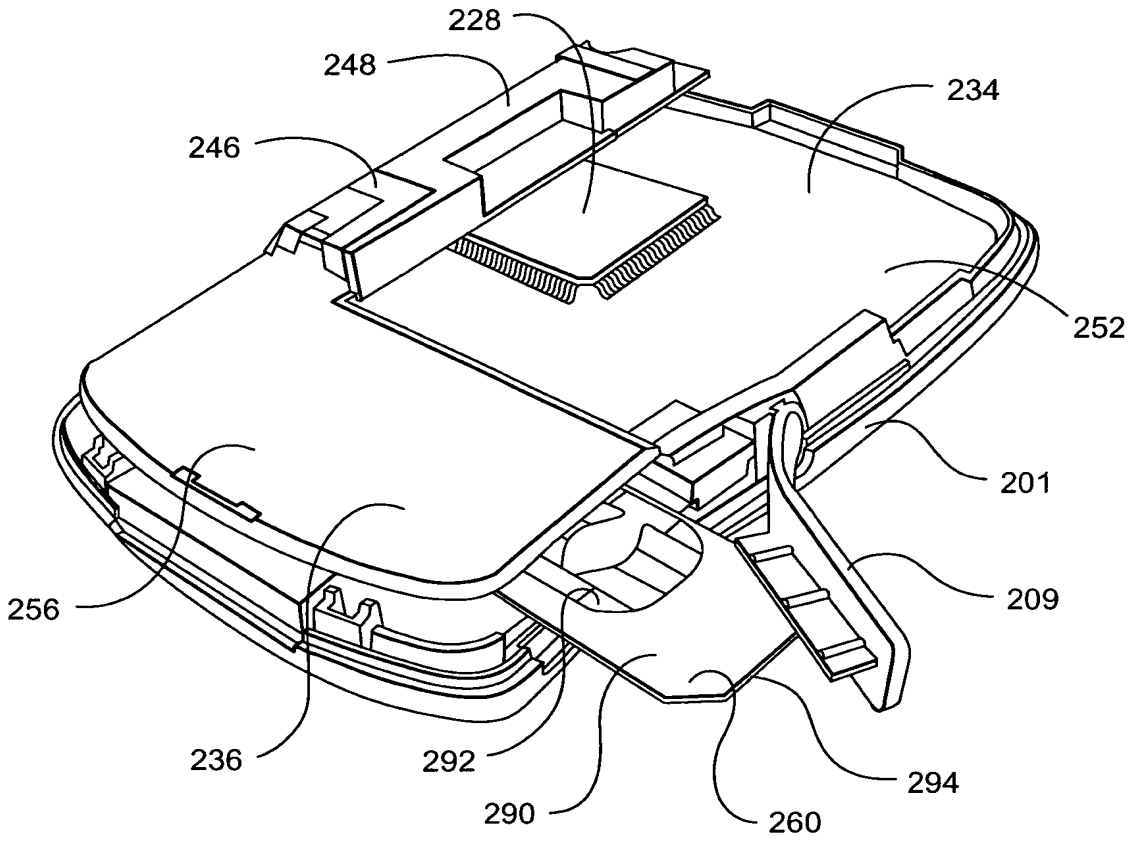


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2006/011263

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 G06F19/00
ADD. G01N33/487

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B G06F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/181798 A1 (AL-ALI AMMAR [US]) 25 September 2003 (2003-09-25) paragraphs [0026] - [0065]; figure 3	1
X	DE 102 37 692 A1 (GHC GLOBAL HEALTH CARE GMBH [DE]) 26 February 2004 (2004-02-26) the whole document	1,2,11, 20,22-25
X	US 2006/248398 A1 (NEEL GARY T [US] ET AL) 2 November 2006 (2006-11-02) paragraphs [0036] - [0059]; figure 10	1-25
X	US 2003/176183 A1 (DRUCKER STEVEN [US] ET AL DRUCKER STEVEN [US] ET AL) 18 September 2003 (2003-09-18) paragraph [0077]; figure 4	1,14-19

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 July 2007	01/08/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Anscombe, Marcel

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2006/011263

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003181798 A1	25-09-2003	US 2005135288 A1	23-06-2005
DE 10237692 A1	26-02-2004	AU 2003253406 A1	11-03-2004
		WO 2004017827 A1	04-03-2004
		EP 1531722 A1	25-05-2005
		US 2006122466 A1	08-06-2006
US 2006248398 A1	02-11-2006	WO 2006118763 A2	09-11-2006
US 2003176183 A1	18-09-2003	US 2005277164 A1	15-12-2005
		US 2005239156 A1	27-10-2005

Electronic Acknowledgement Receipt

EFS ID:	43602491
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	25-AUG-2021
Filing Date:	
Time Stamp:	16:37:59
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	9368USC7_A0130_0090_C7_IDS_14492.pdf	150079 a115082c7a439d97eda5dbb916871ce0e1a0afcc	no	1

Warnings:

Information:					
This is not an USPTO supplied IDS fillable form					
2	Foreign Reference	EP1707115A2.pdf	576177 cd4c344b5eda29fded3de47b1b2ccbe31d819791	no	14
Warnings:					
Information:					
3	Foreign Reference	WO2008051409A2.pdf	1612748 e3d64a38cfdbb73633c34bb372796c58c3462dbb	no	37
Warnings:					
Information:					
4	Foreign Reference	WO2008052199A2.pdf	1985610 f1f2866afdcd0b8d4711963376d03dc33172e6ba	no	46
Warnings:					
Information:					
5	Foreign Reference	WO2008061552A1.pdf	1737112 7750b907cb7d60f9af5aa5a3e3b389acbea8887d	no	45
Warnings:					
Information:					
			Total Files Size (in bytes):	6061726	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/411,154

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	30 minus 20 =	* 10			OR	x 100 =	1000
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 480 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	2820

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/411,154	08/25/2021	3791	2820	A0130.0090.C7	30	1

CONFIRMATION NO. 1823

FILING RECEIPT

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

OC000000128141002

Date Mailed: 09/02/2021

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Wesley Scott Harper, Alameda, CA;

Applicant(s)

ABBOTT DIABETES CARE INC., Alameda, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 17/245,719 04/30/2021 PAT 11116431
which is a CON of 16/228,910 12/21/2018 PAT 11013431
which is a CON of 15/061,774 03/04/2016 PAT 10194844
which is a CON of 13/925,694 06/24/2013 PAT 9310230
which is a CON of 12/769,635 04/28/2010 PAT 8483967
which claims benefit of 61/173,600 04/29/2009

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 09/01/2021

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/411,154**

Projected Publication Date: 12/09/2021

Non-Publication Request: No

Early Publication Request: No

Title

METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

Preliminary Class

600

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

95508 7590 09/29/2021

One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

EXAMINER	
ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
09/29/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPdocketing@onellp.com
PAIRgroup@onellp.com
onellpdocketing@onellp.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/411,154	**Applicant(s)** Harper, Wesley Scott	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 25 August 2021 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

95508 7590 11/09/2021

One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

EXAMINER
LIN, JERRY

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
11/09/2021	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPdocketing@onellp.com
PAIRgroup@onellp.com
onellpdocketing@onellp.com

Office Action Summary	Application No. 17/411,154	Applicant(s) Harper, Wesley Scott	
	Examiner JERRY LIN	Art Unit 1631	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 25 August 2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 23-52 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 23-52 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 8/25/2021.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Status of the Claims

Claims 23-52 are under examination.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed

determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 23-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 8,483,967. Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims require all the limitations of the U.S. Patent with additional limitations. Thus, the subject matter of the U.S. Patent encompasses the subject matter of the instant claims and are not patentably distinct from each other.

Claims 23-52 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 11,116,431. Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims require all the limitations of the U.S. Patent with additional limitations. Thus, the subject matter of the U.S. Patent encompasses the subject matter of the instant claims and are not patentably distinct from each other.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached M-F, 7am-3:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karl Skowronek can be reached on (571) 272-9047. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/JERRY LIN/
Primary Examiner, Art Unit 1631

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	Art Unit
	JERRY LIN	1631

CPC - Searched*		
Symbol	Date	Examiner
A61B5/14532, G16H40/40, A61B5/1473, A61B5/1495, G01D18/00, G01N31/22, G01N33/66	11/04/2021	JL

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See Printout	11/04/2021	JL
Inventor search of Wesley Harper in PALM	11/04/2021	JL

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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	Complete if Known
Application Number	To be assigned
Filing Date	August 25, 2021
First Named Inventor	Wesley Scott Harper
Art Unit	To be assigned
Examiner Name	To be assigned

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*Examiner Initials**	*Cite No.*	*Document Number Number-Kind Code*	*Publication Date MM-DD-YYYY*	*Name of Patentee or Applicant of Cited Document*	*Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear*
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EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)
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				Application Number	To be assigned
				Filing Date	August 25, 2021
				First Named Inventor	Wesley Scott Harper
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	20	of	21	Attorney Docket No: A0130.0090.C7	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		SAKAKIDA, M., et al., "Development of ferrocene-mediated needle-type glucose sensor as a measure of true subcutaneous tissue glucose concentrations", Artificial Organs Today, Vol. 2, No. 2, 1992, pp. 145-158.	
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		TURNER, A.P.F., et al., "Diabetes Mellitus: Biosensors for Research and Management", Biosensors, Vol. 1, 1985, pp. 85-115.	
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Application Number	To be assigned
Filing Date	August 25, 2021
First Named Inventor	Wesley Scott Harper
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0090.C7

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	2002/0107557 A1	08-08-2002	Edell et al.
	2	2003/0004403 A1	01-02-2003	Drinan et al.
	3	2004/0247671 A1	12-09-2004	Prescott et al.
	4	2005/0043598 A1	02-24-2005	Goode, Jr. et al.
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	8	2007/0118030 A1	05-24-2007	Bruce et al.
	9	2008/0312841 A1	12-18-2008	Hayter
	10	2009/0024177 A1	01-22-2009	Shuros et al.
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	15			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
	16	EP 1 707 115 A2	10-04-2006	Codman & Shurtleff, Inc.	
	17	WO 2008/051409 A2	05-02-2008	Bayer Healthcare LLC	
	18	WO 2008/052199 A3	05-02-2008	Abbott Diabetes Care Inc. et al.	
	19	WO 2008/061552 A1	05-29-2008	Lifescan Scotland Limited	
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WEST Search History for Application 17411154

Creation Date: 2021110420:53

Prior Art Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
11116431.pn.	PGPB, USPT, EPAB, JPAB, DWPI	3	OR	YES		11-04-2021
glucose same sensor	PGPB, USPT, EPAB, JPAB, DWPI	55707	OR	YES		11-04-2021
(glucose same sensor) same (failure or error or attenuation or adverse)	PGPB, USPT, EPAB, JPAB, DWPI	5829	OR	YES		11-04-2021
(glucose same sensor same (failure or error or attenuation or adverse)) same (time or gap)	PGPB, USPT, EPAB, JPAB, DWPI	2909	OR	YES		11-04-2021
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(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor same (failure or error or attenuation or adverse) same (time or gap) same (correction or correct or fix or fixed) and (graph or plot))	PGPB, USPT, EPAB, JPAB, DWPI	160	OR	YES		11-04-2021

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L2         3619 L1 AND (FAILURE OR ATTENUATION OR ADVERSE OR
ERROR)

=> s l2 and (gap or time)

L3         1672 L2 AND (GAP OR TIME)

=> s l3 and (graph or plot or line)

L4          114 L3 AND (GRAPH OR PLOT OR LINE)

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L5           80 DUP REM L4 (34 DUPLICATES REMOVED)

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Title of Declarant: Assistant Secretary	
Address of Declarant: 1420 Harbor Bay Parkway, Alameda, CA 94502	

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EFS ID:	44275931
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	14-NOV-2021
Filing Date:	25-AUG-2021
Time Stamp:	14:37:16
Application Type:	Utility under 35 USC 111(a)

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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Wesley Scott Harper

Application No./Patent No.: 17/411,154 Filed/Issue Date: 08/25/2021

Titled: METHOD AND SYSTEM FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

ABBOTT DIABETES CARE INC., a CORPORATION

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

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1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

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   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

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☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Glen Liu/	11/14/2021
Signature	Date
Glen Liu	75,058
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7

CONFIRMATION NO. 1823

183890
One LLP - ADC
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

POA ACCEPTANCE LETTER

OC00000129831745

Date Mailed: 11/17/2021

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/14/2021.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/yteferra/

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7

CONFIRMATION NO. 1823

183890
One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

PUBLICATION NOTICE

OC000000130347609

Title:METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

Publication No.US-2021-0378564-A1
Publication Date:12/09/2021

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

REMARKS

Claims 23, 26-31, 33, 35-50, and 53-58 are pending, of which claims 23, 26-31, 33, 35-37, 39-48, and 50 have been amended without prejudice, and claims 53-58 have been newly added. Claims 24-25, 32, 34, 51-52 have been canceled without prejudice, and claims 1-22 remain canceled without prejudice. Claim 23 is the only independent claim. Support for the amendments and the new claims can be found, for example, at paragraphs [0025], [0030] to [0033], [0038], [0046], and [0051] to [0086], as well as Figures 1 to 6, 7A, and 7B, the original claims, and elsewhere throughout the application published as U.S. Publ. No. 2021/0378564.[1] No new matter has been introduced.

For the reasons set forth below, it is respectfully submitted that the pending claims are allowable.

NON-STATUTORY DOUBLE PATENTING REJECTIONS

Claims 23-52 were rejected on the ground of non-statutory double patenting over claims 1-22 of U.S. Patent No. 8,483,967. *See* 11/9/21 NFOA at 2-3. In addition, claims 23-52 were also rejected on the ground of non-statutory double patenting over claims 1-30 of U.S. Patent No. 11,116,431. *See id.*

It is respectfully submitted that the double patenting rejections have been mooted by the Applicants' amendments to claims 23, 26-31, 33, 35-37, 39-48, and 50 in the instant application. As such, it is respectfully requested that the non-statutory double patenting rejections be withdrawn.

CONCLUSION

Amendments to and/or cancellations of the claims are made without prejudice and solely to clarify the issues before the Examiner and/or to advance prosecution of this application and do not constitute a *de facto* acquiescence to any objection and/or rejection. Accordingly, this response does not concede that previously pending claims are not patentable.

[1] All citations are provided purely for the benefit of the Examiner. These citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader claims, narrower claims, and subject matter that was previously relinquished by virtue of argument or amendment.

Any silence with regard to the rejections of and/or objections to certain dependent claims constitutes a recognition that such are moot based on amendments or remarks made with respect to the independent claim from which the dependent claims depend. Such silence does not constitute a *de facto* acquiescence to any objection and/or rejection.

In view of the foregoing, it is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 444-5970. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: December 20, 2021

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
23 Corporate Plaza, Suite 150
Newport Beach, CA 92660
Attorney for Applicant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Wesley Scott Harper

Application No.: 17/411,154 | Confirmation No.: 1823

Filed: August 25, 2021 | Art Unit: 1631

For: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING | Examiner: Jerry Lin

RESPONSE TO NON-FINAL OFFICE ACTION UNDER 37 C.F.R. § 1.111

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

In response to the Non-Final Office Action dated November 9, 2021 ("11/9/21 NFOA"), please see the following:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 9 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-22. (Canceled)

23. (Currently amended) A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:

~~(1) an on body unit configured to be positioned on a user's body, the on body unit comprising:~~

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user ~~and~~ to provide ~~glucose related~~ sensor data; ~~and~~

a data processing and transmitter unit coupled ~~with~~ to the glucose sensor, the data processing and transmitter unit comprising a power supply, a processor of the data processing and transmitter unit, memory of the data processing and transmitter unit, and a radio frequency transceiver of the data processing and transmitter unit, wherein the data processing and transmitter unit is configured to:

receive the ~~glucose related~~ sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit;

process the ~~glucose related~~ sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit; and

~~store, in memory of the data processing and transmitter unit during a time period associated with a failure mode condition, the glucose related sensor data, the processed sensor data, or both; and~~

transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit; and

~~(2)~~ a receiver unit[[,]] comprising[[:]] a processor of the receiver unit, memory of the receiver unit, a radio frequency transceiver of the receiver unit, [[and]] an antenna, and a display, wherein the receiver unit is configured to:

receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data ~~transmitted by the data processing and transmitter unit~~ over the Bluetooth wireless communication link[[;]],

~~a display configured to display numerical values and graphical representations of the processed sensor data; and~~

~~a processor coupled with memory of the receiver unit, wherein instructions stored in the memory of the receiver unit, when executed by the processor, cause the processor to:~~

~~detect the presence of the data processing and transmitter unit when the data processing and transmitter unit is within a range of the receiver unit,~~

~~establish the Bluetooth wireless communication link with the data processing and transmitter unit,~~

output to the display of the receiver unit, a numerical value representing the processed sensor data,

output to the display of the receiver unit, a first line graph that is a substantially continuous depiction of the processed sensor data over time,

~~output a first graphical representation of the processed sensor data to the display of the receiver unit, wherein the first graphical representation comprises a first line graph, and wherein an end of the first line graph correlates with a time associated with a start of the failure mode condition, and~~

~~output a second graphical representation of the processed sensor data to the display of the receiver unit after the failure mode condition has been corrected, wherein the second graphical representation comprises a second line graph having a length greater than the first line graph~~

wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition;

wherein, during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both, are stored in the memory of the data processing and transmitter unit;

wherein the receiver unit is configured to output to the display, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled, and

wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition.

24-25. (Canceled)

26. (Currently amended) The glucose monitoring system of claim 23 [[25]], wherein the first line graph and the second line graph are outputted to a same graph comprising a first axis having a time unit of measurement and a second axis having a glucose concentration unit of measurement.

27. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a sensor communication error.

28. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a signal error associated with the glucose sensor.

29. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a signal error associated with the data processing and transmitter unit.

30. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a signal error associated with the receiver unit.

31. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a system malfunction associated with the data processing and transmitter unit or a system malfunction associated with the receiver unit.

32. (Canceled)

33. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises an inability of the receiver unit to display or output at least a portion of the ~~graphical representations of the processed sensor data to the display~~ the first line graph.

34. (Canceled)

35. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a sensor instability condition.

36. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a calibration failure condition.

37. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a monitoring system failure condition.

38. (Previously presented) The glucose monitoring system of claim 23, wherein the glucose sensor comprises a working electrode and a counter electrode.

39. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a sensor misposition error.

40. (Currently amended) The glucose monitoring system of claim 23, wherein the on body unit further comprises a temperature sensor, and wherein the ~~failure mode~~ adverse condition comprises a temperature measurement outside a predetermined range.

41. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises an analyte level exceeding a predetermined threshold.

42. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a rate of change of an analyte level exceeding a predetermined threshold.

43. (Currently amended) The glucose monitoring system of claim [[23]] 53, wherein the ~~failure mode~~ adverse condition comprises a signal error associated with the blood glucose reference data.

44. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~failure mode~~ adverse condition comprises a data unavailability condition.

45. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~instructions stored in the memory of the~~ receiver unit~~, when executed by the processor, further cause the processor~~ is further configured to display the second line graph immediately after the correction of the ~~failure mode~~ adverse condition.

46. (Currently amended) The glucose monitoring system of claim 23, wherein the ~~instructions stored in the memory of the~~ receiver unit~~, when executed by the processor, further cause the processor~~ is further configured to wait a predetermined period of time after the correction of the ~~failure mode~~ adverse condition before displaying the second line graph.

47. (Currently amended) The glucose monitoring system of claim 23, wherein the data processing and transmitter unit, the receiver unit, or both is further configured to store time information associated with the ~~failure mode~~ adverse condition.

48. (Currently amended) The glucose monitoring system of claim 23, wherein ~~the on body unit comprises a single integrated housing, and wherein~~ the data processing and transmitter unit and at least a portion of the glucose sensor are disposed within [[the]] a single integrated housing.

49. (Previously presented) The glucose monitoring system of claim 23, wherein the receiver unit comprises a mobile phone.

50. (Currently amended) The glucose monitoring system of claim 23, wherein the time period associated with the ~~failure mode~~ adverse condition comprises at least one hour.

51-52. (Canceled)

53. (New) The glucose monitoring system of claim 23, wherein the glucose monitoring system is further configured for periodic calibration, and wherein the calibration data is based at least in part on glucose reference data received after the portion of the glucose sensor has been positioned under the skin of the user.

54. (New) The glucose monitoring system of claim 53, wherein the glucose monitoring system is further configured for calibration twelve hours after the portion of the glucose sensor has been positioned under the skin of the user.

55. (New) The glucose monitoring system of claim 23, wherein the data processing and transmitter unit is configured to transition from a low-power mode to an operating mode, and wherein the data processing and transmitter unit consumes more power from the power supply in the operating mode than in the low-power mode.

56. (New) The glucose monitoring system of claim 23, wherein the power supply of the data processing and transmitter unit is configured to provide power for about three months of continuous operation.

57. (New) The glucose monitoring system of claim 23, further comprising a secondary receiver unit, wherein the secondary receiver unit is configured to include a limited number of functions as compared with the receiver unit, wherein the secondary receiver unit is configured to receive processed sensor data from the data processing and transmitter unit, and wherein the secondary receiver unit is a watch.

58. (New) The glucose monitoring system of claim 23, wherein the glucose sensor is further configured to continuously sample the biological fluid of the user to provide the sensor data.

REMARKS

Claims 23, 26-31, 33, 35-50, and 53-58 are pending, of which claims 23, 26-31, 33, 35-37, 39-48, and 50 have been amended without prejudice, and claims 53-58 have been newly added. Claims 24-25, 32, 34, 51-52 have been canceled without prejudice, and claims 1-22 remain canceled without prejudice. Claim 23 is the only independent claim. Support for the amendments and the new claims can be found, for example, at paragraphs [0025], [0030] to [0033], [0038], [0046], and [0051] to [0086], as well as Figures 1 to 6, 7A, and 7B, the original claims, and elsewhere throughout the application published as U.S. Publ. No. 2021/0378564.[1] No new matter has been introduced.

For the reasons set forth below, it is respectfully submitted that the pending claims are allowable.

NON-STATUTORY DOUBLE PATENTING REJECTIONS

Claims 23-52 were rejected on the ground of non-statutory double patenting over claims 1-22 of U.S. Patent No. 8,483,967. *See* 11/9/21 NFOA at 2-3. In addition, claims 23-52 were also rejected on the ground of non-statutory double patenting over claims 1-30 of U.S. Patent No. 11,116,431. *See id.*

It is respectfully submitted that the double patenting rejections have been mooted by the Applicants' amendments to claims 23, 26-31, 33, 35-37, 39-48, and 50 in the instant application. As such, it is respectfully requested that the non-statutory double patenting rejections be withdrawn.

CONCLUSION

Amendments to and/or cancellations of the claims are made without prejudice and solely to clarify the issues before the Examiner and/or to advance prosecution of this application and do not constitute a *de facto* acquiescence to any objection and/or rejection. Accordingly, this response does not concede that previously pending claims are not patentable.

[1] All citations are provided purely for the benefit of the Examiner. These citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

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In view of the foregoing, it is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 444-5970. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: December 20, 2021

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
23 Corporate Plaza, Suite 150
Newport Beach, CA 92660
Attorney for Applicant

Electronic Acknowledgement Receipt

EFS ID:	44566536
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	183890
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	20-DEC-2021
Filing Date:	25-AUG-2021
Time Stamp:	17:54:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		9368USC7_A0130_0090_C7_Response_to_NFOA_dated_11_9_2021.pdf	129854 16d63c9d37e8d42512379ec95929de3b3fec47ce	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	8
	Applicant Arguments/Remarks Made in an Amendment	9	10
Warnings:			
Information:			
	Total Files Size (in bytes):	129854	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/411,154	Filing Date 08/25/2021	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $100 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $480 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	12/20/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 30	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CAROLYN E THOMAS/
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".	
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

183890 7590 02/07/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER
LIN, JERRY

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/07/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

TITLE OF INVENTION: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

183890 7590 02/07/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

TITLE OF INVENTION: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIN, JERRY	1631	702-085000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

183890 7590 02/07/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER	
LIN, JERRY	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/07/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/411,154	Applicant(s) Harper, Wesley Scott	
	Examiner JERRY LIN	Art Unit 1631	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the reply filed December 20, 2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/JERRY LIN/
Primary Examiner, Art Unit 1631

Continuation of 3. The allowed claim(s) is/are: 23,26-31,33,35-50 and 53-58

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: The amendments are sufficient to nonstatutory double patenting rejections. The rejections are withdrawn.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JERRY LIN whose telephone number is (571)272-2561. The examiner can normally be reached M-F, 7am-3:30pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karl Skowronek can be reached on (571) 272-9047. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions,

contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JERRY LIN/
Primary Examiner, Art Unit 1631

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	14532	F	2013-01-01
A61B	/	5	/	1473	I	2013-01-01
A61B	/	5	/	1495	I	2013-01-01
G16H	/	40	/	40	I	2018-01-01
G01D	/	18	/	00	I	2013-01-01
G01N	/	31	/	22	I	2013-01-01
G01N	/	33	/	66	I	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	30	
/JERRY LIN/ Primary Examiner, Art Unit 1631	15 January 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	None	None

U.S. Patent and Trademark Office

Part of Paper No.: 20220115

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B5/145	/	5	/	145

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 30	
/JERRY LIN/ Primary Examiner, Art Unit 1631 (Primary Examiner)	15 January 2022 (Date)	O.G. Print Claim(s) None	O.G. Print Figure None

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 30	
/JERRY LIN/ Primary Examiner, Art Unit 1631 (Primary Examiner) 15 January 2022 (Date)	O.G. Print Claim(s) None	O.G. Print Figure None

U.S. Patent and Trademark Office Part of Paper No.: 20220115

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	Art Unit
	JERRY LIN	1631

CPC - Searched*		
Symbol	Date	Examiner
A61B5/14532, G16H40/40, A61B5/1473, A61B5/1495, G01D18/00, G01N31/22, G01N33/66	01/15/2022	JL

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
See Printout	01/15/2022	JL
Inventor search of Wesley Harper in PALM	01/15/2022	JL

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
A61B5	14532, 1473, 1495	01/15/2022	JL
G16H40	40	01/15/2022	JL
G01D18	00	01/15/2022	JL
G01N31	22	01/15/2022	JL
G01N33	66	01/15/2022	JL

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

Bibliographic Data

Application No: 17/411,154

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /JERRY LIN/ Examiner's Signature | Initials

Title: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
08/25/2021	702	1631	A0130.0090.C7
RULE			

APPLICANTS

ABBOTT DIABETES CARE INC., Alameda, CA,

INVENTORS

Wesley Scott Harper, Alameda, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 17245719 04/30/2021 PAT 11116431

17245719 is a CON of 16228910 12/21/2018 PAT 11013431

16228910 is a CON of 15061774 03/04/2016 PAT 10194844

15061774 is a CON of 13925694 06/24/2013 PAT 9310230

13925694 is a CON of 12769635 04/28/2010 PAT 8483967

12769635 has PRO of 61173600 04/29/2009

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

09/01/2021

STATE OR COUNTRY

UNITED STATES

ADDRESS

One LLP - ADC

23 Corporate Plaza

Suite 150

Newport Beach, CA 92660

UNITED STATES

FILING FEE RECEIVED

$7,160

WEST Search History for Application 17411154

Creation Date: 2022011511:00

Prior Art Searches

Query	DB	Hits	Op.	Plur.	Thes.	Date
11116431.pn.	PGPB, USPT, EPAB, JPAB, DWPI	3	OR	YES		11-04-2021
glucose same sensor	PGPB, USPT, EPAB, JPAB, DWPI	55707	OR	YES		11-04-2021
(glucose same sensor) same (failure or error or attenuation or adverse)	PGPB, USPT, EPAB, JPAB, DWPI	5829	OR	YES		11-04-2021
(glucose same sensor same (failure or error or attenuation or adverse)) same (time or gap)	PGPB, USPT, EPAB, JPAB, DWPI	2909	OR	YES		11-04-2021
(glucose same sensor same (failure or error or attenuation or adverse) same (time or gap)) same (correction or correct or fix or fixed)	PGPB, USPT, EPAB, JPAB, DWPI	348	OR	YES		11-04-2021
(glucose same sensor same (failure or error or attenuation or adverse) same (time or gap) same (correction or correct or fix or fixed)) same (graph or plot)	PGPB, USPT, EPAB, JPAB, DWPI	9	OR	YES		11-04-2021
(glucose same sensor same (failure or error or attenuation or adverse) same (time or gap) same (correction or correct or fix or fixed)) and (graph or plot)	PGPB, USPT, EPAB, JPAB, DWPI	233	OR	YES		11-04-2021
		45952	OR	YES		11-04-2021

A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.	PGPB, USPT, EPAB, JPAB, DWPI					
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor)	PGPB, USPT, EPAB, JPAB, DWPI	16904	OR	YES		11-04-2021
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor same (failure or error or attenuation or adverse))	PGPB, USPT, EPAB, JPAB, DWPI	4054	OR	YES		11-04-2021
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor same (failure or error or attenuation or adverse) same (time or gap))	PGPB, USPT, EPAB, JPAB, DWPI	2338	OR	YES		11-04-2021
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor same (failure or error or attenuation or adverse) same (time or gap) same (correction or correct or fix or fixed))	PGPB, USPT, EPAB, JPAB, DWPI	246	OR	YES		11-04-2021
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01d18/00.cpc. or G01n31/22.cpc. or g01n33/66.cpc.) and (glucose same sensor same (failure or error or attenuation or adverse) same (time or gap) same (correction or correct or fix or fixed) and (graph or plot))	PGPB, USPT, EPAB, JPAB, DWPI	160	OR	YES		11-04-2021
(glucose same (monitor or sensor))	PGPB, USPT, EPAB, JPAB, DWPI	72229	OR	YES		01-15-2022
((glucose same (monitor or sensor))) same (gap or adverse or malfunction or error)	PGPB, USPT, EPAB, JPAB, DWPI	6297	OR	YES		01-15-2022

((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error)) same (backfill or correction or correct)	PGPB, USPT, EPAB, JPAB, DWPI	631	OR	YES		01-15-2022
((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct)) same data	PGPB, USPT, EPAB, JPAB, DWPI	327	OR	YES		01-15-2022
((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct) same data) and display	PGPB, USPT, EPAB, JPAB, DWPI	295	OR	YES		01-15-2022
((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct) same data) same (display or graphic or graph)	PGPB, USPT, EPAB, JPAB, DWPI	43	OR	YES		01-15-2022
A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01D18/00.cpc. or G01N31/22.cpc. or G01N33/66.cpc.	PGPB, USPT, EPAB, JPAB, DWPI	46706	OR	YES		01-15-2022
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01D18/00.cpc. or G01N31/22.cpc. or G01N33/66.cpc.) and ((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error))	PGPB, USPT, EPAB, JPAB, DWPI	4362	OR	YES		01-15-2022
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01D18/00.cpc. or G01N31/22.cpc. or G01N33/66.cpc.) and ((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct))	PGPB, USPT, EPAB, JPAB, DWPI	471	OR	YES		01-15-2022
(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01D18/00.cpc. or G01N31/22.cpc. or G01N33/66.cpc.) and ((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct) same data and display)	PGPB, USPT, EPAB, JPAB, DWPI	261	OR	YES		01-15-2022

(A61B5/14532.cpc. or G16h40/40.cpc. or A61B5/1473.cpc. or A61B5/1495.cpc. or G01D18/00.cpc. or G01N31/22.cpc. or G01N33/66.cpc.) and ((glucose same (monitor or sensor)) same (gap or adverse or malfunction or error) same (backfill or correction or correct) same data same (display or graphic or graph))	PGPB, USPT, EPAB, JPAB, DWPI	39	OR	YES		01-15-2022

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

183800 7990 02/07/2022
One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

TITLE OF INVENTION: METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	05/09/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIN, JERRY	1631	702-085000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 ONE LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: ABBOTT DIABETES CARE INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Alameda, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required) ☐ Advance Order - # of Copies

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via EFS-Web ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No.

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Glen Liu/ Date February 8, 2022

Typed or printed name Glen Liu Registration No. 75,058

Electronic Patent Application Fee Transmittal

Application Number:	17411154
Filing Date:	25-Aug-2021
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0090.C7

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1200**

Electronic Acknowledgement Receipt

EFS ID:	44940132
Application Number:	17411154
International Application Number:	
Confirmation Number:	1823
Title of Invention:	METHODS AND SYSTEMS FOR EARLY SIGNAL ATTENUATION DETECTION AND PROCESSING
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	183890
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0090.C7
Receipt Date:	08-FEB-2022
Filing Date:	25-AUG-2021
Time Stamp:	11:08:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1200
RAM confirmation Number	E202228B08314147
Deposit Account	
Authorized User	

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	9368USC7_A0130_0090_C7_Issue_Fee_Transmittal.pdf	331461 424fdbabadc7114ae64a9b24ff1147141ffeef28	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37767 7b2b0f3e9a3c5f59e70fc3cd8746559cb262d344	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	369228		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	08/25/2021	Wesley Scott Harper	A0130.0090.C7	1823

183890 7590 03/14/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

EXAMINER
LIN, JERRY

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
03/14/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPdocketing@onellp.com
adc_alameda_ip_dept@abbott.com
gliu@onellp.com

Corrected ***Notice of Allowability***	**Application No.** 17/411,154	**Applicant(s)** Harper, Wesley Scott	
	Examiner JERRY LIN	**Art Unit** 1631	**AIA (FITF) Status** No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to the reply filed December 20, 2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 23,26-50 and 53-58 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☐ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/JERRY LIN/
Primary Examiner, Art Unit 1631

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

CPC								
Symbol							**Type**	**Version**
A61B	/	5	/	14532			F	2013-01-01
A61B	/	5	/	1473			I	2013-01-01
A61B	/	5	/	1495			I	2013-01-01
G16H	/	40	/	40			I	2018-01-01
G01D	/	18	/	00			I	2013-01-01
G01N	/	31	/	22			I	2013-01-01
G01N	/	33	/	66			I	2013-01-01

CPC Combination Sets								
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JERRY LIN/ Primary Examiner, Art Unit 1631	07 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	None	None

U.S. Patent and Trademark Office

Part of Paper No.: 20220307

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

INTERNATIONAL CLASSIFICATION				
CLAIMED				
A61B5/145	/	5	/	145

NON-CLAIMED				
	/		/	

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 30	
/JERRY LIN/ Primary Examiner, Art Unit 1631 (Primary Examiner) 07 March 2022 (Date)	O.G. Print Claim(s) None	O.G. Print Figure None

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/411,154	Harper, Wesley Scott
	Examiner	**Art Unit**
	JERRY LIN	1631

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	23	10	36	19	46	28	56								
2	26	11	37	20	47	29	57								
3	27	12	38	21	48	30	58								
4	28	13	39	22	49										
5	29	14	40	23	50										
6	30	15	41	24	53										
7	31	16	42	25	43										
8	33	17	44	26	54										
9	35	18	45	27	55										

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	30	
/JERRY LIN/ Primary Examiner, Art Unit 1631	07 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	None	None

PTO/SB/08a (08-03)
Approved for use through 7/31/28. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	To be assigned
Filing Date	August 25, 2021
First Named Inventor	Wesley Scott Harper
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0090.C7

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	2002/0107557 A1	08-08-2002	Edell et al.
	2	2003/0004403 A1	01-02-2003	Drinan et al.
	3	2004/0247671 A1	12-09-2004	Prescott et al.
	4	2005/0043598 A1	02-24-2005	Goode, Jr. et al.
	5	2005/0192493 A1	09-01-2005	Wuori
	6	2006/0099971 A1	05-11-2006	Staton et al.
	7	2006/0161225 A1	07-20-2006	Sormann et al.
	8	2007/0118030 A1	05-24-2007	Bruce et al.
	9	2008/0312841 A1	12-18-2008	Hayter
	10	2009/0024177 A1	01-22-2009	Shuros et al.
	11	2009/0054749 A1	02-26-2009	He
	12	2009/0055149 A1	~~02-26-2009~~ 02/2009	Hayter et al.
	13	2009/0085768 A1	04-02-2009	Patel et al.
	14	2009/0105636 A1	04-23-2009	Hayter et al.
	15			

Change(s) applied to document, /M.HE/ 3/15/2022

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
	16	EP 1 707 115 A2	10-04-2006	Codman & Shurtleff, Inc.	
	17	WO 2008/051409 A2	05-02-2008	Bayer Healthcare LLC	
	18	WO 2008/052199 A3	05-02-2008	Abbott Diabetes Care Inc. et al.	
	19	WO 2008/061552 A1	05-29-2008	Lifescan Scotland Limited	
	20				

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.L/

Examiner Signature	/JERRY LIN/	Date Considered	11/04/2021

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicants unique citation designation number (optional). [2]See Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is govern by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/411,154	04/12/2022	11298056	A0130.0090.C7	1823

183890 7590 03/23/2022

One LLP - ADC
23 Corporate Plaza
Suite 150
Newport Beach, CA 92660

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

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