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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180

30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

CONFIRMATION NO. 8071
POWER OF ATTORNEY NOTICE



Date Mailed: 05/11/2015

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/01/2015.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/qtran/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

CONFIRMATION NO. 8071
POA ACCEPTANCE LETTER



Date Mailed: 05/11/2015

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/01/2015.

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.

/qtran/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

POWER OF ATTORNEY TO PROSECUTE BEFORE THE USPTO
By Assignee

ABBOTT DIABETES CARE INC., assignee of the application(s) for United States Letters Patent identified in the attached statement under 37 CFR 3.73(b), does revoke all powers of attorney previously given and hereby appoints as its attorneys and/or agents, with full power of substitution and revocation, to prosecute this application and transact all business in the United States Patent and Trademark Office, and in countries other than the United States, and to do all things necessary or appropriate therefor before any competent International Authorities in connection with any international patent application(s) corresponding to the above-identified application, all of the registered practitioners identified by Customer Number **95508**.

ONE LLP
4000 MacArthur Blvd.,
East Tower, Suite 500
Newport Beach, CA 92660
(949)-502-2870

The undersigned, also hereby authorizes and empowers all of the registered practitioners associated with Customer Number 95508 to sign statements under 37 CFR 3.73(b) on behalf of the undersigned to establish the undersigned's right to take actions in applications for United States Letters Patent.

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to the address associated with Customer Number 95508.

The individual whose signature is supplied below is authorized to act on behalf of the assignee.

Full Name of Assignee: Abbott Diabetes Care Inc.	
Post Office Address: 1380 South Loop Road, Alameda, CA 94502	
Signature of Declarant or Assignee: 	Date: <i>13-DEC-13</i>
Full Name of Declarant: Susan Tall If Other Than Assignee:	
Title of Declarant: Senior Counsel, Patents & Trademarks	
Address of Declarant: 1380 South Loop Road, Alameda, CA 94502	

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.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Wesley Scott Harper

Application No./Patent No.: 12/769,635 / 8,483,967 Filed/Issue Date: 04/28/2010 / 07/09/2013

Titled: **METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL**

ABBOTT DIABETES CARE INC., a corporation

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest in;
2. ☐ an assignee of less than the entire right, title, and interest in
(The extent (by percentage) of its ownership interest is _____ %); or
3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 024522, Frame 0234, or for which a copy therefore is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☒ As required by 37 CFR 3.73(b)(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.

/Mark Stirrat/

Signature

Mark Stirrat, Reg. No. 50,756

Printed or Typed Name

5/1/2015

Date

Attorney

Title

This collection of information is required by 37 CFR 3.73(b). 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 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.**

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.

Electronic Acknowledgement Receipt

EFS ID:	22236315
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Mark Andrew Stirrat/Alana Fredericks
Filer Authorized By:	Mark Andrew Stirrat
Attorney Docket Number:	TS-02-180
Receipt Date:	01-MAY-2015
Filing Date:	28-APR-2010
Time Stamp:	18:53:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	Abbott_US_POA.pdf	184577 b2416ae7b81987da1da464313f14e566cf82f7be	no	1

Warnings:

Information:

2	Assignee showing of ownership per 37 CFR 3.73	A0130_0090_373Form.pdf	425849 5e80cf1e3e3e827bf2155edc140a74ce0888be5e	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			610426		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					



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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	07/09/2013	8483967	TS-02-180	8071

30349 7590 06/19/2013
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

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 364 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 Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Wesley Scott Harper, Alameda, CA;

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Receipt date: 09/11/2012

PTO/SB/08 (09-08)

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Substitute for form 1449/PTO THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			<i>Complete if Known</i>		
			Application Number	12/769,635	
			Filing Date	April 28, 2010	
			First Named Inventor	Wesley Scott Harper	
			Art Unit	1631	
			Examiner Name	Lin, Jerry	
Sheet	1	of	3	Attorney Docket No: TS-02-180	

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
		US-5,231,988	08-03-1993	Wernicke, et al.	
		US-5,384,547	01-24-1995	Lynk, et al.	
		US-7,043,287	05-09-2006	Khalil, et al.	
		US-7,401,111	07-15-2008	Batman, et al.	
		US-7,826,981	11-02-2010	Goode, et al.	
		US-7,885,698	02-08-2011	Feldman, et al.	
		US-7,912,655	03-22-2011	Power, et al.	
		US-7,912,674	03-22-2011	Killoren Clark, et al.	
		US-7,928,850	04-19-2011	Hayter, et al.	
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		US-8,066,639	11-29-2011	Nelson, et al.	
		US-2002/0095076	07-18-2002	Krausman, et al.	
		US-2007/0032706	02-08-2007	Kamath, et al.	
		US-2007/0078314	04-05-2007	Grounsell, et al.	
		US-2007/0232880	10-04-2007	Siddiqui, et al.	
		US-2008/0071580	03-20-2008	Marcus	
		US-2008/0234992	09-25-2008	Pinaki, et al.	
		US-2008/0255438	10-16-2008	Saudara, et al.	
		US-2008/0287755	11-20-2008	Sass, et al.	
		US-2008/0300572	12-04-2008	Rankers, et al.	
		US-2009/0054750	02-26-2009	Jennewine	
		US-2009/0105570	04-23-2009	Sloan, et al.	
		US-2009/0112154	04-30-2009	Montgomery, et al.	
		US-2009/0157430	06-18-2009	Rule, et al.	
		US-2009/0210249	08-20-2009	Rasch-Menges, et al.	
		US-2009/0247857	10-01-2009	Harper, et al.	
		US-2010/0152548	06-17-2010	Koski	
		US-2010/0160757	06-24-2010	Weinert, et al.	
		US-2010/0191085	07-29-2010	Budiman	
		US-2010/0191087	07-29-2010	Talbot, et al.	
		US-2010/0191472	07-29-2010	Doniger, et al.	
		US-2010/0204557	08-12-2010	Kiaie, et al	
		US-2010/0234710	09-16-2010	~~Hoss, et al.~~ Budiman; Erwin Satrya; et al.	
		US-2010/0259543	10-14-2010	Tarassenko, et al.	
		US-2010/0274515	10-28-2010	Hoss, et al.	
		US-2010/0331651	12-30-2010	Groll	
		US-2011/0004085	01-06-2011	Mensinger, et al.	
		US-2011/0021889	01-27-2011	Hoss, et al.	
		US-2011/0077469	03-31-2011	Blocker, et al.	
		US-2011/0123971	05-26-2011	Berkowitz, et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

Receipt date: 11/23/2010

PTO/SB/08 (09-08)

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Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	13	of	20	Attorney Docket No: TS-02-180	

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
		US-2009/0043542	02-12-2009	Brauker, et al.	
		US-2009/0045055	02-19-2009	Rhodes, et al.	
		US-2009/0055149	02-26-2009	Hayter, et al.	
		US-2009/0062633	03-05-2009	Brauker, et al.	
		US-2009/0062635	03-05-2009	Brauker, et al.	
		US-2009/0062767	03-05-2009	VanAntwerp, et al.	
		US-2009/0063402	03-05-2009	Hayter	
		US-2009/0076356	03-19-2009	Simpson, et al.	
		US-2009/0076360	03-19-2009	Brister, et al.	
		US-2009/0076361	03-19-2009	Kamath, et al.	
		US-2009/0099436	04-16-2009	Brister, et al.	
		US-2009/0105636	04-23-2009	Hayter, et al.	
		US-2009/0124877	05-14-2009	~~Shariati, et al.~~ Goode, JK.; Paul V.; et al.	
		US-2009/0124878	05-14-2009	Goode, et al.	
		US-2009/0124879	05-14-2009	Brister, et al.	
		US-2009/0124964	05-14-2009	Leach, et al.	
		US-2009/0131768	05-21-2009	Simpson, et al.	
		US-2009/0131769	05-21-2009	Leach, et al.	
		US-2009/0131776	05-21-2009	Simpson, et al.	
		US-2009/0131777	05-21-2009	Simpson, et al.	
		US-2009/0137886	05-28-2009	Shariati, et al.	
		US-2009/0137887	05-28-2009	Shariati, et al.	
		US-2009/0143659	06-04-2009	~~Ying, et al.~~ Li; Ying; et al.	
		US-2009/0143660	06-04-2009	Brister, et al.	
		US-2009/0156919	06-18-2009	Brister, et al.	
		US-2009/0156924	06-18-2009	Shariati, et al.	
		US-2009/0163790	06-25-2009	Brister, et al.	
		US-2009/0163791	06-25-2009	Brister, et al.	
		US-2009/0164190	06-25-2009	Hayter	
		US-2009/0164239	06-25-2009	Hayter, et al.	
		US-2009/0164251	06-25-2009	Hayter	
		US-2009/0178459	07-16-2009	Li, et al.	
		US-2009/0182217	07-16-2009	Li, et al.	
		US-2009/0192366	07-30-2009	Mensing, et al.	
		US-2009/0192380	07-30-2009	Shariati, et al.	
		US-2009/0192722	07-30-2009	Shariati, et al.	
		US-2009/0192724	07-30-2009	Brauker, et al.	
		US-2009/0192745	07-30-2009	Kamath, et al.	
		US-2009/0192751	07-30-2009	Kamath, et al.	
		US-2009/0198118	08-06-2009	Hayter, et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

Receipt date: 09/11/2012

PTO/SB/08 (09-08)

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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	3	of	3	Attorney Docket No: TS-02-180	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code-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	T ⁶
		CA-2468577	06-05-2003	Phemi Inc.		
		CA-2617965	10-18-2011	Bayer HealthCare LLC		
		CA-2626349	09-20-2008	Lifescan, Inc.		
		CA-2678336	05-08-2008	Hoffmann La Roche		
		CA-2728831	07-22-2011	Lifescan, Inc.		
		EP-1725163	12-08-2010	e-San Ltd.		
		EP-2031534	03-04-2009	Lifescan, Inc.		
		WO-1999/027849	~~12-04-1997~~	Roche Diagnostics Corp. 06/1999		
		WO-1999/028736	~~12-04-1998~~	Roche Diagnostics Corp. 06/1999		
		WO-2003/057027	07-17-2003	Medtronic MiniMed, Inc.		
		WO-2005/057175	06-23-2005	DexCom, Inc.		
		WO-2005/065538	07-21-2005	Medtronic MiniMed, Inc.		
		WO-2006/020212	02-23-2006	Medtronic MiniMed, Inc.		
		WO-2006/072035	07-06-2006	Lifescan Scotland Ltd.		
		WO-2007/019289	02-15-2007	Bayer HealthCare LLC		
		WO-2008/048452	04-24-2008	Medtronic MiniMed, Inc.		
		WO-2008/052374	05-08-2008	Roche Diagnostics GmbH		
		WO-2008/062099	05-29-2008	Koski, Salla		
		WO-2008/144445	11-27-2008	iSense Corporation		
		WO-2010/062898	06-03-2010	University of Virginia		
		WO-2011/000528	01-06-2011	Roche Diagnostics GmbH		
		WO-2011/104616	09-01-2011	Roche Diagnostics GmbH		

Change(s) applied
to document,
/A.J.P./
6/3/2013

EXAMINER

/Jerry Lin/

DATE CONSIDERED

11/02/2012

Substitute Disclosure Statement Form (PTO-1449)
* 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 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

Receipt date: 09/11/2012

PTO/SB/08 (09-08)

Approved for use through 10/31/2008. OMB 0651-0031

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.

Substitute for form 1449/PTO THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	2	of	3	Attorney Docket No: TS-02-180	

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
		US-2011/0137571	06-09-2011	Power, et al.	
		US-2011/0184752	07-28-2011	~~Pinaki, et al.~~ Ray et al.	
		US-2011/0208027	08-25-2011	Wagner, et al.	
		US-2011/0263959	10-27-2011	Young, et al.	
		US-2011/0264378	10-27-2011	Breton, et al.	

Change(s) applied
to document,
/A.J.P./
6/3/2013

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

Receipt date: 11/23/2010

PTO/SB/08 (09-08)

Approved for use through 10/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	1	of	20	Attorney Docket No: TS-02-180	

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
		US-3,581,062	05-21-1971	Aston	
		US-3,926,760	12-16-1975	Allen, et al.	
		US-3,949,388	04-06-1976	Fuller	
		US-4,036,749	07-19-1977	Anderson	
		US-4,055,175	10-25-1977	Clemens, et al.	
		US-4,129,128	12-12-1978	McFarlane	
		US-4,245,634	01-20-1981	Albisser, et al.	
		US-4,327,725	05-04-1982	Cortese, et al.	
		US-4,344,438	08-17-1982	Schultz	
		US-4,349,728	09-14-1982	Phillips, et al.	
		US-4,373,527	02-15-1983	Fischell	
		US-4,392,849	07-12-1983	Petre, et al.	
		US-4,425,920	01-17-1984	Bourland, et al.	
		US-4,478,976	~~10-23-1994~~	Goertz, et al. 10/1984	
		US-4,494,950	01-22-1985	Fischell	
		US-4,509,531	04-09-1985	Ward	
		US-4,527,240	07-02-1985	Kvitash	
		US-4,538,616	09-03-1985	Rogoff	
		US-4,619,793	10-28-1986	Lee	
		US-4,671,288	06-09-1987	Gough	
		US-4,703,756	11-03-1987	Gough, et al.	
		US-4,731,726	03-15-1988	Allen, III	
		US-4,749,985	06-07-1988	Corsberg	
		US-4,757,022	07-12-1988	Shults, et al.	
		US-4,777,953	10-18-1988	Ash, et al.	
		US-4,779,618	10-25-1988	Mund, et al.	
		US-4,854,322	08-08-1989	Ash, et al.	
		US-4,871,351	10-03-1989	Feingold	
		US-4,890,620	01-02-1990	Gough	
		US-4,925,268	05-15-1990	Iyer, et al.	
		US-4,953,552	09-04-1990	DeMarzo	
		US-4,986,271	01-22-1991	Wilkins	
		US-4,995,402	02-26-1991	Smith, et al.	
		US-5,000,180	03-19-1991	Kuypers, et al.	
		US-5,002,054	03-26-1991	Ash, et al.	
		US-5,019,974	05-28-1991	Beckers	
		US-5,050,612	09-24-1991	Matsumura	
		US-5,055,171	10-08-1991	Peck	
		US-5,068,536	11-26-1991	Rosenthal	
		US-5,082,550	01-21-1992	Rishpon, et al.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (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)

30349 7590 03/04/2013
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

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 facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

Seong-Kun Oh	(Depositor's name)
/Seong-Kun Oh/	(Signature)
May 21, 2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071

TITLE OF INVENTION: Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	~~\$1770~~ \$1780	\$300	\$0	~~\$2070~~ \$2080	06/04/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIN, JERRY	1631	702-019000

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/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form 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 Jackson & Co., 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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Abbott Diabetes Care Inc.

Alameda, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-2019 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Seong-Kun Oh/
 Typed or printed name Seong-Kun Oh

Date May 21, 2013
 Registration No. 48,210

This collection of information 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 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, 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.

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or Fax **(571)-273-2885**

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30349 7590 03/04/2013
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OAKLAND, CA 94611-2802

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Seong-Kun Oh	(Depositor's name)
/Seong-Kun Oh/	(Signature)
May 21, 2013	(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071

TITLE OF INVENTION: Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	~~\$1770~~ \$1780	\$300	\$0	~~\$2070~~ \$2080	06/04/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIN, JERRY	1631	702-019000

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/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form 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 Jackson & Co., 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 has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Abbott Diabetes Care Inc.

Alameda, California

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☒ Issue Fee
☒ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-2019 (enclose an extra copy of this form).

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☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Seong-Kun Oh/
 Typed or printed name Seong-Kun Oh

Date May 21, 2013
 Registration No. 48,210

This collection of information 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 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, 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.

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Electronic Patent Application Fee Transmittal

Application Number:	12769635			
Filing Date:	28-Apr-2010			
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill			
First Named Inventor/Applicant Name:	Wesley Scott Harper			
Filer:	Seong-Kun Oh			
Attorney Docket Number:	TS-02-180			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
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	1780	1780
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				2080

Electronic Acknowledgement Receipt

EFS ID:	15830720
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	21-MAY-2013
Filing Date:	28-APR-2010
Time Stamp:	19:08:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$2080
RAM confirmation Number	6189
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Transmittal Letter	TS-02-180-General-Transmittal.pdf	62016 9be54321a416480c0a981b387ec4aca98475d5f5	no	2
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	TS-02-180-Issue-Fee-Transmittal.pdf	344554 48d84943eca2a5ad16f714b278399d2ccec22b98	no	2
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32301 ecf0d67ceb84bda2c51e0186da04107ce6c2e771	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			438871		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

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/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Inventor	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 1631		
Examiner	: Lin, Jerry		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed please find the following:

1. Transmittal (In Duplicate);
2. Issue Fee Transmittal (1 Page plus Duplicate);
3. Certificate of Transmission (In Duplicate);
4. Deposit Account Authorization (In Duplicate);

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: May 21, 2013

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Inventor	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 1631		
Examiner	: Lin, Jerry		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

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Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: May 21, 2013

By: /Seong-Kun Oh/

Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Inventor : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 1631
Examiner : Lin, Jerry
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

OK TO ENTER: /JL/

04/24/2013

**AMENDMENT AFTER NOTICE OF ALLOWANCE
UNDER 37 CFR 1.312**

Sir:

In response to the Notice of Allowance of March 4, 2013, please amend the above-identified application as follows:

The **Amendments to the Specification** begin on page **2** of this paper.

Remarks/Arguments begin on page **9** of this paper.



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.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071
30349	7590	04/30/2013	EXAMINER	
JACKSON & CO., LLP			LIN, JERRY	
6114 LA SALLE AVENUE				
#507				
OAKLAND, CA 94611-2802			ART UNIT	PAPER NUMBER
			1631	
			NOTIFICATION DATE	DELIVERY MODE
			04/30/2013	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):

uspto@jacolaw.com
docketing@jacolaw.com
mail@jacolaw.com

Response to Rule 312 Communication	Application No. 12/769,635	Applicant(s) HARPER, WESLEY SCOTT
	Examiner JERRY LIN	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

1. ☒ The amendment filed on 11 April 2013 under 37 CFR 1.312 has been considered, and has been:

a) ☐ entered.

b) ☒ entered as directed to matters of form not affecting the scope of the invention.

c) ☐ disapproved because the amendment was filed after the payment of the issue fee.

Any amendment filed after the date the issue fee is paid must be accompanied by a petition under 37 CFR 1.313(c)(1) and the required fee to withdraw the application from issue.

d) ☐ disapproved. See explanation below.

e) ☐ entered in part. See explanation below.

	/Jerry Lin/ Primary Examiner, Art Unit 1631 4/24/2013
--	---

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop ISSUE FEE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **April 11, 2013**.

/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Inventor : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 1631
Examiner : Lin, Jerry
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**AMENDMENT AFTER NOTICE OF ALLOWANCE
UNDER 37 CFR 1.312**

Sir:

In response to the Notice of Allowance of March 4, 2013, please amend the above-identified application as follows:

The **Amendments to the Specification** begin on page **2** of this paper.

Remarks/Arguments begin on page **9** of this paper.

Amendments to the Specification:

Please replace paragraph **[0004]** of the application as filed with the following replacement paragraph:

[0004] Devices and methods for analyte monitoring, e.g., glucose monitoring, and/or therapy management system including, for example, medication infusion device 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 ~~systems~~systems, and therapy management systems.

Please replace paragraph **[0005]** of the application with the following replacement paragraph:

[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]]~~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.

Please replace paragraph **[0018]** of the application with the following replacement paragraph:

[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]]~~That 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.

Please replace paragraph **[0024]** of the application with the following replacement paragraph:

[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~~limited to activation of certain functions or routines such as analyte related data processing, and the like.

Please replace paragraph **[0029]** of the application with the following replacement paragraph:

[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.

Please replace paragraph **[0036]** of the application with the following replacement paragraph:

[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 a communication link 103, where the communication link 103, as described above, may be configured for bi-directional communication.

Please replace paragraph **[0037]** of the application with the following replacement paragraph:

[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~~HIPAA requirements) while avoiding potential data collision and interference.

Please replace paragraph **[0044]** of the application with the following replacement paragraph:

[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 ~~400MHz~~400

MHz to approximately ~~470MHz~~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.

Please replace paragraph **[0045]** of the application with the following replacement paragraph:

[0045] Referring yet again to FIG. 2, also shown is a leak detection circuit 214 coupled to the guard ~~electrode~~contact (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.

Please replace paragraph **[0049]** of the application with the following replacement paragraph:

[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]]~~309 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.

Please replace paragraph **[0054]** of the application with the following replacement paragraph:

[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 a predetermined data processing ~~routine~~routine 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.

Please replace paragraph **[0075]** of the application with the following replacement paragraph:

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

Remarks/Arguments

Applicants gratefully acknowledge the Notice of Allowance mailed March 4, 2013 indicating the allowability of claims 1-22.

Amendment to the specification correct for minor typographical and/or clerical errors. No new matter is added. Applicants respectfully request entry of the same.

In the event that the Examiner deems a telephonic or in person discussion would be helpful in advancing the prosecution of the present application, Applicants respectfully request the Examiner to contact Applicants' representative at (510) 652-6418, x82.

Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: April 11, 2013

By: /Seong-Kun Oh/

Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Telephone: 510-652-6418, Ext. 82
Facsimile: 510-652-5691

Customer No.: 30349

Electronic Acknowledgement Receipt

EFS ID:	15493010
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	11-APR-2013
Filing Date:	28-APR-2010
Time Stamp:	20:37:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	TS-02-180-General-Transmittal.pdf	61953 52bfc1f92e285eccd65b358b4f85cabfae400e50	no	2

Warnings:

Information:

2		TS-02-180-Amendment-After-Allowance.pdf	80264	yes	9
			9f4048d2eea4258f0bb26df2600490d5ddecde0		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment after Notice of Allowance (Rule 312)		1	1	
	Specification		2	8	
	Applicant Arguments/Remarks Made in an Amendment		9	9	
Warnings:					
Information:					
Total Files Size (in bytes):			142217		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

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/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Inventor	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 1631		
Examiner	: Lin, Jerry		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed please find the following:

1. Transmittal (In Duplicate);
2. Amendment After Notice Of Allowance Under 37 CFR 1.312 (9 Pages);
3. Certificate of Transmission (In Duplicate);
4. Deposit Account Authorization (In Duplicate);

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: April 11, 2013

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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/Seong-Kun Oh/

Seong-Kun Oh

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Application No.	: 12/769,635	Confirmation No.	8071
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Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

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Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: April 11, 2013

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

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6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349



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NOTICE OF ALLOWANCE AND FEE(S) DUE

30349 7590 03/04/2013
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/04/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/769,635

04/28/2010

Wesley Scott Harper

TS-02-180

8071

TITLE OF INVENTION: Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1770	\$300	\$0	\$2070	06/04/2013

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.

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If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

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 and an extra copy of the form should be submitted. 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: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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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)

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30349 7590 03/04/2013
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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/769,635

04/28/2010

Wesley Scott Harper

TS-02-180

8071

TITLE OF INVENTION: Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1770	\$300	\$0	\$2070	06/04/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
LIN, JERRY	1631	702-019000

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/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form 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,

1 _____

(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.

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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 has been filed for recordation as set forth in 37 CFR 3.11. 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. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

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☐ A check is enclosed.

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☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

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This collection of information 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 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, 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.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071

30349 7590 03/04/2013
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

EXAMINER

LIN, JERRY

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 03/04/2013

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 312 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 312 day(s).

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 Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

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.

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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.	Applicant(s)	
	12/769,635	HARPER, WESLEY SCOTT	
	Examiner	Art Unit	
	JERRY LIN	1631	

-- 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 amendments and response filed 2/7/2013.
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 1-22. 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).
 - 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)

- | | |
|---|---|
| <ol style="list-style-type: none"> 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 _____ | <ol style="list-style-type: none"> 5. ☐ Examiner's Amendment/Comment 6. ☒ Examiner's Statement of Reasons for Allowance 7. ☐ Other _____ |
|---|---|

/Jerry Lin/
Primary Examiner, Art Unit 1631

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The prior art does not teach disabling the output of a sensor data during an adverse condition, where the sensor data is still being stored and where that stored data is later retrieved and processed after the adverse condition is no longer present.

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."

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 on 7am -5:30pm, M, Tu, Th, and F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
2/22/2013

Search Notes 	Application/Control No. 12769635	Applicant(s)/Patent Under Reexamination HARPER, WESLEY SCOTT
	Examiner JERRY LIN	Art Unit 1631

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
702	19	2/22/2013	JL

SEARCH NOTES		
Search Notes	Date	Examiner
See Printout	2/22/2013	JL
Inventor search of Harper in palm	2/22/2013	JL

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
702	19	2/22/2013	JL

--	--

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **February 7, 2013**.

/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Applicant : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 1631
Examiner : Lin, Jerry
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
OK TO ENTER: /JL/ SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL

02/22/2013

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION FINAL MAILED NOVEMBER 8, 2012

Sir:

In response to the Office Action of November 8, 2012, please amend the above-identified application as follows:

The **Listing of Claims** begins on page **2** of this paper.

Remarks/Arguments begin on page **7** of this paper.

WEST Search History for Application 12769635

Creation Date: 2013022215:56

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
20090033482.pn. or 20090018424.pn.	PGPB, USPT	OR	YES		05-18-2012
analyte same sensor	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor) same calibration	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration) same (processing or process)	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration same (processing or process)) same (output or display or readout)	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration same (processing or process) same (output or display or readout)) and (storage or storing or store or retrieve or retrieving)	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration same (processing or process) same (output or display or readout)) same (storage or storing or store or retrieve or retrieving)	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration same (processing or process) same (output or display or readout) same (storage or storing or store or retrieve or retrieving)) same (disable or disabling)	PGPB, USPT	OR	YES		02-22-2013
(analyte same sensor same calibration same (processing or process) same (output or display or readout) same (storage or storing or store or retrieve or retrieving)) and disabling	PGPB, USPT	OR	YES		02-22-2013
702/19.ccls.	PGPB, USPT	OR	YES		02-22-2013
(702/19.ccls.) and (analyte same sensor)	PGPB, USPT	OR	YES		02-22-2013
(702/19.ccls.) and (analyte same sensor same calibration same (processing or process))	PGPB, USPT	OR	YES		02-22-2013



UNITED STATES PATENT AND TRADEMARK OFFICE

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 Alexandria, Virginia 22313-1450
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BIB DATA SHEET

CONFIRMATION NO. 8071

SERIAL NUMBER 12/769,635	FILING or 371(c) DATE 04/28/2010 RULE	CLASS 702	GROUP ART UNIT 1631	ATTORNEY DOCKET NO. TS-02-180		
APPLICANTS Wesley Scott Harper, Alameda, CA; ** CONTINUING DATA ***** This appln claims benefit of 61/173,600 04/29/2009 ** FOREIGN APPLICATIONS ***** ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 05/10/2010						
Foreign Priority claimed ☐ Yes ☒ No 35 USC 119(a-d) conditions met ☐ Yes ☒ No Verified and Acknowledged <u>/JERRY LIN/</u> Examiner's Signature		☐ Met after Allowance Initials	STATE OR COUNTRY CA	SHEETS DRAWINGS 7	TOTAL CLAIMS 22	INDEPENDENT CLAIMS 3
ADDRESS JACKSON & CO., LLP 6114 LA SALLE AVENUE #507 OAKLAND, CA 94611-2802 UNITED STATES						
TITLE Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill						
FILING FEE RECEIVED 1324	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit			

STN

FILE 'MEDLINE, EMBASE, BIOSIS, COMPUSCIENCE' ENTERED AT 15:58:10 ON 22
FEB 2013

L1 5789 S ANALYTE AND SENSOR
L2 0 S L1 AND DISABLE
L3 515 S L1 AND CALIBRATION
L4 104 S L3 AND (PROCESS OR PROCESSING)
L5 75 DUP REM L4 (29 DUPLICATES REMOVED)

Issue Classification 	Application/Control No. 12769635	Applicant(s)/Patent Under Reexamination HARPER, WESLEY SCOTT
	Examiner JERRY LIN	Art Unit 1631

CPC		
Symbol	Type	Version

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION									
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED				
702	19	G	0	1	N	33 / 48 (2006.01.01)					
CROSS REFERENCE(S)											
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)										

NONE		Total Claims Allowed: 22	
(Assistant Examiner)	(Date)		
/JERRY LIN/ Primary Examiner.Art Unit 1631	2/22/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	None	None

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **February 7, 2013**.

/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Applicant : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 1631
Examiner : Lin, Jerry
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION FINAL MAILED NOVEMBER 8, 2012

Sir:

In response to the Office Action of November 8, 2012, please amend the above-identified application as follows:

The **Listing of Claims** begins on page **2** of this paper.

Remarks/Arguments begin on page **7** of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) 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;
storing sensor data received from the analyte sensor 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 stored during the adverse condition time period after it is determined that the one or more detected adverse conditions is no longer present;
processing the retrieved sensor data stored during the adverse condition time period; and
outputting the processed retrieved sensor data.
2. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Currently Amended) 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;
storing sensor data received from the analyte sensor during a time period of disabled output of information;
determining a successful calibration of the analyte sensor;
retrieving one or more parameters associated with the successful calibration;
after the one or more parameters associated with successful calibration has been retrieved, processing the sensor data stored 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 output of information-~~output~~.

8. (Original) The method of claim 7, wherein the sensor data is analyte concentration data.
9. (Original) The method of claim 8, wherein the analyte concentration data includes blood glucose concentration data.
10. (Original) The method of claim 7, wherein the sensor data is processed in substantially real-time.
11. (Original) 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. (Original) 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. (Original) 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. (Currently Amended) 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 first 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 a display of processed sensor data;

store sensor data received during a time period of disabled display in the first memory;

determine a successful calibration of the sensor;

retrieve one or more parameters associated with the successful calibration;

after the one or more parameters associated with successful calibration have been retrieved, process the sensor data stored 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 display.

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

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

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

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

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

20. (Original) 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. (Currently Amended) 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~~ display substantially immediately upon processing the sensor data.

22. (Currently Amended) 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~~ display only after waiting a predetermined period of time.

Remarks/Arguments

Reconsideration is respectfully requested. Claims 1-22 are pending. Claims 1-22 are rejected.

For the reasons set forth below, Applicant respectfully submits that all pending claims are allowable.

I. Summary of Examiner Interview

Applicant appreciates the Examiner extending a telephonic interview with Applicant's representative on January 15, 2013 and January 22, 2013 during which Applicants' representative Anthony Canning, Reg. No. 62,107, and Examiner Jerry Lin discussed claim amendments in view of the cited art. Agreement was reached that the amendment to independent claims 1, 7, and 14, included herein, overcomes the Hayter and Kamath references.

II. Anticipation Rejections

Claims 1-6 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2009/0033482 (Hayter, et al.). See Office Action page 2.

Applicant respectfully disagrees and traverses the Examiner's rejections.

Notwithstanding the traversal, without acquiescing to the propriety of the Examiner's rejections and for the sole purpose of advancing prosecution of the present application, the claims are amended as shown above. To this end, Applicant reserves the right to pursue claims of the same or similar scope, prior to amendment, in one or more continuing applications.

More specifically, **claim 1** is now directed to a combination including, *inter alia*, 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, storing sensor data received from the analyte sensor 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 stored during the adverse condition time period after it is determined that the one or more detected adverse conditions is no longer present, processing the retrieved sensor data stored during the adverse condition time period, and outputting the processed retrieved sensor data.

Support for the amendment to claim 1 can be found throughout the specification and/or figures as originally filed including in, but not limited to, for example, FIGS. 4-7B and paragraphs [0054]-[0060] of corresponding published application no. 2010/0280782. No new matter is added.

For at least the reasons set forth above, Applicant respectfully submits that all pending claims are allowable.

III. Obviousness Rejections

Claims 7-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hayter, et al. and further in view of U.S. Publication No. 2009/0018424 (Kamath, et al.) See Office Action page 5.

Applicant respectfully disagrees and traverses the Examiner's rejections.

Notwithstanding the traversal, without acquiescing to the propriety of the Examiner's rejections and for the sole purpose of advancing prosecution of the present application, the claims are amended as shown above. To this end, Applicant reserves the right to pursue claims of the same or similar scope, prior to amendment, in one or more continuing applications.

More specifically, **claim 7** is now directed to a combination including, *inter alia*, detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period, disabling output of information associated with the analyte sensor, storing sensor data received from the analyte sensor during a time period of disabled output of

information, determining a successful calibration of the analyte sensor, retrieving one or more parameters associated with the successful calibration, after the one or more parameters associated with successful calibration has been retrieved, processing the sensor data stored 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 output of information. **Claim 14** is now directed to a combination including, *inter alia*, an interface configured to receive sensor data, a first memory configured to store the received sensor data, a processor coupled to the first 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 a display of processed sensor data, store sensor data received during a time period of disabled display in the first memory, determine a successful calibration of the sensor, retrieve one or more parameters associated with the successful calibration, after the one or more parameters associated with successful calibration have been retrieved, process the sensor data stored 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 display.

Support for the amendment to claim 7 and 14 can be found throughout the specification and/or figures as originally filed including in, but not limited to, for example, FIGS. 4-7B and paragraphs [0054]-[0060] of corresponding published application no. 2010/0280782. No new matter is added.

For at least the reasons set forth above, Applicant respectfully submits that all pending claims are allowable.

No Disclaimers Or Disavowals

Amendments to and/or cancellations of the claims are being made without prejudice and solely to clarify issues before the Examiner and/or to advance prosecution of this application and are not intended as a disavowal of any subject matter and do not constitute an agreement or acquiescence to any objection and/or rejection.

Accordingly, by this response Applicant does not concede that previously pending claims are not patentable.

Applicant reserves the right 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 pre-amended and/or cancelled claims, including broader and narrower claims, and including any subject matter found to be disclaimed herein or by any prior prosecution (should such subject matter be found to be disclaimed despite Applicant's statement herein of no such disclaimer). Accordingly, Applicant does not make any disclaimers or disavowals of any subject matter supported by the present disclosure.

Applicant's silence with regard to the Examiner's rejections of and/or objections to certain dependent claims constitutes a recognition by Applicant that the rejections and/or objections are moot based on Applicant's amendment or remarks relative to the independent claim from which the dependent claims depend. Such silence does not constitute an acquiescence to any of the Examiner's objections and/or rejections, and Applicant reserves the right to argue the patentability of such dependent claims at any appropriate time.

Remarks and/or amendments, or a lack of remarks and/or amendments, are not intended to constitute, and should not be construed as, an acquiescence, on the part of Applicant: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in

this case. Applicant reserves the right to challenge the purported teaching and prior art status of the cited references at any appropriate time.

In view of the foregoing, Applicant respectfully submits that all pending claims are allowable, and request the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic or in person discussion would be helpful in advancing the prosecution of the present application, Applicant respectfully requests the Examiner to contact Applicant's representative at (510) 652-6418, x82.

Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: February 7, 2013

By: /Seong-Kun Oh/

Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802

Telephone: 510-652-6418, Ext. 82
Facsimile: 510-652-5691

Customer No.: 30349

Electronic Acknowledgement Receipt

EFS ID:	14908348
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	07-FEB-2013
Filing Date:	28-APR-2010
Time Stamp:	19:27:42
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	Transmittal Letter	TS-02-180-General-Transmittal.pdf	66409 8626fb02fa8b2b094964eb3ef0ccda948f86a491	no	2

Warnings:

Information:

2		TS-02-180-Response-to-OA-Final-as-filed.pdf	94634 e410f581b9419b3355e8c39810b0cc8c96b63c43d	yes	11
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment After Final		1	1	
	Claims		2	6	
	Applicant Arguments/Remarks Made in an Amendment		7	11	
Warnings:					
Information:					
Total Files Size (in bytes):			161043		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **February 7, 2013**.

/Seong-Kun Oh/
Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Applicant : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 1631
Examiner : Lin, Jerry
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed please find the following:

1. Transmittal (In Duplicate);
2. Response to Office Action Final Mailed November 8, 2012 (11 Pages);
3. Certificate of Transmission (In Duplicate);
4. Deposit Account Authorization (In Duplicate);

Claim Fee Calculation:

	Claims After Amendment	Previously Paid For	Present Extra	Rate (\$)	Additional Fee (\$)
Total	22	- 22	= 0	x \$62	\$0
Independent	3	- 3	= 0	x \$250	\$0

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP®

Dated: February 7, 2013

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP®
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/769,635		Filing Date 04/28/2010		☒ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☐ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)		RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=		X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 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.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	02/07/2013	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$	=		X \$62=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$	=		X \$250=	0
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	0
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)		RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=		X \$	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=		X \$	=
	☐ Application Size Fee (37 CFR 1.16(s))									
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			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 number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/ANGELA JOHNSON/

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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071
30349	7590	01/25/2013	EXAMINER	
JACKSON & CO., LLP			LIN, JERRY	
6114 LA SALLE AVENUE				
#507				
OAKLAND, CA 94611-2802				
			ART UNIT	PAPER NUMBER
			1631	
			NOTIFICATION DATE	DELIVERY MODE
			01/25/2013	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):

uspto@jacolaw.com
docketing@jacolaw.com
mail@jacolaw.com

<i>Applicant-Initiated Interview Summary</i>	Application No. 12/769,635	Applicant(s) HARPER, WESLEY SCOTT	
	Examiner JERRY LIN	Art Unit 1631	

All participants (applicant, applicant's representative, PTO personnel):

(1) Jerry Lin (Examiner). (3) ____.

(2) Anthony Canning (Applicant's Representative). (4) ____.

Date of Interview: 22 January 2013.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
 If Yes, brief description: ____.

Issues Discussed ☐101 ☐112 ☒102 ☐103 ☐Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1 and 7.

Identification of prior art discussed: Hayter et al.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Parties discussed potential amendments to the claims to clarify the steps. The Examiner suggested filing the amendments, but cautioned that a new search would probably be required.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/Jerry Lin/ Primary Examiner, Art Unit 1631	
--	--

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071
30349	7590	01/22/2013	EXAMINER	
JACKSON & CO., LLP			LIN, JERRY	
6114 LA SALLE AVENUE				
#507				
OAKLAND, CA 94611-2802			ART UNIT	PAPER NUMBER
			1631	
			NOTIFICATION DATE	DELIVERY MODE
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<i>Applicant-Initiated Interview Summary</i>	Application No.	Applicant(s)	
	12/769,635	HARPER, WESLEY SCOTT	
	Examiner	Art Unit	
	JERRY LIN	1631	

All participants (applicant, applicant's representative, PTO personnel):

(1) Jerry Lin (Examiner). (3) ____.

(2) Seong-Kun Oh (Applicant's Representative). (4) ____.

Date of Interview: 15 January 2013.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
 If Yes, brief description: ____.

Issues Discussed ☐101 ☐112 ☒102 ☒103 ☐Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1 and 7.

Identification of prior art discussed: Hayter et al., Kamath et al.

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Parties discussed the limitation of "outputting the processed retrieved sensor data" in claim 1. Applicant's Representative asked for clarification regarding Hayter et al. The Examiner explained that Hayter et al. teaches creating a new glucose point at the adverse event and then outputting whatever data is collected (paragraph 0143 and 0144). This is sufficient to meet this limitation Applicant's Representative also wanted clarification of the determining step in claim 7. Again, the Examiner pointed to paragraphs 0143 and 0144 of Hayter et al. which teach finding a new glucose point (i.e. recalibration) then processing the sensor data with the new glucose point (i.e. the parameter associated with the successful calibration). This is sufficient to meet this limitation of claim 7.

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☐ Attachment

/Jerry Lin/ Primary Examiner, Art Unit 1631 1/15/2013	
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30349	7590	11/08/2012	EXAMINER	
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Office Action Summary	Application No.	Applicant(s)	
	12/769,635	HARPER, WESLEY SCOTT	
	Examiner	Art Unit	
	JERRY LIN	1631	

-- 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 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 23 August 2012.
- 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) 1-22 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) 1-22 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).
- a) ☐ All b) ☐ Some * c) ☐ None of:
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) | 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/11/2012</u> . | 4) ☐ Other: ____. |

DETAILED ACTION

1. Applicants' arguments, filed August 23, 2012, have been fully considered and they are not persuasive. The following rejections are reiterated. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Status of the Claims

Claims 1-22 are under examination.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hayter et al. (US 2009/0033482 A1).

Regarding claim 1, Hayter et al. disclose a method with the steps of receiving sensor data from an analyte sensor of a sensor monitoring system (Figure 12, paragraphs 0025 and 0066); processing the received sensor data with time corresponding calibration data (paragraph 0098); outputting the

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processed sensor data (paragraph 0048); detecting one or more adverse conditions associated with the sensor monitoring system (paragraphs 0004 and 0114); disabling the output of the sensor data during an adverse condition time period (paragraph 0143); determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system (paragraph 0102); retrieving the sensor data during the adverse condition time period (paragraph 0004); processing the retrieved sensor data during the adverse condition time period (paragraph 0004); and outputting the processed retrieved sensor data (paragraphs 0048 and 0144).

Regarding claim 2, Hayter et al. teach where outputting the processed sensor data includes displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one more combination thereof (paragraphs 0048 and 0050).

Regarding claim 3, Hayter et al. teach where 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 (paragraphs 0004 and 0189).

Regarding claim 4, Hayter et al. teach where the sensor instability condition includes temperature measurement outside a predetermined range (paragraph 0114).

Regarding claim 5, Hayter et al. teach where the calibration failure condition includes a signal error associated with the reference data (paragraph 0114).

Regarding claim 6, Hayter et al. teach storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor (paragraphs 0034 and 0050).

Response to Arguments

4. Applicant has responded to this rejection by citing paragraphs 0004, 0048, and 0144 of Hayter et al. and restating the limitations of claim 1. However, each of the limitations of claim 1 was addressed in the above rejection. Applicant has not pointed to any limitations that were not taught by Hayter et al. Thus, the rejection is maintained.

Applicants also state that Hayter et al. do not teach all the limitations of claim 7 and 14. While, the Examiner agrees, these claims and their limitations are addressed below in the rejection made under 35 U.S.C. §103. Instant claims 7 and 14 were not rejected in the above rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayter et al. (US 2009/0033482 A1) as applied to claims 1-6 above, and further in view of Kamath et al. (US 2009/0018424).

Hayter et al. is applied as above.

Regarding claim 7, Hayter et al. teach a method that includes detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period (paragraphs 0004 and 0114); disabling output of information associated with the analyte sensor (paragraph 0143); determining a successful calibration of the analyte sensor (paragraph 0102); retrieving one or more parameters associated with the successful calibration (paragraph 0156); and displaying the processed sensor data (Figure 3 and paragraph 0048).

However, Hayter et al. do not teach that the displayed data is for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration.

Regarding claim 7, Kamath et al. teach processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration (abstract, paragraph 0835).

Regarding claim 14, Hayter et al. teach an apparatus with an interface to receive sensor data (paragraphs 0038, 0040, and 0069); a first memory configured to store the received sensor data (paragraphs 0086 and 0165); a processor coupled to the memory and configured to process the stored sensor data (Figure 1, paragraph 0027); a second memory coupled to the processor and

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configured to store the processed sensor data (Figure 1, paragraphs 0086 and 0165); and a display unit coupled to the second memory and configured to display the processed sensor data (paragraphs 0048); where the processor is configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period (paragraphs 0004 and 0114); disable display of processed sensor data (paragraph 0143); determine a successful calibration of the sensor (paragraph 0102); retrieve one or more parameters associated with the successful calibration of the sensor (paragraph 0156); and displaying the processed sensor data (Figure 3, paragraph 0048).

However, Hayter et al. do not teach that the displayed data being for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration.

Regarding claim 14, Kamath et al. teach processing the sensor data during the time period of disabled display of sensor data with one or more parameters associated with successful calibration (paragraph 0835).

Regarding claims 8-10, Hayter et al. teach where the sensor data is analyte concentration data (paragraph 0164); where the concentration data include blood glucose concentration data (paragraphs 0101 and 0117); and where the sensor data is process in substantially real-time (paragraph 0144).

Regarding claims 11 and 20, Hayter et al. teach where the condition is 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

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sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature measurement outside a predetermined range, or any combination thereof (paragraphs 0098 and 0114).

Regarding claims 12, 13, 15-19, 21 and 22, Hayter teaches where the sensor is an analyte sensor (paragraph 0004); where the sensor is a glucose sensor (paragraph 0025); where the sensor data corresponds to analyte concentration data (paragraph 0164); where the analyte concentration data includes blood glucose concentration data (paragraphs 0101 and 0117); and where the apparatus is configured to process and display the sensor data substantially in real time (paragraph 0144).

It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the methods of Hayter et al. and Kamath et al. to gain the benefit of a continuous robust glucose monitoring to improve patient care and lower medical costs. Kamath et al. teach that their method offers continuous robust glucose monitoring to improve patient care and lower medical costs (paragraph 0344). Given that both Hayter et al. and Kamath et al. are concerned with monitoring patients, one of ordinary in the art would have been motivated to combine their methods to gain the benefit of continuous monitoring and lower medical costs.

Response to Arguments

7. Applicant has responded to this rejection by restating claims 7 and 14 and stating that Kamath does not teach the processing steps of claims 7 and 14.

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However, Applicant has argued against the references individually. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Hayter et al. teaches disabling output of information associated with the analyte sensor (paragraph 0143). It is during this time that one of ordinary skill in the art at the time of the invention could have processed the sensor data using Kamath et al.'s method. Thus, the combination of the references, not the references individually, teach the limitations of instant claims 7 and 14. This rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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 on 7am -5:30pm, M, Tu, Th, and F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jerry Lin/
Primary Examiner, Art Unit 1631
11/2/2012

Receipt date: 09/11/2012

PTO/SB/08 (09-08)

Approved for use through 10/31/2008. OMB 0651-0031

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Substitute for form 1449/PTO THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	1	of	3	Attorney Docket No: TS-02-180	

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
		US-5,231,988	08-03-1993	Wernicke, et al.	
		US-5,384,547	01-24-1995	Lynk, et al.	
		US-7,043,287	05-09-2006	Khalil, et al.	
		US-7,401,111	07-15-2008	Batman, et al.	
		US-7,826,981	11-02-2010	Goode, et al.	
		US-7,885,698	02-08-2011	Feldman, et al.	
		US-7,912,655	03-22-2011	Power, et al.	
		US-7,912,674	03-22-2011	Killoren Clark, et al.	
		US-7,928,850	04-19-2011	Hayter, et al.	
		US-7,976,467	07-12-2011	Young, et al.	
		US-8,066,639	11-29-2011	Nelson, et al.	
		US-2002/0095076	07-18-2002	Krausman, et al.	
		US-2007/0032706	02-08-2007	Kamath, et al.	
		US-2007/0078314	04-05-2007	Grounsell, et al.	
		US-2007/0232880	10-04-2007	Siddiqui, et al.	
		US-2008/0071580	03-20-2008	Marcus	
		US-2008/0234992	09-25-2008	Pinaki, et al.	
		US-2008/0255438	10-16-2008	Saudara, et al.	
		US-2008/0287755	11-20-2008	Sass, et al.	
		US-2008/0300572	12-04-2008	Rankers, et al.	
		US-2009/0054750	02-26-2009	Jennewine	
		US-2009/0105570	04-23-2009	Sloan, et al.	
		US-2009/0112154	04-30-2009	Montgomery, et al.	
		US-2009/0157430	06-18-2009	Rule, et al.	
		US-2009/0210249	08-20-2009	Rasch-Menges, et al.	
		US-2009/0247857	10-01-2009	Harper, et al.	
		US-2010/0152548	06-17-2010	Koski	
		US-2010/0160757	06-24-2010	Weinert, et al.	
		US-2010/0191085	07-29-2010	Budiman	
		US-2010/0191087	07-29-2010	Talbot, et al.	
		US-2010/0191472	07-29-2010	Doniger, et al.	
		US-2010/0204557	08-12-2010	Kiaie, et al	
		US-2010/0234710	09-16-2010	Hoss, et al.	
		US-2010/0259543	10-14-2010	Tarassenko, et al.	
		US-2010/0274515	10-28-2010	Hoss, et al.	
		US-2010/0331651	12-30-2010	Groll	
		US-2011/0004085	01-06-2011	Mensing, et al.	
		US-2011/0021889	01-27-2011	Hoss, et al.	
		US-2011/0077469	03-31-2011	Blocker, et al.	
		US-2011/0123971	05-26-2011	Berkowitz, et al.	

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		US-2011/0137571	06-09-2011	Power, et al.	
		US-2011/0184752	07-28-2011	Pinaki, et al.	
		US-2011/0208027	08-25-2011	Wagner, et al.	
		US-2011/0263959	10-27-2011	Young, et al.	
		US-2011/0264378	10-27-2011	Breton, et al.	

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		CA-2468577	06-05-2003	Phemi Inc.		
		CA-2617965	10-18-2011	Bayer HealthCare LLC		
		CA-2626349	09-20-2008	Lifescan, Inc.		
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		WO-1999/027849	12-04-1997	Roche Diagnostics Corp.		
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		WO-2003/057027	07-17-2003	Medtronic MiniMed, Inc.		
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		WO-2005/065538	07-21-2005	Medtronic MiniMed, Inc.		
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		WO-2008/144445	11-27-2008	iSense Corporation		
		WO-2010/062898	06-03-2010	University of Virginia		
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		WO-2011/104616	09-01-2011	Roche Diagnostics GmbH		

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Search Notes 	Application/Control No. 12769635	Applicant(s)/Patent Under Reexamination HARPER, WESLEY SCOTT
	Examiner JERRY LIN	Art Unit 1631

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
See Printout	5/18/2012	JL
Inventor search of Harper in palm	5/18/2012	JL
updated	11/2/2012	JL

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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Substitute for form 1449/PTO THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	2	of	3	Attorney Docket No: TS-02-180	

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
		US-2011/0137571	06-09-2011	Power, et al.	
		US-2011/0184752	07-28-2011	Pinaki, et al.	
		US-2011/0208027	08-25-2011	Wagner, et al.	
		US-2011/0263959	10-27-2011	Young, et al.	
		US-2011/0264378	10-27-2011	Breton, et al.	

EXAMINER**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

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 1449/PTO THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	3	of	3	Attorney Docket No: TS-02-180	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code-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	T ⁶
		CA-2468577	06-05-2003	Phemi Inc.		
		CA-2617965	10-18-2011	Bayer HealthCare LLC		
		CA-2626349	09-20-2008	Lifescan, Inc.		
		CA-2678336	05-08-2008	Hoffmann La Roche		
		CA-2728831	07-22-2011	Lifescan, Inc.		
		EP-1725163	12-08-2010	e-San Ltd.		
		EP-2031534	03-04-2009	Lifescan, Inc.		
		WO-1999/027849	12-04-1997	Roche Diagnostics Corp.		
		WO-1999/028736	12-04-1998	Roche Diagnostics Corp.		
		WO-2003/057027	07-17-2003	Medtronic MiniMed, Inc.		
		WO-2005/057175	06-23-2005	DexCom, Inc.		
		WO-2005/065538	07-21-2005	Medtronic MiniMed, Inc.		
		WO-2006/020212	02-23-2006	Medtronic MiniMed, Inc.		
		WO-2006/072035	07-06-2006	Lifescan Scotland Ltd.		
		WO-2007/019289	02-15-2007	Bayer HealthCare LLC		
		WO-2008/048452	04-24-2008	Medtronic MiniMed, Inc.		
		WO-2008/052374	05-08-2008	Roche Diagnostics GmbH		
		WO-2008/062099	05-29-2008	Koski, Salla		
		WO-2008/144445	11-27-2008	iSense Corporation		
		WO-2010/062898	06-03-2010	University of Virginia		
		WO-2011/000528	01-06-2011	Roche Diagnostics GmbH		
		WO-2011/104616	09-01-2011	Roche Diagnostics GmbH		

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

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Electronic Patent Application Fee Transmittal

Application Number:	12769635			
Filing Date:	28-Apr-2010			
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill			
First Named Inventor/Applicant Name:	Wesley Scott Harper			
Filer:	Seong-Kun Oh			
Attorney Docket Number:	TS-02-180			
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
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:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				180

Electronic Acknowledgement Receipt

EFS ID:	13713340
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	11-SEP-2012
Filing Date:	28-APR-2010
Time Stamp:	17:43:33
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 180
RAM confirmation Number	5234
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		TS-02-180-Third-Supplemental-IDS.pdf	301525 bad8ae67c19439a79edf651a282185c071f5242f	yes	5
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Transmittal Letter		1	2	
	Information Disclosure Statement (IDS) Form (SB08)		3	5	
Warnings:					
Information:					
2	Foreign Reference	CA2468577A1.pdf	1586302 7768c3248e05c1836574e9cb0904264f7de2675d	no	50
Warnings:					
Information:					
3	Foreign Reference	CA2617965C.pdf	945419 d06bf3ccd2e6621c8c167bf42847039bf79791f3	no	23
Warnings:					
Information:					
4	Foreign Reference	CA2626349A1.pdf	4894123 f8e554192f571589d67273e25ce7c4ec7c61cb2b	no	108
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5	Foreign Reference	CA2678336A1.pdf	1910398 60924fa29be4101641986e3cad6419cc0cd41af2	no	48
Warnings:					
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6	Foreign Reference	CA2728831A1.pdf	1758906 71351009f7905b9119c9b0220c5989067693f48c	no	49
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7	Foreign Reference	EP1725163B1.pdf	1135571 0060012b0eeef92a025abede672a9ea547a614bd	no	27
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8	Foreign Reference	EP2031534A1.pdf	3408926 655e2848611f8e03c2d7baeac714021c9b7eeff	no	62

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9	Foreign Reference	WO1999027849A1.pdf	1999192	no	67
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14	Foreign Reference	WO2006020212A2.pdf	2459602	no	65
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15	Foreign Reference	WO2006072035A1.pdf	1205916	no	28
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16	Foreign Reference	WO2007019289A1.pdf	972273	no	24
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19	Foreign Reference	WO2008062099A1.pdf	2380438	no	47
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Warnings:					
Information:					
Total Files Size (in bytes):			69496506		

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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.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	1		2	Attorney Docket Number	TS-02-180

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.56(a) and 37 C.F.R. §1.97, Applicant(s) hereby make of record the references listed on the accompanying form, SB/08A and/or SB/08b for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement:

- (a) accompanies a new patent application submitted herewith.
- (b) is filed within three (3) months of the Filing Date or before the mailing date of a First Office Action on the merits or before the mailing date of a First Office Action after the filing of a Request for Continued Examination; **OR**
- (c) ☒ is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned prior to the mailing date of either a final rejection or a notice of allowance, and is accompanied by either the fee (\$180) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below **OR**
- (d) is filed after the mailing date of either a final rejection or a notice of allowance, and the issue fee has not been paid, and is accompanied by the requisite fee (\$180) set forth in 37 CFR §1.17(p) and a certification as specified in 37 CFR §1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- (e) Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- (f) No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the 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.

Each item of information listed in the attached FORM PTO/SB/08a and/or SB/08b may be material to the examination of the above-identified application and is, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR §1.56, §1.97 and §1.98. The Examiner is requested to make these items of official record in this application.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
Examiner Name	Lin, Jerry				
Sheet	2		2	Attorney Docket Number	TS-02-180

Pursuant to notice entitled "Information Disclosure Statements May Be Filed Without Copies Of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003," *Off. Gaz. Pat. Office* 55 (August 5, 2003), no copies of U.S. Patents and U.S. Published Patent Applications are being supplied with this Information Disclosure Statement.

This Information Disclosure Statement under 37 CFR §1.56, §1.97 and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these items constitutes prior art.

If this statement crosses in the mail with an office action, or is otherwise not in the indicated category of 37 C.F.R. §1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this submission as a conditional petition for acceptance of the information disclosure statement.

The Commissioner is authorized to charge any deficiencies and credit any overpayment of fees to our Deposit Account No. 50-2019.

Respectfully submitted,

Date: September 11, 2012

Jackson & Co., LLP®

/Seong-Kun Oh/

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 Reg. No. 48,210
 Attorneys for Applicant(s)
 6114 La Salle Ave., #507
 Oakland, CA 94611-2802
 Tel. 510-652-6418
 Fax. 510-652-5691

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CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 11, 2012
Date

/Seong-Kun Oh/
Seong-Kun Oh

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **August 23, 2012**.

/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Applicant	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 1631		
Examiner	: Lin, Jerry		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: **METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL**

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION MAILED MAY 24, 2012

Sir:

In response to the Office Action of May 24, 2012, please amend the above-identified application as follows:

The **Listing of Claims** begins on page **2** of this paper.

Remarks/Arguments begin on page **7** of this paper.

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) The method of claim 7, wherein the sensor data is analyte concentration data.

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

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

11. (Original) 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. (Original) 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. (Original) 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. (Original) 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. (Original) The apparatus of claim 14, wherein the sensor is an analyte sensor.

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

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

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

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

20. (Original) 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. (Original) 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. (Original) 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.

Remarks/Arguments

Reconsideration is respectfully requested. Claims 1-22 are pending. Claims 1-22 are rejected.

For the reasons set forth below, Applicant respectfully submits that all pending claims are allowable.

I. Anticipation Rejections

Claims 1-6 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2009/0033482 (Hayter, et al.). See Office Action page 2.

Applicant respectfully disagrees and traverses the Examiner's rejections.

As the Examiner is aware, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In rejecting independent claim 1, the Examiner asserts that Hayter discloses "retrieving the sensor data during the adverse condition time period (paragraph 0004); processing the retrieved sensor data during the adverse condition time period (paragraph 0004); and outputting the processed retrieved sensor data (paragraphs 0048 and 0144)." See Office Action, p. 3. The portions of Hayter cited by the Examiner are reproduced for the Examiner's convenience.

[0004] In one embodiment, method and apparatus for detecting a failure state of a calibration routine to calibrate an analyte sensor, retrieving one or more calibration parameters associated with the detected failure state of the calibration routine, determining one or more conditions corresponding to the retrieved one or more calibration parameters to correct the detected failure state of the calibration routine, and generating a notification associated with the determined one or more conditions, is disclosed.

[0048] 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.

[0144] For example, when the 15 minute glucose data including the current glucose level as well as the past 14 minutes of glucose level data is to be displayed or output to the user, and the determined variance of the 15 data points exceeds a preset threshold level (for example, 3.0), the glucose trend information display function may be disabled. In one aspect, the variance may be determined based on the square function of the standard deviation of the 15 data points. In one aspect, this approach may be performed substantially on a real time basis for each minute glucose data. Accordingly, as discussed above, the glucose trend information may be output or displayed substantially in real time, and based on each new glucose data point received from the sensor/transmitter unit.

See Hayter, paragraphs [0004], [0048], and [0144].

On the other hand, **claim 1** is directed to a combination including, *inter alia*, 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.

Furthermore, the Examiner states, with reference to rejections of claims 7 and 14, that "Hayter et al. do not teach that the displayed data being [*sic*] for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration". See Office Action, pp. 4 and 5. For at least the reasons set forth above, Applicant traverses the Examiner's rejections and respectfully submits that pending claims 1-6 are allowable.

II. Obviousness Rejections

Claims 7-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hayter, et al. and further in view of U.S. Publication No. 2009/0018424 (Kamath, et al.). See Office Action page 4.

Applicant respectfully disagrees and traverses the Examiner's rejections.

As the Examiner is aware, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Claim 7 is directed to a combination including, *inter alia*, 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. **Claim 14** is directed to a combination including, *inter alia*, 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.

In rejecting independent claims 7 and 14, the Examiner concedes that “Hayter et al. do not teach that the displayed data being [*sic*] for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration.” See Office Action, pp. 4 and 5. The Examiner then refers to the disclosure of Kamath and asserts that “Kamath et al. teach processing sensor data during the time period of disabled output of information with the one or more parameters associated with successful calibration (abstract, paragraph 0835).” See Office Action, pp. 4 and 5. Applicant disagrees.

The portions of Kamath relied upon by the Examiner are reproduced below for convenience.

Systems and methods of use for continuous analyte measurement of a host's vascular system are provided. In some embodiments, a continuous glucose measurement system includes a vascular access device, a sensor and sensor electronics, the system being configured for insertion into communication with a host's circulatory system.

[0835] In one embodiment, systems and methods are configured to process calibrated sensor data during sensor break-in. In general, signals associated with a calibration and/or measurement phase of the sensor system can be measured during initial sensor break-in. Using a rate method for measuring an analyte (e.g., measuring the rate of change of a step change), a sensor signal can be calibrated with a correction factor to account for the rate of change of the break-in curve. In one exemplary embodiment, the bottom of sequential step responses (e.g., of calibration

phases during sensor break-in) can be fit to a line or curve (e.g., using linear or non-linear regression, such as least squares regression), to extrapolate the rate of change of the curve of the sensor break-in. Accordingly, the rate of change measured in a measurement phase can be corrected to account for the rate of change of the sensor break-in curve, and the sensor signal calibrated. By calibrating during sensor break-in, sensor data can more quickly be provided (e.g., to the user interface) after sensor insertion.

See Kamath, Abstract, paragraph [0835].

As understood, Kamath discloses that signals associated with a calibration and/or measurement phase of the sensor system can be measured during the initial sensor break-in. See Kamath, paragraph [0835]. Kamath, as further understood, discloses that by calibrating during sensor break-in the sensor data can be more quickly provided to the user after sensor insertion. See Kamath, paragraph [0835].

However, as understood, Kamath fails to disclose or otherwise suggest “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,” as required by independent claim 7; nor does Kamath disclose or suggest “a processor coupled to the memory and configured to...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,” as required by independent claim 14.

For at least the reasons set forth above, Applicant respectfully submits that all pending claims are allowable.

No Disclaimers Or Disavowals

Amendments to and/or cancellations of the claims are being made without prejudice and solely to clarify issues before the Examiner and/or to advance prosecution of this application and are not intended as a disavowal of any subject matter and do not constitute an agreement or acquiescence to any objection and/or rejection.

Accordingly, by this response Applicant does not concede that previously pending claims are not patentable.

Applicant reserves the right 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 pre-amended and/or cancelled claims, including broader and narrower claims, and including any subject matter found to be disclaimed herein or by any prior prosecution (should such subject matter be found to be disclaimed despite Applicant's statement herein of no such disclaimer). Accordingly, Applicant does not make any disclaimers or disavowals of any subject matter supported by the present disclosure.

Applicant's silence with regard to the Examiner's rejections of and/or objections to certain dependent claims constitutes a recognition by Applicant that the rejections and/or objections are moot based on Applicant's amendment or remarks relative to the independent claim from which the dependent claims depend. Such silence does not constitute an acquiescence to any of the Examiner's objections and/or rejections, and Applicant reserves the right to argue the patentability of such dependent claims at any appropriate time.

Remarks and/or amendments, or a lack of remarks and/or amendments, are not intended to constitute, and should not be construed as, an acquiescence, on the part of Applicant: as to the purported teachings or prior art status of the cited references; as to the characterization of the cited references advanced by the Examiner; or as to any other assertions, allegations or characterizations made by the Examiner at any time in

this case. Applicant reserves the right to challenge the purported teaching and prior art status of the cited references at any appropriate time.

In view of the foregoing, Applicant respectfully submits that all pending claims are allowable, and request the Examiner's early examination of the pending claims in the present application. In the event that the Examiner deems a telephonic or in person discussion would be helpful in advancing the prosecution of the present application, Applicant respectfully requests the Examiner to contact Applicant's representative at (510) 652-6418, x82.

Respectfully submitted,
JACKSON & CO., LLP[®]

Dated: August 23, 2012

By: /Seong-Kun Oh/

Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802

Telephone: 510-652-6418, Ext. 82
Facsimile: 510-652-5691

Customer No.: 30349

Electronic Acknowledgement Receipt

EFS ID:	13571260
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	23-AUG-2012
Filing Date:	28-APR-2010
Time Stamp:	16:57:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	TS-02-180-General-Transmittal-as-filed.pdf	66205 f9b38246e6b6fc15c3693d40d0b723b8e86aa5d2	no	2

Warnings:

Information:

2		TS-02-180-Response-to-OA-Non-Final-as-filed.pdf	124286 31736303db1c1d2219d479a741dc23cff2a599d	yes	13
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Claims		2	6	
	Applicant Arguments/Remarks Made in an Amendment		7	13	
Warnings:					
Information:					
Total Files Size (in bytes):			190491		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **August 23, 2012**.

_____/Seong-Kun Oh/

Seong-Kun Oh

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Applicant	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 1631		
Examiner	: Lin, Jerry		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: **METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL**

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed please find the following:

1. Transmittal (In Duplicate);
2. Response to Office Action mailed May 24, 2012;
3. Certificate of Transmission (In Duplicate);
4. Deposit Account Authorization (In Duplicate);

Claim Fee Calculation:

	Claims After Amendment	Previously Paid For	Present Extra	Rate (\$)	Additional Fee (\$)
Total	22	- 22	= 0	x \$60	\$0
Independent	3	- 3	= 0	x \$250	\$0

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP®

Dated: August 23, 2012

By: _____/Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP®
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically via the EFS-Web System, and addressed to: Mail Stop AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **August 23, 2012**.

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JACKSON & CO., LLP®

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By: _____/Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP®
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 12/769,635		Filing Date 04/28/2010		☐ To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY ☐ OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(j))	minus 20 =	*	X \$	=	OR	X \$	=			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=		X \$	=			
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 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.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	08/23/2012	CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	Total (37 CFR 1.16(i))	* 22	Minus	** 22	= 0	X \$	=	OR	X \$60=	0
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X \$	=	OR	X \$250=	0
☐ 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	0
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	MINUS	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)
	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 number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/STEFANIE BRYCE/

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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180	8071
30349	7590	05/24/2012	EXAMINER	
JACKSON & CO., LLP			LIN, JERRY	
6114 LA SALLE AVENUE				
#507				
OAKLAND, CA 94611-2802				
			ART UNIT	PAPER NUMBER
			1631	
			NOTIFICATION DATE	DELIVERY MODE
			05/24/2012	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):

uspto@jacolaw.com
docketing@jacolaw.com
mail@jacolaw.com

Office Action Summary	Application No. 12/769,635	Applicant(s) HARPER, WESLEY SCOTT	
	Examiner JERRY LIN	Art Unit 1631	

-- 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 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, 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 02 April 2010.
- 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) 1-22 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) 1-22 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

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).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
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) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/13/10, 11/23/10, 11/14/11</u> . | 6) ☐ Other: ____. |

DETAILED ACTION

Status of the Claims

Claims 1-22 are under examination.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hayter et al. (US 2009/0033482 A1).

Regarding claim 1, Hayter discloses a method with the steps of receiving sensor data from an analyte sensor of a sensor monitoring system (Figure 12, paragraphs 0025 and 0066); processing the received sensor data with time corresponding calibration data (paragraph 0098); outputting the processed sensor data (paragraph 0048); detecting one or more adverse conditions associated with the sensor monitoring system (paragraphs 0004 and 0114); disabling the output of the sensor data during an adverse condition time period (paragraph 0143); determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system (paragraph

Art Unit: 1631

0102); retrieving the sensor data during the adverse condition time period (paragraph 0004); processing the retrieved sensor data during the adverse condition time period (paragraph 0004); and outputting the processed retrieved sensor data (paragraphs 0048 and 0144).

Regarding claim 2, Hayter teaches where outputting the processed sensor data includes displaying the sensor data in one or more of a graphical, numerical, pictorial, audible, vibratory, or one more combination thereof (paragraphs 0048 and 0050).

Regarding claim 3, Hayter teaches where 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 (paragraphs 0004 and 0189).

Regarding claim 4, Hayter teaches where the sensor instability condition includes temperature measurement outside a predetermined range (paragraph 0114).

Regarding claim 5, Hayter teaches where the calibration failure condition includes a signal error associated with the reference data (paragraph 0114).

Regarding claim 6, Hayter teaches storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor (paragraphs 0034 and 0050).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1631

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayter et al. (US 2009/0033482 A1) as applied to claims 1-6 above, and further in view of Kamath et al. (US 2009/0018424).

Hayter et al. is applied as above.

Regarding claim 7, Hayter et al. teach a method that includes detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period (paragraphs 0004 and 0114); disabling output of information associated with the analyte sensor (paragraph 0143); determining a successful calibration of the analyte sensor (paragraph 0102); retrieving one or more parameters associated with the successful calibration (paragraph 0156); and displaying the processed sensor data (Figure 3 and paragraph 0048).

However, Hayter et al. do not teach that the displayed data being for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration.

Regarding claim 7, Kamath et al. teach processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration (abstract, paragraph 0835).

Regarding claim 14, Hayter et al. teach an apparatus with an interface to receive sensor data (paragraphs 0038, 0040, and 0069); a first memory configured to store the received sensor data (paragraphs 0086 and 0165); a processor coupled to the memory

Art Unit: 1631

and configured to process the stored sensor data (Figure 1, paragraph 0027); a second memory coupled to the processor and configured to store the processed sensor data (Figure 1, paragraphs 0086 and 0165); and a display unit coupled to the second memory and configured to display the processed sensor data (paragraphs 0048); where the processor is configured to detect a condition unsuitable for calibration of a sensor for a predetermined time period (paragraphs 0004 and 0114); disable display of processed sensor data (paragraph 0143); determine a successful calibration of the sensor (paragraph 0102); retrieve one or more parameters associated with the successful calibration of the sensor (paragraph 0156); and displaying the processed sensor data (Figure 3, paragraph 0048).

However, Hayter et al. do not teach that the displayed data being for the time period of disabled information output and processing the sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration.

Regarding claim 14, Kamath et al. teach processing the sensor data during the time period of disabled display of sensor data with one or more parameters associated with successful calibration (paragraph 0835).

Regarding claims 8-10, Hayter et al. teach where the sensor data is analyte concentration data (paragraph 0164); where the concentration data include blood glucose concentration data (paragraphs 0101 and 0117); and where the sensor data is process in substantially real-time (paragraph 0144).

Regarding claims 11 and 20, Hayter et al. teach where the condition is 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 (paragraphs 0098 and 0114).

Regarding claims 12, 13, 15-19, 21 and 22, Hayter teaches where the sensor is an analyte sensor (paragraph 0004); where the sensor is a glucose sensor (paragraph 0025); where the sensor data corresponds to analyte concentration data (paragraph 0164); where the analyte concentration data includes blood glucose concentration data (paragraphs 0101 and 0117); and where the apparatus is configured to process and display the sensor data substantially in real time (paragraph 0144).

It would have been obvious for one of ordinary skill in the art at the time of the invention to combine the methods of Hayter et al. and Kamath et al. to gain the benefit of a continuous robust glucose monitoring to improve patient care and lower medical costs. Kamath et al. teach that their method offers continuous robust glucose monitoring to improve patient care and lower medical costs (paragraph 0344). Given that both Hayter et al. and Kamath et al. are concerned with monitoring patients, one of ordinary in the art would have been motivated to combine their methods to gain the benefit of continuous monitoring and lower medical costs.

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 on 7am -5:30pm, M, Tu, Th, and F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. 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
5/18/2012

WEST Search History for Application 12769635

Creation Date: 2012051816:44

Prior Art Searches

Query	DB	Op.	Plur.	Thes.	Date
20090033482.pn. or 20090018424.pn.	PGPB, USPT	OR	YES		05-18-2012

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				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
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/JL/		PCT Application No. PCT/US2010/032863, International Preliminary Report on Patentability and Written Opinion of the International Searching Authority mailed November 10, 2011.	

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				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	1	of	20	Attorney Docket No: TS-02-180	

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				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
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EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's optional citation designation number (optional) 2 Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /JL/

Substitute for form 1449/PTO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	19	of	20	Attorney Docket No: TS-02-180	

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	
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EXAMINER

DATE CONSIDERED

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				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	20	of	20	Attorney Docket No: TS-02-180	

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.	1 ²	
		SHICHIRI, M., et al., "Needle-type Glucose Sensor for Wearable Artificial Endocrine Pancreas", <u>Implantable Sensors for Closed-Loop Prosthetic Systems, Chapter 15</u> , 1985, pp. 197-210.		
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EXAMINER

/Jerry Lin/

DATE CONSIDERED

05/18/2012

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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	3735
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket No: TS-02-180	

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
/JL/		US-2005/0143635	06-30-2005	Kamath, et al.	
/JL/		US-2009/0018424	01-15-2009	Kamath, et al.	
/JL/		US-2009/0033482	02-05-2009	Hayter, et al.	
		US-			
		US-			
		US-			
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/JL/		PCT Application No. PCT/US2010/032863, International Search Report and Written Opinion of the International Searching Authority mailed July 7, 2010.		

EXAMINER

/Jerry Lin/

DATE CONSIDERED

05/18/2012

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Search Notes 	Application/Control No. 12769635	Applicant(s)/Patent Under Reexamination HARPER, WESLEY SCOTT
	Examiner JERRY LIN	Art Unit 1631

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
See Printout	5/18/2012	JL
Inventor search of Harper in palm	5/18/2012	JL

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	1	of	1	Attorney Docket No: TS-02-180	

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
		PCT Application No. PCT/US2010/032863, International Preliminary Report on Patentability and Written Opinion of the International Searching Authority mailed November 10, 2011.	

EXAMINER**DATE CONSIDERED**

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ADVANCE E-MAIL

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)
(PCT Rule 44bis.1(c))

To:

OH, Seong-Kun
Jackson & Co., LLP
6114 La Salle Ave., #507
Oakland, CA 94611
ETATS-UNIS D'AMERIQUE

Date of mailing (day/month/year)

10 November 2011 (10.11.2011)

Applicant's or agent's file reference

TS-02-180PCT

IMPORTANT NOTICE

International application No.

PCT/US2010/032863

International filing date (day/month/year)

28 April 2010 (28.04.2010)

Priority date (day/month/year)

29 April 2009 (29.04.2009)

Applicant

ABBOTT DIABETES CARE INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer

Simin Baharlou

e-mail: pt09.pct@wipo.int

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference TS-02-180PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2010/032863	International filing date (<i>day/month/year</i>) 28 April 2010 (28.04.2010)	Priority date (<i>day/month/year</i>) 29 April 2009 (29.04.2009)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant ABBOTT DIABETES CARE INC.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.																								
In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																									
3.	This report contains indications relating to the following items: <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;">☒</td> <td style="width: 30%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;">☒</td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;">☐</td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	☒	Box No. I	Basis of the report	☐	Box No. II	Priority	☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐	Box No. IV	Lack of unity of invention	☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	☐	Box No. VI	Certain documents cited	☐	Box No. VII	Certain defects in the international application	☐	Box No. VIII	Certain observations on the international application
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☐	Box No. VI	Certain documents cited																							
☐	Box No. VII	Certain defects in the international application																							
☐	Box No. VIII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 01 November 2011 (01.11.2011) Authorized officer Simin Baharlou e-mail: pt09.pct@wipo.int
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PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: SEONG-KUN OH JACKSON & CO., LLP 6114 LA SALLE AVE., #507 OAKLAND, CA 94611		07 JUL 2010	
Applicant's or agent's file reference TS-02-180PCT		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2010/032863	International filing date (day/month/year) 28 April 2010	Priority date (day/month/year) 29 April 2009	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - G01D 18/00 (2010.01) USPC - 604/66			
Applicant ABBOTT DIABETES CARE INC.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 15 June 2010	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/032863

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/032863

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7-22	YES
	Claims	1-6	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-22	NO
Industrial applicability (IA)	Claims	1-22	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Hayter et al. (hereinafter, Hayter).

Referring to Claim 1, Hayter discloses a method, comprising: receiving sensor data from an analyte sensor of a sensor monitoring system (Fig. 12, receive glucose data 1210; [0025], analyte [e.g., glucose] monitoring system 100; [0066], glucose value from the sampled analyte sensor signal may be determined); processing the received sensor data with time corresponding calibration data ([0098], receive the raw glucose data including any data quality check flags, and to apply temperature compensation and/or calibration to the raw data to determine the corresponding glucose data); outputting the processed sensor data ([0048], determine and display the glucose level on the output display 310); detecting one or more adverse conditions associated with the sensor monitoring system ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disabling the output of the sensor data during an adverse condition time period ([0143], if it is determined that the underlying data points associated with the monitored glucose level includes uncertainty or error factor that exceeds the tolerance level, disable or disallow the display or output of the glucose trend information); determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system ([0102], if the calibration validation check is successful); retrieving the sensor data during the adverse condition time period ([0004], retrieving calibration parameters associated with the detected failure state [i.e., adverse condition] of the calibration routine); processing the retrieved sensor data during the adverse condition time period ([0004], the retrieved one or more calibration parameters to correct the detected failure state [i.e., adverse condition] of the calibration routine); and outputting the processed retrieved sensor data ([0048] and [0144], the glucose trend information may be output or displayed).

Referring to Claim 2, Hayter discloses 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 ([0048], determine and display the glucose level on the output display 310; [0050], the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output).

Referring to Claim 3, Hayter discloses 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 ([0004] and [0189], failure state of a calibration routine).

Referring to Claim 4, Hayter discloses wherein the sensor instability condition includes temperature measurement outside a predetermined range ([0114], some circumstance that is preventing calibration, such as skin temperature being out of range).

Referring to Claim 5, Hayter discloses wherein the calibration failure condition includes a signal error associated with the reference data ([0114], the calibration failed because there was an error in the reference glucose reading, or because the reference glucose reading was out of range).

Referring to Claim 6, Hayter discloses including storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor ([0034], storing, retrieving and updating data corresponding to the detected analyte level; [0050], time-stamped blood glucose data).

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Claims 7-22 lack an inventive step under PCT Article 33(3) as being obvious over Hayter in view of Kamath et al. (hereinafter, Kamath).

Referring to Claim 7, Hayter discloses a method, comprising: detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disabling output of information associated with the analyte sensor ([0143], disable or disallow the display or output of the glucose trend information); determining a successful calibration of the analyte sensor ([0102], if the calibration validation check is successful); retrieving one or more parameters associated with the successful calibration ([0156], when current blood glucose value is received or detected [successfully], a prior blood glucose value previously stored or otherwise received is retrieved); and displaying the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310), but is silent on said displayed data being for the time period of disabled information output; and processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration. However, displaying processed data for a specific time period is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected. Furthermore, in disclosing an analyte sensor (Abstract), Kamath teaches processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration ([0835], process calibrated sensor data during sensor break-in [i.e., condition unsuitable for calibration]). Using a rate method for measuring an analyte, a sensor signal can be calibrated with a correction factor [i.e., successful calibration parameter] to account for the rate of change of the break-in curve. Accordingly, the rate of change measured in a measurement phase can be corrected to account for the rate of change of the sensor break-in curve – it is interpreted that the time period of disabled output occurs when a condition unsuitable for calibration is detected). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter as taught by Kamath in order to correct the rate of change measured to account for the rate of change of the sensor break-in curve (Hayter, [0835]).

Referring to Claim 14, Hayter discloses an apparatus, comprising: an interface configured to receive sensor data ([0038], an analog interface 201 configured to communicate with the sensor 101; [0040], the sensor unit 101 is provided four contacts 210, 211, 212, 213, each operatively coupled to the analog interface 201 as shown in Fig. 2; [0069], as every minute, the analog signal from the interface 201 corresponding to the monitored analyte level received from the sensor unit 101 is sampled); a first memory configured to store the received sensor data ([0086], an operational state associated with the sensor unit 101 is retrieved from a storage unit or a memory of receiver 104; [0165], data storage unit of receiver 104); a processor coupled to the memory and configured to process the stored sensor data (Fig. 1 shows a data processing terminal 105 coupled to primary receiver 104; [0027], a data processing terminal 105 for evaluating the data received by the primary receiver unit 104); a second memory coupled to the processor and configured to store the processed sensor data (Fig. 1 shows a data processing terminal 105 coupled to secondary receiver 106; [0086], an operational state associated with the sensor unit 101 is retrieved from a storage unit or a memory of receiver 106; [0165], data storage unit of receiver 104); and a display unit coupled to the second memory and configured to display the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310); wherein the processor is further configured to: detect a condition unsuitable for calibration of a sensor for a predetermined time period ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disable display of processed sensor data ([0143], disable or disallow the display or output of the glucose trend information); determine a successful calibration of the sensor ([0102], if the calibration validation check is successful); retrieve one or more parameters associated with the successful calibration ([0156], when current blood glucose value is received or detected [successfully], a prior blood glucose value previously stored or otherwise received is retrieved); and displaying the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310), but is silent on said displayed data being for the time period of disabled information output; and 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. However, displaying processed data for a specific time period is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected. Furthermore, Kamath teaches processing the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration. ([0835], process calibrated sensor data during sensor break-in [i.e., condition unsuitable for calibration]). Using a rate method for measuring an analyte, a sensor signal can be calibrated with a correction factor [i.e., successful calibration parameter] to account for the rate of change of the break-in curve. Accordingly, the rate of change measured in a measurement phase can be corrected to account for the rate of change of the sensor break-in curve – it is interpreted that the time period of disabled output occurs when a condition unsuitable for calibration is detected). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter as taught by Kamath in order to correct the rate of change measured to account for the rate of change of the sensor break-in curve (Hayter, [0835]).

Referring to Claim 8, Hayter discloses wherein the sensor data is analyte concentration data ([0164], analyte sensor data).

Referring to Claim 9, Hayter discloses wherein the analyte concentration data includes blood glucose concentration data ([0101] and [0117], blood glucose value).

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/032863

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Referring to Claim 10, Hayter discloses wherein the sensor data is processed in substantially real-time ([0144], the glucose trend information may be output or displayed substantially in real-time).

Referring to Claim 11, Hayter discloses 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 ([0098], further data quality check may be performed by the receiver 104/106 on the temperature compensated and calibrated glucose data to determine the rate of change or variance of the measured glucose data. For example, a high variance check or verification is performed on 15 minutes of glucose data stored in the FIFO buffer. If it is determined that the rate of variance exceeds a predetermined threshold, then the data packet in process may be deemed invalid; [0114], some circumstance that is preventing calibration, such as skin temperature being out of range).

Referring to Claim 15, Hayter discloses wherein the sensor (Fig. 1, 101) is an analyte sensor ([0004], analyte sensor).

Referring to Claim 16, Hayter discloses wherein the analyte sensor is a glucose sensor ([0025], analyte [e.g., glucose] monitoring system).

Referring to Claim 17, Hayter discloses wherein the sensor data corresponds to analyte concentration data ([0164], analyte sensor data).

Referring to Claim 18, Hayter discloses wherein the analyte concentration data includes blood glucose concentration data ([0101] and [0117], blood glucose value).

Referring to Claim 19, Hayter discloses configured to process and display the sensor data substantially in real-time ([0144], the glucose trend information may be output or displayed substantially in real-time).

Referring to Claim 20, Hayter discloses 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 ([0098], further data quality check may be performed by the receiver 104/106 on the temperature compensated and calibrated glucose data to determine the rate of change or variance of the measured glucose data. For example, a high variance check or verification is performed on 15 minutes of glucose data stored in the FIFO buffer. If it is determined that the rate of variance exceeds a predetermined threshold, then the data packet in process may be deemed invalid; [0114], some circumstance that is preventing calibration, such as skin temperature being out of range).

Referring to Claims 12 and 21, Hayter discloses wherein the processed sensor data is displayed substantially immediately upon processing ([0144], the glucose trend information may be output or displayed substantially in real-time), but is silent on the data being for the time period of disabled information output. However, the type of data being displayed (i.e., data processed for a specific time period) is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected.

Referring to Claims 13 and 22, Hayter discloses wherein the processed sensor data is displayed ([0144], the glucose trend information may be output or displayed substantially in real-time), but is silent on the data being for the time period of disabled information output, and displaying only after waiting a predetermined period of time. However, the type of data being displayed (i.e., data processed for a specific time period), and the time period during which said data is displayed is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Electronic Acknowledgement Receipt

EFS ID:	11389395
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Michael S. Chen
Filer Authorized By:	
Attorney Docket Number:	TS-02-180
Receipt Date:	14-NOV-2011
Filing Date:	28-APR-2010
Time Stamp:	23:07:51
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TS-02-180-Second-Supplemental-IDS.pdf	182679 b498ca58e94ea796cee31dc4466ffff656832005	yes	3

Multipart Description/PDF files in .zip description							
Document Description			Start	End			
Transmittal Letter			1	2			
Information Disclosure Statement (IDS) Form (SB08)			3	3			
Warnings:							
Information:							
2	Non Patent Literature	TS-02-180PCT-Preliminary-Report-on-Patentability-11-10-11.pdf	384739	no	7		
			33f23e91c4da6bbff9150fe82a19dc7819b0b2d				
Warnings:							
Information:							
Total Files Size (in bytes):			567418				
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.							

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
				Examiner Name	Lin, Jerry
Sheet	1		2	Attorney Docket Number	TS-02-180

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.56(a) and 37 C.F.R. §1.97, Applicant(s) hereby make of record the references listed on the accompanying form, SB/08A and/or SB/08b for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement:

- (a) accompanies a new patent application submitted herewith.
- (b) ☒ is filed within three (3) months of the Filing Date or before the mailing date of a First Office Action on the merits or before the mailing date of a First Office Action after the filing of a Request for Continued Examination; **OR**
- (c) is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned prior to the mailing date of either a final rejection or a notice of allowance, and is accompanied by either the fee (\$180) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below **OR**
- (d) is filed after the mailing date of either a final rejection or a notice of allowance, and the issue fee has not been paid, and is accompanied by the requisite fee (\$180) set forth in 37 CFR §1.17(p) and a certification as specified in 37 CFR §1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- (e) Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- (f) No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the 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.

Each item of information listed in the attached FORM PTO/SB/08a and/or SB/08b may be material to the examination of the above-identified application and is, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR §1.56, §1.97 and §1.98. The Examiner is requested to make these items of official record in this application.

SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	1631
Examiner Name	Lin, Jerry				
Sheet	2		2	Attorney Docket Number	TS-02-180

Pursuant to notice entitled "Information Disclosure Statements May Be Filed Without Copies Of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003," *Off. Gaz. Pat. Office* 55 (August 5, 2003), no copies of U.S. Patents and U.S. Published Patent Applications are being supplied with this Information Disclosure Statement.

This Information Disclosure Statement under 37 CFR §1.56, §1.97 and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these items constitutes prior art.

If this statement crosses in the mail with an office action, or is otherwise not in the indicated category of 37 C.F.R. §1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this submission as a conditional petition for acceptance of the information disclosure statement.

The Commissioner is authorized to charge any deficiencies and credit any overpayment of fees to our Deposit Account No. 50-2019.

Respectfully submitted,

Date: November 14, 2011

Jackson & Co., LLP®

/Michael Chen/

By: Michael Chen
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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

November 14, 2011

Date

/Michael Chen/

Michael Chen

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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	1	of	20	Attorney Docket No: TS-02-180	

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
		US-3,581,062	05-21-1971	Aston	
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EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	2	of	20	Attorney Docket No: TS-02-180	

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
		US-5,106,365	04-21-1992	Hernandez	
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		US-5,628,310	05-13-1997	Rao, et al.	

EXAMINER

DATE CONSIDERED

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				Application Number	12/769,635
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				First Named Inventor	Wesley Scott Harper
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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
		US-5,653,239	08-05-1997	Pompei, et al.	
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		US-5,711,001	01-20-1998	Bussan, et al.	
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		US-6,024,699	02-15-2000	Surwit, et al.	
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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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				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
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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
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				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	15	of	20	Attorney Docket No: TS-02-180	

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
		US-2010/0076283	03-25-2010	Simpson, et al.	
		US-2010/0081906	04-01-2010	Hayter, et al.	
		US-2010/0081908	04-01-2010	Dobbles, et al.	
		US-2010/0081910	04-01-2010	Brister, et al.	
		US-2010/0087724	04-08-2010	Brauker, et al.	
		US-2010/0096259	04-22-2010	Zhang, et al.	
		US-2010/0099970	04-22-2010	Shults, et al.	
		US-2010/0099971	04-22-2010	Shults, et al.	
		US-2010/0119693	05-13-2010	Tapsak, et al.	
		US-2010/0121169	05-13-2010	Petisce, et al.	

EXAMINER**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

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Sheet	16	of	20	Attorney Docket No: TS-02-180	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code-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	T ⁶
		DE-4401400	07-20-1995	Pfeiffer, Ernst		
		EP-0098592	01-18-1984	Fujisawa Pharmaceutical Co., Ltd.		
		EP-0127958	12-12-1984	Genetics International., Inc.		
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		EP-0320109	06-14-1989	Medisense, Inc.		
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		EP-0390390	10-03-1990	Associated Universities, Inc. et al.		
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		WO-2000/049940	08-31-2000	Minimed, Inc.		
		WO-2000/059370	10-12-2000	Cambridge University, Technical Services Limited		
		WO-2000/078992	12-28-2000	TheraSense, Inc.		
		WO-2001/052935	07-26-2001	Medical Research Group, Inc.		
		WO-2001/054753	08-02-2001	Medical Research Group, Inc.		
		WO-2002/016905	02-28-2002	Euro-Celtique, S.A.		
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		WO-2007/016399	02-08-2007	Abbott Diabetes Care Inc.		

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		WO-2007/027788	03-08-2007	Abbott Diabetes Care Inc.		
		WO-2007/041069	04-12-2007	Abbott Diabetes Care Inc.		
		WO-2007/041070	04-12-2007	Abbott Diabetes Care Inc.		
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NON PATENT LITERATURE DOCUMENTS				
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		BENNION, N., et al., "Alternate Site Glucose Testing: A Crossover Design", <u>Diabetes Technology & Therapeutics</u> , Vol. 4, No. 1, 2002, pp. 25-33.		
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				Art Unit	2863
				Examiner Name	Not Yet Assigned
Sheet	19	of	20	Attorney Docket No: TS-02-180	

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	
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Electronic Acknowledgement Receipt

EFS ID:	8900794
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	23-NOV-2010
Filing Date:	28-APR-2010
Time Stamp:	21:41:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		TS-02-180-Supplemental-IDS. pdf	706743 095da142db648229c3151d405308bd1cac2dc643	yes	22

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	Information Disclosure Statement (IDS) Filed (SB/08)	3	22
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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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.			

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Sheet	1		2	Attorney Docket Number	TS-02-180

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.56(a) and 37 C.F.R. §1.97, Applicant(s) hereby make of record the references listed on the accompanying form, SB/08A and/or SB/08b for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement:

- (a) accompanies a new patent application submitted herewith.
- (b) ☒ is filed within three (3) months of the Filing Date or before the mailing date of a First Office Action on the merits or before the mailing date of a First Office Action after the filing of a Request for Continued Examination; **OR**
- (c) is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned prior to the mailing date of either a final rejection or a notice of allowance, and is accompanied by either the fee (\$180) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below **OR**
- (d) is filed after the mailing date of either a final rejection or a notice of allowance, and the issue fee has not been paid, and is accompanied by the requisite fee (\$180) set forth in 37 CFR §1.17(p) and a certification as specified in 37 CFR §1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- (e) Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- (f) No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the 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.

Each item of information listed in the attached FORM PTO/SB/08a and/or SB/08b may be material to the examination of the above-identified application and is, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR §1.56, §1.97 and §1.98. The Examiner is requested to make these items of official record in this application.

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Sheet	2		2	Attorney Docket Number	TS-02-180

Pursuant to notice entitled "Information Disclosure Statements May Be Filed Without Copies Of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003," *Off. Gaz. Pat. Office* 55 (August 5, 2003), no copies of U.S. Patents and U.S. Published Patent Applications are being supplied with this Information Disclosure Statement.

This Information Disclosure Statement under 37 CFR §1.56, §1.97 and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these items constitutes prior art.

If this statement crosses in the mail with an office action, or is otherwise not in the indicated category of 37 C.F.R. §1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this submission as a conditional petition for acceptance of the information disclosure statement.

The Commissioner is authorized to charge any deficiencies and credit any overpayment of fees to our Deposit Account No. 50-2019.

Respectfully submitted,

Date: November 23, 2010

Jackson & Co., LLP®

/Seong-Kun Oh/

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November 23, 2010

Date

/Michael Chen/

Michael Chen

Electronic Acknowledgement Receipt

EFS ID:	8851178
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	23-NOV-2010
Filing Date:	28-APR-2010
Time Stamp:	21:47:28
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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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.

Electronic Acknowledgement Receipt

EFS ID:	8850847
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	23-NOV-2010
Filing Date:	28-APR-2010
Time Stamp:	21:46:15
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					



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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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180

CONFIRMATION NO. 8071

PUBLICATION NOTICE



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30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

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

Publication No.US-2010-0280782-A1

Publication Date:11/04/2010

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 Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, 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 <http://pair.uspto.gov/>. 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 Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	3735
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket No: TS-02-180	

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
		US-2005/0143635	06-30-2005	Kamath, et al.	
		US-2009/0018424	01-15-2009	Kamath, et al.	
		US-2009/0033482	02-05-2009	Hayter, et al.	
		US-			
		US-			
		US-			
		US-			

EXAMINER**DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

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 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	3735
				Examiner Name	Not Yet Assigned
Sheet	2	of	2	Attorney Docket No: TS-02-180	

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
		PCT Application No. PCT/US2010/032863, International Search Report and Written Opinion of the International Searching Authority mailed July 7, 2010.	

EXAMINER

DATE CONSIDERED

Substitute Disclosure Statement Form (PTO-1449)

* 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 Applicant's unique citation designation number (optional) ² Applicant is to place a check mark here if English language Translation is attached

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:

SEONG-KUN OH
JACKSON & CO., LLP
6114 LA SALLE AVE., #507
OAKLAND, CA 94611

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

07 JUL 2010

Applicant's or agent's file reference

TS-02-180PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/US2010/032863

International filing date
(day/month/year)

28 April 2010

Applicant

ABBOTT DIABETES CARE INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference TS-02-180PCT	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2010/032863	International filing date (<i>day/month/year</i>) 28 April 2010	(Earliest) Priority Date (<i>day/month/year</i>) 29 April 2009
Applicant ABBOTT DIABETES CARE INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/032863

A. CLASSIFICATION OF SUBJECT MATTER IPC(8) - G01D 18/00 (2010.01) USPC - 604/66 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) IPC(8) - A61B 5/00, 5/05; G01D 18/00; G01N 1/00 (2010.01) USPC - 204/403.01, 600/347, 604/66, 702/104 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 practicable, search terms used) PatBase		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/0033482 A1 (HAYTER et al) 05 February 2009 (05.02.2009) entire document	1-6
Y		7-22
Y	US 2009/0018424 A1 (KAMATH et al) 15 January 2009 (15.01.2009) entire document	7-22
A	US 2005/0143635 A1 (KAMATH et al) 30 June 2005 (30.06.2005) entire document	1-22
☐ Further documents are listed in the continuation of Box C. ☐		
* 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 application or patent 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 15 June 2010		Date of mailing of the international search report 07 JUL 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201		Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

SEONG-KUN OH
JACKSON & CO., LLP
6114 LA SALLE AVE., #507
OAKLAND, CA 94611

Date of mailing
(day/month/year)

07 JUL 2010

Applicant's or agent's file reference
TS-02-180PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2010/032863

International filing date (day/month/year)

28 April 2010

Priority date (day/month/year)

29 April 2009

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

IPC(8) - G01D 18/00 (2010.01)

USPC - 604/66

Applicant ABBOTT DIABETES CARE INC.

1. This opinion contains indications relating to the following items:



Box No. I Basis of the opinion



Box No. II Priority



Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability



Box No. IV Lack of unity of invention



Box No. V Reasoned statement under Rule 43bis. 1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement



Box No. VI Certain documents cited



Box No. VII Certain defects in the international application



Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

15 June 2010

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (July 2009)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/US2010/032863

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/032863

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement			
1. Statement				
Novelty (N)	Claims	7-22	YES	
	Claims	1-6	NO	
Inventive step (IS)	Claims	None	YES	
	Claims	1-22	NO	
Industrial applicability (IA)	Claims	1-22	YES	
	Claims	None	NO	
2. Citations and explanations:				
Claims 1-6 lack novelty under PCT Article 33(2) as being anticipated by Hayter et al. (hereinafter, Hayter). Referring to Claim 1, Hayter discloses a method, comprising: receiving sensor data from an analyte sensor of a sensor monitoring system (Fig. 12, receive glucose data 1210; [0025], analyte [e.g., glucose] monitoring system 100; [0066], glucose value from the sampled analyte sensor signal may be determined); processing the received sensor data with time corresponding calibration data ([0098], receive the raw glucose data including any data quality check flags, and to apply temperature compensation and/or calibration to the raw data to determine the corresponding glucose data); outputting the processed sensor data ([0048], determine and display the glucose level on the output display 310); detecting one or more adverse conditions associated with the sensor monitoring system ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disabling the output of the sensor data during an adverse condition time period ([0143], if it is determined that the underlying data points associated with the monitored glucose level includes uncertainty or error factor that exceeds the tolerance level, disable or disallow the display or output of the glucose trend information); determining that the one or more detected adverse conditions is no longer present in the sensor monitoring system ([0102], if the calibration validation check is successful); retrieving the sensor data during the adverse condition time period ([0004], retrieving calibration parameters associated with the detected failure state [i.e., adverse condition] of the calibration routine); processing the retrieved sensor data during the adverse condition time period ([0004], the retrieved one or more calibration parameters to correct the detected failure state [i.e., adverse condition] of the calibration routine); and outputting the processed retrieved sensor data ([0048] and [0144], the glucose trend information may be output or displayed). Referring to Claim 2, Hayter discloses 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 ([0048], determine and display the glucose level on the output display 310; [0050], the output 310 may also include an integrated speaker for outputting audible signals as well as to provide vibration output). Referring to Claim 3, Hayter discloses 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 ([0004] and [0189], failure state of a calibration routine). Referring to Claim 4, Hayter discloses wherein the sensor instability condition includes temperature measurement outside a predetermined range ([0114], some circumstance that is preventing calibration, such as skin temperature being out of range). Referring to Claim 5, Hayter discloses wherein the calibration failure condition includes a signal error associated with the reference data ([0114], the calibration failed because there was an error in the reference glucose reading, or because the reference glucose reading was out of range). Referring to Claim 6, Hayter discloses including storing the processed sensor data with the associated time information based on the analyte level detection time by the sensor ([0034], storing, retrieving and updating data corresponding to the detected analyte level; [0050], time-stamped blood glucose data).				

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/032863

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Claims 7-22 lack an inventive step under PCT Article 33(3) as being obvious over Hayter in view of Kamath et al. (hereinafter, Kamath).

Referring to Claim 7, Hayter discloses a method, comprising: detecting a condition unsuitable for calibration of an analyte sensor for a predetermined time period ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disabling output of information associated with the analyte sensor ([0143], disable or disallow the display or output of the glucose trend information); determining a successful calibration of the analyte sensor ([0102], if the calibration validation check is successful); retrieving one or more parameters associated with the successful calibration ([0156], when current blood glucose value is received or detected [successfully], a prior blood glucose value previously stored or otherwise received is retrieved); and displaying the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310), but is silent on said displayed data being for the time period of disabled information output; and processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration. However, displaying processed data for a specific time period is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected. Furthermore, in disclosing an analyte sensor (Abstract), Kamath teaches processing sensor data during the time period of disabled output of information with the one or more parameters associated with the successful calibration ([0835], process calibrated sensor data during sensor break-in [i.e., condition unsuitable for calibration]). Using a rate method for measuring an analyte, a sensor signal can be calibrated with a correction factor [i.e., successful calibration parameter] to account for the rate of change of the break-in curve. Accordingly, the rate of change measured in a measurement phase can be corrected to account for the rate of change of the sensor break-in curve – it is interpreted that the time period of disabled output occurs when a condition unsuitable for calibration is detected). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter as taught by Kamath in order to correct the rate of change measured to account for the rate of change of the sensor break-in curve (Hayter, [0835]).

Referring to Claim 14, Hayter discloses an apparatus, comprising: an interface configured to receive sensor data ([0038], an analog interface 201 configured to communicate with the sensor 101; [0040], the sensor unit 101 is provided four contacts 210, 211, 212, 213, each operatively coupled to the analog interface 201 as shown in Fig. 2; [0069], as every minute, the analog signal from the interface 201 corresponding to the monitored analyte level received from the sensor unit 101 is sampled); a first memory configured to store the received sensor data ([0086], an operational state associated with the sensor unit 101 is retrieved from a storage unit or a memory of receiver 104; [0165], data storage unit of receiver 104); a processor coupled to the memory and configured to process the stored sensor data (Fig. 1 shows a data processing terminal 105 coupled to primary receiver 104; [0027], a data processing terminal 105 for evaluating the data received by the primary receiver unit 104); a second memory coupled to the processor and configured to store the processed sensor data (Fig. 1 shows a data processing terminal 105 coupled to secondary receiver 106; [0086], an operational state associated with the sensor unit 101 is retrieved from a storage unit or a memory of receiver 106; [0165], data storage unit of receiver 104); and a display unit coupled to the second memory and configured to display the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310); wherein the processor is further configured to: detect a condition unsuitable for calibration of a sensor for a predetermined time period ([0004], detecting a failure state of a calibration routine to calibrate an analyte sensor; [0114], when a calibration routine fails, the receiver 104/106 displays a notification indicating that the calibration has failed. If the calibration failed because the reference glucose reading was out of range, the indication would be to repeat the calibration in an hour, allowing time for the glucose level to fall back into the predetermined range); disable display of processed sensor data ([0143], disable or disallow the display or output of the glucose trend information); determine a successful calibration of the sensor ([0102], if the calibration validation check is successful); retrieve one or more parameters associated with the successful calibration ([0156], when current blood glucose value is received or detected [successfully], a prior blood glucose value previously stored or otherwise received is retrieved); and displaying the processed sensor data (Fig. 3 and [0048], determine and display the glucose level on the output display 310), but is silent on said displayed data being for the time period of disabled information output; and 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. However, displaying processed data for a specific time period is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected. Furthermore, Kamath teaches processing the sensor data during the time period of disabled display of sensor data with the one or more parameters associated with the successful calibration. ([0835], process calibrated sensor data during sensor break-in [i.e., condition unsuitable for calibration]). Using a rate method for measuring an analyte, a sensor signal can be calibrated with a correction factor [i.e., successful calibration parameter] to account for the rate of change of the break-in curve. Accordingly, the rate of change measured in a measurement phase can be corrected to account for the rate of change of the sensor break-in curve – it is interpreted that the time period of disabled output occurs when a condition unsuitable for calibration is detected). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter as taught by Kamath in order to correct the rate of change measured to account for the rate of change of the sensor break-in curve (Hayter, [0835]).

Referring to Claim 8, Hayter discloses wherein the sensor data is analyte concentration data ([0164], analyte sensor data).

Referring to Claim 9, Hayter discloses wherein the analyte concentration data includes blood glucose concentration data ([0101] and [0117], blood glucose value).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/032863

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Referring to Claim 10, Hayter discloses wherein the sensor data is processed in substantially real-time ([0144], the glucose trend information may be output or displayed substantially in real-time).

Referring to Claim 11, Hayter discloses 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 ([0098], further data quality check may be performed by the receiver104/106 on the temperature compensated and calibrated glucose data to determine the rate of change or variance of the measured glucose data. For example, a high variance check or verification is performed on 15 minutes of glucose data stored in the FIFO buffer. If it is determined that the rate of variance exceeds a predetermined threshold, then the data packet in process may be deemed invalid; [0114], some circumstance that is preventing calibration, such as skin temperature being out of range).

Referring to Claim 15, Hayter discloses wherein the sensor (Fig. 1, 101) is an analyte sensor ([0004], analyte sensor).

Referring to Claim 16, Hayter discloses wherein the analyte sensor is a glucose sensor ([0025], analyte [e.g., glucose] monitoring system).

Referring to Claim 17, Hayter discloses wherein the sensor data corresponds to analyte concentration data ([0164], analyte sensor data).

Referring to Claim 18, Hayter discloses wherein the analyte concentration data includes blood glucose concentration data ([0101] and [0117], blood glucose value).

Referring to Claim 19, Hayter discloses configured to process and display the sensor data substantially in real-time ([0144], the glucose trend information may be output or displayed substantially in real-time).

Referring to Claim 20, Hayter discloses 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 ([0098], further data quality check may be performed by the receiver104/106 on the temperature compensated and calibrated glucose data to determine the rate of change or variance of the measured glucose data. For example, a high variance check or verification is performed on 15 minutes of glucose data stored in the FIFO buffer. If it is determined that the rate of variance exceeds a predetermined threshold, then the data packet in process may be deemed invalid; [0114], some circumstance that is preventing calibration, such as skin temperature being out of range).

Referring to Claims 12 and 21, Hayter discloses wherein the processed sensor data is displayed substantially immediately upon processing ([0144], the glucose trend information may be output or displayed substantially in real-time), but is silent on the data being for the time period of disabled information output. However, the type of data being displayed (i.e., data processed for a specific time period) is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected.

Referring to Claims 13 and 22, Hayter discloses wherein the processed sensor data is displayed ([0144], the glucose trend information may be output or displayed substantially in real-time), but is silent on the data being for the time period of disabled information output, and displaying only after waiting a predetermined period of time. However, the type of data being displayed (i.e., data processed for a specific time period), and the time period during which said data is displayed is a matter of design choice, which is known in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the above features in the invention of Hayter in order to determine the glucose state of the patient at the time that the unsuitable condition was detected.

Claims 1-22 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Electronic Acknowledgement Receipt

EFS ID:	8003767
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	13-JUL-2010
Filing Date:	28-APR-2010
Time Stamp:	14:39:14
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		TS-02-180-IDS.pdf	573946 f1f1b5f9b4aa2de6976788e64852d292911b15de	yes	4

	Multipart Description/PDF files in .zip description								
	Document Description		Start	End					
	Transmittal Letter		1	2					
	Information Disclosure Statement (IDS) Filed (SB/08)		3	4					
Warnings:									
Information:									
2	NPL Documents	TS-02-180PCT-International-Search-Report.pdf	480862	no	8				
			7e629dbde9d670541cbd7cc02061c065ce337a37						
Warnings:									
Information:									
Total Files Size (in bytes):			1054808						
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.									

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	3735
				Examiner Name	Not Yet Assigned
Sheet	1		2	Attorney Docket Number	TS-02-180

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with the provisions of 37 C.F.R. §1.56(a) and 37 C.F.R. §1.97, Applicant(s) hereby make of record the references listed on the accompanying form, SB/08A and/or SB/08b for consideration by the Examiner in connection with the examination of the above-identified patent application.

This Information Disclosure Statement:

- (a) accompanies a new patent application submitted herewith.
- (b) ☒ is filed within three (3) months of the Filing Date or before the mailing date of a First Office Action on the merits or before the mailing date of a First Office Action after the filing of a Request for Continued Examination; **OR**
- (c) is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned prior to the mailing date of either a final rejection or a notice of allowance, and is accompanied by either the fee (\$180) set forth in 37 CFR §1.17(p) or a certification as specified in 37 CFR §1.97(e), as checked below **OR**
- (d) is filed after the mailing date of either a final rejection or a notice of allowance, and the issue fee has not been paid, and is accompanied by the requisite fee (\$180) set forth in 37 CFR §1.17(p) and a certification as specified in 37 CFR §1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the information disclosure statement.

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- (e) Each item of information contained in the Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
- (f) No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the 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.

Each item of information listed in the attached FORM PTO/SB/08a and/or SB/08b may be material to the examination of the above-identified application and is, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR §1.56, §1.97 and §1.98. The Examiner is requested to make these items of official record in this application.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	12/769,635
				Filing Date	April 28, 2010
				First Named Inventor	Wesley Scott Harper
				Art Unit	3735
				Examiner Name	Not Yet Assigned
Sheet	2		2	Attorney Docket Number	TS-02-180

Pursuant to notice entitled "Information Disclosure Statements May Be Filed Without Copies Of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003," *Off. Gaz. Pat. Office* 55 (August 5, 2003), no copies of U.S. Patents and U.S. Published Patent Applications are being supplied with this Information Disclosure Statement.

This Information Disclosure Statement under 37 CFR §1.56, §1.97 and §1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these items constitutes prior art.

If this statement crosses in the mail with an office action, or is otherwise not in the indicated category of 37 C.F.R. §1.97, it is respectfully requested that this statement be treated in the next appropriate category and made of record. To the extent required, please treat this submission as a conditional petition for acceptance of the information disclosure statement.

The Commissioner is authorized to charge any deficiencies and credit any overpayment of fees to our Deposit Account No. 50-2019.

Date: July 13, 2010

Respectfully submitted,
 Jackson & Co., LLP®
 /Seong-Kun Oh/
 By: Seong-Kun Oh
 Reg. No. 48,210
 Attorneys for Applicant(s)
 6114 La Salle Ave., #507
 Oakland, CA 94611-2802
 Tel. 510-652-6418
 Fax. 510-652-5691

☒ Customer Number or Bar Code Label

30349

(Insert Customer No. or Attach bar code label here)

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

July 13, 2010
Date

/Michael Chen/
Michael Chen



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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
12/769,635	04/28/2010	3735	1324	TS-02-180	22	3

CONFIRMATION NO. 8071

UPDATED FILING RECEIPT



30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

Date Mailed: 06/28/2010

Receipt is acknowledged of this non-provisional 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 APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Applicant(s)

Wesley Scott Harper, Alameda, CA;

Assignment For Published Patent Application

Abbott Diabetes Care Inc., Alameda, CA

Power of Attorney: The patent practitioners associated with Customer Number 30349

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/173,600 04/29/2009

Foreign Applications

If Required, Foreign Filing License Granted: 05/10/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/769,635**

Projected Publication Date: 11/04/2010

Non-Publication Request: No

Early Publication Request: No

Title

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

Preliminary Class

600

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 (1-866-999-4158).

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 Assets Control, 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).

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Mail Stop MISSING PARTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **June 11, 2010**.

/Michael Chen/

Michael Chen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	: 12/769,635	Confirmation No.	8071
Applicant	: Wesley Scott Harper		
Filed	: April 28, 2010		
TC/A.U.	: 3735		
Examiner	: Not Yet Assigned		
Docket No.	: TS-02-180		
Customer No.	: 30349		

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop MISSING PARTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE TO FILE MISSING PARTS
OF NONPROVISIONAL APPLICATION**

Sir:

In response to the "Notice to File Missing Parts of Nonprovisional Application" mailed by the United States Patent and Trademark Office on May 13, 2010, the following documents are enclosed to complete the filing formalities of the above-referenced patent application:

1. Executed Combined Declaration and Power of Attorney (2 Pages);
2. Copy of the Notice to File Missing Parts (2 pages);

A total fee of **\$1,324** for the above-identified application (including the \$330 statutory basic filing fee, \$220 examination fee, \$540 search fee, \$104 for 2 total claims over 20, and \$130 surcharge fee) is being paid using the **EFS-Web** system.

Respectfully submitted,

JACKSON & CO., LLP[®]

Dated: June 11, 2010

By: /Seong-Kun Oh/

Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP[®]
6114 La Salle Ave., #507
Oakland, CA 94611-2802

Telephone: 510-652-6418
Facsimile: 510-652-5691

Customer No.: 30349



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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180

CONFIRMATION NO. 8071

FORMALITIES LETTER



OC000000041557041

30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

Date Mailed: 05/13/2010

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$330 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
- The oath or declaration is missing.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$104** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **\$130** for a non-small entity, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$1324** for a non-small entity

- **\$330** Statutory basic filing fee.
- **\$130** Surcharge.
- The application search fee has not been paid. Applicant must submit **\$540** to complete the search fee.

- The application examination fee has not been paid. Applicant must submit **\$220** to complete the examination fee for a non-small entity.
- Total additional claim fee(s) for this application is **\$104**
 - **\$104** for **2** total claims over 20.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/bnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE
SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILL**

the specification of which (check one) ☐ is attached hereto or ☒ was filed on April 28, 2010 as Application No. 12/769,635 and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
			Yes	No
Number	Country	Day/Month/Year Filed	-----	-----
Number	Country	Day/Month/Year Filed	-----	-----

I hereby claim the benefit under 35 U.S.C. § 119(c) of any United States provisional application(s) below.

61/173,600	April 29, 2009
Application Number	Filing Date
Application Number	Filing Date

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose all information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Application Number	Filing Date	Status: Patented, Pending, Abandoned
--------------------	-------------	--------------------------------------

Application Number	Filing Date	Status: Patented, Pending, Abandoned
--------------------	-------------	--------------------------------------

I HEREBY APPOINT THE LAW FIRM OF JACKSON & CO., LLP WITH ADDRESS: 6114 LA SALLE AVENUE, #507, OAKLAND, CALIFORNIA, 94611-2802, TEL. (510) 652-6418, WITH CUSTOMER NO 30349 AND INCLUDING SEONG-KUN OH, REG. NO. 48,210, KYLA L. HARRIEL, REG. NO. 41,816, KYONG C. OH, REG. NO. 54,346, AND MICHAEL S. CHEN, REG. NO. 62,142, AS MY ATTORNEYS WITH FULL POWER OF SUBSTITUTION TO PROSECUTE THIS APPLICATION AND TRANSACT ALL BUSINESS IN THE PATENT OFFICE CONNECTED THEREWITH.

Send correspondence to Jackson & Co., L.L.P.
 Attn: Kuni Oh
 6114 La Salle Avenue, # 507
 Oakland, CA 94611-2802
 Telephone: 510/652-6418
 Facsimile : 510/652-5691
 Customer No. 30349

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: Wesley Scott Harper

Inventor's signature: Wesley Scott Harper

Date: 6 May 2010

Residence Address: 268 Pine Place 15 Ferro Court

Street or P.O. Box

Milpitas Alameda

California

95035

United States of America

City

State

Zip

Country

Citizenship: United States of America

Post Office Address: 268 Pine Place 15 Ferro Court

Street or P.O. Box

Milpitas Alameda

California

95035

United States of America

City

State

Zip

Country

Corrections made:
 updated address
 Wesley Scott Harper

Wesley Scott Harper

6 May 2010

Electronic Patent Application Fee Transmittal				
Application Number:		12769635		
Filing Date:		28-Apr-2010		
Title of Invention:		Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill		
First Named Inventor/Applicant Name:		Wesley Scott Harper		
Filer:		Seong-Kun Oh/Michael Chen		
Attorney Docket Number:		TS-02-180		
Filed as Large Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Utility application filing	1011	1	330	330
Utility Search Fee	1111	1	540	540
Utility Examination Fee	1311	1	220	220
Pages:				
Claims:				
Claims in excess of 20	1202	2	52	104
Miscellaneous-Filing:				
Late filing fee for oath or declaration	1051	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1324

Electronic Acknowledgement Receipt

EFS ID:	7791896
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	11-JUN-2010
Filing Date:	28-APR-2010
Time Stamp:	13:59:34
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1324
RAM confirmation Number	231
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1	Transmittal Letter	TS-02-180-General-Transmittal.pdf	106965 d308040bab3650adc1714b74b96a4fb3434681e3	no	2
Warnings:					
Information:					
2	Applicant Response to Pre-Exam Formalities Notice	TS-02-180-Response-to-Missing-Parts.pdf	180118 9cfc9d51fed92657bd819323c024ed41ad2fe6b8	no	4
Warnings:					
Information:					
3	Oath or Declaration filed	TS-02-180-Executed-Combined-Declaration-and-POA.pdf	479366 911ec8b195f7b9d5ffe899e0b9b3b8a476abeca	no	2
Warnings:					
Information:					
4	Fee Worksheet (PTO-875)	fee-info.pdf	38418 99bcd2753d3770859687f6b57a916cc0a717856a	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			804867		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Mail Stop MISSING PARTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **June 11, 2010**.

/Michael Chen/

Michael Chen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 12/769,635 Confirmation No. 8071
Applicant : Wesley Scott Harper
Filed : April 28, 2010
TC/A.U. : 3735
Examiner : Not Yet Assigned
Docket No. : TS-02-180
Customer No. : 30349

Title: METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL

Mail Stop MISSING PARTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Enclosed please find the following:

1. Transmittal (In Duplicate);
2. Response to Notice to File Missing Parts mailed May 13, 2010 (2 Pages);
3. Executed Combined Declaration and Power of Attorney (2 Pages);
4. Copy of the Notice to File Missing Parts mailed May 13, 2010 (2 Pages);
5. Certificate of Transmission (In Duplicate);
6. Deposit Account Authorization (In Duplicate);

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP®

Dated: June 11, 2010

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP®
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent Office, number 1-571-273-8300, or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope, or filed electronically and addressed to: Mail Stop MISSING PARTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on **June 11, 2010**.

/Michael Chen/

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TRANSMITTAL

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3. Executed Combined Declaration and Power of Attorney (2 Pages);
4. Copy of the Notice to File Missing Parts mailed May 13, 2010 (2 Pages);
5. Certificate of Transmission (In Duplicate);
6. Deposit Account Authorization (In Duplicate);

The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. **50-2019**. A duplicate of this transmittal is enclosed.

Respectfully submitted,
JACKSON & CO., LLP®

Dated: June 11, 2010

By: /Seong-Kun Oh/
Seong-Kun Oh
Reg. No. 48,210
Attorneys for Applicant(s)

JACKSON & CO., LLP®
6114 La Salle Ave., #507
Oakland, CA 94611-2802
Customer No.: 30349



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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
12/769,635	04/28/2010	Wesley Scott Harper	TS-02-180

CONFIRMATION NO. 8071

FORMALITIES LETTER



OC000000041557041

30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

Date Mailed: 05/13/2010

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$330 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
- The oath or declaration is missing.
A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.
Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$104** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of **\$130** for a non-small entity, must be submitted with the missing items identified in this notice.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$1324** for a non-small entity

- **\$330** Statutory basic filing fee.
- **\$130** Surcharge.
- The application search fee has not been paid. Applicant must submit **\$540** to complete the search fee.

- The application examination fee has not been paid. Applicant must submit **\$220** to complete the examination fee for a non-small entity.
- Total additional claim fee(s) for this application is **\$104**
 - **\$104** for **2** total claims over 20.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

/bnguyen/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101



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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
12/769,635	04/28/2010	3735	0.00	TS-02-180	22	3

CONFIRMATION NO. 8071

30349
JACKSON & CO., LLP
6114 LA SALLE AVENUE
#507
OAKLAND, CA 94611-2802

FILING RECEIPT



OC000000041557040

Date Mailed: 05/13/2010

Receipt is acknowledged of this non-provisional 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 APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Applicant(s)

Wesley Scott Harper, Milpitas, CA;

Assignment For Published Patent Application

Abbott Diabetes Care Inc., Alameda, CA

Power of Attorney: None

Domestic Priority data as claimed by applicant

This appln claims benefit of 61/173,600 04/29/2009

Foreign Applications

If Required, Foreign Filing License Granted: 05/10/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 12/769,635**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

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

Preliminary Class

600

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 (1-866-999-4158).

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

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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.

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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).

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.

**UTILITY
PATENT APPLICATION
TRANSMITTAL**

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.

TS-02-180

First Inventor

Wesley Scott Harper

Title

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

Express Mail Label No.

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☐ **Fee Transmittal Form** (e.g., PTO/SB/17)
2. ☐ **Applicant claims small entity status.**
See 37 CFR 1.27.
3. ☒ **Specification** [Total Pages 29]
Both the claims and abstract must start on a new page
(For information on the preferred arrangement, see MPEP 608.01(a))
4. ☒ **Drawing(s)** (35 U.S.C. 113) [Total Sheets 7]
5. **Oath or Declaration** [Total Sheets]
a. ☐ Newly executed (original or copy)
b. ☐ A copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s)
name in the prior application, see 37 CFR
1.63(d)(2) and 1.33(b).
6. ☒ **Application Data Sheet.** See 37 CFR 1.76
7. ☐ **CD-ROM or CD-R** in duplicate, large table or
Computer Program (Appendix)
☐ Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission**
(if applicable, items a. – c. are required)
a. ☐ Computer Readable Form (CRF)
b. ☐ Specification Sequence Listing on:
i. ☐ CD-ROM or CD-R (2 copies); or
ii. ☐ Paper
c. ☐ Statements verifying identity of above copies

ADDRESS TO:

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450**ACCOMPANYING APPLICATION PARTS**

9. ☐ **Assignment Papers** (cover sheet & document(s))
Name of Assignee Abbott Diabetes Care Inc.
10. ☐ **37 CFR 3.73(b) Statement** ☐ **Power of Attorney**
(when there is an assignee)
11. ☐ **English Translation Document** (if applicable)
12. ☐ **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
☐ Copies of citations attached
13. ☐ **Preliminary Amendment**
14. ☐ **Return Receipt Postcard** (MPEP 503)
(Should be specifically itemized)
15. ☐ **Certified Copy of Priority Document(s)**
(if foreign priority is claimed)
16. ☐ **Nonpublication Request** under 35 U.S.C. 122(b)(2)(B)(i).
Applicant must attach form PTO/SB/35 or equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: _____

Prior application information: Examiner _____ Art Unit: _____

19. CORRESPONDENCE ADDRESS☒ The address associated with Customer Number: 30349 OR ☐ Correspondence address below

Name

Address

City

State

Zip Code

Country

Telephone

Email

Signature

/Seong-Kun Oh/

Date

April 28, 2010

Name

Seong-Kun Oh

Registration No.
(Attorney/Agent)

48,210

This collection of information is required by 37 CFR 1.53(b). 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 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.

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	TS-02-180
		Application Number	
Title of Invention	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill		
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.)

Applicant Information:

Applicant 1					
Applicant Authority		☒ Inventor		☐ Legal Representative under 35 U.S.C. 117	
				☐ Party of Interest under 35 U.S.C. 118	
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	Milpitas	State/Province	CA	Country of Residence	US
Citizenship under 37 CFR 1.41(b)		US			
Mailing Address of Applicant:					
Address 1		268 Parc Place			
Address 2					
City	Milpitas	State/Province	CA		
Postal Code	95035	Country	US		
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.					

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	30349		
Email Address	docketing@jacolaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill		
Attorney Docket Number	TS-02-180	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	7	Suggested Figure for Publication (if any)	1

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	TS-02-180
		Application Number	
Title of Invention	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill		

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). Enter either 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	30349		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.			
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	non provisional of	61173600	2009-04-29
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. 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(a).			
Remove			
Application Number	Country ⁱ	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			☒ Yes ☐ No
Additional Foreign Priority Data may be generated within this form by selecting the Add button.			

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.
Assignee 1

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	TS-02-180
		Application Number	
Title of Invention	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill		

If the Assignee is an Organization check here. ☒			
Organization Name	Abbott Diabetes Care Inc.		
Mailing Address Information:			
Address 1	1360 South Loop Road		
Address 2			
City	Alameda	State/Province	CA
Country	US	Postal Code	94502
Phone Number	510.749.5400	Fax Number	510.749.5401
Email Address			
Additional Assignee Data may be generated within this form by selecting the Add button.			

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Seong-Kun Oh/			Date (YYYY-MM-DD)	2010-04-28
First Name	Seong-Kun	Last Name	Oh	Registration Number	48210

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.**

United States Patent Application for

**METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR
CALIBRATION WITH RETROSPECTIVE BACKFILL**

Inventors/Assignors: Wesley Scott Harper
268 Parc Place
Milpitas, CA 95035
Citizenship: United States of America

Assignee: Abbott Diabetes Care Inc.
1360 South Loop Road
Alameda, CA 94502

METHOD AND SYSTEM FOR PROVIDING REAL TIME ANALYTE SENSOR CALIBRATION WITH RETROSPECTIVE BACKFILLRELATED APPLICATIONS

[0001] The present application claims priority under 35 U.S.C. §119(e) to U.S. provisional application no. 61/173,600 filed April 29, 2009, entitled “Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill”, the disclosure of which is incorporated in its entirety by reference 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 include 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 device 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 Serial 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 Serial 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, US 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 unit 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 US 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 μ A 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 400MHz to approximately 470MHz. 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 a 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.

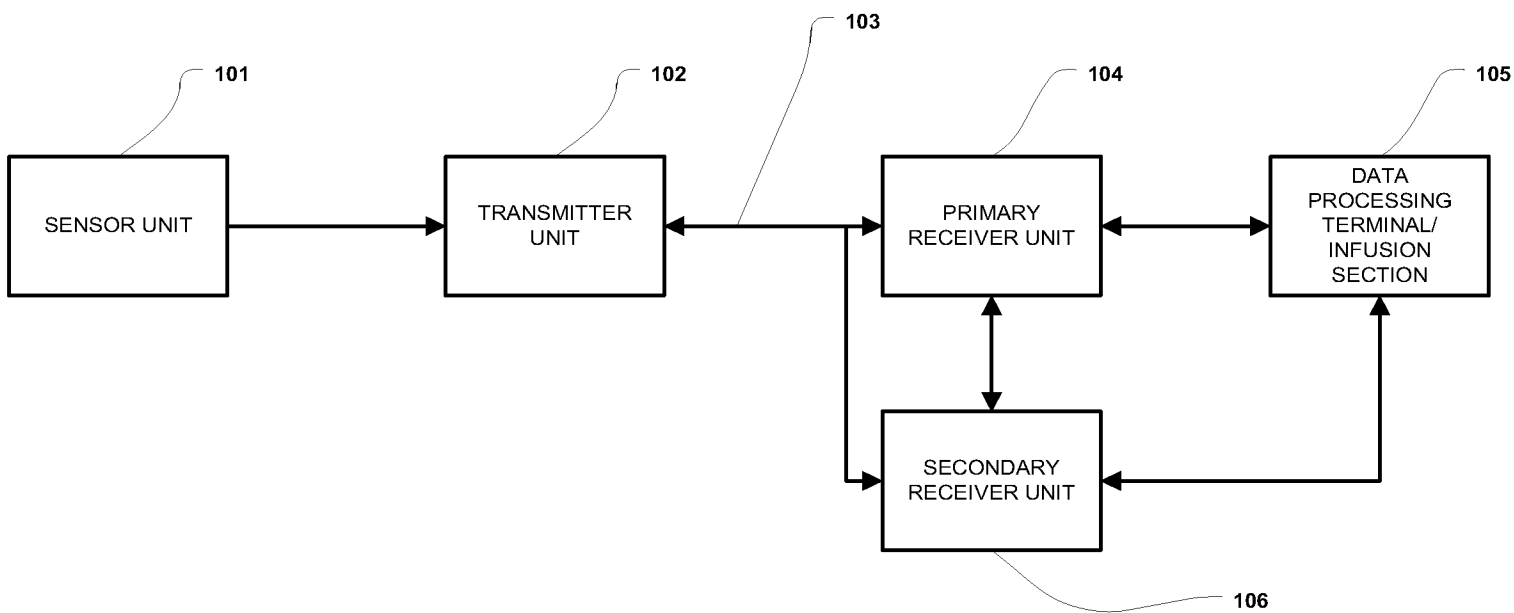
20. The apparatus of claim 14, wherein the condition unsuitable for calibration includes one or more of a failure mode of a sensor, sensor data outside a predetermined acceptable range, a rate of change of sensor data above a predetermined level, a requirement for calibration of a sensor, a temperature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

FIGURE 1

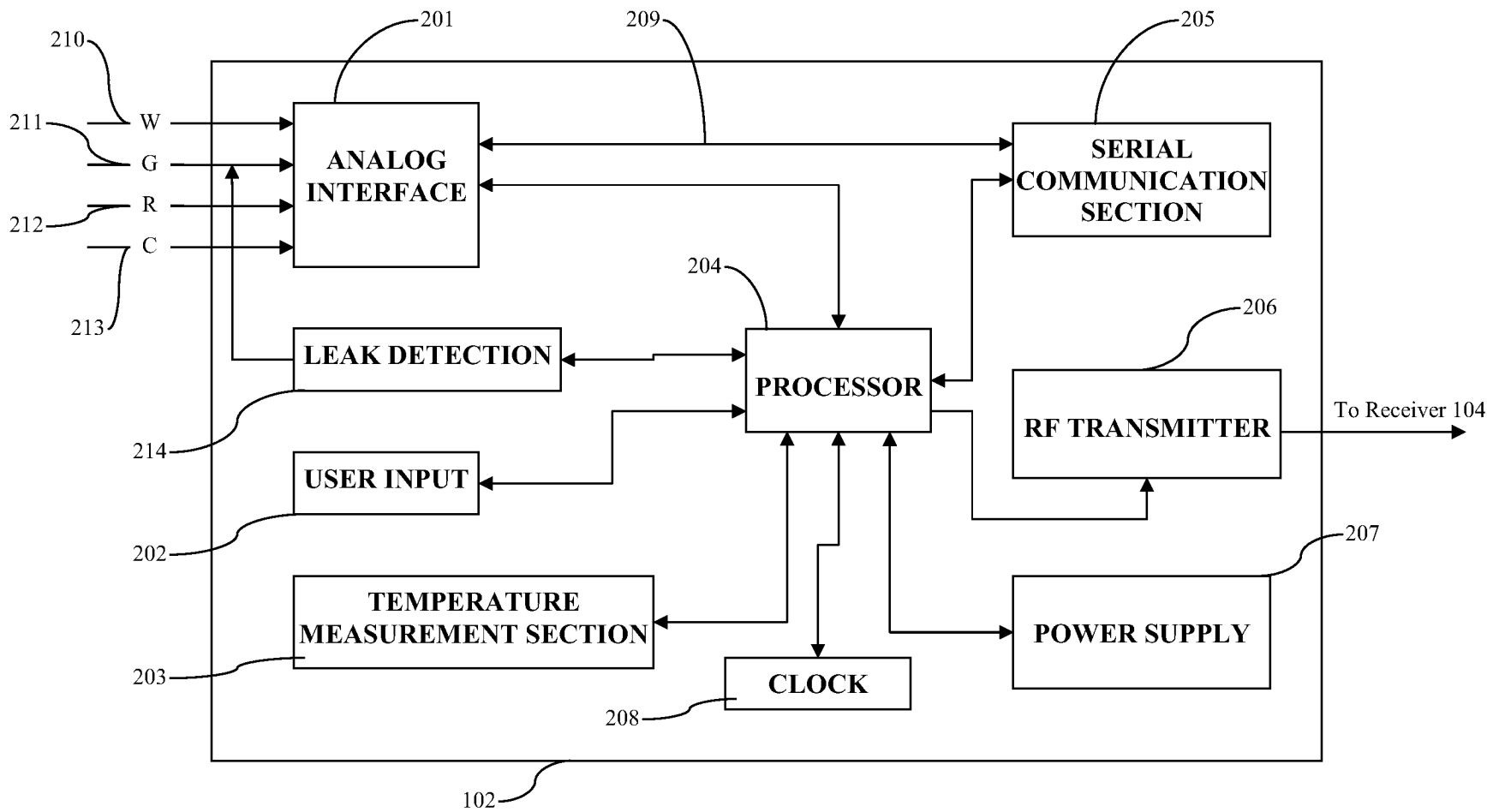


FIGURE 2

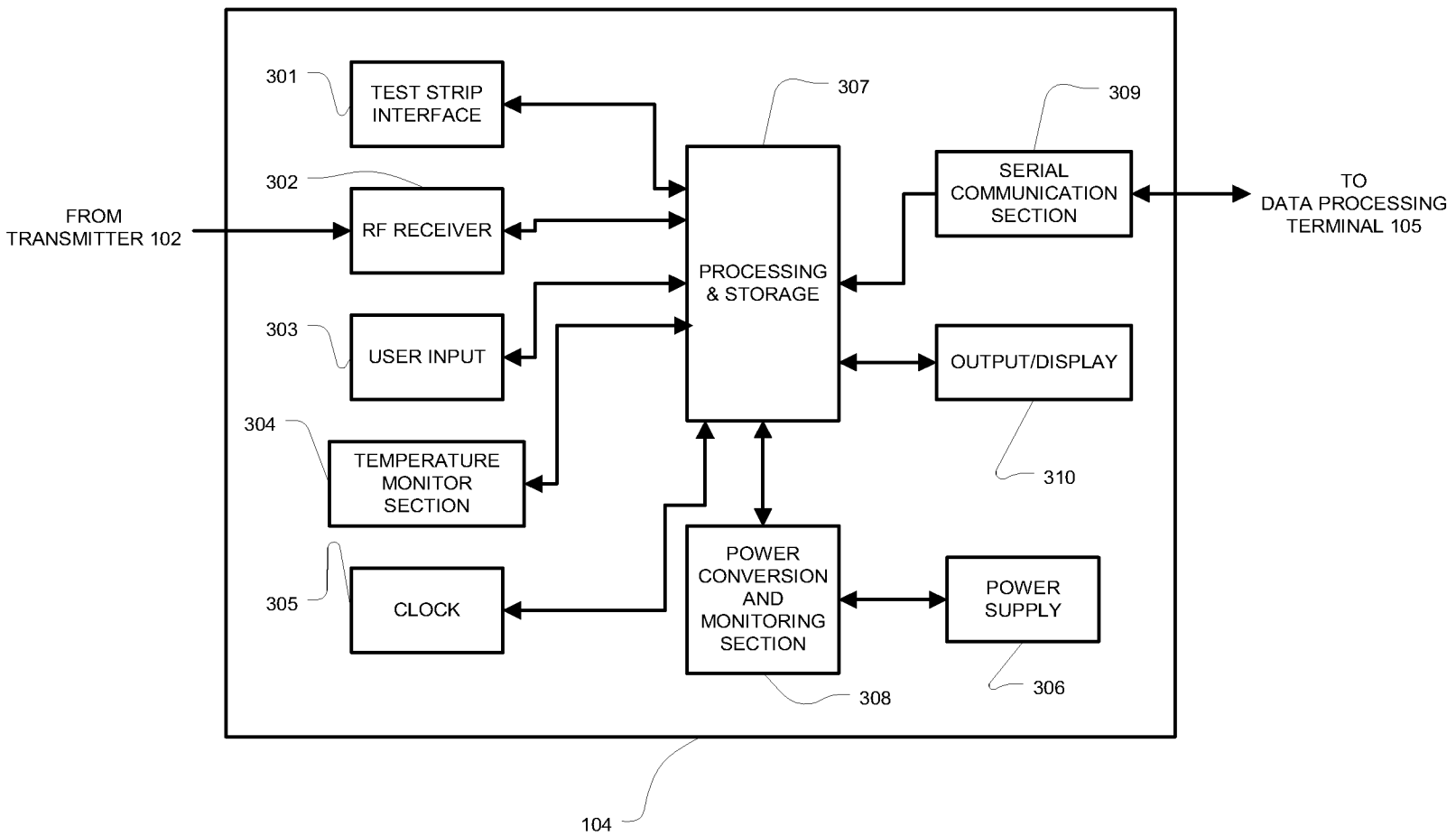
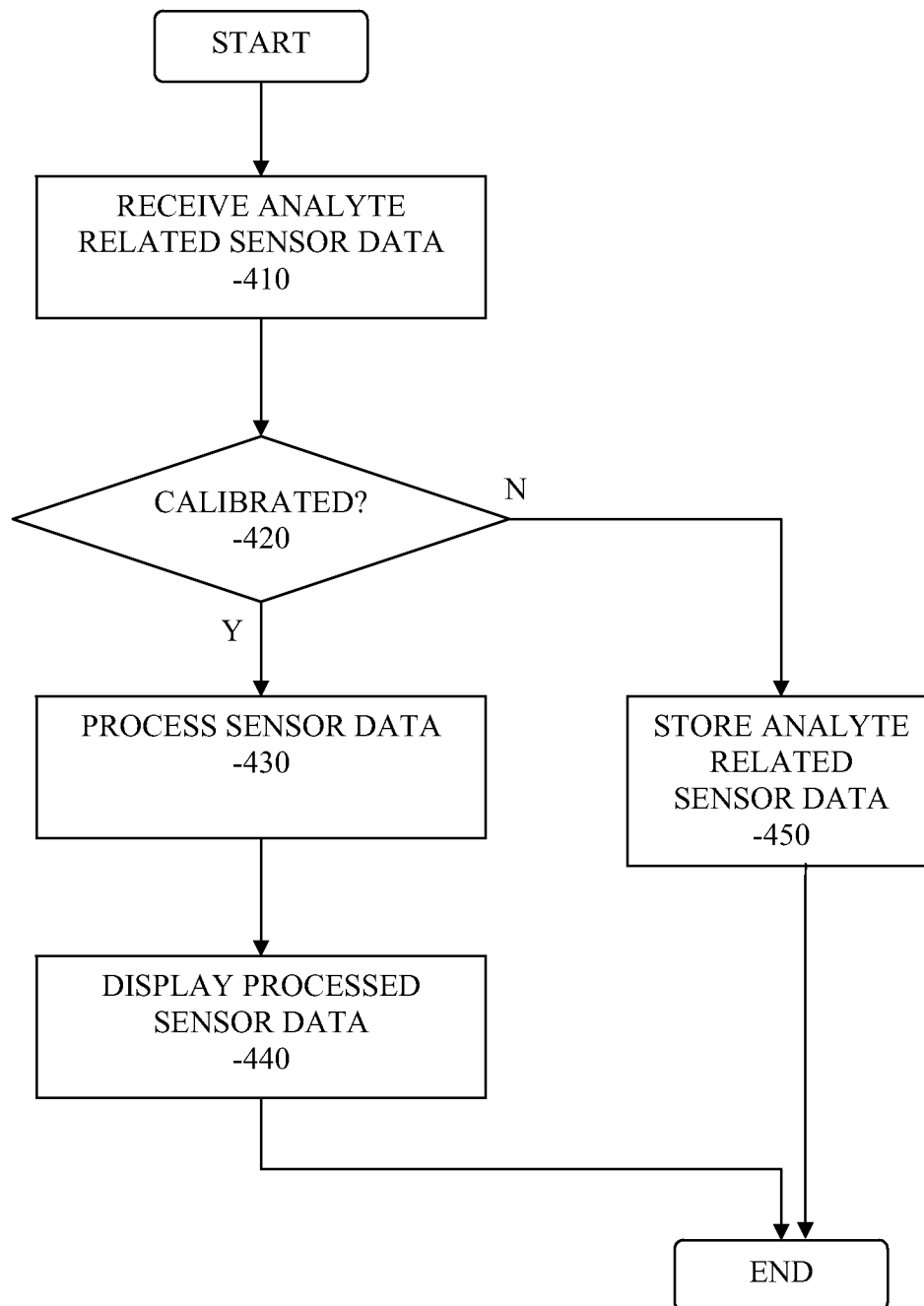
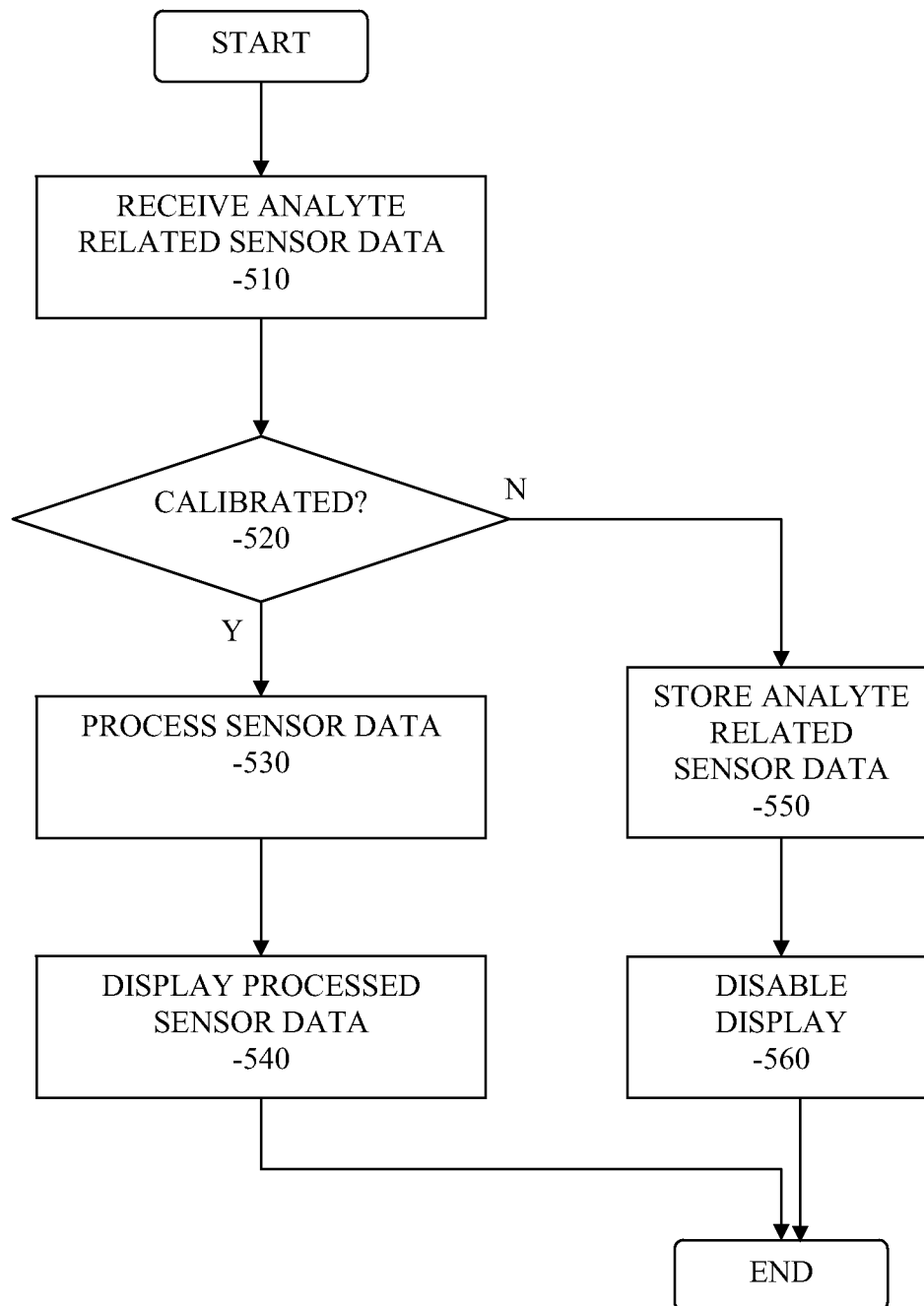
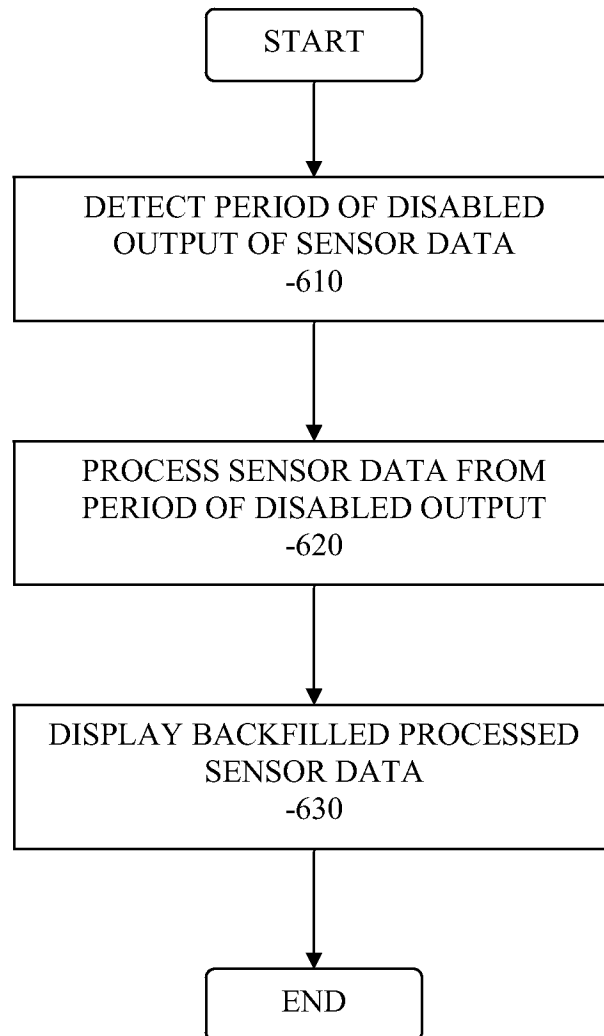


FIGURE 3

**FIGURE 4**

**FIGURE 5**

**FIGURE 6**

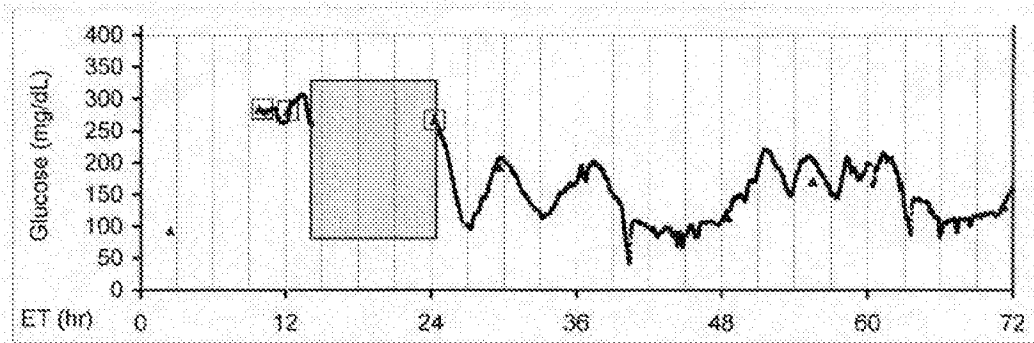


FIGURE 7A

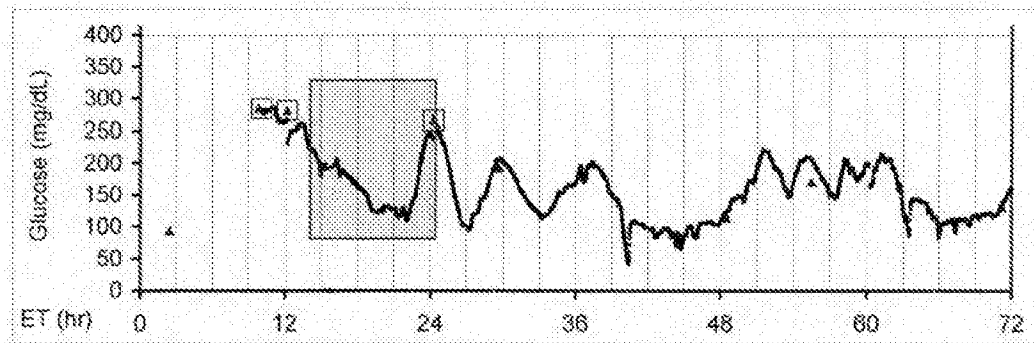


FIGURE 7B

Electronic Acknowledgement Receipt

EFS ID:	7511296
Application Number:	12769635
International Application Number:	
Confirmation Number:	8071
Title of Invention:	Method and System for Providing Real Time Analyte Sensor Calibration with Retrospective Backfill
First Named Inventor/Applicant Name:	Wesley Scott Harper
Customer Number:	30349
Filer:	Seong-Kun Oh/Michael Chen
Filer Authorized By:	Seong-Kun Oh
Attorney Docket Number:	TS-02-180
Receipt Date:	28-APR-2010
Filing Date:	
Time Stamp:	23:33:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal of New Application	TS-02-180-Application-Transmittal.pdf	55680 3d1406d0b3c744aa9ecf9c7f85f04142f1e8a ce1	no	1

Warnings:

Information:

2	Application Data Sheet	TS-02-180-Application-Data-Sheet.pdf	34998 d4591a88d7fdddcf26db639d6fbf0830ec6d864	no	3
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3		TS-02-180-Application-as-filed.pdf	238901 edc1993656c4d790afdc56786c18d9b2cfcb9a02f	yes	29
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	24	
	Claims		25	28	
	Abstract		29	29	
Warnings:					
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4	Drawings-only black and white line drawings	TS-02-180-Figures-as-filed.pdf	239942 df001c243f6e0caa0ef5ba75ad3d5496abdf9313	no	7
Warnings:					
Information:					
Total Files Size (in bytes):			569521		
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. <u>New Applications Under 35 U.S.C. 111</u> 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.					

SCORE Placeholder Sheet for IFW Content

Application Number: 12769635

Document Date: 4/28/2010

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DATE 04/28/10

Approved for use through 7/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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PATENT APPLICATION FEE DETERMINATION RECORD					Application or Docket Number 12/769,635	
Substitute for Form PTO-875						
APPLICATION AS FILED – PART I						
(Column 1)		(Column 2)		SMALL ENTITY		OR
OTHER THAN SMALL ENTITY						
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A		N/A	330
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A		N/A	540
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A		N/A	220
TOTAL CLAIMS (37 CFR 1.16(i))	22	minus 20 = 2	x\$26		x\$52	104
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3	minus 3 = *	x\$110		x\$220	
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR					
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			195		390	
			TOTAL		TOTAL	1194
* If the difference in column 1 is less than zero, enter "0" in column 2.						
APPLICATION AS AMENDED – PART II						
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	SMALL ENTITY		OR
	Total (37 CFR 1.16(i))	Minus **	=	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))			X =		X =
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		N/A
			TOTAL ADD'T FEE		TOTAL ADD'T FEE	
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	SMALL ENTITY		OR
	Total (37 CFR 1.16(i))	Minus **	=	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))			X =		X =
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		N/A
			TOTAL ADD'T FEE		TOTAL ADD'T 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 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.

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